

**The information contained in this document
is intended for healthcare professionals only.**

Trident®

Constrained Acetabular Insert

Surgical Protocol



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Table of Contents

Introduction	1
<hr/>	
Stryker Trident® Constrained Acetabular Insert	1
<hr/>	
Cementless Options	
Primary Surgery	3
Revision Surgery	3
Revising the Metal Shell	3
Retaining the Metal Shell	3
<hr/>	
Trial Evaluation	3
<hr/>	
Component Selection	3
<hr/>	
Implantation	3
<hr/>	
Femoral Bearing Head / Insert Assembly	4
<hr/>	
Constrained Insert Removal	4
<hr/>	
Cementable Options	5
<hr/>	
Trident® Constrained Acetabular Insert Trials	6
<hr/>	
Postoperative Care, Indications, Contraindications and Warnings	8

► Introduction

The Trident® Constrained Acetabular Insert is indicated for use in primary and revision total hip patients who exhibit a high risk of hip dislocation. It should be used when more conservative methods of soft tissue management, such as lengthening the femoral neck or lateralizing the joint's center of rotation, are insufficient for restoring joint stability.

The Trident® Constrained Acetabular Insert offers less range of motion from standard total hip replacement components but can be a better solution when the likelihood of dislocation is high.

Trident® Constrained Acetabular Insert

The Trident® Constrained Acetabular Insert is designed specifically for the Stryker UHR® bipolar head.

The bipolar head is preassembled in the insert and securely retained by a titanium alloy retaining ring. The Trident® 0° and 10° Constrained Acetabular Inserts can only be used in a Trident® Acetabular Shell.

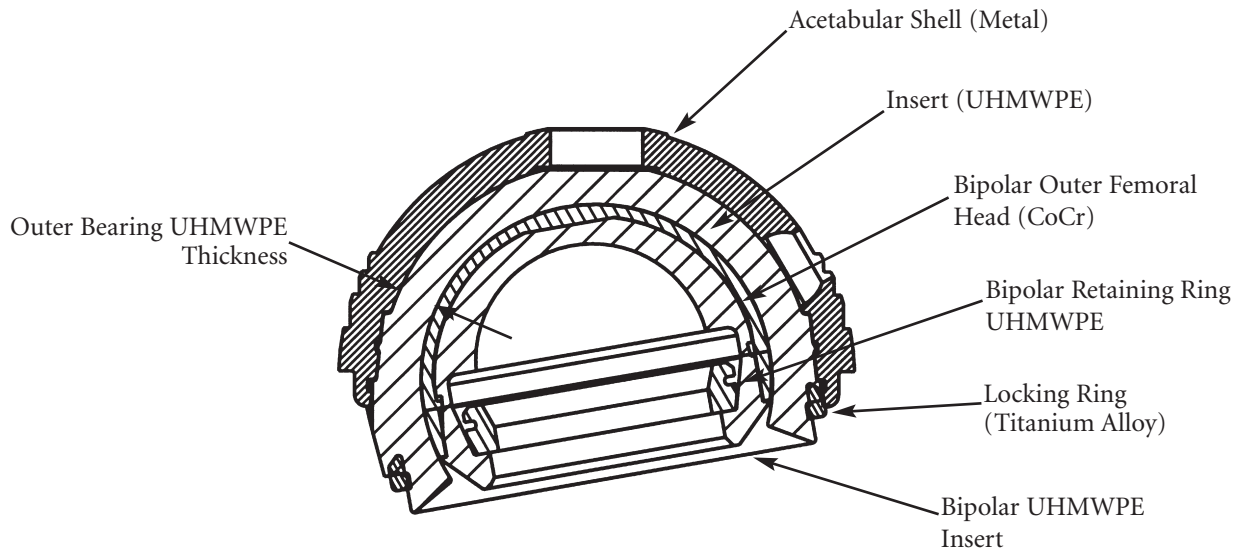
The Trident® 0° All-Poly Constrained Insert can be cemented into an existing shell or cage device, or directly into the acetabulum.

Articulation occurs at both the femoral head-to-bipolar interface and at the bipolar-to-insert interface.

A unique, patented split-ring locking mechanism facilitates ease of femoral head assembly, yet provides the potential for enhanced protection against component disassembly.

A head removal key allows for easy, non-destructive component disassembly.

A dynamic valgus alignment creates a constant neutral alignment of the bipolar within the insert during weight bearing to provide increased head coverage. This prevents inner bearing articulation from occurring on the locking mechanism, thus sparing the mechanism from extreme loading.



Trident® Constrained Acetabular Inserts



Trident® 0° Constrained Acetabular Insert



Trident® 10° Constrained Acetabular Insert



Trident® 0° All-Poly Constrained Acetabular Insert

Table 1: Trident® 0° Constrained Inserts

Trident® Alpha Code*	Trident® Constrained Insert Catalog Number	Bipolar Femoral Head Size (mm)	Bipolar Head OD (mm)	Outer UHMWPE Thickness (mm)	Total Range of Motion***	Outer OD Spherical Diameter (mm)	Head Removal Key Catalog Number	Insert Catalog No.
D	690-00-22D	22	36	5.6	82°	40.4	HI-UHRK-3638**	2270-22D
E	690-00-22E	22	36	7.5	82°	44.4	HI-UHRK-3638**	2270-22E
F	690-00-28F	28	42	6.5	90°	48.5	HI-UHRK-28	2270-28F
G	690-00-28G	28	42	8.1	90°	51.5	HI-UHRK-28	2270-28G
H	690-00-32H	32	46	7.8	94°	55.0	HI-UHRK-32	2270-32H
I	690-00-32I	32	46	9.3	94°	58.0	HI-UHRK-32	2270-32I
J	690-00-32J	32	46	11.3	94°	62.0	HI-UHRK-32	2270-32J

Table 2: Trident® 10° Constrained Inserts

Trident® Alpha Code*	Trident® Constrained Insert Catalog No.	Bipolar Femoral Head Size (mm)	Bipolar Head OD (mm)	Outer Bearing UHMWPE Thickness (mm)	Total Range of Motion***	Outer Bearing OD Spherical Diameter (mm)	Head Removal Key Catalog Number	Insert Trial Catalog No.
E	690-10-22E	22	36	7.9	82°	44.4	HI-UHRK-3638**	2230-22E
F	690-10-22F	22	36	9.9	82°	48.4	HI-UHRK-3638**	2230-22F
G	690-10-28G	28	42	8.4	90°	51.5	HI-UHRK-28	2230-28G
H	690-10-28H	28	42	10.2	90°	55.0	HI-UHRK-28	2230-28H
I	690-10-28I	28	42	11.6	90°	58.0	HI-UHRK-28	2230-28I
J	690-10-28J	28	42	13.7	90°	62.0	HI-UHRK-28	2230-28J

Table 3: Trident® 0° All-Poly Constrained Inserts

Trident® Constrained Insert Catalog No.	Bipolar Femoral Head Size (mm)	Bipolar Head OD (mm)	Outer Bearing UHMWPE Thickness (mm)	Total Range of Motion***	Outer Bearing OD Spherical Diameter (mm)	Head Removal Key Catalog Number	Insert Trial Catalog No.
69-2244	22	36	7.3	82°	44.0	HI-UHRK-3638**	1090-2244
69-2246	22	36	8.3	82°	46.0	HI-UHRK-3638**	1090-2246
69-2248	22	36	9.3	82°	48.0	HI-UHRK-3638**	1090-2248
69-2850	28	42	7.3	90°	50.0	HI-UHRK-28	1090-2850
69-2852	28	42	8.3	90°	52.0	HI-UHRK-28	1090-2852
69-2854	28	42	9.3	90°	54.0	HI-UHRK-28	1090-2854
69-3256	32	46	8.3	94°	56.0	HI-UHRK-32	1090-3256
69-3258	32	46	9.3	94°	58.0	HI-UHRK-32	1090-3258
69-3260	32	46	10.3	94°	60.0	HI-UHRK-32	1090-3260

*The alphabetical letter at the end of a Trident® catalog number identifies compatibility among all Trident® acetabular components.

**NOTE: Special Key for 690-00-22D, 690-00-22E and 690-10-22E, 690-10-22F, 69-2244, 69-2246, 69-2248 only.

***Values calculated using Accolade® TMZF Size 3 stems.

► Cementless Options

Primary Surgery:

When used in a primary surgery, the Stryker femoral and Trident® metal shell components should be implanted in accordance with the applicable Surgical Protocols. However, if an uncemented metal shell is being implanted with the Trident® Constrained Acetabular Insert, supplemental fixation, with a minimum of two (2) bone screws, is recommended.

Revision Surgery:

When the Trident® Constrained Acetabular Insert is chosen for use in the revision of a Trident® Acetabular Component, the existing Trident® insert should be removed in accordance with the appropriate Stryker Surgical Protocol.

Care should be taken not to mar the interior of the existing metal shell when removing the insert. The stability of the metal shell and the locking barbs must be assessed for any damage. Also, remove any tissue that may get wedged between the insert and shell lip.

Revising the Metal Shell:

If the shell requires replacement due to instability, bone loss, damage to the locking ring groove, or any other condition, the metal shell may be replaced with a Stryker Trident® shell in accordance with the appropriate Surgical Protocol. If an uncemented metal shell is being implanted with the Trident® Constrained Acetabular Insert, supplemental fixation, with a minimum of two (2) bone screws, is recommended.

Retaining the Metal Shell:

Once the integrity of the existing metal shell is established, remove any membranes from the screw holes and inside the shell. Also remove any tissue that may impinge the poly engagement at the periphery of the metal shell.

Trial Evaluation

The appropriate size Trident® Constrained Trial Insert is selected to evaluate joint mechanics (**Figure 1**). Refer to the trial table on page 6 for the appropriate size trial insert. The Trident® Constrained Trial Inserts contain a screw mechanism to secure the trial to the acetabular shell. The



Figure 1

trial insert is inserted into the Trident® Acetabular Shell and the screw mechanism must be tightened by using the Stryker Torx® Screw Drivers. Once the trial insert is fully seated, the trial reduction can be performed. Once the trial reduction is performed, remove the trial insert.

Component Selection

Select the appropriate sized Trident® Constrained Acetabular Insert by correlating the insert letter designation (alpha code) with that of the shell (See **Tables 1 & 2** on page 2).

Implantation

For proper seating and locking of the constrained insert, the insert must be both rotationally and axially aligned to the acetabular shell prior to final impaction. While holding the insert in your fingers, rotationally align the insert locking grooves to the barbs of the shell making sure the location of the 10° lip matches that of the trial insert.

Once the insert is rotationally aligned, press the insert into the shell while keeping the axis of the insert parallel to the axis of the shell (**Figure 2**).

Push the insert into the shell until the insert will not go any further. Care must be taken not to rock, tilt, or misalign the insert prior to final impaction, as this may damage the polyethylene locking bead thus preventing proper seating and locking.



Figure 3



Figure 2 (10° insert shown)

Locking of the Trident® Constrained Acetabular Insert into the appropriately sized Trident® metal

shell is the same as standard Trident® Acetabular Polyethylene Inserts. The constrained insert, however, cannot be impacted into the shell with the Stryker Acetabular Cup Insert Impactor (2101-0130).

Locking Insert into Shell

Select the Constrained Liner Inserter/Impactor Tip (2199-20xx) that corresponds to the femoral head size (**Figure 3**).

Thread the tip onto the Trident Cup Positioner/Impactor handle (2101-0200, **Figure 4**) and insert the tip into the bipolar (**Figure 5**). Impact the insert to its final seating with the force and instrument perpendicular to the shell face. Check for proper seating by assuring that the periphery of the insert is in contact with the shell, circumferentially.



Figure 4



Figure 5

Femoral Bearing Head/Insert Assembly

After assembly of the constrained insert into the metal shell, the head of the implanted femoral stem is positioned on the opening of the constrained insert's bipolar component. If utilizing a femoral stem with a modular femoral head, the modular femoral head must be fully seated onto the femoral stem trunnion prior to assembly with the Trident® Constrained Acetabular Insert (See **Table 2** for head compatibility). The bipolar component's opening must be fully visible before introducing the femoral bearing head into the component.

Reduce the stem in the standard fashion by elevating the patient's leg and applying a slight downward force until the head snaps into the bipolar component. The bipolar component has a positive locking mechanism which enables the bipolar and femoral head to be assembled with less than five pounds of force. The locking mechanism consists of a split polyethylene ring which is captured within the bipolar's polyethylene insert. As the femoral head is inserted into the bipolar, the assembly load forces the expansion of the split ring within the bipolar. Upon clearing the maximum diameter of the head, the

ring contracts to its normal diameter, resulting in the entrapment of the head within the bipolar.

Once the joint is reduced, the femoral head is retained within the constrained insert and can be removed only through use of a Stryker UHR® Head Removal Key.

Use of the Head Removal Key

Insert the Head Removal Key into the inner bearing area between the bipolar component and the Threaded Trial Head of the Impactor/Extractor and push upward toward the UHR® head center. This spreads the locking ring within the UHR® component. With a gentle pulling action, remove the Impactor/Extractor Handle assembly *and* the key from the constrained insert *at the same time*.

Constrained Insert Removal

Removal of the constrained acetabular cup insert, if necessary, may be accomplished using a 3.3mm drill bit and a self-tapping bone screw with 3.4mm or higher major thread diameter



Figure 6 Head Removal Key

and a round bullet tip. Rotate the bipolar component within the cup insert to allow the drill access to the medial wall of the insert. Using a 3.3mm drill bit, create a hole slightly off-center of the medial wall of the insert. Caution should be taken to avoid drilling through the dome hole of the metal shell. The deepening of this hole should be stopped before contact is made with the inner surface of the metal shell.

The appropriately-sized bone screw is started into the drill hole (a 35mm screw length or longer is recommended). Advance the screw until the tip contacts the inner surface of the metal shell. Continued advancement of the screw levers the cup insert from its seated position. Once the cup insert has been lifted from its fully-seated position by the bone screw, additional distractive force may be applied with an elevator or osteotome.

If access to the medial wall of the insert is unattainable, the titanium alloy retaining ring on the outer rim of the acetabular insert may be removed using an osteotome and/or forceps. Insert removal may proceed as indicated above, only in the area of the outer rim of the insert.

The cup insert may also be removed by utilizing an osteotome, elevator and/or forceps at the cup insert/metal shell junction, to pry the insert from its locked position within the cup shell.

Table 4:

Femoral Head Compatibility with Stryker Trident® Constrained Insert

Femoral Head Component	Catalog Number Series
CoCr Morse Taper	1001-XXXX
CoCr C-Taper	6001-XXXX
CoCr/LFIT™ Morse Taper	01-XXXX and S-1399-HHXX
CoCr/LFIT™ C-Taper	06-XXXX and S-1400-HHXX
Alumina C-Taper	17-XXXXE
Zirconia Ceramic C-Taper	16-XXXX
Delta Ceramic C-Taper	18-XXXX
Modified V40™ CoCr	6260-4-XXX and 6260-5-XXX
CoCr/LFIT™ V40™	6260-9-XXX
Zirconia V40™	6364-4-XXX
Alumina V40™	6260-7-XXX and 6565-0-XXX
Delta Ceramic V40™	6570-0-XXX
PCA® CoCr +15mm	2284-0-XXX
Modified PCA® CoCr	6280-0-XXX
PCA® Zirconia	6284-3-XXX

WARNING: V40™ femoral heads (catalog number series 6264-4-XXX and 6264-5-XXX) and PCA® femoral heads (catalog number series 6284-0-XXX) are NOT compatible with Stryker UHR® Bipolar and Constrained Acetabular Inserts.

► Cementable Options

Option 1:

Cementing into an Implanted Shell or Cage:

Following the fixation of a shell or cage device, a Trident® All-Poly Constrained Insert may be cemented into the device.

Trialing

To assess head center placement, a trial reduction may be performed by using the appropriate Trident® All-Poly Constrained Trial Insert and head trial to assess joint mechanics and appropriate head center placement. Refer to the trial table on page 6 for the appropriate size trial insert. The Trident® All-Poly Constrained Trial Inserts contain a screw mechanism to secure the trial to a shell or cage with compatible dome hole threads. The screw mechanism must be tightened using the Stryker Torx Screwdrivers.

NOTE: The insert trials are the same size as the actual implant, and do not take into account a cement mantle.



Figure 7

Cementing and Inserting Implant

Once trial reduction is complete, the insert can now be cemented in place (see **Table 3** on page 2). Thread the Constrained Liner Inserter/Impactor Tip onto the Trident® Cup Impactor handle. Mount the selected Trident® All-Poly Constrained Insert on the inserter tip (**Figure 5** on page 3). Place the anteversion rod in the correct position. Mix one pack of Simplex™ bone cement according to the manufacturer's specifications and lavage the inside of

the cup shell. Dry thoroughly prior to the introduction of the bone cement. The cement is mixed and is inserted into the acetabulum in bolus form. Once it has achieved a doughy state, the insert, mounted on the inserter tip, is then pressed gently into the cup and driven deeply into the bed of cement. The angle guide allows assessment of proper cup position, which is typically 40 to 45 degrees of abduction or lateral opening and 10 to 20 degrees of anteversion.

NOTE: When determining the proper angulation of the insert, it is important to critically evaluate the anatomic landmarks and patient anatomy for optimum placement.

It is essential that the insert be compressed into the cup and the introducer held as still as possible until cement has hardened. After the cement is cured, the insert introducer is then carefully removed from the insert. Take special measures to remove all excess bone cement from the edges of the cup by utilizing curettes and osteotomes.

Head Assembly

Go back to page 4 and proceed with the instructions for final implant head assembly.

Option 2:

Cementing into the Acetabulum:

To cement the Trident® All-Poly Constrained Insert directly into the acetabulum, the bone must first be properly prepared. This is done through spherical acetabular reaming.

Reaming

Acetabular reaming is initiated with a reamer size that fits easily into the socket. This allows reaming based on the anatomic center of the acetabulum. Initial reaming should be carried out to identify the medial wall. Reaming should medialize the socket to this point but care should be taken not to compromise or violate the medial wall.

NOTE: If too small a reamer is chosen to begin with, the reaming process may begin eccentrically, thus removing excessive anterior or posterior wall bone

stock with resultant non-anatomic placement of the acetabular component.

The low profile design of the Cutting Edge™ Spherical Reamer necessitates the need to ream 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.

NOTE: Care should be taken 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 help preserve the qualities of the bone/metal composite.

Reaming should be done to the desired implantation size.

NOTE: It is recommended to have a 2mm cement mantle, so 4mm should be added to the respective Trident Constrained Insert Outer Bearing OD Spherical Diameter (see **Table 3** on page 2) to equal the implantation size (i.e., if you ream to 56mm, add cement and implant the insert with a 52mm OD).

NOTE: The Cutting Edge™ 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 resist hard bone and will deflect to cut softer bone. This situation may result in an irregularly shaped or enlarged acetabulum preparation.

Cement Fixation Holes

After completion of reaming, fixation holes may be made in the subchondral plate. These can be made with a flexible drill and drill guide provided in the instrument set, a curette, or a power

bur. A single primary fixation hole should be created in each of three areas: the acetabular dome, ischial ramus, and pubic ramus. Additional holes can be created at the surgeon's discretion.

Trialing

Trialing can be accomplished by using the respective Insert Trial. The insert trials are the same size as the actual implant and do not take into account the cement mantle. The trials should also be used to assess the fit and estimate final orientation of the cup prior to implantation.

NOTE: To maintain a 2mm cement mantle, a trial 4mm greater than the final implant may be used to assess reaming depth. Take care to note the associated head size of the larger trial.

Cementing and Inserting Implant

Once trial reduction is complete, the insert can now be cemented in place. Thread the Constrained Liner Inserter/ Impactor Tip onto the Trident® Cup Impactor handle. Mount the selected Trident® All-Poly Constrained Insert on the inserter tip. Place the anteversion rod in the correct position. Mix one pack of Simplex™ bone cement according to the manufacturer's specifications and lavage the inside of the acetabulum. Dry thoroughly prior to the introduction of the bone cement. The cement is mixed and is inserted into the acetabulum in bolus form. Once it has achieved a doughy state, the insert, mounted on the inserter tip, is then pressed gently into the cup and driven deeply into the bed of cement. The angle guide allows assessment of proper cup position, which is typically 40 to 45 degrees of

abduction or lateral opening and 10 to 20 degrees of anteversion.

NOTE: When determining the proper angulation of the insert, it is important to critically evaluate the anatomic landmarks and patient anatomy for optimum placement.

It is essential that the insert be compressed into the acetabulum and the inserter held as still as possible until cement has hardened. After the cement is cured, the inserter tip is then carefully removed from the insert. Take special measures to remove all excess bone cement from the edges of the cup by utilizing curettes and osteotomes.

Femoral Bearing Head/Insert Assembly

See page 4 for the instructions to perform the final implant head assembly.

Trident® Constrained Acetabular Insert Trials

Trident® 0° Insert Trials	Trident® 10° Insert Trials	Trident® All-Poly Insert Trials
2270-22D	2230-22D	1090-2244
2270-22E	2230-22E	1090-2246
2270-28F	2230-28F	1090-2248
2270-28G	2230-28G	1090-2850
2270-32H	2230-28H	1090-2852
2270-32I	2230-28I	1090-2854
2270-32J	2230-28J	1090-3256
		1090-3258
		1090-3260

Trident® Constrained Acetabular Inserts utilize the Cutting Edge™ Bone Screw Tray and Acetabular Reamer Tray

Drivers (included in Bone Screw Tray)	
Straight Driver Shaft	2107-1014
Universal Driver Shaft	2107-1015
Flexible Driver Shaft	2107-1016
Straight Driver Shaft - 6"	2107-1017
Captive Twist Straight Driver Shaft	2107-2014
Ratchet Handle for Drivers	2107-1000

Additional Required Instruments

Femoral Stem Head Impactor	1104-1000
Head Removal Key 22MM Inner Diameter	HI-UHRK-3638
Head Removal Key 28MM Inner Diameter	HI-UHRK-28
Head Removal Key 32MM Inner Diameter	HI-UHRK-32
Trident Cup Impactor	2101-0200
Constrained Liner Inserter/Impactor Tip	2199-2022
Constrained Liner Inserter/Impactor Tip	2199-2028
Constrained Liner Inserter/Impactor Tip	2199-2032

Cases and Trays

Trident 0° and All-Poly Constrained Insert Trial Tray/Case	2402-3020
Trident 0° and All-Poly Constrained Insert Trial Lid	2402-3090
Double Tier Case	8000-0200
Single Tier Case	8000-0100
Trident 10° Constrained Insert Trial Tray	2402-1100

The system provides the option of either a Single Tier or Double Tier Case. The Double Tier Case accommodates both the 10° Constrained Insert Trial Tray **and** the Eccentric Insert Trial Tray.

Optional

Acetabular Trial Insert Containment Screw-Kit (5/kit)	2230-0010
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(Containment Screw Kit is optional - screws come pre-assembled with the Eccentric and Constrained Trial inserts)

All-Poly Constrained Insert Trial Screw	1090-2000
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(Screws come pre-assembled with the All-Poly Constrained Trials)

► **Postoperative Care,
Indications,
Contraindications and
Warnings**

Description

The Stryker Trident® Constrained Acetabular Insert is comprised of two preassembled components: an outer insert component and a captured UHR® (Universal Head) component. The UHR® component is comprised of an outer shell into which a bearing insert has been permanently assembled. The UHR® bearing insert has a factory assembled UHMWPE retention ring. The outer acetabular insert has a Titanium alloy retaining ring which retains the UHR® head in the plastic portion of the insert and a CoCr alloy circumferential locking wire for secure assembly of the insert to the metal shell. With the exception of the Trident® All-Poly Constrained Inserts, the Stryker Trident® Constrained Acetabular Inserts are designed to be assembled with Trident® metal acetabular shells. The Trident® All-Poly Constrained Acetabular Inserts can be cemented directly into a GAP Cup, GAP Ring, Trident® metal acetabular shell, or directly into the acetabulum. The assembled acetabular component is used in conjunction with any appropriately sized stem of compatible head size, to achieve total reconstructive replacement of the hip joint. Please note the following:

Materials:

- ASTM F-75 -cobalt chromium alloy UHR® outer shell
- ASTM F-648 -ultra-high molecular weight polyethylene (UHMWPE) UHR® bearing insert, Acetabular bearing insert body, UHR® retention ring
- ASTM F-136 -Titanium 6Al-4V ELI alloy retaining ring

Description

Trident® Constrained Acetabular Insert is comprised of two pre-assembled components: an outer insert component and a captured UHR® (Universal Head) component. The UHR® component is comprised of an

outer shell into which a bearing insert has been permanently assembled. The UHR® bearing insert has a factory assembled UHMWPE retention ring. The outer acetabular insert has a Ti alloy retaining ring which retains the UHR® head in the plastic portion of the insert. With the exception of the Trident® All-Poly Constrained Inserts, the Trident® Constrained Acetabular Inserts are designed to be assembled

with Trident® metal acetabular shells. The Trident® All-Poly Constrained Inserts can be cemented directly into a GAP Cup, GAP Ring, Trident® metal acetabular shell, or directly into the acetabulum. The assembled acetabular component is used in conjunction with any appropriately sized Howmedica Osteonics stem of compatible head size, to achieve total reconstructive replacement of the hip joint.

Materials

The devices are manufactured from materials that meet the following ASTM Standards:

Cast CoCr Alloy	ASTM F-75	UHR® outer shell bearing insert
Ultra-High Molecular Weight Polyethylene (UHMWPE)	ASTM F-648	UHR® bearing insert, Acetabular bearing insert body, UHR® retention ring
Titanium 6Al-4V ELI Alloy	ASTM F-136	Retaining ring

Compatibility

- Howmedica Osteonics Constrained Acetabular Inserts are compatible with all Howmedica Osteonics femoral heads except old-style V40 head catalog number series 6264-4-XXX and 6265-5-XXX and old-style P.C.A. head catalog number series 6284-0-XXX.

Indications

- The Trident® Constrained Acetabular Insert is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

Contraindications

- Bone or musculature compromised by disease, infection or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Infection in or about the hip joint.
- Skeletal immaturity.

Warnings

- Closed reduction of a dislocation of this device is not possible. Patients should be made aware that treatment of device dislocation will require additional surgery.
- Patients should be instructed on the impact of excessive loading that can result if the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or excessive muscle loading due to patient weight causing extreme demands on the constrained insert can result in the failure of the device. Extreme demands on the device may also compromise the acetabular shell's fixation in the acetabulum.
- The UHMWPE UHR® retention ring and Ti alloy retaining ring of the constrained insert should not be handled or removed as they are critical to the security of the assembly. Alteration of the factory preassembled device can result in improper function of the retaining mechanisms. Discard or return to manufacturer any constrained insert if the retaining mechanisms appear damaged or mishandled.

- Improper alignment of the acetabular insert within the acetabular shell prior to impaction may result in improper seating of the constrained acetabular insert.
- Removal of the constrained insert after its assembly into the metal shell results in the destruction of the insert. Discard any device removed after the locking mechanism has been engaged, do not reinsert the device.
- Care should be taken not to nick or notch the inner surface of the metal shell during insert removal, which could lead to premature wear of the UHMWPE.
- Old style V40™ femoral head catalog number series 6264-4-XXX and 6264-5-XXX and old style P.C.A.® Femoral Head catalog number series 6284-0-XXX are not compatible with the UHR® Bipolar and Constrained Acetabular Insert.
- Do not substitute another manufacturer's device for any component of the Howmedica Osteonics total hip system. Any such use will negate the responsibility of Howmedica Osteonics for the performance of the resulting mixed component implant.
- Never reuse an implant, even though it may appear undamaged.
- Discard damaged, mishandled, or contaminated implants.
- See the Patient Counseling Information Section for more information.

Precautions

- Protect all components from contamination.
- Do not allow coated surfaces to contact cloth or other fiber-releasing materials.
- Protect polished bearing areas and machined taper surfaces from contact with hard or abrasive surfaces.
- Take care not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

Patient Selection

- Proper implant selection is critical to the stability and longevity of the acetabular implant in hip arthroplasty. Proper implant selection must consider design, fixation, and environmental variables including patient weight, age, bone quality and size, activity level and pre-operative level of health, as well as the surgeon's experience and familiarity with the device. Longevity and stability of the implant may be affected by these factors.
- Patients with high-activity levels and/or higher weight patients are at greater risk for implant complications or failures. For patients with poor proximal bone quality, the use of supplemental adjunctive proximal fixation/support is advised for implant stability.
- The surgeon must evaluate each situation carefully based upon the patient's clinical presentation before making any decisions regarding the selection of the implant.

Adverse Effects

- Dislocation of the hip prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
- Loosening of total hip components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications, including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fatigue fracture of femoral stems has occurred in a small percentage of cases. Stem fracture is more likely to occur in heavy, physically active patients, or when contralateral joint disability results in a disproportionate distribution of weight on the reconstructed joint.
- Wear of polyethylene components may occur. Polyethylene wear has been associated with bone resorption, loosening, and infection.
- Peripheral neuropathies, nerve damage, circulatory compromise, and heterotopic bone formation may occur.
- Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders, gastrointestinal disorders, vascular disorders including thrombus, bronchopulmonary disorders including emboli, myocardial infarction, or death.
- Acetabular pain may occur due to loosening of the implant.
- Intraoperative fissure, fracture, or perforation of the femur, acetabulum, or trochanter can occur due to impaction of the component into the prepared femoral canal or acetabulum. Postoperative femoral or acetabular fracture can occur due to trauma, the presence of defects, or poor bone stock.
- Asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondly, particulate can also be generated by third-body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.
- Very small particles from metal and polyethylene components can be shed from the components during normal use and over time. Although most of this debris stays in the relevant joint (i.e., contained in the synovium) or is trapped by surrounding scar tissue, microscopic particles can migrate throughout the body and on occasions have been described as accumulating in lymph nodes and other parts of the body. Although no significant medical complications

have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. Given the insufficient time period during which patients with these devices have been followed and the fact that these devices are currently being used in younger patients and remain in the body for increasingly longer periods of time, it should be said that the long-term effects, if any, from these particles, are unknown. The long-term effects have been theorized to include:

- Cancer: There is presently no scientific evidence that links metallic or polyethylene debris with cancer. However, the possibility cannot be ruled out.
- Lymphadenopathy and Accumulation in Other Tissues/Organs: There have been a few reports of the accumulation of wear debris in lymph nodes (proximate and distal). Although no medical complications or disease process has been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.
- Systemic Disease: There has been some speculation that there could be an association between migration of debris and as yet unidentified systemic effects. Long-term effects may be demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of debris and systemic disease, it is believed that the benefits of these devices clearly outweigh the potential risks for any such theoretical long-term effect.
- Metal sensitivity reactions have been reported following joint replacement.
- Undesirable shortening or lengthening of the limb.
- Infection can occur.
- Adverse effects may require medical intervention including reoperation, revision, arthrodesis of the involved joint, Girdlestone, or amputation of the limb.

Use and Implantation

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
- The Surgical Protocol for the appropriate Howmedica Osteonics hip system provides additional procedural information.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- Specialized instruments are available and should be used to ensure accurate implantation of prosthetic components.
- To preserve the integrity of the actual implants and their sterile packaging, use the recommended trial components for size determination, trial reduction and range-of-motion evaluation.
- Proper selection, placement, and fixation of the implant components are critical factors affecting implant service life. The durability of prosthetic implants is affected by many biologic, biomechanic and other extrinsic factors that limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.

Information for the Patient

- Advise patients of the limitations of the reconstruction and the need to protect the implant from full weight bearing until adequate healing has occurred.
- Caution patients to protect the replaced joint from excessive loading, and to follow the physician's instructions regarding activity level, follow-up care, and treatment. Advise patients that the device cannot be expected to withstand indefinitely the same activity levels and loads as a normal healthy joint, that the implant can break or become damaged as a result of excessive loading, and that the device has a finite service life and may need to be replaced in the future.

- Warn the patient of surgical risks and possible adverse effects.
- Dental procedures, endoscopic examinations and other minor surgical procedures have been associated with transient bacteremia. Instruct the patient to inform their doctors that they have an artificial hip replacement, so that their doctors can decide whether to use antibiotic prophylaxis for such procedures.

How Supplied

- These products have been sterilized by gamma radiation.
- Do NOT resterilize.
- Take care to prevent contamination of any components
- Inspect the packaging of sterile products for flaws before opening. In the presence of any flaws, assume that the product is nonsterile.
- Discard ALL nonsterile or contaminated products.

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