SPINE®
CONCEPTS

AXIS-C®

CERVICAL DISC PROSTHESIS

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Description

AXIS-C®

The Axis-C Cervical Disc Prosthesis is designed to replace the damaged cervical disc and optimally restore the natural movement of the spine, accurately replicating the body's physiological biomechanics.

Manufactured with titanium and carbon, it ensures excellent biocompatibility, strength, and durability, providing confidence for both the surgeon and the patient.

Functionality

Functionality of the prosthesis

The Axis-C prosthesis replaces the native disc, maintaining segmental motion and decreasing the risk of adjacent-level degeneration, a common complication in traditional fusion techniques.

The surgery is minimally invasive, allowing faster recovery starting in the first hours after the procedure.

Objectives of the procedure

- Significantly reduce or eliminate pain.
- Remove the damaged disc and restore disc height.
- Maintain mobility of the affected vertebral segment.

Eligible patients

Candidate patients for the intervention

- Patients with skeletal maturity.
- Between 22 and 66 years old.
- Symptomatic intractable cervical disc disease (SCDD).
- Cervical disc herniation.
- Failed arthrodesis.
- Myelopathy associated with spondylotic stenosis of the canal or foramen.
- Radiculopathy with neurological deficit resistant to conservative treatment.
- Pathology in one or two cervical levels.
- Visible loss of disc height compared with adjacent levels.
- Degenerative disc disease.
- Cervical instability.
- Patients with congenitally or surgically fused adjacent levels.
- For primary surgery of degenerative disc disease or extensive anterior decompression.
- Having presented progressive signs or symptoms despite non-surgical treatment.
- Having failed at least 6 weeks of conservative treatment before considering the prosthesis.

Frequent symptoms and pain in candidate patients

- Constant or intermittent neck pain.
- Cervical stiffness or “locked neck.”
- Radicular pain toward the arms.
- Pain radiating to the shoulder, arm, or hand.
- Pain when coughing, sneezing, or straining.
- Tingling, numbness, or loss of sensation.
- Weakness in arms or hands.
- Difficulty gripping objects or performing fine motor tasks.
- Inter-scapular pain.
- Pain between shoulder blades.
- Hand clumsiness.
- Gait imbalance.
- Sensation of tight bands in arms or legs.
- Cervicogenic headache.

Benefits

Short term

- Rapid relief of nerve pain (radiculopathy).
- Improvement of arm pain within hours or days.
- Faster recovery than traditional fusion.
- Light daily activities in 1–2 weeks.
- Less postoperative stiffness.
- Return to administrative work in 2–4 weeks.

Long term

- Lower risk of adjacent segment disease.
- Preservation of movement at the treated level.
- Lower need for additional surgeries (vs. ACDF).
- Maintenance of cervical mobility.
- Long durability of the prosthesis.
- Reduction of chronic pain.
- Greater functionality and quality of life.
- Low reoperation rate.

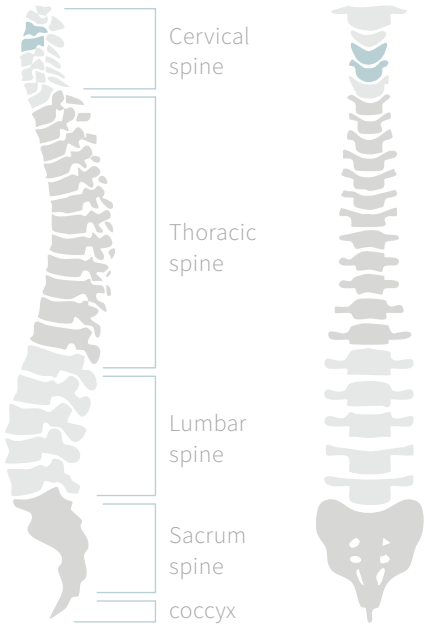
Procedure success

Cervical disc prosthesis surgery is considered successful when:

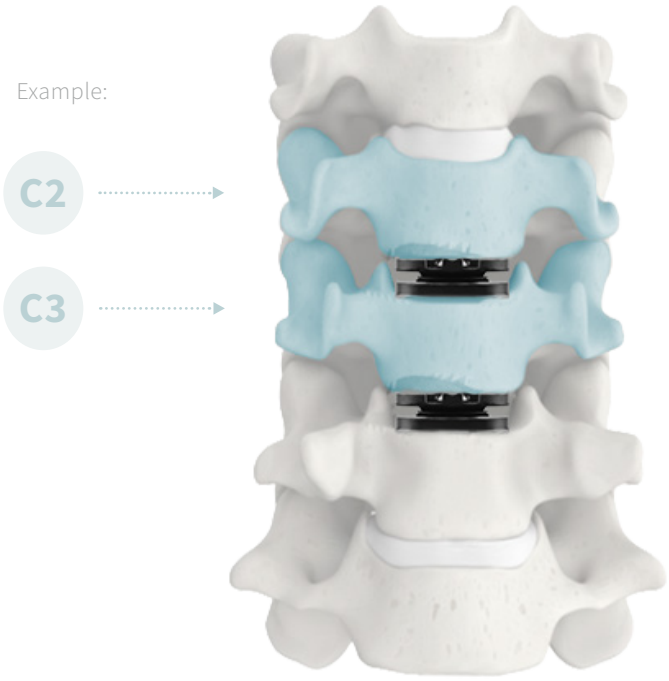
- Mobility is maintained.
- Significant pain relief.
- Complications or need for fusion are avoided.
- The patient regains functionality.

Product information

Levels of use: **Cervical spine (C2 - C7)**



Example:



Materials: **Titanium and carbon.**

Titanium is primarily used to:

It is highly biocompatible, meaning the body accepts it very well.

It promotes osteointegration, allowing the bone to naturally adhere to the prosthesis.

It has excellent mechanical strength, supporting repetitive neck loads and movements without deforming.

It is corrosion-resistant, making it ideal for remaining inside the body for a lifetime.

It allows for radiopaque markers, which help visualize the prosthesis on X-rays or fluoroscopy.

Carbon allows for:

Mimicking the elasticity of bone, better absorbing loads and preventing excessive stress on the vertebrae.

Reducing imaging artifacts, enabling clearer radiological studies and postoperative follow-up.

Making the prosthesis lighter without compromising strength or durability.

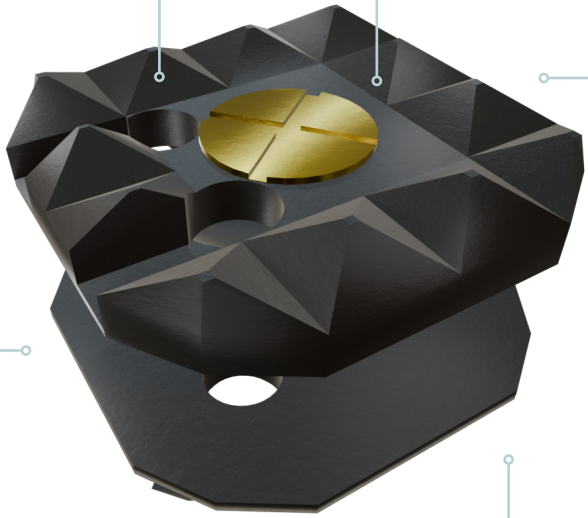
Decreasing excessive rigidity, supporting a more natural cervical spine biomechanics.

Plasma Sprayed Titanium and Hydroxyapatite Coated Endplates

- Encourage bony ongrowth for long term stability.

Superior Dome

- Designed to match the natural, bony anatomy, enabling short and long term stability.



Lateral Inclined Teeth

- The teeth purchase in to the apophyseal ring to provide initial stability.
- Designed to resist migration.

Patented, Mobile Bearing Core

- Ultra-high Molecular Weight Polyethylene insert.
- Domed surface designed to articulate angulary with the superior endplate.
- Flat bottom designed to translate up to 1 mm and rotate on the inferior endplate.

Intact Endplates

- Cobalt Chromium Molybdenum Alloy endplates.
- Tabs provide a safety stop designed to control mobility and to resist expulsion.

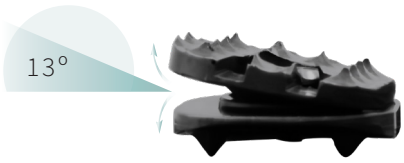
Components and their benefit

Available sizes (mm):

- 14 x (4 - 8) mm.
- 16 x (4 - 8) mm.

Mobility and ranges of motion:

A 13° angulation in both the sagittal and coronal planes helps maintain the natural physiological range of a healthy cervical disc.



Absorption or compression capacity:

- 13 degrees of freedom.
- Shock absorption.
- Controlled resistance to rotational and translational movements.
- Adaptative center of rotation.
- No wear debris linked to friction.

Recommendations

Patient selection:

Proper patient selection and adherence to postoperative treatment directly influence outcomes.

Patients outside the established criteria

Patients who have or present:

- Systemic or local infection at the surgical site.
- Osteoporosis (DEXA T ≤ -2.5).
- Cervical instability with translation >3 mm or rotation >11°.
- Senile problems.
- Known allergy or sensitivity to prosthesis materials.
- Vertebral bodies compromised at the treatment level due to previous cervical trauma, significant anatomical deformity, or disease.
- Severe facet joint disease or degeneration.
- Severe spondylosis (bridging osteophytes or disc height loss >50%).
- Alcoholism or drug abuse.
- Severe mental illness.
- Advanced degeneration limiting prosthesis lifespan.
- Severe cervical deformity.
- Previous cervical spine surgery, including surgery at the affected level.

Surgical indications

Includes warnings for use, decontamination, cleaning, sterilization protocols, and essential preoperative considerations.

Decontamination, cleaning, and sterilization

Decontamination: Immerse prostheses and instruments in a bactericidal and fungicidal solution, such as 0.5% diluted didecyldimethylammonium chloride (5 mL per 1 L of warm water). Immersion time: 20 min. Rinse with demineralized water.

Cleaning: Wash prostheses and instruments in an automatic LANCER-type machine using appropriate cleaning products, rinse, and dry. Exclude any product that may damage the material (bleach, formalin…).

Sterilization: We recommend autoclave sterilization for prostheses and instruments:

- Preheating 25’ at 110°C (1 bar)
- Vacuum 5’ (0.8 bar below atmospheric pressure)
- Heating 5’ at 120°C (1 bar)
- Vacuum 5’ (0.8 bar)
- Sterilization 18’ at 134°C (2 bar)
- Drying 20’ back to room temperature.

Preoperative indications:

Preferably perform preoperative AP and lateral radiographs to determine the ideal size of the cervical disc prosthesis to be implanted.

Perform CT or MRI ensuring slices are parallel to vertebral endplates.

A minimum anteroposterior depth of 14 mm is required at the affected level, verified by preoperative radiograph.

Should only be used by surgeons experienced in anterior cervical spine procedures and who have received hands-on training in the use of this device.

Only surgeons familiar with the prosthesis components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks should use it.

Lack of experience or training may increase adverse events, including neurological complications.

Proper size selection is essential for correct device placement and function.

Due to proximity to vascular and neurological structures, there is risk of serious or fatal hemorrhage and neurological injury (care must be taken to identify and protect these structures).

To minimize the risk of periprosthetic vertebral fractures, surgeons must consider comorbidities, past and current medications, and previous treatments.

An osteoporosis screening questionnaire (SCORE) may be used to determine if a DEXA scan is needed.

Patients must be informed about possible adverse effects.

Preoperative planning can be used to estimate prosthesis size and ensure the full size range is available for surgery.

The procedure must not be performed if the appropriate size range is not available.

Operative precautions:

Use aseptic technique when removing the prosthesis from the inner packaging. Carefully inspect each component and packaging for signs of damage, including damage to the sterile barrier.

Do not use the prosthesis if the packaging is damaged or if the prosthesis shows signs of damage.

Handle the prosthesis carefully to avoid contact with objects that may damage it.

Damaged prostheses are no longer functionally reliable. Visual inspection is recommended before implantation.

If any part appears damaged or not fully assembled, do not use it.

To avoid unnecessary damage to bearing surfaces, ensure no tissues or debris remain inside the device.

Prostheses must never be reused or reimplanted.

Perform complete discectomy of the disc space between the uncus and up to the posterior ligament.

Carefully decompress the foramina bilaterally.

Remove all anterior and posterior osteophytes from the superior and inferior endplates.

Adequately cover bleeding with bone wax.

To prevent weakening of vertebral endplates, avoid using a burr during preparation.

Use the Caspar retractor as necessary to maintain or adjust distraction.

Ensure correct alignment and placement of device components, as misalignment may cause excessive wear or premature failure.

Postoperative care:

Patients must be instructed on postoperative care and informed about the importance of following these steps for successful treatment.

- Avoid heavy lifting.
- Avoid repetitive bending.
- Avoid prolonged or strenuous activities initially and for weeks to months depending on individual progress and prosthesis stability/function.

Note for the physician: Although the clinician is the expert intermediary between the company and the patient, the important medical information in this document must be conveyed to the patient.

Possible side effects

Risks associated with cervical disc prosthesis use correspond to adverse events that may occur in any surgical procedure, especially cervical spine surgery:

- Adverse reactions to anesthesia.
- Pulmonary complications such as pneumonia or atelectasis.
- Wound infection.
- Systemic infection.
- Abscess.
- Cellulitis.
- Wound dehiscence.
- Inflammation.
- Wound hematoma.
- Thrombosis.
- Pulmonary ischemia.
- Pulmonary embolism.
- Thromboembolism.
- Hemorrhage.
- Thrombophlebitis.
- Organ damage.
- Spinal cord or nerve root injury.
- Paralysis.

Surgical instruments

*Pending technical info about Surgical Instruments

*Provisional placeholder:

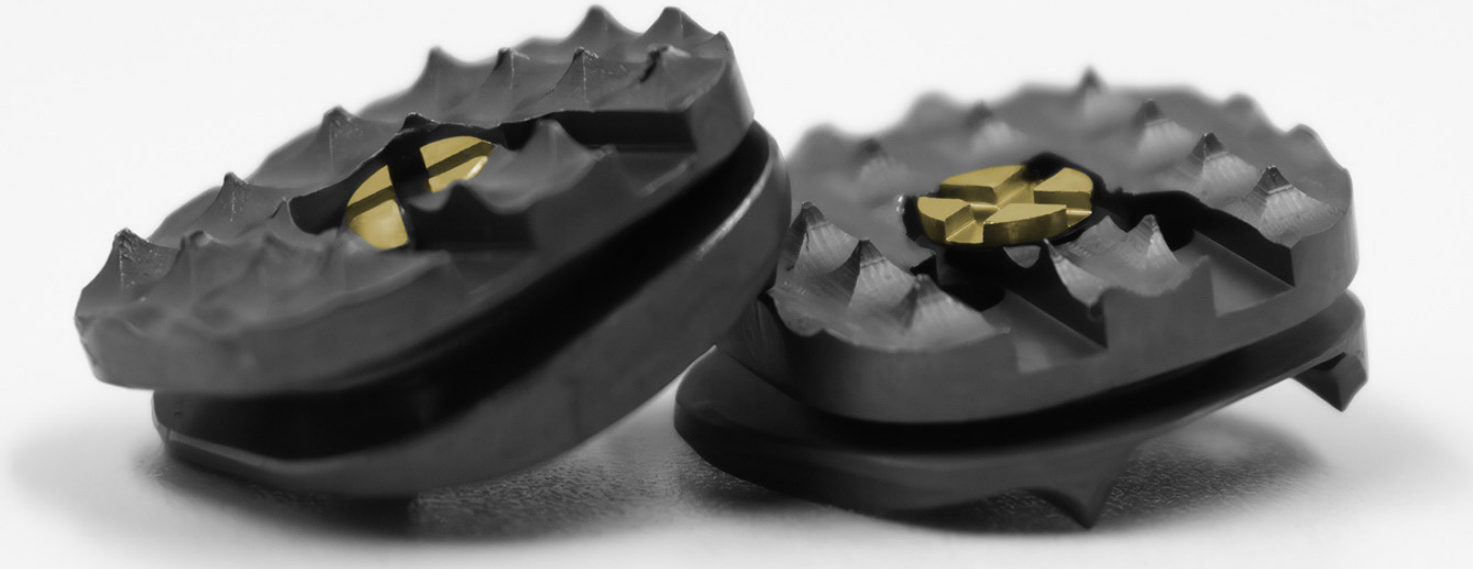
Design Feature	Functional Benefit	Anatomical Consideration
Dual Convexity Plates	Optimized endplate contact	Matches vertebral anatomy
Micro-textured Surface with Fixation Elements	Immediate stability	Resists initial migration
Bidirectional Grooving	Multiplanar migration resistance	Addresses physiological force vectors
Comprehensive Sizing Range	Anatomical matching	Accommodates patient variability

Summary

The AXIS-C® Cervical Disc Prosthesis integrates refined engineering principles with clinical requirements to address the complex challenges of cervical disc arthroplasty. Through its anatomical design, comprehensive fixation system, and preservation of physiological motion characteristics, the device aims to provide a functional solution for degenerative cervical pathology while maintaining segmental mobility.

The systematic approach to indications, contraindications, and surgical technique emphasizes the importance of appropriate patient selection and meticulous surgical execution in achieving optimal clinical outcomes. The provided information is intended to support medical professionals in understanding the device characteristics, applications, and technical considerations relevant to its use in clinical practice.

This document is intended for medical professionals only. The product is intended for use by qualified healthcare providers with appropriate training in spinal surgical procedures. For complete information regarding technique, warnings, precautions, and potential adverse events, please consult the full Instructions for Use provided with the product.



POLYAXIAL PEDICLE SCREW EX

CATALOG NO.	DESCRIPTION	Ø	SIZE
4545-30760	Polyaxial pedicle screw EX		60mm
4545-30765	Polyaxial pedicle screw EX		65mm
4545-30770	Polyaxial pedicle screw EX	Ø 7.5	70mm
4545-30775	Polyaxial pedicle screw EX		75mm
4545-30780	Polyaxial pedicle screw EX		80mm
4545-30835	Polyaxial pedicle screw EX		35 mm
4545-30840	Polyaxial pedicle screw EX		40 mm
4545-30845	Polyaxial pedicle screw EX		45 mm
4545-30850	Polyaxial pedicle screw EX		50 mm
4545-30855	Polyaxial pedicle screw EX	Ø 8.5	55 mm
4545-30860	Polyaxial pedicle screw EX		60 mm
4545-30865	Polyaxial pedicle screw EX		65 mm
4545-30870	Polyaxial pedicle screw EX		70 mm
4545-30875	Polyaxial pedicle screw EX		75 mm
4545-30880	Polyaxial pedicle screw EX		80 mm

SET SCREW

CATALOG NO.	DESCRIPTION
4545-10001	Set screw

ROD CURVED

CATALOG NO.	DESCRIPTION	Ø	SIZE
4545-31040	Rod Curved		40mm
4545-31045	Rod Curved		45mm
4545-31050	Rod Curved		50mm
4545-31055	Rod Curved		55mm
4545-31060	Rod Curved		60mm
4545-31065	Rod Curved		65mm
4545-31070	Rod Curved		70mm
4545-31075	Rod Curved		75mm
4545-31080	Rod Curved		80mm
4545-31085	Rod Curved		85mm
4545-31090	Rod Curved		90mm
4545-31095	Rod Curved		95mm
4545-31100	Rod Curved		100mm
4545-31110	Rod Curved	Ø 5.5	110mm
4545-31120	Rod Curved		120mm
4545-31130	Rod Curved		130mm
4545-31140	Rod Curved		140mm
4545-31150	Rod Curved		150mm
4545-31160	Rod Curved		160mm
4545-31170	Rod Curved		170mm
4545-31180	Rod Curved		180mm
4545-31190	Rod Curved		190mm
4545-31200	Rod Curved		200mm
4545-31250	Rod Curved		250mm
4545-31300	Rod Curved		300mm
4545-31350	Rod Curved		350mm
4545-31400	Rod Curved		400mm

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CERVICAL DISC PROSTHESIS

SPINE®
CONCEPTS

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251 Little Falls Drive
Wilmington, DE 19808, USA

Phone: (302) 202-9212

Toll free: (888) 368-0323