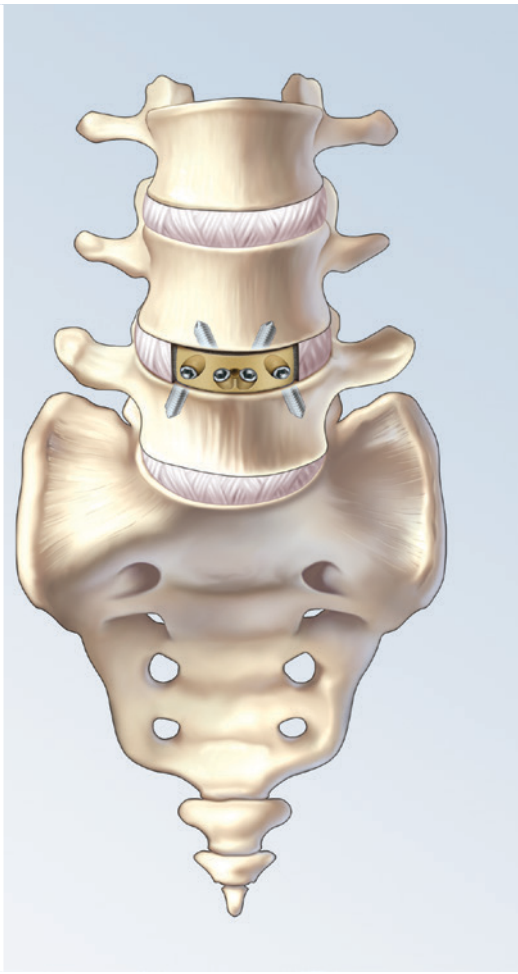
Arcadius®XP L: Evolution Spinal System

Surgical Technique



Aesculap Spine

AESCULAP®
Implant Systems

Arcadius®XP L: Evolution Spinal System

Surgical Technique

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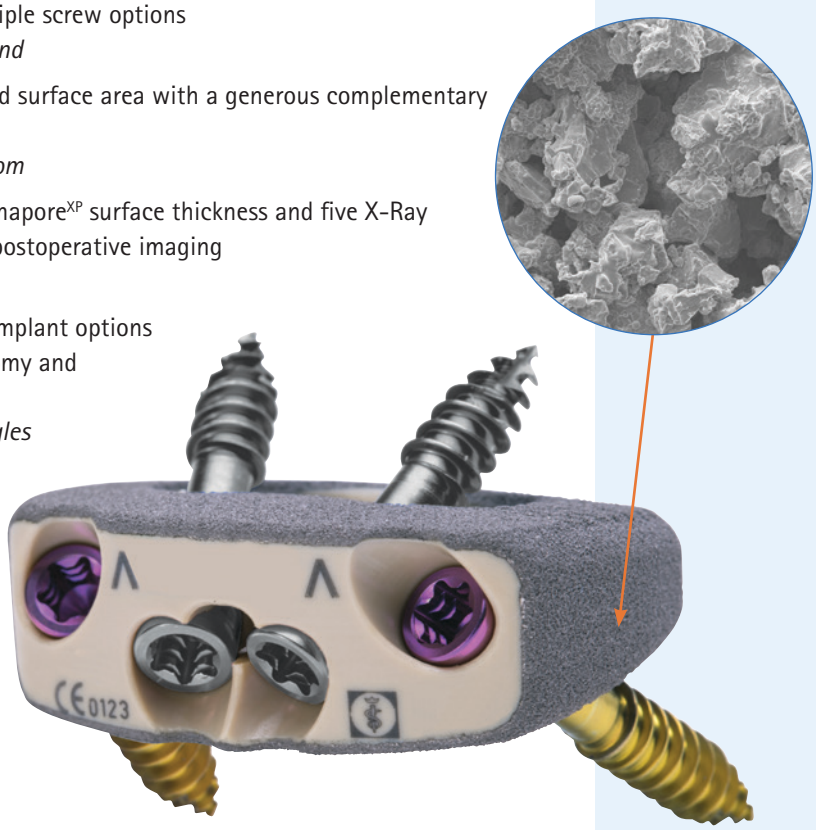
I. System Overview

Plasmapore®XP Surface Enhanced Lumbar Stand Alone Interbody

Fusion you can see demands picture perfect stability.

- The divergent, four screw, ArcadiusXP L intrinsic design yields the PlasmaporeXP surface stability you have come to depend on, now evolved with multiple screw options
  - *Designed with your picture perfect fusion in mind*
- Maximized PlasmaporeXP enhanced nano-textured surface area with a generous complementary graft window
  - *For bone built as nature intended – atom by atom*
- Radiolucent PEEK-OPTIMA® core, optimized PlasmaporeXP surface thickness and five X-Ray marker pins allow for clearly defined intra- and postoperative imaging
  - *For improved visibility during imaging*
- Wide variety of PlasmaporeXP surface enhanced implant options to meet the requirements of your patient's anatomy and next generation instrumentation
  - *Intuitively designed to accommodate steep angles*
- Dedicated anterior approach discectomy preparation instrument platform
  - *Designed to enable your best carpentry*



II. Indications and Contraindications

Indications and Intended Use

- Intended to be used with four bone screws if no supplemental fixation is used.
- Indicated as an intervertebral body fusion device designed for use with autograft.
- Intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1.
- Indicated for use in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).
- Patients should be skeletally mature and have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap Implant Systems 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 Arcadius®XP L Spinal System
- 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 cooperation by the patient
- All cases that are not listed under indications

III. Warnings and Precautions

Warnings

- 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.
- There is a risk of insufficient stability or implant failure if less than four bone screws are used. If the physician chooses to use less than four bone screws, an additional supplemental fixation system such as the Aesculap Implant Systems S4® Spinal System should be used to augment stability.
- There is a risk of migration and subsidence if the vertebral body endplates are over prepared. Make certain that the base and cover plates of the adjacent vertebral bodies are not weakened.
- The Plasmapore®XP enhanced surfaces of the Arcadius®XP L cage may be damaged by improper handling. Avoid direct contact with the Plasmapore®XP enhanced surfaces; handle implants carefully.
- Inaccurate markings of the midline may result in incorrect positioning of the implant. Always mark the midline under x-ray visualization. Determine the center of the vertebral disc using a midline marker under x-ray visualization.
- If the implant is inserted too deeply, the spinal canal and other posterior elements may be compressed. It is recommended that the Arcadius®XP L implant inserter/manipulator is used with a depth stop.
- Engaging the screwdriver incorrectly when turning the bone screw into the Arcadius®XP L cage may result in damage to the bone screws. It is recommended to fully insert the tip of the screwdriver into the bone screw.

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III. Warnings and Precautions *(Continued)*

Warnings

- Backing out or loosening of the bone screw may occur if the bone screw is not fully inserted into the Arcadius^{XP} L cage. Insert the bone screw until it is fully engaged.
- Avoid damage to the Plasmapore®^{XP} enhanced implant surfaces caused by instruments (e.g. high frequency surgical devices) applied close to the implant.

Precautions

- The Arcadius^{XP} L Spinal System has not been evaluated for safety and compatibility in the MR environment. The Arcadius^{XP} L Spinal System has not been tested for heating or migration in the MR environment.
- Based upon fatigue 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 system.
- Components of the Arcadius^{XP} L Spinal System should not be used with components of any other system or manufacturer.

IV. Surgical Technique

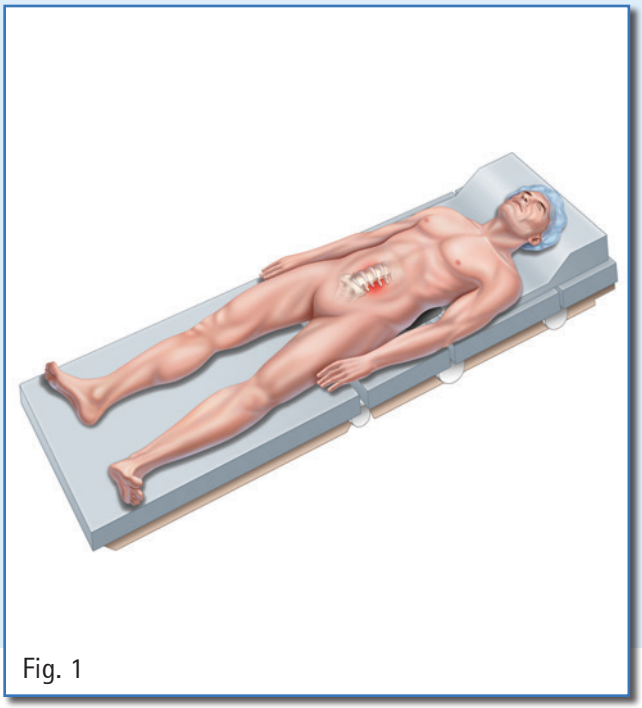

Fig. 1

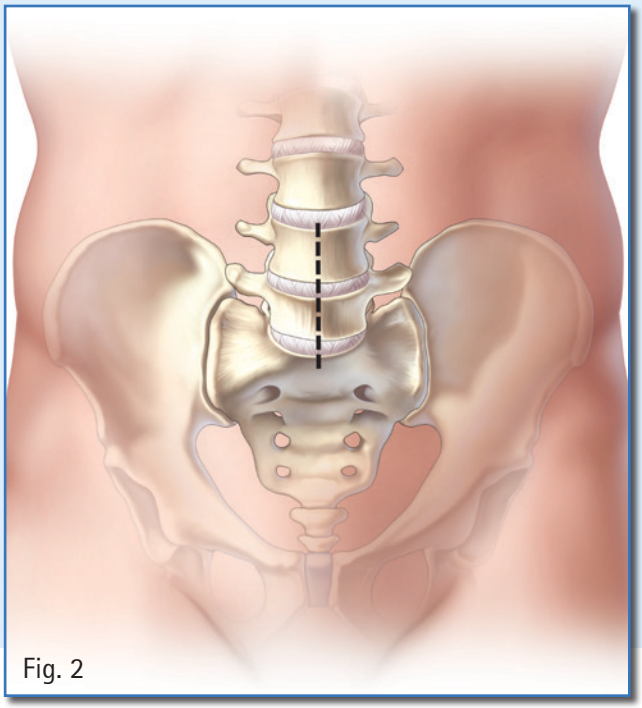

Fig. 2

1. Patient Positioning and Exposure

- Anterior access will be required for insertion of the Arcadius®XP L device. 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. Preoperative radiographs should be taken to measure disc heights and the required implant range. It is recommended to examine the lateral radiograph to assure that the surgical incision will allow for proper access to the corresponding disc space.
- Place the patient in the 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).

Note: *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.

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IV. Surgical Technique *(continued)*

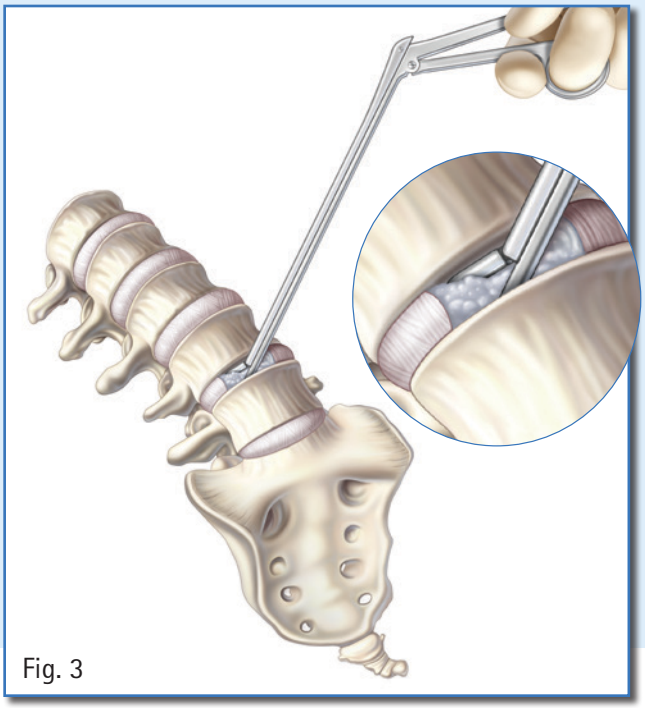

Fig. 3

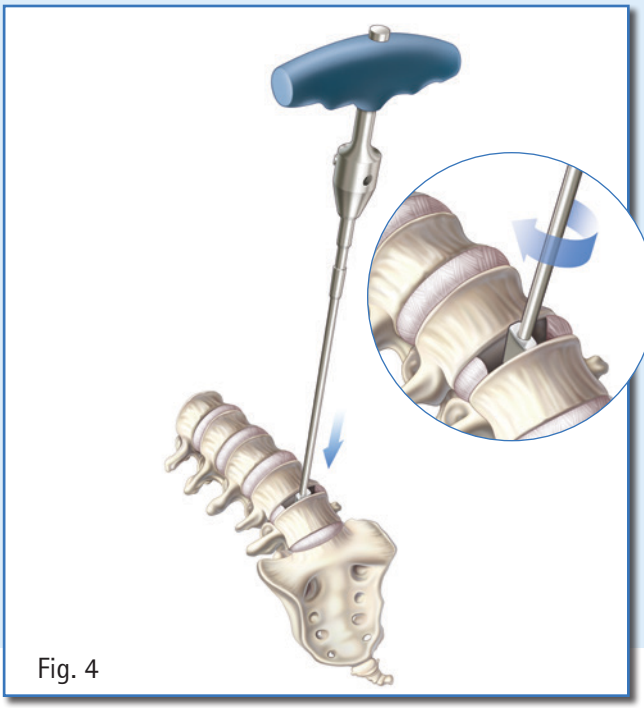

Fig. 4

2. Preparation

- Prepare the intervertebral space by utilizing anterior discectomy instruments that the surgeon feels are 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.
- Distractors can be 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).

Note: *Each distractor contains a 9° lordotic angle.*

IV. Surgical Technique *(continued)*

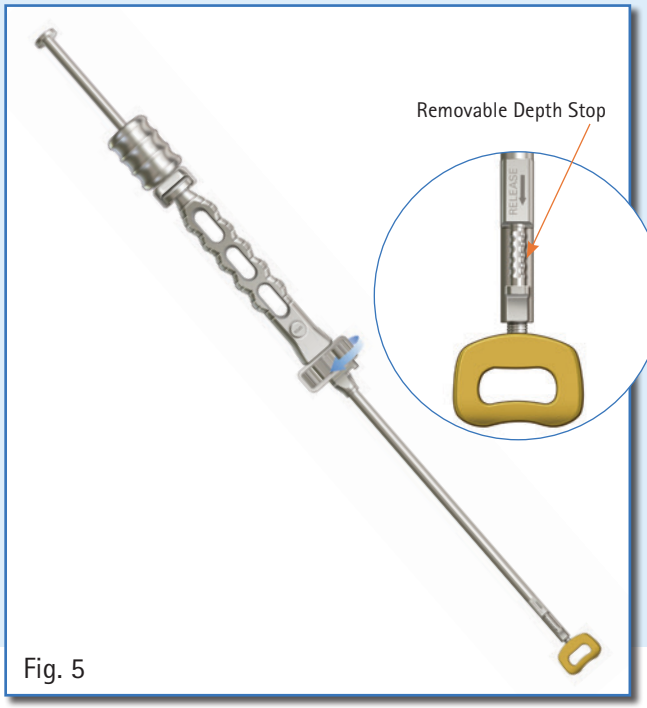

Fig. 5

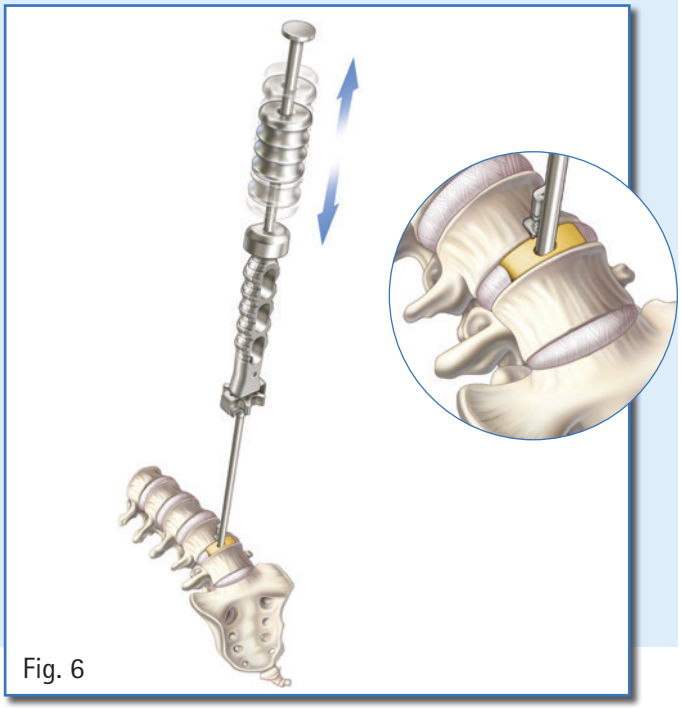
Fig. 6

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. **(See pages 25-26 for available sizes.)**
- Select an appropriately-sized trial implant based on patient anatomy and preoperative radiographic analysis.
- Attach the trial implant to the trial insertion instrument (ME020R).
  - Attach the slap hammer handle to the trial insertion instrument (SJ108T).
  - Thread the trial implant onto the trial insertion instrument by turning the large proximal knob in a clockwise direction (Fig. 5).

Note: *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. 6).
- Manipulate the trial implant as needed to attain the desired position.
- Continue to evaluate trial implants until a firm and secure fit is achieved.
- Assess final trial implant fit and position with intraoperative AP and lateral fluoroscopy.

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IV. Surgical Technique *(continued)*

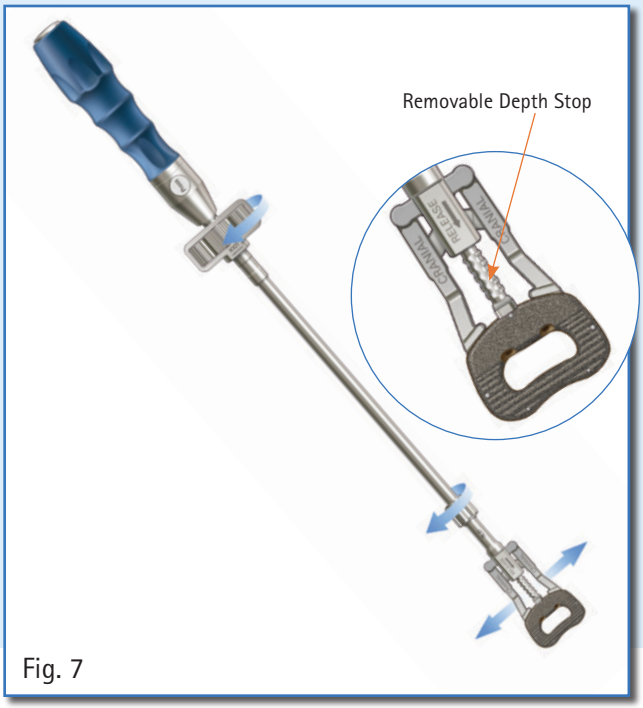

Fig. 7

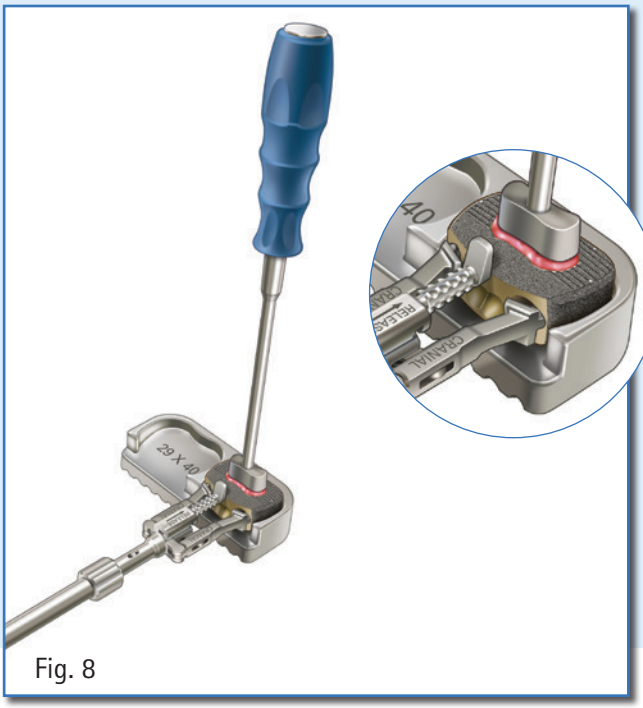

Fig. 8

4. Implant Preparation and Insertion

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

> **Note:** *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 insertion instrument (Fig. 7).
    - Attach selected handle to the implant insertion instrument (ME015R).
    - Ensure that the small distal knob of the implant insertion instrument 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.
    - Attach and secure selected implant to the distal end of the implant insertion instrument by turning the large proximal knob in a clockwise direction.
  - Fill the implant with autograft material by utilizing the packing block and tamp (SJ604R/SJ608R).
    - Place the implant into the corresponding footprint space of the packing block and fill with autograft material.
    - Use the tamp to firmly pack autograft material into the implant (Fig. 8).

IV. Surgical Technique *(continued)*

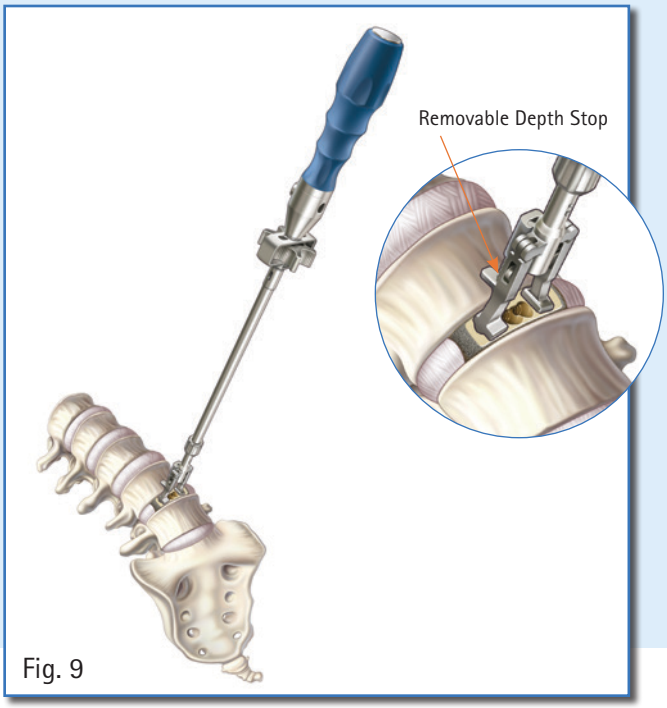

Fig. 9

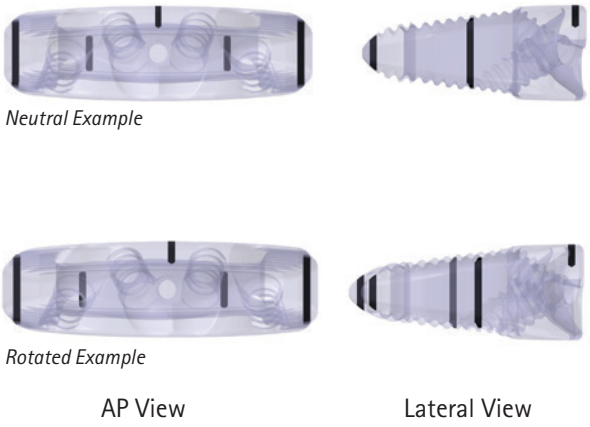

Fig. 10

Note: *The implant insertion instrument 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**
  - Ensure that the implant inserter is oriented in the cranial position.
  - Reference the midline and gently advance the implant into the disc space (Fig. 9).

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

  - Assess implant position with intraoperative AP and lateral fluoroscopy.

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

- **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. 10).
- Manipulate the implant as needed to attain the desired position.
- Obtain additional AP and lateral fluoroscopic images to document midline placement and neutral alignment.

Note: *It is recommended that the implant insertion instrument is left attached to the implant for medial screw hole preparation and screw insertion (Figure 11a).*

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IV. Surgical Technique *(continued)*

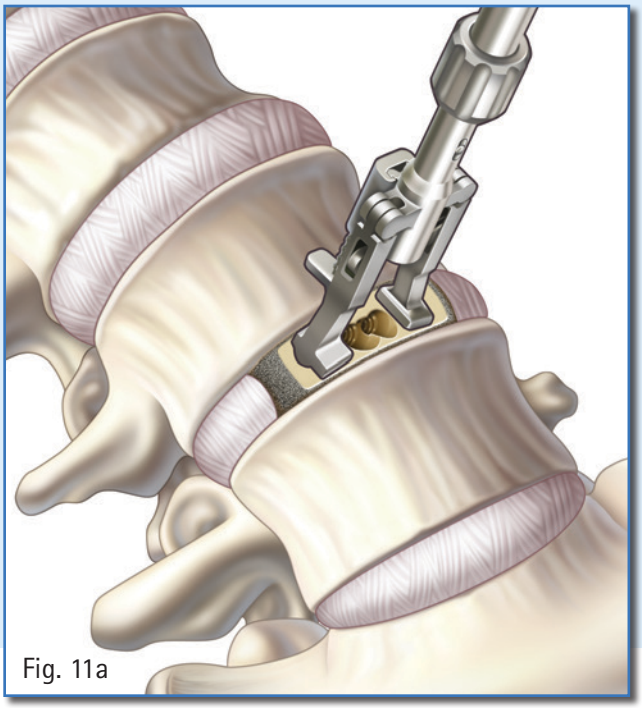

Fig. 11a

Fig. 11b

5. Screw Preparation and Insertion

- For ease of bone screw insertion, it is recommended that a pilot hole is created at the intended screw placement site.
- A variety of instruments is available to meet surgeon preference for screw hole preparation and screw insertion. **(See page 27 for instrument selection.)**

Note: *All screwdrivers are self-retaining hexalobe heads for strength and control.*

- The Arcadius^{XP} L device is intended to be used with four bone screws.
  - Bone screws are available in two lengths: 25 mm and 30 mm.
  - Both 4.7 diameter screw options feature a hexalobe screw head design (Figure 11b).
  - **Performance Screw**
    - Aggressive, threaded to the tip, self-tapping, self-drilling workhorse screw
  - **Compression Screw**
    - Mild lag design self-tapping, self-drilling compression screw that bites with confidence
    - When a separation of the interbody and endplate is evident, usually in the superior surface, use of the Arcadius^{XP} L compression screw will aid in closing this gap by applying a compressive load or "lag" to the endplate bone interbody interface. This will aid in bone/prosthesis contact and accentuate initial stability.
    - Anatomic consideration and purchase requirements are taken into account when selecting screw size for the inferior screws. Assemble the compression screw selected to the hexalobe U-Joint screwdriver (ME014R), hexalobe ball joint screwdriver (ME174R), hexalobe flexible screwdriver (ME176R), or hexalobe straight screwdriver (ME054R) and handle. Relevant trajectory and dimensional information can be found on pages 25-26.

Note: *It is important to consider patient anatomy at the surgical level, and implant footprint size, height and lordotic angle when selecting the proper screw length. Analysis of lateral screw length is essential to avoid screw contact with adjacent neural elements.* **It is recommended that shorter (25mm) screws are placed laterally, especially if the small implant footprint is used.** *Please refer to the implant and screw diagram on* **pages 25-26** *to determine the proper screw length for the implant used.*

IV. Surgical Technique *(continued)*

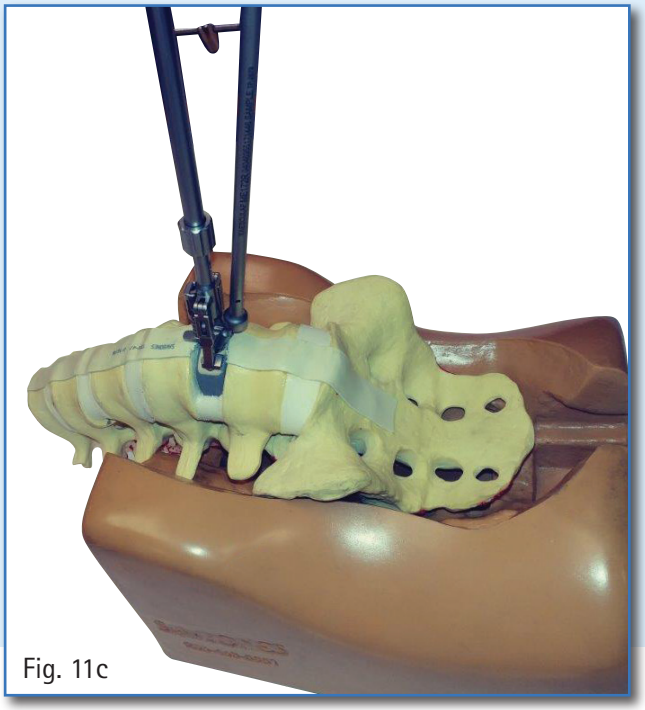

Fig. 11c

Caution: *When anticipating posterior stabilization, consider the trajectory of the pedicle screw and take into account the inferior screws of the Arcadius®XP L and their posterior lateral trajectory. To avoid pedicle screw contact, you have two options:*

1. *The Arcadius®XP L implant can be rotated or flipped upside down. This will allow the inferior screws to have a more medial trajectory, thus substantially reducing the chance of pedicle screw contact.*
2. *Use shorter screws (25 mm) for the inferior directed screw holes.*

5a. Medial Screw Hole Preparation and Insertion

- Utilize the implant insertion instrument (ME015R) with choice of awl (ME172R/ME190R/ME017R) and screwdriver (ME052R/ME054R/ME174R/ME176R).
- Maintain final implant position as determined with fluoroscopy.

Note: *It is recommended to prepare screw holes and insert screws utilizing x-ray guidance.*

- The implant insertion instrument can be utilized for implant stabilization during medial screw hole preparation and insertion (Fig. 11c).

Note: *Use of the implant insertion instrument for medial screw hole preparation and screw insertion is optional and is not required.*

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IV. Surgical Technique *(continued)*

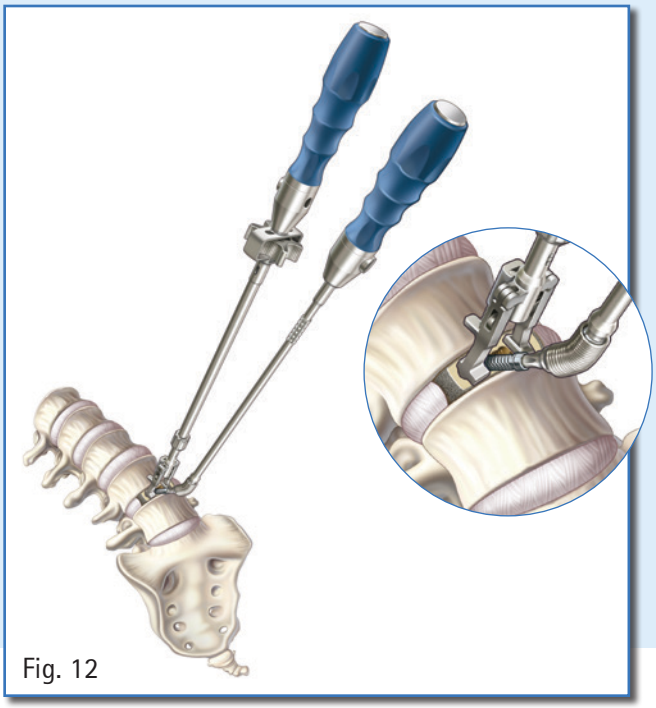

Fig. 12

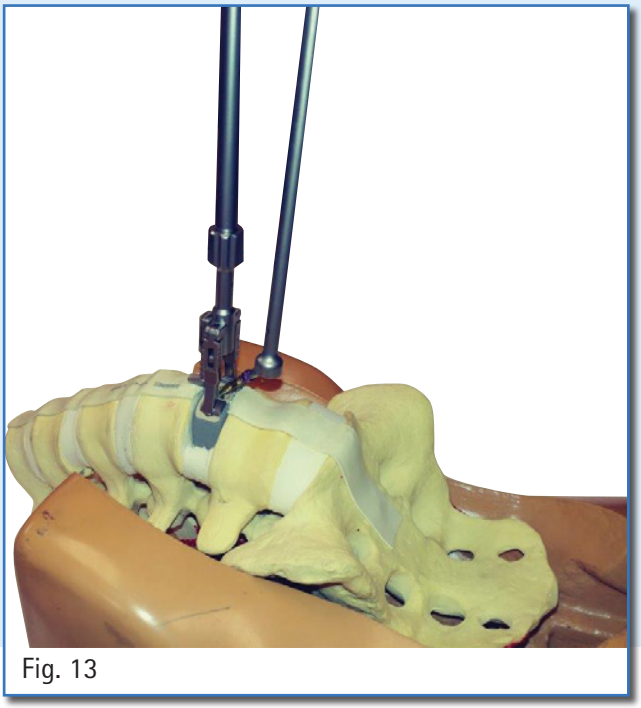

Fig. 13

- **Medial Screw Hole Preparation**
  - Attach desired handle to bone awl.
  - Guide the bone awl through the distal opening of the implant insertion instrument (caudal side) (Fig. 11c).
  - Insert the bone awl into one of the medial screw holes until a hard stop is reached. A hard stop indicates that the awl has punctured the cortical layer of bone.

Note: *The bone awl is self-guiding and self-centering and does not require use of a drill guide.*

- **Medial Screw Insertion**
- Select a bone screw based on patient anatomy at the surgical level, the implant size used and the implant and screw diagram on page 25-26.
  - Attach desired handle and selected bone screw to the desired screwdriver (ME052R/ME054R/ME174R/ME176R).
  - Guide the screw through the distal opening of the implant insertion instrument (caudal side, directed superiorly).
  - Insert the screw into the prepared medial screw hole (Fig. 12 & Fig. 13).
  - Turn the screwdriver in a clockwise motion to advance the bone screw into the vertebral body.

- If using the compression screw, the threads will disengage from the interbody briefly. During this time, the surgeon should notice the bone being pulled towards the implant and the gap reducing. The threads will re-engage to help overcome the locking mechanism.

Caution: *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 additional **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. Do not turn past the hard stop, especially with the compression screw. See page 22 for detail on locking mechanism.*

Caution: *It is important to note that when using the compression screw, the compression effect will occur prior to passing the locking mechanism.* **Additional compression will not be gained by overtightening.** *Overtightening the screw may cause the PEEK cage to strip or fracture.*

IV. Surgical Technique *(continued)*

Note: Please refer to page 22 for a detailed description of the Arcadius®XP L locking mechanism.

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

5b. Adjacent Lateral Screw Hole Preparation and Insertion:

- Utilize your choice of bone awl (ME172R/ME190R/ME017R) and screwdriver (ME052R/ME176R/ME054R/ME174R).
- Remove the implant insertion instrument to gain access to lateral screw holes.

Note: *It is recommended to prepare screw holes and insert screws utilizing AP and lateral x-ray guidance. Lateral screw hole preparation and insertion will require removal of the insertion device.*

- **Lateral Screw Hole Preparation**
  - Attach desired handle to desired bone awl.
  - Guide the bone awl into one of the lateral screw holes and insert until a hard stop is reached. A hard stop indicates that the awl has punctured the cortical layer of bone (Fig. 13).

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IV. Surgical Technique *(continued)*

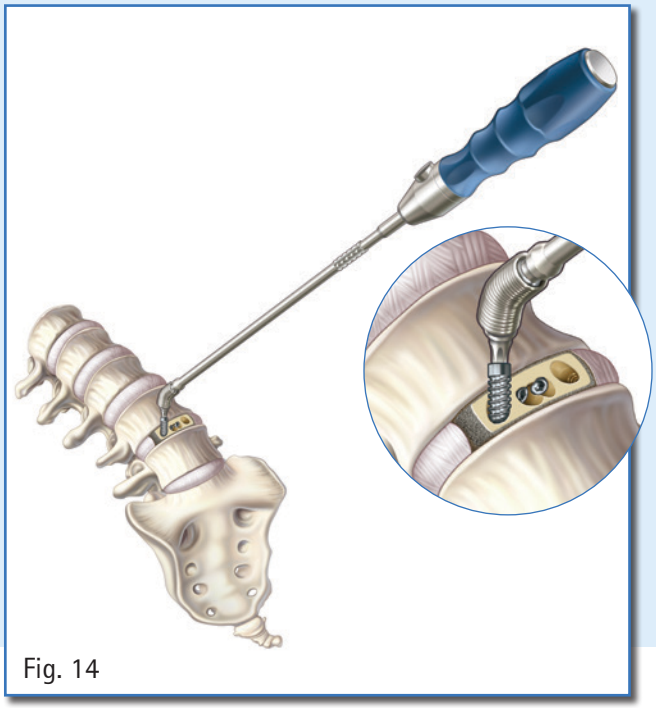

Fig. 14

- **Lateral Screw Insertion**
- Select a bone screw based on patient anatomy at the surgical level, the implant size used and the implant and screw diagram on pages 25-26.
  - Guide the screwdriver with screw attached into the prepared lateral screw hole.
  - Turn the screwdriver in a clockwise motion to advance the bone screw into the vertebral body (Fig. 14).
  - Ensure that the bone screw has threaded past the locking rim and is fully seated (as per the caution box on page 14).
- Repeat the steps outlined above for pilot hole creation and bone screw placement to insert the final lateral screw.

IV. Surgical Technique *(continued)*

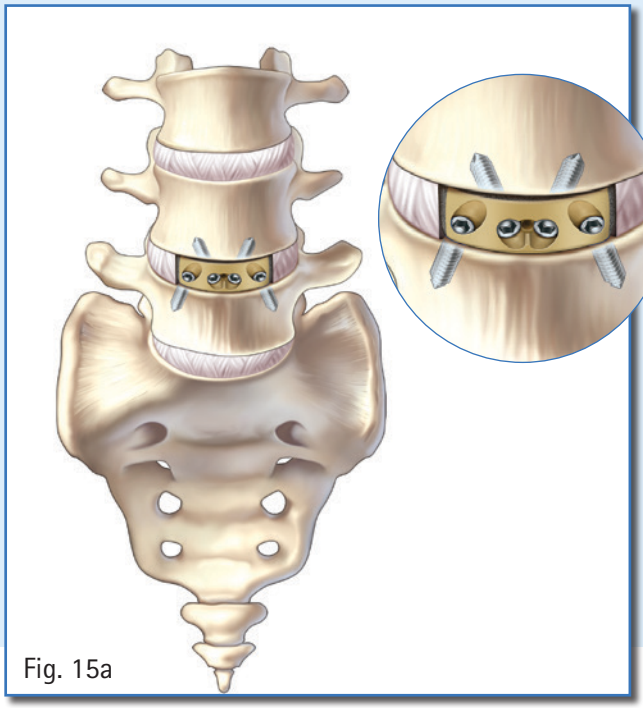

Fig. 15a

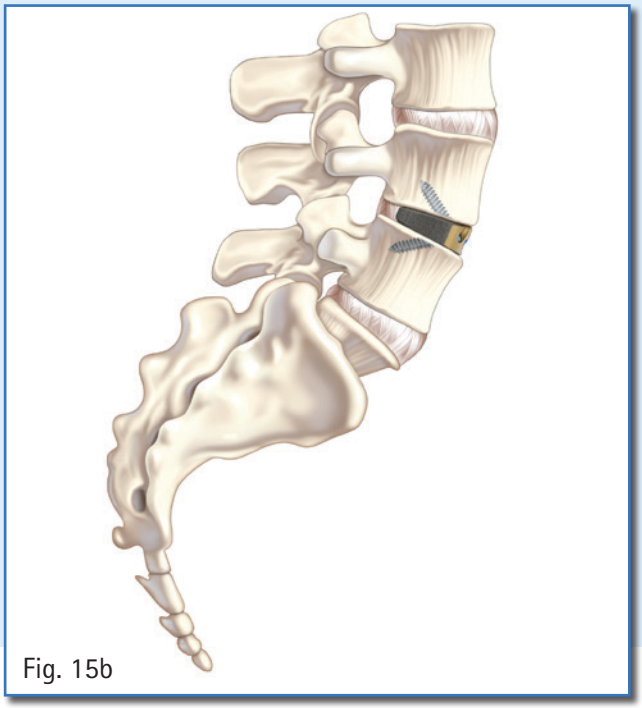

Fig. 15b

- AP and lateral views of a fully assembled construct are shown above. (Fig. 15a and 15b).

Recommended Drill Guide Selection: *When the U-joint drill, ball joint drill, straight drill or straight bone awl are utilized for screw hole preparation, the corresponding drill guide must be used.*

Screw Hole Preparation Instrument	Required Drill Guide	Instrument Assembly	Extension Distance (mm)	Extension Distance through Average Implant (mm)
U-Joint and Ball Joint Drill	Angled 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
U-Joint and Ball 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

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IV. Surgical Technique *(continued)*

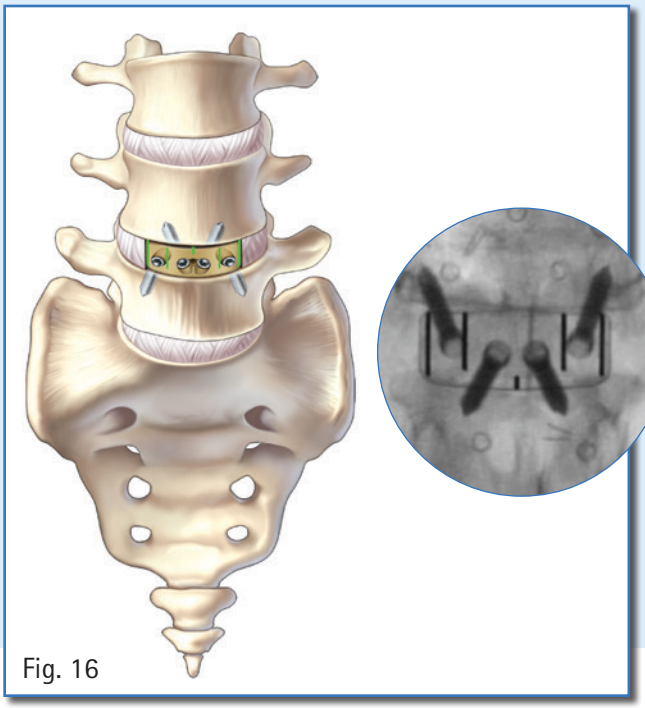


Fig. 16

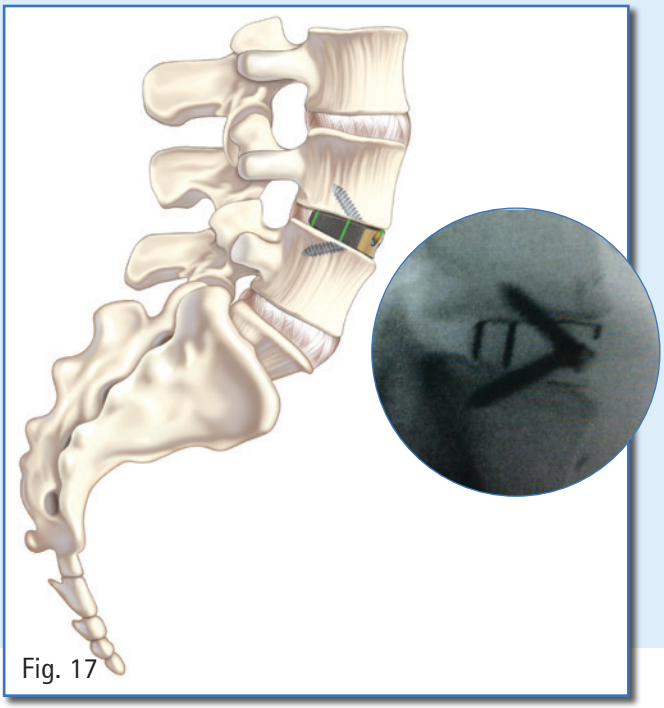


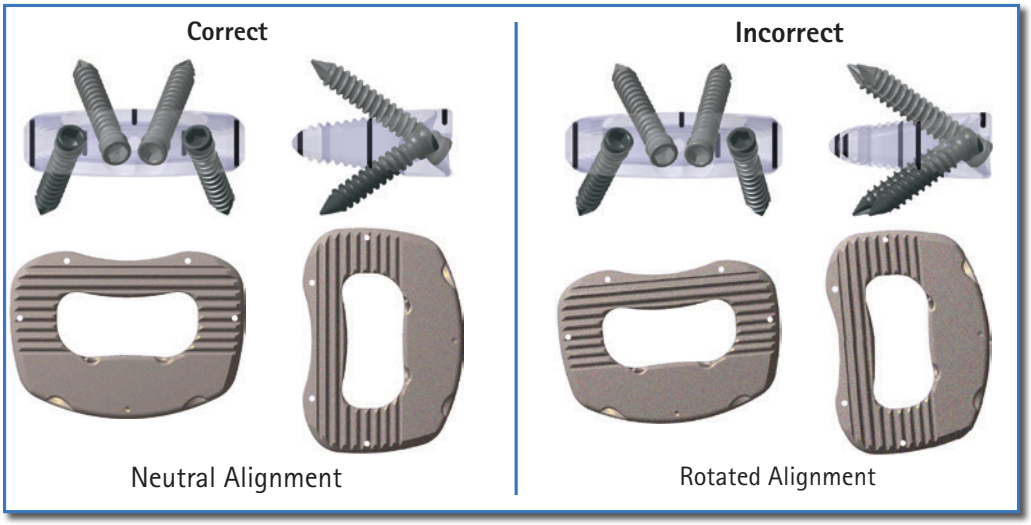
Fig. 17

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. 16).
  - 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. 17).
  - The final AP and lateral images should reflect neutral alignment of the Arcadius^{XP} L construct (Figures 16 and 17).

Note: *The green lines in Figures 16 and 17 represent the location of the implant x-ray markers in both the AP and lateral views.*

Arcadius^{XP} L Implant X-Ray Marker Alignment: *The drawings below illustrate the x-ray markers of the Arcadius^{XP} L construct in neutral and rotated alignment.*



IV. Surgical Technique *(continued)*

7. Implant and Screw Removal

- 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 counterclockwise motion.

Note: *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 ArcadiusXP L implant.
- The implant inserter may be reattached once the screws are removed to assist in final removal of the interbody.

Important information regarding optional instrumentation:

Impactor (SJ606R): An impactor is available in the instrument set for assistance with final implant placement. It is recommended that the impactor is placed in the center of the implant so that the curvature of the impactor aligns with the curvature of the anterior surface of the implant. It is not necessary to use excessive force with the impactor to position or seat the implant.

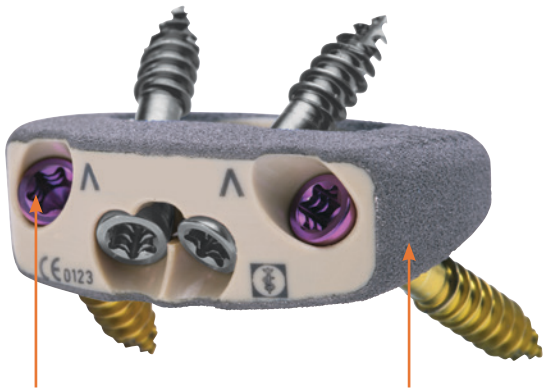
Arcadius®XP L: Evolution Spinal System

Surgical Technique

IV. Surgical Technique *(continued)*

- **Compression Screw Removal**
  - Featured Instrument: Arcadius^{XP} L Screw Removal Shaft (ME078R)
  - Thread the Arcadius^{XP} L Screw Removal Shaft (ME078R) and handle to the selected screw to be removed by engaging the internal thread mechanism in the screw head. This is accomplished by rotating the removal tool counterclockwise. This will engage the inside thread mechanism and continue to advance the screw removal. The left handed thread will allow the user to continue to unthread the implant without disengaging the removal instrument.
  - Use light but positive force while unthreading the screw to back out the screw.
  - Repeat the bone screw removal process for the remaining bone screws.
  - Implant removal instructions are on page 19.

V. Implant Information

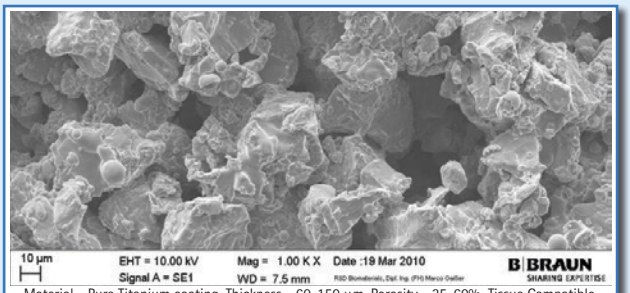


Integrated dual-locking mechanism with single-step activation you can feel.

Implants available in:

- Two implant footprints: 25 mm x 35 mm and 29 mm x 40 mm
- Six heights: 10, 12, 14, 16, 18 and 20 mm
- Three lordotic angles: 4, 9 and 14 degrees

Fig. 18



Material - Pure Titanium coating, Thickness - 60-150 µm, Porosity - 35-60%, Tissue Compatible

Fig. 19

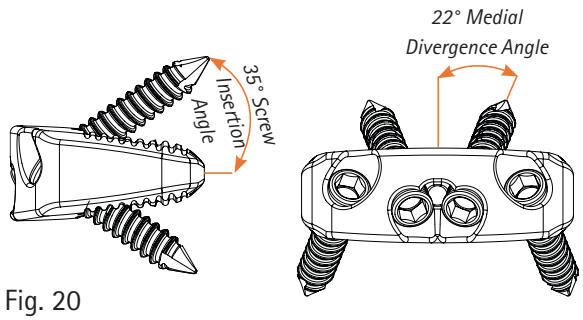


Fig. 20

1. Implant Information (Fig. 18)

- Manufactured from radiolucent PEEK-OPTIMA®*
- Featuring Plasmapore®XP osteoconductive pure Titanium porous surface enhancement (Fig. 19)
- Wide variety of options for optimized fit:
  - Two implant footprints: 25 mm x 35 mm and 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
- Five Tantalum marker pins for x-ray verification

Note: *X-ray markers are located 1 mm from edge of implant.*

Bone Screw Information (Fig. 18)

- Manufactured from a Titanium alloy (Ti6Al4V)
- Bone screws are self-centering, self-drilling and self-tapping.
- Both the Performance and Compression Screws feature a hexalobe head design.
- Bone screw diameter is 4.7 mm.
- Available in two lengths: 25 mm and 30 mm

Construct Information (Fig. 20)

- 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.*

Arcadius®XP L: Evolution Spinal System

Surgical Technique

V. Implant Information *(continued)*

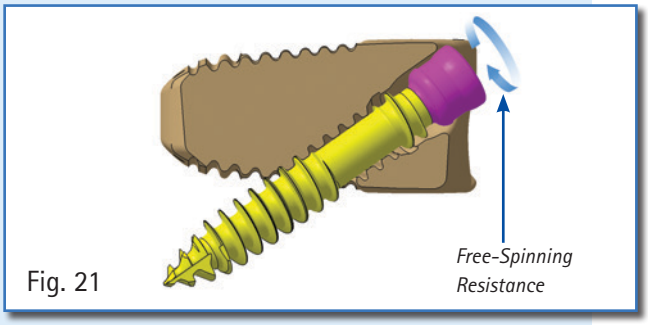


Fig. 21

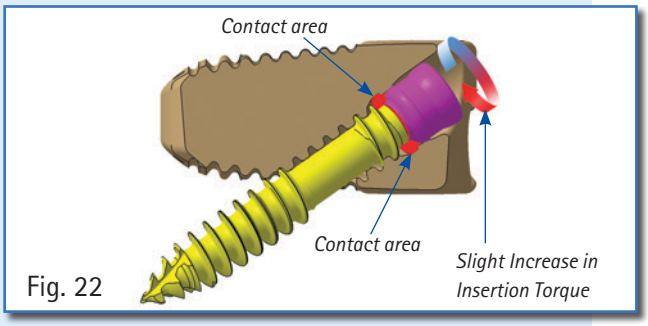


Fig. 22

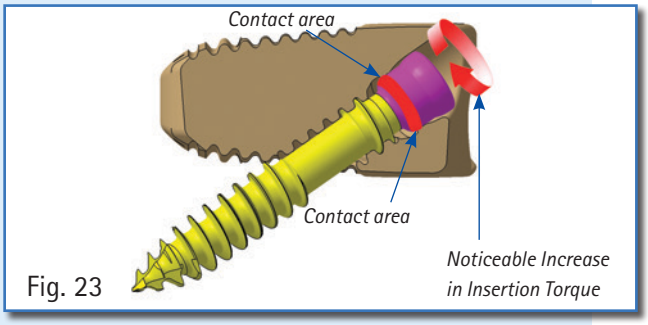


Fig. 23

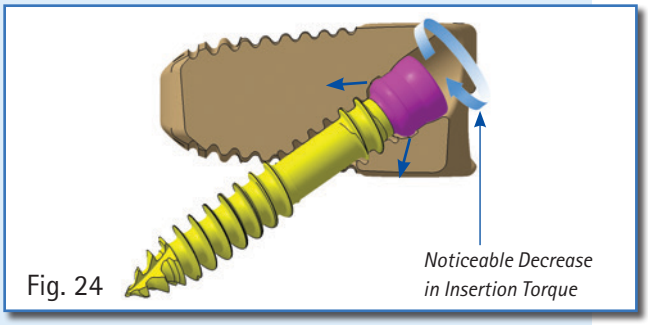


Fig. 24

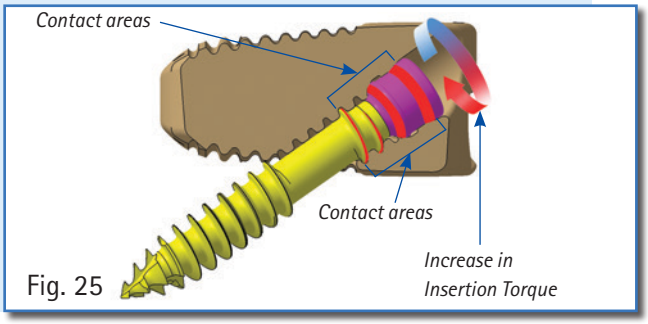


Fig. 25

2. Locking Mechanism Information

- The Arcadius^{XP} L implant incorporates a dual-locking mechanism feature to prevent screws from backing out. The following section describes how the locking mechanism functions from a user's perspective. Tactile feedback is similar with the compression screw and with the performance screw.

First Locking Mechanism

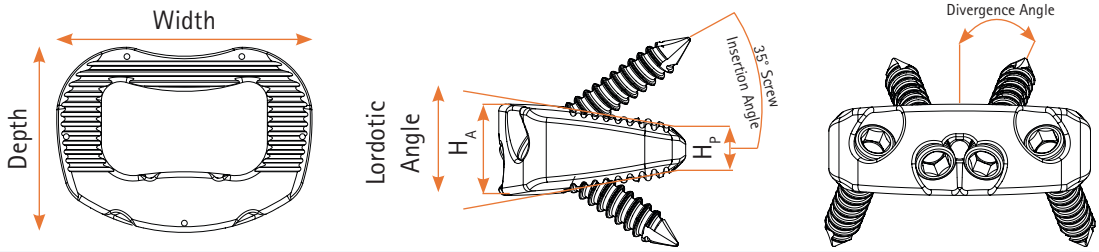
- There is an internal locking rim integrated into each screw hole of the Arcadius^{XP} L implant.
- The first locking mechanism is activated during bone screw insertion.
  - Upon insertion, the bone screw can be easily turned without encountering resistance (Fig. 21).
  - As the shoulder of the bone screw comes into contact with the lead-in taper of the locking rim, a slight **increase** in insertion torque will be felt (Fig. 22).
  - A noticeable **increase** in insertion torque will be felt as the shoulder of the bone screw passes through the locking rim, causing the locking rim to expand (Fig. 23).
  - After the shoulder of the bone screw passes through the expanded locking rim, the locking rim will seat and lock into final position. At this point, a noticeable **decrease** in insertion torque will be felt (Fig. 24).

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 (Fig. 25).
  - After the first locking mechanism has been activated, continue to advance the bone screw.
  - As the bone screw approaches full insertion, the threads of the bone screw will contact the inner threads of the implant, and a noticeable **increase** in insertion torque will be felt.
  - 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. Once hardstop is reached, screws should only be turned a maximum of another 90° (one quarter turn).

Caution: *It is important that the two locking mechanisms are engaged to prevent screws from backing out.*

VI. Implant Overview ST0480 (Implant Bank)



Item No.	Implant Description	Footprint Depth (mm)	Footprint Width (mm)	Lordotic Angle (°)	Anterior Height H_A (mm)	Posterior Height H_P (mm)	Graft Volume (cc)
SO810P	Arcadius®XP L Implant 25 x 35 x 10 mm, 4°	25	35	4	10.2	7.4	1.75
SO812P	Arcadius®XP L Implant 25 x 35 x 12 mm, 4°	25	35	4	12.2	9.4	2.10
SO814P	Arcadius®XP L Implant 25 x 35 x 14 mm, 4°	25	35	4	14.2	11.4	2.64
SO816P	Arcadius®XP L Implant 25 x 35 x 16 mm, 4°	25	35	4	16.2	13.4	2.82
SO818P	Arcadius®XP L Implant 25 x 35 x 18 mm, 4°	25	35	4	18.2	15.4	3.18
SO820P	Arcadius®XP L Implant 25 x 35 x 20 mm, 4°	25	35	4	20.2	17.4	3.54
SO840P	Arcadius®XP L Implant 25 x 35 x 10 mm, 9°	25	35	9	10.2	6.0	1.63
SO842P	Arcadius®XP L Implant 25 x 35 x 12 mm, 9°	25	35	9	12.2	8.0	1.99
SO844P	Arcadius®XP L Implant 25 x 35 x 14 mm, 9°	25	35	9	14.2	10.0	2.35
SO846P	Arcadius®XP L Implant 25 x 35 x 16 mm, 9°	25	35	9	16.2	12.0	2.71
SO848P	Arcadius®XP L Implant 25 x 35 x 18 mm, 9°	25	35	9	18.2	14.0	3.07
SO850P	Arcadius®XP L Implant 25 x 35 x 20 mm, 9°	25	35	9	20.2	16.0	3.43
SO870P	Arcadius®XP L Implant 25 x 35 x 10 mm, 14°	25	35	14	10.2	4.5	1.45
SO872P	Arcadius®XP L Implant 25 x 35 x 12 mm, 14°	25	35	14	12.2	6.3	1.81
SO874P	Arcadius®XP L Implant 25 x 35 x 14 mm, 14°	25	35	14	14.2	8.3	2.17
SO876P	Arcadius®XP L Implant 25 x 35 x 16 mm, 14°	25	35	14	16.2	10.3	2.53
SO878P	Arcadius®XP L Implant 25 x 35 x 18 mm, 14°	25	35	14	18.2	12.3	2.89
SO880P	Arcadius®XP L Implant 25 x 35 x 20 mm, 14°	25	35	14	20.2	14.3	3.25
SO825P	Arcadius®XP L Implant 29 x 40 x 10 mm, 4°	29	40	4	10.2	7.1	3.26
SO827P	Arcadius®XP L Implant 29 x 40 x 12 mm, 4°	29	40	4	12.2	8.8	3.95
SO829P	Arcadius®XP L Implant 29 x 40 x 14 mm, 4°	29	40	4	14.2	10.8	4.63
SO831P	Arcadius®XP L Implant 29 x 40 x 16 mm, 4°	29	40	4	16.2	12.8	5.31
SO833P	Arcadius®XP L Implant 29 x 40 x 18 mm, 4°	29	40	4	18.2	14.8	6.00
SO835P	Arcadius®XP L Implant 29 x 40 x 20 mm, 4°	29	40	4	20.2	16.8	6.69
SO855P	Arcadius®XP L Implant 29 x 40 x 10 mm, 9°	29	40	9	10.2	5.5	3.05
SO857P	Arcadius®XP L Implant 29 x 40 x 12 mm, 9°	29	40	9	12.2	7.3	3.73
SO859P	Arcadius®XP L Implant 29 x 40 x 14 mm, 9°	29	40	9	14.2	9.3	4.42
SO861P	Arcadius®XP L Implant 29 x 40 x 16 mm, 9°	29	40	9	16.2	11.3	5.10
SO863P	Arcadius®XP L Implant 29 x 40 x 18 mm, 9°	29	40	9	18.2	13.3	5.79
SO865P	Arcadius®XP L Implant 29 x 40 x 20 mm, 9°	29	40	9	20.2	15.3	6.47
SO885P	Arcadius®XP L Implant 29 x 40 x 10 mm, 14°	29	40	14	10.2	3.8	2.70
SO887P	Arcadius®XP L Implant 29 x 40 x 12 mm, 14°	29	40	14	12.2	5.3	3.39
SO889P	Arcadius®XP L Implant 29 x 40 x 14 mm, 14°	29	40	14	14.2	7.3	4.07
SO891P	Arcadius®XP L Implant 29 x 40 x 16 mm, 14°	29	40	14	16.2	9.3	4.76
SO893P	Arcadius®XP L Implant 29 x 40 x 18 mm, 14°	29	40	14	18.2	11.3	5.44
SO895P	Arcadius®XP L Implant 29 x 40 x 20 mm, 14°	29	40	14	20.2	13.3	6.13

Arcadius®XP L: Evolution Spinal System

Surgical Technique

VI. Implant Overview *(continued)*

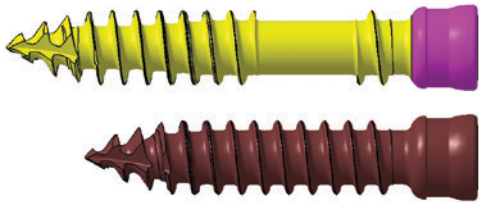
Implant Bank Configuration (ST0484) 25 x 35 mm Footprint Width

Height	4 Degrees	Qty.	9 Degrees	Qty.	14 Degrees	Qty.
10 mm	SO810P	2	SO840P	2	SO870P	2
12 mm	SO812P	2	SO842P	2	SO872P	2
14 mm	SO814P	2	SO844P	2	SO874P	2
16 mm	SO816P	1	SO846P	2	SO876P	2
18 mm	SO818P	1	SO848P	1	SO878P	1
20 mm	SO820P	1	SO850P	1	SO880P	1

Implant Bank Configuration (ST0484) 29 x 40 mm Footprint Width

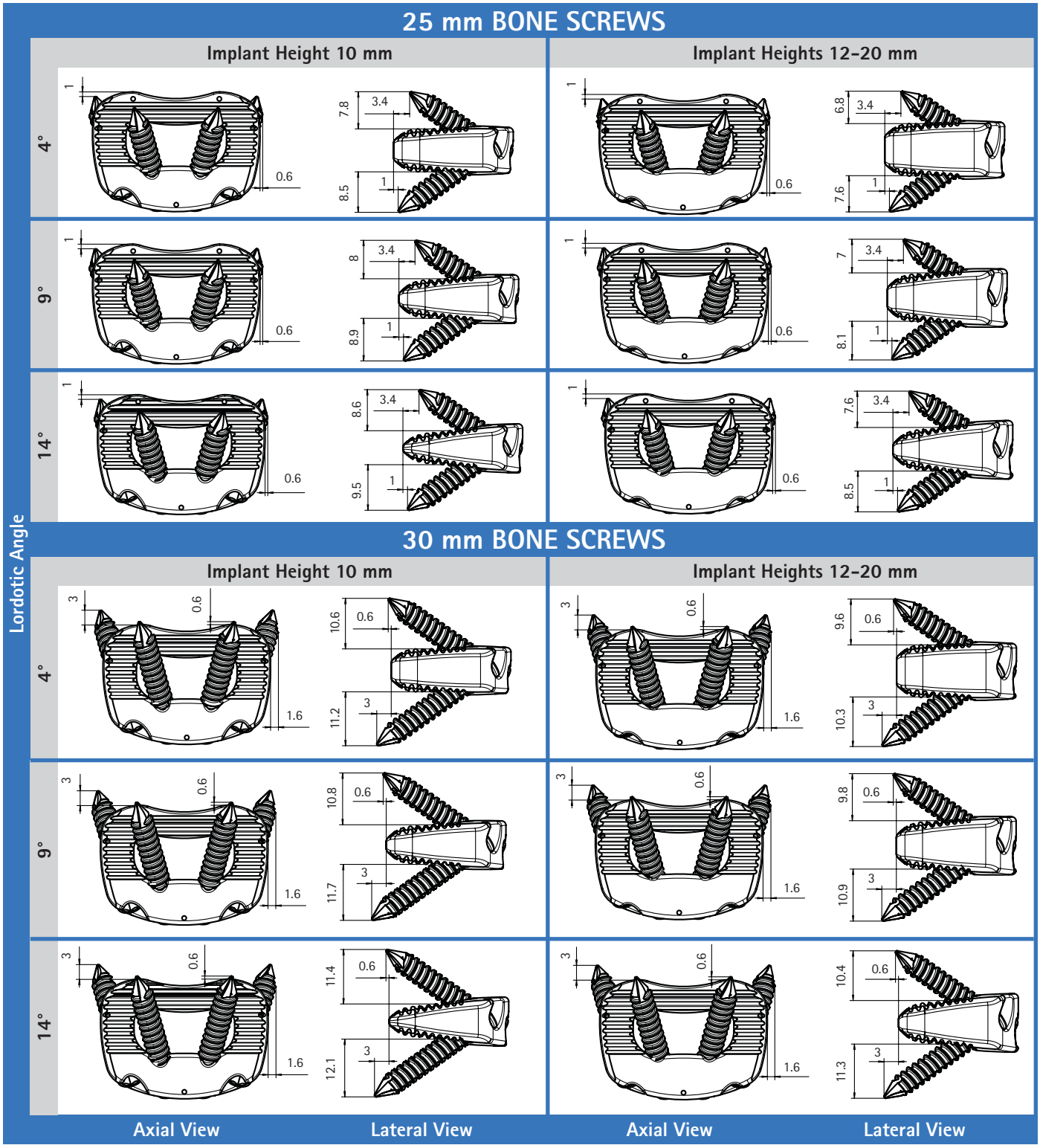
Height	4 Degrees	Qty.	9 Degrees	Qty.	14 Degrees	Qty.
10 mm	SO825P	1	SO855P	1	SO885P	1
12 mm	SO827P	1	SO857P	2	SO887P	2
14 mm	SO829P	1	SO859P	2	SO889P	2
16 mm	SO831P	1	SO861P	2	SO891P	2
18 mm	SO833P	1	SO863P	1	SO893P	1
20 mm	SO835P	1	SO865P	1	SO895P	1

Item No.	Bone Screw Description (Qty. 12/Length in ST0651)	Total Length (mm)
ME177T	Arcadius® L Compression Screw	25
ME178T	Arcadius L Compression Screw	30
ME186T	Arcadius L Performance Screw	25
ME187T	Arcadius L Performance Screw	30



VII. Implant and Screw Diagrams

Small Implant Footprint (25 mm X 35 mm)



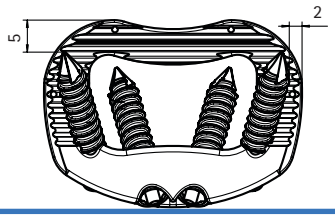
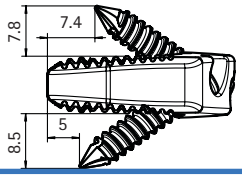
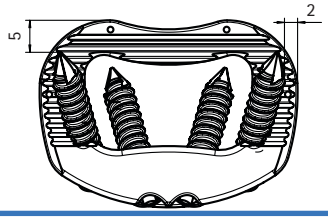
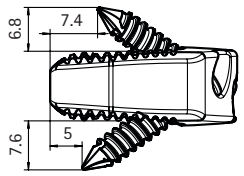
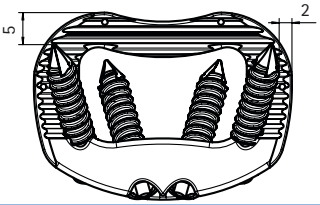
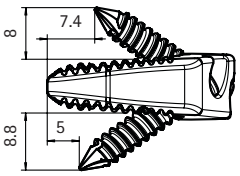
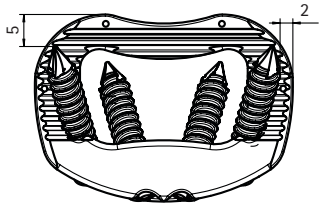
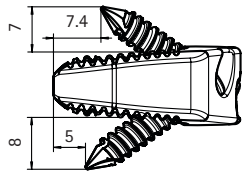
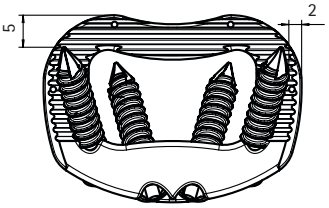
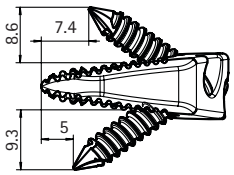
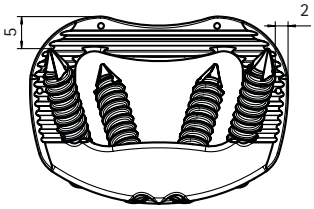
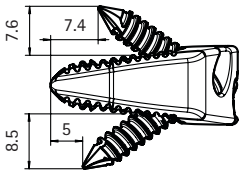
Arcadius®XP L: Evolution Spinal System

Surgical Technique

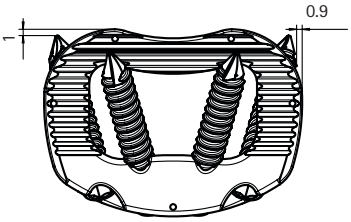
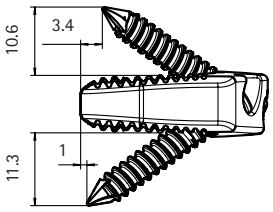
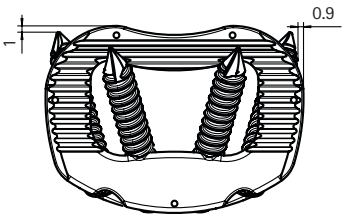
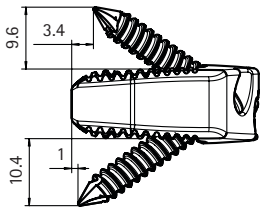
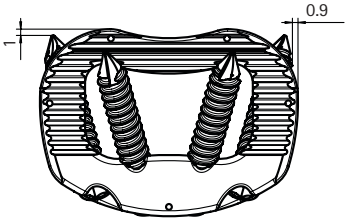
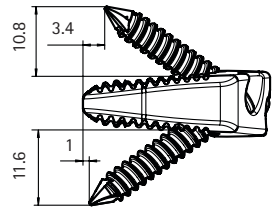
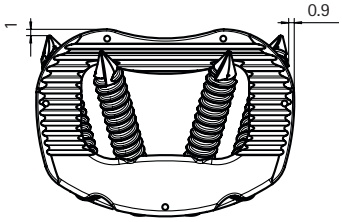
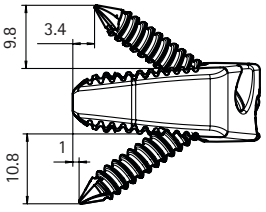
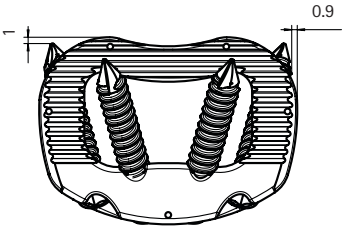
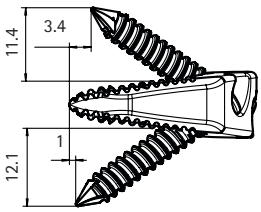
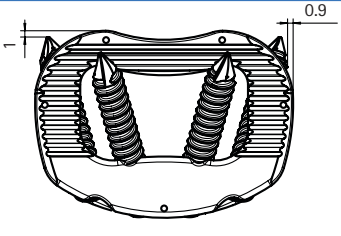
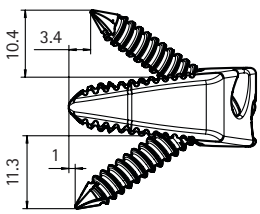
Large Implant Footprint (29 mm X 40 mm)

Caudal view of implant is illustrated for inferior 25 mm screw visibility.

25 mm BONE SCREWS

Lordotic Angle	Implant Height 10 mm		Implant Heights 12–20 mm	
	Axial View	Lateral View	Axial View	Lateral View
4°				
9°				
14°				

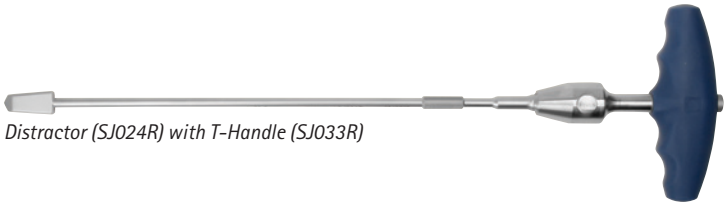
30 mm BONE SCREWS

Lordotic Angle	Implant Height 10 mm		Implant Heights 12–20 mm	
	Axial View	Lateral View	Axial View	Lateral View
4°				
9°				
14°				

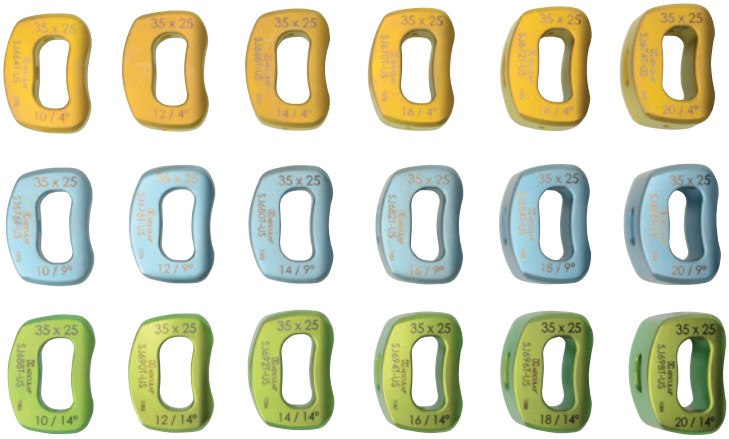
VIII. Instrument Overview (ST0651)

Arcadius®XP L Distraction/Trial Tray

	Item No.	Description	Qty.
	ME406	Arcadius L Distraction/Trial Tray - Lid	1
	ME407	Arcadius L Distraction/Trial Tray - Base	1
	ME408	Arcadius L Distraction/Trial Tray - Top	1
	SJ020R	Distractor, 10 mm	1
	SJ022R	Distractor, 12 mm	1
	SJ024R	Distractor, 14 mm	1
	SJ026R	Distractor, 16 mm	1
	SJ028R	Distractor, 18 mm	1
	SJ030R	Distractor, 20 mm	1



Distractor (SJ024R) with T-Handle (SJ033R)

	ME049	Trial Implant Caddy 35 x 25 mm	1
	SJ664T	Trial Implant 4° 25 x 35 x 10 mm	1
	SJ666T	Trial Implant 4° 25 x 35 x 12 mm	1
	SJ668T	Trial Implant 4° 25 x 35 x 14 mm	1
	SJ670T	Trial Implant 4° 25 x 35 x 16 mm	1
	SJ672T	Trial Implant 4° 25 x 35 x 18 mm	1
	SJ674T	Trial Implant 4° 25 x 35 x 20 mm	1
	SJ676T	Trial Implant 9° 25 x 35 x 10 mm	1
	SJ678T	Trial Implant 9° 25 x 35 x 12 mm	1
	SJ680T	Trial Implant 9° 25 x 35 x 14 mm	1
	SJ682T	Trial Implant 9° 25 x 35 x 16 mm	1
	SJ684T	Trial Implant 9° 25 x 35 x 18 mm	1
	SJ686T	Trial Implant 9° 25 x 35 x 20 mm	1
	SJ688T	Trial Implant 14° 25 x 35 x 10 mm	1
	SJ690T	Trial Implant 14° 25 x 35 x 12 mm	1
	SJ692T	Trial Implant 14° 25 x 35 x 14 mm	1
	SJ694T	Trial Implant 14° 25 x 35 x 16 mm	1
	SJ696T	Trial Implant 14° 25 x 35 x 18 mm	1
	SJ698T	Trial Implant 14° 25 x 35 x 20 mm	1

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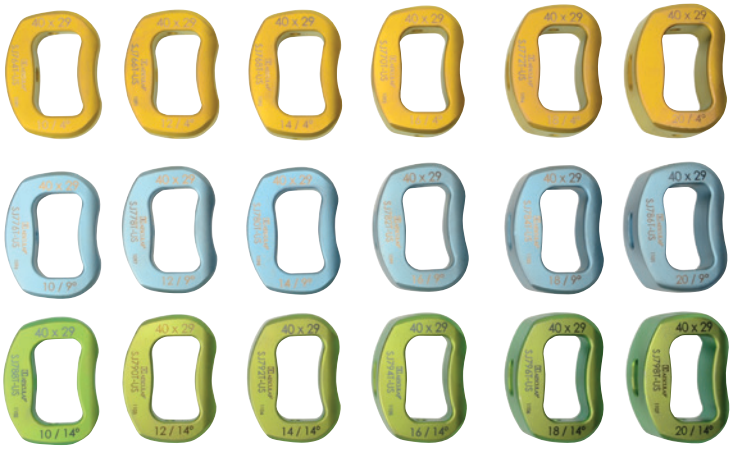
VIII. Instrument Overview (ST0651) *(continued)*

Arcadius[XP] L Distraction/Trial Tray *(continued)*

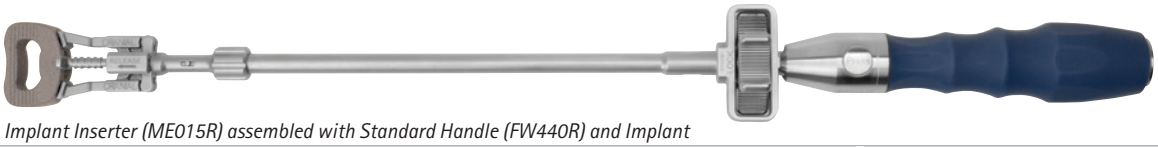
	Item No.	Description	Qty.
	ME050	Trial Implant Caddy 40 x 29 mm	1
	SJ764T	Trial Implant 4° 29 x 40 x 10 mm	1
	SJ766T	Trial Implant 4° 29 x 40 x 12 mm	1
	SJ768T	Trial Implant 4° 29 x 40 x 14 mm	1
	SJ770T	Trial Implant 4° 29 x 40 x 16 mm	1
	SJ772T	Trial Implant 4° 29 x 40 x 18 mm	1
	SJ774T	Trial Implant 4° 29 x 40 x 20 mm	1
	SJ776T	Trial Implant 9° 29 x 40 x 10 mm	1
	SJ778T	Trial Implant 9° 29 x 40 x 12 mm	1
	SJ780T	Trial Implant 9° 29 x 40 x 14 mm	1
	SJ782T	Trial Implant 9° 29 x 40 x 16 mm	1
	SJ784T	Trial Implant 9° 29 x 40 x 18 mm	1
	SJ786T	Trial Implant 9° 29 x 40 x 20 mm	1
	SJ788T	Trial Implant 14° 29 x 40 x 10 mm	1
	SJ790T	Trial Implant 14° 29 x 40 x 12 mm	1
	SJ792T	Trial Implant 14° 29 x 40 x 14 mm	1
	SJ794T	Trial Implant 14° 29 x 40 x 16 mm	1
	SJ796T	Trial Implant 14° 29 x 40 x 18 mm	1
	SJ798T	Trial Implant 14° 29 x 40 x 20 mm	1
	FW440R	Handle	3
	SJ708T	Slap Hammer Handle	2
	ME020R	Trial Insertion Instrument	2

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

	SJ709R	Slap Hammer Extension	1
	SJ705R	Ratchet Handle	2
	SJ033R	T-Handle	2

VIII. Instrument Overview (ST0651) *(continued)*

Arcadius®XP L Insertion Tray

	Item No.	Description	Qty.
	ME409	Arcadius L Insertion Tray - Lid	1
	ME410	Arcadius L Insertion Tray - Base	1
	ME412	Arcadius L Insertion Tray - Top Level	1
	ME414	Arcadius L Insertion Tray - Lower Level	1
	ME052R	Arcadius^{XP} L Hexalobe U-Joint Screwdriver	2
	ME176R	Arcadius^{XP} L Hexalobe Flexible Screwdriver	1
	ME054R	Arcadius^{XP} L Hexalobe Straight Screwdriver	1
	ME078R	Arcadius^{XP} L Hexalobe Screw Extraction Instrument	1
	FW076R	S$^{4®}$ C Rod Holding Forceps	1
	ME172R	Arcadius^{XP} L Hexalobe Ball Joint Awl	1
	ME173R	Arcadius^{XP} L Hexalobe Ball Drill	1
	ME174R	Arcadius^{XP} L Hexalobe Ball Screwdriver	2
	ME189R	Arcadius^{XP} L U-Joint Drill	1
	ME190R	Arcadius^{XP} L U-Joint Awl	1
	ME015R	Implant Inserter/Manipulator	2
 *Implant Inserter (ME015R) assembled with Standard Handle (FW440R) and Implant*			
	SJ608R	Tamp	1
	SJ604R	Packing Block	1
	SJ724R	Straight Drill Guide	1
	SJ606R	Impactor	1
	SJ722R	Angled Drill Guide	1

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VIII. Instrument Overview (ST0651) *(continued)*

Arcadius[XP] L Insertion Tray *(continued)*

	Item No.	Description	Qty.
	ME018R	Implant Extraction Instrument	1
	ME017R	Straight Bone Awl	1
	SJ725R	Straight Drill	1

Arcadius[XP] L Disc Prep Tray

	Item No.	Description	Qty.
	ME427	Arcadius L Disc Prep Tray - Base	1
	ME428	Arcadius L Disc Prep Tray - Lid	1
	ME429	Arcadius L Disc Prep Tray - Top Level	1
	ME430	Arcadius L Disc Prep Tray - Lower Level	1
	ME831	Detachable Wedges Caddy	1
	BB085R	Scalpel #4L	1
	FF529R	miaspas® TL Rongeur 4 mm 320 mm Straight	1
	FF530R	miaspas TL Rongeur 6 mm 320 mm Straight	1
	ME162R	Kerrison 40° Up 3 mm 300 mm	1
	ME163R	Kerrison 40° Up 5 mm 300 mm	1
	FG052R	Sypert Bone Rongeur 8/360 mm	1
	FW960R	Angled Distractor	2
	ME616R	Rasp, 14 x 33 mm	1
	ME618R	Cup Curette, 5.2 x 7.3 mm	1
	ME619R	Cup Curette, 5 x 9 mm	1

VIII. Instrument Overview (ST0651) *(continued)*

	**ME620R**	Angled Cup Curette 30°, 5.2 x 7.3 mm	1
	**ME624R**	Small Teadrop Curette, 8.3 x 19 mm	1
	**ME625R**	Box Curette, 14 x 13.8 mm	1
	**ME641R**	Reversed Angle Cup Curette 60° 5.2 x 7.3 mm	1
	**ME644R**	Cup Curette Straight 0° 7.5 x 9.0 mm	1

Arcadius®XP L Disc Prep Tray *(continued)*

	Item No.	Description	Qty.
	**BT070R**	Probe Hook	1
	**FW940R**	Stem for Wedge Attachment	1
	**FW941R**	6 mm Detachable Wedge	1
	FW942R	8.5 mm Detachable Wedge	1
	FW943R	10 mm Detachable Wedge	1
	FW944R	12 mm Detachable Wedge	1
	**ME628R**	14 mm Detachable Wedge	1
	ME629R	16 mm Detachable Wedge	1
	ME630R	18 mm Detachable Wedge	1
	ME631R	20 mm Detachable Wedge	1
	ME632R	22 mm Detachable Wedge	1
	ME633R	24 mm Detachable Wedge	1
	**ME182R**	Cobb Elevator Anterior Approach (1/2")	1
	**ME183R**	Cobb Elevator Anterior Approach (3/4")	1

Arcadius®XP L Screw Caddy Tray

	Item No.	Description	Qty.
	ME425	Arcadius L Screw Caddy Tray - Lid	1
	ME426	Arcadius L Screw Caddy Tray - Base	1
	ME022	Arcadius Compression Caddy	1
	ME023	Arcadius Performance Caddy	1
	**ME177T**	Arcadius Compression Bone Screw 25 mm	12
	ME178T	Arcadius Compression Bone Screw 30 mm	12
	**ME186T**	Arcadius Performance Bone Screw 25 mm	12
	ME187T	Arcadius Performance Bone Screw 30 mm	12

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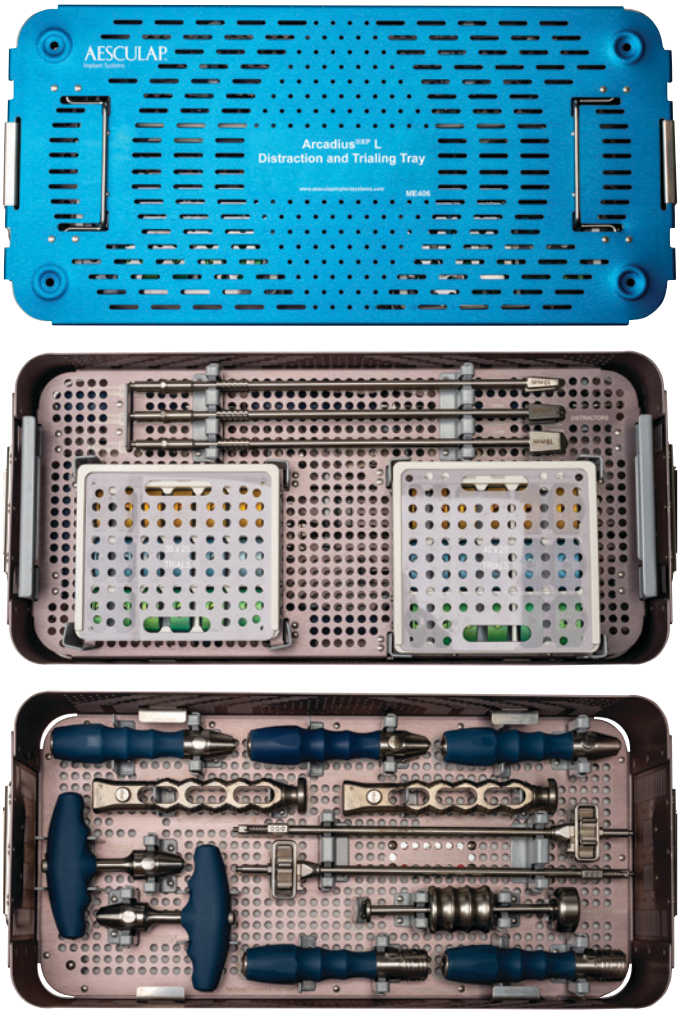
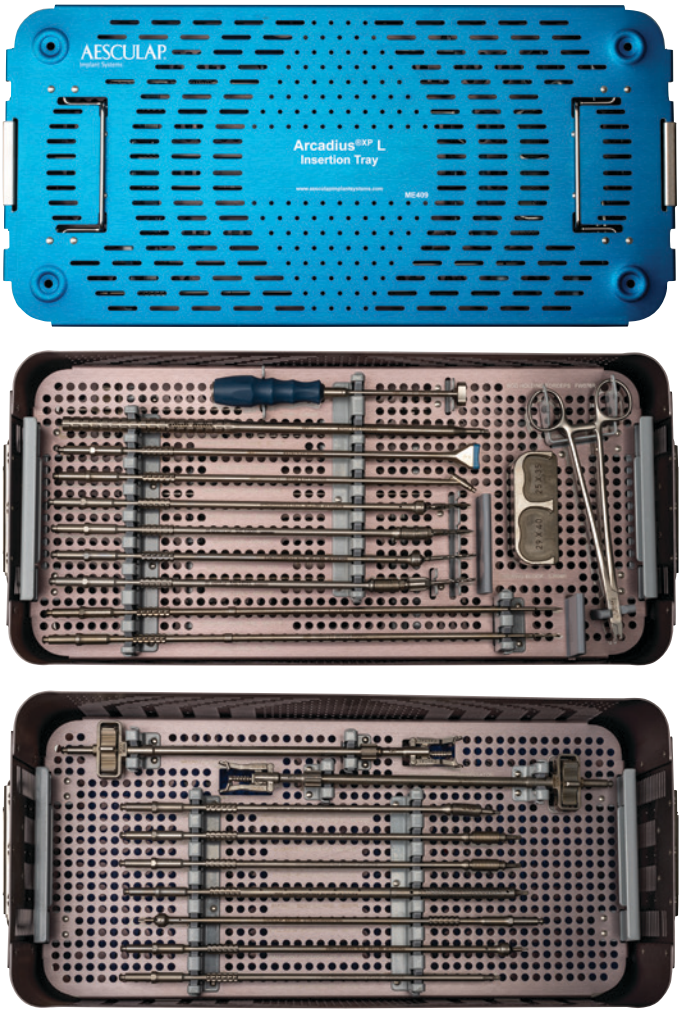
IX. Instrument Tray Configuration (ST0651)

Arcadius^{XP} L Distraction/Trial Tray

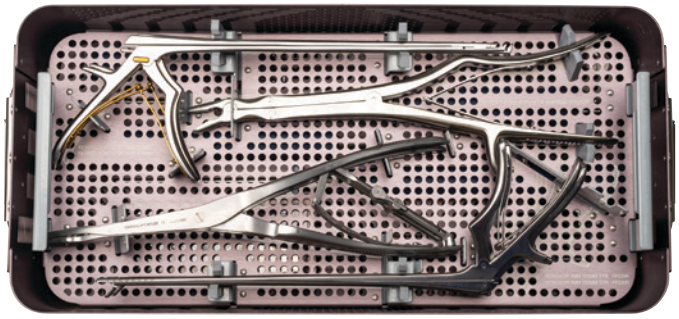


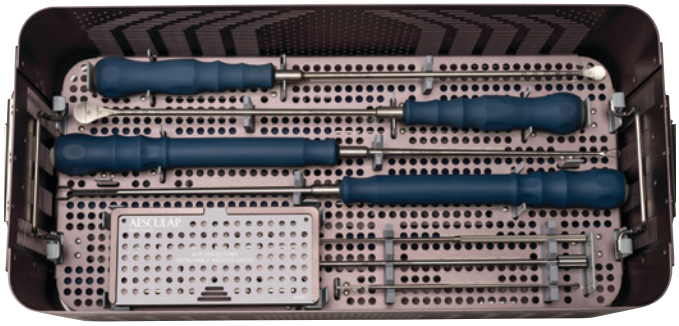
Arcadius^{XP} L Insertion Tray

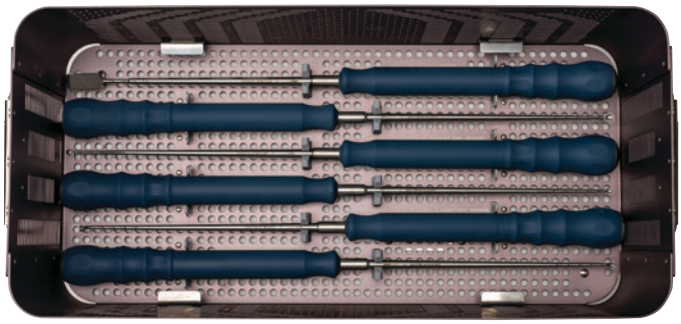


IX. Instrument Tray Configuration (ST0651) *(continued)*

Arcadius®XP L Disc Prep Tray







Arcadius®XP L Screw Caddy Tray

Arcadius®XP L: Evolution Spinal System

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Notes

Aesculap Implant Systems, LLC | 3773 Corporate Parkway | Center Valley, PA | 18034
Phone 866-229-3002 | Fax 610-984-9096 | www.aesculapimplantsystems.com

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