B BRAUN
SHARING EXPERTISE

SPINE SURGERY

AESCULAP® Arcadius XP L®

STAND-ALONE INTERBODY FUSION SYSTEM

SURGICAL MANUAL

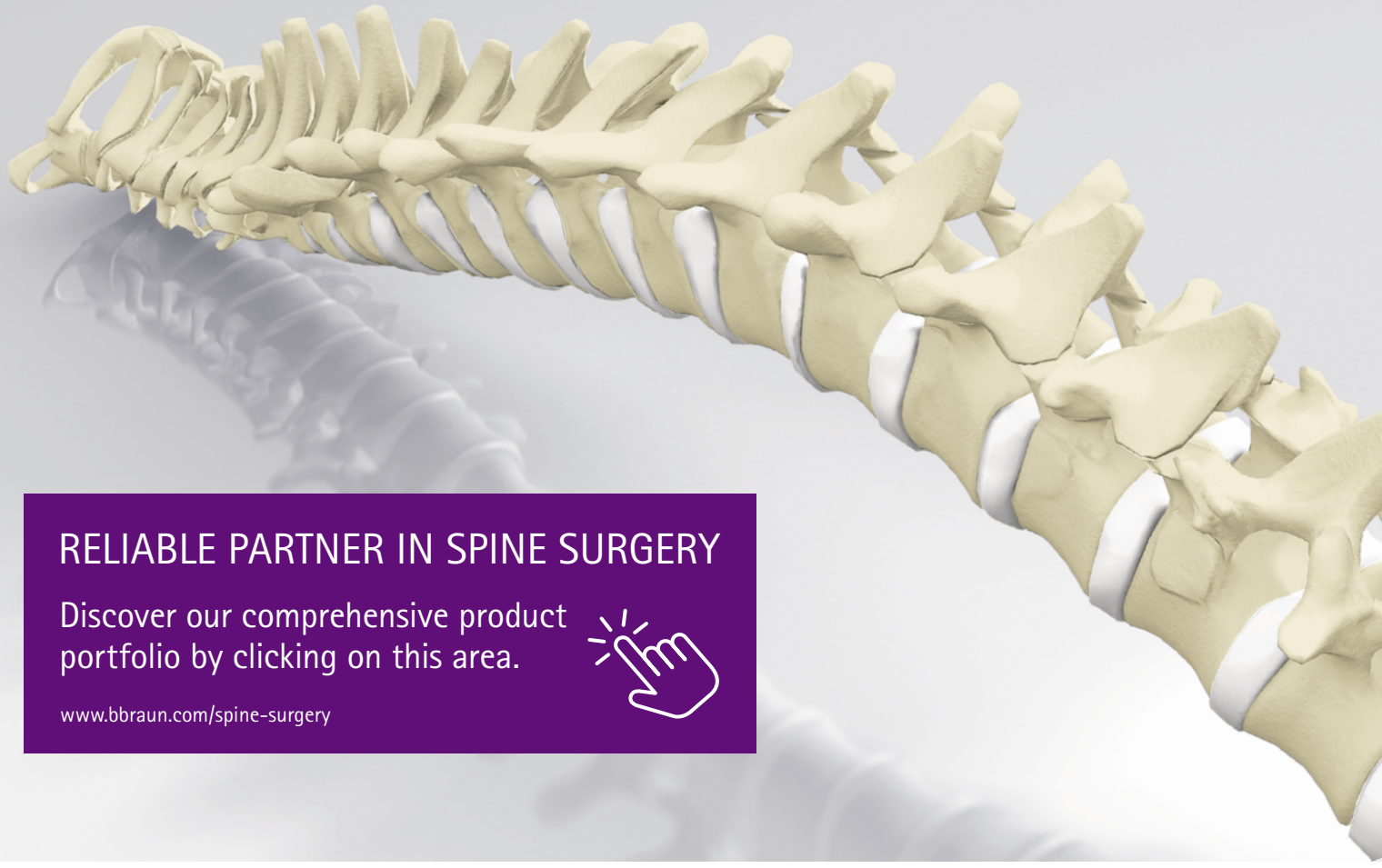
AESCULAP® LUMBAR SPINE

PROTECTING AND PRESERVING SPINAL STABILITY

Modern lifestyle has resulted in increasing physical inactivity among people all over the world. Of the many medical problems associated with this, spinal disorders are among the most critical. This is even more significant as the spinal column is one of the most important structures in the human body.

It supports and stabilizes the upper body and is the center of our musculoskeletal system, which gives the body movement. Our work in the field of spine surgery is dedicated to protecting the spinal column and preserving its stability. We support spine surgeons with durable, reliable products and partner services for reliable procedures and good clinical outcomes (1-7).

Our philosophy of sharing expertise with healthcare professionals and patients allows us to develop innovative implant and instrument systems that help to preserve stability and stabilize the cervical and thoracolumbar spine.



RELIABLE PARTNER IN SPINE SURGERY

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AESCULAP® Arcadius XP® L

CONTENT

SYSTEM DESCRIPTION

The Arcadius XP L® Interbody Fusion System is a stand alone device intended to be used with four bone screws if no supplement fixation is used to stabilize the lumbar spine through an anterior approach. Arcadius XP L® combines high primary and secondary stability (8, 9) and improved imaging properties (10). PLASMAPORE XP® osteoconductive coating was developed to promote implant stability and bony ingrowth (8, 9). Implant design and flexible instrumentation allow an accessibility from a wide range of angles for instrumentation and hence provide ease in screw insertion.

SYSTEM FEATURES

- PLASMAPORE XP® coating
- Wide variety of implant options
- Generous graft window
- Surface texturing
- Five X-Ray marker pins
- Midline accessibility for screw insertion
- Diverging screw design
- Dual locking mechanism
- Self-centering, self-drilling and self-tapping bone screws
- Comprehensive array of instrumentation

AESCULAP® XP

THE CHOICE OF EXPERTS

IMPLANT DESIGN

BUILT ON EXPERIENCE

Aesculap has many years of experience in applying PLASMAPORE® coatings to titanium orthopaedic and spine implants (11-13) to develop the PLASMAPORE XP® coating for PEEK spinal implants.

INNOVATIVE SURFACE ENHANCING TECHNOLOGY

PLASMAPORE XP® is an osteoconductive pure titanium coating (Ti/ISO 5832-2) which enables bone ingrowth due to its balanced relation between pore depth, porosity and roughness (8).

ENHANCED STABILITY

The benefits of PLASMAPORE XP® in combination with the diverging screw design contribute to the implant stability (9, 14).

IMPLANT FIT

Wide variety of implant sizes are designed to fit with varying patient anatomies.

ACCESSIBILITY FROM DIVERSE ANGLES

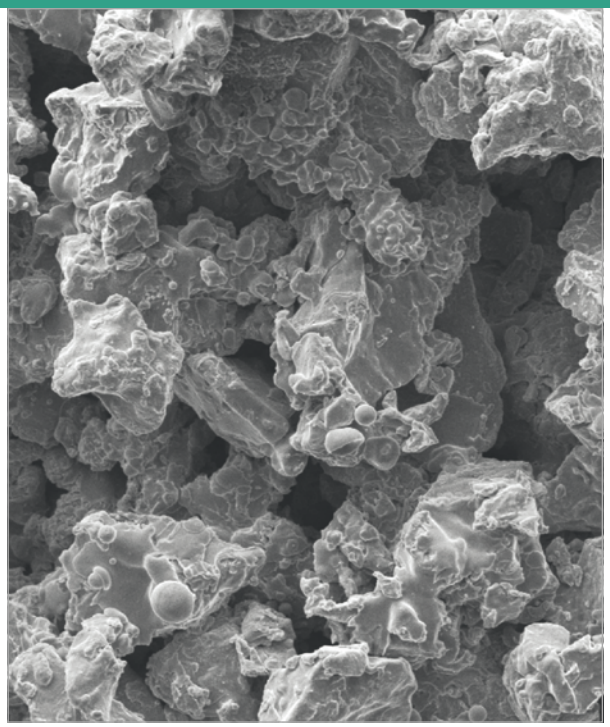
Implant design and flexible instrumentation allow an accessibility from a wide range of angels for instrumentation and hence provide ease in screw insertion.

SIMPLE LOCKING MECHANISM

Integrated dual locking mechanism with single-step activation.

EXCELLENT IMAGING PROPERTIES

The PLASMAPORE XP® coating together with the X-Ray marker pins allow the visualization of implant contour and localization (10).



PLASMAPORE$^{XP®}$ structure under the microscope (magnification: 1000 x)

INTENDED USE

The Arcadius^{XP} L® Interbody Fusion System is a stand alone device intended to be used with four bone screws if no supplement fixation is used to stabilize the lumbar spine through an anterior approach.

The system contains:

- Cages in different heights, angles and footprints
- Bone screws in different lengths

Levels of anterior lumbar interbody fusion for the indications listed in the instructions for use are from L2-S1.

Note:

- For further information please see instructions for use TA-No. 015555.

Fig. 1

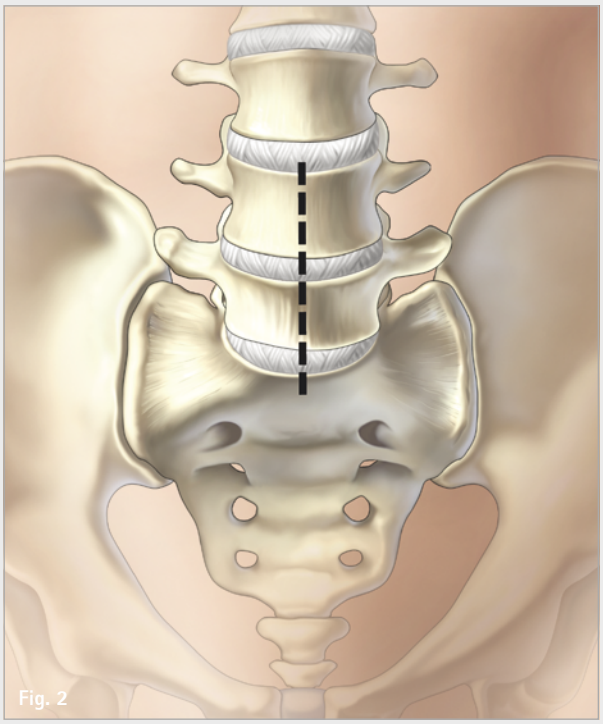


Fig. 2

B.1. PATIENT POSITIONING AND EXPOSURE

Anterior access will be required for insertion of the Arcadius XP L® Interbody Fusion System. 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 graft range. It is recommended that the lateral X-ray is examined to ensure that the surgical incision provides the correct access to the appropriate disc space.

- Place the patient in supine position. A lumbar roll can be placed under the patient's lower back to allow for increased lordosis of the targeted level(s) (Fig. 1).

The surgical approach should be accomplished in a manner consistent with a standard anterior lumbar fusion procedure.

- Provide the level of exposure to the implantation site that the surgeon deems necessary to perform the surgery (Fig. 2).

INFORMATION

Identification of the iliolumbar and ascending lumbar vein is recommended with ligation and division as needed. This is an important step in any anterior lumbar procedure, especially at the L4-L5 level.

Utilize anterior-posterior (AP) fluoroscopy to confirm the operative level and accurately delineate the midline.

- The midline should be marked for continued reference during the remainder of the case, as precise midline placement of the device is an important goal.

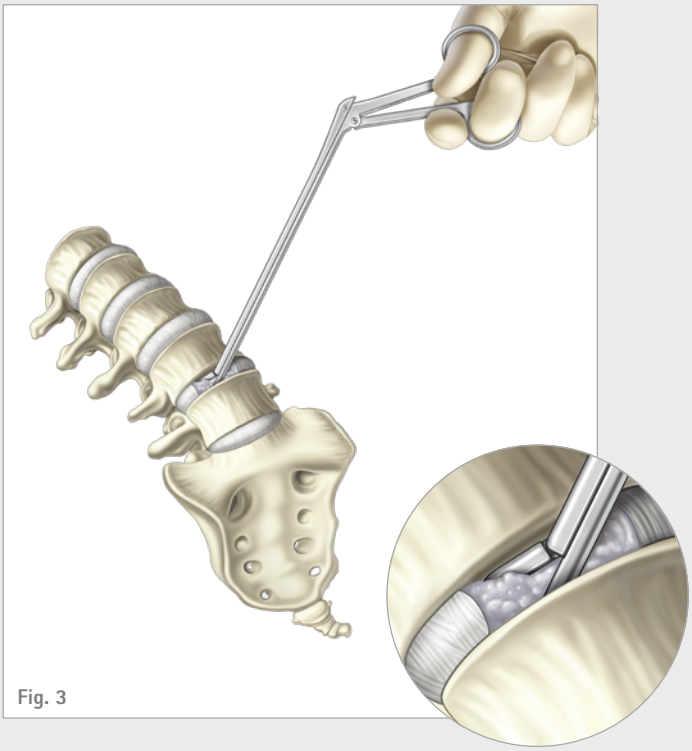


Fig. 3

B.2. PREPARATION

Prepare the intervertebral space utilizing anterior discectomy instruments that the surgeon deems necessary and clinically prudent to properly prepare the disc space and vertebral endplates.

- Expose the disc and remove disc material (Fig. 3).
- Carefully resect the cartilaginous endplates and ensure preservation of the bony vertebral endplates.

INFORMATION

Make certain that the endplates of the neighboring vertebral bodies are not weakened, in order to minimize the risk of migration.

Make certain that the implant bed is properly prepared to avoid damage to the implant when it is driven in.

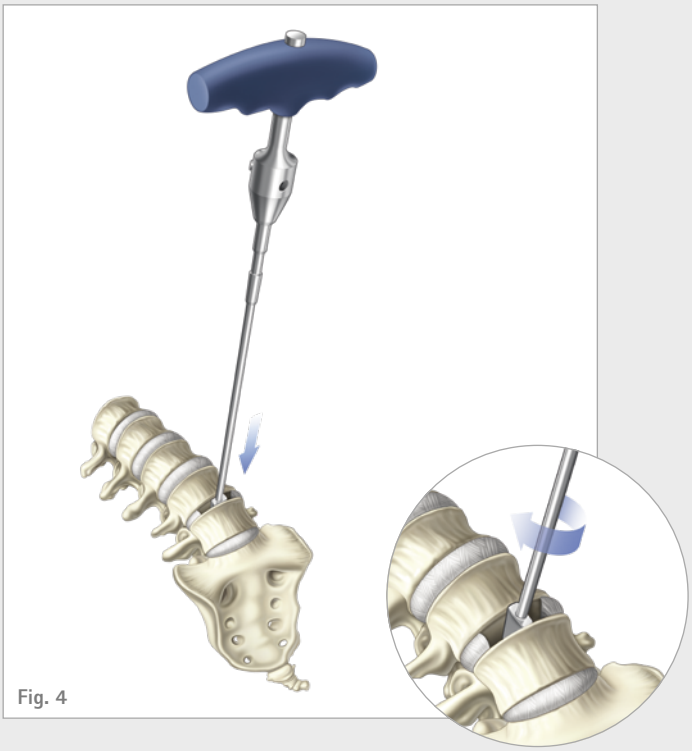


Fig. 4

- Distractors are used to gradually achieve the desired working height.
  - Attach a T-Handle to a distractor.
  - Insert the distractor into the disc space horizontally
  - Rotate distractor by 90° to achieve specified working height (Fig. 4).

INFORMATION

Each distractor contains a 9° lordotic angle.

- Use the distractors and perform carefully and stepwise a proper distraction. Do not use the implant for distraction of the disc space when inserting it.

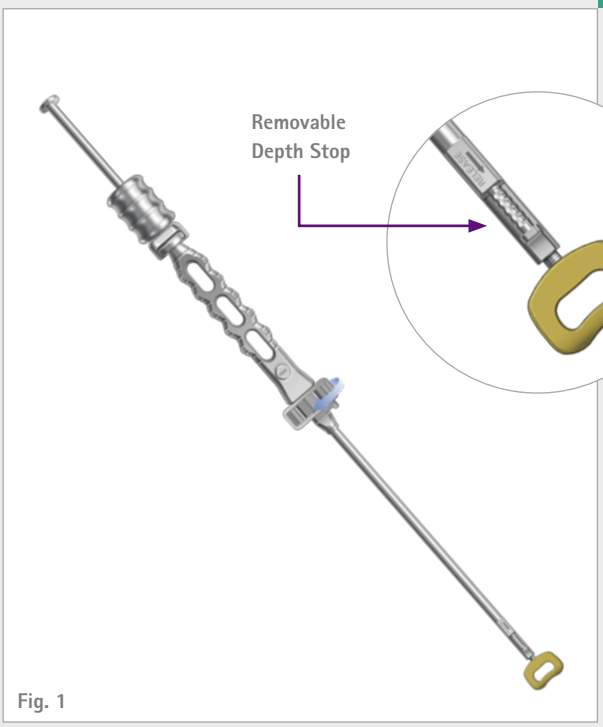


Fig. 1

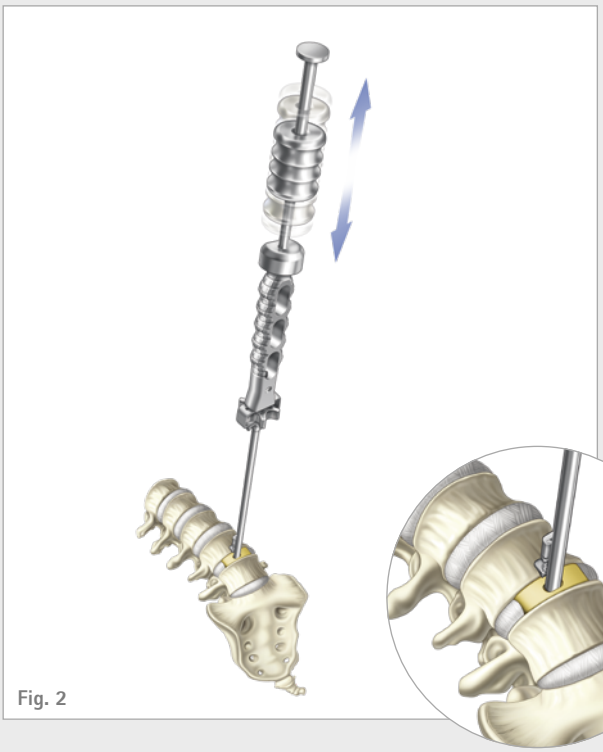


Fig. 2

B.3. IMPLANT SIZING

Trial implants are available in two footprint sizes, three lordotic angles, and six heights. Each trial implant is color-coded by lordotic angle, and labeled with the corresponding footprint, height and lordotic angle.

- Select an appropriate sized trial implant based on patient anatomy and pre-operative radiographic analysis.
- Attach the trial implant to the trial insertion instrument.
  - Attach the slap hammer handle to the trial insertion instrument.
  - Thread the trial implant onto the trial insertion instrument by turning the large proximal knob in a clockwise direction (Fig. 1).

INFORMATION
Either slap hammer FJ666R or slap hammer handle SJ708T with slap hammer extension SJ709R can be used.

INFORMATION
The trial insertion instrument contains a removable depth stop. It is recommended that the depth stop is utilized to ensure that the trial implant is seated flush with the anterior border of the vertebral body.

- Reference the midline marker and utilize the slap hammer or mallet to gently advance the trial into the disc space (Fig. 2).
- Manipulate the trial implant as needed to attain the desired position.
- Continue to evaluate trial implants until a firm fit is achieved.
- Assess final trial implant fit and position with intraoperative AP and lateral fluoroscopy.

INFORMATION
Always check the correct size and location every time with X-Ray controlling by using trial implants.

Fig. 3

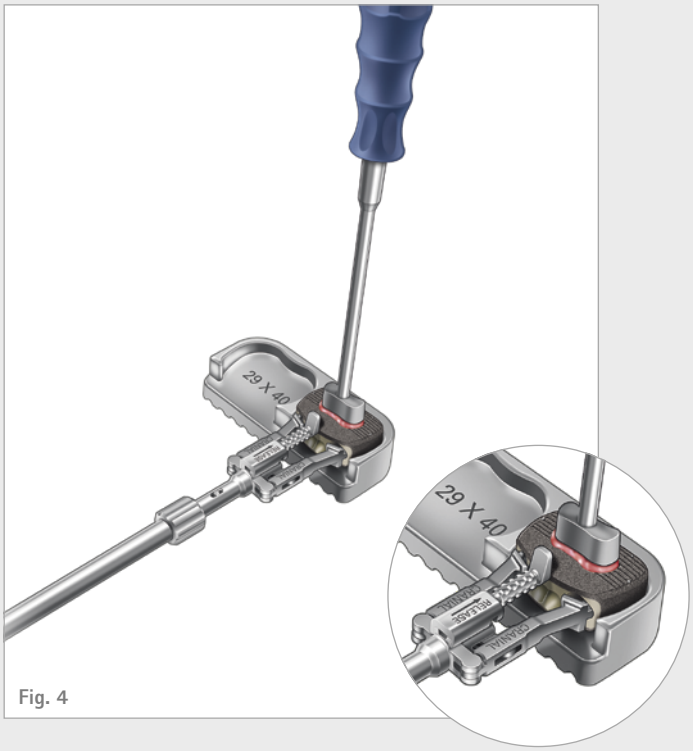


Fig. 4

B.4. IMPLANT PREPARATION AND INSERTION

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

INFORMATION

Avoid direct contact with the coated surfaces, handle implants carefully.

The dimensions of the trial implants were designed to match the Arcadius^{XP} L® implants (footprint, height and lordotic angle).

Implant Preparation

- Attach the Arcadius^{XP} L® implant to the implant inserter (Fig. 3). The standard implant inserter is ME015R, which holds the implant via the lateral screw holes. Alternatively, SJ605R can be used which holds the implant via the medial screw holes.
  - Attach selected handle to the implant inserter.
  - Ensure that the small distal knob of the implant inserter is fully tightened prior to use. This knob can be loosened for sterilization purposes.
  - The distal end of the implant inserter is labeled with the word "cranial" for orientation purposes during implant insertion. Orient the implant inserter in the cranial position and align distal end with the lateral screw holes of the selected implant.
  - The implant is labeled with two arrows (∧∧) which indicate the direction of the medial screws. Ensure that the arrows point to cranial direction during attaching the implant to the inserter.
  - Attach and secure selected implant to the distal end of the implant inserter by turning the large proximal knob in a clockwise direction.
- Fill the implant with bone material by utilizing the packing block and tamp (Fig. 4).

INFORMATION

Do not use force during filling to avoid implant damaging.

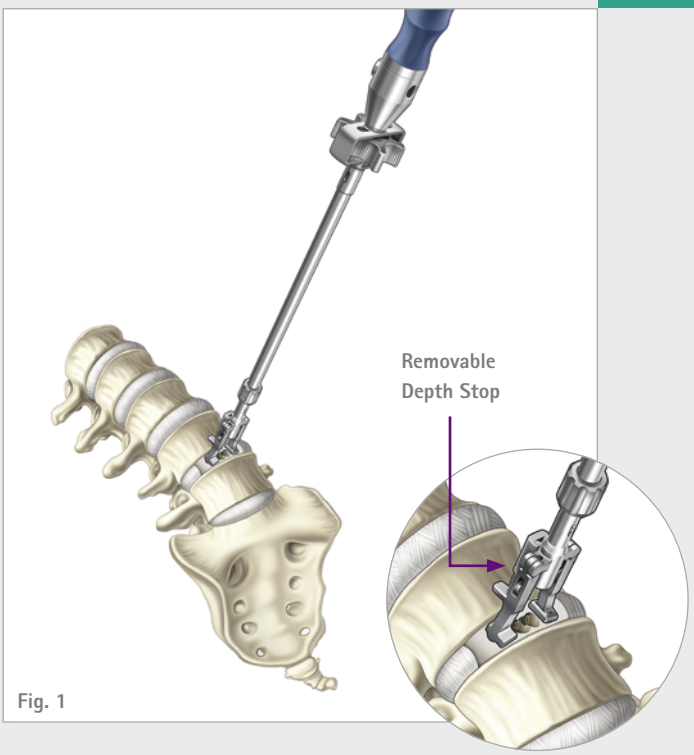


Fig. 1

INFORMATION

The implant inserter contains a removable depth stop. It is recommended that the depth stop is utilized to ensure that the implant is seated flush with the anterior border of the vertebral body.

Implant Insertion

- Recheck the connection between the implant and the inserter and ensure that the implant inserter is oriented in the cranial position.
- Reference the midline and gently advance the implant into the disc space (Fig. 1).

Caution:

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

- Always mark the midline under X-Ray visualization.
- Assess implant position with intraoperative AP and lateral fluoroscopy.

INFORMATION

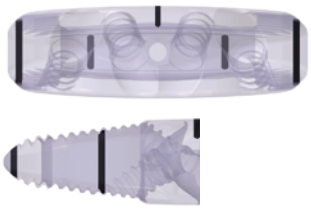
Gently advance the implant into the disc space.

Do not distract via the inserter and implant respectively. Avoid canting and levering, and take care to maintain an alignment parallel to the endplates.

Carefully insert the cage and avoid too much force.

Arcadius^{XP} L$^{®}$ X-Ray Marker Alignment

Neutral Example



Rotated Example

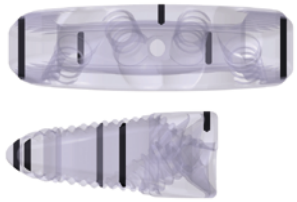


Fig. 2

Assessment of Implant Position

- Obtain an AP fluoroscopic image to confirm midline placement of the device.
- Obtain a lateral fluoroscopic image to confirm that the anterior edge of the implant is seated flush with the anterior border of the vertebral body.
- Observe the X-Ray markers in both the AP and lateral views to ensure that the implant is not rotated within the disc space (Fig. 2).

- Manipulate the implant as needed to attain the desired position.
- Obtain additional AP and lateral fluoroscopic images to document midline placement and neutral alignment.
- The impactor could be used to correct the position of the implant after the implant insertion has been removed.

INFORMATION

It is recommended that the implant inserter is left attached to the implant for medial screw hole preparation and screw insertion.

It is recommended to confirm implant position prior to removing the implant inserter.

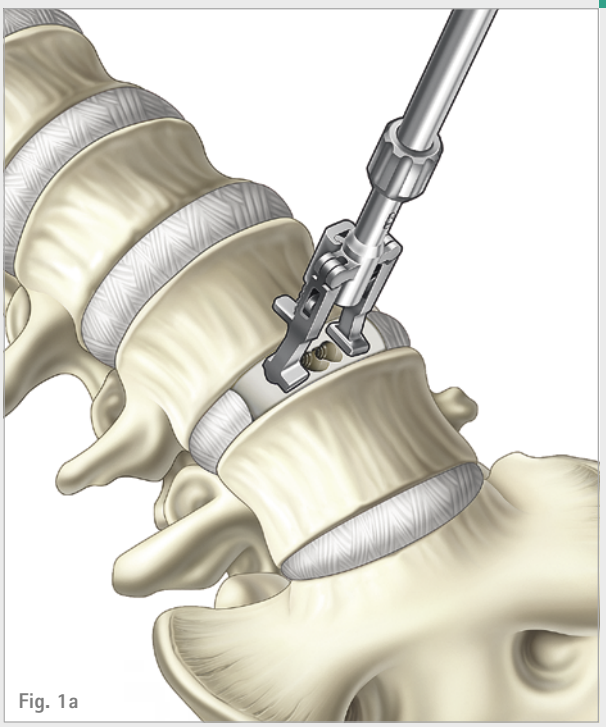


Fig. 1a

B.5. SCREW PREPARATION AND INSERTION

- For bone screw insertion, it is recommended that a pilot hole is created at the intended screw placement site.
  Special instruments are available to meet surgeon preference for screw hole preparation and screw insertion. (See page 18 & 33 & 34 for instrument selection)

INFORMATION
All screwdrivers are self-retaining.

- The Arcadius XP L® Interbody Fusion System is intended to be used with four bone screws.
  - Bone screws are available in two lengths: 25 mm and 30 mm.
  - The 25 mm screws are blue in color, the 30 mm screws are gold in color.

- It is important to consider the implant footprint size, height and lordotic angle when selecting the proper screw length. Please refer to the implant and screw diagram on pages 26/27 to determine the proper screw length for the implant used.

- Fully insert the tip of the screwdriver into the bone screw to avoid damage to the bone screws.
- Only screw in bone screws hand-tight into Arcadius XP L® cages.

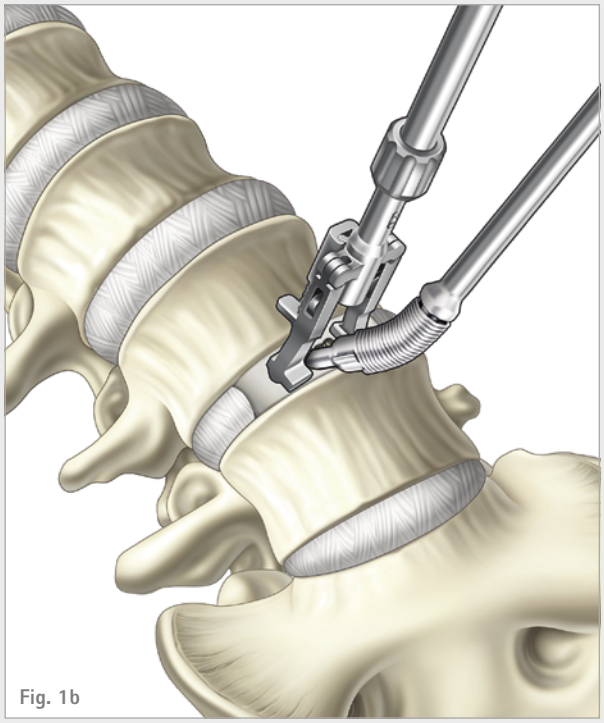


Fig. 1b

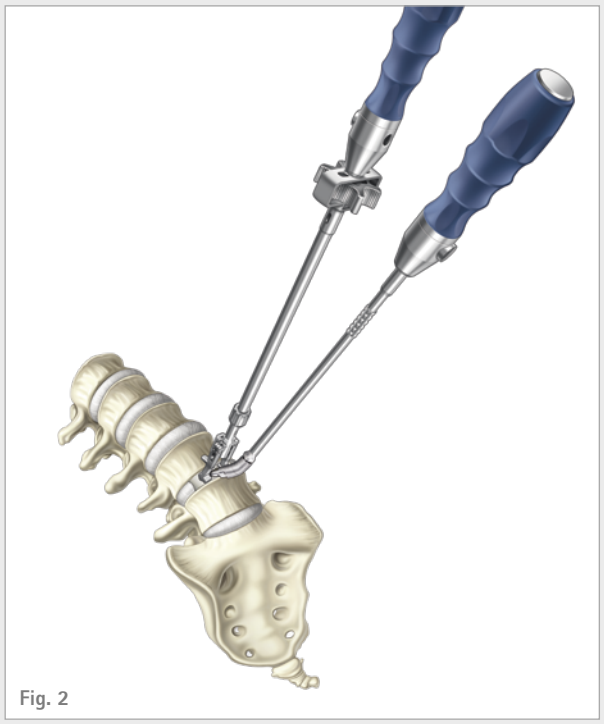


Fig. 2

B.5.1. MEDIAL SCREW HOLE PREPARATION AND SCREW INSERTION

- Featured instruments: implant inserter (ME015R) with U-Joint bone awl (ME190R) and U-Joint screwdriver (ME014R).
- Maintain final implant position as determined with fluoroscopy.

INFORMATION

It is recommended to prepare screw holes and insert screws utilizing X-Ray guidance.

- The implant inserter can be utilized for implant stabilization during medial screw hole preparation and insertion (Fig. 1a).

Medial Screw Hole Preparation

- Attach desired Handle to U-Joint bone awl.
- Guide the U-Joint bone awl through the distal opening of the implant inserter (caudal side) (Fig. 1b).
- Insert the U-Joint bone awl by hand into one of the medial screw holes until a hard stop is reached. A hard stop in the cage indicates that the U-Joint bone awl has punctured the cortical layer of bone (Fig. 2).

INFORMATION

The U-Joint bone awl is self-guiding and self-centering and does not require use of a drill guide.

Do not use a mallet with the U-Joint bone awl. The U-Joint bone awl must be advanced into the bone by hand only.

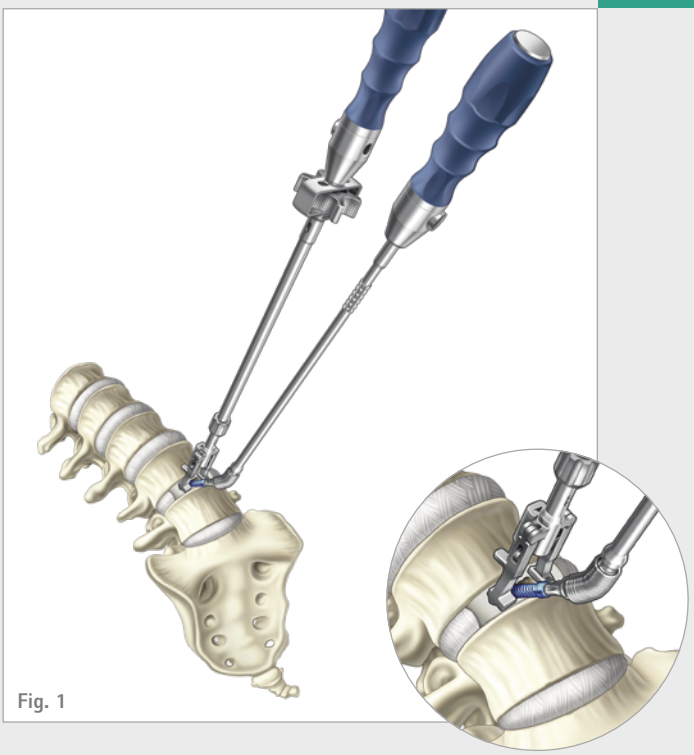


Fig. 1

Medial Screw Insertion

- Select a bone screw based on the implant size used and the implant and screw diagram on pages 26/27.
- Attach desired handle and selected bone screw to the U-Joint screwdriver.
- Guide the screw through the distal opening of the implant inserter (caudal side).
- Insert the screw into the prepared medial screw hole (Fig. 1).
- Turn the U-Joint screwdriver in a clockwise motion to advance the bone screw into the vertebral body.
- Ensure that the bone screw has threaded past the locking rim and is fully seated.

- Upon screw insertion the surgeon will feel an increase in torque as the shoulder of the screw passes through the locking rim, followed by a decrease in torque after the shoulder of the screw passes through the locking rim.
- An increase in torque will indicate that the screw is approaching full insertion into the implant, and a hard stop will indicate that the screw is fully seated.

INFORMATION

Please refer to page 23 for a detailed description of the Arcadius XP L® locking mechanism.

- Repeat the steps outlined above for pilot hole creation and bone screw placement to insert the second medial screw.

Fig. 2

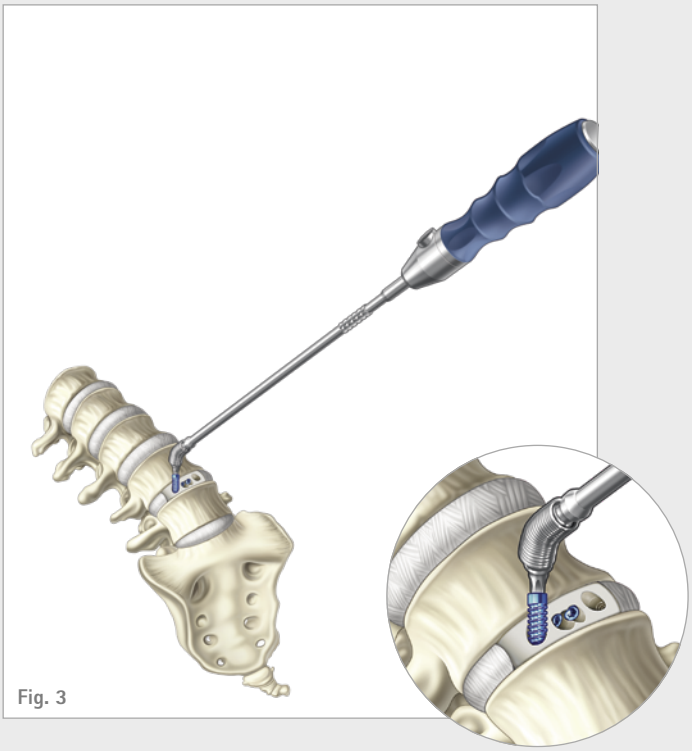


Fig. 3

B.5.2. LATERAL SCREW HOLE PREPARATION AND SCREW INSERTION

- Featured instruments: U-Joint bone awl (ME190R) and U-Joint screwdriver (ME014R).
- Remove the implant inserter to gain access to lateral screw holes.

INFORMATION

It is recommended to prepare screw holes and insert screws utilizing X-Ray guidance.

Lateral Screw Hole Preparation

- Attach desired Handle to U-Joint bone awl.
- Guide the U-Joint bone awl into one of the lateral screw holes and insert by hand until a hard stop is reached. A hard stop indicates that the U-Joint bone awl has punctured the cortical layer of bone (Fig. 2).

INFORMATION

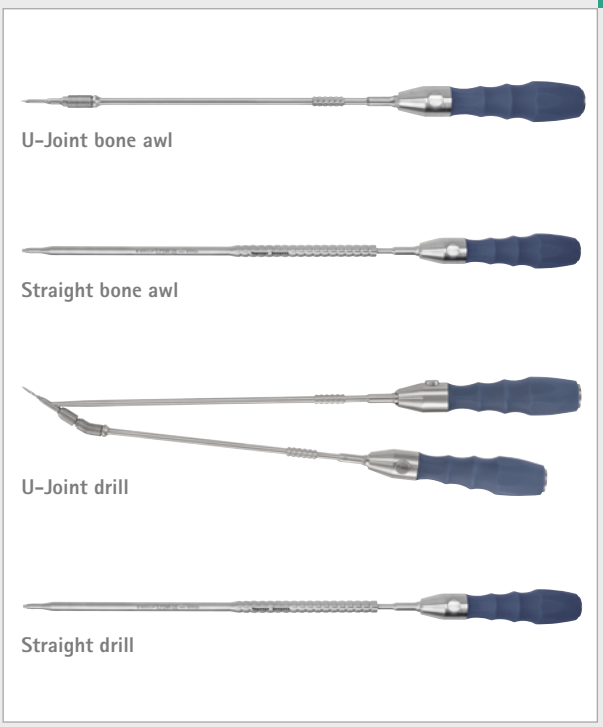
Do not use a mallet to insert the U-Joint bone awl.

Lateral Screw Insertion

- Select a bone screw based on the implant size used and the implant and screw diagram on pages 26/27.
- Guide the U-Joint screwdriver with screw attached into the prepared lateral screw hole.
- Turn the U-Joint screwdriver in a clockwise motion to advance the bone screw into the vertebral body (Fig. 3).
- Ensure that the bone screw has threaded past the locking rim and is fully seated.
- Repeat the steps outlined above for pilot hole creation and bone screw placement to insert the final lateral screw.
- A fully assembled construct is shown on page 19 (Fig. 1/2).

Caution:

Risk of damaged locking mechanism in case of screw replacement. Replace the cage when a fully inserted and locked screw has to be removed and exchanged.



Recommended Drill Guide Selection

When the straight bone awl, flexible drill, or straight drill are utilized for screw hole preparation, the corresponding drill guide must be used.

Screw Hole Preparation Instrument	Required Drill Guide	Extension Distance (mm)	Extension Distance through Average Implant (mm)
U-Joint bone awl	N / A	21.5	Medial screw holes: 13.4 Lateral screw holes: 15.4
Straight bone awl	Straight drill guide	16.3	Medial screw holes: 11.4 Lateral screw holes: 13.3
U-Joint drill	Angeled drill guide	16.3	Medial screw holes: 11.4 Lateral screw holes: 13.3
Straight drill	Straight drill guide	16.3	Medial screw holes: 11.4 Lateral screw holes: 13.3

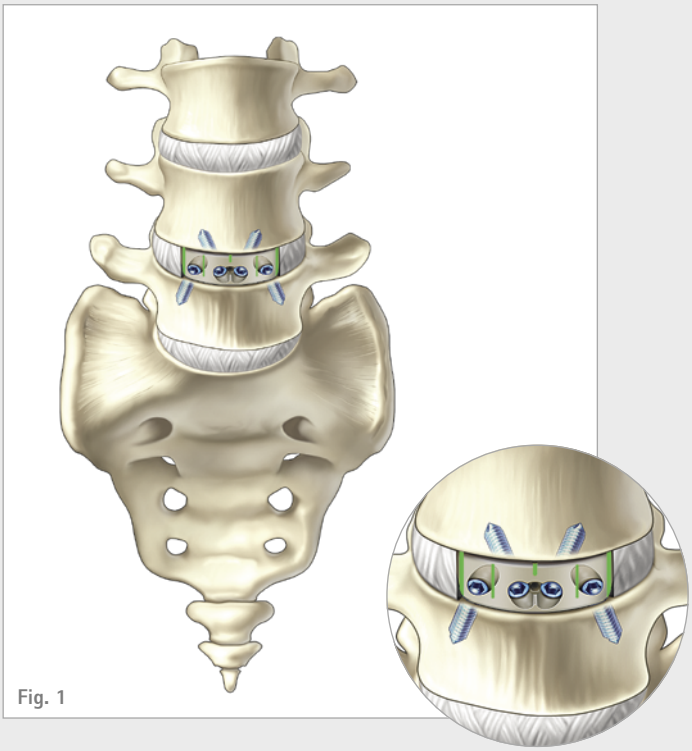


Fig. 1

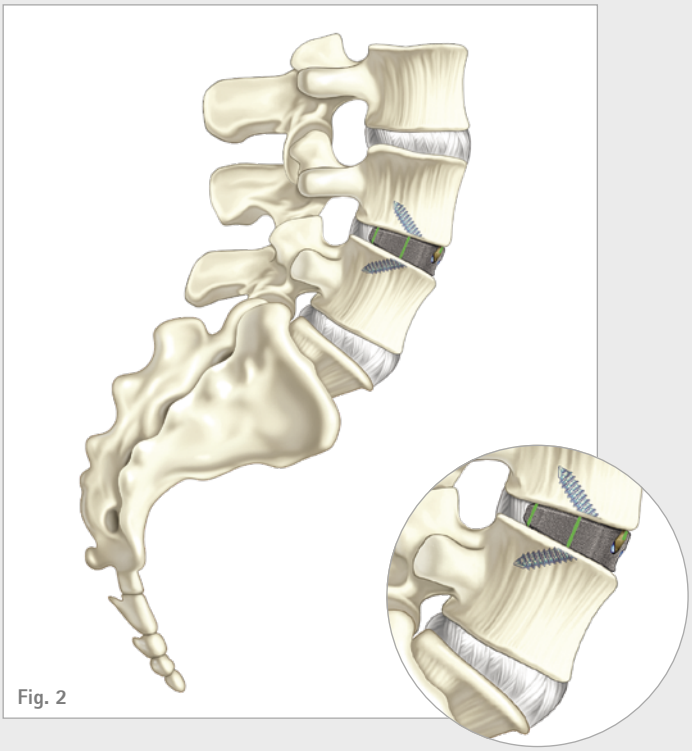


Fig. 2

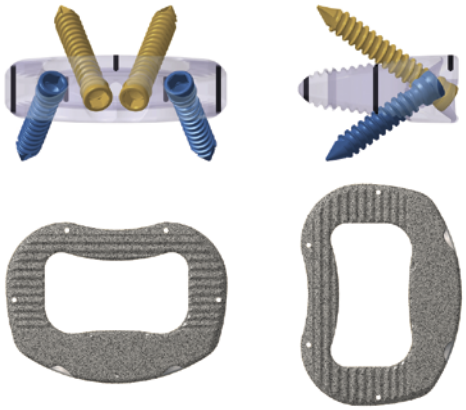
B.6. VERIFICATION OF FINAL IMPLANT PLACEMENT

- It is recommended that final AP and lateral radiographs are obtained.
  - The final AP image should confirm midline placement of the device (Fig. 1).
  - The final lateral image should confirm that the anterior edge of the implant is seated flush with the anterior border of the vertebral body (Fig. 2).
  - The final AP and lateral images should reflect neutral alignment of the Arcadius^{XP} L$^{®}$ construct (Fig. 1 / 2).

INFORMATION

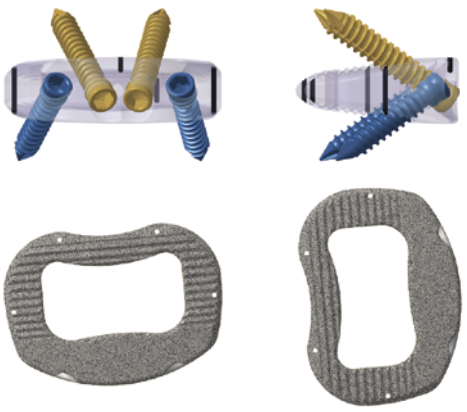
The green lines in Figures 1 & 2 represent the location of the implant X-Ray markers in both the AP and lateral views.

Correct ✓



Neutral Alignment

Incorrect ✗



Rotated Alignment

B.7. IMPLANT REMOVAL

- Featured instruments: screwdrivers (ME014R, ME013R, ME016R) and implant extraction instrument (ME018R).
- Attach desired handle to preferred screwdriver.
- Guide and attach the screwdriver to a bone screw in the Arcadius XP L® implant.
- Retract the bone screw from the vertebral body by turning the screwdriver in a counter-clockwise motion.

INFORMATION

If a fully seated bone screw is removed from the implant, a small piece of PEEK debris from the locking rim of the locking mechanism may be present.

- Repeat the bone screw removal process for the remaining bone screws in the Arcadius XP L® implant.
- Attach desired handle to the implant extraction instrument.
- Turn the implant extraction instrument in a clockwise direction to secure into an implant screw hole.
- Apply an extraction force to the implant extraction instrument to remove the implant from the disc space.

Arcadius XP L® X-Ray marker alignment

The drawings left illustrate the X-Ray markers of the Arcadius XP L® construct in neutral and rotated alignment.

AESCULAP® Arcadius XP® L

C | IMPLANT INFORMATION

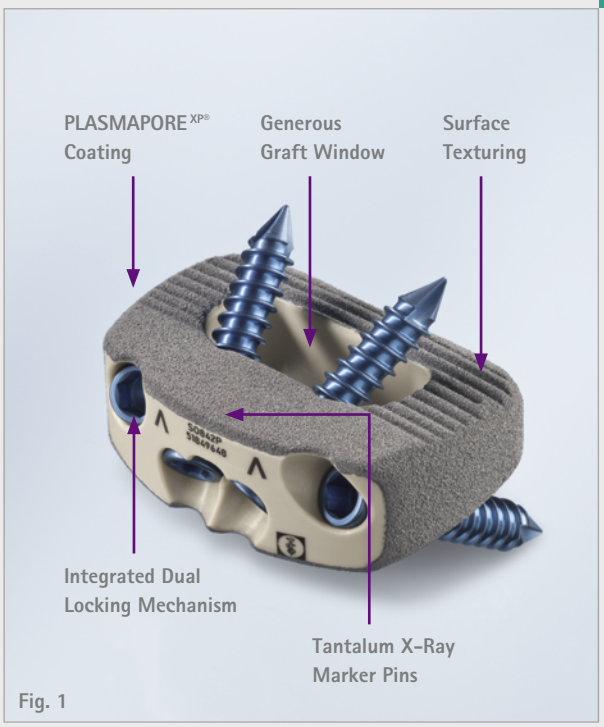


Fig. 1


Fig. 2

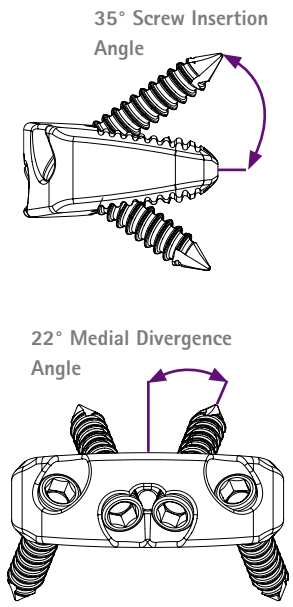


Fig. 3

Implant Information (Fig. 1)

- Manufactured from radiolucent PEEK-OPTIMA®*
- With porous Titanium coating PLASMAPORE XP®
- Variety of options for precise fit
  - Two implant footprints: 25 mm x 35 mm, 29 mm x 40 mm
  - Six heights: 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm
  - Three lordotic angles: 4°, 9° and 14°
- Medial orientation of screw holes for accessibility
- Wide central opening for packing of bone graft material
- Surface texturing for additional stability
- 5 Tantalum marker pins for X-Ray verification

INFORMATION

X-Ray markers are located 1 mm from edge of implant.

Bone Screw Information (Fig. 2)

- Manufactured from a Titanium alloy (Ti6Al4V)
- Bone screws are self-centering, self-drilling, and self-tapping
- Bone screw diameter is 4.5 mm
- Available in 2 lengths
  - 25 mm – blue in color
  - 30 mm – gold in color

Construct Information (Fig. 3)

- Diverging screw design
  - 22° medial divergence
- Screw insertion angle
  - 35° cranial-caudal orientation
- Dual locking mechanism

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

Fig. 4

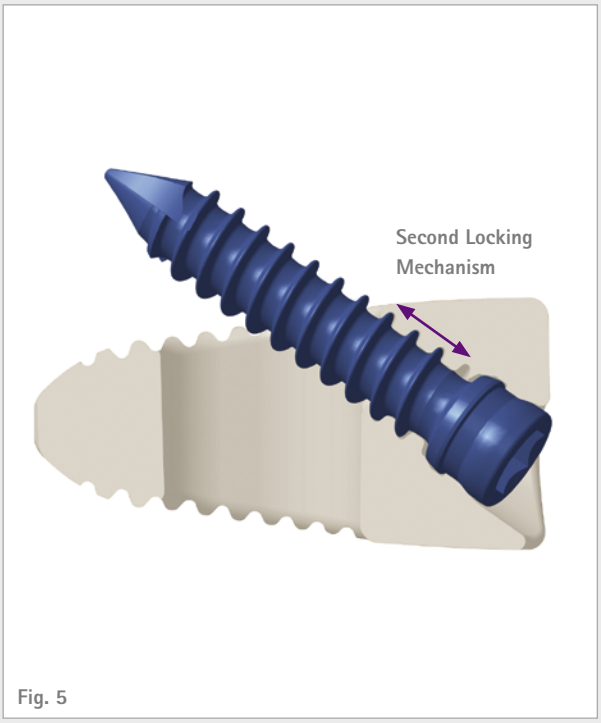


Fig. 5

Locking Mechanism Information

The Arcadius XP L® incorporates a dual locking mechanism feature to prevent bone screws from backing out.

First Locking Mechanism

There is an internal locking rim integrated into each screw hole of the Arcadius XP L® implant.

- The first locking mechanism is activated during bone screw insertion.
  - During insertion, the shoulder of the bone screw will pass through the lead-in taper of the locking rim. This will cause the locking rim to expand. At this point, the surgeon will feel a noticeable increase in insertion torque.
  - After the shoulder of the bone screw passes through the lead-in taper of the locking rim, the locking rim will seat and lock into final position. At this point, the surgeon will feel a noticeable decrease in insertion torque (Fig. 4).

Second Locking Mechanism

The inner threads of the Arcadius XP L® implant and the threads of the bone screw comprise the second locking mechanism.

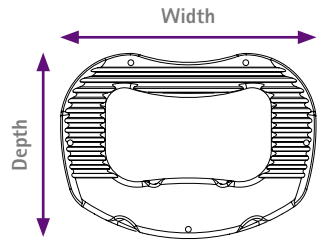
- The second locking mechanism is activated by fully inserting and seating the bone screw into the Arcadius XP L® implant.
  - After the first locking mechanism has been activated, continue to advance the bone screw.
  - As the bone screw approaches full insertion, the surgeon will feel a noticeable increase in insertion torque.
  - Continue to hand-tighten the bone screw until a hard stop is reached. This indicates that the bone screw is fully seated and the second locking mechanism has been activated. It is not necessary to apply excessive torque to the bone screw (Fig. 5).

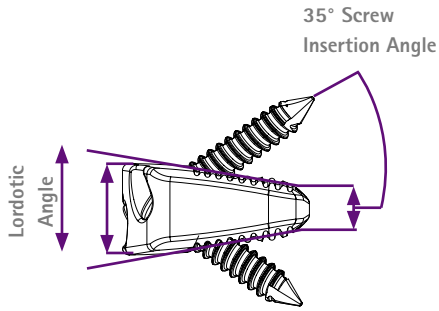
Caution:

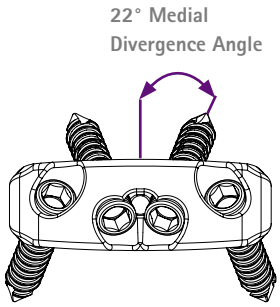
It is important that the two locking mechanisms are engaged to prevent screws from backing out!

AESCULAP® Arcadius XP L®

D | IMPLANT OVERVIEW



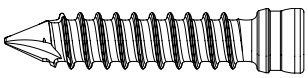
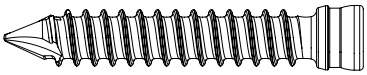




IMPLANTS	Article No.	Lordosis	Size (Height x Width x Depth)
	SO810P	4°	10 x 35 x 25 mm
	SO812P		12 x 35 x 25 mm
	SO814P		14 x 35 x 25 mm
	SO816P		16 x 35 x 25 mm
	SO818P		18 x 35 x 25 mm
	SO820P		20 x 35 x 25 mm
	SO840P	9°	10 x 35 x 25 mm
	SO842P		12 x 35 x 25 mm
	SO844P		14 x 35 x 25 mm
	SO846P		16 x 35 x 25 mm
	SO848P		18 x 35 x 25 mm
	SO850P		20 x 35 x 25 mm
	SO870P	14°	10 x 35 x 25 mm
	SO872P		12 x 35 x 25 mm
	SO874P		14 x 35 x 25 mm
	SO876P		16 x 35 x 25 mm
	SO878P		18 x 35 x 25 mm
	SO880P		20 x 35 x 25 mm
	SO825P	4°	10 x 40 x 29 mm
	SO827P		12 x 40 x 29 mm
	SO829P		14 x 40 x 29 mm
	SO831P		16 x 40 x 29 mm
	SO833P		18 x 40 x 29 mm
	SO835P		20 x 40 x 29 mm

IMPLANTS	Article No.	Lordosis	Size (Height x Width x Depth)
	SO855P	9°	10 x 40 x 29 mm
	SO857P		12 x 40 x 29 mm
	SO859P		14 x 40 x 29 mm
	SO861P		16 x 40 x 29 mm
	SO863P		18 x 40 x 29 mm
	SO865P		20 x 40 x 29 mm
	SO885P	14°	10 x 40 x 29 mm
	SO887P		12 x 40 x 29 mm
	SO889P		14 x 40 x 29 mm
	SO891P		16 x 40 x 29 mm
	SO893P		18 x 40 x 29 mm
	SO895P		20 x 40 x 29 mm

PEEK-OPTIMA®*
PLASMAPORE$^{XP®}$ surface coating, pure titanium according to ISO 5832-2 / ASTM F1580.

SCREWS	Article No.	Total Length	Description
	**SJ701T**	25 mm	SIBD Bone Screw, Ø 4.5 mm
	**SJ702T**	30 mm	

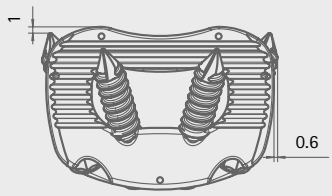
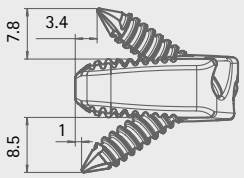
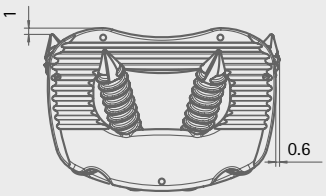
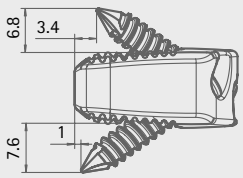
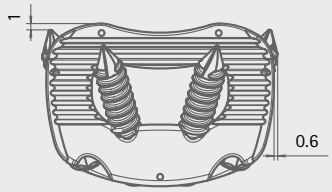
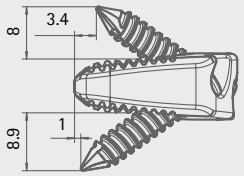
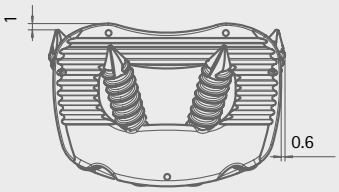
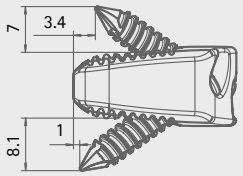
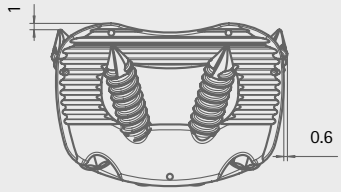
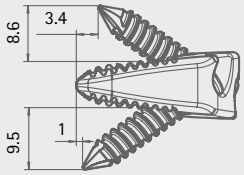
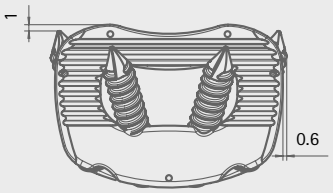
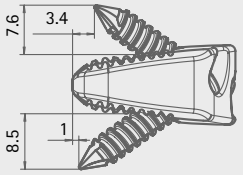
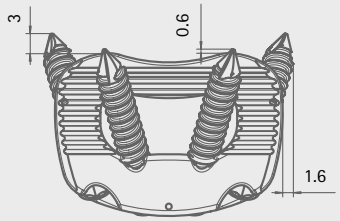
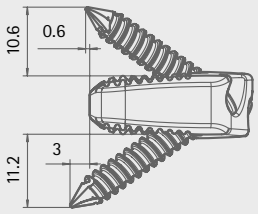
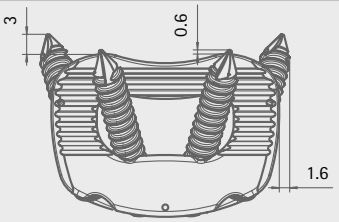
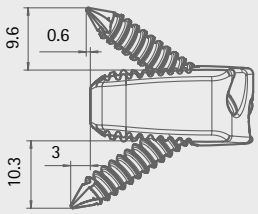
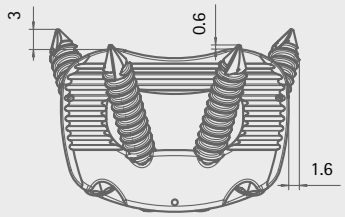
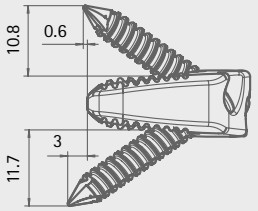
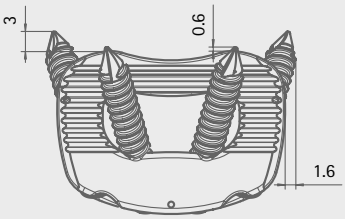
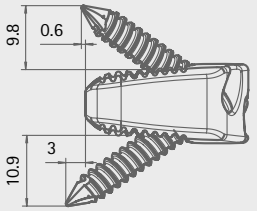
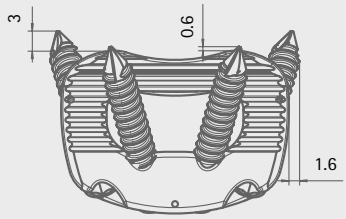
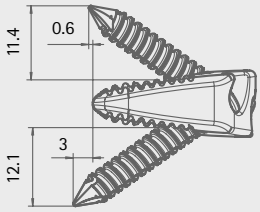
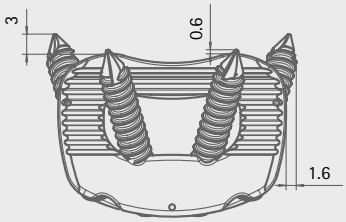
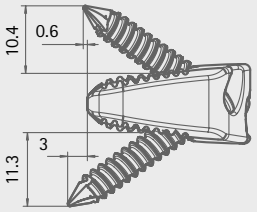
ISOTAN®$_F$ wrought titanium alloy Ti6Al4V according to ISO 5832-3.

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

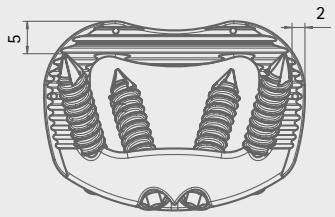
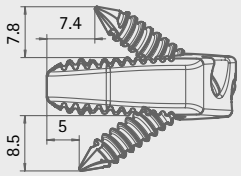
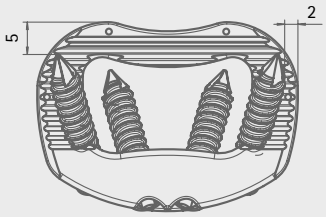
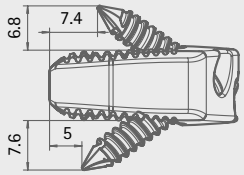
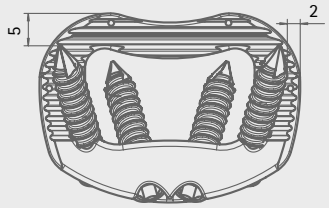
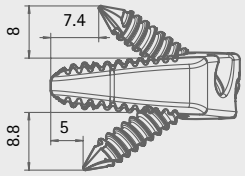
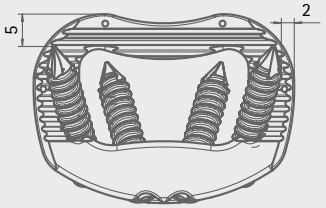
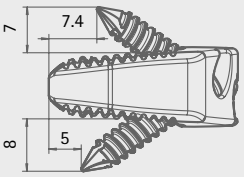
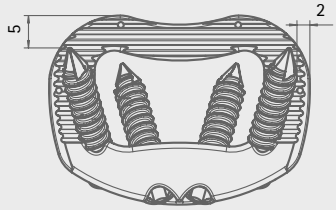
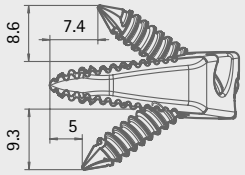
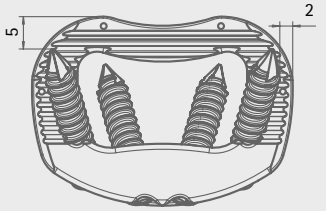
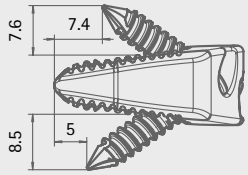
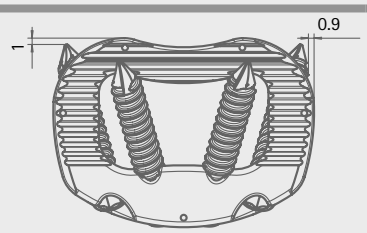
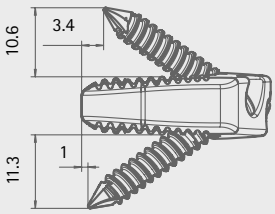
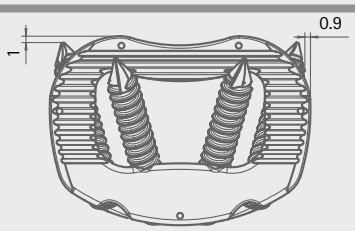
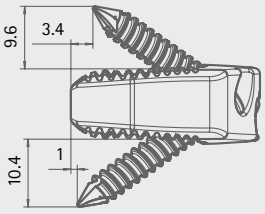
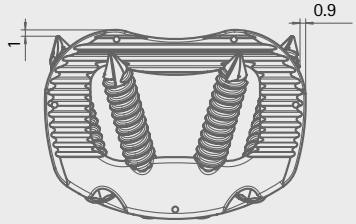
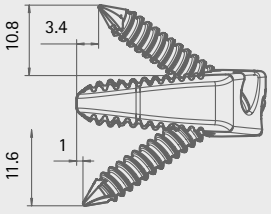
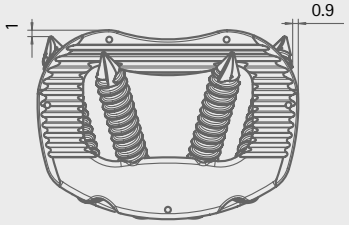
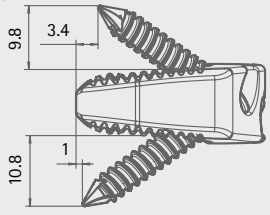
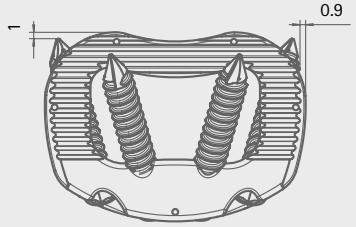
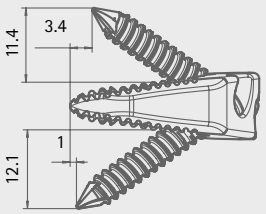
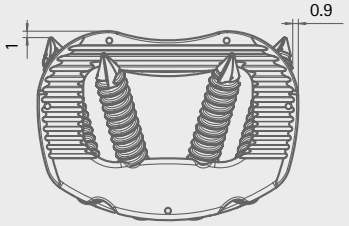
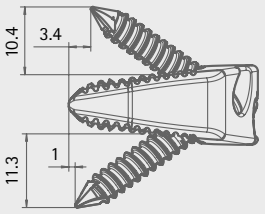
AESCULAP® Arcadius XP L®

D | IMPLANT AND SCREW DIAGRAMS

Small Implant Footprint (25 mm x 35 mm)

	Implant Height 10 mm		Implant Height 12 – 20 mm	
25 MM BONE SCREWS				
4°				
9°				
14°				
30 MM BONE SCREWS				
4°				
9°				
14°				
	Axial View	Lateral View	Axial View	Lateral View

Large Implant Footprint (29 mm x 40 mm)

	Implant Height 10 mm		Implant Height 12 – 20 mm	
25 MM BONE SCREWS				
4°				
9°				
14°				
30 MM BONE SCREWS				
4°				
9°				
14°				
	Axial View	Lateral View	Axial View	Lateral View

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D | INSTRUMENT OVERVIEW

HANDLES	Article No.	Description	Quantity
	**FW440R**	Standard Handle	2
	**SJ705R**	Ratchet Handle	2*
	**SJ033R**	T-Handle	1
	**FJ666R**	Slap Hammer Handle	1

PREPARATION	Article No.	Description	Quantity
	**FK822R**	Box Curette, Straight	1
	**FK780R**	Scoop, Straight	1

DISTRACTORS	Article No.	Anterior Height	Lordotic Angle	Quantity
	SJ020R	10 mm	9°	1
	SJ022R	12 mm	9°	1
	SJ024R	14 mm	9°	1
	**SJ026R**	16 mm	9°	1
	**SJ028R**	18 mm	9°	1
	**SJ030R**	20 mm	9°	1

Distractor (SJ024R) with T-Handle (SJ033R)

** This article is optional. Please note that there are no additional storing elements in the trays for optional instruments.*

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D | INSTRUMENT OVERVIEW

25 MM X 35 MM TRIAL IMPLANTS	Article No.	Lordotic Angle	Height	Quantity
	SJ664T	4°	10 mm	1
	SJ666T	4°	12 mm	1
	SJ668T	4°	14 mm	1
	SJ670T	4°	16 mm	1
	SJ672T	4°	18 mm	1
	SJ674T	4°	20 mm	1
	SJ676T	9°	10 mm	1
	SJ678T	9°	12 mm	1
	SJ680T	9°	14 mm	1
	SJ682T	9°	16 mm	1
	SJ684T	9°	18 mm	1
	SJ686T	9°	20 mm	1
	SJ688T	14°	10 mm	1
	SJ690T	14°	12 mm	1
	SJ692T	14°	14 mm	1
	SJ694T	14°	16 mm	1
	SJ696T	14°	18 mm	1
	SJ698T	14°	20 mm	1

TRIAL INSERTION INSTRUMENT	Article No.	Description	Quantity
	ME020R	Trial Insertion Instrument	1

Trial Insertion Instrument (ME020R) assembled with Slap Hammer Handle (FJ666R) with Trial Implant

Trial Insertion Instrument (ME020R) assembled with Slap Hammer Handle (SJ708T) and Slap Hammer Extension (SJ709R) with Trial Implant

29 MM X 40 MM TRIAL IMPLANTS

Article No.	Lordotic Angle	Height	Quantity
SJ764T	4°	10 mm	1
SJ766T	4°	12 mm	1
SJ768T	4°	14 mm	1
SJ770T	4°	16 mm	1
SJ772T	4°	18 mm	1
SJ774T	4°	20 mm	1
SJ776T	9°	10 mm	1
SJ778T	9°	12 mm	1
SJ780T	9°	14 mm	1
SJ782T	9°	16 mm	1
SJ784T	9°	18 mm	1
SJ786T	9°	20 mm	1
SJ788T	14°	10 mm	1
SJ790T	14°	12 mm	1
SJ792T	14°	14 mm	1
SJ794T	14°	16 mm	1
SJ796T	14°	18 mm	1
SJ798T	14°	20 mm	1

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D | INSTRUMENT OVERVIEW

IMPLANT INSERTION INSTRUMENT	Article No.	Description	Quantity
	**ME015R**	Implant Inserter / Manipulator	1
	**SJ605R**	Implant Inserter	1*
 Implant Inserter (ME015R) with Standard Handle (FW440R)			

IMPLANT EXTRACTION INSTRUMENT	Article No.	Description	Quantity
	ME018R	Implant Extraction Instrument	1

IMPACTOR	Article No.	Description	Quantity
	**SJ606R**	Impactor	1

PACKING BLOCK AND TAMP	Article No.	Description	Quantity
	**SJ604R**	Packing Block	1*
	**SJ608R**	Tamp	1*

DRILLS	Article No.	Description	Quantity
	ME189R	U-Joint Drill	1
	SJ725R	Straight Drill	1
BONE AWLS	**Article No.**	**Description**	**Quantity**
	ME190R	U-Joint Bone Awl	1
	ME017R	Straight Bone Awl	1
DRILL GUIDES	**Article No.**	**Description**	**Quantity**
	SJ724R	Straight Drill Guide	1
	**SJ722R**	Angled Drill Guide	1

Recommended Drill Guide Selection

U-Joint Drill (ME189R) through Angled Drill Guide (SJ722R) with Standard Handle (FW440R)

U-Joint Bone Awl (ME190R) with Standard Handle (FW440R) – no drill guide required

Straight Drill (SJ725R) through Straight Drill Guide (SJ724R) with Standard Handle (FW440R)

Straight Bone Awl (ME017R) through Straight Drill Guide (SJ724R) with Standard Handle (FW440R)

** This article is optional. Please note that there are no additional storing elements in the trays for optional instruments.*

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D | INSTRUMENT OVERVIEW

SCREWDRIVERS	Article No.	Description	Quantity
	ME014R	U-Joint Screwdriver	1
	ME013R	Straight Ball Hex Screwdriver	1
	ME016R	Straight Hex Screwdriver	1

TRAYS	Article No.	Description	Quantity
	SJ624R	Tray Preparation Instruments	1
	TF228	Graphic template for SJ624R	1
	SJ625R	Insert Trial Implants	1
	SJ626R	Tray Implantation Instruments 1	1
	TF229	Graphic template for SJ626R	1
	SJ627R	Insert Bone Screws/Small Parts	1
	SJ628R	Tray Implantation Instruments 2	1
	TF230	Graphic template for SJ628R	1
	JA475R	Lid for Preparation and Implantation Trays	3

RECOMMENDED CONTAINER	Article No.	Description	Quantity
	JK442	Bottom for 1/1 container Height: 135 mm	1
	JK444	Bottom for 1/1 container Height: 187mm	1
	JK489	Full-size lid w/ retention plate silver	2

AESCULAP® Arcadius XP® L

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Testing was undertaken to determine the mechanical properties for the Aesculap Arcadius XP System. The following static testing were conducted: axial compression, shear

compression and torsion (in a load to failure mode), subsidence, and expulsion (with and without screws). The tests were conducted according to the corresponding ASTM standards. Based on the results, the risk of implant failure as dislocation or deformity due to forces at a physiological load situation is unlikely to occur in the case of the AESCULAP® Arcadius^{XP} L® implant.

AESCULAP® Arcadius XP L®

NOTES

AESCULAP® – a B. Braun brand

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