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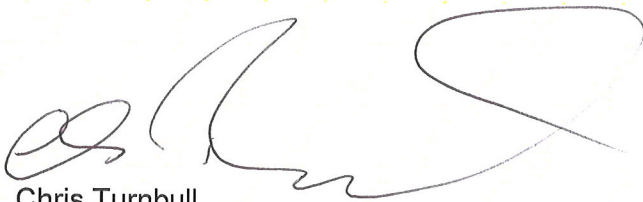
Bivona Tracheostomy Tube Reprocessing

To whom it may concern,

Following customer request, this letter clarifies that routine cleaning of the Tracheostomy tube that does not involve the use of any mechanical abrasion or sanitising. (e.g. washing in warm water with a mild soap solution) is not intended to be classified as "Reprocessing" as described in the Instructions for Use (IFU). It therefore is not subject to the 10 times (adult) or 5 times (neonatal or paediatric) maximum limit on the number of reprocessing cycles that is recommended for the product.

It should be noted that the "Indications For Use" within the IFU which state that "The Bivona Tracheostomy Tube is intended to provide direct airway access for a tracheotomized patient for up to 29 days", is a regulatory requirement which must be observed.

Please see Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.



Chris Turnbull

R&D Director
Smiths Medical Airway Franchise