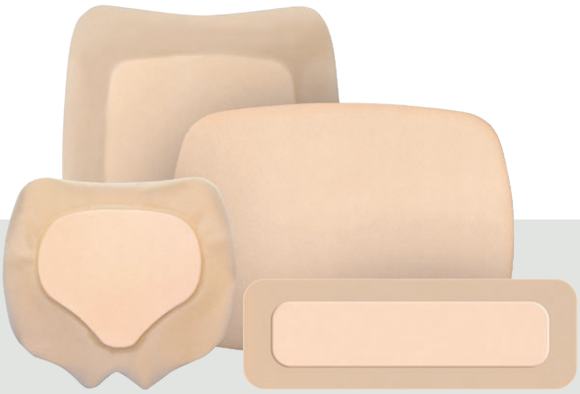
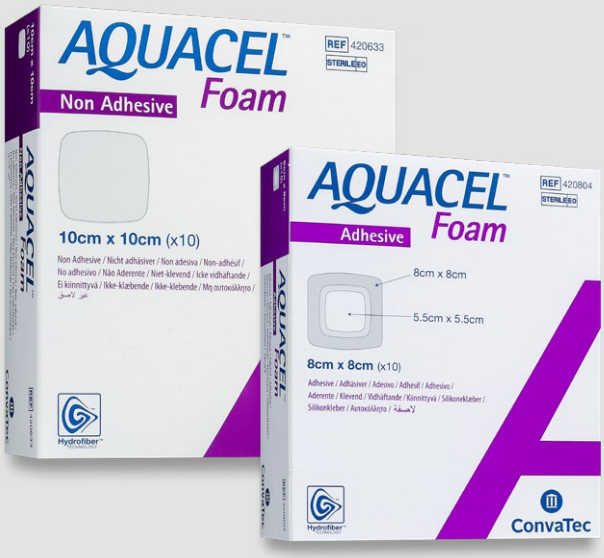
AQUACEL® Foam





PRODUCT DESCRIPTION:

AQUACEL™ Foam dressing is a sterile, Hydrofiber™ foam wound dressing, consisting of:

- a waterproof, breathable outer polyurethane film which provides a bacterial and viral barrier
- a soft, multi-layered, absorbent central pad containing polyurethane foam and Hydrofiber™ (Sodium carboxymethylcellulose) wound contact layer. The pad absorbs and retains moisture, exudates and bacteria.
- AQUACEL™ Foam Adhesive has a silicone adhesive skin contact border to adhere the dressing to the patient.

AQUACEL™ Foam Dressings

Dressing Size PAD	Max wound size	CVT number	pieces/ package
AQUACEL™ Foam Adhesive			
8 X 8 CM	3 X 3 CM	420804	10
10 X 10 CM	5 X 5 CM	420680	10
12,5 X 12,5 CM	6,5 X 6,5 CM	420619	10
15 X 15 CM	9 X 9 CM	422350	10
17,5 x 17,5 cm	11,5 x 11,5 cm	420621	10
21 x 21 cm	15 x 15 cm	420623	5
25 x 30 cm	19 x 24 cm	420624	5
AQUACEL™ Foam Adhesive Post op			
8 x 13 cm	2 x 7 cm	421149	10
10 x 20 cm	4 x 13 cm	421151	10
10 x 25 cm	4 x 18 cm	421153	10
10 x 30 cm	4 x 23 cm	421155	10
AQUACEL™ Foam Adhesive Heel/Multisite			
19,8 x 14 cm	12 x 7cm	420625	5
AQUACEL™ Foam Adhesive Sacral			
20 x 16,9 cm	11,5 x 9,5 cm	420626	5
24 x 21,5 cm	15,5 x 13,5 cm	420828	5
AQUACEL™ Foam Non-Adhesive			
5 x 5 cm	2 x 2 cm	420631	10
10 x 10 cm	5 x 5 cm	420633	10
15 x 15 cm	6,5 x 6,5 cm	420635	5
10 x 20 cm	4 x 13 cm	413623	10
15 x 20 cm	6,5 x 10 cm	420637	5
20 x 20 cm	10 x 10 cm	420636	5

The dressing may be cut; if cut, additional tape or film dressing should be used to create a seal and ensure a bacterial barrier.

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CLINICAL BENEFITS:[2]

AQUACEL™ Foam is designed to protect fragile skin from moisture, shear and friction damage.

AQUACEL™ Foam is designed to provide a moist wound healing environment, aiding autolytic debridement and removing dead-space between the wound and dressing interface.

AQUACEL™ Foam is designed to manage excess exudate levels which may further damage the wound bed and surrounding skin.

INTENDED USE:

AQUACEL™ Foam dressings may be used, with the consultation of a healthcare professional, for the management of exuding, non-exuding wounds and protection of intact skin.

AQUACEL™ Foam dressing may be included in a comprehensive protocol of care to protect intact skin against breakdown.

AQUACEL™ Foam dressings may be used as a primary or secondary dressing.

INDICATIONS FOR USE:

AQUACEL™ Foam dressing is indicated for the treatment of:

- Leg ulcers
- Pressure Ulcers
- Diabetic Foot Ulcers
- Surgical Wounds
- Partial thickness burns
- Traumatic wounds

INTENDED USER:

AQUACEL™ Foam dressings are to be used by health care professionals, patients and carers.

INTENDED PATIENT POPULATION:

AQUACEL™ Foam dressings are intended to be used on patients with one of the wound types listed in the indications or those who require skin protection from breakdown.

DIRECTIONS FOR USE

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

DURATION OF USE

AQUACEL™ Foam dressings can be worn for up to 7 days, dressings should be changed earlier if clinically indicated, and are safe for continuous use.

Do not re-use

ADDITIONAL INFORMATION

Can be used with compression therapy*[1]	YES
Help facilitate easy removal	YES
MRI safe	YES
Exudate levels	AQUACEL® Foam is designed to manage excess exudate levels which may further damage the wound bed and surrounding skin[3]

* The absorbency aspect of this in-vitro test method was carried out in accordance with BS EN 13726-1:2002.

CONTRAINDICATIONS

AQUACEL™ Foam dressings should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or components stated above.

AQUACEL™ Foam dressings are not compatible 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	 Sodium carboxymethylcellulose, Polyurethane Film, Polyurethane Foam and Silicone* *in Aquacel Foam Adhesive
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 country laws and regulations.

References:
Jade Steven et al. ConvaTec GDC, Deeside, Flintshire, CH5 2NU (2017) In-vitro Bio-Physical Performance Characteristics of AQUACEL® Foam Dressings, BS EN 13726-1:2002- Test Methods for Primary Wound Dressings. Part 1: Aspects of Absorbency, Section 3.2.
2. AquacelTM Foam IFU, Revised: 2023-04. 1714576V1
3. Clinical Evaluation Report RPT-005767, Aquacel Foam_DHF 704_CER, Convatec (6-Oct-2021) Data on file

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For full description and instructions for use please see IFU in product box
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