Valid on 04 Aug 2023

MectaLIF® TRANSFORAMINAL

LUMBAR INTERBODY FUSION DEVICE

MODULAR DESIGN OFFERS FREEDOM OF CHOICE

Surgical Technique

Joint | **Spine** | Sports Med

Medacta International

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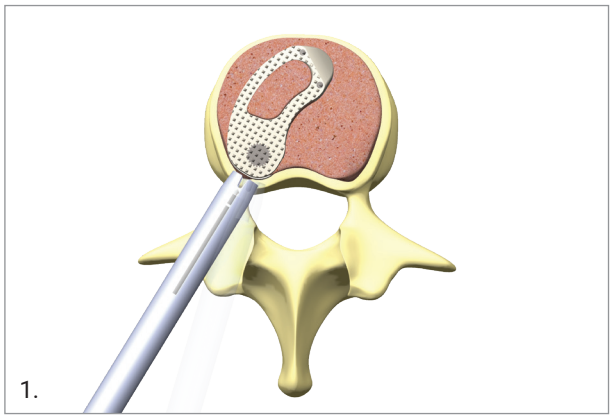
1. INTRODUCTION

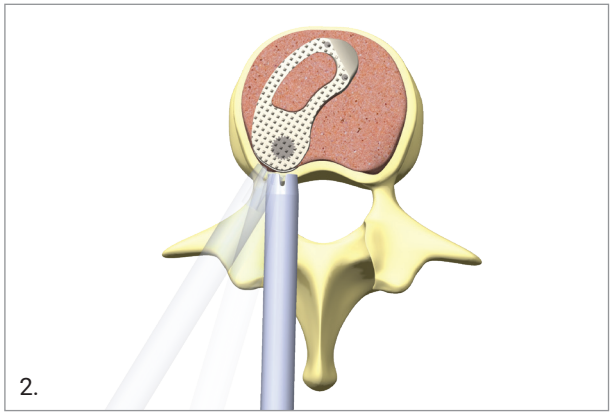
The anatomical design of our MectaLIF Intervertebral Body Fusion Device matches the given biological conditions in each patient and pathology and meets the requirements of the treating surgeon. The PLIF procedure, popularized in the 1950's and 1960's by Cloward, who inserted iliac crest bone into the intervertebral disc space, lost popularity because of the complication rate and technical difficulties. In the 1980's spacers made of titanium or carbon fiber reinforced PEEK were designed to overcome these challenges.

The recent development of the Transforaminal Lumbar Interbody Fusion (TLIF) technique, first described by Professor Harms and Doctor Jeszenszky, offers the benefit of a 360° fusion utilizing a unilateral posterior-only approach. The TLIF technique can therefore be considered as less invasive compared to the PLIF with similar result.

Our unique MectaLIF Transforaminal system with its titanium gear interfacing with the inserter at variable angles from 0-60° enables the surgeon to alter the angle of the cage in situ in 15° increments and to reposition during surgery without switching instrumentation. This feature is very beneficial for both open and MIS-surgery and ensures constant control during implant positioning without the need to disengage the inserter instrument, in order to optimize implant positioning in both the coronal and sagittal planes.



1.



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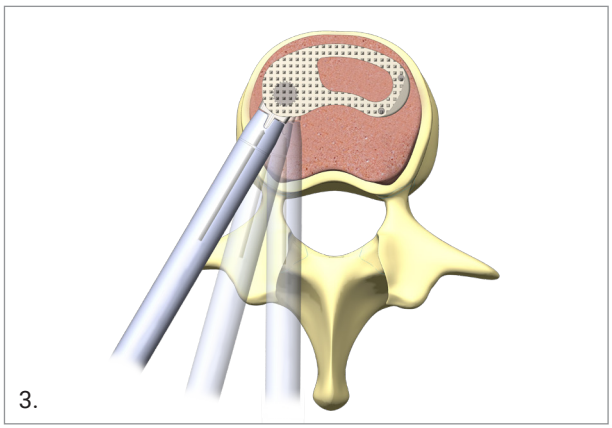


3.

Other features include:

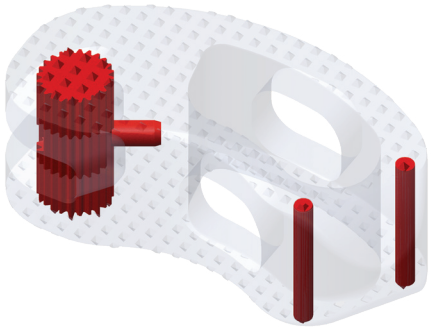
- The locking mechanism enables fast and secure, single handed locking of the implant to the inserter
- Bi-convex superior/inferior surface to match the natural anatomy of the endplates
- Curved anatomical-like design to facilitate an optimal load transfer and maximize the implant endplate contact
- Large central as well as lateral window to receive filling material (bone graft or substitute) to accelerate the occurrence of fusion through the implant
- Bullet nosed tip to aid insertion in tight spaces in a reproducible and controlled way
- Radiopaque marker pins located on the distal edge of the implant, and a gear located proximally, enables radiographic visualization of implant position
- Shapes ranging from parallel to lordotic to restore natural sagittal alignment
- Pyramid shaped teeth-surface, superior and inferior of the implant designed for enhanced stability and to prevent implant migration

Available in Peek and Peek Titanium coated (Ti-PEEK):

- PEEK, radiolucent and optimizes the load transfer between the cage and the adjacent vertebral bodies and reduces the affects of stress shielding on the graft material
- TiPEEK, is a titanium coated PEEK cage that combines the features from PEEK with the osteo-conductive features of titanium.

1.1 MATERIALS & MARKERS

- Biocompatible radiolucent PEEK with a favorable modulus of elasticity allows a clear assessment of bony fusion through the device
- Radiopaque marker pins and in the gear allow easy and clear visualization
- TiPEEK, is a titanium coated PEEK cage that combines the features from PEEK with the features of titanium. Titanium coating provides osteoconductive features



4.

1.2 INDICATIONS

The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

The MectaLIF Transforaminal Intervertebral Body Fusion Device can be used either with an open or a minimally invasive technique.

1.3 CONTRAINDICATIONS

The MectaLIF Transforaminal Intervertebral Body Fusion Device in combination with a pedicle screw system should not be implanted in patients with active systemic infection or infection localized to the site of implantation.

1.4 PRE-OPERATIVE PLANNING

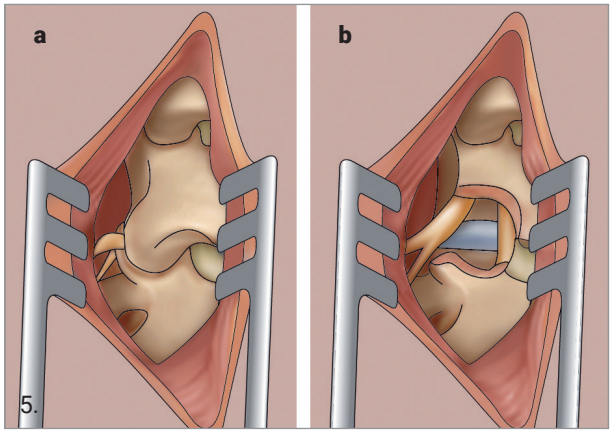
Prior to any surgical implantation of the device, it is critical to evaluate the patient's pre-operative MRI and/or CT to template and determine the most appropriate size and type of implant to be used so as to match the patient's anatomy.

2. SURGICAL TECHNIQUE TRANSFORAMINAL - TLIF

2.1 EXPOSURE AND PREPARATION - TLIF

The TLIF technique can be performed via an open, mini-open or minimally-invasive approach. Start the skin incision and dissection laterally from the midline. Locate the spinous process and the lamina of the corresponding operative level(s) (A). Prepare a window for transforaminal approach, using an osteotome or drill, to remove the inferior articular facet of the cranial vertebra and the superior articular facet of the caudal vertebra (B). Additional bone removal may be carried out using a Kerrison rongeur.

CAUTION
Ensure protection of the neural elements by using the appropriate retractors.



5.

Divide the ligamentum flavum from the inferior portion of the lamina. Expose the traversing nerve root and dural tube from the soft tissue, then probe with ball point instrument. Gently retract the nerve root and the dural tube medially. Then create the annular window with an annulus knife in standard fashion.

To facilitate distraction during disc space preparation, pedicle screws and distraction rod can be inserted on the contralateral side, with or without concomitant use of a laminar spreader.

Use a combination of curettes, pituitary rongeurs, and shavers to remove the disc material and the cartilaginous endplate from both vertebral bodies.

NOTE
Thorough endplate preparation consisting of removal of soft tissue and cartilaginous endplate is essential to obtain good vascularization of the bone graft.

WARNING
Excessive endplate preparation can weaken the endplates and predispose to fracture or device subsidence. It is therefore of paramount importance to remove only the cartilaginous portion of the endplates, and to maintain the integrity of the underlying bony endplates wich provides compressive resistance.

Following endplate preparation, the remaining critical steps include adequate removal of extruded disc fragments, adequate decompression of the traversing and exiting nerve roots, and to provide entry to the disc space for distraction with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.

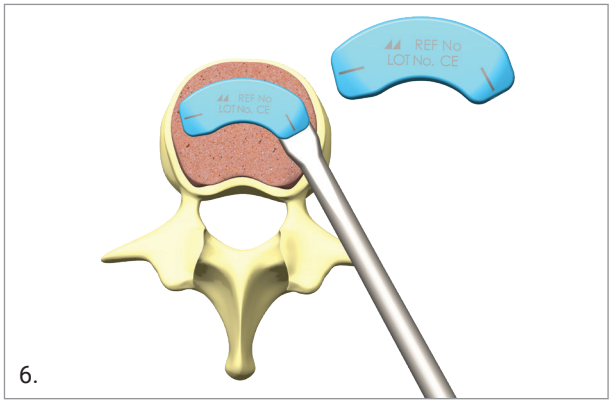
CAUTION
Be sure to remove osteophytes and posterior lips of the adjacent vertebral body with an osteotome so as to avoid neural impingement or graft malalignment.

The disc space is sequentially distracted until adequate disc space height is obtained and desired foraminal heights are restored. Insert the distracters with the curved sides touching the endplates. Insert distracters sequentially until the desired height is obtained.

WARNING
It is critical to ensure that the segment is not overdistracted.

2.2 TRIAL INSERTION - TLIF

For insertion of the Trials the MectaLIF Posterior inserter shall be used. Each Trial has one threaded hole on both sides corresponding to 15° and 60°.



6.

Select the angle desired and the size of the Trial implant as determined during preoperative templating and confirmed intraoperatively by fluoroscopy and secure it to the MectaLIF Posterior Handle/Inner Rod assembly.

Insert the Trial implant into the disc space by light impaction and confirm the proper position with the aid of anterior-posterior and lateral fluoroscopy. If the Trial implant is too loose or too tight, try the next larger/smaller size until a secure fit is achieved. Using the largest possible implant improves stability by creating tension on the ligaments and the remaining annulus fibrosus.

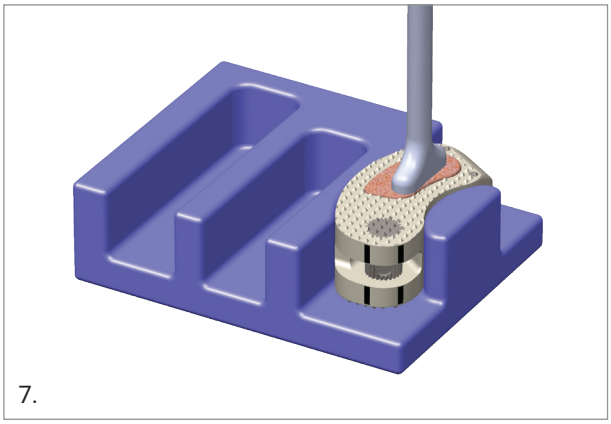
Remove the Trial implant assembly and select the matching implant. If necessary, the Slap Hammer or the Slotted Hammer is available to assist in safe removal of the Trial implant.

2.3 IMPLANT PLACEMENT - TLIF

Prepare autologous bone graft and/or synthetic bone graft substitute. Mixed with autologous bone graft and/or freshly aspirated bone marrow; place it at the anterior rim of the intervertebral body and impact it gently before inserting the implant.

Gently pack bone graft and/or synthetic bone graft substitute into the opening of the cage using the filler block and bone tamp.

Different shapes of bone graft impactors are available in the set.



7.

Beside the standard MectaLIF Transforaminal inserter, the Enhanced MectaLIF Transforaminal inserter is available. The main difference between the inserters is the locking mechanism used to engage and disengage the cage (Fig. 8 - 9).

Assemble the MectaLIF Transforminal Inserter (see Chapter 5 for further details).

Standard MectaLIF Transforaminal Inserter:

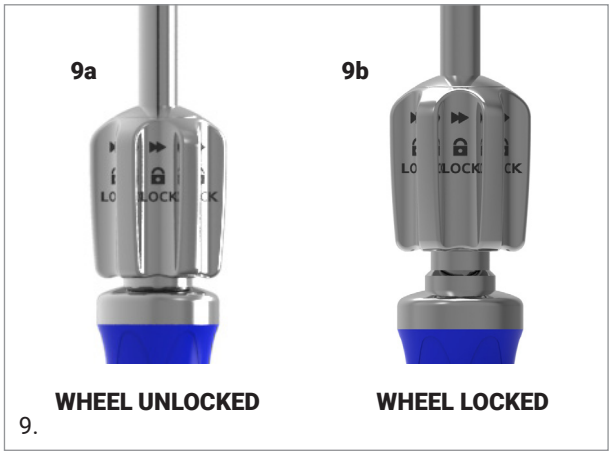
To attach the implant to the Inserter, turn the thumb wheel to the open position and attach the implant between the marks indicated on the implant. Turn the thumb wheel on the instrument 90° to lock the Inserter to the implant.

WHEEL UNLOCKED **WHEEL LOCKED**

8.

Enhanced MectaLIF Transforaminal Inserter:

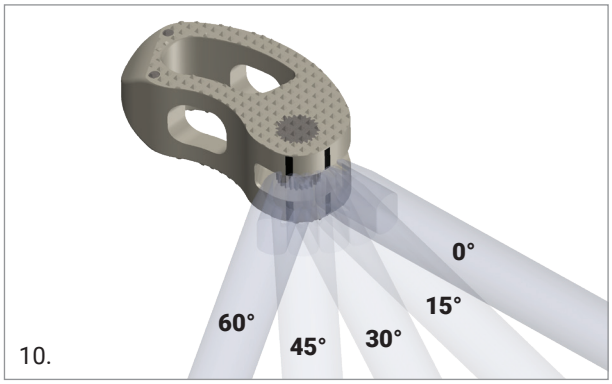
To attach the implant to the Inserter, turn the thumbwheel clockwise until it reaches the lowest position (Fig. 9a). Attach the inserter between the marks indicated on the implant. Turn the thumbwheel counterclockwise to lock the implant. When the thumbwheel reaches the highest position (Fig. 9b) the cage is properly engaged.



WHEEL UNLOCKED **WHEEL LOCKED**

9.

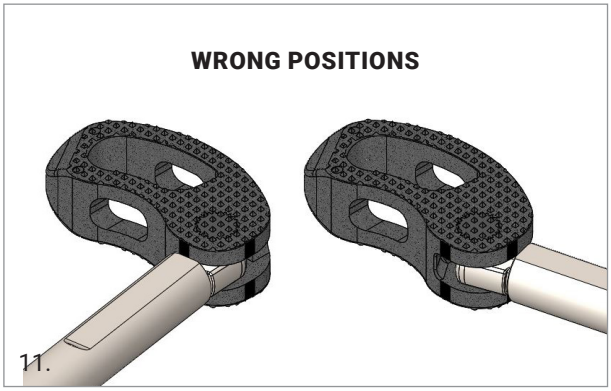
The angle can be altered between 0° to 60° in 15° increments at any time during surgery.



10.

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

CAUTION
Do not force the inserter beyond the final positioning markers. This could cause deformation of the Inserter tip.



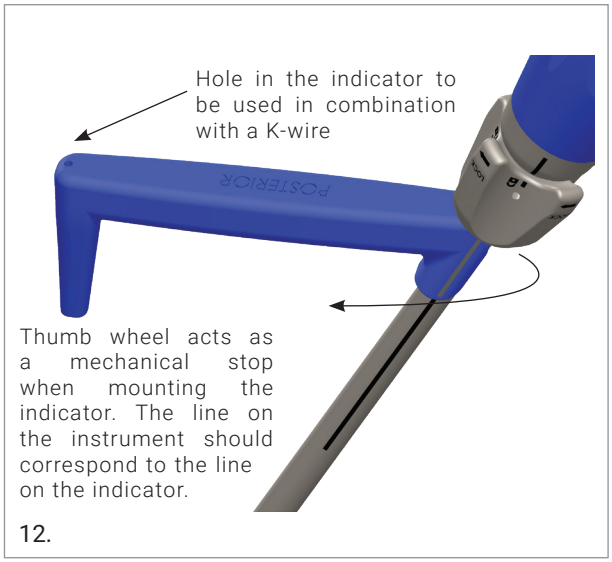
11.

CAUTION
For final positioning use the transforaminal implant impactor if needed.

CAUTION
Protect the nerve root and thecal sac with a suitable instrument.

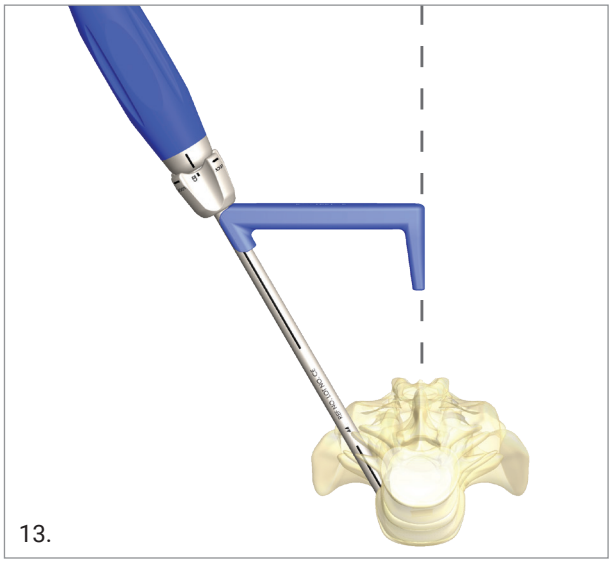
The Implant Position Indicator will assist to determine the position of the implant in-situ. Snap on the implant position indicator on the shaft of the inserter (Standard or Enhanced) and slide it as close to the turning wheel as possible.

NOTE
The markings on the inserter should correspond to the markings on the Implant Position Indicator.



12.

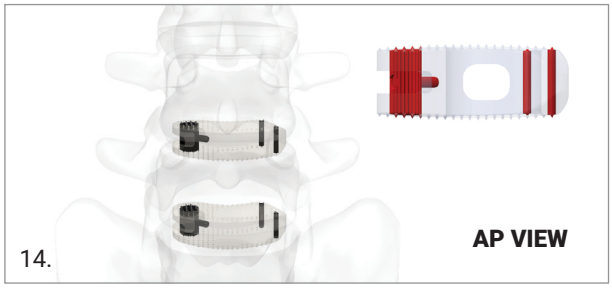
The proximal tip of the implant position indicator will point at the spinous process and center of the implant, when the 60° position is being used.


13.

3. RADIOGRAPHIC POSITIONING

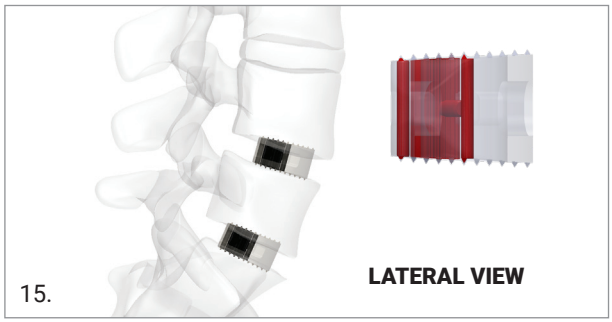
Confirm the implant is correctly positioned via radiographic imaging.

Correct AP View. The distance between the two markers and the gear should be equal when the implant is positioned perfectly centered (dimension a, figure below).



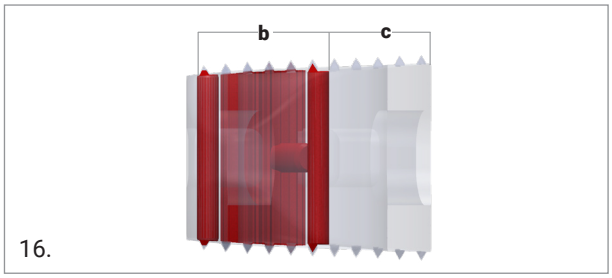
14.

Correct Lateral view. The implant appears as in figure below. The gear should be centered between the two markers when the implant is properly positioned.



15.

The table below reports the related dimensions of the radiolucent / radiopaque portions of the cage, depending on the footprint.



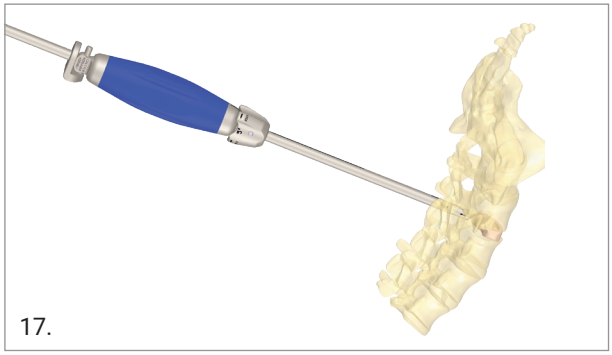
16.

FOOTPRINT (mm)	B (mm)	C (mm)
30x12	9.1	4.4
30x14		6.0
34x12		5.7
34x14		7.0

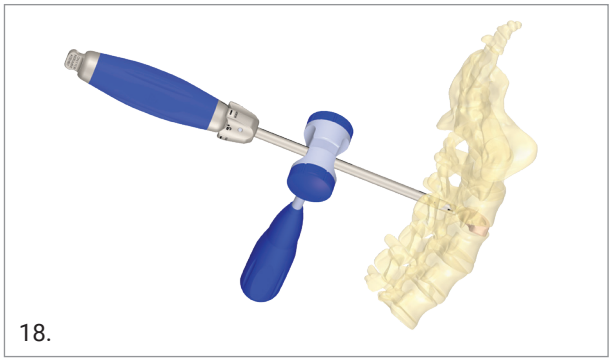
If necessary tap the implant into position with the Implant Impactor and the Slotted Hammer.

4. IMPLANT REMOVAL

Attach the MectaLIF Transforaminal Inserter to the implant and remove the implant from its site. Use the Slap Hammer or the Slotted Hammer to assist in safe removal of the implant.



17.



18.

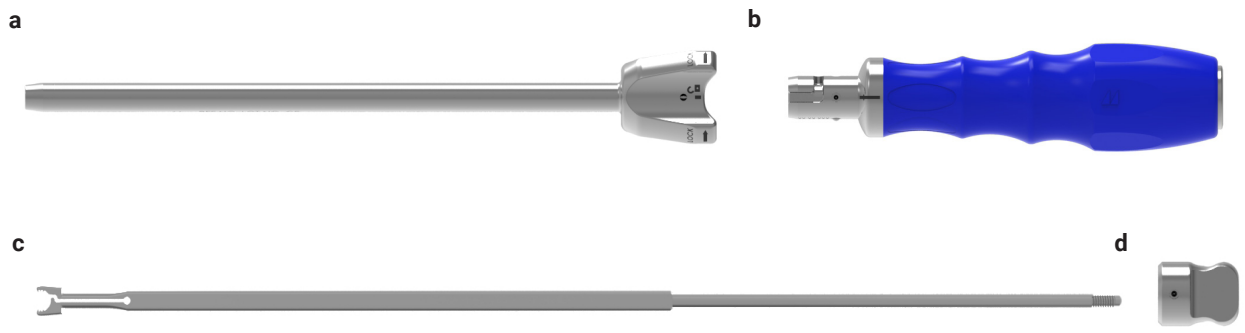
For any further information related to the MectaLIF Intervertebral Body Fusion Devices please refer to the package insert.

The MectaLIF Transforaminal implants are supplied sterile in single-use packages and should never be re-used. MectaLIF TransForaminal Inserter - Assembly Instructions

5. MECTALIF TRANSFORAMINAL INSERTERS - ASSEMBLY INSTRUCTIONS

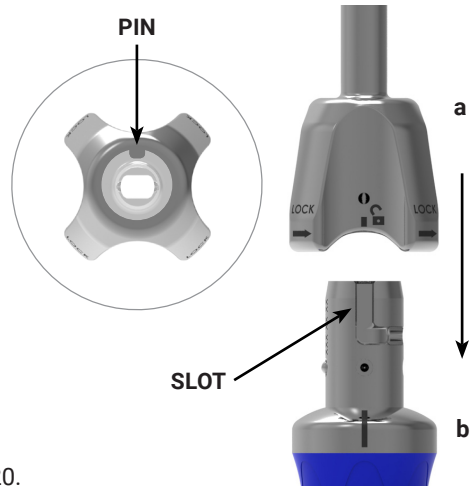
5.1 STANDARD MECTALIF TRANSFORAMINAL INSERTER

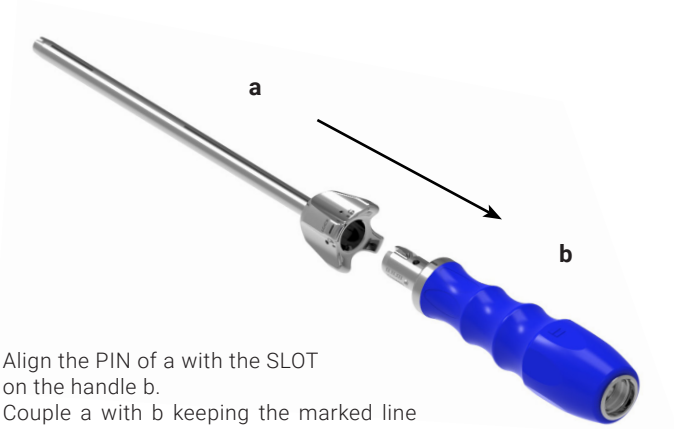
COMPONENTS



19.

ASSEMBLY STEP 1

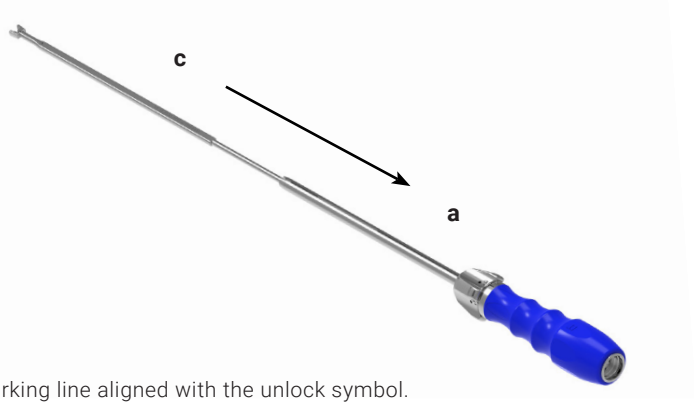




Align the PIN of a with the SLOT on the handle b.
Couple a with b keeping the marked line on b aligned with the unlock symbol.

20.

ASSEMBLY STEP 2



Keep the marking line aligned with the unlock symbol.
Insert part c in part a.

21.

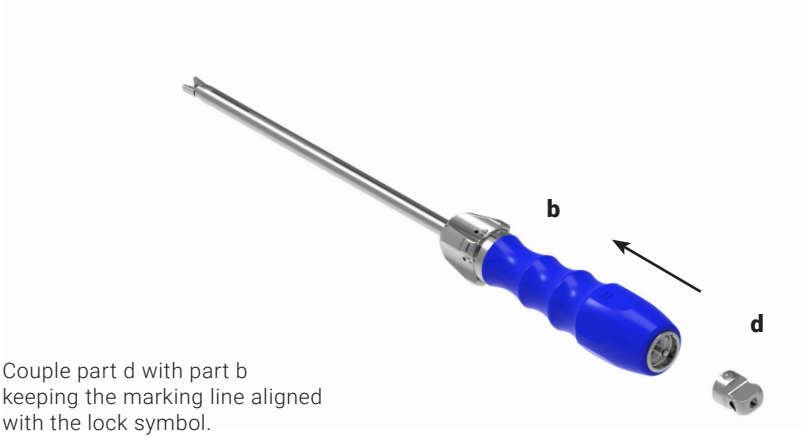
ASSEMBLY STEP 3

Lock before next step

Rotate part a on part b moving the marking line from unlock symbol to the lock symbol.

22.

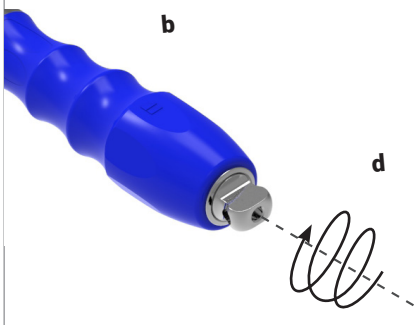
ASSEMBLY STEP 4



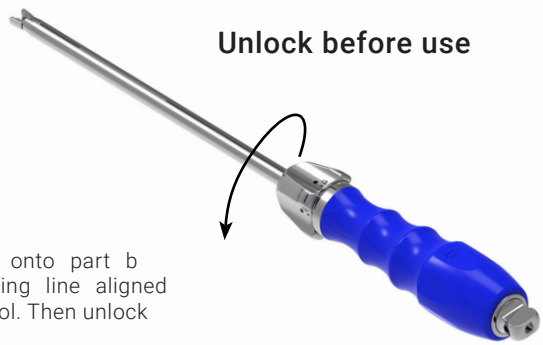
Couple part d with part b keeping the marking line aligned with the lock symbol.

23.

ASSEMBLY STEP 5



Unlock before use

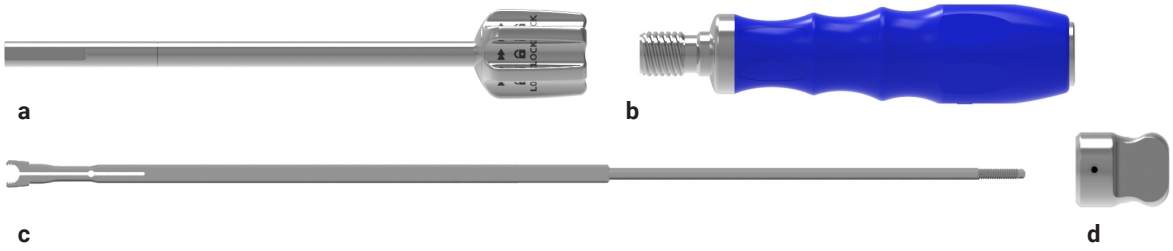


Screw on part d onto part b keeping the marking line aligned with the lock symbol. Then unlock it before use.

24.

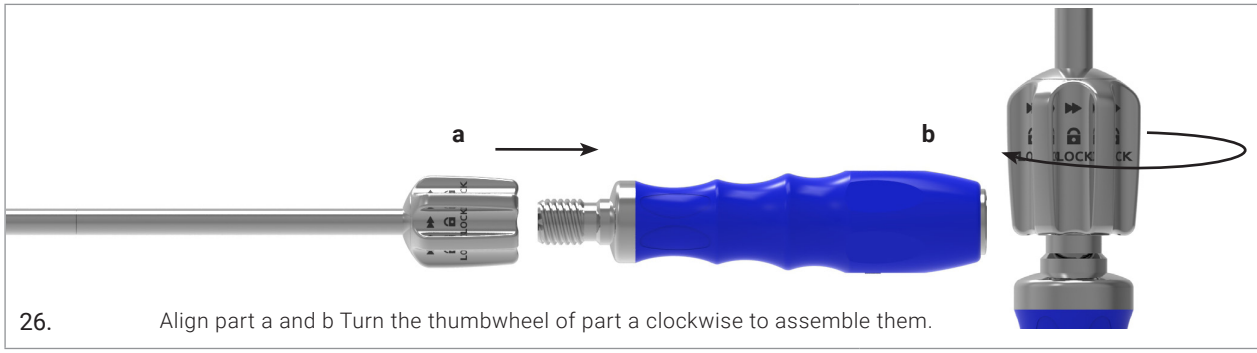
5.2 ENHANCED MECTALIF TRANSFORAMINAL INSERTER

COMPONENTS



25.

ASSEMBLY STEP 1

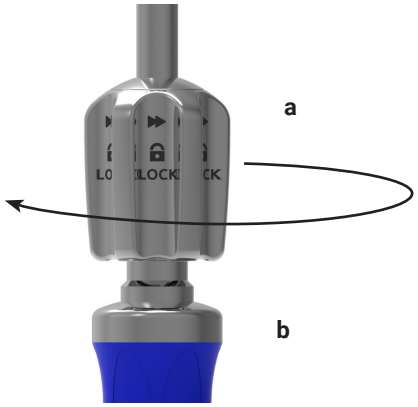


26. Align part a and b Turn the thumbwheel of part a clockwise to assemble them.

ASSEMBLY STEP 2

27. Insert part c into part a

ASSEMBLY STEP 3



28.

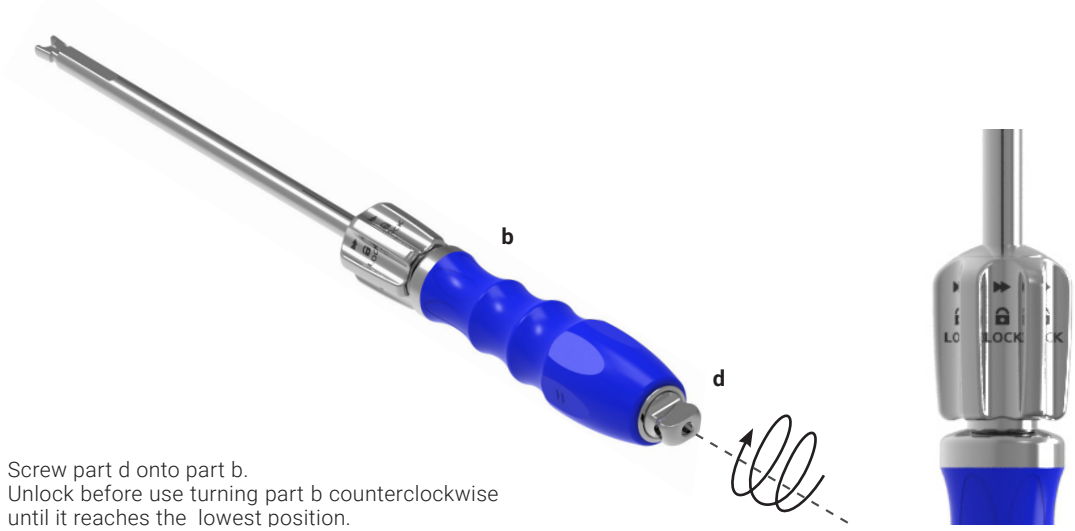
Lock before next step.

Rotate part a clockwise on part b, until the thumbwheel reaches the highest position

ASSEMBLY STEP 4

29. Couple part c with part d.

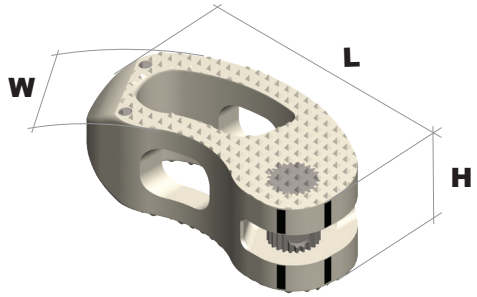
ASSEMBLY STEP 5



30. Screw part d onto part b.
Unlock before use turning part b counterclockwise until it reaches the lowest position.

6. IMPLANT NOMENCLATURE

MECTALIF TRANSFORAMINAL PEEK



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03.23.058	12x30x14	
03.23.055	12x30x15	
03.23.061	14x30x8	5°
03.23.062	14x30x9	
03.23.066	14x30x10	
03.23.063	14x30x11	
03.23.067	14x30x12	
03.23.064	14x30x13	
03.23.068	14x30x14	
03.23.065	14x30x15	
03.23.071	12x34x8	5°
03.23.072	12x34x9	
03.23.076	12x34x10	
03.23.073	12x34x11	
03.23.077	12x34x12	
03.23.074	12x34x13	
03.23.078	12x34x14	
03.23.075	12x34x15	
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03.23.082	14x34x9	
03.23.086	14x34x10	
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03.23.087	14x34x12	
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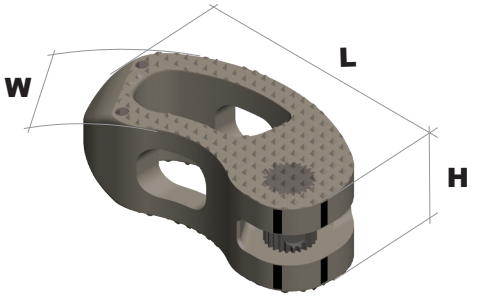
03.23.088	14x34x14	
03.23.085	14x34x15	

MECATALIF TRANSFORAMINAL TiPEEK



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03.23.154	12x30x13	
03.23.158	12x30x14	
03.23.155	12x30x15	
03.23.161	14x30x8	5°
03.23.162	14x30x9	
03.23.166	14x30x10	
03.23.163	14x30x11	
03.23.167	14x30x12	
03.23.164	14x30x13	
03.23.168	14x30x14	
03.23.165	14x30x15	
03.23.171	12x34x8	5°
03.23.172	12x34x9	
03.23.176	12x34x10	
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03.23.177	12x34x12	
03.23.174	12x34x13	
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03.23.183	14x34x11	
03.23.187	14x34x12	
03.23.184	14x34x13	
03.23.188	14x34x14	
03.23.185	14x34x15	

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilised in an autoclave respecting the regulations of the country EU, directives where applicable and following the instruction for use of the autoclave manufacturer. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices" available at www.medacta.com.

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