SURGICAL TECHNIQUE

DURALOC® Option

CERAMIC ACETABULAR CUP SYSTEM

- IMPROVED WEAR REDUCTION
- PROVEN FIXATION
- PRECISE INSTRUMENTATION
- RELIABILITY

DePuy
a Johnson & Johnson company

CERAMIC ACETABULAR CUP SYSTEM

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TEMPLATING AND PREOPERATIVE PLANNING

The primary goal of total hip arthroplasty is the anatomic reconstruction of the hip joint, resulting in favorable prosthetic joint load and function. Mechanically, the goals are to create a stable articulation with an optimized range of motion, restore biomechanics for muscular efficiency and equalize limb lengths. Meeting these goals begins with a thorough roentgenographic analysis of the hip with comparison to the contralateral side in anteroposterior (A/P) and lateral projections. The desired magnification for all imaging should be 20 percent, which corresponds to the templates provided for the DURALOC® Option system. Magnification markers taped to the patient's leg at the level of the trochanter will assist in determining actual magnification.

For the A/P projection, place both extremities in 15 degrees of internal rotation to position the head and neck parallel to the coronal plane. Center the beam on the symphysis pubis and ensure the proximal femoral shaft is included in the radiograph. The radiographs should clearly demonstrate the acetabular configuration and the endosteal and periosteal contours of the femoral head, neck and proximal femur.

Frequently, the affected hip is fixed in external rotation, which can lead to underestimation of the amount of offset present. In this situation it may be helpful to template the normal hip. Take a Lowenstein lateral with the patient on his/her side, and the trochanter, ankle and knee on the table. Alternately, take a Johnson's lateral for a detailed examination of the anatomic version and anterior osteophytes. Take into consideration any anatomical anomaly, dysplasia, previous fracture or leg length discrepancy.

The DURALOC Option templates allow measurement of any hip that can be accommodated by the DURALOC Option Acetabular Cup System primary components (48-66 mm). Using the A/P radiograph, position the template 35-45 degrees to the interteardrop or interischial line so that the inferomedial aspect of the cup abuts the teardrop and the superior-lateral cup is not excessively uncovered (**FIGURES 1A AND 1B**).

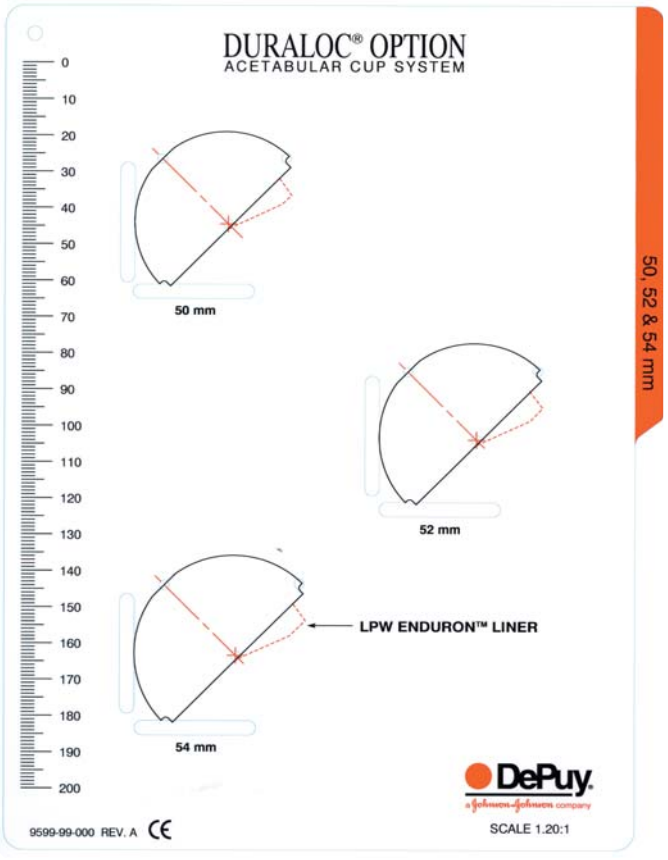
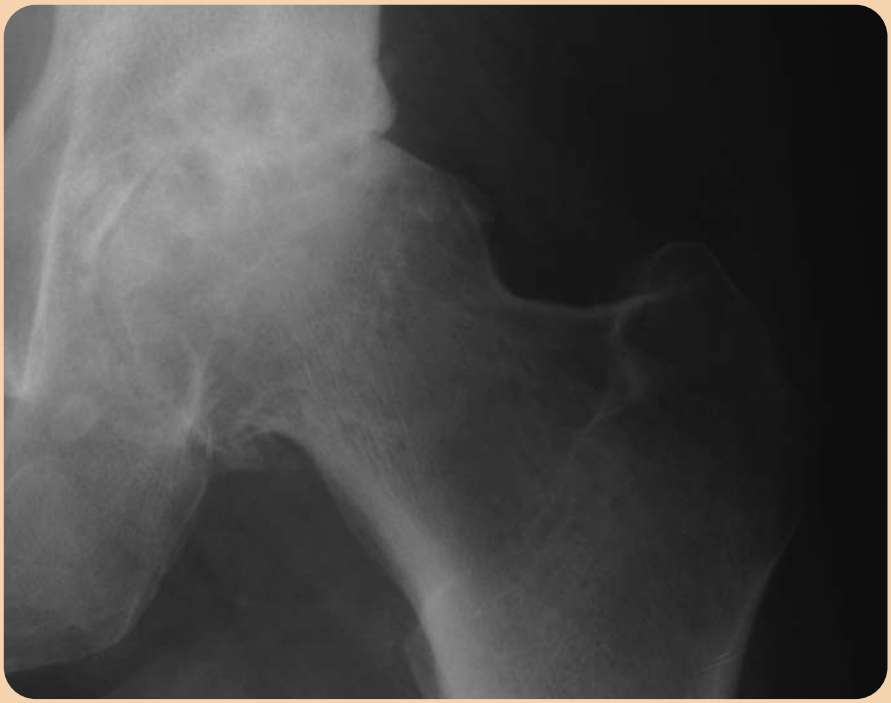
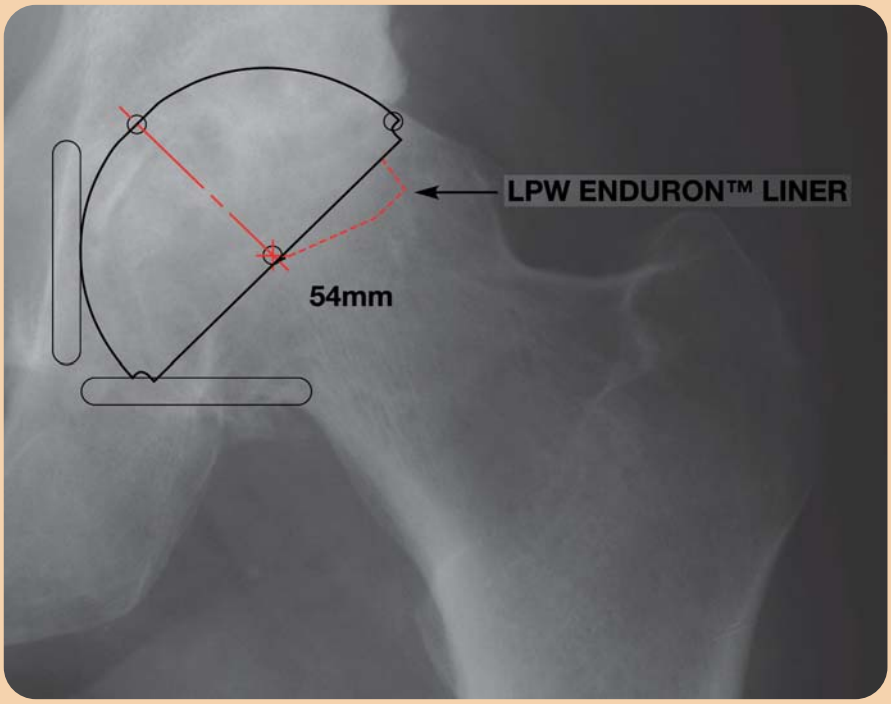


FIGURE 1A



Acetabulum with good lateral coverage

FIGURE 1B



Properly positioned acetabular template

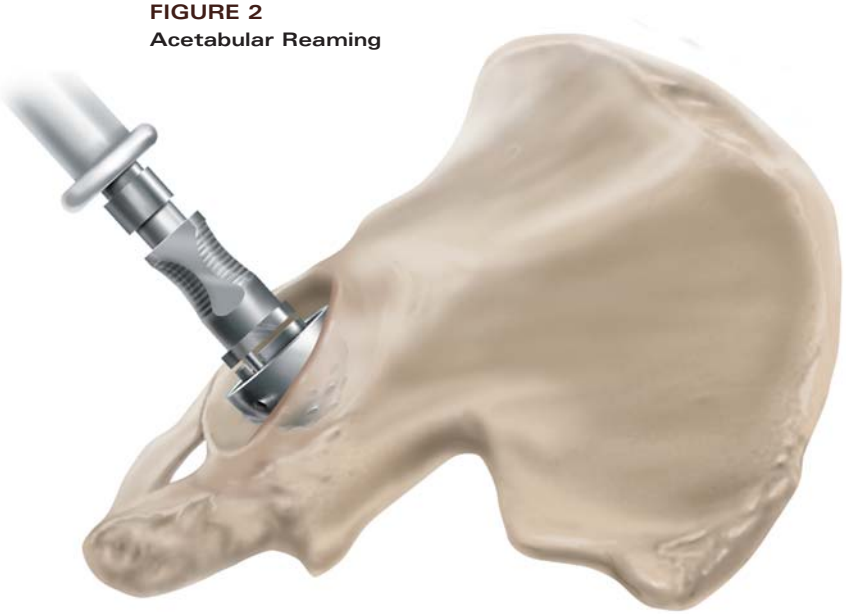
ACETABULAR REAMING

Ensure complete exposure of the entire acetabular rim. Any excess soft tissues and osteophytes should be removed from the rim and bed of the acetabulum. The acetabulum may now be reamed to restore the center of the original acetabulum.

Initially employ a grater 6-8 mm smaller than the anticipated acetabular component size to deepen the acetabulum to the level determined by preoperative templating (**FIGURES 2 AND 3**). Introduce reamers at 35 to 45 degrees of abduction and 15 to 20 degrees of anteversion. In the lateral decubitus position, the pelvis may be flexed. A 30 to 35 degree anteversion is recommended.

Subsequent reaming should proceed in 1-2 mm increments until healthy, bleeding subchondral bone is exposed and the deepened socket becomes a true hemisphere. Use a curette to free all cysts of fibrous tissue. Pack any defects densely with cancellous bone.

FIGURE 2
Acetabular Reaming



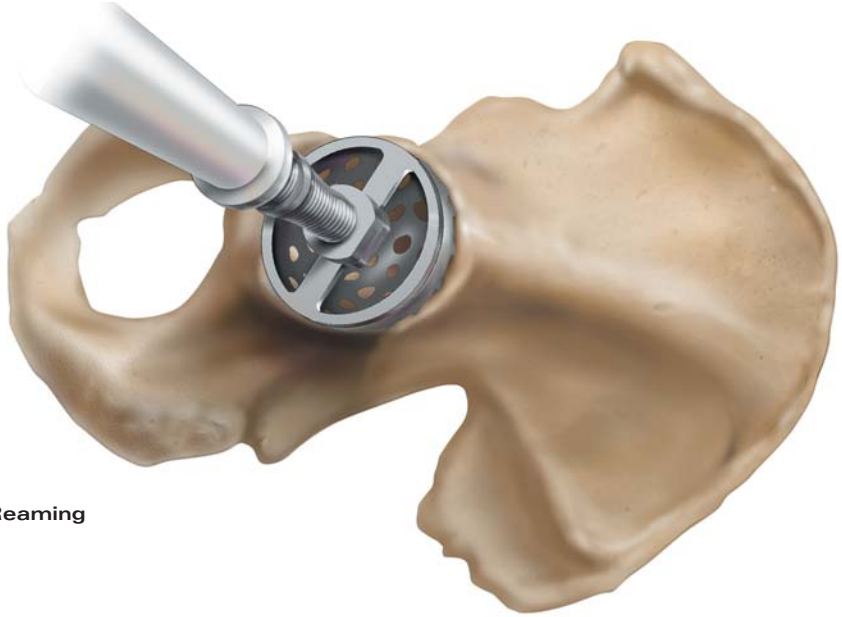


FIGURE 3
Acetabular Reaming

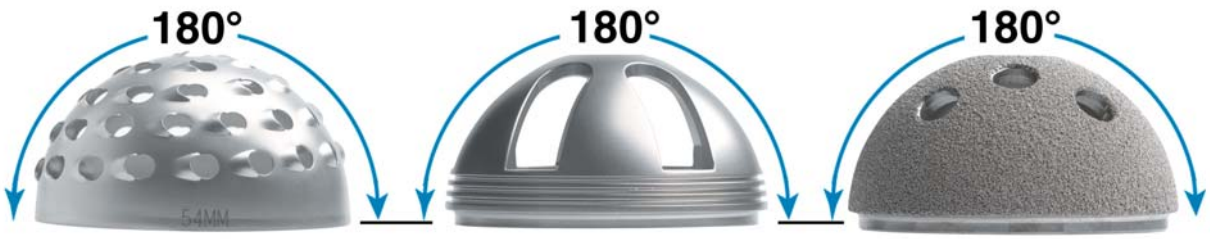
It is important to understand that the DURALOC Option instrumentation is marked with the true dimensions. The graters, shell trials and actual DURALOC Option shells are all 180 degrees (**FIGURE 4**).

Care should be taken to avoid penetration of the medial wall of the acetabulum and to maintain as much of the subchondral plate as possible, removing only sclerotic bone.

If adequate healthy bone is not obtained, larger reamers should be used. Only the periphery should be reamed and further medialization should be avoided. The anterior and posterior columns should be regularly assessed for thickness and strength.

Under-reaming of the acetabulum is dependent on bone quality and the size of the acetabular component. A 1 mm under-ream is usually sufficient in smaller sockets, while a larger socket may require 1-2 mm under-ream. Likewise, soft bone will more readily accommodate a greater press-fit of the acetabular component than sclerotic bone.

FIGURE 4



54 mm Quickset grater reams a 54 mm cavity

54 mm trial shell is 54 mm in diameter

54 mm DURALOC Option acetabular shell is 54 mm in diameter as measured over the Porocoat® Porous Coating

DETERMINING THE ABDUCTION ANGLE

The preoperative A/P X-ray can help determine the ideal abduction angle (**FIGURE 5**). The lateral ilium is a useful landmark as an intraoperative guide to a proper abduction angle. In a normal acetabulum with good coverage, if the implanted socket lies flush with a normal lateral pillar, the abduction angle is usually correct (**FIGURE 6**).

However, degenerative sockets often have deficient lateral covering. The preoperative A/P X-ray can be helpful in determining how much of the acetabular component should be left uncovered to provide the proper implant abduction angle.

FIGURE 5

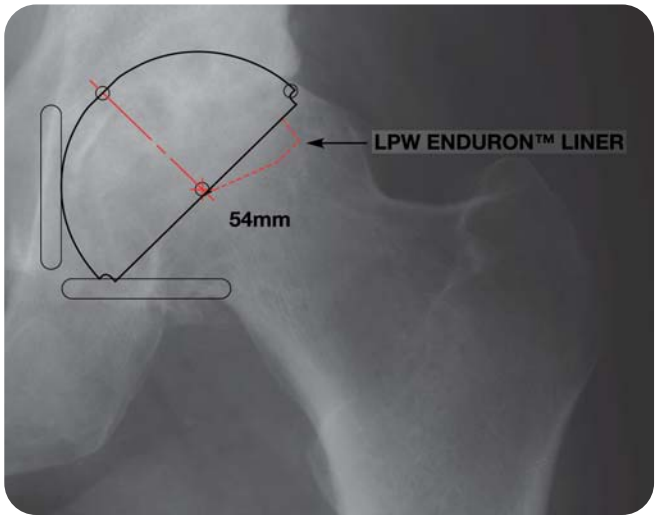
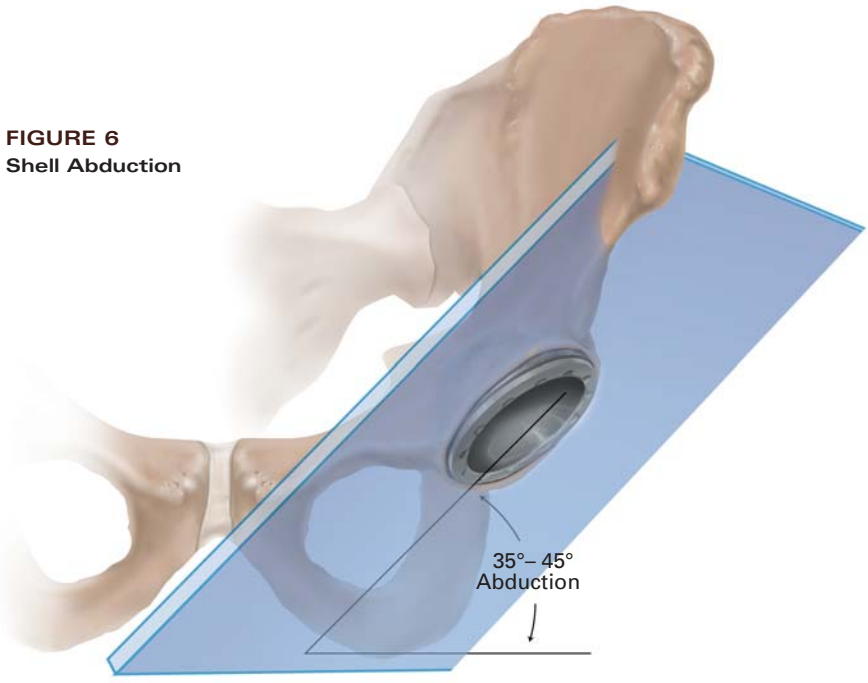


FIGURE 6
Shell Abduction



DETERMINING PROPER ANTEVERSION

The most reliable method for determining proper anteversion is the use of the bony landmark. Other methods are subject to error through a change in patient position during the procedure. Defining the bony landmarks of the ischium and pubis during exposure greatly facilitates proper acetabular component position. The plane created by the pubis and the ischium can serve as a guide for proper acetabular shell orientation. The cup should be slightly more anteverted than the pubis/ischial plane. This relationship should remain constant regardless of the depth of reaming (**FIGURE 7**).

Shell trials in 2 mm incremental sizes are available to assess shell fit and orientation. Contingent on the quality of the prepared bone, select the acetabular trial equal in diameter with the final grater size. The size of the shell trial is as marked on the trial shell (54 mm measures 54 mm). Peripheral rim ridges on the shell trial enhance the stability of the trial shell through trial reduction. Using shell and liner trials in conjunction with the femoral component trials aids in ensuring optimum position of the components.

Place the shell trial in an anatomic orientation with an abduction 35-45 degrees to the transverse plane (**REFER TO FIGURE 6**) and 15-20 degrees anteversion.

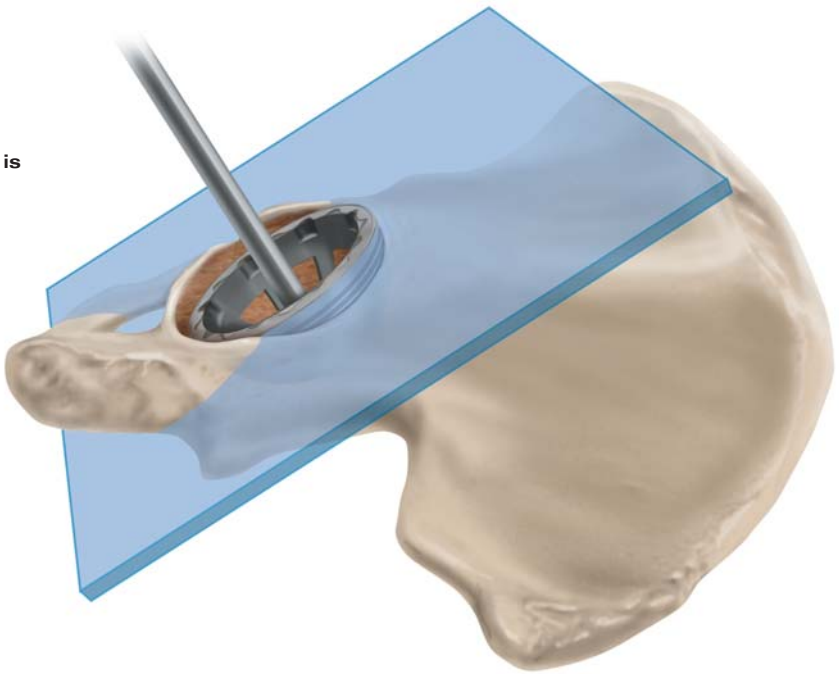


FIGURE 7
Shell anteversion is typically 15°–20°

ACETABULAR SHELL TRIALING AND POSITIONING

Confirm complete shell trial seating by using the indicators on the shell trial. The DURALOC Option shell trials have indicators marked on the rim that match those marked on the definitive shell. These indicate the approximate position of the posterior aspect of the shell when the screw holes are aligned with the roof of the acetabulum. Do not use the shell trial to prepare screw holes. Prepare screw holes only through the final implant. Appropriate trial shell orientation can be verified with external orientation guides in addition to bony landmarks.

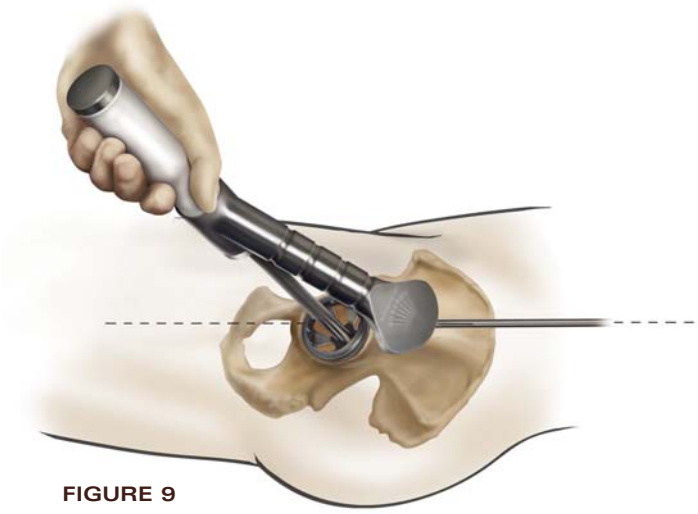


FIGURE 9

With the patient in the lateral decubitus position and the version guide parallel to the floor (**FIGURE 8**) the shell will be in the amount of abduction selected on the handle.

When the extended arm of the version guide, which corresponds to the affected hip, follows the long axis of the patient's body, the trial shell is in 30 degrees of anteversion (**FIGURE 9**).

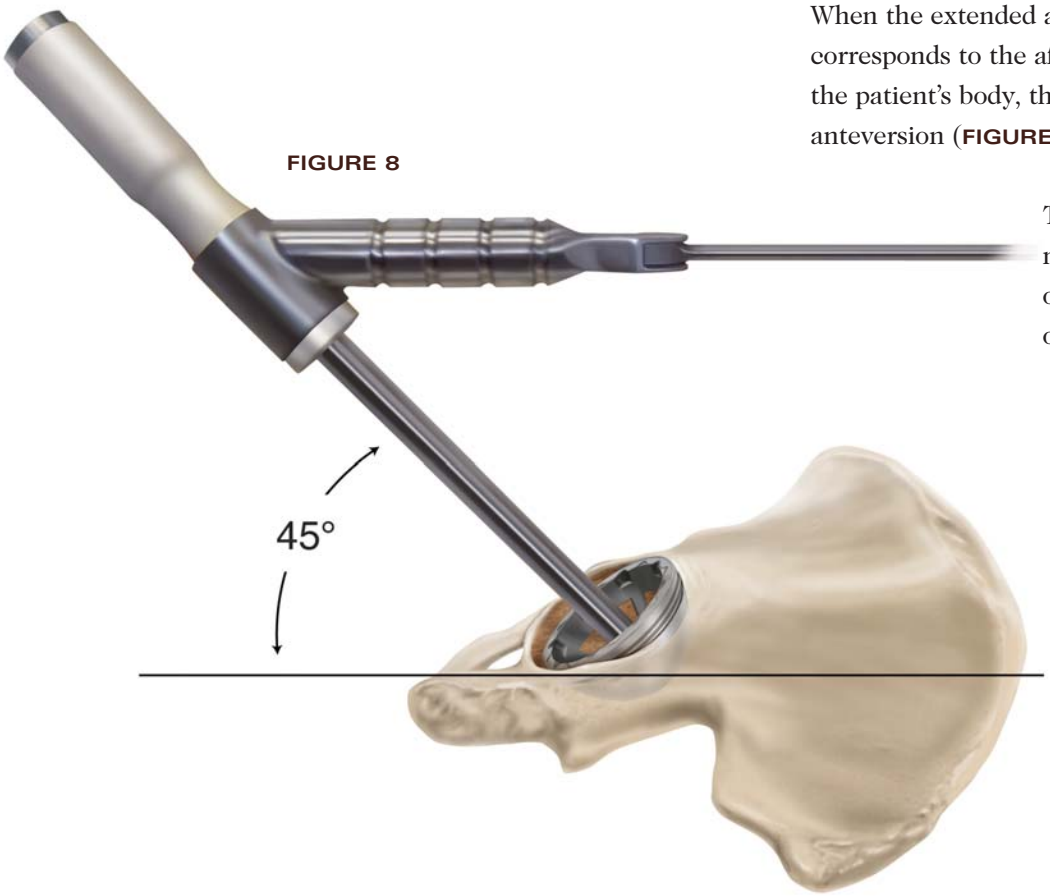


FIGURE 8

The external alignment guide will not be accurate if the pelvis is tilted or if the patient has rolled forward or backward.

ACETABULAR TRIAL LINERS

Following positioning and seating of the acetabular shell trial, place a liner trial into the trial shell. Secure the liner trial to the shell trial through the apical hole screw using a standard hex head screwdriver. There are two alternative liner configurations, one for 28 mm and 32 mm inner diameter (ID) ceramic or standard polyethylene liners and one for 28 mm lipped profile polyethylene liners (**FIGURE 10**). With the femoral component trials in position, assess stability and range of motion. (Note: Additional care should be given to ensure that components are positioned to avoid mechanical impingement.) Couple the liner trial with the shell trial in the desired position

Shell and Liner Trial Sizes	
Shell Trial Size (mm)	**Liner Trial Size (mm)**
48	48, 50
50	48, 50
52	52
54	54, 56
56	54, 56
58	58, 60
60	58, 60
62	62, 64, 66
64	62, 64, 66
66	62, 64, 66

FIGURE 10

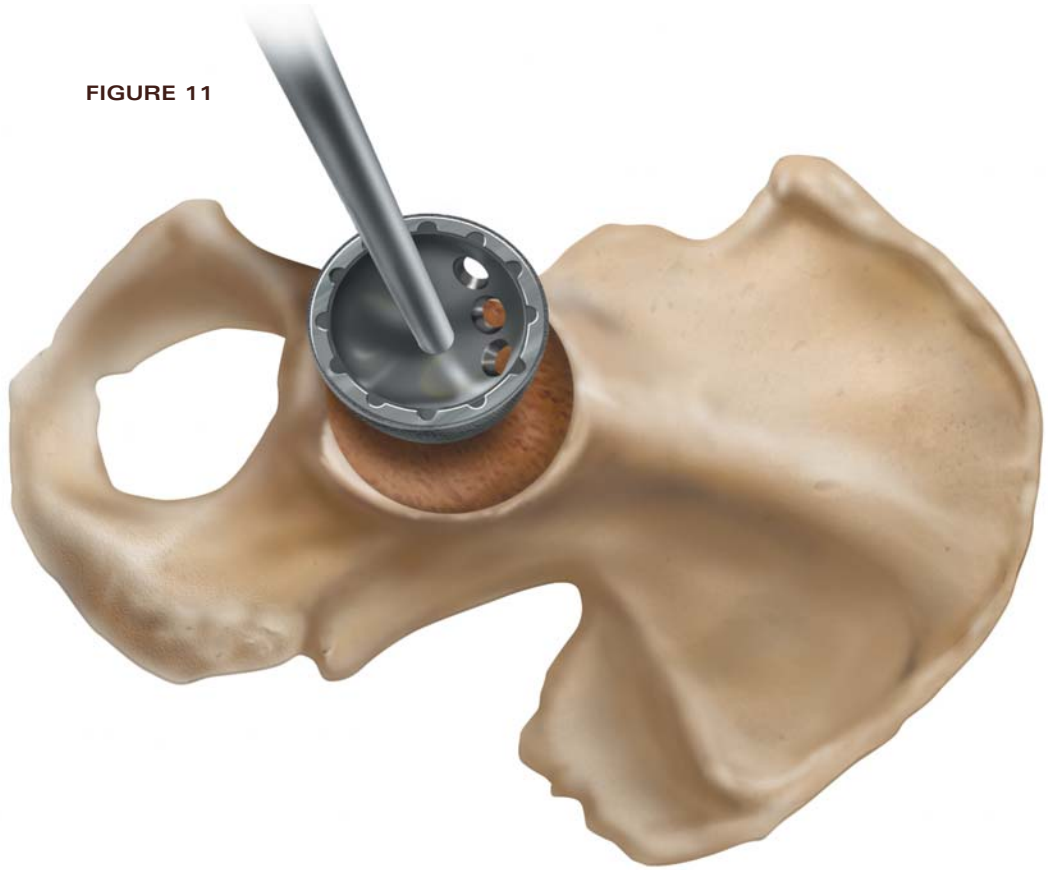
	Standard	Lipped Profile
28 mm polyethylene trial liners are GREEN	 For use with ceramic or standard profile polyethylene liners	 For use with lipped profile polyethylene liners
32 mm ceramic trial liners are BLUE	 For use with ceramic liners only	

SHELL INSERTION

Before implanting the final prosthesis, take the hip through a full range of motion and stability assessment with all trial components in position. Securely thread the permanent acetabular shell prosthesis onto the acetabular cup positioner (**FIGURE 11**). Use the acetabular alignment rod, to assist in component orientation (**AS IN FIGURE 9**).

Anteversion is typically set at 15-20 degrees. Establish this orientation through visual confirmation that the acetabular component is directed fully into the acetabulum. The external alignment guide should be used in conjunction with appropriate bony landmarks and the position of the acetabular trial to determine the best position for the acetabular component (**AS IN FIGURE 8**).

FIGURE 11

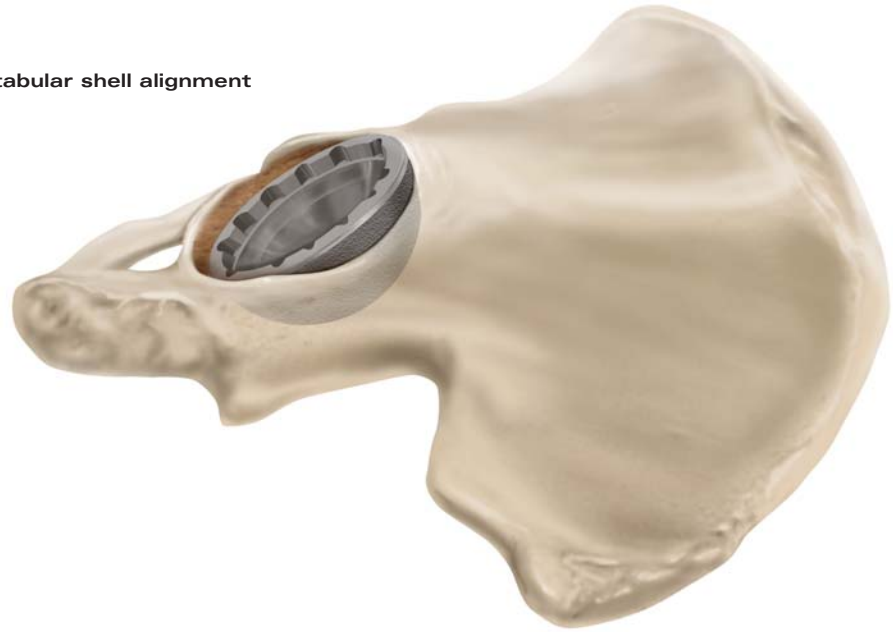


After confirming alignment, impact the prosthesis into position (**FIGURE 12**). Given the nature of a full hemisphere acetabular component, rim contact will occur before dome seating occurs. This may require additional impaction to ensure seating. Confirm seating by sighting through the apex hole and screw holes. An apex hole eliminator may be inserted with a standard hex head screwdriver following shell impaction. Following final component seating, if adjustments to the shell orientation are necessary, thread the impactor handle back into the apex hole to adjust the cup position. Avoid using a punch in the taper region to adjust shell position.

-CAUTION-

Avoid impacting the taper region and the shell face to adjust shell position. As with any other ceramic insert, damage to the taper or the adjacent shell face may increase the risk of fracture and/or chipping of the insert upon its engagement with the shell.

FIGURE 12
Confirm acetabular shell alignment



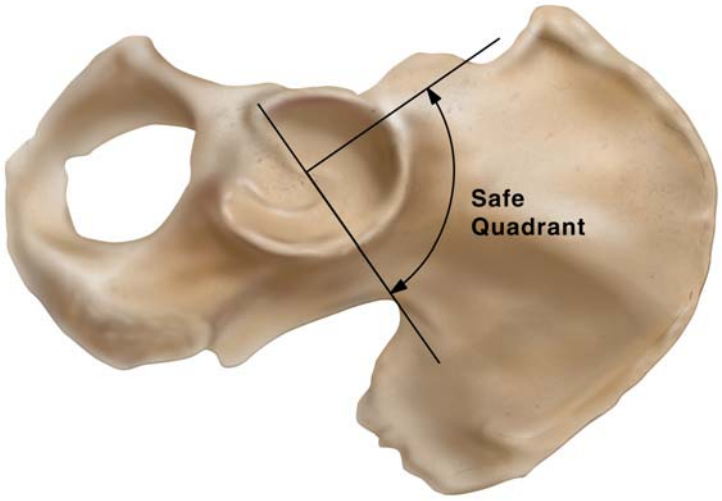
SCREW INSERTION

The DURALOC Option shell, depending on size, has two or three screw holes and is designed for insertion with screws. Duraloc Acetabular Screw Instruments are recommended for screw insertion. Two medial hole alternatives are placed to enable screw placement up the posterior column in either the right or left hip. The single lateral screw provides additional access to the ilium.

Select holes where the prosthesis is to be anchored with cancellous screws so that the screws lie within a safe quadrant. The safe quadrant is defined by two lines from the anterior-inferior iliac spine through the center of the acetabulum and posterior by a line from the sciatic notch to the center of the acetabulum (**FIGURE 13**).

The drill bit is controlled by the drill guide as it passes through selected holes into the acetabulum (**FIGURE 14**). The screw angle may vary by as much as 30 degrees (**FIGURE 15**). The effective lengths of the three drill bits available are 25, 40 and 50 mm. By seating the drill bit completely into the guide, holes corresponding to the effective length of the drill bit will be created.

FIGURE 13



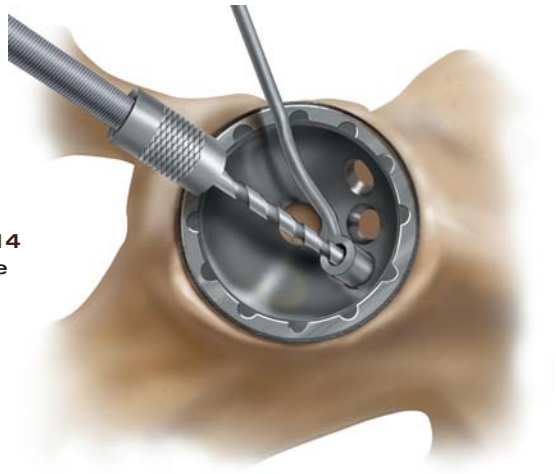
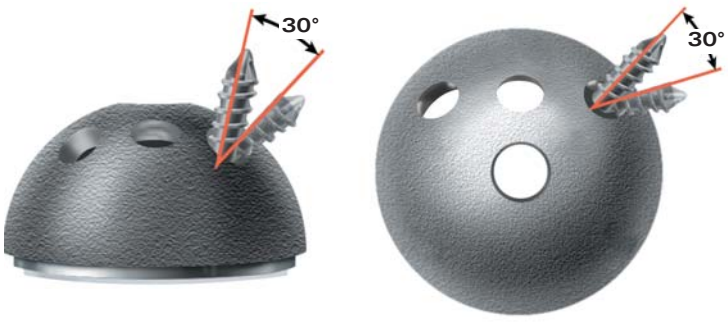


FIGURE 14
Drill Guide

FIGURE 15
Screw Angulation



Verify hole depth using the Duraloc depth gauge (**FIGURE 16**).

Insert 6.5mm Duraloc cancellous bone screws using a hex head screwdriver (**FIGURES 17 AND 18**). The self-tapping screws have four-point cutting flutes with a blunt tip to reduce the risk of neurovascular injury (**FIGURE 19**).

FIGURE 16
Depth Gauge

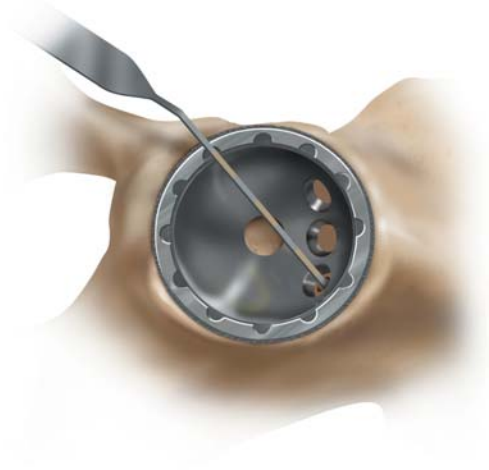


FIGURE 17
Screw Insertion

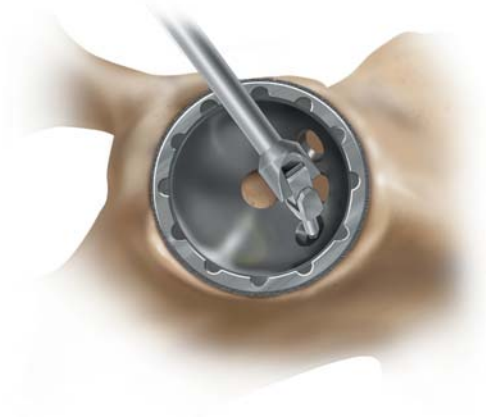


FIGURE 18

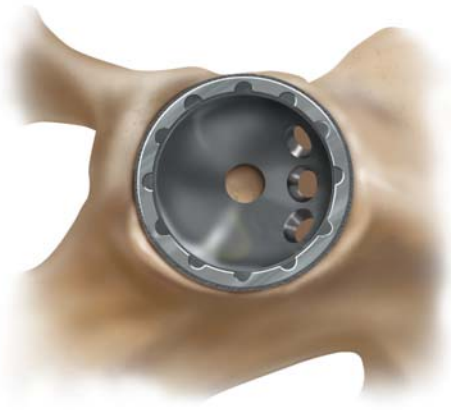
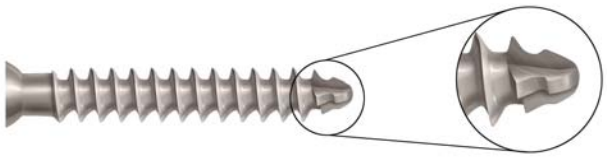


FIGURE 19



SHELL/LINER COMPATIBILITY

The DURALOC Option shell accommodates Enduron® Polyethylene liners and Alumina ceramic inserts to meet individual patient needs. Liners and inserts have been designed to fit a wide range of sizes while maximizing wall thickness.

Shell Diameter				
O.D.	28 mm I.D.			32 mm I.D.
48 or 50	 ceramic	 Std Polyethylene	 LPW Polyethylene	
52		 Std Polyethylene	 LPW Polyethylene	 ceramic
54 or 56		 Std Polyethylene	 LPW Polyethylene	 ceramic
58 or 60		 Std Polyethylene	 LPW Polyethylene	 ceramic
62, 64, 66		 Std Polyethylene	 LPW Polyethylene	 ceramic

CERAMIC INSERT INSERTION

To ensure optimal component placement when using ceramic bearings, trialing is critical. Trials for ceramic inserts exist that help ensure the correct restoration of biomechanics. The 28 mm ceramic insert trials are green and the 32 mm ceramic insert trials are blue.

If correct joint biomechanics, free of mechanical impingement, cannot be obtained with the alternative bearing trials, perform a trial reduction using the DURALOC Option polyethylene liner trials. Then, use the DURALOC Option polyethylene liner that results in joint stability.

28 mm ceramic bearing trial

32 mm ceramic bearing trial

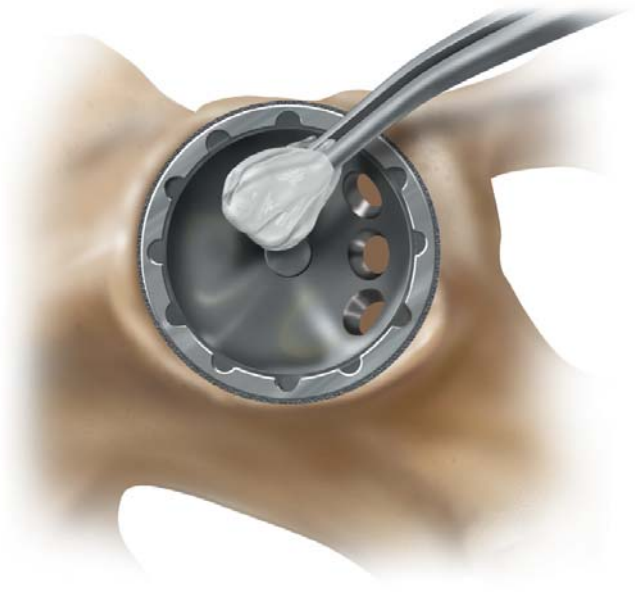


FIGURE 20
Ensure all taper mating surfaces are clean and free of debris

Before impacting a ceramic insert the shell should be irrigated, cleaned and dried. It is essential that the shell be free of any foreign material, blood, or soft tissue (**FIGURE 20**).

Use only the following femoral heads with the DURALOC Option ceramic insert. Use of femoral heads other than those indicated here is contraindicated and will compromise performance.

The DURALOC Option Ceramic Acetabular System is FDA approved only for use with the Summit™ Porocoat® Tapered Hip System and the S-ROM® Modular Hip System.

CERAMIC FEMORAL HEADS

12/14 Taper Articul/eze®	
Cat. No.	**Size (mm)**
1365-73-000	28 mm +1.5
1365-74-000	28 mm +5
1365-76-000	32 mm +1
1365-77-000	32 mm +5
1365-78-000	32 mm +9

11/13 S-ROM Taper	
Cat. No.	**Size (mm)**
52-8323	32 mm +0
52-8330	32 mm +6

SUCTION CUP INSERTION TECHNIQUE

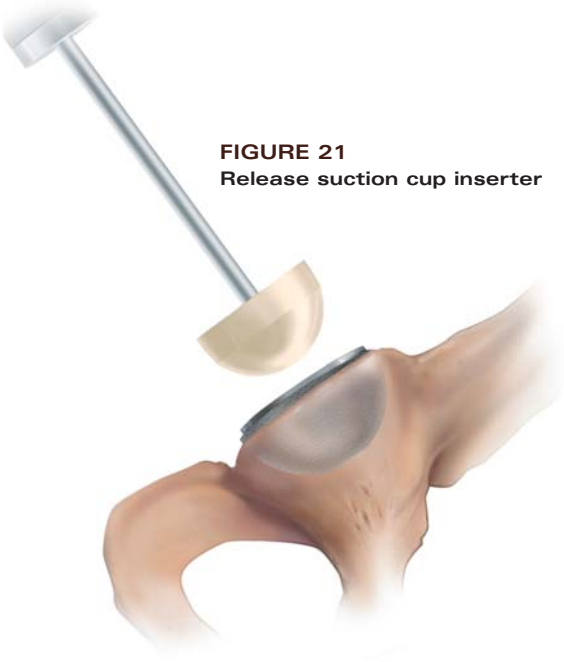


FIGURE 21
Release suction cup inserter

The ceramic insert should be introduced using either the dedicated suction cup inserter described on this page (**FIGURE 21**) or the Gripper described on pages 17-18. When using the suction cup inserter, the insert should be aligned so that it sits flush within the Morse taper of the DURALOC Option shell. Hand pressure alone is required to fully seat the insert in the shell, at which point the rim of the insert will be level with the rim of the shell.

It is important to cautiously release the suction cup insertion instrument from the ceramic insert so the insert does not disengage from the shell. It is recommended that the ceramic insert be secured with a thumb and forefinger placed superiorly and inferiorly while the suction cup instrument is disengaged from the insert (**FIGURE 22**).

Prior to final impaction, examine the insert to ensure it is seated flush relative to the shell face.

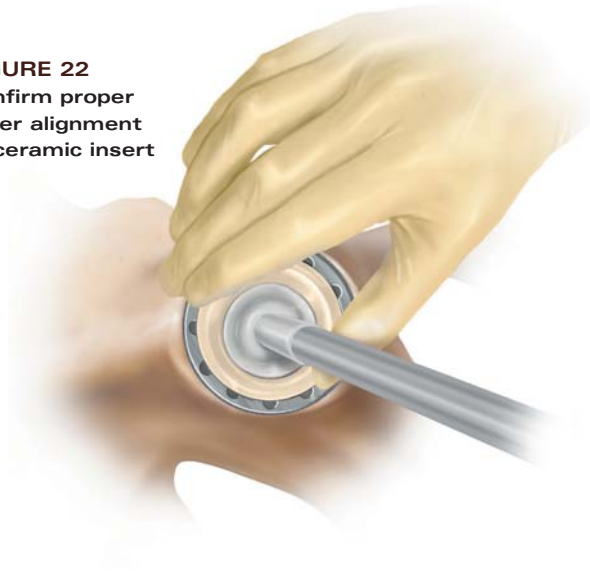


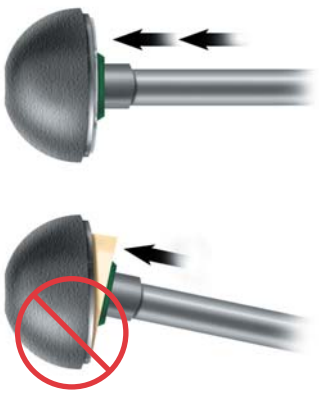
FIGURE 22
Confirm proper taper alignment of ceramic insert

Seat the insert using the ID impactor that corresponds with the implant. It is important to impact the insert directly into the shell with one to two moderate blows (**FIGURE 23**).

In the event that a DURALOC Option Ceramic Insert is impacted and does not seat properly in the shell, it must be removed as shown in the removal technique. After the removal of a DURALOC Option Ceramic Insert that has been impacted, only a polyethylene liner may be used in the shell due to potential damage to the shell taper. In order to use another ceramic insert, the shell must be replaced.

An insert that has been placed, but not impacted, as shown in Figures 21 and 22 may be removed and reinserted prior to impaction.

FIGURE 23
Verify insert alignment and impact insert



-CAUTION-
Prior to final impaction of the insert to the metal shell, correct alignment of the inner/shell assembly must be obtained. As with any other ceramic insert, incorrect alignment of the insert/shell assembly may increase the risk of fracture and/or chipping of the insert upon its engagement with the shell. Once final assembly has been completed, the insert should be visually inspected and palpated for evidence of chipping and/or fracture.

GRIPPER INSERTION TECHNIQUE

STEP 1

Assemble the appropriate size gripper to the inserter shaft aligning the slot of the gripper with the pin of the shaft (**FIGURE A**).

FIGURE A

STEP 2

Thread the appropriate size tip to the shaft (**FIGURE B**). After threading on the tip, pull the gripper down until it contacts the tip (**FIGURE C**).

FIGURE B

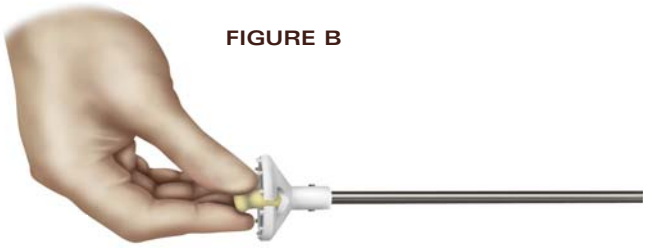


FIGURE C

STEP 3

Press-fit the insert on the gripper component (**FIGURE D**). Verify that the insert is fully seated to ensure proper alignment (**FIGURE E**).

FIGURE D

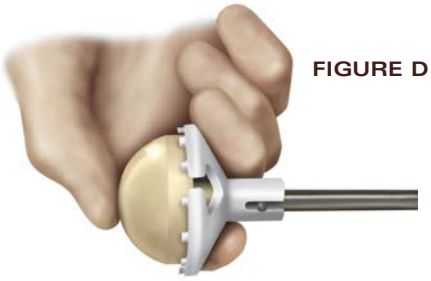


FIGURE E

STEP 4

Cautiously advance the insert into the incision and align the face of the gripper to the face of the cup (**FIGURE F** and **FIGURE G**).

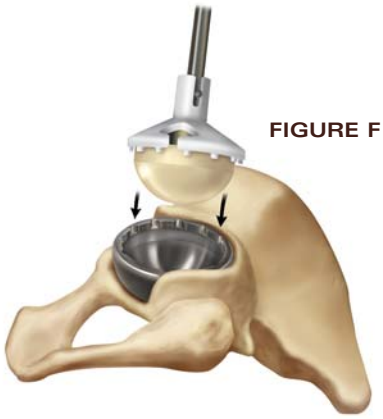


FIGURE F

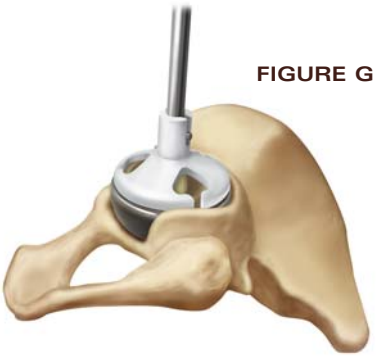


FIGURE G

STEP 5

Proper alignment is achieved when the instrument will no longer rotate due to the locking features between the gripper and cup (**FIGURE H**).

FIGURE H

FIGURE I

STEP 6

Press firmly on handle to introduce the insert into the cup (**FIGURE I**).

Do not attempt to fully engage the taper locking mechanism by striking the end of the Gripper Handle.

STEP 7

Carefully remove instrument (**FIGURE J**).

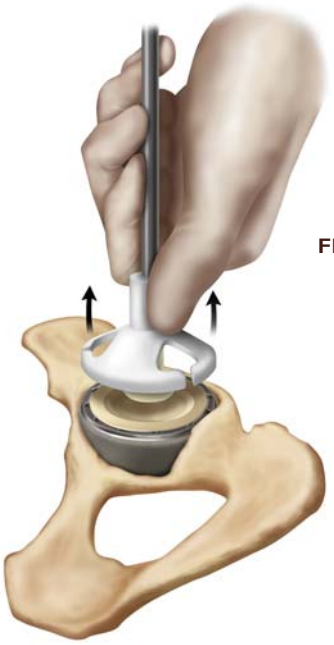


FIGURE J

STEP 8

Palpate the insert to confirm proper taper alignment and seating in the shell (**FIGURE K**).

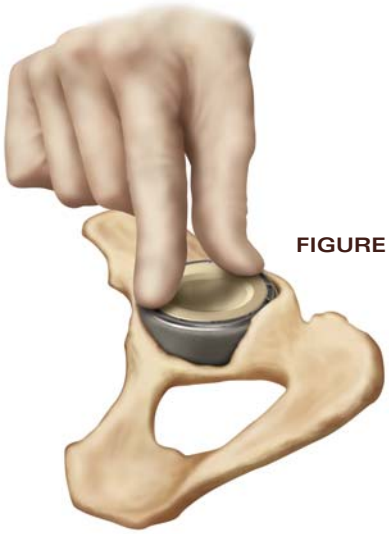


FIGURE K

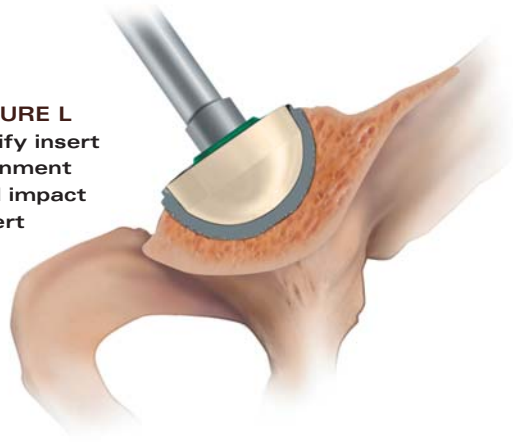


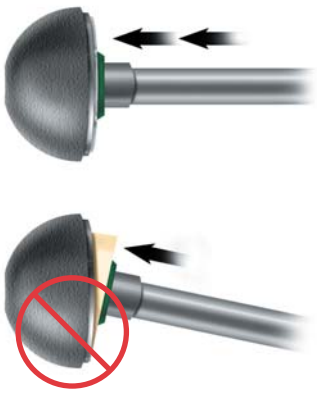
FIGURE L
Verify insert alignment and impact insert

STEP 9

Seat the insert using the ID impactor that corresponds with the implant. It is important to impact the insert directly into the shell with one to two moderate blows (**FIGURE L**).

In the event that a DURALOC Option Ceramic Insert is impacted and does not seat properly in the shell, it must be removed as shown in the removal technique. After the removal of a DURALOC Option Ceramic Insert that has been impacted, only a polyethylene liner may be used in the shell due to potential damage to the shell taper. In order to use another ceramic insert, the shell must be replaced.

An insert that has been placed, but not impacted, may be removed and reinserted prior to impaction.



-CAUTION-

Prior to final impaction of the insert to the metal shell, correct alignment of the inner/shell assembly must be obtained. As with any other ceramic insert, incorrect alignment of the insert/shell assembly may increase the risk of fracture and/or chipping of the insert upon its engagement with the shell. Once final assembly has been completed, the insert should be visually inspected and palpated for evidence of chipping and/or fracture.

CERAMIC INSERT REMOVAL TECHNIQUE

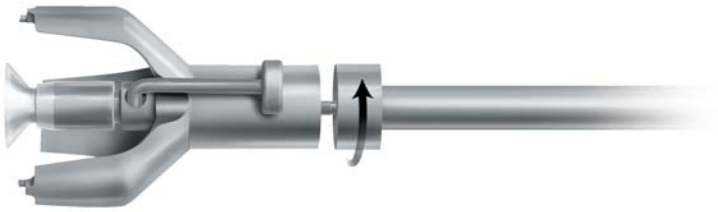
STEP 1

If it is necessary to remove a ceramic insert from a DURALOC Option shell, thread the extractor handle onto the appropriate size alternative bearing (AB) extractor (see chart below for appropriate size extractor) (**FIGURE 24**).

Note: Can be used with 28 mm or 32 mm ID inserts

Extractor Size Chart	
Shell Size	**Use Extractor Marked**
48	48, 50
50	48, 50
52	52
54	54, 56
56	54, 56
58	58, 60
60	58, 60
62	62, 64, 66
64	62, 64, 66
66	62, 64, 66

FIGURE 24



STEP 2

Place the three tips of the AB extractor into any three scallops on the face of the DURALOC Option shell (**FIGURE 25**).

FIGURE 25

STEP 3

Push down the attached lever with thumb pressure to engage the suction cup to the inner diameter of the ceramic insert (**FIGURE 26**).

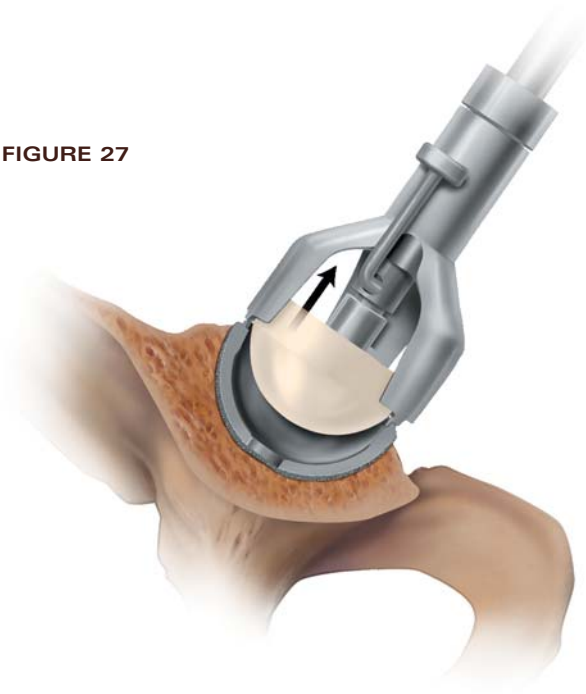
FIGURE 26

STEP 4

To remove the ceramic insert from the shell, impact the extraction handle lightly one to two times. The insert will be lifted out of the shell by the suction cup mechanism (**FIGURE 27**).

Extracted ceramic liners may not be reused.

FIGURE 27

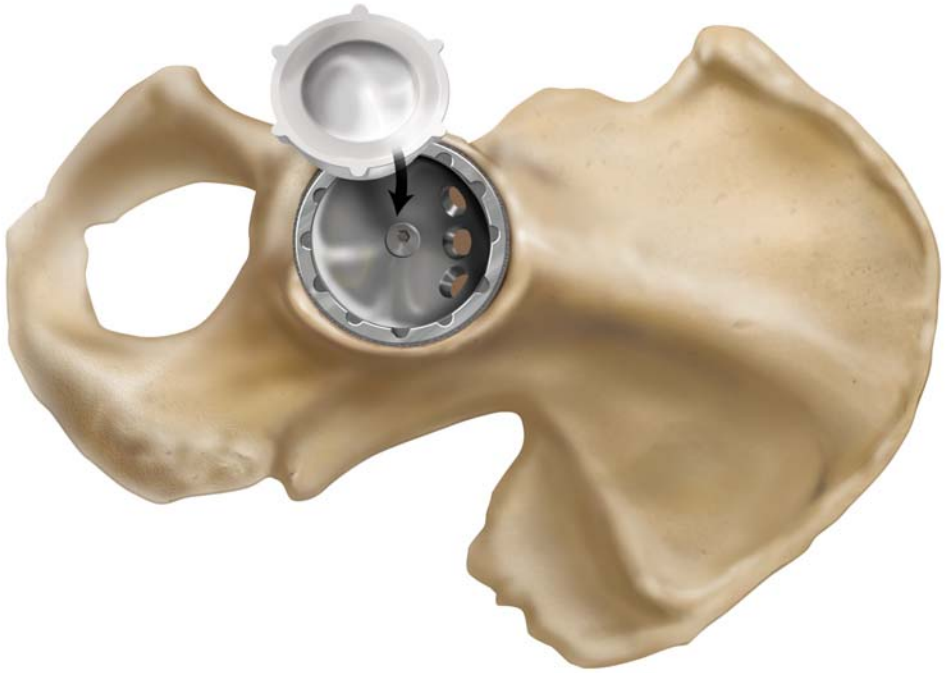


POLYETHYLENE LINER INSERTION AND IMPACTION

Following insertion of the final acetabular shell and femoral component, the trial liners can be used in the shell to confirm liner selection and evaluate joint stability and range of motion.

Prior to inserting the final acetabular liner, thoroughly irrigate and clean the shell. It is important to check the shell/liner locking groove for debris. Remove all soft tissue from the face of the shell so as not to impede liner seating (**FIGURE 28**). An apex hole plug may be used prior to liner insertion.

FIGURE 28
Liner Insertion



POLYETHYLENE LINER INSERTION AND IMPACTION

Before the liner is inserted, introduce the locking ring (packaged with the liner) to the locking ring groove in the shell. Starting with one end of the ring, introduce each bend progressively until the ring is fully seated in the groove (**FIGURE 29**).

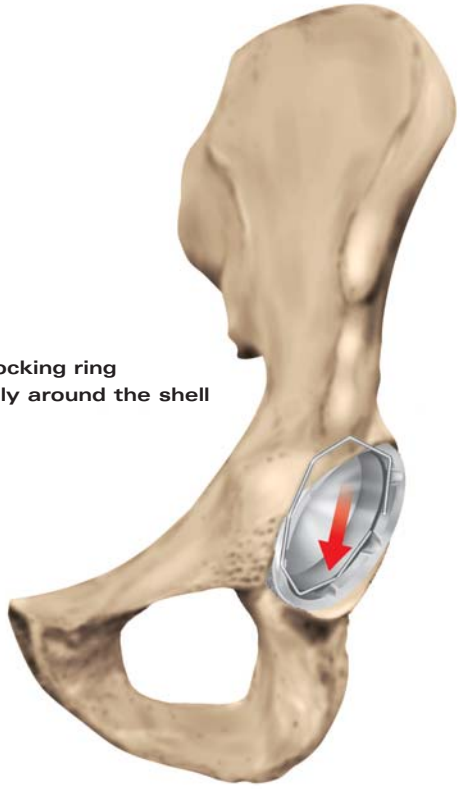


FIGURE 29
Insert the locking ring progressively around the shell

Prior to the insertion/impaction, make the liner's anti-rotational tabs align with the ARD scallops in the shell (**FIGURE 30**). Seat the liner using the ID liner impactor that corresponds with the implant. It is important to impact the liner directly into the shell with one to two moderate blows (**FIGURE 31**).

The definitive polyethylene liner is inserted in the same position as the trial liner.

FIGURE 30
Align the liner anti-rotation tabs with shell scallops

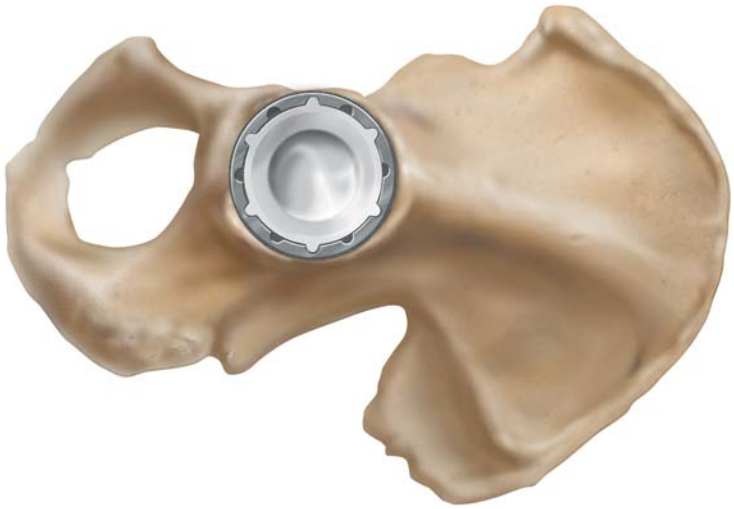
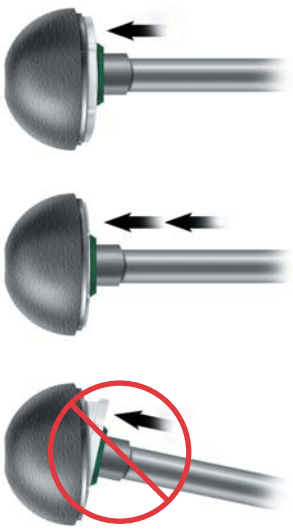


FIGURE 31
LINER IMPACTION



POLYETHYLENE LINER EXTRACTION

A polyethylene liner extractor is available to aid in polyethylene liner extraction and to help ensure the DURALOC Option shell is not damaged during polyethylene liner extraction (**FIGURE 32**).

Open the extractor jaws and place the blunt tip on the outside of the acetabular shell so the contours mate with the rim of the shell (**FIGURE 33**). The teeth of the extractor should dig into the inner diameter of the polyethylene.

FIGURE 33

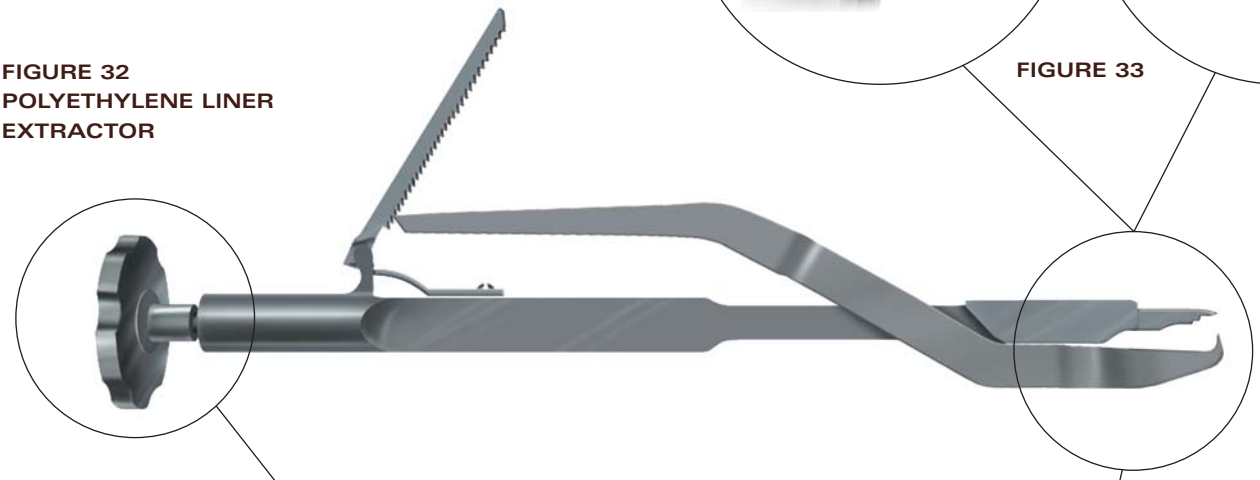


FIGURE 32
POLYETHYLENE LINER EXTRACTOR

FIGURE 34

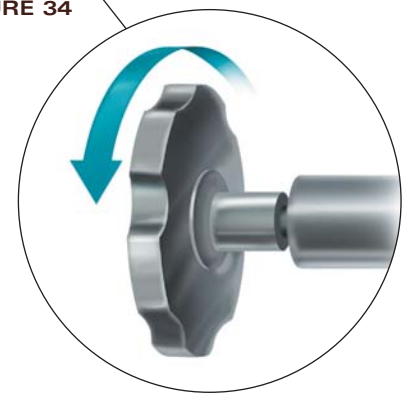


FIGURE 35

Once the blunt tip and teeth are secure on the polyethylene, advance the extraction knob clockwise until the polyethylene is removed (**FIGURES 34 AND 35**).

It is important to note that an extracted polyethylene liner cannot be reused.

DURALOC Option SHELLS

Cat. No.	Description
1599-01-048	DURALOC Option Shell 48 mm
1599-01-050	DURALOC Option Shell 50 mm
1599-01-052	DURALOC Option Shell 52 mm
1599-01-054	DURALOC Option Shell 54 mm
1599-01-056	DURALOC Option Shell 56 mm
1599-01-058	DURALOC Option Shell 58 mm
1599-01-060	DURALOC Option Shell 60 mm
1599-01-062	DURALOC Option Shell 62 mm
1599-01-064	DURALOC Option Shell 64 mm
1599-01-066	DURALOC Option Shell 66 mm

APEX HOLE ELIMINATOR

Cat. No.	Description
1246-03-000	Apex Hole Eliminator

BIOLOX FORTE ALUMINA CERAMIC FEMORAL HEADS

12/14 Taper Articul/eze® for use with the Summit Porocoat Tapered Hip System only

Cat. No.	Size (mm)
1365-73-000	28 mm +1.5
1365-74-000	28 mm +5
1365-76-000	32 mm +1
1365-77-000	32 mm +5
1365-78-000	32 mm +9

11/13 S-ROM Taper for use with the S-ROM Modular Hip System only

Cat. No.	Size (mm)
52-8323	32 mm +0
52-8330	32 mm +6

BIOLOX FORTE CERAMIC INSERTS

Cat. No.	Description
1599-63-048	DURALOC Option Ceramic 28 mm ID x 48 or 50 mm OD
1599-64-052	DURALOC Option Ceramic 32 mm ID x 52 mm OD
1599-64-054	DURALOC Option Ceramic 32 mm ID x 54 or 56 mm OD
1599-64-058	DURALOC Option Ceramic 32 mm ID x 58 or 60 mm OD
1599-64-062	DURALOC Option Ceramic 32 mm ID x 62, 64 or 66 mm OD

DURALOC Option ENDURON LINERS

Cat. No.	Description
Standard Profile	
1599-13-048	DURALOC Option Enduron STD 28 mm ID x 48 or 50 mm OD
1599-13-052	DURALOC Option Enduron STD 28 mm ID x 52 mm OD
1599-13-054	DURALOC Option Enduron STD 28 mm ID x 54 or 56 mm OD
1599-13-058	DURALOC Option Enduron STD 28 mm ID x 58 or 60 mm OD
1599-13-062	DURALOC Option Enduron STD 28 mm ID x 62, 64 or 66 mm OD
Lipped Profile	
1599-23-048	DURALOC Option Enduron LPW 28 mm ID x 48 or 50 mm OD
1599-23-052	DURALOC Option Enduron LPW 28 mm ID x 52 mm OD
1599-23-054	DURALOC Option Enduron LPW 28 mm ID x 54 or 56 mm OD
1599-23-058	DURALOC Option Enduron LPW 28 mm ID x 58 or 60 mm OD
1599-23-062	DURALOC Option Enduron LPW 28 mm ID x 62, 64 or 66 mm OD

6.5 mm DURALOC BONE SCREWS

Cat. No.	Description
1172-15-000	Cancellous Bone Screw 15 mm
1172-20-000	Cancellous Bone Screw 20 mm
1172-25-000	Cancellous Bone Screw 25 mm
1172-30-000	Cancellous Bone Screw 30 mm
1172-35-000	Cancellous Bone Screw 35 mm
1172-40-000	Cancellous Bone Screw 40 mm
1172-45-000	Cancellous Bone Screw 45 mm
1172-50-000	Cancellous Bone Screw 50 mm
1172-55-000	Cancellous Bone Screw 55 mm
1172-60-000	Cancellous Bone Screw 60 mm
1172-65-000	Cancellous Bone Screw 65 mm
1172-70-000	Cancellous Bone Screw 70 mm

DURALOC Option POLYETHYLENE LOCKING RING

Cat. No.	Description
1249-48-000	Dynamic Locking Ring 48 mm (48 and 50 mm shell)
1249-50-000	Dynamic Locking Ring 50 mm (52mm shell)
1249-52-000	Dynamic Locking Ring 52 mm (54 and 56 mm shell)
1249-56-000	Dynamic Locking Ring 56 mm (58 and 60 mm shell)
1249-62-000	Dynamic Locking Ring 62 mm (62, 64 and 66 mm shell)

ACETABULAR SHELL TRIALS

Cat. No.	Description
9599-48-000	DURALOC Option Acetabular Shell Trial 48
9599-50-000	DURALOC Option Acetabular Shell Trial 50
9599-52-000	DURALOC Option Acetabular Shell Trial 52
9599-54-000	DURALOC Option Acetabular Shell Trial 54
9599-56-000	DURALOC Option Acetabular Shell Trial 56
9599-58-000	DURALOC Option Acetabular Shell Trial 58
9599-60-000	DURALOC Option Acetabular Shell Trial 60
9599-62-000	DURALOC Option Acetabular Shell Trial 62
9599-64-000	DURALOC Option Acetabular Shell Trial 64
9599-66-000	DURALOC Option Acetabular Shell Trial 66

DURALOC Option TRIAL LINERS - 28 mm I.D. LPW POLYETHYLENE

Cat. No.	Description
9599-82-000	DURALOC Option Trial LPW 48 or 50
9599-83-000	DURALOC Option Trial LPW 52
9599-84-000	DURALOC Option Trial LPW 54 or 56
9599-85-000	DURALOC Option Trial LPW 58 or 60
9599-86-000	DURALOC Option Trial LPW 62, 64 or 66

28 mm I.D. POLYETHYLENE & CERAMIC*

Cat. No.	Description
9599-74-000	DURALOC Option Trial STD 48 or 50*
9599-75-000	DURALOC Option Trial STD 52
9599-76-000	DURALOC Option Trial STD 54 or 56
9599-77-000	DURALOC Option Trial STD 58 or 60
9599-78-000	DURALOC Option Trial STD 62, 64 or 66

*** Ceramic is only available in sizes 48 and 50 mm.**

32 mm I.D. CERAMIC

Cat. No.	Description
9599-40-000	DURALOC Option Trial 52
9599-41-000	DURALOC Option Trial 54 or 56
9599-42-000	DURALOC Option Trial 58 or 60
9599-43-000	DURALOC Option Trial 62, 64 or 66

INSTRUMENTS

Cat. No.	Description
2015-24-000	ACS/Duraloc Polyethylene Impactor
2244-08-000	Duraloc Curved Shell Impactor
2244-10-000	Acetabular Alignment Guide
2346-01-000	Apex Hole Eliminator Tapered Hex Driver
2360-71-000	Duraloc Straight Shell Impactor
2129-12-000	Impactor Replacement Ball 32
2129-20-000	Impactor Replacement Ball 28
9599-09-000	Ceramic Inserter
9599-10-000	Ceramic Liner Inserter - Spare Tip
9599-08-000	DURALOC Option Polyethylene Extractor
9599-03-000	DURALOC Option Ceramic Liner Extractor 48 or 50
9599-04-000	DURALOC Option Ceramic Liner Extractor 52
9599-05-000	DURALOC Option Ceramic Liner Extractor 54 or 56
9599-06-000	DURALOC Option Ceramic Liner Extractor 58 or 60
9599-07-000	DURALOC Option Ceramic Liner Extractor 62, 64 or 66

Trays	
Cat. No.	**Description**
2244-20-000	Duraloc Impaction Instruments Tray
2244-21-000	Duraloc Polyethylene Extractor/Impactor Tray

SCREW INSTRUMENTATION

Cat. No.	Description
2274-02-000	Duraloc Ratchet Screwdriver Handle
2274-04-000	Duraloc Hex Screwdriver Shaft Rigid
2274-06-000	Duraloc Hex Screwdriver Shaft Flex
2274-08-000	Duraloc Hex Screwdriver Shaft Cardan
2366-86-000	Duraloc Drill Bit 3.2/25
2274-10-000	Duraloc Drill Bit 3.2/40
2366-88-000	Duraloc Drill Bit 3.2/50
2366-84-000	Duraloc Drill Bit 3.8/25
2274-12-000	Duraloc Drill Bit 3.8/40
2366-85-000	Duraloc Drill Bit 3.8/50
2274-20-000	Duraloc Flex Drill Shaft
2274-22-000	Duraloc Rigid Drill Shaft
2274-32-000	Duraloc T-Handle with Hudson
2274-36-000	Duraloc Depth Gauge
2015-28-000	Screw Holding Forceps
2364-12-000	3.8 mm Drill Guide

AB GRIPPER INSERTER

Cat. No.	Description
2218-90-000	AB STRAIGHT INSERTER
2218-90-003	AB CURVED INSERTER
2218-95-002	DURALOC OPTION 28MM TIP
2218-95-003	DURALOC OPTION 32MM TIP
2218-95-048	DURALOC OPTION 48MM GRIPPER
2218-95-052	DURALOC OPTION 52MM GRIPPER
2218-95-054	DURALOC OPTION 54MM GRIPPER
2218-95-058	DURALOC OPTION 58MM GRIPPER
2218-95-062	DURALOC OPTION 62MM GRIPPER
2244-29-000	DURALOC OPT AB INSRT CASE COMP
2244-29-100	DURALOC OPT AB INSERTER TRAY
2244-29-200	DURALOC OPTION AB INSERTER LID
2244-29-500	AB GRIPPER KIT DURALOC OPT US

Essential Product Information

Important: This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information, including a full report of the adverse events.

INTENDED USE/INDICATIONS The Duraloc® Option Hip System is indicated for non-cemented use in primary total hip arthroplasty in skeletally mature patients with non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, congenital hip dysplasia, and post-traumatic arthritis.

THE DURALOC® OPTION ACETABULAR LINERS ARE INTENDED FOR USE ONLY WITH DEPUY BIOLOX® FORTE ALUMINA CERAMIC HEADS. THE CERAMIC HEADS ARE ONLY INDICATED FOR USE WITH SUMMIT and S-ROM FEMORAL STEMS.

CONTRAINDICATIONS Overt or latent infection in or around the hip joint; skeletally immature patients; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; and poor bone quality, such as osteoporosis where, in the surgeon's opinion, there is inadequate bone to support the implant(s).

WARNINGS and PRECAUTIONS The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the hip replacement: obesity or excessive patient weight; manual labor; active sports participation; high levels of patient activity; likelihood of falls; alcohol or drug addiction; other disabilities, as applicable.

WARNINGS: Seat the acetabular shell at a 45° inclination with 15° anteversion for proper positioning. Failure to use the optimum size implant, failure to adequately seat the component adjacent to adequate bone and/or failure to ensure that the component is stable may result in loosening, dislocation, subsidence or fracture of the prosthesis. Avoid impacting the taper region and the shell face to adjust shell position. As with any other ceramic insert, damage to the taper or the adjacent shell face may increase the risk for fracture and/or chipping of the insert upon its engagement with the shell. Prior to final seating of the liner to the metal shell, correct alignment of the liner/shell assembly must be obtained. Incorrect alignment of the liner/shell assembly may increase the risk for fracture and/or chipping of the liner upon its engagement with the shell. Once final assembly has been completed, the insert should be visually inspected and palpated for evidence of chipping and/or fracture. Do not assemble and disassemble the liner component to the acetabular shell. Do not scratch or damage the surface or tapers of the components. Do not use other manufacturer's components with any of the Duraloc Option components. Use only compatible DePuy hip stems, femoral heads, acetabular liners and acetabular shells components with the Duraloc Option components. Do not use any component that has been chipped, scratched, or otherwise damaged during the implant procedure. Do not implant in obese patients. Implants are for single use only.
PRECAUTIONS: Clean surgical debris from the interior of the shell prior to seating the liner into the shell to prevent accelerated bearing wear. Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material. Clean and dry surfaces which lock to ensure proper seating and assembly. Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular liner. Do not alter or modify implants in any way. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone. Always use a trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration, size, etc., as the corresponding components to be permanently implanted. Ceramic acetabular inserts and femoral heads CANNOT be re-sterilized. Do not use these components if the sterile packaging appears damaged.

ADVERSE EVENTS Potential adverse effects of the DURALOC® Option Ceramic on Ceramic Hip were determined from a single center, retrospective study of 959 cases. The frequencies of the complications reported are available in the Instructions for Use. The most frequent adverse events after hip arthroplasty include a change in position of the components, loosening of the components, fracture of components, dislocation, infection, tissue reaction.

Revised: 18 September 2006

For more information about the DURALOC Option Ceramic Cup System or alternative bearings, visit our web site at **www.jnjgateway.com.**

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