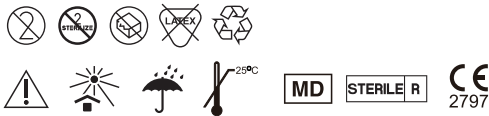


Sterile Calcium Alginate Wound Dressing

REF 1400,1410,1415

INSTRUCTIONS FOR USE



Rev. UMT V1


Foshan United Medical Technologies Ltd.
Southern Medical Devices Industrial Park,
89 Taoyuan East Road,
Shishan, Nanhai Foshan, Guangdong
Province, 528225, P.R. China
www.umtmedical.com


Medwheat Tech Service GmbH
Max-Planck-Straße 4
85609 Aschheim b.
München
Germany

PRODUCT DESCRIPTION:
Sorbsan Flat is a sterile, non-woven, calcium alginate wound dressing, high in Mannuronic acid and low in Guluronic acid. The fibres of Sorbsan well and form a Sodium-Calcium alginate gel in contact with wound exudate. The gel:
• Provides a 'moist wound healing environment'
• Conforms to the contours of the wound
• Minimises pain on dressing removal
• Minimises disruption to newly formed tissue on dressing removal
• Upon contact with a bleeding wound, Sorbsan Flat will promote hemostasis

INDICATIONS FOR USE:
Wound dressing intended for use on breached dermis, where the wounds can heal only by secondary intention:
Suitable for following wound types:
• Wound types such as flat or shallow
• Wounds with moderate to high exudate levels
Sorbsan may also be used in conjunction with graduated compression therapy for the management of venous leg ulceration, when directed and under continuing wound assessment by qualified professionals. Sorbsan may be used on wounds which are clinically infected only when advised by a qualified professional after a full and continuing wound assessment.

CONTRAINDICATIONS:
The Sorbsan wound dressing is not intended for:
• Use on patients with a known sensitivity to Calcium Alginate dressings
• Use with heavily bleeding wounds
• Dry wounds
• Surgical implantation
• Used under gauze

WARNINGS/OBSERVATIONS:
Sorbsan is a sterile, single use product. Do not use if the packaging has been opened or damaged as this could compromise the sterility of the dressing. Sorbsan should not be used with heavily bleeding wounds.

Should consult a healthcare professional if irritation (reddening, inflammation), maceration (whitening of skin), hyper-granulation (excess tissue formation) is observed.

The dressing may adhere if used on very lightly exuding wounds. If the dressing is not easily removed, moisten it with saline solution prior to removal.

The dressing is not intended for use as a surgical sponge and is not intended to control heavy bleeding. Alternative measures must be considered in those emergency situations where exceptional blood loss.

When used for multiple applications, device is intended to have a contact period of less than or equal to 30 days.

Do not use on patients with a known sensitivity to alginates.

For external use only.

METHOD OF USE:
Sorbsan should be applied as advised by a qualified professional after a full and continuing wound assessment.

In the early stages of Sorbsan use, the wound may appear to increase in size. This is to be expected as the moist wound environment encourages autolytic debridement prior to granulation tissue formation and wound healing.

As healing progresses and the wound becomes smaller, less exudate is generally produced. If the wound is not producing enough exudate to gel the Sorbsan fibres, a different dressing choice should be considered in line with existing clinical protocols.

Always use aseptic techniques.














PREPARATION:
• Use existing clinical protocols to clean/debride the wound in preparation for the application of Sorbsan dressings.
• Select a dressing that is of a suitable size and shape.
• Ensure a 5mm overlap around the wound edge to allow for the dressing gelling and conforming to the wound.

DRESSING APPLICATION:
• Apply the dressing centrally over the wound bed.
• Cover with an appropriate secondary dressing as directed by qualified professional or by existing clinical protocols.

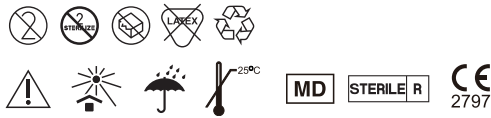
DRESSING WEAR TIME:
• If the secondary needs changing due to exudate leakage, Sorbsan Flat should also be changed.
• It may be necessary at first, when the exudate levels are at their highest, to change Sorbsan Flat daily.
• Where clinically appropriate, the frequency of dressing changes may be reduced as exudate levels decrease.
• When exudate levels are low, good clinical practice indicates that wound dressings should be replaced at least once every seven days. This enables assessment of wound condition, and thus a review of the effectiveness of current treatment practices, to be made.

DRESSING REMOVAL:
After removing secondary dressing:
• Gently lift away any non-gelled parts of the Sorbsan dressing.
• Irrigate the wound with sterile saline (0.9%) solution to remove Sorbsan gel left on the wound site.
• Use existing clinical protocols to clean the wound in order to remove any remaining exudate residue before wound assessment on the application of further dressings.

Storage
Store in a cool, dry place.

SYMBOLS USED ON LABELLING	
	Single use
	Do not Re-sterilize
	Use by: year and month.
	Sterile. Method of sterilisation: Radiation
	Product Reference
	Batch number.
	Attention, see instructions for use.
	Does not contain Latex
	Storage Conditions
	Manufacturer
	EC Representative
	CE mark
	Keep Away from Sunlight
	Keep Dry
	Do not use if package is open or damaged
	Medical Device

INSTRUCTIONS FOR USE



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www.umatmedical.com

EC REP
Medwheat Tech Service GmbH
Max-Planck-Straße 4
85609 Aschheim b.
München
Germany

PRODUCT DESCRIPTION:

Sorbsan Ribbon and Packing are sterile non-woven calcium alginate cavity wound dressings, high in Mannuronic acid and low in Guluronic acid. The fibres of Sorbsan ribbon and packaging swell and form a sodium-calcium alginate gel in contact with wound exudate. This gel:

- Provides a moist wound healing environment, facilitating wound healing
- Conforms to the contours of the wound
- Minimises pain on dressing removal
- Minimises disruption to newly formed tissue on dressing removal
- Upon contact with a bleeding wound, Sorbsan Ribbon/Packing will promote hemostasis

Sorbsan Ribbon and Packing may be used on wounds which are clinically infected only when advised by a qualified professional after a full and continuing wound assessment.

INDICATIONS FOR USE:

Sorbsan Ribbon and Packing wound dressings may be used in cavity wounds where there is a moderate to high level of exudate. If the wound is not producing high enough exudate levels to gel the Sorbsan dressing's fibres, it may be appropriate to change to a different dressing type. Sorbsan Ribbon and Packing are also suitable for the management of bleeding cavity wounds:

- Following toe-nail avulsions
- Pressure ulcers
- Donor and graft sites
- Traumatic wounds

CONTRAINDICATIONS:

The Sorbsan Ribbon and Packing is not intended for:

- Use on patients with a known sensitivity to Calcium Alginate dressings
- Use with heavily bleeding wounds
- Dry wounds
- Surgical implantation
- Used under gauze

WARNING/OBSERVATIONS:

Sorbsan is a sterile, single use product. Do not use if the packaging has been opened or damaged as this could compromise the sterility of the dressing. Sorbsan should not be used with heavily bleeding wounds.

Should consult a healthcare professional if irritation (reddening, inflammation), maceration (whitening of skin), hyper-granulation (excess tissue formation) is observed.

The dressing may adhere if used on very lightly exuding wounds. If the dressing is not easily removed, moisten it with saline solution prior to removal.

The dressing is not intended for use as a surgical sponge and is not intended to control heavy bleeding. Alternative measures must be considered in those emergency situations where exceptional blood loss.

When used for multiple applications, device is intended to have a contact period of less than or equal to 30 days.

Do not use on patients with a known sensitivity to alginates.

For external use only.

METHOD OF USE:

Sorbsan Ribbon and Packing should be applied under medical supervision. Always use aseptic techniques.

PREPARATION:

- Use existing clinical protocols to clean/debride the wound in preparation for the application of Sorbsan Ribbon and Packing dressings.
- Assess the wound in order to determine the most appropriate sized dressing for size and shape of the cavity.

DRESSING APPLICATION:

- Assess the wound for size of wound cavity
- Insert the Sorbsan Packing dressing directly into the wound cavity.
- Do not pack the wound tightly.
- Ensure that a small length (2cm) of dressing remains protruding from the cavity.
- Apply an appropriate secondary dressing over Sorbsan Packing to prevent drying out, and secure with tape or bandage using existing clinical protocols.
- The appropriate choice of secondary dressing is dependent upon the amount of exudate produced by the wound.

DRESSING WEAR TIME:

- If the secondary needs changing due to exudate leakage, Sorbsan Ribbon and Packing should also be changed.
- It may be necessary at first, when the exudate levels are at their highest, to change Sorbsan Ribbon and Packing daily.
- Where clinically appropriate, the frequency of dressing changes may be reduced as exudate levels decrease.
- When exudate levels are low, good clinical practice indicates that wound dressings should be replaced at least once every seven days. This enables assessment of wound condition, and thus a review of the effectiveness of current treatment practices, to be made.

















DRESSING REMOVAL:

- Remove the secondary dressing using existing clinical protocols.
- To remove Sorbsan Ribbon and Packing calcium alginate from the wound, gently pull the protruding length of dressing to lift the nongelled part of the dressing from the wound.
- Irrigate the wound with sterile saline (0.9%) solution to remove Sorbsan gel left in wound site.
- Use existing clinical protocols to clean the wound in order to remove any remaining exudate residue before wound assessment of the application of further dressings.

Storage

Store in a cool, dry place.

SYMBOLS USED ON LABELLING

-  Single use
-  Do not Re-sterilize
-  Use by: year and month.
-  Sterile. Method of sterilisation: Radiation
-  Product Reference
-  Batch number.
-  Attention, see instructions for use.
-  Does not contain Latex
-  Storage Conditions
-  Manufacturer
-  EC Representative
-  CE mark
-  Keep Away from Sunlight
-  Keep Dry
-  Do not use if package is open or damaged
-  Medical Device