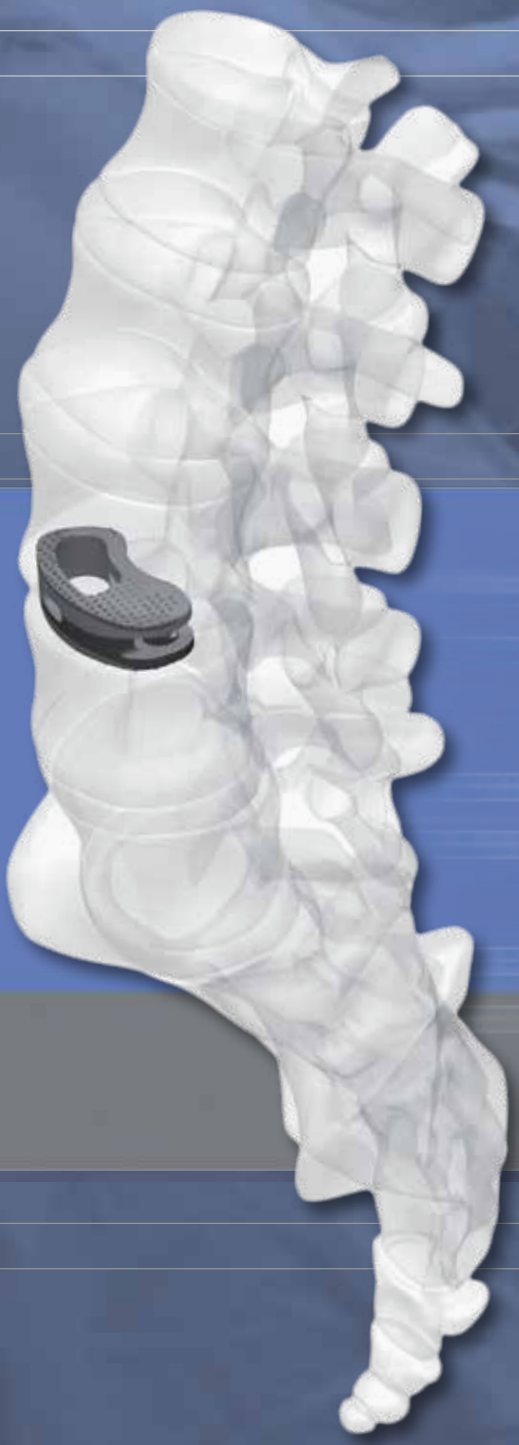
MectaLIF® TRANSFORAMINAL

INTERVERTEBRAL BODY FUSION DEVICE



Surgical Technique

Hip | Knee | Spine | Navigation

Medacta International

CAUTION

Federal law (USA) restricts this device to sale distrribution and use by or on the order of a physician.

ACKNOWLEDGMENTS

Medacta International would like to express its gratitude to

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for their valuable contributions in the development of the MectaLIF implants, instruments and the surgical technique.

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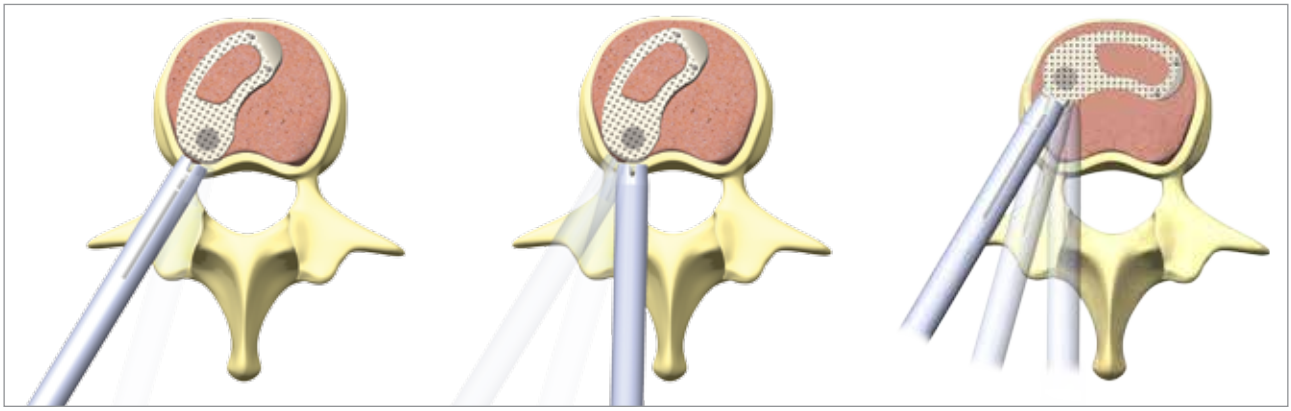
1 INTRODUCTION

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 Prof. Harms and Dr. 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.



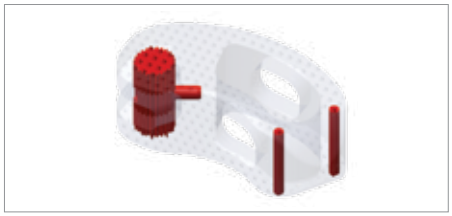
Features include:

- 90° 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
- Bullet nosed tip to aid insertion in tight spaces in a reproducible and controlled way
- Large central as well as lateral window to receive filling material (bone graft or substitute) to accelerate the occurrence of fusion through the implant
- Radiopaque marker pins located on the distal edge of the implant and a gear located proximally enable radiographic visualization of implant position
- Pyramid shaped teeth-surface, superior and inferior of the implant designed for enhanced stability and to prevent implant migration
- Shapes ranging from parallel to lordotic to restore natural sagittal alignment
- 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

Please read the instructions for use thoroughly and, should you have any questions concerning product compatibility, contact your Medacta representative.

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



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. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

3 CONTRAINDICATIONS

The MectaLIF Transforaminal System, 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.

Please see the package insert for the full list of indications, contra-indications, precautions and warnings.

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 to match the patient's anatomy.

5 SURGICAL TECHNIQUE TRANSFORAMINAL - TLIF

5.1 Exposure and Preparation - TLIF

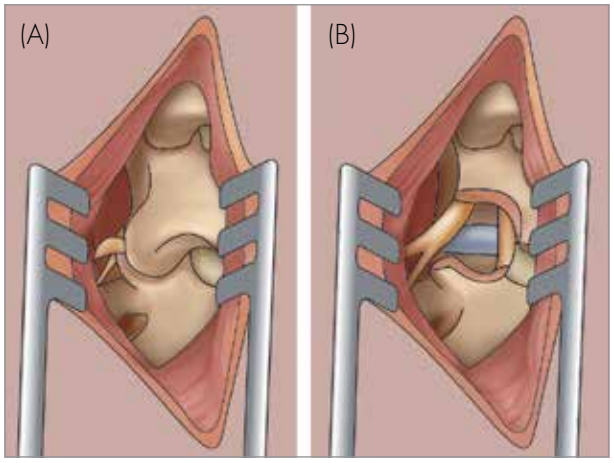
The TLIF technique can be performed via an open, mini-open or minimally-invasive approach.

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.

Additional bone removal may be carried out using a Kerrison rongeur.



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 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.

WARNING

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

CAUTION

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.

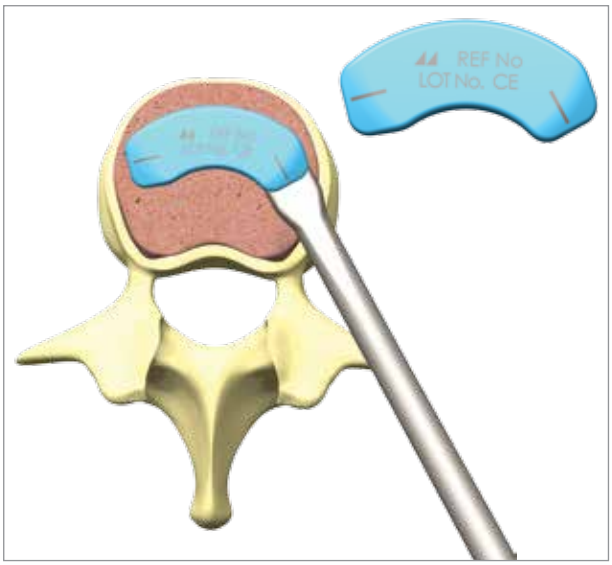
The disc space is sequentially distracted until adequate disc space height is obtained and desired foraminal heights are restored. Insert the distractors with the curved sides touching the endplates. Insert distractors sequentially until the desired height is obtained. It is critical to ensure that the segment is not overdistracted.

WARNING

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

5.2 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°.



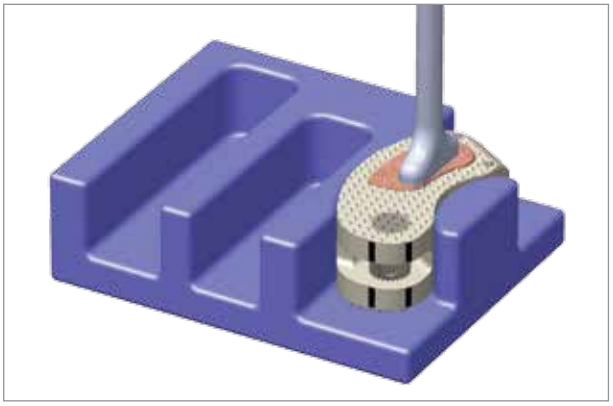
Select the angle desired and the size of the Trial implant as determined during preoperative templating and confirmed intraoperatively by fluoroscopy and secure it to the MectaLIF Posterior Handle/Inner Rod assembly. Insert the Trial implant into the disc space by light impaction and confirm the proper 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 / Slotted Hammer is available to assist in safe removal of the Trial implant.

5.3 Implant Placement - TLIF

Prepare 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.

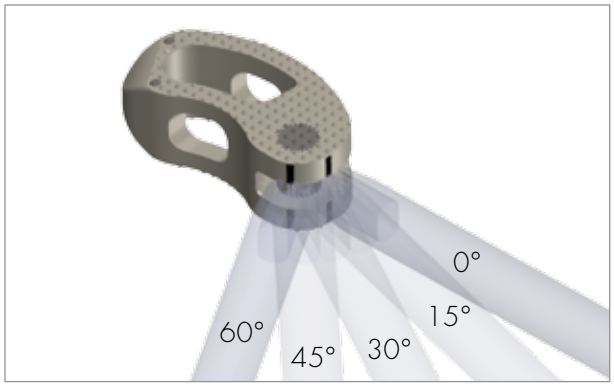
Gently pack bone graft into the opening of the cage using the Bone Filler Block and the Flat Bone Graft Impactor.
Different shapes of bone graft impactors are available in the set.



Assemble the MectaLIF Transforminal Inserter (Page 15).
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

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



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.

CAUTION

For final positioning use the transforaminal implant impactor if needed.

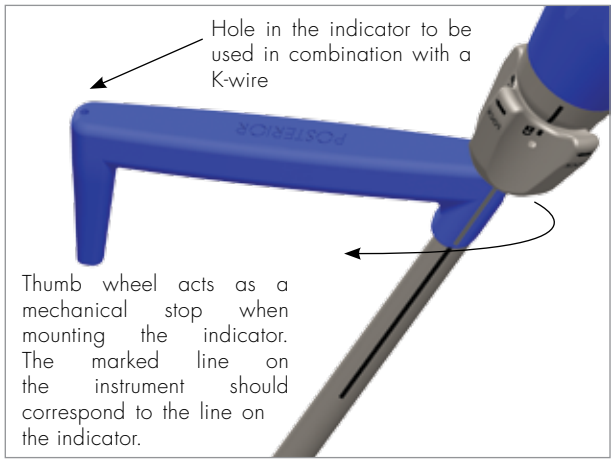
CAUTION

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

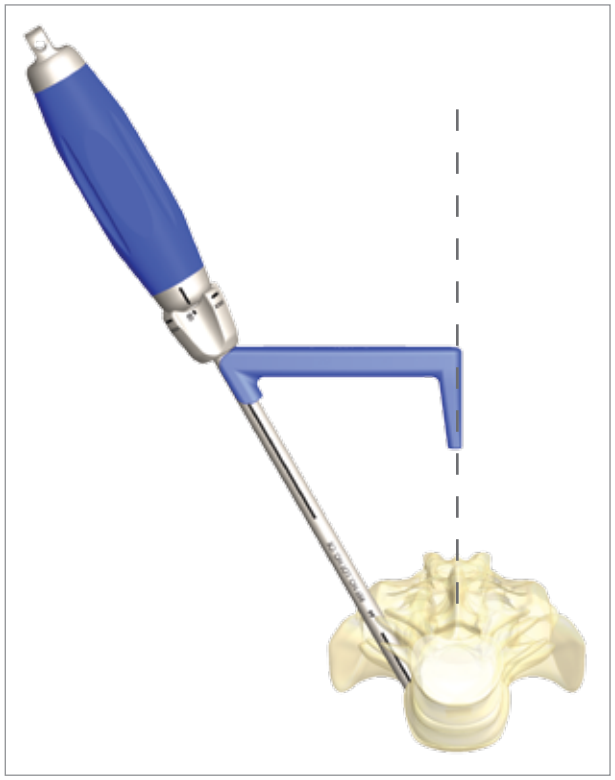
The Implant Position Indicator will assist to determine the position of the implant in-situ. Snap on the implant position indicator on the shaft of the inserter and slide it as close to the turning wheel as possible.

NOTICE

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



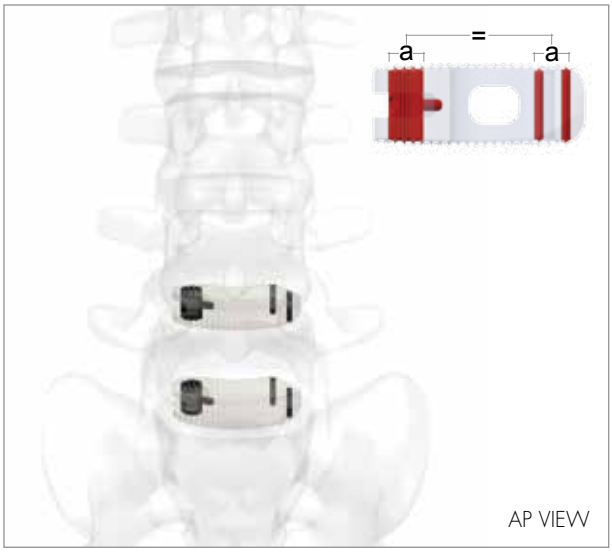
The tip of the implant position indicator will point at the spinous process and center of the implant, when the 60° angle is set.
The hole of the tip can be used in combination with a K-wire.



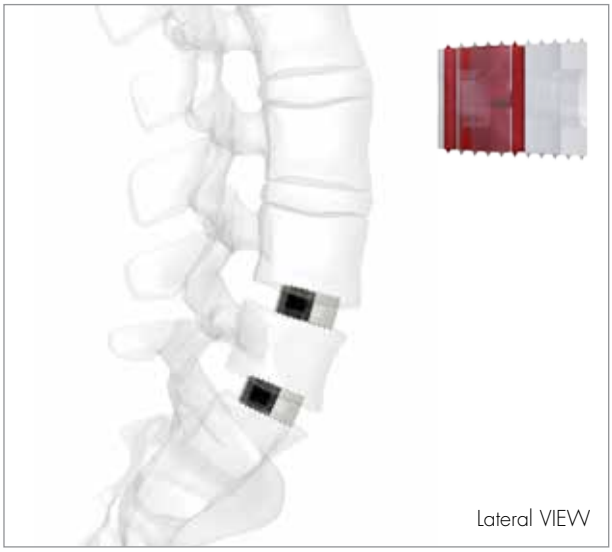
6 RADIOGRAPHIC POSITIONING

Confirm the implant is correctly positioned via radiographic imaging.

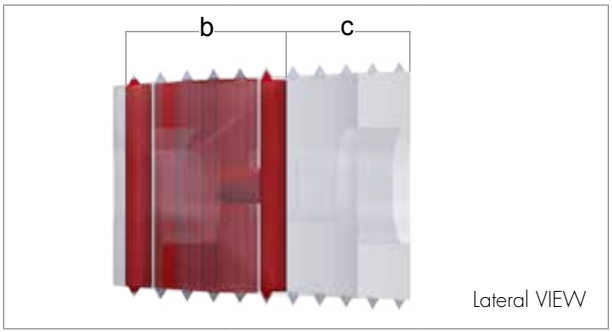
Correct AP View. The distance between the two markers and the gear should be equal when the implant is positioned perfectly centered (dimension a, figure below).



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.



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



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.

7 REMOVAL OF AN INCORRECTLY PLACED IMPLANT

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.

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.

8 RECOMMENDED FIXATION OPTIONS

Supplemental posterior spinal fixation e.g. pedicle screw fixation must be applied.

9 INSTRUMENTATION NOMENCLATURE

TLIF INSTRUMENTATION SET

Ref.	Description	
03.22.10.0013	Bone Filler Block	
03.22.10.0014 03.22.10.0271	Slotted Hammer	
03.22.10.0019 03.22.10.0266	Bone Graft Impactor - Straight	
03.22.10.0020 03.22.10.0267	Bone Graft Impactor - Curved	
03.22.10.0022 03.22.10.0269	Bone Graft Impactor - Flat	
03.22.10.0055	Posterior/Oblique Inner Rod	
03.22.10.0056 03.22.10.0261	Posterior Handle	
03.22.10.0065 03.22.10.0270	Transforaminal Inserter	
03.22.10.0066 03.22.10.0265	Transforaminal Implant Impactor	
03.22.10.0068	Transforaminal Implant Position Indicator	
03.22.10.0054	Trial Caddy - Primary	
03.22.10.0058	Trial Caddy - Addendum	
03.22.10.0300	Posterior Cage System Instrument Tray	

OPTIONAL INSTRUMENT

Ref.	Description	
03.22.10.0067	Temporary Set Screw	
03.22.10.0069	Screw To Screw Distractor	
03.22.10.0100	Slap Hammer	

INSTRUMENT SET

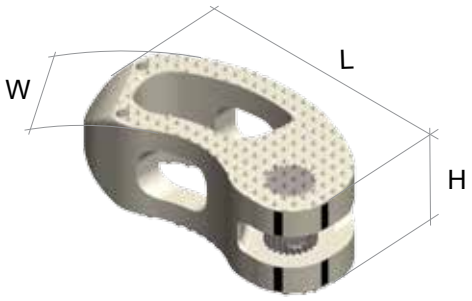
Ref.	Description	
03.22S.004	Instrument set	MectaLIF® Transforaminal
03.22S.005	Instrument set	MectaLIF® Transforaminal & Oblique
03.22S.006	Instrument set	MectaLIF® Transforaminal & Posterior
03.22S.007	Instrument set	MectaLIF® Transforaminal & Posterior & Oblique

MectaLIF Transforaminal Trials 5°

Code	Size	Color
03.22.10.128	12x34x7-Spacer	Light Blue
03.22.10.129	12x34x8	Dark Brown
03.22.10.130	12x34x9	Violet
03.22.10.131	12x34x10	Silver
03.22.10.132	12x34x11	Gold
03.22.10.133	12x34x12	Orange
03.22.10.134	12x34x13	Dark Blue
03.22.10.135	12x34x14	Pink
03.22.10.136	12x34x15	Dark Green

10 IMPLANTS NOMENCLATURE

MectaLIF Transforaminal PEEK

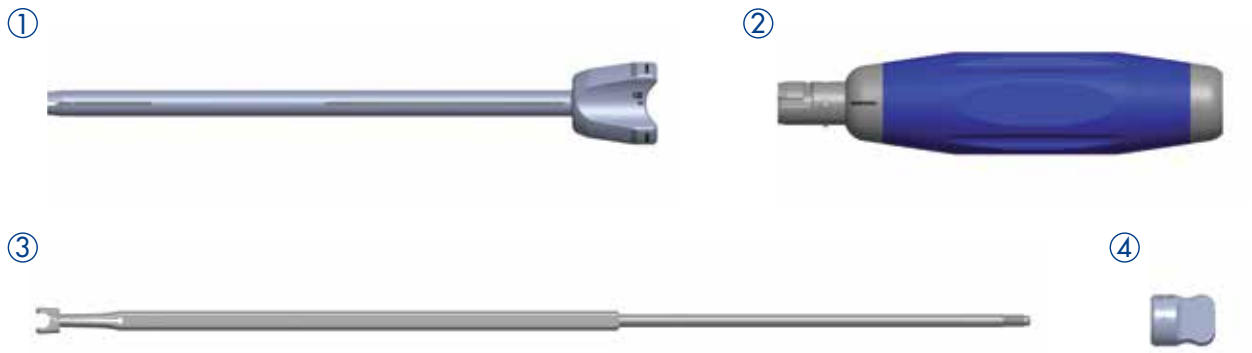


W = Width (mm)
L = Lenght (mm)
H = Anterior Height (mm)

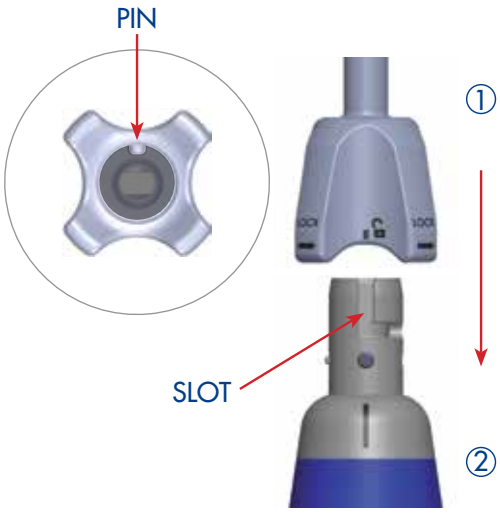
Code	Size (W×L×H)	Lordosis
03.23.051	12x30x8	5°
03.23.052	12x30x9	
03.23.056	12x30x10	
03.23.053	12x30x11	
03.23.057	12x30x12	
03.23.054	12x30x13	
03.23.058	12x30x14	
03.23.055	12x30x15	
03.23.061	14x30x8	5°
03.23.062	14x30x9	
03.23.066	14x30x10	
03.23.063	14x30x11	
03.23.067	14x30x12	
03.23.064	14x30x13	
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	
03.23.081	14x34x8	5°
03.23.082	14x34x9	
03.23.086	14x34x10	
03.23.083	14x34x11	
03.23.087	14x34x12	
03.23.084	14x34x13	
03.23.088	14x34x14	
03.23.085	14x34x15	

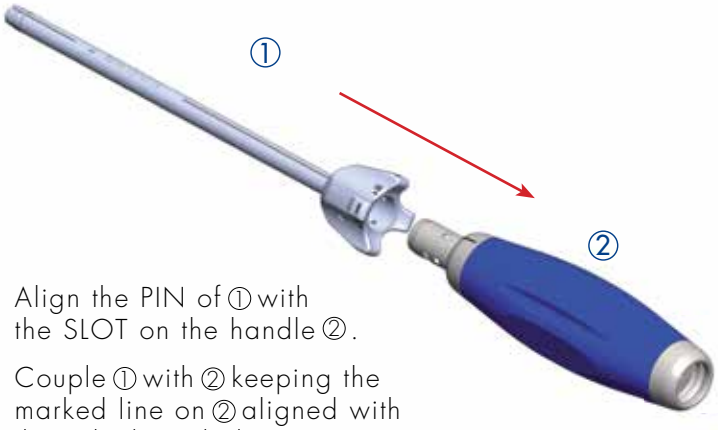
11 MECTALIF TRANSFORAMINAL INSERTER - ASSEMBLY INSTRUCTIONS

Index components



Assembly step 1





Align the PIN of ① with the SLOT on the handle ②.

Couple ① with ② keeping the marked line on ② aligned with the unlock symbol.

Assembly step 2

Keep the marking line aligned with the unlock symbol.

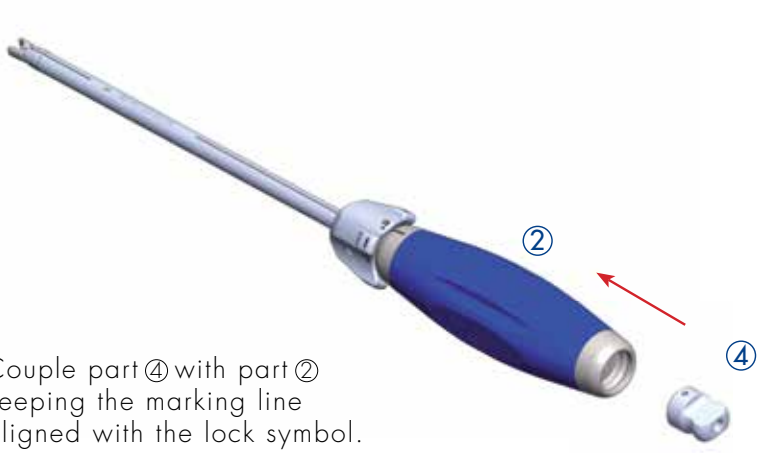
Insert part ③ in part ①.

Assembly step 3

Lock before next step

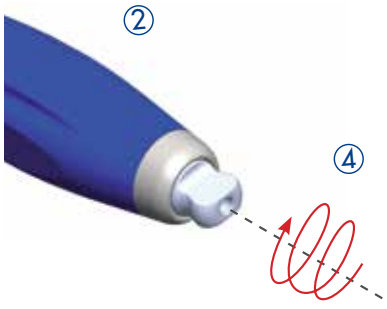
Rotate part ① on part ② moving the marking line from unlock symbol to the lock symbol.

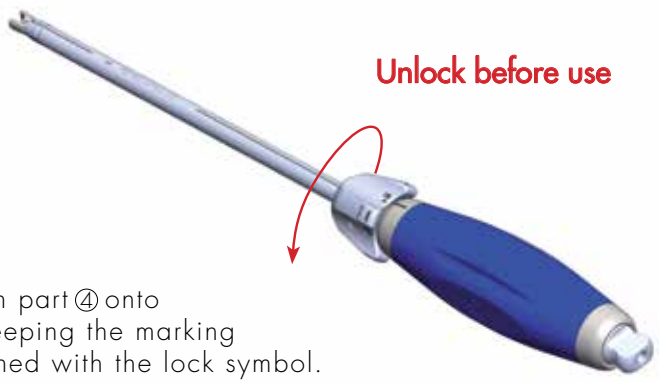
Assembly step 4



Couple part ④ with part ② keeping the marking line aligned with the lock symbol.

Assembly step 5





Unlock before use

Screw on part ④ onto part ② keeping the marking line aligned with the lock symbol.

Then unlock it before use.

NOTES

Part numbers subject to change.

NOTE FOR STERILIZATION

Note for sterilization: the instrumentation is not sterile upon delivery. It must be cleaned before use and sterilized in an autoclave respecting the US regulations, 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 sterilization of Medacta International reusable orthopedic devices" available at www.medacta.com.

Medacta International

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Surgical Technique

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