

# Cue X6R5002 Product Performance Report



**Important: If reaction or injury has occurred call Fresenius Kabi Post-Market Quality Assurance at 1-800-933-6925.**

Incident Date: \_\_\_\_\_ Instrument S/N.: \_\_\_\_\_ Software Version: \_\_\_\_\_ UDI No.: \_\_\_\_\_  
 Lot No.: \_\_\_\_\_ Spinner Video Jet No.: \_\_\_\_\_

**When Was the Problem Detected?**

Before Use    During Use    After Use

**Problem Type (Mark all applicable)**

**Packaging:**  Packaging Open    Mispacked    Discolored    Missing or Illegible Label    Missing or Separated Component (e.g., pinch clamp)  
**Tubeing:**  Flattened    Kinked    Hole    Cut/Sliced    Blocked/Occluded    Discolored    Incorrect Length  
 Separated (e.g. from Y connector)  
**Female Luer with Cap:**  Cracked    Leaking    Discolored    Blocked/Occluded    Poor Fit  
**Male Luer with Cap:**  Cracked    Leaking    Discolored    Blocked/Occluded    Poor Fit  
 Other: \_\_\_\_\_ Associated Alert Name/Code (if applicable): \_\_\_\_\_

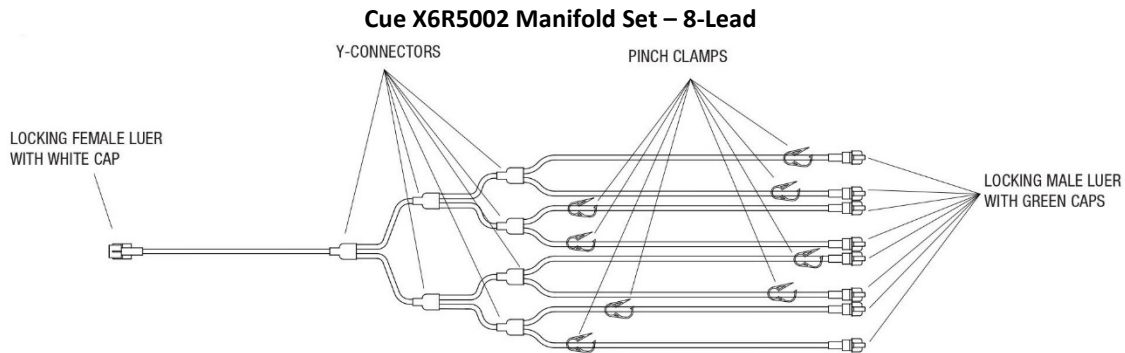
Additional Problem Description/Explanation

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Please circle specific components on the diagram where incident occurred**



Picture available for evaluation?   Yes    No

If a picture is available, please e-mail a clear picture **along with this report** to [mdpmqa.usa@fresenius-kabi.com](mailto:mdpmqa.usa@fresenius-kabi.com)

**Please answer the following questions:**

1. Was there any adverse event or injury?   Yes    No
2. Was the procedure successfully completed?   Yes    No    N/A
3. If no, was the procedure stopped due to a soft goods incident?   Yes    No    N/A
4. Was product lost?   Yes    No    N/A

Check box if you do **NOT** wish to receive response letters.

\_\_\_\_\_ E-mail address for letter recipient (if applicable)

**Kit Return to Fresenius Kabi**

1. Sample available for evaluation?   Yes    No
2. Return label needed?   Yes    No
3. Sample return box needed?   Yes    No

**Center Authorized Signature/Date:**

\_\_\_\_\_

**Fax this report to 1-888-858-2983 or E-mail this report to [mdpmqa.usa@fresenius-kabi.com](mailto:mdpmqa.usa@fresenius-kabi.com) and include a copy of this form when returning a kit.**

**Customer Information (please print)**

*The following information is required to receive a credit*

Facility Name: \_\_\_\_\_  
 Contact Name: \_\_\_\_\_  
 Account Number (if known): \_\_\_\_\_  
 Operator Name: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 City/State/Zip: \_\_\_\_\_  
 Phone Number: \_\_\_\_\_  
 Contact Person's E-mail: \_\_\_\_\_