

THE SCIENCE OF SIMPLICITY

With 2,000,000 stems provided for patients worldwide¹ and thirty years of clinical history, the CORAIL® Total Hip System now has a very 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.

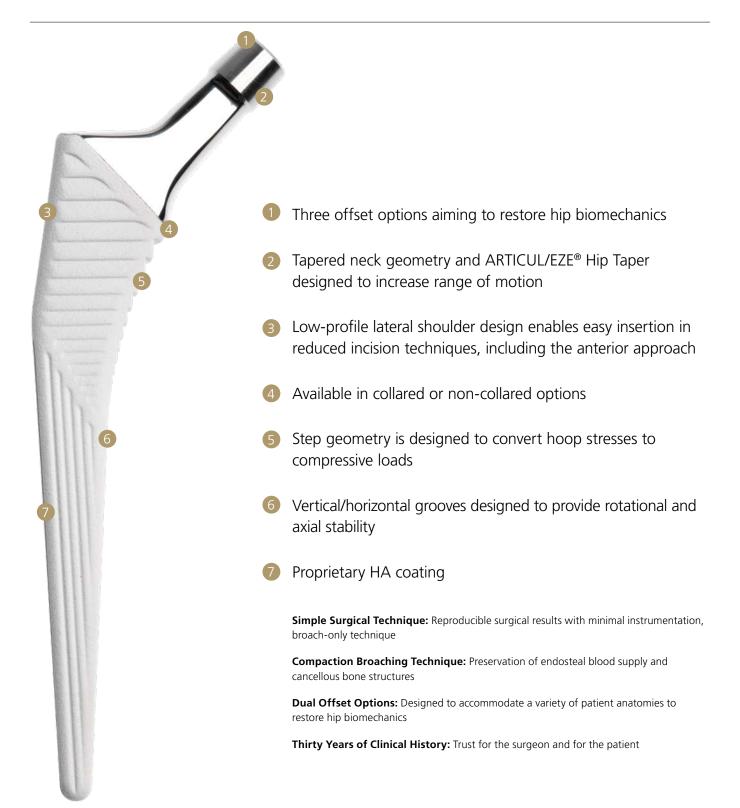
Advancing science, enhancements were made to the original CORAIL Hip to provide options for orthopaedic surgeons treating today's patients.

Enhancements to the CORAIL System include:

- Neck geometry designed for broad 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



PREOPERATIVE PLANNING

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

Radiographs

The first step in accurate templating is obtaining highquality 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.

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.

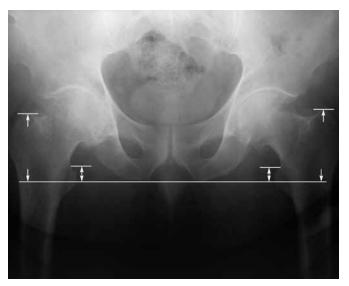


Figure A

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).

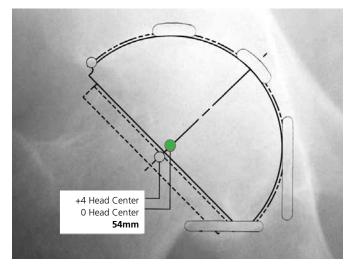


Figure B • Cup center of rotation

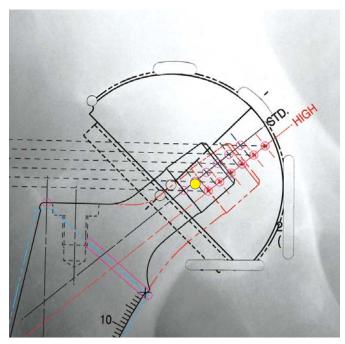
Cementless femoral component selection

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).

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 E).

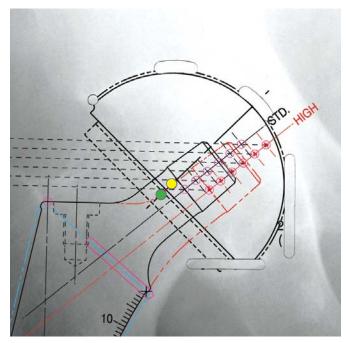


Figure E Head center of rotation

• 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

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 40-45 degrees of lateral opening (abduction) and 15-20 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.



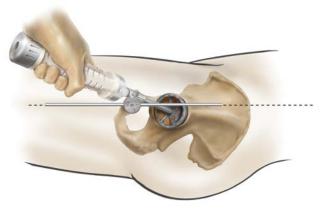
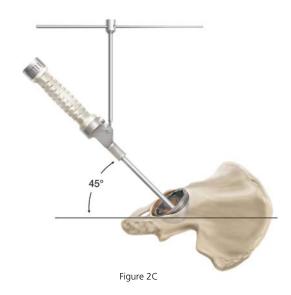


Figure 2B



Metaphyseal preparation

It is important to select a point of entry posterolaterally to the Piriformis Fossa to avoid varus positioning. Use a curette or general instrument to indicate the direction of the canal. To prevent under-sizing or varus positioning, the greater trochanter may be prepared with a Modular Box Osteotome to allow better insertion of the broaches and accomdate multiple approaches to the hip (Figure 3).



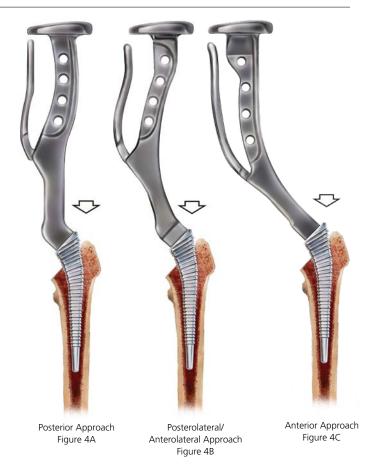
Figure 3

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.



5

Calcar Preparation

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.

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 Hip 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

Я

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.



Acetabular Insert Implantation

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



Figure 9

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).



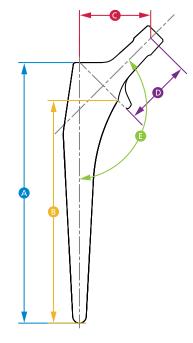
Figure 10



5 years post-op

CORAIL AMT STEM SPECIFICATIONS

| | 135° STANDARD (STD) – COLLARLESS | | | | | |
|------|----------------------------------|-------------------------|--------------------|-------------------------|-------------------------|-------------------|
| Size | Stem Length (mm) (A) | Stem Length (mm) (B) | Offset (mm) (C) | Neck Length (mm) (D) | Neck Shaft Angle (E) | Width (mm) (F) |
| 8 | 115 | 93 | 38.3 | 39 | 135° | 7 |
| 9 | 130 | 108 | 38.8 | 39 | 135° | 8 |
| 10 | 140 | 118 | 39.5 | 39 | 135° | 8 |
| 11 | 145 | 123 | 40.3 | 39 | 135° | 9 |
| 12 | 150 | 128 | 41.0 | 39 | 135° | 10 |
| 13 | 155 | 133 | 41.7 | 39 | 135° | 10 |
| 14 | 160 | 138 | 42.3 | 39 | 135° | 10 |
| 15 | 165 | 143 | 43.0 | 39 | 135° | 10 |
| 16 | 170 | 148 | 43.8 | 39 | 135° | 10 |
| 18 | 180 | 158 | 44.8 | 39 | 135° | 11 |
| 20 | 190 | 168 | 45.8 | 39 | 135° | 11 |



| | 135° HIGH OFFSET (KHO) – COLLARLESS | | | | | |
|------|-------------------------------------|-------------------------|--------------------|-------------------------|-------------------------|-------------------|
| Size | Stem Length (mm) (A) | Stem Length (mm) (B) | Offset (mm) (C) | Neck Length (mm) (D) | Neck Shaft Angle (E) | Width (mm) (F) |
| 9 | 130 | 108 | 45.7 | 43 | 135° | 8 |
| 10 | 140 | 118 | 46.4 | 43 | 135° | 9 |
| 11 | 145 | 123 | 47.2 | 43 | 135° | 9 |
| 12 | 150 | 128 | 47.9 | 43 | 135° | 10 |
| 13 | 155 | 133 | 48.5 | 43 | 135° | 10 |
| 14 | 160 | 138 | 49.2 | 43 | 135° | 10 |
| 15 | 165 | 143 | 49.9 | 43 | 135° | 10 |
| 16 | 170 | 148 | 50.7 | 43 | 135° | 10 |
| 18 | 180 | 158 | 51.8 | 43 | 135° | 11 |
| 20 | 190 | 168 | 52.9 | 43 | 135° | 11 |



| | 125° HIGH OFFSET (KLA) | | | | | |
|------|-------------------------|-------------------------|--------------------|-------------------------|-------------------------|-------------------|
| Size | Stem Length (mm) (A) | Stem Length (mm) (B) | Offset (mm) (C) | Neck Length (mm) (D) | Neck Shaft Angle (E) | Width (mm) (F) |
| 9 | 130 | 108 | 45.6 | 40 | 125 | 8 |
| 10 | 140 | 118 | 46.3 | 40 | 125 | 8 |
| 11 | 145 | 123 | 47.1 | 40 | 125 | 9 |
| 12 | 150 | 128 | 47.8 | 40 | 125 | 10 |
| 13 | 155 | 133 | 48.5 | 40 | 125 | 10 |
| 14 | 160 | 138 | 49.1 | 40 | 125 | 10 |
| 15 | 165 | 143 | 49.8 | 40 | 125 | 10 |
| 16 | 170 | 148 | 50.6 | 40 | 125 | 10 |
| 18 | 180 | 158 | 51.8 | 40 | 125 | 11 |
| 20 | 190 | 168 | 52.8 | 40 | 125 | 11 |

ORDERING INFORMATION

IMPLANTS

| Standard | Collarless | (KS) |
|----------|------------|------|
| Cat. No. | Size | |

| | | _ |
|----------|----------------|---|
| 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 | |
| | | |

Standard Collared (KA)

| Dianaara Co | onarca (1071) | |
|-------------|---------------|--|
| 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 (KHO)

| 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 (KLA)

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

INSTRUMENTS

| COD | ATT | A B CCC | TO 1 | |
|-----|-----|---------|-------|--------|
| COK | AIL | AMI | Broac | h Case |

| 001111111111111 | |
|-----------------|---------------------------------------|
| 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 (STD) |
| L20432 | CORAIL Coxa Vara Neck Segment (KLA) |
| L20433 | CORAIL High Offset Neck Segment (KHO) |
| 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 | Anteversion Osteotome |
| 2570-04-100 | Calcar Planer-Small |
| 2665-99-000 | Broach Case Complete |
| | ' |

CORAIL AMT Core Case Complete 225440000

| Canal Probe |
|---------------------------------------|
| T-Handle |
| Retaining Implant Inserter (2 pcs) |
| Standard Implant Inserter |
| Head Impactor |
| 28 mm Articul/eze +1.5 mm Trial Head |
| 28 mm Articul/eze +5.0 mm Trial Head |
| 28 mm Articul/eze +8.5 mm Trial Head |
| 28 mm Articul/eze +12.0 mm Trial Head |
| 28 mm Articul/eze +15.5 mm Trial Head |
| 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 - DSUS/JRC/0216/1413, 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 | |
| | Note: 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 |

Additional Instruments Compatible with CORAIL Hip System

| L93205 | CORAIL Bone Impactor |
|-----------|-------------------------|
| L93606 | Bone Tamp |
| 257004500 | MI Calcar Reamer Shaft |
| 200147000 | Calcar Mill Small |
| 200148000 | Calcar Mill Medium |
| 200149000 | Excel Calcar Mill Large |



References

1. 1986 - 2015 sales data on file, DePuy International Ltd

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.



DePuy Orthopaedics, Inc.

700 Orthopaedic Drive Warsaw, IN 46582 USA T. +1 (800) 366-8143 DePuy France S.A.S 7 allée Irène Joliot Curie CS 30078 69801 SAINT PRIEST Cedex Tel. +33 (0)4 72 79 27 27 Fax. +33 (0)4 72 79 28 28

www. depuy synthes. com