1. PRODUCT DESCRIPTION

The TracheSeal Wound Dressing is a conformable, sterile, self adhesive wound dressing composed of (i) a hydrocolloid layer (1.7mm thick) and (ii) a polyurethane foam backing material and (iii) a wound location device for placement of a patient’s or carer’s finger. TracheSeal absorbs exudate from the wound and is impermeable to bacteria. The absorption process is characterized by swelling of the hydrocolloid layer in contact with wound exudates, through the formation of a highly cohesive gel providing moist conditions conducive to natural healing. The gel formed is non adherent to the wound so that newly formed tissue is not traumatised when TracheSeal is changed or removed.

2. INDICATIONS

TracheSeal may be used for the management of the neck wound after removal of a tracheostomy tube, until healing is complete.

3. CONTRAINDICATIONS / SAFETY INFORMATION

TracheSeal is a Sterile product and should not be used if the pouch is damaged or has previously been opened. The device can not be resterilised.

TracheSeal should not be used on:
- ulcers caused by chronic infections (tuberculosis, deep mycotic infections, syphilis)
- arteriopathy stage IV
- bites and 3rd degree burns.

TracheSeal should not be used when there is a known sensitivity to hydrocolloids.

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

4. INFORMATION FOR USE

Due to the nature of this dressing it is suitable for the closing of a tracheostomy site, as it will withstand the pressure from airflow attempting to pass through the remaining stoma, it can manage the presence of the existing secretions and is also easily removed for necessary 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 most of the hydrocolloid surface in contact with the wound has been gelled; therefore the interval between dressing changes will depend entirely upon the state of the wound. In the early post decannulation period, and on large or moderately exuding wounds, changes may be required several times a day but may be reduced to once in every 24 hours as healing progresses. (See 4.3)

4.1 Skin Preparation

a) Cleanse the wound with sterile saline and sterile swabs.

b) Dry the skin surrounding the wound.

c) Remove any remains of creams or greasy substances.

4.2 Dressing Application

a) Select the appropriate TracheSeal size that will completely cover the wound surface, ensuring a 2 to 3 cm margin beyond the edges of the wound. TracheSeal may be cut to size before removing the protective liner.

b) 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.

c) The alignment of the button over the stoma site allows more accurate application of finger pressure by the patient/carer

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

4.3 Dressing Changes

TracheSeal is a Sterile product and should not be used if the pouch is damaged or has previously been opened.

TracheSeal is easy to remove due to the formation of a gel at the interface between hydrocolloid layer and wound surface, when a whist blisters 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 after 6 to 24 hours, 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.

a) Gently remove TracheSeal.

b) Remove any remaining debris or gel from the wound, using sterile compresses.

c) Follow procedure 4.1 a) to 4.2 c) to apply new dressing.

TracheSeal is a single use device and once removed MUST NOT be reused or reapplied due to the risk of cross infection or re-infection.

Dispose to clinical waste or if at home to domestic waste.

5. SPECIAL NOTES

TracheSeal is a dynamic dressing – in that it requires patient interaction- the patient must be 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 the benefit of this unique dressing.

In the unlikely instance that there is some tissue necrosis around the tracheostomy wound then 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.

In the management of moderately to heavily exuding wounds, TracheSeal can only make the 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 progress, and suitable treatment of the underlying conditions will be necessary as well. Therefore, if after 4-6 weeks of TracheSeal treatment, there has been no improvement then, in line with accepted wound management practice, the original diagnosis and overall therapy should be reassessed.

TracheSeal should be left in place as long as possible, but not more than 24 hours in order to prevent trauma to the fragile newly formed tissue and to reduce cross contamination through frequent dressing changes.

A yellowish gel with characteristic odour can develop under the dressing; this is not a sign of infection but a normal phenomenon when using hydrocolloid dressings which will disappear after cleaning the wound.

Thick necroses should be removed before applying TracheSeal.

TracheSeal Wound Dressings are intended for single use only.

6. STORAGE / STERILISATION / SYMBOLS ON LABELLING:

Store dressings away from direct sunlight (♀) at ambient temperature (5-30°C) and humidity (♀)

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Γ</td>
<td>Gamma Sterilised</td>
</tr>
<tr>
<td>°</td>
<td>For single use only</td>
</tr>
<tr>
<td>β</td>
<td>Batch number</td>
</tr>
<tr>
<td>Σ</td>
<td>Product code</td>
</tr>
<tr>
<td>Ψ</td>
<td>Attention, see instructions for use</td>
</tr>
<tr>
<td>µ</td>
<td>Use by: year and month</td>
</tr>
<tr>
<td>Ε</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>Δ</td>
<td>Do not use if package is damaged or opened</td>
</tr>
</tbody>
</table>

7. PRESENTATIONS:

TracheSeal is available in the following sizes:

- 10 cm Diameter

Finesse Medical Ltd.,
Royal Canal Business Park,
Athlone Road,
Longford, Ireland

Version: February 27th, rev. 2