

CORAIL[®]
HIP SYSTEM

Revision Stem

CORAIL[®] Revision Hip System

Surgical Technique



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Surgical Technique

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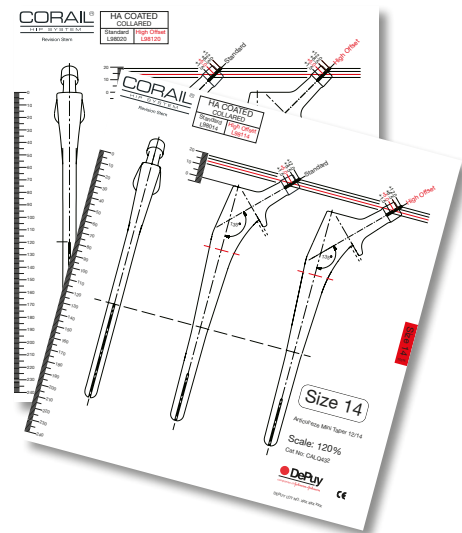
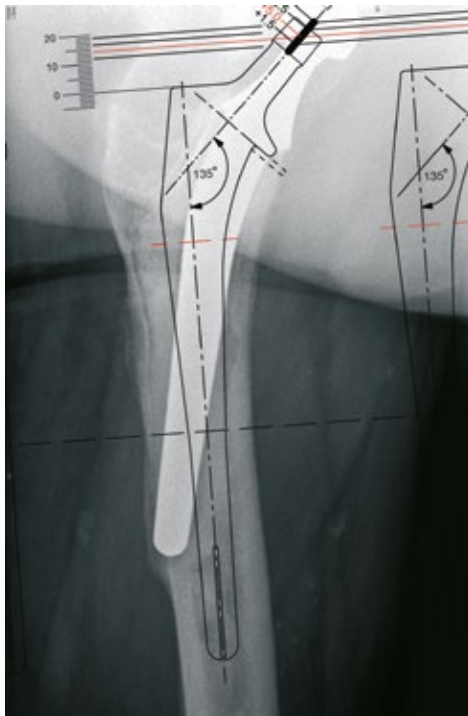
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Pre-operative Planning



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



Posterolateral approach



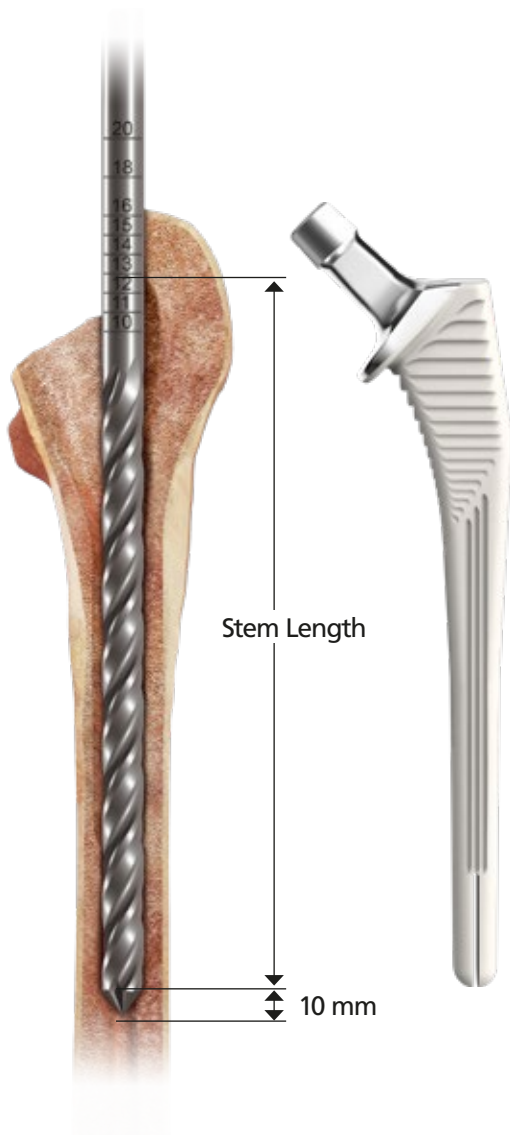
Anterolateral approach

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 instrument 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.

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

Step 2: Femoral Canal Preparation



Distal Reaming

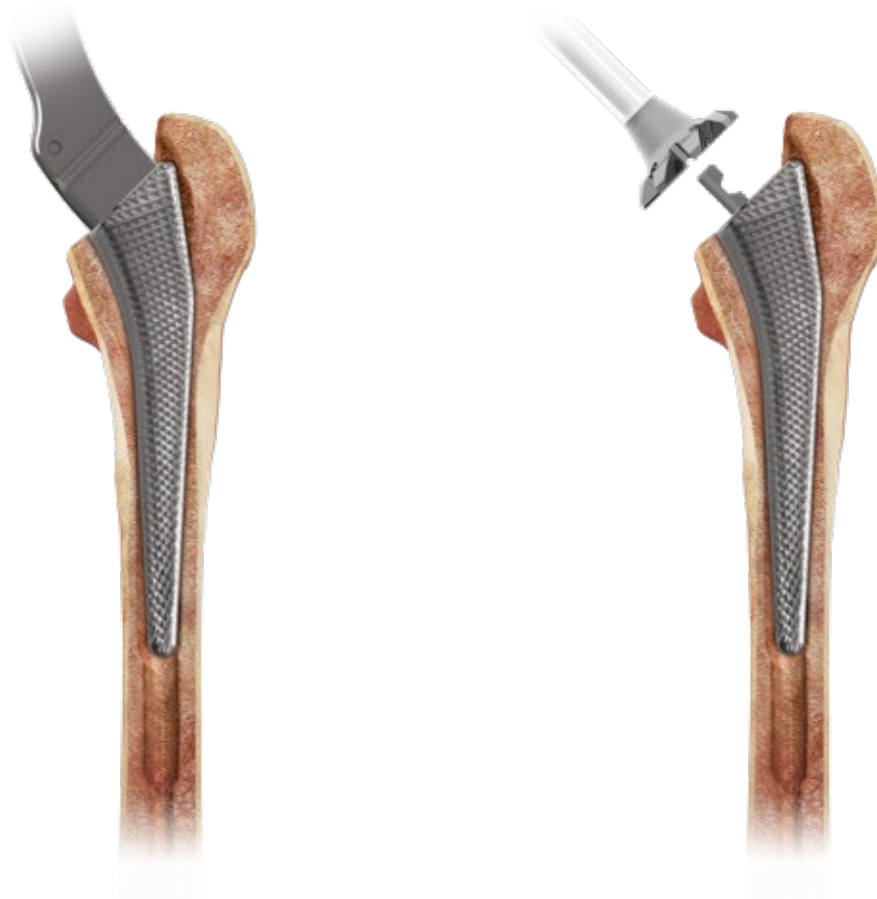
Once the failed implant has been retrieved, the femur is cleared of any remaining cement or debris, if present. Rigid reamers are available in a range of sizes that should be used sequentially to prepare the distal femoral canal.

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.

Note: 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.

Step 3: Metaphyseal Preparation



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.

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

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

Step 4: Trial Stem Introduction



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.

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

Step 5: Neck and Head Trialling



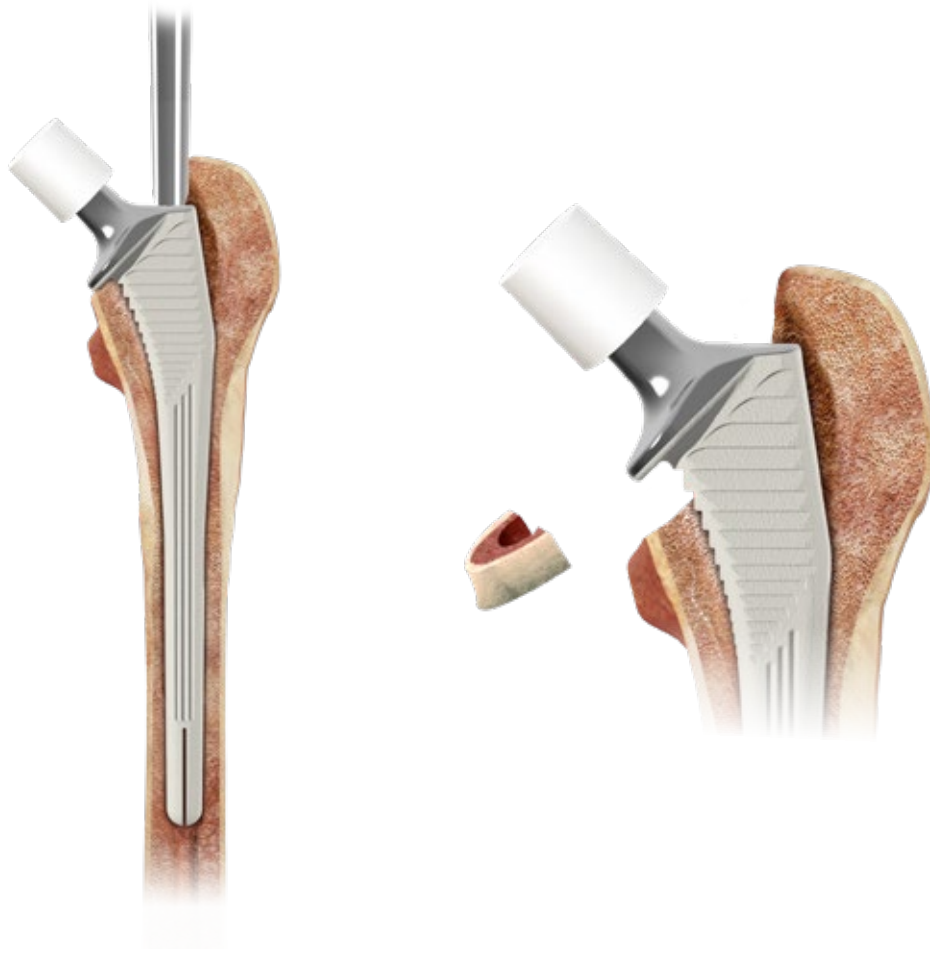
The required trial neck is then attached into the trial stem. Two options are available, standard (STD) and high offset (KHO).

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.

Note: 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.

Step 6: Definitive Stem Introduction



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.

Note: Primary stability of the implant at this stage is crucial.

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: A DePuy Synthes 12/14 ARTICUL/EZE™ Modular Head must be used.

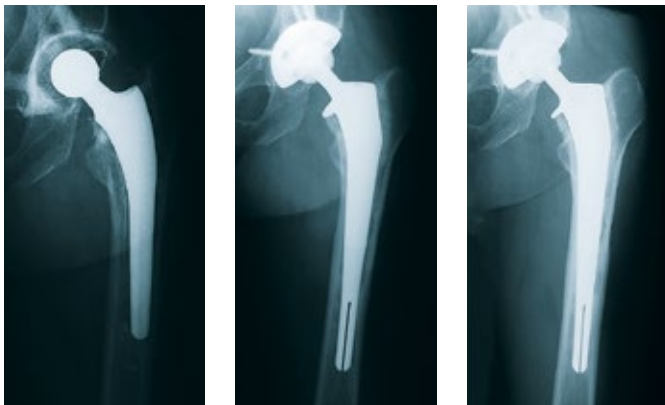


Step 8: Post-operative Protocol

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

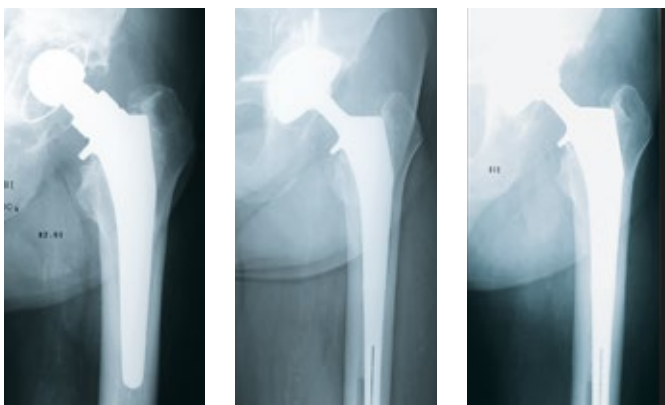
5 years post-op

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 post-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
1365-24-000	ARTICUL/EZE ULTAMET Head 32 mm +13 (skirted)
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 <i>delta</i> Head 28 mm +1.5
1365-28-320	ARTICUL/EZE BIOLOX <i>delta</i> Head 28 mm +5
1365-28-330	ARTICUL/EZE BIOLOX <i>delta</i> Head 28 mm +8.5
1365-32-310	ARTICUL/EZE BIOLOX <i>delta</i> Head 32 mm +1
1365-32-320	ARTICUL/EZE BIOLOX <i>delta</i> Head 32 mm +5
1365-32-330	ARTICUL/EZE BIOLOX <i>delta</i> Head 32 mm +9
1365-36-310	ARTICUL/EZE BIOLOX <i>delta</i> Head 36 mm +1.5
1365-36-320	ARTICUL/EZE BIOLOX <i>delta</i> Head 36 mm +5
1365-36-330	ARTICUL/EZE BIOLOX <i>delta</i> Head 36 mm +8.5
1365-36-340	ARTICUL/EZE BIOLOX <i>delta</i> 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	Alignment Rod
L94005	CORAIL Neck Segment 135° Standard Offset (STD)
L94006	CORAIL Neck Segment 135° High Offset (KHO)
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%

DNI

L98714	DNI CORAIL Revision Stem STD 14 HA
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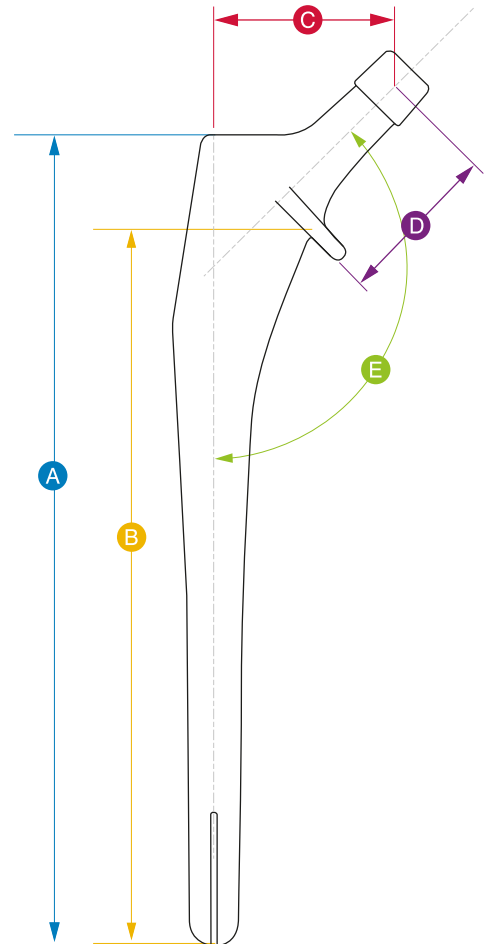
Technical Specification

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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