Mecta-C® CAGE

CERVICAL INTERVERTEBRAL BODY FUSION DEVICE

Surgical Technique

Joint | **Spine** | Sports Med

Medacta International

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1. INTRODUCTION

Mecta-C is an intervertebral body fusion device used for Anterior Cervical Discectomy and Fusion (ACDF). The implant is designed to restore the biomechanical stability of the motion segment while the fusion process is occurring. The Mecta-C implant is indicated for the treatment of degenerative diseases of the cervical disc and can be used for cervical fusion from C2-T1. The technique of anterior cervical discectomy and fusion using the Mecta-C cage is similar to the standard Smith-Robinson technique utilizing bone graft. The physiologic design and the range of available cage sizes allow the surgeon to choose a cage that matches the patient's unique individual anatomy. Mecta-C implants are available in a wide range of sizes and footprints and with either a dome-shaped or flat superior endplate. Mecta-C is also available in two different materials, biocompatible PEEK or osteoconductive Titanium coated PEEK with tantalum spikes and markers to prevent implant migration and to enable comprehensive radiographic assessment.

Both the Mecta-C (PEEK) and the Mecta-C TiPEEK (titanium coated PEEK) implant are radiolucent and enables the surgeon to radiographically monitor the progression to bony fusion. The Mecta-C implant's mechanical structure provides load-bearing capabilities, and the lordotic design restores the anatomic sagittal alignment of the cervical spine.

1.

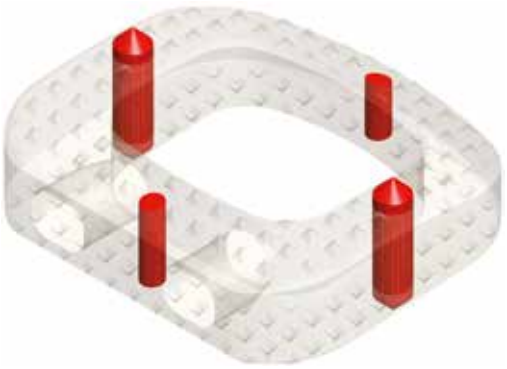
The Mecta-C cervical interbody fusion device has anatomical design features that offer distinctive benefits such as:

- The option of either flat or dome shaped sagittal implant profile for optimal anatomical fit
- Lordotic implants to restore anatomic sagittal alignment
- Mecta-C implants are available in a variety of height options, ranging 4-9mm in 1mm increments
- 5 different footprints to address individual patient anatomy
- Tantalum spikes along with pyramid shaped teeth to provide multi-directional expulsion resistance
- Large central window for maximal bone graft volume
- Available in two versions: PEEK, TiPEEK
- PEEK is radiolucent and optimizes the load transfer between the disc and the adiacent vertebral body and reduces the effect on stress shielding on the graft material
- TiPEEK, is a titanium coated PEEK cage, that combines the features of PEEK with the osteo-conductive properties of titanium
- Fast and secure locking mechanism for cage insertion. The surgeon can select among a versatile Inserter with solid mechanical stop and enhanced in situ visibility

2.

1.1 MATERIALS & MARKERS

- Biocompatible radiolucent PEEK (Polyetheretherketone) allows a clear assessment of bony fusion through the device. PEEK provides an excellent modulus of elasticity and load sharing attributes
- Titanium coating provides osteoconductive features
- Posterior and anterior marker pins allow for a clear radiographic visualization of the device in the coronal and sagittal planes



3.

1.2 INDICATIONS

The Mecta-C PEEK / Mecta-C TiPEEK intervertebral body fusion device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients. The device is designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with supplemental spinal fixation.

The Mecta-C PEEK / Mecta-C TiPEEK device is intended for use at one to three levels in the cervical spine, from C2-T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment, prior to treatment with the device.

1.3 CONTRAINDICATIONS

The Mecta-C implants should not be implanted in patients with active systemic infection or infection localized at the site of implantation.

1.4 PRE-OPERATIVE PLANNING

The review of MRI and/or CT based imaging to template and determine the type/size of the implants in order to match the patient's anatomy is a critical step in the pre-operative planning before each surgery.

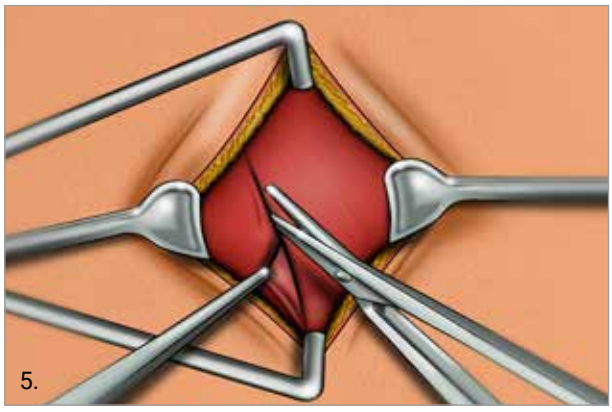
2. SURGICAL TECHNIQUE

2.1 EXPOSURE AND PREPARATION

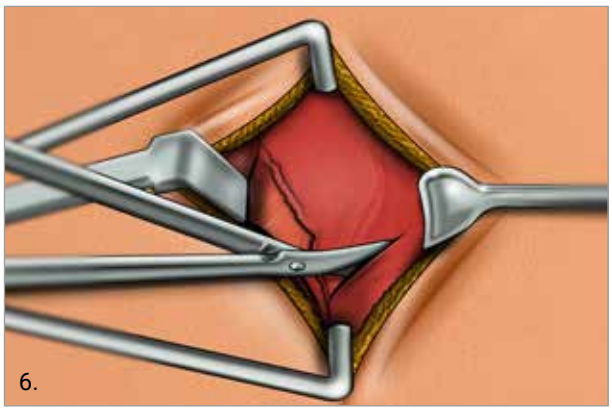
The patient is placed in the supine position with the head slightly extended and resting on an appropriate base. A shoulder bump may be needed to generate the desired amount of cervical lordosis. The arms are secured along the sides of the body. The image intensifier is positioned in such a way to enable adequate intra-operative anteroposterior and lateral imaging.


4.

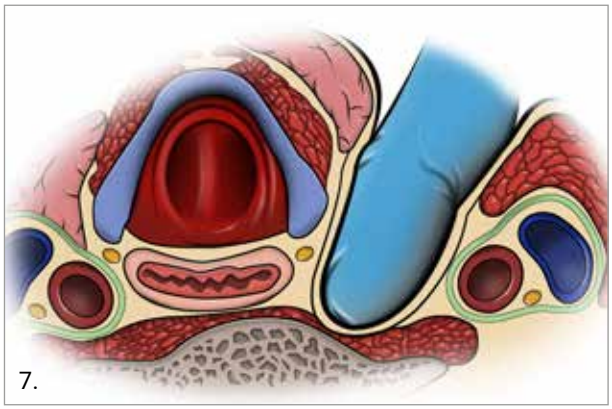
A transverse incision is made along Langer's lines extending approximately from the sternocleidomastoid muscle to the midline. Correct location of the skin incision is accomplished either by using anatomic landmarks or by using image intensifier.


5.

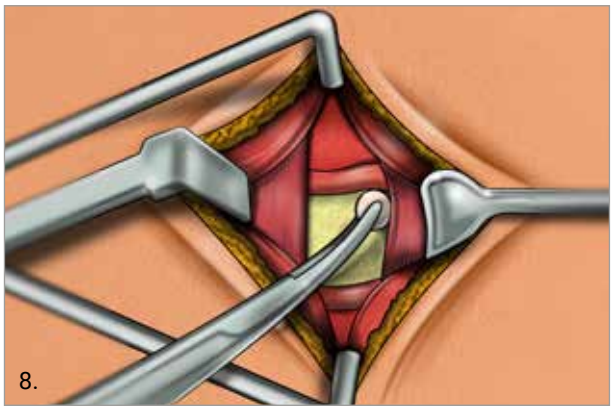
The platysmal layer is then incised either horizontally in line with the incision (shown) or vertically at the discretion of the surgeon.


6.

Incise the pretracheal fascia which allows for retraction of the midline structures. Perform blunt dissection using the index finger to expose the anterior cervical spine.


7.

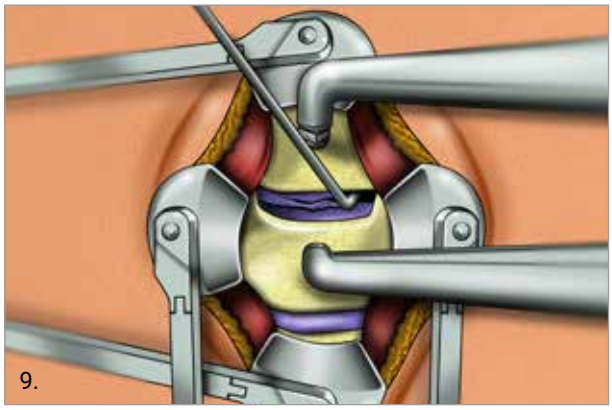
Electrocautery is used to elevate the longus colli muscles. Medio-lateral retractors are placed underneath the longus muscles in order to protect the sympathetic chain. Mark the appropriate disc and perform a lateral X-ray to verify the appropriate level.


8.

2.2 DISC REMOVAL AND PREPARATION OF THE ENDPLATE

For effective visualization and removal of the disc, Caspar Pin distraction, or an equivalent distractor system, is recommended. This step also allows for restoration of segmental lordosis, if desired.

Before distraction of the segment, the intervertebral disc should be incised and partially removed with curettes and pituitary rongeurs . Following distraction, complete removal of intervertebral disc material and cartilaginous endplates is then performed to expose the underlying bony endplate. The Mecta-C Rasp offers a mechanical stop to limit the insertion depth.



9.

NOTE: Overly aggressive endplate preparation may inadvertently violate the bony endplate and compromise the compressive strength of the endplate and should be avoided. If the bony endplate is violated, device subsidence may occur. Whenever possible, always preserve the integrity of the vertebral body endplates.

10.

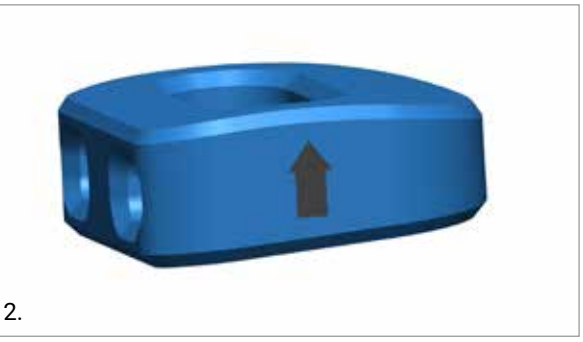
2.3 IMPLANT TRIAL SELECTION

Select the appropriately-sized Lollipop Trial as determined during preoperative planning and as confirmed by intraoperative fluoroscopy. Lollipop Trials are available for the flat implant design, all device heights, and a foot-print of 14x14mm. Optional modular trials are also available which first need to be manually attached to the selected inserter. The set includes two inserters: a standard one and slim version, also called Mecta-C EVO inserter.

11.

Insert the Trial Implant into the disc space by light impaction and confirm proper position, depth, and size with intraoperative fluoroscopy and tactile feel. If the Trial Implant is too loose or too tight, try the next larger/smaller size until a secure fit is achieved. Care should be taken not to overdistract the facet joints which may lead to post-operative neck pain and spasm. After the appropriately-sized Trial Implant has been determined, the comparable size implant is selected.

NOTE: The Dome Shaped Trials have an arrow on the side which points cranially. The trial has to be correctly aligned prior to insertion.



12.

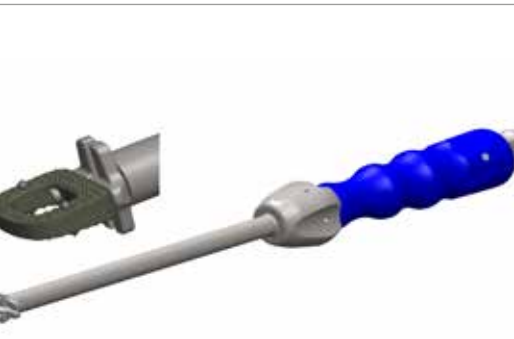
2.4 IMPLANT PLACEMENT

Prepare bone graft for insertion into the device. Gently pack bone graft into the opening of the selected cages using the Filler Block and Bone Tamp. To proceed with the implant insertion select the prefered inserter among the options available in the set: Standard Mecta-C Inserter or Mecta-C EVO inserter.

13.

Standard inserter
Ensure that the Inserter thumb wheel is in the unlocked position. Attach the implant to the Inserter. Turn the thumb wheel 90° to fix the implant firmly to the Inserter. The lock symbol on the thumb wheel should now be aligned with the mark on the handle.

14.



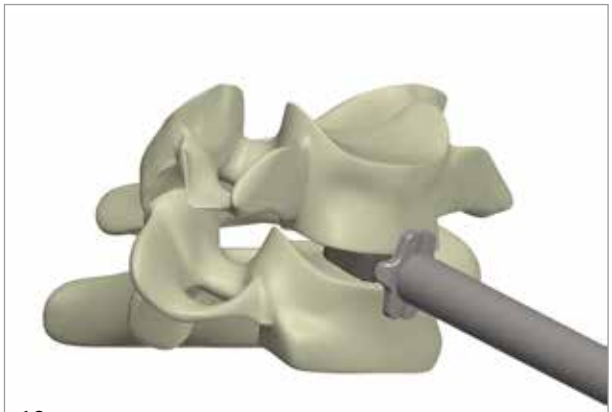
15.

16.

H= Height (mm)
D= Depth (mm)
W= Width (mm)
L= Lordosis (deg°)

17.

Insert the implant straight into the intervertebral disc space by gentle impaction. The stop at the distal end of the Mecta-C Inserter ensures that the implant is not inserted too far into the intervertebral space. The implant should be inserted 1 mm beyond the anterior border of the vertebral bodies and centrally in the antero-posterior direction.



18.

Mecta-C EVO inserter
The set includes a slim Mecta-C EVO inserter. To assemble the cage, screw the inner shaft into the outer shaft by rotating the handle clockwise. Then attach the selected implant to the inserter. To firmly lock the implant, turn the handle clockwise until the inner shaft is in contact with the outer shaft.

Insert the implant straight into the intervertebral disc space by gentle impaction.

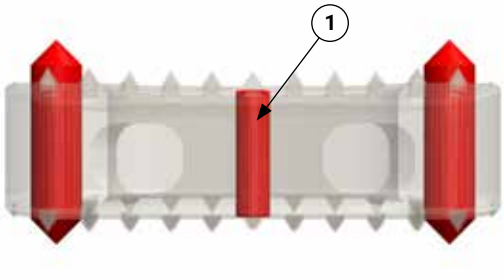
19.

NOTE: The Dome Shaped Implant has a curvature only on the cranial surface whereas the flat implants are symmetrical. The arrow on the anterior aspect of the dome shaped implant indicates the cranial direction. Ensure that the implant is correctly aligned with the arrow pointing upwards.

Relaxing the Caspar Pin distraction reactivates the ligament apparatus which should produces a slight compression of the Mecta-C implant within the intervertebral disc space. Ensure that you have secure fit of the Mecta-C implant after release of the Caspar Pin distraction.
If the Mecta-C implant can be moved slightly in the disc space , there is a risk of migration and the
implant should be replaced with the next larger size.
Check the position of the implant with the image intensifier. If the implant is correctly centered in both planes, the antero-posterior and lateral views should appear similar to the diagrams below.

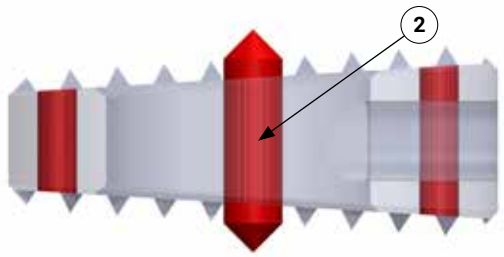
Remove the inserter instrument once the implant position is confirmed to be satisfactory. To detach the standard inserter, turn the thumbwheel until it is in the unlock position. To detach the Mecta-C EVO turn the handle counterclockwise.

A-P view
The anterior and posterior markers of the implant have to overlap each other (1):



20. **AP view**

Lateral view
The two lateral markers have to overlap each other (2)



21. **Lateral view**

NOTE: The Mecta-C Forceps can be used to insert and to remove the implant as an alternative to the Mecta-C inserters.

22.

3. REMOVAL OF AN INCORRECTLY PLACED IMPLANT

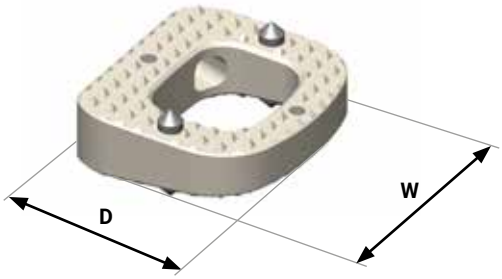
Re-engage the preferred Mecta-C Inserter with the implant and gently remove the implant from its site. Reposition as needed.

4. RECOMMENDED FIXATION OPTIONS

Additional spinal fixation (e.g. Anterior plating) must be applied.

5. IMPLANT NOMENCLATURE

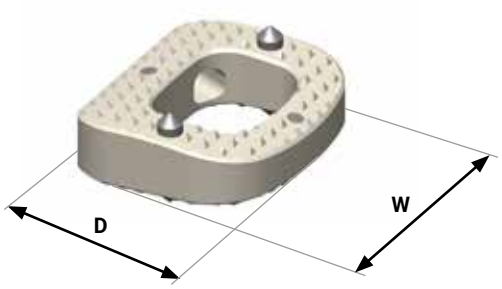
MECTA-C FLAT PEEK



Reference	Size (DxWxH)	Lordosis
03.28.401	12x14x4 mm	7°
03.28.402	12x14x5 mm	
03.28.403	12x14x6 mm	
03.28.404	12x14x7 mm	
03.28.405	12x14x8 mm	
03.28.406	12x14x9 mm	
03.28.407	14x14x4 mm	7°
03.28.408	14x14x5 mm	
03.28.409	14x14x6 mm	
03.28.410	14x14x7 mm	
03.28.411	14x14x8 mm	
03.28.412	14x14x9 mm	
03.28.413*	12x16x4 mm	7°
03.28.414*	12x16x5 mm	
03.28.415*	12x16x6 mm	
03.28.416*	12x16x7 mm	
03.28.417*	12x16x8 mm	
03.28.418*	12x16x9 mm	
03.28.419	14x16x4 mm	7°
03.28.420	14x16x5 mm	
03.28.421	14x16x6 mm	
03.28.422	14x16x7 mm	
03.28.423	14x16x8 mm	
03.28.424	14x16x9 mm	
03.28.425*	15x18x4 mm	7°
03.28.426*	15x18x5 mm	
03.28.427*	15x18x6 mm	
03.28.428*	15x18x7 mm	
03.28.429*	15x18x8 mm	
03.28.430*	15x18x9 mm	

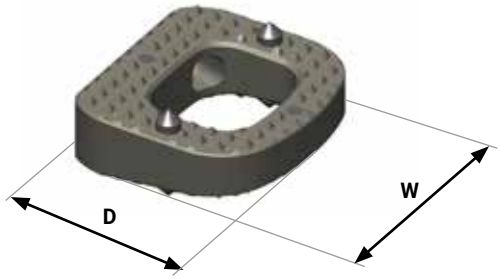
* Special order / request / special forecast

MECTA-C DOME SHAPED PEEK



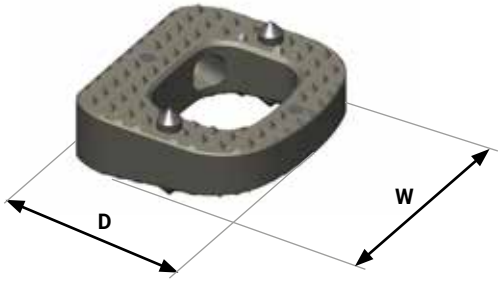
Reference	Size (DxWxH)	Lordosis
03.28.501	12x14x4 mm	5°
03.28.502	12x14x5 mm	
03.28.503	12x14x6 mm	
03.28.504	12x14x7 mm	
03.28.505	12x14x8 mm	
03.28.506	12x14x9 mm	
03.28.507	14x14x4 mm	5°
03.28.508	14x14x5 mm	
03.28.509	14x14x6 mm	
03.28.510	14x14x7 mm	
03.28.511	14x14x8 mm	
03.28.512	14x14x9 mm	
03.28.513*	12x16x4 mm	5°
03.28.514*	12x16x5 mm	
03.28.515*	12x16x6 mm	
03.28.516*	12x16x7 mm	
03.28.517*	12x16x8 mm	
03.28.518*	12x16x9 mm	
03.28.519	14x16x4 mm	5°
03.28.520	14x16x5 mm	
03.28.521	14x16x6 mm	
03.28.522	14x16x7 mm	
03.28.523	14x16x8 mm	
03.28.524	14x16x9 mm	
03.28.525*	15x18x4 mm	5°
03.28.526*	15x18x5 mm	
03.28.527*	15x18x6 mm	
03.28.528*	15x18x7 mm	
03.28.529*	15x18x8 mm	
03.28.530*	15x18x9 mm	

MECTA-C FLAT TIPEEK



Reference	Size (DxWxH)	Lordosis
03.28.601	12x14x4 mm	7°
03.28.602	12x14x5 mm	
03.28.603	12x14x6 mm	
03.28.604	12x14x7 mm	
03.28.605	12x14x8 mm	
03.28.606	12x14x9 mm	
03.28.607	14x14x4 mm	7°
03.28.608	14x14x5 mm	
03.28.609	14x14x6 mm	
03.28.610	14x14x7 mm	
03.28.611	14x14x8 mm	
03.28.612	14x14x9 mm	
03.28.613*	12x16x4 mm	7°
03.28.614*	12x16x5 mm	
03.28.615*	12x16x6 mm	
03.28.616*	12x16x7 mm	
03.28.617*	12x16x8 mm	
03.28.618*	12x16x9 mm	
03.28.619	14x16x4 mm	7°
03.28.620	14x16x5 mm	
03.28.621	14x16x6 mm	
03.28.622	14x16x7 mm	
03.28.623	14x16x8 mm	
03.28.624	14x16x9 mm	
03.28.625*	15x18x4 mm	7°
03.28.626*	15x18x5 mm	
03.28.627*	15x18x6 mm	
03.28.628*	15x18x7 mm	
03.28.629*	15x18x8 mm	
03.28.630*	15x18x9 mm	

MECTA-C DOME SHAPED TIPEEK



Reference	Size (DxWxH)	Lordosis
03.28.701	12x14x4 mm	5°
03.28.702	12x14x5 mm	
03.28.703	12x14x6 mm	
03.28.704	12x14x7 mm	
03.28.705	12x14x8 mm	
03.28.706	12x14x9 mm	
03.28.707	14x14x4 mm	5°
03.28.708	14x14x5 mm	
03.28.709	14x14x6 mm	
03.28.710	14x14x7 mm	
03.28.711	14x14x8 mm	
03.28.712	14x14x9 mm	
03.28.713*	12x16x4 mm	5°
03.28.714*	12x16x5 mm	
03.28.715*	12x16x6 mm	
03.28.716*	12x16x7 mm	
03.28.717*	12x16x8 mm	
03.28.718*	12x16x9 mm	
03.28.719	14x16x4 mm	5°
03.28.720	14x16x5 mm	
03.28.721	14x16x6 mm	
03.28.722	14x16x7 mm	
03.28.723	14x16x8 mm	
03.28.724	14x16x9 mm	
03.28.725*	15x18x4 mm	5°
03.28.726*	15x18x5 mm	
03.28.727*	15x18x6 mm	
03.28.728*	15x18x7 mm	
03.28.729*	15x18x8 mm	
03.28.730*	15x18x9 mm	

* Special order / request / special forecast

Part numbers subject to change.

NOTE FOR STERILISATION

In case the instrumentation is not sterile upon delivery, it must be cleaned before use and sterilized in an autoclave, respecting the regulations of the country, EU directives where applicable, and following the manufacturer's instructions for use of the autoclave. For detailed instructions, please refer to the document "Recommendations for cleaning, decontamination and sterilization of Medacta International reusable orthopaedic devices" available at www.medacta.com.

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