

## HydroClean® plus

Specification no.: D 4.0600-01

Department: R&D

Date: 15.03.19

### 1. General product description

#### **HydroClean® plus**

HydroClean® plus is a hydroactive wound dressing that contains, as a core component, a superabsorbent polyacrylate (SAP) embedded in cellulose fibres. The antibacterial agent polyhexamethylene biguanide (PHMB) is bound to the SAP that is activated (premoistened) with Ringer's solution. The wound contact layer of the dressing consists of a polypropylene knitted fabric to which silicone strips have been applied. The wound contact layer and the silicone strips counteract adhesion to the wound bed. On the side facing away from the wound, a water impermeable polypropylene film, overlaid with a hydrophobic polypropylene non-woven fabric, prevents the wound dressing pad from drying out too early. This enables moisture to be delivered to the wound bed for up to three days, whilst the polypropylene film also prevents the outer surface of the dressing from being soaked. HydroClean® plus delivers Ringer's solution to the wound for up to three days. During this time, interactive and continuous wound irrigation takes place, due to the wound dressing pad also absorbing wound exudate. The PHMB bound in the SAP core has an antibacterial effect and inhibits the growth of bacteria inside the wound pad, thereby reducing the risk of recontamination over the entire application period of up to three days. The SAP used in HydroClean® plus inactivates matrix metalloproteinases (MMP) which impair wound healing. As a result, stagnating healing in chronic wounds can be reactivated.

HydroClean® plus carry the CE marking in accordance with the European directive 93/42/EEC on medical devices. The products are classified as class IIb medical devices. A conformity assessment process had been carried out for HydroClean® plus which shows that HydroClean® plus meet all applicable requirements of the above-mentioned directive. Therefore, the safety and performance of HydroClean® plus is guaranteed within the dedicated framework.

### 2. Use

#### **HydroClean® plus:**

For wet/moist treatment of all wounds, particularly those with impaired healing tendency. HydroClean® plus is especially suitable for the treatment of chronic and poorly healing wounds during the cleansing and granulation stage. HydroClean® plus can also be applied in order to reactivate stagnating healing processes if these are caused by excessive MMP activity.

### 3. Presentation

Sterile, individually sealed, ready-to-use wound dressings in the following sizes:

Size	Unit
4 cm round	Boxes of 10
5.5 cm round	Boxes of 10
7.5x7.5 cm	Boxes of 10
10x10 cm	Boxes of 10

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### 4. Product properties

#### Material composition of HydroClean® plus:



2x polypropylene-nonwoven (one white and one white with blue printing)

polypropylene-foil (off white; watertight, antimicrobial barrier)

The airlaid contains a superabsorbent polyacrylate (SAP) embedded in cellulose and polypropylene fibers, activated with Ringer's Solution containing PHMB.

hydrophobic knitted fabric made of polypropylene

silicone, wound side

### 5. Product requirements

#### HydroClean® plus and HydroClean® plus cavity:

Format	Weight [g]
4 cm round	5.5
5.5 cm round	10.7
7.5x7.5 cm	20.4
10x10 cm	36.7

### 6. Marking

Batch key with a nine-digit code.

Expiry date:

e.g.: 2019 03  
Year Month

Shelf life: 2 years

### 7. Packaging

HydroClean® plus and HydroClean® plus cavity are individually sealed in peel packages and packed in cardboard boxes. Shipment case closed with adhesive tapes in accordance with German Standard DIN. Packaging on euro pallets.

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