

Total Hip Prostheses, Self-Centering™ Hip Prostheses and Hemi-Hip Prostheses

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 and sufficient femoral bone to seat and support the femoral stem. Hemi-hip arthroplasty is indicated in the following conditions: Acute fracture of the femoral head or neck that cannot be reduced and treated with internal fixation; fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation; avascular necrosis of the femoral head; non-union of femoral neck fractures; certain high subcapital and femoral neck fractures in the elderly; degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement; and pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

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. In the USA, ceramic heads are contraindicated for use with any other than UHMWPE cup or metal backed UHMWPE cup.

CAUTION: Ceramic liners are not approved for use in the United States.

WARNINGS and PRECAUTIONS:

Ceramic coated femoral stem prostheses are indicated for uncemented press fit fixation.

CAUTION: DO NOT USE BONE CEMENT FOR FIXATION OF A CERAMIC COATED PROSTHESIS.

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, history of infections, severe deformities leading to impaired fixation or improper positioning, tumors of the supporting bone structures, allergic reactions to materials, tissue reactions, and 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, peripheral neuropathies, tissue reaction.

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



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**SURGICAL
TECHNIQUE**

**CEMENTED
&
PRESS-FIT**

SUMMIT™ BASIC
TAPERED HIP SYSTEM



▶ UNIFIED
INSTRUMENTATION

▶ INTRAOPERATIVE
FLEXIBILITY

▶ PROVEN
BIOMECHANICS

INTRODUCTION

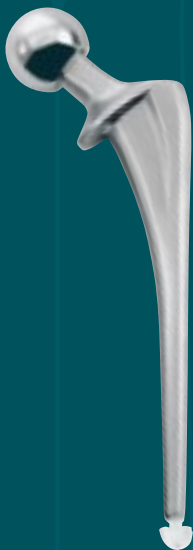
The Summit™ Tapered Hip System's comprehensive set of implants and instruments treat a wide range of patients with differing needs. The Summit system features premium cementless and cemented stems, as well as stems that are specifically designed to meet the challenges of today's healthcare environment.

All Summit stems utilize common instrumentation, so there is no need to learn a new technique to implant a different stem within the system.

The streamlined surgical technique for the Summit Basic Cemented and Press-Fit stems maximizes efficiency in the operating room, while still providing intraoperative flexibility.



SUMMIT BASIC
PRESS-FIT STEM



SUMMIT BASIC
CEMENTED STEM

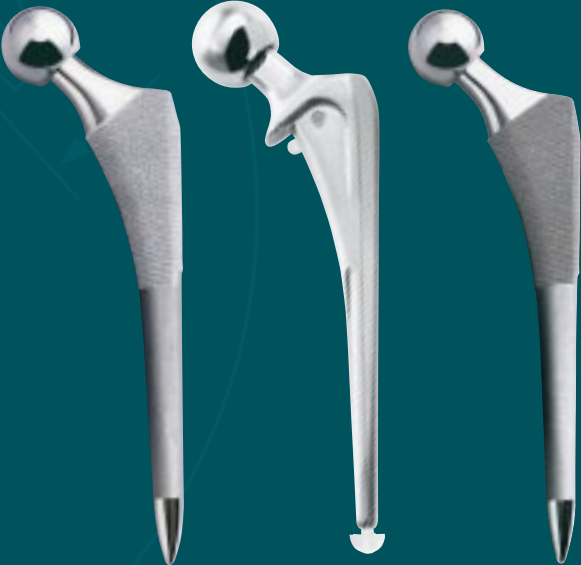


SUMMIT
BROACH

The Summit Basic cemented stem provides excellent results in cemented applications, offering a proximal cobra flange and distal centralization options.

The Summit Basic cemented stem is manufactured from high-strength, forged cobalt chrome alloy. It is available in seven sizes and features a smooth, cement-friendly surface finish. The Summit Basic press-fit stem is a true press-fit cementless stem, manufactured from titanium alloy. It is also available in seven sizes and features a rough, grit-blasted surface finish.

Both of these stems work together with common instruments, allowing you to choose the implant that is best for each patient.



SUMMIT
DUOFIX™ HA STEM

SUMMIT
CEMENTED STEM

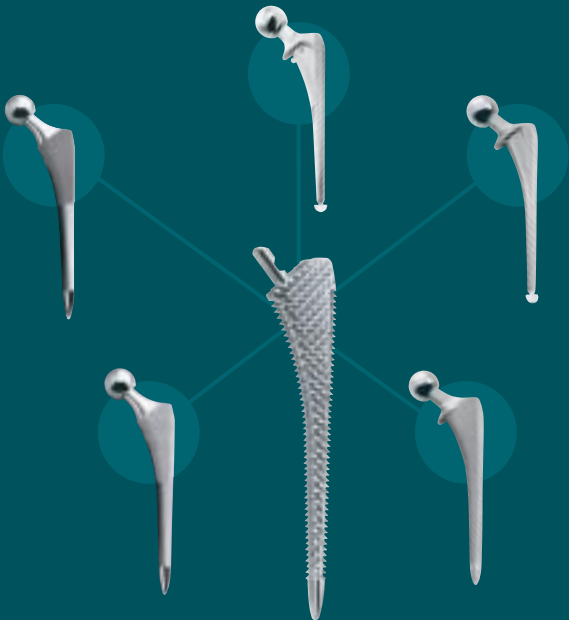
SUMMIT
POROCOAT® STEM

UNIFIED INSTRUMENTATION

One set of broaches for the entire Summit Tapered Hip System.

The Summit Basic Hip is part of the integrated Summit Tapered Hip System. This advanced systems approach provides the following advantages:

- The same instrumentation is used for all implants in the system, dramatically lowering the learning curve.
- Any implant within the Summit system may be used without altering your surgical technique.
- Patients with varying needs, such as bone types and fixation, may be treated with the same instrument set.



FEMORAL NECK OSTEOTOMY

- Perform the preliminary resection of the femoral neck using the neck resection guide to establish the resection level (Figure 1). The neck resection guide should be aligned with the long axis of the femur. It can be used to reference the tip of the greater trochanter or the lesser trochanter.

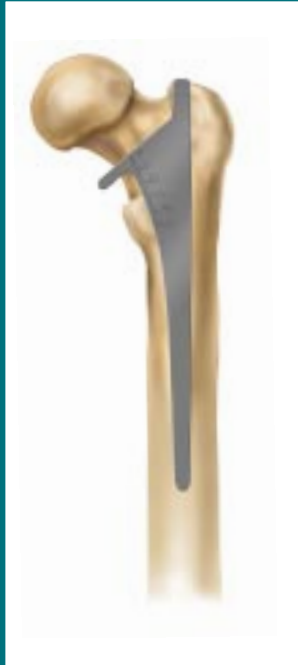


Figure 1

NECK RESECTION LEVEL

ACETABULAR PREPARATION

- Ream the acetabulum until healthy subchondral bone is reached and a hemispherical dome is achieved (Figure 2).
- Insert a trial acetabular cup into the acetabulum and assess bony contact and cup orientation (Figure 3).
- Alternatively, the appropriate acetabular cup implant may be implanted at this time with a trial liner.



Figure 2

ACETABULAR PREPARATION

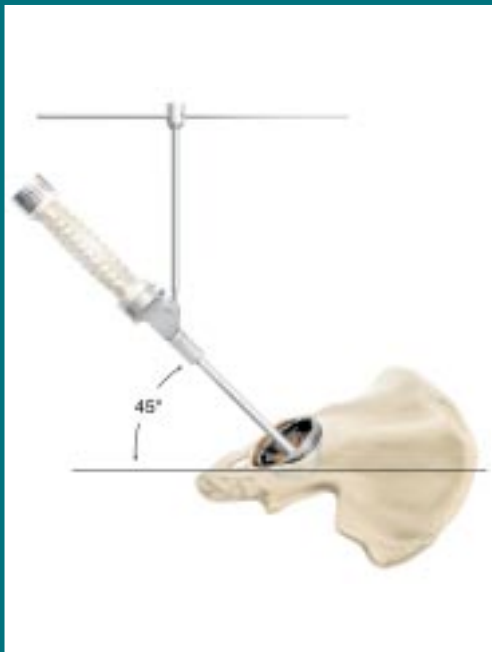


Figure 3

CUP TRIAL AND POSITION

ESTABLISH THE MEDULLARY CANAL

- Use the IM Initiator to create a pilot hole in the proximal femur. Place the IM initiator at the posterior margin of the neck resection, lateral near the piriformis fossa (Figure 4).



Figure 4

CANAL INITIATOR

- Enter the femoral canal using the box osteotome at the junction of the femoral neck and the greater trochanter. The box osteotome should be used to help orient the broaches for correct stem anteversion (Figure 5).



Figure 5

CANAL OPENING

ESTABLISH THE MEDULLARY CANAL *cont.*

- Fully insert the canal probe, a tapered reamer, to establish a direct pathway to the medullary canal. The canal probe should pass easily if proper alignment has been achieved (Figure 6a and 6b).



Figure 6a

CORRECT ALIGNMENT



Figure 6b

INCORRECT ALIGNMENT

The path established by the canal probe will dictate the route for the broaches and the optional tapered reamers. Take caution to ensure neutral alignment of the canal probe (Figure 6b).

FEMORAL BROACHING

- Broaching should begin two to three sizes smaller than the preoperatively templated size.
- Attach the broach to the broach handle in the orientation indicated by the icon etched on the side of the handle (Figure 7).
- Sequentially broach the femoral canal until the broach is seated. Countersink the final broach by 1 to 2 mm so that the upper margin is slightly below the osteotomized femoral neck.
- Direct the broach laterally as it advances to ensure proper alignment.
- Once the appropriately sized broach is seated, remove the broach handle.

| | | | | | | | |
|---------------------|---|---|---|---|---|---|---|
| Press-fit stem size | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Broach | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Cemented stem size | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

The final broach size indicates the correct implant size, press-fit or cemented. There is no need to undersize the cemented stem to create a cement mantle.



Figure 7

BROACH IMPACTION

Tapered reamers are available for femoral preparation. Please see your DePuy Orthopaedics, Inc. representative for details.

BROACH EXTRACTION

- Due to the self-locking nature of the tapered broach, occasionally it may be difficult to remove a broach from the femoral canal. Use the broach extractor to remove broaches that cannot be easily removed using the broach handle.



Figure 8a

- Insert the tip of the extractor into the slot on the lateral shoulder of the broach. Rotate the extractor 90 degrees and use a mallet to extract the broach (Figures 8a and 8b).



Figure 8b

BROACH EXTRACTION

BROACH EXTRACTION

CALCAR MILLING

- Select either the large or small calcar miller and attach it to the power reamer.
- Place the miller over the trunnion of the countersunk broach and mill the calcar to the broach face (Figure 9).

Make certain the miller is rotating before contacting the bone to prevent binding on the calcar.



Figure 9

CALCAR MILLER

TRIAL REDUCTION

- Place the trial neck onto the broach trunnion (Figure 10). The Summit Basic cemented and press-fit stems feature common neck geometry for all sizes, therefore only one trial neck is required. This is the only neck trial available in the Summit Quick Kit. If you are using the standard Summit instrumentation, select the size 0/1 high offset trial neck segment.
- Perform a trial reduction by placing an Articul/eze® trial head directly onto the trial neck segment.
- Perform the trial reduction using a +5.0 mm Articul/eze trial head, to allow for one size up or down without having to use a skirted femoral head. Articul/eze trial heads may be used for trial reduction with trial liners or with the final liner in place.



Figure 10

NECK TRIAL

Note: When using the complete Summit Tapered Hip System instrumentation, choose the 0/1 high trial neck for trial reduction.

STEM INSERTION

- The Summit Basic instrument set does not require you to change your surgical technique when using a cemented or a press-fit implant. The final broach size indicates the correct implant size, whether cemented or press-fit. For example, if the final broach is size 6, then the size 6 implant, either cemented or press-fit, should be utilized.
- Summit Basic cemented implants feature a 1.5 mm average cement mantle. Summit Basic press-fit implants feature a .25 mm press-fit value.

CEMENTED STEM INSERTION

- Prepare the femoral canal using advanced cement techniques, including thorough cleaning and drying of the femoral canal. A cement restrictor and a cement gun are recommended to ensure proper pressurization of the cement. Attach the appropriate distal Cementalizer™ centralizer to the Summit Basic cemented stem and insert it into the femoral canal (Figure 11).

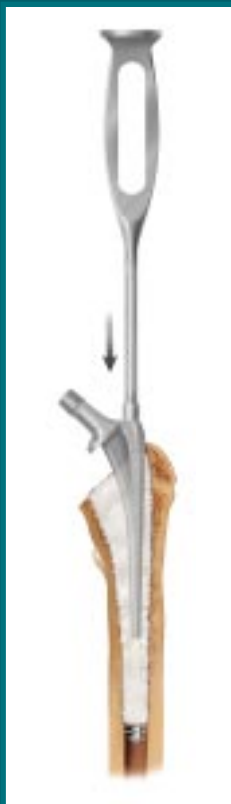


Figure 11

CEMENTED STEM
INSERTION

Recommended Distal Cementalizer Chart (mm)

| | | | | | | | |
|--------------------|-----|-----|------|------|------|------|------|
| Cemented stem size | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Cementalizer | 8.5 | 8.5 | 9.25 | 10.5 | 11.0 | 12.0 | 13.0 |

PRESS-FIT STEM INSERTION

- Insert the implant by hand, noting stem orientation and version. The implant should advance to within 1 in. of the collar.
- Insert the non-threaded stem inserter and advance the implant into position using light mallet blows (Figure 12).
- Final seating position has been achieved when the collar contacts the bone, or when the implant no longer advances with light mallet blows.



Figure 12

PRESS-FIT STEM INSERTION

The Summit Basic press-fit implant may achieve stability up to 5 mm before the collar contacts the bone. If the implant appears to be stable and the collar is more than 5 mm above the bone, remove the implant and ensure that the stem is not in a varus position.

FEMORAL HEAD SELECTION

- Perform the trial reduction using a +5.0 mm Articul/eze trial head, to allow for one size up or down without having to use a skirted femoral head.
- When the appropriate range of motion and stability have been achieved, note the size of the trial head so that the correct implant can be opened (Figure 13).



Figure 13

FEMORAL HEAD SELECTION

FINAL IMPLANTATION

- After trial reduction is complete, open and prepare the final implants.
- Remove all trial components.
- If you have not already done so, insert the appropriate acetabular cup and liner implants.
- Thoroughly clean and dry the neck taper of the Summit Basic stem prior to implanting a femoral head or unipolar sleeve implant.
- Impact the femoral head implant using the femoral head impactor.



Figure 14

FINAL IMPLANTATION:
PRESS-FIT STEM

ACETABULAR OPTIONS

The Summit Basic hip features the Articul/eze taper, and is compatible with a wide range of DePuy acetabular components, including the Pinnacle Acetabular Cup System, the Self-Centering™ Bipolar System and the Modular Cathcart Unipolar.



PINNACLE ACETABULAR
CUP SYSTEM

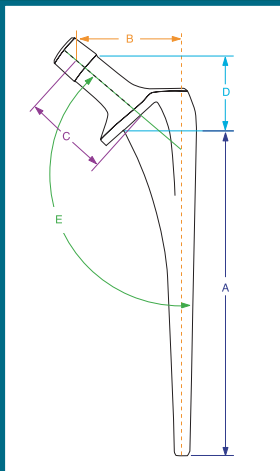


MODULAR
CATHCART
UNIPOLAR

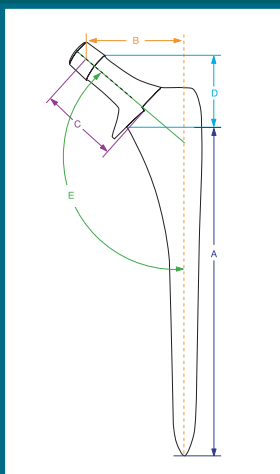


SELF-CENTERING
BIPOLAR

DIMENSIONS



CEMENTED DIMENSIONS



PRESS-FIT DIMENSIONS

| | A | B | C | D | E | |
|-----------|------------------|------------------|------------------|----------------------|------------|-------------|
| Stem Size | Stem Length (mm) | Base Offset (mm) | Neck Length (mm) | Leg Length Adj. (mm) | Neck Angle | Broach Size |

| Cemented | 2 | 96 | 42 | 35 | 27 | 130° | 2 |
|----------|---|-----|----|----|----|------|---|
| | 3 | 107 | 42 | 35 | 27 | 130° | 3 |
| | 4 | 114 | 42 | 35 | 27 | 130° | 4 |
| | 5 | 121 | 42 | 35 | 27 | 130° | 5 |
| | 6 | 128 | 42 | 35 | 27 | 130° | 6 |
| | 7 | 133 | 42 | 35 | 27 | 130° | 7 |
| | 8 | 140 | 42 | 35 | 27 | 130° | 8 |

| Press-Fit | 2 | 130 | 42 | 35 | 27 | 130° | 2 |
|-----------|---|-----|----|----|----|------|---|
| | 3 | 135 | 42 | 35 | 27 | 130° | 3 |
| | 4 | 140 | 42 | 35 | 27 | 130° | 4 |
| | 5 | 145 | 42 | 35 | 27 | 130° | 5 |
| | 6 | 150 | 42 | 35 | 27 | 130° | 6 |
| | 7 | 155 | 42 | 35 | 27 | 130° | 7 |
| | 8 | 160 | 42 | 35 | 27 | 130° | 8 |

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

Cemented Stem

| Cat. No. | Size |
|-------------|------|
| 1570-06-080 | 2 |
| 1570-06-090 | 3 |
| 1570-06-100 | 4 |
| 1570-06-110 | 5 |
| 1570-06-120 | 6 |
| 1570-06-135 | 7 |
| 1570-06-150 | 8 |

Press-fit Stem

| Cat. No. | Size |
|-------------|------|
| 1570-05-080 | 2 |
| 1570-05-090 | 3 |
| 1570-05-100 | 4 |
| 1570-05-110 | 5 |
| 1570-05-120 | 6 |
| 1570-05-135 | 7 |
| 1570-05-150 | 8 |

Distal Centralizers

| Cat. No. | Size (mm) |
|-------------|-----------|
| 1376-46-000 | 8.5 |
| 1376-47-000 | 9.25 |
| 1376-48-000 | 10.0 |
| 1376-38-000 | 10.5 |
| 1376-20-000 | 11.0 |
| 1376-21-000 | 12.0 |
| 1376-22-000 | 13.0 |
| 1376-36-000 | 14.0 |
| 1376-37-000 | 15.0 |
| 1376-26-000 | 16.0 |
| 1376-27-000 | 17.0 |
| 1376-29-000 | 18.0 |
| 1376-30-000 | 19.0 |

Cement Restrictors

| Cat. No. | Size |
|-------------|----------------------------------|
| 5460-10-000 | 1 |
| 5460-12-000 | 2 |
| 5460-14-000 | 3 |
| 5460-16-000 | 4 |
| 5460-18-000 | 5 |
| 5460-20-000 | 6 |
| 5460-22-000 | 7 |
| 5461-10-000 | Small SOLD IN MULTIPLES OF 10 |
| 5461-12-000 | Large SOLD IN MULTIPLES OF 10 |

Articul/eze Femoral Heads – 28 mm

| Cat. No. | Size |
|-------------|-------|
| 1365-11-000 | +1.5 |
| 1365-12-000 | +5.0 |
| 1365-13-000 | +8.5 |
| 1365-14-000 | +12.0 |
| 1365-15-000 | +15.5 |

| Instruments | |
|--------------------|---------------------------------------|
| Cat. No. | Description |
| 2001-42-000 | T-Handle |
| 2001-80-501 | IM Initiator |
| 2570-00-000 | Summit Universal Broach Handle |
| 2570-04-100 | Summit Calcar Planer–Small |
| 2570-04-200 | Summit Calcar Planer–Large |
| 2001-65-000 | Femoral Head Impactor |
| 2570-13-050 | Summit Basic Neck Trial 0/1 High |
| 2570-10-500 | Summit Basic Quick Kit Instrument Set |
| 2570-00-002 | Summit Broach Extractor |
| 2570-05-100 | Summit Standard Implant Inserter |
| 2570-01-600 | Summit Universal Neck Resection Guide |
| 2354-10-000 | Muller Awl Reamer w/Hudson End |
| 2002-31-000 | Anteversio Osteotome, SM |

| Articul/eze Trial Head | |
|-------------------------------|-------------|
| Cat. No. | Size |
| 2530-81-000 | 28 mm +1.5 |
| 2530-82-000 | 28 mm +5 |
| 2530-83-000 | 28 mm +8.5 |
| 2530-84-000 | 28 mm +12 |
| 2530-85-000 | 28 mm +15.5 |

| Summit Broach | |
|----------------------|-------------|
| Cat. No. | Size |
| 2570-00-070 | 1 |
| 2570-00-080 | 2 |
| 2570-00-090 | 3 |
| 2570-00-100 | 4 |
| 2570-00-110 | 5 |
| 2570-00-120 | 6 |
| 2570-00-135 | 7 |
| 2570-00-150 | 8 |

| Optional Summit Tapered Reamer | |
|---------------------------------------|-------------|
| Cat. No. | Size |
| 2570-02-000 | 0/1 |
| 2570-02-100 | 2/3 |
| 2570-02-200 | 4/5 |
| 2570-02-300 | 6/7 |
| 2570-02-400 | 8/9 |