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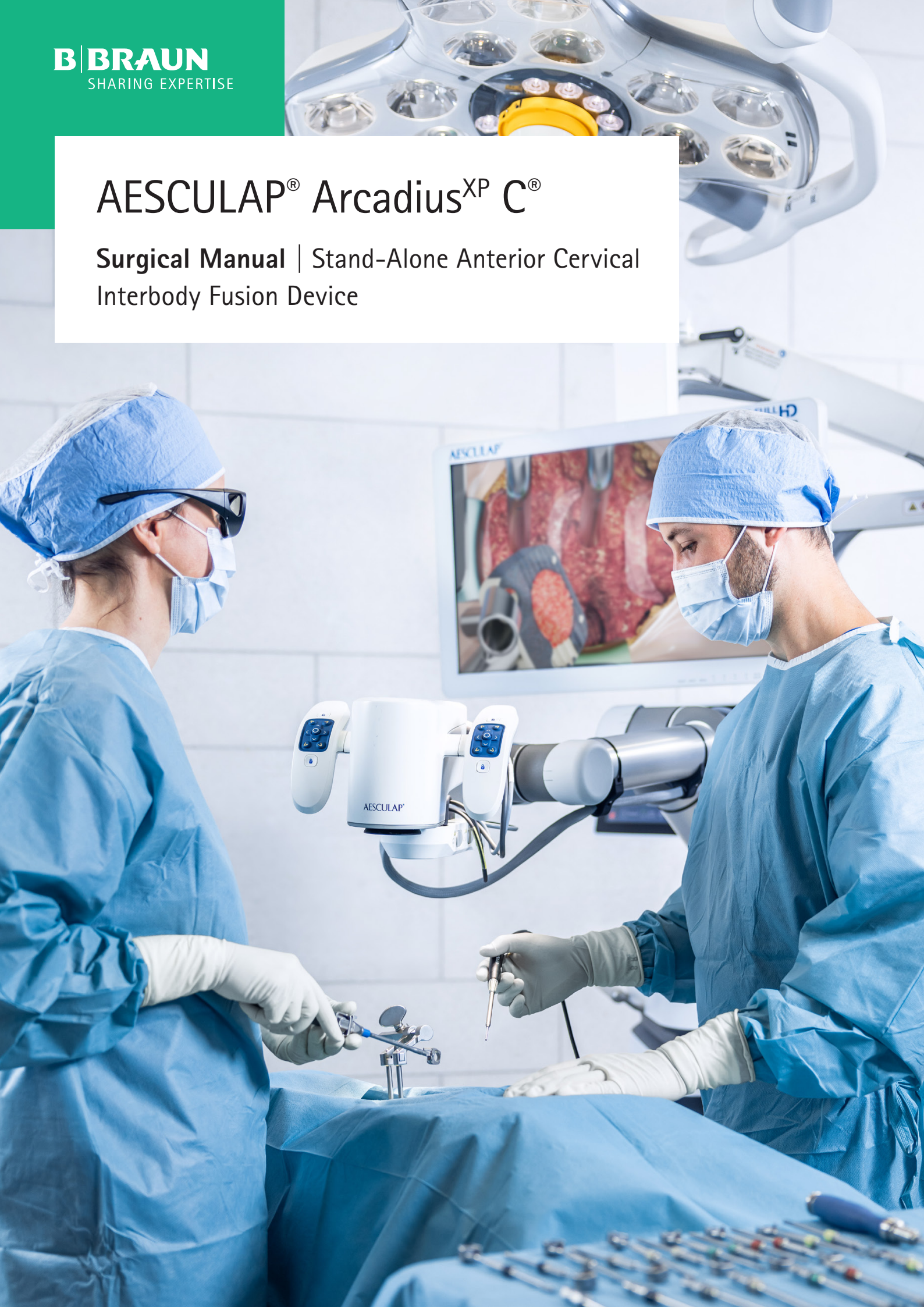
SHARING EXPERTISE

AESCULAP® Arcadius^{XP} C®

Surgical Manual | Stand-Alone Anterior Cervical Interbody Fusion Device



AESCULAP® Arcadius^{XP} C®

Stand-Alone Anterior Cervical Interbody Fusion Device

Part of the AESCULAP®

Spinal platform

Arcadius^{XP} C® is our solution designed for single and multilevel stand-alone ACDF procedures. The 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.

Strength meets elasticity

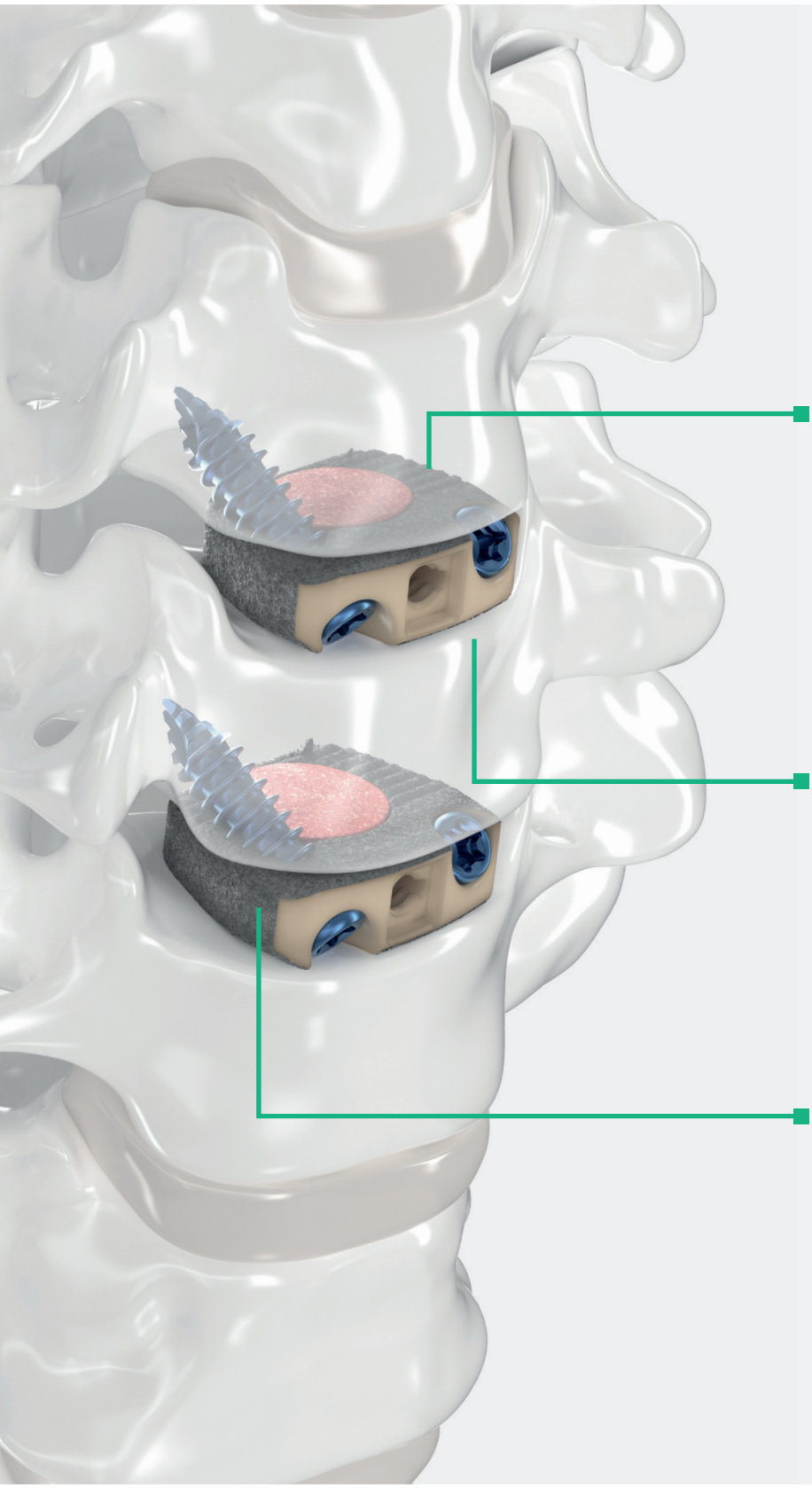
Arcadius^{XP} C® features a smart blend of strength and elasticity, which enhances spinal fusion and improves clinical outcomes.
This is primarily achieved through our unique PLASMAPORE$^{XP®}$ coating, which is the result of extensive research and experience. The roughened surface of the coating promotes osseointegration and high implant stability. Additionally, the high performance PEEK core minimizes the risk of cage subsidence by closely matching the modulus of elasticity of cortical bone (1-18).

Note | This surgical manual is designed to provide guidance for performing ACDF using Arcadius^{XP} C®. Instrumented levels, the selection of implants and the combination of instruments and implants should be tailored to the patient's pathology and the desired treatment concepts of the corresponding surgeon.

Content

AESCULAP® Arcadius^{XP} C®

Stand-Alone Anterior Cervical Interbody Fusion Device



Enhanced stability

The benefits of PLASMAPORE$^{XP®}$ titanium coating in combination with the surface texturing, the generous graft window and the diverging screw design contribute to implant stability (7, 17, 18, 20, 21).

Zero-profile

The 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.

PLASMAPORE$^{XP®}$

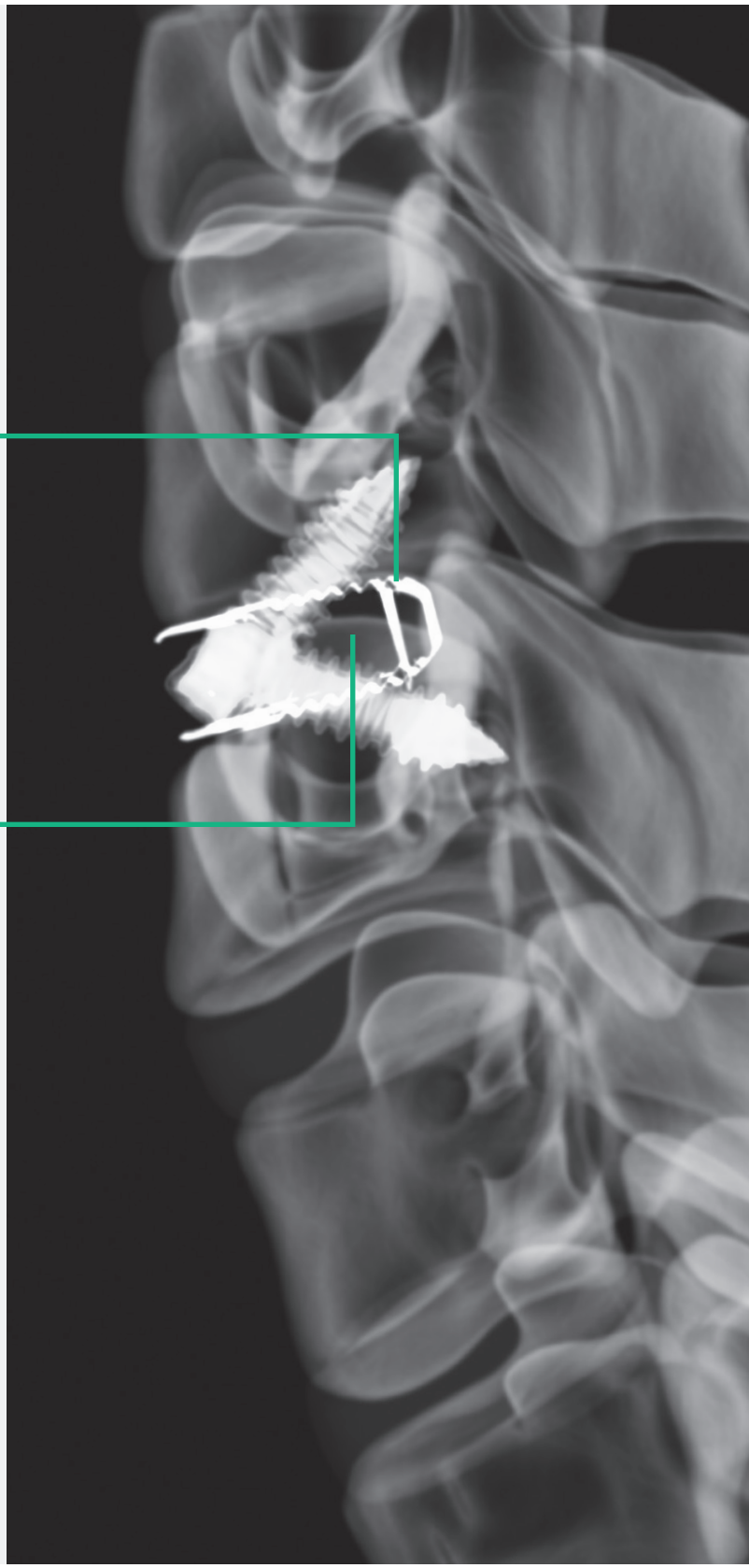
Porosity of up to 60 % creates a very good surface-to-bone contact, offering an enhanced foundation for bony ingrowth (7, 17).

Excellent imaging properties

The radiolucent nature of PEEK allows for clear visibility on X-rays and CT scans, ensuring that surgeons have the necessary imaging to assess the fusion process. The PLASMAPORE$^{XP®}$ surface enhancing technology together with the two radiopaque marker pins, allow good visualization of implant contour and localization (18, 19).

Implant Fit

A wide range of implant sizes is designed to accommodate different patient anatomies.



AESCULAP® XP

THE CHOICE OF EXPERTS

AESCULAP® Arcadius^{XP} C®

1 | General Information

1.1. Arcadius^{XP} C® Implant

Cage Information

Manufactured with a radiolucent PEEK-OPTIMA® core and an osteo-conductive PLASMAPORE$^{XP®}$ surface.

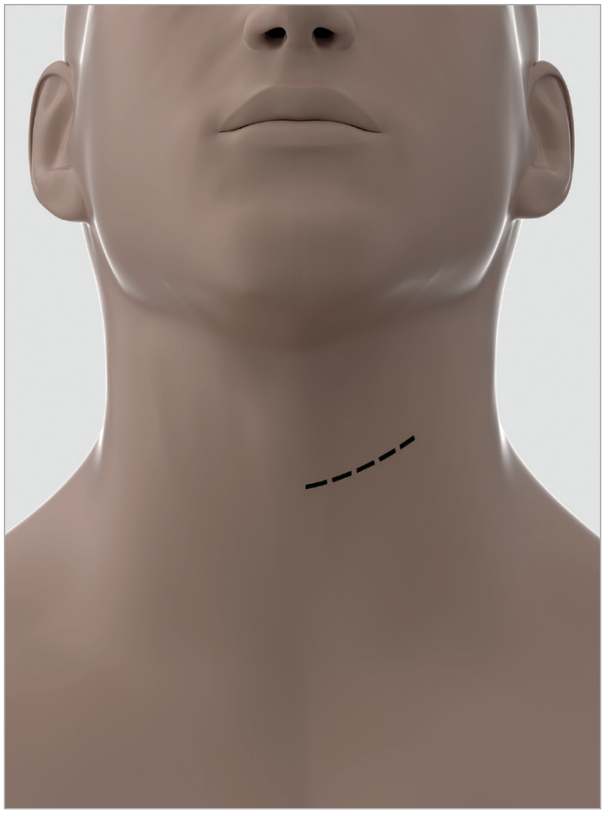
- A wide range of implant sizes is designed to accommodate different patient anatomies:
  - Two implant footprints: 13 mm x 16 mm, 15 mm x 17 mm
  - Seven heights: 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm
  - Two lordotic angles: 4°, 7°
- Wide central opening for packing of bone material
- Surface texturing for additional stability
- Two titanium markers for X-ray verification

Screw and Construct Information

- Manufactured from titanium alloy
- Screws are self-tapping
- Screw diameter is 4 mm
- Available in three lengths: 14 mm, 16 mm and 18 mm
- Construct information:
  - Diverging screw design
  - 35° cranial-caudal orientation
  - Dual locking mechanism

1.2. Intended Use

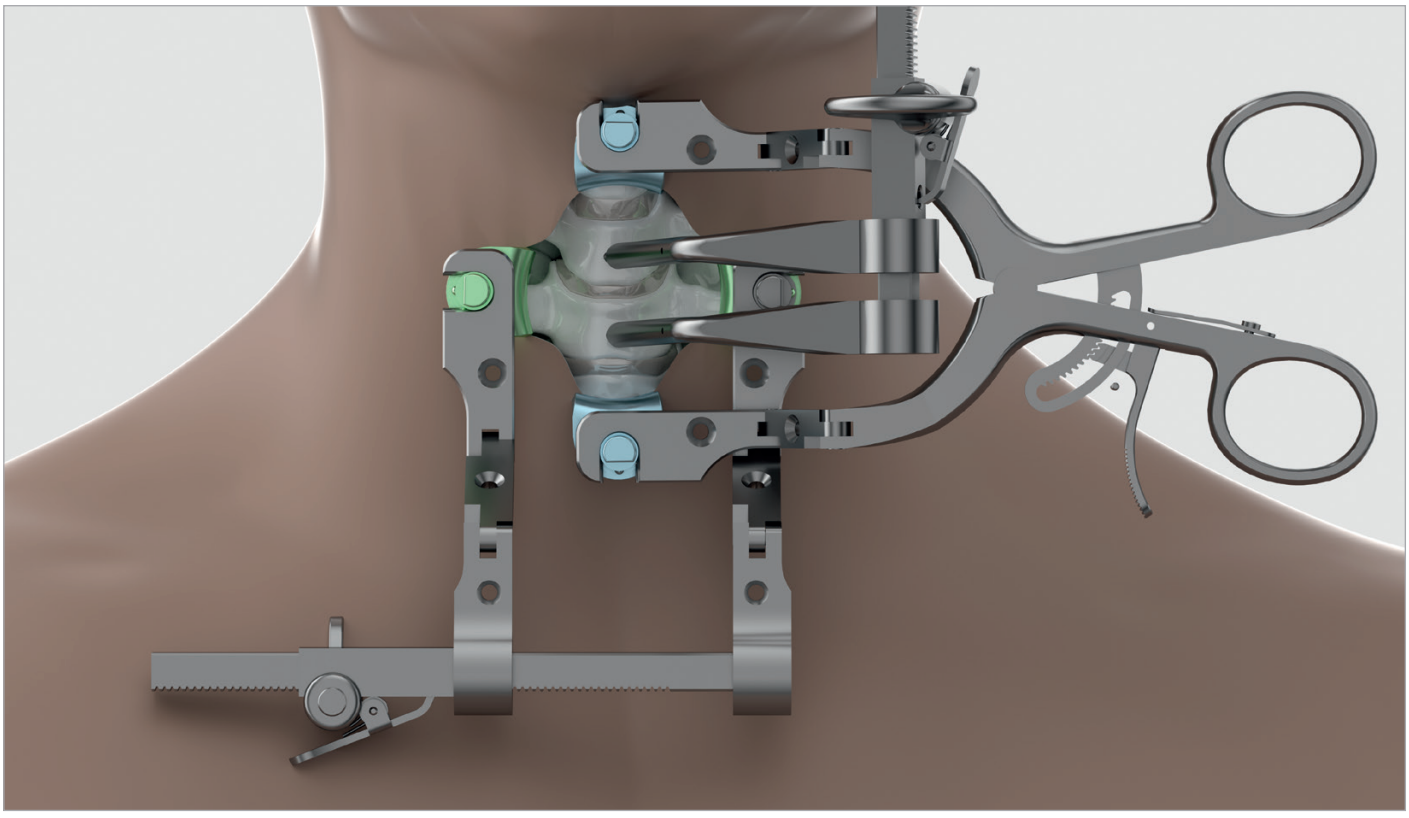
The Arcadius^{XP} C® Spinal System is intended to be used as an inter-body fusion cage as a stand-alone system with two bone screws, for single and multi-level procedures. It is inserted between the vertebral bodies into the disc space from C2-C3 to C7-T1 in skeletally mature patients. For further information please see instructions for use TA-No. 018000.

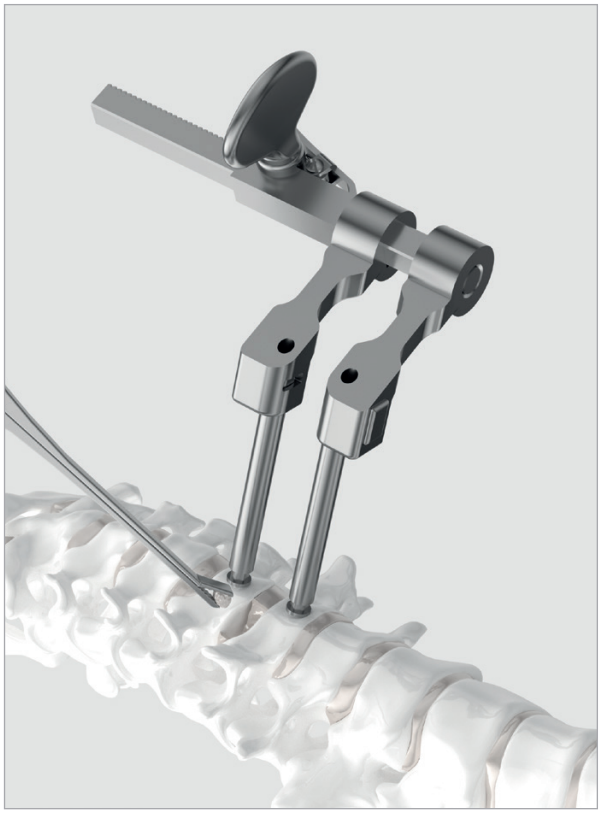


2.1. Patient Positioning and Exposure

Anterior access will be required for insertion of the Arcadius^{XP} C® 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 surgical technique:

- Place the patient in supine position.
- Utilize the standard anterior approach to the cervical spine.
- Provide the level of exposure to the implantation site the surgeon deems necessary to perform the surgery. A cervical retraction system, such as the AESCULAP® Caspar® Cervical Retractor System, can be used to provide adequate visualization to the front of the cervical spine.





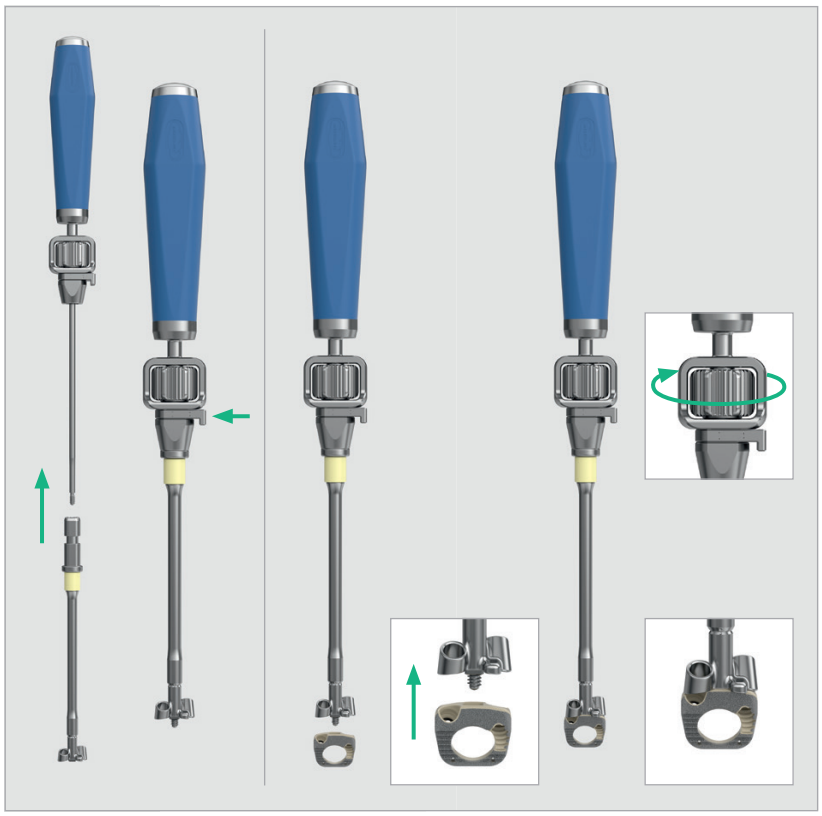
2.2. Preparation

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 the AESCULAP® Caspar® Cervical Distraction System, can be used to gradually achieve the desired working height.
- Perform a thorough discectomy.
- Ensure adequate neural decompression has been established.
- Prepare the endplates to receive the Arcadius^{XP} C® implant.
- Make sure that the endplates are prepared carefully, as excessive removal of the endplates may weaken the construct.

2.3. Implant Sizing

- Anterior osteophytes can prevent the desired positioning of both trial spacers and implants. It is recommended to remove these osteophytes prior to inserting the implant.
- 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.
- The lateral hole in the trial implants can assist in determining the correct orientation of the trial implant in the disc space. Under direct fluoroscopy, the hole through the trial should appear circular. An oval shape indicates possible implant rotation.
- Select an appropriately sized trial implant based on patient anatomy and preoperative radiographic analysis.
- Utilize a hammer to gently advance the trial into the disc space.
- Manipulate the trial implant as needed to attain the desired position.
- Intra-operative imaging may be used to evaluate size and location of the trial implant.
- Continue to evaluate trial implants until a tight fit is achieved.
- Once the appropriate size and height of the implant has been determined, select a rasp to roughen and expose the endplates.



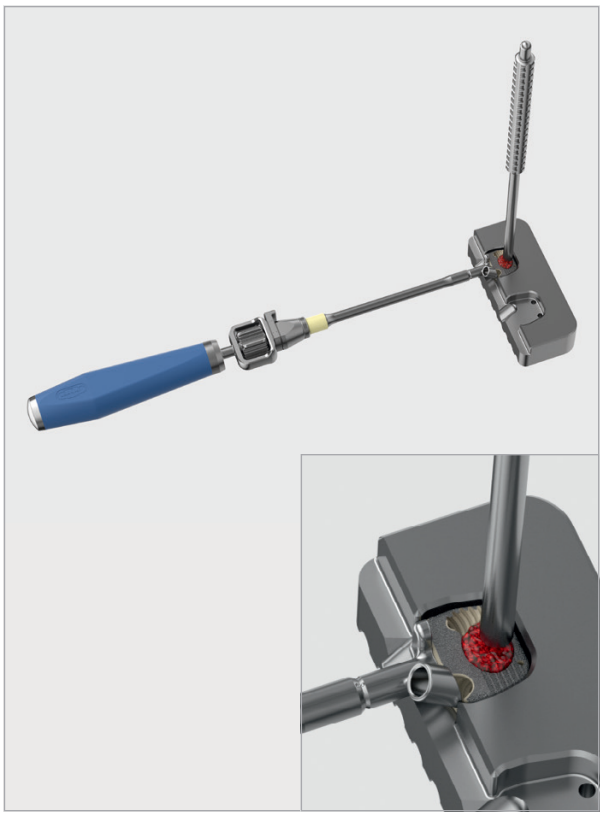
2.4. Implant Preparation and Insertion

- The trial implants are designed to correspond to the dimensions of the coated implant.
- Select an implant that corresponds to the final trial implant size evaluated.
- Avoid direct contact with the coated surfaces, handle implants carefully.
- Handle instruments with care and avoid applying excessive force to them.

Implant Preparation with All-in-One Inserter

- Assemble the all-in-one inserter by attaching the all-in-one guide to the multi-tool handle (ME075T).
- The all-in-one guide should be selected to correspond to the height of the chosen implant.
- Attach and secure the selected Arcadius^XP C® implant to the distal end of the all-in-one inserter by turning the proximal knob in a clockwise direction.

Options for All-In-One Guides (used with ME075T)	Article No.	Description
	ME064R	All-In-One Guide 5 mm
	ME065R	All-In-One Guide 6 mm
	ME066R	All-In-One Guide 7 mm
	ME067R	All-In-One Guide 8 mm
	ME068R	All-In-One Guide 9 mm
	ME069R	All-In-One Guide 10 mm
	ME070R	All-In-One Guide 11 mm



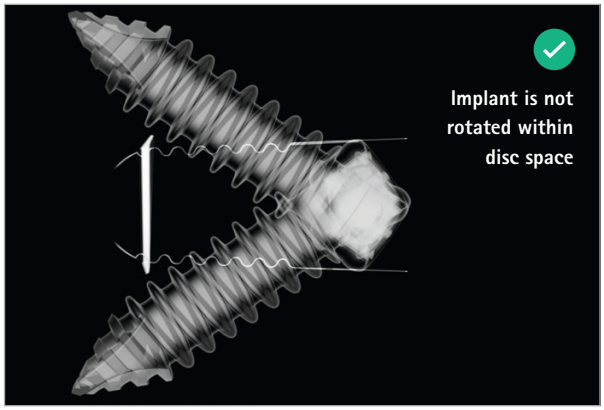
Pack Implant with Bone Material

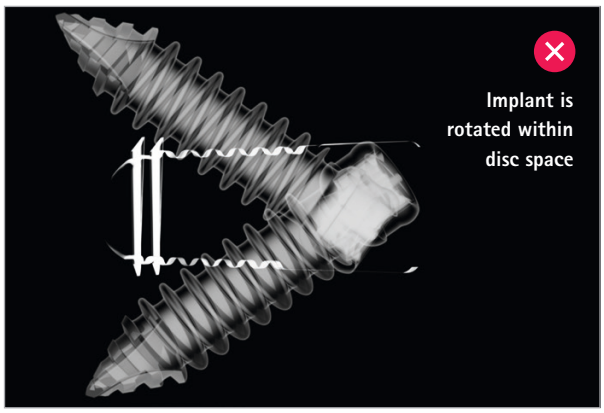
- Fill the implant by using the packing block and tamp.
- When placing the implant in the packing block ensure that the safety stop faces upwards.
- To determine the volume of the graft window, please refer to the table below.

Article No.	Graft Volume in cm^3 or ml	Article No.	Graft Volume in cm^3 or ml	Article No.	Graft Volume in cm^3 or ml	Article No.	Graft Volume in cm^3 or ml
S0706P	0.27	S0726P	0.24	S0746P	0.35	S0766P	0.32
S0707P	0.32	S0727P	0.30	S0747P	0.42	S0767P	0.39
S0708P	0.37	S0728P	0.35	S0748P	0.49	S0768P	0.46
S0709P	0.43	S0729P	0.40	S0749P	0.56	S0769P	0.53
S0710P	0.48	S0730P	0.46	S0750P	0.63	S0770P	0.60
S0711P	0.53	S0731P	0.51	S0751P	0.71	S0771P	0.67
S0712P	0.59	S0732P	0.56	S0752P	0.78	S0772P	0.74

Implant Insertion

- Introduce the implant into the disc space.
- To ensure a good implant position it is important to consider the midline and neutral alignment during implantation.
- The positive stop at the end of the all-in-one guide ensures that the device is positioned flush with the anterior border of the vertebral body.





Verification of Implant Placement

- Obtain intraoperative AP fluoroscopic images to confirm midline placement of the device.
- Obtain intraoperative lateral fluoroscopic images to confirm correct implant placement
- X-ray markers are located 1 mm from the posterior edge of the implant.
- Observe the X-ray markers in both the AP and lateral views to ensure that the implant is not rotated within the disc space.
- Prior to screw placement, manipulate the implant as needed by gently tapping the impactor with a hammer.
- Relaxing the Caspar® Cervical Distractor places the implant in compression. This allows the PLASMAPORE^XP® coating and the grooves on the Arcadius^XP C® implant surfaces to encounter the vertebral body endplates, thereby producing a more secure fit within the intervertebral disc space.
- Leave the all-in-one guide attached to the implant and check whether the implant is stable and securely positioned.
- If the implant can be easily moved in the intervertebral space, there is a risk of dislocation, and the implant should be replaced with the next largest size in height.

2.5. Screw Fixation

- 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 the surgeon's preference for screw hole preparation and screw insertion. By using the all-in-one guide, the awl and drill cannot progress past the posterior border of the implant.

Awling

- It is recommended to prepare screw holes and insert screws using X-ray guidance.
- The perforation of the cortex is created with a bone awl.
- When using the U-joint or the fixed angle bone awl please attach the desired handle.
- Introduce the bone awl into the all-in-one guide and insert until a hard stop is reached. A hard stop indicates the awl has punctured the cortical layer of the bone.
- While perforating the cortex, make sure that the all-in-one guide remains in position.
- The awl must be pushed / advanced by hand only.
- Remove the bone awl while maintaining alignment of the hole and implant.

Instruments – Options for Bone Awl	Article No.	Description
	ME060R	U-Joint Bone Awl
	ME061R	Fixed Angle Bone Awl
	ME062R	Straight Bone Awl

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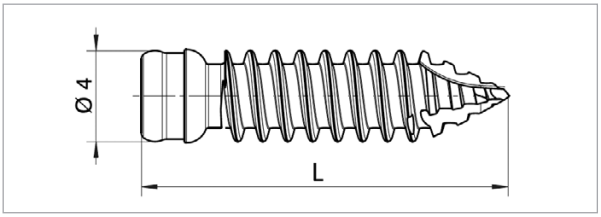
Instruments – Options for Drill	Article No.	Description
	ME058R	U-Joint Drill
	ME059R	Fixed Angle Drill



Article No.	Description	Length	Color
S0791TS	Arcadius^{XP} C® Bone Screw 4.0 mm	14 mm	Blue
S0792TS	Arcadius^{XP} C® Bone Screw 4.0 mm	16 mm	Gold
S0793TS	Arcadius^{XP} C® Bone Screw 4.0 mm	18 mm	Green

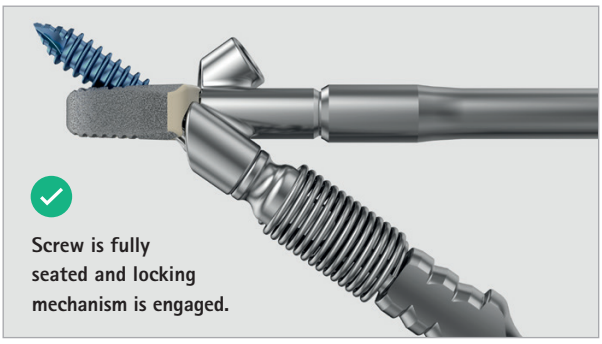
Drilling

- The diameter of the Arcadius^{XP} C® screws is 4.0 mm.
- The drills are undersized by 1.5 mm of the final screw diameter.
- Attach the handle to the desired drill.
- Place the drill into the all-in-one guide and drill until it no longer advances.
- While drilling, make sure that the all-in-one guide remains in position.
- Remove the drill while maintaining alignment of the hole and implant.
- Select a bone screw based on patient anatomy and the implant size used. Analysis of screw length is essential to avoid screw contact with adjacent neural elements.

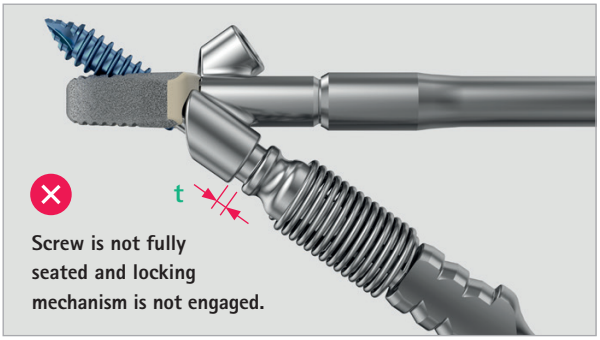
Instruments – Options for Driver	Article No.	Description
	ME055R	U-Joint Screwdriver
	ME056R	Fixed Angle Screwdriver
	ME057R	Straight Screwdriver

Screw Insertion

- Attach the handle to the desired screwdriver.
- All screwdrivers are self-retaining. Fully insert the tip of the screwdriver into the bone screw and ensure proper fixation.
- Guide the screwdriver with screw attached into the prepared screw hole, maintaining the all-in-one guide in position.
- Turn the screwdriver clockwise to advance the screw into the vertebral body.



- Ensure the bone screw is fully seated. This can be visually confirmed when the screwdriver's collar aligns perfectly with the edge of the all-in-one guide.
- Note that further insertion of the screw may damage the implant.
- Repeat steps previously outlined for pilot hole creation and bone screw placement to insert the final screw.
- The placement of the screw and the final implant placement shall be confirmed with intraoperative imaging prior to detaching the all-in-one guide.
- Replace the cage if a fully inserted and locked screw must be removed and replaced, as there is the risk of damaging the locking mechanism.



Dual Locking Mechanism

The Arcadius^XP C® ACDF device incorporates a dual locking mechanism to prevent screws from backing out. The following section describes how the locking mechanism functions from a user's perspective:

- Upon insertion, the screw can be easily turned without encountering resistance.
- As the shoulder of the screw meets the locking rim of the cage, a slight increase in insertion torque will be felt.
- Once the shoulder of the screw passes through the locking rim, a noticeable decrease in insertion torque will be felt.
- First locking mechanism: after the shoulder of the screw passes through the locking rim, the locking rim will seat into its final position. At this point, a noticeable decrease in insertion torque will be felt.
- Second locking mechanism: as the screw approaches full insertion, the threads of the screw will contact the inner threads of the implant, and a noticeable increase in insertion torque will be felt.
- To prevent possible screw backout, it is important that both locking mechanisms are engaged.

2.6. Optional Instruments (All-in-one inserter vs. Multi-tool inserter)

All-in-one inserter

All-in-one guide + Multi-tool handle | ME075T

For implant insertion it is recommended using the all-in-one inserter including a safety stop, as the safety stop ensures that the implant is seated flush against the anterior border of the vertebral body.

When using the all-in-one inserter, the awl/drill cannot progress past the posterior border of the implant.
The corresponding handling is explained on page 10.

Multi-tool inserter

Interbody Inserter | ME063R + Multi-tool handle | ME075T

The multi-tool inserter without safety stop may be used optionally. When using the multi-tool inserter without safety stop, the awl/drill can progress 1 mm past the posterior border of the implant.

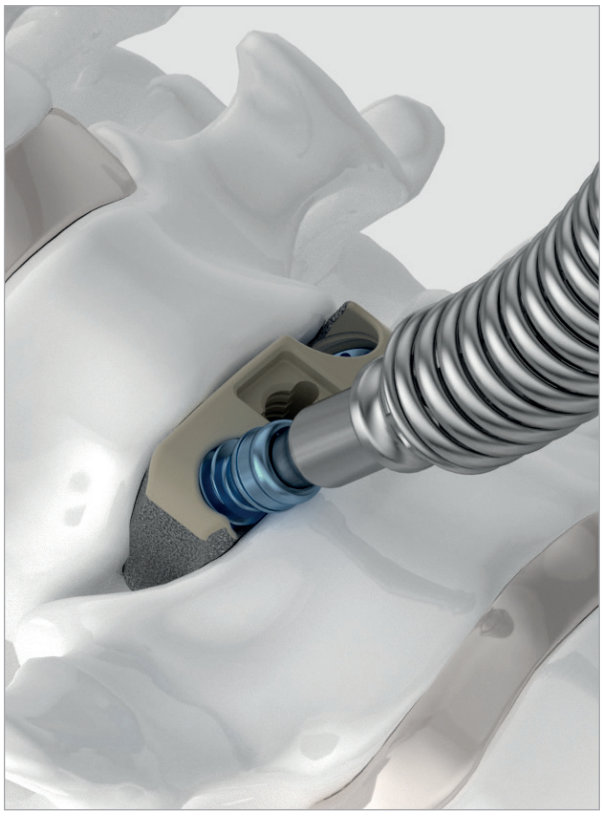
There may be the risk of damaging biological structures and the Arcadius^{XP} C® implant if the drills and bone awls are used without the all-in-one guide.

Impactor

ME071

An impactor is available for assistance with final implant placement before the screws are inserted.

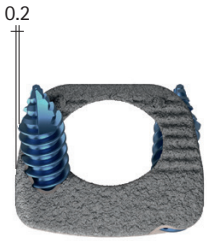
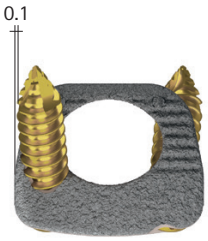
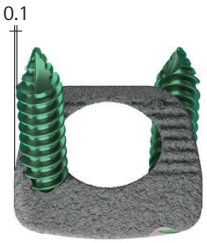
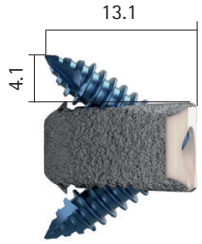
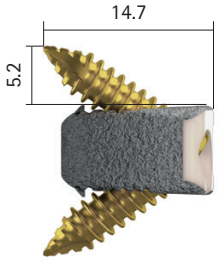
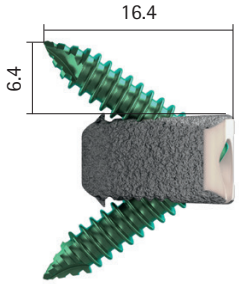
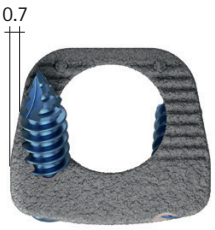
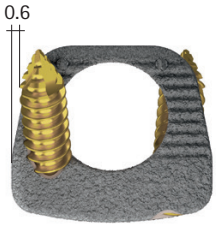
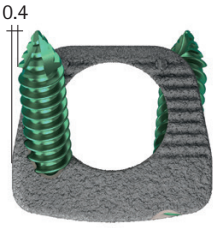
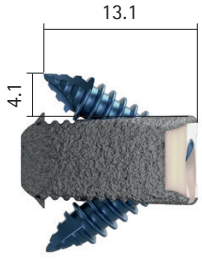
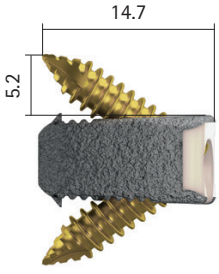
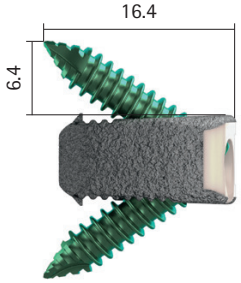
Do not use excessive force with the impactor to position or seat the implant.



2.7. Implant Removal

- Attach the desired handle to the U-joint screw extraction instrument (ME072R).
- Attach the U-joint screw extraction instrument (ME072R) to a screw in the Arcadius^{XP} C® implant by turning the extraction instrument in a counter-clockwise motion.
- Retract the screw from the vertebral body and cage by turning the screwdriver in a counter-clockwise motion.
- Repeat the screw removal process for the remaining screw in the implant.
- Assemble the multi-tool inserter by attaching the multi-tool handle (ME075T) to the interbody inserter (ME063R).
- Turn the proximal knob of the assembled multi-tool inserter in a clockwise direction to secure it to the central opening of the implant.
- Apply an extraction force to the multi-tool inserter to remove the implant from the disc space.

3 | Implant Information and Measurements

	14 mm Screws	16 mm Screws	18 mm Screws
13 x 16 mm **Axial view**			
13 x 16 mm **Lateral view**			
15 x 17 mm **Axial view**			
15 x 17 mm **Lateral view**			

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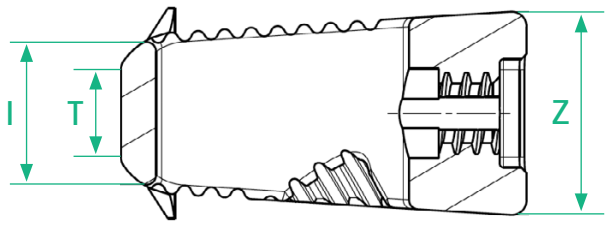
3 | Implant Information and Measurements

13x16 mm, 4°			
Article No.	l in mm	T in mm	Z in mm
SO706P	4.03	2.45	5.5
SO707P	5.03	3.45	6.5
SO708P	6.03	4.45	7.5
SO709P	7.03	5.45	8.5
SO710P	8.03	6.45	9.5
SO711P	9.03	7.45	10.5
SO712P	10.03	8.45	11.5

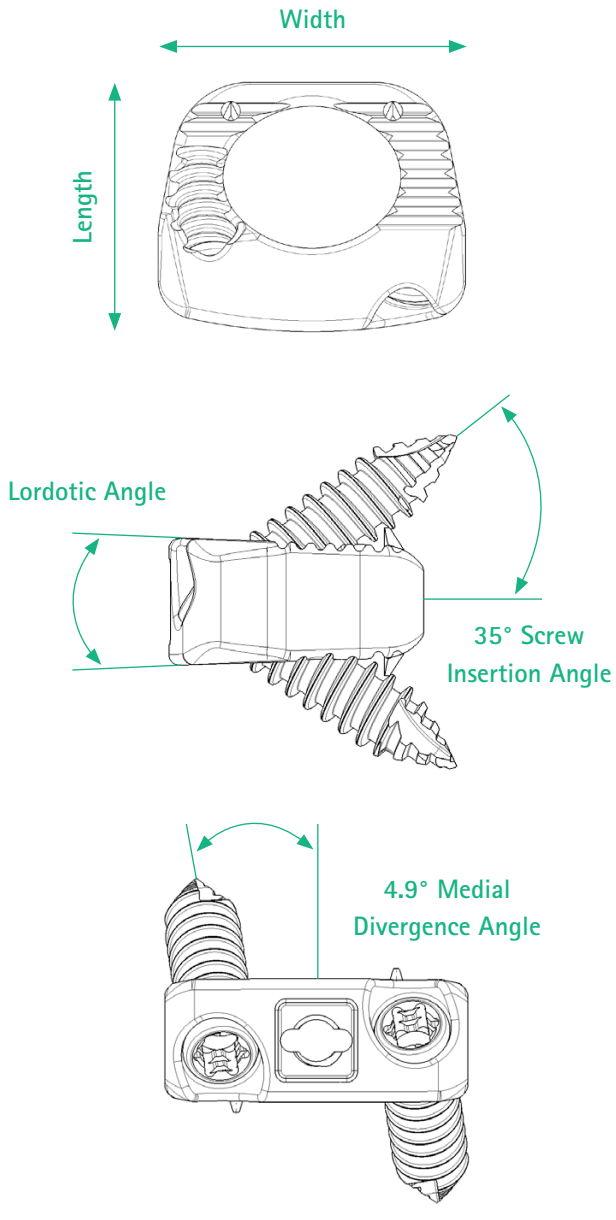
13x16 mm, 7°			
Article No.	l in mm	T in mm	Z in mm
SO726P	3.44	1.8	5.5
SO727P	4.44	2.8	6.5
SO728P	5.44	3.8	7.5
SO729P	6.44	4.8	8.5
SO730P	7.44	5.8	9.5
SO731P	8.44	6.8	10.5
SO732P	9.44	7.8	11.5

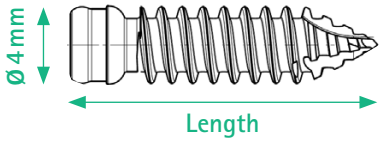


15x17 mm, 4°			
Article No.	l in mm	T in mm	Z in mm
SO746P	3.95	2.3	5.5
SO747P	4.95	3.3	6.5
SO748P	5.95	4.3	7.5
SO749P	6.95	5.3	8.5
SO750P	7.95	6.3	9.5
SO751P	8.95	7.3	10.5
SO752P	9.95	8.3	11.5

15x17 mm, 7°			
Article No.	l in mm	T in mm	Z in mm
SO766P	3.26	1.55	5.5
SO767P	4.26	2.55	6.5
SO768P	5.26	3.55	7.5
SO769P	6.26	4.55	8.5
SO770P	7.26	5.55	9.5
SO771P	8.26	6.55	10.5
SO772P	9.26	7.55	11.5

4 | Implant Overview

Cage Implants	Article No.	Lordosis	Size (Length x Width x Height)
	S0706P	4°	13 x 16 x 5 mm
	S0707P		13 x 16 x 6 mm
	S0708P		13 x 16 x 7 mm
	S0709P		13 x 16 x 8 mm
	S0710P		13 x 16 x 9 mm
	S0711P		13 x 16 x 10 mm
	S0712P		13 x 16 x 11 mm
	S0726P	7°	13 x 16 x 5 mm
	S0727P		13 x 16 x 6 mm
	S0728P		13 x 16 x 7 mm
	S0729P		13 x 16 x 8 mm
	S0730P		13 x 16 x 9 mm
	S0731P		13 x 16 x 10 mm
	S0732P		13 x 16 x 11 mm
	S0746P	4°	15 x 17 x 5 mm
	S0747P		15 x 17 x 6 mm
	S0748P		15 x 17 x 7 mm
	S0749P		15 x 17 x 8 mm
	S0750P		15 x 17 x 9 mm
	S0751P		15 x 17 x 10 mm
	S0752P		15 x 17 x 11 mm
	S0766P	7°	15 x 17 x 5 mm
	S0767P		15 x 17 x 6 mm
	S0768P		15 x 17 x 7 mm
	S0769P		15 x 17 x 8 mm
	S0770P		15 x 17 x 9 mm
	S0771P		15 x 17 x 10 mm
	S0772P		15 x 17 x 11 mm

Screw Implants	Article No.	Diameter	Length
	S0791TS	4 mm	14 mm
	S0792TS		16 mm
	S0793TS		18 mm

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5 | Instrument Overview

Instruments	Article No.	Description	Qty
	ME055R	U-Joint Screwdriver	1
	ME056R	Fixed Angle Screwdriver	1
	ME057R	Straight Screwdriver	1
	ME058R	U-Joint Drill	1
	ME059R	Fixed Angle Drill	1
	ME060R	U-Joint Bone Awl	1
	ME061R	Fixed Angle Bone Awl	1
	ME062R	Straight Bone Awl	1
	ME063R	Interbody Inserter	1

Instruments	Article No.	Description	Qty
	ME064R	All-In-One Guide 5 mm	1
	ME065R	All-In-One Guide 6 mm	1
	ME066R	All-in-one guide 7 mm	1
	ME067R	All-In-One Guide 8 mm	1
	ME068R	All-In-One Guide 9 mm	1
	ME069R	All-In-One Guide 10 mm	1
	ME070R	All-In-One Guide 11 mm	1
	ME071R	Impactor	1
	ME072R	U-Joint Screw Extraction Instrument	1
	ME073R	Tamp	1

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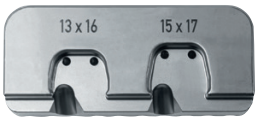
5 | Instrument Overview

Instruments	Article No.	Description	Footprint	Qty
	ME074R	Packing Block		1
	ME075T	Multi-Tool Handle		2
	ME076R	Jeweler Handle		2
	ME077R	Arcadius^{XP} C® Handle w/AO-Chuck		1
	ME079T	Slotted Hammer		(1) Optional
	ME149R	Arcadius^{XP} C® Modular Rasp	13 x 16 mm	1
	ME239R	Arcadius^{XP} C® Modular Rasp	15 x 17 mm	1

Instruments	Article No.	Description	Lordosis	Footprint	Qty
	ME126R	Arcadius^{XP} C® Modular Trial	4°	13 x 16 x 5 mm	1
	ME133R	Arcadius^{XP} C® Modular Trial	7°	13 x 16 x 5 mm	1
	ME142R	Arcadius^{XP} C® Modular Trial	4°	15 x 17 x 5 mm	1
	ME232R	Arcadius^{XP} C® Modular Trial	7°	15 x 17 x 5 mm	1
	ME127R	Arcadius^{XP} C® Modular Trial	4°	13 x 16 x 6 mm	1
	ME134R	Arcadius^{XP} C® Modular Trial	7°	13 x 16 x 6 mm	1
	ME143R	Arcadius^{XP} C® Modular Trial	4°	15 x 17 x 6 mm	1
	ME233R	Arcadius^{XP} C® Modular Trial	7°	15 x 17 x 6 mm	1
	ME128R	Arcadius^{XP} C® Modular Trial	4°	13 x 16 x 7 mm	1
	ME135R	Arcadius^{XP} C® Modular Trial	7°	13 x 16 x 7 mm	1
	ME144R	Arcadius^{XP} C® Modular Trial	4°	15 x 17 x 7 mm	1
	ME234R	Arcadius^{XP} C® Modular Trial	7°	15 x 17 x 7 mm	1
	ME129R	Arcadius^{XP} C® Modular Trial	4°	13 x 16 x 8 mm	1
	ME136R	Arcadius^{XP} C® Modular Trial	7°	13 x 16 x 8 mm	1

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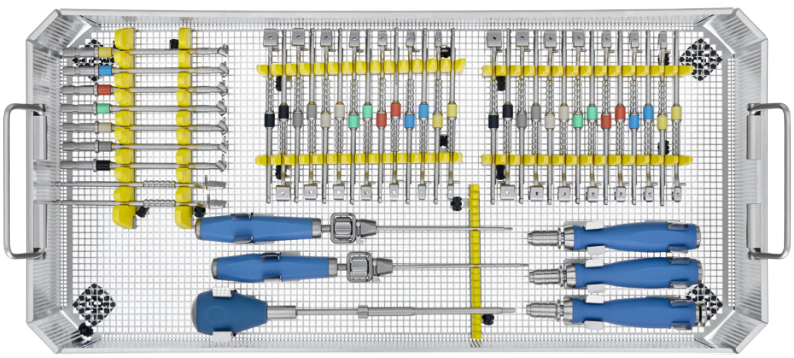
5 | Instrument Overview

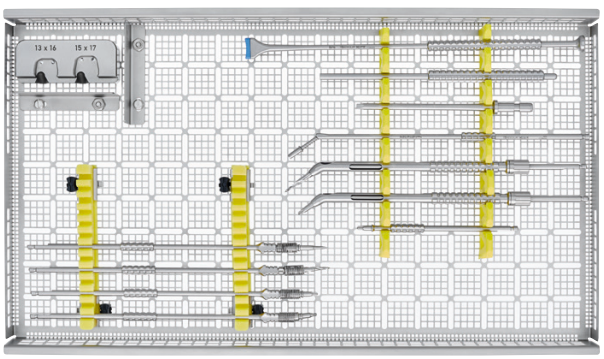
Instruments	Article No.	Description	Lordosis	Footprint	Qty
	ME145R	Arcadius^{XP} C® Modular Trial	4°	15 x 17 x 8 mm	1
	ME235R	Arcadius^{XP} C® Modular Trial	7°	15 x 17 x 8 mm	1
	ME130R	Arcadius^{XP} C® Modular Trial	4°	13 x 16 x 9 mm	1
	ME137R	Arcadius^{XP} C® Modular Trial	7°	13 x 16 x 9 mm	1
	ME146R	Arcadius^{XP} C® Modular Trial	4°	15 x 17 x 9 mm	1
	ME236R	Arcadius^{XP} C® Modular Trial	7°	15 x 17 x 9 mm	1
	ME131R	Arcadius^{XP} C® Modular Trial	4°	13 x 16 x 10 mm	1
	ME138R	Arcadius^{XP} C® Modular Trial	7°	13 x 16 x 10 mm	1
	ME147R	Arcadius^{XP} C® Modular Trial	4°	15 x 17 x 10 mm	1
	ME237R	Arcadius^{XP} C® Modular Trial	7°	15 x 17 x 10 mm	1
	ME132R	Arcadius^{XP} C® Modular Trial	4°	13 x 16 x 11 mm	1
	ME139R	Arcadius^{XP} C® Modular Trial	7°	13 x 16 x 11 mm	1
	ME148R	Arcadius^{XP} C® Modular Trial	4°	15 x 17 x 11 mm	1
	ME238R	Arcadius^{XP} C® Modular Trial	7°	15 x 17 x 11 mm	1

Tray / Container	Article No.	Description	Qty
	JF224R	1/1 Size Perf Basket 540 x 253 x106 mm	1
	JF227R	1/1 Size Perf Basket Lid 544 x 257 mm	1
	JF210R	Tray Insert 1/1 Size	1
Lower Tray			
	JG305	Instrument Rack Type 1 160 x 40 mm	2
	JG317	Instrument Rack Type 4 160 x 40 mm	4
	JG693R	Clamp III f. Fix. of Mot. Handp.	3
	JG694R	Clamp IV f. Fix. of Mot. Handp.	5
	JG695R	Clamp V f. Fix. of Mot. Handp.	1
	JG320	Instrument Rack 120 x 21 mm	1
Upper Tray			
	JG372	Silicone Divider f. Tray Inserts 227 x 30 mm	2
	JG323	Micro Instrument Rack Type 3 123 x 18 mm	2
	JF381R	Limiting Bar w/Screws f/Mini Sz Baskets	2
Container			
	JK442	Bottom For 1/1 Container Height: 135 mm	1
	JK489	Full-Size Lid W/Retention Plate Silver	1

Lower Tray:



Upper Tray:



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