Contour™

ACETABULAR RINGS SURGICAL TECHNIQUE

Contour™

ACETABULAR RINGS SURGICAL TECHNIQUE

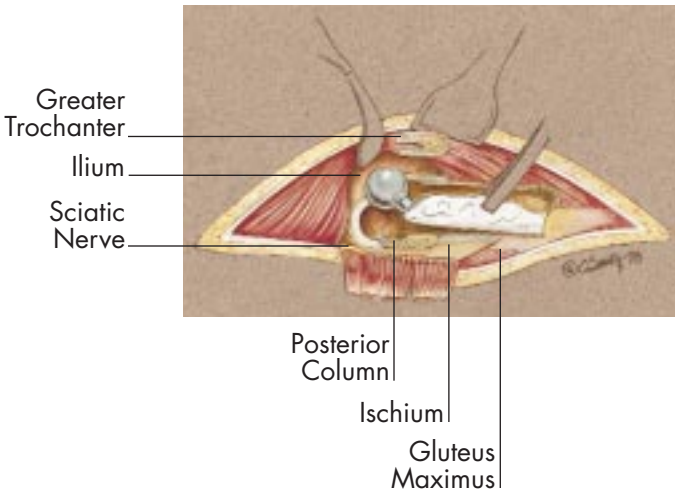
Technique described by

Joseph Schatzker M.D.,
B.Sc. (Med.), FRCS (C)

Allan E. Gross, M.D.,
FRCS (C)

Contour Acetabular Rings can prove to be a most viable surgical solution for acetabular defects in primary and revision procedures. Used in conjunction with allograft bone, Contour's design protects the graft while providing a stable base of fixation for the cement and the polyethylene cup. In addition, Contour Acetabular Rings allow proper anatomical positioning of the polyethylene socket independent of the metal ring.

Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.



Positioning of the Patient

In primary cases, the patient may be positioned either supine or in the lateral decubitus position. All revisions are done with the patient in the lateral decubitus position.

Surgical Exposure

For primary implantation of the Reinforcement ring, the exposure is the same as for a primary total hip replacement.

The Contour Acetabular Reconstruction ring requires a more extensive exposure because access must be gained from superoposteriorly down the posterior column to the ischium. Posterior column defects require structural grafting more often than anterior column defects. Exposure of this magnitude necessitates a trochanteric osteotomy, but it is our experience that an anterior trochanteric slide, rather than a transverse trochanteric osteotomy, is sufficient and provides a more stable fixation of the greater trochanter after the surgery.

Preparation of the Acetabulum

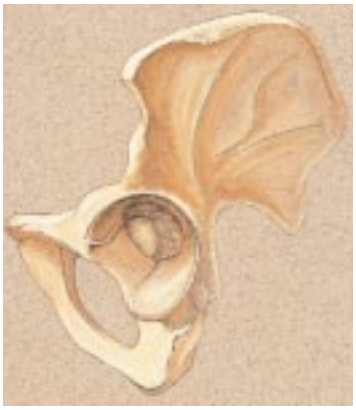
The previous implant must be removed without causing any further bone loss. Once the implant is removed, all cement and membrane must be carefully extracted. Great care should be exercised in removing intrapelvic cement. A CT-scan combined with dye supplement to visualize the great vessels and the ureter may be required. In the absence of infection, cement may be left in its intrapelvic position and allograft is then interposed between the cement and the Contour Reconstruction ring.

It is extremely important to define completely the entire circumference of the acetabulum to be able to define a defect as contained or uncontained. If acetabular reamers are used, the outer diameter of the implant should match or be 2 mm larger than the final reamer.

Preparation and Implantation of the Bone Graft

Medial wall defects, particularly if extensive, are covered with cancellous allograft slices prepared from femoral heads. The remainder of the defects are filled with morsellized allograft bone. The morsellized bone should be small chunks instead of a slurry of bone which would make impaction impossible. In the case of uncontained segmental acetabular defects, bulk allograft must be used. Although it is preferable to use true acetabular allograft bone, some defects can be managed with male femoral heads.

Morsellized allograft bone is used to fill cavitary defects. It is firmly impacted with smooth acetabular impaction domes. Reversing the acetabular reamers can also be used, but these do not provide the same degree of impaction. Major medial wall deficiencies should be managed with slices of allograft to provide containment of the morsellized allograft bone used to fill the remainder of the defect. This prevents the morsellized allograft bone from being impacted into the pelvis.



Contained Cavity Defect

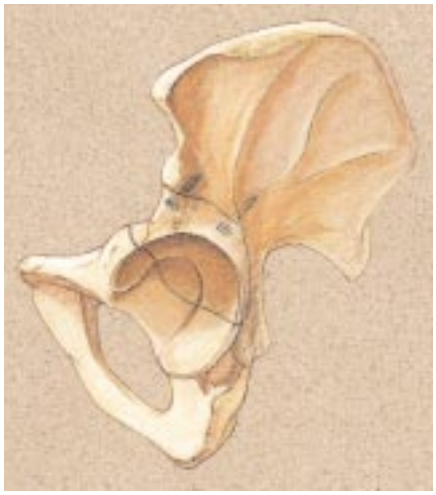
Morsellized Allograft Bone Impacted Into Cavity Defect

Global Contained Cavity Defect Including Medial Wall

Morsellized Allograft Bone Impacted Into Global Cavitary Defect

Major Column Defect

Restoration of Bone Stock by Major Column Allograft



Preparation and Implantation of the Bone Graft

If there is a major segmental defect, this must be defined accurately by clearing all soft tissue from the acetabular boundaries. Once the defect is defined, the structural allograft is sculpted to fit the defect and then held with two cancellous screws. The most common reconstruction involves the posterior column. In this case, the screws are usually directed superiorly into the dome. Structural allograft is often combined with morsellized allograft that is used to fill adjacent cavitary defects.

Indications for the Contour Reinforcement Ring

The Contour Reinforcement Ring is used where the bone deficits are such that the surgeon can still get adequate support for the ring superoposteriorly and inferomedially against the host bone. The indications for this device are:

a) Primary Hip Replacement
   1. Severe osteoporosis
   2. Large acetabular erosions or cysts
   3. Mild to moderate protrusio where the ring can still be seated superoposteriorly and inferomedially against host bone

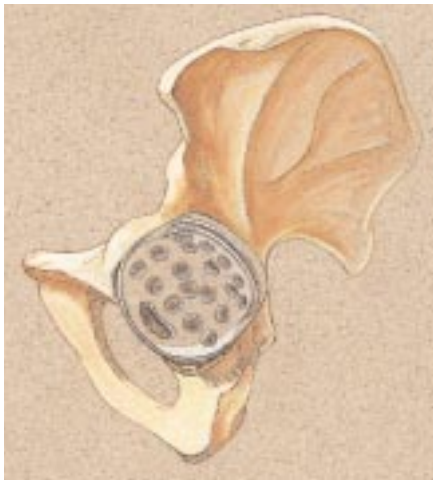
b) Revision Arthroplasty of the Hip
   1. Contained cavitary defects in conjunction with morsellized allograft bone
   2. For small segmental rim defects that do not involve the columns but may require a small structural graft that can be protected by the ring

Contraindications for Contour Reinforcement Ring

1. Major segmental defects involving the dome or posterior column
2. Medial wall segmental defects
3. Any bone defect that involves more than 50% of the acetabulum (contained or uncontained)

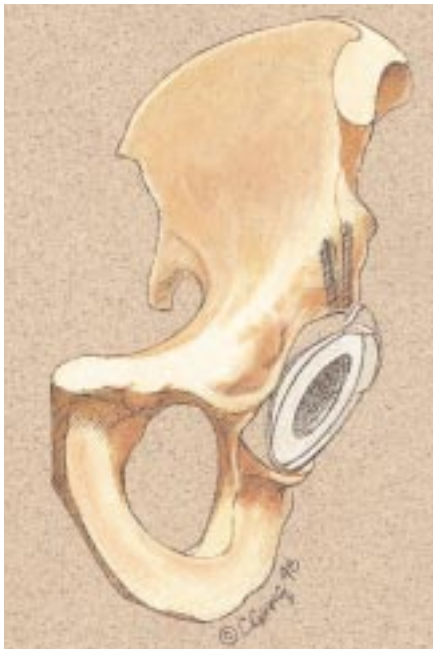
It is extremely important that the Reinforcement ring is supported by host bone along its rim superoposteriorly and inferomedially. It must be seated firmly against bone with no toggling. **If the ring is supported primarily against morsellized allograft bone, the device will obtain anchorage only superoposteriorly and will fail because of the hinge-like forces that will be placed upon it.**

Reinforcement Ring Insertion



Acetabular Screw Alignment

Acetabular Screw Alignment A-P View



Contour Reinforcement Ring Insertion

The Contour Reinforcement Ring is fitted superiorly against the superior rim of the acetabulum, posteriorly against the posterior wall and column, and inferomedially against the floor of the acetabulum. The ring must have good purchase and support superiorly and posteriorly and it must rest inferomedially against host bone and not on morsellized allograft bone. It must have a firm seat and must not have any potential for toggling. The Contour Reinforcement Ring has a threaded center hole for the threaded cup positioner.

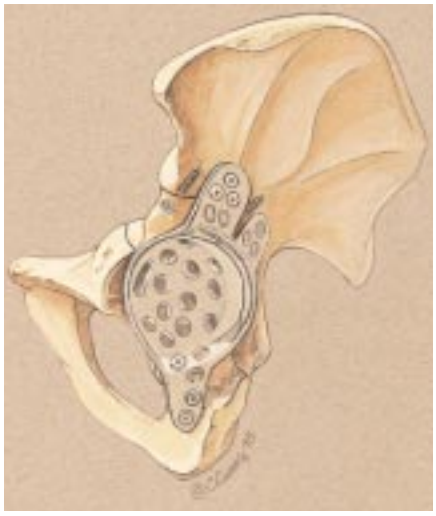
The Reinforcement ring is secured with screws that are directed into the dome of the acetabulum. It is best to start with a central screw which forces the ring upwards and medially in line with the resultant forces and in about 15-20° to the vertical axis of the body. At least three screws should be inserted into this area of the dome. Screws can be inserted along the rim if necessary but must have the same direction as those entering the plane more centrally. Screws should not be directed anteriorly or medially because of the danger of penetration into the pelvis and risk to vital structures.

Indications for the Contour Reconstruction Ring

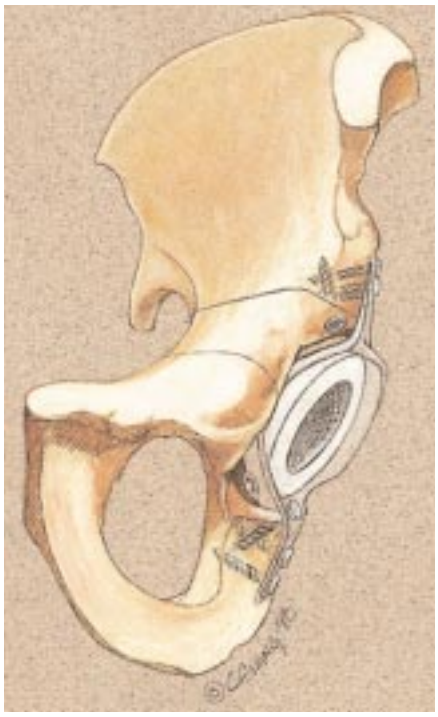
The Contour Reconstruction Ring can be used as long as there is support superoposteriorly against the ilium and inferiorly against the ischium.

1. Large cavitary defects involving all quadrants of the acetabulum. This device is used in conjunction with morsellized allograft bone. The ring is screwed to the ilium and the dome, and must be supported by the posterior column and the ischium.
2. Medial wall segmental defects where this device can be used in conjunction with cancellous allograft slices and morsellized bone.
3. Segmental defects that involve anterior or posterior column and involve more than 50% of the acetabulum. The device is used in conjunction with a solid acetabular allograft.
4. Pelvic discontinuity may occur if there is a discontinuity of both columns or a massive global bone defect involving both columns. The pelvic discontinuity is stabilized by the ring being fixed by screws to both the ilium and ischium. The bone deficiency is replaced with a structural graft (usually replacing the posterior column). The graft is fixed superiorly to the ilium, and if possible, inferiorly to the ischium with 6.5 mm cancellous screws before application of the ring.

Reconstruction Ring Fixed to Ilium and Ischium



Reconstruction Ring with All-Poly Cup A-P View



Contour Reconstruction Ring Insertion

The Contour Reconstruction Ring is stabilized superoposteriorly by at least three screws in the superior flanges or through the ring into the dome. It should be buttressed against the posterior column, the inferior rim of the acetabulum, and the ischium, before screw insertion.

If a structural bulk allograft is being used, it is important to use screws in both the superior and inferior flanges to stabilize the ring and bridge the allograft. If it is impossible to gain good purchase of the screws in the inferior flange sitting on the ischium, it can be used as a buttress against the ischium or slotted into the ischium.

As an alternative, the inferior flange can be buttressed against the ischium with a screw being placed through the ring adjacent to the flange and into the body of the ischium.

If there is a pelvic discontinuity, the inferior flange should be screwed to the ischium. If there is no pelvic discontinuity, the inferior flange can be slotted into or buttressed against the ischium without screws.

Screws passing through the ring can also be used to add to the fixation of the solid allograft, but great care must be exercised so that the screws do not penetrate anteriorly or medially.

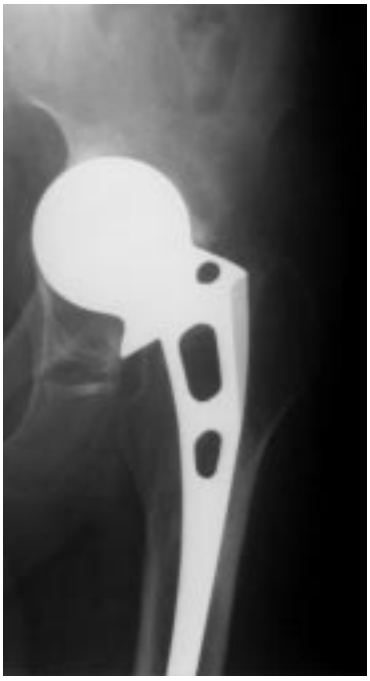
It is important to contour this device very closely to the bone before placing the screws. **If the device is not contoured, tightening the screws either superiorly or inferiorly causes the device to lift off the bone.**

The ring must not be inserted too vertically or the inferior rim will impinge on the neck of the femoral component, producing instability or loosening.

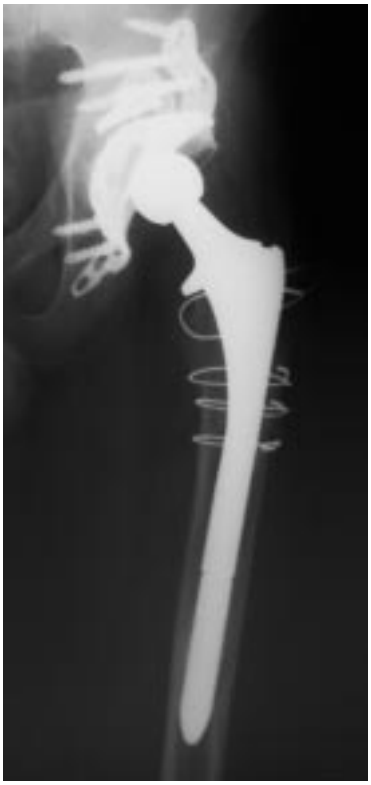
In summary, if the Contour Reconstruction ring is used to reconstruct cavitary defects where stability of the ring can be gained against the ilium and dome superiorly and the posterior wall and column, then inferiorly, it is enough to buttress the ring against the inferior acetabular remnant or the ischium. If it is used in conjunction with a structural acetabular allograft or in the presence of a pelvic discontinuity, the inferior flange should be fixed to the ischium by screws or slotted into the ischium. If possible, at least three screws should be used in the superior and one or two screws through the inferior flanges.

Cementing the Polyethylene Cup

The polyethylene cup is oriented relative to the pelvis and the long axis of the patient. Do not reference the position of the ring when determining the proper position of the polyethylene socket. Select the polyethylene socket size that corresponds to, or is 2 mm smaller than, the inner diameter size of the metal ring.



Global Contained Cavitary Defect



Notes

Reconstruction Ring

Implant Cat. No.	O.D.	I.D.	Side
7133-7150	50	46	Left
7133-7156	56	52	Left
7133-7162	62	58	Left
7133-7250	50	46	Right
7133-7256	56	52	Right
7133-7262	62	58	Right

Reinforcement Ring

Implant Cat. No.	Trial Cat. No.	O.D.	I.D.
7133-7044	**7136-7044**	44	40
7133-7047	**7136-7047**	47	43
7133-7050	**7136-7050**	50	46
7133-7053	**7136-7053**	53	49
7133-7056	**7136-7056**	56	52
7133-7059	**7136-7059**	59	55
7133-7062	**7136-7062**	62	58
7133-7065	**7136-7065**	65	61
7133-7068	**7136-7068**	68	64

Preoperative Templates

(Not Shown)

Cat. No.	Description
7138-0365	Reinforcement
7138-0362	Reconstruction

6.5 mm Screws for Contour

Cat. No.	Length
7142-0974	15 mm
7142-0976	20 mm
7142-0978	25 mm
7142-0980	30 mm
7142-0982	35 mm
7142-0984	40 mm
7142-0986	45 mm
7142-0988	50 mm

Catalog Information

Acetabular Reamer Domes

Cat. No.	Size	Cat. No.	Size
41-7138	38 mm	41-7154	54 mm
41-7139	39 mm	41-7155	55 mm
41-7140	40 mm	41-7156	56 mm
41-7141	41 mm	41-7157	57 mm
41-7142	42 mm	41-7158	58 mm
41-7143	43 mm	41-7159	59 mm
41-7144	44 mm	41-7160	60 mm
41-7145	45 mm	41-7161	61 mm
41-7146	46 mm	41-7162	62 mm
41-7147	47 mm	41-7163	63 mm
41-7148	48 mm	41-7164	64 mm
41-7149	49 mm	41-7165	65 mm
41-7150	50 mm	41-7166	66 mm
41-7151	51 mm	41-7167	67 mm
41-7152	52 mm	41-7168	68 mm
41-7153	53 mm		

Impaction Domes

Cat. No.	Description
7136-7341	41 mm
7136-7344	44 mm
7136-7347	47 mm
7136-7350	50 mm
7136-7353	53 mm
7136-7356	56 mm
7136-7359	59 mm
7136-7362	62 mm
7136-7365	65 mm
7136-7368	68 mm

Dome Handle with Positive Lock

Cat. No. 7136-2105

T-Handle

Cat. No. 7136-4006

Acetabular Cup Positioner/Impactor

Cat. No. 73-2120

Contour Flange Bender

Cat. No. 7136-7001

Vice Grip Pliers

Cat. No. 7136-7537

Acetabular Screw Drill Guide

Cat. No. 7136-2101

Catalog Information

Twist Drill

Cat. No.	Diameter
21-0442	3.2 mm

Acetabular Screw Flexible Drill

Cat. No.	Length
7136-2115	15 mm
7136-2125	25 mm
7136-2135	35 mm
7136-2150	50 mm

Depth Gauge

Cat. No. 7136-2012

Reflection Curved Screw Forceps

Cat. No.	Bend
73-2136	35°
73-2137	75°

Acetabular Cup Screwdriver Ratchet Handle

Cat. No. 73-2112

Straight Screwdriver Shaft

Cat. No. 7136-2011

Acetabular Cup Universal Screwdriver Shaft

Cat. No. 73-2113

Flexible Screwdriver Shaft

Cat. No. 7136-2010

Mallet

Cat. No. 7136-2106

Catalog Information

Polyethylene Cup

Cat. No.	O.D.	I.D.
7135-2240	40 mm	22 mm
7135-2243	43 mm	22 mm
7135-2246	46 mm	22 mm
7135-2249	49 mm	22 mm
7135-2252	52 mm	22 mm
7135-2255	55 mm	22 mm
7135-2258	58 mm	22 mm
7135-2261	61 mm	22 mm
7135-2846	46 mm	28 mm
7135-2849	49 mm	28 mm
7135-2852	52 mm	28 mm
7135-2855	55 mm	28 mm
7135-2858	58 mm	28 mm
7135-2861	61 mm	28 mm
7135-3249	49 mm	32 mm
7135-3252	52 mm	32 mm
7135-3255	55 mm	32 mm
7135-3258	58 mm	32 mm
7135-3261	61 mm	32 mm

Positioner

Cat. No. MT-2200

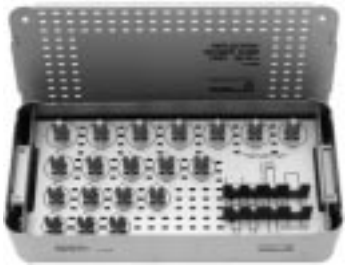
X-Bar

Cat. No. MT-2201

Placement Head

Cat. No.	Size
MT-2222	22 mm
MT-2228	28 mm
MT-2232	32 mm

Catalog Information



Reamer Dome Tray
38 mm - 70 mm
Cat. No. 73-1004

Impactor Dome Tray
Cat. No. 7136-7004

All-Poly Cup Instrument Tray
Cat. No. 7136-2110

IMPORTANT MEDICAL INFORMATION

Warnings and Precautions
Total Hip System

IMPORTANT NOTE

Total hip replacement arthroplasty has become a successful procedure for relieving pain and restoring motion in patients who are disabled from hip arthropathy. The goals of total hip replacement are to decrease pain, increase function, and increase mobility.

MATERIALS

The Total Hip System is manufactured from materials as outlined below. The component material is provided on the outside carton label.

Component	Material	Material Standards
Femoral Components	Ti-6Al-4V or Co-Cr-Mo	ASTM F 136 and ISO 5832/3 or ASTM F 1472 and ISO 5832/3 or ASTM F 799 and ISO 5832/12 or ASTM F 75 and ISO 5832/4
Acetabular shells Proximal pads Taper sleeves Distal sleeves Fixation screws and pegs Hole covers	Ti-6Al-4V	ASTM F 1472 and ISO 5832/3
Acetabular components Acetabular liners	UHMWPE	ASTM F 648
Femoral centralizers Acetabular spacer pods	PMMA	Not applicable
X-ray marking wire	Co-Cr-Mo	ASTM F 90 and ISO 5832/5
Acetabular Reconstruction Ring Acetabular Reinforcement Ring	CP Titanium	ASTM F 67 and ISO 5832/2
Femoral Heads	Co-Cr-Mo Zirconia Ceramic	ASTM F 799 and ISO 5832/12 ISO 13356

Porous titanium components and porous Co-Cr-Mo components are coated with commercially pure (C.P.) titanium beads (ASTM F 67 and ISO 5832/2) and Co-Cr-Mo beads (ASTM F 75), respectively. Hydroxylapatite coatings include HA (ASTM F 1185) that is applied either on a grit blasted or porous surface. NOTE: HA coated porous implants are not available in the USA.

Zirconia ceramic femoral heads are yttria stabilized zirconia ceramic.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomenon, in spite of the millions of implants in use.

DESCRIPTION OF SYSTEM

The Total Hip System consists of femoral components, proximal pads, taper sleeves, distal sleeves, acetabular components, fixation screws and pegs, hole covers, centralizers, and femoral heads. Components may be grit blasted, porous coated, hydroxylapatite (HA) coated, or HA porous coated. All implantable devices are designed for single use only.

Femoral Components

Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth. Proximally and distally modular femoral components accept proximal pads and distal sleeves, respectively. Non-porous femoral components can feature PMMA centralizers that help produce a uniform thickness of cement in a concentric manner.

Femoral components are available with a small, large (14/16), or 12/14 global taper (gage diameters 0.404, 0.564, and 0.500 inches, respectively).

Small taper femoral components mate and lock directly with a 22 mm metal or ceramic head. The small taper also mates with a taper sleeve which, in turn, mates with either metal or ceramic heads (26, 28, or 32 mm), bipolar or unipolar components.

Large taper femoral components mate and lock with either metal heads (26, 28, or 32 mm), ceramic heads (22, 28 or 32 mm), bipolar or unipolar components.

Femoral components with a 12/14 taper mate and lock with either metal heads (22, 26, 28, or 32 mm), ceramic heads (26 or 28 mm), bipolar or unipolar components.

Small, large, and 12/14 taper femoral component tapers are machined to mate and lock with ceramic heads, thus preventing rotation of the ceramic head on the stem, the latter would cause wear of the stem taper.

Taper Sleeves

A taper sleeve is required to be impacted on the small taper femoral component prior to impacting a femoral head size 26, 28, or 32 mm. A taper sleeve is required to attach a unipolar head. Unipolar taper sleeves are available in small, large, and 12/14 tapers. Never place more than one taper sleeve on a femoral component.

Femoral Heads

Cobalt chromium (22, 26, 28, and 32 mm) and ceramic (22, 26, 28, and 32 mm) heads are available in multiple neck lengths for proper anatomic and musculature fit. Heads are highly polished for reduced friction and wear. The following zirconia ceramic heads are available for use only with small (0.404) and large (.564) taper femoral components:

Zirconia Ceramic	Head Diameter	Neck Length	
42-7815	32 mm	Standard	0 mm
42-7816	32 mm	Long	4 mm
42-7817	32 mm	X-Long	8 mm
42-7818	28 mm	Standard	0 mm
42-7819	28 mm	Long	4 mm
42-7820	28 mm	X-Long	8 mm

Note: 32 mm heads with a -3 mm neck length are not available for use with the small taper stems.

In addition to the components listed above, the following components are available for use only with small (0.404) taper femoral components:

Zirconia Ceramic	Head Diameter	Neck Length	
7132-0002	22 mm	Long	4 mm
7132-0006	22 mm	X-Long	8 mm

Note: 22 mm Zirconia Ceramic Heads used with small (0.404) taper femoral components are not available in the USA.

The following zirconia ceramic heads are available for use only with 12/14 taper femoral components:

Zirconia Ceramic	Head Diameter	Neck Length	
7132-0028	28 mm	Standard	0 mm
7132-0428	28 mm	Long	4 mm
7132-0828	28 mm	X-Long	8 mm
7132-0026	26 mm	Standard	0 mm
7132-0426	26 mm	Long	4 mm
7132-0826	26 mm	X-Long	8 mm
7132-0422	22 mm	Long	4 mm
7132-0822	22 mm	X-Long	8 mm

Acetabular Components

Acetabular components can be one piece all polyethylene or two-piece components consisting of a titanium shell and a polyethylene liner. Please see Warnings and Precautions for specific information on screws, pegs and hole covers use. Acetabular reinforcement and reconstruction rings are used with an all polyethylene acetabular component.

Femoral components and femoral heads are designed for use with any Smith & Nephew polyethylene acetabular component or polyethylene-lined, metal-backed acetabular component having an appropriately-sized inside diameter.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and / or protrusion as a result of the indications listed previously.

Some of the diagnoses listed above and below may also increase the chance of complications and reduce the chance of a satisfactory result.

Contraindications

1. Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately- sized implant, e.g.:
   a. blood supply limitations;
   b. insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and
   c. infections or other conditions which lead to increased bone resorption.
2. Mental or neurological conditions which tend to impair the patient's ability or willingness to restrict activities.
3. Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
4. Skeletal immaturity.
5. The zirconia ceramic head is contraindicated for use with any other product than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.

Contraindications may be relative or absolute and must be carefully weighted against the patient's entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others.

Conditions presenting increased risk of failure include: osteoporosis, metabolic disorders which may impair bone formation, and osteomalacia.

Possible Adverse Effects

1. Wear of the polyethylene articulating surfaces of acetabular components has been reported following total hip replacement. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop during or as a result of the surgical procedure and cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particles may also be generated by third-body particles lodged in the polyethylene articular surface. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, looseness of acetabular or femoral components, extraneous bone, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intrapelvic protrusion of acetabular component, femoral impingement, periarticular calcification, and/or excessive reaming.
5. Fracture of the pelvis or femur: postoperative pelvic fractures are usually stress fractures. Femoral fractures are often caused by defects in the femoral cortex due to misdirected reaming, etc. Intraoperative fractures are usually associated with old congenital deformity, improper stem selection, improper broaching, and/or severe osteoporosis.
6. Infection, both acute post-operative wound infection and late deep wound sepsis.
7. Neuropathies; femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.
8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.
9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarticular calcification with or without impediment to joint mobility can cause decreased range of motion.
10. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
11. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement.
12. Damage to blood vessels.
13. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.
14. Delayed wound healing.
15. Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.
16. Failure of the porous coating/ substrate interface or hydroxylapatite

coating/ porous coating bonding may result in bead separation delamination.

17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Varus stem alignment may also be responsible.

WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from different manufacturers. Additional Warnings and Precautions may be included in component literature.

Preoperative

1. Use extreme care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.
4. Surgical technique information is available upon request. The surgeon should be familiar with the technique.
5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.
6. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper. (See sterilization section, below.)
7. Select components such that the Zirconia ceramic head always articulates with a UHMW polyethylene cup or a metal backed UHMW polyethylene cup. Zirconia ceramic should never articulate against metal because severe wear of the metal will occur.
8. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper on the stem is machined to tightly mate and lock with the ceramic head thus preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head.
9. The zirconia ceramic head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that when used with a polyethylene acetabular component, the yttria stabilized zirconia ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.

Intraoperative

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Correct selection of the neck length and cup, and stem positioning, are important. Muscle looseness and/or malpositioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stresses which must be borne by the stem. The component should be firmly seated with the component insertion instruments.
3. Care should be taken not to scratch, bend (with the exception of the Reconstruction Rings) or cut metal components during surgery for the reasons stated in Number One of the "Pre-Operative" section of "Warnings and Precautions."
4. **A +12 mm or +16 mm femoral head should not be used with any small taper stems.**
5. **Distal sleeves should not be used to bridge cortical defects that lie within 25 mm of the tip of the base stem.**
6. Matrix small taper stem sizes 8S - 10L must have a minimum neck length of +8 mm when used with a bipolar component; and small taper stem sizes 12S - 16L must have a minimum neck length of +4 mm when used with a bipolar component.
7. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers.
8. Clean and dry stem taper prior to impacting the femoral head or taper sleeve. The modular femoral head component must be firmly seated on the femoral component to prevent disassociation.
9. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrage. Do not place a screw in the center hole of the acetabular prosthesis.

   Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury.

   Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, or a new shell if necessary.
10. USE ONLY REFLECTION® TITANIUM BONE SCREWS, UNIVERSAL CANCELLOUS BONE SCREWS, TAPERED PEGS, AND HOLE COVERS with the Reflection Acetabular Component and USE ONLY OPTI-FIX® TITANIUM BONE SCREWS AND UNIVERSAL CANCELLOUS BONE SCREWS with the Opti-Fix Acetabular Component. The Reflection Interfit and the Reflection For Screws Only (FSO) shells accept Universal Cancellous, Reflection screws, and tapered screw-hole covers, not pegs. Tapered pegs can only be used with Reflection V Shells. The threaded center hole in Reflection Shells only accepts the threaded hole cover, not screws or pegs. The InterFit threaded hole cover is only for use with Reflection Interfit. The Reflection threaded hole cover can be used with both Reflection and InterFit shells. Refer to product literature for proper adjunctive fixation and hole cover usage.
11. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue does not interfere with the shell/liner interface. Chilling the liner reduces the impaction force required to seat the liner. Modular components must be assembled securely to prevent disassociation. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.
12. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
13. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.
14. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of looseness, etc. and replaced if necessary. The head/neck component should be changed only when clinically necessary.
15. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture of these components.
16. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is often very small and straight and may require an extra-small straight femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that the true acetabulum is rudimentary and shallow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.
17. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of the medial acetabular wall, femur, or greater trochanter.
18. Revision procedures for previous arthroplasty, Girdlestone, etc., are technically demanding and difficult to exercise. Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, or improper positioning of components. Postoperative instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.
19. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked for early contact or instability.

Postoperative

1. Postoperative directions and warnings to patients by physicians, and patient care, are extremely important. Gradual weight bearing is begun after surgery in ordinary total hip arthroplasty. However, with trochanter osteotomy or certain complex cases, weight-bearing status should be individualized with the non or partial weight-bearing period extended.
2. Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip.
3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, and clothing, and similar activities, precautions should be taken to avoid placing excessive load on the operative part of the body.
4. Postoperative therapy should be structured to regain muscle strength around the hip and a gradual increase of activities.
5. Periodic x-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.
6. Prophylactic antibiotics should be recommended to the patient similar to those suggested by the American Heart Association for conditions or situations that may result in bacteremia.

PACKAGING AND LABELING

Components should only be accepcted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

Metal Components

Nonporous metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum dwell time of 4 minutes at 270oF to 275oF (132oC to 135oC), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- Gravity Cycle: 270oF to 275oF (132oC to 135oC) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.

Do not resterilize femoral prostheses with ceramic heads seated on the stem.

If porous coated implants are inadvertently contaminated, return the unsoiled prosthesis to Smith & Nephew for resterilization. DO NOT RESTERILIZE porous coated implants. The porous coating requires special cleaning procedures.

Plastic Components

Plastic components may be resterilized by ethylene oxide gas. The following parameters are recommended as starting points for cycle validation by the health care facility:

Sterilant	Temp.	Humidity	Maximum Pressure	Concentration	Exposure Time
10% EtO 90% HCFC	130˚F (55˚C)	40-60%	28 PSIA (1930 millibar)	550-650 mg/L	120 minutes
10% EtO 90% HCFC	100˚F (38˚C)	40-60%	28 PSIA (1930 millibar)	550-650 mg/L	6 hours
100% EtO	131˚F (55˚C)	30-60%	10 PSIA (689 millibar)	736 mg/L	30 minutes

Suggested initial starting point for aeration validation is 12 hours at 122˚F (50˚C) with power aeration. Consult aerator manufacturer for more specific instructions.

Ceramic Components

Do not resterilize ceramic femoral heads.

INFORMATION

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Smith+Nephew

Leadership in Worldwide Healthcare

Smith & Nephew, Inc. • 1450 Brooks Road • Memphis, TN 38116 U.S.A.
(901) 396-2121 • For information: 1-800-821-5700 • For orders and order inquiries: 1-800-238-7538

7/99 7138-0488