



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

P960054

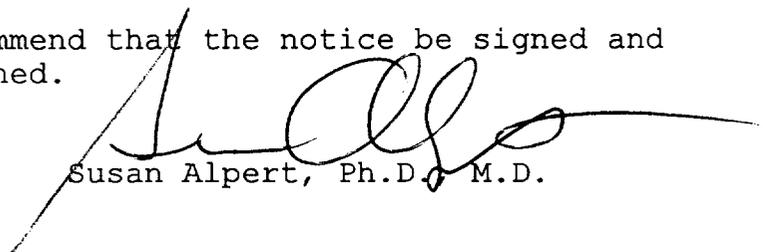
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Date: June 19, 1997
From: Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)
Subject: Premarket Approval of Johnson and Johnson
Professional's S-ROM Poly-Dial Constrained Liner
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 Hany Demian, CDRH, HFZ-410, June 12, 1997, 594-2036

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[DOCKET NO. _____]

Johnson and Johnson Professional, Inc.; Premarket Approval of the S-ROM Poly-Dial
Constrained Liner

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Johnson and Johnson, Raynham, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the S-ROM Poly-Dial Constrained Liner. 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 20, 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:

Mr. Hany Demian,
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 26, 1996, Johnson and Johnson Professional, Raynham, MA, 02767-0350, submitted to CDRH an application for premarket approval of Johnson and Johnson Professional's S-ROM Poly-Dial Constrained Liner. The device is a constrained acetabular liner and is indicated for use as a component of a total 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 20, 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 the Federal Food, Drug, and Cosmetic Act (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: _____.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 1997

Mr. John Ferros
Senior Regulatory Affairs Specialist
Johnson and Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: P960054
Johnson and Johnson's S-ROM Poly-Dial Constrained Liner
Filed: December 26, 1996
Amended: March 17 and 25, April 4, 8 and 21, May 22 and 27,
June 2, 3, 9, 17 and 20, 1997

Dear Mr. Ferros:

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 Johnson and Johnson's S-ROM Poly-Dial Constrained Acetabular Liner. This device is indicated for use as a component of a total hip prosthesis in primary or 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. 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

Page 2 - Mr. Ferros

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.

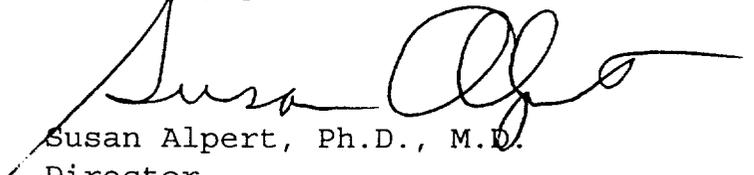
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

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 Mr. Hany Demian 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 Effectuated" 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 Liner
Device Trade Name: S-ROM® Poly-Dial Constrained Liner
Applicant's Name: Johnson and Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Premarket Approval (PMA) Application No: P960054

Date of Panel Recommendation: June 10, 1997

Date of Good Manufacturing Practice Inspection: May 5-7, 1997

Date of Notice of Approval to Applicant: June 19, 1997

II. DEVICE DESCRIPTION

The S-ROM® Poly-Dial Constrained Acetabular Liner (or insert) is a device with several components. The components includes the S-ROM® Poly-Dial constrained acetabular liner, reinforcing ring, and peripheral bone screws. The hollow spherical constrained acetabular liner (UHMWPE) fits into the metal acetabular shell and articulates with the spherical metal femoral heads of the S-ROM® total hip replacement system (26*mm, 28mm, 29*mm and 32mm: * special request). The S-ROM® Poly-Dial Liner can be used with J&J Professional's ZTT™I, ZTT™II, SuperCup™, and Arthopor series metal acetabular shells and a locked in place with peripheral bone screws. The peripheral bone screws are available in 3.5 and 5.0 mm diameter and varying lengths (25 to 55mm). The UHMWPE liner has a slight equatorial overlap to allow for mechanical capture of the femoral head.

The reinforcing ring is a made of titanium alloy (Ti 6Al 4V ELI). This metal ring fits into a groove on the outer surface of the liner. This ring reinforces the capture of the femoral head within the liner.

The S-ROM® Poly-Dial Constrained Acetabular liner is available with either a neutral 0° or an offset, 10° face angle. In the latter liner, the rim of the liner sits at a 10° angle to the rim of the metal acetabular shell. The orientation of this 10° angle can be rotated, a full 360° around the rim of the metal acetabular shell.

Materials:

- ASTM F-648 Ultra high molecular weight polyethylene (UHMWPE)
- ASTM F-136 Titanium 6Al-4V ELI alloy

The S-ROM® constrained liners are available in medium (M) series, large (L) series, and extra large (XL) series configurations.

III. INDICATION FOR USE

The S-ROM® Poly-Dial Constrained Liner is indicated for use as a component of a total hip prosthesis in primary or 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.

IV. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE EFFECTS, AND INSTRUCTIONS FOR UTILIZATION AND IMPLANTATION

1. CONTRAINDICATIONS:

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

2. WARNINGS:

- a. Closed reduction of this device is not possible. Patients should be made aware that treatment of device dislocation will require additional surgery.
- b. Use of other manufacturers' components with this implant may lead to premature wear or failure of the device. Please consult the compatibility chart for proper J&J Professional component selection.
- c. The metal shell and S-ROM® constrained acetabular liner require anatomical cup alignment to prevent impingement of the liner and the femoral neck. Careful trial positioning testing and range of motion testing should be performed during surgery to prevent impingement of the constrained liner with the femoral component which may lead to dislocation of the femoral ball from the polyethylene liner.
- d. Only one attempt to assemble the reinforcing ring on the constrained acetabular liner should be made. If the device is not assembled correctly the first time, then remove and replace with a new liner and reinforcing ring.

- e. **Do not install** the S-ROM[®] constrained acetabular liner without the installation of the reinforcing ring in place because it constrains the polyethylene of the liner aiding in femoral ball capture.
- f. **Do not use** locking pins because they may prevent correct assembly of reinforcing ring. Use only the S-ROM[®] Peripheral Bone Screws (a minimum of 2) to lock the position of the constrained acetabular liner.
- g. **Do not place** a peripheral bone screw at the low point of 10° face angle because it may prevent proper seating of reinforcing ring.
- h. **Do not use** steam autoclaving for reesterilization of the UHMWPE liner, as it may result in serious deformation and material deterioration.
- i. Bending, contouring, or modifying this device may adversely affect the implant potentially leading to early implant failure.
- j. 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.

3. PRECAUTIONS:

- a. Careful selection of the screws and femoral heads is needed to correctly seat the liner and prevent impingement. See surgical technique.
- b. The implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.
- c. Inspect implants for nicks, scratches, or other defects that may cause failure of the implant.
- d. To prevent contamination of this prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surfaces before the final decision to implant has been made.
- e. An implant should never be reused. Any implant once assembled and disassembled should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.
- f. The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

4. GENERAL ADVERSE EFFECTS REPORTED FOR 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. Store Poly-Dial Constrained Acetabular Liner in a cool temperature environment (20°F-70°F) prior to surgery.
- b. Before clinical use of this device the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. The surgeon should refer to the surgical manual for details on the use of the instrument system and implantation of the prosthesis.
- c. Install a minimum of two Peripheral Screws anteriorly, posteriorly, or superiorly placed at 60° increments around the rim of the metal acetabular shell. Two additional peripheral screws are recommended for further fixation. Use of a peripheral screw at the low point of the 10° face angle may prevent proper seating of the reinforcing ring.
- d. A trial component 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.

- e. Be certain that the series letter of the shell matches the series letter of the liner (e.g., M series shells are only for use with M series liners).

6. PATIENT COUNSELING INFORMATION:

- a. In addition to the patient related information contained in the Warnings and Adverse Effects sections, the following information should be conveyed to the patient:
- b. The prosthesis will not restore function to the level of normal healthy bone, and the patient should be instructed as to the limitations of the device.
- c. Wear of components can occur and potentially lead to future complications, including bone resorption and loosening, necessitating the removal and replacement of the prosthetic component.
- d. While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign material which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and load of normal healthy bone.
- e. Adverse effects may necessitate reoperation, revision, or fusion of the involved joint, Girdlestone and/or amputation of the limb.
- f. The patient should be instructed that significant reduction in range of motion is inherent to the design characteristics of a constrained acetabular liner.

V. SPECIFIC ADVERSE EVENTS FOR S-ROM® POLY-DIAL CONSTRAINED LINER

Two published case series describe the use of the S-ROM® Poly-Dial Constrained Acetabular Liner (Series 1: Lombardi AV, Mallory TH, Kraus TJ, and Vaugh BK, Preliminary report on the S-ROM constraining acetabular insert: a retrospective clinical experience, Orthopedics 1991; 14:297-303; and Series 2: Anderson MJ, Murry WR, Skinner HB, Constrained acetabular components, J Arthroplasty 1994; 9:17-23).

The adverse events reported in two published case series are listed below. The adverse events include bone screw breakage, dislocation due to component malfunctioning and neurologic/other problems, deep sepsis, and peroneal nerve palsies.

Table 1: Reported Adverse Events for Two Case Series Studies

Event	Number of Events in Series 1 n=55	Number of Events in Series 2 n=21
Dislocation	n=8 in 5 patients (14.5%)	n=6 (28.5%)
Deep Sepsis	0	n=1 (4.7%)
Peroneal nerve palsies	0	n=2 (9.5%)

Series 1 - data presented in Lombardi et al., 1991; Series 2- data presented in Anderson et al., 1994

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Depending on individual circumstances, alternate procedures might include use of a semi-constrained hip prosthesis, hip joint fusion, or external bracing.

VII. MARKETING HISTORY

The application was submitted in response to the final rule published in the Federal Register of September 27, 1996 (61 FR50704), requiring the submission of PMA applications for hip joint metal/polymer constrained cemented or uncemented prostheses. The device was cleared by FDA for commercial distribution on 20, April 1987. All sales of the S-ROM® Poly-Dial Constrained liner are in the United States. There are no foreign sales. From September 1991 through March 1997, 5468 units were sold per year.

To date, the device has not been withdrawn from any market for any reason related to its safety and effectiveness.

VIII. SUMMARY OF PRECLINICAL STUDIES

1. CONSTRAINED SOCKET PULL-OUT TESTING:

Pull-out testing was performed to determine the forces required to separate the femoral head from the constrained socket using a straight pull mode. No leveraging of the stem against the socket lip was used.

Preliminary testing was performed to determine the correct loading range. It was decided to use a test set-up with a load range of 300 to 1000 pounds because the estimated that the pull required to separate the head from the constrained socket was 600 pounds. This testing showed that since the socket separated from the cup, i.e. failure mode, at 304 pounds a lower range would be more appropriate. The lower range chosen was 100 - 500 pounds.

The results show an average pull out load of 273.6 lbs. The failure mode was the femoral head separating from the acetabular shell. This suggests that the S-ROM® constrained liner can be indicated for use as a component of a total hip prosthesis (primary or revision) in patients at high risk of hip dislocation.

2. SHELL/LINER INCONGRUITY ANALYSIS:

Several mechanisms can cause for the generation of debris. Debris can cause damage to occur on the articulating surfaces of the polyethylene components which can lead to long-term implant instability.

The significance of the polyethylene/metal conformity rests in the understanding that high contact and subsurface stresses in polyethylene contribute to wear and debris formation. In a modular acetabular component, lack of conformity between a polyethylene liner and its acetabular shell limits the surface area available for load transfer and concentrates the surface and subsurface stresses in regions of contact. A high degree of conformity between the liner and shell not only maximizes the area for load transfer, but reduces "gap closure" deformation and its associated stresses under load. This allows for less wear debris generation due to the conformity between the components.

Testing was done to test the Joint Medical Products S-ROM® modular acetabular system for the degree of polyethylene/metal conformity in an assembled, unloaded condition. Three of each type of shell were tested, each having a 52mm outer diameter and with all polyethylene inserts designed for 28mm head diameters. Testing consisted of the same S-ROM® modular acetabular systems, but with a different number of holes and hole placement, a one hole and a four hole configuration. Both were evaluated and the influence of the non-conformities on the generation of wear debris assessed.

Results of the one hole configuration showed the percent of unsupported polyethylene ranges to be from 31.1% to 34.0%, while the four hole configuration showed the percent of unsupported polyethylene ranges to be from 41.3% to 44.1%. The four hole system reduces the polyethylene support by 15.4% and gaps range from 25.9% to 28.7%. Also noted was that of a possible contact area of approximately 23.1cm in the S-ROM®, actual polyethylene/metal contact ranges from 15.2 to 15.9cm in the one hole configuration and from 14.1 to 14.8cm in the four hole design.

The moderate degree of conformity in the S-ROM® modular acetabular systems may reduce the generation of stress associated wear debris.

3. STERILITY:

The S-ROM® Poly-Dial Constrained liner is supplied as a sterile product. The Liner (ask sponsor what about the metal ring) is sterilized by gamma irradiation using a validated irradiation cycle to ensure a sterility assurance level of 10^{-6} .

4. STABILITY TESTING:

Johnson and Johnson has conducted stability testing on the S-ROM® Poly-Dial Constrained Liner to determine seal strength and amount of dye penetration into the inner and outer blister packaging. For the seal strength testing, all aged (61 months) samples exhibited greater than 1 pound per inch seal strength which was considered adequate. For the dye penetration testing, all aged (94 months) samples passed. The results support a shelf-life of 5 years for Johnson & Johnson's S-ROM® Poly-Dial Constrained Liner.

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IX. SUMMARY OF CLINICAL INVESTIGATIONS

Two published case series describe the use of the S-ROM® Poly-Dial Constrained Acetabular Liner (Series 1: Lombardi AV, Mallory TH, Kraus TJ, and Vaugh BK, Preliminary report on the S-ROM constraining acetabular insert: a retrospective clinical experience, Orthopedics 1991; 14:297-303; and Series 2: Anderson MJ, Murry WR, Skinner HB, Constrained acetabular components, J Arthroplasty 1994; 9:17-23).

Series 1 describes the experience with 57 arthroplasties using the S-ROM® constrained Poly-Dial Liner in 55 patients (30 female). The mean age was 69 (range 39-91). There were 6 primary procedures (4 for trauma, and 2 for osteoarthritis complicated by poliomyelitis and myositis ossificans) and 51 revisions of previous surgeries; the mean number of previous revisions in these patients was 2.3 (range 1-6). Thirty-one revisions were for dislocation, 7 for femoral fractures, 6 for aseptic loosening, 4 for flail hip, and 3 for conversion of arthrodesis. Thirteen of the 31 patients had multiple dislocations (mean 2.7, range 2 to 5).

Series 2 describes 22 consecutive patients in to receive the S-ROM® Poly-Dial constrained acetabular liner. One patient who did not meet the inclusion criteria was excluded from further analysis. Eighteen patients received the device because of chronic dislocation of their previous hip prostheses; the final three were treated because joint instability was encountered during a revision procedure. Patients were followed for an average of 31 months (range 24 to 64 months).

Both Case Series Summary Data are presented in the following table:

Table 2 - Summary Data

	Series 1	Series 2
Mean Follow up in months (range)	28 (24-35)	31 (21-64)
Subsequent Dislocation*	8/55 or 14.5%	6/21 or 29%
Final Harris Hip Score (range)	67 (29-94)	76 (32-100)
Acetabulum Radiographically stable	48/50 or 96%	21/21 or 100%

Series 1 - data presented in Lombardi et al., 1991; Series 2- data presented in Anderson et al., 1994

* 3 patients had 2 subsequent dislocations while 2 had one subsequent dislocation

In series 1, the average follow up period was 28 months (range 24 to 35). Five of the 55 patients subsequently dislocated their hip a total of 8 times at a mean of 2.5 months (range 1 to 9). The outcomes were compared the S-ROM® Poly-Dial Constrained Acetabular liner to a non-randomized, concurrent series of 155 patients in their own practice who underwent 176 revision total hip arthroplasties not using the S-ROM® Poly-Dial Constrained Acetabular Liner. The dislocation rate among these comparison group of patients was 19%.

Series 2 outcomes included recurrent hip dislocation and Harris hip score. Six of the patients (29%) dislocated their hips during the evaluation period at a mean of 10 months (range 1 to 30). Two of these 6 went on to have additional dislocations of their prosthetic hips. One dislocation was attributable to trauma; the others occurred during ordinary activities. The average final Harris Hip Score was 76. In addition, patients were evaluated using the Hospital for Special Surgery (HSS) hip rating scale at last evaluation. There were 7 excellent, 2 good, 2 fair, and 10 poor outcomes. Six of the poor outcomes were due to the dislocations; the remaining 4 were due to continuing analgesic use.

X. PANEL RECOMMENDATION

At the June 10, 1997 meeting of the Orthopedic Devices Advisory Committee (Panel), the Panel recommended the Johnson and Johnson Poly-Dial S-ROM® Constrained Liner was approvable subject to labeling modifications and the approval by the Center for Device 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 warning statement for active patients
- To include the information contained within the package insert in the surgical manual; and
- Provide specific directions and limitations regarding the use of the reinforcing ring and bone screws.

XI. CDRH DECISION

Reports of significant human experience with the marketed device is sufficient under 21 CFR 860.7 for the determination of 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 May 5-7, 1997 determined the manufacturing facilities to be in compliance with Good Manufacturing Practices (GMP) regulations.

CDRH issued an approval order on June 19, 1997.

XII. APPROVAL SPECIFICATIONS

Instruction for Utilization and Implantation : See labeling (Attachment 1)

Hazards to Health from the Use of the Device: See indications, contraindications, warnings, precautions, and adverse events in the labeling (Attachment 1).

Post-approval Requirements and Restrictions: See approval order.

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. Anderson MJ, Murray WR, Skinner HB. Constrained acetabular components. *J Arthroplasty* 1994;9:17-23.

JUN 1 9 1998 **DRAFT**

INSTRUCTION MANUAL
Please Read Before Use

S-ROM® Poly-Dial Constrained Acetabular Liner

JJO logo

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

For product information:
1-800-526-2459
To reorder:
1-800-255-2500

Authorized European Representative
JJO logo
Johnson & Johnson Medical Ltd.
London Road, Bracknell, Berkshire RG12 2AT
United Kingdom
(01344) 864050

CE
0086

S-ROM® Poly-Dial Constrained Acetabular Liner

For Single Use Only

STERILE R

Description

The S-ROM® Poly-Dial Constrained Acetabular Liner (or insert) is a device with several components. The components includes the S-ROM® Poly-Dial constrained acetabular liner, reinforcing ring, and peripheral bone screws. The hollow spherical constrained acetabular liner (UHMWPE) fits into the metal acetabular shell and articulates with the spherical metal femoral heads of the S-ROM® total hip replacement system (26*mm, 28mm, 29*mm and 32mm: * special request). The S-ROM® Poly-Dial Liner can be used with J&J Professional's ZTT™I, ZTT™II, SuperCup™, and Arthopor series metal acetabular shells and a locked in place with peripheral bone screws. The peripheral bone screws are available in 3.5 and 5.0 mm diameter and varying lengths (25 to 55mm). The UHMWPE liner has a slight equatorial overlap to allow for mechanical capture of the femoral head.

The reinforcing ring is a made of titanium alloy (Ti 6Al 4V ELI). This metal ring fits into a groove on the outer surface of the liner. This ring reinforces the capture of the femoral head within the liner.

The S-ROM® Poly-Dial Constrained Acetabular liner is available with either a neutral 0° or an offset, 10° face angle. In the latter liner, the rim of the liner sits at a 10° angle to the rim of the metal acetabular shell. The orientation of this 10° angle can be rotated, a full 360° around the rim of the metal acetabular shell.

Materials:

- ASTM F-648 Ultra high molecular weight polyethylene (UHMWPE)
- ASTM F-136 Titanium 6Al-4V ELI alloy

The S-ROM constrained liners are available is medium (M) series, large (L) series, and extra large (XL) series configurations.

Indications

The S-ROM® Poly-Dial Constrained Liner is indicated for use as a component of a total hip prosthesis in primary or 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

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

- Skeletal immaturity.

Warnings (see Patient Counseling Information)

- Closed reduction of this device is not possible. Patients should be made aware that treatment of device dislocation will require additional surgery.
- Use of other manufacturers' components with this implant may lead to premature wear or failure of the device. Please consult the compatibility chart for proper J&J Professional component selection.
- The metal shell and S-ROM constrained acetabular liner require anatomical cup alignment to prevent impingement of the liner and the femoral neck. Careful trial positioning testing and range of motion testing should be performed during surgery to prevent impingement of the constrained liner with the femoral component which may lead to dislocation of the femoral ball from the polyethylene liner.
- Only one attempt to assemble the reinforcing ring on the constrained acetabular liner should be made. If the device is not assembled correctly the first time, then remove and replace with a new liner and reinforcing ring.
- **Do not install** the S-ROM constrained acetabular liner without the installation of the reinforcing ring in place because it constrains the polyethylene of the liner aiding in femoral ball capture.
- **Do not use** locking pins because they may prevent correct assembly of reinforcing ring. Use only the S-ROM Peripheral Bone Screws (a minimum of 2) to lock the position of the constrained acetabular liner.
- **Do not place** a peripheral bone screw at the low point of 10° face angle because it may prevent proper seating of reinforcing ring.
- **Do not use** steam autoclaving for reesterilization of the UHMWPE liner, as it may result in serious deformation and material deterioration.
- Bending, contouring, or modifying this device may adversely affect the implant potentially leading to early implant failure.
- 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.

Precautions

- Careful selection of the screws and femoral heads is needed to correctly seat the liner and prevent impingement. See surgical technique.
- The implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.
- Inspect implants for nicks, scratches, or other defects that may cause failure of the implant.
- To prevent contamination of this prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surfaces before the final decision to implant has been made.
- An implant should never be reused. Any implant once assembled and disassembled should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.
- The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

Adverse Events

Two published case series describe the use of the S-ROM Poly-Dial Constrained Acetabular Liner (Series 1: Lombardi AV, Mallory TH, Kraus TJ, and Vaugh BK, Preliminary report on the S-ROM constraining acetabular insert: a retrospective clinical experience, Orthopedics 1991; 14:297-303; and Series 2: Anderson MJ, Murry WR, Skinner HB, Constrained acetabular components, J Arthroplasty 1994; 9:17-23).

The adverse events reported in two published case series are listed below. The adverse events include bone screw breakage, dislocation due to component malfunctioning and neurologic/other problems, deep sepsis, and peroneal nerve palsies.

Table 1: Reported Adverse Events for Two Case Series Studies

Event	Number of Events in Series 1 n=55	Number of Events in Series 2 n=21
Dislocation	n=8 in 5 patients (14.5%)	n=6 (28.5%)
Deep Sepsis	0	n=1 (4.7%)
Peroneal nerve palsies	0	n=2 (9.5%)

Series 1 - data presented in Lombardi et al., 1991; Series 2- data presented in Anderson et al., 1994

In addition to the adverse events reported in these two case series, the following have been reported 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

Series 1 describes the experience with 57 arthroplasties using the S-ROM constrained Poly-Dial Liner in 55 patients (30 female). The mean age was 69 (range 39-91). There were 6 primary procedures (4 for trauma, and 2 for osteoarthritis complicated by poliomyelitis and myositis ossificans) and 51 revisions of previous surgeries; the mean number of previous revisions in these patients was 2.3 (range 1-6). Thirty-one revisions were for dislocation, 7 for femoral fractures, 6 for aseptic loosening, 4 for flail hip, and 3 for conversion of arthrodesis. Thirteen of the 31 patients had multiple dislocations (mean 2.7, range 2 to 5).

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Instructions for Utilization and Implantation

- Store Poly-Dial Constrained Acetabular Liner in a cool temperature environment (20°F-70°F) prior to surgery.
- Before clinical use of this device the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. The surgeon should refer to the surgical manual for details on the use of the instrument system and implantation of the prosthesis.
- Install a minimum of two Peripheral Screws anteriorly, posteriorly, or superiorly placed at 60° increments around the rim of the metal acetabular shell. Two additional peripheral screws are recommended for further fixation. Use of a peripheral screw at the low point of the 10° face angle may prevent proper seating of the reinforcing ring.

- A trial component 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.
- Be certain that the series letter of the shell matches the series letter of the liner (e.g., M series shells are only for use with M series liners).

Patient Counseling Information (see Warnings and Adverse Events)

The following information should also be conveyed to the patient:

- The prosthesis will not restore function to the level of normal healthy bone, and the patient should be instructed as to the limitations of the device.
- Wear of components can occur and potentially lead to future complications, including bone resorption and loosening, necessitating the removal and replacement of the prosthetic component.
- While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign material which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and load of normal healthy bone.
- Adverse effects may necessitate reoperation, revision, or fusion of the involved joint, Girdlestone and/or amputation of the limb.
- The patient should be instructed that significant reduction in range of motion is inherent to the design characteristics of a constrained acetabular liner.

Sterility and Handling

- The S-ROM acetabular components are supplied presterilized by a minimum of 25 kGy of gamma radiation.
- **Do Not Resterilize**
- J&J Professional guarantees the sterility of presterile components unless the package is damaged or opened.

Handle Carefully-Protect from Damage and Contamination.

Back Cover -- Symbols

For single Use only
 Use by
 Sterilized by gamma irradiation
 Lot Batch Code
 See Instructions for Use in Surgical Technique
 Lift

Date of manufacture

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Johnson & Johnson Professional, Inc., 1996
 LCN 194144-001/A
 Printed in USA 5/96

J&J Professional S-ROM Poly-Dial Constrained Liner Compatibility Chart

S-ROM Metal Acetabular Shells		M-28 Series Cup Diam O.D. (mm)	L-32 Series Cup Diam O.D. (mm)	XL-46 Series Cup Diam O.D. (mm)
ZTTI	Deep Profile 0	48,50,52	52,54,56,58,60,62,64,66	
	Deep Profile +6		54,56,58,60,62,64,66	
ZTTII	Deep Profile 0	48,50,52	52,54,56,58,60,62,64,66	
	Deep Profile +6		54,56,58,60,62,64,66	
ARTHOPOR I	Deep Profile 0	45,48,51	51,54,57,60,63,66,69,72	66,69,72
ARTHOPOR II	Deep Profile 0	48,51	51,54,57,60,63,66	69,72,75
	Deep Profile +6		54,57,60,63,66	
OBLONG CUP ARTHOPOR II E-15	Deep Profile 0	51,54	57,60,63,66	
OBLONG CUP ARTHOPOR II E-25	Deep Profile 0	51, left/right 54, left/right	57, left/right 60, left/right 63, left/right 66, left/right	
SUPERCUP	Deep Profile 0	45,48,51	51,54,57,60,63,66,69,72	66,69,72

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S-ROM Constrained Liner	Metal Head Size	Metal Head Size	Metal Head Size
0° Face Angle	28 mm	28, 32 mm	
10° Face Angle	28, 29 mm	26, 28,29, 32 mm	32 mm

S-ROM Peripheral Bone Screws	Lengths (mm)
3.5 mm diameter	25,30,40,45
5.0 mm diameter	25,30,35, 40, 45, 50, 55

S-ROM Dome Screws	Lengths (mm)
6.5 mm diameter	15, 20, 25, 30, 35, 40, 45, 50, 55

Additional surgical techniques are available from your local J&J Professional sales representative or distributor.