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See OMB statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (2/13)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 of ____

Mfr Report #

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
MG In confidence	29 3/29/1984	☑ Female ☐ Male	130 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☑ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
3/5/3014	5/6/2014

5. Describe Event or Problem

29 year old woman with end stage renal disease underwent laparoscopic insertion of CAPD catheter using Medcomp CAPD catheter. Connector and Cap/clip was applied but that that night patient presented to local hospital with clear leakage through her dressing and the cap was found to be in the dressing, having come disconnected from the PD catheter. patient required hospitalization for peritonitis.

FDA3500a report filed after the peritoneal dialysis clinic complained to the surgeon about the Medcomp connector forming a loose and unreliable connection with the Fresenius transfer sets in two additional patients.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Chronic Kidney Disease Stage 5, dialysis dependent.

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: I-Series Peritoneal Dialysis Catheter

2. Common Device Name	2b. Procode
57cm double cuff peritoneal cath	

3. Manufacturer Name, City and State
Medcomp - Medical Components, Inc
Harleysville PA 19438

4. Model #	Lot #	5. Operator of Device
	MBGP030	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
MC20IC57DC	08/2016	☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
3/5/2014	

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☑ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Eric Ladenheim MD
6153 N Thesta Street
Fresno CA 93710

Phone #	Email Address
559-446-1065	eladenheim@ladenheim.net

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Physician	☐ Yes ☑ No ☐ Unk.

MEDWATCH

FORM FDA 3500A (2/13) *(continued)*

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One**
☑ User Facility ☐ Importer

2. **UF/Importer Report Number**

3. **User Facility or Importer Name/Address**
LDAC Surgery Center, Inc
6153 N Thesta Street
Fresno CA 93710

4. **Contact Person**
Eric Ladenheim MD

5. **Phone Number**
559-446-1065

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
05/06/2014

7. **Type of Report**
☑ Initial
☐ Follow-up # _____

8. **Date of This Report** *(mm/dd/yyyy)*
5/6/2014

9. **Approximate Age of Device**
new

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code: C26849 – FDA 2252 – _____
Device Code: C63142 – FDA 2183 – _____

11. **Report Sent to FDA?**
☑ Yes 5/6/2014 *(mm/dd/yyyy)*
☐ No

12. **Location Where Event Occurred**
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ *(Specify)*

13. **Report Sent to Manufacturer?**
☑ Yes 5/6/2014 *(mm/dd/yyyy)*
☐ No

14. **Manufacturer Name/Address**
Medcomp - Medical Components, Inc
1499 Delp Drive
Harleysville PA 19438

G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
Name
Address
Email Address

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*

5.
(A)NDA # _____
IND # _____
BLA # _____
PMA/ 510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # ____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
☐ Death
☐ Serious Injury
☐ Malfunction

2. **If Follow-up, What Type?**
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?**
☐ Yes ☐ No

6. **Event Problem and Evaluation Codes** *(Refer to coding manual)*
Patient Code: _____ – _____ – _____
Device Code: _____ – _____ – _____
Method: _____ – _____ – _____ – _____
Results: _____ – _____ – _____ – _____
Conclusions: _____ – _____ – _____ – _____

7. **If Remedial Action Initiated, Check Type**
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other: _____

8. **Usage of Device**
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
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