Procotyl® P

Acetabular Cup System - *new kit*

SURGICAL TECHNIQUE

MicroPort Orthopedics

Full Function, Faster®

Table of Contents

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience and patient condition. Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects.

Instructions For Use package inserts are also available by contacting the manufacturer.

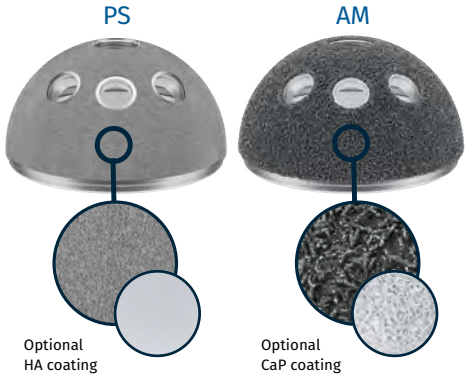
Contact information can be found on the back of this Surgical Technique and the Instructions For Use package inserts are available on the website listed. Please contact your local MicroPort Orthopedics representative/ distributor for product availability.

Chapter 1

Procotyl® P Design Features

Ordering Information		
Templates	PP15XR00	0° Lip Liner
	PP15XR15	15° Lip Liner
Surgical Technique	New kit	021214
	Converted Kit	021215
Instruments	PPPLKIT1	Procotyl® P conversion kit
	PPPLKIT2	Procotyl® P screw kit
	PPPLKIT3	Procotyl® P kit
Implants	PAMQKITA	Procotyl® P AM Quad
	PAMSKITA	Procotyl® P AM Solid
	PAMQCKTA	Procotyl® P AM Quad (+CaP)
	PAMSCKTA	Procotyl® P AM Solid (+CaP)
	PPSQHKTA	Procotyl® P PS Quad (+HA)
	PPSSHKTA	Procotyl® P PS Solid (+HA)
	PPSQKITA	Procotyl® P PS Quad
	PPSSKITA	Procotyl® P PS Solid
	PPACKITA	Procotyl® P A-Class® liner
	PPECKITA	Procotyl® P E-Class® liner
	PPCCKITA	Procotyl® P ceramic liner

Procotyl® P shells are available machined from Ti6Al4V alloy with Titanium plasma spray coating (PS) (with or without additional layer of Hydroxyapatite) and in Ti6Al4V Grade 5 alloy made by additive manufacturing technology (AM), (with or without an additional layer of CaP).



Radial grooves
12 radial grooves for polyethylene liner coupling.

Quad design
Option with open screwholes for screw positioning.

Minimized Shell Thickness
Decreases stiffness for optimized liner thickness.

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

Liners
A-Class® crosslinked polyethylene, E-Class® Vitamin E polyethylene available in flat or with a 15° anti-luxation rim.
Biolox® Delta* ceramic.

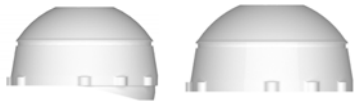
Apical plug
Can be ordered separately in case surgeon prefers to close the dome hole.

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

Procotyl® P Sizing Charts

A-Class®

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



Shell Size (mm)	Group	Head Size		
		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

*Available on demand

E-Class®

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

Shell Size (mm)	Group	Head Size		
		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

*Biolox® Delta***

Ceramic articulating sizes

Shell Size (mm)	Group	Head Size		
		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

Group / Color	Shell Size (mm)
A	42-44
C	46-48
E	50-51
F	50-58
G	60-70

**Trademark of CeramTec Ag

Procotyl® P System Overview

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

Acetabular Shells

Plasma Spray | *Additive Manufacturing*

Quad (3 holes)

+ HA

Solid

+ HA

Quad (3 holes)

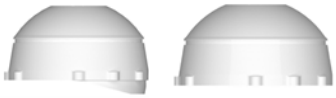
+ CaP

Solid

+ 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

Chapter 3

Surgical Technique

This surgical technique describes the implantation of Procotyl® system when using a PPPLKIT3 (Procotyl® P kit) and PPPLKIT2 (Procotyl® P screw kit).

Preoperative Planning

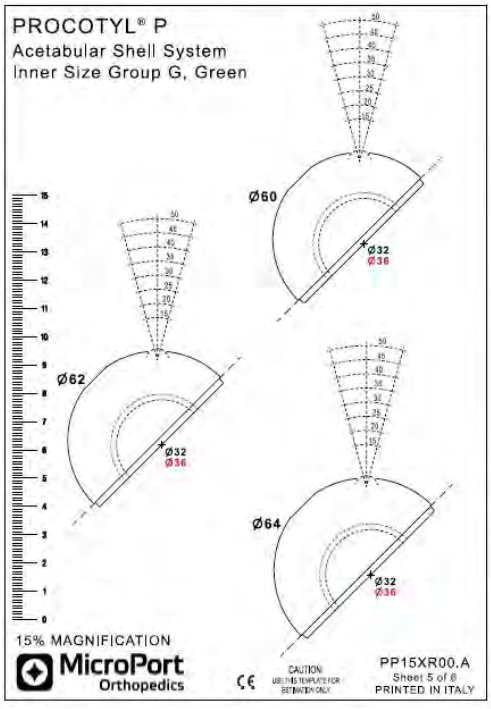
Pre-operative assessment of the appropriate size and position of the acetabular component will provide intra-operative guidance for acetabular reaming. A bilateral A/P x-ray of the pelvis will aid in leg length and offset assessment and management. Leg length discrepancies should be determined pre-operatively and addressed intra-operatively.

Radiographic overlays for the Procotyl® P Acetabular Cup System are available in 15% magnification, with 0° or 15° liners (PP15XR00 and PP15XR15, respectively). To determine the acetabular cup size and position, place the overlay outline at approximately 45° of abduction and the center of rotation within the anatomic center of the acetabular image.

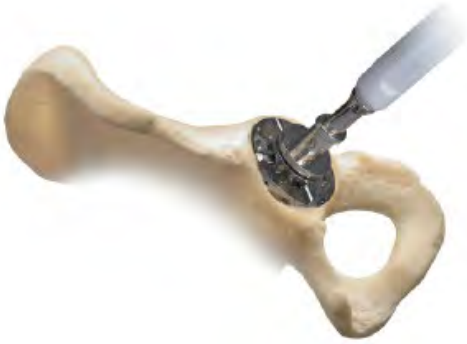
NOTE: Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip.

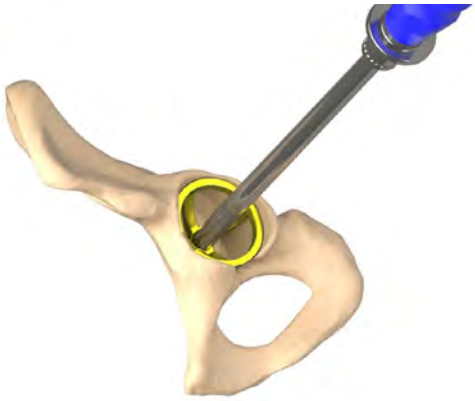
NOTE: The use of a magnification marker will aid in determining the x-ray magnification.

CAUTION: Pre-operative templating is intended for estimation purposes only. Final component size and position should be determined intra-operatively.



PP15XR00 and PP15XR15





Preparation of the Acetabulum

Osteophytes should be removed to enable assessment of the true acetabular rim. Reaming should be sequential and start with the smallest reamer that conforms to the acetabular cavity. Reaming to the edge of the reamer will mimic a full hemisphere. Gradually enlarge the acetabulum by reaming articular cartilage until a continuous surface of cancellous bone is exposed. Complete seating of the implant can be confirmed through the apical hole.

NOTE: Procotyl® P shells come in 2mm increments, ranging from 42 - 68mm.

NOTE: Reamers are not included in the Procotyl® P instrument set and needs to be ordered separately.

Ream to the size of the component to be implanted. This will provide a 1.3mm press fit. Reaming depth, acetabular shape and size can be confirmed by using a trial shell sizer.

Sizing the Acetabulum

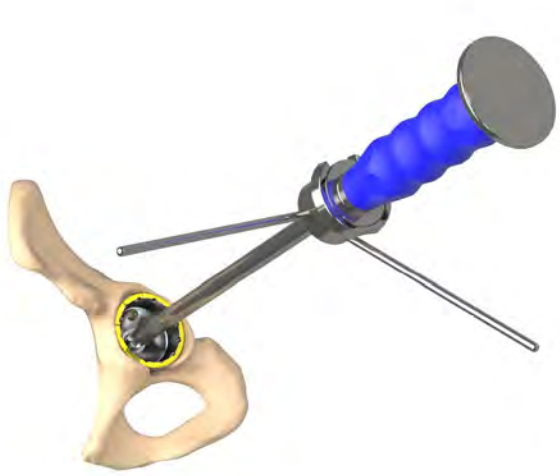
A trial shell (PPPSTA42 – PPPSTG70) corresponding to the size of the final reamer is attached to the cup impactor (PPPSTIMP or PPPSTIMK, depending on surgeon preference). Following trialing, the shell has to be removed from the cup impactor instrument. Use of the trial acetabular components is strongly suggested in order to verify depth of reaming.

NOTE: The trial shells are undersized in dimensions compared to the corresponding final implant and do not take the 1.3mm press-fit into account.

PPPSTA42-PPPSTG70

PPPSTIMP

PPPSTIMK



Press Fit Information

Nominal Size	Reamer Size	Actual Dimension
42	42	43.3
44	44	45.3
46	46	47.3
48	48	49.3
50	50	51.3
52	52	53.3
54	54	55.3
56	56	57.3
58	58	59.3
60	60	61.3
62	62	63.3
64	64	65.3
66	66	67.3
68	68	69.3
70	70	71.3

Inserting the Shell

Thread the appropriate size shell onto the impactor instrument. In case a quad shell option is implanted, three incisions on the rim of the shell corresponding to the location of the screw holes should be positioned between the plane of the anterior superior iliac spine and the anterior inferior iliac spine. Impact the cup into the acetabulum.

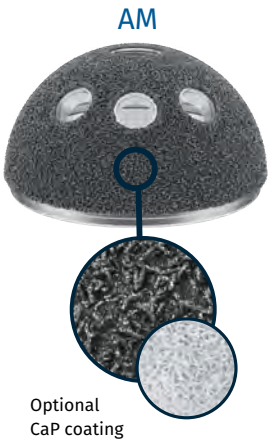
If desired, a version module (PPPSTIVD) can be clipped on the impactor to help verifying inclination and version on the implant.

Once the shell is impacted, the PPPSTIMK cup inserter instrument can be removed by turning the rear knob counter-clockwise.
Once the shell in impacted, the PPPSTIMP cup inserter instrument can be removed by unscrewing the instrument turning it counter-clockwise. Complete seating of the implant can be confirmed through the apical hole.

NOTE: For the SuperPath® surgical approach, either the Prime SuperPath® adaptor (P3CIMPAD) or the Procotyl® P cup impaction portal adapter (PPSP0110) must be used per the SuperPath® surgical technique.

NOTE: For an anterior surgical approach, the Procotyl® P offset cup impactor (PPPCRIMP) must be ordered separately.

WARNING: When implanting an additive manufacturing Procotyl® P, pay attention to its handling. The rough structure of the external portion of the shell can cause damage to surgical gloves and it is therefore recommended to handle the shell using the polyurethane protection provided in the product packaging.

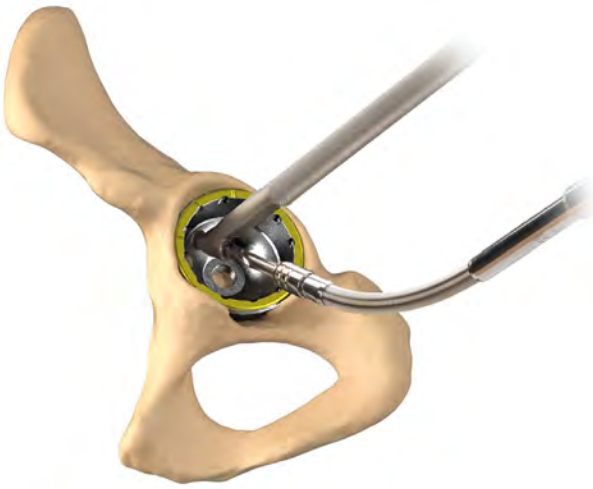


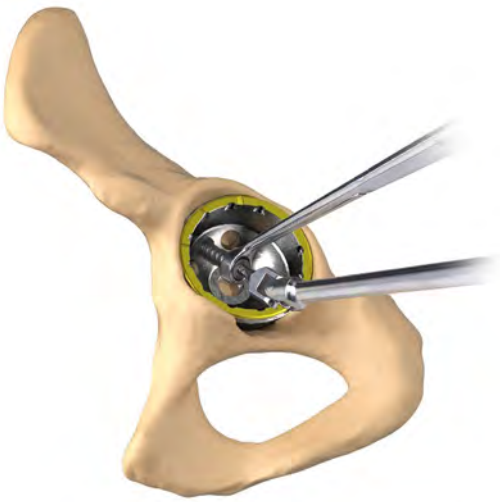

PPSP0110


PPPSTIVD


PPPCRIMP


P3CIMPAD





Screw Placement and Fixation (if quad option is implanted)

Procotyl® P quad shells are designed to allow additional fixation by means of screws. Determine screw location and select a suitable length drill bit. Drill bits are provided in 3.2 and 4.5mm diameters (8400FD05-06; 8400FD08-09). Engage the selected drill bit on the flexible drill shaft (8400FD12); the drill guide accommodates 3.2 and 4.5mm diameters (8400DG01). Insert the drill into the guide and carefully drill through the acetabular cortex.

Use the screw depth gauge (8400SG02) to determine the appropriate screw length.

CAUTION: Due to intra-pelvic vascular structures, screw placement in the medial aspect of the acetabulum must be carefully considered.

8400FD05-06, 08-09

4820SH0000

Grasp the screw head with the screw holding forceps (4820SH0000) and utilize the hex screwdiver to orient and fixate the screw (8400SD03 cardan or 8400SD06 solid screwdriver connected to 8400SD11 handle).

Centralize the screw to protect the threads from abrasion and assures countersinking of the screw head within the hole. Release the screw holding forceps (4820SH0000) to allow for countersinking of the screw head, which allows full seating of the prosthetic liner.

Full seating of the liner can be confirmed with the use of a trial liner prior to impacting the prosthetic liner, or by manually examining the inner surface of the shell to check if the screw head is proud.

CAUTION: To ensure proper prosthetic liner seating in the shell, all screw heads must be seated below the inner surface of the shell. Full and unobstructed seating is crucial to implant fit and longevity.

8400FD12

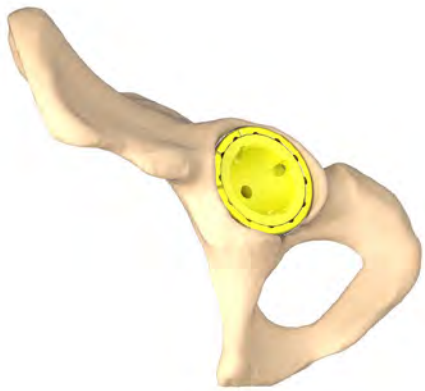
8400DG01

8400SG02

8400SD03

8400SD06

8400SD11



Trial Liner Placement

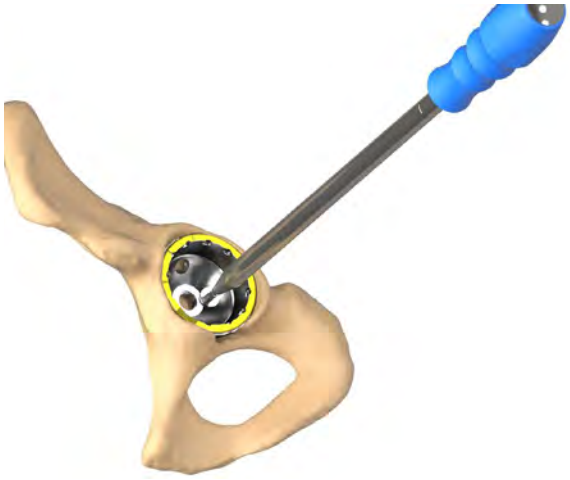
Trial liners that match the prosthetic implant are available to evaluate the optimum position of the implant and the preferred liner (PPP***LS with 0° and PPP***LL with 15° lip). With the prosthetic shell secured within the reamed cavity, insert the trial liner into the shell.

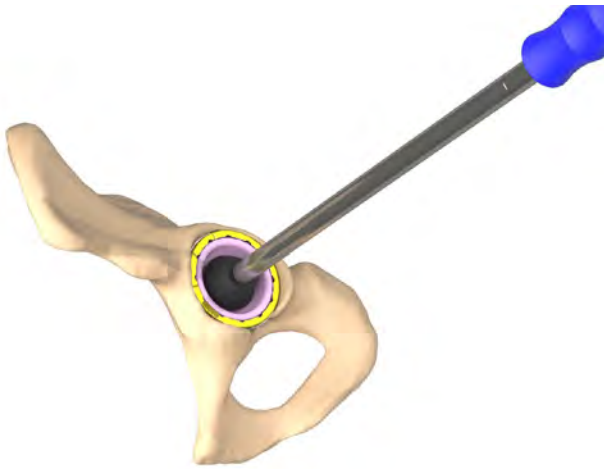
NOTE: Care should be taken to avoid neck/liner impingement in all potential positions. The acetabular component should be repositioned as necessary to relieve impingement. Alternatively, a change of modular neck could possibly solve the impingement phenomenon.

If a lipped liner is to be used, a reference mark should be made on the acetabulum to aid in proper positioning of the final liner implant.

*PPP***LS*

*PPP***LL*





Dome Plug Insertion (Optional)

After a satisfactory trial reduction and assessment of joint stability, the dome hole can be sealed with a dedicated plug.
NOTE: The apical plug is not included in the shell implant box and must be ordered separately (PPAP0000). The plug can be attached to the tip of the straight hex driver shaft (PPP35HSC) and will be kept in place by the retaining mechanism.

NOTE: The dome hole plug should not be inserted until a trial reduction with the trial liner is completed.

Liner Placement - Ceramic

Prior to inserting the final acetabular liner, thoroughly irrigate and clean the shell.
Ensure the interior of the shell is dry and free of debris and overhanging soft tissue that may impede liner seating.

Ceramic liners are inserted by hand. The inserter handle (PPPFLIMP) with mounted liner positioner (PPPLPM**) is applied and fixation is achieved by some light taps.

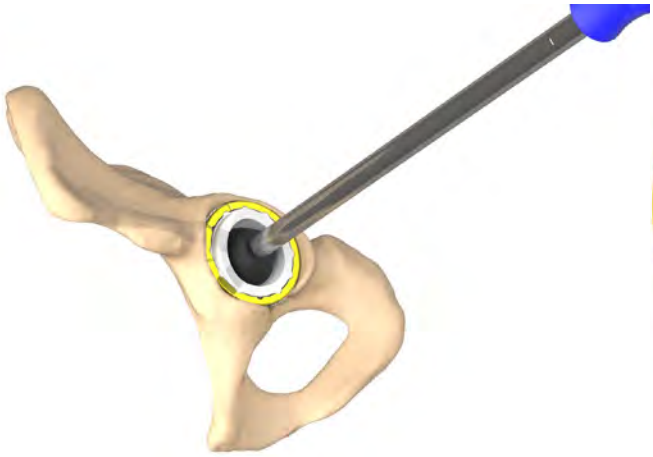
CAUTION: Make sure that the rim of the liner is circumferentially flush with the face of the shell before final seating.

PPAP0000

PPP35HSC

PPPFLIMP

PPPLPM28-32-36



Liner Placement - polyethylene

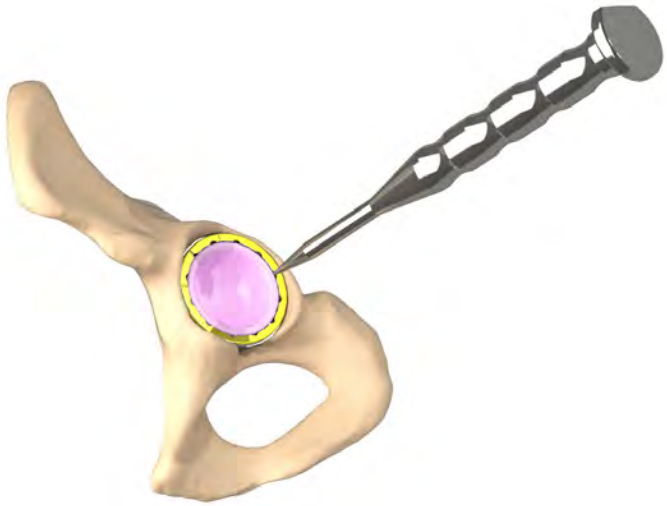
The liner positioner (PPPLPM**) is mounted on the inserter handle (PPPFLIMP).

Prior to inserting the final acetabular liner, thoroughly irrigate and clean the shell. Ensure the interior of the shell is dry and free of debris and overhanging soft tissue that may impede liner seating.

Insert the liner by hand in the shell, ensuring that the face of the liner is parallel with the face of the shell. Rotate the liners to ensure that the tabs are aligned and engaged with the shell. Apply gentle manual pressure to the dome region to provisionally secure the liner in place.

Prior to impacting the liner, ensure the handle is on axis with the shell. Impacting the liner off-axis may prevent complete seating. Apply a series of firm mallet blows on-axis to fully seat and engage the liner. Check to ensure the liner is fully seated by running your finger around the face of the shell. When properly seated, the polyethylene liner face and tabs will sit flush with the face of the shell.

CAUTION: Impacting the liner in a tilted position or impacting the liner off-axis may prevent complete seating.



If the removal of the implant is required due to revision, the surgeon should call the number on the back page of this surgical technique and select the option for customer service to receive instructions for returning the explanted device to the manufacturer for investigation

Poly Liner Removal

To remove a poly liner, a flexible drill bit (8400FD05-06; 8400FD08-09) with an acetabular drill guide (8400DG01) is used to drill a hole slightly off center from the liner apex. Using a 3.5mm hex screwdriver, a cancellous screw (20mm)(18080301) is then advanced into the drilled hole until the liner is removed.

Ceramic Liner Removal

To remove a ceramic liner a liner extractor (APA09314) is used. Position the tip of the liner extractor in a dimple in the face of the cup and apply some short mallet strokes. This results in a counteraction loosening the liner; repetitive action might be necessary.

18080301

APA09314

Chapter 4

Indications and Warnings

Intended Use

Acetabular Fixation Screws
Perforation of the pelvis with dome fixation screws or rim screws is to be completely avoided. Care is to be used when determining and selecting the proper length of screws to be used to prevent perforation of the pelvis.

Modular Acetabular Shell/Liner
Fixation screws, when used, should be fully seated to ensure stable fixation of the shell, and avoid interference with the liner component. Before implanting, be certain the selected shell and liner are compatible. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell and the shell must be thoroughly dried. Debris and fluid may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.

In order to prevent mismatch of tapers:
• Modular liners from MicroPort Scientific Cooperatief U.A. must be used only with shell components of the same system from MicroPort Scientific Cooperatief U.A.
• An exception to this rule is that MicroPort Biolox® delta ceramic liner components can be used with MicroPort Scientific Cooperatief U.A shells, as described in the product specific warnings section.

Other Modular Components (Femoral Head)
Always follow the recommended surgical technique. Failure to adhere to the advised assembly instructions may have potential to increase risk of fretting corrosion, fretting fracture or disassociation of the product. Prior to assembly, surgical debris must be cleaned from the interior of the female seat to ensure proper locking. Ensure components are firmly seated to prevent disassociation.

Ceramic femoral heads and acetabular liners should not be placed on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

On rare occasions, in vivo fracturing of the ceramic components may occur. In order to minimize this risk, the components were individually examined before delivery. Extremely careful handling is required with ceramic devices, which must not be used if dropped, even in the absence of any apparent damage. Even small scratches or impact points can cause wear and tear or fracture and lead to complications.

Cause of fracture can be an overload on the prosthesis, for example through incorrect placement of the ceramic head on the stem taper or a wrong or missing fit between the ceramic head and the stem taper.

The use of prosthesis components which are not released by MicroPort for combination with a ceramic component can also lead to the fracture of the implant.
The recommended position of the acetabular insert (inclination/ anteversion) must be observed. Only use a plastic tip to introduce the ceramic devices. Fracture of ceramic components is a serious complication. Only use a plastic tip to introduce the ceramic devices. Impact according to the recommended surgical technique.

Patients should be advised to report unusual noise and/ or sharp pain as both can be an indication of fracture. Decision to revise should not be postponed as ceramic fragments can cause severe damage to surrounding soft tissue and metal components. Revision outcomes after ceramic fractures can be compromised by the remaining ceramic debris present in the tissue even after careful debridement. Damage has been reported in polyethylene and metal components used in revisions after ceramic fractures.

Surgeons are advised to carefully consider all available implant options on an individual basis. It must be noted that removal of all components including femoral stems and acetabular shells may not prevent accelerated wear due to ceramic debris in the tissue. Partial or complete synovectomy has been recommended by some authors.

The joint may not luxate during movement or subluxate through impingement of the implant components or of soft tissue. Seat the acetabular shell at a 45° inclination with 15° anteversion for proper positioning to decrease the chance of dislocation. The inclination of the cup components should not significantly exceed or fall below a value of 40-45°. The anteversion of the cup components should not significantly exceed or fall below a value of 10-20°. Outside this range there are restrictions in movement which can lead to subluxations and/or dislocations of the femoral head from the ceramic insert. For a cup position which lies outside the abovementioned values, a ceramic insert must not be used.

For acetabular shells in retroversion, a ceramic insert must not be used. Possible consequences are an increase in the surface pressure on the cup edge with grain break-out from the ceramic insert associated with increased ceramic debris. Excessive ceramic debris can lead to adverse tissue reactions, loosening of the prosthesis and in extremecases ceramic breakage.

Ensure adequate joint tension is achieved on implantation, as luxation can also lead to the adverse results listed above. Always ensure proper alignment and seating of the acetabular liner before impacting to prevent chipping or damage.

Revision Surgery
Remove all ceramic particles. Any existing polyethylene acetabular bearing must also be removed, even if it is fixed in place.

IMPORTANT
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MicroPort Orthopedics

Full Function, Faster®

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