



**PRODUCT INFORMATION NOTICE**  
**PORTEX<sup>®</sup>-BIVONA<sup>®</sup>-TRACHEOSTOMY TUBES**

The Bivona Tracheostomy Tube is intended to provide direct airway access for a tracheotomised patient for 29 days. Bivona tracheostomy tubes can be re-processed up to ten times for single patient reuse for adults, and up to five times for paediatric or neonatal patients. This Product Information Notice is intended to advise users that they can apply the instructions below to all Portex<sup>®</sup> Bivona<sup>®</sup> Tracheostomy Tubes that are recommended for re-processing. These re-processing instructions have been validated to ensure that there will be no adverse effect to the product.

**ALWAYS FOLLOW THE INSTRUCTIONS FOR USE.**

**CLEANING:**

**1. Hospital or sterilization service re-processing**

**1.1 Step 1 cleaning**

- 1.1.1 Following removal from the patient, the device should be placed in a suitable container and marked clearly with the patient's reference/identifier. Tracking of the device should be conducted in accordance with local hospital procedures for the re-processing of **single patient** use devices.
- 1.1.1.2 Following the instructions for use for an enzymatic solution (preferably using a neutral non-coloured and non-scented cleaner e.g. Ruhof 345APANS Endozyme AW Plus No Scent), remove all biological material from the tracheostomy tube, by soaking and gentle manual cleaning.
- 1.1.1.3 Inspect for any residual contamination and, if necessary, remove it by repeat soaking in enzymatic solution and then light rubbing with a soft cleaning implement.
- 1.1.1.4 Inspect the product for any signs of damage. Discard the product if there is any sign of damage.

**1.1.2 Step 2 Method 1 Sanitization Instructions:**

- 1.1.2.1 Place the product and its obturator separately in an HTM 2030/ISO 15883-2 compliant washer/disinfector/dryer. Follow the manufacturer's instructions for a thermal disinfection cycle giving a minimum  $A_0$  value of 600 (ref. ISO 15883-2). Ensure that the wash reaches all parts of the product to be cleaned. This will mean flushing through the tube bore and talk attachment tube (if fitted).
- 1.1.2.2 Using aseptic technique, inspect the dry/disinfected product for any signs of damage. Discard the product if there is any sign of damage.
- 1.1.2.3 Store product in sealed plastic bag or container, marked with the patient's reference/identifier.

**1.1.3 Alternate Step 2 Method 2 Sterilization Instructions:**

- 1.1.3.1 Insert the obturator into the tube and wrap in protective lint-free cloth or place them in a sterilization pouch.
- 1.1.3.2 Sterilize in a gravity displacement steam autoclave at 121° C (250° F) for 40 minutes

## **1.2 Hospital ward or home-care re-processing:**

### **1.2.1 Step 1 Cleaning:**

- 1.2.1.1 Following removal, place the tube in a sealed plastic bag or container until ready to soak will avoid drying out and hardening of secretions.
- 1.2.1.2 Soak the tracheostomy tube and its obturator, separately, in a container of warm water containing a mild soap solution for a period of 60 minutes. Ensure that the wash reaches all parts of the product to be cleaned. This may mean using a syringe to flush through the talk attachment tube (if fitted) and manipulating small tubes to ensure that the liquid does fully fill the bore.
- 1.2.1.3 Remove any contamination with a lint free swab. Small tracheostomy tube bores can be cleaned by pulling a small portion of a lint free swab through the tube.
- 1.2.1.4 Inspect for any residual contamination and, if necessary, repeat the soak and clean operations.
- 1.2.1.5 Rinse the tube inside and outside with clean warm water, flushing thoroughly with water and then air dry.
- 1.2.1.6 Store in a clean sealed plastic bag or container.

### **1.2.2 Step 2 Method 1 Sanitization Instructions:**

- 1.2.2.1 One method of sanitising the product is to place the cleaned tube and obturator in an electric steam disinfectant ("baby bottle sterilizer") e.g. Advent.
- 1.2.2.2 The sanitization process must be conducted in accordance with the supplier's instructions for use.
- 1.2.2.3 The tube and obturator must be taken out of the bag prior to placement in the unit. The obturator must be placed in the unit alongside the tube, not assembled into the tube.
- 1.2.2.4 Items remain disinfected (if the sterilizer is unopened) for 1 or more hours as stated in the individual manufacturer's instructions.

### **1.2.3 Alternative Step 2: Method 2 Sanitization Instructions:**

- 1.2.3.1 Remove the tube and the obturator from its container and place in a pan of rapidly boiling clean water.
- 1.2.3.2 Cover the pan and REMOVE IT FROM THE HEAT. Allow the water to cool to "hand hot" before removing the parts.
- 1.2.3.3 Handle the obturator by its handle and the tube by its neck flange.

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