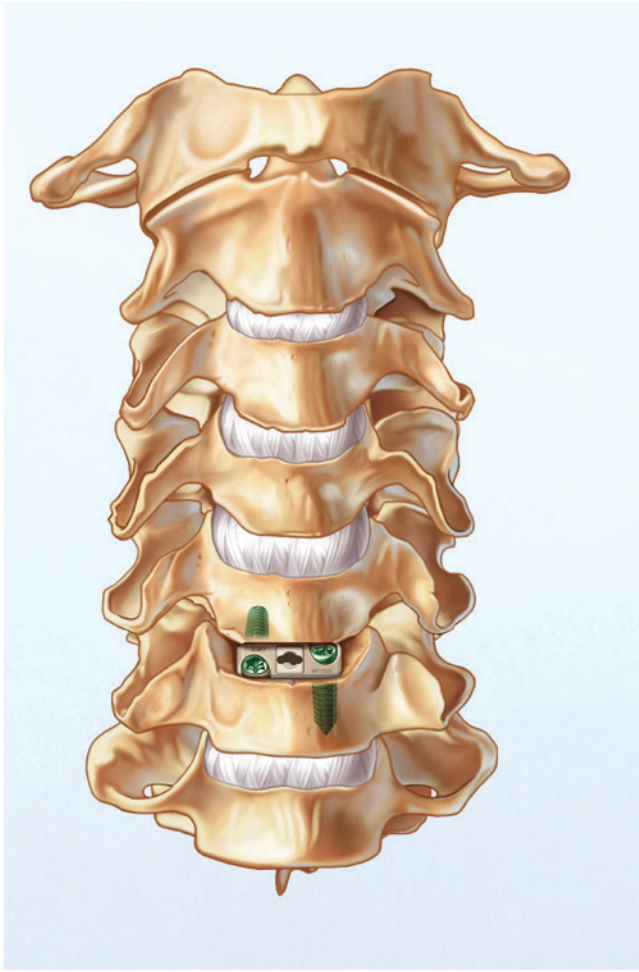
Arcadius®XP C Spinal System

Stand-Alone Anterior Cervical Discectomy and Fusion (ACDF) Interbody Device Surgical Technique



Aesculap Spine

AESCULAP®
Implant Systems

Arcadius®XP C Spinal System

Stand-Alone Anterior Cervical Discectomy and Fusion (ACDF) Interbody Device Surgical Technique

Table of Contents:

I. System Overview

System Features:

- Wide variety of implant options
- Generous graft window
- Surface texturing
- Two X-ray marker pins in the cage
- Midline accessibility for screw insertion
- Diverging screw design
- Dual locking mechanism
- Self-tapping bone screws
- Comprehensive array of instrumentation

Design Advantages:

- Optimized implant fit – Implants are available in a variety of options to meet the requirements of varying patient anatomies.
  - Implant footprints: 13 mm x 16 mm, 15 mm x 17 mm
  - Heights: 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm and 11 mm
  - Lordotic angles: 4°, 7°
- Unique implant design – Requires no additional supplementary fixation system when used with the supplied bone screws.
- Comprehensive array of instrumentation – Intuitively designed to accommodate steep angles and provide ease in screw insertion.
- Bone screws are self-tapping.
  - Screws are 4 mm in diameter and offered in 14 mm, 16 mm and 18 mm lengths.
- Simple and secure locking mechanism – Implant contains an integrated dual locking mechanism with single-step activation.
- Maximized stability – Provided by optimized implant fit, large graft window, surface texturing and two diverging bone screws.
- Excellent imaging properties – Plasmapore®XP surface enhancing technology and X-ray marker pins allow for improved visibility during imaging.
- Zero-profile – Intrinsic design does not add profile to the anterior border of the vertebral body, limiting risk of damage to adjacent soft tissue and blood vessels.

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II. Indications for Use and Contraindications

Indications for Use:

The Arcadius^{XP} C Spinal System is intended to be used as an intervertebral body fusion device as a stand-alone system used with the supplied bone screws and requires no additional supplementary fixation. It is intended for spinal fusion procedures at one level in the cervical spine from the C2-C3 disc space to the C7-T1 disc space for the treatment of cervical degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies) using autograft bone. Patients should be skeletally mature and must have undergone a regimen of at least six (6) weeks of nonoperative treatment prior to being treated with the Arcadius^{XP} C Spinal System.

Contraindications

Any medical or surgical condition that could preclude the potential success of the implantation. These include:

- Existing or risk of acute or chronic infections, fever/leukocytosis
- Progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis or osteomyelitis which may prevent adequate fixation.
- Severe defects of the bony structures of the spine which are a prerequisite for stable implantation of the cages.
- Bone tumors in the region of the implant anchoring
- Proven or suspected allergy/foreign body reactions to implant materials
- Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician, taking into account the risks versus the benefits to the patient.
- Patients resistant to following postoperative restrictions on movement, especially in athletic and occupational activities
- Systemic, metabolic and degenerative diseases
- Psychosocial problems; unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Prior fusion at the level(s) to be treated
- 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.
- Increased risk of migration is possible due to over-preparation of the vertebral body endplates. When preparing the implant bed, make certain that the base and cover plates of the adjacent vertebral bodies are not weakened.
- The coated surfaces of the Arcadius^{XP} C Spinal System cage may be damaged by improper handling. Avoid direct contact with the coated surfaces. Handle implants carefully.
- Risk of insufficient stability or implant failure is possible due to using fewer than the two internal screw fixations provided. Apply both screws or use an additional supplemental spinal fixation system that has been cleared for use in the cervical spine, such as cervical plating systems.
- Excessive insertion forces may cause damage to the implant.

III. Warnings and Precautions *(continued)*

WARNINGS *(continued)*

- Backing out and loosening of the bone screw can occur when the screw is not fully inserted into the cage. Insert the bone screw until it is fully engaged.
- Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union) fracture of the vertebra, neurological injury and vascular or visceral injury.
- Inaccurate markings of the midline may result in incorrect position 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.

CAUTION

- Based upon dynamic testing results, physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the Arcadius®XP C Spinal System.
- Avoid using high frequency and/or electrocautery surgical devices in proximity to the implant to avoid damage to the ArcadiusXP C Spinal System cages. Remove and replace the implant if the implant is damaged.

PRECAUTIONS

- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Avoid mixing unalloyed titanium, titanium alloy, stainless steel and other cobalt alloy implants for implants that are in contact with each other.
- Components of the ArcadiusXP C Spinal System should not be used with components of any other system or manufacturer.

MRI SAFETY INFORMATION

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

Please refer to product insert for complete system description, indications and warnings.

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Stand-Alone Anterior Cervical Discectomy and Fusion (ACDF) Interbody Device Surgical Technique

IV. Surgical Technique

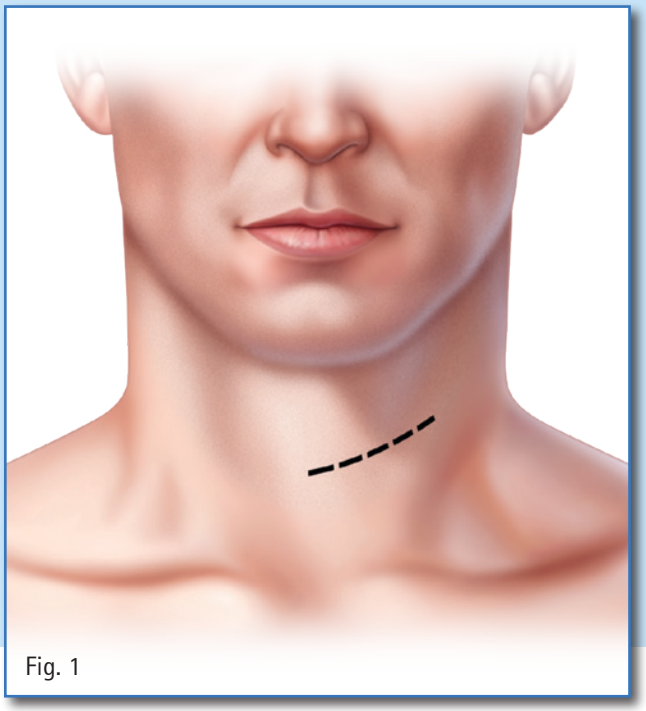

Fig. 1

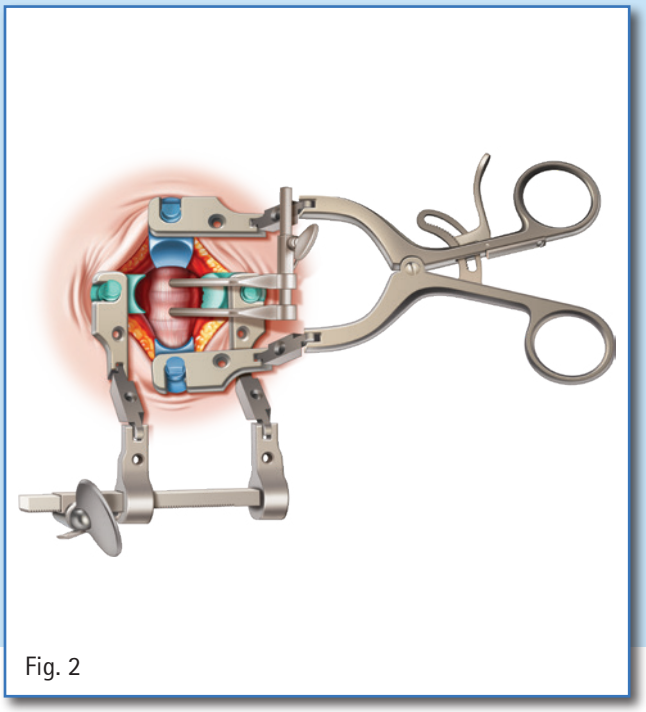

Fig. 2

a. Patient Positioning and Exposure

1. Anterior access will be required for insertion of the Arcadius[XP] C Spinal System ACDF 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 required implant range. Patient positioning and exposure of the anterior cervical spine are performed in accordance with the standard anterior cervical surgical technique:
   - Place the patient in the supine position.
   - Utilize the standard anterior approach to the cervical spine. (Fig. 1)
   - Provide the level of exposure to the implantation site the surgeon deems necessary to perform the surgery. A cervical retraction system, such as Aesculap's Caspar™ Cervical Retractor System, can be used to provide adequate visualization to the front of the cervical spine. (Fig. 2)

IV. Surgical Technique *(continued)*

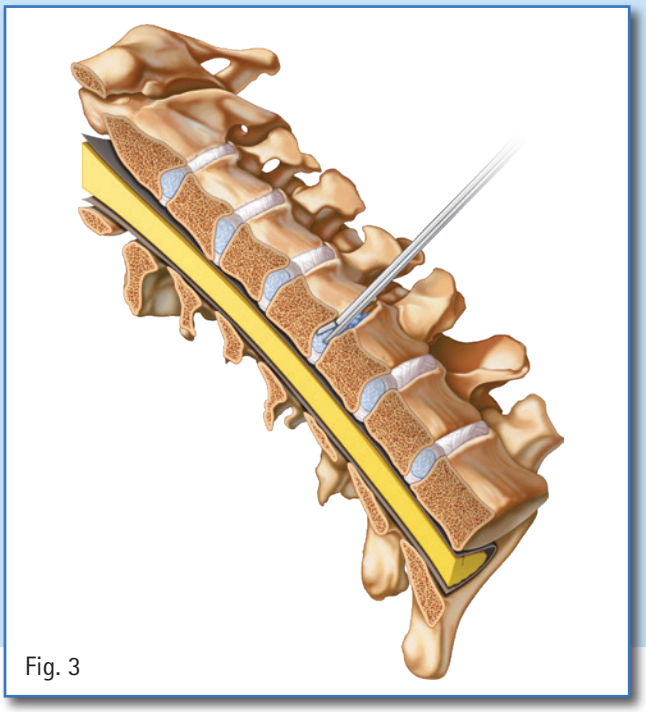

Fig. 3

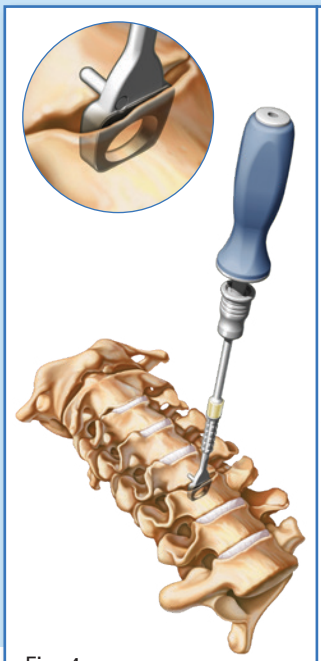

Fig. 4

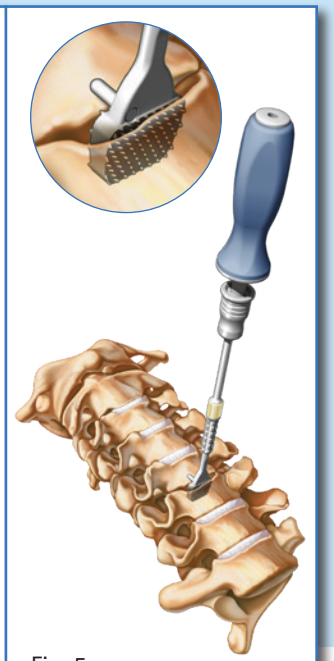

Fig. 5

b. Preparation

1. Prepare the intervertebral space by utilizing the anterior discectomy instruments the surgeon feels are necessary to properly prepare the disc space and vertebral endplates.
   - A cervical distraction system, such as Aesculap's Caspar™ Cervical Distraction System, can be used to gradually achieve the desired working height.
   - Perform a thorough discectomy. (Fig. 3)
   - Ensure adequate neural decompression has been established.
   - Prepare the endplates to receive the Arcadius®XP C Spinal System implant.

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

c. Implant Sizing

1. Proper implant size can be established using the trial spacers while the interspace is distracted. Trial implants are available in two footprint sizes, two lordotic angles and seven heights. Each trial implant is color-coded by implant height and labeled with the corresponding footprint, height and lordotic angle.
2. Select an appropriately-sized trial implant based on patient anatomy and preoperative radiographic analysis. (Table 1 on page 8)
3. Utilize the cottle mallet to gently advance the trial into the disc space.
4. Manipulate the trial implant as needed to attain the desired position. (Fig. 4)
5. Continue to evaluate trial implants until a tight fit is achieved.
6. Assess the final implant fit and position with intraoperative AP and lateral fluoroscopy.
7. Once the appropriate size and height of the implant has been determined, select the corresponding color-coded rasp. The rasp is used to roughen and expose the end plates and prepare them for the placement of the corresponding sized implant. (Fig. 5)

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

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IV. Surgical Technique *(continued)*

Rasp/Trial Color Code (Table 1)

Trial Part No.	Rasp Part No.	Lordosis	Footprint	Height	Color
ME126R	US039R	4°	13x16	5 mm	Yellow
ME133R	US139R	7°	13x16	5 mm	
ME142R	US058R	4°	15x17	5 mm	
ME232R	US214R	7°	15x17	5 mm	
ME127R	US044R	4°	13x16	6 mm	Blue
ME134R	US198R	7°	13x16	6 mm	
ME143R	US059R	4°	15x17	6 mm	
ME233R	US217R	7°	15x17	6 mm	
ME128R	US054R	4°	13x16	7 mm	Red
ME135R	US199R	7°	13x16	7 mm	
ME144R	US068R	4°	15x17	7 mm	
ME234R	US218R	7°	15x17	7 mm	
ME129R	US055R	4°	13x16	8 mm	Green
ME136R	US211R	7°	13x16	8 mm	
ME145R	US069R	4°	15x17	8 mm	
ME235R	US219R	7°	15x17	8 mm	
ME130R	US056R	4°	13x16	9 mm	White
ME137R	US212R	7°	13x16	9 mm	
ME146R	US093R	4°	15x17	9 mm	
ME236R	US220R	7°	15x17	9 mm	
ME131R	US057R	4°	13x16	10 mm	Grey
ME138R	US213R	7°	13x16	10 mm	
ME147R	US099R	4°	15x17	10 mm	
ME237R	US222R	7°	15x17	10 mm	
ME132R	N/A	4°	13x16	11 mm	Black
ME139R	N/A	7°	13x16	11 mm	
ME148R	N/A	4°	15x17	11 mm	
ME238R	N/A	7°	15x17	11 mm	

IV. Surgical Technique *(continued)*

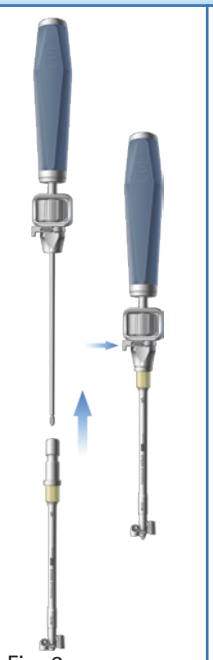
Fig. 6

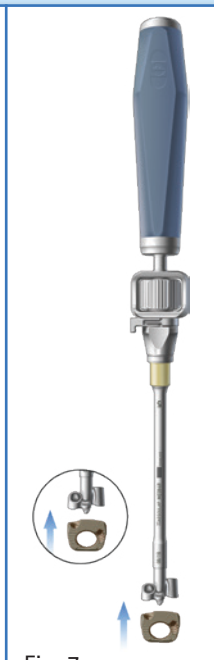
Fig. 7

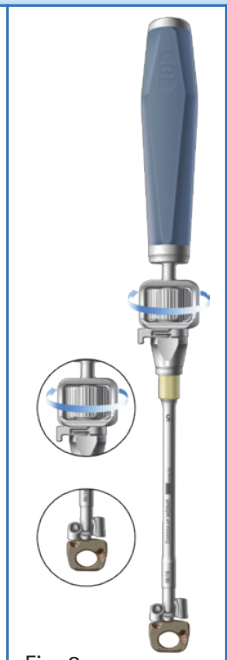
Fig. 8

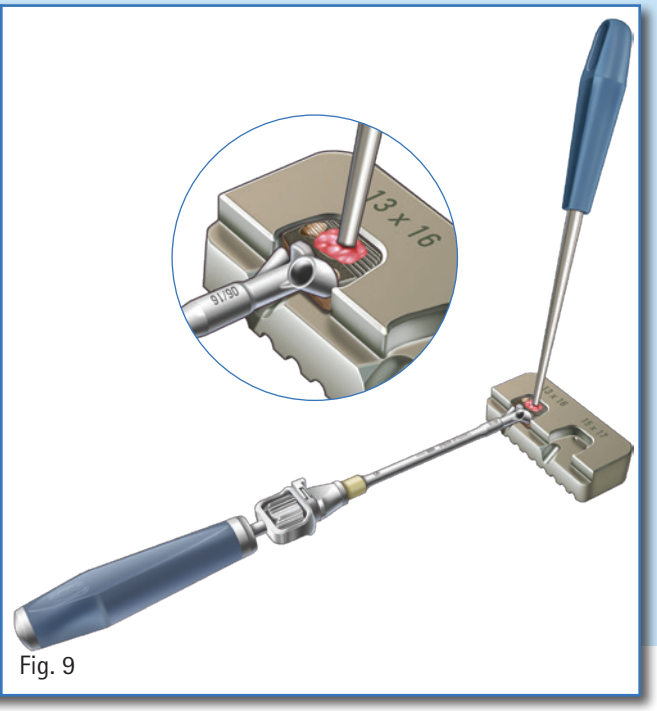

Fig. 9

d. Implant Preparation and Insertion

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

> **Note:** *The dimensions of the trial implants are designed to match the Arcadius®XP C Spinal System implants (footprint, height and lordotic angle).*

2. Implant Preparation
   - Assemble the All-in-One guide or universal inserter to the multi-tool handle. (Fig. 6)
   - All-in-One guide should be selected to correspond to the height of the chosen implant. (Table 2 on page 10)
   - Attach and secure the selected Arcadius^{XP} C Spinal System implant to the distal end of the insertion instrument. (Fig. 7)

> **Note:** *The insertion instrument consists of an All-in-One Guide with a safety stop or, alternatively, an inserter without a safety stop. It is recommended that the safety stop be utilized to ensure the implant is seated flush against the anterior border of the vertebral body.*

   - Attach and secure the selected implant to the distal end of the insertion instrument by turning the proximal knob in a clockwise direction. (Fig. 8)
   - Fill the implant with autograft material by utilizing the packing block and tamp. (Fig. 9)
   - Place the implant into the corresponding footprint space of the packing block.
   - Fill the implant with autograft material, and use the tamp to firmly pack autograft material into the implant.
   - To determine the volume of the grafts window, please see table below.

Item No.	Graft Volume in cm³
S0726P	0.24
S0727P	0.30
S0728P	0.35
S0729P	0.40
S0730P	0.46
S0731P	0.51
S0732P	0.56
S0706P	0.27
S0707P	0.32
S0708P	0.37

Item No.	Graft Volume in cm³
S0709P	0.43
S0710P	0.48
S0711P	0.53
S0712P	0.59
S0766P	0.32
S0767P	0.39
S0768P	0.46
S0769P	0.53
S0770P	0.60
S0771P	0.67

Item No.	Graft Volume in cm³
S0772P	0.74
S0746P	0.35
S0747P	0.42
S0748P	0.49
S0749P	0.56
S0750P	0.63
S0751P	0.71
S0752P	0.78

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IV. Surgical Technique *(continued)*

Options for Inserter (both used with ME075R) (Table 2)

Item No.	Description	Height	Color	
ME063R	Interbody Insertion Instrument	Universal	N/A	
ME064R	All-in-One Guides for Interbody	5 mm	Yellow	
ME065R	All-in-One Guides for Interbody	6 mm	Blue	
ME066R	All-in-One Guides for Interbody	7 mm	Red	
ME067R	All-in-One Guides for Interbody	8 mm	Green	
ME068R	All-in-One Guides for Interbody	9 mm	White	
ME069R	All-in-One Guides for Interbody	10 mm	Grey	
ME070R	All-in-One Guides for Interbody	11 mm	Black	

Warning: *Incorrect selection of the All-in-One Guide will result in implant damage and malfunction of the locking mechanism during the pilot hole preparation and bone screw insertion surgical steps. Confirm that the selected All-in-One Guide corresponds to the selected Arcadius®XP C implant.*

Note: The All-in-One Guides are color coded to match the height of the corresponding implant (5 mm - yellow, 6 mm - blue, 7 mm - red, 8 mm - green, 9 mm - natural, 10 mm - gray and 11 mm - black).

IV. Surgical Technique *(continued)*

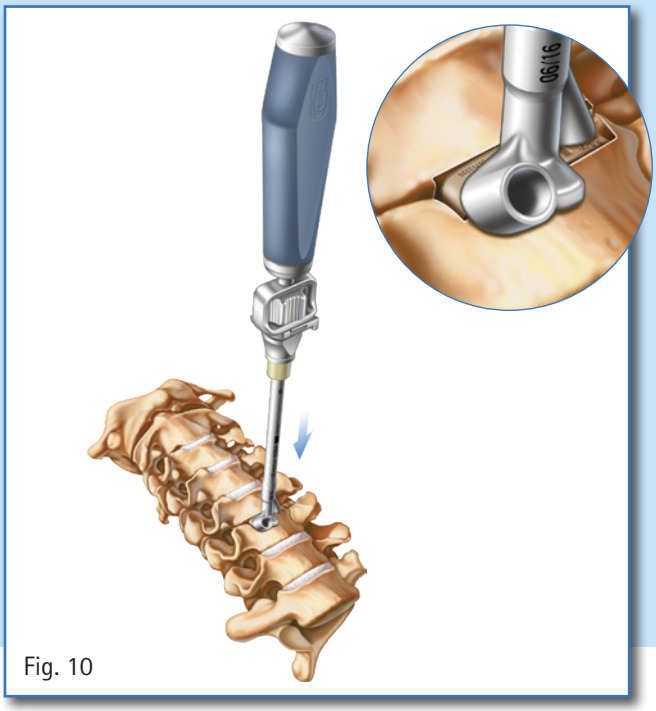

Fig. 10

3. Implant Insertion
   - Introduce the implant into the disc space. The implant should be inserted centrally in AP. (Fig. 10)

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

Note: *If using an All-in-One Guide with the safety stop, a positive stop at the end of the insertion sleeve ensures that the graft is positioned flush with the anterior border of the vertebral body and helps prevent over insertion and spinal canal compromise.*

4. Verification of Implant Placement
   - Obtain AP fluoroscopic images to confirm midline placement of the device.
   - Obtain lateral fluoroscopic images to confirm the anterior edge of the implant is seated flush with the anterior border of the vertebral body.

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

   - Observe the X-ray markers in both the AP and lateral views to ensure that the implant is not rotated within the disc space.
   - Manipulate the implant as needed by gently tapping the impactor with the mallet.
   - Relax the Caspar™ Distractor.

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

   - Check whether the implant is stable and securely positioned.

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IV. Surgical Technique *(continued)*

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

- Obtain additional AP and lateral fluoroscopic images to document midline placement and neutral alignment.
- The final AP and lateral images should reflect neutral alignment of the Arcadius^{XP} C Spinal System implant.

5. Once satisfied with the implant location and fit, remove the insertion instrument.

Note: *The Arcadius^{XP} C Spinal System implant requires no additional supplementary fixation system when used with the two supplied bone screws.*

IV. Surgical Technique *(continued)*

Fig. 11 - Assembling ME103 (U-Joint Screwdriver is shown)

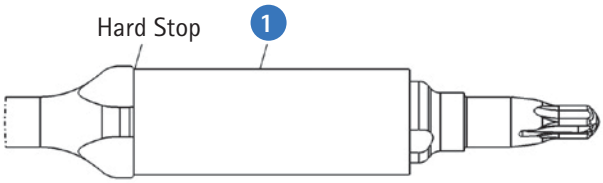

Fig. 12 - Correct sleeve position (U-Joint Screwdriver is shown)

Soft Tissue Protection Sleeve ME103 Assembly:

The Soft Tissue Protection Sleeve is a single-use, disposable sleeve that is used to protect surrounding anatomy from the U-joint mechanism.

The Soft Tissue Protection Sleeve can be assembled to the following instruments: U-Joint Screwdriver (ME055R), U-Joint Bone Awl (ME060R), U-Joint Drill (ME058R) and U-Joint Screw Extraction Instrument (ME072R).

- Obtain additional AP and lateral fluoroscopic images to document midline placement and neutral alignment.
- Prior to assembling the Soft Tissue Protection Sleeve, remove the spring covering the U-joint from the distal end of the shaft
- Slide the sleeve 1 over the distal end until hard stop. (Figs.11 and 12)
- The sleeve 1 can be removed by applying force in the opposite assembly direction.

Caution: *Soft Tissue Protection Sleeve must be sitting flush up against the hard stop of the U-joint instruments. Soft Tissue Protection Sleeve must be checked via a visual inspection before use to make sure it is appropriately assembled. Excessive bending of the sleeve can cause fatigue or failure. The Soft Tissue Protection Sleeve is designed for a single use application. Upon completion of the case, the Soft Tissue Protection Sleeve should be removed and disposed.*

Note: *The single use soft tissue protection sleeve does not ship standard with the Arcadius®XP C Instrument Set (ST0652), but can be ordered separately from Customer Service.*

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Stand-Alone Anterior Cervical Discectomy and Fusion (ACDF) Interbody Device Surgical Technique

IV. Surgical Technique *(continued)*

e. Screw Preparation and Insertion

1. 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 are available to meet surgeon preference for screw hole preparation and screw insertion. (Tables 3 and 4 on page 15)
   The Arcadius^{XP} C Spinal System is intended to be used with two bone screws.
   - Bone screws are available in three lengths: 14 mm, 16 mm and 18 mm (Table 5 on page 16)

Note: *All screwdrivers are self-retaining. 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.*

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

Caution: *A mallet must not be used to advance the awl especially for 5 mm and 6 mm implants. The awl must be pushed/advanced by hand only.*

IV. Surgical Technique *(continued)*

Options for Bone Awl (Table 3)

Item No.	Description
ME060R	U-Joint Bone Awl

ME061R	Fixed Angle Bone Awl

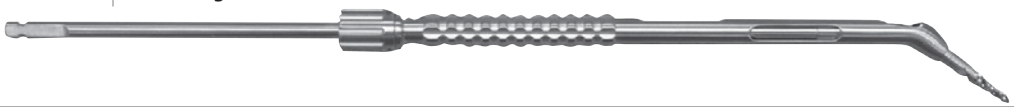
ME062R	Straight Bone Awl

ME402R	Ball Joint Awl

Options for Drill (Table 4)

Item No.	Description
ME058R	U-Joint Drill

ME059R	Fixed Angle Drill



ME403R	Ball Joint Drill Drill

Note: *When using the All-in-One guide, the awl/drill cannot progress past the posterior border of the implant. When using the universal inserter, the awl/drill can progress 1 mm past the posterior border.*

Warning: *Risk of damaging biological structures (spinal cord, spinal nerve roots, ligaments, soft tissues, etc.) and the Arcadius®XP C implant if the drills and bone awls are used without the All-in-One Guide.*

- *It is recommended to use the drills and bone awls with the All-in-One Guide.*

Warning: *Risk of damage to the ArcadiusXP C implant in the course of incorrectly advancing the bone awls and drills.*

- *Do not apply an excessive compressive/hammering/bending/tilting/levering force to the bone awls and the drills.*
- *Keep the instrument's tip directly aligned with the hole axis of the All-in-One Guide or the hole axis of the ArcadiusXP C implant.*
- *The bone awls and the drills must be pushed/advanced by hand only.*

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IV. Surgical Technique *(continued)*

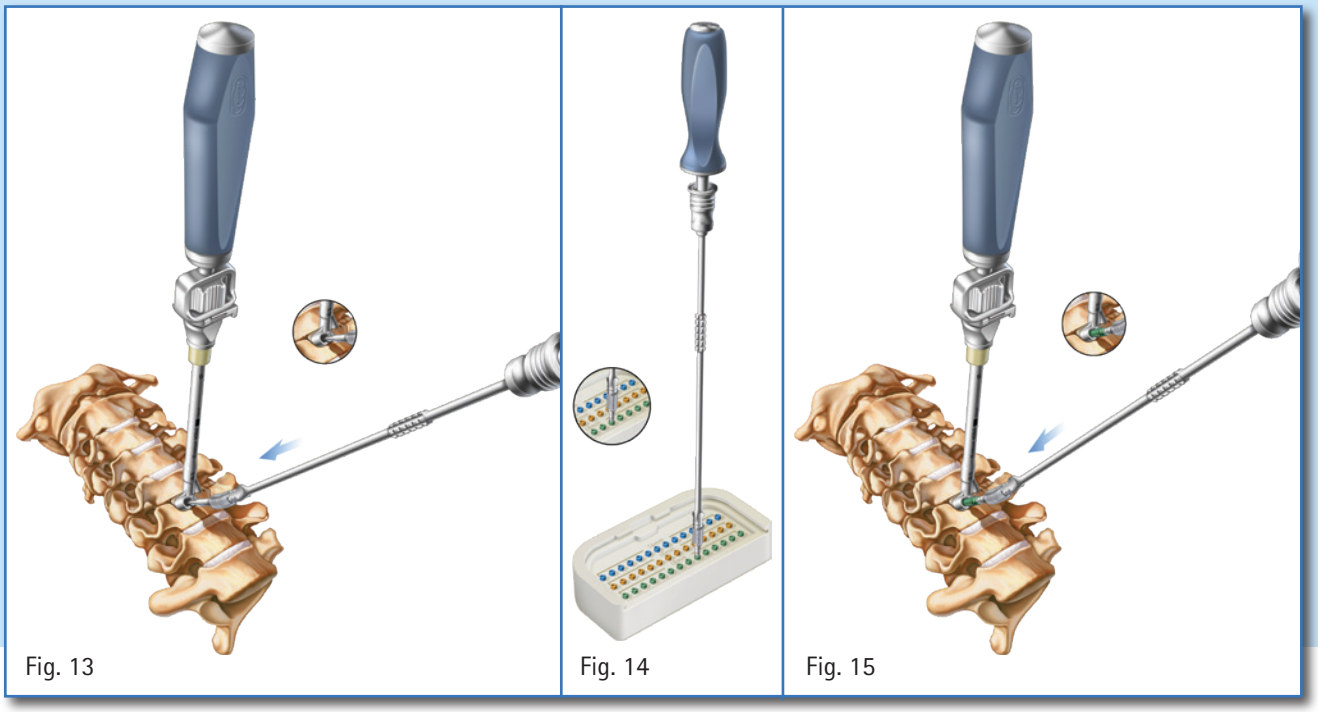


Fig. 13 Fig. 14 Fig. 15

e. Screw Preparation and Insertion *(continued)*

2. Attach desired handle to bone awl.
3. Guide bone awl into one of the screw holes and insert until a hard stop is reached. A hard stop indicates the awl has punctured the cortical layer of bone.
4. Drill of preference is then placed into the All-in-One Guide and drilled until it no longer advances. (Fig. 13)
5. Select a bone screw based on patient anatomy at the surgical level and the implant size used. (Fig. 14) (Table 5)
6. Guide the selected screwdriver with screw attached into the prepared screw hole. (Fig. 15) (Table 6)
7. Turn the selected screwdriver in a clockwise motion to advance the bone screw into the vertebral body.

Repeat steps previously outlined for pilot hole creation and bone screw placement to insert the final screw. Ensure the bone screw has threaded past the locking rim and is fully seated.

For more information about the locking mechanism, please see page 20.

Bone Screws (Table 5)

Item No.	Description	Length	Color
SO791T	Arcadius^{XP} C Bone Screw 4.0 mm	14 mm	Blue
SO792T	Arcadius^{XP} C Bone Screw 4.0 mm	16 mm	Gold
SO793T	Arcadius^{XP} C Bone Screw 4.0 mm	18 mm	Green

Options for Driver (Table 6)

Item No.	Description	
ME055R	U-Joint Screwdriver	
ME056R	Fixed Angle Screwdriver	
ME057R	Straight Screwdriver	
ME404R	Hexalobe Ball Joint Screwdriver	

IV. Surgical Technique *(continued)*

f. Implant Removal (If Necessary)

1. Attach desired handle to screw removal tool (ME072R).
2. Guide and attach the screw removal tool (ME072R) to a bone screw in the Arcadius®XP C Spinal System implant.
3. Retract the bone screw from the vertebral body by turning the screwdriver in a counter-clockwise motion.
4. Repeat the bone screw removal process for the remaining bone screw in the Arcadius®XP C Spinal System implant.
5. Attach desired handle to implant inserter.
6. Turn implant inserter in a clockwise direction to secure into an implant screw hole.
7. Apply an extraction force to the inserter to remove the implant from the disc space.

g. Verification of Final Implant Placement

1. It is recommended that final AP and lateral radiographs are obtained.
   - Final AP image should confirm midline placement of the device.
   - The final lateral image should confirm that the anterior edge of the implant is seated flush with the anterior border of the vertebral body.

h. Appendix

Impactor: 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 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 C Spinal System

Stand-Alone Anterior Cervical Discectomy and Fusion (ACDF) Interbody Device Surgical Technique

V. Implant Information

Manufactured with a radiolucent PEEK-OPTIMA® core and an osteoconductive Plasmapore®XP surface.

- Variety of options for optimized fit:
  - Two implant footprints: 13 mm x 16 mm, 15 mm x 17 mm
  - Seven heights: 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm and 11 mm
  - Two lordotic angles: 4°, 7°
- Wide central opening for packing of bone graft material
- Surface texturing for additional stability
- Two titanium markers for X-ray verification

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

a. Implant Bone Screw and Construct Information

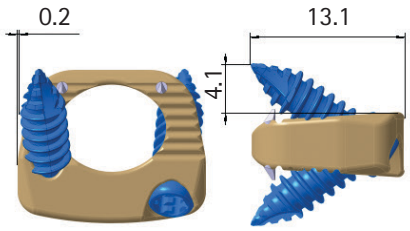
- Manufactured from titanium alloy (Ti6Al4V)
- Bone screws are self-tapping
- Bone screw diameter is 4 mm
- Available in three lengths: 14 mm, 16 mm and 18 mm
- Construct information:
  - Diverging screw design
  - 35 degree cranial-caudal orientation
  - Dual locking mechanism

PEEK-OPTIMA is a registered trademark of Invibio Limited.

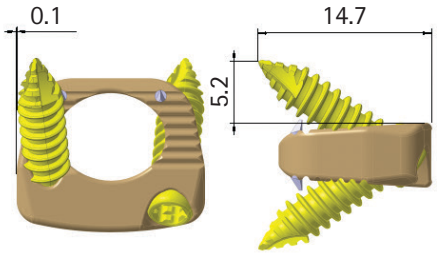
V. Implant Information *(continued)*

Small Implant Footprint (13 mm x 16 mm), Implant Height 5–11 mm, Lordotic Angle 7° and 4°

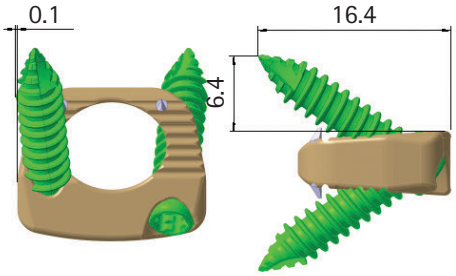
14 mm Bone Screws



16 mm Bone Screws

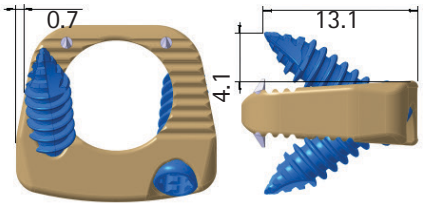


18 mm Bone Screws



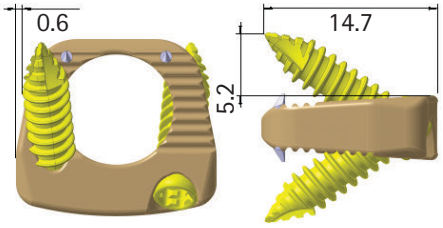
Large Implant Footprint (15 mm x 17 mm), Implant Height 5–11 mm, Lordotic Angle 7° and 4°

14 mm Bone Screws



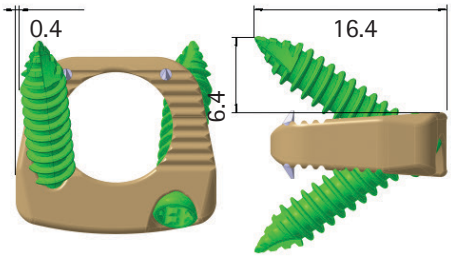
Axial View Lateral View

16 mm Bone Screws



Axial View Lateral View

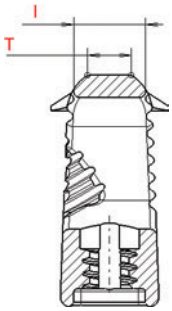
18 mm Bone Screws



Axial View Lateral View

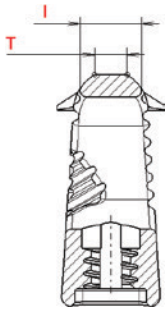
Posterior Height Measurements

13 x 16, 4° Footprint



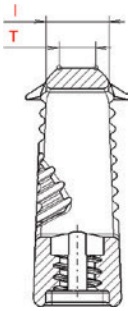
Item No.	T	I
S0706P	2.45	4.03
S0707P	3.45	5.03
S0708P	4.45	6.03
S0709P	5.45	7.03
S0710P	6.45	8.03
S0711P	7.45	9.03
S0712P	8.45	10.03

13 x 16, 7° Footprint



Item No.	T	I
S0726P	1.8	3.44
S0727P	2.8	4.44
S0728P	3.8	5.44
S0729P	4.8	6.44
S0730P	5.8	7.44
S0731P	6.8	8.44
S0732P	7.8	9.44

15 x 17, 4° Footprint



Item No.	T	I
S0746P	2.3	3.95
S0747P	3.3	4.95
S0748P	4.3	5.95
S0749P	5.3	6.95
S0750P	6.3	7.95
S0751P	7.3	8.95
S0752P	8.3	9.95

15 x 17, 7° Footprint

Item No.	T	I
S0766P	1.55	3.26
S0767P	2.55	4.26
S0768P	3.55	5.26
S0769P	4.55	6.26
S0770P	5.55	7.26
S0771P	6.55	8.26
S0772P	7.55	9.26

Arcadius®XP C Spinal System

Stand-Alone Anterior Cervical Discectomy and Fusion (ACDF) Interbody Device Surgical Technique

V. Implant Information *(continued)*

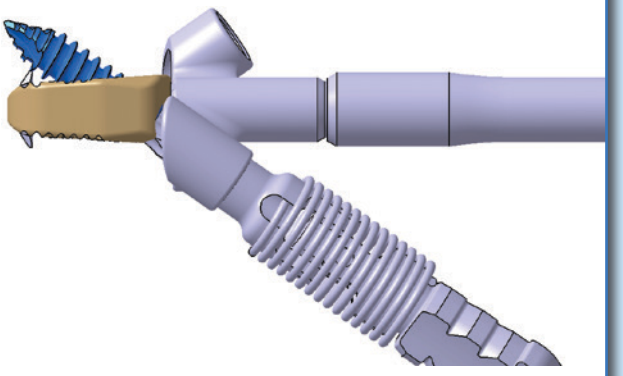


Fig. 16 - Correct: Screw is fully seated and locking mechanism is engaged.

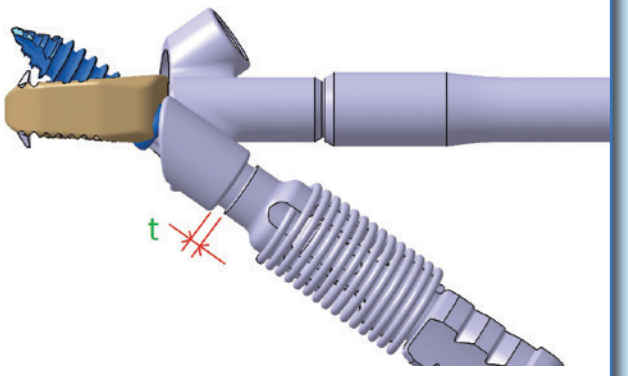


Fig. 17 - Incorrect: Screw is not fully seated and locking mechanism is not engaged.

b. Locking Mechanism Information

- The Arcadius^{XP} C Spinal System 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:
  - First locking mechanism: internal locking rim integrated into each screw hole of the implant that is activated during bone screw insertion.
- Upon insertion, the bone screw can be easily turned without encountering resistance.
- 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.
- 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.
- 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.
  - Second locking mechanism: inner threads of the implant and the threads of the bone screw comprise the second locking mechanism. This locking mechanism is activated by fully inserting and seating the bone screw into the implant.
- After 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.

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

VI. Implant Overview (ST0632)

Item No.	Implant Description	Footprint Depth	Footprint Width	Lordotic Angle	Qty. Per Set
SO706P	Arcadius®XP C Implant 4° 13 x 16 x 5 mm	13 mm	16 mm	4°	3
SO707P	Arcadius®XP C Implant 4° 13 x 16 x 6 mm	13 mm	16 mm	4°	3
SO708P	Arcadius®XP C Implant 4° 13 x 16 x 7 mm	13 mm	16 mm	4°	3
SO709P	Arcadius®XP C Implant 4° 13 x 16 x 8 mm	13 mm	16 mm	4°	2
SO710P	Arcadius®XP C Implant 4° 13 x 16 x 9 mm	13 mm	16 mm	4°	2
SO711P	Arcadius®XP C Implant 4° 13 x 16 x 10 mm	13 mm	16 mm	4°	1
SO712P	Arcadius®XP C Implant 4° 13 x 16 x 11 mm	13 mm	16 mm	4°	1
SO726P	Arcadius®XP C Implant 7° 13 x 16 x 5 mm	13 mm	16 mm	7°	3
SO727P	Arcadius®XP C Implant 7° 13 x 16 x 6 mm	13 mm	16 mm	7°	3
SO728P	Arcadius®XP C Implant 7° 13 x 16 x 7 mm	13 mm	16 mm	7°	3
SO729P	Arcadius®XP C Implant 7° 13 x 16 x 8 mm	13 mm	16 mm	7°	2
SO730P	Arcadius®XP C Implant 7° 13 x 16 x 9 mm	13 mm	16 mm	7°	2
SO731P	Arcadius®XP C Implant 7° 13 x 16 x 10 mm	13 mm	16 mm	7°	1
SO732P	Arcadius®XP C Implant 7° 13 x 16 x 11 mm	13 mm	16 mm	7°	1
SO746P	Arcadius®XP C Implant 4° 15 x 17 x 5 mm	15 mm	17 mm	4°	3
SO747P	Arcadius®XP C Implant 4° 15 x 17 x 6 mm	15 mm	17 mm	4°	3
SO748P	Arcadius®XP C Implant 4° 15 x 17 x 7 mm	15 mm	17 mm	4°	3
SO749P	Arcadius®XP C Implant 4° 15 x 17 x .8 mm	15 mm	17 mm	4°	2
SO750P	Arcadius®XP C Implant 4° 15 x 17 x 9 mm	15 mm	17 mm	4°	2
SO751P	Arcadius®XP C Implant 4° 15 x 17 x 10 mm	15 mm	17 mm	4°	1
SO752P	Arcadius®XP C Implant 4° 15 x 17 x 11 mm	15 mm	17 mm	4°	1
SO766P	Arcadius®XP C Implant 7° 15 x 17 x 5 mm	15 mm	17 mm	7°	3
SO767P	Arcadius®XP C Implant 7° 15 x 17 x 6 mm	15 mm	17 mm	7°	3
SO768P	Arcadius®XP C Implant 7° 15 x 17 x 7 mm	15 mm	17 mm	7°	3
SO769P	Arcadius®XP C Implant 7° 15 x 17 x 8 mm	15 mm	17 mm	7°	2
SO770P	Arcadius®XP C Implant 7° 15 x 17 x 9 mm	15 mm	17 mm	7°	2
SO771P	Arcadius®XP C Implant 7° 15 x 17 x 10 mm	15 mm	17 mm	7°	1
SO772P	Arcadius®XP C Implant 7° 15 x 17 x 11 mm	15 mm	17 mm	7°	1

Arcadius®XP C Spinal System

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VII. Instrument Overview (ST0652)

The Arcadius^{XP} C Spinal System includes manual surgical instruments that are considered to be Class I exempt devices. They are made of surgical grade stainless steel (according to ISO 7153/1) with handles composed of silicone.

ME055R - U-Joint Screwdriver

ME056R - Fixed Angle Screwdriver

ME057R - Straight Screwdriver

ME058R - U-Joint Drill

ME059R - Fixed Angle Drill

ME060R - U-Joint Bone Awl

ME061R - Fixed Angle Bone Awl

ME062R - Straight Bone Awl

ME063R - Interbody Insertion Instrument

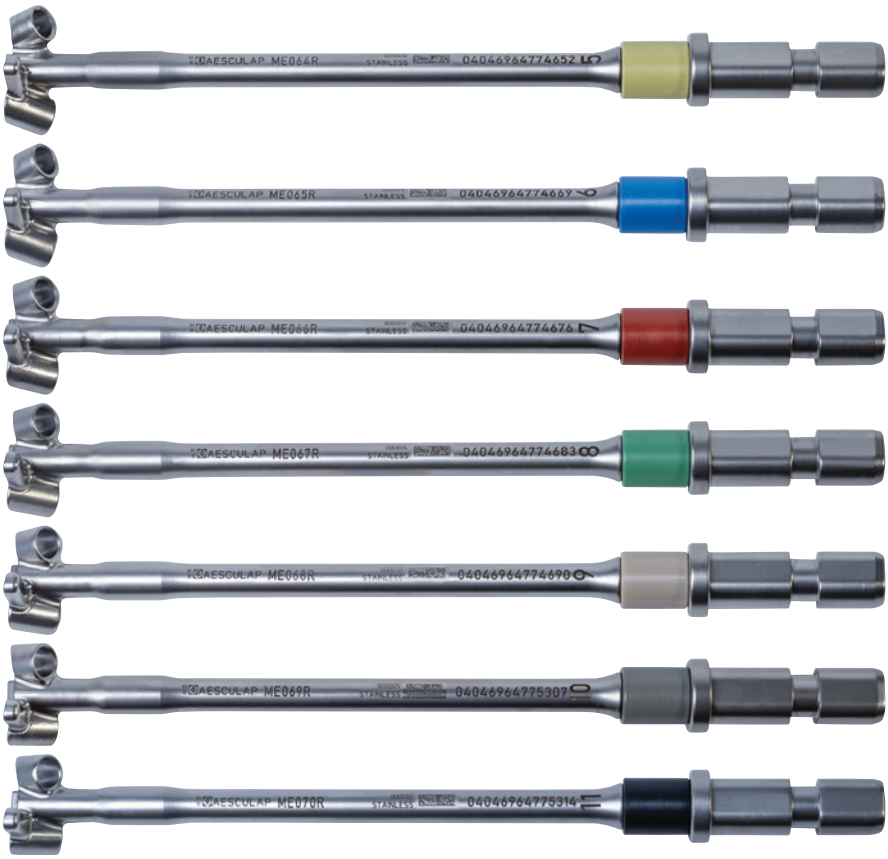
ME402R - Ball Joint Awl

VII. Instrument Overview (ST0652) *(continued)*

ME403R - Ball Joint Drill

ME404R - Hexalobe Ball Joint Screwdriver

ME064R, ME065R, ME066R, ME067R, ME068R, ME069R, ME070R (7 sizes) - All-in-One Guides for Interbody



ME071R - Impactor

ME072R - U-Joint Screw Extraction Instrument

ME073R - Tamp

Arcadius®XP C Spinal System

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VII. Instrument Overview (ST0652) *(continued)*

ME074R - Packing Block

ME075R - Multi-Tool Handle

GREAT-HJ0011-S09 - Modular Jeweler Handle

GREAT-HJ0012-S09 - Modular Handle

ME079R - Slotted Mallet

VII. Instrument Overview (ST0652) *(continued)*

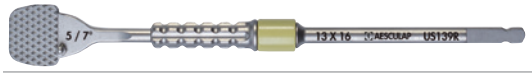
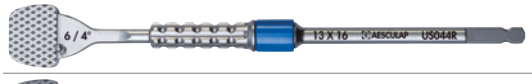
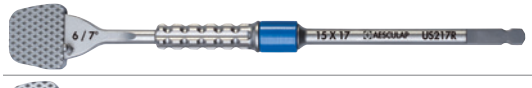
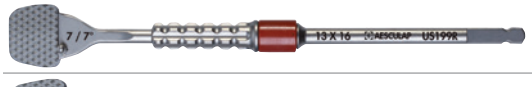
	Item No.	Description	Lordosis	Footprint	Color
	**ME126R**	Arcadius^{XP} C Modular Trial	4°	13 x 16 x 5 mm	Yellow
	**ME133R**	Arcadius^{XP} C Modular Trial	7°	13 x 16 x 5 mm	
	**ME142R**	Arcadius^{XP} C Modular Trial	4°	15 x 17 x 5 mm	
	**ME232R**	Arcadius^{XP} C Modular Trial	7°	15 x 17 x 5 mm	
	**ME127R**	Arcadius^{XP} C Modular Trial	4°	13 x 16 x 6 mm	Blue
	**ME134R**	Arcadius^{XP} C Modular Trial	7°	13 x 16 x 6 mm	
	**ME143R**	Arcadius^{XP} C Modular Trial	4°	15 x 17 x 6 mm	
	**ME233R**	Arcadius^{XP} C Modular Trial	7°	15 x 17 x 6 mm	
	**ME128R**	Arcadius^{XP} C Modular Trial	4°	13 x 16 x 7 mm	Red
	**ME135R**	Arcadius^{XP} C Modular Trial	7°	13 x 16 x 7 mm	
	**ME144R**	Arcadius^{XP} C Modular Trial	4°	15 x 17 x 7 mm	
	**ME234R**	Arcadius^{XP} C Modular Trial	7°	15 x 17 x 7 mm	
	**ME129R**	Arcadius^{XP} C Modular Trial	4°	13 x 16 x 8 mm	Green
	**ME136R**	Arcadius^{XP} C Modular Trial	7°	13 x 16 x 8 mm	
	**ME145R**	Arcadius^{XP} C Modular Trial	4°	15 x 17 x 8 mm	
	**ME235R**	Arcadius^{XP} C Modular Trial	7°	15 x 17 x 8 mm	
	**ME130R**	Arcadius^{XP} C Modular Trial	4°	13 x 16 x 9 mm	White
	**ME137R**	Arcadius^{XP} C Modular Trial	7°	13 x 16 x 9 mm	
	**ME146R**	Arcadius^{XP} C Modular Trial	4°	15 x 17 x 9 mm	
	**ME236R**	Arcadius^{XP} C Modular Trial	7°	15 x 17 x 9 mm	

Continued on next page

Arcadius®XP C Spinal System

Stand-Alone Anterior Cervical Discectomy and Fusion (ACDF) Interbody Device Surgical Technique

VII. Instrument Overview (ST0652) *(continued)*

	Item No.	Description	Lordosis	Footprint	Color
	ME131R	Arcadius^{XP} C Modular Trial	4°	13 x 16 x 10 mm	Grey
	ME138R	Arcadius^{XP} C Modular Trial	7°	13 x 16 x 10 mm	
	ME147R	Arcadius^{XP} C Modular Trial	4°	15 x 17 x 10 mm	
	ME237R	Arcadius^{XP} C Modular Trial	7°	15 x 17 x 10 mm	
	ME132R	Arcadius^{XP} C Modular Trial	4°	13 x 16 x 11 mm	Black
	ME139R	Arcadius^{XP} C Modular Trial	7°	13 x 16 x 11 mm	
	ME148R	Arcadius^{XP} C Modular Trial	4°	15 x 17 x 11 mm	
	ME238R	Arcadius^{XP} C Modular Trial	7°	15 x 17 x 11 mm	
	US039R	Arcadius^{XP} C Modular Rasp	4°	13 x 16 x 5 mm	Yellow
	US139R	Arcadius^{XP} C Modular Rasp	7°	13 x 16 x 5 mm	
	US058R	Arcadius^{XP} C Modular Rasp	4°	15 x 17 x 5 mm	
	US214R	Arcadius^{XP} C Modular Rasp	7°	15 x 17 x 5 mm	
	US044R	Arcadius^{XP} C Modular Rasp	4°	13 x 16 x 6 mm	Blue
	US198R	Arcadius^{XP} C Modular Rasp	7°	13 x 16 x 6 mm	
	US059R	Arcadius^{XP} C Modular Rasp	4°	15 x 17 x 6 mm	
	US217R	Arcadius^{XP} C Modular Rasp	7°	15 x 17 x 6 mm	
	US054R	Arcadius^{XP} C Modular Rasp	4°	13 x 16 x 7 mm	Red
	US199R	Arcadius^{XP} C Modular Rasp	7°	13 x 16 x 7 mm	
	US068R	Arcadius^{XP} C Modular Rasp	4°	15 x 17 x 7 mm	
	US218R	Arcadius^{XP} C Modular Rasp	7°	15 x 17 x 7 mm	

Continued on next page

VII. Instrument Overview (ST0652) *(continued)*

	Item No.	Description	Lordosis	Footprint	Color
	**US055R**	Arcadius^{XP} C Modular Rasp	4°	13 x 16 x 8 mm	Green
	**US211R**	Arcadius^{XP} C Modular Rasp	7°	13 x 16 x 8 mm	
	**US069R**	Arcadius^{XP} C Modular Rasp	4°	15 x 17 x 8 mm	
	**US219R**	Arcadius^{XP} C Modular Rasp	7°	15 x 17 x 8 mm	
	**US056R**	Arcadius^{XP} C Modular Rasp	4°	13 x 16 x 9 mm	White
	**US212R**	Arcadius^{XP} C Modular Rasp	7°	13 x 16 x 9 mm	
	**US093R**	Arcadius^{XP} C Modular Rasp	4°	15 x 17 x 9 mm	
	**US220R**	Arcadius^{XP} C Modular Rasp	7°	15 x 17 x 9 mm	
	**US057R**	Arcadius^{XP} C Modular Rasp	4°	13 x 16 x 10 mm	Grey
	**US213R**	Arcadius^{XP} C Modular Rasp	7°	13 x 16 x 10 mm	
	**US099R**	Arcadius^{XP} C Modular Rasp	4°	15 x 17 x 10 mm	
	**US222R**	Arcadius^{XP} C Modular Rasp	7°	15 x 17 x 10 mm	

Arcadius®XP C Spinal System

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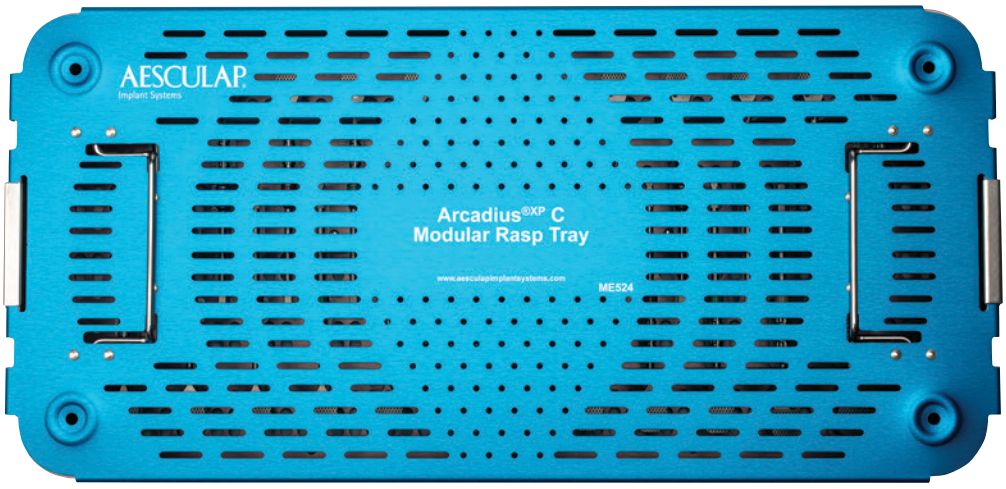
VIII. Tray Overview

Tray 1 – Modular Rasp Tray



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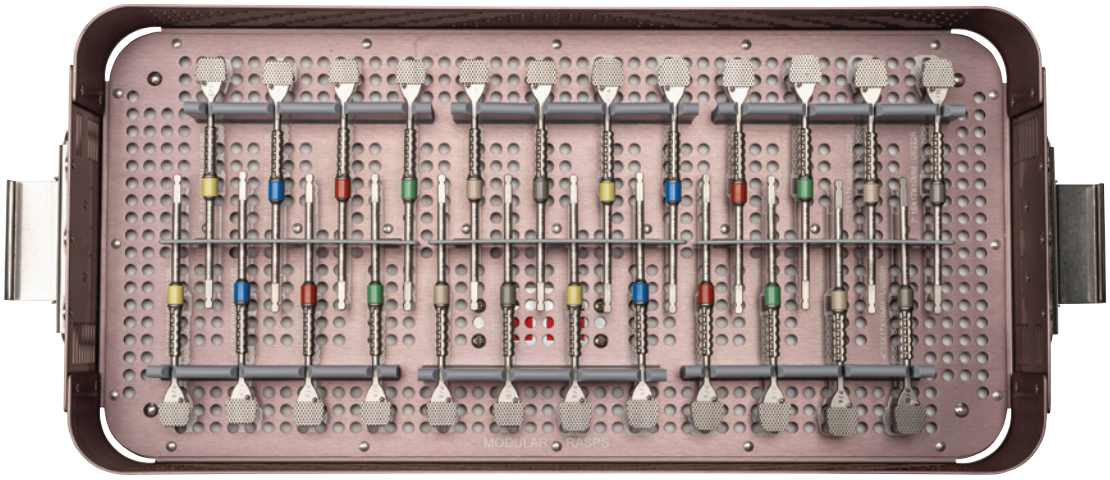
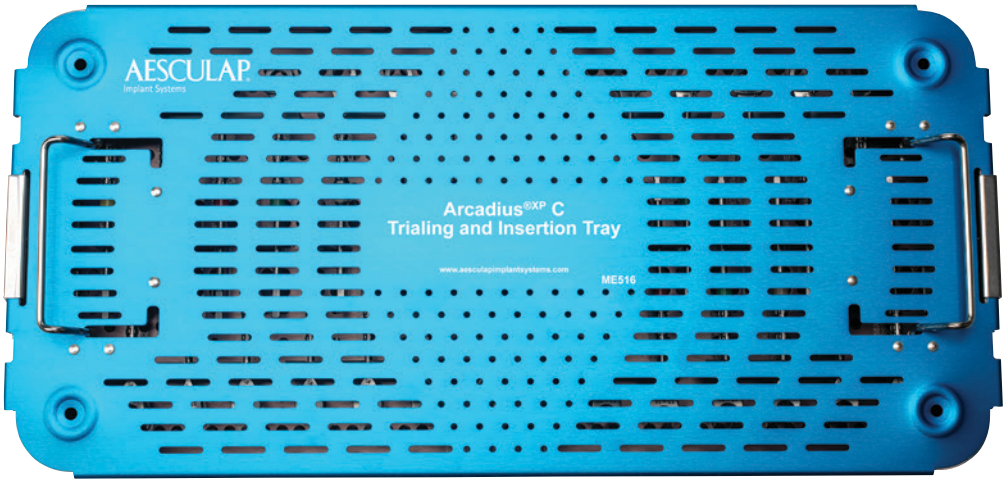


Tray 2 – Trialing and Insertion Tray



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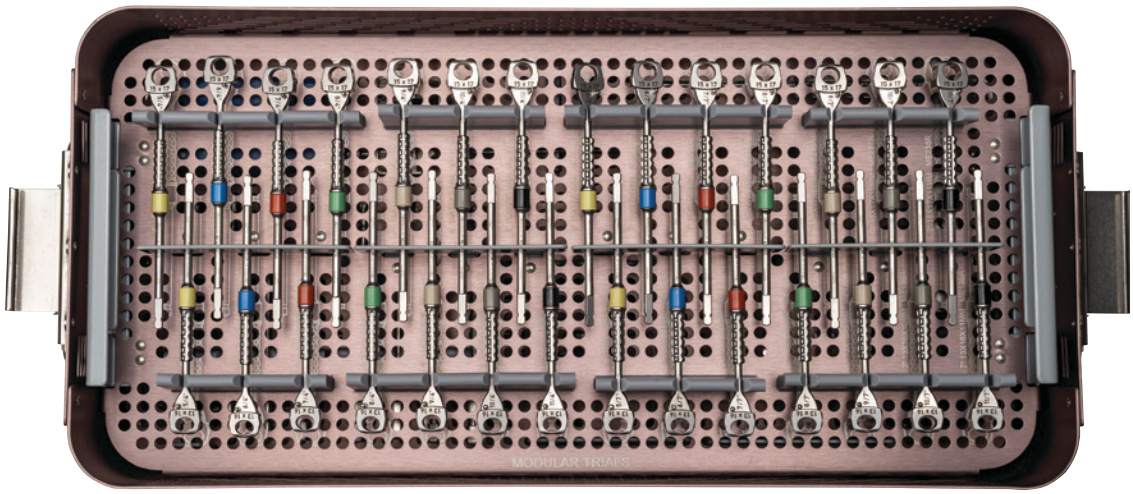
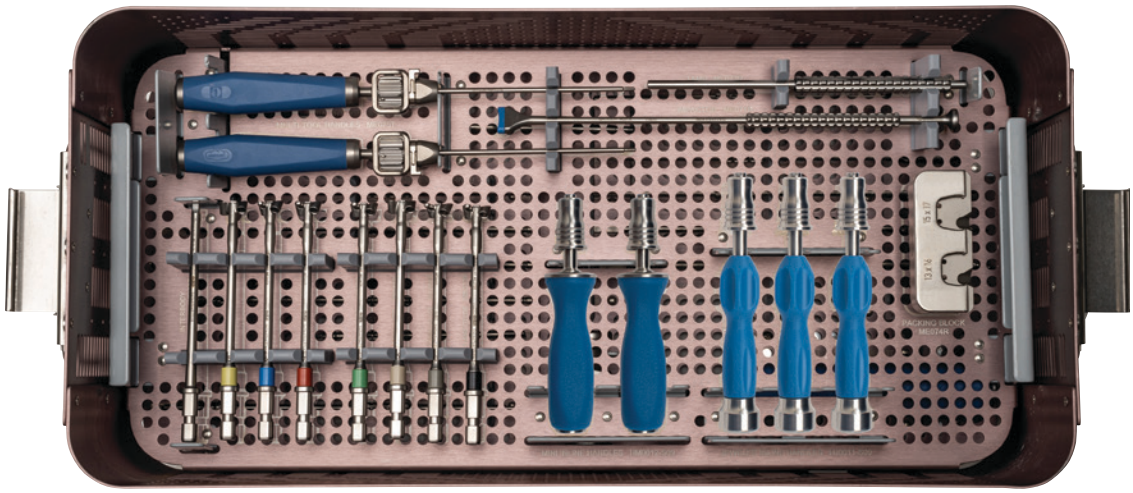
VIII. Tray Overview *(continued)*

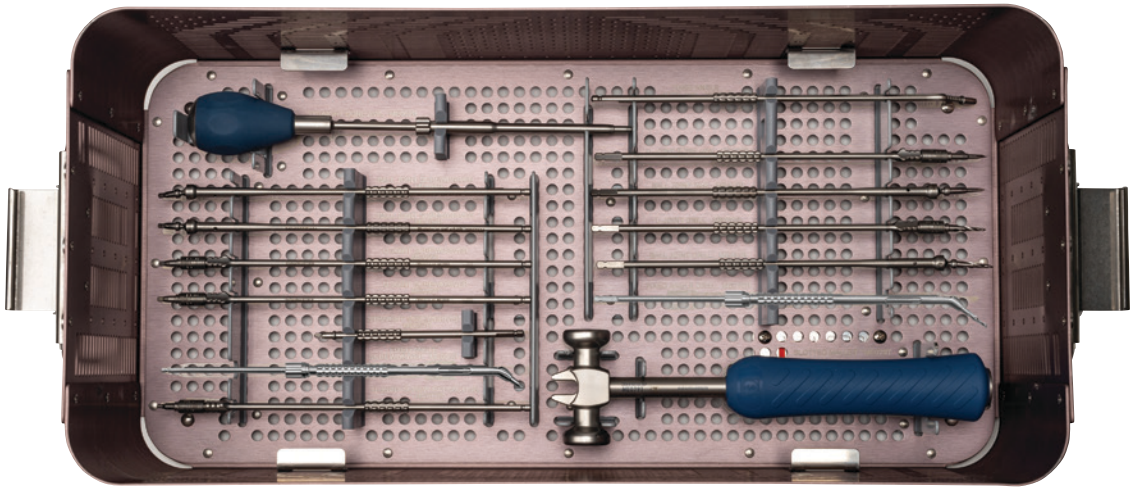
Tray 2 – Trialing and Insertion Tray *(continued)*



Level 1



Level 2



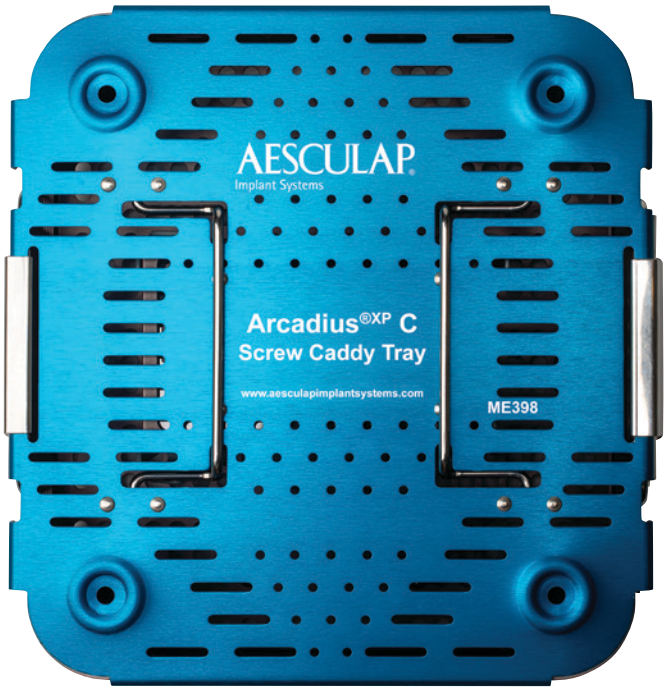
Level 3

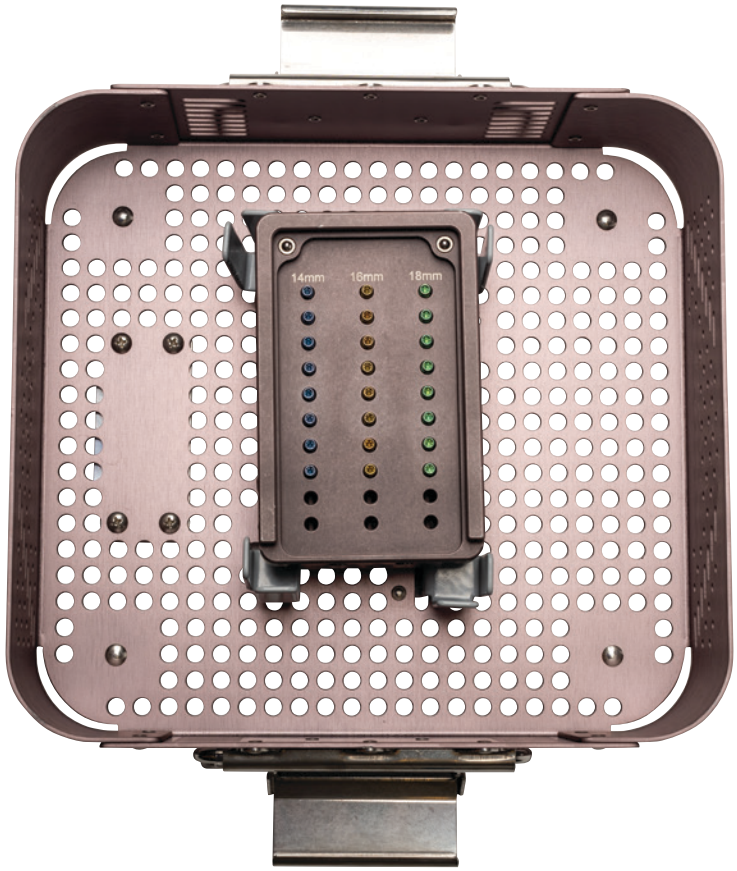
Arcadius®XP C Spinal System

Stand-Alone Anterior Cervical Discectomy and Fusion (ACDF) Interbody Device Surgical Technique

VIII. Tray Overview *(continued)*

Screw Caddy





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Notes

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