

**Epsilon™ Durasul® Constrained Insert**  
Stability without compromise



# Epsilon™ Durasul® Constrained Insert

## Stability without compromise

### The Problem:

Dislocation is the second most common major complication in THA, occurring after 0.4 - 7% of primary THAs and up to 19% of revision THAs.<sup>1,3,4,7</sup> Dislocation can be physically destructive, leading to abductor tissue damage. Reoperation results in stability in only 69% of cases.<sup>2</sup>

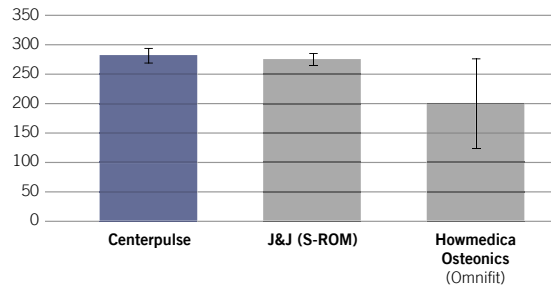
Constrained inserts are designed to reduce the incidence of dislocation. However, the design of traditional constrained inserts severely restricts ROM, leading to impingement. This may lead to component failure,<sup>8,5</sup> dislocation,<sup>6,7</sup> and implant loosening.<sup>8</sup>

### Constraining Functionality Retained

In lever-out testing, the Epsilon Durasul Constrained Insert performed as well as the two most commonly used constrained liners.<sup>13</sup>

#### Lever-out Testing

Lever-out of head from liner.  
(in - lbs)

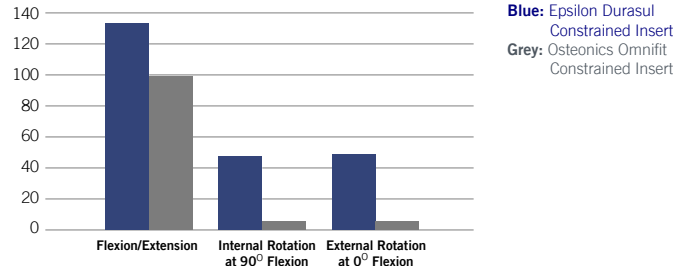


### ROM Increased over Traditional Constrained Insert

In testing using a sawbones set-up and a three-dimensional goniometer, the Epsilon Durasul Constrained Insert demonstrated much-improved ROM when compared to a traditional constrained liner.<sup>14</sup>

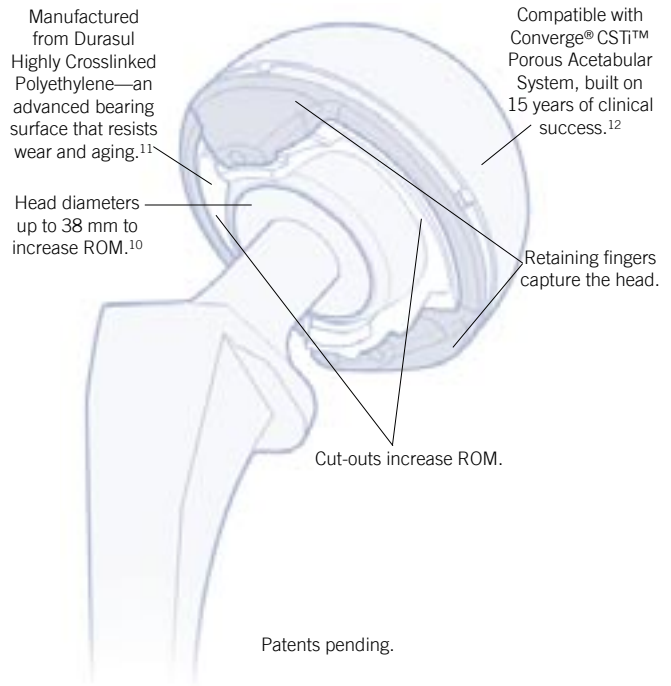
#### ROM Testing

Range of motion.  
(degree)



### The Solution:

#### Epsilon™ Durasul® Constrained Insert



### Cut-outs increase ROM where it is needed most

In a study of 111 retrieved acetabular components, researchers identified two primary sites of impingement damage.<sup>9</sup> One site occurred where the neck impinged during full flexion or flexion plus internal rotation (anterior-superior). The second site occurred where the neck impinged during external rotation in extension (posterior-inferior).

Based on these findings, the Epsilon Durasul Constrained Insert was designed with cut-outs that may be placed where impingement is most likely to occur.

For a left hip, the smaller, superior retaining finger is placed at one o'clock to optimize ROM.

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## Joint Exposure

No specific type of incision or exposure is required for implantation of the Epsilon Durasul Constrained Insert. The operation may be done using a Kocher-Langenbach posterolateral incision or a direct lateral incision, among others. The majority of cases utilizing constrained inserts are revision cases, and in these cases, the Kocher-Langenbach approach is common. In primary cases, either a posterolateral or direct lateral incision may be used. However, any approach that gives wide exposure of the acetabulum may be utilized.

**Note:** To ensure proper impaction of the polyethylene liner, placement of constraining fingers, and assembly of the metal constraining ring, all soft tissue must be fully cleared/retracted to allow full visualization of the periphery of the acetabulum. This implant is not recommended at this time for use with a minimally invasive exposure.

## Acetabular Preparation and Shell Placement

### Acetabular Preparation

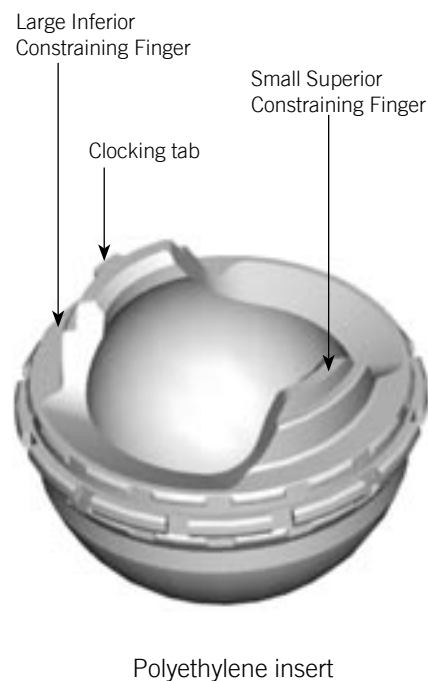
The Epsilon Durasul Constrained Insert is to be used only with a Converge Acetabular Shell or other Epsilon-compatible shell. Standard operative procedures for the Converge Acetabular System should be used for acetabular preparation and shell implantation. In general, the preparation of the acetabular recess follows the usual guidelines, namely maximizing the contact with available host bone and maximizing the coverage with host bone.

### Shell Placement

The recommended shell placement for use with the Epsilon Durasul Constrained Insert is slightly non-standard. That is, for most cases the optimum degree of abduction is about 55°, rather than 45°. Studies have demonstrated that increasing the shell abduction to 55° increases the range of motion of the total hip joint.<sup>15,16</sup> Typically, abduction angles of this degree are not recommended because they may lead to a higher dislocation risk. However, since the head is constrained in this insert design, the higher range of motion provided by the higher abduction angle does not increase the risk of dislocation. Failure to abduct the shell to 55° will fail to optimize the range of motion of the Epsilon Durasul Constrained Insert.

The optimum degree of anteversion is standard, about 30°. Because “anteversion is additive” (meaning that the femoral anteversion and the acetabular anteversion should be added together in determining total anteversion), there is some

Figure 1



flexibility in the amount of anteversion of the acetabular component. For example, if a previously inserted femoral component is retained in a revision operation and is in neutral anteversion, the acetabular component should be anteverted more than usual. On the other hand, if the femoral component is in more than the usual 15° of anteversion, then one needs to be sure that there is not excessive anteversion on the acetabular component.

One special feature of the use of larger femoral heads (>32 mm in diameter) is that the increased range of motion permits the use of a slightly increased amount of total anteversion. Thus, if the femoral anteversion were at 15°, the larger head diameter would permit an increased amount of acetabular anteversion, such as 30°. Therefore, in revision cases where the femoral component is being retained, the surgeon should determine the degree of anteversion of the existing femoral component prior to determining the optimum anteversion for the acetabular component.

### Screw Fixation

**Note:** In both primary and revision cases, screw fixation is highly recommended, as the use of any constrained insert may lead to higher forces at the shell-to-bone interface.

Screws augment both the initial stability and the long-term stability achieved through bony ingrowth. Screw placement follows the standard procedure for the Converge Acetabular System. The standard admonitions regarding the appropriate placement and length of screws should be followed to maximize fixation and minimize the risk to neuro-vascular structures.

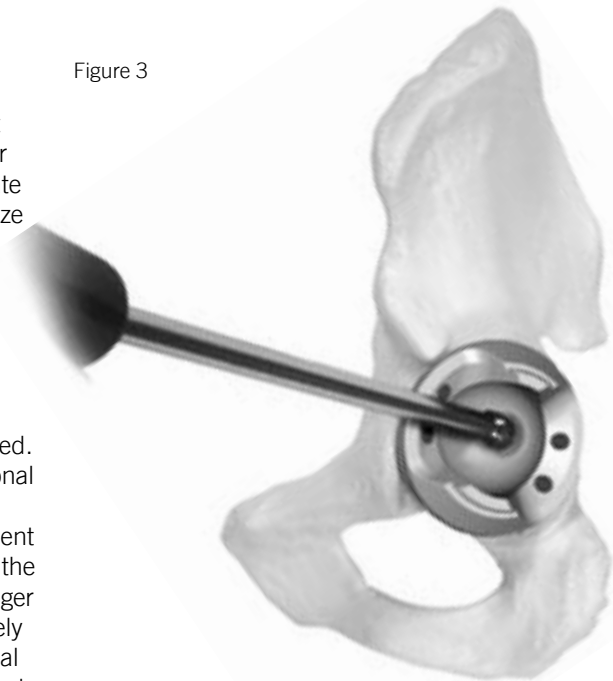
### Trial Reduction and Range of Motion

Based on the size of the acetabular shell and femoral head to be used, the appropriate trial constrained insert is selected. The aim of the trial reduction is to locate the optimal rotational position of the constraining fingers (Figure 1) to maximize range of motion. This position may vary from patient to patient because of variations in anatomy and shell placement. For the initial trial range of motion, the small superior constraining finger of the appropriate-sized trial insert is placed at approximately 1:00 for a left hip or 11:00 for a right hip (Figure 2). The trial insert is rotationally secured by the interlock of the peripheral notches on the trial with the anti-rotation pegs on the acetabular shell. The trial inserts contain a captured screw at the apex that is threaded into the dome of the acetabular shell with a straight hex-head screw driver (Figure 3).

Figure 2



Figure 3



# Epsilon™ Durasul® Constrained Insert Surgical Technique

**Warning:** The captured screw is intended only to temporarily hold the trial insert in place and should not be overly tightened. Two-finger tightening is sufficient. Breakage can occur with excess torque on the captured screw.

**Note:** The trial insert is used only to assess leg length and range of motion. It does not constrain the femoral head, as the actual implant does.

A trial femoral head with the appropriate neck length is placed on the trunion of the femoral component and reduced into the trial insert. After the leg length and femoral offset are verified, a trial range of motion is conducted. The key ranges of motion should be assessed, specifically:

- Maximum flexion in neutral rotation,
- Maximum internal rotation with 90° of flexion,
- Full extension (but not hyper-extension),
- Full external rotation in full extension.

If the trial range of motion indicates that the orientation of the constraining fingers does not optimize the range of motion, such as might be indicated by premature neck-insert impingement, the captured screw at the dome of the trial insert can be released and the trial insert rotated to another position. Once the optimum orientation of the trial insert is determined, the position of the small superior constraining finger is noted on the acetabular shell.

## Insert Placement

The small superior constraining finger of the constrained liner is aligned in the acetabular shell to replicate the orientation that had provided optimum range of motion during assessment using the trial insert (Figure 4). The appropriately sized constrained insert impactor is threaded onto the straight impactor handle until the threads are completely seated (Figure 5).

**Note:** The constrained insert impactors are sized according to the inner diameter of the insert (or femoral head size).

The constrained insert impactor is placed onto the constrained insert such that the protruding polyethylene constraining fingers fit into annular recesses of the insert impactor. Two or three moderate impaction blows are applied to the impactor handle with a surgical mallet to seat the insert into the shell (Figure 6).

Figure 4



Figure 5



Figure 6



**Note:** All soft tissue must be completely removed from the periphery of the shell in order to avoid trapping of any soft tissue between the insert and the shell. Any trapping of soft tissue will likely result in difficulty seating the insert into the shell.

### Preparation of Constraining Ring

First, the metal constraining ring is placed over the femoral head and allowed to rest around the neck of the femoral stem (Figure 7). The ring must be placed on the stem in the proper orientation. The side of the ring with the two protruding fingers must point toward the femur. The flat side of the ring, which will contact the face of polyethylene liner, must be craniad or toward the patient's acetabulum.

**Note:** For clarification, the ring is engraved with "THIS FACE TOWARD FEMUR" and "THIS FACE TOWARD ACETABULUM".

### Femoral Head Reduction

**Warning:** The metal constraining ring must be in place around the femoral neck before reducing the head into the liner.

Ensure that the appropriately sized femoral head is used. The head size is indicated on the insert packaging and is also marked on the insert. For instance, a size 38 x 55 insert is used in a size 55-mm shell with a 38-mm femoral head.

The femoral head is reduced into the constrained insert by applying a continuous, steady force axially along the femur (Figure 8). Attempts should not be made to reduce the femoral head into the insert with a sudden impaction force. Because of the material properties of polyethylene, sudden impaction actually requires a higher force to be applied.

### Constraining Ring Assembly to Insert

To attach the metal constraining ring to the insert, advance the ring from around the femoral neck to the face of the insert. To ensure proper alignment of the ring, the clocking tab on the large inferior constraining finger of the insert must interfit with the clocking slot on the large protruding finger on the metal ring (Figure 1). When properly positioned, the small protruding finger of the ring is aligned with the small superior constraining finger of the insert, and the large protruding finger of the ring is aligned with the large inferior finger of the insert.

Figure 7



Figure 8



Figure 9



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An appropriately sized ring impactor is threaded onto the straight impactor handle until the threads are completely seated (Figure 9). The three pegs of the ring impactor are inserted into the three holes on the constraining ring (Figure 10). Two or three moderate impaction blows are applied with a surgical mallet to seat the ring onto the insert (Figure 11).

**Note:** The ring impactors are sized according to the inner diameter of the insert (or femoral head size).

**Note:** Soft tissue must be cleared from the periphery of the polyethylene insert in order to avoid trapping of the soft tissue between the insert and the metal constraining ring. This trapping of soft tissue may result in difficulty seating the insert into the shell. If difficulty assembling the ring is encountered, check the periphery for soft tissue trapping.

After assembling the constraining ring to the insert, the range of motion is re-checked, and joint stability is checked by applying traction on the femur. If both range of motion and stability are satisfactory, closure of the wound proceeds as usual.

## Insert Removal

### Metal Constraining Ring Removal

To remove the constraining ring, insert a flat instrument, such as a quarter-inch osteotome, under the ring (Figure 12). Apply rotational torque to the instrument in order to pry the constraining ring from the polyethylene snap feature. Carefully repeat this process at a few sites around the periphery of the ring until the ring is loosened from the insert.

If the previously described prying method is unsuccessful, use a high-speed cutting tool, such as a Midas Rex™, to make two diametrically opposed cuts through the thinnest portion of the ring.

Figure 10



Figure 11



Figure 12



## Polyethylene Insert Removal

### Bone Screw Method

The Bone Screw Method may be used to remove any Epsilon insert from a Converge Acetabular Cup. This technique utilizes two 50-mm bone screws to force the insert out of the shell. The first screw is driven a few turns into the face of the insert near the rim of the shell, and the second screw is placed on the opposite side of the insert, also near the rim of the shell (Figure 13). Alternately advance each screw by a few turns. When the screw tips reach the metal shell, each advancement of the screw will work the insert snap feature out of the shell. Continue this process until the polyethylene insert's snap feature is disengaged from the shell (Figure 14). An osteotome may be used to lever the insert completely away from the liner once a section of the snap feature has been disengaged.

### Osteotome Method I

This osteotome method utilizes two curved 8-mm surgical osteotomes to lever out the insert from the shell. The first osteotome is placed under the outer rim of the insert and the face of the shell. The second curved osteotome is positioned near the face of the metal shell and slightly driven into the outer surface of the polyethylene insert to achieve optimal purchase. By levering the osteotomes on the face of the shell, gradually "walk" the insert out of the shell in increments of about 1-3 mm by alternating the levering motion of the osteotomes. Note that the insert may only advance 1-3 mm per stroke (Figure 15).

### Osteotome Method II

The insert may also be removed by creating a slot in an area between the inner diameter and the outer rim. A curved osteotome may then be placed into the slot to lever the insert away from the shell.

Special care should be taken not to lever against the snap feature on the shell inner diameter if the shell will be used with another insert.

**Note:** This insert, like all inserts, should not be re-implanted after using these methods of removal.

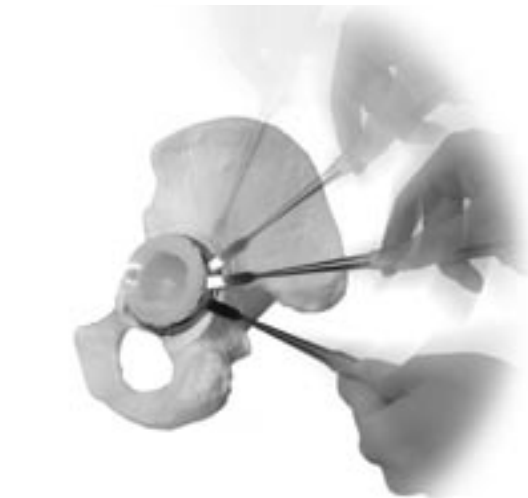
Figure 13



Figure 14



Figure 15



# Epsilon™ Durasul® Constrained Insert Surgical Technique

## Important Information for the Physician

### EPSILON™ DURASUL® CONSTRAINED ACETABULAR INSERT

#### Description of Prosthesis

The Epsilon Durasul Constrained Acetabular Insert consists of a Durasul polyethylene liner (UHMWPE, ASTM F648) and a metallic reinforcement ring (Ti-6Al-4V, ASTM F136) which are to be assembled at the time of surgery to an appropriate Centerpulse Orthopedics femoral head and acetabular shell component which has been fixated with supplemental bone screws.

The liner portion of the insert has two hoods which extend beyond the equator of the shell to allow for mechanical capture of the femoral head. The reinforcing ring is designed to fit into a snap lock feature around the outer surface of the liner. The reinforcing ring provides additional constraint of the femoral head within the liner.

#### Information for Use

The advancement of total joint replacement has provided the surgeon a means of restoring mobility and reducing pain for many patients. While total hip replacements are largely successful in attaining these goals, no total joint replacement can be expected to withstand the activity levels and loads of normal healthy bone.

In using these implants, the surgeon should be aware that the following factors can be of extreme importance to the eventual success of the procedure:

- A. Correct and initial size selection of the implant(s) is extremely important. The potential for success in total joint replacement is increased by selecting the proper size, shape and design of the implant(s). Any total joint prosthesis requires careful seating and adequate support, and should be restricted to limited functional stress.
- B. In selecting patients for total joint replacement, the following factors can be of extreme importance to the eventual success of the procedure:

1. The patient's weight: An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the cement and/or device (if the device is cemented).
  2. The patient's occupation or activity: If the patient is involved in an occupation or activity that involves substantial walking, running, lifting and/or muscle strain, the resultant forces can cause failure of the cement and/or device (if the device is cemented).
  3. A condition of senility, mental illness, or substance abuse, e.g., alcoholism: These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant failure or other complications.
  4. Certain degenerative diseases: In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected life of the device. In such cases, total hip replacement can be considered only as a temporary relief from pain or as an intermediate procedure.
  5. Foreign body sensitivity: Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
  6. Infection: Local infection, recent or chronic, may be a contraindication for the use of a total joint replacement. Extreme care should be used in patient selection in the event of recent or chronic infection.
- C. Careful handling of all components is very important.
    1. Inspect packages for punctures and other damage prior to surgery.
    2. The devices, particularly surfaces to be mated with polyethylene components, should be protected from mechanical damage and not be allowed to contact any metallic or other hard surface.

## Assembly of Components

The Epsilon Durasul Constrained Insert is placed in several steps after achieving fixation of the acetabular shell component and bone screws as well as the femoral stem/femoral head. First, the Durasul liner is positioned to align the slots of the insert with the anti-rotation tabs of the shell. Utilizing the insert impactor, the liner is malleted into place, snapping it into the locking groove of the shell. Next, the reinforcing ring is placed around the neck of the femoral stem paying careful attention to orient it such that the insert/ring snap lock feature may be engaged (NOTE: Care should be taken to protect both metallic surfaces from becoming nicked or scratched, as early stress related failures may result). The head of the previously placed femoral stem is then reduced into the liner. Finally, the reinforcing ring is properly oriented around the insert and snapped into place using the appropriately sized ring impactor. It is important that only compatible Centerpulse Orthopedics Inc. instruments be used in conjunction with these components, as other instruments may nick, scratch, or otherwise damage the component. For suggested detailed assembly steps, please refer to the Centerpulse Orthopedics Surgical Technique for this device (available separately).

## Indications and Contraindications

Indications and contraindications for the use of this component may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures.

Patient selection will be largely dependent on patient's age, general health conditions of available bone stock, prior surgery and anticipated further surgeries. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity.

### A. Indications

Primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered. The fixation method of the acetabular components with which this device is intended to be used is porous cementless with supplemental screws, and the fixation method of the femoral components with which this device is intended to be used is cemented, porous cementless, or non-porous cementless fixation, as indicated for use by each respective femoral component.

### B. Contraindications

1. Patient physical conditions that would eliminate or tend to eliminate adequate implant support, prevent the use of an appropriate sized implant, or otherwise lead to inadequate skeletal fixation.
2. Active infection of the hip joint, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.
3. Other conditions that will place excessive demands on the joint:
  - Charcot's joints
  - muscle deficiencies
  - multiple joint disabilities
  - refusal to modify postoperative physical activities
  - obesity
4. Conditions that tend to impose severe loading on the affected extremity include, but are not limited to, the following:
  - obesity
  - heavy labor
  - active sports
  - history of falls
  - general neurological abnormalities or other factors (e.g., mental illness, senility, drug use, alcoholism) which tend to preempt the patient's ability or willingness to follow the surgeon's postoperative instructions.
5. Physical conditions that tend to adversely affect the stable fixation of the implants include, but are not limited to, the following:
  - Skeletal immaturity
  - marked osteoporosis
  - systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies)
  - history of general or local infectious disease
  - tumors and/or cysts of the supporting bone structure

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- suspected allergic reactions to metals, polyethylene, bone cement
  - other joint disability (i.e., knees or ankles)
  - severe deformity leading to impaired anchorage or improper positioning of implants.
6. The safety and effectiveness of this device when used in combination with ceramic femoral heads has not been established.

## Warnings and Precautions

### A. Preoperative

1. The preoperative planning and surgical technique for implantation represent principles that are basic to sound surgical management in total hip replacement. Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is suggested in the performance of this surgery. Review of the use and handling of these instruments is important. Bent or damaged instruments may lead to improper implant position and result in implant failure. A surgical technique brochure fully describing the procedure is available from Centerpulse Orthopedics Inc.
2. When total hip replacement is being considered, particularly for the young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the limitations of the devices being used (including limits in range of motion and activity), the possible consequences resulting from these limitations and, therefore, the necessity of following the doctor's preoperative instructions.
3. Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively.
4. X-ray templates should be used to estimate implant sizes, placement and joint alignment. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra implant components are recommended. All packages and implants should be thoroughly inspected prior to surgery for possible damage (see "Sterilization" section).
5. The correct handling of the implant is extremely important. The components should be used without nicks, scratches, or other alterations; these can produce defects and stresses that may become the focal point for eventual failure of the implant.
6. A surgical implant must not be reused under any circumstances. Once implanted and subsequently removed, an implant should be discarded. Even though the implant may appear undamaged, it may have small defects and internal stress patterns that may lead to failure. Only new implants should be used. Do not alter implants prior to use.
7. The use of polymethylmethacrylate (PMMA) bone cement can be helpful in securing, supporting and stabilizing certain devices in bone, but it neither replaces the support function of sound bone nor eliminates the need for additional support during healing. When using cement for implant fixation, care should be used to ensure complete cement support on all parts of the device embedded in the bone cement to help prevent possible stress concentrations that may lead to failure.
8. Only compatible Centerpulse Orthopedics Inc. components and instruments should be used in conjunction with these components. Use of components from other manufacturers is not recommended as premature failure may result.
9. Closed reduction of this device is not possible. Patients should be informed that treatment for such device dislocation will require additional surgery.
10. The safety and effectiveness of the use of this component in bilateral applications have not been established.

11. It is important to consider component placement, including the possibility of component malposition, and the effect on range of motion when implanting modular heads (with sleeves or skirts) and extended liners. A malpositioned acetabular cup may yield the potential for impingement, premature dislocation, and subsequent revision of the device.

B. Intraoperative

1. The correct selection of the implant(s) is extremely important. Selection of the implant(s) refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.
2. Stem and cup positioning and neck length are of critical importance. Subluxation, dislocation, and/or fracture of components may result due to muscle looseness and/or malpositioning of components.
3. Care should be taken to properly align the liner within the shell so as to avoid impingement with the femoral neck. Trial components are provided to assist in determining appropriate position and range of motion. Impingement may result in dislocation of the head from the liner.
4. DO NOT use the liner without the reinforcing ring in position. The purpose of the ring is to provide additional constraint of the head within the liner.
5. DO NOT use the constrained liner in an acetabular shell which has not or cannot be fixated with supplemental bone screws. Bone screws are recommended to maintain position/integrity of the components under the forces which may be seen due to the increased degree of constraint.
6. Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the metal/plastic/articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.

C. Postoperative Care

Postoperative care is important. The patient should be instructed on the limitations of this device and should be cautioned regarding the load-bearing, range of motion, and activity levels permissible. Early load-bearing should be carefully controlled.

1. Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation or thromboembolism.
2. Postoperative therapies, patient handling (e.g., changing dressings, placing on bedpans, etc.) and patient activities should be structured to prevent excessive loading of the operative hip. The surgical procedure/approach chosen, the patient's age and/or bone quality may necessitate extending the period of limited weight bearing.
3. Periodic x-rays are recommended for close comparison with postoperative x-rays to detect long-term evidence or progressive changes in implant position or loosening. X-rays may also detect evidence of bending, cracking and/or disassembly of components or changes in fixation or support.
4. The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

D. Adverse Events

The potential adverse effects are similar to those occurring with any total hip replacement. These effects are often attributable to factors listed under "Warnings and Precautions" and commonly include:

1. Changing position of the prosthesis (bending, loosening, fracture and/or disassembly of components) with or without clinical symptoms.
2. Perforation, fissure, fracture of the acetabulum, femur or trochanter and/or trochanteric avulsion.
3. Subluxation, dislocation, decreased range of motion, and shortening or lengthening of the extremity
4. Fractures of the femur. Postoperative fractures are usually stress fractures. Fractures are usually evidence of defects in the cortex due to prior screw holes and misdirected reaming and/or inadequate maldistributed bone cement. Intraoperative fractures are usually associated with revision surgery deformity and/or severe osteoporosis.

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5. Ectopic ossification.
6. Early or late infection.
7. Cardiovascular disorders including damage to blood vessels (iliac, obturator and femoral artery), wound hematoma, venous thrombosis, pulmonary embolism and myocardial infarction.
8. Temporary or permanent neuropathies, including femoral, sciatic, peroneal or obturator.
9. Pulmonary disorders including pneumonia and atelectasis.
10. Aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, femoral medialization, or muscular deficiencies.
11. Excessive wear of the acetabular component from damage to mating wear surfaces or debris particles.
12. Tissue reactions and allergy to corrosion or wear products.
13. Urological complications, especially urinary retention and infection.
14. Aseptic loosening.
15. Possible detachment of coating (CSTi) could be associated with increased metal or third body debris.
16. Other complications associated with general surgery, drugs, or ancillary devices used, blood, etc.
17. Revision, reoperation or medical/surgical intervention to correct or alleviate one or more of these or other adverse events.

Once dislocated, additional surgery will be required to reduce the joint. Patients should also be informed that significant reduction in the range of motion is inherent to the design characteristic of a constrained acetabular liner, and activities that may force the joint to exceed those range of motions limits should be avoided.

## **Sterilization**

Unless otherwise indicated, all components are provided sterile and are supplied packaged in protective trays or pouches.

The Durasul liner is sterilized by Ethylene Oxide (EtO). The reinforcing ring is sterilized by a minimum of 25 kGy (2.5 Mrads) of gamma irradiation.

CENTERPULSE ORTHOPEDICS INC. DOES NOT RECOMMEND RESTERILIZATION OF IMPLANTABLE DEVICES.

## **E. Patient Counseling**

Surgeons and patients should be aware of the possibility of component fracture, including fracture of the reinforcement ring. Failure or disassociation of this locking ring may require additional surgery. Patients should be advised to contact their physician if they experience pain, new and/or sudden restrictions on range of motion, infection, or any other signs of possible device component fracture.

Patients should also be counseled that this prosthesis will not restore function to the level expected with a normal healthy joint. The range of motion achievable with a constrained liner is less than the range of motion of a normal joint, and less than the range of motion with a hemispherical prosthesis. The patient should be told that, although the constrained hip liner provides resistance to dislocation, it can dislocate if subjected to excessive loading and range of motion.

## Ordering Information

### Epsilon Durasul Constrained Inserts

Catalog No.	Description
4380-28-051/053	Epsilon Durasul Constrained Insert, ID 28, Sizes 51-53
4380-32-055/059	Epsilon Durasul Constrained Insert, ID 32, Sizes 55-59
4380-38-061/071	Epsilon Durasul Constrained Insert, ID 38, Sizes 61-71

### Epsilon Durasul Constrained Insert Instrumentation

Catalog No.	Description
9375-28-051/053	Epsilon Durasul Constrained Trial Insert, ID 28, Sizes 51-53
9375-32-055/059	Epsilon Durasul Constrained Trial Insert, ID 32, Sizes 55-59
9375-38-061/071	Epsilon Durasul Constrained Trial Insert, ID 38, Sizes 61-71
9376-00-028	Epsilon Durasul Constrained Insert Impactor, Size 28
9376-00-032	Epsilon Durasul Constrained Insert Impactor, Size 32
9376-00-038	Epsilon Durasul Constrained Insert Impactor, Size 38
9377-00-028	Epsilon Durasul Constraining Ring Impactor, Size 28
9377-00-032	Epsilon Durasul Constraining Ring Impactor, Size 32
9377-00-038	Epsilon Durasul Constraining Ring Impactor, Size 38

### Universal Acetabular Instrumentation

Catalog No.	Description
9340-00-000	Straight Impactor Handle
9366-00-063	Epsilon Acetabular Insert Extractor
9366-00-015	Straight Hex Head Screw Driver
9366-00-016	Universal Hex Head Screw Driver
9366-00-017	Universal Hex Head Screw Driver Shaft

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