Report Generated on 7/8/2003 16:18:12

PRODUCT COMPLAINT REPORT

ISSUE CAPTURE INFORMATION

Record No.: 117014

Date Record Entered: 13-Jan-2003 **Entered By:** CYNTHIA HITCHCOCK

Contact: SACHS, BART **Title:** Surgeon **Phone:** 972-378-0986

Synthes Account: 382723

Facility: Presbyterian Hospital of Plano
Address: 6200 W. PARKER ROAD
PLANO, TX 75093-7914
United States

Associated Entities:

Role	Name
Manufacturer	Norian Corporation
Patient	ESKIND, LOIS
Sales Consultant	Burgess, Patrick
Surgeon	SACHS, BART

Date of Event: 13-Jan-2003 **Approx Date:** No **Communication Method:** Phone

Investigated By: HITCHCOCK, CYNTHIA

Issue Classification External Issue\External Complaint\Norian Complaint

Issue Description:

Dr. Sachs reported that during a Vertebral Plasty surgery for Vertebral compression fractures the patient expired. Dr Sachs did not attribute the death to the Norian produc

Additional Information:

Dr. added 6 grams of barium sulfate.
Injected SRS into L4 then injected into L2 after injection into L2 patients heart stopped. CPR was administrated for approximately 30 minutes and patient expired.
Doctor was asked if the Norian product contributed to the death? Doctor's response, "If I thought that there was a problem with the product I wouldn't have used it (the product)". Dr. Sach reported he does not attribute the product to the death.
Patient was a smoker with multiple heart attacks, arteriolosclerosis. She was a bed ridden for 8 weeks prior due to pain.

Products:

Model #	Model Description	Serial/Lot #	Quantity	Unit of Measure
SRS-010-US	SRS BONE CEMENT 10CC-STERILE	N327501	1	EA
SRS-010-US	SRS BONE CEMENT 10CC-STERILE	N327101	1	EA

Issue AKA Supplemental Information:

Code Type	Code Value

Secondary Issue Classification(s):

* Product type\Implant
* Injury Type\Not Applicable-Not Reportable
* Complaint Type\S14 - SRS, Misc.
* Company\Norian

Record Status: Closed
Date Record Closed: 7/8/2003
Reply Requested: No

P. Lintner 7/8/03.
Closed By: PAT LINTNER
7/8/03

GOVERNMENT'S EXHIBIT 4

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PRODUCT COMPLAINT REPORT

REGULATORY REPORTING INFORMATION

Record No.: 117014

Date Co. Notified 13-Jan-2003

MedWatch #:

MDR Reportable? No

If Not, Rationale:
Does not meet the definition of an MDR Reportable event. Medical professional did not believe the product caused or contributed to patients death.

Investigate? Yes

If No, Rationale:

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PRODUCT COMPLAINT REPORT

Record No.: 117014

RETURNED PRODUCT(S) ANALYSIS INFORMATION

Product Received in Paoli:

Device History Record Search/Review

Reviewed? Yes Date Reviewed: 08-Jul-2003

Reviewed By: LINTNER, PAT

Search Findings: The pouch lot records were reviewed and no irregularities were found

Product Analysis Details

Evaluated By: LINTNER, PAT Evaluation Date:

Analysis Findings: The product was not available for return/evaluation. A review of the device history records indicated product was made to specification.

Product Received in Paoli:

Device History Record Search/Review

Reviewed? Yes Date Reviewed: 03-Jul-2003

Reviewed By: LINTNER, PAT

Search Findings: The pouch lot records were reviewed and no irregularities were found

Product Analysis Details

Evaluated By: LINTNER, PAT Evaluation Date:

Analysis Findings: The product was not available for return/evaluation. A review of the device history records indicated product was made to specification.

MDR Decision Tree for Issue ID: 117014

Situation: A complaint or information involving a Synthes device has been received.
Directions: Apply the complaint description or information received to the following questions. If any of these questions cannot be answered, follow-up with the customer or person reporting this information is required.

Total Decision Category Tree Path:
Question 1\Question 2\Question 3\Report Not Required (#3)

Person Responsible for Decision	Date Decided
ESPOSITO, DOMINICK	23-January-2003

Category Node	Help Text for Category Node
Question 1	1. Does the information reasonably suggest a Synthes/Norian device has or may have caused or contributed to a death or serious injury, whether the product was misused or not? If Yes - Go to #4, else No - Go to #2
Question 2	2. Does the info reasonably suggest that a Synthes/Norian device has malfunctioned (i.e. failed to meet any of its performance specifications or has not performed as intended), regardless of whether it was misused? If Yes - Go to #3 else No - Report not required
Question 3	3. If this malfunction were to recur, would it likely result in a death or serious injury? Note: Synthes interprets "likely" to mean that if the malfunction has resulted in a death or serious injury once within the past two years, it is "likely" to cause or contribute to a death or serious injury should it recur. If Yes - Go to #8 else No - Report Not Required
Report Not Required (#3)	

DECISION SUMMARY & REVIEW

___ Reportable Event - Submission Required: ___ 5 Day Report ___ 30 Day Report ___ Baseline Report

_X_ Non-Reportable Event (rationale for non-reportable):

Does not meet the definition of an MDR Reportable event.

_X_ **Verified Death or Serious Injury has not occurred in the past two years.**

Determination made by: _____ Title: QA Manager Date: 7/8/03

Determination reviewed by: _____ Title: QC Engr Date: 7/8/03

SUBMISSION VERIFICATION

Date of Submission(s) _____ MDR Reference Number _____

Submitted by: _____ Title: _____ Date: _____

*ORIGINAL WAS MISPLACED
ORIGINALLY SIGNED AT TIME OF ENTRY OF ISSUE WITHIN TIMING REQUIRED LPL 7/8/03

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