DESIGN RATIONALE

CEMENTED
FEMORAL STEM

SUMMIT™

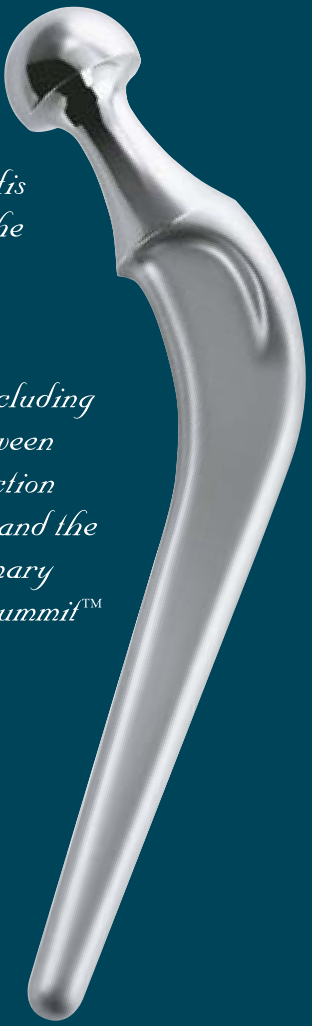
CEMENTED HIP SYSTEM

- PRECISION TECHNIQUE
- CEMENT MANTLE INTEGRITY
- BIOMECHANICAL EXCELLENCE

DePuy
a Johnson & Johnson company

Sir John Charnley began his pursuit of what would become known as low-friction arthroplasty over 40 years ago. His unrelenting quest resulted in one of the greatest surgical advances of the twentieth century, successful total hip arthroplasty.

Charnley's theories on hip arthroplasty, including the management of the delicate balance between reproducible surgical technique, the interaction between bone cement and implant geometry and the restoration of biomechanics remain the primary principles of hip reconstruction today. The Summit™ cemented implant is built upon the sound foundation of Sir John Charnley's theories and advanced through the application of modern engineering technology.



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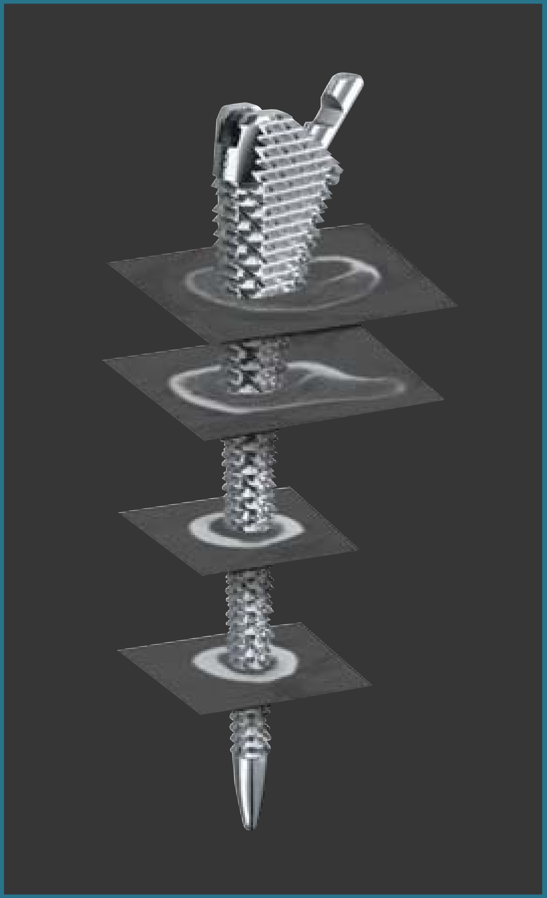
PRECISION TECHNIQUE

Optimum Clinical Results

The clinical success of cemented hip arthroplasty revolves around a sound surgical technique. The combination of the broach geometry, cement mantle and implant design must work in concert to achieve excellent clinical results.



▲ Input from the DePuy Global CT database, combined with extensive radiographic analysis, was used to create the broach geometry that directly correlates to the geometry of the femur. The result is a broach developed to meet the needs of the majority of patients.[1]

▲ The shape of the tapered broach envelope allows the femoral cavity to accept the combined construct of the stem and cement mantle. The resulting cement mantle meets the clinically established thickness criteria for the critical medial proximal and distal regions of the stem.[2]

The patented centralization system aids in balancing the cement mantle surrounding the femoral component. This balanced cement mantle aids in equalizing stress transmission from the femoral component through the cement mantle to the bone.[3]

The precise broach configuration and patented centralization system were developed to work in tandem with advanced cementing techniques. These techniques include a distal canal plug, pulsatile lavage canal cleansing and drying, retrograde injection of vacuum mixed SmartSet® MV Bone Cement, and canal pressurization to aid in long-term favorable clinical results.

COMPOSITE ROM

The Summit cemented hip system biomechanical architecture results in a composite range of motion that greatly exceeds the range required for the normal daily activities of most hip replacement patients. This expanded composite range of motion provides the surgeon more freedom in the positioning of implants for each individual patient compared to traditional hip stem designs.[9]

The neck geometry has been optimized for increased range of motion. The anterior-posterior neck flats provide increased range of motion in flexion and extension.

The clinically proven Articul/eze 12/14 taper has been shortened so that it is fully captured by all non-skirted Articul/eze heads, thus eliminating the creation of a false skirt due to trunnion protrusion.

The polished neck is designed to reduce wear debris generation secondary to prosthetic impingement.[1, 9]

HEAD DIAMETERS 22-36 mm

Five femoral head diameters allow manipulation of the head-to-neck and head-to-cup ratios enabling management of range of motion and stability based on individual patient anatomy.

BIOMECHANICAL EXCELLENCE

Dual Offsets for High-Function Biomechanical Restoration

Biomechanical restoration is critical to the functional outcome of hip arthroplasty and improves the longevity of the procedure. Data from radiographic and prototype analysis, combined with clinical experience from Summit cementless stems, resulted in a biomechanical architecture unmatched in restoring leg length, offset and range of motion for exceptionally high function.[7,8]

Progressive offset configuration enables optimal biomechanical restoration without increasing leg length.[1]

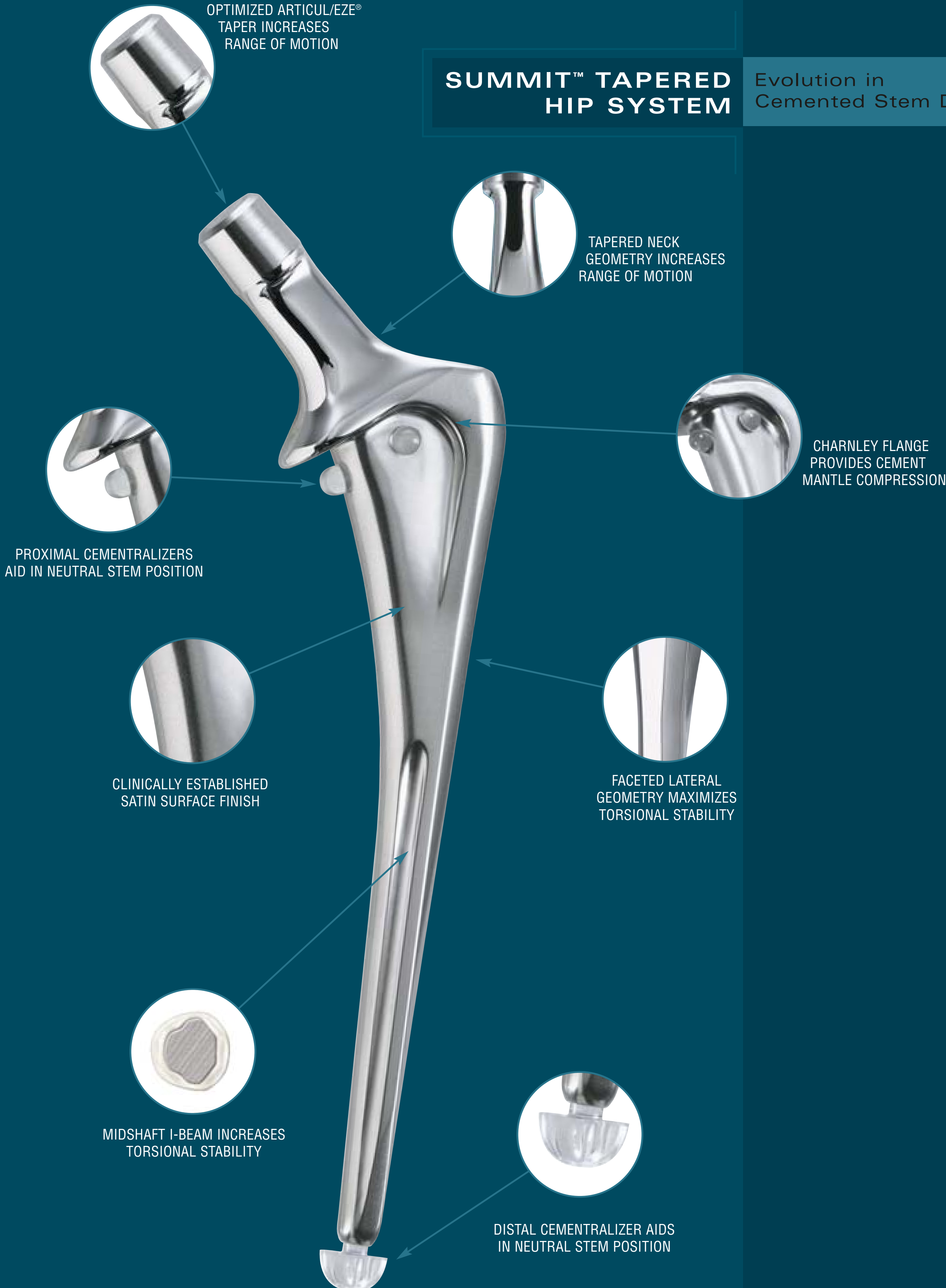
By increasing joint offset the surgeon can lower the joint reactive forces and potentially minimize loosening, wear debris and dislocation.[2]

Biomechanical restoration is accomplished through dual offset options for each stem. The definitive offset can be determined intraoperatively with the use of trial neck segments.

- The constant 130-degree neck shaft angle is achieved in the high offset stems by shifting the neck geometry of the femoral component medially by a proportional amount.
- A 130-degree neck shaft angle, in both standard and high offset implants, enables femoral offset restoration and soft tissue tensioning without affecting leg length.
- The high offset option directly lateralizes the stem by 6-8 mm, depending on stem size.

SUMMIT™ TAPERED HIP SYSTEM

Evolution in Cemented Stem Design



CEMENT MANTLE INTEGRITY

The Composite Beam

Cement has historically been the weak link in cemented THA. The Summit cemented design team took surgical thinking a step further by looking at the cement mantle and the harmony created by the composite of stem, cement and bone. Because bone cement is three times stronger in compression than in shear or tension, the cement mantle longevity is directly related to the ability of the composite to redirect both axial and torsional shear forces into compression during high levels of activity.[4]

The satin surface finish of the Summit cemented hip is based on the surface finish established by Charnley.[5]

Cemented stems are under torsional loads during high levels of patient activity such as stair climbing or rising from a chair. The Summit stem has been designed to load the cement mantle in compression while minimizing shear. The features of the Summit cemented stem that create compression to the surrounding cement mantle are:

- The vertical element of the Charnley flange
- The broad proximal A/P geometry
- The lateral and A/P faceted geometry
- Distal I-beam

Axial loads encountered during the gait cycle are converted into compression through the innovative stem geometry. The result is compressive loading of the cement mantle and surrounding femur thus creating a positive bone modeling response. Axial loads are converted into compression by use of the following features:

- The horizontal element of the Charnley flange
- The lateral proximal taper
- The distal A/P facets
- Medial to lateral proximal taper

The stem's cross-sectional geometry has been designed to maximize compression to the surrounding cement mantle during torsional loading encountered during high levels of activity.[6]

OPTIMAL CEMENT MANTLE INTEGRITY

SURGICAL TECHNIQUE OVERVIEW

For a more detailed surgical technique, see the Summit Tapered Hip System Cemented Surgical Technique (Cat. No. 0612-28-050).

IMPORTANT

This Essential Product Information summary 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 indicated 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 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.

CONTRAINDICATIONS

THA is 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.

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

Step One

CANAL INITIATION AND DEFINITION

Step Two

FEMORAL BROACHING AND CALCAR PLANING

Step Three

OFFSET SELECTION

Step Four

CANAL PREPARATION

Step Five

ADVANCED CEMENT TECHNIQUE

Step Six

IMPLANTATION

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The Summit Cemented Femoral Stem is intended for cemented use only.

For more information about the Summit Tapered Hip System, visit our web site at **www.summithip.com.**

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