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**CUSTOMER INFORMATION BULLETIN**

**Date of Issue:** November 2011

**CIB Number:** 14112011

**Products Affected:** Bivona® Neonatal, Pediatric and Flexextend Tracheostomy Tubes with the integrated connector that does not require use of a disconnect wedge

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Smiths Medical has become aware of an issue with some customers experiencing difficulty disconnecting accessories from the 15mm connector of the Bivona® Neonatal, Pediatric and Flexextend Tracheostomy Tubes (“Tracheostomy Tube”) with the integrated connector that does not require use of a disconnect wedge.

**Description of the Issue:**

If the circuit or adapter is connected to the 15mm connector with excessive force, then the user may have difficulty or may be unable to disconnect the circuit or adapter from the 15mm connector. As a result, we recommend using a two-handed technique along with a twist and push/pull method to connect/disconnect the tube from the circuit or adapter (i.e., HME, speaking valve or breathing circuit connector).

It is important to follow the Instructions for Use supplied with these products, along with the directions below, for the safe and effective use of these products. Do not force the connection together too tightly as this may result in difficulty disconnecting the accessory from the 15mm connector.

A video depicting this information is available for viewing on the Smiths Medical website at:

<http://www.smiths-medical.com/education-resources/videos/airway/index.html>

**Connecting an Accessory to the 15mm Connector:**

1. Put on non-sterile gloves.
2. Stabilize the base of the connector with one hand to minimize movement and trauma to the stoma.
3. Connect accessory to the top of tube's 15mm connector with your other hand.
4. Gently press downward until you feel resistance, and then continue to gently push down while simultaneously *twisting* the accessory with a quarter turn.

**Note:** Practice applying each accessory to the 15mm connector several times to gain experience with the appropriate downward pressure required.



**Disconnecting:**

1. Put on non-sterile gloves.
2. While firmly holding the base of the connector with one hand, use your other hand to gently rotate the accessory while pulling up, which loosens the seal.

