MicroPort Orthopedics

HIP PRODUCT BROCHURE

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Prime™ Acetabular Cup System

The Prime™ acetabular cup system is the next step in the evolution of the successful Dynasty® acetabular cup system. The system is optimized for a highly cross-linked ultra-high molecular weight polyethylene bearing surface, eliminating the compromises associated with modularity to accommodate alternative bearing surfaces. By focusing on a singular bearing surface, the shell has also been optimized for modern bone fixation surfaces. Designed with simple, versatile instrumentation, the system can be used with a variety of surgical approaches.

DESIGN FEATURES

	PRIME™ SYSTEM
Shell sizes	46 – 68mm in 2mm increments
Liner diameter	22, 28, 32, 36, 40, and 44mm
Bearing surfaces	A-Class® Highly Cross-linked Polyethylene and E-Class™ Vitamin E Blended Highly Cross-linked Polyethylene
Shell options	Solid, 3-hole MH
Shell coating	BioFoam® Cancellous Titanium
Liner types	Standard, lipped, and lateralized/face changing

Robust Locking Mechanism
Allows for multiple liner configuration options, promotes easy liner insertion, and maximizes push-out strength

Optimized Screw Hole Locations
Create divergent fixation and allow for 18° of screw angulation

Square Impaction Dimple
Provides rotational control during implantation and functions with a quick release impactor mechanism

Optimized Head to Shell Ratio
Allows the use of a 36mm head and liner in a 50mm shell with no compromise to liner thickness

Minimized Shell Thickness
Decreases stiffness, discourages stress-shielding, and allows for optimized liner thickness

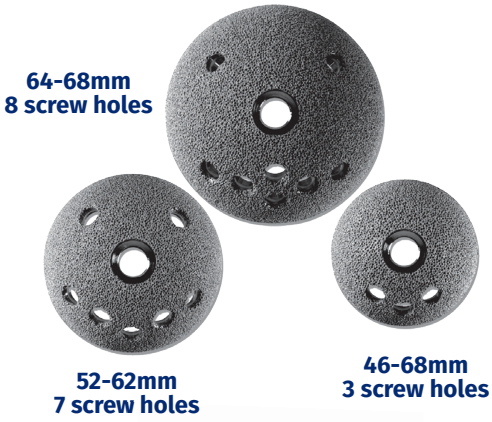
Design features of the Prime™ Acetabular Cup System

Dynasty® Acetabular Cup System

The Dynasty® acetabular cup system offers the benefits of cementless press-fit design together with its clinical established A-Class® highly cross-linked polyethylene. The configuration of Dynasty® shells allows for up to 10 screw holes on the larger diameter cups in conjunction with the latest bone fixation technology, BioFoam® cancellous titanium, making this cup the ultimate primary and revision option.

DESIGN FEATURES

	DYNASTY® POROUS-COATED SYSTEM	DYNASTY® BIOFOAM® SYSTEM
Shell sizes	46-68 in 2mm increments	46-76 in 2mm increments
Poly liner diameters	28-46	28-54
Bearing surface	A-Class® Highly Cross-linked Polyethylene	A-Class® Highly Cross-linked Polyethylene
Number of screw holes	3	3, 7, 8, 10 depending on cup size
Shell coating	Porous beads	BioFoam® Cancellous Titanium
Revision poly option	36mm ID from a 52-68mm	36mm ID from a 52-68mm
Liner types	Standard, 15 degree	Standard, 15 degree



HEAD OPTIONS

CoCr metal

Biolox® Delta® ceramic head

Biolox® Delta® option head

Titanium Sleeve
used with Biolox® Delta® option head

A-Class® backfilled metal

BCH® ceramic head

Titanium Sleeve
used with Backfilled metal & BCH® ceramic heads

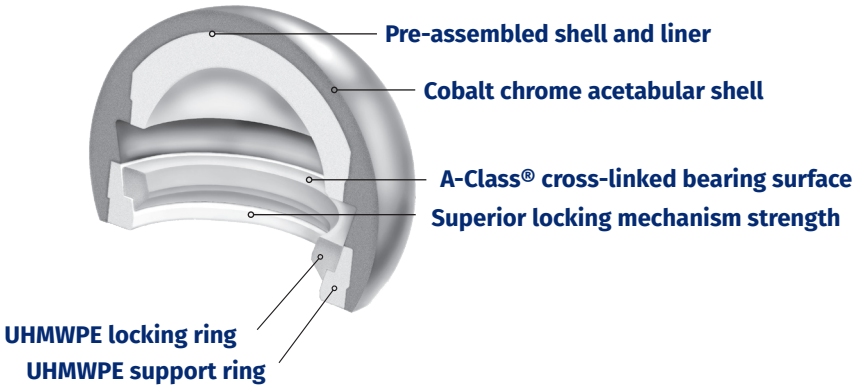
Gladiator® Bipolar Acetabular System

Gladiator® bipolar acetabular system is a bipolar hip implant design that features a cross-linked polyethylene bearing surface with an enhanced lock detail designed for strength. Historical concerns with traditional bipolar designs have included loosening of the insert, disassociation of the head from the shell, and osteolysis resulting from polyethylene wear. This system is designed to address these concerns to give surgeons greater confidence when using a bipolar implant.

There is an UHMWPE support ring inside the shell that is permanently fixed. There is also an UHMWPE locking ring that assembles above the support ring and locks into place once the head is inserted into the shell.

DESIGN FEATURES

	GLADIATOR® BIPOLAR ACETABULAR SYSTEM
Shell sizes	36 – 59mm
Head diameters	22 – 36mm
Bearing surface	A-Class® Highly Cross-linked Polyethylene



Design features of Gladiator® Bipolar Acetabular System

Locking ring in its "unlocked" position, without the head in the shell.

Head has been inserted. This causes the locking ring to engage and locks the head into place.

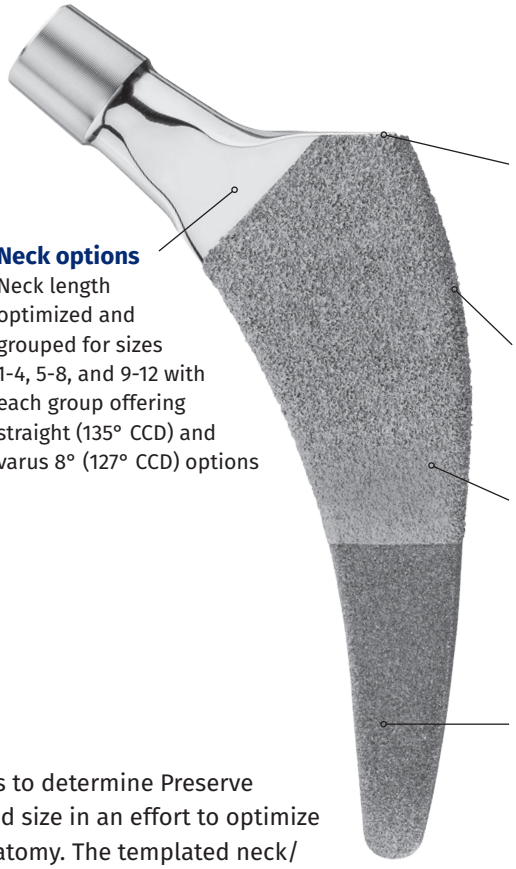
Profemur® Preserve Stem

DESIGN FEATURES

ABBREVIATED TECHNIQUE: BROACH ONLY
Broach to templated size
Implant size corresponding to broach

SIZES	
Neck	Optimized length
Stem	1–12

For additional risk information, please consult the Instructions For Use package insert.



Neck options
Neck length optimized and grouped for sizes 1-4, 5-8, and 9-12 with each group offering straight (135° CCD) and varus 8° (127° CCD) options

Driving platform
Dimple designed for unidirectional loading during stem insertion and oval slot designed for rotational control during stem insertion

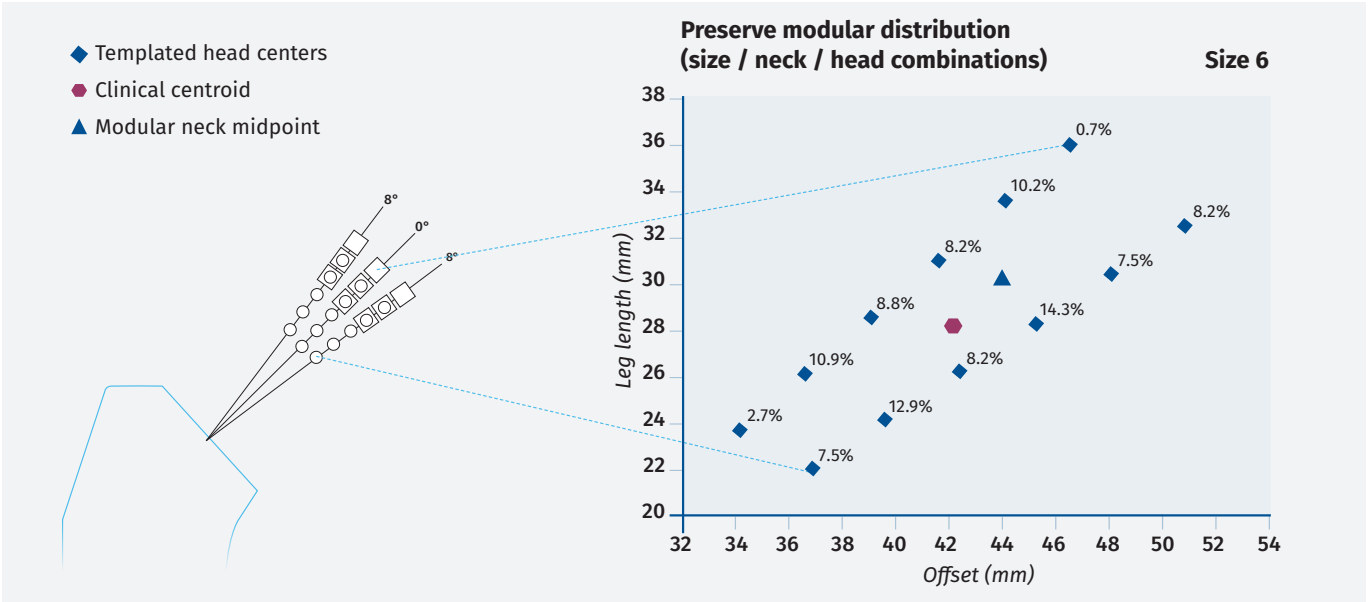
Lateral shoulder
Reduced material helps to conserve bone and ease insertion

Plasma spray
Tapered spray to provide additional 1mm (0.5mm per side) proximal and 0.2mm (0.1mm per side) distal press-fit to assist initial stability

Surface roughness
Grit-blasted design to promote bone apposition and scratch fit

DESIGNED TO MAXIMIZE HEAD CENTER COVERAGE

The design team reviewed over 900 radiographs to determine Preserve modular stem size, modular neck type, and head size in an effort to optimize component placement with existing patient anatomy. The templated neck/head combinations were converted into a frequency distribution to calculate the clinical centroid for each stem size.



Profemur® TL2 Stem

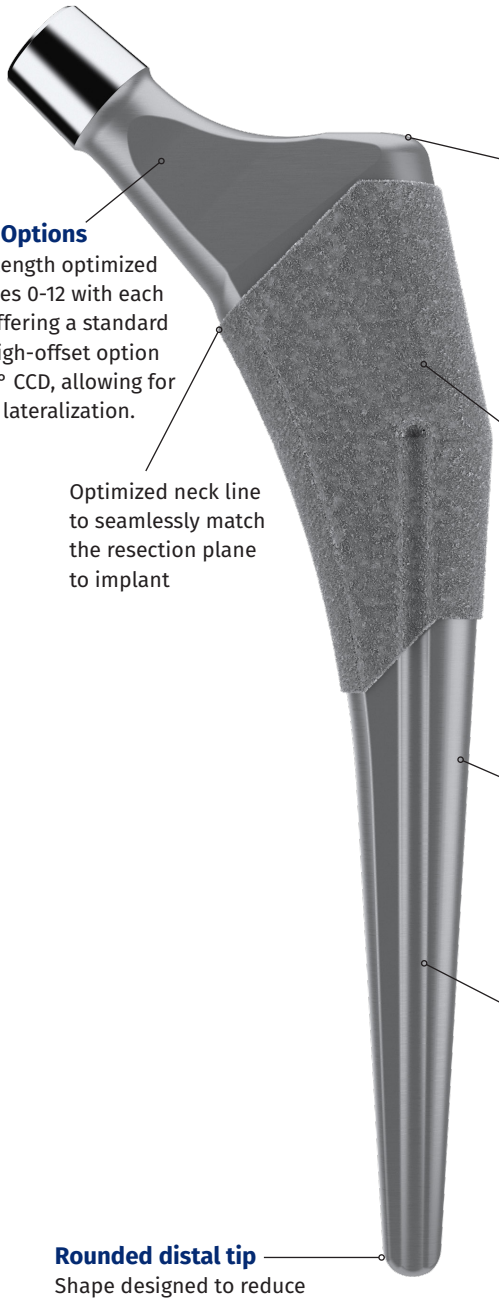
DESIGN FEATURES

ABBREVIATED TECHNIQUE: BROACH ONLY
Broach to templated size
Implant size corresponding to broach

SIZES	
Neck	Optimized length for each size grouping
Stem	0–12

Available in Classic only

For additional risk information, please consult the Instructions For Use package insert.



Driving platform
Dimple designed for unidirectional loading during stem insertion and oval slot designed for rotational control during stem insertion

Neck Options
Neck length optimized for sizes 0-12 with each size offering a standard and high-offset option at 133° CCD, allowing for direct lateralization.

Plasma spray
Designed to provide additional 1mm press-fit (0.5mm per side) to assist initial stability

Optimized neck line to seamlessly match the resection plane to implant

Surface roughness
Titanium stem surface has glass-beaded texture

Distal groove
Designed to assist rotational stability

Rounded distal tip
Shape designed to reduce the risk of fracture during insertion and minimize point contact after implantation

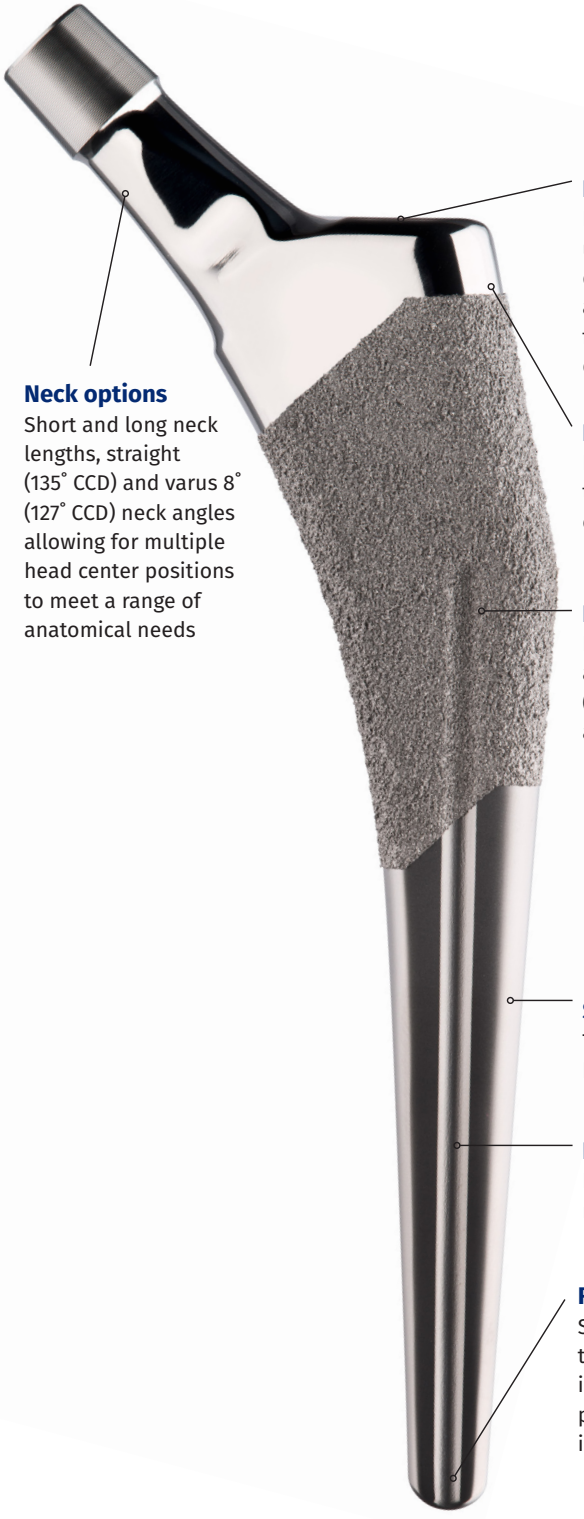
Profemur® TL Stem

DESIGN FEATURES

ABBREVIATED TECHNIQUE: BROACH ONLY
Broach to templated size
Implant size corresponding to broach

SIZES	
Neck	Short and long lengths
Stem	1–12

For additional risk information, please consult the Instructions For Use package insert.



Neck options
Short and long neck lengths, straight (135˚ CCD) and varus 8˚ (127˚ CCD) neck angles allowing for multiple head center positions to meet a range of anatomical needs

Driving platform
Dimple designed for unidirectional loading during stem insertion and oval slot designed for rotational control during stem insertion

Lateral shoulder
Reduced material helps to conserve bone and ease insertion

Plasma spray
Designed to provide additional 1mm press-fit (0.5mm per side) to assist initial stability

Surface roughness
Titanium stem surface has glass-beaded texture

Distal groove
Designed to assist rotational stability

Rounded distal tip
Shape designed to reduce the risk of fracture during insertion and minimize point contact after implantation

Profemur® Gladiator® Stems

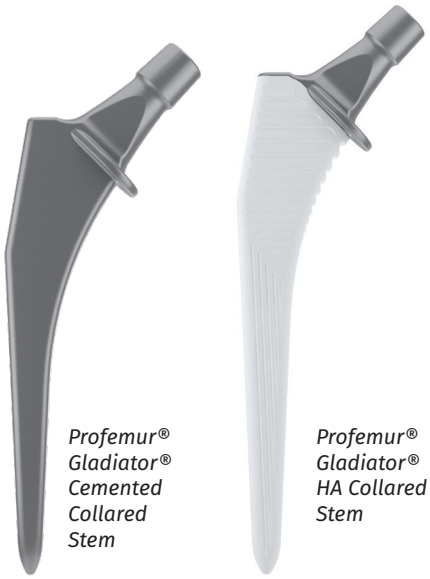
DESIGN FEATURES

ABBREVIATED TECHNIQUE: BROACH ONLY
Broach to templated size
Implant size corresponding to broach

SIZES	
Neck	Medium length
Stem	1-10

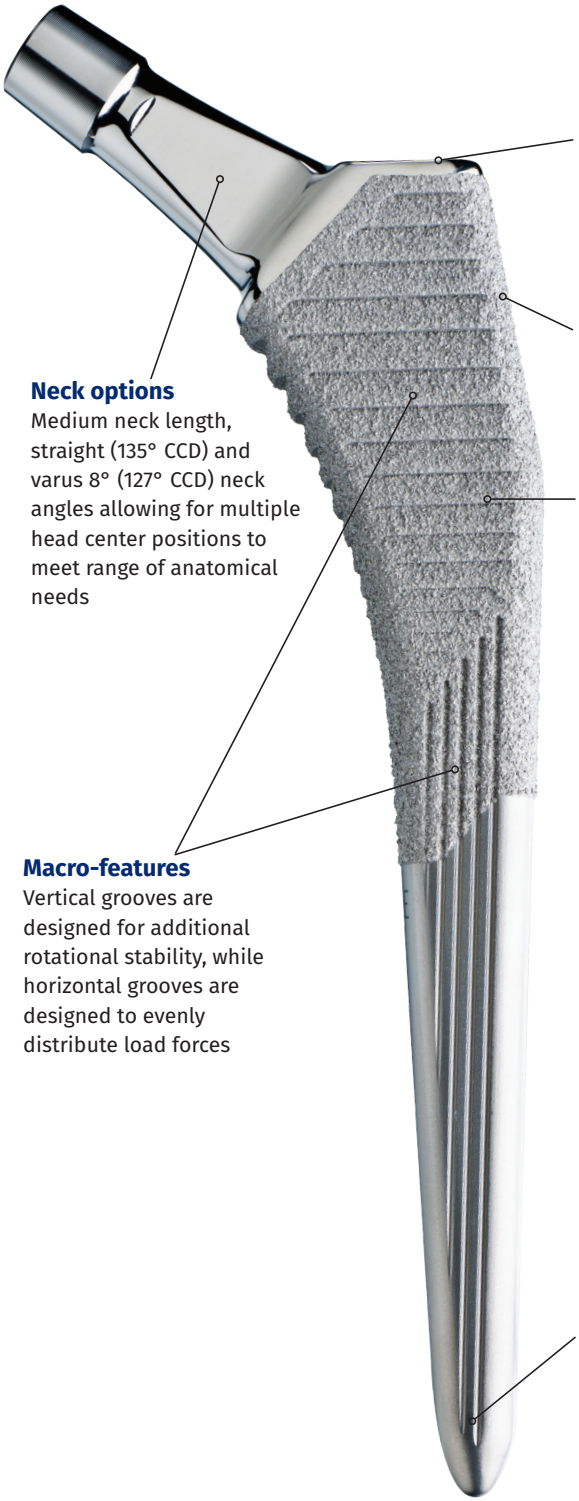
PRESS FIT STEM SIZES	
Neck	Medium length
Stem	4,6,8,10,12

For additional risk information, please consult the Instructions For Use package insert.



Profemur® Gladiator® Cemented Collared Stem

Profemur® Gladiator® HA Collared Stem



Driving platform
Dimpled driving platform for unidirectional loading during stem insertion

Lateral shoulder
Reduced material helps to conserve bone and ease insertion

Neck options
Medium neck length, straight (135° CCD) and varus 8° (127° CCD) neck angles allowing for multiple head center positions to meet range of anatomical needs

Plasma spray
Coating thickness provides 1.0mm (0.5mm per side) additional press-fit

Macro-features
Vertical grooves are designed for additional rotational stability, while horizontal grooves are designed to evenly distribute load forces

Reduced tip
To minimize point contact in the thigh for comfort

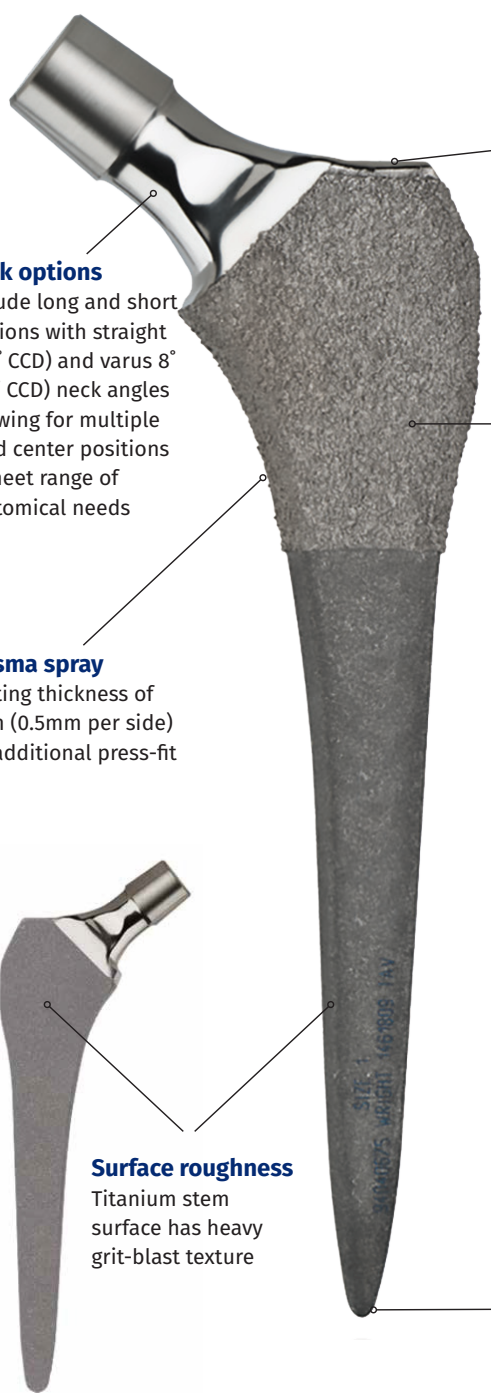
Profemur® Z and Plasma Z Stems

DESIGN FEATURES

ABBREVIATED TECHNIQUE: BROACH ONLY
Broach to templated size
Implant size corresponding to broach

SIZES	
Neck	Short and long lengths
Stem	1–9

For additional risk information, please consult the Instructions For Use package insert.



Driving platform
Dimple designed for unidirectional loading during stem insertion and oval slot designed for rotational control during stem insertion

Neck options
Include long and short versions with straight (135˚ CCD) and varus 8˚ (127˚ CCD) neck angles allowing for multiple head center positions to meet range of anatomical needs

Trochanteric wing
Increased trochanteric wing designed to contribute to proximal fill and rotational stability

Plasma spray
Coating thickness of 1mm (0.5mm per side) for additional press-fit

Dual taper geometry
Design intended to provide optimal primary fixation and load transfer

Rectangular cross-section
Designed to provide rotational stability and conserves bone for increased vascularization

Surface roughness
Titanium stem surface has heavy grit-blast texture

Rounded distal tip
Shape designed to reduce risk of fracture during insertion and minimize point contact after implantation

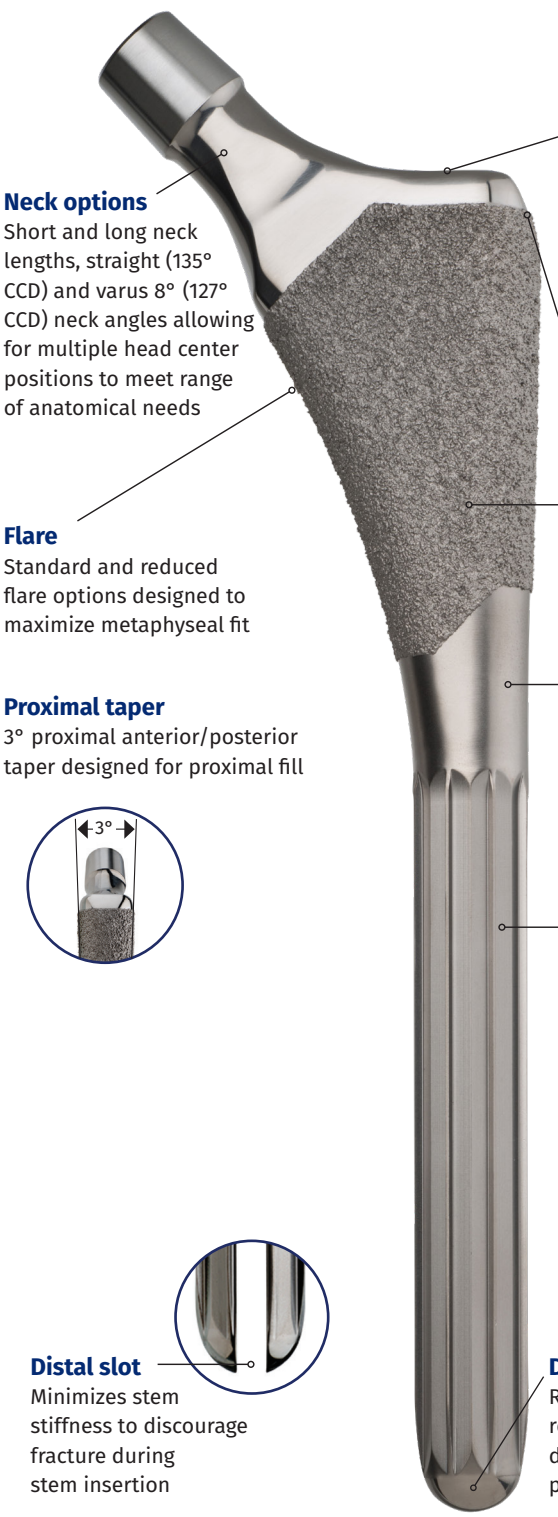
Profemur® Renaissance® Stem

DESIGN FEATURES

ABBREVIATED TECHNIQUE: REAM & BROACH
Ream to templated size or cortical chatter
Sequentially broach with reduced flare broaches to corresponding reamer size
If it is not secure, switch to standard flare broach or ream and broach to larger stem size
Implant size and flare corresponding to broach size and flare

SIZES	
Neck	Short and long lengths
Stem	10–16 (Reduced flare) 10–18 (Standard flare)

For additional risk information, please consult the Instructions For Use package insert.



Driving platform
Dimple designed for unidirectional loading during stem insertion and oval slot designed for rotational control during stem insertion

Neck options
Short and long neck lengths, straight (135° CCD) and varus 8° (127° CCD) neck angles allowing for multiple head center positions to meet range of anatomical needs

Lateral shoulder
Rounded lateral shoulder designed to ease stem insertion and minimize risk of fracture

Flare
Standard and reduced flare options designed to maximize metaphyseal fit

Plasma spray
Coating thickness provides 1.0mm (0.5mm per side) additional press-fit

Proximal taper
3° proximal anterior/posterior taper designed for proximal fill

Surface roughness
Titanium stem surface has glass-beaded texture

Distal splines
Designed to provide additional 1mm press-fit (0.5mm per side) for rotational stability

Distal slot
Minimizes stem stiffness to discourage fracture during stem insertion

Distal bullet tip
Round distal tip designed to reduce the risk of fracture during insertion and minimize point contact after implantation

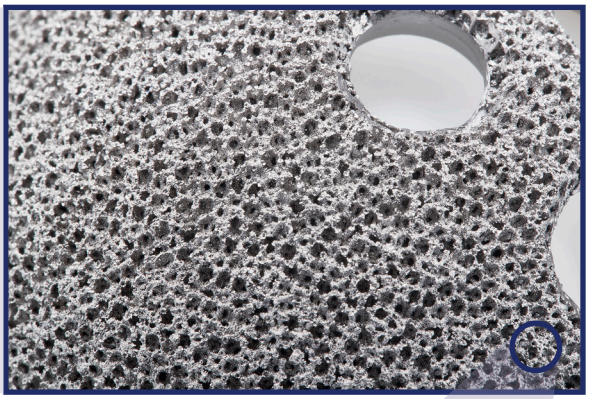
BioFoam® Cancellous Titanium

STRUCTURE

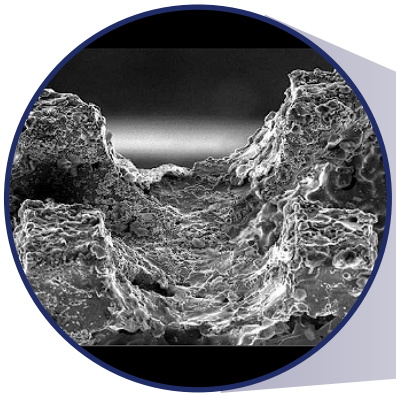
Cancellous or trabecular bone is composed of a network of rod- and plate-like elements that provide porous macrostructure for blood vessels and marrow.

The structure of Biofoam® cancellous titanium metal resembles that of trabecular bone. Made from commercially pure titanium, the pore cell size averages 530µm and the diameter of interconnecting pores averages 200µm. The porosity is between 60 and 70%, creating an open cell structure that allows deep bone fixation for long-term stability.

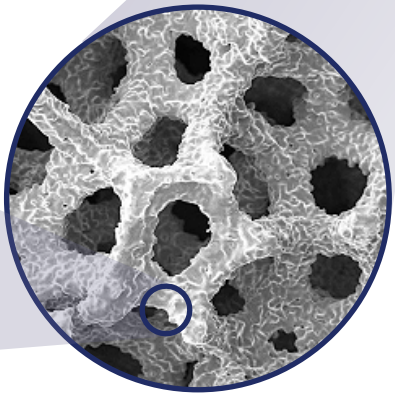
BioFoam® Cancellous Titanium on Prime™ Acetabular Cup System



Structure of BioFoam®



Trabecular structure of BioFoam® Cancellous Titanium, 200x original magnification



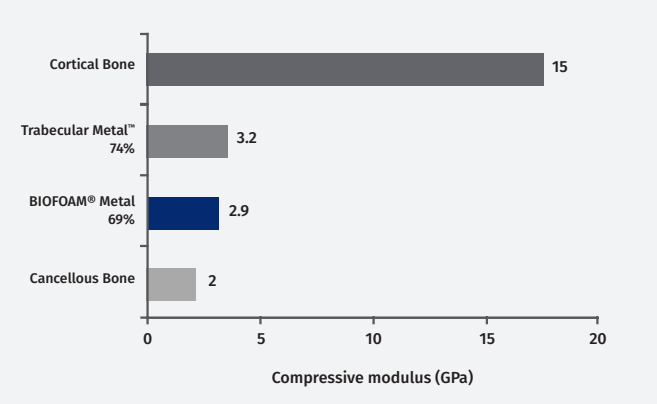
Trabecular structure of BioFoam® Cancellous Titanium, 100x original magnification

BioFoam® Cancellous Titanium

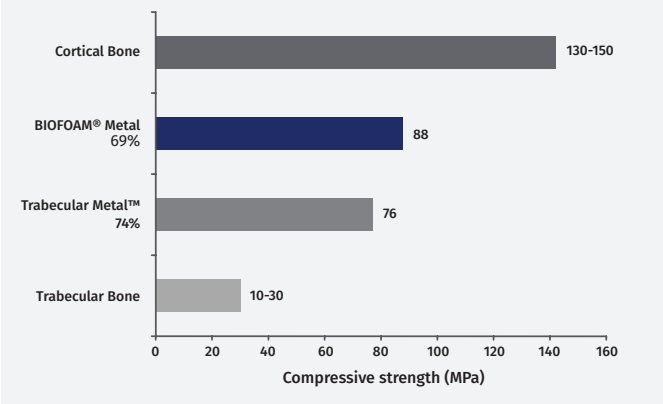
COMPRESSIVE STRENGTH & MODULUS

Compressive strength measures the maximum amount of compressive load a material can bear prior to fracturing. Compressive modulus is a normalized measure of a material's stiffness measuring how much a material compresses under load without permanently deforming.

BioFoam® cancellous titanium is engineered to have a modulus similar to that of bone facilitating even and consistent bone loading to prevent stress shielding, promote long-term interdigitation, and enhance stability.



Compressive strength of Biofoam® metal as compared to bone and Trabecular Metal™

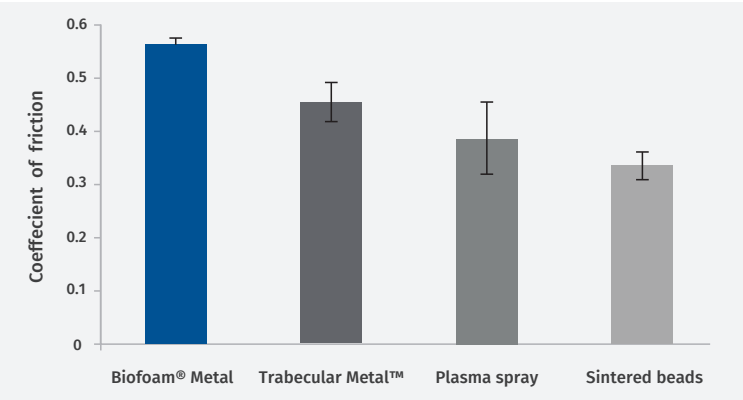


Compressive modulus of Biofoam® metal as compared to bone and Trabecular Metal™

FRICTIONAL PROPERTIES

Frictional resistance provides initial stability between the implant and bone, thereby helping prevent the implant from movement immediately following implantation. Immediate rigid fixation is crucial to the ingrowth process. If the implant is moving, it is no longer working as a stable construct for bone growth, and the bone will not be able to attach itself to the implant for long-term fixation.

In a study, BioFoam® cancellous titanium had a significantly higher coefficient of friction than porous tantalum (Trabecular Metal), plasma spray, and sintered beads (p=0.007, 0.051 and 0.001, respectively.)

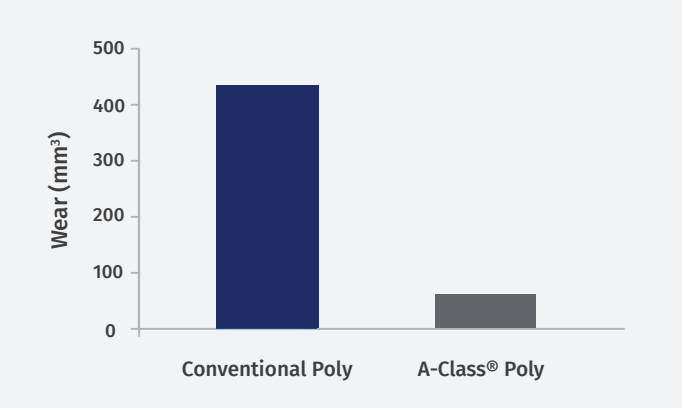


Frictional properties of Biofoam® metal compared to traditional ingrowth coatings and Trabecular Metal™

A-Class® Highly Cross-linked Polyethylene

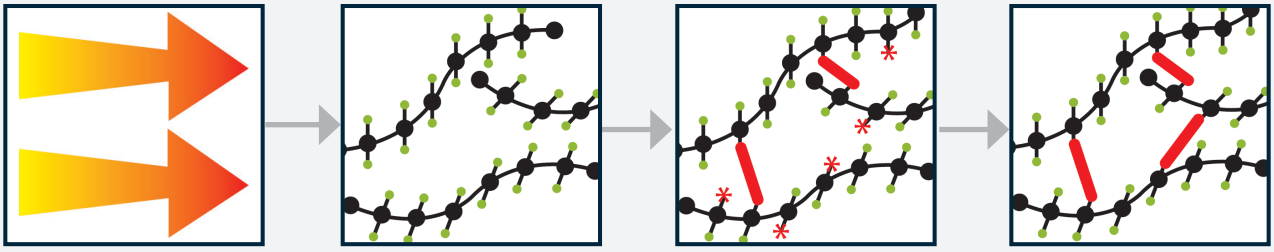
DESIGN FEATURES

- **No oxidation[1]**
- **Undetectable free radicals[2]**
- **92% or greater reduction in wear[3]**



Wear rate per million cycles of A-Class® highly Cross-linked Polyethylene

MicroPort Orthopedics utilizes the following manufacturing processes for cross-linking its A-Class® polyethylene.



Poly material selection

Process begins with compression molded GUR 1020, which has a higher impact strength, tensile strength, and yield strength than GUR 1050[7].

Cross-linking process

GUR 1020 rods are gamma irradiated to a dose of 7.5 MRads to facilitate cross-linking and enhanced wear resistance, but also maintain mechanical properties of the material.

Heat treatment

Following irradiation, the rods are heated above the melting point of the polyethylene to eliminate residual free radicals, form additional cross-links, and improve the oxidative stability of the material[8].

Machining and final sterilization

Liners are machined, cleaned, packaged, and sterilized using ETO sterilization, which does not reintroduce free radicals or cause any other measurable change to the polymer.

E-Class™ Vitamin E Blended Highly Cross-linked Polyethylene

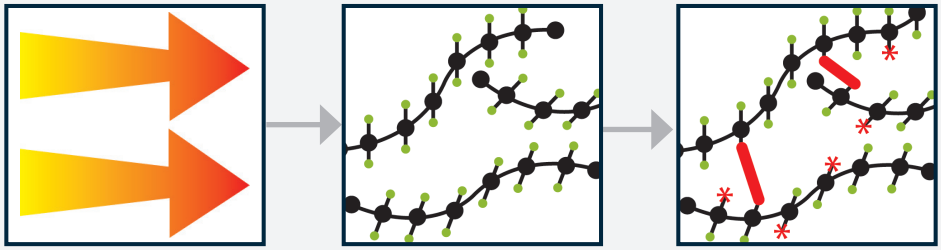
Joint replacement is occurring in increasingly younger patients. Over 20% of primary total hip arthroplasty (THA) procedures in the United States occur in patients 55 years of age or younger. This younger patient population expects to remain active throughout their lives, creating a need for longer-lasting and higher performance implants.

Reference: 2018 National Inpatient Sample, Hospital Cost and Utilization Project, Agency for Healthcare Research and Quality, US DHHS

DESIGN FEATURES

- **Improves wear resistance[5]**
- **Undetectable free radicals[6]**
- **Maintains mechanical strength[6]**

MicroPort Orthopedics utilizes the following manufacturing processes for cross-linking its E-Class™ Vitamin E blended highly cross-linked polyethylene.



Poly material selection

Process begins with compression molded GUR 1020, which has a higher impact strength, tensile strength, and yield strength than GUR 1050[7].

Vitamin E treatment

Following irradiation, Vitamin E stabilizes any remaining free radicals and continuously prevents oxidation. The presence of Vitamin E eliminates the need for remelting, resulting in improved mechanical strength.

Cross-linking process

GUR 1020 rods are gamma irradiated to a dose of 10 MRads to facilitate cross-linking and enhanced wear resistance, but also maintain mechanical properties of the material.

Machining and final sterilization

Liners are machined, cleaned, packaged, and sterilized using ETO sterilization, which does not reintroduce free radicals or cause any other measurable change to the polymer.

1. Benchtop data on file at MicroPort Orthopedics.
2. Benchtop data on file at MicroPort Orthopedics.
3. Compared to conventional poly. Benchtop data on file at MicroPort Orthopedics.
4. Reference: 2018 National Inpatient Sample, Hospital Cost and Utilization Project, Agency for Healthcare Research and Quality, US DHHS
5. Compared to conventional polyethylene. Benchtop data on file at MicroPort Orthopedics.
6. Benchtop data on file at MicroPort Orthopedics.
7. “Standard Specification for Ultra-High-Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants”. ASTM International, 2014. F648-14.
8. Benchtop data on file at MicroPort Orthopedics.

MicroPort Orthopedics

MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN USA 38002
866 872 0211

microportortho.com

The CE-Marking of Conformity is applied per catalog number and appears on the outer package label, if applicable.

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