



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

Public reporting burden for this collection of information is estimated to average 30 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 the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not allowed to respond to, a collection of information unless it displays a currently valid OMB control number.

- FDA FORM 3670 (06/23)
OMB Number: 0910-0471
Expiration date: 08/31/2026

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EDIT REPORT

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CONTACT INFORMATION

User facility name: ⓘ

Address: ⓘ

Contact's name: ⓘ

Contact's phone number: ⓘ

Contact's fax number: ⓘ

Contact's email address: ⓘ

Occupation of Contact: ⓘ

Name of initial reporter: ⓘ

Address of initial reporter: ⓘ

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EVENT INFORMATION

Event title: ⓘ

short description to help you identify this event

Total of 20 characters allowed. You have 18 left

When did the event happen? ⓘ

mm/dd/yyyy

How many days ago did you first become aware of the event? ⓘ

- ☐ less than or equal to 10 days ago ☐ more than 10 days ago

Date of this report: ⓘ

mm/dd/yyyy

Where did this event occur? ⓘ

- ☐ Hospital ☐ Home
☐ Nursing home ☐ Outpatient treatment facility
☐ Outpatient diagnostic facility ☐ Ambulatory surgical facility
☐ Laboratory not within a hospital ☐ Physician's office
☐ Not known ☐ Not applicable
☐ Other

The device(s) may have caused or contributed to: ⓘ

Check all that apply

- ☐ Death
☐ Serious injury
☐ Potential harm to a health care provider [Indicates voluntary report]
☐ Minor injury to the patient or health care provider [Indicates voluntary report]
☐ Potential for patient harm [Indicates voluntary report]
☐ Not known
☐ Not applicable

Was there a problem with the device (such as a defect, malfunction, break, etc)? ⓘ

- ☐ Yes ☐ No
☐ Not known ☐ Not applicable

Was someone directly "operating" the device at the time of the event? ⓘ

- ☐ Yes ☐ No
☐ Not known ☐ Not Applicable

Were there other devices being used on the patient at the time of the event that may have caused or contributed to the event? ⓘ

Total of 6000 characters allowed. You have 6000 left

Were there other therapies being used on the patient at the time of the event that may have caused or contributed to the event? ⓘ

Check all that apply

- ☐ Cardiac Drugs ☐ Chemotherapy
☐ Dialysis ☐ Immunotherapy
☐ Long-Term Antibiotics ☐ Prenatal medication
☐ Other ☐ No other therapies
☐ Not known ☐ Not applicable

Describe the event or problem. ⓘ

Please provide as much detail as possible.

Total of 8000 characters allowed. You have 7999 left

What was the original intended procedure? ⓘ

Total of 6000 characters allowed. You have 6000 left

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PATIENT INFORMATION

Patient identifier: ⓘ

Provide the patient's initials or some other identification code number that will allow both the submitter and the initial reporter (if different) to locate the case if contacted for follow-up. **Do not use the patient's name, initials, social security number, medical record number, date of birth, or other identifiers in the report.** If no patient was involved, enter 'none'.

Total of 10 characters allowed. You have 9 left

Patient's age at time of event: ⓘ

 Not applicable

Patient's weight: ⓘ

Type the numerical value in the first box, then use the second box to choose if the value reflects ounces, pounds, grams, or kilograms.

 Not applicable

Patient Sex ⓘ

Enter the patient's sex at birth (the sex that a person has or was assigned to at birth)(check one)

- ☐ Male ☐ Female

Patient's Race ⓘ

Indicate the race of the patient as reported by the patient. You may choose multiple answers for race. **Please do NOT make a best guess.**

- ☐ American Indian or Alaskan Native ☐ Asian
☐ Black or African American ☐ Native Hawaiian or other Pacific Islander
☐ White

Patient Ethnicity ⓘ

(check one)

- ☐ Hispanic/Latino ☐ Not Hispanic/Latino

Did the patient have any of the following preexisting characteristics that may have contributed to the event? ⓘ



Check all that apply

- | | |
|---|---|
| ☐ Allergies | ☐ Alcohol/drug use |
| ☐ COPD | ☐ Coronary heart disease |
| ☐ Diabetes | ☐ Hepatic/renal dysfunction |
| ☐ Hypertension | ☐ Immuno-compromised |
| ☐ Morbidly obese | ☐ Pneumonia |
| ☐ Pregnancy | ☐ Premature infant |
| ☐ Smoking | ☐ Stroke |
| ☐ Surgery | ☐ Relevant accidents (e.g. Hit head) |
| ☐ Other | ☐ No preexisting characteristics |
| ☐ Not known | ☐ Not applicable |

Please provide any other information about the patient that may have influenced the outcome of the event. ⓘ

Total of 6000 characters allowed. You have 6000 left

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EDIT REPORT

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DEVICE INFORMATION

Unique Device Identifier (UDI): ⓘ

For more information regarding the UDI # [refer to the UDI webpage](#)

Total of 150 characters allowed. You have 150 left

[Parse UDI into DI and PI fields](#)

Type of device: ⓘ

Total of 80 characters allowed. You have 79 left

Device manufacturer's name: ⓘ

Total of 50 characters allowed. You have 50 left

Device brand name: ⓘ

Total of 80 characters allowed. You have 80 left

Approximate age of device: ⓘ

Type the numerical value in the first box, then use the second box to choose if the value reflects ounces, pounds, grams, or kilograms.

 Not applicable

If a disposable device, was the packaging saved? ⓘ ⚡

- ☐ Yes
 ☐ No
 ☐ Not known
 ☐ Not applicable

Is this a single use device that was reprocessed and reused on a patient? ⓘ ⚡

- ☐ Yes
 ☐ No
 ☐ Unknown

Is this a laboratory device or laboratory test? ⓘ ⚡

- ☐ Yes
 ☐ No

Was this device serviced by a third party? ⓘ ⚡

- ☐ Yes
 ☐ No
 ☐ Unknown

Device Identifier (DI): ⓘ

Total of 25 characters allowed. You have 25 left

[Query AccessGUID](#)

Device serial #: ⓘ

Total of 30 characters allowed. You have 30 left

Device model #: ⓘ

Total of 80 characters allowed. You have 80 left

Device lot #: ⓘ

Total of 30 characters allowed. You have 30 left

Device catalog (REF) #: ⓘ

Total of 30 characters allowed. You have 30 left

Other device #: ⓘ

Total of 80 characters allowed. You have 80 left

Expiration date: ⓘ

mm/dd/yyyy

If the device was implanted, give implant date: ⓘ

mm/dd/yyyy

If the device was explanted, give explant date: ⓘ

mm/dd/yyyy

Was the device returned to the manufacturer? ⓘ ⚡

- ☐ Yes
 ☐ No
 ☐ Not known
 ☐ Not applicable

Is the device involved in this event available at your facility for evaluation? ⓘ ⚡

- ☐ Yes
 ☐ No
 ☐ Not known
 ☐ Not applicable

Have you made the manufacturer aware of this problem/issue? ⓘ ⚡

- ☐ Yes
 ☐ No
 ☐ Unknown

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TEST INFORMATION

Test performed: ⓘ

Total of **150** characters allowed. You have 150 left

Date test was performed/administered: ⓘ

mm/dd/yyyy

mm/dd/yyyy



Test results: ⓘ

Total of **6000** characters allowed. You have 6000 left

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ATTACHMENTS

Select document to upload:

Choose Files

* document size must be less than 5MB (5120KB)

Upload

No Documents available for this report.