CAUTION

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

The Medacta Portfolio offers a couple of alternative minimally invasive retractor systems in lumbar posterior fixation depending on the approach.

The Medacta MINI OPEN Retractor allows for decompression, fusion and fixation through a Transforaminal, Wiltse approach, while the M.U.S.T. MC retractor allows for decompression, fusion and fixation through a Midline Cortical approach.

2. M.U.S.T. MINI OPEN

The Medacta MINI OPEN Retractor allows for decompression, fusion and fixation through a minimally invasive approach, however providing the surgeon the same versatility of an open procedure.

The Medacta MINI OPEN Retractor represents a gentle interface to the soft tissues, potentially allowing to reduce blood loss and scarring, improve the patient’s recovery time and shorten the hospital stay.

FEATURES

Cranial / Caudal blades
- Radiolucent (Aluminium)
- Left / Right Configuration
- Anatomical blades. With a specific design matching the spine anatomy. 60 – 100 mm Length (10 mm increment)
- MIS Blades. Straight design. 50-120mm (10 mm increment)
- Illuminated anatomical blades. To be used in combination with a light source and cables with a specific design matching the spine anatomy. 30 – 100 mm Length (10 mm increment, right and left configuration)
- Illuminated MIS blades, straight design. To be used in combination with a light source and cables. 30 – 120 mm Length (10 mm increment)

Medial / Lateral blades
- Radiolucent (Aluminium)
- Convex and Straight Design
- 50 – 120mm Length (10 mm increment)
- 15mm and 20mm wide configuration
4. Cranial / Caudal frame
- Couple with the Medial / Lateral blades for optimal distraction
- Allows for blades 30° tilting excursion for additional access

Medial / Lateral frame
- Fits under the Cranial / Caudal blades for optimal distraction

MIS Medial Arms
- Couple with the Cranial / Caudal frame for aided distraction / retraction
- Allows for blades 30° tilting excursion for additional access
- Two designs available: Ratcheting and Pivoting

5. Distraction Handle
- Medial and Lateral
- Allows Medial / Lateral independent distraction

Light cables
- Biforcated surgical illuminator. Designed to be mounted on the illuminated blades, sterile packaged

6. Cable extension, for Light Source to Biforcated surgical illuminator connection
- Adaptors, for Light Source to Cable extension connection.

3. SURGICAL TECHNIQUE

Perform a posterior incision through the skin and fascia approximately 2 – 4 cm from the midline.
Allow for muscle splitting within the multifidus and longissimus cleavage plane.
4. SURGICAL STEPS FOR MINI OPEN RETRACTION

4.1 PEDICLE PREPARATION
Target the pedicle and perforate the outer cortex with the Cannulated Awl.

WARNING
Confirm the pedicle anatomical positioning with radiographic imaging.

Remove the inner pin from the Cannulated Awl and insert the K-wire, carefully advance it through the incision.

WARNING
Control the k-wire position under radiographic imaging and make sure it does not slip off during the procedure.

4.2 DILATOR INSERTION

Multi-Step Dilation
Insert the Dilator size 1 – 8mm over the k-wire. Continue dilation sliding over the Dilator size 2 – 16mm and finally place the Dilator size 3 – 22mm over each other.

NOTE: The markings on the dilators indicate the appropriate length of the blades. The retractor has a diameter of 22 mm matching with the Dilator size 3.
**Single Step Dilation - Anatomical**

Alternatively, place the Anatomical Dilator aligned in the direction of muscle fibers; Rotate the dilator thus allowing the muscle splitting.

**NOTE:** The markings on the dilators indicates the appropriate length of the blades.

### 4.3 RETRACTOR PLACEMENT

Select the retraction blades in accordance with the markings on the final dilator (Fig. 10).

Slide the blades over the dilator and place it through the incision until in a stable position (Fig. 11).

Alternatively, attach the Cranial / Caudal blades to the retractor frame and insert it over the dilator and into the incision.

To assemble the frame onto the Cranial / Caudal blades, the frame must be initially set to the “unlocked” configuration with dedicated T-Handle (Fig. 12).
NOTE: When set to the "unlocked" position the two arms are free to slide apart to facilitate engagement with the blades. After appropriate engagement with the blades turn the frame to the "lock" position with the dedicated T-Handle.

NOTE: When set to the "lock" position the two arms are engaged to the ratchet mechanism and the knob can be used for a fine-tuned longitudinal sliding.

4.4 RETRACTOR SYSTEM LOCK

When the Retractor System is assembled and placed over the bony anatomy, lock it in place with the instrument holder. To assemble the instrument holder to the Retractor, align the Arm Connector to the recess of the frame and tighten the knob with the T-Handle. Fix the central knob when desired angulation of the Flexible Arm is achieved.

NOTE: Due to the specific coupling of the Arm Connector and the frame, the support system grants optimal stability of the Retractor and can be assembled in three possible positions (A, B, C) to provide great flexibility at the Retracting system.

OPTION

If the enhanced frame is used, the arm angulation can be locked with the T-Handle (Fig. 14).
Once the frame is inserted and stable in position, the dilators and the k-wire are removed establishing a corridor for the surgery.

**OPTION**
The k-wire can be maintained for subsequent guided insertion of a cannulated screw.

### 4.5 FRAME EXPANSION

To expand the Retractor turn the paddle in a counterclockwise direction.
Additional retraction can be reached by tilting the blades with the T-handle. Blades can be angulated up to 30° providing an aid in the visualisation of the intraoperative field (see figure below).

**4.6 ENHANCED RETRACTION**

Medial / Lateral blades can be used for further retraction.

Choose the length of the Medial / Lateral blades consistently to the length of the already placed Cranial / Caudal blades.

**Medial Retractor Blade**

Couple the preferred MIS Medial Arm with the Medial and match the assembly onto the Cranial / Caudal frame. Retract and tilt the Blade with the T-handle, if necessary.

When the Ratcheting Medial Arm is used (Fig. 22), blade retraction can be performed through the proximal pin (A), while blade tilt can be adjusted by acting on the distal pin (B).

The Pivoting Medial Arm can also be used (Fig. 23) to fix it over the frame the middle lateral pin can be regulated (C).

Arm retraction and angulation can be freely adjusted and then fixed with the upper proximal pin (D), while blade tilt can be regulated by means of the distal pin (E).
Medial And Lateral Retractor Blades

Place the Medial / Lateral frame into the Cranial / Caudal frame and into the incision; expand the Medial / Lateral frame to the desired retraction length.

Alternatively, the Blade Holder can be used in combination with the Medial Arm to perform Medial / Lateral retraction.

The Blade Holder can also be used in combination to the Cranial / Caudal frame to perform lateral retraction only.

4.7 LIGHT SYSTEM

The Mini Open set includes the illuminated blades allowing the surgeon the use of optical illumination for a better in situ visualization.

The light source (not provided by the system) is attached to an extension cable (reusable) and then Biforcated cables (sterile, single use) are linked and mounted on the specifically designed illuminated blades.

The available adaptors allow to connect most of the light sources on the market to Medacta light system.
5. SURGICAL STEPS FOR PEDICLE SCREW INSERTION

5.1 SCREW INSERTION

Using the surgical access generated with the Retractor proceed to insert the pedicle screws.

To implant the screws in the pedicles, please follow the procedure described in the Medacta M.U.S.T. Pedicle Screw System surgical technique (ref. 99.46.12US).

Using the Blade-Implant Connector Holder or the Temporary Set Screwdriver, slide the Blade-Implant Connector within the blade rail to reach the tulip (Fig. 28 & Fig. 29).

5.2 PARALLEL DISTRACTION

The M.U.S.T. Pedicle Screw System provides the possibility to perform parallel distraction using the Retractor system; this allows the proper distraction to facilitate the interbody fusion device implantation.

OPTION

The Blade-Implant Connector insertion can be guided with the k-wire when cannulated screws are used.

WARNING

During insertion of the Blade-Implant Connector, verify the proper engagement of the dove-tail end into the rail (Fig. 30).

NOTE: During this phase it can be useful to switch the frame in the “unlocked” configuration. The “lock” configuration must be recovered as soon as this step is accomplished.
Lock the connector to the Screw head using the Temporary Set Screw.

The Temporary Set screw can be inserted with the Cannulated Setscrewdriver, guided by the k-wire, or with a standard or enhanced Setscrewdriver.

Perform desired distraction by means of the frame ratchet.

Lordotic distraction can be reached by tilting the blades into a desired angle (see figure below).
6. SURGICAL STEPS FOR IMPLANT-BLADE HYBRID TECHNIQUE

As an alternative, it is also possible to insert the Pedicle Screw first, by a percutaneous approach, having the screw already coupled with a dedicated connector for subsequent blade and frame coupling. For this technique, cannulated screws and percutaneous tubes are used. Please refer also to 99.perc46.12US.

The “hybrid” technique has been developed in order to potentially save surgical time by reducing the surgical steps in comparison with the standard technique.

6.1 PEDICLE PREPARATION

Prepare the pedicle cannulated Awl as described in paragraph 3.1. Remove the Awl and leave the K-wire in place. Proceed with the assembly of the enhanced cannulated pedicle screw with the Percutaneous Tower 03.52.10.0001 (see M.U.S.T. Percutaneous Minimal Invasive System Surgical Technique 99.perc46.12US).

35.

Insert the hybrid connector 03.52.10.0217 into the Tower slot and the hybrid screw driver 03.52.10.0216 into the upper axial hole of the Tower itself.

6.2 PEDICLE SCREW AND BLADE PLACEMENT

Insert the pedicle screw on the K-wire using a cannulated handle from the M.U.S.T. set.

36.

Remove the screw driver keeping the hybrid connector in place. Insert the temporary set screw 03.52.10.0212 with the aid of the cannulated temporary set screw driver and fix, without tightening, the connector.
Slide the blade through the connector. The Percutaneous Tower acts as a dilator.

NOTE: The Percutaneous Tower is provided with a measurement scale to indicate the length of the blade to be used.

6.3 PERCUTANEOUS TOWER REMOVAL

Remove the Percutaneous Tower by pushing the release button. After that the K-wire can be pulled out.

Repeat the previous steps in order to place the second pedicle screw along with the blade.

Proceed with the frame assembly. To fasten the engagement, the frame should be in the "unlock" position (see paragraph 3.3).
7. SURGICAL STEPS FOR INTERBODY FUSION DEVICE INSERTION

Using the surgical access provided with the Retractor, proceed with the interbody fusion device implantation (Fig. 43).

Perform the discectomy and the endplate preparation with dedicated instruments according to the usual fashion.

If you are planning to implant the MectaLIF cages, please follow the procedure described in the dedicated surgical techniques (ref. 99.44.12US & 99.44TLIF.12US).

The MectaLIF Oblique and Posterior as well as the MectaLIF Transforaminal Interbody Devices can be implanted in combination with the use of the M.U.S.T. Mini Open system through a minimally invasive procedure.

In particular, the MectaLIF Oblique Interbody Device, which is implanted at a 30° angle in the sagittal plane, results as an optimal interface with the current retractor / distractor system (Fig. 43).

The MectaLIF Oblique and Posterior cages can also be implanted by using the MectaLIF Posterior Offset Handle and the MectaLIF Oblique Offset Handle, respectively.

The MectaLIF offset handles can be coupled with either the Inner Shaft or the Extended Inner Shaft, keeping optimal visibility over the surgical space (Fig. 44).

The mark “MEDIAL” on the shaft indicates proper alignment of the instrument with respect to the patient.

Attach the implant perpendicular to the Inner Shaft / Handle assembly, screw the thread of the Inner Shaft to the threaded hole and secure it firmly.

Ensure that the orientation of the implant is correct, as shown in Fig. 45 for Oblique Implants or Fig. 46 for Posterior Implants.
8. SURGICAL STEPS FOR ROD PLACEMENT AND ADJUSTMENTS

8.1 ROD INSERTION

Using the Temporary Set Screwdriver, remove the Temporary Setscrews from the tulip and then proceed to remove the Blade-Implant Connector, with the Blade-Implant Connector Holder.

Position the rod into the selected pedicle screw heads (Fig. 47). The use of the Rod Insertion Forceps may help to easily insert the rod in the space generated between the Cranial/Caudal Blades.

Perform the Rod reduction according to the usual Techniques described in the Medacta M.U.S.T. Pedicle Screw System surgical technique (ref. 99.46.12US).

8.2 COMPRESSION AND DISTRACTION

Further compression/distraction can be performed at this time. In either maneuver, the set screw on one side of the motion segment should be tightened while the other must be in place but untightened. The untightened screw must be coupled with the Countertorque/Set Screwdriver system.

Compression occurs by acting against the tightened screw with the Compressor Lever (Fig. 48).
Similarly, distraction is reached pushing the Distraction Lever against the tightened screw (Fig. 49).

Once desired compression or distraction has been achieved, final tightening has to be performed.

For the M.U.S.T. pedicle screws, please follow the same procedure previously described in the dedicated surgical technique of the Medacta M.U.S.T. screws (99.46.12US).

Finally, remove the MIS frame and the retraction blades to complete the implant procedure.
The Medacta M.U.S.T. MC retractor allows for decompression, fusion and fixation through a minimally invasive Midline Cortical approach, but nevertheless offering the surgeon the same versatility of an open procedure.

M.U.S.T. MC Retractor
- Couples with the blades for optimal distraction
- Lateral mounting of the blades also allows for quick in situ connection
- Allows for 30° tilting excursion of the blades for improved access

Light system
- Clip to connect the blade with the surgical illuminator
- Bifurcated surgical illuminator, sterile packed
- Cable extension, for connection of Light Source to Bifurcated surgical illuminator
- Adapters, for connection of Light Source to Cable extensions

FEATURES

M.U.S.T. MC blades
- Radiolucent (Aluminium)
- Left / Right Configuration
- Anatomical blades, specifically designed to match the spine anatomy
- 40 – 120 mm Lengths (10 mm increments)
- 20, 30 and 40 mm Widths
- Compatible with the light system
10. SURGICAL TECHNIQUE

Perform a midline posterior incision through the skin and fascia.
Allow for muscle splitting within the multifidus and longissimus cleavage plane.

10.1 RETRACTOR PLACEMENT

Select the retraction blades according to the patient’s anatomy.

To assemble the frame, it must be initially set to the “unlocked” position with the dedicated T-Handle (Fig. 55).

NOTE: When set to the “unlocked” position, the two arms are free to slide apart to facilitate engagement with the blades.

After mounting the frame, set it to the “locked” position.

NOTE: When set to the “locked” position, the two arms are engaged to the ratchet mechanism and the knob can be used for a fine-tuned retraction.

Attach the blades to the Retractor frame and insert it through the incision until a stable position is reached (Fig. 57). For an optimal fitting, match the anatomical blade with the spine anatomy at the articular process (Fig. 58).
According to the design, the blades are mounted from the lateral side, thus also allowing the surgeon for quick in situ connection (Fig. 59).

**OPTION**

10.2 FRAME EXPANSION

To expand the Retractor, turn the knob counterclockwise.

Additional retraction can be obtained by tilting the blades with the T-handle. Blades can be angulated up to 30°, so as to provide a better view of the intraoperative field (Fig. 61).

**OPTION**

The Blade Holder can be used in combination with the frame to perform further retraction.
10.3 LIGHT SYSTEM

The M.U.S.T. MC Retractor set includes the clip to hold the light cables in position when a light system is needed, thus allowing the surgeon the use of optical illumination for a better in situ visualization.

The light source (not part of the MUST MC system) is attached to an extension cable (reusable) and then bifurcated cables (sterile, single use) are connected. The ends of the bifurcated cable are held in position by the cable clip and provide in situ illumination, passing through the holes on the blade.

The available adapters allow for connection of most of the light sources available on the market to the Medacta light system.

10.4 PEDICLE SCREW INSERTION

Using the surgical access generated by the Retractor, proceed to insert the pedicle screws.

To implant the screws in the pedicles, please follow the procedure described in the Medacta M.U.S.T. Pedicle Screw System surgical technique (ref. 99.46.12US).

10.5 INTERBODY FUSION DEVICE INSERTION

Using the surgical access generated by the Retractor, proceed with the interbody fusion device implantation. Perform the discectomy and the endplate preparation with the dedicated instruments, according to the preferred technique.

If you are planning to implant the Medacta M.U.S.T. pedicle screws in combination with the modular tap distractor and the MectaLIF cages, please follow the procedure described in the dedicated surgical techniques (ref. 99.46.12US, 99.44.12US and 99.44TLIF.12US).
NOTE FOR STERILIZATION

The instrumentation is not sterile upon delivery. Instruments must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable, and following the manufactures instructions for use of the autoclave. For detailed instructions please refer to the document “Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices” available at www.medacta.com.