Arcos™ Modular Femoral Revision System

Design Rationale
Introduction

Revisions involving the femur continue to be one of the most difficult operations faced by surgeons today. While the published clinical results for revision total hip arthroplasty have shown favorable results, leg length discrepancies and instability are still a concern. Leg length discrepancies and instability can be addressed by implant design. One-piece and modular femoral stems have been used for the past twenty years to address femoral revision cases. However, modular implants provide surgeons the flexibility to adjust leg length and apply the necessary anteversion or retroversion to address stability. In addition, both metaphyseal and diaphyseal defects may be addressed independently.

Biomet was at the forefront of implant design for revision hip arthroplasty with the introduction of the Modular Calcar System in 1992. This revision system was one of the first modular systems to address complex femoral reconstruction with a porous coated, modular calcar-replacing proximal body and modular distal stem segments. Biomet was also the first company to address taper strength at the modular junction with the introduction of Roller Hardening Technology in 2000. The Arcos™ Modular Femoral Revision System builds upon the clinical success of this platform, design philosophies and technology while expanding the options available to address varying needs of patients and surgeons (Figure 1).

Surgeon Developers

The design team for the Arcos™ platform includes surgeons with vast experience in addressing complex revision hip situations. Each brings a different philosophy to the design to ensure that various implant and surgical technique preferences were incorporated into the platform.

The design team includes the following:

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System Overview

The Arcos™ Modular Femoral Revision System is a comprehensive, press-fit revision femoral component consisting of three proximal and five distal stem bodies with multiple designs for reconstruction of various defects associated with femoral revision surgery. Auxiliary implants are available to aid in fixation and include trochanter reattachment claws, bolts and interlocking screws. This system is for use with Type I taper modular heads and compatible acetabular shells/liners and screws. Components are available in a variety of designs and sizes to offer 117 proximal/distal combinations for various femoral defects.
The Arcos™ Modular Femoral Revision System is intended for the following indications:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
5. Revision of previously failed total hip arthroplasty

Relative contraindications include:

1. Uncooperative patient or patient with neurologic disorders who is incapable of following directions
2. Osteoporosis
3. Metabolic disorders which may impair bone formation
4. Osteomalacia
5. Distant foci of infections which may spread to the implant site
6. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
7. Vascular insufficiency, muscular atrophy, or neuromuscular disease

Absolute contraindications include infection, sepsis, and osteomyelitis.

Surgical Technique and Instrumentation

The Arcos™ instrumentation is simple and intuitive. Common proximal implant and instrument geometries (Figure 2) allow for intraoperative revision efficiency, reducing the number of instruments required to a number comparable to a primary hip surgery. In addition, the platform design provides the flexibility to use any implant combination with the surgical technique that is required to address the needs of the patient. This platform allows the implant to be assembled in any of the following ways:

- Back table/sterile field
- Preparation of the proximal femur after the distal stem is implanted (ream-over)
- Locking of the modular taper once the proximal and distal segments are inserted into the femur

Figure 2: Common Implant and Instrument G

Detailed System Description

In femoral revisions, it is necessary to address deficiencies of the metaphysis and the diaphysis independently. The use of a modular system can be a valuable tool when addressing proximal to distal mismatch. The Arcos™ Modular Femoral Revision System offers implant options to address deficiencies in both regions of the femur to accommodate the specific needs of the patient and the surgical procedure and implant preference of the surgeon.
Proximal Body Design

The Arcos™ system includes broached, calcar replacing and cone proximal body options to meet various patient needs, along with the surgeons’ preferred technique and femoral reconstruction philosophy. All proximal body options are available in standard and high offsets (Figure 3), with a reduced proximal profile (RPP) option to address a wider range of femoral revision requirements. In addition, all proximal bodies are coated with Biomet’s clinically proven PPS® (Porous Plasma Spray) coating to allow for initial scratch-fit stability and biologic fixation.1–8

To simplify implant nomenclature the proximal body size is labeled A,B,C,D,E,F or G. The smallest size (A) has a distal diameter of 18.5mm over the PPS® coating. The distal diameter of each body increases 2mm (1mm per side) per increased size increment (e.g., size B distal diameter is 20.5mm).

Broached Proximal Body

Vertical body height options: 60mm
Size options: A–F

According to the Mallory classification of femoral defects, Type I and II femoral defects involve severe loss of cancellous bone, minimal damage to the calcar and intact diaphyseal cortex (Figure 5).9 The broached proximal body (Figure 6) design addresses these defect types. This proximal body is an anatomic fit and fill geometry designed to provide initial stability and bone contact.

Figure 3: All proximal body options are available in standard and high offsets.

Figure 4: The distal diameter of each proximal body increases 2mm (1mm per side) per increased size increment.

Figure 5: The broached proximal body is designed for Type I and II femoral defects.

Figure 6: The broached proximal body is an anatomic fit and fill geometry designed to provide initial stability and bone contact.
Calcar Proximal Body

Vertical body height options: 50 and 60mm
Size options: 50mm: A  60mm: A–F
The calcar replacing proximal body is designed for cases that involve deficiencies in the medial calcar where proximal femoral support is desired. Type IIIa, IIIb, and IIIc femoral defects are defined as violations of the proximal femur above, into and below the lesser trochanter, respectively (Figure 7). To address these various defect types, the calcar replacing body offers three resection level options: 0, +10 and +20 (Figure 8).

Cone Proximal Body

Vertical body height options: 50, 60, 70 and 80mm
Size options: 50mm: A  60–80mm: A–G
If the proximal femur does not require proximal femoral loading or if the proximal femur is too small to accommodate a fit and fill style implant, cone bodies can be used (Figure 9). The Arcos™ cone body offers a three degree tapered body and four different vertical height options (Figure 10). The implant design and vertical height options allow for the preparation of the proximal femur after the distal stem is implanted to achieve the desired vertical offset and version adjustment (Figure 11).

Figure 7: The calcar replacing proximal body is designed for Type IIIa, IIIb and IIIc femoral defects.

Figure 8: The calcar replacing body offers three resection level options: 0, +10 and +20.

Figure 9: When the proximal femur is too small to accommodate a fit and fill style implant (broached body), the cone body option can be used.

Figure 10: The cone proximal body has a three degree tapered body and four different vertical height options.

Figure 11: The cone proximal body design allows for the preparation of the proximal femur after the distal stem is implanted to achieve the desired vertical offset and version adjustment.
Auxiliary Implant Designs

One of the unique aspects of modular revision implants offered by Biomet has been the ability to use a bolt and claw auxiliary implant to reattach the trochanteric fragment directly to the modular proximal body. The first generation of implants required the bolt to be captured medially. The Arcos™ system allows for a lateral only attachment of the bolt to the implant (Figure 12). This new design reduces the risk of bolt loosening and provides accurate measurement. By reattaching the fragment in this method, the soft tissues and bony fragment are stabilized, providing an added level of joint stability.

![Figure 12: The Arcos™ system allows for a lateral only attachment of the bolt to the implant.](image)

The cobalt chrome (CoCr) claw is offered in 100mm lengths with two options; a full profile for larger trochanters and a reduced profile for smaller trochanters (Figure 13). These CoCr claws also have the option to utilize a cable attachment for additional stability of the implant and bone fragment.

![Figure 13: The cobalt chrome (CoCr) claw is offered in 100mm lengths in full and reduced profile options.](image)

Distal Stem Design

The Arcos™ system offers five distal geometry options to address differing quality of diaphyseal bone, desired fixation and surgical technique. This system offers both clinically proven PPS® coated and grit blasted distal stem options. Biomet has a long clinical heritage of coating its implants with titanium PPS® coating, which helps achieve long-term fixation and implant stability. Biomet has also offered splined stems blasted with a rough blast media to provide additional fixation and rotational stability. Both splined and PPS® coated stems have been shown to withstand the rotational forces seen in the femur during daily activities.10

PPS® Coated Distal Stems

Arcos™ PPS® coated distal stem options provide for fixation throughout the diaphysis. The Arcos™ system offers a slotted, bullet-tip and interlocking PPS® coated stem design. All PPS® coated stem designs utilize the same instrumentation, allowing for intraoperative flexibility. These stem options are available in multiple lengths to address differing severities of diaphyseal defect. All PPS® coated distal stem diameter options are sized to include the PPS® coating as indicated on the implant packaging. For example, a 12mm stem, as labeled, measures 12mm over PPS® coating.
Slotted Distal Stem
Stem design and length options: bowed stem available in 150, 200 and 250mm lengths
The bowed, coronal slotted distal stem design matches the natural anatomy of the femur to reduce the risk of anterior impingement, allowing for extended distal fixation and a gradual separation from the cortex designed to reduce thigh pain.

Figure 14: The slotted distal stem is a bowed stem design with a coronal slot.

Bullet-tip Distal Stem
Stem design and length options: straight stem available in 115mm; bowed stem available in 150, 200 and 250mm lengths
The bullet-tip distal stem design is fully PPS® coated with a polished bullet-shaped distal tip that provides a gradual separation from the cortex to reduce distal stresses.

Figure 15: The bullet-tip distal stem is fully PPS® coated with a polished bullet-shaped distal tip.
Interlocking Distal Stem

Stem design and length options: bowed stem available in 200, 250 and 300mm lengths
The interlocking and bullet-tip distal stems are similar. However, the interlocking distal stem option incorporates interlocking screw holes that are inserted percutaneously for initial rotational stability in complex femoral reconstruction.

Note: Distal stems and interlocking screws pending 510(k), not available for sale in the United States.

STS™ (Splined Tapered Stem) Distal Stem

Stem design and length options: straight stem available in 150 and 190mm lengths
When an intact diaphysis is present, a non-coated, splined, tapered stem provides a viable option for fixation, particularly when the defect is superior to the femoral bow. The Arcos™ STS™ distal stems are splined to maximize rotational stability and blasted with a rough 30 grit blast media to provide a biologic fixation surface. The three-degree taper transfers load from the proximal to the distal portion of the femur, thus reducing stress shielding. In addition, the 190mm stem design incorporates an anterior relief to reduce the risk of anterior impingement. The diameter on the splined distal stem option is 1mm larger than indicated on the implant packaging to allow for press-fit beyond thereamed diameter.

Figure 16: The interlocking distal stem is fully PPS® coated with a polished bullet-shaped distal tip and interlocking screw holes.

Figure 17: The STS™ distal stem is splined with a three-degree taper and 30 grit blast media.
ETO (Extended Trochanteric Osteotomy)  
Distal Stem

Stem design and length options: kinked stem available in 250mm length

Extended trochanteric osteotomy provides surgeons with a valuable tool in the revision of a well-fixed cementless stem and/or for the removal of cement in unsuccessful cemented applications. In these cases, it is difficult to utilize a splined stem and often a fully porous coated stem is used. The femur below the osteotomy is often able to support a splined stem, but when replacing the trochanteric fragment there is need for biologic fixation. To address this common need, the Arcos™ system offers a stem specifically designed for these surgical situations. The ETO stem provides dual mode fixation for stability in both the intact diaphysis and for repair of the trochanteric fragment.

The Arcos™ ETO distal stem is the first modular stem in the industry to combine two forms of fixation; PPS® coating for biologic fixation and grit blasted splines that allow for bone on-growth. These are combined on one distal stem option to provide dual mode fixation in complex femoral reconstruction when extended trochanteric osteotomy is necessary.

Roller Hardened Taper Junction

The use of a modular junction is a requirement for any system that allows for modularity. Although modular taper junctions have been in use since 1992, the issue of a taper junction fracture is always a concern. To reduce the risk of fracture, there are different methods for strengthening the taper junction. Biomet is the only manufacturer that uses a patented roller hardening manufacturing process for the modular taper junction. Roller hardening is a specialized process used to compress or “work harden” the taper region of the distal stem. This process increases the hardness of the titanium alloy metal at the interface of the taper junction, thus making the construct more resistant to fretting. Greater resistance to fretting translates into significantly greater fatigue strength of the modular distal stem. This manufacturing technology reduces the risk of taper fractures in comparison to machined-only tapers.

In addition to the use of roller hardened tapers, it is also imperative to protect the taper junction in cases where the proximal femur is deficient. The use of medial or lateral strut grafts to protect the modular taper junction is critical in these types of situations.
Proven Fixation – PPS® Porous Plasma Spray Coating

Biomet was the first orthopedic company to introduce a plasma-sprayed prosthesis with the release of the PPS® coated Taperloc® hip stem in 1982. The Arcos™ Modular Femoral Revision System features this same PPS® coating, a proprietary process that is instrumental to Biomet’s clinical success. The PPS® plasma spray application is unique in that only the titanium powder used to create the coating is heated, while the implant’s substrate is retained at near ambient temperatures (Figure 20). This unique process enables the implant to maintain its mechanical properties and has been shown to help guard against osteolysis and allow both immediate and long-term fixation.4–8

The heating effect of the PPS® process is transient (lasting only milliseconds). Therefore, the substrate material remains virtually unaffected and the fatigue properties are maintained.

Figure 20: Titanium PPS® (Porous Plasma Spray) coating being applied through a heated plasma arc.

Biomet’s PPS® coating has irregularly shaped molten titanium particles that splatter upon impaction with the substrate surface (Figure 21), creating a micro-rough texture and generating a wide distribution of pore-size between 100 and 1,000 microns. The larger distribution of pore size, in conjunction with micro-rough texture and enhanced biocompatibility of titanium, allows for immediate fixation via mechanical interlocking and long-term biologic fixation. This has enabled Biomet PPS® coating’s clinically proven success for over 20 years which has been documented in a variety of published clinical papers.1–8

Figure 21: The irregularly shaped titanium particles sprayed onto the substrate result in a wide pore size distribution.
References


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