# Technical data sheet



# HydroClean® HydroClean® cavity

Hydr

Specification no.:

D 4.0500-01

Department:

R&D

Date:

26.07.2019

#### General product description

# HydroClean®:

HydroClean is a hydroactive wound dressing that contains, as a core component, a superabsorbent polyacrylate (SAP) embedded in cellulose fibers and 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. Hydro-Clean 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 SAP used in HydroClean inactivates matrix metalloproteinases (MMP) which impair wound healing. As a result, stagnating healing in chronic wounds can be reactivated.

# HydroClean® cavity:

HydroClean cavity is a hydroactive wound dressing that contains, as a core component, a superabsorbent polyacrylate (SAP) embedded in cellulose fibres and activated (premoistened) with Ringer's Solution. The wound pad is covered with polypropylene knitted fabric on all sides. HydroClean cavity 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 SAP used in HydroClean cavity inactivates matrix metalloproteinases (MMP) which impair wound healing. As a result, stagnating healing in chronic wounds can be reactivated.

HydroClean® and HydroClean® cavity 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® and HydroClean® cavity which shows that HydroClean® and HydroClean® cavity meet all applicable requirements of the above-mentioned directive. Therefore, the safety and performance of HydroClean® and HydroClean® cavity is guaranteed within the dedicated framework.

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# 2. Use

# HydroClean®:

HydroClean is suitable for wet/moist treatment of wounds, in particular of wounds with impaired healing tendency. The product is especially suitable for the treatment of chronic and poorly healing wounds during the cleansing and granulation stage. HydroClean can also be used for the treatment of infected wounds. HydroClean can furthermore be used to reactivate stagnating healing processes if these are caused by excessive MMP activity.

# HydroClean® cavity:

HydroClean cavity is suitable for wet/moist treatment of wounds, in particular of wounds with impaired healing tendency. The product is especially suitable for the treatment of chronic and poorly healing wounds during the cleansing and granulation stage. HydroClean cavity can also be used for the treatment of infected wounds. HydroClean cavity can furthermore be used to reactivate stagnating healing processes if these are caused by excessive MMP activity.

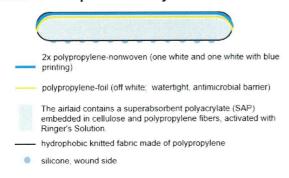
#### 3. Presentation

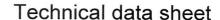
Sterile, individually sealed, ready-to-use wound dressings in the following sizes:

Size	Unit
4 cm round	Boxes of 10
4x8 cm oval	Boxes of 10
5.5 cm round	Boxes of 10
7.5x7.5 cm	Boxes of 10
8x14 oval	Boxes of 10
10x10 cm	Boxes of 10
10x17 cm	Boxes of 10

### 4. Product properties

# Material composition of HydroClean®:







# HydroClean® HydroClean® cavity

Clear Store Specification no.: D 4.0500-01

Department: R&D

Date: 26.07.2019

# Material composition of HydroClean® cavity:



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

hydrophobic knitted fabric made of polypropylene

# 5. Product requirements

# HydroClean® and HydroClean® cavity:

Format	Weight [g]
4 cm round	5.5
4x8 cm oval	10.4
5.5 cm round	10.7
7.5x7.5 cm	20.4
8x14 oval	32.8
10x10 cm	36.7
10x17 cm	62.1

# Marking

Batch key with a nine-digit code.

Expiry date:

e.g.: 2016 02

Year Month

Shelf life: 3 years

# Packaging

HydroClean® and HydroClean® 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.

Date: 26.07.2019

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