



- 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 45 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

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- **FDA FORM 3670 (06/20)**
OMB Number: 0910-0471
Expiration date: 07/31/2023

[Enter the report form](#)



USER FACILITY

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CONTACT INFORMATION

User facility name:

Address: [limit: 50 lines of text]

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: [limit: 50 lines of text]

[Back To Top](#)

DEVICE INFORMATION

Unique Device Identifier (UDI): Parse UDI into DE and PI fields

Type of device:

Device manufacturer's name:

Device manufacturer's street address: (Line 1)

Street address: (Line 2)

City:

State:
(Please limit your response to 2 characters)

Zip:

Device brand name:

Approximate age of device: Years

If a disposable device, was the packaging saved? (Optional) 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

Device Identifier (DI): Query AccessGUID

Device serial #:
(Please limit your response to 30 characters)

Device model #:

Device lot #:
(Please limit your response to 30 characters)

Device catalog (REF) #:
(Please limit your response to 30 characters)

Other device #:

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



USER FACILITY

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Save & Exit

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Set Report Status

ATTACHMENT LIST

Select document to upload: No file selected.

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

No Document found for this Report.


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ADMINISTRATION

[Contact Info](#) | [Event](#) | [Patient](#) | [Device](#) | [Test](#) | [Attachment](#)

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EVENT INFORMATION

Event title: (short description to help you identify this event) ?

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
 more than 10 days ago

Date of this report: (mm/dd/yyyy) ?

Where did this event occur? ?

<input type="radio"/> Hospital	<input type="radio"/> Home
<input type="radio"/> Nursing home	<input type="radio"/> Outpatient treatment facility
<input type="radio"/> Outpatient diagnostic facility	<input type="radio"/> Ambulatory surgical facility
<input type="radio"/> Laboratory not within a hospital	<input type="radio"/> Physician's office
<input type="radio"/> Not known	<input type="radio"/> Not applicable
<input type="radio"/> 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? ?
(limit: 50 lines of text)

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)

<input type="checkbox"/> Cardiac Drugs	<input type="checkbox"/> Chemotherapy
<input type="checkbox"/> Dialysis	<input type="checkbox"/> Immunotherapy
<input type="checkbox"/> Long-Term Antibiotics	<input type="checkbox"/> Prenatal medication
<input type="checkbox"/> Other	<input type="checkbox"/> No other therapies
<input type="checkbox"/> Not known	<input type="checkbox"/> Not applicable

Describe the event or problem. Please provide as much detail as possible. ?
(limit: 50 lines of text)

What was the original intended procedure? ?

Back To Top

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PATIENT INFORMATION

Patient identifier: (DO NOT USE the patient's name, initials, social security number, date of birth, medical record number or other personal identifiers) [?]

(Please limit your response to 8 characters)

Patient's age at time of event: [?]

Years

Patient's gender: [?]

- Male Female
 Not known Not applicable

Patient's weight: (select unit or "do not know") [?]

Kilograms

Patient's race and ethnic background (check all that apply): [Optional] [?]

- | | |
|--------------------------------------------------------------------|---------------------------------------------|
| <input type="checkbox"/> American Indian or Alaskan Native | <input type="checkbox"/> Asian |
| <input type="checkbox"/> Black or African American | <input type="checkbox"/> Hispanic or Latino |
| <input type="checkbox"/> Native Hawaiian or other Pacific Islander | <input type="checkbox"/> White |
| <input type="checkbox"/> Unknown | <input type="checkbox"/> Not applicable |

Did the patient have any of the following preexisting characteristics that may have contributed to the event? (Check all that apply) [?]

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

Please provide any other information about the patient that may have influenced the outcome of the event. [?] [limit: 50 lines of text]

TEST INFORMATION

Test performed:

Date test was performed/administered: (mm/dd/yyyy)

Test results: [limit: 50 lines of text]

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