ProSpace™ XP Interbody System

Surgical Technique

Aesculap Spine

AESCULAP®
Implant Systems

ProSpace™XP Interbody System

Surgical Technique

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I. System Overview

The ProSpace™XP Interbody System is an interbody spacer used in PLIF (Posterior Lumbar Interbody Fusion) procedures. It is a comprehensive system offering a complete line of implants made of radiolucent PEEK-OPTIMA®* featuring Plasmapore®XP, an osteoconductive porous Titanium coating. The system is supported by high-quality, easy-to-use instrumentation designed for open, percutaneous, and mini-open approaches.

System Features:

- Wide variety of implant options
- 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
- **Innovative Surface Enhancing Technology** –The Plasmapore^XP coating is an osteoconductive pure Titanium porous coating with proven biocompatibility
- **Enhanced Stability** – The aggressive teeth 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 ProSpace PEEK Interbody System
- **Excellent Imagining Properties** – Plasmapore^XP coating and X-Ray markers allow for improved visibility during imaging
- **Comprehensive Instrumentation** – The ProSpace^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

When used as an Intervertebral Body Fusion System:
The ProSpace^{XP} Spinal System is indicated for spinal fusion procedures at one or two contiguous levels (L2-S1) 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. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at involved levels. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s). The ProSpace^{XP} Spinal Implant System is intended for use with supplemental spinal fixation systems that have been cleared for use in the lumbrosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The ProSpace^{XP} Spinal Implant System implants can be used individually or in pairs. The ProSpace^{XP} Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being 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

WARNING

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

WARNING

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.

WARNING

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.

WARNING

Excessive insertion forces may cause damage to the implant.

WARNING

Avoid damage to the Plasmapore®XP coated implant surfaces caused by instruments (e.g. High Frequency surgical devices) applied close to the implant. If there is damage to the PlasmaporeXP surface, replace the damaged implant with a new implant.

CAUTION

Damage to the implant thread!

- Keep to the thread axis when attaching the implant onto the insertion instrument.
- Ensure the implant is flush with the insertion instrument.

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 Aesculap PlasmaporeXP implant when used as an intervertebral body fusion device.

PRECAUTION

The Aesculap PlasmaporeXP Spinal Implant System has not been evaluated for safety and compatibility in the MR environment. The Aesculap PlasmaporeXP Spinal Implant System has not been tested for heating or migration in the MR environment.

Note: The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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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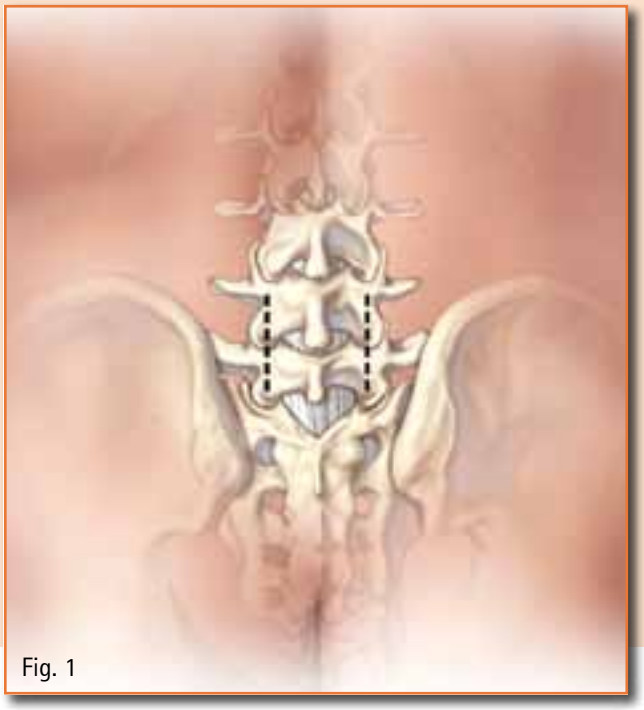

Fig. 1

1. Patient Positioning and Exposure

Posterior access will be required for the insertion of the ProSpace^{XP} implant. It is recommended to determine the appropriate implant height preoperatively. Fluoroscopy is recommended for intra operative determination of the ProSpace^{XP} Implant position.

- Place patient on the operating table in prone position and open the operating site using the standard PLIF exposure. (Fig. 1)

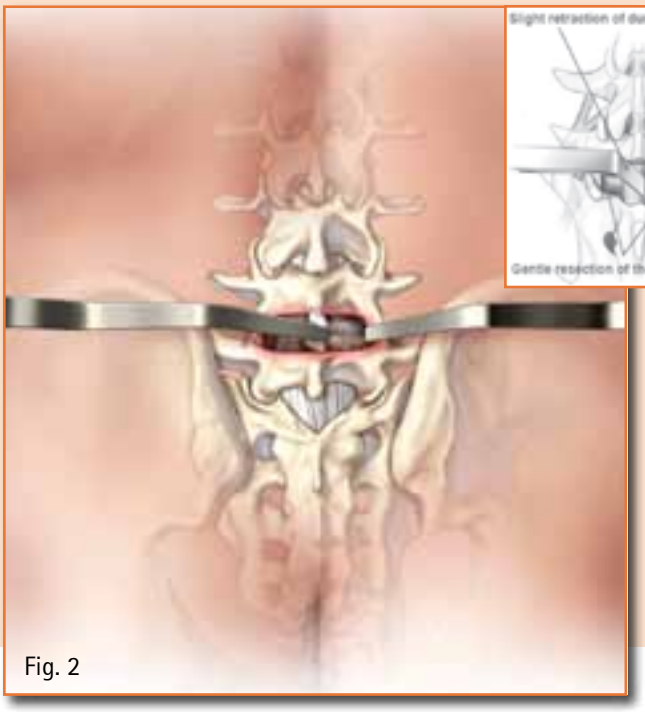

Fig. 2

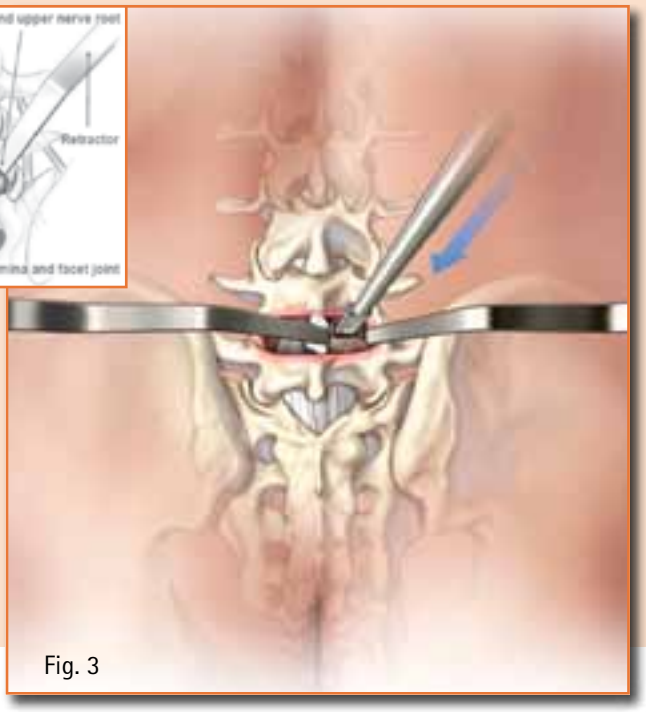

Fig. 3

2. Bone Resection (Laminectomy)

After the desired level of the lumbar spine has been reached using standard procedures, the necessary bone resection is carried out using osteotomes (FJ658R) and kerrisons (bone punches).

- Perform a laminectomy to the medial aspect of the facet.

Accessing the Disc Space

- Once the bone resection is complete, carefully retract the dura and upper nerve root in the desired direction using the nerve root retractors (FJ051R – FJ054R). (Fig. 2 and inset)

In addition to retracting, the retractors can be used to protect surrounding tissues.

- Resect the disc material using rongeurs and forceps on both sides of the disc to make space for insertion of the distractors. (Fig. 3)

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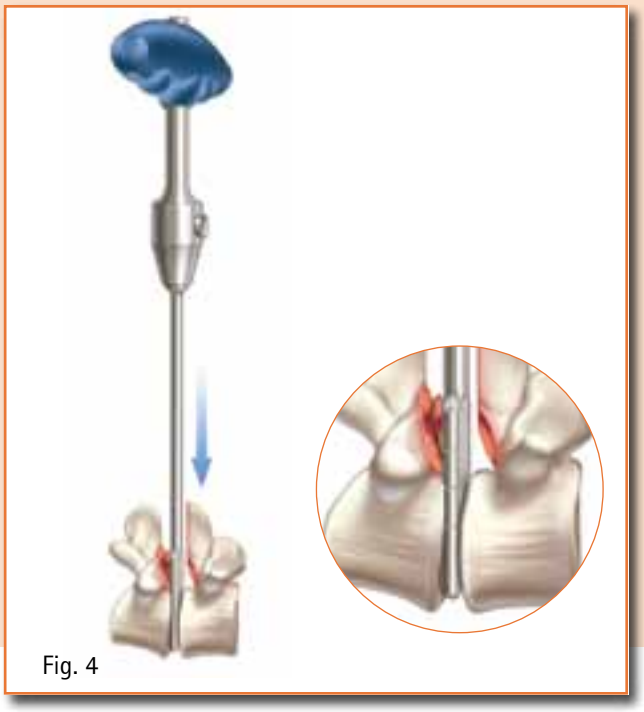

Fig. 4

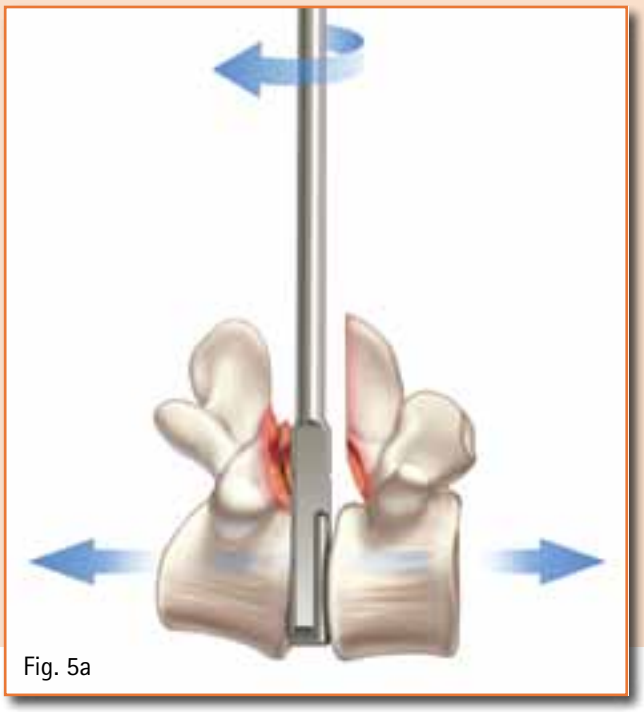

Fig. 5a

3. Distraction

Distraction by Paddle Distractors

The distractors (FJ647R – FJ657R) are inserted to restore the natural disc height. The distractors can be attached to the T-Handle (SJ804R).

- Insert a distractor horizontally and rotate it clockwise to lever the vertebrae apart. (Figs. 4 & 5a)
- To achieve a gradual distraction, insert the distractors in one millimeter height increments, then continue to alternate from one side to the other until the desired distraction is obtained.

Note: *The clockwise rotation of the distractors is blunt whereas the counterclockwise rotation utilizes a sharp rim to partially remove a small layer of cartilage.*

The distractors are available in the following heights:

Distractors	
FJ647R	7 mm Distractor
FJ648R	8 mm Distractor
FJ649R	9 mm Distractor
FJ650R	10 mm Distractor
FJ651R	11 mm Distractor
FJ652R	12 mm Distractor
FJ653R	13 mm Distractor
FJ654R	14 mm Distractor
FJ655R	15 mm Distractor
FJ656R	16 mm Distractor
FJ657R	17 mm Distractor

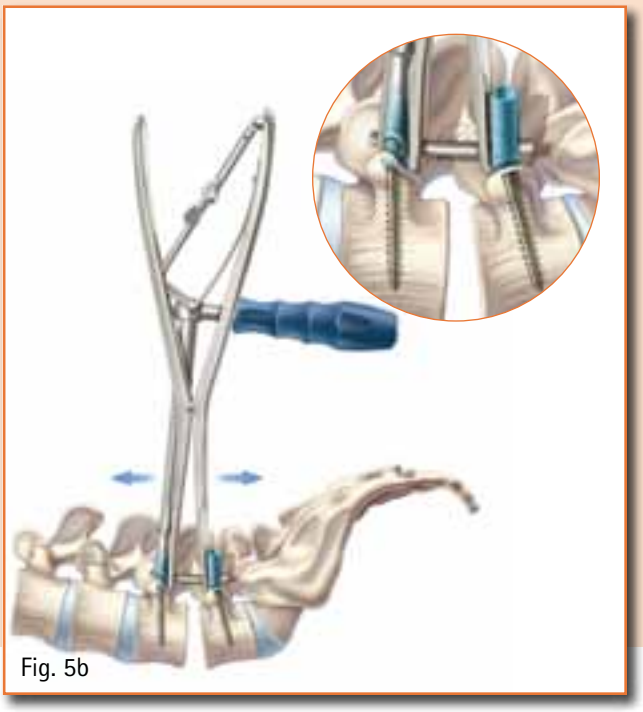

Fig. 5b

Distraction off Pedicle Screws
An alternate method of distraction is shown in Fig. 5b.

If additional distraction is desired, and pedicle screws have already been inserted, distraction can be achieved using forceps (FW281R). Please note that the forceps (FW281R) are part of the S$^{4®}$ Spinal System.

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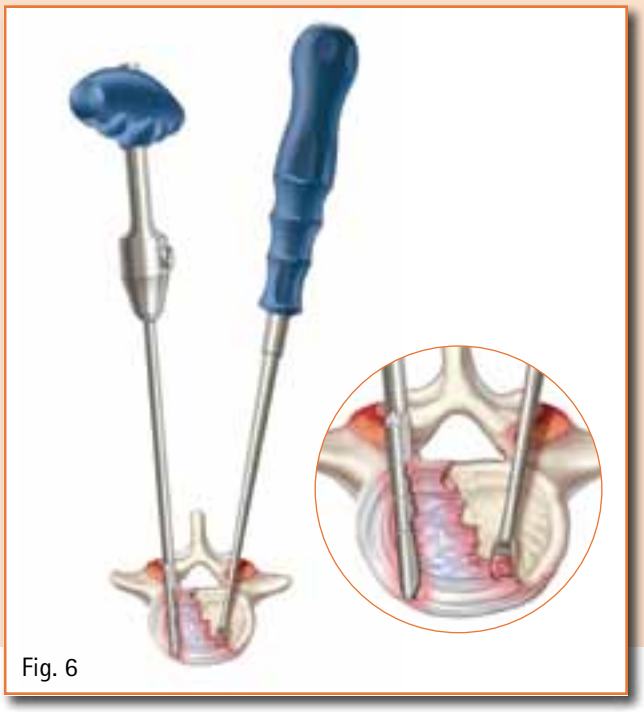

Fig. 6

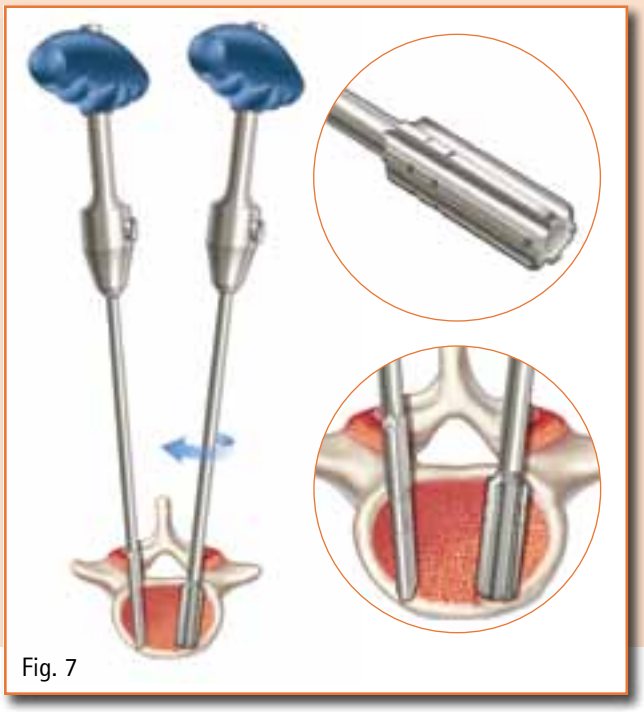

Fig. 7

4. Disc Removal

The disc space height is maintained by using the distractor on the contra-lateral side and the nerve roots are retracted using the nerve root retractor.

- Clear the disc space using the rongeurs, cup curettes (FJ678R), and box curettes (FJ681R). (Fig. 6)
- Utilize the reamers (SJ807R – SJ815R, SJ876R, SJ877R) to remove disc material and roughen endplates by inserting and then rotating the instrument. (Fig. 7)

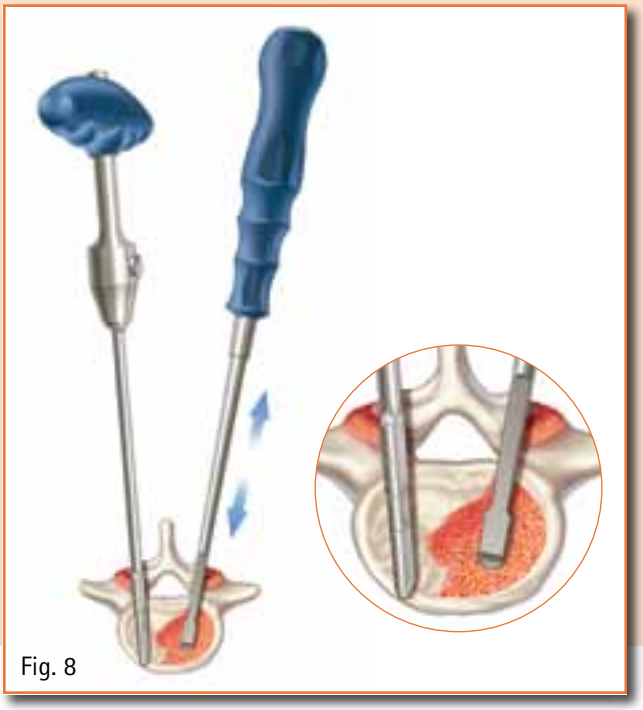

Fig. 8

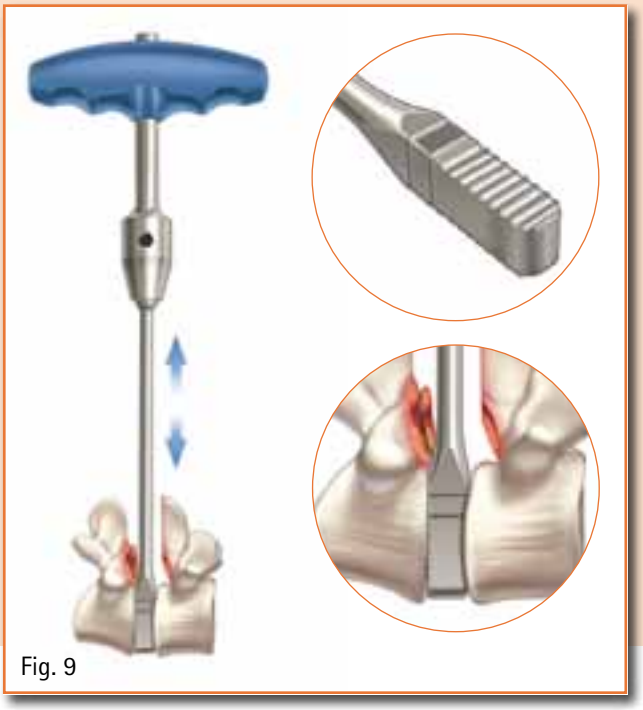

Fig. 9

5. Endplate Exposure and Preparation

- After complete removal of the disc material, use the straight bone rasp (FJ684R) to refresh the cartilaginous endplates with the existing distractor still in place. (Fig. 8)

The rasps (SJ817R – SJ827R) were designed slightly smaller than the height of the implant to achieve a "Press-Fit" between the implant and the vertebral bodies. The rasps can be attached to the T-Handle (SJ804R).

- Use the rasps to assist in the removal of the cartilaginous layers of the endplates and expose bleeding bone. (Fig. 9)

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

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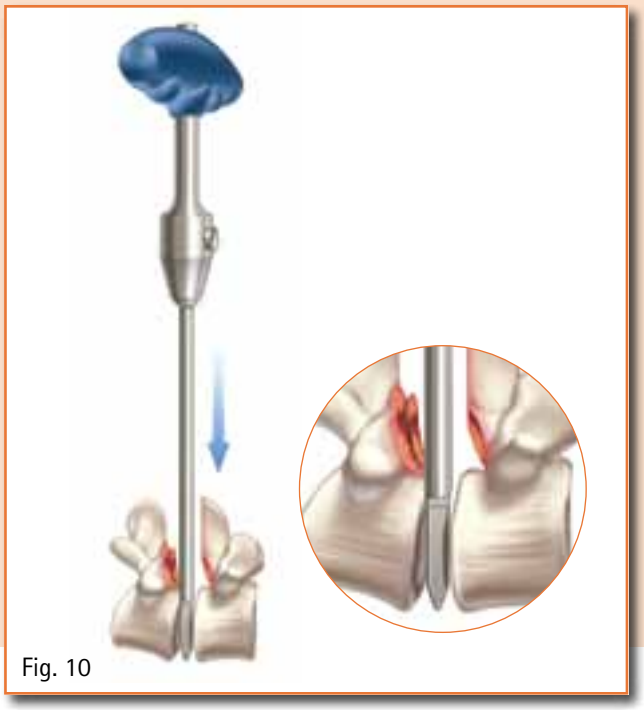


Fig. 10

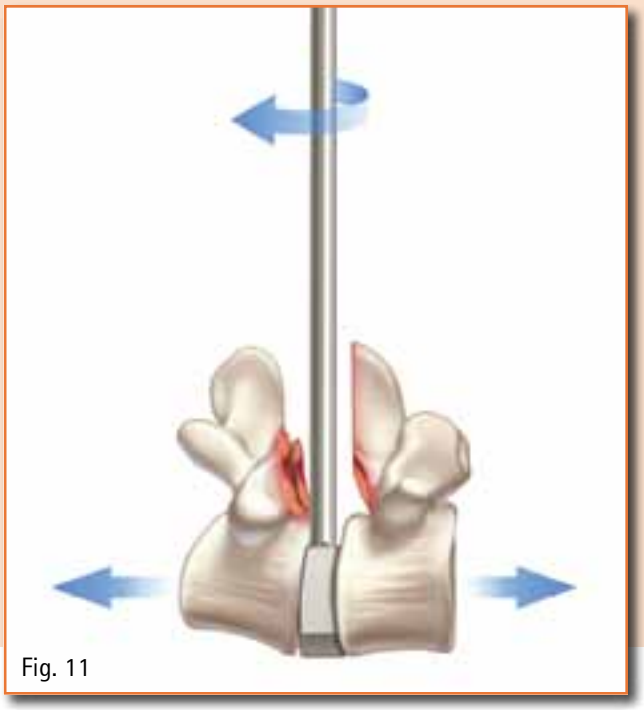
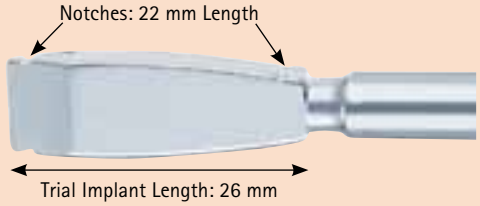


Fig. 11

6. Implant Trials

The trials (SN252R – SN262R) are used to determine the appropriate implant height and length that will be required. The implant trials are available in heights from 7 to 17 mm in 1 mm increments and 5° lordosis. The implant trial should be equivalent in height to the prior level of distraction. The trials are attached to the T-Handle (SJ804R).

Note: *The ProSpace implant trials are available in heights from 7 to 17 mm and 5° lordosis. The trials measure 26 mm in length and 22 mm length is identified by the two superior and two inferior notched markings on the trials (below).*



- Starting with the smallest size, insert the trial implant horizontally and rotate clockwise. (Figs. 10 & 11)
- If the implant trial appears too small, insert the next largest size until the most secure fit is achieved.
- Use fluoroscopy and tactile feedback to confirm the fit of the trial spacer. The adequate trial implant indicates the height and length of the ProSpace™XP implant to be inserted.
- Select the ProSpace^{XP} implant corresponding to the correct trial.
- Remove the trial spacer.

Note: *As a result of the enhanced stability gained through the roughened surface of the Plasmapore^{XP} coating, oversized ProSpace^{XP} implants may be difficult to insert. Please be advised when trialing that the ProSpace^{XP} implants should be right-sized, not oversized, as it may be difficult to insert the implant.*

Fig. 12

Fig. 13

7. Implant Attachment to Insertion Instrument

- Attach the appropriately sized ProSpace™XP implant to the ProSpace PEEK insertion instrument (SN002R).
- Grasp the ProSpace^{XP} implant between the two grooves so the caudal end is flush with the shaft at the point of attachment. (Fig. 12)
- Turn the knob at the proximal end of the insertion instrument clockwise until the implant is secured tightly on the inserter and the knob can no longer be turned clockwise. (Fig. 12)

Note: *Excessive tightening of the knob at the proximal end of the insertion instrument is not required.*

- Prior to insertion, fill the ProSpace^{XP} implant with autogenous bone graft by using the packing block (SN004R) and tamp (FF913R). (Fig. 13)

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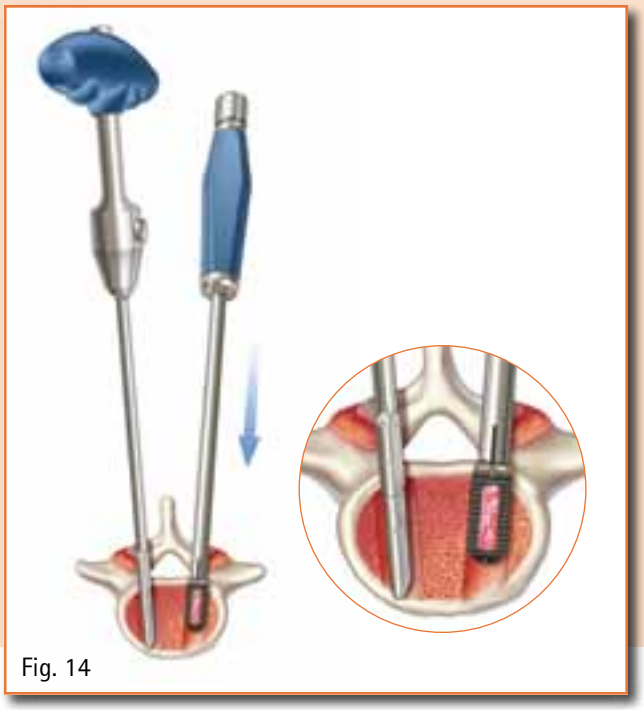


Fig. 14

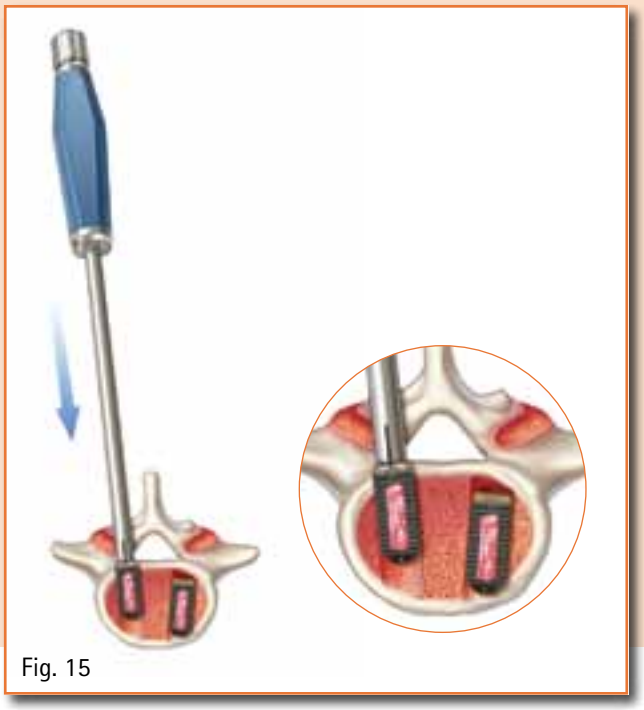


Fig. 15

8. Implant Insertion

- With the distractor still in place, insert the first ProSpace™XP implant. (Fig. 14)

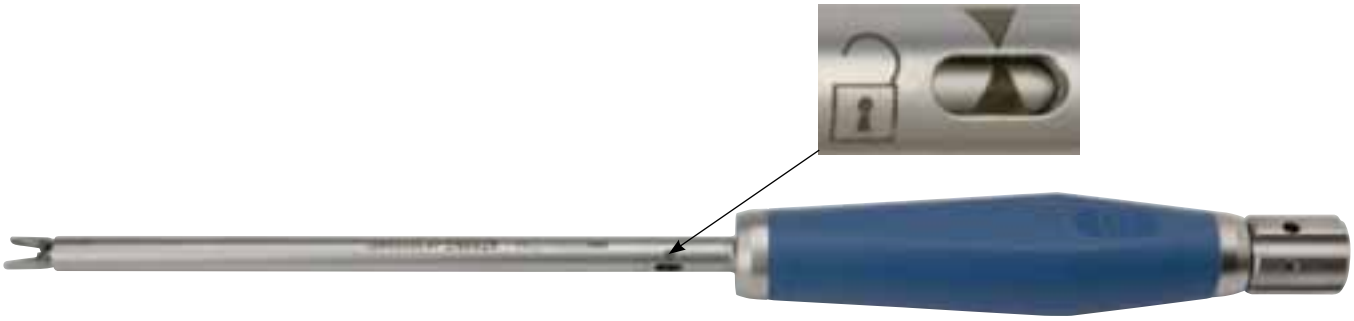
Detaching the Implant from the Insertion Instrument

To release the implant from the insertion instrument, refer to the etching on the inserter next to the unlock symbol (see below).

- Turn the knob at the proximal end of the insertion instrument counterclockwise (approximately four complete turns) until the two arrows line up (below). This indicates the implant is unlocked and the insertion instrument can be easily removed.

Insertion on the Contra-Lateral Side

- After the first ProSpace™XP spacer is successfully placed, remove the distractor from the disc space.
- Repeat the described operative steps for the contra-lateral side to insert the second ProSpace™XP implant. (Fig. 15)
- Bone material can be packed between both implants.



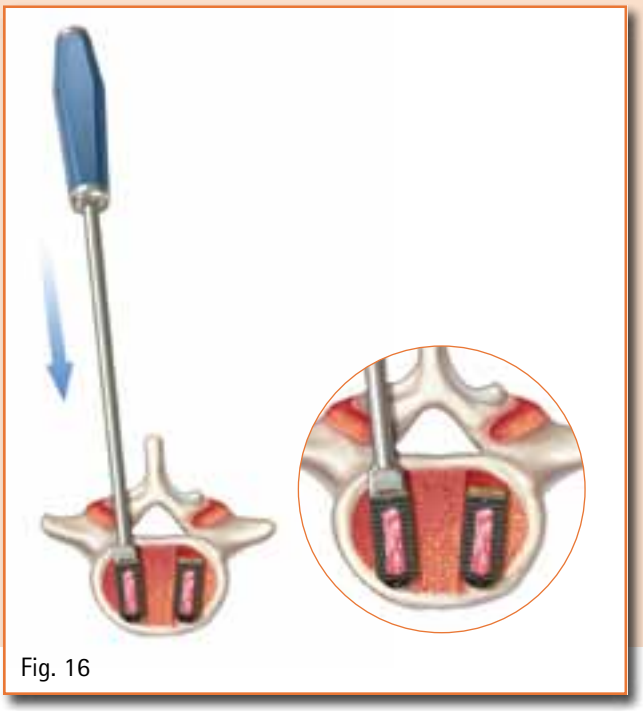


Fig. 16

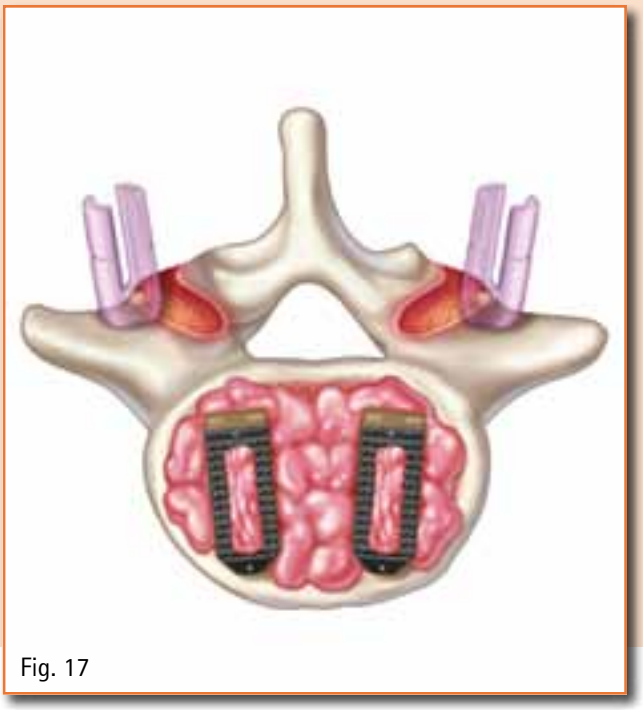


Fig. 17

9. Implant Positioning and Final Placement

- Use the Impactor (SN003R) to achieve the final positioning of the ProSpace^{XP} implants. (Fig. 16)
- Use fluoroscopy to verify the final placement of the ProSpace™^{XP} implants.
- It is recommended to pack bone material around the ProSpace^{XP} implants to support a solid fusion. (Fig. 17)

Note: *The ProSpace^{XP} Interbody System is intended for use with supplemental fixation such as S$^{4®}$ or S^{4} Element® Posterior Lumbar Pedicle Screws.*

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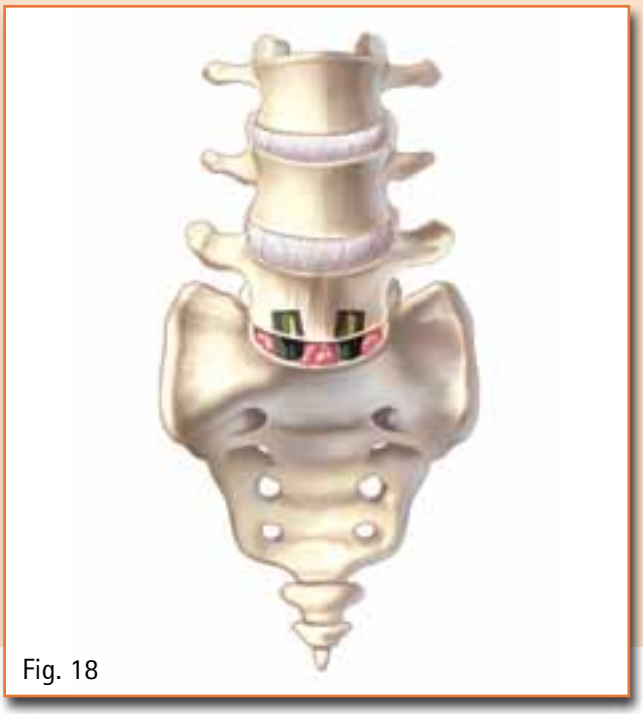

Fig. 18

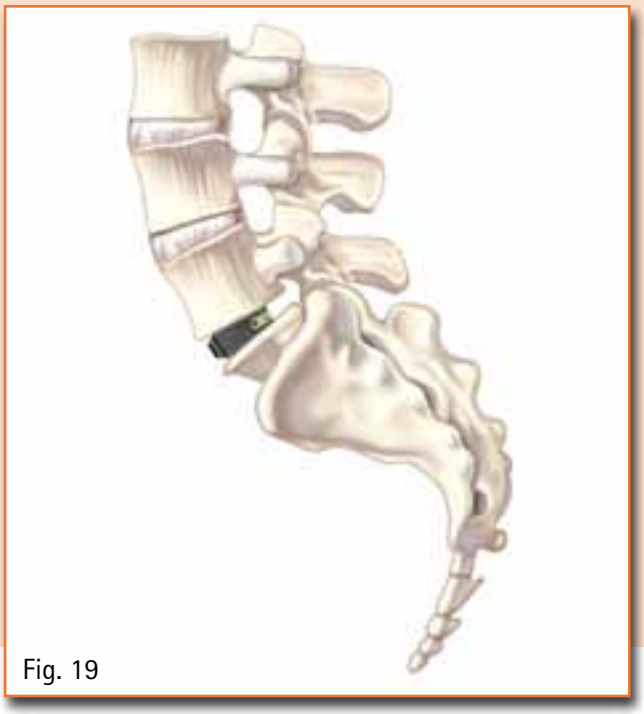

Fig. 19

Verification of Final Implant Placement

- Obtain fluoroscopic images and 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. 18 & 19)

Note: *The green lines in figures 18 & 19 represent the location of the implant X-Ray markers in both the AP and lateral views.*

- 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.*

- The final AP and lateral images should reflect neutral alignment of the ProSpace™XP implant. (Figs. 18 & 19)

10. Implant Removal

- Guide and attach the distal end of the insertion instrument (SN002R) to the implant. Grasp the ProSpace™XP implant between the two grooves so the caudal end is flush with the shaft at the point of attachment.
- Secure the insertion instrument to the implant by turning the proximal knob in a clockwise direction.
- Apply an extraction force to the insertion instrument to remove the implant from the disc space.
- An explanted implant should never be re-implanted. Even though the device may appear intact, it may have small internal stress patterns which may lead to early breakage.

11. Postoperative Treatment

- Adequately instruct the patient on the use and limitations of the device and that weight bearing and physical activity may result in premature loosening, bending, or fracture of the device. The patient should be made aware that a PEEK implant is not as strong as healthy bone and will fracture under normal load bearing in the absence of complete bone healing.
- Non-union of bone will result in excessive and repeated stresses on the implant which may cause eventual bending, loosening, or breakage of the device. Where there is a non-union, or if the components loosen, bend, or break, the device should be explanted before injury occurs.

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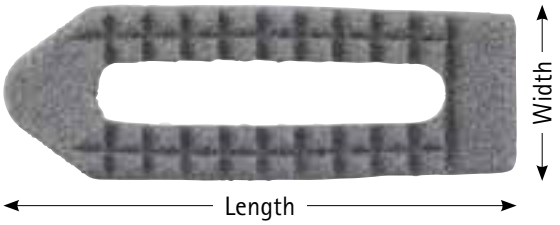
IV. Implant Options



8.5 mm Width ProSpace^{XP} Implant Options

8.5 mm x 22 mm Footprint (Width x Length)				8.5 mm x 26 mm Footprint (Width x Length)			
Height	Lordosis			Height	Lordosis		
	0°	5°	8°		0°	5°	8°
7 mm	S0107P	S0117P		7 mm	S0137P	S0147P	
8 mm	S0108P	S0118P	S0128P	8 mm	S0138P	S0148P	S0158P
9 mm	S0109P	S0119P	S0129P	9 mm	S0139P	S0149P	S0159P
10 mm	S0110P	S0120P	S0130P				
11 mm	S0111P	S0121P	S0131P				

10.5 mm Width ProSpace^{XP} Implant Options

10.5 mm x 22 mm Footprint (Width x Length)				10.5 mm x 26 mm Footprint (Width x Length)			
Height	Lordosis			Height	Lordosis		
	0°	5°	8°		0°	5°	8°
10 mm	S0410P	S0420P	S0430P	10 mm	S0440P	S0450P	S0460P
11 mm	S0411P	S0421P	S0431P	11 mm	S0441P	S0451P	S0461P
12 mm	S0412P	S0422P	S0432P	12 mm	S0442P	S0452P	S0462P
13 mm	S0413P	S0423P	S0433P	13 mm	S0443P	S0453P	S0463P

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

IV. Instrument Overview

Nerve Root Retractors

Item No.	Size
FJ051R	Small
FJ052R	Medium
FJ053R	Large
FJ054R	X-Large

Distractors

Item No.	Size
FJ647R	7 mm
FJ648R	8 mm
FJ649R	9 mm
FJ650R	10 mm
FJ651R	11 mm
FJ652R	12 mm
FJ653R	13 mm
FJ654R	14 mm
FJ655R	15 mm
FJ656R	16 mm
FJ657R	17 mm

T-Handle

Item No.	Description
SJ804R	T-Handle for distractors, reamers, rasps, and trials

Osteotome

Item No.	Size
FJ658R	8 mm / 300 mm

Straight Cup Curette

Item No.	Size
FJ678R	6.3 mm / 350 mm

Straight Box Curette

Item No.	Size
FJ681R	6 mm / 350 mm

Straight Bone Rasp

Item No.	Size
FJ684R	8 mm / 350 mm

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Reamers

Item No.	Size
SJ807R	7 mm
SJ808R	8 mm
SJ809R	9 mm
SJ810R	10 mm
SJ811R	11 mm
SJ812R	12 mm
SJ813R	13 mm
SJ814R	14 mm
SJ815R	15 mm
SJ876R	16 mm
SJ877R	17 mm

Rasps

Item No.	Size
SJ817R	7 mm
SJ818R	8 mm
SJ819R	9 mm
SJ820R	10 mm
SJ821R	11 mm
SJ822R	12 mm
SJ823R	13 mm
SJ824R	14 mm
SJ825R	15 mm
SJ826R	16 mm
SJ827R	17 mm

Trials

Item No.	Height
SN252R	7 mm
SN253R	8 mm
SN254R	9 mm
SN255R	10 mm
SN256R	11 mm
SN257R	12 mm
SN258R	13 mm
SN259R	14 mm
SN260R	15 mm
SN261R	16 mm
SN262R	17 mm

IV. Instrument Overview

Insertion Instrument	
Item No.	**Description**
SN002R	ProSpace PEEK Inserter

Packing Block	
Item No.	**Description**
SN004R	ProSpace PEEK Packing Block

Tamp	
Item No.	**Size**
FF913R	3 mm

Impactor	
Item No.	**Description**
SN003R	ProSpace PEEK Impactor

Slap Hammer	
Item No.	**Description**
FW579R	Slotted Hammer

ProSpace™XP Interbody System

Notes

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Aesculap Implant Systems, LLC - a B. Braun company

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