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Back Pain - Invasive Procedures - Medical Clinical Policy Bulletins | Aetna

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Policy

Aetna considers *any* of the following injections or procedures medically necessary for the treatment of back pain; provided, however, that *only 1* invasive modality or procedure will be considered medically necessary at a time.

I. Facet joint injections (intra-articular and medial branch blocks) are considered medically necessary in the *diagnosis* of facet pain in persons with severe chronic neck and back pain that limits daily activities and has lasted more than 3 montfhs despite appropriate conservative treatment (including, but not limited to rest, systemic medications, and/or physical therapy), with symptoms suggestive of facet joint syndrome (symptoms of facet joint syndrome include absence of radiculopathy, pain that is aggravated by extension, rotation or lateral bending of the spine and is not typically associated with any neurological deficits), where facet mediated pain is confirmed by provocative testing on physical examination (to confirm that pain is exacerbated by extension and rotation), imaging studies suggest no other obvious cause of pain, and radiofrequency facet neurolysis is being considered.

Diagnostic facet joint injections are considered experimental and investigational for neck and back pain with untreated radiculopathy. Facet joint injections (intra-articular and medial branch blocks) are considered experimental and investigational as *therapy* for back and neck pain and for all other indications because their effectiveness for these indications has not been established. Aetna considers diagnostic facet joint injections not medically necessary where radiofrequency facet neurolysis is not being considered.

A set of facet joint injections (intra-articular or medial branch blocks) means up to 6 such injections per sitting, and this can be repeated once at the same levels and side, no sooner than one week after the initial set of injections, to establish the diagnosis. Additional sets of facet injections or medial branch blocks at the same levels and side are considered experimental and investigational because they have no proven

value.

Aetna considers ultrasound guidance of facet injections experimental and investigational because of insufficient evidence of its effectiveness.

II. Trigger point injections of corticosteroids and/or local anesthetics, are considered medically necessary for treating members with chronic neck or back pain or myofascial pain syndrome, when *all* of the following selection criteria are met:

A. Conservative treatment such as bed rest, exercises, heating or cooling modalities, massage, and pharmacotherapies such as non-steroidal anti-inflammatory drugs (NSAIDS), muscle relaxants, non-narcotic analgesics, should have been tried and failed, *and*
B. Symptoms have persisted for more than 3 months, *and*
C. Trigger points have been identified by palpation; *and*
D. Trigger point injections are not administered in isolation, but are provided as part of a comprehensive pain management program, including physical therapy, patient education, psychosocial support, and oral medication where appropriate.

Trigger point injections are considered experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

A trigger point is defined as a specific point or area where, if stimulated by touch or pressure, a painful response will be induced. A set of trigger point injections means injections in several trigger points in one sitting. It is not considered medically necessary to repeat injections more frequently than every 7 days. Up to 4 sets of injections are considered medically necessary to diagnose the origin of a patient's pain and achieve a therapeutic effect; additional sets of trigger point injections are not considered medically necessary if no clinical response is achieved. Once a diagnosis is established and a therapeutic effect is achieved, it is rarely considered medically necessary to repeat trigger point injections more frequently than once every 2 months. Repeated injections extending beyond 12 months may be reviewed for continued medical necessity.

III. Sacroiliac joint injections are considered medically necessary to relieve pain associated with lower lumbosacral disturbances in members who meet *both* of the following criteria:

A. Member has back pain for more than 3 months; *and*
B. The injections are not used in isolation, but are provided as part of a comprehensive pain management program, including physical therapy, patient education, psychosocial support, and oral medication where appropriate.

Sacroiliac joint injections are considered experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

Up to 2 sacroiliac injections are considered medically necessary to diagnose the patient's pain and achieve a therapeutic effect. It is not considered medically necessary to repeat these injections more frequently than once every 7 days. If the member experiences no symptom relief or functional improvement after 2 sacroiliac joint injections, additional sacroiliac joint injections are not considered medically necessary. Once the diagnosis is established, it is rarely medically necessary to repeat sacroiliac injections more frequently than once every 2 months. Repeat injections extending beyond 12 months may be reviewed for continued medical necessity. Ultrasound guidance of sacroiliac joint injections is considered not medically necessary.

IV. Epidural injections of corticosteroid preparations (e.g., Depo-Medrol), with or without added anesthetic agents, are considered medically necessary in the outpatient setting for management of persons with radiculopathy or sciatica when *all* of the following are met:

A. Pain is radicular in nature (radicular signs may include, but are not limited to, a positive straight leg raise or a dermatomal pattern of sensory loss). Note: In low back pain, radicular means pain and/or numbness that radiates below the knee; in neck pain, it is pain, numbness or weakness in the shoulder, arm, wrist or hand.
B. Intraspinal tumor or other space-occupying lesion, or non-spinal origin for pain, has been ruled out as the cause of pain; and
C. Member has failed to improve after 4 or more weeks of conservative treatments (e.g., rest, systemic analgesics and/or physical therapy); *and*
D. No more than three nerve root levels may be injected per session (in either the diagnostic or therapeutic phases); *and*
E. Epidural injections are provided as part of a comprehensive pain management program, which includes physical therapy, patient education, psychosocial support, and oral medications, where appropriate.

Epidural injections of corticosteroid preparations, with or without added anesthetic agents, are considered experimental and investigational for all other indications (e.g., non-specific low back pain [LBP] and failed back syndrome) because their effectiveness for indications other than the ones listed above has not been established.

During the diagnostic phase, the individual may receive two injections at intervals of no sooner than two weeks. If the diagnostic phase is completed and unsuccessful, additional epidural injections are considered not medically necessary. Note: A successful diagnostic phase is one in which there is a 50% reduction in pain and/or symptoms.

Therapeutic epidural injections beyond the diagnostic phase are considered medically necessary, if the diagnostic injections resulted in at least a 50% relief in pain and/or symptoms, and the epidural injections are provided as part of a comprehensive pain management program, which includes physical therapy, patient education, psychosocial support, and oral medications, where appropriate. If the member experiences less than 50% relief of pain after three epidural injections, additional epidural injections are not considered medically necessary. In the therapeutic phase, repeat epidural injections more frequently than every two months are not considered medically necessary. A total of four therapeutic epidural steroid injections per region (ie, cervical, thoracic, lumbar) per rolling 12-month period are considered medically necessary, only upon return of pain and/or deterioration in function and only when responsiveness to prior injections has occurred (ie, the individual should have at least a 50% reduction in pain and/or symptoms for two months). Additional therapeutic epidural injections per region per rolling 12-month period are considered experimental and investigational because they have no proven value.

Aetna considers ultrasound guidance of epidural injections experimental and investigational because of insufficient evidence of its effectiveness.

See also CPB 0722 - Selective Nerve Root Blocks

V. Chymopapain chemonucleolysis is considered medically necessary for the treatment of sciatica due to a herniated disc when *all* of the following are met:

A. Member has leg pain worse than LBP; *and*

B. Member has radicular symptoms reproduced by sciatic stretch tests; *and*
C. Member has only a single-level herniated disc with nerve root impingement at clinically suspected level demonstrated by MRI, CT, or myelography; *and*
D. Member has objective neurologic deficit (e.g., diminished deep tendon reflex, motor weakness, or hypalgesia in dermatomal distribution); *and*
E. Pain not relieved by at least 6 weeks of conservative treatments.

Chymopapain chemonucleolysis is considered experimental and investigational for all other indications, including the following because its effectiveness for these indications has not been established:

A. Acute LBP alone
B. Cauda equina syndrome
C. For herniated thoracic or cervical discs
D. Multiple back operations (failed back surgery syndrome)
E. Neurologic disease (e.g., multiple sclerosis)
F. Pregnancy
G. Profound or rapidly progressive neurologic deficit
H. Sequestered disc fragment
I. Severe spinal stenosis
J. Severe spondylolisthesis
K. Spinal cord tumor
L. Spinal instability
M. When performed with chondroitinase ABC or agents other than chymopapain

VI. Percutaneous lumbar discectomy, manual or automated, is considered medically necessary for treatment of herniated lumbar discs when *all* of the following are met:

A. Member is otherwise a candidate for open laminectomy; *and*
B. Member has failed 6 months of conservative treatment; *and*
C. Diagnostic studies show that the nuclear bulge of the disc is contained within the annulus (i.e., the herniated disc is contained); *and*
D. Member has no previous surgery or chemonucleolysis of the disc to be treated; *and*
E. Member must have typical clinical symptoms of radicular pain corresponding to the level of disc involvement.

Percutaneous lumbar diskectomy is considered experimental and investigational for all other indications because its effectiveness for indications other than the one listed above has not been established.

Note: Clinical studies have not established any clinically significant benefit of use of a laser over use of a scalpel for percutaneous lumbar diskectomy.

VII. Non-pulsed radiofrequency facet denervation (also known as facet neurotomy, facet rhizotomy, or articular rhizolysis) is considered medically necessary for treatment of members with intractable cervical or back pain with or without sciatica in the outpatient setting when *all* of the following are met:

A. Member has experienced severe pain limiting activities of daily living for at least 6 months; *and*
B. Member has had no prior spinal fusion surgery; *and*
C. Neuroradiologic studies are negative or fail to confirm disc herniation; *and*
D. Member has no significant narrowing of the vertebral canal or spinal instability requiring surgery; *and*

E. Member has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g., anti-inflammatory agents, analgesics and muscle relaxants); *and*
F. Trial of facet joint injections has resulted in a significant reduction in pain. Significant reduction in pain after a diagnostic facet joint injection is defined as a 50% or greater reduction in pain and/or symptoms.

Non-pulsed radiofrequency facet denervation is considered experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

Provided that greater than 50% pain relief is obtained for at least twelve weeks, further facet denervation procedures should be at intervals of at least six months per level per side, at a maximum of twice per rolling calendar year. Only 1 treatment procedure per level per side is considered medically necessary in a 6-month period.

See also CPB 0735 - Pulsed Radiofrequency.

VIII. Pedicle screws for spinal fixation are considered medically necessary for the following indications:

A. Fusion adjacent to prior lumbar fusion
B. Fusion after decompression
C. Pseudoarthrosis repair
D. Revision lumbar disc surgery requiring instrumentation because of instability at the previous level of surgery
E. Scoliosis and kyphosis requiring spinal instrumentation
F. Segmental defects or loss of posterior elements following tumor resection
G. Spinal trauma of all types including fractures and dislocations
H. Spondylolisthesis -- grades I to IV
I. Thoracic fractures

Pedicle screw fixation is considered experimental and investigational for all other indications, including the following because its effectiveness for indications other than the ones listed above has not been established:

A. Decompressive laminectomy for spinal stenosis without evidence of instability
B. Degenerative disc disease
C. Failed lumbar surgery without documentation of instability pattern or pseudarthrosis
D. First time intervertebral disc herniation
E. Isolated LBP without spinal instability or neurologic deficits
F. Single-level discectomy

IX. Intervertebral body fusion devices (spine cages) (see appendix) are considered medically necessary for use with allograft or autogenous bone graft in members who meet criteria for lumbar spinal fusion as outlined in CPB 0743 Spinal Surgery: Laminectomy and Fusion and for thoracic fusion. Spine cages for cervical fusion are considered medically necessary for members who meet criteria in CPB 0743 Spinal Surgery: Laminectomy and Fusion with any the following indications for use of a cervical cage:

A. Multilevel (3 or more vertebral bodies) cervical corpectomy (removal of half or more of vertebral

body, not mere removal of osteophytes and minor decompression) in the treatment of one of the following:

1. For tumors involving one or more vertebrae, *or*
2. Greater than 50 % compression fracture of vertebrae, *or*
3. Retropulsed bone fragments, *or*
4. Central canal stenosis with myelopathy.

B. Multilevel (3 or more vertebral bodies) cervical fusion for pseudarthrosis in persons with prior fusion; *or*
C. For adjacent level disease that has developed in persons with a prior cervical fusion involving a plate, in order to avoid dissection for plate removal; *or*
D. Multilevel (3 or more discs) cervical discectomy in persons meeting criteria for cervical discectomy in CPB 0743 - Spinal Surgery: Laminectomy and Fusion; *or*
E. Persons with religious or cultural beliefs that preclude the use of cadaver bone, such as the Native American population in the Southwestern United States, who have poor bone stock (e.g., due to osteoporosis, osteogenesis imperfecta, ESRD, diabetes, long-term steroid use, immunosuppression after transplant, or parathyroid deficiency).

Spine cages are otherwise not considered medically necessary for cervical fusion because they have not been proven more effective than bone graft for this indication.

Spine cages are considered experimental and investigational for indications other than fusion because their effectiveness for indications other than those listed above has not been established.

Expandable cages are considered medically necessary for persons who meet criteria for fusion in CPB 743 - Spinal Surgery: Laminectomy and Fusion, and who meet either of the following criteria: 1) At L_5-S_1, where disc morphologic is hard to reconstruct using standard, static cages; or 2) in persons with bone loss at the fusion site; 3) bone loss due to tumor or fracture at fusion site. Expandable cages are considered experimental and investigational for all other indications.

X. Percutaneous polymethylmethacrylate vertebroplasty (PPV) or kyphoplasty is considered medically necessary for members with persistent, debilitating pain in the cervical, thoracic or lumbar vertebral bodies resulting from *any* of the following:

A. Multiple myeloma; *or*
B. Painful and/or aggressive hemangiomas; *or*
C. Painful vertebral eosinophilic granuloma; *or*
D. Painful, debilitating osteoporotic collapse/compression fractures (e.g., Kummell's disease); *or*
E. Primary malignant neoplasm of bone or bone marrow; *or*
F. Secondary osteolytic metastasis, excluding sacrum and coccyx; *or*
G. Steroid-induced fractures

AND all of the following criteria have been met:

A. Other causes of pain such as herniated intervertebral disk have been ruled out by computed tomography or magnetic resonance imaging; *and*
B. Severe debilitating pain or loss of mobility that cannot be relieved by optimal medical therapy (e.g.,

acetaminophen, NSAIDS, narcotic analgesics, braces, physical therapy, etc.); *and*
C. The affected vertebra has not been extensively destroyed and is at least 1/3 of its original height.

XI. Lateral (including extreme [XLIF], extra and direct lateral [DLIF]) interbody fusion is considered an acceptable method of performing a medically necessary anterior interbody fusion. See CPB 0743 Spinal Surgery: Laminectomy and Fusion.
XII. Coccygectomy is considered medically necessary for individuals with coccygodynia who have tried and failed to respond to 6 months of conservative management.
XIII. Vertebral body replacement spacers (e.g., AVS AL PEEK Spacer) are considered medically necessary for vertebral body replacement used in spine surgery for persons with a collapsed, damaged or unstable vertebral body resected or excised during total and partial vertebrectomy procedures due to tumor or trauma (vertebral body replacement should not be confused with Interspinous distraction devices (spacers) (e.g., X-Stop)).
XIV. Minimally invasive transforaminal lumbar interbody fusion with *direct visualization* is considered medically necessary when criteria are met in CPB 743 - Spinal Surgery: Laminectomy and Fusion.

For intercostal nerve blocks, see CPB 863 - Peripheral Nerve Blocks.

Experimental and Investigational Interventions

Aetna considers *any* of the following injections or procedures experimental and investigational:

- AccuraScope procedure;
- Annulus repair devices (Xclose Tissue Repair System, Barricaid, Disc Annular Repair Technology (DART) System)
- BacFast HD for isolated facet fusion;
- Chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate) of facet joints;
- Coccygeal ganglion (ganglion impar) block for coccydynia, pelvic pain, and all other indications;
- Cryoablation (cryoanesthesia, cryodenervation, cryoneurolysis, or cryosurgery) for the treatment of lumbar facet joint pain;
- Deuk Laser Disc Repair;
- Devices for annular repair (e.g., Inclose Surgical Mesh System);
- Dynamic (intervertebral) stabilization (e.g., BioFlex, CD Horizon Agile Dynamic Stabilization Device, DSS Dynamic Soft Stabilization System, Dynabolt Dynamic Stabilization System, Dynesys Spinal System, Graf ligamentoplasty/Graf artificial ligament, Isobar Spinal System, NFix, Satellite Spinal System, Stabilimax NZ Dynamic Spine Stabilization System, and the Zodiak DynaMo System);
- Endoscopic disc decompression, ablation, or annular modulation using the DiscFX System;
- Endoscopic laser foraminoplasty, endoscopic foraminotomy, laminotomy, and rhizotomy (endoscopic radiofrequency ablation);
- Endoscopic transforaminal diskectomy;
- Epidural fat grafting during lumbar decompression laminectomy/discectomy;
- Epidural injections of lytic agents (e.g., hyaluronidase, hypertonic saline) or mechanical lysis in the treatment of adhesive arachnoiditis, epidural fibrosis, failed back syndrome, or other indications;
- Epidural steroid injections for the treatment of non-radicular low back pain;
- Epiduroscopy (also known as epidural myeloscopy, epidural spinal endoscopy, myeloscopy, and spinal endoscopy) for the diagnosis and treatment of intractable LBP or other indications;
- Facet chemodenervation/chemical facet neurolysis;
- Facet joint allograft implants (NuFix facet fusion, TruFuse facet fusion)
- Facet joint implantation (Total Posterior-element System (TOPS) (Premia Spine), Total Facet

Arthroplasty System (TFAS) (Archus Orthopedics), ACADIA Facet Replacement System (Facet Solutions/Globus Medical);

- Far lateral microendoscopic diskectomy (FLMED) for extra-foraminal lumbar disc herniations or other indications;
- Hardware injections/blocks;
- Interlaminar lumbar instrumented fusion (ILIF);
- Interspinous and interlaminar distraction devices (see Appendix);
- Interspinous fixation devices (CD HORIZON SPIRE Plate, PrimaLOK SP, SP-Fix Spinous Process Fixation Plate, and Stabilink interspinous fixation device) for spinal stenosis or other indications (see Appendix)
- Intradiscal, paravertebral, or epidural oxygen or ozone injections;
- Intradiscal steroid injections;
- Intravenous administration of corticosteroids, lidocaine, magnesium, Toradol or vitamin B12 (cyanocobalamin) as a treatment for back pain;
- Khan kinetic treatment (KKT);
- Laser facet denervation;
- Least invasive lumbar decompression interbody fusion (LINDIF);
- Microendoscopic discectomy (MED; same as lumbar endoscopic discectomy utilizing microscope) procedure for decompression of lumbar spine stenosis, lumbar disc herniation, or other indications;
- Microsurgical anterior foraminotomy for cervical spondylotic myelopathy or other indications;
- Microsurgical lumbar sequestrectomy for the treatment of lumbar disc herniation;
- Minimally invasive/endoscopic cervical laminoforaminotomy for cervical radiculopathy/lateral and foraminal cervical disc herniations or other indications;
- Minimally invasive lumbar decompression (MILD) procedure (percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements under indirect image guidance) for lumbar canall stenosis or other indications;
- Minimally invasive thoracic discectomy for the treatment of back pain;
- Minimally invasive *endoscopic* transforaminal lumbar interbody fusion (endoscopic MITLIF; same as endoscopic MAST fusion) for lumbar disc degeneration and instability or other indications;
- OptiMesh grafting system;
- Percutaneous cervical diskectomy;
- Percutaneous endoscopic diskectomy with or without laser (PELD) (also known as arthroscopic microdiskectomy or Yeung Endoscopic Spinal Surgery System [Y.E.S.S.]);
- Piriformis muscle resection and other surgery for piriformis syndrome;
- Psoas compartment block for lumbar radiculopathy or myositis ossification;
- Racz procedure (epidural adhesiolysis with the Racz catheter) for the treatment of members with adhesive arachnoiditis, epidural adhesions, failed back syndrome from multiple previous surgeries for herniated lumbar disk, or other indications;
- Radiofrequency denervation for sacroiliac joint pain;
- Radiofrequency lesioning of dorsal root ganglia for back pain;
- Radiofrequency lesioning of terminal (peripheral) nerve endings for back pain;
- Radiofrequency/pulsed radiofrequency ablation of trigger point pain;
- Sacroiliac fusion or pinning for the treatment of LBP due to sacroiliac joint syndrome; Note: Sacroiliac fusion may be medically necessary for sacroiliac joint infection, tumor involving the sacrum, and sacroiliac pain due to severe traumatic injury where a trial of an external fixator is successful in providing pain relief;
- Sacroiliac joint fusion (e.g., by means of the iFuse System and the SImmetry Sacroiliac Joint Fusion System);
- Sacroplasty for osteoporotic sacral insufficiency fractures and other indications;

- Total Facet Arthroplasty System (TFAS) for the treatment of spinal stenosis;
- Vesselplasty (e.g., Vessel-X).

See also CPB 0602 - Thermal Intradiscal Procedure.

Reimbursement Notes:

- *Laser*: Clinical studies have not established a clinically significant benefit of use of a laser over a scalpel in spinal surgery. No additional benefit will be provided for the use of a laser in spinal surgery.
- *Microscope and endoscope*: Use of a microscope or endoscope is considered an integral part of the spinal surgery and not separately reimbursable.

Background

Epidural Steroids

An epidural steroid finjection is an injection of long lasting steroid in the epidural space -- that is the area which surrounds the spinal cord and the nerves coming out of it. An epidural steroid injection is used to help reduce radicular spinal pain that may be caused by pressure on a spinal nerve root as a result of a herniated disc, degenerative disc disease or spinal stenosis. This treatment is most frequently used for low back pain, though it may also be used for cervical (neck) or thoracic (midback) pain. A combination of an anesthetic and a steroid medication is injected into the epidural space near the affected spinal nerve root with the assistance of fluoroscopy which allows the physician to view the placement of the needle.

Approaches to the epidural space for the injection include:

- Caudal – the epidural needle is placed into the tailbone (coccyx) allowing the treatment of pain which radiates into the lower extremities. This approach is commonly used to treat lumbar radiculopathy after prior surgery in the low back (post-laminectomy pain syndrome).
- Cervical – the epidural needle is placed in the midline in the back of the neck to treat neck pain which is associated with radiation of pain into an upper extremity (cervical radiculopathy).
- Interlaminar – the needle is placed between the lamina of two vertebrae directly from the middle of the back. Also called translaminar, this method accesses the large epidural space overlying the spinal cord, and is the most commonly used approach for cervical, thoracic, and lumbar epidural injections. Medication is delivered to the nerve roots on both the right and left sides of the inflamed area at the same time.
- Lumbar – the epidural needle is placed in the midline in the low back to treat back pain which is associated with radiation into a lower extremity (lumbar radiculopathy).
- Thoracic – the epidural needle is placed in the midline in the upper or middle back.
- Transforaminal – the needle is placed to the side of the vertebra in the neural foramen, just above the opening for the nerve root and outside the epidural space; this method treats one side at a time.

The goal of this treatment is to reduce inflammation and block the spinal nerve roots to relieve radicular pain or sciatica. It can also provide sufficient pain relief to allow the individual to progress with their rehabilitation program.

The efficacy of epidurally administered steroids has been demonstrated without adverse consequence in a large number of patients with reproducible results. In a large number of studies, long-term relief of pain (greater than 3 months) can be achieved in at least 10 to 30 % of patients, while short-term relief (less than 1 month) can be achieved in 60 to 100 % of patients. Results for cervical pain are somewhat lower than those for lumbar pain.

Such therapy is considered under accepted guidelines to be indicated in patients with low back and cervical pain that has not resolved after only a short period of more conservative measures since studies have shown a better response to therapy in patients whose pain is of shorter duration. Even if pain relief is temporary, it may have long-term benefit because it allows initiation of physical therapy or other rehabilitative measures at an earlier stage. Most authors indicate that a limit on number of injections is appropriate, and that most patients will respond with 3 or fewer injections.

The American Academy of Neurology's assessment on the use of epidural steroid injections in the treatment of radicular lumbosacral pain (Armond et al, 2007) concluded that:

- Epidural steroid injections may result in some improvement in radicular lumbosacral pain when determined between 2 and 6 weeks following the injection, compared to control treatment (Level C, Class I to III evidence). The average magnitude of effect is small, and the generalizability of the observation is limited by the small number of studies, limited to highly selected patient populations, the few techniques and doses studied, and variable comparison treatments.
- In general, epidural steroid injections for radicular lumbosacral pain have shown no impact on average impairment of function, on need for surgery, or on long-term pain relief beyond 3 months. Their routine use for these indications is not recommended (Level B, Class I to III evidence).
- Data on use of epidural steroid injections to treat cervical radicular pain are inadequate to make any recommendation (Level U).

Guidelines from the American Pain Society (Chou et al, 2009) questioned the clinical value of epidural injection for long-term use or for use of non-radicular back pain. A recommendation for epidural steroid injection for patients with symptomatic spinal stenosis was not offered based on insufficient or poor evidence.

Langer-Gould et al (2013) discussed the American Academy of Neurology (AAN)'s top five recommendations in the “Choosing Wisely” campaign promoting high-value neurologic medicine and physician-patient communication. They noted that 1 of the 11 finalist recommendations was “Don’t perform epidural steroid injections to treat non-radicular low back pain”.

Trigger Point Injections

Trigger point injections (TPI) are injections of saline or a local anesthetic, with or without a steroid medication, into a painful area of a muscle that contains the trigger point. The purpose of a TPI is to relax the area of intense muscle spasm, effectively inactivate the trigger point and provide prompt symptomatic pain relief. TPI is the most common interventional technique used in pain medicine.

Trigger points have also been treated with dry needling. Dry needling is not to be confused with traditional Chinese acupuncture, even though it does make use of acupuncture-type needles. Acupuncture follows the principles of energy flow as a guide to where the needles will be inserted; in dry needling, needles are inserted directly into a myofascial trigger point, in an attempt to inactivate it, thereby decreasing the associated pain. Dry needling, even though it targets a trigger point, also differs from a trigger point injection, as there is no injection of medication or fluid.

A myofascial trigger point is a discrete focal tenderness, 2-5 mm in diameter that is located in distinct tight bands or knots of skeletal muscle (AHFMR, 2002). When palpated, these hyper-irritable areas cause pain in distant areas, or referred pain zones, which are specific for each trigger point. Trigger point injection, or direct wet needling, involves injection of fluid directly into the trigger point located in the taut muscle band. The main objective of trigger point injection is fast pain relief and elimination of muscle spasm in order to break the pain cycle. This facilitates physical therapy aimed at reducing muscle contracture and increasing range of

motion. Trigger point injection is rarely used in isolation but is generally part of a multi-disciplinary approach aimed at treating both the trigger points and reducing all contributing factors (Scott and Guo, 2005; AHFMR, 2002; Sanders et al, 1999). Thus, treatment may also include patient education, psychosocial support, oral medications, and physical therapy to improve the strength and flexibility of the affected musculoskeletal systems. An assessment conducted by the Alberta Heritage Foundation for Medical Research (Scott and Guo, 2005) found that the evidence for the effectiveness of trigger point injections when used as the sole treatment for patients with chronic head, neck, and shoulder pain and whiplash syndrome was inconclusive, regardless of whether sterile water, saline, or botulinum toxin is injected. The assessment found that the combined use of dry needling and trigger point injection with procaine offers no obvious clinical benefit in the treatment of chronic craniofacial pain, while the effectiveness of trigger point injection for the treatment of cervicogenic headache is unknown. In contrast, the assessment found that trigger point injection with lidocaine may be useful in the treatment of joint pain caused by osteoarthritis (Scott and Guo, 2005). The assessment found no proof that triggers point injection is more effective than other less invasive treatments, such as physical therapy and ultrasound, in achieving pain relief, and there is some suggestion that the only advantage of injecting anesthetic into trigger points is that it reduces the pain of the needling process (Scott and Guo, 2005). Usually, approximately 3 treatments are necessary to abolish a trigger point completely (AHFMR, 2002). A number of trigger points may be injected in 1 session, but rarely more than 5. Repeated injections in a particular muscle are not recommended if 2 or 3 previous attempts have been unsuccessful (Alvarez and Rockwell, 2002; Sanders et al, 1999). The pain relief may last for the duration of the anesthetic to many months, depending on the chronicity and severity of the trigger points and the concomitant treatment of perpetuating factors. According to available guidelines, use of trigger point injections should be short-term and part of a comprehensive rehabilitation program. Available guidelines indicate that, while there are a number of uncontrolled case studies using trigger point injections in more acute pain presentations, there is virtually no consistent evidence for its application with chronic non-malignant pain syndrome patients to date (Sanders et al, 1999; AHFMR, 2002).

Lumbar Laminectomy with or without Fusion

Laminectomy and laminotomy involve removal of a small part of the bony arches of the spinal canal, called the lamina, which increases the size of the spinal canal. A laminectomy or laminotomy is most commonly performed for a diagnosis of spinal stenosis. During a laminectomy the entire lamina is removed while only a portion of the lamina is removed in a laminotomy. These procedures are also often done with either a discectomy or a foraminectomy/foraminotomy.

Most individuals with acute low back problems spontaneously recover activity tolerance within 4 to 6 weeks of conservative therapy (AHCPR, 1994). Conservative therapy for acute low back pain (LBP) includes:

- Avoidance of activities that aggravate pain
- Chiropractic manipulation in the first 4 weeks if no radiculopathy
- Cognitive support and reassurance that recovery is expected
- Education regarding spine biomechanics
- Exercise program
- Heat/cold modalities for home use
- Limited bed rest with gradual return to normal activities
- Low impact exercise as tolerated (e.g., walking, swimming, stationary bike)
- Non-narcotic analgesics
- Pharmacotherapy (e.g., non-narcotic analgesics, non-steroidal anti-inflammatory drugs [NSAIDs] (as second-line choices), avoid muscle relaxants, or only use during the first week, avoid narcotics).

If conservative therapy fails to relieve symptoms of sciatica and radiculopathy and there is strong evidence of dysfunction of a specific nerve root confirmed at the corresponding level by findings demonstrated by CT/MRI,

lumbar laminectomy may be proposed as a treatment option. The goal of lumbar laminectomy is to provide decompression of the affected nerve root to relieve the individual's symptoms. It involves the removal of all or part of the lamina of a lumbar vertebra. The addition of fusion with or without instrumentation is considered when there are concerns about instability.

Decompression with or without Discectomy for Cauda Equine Syndrome

Cauda equina ("horse's tail") is the name given to the lumbar and sacral nerve roots within the dural sac caudal to the conus medullaris. Cauda equina syndrome is usually the result of a ruptured, midline intervertebral disk, most commonly occurring at the L4 to L5 level. However, tumors and other compressive masses may also cause the syndrome. Individuals generally present with progressive symptoms of fecal or urinary incontinence, impotence, distal motor weakness, and sensory loss in a saddle distribution. Muscle stretch reflexes may also be reduced. The presence of urinary retention is the single most consistent finding (Perron and Huff, 2002).

In acute cauda equine syndrome, surgical decompression as soon as possible is recommended. In a more chronic presentation with less severe symptoms, decompression could be performed when medically feasible and should be delayed to optimize the patient's medical condition; with this precaution, decompression is less likely to lead to irreversible neurological damage (Dawodu, 2005).

Cervical Laminectomy with or without Fusion

A cervical laminectomy (may be combined with an anterior approach) is sometimes performed when acute cervical disc herniation causes central cord syndrome or in cervical disc herniations refractory to conservative measures. Studies have shown that an anterior discectomy with fusion is the recommended procedure for central or anterolateral soft disc herniation, while a posterior laminotomy-foraminotomy may be considered when technical limitations for anterior access exist (e.g., short thick neck) or when the individual has had prior surgery at the same level (Windsor, 2006).

Discectomy alone is regarded as a technique that most frequently results in spontaneous fusion (70 to 80 %). Additional fusion techniques include the use of bone grafts (autograft, allograft or artificial) with or without cages and/or the use of an anterior plate. Based on the clinical evidence, autologous or cadaveric bone grafting, with or without plating, remains the gold standard for cervical fusion. Therefore, use of an intervertebral cage for cervical fusion is considered experimental and investigational. A Cochrane systematic review (2004) reported the results of fourteen studies (n = 939) that evaluated three comparisons of different fusion techniques for cervical degenerative disc disease and concluded that discectomy alone has a shorter operation time, hospital stay, and post-operative absence from work than discectomy with fusion with no statistical difference for pain relief and rate of fusion. The authors concluded that more conservative techniques (discectomy alone, autograft) perform as well or better than allograft, artificial bone, and additional instrumentation; however, the low quality of the trials reviewed prohibited extensive conclusions and more studies with better methodology and reporting are needed.

An assessment by the BlueCross BlueShield Association Technology Evaluation Center (BCBSA, 2014) stated: "The choice of bone material for interbody fusion in [anterior cervical discectomy and fusion] ACDF has important clinical implications. Allograft bone has several drawbacks, including a minute (albeit unproven) risk of infectious disease transmission; possible immunological reaction to the allograft; and possible limited commercial availability of appropriate graft material. In contrast, the use of autograft bone in ACDF has potentially substantial morbidities at the harvest site, generally the iliac crest. These include moderate-to-severe, sometimes prolonged pain; deep infection; adjacent nerve and artery damage; and increased risk of stress fracture. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90%–100%) and

satisfactory outcomes for single-level, anterior-plated ACDF using either bone source. Thus, the choice of graft material involves a trade-off between the risks specific to autograft harvest versus those specific to use of allograft material."

A systematic review of randomized controlled trials found no reliable evidence for use of cages over autograft for cervical spinal fusion (Jacobs et al, 2011). Noting that the number of surgical techniques for decompression and anterior cervical interbody fusion (ACIF) for cervical degenerative disc disease has increased, the investigators sought to determine which technique of ACIF gives the best outcome. From a comprehensive search, the investigators selected randomized studies that compared anterior cervical decompression and ACIF techniques, in patients with chronic single- or double-level degenerative disc disease or disc herniation. Risk of bias was assessed using the criteria of the Cochrane back review group. A total of 33 studies with 2,267 patients were included. The major treatments were discectomy alone and addition of an ACIF procedure (graft, cement, cage, and plates). The investigators stated, at best, there was very low-quality evidence of little or no difference in pain relief between the techniques. The investigators found moderate quality evidence for few secondary outcomes. The investigators found that Odom's criteria were not different between iliac crest autograft and a metal cage (risk ratio [RR]: 1.11; 95 % confidence interval [CI]: 0.99-1.24). Bone graft produced more fusion than discectomy (RR: 0.22; 95 % CI: 0.17-0.48). Complication rates were not different between discectomy and iliac crest autograft (RR: 1.56; 95 % CI: 0.71-3.43). Low-quality evidence was found that iliac crest autograft results in better fusion than a cage (RR: 1.87; 95 % CI: 1.10-3.17); but more complications (RR: 0.33; 95 % CI: 0.12-0.92). The investigators concluded that, when fusion of the motion segment is considered to be the working mechanism for pain relief and functional improvement, iliac crest autograft appears to be the gold standard. The investigators stated that, when ignoring fusion rates and looking at complication rates, a cage as a gold standard has a weak evidence base over iliac crest autograft, but not over discectomy.

An evidence review by Epstein et al (2012) reached similar conclusions. Epstein (2012) noted that grafting choices available for performing anterior cervical diskectomy/fusion (ACDF) procedures have become a major concern for spinal surgeons, and their institutions. The "gold standard", iliac crest autograft, may still be the best and least expensive grafting option; it deserves to be reassessed along with the pros, cons, and costs for alternative grafts/spacers. Although single or multilevel ACDF have utilized iliac crest autograft for decades, the implant industry now offers multiple alternative grafting and spacer devices; (allografts, cages, polyether-etherketone (PEEK) amongst others). While most studies have focused on fusion rates and clinical outcomes following ACDF, few have analyzed the "value-added" of these various constructs (e.g. safety/ efficacy, risks/complications, costs). Epstein (2012) found that the majority of studies document 95%-100% fusion rates when iliac crest autograft is utilized to perform single level ACDF (X-ray or CT confirmed at 6-12 postoperative months). Although many allograft studies similarly quote 90%-100% fusion rates (X-ray alone confirmed at 6-12 postoperative months), a recent "post hoc analysis of data from a prospective multicenter trial" (Riew KD et. al., CSRS Abstract Dec. 2011; unpublished) revealed a much higher delayed fusion rate using allografts at one year 55.7%, 2 years 87%, and four years 92%. The author found no clinically significant differences in cervical spine fusion outcomes between autograft and cages, despite an up to 10-fold difference in cost among various constructs. The author concluded that iliac crest autograft utilized for single or multilevel ACDF is associated with the highest fusion, lowest complication rates, and significantly lower costs compared with allograft, cages, PEEK, or other grafts. As spinal surgeons and institutions become more cost conscious, we will have to account for the "value added" of these increasingly expensive graft constructs.

Kersten et al (2015) stated that polyetheretherketone (PEEK) cages have been widely used during the past decade in patients with degenerative disorders of the cervical spine. Their radiolucency and low elastic modulus make them attractive attributes for spinal fusion compared with titanium and bone graft. Still, limitations are seen such as pseudoarthrosis, subsidence, and migration of the cages. The authors stated that limited evidence on the clinical outcome of PEEK cages is found in the literature other than noncomparative cohort studies with

only a few randomized controlled trials. The authors conducted a systematic evidence review to assess the clinical and radiographic outcome of PEEK cages in the treatment of degenerative disc disorders and/or spondylolisthesis in the cervical spine. The systematic review included all randomized controlled trials and prospective and retrospective nonrandomized comparative studies with a minimum follow-up of 6 months and all noncomparative cohort studies with a long-term follow-up of more than 5 years. The primary outcome variable was clinical performance. Secondary outcome variables consisted of radiographic scores. The MEDLINE, EMBASE, and Cochrane Library databases were searched according to the Preferred Reporting Items of Systematic reviews and Meta-Analyses statement and Metaanalysis Of Observational Studies in Epidemiology guidelines. A total of 223 studies were identified, of which 10 studies were included. These comprised two randomized controlled trials, five prospective comparative trials, and three retrospective comparative trials. The authors found minimal evidence for better clinical and radiographic outcome for PEEK cages compared with bone grafts in the cervical spine. No differences were found between PEEK, titanium, and carbon fiber cages. The authors stated that future studies are needed to improve methodology to minimize bias. Publication of lumbar interbody fusion studies needs to be promoted because differences in clinical and/or radiographic scores are more likely to be demonstrated in this part of the spine.

The Joint Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and Congress of Neurological Surgeons (Ryken et al, 2009) conducted a systematic review to determine the efficacy of cervical interbody grafting techniques. The National Library of Medicine and Cochrane Database were queried using MeSH headings and keywords relevant to cervical interbody grafting. Abstracts were reviewed and studies that met the inclusion criteria were selected. The guidelines group assembled an evidentiary table summarizing the quality of evidence (Classes I-III). Disagreements regarding the level of evidence were resolved through an expert consensus conference. The group formulated recommendations that contained the degree of strength based on the Scottish Intercollegiate Guidelines network. Validation was done through peer review by the Joint Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons. The authors found that autograft bone harvested from the iliac crest, allograft bone from either cadaveric iliac crest or fibula, or titanium cages and rectangular fusion devices, with or without the use of autologous graft or substitute, have been successful in creating arthrodesis after 1- or 2-level anterior cervical discectomy with fusion (Class II). Alternatives to autograft, allograft, or titanium cages include polyetheretherketone cages and carbon fiber cages (Class III). Polyetheretherketone cages have been used successfully with or without hydroxyapatite for anterior cervical discectomy with fusion. Importantly, recombinant human bone morphogenic protein-2 carries a complication rate of up to 23-27% (especially local edema) compared with 3% for a standard approach. The authors concluded that current evidence does not support the routine use of interbody grafting for cervical arthrodesis. Multiple strategies for interbody grafting have been successful with Class II evidence supporting the use of autograft, allograft, and titanium cages.

The Congress of Neurological Surgeons assessment (Ryken et al, 2009) stated that “class II evidence indicates that either autograft bone harvested from iliac crest, allograft bone from either cadaveric iliac crest or fibula, or titanium cages and rectangular fusion devices, with or without autologous graft or substitute are excellent interbody treatment options for obtaining cervical arthrodesis. There is an expected autograft fusion rate for non-instrumented single-level fusions better than 80% and for 2-level fusion of better than 70%. With allograft, the expected fusion rate for non-instrumented single-level fusion is > 80%, and is > 50% for 2-level fusion. The use of titanium cages carries an expectation of a fusion rate of > 70%, and often > 90% with avoidance of donor site morbidity.” The CNS assessment stated: “In choosing a graft strategy, no single type of graft has not proven consistently superior to the other. Class III evidence suggests that the surgeon consider the increased rate of subsidence with allograft but also understand that subsidence does not correlate with clinical outcome. Class III evidence also suggests that the surgeon factor in the incidence of donor pain and decrease in patient satisfaction reported with the harvest of autograft iliac crest graft.” The assessment stated: “If alternatives to auto- and

allograft are preferred, therapeutic options are as follows: PEEK may be considered with or without the use of hydroxyapatite after ACDF. There is an expectation of fusion rates > 90% with fewer complications due to the absence of graft harvesting (Class III). Carbon fiber cages may be considered as well with fusion rates ranging from 55 to 62% in the larger studies (Class III). Polymethyl-methylmethacrylate may be considered to preserve intervertebral distraction after discectomy, but is a poor fusion substrate (Class II). All of the above options appear to have similar clinical outcomes equivalent to the use of bone." The CNS assessment concluded that, "Given the generally high rates of improved clinical outcome with anterior cervical discectomy and fusion, regardless of methodology, the evaluation of medical-economic factors may play an important role in future studies."

A Senate Finance Committee Report (2012) focusing on Infuse, one substitute for bone graft, noted that company officials inserted language into studies that promoted the substitute as a better technique than the autograft technique by emphasizing the pain associated with the autograft technique.

Chemonucleolysis

Chemonucleolysis is a procedure that involves the dissolving of the gelatinous cushioning material in an intervertebral disk by the injection of chymopapain or other enzyme. The AHCPR evidence-based guideline on the management of acute back pain and the medical literature supports the use of chemonucleolysis (CNL) with chymopapain as a safe and effective alternative to surgical disc excision in the majority of patients who are candidates for surgery for intractable sciatica due to herniated nucleus pulposus (HNP). Chemonucleolysis involves the enzymatic degradation of the nucleus pulposus, and has been shown to be more effective than percutaneous discectomy since it can be successfully performed for protruded and extruded discs, just as long as the herniated disc material is still in continuity with the disc of its origin. Following CNL, in many cases, relief of sciatica is immediate; however, in up to 30 % of patients, maximal relief of symptoms may take up to 6 weeks. The overall success rate for CNL in long-term follow-up (7 to 20 years) in 3,130 patients from 13 contributors averaged 77 % (range of 71 to 93 %), the same as that reported for surgical discectomy. In the United States, CNL is approved by the Food and Drug Administration (FDA) for use in the lumbar spine only.

Facet Joint Blocks and Medial Branch Blocks

Facet injections, also known as facet blocks, are injections of a local anesthetic, with or without a steroid medication, into the facet joints or around the nerve supply (the medial branch nerve) to the joints. Facet injections may be given for diagnostic purposes to determine if the facet joint is the source of pain or it may be performed to treat facet pain that has previously been detected.31 The injections are fluoroscopically guided. If the pain is relieved, the physician will know that the facet joint appears to be the source of pain. This may be followed with therapeutic injections of anti-inflammatory (steroid) and/or local anesthetic medications to relieve pain for longer periods. Facet denervation may also follow a successful diagnostic facet block.

Degenerative changes in the posterior lumber facet joints have been established as a source of LBP that may radiate to the leg. Pain impulses from the medial branches of lumbar dorsal rami can be interrupted by blocking these nerves with anesthetic (facet block) or coagulating them with a radiofrequency wave (radiofrequency facet denervation). Typically, facet joint blocks are performed as a part of a work-up for back or neck pain (Wagner, 2003). Pain relief following a precise injection of local anesthetic confirms the facet joint as the source of pain. Based on the outcome of a facet joint nerve block, if the patient gets sufficient relief of pain but the pain recurs, denervation of the facet joint may be considered.

A number of uncontrolled studies have suggested positive effects of facet injections on chronic back pain (Wagner, 2003). However, randomized controlled trials (RCTs) have failed to demonstrated a benefit. A well-designed trial (n = 101) of patients who responded to a local anesthetic injection into the facet joint published in

the *New England Journal of Medicine* found no difference in the likelihood of pain relief following randomization to glucocorticoid or saline facet joint injection at either 1 or 3 months post injection (Carette et al, 1991). A higher proportion of patients in the steroid injection group reported marked improvement after 6 months (46 % versus 15 %), but the benefit was attenuated after controlling for co-interventions used in the steroid group, and there is no biologic explanation for a delayed benefit from steroids. A second, smaller trial found no differences between steroid and/or bupivacaine injection compared to placebo (Lilius et al, 1989).

A number of systematic evidence reviews and evidence-based guidelines have evaluated the literature on facet injections for chronic back pain. Guidelines from the American Pain Society (Chou et al, 2009) stated: "We found good or fair evidence that ... facet joint injection ... are not effective." Guidelines from the American Association of Neurological Surgeons (Resnick et al, 2005) state: "Facet injections are not recommended as long-term treatment for chronic low-back pain." Guidelines from the American College of Occupational and Environmental Medicine (Hegmann, 2007) state that therapeutic facet joint injections for acute, subacute, chronic low back pain or radicular pain syndrome are "not recommended". An assessment by the Canadian Agency for Drugs and Technologies in Health (Zakaria et al, 2007) concluded: "According to the RCTs [randomized controlled trials] completed to date, FJIs [facet joint injections] with local anesthetics or steroids have not been proven to be superior to placebo for the treatment of chronic LBP [low back pain]. Steroid FJIs have not been proven to be superior to local anesthetic FJIs in the treatment of chronic neck pain secondary to a motor vehicle accident. The studies are limited. ..." An assessment for *BMJ Clinical Evidence* (McIntosh and Hall, 2007) concluded that facet injections for chronic back pain are of "unknown effectiveness". A Cochrane systematic evidence review found no clear differences between facet joint glucocorticoid and placebo injections (Staal et al, 2008). A review in UpToDate (Chou, 2009) stated: "Evidence is unavailable, unreliable, or contradictory regarding the effectiveness of glucocorticoid injections for other sites, including ... facet joint injections .... We suggest not performing these procedures for chronic low back pain".

Sacroiliac Joint Injections

Sacroiliac (SI) joint injections are performed by injecting a local anesthetic, with or without a steroid medication, into the SI joints. These injections may be given for diagnostic purposes to determine if the SI joint is the source of the low back pain or it may be performed to treat SI joint pain that has previously been detected/diagnosed. If the pain is relieved, the physician will know that the SI joint appears to be the source of pain. This may be followed up with therapeutic injections of anti-inflammatory (steroid) and/or local anesthetic medications to relieve pain for longer periods.

In a prospective, single-blinded, randomized controlled trial, Jee and colleagues (2014) compared the safety and short-term effects of ultrasound (US)-guided SIJ injections with fluoroscopy (FL)-guided SIJ injections in patients with non-inflammatory SIJ dysfunction (n = 120). All procedures were performed using an FL or US apparatus. Subjects were randomly assigned to either the FL or US group. Immediately after the SIJ injections, fluoroscopy was applied to verify the correct placement of the injected medication and intravascular injections. Treatment effects and functional improvement were compared at 2 and 12 weeks after the procedures. The verbal numeric pain scale and ODI improved at 2 and 12 weeks after the injections without statistical significances between groups. Of 55 US-guided injections, 48 (87.3 %) were successful and 7 (12.7 %) were missed. The FL-guided SIJ approach exhibited a greater accuracy (98.2 %) than the US-guided approach. Vascularization around the SIJ was seen in 34 of 55 patients. Among the 34 patients, 7 had vascularization inside the joint, 23 had vascularization around the joint, and 4 had vascularization both inside and around the joint; 3 cases of intravascular injections occurred in the FL group. The authors concluded that the US-guided approach may facilitate the identification and avoidance of the critical vessels around or within the SIJ. Function and pain relief significantly improved in both groups without significant differences between groups. The US-guided approach was shown to be as effective as the FL-guided approach in treatment effects.

However, diagnostic application in the SIJ may be limited because of the significantly lower accuracy rate (87.3 %).

Radiofrequency Facet Denervation

Radiofrequency ablation (may also be referred to as RFA, percutaneous radiofrequency neuroablation, radiofrequency coagulation, radiofrequency denervation, radiofrequency lesioning, radiofrequency neuroablation, radiofrequency neurotomy or rhizotomy [articular rhizolysis]) involves the use of radiofrequency energy to denervate a nerve. One of the most commonly performed neuroablative procedures is facet denervation, which is the destruction or interruption of a facet joint nerve to relieve chronic pain in the cervical, thoracic or lumbar region of the spine.

Facet joints of the spine have joint capsules that are supplied by a branch of the posterior ramus of the spinal nerve. Percutaneous radiofrequency facet denervation, also known as radiofrequency facet joint rhizotomy or facet neurotomy, involves selective denervation using radiofrequency under fluoroscopic guidance. As a method of neurolysis, radiofrequency facet denervation has been shown to be a very safe procedure and can offer relief for many patients with mechanical LBP in whom organic pathology, most commonly a herniated lumbar disc, has been eliminated. According to the literature, it offers advantages over conventional neurolytic agents (e.g., phenol, alcohol, and hypertonic saline) because of its long lasting effects, the relative lack of discomfort, and its completely local action without any random diffusion of the neurolytic agent. Because there are no reliable clinical signs that confirm the diagnosis, successful relief of pain by injections of an anesthetic agent into the joints are necessary before proceeding with radiofrequency facet denervation. Results from many studies have shown that radiofrequency facet denervation results in significant (excellent or good) pain relief, reduced use of pain medication, increased return-to-work, and is associated with few complications. Success rate, however, depends on a careful selection of patients.

Laser Facet Denervation

Neuroablative techniques in pain management consist of several surgical and non-surgical methods to denervate a nerve. The goal of denervation is to "shut off" the pain signals that are sent to the brain from the joints and nerves. An additional objective is to reduce the likelihood of, or to delay, any recurrence by selectively destroying pain fibers without causing excessive sensory loss, motor dysfunction or other complications.

Laser ablation involves the use of laser to denervate a nerve. There is a lack of published evidence of laser facet denervation for lumbar facet pain.

Facet Chemodenervation/Chemical Facet Neurolysis

Chemical neurolysis (also referred to as chemical ablation, chemical denervation or chemodenervation) involves injection of neurolytic agents [eg, phenol, alcohol or hypertonic saline]) to denervate a nerve. The use of chemical facet injections such as alcohol, phenol and hypertonic saline has been proposed as an option for lumbar facet pain. However, there is a lack of published data to support the safety and effectiveness of this technique.

Pedicle Screw Fixation

Pedicle screw fixation systems consist of steel or titanium plates that are longitudinally inter-connected and anchored to adjacent vertebrae using bolts, hooks, or screws. Pedicle screw fixation in the spine is used to produce a rigid connection between 2 or more adjacent vertebrae in order to correct deformity and to stabilize the spine, thereby reducing pain and any neurological deficits. It is most often used in the lumbosacral spine from L1 though S1, and may also be used in the thoracic spine. Excision of tissues compressing the spinal cord

(posterior decompression) is a common treatment for patients with herniated or subluxed vertebrae (spondylolisthesis), degenerative intervertebral discs, certain types of vertebral fractures, or spinal tumors. Spinal instability following decompression may be sufficiently severe to require stabilization by bony fusion (arthrodesis) of affected and adjacent vertebrae using implanted autologous bone grafts. Following placement of the graft, sufficient mechanical stability to allow its incorporation may be provided by combinations of various surgically implanted hooks, rods, or wires. However, severe instability may require surgical implantation of plates or rods anchored to vertebral pedicles using screws (pedicle screw fixation systems) in order to provide rigid 3-column fixation and minimize the risk of incomplete fusion (pseudoarthrosis or pseudarthrosis) or loss of alignment during fusion. The current medical literature suggests that rigid fixation of the lumbar spine with pedicle screws improves the chances of successful fusion as compared with patients with lumbar spine fusion not supplemented with internal fixation. Internal fusion and fixation are major operative procedures with significant risks and according to the available literature should be reserved for patients with spinal instability associated with neurological deficits, major spinal deformities, spinal fracture, spinal dislocation or complications of tumor. Spinal fusion and pedicle screw fixation has been shown not to be effective for the treatment of isolated chronic back pain, and surgery is not advocated to treat this diagnosis in the absence of instability or neurological deficits. In July 1998, the FDA re-classified into Class II the pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute or chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Pedicle screw systems intended for any other uses are considered post-amendment Class III devices for which pre-market approval is required.

Intervertebral Body Fusion Devices (Spine Cages)

A spine cage, also known as an interbody cage, is a small hollow cylindrical device, usually made of titanium, with perforated walls. The device is placed in the disc space between 2 vertebrae to restore lost disc height resulting from a collapsed disc and to relieve pressure on nerve roots. Currently, there are 2 intervertebral body fusion devices approved by the FDA: the BAK Interbody Fusion System (Spine-Tech, Inc.), and the Ray Threaded Fusion Cage (Surgical Dynamics, a subsidiary of United States Surgical Corporation). The BAK (Bagley and Kuslich) Interbody Fusion System and the Ray Threaded Fusion Cage (TFC) are hollow cylinders made of titanium, which may be implanted by anterior or posterior approach. Unlike pedicle screws, both of these fusion devices are permanent implants, as the literature describes bone growing into and through the implant. The safety and effectiveness of these fusion devices have not been established in 3 or more levels to be fused, previous fusion attempt at the involved level(s), spondylolisthesis or retrolisthesis of Grade II or greater. Although the BAK has received FDA approval for implantation laparoscopically, studies performed for FDA approval demonstrated significantly greater incidence of complications from anterior spinal reconstructive surgery using a laparoscopic approach than using an open approach. Furthermore, patients with laparoscopically implanted BAK fusion devices were followed for only 6 months; thus, the long-term stability of laparoscopically implanted BAK cages is unknown. Thus, coverage of laparoscopic (endoscopic) implantation of the BAK should be denied as experimental and investigational. (See discussion of anterior endoscopic spinal reconstructive surgery above).

Vertebroplasty

Percutaneous polymethylmethacrylate vertebroplasty (PPV) is a therapeutic, interventional radiologic procedure, which consists of the injection of an acrylic bone cement (usually methyl methacrylate) into a cervical, thoracic or lumbar vertebral body lesion for the relief of pain and the strengthening of bone. The procedure is performed under fluoroscopic guidance with local anesthesia and moderate sedation. This

procedure is being used for patients with lytic lesions due to bone metastases, aggressive hemangiomas, or multiple myeloma, and for patients who have medically intractable debilitating pain resulting from osteoporotic vertebral collapse.

Examples of PMMA include, but may not be limited to, Ascendx Cement, Cobalt HV, Cobalt V Radiopaque Vertebroplasty Bone Cement, Cohesion, Kyphx HV-R, Opacity+, Osteopal, Osteopal V, SPACE CpsXL, Spine-Fix Biomimetic Bone Cement, StabiliT ER, Vertecern and Vertefix Radiopaque Bone Cement. An alternative to traditional bone cement is Cortoss Bone Augmentation Material. Cortoss is an injectable, non-resorbable synthetic material that functions as a strengthening agent for injection into vertebral bodies with compression fractures.

Results from two uncontrolled prospective studies and several case series reports, including one with 187 patients, indicated that percutaneous vertebroplasty can produce significant pain relief and increase mobility in 70 % to 80 % of patients with osteolytic lesions in the vertebrae. In these reports, pain relief was apparent within 1 to 2 days after injection, and appeared to persist for at least several months up to several years. While experimental studies and preliminary clinical results suggest that percutaneous vertebroplasty can also strengthen the vertebral bodies and increase mobility, it remains to be proven whether this procedure can prevent additional fractures in the injected vertebrae. In addition, the duration of effect was not known; there were no long-term follow-up data on most of these patients, and these data may be difficult to obtain and interpret in patients with an underlying malignant process because disease progression may confound evaluation of the treatment effect. Complications were relatively rare, although some studies reported a high incidence of clinically insignificant leakage of bone cement into the paravertebral tissues. In a few cases, the leakage of polymer caused compression of spinal nerve roots or neuralgia. Several instances of pulmonary embolism were also reported.

The FDA (2004) notified healthcare professionals about complications related to the use of polymethylmethacrylate bone cement to treat osteoporotic compression fractures of the spine using vertebroplasty and kyphoplasty. Reported complications, such as soft tissue damage and nerve root pain and compression, are related specifically to the leakage of bone cement. Other reported complications include pulmonary embolism, respiratory and cardiac failure, and death.

Percutaneous vertebroplasty is an in-patient procedure because it may cause compression of adjacent structures and require emergency decompressive surgery. In addition, radiation therapy or concurrent surgical interventions, such as laminectomy, may also be required in patients with compression of the spinal cord due to ingrowth of a tumor. An assessment of percutaneous vertebroplasty by the National Institute for Clinical Excellence (NICE, 2003) concluded that "current evidence on the safety and efficacy of percutaneous vertebroplasty appears adequate".

However, 2 subsequently published RCTs published in the *New England Journal of Medicine* have found no significant benefit with vertebroplasty. In the Investigational Vertebroplasty Safety and Efficacy Trial (INVEST), Kallmes et al (2009) reported that pain and disability outcomes at 1 month in a group of patients who underwent vertebroplasty were similar to those in a control group that underwent a sham procedure. In the other trial, Buchbinder et al (2009) measured pain, quality of life, and functional status at 1 week and at 1, 3, and 6 months after sham and active vertebroplasty and found there were no significant between-group differences at any time point. As in INVEST, patients in the 2 study groups had improvement in pain.

The Society for Interventional Radiology (SIR, 2009) had identified a number of issues in interpreting these studies, including potential biases in patient selection, the use of vertebroplasty in older (greater than 3 months) fractures, and a potentially inadequate amount of polymethylmethacrylate (PMMA) that was injected into the vertebrae. The SIR concluded: "We recognize the value of randomized controlled trials and evidence-based

medicine. But based on the above-discussed weakness in the studies and the degree of discordance between the outcomes of these studies, prior studies and experience, we believe it is premature -- and possibly incorrect -- to conclude that vertebroplasty is no better than a control sham procedure (trigger point, facet injection). We suggest waiting for the results of the VERTOSS 2 trial to be published and encourage larger clinical trials to address the weaknesses of the two *New England Journal of Medicine* articles".

In a retrospective study, He and colleagues (2008) examined if a repeat percutaneous vertebroplasty (PV) is effective on pain-relief at the vertebral levels in patients who had previously undergone PV. Of the 334 procedures of PV performed in 242 patients with osteoporotic vertebral compression fractures from October 2000 to June 2006 in the authors' institute, 15 vertebrae in 15 patients with unrelieved pain in 4 to 32 days after an initial PV were treated with a repeat vertebroplasty. The clinical outcomes were assessed by measurements of visual analog scale (VAS), and the imaging features were analyzed pre- and post-procedure. The mean volume of polymethylmethacrylate injected in each vertebra was 4.0 ml (range of 1.5 to 9 ml) in the repeat PV. During the first month of follow-up after repeat PV in this series, a mean VAS scores of the pain level was reduced from 8.6 (range of 7 to 10) pre-procedure to 1.67 points (range of 0 to 4) post-procedure, with a mean reduction of 6.93 points (range of 4 to 8). Complete and partial pain relief were reached in 11 (73 %) and 4 patients (27 %), respectively in a mean follow-up of 15 months. No serious complications related to the procedures occurred, however asymptomatic polymethylmethacrylate leakage around vertebrae was demonstrated on radiograph or computed tomography in 2 patients. The authors concluded that the outcomes of this series suggested that repeat PV is effective at the same vertebral levels in patients without pain-relief who underwent previous PV. Absent or inadequate filling of cement in the unstable fractured areas of the vertebral body may be responsible for the unrelieved pain after the initial PV.

An accompanying editorial by Kallmes (2008) of the afore-mentioned article stated that "[u]nfortunately, limitations in the current study likely preclude definitive answers, but still the series may help focus future studies". The editorialist also noted that while the authors found insufficient or absent filling in 100 % of the failed cases, they did not provide any information regarding the frequency in which they had insufficient or absent filling in the other 227 (successful) cases. Furthermore, Kallmes is still somewhat concerned about the safety of the repeat procedure.

Absolute contraindications to percutaneous vertebroplasty or kyphoplasty (balloon-assisted vertebroplasty) include, but may not be limited to, the following:

- Allergy to bone cement or contrast media; or
- Asymptomatic vertebral compression fractures; or
- Individual is improving with medical therapy; or
- Nonfractured vertebral levels; or
- Ongoing local or systemic infection; or
- Osteomyelitis of the target vertebra; or
- Prophylactic treatment for osteoporosis to prevent future fractures; or
- Retropulsed bone fragment resulting in myelopathy; or
- Spinal canal compromise secondary to tumor resulting in myelopathy; or
- Uncorrected coagulation disorders.

Relative contraindications to percutaneous vertebroplasty include, but may not be limited to, the following:

- Asymptomatic retropulsion of a fracture fragment causing significant spinal compromise; or
- Asymptomatic tumor extension into the epidural space; or
- Radiculopathy in excess of vertebral pain, caused by a compressive syndrome unrelated to vertebral collapse.

Kyphoplasty

Kyphoplasty (also known as balloon-assisted vertebroplasty) is a minimally-invasive orthopedic procedure, which has been developed to restore bone height lost due to painful osteoporotic compression fractures. It is a modification of the vertebroplasty procedure, and involves the insertion of 1 or 2 balloon devices into the fractured vertebral body. Once inserted, the surgeon inflates the balloon(s) to create a cavity and to compact the deteriorated bone with the intent to restore vertebral height. The balloon(s) are then removed and the newly created cavity is filled with the surgeon's choice of bone filler material, creating an internal cast for the fractured area.

The Kiva VCF Treatment System is an implantable device which has been proposed for use with a vertebroplasty or kyphoplasty procedure for reduction and treatment of spinal fractures. PMMA bone cement is used to fill the implant once it is placed.

An assessment of balloon kyphoplasty by the National Institute for Health and Clinical Excellence (NICE, 2006) concluded that "[c]urrent evidence on the safety and efficacy of balloon kyphoplasty for vertebral compression fractures appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance". The NICE assessment reviewed 3 non-randomized studies, 2 of which compared balloon kyphoplasty with conventional medical care (physical and analgesic therapy) and 1 which compared the procedure with vertebroplasty. All 3 studies found that patients who had undergone balloon kyphoplasty had improved pain scores compared with the control group at a maximum follow-up of 24 months. The assessment noted that the specialist advisors to NICE expressed uncertainties about whether the improvements following balloon kyphoplasty (reduced pain and height restoration) are maintained in the long term. In clinical studies, the most common complication following balloon kyphoplasty was cement leakage, occurring in up to 11 % of patients. Other potential complications of kyphoplasty include infection, allergy, and spinal cord or nerve root injury caused by incorrect needle placement.

Based on the results of an assessment, the Ontario Ministry of Health and Long Term Care (2004) reached the following conclusions about balloon kyphoplasty: "There are currently two methods of cement injection for the treatment of osteoporotic VCFs. These are vertebroplasty and balloon kyphoplasty. Although no RCT has been conducted to compare the two techniques, the existing evidence shows that balloon kyphoplasty is a reasonable alternative to vertebroplasty, given the lower reported peri-operative and long-term complications of balloon kyphoplasty".

Wardlaw et al (2009) reported positive results with kyphoplasty compared with non-surgical care in a non-blinded, multi-center RCT. The investigators randomly assigned 300 adults with 1 to 3 acute vertebral fractures to kyphoplasty (n = 149) or non-surgical care (n = 151). At 1 month, mean SF-36 Physical Component Score (PCS) improved by 7.2 points (95 % confidence interval [CI]: 5.7 to 8.8) in the kyphoplasty group, and by 2.0 points (95 % CI: 0.4 to 3.6) in the non-surgical group, a difference between groups that was statistically significant ($p < 0.0001$). The investigators reported that the frequency of adverse events did not differ between groups. There were 2 serious adverse events related to kyphoplasty (hematoma and urinary tract infection); other serious adverse events (such as myocardial infarction and pulmonary embolism) did not occur peri-operatively and were not related to procedure.

The California Technology Assessment Forum (Karliner, 2009) concluded that balloon kyphoplasty meets CTAF criteria for safety, effectiveness and improvement in health outcomes for the treatment of recent (less than 3 month old) osteoporotic vertebral compression fractures confirmed by MRI.

Sacroplasty

Sacroplasty is a variation of the vertebroplasty technique, and involves the injection of polymethylmethacrylate cement into sacral insufficiency fractures for stabilization. Under fluoroscopic guidance, PMMA is injected into the sacrum at the fracture site, in an attempt to stabilize the fracture. Sacral insufficiency fractures (SIFs) can cause LBP in osteoporotic patients. Symptomatic improvement may require up to 12 months. Treatment includes limited weight-bearing and bed rest, oral analgesics, and sacral corsets. Significant mortality and morbidity are associated with pelvic insufficiency fractures. Percutaneous sacroplasty is being developed as an alternative treatment for SIF patients.

Frey et al (2007) reported on a prospective observational cohort study of the safety and efficacy of sacroplasty in consecutive osteoporotic patients with SIFs. Each procedure was performed under intravenous conscious sedation using fluoroscopy. Two bone trochars were inserted between the sacral foramen and sacroiliac joint through which 2 to 3 ml of polymethylmethacrylate was injected. A total of 37 patients, 27 females, were treated. Mean age was 76.6 years, and mean symptom duration was 34.4 days. All patients were available at each follow-up interval except 1 patient who died due to unrelated pulmonary disease before the 4-week follow-up. The investigators reported that mean VAS score at baseline was 7.7 and 3.2 within 30 mins, and 2.1 at 2, 1.7 at 4, 1.3 at 12, 1.0 at 24, and 0.7 at 52 weeks post-procedure. The investigators found that improvement at each interval and overall was statistically significant using the Wilcoxon Rank Sum Test. One case of transient S1 radiculitis was encountered. The investigators concluded that sacroplasty appears to be a safe and effective treatment for painful SIF. Limitations of this study include its small size, limited duration of follow-up, and lack of control group.

Vesselplasty

Vesselplasty (Vessel-X, A-Spine Holding Group Corp., Taipei, Taiwan) is an image-guided procedure that attempts to solve the problem of cement leakage out of the vertebral body, which can happen during both vertebroplasty and kyphoplasty. Cement leakage, a common problem with vertebroplasty particularly in lytic lesions (Mathis and Wong, 2003), has been reported in up to 30 % to 70 % of cases. Most occurrences, however, are asymptomatic (Cortet et al, 1997). Vesselplasty uses a porous polyethylene terephthalate balloon to create both a cavity and contain the cement, thereby, allowing only a small amount of cement to permeate into the vertebral body.

Flors et al (2009) evaluated the use of vesselplasty to treat symptomatic vertebral compression fractures (VCFs) in 29 patients. All patients had been undergoing medical therapy for 1 or more painful VCFs. Pain, mobility, and analgesic use scores were obtained, and restoration of vertebral body height was evaluated. A 2-tailed paired Student's t test was used to compare differences in the mean scores for levels of pain, mobility, and analgesic use before and after the procedure and to evaluate changes in vertebral body height. Seven of the 29 patients had fractures in more than 1 level, for a total of 37 procedures. The cause of the vertebral collapse was osteoporosis in 27 (73 %), high-impact trauma in 5 (13.5 %), myeloma in 3 (8 %), and metastatic fracture in 2 (5.4 %). The average pain score before treatment was 8.72 +/- 1.25 (SD), whereas the average pain score after treatment was 3.38 +/- 2.35. The average mobility score before treatment was 2.31 +/- 1.94, whereas the average mobility score after treatment was 0.59 +/- 1.05 ($p < 0.001$). The average analgesic use score before treatment was 3.07 +/- 1.46, whereas it was 1.86 +/- 1.90 after treatment ($p < 0.001$). There was no evidence of clinical complications. The authors concluded that vesselplasty offers statistically significant benefits in improvements of pain, mobility, and the need for analgesia in patients with symptomatic VCFs, thus providing a safe alternative in the treatment of these fractures.

While vesselplasty appears to be a promising new technique for VCFs, there is insufficient evidence of its safety and effectiveness. Prospective, randomized, controlled studies with a larger number of patients and long-term follow-up are needed.

Epiduroscopy

Epiduroscopy involves insertion of a fiberoptic camera through the sacral hiatus into the lower epidural space, which is then guided upwards towards the lower lumbar discs and nerve roots. Epidural adhesions can be released and anesthetic and steroid injected around nerve roots. In September 1996, the epiduroscope (myeloscope) was cleared by the FDA for visualization of the epidural space. It has been used in the outpatient setting for the diagnosis and treatment of intractable LBP. Insertion of this miniature fiberoptic scope into the epidural space allows direct visualization of scarring and placement of a catheter through which fluid is injected under pressure to break down scar tissue and lyse adhesions. Although a number of pain treatment centers advertise the availability of this technique and claim it to be successful, there is insufficient scientific evidence in the peer-reviewed medical literature to support the clinical utility of this technique for diagnosis or therapy in patients with spinal pain syndromes, including those with failed back surgery syndromes. Moreover, currently available non-invasive technologies allow adequate visualization of the epidural space to confirm pathology contained therein. An assessment of epiduroscopy for the Australian Safety and Efficacy Register of New Interventional Procedures (ASERNIP-S, 2003) concluded that "[t]here is little high-quality evidence available on the safety and efficacy of epiduroscopically guided surgery/drug delivery... More studies are needed to compare the safety and efficacy of epiduroscopy relative to other procedures". An assessment by the National Institute for Clinical Excellence (NICE, 2004) concluded that "current evidence on the safety and efficacy of endoscopic epidural procedures does not appear adequate for these procedures to be used without special arrangements for consent and for audit or research." The NICE assessment found that "The studies identified were small and uncontrolled. Some measures used in these studies to assess outcomes, such as scores of pain and function, were of unknown validity".

Epidural Lysis of Adhesions

Epidural lysis of adhesions is a pain management procedure that has been proposed as a method to relieve chronic back pain. This procedure may also be known as adhesiolysis, endoscopic adhesiolysis, epidurolysis, percutaneous adhesiolysis or percutaneous epidural neuroplasty. It differs from epidural injections as it attempts to treat the neural (nerve) adhesions that cause the pain. Epidural lysis of adhesions can be performed by use of a fiberoptic endoscope (epiduroscopy), percutaneously with the use of a catheter (flexible tube) or with the more specialized Racz catheter.

In epiduroscopy, normal saline is injected into the sacral canal to distend and decompress the epidural space; purportedly the fiberoptic endoscope can then directly disrupt the fibrosis, scar tissue or adhesions. This procedure is generally an outpatient procedure utilizing local anesthesia and light sedation.

In the percutaneous procedure utilizing the Racz catheter, the specialized epidural catheter is inserted under fluoroscopy via the sacral canal. The injection of dye (an epidurogram) may indicate the area of adhesions and provide a way to perform lesion-specific lysis utilizing the flexible wire embedded catheter. Local anesthetic, corticosteroid and hypertonic sodium chloride solution injections via the catheter are performed daily for three days. During this time the catheter is left in place and the individual is generally hospitalized.

A similar version of the procedure involves a single use catheter (instead of the Racz catheter) which is removed after the lysis is completed. The procedure may be repeated at a later date, but would require a new catheter placement.

The Racz catheter is a small caliber, flexible catheter that is introduced into the sacral hiatus and into the lumbro-sacral epidural space. The Racz catheter is used to release adhesions deliver steroids and anesthetics into the epidural space. There is no evidence from adequate well-designed RCTs in the peer-reviewed medical literature supporting the safety and effectiveness of manipulation of an indwelling epidural Racz catheter or

epidural injections of hypertonic saline or hyaluronidase to relieve back pain in patients with epidural adhesions, adhesive arachnoiditis, or failed back syndrome from multiple previous surgeries for herniated lumbar disk. The Racz epidural catheter was cleared by the FDA based on a 510(k) pre-market notification (PMN) due to FDA's judgment that the device was "substantially equivalent" to devices that were marketed prior to the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act; thus, the manufacturer was not required to provide the evidence of effectiveness that is necessary to support a pre-market approval (PMA) application. Most of the reported studies of the Racz catheter are retrospective (Racz and Holubec, 1989; Manchikanti et al, 2001; Manchikanti et al, 1999) or lacking a control group (Racz et al, 1999). Manchikanti, founder and president of the American Society of Interventional Pain Physicians (ASIPP), is a leading advocate of the use of the Racz catheter (Manchikanti et al, 1999; Manchikanti and Bakhit, 2000; Manchikanti and Singh, 2002). He is lead author of ASIPP guidelines which incorporate the Racz catheter into the management of chronic spinal pain (Manchikanti et al, 2003). Manchikanti et al (2001, 2004) has reported the results of 2 controlled clinical studies of the Racz catheter in the ASIPP's official journal Pain Physician. One of these studies involved 45 patients with chronic LBP, 30 of whom received Racz catheter treatment, and a control group of 15 patients who did not receive Racz catheter treatment. The study was unblinded and utilized a biased control group, as control group subjects were patients who refused Racz catheter treatment, either because coverage was denied by their insurer or for other reasons (Manchikanti et al, 2001). In another study, subjects with chronic LBP were randomized to a sham control group or 2 treatment groups (n = 25 in each group). Nineteen of 25 subjects in the control group were unblinded or lost to follow-up before completion of the 12-month study (Manchikanti et al, 2004). Both of these controlled clinical studies involve small groups of patients and are from the same group of investigators from a single private practice, raising questions about the generalizability of the findings (Manchikanti et al, 2001: Manchikanti et al, 2004). The small sample sizes of these studies do not allow adequate evaluation of potential adverse outcomes that may occur with the procedure (Fibuch, 1999). A Joint Health Technology Assessment of the German Medical Association and the German National Association of Statutory Health Insurance Physicians (KBV, 2003) concluded that, "due to insufficient evaluation and lack of empirical data, at present there is no convincing evidence for the efficacy or effectiveness of the Racz treatment procedure".

The National Institute for Clinical Excellence (NICE, 2004) assessed mobilization and division of epidural adhesions, and concluded that "[c]urrent evidence on the safety and efficacy of endoscopic division of epidural adhesions does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research". The assessment noted that studies of epidural lysis of adhesions are "small and uncontrolled". In addition, NICE noted that "[s]ome measures used in the studies to assess outcomes, such as scores of pain and function, were of unknown validity". NICE stated that the main safety concerns are infection, bleeding, neurological damage, epidural hematoma, and damage to the nerve roots or cauda equina.

Veihelmann et al (2006) examined if epidural neuroplasty is superior to conservative treatment with physiotherapy in treating patients with chronic sciatica with or without LBP. A total of 99 patients with chronic LBP were enrolled in this study and randomly assigned into either a group with physiotherapy (n = 52) or a second group undergoing epidural neuroplasty (n = 47). Patients were assessed before and 3, 6, and 12 months after treatment by a blinded investigator. After 3 months, the VAS score for back and leg pain was significantly reduced in the epidural neuroplasty group, and the need for pain medication was reduced in both groups. Furthermore, the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced until 12 months after the procedure in contrast to the group that received conservative treatment. The authors concluded that epidural neuroplasty results in significant alleviation of pain and functional disability in patients with chronic LBP and sciatica based on disc protrusion/prolapse or failed back surgery on a short-term basis as well as at 12 months of follow-up. Moreover, these investigators stated that further prospective randomized double-blinded studies are needed to prove the effectiveness of epidural neuroplasty in comparison to placebo and in comparison to open discectomy procedures.

Microsurgical Anterior Foraminotomy

Microsurgical anterior foraminotomy has been developed to improve the treatment of intractable cervical radiculopathy. This new technique provides direct anatomical decompression of compressed nerve roots by removing the compressive spondylotic spur or disc fragments through the holes of unilateral anterior foraminotomies. Using microsurgical instruments, the surgical approach exposes the lateral aspect of the spinal column through a small incision at the front of the neck in a naturally occurring crease. The affected nerve root is exposed, and a herniated disc or bone spur is removed to decompress the nerve. By removing only the herniated portion of the disc, the procedure is intended to preserve normal disc function and avoid bone fusion. As it utilizes a microsurgical technique that minimizes laminectomy and facet trauma, this technique does not require bone fusion or post-operative immobilization. However, there is a paucity of clinical studies to validate the effectiveness of this approach. The studies reported in the medical literature involve a small number of patients, are published by just one author, and a considerable portion of each article discusses only the technical aspects of the procedure.

Open Sacroiliac Fusion

Sacroiliac fusion involves bony fusion of the sacroiliac joint for stabilization. Sacroiliac joint (SIJ) fusion has been suggested as a possible treatment option for individuals with low back pain due to sacroiliac joint dysfunction or syndrome. This procedure may be performed by an open surgical approach or as a minimally invasive procedure in order to place plates and/or screws to develop a bony fusion across the SIJ for stabilization. There is insufficient scientific evidence to support use of sacroiliac fusion in treating LBP due to sacroiliac joint syndrome.

In the 1920's, sacroiliac dysfunction was a common diagnosis and fusion of this joint was the most common form of back surgery. However, there is little evidence that the sacroiliac joint is a common source of back pain. European guidelines on the diagnosis and treatment of pelvic girdle pain (Vleeming et al, 2004) recommend against the fusion of sacroiliac joints. The guidelines note that severe traumatic cases of pelvic girdle pain can be an exception to this recommendation, but only when other non-operative treatment modalities have failed. In that case, pre-operative assessment with an external fixator for 3 weeks to evaluate longer lasting effects of fixation, is recommended (Wahlheim, 1984; Slatis and Eskola, 1989; Sturesson et al, 1999). The authors identified no controlled trials of sacroiliac fusion. Available evidence consists of cohort studies (level D evidence) (Smith-Petersen and Rogers, 1926; Gaenslen, 1927; Hagen, 1974; Olerud and Wahlheim, 1984; Waisbrod et al, 1987; Moore, 1995; Keating, 1995; Belanger and Dall, 2001; Berthelot et al, 2001; van Zwienen et al, 2004; Giannikas et al, 2004). The guidelines note that, in all reports of fusion surgery, an operation took place only on patients in whom non-operative treatment had been unsuccessful. The cohort studies included from 2 to 77 patients and the results were assessed by the authors as fair to excellent in 50 to 89 % of the patients. However, controlled studies are necessary to reach firm conclusions about the effectiveness of this procedure in the treatment of back pain.

Guidelines on treatment of LBP from the Colorado Department of Labor and Employment (2005) state that sacroiliac joint fusion is of limited use in trauma and is considered to be under investigation for patients with typical mechanical LBP: "Until the efficacy of this procedure for mechanical low back pain is determined by an independent valid prospective outcome study, this procedure is not recommended for mechanical low back pain".

Microdiskectomy

Discectomy (diskectomy) is the most common surgical treatment for ruptured or herniated discs, particularly of the lumbar spine, though it may also be used on the cervical or thoracic spine. During a discectomy, the surgeon

removes the section of the disc that is protruding from the disc wall and any other disc fragments that may be pressing on a nerve root or the spinal cord. A discectomy may be "open" or it may be performed microscopically (known as a microdiscectomy). Both procedures allow for direct visualization of the vertebra, disc and other surrounding structures. The microdiscectomy utilizes a special microscope or magnifying instrument to view the disc and nerves, which makes it possible to remove the disc material through a smaller incision. This smaller incision reduces the risk of damage to the surrounding tissues, which decreases the potential complications.

Endoscopic Diskectomy

There is insufficient evidence from clinical studies proving additional benefits from using an endoscope for performing disc decompression (such as in percutaneous endoscopic diskectomy or endoscopic laser percutaneous diskectomy (LASE)). At this time there are no reliable clinical studies of endoscopic spinal surgery that have included an adequate comparison group of patients receiving open procedures. In addition, there is limited evidence on the long-term outcomes resulting from these endoscopic procedures. Gibson et al (2002), reporting on the results of a systematic review of studies on surgery for lumbar disc prolapse, explained that "[t]here is currently no evidence supporting endoscopic... treatment of disc prolapse".

Yeung Endoscope Spine Surgery (Arthroscopic Microdiskectomy, Percutaneous Endoscopic Diskectomy with or without Laser (PELD))

An arthroscopic microdiscectomy, also known as a percutaneous endoscopic discectomy (PED), has been proposed as another alternative to the traditional open procedure or the microdiscectomy. A cannula is inserted, with fluoroscopic guidance, near the spine through which an endoscope and very small surgical instruments are then inserted. The herniated portion of the disc can then be removed. This procedure does not allow direct visualization of the disc or surrounding tissues and is generally performed under conscious sedation, rather than general anesthesia. Examples of devices used in an arthroscopic microdiscectomy/percutaneous endoscopic discectomy include, but may not be limited to, the AccuraScope DND, Joimax iLESSYS, Joimax TESSYS or Yeung Endoscopic Spinal System (Y.E.S.S.).

Yeung Endoscopic Spinal Surgery (YESS) (also known as arthroscopic microdiskectomy or percutaneous endoscopic diskectomy (PELD)) is an endoscopic approach to lumbar disc surgery that involves a multi-channel scope and special access cannulae that allow spinal probing in a conscious patient, diagnostic endoscopy, and "minimally invasive surgery" (Yeung and Porter, 2002). The Yeung Endoscope Spine System (Y.E.S.S.) (Richard Wolf Surgical Instrument Corp., Vernon Hills, IL) or similar specialized instruments may be used to perform these procedures. The spinal endoscope is used to direct probing and targeted fragmentectomy of disc herniations. In addition, the approach may be used for foraminoplasty, where an endoscope-assisted laser is used to widen the exit route foramina of the lumbar spine and ablate any protruding portions of the intervertebral disk. Typically, procedures are performed at several levels of the spine, either simultaneously or in close temporal succession. Other adjunctive therapeutic procedures may be performed such as applying chemonucleolytic agents, lasers, radiofrequency technology, electrothermal energy, flexible mechanical instruments or intradiscal steroids. Supporters of arthroscopic microdiskectomy state that it provides visualization at the same time as application of therapeutic services. In addition, they argue that the ability to provoke pain while the patient is in the aware state and able to communicate during surgery allows the surgeon to better identify and treat the source of the patient's back pain. However, there is inadequate evidence to determine whether the results of arthroscopic microdiskectomy are as durable or as effective as open spinal surgery. A particular concern is whether this microendoscopic approach allows for adequate visualization of the spine during surgery. Literature to date on arthroscopic microdiskectomy has been limited to review articles and reports of retrospective case series. There are no published prospective, RCTs of arthroscopic microdiskectomy, and there are no prospective studies with long-term follow-up. In addition, the studies of

Y.E.S.S. that have been published thus far have been from a single investigator group, raising questions about the generalization of the findings. Thus, arthroscopic microdiskectomy does not meet Aetna's criteria.

Minimally Invasive Lumbar Decompression Procedures

Minimally invasive approaches for laminectomy, laminotomy, foraminectomy or foraminotomy have also been proposed as a newer treatment option by some surgeons. They may utilize either an endoscopic or laparoscopic approach for the procedure, which allows direct visualization of the surgical field.

Additionally, percutaneous procedures have been proposed as an alternative surgical approach for laminectomy, laminotomy, foraminectomy or foraminotomy. The percutaneous procedures are generally performed in an outpatient setting with the individual awake but sedated. Percutaneous spinal procedures do not allow direct visualization of the surgical field. Examples of percutaneous image-guided decompression procedures for lumbar spinal stenosis are the MILD procedure and decompression with the Totalis Direct system, both of which utilize trocars to access the area of stenosis (resection of the ligamentum flavum).

The North American Spine Society defines an open procedure done through an incision of approximately one inch or more. Minimally invasive lumbar decompression is performed through small incisions of less than 1 inch. Minimally invasive lumbar decompression procedures include those performed under direct visualization using specialized tubular retractors, and procedures performed under indirect visualization.

These approaches are not supported by reliable evidence in the peer reviewed published medical literature. These centers typically advertise their "unique" methods of performing spine surgery through very small portals using specialized instruments that often have been developed by the centers themselves. These procedures are often performed while the patient is conscious under moderate sedation. Typically, several surgical procedures are performed at multiple levels simultaneously or on successive days until the patient reports pain relief or surgery is exhausted. Proponents argue that these procedures involve fewer anesthetic risks, a smaller incision, reduced blood loss, faster post-operative recovery and performance of surgery in an outpatient setting.

An important concern about this minimally invasive approach is the limited visualization of the spine, such that the surgeon cannot reliably identify and ensure complete removal all bone spurs and other structures impinging on nerves. In addition, the performance of several surgical procedures in close temporal succession does not allow adequate evaluation of the outcomes of one surgical procedure before subsequent surgical procedures are performed.

One center advertises that they manufacture special instruments and develop new techniques to perform complex microscopic laser spinal surgeries through portals of 1/4 to 1/2 of an inch under conscious sedation. They state that they have developed "unique" methods of performing endoscopic surgeries. The center states that they are the only facility that performs endoscopic spinal joint surgery, thoracic laser discectomy, endoscopic sacroiliac joint surgery, endoscopic hardware removal, or endoscopic bio-absorbable fusions or intradiscal stem cell therapy. The center also asserts that their unique minimally invasive spine surgery techniques are so advanced that patients who have failed other minimally invasive or conventional spine surgeries may benefit from their procedures. The center advertises that they have performed over 7,000 of these minimally invasive spinal surgeries. Although they state that they regularly publish their findings in peer-reviewed journals, what evidence they have published is limited to small, uncontrolled case series focusing on short-term followup (Haufe et al, 2008; Haufe and Mork, 2007; Haufe and Mork, 2006; Haufe and Mork, 2005; Haufe and Mork, 2004).

Another center makes similar claims for the effectiveness of unique endoscopic laser spinal surgical procedures

performed under conscious sedation with patented instruments. The center performs spinal procedures using videoendoscopy and specially adapted surgical probes. Procedures include specialized methods of laser diskectomy, laser lumbar facet debridement, laser foraminoplasty, and laser debridement of spinal processes. The center's website includes testimonials and a list of abstracts presented at meetings, but the center has not published the results of their procedures in peer-reviewed publications. The center recently announced initiation of an outcome study to evaluate outcomes of their procedures in persons with failed back syndrome.

Another center offers unique endoscopic laser methods of performing surgery for back and neck pain. The primary procedures include foraminotomy, laminotomy, percutaneous endoscopic discectomy, and facet thermal ablation. The center advertises the ability to complete all necessary evaluation, pre-operative preparation, surgery, and post-operative physical therapy within 1 week. The center advertises that advantages of their method of minimally invasive surgery includes no general anesthesia, no hospitalization, minimally invasive surgery, minimal scar tissue formation, and the availability of outpatient procedures. The center states that the most prominent difference between their techniques and that of other spinal centers is the endoscopic method in which they enter the body to minimize trauma, scar tissue formation, and healing times. The center states that their surgeons have performed approximately 10,000 surgeries collectively for over 10 years. Their website includes testimonials. However, they have not submitted their results for peer-review publication.

mild® (Vertos Medical) is a new procedure for pain relief from symptomatic central lumbar canal stenosis. It entails limited percutaneous laminotomy and thinning of the ligamentum flavum in order to increase the critical diameter of the stenosed spinal canal.

In a retrospective study, Lingreen and Grider (2010) examined the minor adverse events and peri-procedural course associated with the MILD procedure. In addition, these researchers evaluated the effectiveness of the procedure with regard to pain relief and functional status. A total of 42 consecutive patients meeting MRI criteria for MILD underwent the procedure performed by 2 interventional pain management physicians working at the same center. The pre- and post-procedure VAS as well as markers of global function were recorded. Major and minor adverse events were tracked and patient outcomes reported. There were no major adverse events reported. Of the minor adverse events, soreness lasting 3.8 days was most frequently reported. No patients required over-night observation and only 5 required post-operative opioid analgesics. Patients self-reported improvement in function as assessed by ability to stand and ambulate for greater than 15 mins, whereas prior to the procedure 98 % reported significant limitations in these markers of global functioning. Visual analog pain scores were significantly decreased by 40 % from baseline; 86 % of the patients reported that they would recommend the MILD procedure to others. The authors concluded that the MILD procedure appears to be a safe and likely effective option for treatment of neurogenic claudication in patients who have failed conservative therapy and have ligamentum flavum hypertrophy as the primary distinguishing component of the stenosis.

In a multi-center, non-blinded, prospective clinical study, Chopko and Caraway (2010) evaluated the clinical application and patient safety and functional outcomes of the MILD procedure in the treatment of symptomatic central canal spinal stenosis. A total of 78 patients were enrolled in the MiDAS I Study and treated with the MILD procedure for lumbar decompression. Of these patients, 6-week follow-up was available for 75 patients. Outcome measures were VAS, Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and SF-12v2 Health Survey. Outcomes were assessed at baseline and 6 weeks post-treatment. There were no major device or procedure-related complications reported in this patient cohort. At 6 weeks, the MiDAS I Study showed statistically and clinically significant reduction of pain as measured by VAS, ZCQ, and SF-12v2. In addition, improvement in physical function and mobility as measured by ODI, ZCQ, and SF-12v2 was statistically and clinically significant in this study. In this 75-patient series, and in keeping with a previously published 90-patient safety cohort, the MILD procedure proved to be safe. Further, based on near-term follow-

up, the MILD procedure showed efficacy in improving mobility and reducing pain associated with lumbar spinal canal stenosis. Limitations of this study were: (i) this was a preliminary report encompassing only a 6-week follow-up, and (ii) there was no control group.

Deer and Kapural (2010) assessed the acute safety of the MILD procedure. Manual and electronic chart survey was conducted by 14 treating physicians located in 9 states within the United States on 90 consecutive patients who underwent the MILD procedure. Patients requiring lumbar decompression via tissue resection at the peri-laminar space, within the inter-laminar space and at the ventral aspect of the lamina were treated. Data collected included any complications and/or adverse events that occurred during or immediately following the procedure prior to discharge. Of 90 procedures reviewed, there were no major adverse events or complications related to the devices or procedure. No incidents of dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, or hematoma were observed. Limitations of this study were: (i) data were not specifically collected; however, regardless of difficulty, in this series none of the procedures was aborted and none resulted in adverse events, and (ii) efficacy parameters were not collected in this safety survey. The authors concluded that this study demonstrates the acute safety of the MILD procedure with no report of significant or unusual patient complications. They noted that additional studies are currently underway to establish complication frequency and longer-term safety profile associated with this treatment.

Laser Diskectomy

Laser discectomy is also known as laser-assisted discectomy, laser disc decompression or laser-assisted disc decompression (LADD). Though this procedure is called a discectomy, it does not actually remove the disc, but utilizes a laser to "vaporize" a small portion of the nucleus pulposus in order to purportedly decompress a herniated disc. Laser discectomy may be performed either laparoscopically or percutaneously.

Laser diskectomy involves the use of a laser to vaporize a small portion of the nucleus pulposus in order to decompress a herniated disc. In laparoscopic laser diskectomy, the procedure is done through a laparoscope, which allows visualization of the disc, disc space and other structures. The surgeon places a laser through a delivery device that has been directed under radiographic control to the disc. The annulus of the disc is opened and is then excised with a laser device which is inserted through the laparoscope. It uses many of the same techniques used in automated percutaneous discectomy. An endoscope may be used in conjunction with this procedure to visualize the disc space and nucleus pulposus, or the procedure may be done percutaneously. By contrast, percutaneous disc decompression uses an x-ray to localize the tip of the needle/trocar to ensure that it is in the appropriate level and location. Percutaneous laser discectomy is performed under a local anesthetic. Under x-ray (fluoroscopic) guidance, a needle is inserted through the skin into the disc. A flexible quartz fiber is then threaded through the needle and into the disc, which delivers the laser energy.

The mechanism of action for pain relief in LADD is not well understood; most believe that the primary mechanism of pain reduction after LADD is its decrease in intradiscal pressure. According to the literature, laser-assisted disc decompression appears to be a safe procedure, but studies have not compared it to open surgical alternatives or other percutaneous methods. Randomized controlled trials are needed to compare current standard alternatives to both LADD and conservative treatment. A Cochrane review of surgical procedures for lumbar disc herniation concluded that "[t]here is currently no evidence supporting endoscopic (micro-suction) or laser treatment of disc prolapse" (Gibson et al, 2002). A systematic review of the literature on percutaneous endoscopic laser discectomy for the Royal Australasian College of Surgeons (Boult et al, 2000) reached similar conclusions: "Given the extremely low level of evidence available for this procedure it was recommended that the procedure be regarded as experimental until the results are available from a controlled clinical trial, ideally with random allocation to an intervention and control group".

An assessment of laser lumbar diskectomy conducted for the National Institute of Clinical Excellence (NICE,

2003) concluded that current evidence on the safety and efficacy of laser lumbar discectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. A systematic evidence review by Jordan et al (2003) similarly concluded that the effectiveness of laser diskectomy is "unknown".

Microdiscectomy

Microdiscectomy refers to removal of protruding disc material, using an operating microscope to guide surgery. Dent (2001) recently assessed the evidence supporting the use of microdiscectomy for prolapsed intervertebral disc, and found no evidence of differences in clinical outcomes between microdiscectomy and standard open discectomy. A Cochrane review found evidence that microdiscectomy takes longer to perform than standard open discectomy (Gibson et al, 2002). The review found no evidence of difference in short- or long-term symptom relief or complications, or length of inpatient stay. Similarly, a systematic assessment of the literature by Jordan et al (2003) concluded that microdiskectomy has not been shown to be more effective than standard diskectomy.

Microendoscopic Discectomy

Microendoscopic discectomy (MED) procedure combines conventional lumbar microsurgical techniques with endoscopy and is performed at an outpatient setting. It is employed for the treatment of lumbar spine stenosis and lumbar disc herniation. It has been suggested that MED is less invasive (no damage to muscle, bone or soft tissue) compared with traditional open microdiscectomy. Moreover, MED allegedly allows an early return to work. However, this endoscopic procedure is difficult because of the limited exposure and 2-dimensional video display. The potential injury of the nerve root and prolonged surgical time remain as matters of serious concern. Currently, there is insufficient evidence to support the clinical value of this procedure especially its long-term effectiveness.

Muramatsu et al (2001) examined if MED was minimally invasive with respect to the nerve roots, cauda equina, and paravertebral muscles by comparing the post-operative magnetic resonance imaging findings in patients treated by MED and the conventional Love's method. The authors concluded that MED had an effect on the nerve roots and cauda equina that was comparable with that of Love's method. The magnetic resonance images of the route of entry failed to show that MED is appreciably less invasive with respect to the paravertebral muscles. Furthermore, in a review on the various minimally invasive procedures available for the treatment of lumbar disc disease, Maroon (2002) stated that although all percutaneous techniques (including MED) have been reported to yield high success rates, to date no studies have demonstrated any of these to be superior to microsurgical discectomy, which continues to be regarded as the standard with which all other techniques must be compared.

Far Lateral Microendoscopic Diskectomy (FLMED)

Extra-foraminal lumbar disc herniations (ELDHs) at the lumbo-sacral junction are an uncommon cause of L5 radiculopathy. The surgical anatomy of the extra-foraminal space at L5 to S1 is challenging for the various open surgical approaches that have been described for ELDHs in general. Reports specifically describing minimally invasive surgical approaches to lumbo-sacral ELDHs are lacking.

There is currently insufficient evidence to support the use of far lateral microendoscopic discectomy (FLMED). O'Toole and colleagues (2007) reported the novel use of far lateral microendoscopic discectomy (FLMED) to lumbo-sacral ELDH. To better define the unique anatomical features of extra-foraminal approaches to the lumbo-sacral junction as they apply to minimal access techniques. A cadaveric investigation a well as a clinical case were performed, and a thorough review of the literature was conducted. A single patient with an extra-

foraminal disc herniation at the lumbo-sacral junction underwent evaluation and surgery. The patient's self-reported pain levels were documented. Physiologic outcome was judged on pre- and post-operative motor and sensory examinations. Functional capacity was assessed by work status and ability to perform activities of daily living. Far lateral microendoscopic discectomy was performed in 2 fresh human cadavers at the lumbo-sacral junction. Qualitative assessments of the surgical anatomy were made, and intra-operative fluoroscopy and endoscopic photographs were obtained to document the findings. A patient with refractory pain and sensori-motor deficits from compression of the L5 nerve root by an ELDH underwent FLMED. The literature was carefully reviewed for the epidemiology of ELDHs at the lumbo-sacral junction and the surgical techniques used to treat them. The postero-lateral surgical corridor to the lumbo-sacral disc was consistently constrained by the sacral ala and to a lesser extent the lateral facet and L5 transverse process. Resection of the superior ala exposed the exiting nerve root and provided ample access to the disc. In the clinical case, the patient enjoyed immediate pain relief, was discharged in 3 hours, and returned to full work and social activities. Follow-up neurological examination revealed no sensory or motor deficit. The authors concluded that FLMED offers a safe and effective approach to ELDHs at the lumbo-sacral junction by combining satisfactory visualization for adequate resection of the sacral ala with the benefits of reduced tissue injury and faster recovery times that accompany minimally invasive techniques.

Pirris and colleagues (2008) noted that surgical access to ELDHs is complicated due to the unique anatomical constraints of the region. Minimizing complications during microdiscectomies at the level of L5 to S1 in particular remains a challenge. The authors reported on a small series of patients and provided a video presentation of a minimally invasive approach to L5 to S1 ELDHs utilizing a tubular retractor with microscopic visualization.

Dynamic Stabilization

Failed back surgery syndrome (FBSS) is reported to occur in 5 to 50 % of cases of lumbar spine operation. A marked rise in the number of performed spinal procedures has also led to an increase in the number of FBSS cases, which is the consequence of biological, psychological, social, and/or economical causes. Patient selection and correct indications are of key importance for successful surgical intervention of this syndrome. Surgical interventions that have been used for FBSS treatment include decompression, stabilization and fusion, as well as dynamic stabilization/neutralization procedures (Chrobok et al, 2005).

Dynamic spinal stabilization devices are proposed as a way to provide immobilization and stabilization of spinal segments in skeletally mature individuals as an adjunct to fusion in the treatment of chronic instabilities or deformities of the thoracic, lumbar and sacral spine including, but not limited to, degenerative spondylolisthesis (with objective evidence of neurologic impairment) or previous failed spinal fusion. They are also cleared by the US Food and Drug Administration (FDA) for individuals who are receiving fusions with autogenous graft only, those who are having the device fixed or attached to the lumbar or sacral spine and those who are having the device removed after the development of a solid fusion mass.

These devices attach to the spine by way of titanium alloy screws that have been implanted into the spinal bone. Two screws are implanted per vertebra in two or three adjacent vertebrae. The protruding ends of the screws are attached to polyethylene-terephthalate cords. These cords are surrounded by a set of solid polycarbonate-urethane spacers. The system is designed to stabilize the spine by the polyethylene cords pulling against the spinal motions that separate the vertebrae. At the same time, the polycarbonate spacers push against the spinal motions that compress the vertebrae. These devices differ from traditional instrumentation used during spinal fusion, as they are non-rigid and allow some movement of the spine segments. Examples of dynamic spinal stabilization devices include, but may not be limited to, the Dynesys Stabilization System, the BAR Posterior Pedicle Screw System and the N Fix II Pedicle Screw System.

The use of rigid instrumentation in the treatment of degenerative spinal disorders seems to increase the fusion rate of the lumbar spine. However, rigid devices are associated with adverse effects such as pseudoarthrosis and adjacent segment degeneration. The use of semi-rigid and dynamic devices has been advocated to decrease such adverse effects of rigid fixation and thereby to attain a more physiological bony fusion (Korovessis et al, 2004). Dynamic stabilization systems (e.g., the Dynesys Spinal System) are intended to restrict segmental motion and thus prevent further degeneration of the lumbar spine. The Dynesys, a non-fusion pedicle screw stabilization system (a flexible posterior stabilization system), was developed in an attempt to overcome the inherent disadvantages of rigid instrumentation and fusion. It uses flexible materials threaded through pedicle screws rather than rigid rods or bone grafts alone as an adjunct to fusion. The Dynesys is installed posteriorly, and does not require bone to be taken from the hip, as is required in other fusion procedures. It is designed to prevent over-loading the disc, but it restricts extension and loses lordosis (Sengupta and Mulholland, 2005; Putzier et al, 2005).

The Dynesys Spinal System (Centerpulse Spine-Tech, Inc., Minneapolis, MN) was cleared by the FDA via a 510(k) pre-market notification in March 2004. According to the product labeling, it is indicated to provide stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence or neurological impairment, kyphosis; and failed previous fusion (pseudoarthrosis). In addition, the product labeling states that the Dynesys system is intended for use in persons who meet all of the following criteria:

- Patients who are receiving fusions with autologous graft only; and
- Patients who are having the device attached to the lumbar or sacral spine; and
- Patients who are having the device removed after the development of a solid fusion mass.

The Dynesys Stabilization System has also been proposed for immobilization and stabilization of spinal segments without a spinal fusion procedure; at this time the FDA has not approved this application. Although the Dynesys has been in clinical use for several years, there is insufficient evidence demonstrating that implantation of this device results in improved health outcomes compared to standard treatments.

A more recent development has been a hybrid device, the Zimmer DTO Implant, which combines the Dynesys Dynamic Stabilization System with the rigid stabilization of the OPTIMA ZS Spinal System. This device is an attempt to offer a new segmental solution for treating degenerative lumbar spine pathologies with different stages of degeneration at contiguous levels.

Dynamic spinal stabilization devices may also be semi-rigid in design. These devices purportedly allow less spinal movement than the non-rigid, but more than traditional spinal fusion instrumentation. Examples of semi-rigid devices include the CD HorizoN Agile Dynamic Spinal Stabilization Device and the Isobar Spinal System.

In a RCT, Korovessis et al (2004) examined the short-term effects of rigid versus semi-rigid and dynamic instrumentation on the global and segmental lumbar spine profile, subjective evaluation of the result, and the associated complications. The study did not examine objective functional outcomes. They compared 3 equal groups of 45 adult patients, who underwent primary decompression and stabilization for symptomatic degenerative lumbar spinal stenosis. Patients were randomly selected and received either the rigid (Group A), or semi-rigid (Group B), or dynamic (Group C) spinal instrumentation with formal decompression and fusion. The mean ages for the 3 groups were 65 +/- 9, 59 +/- 16, and 62 +/- 10 years, respectively. All patients had detailed roentgenographical study including computed tomography (CT) scan and magnetic resonance imaging (MRI) before surgery to the latest follow-up observation. The following roentgenographical parameters were measured and compared in all spines: lumbar lordosis (L1 to S1), total lumbar lordosis (T12 to S1), sacral tilt, distal lordosis (L4 to S1), segmental lordosis, vertebral inclination, and disc index. The SF-36 health survey

and visual analog scale (VAS) was used before surgery to the latest evaluation. All patients were evaluated after a mean follow-up of 47 +/- 14 months. Both lumbar and total lordosis correction did not correlate with the number of the levels instrumented in any group. Total lordosis was slightly decreased after surgery (3 %, $p < 0.05$) in Group C. The segmental lordosis L2 to L3 was increased after surgery by 8.5 % ($p < 0.05$) in Group C, whereas the segmental lordosis L4 to L5 was significantly decreased in Groups A and C by 9.8 % ($p = 0.01$) and 16.2 % ($p < 0.01$), respectively. The disc index L2 to L3 was decreased after surgery in Groups A and C by 17 % ($p < 0.05$) and 23.5 % ($p < 0.05$), respectively. The disc index L3 to L4 was increased in Group C by 18.74 % ($p < 0.01$). After surgery, the disc index L4 to L5 was decreased in all 3 groups: Group A by 21 % ($p = 0.01$), Group B by 13 % ($p < 0.05$), and Group C by 13.23 % ($p < 0.05$). The disc index L5 to S1 was significantly decreased in Group B by 13 % ($p < 0.05$). The mean pre-operative scores of the SF-36 before surgery were 11, 14, and 13 for Groups C, B, and A, respectively. In the first year after surgery, there was a significant increase of the pre-operative SF-36 scores to 65, 61, and 61 for Groups C, B, and A, respectively, that represents an improvement of 83 %, 77 %, and 79 %, respectively. In the second year after surgery and thereafter, there was a further increase of SF-36 scores of 19 %, 23 %, and 21 % for Groups C, B, and A, respectively. The mean pre-operative scores of VAS for LBP for Groups C, B, and A were 5, 4.5, and 4.3, respectively, and decreased after surgery to 1.9, 1.5, and 1.6, respectively. The mean pre-operative scores of the VAS for leg pain for Groups C, B, and A were 7.6, 7.1, and 6.9, respectively, and decreased after surgery to 2.5, 2.5, and 2.7, respectively. All fusions healed radiologically within the expected time in all 3 groups without pseudoarthrosis or malunion. Delayed hardware failure (1 screw and 2 rod breakages) without radiological pseudoarthrosis was observed in 2 patients in Group C 1 year and 18 months following surgery. There was no adjacent segment degeneration in any spine until the last evaluation. These investigators concluded that all 3 instrumentations applied over a short area for symptomatic degenerative spinal stenosis almost equally maintained the pre-operative global and segmental sagittal profile of the lumbosacral spine and was followed by similarly significant improvement of both self-assessment and pain scores. Hardware failure occurred at a low rate following dynamic instrumentation solely without radiologically visible pseudoarthrosis or loss of correction. These researchers further noted that because of the similar clinical and radiological data in all 3 groups and the relative small number of patients that were included in each group, it is difficult to make any recommendation in favor of any instrumentation.

Putzier et al (2005) examined the effect of dynamic stabilization on the progression of segmental degeneration after nucleotomy. A total of 84 patients underwent nucleotomy of the lumbar spine for the treatment of symptomatic disc prolapse. Additional dynamic stabilization (the Dynesys system) was performed in 35 subjects. All patients showed signs of initial disc degeneration (Modic Type I - changes in the vertebral end plate are frequently associated with degenerative disc disease. Type 1 changes include decreased signal intensity on T1-weighted and increased signal intensity on T2-weighted MRI). Evaluation was carried out before surgery, 3 months after surgery, and at follow-up. The mean duration of follow-up was 34 months. Examinations included radiographs, MRI, physical examination, and subjective patient evaluation using Oswestry score and VAS. Clinical symptoms, Oswestry score, and VAS improved significantly in both groups after 3 months. At follow-up, a significant increase in the Oswestry score and in the VAS was seen only in the non-stabilized group. In the dynamically stabilized group, no progression of disc degeneration was noted at follow-up, while radiological signs of accelerated segmental degeneration existed in the solely nucleotomized group. There were no implant-associated complications. These investigators concluded that the Dynesys system is useful to prevent progression of initial degenerative disc disease of lumbar spinal segments following nucleotomy. Moreover, the same group of researchers noted that the Dynesys system seems not to be indicated for treating marked deformities or if osseous decompression needs to be performed (Putzier et al, 2004).

In contrast to the observation of Korovessis et al (2004) and Putzier et al (2005), a number of investigators have questioned whether the Dynesys Spinal System offers any clinical advantages over rigid instrumentation (Hopf et al, 2004; Grob et al, 2005; Schwarzenbach et al, 2005).

In a clinical trial, Hopf et al (2004) compared the use of artificial disc replacement with dynamic stabilization procedure (Dynesys' method) in the treatment of patients with LBP. Indications for the operation were unsuccessful conservative treatment for over 6 months, segmental pain, age of less than 45 years, evidence of mono- or bi-segmental disc degeneration, with or without disc prolapse, demonstrated by MRI, exclusion of psychogenic disease and positive pre-operative, diagnostic measures such as facet joint infiltration and discography. These investigators stated that in younger patients with mono- or bi-segmental disc degeneration there is an indication for the implantation of an artificial disc. Contraindications for the operation are facet joint arthrosis and age of over 45 years. The investigators commented that the indication in subjects with a classic FBSS is still unclear, the improvement of the instrumentation and a further adaptation of the systems to the known biomechanics of the lumbar spine are mandatory as is an intensive discussion of the operative procedure in the case of revision operations. These authors further noted that the Dynesys' method, with the inherent danger of segmental kyphozitation, a published, significant revision quota combined with a reduction of motility, does not fulfill this criterion.

In a retrospective study, Grob and colleagues (2005) assessed patient-oriented outcome after implantation of the Dynesys Spinal System. A total of 50 consecutive patients instrumented with the Dynesys over the preceding 40 months were invited to complete a postal, patient-oriented follow-up questionnaire. The data from 31 of these subjects (11 men and 20 women; mean age of 50 years), with at least 2 years' follow-up, were analyzed. The primary indication for surgery was degenerative disease (disc/stenosis) with associated "instability"; 11 of 31 (35 %) patients had had prior spinal surgery. One-level instrumentation was performed in 32 % cases, 2-level instrumentation in 52 % cases, 3-level in 13 % cases, and 4-level in 3 % cases. Thirteen of 31 (42 %) patients underwent additional decompression. Within the 2-year follow-up period, 6 of 31 (19 %) patients had needed or were scheduled for another surgical intervention. At follow-up, mean back and leg pain (0 to 10 VAS) were 4.7 and 3.8, respectively. The following global outcomes were reported: (i) back symptoms -- 67 % improved, 30 % same, 3 % worse; (ii) leg symptoms - 64 % improved, 21 % same, 14 % worse; (iii) ability to do physical activities/sports - 40 % improved, 33 % same, 27 % worse; (iv) quality of life - 50 % improved, 37 % same, 13 % worse; (v) how much the operation helped - 29 % helped a lot, 23 % helped, 10 % only helped a little, 35 % didn't help, 3 % made things worse. These investigators concluded that their findings indicated that both back and leg pain are, on average, still moderately high 2 years following instrumentation with the Dynesys Spinal System. Only 50 % of the patients declared that the operation had helped and had improved their overall quality of life; less than 50 % reported improvements in functional capacity. The re-operation rate following implantation of the Dynesys was relatively high. The investigators concluded that these results provide no support for the notion that semi-rigid fixation of the lumbar spine resulted in better patient-oriented outcomes than those typical of fusion.

In a recent review on posterior dynamic stabilization systems, Schwarzenbach et al (2005) stated that their experience with the Dynesys has shown that this method has limitations in "elderly patients with osteoporotic bone or in patients with a severe segmental macro-instability combined with degenerative spondylolisthesis and advanced disc degeneration. Such cases have an increased risk of failure. Only future randomized evaluations will be able to address the potential reduction of accelerated adjacent segment degeneration. The few posterior dynamic stabilization systems that have had clinical applications so far have produced clinical outcomes comparable with fusion. No severe adverse events caused by these implants have been reported. Long-term follow-up data and controlled prospective randomized studies are not available for most of the cited implants but are essential to prove the safety, efficacy, appropriateness, and economic viability of these methods".

In a review on dynamic stabilization in the surgical management of painful lumbar spinal disorders, Nockels (2005) concluded that posterior dynamic stabilization systems may provide benefit comparable to fusion techniques, but without the elimination of movement. Moreover, the author also noted that further study (well-designed prospective, randomized, controlled trial) is needed to ascertain optimal design and clinical

indications.

In a systematic evidence review on non-rigid stabilization procedures for the treatment of LBP, the National Institute for Health and Clinical Excellence (NICE, 2005) stated that "current evidence on the safety of these procedures is unclear and involves a variety of different devices and outcome measures. Therefore, these procedures should not be used without special arrangements for consent and for audit or research". Additionally, the specialist advisors to the Institute's Interventional Procedures Advisory Committee noted that these procedures may be undertaken concurrently with disc decompression or discectomy. Thus, it is difficult to ascertain what clinical benefit is derived from the implants themselves. The specialist advisors noted that the reported adverse events include infection, malpositioned or broken screws leading to nerve root damage, cerebrospinal fluid leak, failure of the bone/implant interface, and failure to control pain. The theoretical risks with the techniques include: device failure (particularly long-term), increased lordosis, and root damage caused by loose or misaligned screws.

Welch and colleagues (2007) presented the preliminary clinical outcomes of dynamic stabilization with the Dynesys spinal system as part of a multi-center randomized prospective FDA investigational device exemption (IDE) clinical trial. This study included 101 patients from 6 IDE sites (no participants were omitted from the analysis) who underwent dynamic stabilization of the lumbar spine with the Dynesys construct. Patient participation was based on the presence of degenerative spondylolisthesis or retrolisthesis (Grade I), lateral or central spinal stenosis, and their physician's determination that the patient required decompression and instrumented fusion for 1 or 2 contiguous spinal levels between L1 and S1. Subjects were evaluated pre-operatively, post-operatively at 3 weeks, and then at 3-, 6-, and 12-month intervals. The 100-mm VAS was used to score both lower-limb and back pain. Patient functioning was evaluated using the Oswestry Disability Index (ODI), and the participants' general health was assessed using the Short Form-12 questionnaire. Overall, patient satisfaction was also reported. One hundred one patients (53 women and 48 men) with a mean age of 56.3 years (range of 27 to 79 years) were included. The mean pain and function scores improved significantly from the baseline to 12-month follow-up evaluation, as follows: leg pain improved from 80.3 to 25.5, back pain from 54 to 29.4, and ODI score from 55.6 to 26.3 %. The authors concluded that the early clinical outcomes of treatment with Dynesys are promising, with lessening of pain and disability found at follow-up review. Dynesys may be preferable to fusion for surgical treatment of degenerative spondylolisthesis and stenosis because it decreases back and leg pain while avoiding the relatively greater tissue destruction and the morbidity of donor site problems encountered in fusion. However, long-term follow-up care is still recommended.

In a prospective case series, Kumar et al (2008) examined the radiological changes in the intervertebral disc after Dynesys dynamic stabilization. A total of 32 patients who underwent Dynesys procedure and have completed 2-year follow-up MRI scans were included in this study. Pre-operative and 2-year post-operative lumbar MRI scans were evaluated by 2 independent observers. T2-weighted mid-sagittal images were used and disc degeneration were classified according to the Woodend classification of disc degeneration. Anterior and posterior intervertebral disc heights were also measured. Of the 32 patients, 20 patients underwent Dynesys procedure alone and 12 underwent additional fusion at 1 or more levels. A total of 70 levels were operated on, of which 13 levels were fused. There was a statistically significant increase in the mean Woodend score at the operated levels in the Dynesys alone group, a change from 1.95 before surgery to 2.52 after surgery ($p < 0.001$). The mean Woodend scores changed from 1.27 pre-operative to 1.55 post-operative ($p = 0.066$) at the proximal adjacent levels, and from 1.37 to 1.62 at the distal levels ($p = 0.157$). There was good inter-observer agreement (weighted k score of 0.819). The anterior intervertebral disc height reduced by 2 mm from 9.25 to 7.17 ($p < 0.001$). The posterior disc height increased by 0.14 mm but this change insignificant. The authors concluded that disc degeneration at the bridged and adjacent segment seems to continue despite Dynesys dynamic stabilization.

The Stabilimax NZ Dynamic Spinal Stabilization System is an investigational device that is being evaluated for the treatment of patients with symptomatic spinal stenosis. The Stabilimax NZ is inserted and fixed to the vertebra by means of pedicle screws in exactly the same manner a fusion device is inserted and attached. The only difference is that for the Stabilimax NZ no bone graft will be placed around or between the vertebra to promote bone growth for fusion. It should be noted that a clinical trial sponsored by Applied Spine Technologies to evaluate if the Stabilimax NZ is at least as safe and effective as the control therapy of fusion in patients receiving decompression surgery for the treatment of clinically symptomatic spinal stenosis at 1 or 2 contiguous vertebral levels from L1 to S1 has been suspended (Applied Spine Technologies, 2008); the reason for this suspension is unclear.

Graf artificial ligament stabilization (Graf) is primarily used to stabilize the unstable vertebral segment without rigid fusion (Noorani and Topfer, 2006). The Graf technique involves insertion of pedicle screws into each vertebra to be stabilized which are then attached to one another with Dacron loops. This method has the theoretical advantages of simplicity (to surgeons familiar with the insertion of pedicle screws), avoidance of bone graft donor site problems, and allowing a spinal fusion to be attempted at a later date if considered necessary (Noorani and Topfer, 2006). The concept of ligament stabilization was introduced by H. Graf in the early 1990s and performed in patients with chronic back pain as a less invasive technique than spinal or posterio-lateral fusion.

In a retrospective, long-term, follow-up study, Kanayama et al (2007) reported minimum 10-year follow-up results of posterior dynamic stabilization using Graf artificial ligament (Graf ligamentoplasty) and evaluated the role and limitations of this procedure in the treatment of degenerative lumbar disorders. A total of 56 consecutive patients who underwent Graf ligamentoplasty were reviewed at a minimum 10-year follow-up. Forty-three patients in the original cohort had sufficient clinical and radiographical follow-up for analysis. The pathologies included degenerative spondylolisthesis in 23 patients, disc herniation with flexion instability in 13 patients, spinal stenosis with flexion instability in 4 patients, and degenerative scoliosis in 3 patients. Single-level procedures were performed in 36 patients; multi-level procedures were performed in 7 patients. Radiographical and clinical assessments were performed before surgery and at the final follow-up. Disability due to LBP and/or sciatic symptoms was significantly improved in the patients with degenerative spondylolisthesis or flexion instability. However, degenerative scoliosis and/or laterolisthesis were associated with poor clinical improvement. In radiographical assessment, segmental lordosis was maintained in 10.9 degrees, and flexion-extension motion was averaged 3.6 degrees at the final follow-up. Facet arthrodesis eventually occurred in 14 patients (32.6 %) at an average of 82 months after surgery. Additional surgeries were required in 3 patients (7.0 %) for adjacent segment pathologies. The authors concluded that long-term results showed that Graf ligamentoplasty is an effective treatment option for low-grade degenerative spondylolisthesis and flexion instability. However, this procedure has limitations to correct spinal deformity, and is not advocated for the treatment of degenerative scoliosis and laterolisthesis.

In a discussion of the afore-mentioned study, Fraser (2007) stated that "[p]erhaps the main value of this retrospective study is the finding that Graf ligamentoplasty is not effective in the treatment of patients with degenerative scoliosis, but the long-term efficacy of the Graf procedure for other lumbar conditions is yet to be proven".

Putzier et al (2010) compared dynamic fixation of a clinically asymptomatic initially degenerated segment adjacent to fusion (iASD), with circumferential lumbar fusion alone. A total of 60 patients with symptomatic degeneration of L5/S1 or L4/L5 (Modic greater than or equal to 2 degrees) and asymptomatic iASD (Modic = 1 degrees, confirmed by discography) were divided into 2 groups; 30 patients were treated with circumferential single-level fusion (SLF). In dynamic fixation transition (DFT) patients, additional posterior dynamic fixation of iASD was performed. Pre-operatively, at 12 months, and at a mean follow-up of 76.4 (60 to 91) months,

radiological (MRI, X-ray) and clinical (ODI, VAS, satisfaction) evaluations assessed fusion, progression of adjacent segment degeneration (PASD), radiologically adverse events, functional outcome, and pain. At final follow-up, 2 non-fusions were observed in both groups. A total of 6 SLF patients and 1 DFT patient presented a PASD. In 2 DFT patients, a PASD occurred in the segment superior to the dynamic fixation, and in 1 DFT patient, a fusion of the dynamically fixated segment was observed. A total of 4 DFT patients presented radiological implant failure. While no differences in clinical scores were observed between groups, improvement from pre-operative conditions was significant (all $p < 0.001$). Clinical scores were equal in patients with PASD and/or radiologically adverse events. The authors do not recommend dynamically fixating the adjacent segment in patients with clinically asymptomatic iASD. The lower number of PASD with dynamic fixation was accompanied by a high number of implant failures and a shift of PASD to the superior segment.

In summary, despite some preliminary evidence that dynamic stabilization systems (e.g., the Dynesys) have produced clinical outcomes comparable to that of fusion, the clinical value of dynamic stabilization awaits the findings of prospective, RCTs, which are an essential requirement for practice of evidence-based medicine.

Inter-Spinous and Interlaminar Stabilization Procedures

Lumbar spinal stenosis (LSS) refers to narrowing of the lumbar spinal canal, lateral recess, or foramen resulting in neurovascular compression that may lead to pain. Spinal stenosis may be classified by etiology (e.g., congenital or acquired) or symptomatology (e.g., radiculopathy, neurogenic claudication, or mechanical back pain). It can also be classified radiographically, by the location of the stenosis (e.g., central canal, lateral recess, or intervertebral foramen) or by the presence of deformity such as spondylolisthesis or scoliosis. Overlapping in the classification of LSS can occur in that central stenosis with thecal sac compression usually leads to neurogenic claudication, while lateral recess compression is associated with compression of an individual nerve root, thus resulting in radiculopathy. Although symptoms may arise from narrowing of the spinal canal, not all patients with narrowing develop symptoms. The reason why some patients develop symptomatic stenosis and others do not is still unknown. Therefore, LSS does not refer to the pathoanatomical finding of spinal canal narrowing. It is a clinical syndrome of lower extremity pain caused by mechanical compression on neural elements or their vascular supply (Truumees, 2005).

Non-surgical treatments (e.g., activity modification, medications such as NSAIDs, physical therapy that focuses on flexion-based exercises, as well as epidural steroid injections) are usually the first treatment choice for patients suffering from neurogenic intermittent claudication (NIC) secondary to LSS. If symptoms failed to improve with non-surgical treatments, decompressive surgery (e.g., laminectomy, facetectomy, multi-level laminotomies, fenestration, distraction laminoplasty, and microscopic decompression), with or without fusion, may be necessary. Moreover, several studies reported that surgical treatment produces better outcomes than non-surgical treatment in the short-term; however, the results tend to deteriorate with time (Yuan et al, 2005).

While fusion operations have traditionally been used to manage many disorders of the lumbar spine related to instability, pain, or deformity, concern over the long-term effects of fusion on adjacent spinal segments has led to the development of new approaches such as inter-spinous distraction procedures.

Examples of US Food and Drug Administration (FDA) approved interspinous process spacers include, but may not be limited to, the Superion Interspinous Spacer, the X-Stop Interspinous Process Decompression (IPD) System and the X-Stop PEEK IPD System.

Interspinous process decompression is a minimally invasive surgical procedure that is proposed to relieve the symptoms of lumbar spinal stenosis in those patients who do not respond to conservative, nonsurgical treatment. The procedure involves implanting interspinous process decompression spacers between the spinous processes of the vertebrae which appear to be the source of the symptoms. The spacers can be implanted at one

or two lumbar levels and are designed to remain in place without being permanently affixed to the bone or ligamentous structures of the spine.

The X-Stop Inter-Spinous Process Distraction/Decompression System (St. Francis Medical Technologies, Inc., Alameda, CA) was developed to provide an alternative therapeutic. The principal behind the X-Stop (eXtension-Stop) is that by decompressing the affected spinal segment and maintaining it in a slightly flexed position (and also preventing extension) the symptoms of LSS can be relieved. Additionally, it allows the patient to resume their normal posture rather than flex the entire spine. The X-Stop is made of titanium alloy and is available in 5 sizes -- 6, 8, 10, 12, and 14 mm in diameter. It consists of 2 major parts: (i) the universal wing, and (ii) the main body (with oval spacer and tissue expander). The wings prevent anterior and lateral movement while the supraspinous ligament prevents posterior displacement. The oval spacer swivels, making it self-aligning relative to the uneven surface of the spinous process. This ensures that no sharp edges come into contact with the spinous process and that compressive loads are distributed equally on the surface of the bone.

The X-Stop Inter-Spinous Process Distraction/Decompression System gained FDA's PMA in November 2005 for use in alleviating the symptoms of patients with LSS. The X-Stop is intended to be used in patients with symptomatic LSS at 1 or 2 levels who have failed at least 6 months of conservative treatment. Under local anesthesia, the implant is inserted between the spinous processes of the affected level(s), and prevents extension at those levels. Talwar et al (2005) stated that patients with lower bone mineral density must be approached with more caution during insertion of the inter-spinous process implant.

According to SFMT Europe B.V., a subsidiary of St. Francis Medical Technologies, the X-Stop is indicated for any of the following conditions:

- Axial-load induced back pain; or
- Baastrup's syndrome (also known as kissing spines); or
- Contained herniated nucleus pulposus; or
- Degenerative and/or iatrogenic (post-discectomy) disc syndrome; or
- Facet syndrome; or
- Neurogenic intermittent claudication due to central and/or lateral-recess LSS; or
- Spondylolisthesis up to grade 1.5 (of 4) (about 35 %), with NIC; or
- Unloading of disc adjacent to a lumbar fusion procedure, primary or secondary.

There is a scarcity of randomized controlled studies on the clinical value of the X-Stop for the indications listed above, especially its long-term (over 2 years) benefits. Currently, available evidence on this device is mainly from J.F. Zucherman and K.Y. Hsu (developers of this technology), and their associates.

Verhoof and colleagues (2008) stated that the X-Stop inter-spinous distraction device has been reported to be an alternative to conventional surgical procedures in the treatment of symptomatic degenerative lumbar spinal stenosis. However, the effectiveness of the X-Stop in symptomatic degenerative lumbar spinal stenosis caused by degenerative spondylolisthesis is not known. A cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis were treated with the X-Stop inter-spinous distraction device. All patients had LBP, neurogenic claudication and radiculopathy. Pre-operative radiographs revealed an average slip of 19.6 %. Magnetic resonance imaging of the lumbo-sacral spine showed a severe stenosis. In 10 patients, the X-Stop was placed at the L4 to L5 level, whereas 2 patients were treated at both, L3 to L4 and L4 to L5 level. The mean follow-up was 30.3 months. In 8 patients, a complete relief of symptoms was observed post-operatively, whereas the remaining 4 patients experienced no relief of symptoms. Recurrence of pain, neurogenic claudication, and worsening of neurological symptoms was observed in 3 patients within 24 months. Post-operative radiographs and MRI did not show any changes in the percentage of slip or spinal dimensions. Finally, secondary surgical treatment by decompression with postero-lateral fusion was performed

in 7 patients (58 %) within 24 months. The authors concluded that the X-Stop inter-spinous distraction device showed an extremely high failure rate, defined as surgical re-intervention, after short term follow-up in patients with spinal stenosis caused by degenerative spondylolisthesis. They do not recommend the X-Stop for the treatment of spinal stenosis complicating degenerative spondylolisthesis.

Lindsey et al (2003) examined the kinematics of the instrumented lumbar spine and adjacent levels due to the insertion of the X-Stop. Seven lumbar spines (L2 to L5) were tested in flexion-extension, lateral bending, and axial rotation. Images were taken during each test to determine the kinematics of each motion segment. The X-Stop was inserted at the L3 to L4 level, and the test protocol was repeated. These researchers found that the X-Stop does not significantly alter the kinematics of the motion segments adjacent to the instrumented level.

In a study using 7 cadaveric spines (L2 to L5), Fuchs et al (2005) noted that the X-Stop may be used in conjunction with a unilateral medial facetectomy or unilateral total facetectomy. However, it should not be used in conjunction with bilateral total facetectomy. In another cadaveric L2 to L5 spine study (n = 7), Wiseman et al (2005) reported that inter-spinous process decompression by placing the X-Stop between the L3 to L4 spinous processes will unlikely cause adjacent level facet pain or accelerated facet joint degeneration. Furthermore, pain induced from pressure originating in the facets and/or posterior anulus of the lumbar spine may be relieved by inter-spinous process decompression. Richards et al (2005) quantified the effect of the X-Stop on the dimensions of the spinal canal and neural foramina during flexion and extension. By means of a positioning frame, 8 specimens (L2 to L5) were positioned to 15 degrees of flexion and 15 degrees of extension. Each specimen was assessed using magnetic resonance imaging (MRI), with and without the X-Stop, placed between the L3 to L4 spinous processes. Canal and foramina dimensions were compared between the intact and implanted specimens. These investigators concluded that the X-Stop prevents narrowing of the spinal canal and foramina in extension.

Lee and colleagues (2004) reported their preliminary findings on the use of the X-Stop for LSS in elderly patients (n = 10). Subjects were evaluated post-operatively by MRI and the Swiss Spinal Stenosis Questionnaire. Cross-sectional areas of the dural sac and intervertebral foramina at the stenotic level were measured post-operatively and compared with the pre-operative values. After implantation of the X-Stop, the cross-sectional area of the dural sac increased 16.6 mm2 (22.3 %) and intervertebral foramina increased 22 mm2 (36.5 %). The intervertebral angle as well as the posterior disc height changed significantly. A total of 70 % of the patients stated that they were satisfied with the surgical outcome.

In a multi-center, prospective, randomized, controlled trial, Zucherman and colleagues (2005) compared the outcomes of X-Stop treated NIC patients (n = 100) with their non-operatively treated counterparts (n = 91). The primary outcomes measure was the Zurich Claudication Questionnaire (ZCQ) -- a patient-completed, validated instrument for NIC. At every follow-up visit, X-Stop treated patients had significantly better outcomes in each domain of the ZCQ. At 2 years, the X-Stop treated patients improved by 45.4 % over the mean baseline Symptom Severity score compared with 7.4 % in the control group; the mean improvement in the Physical Function domain was 44.3 % in the X-Stop group and -0.4 % in the control group. In the X-Stop group, 73.1 % patients were satisfied with their treatment compared with 35.9 % of control patients.

Siddiqui et al (2007) reported on the one year results of a prospective observational study of the X Stop interspinous implant for the treatment of lumbar spinal stenosis. Forty consecutive patients were enrolled and surgically treated with X Stop implantation. The X Stop device was implanted at the stenotic segment, which was either at 1 or 2 levels in each patient. Sixteen of 40 patients failed to complete all clinical questionnaires at each of the specified time intervals and were excluded from the study. The investigators reported that, by 12 months after surgery, 54 % of the 24 remaining patients reported clinically significant improvement in their symptoms, 33 reported clinically significant improvement in their physical function, and 71 % expressed satisfaction with the procedure. Twenty-nine percent of patients required caudal epidural after 12 months for

recurrence of their symptoms of neurogenic claudication. The investigators noted that, although this study indicates that the X Stop offers significant short-term improvement, these results were less favorable than the previous randomized clinical study. Limitations of this study include the lack of a control group, short duration of follow-up, and high proportion of dropouts.

In a literature review, Christie et al (2005) evaluated the mechanisms of action and effectiveness of inter-spinous distraction devices in managing symptomatic lumbar spinal pathology. They stated that these devices continue to be evaluated in clinical trials; and that although the use of inter-spinous implants is still experimental, the early results are promising, and it is likely that future studies will establish a niche for them in the management of lumbar spinal pathology.

Bono and Vaccaro (2007) reviewed interspinous process devices for the lumbar spine, and stated that, although some clinical data exist for some of these devices, defining the indications for these minimally invasive procedures will be crucial. "Indications should emerge from thoughtful consideration of data from randomized controlled studies".

Based upon a systematic evidence review on inter-spinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine, the National Institute for Health and Clinical Excellence (NICE, 2006) concluded that "evidence of efficacy is limited and is confined to the medium and short term. These procedures should only be used in the context of special arrangements for consent, audit and research". Additionally, the specialist advisors to the Institute's Interventional Procedures Advisory Committee noted that given the fluctuating symptoms associated with this condition, the assessment of outcomes in clinical studies may be unreliable. Furthermore, some advisors questioned the long-term effectiveness of the procedure.

The questions regarding the long-term effectiveness of the X-Stop raised by Christie et al (2005) as well as some specialist advisors of the National Institute for Health and Clinical Excellence's Interventional Procedures Advisory Committee (2006) are congruous with those raised by documents released by the FDA in 2004 prior to a public hearing on the product. The FDA's PMA review stated that "although the device can be inserted with a minimally invasive operative technique as an outpatient procedure with generally a local anesthetic a decision as to the safety and effectiveness of this device is based solely on 24 month data because information on the patient outcomes after 24 months is not available. This information becomes important when looking at pain relief and return to function. Even though the goal of the study was accomplished showing a significant, statistical difference between the investigational and control groups, more patients report improvement at 12 months than at 24 months. Contrary to what has been observed in spinal fusion studies, in this study, a percentage of patients whose symptoms improved at 6 and 12 months show a trend of regression of pain and function symptoms toward baseline levels. There appears to be a trend with early pain relief but the data suggests that in about 15 % of patients initially successfully treated by the X-stop had only temporary relief".

On August 31, 2004, the FDA's Orthopaedic and Rehabilitation Devices Panel voted 5 to 3 to recommend a "not approvable" decision on the PMA for the X-Stop. The Panel cited concern with the need to identify the patient population that is most likely to benefit from the device, noting that overall effectiveness was not demonstrated in a majority of the clinical study population. The Panel also cited concerns with the longer term effectiveness of the device (longer than 2 years), with potential bias in the clinical study, and with the need for radiographic or other objective evidence of the device's mechanism of effect on the spine in patients.

As a condition of approval, the FDA has required the manufacturer to conduct a post-marketing study of the long-term safety and effectiveness of the X-Stop in patients who received the X-Stop under the Investigational Device Exemption (IDE). The FDA has required the manufacturer to conduct an additional post-approval study involving 240 patients at up to 8 clinical sites.

Guidelines from the North American Spine Society (NASS, 2007) concluded that there was insufficient evidence to support the use of the XSTOP in persons with lumbar spinal stenosis. The NASS guidelines noted: "Although the study cited in support of this recommendation is a level I study, it is a single study. Therefore, until further evidence is published there remains insufficient evidence to make a recommendation [about the use of the XSTOP in lumbar spinal stenosis]". More recently, guidelines from the North American Spine Society (NASS, 2011) concluded: "there is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis."

In summary, the clinical value of X-Stop for patients with LSS is still uncertain. In particular, whether its reported benefit will decline over time will require more research with longer-term evaluation. Additionally, further randomized controlled studies are needed to compare these inter-spinous process implants with traditional surgical interventions such as laminectomy and/or fusion.

In December 2004, the FDA granted 510(k) approval for ExtenSure bone allograft inter-spinous spacer device, which is a cylindrically fashioned piece of allograft bone intended to effect distraction, restore and maintain the space between 2 adjacent spinous processes and indirectly decompress a stenotic spinal canal at 1 or 2 levels. The procedure promotes fusion of the allograft to the spinous process above, while allowing motion between the allograft and the spinous process below. It is thought that this would provide a long-term solution to implant stability while retaining segmental motion. It may also be used to facilitate fusion between 2 or more adjacent spinous processes. This is similar to the action of the X-Stop device. However, there is a lack of clinical studies demonstrating effectiveness of the ExtenSure device.

The TOPS System, a total posterior arthroplasty implant, is an alternative to spinal fusion that is designed to stabilize but not fuse the affected vertebral level following decompression surgery to alleviate pain stemming from lumbar spinal stenosis while maintaining range of motion. It is indicated for patients with lower back and leg pain resulting from moderate-to-severe lumbar spinal stenosis at a single level between L3 and L5 that may be accompanied by facet arthrosis or degenerative spondylolisthesis. The TOPS System is not available for commercial use in the United States. Enrollment for an FDA investigational device exemption study commenced in May 2008.

In a review of the evidence on surgery for LBP for the American Pain Society's clinical practice guideline, Chou et al (2009) concluded that surgery for radiculopathy with herniated lumbar disc and symptomatic spinal stenosis is associated with short-term benefits compared to non-surgical therapy, though benefits diminish with long-term follow-up in some trials. For non-radicular back pain with common degenerative changes, fusion is no more effective than intensive rehabilitation, but associated with small -to-moderate benefits compared to standard non-surgical therapy. Moreover, they stated that although there is fair evidence that an inter-spinous spacer device is moderately more effective than non-surgical therapy for 1- or 2-level spinous stenosis, there are insufficient data to evaluate long-term benefits and harms.

The Coflex (Paradigm Spine) is an interlaminar spinal stabilization device for persons with lumbar stenosis that is implanted following laminectomy and decompression. The device is intended to provide benefits over fusion, including durable pain relief, maintenance of spinal motion, reduced hypermobility of adjancent segments resulting in reduced degeneration at adjacent levels. A pivotal randomized controlled clinical trial evaluated the noninferiority of the Coflex interlaminar stabilization with instrumented posterolateral spinal fusion (pedicle screw fixation) in subjects with back pain and spinal stenosis and no or mild instability (up to grade 1 spondylolisthesis) who had failed conservative management. The primary outcome of the study is improvements in Oswestry Disability Index (ODI) score, and secondary outcomes include the Visual Analog Scale (VAS) back and leg pain, and the Zurich Claudication Questionnaire (ZCQ) score. Other endpoints measured include range of motion at the level adjacent to the procedure, as range of motion has been found to be related to the development of adjacent level degeneration and disease. Subjects were followed over a two-

year period. Limitations of the study include the lack of blinding and the intermediate duration of the study. In addition, the study compared the effectiveness of the Coflex device with spinal fusion in spinal stenosis subjects with no instability; however, the benefits of spinal fusion this group of patients is uncertain.

In a prospective, randomized, multi-center, FDA IDE trial, Davis et al (2013a) evaluated the safety and effectiveness of Coflex interlaminar stabilization compared with posterior spinal fusion (PSF) in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis. A total of 322 patients (215 Coflex and 107 fusions) from 21 sites in the U.S. were enrolled between 2006 and 2010. Subjects were randomized to receive laminectomy and Coflex interlaminar stabilization or laminectomy and postero-lateral spinal fusion with spinal instrumentation in a 2:1 ratio. Overall device success required a 15-point reduction in ODI, no re-operations, no major device-related complications, and no post-operative epidural injections. Patient follow-up at minimum 2 years was 95.3 % and 97.2 % in the Coflex and fusion control groups, respectively. Patients taking Coflex experienced significantly shorter operative times ($p < 0.0001$), blood loss ($p < 0.0001$), and length of stay ($p < 0.0001$). There was a trend toward greater improvement in mean ODI scores in the Coflex cohort ($p = 0.075$). Both groups demonstrated significant improvement from baseline in all VAS back and leg parameters. Patients taking Coflex experienced greater improvement in Short-Form 12 physical health outcomes ($p = 0.050$) and equivalent mental health outcomes. Coflex subjects experienced significant improvement in all ZCQ outcomes measures compared with fusion (symptom severity [$p = 0.023$]; physical function [$p = 0.008$]; satisfaction [$p = 0.006$]). Based on the FDA composite for overall success, 66.2 % of Coflex and 57.7 % of fusions succeeded ($p = 0.999$), thus demonstrating non-inferiority. The overall adverse event rate was similar between the groups, but Coflex had a higher re-operation rate (10.7 % versus 7.5 %, $p = 0.426$). At 2 years, fusions exhibited increased angulation ($p = 0.002$) and a trend toward increased translation ($p = 0.083$) at the superior adjacent level, whereas Coflex maintained normal operative and adjacent level motion. The authors concluded that Coflex interlaminar stabilization is a safe and effective alternative, with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low-grade spondylolisthesis.

In a prospective, randomized, multi-center FDA IDE trial, Davis et al (2013b) evaluated the safety and effectiveness of Coflex Interlaminar Stabilization compared with PSF to treat low-grade spondylolisthesis with spinal stenosis. A total of 322 patients from 21 sites in the U.S. were enrolled between 2006 and 2008 for the IDE trial. The current study evaluated only the subset of patients from this overall cohort with Grade 1 spondylolisthesis (99 in the Coflex group and 51 in the fusion group). Subjects were randomized 2:1 to receive decompression and Coflex interlaminar stabilization or decompression and PSF with spinal instrumentation. Data collected included peri-operative outcomes, ODI, back and worse leg VAS scores, 12-Item Short Form Health Survey, ZCQ, and radiographic outcomes at a minimum of 2 years. The FDA criteria for overall device success required the following to be met: 15-point reduction in ODI, no re-operations, no major device-related complications, and no post-operative epidural injections. At a minimum of 2 years, patient follow-up was 94.9 % and 94.1 % in the Coflex and fusion control groups, respectively. There were no group differences at baseline for any demographic, clinical, or radiographic parameter. The average age was 63 years in the Coflex cohort and 65 years in the fusion cohort. Coflex subjects experienced significantly shorter operative times ($p < 0.0001$), less estimated blood loss ($p < 0.0001$), and shorter length of stay ($p < 0.0001$) than fusion controls. Both groups experienced significant improvements from baseline at 2 years in ODI, VAS back, VAS leg, and ZCQ, with no significant group differences, with the exception of significantly greater ZCQ satisfaction with Coflex at 2 years. The FDA overall success was achieved in 62.8 % of Coflex subjects (59 of 94) and 62.5 % of fusion controls (30 of 48) ($p = 1.000$). The re-operation rate was higher in the Coflex cohort (14 [14.1 %] of 99) compared with fusion (3 [5.9 %] of 51, $p = 0.18$), although this difference was not statistically significant. Fusion was associated with significantly greater angulation and translation at the superior and inferior adjacent levels compared with baseline, while Coflex showed no significant radiographic changes at the operative or index levels. The authors concluded that low-grade spondylolisthesis was effectively stabilized by Coflex and

led to similar clinical outcomes, with improved per-operative outcomes, compared with PSF at 2 years. Re-operation rates, however, were higher in the Coflex cohort. Patients in the fusion cohort experienced significantly increased superior and inferior level angulation and translation, while those in the Coflex cohort experienced no significant adjacent or index level radiographic changes from baseline. Coflex Interlaminar Stabilization is a less invasive, safe, and equally effective clinical solution to PSF to treat low-grade spondylolisthesis, and it appears to reduce stresses at the adjacent levels.

The major drawback associated with these 2 studies were: (i) lack of patient blinding, (ii) these studies did not assess the effectiveness of a fusion group consisting of lumbar intervertebral cages or BMP, and (iii) it is possible a subset of patients with a stable slip and with minimal back pain may benefit from decompression only, without the need for stabilization. Furthermore, long-term data are needed to ascertain if motion preservation with the Coflex device will lead to lower re-operation rates for adjacent level disease compared with fusion.

Also, an UpToDate review on " Subacute and chronic low back pain: Surgical treatment" (Chou, 2013) does not mention Coflex/interlaminar stabilization as a therapeutic option.

The pivotal investigational device exemption (IDE) trial for Coflex® Interlaminar Technology was a non-blinded, randomized, multi-center, non-inferiority trial of Coflex® compared to postero-lateral fusion with pedicle screw fixation. A total of 344 patients were randomized in a 2:1 ratio (215 Coflex® and 107 fusion controls, with 22 protocol violators). This study was conducted in a restricted population with numerous exclusion criteria. Compared to fusion, implantation of the Coflex® device required less operative time (98.0 versus 153.2 mins) and resulted in less blood loss (109.7 versus 348.6 cc) and a shorter hospital stay (1.9 versus 3.2 days). Composite clinical success (a combination of a minimum 15-point improvement in Oswestry Disability Index (ODI), no re-operations, no device-related complications, and no epidural steroid injections in the lumbar spine) at 24 months achieved non-inferiority compared to postero-lateral fusion (66.2 % Coflex® and 57.7 % fusion). Secondary effectiveness criteria, which included the ZCQ, visual analog score (VAS) for leg and back pain, Short Form-12 (SF-12), time to recovery, patient satisfaction, and several radiographic endpoints, tended to favor the Coflex® group by Bayesian analysis. In this analysis, non-overlapping confidence intervals imply statistically reliable group differences. For example, ZCQ composite success was achieved in 78.3 % of Coflex® patients (95 % confidence interval [CI]: 71.9 % to 84.7 %) compared to 67.4 % of controls (95 % CI: 57.5 % to 77.3 %). The percentage of device-related adverse events was the same for the 2 groups (5.6 % Coflex® and 5.6 % control), and a similar percentage of asymptomatic spinous process fractures were observed. The FDA considered the data in this non-blinded study to support reasonable assurance of safety and effectiveness for device approval, but approval is conditional on 2 additional studies that will provide longer-term follow-up (in the IDE cohort) and evaluate device performance under actual conditions of use (decompression alone versus decompression with Coflex®).

Wouter et al (2014) commented that the FDA does not demand that the experimental treatment for a device is compared with the "gold standard." The author noted that interspinous process device (IPD) treatment with bony decompression was approved in the United States,after the publication of an FDA study on IPD treatment (citing Davis, et al., 2013). However, this study did not compare the experimental treatment (IPD) with the "gold standard" (bony decompression) but with another experimental treatment (bony decompression with fixation techniques). Wouter, et al. (2014) noted that most studies of interspinous process devices (IPD) did not compare the results with other interventions and most did not have prospective study designs. The authors stated that it took 30 years (from the introduction of the Wallis IPD in 1984 until 2013) until 2 prospective studies of IPDs were published that compared IPD treatment with conventional (surgical) care (citing Moojen, et al., 2013; Davis, et al., 2013; Moojen, et al., 2010; Stromqvist, et al., 2013). These studies showed that treatment with IPD was not superior to bony decompression without implants and that IPD treatment resulted in

a higher reoperation rate (citing Moojen, et al., 2013: Stromqvist, et al., 2013). A third study of an IPD (X-Stop) was terminated because of the high number of reoperations (complications) in the experimental (IPD) group (Lønne, 2013).

Richter et al (2010) reported a prospective case control study of the Coflex® device in 60 patients who underwent decompressive surgery. The 2-year follow-up from this study was published in 2014 (Richter et al). These investigators prospectively evaluated the outcome of symptomatic lumbar spinal stenosis (LSS) treated with decompressive surgery alone in comparison with additional implantation of the Coflex interspinous device. A total of 62 patients with symptomatic LSS were treated with decompressive surgery; 31 of these patients received an additional Coflex device. Pre-operatively and post-operatively, disability and pain scores were measured using the ODI, the Roland-Morris Disability Questionnaire, the VAS, and the pain-free walking distance. Patients underwent post-operative assessments at 3, 6, 12, and 24 months including the above-mentioned scores and patient satisfaction. There was a significant improvement ($p < 0.001$) in the clinical outcome assessed in the ODI, the Roland-Morris Disability Questionnaire, the VAS, and the pain-free walking distance at all times of re-investigation compared with the base line in both groups. Up to 2 years after surgery, there were no significant differences between both groups in all ascertained parameters, including the patient satisfaction and subjective operation decision. The authors concluded that the results of this first prospective controlled study indicated that the additional placement of a Coflex interspinous device does not improve the already good clinical outcome after decompressive surgery for LSS in the 24-month follow-up interval.

In a randomized controlled trial, Moojen et al (2013) examined if interspinous process device implantation is more effective in the short-term than conventional surgical decompression for patients with intermittent neurogenic claudication due to lumbar spinal stenosis. A total of 203 participants were referred to the Leiden-The Hague Spine Prognostic Study Group between October 2008 and September 2011; 159 participants with intermittent neurogenic claudication due to lumbar spinal stenosis at 1 or 2 levels with an indication for surgery were randomized. A total of 80 participants received an interspinous process device and 79 participants underwent spinal bony decompression. The primary outcome at short-term (8 weeks) and long-term (1 year ????) follow-up was the Zurich Claudication Questionnaire score. Repeated measurements were made to compare outcomes over time. At 8 weeks, the success rate according to the Zurich Claudication Questionnaire for the interspinous process device group (63 %, 95 % confidence interval [CI]: 51 % to 73 %) was not superior to that for standard bony decompression (72 %, CI: 60 % to 81 %). No differences in disability (Zurich Claudication Questionnaire; $p = 0.44$) or other outcomes were observed between groups during the 1st year. The repeat surgery rate in the interspinous implant group was substantially higher ($n = 21$; 29 %) than that in the conventional group ($n = 6$; 8 %) in the early post-surgical period ($p < 0.001$). The authors concluded that this double blinded study could not confirm the hypothesized short-term advantage of interspinous process device over conventional "simple" decompression and even showed a fairly high re-operation rate after interspinous process device implantation. Furthermore, for orthopedic studies with implanted device, 1 year follow-up would not be considered long-term.

Mohi Eldin (2014) evaluated the safety and effectiveness of the Coflex Dynamic Distraction Stabilization (DDS) device in treating patients with degenerative diseases of the lumbar spine (DDLS), especially lumbar canal stenosis (LCS), to confirm its indications for implantation and to evaluate the clinical outcomes of patients. This study was part of a multi-center prospective, case-controlled study in Egypt to determine the safety and efficacy of minimally invasive spinal procedures; of these, the Coflex implant, a functionally dynamic U-shaped titanium interspinous implant, was included in the present study. From June 2008 until July 2013, these researchers treated 42 patients with this Coflex procedure. Median follow-up was 22.5 months. At the time of follow-up, all patients completed questionnaires and underwent clinical examination and spinal radiography. A significant number of patients showed pain relief. Pre-operatively, 30/42 (71 %) patients complained of moderate or severe low back pain (LBP). Post-operatively, the LBP in 6 (14 %) patients did

improve, 24 (57 %) even showed no low back pain anymore. Mean pre-operative walking distance was less than 1,000m in 36 (86 %) patients. Post-operatively, all 42 (100 %) patients could walk greater than 1,000m. Significant pain relief (greater than 50 %) in months was calculated. Radiological results showed that endplate angles when were acute pre-operatively, always became less acute post-operatively, and the foraminal height always increased. Segmental range of motion (ROM) showed maintenance of the dynamic movements at the operated level. Disc height showed significant changes after the procedure in both anterior and posterior disc heights. The authors noted that merging the clinical and radiological results of the current study suggested that these effects produce a clinical benefit for LCS patients treated with the Coflex spacer. Though this series has limitations of a smaller sample size, it nevertheless confirmed the satisfactory results. These researchers stated that they will continue to follow the patients enrolled in this study, together with new cases and will report on the longer follow-up. This was a small study (n = 42) with mid-term follow-up (median of 22.5 months). There is a lack of data on durability; well-designed studies with more subjects and longer follow-up are needed.

Yuan, et al. (2017) retrospectively compared the at least 5-year clinical and radiological outcomes of Coflex stabilization and PLIF for lumbar degenerative disease. Eighty-seven consecutive patients with lumbar degenerative disease were retrospectively reviewed. Forty-two patients underwent decompression and Coflex interspinous stabilization (Coflex group), 45 patients underwent decompression and PLIF (PLIF group). Clinical and radiological outcomes were evaluated. Coflex subjects experienced less blood loss, shorter hospital stays and shorter operative time than PLIF (all $p < 0.001$). Both groups demonstrated significant improvement in Oswestry Disability Index and visual analogue scale back and leg pain at each follow-up time point. The Coflex group had significantly better clinical outcomes during early follow-up. At final follow-up, the superior and inferior adjacent segments motion had no significant change in the Coflex group, while the superior adjacent segment motion increased significantly in the PLIF group. At final follow-up, the operative level motion was significantly decreased in both groups, but was greater in the Coflex group. The reoperation rate for adjacent segment disease was higher in the PLIF group, but this did not achieve statistical significance (11.1% vs. 4.8%, $p = 0.277$). Both groups provided sustainable improved clinical outcomes for lumbar degenerative disease through at least 5-year follow-up.

In an extension of the study repoted by Davis, et al. in 2013, Musacchio, et al. (2016) reported on five-year outcomes of a prospective, randomized, controlled trial conducted at 21 centers. Patients with moderate to severe lumbar stenosis at one or two contiguous levels and up to Grade I spondylolisthesis were randomized (2:1 ratio) to decompression and interlaminar stabilization (D+ILS; n=215) using the Coflex Interlaminar Stabilization device or decompression and fusion with pedicle screws (D+PS; n=107). Clinical evaluations were made preoperatively and at 6 weeks and 3, 6, 12, 18, 24, 36, 48, and 60 months postoperatively. Overall FDA success criteria required that a patient meet 4 criteria: 1) >15 point improvement in Oswestry Disability Index (ODI) score; 2) no reoperation, revision, removal, or supplemental fixation; 3) no major device-related complication; and 4) no epidural steroid injection after surgery. At 5 years, 50.3% of D+ILS vs. 44% of D+PS patients ($p>0.35$) met the composite success criteria. Reoperation/revision rates were similar in the two groups (16.3% vs. 17.8%; $p >0.90$). Both groups had statistically significant improvement through 60 months in ODI scores with 80.6% of D+ILS patients and 73.2% of D+PS patients demonstrating >15 point improvement ($p>0.30$). VAS, SF-12, and ZCQ scores followed a similar pattern of maintained significant improvement throughout follow-up. On the SF-12 and ZCQ, D+ILS group scores were statistically significantly better during early follow-up compared to D+PS. In the D+ILS group, foraminal height, disc space height, and range of motion at the index level were maintained through 5 years. This study compared the effectiveness of the Coflex device with spinal fusion in spinal stenosis subjects, some with low-grade spondylolisthesis; however, the benefits of spinal fusion in persons with spinal stenosis with low-grade spondylolisthesis are uncertain (see, e.g., Försth, et al., 2016; Puel & Moojen, 2016; Ghogawala, et al., 2016).

The Work Loss Data Institute's guideline on "Low back -- lumbar & thoracic (acute & chronic)" (2013) listed

interspinous decompression device (X-Stop) as one of the interventions/procedures that were considered, but was not recommended.

The North American Spine Society (NASS)'s clinical guideline on "Diagnosis and treatment of degenerative lumbar spondylolisthesis" (2014) stated that "There is insufficient and conflicting evidence to make a recommendation for or against the efficacy of interspinous spacers versus medical/interventional treatment in the management of degenerative lumbar spondylolisthesis patients. Grade of Recommendation: I (Insufficient Evidence)".

Puzzilli et al (2014) evaluated patients who were treated for symptomatic lumbar spinal stenosis with interspinous process decompression (IPD) implants compared with a population of patients managed with conservative treatment. A total of 542 patients affected by symptomatic lumbar spine degenerative disease were enrolled in a controlled trial; 422 patients underwent surgical treatment consisting of X-STOP device implantation, whereas 120 control cases were managed conservatively. Both patient groups underwent follow-up evaluations at 6, 12, 24, and 36 months using the Zurich Claudication Questionnaire, the visual analog scale (VAS) score and spinal lumbar X-rays, CT scans and MR imaging. One-year follow-up evaluation revealed positive good results in the 83.5 % of patients treated with IPD with respect to 50 % of the non-operative group cases. During the first 3 years, in 38 out of the 120 control cases, a posterior decompression and/or spinal fixation was performed because of unsatisfactory results of the conservative therapy. In 24 (5.7 %) of 422 patients, the IPD device had to be removed, and a decompression and/or pedicle screw fixation was performed because of the worsening of neurological symptoms. The authors concluded that these findings supported the effectiveness of surgery in patients with stenosis; IPD may offer an effective and less invasive alternative to classical microsurgical posterior decompression in selected patients with spinal stenosis and lumbar degenerative disk diseases.

Doulgeris et al (2015) compared an interspinous fusion device with posterior pedicle screw system in a lateral lumbar interbody lumbar fusion. These researchers biomechanically tested 6 cadaveric lumbar segments (L1 to L2) under an axial preload of 50N and torque of 5Nm in flexion-extension, lateral bending and axial rotation directions. They quantified range of motion, neutral zone/elastic zone stiffness in the following conditions: intact, lateral discectomy, lateral cage, cage with interspinous fusion, and cage with pedicle screws. A complete lateral discectomy and annulectomy increased motion in all directions compared to all other conditions. The lateral cage reduced motion in lateral bending and flexion/extension with respect to the intact and discectomy conditions, but had minimal effect on extension stiffness. Posterior instrumentation reduced motion, excluding interspinous augmentation in axial rotation with respect to the cage condition. Interspinous fusion significantly increased flexion and extension stiffness, while pedicle screws increased flexion/extension and lateral bending stiffness, with respect to the cage condition. Both posterior augmentations performed equivalently throughout the tests except in lateral bending stiffness where pedicle screws were stiffer in the neutral zone. The authors concluded that a lateral discectomy and annulectomy generated immediate instability. Stand-alone lateral cages restored a limited amount of immediate stability, but posterior supplemental fixation increased stability. Both augmentations were similar in a single level lateral fusion in-vitro model, but pedicle screws are more equipped for coronal stability. They stated that an interspinous fusion is a less invasive alternative than pedicle screws and is potentially a conservative option for various interbody cage scenarios.

Hirsch et al (2015) stated that lumbar spinal stenosis is a major public health issue. Interspinous devices implanted using minimally invasive techniques may constitute an alternative to the reference standard of bony decompression with or without intervertebral fusion. However, their indications remain unclear, due to a paucity of clinical and biomechanical data. These investigators evaluated the effects of four interspinous process devices implanted at L4 to L5 on the intervertebral foramen surface areas at the treated and adjacent levels, in flexion and in extension. Six fresh frozen human cadaver lumbar spines (L2 to sacrum) were tested

on a dedicated spinal loading frame, in flexion and extension, from 0 to 10 N·m, after preparation and marking of the L3 to L4, L4 to L5, and L5 to S1 foramina. Stereoscopic 3D images were acquired at baseline then after implantation at L4 to L5 of each of the 4 devices (Inspace(®), Synthes; X-Stop(®), Medtronic; Wallis(®), Zimmer; and Diam(®), Medtronic). The surface areas of the 3 foramina of interest were computed. All 4 devices significantly opened the L4 to L5 foramen in extension. The effects in flexion separated the devices into 2 categories. With the 2 devices characterized by fixation in the spinous processes (Wallis(®) and Diam(®)), the L4 to L5 foramen opened only in extension; whereas with the other 2 devices (X-Stop(®) and Inspace(®)), the L4 to L5 foramen opened not only in extension, but also in flexion and in the neutral position. None of the devices implanted at L4 to L5 modified the size of the L3 to L4 foramen. X-Stop(®) and Diam(®) closed the L5 to S1 foramen in extension, whereas the other 2 devices had no effect at this level. The authors concluded that these findings demonstrated that interspinous process devices modified the surface area of the interspinous foramina in-vitro. They stated that clinical studies are needed to clarify patient selection criteria for interspinous process device implantation.

Lee, et al. (2015) conducted a systematic literature review of interspinous dynamic stabilization, including DIAM, Wallis, Coflex, and X-STOP, to assess its safety and efficacy. A literature search was done in Korean and English, by using eight domestic databases which included KoreaMed and international databases, such as Ovid Medline, Embase, and the Cochrane Library. A total of 306 articles were identified, but the animal studies, preclinical studies, and studies that reported the same results were excluded. As a result, a total of 286 articles were excluded and the remaining 20 were included in the final assessment. Two assessors independently extracted data from these articles using predetermined selection criteria. Qualities of the articles included were assessed using Scottish Intercollegiate Guidelines Network (SIGN). The complication rate of interspinous dynamic stabilization has been reported to be 0% to 32.3% in 3- to 41-month follow-up studies. The complication rate of combined interspinous dynamic stabilization and decompression treatment (32.3%) was greater than that of decompression alone (6.5%), but no complication that significantly affected treatment results was found. Interspinous dynamic stabilization produced slightly better clinical outcomes than conservative treatments for spinal stenosis. Good outcomes were also obtained in single-group studies. No significant difference in treatment outcomes was found, and the studies compared interspinous dynamic stabilization with decompression or fusion alone. The authors of the systematic review concluded that no particular problem was found regarding the safety of the technique. Its clinical outcomes were similar to those of conventional techniques, and no additional clinical advantage could be attributed to interspinous dynamic stabilization. However, few studies have been conducted on the long-term efficacy of interspinous dynamic stabilization. Thus, the authors suggest further clinical studies be conducted to validate the theoretical advantages and clinical efficacy of this technique.

Interspinous Fixation Devices

Spinous process fixation is promoted as a minimally invasive spine surgery technique that stabilizes the lumbar spine with less dissection and trauma to the vertebra than the current gold standard, pedicle screw (PS) fixation (Lopez, et al., 2016). Interspinous fixation devices (IFD) aim to provide rigidity comparable with PS fixation by bilaterally securing plates to the lateral aspects of 2 adjacent spinous processes, effectively clamping the motion segment together. IFD implantation has been applied to posterolateral and interbody fusion procedures. Certain IFD products are designed to achieve additional stability through interspinous bony fusion. Proponents have noted that IFD placement is a more expedient procedure that requires a single, less obtrusive midline incision. Multiple IFDs have been designed and are indexed in the literature using various terminology, including spinous process clamps, plates, and anchors. These are not to be confused with interspinous spacers" (X-Stop, Wallis, or DIAM devices), which reduce extension through dynamic stabilization with the aim of decreasing symptoms of lumbar spinal stenosis.

Lopez, et al. (2016) systematically reviewed the available literature on interspinous rigid fixation/fusion devices (IFD) to explore the devices' efficacy and complication profile. A systematic review of the past 10 years of English literature was conducted according to PRISMA guidelines. The timeframe was chosen based on publication of the first study containing a modern IFD, the SPIRE, in 2006. All PubMed publications containing MeSH headings or with title or abstract containing any combination of the words "interspinous," "spinous process," "fusion," "fixation," "plate," or "plating" were included. Exclusion criteria consisted of dynamic stabilization devices (X-Stop, DIAM, etc.), cervical spine, pediatrics, and animal models. The articles were blinded to author and journal, assigned a level of evidence by Oxford Centre of Evidence-Based Medicine (OCEBM) criteria, and summarized in an evidentiary table. A total of 293 articles were found in the initial search, of which 15 remained after examination for exclusion criteria. No class I or class II evidence regarding IFDs was found. IFDs have been shown by methodologically flawed and highly biased class III evidence to reduce instability at 1 year, without statistical comparison of complication rates against other treatment modalities

Piriformis Muscle Resection

Piriformis syndrome is believed to be a condition in which the piriformis muscle, a narrow muscle located in the buttocks, compresses or irritates the sciatic nerve. There is debate within the medical community whether this is a discrete condition, since it lacks objective evidence, and thus can not be reliably evaluated. Pain associated with piriformis syndrome is exacerbated in prolonged sitting. Specific physical findings are tenderness in the sciatic notch and buttock pain in flexion, adduction, and internal rotation of the hip. Imaging modalities are rarely helpful. Physical therapy is a mainstay of conservative treatment; and is usually enhanced by local injections (Papadopoulos and Khan, 2004). There is insufficient evidence regarding the effectiveness of section of the piriformis muscle as a treatment for piriformis syndrome.

Endoscopic Laser Foraminoplasty

Endoscopic laser foraminoplasty (decompression) is primarily employed to treat patients with back pain caused by a prolapsed intervertebral disc. This endoscope-assisted laser technique is used to widen the lumbar exit route foramina in the spine. A laser is inserted to ablate portions of the intervertebral disc that have protruded. Hafez and associates (2001) noted that laser ablation of bone and ligament for nerve root decompression using the Ho: YAG laser may offer substantial advantages, but the risk of serious complication may only be avoided if the technique is combined with saline irrigation.

Knight and colleagues (2001) reported that the complication rate of endoscopic laser foraminoplasty is significantly lower than that reported following conventional spinal surgery. From these results, these investigators concluded that endoscopic laser foraminoplasty as a treatment for chronic LBP and sciatica presents less risk to a patient than conventional methods of spinal surgery. On the other hand, the National Institute for Clinical Excellence's (2003) guidance on this procedure stated that current evidence on the safety and effectiveness of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Moreover, the Specialist Advisors believed the effectiveness of this procedure to be unproven; and they also noted a number of potential complications including nerve injury and infection. Takeno et al (2006) stated that percutaneous lumbar disc decompression is associated with significant risk of disc, end-plate, and nerve root injuries, contrary to the general belief that the procedure is minimally invasive. Their findings highlight the need for careful diagnosis and sufficient technical skill when selecting percutaneous lumbar disc decompression as a treatment option.

Percutaneous Discectomy

Percutaneous disc decompression is a procedure specifically for a herniated disc in which the core of the disc

has not broken through the disc wall. Performed through a needle in the skin, it is a form of surgery in which small bits of disc are removed to relieve pressure on the nerves surrounding the disc. The procedure may be performed with a cutting instrument or laser. Although the literature indicates that open laminectomy is an acceptable and, at times, necessary method of treatment for herniated intervertebral discs, percutaneous discectomy has emerged as a method of treatment for contained and non-migrated sequestered herniated discs. It has taken on 2 different forms: the selective removal of nucleus pulposus from the herniation site with various manual and automated instruments under endoscopic control (percutaneous nucleotomy with discoscopy, arthroscopic microdiscectomy, percutaneous endoscopic discectomy); the other is the removal of nucleus pulposus from the center of the disc space with one single automated instrument (automated percutaneous lumbar discectomy) to achieve an intradiscal decompression.

Automated percutaneous lumbar discectomy (APLD), or automated percutaneous mechanical lumbar discectomy, is another newer approach for surgical treatment of herniated discs. In this procedure, under local anesthesia and fluoroscopic guidance, a cannula is inserted into the disc; an automated cutting and aspiration device is then inserted through the cannula and the disc material is removed. As with the arthroscopic microdiscectomy/PED, APLD does not allow direct visualization of the disc or surrounding tissues. An example of a device used for this type of procedure includes, but may not be limited to, the Stryker Dekompressor Lumbar Discectomy Probe.

Automated percutaneous discectomy refers to techniques using minimal skin incisions (generally several, all less than 3 to 5 mm) to allow small instruments to be inserted, using radiography to visualize these instruments, and using extensions for the surgeon to reach the operative site without having to dissect tissues. Lasers to vaporize the nucleus pulposus have become an additional percutaneous option. Proponents of percutaneous lumbar discectomy cite several potential advantages over open discectomy procedures, including reduced morbidity, less potential for perineural scarring, less intra-operative blood loss, fewer complications of epidural fibrosis, transverse myelitis or disc space infection, reduced patient recovery times, and a faster return to normal activity. Initial case series focusing on lumbar disc disease reported encouraging results and the technique was widely adopted (Onik, 1990; Fiume et al, 1994; Ohnmeiss et al, 1994; Kotilainen and Valtonen, 1998). However, controlled trials reported less impressive results.

An interventional guidance on laser lumbar discectomy issued by the National Institute for Health and Clinical Excellence (NICE, 2003) stated that "Current evidence on the safety and efficacy of laser lumbar discectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research". The guidance noted that in an uncontrolled study of 348 patients with chronic back pain, 210 (60 %) patients reported good or excellent results at 1 year, however, the validity of the studies on this procedure were compromised by high rates of loss to follow-up and the lack of long-term data on efficacy outcomes.

A review of minimally invasive procedures for disorders of the lumbar spine (Deen et al, 2003) stated that "Percutaneous lumbar diskectomy techniques hold considerable promise; however, lumbar microdiskectomy is the gold standard for surgical treatment of lumbar disk protrusion with radiculopathy".

A National Institute for Health and Clinical Excellence (NICE, 2005) guidance on automated percutaneous mechanical lumbar discectomy stated that "Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research".

A Cochrane review on surgical interventions for lumbar disc prolapse (Gibson and Waddell, 2007) examined

the evidence on automated percutaneous discectomy and laser discectomy. The reviewers found four trials on automated percutaneous discectomy that met their inclusion criteria: 2 trials that compared automated percutaneous discectomy with chymopapain (Revel, 1993; Krugluger, 2000) and 2 that compared automated percutaneous discectomy with microdiscectomy (Chatterjee, 1995; Haines, 2002). The reviewers reported that the results from these 4 trials suggested that automated percutaneous discectomy produced inferior results to either more established procedure. The reviewers found 2 trials that met their inclusion criteria on laser discectomy: 1 trial compared the effects of a Nd-YAG-laser with that of a diode laser (Paul and Hellinger, 2000) and reported slight vaporization with both lasers and excellent shrinkage of disc tissue, however, no comparative outcome results were published; the other trial compared chemonucleolysis with laser discectomy (Steffen and Wittenberg, 1997) and reported that the study results favored chemonucleolysis. The reviewers concluded that while microdiscectomy gives broadly comparable results to open discectomy, the evidence on other minimally invasive techniques remains unclear (with the exception of chemonucleolysis using chymopapain, which is no longer widely available).

Nezer and Hermoni (2007) reviewed the evidence for percutaneous discectomy and percutaneous intradiscal radiofrequency thermocoagulation from 4 leading evidence-based databases: the National Institute for Clinical Excellence (NICE), which is an independent organization responsible for providing national guidance on treatments, the Cochrane Library, which is the largest library world-wide for systematic reviews and randomized controlled trials, the Center for Review and Dissemination at the University of York, which undertakes reviews of research about the effects of interventions in health and social care and finally, a search via Medline. The authors concluded that "The results from those systematic reviews and randomized trials show that, at present, unless or until better scientific evidence is available, automated percutaneous discectomy and laser discectomy should be regarded as research techniques".

Goupille et al (2007) reviewed the literature on percutaneous laser disc decompression for treating lumbar disc herniation and stated that "[e]xperimental and clinical studies have investigated the modality of percutaneous laser disc decompression, but no consensus exists on the type of laser to use, the wavelength, duration of application, or appropriate energy applied. Studies have evaluated the impact of different techniques on the amount of disc removed, intradisc[al] pressure, and damage to neighboring tissue. Several open studies have been published, but their methodology and conclusions are questionable, and no controlled study has been performed". The authors concluded that "Although the concept of laser disc nucleotomy is appealing, this treatment cannot be considered validated for disc herniation-associated radiculopathy resistant to medical treatment".

A California Technology Assessment (2008) reviewed the scientific evidence for percutaneous laser disc decompression in the treatment of symptomatic lumbar disc herniation and found no published randomized, concurrently controlled, blinded trials comparing outcomes of percutaneous laser disc decompression with conventional conservative measures or open discectomy or laminectomy. The authors reported that the published articles concerning percutaneous laser disc decompression are almost all uncontrolled case series: 2 non-randomized comparative trials (Ohnmeiss et al, 1994, Tassi, 2006) and 1 systematic review (Boult et al, 2000) of percutaneous laser disc decompression have been published. The assessment stated that "The published data are not sufficient to conclude that the efficacy and safety of the percutaneous laser disc decompression procedure have been established in the investigational setting, let alone under conditions of usual medical practice. Percutaneous laser disc decompression requires further evaluation in a randomized controlled trial to assess its efficacy as an alternative treatment for symptomatic lumbar disc herniation".

An assessment by the National Institute for Health and Clinical Excellence (NICE, 2008) of percutaneous endoscopic laser lumbar diskectomy concluded that "[c]urrent evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate in quantity and quality. Therefore this

procedure should only be used with special arrangements for clinical governance, consent, and audit or research". The specialist advisors to NICE considered theoretical adverse events to include a higher risk of nerve or dural injury because of the poor visual field and disorientation, and a higher probability of missed fragments. One specialist advisor stated that there had been cases of heat damage to the cauda equine when laser was used for lumbar discectomy with concomitant foraminoplasty.

An assessment by NICE (2008) reached similar conclusions about the unproven status of percutaneous endoscopic laser cervical diskectomy. The NICE assessment concluded that "[c]urrent evidence on the safety and efficacy of percutaneous endoscopic laser cervical diskectomy is inadequate in quantity and quality. Available evidence reviewed by NICE was limited to uncontrolled case series". The specialist advisors to NICE considered the most important theoretical risk of the procedure to be heat damage to nerve roots or to the spinal cord, potentially leading to quadriplegia. One specialist advisor stated that neurological damage had occurred in a patient as a result of using laser in the spine. The NICE review committee noted that the extent to which laser ablation was used instead of, or in addition to, mechanical methods of removing prolapsed disc material was unclear in much of the published evidence.

All of the trials reviewed above focused on lumbar disc herniation. There were no clinical trials of percutaneous discectomy of cervical or thoracic disc herniation.

Xclose Tissue Repair System

An annular (annulus) repair/closure may be performed following a spinal decompression (discectomy) surgery. It has been proposed that annular closure may reduce the risk of disc reherniation and the need for a fusion. Examples of devices used in an annular repair include the Inclose Surgical Mesh System and Xclose Tissue Repair System.

The Xclose™ Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) has received 510(k) clearance for use in soft tissue approximation for procedures such as general and orthopedic surgery. It is being investigated as a method of soft tissue re-approximation of the anulus fibrosus after a lumbar discectomy procedure. However, there is insufficient evidence of the clinical effectiveness of the Xclose Tissue Repair System following a lumbar discectomy procedure. Randomized controlled studies are needed to determine whether closing the anulus following a lumbar discectomy procedure will result in improved clinical outcomes (i.e., decrease in re-herniation rates). To evaluate the benefits of anulus fibrosis repair utilizing the Xclose Tissue Repair system, Anulex is sponsoring a prospective, controlled, randomized study that will compare discectomy patients who receive anular repair using the Xclose Tissue Repair System to those who receive a standard discectomy without using the Xclose. However, results from this study have not yet been published in the peer-reviewed medical literature.

Radiofrequency Denervation for Sacroiliac Joint Pain

Cohen et al (2008) carried out a randomized placebo-controlled study in 28 patients with injection-diagnosed sacroiliac joint pain. Fourteen patients received L4 to L5 primary dorsal rami and S1 to S3 lateral branch radiofrequency (RF) denervation using cooling-probe technology after a local anesthetic block, and 14 patients received the local anesthetic block followed by placebo denervation. Patients who did not respond to placebo injections crossed-over and were treated with RF denervation using conventional technology. One, 3, and 6 months after the procedure, 11 (79 %), 9 (64 %), and 8 (57 %) RF-treated patients experienced pain relief of 50 % or greater and significant functional improvement. In contrast, only 2 patients (14 %) in the placebo group experienced significant improvement at their 1-month follow-up, and none experienced benefit 3 months after the procedure. In the cross-over group (n = 11), 7 (64 %), 6 (55 %), and 4 (36 %) experienced improvement 1, 3, and 6 months after the procedure. One year after treatment, only 2 patients (14 %) in the treatment group

continued to demonstrate persistent pain relief. The authors concluded that these results provide preliminary evidence that L4 and L5 primary dorsal rami and S1-S3 lateral branch RF denervation may provide intermediate-term pain relief and functional benefit in selected patients with suspected sacroiliac joint pain. They stated that larger, multi-centered studies with long-term follow-up and comprehensive outcome measures are needed to confirm these results, further establish safety and determine the optimal candidates and treatment parameters.

Drawbacks of this study, albeit a randomized controlled one, include small number of patients as well as "poor" long-term results (only 14 % in the treatment group showed continued pain relief after 1 year). In addition, a systematic review on sacroiliac joint interventions (Hansen et al, 2007) concluded that the evidence for RF neurotomy in managing chronic sacroiliac joint pain is limited.

In an observational study, Karaman et al (2011) examined the safety and effectiveness of novel cooled RF application for sacral lateral-branch denervation. Patients experiencing chronic sacroiliac pain were selected for this study. Fluoroscopy guidance cooled RF denervation was applied on the L5 dorsal ramus and the S1 to S3 lateral branches on patients who had twice undergone consecutive joint blockages to confirm the diagnosis and obtained at least 75 % pain relief. At the 1st, 3rd and 6th month post-operatively, the patients' pain was evaluated using a VAS, and their physical function was evaluated with the ODI. Cooled RF was applied on a total of 15 patients. Prior to the procedures, the median VAS score (interquartile range) was 8 (7 to 9), but at the 1st, 3rd and 6th month, this had fallen to 3 (1 to 4), 2 (1 to 3) and 3 (2 to 4). The baseline median ODI score (interquartile range) was 36 (32 to 38), while at the 1st, 3rd and 6th month, it was 16 (8 to 20), 12 (9 to 18) and 14 (10 to 20), respectively. At the final control, while 80 % of the patients reported at least a 50 % decline in pain scores, 86.7 % of those reported at least a 10-point reduction in ODI scores. The authors concluded that the cooled RF used for sacroiliac denervation was an effective and safe method in the short-to-intermediate term. The major drawbacks of this study were its small sample size (n = 15) and short follow-up period (6 months). The authors stated that RCTs with longer follow=up period are needed.

Stelzer et al (2013) retrospectively evaluated the use of cooled RF lateral branch neurotomy (LBN) to treat chronic SIJ-mediated LBP in a large European study population. The electronic records of 126 patients with chronic LBP who underwent treatment with cooled RF LBN were identified. Subjects were selected for treatment based on physical examination and positive response (greater than or equal to 50 % pain relief) to an intra-articular SIJ block. Cooled RF LBN involved lesioning the L5 dorsal ramus and lateral to the S1, S2, and S3 posterior sacral foraminal apertures. Visual analog scale pain scores, quality of life, medication usage, and satisfaction were collected before the procedure, at 3 to 4 weeks post-procedure (n = 97), and once again between 4 and 20 months post-procedure (n = 105). When stratified by time to final follow-up (4 to 6, 6 to 12, and greater than 12 months, respectively): 86 %, 71 %, and 48 % of subjects experienced greater than or equal to 50 % reduction in VAS pain scores, 96 %, 93 %, and 85 % reported their quality of life as much improved or improved, and 100 %, 62 %, and 67 % of opioid users stopped or decreased use of opioids. The authors concluded that the current results showed promising, durable improvements in pain, quality of life, and medication usage in a large European study population, with benefits persisting in some subjects at 20 months after treatment. The main drawbacks of this study were its retrospective nature, lack of a control group, difficulty in contacting certain subjects, missing data for some subjects, as well as variable length of time to final follow-up.

Ho and colleagues (2013) noted that SIJ pain is a common cause of chronic LBP. Different techniques for RF denervation of the SIJ have been used to treat this condition. However, results have been inconsistent because the variable sensory supply to the SIJ is difficult to disrupt completely using conventional RF. Cooled RF is a novel technique that uses internally cooled RF probes to enlarge lesion size, thereby increasing the chance of completely denervating the SIJ. These researchers evaluated the effectiveness of cooled RF denervation using

the SInergyTM cooled RF system for SIJ pain. The charts of 20 patients with chronic SIJ pain who had undergone denervation using the SInergyTM cooled RF system were reviewed at 2 years following the procedure. Outcome measures included the Numeric Rating Scale for pain intensity, Patient Global Impression of Change, and Global Perceived Effect for patient satisfaction. Fifteen of 20 patients showed a significant reduction in pain (a decrease of at least 3 points on the Numeric Rating Scale). Mean Numeric Rating Scale for pain decreased from 7.4 ± 1.4 to 3.1 ± 2.5, mean Patient Global Impression of Change was "improved" (1.4 ± 1.5), and Global Perceived Effect was reported to be positive in 16 patients at 2 years following the procedure. The authors concluded that cooled RF denervation showed long-term effectiveness for up to 2 years in the treatment of SIJ pain. Limitations of this study included: (i) small sample size (n = 20), (ii) it was a retrospective review with no placebo-control or sham-control group, and (iii) no comparison with conventional RF treatment for SIJ pain.

Facet Joint Implantation

Facet joint replacement/implant is a new device/procedure for facet joint degeneration, which may be used in conjunction with a spinal fusion. It is purported as a system for facet joint reconstruction, matching the joint shape and size in order to provide pain relief, normal motion and stability. An example of this device includes, but may not be limited to, the Acadia Facet Replacement System. Please note: the Acadia is not US Food and Drug Administration (FDA) approved; it is currently in an ongoing clinical trial.

Spinal facet (zygapophyseal) joints are diarthroidal joints that provide both sliding articulation and load transmission features. In addition to the intervertebral disc, facet joints help to support axial, torsional and shear loads that act on the spinal column. Thus, facet joints play an important role in maintaining segmental stability of the spinal cord. Pathology of the facet joints may result in back/neck pain as well as segmental instability within the spine. One of the most common treatment for spinal trauma or degenerative diseases/disorders is arthrodesis (spinal fusion) of one or more vertebral segments. However, spinal fusion decreases function by limiting the range of motion (ROM) for patients in flexion, extension, rotation, and lateral bending. It also creates increased stresses that may lead to accelerated degeneration of adjacent non-fused vertebral segments. Furthermore, pseudoarthrosis, as a result of an incomplete or ineffective fusion, may reduce or even eliminate the desired pain relief. Finally, migration of the fusion device may occur.

Researchers have tried to recreate the natural biomechanics of the spine by the use of artificial discs, which provide for articulation between vertebral bodies to recreate the full ROM allowed by the elastic properties of the natural intervertebral disc that directly connects two opposed vertebral bodies. However, artificial discs available to date do not fully address the mechanics of motion of the spinal column.

Facet joint implantation is a new approach to overcome the shortcomings of currently available devices/implants. These implants are employed to replace a bony portion of the facets so as to remove the source of arthritic-, traumatic-, or other disease-mediated pain. In conjunction with artificial disc replacements, facet joint implantation may represent a way to recreating a fully functional motion segment that is compromised due to disease or trauma. This combination can supposedly eliminate all sources of pain, return full function and ROM, and completely restore the natural biomechanics of the spinal column. Moreover, degenerative or traumatized facet joints may be replaced in the absence of disc replacement when the natural intervertebral disc is unaffected by the disease or trauma. Facet implants include a superior implant for placement on a superior articulating surface and an inferior implant for placement on an inferior articulating surface. These facet implants are positioned within the affected facet joint(s) for distraction, thus increasing the area of the canals and openings through which the spinal cord and nerves must pass, and decreasing pressure on the spinal cord and/or nerve roots. These implants can be inserted via a lateral or posterior approach.

While facet joint implants are designed to provide patients with degenerative or traumatized facet a motion-

preserving alternative to spinal fusion, and to restore the natural motion, stability, and balance to the spine, there is currently a lack of evidence regarding their clinical benefits. The North American Spine Society's guideline on the diagnosis and treatment of degenerative lumbar spinal stenosis (2007), the American College of Occupational and Environmental Medicine's guideline on low back disorders (2007), and the Work Loss Data Institute's guideline on low back -- lumbar and thoracic (2008) did not mention the use of facet implant/arthroplasty. Furthermore, in a review on the treatment of neck pain by the Bone and Joint Decade 2000-2010 Task Force on neck pain and its associated disorders facet implant/arthroplasty is not mentioned as an option (Carragee et al, 2009).

Lateral Interbody Fusion

A proposed minimally invasive approach to spinal fusion uses a laparoscope (endoscope), and purports to decrease injury to surrounding tissues and promote a quicker recovery time. There are several types of these procedures/techniques including, but not limited to, direct lateral interbody fusion (DLIF), extreme lateral interbody fusion (XLIF), and laparoscopic anterior lumbar interbody fusion (LALIF).

The aim of lateral interbody fusion in the lumbar spine is to achieve a spinal fusion procedure via a lateral approach in order to avoid the major muscle groups in the back (posterior approach) or the organs and blood vessels in the abdomen (anterior approach) (NICE, 2009). A probe is inserted under fluoroscopic guidance through the psoas muscle, to lie alongside the affected disc, via a lateral approach.

Nerve monitoring is recommended to avoid damage to motor nerves. However, lower limb dysthesia may occur from damage of sensory nerves (NICE, 2009). In one study, 30 % of patients developed post-operative numbness, and in 2/3 of these patients the numbness lasted longer than 1 month (Bergey et al, 2004).

Extreme lateral interbody fusion (XLIF) is a novel surgical technique for anterior lumbar interbody fusion. In XLIF (NuVasive, Inc., San Diego, CA) access to the disc space is achieved through 2 small incisions from the side of the body instead of through the muscles of the back. The proposed benefits of XLIF include reduced operative time, reduced blood loss, minimal scarring and reduced hospital stay. However, the procedure is technically difficult to perform and vertebral access is limited to those vertebrae of the spine that are available from the side of the body.

Because the extreme lateral lumbar approach is relatively new, long-term data about XLIF is not currently available and the published data "is sparse at best" (Bahtia et al, 2008). In a feasibility study of XLIF for anterior lumbar interbody fusion (n = 13), Ozgur, et al (2006) reported that the technique allowed anterior access to the disc space without an approach surgeon or the complications of an anterior intra-abdominal procedure; however, the authors concluded that longer-term follow-up and data analysis are needed. A paucity of significant long-term data exists in the literature regarding outcomes of XLIF (Bahtia et al, 2009).

Direct lateral interbody fusion (DLIF) uses a similar approach as XLIF. Knight et al (2009) reported on the results of a prospective chart review (n = 98) of complications from DLIF or XLIF compared to a historical cohort of patients who underwent an open posterior approach. The investigators reported that there was no statistically significant difference in the total complication rate between patients treated with lateral interbody fusion techniques (22.4 %) and patients treated with an open postero-lateral approach (22.5 %). In the lateral interbody fusion group, nerve root damage occurred in 3 % (2/58) of patients; both showed residual motor effects at 1-year follow-up.

Eck et al (2007) stated in a review of anterior minimally invasive back procedures that minimally invasive techniques for lumbar spine fusion are often associated with significantly greater incidence of complications and technical difficulty than their associated open approaches. An assessment of lateral interbody fusion

techniques, including extreme, extra and direct lateral interbody fusion, by the National Institute for Health and Clinical Excellence (NICE, 2009) concluded that current evidence on the safety and efficacy of lateral interbody fusion in the lumbar spine is inadequate in quantity and quality. The assessment noted that a very limited number of clinical efficacy outcomes were reported.

The North American Spine Society (NASS) Operative Coding Committee (Mitchell, 2006) stated that XLIF should be reported using the same Current Procedural Terminology (CPT) codes as an anterior interbody fusion. In addition, NASS has concluded that lateral interbody fusion (XLIF or DLIF) should not be considered experimental or investigational (Baker, 2010). NASS has stated that, while additional clinical outcomes data would be helpful for any surgical procedure including lateral interbody fusion, these data are not needed to endorse continued use of these forms of interbody fusion. NASS explained that "if one were to consider [lateral interbody fusion] as experimental or investigational, than one would need to conclude that there is only one correct method of performing an anterior lumbar interbody fusion, that all surgeons access the spine through the exact same tissue planes, and that the disc and vertebral bodies are all accessed in the exact same orientation. Not only is this technically impossible, it is not verifiable" (Baker, 2010).

Minimally Invasive/Endoscopic Cervical Laminoforaminotomy

Choi et al (2007) performed a prospective analysis of the first 20 patients operated for cervical radiculopathy by a new modification of trans-corporeal anterior cervical foraminotomy technique. To evaluate early results of a functional disc surgery in which decompression for the cervical radiculopathy is done by drilling a hole in the upper vertebral body and most of the disc tissue is preserved. A total of 20 patients suffering from cervical radiculopathy not responding to conservative treatment were chosen for the new technique. Upper vertebral trans-corporeal foraminotomy was performed with the modified technique in all the patients. All the patients experienced immediate/early relief of symptoms. No complications of vertebral artery injury, Horner's syndrome or recurrent laryngeal nerve palsy were noted. Modified trans-corporeal anterior cervical microforaminotomy is an effective treatment for cervical radiculopathy. It avoids unnecessary violation of the disc space and much of the bony stabilizers of the cervical spine. The authors stated that short-term results of this technique are quite encouraging; longer-term analysis can help in outlining the true benefits of this technique.

Holly et al (2007) described the surgical indications, technique, and preliminary clinical outcomes in a series of patients who underwent the 2-level minimally invasive posterior cervical foraminotomy procedure. This report was composed of 21 consecutive patients with cervical radiculopathy who underwent a minimally invasive 2-level posterior cervical foraminotomy at the authors' institution between 2003 and 2005. Magnetic resonance imaging demonstrated foraminal or postero-lateral pathology at 2 ipsilateral adjacent spinal levels in each patient. Radicular arm pain was the most common presenting symptom, and was encountered in all 21 patients. The mean follow-up for the patients was 23 months (range of 12 to 36). Complete resolution of pre-operative symptoms was achieved in 19 out of 21 patients (90 %). Sixteen patients were discharged home the same day of surgery, and the mean estimated blood loss was 35 ml (range of 10 to 100 ml). There were no peri-operative complications. The authors concluded that minimally invasive 2-level posterior cervical foraminotomy can be safely performed on an outpatient basis with results comparable to that of conventional foraminotomy. This procedure should be considered as a potential alternative to 2-level anterior cervical discectomy and fusion or open foraminotomy in selected patients.

In an editorial on minimally invasive/endoscopic versus "open" posterior cervical laminoforaminotomy, Epstein (2009) stated that there is a need to address the complications of minimally invasive surgery in general, and minimally invasive/endoscopic laminoforaminotomy in particular to make it clear when minimally invasive is not only minimally effective, but also potentially "maximally" harmful.

Minimally Invasive Transforaminal Lumbar Interbody Fusion (MITLIF)

Minimally invasive transforaminal lumbar interbody fusion is performed through small incisions using specialized retractors that gradually open an operative corridor through the muscles rather than pulling the muscles aside as with conventional open surgery. Endoscopes are used to visualize the spine and TLIF is performed with specialized instruments through the retractors with less trauma to soft tissues, which may result in reduced operative time and hospitalization. The operation is carried out by means of fluoroscopic guidance.

Although operative time, blood loss and hospitalization were lower for MITLIF compared with more traditional procedures, there was little difference between MITLIF and open TLIF in the single study that compared them, except for lower blood loss and a higher number of complications in the MITLIF group. Overall, due to deficiencies in study design and the relatively small numbers of patients studied, the evidence is insufficient to demonstrate long-term safety and effectiveness of MITLIF, or to determine whether this technique is equivalent to open TLIF or more established surgeries such as anterior-posterior lumbar interbody fusion (APLIF) and posterior lumbar interbody fusion (PLIF). It is also unknown how the various techniques for MITLIF compare with one another.

Isaacs and associates (2005) retrospectively compared 20 patients receiving MITLIF with 24 patients receiving traditional PLIF. All patients had grade I or II spondylolisthesis or mechanical LBP and radiculopathy and had failed conservative therapy. Two interbody grafts were placed with bilateral pedicle screws using Medtronic instrumentation in the MITLIF group. One senior surgeon supervised all MITLIF operations, while 5 surgeons performed the PLIF operations. Mean operative time was 300 mins in MITLIF recipients versus 276 mins in PLIF recipients. For the MITLIF and PLIF groups, respectively, the mean estimated blood loss (EBL) was 226 and 1147 ml ($p < 0.001$); mean hospital length of stay (HLOS) was 3.4 versus 5.1 days ($p < 0.02$) and complications occurred in 1 versus 6 patients in these groups, respectively. The retrospective nature of this design limits the ability to draw firm conclusions regarding efficacy.

In a case-series study, Deutsch and Musacchio (2006) prospectively evaluated 20 patients with degenerative disc disease (DDD); all of whom had failed conservative therapy and who received MITLIF with unilateral pedicle screw placement. Mean operative time was 246 mins, mean EBL was 100 ml and mean HLOS was 2.5 days. At follow-up from 6 to 12 months, a good result (greater than 20 % decrease in ODI) was observed in 17/20 (85 %) patients with no improvement in 3 (15 %). Mean ODI decreased from 57 % to 25 %, VAS score decreased from 8.3 to 1.4 ($p < 0.005$) and 13/20 (65 %) patients displayed some degree of fusion at 6 months. Cerebrospinal fluid (CSF) leaks occurred in 2 patients, and 1 new post-operative radiculopathy was observed, which resulted in further surgery to re-adjust a pedicle screw.

Villavicencio et al (2006) retrospectively compared outcomes in 167 consecutive patients with DDD treated with MITLIF (n = 73), open TLIF (n = 51), or APLIF (n = 43). Patients who underwent MITLIF had fewer previous surgeries (18 %) compared with TLIF (39 %) or APLIF (49 %) recipients. The mean operative time for APLIF was 455 mins, for MITLIF 255 mins, and open TLIF 222 mins. The mean blood loss for APLIF was 550 ml, for minimally invasive TLIF 231 ml, and open TLIF 424 ml. The mean hospitalization time for APLIF was 7.2 days, for MITLIF 3.1 days, and open TLIF 4.1 days. The total rate of complications was 76.7 % for APLIF, including 62.8 % major and 13.9 % minor complications. The MITLIF patients group had the total 30.1 % rate of complications, 21.9 % of which were minor and 8.2 % major complications. There were no major complications in the open TLIF patients group, with 35.3 % minor complications. The authors concluded that APLIF is associated with a more than 2 times higher complication rate, significantly increased blood loss, and longer operative and hospitalization times than both percutaneous and open TLIF for lumbar disc degeneration and instability. This study was limited by its retrospective design.

In a retrospective study, Scheufler and co-workers (2007) reported technique, clinical outcomes, and fusion

rates of percutaneous transforaminal lumbar interbody fixation (pTLIF). Results were compared with those of mini-open transforaminal lumbar interbody fixation (oTLIF) using a muscle splitting (Wiltse) approach. Percutaneous transforaminal lumbar interbody fixation was performed in 43 patients with single-level and 10 patients with bi- or multi-level lumbar discopathy or degenerative pseudolisthesis resulting in axial back pain and claudication, pseudo-radicular, or radicular symptoms. Post-operative pain was significantly lower after pTLIF after the second post-operative day ($p < 0.01$). The overall clinical outcome was not different from oTLIF at 8 and 16 months. The authors concluded that pTLIF allows for safe and efficient minimally invasive treatment of single and multi-level degenerative lumbar instability with good clinical results. They stated that further prospective studies investigating long-term functional results are needed to evaluate the definitive merits of percutaneous instrumentation of the lumbar spine.

Park and Foley (2008) discussed their retrospective review study results in 40 patients who underwent MITLIF for symptomatic spondylolisthesis utilizing this approach. Thirty cases involved a degenerative spondylolisthesis while the remaining 10 were isthmic. The minimum follow-up was 24 months with a mean of 35 months. The authors concluded that MITLIF for symptomatic spondylolisthesis appears to be an effective surgical option with results that compare favorably to open procedures. However, the findings of this study are limited by study design, small patient numbers and the lack of a control group.

TruFuse Facet Fusion

TruFuse facet fusion (miniSURG Corp., Clearwater, FL) is a minimally invasive back procedure that uses specially designed bone dowels made from allograft material (donated cortical bone) that are inserted into the facet joints. The procedure is designed to stop facet joints from moving and is intended to eliminate or reduce back pain caused by facet joint dysfunction. There are no published studies of the effectiveness of the TruFuse product in the peer reviewed published literature. A systematic evidence review of TruFuse by the American Association of Neurological Surgeons (AANS) concluded, "[t]here is insufficient objective information to evaluate the safety and utility of this device or to make recommendations regarding clinical usage".

Nu-Fix

Nu-Fix (Nutech Medical, Birmingham, AL) is a cortical screw that is used for facet arthrosis with spine pain, Nu-Fix was cleared by the FDA based upon a 510(k) premarket notification. This allograft interference screw is percutaneuosly or through stab incision, inserted into the facet joint (cervical, thoracic, or lumbar) to stiffen the joint and promote fusion.

A technical assessment of Nufix prepared by the American Association of Neurological Surgeons (2009) reached the following conclusions about the Nufix: "Nu-Fix is FDA approved as a threaded bone dowel for minimally invasive facet fusion. Marketing has been primarily aimed at non-surgeons in out patient pain clinic settings. There is no published data to assess safety, efficacy, or outcomes. There is no relevant biomechanical data available to use as a comparison to currently performed spinal fusion procedures. Manufacturer sponsored literature is very limited in number, scope and follow-up. In conclusion there is insufficient objective information to evaluate the safety and utility of this device or to make recommendations regarding clinical usage".

Epidural Fat Graft during Lumbar Decompression Laminectomy/Discectomy

Epidural fat grafts have been used to prevent epidural and perineural fibroses. In a case series study, Martin-Ferrer (1989) reported failure of autologous fat grafts to prevent post-operative epidural fibrosis in surgery of the lumbar spine in 3 patients. Hypertrophic epidural scarring occurred in these 3 cases despite the presence of autologous fat grafts. Histopathological examination of the fat removed from 2 patients who were operated on

a second time showed a fibrotic infiltration into the fat graft. One randomized study (Mackay et al, 1995) found no reduction in fibrosis with use of epidural fat graft in lumbar laminectomy and discectomy. A non-randomized comparative study (Gorgulu et al, 2004) found no improvement in long-term outcomes with use of epidural fat grafts in lumbar disc surgery. Moreover, there were reports of cauda equina syndrome following hemi-ilaminectomy and discectomy for lumbar disc herniation. Computed tomography-scan revealed the migration of the free fat graft used for preventing peridural scar formation; and removal of the graft resulted in patients' recovery (Urvoy et al, 1990; Imran and Halim, 2005).

Interlaminar Lumbar Instrumented Fusion (ILIF)

Interlaminar lumbar instrumented fusion (ILIF) combines direct neural decompression with an allograft inter-spinous spacer to maintain the segmental distraction and a spinous process fixation plate to maintain stability for eventual segmental fusion. Nuvasive, Inc. (San Diego, CA) is conducting a clinical trial to evaluate ILIF in patients with single-level degenerative disc disease (DDD) of the lumbar spine. The estimated completion date is July 2012. (Available at: http://clinicaltrials.gov/ct2/show/NCT01019057.)

Sharma et al (2011) evaluated the radiographical change in the coronal and sagittal plane alignment of the lumbar spine after the lateral lumbar interbody fusion (LLIF) approach using XLIF cages (Nuvasive, Inc.). Radiographical and clinical outcomes, and complications associated with the approach were also described. A retrospective review of 43 consecutive patients' pre-operative, immediate post-operative, and 1-year follow-up radiographs was done. All patients had LLIF procedure performed for lumbar DDD, spondylolisthesis, or de novo scoliosis. The radiographical measurements were taken to assess change in the sagittal and coronal plane alignment of the individual instrumented disc level, overall lumbar spine, and lumbar scoliotic curves. The radiographs were also analyzed for fusion at 1 year, end-plate fracture, and other complications. Patients' hospital and clinic charts were reviewed to identify the complications and patient outcomes. There was a mean correction of 3.7 degrees ($p \leq 0.001$) at each instrumented disc level in coronal plane in 87 instrumented levels. Similarly, there was a mean gain of 2.8 degrees ($p \leq 0.001$) of lordosis at each level. In 25 patients with lumbar scoliosis (greater than 10 degrees), mean scoliosis angle correction was 10.4 degrees ($p = 0.001$, 43 %). There was no significant change in the overall coronal or sagittal plane alignment of the lumbar spine. The most common post-operative complication (25 %) was anterior thigh pain, which was transitory in the majority of cases. End-plate breach was common at the instrumented disc levels; however, it was non-progressive in most of the cases, and did not affect the fusion or alignment at the instrumented levels. The outcome scores were improved significantly at the final follow-up. The authors concluded that the LLIF approach is effective in correcting the coronal plane deformity and in gaining lordosis at individual instrumented levels. They parallelized adjacent end plates to correct the lumbar scoliotic curves. The complications are mostly approach-related and transitory. The authors stated that a larger cohort with long-term follow-up is needed to establish the advantages and shortcomings of the procedure.

Khan Kinetic Treatment (KKT)

The Khan Kinetic Treatment, manufactured by Datrend Systems Inc (Richmond, British Columbia, Canada), is a medical device for the treatment of spine-related abnormalities causing pain. According to the manufacturer, the KKT uses high-frequency small-amplitude sinusoidal waves to vibrate the vertebrae and repeatedly activate associated neuromuscular structures, which evoke multiple mechanisms of pain relief. In a small, unblinded, randomized trial without placebo control, Desmoulin et al (2007) presented their initial findings on the use of KKT as a chronic neck pain treatment. They reported that, compared with a control group, the treatment group lowered both their self-recorded neck pain scores ($p = 0.012$) as well as pain medication dose ($p = 0.048$), although current functional assessment questionnaires (range of motion, overall activity, and recreation/work activities) did not detect changes ($p = 0.233$, 0.311, and 0.472, respectively). Limitations of this study included a lack of blinding and lack of placebo control. The authors concluded that although they await randomized,

placebo-controlled trials and additional results from ongoing mechanistic studies, initial results show that KKT is potentially an effective treatment for chronic neck pain and may contribute to the reduction of pain relieving. Other published literature on KKT spine treatment consists of a study of the effect of KKT in an animal model (Desmoulin et al, 2010).

The OptiMesh Grafting System

OptiMesh is a conformable, porous, polymeric containment device that is inserted into the evacuated disc space and filled with a mixture of cortico-cancellous allograft with demineralized bone matrix, autograft, and bone marrow aspirate to aid traumatic fracture repair and interbody fusion. Evidence is limited to a single case study that utilized OptiMesh for a compression fracture. Long-term safety and effectiveness have not been established. OptiMesh received 510(k) approval in November, 2003 as a class II device. The device is intended to maintain bone graft material within a vertebral defect. This device is contraindicated for patients with instability and does not provide structural support. The safety and effectiveness of OptiMesh used for fusion of the interbody space has not been established. Further studies are needed to evaluate its safety and effectiveness.

Inamasu et al (2008) reported a patient with a flexion-distraction injury of the L1 vertebra treated with a combination of short-segment posterior fixation and Optimesh (Spineology Inc., St. Paul, MN), a flexible balloon-shaped mesh that is deployed into the fractured vertebra together with allograft. The patient, a 47-year-old man, was admitted after sustaining a motor vehicle accident. Imaging studies showed an L1 compression fracture. The patient had no neurological deficits and was treated conservatively. However, intense back pain persisted and significant kyphosis was noted when he mobilized. Review of the imaging studies strongly suggested disruption of the posterior spinal ligaments. Surgical intervention was performed to address both restoration of the posterior tension band and anterior column height simultaneously. The combined procedure consisted of short-segment posterior fixation from T12 to L2, and placement of OptiMesh filled with allograft into the L1 vertebral body. The anterior column height was restored and spinal alignment was corrected by the procedure, and the patient's back pain subsided soon after the procedure. The role of minimally invasive procedures for reconstruction of the vertebral column height, including the OptiMesh system, in patients with thoracolumbar compression fracture seems promising. However, the long-term effectiveness of these new techniques is unknown. It also remains to be seen how the delivery of allograft into the fractured vertebra via OptiMesh affects remodeling, and whether the restored vertebral height is maintained.

Radiofrequency/Pulsed Radiofrequency Ablation of Trigger Point Pain

Tamimi et al (2009) noted that clinical reports using pulsed radiofrequency (PRF) have shown promise in the treatment of a variety of focal, neuropathic conditions. To date, scant data exist on the use of PRF to treat myofascial and neuromatous pain. All cases in which PRF was used to treat myofascial (trigger point) and neuromatous pain within the authors' practice were evaluated retrospectively for technique, efficacy, and complications. Trigger points were defined as localized, extremely tender areas in skeletal muscle that contained palpable, taut bands of muscle. A total of 9 patients were treated over an 18-month period. All patients had longstanding myofascial or neuromatous pain that was refractory to previous medical management, physical therapy, and trigger point injections. Eight out of 9 patients experienced 75 to 100 % reduction in their pain following PRF treatment at initial evaluation 4 weeks following treatment. Six out of 9 (67 %) patients experienced 6 months to greater than 1 year of pain relief. One patient experienced no better relief in terms of degree of pain reduction or duration of benefit when compared with previous trigger point injections. No complications were noted. The authors concluded that this review suggested that PRF could be a minimally invasive, less neurodestructive treatment modality for these painful conditions and that further systematic evaluation of this treatment approach is warranted.

Lee et al (2011) noted that recently, clinical reports using PRF have shown favorable effects in the treatment of

a variety of focal pain areas, even in non-nervous tissues; however, the mechanism of effect underlying this treatment to non-nervous tissue remains unclear. These researchers reported the case of a 67-year old male who presented with pain reliving point in the posterior neck. The patient had pain in the posterior neck for 3 years. The pain subsided with pressure applied to a point in the posterior neck. There were no specific abnormal findings on laboratory testing and radiological examinations. After PRF treatment to the pain-relieving point, he had pain relief that lasted more than 5 months.

The CoFlex-F Implant

The Coflex-F implant is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1 to S1) that can be delivered through a minimally invasive approach. The implant is a type of posterior fixation instrumentation intended to rigidly hold vertebrae together while spinal fusion occurs. It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients suffering from DDD, with or without attendant grade I spondylolisthesis. On October 6, 2010, the Coflex-F implant was cleared by the FDA via the 501(k) process for the purpose of achieving stabilization to facilitate fusion in patients treated for DDD (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); with up to grade 1 spondylolisthesis. However, the Belgian Health Care Knowledge Center (2011) stated that that it is unclear what data for the Coflex-F was submitted for FDA clearance.

An UpToDate review on "Lumbar spinal stenosis: Treatment and prognosis" (Levin, 2012) states that "Intraspinous spacer implantation -- A potentially less invasive treatment option involves implanting a device between the spinous processes at one or two vertebral levels, relieving compression. This procedure is said to be appropriate for those patients with spinal stenosis without spondylolisthesis who have intermittent claudication symptoms that are exacerbated in extension and relieved in flexion .... It is unclear how this newer procedure compares with the standard surgical procedure, decompressive laminectomy, in terms of effectiveness, side effects, recovery time and long-term outcomes. This treatment does not appear to be helpful in patients who have spondylolisthesis".

Coccygectomy

Patel et al (2008) stated that coccydynia is a term that refers to pain in the region of the coccyx. Most cases are associated with abnormal mobility of the coccyx which may trigger a chronic inflammatory process leading to degeneration of this structure. In some patients this instability may be detected on dynamic radiographs. Non-surgical management remains the gold standard treatment for coccydynia, consisting of decreased sitting, seat cushioning, coccygeal massage, stretching, manipulation, local injection of steroids or anesthetics, and postural adjustments. Those patients who fail these conservative modalities may potentially benefit from coccygectomy. However, surgical intervention is typically reserved for patients with evidence of advanced coccygeal instability (e.g., subluxation or hypermobility) or spicule formation, as this population appears to exhibit the greatest improvement post-operatively.

Trollegaard et al (2010) reported that between 1993 and 2008, a total of 41 patients underwent total coccygectomy for coccydynia which had failed to respond to 6 months of conservative management. Of these, 40 patients were available for clinical review and 39 completed a questionnaire giving their evaluation of the effect of the operation. Excellent or good results were obtained in 33 of the 41 patients, comprising 18 of the 21 patients with coccydynia due to trauma, 5 of the 8 patients with symptoms following childbirth and 10 of 12 with idiopathic onset. In 8 patients the results were moderate or poor, although none described worse pain after the operation. The only post-operative complication was superficial wound infection, which occurred in 5 patients and which settled fully with antibiotic treatment. One patient required re-operation for excision of the distal cornua of the sacrum. The authors concluded that total coccygectomy offered satisfactory relief of pain in

the majority of patients regardless of the cause of their symptoms.

The Work Loss Data Institute's clinical practice guideline on "Low back - lumbar & thoracic (acute & chronic)" (2011) recommended the use of coccygectomy. Furthermore, an UpToDate review on "Coccydynia (coccygodynia)" (Fletcher, 2012) suggests that coccygectomy be performed only as a last resort for intractable cases.

BacFast HD

According to the manufacturer, BacFast HD (Hyper-Demineralized) is a demineralization technology used to expose the collagen surface. With the use of HD technology and increased collagen surface area, BacFast HD also provides the graft with osteo-inductive properties without compromising the structural integrity of the graft. These characteristics, coupled with an osteo-conductive design through increased surface contact and locking edges to prevent migration, BacFast HD is engineered with a focus on fusion as well as facet stabilization. Benefits of the facet stabilization procedure using BacFast HD are thought to include (i) osteo-inductive surface for enhanced fusion, (ii) stabilization of the spine, and (iii) reduction of pain, blood loss, and tissue/bone destruction.

Oxygen-Ozone Therapy (Injection)

Kallewaard and colleagues (2010) stated that an estimated 40 % of chronic lumbosacral spinal pain is attributed to the discus intervertebralis. Degenerative changes following loss of hydration of the nucleus pulposus lead to circumferential or radial tears within the annulus fibrosus. Annular tears within the outer annulus stimulate the ingrowth of blood vessels and accompanying nociceptors into the outer and occasionally inner annulus. Sensitization of these nociceptors by various inflammatory repair mechanisms may lead to chronic discogenic pain. The current criterion standard for diagnosing discogenic pain is pressure-controlled provocative discography using strict criteria and at least 1 negative control level. The strictness of criteria and the adherence to technical detail will allow an acceptable low false-positive response rate. The most important determinants are the standardization of pressure stimulus by using a validated pressure monitoring device and avoiding overly high dynamic pressures by the slow injection rate of 0.05 mL/s. A positive discogram requires the reproduction of the patient's typical pain at an intensity of greater than 6/10 at a pressure of less than 15 psi above opening pressure and at a volume less than 3.0 ml. Perhaps the most important and defendable response is the failure to confirm the discus is symptomatic by not meeting this strict criteria. Various interventional treatment strategies for chronic discogenic LBP unresponsive to conservative care include reduction of inflammation, ablation of intradiscal nociceptors, lowering intra-nuclear pressure, removal of herniated nucleus, and radiofrequency ablation of the nociceptors. Unfortunately, most of these strategies do not meet the minimal criteria for a positive treatment advice. In particular, single-needle radiofrequency thermo-coagulation of the discus is not recommended for patients with discogenic pain (2 B-). Interestingly, a little used procedure, radiofrequency ablation of the ramus communicans, does meet the (2 B+) level for endorsement. The authors concluded that there is currently insufficient proof to recommend intradiscal electrothermal therapy (2 B±) and intradiscal biacuplasty (0). It is advised that ozone discolysis, nucleoplasty, and targeted disc decompression should only be performed as part of a study protocol; future studies should include more strict inclusion criteria.

In a systematic review and meta-analysis of RCTs, Magalhaes et al (2012) evaluated the therapeutic results of percutaneous injection of ozone for LBP secondary to disc herniation. A comprehensive literature search was conducted using all electronic databases from 1966 through September 2011. The quality of individual articles was assessed based on the modified Cochrane review criteria for randomized trials and criteria from the Agency for Healthcare Research and Quality. The outcome measure was short-term pain relief of at least 6 months or long-term pain relief of more than 6 months. A total of 8 observational studies were included in the systematic review and 4 randomized trials in the meta-analysis. The indicated level of evidence for long-term pain relief

was II-3 for ozone therapy applied intradiscally and II-1 for ozone therapy applied paravertebrally. The grading of recommendation was 1C for intradiscal ozone therapy and 1B for paravertebral ozone therapy. The authors concluded that ozone therapy appears to yield positive results and low morbidity rates when applied percutaneously for the treatment of chronic LBP. The main drawbacks of this review were the lack of precise diagnosis and the frequent use of mixed therapeutic agents. The meta-analysis included mainly active-control trials. No placebo-controlled trial was found.

The Work Loss Data Institute's clinical guideline on "Low back - lumbar & thoracic (acute & chronic)" (2011) listed oxygen-ozone therapy (injection) as interventions/procedures that are under study and are not specifically recommended.

Minimally Invasive Sacroiliac Joint Fusion

Sacroiliac joint (SIJ) fusion has been suggested as a possible treatment option for individuals with low back pain due to sacroiliac joint dysfunction or syndrome. This procedure may be performed by an open surgical approach or as a minimally invasive procedure in order to place plates and/or screws to develop a bony fusion across the SIJ for stabilization. The iFUSE Implant System consists of small titanium implants placed across the sacroiliac joint to stabilize and fuse it via a minimally invasive (percutaneous) approach with use of fluoroscopy to visualize proper placement of the implants. Other minimally invasive systems for SIJ fusion include the SIJFuse Sacroiliac Joint Fusion Device System, Silex Sacroiliac Joint System and SImmetry Sacroiliac Joint Fusion System.

In a consecutive case-series study, Buchowski et al (2005) described the outcome of sacro-iliac joint (SIJ) arthrodesis for SIJ disorders, with the hypothesis that SI arthrodesis leads to improved post-operative function. The patient population consisted of 20 patients undergoing SIJ arthrodesis between December 1994 and December 2001. Patients undergoing concomitant procedures at the time of SIJ arthrodesis were excluded. The 3 men and 17 women in the study group had an average age of 45.1 years (range of 21.8 to 66.4 years), a mean duration of symptoms of 2.6 years (range of 0.5 to 8.0 years), and a mean follow-up period of 5.8 years (range of 2.0 to 9.0 years). Outcome measures included general health and function, clinical evaluation, and radiographic assessment. For all 20 patients, non-operative treatment had failed, and for all, the diagnosis was confirmed by pain relief with intra-articular SIJ injections under fluoroscopic guidance. Sacroiliac joint arthrodesis (via a modified Smith-Petersen technique) was recommended only when a positive response to the injection was noted, and patients had recurrence of symptoms after the initial positive response. Pre-operative and post-operative general health and function were assessed via the 36-item Short-Form (SF-36) Health Survey and American Academy of Orthopaedic Surgeons (AAOS) Modems Instrument, which were collected prospectively. Medical records and plain radiographs were reviewed retrospectively to determine the clinical and radiographic outcome. Multiple etiologies of sacroiliac symptoms were observed: SIJ dysfunction (13 patients), osteoarthritis (5 patients), and spondyloarthropathy and SIJ instability (1 each). Seventeen patients (85 %) had solid fusion. Fifteen patients (75 %) completed pre-operative and post-operative SF-36 forms. Significant ($p < or = 0.05$) improvement occurred in the following categories: physical functioning, role physical, bodily pain, vitality, social functioning, role emotional, as well as neurogenic and pain indices. Improvement (not statistically significant) was also noted in general and mental health. The authors concluded that for carefully selected patients, SI arthrodesis appears to be a safe, well-tolerated, and successful procedure, leading to significant improvement in functional outcome and a high fusion rate. Limitations of this study were: (i) the 85 % fusion rate may be an over-estimation because more precise methods (such as a CT scan) were not used to confirm successful arthrodesis, (ii) small number of patients ($n = 20$), and (iii) only 75 % of patients were available for follow-up.

Wise and Dall (2008) compared efficacy and outcomes of a new technique for SI arthrodesis. This study described the radiographic and clinical outcomes of this procedure. A total of 13 consecutive patients

underwent minimally invasive SI arthrodesis between February and December 2004 at a single teaching hospital and were prospectively followed. Six patients had bilateral fusions for a total of 19 joints. The average age was 53.1 (range of 45 to 62). Average body mass index was 31.2 (range of 21.9 to 46.9). Mean follow-up was 29.5 months (range of 24 to 35). Diagnosis was confirmed using fluoroscopically guided intra-articular injections of local anesthetic and corticosteroid when their pain was relieved 2 or more hours. Arthrodesis was only performed on patients with positive injections who subsequently had their symptoms recur. Outcome measurements included radiographic assessment for fusion and improvement in VAS for LBP, leg pain, and dyspareunia. Computed tomography scan to evaluate implant placement was performed post-operatively and again at 6 months to assess fusion. The overall fusion rate was 89 % (17/19 joints). Significant improvements were seen in final LBP score on a VAS (0 to 10) (average improvement 4.9, p < or = 0.001). Leg pain improved an average of 2.4 (p = 0.013). Dyspareunia improved an average of 2.6 (p = 0.0028). One patient was revised to an open arthrodesis secondary to nonunion and persistent pain. There were no infections or neurovascular complications. The authors concluded that minimally invasive SI arthrodesis via a percutaneous posterior approach is a safe and efficacious procedure, leading to a high fusion rate and significant improvement in LBP, leg pain, and dyspareunia. Limitations of this study were its small sample size and the lack of a control group.

In a consecutive case-series study, Al-Khayer (2008) reported a new percutaneous SIJ arthrodesis technique utilizing a Hollow Modular Anchorage screw. Pre-operative and post-operative Oswestry Disability Index (ODI), VAS for pain, and post-operative subjective patients' satisfaction were assessed for all patients. Minimum 2 years follow-up was documented. A total of 9 patients underwent SIJ arthrodesis with the new technique. The mean ODI value dropped from 59 (range of 34 to 70) pre-operatively to 45 (range of 28 to 60) post-operatively (p < or = 0.005). The mean VAS value dropped from 8.1 (range of 7 to 9) pre-operatively to 4.6 (range of 3 to 7) post-operatively (p < or = 0.002). The mean patients' satisfaction was 6.8 (range of 5 to 8). The authors concluded that the new technique may offer a safe and effective treatment for intractable SIJ pain. Limitations of this study were its small sample size, lack of a control group, and despite the encouraging radiographic findings, the exact fusion status of SIJ arthrodesis cannot be determined by plain radiographs.

Khurana et al (2009) examined the effects of percutaneous fusion of the SIJ with hollow modular anchorage screws. These investigators reviewed 15 consecutive patients, 11 women and 4 men, with a mean age of 48.7 years (37.3 to 62.6), who between July 2004 and August 2007 had undergone percutaneous SI fusion using hollow modular anchorage screws filled with demineralized bone matrix. Each patient was carefully assessed to exclude other conditions and underwent pre-operative CT and MR scans. The diagnosis of symptomatic SI disease was confirmed by an injection of local anesthetic and steroid under image intensifier control. The short form-36 questionnaire and Majeed's scoring system were used for pre- and post-operative functional evaluation. Post-operative radiological evaluation was performed using plain radiographs. Intra-operative blood loss was minimal and there were no post-operative clinical or radiological complications. The mean follow-up was for 17 months (9 to 39). The mean short form-36 scores improved from 37 (23 to 51) to 80 (67 to 92) for physical function and from 53 (34 to 73) to 86 (70 to 98) for general health (p = 0.037). The mean Majeed's score improved from 37 (18 to 54) pre-operatively to 79 (63 to 96) post-operatively (p = 0.014). There were 13 good to excellent results. The remaining 2 patients improved in short form-36 from a mean of 29 (26 to 35) to 48 (44 to 52). Their persistent pain was probably due to concurrent lumbar pathology. The authors concluded that percutaneous hollow modular anchorage screws are a satisfactory method of achieving SI fusion.

In a retrospective study, Rudolf (2012) evaluated the safety and effectiveness of minimally invasive SIJ fusion using a series of triangular, porous plasma spray coated titanium implants. A total of 50 consecutive patients were treated by a single orthopedic spine surgeon in private practice. Medical charts were reviewed for peri-operative metrics, complications, pain, quality of life and satisfaction with surgery. All patients were contacted at a 24 months post-op to assess SIJ pain, satisfaction with surgery and work status. An early and sustained

statistically significant improvement in pain function was identified at all post-operative time points (ANOVA, $p < 0.000$). A clinically significant improvement (greater than 2 point change from baseline) was observed in 7 out of 9 domains of daily living. The complication rate was low and more than 80 % of patients would have the same surgery again. The authors concluded that minimally invasive SIJ fusion appears to be a safe and effective procedure for the treatment of SIJ disruption or degenerative sacroiliitis. The drawbacks of this study included its retrospective design, small sample size, a single surgeon's experience, a non-standard outcomes measure, and the lack of a comparator group. Moreover, the author noted that prospective studies are currently underway to further evaluate this technology.

In a retrospective study, Sachs and Capobianco (2012) evaluated the safety and effectiveness of minimally invasive SIJ arthrodesis via an ileo-sacral approach in patients who were refractory to conservative care. These investigators reported on the first 11 consecutive patients treated with a novel minimally invasive SIJ fusion system by a single surgeon. Medical charts were reviewed for peri-operative metrics and baseline pain scores recorded using a 0 to 10 numerical rating scale. Ninety one percent (91 %) of patients were female and the average patient age was 65 years (range of 45 to 82). Mean baseline pain score (SD) was 7.9 (+/- 2.2). Mean pain score at the 12 month follow-up interval was 2.3 (+/- 3.1), resulting in an average improvement of 6.2 points from baseline, representing a clinically and statistically significant ($p = 0.000$) improvement. Patient satisfaction was very high with 100 % indicating that they would have the same surgery again for the same result. The authors concluded that the findings of this small case series illustrated the safety and effectiveness of minimally invasive SIJ fusion using a series of triangular porous plasma coated titanium implants in carefully selected patients. Moreover, they stated that larger multi-centered studies are needed.

The Work Loss Data Institute's clinical guideline on "Low back - lumbar & thoracic (acute & chronic)" (2011) does not mention sacroiliac joint fusion as a therapeutic option. In fact, the Work Loss Data Institute's clinical guideline on "Hip & pelvis (acute & chronic)" (2011) listed sacroiliac joint fusion as one of the interventions/procedures were considered, but are not recommended. In a systemic review on "The therapeutic effectiveness of sacroiliac joint interventions" (Hansen et al, 2012), sacroiliac joint fusion is not mentioned as a therapeutic option. Furthermore, American College of Occupational and Environmental Medicine's clinical guideline on "Low back disorders" (ACOEM, 2011) did not recommend sacroiliac joint fusion for any low back pain conditions because of insufficient evidence.

In a retrospective study, Sachs and Capobianco (2013) reported on the safety and effectiveness of MIS SIJ arthrodesis using a series of triangular, porous plasma coated implants in patients who were refractory to conservative care. These investigators reported on the first 40 consecutive patients with 1-year follow-up data that underwent MIS SIJ fusion with the iFUSE Implant System (SI-BONE, Inc., San Jose, CA) by a single surgeon. Medical charts were reviewed for demographics, peri-operative metrics, complications, pain scores, and satisfaction. Mean age was 58 years (range of 30 to 81) and 75 % of patients were female. Post-operative complications were minimal and included transient trochanteric bursitis (5 %), facet joint pain (20 %), and new LBP (2.5 %). There were no re-operations at 1 year. Mean pain score improved from 8.7 (1.5 SD) at baseline to 0.9 (1.6) at 12 months, a 7.8-point improvement ($p < 0.001$). Patient satisfaction was very high. The authors concluded that the results of this case series reveal that MIS SIJ fusion using the iFUSE Implant System is a safe and effective treatment option in carefully selected patients. This was an extension of the 2012 study by these investigators. The findings of this small study are promising. Moreover, the authors stated that "additional prospective controlled trials are underway".

Miller et al (2013) stated that MIS SIJ arthrodesis was developed to minimize the risk of iatrogenic injury and to improve patient outcomes compared with open surgery. Between April 2009 and January 2013, a total of 5,319 patients were treated with the iFUSE SI Joint Fusion System® for conditions including SIJ disruption and degenerative sacroiliitis. A database was prospectively developed to record all complaints reported to the

manufacturer in patients treated with the iFUSE device. Complaints were collected through spontaneous reporting mechanisms in support of ongoing mandatory post-market surveillance efforts. Complaints were reported in 204 (3.8 %) patients treated with the iFUSE system. Pain was the most commonly reported clinical complaint (n = 119, 2.2 %), with nerve impingement (n = 48, 0.9 %) and recurrent SIJ pain (n = 43, 0.8 %) most frequently cited. All other clinical complaints were rare (less than or equal to 0.2 %). Ninety-six revision surgeries were performed in 94 (1.8 %) patients at a median follow-up of 4 (range of 0 to 30) months. Revisions were typically performed in the early post-operative period for treatment of a symptomatic mal-positioned implant (n = 46, 0.9 %) or to correct an improperly sized implant in an asymptomatic patient (n = 10, 0.2 %). Revisions in the late post-operative period were performed to treat symptom recurrence (n = 34, 0.6 %) or for continued pain of undetermined etiology (n = 6, 0.1 %). The authors concluded that analysis of a post-market product complaints database demonstrated an overall low-risk of complaints with the iFUSE SIJ Fusion System in patients with degenerative sacroiliitis or SIJ disruption. The authors noted that the initial results are promising; however, clinical effectiveness outcomes were not assessed in this study.

Noting that there is minimal literature published on percutaneous fixation of the sacroiliac joint, Kim, et al. (2014) reported on a retrospective review of 31 patients operated on by a single surgeon. The investigators reported that 27 patients expressed satisfaction, 4 patients did not. Pain relief was noted to be Complete (16 patients), Excellent (5 patients), Good (9 patients), and Fair (1 patients). Four patients had postoperative complications. These were infected hematoma (2), L5 nerve root irritation (1), and L5-S1 discitis (1). One patient required revision. On 6 month postop CT scan, 18/19 patients had radiographic evidence of bone ingrowth and bone into or across the SI joint was evident in 8/19 patients. Lucency was noted around at least one implant in 5/19 patients.

In an editorial regarding “Stabilization of the sacroiliac joint”, Shaffrey and Smith (2013) stated that “There are numerous unanswered questions regarding patient selection for SIJ fusion or stabilization. There are an increasing number of surgical techniques for treating SIJ pathology and it is not clear which method may provide the best outcomes. Without prospective trials with non-conflicted surgeons and standardized selection criteria, the true role for SIJ fusion procedures in the management of chronic lower back pain will remain murky. The consequences of the unsupported enthusiasm for the surgical management of discogenic back pain still negatively impacts the public perception of spinal surgeons. Much more high quality information is needed regarding the surgical management of SIJ pathology before widespread use of this technique should be adopted”.

Whang and colleagues (2015) noted that sacroiliac (SI) joint pain is a prevalent, under-diagnosed cause of lower back pain. SI joint fusion can relieve pain and improve quality of life in patients who have failed non-operative care. To-date, no study has concurrently compared surgical and non-surgical treatments for chronic SI joint dysfunction. These researchers conducted a prospective randomized controlled trial of 148 subjects with SI joint dysfunction due to degenerative sacroiliitis or sacroiliac joint disruptions who were assigned to either minimally invasive SI joint fusion with triangular titanium implants (n = 102) or non-surgical management (NSM, n = 46). SI joint pain scores, Oswestry Disability Index (ODI), Short-Form 36 (SF-36) and EuroQol-5D (EQ-5D) were collected at baseline and at 1, 3 and 6 months after treatment commencement. Six-month success rates, defined as the proportion of treated subjects with a 20-mm improvement in SI joint pain in the absence of severe device-related or neurologic SI joint-related adverse events or surgical revision, were compared using Bayesian methods. Subjects (mean age of 51, 70 % women) were highly debilitated at baseline (mean SI joint VAS pain score 82, mean ODI score 62). Six-month follow-up was obtained in 97.3 %. By 6 months, success rates were 81.4 % in the surgical group versus 23.9 % in the NSM group (difference of 56.6 %, 95 % posterior credible interval 41.4 to 70.0 %, posterior probability of superiority > 0.999). Clinically important (greater than or equal to 15 point) ODI improvement at 6 months occurred in 75 % of surgery subjects versus 27.3 % of NSM subjects. At 6 months, quality of life improved more in the surgery group and

satisfaction rates were high. The mean number of adverse events in the first 6 months was slightly higher in the surgical group compared to the non-surgical group (1.3 versus 1.0 events per subject, p = 0.1857). The authors concluded that the 6-month follow-up from this level 1 study showed that minimally invasive SI joint fusion using triangular titanium implants was more effective than non-surgical management in relieving pain, improving function and improving quality of life in patients with SI joint dysfunction due to degenerative sacroiliitis or SI joint disruptions. This was a study with short-term follow-up (6 months); well-designed studies with long-term follow-up are needed to ascertain the clinical effectiveness of SI fusion.

Soriano-Baron et al (2015) stated that minimally invasive placement of SIJ fusion implants is a potential treatment for SIJ disruptions and degenerative sacroiliitis. Biomechanical studies of screw fixation within the sacrum have shown that placement and trajectory are important in the overall stability of the implant. Although clinical results have been promising, there is the possibility that a more optimal arrangement of implants may exist.

Zaidi et al (2015) stated that the SI joint (SIJ) and surgical intervention for treating SIJ pain or dysfunction has been a topic of much debate in recent years. There has been a resurgence in the implication of this joint as the pain generator for many patients experiencing low-back pain, and new surgical methods are gaining popularity within both the orthopedic and neurosurgical fields. There is no universally accepted gold standard for diagnosing or surgically treating SIJ pain. The authors systematically reviewed studies on SIJ fusion in the neurosurgical and orthopedic literature to investigate whether sufficient evidence exists to support its use. A literature search was performed using MEDLINE, Google Scholar, and OvidSP-Wolters Kluwer Health for all articles regarding SIJ fusion published from 2000 to 2014. Original, peer-reviewed, prospective or retrospective scientific papers with at least 2 patients were included in the study. Exclusion criteria included follow-up shorter than 1-year, non-surgical treatment, inadequate clinical data as determined by 2 independent reviewers, non-English manuscripts, and nonhuman subjects. A total of 16 peer-reviewed journal articles met the inclusion criteria: 5 consecutive case series, 8 retrospective studies, and 3 prospective cohort studies. A total of 430 patients were included, of whom 131 underwent open surgery and 299 underwent minimally invasive surgery (MIS) for SIJ fusion. The mean duration of follow-up was 60 months for open surgery and 21 months for MIS. SIJ degeneration/arthrosis was the most common pathology among patients undergoing surgical intervention (present in 257 patients [59.8 %]), followed by SIJ dysfunction (79 [18.4 %]), postpartum instability (31 [7.2 %]), post-traumatic (28 [6.5 %]), idiopathic (25 [5.8 %]), pathological fractures (6 [1.4 %]), and HLA-B27+/rheumatoid arthritis (4 [0.9 %]). Radiographically confirmed fusion rates were 20 % to 90 % for open surgery and 13 % to 100 % for MIS. Rates of excellent satisfaction, determined by pain reduction, function, and quality of life, ranged from 18 % to 100 % with a mean of 54 % in open surgical cases. For MIS patients, excellent outcome, judged by patients' stated satisfaction with the surgery, ranged from 56 % to 100 % (mean of 84 %). The re-operation rate after open surgery ranged from 0 % to 65 % (mean of 15 %). Re-operation rate after MIS ranged from 0 % to 17 % (mean of 6 %). Major complication rates ranged from 5 % to 20 %, with 1 study that addressed safety reporting a 56 % adverse event rate. The authors concluded that surgical intervention for SIJ pain is beneficial in a subset of patients. However, with the difficulty in accurate diagnosis and evidence for the efficacy of SIJ fusion itself lacking, serious consideration of the cause of pain and alternative treatments should be given before performing the operation.

Duhon, et al. (2016) reported on a prospective uncontrolled industry sponsored study of subjects with SI joint dysfunction who underwent minimally invasive SI joint fusion with triangular titanium implants. One hundred ninety-four patients were enrolled between August 2012 and December 2013 at 26 sites. Of these, 10 withdrew prior to SI joint fusion and data from 12 subjects at a single site were eliminated due to the site's persistent non-compliance with the study protocol, leaving 172 subjects enrolled and treated. Two additional sites were terminated more than 1 year into the study for protocol non-compliance, resulting in 3 additional subjects not having 24-month study follow-up. Subjects underwent structured assessments preoperatively and at 1, 3, 6, 12,

18 and 24 months postoperatively, including SIJ pain ratings (0-100 visual analog scale), Oswestry Disability Index (ODI), Short Form-36 (SF-36), EuroQOL-5D (EQ-5D), and patient satisfaction. Adverse events were collected throughout follow-up. All participating patients underwent a high-resolution pelvic CT scan at 1 year. The primary study endpoint, evaluated at six months after the most recent SI joint fusion, was a binary success/failure composite endpoint. A subject was considered a success if all of the following were met: reduction from baseline VAS SI joint pain by at least 20 points, absence of device-related serious adverse events, absence of neurological worsening related to the sacral spine, and absence of surgical re-intervention (removal, revision, reoperation, or supplemental fixation) for SI joint pain. Of the 172 participants, 167 (97.1%) had 6-month follow-up, 157 (91.3%) had 12-month follow-up and 149 (86.6%) had 24-month follow-up. At month 6, 138 of 172 subjects met the study's success endpoint definition, for an intent-to-treat success rate of 80.2% (95% posterior credible interval 73.8-85.7%). Using available data only, the 12-month success rate was 127/159 (79.9%) and the 24-month success rate was 119/149 (79.9%). SIJ pain decreased from 79.8 at baseline to 30.4 at 12 months and 26.0 at 24 months ($p<.0001$ for change from baseline). ODI decreased from 55.2 at baseline to 31.5 at 12 months and 30.9 at 24 months ($p<.0001$ for change from baseline). The proportion of subjects taking opioids for SIJ or low back pain decreased from 76.2% at baseline to 55.0% at 24 months ($p <.0001$). At the time of the report, 8 subjects (4.7%) had undergone one or more revision SIJ surgeries. 7 device-related adverse events occurred. CT scan at one year showed a high rate (97%) of bone adherence to at least 2 implants on both the iliac and sacral sides with modest rates of bone growth across the SIJ.

Polly et al. (2016) described short and mid-term results of a randomized controlled trial of minimally invasive SIJ fusion. Subjects with SIJ dysfunction were randomly assigned to minimally invasive SIJ fusion with triangular titanium implants (SIJF, n = 102) or non-surgical management (NSM, n = 46). SIJ pain (measured with a 100-point visual analog scale, VAS), disability (measured with Oswestry Disability Index, ODI) and quality of life scores were collected at baseline and at scheduled visits to 24 months. Diagnosis of SIJ dysfunction was based on a history of pain at or near the SI joint, positive provocative testing on at least 3 of 5 physical examination tests, and at least a 50% decrease in pain after image-guided injection/arthrogram into the SI joint with local anesthetic.Crossover from non-surgical to surgical care was allowed after the 6-month study visit was complete. After the 6-month visit, 39 of 44 (89%) NSM subjects who were still participating crossed over to surgical treatment, and all crossover procedures were SIJF using the study device. The authors stated that subjects who had crossed over were not included in the report because they are continuing to be evaluated. In the SIJF group, 13 subjects withdrew prior to month 24. One site was terminated after 12-month subject visits were complete due to "persistent non-compliance with the study protocol." The primary study endpoint, evaluated at 6 months after the most recent SIJF, was a binary success/failure composite measure. A subject was considered to be a success if all of the following criteria were met: reduction in VAS SIJ pain score by at least 20 points from baseline, absence of device-related serious adverse events, absence of neurological worsening related to the lumbosacral nerve roots, and absence of surgical re-intervention (i.e. removal, revision, reoperation, or supplemental fixation) for SIJ pain. By month 6, 84 of 102 SIJF subjects (82%, 95% posterior credible interval [CI] 74-89%) and 12 of 46 NSM subjects (26%, 14-41%) met the study's primary success endpoint. In the SIJF group, the mean SIJ pain score improved from 82.3 at baseline to 30.1 at 6 month follow-up, 28.6 at 12 months and 26.7 at 24 months. In the NSM group, mean SIJ pain improved from 82.2 to 70.3 at 6 months (12.2-point improvement). Limitations include lack of blinding and large crossovers after 6 months. In addition, the nonsurgical option described usual care “consistent with existing US practices and directed by each site investigator for each subject” and not an intensive multidisciplinary back pain intervention (Chou, et al., 2009). This was an industry sponsored study; the study sponsor also performed the statistical analysis and participated in the writing.

Sturesson, et al. (2016) reported on the short-term (6 month) results of a randomized study of minimally invasive SIJ fusion (SIJF) versus conservative management (CM) in subjects (n=103) with chronic sacroiliac joint pain. At 6 months, mean LBP improved by 43.3 points in the SIJF group and 5.7 points in the CM group

(difference of 38.1 points, $p < 0.0001$). This study suffers from similar limitations as the study by Polly, et al.

The North American Spine Society (2015) has posted online insurance coverage policy recommendation for sacroiliac joint fusion. The coverage recommendation notes: "Due to the relatively moderate evidence, it is particularly critical that inclusion criteria are scrutinized and patient selection is executed with vigilance. The procedure itself has proven to be relatively safe. There is a valid concern for bias in that the overwhelming majority of the data produced so far has been industry-sponsored and generally composed of case series. However there are some data on five-year outcomes that demonstrate sustained benefit that does not appear to degrade from 1 year to 5 year time-points. The committee will revisit the quality of forthcoming evidence as it is produced in re-evaluations of the indications and coverage of this procedure."

Cryoablation for the Treatment of Lumbar facet Joint Pain

Birkenmaier et al (2007) stated that facet joint pain is an important aspect of degenerative lumbar spine disease, and radiofrequency medial branch neurotomy remains an established therapy, while cryodenervation has still been poorly examined. This study was undertaken to examine the effects of medial branch cryodenervation in the treatment of lumbar facet joint pain. This was a prospective clinical case series. Patient selection was based on the history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodenervation was performed using a Lloyd Neurostat 2000. Target parameters were LBP (VAS), limitation of activity (McNab) and overall satisfaction. A total of 50 patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72 %) were pain-free or had major improvement of LBP; 13 (28 %) had no or little improvement. Including failures, mean LBP decreased significantly from 7.7 pre-operatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months ($p < 0.0001$). Limitation of the activities of daily living improved parallel to reduced pain. The authors concluded that these findings suggested that medial branch cryodenervation is a safe and effective treatment for lumbar facet joint pain. Moreover, they stated that at the 12 month follow-up period, the failure rate rose to 43 %.

An UpToDate review on “Subacute and chronic low back pain: Nonsurgical interventional treatment” (Chou, 2013) discusses the use of facet joint injection and medial branch block; but does not mention the use of cryoablation as a therapeutic option.

Minimally Invasive Thoracic Discectomy

Kasliwal and Deutsch (2011) stated that the management of symptomatic thoracic disc herniation (TDH) has evolved tremendously ever since the first laminectomy was performed. The last decade has witnessed the evolution of minimally invasive approaches for TDH most of which have been posterior/postero-lateral. Traditional anterior approaches involve a thoracotomy or more recently, thoracoscopic techniques. The authors described a less invasive anterior retropleural surgical approach to address central thoracic disk herniations that is less extensive than a thoracotomy and allows better anterior access than posterior or postero-lateral approaches. The retropleural approach allows the use of the operative microscope with a tubular retractor in the anterior thoracic spine. A total of 7 patients with central disc herniation who were managed with the minimally invasive lateral retropleural approach from 2007 to 2010 at their institution were included in the study. Surgical technique consisted of a lateral position followed by retro-pleural exposure through tubular retractor system without the need of intra-operative lung collapse. Clinical details including age, sex, clinical presentation, surgical details, complications and outcome at last follow-up were analyzed. Patients age ranged in age from 30 to 70 years (mean of 52 years). The duration of symptoms ranged from 4 days to 3 years. All patients presented with thoracic myleopathy on physical examination. The average length of stay in the hospital was 2.6 days (range of 1 to 4 days). Follow-up was available for all the patients. Myelopathy was assessed by the Nurick scale. On examination, 3 of 7 patients improved by 1 point on the Nurick scale. No patient deteriorated after surgery. There were no complications related to the approach. The authors concluded that a minimally

invasive retropleural approach using tubular retractor system for central thoracic disc herniation is feasible and may be a less invasive anterior alternative to a thoracotomy. This was a small feasibility study.

Regev et al (2012) noted that surgical decompression of thoracic disc herniations is technically challenging because retraction of the thecal sac in this area must be avoided. Standard open thoracic discectomy procedures require fairly extensive soft tissue dissection and vertebral resection to provide safe decompression of the spinal cord. These researchers described their experience using a minimally invasive, transforaminal thoracic discectomy (MITTD) technique for the treatment of thoracic disc herniation. A total of 12 patients undergoing MITTD were evaluated pre-operatively and post-operatively at 1-, 3-, and 6-month intervals with neurologic examination, and were graded using the American Spinal Injury Association (ASIA) impairment scale and a pain visual analog scale (VAS). Thoracic instability and bony fusion were assessed clinically and radiographically with plain radiographs and computed tomography (CT) scans. Surgical time, blood loss, complications, and hospital length of stay were recorded. Twelve patients (7 men and 5 women) underwent MITTD. The median surgical time was 128 (80 to 185) minutes, the median estimated blood loss was 100 (30 to 250) mL, and the median hospital stay was 2 (1 to 4) nights. All discs were successfully removed, and a CT or magnetic resonance imaging confirmed adequate cord decompression in all cases. All patients reported easing of neurologic symptoms and improved walking ability. The median VAS scores improved from 4.5 to 2 for back pain. The ASIA score improved from D to E in the 2 patients who suffered from motor weakness. Pre-operative sensory deficit was reduced in 3 of the 5 patients. Patients who suffered from sexual and urinary disturbances did not report improvement. Serious systemic or local complications and neurologic deterioration were not reported. The authors concluded that the transforaminal approach enabled sufficient access to the midline of the spinal canal without extensive resection of the facet joint or the adjacent pedicle. Because most of the osseous and ligamentous structures were preserved, additional instrumentation was not required to prevent postoperative instability. They stated that these early results suggested that minimally invasive thoracic discectomy by transforaminal microscopic technique is a valuable choice in the management of thoracic disc herniation. These preliminary results need to be validated by well-designed studies.

In a case-series study, Smith et al (2013) presented operative details and clinical follow-up of a series of patients with thoracic disk herniation treated with the minimally invasive technique of thoracic microendoscopic diskectomy (TMED). TMED was performed in 16 consecutive patients (age range of 18 to 79 years old) with 18 thoracic disk herniations. One patient with a calcified herniation in a direct ventral location was not included in this series. Patients were positioned prone, and a tubular retractor system was placed through a muscle dilating approach. The procedure was performed with endoscopic visualization. Outcomes were assessed using modified McNab criteria. There were no complications, and no case required conversion to an open procedure. The mean operative time was 153 minutes per level, and mean blood loss was 69 mL per level. Mean hospital stay was 21 hours. At a mean follow-up of 24 months (median of 22 months), 13 patients (81 %) had excellent or good outcomes, 1 patient (6 %) had a fair outcome, and 2 patients (13 %) had poor outcomes. The 2 patients with poor outcomes had neurologic diagnoses (multiple sclerosis and multiple systems atrophy) that were ultimately proven to be responsible for their symptoms and deficits. The authors concluded that TMED is a safe and effective minimally invasive postero-lateral approach for the treatment of thoracic disk herniations that lacks the morbidity associated with traditional approaches. The findings of this case-series study need to be validated by well-designed studies.

Furthermore, the Work Loss Data Institute's clinical practice guideline on "Low back - lumbar & thoracic (acute & chronic)" (2011) did not mention the use of minimally invasive thoracic discectomy as a therapeutic option.

Dynamic (intervertebral) stabilization

Li and colleagues (2011) explored the value of application of Bioflex dynamic stabilization system in treating

multi-segment lumbar degenerative disease. Clinical data of 13 patients with multi-segment lumbar degenerative disease (8 males and 5 females; average age of 65.0 years, range of 51 to 72) were retrospectively analyzed between April 2008 and May 2009. The involved area included L3 to S1 in 7 cases, L2 to S1 in 3 cases, L3 to L5 in 1 cases, L4 to S1 in 2 cases. All patients underwent decompression, dynamic stabilization with Bioflex system, according to the severity of degenerative disc with/without interbody fusion. The clinical effects were evaluated by VAS, ODI. Range of motion and fusion segments were also observed. The mean follow-up period was 19.5 months (range of 12 to 26). The mean operative time was 183.4 mins (range of 90 to 240) and the mean volume of blood loss was 610.2 ml (range of 400 to 1,220 ml). The mean VAS score was 7.8 +/- 1.3 pre-operatively, 2.3 +/- 0.9 post-operatively and 2.1 +/- 0.8 at the last follow-up. The average ODI was (60.50 +/- 4.40) % pre-operatively, (17.80 +/- 2.10) % post-operatively and (16.20 + 2.40) % at the last follow-up. The VAS and ODI significant improved in post-operatively ($p < 0.05$), and there was no statistical difference between post-operative and last follow-up ($p > 0.05$). ROM of whole lumbar and non-fused segment showed obviously decreased and adjacent segment showed insignificant increased. The fusion rate of interbody fusion level was 95.0 % (19/20). The authors concluded that the preliminary clinical results showed the Bioflex system combined with intebody fusion is a safe and effective technique in treating multi-segment lumbar degenerative disease. These preliminary findings need to be validated by well-designed studies.

Zhang and associates (2012) examined the short-term effectiveness of ISOBAR TTL semi-rigid dynamic stabilization system (ISOBAR TTL system) in treatment of lumbar degenerative disease. Between June 2007 and May 2011, a total of 38 cases of lumbar degenerative disease were treated, including 24 males and 14 females with an average age of 51.2 years (range of 21 to 67). The disease duration was 8 months to 10 years (mean of 4.7 years). In 38 cases, there were 4 cases of grade I spondylolisthesis, 11 cases of lumbar instability and lumbar disc protrusion, 21 cases of lumbar spinal stenosis and lumbar disc protrusion, and 2 cases of post-operative recurrence of lumbar disc protrusion. There were 22 cases of adjacent segment disc degeneration. All cases underwent posterior decompression and implantation of ISOBAR TTL system. The double-segment-fixed patients underwent interbody fusion. Visual analog scale and Japanese Orthopedic Association scores for LBP were used to evaluate clinical outcomes. The ROM at the semi-rigid dynamic stabilization segment was also measured. The other cases achieved healing of incision by first intention, except 1 case of delayed healing. All the patients were followed-up for 8 to 53 months (mean of 27.8). After operation, ISOBAR TTL system showed reliable fixation, and no loosening, breakage, or kyphosis deformity occurred. No adjacent segment degeneration was observed. The ROM of the fixed segments was 0 to 1 degrees in 3 cases, 1 to 2 degrees in 4 cases, 2 to 3 degrees in 14 cases, 3 to 4 degrees in 15 cases, and greater than 4 degrees in 2 cases. At last follow-up, the VAS score was 1.93 +/- 2.43, and was significantly lower than pre-operative score (8.20 +/- 1.78) ($t = 7.761$, $p = 0.000$). Japanese Orthopedic Association score was 23.06 +/- 7.75, and was significantly higher than pre-operative score (4.87 +/- 3.44) ($t = 10.045$, $p = 0.000$). According to Stauffer-Coventry evaluation standard, the results were excellent in 32 cases, good in 3 cases, fair in 2 cases, and poor in 1 case, with an excellent and good rate of 92.1 %. The authors concluded that good short-term effectiveness can be achieved by surgical intervention with ISOBAR TTL system in treatment of lumbar degenerative disease. The results of this small study need to be validated by well-designed studies.

Li and co-workers (2013) retrospectively evaluated the indications, safety and efficacy of a new dynamic stabilization system (the Isobar TTL Semi-Rigid Rod System, Scient'x, Bretonneux, France) for the treatment of lumbar degenerative disease in 37 consecutive patients (M:F = 16:21, mean age of 40.2 years) with lumbar degenerative disease who underwent surgery between June 2006 and May 2009. One patient was lost to follow-up. Clinical outcomes were evaluated using the ODI and the VAS; ROM and disc height index (DHI) were assessed with radiography. Patients were followed for a mean of 24 months (range of 12 to 36 months). At the 3-month follow-up, there was significant improvement in VAS and ODI ($p < 0.05$); at long-term follow-up VAS showed additional significant improvement ($p < 0.05$) and ODI remained stable. At short-term follow-up, DHI was significantly restored ($p < 0.05$) and ROM declined slightly (but not significantly); however, at long-term

follow-up DHI was significantly reduced ($p < 0.05$) compared to short-term follow-up and ROM was significantly decreased compared to the pre-operative values ($p < 0.05$). There were new signs of degeneration at adjacent levels in 14 patients (39 %) on long-term follow-up MRI. Revision was required in 3 patients (8 %) 24 months after the first operation due to adjacent segment disease. Screw loosening was observed in 4 patients (11 %). The authors concluded that the Isobar System after microsurgical decompression for lumbar degenerative disease provided excellent improvement in leg and back pain and patient satisfaction at late follow-up; however, evidence to suggest that Isobar outperforms traditional fusion is lacking. Moreover, they stated that larger studies of longer duration are warranted.

Total Facet Arthroplasty System

The Total Facet Arthroplasty System (TFAS; Facet Solutions, Inc., Hopkinton, MA) is a non-fusion spinal implant indicated for treatment of moderate-to-severe spinal stenosis. The TFAS replaces the diseased facets (and lamina, if necessary, to attain adequate decompression) following surgical removal.

Phillips et al (2009) stated that lumbar fusion is traditionally used to restore stability after wide surgical decompression for spinal stenosis. The TFAS is a motion-restoring implant suggested as an alternative to rigid fixation after complete facetectomy. In a biomechanical in-vitro study, these researchers investigated the effect of TFAS on the kinematics of the implanted and adjacent lumbar segments. A total of 9 human lumbar spines (L1 to sacrum) were tested in flexion-extension (+8 to -6Nm), lateral bending (+/-6Nm), and axial rotation (+/-5Nm). Flexion-extension was tested under 400 N follower preload. Specimens were tested intact, after complete L3 laminectomy with L3 to L4 facetectomy, after L3 to L4 pedicle screw fixation, and after L3 to L4 TFAS implantation. Range of motion was assessed in all tested directions. Neutral zone and stiffness in flexion and extension were calculated to assess quality of motion. Complete laminectomy-facetectomy increased L3 to L4 ROM compared with intact in flexion-extension (8.7 +/- 2.0 degrees to 12.2 +/- 3.2 degrees, $p < 0.05$) lateral bending (9.0 +/- 2.5 degrees to 12.6 +/- 3.2 degrees, $p = 0.09$), and axial rotation (3.8 +/- 2.7 degrees to 7.8 +/- 4.5 degrees $p < 0.05$). Pedicle screw fixation decreased ROM compared with intact, resulting in 1.7 +/- 0.5 degrees flexion-extension ($p < 0.05$), 3.3 +/- 1.4 degrees lateral bending ($p < 0.05$), and 1.8 +/- 0.6 degrees axial rotation ($p = 0.09$). The Total Facet Arthroplasty System restored intact ROM ($p > 0.05$) resulting in 7.9 +/- 2.1 degrees flexion-extension, 10.1 +/- 3.0 degrees lateral bending, and 4.7 +/- 1.6 degrees axial rotation. Fusion significantly increased the normalized ROM at all remaining lumbar segments, whereas TFAS implantation resulted in near-normal distribution of normalized ROM at the implanted and remaining lumbar segments. Flexion and extension stiffness in the high-flexibility zone decreased after facetectomy ($p < 0.05$) and increased after simulated fusion ($p < 0.05$). The Total Facet Arthroplasty System restored quality of motion parameters (load-displacement curves) to intact ($p > 0.05$). The quality of motion parameters for the whole lumbar spine mimicked L3 to L4 segmental results. The authors concluded that TFAS restored ROM and quality of motion at the operated segment to intact values and restored near-normal motion at the adjacent segments.

Sjovold et al (2012) noted that to gain insight into a new technology, a novel TFAS was compared to a rigid posterior fixation system (UCR). The axial and bending loads through the implants and at the bone-implant interfaces were evaluated using an ex- vivo biomechanical study and matched finite element analysis. Kinematic behavior has been reported for TFAS, but implant loads have not. Implant loads are important indicators of an implant's performance and safety. The rigid posterior fixation system is used for comparison due to the extensive information available about these systems. Unconstrained pure moments were applied to 13 L3 to S1 cadaveric spine segments. Specimens were tested intact, following decompression, UCR fixation and TFAS implantation at L4 to L5. UCR fixation was via standard pedicle screws and TFAS implantation was via PMMA-cemented trans-pedicular stems. Three-dimensional 10 Nm moments and a 600 N follower load were applied; L4 to L5 disc pressures and implant loads were measured using a pressure sensor and strain gauges, respectively. A finite element model was used to calculate TFAS bone-implant interface loads. UCR

experienced greater implant loads in extension ($p < 0.004$) and lateral bending ($p < 0.02$). Under flexion, TFAS was subject to greater implant moments ($p < 0.04$). At the bone-implant interface, flexion resulted in the smallest TFAS (average = 0.20 Nm) but greatest UCR (1.18 Nm) moment and axial rotation resulted in the greatest TFAS (3.10 Nm) and smallest UCR (0.40 Nm) moments. Disc pressures were similar to intact for TFAS but not for UCR ($p < 0.04$). The authors concluded that these findings were most applicable to the immediate post-operative period prior to re-modeling of the bone-implant interface since the UCR and TFAS implants are intended for different service lives (UCR -- until fusion, TFAS -- indefinitely). The Total Facet Arthroplasty System reproduced intact-like anterior column load-sharing -- as measured by disc pressure. The highest bone-implant moment of 3.1 Nm was measured in TFAS and for the same loading condition the UCR interface moment was considerably lower (0.4 Nm). For other loading conditions, the differences between TFAS and UCR were smaller, with the UCR sometimes having larger values and for others the TFAS was larger. The long-term physiological meaning of these findings was unknown and demonstrated the need for a better understanding of the relationship between spinal arthroplasty devices and the host tissue as development of next generation motion-preserving posterior devices that hope to more accurately replicate the natural functions of the native tissue continues.

The TFAS clinical trial is a multi-center, prospective, randomized controlled clinical trial comparing the safety and effectiveness of the TFAS to spinal fusion surgery in the treatment of moderate-to-severe degenerative lumbar spinal stenosis. However, the status of this clinical trial is unknown (last verified February 2009). http://www.clinicaltrials.gov/ct2/show/NCT00418197?term=Total+Facet+Arthroplasty+System&rank=1.

The AccuraScope procedure

The AccuraScope procedure is employed to treat LBP. It entails the use of a thin, flexible catheter that is inserted into the center of the spinal canal. Once inside the spinal canal, the catheter can be maneuvered to multiple levels of the lumbar spine, both sides. Using a high-definition camera and other diagnostic tools, the procedure's goals are (i) to pin-point all sources of chronic lower spine symptoms and (ii) treat them with advanced tools including a laser. This out-patient procedure usually takes less than 45 minutes. http://northamericanspine.com/accurascope/. However, there is a lack of evidence regarding the effectiveness of the AccuraScope procedure.

Chemical Ablation of Facet Joints

The American Society of Anesthesiologists Task Force on Chronic Pain Management/American Society of Regional Anesthesia and Pain Medicine's practice guidelines on "Chronic pain management" (2010) stated that "Conventional or other thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain". Furthermore, an UpToDate review on "Subacute and chronic low back pain: Nonsurgical interventional treatment" (Chou, 2014) states that "Glucocorticoid injections into the facet joint have not been shown to be effective in the treatment of low back pain. A 2009 American Pain Society guideline recommends against their use. There are limited data regarding the efficacy of facet joint injection with glucocorticoids. Two evidence-based reviews concluded that there is not sufficient evidence to support their use. Similarly, a more recent trial comparing facet joint glucocorticoid injection and systemic glucocorticoids found no difference in either pain or functional capacity over six months between the groups, although patients receiving facet injections had a decrease in nonsteroidal antiinflammatory drug use. Blocks to the medial branch of the primary dorsal ramus, innervating the facet joints have been used both diagnostically and therapeutically for presumed facet joint pain. However, there are no trials comparing efficacy of medial branch blocks to placebo injections".

The Deuk Laser Disc Repair®

Deuk Laser Disc Repair® is a surgical technique that incorporates 3 distinct procedures including a selective partial discectomy, foraminoplasty, and annular debridement. All of the results of full-length articles in peer-reviewed journals of the Deuk Laser Disc Repair are from a single investigator group. These studies did not include internal comparison groups of patients undergoing ACDF.

Deukmedjian et al (2012) stated that cervical Deuk Laser Disc Repair(®) is a novel full-endoscopic, anterior cervical, trans-discal, motion preserving, laser assisted, non-fusion, out-patient surgical procedure to safely treat symptomatic cervical disc diseases including herniation, spondylosis, stenosis, and annular tears. These researchers described a new endoscopic approach to cervical disc disease that allows direct visualization of the posterior longitudinal ligament, posterior vertebral endplates, annulus, neuroforamina, and herniated disc fragments. All patients treated with Deuk Laser Disc Repair were also candidates for ACDF. A total of 142 consecutive adult patients with symptomatic cervical disc disease underwent Deuk Laser Disc Repair during a 4-year period. This novel procedure incorporates a full-endoscopic selective partial decompressive discectomy, foraminoplasty, and posterior annular debridement. Post-operative complications and average volume of herniated disc fragments removed were reported. All patients were successfully treated with cervical Deuk Laser Disc Repair. There were no post-operative complications. Average volume of herniated disc material removed was 0.09 ml. The authors concluded that potential benefits of Deuk Laser Disc Repair for symptomatic cervical disc disease include lower cost, smaller incision, non-fusion, preservation of segmental motion, out-patient, faster recovery, less post-operative analgesic use, fewer complications, no hardware failure, no pseudoarthrosis, no post-operative dysphagia, and no increased risk of adjacent segment disease as seen with fusion.

Deukmedjian et al (2013) stated that the Deuk Laser Disc Repair(®) is a new full-endoscopic surgical procedure to repair symptomatic cervical disc disease. In this study, a prospective cohort of 66 consecutive patients underwent cervical Deuk Laser Disc Repair(®) for 1 (n = 21) or 2 adjacent (n = 45) symptomatic levels of cervical disc disease and were evaluated post-operatively for resolution of headache, neck pain, arm pain, and radicular symptoms. All patients were candidates for ACDF or arthroplasty. The Mann-Whitney Wilcoxon test was used to calculate p values. All patients (n = 66) had significant improvement in pre-operative symptoms with an average symptom resolution of 94.6 %. Fifty percent (n = 33) had 100 % resolution of all pre-operative cervicogenic symptoms. Only 4.5 % (n = 3) had less than 80 % resolution of pre-operative symptoms. Visual analog scale significantly improved from 8.7 pre-operatively to 0.5 post-operatively ($p < 0.001$) for the cohort. Average operative and recovery times were 57 and 52 minutes, respectively. There were no peri-operative complications. Recurrent disc herniation occurred in 1 patient (1.5 %). Average post-operative follow-up was 94 days and no significant intergroup difference in outcomes was observed ($p = 0.111$) in patients with less than 90 days (n = 52) or greater than 90 days (n = 14, mean 319 days) follow-up. No significant difference in outcomes was observed ($p = 0.774$) for patients undergoing 1- or 2-level Deuk Laser Disc Repair(®). Patients diagnosed with post-operative cervical facet syndrome did significantly worse ($p < 0.001$). The authors concluded that Deuk Laser Disc Repair(®) is a safe and effective alternative to ACDF or arthroplasty for the treatment of 1 or 2 adjacent symptomatic cervical disc herniations with an overall success rate of 94.6 %.

Least Invasive Lumbar Decompression Interbody Fusion (LINDIF)

In a case-series study, Osman (2012) the feasibility of the least invasive lumbar decompression, interbody fusion (LINDIF) and percutaneous pedicle screw implantation, for disorders which are usually treated by open decompression, fusion and pedicle screw implantation. Patients completed VAS forms and Roland-Morris questionnaires pre- and post-operatively. Surgical procedures included arthroscopic decompression of the foramina and the discs; end-plate preparation and implantation of allograft bone chips and BMP-2 on collagen carrier; and percutaneous implantation of pedicle screws. Patients' charts were reviewed for operative notes,

hospital stay, medications, and imaging studies. The latest x-ray and CT scan films were reviewed and analyzed. Patients were followed up for the minimum of 6 months. Outcome measures included operating time; intra-operative blood loss; hospital stay; VAS scores for back and leg pain; Roland-Morris Disability Questionnaire; and post-operative imaging studies. A total of 60 patients met the inclusion criteria. The average age is 52.8 years. The duration of illness ranged 2 months to 32 years. All patients had back and leg pain. Follow-up averaged 12 months; OR time was 2:90 hours. Estimated blood loss averaged 57.6 cc. Hospital stay averaged 2.6 days. Pre- and post-operative back pain averaged 7.5 and 2, respectively ($p < 0.005$). Pre- and post-operative leg pain averaged 7.0 and 1.7, respectively ($p < 0.005$). A total of 47 imaging studies available at the last visits including x-ray and CT scan, showed solid fusion in 28 (59.6 %) patients, stable fixation in 17 (36.2 %), and osteolysis around the pedicle screws in 2 patients (4.2 %). All patients had improved motor function and 2 patients complained of residual numbness; 8 (13 %) patients complained of residual discomfort on the extension of the lumbar spine; 1 patient (1.6 %) had medial penetration of 1 S1 screw with S1 nerve root irritation which required revision; 1 patient with painful loose pedicle screws required hardware removal. Both patients had satisfactory outcome after their 2nd operations. The authors concluded that the LINDIF produced satisfactory results in all demographics. Anesthesia time was consistently short, blood loss was negligible. Hospital stay was brief for most healthy patients irrespective of age. The results of this study demonstrated how drastically the surgery related morbidity, and the economics thereof, can be reduced. They stated that the outcomes relating to patients in the age group of 71 to 90 years are particularly encouraging, given their increasing proportion in the population. The findings of this study need to be validated by well-designed studies.

Microsurgical Lumbar Sequestrectomy for the Treatment of Lumbar Disc Herniation

Ran and colleagues (2015) stated that lumbar disc removal is currently the standard treatment for lumbar disc herniation. No consensus has been achieved whether aggressive disc resection with curettage (discectomy) versus conservative removal of the offending disc fragment alone (sequestrectomy) provides better outcomes. These researchers compared the re-herniation rate and clinical outcomes between discectomy and sequestrectomy by literature review and a meta-analysis. They performed a systematic search of PubMed, Medline, Embase and the Cochrane Library up to June 1, 2014. Outcomes of interest assessing the 2 techniques included demographic and clinical baseline characteristics, peri-operative variables, complications, recurrent herniation rate and post-operative functional outcomes. A total of 12 eligible trials evaluating discectomy versus sequestrectomy were identified including 1 RCT, 5 prospective and 6 retrospective comparative studies. In contrast to discectomy, sequestrectomy was associated with significantly less operative time ($p < 0.001$), lower VAS for LBP ($p < 0.05$), less post-operative analgesic usage ($p < 0.05$) and better patients' satisfaction ($p < 0.05$). Recurrent herniation rate, re-operation rate, intra-operative blood loss, hospitalization duration and VAS for sciatica were without significant difference. The authors concluded that according to their pooled data, sequestrectomy entailed equivalent re-herniation rate and complications compared with discectomy, but maintained a lower incidence of recurrent LBP and higher satisfactory rate. They stated that high-quality prospective RCTs are needed to evaluate these 2 procedures.

In a meta-analysis, Huang et al (2015) compared the effects of sequestrectomy and microdiscectomy in the treatment of patients with lumbar herniated discs (LHD). Clinical trials published in PubMed, Embase, and Web of Science were systematically reviewed to compare the effects of sequestrectomy and microdiscectomy for LHD. Outcomes included re-herniation rate, duration of surgery, length of hospital stay, and post-operative VAS scales for leg and back pains. A fixed-effects or random-effects were used to pool the estimates, depending on the heterogeneity among the studies. A total of 5 cohorts and 2 RCTs with a total of 929 patients met the inclusion criteria and were included in this meta-analysis. All patients underwent sequestrectomy or microdiscectomy. Pooled estimates showed that patients treated with sequestrectomy had comparable effects in re-herniation rate (RR = 1.36, 95 % CI: 0.81 to 2.27; $p = 0.240$), length of hospital stay (WMD = -0.22 days, 95

% CI: -0.45 to 0.01; p = 0.060), and post-operative VAS scales for leg pain (WMD = 0.53, 95 % CI: -1.54 to 2.60; p = 0.617) or back pain (WMD = 0.18, 95 % CI: -1.64 to 2.00; p = 0.846), but had a shorter duration of surgery (WMD = -6.97 minutes, 95 % CI: -12.15 to -1.78; p = 0.008), when compared with those treated with microdiscectomy. The authors concluded that based on the current evidence, sequestrectomy significantly reduced the operational time, but had similar effects on re-herniation rate, length of hospital stay, and post-operative VAS scales for leg and back pains, when compared with microdiscectomy. They stated that further well-designed RCTs are needed to validate these findings.

In a systematic review, Azarhomayoun et al (2015) compared the effects of sequestrectomy versus conventional microdiscectomy for LDH. These investigators searched Medline and Embase from 1980 to November 2014. They selected RCTs and non-randomized prospective studies of conventional discectomy versus sequestrectomy for adult patients with LDH that evaluated the following primary outcomes: radicular pain or LBP as measured by a VAS, or neurological deficits of the lower extremity. These researchers also evaluated the following secondary outcomes: complications of surgery, re-herniation rate, duration of hospital stay, post-operative analgesic use, and health-related quality-of-life measures. Two authors independently reviewed citations and articles for inclusion. They assessed the risk of bias, synthesized data, and the level evidence using standard methodological procedures as recommended by the Cochrane Back Review Group. These investigators identified 5 studies (746 participants) of sequestrectomy versus microdiscectomy; 1 study was RCT and the other 4 were non-randomized prospective comparisons; all studies were assessed as being at a high-risk of bias. There were no significant differences for leg pain, LBP, functional outcomes, complications, and hospital stay or recurrence rate for 2 years (level of evidence: Low). Sequestrectomy was associated with less analgesic consumption versus discectomy (level of evidence: Very low). The authors concluded that sequestrectomy and standard microdiscectomy were associated with similar effects on pain after surgery, recurrence rate, functional outcome, and complications; more evidence is needed to determine whether sequestrectomy is associated with less post-operative analgesic consumption (Level of Evidence: 2).

Appendix

Table 1: Noncovered Interspinous Fixation Devices (considered experimental and investigational; not an all-inclusive list)

- Affix II and Affix II Mini Spinous Process Plating System (NuVasive)
- Aileron Interspinous Fixation System (Life Spine)
- Aspen Spinous Process Fixation System (Lanx)
- Axle (X-Spine)
- BacFuse (Pioneer Surgical)
- BridgePoint (Alphatec)
- CD Horizon Spire Fixation System (Medtronic Sofamor Danek)
- Coflex-F (Paradigm Spine)
- Inspan (Spine Frontier)
- Minuteman Interspinous Interlaminar Fusion Device (Spinal Simplicity)
- PrimaLOK (OsteoMed)
- Octave (Life Spine)
- StabiLink MIS Interspinous Fixation Device (Southern Spine)
- SP-Fix Spinous Process Fixation System (Globus Medical)

Table 2: Noncovered Interspinous and Interlaminar Distraction Devices (considered experimental and investigational; not an all-inclusive list)

- Aperius PercLID System (Kyphon/ Medtronic Spine)

- Coflex Interlaminar Technology Implant (Paradigm Spine)
- CoRoent Extensure (Nuvasive)
- DIAM Spinal Stabilization System (Medtronic Sofamor Danek)
- ExtenSure (Nuvasive)
- FLEXUS (Globus Medical)
- Falena Interspinous Decompression Device (Mikai Spine)
- Helifix Interspinous Spacer System (Alphatec Spine)
- In-Space (Synthes)
- NL-Prow Interspinous Spacer (Non-Linear Technologies)
- Stenofix (Synthes)
- Superion ISS Interspinous Spacer System (VertiFlex)
- Wallis System (Abbott Spine/ Zimmer Spine)
- X-STOP Interspinous Process Decompression (IPD) System (Kyphon/ Medtronic Spine)
- X-STOP PEEK Interspinous Process Decompression (IPD) System (Kyphon/ Medtronic Spine)

Spine Cages (Not an all-inclusive list) (considered medically necessary when criteria are met)

- A-CIFT SoloFuse (SpineFrontier)
- ACIS cage (Synthes)
- Acromed Lumbar I/F Cage (Depuy)
- Aero AL
- Aero C
- Aesculap PEEK
- Alamo Spine Cage
- Aleutian Spacer System (K2M)
- ALIF Spine Truss System (4web)
- Alphatec Novel TL Spacer System
- Anatomic PEEK PTC cervical fusion system
- Ancora spacer
- AnyPlus PEEK TLIF
- Apache spacer (Genesys)
- Arch ODL spacer
- Arena-C
- Ascential
- Athlet
- Atlantis translational plate fixation
- Avenue-L
- AVS Anchor-L Lumbar Cage System (Stryker)
- AVS AS PEEK (Stryker)
- AVS Navigator (Stryker)
- AVS PL PEEK
- BAK Interbody Fusion System
- Bengal Corpectomy Cage (Depuy)
- BoneBac Interbody System
- Brantigan
- Brigade (Nuvasive)
- Bullet-Tip PEEK VBR/IBF (RTI Surgical)
- CALIX cage (X-Spine)
- Cambria anterior cervical interbody system

- Capstone PEEK Cage (Medtronic)
- Cascadia TL implant system
- Cavetto cage
- C-Boxe
- Cezanne II
- Chesapeake Spinal System (K2M)
- ChoiceSpine
- Cimplicity (SpineSmith)
- Clariance TLIF cage
- Clydesdale (Medtronic)
- Co Roent XL (Nuvasive)
- Coalition Spacer (Globus)
- Concorde Bullet Spine System
- Construct Mini
- Continental (Globus)
- Corelink Anterior Cervical Interbody Cage System (Foundation)
- Cornerstone PSR Spinal System (Medtronic)
- CoRoent Interbody Cage (Nuvasive)
- Cougar Cage System (Depuy)
- Coveris
- C-Plus
- Crescent cage
- Devex TLIF Cage
- Dorado (Spine Frontier)
- DTRAX Cervical Cage (Providence Medical Technology)
- Ebi PEEK optima spacer
- Emerald cervical PEEK system (Glasir)
- Eminent DLIF PEEK Cage
- Endoskeleton TCS
- Express IBFD (Advanced Vertebral Solutions)
- Foundation (CoreLink)
- Foundation Cervical Interbody Device
- Fuse (Medtronic)
- FuseLox Lumbar Cage (Captiva Spine)
- Harpoon, Hawkeye, Hornet, Shark
- Honour Orb
- IN:C2 spacer
- InFill Lateral Interbody Device
- Innovasis PEEK cage
- Integra Vu POD
- Interfuse - T
- Irix-C (X Spine)
- Juliet Lumbar Interbody Fusion Device
- LANX Lateral Cage
- LDR ROI-A Implant System
- Leopard (DuPuy)
- Levo fixed cage (non-expandable)
- LLC Reveal VBR System (Theken)
- Lucent Magnum (Spinal Elements)

- Lucent TiBond Interbody System (Spinal Elements)
- Luna Interbody Fusion System
- Magnum + Stand-alone Lumbar Interbody Fusion system
- Maxim surgical X-Treme interbody fusion system
- MectaLIF transforaminal lumbar interbody fusion device (Genesys)
- Medyssey BN
- NanoLOC (Titan)
- Nanovis cage
- NEXXT spine intervertebral cage
- Novel Spinal System
- OLIF PEEK (Medtronic)
- OLIF 51 (Medtronic)
- Orio intervertebral body fusion cage
- Osteofix Pillar (AL, SA, PL, TL)
- OsteoStim (Biomet)
- Pathway AVID (Custom Spine)
- Pillar SA PEEK Spacer (Orthofix)
- Pinnacle
- Pioneer Interbody Fusion (IBF)/Vertebral Body Replacement System (C-Plus)
- Precision Vault ALIF System (Precision Spine)
- Prevail Interbody Device (Medtronic)
- PRO-LINK Stand-Alone Cervical Spacer System (Life Spine)
- Pulse cervical cage system (DePuy)
- Ravine (K2M)
- Ray Threaded Fusion Cage (Synthes)
- Renovis PEEK ALIF Cage
- Rise (Globus)
- ROI-C
- RTI\VBR\IBF
- Scarlet AC-T Secured Anterior Cervical Cage (SpineArt)
- Signus cage
- Silverstone IBF System
- Solitaire C Cervical Spacer System
- Spine 360 plate & cage for cervical fusion
- Spine 360 Cervical Interbody Fusion System
- Spine Vu c-POD Intervertebral Body Fusion Device (Theken)
- Stalif-C (Cervical Cage)
- Stalif Midline and Stalif Midline ABO Screws
- Stingray
- Surgical Titanium Mesh (Depuy)
- Sustain-O (Globus)
- Syncage (Synthes)
- SYNFIX LR system (Synthes)
- T-Pal (Synthes)
- Timberline Cage (Lanx)
- TiNano (Aurora Spine)
- TiLink-T
- Titanium PL cage (Stryker)
- Tomcat (Choice Spine)

- Transcontinental (Globus)
- Tryptik CA (Spineart)
- Valeo-C
- Valeo II LL
- Vault ALIF system
- Velofix
- Vertigraft (Lifenet)
- Vertu TiBond PEEK cage
- Vikos (K2M)
- XP L Spinal System (Arcadius)
- Zavation cage
- Zero-P Zero-Profile Anterior Cervical Interbody Fusion Device (Synthes)
- Zeus A
- Zeus C cervical spacer
- Zeus L
- Zeus T
- Zimmer TM-S cervical fusion device
- Zyston Curved Spacer System
- Zyston Straight Spacer System

Table 3: Expandable Spine Cages (considered medically necessary when criteria for expandable cages are met; not an all-inclusive list)

- Acculif Expandable Cage (Stryker)
- Bengal Stackable
- Elevate Expandable Cage (Medtronic)
- Globus Altera Expandable Cage
- Globus Caliber Expandable Cage
- Globus Fortify Corpectomy Spacer
- Globus Latis Expandable Cage
- Globus Magnify
- Globus Magnify S
- Leva Expandable Cage
- Nuvasive X-Core Expandable Cage
- Omni VBR Expandable cage
- Per 360 expandable cage
- Staxx XD Expandable Cage
- Ulrich ADDPlus
- Wenzel Spine Varilift Expandable Cage

Table 4: Pedicle Screw Systems (considered medically necessary when criteria are met) (not an all-inclusive list)

- ABC Cervical Plating System
- Accufit ALIF plate (Precison Spine)
- AcuFx Thinline
- Aesculap S4
- Alphatec ASPIDA anterior lumbar plating system
- Altus Cervical Spine Plate System

- Anax (U & I Corporation)
- Antegra plate (Synthes)
- Anterior cervical stabilization system (Southern Spine)
- Anterior tension band (ATB) (Synthes)
- Apelo
- Apex Deformity Spine System
- Arch ODL Fixation System
- Arsenal
- Archon Anterior Cervical Plate System
- Armada Spinal System
- Aspect Plate and Screws
- Aspen MIS Fusion System
- Assure (Globus)
- Astra Spine System
- Athena
- Atlantis Translational Plate for Cervical Fusion
- Aviator Anterior Cervical plating system
- Balboa plate
- Binary plates and screws (Genesys spine)
- Biomet MaxAn Cervical Plate System
- Blackbird spinal system (Choice Spine)
- Blueridge Cervical Plate and Screws
- Brigade anterior plate system
- Cabo
- Caplox II Spinal System (non-cervical)
- CapSure PS3 Spine System
- Cayman KZ plate
- CD Horizon Legacy Spinal System
- CD Horizon Spine Fixation System
- Centerpiece plate
- Cequence
- Certix Spinal Implant Syste
- Cervifix Cervical Spine Locking Plate (CSLP)
- ClickX pedicle screw
- Coral Spinal System
- Corelink Tiger pedicle screws
- CREO system
- Decade plate
- Degas plate
- Denali Degenerative Spine System
- Diamond (Amendia)
- Dio Medical Rex Anterior Cervical Plate System
- Dynatran anterior cervical plate
- Eagle plate
- Ellipse Occipito-Cervical-Thoracic spinal system
- EOS spinal system (Korean Bone Bank)
- Erisma - LP
- Everest Pedicle Screw Spinal System
- Excella

- Expedium Vectra
- Express pedicle screw and rod system
- Firebird Hallmark plate for cervical fusion
- Flamenco
- Fortress Pedicle Screw System
- Fortex pedicle screw (X-spine)
- Fortibridge plate
- G surgical plate system T loc
- Genesis Ti-lock
- Globus Extend plate
- Gruve
- Hyper-C
- Iliad spinal thoracolumbar system (Medyssey)
- Illico pedicle screw system (Alphatec)
- Inion absorbable plate (Globus)
- Invizia plate
- Invue plate
- Iris anterior cervical plate
- Kinetic-SL Dynamic Anterior Cervical Plate System
- King Cobra Anterior Cervical Plate
- Lanx Pedicle Screw Spinal System
- Leucadia
- Lineum OCT spine system
- Lnk thoraco-lumbar pedicle screw system
- Lotus System
- Malibu
- Mambo plate
- Manta Ray Anterior Cervical Plate System
- Mantis
- Medessy screws
- Medical Mesa System
- Medical N Cervical Plate System
- Mercury Spine Element screw and rod system
- MonoPoly Pedicle Screw System ((Signus)
- Mosaic System
- Mountaineer OCT Spinal System
- MUST pedicle screw sytem (Medacta)
- Nautilus Thoracolumbar Spinal System
- NEO SL
- Newport MIS system
- Nexlink rods and screws
- Nexxt structured plate
- Ni-lock
- Osteonics Techtonix System
- Optio-C Anterior Cervical Plate
- Pagoda
- Palisades
- Pathfinder NXT Sequoia Pedicle Screw
- Pedfuse pedicle screw system

- Perpos pedicle screws
- Phoenix Minimally Invasive Spinal Fixation System
- Pioneer Posterior Occipito-Cervico-Thoracic (OCT) System
- Polaris 5.5
- Polyaxial spinal system (Zimmer)
- Precept Spinal System
- Preference Pedicle Screw System
- Proliant Polyaxial Pedicle Screw System
- Quantum (RTI Surgical)
- Quintex anterior plating system
- Reflex Hybrid Anterior Cervical Plate System
- Reform
- Reliance Screw System
- ReSet (Spine Frontier)
- ReSpond (Spine Frontier)
- ReTurn (Spine Frontier)
- Revere stabilization system
- Revolve Pedicle Screw
- Rhausler anterior cervical plate system
- Romeo MIS
- Santis Hybrid Pedicle Screw System
- Sapphire Anterior Cervical Plate System
- Savannah High Top
- Sintea Plustek's Posterior Lumbar System Pedicle Screws
- Skyline
- Sniper screws
- Snowcap anterior cervical plate
- Solera screws (Medtronic)
- SpheRx DBR H
- Spider Cervical Plating System
- Spinal USA Simplicity Solo
- Spine 360 Talon Pedicle screw system
- Spine ST360
- SpineWave
- Spire Z (Medtronic)
- Starfire
- Streamline TL
- Struxxure
- SureLoc PC posterior cervical system (SLOK)
- Swift Anterior Cervical Plate System
- Synapse
- Tempus Cervical Plate system
- Tilock
- Timberline Plate
- Trestle Anterior Cervical Plating System
- Trinica Anterior Cervical Plate
- TSRH 3DX pedicle screws (Medtronic)
- Typhoon
- Uniplate 2

- Valencia Pedicle Screws (Altus)
- Valiant ALIF plate system
- Van Gogh plate
- Vectra (Synthes)
- Venus Facet Screw System
- Vertex Reconstruction System
- Viper Screws
- Virage system
- Vitality
- VuePoint OCT System
- XIA 3
- XIA 4.5
- Zavation Pedicle Screw System
- Zavation cervical plate
- Zevo anterior cervical plate system
- Zodiac Posterior screws
- Zou plate (Corelink)

CPT Codes /HCPCS Codes/ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Coccygectomy:

CPT codes covered if selection criteria are met:

27080	Coccygectomy, primary

ICD-10 codes covered if selection criteria are met:

M53.3	Sacrococcygeal disorders, not elsewhere classified [for individuals with coccygodynia who have tried and failed to respond to 6 months of conservative management]

Facet joint injections **[not covered for intradiscal and/or paravertebral oxygen/ozone injection]**:

CPT codes covered if selection criteria are met:

64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	second level
64492	third and any additional level(s) level
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	second level
64495	third and any additional level(s) level
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
+ 0214T	second level
+ 0215T	third and any additional level(s)
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level

+ 0217T	second level
+ 0218T	third and any additional level(s)

Other CPT codes related to the CPB:

72275	Epidurography, radiological supervision and interpretation
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)
77021	Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation

Other HCPCS codes related to the CPB:

Q9951, Q9958 - Q9967	High and low osmolar contrast material

ICD-10 codes covered if selection criteria are met:

M53.0 - M53.1	Cervicocranial - cervicobrachial syndrome
M53.81 - M53.83	Other specified dorsopathies [cervical region]
M54.2	Cervicalgia
M54.6	Pain in thoracic spine
M54.30 - M54.5	Sciatica and lumbago
M54.9	Dorsalgia, unspecified [backache]

Ganglion Nerve Block:

CPT codes not covered for indications listed in the CPB:

64450	Injection, anesthetic agent; other peripheral nerve or branch [coccygeal ganglion (ganglion impar) block]

ICD-10 codes not covered for indications listed in the CPB:

M53.3	Sacrococcygeal disorders, not elsewhere classified [coccygodynia]

Trigger point Injections:

CPT codes covered if selection criteria are met:

20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscles(s) [no repeats more than every 7 days, up to four sets to diagnose and achieve therapeutic effect, no additional sets if no clinical response, once diagnosed and therapeutic effect achieved, no repeats more than once every two months and beyond 12 months requires clinical review]
20553	single or multiple trigger point(s), 3 or more muscles(s) [no repeats more than every 7 days, up to four sets to diagnose and achieve therapeutic effect, no additional sets if no clinical response, once diagnosed and therapeutic effect achieved, no repeats more than once every two months and beyond 12 months requires clinical review]

Other CPT codes related to the CPB:

76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)
77021	Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and

	interpretation
97001 - 97139	Physical medicine and rehabilitation modalities and therapeutic procedures

Other HCPCS codes related to the CPB:

E0200 - E0239	Heat/cold application
S9117	Back school, per visit

ICD-10 codes covered if selection criteria are met:

M79.1	Myalgia

Sacroiliac joint injections:

CPT codes covered if selection criteria are met:

27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid [up to two injections to diagnose and achieve therapeutic effect, no repeats more than once every 7 days, no additional injections more once every two months or beyond 12 months]

CPT codes not covered for indications listed in the CPB:

76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation

Other CPT codes related to the CPB:

77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, subarachnoid or sacroilliac joint), including neurolytic agent destruction

HCPCS codes covered if selection criteria are met:

G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

Other HCPCS codes related to the CPB:

G0259	Injection procedure for sacroiliac joint; arthrography

ICD-10 codes covered if selection criteria are met:

M54.30 - M54.5	Sciatica and lumbago [more than 3 months duration and part of a comprehensive pain management program, including physical therapy, patient education, psychosocial support, and oral medication where appropriate]

Epidural injections of corticosteroid preparations:

CPT codes covered if selection criteria are met:

62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62321	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal);

	with imaging guidance (ie, fluoroscopy or CT)
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminarepidural or subarachnoid, cervical or thoracic; without imaging guidance
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)
64479	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level
+64480	each additional level (List separately in addition to code for primary procedure)
64483	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level
+64484	each additional level (List separately in addition to code for primary procedure)

Other CPT codes related to the CPB:

72275	Epidurography, radiological supervision and interpretation
97161-97168	Physical therapy evaluations

Other HCPCS codes related to the CPB:

J1020	Injection, methylprednisone acetate, 20 mg
J1030	Injection, methylprednisone acetate, 40 mg
J1040	Injection, methylprednisone acetate, 80 mg

ICD-10 codes covered if selection criteria are met:

M47.20 - M47.28	Other spondylosis with radiculopathy
M50.10 - M50.13	Cervical disc disorder with radiculopathy
M51.14 - M51.17	Intervertebral disc disorders with radiculopathy
M53.0 - M53.1	Cervicocranial - cervicobrachial syndrome
M53.81 - M53.83	Other specified dorsopathies [cervical region]
M54.10 - M54.18	Radiculopathy
M54.2	Cervicalgia
M54.30 - M54.5	Sciatica and lumbago
M54.6	Pain in thoracic spine
M54.9	Dorsalgia, unspecified

ICD-10 codes not covered for indications listed in the CPB:

C41.2	Malignant neoplasm of vertebral column
C41.4	Malignant neoplasm of pelvic bones, sacrum, and coccyx
C70.1	Malignant neoplasm of spinal meninges
C72.0	Malignant neoplasm of spinal cord
C79.31	Secondary malignant neoplasm of brain
C79.49	Secondary malignant neoplasm of other parts of nervous system [includes spinal cord]
C79.51 - C79.52	Secondary malignant neoplasm of bone and bone marrow
D16.6	Benign neoplasm of vertebral column
D16.8	Benign neoplasm of pelvic bones, sacrum, and coccyx
D32.1	Benign neoplasm of spinal meninges
D33.4	Benign neoplasm of spinal cord
D42.0 - D42.9	Neoplasm of uncertain behavior of meninges
D43.0 - D43.2, D43.4	Neoplasm of uncertain behavior of brain and spinal cord
D49.7	Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system

Chymopapain chemonucleolysis:

CPT codes covered if selection criteria are met:

62292	Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar

Other CPT codes related to the CPB:

62302 - 62305	Myelography via lumbar injection, including radiological supervision and interpretation
72125 - 72133	Computed tomography, spine
72141 - 72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents
72240 - 72270	Myelography of spine

ICD-10 codes covered if selection criteria are met:

M51.06 - M51.07	Intervertebral disc disorders with myelopathy, lumbar/lumbosacral region
M51.26 - M51.27	Other intervertebral disc displacement, lumbar/lumbosacral regions
M54.30 - M54.32	Sciatica [due to herniated disc]

ICD-10 codes not covered for indications listed in the CPB:

C41.2	Malignant neoplasm of vertebral column
C41.4	Malignant neoplasm of pelvic bones, sacrum, and coccyx
C70.1	Malignant neoplasm of spinal meninges
C72.0	Malignant neoplasm of spinal cord
C79.31	Secondary malignant neoplasm of brain
C79.49	Secondary malignant neoplasm of other parts of nervous system [includes spinal cord]
C79.51 - C79.52	Secondary malignant neoplasm of bone and bone marrow
D16.6	Benign neoplasm of vertebral column [excludes sacrum and coccyx]
D16.8	Benign neoplasm of pelvic bones, sacrum, and coccyx
D32.1	Benign neoplasm of spinal meninges
D33.4	Benign neoplasm of spinal cord
D42.0 - D42.9	Neoplasm of uncertain behavior of meninges

D43.0 - D43.2	Neoplasm of uncertain behavior of brain
D43.4	Neoplasm of uncertain behavior of spinal cord
D49.7	Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system
G00.0 - G99.8	Diseases of the nervous system
G83.4	Cauda equina syndrome
M43.06 - M43.08	Spondylolysis, lumbar, lumbosacral, sacral and sacrococcygeal, region
M43.10 - M43.19	Spondylolisthesis [acquired]
M43.27 - M43.28	Disorders of sacrum
M53.2x7 - M53.2x8 M53.87 - M53.88	
M43.8x9	Other specified deforming dorsopathies, site unspecified
M48.00 - M48.01 M48.03 - M48.08	Spinal stenosis, other than cervical
M48.02	Spinal stenosis, cervical region
M50.00 - M50.03	Cervical disc disorder with myelopathy
M50.20 - M50.23	Other cervical disc displacement
M51.04 - M51.05	Thoracic, thoracolumbar intervertebral disc disorder with myelopathy
M51.24 - M51.25	Other thoracic, thoracolumbar disc displacement
M53.2x7 - M53.2x8	Spinal instabilities, lumbosacral, sacral, sacrococcygeal region
M54.03 - M54.09, M62.830	Other symptoms referable to back
M54.5	Low back pain [lumbago]
M54.6	Pain in thoracic spine
M54.89 - M54.9	Other and unspecified dorsalgia
M96.1	Postlaminectomy syndrome, not elsewhere classified
O01.9 - O94	Complications of pregnancy, childbirth, and the puerperium
Q76.2	Congenital spondylolisthesis
R29.810 - R29.898	Other symptoms and signs involving the nervous and musculoskeletal systems
Z34.00 - Z34.93	Encounter for supervision of normal pregnancy

Percutaneous lumbar discectomy or laser-assisted disc decompression (LADD):

CPT codes covered if selection criteria are met:

62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)

Other CPT codes related to the CPB:

62267	Percutaneous aspiration within the nucleus pulposus, intervertebral disc, or paravertebral tissue for diagnostic purposes
62303 - 62305	Myelography via lumbar injection, including radiological supervision and interpretation
63001 - 63091	Laminectomy, discectomy and related procedures (eg, decompression of spinal cord)
63185 - 63190	Laminectomy with rhizotomy
72125 - 72133	Computed tomography, spine
72141 - 72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents

72240 - 72270	Myelography of spine
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)

HCPCS codes not covered for indications listed in the CPB:

G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

Other HCPCS codes related to the CPB:

C2614	Probe, percutaneous lumbar discectomy

ICD-10 codes covered if selection criteria are met:

M51.06 - M51.07	Intervertebral disc disorder with myelopathy, lumbar/lumbosacral region
M51.26- M51.27	Other intervertebral disc displacement, lumbar/lumbosacral regions

Minimally Invasive Lumbar Decompression (MILD):

CPT codes not covered for indications listed in the CPB:

0274T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T	lumbar

Radiofrequency facet denervation:

CPT codes covered if selection criteria are met:

64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64635	lumbar or sacral, single facet joint
64636	lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)

Other CPT codes related to the CPB:

22548 - 22812	Arthrodesis, vertebra
62302 - 62305	Myelography via lumbar injection, including radiological supervision and interpretation
64479 - 64484	Injection, anesthetic agent and/or steroid, transforaminal epidural
72125 - 72133	Computed tomography, spine
72141 - 72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents
72240 - 72270	Myelography of spine
97001 - 97139	Physical medicine and rehabilitation modalities and therapeutic procedures

Other HCPCS codes related to the CPB:

L0112 - L0999	Orthotic devices-spinal

ICD-10 codes covered if selection criteria are met:

M53.0 - M53.1	Cervicocranial - cervicobrachial syndrome
M53.81 - M53.83	Other specified dorsopathies [cervical region]
M54.2	Cervicalgia

M54.30 - M54.5	Sciatica and lumbago
M54.6	Pain in thoracic spine
M54.9	Dorsalgia, unspecified [backache]

ICD-10 codes not covered for indications listed in the CPB:

M43.27 - M43.29 M53.2x7 - M53.2x8 M53.87 - M53.88	Disorders of sacrum
M50.00 - M51.9	Intervertebral disc disorders

Pedicle screws for spinal fixation:

CPT codes covered if selection criteria are met:

22840 - 22847	Spinal instrumentation

Other CPT codes related to the CPB:

22548 - 22812	Arthrodesis, vertebra
63001 - 63091	Laminectomy, discectomy and related procedures (eg, decompression of spinal cord)

HCPCS codes covered if selection criteria are met:

Pedicle screw systems - no specific code (not all inclusive):

(e.g. Apex Deformity Spine System, Cervifix Cervical Spine Locking Plate (CSLP), Preference Pedicle Screw System)

ICD-10 codes covered if selection criteria are met:

M40.00 - M40.57	Kyphosis and lordosis [requiring spinal instrumentation]
M41.00 - M41.9	Idiopathic scoliosis [infantile, juvenile/adoloescent, thoracogenic, neuromuscular]
M43.00 - M43.19	Acquired spondylolisthesis [grades I-IV]
M96.1	Postlaminectomy syndrome, not elsewhere classified
Numerous options (7th character must be "K")	Nonunion of fractures [pseudoarthrosis]
Q67.5	Congenital deformities of spine
Q76.2	Congenital spondylolisthesis
Q76.411 - Q76.419	Congenital kyphosis [not associated with scoliosis]
Q76.49	Other congenital malformations of spine, not associated with scoliosis
S12.000+ - S12.691+ S12.9xx+, S22.000+ - S22.089+ S32.000+ - S32.2xx+	Fracture of vertebral column, without mention of spinal cord injury
S13.100+ - S13.181+ S23.100+ - S23.171+ S33.100+ - S33.39x+	Dislocation of vertebrae

ICD-10 codes not covered for indications listed in the CPB:

M50.30 - M50.33 M51.34 - M51.37	Other disc degeneration
M54.5	Low back pain [lumbago]

Transforaminal lumbar interbody fusion:

CPT codes covered if selection criteria are met:

22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)

ICD-10 codes covered if selection criteria are met:

C41.2	Malignant neoplasm of vertebral column, excluding sacrum and coccyx
C70.1	Malignant neoplasm of spinal meninges
C79.31 - C79.32	Secondary malignant neoplasm of brain and spinal cord
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.51 - C79.52	Secondary malignant neoplasm of bone and bone marrow
D32.1	Benign neoplasm of spinal meninges
D33.4	Benign neoplasm of spinal cord
D42.0 - D42.9	Neoplasm of uncertain behavior of meninges
D43.0 - D43.2, D43.4	Neoplasm of uncertain behavior of brain and spinal cord
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
G06.1	Intraspinal abscess and granuloma
M40.50 - M40.57	Lordosis, unspecified
M41.00 - M41.35, M41.80 - M41.9	Scoliosis
M43.00 - M43.19	Spondylolysis and spondylolisthesis
M46.20	Osteomyelitis of vertebra, site unspecified
M46.30	Infection of intervertebral disc (pyogenic), site unspecified
M48.06 - M48.07	Spinal stenosis, lumbar and lumbosacral region
M48.50x+ - M48.58x+, M80.08x+, M84.48x+, M84.58x+, M84.68x+	Pathologic fracture of vertebrae
M86.18	Other acute osteomyelitis, other site [spinal]
M86.28	Subacute osteomyelitis, other site [spinal]
M86.68	Other chronic osteomyelitis, other site [spinal]
M96.0	Pseudoarthrosis after fusion or arthrodesis
M96.5	Postradiation scoliosis
Numerous options	Nonunion of fracture [Codes not listed due to expanded specificity]
Q76.2	Congenital spondylolisthesis
S31.000+	Unspecified open wound of lower back and pelvis without penetration into retroperitoneum
S32.000+ - S32.059+	Fracture of lumbar vertebra
S33.100+ - S33.141+	Subluxation and dislocation of lumbar vertebra
S34.101+ - S34.129+	Other and unspecified injury of lumbar spinal cord
Z98.1	Arthrodesis status

Intervertebral body fusion devices:

CPT codes covered if selection criteria are met:

22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)

Other CPT codes related to the CPB:

20936 - 20938	Autograft for spine surgery

HCPCS codes covered if selection criteria are met:

Spine Cages - no specific code (not an all-inclusive list):

(e.g., BAK Interbody Fusion System, Ray Threaded Fusion Cage, STALIF stand-alone anterior lumbar fusion cage, carbon fiber cage)

ICD-10 codes covered if selection criteria are met:

M25.78	Osteophyte, vertebrae [of spine causing spinal cord or nerve root compression, confirmed by imaging studies] [see criteria in CPB 743]
M50.00 - M50.03	Cervical disc disorders with myelopathy [see criteria in CPB 743]
M50.20 - M50.23	Other cervical disc displacement [see criteria in CPB 743]
M51.34 - M51.37	Other thoracic, thoracolumbar and lumbosacral intevertebral disc degeneration [see criteria in CPB 743]
M54.11 - M54.13	Radiculopathy, cervical region [see criteria in CPB 743]
Q76.2	Congenital spondylolisthesis [see criteria in CPB 743]

Percutaneous polymethylmethacrylate vertebroplasty (PPV) or kyphoplasty:

CPT codes covered if selection criteria are met:

22510 - 22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic or lumbosacral
22512	each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)
22513 - 22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic or lumbar
22515	each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

ICD-10 codes covered if selection criteria are met:

C41.2	Malignant neoplasm of vertebral column

C41.4	Malignant neoplasm of pelvic bones, sacrum, and coccyx
C70.1	Malignant neoplasm of spinal meninges
C72.0	Malignant neoplasm of spinal cord
C79.31	Secondary malignant neoplasm of brain
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.51 - C79.52	Secondary malignant neoplasm of bone and bone marrow
C83.30 - C95.92	Malignant neoplasm of lymphoid, hematopoietic and related tissue
D18.09	Hemangioma of other sites [painful and/or aggressive]
E88.89	Other specified metabolic disorders [painful vertebral eosinophilic granuloma]
M48.30 - M48.38	Traumatic spondylopathy
M48.50x+ - M48.58x+ M80.08+, M80.88x+ M84.58x+, M84.68x+	Pathological fracture of vertebra(e) [painful, debilitating osteoporotic collapse/compression fractures]
M81.0 - M81.8	Osteoporosis
S12.000+ - S12.691+ S12.9xx+, S22.000+ - S22.089+ S32.000+ - S32.2xx+	Fracture of vertebral column, without mention of spinal cord injury [steroid-induced] [with spinal cord injury, use spinal cord injury codes also]

ICD-10 codes not covered for indications listed in the CPB:

M50.20 - M51.9	Intervertebral disc disorders

Endoscopic Spinal surgery:

Other CPT codes related to the CPB:

62267	Percutaneous aspiration within the nucleus pulposus, intervertebral disc, or paravertebral tissue for diagnostic purposes
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)

Vertebral body replacement spacers (e.g., AVS AL PEEK Spacer):

No specific code

ICD-10 codes covered if selection criteria are met:

M43.8X9	Other specified deforming dorsopathies, site unspecified [damaged or unstable vertebral body resected or excised during total and partial vertebrectomy procedures]
M48.50x+ - M48.58x+	Collasped vertebra, not elsewhere classified

Experimental and Investigational Interventions for treatment of back pain:

Chronic Back Pain:

Other CPT codes related to the CPB:

96365 - 96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis

HCPCS codes not covered for indications listed in the CPB:

J2001	Injection, lidocaine HCL for intravenous infusion 10 mg

ICD-10 codes not covered for indications listed in the CPB:

M54.5	Low back pain
M54.9	Dorsalgia, unspecified

Endoscopic transforaminal diskectomy:

CPT codes not covered for indications listed in the CPB:

62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar [not covered for endoscopic transforaminal discectomy]

Other CPT codes related to the CPB:

96365 - 96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug [magnesium, Toradol and vitamin B12 cyanocobalamin] for the treatment of back pain)

HCPCS codes not covered for indications listed in the CPB:

J1885	Injection, ketorolac tromethamine per 15 mg [Toradol]
J3420	Injection, vitamin B-12 cyanocobalamin, up to 1000 mg
J3475	Injection, magnesium sulfate, per 500 mg

ICD-10 codes not covered for indications listed in the CPB:

M54.5	Low back pain
M54.9	Dorsalgia, unspecified

Minimally Invasive Thoracic diskectomy:

CPT codes not covered for indications listed in the CPB:

22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic

Percutaneous cervical diskectomy:

Minimally Invasive Lumbar Decompression (MILD):

CPT codes not covered for indications listed in the CPB:

0274T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T	lumbar

HCPCS codes not covered for indications listed in the CPB:

G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

Epiduroscopy:

Other CPT codes related to the CPB:

62318	Injection, including catheter placement, continuous infusion or intermittent bolus, not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid; cervical or thoracic

62319	lumbar, sacral (caudal)
72275	Epidurography, radiological supervision and interpretation

Epidural injections of lytic agents:

CPT codes not covered for indications listed in the CPB:

62280	Injection/infusion of neurolytic substance (eg, alcohol, phenol, iced saline solutions), with or without other therapeutic substance; subarachnoid Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation [not covered for chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate) of facet joints]
62281	epidural, cervical or thoracic [not covered for chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate) of facet joints]
62282	epidural, lumbar, sacral (caudal) [not covered for chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate) of facet joints]

Other CPT codes related to the CPB:

72275	Epidurography, radiological supervision and interpretation

HCPCS codes not covered for indications listed in the CPB:

J3470	Injection, hyaluronidase, up to 150 units
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 USP unit (up to 999 USP units)
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 USP units
J3473	Injection, hyaluronidase, recombinant, 1 USP unit

ICD-10 codes not covered for indications listed in the CPB:

G03.0 - G03.9	Meningitis due to other and unspecified causes
M43.00 - M43.9	Dorsopathies
M54.10	Radiculopathy, site unspecified
M79.2	Neuralgia and neuritis, unspecified
S12.000S - S12.691S S12.9xxS, S22.000S - S22.089S S32.000S - S32.2xxS	Fracture of vertebral column, sequela
S39.002+ - S39.003+ S39.092+ - S39.093+ S39.82x+ - S39.83x+ S39/92x+ - S39.93x+	Other injuries of other sites of trunk

Microsurgical anterior foraminotomy:

Nospecific codes

Other CPT codes related to the CPB:

63075 - 63078	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy

Other HCPCS codes related to the CPB:

S2350	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace
S2351	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, each additional interspace (list separately in addition to code for primary procedure)

Sacroiliac fusion:

CPT codes not covered for indications listed in the CPB:

27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed [may be medically necessary for sacroiliac joint infection, tumor involving the sacrum, and sacroiliac pain due to severe traumatic injury where a trial of an external fixator is successful in providing pain relief]

Sacroplasty:

CPT codes not covered for indications listed in the CPB:

0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

Racz procedure (epidural adhesiolysis with the Racz catheter):

CPT codes not covered for indications listed in the CPB:

62263	Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days
62264	1 day

Other CPT codes related to the CPB:

72275	Epidurography, radiological supervision and interpretation

Microdiskectomy:

Other CPT codes related to the CPB:

22220 - 22226	Osteotomy of spine, including discectomy, anterior approach
62267	Percutaneous aspiration within the nucleus pulposus, intervertebral disc, or paravertebral tissue for diagnostic purposes
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)
+ 69990	Operating microscope
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)

Other HCPCS codes related to the CPB:

C2614	Probe, percutaneous, lumbar discectomy
S2350	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace
S2351	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, each additional interspace (list separately in addition to code for primary procedure)

Microendoscopic discectomy (MED):

Other CPT codes related to the CPB:

22206	Osteotomy of spine, posterior or posterolateral approach, three columns, one vertebral segment (eg, pedicle/vertebral body subtraction); thoracic
22207	lumbar
+ 22208	each additional vertebral segment (List separately in addition to code for primary procedure)
22214	Osteotomy of spine, posterior or posterolateral approach, one vertebral segment; lumbar
+ 22216	each additional vertebral segment (List separately in addition to primary procedure)
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar
+ 22226	each additional vertebral segment (List separately in addition to code for primary procedure)
62287	Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)
+ 69990	Operating microscope
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)

Other HCPCS codes related to the CPB:

C2614	Probe, percutaneous, lumbar discectomy
S2350	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace
S2351	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, each additional interspace (list separately in addition to code for primary procedure)

Intercostal nerve blocks:

CPT codes not covered for indications listed in the CPB:

64420	Injection, anesthetic agent; intercostal nerve single
64421	intercostal nerves, multiple, regional block

ICD-10 codes not covered for indications listed in the CPB:

G54.8	Other nerve root and plexus disorders [intercostal neuritis]

Inter-spinous distraction (X Stop Device, Coflex interspinous stablilization spinal implant, Extensure bone allograft inter-spinous spacer, Eclipse inter-spinous distraction device, and the TOPS System):

CPT codes not covered for indications listed in the CPB:

22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level

22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine

HCPCS codes not covered for indications listed in the CPB:

C1821	Interspinous process distraction device (implantable)

Piriformis muscle resection:

No specific codes

CPT codes not covered for indications listed in the CPB:

27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)
64712	Neuroplasty, major peripheral nerve, arm or leg, open; sciatic nerve [not covered for surgery for piriformis syndrome]

ICD-10 codes not covered for indications listed in the CPB:

G57.00 - G57.03	Lesion of sciatic nerve
M25.751 - M25.759	Osteophyte, hip
M54.30 - M54.32	Sciatica
M70.60 - M70.72	Trochanteric and other bursitis
M76.00 - M76.22	Enthesopathies, hip

Radiofrequency denervation for sacroiliac joint pain:

CPT codes not covered for indications listed in the CPB:

27035	Denervation, hip joint, intrapelvic or extrapelvic intrarticular branches of sciatic, femoral, or obturator nerves [not covered when specified as radiofrequency denervation for sacroiliac pain]

ICD-10 codes not covered for indications listed in the CPB:

G57.00 - G57.03	Lesion of sciatic nerve
M25.751 - M25.759	Osteophyte, hip
M54.14 - M54.17	Radiculopathy, thoracic or lumbosacral region
M54.30 - M54.32	Sciatica
M70.60 - M70.72	Trochanteric and other bursitis
M72.9	Neuralgia and neuritis, unspecified
M76.00 - M76.22	Enthesopathies, hip

Facet joint implantation:

CPT codes not covered for indications listed in the CPB:

0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
0220T	thoracic
0221T	lumbar
0222T	each additional vertebral segment (List separately in addition to code for primary procedure)

Epidural fat grafting :

Other CPT codes related to the CPB:

20926	Tissue grafts, other (e.g., paratenon, fat, dermis) [not covered during lumbar decompression laminectomy/discectomy]

Endoscopic disc decompression :

CPT codes not covered for indications listed in the CPB:

62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar

No specific codes:

AccuraScope procedure, ACIS cage (Synthes), Ancora spacer, Aspen spinous process fixation system, Barricaid and DART disc annular repair devices, Brantigan, Brigade anterior plate system, Brigade (Nuvasive), Cambria anterior cervical interbody system, Cavetto cage, Centerpiece plate, Crescent cage, CD HORIZON SPIRE Plate, PrimaLOK SP, and SP-Fix Spinous Process Fixation Plate, Coccygeal ganglion (ganglion impar) blockade for pelvic pain, Degas plate, Deuk Laser Disc Repair, Diamond (Amendia), DiscFX System, Dynamic (intervertebral) stabilization devices -- BioFlex, CD Horizon Agile Dynamic Stabilization Device, Dynamic stabilization (e.g., Dynesys Spinal System and the Stabilimax NZ Dynamic Spine Stabilization System), Ebi PEEK optima spacer, Ellipse Occipito-Cervical-Thoracic spinal system, Endoscopic laser foraminoplasty, EOS spinal system (Korean Bone Bank), Epidural ozone, Extreme lateral interbody fusion (XLIF), G surgical plate system T loc, Illico pedicle screw system (Alphatec), IN:C2 spacer, Interlaminiar lumbar instrumented fusion (ILIF), Invizia plate, Kinetic-SL Dynamic Anterior Cervical Plate System, LINDIF, OptiMesh grafting system, Oxygen injection, Psoas compartment block, Radiofrequency lesioning of dorsal root ganglia, Radiofrequency lesioning of terminal (peripheral) nerve endings, Radiofrequency/pulsed radiofrequency ablation of trigger points, Stabilink interspinous fixation device, Total Facet Arthroplasty System, TSRH 3DX pedicle screws (Medtronic), Van Gogh plate, Vesselplasty (e.g., Vessel-X), Yeung Endoscopic Spinal Surgery System, Y.E.S.S., Xclose Tissue Repair System, Zeus C cervical spacer

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Facet Joint Injections

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Policy History

- Last Review 12/23/2016
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- Review History
- Definitions

Additional Information

- Clinical Policy Bulletin Notes