MicroPort

PRIME ACETABULAR CUP SYSTEM

Surgical Technique

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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.

INDICATIONS AND WARNINGS

Please refer to package label and package insert for device compatibility information.

IFUs and Contraindications Intended Use

MicroPort total hip 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:

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

The cross-linked " PRIME A-CLASS®" and "E-CLASS™ Poly (UHMWPE) Liners" are designed to articulate with the following ceramic femoral heads:

- Alumina "Ceramic Femoral Head" (Biolox Forte diameters 28-36mm)
- Alumina "CONSERVE® Total BCH® Femoral Head" (diameter range 40-44mm)
- Alumina Matrix Composite "Biolox Delta Femoral Head" (diameter range 28-40mm)
- Alumina Matrix Composite "Delta Option Head" (diameter range 28-44m

The cross-linked "PRIME A-CLASS®" and "E-CLASS™ Poly Liners" are to be used with ceramic heads or the following metal heads (Some designs are not available in U.S. or European Union):

- Femoral Head CoCr with the SLT taper
- LINEAGE®/TRANSCEND® Femoral Head SuperFinished CoCr with the SLT taper
- CONSERVE® BFH® Head with the SLT taper
- CONSERVE® A-CLASS® BFH® Head with the SLT taper
- CONSERVE® Total A-CLASS® Femoral Head with the SLT tap

Ceramic Femoral Heads

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 Femoral Head") are indicated for use with titanium alloy, cobalt chrome, or MicroPort stainless steel (not available in the U.S. or Canada) femoral stems. 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 torsionresistant 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. 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. Metal heads should not be used after a ceramic fracture. 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.

Important

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 insert is available on the website listed.

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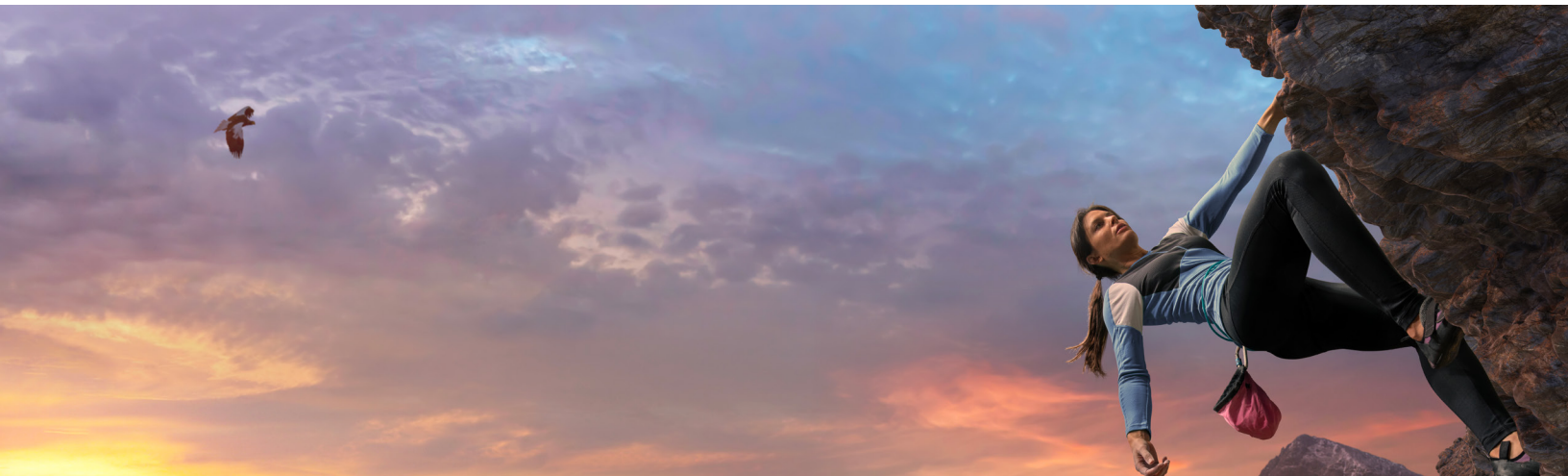

Introduction

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 singular bearing surface, the shell has also been optimized for modern biological fixation. Designed with simple, versatile instrumentation, the system can be used with a variety of surgical approaches.

SURGEON DESIGN TEAM

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Design overview

INTELLIGENT DESIGN

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

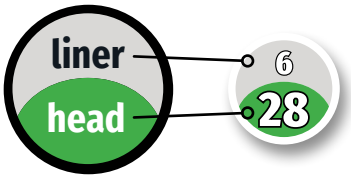
Minimized shell thickness

decreases stiffness, discourages stress shielding, and allows for optimized liner thickness

Self-Positioning Anti-Rotational Tabs
creates an interference fit with the liner to maximize rotational stability while allowing ease of insertion

BioFoam® and AM BioFoam® Cancellous Titanium
provides immediate fixation and promotes press-fit

SPECIFICATIONS KEY



Liner thickness is noted in grey field and head size is noted in color field. All values are in millimeters.

- Liner thickness increases in 2mm increments within group.
- Head sizes increase in 4mm increments within group.

Groups:
Groups are color-coded.

B

C

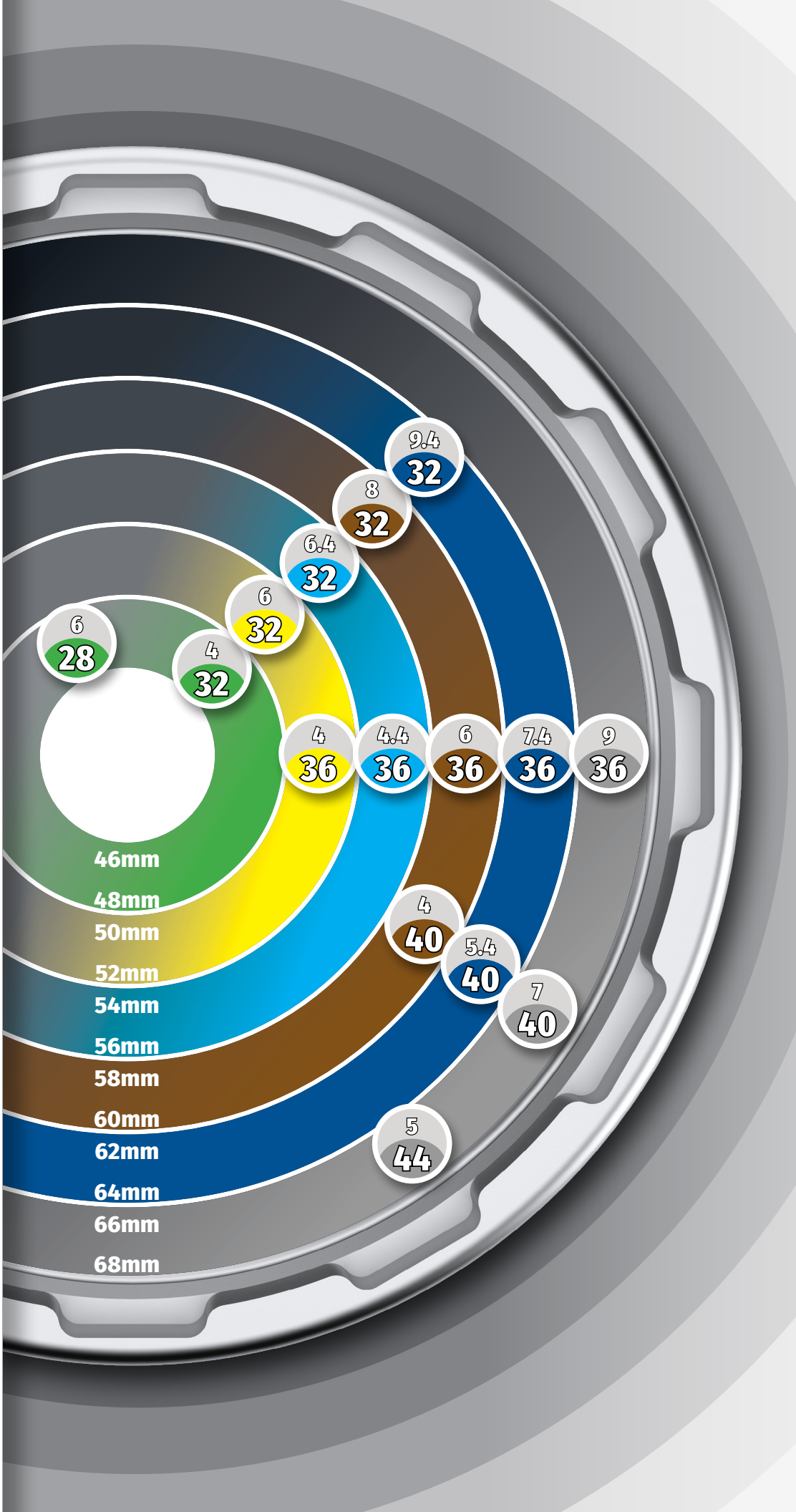
D

E

F

G

NOTE: Measurements represent liner thickness at the load-bearing point.



SHELL OPTIONS

For complete ordering information, refer to the Prime Ordering Guide (017223). Some devices may not be available in all markets.

Solid

Quad
Available in traditional BioFoam®
and AM BioFoam®

Multi-Hole

LINER OPTIONS

NOTE: All liners are available in both A-Class® Highly Cross-Linked Polyethylene and E-Class™ Vitamin E Blended Highly Cross-Linked Plolyethylene.

Standard

Lipped

Lateralized Face-Changing

HEAD OPTIONS

NOTE: Corresponding sleeves shown below.

Biolox® Delta®
ceramic head

Biolox® Delta® Option
ceramic heads
and sleeves

Titanium Sleeve
used with option
ceramic head

A-Class®
backfilled metal

Titanium Sleeve
used with
backfilled metal

CoCr Metal

Surgical technique

Preoperative planning

Preoperative assessment of the appropriate size and position of the acetabular component will provide intra-operative guidance for acetabular reaming.

An A/P x-ray of the pelvis will aid in leg length and offset assessment and management. Leg length discrepancies should be determined preoperatively and addressed intra-operatively. Radiographic overlays for the Prime Acetabular Cup System are available in 15% magnification.

CAUTION: Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively. Accurate preoperative templating requires good quality standardized radiographs of the appropriate anatomy.

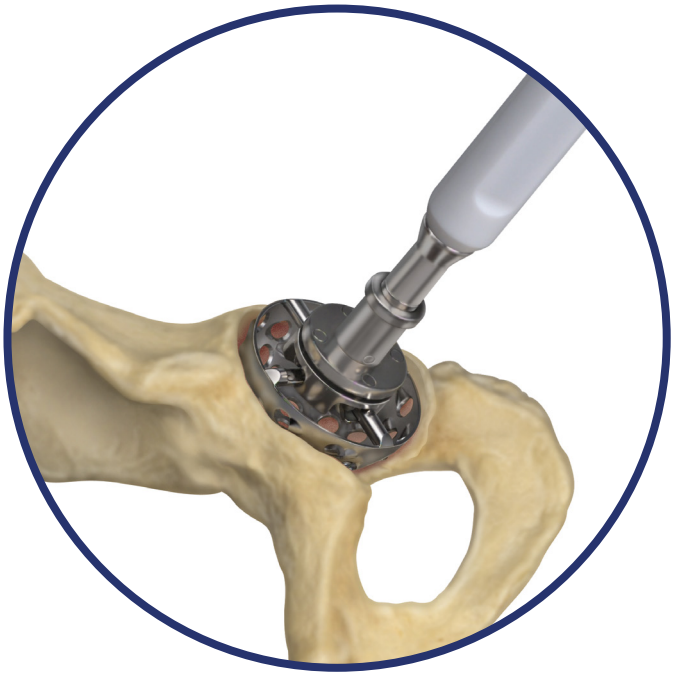
Digital template files are available for all major PACS software packages. Please contact your local sales representative for instructions on how to download.

Prime cup reaming guide

Group	Color key	Cup diameter	1.5mm Press-Fit to:
B	●	46mm	45mm
B	●	48mm	47mm
C	●	50mm	49mm
C	●	52mm	51mm
D	●	54mm	53mm
D	●	56mm	55mm
E	●	58mm	57mm
E	●	60mm	59mm
F	●	62mm	61mm
F	●	64mm	63mm
G	●	66mm	65mm
G	●	68mm	67mm

Preparation of the acetabulum

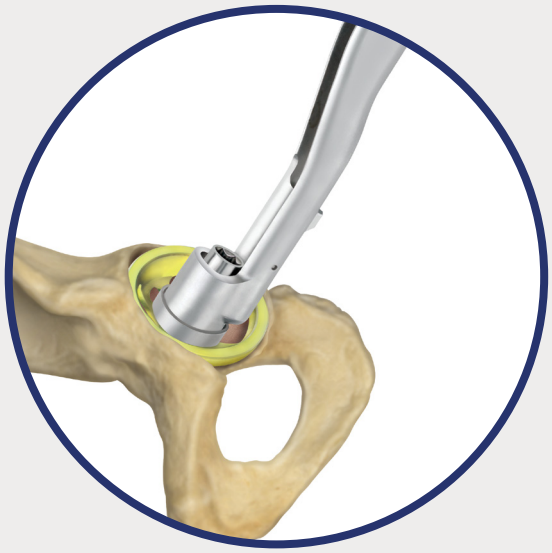
Ream the acetabulum sequentially, starting with the smallest reamer that conforms to the acetabular cavity. Gradually enlarge the acetabulum by reaming articular cartilage until a continuous surface of cancellous bone is exposed. Final reamer should be 1mm smaller than the cup to be implanted.



Sizing the acetabulum

Assemble the modular impactor handle, the straight or curved shell impactor, and the threaded adapter. Thread the trial shell onto the impactor assembly to check the size of the acetabulum. For ease of insertion, the trial shells are a complete hemisphere and are undersized by 1mm compared to the actual implant. They also have four large open windows for visualization.

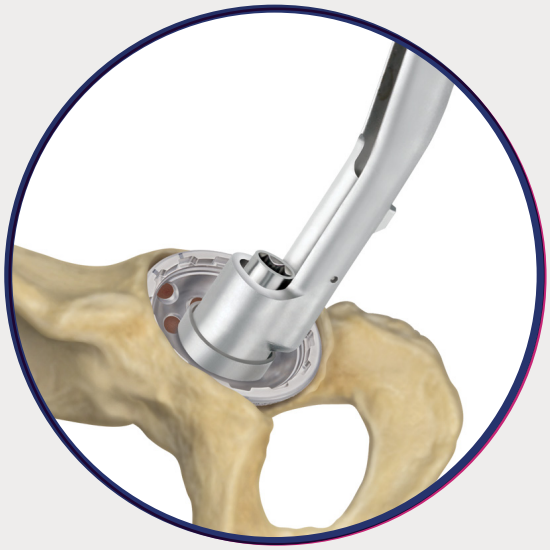
NOTE: The curved shell Impactor, the straight shell Impactor, and the threaded adapter must be ordered separately.



Inserting the shell

Remove the threaded adapter and replace with the quick release adapter then thread the appropriate size shell onto the impactor assembly. Laser markings 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 making sure the screw holes are in the appropriate location. Complete seating of the implant can be confirmed through the apical hole and screw holes. Once the shell is impacted, insert the cup impactor driver into the quick release adapter and turn it one quarter counter-clockwise to disengage the impactor assembly from the shell.

NOTE: The quick release adapter must be ordered separately. The threaded adapter can also be used for shell insertion and impaction. For the SuperPath® surgical approach, the Prime cup impaction portal adapter must be ordered separately and used per the SuperPath® surgical technique.



Modular Impactor Handle
P/N P3MODIMP

Straight Shell Impactor
P/N P3SIMSTR

Curved Shell Impactor
P/N P3SIMCUR

Threaded Adapter
P/N P3SIMTHA

Quick Release Adapter
P/N P3SIMQRA

Cup Impactor Driver
P/N 20162012

20mm Drill Bit
P/N P3FDB420

40mm Drill Bit
P/N P3FDB440

Short Flexible Drill Shaft
P/N 8400FD12

Long Flexible Drill Shaft
P/N P3FLDRSH

Ratchet Screwdriver Handle
P/N 8400SD11

3.5mm Hex Universal Joint Driver
P/N 8400UD03

Adjustable Drill Guide
P/N P3DRGADJ

Angled Screw-Holding Forceps
P/N P3SCHOAN

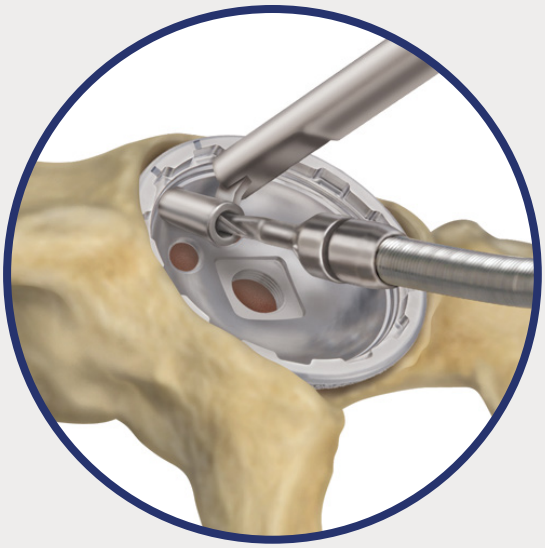
In-Line Screw-Holding Forceps
P/N P3SCHOIL

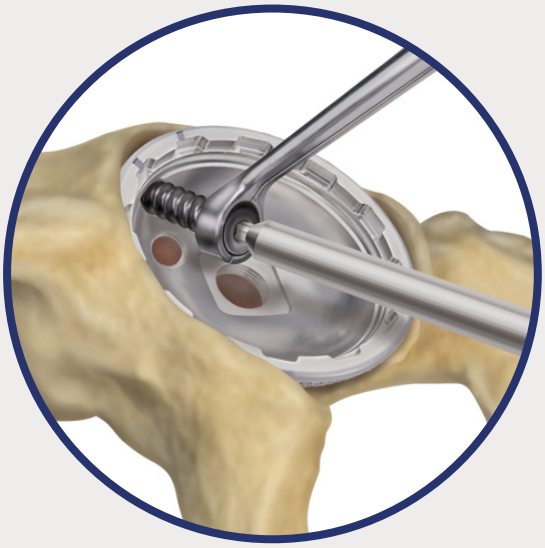
Short Ball-and-Socket Torx Screwdriver
P/N P3SDTOBS

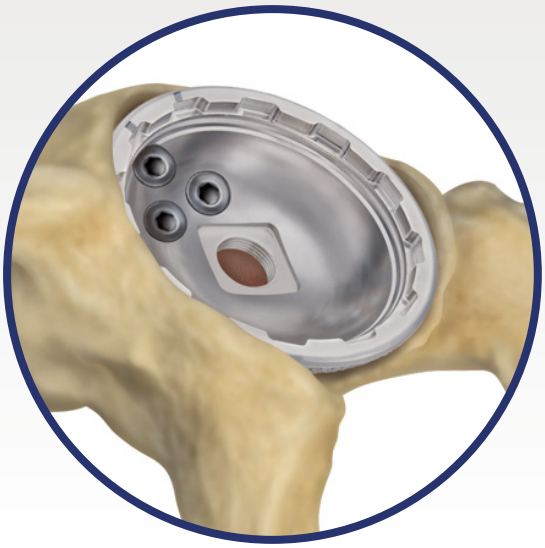
PRIME Universal Joint Torx Driver
P/N P3SDTOUS

Long Straight Torx Screwdriver
P/N P3SDTOSL

Long Ball-and-Socket Torx Screwdriver
P/N P3SDTOBL







Screw placement

Determine the screw location and select a suitable length drill bit. Drill bits are 4mm in diameter and provided in 20mm and 40mm lengths. Assemble the selected drill bit onto the short flexible drill shaft or long flexible drill shaft.

Position the adjustable drill guide into the shell ensuring that it is placed into one of the screw holes. Insert the drill bit into the adjustable drill guide and carefully drill through the acetabular cortex.

NOTE: The 40mm drill bit has a gold-colored coating (TiN) until the 30mm mark to help determine appropriate screw length.

With the angled screw-holding forceps or in-line screw-holding forceps, grasp the screw head and utilize a torx screwdriver attached to the ratchet screwdriver handle to orient and fixate the screw. Release the screw-holding forceps to allow for the countersinking of the screw head.

Ensure the screw head is completely seated and does not protrude into the shell space, as this may prevent the liner from seating.

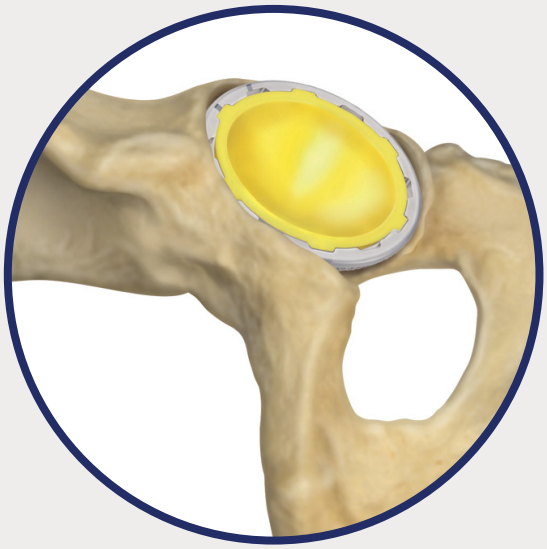
NOTE: A short ball-and-socket torx screwdriver, short straight torx screwdriver, long ball-and-socket torx screwdriver, and long straight torx screwdriver are included in the Prime general instrument kit. Short drivers are intended for traditional surgical approaches such as posterior. The longer drivers are intended for portal assisted approaches, but may also be helpful in high BMI patients. The ball-and-socket versions are intended for other small incision approaches such as anterior or direct superior.

Trial liner placement

Trial liners are available to evaluate the position of the final implant. The trial liners can be used with the final shell implant. Perform a trial reduction.

Once a well-balanced hip joint has been achieved, remove the trial liner. Trial liners have two inset grooves to assist with removal. A Cobb elevator can be used to lever out the trial liners.

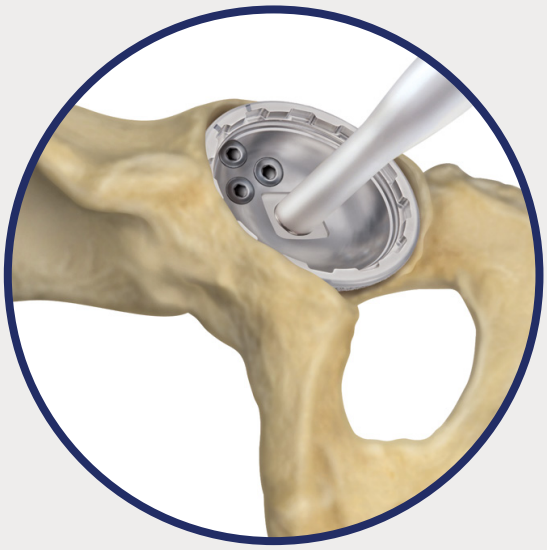
NOTE: For SuperPath® users, the SuperPath® trial liner remover must be ordered separately.



Apical hole plug insertion

Do not insert the apical hole plug until after final trial reduction with the trial liners. After the trial reduction, seal the apical hole with the apical hole plug. The poly rod will break off at the plug once it is tightened into the apical hole. A final tightening of the hole plug should be performed using the 3.5mm hex screwdriver.

NOTE: The apical hole plug/poly rod must be ordered separately.



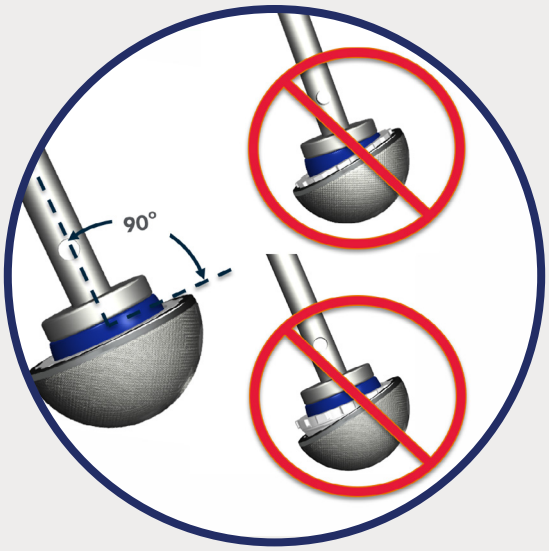
3.5mm Hex Screwdriver
P/N PP275400

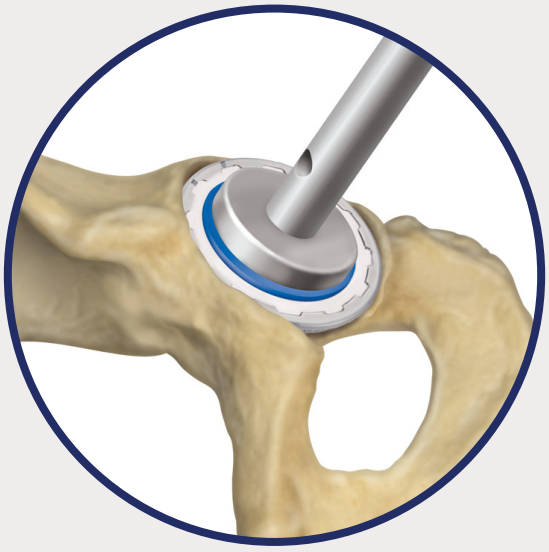
Apical Hole Plug / Rod
P/N 3818000200

Straight Liner Impactor
P/N P3LIMSTR

Curved Liner Impactor
P/N P3LIMCUR

Trial Head Impactor
P/N 33330015





Liner insertion

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 ensuring that the face of the liner is parallel with the face of the shell and 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.

Assemble the modular impactor handle, the straight liner impactor or the curved liner impactor, and the liner impactor tip. Tighten the trial head impactor in a clockwise direction until it can no longer be turned. Attach the appropriate femoral head trial corresponding to the liner inner diameter.

Place the head trial into the liner. 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.

Liner extraction

Assemble the liner extraction guide handle and the liner extraction guide that corresponds with the liner inner diameter.

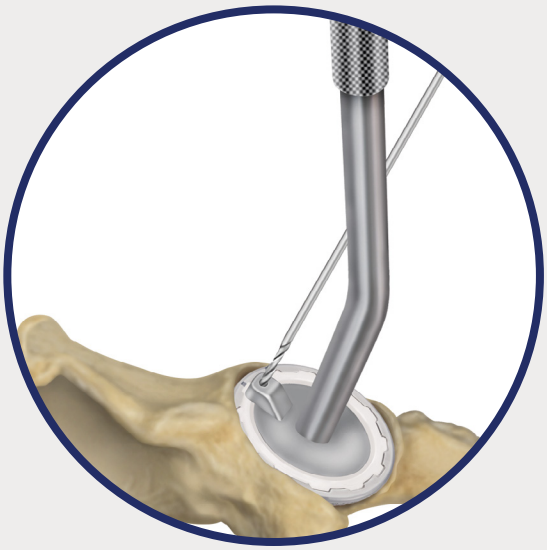
Seat the liner extraction guide into the liner and with the liner extraction drill, drill a hole in the rim of the liner. Remove the liner extraction guide and thread the liner extraction screw into the drilled hole, which will cause the poly liner to disengage from the shell.

If the metal shell is scratched during the process of removing the liner, it should also be removed and replaced.

NOTE: If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation. Refer to ordering guide.

If removing a lateralized (15 degree liner), angle the drill bit at approximately 15 degrees from the axis of the shell and drill the pilot hole for a screw (do so on the low-walled side).

Should the drill cut through the inner diameter of the polyethylene, drill a new hole in an alternate location around the rim, slightly decreasing the entrance angle relative to the axis of the shell.



Shell removal

Should removal of the metal shell ever be necessary, an osteotome, small burr or cup extraction osteotome can be passed around the cup periphery to loosen the fixation interface.

- Begin by removing all bone screws from the acetabular shell.
- Impact with a mallet 45 degree bent or curved osteotomes sequentially around the periphery of the shell and work toward the apex of the shell to separate any ingrown bone from the shell until the implant is fully unseated.
- If the bone near the rim is sclerotic, preparation may be initiated with a straight osteotome.
- Attach inserter handle to apex of shell once liner and all bone screws have been removed to assist in final explantation.
- Careful examination of the removed component and remaining acetabular bed is recommended to ensure the structural preservation of the anterior and posterior columns as well as the medial wall.
- Any osteolytic cysts should be curetted and irrigated.

Liner Extraction Guide Handle
P/N P3LXDGHA

Liner Extraction Guide
P/N P3LXDG22
-P3LXDG44

Liner Extraction Drill
P/N P3LEXTDR

Liner Extraction Screw
P/N P3LEXTSC

Notes

Notes

MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN USA 38002
866 872 0211

microportortho.com

The CE-Marking of Conformity is applied per catalog number and appears on the outer package label, if applicable.

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