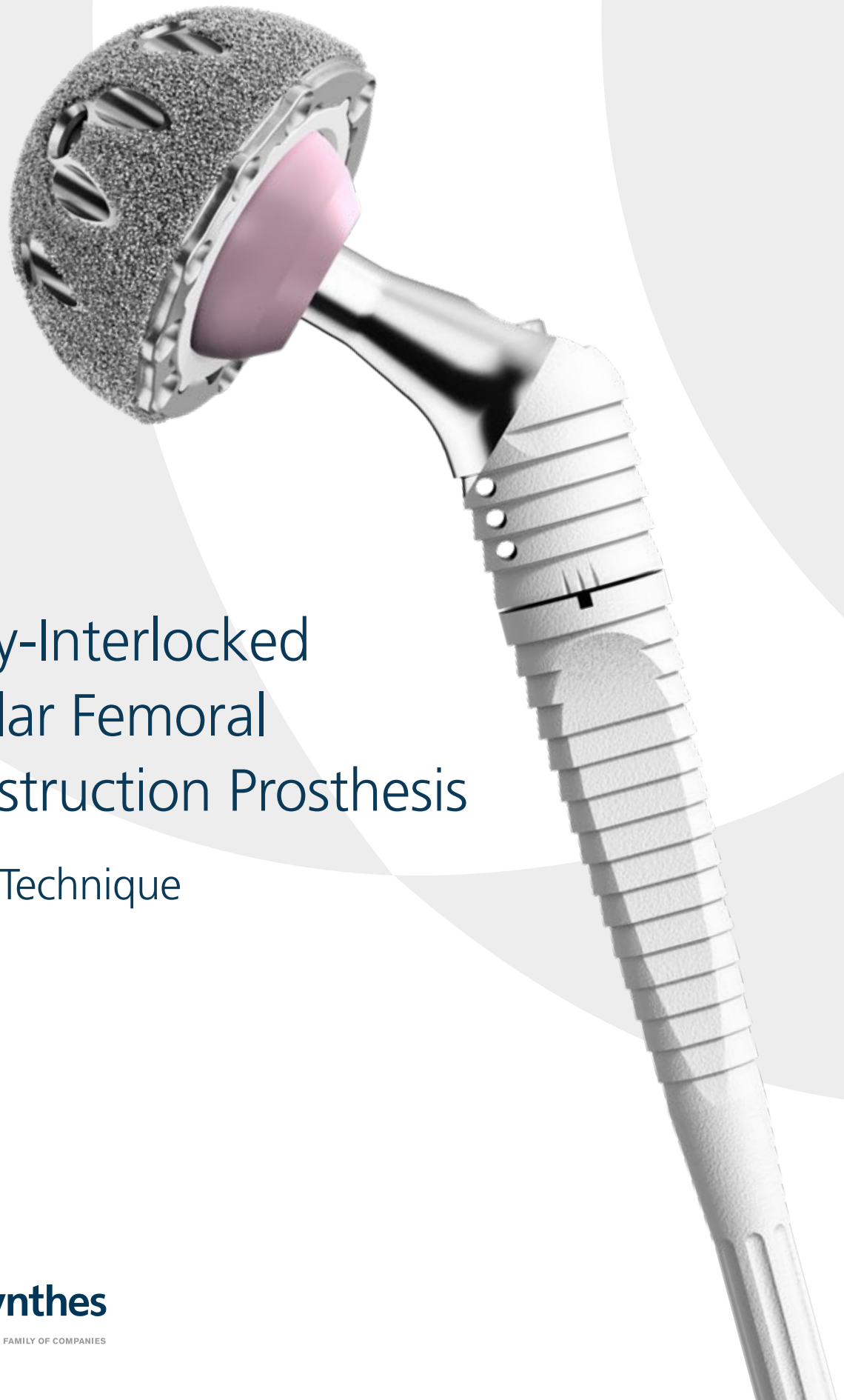


REEF



Distally-Interlocked Modular Femoral Reconstruction Prosthesis

Surgical Technique

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Surgical Technique

Preoperative planning makes it possible to:

1. Identify the **lower level of the extended trochanteric osteotomy (ETO) required to fully remove** the failed primary implant and any cement; this involves taking measurements in relation to several reference points (the top of the greater trochanter and the lesser trochanter, the femoral condyle, and any osteosynthesis material still in place).
2. Locate the **level of implantation** of the REEF stem, which can be measured from the **reference point for the metaphyso-diaphyseal junction of the stem**, as marked on the X-ray template, and the **lower level of the ETO flap (i.e. distance D in Figure 3 and Figure 6)**.
3. Estimate the size of the components required for the reconstruction in terms of:
 - **Stem diameter:** in order to achieve **optimal filling** of the healthy diaphyseal area the stem should completely fill the femoral canal allowing a press-fit in order to obtain primary stability and promote osteointegration.
 - **Stem length:** to ensure **reliable anchorage in the diaphyseal or lower diaphyso-metaphyseal area**, remembering that **the most proximal screw-hole must be a minimum of 5 cm below the lower part of the ETO flap**.
 - **Trochanteric height:** the choice of trochanteric component height should allow reconstruction of the femoral centre of rotation and equalisation of leg length.
 - **Lateral wing:** chosen in cases where lateralisation of the greater trochanter is required.
4. Set the number of interlocking screws, their lengths and positions.

The planning must take account of any shortening of the lower limb. It is conducted using the X-ray templates (code - 907269000; scale 1.2) on the AP and ML radiographs. A radiographic image of the whole femur and angular measurement (AP X-ray measurements of both lower limbs) must also be available.

Approach

Extended Trochanteric Osteotomy

Regardless of the initial approach selected (posterior, lateral or anterior), it is obligatory that the approach be made via the transfemoral route (Wagner technique), with a large flap that includes the greater trochanter (Figure 1) instead of a simple trochanterotomy which is insufficient to expose any existing bone lesions and explant the failed hardware. There must be no interference with the vascularisation when handling the muscles and their insertions.

The distal border of the osteotomy is made using a saw, around the lateral semi-circumference of the external cortex at the level identified during the preoperative planning. The posterior osteotomy is performed on the linea aspera of the femur using an oscillating saw. The anterior border of the flap is prepared by drilling a series of holes through the muscular masses, guided by the drill guide plate. The plate is positioned along the length of the femur, opposite to the linea aspera on the anterior face. It is fixed by two drill bits, to ensure that the series of holes are perfectly in line. Anterior osteoclasis completes the osteotomy, opening the femur like a book (Figure 2).

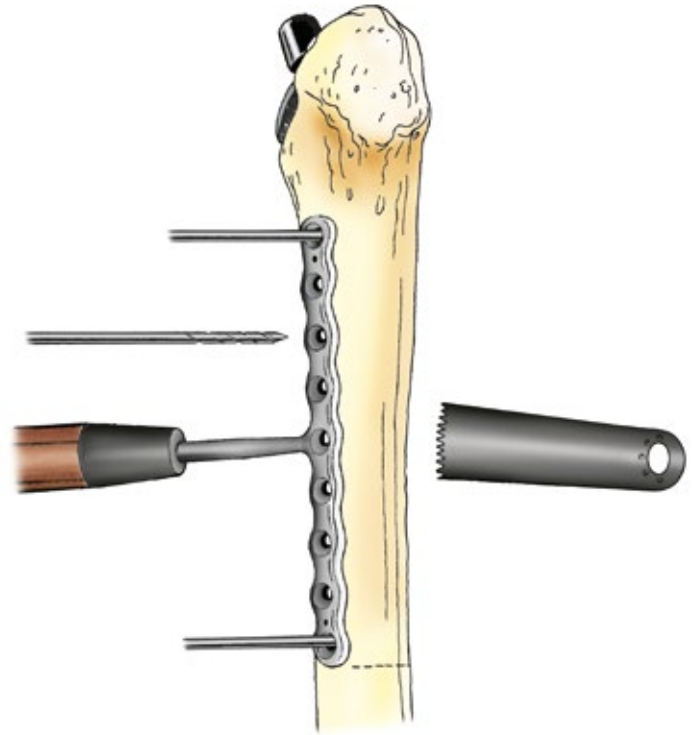


Figure 1

Removal of the Failed Implant

Removal of the failed implant, the surrounding cement, fibrous membrane and any debris, will then be quick and thorough, without the risk of aggravation of the pre-existing damage or setting a false route. The intramedullary cavity is cleared, curetted down to healthy bone and reamed if necessary. It is now possible to correctly assess any lesions, examining the condition of the cortex and any bone defects or discontinuity.

Once this assessment has been completed, some bone-grafting may prove necessary (Figure 2). Decisions taken during pre-operative planning as to the likely configuration of stem length, diameter and type can be reviewed at this stage.

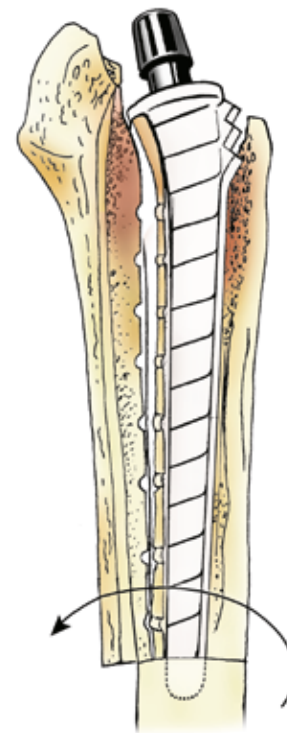


Figure 2

Trial Implants

Once the distal diaphysis has been carefully reamed, a trial stem is selected, either of the same diameter or next size available. Stability is assessed using the following criteria:

- Distal stem position with regards to height (distance between the groove on the trial stem, marking the metaphyso-diaphyseal junction, and the lower part of the flap). The distance 'D' is checked using the ruler (Figure 3).
- Stem primary stability in both the axial and rotational planes is achieved (note: should adequate press-fit not be achieved with the original size selection, a stem of the next larger diameter should be tried).
- The surgeon should ensure that optimum filling of the femoral canal is achieved (press-fit corresponding to cementless stem philosophy)
- Stem press fit can be checked intra-operatively by fluoroscopy to ensure maximum diaphyseal fill.

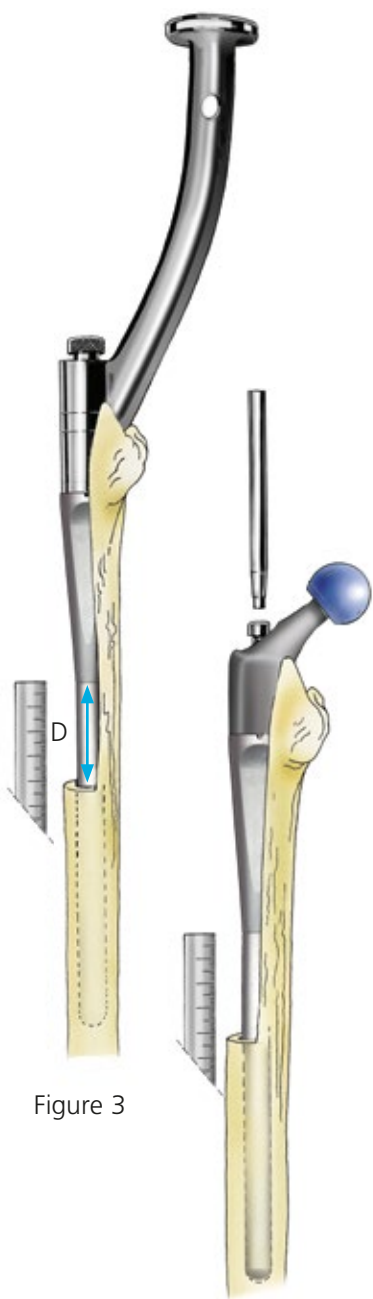


Figure 3

The trial stem, mounted on its handle, is introduced into the femoral canal to the depth identified during planning (Figure 4). An "ANTE" marking on its anterior surface makes it easier to position it in relation to the femoral curve. The junction between the conical metaphyseal area and the cylindrical diaphyseal area is represented by a groove on the trial stem. (On the final implant, this level is represented by the upper limit of the vertical macrostructures). The trial stem must be stable within the femoral canal and the handle is then removed.

The surgeon should ensure that stability is achieved by the optimal filling of the femoral canal and not due to misalignment of the stem and the femoral curve. Care should be taken not to undersize the stem in an effort to gain femoral depth, especially in larger patients.

The pre-determined trial trochanteric component is mounted in place. Its anteversion is selected, depending on stability and the possible risk of impingement. It is adjusted according to the reference point marked on the anterior and posterior and lateral surfaces of the proximal end of the stem, to match the patient's anatomy. The central mark on the trochanteric component represents a neutral position, while the other two marks indicate positions of -10° and $+10^{\circ}$ of anteversion. When the trochanteric component has been positioned for the appropriate anteversion, the interlocking screw is tightened. Trial reduction is carried out once the selected trial head is set in place. Mobility and stability tests are conducted.

Figure 4

Stabilisation of the greater trochanter or the femoral flap may be improved by fitting a trial trochanteric wing. At this stage, it is still possible to make changes to the anteversion, the height of the trochanteric component or the length of the neck.

Once the choice of the components has been confirmed, the trial components are removed and the final stem prepared.

NOTE: femoral curvature may give a false sense of primary stability if misaligned, it is thus recommended to check the degree of press fit along the length of the stem intra-operatively through X-ray or similar imaging modalities.

Final Implants

Assembly of the Targeting Frame

The final stem corresponding to the trial implant in terms of length and diameter is mounted on the corresponding targeting frame (right/left). Using the "ANTE" and "POST" marking ensure the stem is correctly orientated before assembly with the targeting frame.

When assembling the final Implant & the targeting frame, ensure the locking screw of the frame is aligned and fully seated in the corresponding hole on the distal stem.

In addition, the orientation "key" on the targeting frame should seat entirely into the corresponding recess in the stem, thus ensuring the stem is correctly orientated and the threaded section is not loaded during implantation.

A table test is conducted to check the targeting frame curve and the correct alignment of the screw holes with the final implant (Figure 5).

Implantation of the Metaphyso-Diaphyseal Stem

The stem may be introduced by mounting it directly on its targeting frame or by temporarily using the handle.

It is inserted to the level identified during planning and checked using the trial stem (distance 'D') (Figure 6).

In order to check that the final stem is correctly positioned at the same height as the trial stem, the distance 'D' from the position of the upper end of the vertical macrostructures of the metaphyso-diaphyseal stem and the lower end of the osteotomy is determined using the ruler.



Figure 5



Figure 6

Final Implants

Distal Screw Placement

If not already attached, the appropriate targeting frame (right or left) replaces the handle. It is positioned on the cone and firmly locked in place. Again, ensure both surfaces are flush and the 'locking key' is seating in the corresponding recess in the implant. Should any gap occur here, the offset will incur misalignment of the drill guides and the implant holes. Holes in the targeting device are designed to accept the drill guides and drill bits used to prepare the femoral cortices for the locking screws (Figure 7).

For greater precision, screw placement always begins with the proximal screw. It should be remembered that the **most proximal screw must be a minimum of 5 cm below the lower part of the flap**. Adequate distal fixation will provide essential primary stability of the stem until healing of the femoral osteotomy and reconstruction of the proximal bone.

The centre punch is inserted into the 5 mm drill guide and lightly tapped to mark the cortex. The centre punch is then removed and the 5 mm drill is positioned in the drill guide and **used only for the external cortex**. The 3.5 mm drill guide is then inserted into the 5 mm drill guide and the 3.5 mm drill is used for the internal cortex (Figure 8).

The length of the screw to be used is determined using the screw depth measure. The screw is locked using the screwdriver, which is left in place to enhance the stability of the targeting device and allowing the distal screws to be drilled with greater precision. Ensure all available screw holes are used. Once the screw placement is completed, the targeting frame can be removed.

Before implanting the cortical bone screws, ensure they are undamaged, free of scratches and straight.

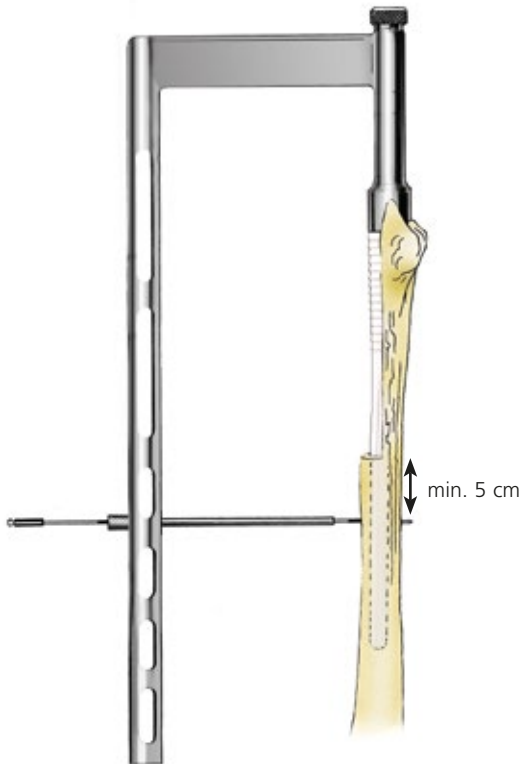


Figure 7

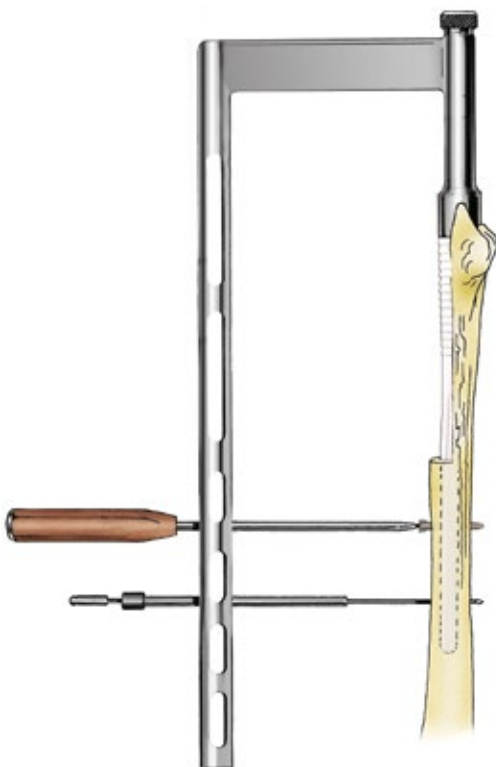


Figure 8

Placement of the trial trochanteric component and wing

At this point, the trial trochanteric component and wing may be re-fitted in order to confirm that the length of the limb, stability of the prosthesis and anteversion have been restored (Figure 9). Before assembling any components care must be taken to ensure both surfaces are free from any debris or fluid that could interfere with the stability and strength of the taper connection. Surfaces must be cleaned and dried before assembly and impaction.

The final trochanteric component, with or without a flange, may then be firmly inserted on the stem taper and impacted, ensuring that the planned anteversion value is used. It is imperative to use the dedicated impactor to ensure proper fixation of the taper connection between components.

To ensure the Trochanteric component is secure, the final locking screw must be used and fully inserted until flush using the T-Handle Hex Driver (i.e. L95815). It is important to ensure there is no debris on any mating faces or threaded sections before assembly.

NOTE: If the anteversion after impaction is not correct, the trochanteric component can be removed by removing the locking screw (if any were used) and screwing the T-handle trochanteric component extractor until the trochanteric component is detached.

If calcar grafting is to be performed, this can be stabilised and reinforced by using a trochanteric component with a collar.

Trochanteric Wing

The locking screw supplied sterile with the trochanteric component is used to interlock the connection between the trochanteric component and the stem, according to the selected anteversion.

If a lateral wing is required, its connection feature is placed between the trochanteric component and the locking screw. The screw is then tightened in the same way.

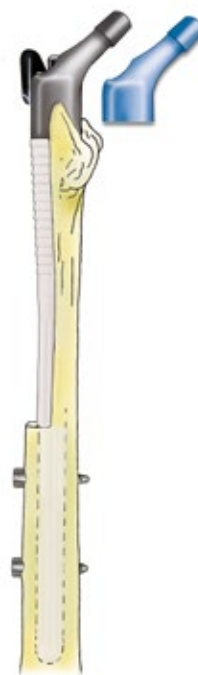


Figure 9

Final Implants

Warning: Use only the screw supplied with the definitive trochanteric component. Do not implant the trial screws (i.e. L93507 and L93510)

Femoral Head Impaction

After carefully cleaning and drying the stem taper, the appropriate femoral head is positioned and lightly impacted with the dedicated impactor (L93206) to engage the taper (Figure 10). A final reduction of the assembly is then performed.

Femoral Reconstruction

Reconstruction of the femoral shaft around the final implant is then undertaken. Re-attachment of the osteotomy is achieved by the use of cerclage cables (Figure 11).

Bone grafting is not essential but may be desired. Large structural grafts may be used for calcar reconstruction or filling of cortical defects. Morsellised compacted bone should be used to fill in any residual cavities.



Figure 10

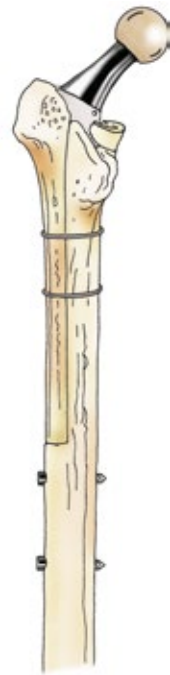


Figure 11

Post-Operative Protocol

Strict adherence by the patient to the surgeon's instructions and warnings is extremely important. Accepted practices should be followed in postoperative care.

The patient should be released from the hospital with complete written instructions and warnings regarding concerning exercises/therapies, care and all limitations/restrictions on her/his activity as well as those in relation to exposure to magnetic fields.

Weight bearing is dependent upon the healing of the femoral flap. Weight-bearing, even partial, will not be prescribed until radiological proof is obtained of osteointegration in the healthy area of the stem and associated healing of the osteotomy and/or any other femoral damage to the proximal femur up to the lower limit of the conical metaphyso-trochanteric section. This is generally achieved at between 45 and 90 days. Partial weight-bearing will then be permitted, with the support of a walking aid.

A continuing periodic patient follow-up is recommended. Due to the unknown functional lifetime of the implant, particularly with respect to implant fixation and UHMWPE bearing surfaces, A-P radiographs of the pelvis should be taken at each follow-up then compared with previous radiographs and correlated with the clinical assessment of the patient. If any radiographic changes are observed, such as the occurrence of radiolucencies, bone resorption or any changes in the position of an implant, these changes should be closely monitored to determine whether they are static or progressive and the patient treated appropriately.

Implants

ARTICUL/EZE™ Trial Heads

| Cat. No. | Description |
|-----------|--------------------|
| 253069000 | 22.225 mm / +4 (M) |
| 253070000 | 22.225 mm / +7 (L) |
| 253081000 | 28 mm / +1.5 (S) |
| 253082000 | 28 mm / +5 (M) |
| 253083000 | 28 mm / +8.5 (L) |
| 253084000 | 28 mm / +12 (XL) |
| 253091000 | 32 mm / +1 (S) |
| 253092000 | 32 mm / +5 (M) |
| 253093000 | 32 mm / +9 (L) |
| 253094000 | 32 mm / +13 (XL) |



Distal Stems

| | |
|--------|------------------------------------|
| L92412 | Stem Ø 10 mm Length 225 mm 1 Hole |
| L92414 | Stem Ø 10 mm Length 275 mm 1 Hole |
| L92416 | Stem Ø 10 mm Length 325 mm 1 Hole |
| L92418 | Stem Ø 10 mm Length 375 mm 1 Hole |
| L92422 | Stem Ø 12 mm Length 225 mm 2 Holes |
| L92424 | Stem Ø 12 mm Length 275 mm 2 Holes |
| L92426 | Stem Ø 12 mm Length 325 mm 2 Holes |
| L92428 | Stem Ø 12 mm Length 375 mm 2 Holes |
| L92432 | Stem Ø 14 mm Length 225 mm 2 Holes |
| L92434 | Stem Ø 14 mm Length 275 mm 2 Holes |
| L92436 | Stem Ø 14 mm Length 325 mm 3 Holes |
| L92438 | Stem Ø 14 mm Length 375 mm 3 Holes |
| L92442 | Stem Ø 16 mm Length 225 mm 2 Holes |
| L92444 | Stem Ø 16 mm Length 275 mm 2 Holes |
| L92446 | Stem Ø 16 mm Length 325 mm 3 Holes |
| L92448 | Stem Ø 16 mm Length 375 mm 3 Holes |
| L92452 | Stem Ø 18 mm Length 225 mm 2 Holes |
| L92454 | Stem Ø 18 mm Length 275 mm 2 Holes |
| L92456 | Stem Ø 18 mm Length 325 mm 3 Holes |
| L92458 | Stem Ø 18 mm Length 375 mm 3 Holes |
| L92462 | Stem Ø 20 mm Length 225 mm 2 Holes |
| L92464 | Stem Ø 20 mm Length 275 mm 2 Holes |
| L92466 | Stem Ø 20 mm Length 325 mm 3 Holes |
| L92468 | Stem Ø 20 mm Length 375 mm 3 Holes |



Femoral Heads

| | |
|-----------|--|
| 136529000 | ARTICUL/EZE Head CoCr 22.225 mm +4 (M) |
| 136530000 | ARTICUL/EZE Head CoCr 22.225 mm +7 (L) |
| 136511000 | ARTICUL/EZE Head CoCr 28 mm +1.5 (S) |
| 136512000 | ARTICUL/EZE Head CoCr 28 mm +5 (M) |
| 136513000 | ARTICUL/EZE Head CoCr 28 mm +8.5 (L) |
| 136514000 | ARTICUL/EZE Head CoCr 28 mm +12 (XL) |
| 136521000 | ARTICUL/EZE Head CoCr 32 mm +1 (S) |
| 136522000 | ARTICUL/EZE Head CoCr 32 mm +5 (L) |
| 136523000 | ARTICUL/EZE Head CoCr 32 mm +9 (M) |



| Cat. No. | Description |
|-----------|--|
| 136524000 | ARTICUL/EZE Head CoCr 32 mm +13 (XL) |
| 136528310 | ARTICUL/EZE Head BIOLOX DELTA 28 mm +1.5 (S) |
| 136528320 | ARTICUL/EZE Head BIOLOX DELTA 28 mm +5 (M) |
| 136528330 | ARTICUL/EZE Head BIOLOX DELTA 28 mm +8.5 (L) |
| 136532310 | ARTICUL/EZE Head BIOLOX DELTA 32 mm +1 (S) |
| 136532320 | ARTICUL/EZE Head BIOLOX DELTA 32 mm +5 (M) |
| 136532330 | ARTICUL/EZE Head BIOLOX DELTA 32 mm +9 (L) |
| 136536310 | ARTICUL/EZE Head BIOLOX DELTA 36 mm +1.5 (S) |
| 136536320 | ARTICUL/EZE Head BIOLOX DELTA 36 mm +5 (M) |
| 136536330 | ARTICUL/EZE Head BIOLOX DELTA 36 mm +8.5 (L) |
| 136536340 | ARTICUL/EZE Head BIOLOX DELTA 36 mm +12 (XL) |



| | |
|---------|---|
| 9111121 | ARTICUL/EZE Head Alumina Ceramic 28 mm +1.5 (S) |
| 9111122 | ARTICUL/EZE Head Alumina Ceramic 28 mm +5 (M) |
| 9111123 | ARTICUL/EZE Head Alumina Ceramic 28 mm +8.5 (L) |
| 9111131 | ARTICUL/EZE Head Alumina Ceramic 32 mm +1 (S) |
| 9111132 | ARTICUL/EZE Head Alumina Ceramic 32 mm +5 (M) |
| 9111133 | ARTICUL/EZE Head Alumina Ceramic 32 mm +9 (L) |



ARTICUL/EZE CERAMAX™ Heads: Refer to Cat No: DSEMIJRC/0615/0319(2)
ARTICUL/EZE ULTAMET Heads: Refer to Cat No: DSEMIJRC/0615/0319(2)

Trochanteric Components

| | |
|--------|---|
| L92405 | Trochanteric Component 25 mm Collared + Locking screw 16 mm |
| L92406 | Trochanteric Component 25 mm Collarless + Locking screw 16 mm |
| L92408 | Trochanteric Component 35 mm Collared + Locking screw 26 mm |
| L92409 | Trochanteric Component 35 mm Collarless + Locking screw 26 mm |



Screws

| | |
|--------|---------------------------|
| L92370 | Screw Ø 5 mm Length 20 mm |
| L92372 | Screw Ø 5 mm Length 25 mm |
| L92374 | Screw Ø 5 mm Length 30 mm |
| L92376 | Screw Ø 5 mm Length 35 mm |
| L92378 | Screw Ø 5 mm Length 40 mm |
| L92380 | Screw Ø 5 mm Length 45 mm |
| L92382 | Screw Ø 5 mm Length 50 mm |
| L92384 | Screw Ø 5 mm Length 55 mm |
| L92386 | Screw Ø 5 mm Length 60 mm |
| L92388 | Screw Ø 5 mm Length 65 mm |
| L92390 | Screw Ø 5 mm Length 70 mm |
| L92392 | Screw Ø 5 mm Length 75 mm |
| L92394 | Screw Ø 5 mm Length 80 mm |



Lateral Wings

| | |
|--------|---------------------|
| L92401 | Lateral Wing size 1 |
| L92402 | Lateral Wing size 2 |
| L92403 | Lateral Wing size 3 |



Instruments

Trays and Cases

| Cat. No. | Description |
|----------|--------------------------|
| L93384 | Tray No. 1 |
| L93385 | Top Tray No. 2 |
| L93386 | Bottom Tray No. 2 |
| L93387 | Top Tray No. 3 |
| L93388 | Bottom Tray No. 3 |
| L93381 | Tray Cover No. 1 |
| L93382 | Tray Cover No. 2 |
| L93383 | Tray Cover No. 3 |
| CONTREE1 | Steri. Case - Tray No. 1 |
| CONTREE2 | Steri. Case - Tray No. 2 |
| CONTREE3 | Steri. Case - Tray No. 3 |
| L93206 | Head Impactor |

Trial Wings

| Cat. No. | Size | Image |
|----------|--------|-------|
| L93501 | Size 1 | |
| L93502 | Size 2 | |
| L93503 | Size 3 | |

Trial Stems

| | |
|--------|--------------------------|
| L93512 | Ø 26-10 mm Length 225 mm |
| L93514 | Ø 26-10 mm Length 275 mm |
| L93516 | Ø 26-10 mm Length 325 mm |
| L93518 | Ø 26-10 mm Length 375 mm |
| L93522 | Ø 26-12 mm Length 225 mm |
| L93524 | Ø 26-12 mm Length 275 mm |
| L93526 | Ø 26-12 mm Length 325 mm |
| L93528 | Ø 26-12 mm Length 375 mm |
| L93532 | Ø 26-14 mm Length 225 mm |
| L93534 | Ø 26-14 mm Length 275 mm |
| L93536 | Ø 26-14 mm Length 325 mm |
| L93538 | Ø 26-14 mm Length 375 mm |
| L93542 | Ø 26-16 mm Length 225 mm |
| L93544 | Ø 26-16 mm Length 275 mm |
| L93546 | Ø 26-16 mm Length 325 mm |
| L93548 | Ø 26-16 mm Length 375 mm |
| L93552 | Ø 26-18 mm Length 225 mm |
| L93554 | Ø 26-18 mm Length 275 mm |
| L93556 | Ø 26-18 mm Length 325 mm |
| L93558 | Ø 26-18 mm Length 375 mm |
| L93562 | Ø 26-20 mm Length 225 mm |
| L93564 | Ø 26-20 mm Length 275 mm |
| L93566 | Ø 26-20 mm Length 325 mm |
| L93568 | Ø 26-20 mm Length 375 mm |



Trial Trochanteric Components

| Cat. No. | Description |
|----------|---------------------|
| L93505 | Blue - Height 25 mm |
| L93508 | Grey - Height 35 mm |



Trial Locking Screws

| | |
|--------|--|
| L93507 | Length 16 mm (to be used with L93505 Blue - Height 25 mm) |
| L93510 | Length 26 mm (to be used with L93508 Grey - Height 35 mm) |



Miscellaneous

| | |
|-----------|--|
| L93570 | Stem Handle |
| L93572 | Targeting Device Right |
| L93574 | Targeting Device Left |
| L93575 | Drill Bit Fl. 3,5 Length 275 mm |
| L93577 | Drill Guide Ø 3.5 mm |
| L93597 | Drill Guide Ø 5 mm |
| L93582 | Hex Screwdriver Fl. 3.5 mm |
| L93584 | Depth Gauge |
| 443730 | Ruler Length 300 mm* |
| L93586 | Drilling Template |
| L93587 | Trocar |
| L93588 | Drill Bit Fl. 5 Length 190 mm |
| L93589 | Trochanteric Component Impactor |
| L95815 | T-Handled Hex Screwdriver Fl. 4.5 mm |
| L95820 | T-Handled Trochanteric Component Extractor |
| 907269000 | X-Ray Templates (scale 1.2) |



* MEDICON eG, Gänsäcker 15, 78532 Tuttlingen, Germany

| Legal Manufacturer Vs Product | |
|-------------------------------|-------------------------------|
| DePuy (Ireland) | REEF Instruments and Implants |
| DePuy International | ARTICUL/EZE heads |
| MEDICON | Ruler (443730) |

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