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 # 2024168-2025-12345
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)*
xxxx

2. Age 80
☒ 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)*
11-Feb-2025

4. **Date of this Report** *(01-JAN-1900)*
16-Apr-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**

User Facility MedWatch report received that states:

"TWO (2) PERCLOSE DEVICES FAILED TO DEPLOY PROPERLY. TWO (2) NEW DEVICES OPENED AND USED WITHOUT INCIDENT. REFERENCE REPORT MW1234567/MW1234568."

No additional information was provided.

6. **Relevant Test/Laboratory Data** **Date** *(01-JAN-1900)*	**Relevant Test/Laboratory Data** **Date** *(01-JAN-1900)*
Relevant tests/lab data were requested; however,not provided from the facility reporter.	

Additional comments

Based on the information provided, a definitive cause for the reported deployment issue could not be determined. Factors that may contribute to failure to deploy include, but not limited to, needle deflection during plunger deployment due to interaction with patient anatomy or failure to maintain a stable position of the device with respect to the tissue tract. The subsequent treatment appears to be related to circumstances of the procedure. Based on the results of the complaint investigation, there is no indication of a product quality issue with respect to the design, manufacture, or labeling of the device.

The additional Perclose ProGlide device referenced in B5 is filed under separate MedWatch report number.

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

Patient age, sex, gender, weight, ethnicity, race, and other relevant medical history were requested; however, not provided from the facility reporter.

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 **OR** *(e.g., 01-Jan-1900)*	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**
Perclose ProGlide™	Device, Hemostasis, Vascular	MGB

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

ABBOTT VASCULAR INC. 3200 Lakeside Drive Santa Clara, CA, 95054-2807, UNITED STATES

4. **Model #**	**Lot #**	**Catalog #**
12673-03	4112341	12673-03

Expiration Date *(01-JAN-1900)*	**Serial #**
03-Oct-2025	NI

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
Doe	John

Address: ST LUKES HOSPITAL

City	State/Province/Region	ZIP/Postal Code	Country
	UNITED STATES		--

Phone # Email

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

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@abbott.com	1 (951) xxx-xxxx

Address
Abbott Vascular 26531 Ynez Rd. Temecula, CA, 92591-4628, 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)*
Regulatory Agency (FDA)

3. **Date Received by Manufacturer** *(01-JAN-1900)*
14-Mar-2025

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**
2024168-2025-12345

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** *(check all that apply.)*
- ☐ 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
- ☒ No

4. **Device Manufacture Date** *(01-JAN-1900)*
20-Nov-2024

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

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

Health Effect – Clinical Code	Health Effect – Impact Code	Medical Device Problem Code	Component Code
4582	4641	2610	4755

Type of Investigation	Investigation Findings	Investigation Conclusions
4111, 3331, 4115, 4109	3221	4315

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

8. **Usage of Device**
- ☒ 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**
MW1234567

11. **Additional Manufacturer Narrative**

The device was not returned for analysis. Production record and Corrective and Preventative Actions (CAPA) reviews were performed and revealed no indication of a product quality issue. Additionally, a query of the complaint handling database for the reported lot revealed there is no indication of a lot specific issue.

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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