Procotyl® P

Acetabular Cup System

Design Rationale

MicroPort Orthopedics

Full Function, Faster®

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Procotyl® P System Overview

Multibearing acetabular system offering a wide range of acetabular shell options with a single and effcient instrument platform.

Plasma Spray	Acetabular Shells	*Additive Manufacturing*

Quad (3 holes)

Solid

Quad (3 holes)

Solid

+ HA

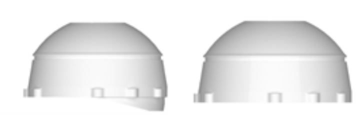
+ HA

+ CaP

+ CaP

Liners

A-Class® x-linked Polyethylene



E-Class® Vitamin E Polyethylene

Biolox® Delta® Ceramic

Femoral Heads

Metal Heads

Ceramic Heads

Accessories

Apical Plug

Screws

Introduction

The Procotyl® P Acetabular Cup System is the next step in the evolution of the successful cup systems developed at MicroPort. It supports a variety of surgical approaches and is optimized for accepting multiple bearing options to accommodate surgical preferences.

- Multiple fixation and bearing options
- Hemispherical design
- Simple, versatile instrumentation

1995

Interseal®

- Accepted polyethylene liners
- Shells ranged from size 46-72mm In solid, quad, and multi-hole deep profile options
- Shell contained a 14° flare
- Head size options were 28 and 32mm

1998

Transcend®

- Accepted ceramic and metal liners
- Shells ranged from size 46-68mm in solid and quad options
- Shell contained a 14° flare
- Head size options were 28, 32, and 36mm

2000

Lineage®

- Combination of the Interseal® and Transcend® Cup Systems
- Accepted polyethylene, highly cross-linked polyethylene, metal, and ceramic liners
- Shells ranged from size 46-68mm in solid, quad, spiked, HA-coated, and multi-hole deep profile options
- Included both a 14° rim flare and a hemispherical shell options

The Procotyl® P Acetabular Cup System is the next generation of MicroPort Orthopedics' acetabular cup systems and is built on over 25 years of experience.

2006	2007	2020

Procotyl® L

- Cementless rim flare cup design
- Sintered Titanium beads coating
- A-Class® highly cross-linked polyethylene and Biolox® Delta* liners
- 97.6% survivorship at 6 years follow-up [1,2]
- 10A* rating on ODEP

Dynasty®

- Accepts highly cross-linked polyethylene liners
- Shells range from size 46-68mm with a porous coating and 46-76mm with the Biofoam® Cancellous Titanium Coating
- Includes both quad and multi-hole shell options

Procotyl® P

- Hemispherical Shape
- Accepts highly cross-linked A-Class® and E-Class® polyethylene, and ceramic liners
- Machined with plasma spray (PS) and additive manufacturing (AM) options
- Solid or with 3 holes for additional screw fixation
- Available with hydroxyapatite (HA) or Calcium Phosphate (CaP) coating options

Design Features

Optimized Head to Shell Ratio
Allows the use of a 36mm head and liner in a 50mm shell

Locking mechanism
18° taper for ceramic liners and circumferential groove for polyethylene liners

Hemispherical shape
Shell size is inclusive of nominal press-fit (1.3mm on the diameter)

Radial grooves
12 grooves with a resolution of 30° for polyethylene liner alignment to maximize torque and rotational stability

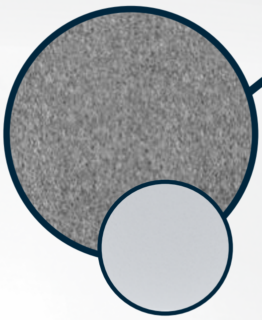
Quad design
Option with open screwholes for poly-axial screw positioning within 15° cone. Recessed design to prevent liner seating issues

Minimized Shell Thickness
Decreases stiffness for optimized liner thickness

Apical plug
Procotyl® P shells have the option of an apical plug which can be ordered separately in case surgeon prefers to close the dome hole

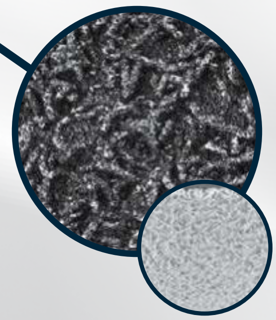
PS option
Titanium plasma spray coating with or without additional hydroxyapatite coating

AM option
Titanium trabecular structure obtained with additive manfacturing technology with or without additional Calcium Phosphate deposition



Coating Specifications:
Roughness: Rz 40-90 µm
Porosity: 20% - 40%

Structure Specifications:
Average pore size: 350-600µm
Porosity: 40-75%
Layer thickness: 500-1300µm
Strut size: 250-530µm



Procotyl® P

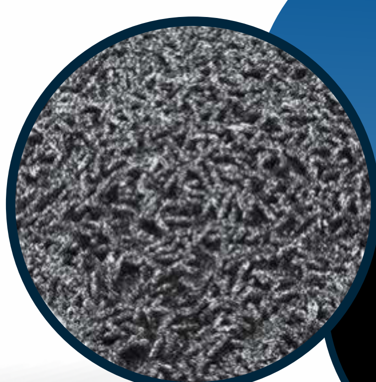
Additive Manufacturing

Additive manufacturing (AM) technology is also commonly known as 3D printing. It is a manufacturing process that involves the use of a laser or electron beam to sinter under protected atmosphere metal powders into a solid part that is “printed” layer-by-layer.

This technology allows to manufacture monolitic components with an open structure on the outside, such as innovative porous structure for biological fixation. The model utilizes simple geometrical elements which can be linearly expanded into 3D lattice structures, having adjustable strut dimensions and spacings to control the porosity or density.

With the layer-over-layer process, once a layer of powder has been selectively melted, the build platform is lowered, new powder is deposited and raked, and the process is repeated until the object is built.

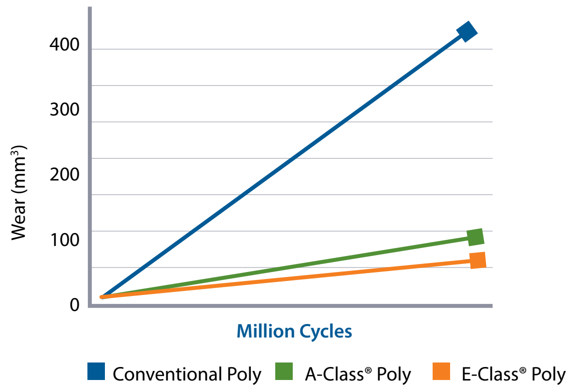
The whole implant (dense and porous parts) is produced in a single step, although several post-processing steps such as powder removal, heat treatment and post-machining must be performed. This methodology involves multiple interconnected parameters to be controlled and optimized and it has been estimated that more than 130 variables are involved in the entire additive manufacturing process.



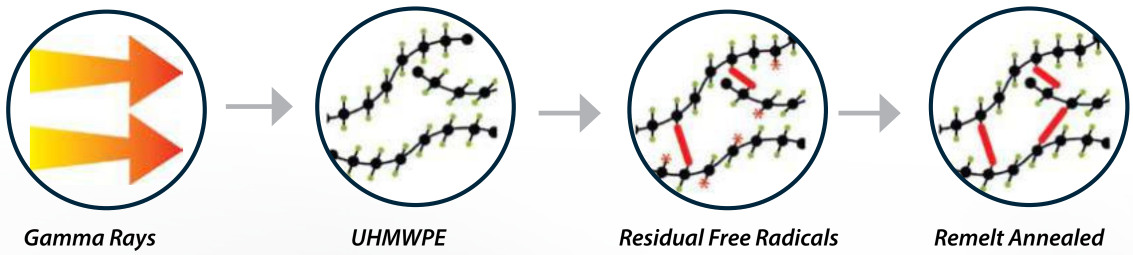
Polyethylene options

MicroPort's polyethylene options A-Class®and E-Class®

- Improved Wear Resistance [3]
- Maintained Mechanical Strength [4]



MicroPort Orthopedics utilizes the following manufacturing processes for it's polyethylene options.



Poly Material Selection

For A-Class® crosslink polyethylene, the process begins with compression molded GUR 1020, which has a higher impact strength, tensile strength, and yield strength than GUR 1050[6].

For E-Class® liners, the process begins with Vitamin E blend GUR1020 compression molded and extruded into rods.

Heat Treatment

Following irradiation, the A-Class® 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[7].

For E-Class® liners, following radiation, Vitamin E stabilizes the remaining free radicals.

Cross-Linking Process

GUR 1020 rods are gamma irradiated to a dose of 7.5 MRads to10Mrad to facilitate cross-linking and enhanced wear resistance, but also maintain mechanical properties of the material.

Finishing

Hip liners are then machined, cleaned, packaged and EtO sterilized. EtO sterilization is used because it does not reintroduce free radicals or cause measurable changes to the polyethyelene.

Optimized Head to Shell Ratio

Head Diameter	Ten-Year Cumulative Dislocation Rate[5] (postero-lateral approach)
22mm	12.1%
28mm	6.9%
32mm	3.8%

The importance of head diameter and its effect on dislocation has been widely recognized in the industry. Clinical data demonstrates that the use of larger femoral heads decrease the risk of dislocation and impingement while increasing range of motion.[5-6]

A-Class®

X-linked polyethylene articulating sizes (flat and 15° rim)

Shell Size (mm)	Group	Head Size (mm)		
		28	32	36
42	A			
44				
46	C	28		
48		28		
50	E		32	
52			32	
54			32	
56	F		32*	36
58			32*	36
60 - 70	G		32*	36

E-Class®

Vitamin E polyethylene articulating sizes (flat and 15° rim)

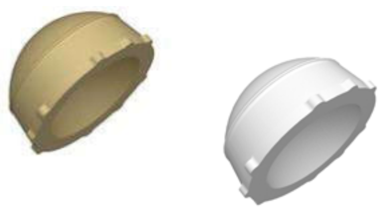
Shell Size (mm)	Group	Head Size (mm)		
		28	32	36
42	A	28		
44		28		
46	C	28*	32	
48		28*	32	
50	E		32*	36
52			32*	36
54			32*	36
56	F		32*	36
58			32*	36
60 - 70	G		32*	36

*Available on demand

Versatility

Multibearing Options

Polyethylene Liners



- Polyethylene liners 12 cut-outs on shell (30° apart)
- 9 Radial Tabs (3 groups 30°, every 120°)
- Provide maximized torque resistance and rotational stability
- Tabs partially engage and provide initial alignment prior to final impaction of lock detail

Ceramic Liners

Rim-lock Biolox® Delta* ceramic liners already used in the MicroPort portfolio, with optimization of couplings and inventory.

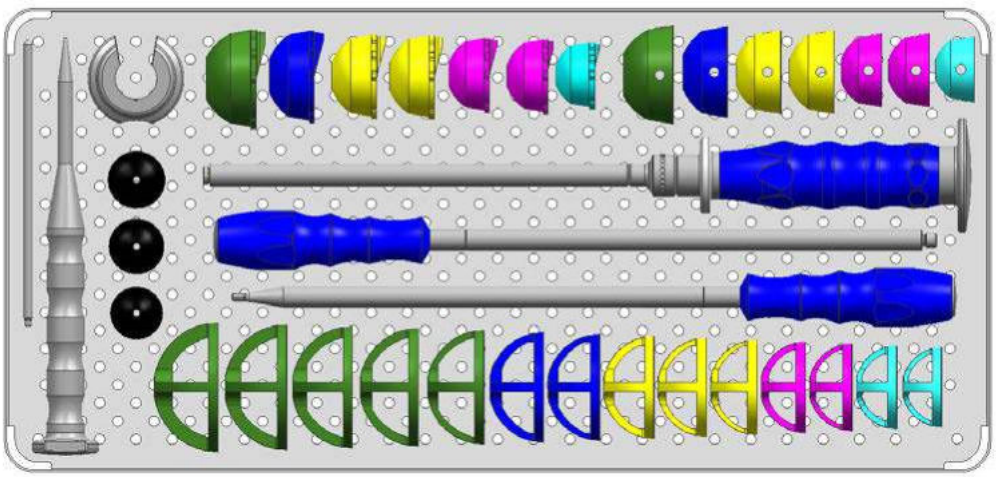
*Biolox® Delta**

Ceramic articulating sizes

Shell Size (mm)	Group	Head Size (mm)		
		28	32	36
42	A	28		
44		28		
46	C		32	
48			32	
50	E			36
52				36
54				36
56	F			36
58				36
60-70	G			36

Instruments

Procotyl® P instruments have been designed to allow to utilize your current Procotyl® L kits via an optimized transition plan. Additionally, brand new Procotyl® P instruments kits are available also.



Compatibility

The Procotyl® P Acetabular System was designed for compatibility with a variety of surgical approaches, including the modern, soft tissue-sparing MicroPort surgical philosophies, such as SuperPath® and Anterior Path®.

SuperPath®

The Direct Superior Portal Assisted Total Hip Approach

Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level. There are risks and recovery times associated with surgery and there are certain individuals who should not undergo surgery.

References

1. Parker A, Fitch D "Patient Reported Outcomes and Mid-term Survivorship of a Hydroxyapatite Coated Acetabular Cup with a Delta Ceramic on Delta Ceramic Bearing Compared with Other Cementless Cups" ISTA 29th Annual Congress, Boston, October 5-8, 2016
2. Parker A, Fitch D "Mid-term Survivorship and Patient Reported Outcomes of a Hydroxyapatite Coated Acetabular Cup with Metal on XLPE Articulation Compared with Other Cementless Cups in the NJR Registry" ISTA 29th Annual Congress, Boston, October 5-8, 2016
3. Compared to conventional polyethylene. Benchtop data on file at MicroPort Orthopedics.
4. Benchtop data on file at MicroPort Orthopedics.
5. Berry, DJ et al. "Effect of femoral head diameter and operative approach on risk of dislocation after primary hip arthroplasty". J Bone Joint Surg Am. 2005 Nov; 87 (11): 2456-63.
6. Bartz, RL et al. " The effect of femoral component head size on posterior dislocation of the artificial hip joint". J Bone Joint Surg Am. 2000 Sep; 82 (9): 1300-7.

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MicroPort Orthopedics

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