CeSpace™XP Interbody System

Surgical Technique

Aesculap Spine

AESCULAP®
Implant Systems

CeSpace™XP Interbody System

Surgical Technique

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System Overview

The CeSpace™XP Interbody System brings an innovative surface enhancing technology, Plasmapore®XP, to ACDF procedures. The combination of a PEEK-OPTIMA® core with the osteoconductive Plasmapore™XP coating delivers enhanced implant stability, artifact free visualization, and proven biocompatibility.

System Features

- Plasmapore™XP osteoconductive coating
- Wide variety of implant options
- Generous graft window
- Surface texturing
- X-Ray marker pins
- Individually sterile packed
- Comprehensive array of instrumentation

Design Advantages

- **Built on Experience** – Aesculap maximized 20 years of success in applying Plasmapore™XP coatings to Titanium orthopedic and spine implants to develop the Plasmapore™XP coating for PEEK spinal implants
- I**nnovative Surface Enhancing Technology** –The Plasmapore™XP is an osteoconductive pure Titanium porous coating with proven biocompatibility
- **Enhanced Stability** – The superior and inferior ridges plus the roughened surface area provided by the osteoconductive Plasmapore™XP coating delivers enhanced implant stability and helps prevent implant migration
- **Optimized Implant Fit** – Wide variety of implant sizes and anatomical shape helps ensure compatibility with varying patient anatomies
- **Proven Implant Design** – Implant and instrument design are identical to Aesculap's established CeSpace PEEK Interbody System
- **Excellent Imagining Properties** – Plasmapore™XP coating and X-Ray marker pins allow for improved visibility during imaging
- **Comprehensive Instrumentation** – The CeSpace™XP Interbody System is supported by simple, user-friendly instrumentation for easy implantation

** PEEK-OPTIMA is a registered trademark of Invibio® Biomaterial Solutions*

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II. Indications and Contraindications

Indications for Use

- Intended as an Intervertebral body fusion device designed for use with autogenous bone graft.
- Intended for spinal fusion procedures at one level in the cervical spine from C3-C7.
- Intended for use in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Intended for use with supplemental spinal fixation systems such as the Aesculap S4® System.
- Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

Contraindications

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the PEEK devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

Warnings and Precautions

Implants supplied in sterile condition must not be resterilized or reused under any circumstances. Danger to the patient and possible loss of implant functionality may result from resterilization!

Warnings
Increased risk of migration due to over-preparation of the vertebral body endplates! When preparing the implant bed, make certain that the base and cover plates of the adjacent vertebral bodies are not weakened.

Warnings
Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union) fracture of the vertebra, neurological injury, and vascular or visceral injury.

Warnings
Avoid damage to the Plasmapore®XP coated implant surfaces caused by instruments (e.g. High Frequency surgical devices) applied close to the implant.

Caution
Based upon dynamic testing results physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the CeSpace implant when used as an intervertebral body fusion device.

Precaution
The CeSpace™ PEEK and CeSpace®XP Spinal Implant Systems have not been evaluated for safety and compatibility in the MR environment. The CeSpace PEEK and CeSpace®XP Spinal Implant Systems have not been tested for heating or migration in the MR environment.

Risks

The surgical intervention involves the following potential risks:

- Neurological complications caused by over distraction or trauma of the nerve roots or dura
- Loss of intervertebral disk height due to removal of healthy bone material

Complications that can generally occur in connection with intervertebral surgery:

- Pseudarthrosis
- Incorrect implant position
- Spondylolisthesis
- Loss of fixation; dislocation or migration

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III. Surgical Technique

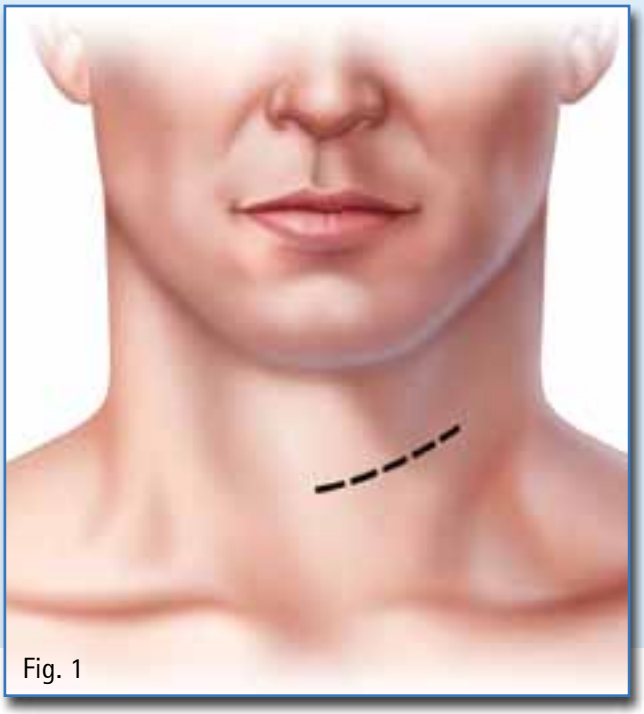

Fig. 1

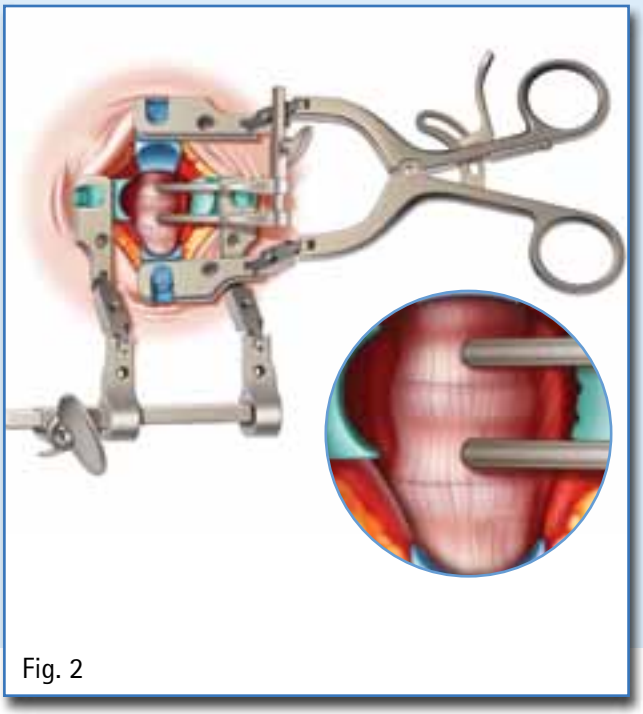

Fig. 2

1. Patient Positioning and Exposure

Anterior access will be required for the insertion of the CeSpace^{XP} implant. As with any procedure, it is important to understand the lordotic angle of disc spaces and the surrounding anatomy in order to plan for anterior surgery. Pre-operative radiographs should be taken to measure disc heights and the required implant range. Patient positioning and exposure of the anterior cervical spine is performed in accordance with the standard anterior cervical surgical technique.

- Place the patient in the supine position.
- Utilize the standard anterior approach to the cervical spine. (Fig. 1)
- Provide the level of exposure to the implantation site that the surgeon deems necessary to perform the surgery. A cervical retraction system, such as Aesculap's Caspar Cervical Retractor System, can be used to provide adequate visualization to the front of the cervical spine. (Fig. 2)

Fig. 3

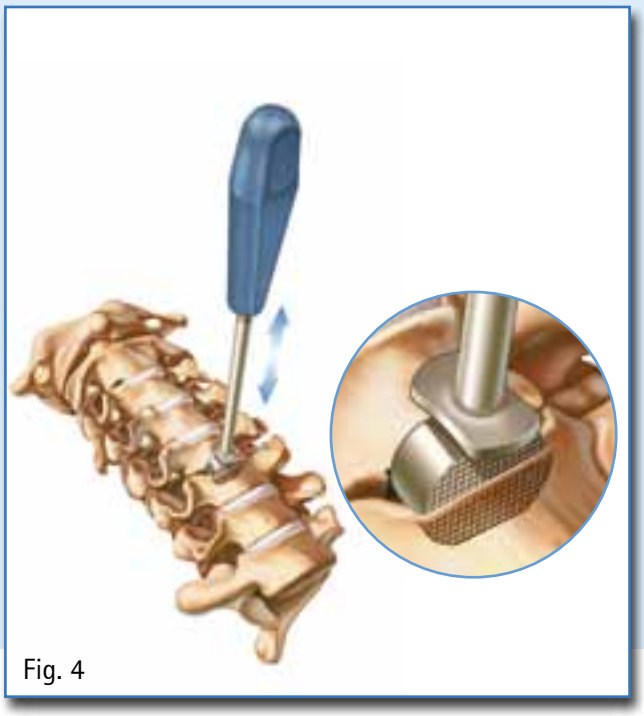

Fig. 4

2. Preparation / Discectomy

Prepare the intervertebral space by utilizing anterior discectomy instruments that the surgeon feels are necessary to properly prepare the disc space and vertebral endplates.

- A cervical distraction system, such as Aesculap's Caspar Cervical Distraction System, can be used to gradually achieve the desired working height. (Fig. 2)
- Perform a thorough discectomy. (Fig. 3)
- Ensure adequate neural decompression has been established.
- Prepare the endplates to receive the CeSpace™XP implant. (Fig. 4)

Note: *Excessive removal of the endplates may weaken the construct and cause subsidence of the implant.*

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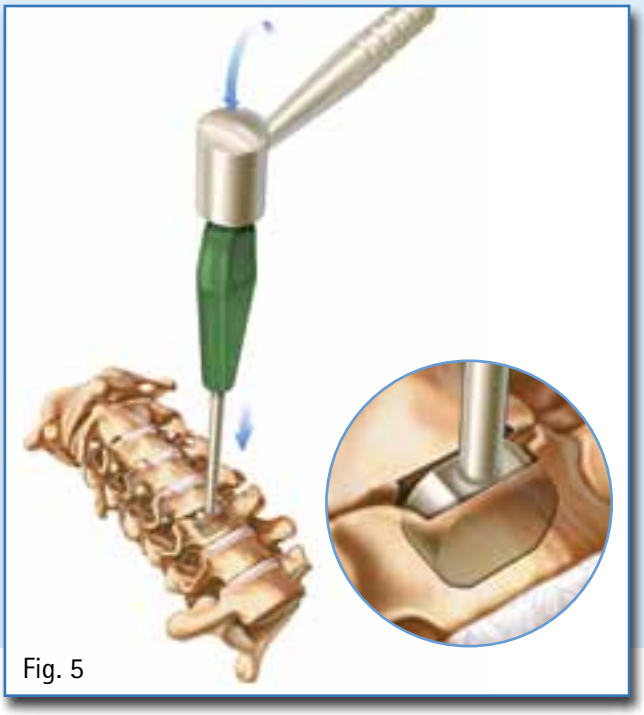

Fig. 5

3. Implant Sizing

Proper implant size can be established using the trial spacers while the interspace is distracted. Trial implants are available in two footprint sizes, two lordotic angles, and eight heights. Each trial implant is color-coded by footprint size and labeled with the corresponding footprint, height, and lordotic angle. (See page 13 for available sizes.)

- Select an appropriate sized trial implant based on patient anatomy and pre-operative radiographic analysis.
- Utilize the cottle mallet to gently advance the trial into the disc space. (Fig. 5)
- Manipulate the trial implant as needed to attain the desired position.
- Continue to evaluate trial implants until a tight fit is achieved.
- Assess the final implant fit and position with intraoperative AP and lateral fluoroscopy.

Note: *A properly chosen implant will ensure disc height is maintained and implant migration is minimized.*

Fig. 6

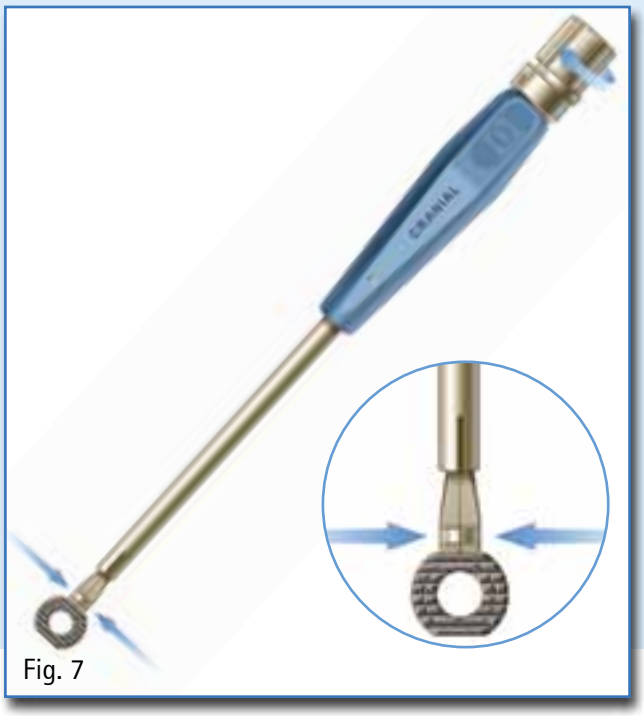

Fig. 7

4. Implant Preparation and Insertion

- Select the implant that corresponds to the final trial implant size evaluated.

> **Note:** *The dimensions of the trial implants were designed to match the CeSpace™XP implants (footprint, height, and lordotic angle).*

Implant Preparation

- Attach and secure the selected CeSpace™XP implant to the distal end of the insertion instrument.
  - Insert the inner shaft (FJ497R or FJ415R) into the insertion instrument handle and secure.

> **Note:** *The insertion instrument consists of a handle plus an inner shaft with a safety stop (FJ497R) or alternatively without a safety stop (FJ415R). It is recommended that the safety stop is utilized to ensure that the implant is seated 1 to 2 mm beyond the anterior border of the vertebral body.*

  - The handle of the insertion instrument is labeled with the word "Cranial" for orientation purposes during implant insertion. Orient the insertion instrument in the Cranial position and align the distal end with the bilateral holes of the selected CeSpace™XP implant. (Fig. 6)

> **Note:** *Laser markings on the insertion instrument indicate the cranial and caudal side of the instrument. In addition, each CeSpace™XP Implant has an arrow to denote its cranial orientation.*

  - Attach and secure the selected implant to the distal end of the insertion instrument by turning the proximal knob in a clockwise direction. (Fig. 7)

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Fig. 8

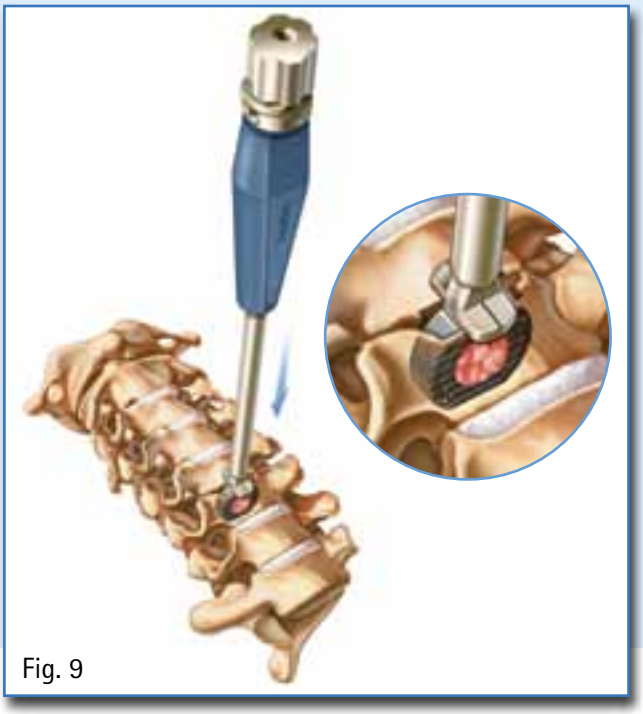

Fig. 9

4. Implant Preparation and Insertion *(continued)*

- Fill the implant with autograft material by utilizing the packing block and tamp. (Fig. 8)
  - Place the implant into the corresponding footprint space of the packing block.
  - Fill the implant with autograft material.
  - Use the tamp to firmly pack autograft material into the implant.

Implant Insertion

- Ensure that the insertion instrument is oriented in the Cranial position.
- Introduce the implant into the disc space. The implant should be inserted centrally in AP and with a distance of approximately 1-2 mm to both the anterior and posterior rim. (Fig. 9)

Caution: *It is important to consider the midline and neutral alignment while implanting this device to avoid placing neural elements at risk.*

Note: *If using the inserter with safety stop (FJ497R), a positive stop at the end of the insertion sleeve ensures that the graft is positioned within the vertebral space, and helps prevent over insertion and spinal canal compromise.*

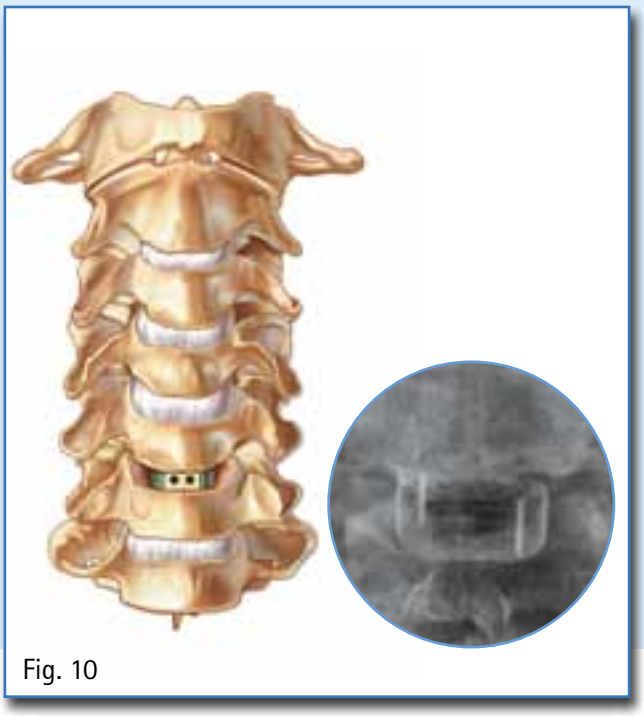

Fig. 10

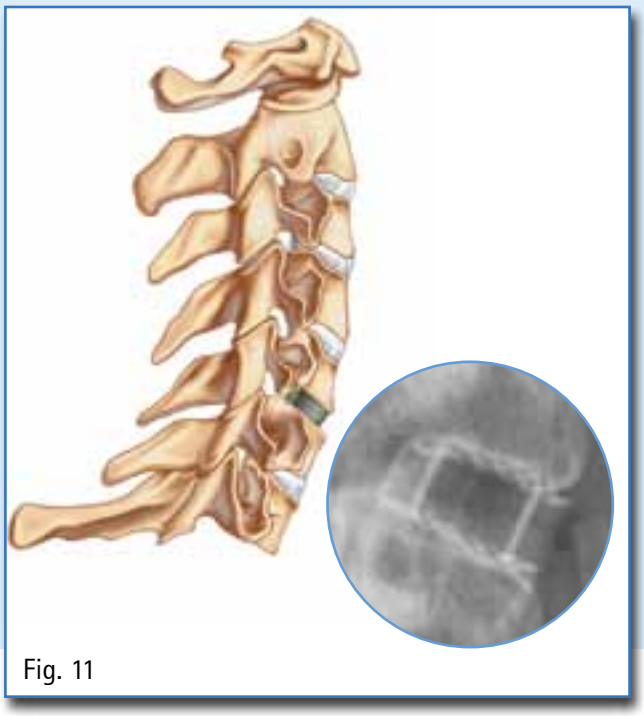

Fig. 11

5. Verification of Final Implant Placement

- Obtain AP fluoroscopic images to confirm midline placement of the device.
- Obtain lateral fluoroscopic images to confirm that the anterior edge of the implant is seated 1 to 2 mm beyond the anterior border of the vertebral body.

Note: *It is recommended to confirm implant position prior to removing the insertion instrument.*

- Observe the X-Ray markers in both the AP and lateral views to ensure that the implant is not rotated within the disc space. (Figs. 10 & 11)

Note: *The green lines in Figures 10 & 11 represent the location of the implant X-Ray markers in both the AP and lateral views.*

- Manipulate the implant as needed by gently tapping the impactor with the mallet.
- Relax the Caspar Distractor.

Note: *Relaxing the Caspar Distractor places the implant in compression. This allows the grooves on the superior and inferior surfaces of the CeSpace^{XP} implant to come in contact with the vertebral body endplates, thereby producing a more secure fit within the intervertebral disc space.*

- Check whether the implant is stable and securely positioned.

Caution: *If the implant can be moved slightly in the intervertebral space, there is a risk of dislocation and the implant should be replaced with the next largest size in height.*

- Obtain additional AP and lateral fluoroscopic images to document midline placement and neutral alignment.
- The final AP and lateral images should reflect neutral alignment of the CeSpace™^{XP} implant. (Figs. 10 & 11)
- Once satisfied with the implant location and fit, remove the insertion instrument.

Note: *Additional stabilization utilizing internal fixation such as the Quintex™ Anterior Cervical Plate or the ABC Anterior Cervical Plate is required when using the CeSpace^{XP} Interbody System.*

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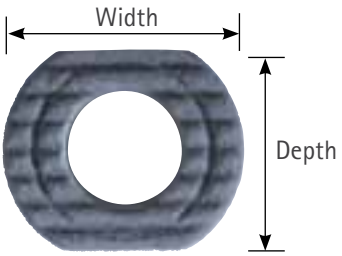
6. Implant Removal

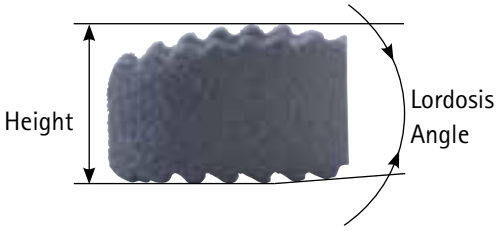
- Insert the inner revision shaft (FJ499R) into the insertion instrument handle and secure.
- Guide and attach the distal end of the insertion instrument to the implant by turning the proximal knob in a clockwise direction.
- Apply an extraction force to the implant insertion instrument with inner revision shaft to remove the implant from the disc space.

IV. Implant Options

14 mm x 11.5 mm Footprint			
Height (mm)	Width x Depth (mm)	Lordosis (°)	Item No.
5	14 x 11.5	5	SO255P
6	14 x 11.5	5	SO256P
7	14 x 11.5	5	SO257P
8	14 x 11.5	5	SO258P
9	14 x 11.5	5	SO259P
10	14 x 11.5	5	SO260P
11	14 x 11.5	5	SO261P
5	14 x 11.5	0	SO245P
6	14 x 11.5	0	SO246P
7	14 x 11.5	0	SO247P
8	14 x 11.5	0	SO248P
9	14 x 11.5	0	SO249P
10	14 x 11.5	0	SO250P
11	14 x 11.5	0	SO251P



16 mm x 13.5 mm Footprint			
Height (mm)	Width x Depth (mm)	Lordosis (°)	Item No.
5	16 x 13.5	5	SO275P
6	16 x 13.5	5	SO276P
7	16 x 13.5	5	SO277P
8	16 x 13.5	5	SO278P
9	16 x 13.5	5	SO279P
10	16 x 13.5	5	SO280P
11	16 x 13.5	5	SO281P
12	16 x 13.5	5	SO282P
5	16 x 13.5	0	SO265P
6	16 x 13.5	0	SO266P
7	16 x 13.5	0	SO267P
8	16 x 13.5	0	SO268P
9	16 x 13.5	0	SO269P
10	16 x 13.5	0	SO270P
11	16 x 13.5	0	SO271P
12	16 x 13.5	0	SO272P



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V. Instrument Overview

Rasps

14 mm PEEK Rasps (Blue Handle)

Item No.	Lordosis	Size (DxWxH)	Item No.	Lordosis	Size (DxWxH)
MB427R	5°	11.5 x 14 x 5 mm	MB435R	0°	11.5 x 14 x 5 mm
MB428R	5°	11.5 x 14 x 6 mm	MB436R	0°	11.5 x 14 x 6 mm
MB429R	5°	11.5 x 14 x 7 mm	MB437R	0°	11.5 x 14 x 7 mm
MB430R	5°	11.5 x 14 x 8 mm	MB438R	0°	11.5 x 14 x 8 mm
MB431R	5°	11.5 x 14 x 9 mm	MB439R	0°	11.5 x 14 x 9 mm
MB432R	5°	11.5 x 14 x 10 mm	MB440R	0°	11.5 x 14 x 10 mm
MB433R	5°	11.5 x 14 x 11 mm	MB441R	0°	11.5 x 14 x 11 mm

16 mm PEEK Rasps (Green Handle)

Item No.	Lordosis	Size (DxWxH)	Item No.	Lordosis	Size (DxWxH)
MB434R	5°	13.5 x 16 x 12 mm	MB442R	0°	13.5 x 16 x 12 mm

Trial Instruments

14 mm PEEK Trial Instruments (Blue Handle)

Item No.	Lordosis	Size (DxWxH)	Item No.	Lordosis	Size (DxWxH)
FJ385R	5°	11.5 x 14 x 5 mm	FJ435R	0°	11.5 x 14 x 5 mm
FJ386R	5°	11.5 x 14 x 6 mm	FJ436R	0°	11.5 x 14 x 6 mm
FJ387R	5°	11.5 x 14 x 7 mm	FJ437R	0°	11.5 x 14 x 7 mm
FJ388R	5°	11.5 x 14 x 8 mm	FJ438R	0°	11.5 x 14 x 8 mm
FJ389R	5°	11.5 x 14 x 9 mm	FJ439R	0°	11.5 x 14 x 9 mm
FJ390R	5°	11.5 x 14 x 10 mm	FJ440R	0°	11.5 x 14 x 10 mm
FJ391R	5°	11.5 x 14 x 11 mm	FJ441R	0°	11.5 x 14 x 11 mm

16 mm PEEK Trial Instruments (Green Handle)

Item No.	Lordosis	Size (DxWxH)	Item No.	Lordosis	Size (DxWxH)
FJ395R	5°	13.5 x 16 x 5 mm	FJ445R	0°	13.5 x 16 x 5 mm
FJ396R	5°	13.5 x 16 x 6 mm	FJ446R	0°	13.5 x 16 x 6 mm
FJ397R	5°	13.5 x 16 x 7 mm	FJ447R	0°	13.5 x 16 x 7 mm
FJ398R	5°	13.5 x 16 x 8 mm	FJ448R	0°	13.5 x 16 x 8 mm
FJ399R	5°	13.5 x 16 x 9 mm	FJ449R	0°	13.5 x 16 x 9 mm
FJ400R	5°	13.5 x 16 x 10 mm	FJ450R	0°	13.5 x 16 x 10 mm
FJ401R	5°	13.5 x 16 x 11 mm	FJ451R	0°	13.5 x 16 x 11 mm
FJ402R	5°	13.5 x 16 x 12 mm	FJ452R	0°	13.5 x 16 x 12 mm

V. Instrument Overview

Insertion Instrument

Item No.	Description
FJ415R	CeSpace™XP Insertion Instrument

Insertion Instrument with Safety Stop

Item No.	Description
FJ497R	CeSpaceXP Insertion Instrument with safety stop*

Revision Instrument

Item No.	Description
FJ499R	CeSpaceXP Revision Instrument*

**To be used with FJ415R*

Packing Block

Item No.	Description
FJ413P	CeSpaceXP Packing Block

Tamp

Item No.	Description
FF914R	Caspar Graft Positioning Tamp, 5 mm Dia.

Impactor

Item No.	Description
FJ102R	CeSpace Bone® Impactor, 245 mm

Cottle Mallet

Item No.	Description
FL038R	Cottle Mallet Flat Round, 235g, 30 mm x 184 mm

For additional information, contact Customer Service at 1-866-229-3002 or visit our website at www.aesculapimplantsystems.com.

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