**INSTRUCTION FOR USE**

# 200 mm

**TRACHESEAL STERILE WOUND DRESSING - INSTRUCTIONS FOR USE**

1. **PRODUCT DESCRIPTION** TracheSeal is a single use device and once removed MUST NOT be reused or reapplied due to The TracheSeal Wound Dressing is a conformable, sterile, self adhesive wound dressing the risk of cross infection or re-infection.

composed of (i) a silicone wound contact layer (0.2mm thick) and (ii) a polyurethane foam pad

and (iii) a water-proof pu film backing and (iv)a wound location device for placement of a patient’s Dispose to clinical waste or if at home to domestic waste. or carer’s finger. TracheSeal absorbs exudate from the wound and is impermeable to bacteria.

The absorption process is characterized by swelling of the polyurethane foam pad in contact with **5. SPECIAL NOTES & CAUTIONS**

wound exudates through the perforated silicone wound contact layer, providing moist conditions

conducive to natural healing. The soft silicone wound contact layer is non-adherent to the wound TracheSeal is a dynamic dressing – in that it requires patient interaction- the patient must be so that newly formed tissue is not traumatised when TracheSeal is changed or removed. informed of the importance when using TracheSeal of firm finger pressure to the Central button

whenever they speak or cough. Failure to achieve this patient compliance significantly reduces

1. **INDICATIONS** the benefit of this unique dressing.

TracheSeal may be used for the management of the neck wound after removal of a

tracheostomy tube, until healing is complete. In the unlikely instance that there is some tissue necrosis around the tracheostomy wound then

Post decannulation site of tracheostomy the wound may initially appear to increase in size in the early stages of TracheSeal treatment.

This is normal and occurs as any wound debris is removed from the edges of the wound.

## CONTRAINDICATIONS / SAFETY INFORMATION

TracheSeal is a sterile product and should not be used if the pouch is damaged or has previously In the management of moderately to heavily exuding wounds, TracheSeal can only make the been opened. The device cannot be resterilised. overlying environment more conducive to healing. There are cases where healing is impaired as a result of underlying conditions; in these instances, TracheSeal alone may make little or no

TracheSeal should not be used on: progress, and suitable treatment of the underlying conditions will be necessary as well. Therefore,

.ulcers caused by chronic infections (tuberculosis, deep mycotic infections, syphilis) if after 4-6 weeks of TracheSeal treatment, there has been no improvement then, in line with

. arteriopathy stage IV accepted wound management practice, the original diagnosis and overall therapy should be

. bites and 3rd degree burns. reassessed.

TracheSeal should not be used when there is a known sensitivity to silicone. TracheSeal should be left in place as long as possible, but not more than 5 days in order to TracheSeal should not be used together with oxidizing agents such as hypochlorite solutions or prevent trauma to the fragile newly formed tissue and to reduce cross contamination through hydrogen peroxide. frequent dressing changes.

Wounds showing clinical signs of infection (temperature, pus, inflammatory signs) should be Thick necroses should be removed before applying TracheSeal. treated under medical control before use of TracheSeal can be resumed.

## INFORMATION FOR USE

Due to the nature of this dressing it is suitable for the closing of a tracheostomy site, as it will

TracheSeal Wound Dressings are intended for single use only.

## STORAGE / STERILISATON / SYMBOLS ON LABELLING:

withstand the pressure from airflow attempting to pass through the remaining stoma, it can Store Tracheseal dressings away from direct sunlight ( ) at ambient temperature (5-40°C) and manage the presence of the existing secretions and is also easily removed for necessary humidity ( )

changes without damaging surrounding skin or the wound edges.

TracheSeal is very simple to apply, requiring no special skills or equipment. Dressing changes should normally occur when the polyurathane foam pad has been fully-absorbed; therefore, the interval between dressing changes will depend entirely upon the state of the wound. In the early

Explanation of symbols

STERILE EO Sterilised by Ethylene Oxide

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CE Mark

post decannulation period, and on large or moderately exuding wounds, changes may be required more frequently but may be reduced as healing progresses and exudate levels are reduced (see Section 4.3).

## Skin Preparation

1. Cleanse the wound with sterile saline and sterile swabs.
2. Dry the skin surrounding the wound.
3. Remove any remains of creams or greasy substances.

**REF**

2

Catalogue Number

Consult instructions for use Do not reuse

Manufacturer Keep dry

LOT

Batch Code

Use by date

Do not use if package is damaged Caution

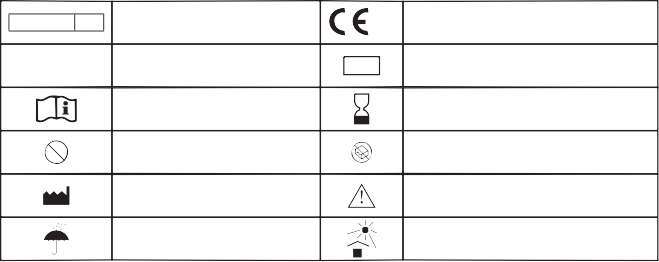
Keep away from direct sunlight

## PRESENTATIONS:

* 1. **Dressing Application TracheSeal is available in the following sizes:**

- 7.5 cm Round

1. Select the appropriate TracheSeal size that will completely cover the wound surface, ensuring - 7.5 cm Square a 2 to 3 cm margin beyond the edges of the wound. - 7.5cm Oval
2. Remove the protective liner from the TracheSeal and align the central button directly/centrally over the stoma site. Having aligned the TracheSeal apply to the skin, gently pressing the edges of the dressing. No additional fixation tape is necessary.
3. The alignment of the button over the stoma site allows more accurate application of finger pressure by the patient/carer



280 mm

(d) Ensure the patient/carer is aware of the clinical requirements to apply pressure to the button as per instructions in section 5

## Dressing Changes

TracheSeal is easy to remove due to the soft silicone layer when a whitish blister has formed, and approaches the edges of the dressing. This makes for more comfortable dressing changes with little or no associated trauma, helping to produce improved wound healing.

TracheSeal should be changed as required, depending on the amount of exudate from the wound. Where loss of adhesion around the wound occurs, the dressing should be changed immediately. Where leakage occurs, the dressings should be changed immediately.

1. Gently remove TracheSeal.
2. Remove any remaining debris or gel from the wound, using sterile compresses.
3. Follow procedure 4.1 a) to 4.2 c) to apply new dressing.

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