Reduce the Risk of Esophageal Trauma Associated with Placement and Removal of Esophageal Stethoscopes

White Paper

Introduction

During most surgeries where the patient is under general anesthesia, an esophageal stethoscope with temperature sensor is used to monitor the patient's core body temperature. This type of device is comprised of a specially formulated PVC tube with an acoustic transmitting balloon over the tip to facilitate auscultation of heart and lung sounds. The device must be inserted orally into the esophagus where it passes and comes into contact with the sensitive tissue that lines the esophagus. It has been reported that during the insertion and removal of the device, the rough non-beveled edges can cause tissue traumas to occur, requiring further medical intervention. To help reduce the risk of this type of injury, Starboard Medical has taken an innovative approach to the design and manufacturing of their esophageal stethoscope with temperature sensor.

Problem

New initiatives and evidence based practice guidelines recommend to maintain normothermic temperature, measure and record the patient's body temperature for all surgeries greater than a ½ hour in length. As such the use of temperature monitoring probes such as the Esophageal Stethoscope with temperature sensor (ES) are common practice. However, not all Esophageal Stethoscopes are created equal or with the patient in mind. Many manufacturers reduce production costs by utilizing components that are "universal" between different size devices, which leads to issues with fitment. This, combined with manufacturing processes that are more cost efficient but less caring, lead to rough cuts and uneven edges known to cause esophageal trauma and patient discomfort. In fact, it was reported to the FDA maude event reporting system that a competitor's ES caused "massive esophageal bleeding from laceration to the esophagus as the tip of the product was inserted". **Figure 1** displays the rough edge at the balloon tubing interface of the competitor's device, this is most likely the cause of the above mentioned complaint. Another area on standard ES's that can cause possible tissue trauma is the tip of the tube covered by the balloon. Most manufacturers fail to take the extra step to bevel the tube tip leaving it sharp and abrasive. Tubes that are not beveled can cause the balloon to tear interfering with sound transmission and they may also cause esophageal laceration.

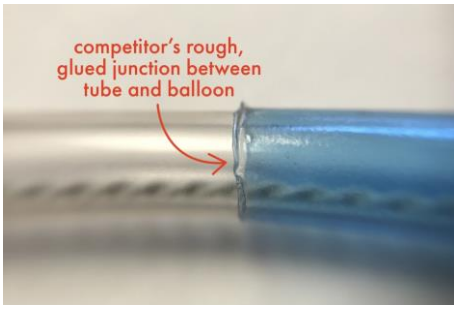

Figure 1: Rough transition between balloon and PVC tube (Competitor's ES)

Solution

Starboard Medical takes pride in "raising the bar" when it comes to patient comfort, while maintaining a high level of accuracy and dependability. To help reduce the risk of esophageal trauma during insertion and removal, Starboard Medical uses balloons that are specific to each size of the ES to ensure proper fitment. Secondly, a heat bonding technique is used during manufacturing to eliminate any rough or sharp edges that may occur between the balloon and the tube. This also helps assure the balloon remains attached. Lastly, every Starboard Medical ES tubing tip is beveled during production to eliminate the sharp and abrasive cut edge found in other devices. **Figure 2** illustrates the smooth balloon transition found on the Starboard Medical ES.

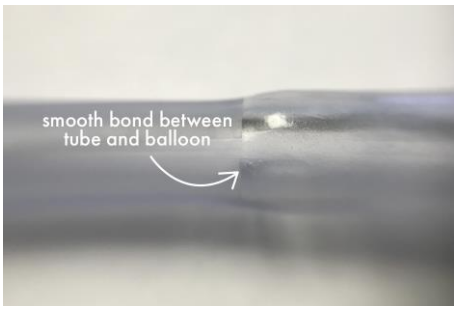

Figure 2: Smooth transition between balloon and tube found in Starboard Medical's ES

Conclusion

As seen above, there is virtually no edge between the balloon and tube with the Starboard Medical's Esophageal Stethoscope. This helps prevents trauma to the sensitive tissues lining the esophagus. If you desire to help reduce the risk of esophageal injury during use of the ES temperature monitoring, you should consider Starboard Medical's Esophageal Stethoscope

References: FDA: MAUDE Adverse Event Report, Report # 9613793-2013-00002

Link to report

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