Atrauman Silicone®

General Product Description/Intended Purpose

Atrauman Silicone is a soft and permeable wound contact layer made of a polyethylene terephthalate (PET) mesh as carrier material which is coated on both sides with (polydimethylsiloxane-based) silicone gel.
The product is sterilised with ethylene oxide.

Atrauman Silicone is a single-use wound contact layer for the treatment of superficial, acute and chronic, slightly to moderately exuding wounds, only applied by professional users.
Atrauman Silicone may be applied as a primary dressing in combination with an absorbent secondary wound dressing or with the Vivano negative pressure therapy system. Atrauman Silicone functions as protection before adhering the secondary dressing or the negative pressure dressing over the wound. This wound contact layer is permeable for exudate.
Furthermore, Atrauman Silicone may be applied as a protective layer on non-exuding wounds and on sites with sensitive skin.
Atrauman Silicone is considered a medical device in Class IIb.

Application/Indication

Atrauman Silicone is a wound contact layer for the treatment of superficial, acute and chronic, slightly to moderately exuding wounds of all types (including burn wounds);

- the combination with the Vivano negative pressure wound therapy system especially on wound sites with exposed organs and other sensitive structures (such as breached skin and underlying tissues);
- the use as protective layer on non-exuding wounds and on sensitive skin areas (such as parchment skin or mesh graft)

Properties and mode of action
Atrauman Silicone is a thin, soft and drapable wound contact layer. It enables good contact with the wound bed and is permeable to exudate. Through cutting to size with sterile scissors, Atrauman Silicone can be adapted to various wound sizes, shapes and locations. The silicone layer adheres gently and securely to dry but not to moist surfaces. This way it does not adhere to the wound and the dressing can therefore be removed almost painlessly.
In combination with a secondary dressing or with the Vivano negative pressure wound therapy system, the wound contact layer makes changing the dressing atraumatic and almost painless.
Atrauman Silicone is not absorbent. Through the open mesh structure, the passage of wound exudate into an absorbent secondary dressing is enabled.
Please be aware that the quantity of exudate can also have an influence on the frequency of dressing changes and, accordingly, the risk of maceration.

Please follow the instructions when changing the secondary dressing.
Before applying the dressing for the first time, and after each dressing change, the wound must be thoroughly cleansed in accordance with the physician's instructions.

- Dry the skin around the wound.
- Select an Atrauman Silicone size which precisely covers the wound. You can cut Atrauman Silicone to size accordingly. Use sterile scissors.
- If you have to use more than one piece, ensure that the pores are exposed where the pieces of Atrauman Silicone overlap.
- Remove Atrauman Silicone with both covering films from the peel package.
- Firmly hold the longer of the two covering films while pulling off the other one.
- Place the wound dressing onto the wound and smooth it out. Then remove the remaining covering film.
- To absorb wound exudate, affix a sterile, absorbent wound dressing (e.g. Zetuvit plus, RespoSorb Super) or a sterile negative pressure wound dressing for the negative pressure wound therapy over Atrauman Silicone.

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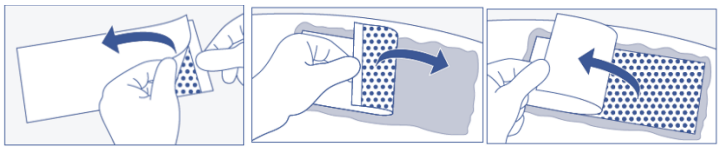
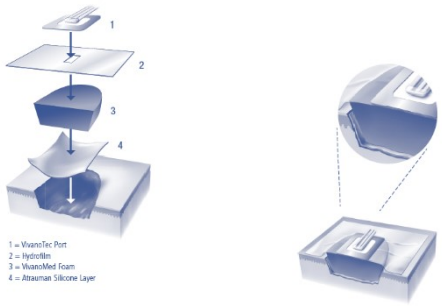
Please pay attention to the relevant instructions for use before combining it with the Vivano negative pressure wound therapy system.

- Depending on the condition of the wound, Atrauman Silicone can be left on the wound for up to 7 days if medically required. However, after a maximum of three days, you should check the wound for ingrowth of tissue. This is particularly important if organs and other sensitive structures are exposed directly under the silicone wound contact layer when combined with VivanoMed Foam.
- When changing the dressing you can leave Atrauman Silicone on the wound if medically required.
- If you are using Atrauman Silicone for the fixation of skin transplants, you should not change the dressing before the fifth day after the graft.



Negative pressure wound therapy

In combination with the Vivano negative pressure wound therapy system, the wound contact layer directs exudate into the VivanoMed Foam open pore negative pressure foam dressing. Please follow the instructions for use when changing the VivanoMed Foam negative pressure foam dressing.



Reference Numbers

Reference Number	Description	Size [cmxcm]	Sales Unit / products per Foldingbox [pcs]	Foldingbox per Shipping Carton
499567/1	Atrauman Silicone 5x7 P5	5x7	5	10
499568/1	Atrauman Silicone 5x7 P10	5x7	10	10
499562/1	Atrauman Silicone 7,5x10 P10	7,5x10	10	4
499564/1	Atrauman Silicone 10x20 P10	10x20	10	8
499561/1	Atrauman Silicone 7,5x10 P5	7,5x10	5	4
499563/1	Atrauman Silicone 10x20 P5	10x20	5	8
499565/1	Atrauman Silicone 20x30 P5	20x30	5	4

Atrauman Silicone®

Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings
Contraindications

Do not use Atrauman Silicone on patients who may be allergic to any of its ingredients.

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 women, 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.

Sterile Device

Single sterile barrier system. 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 Atrauman Silicone should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

Notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
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 authorized representative and to your national authority.

Labelling

Lot-No. with 8-Digit Code

e.g.:

0	12	XXXXX
year	week of production	for internal purposes only

Manufacturing Date

e.g.: 

2020	04	07
year	month	day

Use-by-Date

e.g.: 

2020	04	07
year	month	day

Atrauman Silicone®

Shelf Life: 5 years

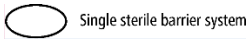
Medical Device

MD

Unique Device Indetification (UDI)

UDI

Single Sterile Barrier Symstem



Latest Date of Revision: 2020-11-24