DePuy Synthes
COMPANIES OF Johnson&Johnson

CORAIL® REVISION STEM

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SURGICAL TECHNIQUE

CORAIL®
HIP SYSTEM
Revision Stem

Cover Image: Revision Solution shown is CORAIL Revision Stem with 36 mm ULTAMET™ head and PINNACLE® Deep Profile Revision Cup with GRIPTION® Coating

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PRODUCT RATIONALE

Introduction

With the likely increase in both primary and revision surgery expected in the coming years[1] and the changing demographics of the patient population[2] there is a greater emphasis on treating patients as conservatively as possible.[3] The use of hydroxyapatite (HA) coated stems in both primary and revision surgery has provided positive, reproducible outcomes across the range of femoral defects and has shown fast implant-to-bone integration.[4]

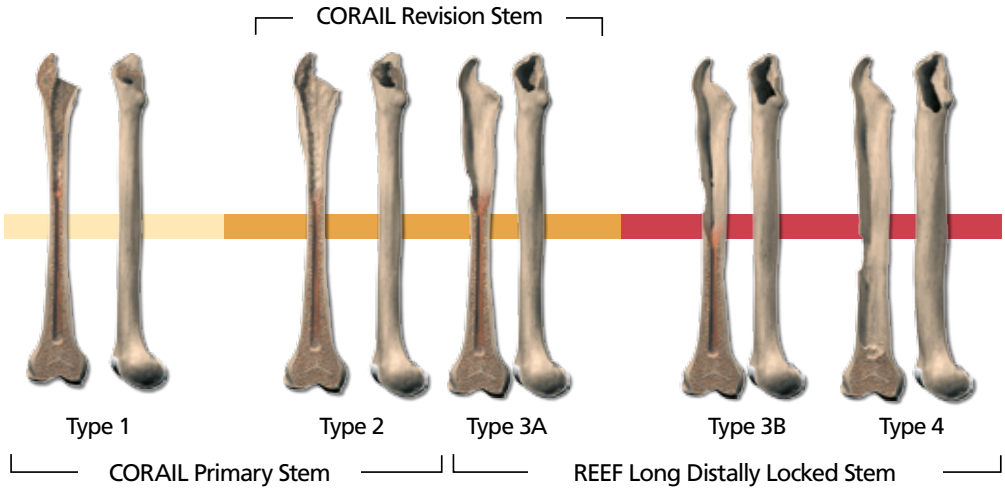
CORAIL Revision Stem

The CORAIL Revision Stem is an evolution of the KAR™ stem, specifically for revision surgery.[5,6] Manufactured from forged titanium alloy[7], it shares the CORAIL hip's design rationale of stereostability, macro and micro surface detailing, HA coating, ARTICUL/EZE® 12/14 Mini Taper and is compatible with the range of DePuy Synthes' High Performance Bearing options. The CORAIL Revision Stem offers the surgeon a range of stems for mild to moderate situations (types 2 and 3A of Paprosky's Classification[8]) making it suitable for the majority of revision cases. The CORAIL Revision Stem is also indicated for primary implantation in a cavernous femur.

The surgical technique shares a similar straightforward procedure for implantation as the primary CORAIL stem. During femoral preparation, reamers are used to calibrate the distal cavity of the femur. Machined diamond-tooth broaches remove cement and/or debris and re-shape the metaphyseal region to a quadrangular envelope with the correct anteversion.

A trial stem is also used to allow verification of the correct preparation of the femur to ensure easy insertion of the final stem.

Paprosky's Classification



Achieving Stem Stability in the Proximal Femur

As an evolution of the CORAIL primary and KAR revision stems, the CORAIL Revision Stem is designed to achieve secure initial and long term mechanical stability in the femur. It is shaped to resist both axial and torsional loosening forces. In the frontal plane, the stem's pronounced lateral flare and medial curve provide axial and rotational stability. The lateral flare is fully supported by the infero-lateral aspect of the greater trochanter. In the lateral plane a progressive anterior to posterior tulip flare fills the metaphysis and, in combination with horizontal grooves around the circumference of the stem, further reinforces axial stability.

The well-defined rectangular section and vertical grooves confer rotational stability. The stem's proximal collar acts as a support to improve axial stability. To compensate for weakness or absence of bone in the calcar region, the use of a structural horseshoe allograft is recommended. The calcar graft is compressed and stabilised by the stem's collar and is loaded by its medial curve.[9,10,11]

Proximal Load Transfer

The CORAIL Revision Stem has been designed to transfer maximum load to the remaining bone in the proximal femur. As the metaphysis is not intact, stability is achieved through a combination of both metaphyseal and proximal diaphyseal support. The longer stem aids correct axial alignment. To avoid distal load transfer, slots in the coronal and the sagittal planes help to prevent the stem from locking in the isthmus.

PRODUCT RATIONALE

Diamond-Tooth Broaches

Machined diamond-tooth broaches are designed to be more aggressive as this is often required during revision surgeries.

The stem is implanted line to line, therefore the femur is prepared using a broach of the same size which excludes the thickness of the HA coating.

HA Coating

The CORAIL Revision Stem is cementless and fully coated with hydroxyapatite to a thickness of 155 microns.[12] The stem's surface is blasted, before coating with hydroxyapatite, to assure a strong coating-to-implant bond.

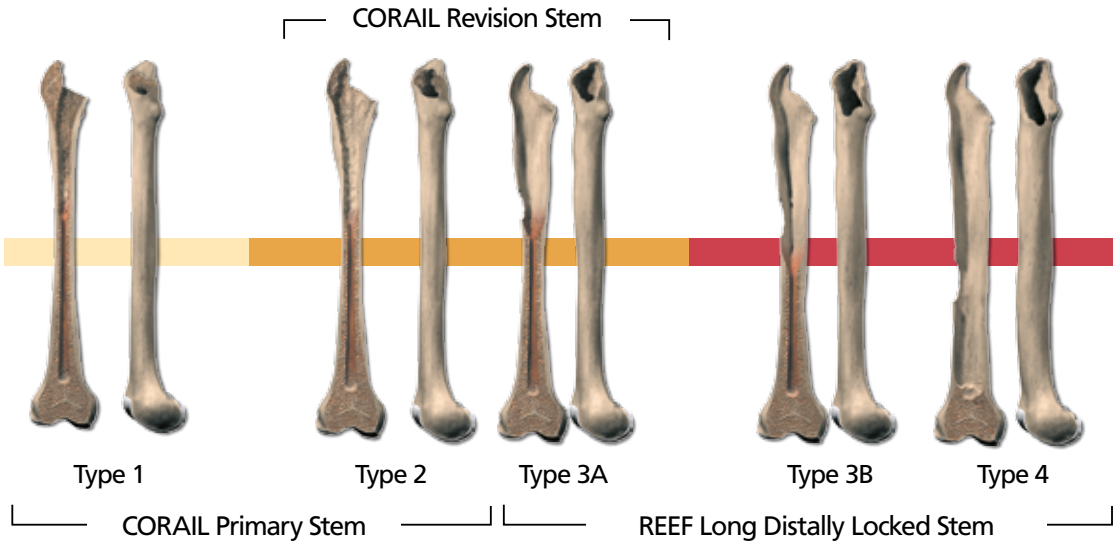
Hydroxyapatite is highly biocompatible and does not trigger an inflammatory or macrophagic reaction.[9,13] This highly osteoconductive medium, with its similarities in chemical and mineral content to human bone, stimulates fast implant to femur integration – even in cases of significant bone deficiency.[13] The biochemical process bridges gaps of up to 2 mm between implant and bone.[12] The macro and micro-textural contours of the CORAIL Revision Stem provide an extensive surface area, producing the ideal conditions for bone on-growth.[9,12]

Distal Stem Design

Two distal slots are designed to allow elasticity in the distal portion of the stem which helps in adapting to the patient's femoral morphology. These distal slots allow fitting of the stem into the femoral canal and thus an easy insertion of the final implant. The increased flexibility also minimises the potential for thigh pain and stress shielding in the proximal femur.[5]

INDICATIONS

Paprosky's Classification



For total hip arthroplasty, a common defect categorisation, like Paprosky's Classification[8], can be used to specify the indications and the surgical strategy.

For Type 1 defects, the standard CORAIL stem is used, except in the case of insufficient primary stability, in which case the CORAIL Revision Stem prosthesis should be used.

The CORAIL Revision Stem is indicated in Paprosky defects Types 2 and 3A.

There are two situations in which the CORAIL Revision Stem is used in primary surgery:

- When dealing with very large cylindrical femurs with thin cortical walls in which the CORAIL stem would not achieve optimum stability – in such cases the CORAIL Revision Stem would be selected as it is longer and enables good primary stability
- In very old patients with osteoporotic bone, the CORAIL Revision Stem makes it possible to achieve good primary stability

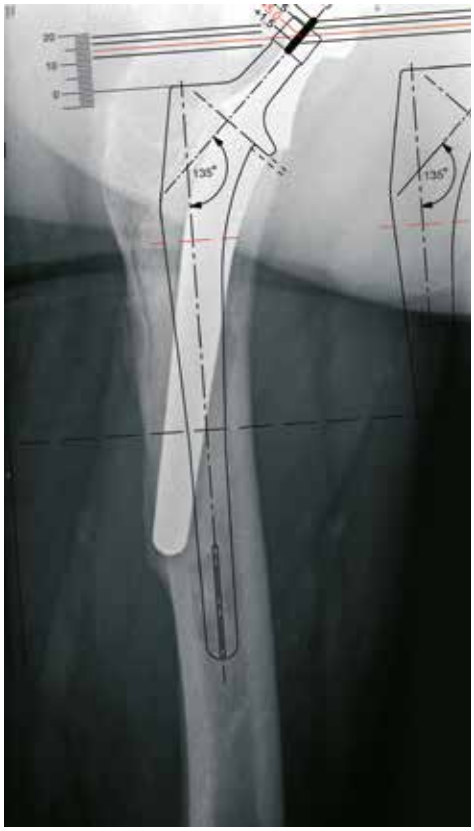
(For guidance on primary neck resection please consult the CORAIL primary stem surgical technique.)

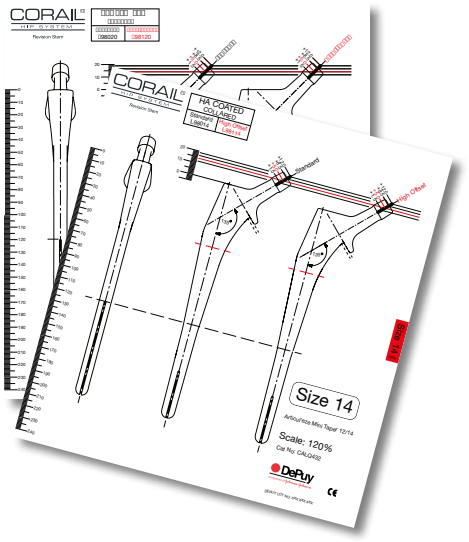
For revision total hip arthroplasty, the indication should be confirmed during the procedure after removal of the implant and all cement debris.

In all cases, the stability of the stem must be achieved prior to inserting bone graft. Therefore, the bone graft serves only to fill defects and not to ensure the stability of the stem. A wedge bone graft would fail to achieve sufficient stability and therefore would lead to potential failure of the stem. If insufficient primary stability is observed, a longer, distally locked stem should be used to achieve primary stability.

In the case of defects Type 3B and 4, it is often impossible to achieve primary stability with a CORAIL Revision Stem and therefore a longer, distally locked prosthesis must be used.

PRE-OPERATIVE PLANNING





Pre-operative planning is essential for precise reconstruction of the hip joint. The CORAIL Revision Stem prosthesis comes with a comprehensive set of X-ray templates which include a clear indication of the scale used and both standard and high offsets for all sizes of the range. These are used with radiographs showing the AP view of the pelvis and AP and lateral views of the affected femur, covering the full length of the prosthesis to be revised, as well as any occlusion in the distal femoral canal.

The AP view provides the necessary information needed to determine:

- Implant alignment and the size of component required for combination fixation in the metaphysis and diaphysis: in accordance with the philosophy of three-point-contact to ensure good primary stability
- The type of implant, Standard or High Offset. Associated with neck length, this choice allows restoration of the offset, leg length and patient's natural anatomy
- Dedicated witness marks on both the X-Ray templates and the trial stems define the required level of implantation, described as the 'minimal embedding level' – this ensures adherence to the three-point-contact design philosophy.
- Where necessary, the appropriate height of calcar bone grafting required
- Make note of anatomical landmarks (e.g. pelvic tear drop, greater trochanter etc) in relation to the templated stem for implant and trial intra-operative reference points

The lateral view may then be used to confirm implant version and alignment, to identify any defects that cannot be seen on the AP view and to check the compatibility of the stem with the femoral curvature.

A transfemoral approach to retrieve the femoral implant is not a contraindication for the CORAIL Revision Stem. The level must be defined using x-ray templates and be above the longitudinal distal slots.

STEP 1: SURGICAL APPROACH

NOTE 1.1

Prior to surgery, the instruments should be checked for damage or wear. All assembly/ dissassembly instructions should be tested to avoid any peri-operative issues related to the use of instruments.

Posterolateral approach

Anterolateral approach

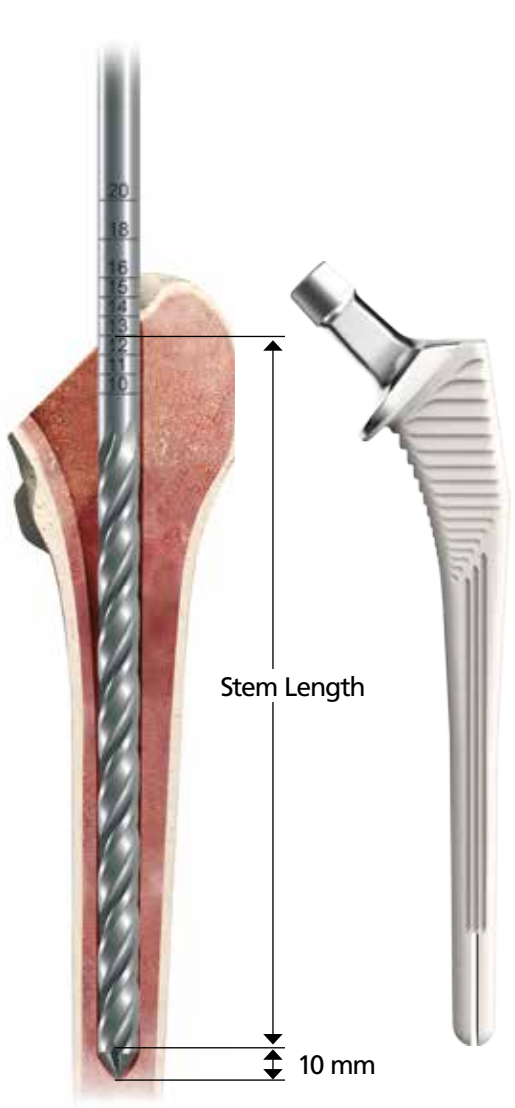
Any of the standard surgical approaches may be used to implant the CORAIL Stem or CORAIL Revision Stem.

The CORAIL Revision Stem can be implanted using either of two instruments sets – the full/ stand-alone CORAIL Revision Stem instrument set which comprises both the Core Instrumentation and Femoral Preparation Instruments; or the CORAIL Revision Stem upgrade set, which is opened alongside a standard CORAIL instrument set and contains only the Femoral Preparation Instruments.

STEP 2: FEMORAL CANAL PREPARATION

NOTE 2.1

The use of a transfemoral approach can be used during the implantation of a CORAIL Revision Stem. Generally, the femoral tube is closed by cerclage wiring to reconstruct the femoral shaft, and then the femoral preparation is carried out as it would be for a closed femur procedure. The primary stability of the stem inside the host bone is the limiting factor.



Distal Reaming

Once the failed implant has been retrieved, the femur is cleared of any remaining cement or debris, if present. Rigid reamers are available in a range of sizes that should be used sequentially to prepare the distal femoral canal.

Reaming should begin in a central position in alignment with the intramedullary canal. A 10 mm reamer can be used as a starter to allow the easy introduction of the 11 mm reamer. It may be necessary to increase the size of the reamer to a 12mm or 13mm to allow free passage of the trial stem to the desired depth. In all cases, trialling should be performed to evaluate stem seating and stability.

Each rigid reamer has mechanical engravings showing the desirable depth of reaming, corresponding to each stem length (lengthened by 10 mm to take into account the tapered shape) as referenced from the tip of the stem to the shoulder of the stem.

STEP 3: METAPHYSEAL PREPARATION

NOTE 3.1

Recommendation: To ensure correct seating and no distal restriction a trial reduction should be performed using the corresponding trial stem.

NOTE 3.2

The Revision broaches are intended for preparation of CORAIL Revision stems only.

Access to the femoral canal should be enlarged laterally into the greater trochanter, using a box chisel, to ensure that the broaches do not enter the femur in varus. The first broach, with a size adapted to the defect, is attached to the broach handle and the proximal femur is prepared by progressively increasing broach sizes.

The CORAIL Revision Stem instrument set contains both size 8 and size 9 diamond-tooth broaches which can be used as 'starter' broaches.

The preparation of the proximal femur requires the metaphyseal region to be re-shaped to a quadrangular bone cavity aiming for the correct pre-operatively planned anteversion by using the broaches. It is essential that the final broach is completely rotationally and axially stable in the femur in order to ensure stem stability in the metaphysis. To test for appropriate stability, rotational and axial pressure should be applied to the broach handle without movement of the broach inside the femoral canal. Distal stem stability alone is not sufficient.

If necessary, the calcar mill can be used carefully on the remaining calcar in order to produce a flat surface upon which to seat the implant collar & prevent the formation of stress raisers.

Important note: The Revision broaches are intended for preparation of CORAIL Revision stems only.

STEP 4: TRIAL STEM INTRODUCTION

NOTE 4.1

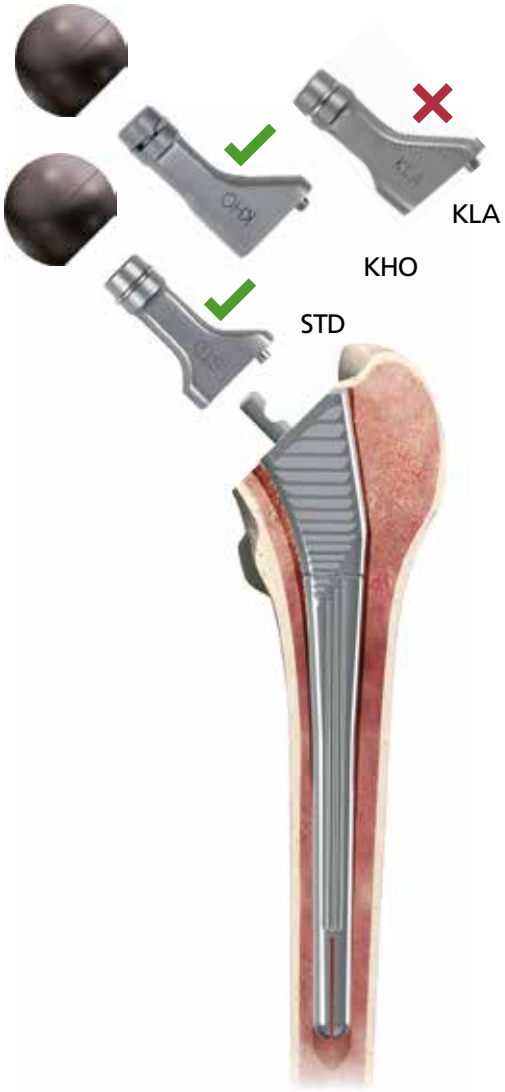
The trial stem should seat at the same height as the broach. if it seats higher it may then be necessary to use the 13mm reamer to open the canal distally.

The final broach is extracted and the trial stem of the same size is attached to the broach handle. The trial stem is lightly inserted into the femoral canal using a hammer. It should be stable at the level defined during pre-operative planning relative to the greater and lesser trochanter.

It may be necessary to ream distally using the 12 mm or 13 mm reamers to allow free passage of the trial stem to the desired depth.

If the trial stem is not stable, a trial stem one size larger can be tried in order to obtain stability at the correct level. In case visual access is available, it can be useful to check that the 'minimal embedding level' is reached using the dedicated witness groove on the trial stem.

STEP 5: NECK AND HEAD TRIALLING



NOTE 5.1

When using the CORAIL Revision Stem upgrade set, care should be taken not to use the coxa-vara trial neck (KLA) which is available as part of the CORAIL primary instrument set.

The required trial neck is then attached into the trial stem. Two options are available, standard (STD) and high offset (KHO).

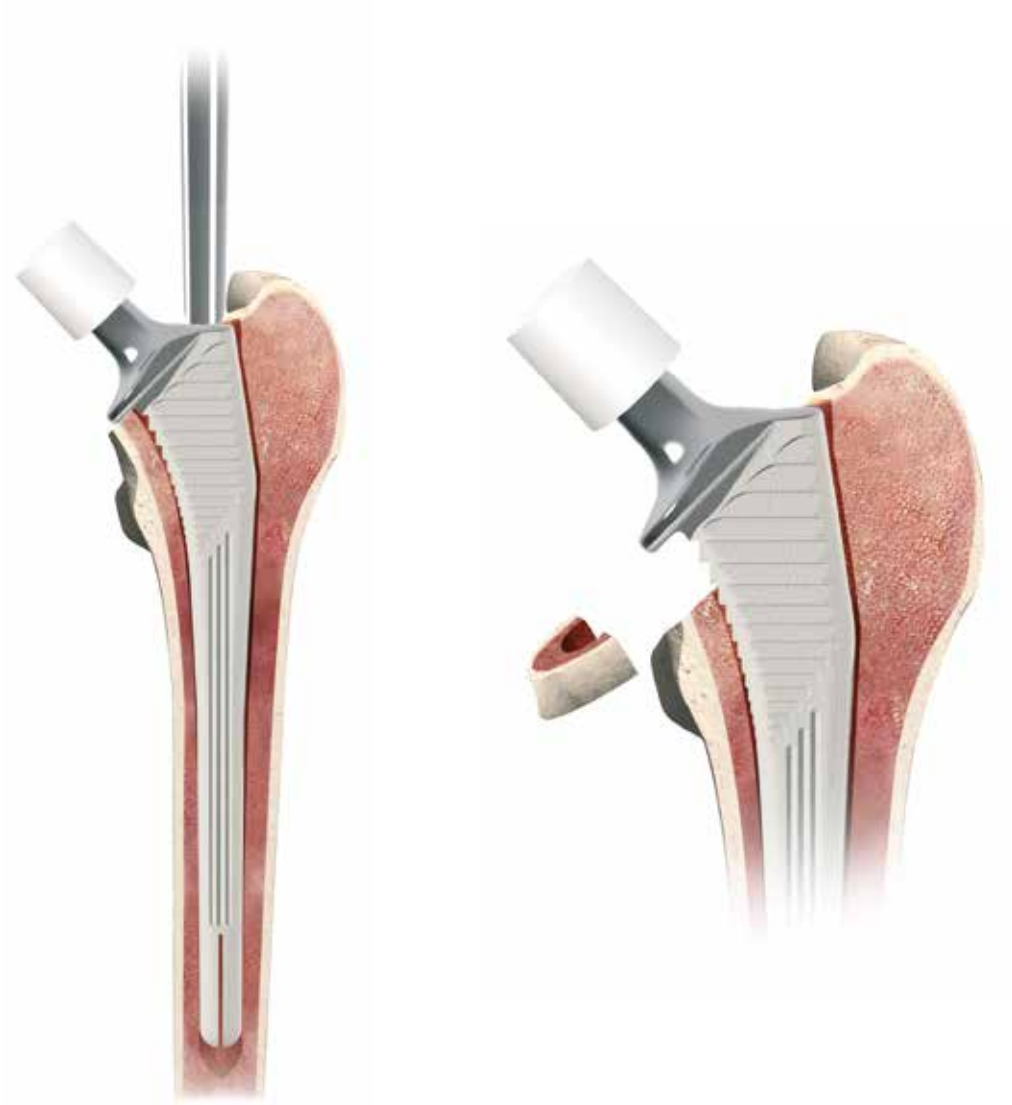
The high offset variant offers up to 7 mm of direct lateralisation, depending on the size and will increase soft tissue tension without affecting leg length.

A trial head is placed on the neck of the trial stem, and the hip is reduced and assessed for stability, through a full range of motion.

STEP 6: DEFINITIVE STEM INTRODUCTION

NOTE 6.1

Primary stability of the implant at this stage is crucial.



Important note: The protective covers should be left on until the components are ready to be implanted. Before implanting a femoral head, the male taper on the femoral stem should be wiped clean of any blood, bone chips or other foreign materials.

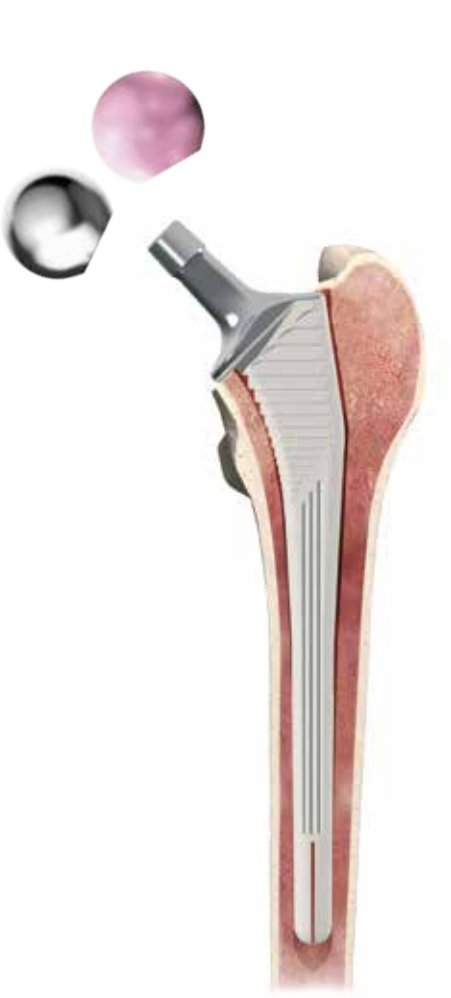
The definitive implant of same size as the trial stem and same offset as the trial neck is inserted into the femoral canal. The introduction is managed using the stem impactor while ensuring the correct restored anteversion is applied.

The stem is cautiously impacted using a hammer while avoiding any impact on the neck.

Where a horseshoe-shaped structural allograft is used, this should be placed to fill the defect before final impaction. The graft will be stabilised by the collar after final impaction. The goal of this calcar graft is to ensure the right level of implantation and minimise the potential for subsidence.

An optional reduction using a the trial head can be done at this stage.

STEP 7: FEMORAL HEAD IMPACTION



Clean and dry the stem taper carefully to remove any particulate debris. Place the femoral head onto the taper and lightly tap using the head impactor. Ensure bearing surfaces are clean and avoid any damage to the bearing surface during reduction.

NOTE 7.1

A DePuy Synthes 12/14 ARTICUL/EZE modular head must be used.

STEP 8: POST-OPERATIVE PROTOCOL

The post-operative management of the patient, including the extent to which weight bearing is permitted, is defined by the surgeon according to quality of the bone stock and the stability of the implant. Immediate weight bearing can thus be considered for primary or revision surgery if adequate bone stock remains.

In all the cases, the duration of protected weight bearing is dependent upon the condition of the femur and radiological evidence of osteointegration and if applicable, the consolidation and/or healing of the transfemoral osteotomy or the femoroplasty. This is generally reached after 45 days.

RADIOGRAPHIC CASES

Pre-op

6 months post-op

5 years post-op

Case Study 1

Pre-op: Revision of a loose cemented femoral stem (Paprosky Type 3A) was performed in 1992. Subsidence of the loose stem and thinning of the lateral cortex are observed.

6-months post-op: Follow-up shows good alignment of the KAR prosthesis and placement of a calcar graft under the collar.

5 years post-op: The patient is satisfied with his hip replacement. The prosthesis is stable. Extensive regeneration of both cortices with endosteal ossification is evident.

Pre-op

1 year post-op

10 years post-op

Case Study 2

Pre-op: Revision of a loose cemented femoral stem (Paprosky Type 2) was performed in 1991.

Post-op: The radiograph at 12-months shows a good result achieved with the KAR femoral stem both in terms of stability and restoration of the centre of rotation.

10 years post-op: The patient is asymptomatic and is satisfied with the hip replacement. Restoration of bone density is satisfactory and implant stability is confirmed.

Pre-op

2 weeks p ost-op

5 years post-op

Case Study 3

Pre-op: Revision of a loose cemented femoral stem (Paprosky Type 2) was performed in 1993.

Post-op: A radiograph taken at 2 weeks follow-up shows good stability of the KAR femoral stem, both in the proximal and distal regions. A cortical window has been used to remove the cement restrictor. The metaphysis has been bone grafted, and the calcar reconstructed using a substantial allograft.

5 years post-op: The patient is satisfied with his hip replacement. Good bone ingrowth can be noted, with signs of endosteal bone formation and restoration of adequate cortical density. No radiolucency is observed.

ORDERING INFORMATION: IMPLANTS

CORAIL Revision Stem

L98010	CORAIL Revision Stem STD 10
L98011	CORAIL Revision Stem STD 11
L98012	CORAIL Revision Stem STD 12
L98013	CORAIL Revision Stem STD 13
L98014	CORAIL Revision Stem STD 14
L98015	CORAIL Revision Stem STD 15
L98016	CORAIL Revision Stem STD 16
L98018	CORAIL Revision Stem STD 18
L98020	CORAIL Revision Stem STD 20
L98110	CORAIL Revision Stem HO 10
L98111	CORAIL Revision Stem HO 11
L98112	CORAIL Revision Stem HO 12
L98113	CORAIL Revision Stem HO 13
L98114	CORAIL Revision Stem HO 14
L98115	CORAIL Revision Stem HO 15
L98116	CORAIL Revision Stem HO 16
L98118	CORAIL Revision Stem HO 18
L98120	CORAIL Revision Stem HO 20

ARTICUL/EZE ULTAMET Heads

1365-29-000	ARTICUL/EZE ULTAMET Head 22.225 mm +7
1365-30-000	ARTICUL/EZE ULTAMET Head 22.225 mm +4
1365-11-500	ARTICUL/EZE ULTAMET Head 28 mm +1.5
1365-12-500	ARTICUL/EZE ULTAMET Head 28 mm +5
1365-13-500	ARTICUL/EZE ULTAMET Head 28 mm +8.5
1365-50-000	ARTICUL/EZE ULTAMET Head 36 mm -2
1365-51-000	ARTICUL/EZE ULTAMET Head 36 mm +1.5
1365-52-000	ARTICUL/EZE ULTAMET Head 36 mm +5
1365-53-000	ARTICUL/EZE ULTAMET Head 36 mm +8.5
1365-54-000	ARTICUL/EZE ULTAMET Head 36 mm +12
1365-04-000	12/14 ARTICUL/EZE 40 mm M Spec Head -2 Offset
1365-05-000	12/14 ARTICUL/EZE 40 mm M Spec Head +1.5 Offset
1365-06-000	12/14 ARTICUL/EZE 40 mm M Spec Head +5 Offset
1365-07-000	12/14 ARTICUL/EZE 40 mm M Spec Head +8.5 Offset
1365-08-000	12/14 ARTICUL/EZE 40 mm M Spec Head +12 Offset
1365-60-000	12/14 ARTICUL/EZE 44 mm M Spec Head -2 Offset
1365-61-000	12/14 ARTICUL/EZE 44 mm M Spec Head +1.5 Offset
1365-62-000	12/14 ARTICUL/EZE 44 mm M Spec Head +5 Offset
1365-63-000	12/14 ARTICUL/EZE 44 mm M Spec Head +8.5 Offset
1365-64-000	12/14 ARTICUL/EZE 44 mm M Spec Head +12 Offset

ARTICUL/EZE BIOLOX® delta Heads

1365-28-310	ARTICUL/EZE BIOLOX *delta* Head 28 mm +1.5
1365-28-320	ARTICUL/EZE BIOLOX *delta* Head 28 mm +5
1365-28-330	ARTICUL/EZE BIOLOX *delta* Head 28 mm +8.5
1365-32-310	ARTICUL/EZE BIOLOX *delta* Head 32 mm +1
1365-32-320	ARTICUL/EZE BIOLOX *delta* Head 32 mm +5
1365-32-330	ARTICUL/EZE BIOLOX *delta* Head 32 mm +9
1365-36-310	ARTICUL/EZE BIOLOX *delta* Head 36 mm +1.5
1365-36-320	ARTICUL/EZE BIOLOX *delta* Head 36 mm +5
1365-36-330	ARTICUL/EZE BIOLOX *delta* Head 36 mm +8.5
1365-36-340	ARTICUL/EZE BIOLOX *delta* Head 36 mm +12

All 12/14 heads available in the DePuy Synthes portfolio are compatible with the CORAIL Revision Stem with a maximum offset of 13 mm:

- "Classical" heads: all 12/14 ARTICUL/EZE, 12/14 CoCr, 12/14 BIOLOX femoral heads, aSPHERE ARTICUL/EZE 12/14
- In case of ceramic head revision, BIOLOX delta TS heads should be used, as these are designed for revision of BIOLOX ARTICUL/EZE heads.

ORDERING INFORMATION: INSTRUMENTS

Femoral Preparation Instrument Trays

L98704	CORAIL Revision Set Femoral Preparation - Lid
L98703	CORAIL Revision Set Femoral Preparation - Top
L98702	CORAIL Revision Set Femoral Preparation - Middle
L98701	CORAIL Revision Set Femoral Preparation - Bottom
L98700	CORAIL Revision Set Femoral Preparation - Base

Femoral Preparation Set Parts

L98610	Reamer - Diameter 10 mm
L98611	Reamer - Diameter 11 mm
L98612	Reamer - Diameter 12 mm
L98613	Reamer - Diameter 13 mm

Note: Revision broaches are not intended for use with the Primary stem.

L98408X	Diamond-tooth Broach - size 8
L98409X	Diamond-tooth Broach - size 9
L98410X	Diamond-tooth Broach - size 10
L98411X	Diamond-tooth Broach - size 11
L98412X	Diamond-tooth Broach - size 12
L98413X	Diamond-tooth Broach - size 13
L98414X	Diamond-tooth Broach - size 14
L98415X	Diamond-tooth Broach - size 15
L98416X	Diamond-tooth Broach - size 16
L98418X	Diamond-tooth Broach - size 18
L98420X	Diamond-tooth Broach - size 20

L98510	Trial Stem - Size 10
L98511	Trial Stem - Size 11
L98512	Trial Stem - Size 12
L98513	Trial Stem - Size 13
L98514	Trial Stem - Size 14
L98515	Trial Stem - Size 15
L98516	Trial Stem - Size 16
L98518	Trial Stem - Size 18
L98520	Trial Stem - Size 20

Core Instrument Trays

L98706	CORAIL Revision Set Core Instrument - Lid
L20503	Superior Thermoformed Tray
L98705	CORAIL Revision Set Core Instrument - Middle Tray
L20501	Inferior Thermoformed Tray
L98707	CORAIL Revision Set Core Instrument - Base

Core Instrument Set Parts

1524-00-000	Hudson Müller Adaptor*
2001-65-000	Head Impactor
2002-31-000	Osteotome

2530-69-000	Trial Head 22,2 mm +4
2530-70-000	Trial Head 22,2 mm +7
2530-81-000	Trial Head 28 mm +1,5
2530-82-000	Trial Head 28 mm +5
2530-83-000	Trial Head 28 mm +8,5
2530-84-000	Trial Head 28 mm +12
2530-91-000	Trial Head 32 mm +1
2530-92-000	Trial Head 32 mm +5
2530-93-000	Trial Head 32 mm +9
2530-94-000	Trial Head 32 mm +13

2570-04-100	Calcar Mill Small
2570-04-200	Calcar Mill Large

2598-07-570	Straight Two-Piece Impactor
2570-05-100	Stem Impactor
9522-11-500	Curved Broach Handle
9653-68-000	Anteversion Axis

L20431	Standard Neck Segment
L20433	High Offset Neck Segment
L20440	Neck Resection Guide
L93205	Bone Impactor
L93606	Bone Tamp

X-Ray Templates

CALQ430	CORAIL Revision Stem - Scale 100%
CALQ431	CORAIL Revision Stem - Scale 115%
CALQ432	CORAIL Revision Stem - Scale 120%

DNIs

L98714	DNI CORAIL Revision Stem STD 14 HA
L98724	DNI CORAIL Revision Stem STD 14

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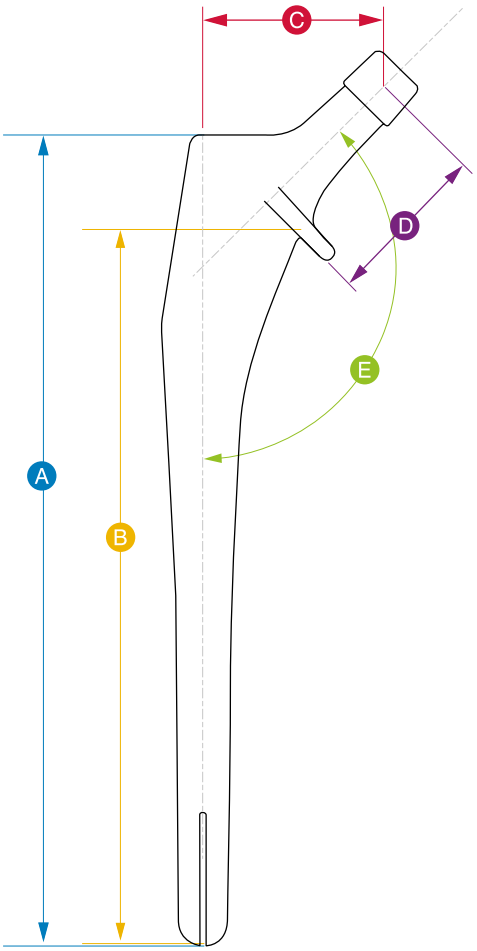
Switzerland

CE

TECHNICAL SPECIFICATION

CORAIL Hip System - Revision Standard Offset Stem

Stem Size	Stem Length (mm) (A)	Stem Length (mm) (B)	Offset (mm) (C)	Neck Length (mm) (D)	Neck Shaft Angle (E)
10	180	157	39.5	38.5	135°
11	185	162	40.0	38.5	135°
12	190	167	41	38.5	135°
13	195	172	41.5	38.5	135°
14	200	177	42.5	38.5	135°
15	205	182	43	38.5	135°
16	210	187	44	38.5	135°
18	220	197	45	38.5	135°
20	230	207	46	38.5	135°



CORAIL Hip System - Revision High Offset Stem

Stem Size	Stem Length (mm) (A)	Stem Length (mm) (B)	Offset (mm) (C)	Neck Length (mm) (D)	Neck Shaft Angle (E)
10	180	157	46.5	43.2	135°
11	185	162	47.0	43.2	135°
12	190	167	48.0	43.2	135°
13	195	172	48.5	43.2	135°
14	200	177	49.0	43.2	135°
15	205	182	50.0	43.2	135°
16	210	187	50.5	43.2	135°
18	220	197	51.5	43.2	135°
20	230	207	52.5	43.2	135°

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