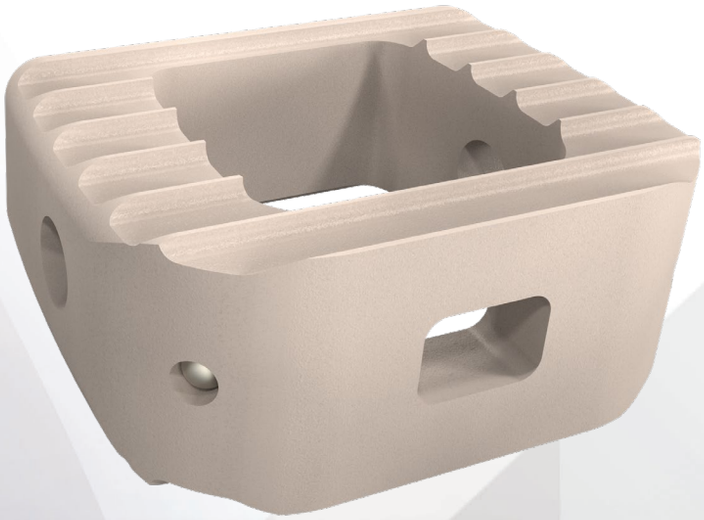
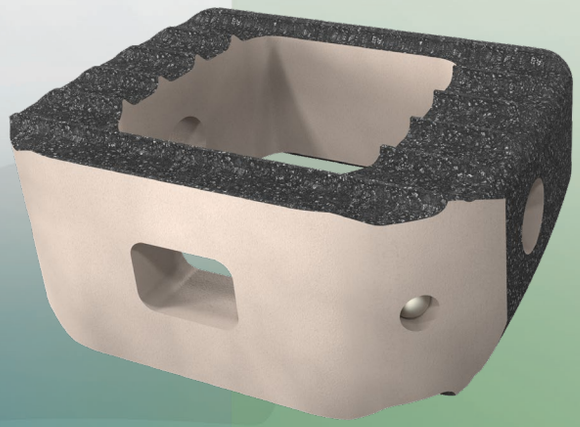
ChoiceSpine™
Propelling Spinal Surgery





ASCENDANT® Surgical Technique

PEEK and Titanium Coated Cervical Spacer

ASCENDANT®

The Ascendant Cervical Spacer System is an anterior cervical discectomy and fusion device offered in either pure PEEK Optima® or a plasma-sprayed, titanium-coated PEEK. It is offered in a variety of heights, footprints, and sagittal profiles to accommodate varying anatomical conditions, and it features a large open chamber to allow for filling of autogenous bone graft.

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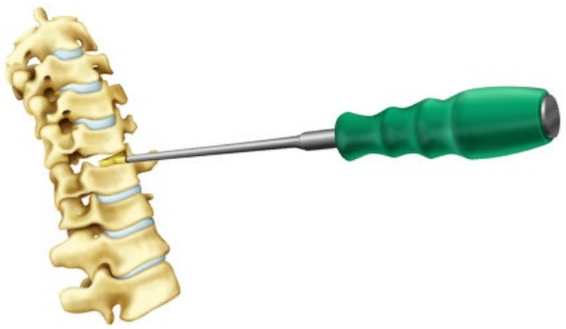
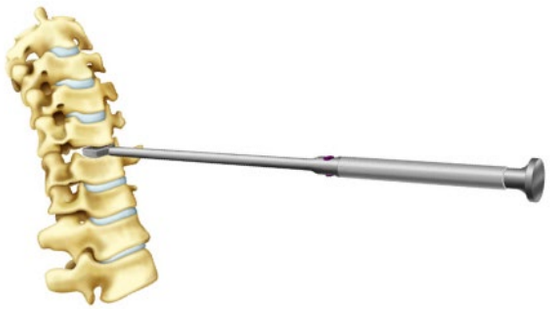
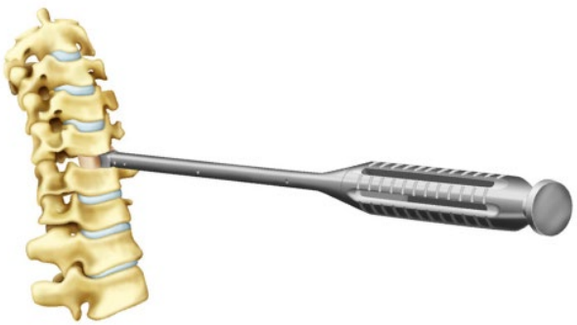


1. Preparing the endplates



2. Trial sizing

3. Attaching implant to inserter



4. Inserting implant

DETAILED OPERATIVE TECHNIQUE

SURGICAL APPROACH

Identify the affected level radiographically. Using a standard surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following the appropriate technique for the given indication.

DISTRACTION

Use the surgeon's preferred distraction method. If using a caspar distractor, place one distraction pin in the vertebral body superior to the affected level and the other distraction pin in the vertebral body inferior to the affected level. The pin distractor is then placed over the pins and opened as needed to distract the vertebral bodies. Use caution to not over distract the vertebral segment.

DISCECTOMY

Use the surgeon's preferred discectomy instruments and procedure to remove the intervertebral disc and osteophytes as needed. Use the rasps and curettes to prepare the endplates just enough to create a surface that will encourage vascularization between the endplates and the graft without weakening cortical bone (Figure 1).

CAUTION: Aggressive preparation of an endplate may remove excessive bone and weaken the endplate.

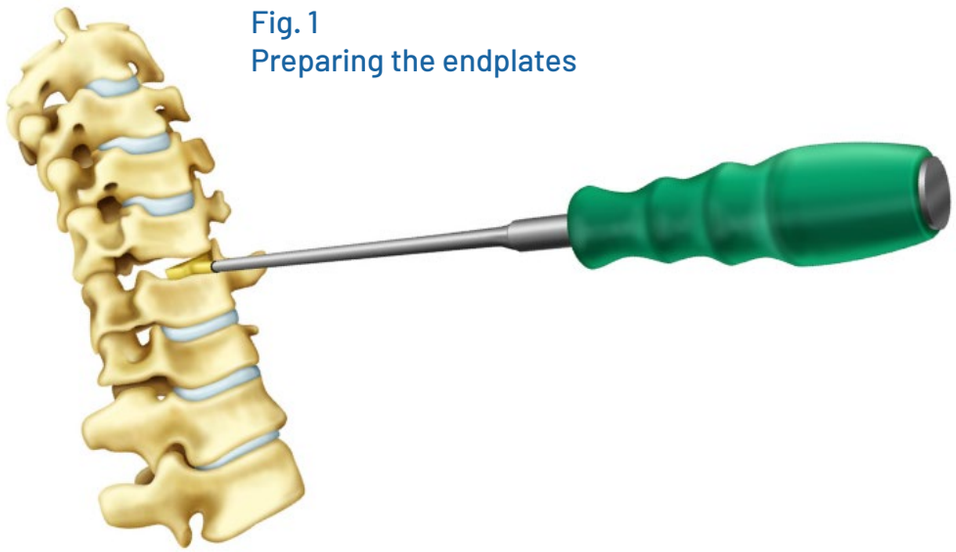
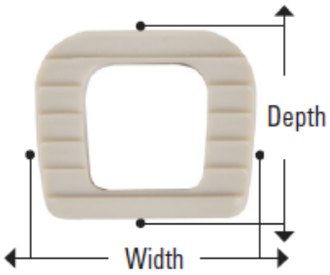


Fig. 1
Preparing the endplates



Two footprints - 14Wx12D & 16Wx14D

Three sagittal profiles - lordotic, parallel, and convex heights from 5mm to 12mm

IMPLANT SIZE SELECTION

Choose a parallel, lordotic or convex trial of the appropriate height and footprint. The selection of the trial size is dependent upon the height and depth of the intervertebral space and the individual patient anatomy and disc preparation.

Insert the appropriate sized trial into the disc space and check for a secure fit. If necessary, use incrementally larger sizes until a tight fit is obtained. Use radiographic imaging to confirm the implant depth and height as well as endplate coverage (Figure 2).

Trials are available with and without depth stops. The stops allow for a maximum of 2mm of countersink into the disc space.

Note: The trials are color coded to indicate whether it is a 14Wx12D or 16Wx14D footprint, and whether it is parallel, lordotic, or convex.

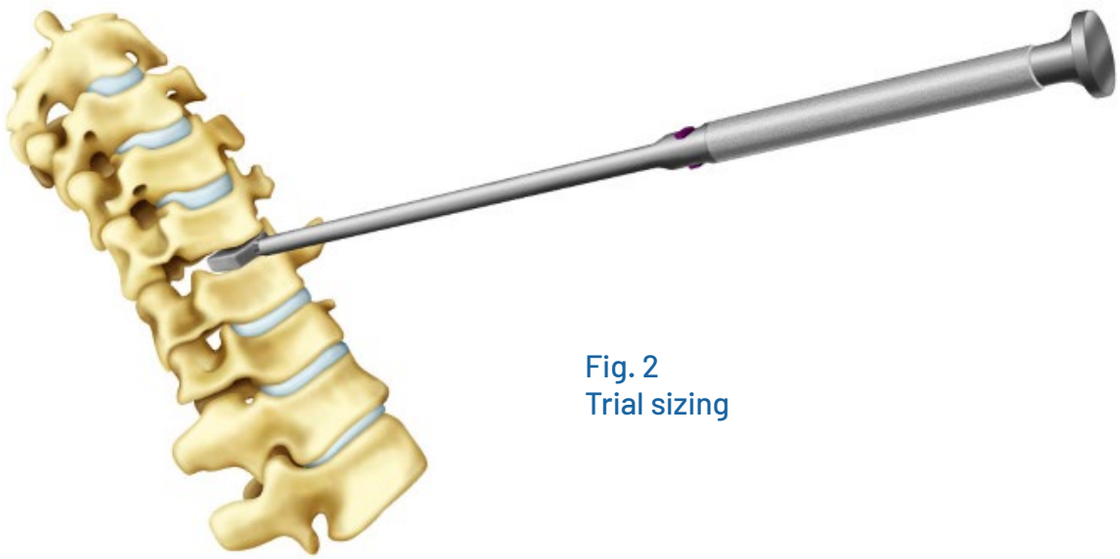


Fig. 2
Trial sizing

IMPLANT CONNECTION TO INSERTER

Select the appropriate implant size as determined in the trialling step. Attach the distal tip of the inserter into the rectangular opening in the anterior face of the implant (Figure 3). Place the locking shaft into the inserter to lock the implant into place (Figures 4 and 5).

Note: The domed implant version has pronounced radial dome on the superior side. There is an arrow on the posterior end of the device to indicate which side is domed.

Once the implant is attached to the inserter (Figure 6), fill the center graft window with autograft. The graft loading block and tamp can be used if necessary.

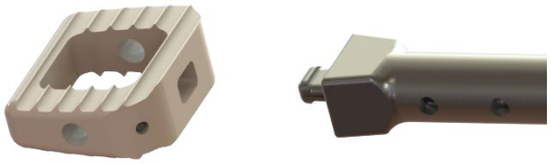


Fig. 3
Inserter attachment

Fig. 4
Inserter shaft engagement

Fig. 5
Inserter attached to implant

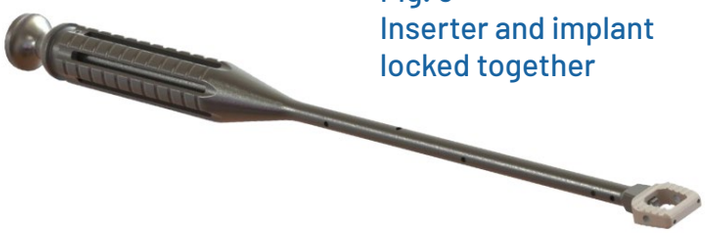


Fig. 6
Inserter and implant locked together

IMPLANT INSERTION

Insert the implant into the disc space until the implant is flush with the anterior surface of the vertebral body (Figure 7).

Confirm the final position of the implant under radiographic imaging. Radiographic markers are incorporated in the implant to enable accurate assessment of implant position.

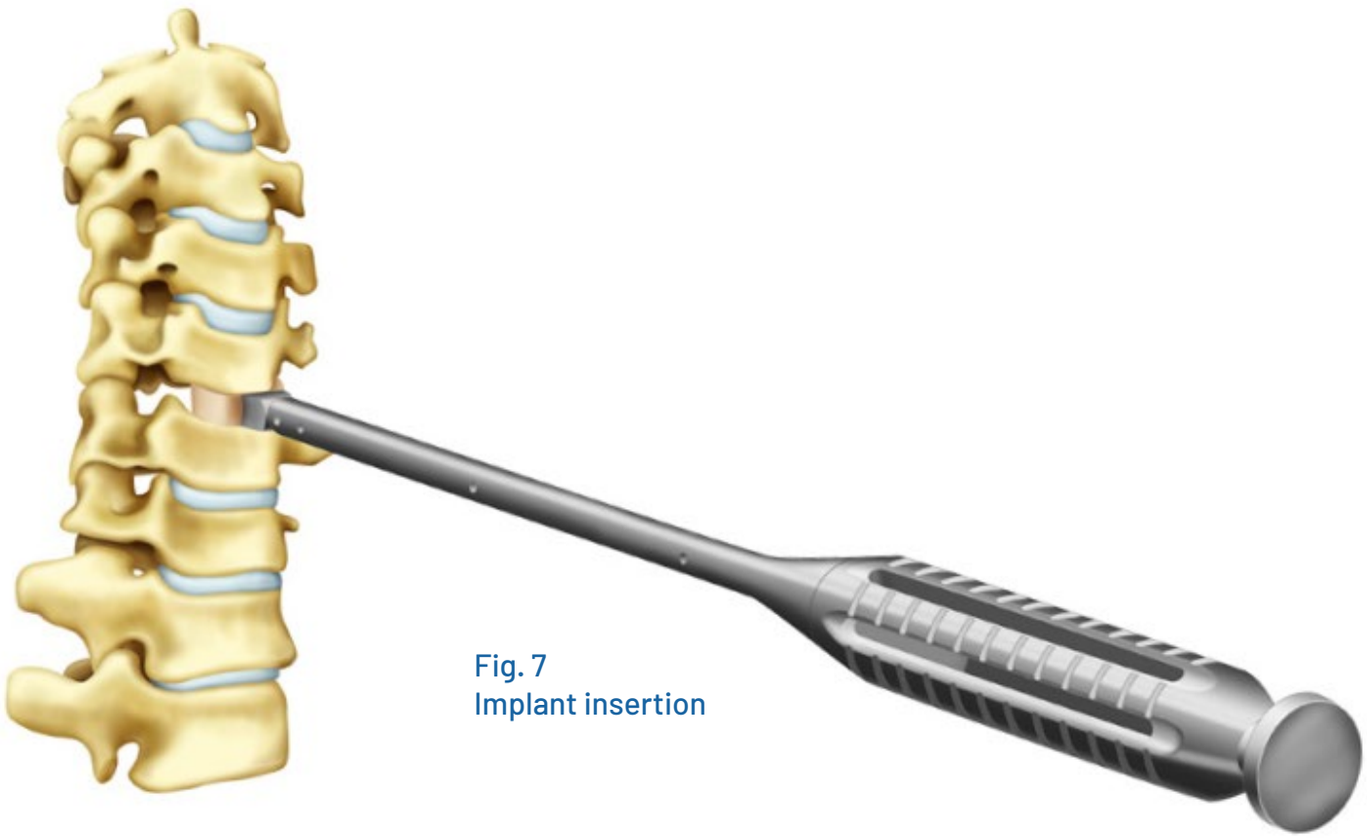


Fig. 7
Implant insertion

IMPLANT REMOVAL

If it becomes necessary to remove the implant, carefully observe the implant position and the presence of any scar tissue, which can make exposure more challenging compared to the unoperated spine.

To remove the implant, use a standard operating instrument like a kocher to grasp the implant and proceed with removal. Alternatively, the implant inserter can be reattached to the implant with the locking shaft in place as described in Figures 3, 4 and 5 so that the implant can be removed. If the implant cannot be easily removed, a cobb elevator or osteotome should be used to loosen the bone to implant interface.

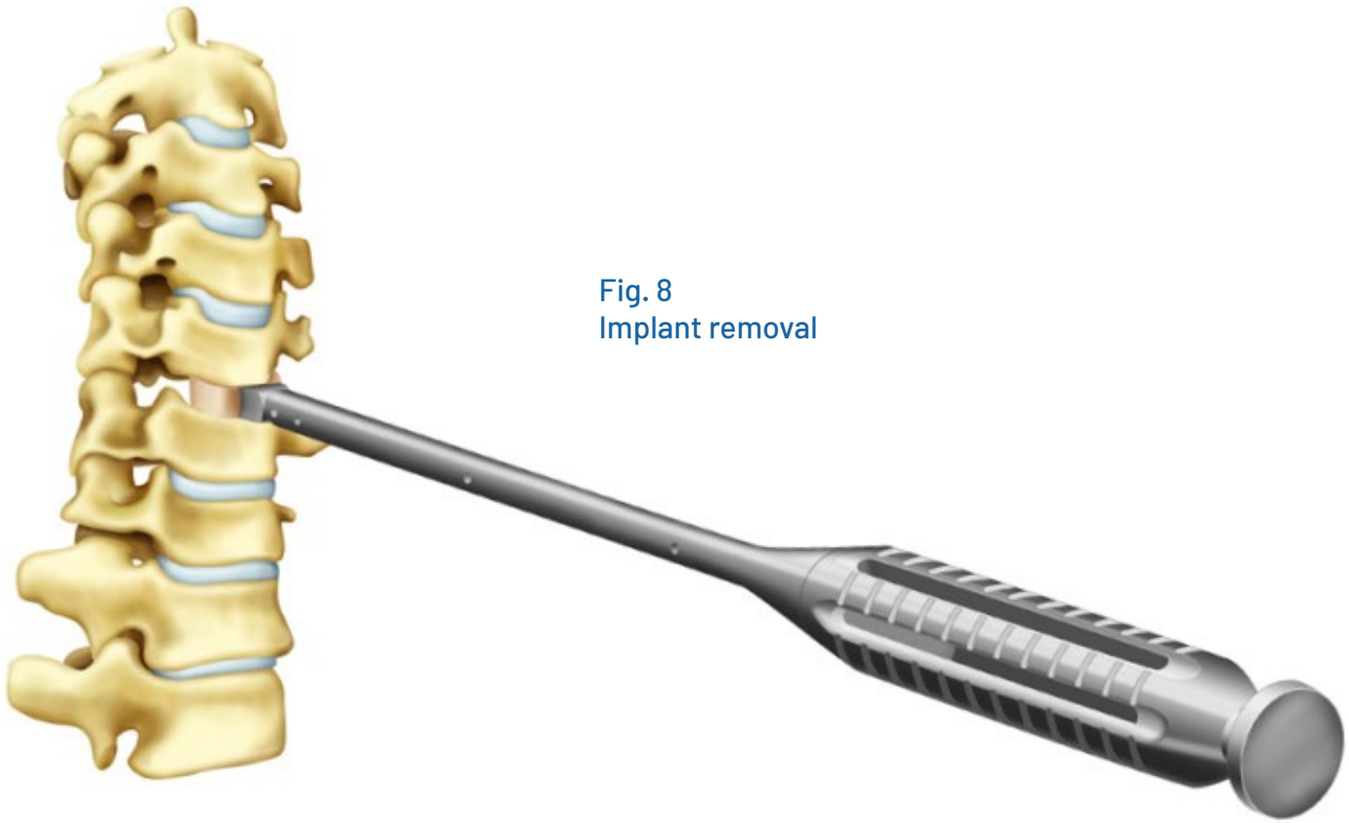


Fig. 8
Implant removal

IMPLANT LISTING

Catalog Number	*Part Description*
Ascendant™	
05-090-10-1405	C-IBD 14W x 12D X 5H Lordotic
05-090-10-1406	C-IBD 14W x 12D X 6H Lordotic
05-090-10-1407	C-IBD 14W x 12D X 7H Lordotic
05-090-10-1408	C-IBD 14W x 12D X 8H Lordotic
05-090-10-1409	C-IBD 14W x 12D X 9H Lordotic
05-090-10-1410	C-IBD 14W x 12D X 10H Lordotic
05-090-10-1411	C-IBD 14W x 12D X 11H Lordotic
05-090-10-1412	C-IBD 14W x 12D X 12H Lordotic
05-090-11-1405	*C-IBD 14W x 12D X 5H Parallel*
05-090-11-1406	*C-IBD 14W x 12D X 6H Parallel*
05-090-11-1407	*C-IBD 14W x 12D X 7H Parallel*
05-090-11-1408	*C-IBD 14W x 12D X 8H Parallel*
05-090-11-1409	*C-IBD 14W x 12D X 9H Parallel*
05-090-11-1410	*C-IBD 14W x 12D X 10H Parallel*
05-090-11-1411	*C-IBD 14W x 12D X 11H Parallel*
05-090-11-1412	*C-IBD 14W x 12D X 12H Parallel*
05-090-12-1405	C-IBD 14W x 12D x 5H Convex
05-090-12-1406	C-IBD 14W x 12D x 6H Convex
05-090-12-1407	C-IBD 14W x 12D x 7H Convex
05-090-12-1408	C-IBD 14W x 12D x 8H Convex
05-090-12-1409	C-IBD 14W x 12D x 9H Convex
05-090-12-1410	C-IBD 14W x 12D x 10H Convex
05-090-12-1411	C-IBD 14W x 12D x 11H Convex
05-090-12-1412	C-IBD 14W x 12D x 12H Convex
05-090-10-1605	*C-IBD 16W x 14D x 5H Lordotic*
05-090-10-1606	*C-IBD 16W x 14D x 6H Lordotic*
05-090-10-1607	*C-IBD 16W x 14D x 7H Lordotic*
05-090-10-1608	*C-IBD 16W x 14D x 8H Lordotic*
05-090-10-1609	*C-IBD 16W x 14D x 9H Lordotic*
05-090-10-1610	*C-IBD 16W x 14D x 10H Lordotic*
05-090-10-1611	*C-IBD 16W x 14D x 11H Lordotic*
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05-090-11-1607	C-IBD 16W x 14D X 7H Parallel
05-090-11-1608	C-IBD 16W x 14D X 8H Parallel
05-090-11-1609	C-IBD 16W x 14D X 9H Parallel
05-090-11-1610	C-IBD 16W x 14D X 10H Parallel
05-090-11-1611	C-IBD 16W x 14D X 11H Parallel
05-090-11-1612	C-IBD 16W x 14D X 12H Parallel
05-090-12-1605	*C-IBD 16W x 14D x 5H Convex*
05-090-12-1606	*C-IBD 16W x 14D x 6H Convex*
05-090-12-1607	*C-IBD 16W x 14D x 7H Convex*
05-090-12-1608	*C-IBD 16W x 14D x 8H Convex*
05-090-12-1609	*C-IBD 16W x 14D x 9H Convex*
05-090-12-1610	*C-IBD 16W x 14D x 10H Convex*
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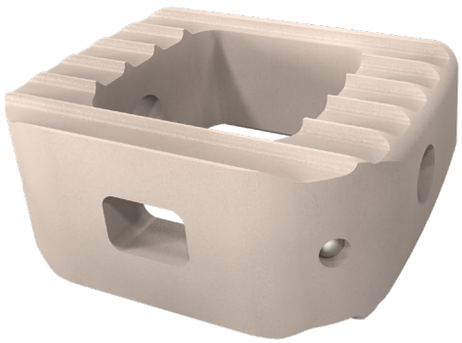

IMPLANT LISTING

Catalog Number	*Part Description*
Ascendant™ PC	
05-090-30-1405	C-IBD 14W x 12D X 5H Lordotic, Ti
05-090-30-1406	C-IBD 14W x 12D X 6H Lordotic, Ti
05-090-30-1407	C-IBD 14W x 12D X 7H Lordotic, Ti
05-090-30-1408	C-IBD 14W x 12D X 8H Lordotic, Ti
05-090-30-1409	C-IBD 14W x 12D X 9H Lordotic, Ti
05-090-30-1410	C-IBD 14W x 12D X 10H Lordotic, Ti
05-090-30-1411	C-IBD 14W x 12D X 11H Lordotic, Ti
05-090-30-1412	C-IBD 14W x 12D X 12H Lordotic, Ti
05-090-31-1405	*C-IBD 14W x 12D X 5H Parallel, Ti*
05-090-31-1406	*C-IBD 14W x 12D X 6H Parallel, Ti*
05-090-31-1407	*C-IBD 14W x 12D X 7H Parallel, Ti*
05-090-31-1408	*C-IBD 14W x 12D X 8H Parallel, Ti*
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05-090-32-1407	C-IBD 14W x 12D x 7H Convex, Ti
05-090-32-1408	C-IBD 14W x 12D x 8H Convex, Ti
05-090-32-1409	C-IBD 14W x 12D x 9H Convex, Ti
05-090-32-1410	C-IBD 14W x 12D x 10H Convex, Ti
05-090-32-1411	C-IBD 14W x 12D x 11H Convex, Ti
05-090-32-1412	C-IBD 14W x 12D x 12H Convex, Ti
05-090-30-1605	*C-IBD 16W x 14D x 5H Lordotic, Ti*
05-090-30-1606	*C-IBD 16W x 14D x 6H Lordotic, Ti*
05-090-30-1607	*C-IBD 16W x 14D x 7H Lordotic, Ti*
05-090-30-1608	*C-IBD 16W x 14D x 8H Lordotic, Ti*
05-090-30-1609	*C-IBD 16W x 14D x 9H Lordotic, Ti*
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05-090-32-1608	*C-IBD 16W x 14D x 8H Convex, Ti*
05-090-32-1609	*C-IBD 16W x 14D x 9H Convex, Ti*
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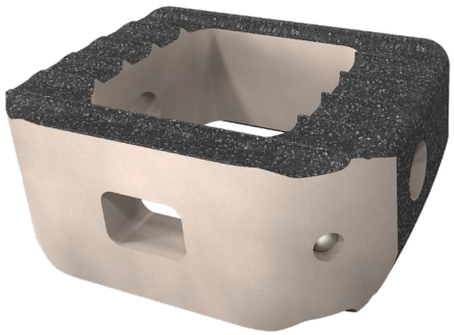
05-090-32-1612	*C-IBD 16W x 14D x 12H Convex, Ti*



INSTRUMENT LISTING

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05-099-05-1405	Lordotic Trial 14W x 12D x 5H
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05-099-05-1407	Lordotic Trial 14W x 12D x 7H
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05-099-05-1409	Lordotic Trial 14W x 1vD x 9H
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05-099-06-1406	*Parallel Trial 14W x 12D x 6H*
05-099-06-1407	*Parallel Trial 14W x 12D x 7H*
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05-099-06-1410	*Parallel Trial 14W x 12D x 10H*
05-099-06-1411	*Parallel Trial 14W x 12D x 11H*
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05-099-07-1407	Convex Trial 14W x 12D x 7H
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05-099-06-1607	Parallel Trial 16W x 14D x 7H
05-099-06-1608	Parallel Trial 16W x 14D x 8H
05-099-06-1609	Parallel Trial 16W x 14D x 9H
05-099-06-1610	Parallel Trial 16W x 14D x 10H
05-099-06-1611	Parallel Trial 16W x 14D x 11H
05-099-06-1612	Parallel Trial 16W x 14D x 12H
05-099-07-1605	*Convex Trial 16W x 14D x 5H*
05-099-07-1606	*Convex Trial 16W x 14D x 6H*
05-099-07-1607	*Convex Trial 16W x 14D x 7H*
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05-099-07-1609	*Convex Trial 16W x 14D x 9H*
05-099-07-1610	*Convex Trial 16W x 14D x 10H*
05-099-07-1611	*Convex Trial 16W x 14D x 11H*
05-099-07-1612	*Convex Trial 16W x 14D x 12H*

INSTRUMENT LISTING

05-099-01-2000	Inserter	
05-099-01-2006	Inserter shaft	
05-099-10-0000	Straight rasp	
05-099-14-0000	Straight ring curette	
05-099-16-0003	Graft loading base	
05-099-17-0000	Graft impactor	
05-099-30-0000	Mallet	
05-099-01-0020	Tamp	

ASCENDANT PEEK

General Description:
The Ascendant Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK Optima® LT1 (polyetheretherkeytone) implant cage with tantalum radiographic markers. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints and lordotic angles to accommodate varying anatomical conditions. The device features an enclosed chamber intended to be filled with autogenous and or/allogenic bone graft material. The Ascendant Cervical Spacer System is intended to be used with supplemental fixation (i.e., an anterior cervical plate).

Indications for Use:
The Ascendant Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one-disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Ascendant Cervical Spacer System is to be used with autogenous bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Contraindications:
Contraindications for the Ascendant Cervical Spacer System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Morbid obesity
3. Pregnancy
4. Grossly distorted anatomy due to congenital abnormalities
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
6. Rapid joint disease, bone absorption, osteopenia, osteomalcia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation
7. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
8. Suspected or documented material allergy or intolerance
9. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
10. Patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions
11. Any case not needing an autogenous and or/allogenic bone graft and fusion.
12. Any condition not described in the indications for Use
13. Prior fusion at the level(s) to be treated

Warnings and Precautions:
The Ascendant Cervical Spacer System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results.
The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
The Ascendant Cervical Spacer System is not intended to be the sole means of spinal support. This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. Autogenous and or/allogenic bone grafting must be part of the spinal fusion procedure in which the Cervical Spacer System is used. Use of this product without an autogenous and or/allogenic bone graft may not be successful. The spinal implant cannot stand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. Based on fatigue testing results, when using the Ascendant Cervical Spacer System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

The Ascendant Cervical Spacer System has not been evaluated for safety and compatibility in the MR environment. The Ascendant Cervical Spacer System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Ascendant Cervical Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

ASCENDANT PC

General Description:
The Ascendant™ PC Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK Optima® LT1 (polyetheretherkeytone) implant cage with CP titanium coating and tantalum radiographic markers. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints and lordotic angles to accommodate varying anatomical conditions. The device features an enclosed chamber intended to be filled with autogenous and or/allogenic bone graft material.

Indications for Use:
The Ascendant PC Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Ascendant PC Cervical Spacer System is to be used with autogenous and/or allogenic bone graft composed of cancellous and / or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Contraindications:
Contraindications for the Ascendant PC Cervical Spacer System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Morbid obesity
3. Pregnancy
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
6. Rapid joint disease, bone absorption, osteopenia, osteomalcia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
8. Suspected or documented material allergy or intolerance
9. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
10. Patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions
11. Any case not needing an autogenous and or/ allogenic bone graft and fusion
12. Any condition not described in the Indications for Use
13. Prior fusion at the level(s) to be treated

Warnings and Precautions:
The Ascendant PC Cervical Spacer System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

The Ascendant PC Cervical Spacer System is not intended to be the sole means of spinal support. This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. Autogenous and or/allogenic bone grafting must be part of the spinal fusion procedure in which the Cervical Spacer System is used. Use of this product without an autogenous and or/allogenic bone graft may not be successful. The spinal implant cannot stand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. Based on fatigue testing results, when using the Ascendant PC Cervical Spacer System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

The Ascendant PC Cervical Spacer System has not been evaluated for safety and compatibility in the MR environment. The Ascendant PC Cervical Spacer System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Ascendant PC Cervical Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Notes

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LIT# Ascendant STG | REV F | 9/19