



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

P960067

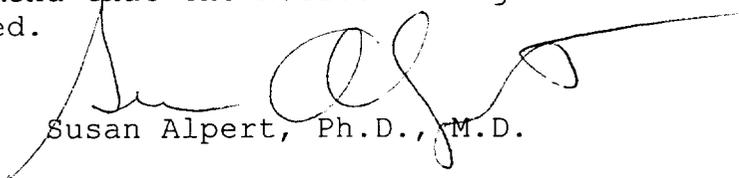
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Date: June 13, 1997  
From: Director, Office of Device Evaluation (HFZ-400)  
Center for Devices and Radiological Health (CDRH)  
Subject: Premarket Approval of Osteonics® Corporation's  
Osteonics® Constrained Acetabular Insert  
To: The Director, CDRH  
ORA \_\_\_\_\_

ISSUE. Publication of a notice announcing approval of the  
subject PMA's.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:  
(1) premarket approval orders for the above  
referenced medical devices (Tab B); and  
(2) the availability of summaries of safety and  
effectiveness data for the devices (Tab C).

RECOMMENDATION. I recommend that the notice be signed and  
published.

  
Susan Alpert, Ph.D., M.D.

Attachments  
Tab A - Notice  
Tab B - Order  
Tab C - S & E Summary

DECISION

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date \_\_\_\_\_

Prepared by Erin Keith, CDRH, HFZ-410, June 13, 1997, 594-2036

**DRAFT**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[DOCKET NO. \_\_\_\_\_]

Osteonics Corp.; Premarket Approval Of the Osteonics Constrained Acetabular Insert

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Osteonics Corp., Allendale, NJ, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Osteonics Constrained Acetabular Insert. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 13, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

## FOR FURTHER INFORMATION CONTACT:

Ms. Erin Keith,  
Center for Devices and Radiological Health (HFZ-410),  
Food and Drug Administration,  
9200 Corporate Blvd.,  
Rockville, MD 20850,  
301-594-2036.

SUPPLEMENTARY INFORMATION: On December 16, 1996, Osteonics Corp., Allendale, NJ, 07401-1677, submitted to CDRH an application for premarket approval of the Osteonics Constrained Acetabular Insert. The device is a constrained hip and 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.

On June 10, 1997, the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 13, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

### Opportunity for Administrative Review

Section 515(d)(3) of Federal Food, Drug, and Cosmetic (the act), (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the

heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: \_\_\_\_\_.

\_\_\_\_\_



Mr. Robert A. Koch, J.D.  
Director, Regulatory Affairs  
Osteonics Corporation  
59 Route 17  
Allendale, New Jersey 07401-1677

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 13 1997

Re: P960047  
Osteonics Constrained Acetabular Insert  
Filed: December 16, 1996  
Amended: January 7, March 24 and 26, April 11 and 29, and  
June 10 and 12, 1997

Dear Mr. Koch:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Osteonics Constrained Acetabular Insert. This device is indicated for use as a component of a total hip prosthesis in patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint laxity, or intraoperative instability. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may continue commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act

(the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

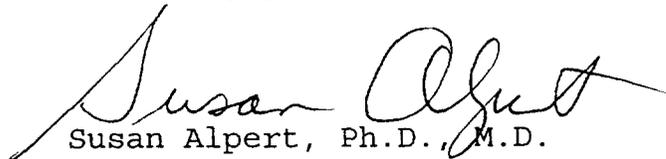
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Erin Keith at (301) 594-2036.

Sincerely yours,



Susan Alpert, Ph.D., M.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**CONDITIONS OF APPROVAL**

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
- (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
  - (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and
  - (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies

of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
  - (a) has not been addressed by the device's labeling or
  - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)  
Center for Devices and Radiological Health  
Food and Drug Administration  
1350 Piccard Drive, 340  
Rockville, Maryland 20850  
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)  
Center for Devices and Radiological Health  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

## SUMMARY OF SAFETY AND EFFECTIVENESS

### I. GENERAL INFORMATION

Device Generic Name: Constrained Acetabular Insert

Device Trade Name: Osteonics Constrained Acetabular Insert

Applicant's Name and Address:

Osteonics Corporation  
59 Route 17  
Allendale, NJ 07401-1677

Premarket Approval (PMA) Number: P960047

Date of Panel Recommendation: June 10, 1997

Date of Good Manufacturing Practice Inspection: April 4, 1997

Date of Notice of Approval to Applicant: June 13, 1997

### II. INDICATION FOR USE

The 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.

### III. DEVICE DESCRIPTION

The Osteonics Constrained Acetabular Insert is a prosthetic hip joint made of titanium (Ti) and ultra high molecular weight polyethylene (UHMWPE). The device utilizes a bipolar head design, which is captured within an outer UHMWPE acetabular insert. A bipolar device generally consists of a femoral head which is captured within a larger, polyethylene-lined head such that there is articulation both at the head-to-bipolar interface and at the bipolar-to-cartilage interface. In the Osteonics Constrained Acetabular Insert device, the traditional bipolar assembly is itself captured by an outer polyethylene liner which, in turn, is assembled to a standard acetabular shell. The articulation occurs at both the head-to-bipolar interface and at the bipolar-to-insert interface.

The spherical head of the femoral stem is restrained within the device by an UHMWPE ring. The bipolar component/acetabular liner assembly is restrained within the acetabular cup by small protrusions (or "barbs") which snap over a cobalt chromium alloy circumferential retaining wire which wraps around the outside of the device. The Osteonics Constrained Acetabular Insert can be used with any appropriately sized Osteonics Femoral head.

The device is preassembled by the manufacturer from the following 6 components:

1. an inner UHMWPE bearing insert which fits over the metal spherical head of the femoral component of a total hip prosthesis. The inner diameter of this insert can be either 22, 26, or 28 mm, corresponding to standard diameters of the spherical head of femoral prostheses;
2. an UHMWPE retaining ring which snap-fits over the femoral head and fits within the mouth of the inner UHMWPE insert. This ring is the component of the device which holds the femoral head within the device;
3. a cobalt chromium alloy shell which fits over the inner UHMWPE insert;
4. an outer UHMWPE insert, which fits over the cobalt chromium alloy shell. This outer insert consists of a hemisphere which is built up by an additional overhang of 10° on one side. This overhang can be positioned in any direction around the acetabular cup. Outer diameters for this outer shell of 52 to 61 mm are available. Rotation of the device also takes place between the cobalt chromium alloy shell and the outer UHMWPE insert;
5. a Ti alloy retaining ring which reinforces the mouth of the outer UHMWPE insert. This ring reinforces the capture of the mouth of the outer UHMWPE insert over the inner shell (items 1-3 above); and
6. a cobalt chromium alloy circumferential locking wire which fits flush around the outer surface of the outer UHMWPE insert. Perpendicular to this locking wire are 8 grooves, equally spaced around the hemisphere, 6 mm in length and 2 mm deep. These grooves provide space for short metal projections in the acetabular socket, called "barbs", to snap over this ring and thereby retain the device in the acetabular shell.

#### IV. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE EFFECTS, INSTRUCTIONS FOR IMPLANTATION AND UTILIZATION, AND PATIENT COUNSELING INFORMATION

1. CONTRAINDICATIONS:

- a. Bone or musculature compromised by disease, infection or prior implantation which cannot provide adequate support or fixation for the prosthesis.
- b. Any active or suspected infection in or about the hip joint.
- c. Skeletal immaturity.

## 2. WARNINGS

- a. 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.
- b. 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.
- c. 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.
- d. 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.
- e. 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.
- f. 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.

- g. 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 Osteonics component selection.
- h. See the Patient Counseling Information Section for more information.

3. PRECAUTIONS:

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

4. GENERAL ADVERSE EFFECTS REPORTED FOR ANY TOTAL HIP REPLACEMENT SURGERY :

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.

- a. death
- b. pulmonary embolism
- c. myocardial infarction
- d. infection
- e. nerve impingement or damage
- f. vascular disorders (including thrombus)
- g. heterotopic bone formation

- h. material sensitivity reactions
- i. gastrointestinal complications
- j. genitourinary complications
- k. loosening of total hip components
- l. localized progressive bone resorption (osteolysis)
- m. pain
- n. dislocation of the hip prosthesis

5. INSTRUCTION FOR UTILIZATION AND IMPLANTATION

- a. Before clinical use the surgeon should thoroughly understand all aspects of surgical procedure and limitations of the device.
- b. In situations where an uncemented acetabular shell is implanted coincident with the constrained acetabular insert, supplemental screw fixation should be utilized with the shell.
- c. 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.
- d. A trial reduction can be performed with the constrained insert in place. Please consult the compatibility chart for proper dislocation key sizing.
- e. Bearing areas must always be clean and free of debris prior to assembly.
- f. A complete intraoperative range of motion must be obtained with no visual or tactile obstructions.

- g. The Osteonics Surgical Protocol for the constrained insert provides additional procedural information.

## 6. 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:

- a. 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 Osteonics Constrained Acetabular Insert ranges between 72° and 82°, depending on the femoral head size.
- b. 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.
- c. 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 physicochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- d. Adverse effects may necessitate reoperation, revision, fusion of the involved joint, Girdlestone and/or amputation of the limb.
- e. Patients should be instructed that significant reduction in the range of motion is inherent to the design characteristics of a constrained acetabular insert. The maximum range of motion for the Osteonics Constrained Acetabular Insert ranges between 72° and 82°, depending on the femoral head size.

## V. SPECIFIC ADVERSE EVENTS FOR OSTEONICS CONSTRAINED ACETABULAR INSERT

The following are the more frequently recorded adverse events (two or more events) for two uncontrolled retrospective case series using the Osteonics Constrained Acetabular Insert.

Recorded Adverse Events		
Event	Number of Events	Percent (n=123)
Reoperation for Dislocation	4	3.3
Reoperation for Infection	7	5.7
Reoperation for Miscellaneous Femoral	4	3.3
Reoperation for Acetabular Loosening	3	2.4
Trochanteric Non-union	16	13.0
Deep Vein Thrombosis	2	1.6

VI. ALTERNATE PRACTICES AND PROCEDURES

Depending on individual circumstances, alternate procedures might include use of an semi-constrained hip prosthesis, hip joint fusion, external bracing or other commercially available constrained acetabular insert.

VII. MARKETING HISTORY

The applicatioin was submitted in response to the final rule published in the Federal Register of September 27, 1996 (61 FR 50704), requiring the submission of PMA applications for hip joint metal/polymer constrained cemented or uncemented prostheses. The Osteonics Constrained Acetabular Bearing Insert has been marketed in the USA since April 1989, through the premarket notification (510(k)) process.

As of 13 November 1996 a total of 1293 devices had been sold worldwide, of which 1224 had been sold in the United States. Internationally, 69 units have been sold; 60 in Japan, 4 in Canada, 4 in the Netherlands, and one in France. To date, this product has not been withdrawn from any market for any reason related to the safety and effectiveness of the device.

## VIII. SUMMARY OF PRECLINICAL STUDIES

The primary objective of the preclinical studies was to define the mechanical characteristics of the device. Testing was conducted to determine the fatigue strength, cam-out force and tensile distractive force of the device.

### 1. Component Testing

#### a. Insert with Ti retention Ring Fatigue Strength

Fatigue testing of the insert with Ti retention ring was performed. The endurance limit was determined to be 1500 lbs. This result indicates the device should survive physiologic loading.

#### b. Cam-Out Resistance

Femoral head and constrained acetabular cup combinations were tested to determine the cam-out (level-out) moment necessary to separate the two total hip replacement components. The moment necessary for separation of the components was dependent on the femoral head size and ranged from 270 to 410 in-lbs. These results indicate the device should survive physiologic loading.

#### c. Insert/Outer Head Distraction Force

This test was designed to measure the locking capacity of the 9 barb extensions incorporated within the inner diameter of the Outer Head to secure the Insert. The force necessary to separate the Inner and Outer heads was reported to be 331.5 in-lbs. This result is comparable to other commercially available devices and is expected to survive physiological loading.

- d. Assembly and Disassembly Loads for the Osteonics Constrained Acetabular insert and locking groove  
The objective of this study was to determine the loads necessary to assemble and disassemble a 26 mm femoral head into a constrained acetabular insert (40 -61 mm). Assembly loads were determined to range from 55 to 82 lbs. Disassemble loads ranged from 375 to 700 lbs. It is possible to assemble the device with one mallet strike.

2. Characterization of UHMWPE

The UHMWPE used in the construction of this device was characterized by its ultimate tensile strength, tensile yield strength, tensile modulus, percent elongation, density, percent crystallinity, melting temperature and molecular weight. These data were comparable to data provided for other UHMWPE components of commercially available total semi-constrained hip replacement devices. The UHMWPE conforms to the voluntary consensus standard ASTM (American Society for Testing and Materials) F 648-96.

3. Shelf Life Studies:

The results of real time testing indicate the packaging is capable of maintaining sterility of the device for 5 to 7 years.

## IX. SUMMARY OF CLINICAL INVESTIGATIONS

Two separate retrospective reviews of case series performed using the Osteonics Constrained Acetabular Insert were the basis for marketing approval in the USA for the Osteonics 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, adverse events 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.

<b>Demographics of the Series One</b>			
<b>Category</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Number of Cases	65 (64.4%)	36 (35.6%)	101 (100%)
Mean Patient Age	70.9 years	70.3 years	N/A
Patient Age Range	31-92 years	34-87 years	31-92 years
Mean Patient Weight	149.6 lbs	185.3 lbs	N/A
Patient Weight Range	100-200 lbs	120-278 lbs	100-278 lbs
Number of Bilateral Patients	3	0	3
Number of Unilateral Patients	59	36	95
Number of Left Hip Implants	33	14	47
Number of Right Hip Implants	32	22	54

Postoperative Pain Rating for All Evaluated Cases (mean evaluation at 54 months) for Series One		
Rating	Frequency at Latest Evaluation	Percent n=96
None	68	70.8
Mild	16	16.7
Moderate	8	8.3
Severe	4	4.2
<b>Subtotal</b>	<b>96</b>	<b>100.0</b>
Unspecified	5	--
<b>Total</b>	<b>101</b>	<b>--</b>

Postoperative Limp Rating for All Cases Evaluated (mean follow-up time of 54 months) for Series One		
Rating	Frequency at Latest Evaluation	Percent n=97
None	35	36.1
Mild	35	36.1
Moderate	16	16.5
Severe	6	6.2
Unable to Walk	5	5.2
<b>Subtotal</b>	<b>97</b>	<b>100.00</b>
Unspecified	4	--
<b>Total</b>	<b>101</b>	<b>--</b>

Postoperative Use of Support Rating for All Cases Evaluated (54 month mean follow-up time) for Series One		
Rating	Frequency at Latest Evaluation	Percent n=97
None	23	23.7
Cane	29	29.9
Walker/Crutches	35	36.1
Unable to Walk	10	10.3
<b>Subtotal</b>	<b>97</b>	<b>100.0</b>
Unspecified	4	--
<b>Total</b>	<b>101</b>	<b>--</b>

Reported Adverse Events for Series One		
Event	Number of Events	Percent (n=101)
Reoperation for Dislocation	4	4.0
Reoperation for Infection	7	6.9
Reoperation for Femoral Miscellaneous <sup>a</sup>	3	3.0
Reoperation for Other Reasons	2	2.0
Trochanteric Non-union	16	15.8
Deep Vein Thrombosis	2	2.0
Miscellaneous <sup>b</sup>	11	10.9

- a One case each of loose femoral stem, removal of a wire, fracture below femoral prosthesis
- b One case each of sciatic palsy, decubitus ulcer, severe heterotopic bone formation, sponge in canal, intraoperative fracture, acute abdominal problems, anterior acetabular fracture, medial wall fracture, saphenous nerve palsy, trochanteric bursitis, and cardiac complications.

Patient Demographics for Series Two			
Category	Female	Male	Total
Number of Cases	16 (76.2%)	5 (23.8%)	21
Mean Patient Age	N/A	N/A	69 years
Patient Age Range	N/A	N/A	42-93

Patient Demographics for Series Two			
			years
Mean Patient Weight	N/A	N/A	154.7 lbs
Patient Weight Range	N/A	N/A	115-198.9 lbs
Number of Bilateral Cases	N/A	N/A	2
Number of Unilateral Cases	N/A	N/A	19

Clinical Rating For Series Two				
Rating Scale	Preop Mean	Preop Range	Latest Evaluation Mean	Latest Evaluation Range
HHS <sup>a</sup>	16.3	6-32	32.2	12-40
Harris <sup>b</sup>	45.5	18-69	82.0	20-99

- a. Scale is 0-40 with 40 indicating absence of pain and optimum function  
b. Scale is 0-100 with 100 indicating absence of pain and optimum functional ability

Adverse Events for Series Two	
Adverse Event	Number of Events n=21
Acetabular Allograft Failure	1
Osteolysis of Femoral Allograft	1
<b>Total</b>	<b>2</b>

X. PANEL RECOMMENDATION

At a June 10, 1997 meeting of the Orthopedic Devices Advisory Committee (Panel), the Panel recommended the Osteonics Corporation's PMA for the Osteonics Constrained Acetabular Insert was approvable subject to labeling modifications and the approval by the Center for Devices and Radiological Health (CDRH). The Panel recommended the following labeling modifications:

- Modification of the Indications for Use statement to include patients with neuromuscular disorders and muscular laxity;
- Inclusion of a warning statement for active patients
- To include the information contained within the package insert in the surgical manual; and
- Provide a statement indicating in the case of the primary surgery patient, when the device is used in conjunction with an uncemented acetabular shell, the shell should utilize supplemental screw fixation.

## XI. CDRH DECISION

Reports of significant human experience with the marketed device is sufficient under 21 CFR 860.7 for the purposes of determining safety and effectiveness. Therefore, it is reasonable to conclude that the benefits of the use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use. CDRH concurred with the Panel recommendation. The applicant amended the PMA to address the labeling issues raised by the Panel.

FDA inspections completed April 4, 1997 determined the manufacturing facilities to be in compliance with Good Manufacturing Practices (GMP) regulations.

CDRH issued an approval order on June 13, 1997.

## XII. APPROVAL SPECIFICATIONS

- Direction for use: See the labeling
- Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling

## XIII. REFERENCES

1. Lombardi AV, Mallory TH, Kraus TJ, Vaughn BK. Preliminary report on the S-ROM constraining acetabular insert: a retrospective clinical experience. Orthopedics 1991;14:297-303.
2. Fisher DA, Kiley K. Constrained acetabular cup disassembly. J Arthroplasty 1994;9:325-9.
3. Anderson MI, Murray WR, Skinner HB. Constrained acetabular components. I  
• Modification of the indications for Use statement to include patients with neuromuscular disorders and muscular laxity;  
• Inclusion of a warning statement for active patients  
  
• To include the information contained within the package insert in the surgical manual; and  
• Provide a statement indicating in the case of the primary surgery patient, when the device is used in conjunction with an uncemented acetabular shell, the shell should utilize supplemental screw fixation.

# OSTEONICS

## Constrained Acetabular Insert

STERILE

## Constrained Acetabular Insert

### Description

Osteonics Constrained Acetabular Insert is comprised of two pre-assembled components: an outer insert component and a captured UHR<sup>®</sup> (Universal Head) component. The UHR component is comprised of an outer shell into which a bearing insert has been permanently assembled. The UHR bearing insert has a factory assembled UHMWPE retention ring. The outer acetabular insert has a Ti alloy retaining ring which retains the UHR Head in the plastic portion of the insert 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 52 mm or larger outer diameter Osteonics<sup>®</sup> standard profile metal acetabular shell. The assembled acetabular component is used in conjunction with any appropriately sized Osteonics stem of compatible head size, to achieve total reconstructive replacement of the hip joint. The Osteonics<sup>®</sup> Constrained Acetabular Insert is available in three inner diameter sizes and five 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 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 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 Studies

Event	Number of Events in Series One n=101	Number of Events in Series Two 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	3 (3.0%) <sup>a</sup>	1 (4.8%) <sup>b</sup>
Miscellaneous		
Reoperation for Other Reasons	2(2.0%)	
Deep Vein Thrombosis	2 (2.0%)	
Acetabular Allograft Failure		1 (4.8%)
Miscellaneous	11 <sup>c</sup>	

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 Osteonics Constrained Acetabular Insert were the basis for marketing approval in the USA for the Osteonics 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

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

Table C Series One: Postoperative Pain Rating for All Evaluated Cases

Rating	Frequency at Latest Evaluation	Percent n=96
None	68	70.8
Mild	16	16.7
Moderate	8	8.3
Severe	4	4.2
Subtotal	96	100.0
Unspecified	5	--
Total	101	--

Table D Series One: Postoperative Limp Rating for All Evaluated Cases

Rating	Frequency at Latest Evaluation	Percent n=97
None	35	36.1
Mild	35	36.1
Moderate	16	16.5
Severe	6	6.2
Unable to Walk	5	5.2
Subtotal	97	100.00
Unspecified	4	--
Total	101	--

Table E Series One: Postoperative Support Rating for All Evaluated Cases

Rating	Frequency at Latest Evaluation	Percent n=97
None	23	23.7
Cane	29	29.9
Walker/Crutches	35	36.1
Unable to Walk	10	10.3
Subtotal	97	100.0
Unspecified	4	--
Total	101	--

Table F Series Two: Pain Evaluation Results

Rating Scale <sup>a</sup>	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

<sup>a</sup> 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 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 Osteonics Constrained Acetabular Insert ranges between 72° and 82°, 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 physicochemical 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.
- Patients should be instructed that significant reduction in the range of motion is inherent to the design characteristics of a constrained acetabular insert. The maximum range of motion for the Osteonics Constrained Acetabular Insert ranges between 72° and 82°, depending on the femoral head size.

## Sterilization

- This acetabular component has been sterilized by gamma radiation.
- 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.**

4313 Rev 3

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# OSTEONICS

THE SCIENCE OF BETTER FIT  
59 ROUTE 17 ALLENDALE, NJ 07401  
A Subsidiary of Stryker Corp.

## Osteonics® Constrained Acetabular Insert Compatibility Chart

Osteonics® Constrained Acetabular Insert	Inner Diameter (I.D.)	Outer Diameter (O.D.)	Series I Osteonics® Acetabular Shell O.D.	Series II Osteonics® Acetabular Shell O.D.	Osteonics® SecurFit™ X'tra Shell O.D.	Trial Head Dislocating Key
2099-2252	22mm	52mm	52mm	N/C	N/C	HI-UHRK-3638*
2099-2254	22mm	54mm	54mm	54 & 56mm	58 & 60mm	HI-UHRK-3638*
2099-2256	22mm	56mm	56mm	N/C	N/C	HI-UHRK-22
2099-2258	22mm	58mm	58mm	58 & 60mm	62 & 64mm	HI-UHRK-22
2099-2261	22mm	61mm	61-72mm	62-72mm	66 & 68mm	HI-UHRK-22
2099-2656	26mm	56mm	56mm	N/C	N/C	HI-UHRK-26
2099-2658	26mm	58mm	58mm	58 & 60mm	62 & 64mm	HI-UHRK-26
2099-2661	26mm	61mm	61-72mm	62-72mm	66 & 68mm	HI-UHRK-26
2099-2858	28mm	58mm	58mm	58 & 60mm	62 & 64mm	HI-UHRK-28
2099-2861	28mm	61mm	61-72mm	62-72mm	66 & 68mm	HI-UHRK-28

N/C = Not Compatible

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

## **Surgical Protocol**

### **Osteonics® Constrained Acetabular Insert**

The 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.

*Primary Surgery:* When used in a primary surgery, the Osteonics femoral component is implanted in accordance with its applicable Osteonics Surgical Protocol. The Osteonics modular metal shell is also implanted in accordance with its applicable Osteonics Surgical Protocol. However, when utilizing an uncemented Osteonics metal shell with the constrained acetabular insert, supplemental fixation with bone screws is recommended.

*Revision Surgery:* When the Osteonics Constrained Acetabular Insert is to be used in a revision surgery, the existing Osteonics insert is removed in accordance with its applicable 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 should be assessed for any damage as well. (If the shell requires replacement, whether the shell is unstable, the barbs are damaged, or otherwise, the metal shell should be replaced with another Osteonics shell in accordance with the applicable Osteonics Surgical Protocol. If the metal shell is being replaced with an uncemented Osteonics metal shell, supplemental fixation with bone screws is recommended.)

Once the integrity of the existing metal shell is established, remove any membrane 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. Address lysis if necessary.

**Consult the Compatibility Chart for appropriate selection of an Osteonics metal shell and femoral head size.**

*Instructions for Seating the Osteonics Constrained Insert into an Osteonics Modular Acetabular Shell:*

The method for the assembly of an Osteonics Constrained Acetabular Insert to the associated Osteonics metal shell parallels that of Osteonics standard acetabular inserts. However, rather than utilizing the Osteonics Acetabular Cup Insert Impactor, an Osteonics Threaded Trial Head is utilized with an Osteonics Threaded Impactor/Extractor Handle to assemble the constrained insert into the shell.

First, a Threaded Trial Head with the same outer diameter as the inner diameter of the selected constrained insert is threaded onto the Threaded Impactor/Extractor Handle. The trial head of the assembled instrument is inserted into the bipolar component of the constrained insert. Next, the

insert is positioned in the metal shell. The extended 10° face of the insert is indexed to the desired coverage location and the scribe mark is aligned with the markings on the face of the shell. This allows alignment of the insert recesses to the shell's barbs. The insert is then lightly tapped into place with a mallet. Care must be taken not to rock the insert into place which might result in damage to the locking wire. If the locking wire is damaged, the constrained insert must be discarded.

The trial head of the impactor/extractor is disassembled from the acetabular construct through the use of an Osteonics UHR Head Removal Key of equivalent diameter. The removal key is inserted into the inner bearing area between the bipolar component and the trial head of the impactor/extractor and squeezed. With a gentle pulling action, the impactor/extractor is removed from the constrained insert. **Consult the compatibility chart for appropriate section of an Osteonics UHR Head Removal Key.**

*Instructions for Seating the Osteonics Femoral Head into the Osteonics Constrained Acetabular Insert:*

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. Care must be taken to ensure that the bipolar component's opening is fully visible before introducing the bearing head into the bipolar component of the constrained insert.

The stem is then reduced in the standard fashion by elevating the patient's leg and applying a slight downward force until the head snaps into the bipolar component. This component has a positive locking mechanism which enables the bipolar and the 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 with the bipolar. Upon clearing the maximum diameter of the head, the ring contracts to its normal diameter, resulting in the head being captured 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 an Osteonics UHR Head Removal Key.

## Osteonics® Constrained Acetabular Insert Compatibility Chart

Osteonics® Constrained Acetabular Insert	Inner Diameter (I.D.)	Outer Diameter (O.D.)	Series I Osteonics® Acetabular Shell O.D.	Series II Osteonics® Acetabular Shell O.D.	Osteonics® SecurFit™ Xtra Shell O.D.	Trial Head Dislocating Key
2099-2252	22mm	52mm	52mm	N/C	N/C	HI-UHRK-3638*
2099-2254	22mm	54mm	54mm	54 & 56mm	58 & 60mm	HI-UHRK-3638*
2099-2256	22mm	56mm	56mm	N/C	N/C	HI-UHRK-22
2099-2258	22mm	58mm	58mm	58 & 60mm	62 & 64mm	HI-UHRK-22
2099-2261	22mm	61mm	61-72mm	62-72mm	66 & 68mm	HI-UHRK-22
2099-2656	26mm	56mm	56mm	N/C	N/C	HI-UHRK-26
2099-2658	26mm	58mm	58mm	58 & 60mm	62 & 64mm	HI-UHRK-26
2099-2661	26mm	61mm	61-72mm	62-72mm	66 & 68mm	HI-UHRK-26
2099-2858	28mm	58mm	58mm	58 & 60mm	62 & 64mm	HI-UHRK-28
2099-2861	28mm	61mm	61-72mm	62-72mm	66 & 68mm	HI-UHRK-28

N/C - Not Compatible

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

# OSTEONICS

THE SCIENCE OF BETTER FIT  
FACILITY: ALLENDALE, NJ 07401, U.S.A.



**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a licenced Physician.

**Warning:** Read package insert before use 

**STERILE** 

BLL4201

ID#: 531984E

CAT.: 2099-2254

DB FMT.: 2099-A

LB FMT.: 2099-A

CASE: SAMPLE

W/O: 123456

REL: 123

QIN4313 (CE MARK)

13:26:24

11-14-1996

OSTEONICS Quantity 1 Catalog No. 2099-2254

Constrained Acetabular Insert 54mm O.D.

- Includes Pre-assembled UH1-36-22 Universal Head
- Consult Compatibility Chart



22mm I.D.



ID#: 5 3 1 9 8 4 E

OSTEONICS

69 Route 17  
Allendale, New Jersey  
07401-1677

A Subsidiary of Stryker Corp.

Tamper Evident Seal

Notice: Do Not Use if Package  
Is Damaged or Opened

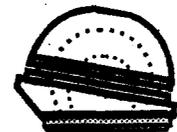
Made in the U.S.A.

OSTEONICS

Quantity 1 Catalog No.  
Quantité 1 REF  
Menge 2099-2254  
Cantidad

- Constrained Acetabular Insert**
- Includes Pre-assembled UH1-36-22 Universal Head
  - Consult Compatibility Chart
- Insert Acetabulaire Contraint**
- Incluse une Tête Universelle UH1-36-22 Pré-assemblée
  - Consulter le Tableau de Compatibilité
- "Constrained" Acetabulum Einsatz**
- Enthält Vorfabrikerten UH1-36-22 Universal Kopf
  - Kompatibilitätstabelle Beachten
- Inserio Acetabolare Vincolato**
- Incluso di Testa Universale UH1-36-22 Pre-assemblata
  - Consultare la Tabella di Compatibilità
- Núcleo Acetabular Construido**
- Incluye Cabeza Universal UH1-36-22 Ensamblada
  - Consultar Plano de Compatibilidades

54mm O.D.



22mm I.D.

Tamper Evident Seal  
Étiquette-Contrôle de Scellage  
Sicherheitsverpackung  
Stigillo Anti-Manomissione  
Precinto Protector

Notice: Do not use if package  
is damaged or opened  
Attention: Ne pas utiliser si l'emballage  
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Hinweis: Bei beschädigter oder  
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Made in the U.S.A.

# OSTEONICS

CAT. NO.: 2099-2254

Constrained Acetabular Insert

CASE CODE: **SAMPLE**

ID#: 531984E



ID#: 5 3 1 9 8 4 E



CAT. NO.: 2 0 9 9 - 2 2 5 4



CASE CODE: S A M P L E

REORDER / RECORD  
OSTEONICS 2099-2254  
Constrained Acetabular Insert  
CASE CODE: **SAMPLE**



ID#: 5 3 1 9 8 4 E

REORDER / RECORD  
OSTEONICS 2099-2254  
Constrained Acetabular Insert  
CASE CODE: **SAMPLE**



ID#: 5 3 1 9 8 4 E

REORDER / RECORD  
OSTEONICS 2099-2254  
Constrained Acetabular Insert  
CASE CODE: **SAMPLE**



ID#: 5 3 1 9 8 4 E

REORDER / RECORD  
OSTEONICS 2099-2254  
Constrained Acetabular Insert  
CASE CODE: **SAMPLE**



ID#: 5 3 1 9 8 4 E

REORDER / RECORD  
OSTEONICS 2099-2254  
Constrained Acetabular Insert  
CASE CODE: **SAMPLE**



ID#: 5 3 1 9 8 4 E

Catalog No. REF 2099-2254

Storage Conditions  
Conditions de stockage  
Lagerungsbedingungen  
Istruzioni per l'immagazzinamento  
Condiciones de almacenamiento

-20°C  
-49°C

Material  
Materiale  
Material  
Material  
Material  
CoCr  
UMWPE  
Ti6Al4V

I.D.# SN 531984E

Expiration Date  
2001-11

Sterilization Date  
1996-11

Case Code  
LOT **SAMPLE**

OSTEONICS  
CE0473

