Reset Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500A

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

Form Approved: OMB No. 0910-0291
Expires: 6-30-2025
See PRA statement on page 6.

FDA USE ONLY
Mfr report # 3012120746-2025-12345
UF/Importer Report #
Exemption/Variance #

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-JAN-1900.

A. PATIENT INFORMATION

1. **Patient Identifier** *(In confidence)*

2. Age
☐ Year(s) ☐ Week(s)
☐ Month(s) ☐ Day(s)

or Date of Birth *(e.g., 01-Jan-1900)*

3. **Sex:** Enter the patient's sex at birth *(the sex that a person has or was assigned to at birth).*
☐ Male
☐ Female

SECTION REMOVED

4. **Weight**
☐ lb
☐ kg

5. **Ethnicity** *(Check one)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

6. **Race** *(check all that apply)*
☐ American Indian/Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian/ Other Pacific Islander
☐ White

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. **Type of Report** *(check all that apply)*
☒ Adverse Event
☒ Product Problem *(e.g., defects/malfunctions)*

2. **Outcome Attributed to Adverse Event** *(check all that apply)*
☒ Death – Date of death *(01-JAN-1900):*
☐ Life-threatening
☐ Hospitalization (initial or prolonged)
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. **Date of Event** *(01-JAN-1900)*
03-Sep-2023

4. **Date of this Report** *(01-JAN-1900)*
03-Jan-2025

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see instructions

(continued on next page)

5. **Describe Event or Problem**

It was reported that after a routine Cryoballoon ablation procedure for atrial fibrillation, the patient was transferred from the operating room to the ward in stable condition, with normal blood pressure and heart rate, and feeling well. However, shortly thereafter, the patient's condition deteriorated rapidly, resulting in a drop in blood pressure and eventual asystole. Despite resuscitation efforts, the patient passed away. An autopsy revealed a significant accumulation of blood in the abdominal cavity, caused by a venous tear. According to the physician, during the insertion of the FlexCath Advance system (with the FlexCath Cross needle/dilator) into the venous system, the FlexCath Cross needle/dilator system detached and inadvertently retracted from the FlexCath, causing the venous tear that ultimately led to the patient's death on the ward. Device was discarded.

6. **Relevant Test/Laboratory Data**	**Date** *(01-JAN-1900)*	**Relevant Test/Laboratory Data**	**Date** *(01-JAN-1900)*

Additional comments

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, tobacco product use, alcohol use, and liver/kidney problems, etc.)*

C. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. **Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
		--

NDC # or Unique ID	Manufacturer/Compounder Name	Lot #

2. **List Medical Product and Treatment Given at the Same Time of the Event and Date** *(Do not include treatment for initial event)*

3. **Dose or Amount**	**Frequency**	**Route**
	--	--
Unit	**Other Frequency**	**Other Route**
--		

4. **Treament Dates/Therapy Dates** *(give best estimate of length of treatment (start/stop) or date of dose reduction.)*

Therapy started on *(e.g., 01-Jan-1900)*	Therapy stopped on *(e.g., 01-Jan-1900)*	Dose Reduced *(e.g., 01-Jan-1900)* **OR**	Duration	Unit
				--

5. **Diagnosis for use** *(indication)*	6. **Product Type** *(check all that apply)*	7. **Expiration Date** *(e.g., 01-Jan-1900)*
	☐ OTC ☐ Generic ☐ Compounded ☐ Biosimilar	

8. **Event Abated after use Stopped or Dose Reduced?**	9. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply	☐ Yes ☐ No ☐ Doesn't apply

SUSPECT PRODUCT #2

1. **Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
		--

NDC # or Unique ID	Manufacturer/Compounder Name	Lot #

2. **List Medical Product and Treatment Given at the Same Time of the Event and Date** *(Do not include treatment for initial event)*

3. **Dose or Amount**	**Frequency**	**Route**
Unit --	**Other Frequency**	**Other Route**

4. **Treament Dates/Therapy Dates** *(give best estimate of length of treatment (start/stop) or date of dose reduction.)*

Therapy started on *(e.g., 01-Jan-1900)*	Therapy stopped on *(e.g., 01-Jan-1900)*	Dose Reduced *(e.g., 01-Jan-1900)* **OR**	Duration	Unit
				--

5. **Diagnosis for use** *(indication)*	6. **Product Type** *(check all that apply)*	7. **Expiration Date** *(e.g., 01-Jan-1900)*
	☐ OTC ☐ Generic ☐ Compounded ☐ Biosimilar	

8. **Event Abated after use Stopped or Dose Reduced?**	9. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply	☐ Yes ☐ No ☐ Doesn't apply

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**	2a. **Common Device Name**	2b. **Procode**
AcQCross Qx Integrated Transseptal Dilator/Needle	Integrated Transseptal Dilator/Needle	DYB

3. **Manufacurer Name, City and State**

Acutus Medical, Inc. 2210 Faraday Ave Suite 100 Carlsbad, CA, 92008, UNITED STATES

4. **Model #**	**Lot #**	**Catalog #**
900304	UNK	

Expiration Date *(01-JAN-1900)*	**Serial #**

Unique Device Identifier *(UDI)* **#**

5. **Operator of Device**	6a. **If Implanted, Give Date** *(01-JAN-1900)*	6b. **If Explanted, Give Date** *(01-JAN-1900)*
☐ Health Professional ☐ Patient/Consumer ☒ Other OHP		

7a. **Is this a single-use device that was reprocessed and reused on a patient?**	7b. **If yes, enter the name and address of the reprocessor**
☐ Yes ☒ No	

8. **Was this device ever serviced by a third-party servicer?**	9. **Is this Device Available for Evaluation?** *(Do not send to FDA)*
☐ Yes ☐ No ☒ Unknown	☐ Yes ☒ No ☐ Returned to manufacturer on *(01-JAN-1900)*

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

Product Name	Therapy Start Date *(01-JAN-1900)*	Therapy End Date *(01-JAN-1900)*
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

E. INITIAL REPORTER

1. **Name and Address**

Last Name	First Name

Address

City	State/Province/Region	ZIP/Postal Code	Country
	CROATIA		--

Phone # Email

2. **Health Professional?**	3. **Occupation** *(Select from list)*	4. *Initial reporter also sent report to FDA*
☒ Yes ☐ No	Physician	☐ Yes ☒ No ☐ Unknown

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

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

2. **User Facility/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(01-JAN-1900)*
16-Apr-2025

7. **Type of Report**

8. **Date of This Report** *(01-JAN-1900)*

9. **Approximate Age of Device**

10. **Adverse Event Problem** *(Refer to coding manual)*

Health Effect – Clinical Code	Health Effect – Impact Code	Medical Device Problem Code	Component Code

11. **Report Sent to FDA?**
(If Yes, enter date (01-JAN-1900))
☐ Yes ☒ No

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

13. **Report Sent to Manufacturer?**
(If Yes, enter date (01-JAN-1900))
☐ Yes
☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office** *(and Manufacturing Site for Devices)* **or Compounding Outsourcing Facility**

Name	Email Address	Phone Number
John Doe	JD@acutus.com	1 (442) XXX-XXXX

Address
Acutus Medical, Inc. 2210 Faraday Ave Suite 100 Carlsbad, CA, 92008, UNITED STATES

Compounding Outsourcing Facility 503B?
☐ Check box if applicable

Outsourcing Facility

2. **Report Source** *(check all that apply)*
☒ Foreign ☐ Literature ☒ Health Professional ☒ Company Representative
☐ Study ☐ Consumer ☐ Use Faciltiy ☐ Distributor/Importer ☐ Other *(Please list)*

3. **Date Received by Manufacturer** *(01-JAN-1900)*
12-Dec-2024

4. **NDA #**	**ANDA #**	**IND #**	**BLA #**	**PMA/510***(k)* #

Check all that apply:
☐ Combination product ☐ Pre-ANDA ☐ Pre-1938 ☐ OTC ☐ Compounded Product

5. **If IND/Pre-ANDA, Give Protocol #**

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

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

8. **Manufacturer Report Number**
3012120746-2025-12345

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** *(check all that apply.)*
- [x] Death
- [ ] Malfunction
- [ ] Serious Injury
- [ ] Summary Report
  No. of events summarized

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

3. **Device Evaluated by Manufacturer?**
- [ ] Yes
- [x] No

4. **Device Manufacture Date** *(01-JAN-1900)*

5. **Labeled for Single Use?**
- [x] Yes
- [ ] No

6. **Adverse Event Problem** *(Refer to coding manual)*

Health Effect – Clinical Code	Health Effect – Impact Code	Medical Device Problem Code	Component Code
914, 1762, 3160	1802, 4647	2923	4742

Type of Investigation	Investigation Findings	Investigation Conclusions
4115	3233	11

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

8. **Usage of Device**
- [x] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

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

10. **Related Report Number**

11. **Additional Manufacturer Narrative**

Pending follow-up information to complete investigation.

This section applies only to requirements of the Paperwork Reduction Act of 1995. This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 73 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

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