DYNASTY®

Acetabular Cup System

SURGICAL TECHNIQUE

MicroPort Orthopedics

Full Function, Faster™

Table of Contents

Dynasty® Acetabular Cup System

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 package insert is available on the website listed.

Package inserts can be found under:
Prescribing information on ortho.microport.com

Chapter 1

Design Features

DYNASTY® Acetabular Cup System
From Primary to Revision Options

Ordering Information		
X-RayTemplates	DSEUXR15	
Surgical Technique	007951B	
Instruments	DNEUKIT1	Acetabular Instruments
	DNEUKIT2	Trial LIners
	DNEUKIT3	Size 70-76 Trial Shells and Liners
	8400KIT1	Screw
Implants	DNFLKITB	DYNASTY® BIOFOAM® Shells (Size 46-68mm)
	Large sizes	DYNASTY® BIOFOAM® Shells (Size 70-76mm)
	DNFLKITD	DYNASTY® Porous-Coated Shells
	DNFLKITI	Standard A-CLASS® Poly-Liners
	DNFLKITL	A-CLASS® 15˚ Poly-Liners
	1808KITL	Acetabular Screws
	CERAKITA	Biolox® Delta Head

	DYNASTY® Porous-Coated	DYNASTY® BIOFOAM®
Shell Sizes	46-68 in 2mm Increments	46-76 in 2mm Increments
Head Options	Metal & Ceramic	Metal & Ceramic
Poly Liner Diameters	28-36	28-36
Bearing Surface	A-CLASS® Cross Linked Poly	A-CLASS® Cross Linked Poly
Number of Screw Holes	3	3,7,8,10 (Depending on Cup)
Coating	Porous Beads	Cancellous Titanium

Outer Geometry: full hemispherical design, 1mm overall press-fit

2 options for optimal ingrowth surface
- Sintered Titanium beads
- BIOFOAM®

Additional Screw fixation
- 3 holes for Porous Coated option.
- 3, 7, 8, 10 holes depending on Cup Size (for BIOFOAM® option only)

Standard and 15° A-CLASS® Polyethylene liners

Chapter 2

Preoperative Planning

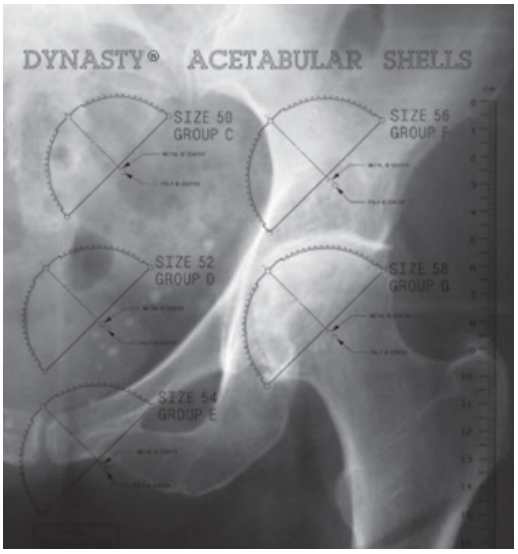


Figure 1

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

An A/P X-ray (Figure 1) of the pelvis will aid in leg length and offset assessment. Accurate templating requires good quality standardized radiographs of the pelvis and operated hip. Leg length discrepancies should be determined preoperatively and addressed intraoperatively.

Radiographic overlays for the DYNASTY® BIOFOAM® Acetabular Cup System are available in 15 percent magnification (DSEUXR15).

CAUTION: Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively.

Chapter 3

Surgical Technique

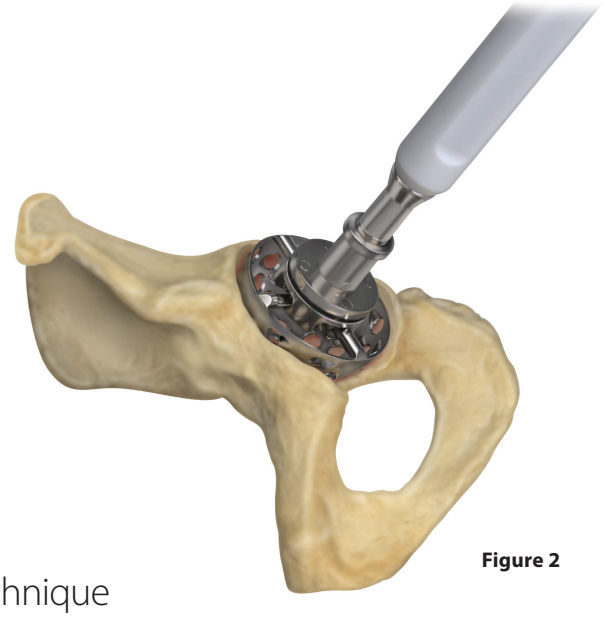


Figure 2

Surgical Technique

Preparation of the Acetabulum

Ream the acetabulum sequentially, starting with the smallest reamer that conforms to the acetabular cavity (Figure 2). Gradually enlarge the acetabulum by reaming articular cartilage until a continuous surface of cancellous bone is exposed. Reaming to the size of the final component will provide 1.0mm overall press-fit.

NOTE: Reamers are not included in the DYNASTY® instruments set

DYNASTY® Cup Reaming Guide

Item Number Porous- Coated	Item Number BIOFOAM®	Cup Diameter	1mm Press-Fit Ream To:	Group
DSPCGB46	DSBFGB46	46mm	46mm	Group B
DSPCGB48	DSBFGB48	48mm	48mm	Group B
DSPCGC50	DSBFGC50	50mm	50mm	Group C
DSPCGD52	DSBFGD52	52mm	52mm	Group D
DSPCGE54	DSBFGE54	54mm	54mm	Group E
DSPCGF56	DSBFGF56	56mm	56mm	Group F
DSPCGG58	DSBFGG58	58mm	58mm	Group G
DSPCGG60	DSBFGG60	60mm	60mm	Group G
DSPCGG62	DSBFGG62	62mm	62mm	Group G
DSPCGH64	DSBFGH64	64mm	64mm	Group H
DSPCGH66	DSBFGH66	66mm	66mm	Group H
DSPCGH68	DSBFGH68	68mm	68mm	Group H
	DSBFGJ70	70mm	70mm	Group J
	DSBFGJ72	72mm	72mm	Group J
	DSBFGJ74	74mm	74mm	Group J
	DSBFGK76	76mm	76mm	Group K

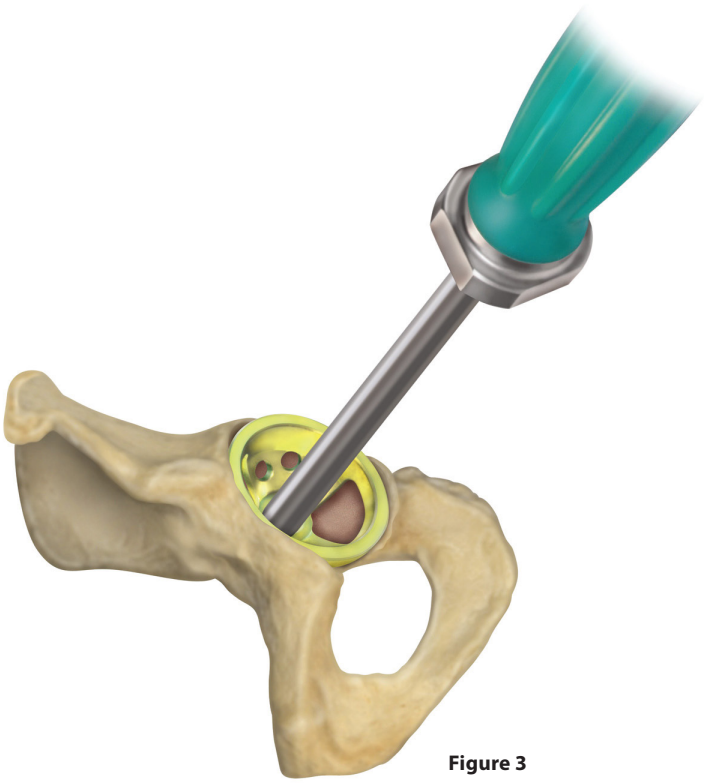


Figure 3

Sizing the Acetabulum

Thread the trial shell (3301GB46-3300GK76) onto the shell impactor (33330010) 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 (Figure 3).

Trial Shell
(3301GB46 – 3301GB48)
(3300GC50 – 3300GK76)

Shell Impactor
(33330010)

DYNASTY® Trial Shell

Item Number	Trial Size	Group
3301GB46	46mm	Group B
3301GB48	48mm	Group B
3300GC50	50mm	Group C
3300GD52	52mm	Group D
3300GE54	54mm	Group E
3300GF56	56mm	Group F
3300GG58	58mm	Group G
3300GG60	60mm	Group G
3300GG62V1	62mm	Group G
3300GH64V1	64mm	Group H
3300GH66V1	66mm	Group H
3300GH68V1	68mm	Group H
3300GJ70	70mm	Group J
3300GJ72	72mm	Group J
3300GJ74	74mm	Group J
3300GK76	76mm	Group K

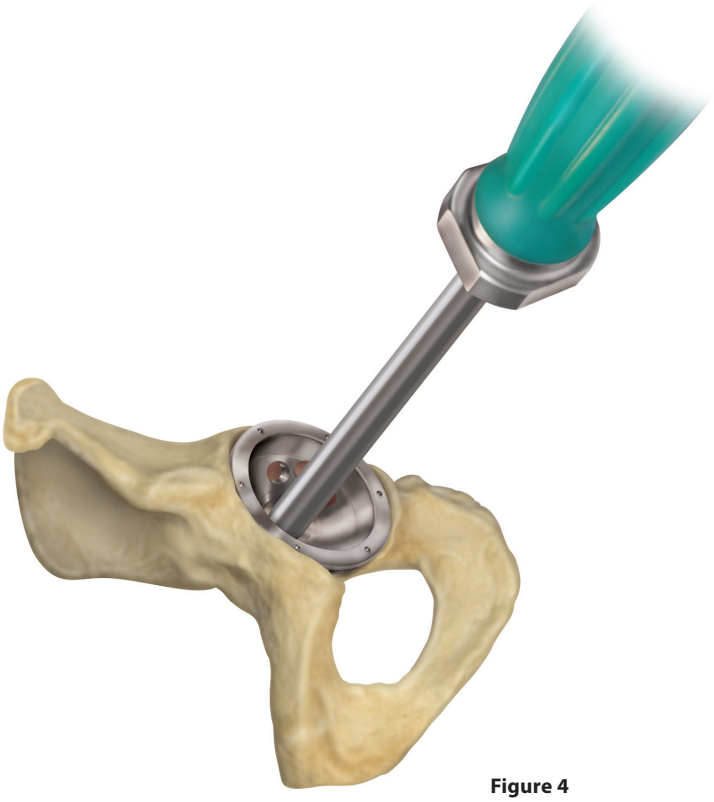


Figure 4

Inserting the Shell

Thread the appropriate size shell onto the shell impactor (33330010). 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 (Figure 4). Complete seating of the implant can be confirmed through the apical hole and screw holes.

CAUTION: Caution should be taken to avoid scratching or denting the rim or internal taper of the shell. Injury to the shell taper will create stress-risers at the shell-liner interface.If the locking mechanism is damaged during implantation, the shell should be replaced.

Shell Impactor
(33330010)

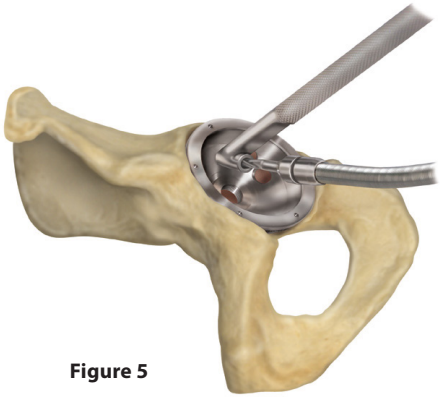


Figure 5

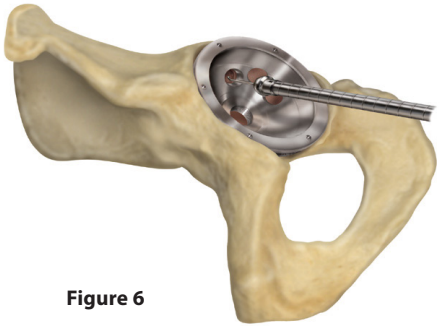


Figure 6

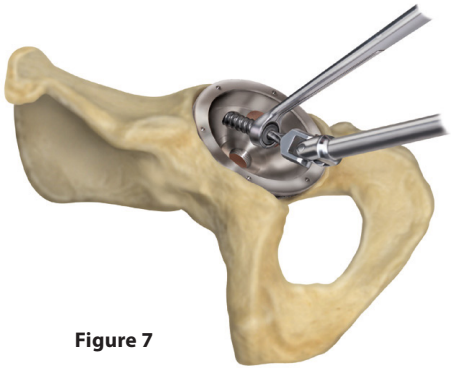


Figure 7

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, (8400FD04-8400FD06, 8400FD07-8400FD10). The modular drill bits have to be used by attaching them to the flexible drill bit shaft (8400FD12). The drill guide (8400DG01) 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 drill into the guide and carefully drill through the acetabular cortex. (Figure 5)

Use the screw depth gauge (8400SG02) to determine the appropriate length screw. (Figure 6)

Grasp the screw head with the screw-holding forceps (4820SH0000) and utilize the hex screwdriver (8400SD03 or 8400SD06 connected to the screw driver handle 8400SD11) to orient and fixate the screw (Figure 7). 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.

CAUTION: Due to intrapelvic vascularity, screw placement in the medial aspect of the acetabulum must be carefully considered.

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.

Modular drill bits
(8400FD04-8400FD06,
8400FD07-8400FD10)

Screw depth gauge
(8400SG02)

Cardan Screw Driver
(8400SD03)

Screw driver handle
(8400SD11)

Flexible drill bit shaft
(8400FD12)

Drill guide
(8400DG01)

6.5mm Screw-Holding Forceps
(4820SH0000)

Solid screw driver bit
(8400SD06)

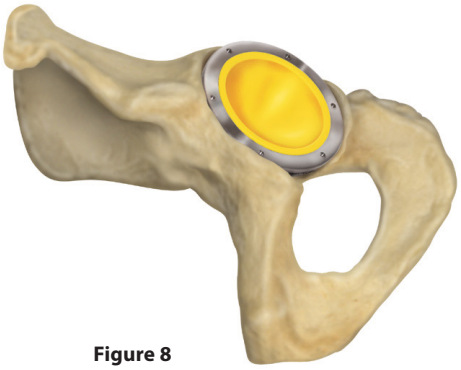


Figure 8

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. (Figure 8)

DYNASTY® Standard Poly Trial Liner

Item Number	Trial Diameter	Group
3304GB28	28mm ID	Group B
3304GC32	32mm ID	Group C
3304GD36	36mm ID	Group D
3304GE36	36mm ID	Group E
3304GF36	36mm ID	Group F
3304GG36	36mm ID	Group G
3304GH36	36mm ID	Group H
3304GJ36	36mm ID	Group J
3304GK36	36mm ID	Group K

DYNASTY® 15˚ 'Lipped' Poly Trial Liners

Item Number	Trial Diameter	Group
3304LB28	28mm ID	Group B
3304LC32	32mm ID	Group C
3304LD36	36mm ID	Group D
3304LE36	36mm ID	Group E
3304LF36	36mm ID	Group F
3304LG36	36mm ID	Group G
3304LH36	36mm ID	Group H
3304LJ36	36mm ID	Group J
3304LK36	36mm ID	Group K

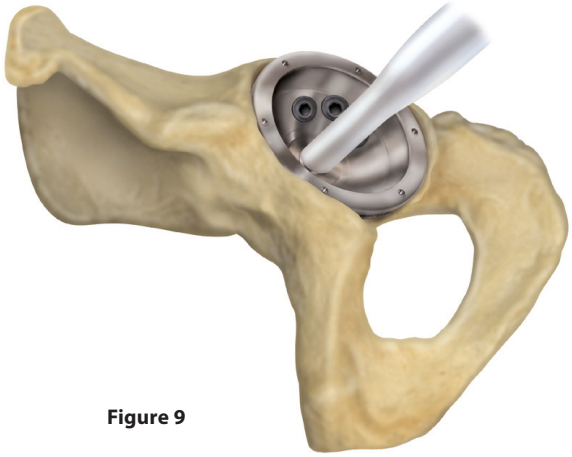


Figure 9

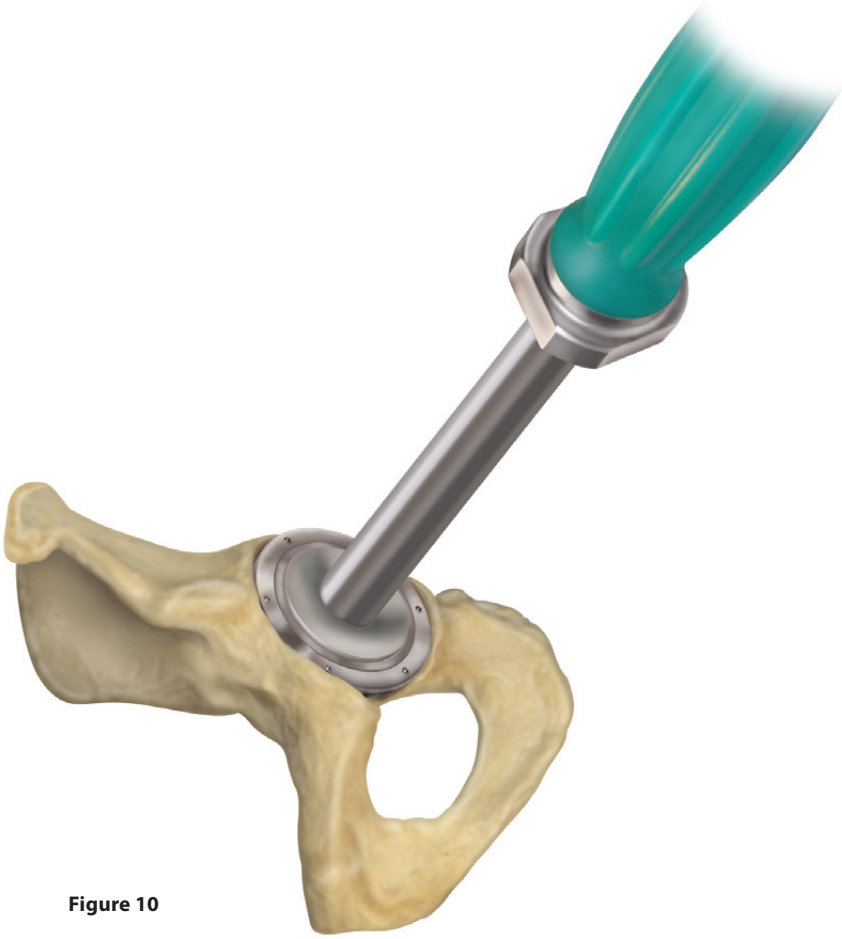


Figure 10

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. (Figure 9)

NOTE: Apical hole plug is sold separately. Part number 3818000200.

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 (33330015) to the impactor handle (33330020). 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 I.D. (41102800, 41103200, 41103600). Place head trial into the liner and apply a series of firm mallet blows to fully seat and engage the liner. (Figure 10)

NOTE: DYNASTY® liners sit slightly above the surface of the shell.

Femoral Head Trial
(41102800, 41103200, 41103600)

Impactor Handle
(33330020)

Trial Head Impactor
(33330015)

Chapter 4

Implant Removal

Figure 11

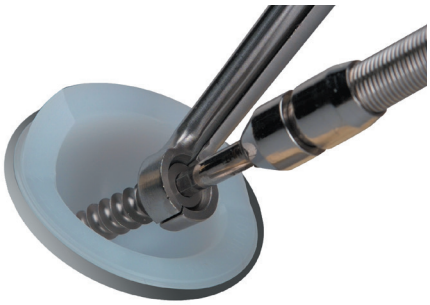


Figure 12

Prosthetic Extraction

To remove a poly liner, utilize the flexible drill bit (8400FD04-8400FD06, 8400FD07-8400FD10) with an acetabular drill guide (8400DG01) and drill a hole slightly off-center from the liner apex. (Figure 11)

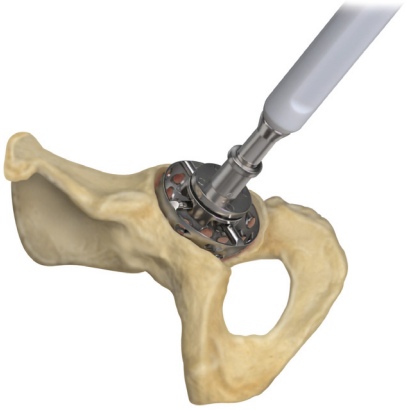
Using a 3.5mm hex screwdriver (8400SD03 cardan or 8400SD06 fixed screwdriver connected to 8400SD11 handle), thread a 20mm cancellous screw (18080301) into the drilled hole. (Figure 12)

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.

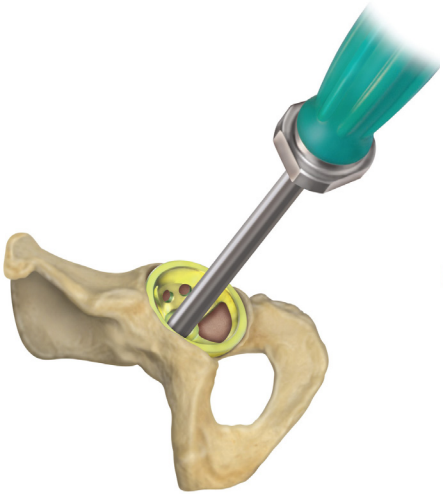
20mm Cancellous Screw
(18080301)

Chapter 5

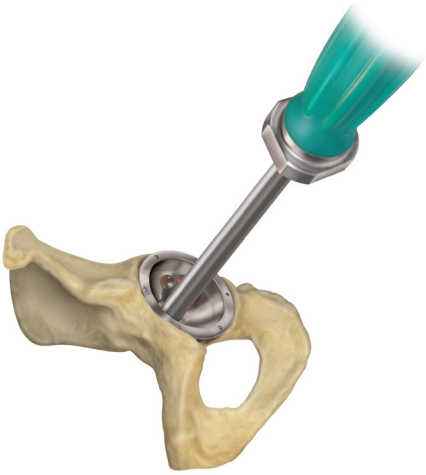
Technique Overview



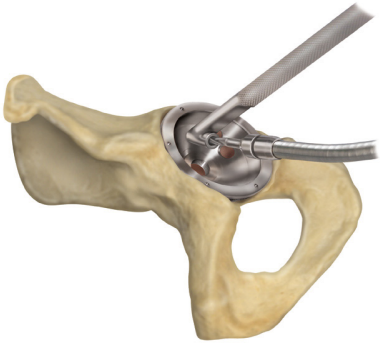
1. Preparation of the Acetabulum - reaming



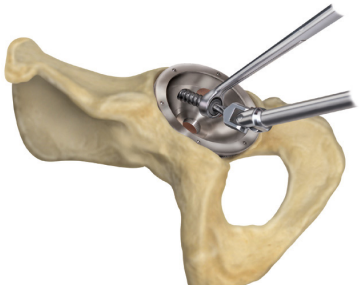
2. Sizing the Acetabulum



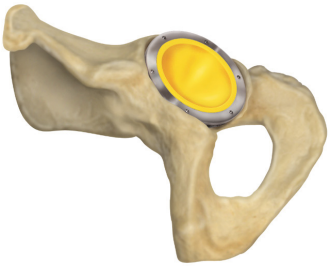
3. Inserting the shell



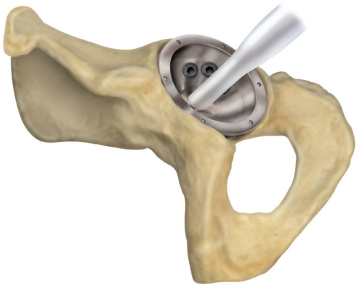
4. Screw Placement - drilling



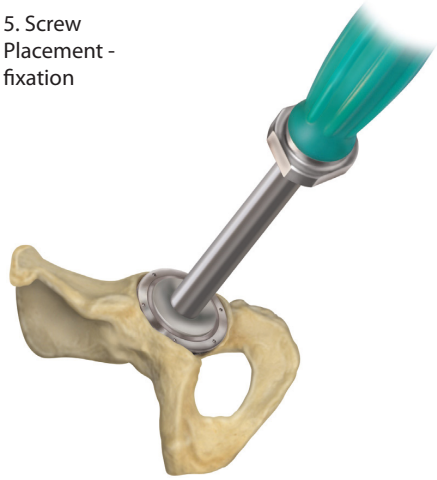
5. Screw Placement - fixation



6. Trial Liner Placement



7. Apical Hole Plug Insertion



8. Liner Placement

Chapter 6

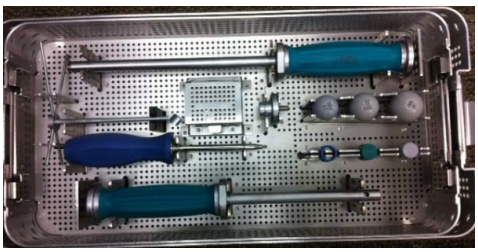
Ordering Information

DYNASTY® Acetabular Instrumentation
DNEUKIT1 - General Instrument kit

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

NOTE:
Curved impactors and alignment rod have to be ordered separately since they are optional in the kit.

Item Number	DNEUKIT1	Size	Group	
DNEUTRA1	DYNASTY® EU Tray 1			
3301GB46	DYNASTY® Trial Shell	46	Group B	
3301GB48	DYNASTY® Trial Shell	48	Group B	
3300GC50	DYNASTY® Trial Shell	50	Group C	
3300GD52	DYNASTY® Trial Shell	52	Group D	
3300GE54	DYNASTY® Trial Shell	54	Group E	
3300GF56	DYNASTY® Trial Shell	56	Group F	
3300GG58	DYNASTY® Trial Shell	58	Group G	
3300GG60	DYNASTY® Trial Shell	60	Group G	
3300GG62V1	DYNASTY® Trial Shell	62	Group G	
3300GH64V1	DYNASTY® Trial Shell	64	Group H	
3300GH66V1	DYNASTY® Trial Shell	66	Group H	
3300GH68V1	DYNASTY® Trial Shell	68	Group H	
DNEUTRA2	DYNASTY® EU Tray 2			
41102800	DYNASTY® Head Trial 28mm			
41103200	DYNASTY® Head Trial 32mm			
41103600	CONSERVE® Total Head Trial 36mm			
APA0TSS3	CONSERVE® Total Trial Sleeve S			
APA0TSM0	CONSERVE® Total Trial Sleeve M			
APA0TSL3	CONSERVE® Total Trial Sleeve L			
33330015	DYNASTY® Trial Head Impactor			
33330010	DYNASTY® Straight Shell Impactor			
33330020	DYNASTY® Straight Liner Impactor			
33330080	DYNASTY® Straight Handle Alignment Guide			
33330001	DYNASTY® Trial Liner Screw			
33330002	DYNASTY® Screwdriver			



Ordering Information

DYNASTY® Acetabular Instrumentation
DNEUKIT2 - Trial liners kit

Item Number	DNEUKIT2	Size	Group	
3304GB28	DYNASTY® STD Poly Trial Liner	28	Group B	
3304GC32	DYNASTY® STD Poly Trial Liner	32	Group C	
3304GD36	DYNASTY® STD Poly Trial Liner	36	Group D	
3304GE36	DYNASTY® STD Poly Trial Liner	36	Group E	
3304GF36	DYNASTY® STD Poly Trial Liner	36	Group F	
3304GG36	DYNASTY® STD Poly Trial Liner	36	Group G	
3304GH36	DYNASTY® STD Poly Trial Liner	36	Group H	
3304LB28	DYNASTY® 15DG Poly Trial Liner	28	Group B	
3304LC32	DYNASTY® 15DG Poly Trial Liner	32	Group C	
3304LD36	DYNASTY® 15DG Poly Trial Liner	36	Group D	
3304LE36	DYNASTY® 15DG Poly Trial Liner	36	Group E	
3304LF36	DYNASTY® 15DG Poly Trial Liner	36	Group F	
3304LG36	DYNASTY® 15DG Poly Trial Liner	36	Group G	
3304LH36	DYNASTY® 15DG Poly Trial Liner	36	Group H	

NOTE:
Trial liners have to be ordered separately with kit DNEUKIT2.

DYNASTY® Acetabular Instrumentation
DNEUKIT3 - Additional 70-76mm trial kit

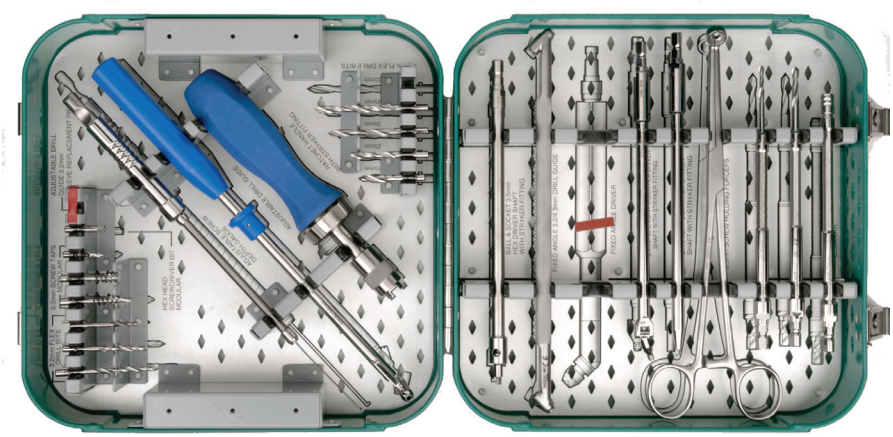
Item Number	DNEUKIT3	ID/Size	Group	
3304GJ36	DYNASTY® STD Poly Trial Liner	36	Group J	
3304GK36	DYNASTY® STD Poly Trial Liner	36	Group K	
3304LJ36	DYNASTY® 15DG Poly Trial Liner	36	Group J	
3304LK36	DYNASTY® 15DG Poly Trial Liner	36	Group K	
3300GJ70	DYNASTY® Trial Shell	70	Group J	
3300GJ72	DYNASTY® Trial Shell	72	Group J	
3300GJ74	DYNASTY® Trial Shell	74	Group J	
3300GK76	DYNASTY® Trial Shell	76	Group K	

NOTE:
Trial shells and liners for sizes 70-76mm have to be ordered separately with kit DNEUKIT3.

DYNASTY® Acetabular Screw Instruments

8400KIT1 SCREW INSTRUMENT KIT

Catalog Number	Description
4820SH0000	SCREW HOLDER
8400DG01	FIXED ANGLE DRILL GUIDE 3.2mm/4.5mm
8400DG03	ADJUSTABLE DRILL GUIDE
8400FD04	FLEX DRILL BIT 3.2 X 15MM
8400FD05	FLEX DRILL BIT 3.2 X 25MM
8400FD06	FLEX DRILL BIT 3.2 X 35MM
8400FD07	FLEX DRILL BIT 4.5 X 15MM
8400FD08	FLEX DRILL BIT 4.5 X 25MM
8400FD09	FLEX DRILL BIT 4.5 X 35MM
8400FD10	FLEX DRILL BIT 4.5 X 45MM
8400SD02	HEX HEAD SCREWDRIVER BIT MODULAR
8400SD03	CARDAN 3.5MM HEX DRIVER SHAFT
8400SD04	BALL & SOCKET 3.5MM HEX DRIVER SHAFT STRAIGHT SOLID
8400SD06	HEX DRIVER SHAFT STRAIGHT SOLID 3.5MM
8400SG02 OR 8400SG01	FLEXIBLE SCREW DEPTH GAUGE
8400ST01	SCREW TAP MODULAR 6.5 X 15MM
8400ST02	SCREW TAP MODULAR 6.5 X 25MM
8400ST03	SCREW TAP MODULAR 6.5 X 35MM
84003000	ACETABULAR SCREW INSTRUMENT CASE
8400SD11 or 2002QCRH	QUICK CONNECT RACHET HANDLE
8400FD12 or 8400FD01	FLEXIBLE DRILL BIT SHAFT



DYNASTY® BIOFOAM® Implants
Ordering Information

DYNASTY® Porous Coated Shells
DNFLKITD

Item Number	Trial Diameter	Group
DSPCGB46	46mm	Group B
DSPCGB48	48mm	Group B
DSPCGC50	50mm	Group C
DSPCGD52	52mm	Group D
DSPCGE54	54mm	Group E
DSPCGF56	56mm	Group F
DSPCGG58	58mm	Group G
DSPCGG60	60mm	Group G
DSPCGG62	62mm	Group G
DSPCGH64	64mm	Group H
DSPCGH66	66mm	Group H
DSPCGH68	68mm	Group H

DYNASTY® BIOFOAM® Shells
DNFLKITB

Item Number	Trial Diameter	Group
DSBFGB46	46mm	Group B
DSBFGB48	48mm	Group B
DSBFGC50	50mm	Group C
DSBFGD52	52mm	Group D
DSBFGE54	54mm	Group E
DSBFGF56	56mm	Group F
DSBFGG58	58mm	Group G
DSBFGG60	60mm	Group G
DSBFGG62	62mm	Group G
DSBFGH64	64mm	Group H
DSBFGH66	66mm	Group H
DSBFGH68	68mm	Group H

DYNASTY® BIOFOAM® Shells
Large sizes (spare parts to be ordered separately)

Item Number	Trial Diameter	Group
DSBFGJ70	70mm	Group J
DSBFGJ72	72mm	Group J
DSBFGJ74	74mm	Group J
DSBFGK76	76mm	Group K

DYNASTY® BIOFOAM® Implants
Ordering Information

DYNASTY® Standard A-CLASS® Poly Trial Liner
DNFLKITI

Item Number	Trial Diameter	Group
DLXPGB28	28mm	Group B
DLXPGC32	32mm	Group C
DLXPGD36	36mm	Group D
DLXPGE36	36mm	Group E
DLXPGF36	36mm	Group F
DLXPGG36	36mm	Group G
DLXPGH36	36mm	Group H
DLXPGJ36	36mm	Group J
DLXPGK36	36mm	Group K

DYNASTY® 15˚ A-CLASS® Poly Trial Liners
DNFLKITL

Item Number	Trial Diameter	Group
DLXPLB28	28mm	Group B
DLXPLC32	32mm	Group C
DLXPLD36	36mm	Group D
DLXPLE36	36mm	Group E
DLXPLF36	36mm	Group F
DLXPLG36	56mm	Group G
DLXPLH36	36mm	Group H
DLXPLJ36	36mm	Group J
DLXPLK36	36mm	Group K

DYNASTY® LINEAGE® Acetabular Screws
1808KITL

Item Number	Description	Length
18080300	6.5 Cancellous Screw	15mm
18080301	6.5 Cancellous Screw	20mm
18080302	6.5 Cancellous Screw	25mm
18080303	6.5 Cancellous Screw	30mm
18080304	6.5 Cancellous Screw	35mm
18080305	6.5 Cancellous Screw	40mm
18080306	6.5 Cancellous Screw	45mm
18080307	6.5 Cancellous Screw	50mm

Biolox® Delta Head*
CERAKITA
* Trademark of Cermatec AG

Catalog #	Size	Head Length
PHA04402	28mm	-3.5
PHA04404	28mm	0.0
PHA04406	28mm	+3.5
PHA04408	32mm	-4.0
PHA04410	32mm	0.0
PHA04412	32mm	+4.0
PHA04414	36mm	-4.0
PHA04416	36mm	0.0
PHA04418	36mm	+4.0

CoCr Super Finish Head
SUFIKITA

Catalog #	Size	Head Length
26000017	28mm	- 3.5
26000018	28mm	+ 0.0
26000019	28mm	+ 3.5
26000020	28mm	+ 7.0
26000021	32mm	- 3.5
26000022	32mm	+ 0.0
26000023	32mm	+ 3.5
26000024	32mm	+ 7.0
26000025	36mm	- 3.5
26000026	36mm	+ 0.0
26000027	36mm	+ 3.5
26000028	36mm	+ 7.0

Chapter 7

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

Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

DYNASTY® modular shells with porous metal bead coating may be used in either cemented or 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.

Additional Contraindications

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

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.

NOTE: There is currently no clinical evidence supporting the long term use of large diameter femoral heads with cross-linked polyethylene liners.

In order to prevent mismatch of tapers:

- Modular liners from MicroPort must be used only with shell components of the same system from MicroPort.

Other Modular Components

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. Prior to assembly, surgical debris must be cleaned from the interior of the female seat of the proximal body 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. Do not resterilize femoral prostheses with ceramic femoral heads seated on the stem. Please refer to the content below for 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 liners only. The superfinished cobalt chrome femoral heads are designed to articulate with UHMWPE liners.

The superfinished cobalt chrome femoral heads are designed to articulate with UHMWPE liners. Ceramic femoral heads 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 light 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. 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.

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.

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 package insert is available on the website listed.

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