# Rolynn MEDICAL LTD.

## **P<sup>3</sup> Medical Technical Data Sheet**



### **Tracheseal**

#### **General Description**

The TracheSeal integrated Tracheostomy Dressing consists of a circular section of Hydrocolloid with PU film/foam laminate fused with a wound location device, the "toggle", is on the dressing centrally, allowing easy location for correct position to press and support the healing wound beneath following decanulation of a tracheostomy tube. The hydrocolloid side is covered by a polyester release liner

#### Intended Use

The device is used on patients immediately following the removal of a tracheostomy tube until the healing is complete. The Hydrocolloid absorbs exudate from the wound, whilst the PU film layer is vapour permeable, and water and bacterial impermeable.

#### **Technical details**

Materials: PU film, foam, self-adhesive hydrocolloid, PET release liner, thermoplastic elastomer

Latex status: Latex Free



#### **Regulatory Compliance**

Meets the essential requirements of directive 93/42/EEC as amended 2007/47/EC for Class IIa medical devices

Part Number and Sizes	
Part Number	Diameter Size (cm)
TS0001	10
TS0002	7.5

PackagingUnit pack:Single packed: film front fully peel-able pouchShelf pack:Corrugated board carton of 10 pieces

Shelf Life 3 Years

#### Manufacturing environment

Manufactured in a cleanroom constructed to comply with ISO 14644 Class 8 @ 0.5µ manned

Sterilisation Terminally sterilised by Gamma Irradiation

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