

## HydroTac® HydroTac® Concave HydroTac® Comfort (incl. HydroTac® Border Multisite) HydroTac® Sacral

### General Product Description/Intended Purpose

The HydroTac range of products consists of sterile, single-use foam dressings with a gas-permeable, waterproof and bacteria-resistant outer layer of polyurethane. The wound-facing surface of the dressing has a mesh structure and is impregnated with a hydrogel that acts as a moisture reservoir. The gel consists of a hydrated polyurea/polyurethane hybrid polymer containing propylene glycol. The "comfort" version of the dressing has a protruding border coated with a polyacrylate adhesive, enabling it to adhere to the surrounding, intact skin. Some bordered products in the range contain cuts along the border to enable better conformability with body contours.

The dressings come in a range of sizes and shapes to match the wound dimensions, and are available in the following variants:

- **HydroTac®**: this non-border dressing can be cut into the desired size, but an additional dressing material is required for fixation (e.g., a Peha-haft bandage or Omnifix elastic dressing).
- **HydroTac® concave**: a non-border version with a special shape designed for application on the heel or elbow.
- **HydroTac® comfort (incl. HydroTac border multisite)**: this version features an adhesive border that is coated with polyacrylate adhesive. Thus, no secondary dressing is required for fixation.
- **HydroTac® sacral**: a special shape designed for use in the sacrum area, with an adhesive border that is coated with a polyacrylate adhesive.

The HydroTac range of products is used to promote wound healing in lightly to moderately exuding chronic or acute wounds during the granulation and epithelialization phases of the healing process.

HydroTac®/HydroTac® concave and HydroTac® comfort/sacral carry the CE-mark according to EU directive 93/42/EEC for medical devices. According to the MDD, the HydroTac range of products is considered a medical device in Class IIb. A conformity assessment has been performed for HydroTac®/HydroTac® concave and HydroTac® comfort/sacral and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use and effectiveness of HydroTac®/HydroTac® concave and HydroTac® comfort/sacral, therefore, is ensured if the product is used in line with the intended purpose.

### Application/Indication

The HydroTac range of products is used to promote wound healing in lightly to moderately exuding chronic or acute wounds during the granulation and epithelialization phases of the healing process.

The HydroTac range of products is intended to be applied by wound care professionals. Wound care professionals may delegate dressing changes to patients and/or their relatives (non-professionals under guidance of professionals).

### Composition

#### HydroTac®/HydroTac® concave

No.	Dressing layer	Raw material & function
1	Backing material	Elastic, water-vapour permeable foil made of polyurethane
2	Absorbing foam	Soft, absorbent foam made of polyurethane
3	Wound contact layer	Water containing polyurea/hybrid polyurethane-polymer with propylene glycol in net structure
4	Cover sheet	Siliconized polypropylene foil, printed with numbers 1 and 2

## Technical Data Sheet

HydroTac®

HydroTac® Concave

HydroTac® Comfort (incl. HydroTac® Border Multisite)

HydroTac® Sacral

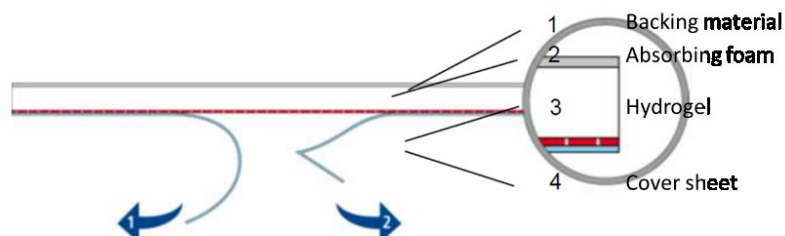


Fig. 1: Sectional construction of HydroTac®/HydroTac® concave

HydroTac® comfort (incl. HydroTac border multisite)/HydroTac® sacral

No.	Dressing layer	Raw material & function
1	Backing material	Elastic, water-vapour permeable foil made of polyurethane
2	Absorbing foam	Soft, absorbent foam made of polyurethane
3	Wound contact layer	Water containing polyurea/hybrid polyurethane-polymer with propylene glycol in net structure
1b	Adhesive	Acrylic adhesive
4	Cover sheet	Siliconized polypropylene foil, printed with numbers 1 and 2

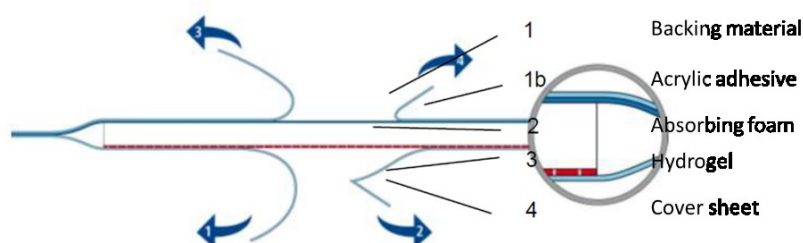


Fig. 2: Sectional construction of HydroTac® comfort/HydroTac® sacral

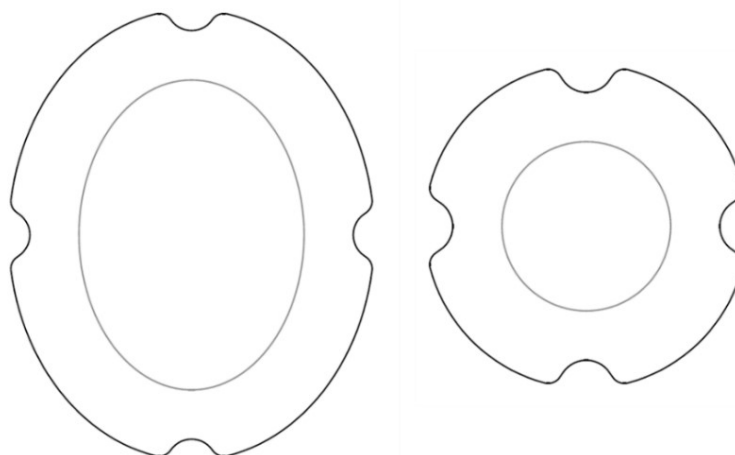


Fig. 3: Design drawing of HydroTac® border multisite

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HydroTac®

HydroTac® Concave

HydroTac® Comfort (incl. HydroTac® Border Multisite)

HydroTac® Sacral

### Reference Numbers

Product	Size (cm)	Wound pad size (cm)	Pack size	Current
HydroTac	10 x 10	n/a	P 3	685831
HydroTac	10 x 10	n/a	P10	685832
HydroTac	10 x 20	n/a	P 3	685833
HydroTac	10 x 20	n/a	P10	685841
HydroTac	12,5 x 12,5	n/a	P 3	685836
HydroTac	12,5 x 12,5	n/a	P10	685837
HydroTac	15 x 15	n/a	P 3	685839
HydroTac	15 x 15	n/a	P10	685840
HydroTac	15 x 20	n/a	P10	685843
HydroTac	20 x 20	n/a	P 3	685844
HydroTac	20 x 20	n/a	P10	685842
HydroTac	12,5 x 12,5	n/a	P 16	685846
HydroTac	6 round	n/a	P 3	685848
HydroTac	6 round	n/a	P10	685849
HydroTac concave	18 x 18,5	n/a	P3	685824
HydroTac concave	18 x 18,5	n/a	P10	685825
HydroTac comfort	8 x 8	3,5 x 3,5	P 16	685808
HydroTac comfort	12,5 x 12,5	7,5 x 7,5	P 16	685809
HydroTac comfort	8 x 8	3,5 x 3,5	P10	685810
HydroTac comfort	6,5 x 10	2,5 x 6	P10	685811
HydroTac comfort	10 x 20	5 x 14	P10	685813
HydroTac comfort	10 x 30	5 x 25	P10	685830
HydroTac comfort	12,5 x 12,5	7,5 x 7,5	P 3	685814
HydroTac comfort	12,5 x 12,5	7,5 x 7,5	P10	685815
HydroTac comfort	8 x 15	3 x 10	P10	685807
HydroTac comfort	15 x 15	10 x 10	P 3	685817
HydroTac comfort	15 x 15	10 x 10	P10	685818
HydroTac comfort	15 x 20	9 x 14	P 3	685820
HydroTac comfort	15 x 20	9 x 14	P10	685821
HydroTac comfort	20 x 20	14 x 14	P 3	685822
HydroTac comfort	20 x 20	14 x 14	P10	685812
HydroTac border multisite	11,5 round	Ø 6	P10	n.a.
HydroTac border multisite	13 x 16 oval	8 x 11	P10	n.a.
HydroTac sacral	18 x 18	13 x 10,6	P 3	685826
HydroTac sacral	18 x 18	13 x 10,6	P10	685827
HydroTac sacral	22 x 22	16 x 13,6	P 3	685828
HydroTac sacral	22 x 22	16 x 13,6	P10	685850

# HydroTac® HydroTac® Concave HydroTac® Comfort (incl. HydroTac® Border Multisite) HydroTac® Sacral

### Contra-Indication

The HydroTac range of products is not indicated for heavily exuding wounds. In addition, the HydroTac range of products should not be used on patients who may be allergic to any of its components/ingredients, especially propylene glycol, polyurethane or acrylic based adhesive.

### Undesirable Side Effect

As any other medical device, this product can have side effects, which does not occur for everybody. General side effects of HydroTac:

In rare cases HydroTac may cause allergic reactions.

In rare cases HydroTac may cause local skin reactions (irritation, redness, swelling, etc.).

In rare cases HydroTac may adhere too strongly.

In very rare cases HydroTac may cause skin stripping.

In very rare cases parts of HydroTac may remain in the wound.

### Precautions

Prior to the treatment of wounds with impaired healing, a medical assessment of the wound condition and the cause of the healing disorder should be undertaken. Treatment with the dressing cannot replace the treatment of the underlying cause of impaired healing. In the case of clinically infected wounds and in areas with exposed bones and tendons, the HydroTac range of products should only be used only under medical supervision. The HydroTac range of products may be used with full-thickness second degree and third degree burns under medical supervision following debridement of necrotic tissue or surgical treatment. Do not use the dressing concurrently with oxidants such as hypochlorite solutions or hydrogen peroxide. Application of the HydroTac range of products on children under 5 years of age and on pregnant or nursing women should take place only after consultation with a qualified physician.

### Sterile Device

HydroTac is a sterile medical device, sterilized by irradiation. Do not use if package is damaged.

### Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

### Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of HydroTac should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

### Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

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HydroTac® Sacral

### Product Performance Characteristics

HydroTac®/HydroTac® concave

Property	Test method	Unit	Result
Absorption	TM00 0030	g/cm <sup>2</sup>	> 0,4
Moisture vapor transmission rate, upright	TM00 0188-01 DIN EN 13726-2	g/m <sup>2</sup> 24h	≥ 1000

HydroTac® comfort (incl. HydroTac border multisite)/HydroTac® sacral

Property	Test method	Unit	Result
Absorption	TM00 0030	g/cm <sup>2</sup>	> 0,4
Moisture vapor transmission rate, upright	TM00 0188-01 DIN EN 13726-2	g/m <sup>2</sup> 24h	≥ 1000
Adhesion	TM00 0091-01	N/25mm	> 2

All data refer to sterile products.

### Labelling

Lot-No. with 9-Digit Code

e.g.:



1  
year

234  
for internal  
purpose only

56  
week

789  
for internal  
purposes only

Manufacturing Date

e.g.:



2020-03-06

year-month-day

Use-by-Date

e.g.:



2020-03-06

year-month-day

Shelf Life: 3 years

Medical Device



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HydroTac® Concave

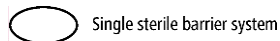
HydroTac® Comfort (incl. HydroTac® Border Multisite)

HydroTac® Sacral

### Unique Device Identification (UDI)



### Single Sterile Barrier System



### **Packaging**

HydroTac®/HydroTac® concave and HydroTac® comfort (incl. HydroTac border multisite)/HydroTac® sacral is sealed individually in peel pouch-es. Peel pouches are packed in folding boxes. Boxes are packed in transport carton acc. to DIN, sealed with adhesive tapes, packed onto Euro pallet.

**Latest Date of Revision:** 2020-05-18