Procotyl® L

Acetabular Cup System

SURGICAL TECHNIQUE

MicroPort Orthopedics

Full Function, Faster®

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.

Table of Contents

Chapter 1

Indications and Warnings

Indications and Warnings

Intended Use
MicroPort acetabular systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of functional deformity; and,
4. Revision procedures where other treatments or devices have failed

The Procotyl® L Shells are intended only for uncemented arthroplasty.

Contraindications
Patients should be warned of these contraindications.

Contraindications include:

1. Overt infection;
2. Distant foci of infections (which may cause hematogenous spread to the implant site);
3. Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4. Skeletally immature patients (patient is less than 21 years of age at the time of surgery);
5. Cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6. Neuropathic joints;
7. Hepatitis or HIV infection;
8. Neurological or musculoskeletal disease that may adversely affect gait or weightbearing.

Preoperative Precautions
Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

Product Specific Warnings and Precautions
NEVER combine modular or hard bearing components made by different manufacturers.

Ceramic/ceramic articulating combinations should only combine bearing components from a single manufacturer to ensure the two components possess compatible manufacturing tolerances.

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

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 must be used only with shell components of the same system from MicroPort.
- An exception to this rule is that all MicroPort 18° taper liner components can be used with MicroPort 18° modular acetabular shells.

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.

The femoral head, neck taper of the femoral component, modular neck tapers, body taper, female seat of the proximal body **must** be clean and dry before assembly. Impact according to the recommended surgical technique. Scratching of femoral heads, modular necks and proximal and distal stem tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Do not resterilize femoral prostheses with ceramic femoral heads seated on the stem, as sterilization may cause undetectable ceramic damage. Please refer to the section below named Hip Bearing System or specific warnings and precautions regarding ceramic femoral heads.

Stems and modular necks with the 12/14 SLT Taper should only be used in combination femoral heads with the 12/14 SLT Taper.

Cobalt chrome femoral heads with the 12/14 SLT Taper are designed for use with cobalt-chrominum-molybdenum, titanium alloy and (ISO 5832-9) stainless steel femoral components with the 12/14 SLT Taper and to articulate with UHMWPE bearings only. The superfinished cobalt chrome femoral heads are designed to articulate with UHMWPE bearings.

Alumina Matrix Composite (Biolox® Delta) acetabular liners are designed for use with the following ceramic femoral heads (manufactured by CeramTec and packaged by MicroPort)

- Alumina Matrix Composite Ceramic Heads: Biolox® Delta Femoral Head

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.

CoCr Modular necks are not for use with the following devices:

- Alumina (Biolox® Forte) Ceramic Femoral Head size 28mm long
- Profemur® E Size 0 Hip Stem

Do not place ceramic components on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

The ceramic femoral head is placed on the stem taper by twisting lightly and using axial manual pressure until it sits firmly.

Place the plastic head impactor on the pole of the ceramic femoral head, and with a moderate tap of the hammer in an axial direction, firmly and definitively fix it on the stem taper. The surface structure of the metal taper becomes distorted plastically by the tapping of the impactor, causing an optimal distribution of pressure and a torsion-resistant fixation.

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 size 28mm "Long Neck" Alumina (Biolox® Forte) Ceramic Femoral Heads are indicated for use only with titanium alloy femoral stems. All other sizes of the Alumina (Biolox® Forte) Ceramic Femoral Heads and all sizes of the Alumina Matrix Composite Heads (Biolox® Delta) are indicated for use with titanium alloy, cobalt chrome, or MicroPort stainless steel (not available in the US or Canada) femoral stems.

The cross-linked Procotyl® Poly (UHMWPE) Liners are designed to articulate with the following ceramic femoral heads:

- Alumina "Ceramic Femoral Head" (Biolox Forte diameters 28-36mm)
- Alumina Matrix Composite "Biolox Delta Femoral Head" (diameter range 28-40mm)

Outside the U.S., alumina ceramic (Biolox Forte) acetabular liners are designed for use with the following Biolox ceramic femoral heads:

- Alumina "Ceramic Femoral Head"
- Alumina "Biolox Forte Femoral Head"
- Alumina Matrix Composite Ceramic Heads: "Biolox Delta Femoral Head"

Outside the U.S., Alumina Matrix Composite (Biolox Delta) acetabular liners are designed for use with the following ceramic femoral heads (manufactured by CeramTec and packaged by MicroPort):

- Alumina Matrix Composite Ceramic Heads: "Biolox Delta Femoral Head"

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. 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 above-mentioned 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.

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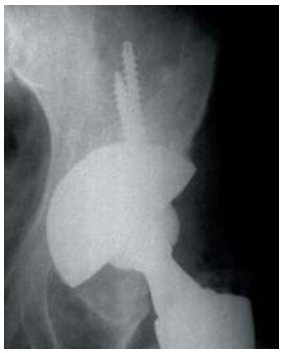
Chapter 2

Design Rationale



The 3 in-line screw holes are positioned away from the dome of the cup to achieve a maximum lever arm, optimal purchase in the illiac wing and thereby maximizing stability. The screws have a 20º freedom of direction.

X-ray courtesy of Dr. E. Tozzi, Pisa-Calambrone, Italy

Design Rationale

The Procotyl® L Acetabular Cup System provides surgical flexibility for shell fixation and bearing material choices. The shells are manufactured from titanium alloy, the material of choice for bio-compatibility. An irregularly layered porous titanium bead coating enhances initial fixation and long term bone apposition. An average porosity of 30% allows for enhanced bone ingrowth. Cups are available with or without additional hydroxyapatite coating. Three screw holes located in one quadrant of the cup allow for surgical flexibility.

Intra-operative flexibility: Procotyl® L Acetabular Cup System accepts ceramic and and A-Class® advanced cross-linked poly liners. Liners are securely locked by the Rim-Lock fixation system and the 18° internal taper.

Procotyl® L acetabular components are indicated to be used in conjunction with Profemur® femoral components, either with a modular or a fixed neck option.

Today's orthopedic surgeons face many challenges with acetabular fixation. As improved mechanical designs, bearing materials and techniques diminish short term failures, the focus has moved to long term survivorship.

The Procotyl® L Acetabular Cup System has integrated several design features to address contemporary issues. The intrinsic design features that address contemporary two-piece acetabular cup issues, coupled with multiple liner configurations, make the Procotyl® L Acetabular Cup System the choice for surgeons requiring a wide range of primary, revision and bearing material options. The unique internal taper and Rim-Lock locking groove allows polyethylene or ceramic bearing liners to be used in a single shell design. A 14° rim flare geometry transfers load to the periphery of the acetabulum, encouraging long term intrinsic stability. Cups come with three holes for additional fixation by means of screws. From size 44 and up these holes are provided with a plug, including the apical hole.

Chapter 3

Procotyl® L Cup Design Features

Ordering Information		
Templates	LNG2CL01E	0˚ Lip Liner
	LNG2CL02E	15˚ Lip Liner
Surgical Technique	011088	
Instruments	APH04410	
Implants	PLPCKITA	Non-coated Cups
	PLHAKITA	HA-coated Cups
	CERAKITB	Ceramic Liners
	XLINKITB	Poly Liners
	SUFIKITA	Metal Heads
	CERAKITA	Ceramic Heads

Secure initial stability
Additional screw fixation

Optimal ingrowth surface
Sintered Titanium beads
30% Porosity - avg.
114 µm pore size

Increase ball bearing diameters
46mm cup - 32mm head
52mm cup - 36mm head

56mm cup - 40mm head
(Ceramic heads only)

Optimal outer geometry
- Hemi-spherical - Single radius 152°
- Flattened dome
- Equatorial rim flare (14º)

Comes in sizes 42 - 68
(2 mm increments)

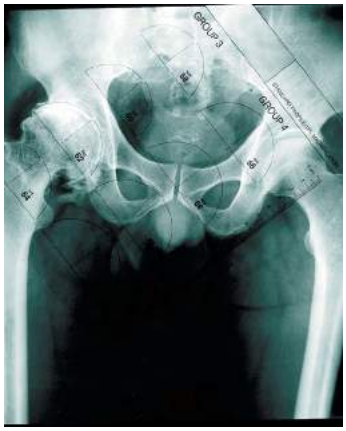
Procotyl® L cup
accommodates 2 types of liners

A-CLASS® Advanced X-linked Poly liner
- 0° and 15° lip options
- 360° lip position
- 28, 32 and 36mm inside diameters

Ceramic liner
- Alumina Matrix composite
- 0° lip
- Standard offset
- Taper locking
- 28, 32, 36 and 40mm inside diameters

Chapter 4

Preoperative Planning



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® L Acetabular Cup System are available in 15% magnification, with 0° or 15° liners. 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.

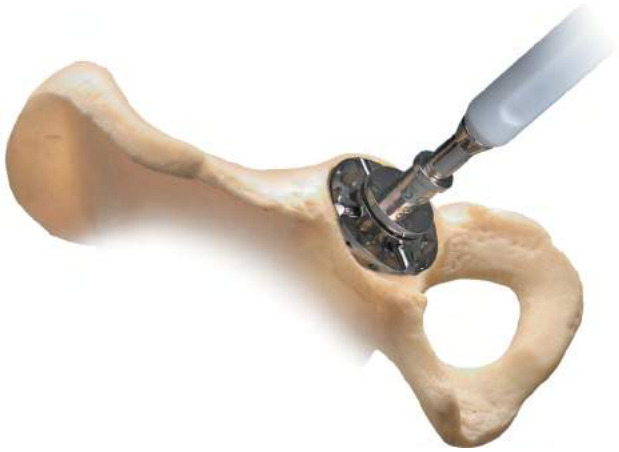
NOTE: Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip.

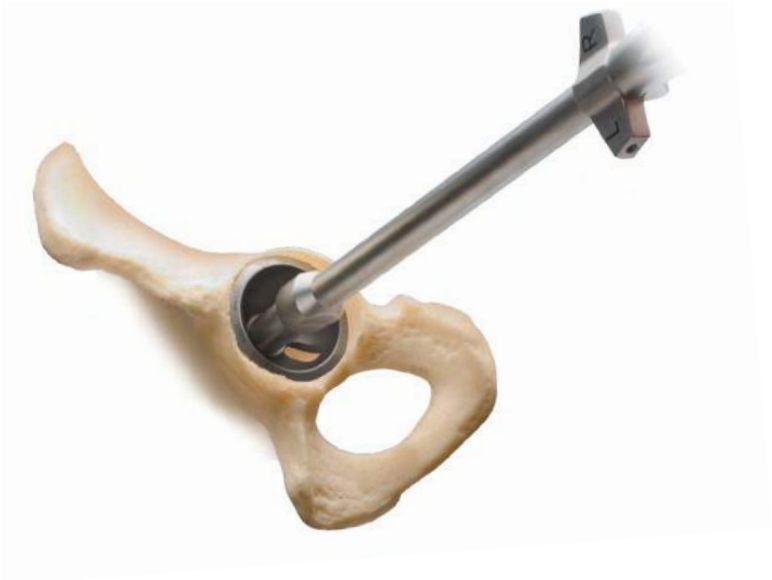
NOTE: The use of a magnification marker will aid in determining the x-ray magnification.

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

Chapter 5

Surgical Technique





Preparation of the Acetabulum

Osteophytes should be removed to enable assessment of the true acetabular rim. Reaming should be equential 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.

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

NOTE: Reamers are not included in the Procotyl® L instrument set.

Ream to the size of the component to be implanted. This will provide a 2mm press fit at the rim, and a 1mm press fit at the dome.

Reaming depth, acetabular shape and size can be confirmed by using a trial shell sizer.

Procotyl® L Cup Reaming Guide

For equatorial press-fit of	1mm ream to	2mm ream to
Procotyl® L size 42	43mm	42mm
Procotyl® L size 44	45mm	44mm
Procotyl® L size 46	47mm	46mm
Procotyl® L size 48	49mm	48mm
Procotyl® L size 50	51mm	50mm
Procotyl® L size 52	53mm	52mm
Procotyl® L size 54	55mm	54mm
Procotyl® L size 56	57mm	56mm
Procotyl® L size 58	59mm	58mm
Procotyl® L size 60	61mm	60mm
Procotyl® L size 62	63mm	62mm
Procotyl® L size 64	65mm	64mm
Procotyl® L size 66	67mm	66mm
Procotyl® L size 68	69mm	68mm

A trial shell adapter (APA09310) is put onto the tip of the cup inserter instrument before mounting the trial shell which corresponds with the final reamer. The adapter is kept in place by a locking ring; the shell is fixed by turning the central rod of the cup inserter clock-wise. Following trialing the shell and adapter are to be removed from the cup inserter instrument.

Use of the Procotyl® L trial acetabular components is strongly suggested in order to verify depth of reaming as the initial stability of the acetabular component is predominantly provided by its rim flare. Reaming therefore needs to be performed sufficiently deep in order to fully seat the cup within the bony cavity.

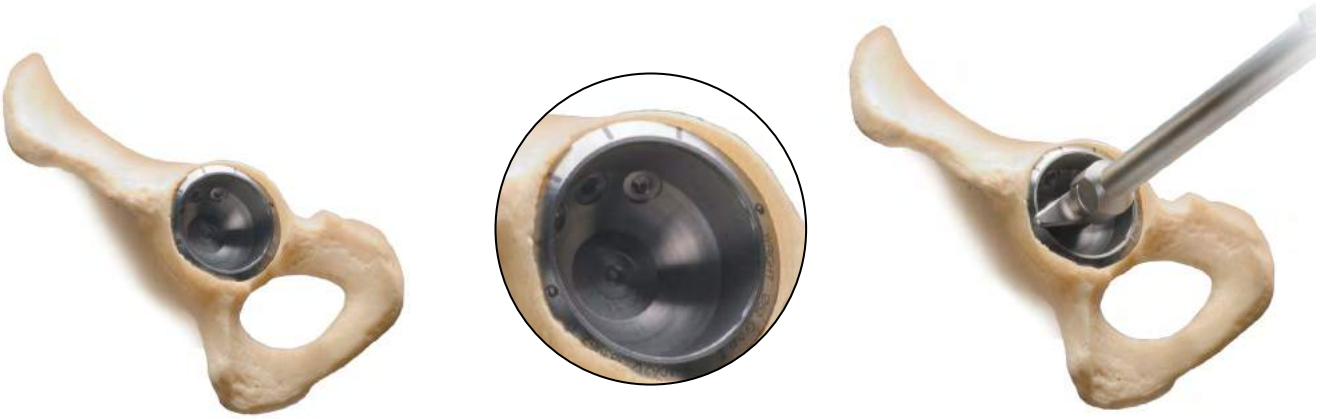
NOTE: The trial shells are equal in dimensions to the corresponding final implant but without rim flare and porous coating.

NOTE: In cases where hard (sclerotic) bone is encountered and/ or most of the subchondral plate is kept intact, the user may experience some difficulty inserting the trial shell. This may indicate a very tight fit with the shell and it is recommended that the cavity is reamed up by 1mm. In cases where there is no hard bone and the trial cup can easily be inserted but nevertheless initial final implant stability can not be obtained, it may be of help to ream the acetabular cavity slightly deeper with the last used reamer.

APA09310

APA09301

APA09322 - 48



Inserting the Shell

A full series of cup size dedicated adapters (APA09303 - APA09309) is available in the instrument kit. The adapter corresponding to the preferred cup size is put onto the tip of the cup impactor (APA09301), followed by the acetabular component. The pins on both arms of the adapter are to match the dimples in the face of the cup. This method of stabilization provides full control over the position of the cup at impaction.

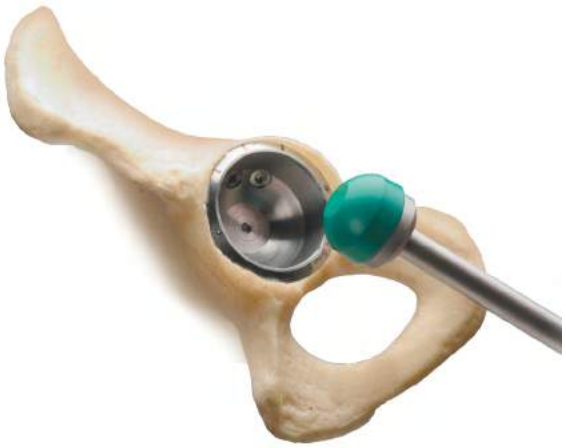
NOTE: The face of the shell has three laser marked lines that correspond to the screw hole locations. Position the marks between the plane of the anterior-superior and the anterior-inferior iliac spine.

Seat the shell with a series of firm mallet blows on the end of the impactor.

Once seated, the cup inserter instrument can be removed by turning the central rod counter-clockwise. Complete seating of the implant can be confirmed through the apical hole.

APA09301

APA09303 - 09



Inserting the Shell (continued)

Screw placement can begin once the shell component is securely positioned and the impactor (APA09301) is removed.

In case re-positioning of the cup is required, the cup inserter instrument (APA09301) can be mounted again and the cup can be removed, re-oriented and re-implanted.

If a deeper seating is preferred, it might help to attach the cup impactor tip (PPR68070) to the universal rod (PPR68030) and use this as a cup inserter device. The flat of the cup impactor tip is to be positioned properly against the flat of the cup dome before hitting the universal handle with a hammer.

Two alignment rods (APA09302) can be mounted on the inserter to aid in positioning the implant at 45° of abduction and 15° of ante-version. Position the longitudinal guide rod 90° to the midline of the patient to position the shell at 45°. Position the transverse guide rod parallel to the midline of the patient as this will place the implant at 15° of inclination. Positions given are based on a posterior approach / affected side up.

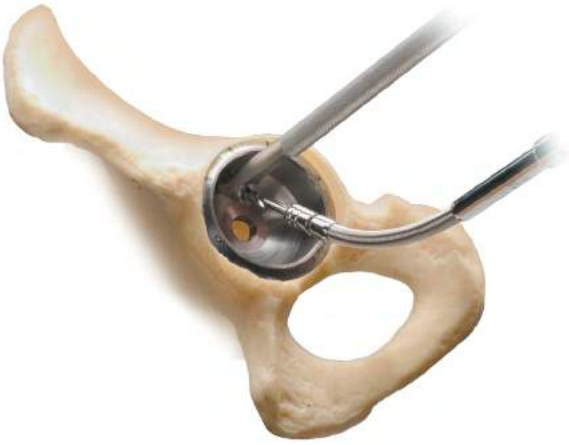
NOTE: The patient might have shifted during surgery and the alignment rods can therefore only be seen as an orientation guide.

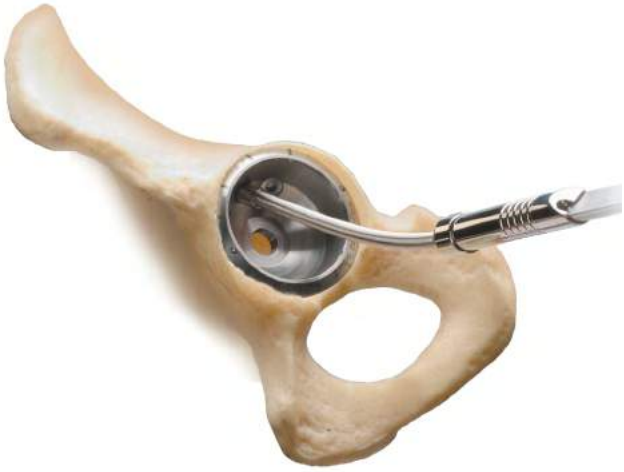
PPR68030

APA09301

PPR68070

APA09302





Screw Placement and Fixation

Procotyl® L 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.

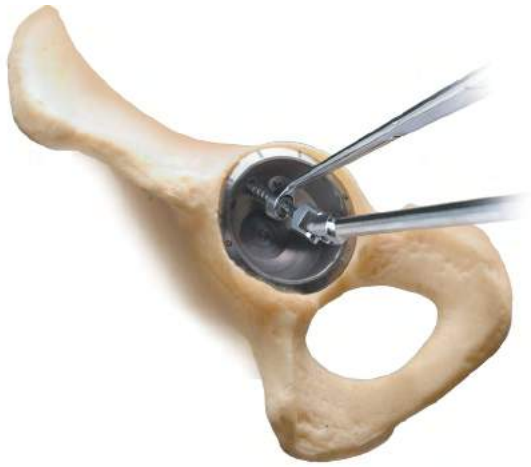
CAUTION: Due to intra-pelvic vascular structures, screw placement in the medial aspect of the acetabulum must be carefully considered.

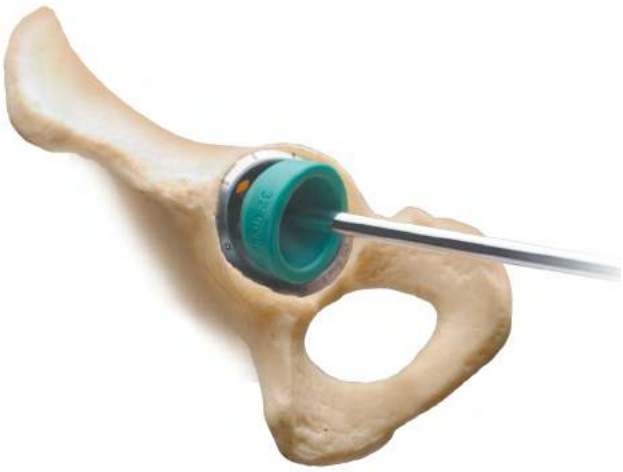
8400FD05-06, 08-09

8400FD12

8400DG01

8400SG02





Screw Placement and Fixation (continued)

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.

Trial Liner Placement

Trial liners that match the prosthetic implant are available to evaluate the optimum position of the implant and the preferred liner (APA09482-98; APA09400-02 with 0˚ and APA09464-74 with 15˚ lip). With the prosthetic shell secured within the reamed cavity, insert the trial liner into the shell.

4820SH0000

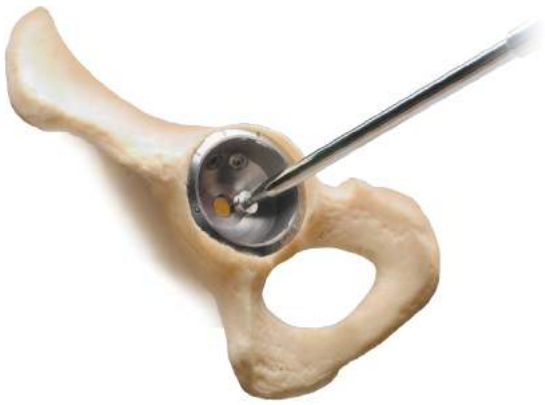
8400SD03

8400SD06

8400SD11

APA09482-98;APA09400-02

APA09464-74



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.

Position the trial liner in the desired orientation and secure it with the captured screw using a 3.5mm hex screwdriver (8400SD09 cardan or 8400SD10 solid screwdriver connected to 8400SD11 handle). 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.

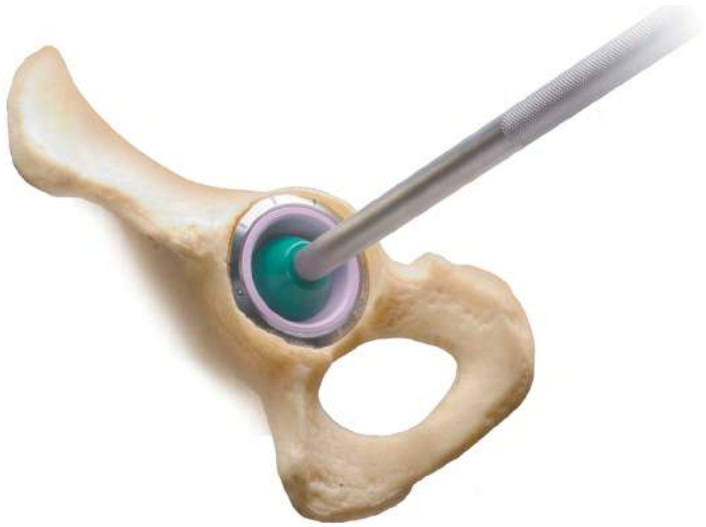
NOTE : The hard-on-hard liners allow for larger bearing diameters than polyethylene liners, which causes an 'overlap' in the femoral head size range. The difference between group C 28/32 and group E 32/36 is made clear by trial liner colour coding.

Dome Plug Insertion

After a satisfactory trial reduction and assessment of joint stability, seal the dome hole with the special plug.

Whereas the screw hole plugs are pre-mounted, the dome hole plug comes separate in the packaging (except size 42mm). The plug can be attached to the tip of the straight hex driver shaft (8400SD10) 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

Assemble a 0° (APA07054-56; APA09311) or 15° (APA07060-62; APA09312) lipped liner positioner to the impactor handle (PPR68030). Place the liner and hold it by hand.

Place the liner in the selected position making sure the face of the liner is parallel to the face of the shell. Apply a series of firm mallet blows to fully seat the liner, followed by removal of the inserter.

CAUTION: Improper position and impaction of the liner will damage the liner.

Hard-on-hard bearing liners are inserted by hand. The inserter handle (PPR68030) with mounted liner positioner (PPR68038 for 28; APA04565 for 32; APA09313 for 36 and APA09440 for 40) is applied and fixation is achieved by some light taps.

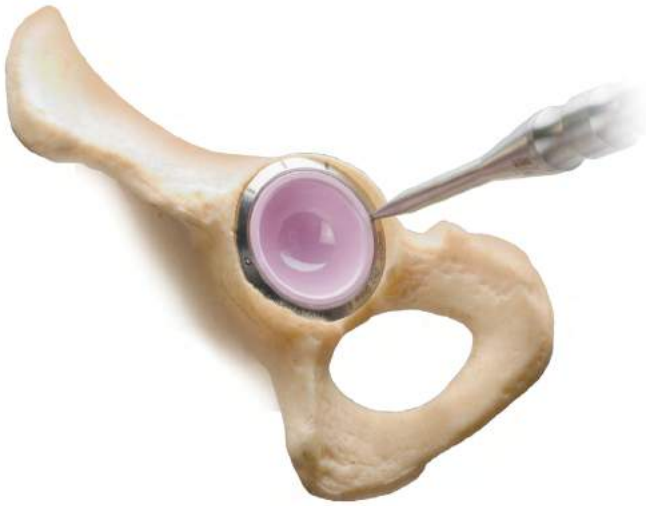
NOTE: Make sure that the rim of the liner is circumferentially flush with the face of the shell before final seating.

APA07054-56; APA09311

APA07060-62; APA09312

PPR68030

PPR68038 ; APA04565; APA09313; APA09440



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.

X-linked Poly Liner Removal

Rremove 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

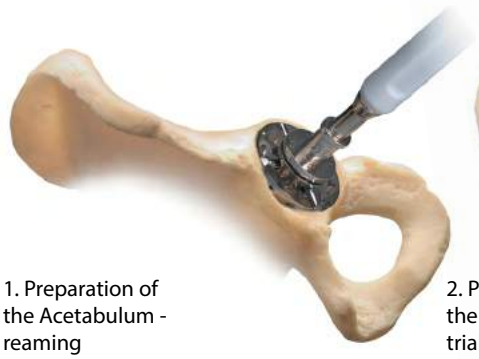
To remove a ceramic liner a liner extractor (APA09314) is used. Position the tip of the liner extractor in a dimple in the face of the cup and apply some short mallet strokes. This results in a counteraction loosening the liner; repetitive action might be necessary.

18080301

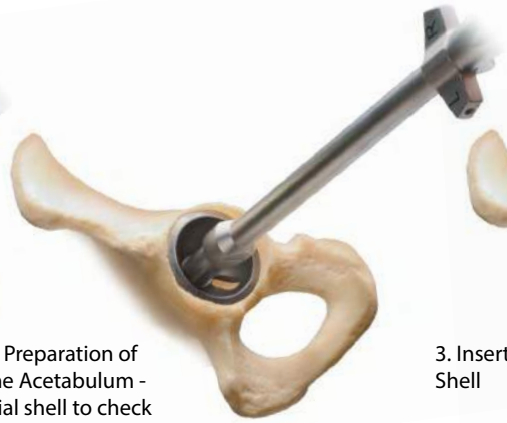
APA09314

Chapter 6

Technique Overview



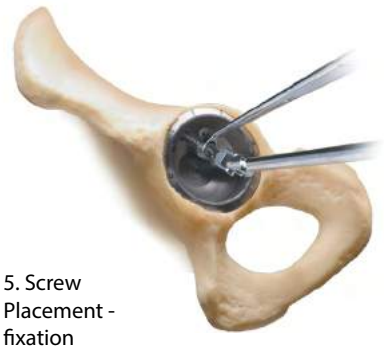
1. Preparation of the Acetabulum - reaming



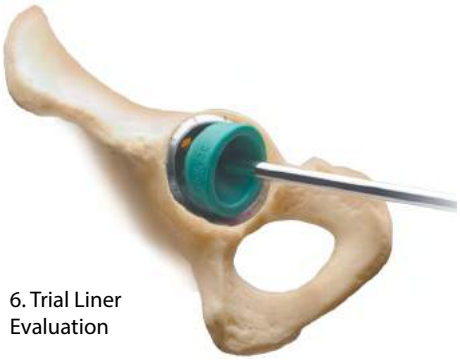
2. Preparation of the Acetabulum - trial shell to check reamed cavity

3. Inserting the Shell

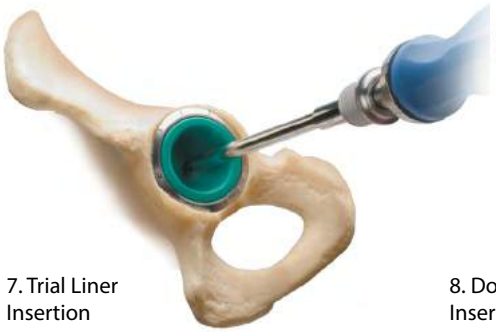
4. Screw Placement - drilling



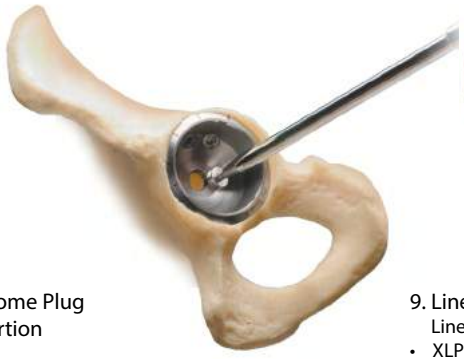
5. Screw Placement - fixation



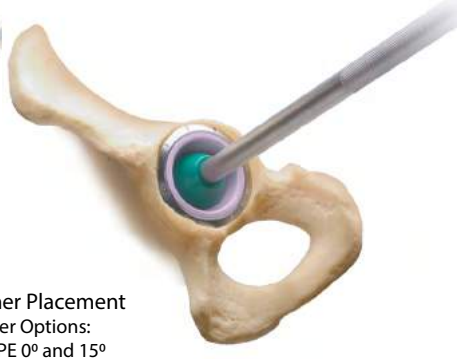
6. Trial Liner Evaluation



7. Trial Liner Insertion



8. Dome Plug Insertion



9. Liner Placement

Liner Options:

- XLPE 0º and 15º
- Ceramic

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