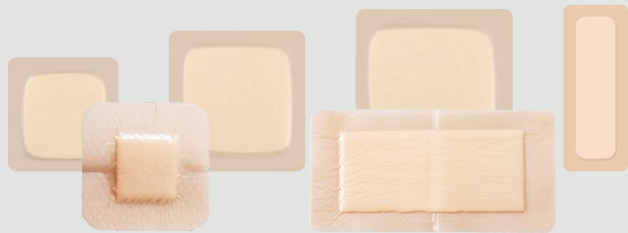


FoamLite™ ConvaTec



PRODUCT DESCRIPTION:¹

Foam Lite ConvaTec™ dressing is a thin, conformable, laminated polyurethane layered foam dressing. The dressing consists of a waterproof outer polyurethane film and an absorbent foam pad with a perforated gentle silicone adhesive.

The outer film layer provides a waterproof, viral and bacterial barrier which protects the wound from external contamination helping reduce the risk of infection. The dressing film backing acts as a barrier to the wound against bacteria and blood borne viral pathogens (e.g. HIV and Hepatitis viruses).

The wound contact surface is coated with a perforated gentle silicone adhesive layer which helps provide secure skin friendly adhesion.

Foam Lite ConvaTec™ Dressings

Dressing Size cm	CVT number	pieces/package
5x5 cm	421927	10
8x8 cm	421557	10
10x10 cm	421559	10
15x15 cm	421561	10
5,5x12 cm	421563	10
10x20 cm	421928	10

Foam Lite ConvaTec™ dressings may be cut to shape and size as directed by a healthcare professional. If the dressing is cut, additional tape may be required to secure it in place.

CLINICAL BENEFITS:¹

Foam Lite ConvaTec™ dressing is designed for low exuding wounds and helps maintain a moist wound environment which can help promote faster wound closure.

Foam Lite ConvaTec™ dressing is designed to remain in place without the need for secondary retention.

Foam Lite ConvaTec™ dressing can be repositioned during application.

PRECAUTION AND WARNINGS:

Sterility is guaranteed unless pouch is damaged or opened prior to use. This device is for single-use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination.

The wound should be inspected during dressing changes for: (1) signs of infection (increased pain, bleeding, warmth/redness of surrounding tissue, wound exudate), (2) there is a change in wound color and/or odor, (3) any other unexpected symptoms occur (e.g. maceration or hypergranulation).

This wound dressing should not be used with other wound care products without first consulting a healthcare professional.

DIRECTIONS FOR USE:

Always check instructions for use please see IFU in product box before clinical use



INDICATIONS FOR USE:

Foam Lite ConvaTec™ dressings are intended for the management of a wide range of low / non exuding wounds. Under medical supervision Foam Lite ConvaTec™ dressings may be used for the management of both chronic and acute wounds such as, but not limited to:

- Leg ulcers, pressure ulcers and diabetic ulcers
- Surgical wounds (e.g. post operative wounds left to heal by secondary intent and donor sites)
- Partial thickness (second degree) burns
- Traumatic wounds (e.g. abrasions, lacerations, blisters, minor cuts and skin tears)

DURATION OF USE:

The dressing should be changed when clinically indicated (e.g. leakage, bleeding, increased pain, suspicion of infection). Maximum recommended wear time is up to seven days.



Do not re-use

ADDITIONAL INFORMATION:





Compression therapy	This wound dressing should not be used with other wound care products without first consulting a healthcare professional.
Help facilitate easy removal ^{2,3}	YES
Exudate levels	Low/Non-Exuding
MRI safe	YES
Waterresistant	YES

CONTRAINDICATIONS:

Foam Lite ConvaTec™ dressings should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.

Foam Lite ConvaTec™ dressings are not compatible with oil based products or emollients such as petrolatum.

Do not use Foam Lite ConvaTec™ dressings with oxidising agents such as hydrogen peroxide or hypochlorite solutions.

STERILIZATION:	
Sterile	YES
Method	Sterilized using ethylene oxide
CERTIFICATIONS:	
CE mark	CE 2797
MDR 2017/745	Class IIb
MATERIAL SPECIFICATIONS:	
List of ingredients	 Adhesive coated outer PU film, Polyurethane (PU) Foam, Perforated Silicone trilaminate
STORAGE AND HANDLING:	
Before Use	Keep away from sunlight
  	Keep dry.
	Store at room temperature (10°C - 25°C/50°F - 77°F).
After use	After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local laws and regulations.

References:

1. FoamLite™ Convatec IFU Revised 2022-02 1714552A4.
2. In vitro Performance of Foam Lite™ ConvaTec Data on File WHRI4680 MS132.
3. Meuleneire, F and Rücknagel, H. (2013). Soft silicone dressings made easy. Wounds International. www.woundsinternational.com

Convatec Limited

First Avenue,
Deeside Industrial Park Deeside,
Flintshire CH5 2NU,
UK



UNOMEDICAL A/S

Aaholmvej 1-3, Osted
4320 LEJRE
DENMARK



Convatec Denmark A/S

CVR 31477093,
Transformervej 14, 1. , 2860 Soborg,
Denmark
Tlf.: +45 48 16 74 74
www.convatec.dk

Convatec Norway AS

Org. nummer: MVA 992 780 118
Visiting address:
Nils Hansens Vei 8, 0667 Oslo
Postadresse:
Postboks 6464 Etterstad, 0605 Oslo
Tlf.: +47 21 09 67 90
www.convatec.no

Convatec (Sweden) AB

Organisationsnummer: 556754-8473,
Box 3096, 16973 Solna, Sweden
Visiting address:
Gustav III:s Boulevard 42, plan 9,
16973 Solna, Sweden
Tlf.: +46 020-21 22 22
www.convatec.se

Convatec Oy

Y-tunnus 1644589-9,
Aviapolis, Karhumäentie 3, 01530 VANTAA,
Finland
P: +358 020 7659 600
www.convatec.fi