Saturn Family - Labels - IFU - EU MDR

Technical Document			
Title	Saturn Family - Labels - IFU - EU MDR	**Project Number**	N/A
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Related Documents	Saturn Labels – EU MDR		
Reference Documents/ Standards	N/A		
Abstract	This document contains the Instructions for Use of the product family Saturn , considering the manufacturing location: • Galaxy House, 31 Herald Way, Binley Industrial Estate, Coventry, CV3 2RQ, United Kingdom. This document should be signed and approved by Regulatory Affairs before being printed.		

Saturn

Wound Dressing - Strengthened Cellulose Fibre

Instruction for use

Product Description:

Saturn (120gsm) wound Dressings are a soft, conformable non-woven dressing made from a blend of gel forming cellulose ethyl sulfonate (CES fibres) and strengthening cellulose fibre(s). When it comes into contact with wound exudate or blood the absorbent dressing forms a gel which creates a moist wound environment that may support autolytic debridement and the healing process. Through the gel formation, debris and any bacteria found in the wound exudate can be retained inside the fibre dressing and removed when the dressing is changed. When dry, Saturn wound dressings can easily be cut to the size of the wound. Even when the dressing is moist, as a gelled fibre, its structure remains intact. The high vertical absorption of exudate into the fibre dressing protects the wound environment and the wound edge[1], thus supporting the healing process.
The product can also be used under compression. Prescription only.

Indication for use

- The product is for a single use only
- This product is to be used for wounds with moderate to heavy exudate
- The product may be used for the treatment of acute or chronic wounds
- The product may be used for the treatment of leg ulcers, pressure ulcers (Stage II to IV) and diabetic ulcers
- The product may be used for surgical wounds (e.g. post-operative, wounds left to heal by secondary intent and donor sites)
- The product may be used for partial thickness burns
- The product may be used for traumatic wounds (e.g. abrasions and lacerations)
- The product may be used for exuding oncology wounds if:

moderate or heavily exuding

superficial or

cavity

The Saturn wound dressing has a supportive effect in that it protects the wound edge and the surrounding skin frommaceration.[1]

Contraindications:

The product should not be used for people who are sensitive or allergic to the dressing and its components.

Application:

Preparing the wound

- Clean the wound carefully. The skin surrounding the wound should be clean and dry.

Applying the wound dressing

- The size of the dressing should match the wound area. Keep the product away from the wound while cutting it to size.
- Place the dressing on the moist wound, overlapping the wound edges by approximate 1 cm. If there is a low amount of exudate present, moisten the dressing with physiological saline solution (0.9%).
- For cavity wounds use the Rope format. Pack wounds lightly and leave approximate 2.5cm overlappingthe wound edges.

- Apply a suitable moisture-retaining secondary dressing to keep the product in place.

Changing the dressing:

The dressing should be changed when medically indicated (e.g. when the dressing has reached its absorbent capacity or whenever good wound care practice dictates a change is needed). The interval between changes should be no more than 7 days. The product can be removed using e.g. sterile forceps. Should the dressing adhere to wounds with lower exudate levels, moisten it with physiological saline solution (0.9%) before changing the dressing so that the healing process is not disturbed. Any gel residue on the wound should be removed when cleansing the wound. Wound cavities in particular should be well irrigated.

The treatment should be discontinued after 30 days. Dispose in accordance with local guidance.

Caution:

- If signs of infection are detected clinically the healthcare professional responsible for the treatment must decide on the next course of action.
- If signs of an allergic reaction are detected, discontinue the use of the product and seek advice from a healthcare professional on the next course of action.
- Product is sterilised by irradiation and must not be re-sterilised.
- Product remains sterile unless the package is opened or damaged.
- Saturn is not intended to be used on wounds with severe bleeding, inside internal body cavities or closed wounds.
- Increased infection risk: after the first use, the dressing may harbor bacteria and debris from the wound, which can transfer back into the wound on reuse. This contamination increases the risk of infection or reinfection, as reused dressings cannot maintain a sterile environment.
- Reduced absorbency: the dressing is engineered to absorb and lock in wound exudate efficiently during a single use. Reusing it compromises this ability, as the dressing may already be partially or fully saturated, leading to inadequate absorption of exudate. This can cause fluid to pool on the wound bed, which can lead to maceration (softening) of the surrounding skin.
- Loss of structural integrity: the dressing is composed of fibres designed to maintain a certain structure for optimal wound coverage and exudate management. Reusing the dressing can cause the fibres to break down, reducing its structural integrity, which may result in incomplete wound coverage or dressing fibres being left in the wound.
- Delayed healing: due to the compromised absorbency and increased infection risk, reuse of the dressing can delay the healing process. A clean, effective dressing promotes optimal wound conditions, while a reused dressing may hinder progress, potentially leading to chronic or poorly healing wounds.
- Potential for skin irritation: if the dressing is damaged, residual fibres, or degraded materials may irritate the wound or surrounding skin, causing discomfort and potentially worsening the wound.

[1] The properties mentioned above refer to the current in vitro data.

Speciality Fibres and Materials Ltd
Galaxy House, 31 Herald Way, Binley Industrial Estate, CV3 2RQ, Coventry, United Kingdom
Tel: +44 (0) 2476708200 www.sfm-limited.com

EC REP Advena Ltd
Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013
Malta
Tel: +44 (0) 19 26800153