PINNACE BULAR CUP SYSTEM

DESIGN RATIONALE



FREEDOM TO CHOOSE PROVEN MODULAR SOLUTIONS'

The Pinnacle[®] Acetabular Cup System is uniquely designed with a range of acetabular cup options, biological and mechanical fixation alternatives and advanced bearing technologies which provide you the power to choose the precise combination that best meets the individual needs of each patient.

Proven Clinical Performance¹

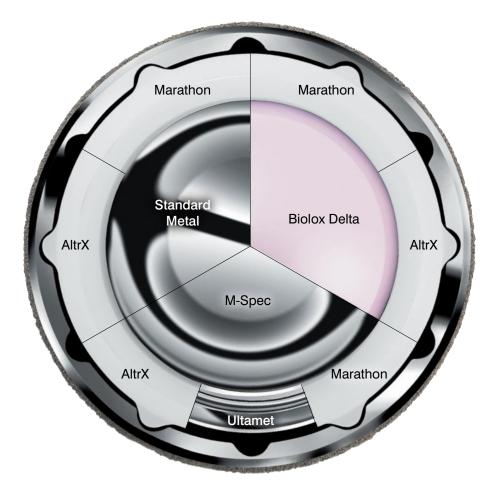
The Pinnacle system was developed with a team of surgeon thought-leaders from across the country. They utilized the proven Porocoat[®] Porous Coating fixation and combined it with engineering advances such as the patented Variable Interface Prosthesis (VIP) taper technology. This allows for the support of optimum performance metal and cross-linked polyethylene liners without compromising cup/insert congruency.

- Over 300,000 implanted
- 99.9 percent survivorship at 5 years¹



WEAR REDUCTION ADVANCED BEARING TECHNOLOGY

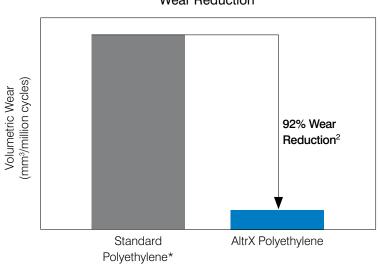
The Pinnacle system offers multiple liner and advanced bearing options for wear reduction and surgical flexibility in restoring proper patient biomechanics. With options that include advanced, industry-changing Ultamet[®] and Ultamet[®] XL metal-on-metal, Marathon[®] and AltrX[™] cross-linked polyethylenes and fourth-generation Biolox Delta ceramic heads, the surgeon has the ability to restore function, increase stability and reduce wear all within one acetabular cup.







AltrX is an ultra-low-wear polyethylene that offers a viable alternative to alternative bearings. Using the unique Altra-Link[™] process, AltrX polyethylene optimizes the balance between wear reduction and mechanical integrity. AltrX polyethylene starts with a base resin bar stock of GUR 1020 and is then moderately cross-linked at 7.5 Mrads, resulting in a material that is mechanically tough while providing 92 percent reduction in wear and resistance to oxidation compared to standard polyethylene.²



Wear Reduction²

FIT PATIENTS WITH CONFIDENCE

Today's patients require more from implants than previous generations of total hip recipients. As patients elect to undergo hip surgery at younger ages, there is greater need for advanced hip technologies that can restore function, reduce wear and improve stability for increasingly active patients.



The first FDA-cleared cross-linked polyethylene, Marathon polyethylene produces an 86 percent reduction in hip simulator wear rates when compared to standard polyethylene.³⁵



AltrX polyethylene offers 92 percent wear reduction over standard polyethylene, and uses a unique Altra-Link material enhancement process to optimize the balance between wear reduction and mechanical integrity.²

Marathon and AltrX cross-linked polyethylene liners offer 180 degrees of head coverage with inner diameter sizes ranging from 28-48 mm.





+4 mm Neutral Head center is lateralized 4 mm.



+4 10-Degree Face-Changing Effectively shifts range of motion by 10 degrees.



Lipped Liner Provides 4 mm of lateralization with a 15-degree lip for added stability.



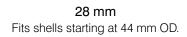
These liner styles are available in Marathon and AltrX polyethylene.

MAXIMIZED HEAD-TO-SHELL RATIO

Ultamet and Ultamet XL bearings maximize femoral head size allowing for enhanced stability, range of motion and wear resistance.*³



Made with high-carbon cobalt chrome, Ultamet inserts and M-specification metal heads maximize wear resistance and stability.⁶ Optimized diametrical clearance and sphericity provide true fluid film lubrication and low wear.



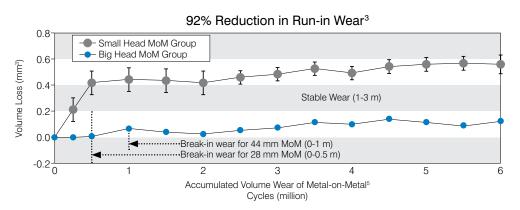


36 mm Fits shells starting at 50 mm OD.





The first modular metal-on-metal bearing system to offer 40 mm and 44 mm ID inserts, Ultamet XL offers increased stability and improved wear compared to 28 mm Ultamet inserts.³ In a wear simulator study, Ultamet XL bearings significantly reduced run-in wear and achieved an average volumetric wear of only 0.04 mm³/million cycles.³



40 mm Fits shells starting at 56 mm OD.



44 mm Fits shells starting at 62 mm OD.



*Compared to Pinnacle metal-on-polyethylene bearings.

INTRAOPERATIVE CHOICE WITHOUT COMPROMISE

Success of the Pinnacle Acetabular Cup System results from its breadth of intraoperative choices, including shell design, bearing materials and size options.

- Implant a 36 mm head in a 50 mm cup without compromising modularity and adjunct fixation.
- If a liner needs to be revised, remove and replace the liner without disturbing a well-fixed cup.
- Large femoral heads provide options for increasing stability and ROM as well as reducing wear.



VIP Taper

The inside of the Pinnacle acetabular shell is comprised of two distinct regions: the central dome region and the Variable Interface Prosthesis (VIP) taper. The central dome region covers approximately 140 degrees of the interior of the shell providing excellent backside support to polyethylene liners. Peripheral to the dome is the patented VIP taper, which extends to the face of the acetabular shell. This taper provides advanced modularity – improved polyethylene performance and the ability to support hard bearing inserts all without compromise.

PRIMARY MODULAR SHELL DESIGNS

100 Series

Maximizes host bone contact with Porocoat Porous Coating for biological fixation. Available in sizes 48-66 mm.



Available in DuoFix HA

Multi-Hole

Eight to 12 screw holes, depending on shell size, for optional adjunct fixation. Available in sizes 48-72 mm.



300 Series

Three porous-coated spikes enhance initial fixation and directional stability of the shell upon impaction. Available in sizes 48-66 mm.



Sector

Three screw holes for optional adjunct fixation and access to the ilium and posterior column. Available in sizes 48-66 mm.



Available in DuoFix HA

Bantam

For smaller patients or acetabular dimensions. Multi-hole style only. Available in sizes 38-46 mm.





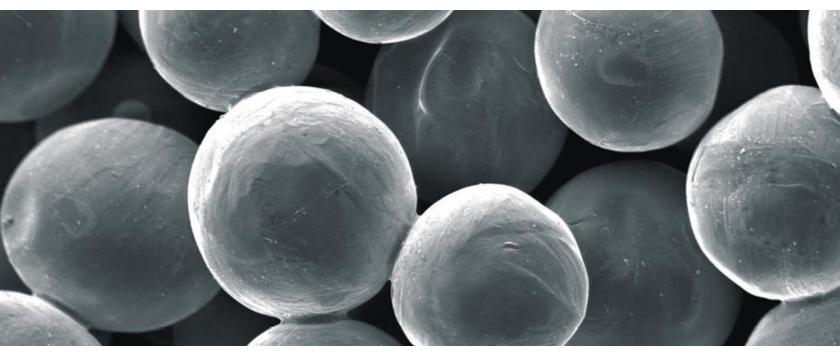
Pinnacle Revision Shells

Pinnacle Revision shells are designed to enhance stability and biomechanical optimization while providing immediate and long-term fixation, primarily in hip revision cases. Three different designs of Pinnacle Revision shells are available: Multi-Hole II, Standard Profile and Deep Profile DPx. The shells feature the VIP taper. Multiple screw holes provide several fixation options. The Standard Profile and Deep Profile DPx versions include peripheral screw holes around the opening of the shell.

MAXIMIZED FIXATION

POROCOAT POROUS COATING

The Porocoat Porous Coating on the back of all Pinnacle acetabular shells is a proprietary porous surface composed of commercially pure titanium sintered metal beads. After more than 30 years, clinical data continue to provide evidence that Porocoat Porous Coating successfully achieves initial stability and provides extensive long-term biological fixation.⁷



Magnification of Porocoat Porous Coating



In-growth - 4 weeks



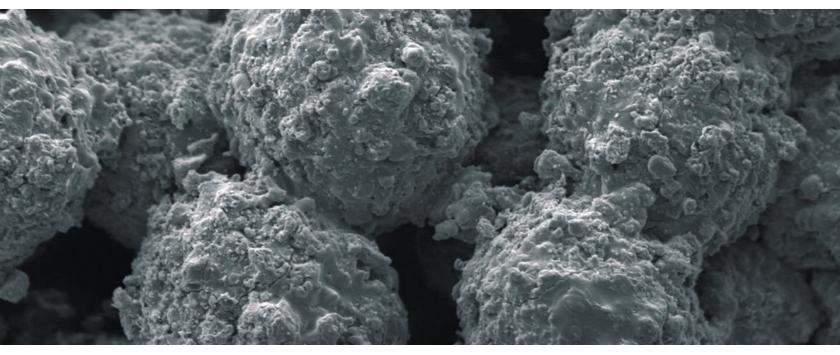
In-growth - 8 weeks



In-growth - 12 weeks



The DuoFix Fixation System adds a coating of low crystalline, highly amorphous hydroxyapatite (HA) over Porocoat Porous Coating. The DuoFix double coating helps in-growth into the implant and seals the acetabulum against particulate debris, which may minimize the risk of osteolysis and late implant loosening.⁸



Magnification of Porocoat Porous Coating with 35 microns of HA coating.

Acetabular shells with hydroxyapatite (HA) coating over a rough surface, such as Porocoat Porous Coating, have demonstrated reduced radiolucencies around the shell.⁹⁻¹¹ These implants can elicit a bone-conduction effect, contributing to new bone formation prior to the HA coating being absorbed.¹² HA-coated shells also have been shown to achieve early fixation, reducing the need for additional screw fixation.¹³

MAXIMIZING STABILITY ENABLING MOTION

To optimize range of motion while maximizing stability, the Pinnacle Acetabular Cup System is designed with an emphasis on versatility – in head size, liner shape and constraining liners. These multiple options and components have the potential to provide important benefits such as increased jump distance and improved range of motion of the implant.

Large Femoral Head Options

Larger femoral head diameters improve available range of motion of the implant and increase the distance required to completely dislocate the femoral head from the liner, resulting in greater head stability.

Polyethylene Liner Options

Having multiple liner alternatives provides more options for restoring patient biomechanics and reducing the potential for mechanical impingement, while enhancing stability.



ES³[™] Liners

Made with Marathon cross-linked polyethylene, ES³ liners are designed to work with Pinnacle Revision shells to enhance stability by increasing head size and jump distance.



ES^{c™} Constraining Liners

Designed for dislocation-prone hips, a titanium locking ring locks the liner into the Pinnacle shell while a chamfered titanium constraining ring locks the femoral head into the ES^c liner.





Optimized Function

159°

The Ultamet XL metal-on-metal bearing system offers excellent jump height and range of motion for a modular system – up to 159 degrees ROM and a 20 mm jump distance. The high-strength forged titanium cup design offers a large interior diameter, making it possible to insert heads up to 44 mm with metal-on-metal bearings and 48 mm with metal-on-polyethylene bearings.

SURGEON TEAM

The Pinnacle Acetabular Cup System was designed in conjunction with the following surgeons:

William P. Barrett, MD Proliance Surgeons, Seattle, WA Director, Center for Joint Replacement Renton, Washington

Daniel Berry, MD Professor of Orthopaedics Mayo Medical School Chairman, Department of Orthopedic Surgery Mayo Clinic Rochester, Minnesota

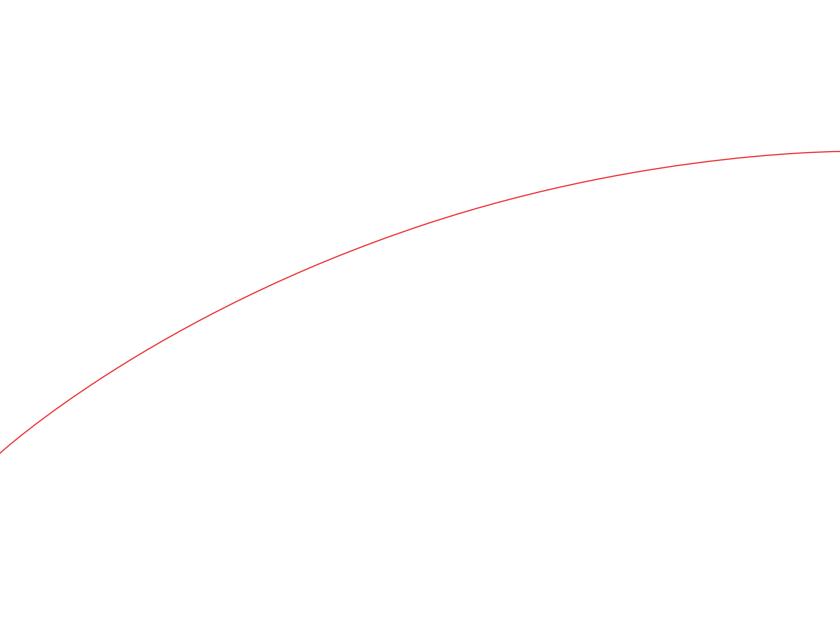
Gregory Brick, MD Assistant Clinical Professor Harvard Medical School Boston, Massachusetts John Callaghan, MD Professor, Department of Orthopaedics University of Iowa College of Medicine Iowa City, Iowa

Charles Engh, MD Clinical Associate Professor University of Maryland School of Medicine Baltimore, Maryland

Thomas Fehring, MD Co-Director, OrthoCarolina Hip and Knee Center OrthoCarolina Charlotte, North Carolina William Griffin, MD Co-Director, OrthoCarolina Hip and Knee Center OrthoCarolina Charlotte, North Carolina

Thomas Schmalzried, MD Associate Director Joint Replacement Institute at Orthopaedic Hospital Assistant Professor of Orthopaedic Surgery Chief of Joint Replacement Harbor-UCLA Medical Center Los Angeles, California





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DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581-0988

USA Tel: +1 (800) 366 8143 Fax: +1 (574) 371 4865

DePuy International Ltd St Anthony's Road Leeds LS11 8DT England Tel: +44 (113) 387 7800 Fax: +44 (113) 387 7890