

# Tracoe Purofoam-T – product information

Document Reference: DOC-RN-1148

Date: 07 October 2025

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# Tracoe Purofoam-T – product information

## 1. General Description

Tracoe Purofoam-T can be used by lay persons and/or health care professionals.

A soft, sterile, conforming, non-adherent absorbent foam dressing with an aesthetically pleasing semi-permeable film backing and key-hole fenestration to allow ease of placing around a tube, cannula or peg site.

The dressing offers softness and air permeability, perfect for the treatment of low/medium (Tracoe Purofoam-T Large Lite) and medium/high (Tracoe Purofoam-T Large/Small) exuding wounds and secretions.

The dressing provides a cushioning effect surrounding the wound. It is absorbent, lightweight and provides a rapid uptake of exudate. The dressing has a bacteria-proof polyurethane backing, is breathable and prevents strike-through and maceration.

## 2. Overview of Theory/ Principles of Operation

- Hydrophilic Foam
- Bacteria proof, low friction, thin film backing
- Maintains a moist wound healing environment
- Soft & Conformable
- Flexible & Versatile

## 3. Composition

Polyurethane foam and film backing

## 4. Device Variants

The Tracoe Purofoam-T dressings are available in the following variants:

Product	Size	Part Number
Tracoe Purofoam-T Large	8cm x 8cm x 0.5cm	CR4555
Tracoe Purofoam-T Small	6.5cm x 5cm x 0.5cm	CR4557
Tracoe Purofoam-T Large Lite	8cm x 8cm x 0.25cm	CR4556

## 5. Accessories

The Tracoe Purofoam-T does not comprise any accessories.

## 6. Features

- Hydrophilic Foam
- Bacteria proof, low friction, thin film backing
- Maintains a moist wound healing environment
- Soft & Conformable
- Flexible & Versatile

## 7. Indications

### Tracoe Purofoam-T

Should be used for managing secretions around intact skin and improving comfort for patients with a tracheostomy tube, cannula or peg site.

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### 8. Contra-indications

#### Tracoe Purofoam-T

- Do not use with oxidising agents such as hypochlorite solutions or hydrogen peroxide as these can break down the absorbent component of the dressing. Not suitable for arterial Bleeds, heavy bleeding wounds.

### 9. Directions of Use

#### Tracoe Purofoam-T

Ensure the area has been cleaned. Gently dry the surrounding skin.

Apply with care – pink film side up and white side next to skin. Open the key-hole and gently place the dressing around the tube, rod or cannula. Training may be required to avoid potential trauma. If in doubt, seek professional medical advice from a doctor or healthcare professional.

Tracoe Purofoam-T can be left in place for up to 7 days but should be changed if soiled or damp from secretions or exudate. If exudate is visible around the edges of the dressing this is a clear indication that a dressing change is required. Clinical observation is necessary to determine required frequency of change.

### 10. Product Specification

Name:	Tracoe Purofoam-T Large
Code:	CR4555
Size:	8cm x 8cm x 0.5cm
Sterilisation:	Ethylene Oxide
Expiry:	5 Years
Storage:	Keep dry, keep away from sunlight
Product Dimensions:	Length: 80mm +/- 5mm Width: 80mm +/- 5mm
Pack Dimensions:	Length: 170mm Depth: 55mm Height: 155mm

Name:	Tracoe Purofoam-T Small
Code:	CR4557
Size:	6.5cm x 5cm x 0.5cm
Sterilisation:	Ethylene Oxide
Expiry:	5 Years
Storage:	Keep dry, keep away from sunlight
Product Dimensions:	Length: 65mm +/- 5mm Width: 50mm +/- 5mm
Pack Dimensions:	Length: 125mm Depth: 55mm Height: 150mm

Name:	Tracoe Purofoam-T Large Lite
Code:	CR4556
Size:	8cm x 8cm x 0.25cm
Sterilisation:	Ethylene Oxide
Expiry:	5 Years
Storage:	Keep dry, keep away from sunlight
Product Dimensions:	Length: 80mm +/- 5mm Width: 80mm +/- 5mm
Pack Dimensions:	Length: 170mm Depth: 30mm Height: 155mm

## Tracoe Purofoam-T – product information

### 11. GMDN

15624- Tracheostomy tube dressing, sterile

#### Definition:

A pad designed to conform around a tracheostomy tube at its insertion site to provide protection for the skin and/or to absorb secretions. It is typically designed with a slit or hole to facilitate tube fitting. This is a single-use device.

### 12. CE Mark

SGS Certificate number GB19/964732.00

### 13. Classification

Tracoe Purofoam-T is classified as Class IIb Medical Device Directive 93/42/EEC amended by Directive 2007/47/EC, Rule 4 (Secondary Intent).

### 14. Latex

Based on the current knowledge at the date of this statement - latex is not part of the composition, however these products were never officially tested.

### 15. Hazardous Components

Tracoe Purofoam-T Range of products does not contain substances classified as hazardous under EC nor US OSHA regulations.

### 16. UDI-DI

GTIN	Product Family	Product Code	Product Description	Packaging Level
05060031485424	Purofoam-T	CR4555	8cm x 8cm	Primary Package
05060031485431	Purofoam-T	CR4555	8cm x 8cm	Retail Carton
05060031485448	Purofoam-T	CR4555	8cm x 8cm	Shipper Box
05060031485455	Purofoam-T	CR4555	8cm x 8cm	Pallet
05060031485462	Purofoam-T	CR4556	8cm x 8cm (Lite)	Primary Package
05060031485479	Purofoam-T	CR4556	8cm x 8cm (Lite)	Retail Carton
05060031485486	Purofoam-T	CR4556	8cm x 8cm (Lite)	Shipper Box
05060031485493	Purofoam-T	CR4556	8cm x 8cm (Lite)	Pallet
05060031485509	Purofoam-T	CR4557	6.5cmx 5cm	Primary Package
05060031485516	Purofoam-T	CR4557	6.5cmx 5cm	Retail Carton
05060031485523	Purofoam-T	CR4557	6.5cmx 5cm	Shipper Box
05060031485530	Purofoam-T	CR4557	6.5cmx 5cm	Pallet

### 17. Risk Management

A thorough risk assessment is conducted throughout the product lifecycle, and maintained at Brightwake Ltd. The full assessments can be found linked to the technical file.

The risk management file, complaints and sales history are maintained at Brightwake Ltd. The risk management documents are linked to the technical file. The data obtained from post market surveillance is used, and maintained within the Regulatory Affairs department in accordance to SOP 4a. Complaint information is created by the customer services team ([SOP 4b](#)), and where complaints have led to corrective action records are maintained within the corrective and preventative action processes ([SOP 5b](#)).

### 18. Sterilisation

The Tracoe Purofoam-T dressings are supplied as sterile medical devices. Sterilisation is performed externally, and the method of sterilisation is Ethylene Oxide (EtO).

## Tracoe Purofoam-T – product information

### 19. Manufacturer address

Brightwake Limited  
Lowmoor Business Park  
Kirkby In Ashfield  
NG17 7JZ  
United Kingdom

### 20. Distributor address

Coloplast A/S  
Holtedam 1  
3050 Humlebæk  
Denmark

### 21. Version History

<b>Version:</b>	<b>Reason for Revision:</b>	<b>Date:</b>
Issue 1	New Document	23/Sept/2025
Issue 2	Various updates to the document as per the customer request.	07/Oct/2025