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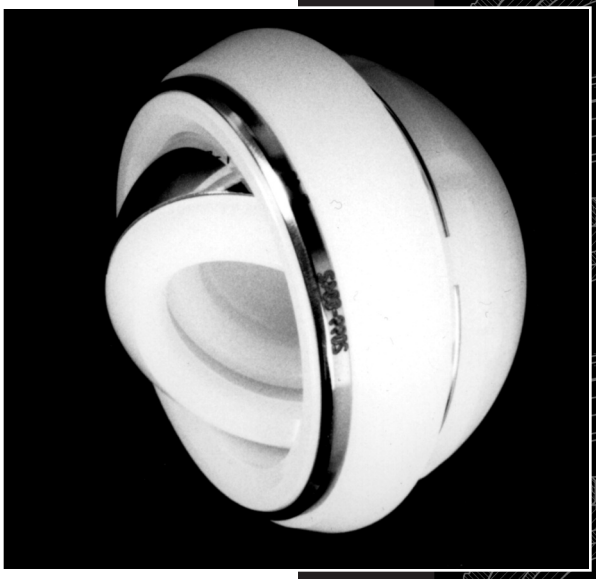
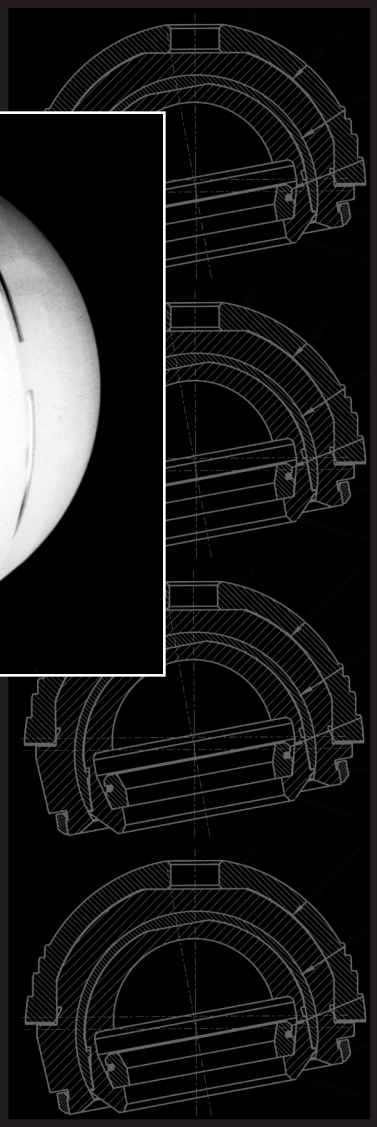
Constrained Acetabular Insert

Surgical Protocol





Howmedica Osteonics Constrained Acetabular Insert

Surgical Protocol

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Howmedica Osteonics Constrained Acetabular Insert

A Howmedica Osteonics UHR bipolar head is pre-assembled to, and captured within a Howmedica Osteonics Omnifit Cup Insert. The diameter of the mouth of the insert is less than the insert's inner diameter, so the bipolar is securely retained within the insert.

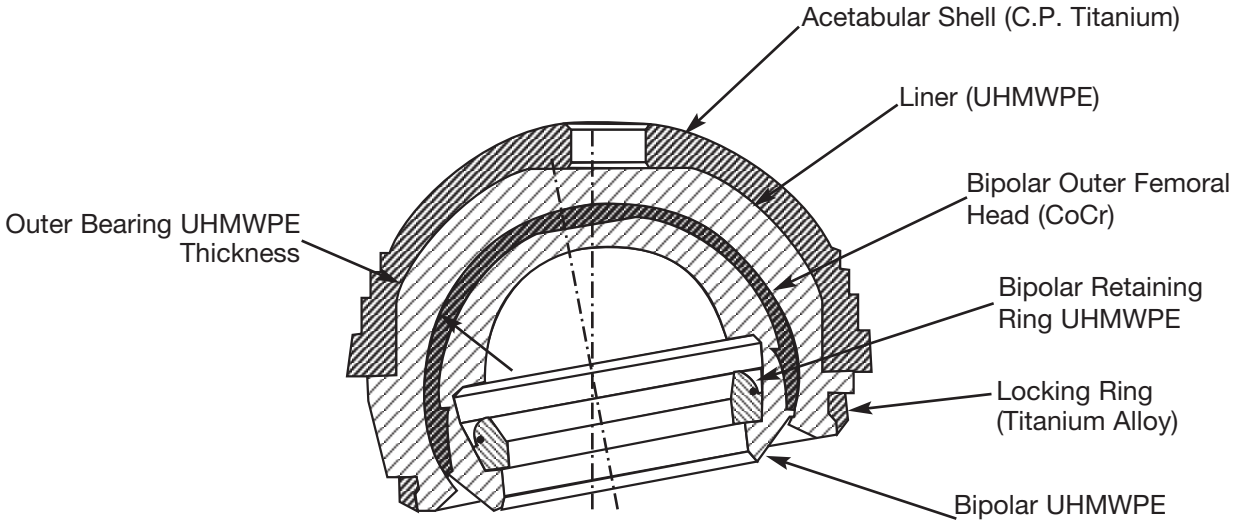
A titanium alloy retaining ring further strengthens the insert's ability to retain the bipolar component.

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

A unique, split-ring locking mechanism facilitates ease of femoral head assembly, yet provides enhanced security against component disassembly.

A head removal key allows for easy, atraumatic 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 during component loading. This prevents inner bearing articulation from occurring on the locking mechanism, thus sparing the mechanism from potential undue wear.



Constrained Acetabular Liner

Table 1
UHMWPE Thickness Chart

Constrained Insert Catalog Number	Acetabular Shell OD (mm)	Bipolar Femoral Head Size (mm)	Outer Bearing UHMWPE Thickness (mm)
2099-2250	50	22	7.3
2099-2252	52	22	4.8
2099-2254	54	22	5.8
2099-2256	56	22	4.3
2099-2258	58	22	4.4
2099-2261	61	22	5.9
2099-2266	66	22	7.4
2099-2270	70	22	8.9
2099-2274	74	22	10.4
2099-2656	56	26	4.3
2099-2658	58	26	4.4
2099-2661	61	26	5.9
2099-2666	66	26	7.4
2099-2670	70	26	8.9
2099-2674	74	26	10.4
2099-2858	58	28	4.4
2099-2861	61	28	5.9
2099-2866	66	28	7.4
2099-2870	70	28	8.9
2099-2874	74	28	10.4

Constrained Insert

Introduction

The Constrained Acetabular Insert is indicated for use in primary and revision total hip patients who are at a high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability. It should be used where more conservative methods of soft tissue management (such as lengthening the femoral neck or lateralizing the acetabular component's center of rotation) are insufficient and the only other viable alternatives might include hip fusion, bipolars, or resection arthroplasty.

The range of motion for the constrained acetabular insert is less than that for standard total hip replacement components (Table 2), but clearly greater than the potential surgical alternatives stated above.

Primary Surgery:

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

Revision Surgery:

When the Constrained Acetabular Insert is used in a revision surgery, the existing Howmedica Osteonics insert is removed in accordance with the appropriate Howmedica Osteonics Surgical Protocol. Care should be taken not to nick the interior of the existing metal shell when removing the insert. The stability of the metal shell should be assessed. The locking barbs must be assessed for any damage as well.

Revising the Metal Shell:

If the shell requires replacement due to instability, bone loss, damage to the locking ring, or any other condition, the metal shell must be replaced with another Howmedica Osteonics shell in accordance with the appropriate Surgical Protocol. If an uncemented metal shell is being implanted with the Constrained Acetabular Insert, supplemental fixation with bone screws should be employed.

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 locking wire at the periphery of the metal shell.

Table 2
Range of Motion Chart

Constrained Insert Catalog Number	Inner Femoral Head Diameter (mm)	Outer Acetabular Shell Diameter (mm)	Total Range of Motion
2099-2250	22	50	72°
2099-2252	22	52	72°
2099-2254	22	54	72°
2099-2256	22	56	82°
2099-2258	22	58	84°
2099-2261	22	61	84°
2099-2266	22	66	84°
2099-2270	22	70	84°
2099-2274	22	74	84°
2099-2656	26	56	84°
2099-2658	26	58	84°
2099-2661	26	61	84°
2099-2666	26	66	84°
2099-2670	26	70	84°
2099-2674	26	74	84°
2099-2858	28	58	84°
2099-2861	28	61	84°
2099-2866	28	66	84°
2099-2870	28	70	84°
2099-2874	28	74	84°

Component Selection

Select an appropriately-sized Constrained Acetabular Insert based on the Compatibility Chart below.

Implantation

Locking of the Constrained Acetabular Insert into the appropriately sized Howmedica Osteonics metal shell parallels that of standard Howmedica Osteonics Series II Polyethylene Acetabular Inserts. The constrained liner however, cannot be impacted into the shell with the Howmedica Osteonics Acetabular Cup Insert Impactor.

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. Holding the insert in your fingers, rotationally align the insert locking grooves to the barbs. To assist with this alignment, position the single scribe mark on the lip of the insert in line with one of the scribe marks on the shell (Figure 1). Hint: The insert scribe line is most visible when filled with blood.

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 metal locking wire contacts the barbs inside the shell at which point the insert will not go any further. In this position, the locking wire should be completely covered by the acetabular shell (Figure 3). Care must be taken not to rock, tilt, or misalign the insert prior to final impaction as this may damage the locking wire and prevent proper seating and locking (Figure 4).

Figure 1

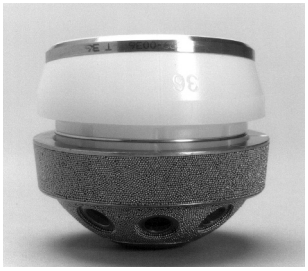


Figure 2

Figure 3

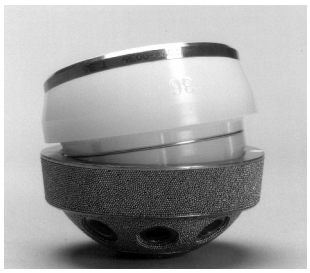


Figure 4

Table 3

Compatibility Chart

Constrained Insert Catalog Number	Inner Diameter (mm)	Series I Shell OD (mm)	Series II Shell OD (mm)	Howmedica Osteonics Secur-Fit X'tra Shell OD (mm)
2099-2250	22	50	50 & 52	54 & 56
2099-2252	22	52	N/C	N/C
2099-2254	22	54	54 & 56	58 & 60
2099-2256	22	56	N/C	N/C
2099-2258	22	58	58 & 60	62 & 64
2099-2261	22	61 thru 72	62 thru 72	66 & 68
2099-2266	22	N/C	N/C	70 & 72
2099-2270	22	N/C	N/C	74 & 76
2099-2274	22	N/C	N/C	78 & 80
2099-2656	26	56	N/C	N/C
2099-2658	26	58	58 & 60	62 & 64
2099-2661	26	61 thru 72	62 thru 72	66 & 68
2099-2666	26	N/C	N/C	70 & 72
2099-2670	26	N/C	N/C	74 & 76
2099-2674	26	N/C	N/C	78 & 80
2099-2858	28	58	58 & 60	62 & 64
2099-2861	28	61 thru 72	62 thru 72	66 & 68
2099-2866	28	N/C	N/C	70 & 72
2099-2870	28	N/C	N/C	74 & 76
2099-2874	28	N/C	N/C	78 & 80

N/C = Not Compatible

To lock the insert into the shell, either of two methods may be used:

Method One

Use the Femoral Head Impactor (Figure 5A) to strike against the spherical surface of the inner bipolar metal shell (Figure 5B). Impact the insert to its final seating with the force and instrument perpendicular to the Insert Locking Ring (Figure 5C). Check for proper seating by assuring that the periphery of the liner is in contact with the shell, circumferentially.

Method Two

Select a Threaded Trial Head with the same outer diameter as the inner diameter of the chosen constrained insert (Figure 6A). Also, select an appropriately sized head removal key (Figure 6B). *See Table 4 for Head Removal Key Selection.*

WARNING: Ensure the Head Removal Key is available to remove the Threaded Trial Head before proceeding.

Assemble the Howmedica Osteonics Threaded Trial Head onto the Howmedica Osteonics Threaded Impactor/ Extractor Handle (Figure 6C).

Once assembled, insert the Threaded Trial Head into the bipolar component of the constrained liner. Impact the insert to its final seating with the force and instrument perpen-dicular to the Insert Locking Ring (Figure 6D). Check for proper seating by assuring that the periphery of the liner is in contact with the shell circumferentially. Once the insert is seated, remove the Threaded Trial Head/Impactor/ Extractor Handle assembly from the constrained bearing insert with the selected 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.***

Table 4
Constrained Insert / Head Removal Key Compatibility Chart

Constrained Insert Catalog Number	Head Removal Key Catalog Number
2099-2250	HI-UHRK-3638*
2099-2252	HI-UHRK-3638*
2099-2254	HI-UHRK-3638*
2099-2256	HI-UHRK-22
2099-2258	HI-UHRK-22
2099-2261	HI-UHRK-22
2099-2266	HI-UHRK-22
2099-2270	HI-UHRK-22
2099-2274	HI-UHRK-22
2099-2656	HI-UHRK-26
2099-2658	HI-UHRK-26
2099-2661	HI-UHRK-26
2099-2666	HI-UHRK-26
2099-2670	HI-UHRK-26
2099-2674	HI-UHRK-26
2099-2858	HI-UHRK-28
2099-2861	HI-UHRK-28
2099-2866	HI-UHRK-28
2099-2870	HI-UHRK-28
2099-2874	HI-UHRK-28

*Note: Special Key for 2099-2250, 2099-2252 and 2099-2254 Only


Figure 5A

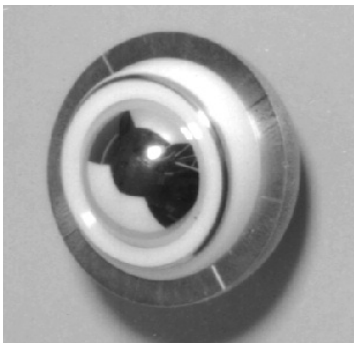


Figure 5B


Figure 5C


Figure 6A Constrained Insert


Figure 6B Head Removal Key


Figure 6C


Figure 6D

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 trunion prior to assembly with the constrained acetabular insert (See Table 5 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 Howmedica Osteonics UHR Head Removal Key.

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 and a round bullet tip. Rotate the bipolar component within the cup insert to allow drill access to the medial wall of the insert. Using a 3.3 mm 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 35 mm 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 5:

Femoral Head Compatibility with Howmedica Osteonics Constrained Insert

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

WARNING: Old style V40 femoral heads (catalog number series 6264-4-XXX and 6264-5-XXX) and old style PCA femoral heads (catalog number series 6284-0-XXX) are NOT compatible with Howmedica Osteonics UHR Bipolar and Constrained Acetabular Inserts.

POSTOPERATIVE CARE, INDICATIONS, CONTRAINDICATIONS AND WARNINGS

Description

Howmedica Osteonics 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 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. The Constrained Acetabular Insert is designed to be assembled with a 50 mm or larger outer diameter Howmedica Osteonics standard profile metal acetabular shell. 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. The Constrained Acetabular Insert is available in three inner diameter sizes and nine outer diameter sizes (consult compatibility chart). Please note the following:

Materials:

- ASTM F-75 -cobalt chromium alloy UHR outer shell, Acetabular bearing insert locking wire
- 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

Indications

The Howmedica Osteonics 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, CoCr alloy circumferential locking wire 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 damage to the locking wire or 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.
- Use of another manufacturer's femoral head or acetabular shell components may lead to premature wear or failure of the device. Please consult the compatibility chart for proper Howmedica Osteonics component selection.
- See the Patient Counseling Information Section for more information.

Precautions

- Never reuse an implant.
- Care must be taken to protect the components and any polished bearing surfaces from being marred, nicked or notched.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

Adverse Effects

The adverse events reported for two case series are listed in Table A. The adverse events included reoperation due to redislocation, infection, femoral loosening, bone graft failure, trochanteric non-union and deep vein thrombosis.

Table A: Reported Adverse Events for Two Case Series

	Series One Number of Events n=101	*Series Two* Number of Events n=21
Trochanteric Non-union	16 (15.8%)	
Reoperation due to Infection	7 (6.9%)	
Reoperation due to Dislocation	4 (4.0 %)	
Reoperation for Femoral Miscellaneous	3 (3.0%)[a]	1 (4.8%)[b]
Reoperation for Other Reasons	2 (2.0%)	
Deep Vein Thrombosis	2 (2.0%)	
Acetabular Allograft Failure		1 (4.8%)
Miscellaneous	11[c]	

a One case each of loose femoral stem, removal of wire, and fracture below femoral prosthesis.

b Osteolysis of femoral allograft.

c One case each (0.9%) of sciatic palsy, decubitus ulcer, severe heterotopic bone formation, sponge in the canal, intraoperative fracture, acute abdominal problems, anterior acetabular fracture, medial wall fracture, saphenous nerve palsy, trochanteric bursitis, and cardiac complications.

In addition to the adverse events reported in these case series, the following are some of the reported complications associated with any total hip replacement surgery:

- death
- pulmonary embolism
- myocardial infarction
- infection
- nerve impingement or damage
- vascular disorders (including thrombus)
- heterotopic bone formation
- material sensitivity reactions
- gastrointestinal complications
- genitourinary complications
- loosening of total hip components
- localized progressive bone resorption (osteolysis)
- pain
- dislocation of the hip prosthesis

Clinical Results

Two separate retrospective reviews of case series performed using the Howmedica Osteonics Constrained Acetabular Insert were the basis for marketing approval in the USA for the Constrained Acetabular Insert. The first series (Series One) involved 101 inserts implanted in 98 patients by two private practice surgeons. The second case series (Series Two) involved 21 inserts implanted into 20 patients by one private practice surgeon. Patients in each series were selected for the surgery based on the respective surgeon's individual practice, in situations where standard total hip arthroplasty was not considered a viable option by the surgeons.

Patients included in Series One received their implants between April 1988 and October 1992, at two centers. The implantation dates were not specified for Series Two patients. The following tables describe the patient demographics and the clinical ratings outcomes for the patients in Series One and Series Two. For Series One, the mean patient follow up was 54 months and the range was 0.25 to 97 months. For Series Two, the mean patient follow-up was 27.5 months and the range was 12 to 63 months.

Table B:
Patient Demographics for Case Series One and Two

	Series One			Series Two		
Category	Female	Male	Total	Female	Male	Total
No. Cases	65	36	101	16	5	21
	(64.4%)	(35.6%)		(76.2%)	(23.8%)	
Mean Age	70.9 yrs	70.3 yrs	70.7 yrs	na	na	69
(Range)	(31-92)	(34-87)	(31-92)			(42-93)
Mean Weight	149.6 lbs	185.3 lbs	162.3 lbs	na	na	154.7 lbs
(Range)	(100-200)	(120-287)	(100-287)			(115-198.9)

Table C

Series One - Postoperative Rating for All Evaluated Cases

Post-op Pain		Post-op Limp		Post-op Support	
Rating	Frequency (%) at Latest Evaluation	Rating	Frequency (%) at Latest Evaluation	Rating	Frequency (%) at Latest Evaluation
None	68 (70.8%)	None	35 (36.1%)	None	23 (23.7%)
Mild	16 (16.7%)	Mild	35 (36.1%)	Cane	29 (29.9%)
Moderate	8 (8.3%)	Moderate	16 (16.5%)	Walker/Crutches	35 (36.1%)
Severe	4 (4.2%)	Severe	6 (6.2%)	Unable to Walk	10 (10.3%)
Subtotal (n)	96 (100%)	Unable to Walk	5 (5.2%)	Subtotal (n)	97 (100%)
Unspecified	5	Subtotal (n)	97 (100%)	Unspecified	4
Total	101	Unspecified	4	Total	101
		Total	101		

Table D

Series Two - Pain Evaluation Results

Rating Scale *	Preop Mean	Preop Range	Latest Evaluation Mean	Latest Evaluation Range
HHS	16.3	6-32	32.2	12-40
Harris	45.5	18-69	82.0	20-99

*The HHS scale is from 0 to 40 with 40 indicating the absence of pain and optimum functionality. The Harris scale is 0 to 100 with 100 indicating the absence of pain and optimum functionality.

Instructions for Utilization and Implantation

- Before clinical use the surgeon should thoroughly understand all aspects of surgical procedure and limitations of the device.
- In situations where an uncemented acetabular shell is implanted coincident with the constrained acetabular insert, supplemental screw fixation should be utilized with the shell.
- The recommended gauge and trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging. Please consult the compatibility chart for proper component selection.
- A trial reduction can be performed with the constrained insert in place. Please consult the compatibility chart for proper dislocation key sizing.
- Bearing areas must always be clean and free of debris prior to assembly.
- A complete intraoperative range of motion must be obtained with no visual or tactile obstructions.
- The Howmedica Osteonics Surgical Protocol for the constrained insert provides additional procedural information.

Patient Counseling Information

In addition to the patient related information contained in the Warnings and Adverse Effects sections, the following information should be conveyed to the patient:

- The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should be instructed as to the limitations of the device. The maximum range of motion for the Constrained Acetabular Insert ranges between 72° and 84°, depending on the femoral head size.
- Wear of the components can occur and potentially lead to future complications, including bone resorption and loosening, necessitating the removal and replacement of the prosthetic components.
- While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Adverse effects may necessitate reoperation, revision, fusion of the involved joint, Girdlestone and/or amputation of the limb.

Sterilization

- Do not resterilize. If the package is opened but the product is not used, if there are flaws in the sterile barrier, if the product is damaged, mishandled, or contaminated, the component must be discarded or returned to the supplier. Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.
- Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

NOTES

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