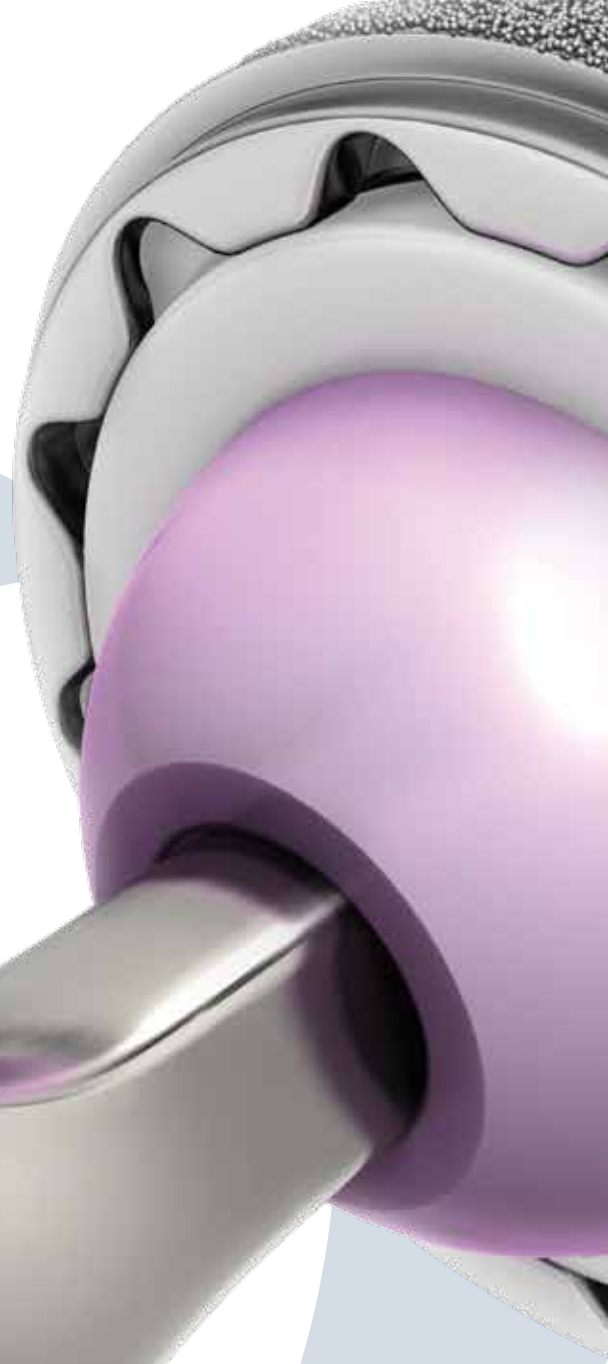


CORAIL[®] HIP SYSTEM



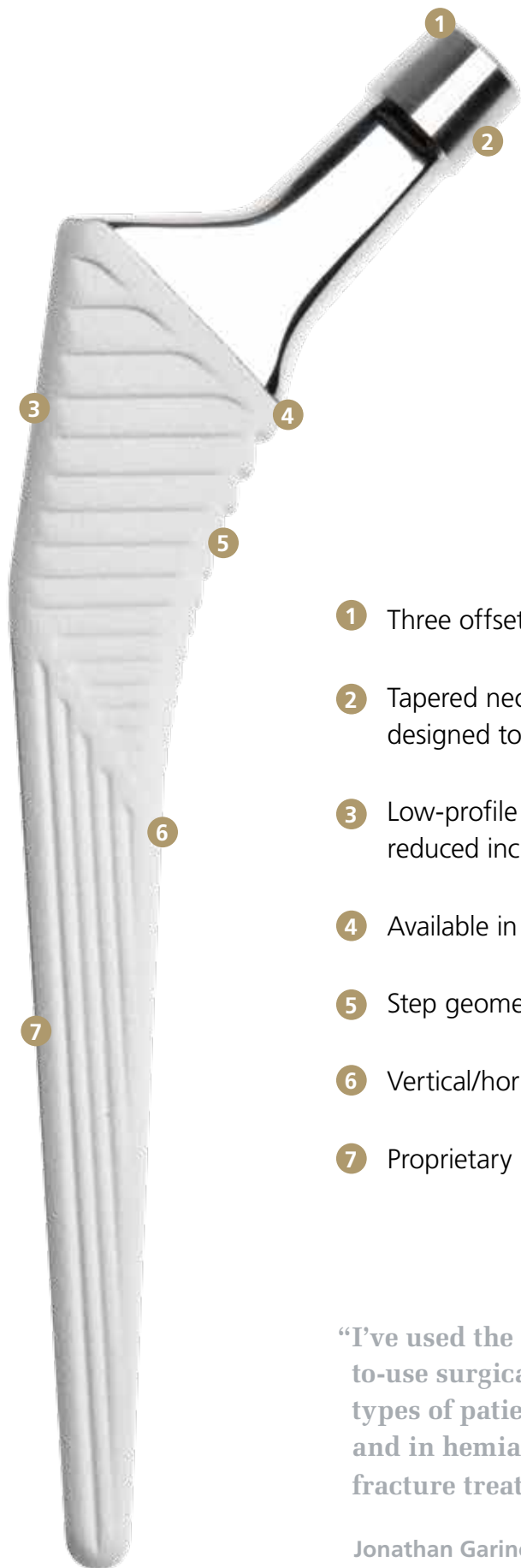
THE SCIENCE OF SIMPLICITY

“The advanced features of the CORAIL stem, and its bone-preserving surgical technique, have made it a great choice for minimally invasive hip surgery. More than twenty years ago, we began a revolution with the use of HA in orthopaedics. Today we face an exciting new era, and we look forward with confidence in sharing continued success with the world’s orthopaedic community.”

ARTRO Group - Design Surgeon Team, Clinique d'Argonay
International Visitation Centre - Annecy, France

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



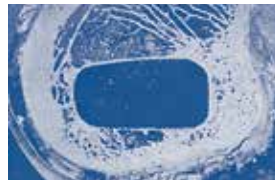
- 1 Three offset options to restore hip biomechanics
- 2 Tapered neck geometry and Articul/eze® taper designed to increase range of motion
- 3 Low-profile lateral shoulder design enables easy insertion in reduced incision techniques, including the anterior approach.
- 4 Available in collared or non-collared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

“I’ve used the CORAIL since 1998 and with its easy-to-use surgical technique, choose to use it on many types of patients, including those with osteopenia and in hemiarthroplasty cases for femoral neck fracture treatment.”

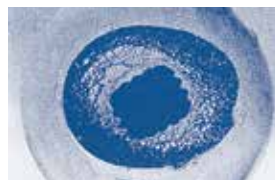
Jonathan Garino, MD - Philadelphia, Pennsylvania

Proven Fixation

CORAIL stepped geometry is oriented to minimize shear forces and maximize compression loading in host cancellous bone.



Proximal trapezoid cross section resists axial/torsional stresses and promotes initial stability.



Distal quadrangular cross section provides rotational stability without cortical contact



1 year post-op



16 years post-op

LONG-TERM SURVIVORSHIP

98.3% — Survivorship at 10 and 14 years¹

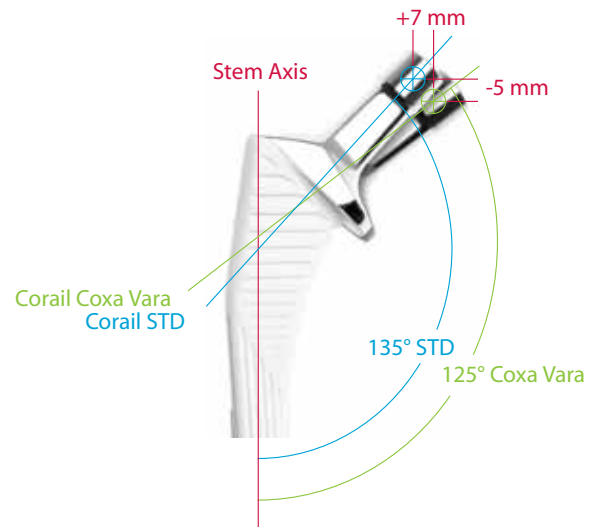
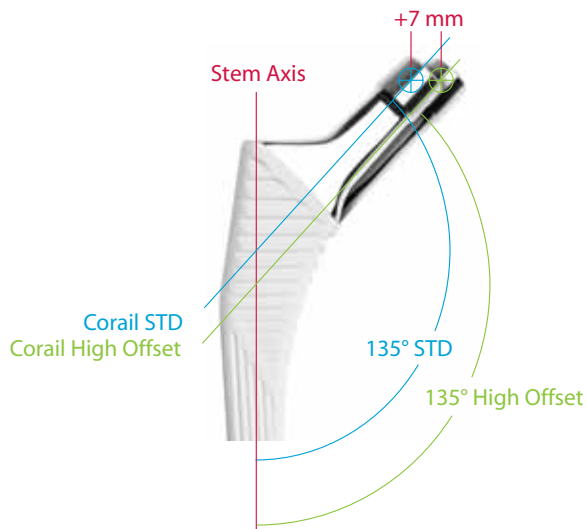
98.9% — Survivorship in 100 consecutive cases at 8 years²

97.0% — Survivorship in 5,456 cases at 15 years³

“I find the CORAIL stem design and HA coating provides initial stability for my patients.”

William Lanzer, MD - Seattle, Washington

Enhanced Biomechanics



COLLARLESS STEM OPTIONS

Standard and high offset collarless stem options enable femoral offset restoration and soft-tissue tensioning.

High offset collarless option adds +7 mm of direct lateralization to restore hip biomechanics in a wider range of patients.

COLLARED STEM OPTIONS

Collared stems are available in both standard and coxa vara offset to control subsidence and add rotational stability in patients with osteopenic bone.

Coxa vara collared neck option offers an increased offset and varus neck angle for femoral restoration and proper soft-tissue tensioning of varus neck angled patients.



NECK ENHANCEMENTS

Narrowed anterior-posterior neck dimensions and optimized Articul/eze taper increase range of motion and reduce risk of mechanical impingement.

Articul/eze 12/14 taper is fully captured by all nonskirted Articul/eze heads, eliminating the creation of a false skirt due to trunnion protrusion.

Polished neck is designed to generate less wear debris secondary to prosthetic impingement.

“I use the CORAIL because of its ease of implantation and long track record. Used with the PINNACLE® Acetabular Cup System, it lets me select multiple options in order to optimize hip biomechanics in my patients.”

Charles R. Clark, MD - Iowa City, Iowa

Bone Preserving Philosophy

COMPACTION BROACHING

A philosophy of respecting and preserving patient anatomy, biology and physiology are key to the CORAIL success.

Compressing and compacting the cancellous bone during the broaching process maintains the medullary canal endosteum, preserving blood supply to the bone and the bone/implant interface.



Compaction broaching creates an excellent bone/implant contact ratio and high pullout strength, and it increases prosthetic torsional stability.



Compaction broaching preserves the blood supply to promote healing and growth of bone around the implant, and this technique has shown excellent long-term survivorship.^{2,3}



18 years post-op

“Compaction broaching coupled with CORAIL creates ‘silent’ hip replacement. We haven’t seen any adverse, long-term radiographic changes.”

James Caillouette, MD - Newport Beach, California

“I find the CORAIL stem and instrumentation facilitate ease of insertion using an anterior approach.”

Joel Matta, MD - Los Angeles, California

Heritage

The fully HA-coated CORAIL Total Hip System can be used in a variety of types and sizes of femora.⁴



Type A: Champagne Flute

Type B: Proportional Shape

Type C: Stovepipe

**“I find it to be reproducible and easy to implant,
and use it on many different types of patients.”**

Sam Sydney, MD - Baltimore, Maryland

**“After independently reviewing the ARTRO Group CORAIL
data in 1998, I decided to try the CORAIL stem. I’m pleased
with the results and now use it on many types of patients.”**

Mark Froimson, MD - Cleveland, Ohio

Surgical Technique



Step 1: Neck Osteotomy



Step 2: Femoral Canal Preparation



Step 3: Offset Selection & Head Trialing



Step 4: Femoral Component Insertion

Essential Product Information - CORAIL AMT Hip

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 of 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. Vidalain JP. CORAIL Stem Long-Term Results based on the 15-Years ARTRO Group Experience. Fifteen Years of Clinical Experience with Hydroxyapatite Coatings in Joint Arthroplasty, Ed. Springer, 217-224; 2004.
2. Rokkum M, Brandt M, Bye K, Hetland KR, Waage S, Reigstad A. Polyethylene wear, osteolysis and acetabular loosening with an HA coated hip prosthesis. A follow-up of 94 consecutive arthroplasties. J Bone Joint Surg Br. 1999;81(4):582-9.
3. Hallan, G, Lie SA, Furnes O, Engesaeter LB, Vollset SE, Havelin LI. Medium - and long-term performance of 11,516 uncemented primary femoral stems from the Norwegian arthroplasty register. The Journal of Bone and Joint Surgery. 2007;89-B:1574-80.
4. Chatelet JC, Setiey L. Long-term study of osteolysis around the hydroxyapatite-coated total hip arthroplasty without cement. British Editorial Society of Bone and Joint Surgery. 2004;86-B (supple 1):39.

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.



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