

HYDROCELLULAR DRESSINGS



Device Description:

- ESPUMA® NON-ADHESIVE** is a Polyurethane foam, laminated with water-proof, bacteria-proof and virus -proof polyurethane film that prevents the strike of external infections and leakage of exudates.
- ESPUMA® SEALED EDGES** is the same as above description but with another perforated TPU layer as the wound contact layer and the edges of the dressing are sealed.
- ESPUMA® ADHESIVE** is the same composites of ESPUMA® NON-ADHESIVE with TPU wound contact layer, placed centrally on Adhesive Polyurethane film substrate.
- ESPUMA® ADHESIVE PLUS** is the same composites of ESPUMA® NON-ADHESIVE, placed centrally on a colloid Adhesive polyurethane film substrate that extends beyond the margin of the island pad.

Intended purpose:

Hydrocellular Dressings are intended to assist healing of different types of wounds, burns and skin related diseases and conditions.

Indications:

Variant	Indications
<p>ESPUMA® ADHESIVE ESPUMA® SEALED EDGES</p>	<p>Under supervision of a healthcare professional, dressings can be used in management of partial to full thickness wounds including:</p> <ul style="list-style-type: none"> -Ulcers (venous, arterial, diabetic) -Pressure ulcers -Donor sites -Surgical incision and excisions -Burns (first and second degree) <p>Espuma Adhesive dressings are also indicated for use on Lacerations and abrasions and for exudate absorption. Can be used throughout the healing process to provide protection for the types of wounds indicated.</p>
<p>ESPUMA®NON-ADHESIVE ESPUMA®ADHESIVE PLUS</p>	<p>Under supervision of a healthcare professional, dressings can be used in management of partial to full thickness wounds including:</p> <ul style="list-style-type: none"> -Ulcers (venous, arterial, diabetic) -Pressure ulcers -Donor sites -Post-operative wounds -Second degree burns -Skin abrasions <p>Can be used throughout the healing process to provide protection for the types of wounds indicated.</p>

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Intended patient population:

Suitable for all patient populations.

Intended users:

Hydrocellular Dressings can be used by healthcare professionals or lay persons under supervision of health care professionals.

Performance characteristics:

- Hydrocellular dressings are made from a polyurethane base and are permeable to both gases and water vapor. Their hydrophilic properties allow high absorptive properties while they also provide thermal insulation. Foam dressings also provide a cushioning action that allows pressure relief for patients subjected to long hospitalization periods. This creates a prophylactic indication for pressure injuries.
- Hydrocellular dressings absorb exudates and provide moisture balance to wounds as: moist wound environment hastens the healing of both acute and chronic wounds and promotes the growth of new tissue. A balanced moist wound environment facilitates cellular growth and collagen proliferation within a healthy noncellular matrix. It also facilitates the action of growth factors, cytokines, and chemokines, thus promoting cellular growth and the establishment of a provisional wound matrix.
- The dressing is protected with semi-permeable film backings that are waterproof and act as bacterial barriers. The dressing is easy to apply and minimizes trauma on removal.
- The Non-Adhesive variants are suitable for use on fragile skin due to the absence of adhesive.

A description of other devices, which are intended to be used in combination with it:

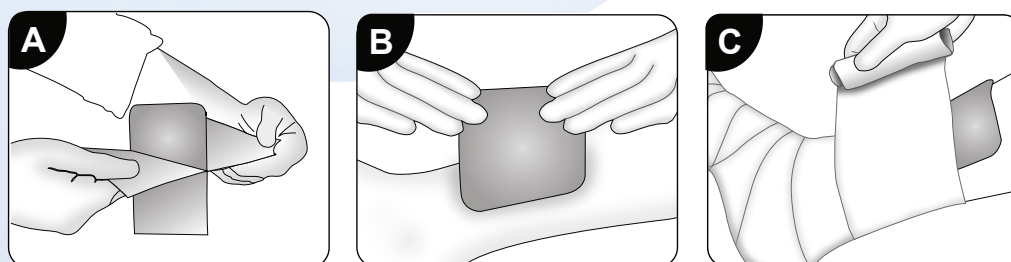
- Hydrocellular dressings can be used as a secondary dressing on dry/necrotic wounds in combination with hydrogels (Cavidagel®).
- Hydrocellular dressings can be used as a secondary dressing on heavily exuding wounds in combination with hydrofibres (Fibrosol® Extra non-adhesive).
- Hydrocellular dressings can be used as a primary dressing under compression bandaging (Gauza®).
- Hydrocellular dressings can be used in combination with Fixation tapes.

Instructions for use:

1. Cleanse the wound in accordance with local clinical protocols.
2. Select an appropriate dressing size that overlaps the wound margin by at least two centimeters.
3. Remove the sterile dressing from the package using aseptic technique.

For Non-adhesive variants:

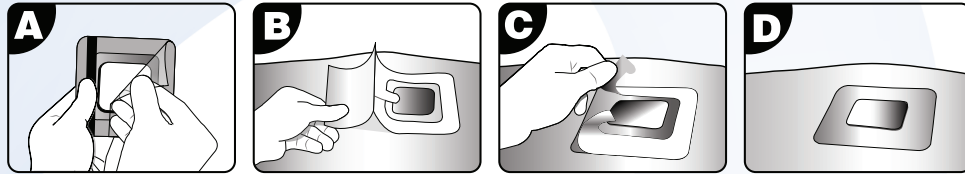
1. Non-Adhesive variants can be cut to fit awkward areas. When used under compression therapy, the dressing must be cut to the size of the wound.
2. Place the dressing on the wound site.
3. Fixation tapes or conforming bandage should be used to secure the dressing in place.



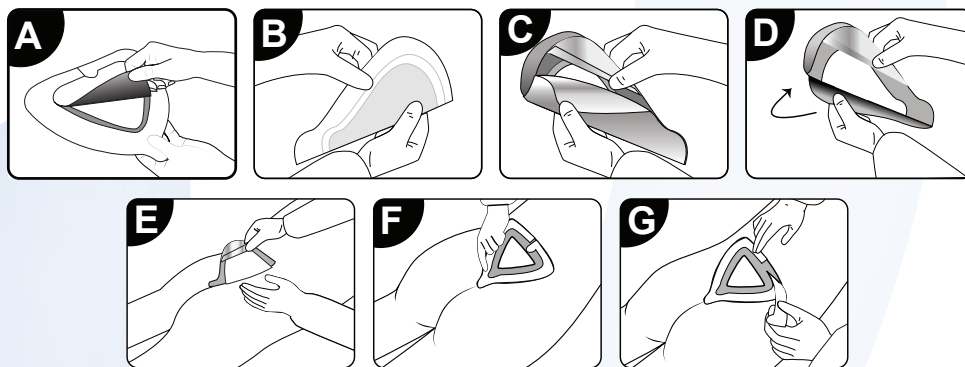
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For adhesive variants:

1. Remove the central paper window (if present).
2. Remove the large flap of the release liner to expose the adhesive portion of the dressing.
3. Position into place while removing the smaller flap of the release liner of the dressing.
4. Slowly remove the paper frame while smoothing down around the dressing to ensure good adhesion.
5. To remove the dressing, loosen the border before lifting the dressing away from the wound.



ESPUMA® Adhesive variants (Sacral)



Instruction of device change

Instruction of change:

-Dressing change frequency will depend on patient condition as well as wound exudate level. It Can remain in place for up to 7 days or until exudate is visible and approaches 1.5cm from the edge of the dressing depending on wound condition and exudate level or as instructed by health care professional, whichever is sooner.

-To remove an adhesive dressing, loosen the adhesive film border before lifting the dressing away from the wound.

-To remove non-adhesive dressing, gently lift the corners of the dressing away from the wound.

Cleanse the wound prior to application of new dressing.

Precautions change/application:

-Any active bleeding at the insertion site should be stabilized before applying the dressing.

-Do not stretch the dressing during application. Mechanical skin trauma may result if the dressing is applied with tension.

-The skin should be dry and free of detergent residue to prevent skin irritation and to ensure good adhesion.

-Antimicrobial ointments containing polyethylene glycols may compromise the strength of the cover dressing film.

-Fix the non-adhesive dressing edges with waterproof Fixation film to protect from water when showering.

-Dressings applied to the Sacral region shall be removed from the top edge and down towards the anus to minimize the risk of transmitting infection.

Other information:

-The polyurethane foam used in the product may change colour to more yellow when it is exposed to light, air and/or heat. The colour change has no influence on product properties when used before expiry date.

-Contact the manufacturer for technical support.

-Report serious incidents to the manufacturer and the competent authority.

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ESPUMA® NON-ADHESIVE	Size	Pieces/Box	Boxes/Case	Case Dimensions
ESPUMA5050	50x50 mm	10	48	
ESPUMA7575	75x75 mm	10	48	
ESPUMA75100	75x100 mm	10	48	
ESPUMA100100	100x100 mm	10	48	
ESPUMA100150	100x150 mm	5	24	
ESPUMA100200	100x200 mm	5	24	
ESPUMA100250	100x250 mm	5	24	
ESPUMA100300	100x300 mm	5	24	
ESPUMA100350	100x350 mm	5	24	
ESPUMA150150	150x150 mm	5	24	
ESPUMA150200	150x200 mm	10	48	
		3	24	
ESPUMA200200	200x200 mm	3	24	
ESPUMA165180C	165x180 mm Concave	3	24	
ESPUMAS220220S	220x220 mm Sacral	3	24	
ESPUMA150250	150x250 mm	3	24	
ESPUMA200300	200x300 mm	3	24	
ESPUMA200400	200x400 mm	3	24	
ESPUMA200500	200x500 mm	3	24	
ESPUMA100125	100x125 mm	5	24	
ESPUMA125125	125x125 mm	5	24	
ESPUMA170170S	170x170 mm Sacral	3	24	
ESPUMA175175	175x175 mm	3	24	
ESPUMA200250	200x250 mm	3	24	
ESPUMA300300	300x300 mm	3	24	
ESPUMA400400	400x400 mm	3	24	
ESPUMA130200H	130x200 mm heel butterfly	3	24	
ESPUMA120130H	120x130 mm heel	3	24	
ESPUMA100180H	100x180 mm Heel	5	24	
ESPUMA170170	170x170 mm	3	24	

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ESPUMA® NON-ADHESIVE	Size	Pieces/Box	Boxes/Case	Case Dimensions
ESPUMA220220	220x220 mm	3	24	
ESPUMA50	50Ø mm circular	10	48	
ESPUMA100	100Ø mm circular	10	48	
ESPUMA6565T	65x65 mm Tracheostomy	10	48	
ESPUMA8080T	80x80 mm Tracheostomy	10	48	
ESPUMA6080T	60x80 mm Tracheostomy	10	48	
ESPUMA8090T	80x90 mm Tracheostomy	10	48	
ESPUMA9090	90x90 mm Cavity	10	48	
ESPUMA9090T	90x90 mm Tracheostomy	10	48	
ESPUMA100120	100x120 mm	5	24	
ESPUMA5070	50x70 mm	10	48	
ESPUMA8888	88x88 mm	10	48	
ESPUMA90110	90x110 mm	10	48	
ESPUMA6085	60x85 mm	10	48	
ESPUMA6090	60x90 mm	10	48	
ESPUMA190220	190x220 mm	5	24	
ESPUMA100600	100x600 mm	3	24	
ESPUMA20300	20x300 mm Cavity	5	24	
ESPUMA2590	25x90 mm Cavity	5	24	
ESPUMA20400	20x400 mm Cavity	1	48	
ESPUMA20450	20x450 mm Cavity	1	48	
ESPUMA25450	25x450 mm Cavity	1	48	
ESPUMA50400	50x400 mm Cavity	1	48	
ESPUMA25400	25x400 mm Cavity	1	48	
ESPUMAGLOVE	Glove	1	24	
ESPUMA7585	75x85 mm	10	48	
ESPUMA105135H	105x135 mm (heel)	5	24	

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ESPUMA® SEALED EDGE	Size	Pieces/Box	Boxes/Case	Case Dimensions
ESPUMAS5050	50x50 mm	10	48	
ESPUMAS7575	75x75 mm	10	48	
ESPUMAS75100	75x100 mm	10	48	
ESPUMAS100100	100x 100 mm	10	48	
ESPUMAS100150	100x 150 mm	5	24	
ESPUMAS100200	100x200 mm	5	24	
ESPUMAS100250	100x250 mm	5	24	
ESPUMAS100300	100x300 mm	5	24	
ESPUMAS100350	100x350 mm	5	24	
ESPUMAS150150	150x 150 mm	5	24	
ESPUMAS150200	150x200 mm	"10	"48	
		3"	24"	
ESPUMAS200200	200x200 mm	3	24	
ESPUMAS165180C	165x180 mm Concave	3	24	
ESPUMAS220220S	220x220 mm Sacral	3	24	
ESPUMA150250	150x250 mm	3	24	
ESPUMAS200300	200x300 mm	3	24	
ESPUMA200400	200x400 mm	3	24	
ESPUMA200500	200x500 mm	3	24	
ESPUMAS100125	100x 125 mm	5	24	
ESPUMAS125125	125x 125 mm	5	24	
ESPUMAS170170S	170x170 mm Sacral	3	24	
ESPUMAS175175	175x 175 mm	3	24	
ESPUMAS200250	200x250 mm	3	24	
ESPUMAS300300	300x300 mm	3	24	
ESPUMAS400400	400x400 mm	3	24	
ESPUMAS130200H	130x200 mm heel butterfly	3	24	
ESPUMAS120130H	120x 130 mm heel	3	24	
ESPUMAS100180H	100x 180 mm Heel	5	24	
ESPUMAS170170	170x 170 mm	3	24	
ESPUMAS220220	220x220 mm	3	24	
ESPUMAS50	50Ø mm circular	10	48	
ESPUMA100	100Ø mm circular	10	48	
ESPUMAS6565T	65x65 mm Tracheostomy	10	48	
ESPUMAS8080T	80x80 mm Tracheostomy	10	48	
ESPUMAS6080T	60x80 mm Tracheostomy	10	48	
ESPUMAS8090T	80x90 mm Tracheostomy	10	48	
ESPUMAS9090	90x90 mm Cavity	10	48	

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ESPUMA® SEALED EDGES	Size	Pieces/Box	Boxes/Case	Case Dimensions
ESPUMAS9090T	90x90 mm Tracheostomy	10	48	
ESPUMAS100120	100x120 mm	5	24	
ESPUMAS5070	50x70 mm	10	48	
ESPUMAS8888	88x88 mm	10	48	
ESPUMAS90110	90x110 mm	10	48	
ESPUMAS6085	60x85 mm	10	48	
ESPUMAS6090	60x90 mm	10	48	
ESPUMAS190220	190x220 mm	5	24	
ESPUMAS100600	100x600 mm	3	24	
ESPUMAS20300	20x300 mm Cavity	5	24	
ESPUMAS2590	25x90 mm Cavity	5	24	
ESPUMAS20400	20x400 mm Cavity	1	48	
ESPUMAS20450	20x450 mm Cavity	1	48	
ESPUMAS25450	25x450 mm Cavity	1	48	
ESPUMAS50400	50x400 mm Cavity	1	48	
ESPUMAS25400	25x400 mm Cavity	1	48	
ESPUMASGLOVE	Glove	1	24	
ESPUMAS7585	75x85 mm	10	48	
ESPUMAS105135H	105x135 mm (heel)	5	24	

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ESPUMA® ADHESIVE	Size	Pieces/Box	Boxes/Case	Case Dimensions
ESPUMAADH5050	50x50 mm	10	48	
ESPUMAADH7575	75x75 mm	10	48	
ESPUMAADH75100	75x100 mm	10	48	
ESPUMAADH100100	100x100 mm	10	48	
ESPUMAADH100150	100x150 mm	5	24	
ESPUMAADH100200	100x200 mm	5	24	
ESPUMAADH100250	100x250 mm	5	24	
ESPUMAADH100300	100x300 mm	5	24	
ESPUMAADH100350	100x350 mm	5	24	
ESPUMAADH150150	150x150 mm	5	24	
ESPUMAADH150200	150x200 mm	10 3	48 24	
ESPUMAADH200200	200x200 mm	3	24	
ESPUMAADH160180C	160x180 mm Concave	3	24	
ESPUMAADH165180C	165x180 mm Concave	3	24	
ESPUMAADH220220S	220x220 mm Sacral	3	24	
ESPUMAADH200300	200x300 mm	3	24	
ESPUMAADH6565	65x65 mm	10	48	
ESPUMAADH100125	100x125 mm	5	24	
ESPUMAADH125125	125x125 mm	5	24	
ESPUMAADH170170S	170x170 mm Sacral	3	24	
ESPUMAADH175175	175x175 mm	3	24	
ESPUMAADH7585	75x85 mm	10	48	
ESPUMAADH7090	70x90 mm	10	48	
ESPUMAADH100180H	100x180 mm Heel	5	24	
ESPUMAADH140185	140x185 mm	3	24	
ESPUMAADH75200	75x200 mm	5	24	
ESPUMAADH90110	90x110 mm	5	24	
ESPUMAADH190220	190x220 mm	3	24	
ESPUMAADH200265H	200x265 mm Heel	3	24	
ESPUMAADH125225	125x225 mm	3	24	
ESPUMAADH220220	220x220 mm	3	24	
ESPUMAADH170170	170x170 mm	3	24	
ESPUMAADH4050	40x50 mm	10	48	
ESPUMAADH50125	50x125 mm	5	24	
ESPUMAADH60120	60x120 mm	5	24	
ESPUMAADH90150	90x150 mm	5	24	
ESPUMAADH180180	180x180 mm	3	24	
ESPUMAADH175230	175x230 mm	3	24	
ESPUMAADH180280	180x280 mm	3	24	
ESPUMAADH225225	225x225 mm	3	24	

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ESPUMA® ADHESIVE	Size	Pieces/Box	Boxes/Case	Case Dimensions
ESPUMAADH220250S	220x250 mm (sacral)	3	24	
ESPUMAADH160200S	160x200 mm (sacral)	3	24	
ESPUMAADH168171S	168x171 mm (sacral)	3	24	
ESPUMAADH216230S	216x230 mm (sacral)	3	24	
ESPUMAADH220230H	220x230 mm (heel)	3	24	
ESPUMAADH185240H	185x240 mm (heel)	3	24	
ESPUMAADH230232H	230x232 mm (heel)	3	24	
ESPUMAADH7595	75x95 mm (oval)	10	48	
ESPUMAADH135165	135x165 (oval)	5	24	
ESPUMAADH160200	160x200 mm (oval)	3	24	
ESPUMAADH171179	171x179 mm (multisite)	3	24	
ESPUMAADH170	"170 mm (round contour)"	3	24	
ESPUMAADH230230S	230x230 mm (Sacral)	3	24	
ESPUMAADH190200H	190x200 mm (heel)	3	24	

HYDROCELLULAR DRESSINGS

ESPUMA [®] ADHESIVE PLUS	Size	Pieces/Box	Boxes/Case	Case Dimensions
ESPADHPLUS5050	50x50 mm	10	48	
ESPADHPLUS7575	75x75 mm	10	48	
ESPADHPLUS75100	75x100 mm	10	48	
ESPADHPLUS100100	100x100 mm	10	48	
ESPADHPLUS100150	100 x 150 mm	5	24	
ESPADHPLUS100200	100 x 200 mm	5	24	
ESPADHPLUS100250	100x250 mm	5	24	
ESPADHPLUS100300	100x300 mm	5	24	
ESPADHPLUS100350	100x350 mm	5	24	
ESPADHPLUS150150	150 x 150 mm	5	24	
ESPADHPLUS150200	150x200 mm	10 3	48 24	
ESPADHPLUS200200	200 x 200 mm	3	24	
ESPADHPLUS160180C	160 x 180 mm Concave	3	24	
ESPADHPLUS165180C	165 x 180 mm Concave	3	24	
ESPADHPLUS220220S	220 x 220 mm Sacral	3	24	
ESPADHPLUS200300	200x300 mm	3	24	
ESPADHPLUS6565	65x65 mm	10	48	
ESPADHPLUS100125	100x125 mm	5	24	
ESPADHPLUS125125	125x125 mm	5	24	
ESPADHPLUS170170S	170x170 mm Sacral	3	24	
ESPADHPLUS175175	175x175 mm	3	24	
ESPADHPLUS7585	75x85 mm	10	48	
ESPADHPLUS7090	70x90 mm	10	48	
ESPADHPLUS100180H	100x180 mm Heel	5	24	
ESPADHPLUS140185	140x185 mm	3	24	
ESPADHPLUS75200	75x200 mm	5	24	
ESPADHPLUS90110	90x110 mm	5	24	
ESPADHPLUS190220	190x220 mm	3	24	
ESPADHPLUS200265H	200x265 mm Heel	3	24	
ESPADHPLUS125225	125x225 mm	3	24	
ESPADHPLUS220220	220x220 mm	3	24	
ESPADHPLUS170170	170x170 mm	3	24	
ESPADHPLUS4050	40x50 mm	10	48	
ESPADHPLUS50125	50x125 mm	5	24	

HYDROCELLULAR DRESSINGS

ESPUMA [®] ADHESIVE PLUS	Size	Pieces/Box	Boxes/Case	Case Dimensions
ESPADHPLUS60120	60x120 mm	5	24	
ESPADHPLUS90150	90x150 mm	5	24	
ESPADHPLUS180180	180x180 mm	3	24	
ESPADHPLUS175230	175x230 mm	3	24	
ESPADHPLUS180280	180x280 mm	3	24	
ESPADHPLUS225225	225x225 mm	3	24	
ESPADHPLUS220250S	220x250 mm (sacral)	3	24	
ESPADHPLUS160200S	160x200 mm (sacral)	3	24	
ESPADHPLUS168171S	168x171 mm (sacral)	3	24	
ESPADHPLUS216230S	216x230 mm (sacral)	3	24	
ESPADHPLUS220230H	220x230 mm (heel)	3	24	
ESPADHPLUS185240H	185x240 mm (heel)	3	24	
ESPADHPLUS230232H	230x232 mm (heel)	3	24	
ESPADHPLUS7595	75x95 mm (oval)	10	48	
ESPADHPLUS135165	135x165 (oval)	5	24	
ESPADHPLUS160200	160x200 mm (oval)	3	24	
ESPADHPLUS171179	171x179 mm (multisite)	3	24	
ESPADHPLUS170	"170 mm (round contour)"	3	24	
ESPADHPLUS230230S	230x230 mm (Sacral)	3	24	
ESPADHPLUS190200H	190x200 mm (heel)	3	24	

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