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FDA Form 3670

MedSun Report Form for Mailed and Faxed Reports

User Facility Name: _____

Address: _____
_____
_____

Contact Name: _____
Contact Phone #: ( ) _____
Contact Fax #: ( ) _____
Contact's email address: _____
Occupation of Contact: _____
Name of initial reporter: _____
Address of initial reporter: _____
_____

This report is: • Initial

When did the event happen? (Date) ___/___/____

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: (mo/day/year): ___/___/_____

Where did this event occur?

• Hospital	• Home
• Nursing home	• Outpatient treatment facility
• Outpatient diagnostic facility	• Ambulatory surgical facility
• Other	• Not known

• Not applicable	

If you checked hospital, where in the hospital did this event occur?

• Critical Care	• OR
• Skilled nursing unit in hospital	• Other (specify):
• Not known	• Not applicable

What outcomes may be attributed to this event (Check all that apply):

• Death (date___/___/_____)	• 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

If you checked serious injury, please answer the following 3 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.

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

• Yes	• No
• Not known	• Not applicable

What problem did the user have (check all that apply):

• 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

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

• Yes	• No
• Not known	• Not applicable

Who was operating the device (check all that apply)?

• 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 (not the person's name).

_____

_____

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

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	• Chemo Therapy (date: _____)
• Dialysis (date: _____)	• Hormonal Replacement Therapy
• Immuno Therapy	• Long-Term Antiobiotics
• Prenatal medication	• Other
• No other therapies	• Not known
• Not applicable	

List other therapies used on the patient at the time of the event that may have caused or contributed to the event:

Describe the event or problem. Please provide as much detail as possible:

PATIENT INFORMATION

PLEASE USE A SEPARATE PAGE FOR EACH PERSON INVOLVED.

Patient Identifier (use something that will help you remember who the patient is, but not the patient's name or SSN):

_____

Patient's age: _____

• Days
• Weeks
• Months
• Years
• Date of birth (enter above)
• Not known
• Not applicable

Patient's sex:

• Male	• Female
• Not known	• Not applicable

Patient's weight: _____

• Ounces
• Pounds
• Kilograms
• Grams
• Not known
• Not applicable

Patient's ethnic background (Optional):

• American Indian
• Black or African American
• Native Hawaiian or other Pacific Islander
• Asian
• Hispanic or Latino
• White
• Not known
• 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 salpingioherectomy
• Stroke	• Surgery
• Relevant accident (e.g. Hit head)	• Other
• No	• Not known
• Not applicable	

Please list the relevant patient allergies. for example, Latex allergy; a particular medication allergy; allergy to a particular material or biomaterial, etc.

_____
_____
_____
_____

Please describe the relevant accident preceding the event:

_____
_____
_____

Other characteristics or medical conditions: [Optional]

_____
_____

Other pertinent patient information:

_____
_____
_____
_____

DEVICE INFORMATION

PLEASE USE A SEPARATE PAGE FOR EACH DEVICE INVOLVED.

Device manufacturer's name: _____

Device manufacturer's address: _____

_____

City: _____

State: _____

Zip: _____

Device brand name: _____

Type of device: _____

Approximate age of device: _____

Device numbers: Please fill in all that are available.

Device serial #: _____

Device model #: _____

Device lot #: _____

Device Catalog #: _____

Other device #: _____

Expiration Date: _____

Has the facility discontinued use of the device due to the event? [Optional]

• Yes	• No
• Not known	• Not applicable

If the device was implanted, give implant date: (mo/day/year) ___/___/_____

If the device was explanted, give explant date: (mo/day/year) ___/___/_____

Is the device available for evaluation?

• Yes	• No
• Not known	• Not applicable

Was the device returned to the manufacturer?

• Yes	• No
• Not known	• Not applicable

Date device was returned to manufacturer: ___/___/___

Manufacturer comments to site:

Was this a laboratory device? If Yes, please answer the following questions:

Did the problem involve (check all that apply):

1. The reagent?..... ☐
2. The instrument?..... ☐
3. Single use test?..... ☐
4. Something else? (specify)..... ☐

_____

Is this a recurrent problem with this assay, test kit, or instrument?

1. Yes..... ☐
2. No..... ☐

Additional comments_____

_____

_____

_____

Which of the following problems did you observe? (Check all that apply and include additional comments as needed)

1. Calibration ..... ☐
2. Repeated error message..... ☐
3. Reproducibility..... ☐
4. Analytical sensitivity ..... ☐
5. Analytical specificity ..... ☐
6. Quality control ..... ☐
7. Questionable patient results..... ☐
8. Reagent(s)..... ☐
9. Inadequate/unclear instructions for use..... ☐
10. Poor test/instrument design..... ☐
11. Performance described in package insert not met..... ☐
12. Specimen problems..... ☐
13. Patient related problems..... ☐
14. Other (specify) ..... ☐

Product not available to return to manufacturer ☐
9. Discontinued all use of product..... ☐
10. Not known..... ☐
11. Not applicable..... ☐
12. Other (specify):..... ☐

_____

Additional Comments: _____

Please describe any follow-up actions below (check all that apply and include additional comments as needed):

1. Repeated assay, results OK, reported out..... ☐
2. Repeated assay, still problems..... ☐
3. Replaced reagents..... ☐
4. Opened new lot..... ☐
5. Manufacturer notified..... ☐
6. Called for service..... ☐
7. Product returned to manufacturer..... ☐

(Date of return: ___/___/____)

Additional Comments_____

8. Product not available to return to manufacturer ☐
9. Discontinued all use of product..... ☐
10. Not known..... ☐
11. Not applicable..... ☐
12. Other (specify):..... ☐

_____

Additional Comments:

If this is a tissue or cell product, please fill in the following:

These questions were added to gain more information about tissue and cell products

1. Transplant Product Distinct Identification Code (or other identifiers)

_____

2. Indicate any pre-implant problems that were found with the human cell or tissue product: **(Check all that apply)**

- € **No problem was detected with the product.**

- € **Product damage, describe_____**
- € **Packaging problem, describe_____**
- € **Product contamination, describe_____**
- € **Labeling problem, describe_____**
- € **Product Irregularity, describe_____**
- € **Other_____**

3. Was the human cell or tissue manipulated following removal from the packaging prior to transplantation?

- € **Yes. Please describe (e.g., stretched, rinsed in saline):**
  _____
- € **No** (SKIP TO 4)
- € **Unknown** (SKIP TO 4)

4. Was a pre-transplant gram stain of the tissue performed?

- € **Yes, pre-transplant gram stain was performed.**
- € **No, pre-transplant gram stain was not performed.** (SKIP TO 5)
- € **Do not know** (SKIP TO 5)
- € **Other** (Specify) _____

4a. The gram stain result was:

- € **Negative for organisms**
- € **Positive for organisms: RESULT_____**
- € **Unknown**
- € **Other** (Specify) _____

5. Was a pre-implant culture performed?

- € **Yes, pre-implant culture was performed**
- € **No, pre-implant culture was not performed** (SKIP to 6)
- € **Unknown** (SKIP to 6)
- € **Other** (Specify) _____

5a. The culture showed:

- € **No growth of organisms**
- € **Positive growth of organism(s). Identification of organism:**
  _____

€ **Unknown**
€ **Other** (Specify) _____

6. Was the cell or tissue product actually used (transplanted or infused)?

☐ Yes, used
☐ No, not used **(Skip to 8)**
☐ **Not known** (Skip to 8)
☐ **Other** (Specify) _____

7. Date of Transplant/Infusion _____/____/_____
mm/ dd/ yyyy

8. Were any devices transplanted with the tissue?

€ **Yes** (Please provide information in the DEVICE section of the MedSun database)
€ **No**
€ **Unknown**

9. Post-Transplant Adverse Event

Was there a post-transplant adverse event or close call?

€ **Yes, adverse event**
€ **Yes, potential adverse event (or close call)**

€ **No (**Please skip to end to record any additional comments.)

10. For Infection Related Events
(☐ Check here if there was not an infection-related adverse event and skip to 11.)

10a. Culture Results (post-transplant):

Anatomic Site_____ Date___/____/_____
Results_____ mm/ dd/ yyyy

Anatomic Site _____ Date___/____/_____
Results_____ mm/ dd/ yyyy

Anatomic Site _____ Date___/____/_____
Results_____ mm/ dd/ yyyy

10b. Other Study Results:

Test _____ Date___/____/_____ Results_____
mm/ dd/ yyyy

Test _____ Date____/____/_____ Results_____
mm/ dd/ yyyy

Test _____ Date____/____/_____ Results_____
mm/ dd/ yyyy

11. For Non-Infection Related Events (Check all that apply)
(☐ Check here if this does not apply. Proceed to 12.)

€ **Allograft malfunction: Describe_____**
€ **Allograft rejection: Describe_____**
€ **Other**_____

12. Medical Intervention in Response to the Event (Check all that apply)

- € **No intervention**

- € **Antibiotics for prophylaxis**
- € **Antibiotics for treatment**
- € **Required hospitalization**
- € **Required prolonged hospitalization for patient already hospitalized**
- € **Required additional procedure**:
  Specify Procedure_____
  Date Performed: _____
- € **Required explantation** (Specify Date)___/___/____
- € **Required retransplantation** (Specify Date)___/___/____
- € **Unknown**
- € **Other** (Specify) _____

Any Additional Comments:

_____

TESTS

Please enter all relevant tests/laboratory data.

Test	Date	Results