MicroPort Orthopedics

DYNASTY® BIOFOAM®

Acetabular Cup System Surgical Technique

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Indications and Warnings

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

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

Shells with BIOFOAM® metal foam coating and DYNASTY® modular shells with porous metal bead coating are intended only for uncemented arthroplasty.

The size 50 and 54mm alumina ceramic "CONSERVE® Total BCH® Femoral Heads" are only intended for patients with giganticism or malunion of the acetabulum, and/or revision.

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 weight-bearing.

Additional contraindications for the "CONSERVE® Femoral Resurfacing Component/Head" include (Not available in European Union):

1. inflammatory degenerative joint disease;
2. severe osteopenia.

Additional contraindications for a metal-on-metal bearing include (Not available in U.S. or European Union):

1. Patients with known moderate to severe renal insufficiency;
2. Females of childbearing age are contraindicated due to the unknown effects of elevated levels of metal ions on the fetus.

(Canada Only) CONSERVE® Plus and CONSERVE® A-CLASS Total Resurfacing Systems are contraindicated for female patients UNLESS they require heads ≥50mm and there is no evidence of dysplasia.

Product Specific Warnings and Precautions

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.

NEVER combine modular or hard bearing components made by different manufacturers.

Metal/metal (not available in U.S.) articulating combinations should only combine bearing components from a single manufacturer to ensure the two components possess compatible manufacturing tolerances.

The **cross-linked "DYNASTY® A-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 taper

The **cross-linked "DYNASTY® A-CLASS® Poly 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 38-54mm)
- • Alumina Matrix Composite "Biolox Delta Femoral Head" (diameter range 28-40mm)
- Alumina Matrix Composite "Delta Option Head" (diameter range 28-44mm)

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 Orthopedics Inc must be used only with shell components of the same system from MicroPort.

The **"CONSERVE® Total Neck Sleeves"** are only indicated for use with the alumina "CONSERVE® Total BCH® Femoral Heads" or the following metal "CONSERVE® Total A-CLASS® Femoral Heads". These femoral heads are indicated for mandatory use with these modular neck sleeves. Neck sleeves must only be used with femoral stems and necks having the MicroPort 12/14 SLT Taper.

Design Overview

Design History

The History of the Dynasty® Acetabular Cup System

In 1995, Wright launched the Interseal® acetabular system. The Interseal® system accepted polyethylene liners and the shells ranged from size 46-72mm. The Interseal® shell contained a 14° rim flare. Shell options were solid, quad, and multi-hole deep profile. Head size options were 28 and 32mm.

In 1998, Wright launched the Transcend® articulation system as a supplemental system to the Interseal® system. The Transcend® system accepted ceramic and metal bearing surfaces, however, it was only offered in solid and quad shell options. Sizes ranged from 46-68mm and head sizes included 28, 32, and 36mm options. The Transcend® shell was also a 14° rim flare.

In 2000, Wright launched the Lineage® acetabular cup system which was a combination of the Interseal® and Transcend® cup systems. Lineage® ranged from 46-68mm shell sizes. Cup options were solid, quad, spiked, HA-coated and multi-hole deep profile. Bearing surfaces included metal, poly, cross-linked poly, and ceramic. The Lineage® system also has a 14° rim flare as well as a hemispherical shell option.

The Dynasty® acetabular cup system is the culmination of the Interseal®, Transcend® and Lineage® cup designs. Featuring A-Class® cross-linked poly bearing surfaces, the Dynasty® system offers both porous-beaded and BioFoam® coating to attain fixation and bone apposition. Porous-beaded shells range from 46-68mm in 2mm increments, and head sizes range from 28-48mm. BioFoam® shells range from 46-76mm in 2mm increments, and head sizes range from 28-54mm. The Dynasty® cup system also includes color-coordinated trial shells and liners, further accentuating the ease of use of the system.

Dynasty® Acetabular Cup System

Design Features

	Dynasty® porous-coated system	Dynasty® BioFoam® system
Shell sizes	46-68 in 2mm increments	46-76 in 2mm increments
Head options	Metal & ceramic	Metal & ceramic
Poly liner diameters	28-46	28-54
Bearing surface	Cross-linked poly	Cross-linked poly
Number of screw holes	3	3, 7, 8, 10 (depending on cup size)
Shell coating	Porous beads	Cancellous titanium
Revision poly option	36mm ID from a 52-68mm	36mm ID from a 52-68mm

64-68mm
8 screw holes

52-62mm
7 screw holes

46-68mm
3 screw holes

70-76mm
10 screw holes

Ceramic and Metal Head Options

CoCr metal heads

Biolox® Delta® ceramic heads

Biolox® Delta® option ceramic heads and sleeves

Titanium Sleeve
Used with option ceramic head

For complete ordering information, refer to Dynasty® Ordering Guide (021062). Some devices may not be available in all markets.

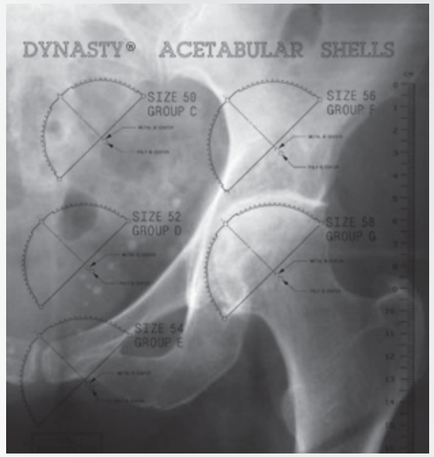
Surgical Technique

Preoperative Planning

Preoperative assessment of the appropriate size and position of the acetabular component will provide intraoperative 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 intraoperatively. Radiographic overlays for the Dynasty® BioFoam® 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.



Dynasty® Biofoam® Cup Reaming Guide

Group	Cup diameter	1mm press-fit ream to:	2mm press-fit ream to:
Group B	46mm	46mm	45mm
Group B	48mm	48mm	47mm
Group C	50mm	50mm	49mm
Group D	52mm	52mm	51mm
Group E	54mm	54mm	53mm
Group F	56mm	56mm	55mm
Group G	58mm	58mm	57mm
Group G	60mm	60mm	59mm
Group G	62mm	62mm	61mm
Group H	64mm	64mm	63mm
Group H	66mm	66mm	65mm
Group H	68mm	68mm	67mm
Group J	70mm	70mm	69mm
Group J	72mm	72mm	71mm
Group J	74mm	74mm	73mm
Group K	76mm	76mm	75mm

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

Preparation of the Acetabulum

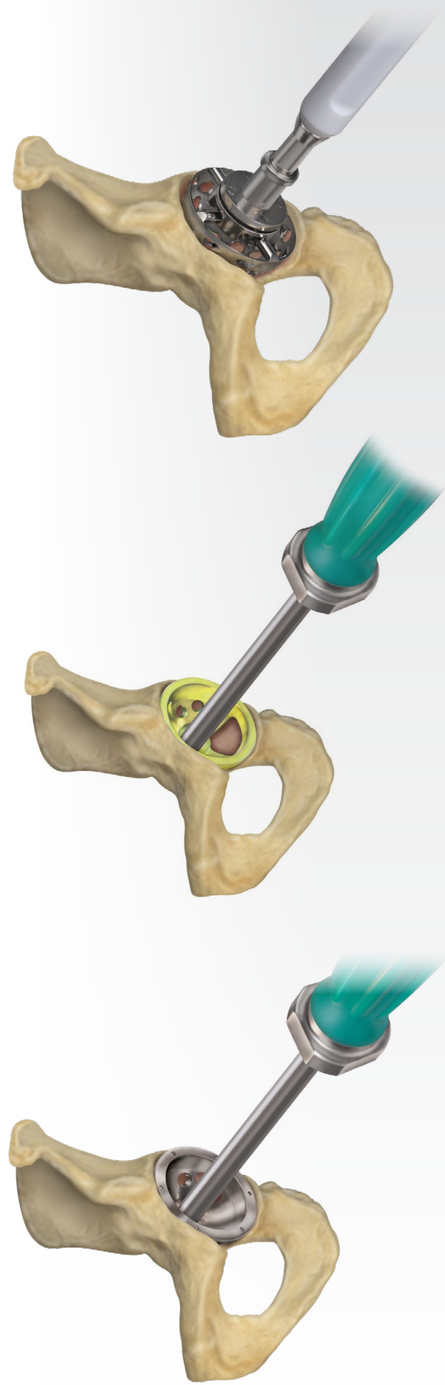
Ream the acetabulum sequentially, starting with the smallest reamer that conforms to the acetabular cavity. Gradually enlarge the acetabulum by reaming articular cartilage until a continuous surface of cancellous bone is exposed.

Sizing the Acetabulum

Thread the trial shell onto the impactor handle to check the size of the acetabulum. The trial shells are a complete hemisphere and are undersized by 1mm compared to the actual implant. The trials also have three large open windows for visualization. The screw holes on the trial shells mimic the location of the screw holes on the implant.

Inserting the Shell

Thread the appropriate size shell onto the impactor. 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.



Straight Shell Impactor
P/N 33330010

Screw Placement

Determine the screw location and select a suitable length drill bit. Modular drill bits are provided in 3.2 and 4.5mm diameters that assemble to the flexible drill shaft. The drill guide is also available 3.2 and 4.5mm diameters with fixed angle and adjustable options.

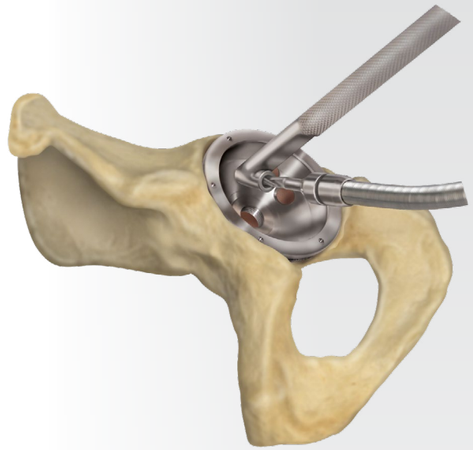
Position the drill guide into the shell ensuring that it is placed into one of the screw holes.

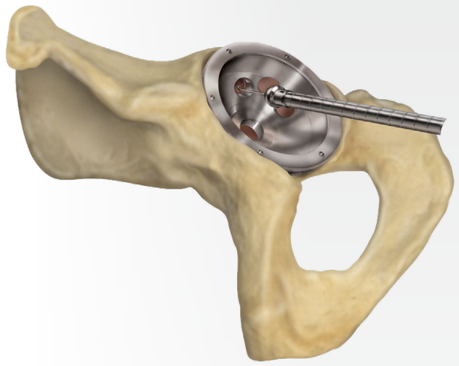
Insert the assembled drill into the guide and carefully drill through the acetabular cortex.

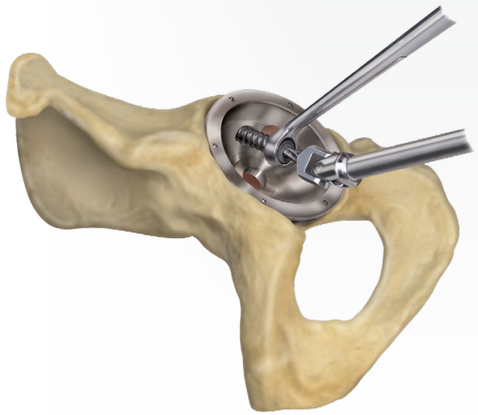
Use the screw depth gauge to determine the appropriate length screw.

Grasp the screw head with the screw-holding forceps and utilize the hex screwdriver 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.







3.2mm Drill Bit
P/N 8400FD04

4.5mm Drill Bit
P/N 8400FD10

Short Flexible
Drill Shaft
P/N 8400FD12

Fixed Angle Drill Guide
P/N 8400DG01

Adjustable Angle Drill
Guide
P/N 8400DG03

Adjustable Screw
Depth Gauge
P/N 8400SG02

Screw-Holding Forceps
P/N 4820SH0000

3.5mm Straight
Screwdriver
P/N 8400SD03

3.5mm Ball-and-Socket
Screwdriver
P/N 8400SD04

3.5mm Universal Joint
Screwdriver
P/N 8400SD06

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.

Apical Hole Plug Insertion

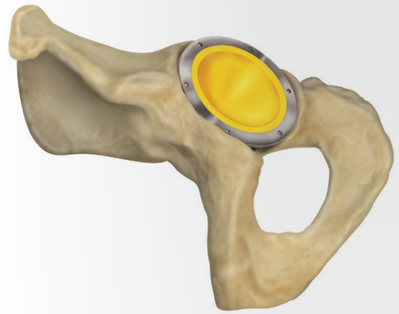
Do not insert the apical hole plug until after final trial reduction with the trial liners. After the trial reduction, seal the apical hole with the apical hole plug. The poly rod will break off at the plug once it is tightened into the apical hole. A final tightening of the hole plug should be performed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

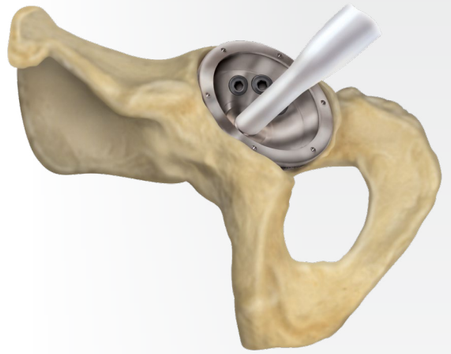
NOTE: The apical hole plug/poly rod must be ordered separately.

Dynasty® Biofoam® Standard Poly Trial Liner

Group	Size
Group B	28mm ID
Group C	32mm ID
Group D	36mm ID
Group E	36mm ID
Group F	40mm ID
Group G	40mm ID
Group H	44mm & 46mm ID
Group J	44mm& 50mm ID
Group K	44mm& 54mm ID

Apical Hole Plug / Rod
P/N 38180002000



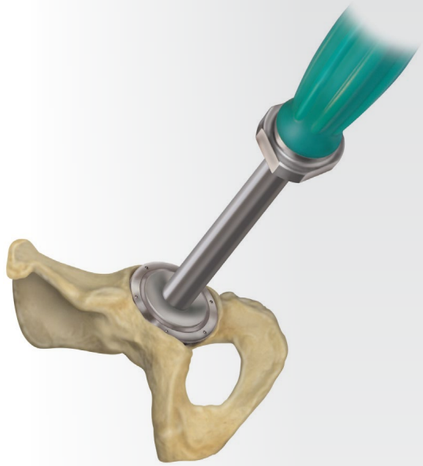


Liner Placement

Clean out any soft tissue from the inner taper area before impacting and engaging the implant and the liner. Insert the liner by hand ensuring that the face of the liner is parallel with the face of the shell. Ensure the liner is flush with the shell.

To engage the implant liner, assemble the modular trial head impactor to the impactor handle. 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 ID. Place head trial into the liner and apply a series of firm mallet blows to fully seat and engage the liner.

NOTE: Dynasty® BioFoam® poly liners sit slightly above the surface of the shell. This allows MicroPort Orthopedics to maximize head size in the system.



3.5mm Hex Screwdriver
P/N 33330002

Straight Liner Impactor
P/N 33330020

Curved Liner Impactor
P/N 33330040

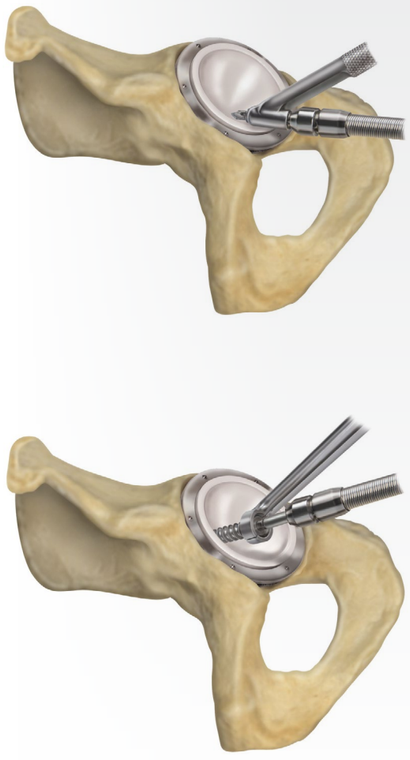
Poly Liner Removal

To remove a poly liner, utilize the flexible drill bit with an acetabular drill guide and drill a hole slightly off-center from the liner apex.

Using a 3.5mm hex screwdriver, thread a 20mm cancellous screw into the drilled hole.

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.

NOTE: Postoperative Care. Additional specific medical information may be provided regarding follow-up care related to the device if necessary. While not required to be included, any general care instructions provided in this section should be presented as guidelines, and should emphasize that the postoperative care is responsibility of the medical professional.



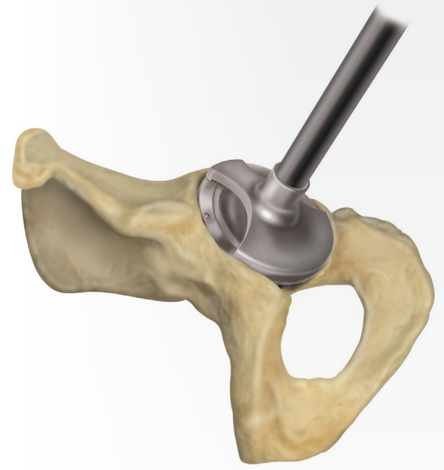
Shell Removal

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.

Metal Liner Removal

To remove a metal liner, thread the appropriate size liner extractor onto the shell impactor handle. Align the four tabs on the extractor with the corresponding four dimples on the shell face. Apply two mallet blows, and inspect the liner for disengagement. Repeat if necessary until the liner is removed.



Dynasty® Biofoam® Liner Extractor

Group	Size
Group B	46-48mm
Group C	50mm
Group D	52mm
Group E	54mm
Group F	56mm
Group G	58-62mm
Group H	64-68mm
Group J	70-74mm
Group K	76mm

NOTE: Metal liners are not available worldwide.

MicroPort Orthopedics

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