Orrum PSO Alert – Cracks in Crescent Jugular Dual Lumen Catheter

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Background & Summary:

The Crescent Jugular Dual Lumen Catheter is a “Single use dual lumen catheter, which provides both venous drainage and reinfusion of blood via the jugular vein, that is indicated for use in adult and pediatric patients with acute respiratory failure requiring Veno-Venous Extracorporeal Membrane Oxygenation where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent (1).” The device is FDA approved for up to 30 days of use (2).

The Orrum PSO (3, 4) has received two reports (NREs #306, 316) within a one-month period related to cracks developing in the Crescent Jugular Dual Lumen Catheter (various sizes), both of which resulted in patient harm. These reports prompted Orrum to conduct a deeper Manufacturer and User Facility Device Experience (MAUDE)(5) database search, revealing 22 similar reports in a 46 month window. A peer-reviewed case report detailing a clinically similar failure was also identified (6)

The frequency and content of the PSO and MAUDE reports and the published case review suggests that the risk of catastrophic device failure is underappreciated by clinicians, resulting in this alert. Additional surveillance, monitoring, and education concerning the potential for failure should assist in minimizing patient risks.

Recommendations:

1. Consider the risk/reward of cannula exchange if the device is bent or otherwise damaged during preparation, insertion, or use.
2. Closely inspect the device prior to insertion for pre-existing damage.
3. Avoid and/or minimize lateral or shear (twisting) stress on the cannula before, during, and after insertion, to the extent possible.
4. After insertion or any manipulation/repositioning, fluoroscopic assessment should include close inspection for uneven spacing between wires, suggesting possible fracture development.
5. Increase surveillance of the device. Daily close visual inspection should be standard. Extra vigilance should be exercised in situations where;
    a. The device use approaches or exceeds the 30-day FDA approval.
    b. The patient is active/ambulatory and the device may be at an increased risk for bends or kinks.

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   c. Patient needs necessitate off-label use of the device, such as any insertion site other than the right jugular vein.
   d. Clinician(s) note unexplained or "false" air/bubble alarms on the ECMO circuit.
6. Use of bubble detection on the extracorporeal circuit, if available, using the most sensitive settings possible.
7. Strongly consider cannula exchange in situations where small leaks or air entrainment prompt cannula fixes and work arounds (examples: bone wax, Dermabond, Tegaderm, additional suturing, etc).
8. Education for the bedside clinician(s) regarding identification and treatment in the case of cannula failure.

**MAUDE Report Summaries:**

Between 08/21/2020 and 04/30/2024, there were 22 reports involving a problem with Crescent Dual Lumen Cannula describing a fracture, crack, or break (fracture being used further in this report). Common characteristics of the MAUDE reports have been summarized by Orrum PSO analysts and include:

Cannula Sizes – Two pediatric (9%), 19 adult (86%), and one unknown (5%) cannula size(s) were reported.

Cannulation Sites – In nine reports (41%), the cannulation site was not identified. In seven reports (32%), cannulation sites other than the Jugular Vein were identified. In four reports, the Right Jugular Vein was identified (18%), and in two reports the Jugular Vein was identified without clarification as to laterality (9%).

Length of Use – In nine reports (41%), the length of use was not identified. In ten reports (45%), the length of use was >30 days (range 30-188 days). Two reports (9%) identified failure at 28 days of use, and one report (5%) identified failure immediately after insertion.

Location of Device Failure – In 12 reports (55%), the location of the fracture is not identified, but in nine of these reports (41% of total), air entrainment to the extracorporeal circuit is noted, suggesting these occurred in or near the extracutaneous portion of the cannula. In ten reports (45%), the location of the facture is noted to be 1-2 cm proximal to the gold suture ring, as seen in the included photographs (Image 1, 2).

Air entrainment was noted in 15 reports (68%), suggesting the fracture involved the negative (drainage) lumen of the cannula. In two reports (9%), blood loss was described in a manner which suggests the fracture involved the lumen carrying oxygenated blood.

Patient Impact – In eleven reports (50%), injury to the patient was identified, including 5 deaths (23% of total). In 8 reports (36%), "no injury" was used to describe the event. In three reports (14%), patient impact was described as "not known" or "not reported."

Manufacturer Recommendations – Suggestions from the device manufacturer to the FDA to avoid device failure include:

1. Avoid bending and replace if bent.
2. Use in the right Jugular Vein only. From the manufacturer (7): “Insertion into a non-indicated vessel (off-label) places excessive stress on the catheter body, which may lead to kinking and mechanical failure. The Crescent catheter is indicated for use in the jugular vein and the IFU warns that circuit lines should be managed to reduce catheter flexing and tubing should remain controlled in order to prevent kinking. If a kink develops, the catheter may need to be replaced.”
3. Use only indicated suture sites. From the manufacturer (7): “Inadequate catheter securement (off label) can place bending stress on the catheter body, which may lead to kinking and mechanical failure. The catheter is designed with integrated suture sites and an optional suture collar for supplemental securement. The IFU cautions that suturing directly on the wire-reinforced section of the catheter can cut, kink, or damage the catheter. The IFU warns that if a catheter kink results in permanent deformation or damage, the catheter may need to be replaced.”
4. Avoid use >30 days. From the manufacturer (7): “Extended duration of use can lead to fatigue and fracture. Safe use of the catheter beyond its 30-day bench test duration has not been demonstrated.”

**PSO Reports:**

Two reports to Orrum PSO described scenarios which suggest these reports were not duplicated in the MAUDE database at the time the search was conducted. In the PSO reports, both patients suffered massive air entrainment into the extracorporeal circuit, resulting in patient harm and/or death. Some similarities exist between the PSO reports and the MAUDE reports.

Cannula Sizes – One report involved a pediatric cannula, the other an adult size.

Location of Device Failure - Both PSO reports involved fractures in the cannula just “below” the gold suture ring (see images 1 and 2, below).

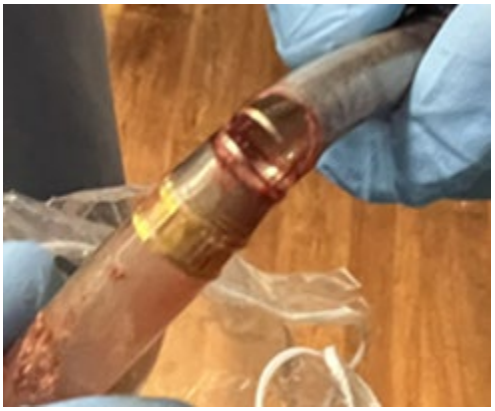 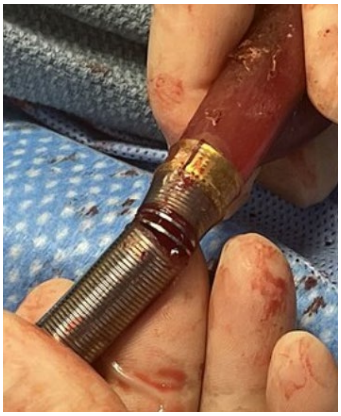
*Image 1, left, and 2, right.*

Length of Use - In one of two reports, the length of use exceeded 30 days, in the other report, the length of use was not noted.

Notable Data Points: In one PSO report, the ECLS system had experienced at least two occurrences of air detection approximately one week prior to the acute, massive failure. Visual inspection revealed no gross air, but this may have been an early warning of device failure.

This same report noted a positive pressure bleed at the insertion site prior to acute device failure, which was treated with additional sutures. As this device sits in the venous system, with no significant positive pressure expected, except for the lumen carrying oxygenated blood, this may have also been an early warning of device failure. Both of these descriptions are similar to the published case report from 2022 (6).

Finally, this same PSO report noted that the cannula was directed laterally toward the shoulder for securement, which likely contributed to the device failure.

More than one PSO analyst involved in the assessment of these events noted firsthand experiences where a dual lumen catheter from another manufacturer (not Medtronic), had failed in the peri-insertion period, presumably due to shear stress applied when twisting the cannula during insertion, and a third device type had noted failures outlined in the earlier referenced case report (6). In one MAUDE report and one PSO report, the providers submitting the reports mentioned hearing word of mouth instances of similar dual lumen cannula failures, or, having experienced additional unreported failures of the same type.

**Conclusions:**

No suspicion of manufacturing defect is present in the Crescent cannula line. Frequently, clinical use of the device may exceed its approved indications, in whole or part due to the high acuity of the patient population and an increasing trend of ambulating ECMO patients. When device failure occurs, it is often sudden and catastrophic, with significant risk of patient injury or death. These risks appear to be underappreciated by clinicians. The mitigation strategies and

potential early warning signs outlined here should be considered by teams caring for patients with this device.

References:


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