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VIAMED Feedback - Product Feedback Positive

**Posey Foam Trach Ties**

Issue ID #64613

Date Created 10/Nov/2015

Issued To: Derek Lamb

Completed Status: Still Outstanding

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**Notes:**

Added by Catrin Hird sent to Derek Lamb

Further to the review by the MHRA regarding Trach Ties I have received the following response from Posey regarding their version, I have not communicated this with Keith as yet:

We reviewed the Medical and Healthcare Products Regulatory Agency's (MHRA) medical device alert (dated: September 11, 2012) (please see Attachment-1). The problem section indicates that "The MHRA is aware of several incidents where the eyelets of tracheostomy tubes appear to have been damaged by the holder. This led to dislodgement of the tube with the subsequent risk of airway loss."

We reviewed the Posey Foam Trach Tie product (Model #8197) and it is made from the foam fabric with Nylon (hook and loop) material. The foam fabric material passes through the eyelets of silicone tracheostomy tubes. The Velcro does not hold the tracheostomy tubes eyelets directly, but the fabric material that passes through the eyelets holds it in place. The Velcro on the Nylon material sticks on the fabric material to hold the tracheostomy tubes via fabric material.

The instruction for use for the Posey Foam Trach Tie (please see Attachment-2) indicates that "Do not force tabs through the slot when removing trach tie. This could cause accidental extubation or displacement of the tube. If the slot is too small to allow for easy removal, cut off the hook and loop tab, and pull the tie gently." We reviewed the Posey Foam Trach Tie (Model #8197) complaint history of last 18 months and there were no prior reports of eyelets of tracheostomy tubes that have been damaged by the Posey Trach Tie which led to dislodgement of the tube with the subsequent risk of airway loss.

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