Technical Data Sheet

Atrauman®

General Product Description/Intended Purpose

Atrauman® are single-use, sterile, non-medicated ointment dressings suitable for the treatment of superficial acute and chronic wounds of any type. As a non-adherent wound contact layer, it is particularly suitable for preventing the secondary dressing from sticking to the wound bed and for keeping wound edges and surrounding skin supple. Due to the neutral properties of the non-medicated ointment mass, Atrauman® is especially useful in dermatology as well as for patients with sensitive skin and those sensitive to certain medications.

Atrauman® is suitable for the treatment on the human skin by professional users.

Atrauman® is classified as a Class IIb medical device.

Composition

Support fabric made of hydrophobic polyester tulle, impregnated with a non-medicated ointment based on triglycerides (neutral fats). The ointment contains (INCI-assigned names): Caprylic/Capric/Myristic/Stearic Triglyceride; Bis-Diglyceryl Polyacyladipate-2

Application/Indication

Atrauman® is suitable for the treatment of superficial acute and chronic wounds of any type.

Due to the neutral properties of the non-medicated ointment mass, Atrauman® is especially useful in dermatology as well as for patients with sensitive skin and those sensitive to certain medications.

Take the dressing out of the peel pack with both cover papers in place and, if needed, cut it with sterile scissors to the size of the wound. After removal of one of the cover papers, place this side of the dressing onto the wound and remove the second cover. Place a sterile, absorbent dressing pad over the Atrauman® dressing to absorb exudate. Unless otherwise prescribed by the physician or another healthcare professional, apply a new Atrauman® dressing at each dressing change. The wear time of the dressing depends on the condition of the wound and the level of exudate.

Reference Numbers

Packaging	5x5	7.5x10	10x10	10x20	20x30
P10	499 510	499 513	499 514		499 515
P30				499 536	
P50	499 550	499 553			

Contra-Indications

Do not use Atrauman® on patients who may by allergic to any of its ingredients

Atrauman®

Sterile Device

Atrauman® is a sterile device, sterilized by radiation sterilization.
Do not use if sterile packaging is damaged.

Product disposal

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

Special precautions

In the absence of available data supporting the use of this dressing on sensitive population groups such as infants, children, pregnant or nursing woman, and in the absence of data to the contrary, on these population groups this dressing should be used with caution following a clinician's recommendation.

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.

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 performance characteristics

Property	Test method	Unit	Requirement
Sealing strength primary packaging	TM00 0052-01	N/15mm	0.7-5.2
Dropping point	TM00 0020	°C	35-45
Ointment weight	PH 219/005	g/m²	140-190

All data refer to sterile products.

Atrauman®

Labelling

Lot-No. with 8-digit code

e.g.:

LOT	0	003	12	XX
	year	Number of production order of reference within a year	week of production	for internal purposes only

Manufacturing date

e.g.:	2015 year	04 month	07 day

Expiry date

e.g.:	2015 year	04 month	07 day

Shelf life: 5 years

Medical Device

MD

Unique Device Indetification (UDI)

UDI

I.a. Single Sterile barrier Symstem

Single sterile barrier system

Latest date of revision: 2019-10-07