NOTE

This document describes the Mecta®ACL SB (Medacta Single Bundle) surgical technique using harvested autologous hamstrings tendons. Medacta Extracortical Femoral Button and Medacta MectaScrew Interference Screw are used for graft fixation.
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1. INTRODUCTION

This surgical technique describes how to perform a Single Bundle ACL reconstruction using Medacta Extracortical Femoral Button on the femoral side and Medacta MectaScrew Interference Screws on the tibial one.

**CAUTION**

Federal law (USA only) restricts these devices to sale distribution and use by or on the order of physician.

1.1 INDICATIONS OF USE

Extracortical Femoral Button: reconstructive therapy of ruptures to the anterior and posterior cruciate ligament by means of autologous grafts.

MectaScrew Interference Screw: reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of auto- and allografts.

1.2 CONTRAINDICATIONS

Medacta Single Bundle ACL reconstruction using an Extracortical Femoral Button and an Interference Screw is contraindicated where there is:

- Osteoporosis and osteomalacia
- Degenerative osteopathies
- Adiposity or patient overweight, leading to excessive strain on the fixation button
- Osteomata in the area in which the fixation button is to be placed
- Deformities of the bone, or general conditions of the bones which exclude implantation of a fixation button in the opinion of a physician
- Systemic diseases and metabolic disorders that may compromise surgical outcome

2. IMPLANTS OVERVIEW

2.1 EXTRACORTICAL FEMORAL BUTTON

The Medacta Extracortical Femoral Button is used for the femoral fixation of the graft. Two additional USP#2/EP5 sutures (preferably in two different colours) have to be loaded on the side holes to pull the implant (pulling suture) towards the femoral tunnel and to flip it (flipping suture) once it has reached the extracortical position (inside-out technique). The flip length of the Medacta Extracortical Femoral Button is about 7 mm.

The Medacta Extracortical Femoral Button assembled with the loop suture (without the flipping and the pulling sutures) is represented in image 2.

2.2 INTERFERENCE SCREW

Interference screws are used for the tibial and the femoral fixation of the graft. When inserting the interference screw, high fixation strength on the graft is immediately achieved after the reconstruction thanks to the press fit obtained between the screw and the graft within the prepared bone tunnel.

The interference screws are provided in different lengths and diameters (see table below). Select the appropriate configuration according to the reinforced graft size and use the corresponding screwdriver (see paragraph 3.7).

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3. INSTRUMENTS OVERVIEW

3.1 PREPARATION TABLE

The preparation table is designed to enable cleaning and preparation of the graft. It is composed of a main board (Ref. 05.05.10.0009), a plastic cleaning panel (Ref. 05.05.10.0011), two graft clamps (Ref. 05.05.10.0010), a loop sizer (Ref. 05.05.10.0083) and dedicated implant/suture supports (Ref. 05.05.10.0012 and Ref. 05.05.10.0014).

The clamps are designed to fix the graft and have special recessed areas on their back sides that ensure proper placement of the implant/suture support devices. These clamps can slide along a scaled track to adequately tension the graft. The scale enables evaluation of the length of the graft.

To insert/remove the plastic cleaning board, verify that the fixation button of the metal board is in the open position and slide in/out the board from the right end side of the table. The plastic board fixation clamp can be used, if desired, to fix one side of the graft before cleaning it.

An additional support is available, if desired, to manage free sutures coming from the tibial side of the graft. It can be positioned on the graft clamp (like the other support). Sutures can be wrapped around the suture post.

4. The preparation table enables:

- Preparation of the tendon graft and to set its length
- Setting of the button loop length (for this step, a dedicated loop sizer, Ref. 05.05.10.0083, is available)
- Strengthening of the femoral and tibial tips of the tendon graft by applying reinforcing sutures (reinforcement phase)
- A dedicated implant support can be assembled within the graft clamps to allow the insertion of the reinforced graft into the Medacta Extracortical Femoral Button (Ref. 05.05.0002) loop. To insert the implant, press the dedicated supports' legs.

5. GRAFT CLAMP

The graft clamp holds the Medacta implant support and the tips of the tendon graft during the preparation phase. By moving the clamp along the board track it is possible to tension the graft. Press the lower bar down to fix the clamp. To prevent the graft from slipping during the reinforcement phase, the graft edge needs to be fixed in the clamp, and locked using the upper wheel.

To insert/remove the Medacta supports, press the golden locking button positioned at the rear of the clamp and slide the supports into/out of the dedicated slot.

6. LOOP SIZER

The loop sizer has to be coupled with the preparation table during the graft preparation phase when no continuous loop button is used.

Insert the instrument within the rail of the preparation board, in between the two graft clamps, maintaining the instrument perpendicular to the rail during insertion. Rotate the device counterclockwise to stabilize it on the preparation table (it will only rotate in one direction). Slide the instrument to the desired position. To properly evaluate the length of the button loop, the instrument has to lie flat against the femoral button support.

To disassemble the device, rotate the instrument 90° degrees within the preparation table rail (it will only rotate in one direction) and remove it.
3.2 FEMORAL AIMER

The femoral aimer is used to properly place a Ø2.4 mm k-wire in the femoral bone. It features a tip that enables direct vision of the insertion site of the ACL and a nose which ensures a proper fit on the femoral condyle.

Different versions are available according to the preferred surgical approach (anteromedial or transtibial).

Femoral aimer for anteromedial (AM) approach

Femoral aimer for transtibial (TT) approach

For each version, two tip configurations are available:
- For Ø7 and Ø8 mm tunnels with at least 2 mm back wall offset
- For Ø9 and Ø10 mm tunnel with at least 2 mm back wall offset

According to the reinforced graft size, select the femoral aimer that provides the best aim for the ACL femoral insertion.

3.3 REAMERS AND DRILLS

Cannulated headed reamers (from Ø 4.5mm up to Ø 12mm with 0.5 mm increments) and manual cannulated drills (from 6mm up to 12mm) with dedicated quick connection T-handle are both available to slide along a Ø 2.4mm k-wire.

3.4 DILATOR

The dilator can be used on both femur and tibia.

Each dilator is cannulated in order to slide along a Ø2.4 mm k-wire. Different sizes are available (head diameter from Ø6 mm up to Ø12 mm, by 0.5 mm increments) and must be selected according to the size of the reinforced graft and the surgeons’ preference.

The dilator tip features two flat portions decreasing the friction within the bone tunnel during the dilation. In order to evaluate the tunnel depth, the dilator is graduated. A handle with a dedicated button system facilitates quick and safe assemble/disassemble of each dilator that is available.

To insert the dilator, tap it from the back using a hammer on the designated end position, rotate the dilator about 180° degrees to fully dilate the tunnel. To remove it, use a hammer or the slide hammer (see paragraph 3.6), coupling it with the backside of the dilator handle.

3.5 REVERSE LENGTH GAUGE

The reverse length gauge (Ref. 05.05.10.0022) helps the surgeon for the femoral tunnel length (see paragraph 4.1).

NOTE: As an alternative, a standard length gauge is available (Ref. 05.05.10.0021).

3.6 SLIDE HAMMER

The slide hammer (Ref. 05.05.10.0001) has been designed with a self-locking mechanism to be coupled with the dilator handle. It enables easy removal of the dilator in case of significant friction between the dilator and the bone.
NOTE: as an alternative, the standard hammer (Ref. 05.05.10.0050) can be used.

3.7 TIBIAL AIMER

The tibial aimer consists of two different components (image 15 and 16):

- Tibial aimer with adjustable angle (from 45° up to 70° degrees, on image 15) between the drill axis (tunnel axis) and the tibial plateau reference plane (tip reference)
- Cannulated bullet for the use of a Ø2.4 mm k-wire. Its design prevents accidental disassembly during usage (image 16)

![Diagram](image 15)

![Diagram](image 16)

With reference to image 16, the aiming arc features:

- A tip that allows proper positioning and firm fixation of the aimer on the ACL tibial insertion point
- A dedicated lever (bullet lever) that allows bullet fixation, preventing it from slipping from the lower arc body
- A dedicated locking lever (aiming arc locking lever) that allows the lower arc of the body to be fixed into the desired working configuration angulation, which can be checked on the scale marked on the lower arc body
- A dedicated button (button) prevents accidental disassembly of the lower arc during usage if the aiming arc locking lever is left open
- A tip to tip design allows visualization of the exit point of the k-wire before its placement

Once the working configuration has been selected, insert the bullet into the aiming arc from behind by pressing the bullet lever (see paragraph 6.1).

3.8 SCREWDRIVER

The screwdriver is used to properly place the Medacta MectaScrew interference screw, ensuring the appropriate fixation of the graft. Both fixed and quick connect ratchet handle are available.

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NOTE: Each screwdriver is marked with the compatible screws diameter.
4. GRAFT PREPARATION

4.1 SETTING THE GRAFT LENGTH

The graft path inside the bone consists of three different portions:
- Total femoral tunnel (minimum length 20 mm)
- Graft in tunnel length (depending on joint anatomy)
- Tibial tunnel (minimum length 20 mm)
- Flipping length (7 mm)

4.2 GRAFT THICKNESS MEASUREMENT

The semitendinosus is harvested using a tendon stripper. Within Medacta’s portfolio, two different versions are available, labelled Close (Ref. 05.05.10.0023) and Open (Ref. 05.05.10.0024) to adapt the instrument to the individual, anatomical particulars of the patient.

**Close configuration**

17.

**Open configuration**

18.

The tendon is harvested and then placed on the plastic cleaning panel (Ref. 05.05.10.0011) of the preparation board (Ref. 05.05.10.0009) and is freed of muscle residual tissue. The damaged tendon ends are removed and its effective length is measured on the preparation table scale.

4.3 GENERAL INFORMATION ABOUT THE GRAFT PREPARATION

The graft is prepared following these steps:
- The tendon is positioned under tension in between the clamps and is reinforced on both ends as per standard technique
- The tendon is folded according to the selected configuration and inserted in the prepared button loop
- A mark corresponding to the desired graft in tunnel length is made on the tendon femoral side to guide the implant flipping after graft passage in the femoral tunnel
- Two additional sutures are assembled with the Medacta Extracortical Femoral Button for its insertion (pulling suture) and flipping (flipping suture)

**CAUTION**

During the surgical procedure, after the graft has been harvested and prepared, it must be stored in a moist gauze while other surgical tasks are completed (such as addressing meniscal pathology and creating the femoral and tibial tunnels).

4.4 GRAFT REINFORCEMENT

After the cleaning phase, the tendon is fixed under tension in between the graft clamps.

The two tendon ends are reinforced with USP#2/EP5 sutures. Three or four additional stitches are run inward from the end of the tendon and back out again.

**CAUTION**

Pay attention to place the reinforcing stitches between the initial whipstitch sutures to keep the tendon to spread open and to increase the compression of sutures.

**OPTION**

If the four-strand preparation is chosen, use two different suture colors to stitch each tendon’s end. This aids to identify the two ends of each tendon for pulling during tibial fixation.

The lead sutures are manually tensioned reaching the maximum tension to secure the suture material firmly in the graft tissue.

**FEMORAL SIDE**

Fit the Medacta Extracortical Femoral Button into its support. Load the central holes using a USP#2/EP5 suture. Pass again one end of the suture through the same holes to create an open double loop.

Two additional USP#2/EP5 sutures (preferably in two different colours) have to be loaded on the side holes to pull the implant (pulling suture) towards the femoral tunnel and to flip it (flipping suture) once it has reached an extracortical position (inside-out technique). The flip length of the Medacta Extracortical Button is about 7 mm.
Insert the loaded button and its support in the clamp slot. Position the clamp at the end of the rail on the preparation table.

The open double loop is clamped with a standard clamp (not provided) and placed on the preparation table scale.

At this point, one end of the lead suture of the femoral side is passed through the two central holes of the Medacta Extracortical Femoral Button (where the double loop has been previously set) and then clamped with the other suture end to form a loop.

**4.5 STRAND TECHNIQUES**

The number of strands in the final graft construct ranges from three-stranded grafts to six-stranded grafts. The most commonly used configurations are the four-strand and the three-strand grafts.

**THREE-STRAND PREPARATION**

After the tendon has been cleaned and reinforced, it is folded in three limbs of equal length. One limb is passed through the double loop of the Medacta Extracortical Femoral Button.

A suture (a) is passed through the free graft loop. The graft has now a S-shaped configuration with one sutured end pointing toward the Medacta Extracortical Femoral Button while the other sutured end and suture (a) point toward the tibial side.

**CAUTION**

Make sure that the sutured graft end does not extend past the lead sutures loop.

The graft is pretensioned on the preparation board securing the sutures free ends of the tibial side to the Medacta Suture Support.

**FOUR-STRAND PREPARATION**

A four-strand graft can be prepared using one ST (Semitendinosus Tendon) combined with a GR (Gracilis Tendon) or a ST tendon cut in half.

After the tendons have been cleaned and reinforced, they are doubled over the loop of Medacta Extracortical Femoral Button and their lengths are equalized. Now the tendons form a quadruple hamstring graft.

The graft is pretensioned on the preparation board securing the sutures free ends to the Medacta Suture Support.
4.6 GRAFT SIZE EVALUATION

The graft sizer has holes to help evaluate the reinforced graft cross section while the graft is assembled on the preparation table. Each slot features an opening through which sutures coming from the graft can be passed. All the edges are rounded to avoid harming the tendon during usage.

The graft sizer is designed with two components that can be rotated obtaining two working configurations:

• Open configuration: the suture slots of the two components are congruent and sutures can be passed through. Graft slots are not congruent between the two components (the tendon cannot be inserted through these openings)

• Closed configuration: the suture slots of the two components are not congruent and sutures cannot exit from these. Graft slots are congruent between the two components (the tendon can be inserted through these openings)

Two sizes are available labelled as Small and Large.

Graft Sizer Small (Ref. 05.05.10.0055), measuring graft sizes from Ø4.5 mm up to Ø8.5 mm:

Graft Sizer Large (Ref. 05.05.10.0056), measuring graft sizes from Ø9 mm up to Ø12 mm:

Read the thickness of the graft. This evaluation is important to set the dimension of the bone tunnels (select instruments' size according to this evaluation).
5. FEMORAL TUNNEL CREATION – ANTEROMEDIAL APPROACH

NOTE: this step has to be performed if the anteromedial approach has been selected. In case of transtibial approach, go to section 7.

5.1 K- WIRES POSITIONING AND DRILLING

Perform this step with the knee at 110°-120° degrees of flexion.

Position the femoral aimer on the ACL femoral insertion site.

NOTE: if desired, before placing the aimer, mark the femoral ACL insertion site using a microfracture (Ref. 05.05.10.0084).

29. Insert the k-wire in the central hole of the aimer and drill it through the femur. The exit point of the k-wire represents the desired position of the Medacta Extracortical Femoral Button.

30. Remove the aimer and insert the k-wire further until the proximal laser marking is aligned with the intra-articular surface of the lateral condyle. Remove the aimer and verify if the k-wire is properly placed.

31. If desired, measure the length of the tunnel using the reverse length gauge (Ref. 05.05.10.0022). Insert the reverse length gauge on the distal portion of the central k-wire and slide it up to the patient bone (if necessary, make a small skin incision to facilitate instrument positioning). Evaluate the intraosseous femoral tunnel length using the distal marking of the k-wire and the scale of the length gauge.

32. Slide the reverse length gauge from the distal portion of the central k-wire that protrudes from the femur. Using the distal marking on the k-wire check the femoral tunnel length on the length gauge.

CAUTION
Pay attention to the sharp k-wire tip when inserting the reverse length gauge on the k-wire.

Overdrill the k-wire with a cannulated headed reamer. Its size has to be selected according to the dimension of the reinforced harvested graft, continue drilling up to 20-25 mm depth.
OPTION
A smaller reamer with respect to the size of the reinforced graft can be used and, after this, the bone should be dilated using an oval dilator with the head diameter size equal to the reinforced graft size. Rotate the dilator during insertion in order to create the correct final shape of the tunnel.

Overdrill the k-wire with a Ø4.5 mm cannulated headed reamer, up to the contra cortical side.

The final femoral tunnel (20-25 mm minimum depth, same diameter of the reinforced graft) has now been created.

6. TIBIAL TUNNEL CREATION

6.1 K- WIRES POSITIONING AND DRILLING
Once the working configuration has been selected, insert the bullet into the tibial aimer from behind by pressing the bullet lever. To properly position the bullet, insert it aligning the laser marking on its tip with the one on the tibial aimer (a). At this point, rotate the bullet by 60° degrees (clockwise) to engage it into the working position (b). Freely slide the bullet back or forward (c).

The tip is inserted through the anteromedial portal and is positioned targeting the ACL tibial insertion site (use the anterior horn of the lateral meniscus as a reference). The tip to tip design of the aimer allows visualization of the exit point of the k-wire before its placement.

The bullet is advanced towards the tibia.

The length of the tibial tunnel can be evaluated using the scale marked on the bullet. The tunnel should be at least 35 mm long. Drill the k-wire through the bullet.

NOTE: stop drilling as soon as the tip of the k-wire comes into contact with the tip of the aimer.
Remove the aiming arc and the bullet, keeping the k-wire in place. Insert the k-wire until it is visible in the joint.

Over-drill the k-wire using a cannulated headed reamer, select the size according to the dimension of the reinforced harvested graft.

**NOTE:** manual cannulated drills with dedicated quick connection handle are also available to perform this step.

**OPTION**
A smaller reamer with respect to the size of the reinforced graft can be used and, after this, the bone has to be dilated using an oval dilator with head diameter size equal to reinforced graft size. Rotate the dilator during its insertion in order to obtain the correct final shape of the canal.

Final result.
7. FEMORAL TUNNEL CREATION – TRANSTIBIAL APPROACH

**NOTE:** this step has to be performed if the transtibial approach has been selected. In case of anteromedial approach, go to section 4.

### 7.1 K- WIRES POSITIONING AND DRILLING

Remove the aimer and advance the k-wire in order to align the proximal laser marking with the femoral condyle intra-articular cortical surface. Check if the k-wire is properly placed.

If desired, measure the length of the tunnel using the reverse length gauge (Ref. 05.05.10.0022). Insert the reverse length gauge on the distal portion of the central k-wire and slide it up to the patient bone (if necessary, make a small skin incision to facilitate instrument positioning). Evaluate the intraosseous femoral tunnel length using the distal marking of the k-wire and the scale of the length gauge (image 34).

**CAUTION**
Pay attention to the sharp k-wire tip when inserting the reverse length gauge on the k-wire.

Overdrill the k-wire with a cannulated headed reamer, its size should be selected according to the dimension of the reinforced harvested graft (continue drilling up to 20-25 mm depth).

**OPTION**
A smaller reamer with respect to the size of the reinforced graft can be used and, after this, the bone should be dilated using an oval dilator with the head diameter size equal to the reinforced graft size. Rotate the dilator during insertion in order to create the correct final shape of the tunnel.

Overdrill the k-wire with a Ø4.5 mm cannulated headed reamer, up to the opposite side.

The final femoral tunnel (20-25 mm minimum depth, same diameter as the reinforced graft) is now created.
8. GRAFT INSERTION AND FIXATION

Using a passing k-wire, both the pulling and the flipping sutures of the Medacta Extracortical Femoral Button are inserted transtibially up to the extracortical femoral side.

With the knee fully extended or slightly flexed, insert Medacta MectaScrew interference screw on the lateral side of the graft.

**OPTION**

If the four-strand preparation was chosen, the two different suture colors used for stitching aid to identify the two ends of each tendon for pulling during tibial fixation.

**CAUTION**

If difficulties are experienced in disengaging the screwdriver from the screw, do not tug on the screwdriver or wiggle around but gently tap the front edge of the handle with a mallet in order to free the screwdriver and then easily withdraw it.

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Use the pulling suture of the Medacta Extracortical Femoral Button to pull the implant through the femoral tunnel until the mark previously made on the graft reaches the inferior opening of the femoral tunnel (image 49 and 50).

At this point, the button is towed outside the femoral tunnel. Retract the graft by pulling the sutures coming from the tibial tunnel to set the flipped button against the lateral femoral cortex achieving a stable fixation. The graft should remain at least 20 mm inside the femoral tunnel.

**NOTE:** in case of anteromedial approach, when the graft is visible in the joint, use an arthroscopic knee probe to facilitate the passage of the graft from the tibial to the femoral tunnel.

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**Final result.**
## 9. IMPLANTS AND INSTRUMENTS NOMENCLATURE

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<td>Resorbable Interference Screw 8x30 T25</td>
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<td>05.05.0074</td>
<td>Resorbable Interference Screw 9x30 T25</td>
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</table>
Metal trays designed with dedicated brackets to contain the instruments of the set.

The MectaACL SB Set (Ref. 05.05.10.9003) is available in different configurations. Femoral aimers are customizable according to the chosen surgical approach (anteromedial or transtibial). If cannulated screwdrivers are chosen, the tray is completed with Ø 1.1 mm Nitinol guidewires.

<table>
<thead>
<tr>
<th>REF. NO.</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>05.05S.001</td>
<td>Sports Medicine - Knee General Tray</td>
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<td>05.05S.004</td>
<td>Sports Medicine - Knee Preparation Table Tray</td>
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<td>05.05S.003</td>
<td>MectaACL SB Tray - Transtibial Approach &amp; Cannulated Screwdrivers</td>
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<td>05.05S.005</td>
<td>MectaACL SB - Anteromedial Approach &amp; Cannulated Screwdrivers</td>
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<tr>
<td>05.05S.006</td>
<td>MectaACL SB Tray - Anteromedial Approach &amp; NonCannulated Screwdrivers</td>
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<tr>
<td>05.05S.007</td>
<td>MectaACL SB Tray - Transtibial Approach &amp; NonCannulated Screwdrivers</td>
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<tr>
<td>05.05S.011</td>
<td>MectaACL SB Tray – Anteromedial Approach &amp; Cannulated Screwdrivers, w/o dilators</td>
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<tr>
<td>05.05S.012</td>
<td>MectaACL SB Tray – Anteromedial Approach &amp; NonCannulated Screwdrivers, w/o dilators</td>
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<td>05.05S.013</td>
<td>MectaACL SB Tray – Transtibial Approach &amp; Cannulated Screwdrivers, w/o dilators</td>
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<td>05.05S.014</td>
<td>MectaACL SB Tray – Transtibial Approach &amp; NonCannulated Screwdrivers, w/o dilators</td>
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<td>05.05S.017</td>
<td>SportsMed Cannulated Drills with T-Handle.</td>
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<td>05.05S.008</td>
<td>Cannulated Headed Reamers Tray</td>
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<td>05.05.10.0133</td>
<td>Ligament reconstruction wires kit</td>
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<td>05.05.10.0118</td>
<td>Cannulated Screwdriver Shaft T20</td>
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<td>Cannulated Screwdriver Shaft T40</td>
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<td>05.05.10.0124</td>
<td>Quick Connect Ratchet Handle cannulated</td>
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<tr>
<td>05.05.10.0134</td>
<td>T-Handle Zimmer Hall connection</td>
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</table>
Part numbers subject to change.

NOTE FOR STERILISATION

If not specified, the instruments are not sterile and must be cleaned before use and sterilised in an autoclave in accordance with the regulations of the country, US directives where applicable and following the instructions 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.