C-Stem™ AMT

ARTICUL/EZE® MINI TAPER

DePuy
a Johnson & Johnson company

DESIGN RATIONALE

- POSITIVE BONE REMODELING
- ENHANCED BIOMECHANICS
- CEMENT MANTLE INTEGRITY

ORIGINAL C-STEM™— AN EVOLUTION

X-ray post-op

4 years post-op

Published Results

The original C-Stem™ has been in clincal use for over ten years. The following clinical results were published in a seven-year follow-up paper by Professor Michael Wroblewski at Wrightington Hospital. The results reveal why the new C-Stem™ AMT's intramedullary geometry has remained the same as the original C-Stem.

Primary C-Stem

- At a mean follow-up of 41 months (range: one to seven years), there have been no revisions for aseptic stem loosening[1]
- No stem was considered at risk for loosening[1]
- 20% of cases revealed a subjective radiologic improvement of the bone-cement interface[1]

C-STEM™ AMT—AN EVOLUTION

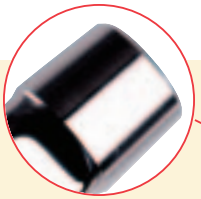
C-Stem AMT Pre-op

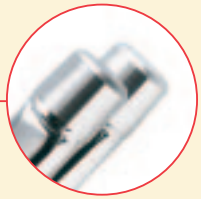
C-Stem AMT Immediate Post-op

C-Stem AMT maintains the intramedullary geometry of the original C-Stem and improves upon the extramedullary geometry with enhanced biomechanics. These enhanced biomechanics provide the following advantages:

- Reduced risk of impingement
- Increased range of motion
- Increased offset options
- Increased head size options including 36 mm heads

Optimized Articul/eze® mini taper *increases range of motion through the elimination of a false skirt*





C-Stem AMT is available in both ***standard and high offset*** *to best restore patient anatomy*

Highly-polished surface finish *provides a cement-friendly surface that works with the bone cement*

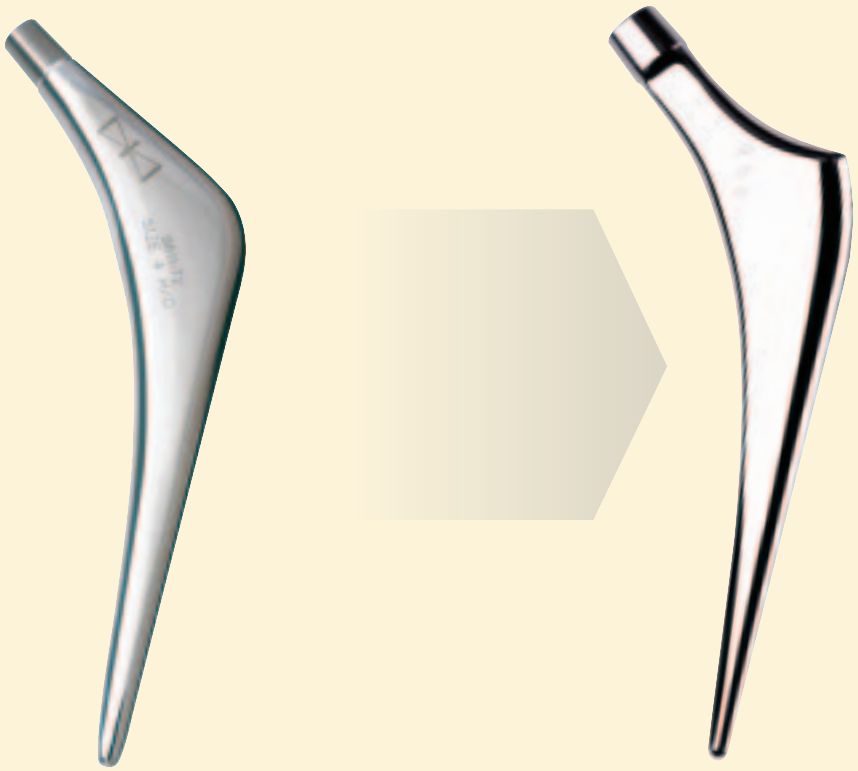
Triple taper stem geometry *provides improved load transfer that has been clinically shown to produce positive bone remodeling, controlled subsidence and a reduction in cement mantle stresses*[1]

Tapered neck geometry *increases range of motion*

Void centralizer *aids stem centralization and minimizes cement mantle strain at the distal tip of the stem*

Cemented THA continues to evolve and improve as time and experience reveal which design features improve results. The original C-Stem hip system established a tapered slip stem that not only worked within the bone cement mantle, but was also the first stem to demonstrate positive bone remodeling through anatomical loading of the femur.[1]

The C-Stem AMT builds upon the clinical success of the original C-Stem system from the neck down and improves upon it from the neck up with enhanced biomechanics. These design enhancements provide more options to accurately address the anatomy of each patient.



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Maximizing Survivorship: **Positive Bone Remodeling**

Cemented hip stems that encourage growth of a strong supportive bone around the implant will aid in implant survival.[2]

In a natural and complete femur, load is accepted through the femoral head and transmitted down the bone through the cortices. Resecting the femoral neck and implanting a dual tapered cemented stem changes that pattern.

- Load is passed along the centerline of the stem and released through the distal tip
- Proximal cortices are bypassed and "unloaded"
- The non-stressed bone is resorbed
- If the stem doesn't transfer the load, negative bone remodeling is inevitable

Load transfer patterns for the natural femur

*Load transfer pattern from conventional **dual taper** highly-polished cemented stems*

The profile of the C-Stem AMT anatomically transfers load to the proximal, medial femur, causing positive bone remodeling. This unique load transfer:

- Reduces stress shielding
- Increases bone density by virtue of loading the proximal bone

The increased bone density provides for more durable support of the cement mantle and prosthesis.[1,3]

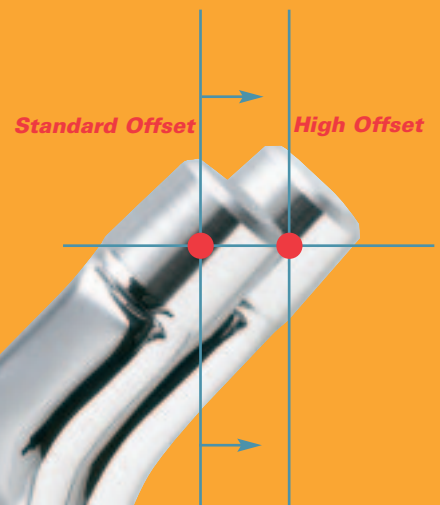
*Load transfer patterns around the **triple taper** C-Stem AMT*

Deepened medial profile loads proximal femur

- Greater depth in the medial curve brings the loading area closer to the medial calcar
- Load transfers directly to supportive bone in the proximal femur and reduces progressively as the smooth curve slims towards the distal tip
- Strong cortical bone is loaded positively, preventing negative bone remodeling and minimizing distal load transfer

Optimizing Function: **Enhanced Biomechanics**

- Progressive offset configuration enables optimal biomechanical restoration without increasing leg length.
- Increasing the joint offset can lower the joint reactive forces. This can result in less loosening, wear debris and dislocation.
- Biomechanical restoration is achieved through dual offset options for each stem.
- Trial neck segments can determine the definitive offset intra-operatively.



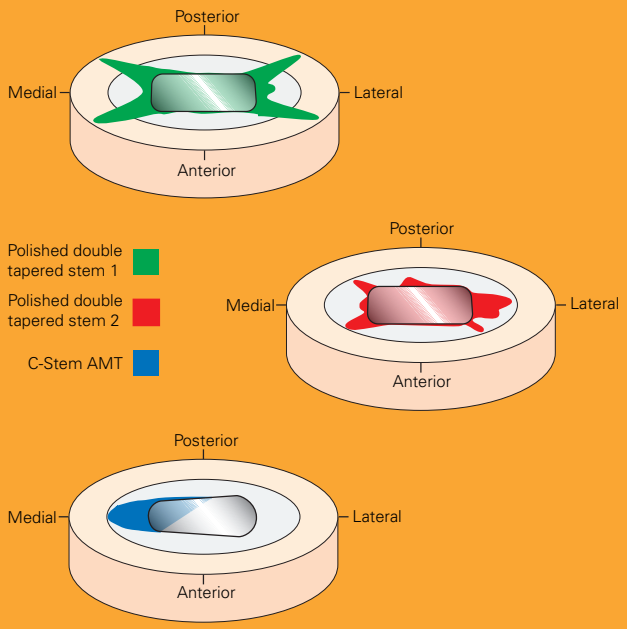
Using the same enhanced biomechanics as the Summit™ Platform, the C-Stem AMT provides surgeons more ways to restore function.

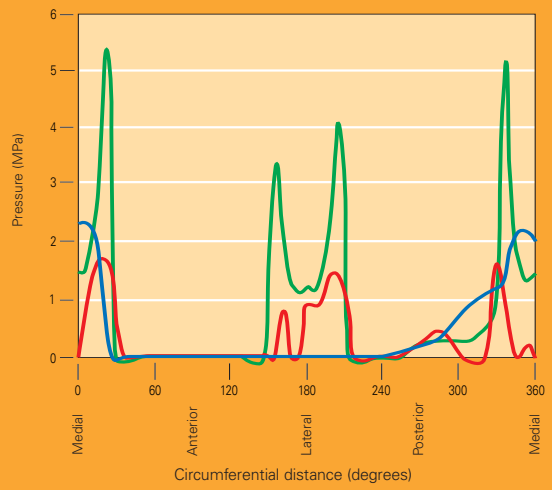
- Enables proper leg length restoration, increased range of motion and restored offset
- Reduces risk of impingement
- Provides more offset options to restore stability and reduce dislocation

- The high offset option directly lateralizes the stem by 6 to 8 mm, depending on stem size.
- The clinically proven Articul/eze 12/14 taper has been shortened and is fully captured by all non-skirted Articul/eze heads. As a result, there is no false skirt due to trunnion protrusion.[4]
- The polished neck generates less wear debris secondary to prosthetic impingement.[5,6]
- 22.225, 26, 28, 32 and 36 mm head diameter options in metal and 28, 32 and 36 mm in Biolox® Delta™ ceramic increase treatment options.

Maximizing Survivorship: Cement Mantle Integrity

Circumferential Stress Distribution



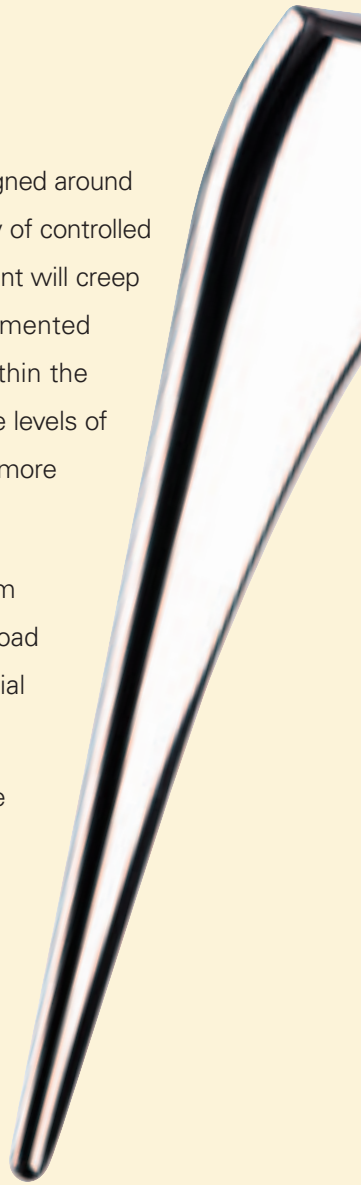


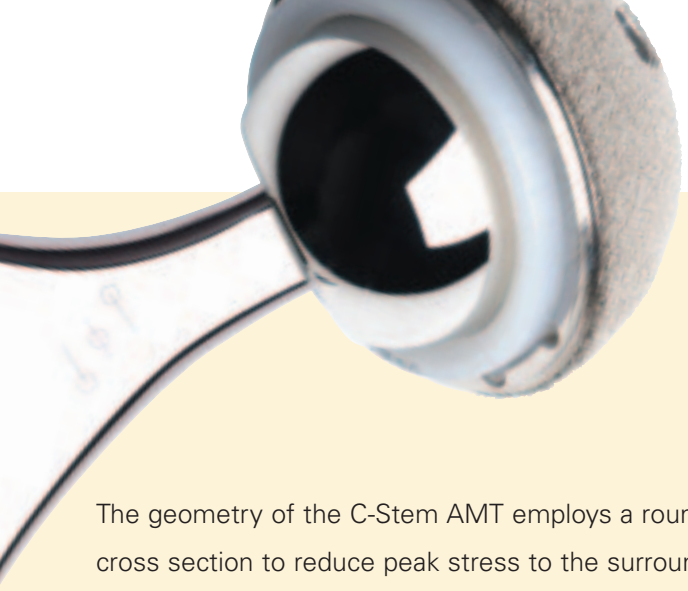
The polished double tapered stems cause stress concentration in the cement along the edges of the stem. Cracks may be initiated at those edges, as shown in histological studies. The C-Stem AMT cross section is smoother, thus reducing the risk of cement mantle fractures.[1]

The C-Stem AMT is designed around the taper slip philosophy of controlled subsidence. Bone cement will creep slightly; therefore, a cemented stem that is designed to work within the bone cement to achieve acceptable levels of controlled subsidence will aid in a more successful total hip arthroplasty.[3]

In its proximal section, the C-Stem AMT has a third taper from its broad lateral surface to the narrow medial face. This design:

- Transfers more compressive load to the proximal medial femur
- Aids in more reliable postoperative stability
- Loads the cement compressively

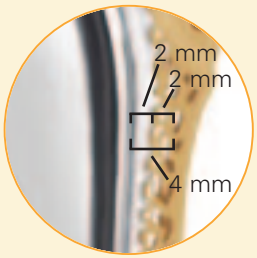




The geometry of the C-Stem AMT employs a rounded cross section to reduce peak stress to the surrounding cement mantle. The chart to the left compares the C-Stem AMT intraosseous geometry to other available polished stems.

C-Stem AMT is a cement-friendly stem. It features:

- Highly-polished surface
- No early cement mantle fracturing during the natural process of cement creep[1]
- The triple taper engages the stem/cement interface for secure fixation and anatomical loading of the femur
- A 2 to 4 mm cement mantle is created by virtue of the broach envelope that is created and the level of interdigitation that is achieved during pressurization



In cemented hip procedures, two types of implants are utilized: the stem and the bone cement. Modern cementing surgical techniques and the use of clinically proven cements such as SmartSet® MV are recommended.

Bone cement creep is inevitable. But a cemented stem that is designed to work with the bone cement can improve results.

- Excessive cement creep could lead to fracturing of the femur
- If subsidence continues the mantle will fracture[3]
- A double tapered stem may subside more than 1 cm[6]
- The triple tapered C-Stem AMT is designed to reduce subsidence and the resulting risk of cement mantle fracture

The Total Procedure

Stem selection involves more than selecting a reliable femoral stem with a simplified surgical technique and instrumentation. Stem choice also determines which alternative bearings and acetabular cups will be used to best restore a high degree of function to your patients.

The C-Stem AMT is compatible with a range of alternative bearing options along with the Pinnacle® Cup portfolio. This comprehensive portfolio includes:

- Metal-on-metal
- Metal-on-cross-linked poly
- Ceramic-on-cross-linked poly
- A variety of head sizes that work with C-Stem AMT's biomechanics aid in restoring offset, increasing ROM, decreasing wear and decreasing risk of impingement

Platform Of Options

The C-Stem AMT is part of a platform of stems that use Summit instrumentation.

The Summit Platform:

- Allows surgeons to choose a stem intra-operatively on a case-by-case basis
- Offers precision that reduces variation in surgical technique from stem to stem
- Streamlined system that uses minimal instrumentation

The C-Stem AMT utilizes the Summit instrumentation; however, it has separate C-Stem AMT broaches that create a customized broach envelope for the geometry of the stem. Combining Summit instrumentation with the C-Stem AMT broaches reduces inventory and simplifies the surgical technique.

ESSENTIAL PRODUCT INFORMATION

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.

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 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, 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.

1. Wroblewski MB, P. Siney and P. Fleming, "Triple taper polished stem in total hip arthroplasty: rationale for the design, surgical technique and 7 years of clinical experience." *Journal of Arthroplasty* 2001;16(8 Supp. 1):37-41.
2. Spitzer A. "The Cemented Femoral Stem: Selecting the Ideal Patient." *Orthopaedics Supplement*, August 2005: s841-s848.
3. Spitzer A. "The Triple-Tapered Stem." *Orthopedic Technology Review*, 2(4), March/April 2002:26-27, 30.
4. Fisher D, M. Watts, "Summit™ Cementless Stem Results," white paper *Orthopaedics Indianapolis.* November, 2004.
5. Bourne R, et al. "Cementless Total Hip Replacement Stems: Anatomic, Cylindrical or Tapered?" A Scientific Exhibit at the 2000 AAOS Meeting.
6. Data on file at DePuy Orthopaedics, Inc.
7. Ek ET and Choong PFM. "Comparison Between Triple-Tapered and Double-Tapered Cemented Femoral Stems in Total Hip Arthroplasty." *The Journal of Arthroplasty*. 20(1), 2005: 94-100.

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

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