



279

American Board
of Plastic Surgery

CENTER FOR SURGICAL EXCELLENCE

6606 10th Avenue North
St. Petersburg, FL 33710

727-341-0337

⊕ AAAASF
accredited.

ADVERSE INCIDENT REPORT

Incident date: 09-22-03

Patient Name: _____ Date of Birth: _____
Address: _____

Admitting Diagnosis: Bilateral Breast Involution
Procedure: Bilateral Endoscopic Breast Augmentation

Brief Description: Patient had a normal pre-op EKG. 2nd degree heart block occurring during surgery. Maintained medically per anesthesiologist with atropine to sinus rhythm for remainder of surgery. Intermittent return of heart irregularity in P.A.C.U.. Telephone consult with patient's cardiologist and an independent cardiologist. Also, consult with anesthesia and surgeon. Decision made for hospital admission with telemetry observation.

Breast Aug → general anesthesia by MD anesthesiologist → no essential surgery
arrangement →

Location of Incident: Center for Surgical Excellence

Type of Incident: Unplanned transfer/admission

Related Factors: 1997 - cardiac ablation

Witness: Robert D. Rehnke MD ME 55774

Thomas Conroy M.D. - anesthesiologist ME 61234

Sandra Reese Richmond RN RN 56581-2

Team Member Reporting: Sandra Reese Richmond RN

Nurse manager

Risk Manager/ Robert D. Rehnke, M.D.

Privileges @ St. Petersburg General Hosp
Palms of Pasadena

Hos

727-341-7776

Robert D. Retinke, M.D.

PROGRESS NOTE

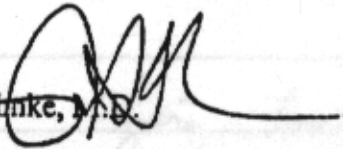
PROGRESS NOTES

PATIENT: [REDACTED]

DATE: 09/22/03

PATIENT NO: [REDACTED]

[REDACTED] is a [REDACTED]-year-old [REDACTED] female who underwent endoscopic breast augmentation today in the office operating room. She is an ASA 2 patient with a past history of supraventricular tachycardia which was treated six years ago with cardiac catheterization and ablation of an aberrant pathway by Dr. Norris. She was treated by Dr. Walsh, her cardiologist, who referred her to Dr. Norris who we sent her to for preoperative EKG which was normal. She underwent the surgery in the office under a general anesthetic and was noted to have periods of bradycardia with second degree heart block during the procedure. This was a stable rhythm with normal blood pressure and 100% O₂ saturation throughout the case. She was treated by her anesthesiologist, Dr. Conroy, with an anticholinergic medication, Robinul. This kept her heart rate in the 70's and 80's. She, however, returned to a second degree block with pulses in the 50's at the end of the procedure prior to extubation. She was transferred in stable condition to the recovery room where she was monitored, and her situation was discussed with Dr. Walsh. He recommended that she could be transferred home and followed up in the office for an outpatient Holter monitor evaluation. I, however, felt uncomfortable discharging her home after elective procedure with a second degree heart block. After discussing this with Dr. Conroy and both with the patient's [REDACTED] and the patient, both of whom are R.N.'s, we all agreed that the patient would receive the best care if she were transferred to Palms of Pasadena on Telemetry. Therefore I called and spoke with Dr. Peter Wassmer and presented the case to him. He agreed to admit the patient to Telemetry at Palms of Pasadena and evaluate and treat her if necessary. She was transferred to Palms of Pasadena via Sun Star ambulance in stable condition, and in fact at the time of the transfer monitor was noted to be in sinus rhythm. We plan to follow her in the hospital with Dr. Wassmer, and we will see her in the office next week to follow-up her surgical recovery progress. She will be returned to Dr. Walsh's office for outpatient evaluation.

Robert D. Retinke, M.D. 

RDR/blb

Printed Date: 09/23/03

[Faint handwritten notes and signatures are visible in the background of the page.]

Robert D. Rehnke, M.D.
PROGRESS NOTES

PATIENT NAME: [REDACTED]

DATE: 9/22/03

pt a hr SVT 5/8 fibrillation 1997 with no symptoms of
arrhythmia after the ablation procedure. During long mapping for
intubation, HR Δ from 70's to 30's. No c BP. HR recovered
5 specific Rx to 70's in 1 minute.

During ablation of dissecting balloon R breast, \downarrow HR again; several
nonconducted P waves noted, with junctional escape beats. Pulsed
0.2 mg IV \rightarrow immediate return of HR to 80's (also deflated balloon
dissector). BP again remained stable.

Inflation of dissecting balloon on @ side several minutes later associated
with recurrence of bradycardia \pm Type II 2^o AV block and junctional
escape beats. ECG tracing printed.

12¹⁵ post-op: ongoing lead block. will discuss Dr. Walsh/Morris
Duncan & Dr. Walsh who suggests 4hr outpt workup; however, after
speaking w pt / pt [REDACTED] / Dr. [REDACTED] we all agree that overnight telemetry
would be safest course of action.

Will transport to Palms of Pasadena for admission to telemetry bed.

Risk Manager / Robert D. Rehnke, M.D.

[Signature]



Thomas Fiala, MD, FRCSC, FACS

OSL 371

Aesthetic Plastic Surgery

Suite 2020, CenterPointe II
220 E. Central Parkway
Altamonte Springs, FL 32701
407-339-3222 • 800-330-4414
Fax: 407-339-3085
www.dr.fiala.com

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Board cert. yes.
American Board of
Plastic Surgery

Abdominoplasty/liposuction - ideal
pt. Entails

Date of surgery: May 12, 2003

Type of surgery: Abdominoplasty with small volume liposuction of flanks

Complication: Death within 24 hours of surgery (patient at home) - May 13, 2003

Tuesday, May 20, 2003

no accreditation
from SCATS

Department of Health / Medical Quality Assurance
4052 Bald Cypress Way
Bin C03
Tallahassee, Florida 32399-3253

AAAASF
accredited

RE: Potential Code 15 Report

Arnold Palmer
Fla. Surg. Center
407-649-9111

To Whom It May Concern:

My P.A.'s in-office surgical suite is AAAASF accredited. At this suite, less than 24 hours prior to [redacted] medical emergency, [redacted] underwent an abdominoplasty with small volume liposuction.

In keeping with voluntary reporting practices, enclosed is my Code 15 Report.

Sincerely,

Thomas Fiala MD.

Thomas Fiala, MD, FACS, FRCSC
Preferred Plastic Surgery of Orlando, P.A.

Patient Name: [REDACTED]

Date of birth: [REDACTED]

SSN: [REDACTED]

Date of surgery: May 12, 2003

Type of surgery: Abdominoplasty with small volume liposuction of flanks

Complication: Death within 24 hours of surgery (patient at home) - May 13, 2003

Cause of death: Pulmonary embolism

Narrative:

This patient desired improvement of her abdominal contour. She had marked abdominal skin and muscle laxity. After a complete evaluation, I felt she was a reasonable candidate for an abdominoplasty ("tummy tuck") procedure combined with small volume flank liposuction. She had no major health history, and had quit smoking over 3 years earlier. Past history included a facelift (done elsewhere) and a breast biopsy. She had no previous difficulties with anesthesia, and no reported previous history of DVT. The risks of the surgery, including major complications, were discussed and documented in detail, both at her initial consultation, and at her pre-operative appointment.

Pre-op lab tests included a CBC, and chemistry panel, which were within normal limits. A pre-op EKG was also obtained, which was within normal limits.

The pre-surgical medical examination was within normal limits. At that time, there was no evidence of any pulmonary problems or DVT.

Surgery was performed at my office surgery suite, which is AAAASF accredited, and registered with the State of Florida. Dr. Peter Rose, a Board-Certified MD Anesthesiologist, administered the general anesthesia (class III procedure).

The patient was brought to the operating room, and general anesthesia was established. Intubation of the patient was straightforward. The suction-assisted lipectomy using a super-wet technique was performed in the flank area, with the patient in the prone position. Less than 1 litre of supernatant fat was removed

Conclusion:

from the flank area. The patient was then returned to the supine position. Thigh-level sequential compression devices (SCD's) were placed on the patient and activated before re-prepping and re-draping the patient for the abdominoplasty. The abdominoplasty with rectus muscle plication was next performed, using accepted techniques.

Intra-operative anesthesia was unremarkable, with the single exception of an episode of bradycardia lasting approximately 30 seconds, which was rapidly diagnosed and treated with intravenous atropine. Blood loss for the procedure was minimal. There was good urine output, indicating appropriate hydration of the patient.

Attachments:

The patient's recovery in the PACU was monitored by Sandra Cooper, RN, an experienced PACU nurse. The patient's recovery was unremarkable; I checked on the patient several times. She had stable vital signs, normal EKG and pulse oximetry, no significant discomfort, and her surgical sites appeared normal. The SCD's were continued in the recovery room and overnight.

Postoperatively, she was kept overnight under supervision, as had been planned. She was monitored by Isabel Meridith, LPN, an ACLS-trained nurse. I personally checked on the patient at approximately 8PM, prior to heading home for the evening - she was speaking normally, appeared comfortable, and her surgical sites appeared normal, without any signs of bleeding, seroma, hematoma or infection. Vital signs, including heart rate and respiratory rate, were normal. I again checked her at approximately 7:45 AM the next day. Again she was awake, alert and speaking, and appeared normal. She had no complaints of any kind. There were no complaints of chest pain or dyspnea. Neither my staff nor I observed any tachypnea or shortness of breath postoperatively. Her dressings were changed. A small amount of nitropaste was applied to a slightly discolored area on the abdominoplasty flap. Pulse rate prior to discharge was approximately 70 beats per minute. She was discharged home in the care of a family friend, [REDACTED] at approximately 8 AM.

Approximately an hour later, my nurse, Sandra Cooper received a phone call from [REDACTED] friend, stating that she had suddenly become unresponsive. 9-1-1 was called, but EMS were unable to revive the patient. She was pronounced dead at approximately 9:30 AM.

Conclusion:

The medical examiner determined that the cause of death was a pulmonary embolism. The medical examiner's full report will be available shortly. The pulmonary embolism occurred despite the use of standard intra-operative and postoperative monitoring techniques, appropriate surgical and anesthetic techniques, and continuous postoperative observation by qualified nurses. All standard precautions to minimize the occurrence of DVT and PE were used, including the use of intra-operative and postoperative pneumatic compression devices, proper patient positioning and appropriate intravenous hydration.

Attachments:

Patient chart
CV, Thomas Fiala, M.D.

1997	Board Certification in Plastic Surgery Royal College of Physicians and Surgeons of Canada
1994	Board Certification in General Surgery Royal College of Physicians and Surgeons of Canada
1984-1988	M.D. Queen's University, Kingston, Ontario
1982-1985	B.A. (Biochem.) Queen's University, Kingston, Ontario

Post-Graduate Education:

1996-1997	Anesthetic Surgery Fellowship with Dr. John Q. Oswaley Davies Medical Center, University of California, San Francisco
1994-1996	Plastic Surgery Residency Program Section of Plastic & Reconstructive Surgery University of Michigan, Ann Arbor, Michigan
1992-1994	Senior & Chief Resident in General Surgery Department of General Surgery, Queen's University, Ontario, Canada
1991-1992	Research Fellow in Plastic & Microvascular Surgery Division of Plastic Surgery, Massachusetts General Hospital, Boston
1989-1991	Resident in General Surgery, Massachusetts General Hospital, Boston
1989-1990	Resident in General Surgery, UCLA Medical Center, Los Angeles
1985-1989	Rotating Internship, Edmonton General Hospital, Edmonton, Canada

CURRICULUM VITAE
THOMAS FIALA, MD, FRCSC, FACS

Current Status:

Private Practice - Aesthetic Plastic Surgery,
Suite 2020, 220 E. Central Parkway
Altamonte Springs, Florida
(407) 339-3222

Post-graduate Education:

- 1999 **Board Certification in Plastic Surgery**
American Board of Plastic Surgery (certificate #5775)
- 1997 **Board Certification in Plastic Surgery**
Royal College of Physicians and Surgeons of Canada
- 1994 **Board Certification in General Surgery**
Royal College of Physicians and Surgeons of Canada
- 1984-1988 **M.D.** Queen's University, Kingston, Ontario
- 1982-1985 **B.A. (Biochem.)** Queen's University, Kingston, Ontario

Post Doctoral Training:

- 1996-1997 **Aesthetic Surgery Fellowship with Dr. John Q. Owsley**
Davies Medical Center, University of California, San Francisco
- 1994-1996 **Plastic Surgery Residency Program**
Section of Plastic & Reconstructive Surgery
University of Michigan, Ann Arbor, Michigan
- 1992-1994 **Senior & Chief Resident in General Surgery**
Department of General Surgery, Queen's University, Ontario, Canada
- 1991-1992 **Research Fellow in Plastic & Microvascular Surgery**
Division of Plastic Surgery, Massachusetts General Hospital, Boston
- 1990-1991 **Resident in General Surgery, Massachusetts General Hospital, Boston**
- 1989-1990 **Resident in General Surgery, UCLA Medical Center, Los Angeles**
- 1988-1989 **Rotating Internship, Edmonton General Hospital, Edmonton, Canada**

**CURRICULUM VITAE
THOMAS FIALA, MD, FRCSC, FACS**

Selected Honors & Awards:

Appointments & Committees:

- Vice-Chairman, Department of Plastic Surgery, Orlando Regional Medical Center, June 2001- 2002
- Member, Surgical / Invasive Committee, Lucerne Hospital, 2000-2001
- Member, YPS (Young Plastic Surgeons) Committee, American Society of Plastic Surgeons, 2001-present
- Florida DOH / AHCA Medical Reviewer for Plastic Surgery, 2001-present

Hospital Privileges:

- Active, Department of Plastic Surgery, Orlando Regional Hospitals
- Active, Same-Day Surgery Center of Orlando
- Active, Florida Surgery Center
- Courtesy, Department of Plastic Surgery, Florida Hospital

Certificates & Society Memberships:

- Fellow, American College of Surgeons
- Fellow, Royal College of Physicians and Surgeons of Canada
- Diplomate, American Board of Plastic Surgery
- Licentiate, Medical Council of Canada
- Diplomate, National Board of Medical Examiners
- Member, American Society of Plastic Surgeons
- Member, American Society for Aesthetic Plastic Surgery
- Member, Florida Society of Plastic Surgeons
- Member, Reed O. Dingman Plastic Surgery Society
- Member, Florida Medical Association
- Member, Orange County Medical Society
- Associate, Royal Conservatory of Music (Toronto)
- Certificate in Management, Crummer Graduate School of Business, Rollins College, Winter Park, Florida

**CURRICULUM VITAE
THOMAS FIALA, MD, FRCSC, FACS**

Selected Honors & Awards:

- Owsley Fellowship recipient - Aesthetic Plastic Surgery
- "Best overall poster presentation" - PSEF Senior Residents' Meeting, 1996
- Merck Frost Resident Award for Teaching Excellence - Canadian Association of General Surgeons, 1994
- MGH/Harvard University Research Fellowship, 1991
- National Science & Engineering Research Council Undergraduate research award, 1984
- Queen's University Entrance Scholarship, 1982-84
- Government of British Columbia Scholarship Award, 1982

Scientific Publications on Aesthetic Surgery Topics

Owsley JQ, Fiala TG

The SMAS-Platysma Facelift: Advantages of a Multi-vector Technique
In "Facelift: State of the Art", Seminars in Plastic Surgery. 2002 Nov; 16(4): 391-404.

Fiala TG, Owsley JQ

Use of the Mitek fixation device in endoscopic browlifting.
Plast Reconstr Surg. 1998 May; 101(6):1700-3.

Owsley JQ, Fiala TG

Update: lifting the malar fat pad for correction of prominent nasolabial folds.
Plast Reconstr Surg. 1997 Sep; 100(3):715-22.

Fiala TG, Lee WP, May JW.

Augmentation mammoplasty: results of a patient survey.
Ann Plast Surg. 1993 Jun; 30(6):503-9.

Cederna PS, Fiala TG, Newman H.

Melkersson-Rosenthal syndrome: reduction cheiloplasty utilizing a transmodiolar labial suspension suture.
Aesthetic Plast Surg. 1998 Mar-Apr; 22(2):102-5.

Book review:

Review of "Lasers in Cutaneous and Cosmetic Surgery" by Lask GP, Lowe NJ. Review published in Annals of Plastic Surgery, April 2001.

CURRICULUM VITAE
THOMAS FIALA, MD, FRCSC, FACS

Scientific Publications on Reconstructive Topics

Fiala TG, Buchman SR, Murazko K.

Use of lumbar periosteal turnover flaps in myelomeningocele closure.
Neurosurgery. 1996 Sep;39(3):522-5; discussion 525-6.

Basile AP, Fiala TG, Yaremchuk MJ, May JW.

The antithrombotic effects of ticlopidine and aspirin in a microvascular thrombogenic model.

Plast Reconstr Surg. 1995 Jun;95(7):1258-64.

Lee WP, Pan YC, Kesmarky S, Randolph MA, Fiala TGS, et al.

Experimental orthotopic transplantation of vascularized skeletal allografts: functional assessment and long-term survival.

Plast Reconstr Surg. 1995 Feb;95(2):336-49; discussion 350-3.

Fiala TG, Paige KT, Davis TL, et al

Comparison of artifact from craniomaxillofacial internal fixation devices: magnetic resonance imaging.

Plast Reconstr Surg. 1994 Apr;93(4):725-31.

Yaremchuk MJ, Fiala TG, Barker F, Ragland R.

The effects of rigid fixation on craniofacial growth of rhesus monkeys.

Plast Reconstr Surg. 1994 Jan;93(1):1-10; discussion 11-5.

Fiala TG, Novelline R, Yaremchuk MJ.

Comparison of CT imaging artifacts from craniomaxillofacial internal fixation devices.

Plast Reconstr Surg. 1993 Dec;92(7):1227-32.

Fiala TG, Wrightson D, Yaremchuk MJ.

An electronic device for surgical glove testing.

Plast Reconstr Surg. 1993 Nov;92(6):1192-4.

Fiala TG, Lee WP, Hong HZ, May JW.

Bacterial clearance capability of living skin equivalent, living dermal equivalent, saline dressing, and xenograft dressing in the rabbit.

Ann Plast Surg. 1993 Jun;30(6):516-9.

Yaremchuk MJ, delVecchio DA, Fiala, TG, Lee WP.

Microfixation of acute orbital fractures.

Ann Plast Surg. 1993 May;30(5):385-97.

Personal: Dr. Fiala is married, and resides in Altamonte Springs, Florida. Leisure pursuits include playing piano and guitar, and when time permits, cycling, sailing and scuba diving.

ost 124 N/U file



STATE OF FLORIDA
Jeb Bush, Governor

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PHYSICIAN OFFICE
ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Agency for Health Care Administration,
Consumer Services Unit, Post Office Box 14000,
Tallahassee, Florida 32317-4000

I. OFFICE INFORMATION

Watson Clinic
Name of office
Lakeland 33804 D.K.
City Zip Code County
B. G. W. R. N. no M.D.
Name of Physician or Licensee Reporting
Watson Clinic, 1600 Lakeland Hills Blvd
Patient's address for Physician or Licensee Reporting

1600 Lakeland Hills Blvd
Street Address
863-680-7859
Telephone
RN 1751902
License Number & office registration number, if applicable

II. PATIENT INFORMATION

[Redacted Patient Information]

1-19-04
Date of Office Visit
Flu Lung Ca.
Purpose of Office Visit
Cat Scan #162
ICD-9 Code for description of incident
NA
Level of Surgery (I) or (II)

III. INCIDENT INFORMATION

1-19-04
Incident Date and Time

Location of Incident:
 Operating Rm
 Other Cat Scan
 Recovery Rm

Note: If the incident involved a death, was the medical examiner notified? Yes No
Was an autopsy performed? Yes No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Responded to Code 99 in Cat Scan Pt.
here for Flu Lung Ca. Cat Scan in progress
contrast was given shortly after Radiology
tech felt pt had breathing problems -
team responded. Unable to get BP even w
doppler - IV was in place fluid opened - Pt
was breathing w/ long periods of apnea - Apical
audible thru lq cont. chest / sales -
Solusollet & epi. Give IV - Pt responsive on
transfer to EMS -

RECEIVED
CONSUMER SERVICES UNIT
04 FEB - 2 AM 8:14

B) ICD-9-CM Codes

ICD #162

Cat Scan ~~contrast~~

no code

adverse event

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)

Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)

Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident

(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

<input type="checkbox"/> Death <input type="checkbox"/> Brain Damage <input type="checkbox"/> Spinal Damage <input type="checkbox"/> Surgical procedure performed on the wrong patient <input type="checkbox"/> A procedure to remove unplanned foreign objects remaining from surgical procedure <input checked="" type="checkbox"/> Any condition that required the transfer outcome of the patient to a licensed hospital Outcome of transfer - e.g., death, brain damage, observation only _____ Name of facility to which patient was transferred _____	<input type="checkbox"/> Surgical procedure performed on the wrong site ** <input type="checkbox"/> Wrong surgical procedure performed ** <input type="checkbox"/> Surgical repair of injuries or damage from a planned surgical procedure ** If it resulted in <input type="checkbox"/> Death <input type="checkbox"/> Brain Damage <input type="checkbox"/> Spinal Damage <input type="checkbox"/> Permanent disfigurement not to include the incision scar <input type="checkbox"/> Fracture or dislocation of bones or joints <input type="checkbox"/> Limitation of neurological, physical, or sensory function; <input type="checkbox"/> Any condition that required the transfer outcome of the patient
---	--

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Cindy Osteen RN 175192, Bunny Gryppano 1751902 Pat Cardin
 Paula Lantier 175042, Kim ABNP 306902
 Dr. Kramer, Dr. Riche, Dr. Amin, Debych MD - PN-1128651

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Michelle Blum - tech

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

V.

[Signature]
1-19-04

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT

1751902
LICENSE NUMBER

DATE REPORT COMPLETED

3:00 pm
TIME REPORT COMPLETED

282

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO: Agency for Health Care Administration, Consumer Services Unit, Post Office Box 14000, Tallahassee, Florida 32317-4000

OFFICE INFORMATION

Name of office: Constantino G. Mendieta MD PA/ Bellaglu Surgical Center

Street Address: 2310 S. Dixie Hwy

City: Miami

Zip Code: 33133

County: Dade

Telephone: 305-860-0717

Name of Physician or Licensee

Reporting: Constantino G. Mendieta MD

License Number: ME 0070055

Locating Information for Physician or Licensee Reporting

2310 S. Dixie Hwy, Miami, F 33133

PATIENT INFORMATION

Patient Name patient

Age :

Gender:

_____ Medicaid

_____ Medicare

LOCATING INFORMATION

Date of Office Visit: First visit 05/27/2003 initial-consultation

Patient Identification Number

Purpose of Office Visit: Gluteal implants and liposuction

Diagnosis: Unsatisfied Gluteal size

ICD-9 Code for Diagnosis N/A

INCIDENT INFORMATION

Location of Incident: 2320 S. Dixie Hwy, Miami Fl 33133

Incident Date and Time 02/02/2004 approximately 14:40

OR # 2 Operating Rm

_____ Recovery Rm

_____ Other

Note: If the incident involved a death, was the medical examiner notified?

_____ Yes

_____ No

Was an autopsy performed?

_____ Yes

_____ No

Describe circumstances of the incident (narrative)

See Narrative Sheet

(use additional sheets as necessary for complete response)

DATE REPORT COMPLETED 02/03/2004

TIME REPORT COMPLETED 18:20

*general anesthesia -> fractured
by CRNA burn on
leg
no procedure
since pt was not
transferred to hosp.
right?*

RECEIVED
CONSUMER SERVICES UNIT
04 FEB 12 PM 3:09

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of Incident
(ICD-9 Codes 01-99.9)- Lipodystrophy, unsatisfied gluteal size
Accident, event, circumstances, or specific agent that caused the injury or event.
(ICD-9 E-Codes) Foam Pad for Pressure points on Knee
Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
Foam pad for Knee Pressure points

(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- Death
 Brain Damage
 Spinal Damage
 Surgical procedure performed on the wrong patient
 A procedure to remove unplanned foreign objects remaining from surgical procedure
 Any condition that required the transfer of the patient to a licensed hospital
 Surgical procedure performed on the wrong site **
 Wrong surgical procedure performed **

Surgical repair of injuries or damage from a planned surgical procedure

** If it resulted in

- Death
 Brain Damage
 Spinal Damage
 Permanent disfigurement not to include the incision scar
 Fracture or dislocation of bones or joints
 Limitation of neurological, physical, or sensory function;
 Any condition that required the transfer of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Ellen Ramey CRNA- License # ARNP 759652

Elena Gonzales- Scrub technician

2320 S. Dixie Hwy, Miami, FL 33133

Constantino G. Mendleta MD - ME 070055 Surgeon

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Ellen Ramey CRNA

Elena Gonzales- Scrub technician

2310 S. Dixie Hwy, Miami, FL 33133

ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response) See Attachment

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT

LICENSE NUMBER ME 070055

DATE REPORT COMPLETED 02/03/2004

TIME REPORT COMPLETED 18:00

STATE OF FLORIDA
Jeb Bush, Governor

02/03/2004

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

Incident Report

SUBMITTER: Health Care Administration, Consumer Services Unit, Post Office Box 14000, Tallahassee, Florida 32317-4000

OFFICE INFORMATION:
Name of office:
Street Address:
City:
Zip Code:
County:
Telephone:
Name of Physician:
Report to:
License #:
Locating Information for:
FACILITY INFORMATION:
Type of Incident:
Age:
Gender:
Medical History:

Patient number [redacted] had undergone a gluteoplasty with liposuction in the past. [redacted] presented stating that [redacted] current implants were too big and desired a smaller buttock (Implants [redacted] felt were to large) as well as desiring more liposuction of [redacted] lower back. Therefore on 02/02/2004 [redacted] underwent a gluteal implant exchange along with liposuction of the lower back. This procedure is done in the prone position and great care is taken to pad all pressure points (knees, elbows, breast, feet etc.). The procedure went well, when the patient was placed in the supine position- in preparation for transfer to the Recovery Room bed- an abrasion/friction burn was noted on the left inner knee. The injury corresponded directly to the position of the ring foam pad we use for padding support. Apparently during the liposuction from the body movements, the padding slipped to a higher position on the knee and from the back and forth movements of liposuction the pad created a friction burn in the location.

- The pad was examined for any foreign bodies that it may have but the pad was intact.
- The wound was treated with flexan and will be monitored closely in our follow up appointments. The patient was informed of the incident.

LOCATING INFORMATION:
Date of Office Visit:
Patient Identification:
Physician Office Visit:
Procedure(s) Performed:
ICD-9 Code for Diagnosis:
INCIDENT INFORMATION:
Location of Incident:
Incident Date and Time:

OP #:
Recovery RM:
Other:
Note: If the incident involves a patient, was the medical examiner notified?
Yes
No
Was an autopsy performed?
Yes
No

Constantino G. Mendieta, M.D. F.A.C.S.

Describe circumstances of the incident (narrative)
See narrative sheet

(use additional sheets as necessary for complete response)

RECEIVED
CONSUMER SERVICES UNIT
02/03/04 12 PM 3:09



CARDIOLOGY ASSOCIATES

Robert E. Garrett, M.D.
Barry L. Kramer, M.D.
Paul M. Popper, M.D., F.A.C.C., F.S.C.A.I.
Sanjay Frasher, M.D.
Louis D. Rosenfield, M.D., F.A.C.C.
David E. Ruggieri, M.D.

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Physician
Adverse
Incident
Report

Paul K. All
Dianne M. Bald
Kathleen M. Ci
Laurie J. DeSo
Judith A. Dro
Deborah Jo Dunham
Thomas E. Flal
Karen M. O'Conno
Marcia H. Stoughton
John Michael W. Woodw

September 2, 2003

Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308

Office procedure

RE: [Redacted]

[Redacted] has been a patient of mine for years. [Redacted] has multiple medical problems, but [Redacted] required a permanent pacemaker insertion. This was done some time in January. It turned out that [Redacted] developed an MRSA infection after the pacer insertion at Charlotte Regional Medical Center. Finally, it was decided after attempts to eradicate the infection to remove the pacemaker on April 7, 2003. This was removed. The MRSA infection continued. [Redacted] was discharged with specific orders where Mederi Home Health Agency was ordered to pack and unpack the wound on a daily basis, at least twice a day, using Iodoform gauze packing.

On one occasion, the patient came into my office with extreme swelling and I was concerned. Mederi Home Health Agency forgot to take the packing out for one week. I removed the packing that day, put a new packing in, and again reiterated the importance of removing and taking the packing out on a daily basis.

I referred the patient to Dr. Asperilla when things were not improving, and he saw the patient during the hospitalization period as well. On June 3, 2003, [Redacted] was again referred back to the Infectious Disease specialist. Dr. Asperilla worked this patient up on multiple occasions. I still was not happy with how the results were going with the MRSA infection, it was still not resolved. I referred the patient to a plastic surgeon, Dr. Christopher Constance in Punta Gorda, Florida. He sent the patient to the Wound Care Clinic of Charlotte Regional Medical Center, and I asked Dr. Constance to see if there was anything that would work to make sure there were no foreign bodies or any other issues explaining whether a debridement of this wound was necessary. Again, Mederi Home Health Agency was seeing this patient twice a day. Finally, the Mederi Home Health Agency and the Wound Care Clinic at Charlotte Regional were managing this patient. For all I knew, they were continuing to pack and unpack the wound.

Still in that period of time, I was not comfortable with the results, so I sent the patient to the Wound Care Clinic at Fawcett Memorial Hospital on August 1, 2003. They were apparently packing and unpacking the wound as well. Finally, the patient was seen by Dr. Jarrah, a chest surgeon, who on August 7, 2003, surgically explored the pacer pocket and found that there was gauze in the pocket. This foreign body was identified as the packing gauze of the Iodoform gauze that either the Mederi Home Health Agency was using and packing, or the Wound Care Clinic of Charlotte Regional Medical Center, or the Wound Care Clinic nurses of Fawcett Memorial Hospital were using. This packing and unpacking the wound was under the responsibility of the nurses and the Wound Care Clinics. Apparently, Dr. Jarrah felt that there was a small amount of packing material that never got removed completely and helped continue this ongoing infection.

US 516 114:43

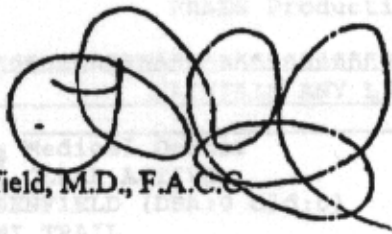
Adverse Incident report dated September 2, 2003

Cardiology Associates

Agency for Health Care Administration
September 2, 2003
Page 2

I am writing this report as an adverse reaction report, whether it was the Fawcett Wound Care Clinic or the Mederi Home Health Agency, or the Charlotte Regional Medical Center Wound Care Clinic facilities that left their packing Iodoform gauze. It was not an operative sponge that was left in the operating room at the time of removal of the pacemaker on April 7, 2003.

Sincerely,



Louis D. Rosenfield, M.D., F.A.C.S.

LDR:jt

PRISM Production (MO-F) 01/22/04
20:55:30
1501/REG-KD
STATE: FL
Zip: 33952
County: CHARLOTTE
Certificate No: 108493 First License: 08/02/1978
Date: 10/30/2001 In Rank Since: 08/02/1978
Next Renewal: 10/29/2003 License Method: EXEN
Current Expiry: 01/31/2006 Renewal Notice: 09/19/2003
In Directory? Include
State Date: 01/01/2001 Fee Exempt? N
Go to view only options
3 22/3

Adverse Incident report dated 9/2/03

Cardiology Associates ~~of [redacted]~~

Dr. M. [redacted] M.D., F.A.C.C., F.R.C.C.
Dr. D. [redacted] M.D., F.A.C.C.
Dr. L. [redacted] M.D.

Paul E. Al
Diane M. Bell
Kathleen M. C
Linda J. DeLo
Judith A. Eng
Deborah S. Eshbach
Thomas E. Fiel
Kerwin N. O'Conor
Marie C. Sougham
John Michael W. Woods

September 2, 2003

Agency for Health Care Administration
1737 Michigan Drive
Tallahassee, FL 32304

Adverse
Incident
Report

iHEADER PRAES Production (MQ-P) 01/22/04
coliver 10:55:35

@tnrbal31/2.2 DISPLAY SUBORDINATE LICENSES 1501/MED-ME@

@ SUPERIOR
@ File: 25500
@ SSN: [redacted] Medical Doctor
@ Lic: 32994 CLEAR, ACTIVE
@ Name: LOUIS D ROSENFELD
@ Addr: 4130 TAMiami TRAIL
@ City: PORT CHARLOTTE
@ State: FL
@ Zip: 33952
@ County: CHARLOTTE

if#	RelationID	Rank	Status	Act Status	Count	Max	Item 1 of 20
@1@	ALTER-SUP	RS	OBLIGATIONS	ACTIVE	0		
@2@	MED DIR	HCCR	CLEAR	ACTIVE	0	5	
@3@	ME LICENSE	LL	DELINQUENT		0		
@4@	OSR	OSR	OBLIGATIONS	ACTIVE	0		

@Action: Select List Exit
@ Select supporting license

1 Sess-1 167.78.1.20 1 22/9

work to make... Again, Archer Home Health Agency was using this patient twice a day. Finally, the Archer Home Health Agency and the Wound Care Clinic at Charlotte Regional were managing this patient. For all I know, they were continuing to pack and inspect the wound.

SNB in that period of time. I was not comfortable with the results, so I sent the patient to the Wound Care Clinic at Fawcett Memorial Hospital on August 1, 2003. They were apparently packing and unpacking the wound as well. Finally, the patient was seen by Dr. Jarrah, a chest surgeon, who on August 7, 2003, surgically explored the pocket and found that there was gauze in the pocket. This foreign body was identified as the packing gauze of the iodine gauze that either the Archer Home Health Agency was using and packing, or the Wound Care Clinic of Charlotte Regional Medical Center, or the Wound Care Clinic nurses of Fawcett Memorial Hospital were using. This packing and unpacking the wound was under the responsibility of the nurses and the Wound Care Clinics. Apparently, Dr. Jarrah felt that there was a small amount of packing material that never got removed completely and helped continue this ongoing infection.



PHYSICIAN OFFICE ²⁰⁰³ SEP 25 PM 2:27
ADVERSE INCIDENT REPORT

duplicate 284

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Name of office: Children's Center for Cancer + Blood diseases Street Address: 2501 N. Orange Ave., Suite 589
City: Orlando Zip Code: 32738 County: Orange Telephone: 407-303 2080
Name of Physician or Licensee Reporting: Fouad HAJJAR, MD License Number & office registration number, if applicable: ME 0066648
Patient's address for Physician or Licensee Reporting: 3040 Aloma Ave., Apt B3, Orlando, FL. 32792 *Bone marrow aspirate with conscious sedation not a procedure?*

II. PATIENT INFORMATION

Patient Name: [REDACTED] Age: Sept 15, 2003 Gender: [REDACTED] Medicaid Medicare:
Patient's Address: [REDACTED] Date of Office Visit: Sept 15, 2003
Patient Identification Number: [REDACTED] Purpose of Office Visit: Diagnostic test - Bone marrow aspirate
Diagnosis: Leukemia ICD-9 Code for description of incident: Level (II)
Level of Surgery (II) or (III): [REDACTED]

III. INCIDENT INFORMATION

Incident Date and Time: 9/15/03 10:53 am Location of Incident: Operating Rm Recovery Rm Other clinic procedure room
Note: If the incident involved a death, was the medical examiner notified? Yes No
Was an autopsy performed? Yes No *N/A*

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient was scheduled for a bone marrow aspirate under conscious sedation in the office. Following mild sedation with 1mg Versed, 75mg of Fentanyl and local xylocain, the procedure was performed over 5 minute period. Patient was alert during procedure but following procedure, she started hyperventilating and could not calm down. Shortly thereafter, she passed out briefly and her sat sat dropped to 87% for couple of seconds. Using tactile stimulation, patient woke and with blow by O2 (15L BB), her sat. immediately came up to 100%. Because of her very lethargic state and her persistent hyperventilation and disorientation, Narcan and Lorazepam reversal agent were given. 9/15

(cont'd)

(cont'd)

was called. EMS arrived around 11⁰⁰ AM. Pt was evaluated by paramedics. Blood sugars was checked and found to be 74.

IV fluid was continued. Pt was by now alert and crying, asking for her mother. She was very appropriate.

I will elect to transfer patient to ER and admit after consultation with Dr. Guido for 24 hours observation.

B) ICD-9-CM Codes

38220	unknown	none
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

Oxygen, BP machine, pulse oximeter

D) Outcome of Incident (Please check)

<input type="checkbox"/> Death <input type="checkbox"/> Brain Damage <input type="checkbox"/> Spinal Damage <input type="checkbox"/> Surgical procedure performed on the wrong patient <input type="checkbox"/> A procedure to remove unplanned foreign objects remaining from surgical procedure <input checked="" type="checkbox"/> Any condition that required the transfer outcome of the patient to a licensed hospital Outcome of transfer - e.g., death, brain damage, observation only <u>observation only</u> Name of facility to which patient was transferred <u>Florida Hospital - Orlando</u>	<input type="checkbox"/> Surgical procedure performed on the wrong site ** <input type="checkbox"/> Wrong surgical procedure performed ** <input type="checkbox"/> Surgical repair of injuries or damage from a planned surgical procedure ** If it resulted in <input type="checkbox"/> Death <input type="checkbox"/> Brain Damage <input type="checkbox"/> Spinal Damage <input type="checkbox"/> Permanent disfigurement not to include the incision scar <input type="checkbox"/> Fracture or dislocation of bones or joints <input type="checkbox"/> Limitation of neurological, physical, or sensory function; <input type="checkbox"/> Any condition that required the transfer outcome of the patient
---	--

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Frank Hajjox MD - ME 0066648
Kerry Gallaway RN - 261982

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Diane Higgins RN - 2694122
Margene Miller RN - 2752342

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Patient was very anxious and hyperventilated during and after procedure. They also "spaced out" - Spontaneous hyperventilation w/ breath holding episode.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Oxygen given @ 15 LBS. Patient & med given in a divided dose. Rouzicim 0.2 mg, all called. Pt transferred to ER - Florida hospital for further monitoring - evaluation.

V. Frank Hajjox MD ME 0066648
 SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT LICENSE NUMBER
9/17/03 17:00
 DATE REPORT COMPLETED TIME REPORT COMPLETED