REEF™

DISTALLY INTERLOCKED MODULAR FEMORAL RECONSTRUCTION PROSTHESIS

DePuy
a Johnson & Johnson company

MEETING THE

DEMANDS OF MAJOR

RECONSTRUCTIVE

SURGERY

REEF™ is a modular implant intented for the management of major femoral defects. Experience in reconstruction of major femoral deficiencies has demonstrated the need for dedicated hip replacements, that should be:

MODULAR - Because the exact requirements of reconstruction can be determined only intra-operatively. Modularity permits femoral implant assembly during surgery. Moreover by allowing choice of length, diameter and version. Modularity ensures a more complete match of implant to patient.

INTERLOCKING - To ensure primary mechanical stability. Distal interlocking helps to guaratee stabe fixation preventing subsidence and rotation [1].

HA COATED - To further increase implant osteointegration. A full coating of hydroxyapatite (HA) leads to ongrowth over the whole intramedullary surface and provides ideal conditions to heal the femur [2].

Meeting the above requirements, REEF™ system completes the CORAIL® group of devices that provides a solution for all cementless total hip replacement indications.

Indications

Loosening

• Treatment of extensive loosening of femoral stems - cemented or not - Paprosky's type 3 and 4 [3]:

Type 3:
- Severely damaged non-supportive metaphysis.
- No calcar.
- Internal cortical wall unusable.

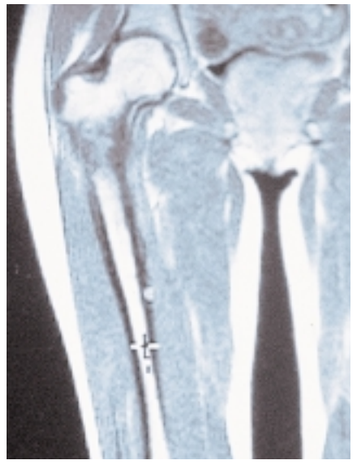
Type 4:
- Type 3 destruction
- Major diaphyseal damage

Fractures

• Management of diaphyseal fractures located below destabilized long femoral stems.

Tumours

• Tumour surgery requiring distal anchorage for the resection of the femur proximally.



Implant description

Trochanteric component

The trochanteric component permits optimum filling of the femoral metaphysis and restoration of the limb length. It is available in two heights with or without collar.
The trochanteric component has a neck-shaft angle of 135 degrees for correct reconstruction of the femoral anatomy.
Additional fixation of detached bone fragments is made possible by a series of medial cerclage cable holes.
The trochanteric component has horizontal step macrostructures to resist subsidence.
Fixation of the trochanteric component to the implant stem is by means of a screw and morse taper. Ten degree variations in version may be chosen according to anterior-posterior witness marks.
The neck culminates in a 12/14 taper for combination with ceramic and cobalt chrome heads.
The trochanteric component intramedullary is fully HA coated.

Distal metaphyseal-diaphyseal stem

The single block stem is composed of the following parts:

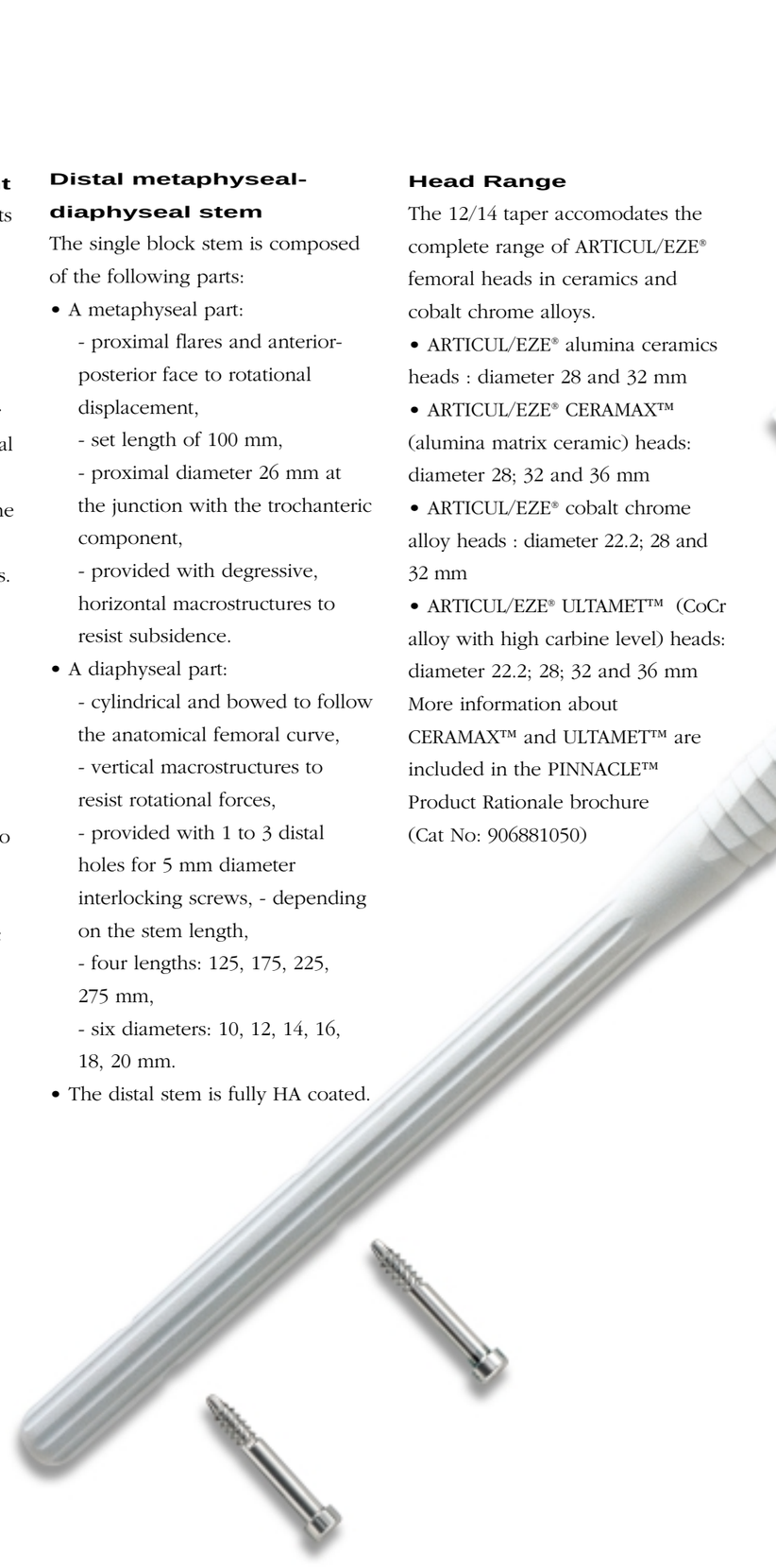
- A metaphyseal part:
  - proximal flares and anterior-posterior face to rotational displacement,
  - set length of 100 mm,
  - proximal diameter 26 mm at the junction with the trochanteric component,
  - provided with degressive, horizontal macrostructures to resist subsidence.
- A diaphyseal part:
  - cylindrical and bowed to follow the anatomical femoral curve,
  - vertical macrostructures to resist rotational forces,
  - provided with 1 to 3 distal holes for 5 mm diameter interlocking screws, - depending on the stem length,
  - four lengths: 125, 175, 225, 275 mm,
  - six diameters: 10, 12, 14, 16, 18, 20 mm.
- The distal stem is fully HA coated.

Head Range

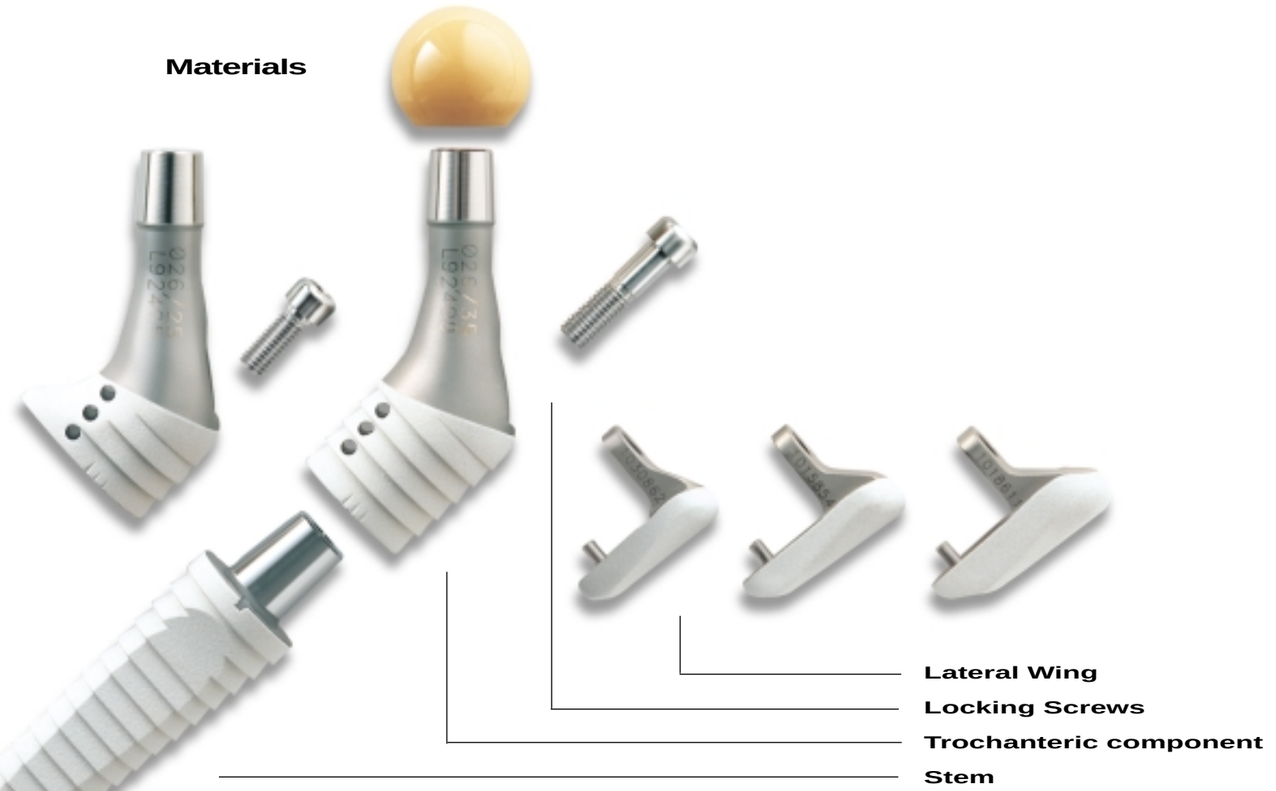
The 12/14 taper accomodates the complete range of ARTICUL/EZE® femoral heads in ceramics and cobalt chrome alloys.

- ARTICUL/EZE® alumina ceramics heads : diameter 28 and 32 mm
- ARTICUL/EZE® CERAMAX™ (alumina matrix ceramic) heads: diameter 28; 32 and 36 mm
- ARTICUL/EZE® cobalt chrome alloy heads : diameter 22.2; 28 and 32 mm
- ARTICUL/EZE® ULTAMET™ (CoCr alloy with high carbine level) heads: diameter 22.2; 28; 32 and 36 mm

More information about CERAMAX™ and ULTAMET™ are included in the PINNACLE™ Product Rationale brochure (Cat No: 906881050)



Materials



Ceramic heads

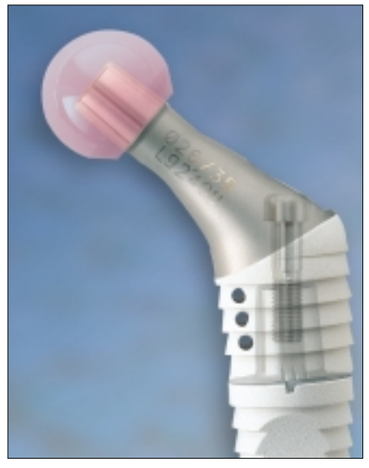
Damaged heads are associated with an increased rate of polyethylene wear [4].
Harder, more durable bearing surfaces are essential for wear rates and debris production. The hardness and the improvement in the surface finish of the ceramic femoral heads significantly reduce the wear of the acetabulum [5]. Pure alumina ceramic has been used in medical applications for more than 20 years, its tribology performance and toughness has been demonstrated [5]. CERAMAX™ heads are made of an innovative alumina matrix ceramic designed to combine superior wear properties with improved fracture resistance [6].

HA coating

REEF™'s HA coating exhibits the same features of CORAIL® which have been clinically proven for 20 years [7]. Its bioactivity facilitates bone ongrowth and efficient osteointegration. The latter ensures long term stability of the implant in the host bone [8].

Titanium alloy

All the components are made of forged titanium alloy TiA16V4 ELI (ASTM F 136), material selected for its excellent biocompatibility and its high fatigue strength.



Surgical Technique

Preoperative planning

Preoperative templating makes it possible to assess the size of components needed for reconstruction. The REEF™'s templates (magnification scale 1.2) enable appreciating the relative dimensions of the different components in the antero-posterior and medio-lateral projections.
A distal stem should be chosen that matches the diameter of the femoral canal and achieves cortical contact with the walls of the canal.
The most proximal screw hole should be positioned at least 5 cm below the most distal defect.
The trochanteric component chosen should reconstruct the height and position of the femoral neck.
The lateral wing is chosen in cases where laterialisation of the greater trochanter is required.

Approach

Regardless of the initial approach selected (posterior, lateral or anterior) the most effective surgical technique is an extensive transfemoral osteotomy (ETO) approach that includes the greater trochanter as part of large flap, instead of a simple trochanterotomy which is insufficient to expose the lesions and explant the failed hardware (fig. 1).
While the approach needs to be extensive, care should also be taken to ensure that the existing lesions are not damaged further, and that the soft tissue attachments and the muscles are handled as gently as possible, in order to preserve the bone's blood supply.
At the distal end, the cortex is cut with a saw around the lateral hemicircumference. The osteotomy is made proximal to the tip of the failed implant, at a level determined during preoperative planning, which will permit a straightforward extraction.
The anterior border of the flap is prepared by drilling a series of holes, guided by the osteoclasis drilling template, and passing through the soft tissues. The osteoclasis drilling template should be positioned anteriorly directly opposite, and parallel to, the linea aspera. It is held in place with two drill sleeves. An anterior osteoclasis completes the osteotomy (fig. 1).

Removal of the failed implant

The failed implant, the surrounding cement, fibrous membrane and the debris may be removed, rapidly and thoroughly,

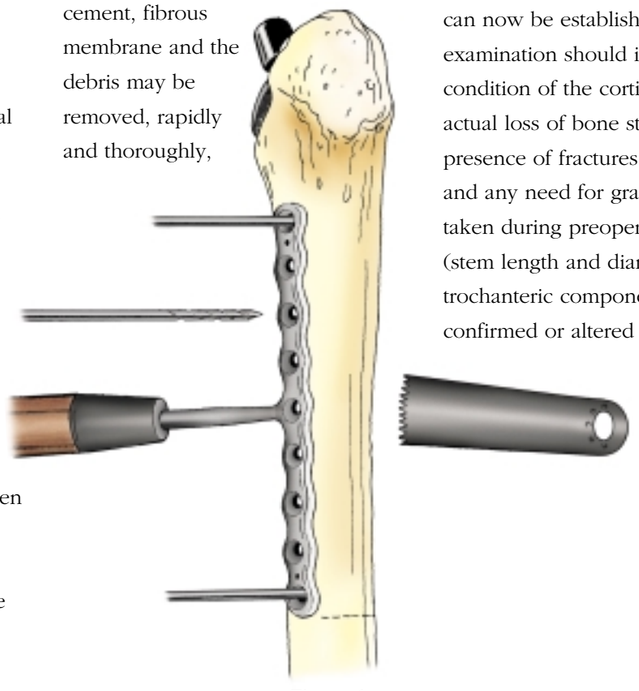


Figure 1

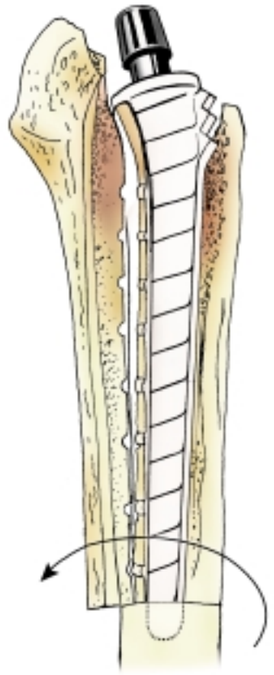


Figure 2

without risk of false route or aggravation of the existing damages.
The intramedullary cavity is cleared and curetted down to healthy bone.
The accurate assessment of defects can now be established. The examination should include the condition of the cortical walls, the actual loss of bone stock, the presence of fractures or fissures, and any need for grafting. Decisions taken during preoperative planning (stem length and diameter, type of trochanteric component) may be confirmed or altered (fig. 2).

Steps in the procedures

Trial Stem

The diaphysis may need to be reamed sparingly and carefully to ensure a proper fitting of the implant. The trial stem is assembled on the stem insertor and introduced into the femoral canal to the depth estimated during templating (fig. 3).
The anterior surface is marked «ANT» to facilitate the orientation with respect to the femoral curvature. The junction between the cylindrical distal part of the stem and flared metaphyseal part is shown on the trial stem by a marker groove. On the final implant, this point is represented by the proximal end of the vertical grooves.
The trial stem should be stable within the femoral canal.
With the stem in place, the stem insertor is removed and the chosen trochanteric component attached.
A witness mark at the proximal end of the trial stem should line up with one of three marks on the trochanteric component to set the version that matches the patient's anatomy. The central mark on the trochanteric component represents the neutral position, whereas the outlying marks representing -10 and +10 degrees of version. When the trochanteric component is set to the required version, the locking screw may be tightened.

Figure 3

Figure 4

A trial head is placed on the taper and a trial reduction carried out.
To ensure that the definitive implant is impacted to the same level as the trial implant, the distance between the marker groove on the trial stem and the horizontal osteotomy should be measured with a ruler (fig. 4).
When the choice of components has been made, the definitive implant is prepared for insertion.
Before insertion, the targeting device is attached and checked with the definitive stem, to ensure that the locking screw holes are correctly aligned (fig. 5).

Figure 5

Distal stem placement

The definitive metaphyseal-diaphyseal stem, attached to the stem insertor, is impacted to the level measured during trial reduction (fig. 6).

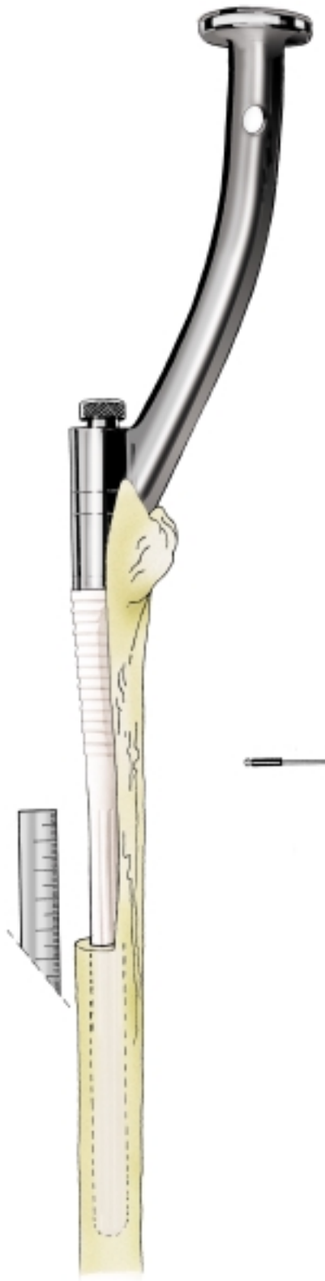


Figure 6

Distal screw placement

The appropriate tragetting device (right or left) is fitted on the taper of the taper part and firmly locked into place. 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 (fig. 7).

After measuring with the screw length gauge, the 5 mm interlocking screws are placed. The proximal screw is inserted first.

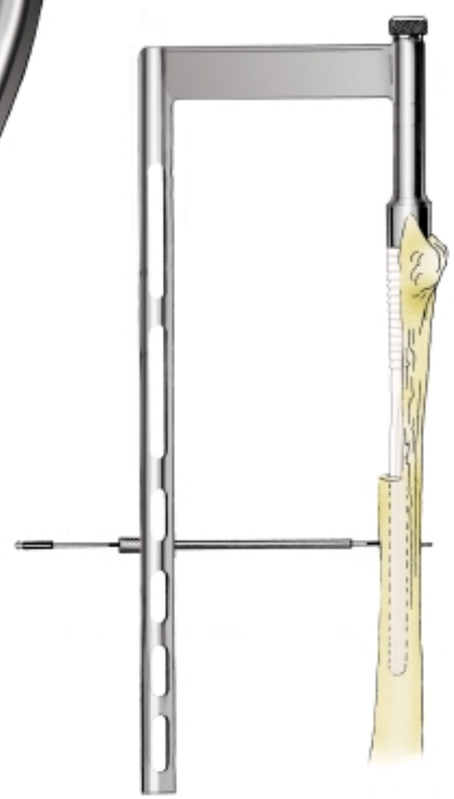


Figure 7

A stab incision is made and the 5 mm drill guide and trocar are advanced through the targeting device to the lateral cortex. The trocar is lightly tapped to indent the bone. It is then removed and replaced by the 3.5 mm drill guide. The 3.5 mm drill bit is passed through the guide and used to drill both cortices. The 3.5 mm drill guide and bit are then removed and replaced by the 5 mm drill bit which is used to overdrill the lateral cortex only (fig. 8). The screwdriver is left in situ, for additional bracing of the targeting device and to allow precision drilling of the distal screw hole(s).

When the distal hole(s) has/have been drilled, the targeting device is removed.

Figure 8

Trial trochanteric component

The trial trochanteric component is re-fitted to confirm limb length, stability and version. In case of a major defect of the greater trochanter, atrophy or instability of the trochanteric flap, a trial wing may be slotted into the trochanteric component to restore the lateral aspect of the greater trochanter (fig. 9).

Definitive trochanteric component

The definitive trochanteric component is then firmly impacted, ensuring that the version is set to the value established during the trial reduction.

It is a main requirement to use the specific impactor to ensure a proper morse taper fixation of both implants.

If a calcar graft is planned, this may be stabilised and loaded by selecting a trochanteric component with a collar. The proximal locking screw (supplied with the definitive trochanteric component) is used to protect the superior hole and to attach the wing to the trochanteric component, when required (fig. 10).

Femoral head impaction

The appropriate head is placed onto the taper and lightly tapped home using the head impactor.

A final reduction is performed.

Reconstruction

The reconstruction of the femoral shaft around the stem can be undertaken.

Reattachment of the flap is achieved by means of cerclage cables (fig 11).

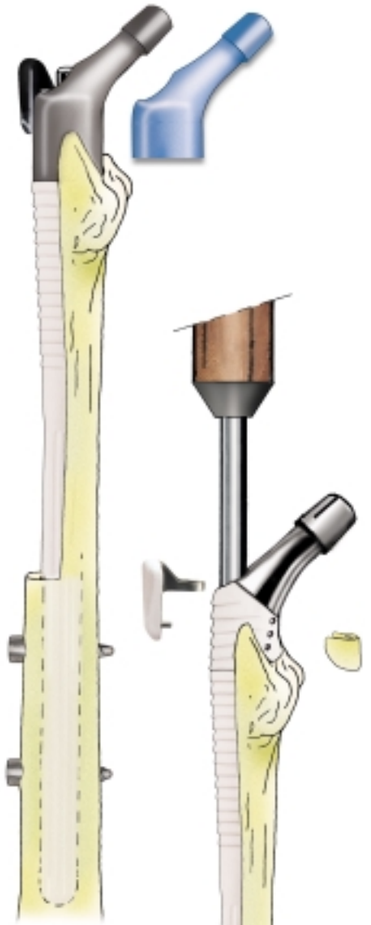


Figure 9

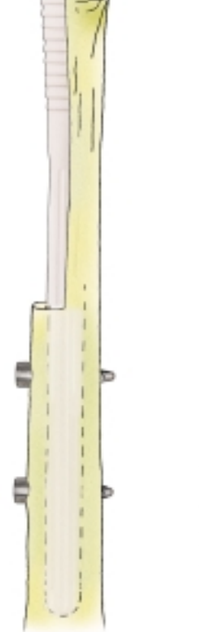


Figure 10

Bone grafting is not essential but may be desirable. Massive structural grafts may be used for calcar reconstruction or filling of cortical defects. Morsellised compacted bone should be used to fill any remaining gaps.

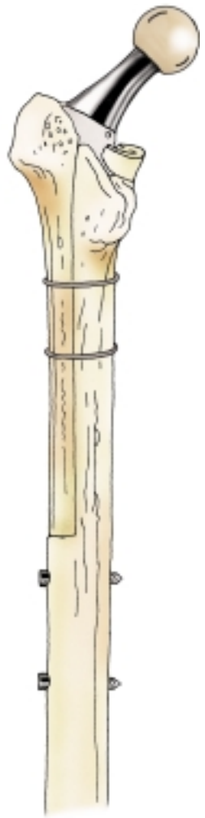


Figure 11

Postoperative management

As a rule, patients are kept off total weight bearing for 45 days with two crutches.

From 45 to 90 days, patients are kept on a protected weight bearing schedule with a stick.

After 90 days, the duration of protected weight bearing is dependent upon the condition of the femur, the healing rate of the bone flap and graft incorporation.

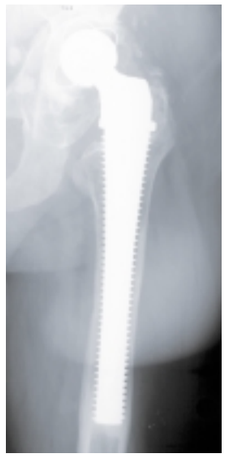
Clinical cases

Preo-perative

Patient operated on in 1986 for revision surgery with a screw implant and cemented PE acetabulum. Evolution into femoral stress-shielding and acetabulum loosening stage IIC. In 1996, insertion of a REEF™ stem and HA threaded acetabular cup.

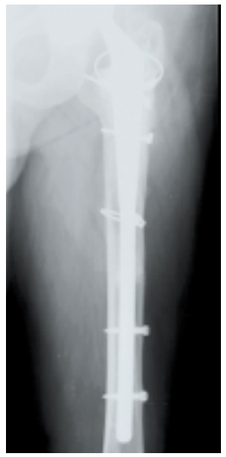
Post-operative

Satisfactory clinical evolution with a PMA score of 5.5.6. and X-rays showing a major metaphyseal bone reconstruction at 5 years follow-up.



Pre-op

3 months Post-op



5 years Post-op

Pre-operative

Female patient operated on in 1988 for revision surgery with a long HA coated stem. In 1995, a traumatic fracture occurred under the stem; revision surgery was necessary including a large femoral flap to extract the stem which was perfecty osteointegrated.

Post-operative

At 7 years follow-up, the clinical result is very satisfactory. X-rays show consolidation and preserved distal femoral trophicity.

Pre-op

3 months Post-op

7 years Post-op

Pre-operative

Female patient age 19, with Ewing sarcoma of the proximal end of the RH femur. Following chemotherapy, in 1995 the patient was operated on with resection of the proximal 2/3 of the femur.

Post-operative

At 3 years follow-up, there is no tumoral relapse. The patient is enjoying a normal function.

Pre-op

3 months Post-op

3 years Post-op

Instrumentation

Tray n°1
Cat. No. L93384
top tray n°2
Cat. No. L93385
Bottom tray n°2
Cat. No. L93386
Top tray n°3
Cat. No. L93387
Bottom tray n°3
Cat. No. L93388
Tray cover n°1
Cat. No. L93381
Tray cover n°2
Cat. No. L93382
Tray cover n°3
Cat. No. L93383
Steri. case - tray n°1
Cat. No. CONTREE1
Steri. case - tray n°2
Cat. No. CONTREE2
Steri. case - tray n°3
Cat. No. CONTREE3
Head impactor
Cat. No. L93206

ARTICUL/EZE® Trial heads

Cat. No. 253069000	22.225 mm / +4 (M)	
Cat. No. 253070000	22.225 mm / +7 (L)	
Cat. No. 253081000	28 mm / +1.5 (S)	
Cat. No. 253082000	28 mm / +5 (M)	
Cat. No. 253083000	28 mm / +8.5 (L)	
Cat. No. 253084000	28 mm / +12 (XL)	
Cat. No. 253091000	32 mm / +1 (S)	
Cat. No. 253092000	32 mm / +5 (M)	
Cat. No. 253093000	32 mm / +9 (L)	
Cat. No. 253094000	32 mm / +13 (XL)	
Cat. No. 253095000	32 mm / +17 (XXL)	

Trial wings

Cat. No. L93501	size 1
Cat. No. L93502	size 2
Cat. No. L93503	size 3

Trial trochanteric components

Cat. No. L93505	blue - height 25 mm
Cat. No. L93508	grey - height 35 mm

Locking screws

Cat. No. L93507	length 16 mm
Cat. No. L93510	length 26 mm

Trial stems

Cat. No. L93512	Ø 26-10 length 225 mm
Cat. No. L93514	Ø 26-10 length 275 mm
Cat. No. L93516	Ø 26-10 length 325 mm
Cat. No. L93518	Ø 26-10 length 375 mm
Cat. No. L93522	Ø 26-12 length 225 mm
Cat. No. L93524	Ø 26-12 length 275 mm
Cat. No. L93526	Ø 26-12 length 325 mm
Cat. No. L93528	Ø 26-12 length 375 mm
Cat. No. L93532	Ø 26-14 length 225 mm
Cat. No. L93534	Ø 26-14 length 275 mm
Cat. No. L93536	Ø 26-14 length 325 mm
Cat. No. L93538	Ø 26-14 length 375 mm
Cat. No. L93542	Ø 26-16 length 225 mm
Cat. No. L93544	Ø 26-16 length 275 mm
Cat. No. L93546	Ø 26-16 length 325 mm
Cat. No. L93548	Ø 26-16 length 375 mm
Cat. No. L93552	Ø 26-18 length 225 mm
Cat. No. L93554	Ø 26-18 length 275 mm
Cat. No. L93556	Ø 26-18 length 325 mm
Cat. No. L93558	Ø 26-18 length 375 mm
Cat. No. L93562	Ø 26-20 length 225 mm
Cat. No. L93564	Ø 26-20 length 275 mm
Cat. No. L93566	Ø 26-20 length 325 mm
Cat. No. L93568	Ø 26-20 length 375 mm

Stem handle
Cat. No. L93570

Targeting device right
Cat. No. L93572

Targeting device left
Cat. No. L93574

Drill bit Ø 3,5 length 275 mm
Cat. No. L93575

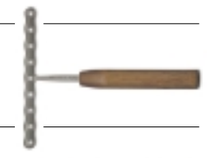
Drill guide

Cat. No. L93577	Ø 3.5 mm
Cat. No. L93597	Ø 5 mm

Hex screwdriver Ø 3.5 mm
Cat. No. L93582

Depth gauge
Cat. No. L93584

Ruler length 300 mm
Cat. No. L93585



Drilling template
Cat. No. L93586

Trocar
Cat. No. L93587

Drill bit Ø 5 length 190 mm
Cat. No. L93588

Trochanteric component impactor
Cat. No. L93589

T-handled hex screwdriver Ø 4.5 mm
Cat. No. L95815

T-handled trochanteric component extractor
Cat. No. L95820

Implants

Trochanteric components

L92405 Trochanteric component 25 mm collared
L92406 Trochanteric component 25 mm collarless
L92408 Trochanteric component 35 mm collared
L92409 Trochanteric component 35 mm collarless

Screws

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

Lateral wings

L92401 Wing size 1
L92402 Wing size 2
L92403 Wing size 3

Distal stems

L92412 Stem diam. 10 length 225 mm 1 hole
L92414 Stem diam. 10 length 275 mm 1 hole
L92416 Stem diam. 10 length 325 mm 1 hole
L92418 Stem diam. 10 length 375 mm 1 hole
L92422 Stem diam. 12 length 225 mm 2 holes
L92424 Stem diam. 12 length 275 mm 2 holes
L92426 Stem diam. 12 length 325 mm 2 holes
L92428 Stem diam. 12 length 375 mm 2 holes
L92432 Stem diam. 14 length 225 mm 2 holes
L92434 Stem diam. 14 length 275 mm 2 holes
L92436 Stem diam. 14 length 325 mm 3 holes
L92438 Stem diam. 14 length 375 mm 3 holes
L92442 Stem diam. 16 length 225 mm 2 holes
L92444 Stem diam. 16 length 275 mm 2 holes
L92446 Stem diam. 16 length 325 mm 3 holes
L92448 Stem diam. 16 length 375 mm 3 holes
L92452 Stem diam. 18 length 225 mm 2 holes
L92454 Stem diam. 18 length 275 mm 2 holes
L92456 Stem diam. 18 length 325 mm 3 holes
L92458 Stem diam. 18 length 375 mm 3 holes
L92462 Stem diam. 20 length 225 mm 2 holes
L92464 Stem diam. 20 length 275 mm 2 holes
L92466 Stem diam. 20 length 325 mm 3 holes
L92468 Stem diam. 20 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)
136515000 ARTICUL/EZE® Head CoCr 28 mm +15.5 (XXL)
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)
136524000 ARTICUL/EZE® Head CoCr 32 mm +13 (XL)
136525000 ARTICUL/EZE® Head CoCr 32 mm +17 (XXL)

911112100 ARTICUL/EZE® Head Alumina 28 mm +1.5 (S)
911112200 ARTICUL/EZE® Head Alumina 28 mm +5 (M)
911112300 ARTICUL/EZE® Head Alumina 28 mm +8.5 (L)
911113100 ARTICUL/EZE® Head Alumina 32 mm +1 (S)
911113200 ARTICUL/EZE® Head Alumina 32 mm +5 (M)
911113300 ARTICUL/EZE® Head Alumina 32 mm +9 (XL)

ARTICUL/EZE® CERAMAX™ heads refer to Cat No: 9080 20 000

ARTICUL/EZE® ULTAMET™ heads refer to Cat No: 9080 20 000

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