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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 single bearing surface, the shell has also been optimized for modern ingrowth 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 |
| Shell Coating | BioFoam® Cancellous Titanium |
| Liner Types | Standard, Lipped, and Lateralsized/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
**Dynasty® Acetabular Cup System**

The Dynasty® Acetabular Cup System offers the benefits of cementless press-fit design together with its clinical proven 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 ingrowth fixation technology, BioFoam®Cancellous Titanium, making this cup the ultimate primary and revision option.

**Design Features**

<table>
<thead>
<tr>
<th></th>
<th>Dynasty® Porous-Coated System</th>
<th>Dynasty® Biofoam® System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shell Sizes</strong></td>
<td>46-66 in 2mm increments</td>
<td>46-76 in 2mm increments</td>
</tr>
<tr>
<td><strong>Poly Liner Diameters</strong></td>
<td>28-46</td>
<td>28-54</td>
</tr>
<tr>
<td><strong>Bearing Surface</strong></td>
<td>A-Class® Highly Cross-Linked Polyethylene</td>
<td>A-Class® Highly Cross-Linked Polyethylene</td>
</tr>
<tr>
<td><strong>Number of Screw Holes</strong></td>
<td>3, 7, 8, 10 Depending on Cup Size</td>
<td>3, 7, 8, 10 Depending on Cup Size</td>
</tr>
<tr>
<td><strong>Shell Coatings</strong></td>
<td>Porous Coated</td>
<td>Biofoam® Cancellous Titanium</td>
</tr>
<tr>
<td><strong>Revision Poly Option</strong></td>
<td>36mm ID from a 52-68mm</td>
<td>36mm ID from a 52-68mm</td>
</tr>
<tr>
<td><strong>Liner Types</strong></td>
<td>Standard, 15 Degree</td>
<td>Standard, 15 Degree</td>
</tr>
</tbody>
</table>

**Head Options**

- CoCr Metal
- Biolox® Delta® Ceramic Head
- A-Class® Backfilled Metal
- Biofoam® Cancellous Titanium
- Titan® Ceramic Head

**Gladiator® Bipolar Acetabular System**

Gladiator® Bipolar Acetabular System is a bipolar hip implant design that features a cross-linked polyethylene bearing surface with a lock detail enhanced 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**

<table>
<thead>
<tr>
<th></th>
<th>Gladiator® Bipolar Acetabular System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shell Sizes</strong></td>
<td>36 - 59mm</td>
</tr>
<tr>
<td><strong>Head Diameters</strong></td>
<td>22 - 36mm</td>
</tr>
<tr>
<td><strong>Bearing Surface</strong></td>
<td>A-Class® Highly Cross-Linked Polyethylene</td>
</tr>
</tbody>
</table>

**Design Features of Gladiator® Bipolar Acetabular System**

- Pre-assembled Shell and Liner
- Cobalt Chrome Acetabular Shell
- A-Class® Cross-linked Bearing Surface
- Superior Locking Mechanism Strength
- UHMWPE Locking Ring
- UHMWPE Support Ring

- Locking ring in its "unlocked" position, without the head in the shell.
- Locking ring engaged.
- Head has been inserted. This causes the locking ring to engage and locks the head into place.
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.

Profemur® Preserve Stems

Driving Platform

Dimpled driving platform 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.

Neck Options

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

Surface Roughness

Grit-blasted design to promote bone apposition and scratch fit.

Profemur® Gladiators® Plasma Stem

Design Features

Abbreviated Technique: Broach Only

Broach to templated size
Implant size corresponding to broach

Sizes

Neck Medium length
Stem 1-10

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

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

Profemur® Preserve Stems

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.

Templated Head Centers
Clinical Centroid
Modular Neck Midpoint

Preserve Modular Distribution
(Size / Neck / Head Combinations)

Size 6

Templated Head Centers

Clinical Centroid

Modular Neck Midpoint

Profemur® Preserve Stems

Driving Platform

Dimpled driving platform 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.

Neck Options

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

Surface Roughness

Grit-blasted design to promote bone apposition and scratch fit.

Profemur® Gladiators® Plasma Stem

Driving Platform

Dimpled driving platform designed for unidirectional loading during stem insertion.

Lateral Shoulder

Reduced material helps to conserve bone and ease insertion.

Neck Options

Medium neck length, straight (135º CCD) and varus 8° (127º 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.

For additional risk information, please consult the Instructions for Use package insert.
Profemur® TL Stem

**Design Features**

**Assessed Technique: Broach Only**

Broach to templated size

Implant size corresponding to broach

**Sizes**

<table>
<thead>
<tr>
<th>Neck</th>
<th>Short and long lengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stem</td>
<td>1-12</td>
</tr>
</tbody>
</table>

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 a range of anatomical needs

**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

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Profemur® Z and Plasma Z Stems

**Design Features**

**Assessed Technique: Broach-only**

Broach to templated size

Implant size corresponding to broach

**Sizes**

<table>
<thead>
<tr>
<th>Neck</th>
<th>Short and long length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stem</td>
<td>1-9</td>
</tr>
</tbody>
</table>

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

**Lateral Shoulder**

Reduced material helps to conserve bone and ease insertion

**Plasma Spray**

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

**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

**Rectangular Cross-Section**

Provides rotational stability and conserves bone for increased vascularization

**Dual Taper Geometry**

Design intended to provide optimal primary fixation and load transfer

**Trochanteric Wing**

Increased trochanteric wing designed to contribute to proximal fill and rotational stability
Profemur® Renaissance® Stem

Design Features

Abbreviated Technique: Ream and Broach

- Ream to templated size or cortical chatter
- Sequentially broach with reduced flare broaches to corresponding reamer size
- If 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

<table>
<thead>
<tr>
<th>Size</th>
<th>Neck Options Short and long neck lengths</th>
<th>Stem Length</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Short and long neck lengths, straight (135° CCD) and varus (127° CCD) neck angles allowing for multiple head center positions to meet range of anatomical needs</td>
<td>10-16 (Reduced flare)</td>
</tr>
<tr>
<td></td>
<td>Standard and reduced flare options designed to maximize metaphyseal fit</td>
<td>10-18 (Standard flare)</td>
</tr>
</tbody>
</table>

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

Profemur® R Stems

Design Features

Abbreviated Technique: Ream and Broach

- Remove primary implant components and ream canal
- Broach distally until cortical contact made
- Proximally ream and broach to prepare proximal femur
- Implant components based trialing

Sizes

<table>
<thead>
<tr>
<th>Size</th>
<th>Proximal Bodies</th>
<th>Stem Length</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8 sizes (X-small - Large)</td>
<td>Short straight, medium and long curved</td>
</tr>
</tbody>
</table>

For additional risk information, please consult the Instructions for Use package insert.
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 ingrowth for long-term stability.

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 ingrowth, and enhance stability.

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.)
A-Class® Highly Cross-Linked Polyethylene

Design Features

- No oxidation
- Undetectable free radicals
- 92% or greater reduction in wear

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.

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.

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.

Machining & 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

Design Features

- Improves wear resistance
- Undetectable free radicals
- Maintains mechanical strength

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.

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 & 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.

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