

# CORAIL<sup>®</sup> HIP SYSTEM



# THE SCIENCE OF SIMPLICITY

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With 1,000,000 stems provided for patients worldwide<sup>1</sup> and two and a half decades of clinical success, the CORAIL® Total Hip System now has the most extensive experience with a hydroxyapatite (HA) coated stem.

Combining basic design features, including shape, surface finish and extensive hydroxyapatite coating, with a simple compaction broach-only surgical technique, the CORAIL Total Hip System has demonstrated reproducible results and long-term biomechanical joint restoration.

Advancing science, enhancements were made to CORAIL to provide solutions for orthopaedic surgeons treating today's higher-demand patients.

## **Enhancements to the CORAIL include:**

- Neck geometry designed for maximum range of motion
- High offset option to treat increased femoral offset patients
- Coxa vara stem option to treat varus neck angled patients

## **US Surgeon Team**

James Caillouette, MD  
Charles R. Clark, MD  
Mark Froimson, MD  
Jonathan; Garino, MD  
William Lanzer, MD  
Joel Matta, MD  
Sam Sydney, MD



- 1 Three offset options to restore hip biomechanics
- 2 Tapered neck geometry and Articul/eze® taper designed to increase range of motion
- 3 Low-profile lateral shoulder design enables easy insertion in reduced incision techniques, including the anterior approach.
- 4 Available in collared or non-collared options
- 5 Step geometry converts hoop stresses to compressive loads
- 6 Vertical/horizontal grooves provide rotational and axial stability
- 7 Proprietary HA coating

**Simple Surgical Technique:** Reproducible surgical results with minimal instrumentation, broach-only technique

**Compaction Broaching Technique:** Preservation of endosteal blood supply and cancellous bone structures

**Dual Offset Options:** Accommodates a variety of patient anatomies to restore hip biomechanics

**Two and a Half-Decade Clinical Success:** Trust for the surgeon and for the patient

# PREOPERATIVE PLANNING

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The CORAIL stem may be implanted using any of the contemporary less invasive approaches as well as the traditional surgical techniques for total hip arthroplasty. The goal of any technique selected is adequate visualization of both the acetabulum and the proximal femur so that a direct view down the femoral canal can be gained and the entire rim and depth of the acetabulum visualized.

Preoperative planning enables the surgeon to prepare for the case and anticipate situations that may arise during surgery. A thorough preoperative plan incorporates elements from the patient's history, physical examination and radiographic analysis.

## **Preoperative planning goals**

1. Determine preoperative leg length discrepancy
2. Assess acetabular component size and placement
3. Determine femoral component, size, position and fit
4. Assess femoral offset

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## Radiographs

The first step in accurate templating is obtaining high-quality radiographs using a standardized protocol with known magnification. Use magnification markers attached to the patient leg at the level of the greater trochanter to verify magnification.

The CORAIL Total Hip System incorporates 20% magnification.

Obtain an anterior/posterior (A/P) view of the pelvis with both extremities in 15 degrees of internal rotation to position the head and neck parallel to the coronal plane. A direct lateral radiograph should also be obtained and used to determine femoral fixation.

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## Determination of leg length discrepancy

Perform a clinical evaluation in conjunction with a radiographic analysis to determine preoperative leg length discrepancy and use both to determine intraoperative leg length management.

To estimate leg length discrepancy radiographically, draw a reference line through the bottom of the ischium (Figure A). Measure the distance from the lesser trochanter landmark to the reference line on each side. The difference between the two is the radiographic leg length discrepancy. Clinical examination should help determine the actual leg length irregularity.

The tip of the greater trochanter may be used as an alternative reference mark in conjunction with the lines through the obturator foramina.

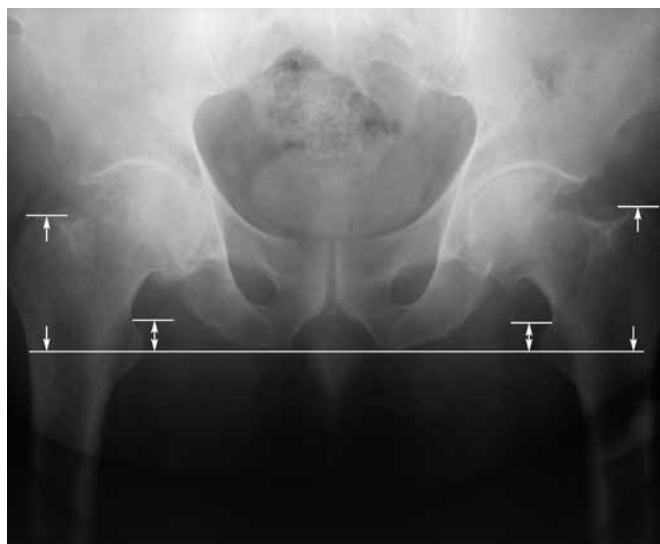


Figure A

### Acetabular cup size and position

Most sizing determinations are made using the A/P radiograph of the hip. Determine the optimal position for the acetabular component and estimate the size using the Pinnacle® Acetabular Cup System template overlays. The acetabular teardrop can be referenced as the interior margin of the acetabular reconstruction.

The goal in cementless acetabular fixation is to optimize position and bone contact. Once this is determined, mark the intended center of rotation of the bearing surface on the A/P radiograph (Figure B).

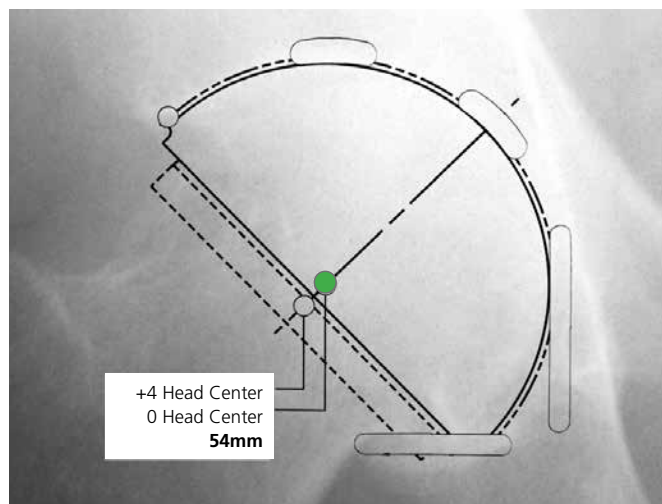


Figure B ● Cup center of rotation

### Cementless femoral component selection

The CORAIL stem is designed to seat in cancellous bone, and cortical contact should be avoided when templating. Select the appropriate template size that is smaller than the cortex in the proximal femur. The femoral template should be in line with the long axis of the femur and the neck resection line drawn at the point where the selected stem provides the desired amount of leg length.

The vertical distance between the planned center of rotation of the acetabular component and the center of rotation of the femoral head constitutes the distance the leg length will be adjusted.

The level of neck osteotomy depends on the stem size and the desired leg length, with the goal of using a non-skirted modular head to optimize range of motion prior to prosthetic impingement. To help properly position the template on the lateral radiograph, estimate the distance between the tip of the greater trochanter and the lateral shoulder of the prosthesis using the A/P radiograph (Figure C).

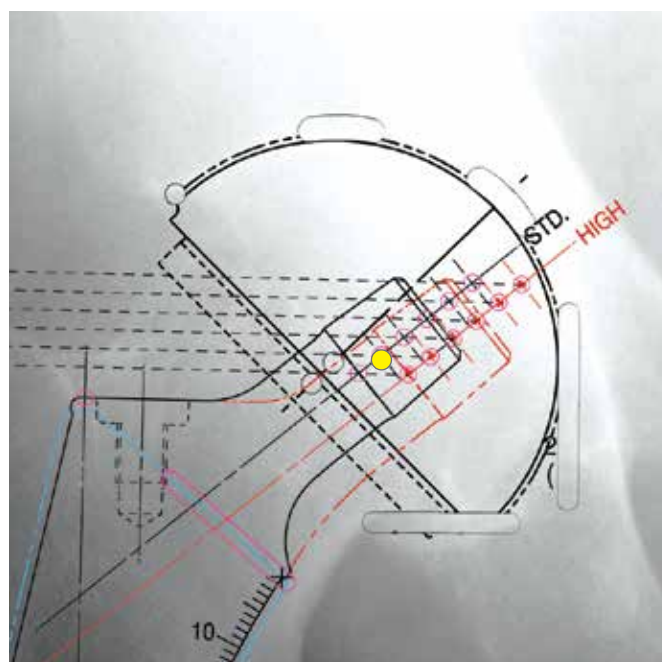


Figure C ● Head center of rotation

Verify that the stem size chosen in the A/P plane also fits in the lateral plane. The lateral radiograph of a properly sized CORAIL implant will not exhibit cortical contact.

## Offset requirements

The CORAIL Total Hip System implants are available with standard, high offset and varus options for all stem body sizes (except 6 and 8). Through templating and intraoperative trialing, determine which option restores proper offset by matching the cup's center of rotation with the desired head center of rotation (Figure D).

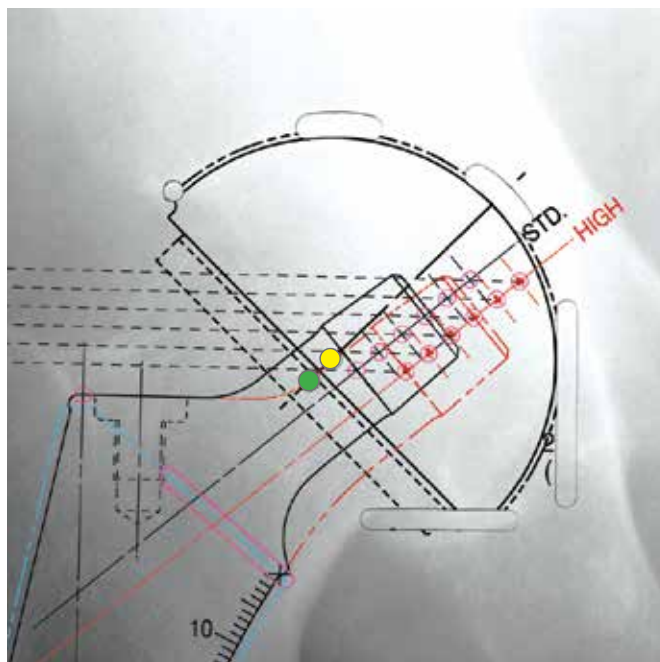


Figure D      ● Head center of rotation  
● Cup center of rotation

# SURGICAL TECHNIQUE

## 1 Neck Osteotomy

The level of the neck resection is determined during preoperative templating. The cut will be approximately 1 cm above the lesser trochanter. Center the resection guide along the neutral axis of the femur and mark the resection line. Perform the osteotomy, taking care to maintain the correct angle (Figure 1).



Figure 1



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## 2

### Reaming and alignment

Make sure that the acetabulum is fully exposed and remove soft tissue from the acetabular rim.

Progressively ream the acetabulum until bleeding subchondral bone is reached and a hemispherical dome is achieved (Figure 2A).

Using the cup impactor, place a trial cup sizer into the reamed acetabulum and assess its position and cortical bone contact.

The inferior rim of the trial cup should typically be level with the bottom of the teardrop. The trial cup angle of orientation should match that recorded during preoperative templating, which is normally 45 degrees of lateral opening (abduction) and 15–30 degrees of anteversion. Confirm this using the external alignment instrumentation (Figures 2B and 2C).

Remove the cup impactor from the trial shell and place the desired liner trial into the cup trial.



Figure 2A

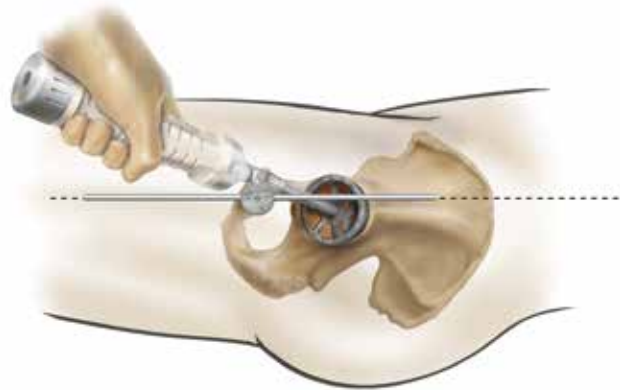


Figure 2B

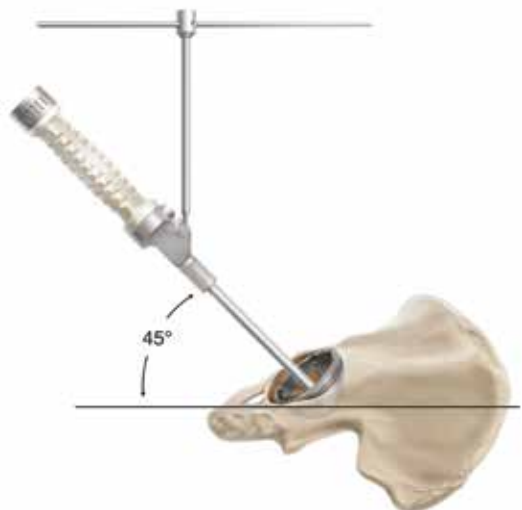


Figure 2C

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**3**  
**Metaphyseal preparation (optional)**

The version osteotome can be used to remove a wedge of cancellous bone, creating a starting cavity for broach insertion. The osteotome can be positioned in a neutral or anteverted fashion, depending on patient anatomy.

A modular osteotome may also be used to accommodate multiple approaches to the hip (Figure 3).



Figure 3

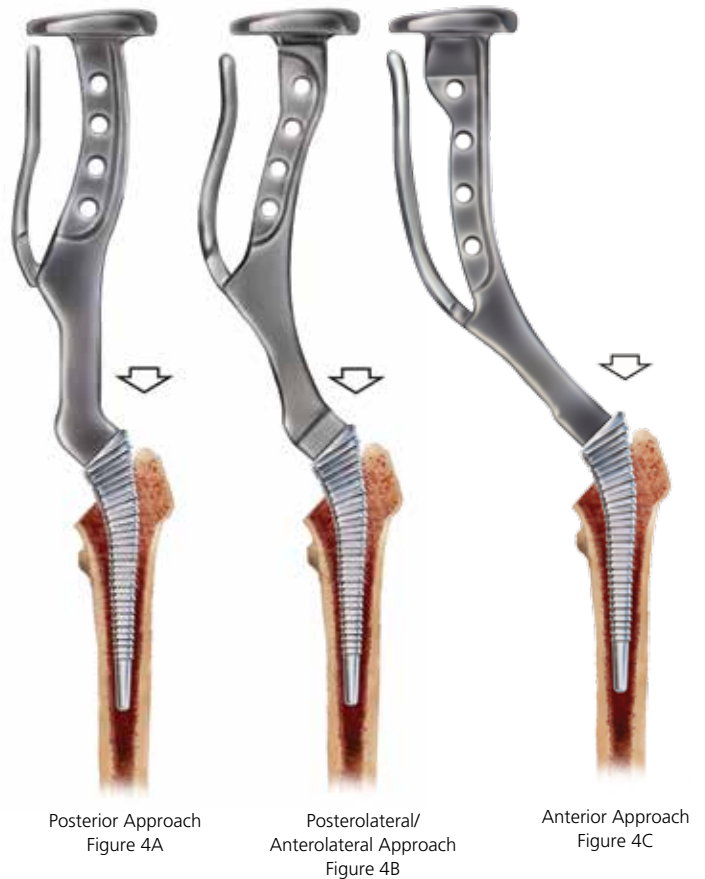
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## 4 Femoral canal preparation

The CORAIL broach is available with several broach handle options depending on the surgical approach (Figures 4A, 4B, 4C); dual-offset handle also available, but not shown. Select the appropriate handle for the surgical approach.

Beginning with the smallest CORAIL compaction broach attached to the selected broach handle, progressively enlarge the metaphyseal cavity by compacting and shaping the cancellous bone until the level of the neck resection is reached. Broaching should continue until complete stability is achieved with the last size broach used without reaching cortical contact in the femoral canal, ensuring cancellous bone preservation. The size of each broach is the same as the corresponding implant without HA (hydroxyapatite) coating (155 microns).

If you impact a broach and it does not fully seat in the canal, it is recommended to go back to the previous size broach and re-establish the broach envelope of cancellous bone to accept the smaller size implant. The CORAIL implant's design allows you to go back to the smaller size.



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## 5 Calcar Preparation (Optional)

Place the calcar planer onto the broach stud and mill the calcar to the broach face, allowing the implant collar (if used) to seat flush against the calcar. Make certain the calcar planer is rotating before engaging calcar to prevent the planer from binding on the calcar.

## 6

### Trial Reduction

Trial neck segments and trial modular heads are available to assess proper component position, joint stability, range-of-motion and leg length (Figures 5A, 5B and 5C). The CORAIL is available in three stem options, a standard collarless/collared stem, a high offset collarless stem, and a coxa vara collared stem and offers the appropriate neck segment to match up with the stem option.

With the CORAIL broach in situ, attach one of the three neck segment options. Perform a trial reduction with a +5 Articul/eze head trial to allow for one up or down adjustment in neck length without using a skirted femoral head (see stem specifications chart in back of the technique for adjustment measurements). Reduce the hip and assess stability through a full range of motion, and check for impingement. Leg length and offset may be adjusted by varying the neck length with the appropriate femoral head. Alternatively, leg length may be reduced with a lower neck cut and advancing the broach or alternatively driving the broach and repeating the calcar milling.



Standard offset collared/collarless (KA/KS)  
Figure 5A



High offset collarless (KHO)  
Figure 5B



Coxa vara collared (KLA)  
Figure 5C

## 7

### Acetabular Shell Insertion

Remove the trial acetabular components and implant the desired acetabular shell (Figure 6). Take care to ensure cup orientation mimics the orientation of the trial component. Insert a trial liner into the shell implant.



Figure 6

## 8 Femoral Component Insertion

CORAIL Total Hip System implants can be inserted with either a threaded retaining inserter or a non-threaded inserter. Both inserters provide rotational control during stem implantation.

A new modular inserter system further enables multiple approaches (see ordering information).

**Prior to using either inserter, the CORAIL stem should be inserted by hand into the femoral canal with 1.5 to 2.0 cm of HA showing above the resection.**

If the retaining inserter is chosen, verify that it is assembled with the inserter shaft threaded into the inserter handle (Figure 7A). Ensure the tines on the inserter are aligned with the recesses of the inserter platform on the top of the implant (Figure 7B). Fully engage the threads of the inserter into the implant to ensure the inserter is securely attached to the implant.

If the non-retaining inserter is chosen, introduce stem by hand into femoral canal (Figure 8A). Ensure the tines of the inserter are aligned with the recesses of the inserter platform on the top of the implant (Figure 8B).

With the taper protected by the cover, gently introduce the implant and impact it in the central axis of the femur, to the level of the HA coating (or the collar) (Figures 7C and 8C). With the prostheses in situ, remove the taper cover and add the trial head and acetabular trial liner to assess implant stability and leg length.

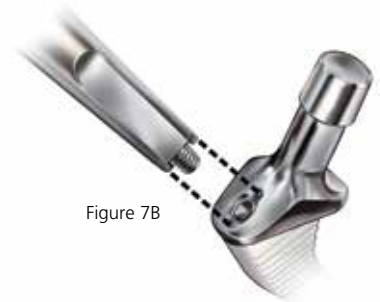


Figure 7B



Figure 7A



Figure 7C



Figure 8A



Figure 8B



Figure 8C

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**9**

**Acetabular Insert Implantation**

Following the final trial reduction, remove the trial acetabular liner and insert the appropriate acetabular liner (Figure 9).



Figure 9

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**10**

**Femoral Head Impaction**

Irrigate, clean and dry the prosthesis to ensure the taper is free of debris. Place the appropriate femoral head onto the taper and lightly tap using the head impactor before reducing the hip (Figure 10).



Figure 10



5 years post-op

# CORAIL® AMT STEM SPECIFICATIONS

## Standard Offset - Collarless/Collared

Size	Stem Length (mm) <b>A</b>	Offset (mm) <b>B</b>	Neck Length (mm) <b>C</b>	Neck Shaft Angle <b>D</b>	Leg Adjustment Length (mm) <b>E</b>
6*	93	30.8	33.8	135°	34
8	95	38.0	38.5	135°	36
9	110	38.5	38.5	135°	36
10	120	39.5	38.5	135°	36
11	125	40.0	38.5	135°	36
12	130	41.0	38.5	135°	36
13	135	41.5	38.5	135°	36
14	140	42.0	38.5	135°	36
15	145	43.0	38.5	135°	36
16	150	43.5	38.5	135°	36
18	160	44.5	38.5	135°	36
20	170	45.5	38.5	135°	36

\* The size 6 is available in collarless only.

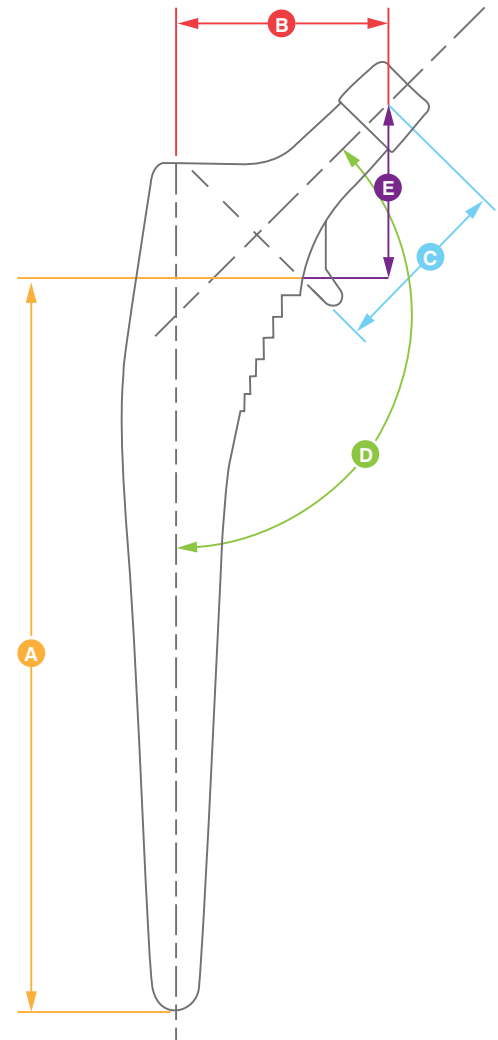
## High Offset - Collarless

Size	Stem Length (mm) <b>A</b>	Offset (mm) <b>B</b>	Neck Length (mm) <b>C</b>	Neck Shaft Angle <b>D</b>	Leg Adjustment Length (mm) <b>E</b>
9	110	45.5	43.2	135°	36
10	120	46.5	43.2	135°	36
11	125	47.0	43.2	135°	36
12	130	48.0	43.2	135°	36
13	135	48.5	43.2	135°	36
14	140	49.0	43.2	135°	36
15	145	50.0	43.2	135°	36
16	150	50.5	43.2	135°	36
18	160	51.5	43.2	135°	36
20	170	52.5	43.2	135°	36

## Coxa Vara Offset - Collared

Size	Stem Length (mm) <b>A</b>	Offset (mm) <b>B</b>	Neck Length (mm) <b>C</b>	Neck Shaft Angle <b>D</b>	Leg Adjustment Length (mm) <b>E</b>
9	110	45.5	40.3	125°	31
10	120	46.5	40.3	125°	31
11	125	47.0	40.3	125°	31
12	130	48.0	40.3	125°	31
13	135	48.5	40.3	125°	31
14	140	49.0	40.3	125°	31
15	145	50.0	40.3	125°	31
16	150	50.5	40.3	125°	31
18	160	51.5	40.3	125°	31
20	170	52.5	40.3	125°	31

Note: All measurements are based on a 28 mm +5.0 Articul/eze head, which is the middle length of non-skirted femoral heads





# ORDERING INFORMATION

## IMPLANTS

### Standard Collarless

Cat. No.	Size
L20106	6
3L92507	8
3L92509	9
3L92510	10
3L92511	11
3L92512	12
3L92513	13
3L92514	14
3L92515	15
3L92516	16
3L92518	18
3L92520	20

### Standard Collared

Cat. No.	Size
3L92498	8
3L92499	9
3L92500	10
3L92501	11
3L92502	12
3L92503	13
3L92504	14
3L92505	15
3L92506	16
3L92508	18
3L92521	20

### High Offset Collarless

Cat. No.	Size
L20309	9
L20310	10
L20311	11
L20312	12
L20313	13
L20314	14
L20315	15
L20316	16
L20318	18
L20320	20

### Coxa Vara Collared

Cat. No.	Size
3L93709	9
3L93710	10
3L93711	11
3L93712	12
3L93713	13
3L93714	14
3L93715	15
3L93716	16
3L93718	18
3L93720	20

## INSTRUMENTS

### CORAIL AMT Broach Case†

L20440	Neck Resection Guide
L20408	Broach Size 8
L20409	Broach Size 9
L20410	Broach Size 10
L20411	Broach Size 11
L20412	Broach Size 12
L20413	Broach Size 13
L20414	Broach Size 14
L20415	Broach Size 15
L20416	Broach Size 16
L20418	Broach Size 18
L20420	Broach Size 20
L20431	CORAIL Standard Offset Neck Segment
L20432	CORAIL Coxa Vara Neck Segment
L20433	CORAIL High Offset Neck Segment
9522-11-500	CORAIL AMT Curved Handle
9522-10-500F	CORAIL AMT Straight Broach Handle
9522-12-500F	CORAIL AMT Extra Curved Handle
2002-31-000	Anteversio Osteotome
2570-04-100	Calcar Planer-Small
2665-99-000	Broach Case Complete

### CORAIL AMT Core Case Complete

2354-10-000	Canal Probe
53-0360	T-Handle
2570-05-000	Retaining Implant Inserter
2570-05-100	Standard Implant Inserter
2001-65-000	Head Impactor
2530-81-000	28 mm Articul/eze +1.5 mm Trial Head
2530-82-000	28 mm Articul/eze +5.0 mm Trial Head
2530-83-000	28 mm Articul/eze +8.5 mm Trial Head
2530-84-000	28 mm Articul/eze +12.0 mm Trial Head
2530-85-000	28 mm Articul/eze +15.5 mm Trial Head
2665-99-003	Core Case Complete

### X-Ray Templates

2665-01-500	Collarless X-Ray Template
2665-02-500	Collared X-Ray Template
2665-03-500	Size 6 X-Ray Template

† Note: For size 6 instrumentation and implant ordering information, see the CORAIL Size 6 surgical technique - EO-75, available from your DePuy Synthes Joint Reconstruction Sales Consultant.

Instruments

**TSS Femoral Core Case 1**

2598-07-400	Base
2598-07-411	Tray
2598-07-410	Lid
2800-88-511	SE Set (includes all instruments)
2598-07-460	Universal Stem Inserter Handle Trial Heads – 2 Sets per Case *accommodates up through size 44 mm
2598-07-570	Retaining Stem Inserter (2 pcs)
2598-07-530	Modular Box Osteotome

**Any two of the below handles accommodated:**

2570-00-000	SUMMIT® Universal Broach Handle
2598-07-540	Long Posterior Broach Handle
2598-07-550	Extra Curved Broach Handle
2598-07-350	Anterior Dual Offset Broach Handle – Left
2598-07-360	Anterior Dual Offset Broach Handle – Right
9522-10-500F	CORAIL AMT Straight Broach Handle
9522-11-500	CORAIL AMT Curved Broach Handle
2598-07-470	CORAIL/TRI-LOCK® Posterior Stem Inserter Shaft
2598-07-480	SUMMIT Posterior Stem Inserter Shaft
2598-07-435	Bullet Tip Stem Inserter Shaft
2598-07-430	Standard Straight Stem Inserter Shaft
2598-07-440	CORAIL/TRI-LOCK Anterior Stem Inserter Shaft
2598-07-450	SUMMIT Anterior Stem Inserter Shaft

**TSS Femoral Core Case 2**

2598-07-421	Base
2598-07-422	Lid
2800-88-512	SE Set (includes all instruments)
2354-10-000	Muller Awl Reamer with Hudson End
2001-42-000	T-Handle
2001-80-501	IM Initiator Sized
9400-80-007	Shielded Calcar Planer
85-3927	Femoral Rasp
9400-80-001	Canal Finder
2001-65-000	Femoral/Humeral Head Impactor
2001-66-000	Replacement Tip Femoral Head Impactor

# ESSENTIAL PRODUCT INFORMATION

## CORAIL AMT HIP

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### **Important**

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

### **Indications**

The CORAIL AMT Hip Prosthesis is intended for use in total hip arthroplasty and is intended for pressfit (uncemented) use. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

HA-coated stems are indicated for cementless use only.

### **Contraindications**

The following conditions are contraindications for total or hemi-hip replacement:

1. Active local or systemic infection.
2. Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.

3. Poor bone quality, such as osteoporosis, where, in the surgeon's opinion, there could be considerable migration of the prosthesis or a significant chance of fracture of the femoral shaft, considerable migration of the prosthesis or a significant chance of fracture of the femoral shaft and/or the lack of adequate bone to support the implant(s).
4. Charcot's or Paget's disease.
5. For hemi-hip arthroplasty, any pathological condition of the acetabulum, such as distorted acetabuli with irregularities, protrusion acetabuli (arthrokatadysis), or migrating acetabuli, that would preclude the use of the natural acetabulum as an appropriate articular surface for the hemi-hip prosthesis.

### **Warnings and Precautions**

- HA coated implants must not be implanted with cement
- When changing the head on a femoral stem which is still in place, it is essential to use a metal-metal interface
- For some stems, head offset 'Warning' notices are visible on labels to limit the maximum offset used for the head. For the CORAIL Revision stem, the maximum offset used for the head is limited to 13mm.

### **Adverse Events**

The following are the most frequent adverse events after hip arthroplasty: change in position of the components, loosening of components, wear or fracture of components, dislocation, infection, peripheral neuropathies, tissue reaction.

## References

1. Data on file at DePuy Orthopaedics, Inc.

**Limited Warranty and Disclaimer:** DePuy Synthes Joint Reconstruction products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

**WARNING:** In the USA, this product has labeling limitations. See package insert for complete information.

**CAUTION:** USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.



*US agent*  
**DePuy Orthopaedics, Inc.**  
700 Orthopaedic Drive  
Warsaw, IN 46582  
USA  
T. +1 (800) 366-8143

*Manufactured by*  
**DePuy France SAS**  
7 Allee Irene Joliot Curie  
69801 St. Priest Cedex  
France

[www.depuyssynthes.com](http://www.depuyssynthes.com)