

SECTION VII

MEDICAL DEVICE REPORTS

FOR METAL / POLYMER CONSTRAINED HIP PROSTHESES

Inclusive dates -January 1985 through December 1998

(A reasonable effort was made to find all adverse reports made for these devices under MDR regulations. However, a small number of reports were likely made under improper product codes, and some device descriptions are ambiguous. In addition, the Agency may have access to additional reports made after December 1998. Therefore, a small number of reports involving these devices may exist that were not found by this search)

SUMMARY

The search found a total of 68 Medical Device Reports that contained 91 adverse events from seven different manufacturers. Sixty-three reports (86 events) involved serious injury and five reports (5 events) were malfunction^s

LIST OF CONSTRAINED HIP MDRs

TOTAL = 91 ADVERSE EVENTS IN 68 REPORTS (7 Manufacturers)

<u>MDR Number</u>	<u>Date Reported</u>	<u>Device Identity</u>	<u>No. of Occur.</u>	<u>Event Description</u>	<u>Event Type</u>
163517	04/18/98	Biomet	1	Dislocation	Serious Inj.
146857	01/19/98	Biomet	1	Dislocation	Serious Inj.
148867	01/15/98	Biomet	1	Broken implant	Serious Inj
064523	01/17/97	Biomet	1	Dislocation	Serious Inj.
064520	01/17/97	Biomet	1	Dislocation	Serious Inj.
051098	11/14/96	Biomet	1	Revision	Serious Inj.
036717	08/30/96	Biomet	1	Broken Ring	Serious Inj .
036712	08/30/96	Biomet	(same event as	MDR#03 67 17)	
726395	08/18/95	Biomet	1	Dislocation-chronic	Serious Inj.
726394	08/18/95	Biomet	1	Dislocation-chronic	Serious Inj.
720298	06/27/95	Biomet	1	Disengaged liner	Serious Inj.
704259	03/29/95	Biomet	1	Disengaged liner	Serious Inj.
452691	12/02/93	Biomet	1	Disengaged liner	Serious Inj.
148070	02/05/98	Exactech	1	Dislocation	Serious Inj.
153151	02/23/98	DePuy	1	Size Mislabeled	Malfunction
124156	09/30/97	DePuy	1	Dislocation	Serious Inj.
149096	01/08/98	Zimmer	1	Revision	Serious Inj.
200147	11/30/98	Zimmer	1	Dislocation	Serious Inj.
201149	12/17/98	Osteonics	1	Dislocation	Serious Inj.
137494	12/09/97	Osteonics	1	Disengaged liner	Serious Inj.
097938	06/10/97	Osteonics	1	Disengaged liner	Serious Inj.
097933	06/10/97	Osteonics	1	Cement loosening	Serious Inj.

000038

MDR Number	Date Reported	Device Identity	No. of Occur.	Event Description	Event Type
097925	06/10/97	Osteonics	1	Ring Dislodged	Serious Inj.
097926	06/10/97	Osteonics	1	Disengaged liner	Serious Inj.
270154	03/03/92	Osteonics	1	Disengaged liner	Serious Inj.
363796	02/08/93	Osteonics	1	Disengaged liner	Serious Inj.
407457	08/27/93	Osteonics	1	Disengaged liner	Serious Inj.
196262	11/1/98	J&J	1	Broken Ring	Serious Inj.
196248	11/1/98	J&J	1	Broken Ring	Serious Inj.
177095	07/15/98	J&J	1	Tapers Unlocked	Serious Inj.
172102	06/11/98	J&J	1	Broken Ring	Serious Inj.
173619	06/22/97	J&J	1	Poor Liner Fit	Malfunction
115634	08/27/97	J&J	1	Disengaged liner	Serious Inj.
091504	05/19/97	J&J	1	Poly Worn Through	Serious Inj.
096489	06/09/97	J&J	8*	Dislocation	Serious Inj.
096496	06/09/97	J&J	1	Dislocation	Serious Inj.
096499	06/09/97	J&J	8**	Dislocation	Serious Inj.
096515	06/09/97	J&J	5***	Dislocation	Serious Inj.
137298	12/11/97	J&J	1	Disengaged liner	Serious Inj.
137300	12/11/97	J&J	1	Broken Ring	Serious Inj.
137301	12/11/97	J&J	1	Broken Ring	Serious Inj.
157925	03/20/98	J&J	1	Dislocation	Serious Inj.
223881	03/05/91	Joint Medical	1	Dislocation	Serious Inj.
288805	05/20/92	Joint Medical	1	Dislocation	Serious Inj.
290139	06/05/92	Joint Medical	1	Dislocation	Serious Inj.
297265	06/26/92	Joint Medical	1	Revision	Serious Inj.
395314	06/09/93	Joint Medical	1	Dislocation	Serious Inj.
397715	07/02/93	Joint Medical	1	Dislocation	Serious Inj.
441357	10/22/93	Joint Medical	1	Dislocation	Serious Inj.
474757	01/18/94	Joint Medical	1	Dislocation	Serious Inj.
486168	02/07/94	Joint Medical	1	Dislocation	Serious Inj.
487677	03/04/94	Joint Medical	1	Dislocation	Serious Inj.
488463	03/09/94	Joint Medical	1	Dislocation	Serious Inj.
488464	03/09/94	Joint Medical	6***	Dislocation	Serious Inj.
490208	03/24/94	Joint Medical	1	Broken Insert	Serious Inj.
493454	04/18/94	Joint Medical	1	Dislocation	Serious Inj.
530952	06/20/94	Joint Medical	1	Insert Wouldn't Fit	Malfunction
526762	07/13/94	Joint Medical	1	Broken Ring	Serious Inj.
559822	10/04/94	Joint Medical	1	Dislocation	Serious Inj.
578668	01/03/95	Joint Medical	1	Dislocation	Serious Inj.
589947	01/17/95	Joint Medical	1	Dislocation	Serious Inj.
803483	04/06/95	Joint Medical	1	Device Split	Malfunction
711181	05/17/95	Joint Medical	1	Dislocation	Serious Inj.
842767	10/27/95	Joint Medical	1	Ring Wouldn't Fit	Malfunction
736850	11/16/95	Joint Medical	1	Dislocation	Serious Inj.
741253	12/06/95	Joint Medical			

(5 cases also reported in J&J MDR#096515)

MDR Number	Date Reported	Device Identity	No. of Occur.	Event Description	Event Type
847139	1/08/95	Joint Medical	1	Ring Migrated	Serious Inj.
743066	01/02/96	Joint Medical	1	Dislocation	Serious Inj.
759554	06/12/96	Joint Medical	1	Revision	Serious Inj.
762 176	06/21/96	Joint Medical	1	Revision	Serious Inj.

*Johnson and Johnson Professional, Inc., became aware of a report of 8 cases of hip dislocations requiring open reduction and/or replacement of hip prostheses from a 1991 article in the *Journal of Orthopaedics (Vol. 14, No.3)*. The events occurred over an unknown period of time preceding the publication.

** Johnson and Johnson Professional, Inc. became aware of a report of 8 cases of hip dislocations requiring open reduction and/or replacement of hip prostheses from a 1994 article in the *Journal of Arthroplasty (Vol. 9, No.1)*. The events described occurred over an unknown period of time preceding the publication.

*** Johnson and Johnson Professional, Inc. became aware of a report of 5 cases of hip dislocations requiring open reduction and/or replacement of hip prostheses from a 1994 article in the *Journal of Arthroplasty (Vol. 9, No. 3)*. The events described occurred over an unknown period of time preceding the publication.

**** This report is based upon a literature article; *Journal of Arthroplasty, (Vol.9, No. 1) 17-23, 1994, Constrained Acetabular Components*. The article reports on revision surgery on 21 patients who had either chronic dislocations, or who had intraoperative instability. Of the 21 patients, 6 subsequently had a total of 8 dislocations. A roentgenogram accompanying the article shows that at least one dislocation involves a femoral head, manufactured by another company, that was not a complete sphere. The package insert cautions about use of the device with heads manufactured to different tolerances or that is not a full sphere. It is unknown if any of these cases were previously reported.

SUMMARY OF EVENT TYPE

SERIOUS INJURY

Adverse Event	Number of Reports	Total Adverse Events
Dislocation	33	56
Disengaged liner	11	11
Ring Broken	7	7
Ring Migration	2	2
Revision	5	5
Cement Loosening	1	1
Broken Insert	2	2
Tapers Unlocked	1	1
Liner Wear	1	1
TOTAL	63	86

MALFUNCTIONS

Adverse Event	Number of Reports	Total Adverse Events
Size Mislabeled	1	1
Device Split	1	1
Poor Liner Fit	2	2
Ring Wouldn't Fit	1	1
TOTAL	5	5

GRAND TOTAL

63 MDR Reports Covering 86 Serious Injuries

5 MDR Reports Covering 5 Malfunctions

68 MDR Reports Covering 91 Adverse Events

STRATIFICATION OF DISLOCATIONS IN MDRs

- 25 Dislocations are of unknown cause**
- 12 Dislocations occurred during normal activities (chair, toilet, turning in bed)**
- 10 Dislocations occurred from lever-out (impingement on acetabular rim)**
- 9 Dislocations were due to misalignment (mixing components from different manufacturers, using skirted head/neck, improper placement angles)**

56 Total which were considered dislocations

- 4 Dislocations/disassociation were attributed to falls**
- 1 Dislocation occurred subsequent to tissue loss from a gunshot**
- 10 Dislocations were subsequent to broken components (10 locking rings)**

15 Total were listed separately from dislocations due to broken components, patient falls, or other extenuating circumstances

000041A

MAUDE Search

BRAND NAME	ARCOM CONSTRAINED LINER
TYPE OF DEVICE	PROSTHESIS, HIP, COMP.
MANUFACTURER	BIOMET, INC. PO BOX 587 WARSAW, IN 46581-0587
DEVICE EVENT KEY	u s 159179
MDR REPORT KEY	163517
EVENT KEY	153665
REPORT NUMBER	1825034- 1998-00029
510(K) NUMBER	K926107
PRODUCT CODE	K77B
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	18-APR-1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	17-APR-1998
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	14-105023
DEVICE LOT NUMBER	274280
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	20-MAR-98
CONCOMITANT MEDICAL PRODUCTS	UNK
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	20-MAR-1998
TYPE OF REPORT	INITIAL

REPORT DATE	15-MAR-1998
DEVICE AGE	4
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
MANUFACTURER NAME	BIOMET, INC.
MANUFACTURER CONTACT	DEB VOYNOVICH P.O. BOX 587 WARSAW, IN 46581-0587 (219) 267 -6639
INITIAL REPORT SOURCE	COMPANY REPRESENTATIVE
DATE MANUFACTURER RECEIVED	20-MAR-1998
MANUFACTURER REPORT NO	1825034- 1998-00029
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	01-OCT-1997
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA
BASELINE BRAND NAME	ARCOM CONSTRAINED LINER
BASELINE GENERIC NAME	PROSTHESIS, HIP, COMP.
BASELINE CATALOGUE NUMBER	14-105023
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	ARCOM CONSTRAINED LINER
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	28-JUL- 1993
DATE CEASED MARKETING	0000003157
EVENT DESCRIPTION	TOTAL HLP ARTHROPLASTY WAS PERFORMED ON 1 1/10/97. REVISION SURGERY OCCURRED ON 02/04/98, DUE TO DISLOCATION AND LOOSENING. IT WAS NOTED THAT THE SUBJECT PATIENT HAS PARKINSON'S AND HAD FALLEN PRIOR TO THE DISLOCATION.

ADDITIONAL MANUFACTURER NARRATIVE

THERE ARE WARNINGS I-N THE PACKAGE INSERT THAT STATE THAT THIS TYPE OF EVENT CAN OCCUR. THIS TYPE OF EVENT IS NOT OCCURRING AT A RATE ABOVE EXPECTED FREQUENCY. NO REMEDIAL ACTION WILL BE TAKEN. NO FURTHER COMPLICATIONS HAVE BEEN REPORTED. CURRENT INFO IS INSUFFICIENT TO PERMIT A VALID CONCLUSION AS TO THE CAUSE OF THE EVENT. A FAX WAS SENT TO INFORM THE USER FACILITY OF THE EVENT. NO MEDWATCH REPORT WAS REC'D FROM THE USER FACILITY.

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(Database Updated February 5, 1999)

MAUDE Search

BRAND NAME	ARCOM CONSTRAINED LINER
TYPE OF DEVICE	PROSTHESIS, HIP, COMP.
MANUFACTURER	BIOMET, INC. PO BOX 587 WARSAW, IN 46581-0587 u s
DEVICE EVENT KEY	143127
MDR REPORT KEY	146857
EVENT KEY	137850
REPORT NUMBER	1825034- 1998-00005
510(K) NUMBER	K926107
PRODUCT CODE	K77B
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	19-JAN- 1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	14-105023
DEVICE LOT NUMBER	980290
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	18-DEC-97
CONCOMITANT MEDICAL PRODUCTS	UNK
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	16-JAN-1998
REPORT SENT TO FDA FLAG	NO

MANUFACTURER NAME	BIOMET, INC.
MANUFACTURER CONTACT	DEB VOYNOVICH P.O. BOX 587 WARSAW, IN 46581-0587 (219) 267 -6639
INITIAL REPORT SOURCE	USER FACILITY
DATE MANUFACTURER RECEIVED	18-DEC-1997
MANUFACTURER REPORT NO	1825034-1 998-00005
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE LABELED FOR SINGLE USE?	01-MAR-1997
TYPE OF DEVICE USAGE	INITIAL
BASELINE BRAND NAME	ARCOM CONSTRAINED LINER
BASELINE GENERIC NAME	PROSTHESIS, HIP, COMP.
BASELINE CATALOGUE NUMBER	18-105023
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	ARCOM CONSTRAINED LINER
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	28-JUL-1993
DATE CEASED MARKETING	0000003157

EVENT DESCRIPTION

TOTAL HIP ARTHROPLASTY WAS PERFORMED ON 07/08/97. REVISION OF THE MODULAR HEAD AND ACETABULAR LINER OCCURRED ON 11/29/97, DUE TO DISLOCATION. A MALLOTY/HEAD RINGLOC SHELL AND CONTRAINED ACETABULAR LINER WERE USED WITH A SKIRTED MODULAR HEAD COMPONENT. THIS COMBINATION IS CONTRAINDICATED IN PRODUCT LABELING.

ADDITIONAL MANUFACTURER NARRATIVE

THERE ARE WARNINGS IN THE PACKAGE INSERT THAT STATE THAT THIS TYPE OF EVENT CAN OCCUR. THIS TYPE OF EVENT IS NOT OCCURRING AT A RATE ABOVE EXPECTED FREQUENCY. NO REMEDIAL ACTION WILL BE TAKEN. NO FURTHER COMPLICATIONS HAVE BEEN REPORTED. CURRENT INFO IS INSUFFICIENT TO PERMIT A VALID CONCLUSION AS TO THE CAUSE OF THE EVENT. BIOMET REC'D A MEDWATCH REPORT FROM THE USER FACILITY. THE REPORT STATES THE SHELL COMPONENT AS AN EXPLANTED DEVICE. THIS DEVICE WAS NOT EXPLANTED. BIOMET HAS CHOSEN NOT TO REPORT THE SHELL COMPONENT.

MAUDE Search

BRAND NAME	ARCOM CONSTRAINED LINER
TYPE OF DEVICE	ACETABULAR CUP IMPLANT
DEVICE EVENT KEY	64644
MDR REPORT KEY	64523
EVENT KEY	6063 1
REPORT NUMBER	1825034- 1997-00005
510(K) NUMBER	K926107
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	17-JAN-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	16-JAN-1997
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPHZATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	14-105023
DEVICE LOT NUMBER	828770
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	17-DEC-96
TYPE OF REPORT	INITIAL
REPORT DATE	16-JAN-1997
DEVICE AGE	8
DATE REPORT TO MANUFACTURER	16-JAN-1997
MANUFACTURER NAME	BIOMET, INC.
MANUFACTURER CONTACT	DEB VOYNOVICH P.O. BOX 587 WARSAW, IN 46581-0587 (219) 267 -6639

DATE MANUFACTURER RECEIVED	17-DEC-1996
MANUFACTURER REPORT NO	1825034- 1997-00005
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	01-APR-1996
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA
BASELINE BRAND NAME	ARCOM CONSTRAINED LINER
BASELINE GENERIC NAME	PROSTHESIS, HIP, COMP.
BASELINE CATALOGUE NUMBER	14-105023
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	ARCOM CONSTRAINED LINER
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	28-JUL-1993
DATE CEASED MARKETING	0000003157

EVENT DESCRIPTION

TOTAL HIP REPLACEMENT SURGERY WAS PERFORMED ON 10/29/96. REVISION SURGERY WAS PERFORMED ON 12/8/96, DUE TO DISLOCATION.

ADDITIONAL MANUFACTURER NARRATIVE

THERE ARE WARNINGS IN THE PACKAGE INSERT THAT STATE THAT THIS TYPE OF EVENT CAN OCCUR. THIS TYPE OF EVENT IS NOT OCCURRING AT A RATE ABOVE EXPECTED FREQUENCY. NO REMEDIAL ACTION WILL BE TAKEN. NO FURTHER COMPLICATIONS HAVE BEEN REPORTED. CURRENT INFO IS INSUFFICIENT TO PERMIT A VALID CONCLUSION AS TO THE CAUSE OF THE EVENT.

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MAUDE Search

BRAND NAME	ARCOM CONSTRAINED LINER
TYPE OF DEVICE	ACETABULAR CUP IMPLANT
MANUFACTURER	BIOMET
	PO BOX 587
	WARSAW, IN
	46581
	u s
DEVICE EVENT KEY	64644
MDR REPORT KEY	64520
EVENT KEY	6063 1
REPORT NUMBER	2200670000- 1996-900 1
510(K) NUMBER	K926107
PRODUCT CODE	K''B
REPORT SOURCE	USER FACILITY
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	17-JAN-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	16-JAN-1997
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	14-105023
DEVICE LOT NUMBER	828770
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	17-DEC-96
CONCOMITANT MEDICAL PRODUCTS	NA
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	27-DEC-1996
TYPE OF REPORT	INITIAL

REPORT DATE	10-JAN-1997
DEVICE AGE	8
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
DATE REPORT TO MANUFACTURER	16-JAN-1997
MANUFACTURER NAME	BTOMET, INC.
MANUFACTURER CONTACT	DEB VOYNOVICH P.O. BOX 587 WARSAW, IN 46581-0587 (219) 267 -6639
MANUFACTURER REPORT NO	1825034- 1997-00005
BASELINE BRAND NAME	ARCOM CONSTRAINED LINER
BASELINE GENERIC NAME	PROSTHESIS, HIP, COMP.
BASELINE CATALOGUE NUMBER	14-105023
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	N 4
BASELINE DEVICE FAMILY	ARCOM CONSTRAINED LINER
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	28-JUL-1993
DATE CEASED MARKETING	0000003157
EVENT DESCRIPTION	TOTAL HIP REPLACEMENT SURGERY WAS PERFORMED ON 10/29/96. REVISION SURGERY WAS PERFORMED ON 12/8/96, DUE TO DISLOCATION.

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BRAND NAME	RING LOC CONSTRAINED LINER
TYPE OF DEVICE	ACETABULAR CUP LINER
MANUFACTURER	BIOMET
	P.O. BOX 587
	WARSAW, IN
	46581-0587
	u s
DEVICE EVENT KEY	38116
MDR REPORT KEY	36712
EVENT KEY	34539
REPORT NUMBER	3600170000-1996-0005
510(K) NUMBER	K950202
PRODUCT CODE	KWB
REPORT SOURCE	USER FACILITY
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	30-AUG-1996
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	07-AUG-1996
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE CATALOGUE NUMBER	RD114576, RD114570
DEVICE LOT NUMBER	058840, 120050
WAS DEVICE AVAHALE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	26-JUL-96
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	07-AUG-1996
DEVICE AGE	2
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	UNKNOWN
DATE REPORT TO MANUFACTURER	07-AUG-1996

MANUFACTURER NAME
MANUFACTURER CONTACT

DIOME I, INC.
 DEB VOYNOVICH
 P.O. BOX 587
 WARSAW, IN
 46581-0587
 (219) 267 -6639

MANUFACTURER REPORT NO

1825034- 1996-00004

BASELINE BRAND NAME

CONSTRAINED LINER & RING

BASELINE GENERIC NAME

PROSTHESIS, HIP, COMPS.

BASELINE CATALOGUE NUMBER

RD114576, RD114570

BASELINE MODEL NUMBER

NA

OTHER BASELINE ID NUMBER

LOT# 058840, 120050

BASELINE DEVICE FAMILY

CONST. ACET. COMPS. (RD)

SHELF LIFE LABELED FLAG

NO

PMA FLAG

NO

510(K) FLAG

YES

PREAMENDMENT FLAG

NO

TRANSITIONAL FLAG

NG

EXEMPT FLAG 510(K)

NO

DATE FIRST MARKETED

15-MAY-1995

DATE CEASED MARKETING

0000000171

EVENT DESCRIPTION

79 YEAR OLD, WHO HAD IN 1994 UNDERWENT REVISION HIP ARTHROPLASTY. PRESENTS NOW WITH PAIN, DISCOMFORT & ROENTGENOGRAPHIC EVIDENCE OF DISLOCATION. CONSTRAINING RING WAS FRACTURED. THERFORE HIP REVISION COMPLETED.

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MAUDE Search

BRAND NAME	ACETABULARCONSTRAINED COMPONENTS
TYPE OF DEVICE	PROTHESIS, HIP, COMPONENTS
MANUFACTURER	BIOMET, INC. P.O. BOX 587 WARSAW, IN 46581-0587 u s
DEVICE EVENT KEY	38116
MDR REPORT KEY	36717
EVENT KEY	34539
REPORT NUMBER	1825034- 1996-00004
510(K) NUMBER	K950202
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	30-AUG-1996
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL,
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	RD114576, RD114570
DEVICE LOT NUMBER	058840, 120050
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	01-AUG-96
CONCOMITANT MEDICAL PRODZJCTS	UNK
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	28-AUG-1996

REPORT SENT TO FDA FLAG

MANUFACTURER NAME
MANUFACTURER CONTACT

NO
 BIOMET, INC.
 DEB VOYNOVICH
 P.O. BOX 587
 WARSAW, IN
 46581-0587
 (219) 267 -6639

INITIAL REPORT SOURCE
DATE MANUFACTURER RECEIVED
MANUFACTURER REPORT NO
EVENT REPORT TYPE
WAS DEVICE EVALUATED BY
MANUFACTURER?
MANUFACTURE DEVICE DATE
LABELED FOR SINGLE USE?
REMEDIAL ACTION
TYPE OF DEVICE USAGE
CORRECTION OR REMOVAL REPORT
NUMBER

COMPANY REPRESENTATIVE
 01 -AUG- 1996
 1825034- 1996-00004
 INJURY
 YES
 01-JUN-1994
 YES
 OTHER
 INITIAL
 NA

BASELINE BRAND NAME
BASELINE GENERIC NAME
BASELINE CATALOGUE NUMBER
BASELINE MODEL NUMBER
OTHER BASELINE ID NUMBER
BASELINE DEVICE FAMILY
SHELF LIFE LABELED FLAG
PMA FLAG
510(K) FLAG
PREAMENDMENT FLAG
TRANSITIONAL FLAG
EXEMPT FLAG 510(K)
DATE FIRST MARKETED
DATE CEASED MARKETING

CONSTRAINED LINER & RING
 PROSTHESIS, HIP, COMPS.
 RD114576, RD114570
 NA
 LOT# 058840, 120050
 CONST. ACET. COMPS. (RD)
 NO
 NO
 YES
 NO
 NO
 NO
 15-MAY-1995
 0000000171

EVENT DESCRIPTION

79 YEAR OLD, WHO HAD IN 1994 UNDERWENT REVISION HIP ARTHROPLASTY. PRESENTS NOW WITH PAIN, DISCOMFORT & ROENTGENOGRAPHIC EVIDENCE OF DISLOCATION. CONSTRAINING RING WAS FRACTURED. THEREFORE HIP REVISION COMPLETED.

ADDITIONAL MANUFACTURER NARRATIVE

THERE ARE WARNINGS IN THE PACKAGING INSERT THAT STATE THAT THIS TYPE OF EVENT CAN OCCUR. THIS EVENT IS NOT OCCURRING AT A RATE ABOVE EXPECTED FREQUENCY. NO REMEDIAL ACTION WILL BE TAKEN. NO FURTHER COMPLICATIONS HAVE BEEN REPORTED.

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(Database Updated February 5, 1999)

Medical Device Reporting Full Display

Access number: 726395

Date received: 08/18/95

-- Product name: CONSTRAINED LINER

Manufacturer: BIOMET, INC.

Street: P.O. BOX 587

City: WARSAW

State: IN

Zipcode: 46580

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: F

(P/F = Preliminary/Final)

Event description: THE COMPONENTS WERE IMPLANTED 7/10/95. THE HIP
SUBSEQUENTLY DISLOCATED SEVERAL TIMES AND WAS
REVISED 7/31/95. A DARK FLUID WAS FOUND IN THE
JOINT UPON REVISION. NO FURTHER COMPLICATIONS HAVE
BEEN REPORTED.

Closeout description:

000056

Medical Device Reporting Full Display

Access number: 726394

Date received: 08/18/95

Product name: CONSTRAINED LINER

Manufacturer: BIOMET, INC.

Street: P.O. BOX 587

City: WARSAW

State: IN

Zipcode: 46580

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: F

(P/F = Preliminary/Final)

Event description: THE COMPONENT WAS IMPLANTED 07/18/95 DUE TO CHRONIC
DISLOCATION. THE COMPONENT DISENGAGED FROM THE
SHELL. THE COMPONENT WAS REVISED ON 8/03/95. THE PT
IS A GUNSHOT VICTIM WITH SOFT-TISSUE AND MUSCLE
LOSS. NO FURTHER COMPLICATIONS HAVE BEEN REPORTED.

Closeout description:

000057

Medical Device Reporting Full Display

Access number: 720298

Date received: 06/27/95

Product name: CONSTRAINED LINER

Manufacturer: BIOMET, INC.

Street: P.O. BOX 587 AIRPORT INDUSTRIAL PARK

City: WARSAW

State: IN

Zipcode: 46580

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: P

(P/F = Preliminary/Final)

Event description: THE COMPONENT WAS IMPLANTED 11/94, AND REVISED
6/9/95 WHEN THE COMPONENT DISENGAGED.

Closeout description:

Medical Device Reporting Full Display

Access number: 704259

Date received: 03/29/95

Product name: CUSTOM CONSTRAINED LINER

Manufacturer: BIOMET, INC.

Street: P.O. BOX 587

City: WARSAW

State: IN

Zipcode: 46580

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: F

(P/F = Preliminary/Final)

Event description: THE COMPONENT DISENGAGED FROM THE SHELL. REVISION
SURGERY WAS PERFORMED ON 3/16/95. NO FURTHER
COMPLICATIONS HAVE BEEN REPORTED.

Closeout description:

000059

Medical Device Reporting Full Display

Access number: 452691

Date received: 12/02/93

Product name: RINGLOCK CONSTRAINED LINER

Manufacturer: BIOMET, INC.

Street: P.O. BOX 587 AIRPORT INDUSTRIAL PARK

City: WARSAW

State: IN

Zipcode: 46580

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: BD114435

Event type: P (P/F = Preliminary/Final)

Event description: DEVICE WAS IMPLANTED ON 10/21/93. X-RAY REVEALED THAT THE CONSTRAINED LINER HAD DISSOCIATED FROM ACETABULAR SHELL COMPONENT. REVISION SURGERY WAS PERFORMED ON 11/30/93 TO REPLACE LINER. NO ADD'L COMPLICATIONS WERE REPORTED.

Closeout description:

000060

MAUDE Search

BRAND NAME	CONSTRAINED LINER
TYPE OF DEVICE	CONSTRAINED LINER
MANUFACTURER	EXACTECH, INC. 4613 NW 6TH STREET GAINESVILLE, FL 32609 u s
DEVICE EVENT KEY	144291
MDR REPORT KEY	148070
EVENT KEY	138988
REPORT NUMBER	1038671-1998-00001
510(K) NUMBER	K960748
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	05-FEB-1998
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	05-JAN-1998
DEVICE OPERATOR	HEALTH PROFESSIONAL,
DEVICE EXPIRATION DATE	NA
DEVICE CATALOGUE NUMBER	902-28-43
OTHER DEVICE ID NUMBER	902-28-43
WAS DEVICE AVAILABLE FOR EVALUATION?	NO ANSWER PROVIDED
IS THE REPORTER A HEALTH PROFESSIONAL?	NO
TYPE OF REPORT	INITIAL
REPORT DATE	04-FEB-1998
DEVICE AGE	1
REPORT SENT TO FDA FLAG	YES
DATE REPORT SENT TO FDA	05-JAN-1998
EVENT LOCATION	OTHER
INITIAL REPORT SOURCE	*
DATE MANUFACTURER RECEIVED	05-JAN-1998
MANUFACTURER REPORT NO	1038671-1998-00001

EVENT REPORT TITLE**DATE OF INCIDENT****WAS DEVICE EVALUATED BY MANUFACTURER? YES****MANUFACTURE DEVICE DATE**

01 -NOV- 1996

LABELED FOR SINGLE USE?**YES****REMEDIAL ACTION**

REVISION

TYPE OF DEVICE USAGE

INITIAL

EVENT DESCRIPTION

CUSTOM CONSTRAINED LINER DISLOCATED.

ADDITIONAL MANUFACTURER NARRATIVE

CUSTOM LINER WAS REVISED WITHOUT INCIDENT. CLOSE EXAMINATION OF THE CONSTRAINED LINER LEADS TO THE CONCLUSION THAT THE DISLOCATION OF THE FEMORAL HEAD FROM THE LINER OCCURRED AS A RESULT OF IMPINGEMENT OF THE FEMORAL STEM NECK ON THE EDGE OF THE LINER. BECAUSE THE LINER IS DESIGNED TO CONSTRAIN THE FEMORAL HEAD IN THE LINER AND PREVENT DISLOCATIONS, THE IMPLANT WILL INHERENTLY HAVE A REDUCED RANGE OF MOTION IN COMPARISON TO A STANDARD LINER. WHEN DESIGNING THE IMPLANT, THE PATIENT'S CASE WAS PRESENTED AS ONE SUFFERING FROM CHRONIC DISLOCATIONS. THE CUSTOM IMPLANT WAS DESIGNED SO THAT THE HEAD WOULD NOT DISLOCATE DURING NORMAL CONDITIONS, PROVIDING A NATURAL RANGE OF MOTION FOR THE LIMB. IN CASE WHERE THE PATIENT WAS PLACING THE LIMB IN A POSITION WHERE THE NECK OF THE FEMORAL IMPLANT WAS EXERTING EXTREME PRESSURE (DUE TO IMPINGEMENT) ON THE LIP OF THE LINER, THE PATIENT WOULD CAUSE THE FEMORAL HEAD TO CANTILEVER OUT OF POSITION. THE DESIGN CONSIDERED THE FACT THAT THE PATIENT HAD AN MCS SHELL THAT WAS WELL FIXED IN BONE AND A DISLOCATION, IN EXTREME CASES, WAS PREFERRED AS OPPOSED TO COMPROMISING THE FIXATION OF THE SHELL. THE LOCKING MECHANISM OF THE LINER TO THE SHELL WAS INTACT THAT THE OVERALL DIMENSIONS OF THE SHELL WERE WITHIN ORIGINAL MANUFACTURING SPECIFICATIONS. AT THE IMPINGEMENT POINT, HOWEVER, THE INSIDE DIAMETER OF THE CONSTRAINING "LIP" WAS OUT OF ROUND AND ABOUT .010 INCHES OUT OF TOLERANCE. THE PLASTIC WAS BELIEVED TO HAVE BEEN DEFORMED, THEREFORE ALLOWING THE HEAD TO DISLOCATE. THE STRESS ON THE LINER LIP WAS HIGH ENOUGH TO CAUSE PLASTIC DEFORMATION OF THE LINER WHICH INDICATES AN EXTREME IMPINGEMENT CONDITION.

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MAUDE Search

BRAND NAME	CUSTOM CONSTRAINED LINER
TYPE OF DEVICE	TOTAL HIP PROSTHESIS
MANUFACTURER	DEPUY ORTHOPAEDICS, INC. 700 ORTHOPAEDIC DR. P.O. BOX 988 WARSAW, IN 46581-0988
DEVICE EVENT KEY	u s 149212
MDR REPORT KEY	153151
EVENT KEY	143822
REPORT NUMBER	1818910-1998-00037
510(K) NUMBER	K964987
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	23-FEB-1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	OTHER
DATE OF REPORT	30-JAN-1998
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	1242-22-978
DEVICE LOT NUMBER	SC4F51
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
CONCOMITANT MEDICAL PRODUCTS	NI
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	30-JAN-1998
TYPE OF REPORT	INITIAL
REPORT DATE	30-JAN-1998
DEVICE AGE	N

REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
MANUFACTURER NAME	DEPUY ORTHOPAEDICS, INC.
MANUFACTURER CONTACT	TERESA OBERLIN
	700 ORTHOPAEDIC DRIVE
	PO BOX 988
	WARSAW, IN
	46581-0988
	(219) 372 -7499
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	30-JAN-1998
MANUFACTURER REPORT NO	1818910-1998-00037
EVENT REPORT TYPE	MALFUNCTION
WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	01 -JAN- 1998
LABELED FOR SINGLE USE?	YES
REMEDIAL ACTION	OTHER
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA
BASELINE BRAND NAME	CUSTOM CONSTRAINED LINER
-- BASELINE GENERIC NAME	NA
BASELINE CATALOGUE NUMBER	1242-22-978
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	TOTAL HIP PROSTHESIS
PMA FLAG	NO
510(K) FLAG	NO
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	YES
DATE FIRST MARKETED	29-JAN-1998
DATE CEASED MARKETING	0000014405
EVENT DESCRIPTION	
COMPLAINANT CLAIMS THAT THE O.D. IS TOO SMALL, I.D. IS CORRECT, BUT LABEL INDICATES A 28MM RESULTING IN A DELAY IN SURGERY.	

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MAUDE Search

BRAND NAME	CUSTOM CONSTRAINED LINER
TYPE OF DEVICE	TOTAL, HIP PROSTHESIS
MANUFACTURER	DEPUY ORTHOPAEDICS, INC. 700 ORTHOPAEDIC DR. P.O. BOX 988 WARSAW, IN 46581-0988 u s
DEVICE EVENT KEY	121561
MDR REPORT KEY	124156
EVENT KEY	116724
REPORT NUMBER	1818910-1997-00196
510(K) NUMBER	K890841
PRODUCT CODE	KV/B
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	30-SEP-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	04-SEP-1997
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	1241-20-994
DEVICE LOT NUMBER	3 04540
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	04-SEP-97
CONCOMITANT MEDICAL PRODZJCTS	NI
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	21 -AUG- 1997
TYPE OF REPORT	INITIAL

REPORT DATE	04-SEP-1997
DEVICE AGE	1
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
MANUFACTURER NAME	DEPUY ORTHOPAEDICS, INC.
MANUFACTURER CONTACT	TERESA OBERLIN
	700 ORTHOPAEDIC DR.
	P.O. BOX 988
	WARSAW, IN
	46581-0988
	(2 19) 3 72 -7499
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	04-SEP-1997
MANUFACTURER REPORT NO	1818910-1997-00196
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	01-OCT-1996
LABELED FOR SINGLE USE?	YES
REMEDIAL ACTION	NA
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA
BASELINE BRAND NAME	CUSTOM CONSTRAINED LINER
BASELINE GENERIC NAME	TOTAL HIP PROSTHESIS
BASELINE CATALOGUE NUMBER	124 1-20-994
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	TOTAL HIP PROSTHESIS
PMA FLAG	NO
510(K) FLAG	NO
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	YES
DATE FIRST MARKETED	14-OCT-1996
DATE CEASED MARKETING	0000013640
EVENT DESCRIPTION	
	THE HIP BALL DISLOCATED FROM THE ACETABULAR POLYETHYLENE LINER.
ADDITIONAL MANUFACTURER NARRATIVE	

THE EVALUATION SHOWED THE LINER WAS DISTORTED AND DAMAGED FROM EXTRACTION. DIMENSIONAL MEASUREMENTS SHOWED THE LINER WAS FOUND TO MEET THE DESIGN REQUIREMENTS. THE DEVICE DID NOT ATTRIBUTE TO THE DISLOCATION.

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MAUDE Search

BRAND NAME	FEMORAL HEAD
MANUFACTURER	ZIMMER
	410 N. FIPPS ST.
	LONGVIEW, TX
	75601
	u s
DEVICE EVENT KEY	145299
MDR REPORT KEY	149096
EVENT KEY	139979
REPORT NUMBER	4576780000- 1997-0049
51 O(K) NUMBER	K911808
PRODUCT CODE	JDI
REPORT SOURCE	USER FACILITY
WAS MANUFACTURER REPORT SUBMITTED?	NO
NUMBER OF DEVICES IN EVENT	2
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	OS-JAN- 1998
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	30-OCT-1997
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE CATALOGUE NUMBER	9026-29
DEVICE LOT NUMBER	14185700
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	30-OCT-1997
TYPE OF REPORT	INITIAL
REPORT DATE	30-OCT- 1997
DEVICE AGE	7
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
DATE REPORT TO MANUFACTURER	30-OCT-1997
EVENT DESCRIPTION	

PT ADMITTED TO ER ON 08/26/1997 WITH DISLOCATION OF HER HIP PROSTHESIS EARLY THAT MORNING. SHE WAS TAKEN TO SURGERY WHERE THE HIP WAS REDUCED IN AN OPEN FASHION AND A REVISION ACETABULAR LINER WAS PLACED. SHE DID WELL POSTOPERATIVELY AND WAS SCHEDULED FOR DISCHARGE ON 08/30/97. BUT EARLY THAT MORNING, ON GOING TO THE BATHROOM, SHE AGAIN FELT PAIN AND DISCOMFORT IN HER HIP. SHE WAS MAINTAINED ON BEDREST AND TAKEN TO SURGERY ON 0910311997 FOR REVISION WITH A CONSTRAINED ACETABULAR CUP. TOLERATED WELL.

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MAUDE Search

BRAND NAME	ZIMMER
TYPE OF DEVICE	F/M ACET SHELL 52MMOD CLUSTER
MANUFACTURER	ZIMMER, INC PO BOX 708 WARSAW, IN 4658 1-0708 u s
DEVICE EVENT KEY	194421
MDR REPORT KEY	200147
EVENT KEY	188039
REPORT NUMBER	1822565-1998-00141
510(K) NUMBER	K902436
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	30-NOV-1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	OTHER
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	00620005222
DEVICE LOT NUMBER	14050800
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
CONCOMITANT MEDICAL PRODUCTS	UNK
TYPE OF REPORT	INITIAL
DEVICE AGE	6
REPORT SENT TO FDA FLAG	NO
MANUFACTURER NAME	ZIMMER, INC.
MANUFACTURER CONTACT	CONNIE MORGAN BOX 708 WARSAW, IN

7001-0100

(219) 372 -4269

USER FACILITY

09-NOV-1998

1822565-1998-00141

INJURY

D

01 -APR- 1997

YES

INITIAL

NA

ZIMMER

ACETABULAR SHELL

00620005222

NA

NA

TRILOGY ACETABUI-AR
SHELLS/CH

NO

NO

YES

NO

NO

NO

25-OCT-1994

0000003707

INITIAL REPORT SOURCE**DATE MANUFACTURER RECEIVED****MANUFACTURER REPORT NO****EVENT REPORT TYPE****WAS DEVICE EVALUATED BY
MANUFACTURER?****MANUFACTURE DEVICE DATE****LABELED FOR SINGLE USE?****TYPE OF DEVICE USAGE****CORRECTION OR REMOVAL REPORT NUMBER****BASELINE BRAND NAME****BASELINE GENERIC NAME****BASELINE CATALOGUE NUMBER****BASELINE MODEL NUMBER****OTHER BASELINE ID NUMBER****BASELINE DEVICE FAMILY****SHELF LIFE LABELED FLAG****PMA FLAG****510(K) FLAG****PREAMENDMENT FLAG****TRANSITIONAL FLAG****EXEMPT FLAG 510(K)****DATE FIRST MARKETED****DATE CEASED MARKETING****EVENT DESCRIPTION**

JUNE 1998 PT HAD A RIGHT TOTAL HIP ARTHROPLASTY AFTER DEVELOPING A FRACTURE THIS PROCEDURE WAS DONE IN EDINBURG, TX. SINCE THEN, PT HAS HAD MULTIPLE DISLOCATIONS AND HAS REQUIRED REDUCTION SEVERAL TIMES. BECAUSE OF RECURRENT DISLOCATIONS AND INSTABILITY, THE PT REQUIRED REPLACEMENT WITH A NEW ACETABULAR COMPONENT WITH SLIGHTLY MORE ANTEVERSION AND ALSO A CONSTRAINED COMPONENT WHICH WOULD RESIST DISLOCATION.

ADDITIONAL MANUFACTURER NARRATIVE

THE USER FACILITY HAS BEEN CONTACTED FOR THE POSSIBLE RELEASE OF THE DEVICE. NO ADD'L INFO AVAILABLE AT THIS TIME. H3: EVALUATION SUMMARY - PRODUCT WAS NOT RETURNED FOR EVALUATION. PROBABLE CAUSE MAY BE USER CAUSED BY MALPOSITIONING ACETABULAR SHELL DURING ORIGINAL SURGERY. H6: EVALUATION CODES: THE PRODUCT WAS NOT RETURNED FOR EVALUATION. THE MFG RECORDS ARE IN ORDER.

MAUDE Search

BRAND NAME	OSTEONICS CONSTRAINED ACETABULAR INSERT
TYPE OF DEVICE	ACETABULAR BEARING INSERT
MANUFACTURER	OSTEONICS CORP. 59 ROUTE 17 ALLENDALE, NJ 07401-1677 u s 134295
DEVICE EVENT KEY	134295
MDR REPORT KEY	137494
EVENT KEY	129293
REPORT NUMBER	2243265-1997-00058
510(K) NUMBER	K851366
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	09-DEC-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	NA
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	2099-2254
DEVICE LOT NUMBER	699802R
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	07-NOV-97
CONCOMITANT MEDICAL PRODUCTS	NA
IS THE REPORTER A HEALTH PROFESSIONAL?	NO

TYPE OF REPORT	INITIAL
REPORT DATE	07-NOV-1997
DEVICE AGE	1
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
INITIAL REPORT SOURCE	COMPANY REPRESENTATIVE
DATE MANUFACTURER RECEIVED	07-NOV-1997
MANUFACTURER REPORT NO	2243265-1997-00058
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	01-OCT-1997
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA
BASELINE BRAND NAME	OSTEONICS CONSTRAINED ACE-TABULAR INSERT
BASELINE GENERIC NAME	ACETABULAR BEARING INSERT
BASELINE CATALOGUE NUMBER	2099-2254
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
DATE CEASED MARKETING	0000012244

EVENT DESCRIPTION

A CONSTRAINED INSERT WAS ORIGINALLY IMPLANTED ON 10/16/1997. ON 10/26/97, THE INSERT REPORTEDLY DISASSOCIATED FROM THE ACETABULAR SHELL. DURING REVISION SURGERY, A NEW INSERT WAS ASSEMBLED WITH THE SHELL, BUT BEFORE THE SURGERY WAS COMPLETED, IT DISASSOCIATED FROM THE SHELL. THE SURGEON REPORTEDLY ATTEMPTED TO CEMENT THE INSERT INTO THE SHELL, BUT WHILE IMPACTING IT, DISCOVERED THE PATIENT'S ACETABULUM HAD FRACTURED. ALL DEVICES WERE REMOVED AND A GIRDLESTONE PERFORMED.

ADDITIONAL MANUFACTURER NARRATIVE

OSTEONICS DISCLAIMER: SUBMISSION OF INFORMATION BY OSTEONICS UNDER THE MEDICAL DEVICE REPORTING REGULATION DOES NOT CONSTITUTE AN ADMISSION THAT THIS INFORMATION IS REQUIRED TO BE REPORTED UNDER THE REGULATION OR THAT THERE IS ANY CASUAL CONNECTION BETWEEN THE PERFORMANCE OF THE DEVICE AND ANY INJURY OR DEATH THAT MAY HAVE OCCURRED. SUBMISSION OF THIS INFORMATION IS NOT AN ADMISSION OF THE ACCURACY OF THE INFORMATION CONTAINED WITHIN THE REPORT, WHICH WAS PROVIDED ORIGINALLY TO THE SUBMITTER BY OUTSIDE SOURCES. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. THE 2099 CONSTRAINED ACETABULAR INSERTS ARE MARKETED UNDER PMA #P960047. A USER FACILITY MEDWATCH REPORT WAS NOT PROVIDED, CONSEQUENTLY SEVERAL BLOCKS IN SECTION F ARE

NOT AVAILABLE UK UNKNOWN. EVALUATION METHOD ACTUAL DEVICES INVOLVED IN INCIDENT WERE EVALUATED. DEVICES FROM THE SAME LOT AS THE ACTUAL DEVICE INVOLVED IN INCIDENT WERE EVALUATED. VISUAL EXAMINATION. REVIEWED MANUFACTURING RECORDS FOR RETURNED DEVICE. TESTED ADDITIONAL MANUFACTURING LOTS, AS WELL AS, MACHINED TEST SAMPLES. EVALUATION RESULTS. MANUFACTURING RECORDS INDICATE ALL REQUIRED MANUFACTURING OPERATIONS AND QUALITY EVALUATIONS WERE PROPERLY COMPLETED. VISUAL EXAMINATION OF THE RETURNED INSERTS REVEALED MARKS WHICH SUGGEST THAT THE LOCKING WIRE BECAME DISLODGED ON BOTH INSERTS AND PREVENTED THE INSERTS FROM PROPERLY LOCKING IN THE SHELL. THE MARKS ALSO SUGGEST THAT THE INSERTS WERE AXIALLY MISALIGNED DURING ASSEMBLY WITH THE SHELL IN SURGERY. PRODUCT TESTING CONFIRMED THAT THE LOCKING WIRES REMAIN IN PLACE WHEN THE RECOMMENDED ASSEMBLY TECHNIQUE IS USED. EVALUATION CONCLUSION. MISALIGNMENT OF THE INSERTS DURING ASSEMBLY WITH THE SHELL IS LIKELY TO HAVE CAUSED A PORTION OF THE LOCKING WIRE TO BECOME DISLODGED. AS A RESULT, THE INSERTS DID NOT FULLY LOCK IN PLACE. NO CONCLUSION CAN BE DRAWN AS TO EXACTLY WHAT MAY HAVE CAUSED THE PATIENT'S ACETABULUM TO FRACTURE.

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(Database Updated February 5, 1999)

Medical Device Reporting Full Display

Access number: 270154
Date received: 03/03/92
Product name: OMNIFIT CONSTRAINED ACETABULAR CUP INSERT
Manufacturer: OSTEONICS CORP.
Street: 2 PEARL COURT
City: ALLENDALE
State: NJ
Zipcode: 07401
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: 2099-2656

Event type: F (P/F = Preliminary/Final)
Event description: UNIT DISASSEMBLED WHILE PT WAS GETTING OFF TOILET. THE DEVICE IDENTIFIED WAS SURGICALLY RETRIEVED FROM THE PT AFTER AN IMPLANT PERIOD OF 1 MONTH. IT DISLOCATED FROM ITS MODULAR ACETABULAR SHELL WHILE THE INDIVIDUAL WAS RISING FROM THE TOILET. THE PT WAS REVISED ON 2/22/92. THE INSERT STATES, IN PERTINENT PART, THAT "HIGH DEMAND ON THE BEARING INSERT CAN RESULT IN THE FAILURE OF THE DEVICE AND ITS MATING SHELL INTRFACE". ADDITIONALLY, THE INSERT STATES THAT "DISLOCATION OF THE HIP PROSTHESIS DUE TO INAPPROPRIATE PT ACTIVITY, TRAUMA OR OTHER BIOMECHANICAL CONDITIONS CAN OCCUR."
Closeout description: THIS REPORT WAS REVIEWED FOR SIGNIFICANT PROBLEMS BUT WAS NOT CLOSED. IT IS BEING CLOSED AT THIS TIME AS PART OF A BATCH CLOSEOUT PROCESS IN ORDER TO PREPARE THE DATABASE TO SERVE AS HISTORICAL SUPPORT TO A REDESIGNED DATABASE.

Medical Device Reporting Full Display

Access number: 363796
Date received: 02/08/93
Product name: OMNIFIT CONSTRAINED ACETABULAR CUP INSERT
Manufacturer: OSTEONICS CORP.
Street: 59 ROUTE 17
City: ALLENDALE
State: NJ
Zipcode: 07401
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: 2099-2252

Event type: F (P/F = Preliminary/Final)
Event description: INSERT DISLOCATED FROM ITS MODULAR ACETABULAR SHELL WHILE THE INDIVIDUAL WAS GETTING UP FROM CHAIR. REQUIRED REVISION SURGERY. DEVICE WAS SURGICALLY RETRIEVED FROM THE PT ON 1/20/93 AFTER AN IMPLANTATION PERIOD OF ONE MONTH. THE INSERT STATES, IN PERTINENT PART, THAT "HIGH DEMAND ON THE BEARING INSERT CAN RESULT IN THE FAILURE OF THE DEVICE AND ITS MATING SHELL INTERFACE." ADDITIONALLY, THE INSERT STATES THAT "DISLOCATION OF THE HIP PROSTHESIS DUE TO INAPPROPRIATE PT

000075

ACTIVITY, TRAUMA OR OTHER BIOMECHANICAL CONDITIONS
CAN OCCUR."

Closeout description:

Medical Device Reporting Full Display

Access number: 407457

Date received: 08/27/93

Product name: OSTEONICS CONSTRAINED ACETABULAR CUP INSERT

Manufacturer: OSTEONICS CORP.

Street: 59 ROUTE 17

City: ALLENDALE

State: NJ

Zipcode: 07401

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: F (P/F = Preliminary/Final)

Event description: PT DISLOCATED. SCHEDULED FOR REVISION SURGERY
8/30/93. THE CONSTRAINED ACETABULAR CUP INSERT
IDENTIFIED WAS SURGICALLY RETRIEVED FROM THE PT
AFTER AN IMPLANTATION PERIOD OF 1.5 MONTHS. THE
INSERT WAS REPORTED TO HAVE BEEN IMPLANTED IN
COMBINATION WITH A FEMORAL STEM MFG BY AN ENTITY
OTHER THAN THIS CO. THE COMPONENTS OF THE INSERT
DISLOCATED ON 8/24/93. THE PT'S PROSTHESIS WAS
REVISED ON 8/30/93. THE INSERT STATES, IN PERTINENT
PART, THAT "HIGH DEMAND ON THE BEARING INSERT CAN
RESULT IN THE FAILURE OF THE DEVICE AND ITS MATING
SHELL INTERFACE." THE INSERT ALSO STATES THAT
"DISLOCATION OF THE HIP PROSTHESIS DUE TO
INAPPROPRIATE PT ACTIVITY, TRAUMA OR OTHER
BIOMECHANICAL CONDITIONS CAN OCCUR." FINALLY, THE
PACKAGE INSERT STATES "CO STRONGLY ADVISES AGAINST
THE USE OF ANOTHER MFR'S FEMORAL COMPONENT WITH ANY
CO ACETABULAR SYSTEM COMPONENT."

Closeout description:

000076

MAUDE Search

BRAND NAME	OSTEONICS CONSTRAINED ACETABULAR INSERT
TYPE OF DEVICE	ACETABULAR BEARING INSERT
MANUFACTURER	OSTEONICS CORP. 59 ROUTE 17 ALLENDALE, NJ 07401-1677 u s
DEVICE EVENT KEY	96584
MDR REPORT KEY	97938
EVENT KEY	92124
REPORT NUMBER	2243265-1997-00028
510(K) NUMBER	K871960
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	10-JUN-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	NA
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	2099-
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	NA
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	UNK
TYPE OF REPORT	INITIAL

REPORT DATE	18-OCT-1996
DEVICE AGE	U
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	18-OCT-1996
MANUFACTURER REPORT NO	2243265-1997-00028
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	D
MANUFACTURE DEVICE DATE	UNK
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA

EVENT DESCRIPTION

EIGHT MONTHS AFTER ORIGINAL SURGERY, PT REPORTED SQUEAKING IN THE HIP. AT 17 MONTHS POST-OP, IT WAS REPORTEDLY DETERMINED THAT THE LOCKING RING ON THE CONSTRAINED INSERT HAD **BROKEN** AND THE INSERT SEPARATED FROM THE ACETABULAR SHELL. REVISION SURGERY WAS PERFORMED TO REPLACE THE ACETABULAR COMPONENT.

ADDITIONAL MANUFACTURER NARRATIVE

NO USER FACILITY WAS PROVIDED. CONSEQUENTLY, SEVERAL BLOCKS IN SECTION F ARE NA OR UNK. EVALUATION METHOD: (CODE 86, OTHER) SINCE A SPECIFIC CATALOG # AND SERIAL # WAS NOT PROVIDED, THE EVALUATION WAS LIMITED TO A REVIEW OF THE INFO PROVIDED. EVALUATION RESULTS: SURGEON WHO PERFORMED THE REVISION SURGERY IS REPORTEDLY OF THE OPINION THAT THE ACETABULAR COMPONENT WAS ORIGINALLY PLACED IN EXCESSIVE ABDUCTION. EVALUATION CONCLUSION: COMPONENT POSITION CONTRIBUTED TO EVENT.

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MAUDE Search

BRAND NAME	OSTEONICS CONSTRAINED ACETABULAR INSERT
TYPE OF DEVICE	ACETABULAR BEARING INSERT
MANUFACTURER	OSTEONICS CORP. 59ROUTE 17 ALLENDALE, NJ 07401-1677 u s
DEVICE EVENT KEY	96579
MDR REPORT KEY	97933
EVENT KEY	92119
REPORT NUMBER	2243265-1997-00027
510(K) NUMBER	K871960
PRODUCT CODE	k WB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	10-JUN-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	NA
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	2099-
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	NA
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	UNK
TYPE OF REPORT	INITIAL

REPORT DATE	18-OCT-1996
DEVICE AGE	U
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	18-OCT-1996
MANUFACTURER REPORT NO	2243265-1997-00027
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	D
MANUFACTURE DEVICE DATE	UNK
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA

EVENT DESCRIPTION

DURING ORIGINAL SURGERY ON 1/26/91, THE OSTEONICS CONSTRAINED INSERT WAS CEMENTED INTO A WELL FIXED UNCEMENTED ACETABULAR COMPONENT FROM ANOTHER MFR. THE INSERT DISLODGED FROM THE CEMENT MANTLE FOUR MONTHS AFTER SURGERY. THE SAME INSERT WAS RE-CEMENTED INTO PLACE WITH NO FURTHER DISLOCATIONS.

ADDITIONAL MANUFACTURER NARRATIVE

NO USER FACILITY WAS PROVIDED. CONSEQUENTLY, SEVERAL BLOCKS IN SECTION F ARE NA AND UNK. EVALUATION METHOD: (CODE 86, OTHER) SINCE A SPECIFIC CATALOG # AND SERIAL # WAS NOT PROVIDED, THE EVALUATION WAS LIMITED TO A REVIEW OF THE INFO PROVIDED. EVALUATION RESULTS (CODE 102) INCOMPATIBLE COMPONENTS. EVALUATION CONCLUSION: (CODE 68, OTHER) THE USE OF AN INCOMPATIBLE DEVICE FROM ANOTHER MFR CONTRIBUTED TO THE EVENT.

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MAUDE Search

BRAND NAME	OSTEONICS CONSTRAINED ACETABULAR INSERT
TYPE OF DEVICE	ACETABULAR BEARING INSERT
MANUFACTURER	OSTEONICS CORP. 59 ROUTE 17 ALLENDALE, NJ 07401-1677
DEVICE EVENT KEY	u s 96571
MDR REPORT KEY	97925
EVENT KEY	92111
REPORT NUMBER	2243265 1997-00026
PMA NUMBER	P800036
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	10-JUN-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	NA
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	2099-
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	NA
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	UNK
TYPE OF REPORT	INITIAL

REPORT DATE 18-OCT-1996
DEVICE AGE U
REPORT SENT TO FDA FLAG NO
EVENT LOCATION HOSPITAL
INITIAL REPORT SOURCE HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED 18-OCT-1996
MANUFACTURER REPORT NO 2243265- 1997-00026
EVENT REPORT TYPE INJURY
WAS DEVICE EVALUATED BY MANUFACTURER? D
MANUFACTURE DEVICE DATE UNK
LABELED FOR SINGLE USE? YES
TYPE OF DEVICE USAGE INITIAL
CORRECTION OR REMOVAL REPORT NUMBER NA

EVENT DESCRIPTION

PT UNDERWENT REVISION SURGERY AFTER COMPLAINING OF PAIN. THE RETAINING RING OF THE CONSTRAINED INSERT HAD DISLODGED AND WAS FOUND AROUND THE NECK OF THE FEMORAL COMPONENT.

ADDITIONAL MANUFACTURER NARRATIVE

NO USER FACILITY WAS PROVIDED. CONSEQUENTLY, SEVERAL BLOCKS IN SECTION F ARE NA OR UNK. EVALUATION METHOD: (CODE 86, OTHER) SINCE A SPECIFIC CATALOG # AND SERIAL # WAS NOT PROVIDED, THE EVALUATION WAS LIMITED TO A REVIEW OF THE INFO PROVIDED. EVALUATION RESULTS: (CODE 79) NONE. EVALUATION CONCLUSION: (CODE 67) NO CONCLUSION CAN BE DRAWN.

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MAUDE Search

BRAND NAME	OSTEONICS CONSTRAINED ACETABULARINSERT
TYPE OF DEVICE	ACETABULAR BEARING INSERT
MANUFACTURER	OSTEONICS CORP. 59 ROUTE 17 ALLENDALE, NJ 0740 1 u s
DEVICE EVENT KEY	96572
MDR REPORT KEY	97926
EVENT KEY	92112
REPORT NUMBER	2243265- 1997-00025
PMA NUMBER	P800036
PRODUCT CODE	† WB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	10-m-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	NA
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	2099-
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	NA
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	UNK
TYPE OF REPORT	INITIAL

REPORT DATE	18-OCT-1996
DEVICE AGE	U
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	18-OCT-1996
MANUFACTURER REPORT NO	2243265- 1997-00025
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	D
MANUFACTURE DEVICE DATE	UNK
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA

EVENT DESCRIPTION

FIFTY-THREE MONTHS AFTER THE ORIGINAL SURGERY, THE CONSTRAINED INSERT DISLOCATED AND THE ACETABULAR SHELL DISLODGED FROM THE ACETABULUM. REVISION SURGERY WAS PERFORMED TO REPLACE BOTH THE ACETABULAR INSERT AND THE SHELL.

ADDITIONAL MANUFACTURER NARRATIVE

OSTEONICS DISCLAIMER: SUBMISSION OF INFORMATION BY OSTEONICS UNDER THE MEDICAL DEVICE REPORTING REGULATION DOES NOT CONSTITUTE AN ADMISSION THAT THE INFORMATION IS REQUIRED TO BE REPORTED UNDER THE REGULATION OR THAT THERE IS ANY CAUSAL CONNECTION BETWEEN THE PERFORMANCE OF THE DEVICE AND ANY INJURY OR DEATH THAT MAY HAVE OCCURRED. SUBMISSION OF THIS INFORMATION IS NOT AN ADMISSION OF THE ACCURACY OF THE INFORMATION CONTAINED WITHIN THE REPORT, WHICH WAS PROVIDED ORIGINALLY TO THE SUBMITTER BY OUTSIDE SOURCES. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT.

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MAUDE Search

BRAND NAME	SROM POLY DIAL INSERT
TYPE OF DEVICE	HIP PROSTHESIS - POLY DIAL INSERT
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONAL, INC. 860 CANAL ST. STAMFORD, CT 06902 u s
DEVICE EVENT KEY	190679
MDR REPORT KEY	196262
EVENT KEY	184424
REPORT NUMBER	1219655-1998-00206
510(K) NUMBER	K87027 1
PRODUCT CODE	Jl i
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	11-NOV-1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	87-3554
DEVICE LOT NUMBER	SC107076
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	22-OCT-98
CONCOMITANT MEDICAL PRODUCTS	UNK
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	10-NOV-1998
REPORT SENT TO FDA FLAG	NO

MANUFACTURER NAME	JOHNSON a JOHNSON PROFESSIONAL, INC.
MANUFACTURER CONTACT	MATTHEW KING 325 PARAMOUNT DRIVE RAYNHAM, MA 02767 (508) 828 -3 106
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	22-OCT-1998
MANUFACTURER REPORT NO	1219655-1998-00206
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	NO
MANUFACTURE DEVICE DATE LABELED FOR SINGLE USE?	UNK YES
TYPE OF DEVICE USAGE	INITIAL
BASELINE BRAND NAME	SROM POLY DIAL INSERT
BASELINE GENERIC NAME	F. P PROSTHESIS - POLY DIAL INSERT
BASELINE CATALOGUE NUMBER	87-3554
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	SROM POLY DIAL INSERT
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	20-APR-1987
DATE CEASED MARKETING	0000021260

EVENT DESCRIPTION

THE CONSTRAINING RING FRACTURED WHILE IMPLANTED, REVISION SURGERY WAS PERFORMED. DISLOCATED PREVIOUSLY AND CLOSED REDUCTION WAS PERFORMED AT DIFFERENT FACILITY BY DIFFERENT SURGEON.

ADDITIONAL MANUFACTURER NARRATIVE

THE DEVICE HAS BEEN FORWARDED FOR EVALUATION, ONCE THE EVALUATION IS COMPLETED A FOLLOW-UP REPORT WILL BE FILED.

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MAUDE Search

BRAND NAME	SROM CONTRAINED LINER
TYPE OF DEVICE	HIP PROSTHESIS - CONSTRAINED LINER
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONAL, INC. 860 CANAL ST. STAMFORD, CT 06902 u s
DEVICE EVENT KEY	190667
MDR REPORT KEY	196248
EVENT KEY	184424
REPORT NUMBER	1219655-1998-00208
510(K) NUMBER	K820648
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	11-NOV-1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	52-1628
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	UNK
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	FOLLOWUP
REPORT DATE	10-NOV-1998
REPORT SENT TO FDA FLAG	NO

INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	22-OCT-1998
MANUFACTURER REPORT NO	1219655-1998-00208
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	NO
MANUFACTURE DEVICE DATE	UNK
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
BASELINE BRAND NAME	SROM CONTRAINED LINER
BASELINE GENERIC NAME	HIP PROSTHESIS - CONSTRAINED LINER
BASELINE CATALOGUE NUMBER	52-1628
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
DATE CEASED MARKETING	0000021259

EVENT DESCRIPTION

THE CONSTRAINING RING FRACTURED "TITLE" PLANTED, REVISION SURGERY WAS PERFORMED. DISLOCATED PREVIOUSLY AND CLOSED REDUCTION WAS PERFORMED AT DIFFERENT FACILITY BY DIFFERENT SURGEON.

ADDITIONAL MANUFACTURER NARRATIVE

DEVICE LOT #WAS NOT MADE AVAILABLE AND DEVICE WAS NOT RETURNED TO JJPI. CORRECTIONS: H6 - EVALUATION CODES HAVE BEEN CORRECTED TO REFLECT UNAVAILABILITY OF LOT # AND DEVICE. H10 - TO READ: JJPI HAS BEEN UNABLE TO OBTAIN THE LOT CODE OF THE S-ROM CONSTRAINED LINER. THE DEVICE WILL NOT BE RETURNED FOR EVALUATION AND WITHOUT LOT CODE, A MFG BATCH RECORD REVIEW COULD NOT BE PERFORMED. AT THIS TIME, JJPI CONSIDERS THIS COMPLAINT CLOSED.

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MAUDE Search

BRAND NAME	SROM CONSTRAINED LINER
TYPE OF DEVICE	HIP PROSTHESIS - CONSTRAINED LINER
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONAL, INC. 860 CANAL ST. STAMFORD, CT 06902 u s
DEVICE EVENT KEY	167353
MDR REPORT KEY	172102
EVENT KEY	161727
REPORT NUMBER	1219655-1998-00100
510(K) NUMBER	K870271
PRODUCT CODE	KWB
REPORT SOURCE.	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	11-JUN-1998
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	521628
DEVICE LOT NUMBER	SC102216
OTHER DEVICE ID NUMBER	NI
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
CONCOMITANT MEDICAL PRODUCTS P.	
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	11-JUN-1998
REPORT SENT TO FDA FLAG	NO
MANUFACTURER NAME	JOHNSON & JOHNSON PROFESSIONALS, INC.

MANUFACTURER CONTACT**MATTHEW KING**

325 PARAMOUNT DRIVE
 RAYNHAM, MA
 02767
 (508) 828 -3 106

INITIAL REPORT SOURCE HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED 04-MAY-1998
MANUFACTURER REPORT NO 1219655-1998-00100
EVENT REPORT TYPE MALFUNCTION
WAS DEVICE EVALUATED BY MANUFACTURER? NO
MANUFACTURE DEVICE DATE 01-SEP-1994
LABELED FOR SINGLE USE? YES
TYPE OF DEVICE USAGE INITIAL
CORRECTION OR REMOVAL REPORT NUMBER NA
BASELINE BRAND NAME S-ROM TOTAL HIP SYSTEM POLY-DIAL INSERT U.H.M.W.P.E.
BASELINE GENERIC NAME POLY-DIAL INSERT, CONSTRAINED
BASELINE CATALOGUE NUMBER 521628
BASELINE MODEL NUMBER NA
OTHER BASELINE ID NUMBER NA
BASELINE DEVICE FAMILY S-ROM TOTAL HIP SYSTEM POLY-DIAL INSERT, U.H.M.W.P.E.
PMA FLAG NO
510(K) FLAG YES
PREAMENDMENT FLAG NO
TRANSITIONAL FLAG NO
EXEMPT FLAG 510(K) NO
DATE FIRST MARKETED 20-APR-1987
DATE CEASED MARKETING 0000004666

EVENT DESCRIPTION

THE CONSTRAINING RING BROKE, THE DEVICE REMAINS IN PT. CURRENTLY, THERE ARE NO PLANS FOR REVISION.

ADDITIONAL MANUFACTURER NARRATIVE

THE DEVICE REMAINS IMPLANTED IN THE PT. THEREFORE AN EVALUATION OF THE DEVICE CANNOT BE DONE. HOWEVER A BATCH RECORD REVIEW OF THE DEVICE HAS BEEN COMPLETED AND NO DISCREPANCIES WERE FOUND ASSOCIATED WITH THIS LOT. AT THIS TIME, JPI CONSIDERS THIS FILE CLOSED.

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MAUDE Search

BRAND NAME	SROM CONSTRAINED LINER
TYPE OF DEVICE	PROSTHETIC HIP - CONSTRAINED LINER
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL ST STAMFORD, CT 06902-0350 u s 168809 173619 163160 1219655-1998-00099 K851421 KWY MANUFACTURER
DEVICE EVENT KEY	
MDR REPORT KEY	
EVENT KEY	
REPORT NUMBER	
510(K) NUMBER	
PRODUCT CODE	
REPORT SOURCE	
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	22-JUN-1998
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	87-5987
DEVICE LOT NUMBER	SC 109278
OTHER DEVICE ID NUMBER	NI
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	05-MAY-98
CONCOMITANT MEDICAL PRODUCTS	NI
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	22-JUN-1998
REPORT SENT TO FDA FLAG	NO
MANUFACTURER NAME	JOHNSON & JOHNSON PROFESSIONALS,

4130.

MATTHEW KING
325 PARAMOUNT DRIVE
RAYNHAM, MA
02767
(508) 828 -3 106

INITIAL REPORT SOURCE

HEALTH PROFESSIONAL

DATE MANUFACTURER RECEIVED

1 1-MAY-1998

MANUFACTURER REPORT NO

1219655-1998-00099

EVENT REPORT TYPE

MALFUNCTION

**WAS DEVICE EVALUATED BY
MANUFACTURER?**

YES

MANUFACTURE DEVICE DATE

UNK

LABELED FOR SINGLE USE?

YES

TYPE OF DEVICE USAGE

INITIAL

**CORRECTION OR REMOVAL REPORT
NUMBER**

NA

BASELINE BRAND NAME

S; JM CONSTRAINED INSERT

BASELINE GENERIC NAMEPROSTHETIC HIP-CONSTRAINED
INSERT**BASELINE CATALOGUE NUMBER**

87-5987

BASELINE MODEL NUMBER

NA

OTHER BASELINE ID NUMBER

NA

BASELINE DEVICE FAMILY

SROM CONSTRAINED INSERT

PMA FLAG

NO

510(K) FLAG

YES

PREAMENDMENT FLAG

NO

TRANSITIONAL FLAG

NO

EXEMPT FLAG 510(K)

NO

DATE FIRST MARKETED

18-SEP-1985

DATE CEASED MARKETING

0000018014

EVENT DESCRIPTION

SURGEON WAS UNABLE TO SEAT FEMORAL HEAD IN LINER OF PT, WHOSE HIP WAS LOOSE IN FLEXION. THE SURGEON THEN DETERMINED THAT THE CONSTRAINED LINER MAY HAVE HAD A DIMENSIONAL DISCREPANCY AND ALTERNATELY USED A NON-CONSTRAINING LINER. THE CHANGE IN THE LINER MAY RESULT IN SUBSEQUENT DISLOCATION, REQUIRING REOPERATION IN THE FUTURE, ACCORDING TO THE SURGEON. NOTE: ORIGINAL COMPLAINT WAS REC'D BY JOHNSON AND JOHNSON PROFESSIONAL, INC ON 5/5/98, LETTER WITH INFO LEADING TO THIS REPORT REC'D ON 5/11/98.

ADDITIONAL MANUFACTURER NARRATIVE

THE DEVICE WAS REC'D AT JJPI AND EVALUATED. THE LINER WAS FUNCTIONALLY TESTED USING THE FEMORAL HEAD, AND NO PROBLEM WAS OBSERVED. THE LINER'S SPHERICAL DIAMETER WAS WITHIN SPEC. THE COMPLAINT COULD NOT BE CONFIRMED. AT THIS TIME, JJPI CONSIDERS THIS COMPLAINT CLOSED.

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(Database Updated February 5, 1999)

Master Event Record

Data Element

Device event key: 000113469
Report source code: M
Subs Mfr Report Flag: Y
Num devices in event: 00001
Num ptnts in event: 00001
MDR report key: 0000115634
Event key: 0000108750
Report number: 1219655-1997-00118
Date FDA received: 27-AUG-1997

Section B Form 3500A or 3500

Adverse event flag: Y
Product problem flag: N
Event outcome: REQUIRED INTERVENTION
Report date: 06-AUG-1997
Event description: PT DISLOCATED HIP IN 1996 AND TREATED WITH A CLOSED REDUCTION. THE PT HAS HAD A HISTORY OF FALLS SINCE HER CLOSED REDUCTION AND AGAIN DISLOCATED HER HIP ON 7/13/97. REVISION SURGERY FOUND THE LINER DISASSOCIATED FROM THE SHELL AND LINER'S CONSTRAINING RING BROKEN. ALL COMPONENTS WERE REMOVED AT THAT TIME.

Section D Form 3500A

Brand name: SROM TOAL HIP SYSTEM-POLY DIAL INSERT, CONSTRAINED
Device type: PROSTHETIC HIP-ACETABULAR LINER
Manufacturer name: JOHNSON & JOHNSON PROFESSIONALS, INC.
Manufacturer street: 325 PARAMOUNT DRIVE
City: RAYNHAM
State: MA
Zip: 02767
Country code: us
Device operator: HEALTH PROFESSIONAL
Device expire date: NA
Device model number: NA
Device cat number: 552710
Device lot number: SO 54706
Other device ID num: NA
Concomitant med prod: LOT#SO493-38. CAT#555073, LOT#SO 43014, CAT#556070,

Section E Form 3500A

Health prof flag: Y

Section F Form 3500A

Report type: F
Rep sent to FDA flag: N

0 0 0 0 9 4

Section G Form 3500A

Report source: HEALTH PROFESSIONAL
Mfr received report: 04-AUG-1997
Report type: F
Manufacturer rep num: 1219655-1997-00118

Section H Form 3500A

Event report type: INJURY
Mfr evaluated flag: Y
Device mfr'ed date: 01-NOV-1993
Single use flag: Y
Previous use code: I
Remove/correct num: NA
Addl mfr narrative:

JJPI HAS REQUESTED THE USER FACILITY TO RETURN THE DEVICE FOR EVALUATION. LOT HISTORY RECORDS HAVE BEEN REVIEWED AND NO DISCREPANCIES WERE FOUND. WHEN THE DEVICE IS RETURNED, JJPI WILL FORWARD IT TO CO'S MFG FACILITY FOR EVALUATION. ONCE THE EVALUATION OF THE DEVICE IS COMPLETE A FOLLOW-UP REPORT WILL BE SUBMITTED. LOCATION IN 1996 FOLLOWED BY A CLOSED REDUCTION WHICH IS NOT RECOMMENDED FOR CONSTRAINED LINERS. THE DEVICE DISLOCATED AGAIN IN 1997. ANOTHER CLOSED REDUCTION WAS ATTEMPTED, BUT IT WAS UNSUCCESSFUL AND THE DEVICES WERE REVISED. DISLOCATION, CLOSED REDUCTIONS, AND FEMORAL IMPRINGEMENT ALL COULD HAVE BEEN CONTRIBUTORY TO FAILURE. NO MATERIAL OR MFG DEFECTS WERE EVIDENT. AT THIS TIME, JJPI CONSIDERS THIS FILE CLOSED.

Baseline brand name: SROM TOAL HIP SYSTEM-POLY DIAL INSERT, CONSTRAINED
Baseline gener name: PROSTHETIC HIP-ACETABULAR LINER
Baseline model num: NA
Baseline catalog num: 552710
Baseline other ID: NA
PMA number: P900043
Date cease marketing: 0000006513
Product code: KWB

000095

MAUDE Search

BRAND NAME	S-ROM TOTAL HIP SYSTEM POLY-DIAL INSERT
TYPE OF DEVICE	HIP ACETABULAR LINER, CONSTRAINED
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL ST STAMFORD, CT 06902 u s
DEVICE EVENT KEY	903 90
MDR REPORT KEY	91504
EVENT KEY	86032
REPORT NUMBER	1219655-1997-00092
510(K) NUMBER	K870271
PRODUCT CODE	AWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	
NUMBER OF PATIENTS INVOLVED	
DATE FDA RECEIVED	19-MAY-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DATE OF REPORT	NA
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	521628
DEVICE LOT NUMBER	SAIO1543
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
DATE RETURNED TO MANUFACTURER	30-APR-97
CONCOMITANT MEDICAL PRODUCTS NI	
IS THE REPORTER A HEALTH	YES

DISTRIBUTOR FACILITY AWARE DATE	NA
TYPE OF REPORT	FOLLOWUP
REPORT DATE	19-MAY-1997
DEVICE AGE	N
REPORT SENT TO FDA FLAG	NO
DATE REPORT SENT TO FDA	NA
EVENT LOCATION	OTHER
DATE REPORT TO MANUFACTURER	NA
MANUFACTURER NAME	JOHNSON & JOHNSON PROFESSIONALS, INC.
MANUFACTURER CONTACT	MATTHEW KING 325 PARAMOUNT DRIVE RAYNHAM, MA 02767 (508) 828 -3 106
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	21-APR 1997
MANUFACTURER REPORT NO	1219655-1997-00092
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	01-FEB-1995
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
BASELINE BRAND NAME	S-ROM TOTAL HIP SYSTEM POLY-DIAL INSERT, U.H.M.W.P.E.
BASELINE GENERIC NAME	POLY-DIAL INSERT, CONSTRAINED
BASELINE CATALOGUE NUMBER	521628
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	S-ROM TOTAL HIP SYSTEM POLY-DIAL INSERT, U.H.M.W.P.E.
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	20-APR-1987
DATE CEASED MARKETING	0000004666
EVENT DESCRIPTION	

REVISION HIP SURGERY FOUND THE NECK OF A FEMORAL STEM PROSTHESIS HAD WORN THROUGH THE U.H.M.P.E. HIP LINER COMPONENT AND HAD FRACTURED THE LINER'S CONSTRAINING RING. THE NEED FOR REVISION SURGERY HAS BEEN ATTRIBUTED TO THE FAILED HIP LINER COMPONENT.

ADDITIONAL MANUFACTURER NARRATIVE

H3-THE ACETABULAR LINER WAS RECEIVED WITH A FRACTURED RETAINING RING. BOTH THE POLYETHYLENE AND THE RETAINING RING SUFFERED DAMAGE BY IMPINGEMENT BY THE FEMORAL HIP. THE RETAINING RING DISPLAYED WEAR AND DEFORMATION OVER A 2 CM LENGTH. THE FRACTURE OCCURRED IN THE MIDDLE OF THAT WORN AREA. THE ULTIMATE MODE OF FAILURE WAS FATIGUE BUT THE CAUSE OF ITS INITIATION WAS FEMORAL IMPINGEMENT. NO MATERIAL OR MANUFACTURING DEFECTS WERE EVIDENT.

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(Database Updated February 5, 1999)

Master Event Record

Data Element

Device event key: 000095261
Report source code: M
Subs Mfr Report Flag: Y
Num devices in event: 00001
Num ptnts in event: 00001
MDR report key: 0000096489
Event key: 0000090818
Report number: 1219655-1997-00039
Date FDA received: 09-JUN-1997

Section B Form 3500A or 3500

Adverse event flag: Y
Product problem flag: N
Event outcome: REQUIRED INTERVENTION
Report date: 09-JUN-1997
Event description: JOHNSON AND JOHNSON PROFESSIONAL, INC., BECAME AWARE OF A REPORT OF 8 CASES OF HIP DISLOCATIONS REQUIRING OPEN REDUCTION AND/OR REPLACEMENT OF HIP PROSTHESES FROM A 1991 ARTICLE IN THE JOURNAL OF ORTHOPAEDICS (VOL. 14, NO.3). THE EVENTS DESCRIBED OCCURRED OVER AN UNKNOWN PERIOD OF TIME PRECEDING THE PUBLICATION.

section D Form 3500A

Brand name: S-ROM TOTAL HIP SYSTEM
Device type: CONSTRAINED HIP PROSTHESES
Manufacturer name: JOHNSON & JOHNSON PROFESSIONALS, INC.
Manufacturer street: 860 CANAL ST
City: STAMFORD
State: CT
Zip: 06902
Country code: us
Device operator: HEALTH PROFESSIONAL
Device expire date: NA
Device model number: NI
Device cat number: NI
Device lot number: NI
Other device ID num: NI
Avail for eval flag: N
Concomitant med prod: NI

Section E Form 3500A

Health prof flag: Y

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Section F Form 3500A

Distr aware of event: *(error)

000099

Report type: I
Report date: *(error)
Device age: *
sent to FDA flag: N
Event location: INVALID DATA

Section G Form 3500A

Report source: LITERATURE
Mfr received report: 05-JUN-1997
Report type: I
Manufacturer rep num: 1219655-1997-00099

Section H Form 3500A

Event report type: INJURY
Mfr evaluated flag: N
Device mfr'ed date: NI
Single use flag: Y
Previous use code: I
Addl mfr narrative: AT THE TIME OF THIS REPORT, JJPI IS NOT ABLE TO DETERMINE WHETHER THE EVENTS WITHIN THIS REPORT, HAVE ALREADY BEEN IDENTIFIED AND REPORTED THROUGH THE MED WATCH SYSTEM. DUE TO THE EXTENDED DATES OF THE PUBLISHED EVENTS, IT IS UNLIKELY THAT THE DEVICES WILL BE RETURNED FOR EVALUATION. OF THE FIVE PTS WHO SUFFERED DISLOCATIONS (8) AFTER CONSTRAINED INSERT REVISION; ONE INVOLVED AN OPEN NECK LENGTH CHANGE, ONE INVOLVED THE METAL CONSTRAINING RING DISENGAGING, TWO INVOLVED CHRONIC PARKINSONISM, AND FOUR HAVE CAUSES WHICH ARE UNKNOWN.
510K number: K901755
Product code: JDI

000100

MAUDE Search

BRAND NAME	S-ROM TOTAL, HIP SYSTEM
TYPE OF DEVICE	CONSTRAINED HIP PROSTHESES
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL ST STAMFORD, CT 06902 u s
DEVICE EVENT KEY	95268
MDR REPORT KEY	96496
EVENT KEY	90825
REPORT NUMBER	1219655-1997-00097
510(K) NUMBER	K851306
PRODUCT CODE	Jr .
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	09-JUN-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NI
DEVICE CATALOGUE NUMBER	NI
DEVICE LOT NUMBER	NI
OTHER DEVICE ID NUMBER	NI
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	NI
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	09-JUN-1997
REPORT SENT TO FDA FLAG	NO
INITIAL REPORT SOURCE	LITERATURE

DATE MANUFACTURER RECEIVED	03-JUN-1997
MANUFACTURER REPORT NO	1219655-1997-00097
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	NO
MANUFACTURE DEVICE DATE LABELED FOR SINGLE USE?	NI
REMEDIAL ACTION	YES
TYPE OF DEVICE USAGE	RECALL
TYPE OF DEVICE USAGE	INITIAL

EVENT DESCRIPTION

JOHNSON AND JOHNSON PROFESSIONAL, INC., BECAME AWARE OF A REPORT OF 1 CASE OF HIP DISLOCATION REQUIRING REPLACEMENT OF THE HIP PROSTHESES FROM A 1997 ARTICLE IN THE JOURNAL OF CONTEMPORARY ORTHOPAEDICS (VOL.23, NO.5). THE EVENTS DESCRIBED OCCURRED OVER AN UNKNOWN PERIOD OF TIME PRECEDING THE PUBLICATION.

ADDITIONAL MANUFACTURER NARRATIVE

AT THE TIME OF THIS REPORT, JJPI IS NOT ABLE TO DETERMINE WHETHER THE EVENTS WITHIN THIS REPORT, HAVE ALREADY BEEN IDENTIFIED AND REPORTED THROUGH THE MED WATCH SYSTEM. DUE TO THE EXTENDED DATES OF THE PUBLISHED EVENTS, IT IS UNLIKELY THAT THE DEVICES WILL BE RETURNED FOR EVALUATION. ONE PT SUFFERED DISLOCATION AFTER CONSTRAINED INSERT REVISION, REASONS UNKNOWN.

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(Database Updated February 5, 1999)

MAUDE Search

BRAND NAME	S-ROM TOTAL, HIP SYSTEM
TYPE OF DEVICE	CONSTRAINED HIP PROSTHESES
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL ST. STAMFORD, CT 06902 u s 95271 96499 90828 1219655-1997-00096 K85 1306 JDI MANUFACTURER
DEVICE EVENT KEY	
MDR REPORT KEY	
EVENT KEY	
REPORT NUMBER	
510(K) NUMBER	
PRODUCT CODE	
REPORT SOURCE	
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	09-JUN-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	M
DEVICE CATALOGUE NUMBER	M
DEVICE LOT NUMBER	M
OTHER DEVICE ID NUMBER	M
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	M
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	09-JUN-1997
REPORT SENT TO FDA FLAG	NO
INITIAL REPORT SOURCE	LITERATURE

DATE MANUFACTURER RECEIVED 03-JUN-1997
MANUFACTURER REPORT NO 1219655-1997-00096
EVENT REPORT TYPE INJURY
WAS DEVICE EVALUATED BY MANUFACTURER? NO
MANUFACTURE DEVICE DATE NI
LABELED FOR SINGLE USE? YES
TYPE OF DEVICE USAGE INITIAL

EVENT DESCRIPTION

JOHNSON AND JOHNSON PROFESSIONAL, INC., BECAME AWARE OF A REPORT OF 8 CASES OF HIP DISLOCATIONS REQUIRING OPEN REDUCTION AND/OR REPLACEMENT OF HIP PROSTHESES FROM A 1994 ARTICLE IN THE JOURNAL OF ARTHROPLASTY (VOL.9,NO. 1). THE EVENTS DESCRIBED OCCURRED OVER AN UNKNOWN PERIOD OF TIME PRECEDING THE PUBLICATION.

ADDITIONAL MANUFACTURER NARRATIVE

AT THE TIME OF THIS REPORT, JJPI IS NOT ABLE TO DETERMINE WHETHER THE EVENTS WITHIN THIS REPORT, HAVE ALREADY BEEN IDENTIFIED AND REPORTED THROUGH THE MED WATCH SYSTEM. DUE TO THE EXTENDED DATES OF THE PUBLISHED EVENTS, IT IS UNLIKELY THAT THE DEVICES WILL BE RETURNED FOR EVALUATION. OF THE SIX PTS WHO SUFFERED DISLOCATIONS (8) AFTER CONSTRAINED INSERT REVISION; FOUR INVOLVED DISASSOCIATION OF THE THE POLYETHYLENE LINERFROM THE METAL CUP, TWO INVOLVED THE FEMORAL HEAD BECOMING DISENGAGED FROM THE LINER ITSELF, AND TWO INVOLVED METAL REINFORCING RING BECOMING DISENGAGED FROM THE NECK OF THE POLYETHYLENE LINER.

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(Database Updated February 5, 1999)

MAUDE Search

BRAND NAME	S-ROM TOTAL, HIP SYSTEM
TYPE OF DEVICE	CONSTRAINED HIP PROSTHESES
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL ST STAMFORD, CT 06902 u s
DEVICE EVENT KEY	95284
MDR REPORT KEY	96515
EVENT KEY	9084 1
REPORT NUMBER	1219655-1997-00098
510(K) NUMBER	K890120
PRODUCT CODE	J i
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	09-JUN-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NI
DEVICE CATALOGUE NUMBER	NI
DEVICE LOT NUMBER	NI
OTHER DEVICE ID NUMBER	NI
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	NI
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	09-JUN-1997
REPORT SENT TO FDA FLAG	NO
INITIAL REPORT SOURCE	LITERATURE

DATE MANUFACTURER RECEIVED 03-JUN-1997
MANUFACTURER REPORT NO 1219655-1997-00098
EVENT REPORT TYPE INJURY
WAS DEVICE EVALUATED BY MANUFACTURER? NO
MANUFACTURE DEVICE DATE NI
LABELED FOR SINGLE USE? YES
TYPE OF DEVICE USAGE INITIAL

EVENT DESCRIPTION

JOHNSON AND JOHNSON PROFESSIONAL, INC., BECAME AWARE OF A REPORT OF 5 CASES OF HIP DISLOCATIONS REQUIRING OPEN REDUCTION AND/OR REPLACEMENT OF HIP PROSTHESES FROM A 1994 ARTICLE IN THE JOURNAL OF ARTHROPLASTY (VOL.9, N0.3). THE EVENTS DESCRIBED OCCURRED OVER AN UNKNOWN PERIOD OF TIME PRECEDING THE PUBLICATION.

ADDITIONAL MANUFACTURER NARRATIVE

AT THE TIME OF THIS REPORT, JJPI IS NOT ABLE TO DETERMINE WHETHER THE EVENTS WITHIN THIS REPORT, HAVE ALREADY BEEN IDENTIFIED AND REPORTED THROUGH THE MED WATCH SYSTEM. DUE TO THE EXTENDED DATES OF THE PUBLISHED EVEN-T'S, IT IS UNLIKELY THAT THE DEVICES WILL BE RETURNED FOR EVALUATION. OF THE FIVE PTS WHO SUFFERED DISLOCATIONS AFTER CONSTRAINED INSERT REVISION; TWO INVOLVED DISSOCIATION OF THE POLYETHYLENE LINER FROM THE METAL BACKED PORTION OF THE ACETABULAR CUP SYSTEM, AND THE CAUSE IS UNKNOWN FOR THE REMAINING THREE PTS.

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(Database Updated February 5, 1999)

MAUDE Search

BRAND NAME	SROM TOTAL HIP - POLYDIAL CONSTRAINED LINER
TYPE OF DEVICE	PROSTHETIC HIP - CONSTRAINED ACETABULAR LINER
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL STREET STAMFORD, CT 06902 u s
DEVICE EVENT KEY	134110
MDR REPORT KEY	137298
EVENT KEY	129110
REPORT NUMBER	1219655-1997-00181
510(K) NUMBER	K ⁰ 70271
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	11 -DEC- 1997
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	OTHER
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	521608
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	NI
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL
REPORT DATE	11 -DEC- 1997

REPORT SENT TO FDA FLAG	NO
MANUFACTURER NAME	JOHNSON & JOHNSON PROFESSIONALS, INC.
MANUFACTURER CONTACT	MATTHEW KING
	325 PARAMOUNT DRIVE
	RAYNHAM, MA
	02767
	(508) 828 -3 106
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	14-NOV-1997
MANUFACTURER REPORT NO	1219655-1997-00181
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	D
MANUFACTURE DEVICE DATE	UNK
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA
BASELINE BRAND NAME	SROMi TOTAL HIP - POLYDIAL CONSTRAINED LINER
BASELINE GENERIC NAME	PROSTHETIC HIP - CONSTRAINED ACETABULAR LINER
BASELINE CATALOGUE NUMBER	521608
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	SROM TOTAL HIP SYSTEM
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	20-APR-1987
DATE CEASED MARKETING	0000012227

EVENT DESCRIPTION

PATIENT IS REPORTED TO BE DISASSOCIATING OUT OF THE INSERT/LINER AND RING ASSEMBLY. NO INJURY HAS OCCURRED WITH THE PATIENT. THERE ARE NO PLANS FOR REVISION AT THIS TIME.

ADDITIONAL MANUFACTURER NARRATIVE

THE DEVICE REMAINS IMPLANTED IN THE PATIENT, REVISION SURGERY IS NOT PLANNED AT THIS TIME. THE DEVICE LOT NUMBER IS UNKNOWN, THEREFORE THE BATCH RECORDS CAN NOT BE REVIEWED. AT THIS TIME, JJPI CONSIDERS THIS FILE CLOSED.

MAUDE Search

BRAND NAME	SROM TOTAL HIP - POLYDIAL CONSTRAINED LINER
TYPE OF DEVICE	PROSTHETIC HIP - CONSTRAINED ACETABULAR LINER
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL STREET STAMFORD, CT 06902 u s
DEVICE EVENT KEY	134112
MDR REPORT KEY	137300
EVENT KEY	129112
REPORT NUMBER	1219655-1997-00182
510(K) NUMBER	K870271
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	11-DEC-1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	521628
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS N	
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL

REPORT SENT TO FDA FLAG	NO
MANUFACTURER NAME	JOHNSON & JOHNSON PROFESSIONALS, INC.
MANUFACTURER CONTACT	MATTHEW KING
	325 PARAMOUNT DRIVE
	RAYNHAM, MA
	02767
	(508) 828-3106
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	14-NOV-1997
MANUFACTURER REPORT NO	1219655-1997-00182
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	D
MANUFACTURE DEVICE DATE	UNK
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA
BASELINE BRAND NAME	S-ROM TOTAL HIP SYSTEM POLY-DTAL INSERT, U.H.M.W.P.E.
BASELINE GENERIC NAME	POLY-DIAL INSERT, CONSTRAINED
BASELINE CATALOGUE NUMBER	521628
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	S-ROM TOTAL HIP SYSTEM POLY-DIAL INSERT, U.H.M.W.P.E.
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	20-APR-1987
DATE CEASED MARKETING	0000004666
EVENT DESCRIPTION	
PATIENT WAS A CHRONIC DISLOCATOR FROM PREVIOUS TOTAL HIP REPLACEMENT RETAINING RING BROKE, REVISION SURGERY WAS NECESSARY.	
ADDITIONAL MANUFACTURER NARRATIVE	
THE DEVICE WILL NOT BE RETURNED FOR EVALUATION. THE DEVICE LOT NUMBER IS UNKNOWN, THEREFORE THE BATCH RECORDS CAN NOT BE REVIEWED. AT THIS TIME, JJPI CONSIDERS THIS FILE CLOSED.	

MAUDE Search

BRAND NAME	SROM TOTAL HIP - POLYDIAL CONSTRAINED LINER
TYPE OF DEVICE	PROSTHETIC HIP - CONSTRAINED ACETABULAR LINER
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL STREET. STAMFORD, CT 06902 u s
DEVICE EVENT KEY	134113
MDR REPORT KEY	137301
EVENT KEY	129113
REPORT NUMBER	1219655-1997-00183
510(K) NUMBER	K87,271
PRODUCT CODE	KWB
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	11-DEC-1997
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	OTHER
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	NA
DEVICE CATALOGUE NUMBER	521628
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
CONCOMITANT MEDICAL PRODUCTS	NI
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	INITIAL,

REPORT DATE	11 DEC 1997
REPORT SENT TO FDA FLAG	NO
MANUFACTURER NAME	JOHNSON & JOHNSON PROFESSIONALS, INC.
MANUFACTURER CONTACT	MATTHEW KING 325 PARAMOUNT DRIVE RAYNHAM, MA 02767 (508) 828 -3 106
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	14-NOV-1997
MANUFACTURER REPORT NO	1219655-1997-00183
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	D
MANUFACTURE DEVICE DATE	UNK
LABELED FOR SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
CORRECTION OR REMOVAL REPORT NUMBER	NA
BASELINE BRAND NAME	S-ROM TOTAL HIP SYSTEM POLY-DIAL INSERT, U.H.M.W.P.E.
BASELINE GENERIC NAME	POLY-DIAL INSERT, CONSTRAINED
BASELINE CATALOGUE NUMBER	521628
BASELINE MODEL NUMBER	NA
OTHER BASELINE ID NUMBER	NA
BASELINE DEVICE FAMILY	S-ROM TOTAL HIP SYSTEM POLY-DIAL INSERT, U.H.M.W.P.E.
PMA FLAG	NO
510(K) FLAG	YES
PREAMENDMENT FLAG	NO
TRANSITIONAL FLAG	NO
EXEMPT FLAG 510(K)	NO
DATE FIRST MARKETED	20-APR-1987
DATE CEASED MARKETING	0000004666

EVENT DESCRIPTION

A FEBRUARY 1997, X-RAY REVEALED THAT THE CONSTRAINING RING WAS BROKEN. THERE ARE NO PLANS FOR REVISION AT THIS TIME.

ADDITIONAL MANUFACTURER NARRATIVE

THE DEVICE REMAINS IMPLANTED IN THE PATIENT, REVISION SURGERY IS NOT PLANNED AT THIS TIME. THE DEVICE LOT NUMBER IS UNKNOWN, THEREFORE THE BATCH RECORDS CAN NOT BE REVIEWED. AT THIS TIME, JJPI CONSIDERS THIS FILE CLOSED.

MAUDE Search

BRAND NAME	SROM CONSTRAINED LINER
TYPE OF DEVICE	PROSTHETIC HIP - CONSTRAINED LINER
MANUFACTURER	JOHNSON & JOHNSON PROFESSIONALS, INC. 860 CANAL ST STAMFORD, CT 06902 u s
DEVICE EVENT KEY	153862
MDR REPORT KEY	157925
EVENT KEY	148427
REPORT NUMBER	1219655-1998-00038
510(K) NUMBER	K923065
PRODUCT CODE	KWL
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	20-MAR-1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	REQUIRED INTERVENTION
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	NA
DEVICE CATALOGUE NUMBER	52-1608
DEVICE LOT NUMBER	SC105359
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	24-FEB-98
CONCOMITANT MEDICAL PRODUCTS	PFC FEMORAL HIP HEAD, CAT# 85-383 1, LOT# 353996
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	FOLLOWUP
REPORT DATE	20-MAR-1998
REPORT SENT TO FDA FLAG	NO
EVENT LOCATION	HOSPITAL

INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	20-FEB-1998
MANUFACTURER REPORT NO	1219655-1998-00038
EVENT REPORT TYPE	INJURY
WAS DEVICE EVALUATED BY MANUFACTURER?	NO
MANUFACTURE DEVICE DATE LABELED FOR SINGLE USE?	UNK
TYPE OF DEVICE USAGE	YES
BASELINE BRAND NAME	INVALID DATA
BASELINE GENERIC NAME	SROM CONSTRAINED LINER
BASELINE CATALOGUE NUMBER	PROSTHETIC HIP - CONSTRAINED LINER
BASELINE MODEL NUMBER	52-1608
OTHER BASELINE ID NUMBER	*
DATE CEASED MARKETING	*
EVENT DESCRIPTION	0000015218

FEMORAL HEAD DISASSOCIATED FROM LINER. LOCKING RING WAS IN TACT. PT WAS RESTING AT HOME AND WOKE UP WITH THE DISASSOCIATION. REVISION SURGERY WAS NECESSARY.

ADDITIONAL MANUFACTURER NARRATIVE

MFG BATCH RECORD REVIEW FOUND NO DISCREPANCIES. DIMENSIONAL ANALYSIS OF DEVICE FOUND A DENT ON THE OUTERMOST RIM OF THE LINER AND NICKS AND SCRATCHES IN THE RING GROOVE. THE CONDITION OF THE EXPLANTED COMPONENT WAS UNREMARKABLE AS DETERMINED FROM IT'S APPEARANCE AND DIMENSIONAL ANALYSIS. IN SUMMARY, THE DIMENSIONAL INFO AVAILABLE SHOWS THAT THE DEVICES WERE MFG IN ACCORDANCE WITH SPECIFIED TOLERANCES AND MATERIALS AND WERE NOT DEFECTIVE. ALTHOUGH CONSTRAINED LINED LINERS HAVE HIGH DISSOCIATION LOADS, DISLOCATIONS ARE REPORTED. HOWEVER, DISLOCATIONS USUALLY OCCUR DUE TO CATASTROPHIC OR TRAUMATIC EVENTS, OR IN CASES WHERE THE PT'S PROFILE EXCEEDS THE "SAFE ZONE" OF THE DEVICE, IN THIS CASE THERE IS NOT SUFFICIENT DATA TO PINPOINT THE CAUSE OF THE ORIGINAL EVENT. AT THIS TIME, JJPI CONSIDERS THIS FILE CLOSED.

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(Database Updated February 5, 1999)

Access	Product Name	Manufacturer	Date	Report type
223881	POLYDIAL CONSTRAINED	JOINT MEDICAL PRODUCT	03/05/91	SERIOUS INJU
288805	POLYDIAL CONSTRAINED	JOINT MEDICAL PRODUCT	05/20/92	SERIOUS INJU
290139	POLY-DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	06/05/92	SERIOUS INJU
37265	POLY-DIAL NON-CONSTRA	JOINT MEDICAL PRODUCT	06/26/92	SERIOUS INJU
395314	POLY-DIAL INSERT, CON	JOINT MEDICAL PRODUCT	06/09/93	SERIOUS INJU
397715	POLY-DIAL INSERT; CON	JOINT MEDICAL PRODUCT	07/02/93	SERIOUS INJU
441357	POLY DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	10/22/93	SERIOUS INJU
474757	POLY DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	01/18/94	SERIOUS INJU
486168	POLYDIAL CONSTRAINED	JOINT MEDICAL PRODUCT	02/07/94	SERIOUS INJU
487677	POLYDIAL CONSTRAINED	JOINT MEDICAL PRODUCT	03/04/94	SERIOUS INJU
488463	POLYDIAL CONSTRAINED	JOINT MEDICAL PRODUCT	03/09/94	SERIOUS INJU
488464	POLYDIAL CONSTRAINED	JOINT MEDICAL PRODUCT	03/09/94	SERIOUS INJU
490208	POLY DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	03/24/94	SERIOUS INJU
493454	POLY DIAL INSERT, CON	JOINT MEDICAL PRODUCT	04/18/94	SERIOUS INJU
526762	POLY DIAL UHMWPE CONS	JOINT MEDICAL PRODUCT	07/13/94	SERIOUS INJU
559822	POLY-DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	10/04/94	SERIOUS INJU
578668	S-ROM POLY-DIAL CONST	JOINT MEDICAL PRODUCT	01/03/95	SERIOUS INJU
589947	S-ROM POLY-DIAL CONST	JOINT MEDICAL PRODUCT	01/17/95	SERIOUS INJU
803483	POLY-DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	04/06/95	MALFUNCTION
711181	S-ROM POLY-DIAL CONST	JOINT MEDICAL PRODUCT	05/17/95	SERIOUS INJU
842767	POLY-DIAL INSERT (CON	JOINT MEDICAL PRODUCT	10/27/95	MALFUNCTION
736850	POLY-DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	11/16/95	SERIOUS INJU
741253	S-ROM POLY-DIAL CONST	JOINT MEDICAL PRODUCT	12/06/95	SERIOUS INJU
847139	POLY-DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	11/08/95	MALFUNCTION
743066	POLY-DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	01/02/96	SERIOUS INJU
762176	POLY-DIAL CONSTRAINED	JOINT MEDICAL PRODUCT	06/21/96	SERIOUS INJU

000115

Medical Device Reporting Full Display

Access number: 223881
Date received: 03/05/91
Product name: POLYDIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: F (P/F = Preliminary/Final)

Event description: PT HAS HAD SEVERAL PREVIOUS DISLOCATIONS. SUBJECT
DEVICE WAS IMPLANTED 10/90. HEAD HAD DISLOCATED
FROM CONSTRAINED INSERT. CUP AND INSERT REMAINED IN
PLACE WITH CONSTRAINING RING STILL LOCKED ONTO
INSERT. THE HEAD REPORTED TO BE USED WAS ANOTHER
MFR'S. THE PACKAGE INSERT CONTRAINDICATES USE WITH
HEADS FROM OTHER MFRS AND ALSO CONTRAINDICATES WITH
HEADS WITH SKIRTS OF DIAMETER FOUND ON THIS HEAD.

Closeout description: THE CAUSE OF THIS EVENT HAS BEEN DETERMINED TO BE
THE USE OF THE DEVICE.

Medical Device Reporting Full Display

Access number: 288805
Date received: 05/20/92
Product name: POLYDIAL CONSTRAINED ACETABULAR CUP INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: F (P/F = Preliminary/Final)

Event description: REVISION DUE TO DISLOCATION.

Closeout description: THIS REPORT WAS REVIEWED FOR SIGNIFICANT PROBLEMS
BUT WAS NOT CLOSED. IT IS BEING CLOSED AT THIS TIME
AS PART OF A BATCH CLOSEOUT PROCESS IN ORDER TO
PREPARE THE DATABASE TO SERVE AS HISTORICAL SUPPORT
TO A REDESIGNED DATABASE.

Medical Device Reporting Full Display

Access number: 290139
Date received: 06/05/92
Product name: POLY-DIAL CONSTRAINED ACETABULAR INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY

000116

Panel code: 87
Product code: KWB
Model number: NA
Event type: F (P/F = Preliminary/Final)
Event description: DISLOCATION AND SUBSEQUENT REVISION SURGERY WAS REPORTED. PT IS CHARACTERIZED AS NON-COMPLIANT.
Closeout description: THIS REPORT WAS REVIEWED FOR SIGNIFICANT PROBLEMS BUT WAS NOT CLOSED. IT IS BEING CLOSED AT THIS TIME AS PART OF A BATCH CLOSEOUT PROCESS IN ORDER TO PREPARE THE DATABASE TO SERVE AS HISTORICAL SUPPORT TO A REDESIGNED DATABASE.

Medical Device Reporting Full Display

Access number: 297265
Date received: 06/26/92
Product name: POLY-DIAL NON-CONSTRAINED ACETABULAR INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: F (P/F = Preliminary/Final)

Event description: DEVICE WAS IMPLANTED IN 1986. PT UNDERWENT REVISION SURGERY 6/16/92.

Closeout description: THIS REPORT WAS REVIEWED FOR SIGNIFICANT PROBLEMS BUT WAS NOT CLOSED. IT IS BEING CLOSED AT THIS TIME AS PART OF A BATCH CLOSEOUT PROCESS IN ORDER TO PREPARE THE DATABASE TO SERVE AS HISTORICAL SUPPORT TO A REDESIGNED DATABASE.

Medical Device Reporting Full Display

Access number: 395314
Date received: 06/09/93
Product name: POLY-DIAL INSERT, CONSTRAINED
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902

Report type: SERIOUS INJURY

Panel code: 87

Product code: JDI

Model number: NA

Event type: F (P/F = Preliminary/Final)

Event description: IT WAS REPORTED THAT THE PT WAS IN BED, SAT UP TO REACH FOR LIGHT SWITCH AND FELT PAIN. IT WAS FURTHER REPORTED THAT THE HIP PROSTHESIS DISLOCATED. THE PRODUCT WAS USED WITH A FEMORAL HEAD WHICH WAS NOT A FULL SPHERE. THE PACKAGE INSERT WARNS THAT THIS PROVIDES LESS SECURITY. (*)

Closeout description:

Medical Device Reporting Full Display

000117

Access number: 397715
Date received: 07/02/93
Product name: POLY-DIAL INSERT; CONSTRAINED
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA
Event type: F (P/F = Preliminary/Final)
Event description: THE PT FELL FROM THE TOILET AND THE FEMORAL
COMPONENT DISLOCATED FROM THE CONSTRAINED INSERT
WHILE THE RING WAS STILL IN PLACE. EXAM OF THE
EXPLANTED DEVICE REVEALS THAT THE FEMORAL HEAD
WHICH WAS USED WAS NOT A FULL SPHERE. THE PACKAGE
INSERT WARNS THAT USE WITH THIS DEVICE OF A FEMORAL
HEAD WHICH IS NOT A FULL SPHERE PROVIDES LESS
SECURITY.

Closeout description:

Medical Device Reporting Full Display

Access number: 441357
Date received: 10/22/93
Product name: POLY DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA
Event type: P (P/F = Preliminary/Final)
Event description: THE PROSTHESIS DISLOCATED. EXAMINATION OF THE
EXPLANTED DEVICE REVEALS THAT IT WAS IMPLANTED IN
CONJUNCTION WITH A FEMORAL HEAD FROM ANOTHER MFR AND
THAT HEAD WAS NOT A COMPLETE SPHERE. LABELING FOR
THE INSERT CAUTIONS THAT USE WITH FEMORAL HEADS
WHICH ARE NOT COMPLETE SPHERES PROVIDES LESS
SECURITY. IN ADDITION, THE FEMORAL HEAD USED IN
CONJUNCTION WITH THIS DEVICE WAS OF A SKIRTED
DESIGN. THE PACKAGE INSERT ALSO WARNS ABOUT THIS.

Closeout description:

Medical Device Reporting Full Display

Access number: 474757
Date received: 01/18/94
Product name: POLY DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT

000118

Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA
Event type: P (P/F = Preliminary/Final)
Event description: THE HIP PROSTHESIS DISLOCATED AND WAS SUBSEQUENTLY REVISED. EXAM OF THE DEVICES USED REVEALED THAT THE FEMORAL HEAD WAS MFG BY A DIFFERENT CO AND THAT THE HEAD DISIGN WAS NOT A FULL SPHERE AND WAS SKIRTED. THE PACKAGE INSERT WARNS ABOUT THE USE OF A HEAD WHICH IS NOT A COMPLETE SPHERE AND WHICH HAS A SKIRT.

Closeout description:

Medical Device Reporting Full Display

Access number: 486168
Date received: 02/07/94
Product name: POLYDIAL CONSTRAINED ACETABULAR INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: P (P/F = Preliminary/Final)

Event description: THE PT DISLOCATED AND SUBSEQUENTLY UNDERWENT REVISION SURGERY.

Closeout description:

Medical Device Reporting Full Display

Access number: 487677
Date received: 03/04/94
Product name: POLYDIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: P (P/F = Preliminary/Final)

Event description: APPROX 8 MONTHS POST-OP, PT BENT OVER AND THE HIP DISLOCATED.

Closeout description:

Medical Device Reporting Full Display

Access number: 488463
Date received: 03/09/94
Product name: POLYDIAL CONSTRAINED ACETABULAR INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST

000119

State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA
Event type: P (P/F = Preliminary/Final)
Event description: IT IS REPORTED THAT DEVICE DISLOCATED. IT IS FURTHER REPORTED THAT THIS DEVICE WAS USED IN CONJUNCTION WITH A SKIRTED FEMORAL HEAD. THE PACKAGE INSERT WARNS ABOUT THE USE OF THE DEVICE IN CONJUNCTION WITH A SKIRTED FEMORAL HEAD.

Closeout description:

Medical Device Reporting Full Display

Access number: 488464
Date received: 03/09/94
Product name: POLYDIAL CONSTRAINED ACETABULAR INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA
Event type: P (P/F = Preliminary/Final)
-Event description: THIS REPORT IS BASED UPON A LITERATURE ARTICLE; JOURNAL OF ARTHROPLASTY, VOL 9 #1 (17-23PG) 1994; "CONSTRAINED ACETABULAR COMPONENTS." THE ARTICLE REPORTS ON REVISION SURGERY IN 21 PTS WHO WERE EITHER CHRONIC DISLOCATORS OR WHO HAD INTRAOPERATIVE INSTABILITY. OF THE 21 PTS, 6 SUBSEQUENTLY HAD A TOTAL OF 8 DISLOCATIONS. A ROENTGENOGRAM ACCOMPANYING THE ARTICLE SHOWS THAT AT LEAST ONE LOCATION INVOLVES A FEMORAL HEAD MFG BY ANOTHER CO WHICH IS NOT A COMPLETE SPHERE. THE PACKAGE INSERT CAUTIONS ABOUT USE OF THE DEVICE WITH HEADS MANUFACTURED TO DIFFERENT TOLERANCES OR WHICH ARE NOT A FULL SPHERE. IT IS UNKNOWN IF ANY OF THE ABOVE CASES WERE PREVIOUSLY REPORTED.

Closeout description:

Medical Device Reporting Full Display

Access number: 490208
Date received: 03/24/94
Product name: POLY DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB

000120

Event type: P (P/F = Preliminary/Final)
Event description: THE PT UNDERWENT REVISION SURGERY AFTER DISLOCATION
OF THE FEMORAL HEAD ALLEGEDLY DUE TO FRACTURE OF
THE INSERT.

Closeout description:

Medical Device Reporting Full Display

Access number: 493454
Date received: 04/18/94
Product name: POLY DIAL INSERT, CONSTRAINED
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA

Event type: P (P/F = Preliminary/Final)
Event description: THE PT DISLOCATED POST-OP.
Closeout description:

Medical Device Reporting Full Display

Access number: 526762
Date received: 07/13/94
Product name: POLY DIAL UHMWPE CONSTRAINED SOCKET
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST.
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA

Event type: P (P/F = Preliminary/Final)
Event description: PT DISLOCATED AND THE CONSTRAINING RING WAS BROKEN.
A REVISION WAS PERFORMED AND A NEW CONSTRAINED
INSERT WAS IMPLANTED. PT TOLERATED THE PROCEDURE
WELL AND AS OF THIS DATE HAD NO FURTHER
COMPLICATIONS.

Closeout description:

Medical Device Reporting Full Display

Access number: 559822
Date received: 10/04/94
Product name: POLY-DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST.
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB

000121

Event type: P (P/F = Preliminary/Final)
Event description: THE PT'S HIP DISLOCATED FOLLOWING SURGERY. THE DR
PERFORMED A REVISION AND THE PT'S CONDITION IS
SATISFACTORY.

Closeout description:

Medical Device Reporting Full Display

Access number: 578668
Date received: 01/03/95
Product name: S-ROM POLY-DIAL CONSTRAINED SOCKET
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST.
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA

Event type: F (P/F = Preliminary/Final)
Event description: THE PT'S HIP DISLOCATED DURING ACTIVITY. REVISION
SURGERY WAS PERFORMED AND DEVICE WAS REPLACED.

Closeout description:

Medical Device Reporting Full Display

Access number: 589947
Date received: 01/17/95
Product name: S-ROM POLY-DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST.
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA

Event type: F (P/F = Preliminary/Final)
Event description: AT AN UNSPECIFIED TIME POST-IMPLANTATION, IT WAS
REPORTED THAT THE PT'S HIP DISLOCATED. A REVISION
WAS PERFORMED AND ANOTHER DEVICE WAS IMPLANTED.

Closeout description:

Medical Device Reporting Full Display

Access number: 803483
Date received: 04/06/95
Product name: POLY-DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST.
City: STAMFORD
State: CT
Zipcode: 06902
Report type: MALFUNCTION
Panel code: 87
Product code: KWB
Model number: NA

000122

Event description: REPORTEDLY, THE DEVICE "SPLIT" WHILE BEING
IMPLANTED.

Closeout description:

Medical Device Reporting Full Display

Access number: 711181

Date received: 05/17/95

Product name: S-ROM POLY-DIAL CONSTRAINED INSERT

Manufacturer: JOINT MEDICAL PRODUCTS CORP.

Street: 860 CANAL ST.

City: STAMFORD

State: CT

Zipcode: 06902

Report type: SERIOUS INJURY

Panel code: 87

Product code: KWB

Model number: NA

Event type: F (P/F = Preliminary/Final)

Event description: PT HIP DISLOCATED AT AN UNSPECIFIED TIME FOLLOWING
A TOTAL HIP ARTHROPLASTY PROCEDURE. A REVISION
SURGERY WAS PERFORMED TO CORRECT THIS CONDITION.

Closeout description:

Medical Device Reporting Full Display

Access number: 842767

Date received: 10/27/95

Product name: POLY-DIAL INSERT (CONSTRAINED

Manufacturer: JOINT MEDICAL PRODUCTS CORP.

Street: 860 CANAL ST.

City: STAMFORD

State: CT

Zipcode: 06902

Report type: MALFUNCTION

Panel code: 87

Product code: KWB

Model number: NA

Event type: F (P/F = Preliminary/Final)

Event description: THE SURGEON ALLEGED THAT THE CONSTRAINING RING
WOULD NOT FIT ON THE INSERT. THE INSERT WAS LEFT
IMPLANTED WITHOUT USING THE CONSTRAINING RING.
IMPLANT DATE: 10/9/95. INSERT WAS NOT RETURNED FOR
EVAL, AS IT WAS LEFT IMPLANTED. HOWEVER, THE
CONSTRAINING RING WAS RETURNED. THE CONSTRAINING
RING MET SPECS AND THEREFORE CO CANNOT EXPLAIN THIS
EVENT. IT SHOULD BE NOTED THAT THE PACKAGE INSERT
WARNS AGAINST THE USE OF A CONSTRAINED INSERT
WITHOUT A CONSTRAINING RING. DEVICE MFR DATE: 6/95.

Closeout description:

Medical Device Reporting Full Display

Access number: 736850

Date received: 11/16/95

Product name: POLY-DIAL CONSTRAINED INSERT

Manufacturer: JOINT MEDICAL PRODUCTS CORP.

Street: 860 CANAL ST.

City: STAMFORD

Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA
Event type: F (P/F = Preliminary/Final)
Event description: DEVICE WAS USED DURING A TOTAL HIP ARTHROPLASTY
PROCEDURE. APPROX TEN DAYS POST-IMPLANTATION, THE
PT'S HIP ALLEGEDLY DISLOCATED. THE SURGEON
PERFORMED A REVISION SURGERY ON 11/15/95 TO ADDRESS
THIS CONDITION.

Closeout description:

Medical Device Reporting Full Display

Access number: 741253
Date received: 12/06/95
Product name: S-ROM POLY-DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL STREET
City: STAMFORD
State: CT
Zipcode: 06902

Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA
Event type: F (P/F = Preliminary/Final)
Event description: DURING SOME MEDICAL RESEARCH AN ARTICLE FROM 1991
WAS DISCOVERED WHICH REFERENCES THE CONSTRAINED
ACETABULAR INSERT. THE ARTICLES MENTIONS 5 CASES OF
DISLOCATION WHICH REQUIRED SOME FORM OF MEDICAL
INTERVENTION. IT IS NOT KNOWN IF THESE CASES WERE
PREVIOUSLY REPORTED OR IF THE PRODUCT CAUSED OR
CONTRIBUTED TO THE DISLOCATIONS. BECAUSE THE
ARTICLE IS ALMOST 5 YRS OLD, INFO MAY NOT BE
AVAILABLE.

Closeout description:

Medical Device Reporting Full Display

Access number: 847139
Date received: 11/08/95
Product name: POLY-DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST.
City: STAMFORD
State: CT
Zipcode: 06902

Report type: MALFUNCTION
Panel code: 87
Product code: KWB
Model number: NA
Event type: F (P/F = Preliminary/Final)
Event description: APPROX 1 YR POST-IMPLANTATION THE CONSTRAINING RING
DETACHED FROM THE ACETABULAR INSERT. THIS DETECTED
DURING AN X-RAY EXAM ON 9/6/95. THERE HAS BEEN NO
MEDICAL INTERVENTION AS OF THIS DATE. HOWEVER,

000124

THE FUTURE.

Closeout description:

Medical Device Reporting Full Display

Access number: 743066
Date received: 01/02/96
Product name: POLY-DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS CORP.
Street: 860 CANAL ST.
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: KWB
Model number: NA

Event type: F (P/F = Preliminary/Final)
Event description: DEVICE WAS USED DURING A TOTAL HIP ARTHROPLASTY
PROCEDURE. SEVERAL MONTHS POST-IMPLANTATION THE
PT'S HIP DISLOCATED REQUIRING A REVISION SURGERY,
WHICH WAS PERFORMED ON 12/29/95. THE DEVICE WAS
USED IN CONJUNCTION WITH A NONSPHERICAL FEMORAL HEAD
(MFG BY ANOTHER CO). THE PACKAGE INSERT INDICATES
THAT THE USE OF A FEMORAL HEAD THAT IS NOT A
COMPLETE SPHERE PROVIDES LESS SECURITY. ALSO,
INSERT STRONGLY ADVISED AGAINST THE USE OF ANOTHER
MFR'S COMPONENTS IN CONJUNCTION WITH CO COMPONENTS.
THE DEVICE WAS DISCARDED BY THE HOSP AND THE LOT#
IS UNKNOWN.

Closeout description:

Medical Device Reporting Full Display

Access number: 762176
Date received: 06/21/96
Product name: POLY-DIAL CONSTRAINED INSERT
Manufacturer: JOINT MEDICAL PRODUCTS JOHNSON AND JOHNSON
Street: 860 CANAL ST.
City: STAMFORD
State: CT
Zipcode: 06902
Report type: SERIOUS INJURY
Panel code: 87
Product code: JDI
Model number: NA

Event type: F (P/F = Preliminary/Final)
Event description: THE DEVICE WAS USED DURING A TOTAL HIP ARTHROPLASTY
PROCEDURE. APPROX EIGHT MONTHS POST-OPERATIVELY A
REVISION SURGERY WAS PERFORMED DUE TO DIFFICULTIES
EXPERIENCED BY THE PT. EVAL ANTICIPATED. IMPLANTED
10/95. EXPLANTED 6/13/96.

Closeout description:

000125