SURGICAL TECHNIQUE

AML®

HIP SYSTEM

Parallel Sided
Unparalleled Results

DePuy
a Johnson & Johnson company

The goal of hip arthroplasty is the recreation of joint biomechanics upon a foundation of stable fixation.

The creation of a biomechanically sound arthroplasty requires the acetabular component be placed in a near anatomic position, that the femoral neck cut be at the correct level and a prosthesis be chosen with a neck length and head combination that will reproduce the desired anatomic offset and joint stability.

The foundation of stable fixation by ingrowth requires that the porous-coated implants, the acetabular cup and the femoral component, be implanted with adequate initial stability to allow subsequent osseointegration.

Preoperative Planning

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.

The goals of preoperative planning are:

- Restore leg length.
- Restore biomechanics.
- Obtain stable fixation.

Achieving these goals can be accomplished with consistent steps:

- Determine preoperative leg length discrepancy and the amount of correction that will be required.
- Determine acetabular component placement and estimate size.
- Determine femoral component distal diameter that will provide 4-6 cm of diaphyseal endosteal cortical contact.
- Determine the appropriate combination of femoral component seating level, component offset and head length to restore leg length and offset.

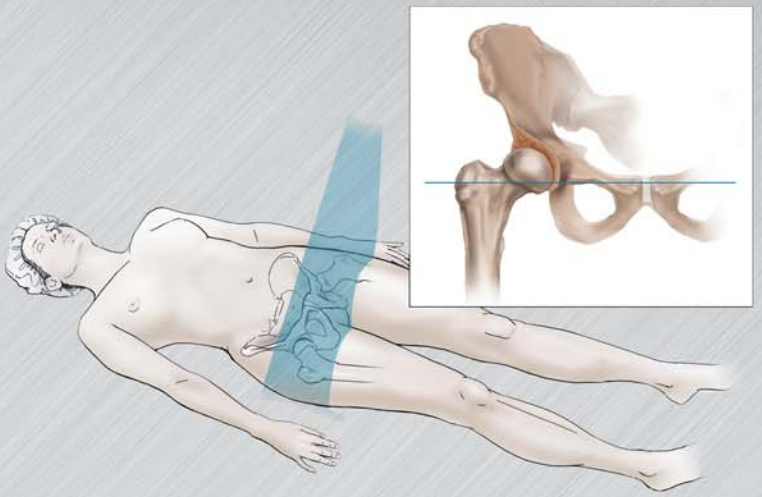


Figure A

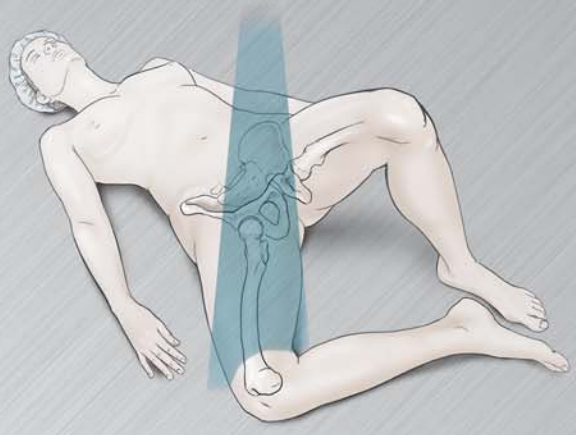


Figure B

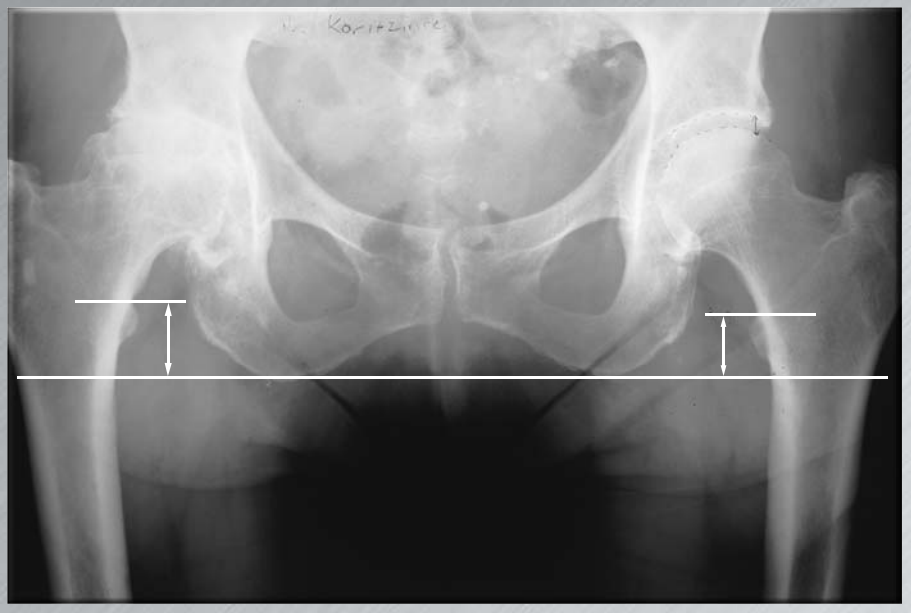
Templating and Radiographs

Accurate templating is critical in determining how to physically execute the hip reconstruction. The first step in accurate templating is obtaining high-quality anterior/posterior (A/P) and lateral radiographs using a standardized protocol with known magnification. The AML templates incorporate 20 percent magnification.

To begin, obtain an A/P view of the pelvis with both legs in 15 degrees of internal rotation to position the head and neck parallel to the coronal plane (Figure A). For the A/P pelvic radiograph, position the patient such that the X-ray beam is centered three inches below the symphysis pubis. The ideal radiograph will clearly show the top of the acetabulum and at least 10 inches of both femurs.

The lateral radiograph should be taken in a modified "frog-leg" position with patient's knee and ankle touching the tabletop and the pelvis slightly oblique (Figure B). This modified "frog-leg" lateral technique standardizes femoral rotation. Position the X-ray beam over the upper half of the femur at a 90-degree angle to the femur and the tabletop. The normal femoral shape is not distorted when the radiographic beam is orthogonal to the radiographic film cassette. In this technique, with the femur closer to the table, the radiographic magnification is less than what appears in the A/P radiograph.

Templating should be performed on the pathological hip. However, when the pathological hip cannot be placed into 15 degrees of internal rotation, is fixed in abduction or adduction, or the acetabular position is abnormal, it is recommended that the templating procedure be executed on the contra-lateral side.

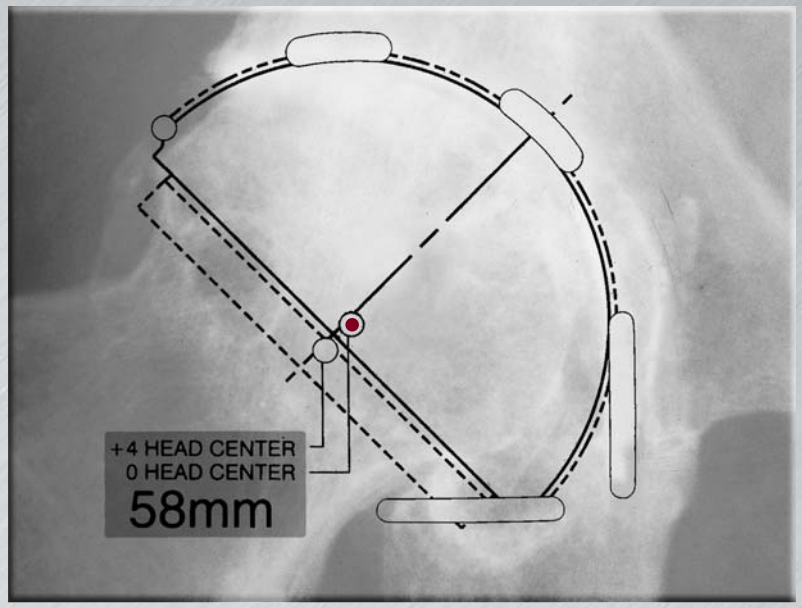


Determination of Leg Length Discrepancy

Determine preoperative leg length by clinical evaluation and confirm it radiographically.

As a radiographic estimate of leg length discrepancy, draw a reference line through the bottom of the obturator foramina. 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. This measurement is confirmed from clinical observations.

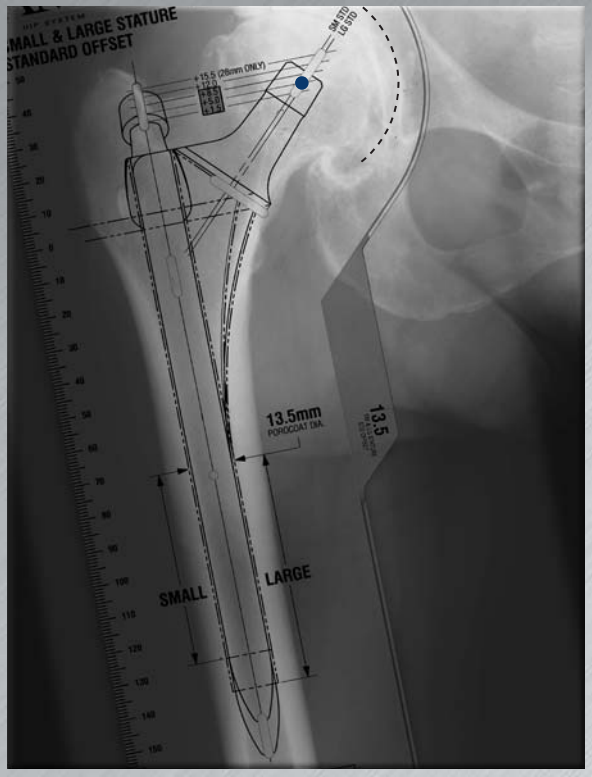
As an alternative, the tip of the greater trochanter may be used as a mark in conjunction with the lines through the obturator foramina.



● Acetabular Center of Rotation

Acetabular Cup Position and Size

Acetabular position and size are determined using template overlays on the A/P radiograph of the hip. The acetabular teardrop can be used as the inferior-medial margin reference point for the acetabular reconstruction. Once acetabular cup position, size and liner are determined, mark the intended center of rotation of the bearing surface on the A/P radiograph. Record the acetabular cup dimensions for future reference.



● Head Center of Rotation

Femoral Templating

Determining Stem Diameter

Position the femoral template overlay along the long axis of the femur. The appropriate stem diameter will fill the canal at the isthmus contacting both endosteal surfaces over at least 4-6 cm.

Determining Pilot Hole Location

When the template is aligned with the long axis of the femur, the appropriate location of the pilot hole in the superior femoral neck/greater trochanter area is determined.

Neck Cut Determination

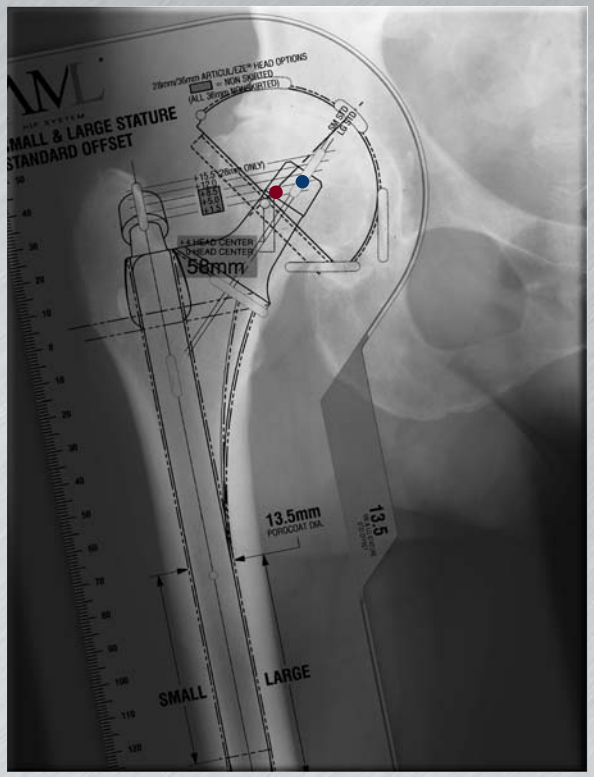
With the femoral template aligned down the long axis of the femur, draw the neck resection line at the point where the selected stem provides the desired amount of leg length correction and offset, with the goal of using a nonskirted modular head to optimize range of motion. It is important to understand that when using a parallel-sided, distally fixed implant the diaphyseal position of the implant may be altered superiorly or inferiorly in the diaphysis to aid in the correction of leg length without affecting offset.

Metaphyseal Size Determination

The correct metaphyseal size is chosen from the standard or the large metaphyseal alternatives.

Lateral Radiograph

The lateral radiograph is then consulted to ensure the stem chosen will adequately fit the femoral canal.



- Head Center of Rotation
- Acetabular Center of Rotation

Offset Requirements

The AML Hip System cementless femoral components are available with a standard offset configuration for the standard metaphyseal body and in standard or high offset configurations for the large metaphyseal body. Through templating, and later intraoperative trialing, the offset option which restores proper biomechanics is determined.

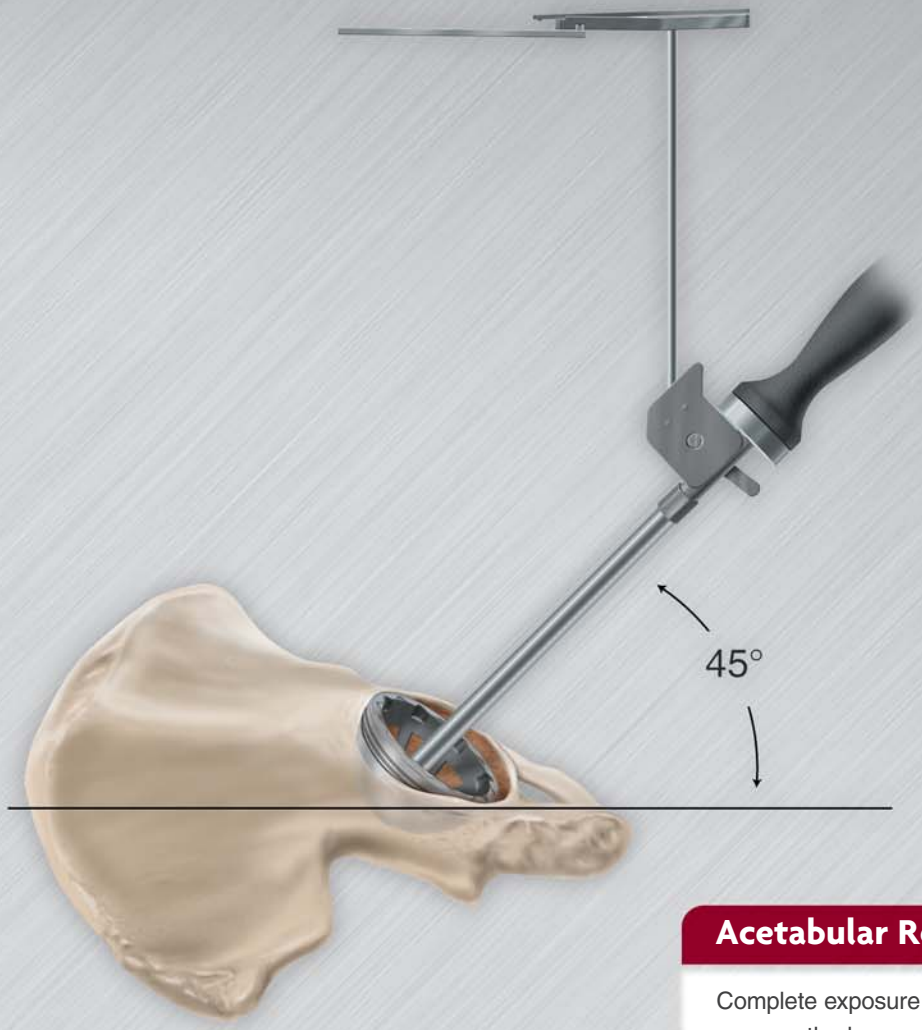
Offset Alternatives

Metaphyseal Stature	Base Offset	Stem Diameters (mm)
Small Stature	40	10.5 - 12.0
Small Stature	43	13.5 - 22.5
Large Stature	40	10.5 - 12.0
Large Stature	45	13.5 - 22.5
Large Stature	52	13.5 - 22.5

Femoral Neck Resection

The AML Hip System surgical instrumentation was developed to accommodate all surgical approaches, in addition to working with smaller incision surgery.

Osteotomize the femoral neck at a 45-degree angle using the neck resection guide. Align the neck resection guide in a neutral position down the long axis of the femur. Determine the resection level by aligning the top of the guide with the tip of the greater trochanter or by referencing a measured resection level above the lesser trochanter. Mark the neck resection and resect the femoral head.



Acetabular Reaming and Alignment

Complete exposure of the acetabulum is essential to accurately prepare the bone and position the implant. Progressively ream the acetabulum until healthy bleeding bone is reached and a hemispherical dome is achieved.

Using the cup impactor, place a trial cup sizer into the reamed acetabulum and assess its position and stability. The trial cup angle of orientation is normally 45 degrees of abduction (lateral opening) and 15-30 degrees of anteversion. Remove the cup impactor from the trial shell and place the desired liner trial into the cup trial.

Establish Medullary Canal

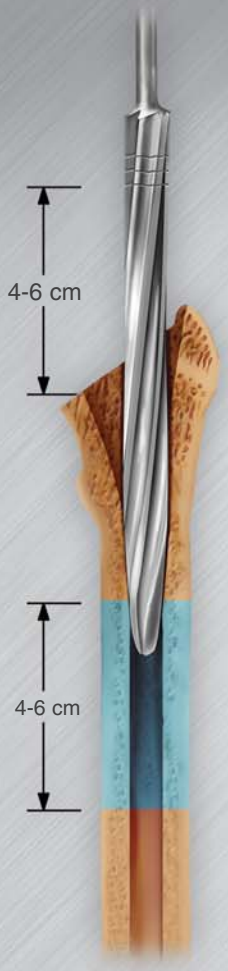
Prepare the pilot hole by placing the IM initiator in the piriformis fossa. This anatomical landmark, posterior and lateral to the femoral neck, serves as a reference point for location of the center of the intramedullary canal. This position can be verified by reviewing the radiographic template overlay positioned on the long axis of the femur.

The IM initiator is sequentially marked in 2 mm increments to enable accurate pilot hole sizing. Neither the diameter nor location of the pilot hole should inhibit access to the femoral canal by the straight diaphyseal reamers. The straight diaphyseal reamers should never contact the bony margins of the pilot hole as contact may misdirect the straight reamers.

Define Medullary Canal

Utilize the tapered canal probe attached to the T-handle to establish a direct pathway to the medullary canal. Advance the canal probe to where the superior margin of the cutting flutes meet the neck resection. The canal probe should pass easily if proper alignment has been achieved. It is important to have circumferential clearance with the canal probe to avoid reaming in a varus orientation.

The path established by the canal probe will dictate the route for the straight rigid diaphyseal reamers and metaphyseal broaches. Take caution to ensure neutral alignment of the canal probe.



Diaphyseal Preparation and Measurement

Preparation

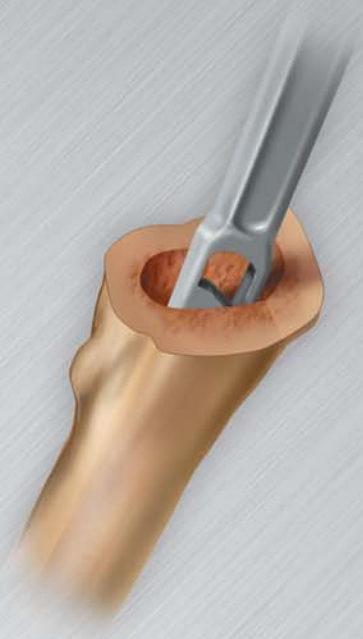
To prepare the diaphysis for the parallel-sided, cylindrical shape of the femoral prosthesis, a series of rigid straight diaphyseal reamers in 0.5 mm increments are employed. Use progressively larger canal reamers, in 0.5 mm increments, to enlarge the canal until the reamer cuts endosteal bone over 4-6 cm. The reamer diameter should be 0.5 mm less than the desired implant size.

During the reaming process, if the straight reamer impinges on the pilot hole, the entrance to the pilot hole must be enlarged. This aids in ensuring that the straight reamer is always centered in the canal and that reamer alignment is controlled by the endosteal femoral canal, preventing varus/valgus reaming.

Measurement

To gauge the amount of endosteal reamer contact, the subsequent reamer is advanced into the canal by hand. The distance that this subsequent reamer remains proud, relative to the reamer depth marking, is the estimated amount of endosteal reamer contact achieved with the previous reamer.

To avoid unnecessary distal reaming, employ the depth marks on the reamer to ensure correct depth is obtained. Refer to the chart at the back of this surgical technique for detailed information on reamer length markings.



Anteversion Orientation

Use the box osteotome to remove a wedge of cancellous bone the same approximate size and shape as the proximal portion of the prosthesis. Orientation should include the desired anteversion.

Femoral Broaching

Begin broaching of the proximal femur two to three sizes smaller than the preoperatively templated size. To ensure proper broach alignment, orient the broach laterally toward the greater trochanter.

Using progressively larger broaches, enlarge the metaphysis to the desired size. There are two metaphyseal broach sizes for every distal diameter. The broach dimensions are slightly smaller than the final porous-coated implant to ensure “scratch” fit. Should the broach become incarcerated during sequential broaching, refer to the Broach Extraction segment of this technique on page 17.

Calcar Planing

The AML Hip System is a collared design; therefore, calcar planing is required. Select either the small or large calcar mill to machine the cut surface of the femoral calcar. Place the planer over the broach stud and mill the calcar to the broach face. To prevent binding, make certain the planer is engaged on the broach stud and is rotating before engaging the calcar.

Retro-Impaction/Broach Extraction

If during sequential broaching or following final trial reduction, the broach becomes incarcerated, retro-impaction on the broach handle can be used to disengage the broach.

If retro-impaction on the broach handle does not disengage the broach, it is recommended that the broach extractor be employed.

To use the broach extractor, insert the tip into the slot on the lateral shoulder of the broach. Rotate the extractor 90 degrees to lock it in place. Use a mallet to extract the broach from the canal.

Trial Reduction

Trial neck segments and trial modular heads are available to assess proper component position, joint stability, range of motion and leg length. Perform a trial reduction with the appropriate neck segment, a +5 Articul/eze® head trial, to allow for one up or down adjustment in neck length without using a skirted femoral head. During trial reduction, thoroughly examine range of motion and stability. Refer to the chart at the back of this surgical technique for detailed base offset, neck length and leg length adjustment information.

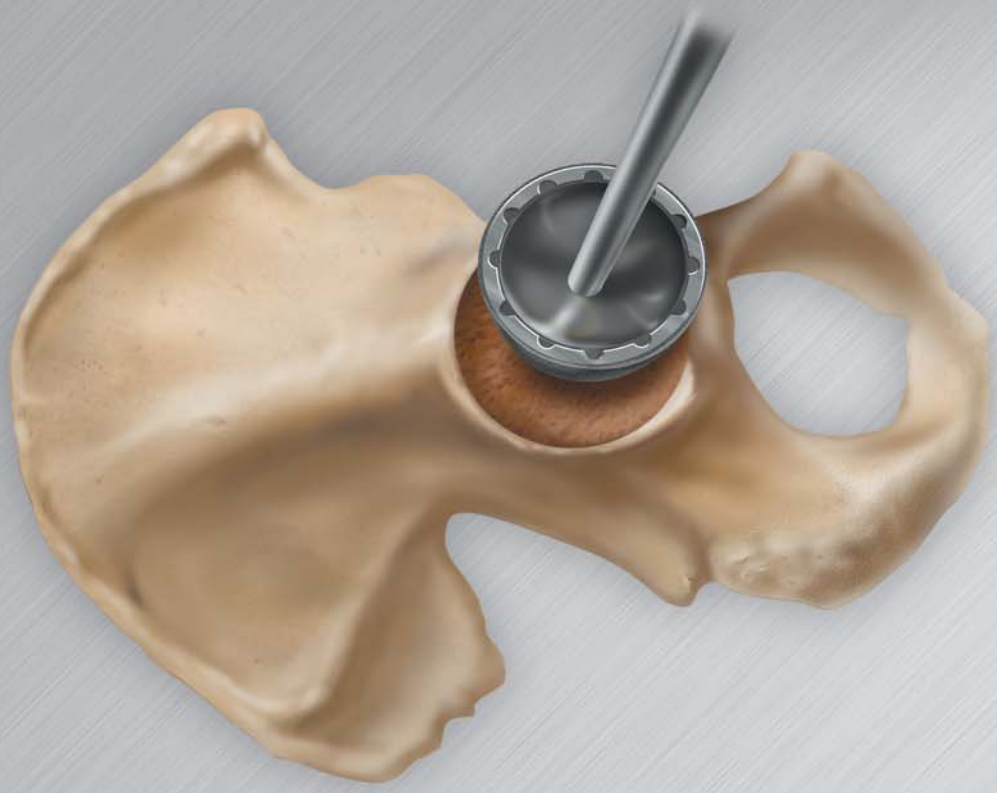
Offset Alternatives

Metaphyseal Stature	Base Offset	Stem Diameters (mm)
Small Stature	40 ○	10.5 - 12.0
Small Stature	43 ●	13.5 - 22.5
Large Stature	40 ○	10.5 - 12.0
Large Stature	45 ●	13.5 - 22.5
Large Stature	52 ●	13.5 - 22.5

○ ● ● ● Trial neck segment color code

Instability Management

- Soft tissue laxity can result in an unstable joint. This can be resolved by increasing modular head length, leaving the distally fixed stem slightly proud relative to the calcar/calcar collar position, or by choosing the high offset option.
- Instability and impingement due to component orientation can occur. This condition can be corrected by choosing a face-changing acetabular liner and positioning it to achieve the desired stability. If the face-changing liner fails, the acetabular shell may require repositioning.
- Where instability is due to acetabular osteophytes or to trochanteric prominence, relieve these areas. Substitution of a longer modular head or selecting the high offset neck trial may be required to relieve bony impingement.



Acetabular Shell Insertion

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

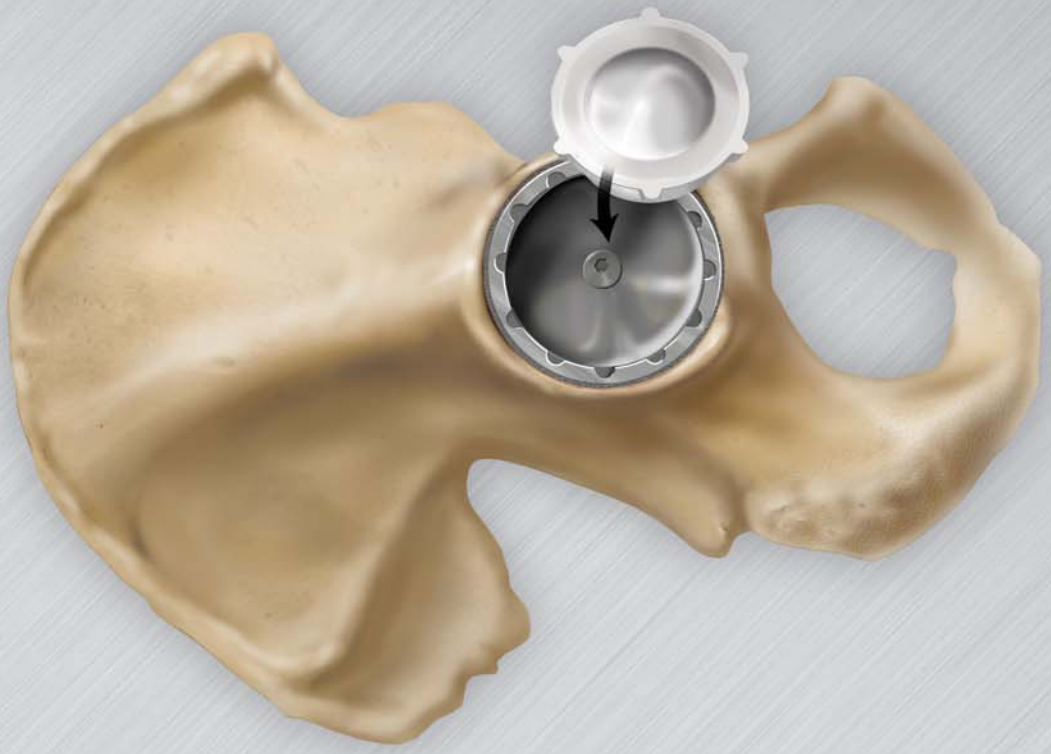
Femoral Component Insertion

Introduce the hip stem to the medullary canal. Rotate the stem into proper orientation and advance the stem into the canal using hand pressure. Care should be taken to ensure the implant is being inserted with the desired amount of anteversion. Small corrections in anteversion may be made during stem impaction. If significant anteversion corrections are required, it is recommended that the implant be removed and reinserted.

Advancing the stem into the final position and achieving 4-6 cm of diaphyseal fixation will require numerous mallet blows. If the stem does not advance with uniform resistance with every mallet blow, it is recommended that the stem be extracted and the diaphysis be reamed line to line.

Final Trial Reduction

Perform a final trial reduction using the trial acetabular liner and trial femoral head. Select the liner and head that result in the correct leg length, greatest stability and optimum range of motion.

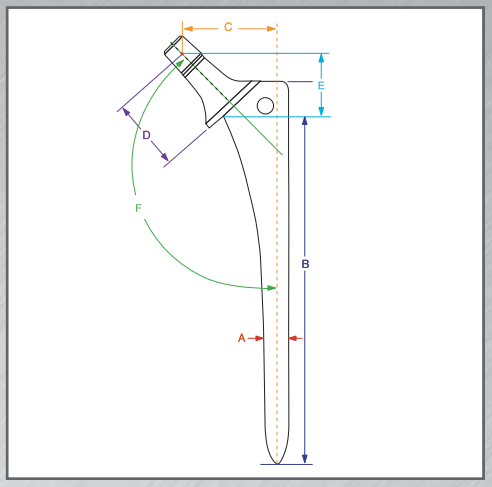


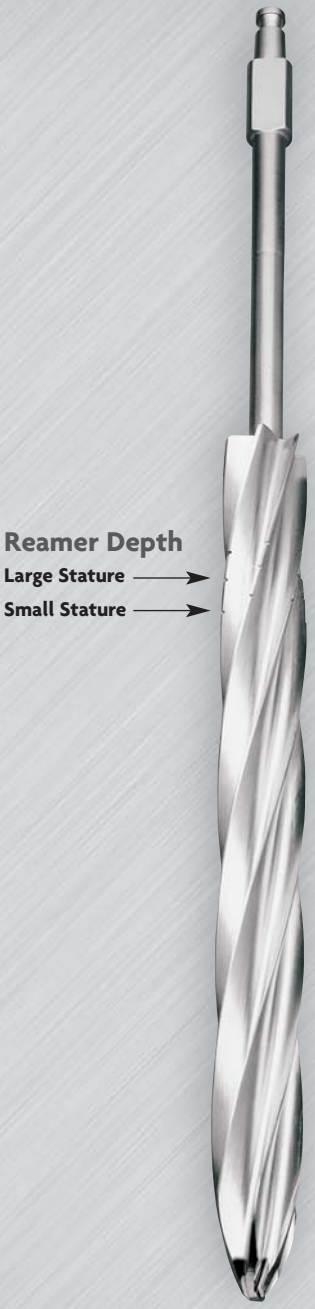
Acetabular Insert Implantation

Following the final trial reduction, remove the trial acetabular liner and insert the appropriate acetabular liner.

Femoral Head Implantation

Clean and dry the Articul/eze taper. Manually introduce the appropriate femoral head by firmly pushing and twisting the femoral head into place on the taper. Using the head impactor, engage the head with several mallet taps.





A	B	C	D	E	F
Diameter	Stem Length	Base Offset	Neck Length	Leg Adjustment Length	Neck Shaft Angle
SMALL					
10.5 mm	155 mm	40 mm ○	30 mm	24 mm	135°
12.0 mm	155 mm	40 mm ○	30 mm	25 mm	135°
13.5 mm	155 mm	43 mm ●	32 mm	26 mm	135°
15.0 mm	155 mm	43 mm ●	32 mm	26 mm	135°
16.5 mm	150 mm	43 mm ●	32 mm	27 mm	135°
18.0 mm	150 mm	43 mm ●	32 mm	27 mm	135°
19.5 mm	150 mm	43 mm ●	32 mm	28 mm	135°
21.0 mm	150 mm	43 mm ●	32 mm	28 mm	135°
22.5 mm	150 mm	43 mm ●	32 mm	29 mm	135°
LARGE					
10.5 mm	160 mm	40 mm ○	30 mm	28 mm	135°
12.0 mm	160 mm	40 mm ○	30 mm	29 mm	135°
13.5 mm	160 mm	45 mm ●	33 mm	30 mm	135°
15.0 mm	160 mm	45 mm ●	33 mm	31 mm	135°
16.5 mm	160 mm	45 mm ●	33 mm	31 mm	135°
18.0 mm	155 mm	45 mm ●	33 mm	31 mm	135°
19.5 mm	155 mm	45 mm ●	33 mm	32 mm	135°
21.0 mm	155 mm	45 mm ●	33 mm	33 mm	135°
22.5 mm	155 mm	45 mm ●	33 mm	33 mm	135°
LARGE HIGH OFFSET					
13.5 mm	160 mm	52 mm ●	37 mm	30 mm	135°
15.0 mm	160 mm	52 mm ●	37 mm	30 mm	135°
16.5 mm	160 mm	52 mm ●	37 mm	31 mm	135°
18.0 mm	160 mm	52 mm ●	37 mm	31 mm	135°
19.5 mm	160 mm	52 mm ●	37 mm	32 mm	135°
21.0 mm	155 mm	52 mm ●	37 mm	32 mm	135°
22.5 mm	155 mm	52 mm ●	37 mm	33 mm	135°

○●●● Trial neck segment color code

INSTRUMENTATION

Reamer

Cat. No.	Size (mm)
2001-84-080	8.0
2001-84-090	9.0
2001-84-095	9.5
2001-84-100	10.0
2001-84-105	10.5
2001-84-110	11.0
2001-84-115	11.5
2001-84-120	12.0
2001-84-125	12.5
2001-84-130	13.0
2001-84-135	13.5
2001-84-140	14.0
2001-84-145	14.5
2001-84-150	15.0
2001-84-155	15.5
2001-84-160	16.0
2001-84-165	16.5
2001-84-170	17.0
2001-84-175	17.5
2001-84-180	18.0
2001-84-185	18.5
2001-84-190	19.0
2001-84-195	19.5
2001-84-200	20.0
2001-84-205	20.5
2001-84-210	21.0
2001-84-215	21.5
2001-84-220	22.0
2001-84-225	22.5
2001-84-250	25.0
2611-30-000	Core 1 Complete

Broach

Cat. No.	Size (mm)
Small	
2001-81-105	10.5
2001-81-120	12.0
2001-81-135	13.5
2001-81-150	15.0
2001-81-165	16.5
2001-81-180	18.0
2001-81-195	19.5
2001-81-210	21.0
2001-81-225	22.5
Large	
2001-82-105	10.5
2001-82-120	12.0
2001-82-135	13.5
2001-82-150	15.0
2001-82-165	16.5
2001-82-180	18.0
2001-82-195	19.5
2001-82-210	21.0
2001-82-225	22.5

Neck Segments

Cat. No.	Size (mm)
2554-40-000	40.0
2554-43-000	43.0
2554-45-000	45.0
2554-52-000	52.0

Core 2 Instruments

Cat. No.	Description
2001-42-000	T-Handle
2001-80-501	IM Initiator Sized
2001-44-000	Excel Osteotome Template
2001-80-504	Excel Broach Handle
85-3928	Broach Handle Alignment Rod
2001-80-502	Calcar Planer Small
2001-80-503	Calcar Planer Large
2001-65-000	Femoral Head Impactor
2001-66-000	Replacement Tip
2002-24-000	Broach Extractor Excel
2354-10-000	Canal Probe
2530-81-000	Articul/eze Trial Head, 28 +1.5 Nk, Green
2530-82-000	Articul/eze Trial Head, 28 +5 Nk, Brown
2530-83-000	Articul/eze Trial Head, 28 +8.5 Nk, Blue
2530-84-000	Articul/eze Trial Head, 28 +12 Nk, Black
2530-85-000	Articul/eze Trial Head, 28 +15.5 Nk, White
2611-20-000	Core 2 Complete

Excel Instruments

Cat. No.	Description
2554-60-000	Short Excel Driver
2554-61-000	Excel Extractor
2554-62-000	Version Control Bar
2002-25-000	Anteversion Osteotome, Med
2520-70-000	Prodigy Impactor
2354-04-000	Excel Implant Driver

Templates

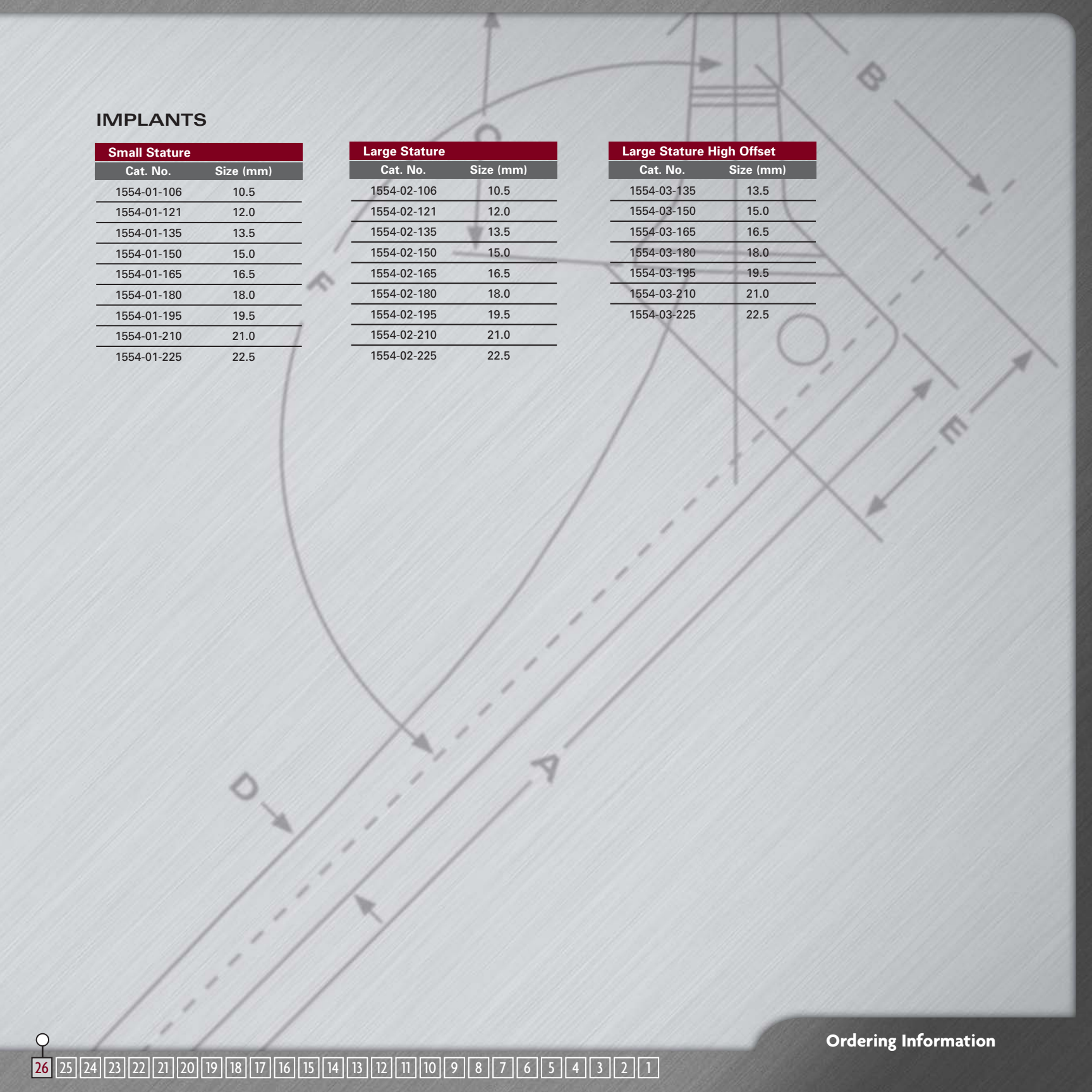
Cat. No.	Description
2991-95-000	All Styles

IMPLANTS

Small Stature	
Cat. No.	Size (mm)
1554-01-106	10.5
1554-01-121	12.0
1554-01-135	13.5
1554-01-150	15.0
1554-01-165	16.5
1554-01-180	18.0
1554-01-195	19.5
1554-01-210	21.0
1554-01-225	22.5

Large Stature	
Cat. No.	Size (mm)
1554-02-106	10.5
1554-02-121	12.0
1554-02-135	13.5
1554-02-150	15.0
1554-02-165	16.5
1554-02-180	18.0
1554-02-195	19.5
1554-02-210	21.0
1554-02-225	22.5

Large Stature High Offset	
Cat. No.	Size (mm)
1554-03-135	13.5
1554-03-150	15.0
1554-03-165	16.5
1554-03-180	18.0
1554-03-195	19.5
1554-03-210	21.0
1554-03-225	22.5



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

Total Hip Arthroplasty (THA) 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. THA is indicated for: a severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previous hip surgery; and certain cases of ankylosis. Hemi-hip arthroplasty is indicated in these conditions where there is evidence of a satisfactory natural acetabulum.

Contraindications

THA and hemi-hip arthroplasty are contraindicated in cases of: active local or systemic infection; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; poor bone quality; Charcot's or Paget's disease; for hemi-hip arthroplasty – pathological conditions of the acetabulum that preclude the use of the natural acetabulum as an appropriate articular surface. Ceramic heads are contraindicated in revision surgery when the femoral stem is not being replaced or for use with any other than a polyethylene or metal-backed polyethylene cup.

Warnings and Precautions

Components labeled for "Cemented Use Only" are to be implanted only with bone cement. The following conditions tend to adversely affect hip replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

Adverse Events

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

For more information about DePuy products, visit our web site at **www.jnjgateway.com.**

DePuy
a Johnson&Johnson company

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 371 4865

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 387 7800
Fax: +44 (113) 387 7890

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