Foundation Dermal Regeneration Scaffold (DRS) Solo

Product Description:
Foundation DRS Solo is a highly conformable, advanced wound care device comprising a porous matrix of chitosan derived from shellfish and sodium chondroitin sulfate, a glycosaminoglycan. The chitosan- glycosaminoglycan biodegradable, porous matrix provides a scaffold for cellular invasion and capillary growth. The device is applied on the surface of the wound, and provides a moist wound environment. The dressing may be replaced or may remain in place, acting as a scaffold to promote cellular infiltration and capillary growth as the dressing degrades.

Foundation DRS Solo is 0.16cm thick and provided in the follow (l x w):

5cm x 5cm (2in x 2in)	10cm x 25cm (4in x 10in)
10cm x 12.5cm (4in x 5in)	20cm x 25cm (8in x 10in)

Indications for Use
Foundation DRS Solo is indicated for the management of wounds including:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First degree burns
- Partial thickness burns (superficial second-degree burns)
- Donor sites and other bleeding surface wounds
- Abrasions
- Trauma wounds (abrasions, lacerations, skin tears)
- Dehisced wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)

Foundation DRS Solo may be cut to size.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

Warnings and Precautions:

- Do not resterilize. Discard all open and unused portions of Foundation DRS Solo.
- Device is sterile if the package is unopened and undamaged. Do not use if package has been compromised.
- Discard device if mishandling has caused possible damage or contamination.
- Excessive bleeding, exudate, acute swelling and infection should be controlled prior to the application of Foundation DRS Solo.
- Do not stretch, expand, spread or re-mesh the device.
- The following conditions are possible with the use of wound dressings. If any of the conditions occur, the device should be removed: infection, chronic inflammation (initial application of wound dressings may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain or swelling.

Contraindications:

- Foundation DRS Solo should not be used on patients with known sensitivity to chitosan or chondroitin materials. Product use should be discontinued should signs of sensitization occur.
- Foundation DRS Solo is not indicated for the treatment of third-degree burns.

Directions:

1. Prepare wound bed as normal, i.e. debridement and irrigation.
2. Remove Foundation DRS Solo from package and cut to size if necessary.
3. Moisten with saline as desired.
4. Apply Foundation DRS Solo directly to the wound site.
5. Cover with a secondary bandage to secure in place.
6. Change dressing as needed. A heavily exuding wound may require frequent dressing changes.
7. Foundation DRS Solo may be left in the wound per physician recommendations.

Storage

- Store between +10°C – +30°C

Packaging: Foundation DRS Solo is provided sterile, as a single-use device in double barrier packaging.

Manufacturer:
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