

Trident® Tritanium™ Acetabular System

Surgical Protocol



For Crossfire® and X3™ Polyethylene
and Trident® Alumina Ceramic
Inserts With Tritanium™
Hemispherical Acetabular Shells

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For Crossfire® and X3™ Polyethylene
and Trident® Alumina Ceramic
Inserts With Tritanium™
Hemispherical Acetabular Shells

Indications

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.



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Introduction

The Trident® Tritanium™ Acetabular System provides surgeons with a highly porous ingrowth surface.

The Trident® Tritanium™ Acetabular System hemispherical shells are manufactured from Commercially Pure Titanium. The Trident® Tritanium™ shells utilize the screw hole pattern and locking mechanism from the Trident® Acetabular System. The shells are available in sizes 48mm-80mm, and offer the option of Alumina Ceramic or Crossfire® or X3™ polyethylene inserts. Refer to **Table 1** for insert and shell compatibility and sizing options.

Trident® Alumina Ceramic Inserts gain fixation within the shell by means of mating tapers. Rotational stability between the components is achieved when the shell's anti-rotational barbs interlock with the insert's scallops. **The Trident® Alumina Ceramic Inserts must be used with Stryker® Orthopaedics Alumina Heads.**

The Trident® Polyethylene Inserts lock into the shell by means of a circumferential ring that engages the shell's mating groove. Rotational stability is achieved when the shell's anti-rotational barbs interlock with the insert's scallops.

The Trident® Tritanium™ Acetabular System utilizes the CuttingEdge™ Total Hip Acetabular Instrumentation. This surgical technique is a guide to preparing the acetabulum for the Trident® Tritanium™ Hemispherical Acetabular implants.



Trident® Tritanium™
Acetabular Shell



Trident®
Alumina
Insert



Crossfire®
Polyethylene
Insert and X3™
Polyethylene
Insert



Alumina
Femoral Head



Bilox® *delta*
Femoral Head



LFIT™ Ion
Implanted CoCr
Femoral Head

TABLE 1: Trident® Product Compatibility**22mm Femoral Head Diameter**

Trident® Titanium™ Hemispherical Shell Size	Alpha Code	Trident® X3™ Crossfire® 0°, 10° Insert Poly Thickness (mm)	Eccentric Insert Poly Thickness (mm)	Elevated Rim Insert Poly Thickness (mm)	10° Constrained Insert Outer Bearing Thickness (mm)	10° Constrained Insert Total Range of Motion	10° Constrained Insert O.D. Spherical Diameter (mm)	Trident® Alumina Ceramic 0° Inserts I.D. (mm)
48	C	9.8	-	-	-	-	-	-
50, 52	D	10.8	-	-	-	-	-	-
54, 56	E	12.8	-	-	7.9	72	44	-
58, 60	F	14.8	-	-	9.9	72	48	-
62, 64	G	16.3	-	-	-	-	-	-
66, 68	H	18.1	-	-	-	-	-	-
70, 72	I	19.6	-	-	-	-	-	-
74, 76, 78, 80	J	21.6	-	-	-	-	-	-

26mm Femoral Head Diameter

Trident® Titanium™ Hemispherical Shell Size	Alpha Code	Trident® X3™ Crossfire® 0°, 10° Insert Poly Thickness (mm)	Eccentric Insert Poly Thickness (mm)	Elevated Rim Insert Poly Thickness (mm)	10° Constrained Insert Outer Bearing Thickness (mm)	10° Constrained Insert Total Range of Motion	10° Constrained Insert O.D. Spherical Diameter (mm)	Trident® Alumina Ceramic 0° Inserts I.D. (mm)
48	C	7.9	-	-	-	-	-	-
50, 52	D	8.9	-	-	-	-	-	-
54, 56	E	10.9	-	-	-	-	-	-
58, 60	F	12.9	-	-	-	-	-	-
62, 64	G	14.4	-	-	-	-	-	-
66, 68	H	16.2	-	-	-	-	-	-
70, 72	I	17.7	-	-	-	-	-	-
74, 76, 78, 80	J	19.7	-	-	-	-	-	-

28mm Femoral Head Diameter

Trident® Titanium™ Hemispherical Shell Size	Alpha Code	Trident® X3™ Crossfire® 0°, 10° Insert Poly Thickness (mm)	Eccentric Insert Poly Thickness (mm)	Elevated Rim Insert Poly Thickness (mm)	10° Constrained Insert Outer Bearing Thickness (mm)	10° Constrained Insert Total Range of Motion	10° Constrained Insert O.D. Spherical Diameter (mm)	Trident® Alumina Ceramic 0° Inserts I.D. (mm)
48	C	5.9	10.5	5.9	-	-	-	-
50, 52	D	7.9	11.6	7.9	-	-	-	28
54, 56	E	9.9	13.5	9.9	-	-	-	-
58, 60	F	11.9	15.6	11.9	-	-	-	-
62, 64	G	13.4	17.1	13.4	8.4	84	51	-
66, 68	H	15.2	18.8	15.2	10.2	84	55	-
70, 72	I	16.7	20.4	16.7	11.6	84	58	-
74, 76, 78, 80	J	18.7	22.4	-	13.7	84	62	-

32mm Femoral Head Diameter

Trident® Titanium™ Hemispherical Shell Size	Alpha Code	Trident® X3™ Crossfire® 0°, 10° Insert Poly Thickness (mm)	Eccentric Insert Poly Thickness (mm)	Elevated Rim Insert Poly Thickness (mm)	10° Constrained Insert Outer Bearing Thickness (mm)	10° Constrained Insert Total Range of Motion	10° Constrained Insert O.D. Spherical Diameter (mm)	Trident® Alumina Ceramic 0° Inserts I.D. (mm)
50, 52	D	5.9	9.5	-	-	-	-	-
54, 56	E	7.9	11.5	7.9	-	-	-	32
58, 60	F	9.9	13.5	9.9	-	-	-	32
62, 64	G	11.4	15.0	11.4	-	-	-	-
66, 68	H	13.2	16.8	13.2	-	-	-	-
70, 72	I	14.7	18.3	14.7	-	-	-	-
74, 76, 78, 80	J	16.7	20.3	-	-	-	-	-

36mm Femoral Head Diameter

Trident® Titanium™ Hemispherical Shell Size	Alpha Code	Trident® X3™ Crossfire® 0°, 10° Insert Poly Thickness (mm)	Eccentric Insert Poly Thickness (mm)	Elevated Rim Insert Poly Thickness (mm)	10° Constrained Insert Outer Bearing Thickness (mm)	10° Constrained Insert Total Range of Motion	10° Constrained Insert O.D. Spherical Diameter (mm)	Trident® Alumina Ceramic 0° Inserts I.D. (mm)
54, 56	E	5.9	9.5	5.9	-	-	-	-
58, 60	F	7.9	11.5	7.9	-	-	-	-
62, 64	G	9.4	13.0	9.4	-	-	-	36
66, 68	H	11.2	14.8	11.2	-	-	-	36
70, 72	I	12.7	16.3	12.7	-	-	-	36
74, 76, 78, 80	J	14.7	18.3	-	-	-	-	-

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Preoperative Planning and X-ray Evaluation

Preoperative planning and X-ray evaluation aids in the selection of the most favorable implant style and optimal size for the patient's hip pathology. Selecting potential implant styles and sizes can facilitate operating room preparation and assure availability of an appropriate size selection. X-ray evaluation may also help detect anatomic anomalies that could prevent the intraoperative achievement of the established preoperative goals.

If a revision of an existing acetabular shell is required, the surgeon's preferred technique for removing the acetabular shell should be used.

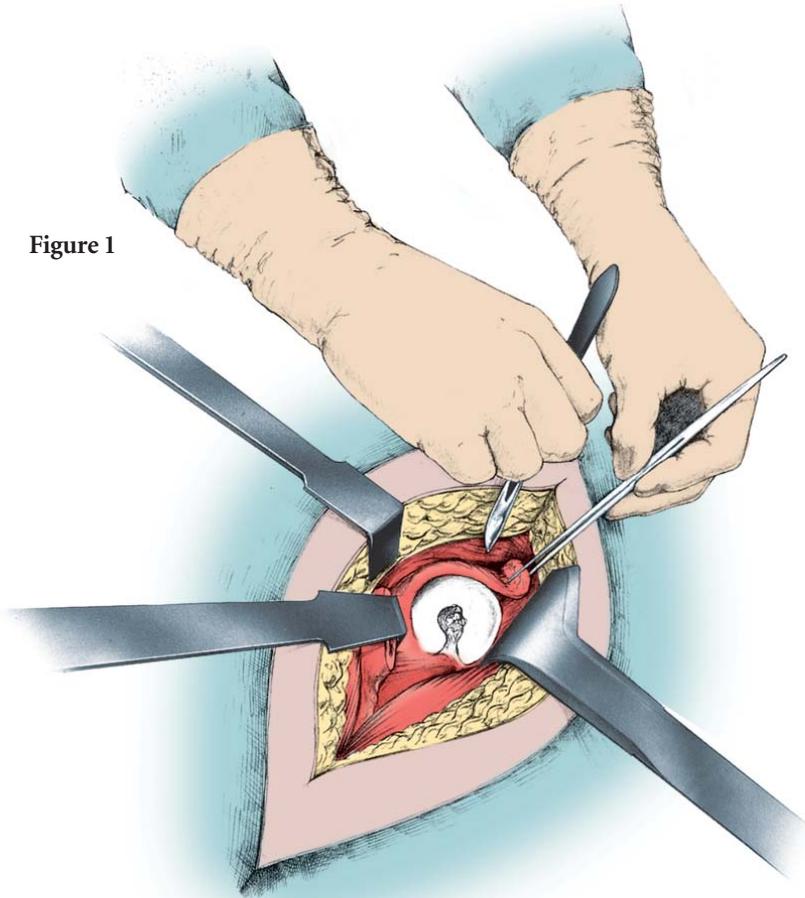
Acetabular Preparation

The acetabulum is prepared by the release and removal of soft tissue using the surgeon's preferred technique to gain adequate exposure for reaming. Excision of the labrum and osteophytes allows for proper visualization of the bony anatomy, and improves ease of reaming.

Stryker® Orthopaedics' Retractors can be utilized to gain acetabular exposure (**Figure 1**).

With the acetabulum exposed, bony defects, can be identified. If necessary, bone grafting options may be considered prior to reaming.

Figure 1



Spherical Reaming

To obtain congruity in the reaming process, an optional 45/20° Abduction/Anteversion Alignment Guide can be attached to the CuttingEdge™ Reamer Handle (Figure 2). The alignment guide, when perpendicular to the long axis of the patient, will orient the reamer handle at 45° of abduction, thereby placing the axis of the spherical reamer at 45° of inclination (Figure 3). The reamer handle may then be positioned at 20° of anteversion by aligning the left/right anteversion rod on the alignment guide so that it is parallel to the long axis of the patient.

It is recommended that initial reaming begin with a CuttingEdge™ Spherical Reamer that is 4mm smaller than the templated or gauged size. The reamer is attached to the reamer handle by pushing down and applying a quarter-turn to lock in place. Reaming progresses in 1mm increments until final desired sizing is achieved. **Due to the porous nature of the Tritanium™ coating, the outer diameter may be larger than the size indicated. The surgeon must consider this in the acetabular preparation.**

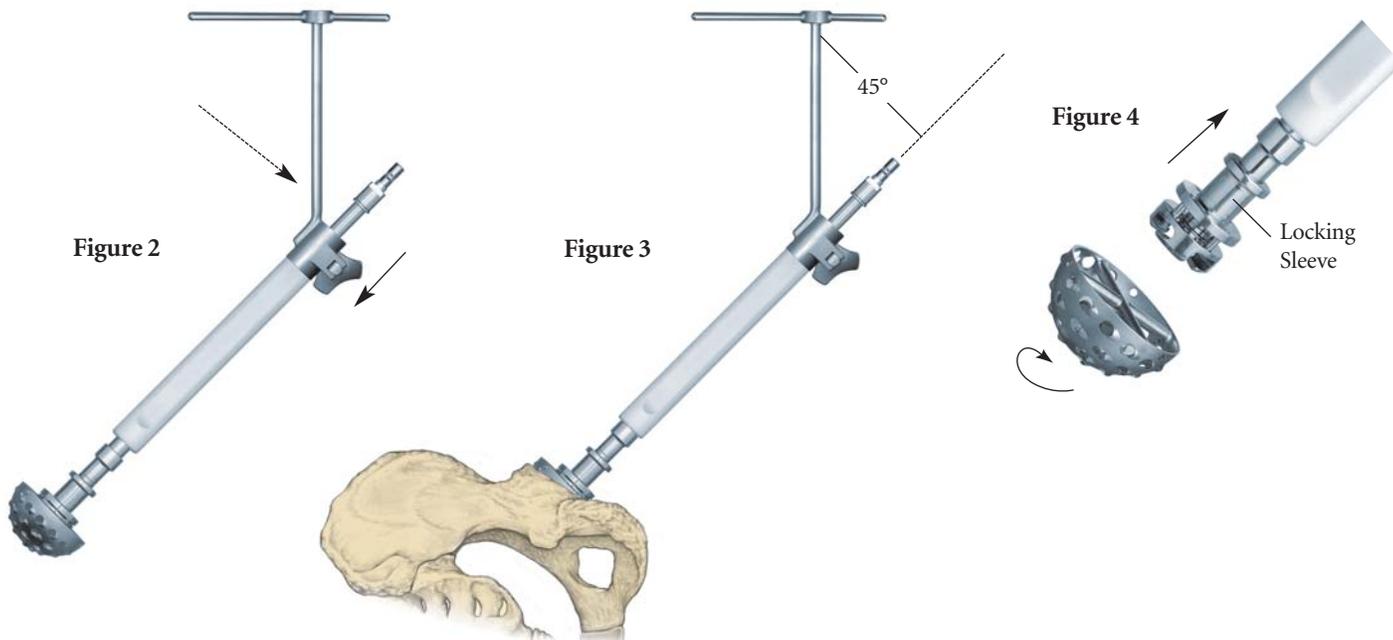
NOTE: Depending on bone quality and surgeon preference, the surgeon may choose to ream line-to-line, or under-ream.

The low profile design of the CuttingEdge™ Spherical Reamer necessitates reaming to the full depth. The reamer head should be driven to the point where the rim/cross bar contacts the acetabular wall at the peripheral lunate region. Removal of the reamer from the handle is performed by pulling back on the locking sleeve and rotating the reamer head a quarter-turn in a clockwise direction (Figure 4).

Care should be taken so as not to enlarge or distort the acetabulum by eccentric reaming. Final acetabular reaming ideally shows the hemispherical acetabulum denuded of cartilage, with the subchondral plate preferably intact, and the anterior acetabular wall preserved.

It is believed that the subchondral plate functions as an important load-sharing and support mechanism. Preserving as much of the subchondral plate as possible may improve the qualities of the bone/metal composite.

Note: The CuttingEdge™ Spherical Reamers are very aggressive and perform best when sharp. Care should be taken to protect the reamer from unnecessary handling, as dull or damaged cutting teeth may cause improper reaming. Dull cutting teeth will deflect to cut softer bone and resist hard bone. This situation may result in an irregularly shaped or enlarged acetabulum preparation.



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Trial Evaluation

Following the reaming procedure, the appropriate Trident® Tritanium™ Window Trial (**Table 2**), of the same diameter as the last spherical reamer used, is threaded onto the CuttingEdge™ Shell Positioner/Impactor and placed in the acetabulum to evaluate the size and congruity of the preparation (**Figure 5**). The trial is “windowed” for visualization and assessment of fit, contact and congruity of the trial within the acetabulum. By inserting the Trident® Trial Insert into the Trident® Tritanium™ Window Trial (**Figures 6 & 7**), joint mechanics can be evaluated. To ensure that the Trial Insert is well fixed to the Trident® Tritanium™ Window Trial during the trial evaluation, an Acetabular Trial Insert Containment Screw can be used. The Containment Screw Kit (2230-0010) is optional (**Figure 6**). The containment screw has a Torx® drive feature and is compatible with Torx® screwdrivers.

To facilitate insertion/removal of the Trial Insert, holding forceps may be placed into the two holes in the plastic face.

When trialing, it is recommended to use a Trident® Tritanium™ Window Trial 1mm-2mm smaller than the implant OD so as not to destroy the press-fit.

Note: The Window Trials (2208-40XX) specific to the Trident® Tritanium™ Acetabular System must be used.

TABLE 2: Trident® Tritanium™ Window Trial/Trial Insert Sizing

Trident® Tritanium™ Window Trial (mm)	Trident® Trial Insert Compatibility Class
46	C
47	C
48	D
49	D
50	D
51	D
52	E
53	E
54	E
55	E
56	F
57	F
58	F
59	F
60	G
61	G
62	G
63	G
64	H
65	H
66	H
67	H
68	I
69	I
70	I
71	I
72	J
73	J
74	J
75	J
76	J
77	J
78	J
79	J
80	J

Figure 5



Figure 6

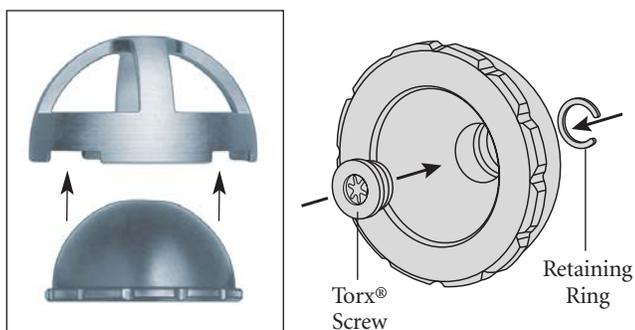
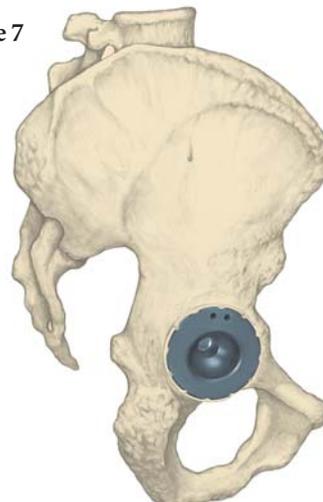


Figure 7



Trident® Tritanium™ Hemispherical Shell Implantation

After completing the trial reduction, select the appropriately sized implant component.

If desired, the CuttingEdge™ Abduction/Anteversion Alignment Guide can be attached to the CuttingEdge™ Shell Positioner/Impactor to help establish the recommended 45° of abduction inclination and 20° of anteversion (Figures 8 & 9).

Caution: Proper pelvic orientation is critical if relying upon the CuttingEdge™ Alignment Guide to achieve the desired abduction/anteversion angles for shell positioning.

The metal shell is threaded onto the impactor at the threaded hole in the dome of the metal shell. It is important to fully engage the threads and seat the impactor against the shell. Otherwise, the threads on the metal shell could become damaged, resulting in difficulty with the removal of the impactor from the shell.

The cluster screw hole pattern holes are intended to be oriented superiorly (Figure 10).

NOTE: Shell positioning must be carefully considered when selecting a ceramic insert as no hooded option is available to adjust joint stability. Proper positioning of the Trident® Tritanium™ Hemispherical Shell will minimize potential impingement and provide stability and articulation between the Alumina Insert and Head. Excessive vertical orientation of the Shell should be avoided as this may lead to premature wear of the ceramic material.

Figure 8

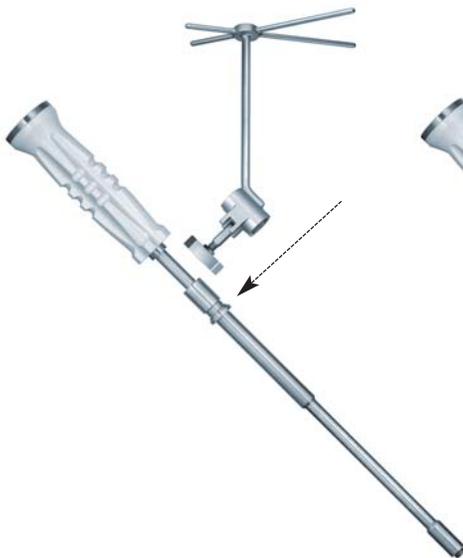


Figure 9

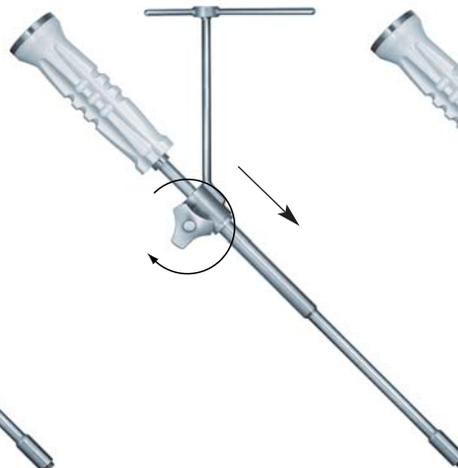
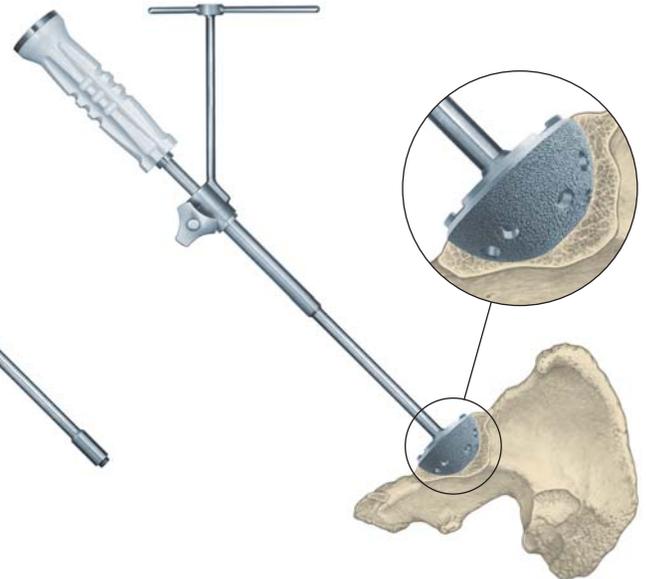


Figure 10



Trident® Tritanium™ Acetabular System

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Trident® Tritanium™ Hemispherical Shell Implantation (cont.)

The recommended metal shell abduction angle of 45° is determined by positioning the alignment guide perpendicular to the long axis of the patient (Figure 11).

Metal shell anteversion is set at approximately 20° by moving the cup impactor so that the left / right anteversion rod is parallel to the long axis of the patient (Figure 12).

The metal shell is impacted into the acetabulum using a mallet until a tight, stable press-fit is achieved. The thumbscrew on the alignment guide is then loosened to remove the guide. After removing the guide, the impactor handle is carefully unthreaded from the shell.

The depth of the shell seating may now be determined by viewing through the threaded hole in the dome. If it is determined that the shell is not fully seated, the CuttingEdge™ Final Cup Impactor may then be required to assist in impacting the shell until it is completely seated in the prepared acetabulum.

Figure 11

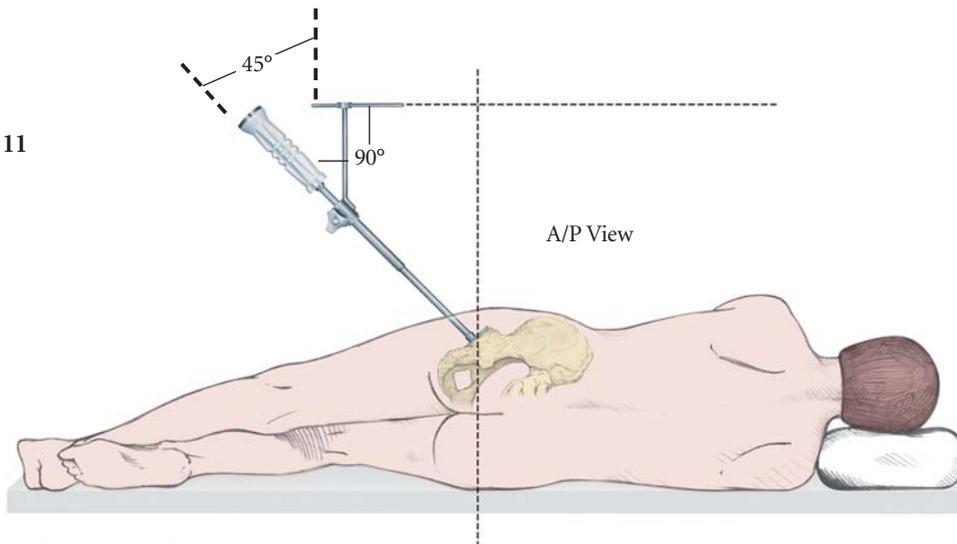
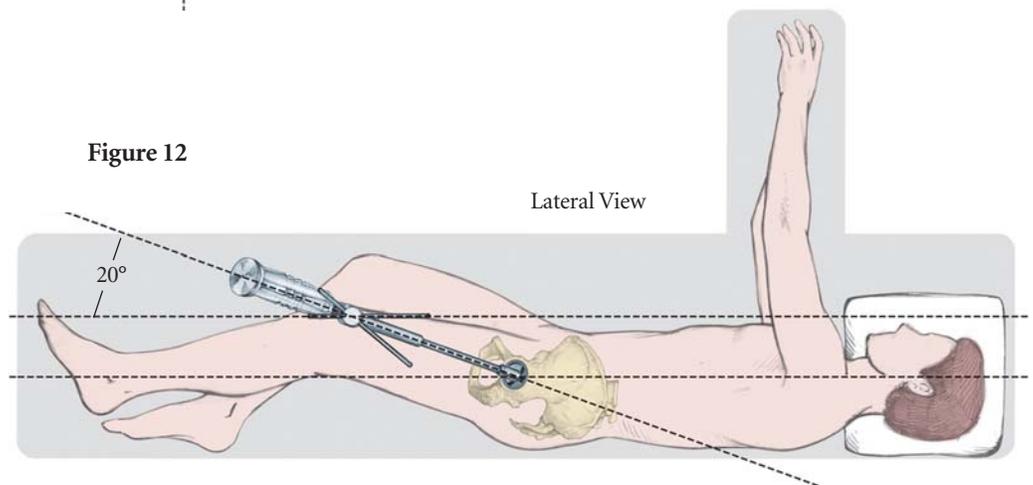


Figure 12



Optional Screw Utilization

Only Stryker® Orthopaedics Cancellous 6.5mm Bone Screws can be used. Stryker® Orthopaedics offers 6.5mm diameter cancellous bone screws for use in the shell dome, which are available in a variety of lengths (Table 3). The surgeon has the option of hex or Torx® screws as shown in Table 3. Stryker® Orthopaedics Cancellous Bone Screws are designed to be inserted or removed only with the assistance of Stryker® Orthopaedics screw instruments.

After determination of the proper site for screw placement, a 3.2mm diameter drill is passed through a drill guide to the desired depth (Figure 13). It is important to use the proper drill guide (6060-5-310 or 6060-5-300) to keep the pilot hole as straight as possible, so that the screw head fully seats. The screw hole is then sounded to determine the hole's depth. The properly sized screw is then selected and implanted into the bone using Stryker® Orthopaedics Screw Drivers with a high torque configuration driver head (Figure 14).

Note: In hard bone, the use of 6.5mm dome screws prepared in the usual fashion may be difficult. The use of a 4.0mm drill bit may make the utilization easier, without substantial compromise of screw purchase.

Caution: Do not pass a drill, screw or any other instrumentation beyond the inner table of the pelvis. Malposition of either the shell screw hole orientation, screw hole preparation or improper use of the screws themselves may contribute to detrimental clinical consequences.

Trial Insert Reduction

After metal shell implantation, the Trident® Trial Insert will provide a final check of hip mechanics.

TABLE 3: Stryker® Orthopaedics Cancellous 6.5mm Bone Screws

Screw Lengths (mm)	Hex Screw Catalog Number	Screw Lengths (mm)	Torx® Screw Catalog Number
12	5260-5-012	15	2080-0015
14	5260-5-014	20	2080-0020
16	5260-5-016	25	2080-0025
18	5260-5-018	30	2080-0030
20	5260-5-020	35	2080-0035
22	5260-5-022	40	2080-0040
24	5260-5-024	45	2080-0045
26	5260-5-026	50	2080-0050
28	5260-5-028	55	2080-0055
30	5260-5-030	60	2080-0060
35	5260-5-035		
40	5260-5-040		
45	5260-5-045		
50	5260-5-050		

Caution: Do not use Trident® 2030-65XX screws.

Figure 13

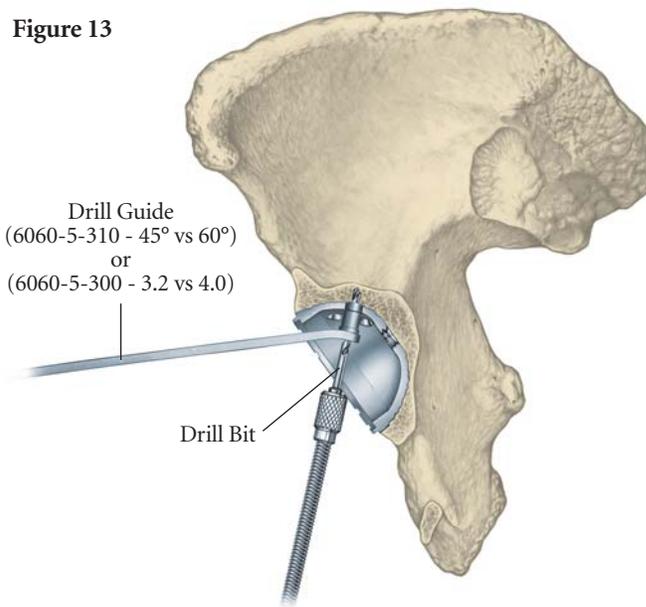
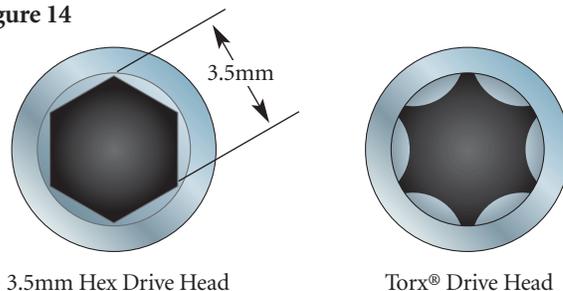


Figure 14



Trident® Tritanium™ Acetabular System

Surgical Protocol

Insert Implantation

Select the appropriate size Silicone Insert Positioner Tip.

Load Silicone Insert Positioner Tip to Insert Positioner/Impactor Handle (Figure 15).

Load either the polyethylene or ceramic insert to Insert Positioner Tip. Press firmly to ensure insert is being securely held (Figure 16).

NOTE: Use caution handling ceramic components during assembly because of brittle nature of the ceramic material. Ceramic and polyethylene components are pre-sterilized and cannot be sterilized after opening.

Ensure that the inside of the shell is clean and free of soft tissue or any other debris, which could prevent the insert from properly sitting in the shell.

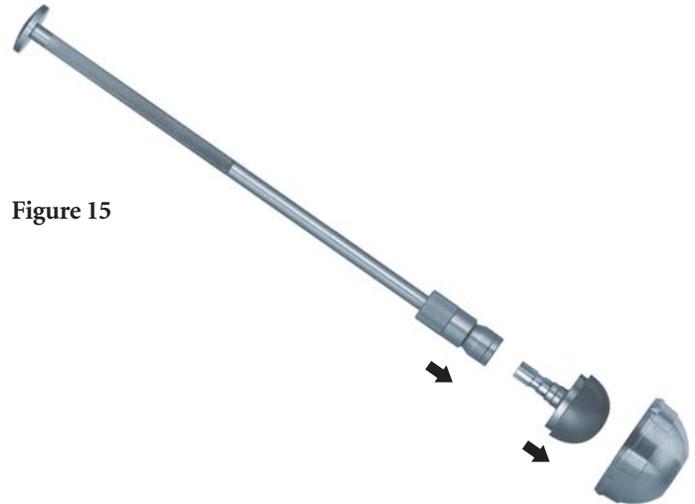


Figure 15



Figure 16

Insert Implantation (cont.)

Gently introduce the ceramic or polyethylene insert making sure that the insert flange scallops are aligned with the slot at the rim of the shell (this allows seating the insert at the initial position supported by four indexing barbs). Once the insert is seated at the initial position, slowly turn and drop the insert into the final pre-locking position (Figure 17).

NOTE: Having a clear view of the rim of the acetabulum will allow easier visualization of the shell's slot and indexing barbs for proper positioning of the insert.

Remove Silicone Insert Positioner Tip from the Insert Positioner/Impactor Handle.

Select appropriate size Plastic Insert Impactor Tip.

Load Plastic Insert Impactor Tip to Insert Positioner/Impactor Handle.

Position Insert Positioner/Impactor Handle into ID of insert. Take care to align handle with axis of shell. Strike handle with approximately four firm mallet blows to fully seat insert.

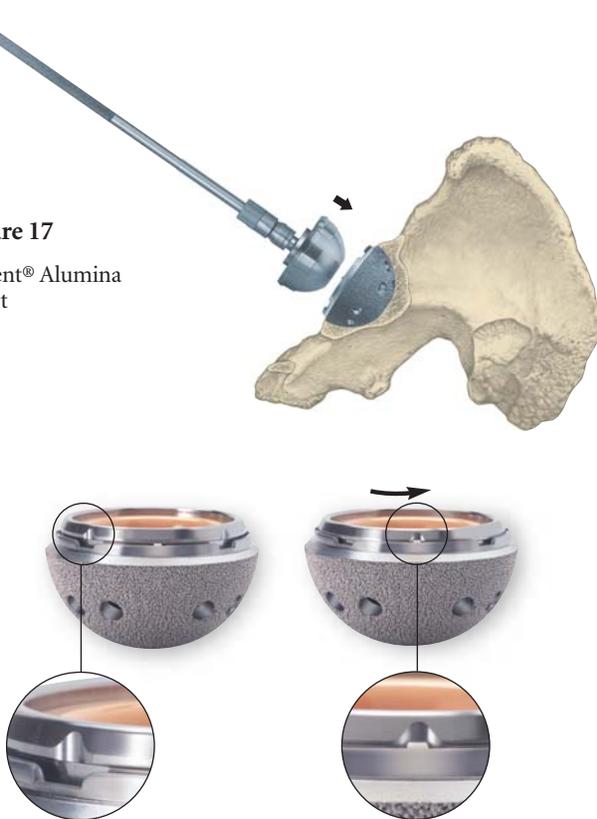
NOTE: In order to obtain a secure lock it is recommended to use only the hard plastic Insert Impactor Tips to impact the ceramic and polyethylene inserts.

Verify insert is fully seated and properly aligned into the acetabular shell. Check the taper lock by running a small osteotome around the periphery of the shell/insert interface.

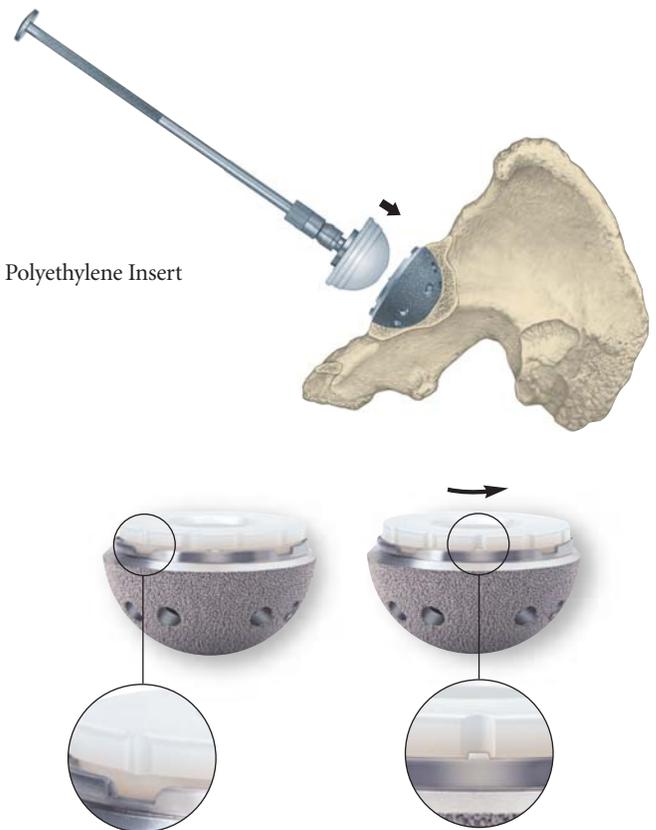
As with any modular interface under load, there is a potential for micromotion and associated fretting and/or corrosion. However, the Trident® design minimizes the amount of motion at the taper interface and should reduce the corrosion potential.

Figure 17

Trident® Alumina Insert



Polyethylene Insert



Trident® Tritanium™ Acetabular System

Surgical Protocol

Removal of the Cup Insert and Shell

Ceramic Insert Removal

The Trident® Alumina Insert Removal Tool is designed to provide the surgeon with two options for extracting the ceramic insert from the Trident® shell.

Option 1: “Flat Head”

Connect the “T” handle to the L-shaped end of the removal tool. Insert the flat end of the removal tool between the shell and ceramic insert at one of the four notches at the shell rim. While applying continuous force toward the center of the shell, twist the “T” handle (like a screwdriver), to dislodge the ceramic insert (**Figure 18**). It may be required to repeat this procedure at the other notches in order to successfully disengage the taper.

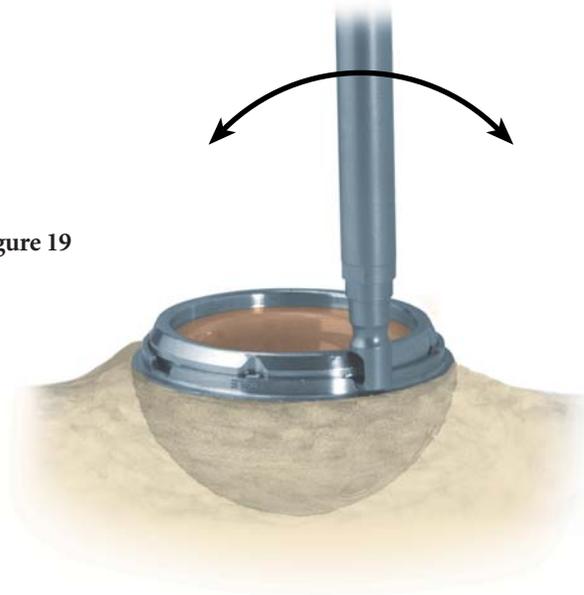
Figure 18



Option 2: “L-Shaped”

Insert the L-shaped end of the removal tool between the shell and ceramic insert at one of the four notches at the shell rim. Apply continuous force toward the center of the shell, and lever the tool in a plane tangent to the shell’s outside edge, to dislodge the ceramic insert (**Figure 19**). It may be required to repeat this procedure at the other notches in order to successfully disengage the taper.

Figure 19



The removal tool may be attached to the Insert Positioner/ Impactor Handle to increase leverage and length for larger patients.

Removal of the Cup Insert and Shell (cont.)

Polyethylene Insert Removal

Utilize a 3/16" (5mm) drill bit to create an off-center hole in the polyethylene insert. Use the "T" handle to thread the Polyethylene Insert Removal Tool into the insert, and advance the tool to the medial wall of the shell to dislodge the insert (Figures 20 & 21).

Revising the Trident® Tritanium™ Acetabular Shell with a Trident® Polyethylene Insert

Should it become necessary to remove the ceramic insert, a Trident® Polyethylene Insert can be inserted into the Trident® Tritanium™ Acetabular Shell.

Carefully remove the Trident® Alumina insert

The Trident® Insert Trials are used to evaluate the shell face position and provide a final check of hip biomechanics. The polyethylene inserts provide 12 different insert orientations within the shell to provide optimal joint stability.

Follow **Insert Implantation**, to insert the polyethylene insert.

Shell

Should removal of the metal shell ever become necessary, an osteotome or small burr can be passed around the cup periphery to loosen the fixation interface. The CuttingEdge™ Universal Shell Positioner can be threaded into the dome hole of the cup. A Slotted Mallet is slid over the positioner shaft to assist with the shell removal.

Figure 20

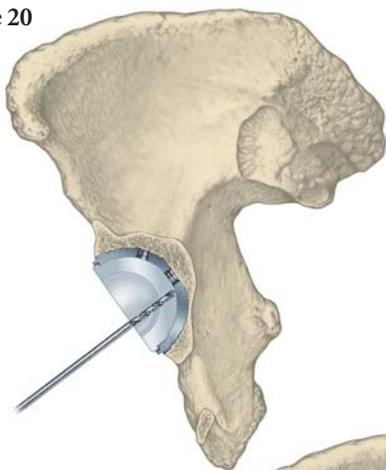
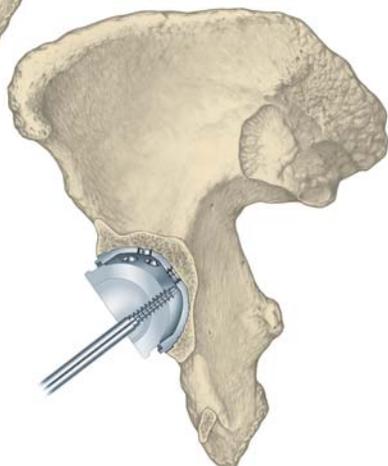


Figure 21



Head Disassembly

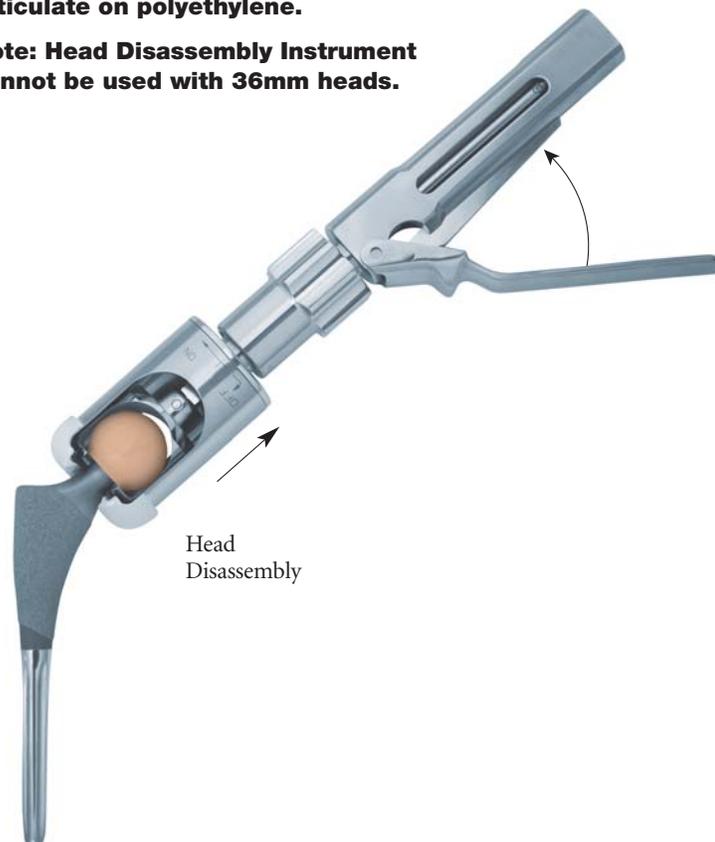
The Head Disassembly Instrument is used to remove an impacted head. Inspect the stem neck taper to verify that no damage has occurred prior to impacting a replacement head. A replacement head may then be attached to the stem neck taper and secured using the Stem Head Impactor.

Note: Revision of Ceramic Components – If a Stryker® Orthopaedics Trident® Ceramic Head needs to be revised for any reason, a new Trident® Ceramic Head must not be affixed to the existing stem trunnion because the trunnion will have been deformed through assembly with the first ceramic head component. If the surgeon wishes to revise with a ceramic head, the entire hip stem must be replaced unless the femoral stem has an intact and undamaged V40™ Taper trunnion. In this situation, the Adaptor Sleeve (catalog # 17-0000E) must be used. A new Trident® Ceramic Head can then be affixed to the Adaptor Sleeve.

Note: If a Trident® Ceramic Insert is being used, Trident® Alumina Ceramic Heads must be used to articulate with the ceramic insert. Trident® BioloX® delta Ceramic Heads are not compatible with Trident® Ceramic Inserts.

If the surgeon wishes to revise the Trident® Ceramic Head with a metal head, inspect the stem trunnion closely for damage. If it appears undamaged, a metal head may then be used. The Trident® Ceramic Insert, however, must be replaced with a Trident® Polyethylene Insert. Metal heads can only articulate on polyethylene.

Note: Head Disassembly Instrument cannot be used with 36mm heads.



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