CODA ONLY

Save & Continue

Save & Exit

Submit To FDA

Cancel

Comment

Properties

Tracking

Send Email

UF Messages

CONTACT INFORMATION

User facility name: Add Comment

Address: [limit: 50 lines of text] Add Comment

Contact's name: Add Comment

Contact's phone number: Add Comment

Contact's fax number: Add Comment

Contact's email address: Add Comment

Occupation of Contact: Add Comment

Name of initial reporter: Add Comment

Address of initial reporter: [limit: 50 lines of text] Add Comment

DEVICE INFORMATION

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:

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 serial #:

(Please limit your response to 30 characters)

Device model #:

Device lot #:

(Please limit your response to 30 characters)

Device catalog #:

(Please limit your response to 30 characters)

Other device #:

Expiration date: (mm/dd/yyyy)

Calendar

If the device was implanted, give implant date: (mm/dd/yyyy)

Calendar

If the device was explanted, give explant date: (mm/dd/yyyy)

Calendar

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

FOLLOW-UP QUESTIONS

Area where the event took place: [Optional]

- ○ Critical Care
- ○ ER
- ○ NICU
- ○ Electrophysiology Lab
- ○ Other
- ○ Not applicable
- ○ OR
- ○ Patient Room
- ○ PICU
- ○ Skilled Nursing Unit
- ○ Not known

If you selected "Other" from the above menu, please specify where the event took place in the hospital.

FOLLOW-UP QUESTIONS

Other location of event: [Optional]

FOLLOW-UP QUESTIONS

Date of death: (mm/dd/yyyy)

Calendar

FOLLOW-UP QUESTIONS

Was intervention required to prevent permanent impairment or damage?

- ○ Yes
- ○ No
- ○ Not known
- ○ Not applicable

Outcomes attributed to serious injury: (Check all that apply)

- ☐ Life-threatening
- ☐ Congenital anomaly
- ☐ Other
- ☐ Not applicable
- ☐ Hospitalization, initial or prolonged
- ☐ Disability
- ☐ Not known

If you checked "Other" above, please describe the outcome.

FOLLOW-UP QUESTIONS

What problem did the user have (Check all that apply) [Optional]

- ☐ Device failed (e.g. broke, couldn't get it to work or stopped working)
- ☐ Device was hard to use
- ☐ Not known
- ☐ Device malfunction - that is, the device did not do what it was supposed to do
- ☐ Other
- ☐ Not Applicable

If you selected "Other" above, please describe the type of person who was operating the device. Do not give the person's name.

FOLLOW-UP QUESTIONS

Date of dialysis: (mm/dd/yyyy)

Calendar

FOLLOW-UP QUESTIONS

Was intervention required to prevent permanent impairment or damage?

- ○ Yes
- ○ No
- ○ Not known
- ○ Not applicable

Outcomes attributed to serious injury: (Check all that apply)

- ☐ Life-threatening
- ☐ Hospitalization, initial or prolonged
- ☐ Congenital anomaly
- ☐ Disability
- ☐ Other
- ☐ Not known
- ☐ Not applicable

If you checked "Other" above, please describe the outcome.

FOLLOW-UP QUESTIONS

What problem did the user have (Check all that apply) [Optional]

- ☐ Device failed (e.g. broke, couldn't get it to work or stopped working)
- ☐ Device malfunction - that is, the device did not do what it was supposed to do
- ☐ Device was hard to use
- ☐ Other
- ☐ Not known
- ☐ Not Applicable

FOLLOW-UP QUESTIONS

Who was operating the device? (Check all that apply) [Optional]

- ☐ Doctor
- ☐ Nurse
- ☐ Allied Health Provider
- ☐ Family Member / Visitor
- ☐ Patient
- ☐ Other
- ☐ Not known
- ☐ Not applicable

If you selected "Other" above, please describe the type of person who was operating the device. Do not give the person's name.

FOLLOW-UP QUESTIONS

Date of dialysis: (mm/dd/yyyy)

Calendar

FOLLOW-UP QUESTIONS

Date of chemotherapy: (mm/dd/yyyy)

Calendar

FOLLOW-UP QUESTIONS

List other therapies used on the patient at the time of the event that may have caused or contributed to the event: [limit: 50 lines of text]

MedSun
Medical Product Safety Network

Create New Report
All Clinics

FDA

Contact Info | Event | Patient | Device | Test

Cancel

RECORD NOT FOUND ERROR occurred getting clinic record

ERROR occurred getting networks for user

EVENT INFORMATION

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

When did the event happen? (mm/dd/yyyy)

Calendar

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)

4/29/2011 Calendar

Where did this event occur?

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

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

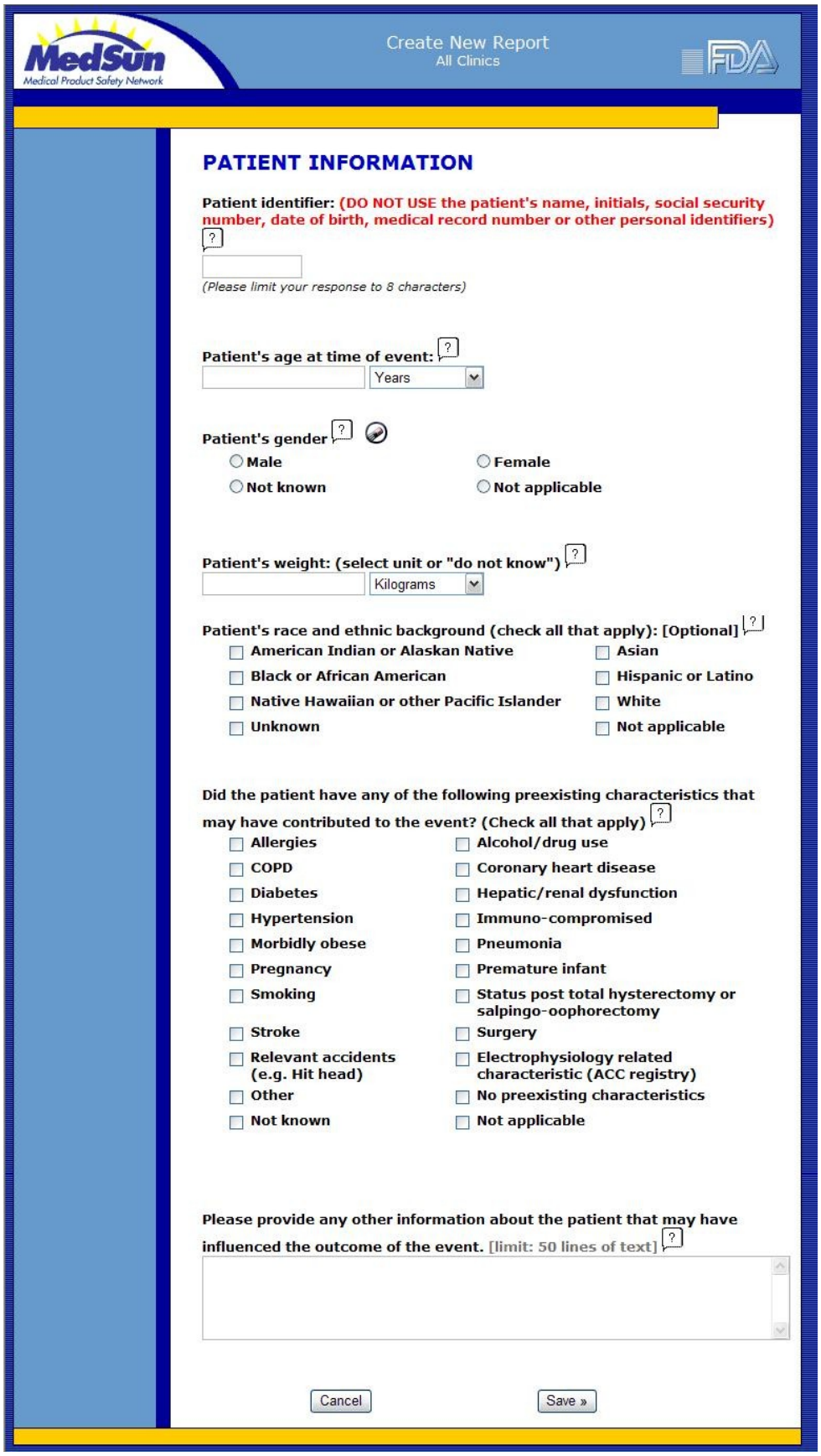
Were there other devices being used on the patient at the time of the event that may have caused or contributed to the event? [limit: 50 lines of text]

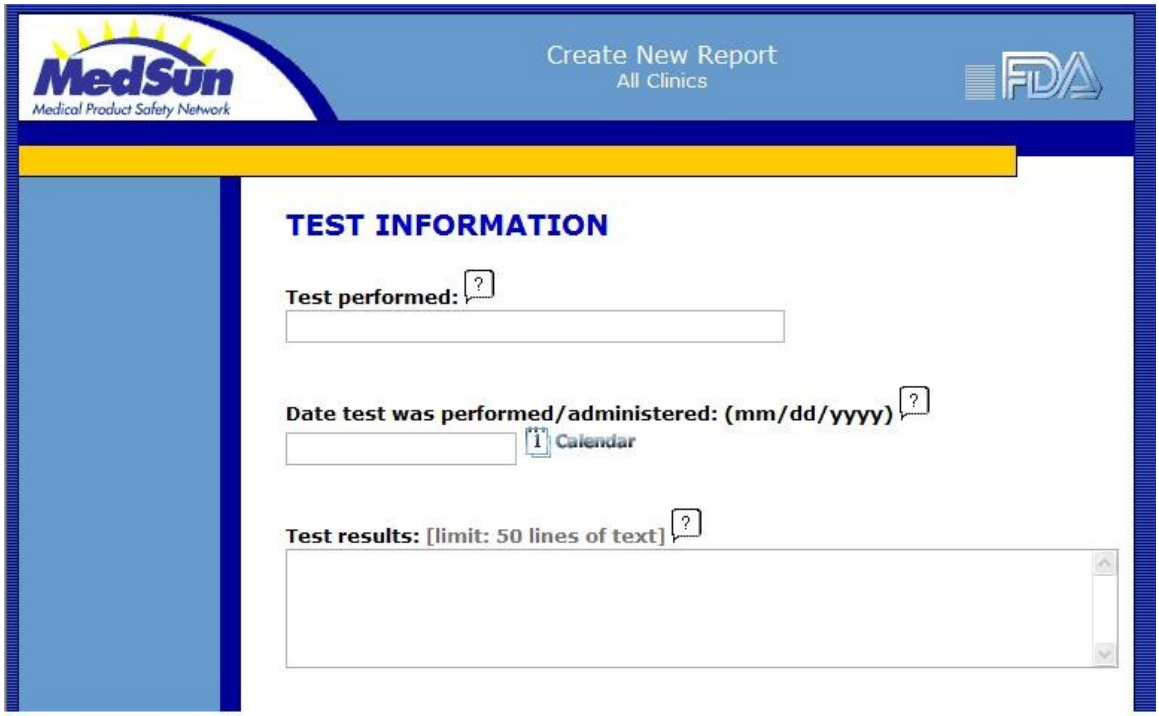
Were there other therapies being used on the patient at the time of the event that may have caused or contributed to the event? (Check all that apply)

- ☐ Cardiac Drugs
- ☐ Chemotherapy
- ☐ Dialysis
- ☐ Hormonal Replacement Therapy
- ☐ 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. [limit: 50 lines of text]

What was the original intended procedure?


MedSun
Medical Product Safety Network
Create New Report
All Clinics
FDA
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]
American Indian or Alaskan Native
Asian
Black or African American
Hispanic or Latino
Native Hawaiian or other Pacific Islander
White
Unknown
Not applicable
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
Status post total hysterectomy or salpingo-oophorectomy
Stroke
Surgery
Relevant accidents (e.g. Hit head)
Electrophysiology related characteristic (ACC registry)
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. [limit: 50 lines of text]
Cancel
Save »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FDA
TEST INFORMATION
Test performed:
Date test was performed/administered: (mm/dd/yyyy)
Calendar
Test results: [limit: 50 lines of text]