US Patent & Trademark Office
Patent Public Search | Text View

United States Patent	12383410
Kind Code	B2
Date of Patent	August 12, 2025
Inventor(s)	Ehteshami; John R. et al.

Dynamic inter vertebral spacer implant

Abstract

Intervertebral spacer implants with dynamic load spreading features responsive to external loads and having attachment mechanisms. The dynamic load spreading features having a native state and a loaded state, which complements vertebral end plate geometry and disperses load to the epiphyseal rim.

Inventors: **Ehteshami; John R. (Paradise Valley, AZ), Zoghi; Mahyar (Phoenix, AZ)**

Applicant: **Additive Implants, Inc.** (Phoenix, AZ)

Family ID: **1000008747799**

Assignee: **Additive Implants, Inc. (Phoenix, AZ)**

Appl. No.: **17/589264**

Filed: **January 31, 2022**

Prior Publication Data

Document Identifier	Publication Date
US 20220151798 A1	May. 19, 2022

Related U.S. Application Data

continuation parent-doc US 16580865 20190924 US 11234838 child-doc US 17589264 continuation parent-doc US 16125640 20180907 US 10299938 20190528 child-doc US 16383142 continuation-in-part parent-doc US 16383142 20190412 US 11045328 20210629 child-doc US 16580865

Publication Classification

Int. Cl.: **A61F2/44** (20060101); A61F2/30 (20060101); A61F2/46 (20060101)

U.S. Cl.:

CPC **A61F2/447** (20130101); **A61F2/442** (20130101); A61F2002/30069 (20130101); A61F2002/30112 (20130101); A61F2002/30179 (20130101); A61F2002/30265 (20130101); A61F2002/30324 (20130101); A61F2002/30593 (20130101); A61F2002/30622 (20130101); A61F2002/30772 (20130101); A61F2002/4629 (20130101)

Field of Classification Search

CPC: A61F (2/447); A61F (2/442)

References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
11432941	12/2021	Biedermann	N/A	A61F 2/446
2020/0093612	12/2019	Blain	N/A	A61F 2/4611

Primary Examiner: Boles; Sameh R

Attorney, Agent or Firm: Maywood IP Law

Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application is a continuation of U.S. patent application Ser. No. 16/580,865 filed on Sep. 24, 2019, entitled DYNAMIC INTERVERTEBRAL SPACER IMPLANT, which is a continuation-in-part of U.S. patent application Ser. No. 16/383,142 filed on Apr. 12, 2019, entitled DYNAMIC INTERVERTEBRAL SPACER IMPLANT, which issued on Jun. 29, 2021 as U.S. Pat. No. 11,045,328. U.S. patent application Ser. No. 16/383,142 is a continuation of U.S. patent application Ser. No. 16/125,640 filed on Sep. 7, 2018, entitled DYNAMIC INTERVERTEBRAL SPACER IMPLANT, which issued on May 28, 2019 as U.S. Pat. No. 10,299,938. (2) The foregoing are incorporated herein by reference as though set forth in their entirety.

TECHNICAL FIELD
(1) The present technology relates to intervertebral spacer implants. More specifically, the present technology relates to spinal interbody fusion implants (spacers) having dynamic elements on at least one side of the implant body. Implants with dynamic or flexible elements allow the spreading of intervertebral load across the end plate of the vertebral body. Increasing the contact area from a point to a large surface and particularly loading the vertebral body toward the outer rim, where the bone density is generally higher, reduces implant subsidence. Additionally, maintaining several points of contact across the end plate reduces implant movement. Lastly, having dynamic elements reduces the overall stiffness of the spacer and allows the bone graft material packed within it to carry part of the load that is being transferred from one adjacent vertebral body to the vertebral body on the opposite side of the spacer. This disclosure is made in the context of intervertebral implants, but the principles disclosed herein are applicable in locations throughout the body.
BACKGROUND

(2) Intervertebral disc pathology can be the result of many factors including injury, aging, environmental factors, tumors, infection, and genetics. Intervertebral disc pathology can result in the absence of physiological loading of vertebral end plates resulting in instability or degenerative changes over time, which may lead to spinal stenosis and neurological complications.
(3) Several surgical techniques have been developed to address intervertebral disc pathology and associated diseases that affect the verbal endplates, to which the discs transmit their load. Spinal decompression with or without disc removal and fusion has become a recognized surgical procedure for mitigating spinal column pain by restoring biomechanical and anatomical integrity to the spine. Spinal fusion is recommended based on a variety of clinical indications. Fusion techniques may involve the excision of intervertebral disc material and the preparation of the disc space for receiving an implant to aid in fusion and transmission of the load from vertebrae and maintain vertebral column shape after the fusion process. The surgically-placed implants (spacers) can rest on the exposed vertebral endplates.
(4) Spinal fusion procedures are generally conducted using a posterior or an anterior approach. Anterior cervical inter-body fusion (ACDF) procedures generally have the advantages of reduced operative times, lower infection rate, and reduced blood loss. Further, anterior procedures do not interfere with the posterior anatomic structure of the spine. Anterior procedures also minimize scarring within the spinal canal and are advantageous from a structural and biomechanical perspective. The generally preferred anterior procedures are particularly advantageous in providing improved access to the disc space, and correspondingly better endplate preparation.
(5) Several inter-body implant systems have been introduced to facilitate inter-body fusion. Traditional threaded implants or cages, of varying shapes and material, are typically packed with bone graft material and surgically placed in the intervertebral disc space. However, a relatively small portion of the vertebral endplate is in contacted with these implants. These implant bodies often engage the softer cancellous bone in the center of the vertebra, rather than the stronger cortical bone, the uncinate process, or the apophyseal rim of the vertebral endplate. The seating of threaded cylindrical implants may also compromise biomechanical integrity by reducing the area in which to distribute mechanical forces, thus increasing the apparent stress experienced by both the implant and vertebrae. Further, a substantial uncontrolled risk of implant subsidence (defined as sinking or settling) into the softer cancellous bone of the vertebral body may arise from such improper seating.
(6) Even open ring-shaped cage or spacer implant systems, generally shaped to mimic the anatomical contour of the vertebral body, lack the ability to complement specific stiffness of the patient's bone. Traditional ring-shaped cages are generally comprised of allograft bone material, harvested from the human donors. Such allograft bone material restricts the usable size and shape of the resultant implant. For example, many of these ring-shaped bones generally have a medial-lateral width of less than 25 mm for the lumbar spine and 14 mm for cervical spine. Therefore, these allograft cages may not be of a sufficient size to contact the strong cortical bone, the uncinate process, or apophyseal rim of the vertebral endplate. These size-limited implant systems may also poorly accommodate related instrumentation such as drivers, reamers, distractors, and the like. For example, these implant systems may lack sufficient structural integrity to withstand repeated impact and may fracture during implantation. Further, other traditional non-allograft ring-shaped cage systems may be size-limited due to various and complex supplemental implant instrumentation, which may obstruct the disc space while requiring greater exposure of the operative field. These supplemental implant instrumentation systems also generally increase the instrument load on the surgeon.
(7) The surgical procedure corresponding to an implant system should preserve as much vertebral endplate bone surface as possible by minimizing the amount of bone removed. This vertebral endplate bone surface, or subchondral bone, is generally much stronger than the underlying cancellous bone. Preservation of the endplate bone stock ensures biomechanical integrity of the

endplates and minimizes the risk of implant subsidence. Thus, proper interbody implant design should provide for optimal seating of the implant while utilizing the maximum amount of available supporting vertebral bone stock.
(8) Traditional interbody spinal implants generally do not seat properly on the preferred structural bone located near the apophyseal rim of the vertebral body, which is primarily composed of preferred dense subchondral bone. Accordingly, there is a need in the art for interbody spinal implants which better utilize the structurally supportive bone of the apophyseal rim.
(9) In summary, separate challenges can be identified as inherent in traditional anterior spinal fusion devices: 1) end-plate preparation; 2) implant retention; 3) implant subsidence; 4) bone graft volume; 5) implant incorporation with vertebral bone; and 6) radiographic visualization.
(10) 1. End-Plate Preparation
(11) There are three traditional end-plate preparation methods. The first is aggressive end-plate removal with box chisel-types of tools to create a match between end-plate geometry and implant geometry. In the process of aggressive end-plate removal, however, the end-plates are typically destroyed. Such destruction means that the load-bearing implant is pressed against soft cancellous bone increasing the risk of implant subsidence.
(12) The second traditional end-plate preparation method preserves the end-plates by just removing cartilage with curettes. The end-plates are concave; hence, if a flat implant is used, the interface will not be well matched and the implant may not be very stable. Even if a convex implant is used, it is very difficult to match the implant geometry with the end-plate geometry, as the end-plate geometry varies from patient-to-patient and on the extent of disease.
(13) The third but lesser used, traditional end-plate preparation method uses threaded fusion cages. The cages are implanted by burring out corresponding threads in the end-plates. This method also violates the structure.
(14) 2. Implant Retention
(15) Traditional implants can migrate and expel out of the intervertebral body space following the path through which the implant was inserted. Typical implants are either threaded into place or have large “teeth” designed to prevent expulsion. Both options can create localized stress risers in the end-plates, increasing the chances of subsidence. The challenge of preventing implant expulsion is especially acute for PEEK implants, because the surface texture of PEEK is very smooth and slippery, with reduced purchase on the adjacent vertebrae.
(16) 3. Implant Subsidence
(17) Subsidence of the implant is a complex issue and has been attributed to many factors. Some of these factors include aggressive removal of the endplate; an implant stiffness significantly greater than the vertebral bone; smaller sized implants which tend to sit in the center of the disc space against the weakest region of the end-plates; and implants with sharp edges which can cause localized stress fractures in the end-plates at the point of contact. The most common solution to the problem of subsidence is to choose a less stiff implant material. This is why PEEK and cadaver bone have become the most common materials for spinal fusion implants. PEEK is less stiff than cortical bone, but more stiff than cancellous bone. PEEK is a preferred choice for loading bone graft within an implant. In accordance with Wolfe's Law, the bone graft within the implant should be loaded in order for it to convert to living bone tissue. Living bone bridging from one vertebral body through the spacer and joining with the second vertebral body is the definition of “interbody fusion” which is one the primary goals of an ACDF procedure.
(18) 4. Bone Graft Volume
(19) Cadaver bone implants are restricted in their size by the bone from which they are machined. Their wall thickness also must be great to create sufficient structural integrity for their desired clinical application. These design restrictions do not leave much room for filling the bone graft material into cortical bone implants. The exposure-driven limitations on implant size narrow the room left inside the implant geometry for bone grafting even for metal implants. Such room is

further reduced in the case of PEEK implants because their wall thickness needs to be greater compared to metal implants due to structural integrity requirements.

(20) 5. Incorporation with Vertebral Bone

(21) In many cases, the typical interbody fusion implant is not able to incorporate with the vertebral bone, even years after implantation. Such inability persists despite the use of a variety of different materials to construct the implants. PEEK has been reported to become surrounded by fibrous tissue which precludes it from incorporating with surrounding bone. Stiff, typically metallic, implants stress shield the bone graft and do not supports its transformation into living bone. In some designs of metal implants, such as those made of commercially pure titanium and titanium alloy, or tantalum and tantalum alloys, have surfaces that allow for bone ingrowth or on-growth and in some case even stimulate bone formation.

(22) 6. Limitations on Radiographic Visualization

(23) For implants made of metal, the metal limits adequate radiographic visualization of the bone graft. Hence it can be difficult to assess fusion, if it is intended to take place. PEEK is radiolucent, so traditional implants made of PEEK need to have radiographic markers embedded into the implants so that implant position can be tracked on an X-ray. Cadaver bone has some radiopacity and does not interfere with radiographic assessment as much as metal implants. Metal implants are dense and inhibit the assessment of boney fusion via x-ray techniques. In addition, they can create significant artifacts when utilizing MRI or CT scans to post-operatively visualize the implant/bone interfaces.

(24) Therefore, a need exists for improvements to interbody implants and the present technology is directed to cure such need.

SUMMARY OF THE INVENTION

(25) The various systems and methods of the present technology have been developed in response to the present state of the art, and in response to the problems and needs in the art that have not yet been fully solved by currently available implants. The systems and methods of the present technology may provide a solution which eases end plate preparation, reduces implant expulsion, improving implant retention, reduces subsidence, allows increased room for bone graft and supports/stimulates bone graft incorporation/fusion, and improves radiographic visualization.

(26) To achieve the foregoing, and in accordance with the technology as embodied and broadly described herein and given the need for an improved interbody spacer implant, this disclosure encompasses improved spinal fusion devices and procedures. In accordance with the disclosure, an interbody spacer implant comprises a body having a generally central axis and a centralized aperture extending through the body near the centralized axis. The body includes a first side having a perimeter and defining a first plane with an opposed second side having a perimeter and defining a second plane. The first side perimeter is connected at a first edge with a perimeter wall and the second side perimeter is connected at a second edge with the perimeter wall. The perimeter wall separates the first side and the second side. The first side further includes at least one lobe extending from the first perimeter toward the generally central axis. The intervertebral spacer implant wherein the at least one lobe may have a base adjacent the perimeter and an end region extending away from the base to a terminus. The base may have a first width and the end region a second width, wherein the first width is greater than that the second width. The base may have a first thickness and the end region a second thickness, wherein the first thickness is greater than the second thickness. The at least one lobe may include a plurality of lobes arranged around the first side perimeter. Each of the plurality of lobes may have a base adjacent the perimeter and an end region extending away from the base to a terminus, and wherein the termini are positioned about the generally central axis. The at least one lobe may extend outward from the first plane. The base may be substantially within the first plane and the end region extends outward from the first plane. The end region may be adapted to contact a first vertebral surface prior to the base or the first edge contacts the first vertebral surface. The end region may be adapted to flex toward the first plane

when the implant is implanted between first and second vertebral bodies and the end region is adapted to have an anti-rotation or anti-movement function when engaged to the first vertebral surface. The at least one lobe may be a cantilever, including a base adjacent the first perimeter, an end region and a terminus. The at least one lobe may be adapted to function as a cantilever when the intervertebral spacer is implanted adjacent a vertebral body, the end region engages the vertebral body before the base or the perimeter, and wherein when the end region engages the vertebral body, the lobe is configured to flex toward the first plane.

(27) In accordance with the disclosure, an intervertebral spacer implant includes a body including a generally central axis and a centralized aperture extending through the body along the generally central axis. The body may further include a first side having a perimeter and defining a first plane, an opposed second side having a perimeter and defining a second plane. The first side perimeter connected at a first edge with a perimeter wall. The second side perimeter connected at a second edge with the perimeter wall, wherein the perimeter wall separates the first side and the second side. The first side further includes at least one lobe extending from the first perimeter into the centralized aperture, toward the generally central axis. The intervertebral spacer implant may further include a first configuration and a second configuration wherein the implant is configured to change from the first configuration to the second configuration during or after implantation, or as fusion occurs, between adjacent vertebral bodies. In the first configuration, the at least one lobe on the first side may extend out of the first plane as the lobe extends from the first perimeter toward the generally central axis and the at least one lobe on the second side may extend out of the second plane as the lobe extends from the second perimeter toward the generally central axis. In the second configuration the at least one lobe of the first side may flex or displace toward the central plane and the at least one lobe of the second side may flex or displace toward the central plane. In the second configuration the first edge and the second edge are configured to disperse a load onto a rim of the first or second vertebral body, respectively. The at least one lobe on the first side may include a first gripper having a gripper base on the lobe and a gripper terminus extending from the base. When changing into the second configuration, the gripper terminus may rotate away from the first edge toward the generally central axis. The intervertebral spacer implant may include a first plow edge near the first edge and a second plow edge near the perimeter wall. The first plow edge and the second plow edge may be separated by a recess.

(28) In accordance with the disclosure, an intervertebral spacer may include a first surface and a second surface connected and separated by a perimeter wall. The first surface may include at least one extension having a first region and a second region. The first region may be adjacent to the perimeter and the second region may extend away from the perimeter. When the implant is implanted adjacent to a vertebral body, the second region is configured to engage the vertebral body before the first region. The first region is capable of transitioning toward the second surface and the second region is capable of transitioning toward the second surface. The first region may require more force to transition than the second region.

(29) In accordance with the disclosure, a method of fusing first and second adjacent vertebral bodies, wherein each vertebral body has endplates facing or opposing one another, includes inserting a spinal spacer into an intervertebral space between the first and second vertebral bodies. The implant is inserted adjacent the concave endplates on the first and second vertebral bodies. The implant includes a body having a generally central axis and a centralized aperture extending through the body near the centralized aperture. The body includes a first side having a perimeter and defining a first plane with an opposed second side having a perimeter and defining a second plane. The first side perimeter is connected at a first edge with a perimeter wall and the second side perimeter is connected at a second edge with the perimeter wall. The perimeter wall separates the first side and the second side. The first side further includes at least one lobe extending from the first perimeter toward the generally central axis. The method includes a step for allowing the first and second vertebral bodies to converge creating a load on the implant. The at least one lobe

engages with one of the concave endplates so that the at least one lobe flexes to a degree commensurate with the increasing load. The method further includes that the implant is in a first native state prior to inserting between the first and second vertebral bodies. The implant transitions to a second loaded state after the first and second vertebral bodies are allowed to converge. In the second loaded state, the at least one lobe is flexed toward a central plane in the implant. The at least one lobe further includes a base adjacent the perimeter, an end region, and a terminus. When the implant transitions to the second loaded state, the base, the end region, and the terminus move relative to one another.

(30) These and other features and advantages of the present technology will become more fully apparent from the following description and appended claims, or may be learned by the practice of the technology as set forth hereinafter.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) Exemplary embodiments of the technology will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings. Understanding that these drawings depict only exemplary embodiments and are, therefore, not to be considered limiting of the invention's scope, the exemplary embodiments of the technology will be described with additional specificity and detail through use of the accompanying drawings in which:

(2) FIG. **1** is a perspective view of an intervertebral spacer implant;

(3) FIG. **2**A is a front perspective view of the implant of FIG. **1**; and FIG. **2**B is a front plan view of the implant of FIG. **1**;

(4) FIG. **3** is a right side plan view of the implant of FIG. **1**;

(5) FIG. **4** is a top plan view of another intervertebral spacer implant;

(6) FIG. **5** is a side perspective view of the implant of FIG. **4**;

(7) FIG. **6** is a top perspective view of yet another intervertebral spacer implant;

(8) FIG. **7**A is a top view of yet another intervertebral spacer implant; FIG. **7**B is an oblique view of the implant of FIG. **7**A; FIG. **7**C is a front view of the implant of FIG. **7**A; FIG. **7**D is a right view of the implant of FIG. **7**A; FIG. **7**E is another oblique view of the implant of FIG. **7**A, from a different direction; and FIG. **7**F is a back view of the implant of FIG. **7**A;

(9) FIG. **8**A is a top view of yet another intervertebral spacer implant; FIG. **8**B is an oblique view of the implant of FIG. **8**A; FIG. **8**C is a front view of the implant of FIG. **8**A; FIG. **8**D is a right view of the implant of FIG. **8**A; FIG. **8**E is another oblique view of the implant of FIG. **8**A, from a different direction; and FIG. **8**F is a back view of the implant of FIG. **8**A;

(10) FIG. **9**A is a top view of yet another intervertebral spacer implant; FIG. **9**B is an oblique view of the implant of FIG. **9**A; FIG. **9**C is a front view of the implant of FIG. **9**A; FIG. **9**D is a right view of the implant of FIG. **9**A; FIG. **9**E is another oblique view of the implant of FIG. **9**A, from a different direction; and FIG. **9**F is a back view of the implant of FIG. **9**A;

(11) FIG. **10**A is a top view of yet another intervertebral spacer implant; FIG. **10**B is an oblique view of the implant of FIG. **10**A; FIG. **10**C is a front view of the implant of FIG. **10**A; FIG. **10**D is a right view of the implant of FIG. **10**A; FIG. **10**E is another oblique view of the implant of FIG. **10**A, from a different direction; and FIG. **10**F is a back view of the implant of FIG. **10**A;

(12) FIG. **11**A is a top view of yet another intervertebral spacer implant; FIG. **11**B is an oblique view of the implant of FIG. **11**A; FIG. **11**C is a front view of the implant of FIG. **11**A; FIG. **11**D is a right view of the implant of FIG. **11**A; FIG. **11**E is another oblique view of the implant of FIG. **11**A, from a different direction; and FIG. **11**F is a back view of the implant of FIG. **11**A;

(13) FIG. **12** is a graph of force versus displacement by finite element analysis of the implant of

FIG. **9**A;
(14) FIG. **13** is a graph of force versus displacement for the implant of FIG. **9**A, a conventional PEEK intervertebral spacer, and a conventional titanium intervertebral spacer, all the same size; and
(15) FIG. **14**A is a finite element analysis contour plot of deformation of the implant of FIG. **9**A under load; and FIG. **14**B is a line drawing corresponding to FIG. **14**A, with iso-deflection lines.
DETAILED DESCRIPTION
(16) Exemplary embodiments of the technology will be best understood by reference to the drawings, wherein like parts are designated by like numerals throughout. It will be readily understood that the components of the technology, as generally described and illustrated in the figures herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description of the embodiments of the apparatus, system, and method is not intended to limit the scope of the invention, as claimed, but is merely representative of exemplary embodiments of the technology.
(17) The phrases "connected to," "coupled to" and "in communication with" refer to any form of interaction between two or more entities, including mechanical, electrical, magnetic, electromagnetic, fluid, and thermal interaction. Two components may be functionally coupled to each other even though they are not in direct contact with each other. The term "abutting" refers to items that are in direct physical contact with each other, although the items may not necessarily be attached together. The term "adjacent" refers to items that are physically near or next to one another and may or may not be in physical contact. The phrase "fluid communication" refers to two features that are connected such that a fluid within one feature is able to pass into the other feature.
(18) The word "exemplary" is used herein to mean "serving as an example, instance, or illustration." Any embodiment described herein as "exemplary" is not necessarily to be construed as preferred or advantageous over other embodiments. While the various aspects of the embodiments are presented in drawings, the drawings are not necessarily drawn to scale unless specifically indicated.
(19) Standard anatomical reference planes and spinal terminology are used in this specification with their customary meanings.
(20) FIGS. **1-3** illustrate, by way of example only, an intervertebral spacer implant **10** for performing an interbody fusion between adjacent vertebral bodies. The implant includes a body **100** with the dimensions of height, width, and length suitable for placement between vertebral bodies. In this example, the height extends along a cephalad-caudal direction, the width extends along a right-left direction, and the length extends along an anterior-posterior direction. The intervertebral spacer implant **10** may be made of any suitable biocompatible material. Various biocompatible materials contemplated include, but are not limited to, poly-ether-ether-ketone (PEEK), other polymers including bioresorbable polymers, ceramics, composites, bone or bone substitute materials, and biocompatible metals including stainless steel, titanium, or tantalum and their alloys. The implant **10** may also include multiple and combinations of the materials. The implant **10** may be manufactured by known methods such as machining, molding, forming, or 3D printing. The implant **10** may be provided in any number of shapes or sizes depending on the specific surgical procedure, need, or patient anatomy. The implant **10** may contain separate radiographic markers of any size of shape suitable to facilitate effective and accurate visualization of implant placement, necessary depending on the base material of the implant.
(21) The intervertebral spacer implant **10** includes a body **100** with a centralized aperture **110**, which is approximately in the center of the body **100**. The centralized aperture may be skewed away from an absolute center of the body **100**. The centralized aperture **110** may be large enough so that the body **100** may be effectively hollow, or the centralized aperture **110** may be small, narrow, or effectively a divot or series of divots in the body **100**, such that the centralized aperture **110** does not pass completely through the body **100**. In this embodiment, the body **100** would not

be hollow or empty. The centralized aperture **110** in any of the contemplated embodiments may allow for bone ingrowth, weight reduction, and space for lobe **150** displacement.

(22) The body **100** includes a leading edge **101** and a trailing edge **102**. In this embodiment, the leading edge **101** may be a posterior side and the trailing edge **102** may be an anterior side. The body **100** includes a first side **120** and a second side **121** opposite one another. The first side **120** may be considered the top or superior aspect of the spacer **100** and the second side **121** may be considered the bottom or inferior aspect of the spacer **100**; however, the top and bottom may also be interchangeable. As shown in FIG. **3**, the first side **120** generally falls within a first plane **105** and the second side **121** generally falls within a second plane **106**. The first plane **105** and the second plane **106** may converge toward the leading end **101** as in FIG. **3**, but they may also take other orientations such as parallel, divergent relative to the leading end **101**, or convergent relative to other points relative to the perimeter wall **142**. The body may also have a generally central plane **107** that passes through the implant **10**. The central plane **107** may be approximately between the first plane **105** and the second plane **106**, and may be generally parallel to the transverse anatomical reference plane. A generally central axis **111** passes through the body **100** through the generally centralized aperture **110** and through the first side **120** and the second side **121**, as depicted in FIG. **3**. The generally central axis **111** may pass through the absolute center of the body **100** or it may be offset or angled in any direction. The axis **111** may be generally parallel to the cephalad-caudal direction.

(23) The first side **120** has a perimeter **130** around the first side **120**. The second side **121** has a second perimeter **131** which extends generally around the second side **121**. The body **100** has a perimeter wall **142** that extends generally around the body **100** of the implant **10**. The first side **120** connects with, or intersects, the perimeter wall **142** at a first edge **140**. The second side **121** connects with, or intersects, the perimeter wall **142** at a second edge **141**. The first edge **140** and second edge **141** may be thin edges as depicted on the leading end **101** in FIG. **1** or a wider edge **140** and **141** as shown in FIG. **3**, on a medial side of the body **100**. The first edge **140** extends around the first perimeter **130** and the second edge **141** extends around the second perimeter **131**. The edges **140**, **141**, as well as the general shape of the body, increases stability of the implant after implantation. The shape and edges **140**, **141** also reduce friction and drag during implantation. As shown in FIG. **2**B, the edges **140**, **141** are angled slightly below the outer first **105** and second **106** planes. The first and second edges **140**, **141** face away from the body **100** and are configured to engage the rim of adjacent vertebral bodies. Depending on the load placed on the implant **10** by the adjacent vertebral bodies, the first and second edges **140**, **141** may bear a substantial amount of the load, which then is dispersed on the rim of the vertebral bodies, rather than the softer central portion of the end plate.

(24) The perimeter wall **142** may be uninterrupted or may have any number of apertures. FIG. **1** depicts side apertures on the sides of the perimeter wall **142**. The side apertures **170** may be in communication with the centralized aperture **110** and may allow for bone growth into and through the body **100**. The side apertures may also allow for radiographic visualization of bone healing. Alternatively, the side apertures **170** may not pass fully through the body **100**. The side apertures **170** may also be contemplated as indentations or divots into the sides of the body **100**. The perimeter wall may have other apertures **173** around the body **100**, usually on the leading edge of the implant **10**. As best viewed in FIGS. **2**A and **2**B, the body **100** may have any number of suitable features such as recesses, holes, notches and the like for engaging an insertion instrument (not shown) without deviating from the scope of the implant **10**. One engagement feature is a threaded receiving aperture **172** in the perimeter wall **142** on the trailing end **102**. The threaded receiving aperture **172** is dimensioned and configured to threadably receive a threaded portion of an insertion instrument. The threaded receiving aperture **172** may extend inwardly toward the generally central axis **111**. In addition to, or replacing, the generally threaded receiving aperture **172**, the perimeter wall **142** may have guide apertures **171**. FIG. **2**A depicts a pair of guide apertures **171** flanking the

threaded receiving aperture **172**. The aperture **172** may also be unthreaded. The guide apertures **171** may function as a support or guide feature for an insertion instrument (not shown) or they may function as another route for bone ingrowth. The guide apertures **171** allow the threaded connection to fixate the insertion instrument to the spacer and allow for positioning of the implant. An inserter with pins, which engage the guide apertures **171**, may torque the implant about an axis through the threaded aperture **172**. Any of the apertures or divots of the implant **10** may have varying shapes, sizes, and orientations, which may be suitable for the surgical implantation of the implant **10**. Additionally, these features may be used for implant repositioning and or removal if required.

(25) As shown in FIG. **1**, the first side **120** has at least one lobe **150** or extension, which may be likened to a cantilever **300**. A cantilever is a structural element anchored at one end to a support, from which it protrudes. When subjected to a structural load, the cantilever carries the load to the support. The lobe is structured to extend from a base **151** to an end or first region **158** and end at a terminus **152** or second region. The base **151** is adjacent to the first perimeter **130**. The end region **158** extends away from the base **151** and the first perimeter **130** and toward the generally central axis **111**. As shown in FIG. **2**A, the lobe **150** has a first width **153** at the base **151** and a second width **154** at the terminus **152**. The width decreases along the end region **158** to the terminus **152**, so that the first width **153** is greater than the second width **154**. The lobes **150** depicted in the figures have a generally curved and convex shape, but it is envisioned that the lobes **150** can have other suitable shapes, such as a terminus **152**, with a width greater than or equal to the base **151**, or a terminus **152** equal in width to the base **151**. Other shapes of the end region **158** are contemplated to include different transitions from the base **151** to the terminus **152**, including symmetrical, asymmetrical, acute, obtuse, or other suitable means. The at least one lobe **150** may be have a convex shape that complements the concave shape of the end plate, along the cephalad or caudal surface.

(26) As shown in FIG. **2**, the lobe **150** has a first thickness **155** at the base **151** and a second thickness **156** at the terminus **152**. The first thickness **155** is greater than the second thickness **156**. The thickness decreases along the end region **158** to the terminus **152**. The lobe **150** depicted in the figures have a generally curved shape, but it is envisioned that the lobes **150** have other suitable shapes, such as a terminus **152** with a width greater than or equal to the base **151**, or a terminus **152** equal in width to the base **151**. Other shapes of the end region **158** are contemplated to include different transitions from the base **151** to the terminus **152**, including symmetrical, asymmetrical, acute, obtuse, or other suitable means.

(27) In addition to having at least one lobe **150**, the implant may have a plurality of lobes **200** about the generally central axis, as shown in FIGS. **1-3**. Furthermore, the at least one lobe **150** or the plurality of lobes **200** may be present on both the first side **120** and the second side **121**. Any number or arrangement of the lobes **150**/**200** are contemplated in order to address patients' needs and anatomy. As shown in FIG. **3**, in a side plan view, the body **100** has first **105** and second planes **106**. The plurality of lobes **200** are present on both the first side **120** and the second side **121**. As depicted in FIG. **3**, the lobe **150** curves or arcs away from the centralized aperture **110** and outward from the first plane **105**. The same orientation and juxtaposition may exist on the second side. The at least one lobe **150** and the plurality of lobes **200** may have a convex profile, which may be complementary to a concave nature of vertebral endplates. With respect to the first side **120**, the base **151** of the lobe **150** as well as the first perimeter **130** and the adjacent first edge **140** may exist within the first plane **105**. The first edge **140** may also be slightly below the first plane **105**, toward the central plane **107**, as shown in FIG. **2**B. Extending from the base **151**, the end region **158** extends outward from the first plane **105**. The terminus **152** may be outside, aligned with, or inside the first plane **105**. This same arrangement or orientation may exist for the second side **121** and the second plane **106**. The second edge **141** may exist within the second plane **106**, or in a directly toward the central plane **107**, as shown in FIG. **2**B.

(28) The end region **158** of at least one lobe **150**, or of the plurality of lobes **200**, is configured to

engage vertebral bodies adjoining the target disc space. In the embodiment depicted in FIGS. **1-3** show a plurality **200** of lobes **150** on both the first side **120** and the second side **121**. In this embodiment, the end region **158** of each of the lobes **150**, extend out of the first **105** and second **106** planes. With this embodiment, the implant **10** is configured so that when the implant **10** is positioned between adjacent vertebrae, the end regions **158** contact the surface of the vertebral bodies prior to the vertebral body contacting any other portion of the implant **10** body **100**. With increased load on the end regions **158** from the vertebrae on the implant **10**, the lobes **150** are capable to flex or bend to absorb or cushion the load on the implant **10**. As the end regions **158** receive the load from the adjacent vertebrae, the lobe flexes toward the respective first **105** and/or second **106** planes, respectively, and toward the central plane **107**. The terminus **152** may flex into the centralized aperture **110** as the lobe **150** flexes. Any portion of the lobe **150** may flex past the first **105** and second **106** planes and continue toward the central plane **107**. The flexibility of the at least one lobe **150** or the plurality of lobes allows the profile of the implant to complement a vertebral endplate that is not fully concave.

(29) The shape of the lobe **150** and the end region **158** may be oriented so that the end region **158** engages the vertebral body closer to the apophyseal rim, containing cortical bone, rather than the soft central cancellous bone. In an embodiment with four lobes **150** on each side **120 121**, the load from the adjacent vertebral bodies may be distributed about the eight total lobes. The dimensions of the lobes **150** having a first thickness **155** greater than the second thickness **156**, allows the end region **158** and the lobe to flex in a non-linear fashion or relative motion. A middle portion of the end region **158** and extending toward the terminus **152** would flex more easily than the lobe nearer the base **151**. By spreading the load of adjacent vertebral bodies across at least one lobe **150** in the implant, and preferably a plurality of lobes **200**, the implant **10** reduces the risk of subsidence into the vertebrae and the cancellous bone, by increasing the contact area between the bone and the implant. The overall force against a localized point on the vertebral endplate is spread, and as the lobe flexes, the contact point between the end region **158** and the vertebra is shifted toward the harder cortical bone at the apophyseal rim, supported by the first edge **140** and the second edge **141**. As the load from the adjacent vertebra increase, the lobes **150** deflect further, and it is possible for the entire load to be supported at the perimeter **130** and the edges **140**, **141** and on the perimeter wall **142**. Any lobe **150** or combination of lobes **150**, **200**, may include surface features that encourage bone ingrowth. The features may include pores, ridges, loops, holes, spaces, grooves, or any known surface that increases purchase or grips on the adjacent bone. As the spacer has been packed with cancellous bone graft when the first and second surfaces deflect they cause the bone graft to support some of the load being transmitted from the adjacent vertebra. In some embodiments, the stiffness of the first and second sides **120**, **121**, in compression along the axis **111** generally parallel with the perimeter wall, is equal to or less than the compressive modulus of cancellous bone. In accordance with structural mechanics, this situation allows the bone graft to support a significant portion of the spinal load and in accordance with Wolfe's Law facilitates its incorporation into the fusion mass.

(30) The implant **10** may include a plurality of anti-migration features designed to increase the friction between the implant and the adjacent contacting surfaces of the vertebral bodies. Such anti-migration features may include ridges, teeth, lugs, or other purchase-inducing surface treatments. The anti-migration features also stabilize the implant by resisting torsional loads, which might inhibit fusion. As shown in an embodiment of FIGS. **4** and **5**, the implant **10** has grippers **160** functioning as an anti-migration feature. These grippers may be located on a lobe **150** in an area of the end region **158** that is configured to engage adjacent vertebral bodies. FIG. **4** shows the grippers **160** aligned generally parallel with the leading and trailing ends **101**, **102**, which may commonly be an anterior-posterior orientation. The grippers may be oriented so that the termini **162** are directed in the same direction, or as shown in FIGS. **5** and **6**, the implant **10** may have multiple grippers on the leading end **101** of the implant body **110**, wherein the gripper termini **162**

are oriented in opposite directions. This orientation allows for better prevention of anterior-posterior expulsion as well as inhibit lift off from the bone during bending motions. Each gripper **160** may have a gripper base **161** located on the lobe **150**, preferably on the end region **158**, and a gripper terminus **162**. The gripper terminus may have a pointed or other engaging geometry to encourage efficient purchase on the vertebral body. The gripper **160** in FIG. **4** has a triangular shape with a relatively pointed or sharp gripper terminus **162**. Each lobe **150** with a gripper **160** may include a divot **163** in the respective lobe **150**, beneath the gripper **160**. The divot **163** is configured to accommodate and to allow the gripper **160** to flex into the lobe **150** when the load from the vertebral bodies are transferred to the implant **10**. Open space between the gripper **160** and the divot may also allow for bone ingrowth and facilitate better implant stabilization. The grippers **160** may also be rigid without substantial flexing and may allow for penetration of the vertebral endplate. Penetration of the endplate may allow blood to flow from the cancellous portion of the vertebral body. FIG. **5** demonstrates grippers **160** on both the first side **120** and the second side **121** of the implant **10**. The gripper terminus **162** may further extend past the outer most part of the end region **158** or the terminus **152** of the lobe **150**.

(31) The implant **10** may have a first and second configuration. In the first configuration, the implant is in a relaxed state, in which the lobes are generally extending out of the first and second planes **105**, **106**, as generally shown in FIGS. **1-5**. The end regions **158**, as well as any gripper **160**, are outside of the planes **105 106** and the edges are either in plane or slightly inward of the planes **105 106**, toward the centralized aperture. The second configuration is a transitioned state, realized when a load has been placed on the implant **10**. The second configuration may also be referred to as a deflected state. In practice, the second configuration occurs after implantation of the implant **10** between two adjacent vertebrae, and the vertebrae are allowed to apply a load on both the first side **120** and the second side **121** of the implant body **100**. As the load increase on the implant body **100**, the end regions **158** on at least one lobe **150** or a plurality of lobes **200**, accept the load. Each lobe **150** responds to the load and flexes inwardly toward the centralized aperture **110** and the central plane **107**. If the lobes contain grippers **160**, the grippers **160** engage and bite into the end plates. The grippers then flex inwardly toward the divots **163**, to a maximum, then the lobe **150** flexes toward the centralized aperture **110**. As the load increases, each lobe **150** may flex, and because the end region **158** has a curvature, the point of contact with the end plate may shift in the direction toward the perimeter **130**, **131**, and thus closer to the rim of the vertebral body. Once the load from the vertebral bodies has stabilized, and based on the patient's anatomy, each lobe **150** within the plurality **200** may have flexed by different amounts, to properly stabilize the spine. The lobes and/or grippers may flex elastically or plastically. Elastic deflection is temporary and the lobes and/or grippers return to the relaxed state when load is removed. Plastic deflection is substantially permanent and the lobes and/or grippers remain deformed when load is removed.

(32) In the transition from the first configuration to the second configuration as the at least one lobe **150** flexes toward the central plane, it is foreseen that the first edge **140** and the second edge **141** receive an increase in the load applied by the adjacent first and second vertebral bodies. As discussed above, the load applied by the adjacent vertebral bodies may be dispersed by the first **140** and second **141** edges onto the outer rims of the endplates. The endplates are able to withstand a greater load than the central portion of the endplates and may rotate when the lobe **150** is flexed to a second configuration. The edge rotation may occur about an axis generally parallel to the base of a lobe **150**. For example, if the first edge **140** is in or outward-from the first plane **105**, when the lobe **150** is flexed toward the first plane **105**, the first edge **140** will rotate up and outward from the first plane **105**. If the first edge **140** is below or inward of the first plane **105**, in the first configuration, when the lobe **150** is flexed to a second configuration, the first edge rotates about an axis parallel the base **151**, both toward and outward the first plane **105**. The movement of the edge away from the centralized aperture may create additional anti-migration features and functions of the implant **10**. The same function may occur on the second side **121** of the implant with the second

edge **141**. The implant **10** may have any variation of edge geometries in the first configuration.
(33) FIG. **6**. shows an implant embodiment **40** having a plurality of lobes **500**. Each lobe **450** has a generally triangular shape with a base **451** and a terminus **452**, with an end region **458** therebetween. Each base **451** has a first width **453** and each terminus has a second width **454**. The first width **453** is generally greater than the second width **454**. The differences in width allow for a cantilever **600** function of each of the lobes **450**, so that the end region can flex toward the centralized aperture when a load is placed on the implant **40**. The implant body **400** has a leading end **401**, a trailing end **402**, with a centralized aperture **410**, and a generally central axis **411**. The implant **40** has a first side **420**, a second side **421**, with a first perimeter **430** and a second perimeter **431**, respectively. The implant body **400** has at least a first edge **440** between the first perimeter **430** and a perimeter wall **442**, as well as a second edge **441** between the second perimeter **431** and the perimeter wall **442**. The body **400** may also have a plurality of apertures like a guide aperture **471**, side apertures **470**, and attachment apertures **472**. The embodiment in FIG. **6** also has first and second plow edges **481**, **482** separated by a recess **480**. The first plow edge is adjacent to the first perimeter **430** and the second plow edge is adjacent the perimeter wall **442**. The first plow edge **481**, the second plow edge **482**, and the recess **480** may extend around the whole perimeter **430**, or may be broken up, as shown in FIG. **6**. The same plow structure may be present on the second side **421**. The first **481** and second **482** plow edges create additional grip and purchase on the rim of the adjacent vertebral bodies, when the implant **40** is implanted. The recess **480** and plow edge supports **483** allow for additional locations for stabilizing bone ingrowth. FIG. **6** depicts additional examples of gripper **460** shapes. Gripper **460** may have a base **461** located closer to the first **440** or second **441** edges or the base **451** of the lobe **450**. The gripper **460** may have a terminus **462** oriented away from the first **420** or second sides **421**.
(34) The implant **10**, **40** may be used in a method of fusing adjacent first and second vertebral bodies. In an exemplary method, the intervertebral space may be distracted prior to insertion of the implant **10**, **40**. Prior to insertion of the implant **10**, **40**, the intervertebral space is prepared. In a method of installation, a discectomy may be performed so that the disc is removed in its entirety. An alternative method may allow for only a portion of the disc to be removed. The endplates of the vertebral bodies may be scraped to expose suitable surfaces, which may bleed, and which may encourage bone ingrowth to the implant. Once the intervertebral space is sufficiently prepared, the implant **10**, **40** may be introduced in a first relaxed state into the space and seated properly. The implant may be implanted via an endoscopic tube or other known implantation means.
(35) After the implant **10**, **40** is positioned, the adjacent vertebral bodies may be allowed to converge, putting a load onto the implant **10**, **40**. The concave endplates are allowed to engage the at least one lobe **150** or a plurality of lobes **200** on the implant **10**, **40**, which then flexes toward a central plane **107**. The complementary shape of the lobes **150**, **200** engage the endplates and assist in properly positioning and securing the implant **10**, **40** in place. The implant **10**, **40** may have grippers **160**, **460** which further and more deeply engage the endplates to assist in keeping the implant in the intended location. The grippers **160**, **460** may also encourage the endplates to bleed, encouraging bone ingrowth. As the load from the vertebral bodies increases, the at least one lobe **150** or the plurality of lobes on a first side **120** or on both the first **120** and second **121** sides of the implant act as a cantilever and flex toward a central plane. The implant **10**, **40** transitions from the first relaxed state to a second loaded state, wherein the implant **10**, **40** is taking on the full load from the adjacent vertebral bodies. During and after the transition to the second loaded state, the first **140** and second **141** edges may engage with the rim of the endplates and disperse the load across this stronger portion of the vertebral body.
(36) FIGS. **7**A-**11**F illustrate a set of implants **50**, **60**, **70**, **80**, **90**, all shown at the same scale. Implant **90** of FIGS. **7**A-F is a 9 mm size; implant **80** of FIGS. **8**A-F is an 8 mm size; implant **70** of FIGS. **9**A-F is a 7 mm size; implant **60** of FIGS. **10**A-F is a 6 mm size; and implant **50** of FIGS. **11**A-F is a 5 mm size. The implants each have the dimensions of height, width, and length suitable

for placement between vertebral bodies. The height extends along a cephalad-caudal direction, the width extends along a right-left direction, and the length extends along an anterior-posterior direction. The implants may be made of any suitable biocompatible material. Various biocompatible materials contemplated include, but are not limited to, poly-ether-ether-ketone (PEEK), other polymers including bioresorbable polymers, ceramics, composites, bone or bone substitute materials, and biocompatible metals including stainless steel, titanium, or tantalum and their alloys. The implants may also include multiple materials and/or combinations of materials. The implants may be manufactured by known methods such as machining, molding, forming, or 3D printing. The implants may be provided in any number of shapes or sizes depending on the specific surgical procedure, need, or patient anatomy. The implants may contain separate radiographic markers of any size of shape suitable to facilitate effective and accurate visualization of implant placement, necessary depending on the base material of the implant.

(37) Implants **50**, **60**, **70**, **80**, **90** illustrate principles for designing metal intervertebral spacer implants whose functional stiffness under normal in vivo load bearing conditions is equal to or less than the functional stiffness of conventional PEEK intervertebral spacer implants, which usually falls within the range of 5,000 N/mm to 20,000 N/mm. Implants **50**, **60**, **70**, **80**, **90** have been designed in titanium alloy for implantation into the cervical spine where normal in vivo load bearing conditions include axial (superior-inferior) compression loads that are less than 400 N, less than 200 N, or less than 130 N. The implants exhibit enhanced flexibility or reduced stiffness under axial compression loads from 0 N to 130 N, 0 N to 200 N, or 0 N to 400 N, despite titanium alloy having a Young's modulus that is much greater than PEEK. Implant stiffness under these axial compression loads may be less than or equal to 20,000 N/mm. Implant stiffness may be less than or equal to 15,000 N/mm, less than or equal to 10,000 N/mm, less than or equal to 5,000 N/mm, less than or equal to 4,000 N/mm, less than or equal to 3,000 N/mm, less than or equal to 2,000 N/mm, less than or equal to 1,000 N/mm, or less than or equal to 500 N/mm. The implants have also been designed to sustain axial compression loads equal to or greater than 1500 N. Under these higher loads, the implants exhibit higher stiffness because the loads are borne mainly by the perimeter wall. While this disclosure is made in the context of implants and loads for the cervical spine, the design principles are adaptable to implants and loads for the thoracic or lumbar spine.

(38) The axial compressive stiffness of the implants disclosed herein is modulated by the lobes on the first and/or second sides of the implants. The lobes progressively deflect under load and thereby decrease the functional stiffness of the implants under normal in vivo loads versus conventional implant designs that have solid first and/or second sides or that lack compliant structures like the lobes. One principle illustrated by implants **50**, **60**, **70**, **80**, **90** is that all lobes share the in vivo load evenly. In other words, each lobe carries the same load, has the same deflection characteristics, has the same stiffness, and/or has the same contact area for a given load. One will appreciate that if the in vivo load is 400 N, and if the implant includes four lobes per side, then the load per lobe is 100N; alternatively, if the implant includes only two lobes per side, then the load per lobe would be 200N. However, implant design is multi-factorial and implant manufacturing necessarily involves numerous tolerances applied to a nominal design. The complete array of design constraints for a specific implant design may result in nominal lobes which carry approximately the same load and have approximately the same deflection characteristics. Each nominal lobe may be the same as every other nominal lobe within ±50% (i.e., lobe **2** is 50% to 150% of lobe **1**). Preferably, each nominal lobe may be the same as every other nominal lobe within ±20%, within ±15%, within ±10%, or within ±5%.

(39) The axial compressive stiffness of the implants **50**, **60**, **70**, **80**, **90** is further modulated by changing the bending stiffness of the perimeter walls. The bending stiffness of the perimeter walls may be reduced in the vicinity of the lobe bases as compared to solid, unmodified perimeter walls. Another principle illustrated by implants **50**, **60**, **70**, **80**, **90** is that the perimeter walls include features which contribute to all lobes sharing the load evenly. In other words, the perimeter wall in

the vicinity of each lobe base is modified to adjust the load/deflection/stiffness of that lobe.
(40) Referring to FIGS. **7**A-F, implant **90** includes the following structures and/or features which may be as described above for implants **10**, **40** and having related reference numbers: body **900**, leading edge/end **901**, trailing edge/end **902**, first plane **905**, second plane **906**, central plane **907**, centralized aperture **910**, central axis **911**, first side **920**, second side **921**, first perimeter **930**, second perimeter **931**, first edge **940**, second edge **941**, perimeter wall **942**, lobe **950**, lobe base **951**, lobe terminus **952**, lobe first width **953**, lobe second width **954**, lobe first thickness **955**, lobe second thickness **956**, lobe end region **958**, side apertures **970**, guide apertures **971**, receiving/attachment aperture **972**, and/or apertures **973**. Implant **90** may optionally include one or more grippers, each with a gripper base and gripper terminus, each optionally associated with a divot, like gripper **160**, **460**, gripper base **161**, **461**, gripper terminus **162**, **462**, and divot **163** of implants **10**, **40**. The lobes **950** of implant **90** may include bone ingrowth and/or ongrowth features as depicted in FIGS. **1-6**, such as pores, ridges, loops, holes, spaces, lobe apertures **974** as shown, grooves, or any known surface that increases purchase or grips on the adjacent bone. The lobe apertures **974** may be filled with porous material.
(41) Implant **90** includes large side apertures **970** and a large aperture **973** in the leading end **901**. These apertures **970**, **973** reduce the bending stiffness of the perimeter wall **942** in the vicinity of the lobe bases **951** of the side and leading lobes **950** to increase the flexibility of the lobes. The trailing end **902** includes the receiving/attachment aperture **972** and the flanking guide apertures **971**, as well as four more apertures **975** which are located in the vicinity of the lobe bases **951** of the trailing lobes **950**. The apertures **971**, **972**, **975** may function together to reduce the bending stiffness of the perimeter wall **942** in the vicinity of the lobe bases **951** of the trailing lobes **950** to increase the flexibility of the lobes. Each aperture **975** is elongated along a side-to-side (right-left) direction. Preferably, the apertures **975** are enlarged toward their lateral (outboard) ends so that the enlargement coincides with each side of the lobe base **951**. Preferably, the lateral ends of the apertures **975** are enlarged toward the first and second sides **920**, **921**, respectively as shown, again to coincide with each side of the lobe base **951**. The illustrated apertures **975** represent one of a plurality of alternative aperture configurations for the 9 mm size implant **90**.
(42) Referring to FIGS. **8**A-F, implant **80** includes the following structures and/or features which may be as described above for implants **10**, **40** and having related reference numbers: body **800**, leading edge/end **801**, trailing edge/end **802**, first plane **805**, second plane **806**, central plane **807**, centralized aperture **810**, central axis **811**, first side **820**, second side **821**, first perimeter **830**, second perimeter **831**, first edge **840**, second edge **841**, perimeter wall **842**, lobe **850**, lobe base **851**, lobe terminus **852**, lobe first width **853**, lobe second width **854**, lobe first thickness **855**, lobe second thickness **856**, lobe end region **858**, side apertures **870**, guide apertures **871**, receiving/attachment aperture **872**, and/or apertures **873**. Implant **80** may optionally include one or more grippers, each with a gripper base and gripper terminus, each optionally associated with a divot, like gripper **160**, **460**, gripper base **161**, **461**, gripper terminus **162**, **462**, and divot **163** of implants **10**, **40**. The lobes **850** of implant **80** may include bone ingrowth and/or ongrowth features as depicted in FIGS. **1-6**, such as pores, ridges, loops, holes, spaces, lobe apertures **874** as shown, grooves, or any known surface that increases purchase or grips on the adjacent bone. The lobe apertures **874** may be filled with porous material.
(43) Implant **80** includes large side apertures **870** and a large aperture **873** in the leading end **801**. These apertures **870**, **873** reduce the bending stiffness of the perimeter wall **842** in the vicinity of the lobe bases **851** of the side and leading lobes **850** to increase the flexibility of the lobes. The trailing end **802** includes the receiving/attachment aperture **872** and the flanking guide apertures **871**, as well as four more apertures **875** which are located in the vicinity of the lobe bases **851** of the trailing lobes **850**. The apertures **871**, **872**, **875** may function together to reduce the bending stiffness of the perimeter wall **842** in the vicinity of the lobe bases **851** of the trailing lobes **850** to increase the flexibility of the lobes. Each aperture **875** is elongated along a side-to-side (right-left)

direction. Preferably, the apertures **875** are enlarged toward their lateral (outboard) ends so that the enlargement coincides with each side of the lobe base **851**. Preferably, the lateral ends of the apertures **875** are enlarged toward the first and second sides **820**, **821**, respectively as shown, again to coincide with each side of the lobe base **851**. The illustrated apertures **875** represent one of a plurality of alternative aperture configurations for the 8 mm size implant **80**. The illustrated aperture **875** resembles the aperture **975** of implant **90**.

(44) Referring to FIGS. **9**A-F, implant **70** includes the following structures and/or features which may be as described above for implants **10**, **40** and having related reference numbers: body **700**, leading edge/end **701**, trailing edge/end **702**, first plane **705**, second plane **706**, central plane **707**, centralized aperture **710**, central axis **711**, first side **720**, second side **721**, first perimeter **730**, second perimeter **731**, first edge **740**, second edge **741**, perimeter wall **742**, lobe **750**, lobe base **751**, lobe terminus **752**, lobe first width **753**, lobe second width **754**, lobe first thickness **755**, lobe second thickness **756**, lobe end region **758**, side apertures **770**, guide apertures **771**, receiving/attachment aperture **772**, and/or apertures **773**. Implant **70** may optionally include one or more grippers, each with a gripper base and gripper terminus, each optionally associated with a divot, like gripper **160**, **460**, gripper base **161**, **461**, gripper terminus **162**, **462**, and divot **163** of implants **10**, **40**. The lobes **750** of implant **70** may include bone ingrowth and/or ongrowth features as depicted in FIGS. **1-6**, such as pores, ridges, loops, holes, spaces, lobe apertures **774** as shown, grooves, or any known surface that increases purchase or grips on the adjacent bone. The lobe apertures **774** may be filled with porous material.

(45) Implant **70** includes large side apertures **770** and a large aperture **773** in the leading end **701**. These apertures **770**, **773** reduce the bending stiffness of the perimeter wall **742** in the vicinity of the lobe bases **751** of the side and leading lobes **750** to increase the flexibility of the lobes. The trailing end **702** includes the receiving/attachment aperture **772** and the flanking guide apertures **771**, as well as four more apertures **775** which are located in the vicinity of the lobe bases **751** of the trailing lobes **750**. The apertures **771**, **772**, **775** may function together to reduce the bending stiffness of the perimeter wall **742** in the vicinity of the lobe bases **751** of the trailing lobes **750** to increase the flexibility of the lobes. Each aperture **775** is elongated along a side-to-side (right-left) direction. Although not shown in this example, the apertures **775** may preferably be enlarged toward their lateral (outboard) ends so that the enlargement coincides with each side of the lobe base **751**. Although not shown in this example, the lateral ends of the apertures **775** may preferably be enlarged toward the first and second sides **720**, **721**, respectively, again to coincide with each side of the lobe base **751**. The illustrated apertures **775** represent one of a plurality of alternative aperture configurations for the 7 mm size implant **70**.

(46) Referring to FIGS. **10**A-F, implant **60** includes the following structures and/or features which may be as described above for implants **10**, **40** and having related reference numbers: body **600**, leading edge/end **601**, trailing edge/end **602**, first plane **605**, second plane **606**, central plane **607**, centralized aperture **610**, central axis **611**, first side **620**, second side **621**, first perimeter **630**, second perimeter **631**, first edge **640**, second edge **641**, perimeter wall **642**, lobe **650**, lobe base **651**, lobe terminus **652**, lobe first width **653**, lobe second width **654**, lobe first thickness **655**, lobe second thickness **656**, lobe end region **658**, side apertures **670**, guide apertures **671**, receiving/attachment aperture **672**, and/or apertures **673**. Implant **60** may optionally include one or more grippers, each with a gripper base and gripper terminus, each optionally associated with a divot, like gripper **160**, **460**, gripper base **161**, **461**, gripper terminus **162**, **462**, and divot **163** of implants **10**, **40**. The lobes **650** of implant **60** may include bone ingrowth and/or ongrowth features as depicted in FIGS. **1-6**, such as pores, ridges, loops, holes, spaces, lobe apertures **674** as shown, grooves, or any known surface that increases purchase or grips on the adjacent bone. The lobe apertures **674** may be filled with porous material.

(47) Implant **60** includes large side apertures **670** and a large aperture **673** in the leading end **601**. These apertures **670**, **673** reduce the bending stiffness of the perimeter wall **642** in the vicinity of

the lobe bases **651** of the side and leading lobes **650** to increase the flexibility of the lobes. The trailing end **602** includes the receiving/attachment aperture **672** and the flanking guide apertures **671**, as well as four more apertures **675** which are located in the vicinity of the lobe bases **651** of the trailing lobes **650**. The apertures **671**, **672**, **675** may function together to reduce the bending stiffness of the perimeter wall **642** in the vicinity of the lobe bases **651** of the trailing lobes **650** to increase the flexibility of the lobes. Each aperture **675** is elongated along a side-to-side (right-left) direction. Although not shown in this example, the apertures **675** may preferably be enlarged toward their lateral (outboard) ends so that the enlargement coincides with each side of the lobe base **651**. Although not shown in this example, the lateral ends of the apertures **675** may preferably be enlarged toward the first and second sides **620**, **621**, respectively, again to coincide with each side of the lobe base **651**. The illustrated apertures **675** represent one of a plurality of alternative aperture configurations for the 6 mm size implant **60**. The illustrated aperture **675** resembles the aperture **775** of implant **70**.

(48) Referring to FIGS. **11**A-F, implant **50** includes the following structures and/or features which may be as described above for implants **10**, **40** and having related reference numbers: body **500**, leading edge/end **501**, trailing edge/end **502**, first plane **505**, second plane **506**, central plane **507**, centralized aperture **510**, central axis **511**, first side **520**, second side **521**, first perimeter **530**, second perimeter **531**, first edge **540**, second edge **541**, perimeter wall **542**, lobe **550**, lobe base **551**, lobe terminus **552**, lobe first width **553**, lobe second width **554**, lobe first thickness **555**, lobe second thickness **556**, lobe end region **558**, side apertures **570**, guide apertures **571**, receiving/attachment aperture **572**, and/or apertures **573**. Implant **50** may optionally include one or more grippers, each with a gripper base and gripper terminus, each optionally associated with a divot, like gripper **160**, **460**, gripper base **161**, **461**, gripper terminus **162**, **462**, and divot **163** of implants **10**, **40**. The lobes **550** of implant **50** may include bone ingrowth and/or ongrowth features as depicted in FIGS. **1-6**, such as pores, ridges, loops, holes, spaces, lobe apertures **574** as shown, grooves, or any known surface that increases purchase or grips on the adjacent bone. The lobe apertures **574** may be filled with porous material.

(49) Implant **50** includes side apertures **570**. This example lacks an aperture in the leading end **501** due to the implant's small size. The apertures **570** reduce the bending stiffness of the perimeter wall **542** in the vicinity of the lobe bases **551** of the side lobes **550** to increase the flexibility of the lobes. The trailing end **502** includes the receiving/attachment aperture **572** and the flanking guide apertures **571**. In this example, the apertures **575** located in the vicinity of the lobe bases **551** of the trailing lobes **550** are merged with the guide apertures **571** so that there is a single aperture **571**, **575** on either side of the receiving/attachment aperture **572**, due to the small size of the implant. The apertures **571**, **575**, **572** may function together to reduce the bending stiffness of the perimeter wall **542** in the vicinity of the lobe bases **551** of the trailing lobes **550** to increase the flexibility of the lobes. Each aperture **571**, **575** is elongated along a side-to-side (right-left) direction. Although not shown in this example, the apertures **571**, **575** may preferably be enlarged toward their lateral (outboard) ends so that the enlargement coincides with each side of the lobe base **551**. Although not shown in this example, the lateral ends of the apertures **571**, **575** may preferably be enlarged toward the first and second sides **520**, **521**, respectively, again to coincide with each side of the lobe base **551**. The illustrated apertures **571**, **575** represent one of a plurality of alternative aperture configurations for the 5 mm size implant **50**.

(50) Referring to FIG. **12**, a force versus displacement curve is shown for a first variant of the 7 mm implant **70** of FIG. **9**A. The curve was generated by finite element analysis. The curve includes a first portion **780** for loads less than or equal to 200 N and displacements less than or equal to 0.2 mm and a second portion **782** for loads greater than 300 N and displacements greater than 0.21 mm. The first portion **780** represents the implant bearing load primarily through the lobes. The second portion **782** represents the implant bearing load primarily through the perimeter wall. The second slope is greater than the first slope. A knee **784** or change in slope is located between the

first and second portions **780**, **782**. These features are characteristic of the force versus displacement curves for the implants **50**, **60**, **70**, **80**, **90**. The first portion **780** may have a slope of 1069 N/mm and an R.sup.2 value of 0.9363. The second portion **782** may have a slope of 40,177 N/mm and an R.sup.2 value of 0.9661.

(51) Referring to FIG. **13**, three force versus displacement curves are shown. The curve **786** is for a second variant of the 7 mm implant **70** of FIG. **9**A. The curve **788** is for a 7 mm conventional PEEK implant. The curve **789** is for a 7 mm conventional titanium implant.

(52) The curve **786** includes a first portion **790** for loads less than or equal to 300 N and displacements less than or equal to 0.2 mm and a second portion **791** for loads greater than 400 N and displacements greater than 0.23 mm. The first portion **790** represents the implant bearing load primarily through the lobes. The second portion **791** represents the implant bearing load primarily through the perimeter wall. The second slope is greater than the first slope. A knee **792** or change in slope is located between the first and second portions **791**, **791**. The first portion **790** may have a slope of 1333 N/mm and an R.sup.2 value of 0.9683. The second portion **791** may have a slope of 10,274 N/mm and an R.sup.2 value of 0.9917. The knee **792** of curve **786** is more gradual than the knee **784** of FIG. **12**.

(53) The curve **788** may have a slope of 6283 N/mm and an R.sup.2 value of 0.9873.

(54) The curve **789** may have a slope of 20,909 N/mm and an R.sup.2 value of 0.995.

(55) Referring to FIGS. **14**A and **14**B, the superior half of the 7 mm implant **70** of FIG. **9**A is shown in a finite element analysis color gradient plot (FIG. **14**A) and again in FIG. **14**B with iso-deflection lines instead of the color plot. The perimeter wall **742** has 0 mm displacement. The terminus **752** of the leading lobe **750** has a displacement of 0.10384 mm at point **796**. The terminus of the right lobe has a displacement of 0.093051 mm at point **797**; the left lobe is a mirror image of the right lobe and has the same displacement. The terminus of the trailing lobe has a displacement of 0.093075 mm at point **798**. Thus, the displacement at point **797** is 89.6% of the displacement at point **796** (within 10%), and the displacement at point **796** is 111.6% of the displacement at point **797** (within 12%).

(56) Any methods disclosed herein comprise one or more steps or actions for performing the described method. The method steps and/or actions may be interchanged with one another and applicable to all embodiments of the intervertebral body implants described herein. In other words, unless a specific order of steps or actions is required for proper operation of the embodiment, the order and/or use of specific steps and/or actions may be modified.

(57) Reference throughout this specification to “an embodiment” or “the embodiment” means that a particular feature, structure or characteristic described in connection with that embodiment is included in at least one embodiment. Thus, the quoted phrases, or variations thereof, as recited throughout this specification are not necessarily all referring to the same embodiment.

(58) Similarly, it should be appreciated that in the above description of embodiments, various features are sometimes grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure. This method of disclosure, however, is not to be interpreted as reflecting an intention that any claim require more features than those expressly recited in that claim. Rather, as the following claims reflect, inventive aspects lie in a combination of fewer than all features of any single foregoing disclosed embodiment. Thus, the claims following this Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment. This disclosure includes all permutations of the independent claims with their dependent claims.

(59) Recitation in the claims of the term “first” with respect to a feature or element does not necessarily imply the existence of a second or additional such feature or element. Elements recited in means-plus-function format are intended to be construed in accordance with 35 U.S.C. § 112 Para. 6. It will be apparent to those having skill in the art that changes may be made to the details of the above-described embodiments without departing from the underlying principles of the

invention.
(60) While specific embodiments and applications of the present invention have been illustrated and described, it is to be understood that the invention is not limited to the precise configuration and components disclosed herein. Various modifications, changes, and variations which will be apparent to those skilled in the art may be made in the arrangement, operation, and details of the methods and systems of the present invention disclosed herein without departing from the spirit and scope of the invention.

Claims

1. An intervertebral spacer implant comprising: a body comprising: a first side configured to contact a first vertebra; a second side opposite the first side and configured to contact a second vertebra adjacent to the first vertebra; a perimeter wall extending around the body between the first and second sides and comprising an aperture; and a hollow interior enclosed by the perimeter wall between the first and second sides; wherein the hollow interior is in communication with the aperture of the perimeter wall but does not extend into the perimeter wall; wherein the first side is configured to flex, such that, with the body implanted between the first vertebra and the second vertebra, in response to pressure between the first vertebra and the second vertebra, a central portion of the first side moves, relative to the perimeter wall, into the hollow interior; wherein the first side comprises a first cantilevered member comprising: a first base adjacent to the perimeter wall; and a first end region extending away from the first base and the perimeter wall, and into the central portion; and the first cantilevered member flexes in response to the pressure such that the first end region moves into the hollow interior; and wherein the first side further comprises a second cantilevered member comprising: a second base adjacent to the perimeter wall; and a second end region extending away from the second base and the perimeter wall, and into the central portion; and the second cantilevered member flexes, independently of the first cantilevered member, in response to the pressure such that the second end region moves into the hollow interior.
2. The intervertebral spacer implant of claim 1, wherein the body further comprises a centralized aperture extending through the first side, the second side, and the hollow interior.
3. The intervertebral spacer implant of claim 1, wherein: the second side comprises a third cantilevered member comprising: a third base adjacent to the perimeter wall; and a third end region extending away from the third base and the perimeter wall; the third cantilevered member flexes in response to the pressure such that the third end region moves into the hollow interior; the second side further comprises a fourth cantilevered member comprising: a fourth base adjacent to the perimeter wall; and a fourth end region extending away from the fourth base and the perimeter wall; and the fourth cantilevered member flexes in response to the pressure such that the fourth end region moves into the hollow interior.
4. The intervertebral spacer implant of claim 1, wherein the first side further comprises a first stiffness that is equal to or less than a compressive modulus of cancellous bone.
5. The intervertebral spacer implant of claim 4, wherein: the first stiffness is applicable to a first level of flexure of the first side; and the first side further comprises a second stiffness, greater than the first stiffness, that is applicable to a second level, greater than the first level, of flexure of the first side.
6. The intervertebral spacer implant of claim 5, wherein the second level of flexure of the first side commences when the pressure exceeds about 200 N.
7. The intervertebral spacer implant of claim 1, wherein the perimeter wall comprises an aperture configured such that, with the body implanted between the first vertebra and the second vertebra, in response to pressure between the first vertebra and the second vertebra, the perimeter wall flexes.
8. The intervertebral spacer implant of claim 7, wherein: the aperture is positioned adjacent to the first base such that flexure of the perimeter wall facilitates pivotal motion of the first base.

9. An intervertebral spacer implant comprising: a body comprising: a first side configured to contact a first vertebra; a second side opposite the first side and configured to contact a second vertebra adjacent to the first vertebra; a perimeter wall extending around the body between the first and second sides; and a hollow interior extending through the body between the first and second sides; wherein the first side extends to cover at least part of the hollow interior; wherein the perimeter wall comprises an aperture configured such that, with the body implanted between the first vertebra and the second vertebra, in response to pressure between the first vertebra and the second vertebra, an edge of the perimeter wall rotates; wherein the first side is configured to flex, such that, with the body implanted between the first vertebra and the second vertebra, in response to the pressure, a central portion of the first side moves, relative to the perimeter wall, into the hollow interior; wherein the first side comprises a first cantilevered member comprising: a first base adjacent to the perimeter wall; and a first end region extending away from the first base and the perimeter wall, and into the central portion; and the first cantilevered member flexes in response to the pressure such that the first end region moves into the hollow interior; and wherein the aperture is positioned adjacent to the first base such that flexure of the perimeter wall facilitates pivotal motion of the first base.

10. The intervertebral spacer implant of claim 9, wherein the aperture comprises an elongated shape generally perpendicular to a central axis of the body.

11. The intervertebral spacer implant of claim 9, wherein: the perimeter wall comprises: a first lateral side comprising the aperture; a second lateral side comprises a second aperture; an anterior side; and a posterior side; and the anterior side and the posterior side each lack apertures configured to provide flexure of the anterior side and the posterior side in response to the pressure.

12. An intervertebral spacer implant comprising: a body comprising: a first side configured to contact a first vertebra; a second side opposite the first side and configured to contact a second vertebra adjacent to the first vertebra; a perimeter wall extending around the body between the first and second sides wherein the first side extends superiorly above the perimeter wall; and a hollow interior circumscribed by the perimeter wall and extending through the body from the first side to the second side; wherein the perimeter wall comprises: a first lateral side comprising a first aperture; a second lateral side comprises a second aperture; an anterior side; and a posterior side; wherein the first aperture and the second aperture are configured such that, with the body implanted between the first vertebra and the second vertebra, in response to pressure between the first vertebra and the second vertebra, the first lateral side and the second lateral side flex; wherein the anterior side and the posterior side each lack apertures configured to provide flexure of the anterior side and the posterior side in response to the pressure; wherein the first side is configured to flex, such that, with the body implanted between the first vertebra and the second vertebra, in response to the pressure, a central portion of the first side moves, relative to the perimeter wall, into the hollow interior; and wherein the first side comprises a first cantilevered member comprising: a first base adjacent to and extending parallel to the first aperture; and a first end region extending away from the first base and the perimeter wall, and into the central portion; the first cantilevered member flexes in response to the pressure such that the first end region moves into the hollow interior; the second side comprises a second cantilevered member comprising: a second base adjacent to and extending parallel to the second aperture; and a second end region extending away from the second base and the perimeter wall, and into the central portion; and the second cantilevered member flexes, independently of the first cantilevered member, in response to the pressure such that the second end region moves into the hollow interior.

13. The intervertebral spacer implant of claim 12, wherein: the first aperture is positioned such that flexure of the first lateral side facilitates pivotal motion of the first base; and the second aperture is positioned such that flexure of the second lateral side facilitates pivotal motion of the second base.