

# FibDex®

## STERILE WOUND DRESSING

FD101001 1 x 10 x 10 cm, 3.9 x 3.9 in  
 FD101005 5 x 10 x 10 cm, 3.9 x 3.9 in  
 FD152001 1 x 15 x 20 cm, 5.9 x 7.9 in  
 FD152005 5 x 15 x 20 cm, 5.9 x 7.9 in  
 FD203001 1 x 20 x 30 cm, 7.9 x 11.8 in  
 FD203005 5 x 20 x 30 cm, 7.9 x 11.8 in

### INSTRUCTIONS FOR USE

#### Intended use

FibDex® is sterile wound dressing intended for use in the treatment of split thickness skin graft donor site wounds. The dressing is intended to maintain a moist environment, protect the wound from infection, and provide mechanical protection, thereby facilitating faster wound healing. FibDex is intended for use by healthcare professionals in a hospital environment and, under the supervision of healthcare professionals, in the home care environment.

#### Contraindications

FibDex should not be applied to an infected wound. No other contraindications affecting the safety of FibDex have been identified in the studies or tests conducted on the product.

#### Side effects

No side effects have been identified in the studies or tests conducted on FibDex.

### Instructions for use



1. Clean the wound carefully following wound care guidelines and using good aseptic technique.



2. Take FibDex wound dressing out of the outer packaging and carefully open the sterile barrier pouch.



3. Moisten FibDex in sterile 0.9% physiological saline for 10 to 20 seconds.



4. Place FibDex on the wound and secure in place with, for example, surgical staples.



5. Cover FibDex with a secondary dressing.



6. Wrap a breathable dressing, such as cotton gauze, over the secondary dressing.

**FibDex is designed to be non-changeable.**

**FibDex will detach itself from the wound once healing has occurred.**

### Using FibDex wound dressing

Please see the pictures in this instructions for use document.

Before using the product, clean the wound carefully following wound care guidelines and using good aseptic technique. If required, FibDex can be cut with sterile scissors to a desired shape or size before use. Ensure that the dressing extends beyond the edges of the wound by at least 0.4 in / 1 cm in each direction. Before applying FibDex to the wound, it should be moistened with sterile 0.9% physiological saline; this will make the dressing soft and conformable. A short wetting time of 10 to 20 seconds is sufficient.

### Placing the FibDex on the wound

FibDex is easy to use because both sides are identical, so the product can be placed on the wound either side up. If there is a need to cover larger wound area, multiple FibDex dressings can be placed side by side so that their edges overlap (by about 0.4 to 1.2 in / 1 to 3 cm). FibDex should be properly secured in place with, for example, surgical staples. FibDex may dislocate from the desired placement, if an attachment is not applied.

Secondary dressing shall be applied on top of FibDex to ensure that FibDex remains moist and flexible during the first days of use. The secondary dressing should be non-adhesive and non-occlusive. (e.g. paraffin gauze or foam dressing). The choice of secondary dressing depends on the exudate level. Wrap a breathable dressing, such as a cotton gauze, over the secondary dressing to help to hold the primary and secondary dressings in place and to absorb possible wound exudate.

The covering dressings should be changed as necessary without removing FibDex.

### Detachment of FibDex

As the healing of the wound progresses, FibDex will start to detach itself, usually beginning at the edges. FibDex should be left in place until the wound has healed and the dressing has detached itself. Staples can be removed according to local medical guidelines. FibDex does not need to be changed and it should not be forcefully removed from the wound, as this could damage the thin epithelialized surface of the skin. As the wound heals, the loose edges of FibDex can be easily cut off, for instance with a sterilised pair of scissors.

It is recommended that FibDex is used for a maximum of 30 days. If FibDex is still attached 30 days after application the treatment should be continued according to the local wound care guidelines and under the supervision of a healthcare professional. If complications occur, a healthcare professional should be contacted immediately. The wound healing process should be monitored regularly by a healthcare professional at all times.

### Precautions

- **Do not use the product if the sterile protective pouch is damaged or wet, or if it has been opened before use.**
- FibDex is a single-use product. **Do not re-use or re-sterilize the product** due to the risk of cross-contamination.
- Before the product is applied, it is important to ensure that the wound exudate level is manageable and that there is no sign of acute swelling or infection.
- Do not apply FibDex to an infected wound.
- If infection or other complications occur, a healthcare professional should immediately be contacted and local wound care guidelines followed.
- It is recommended that FibDex is used for a maximum of 30 days. However, no side effects have been identified in studies where FibDex has been used for longer than 30 days.
- FibDex should be kept dry and clean during the treatment. If the product gets wet, a healthcare professional should immediately be contacted and local wound care guidelines shall be followed.
- In the case of premature detachment of FibDex the healthcare professional should follow the local wound care guidelines.
- Certain underlying diseases, such as diabetes and circulatory disorders, may delay the wound healing process.
- Do not use the product after the expiry date.
- FibDex should not be used on patients, who are allergic or sensitive to product's components (wood cellulose or polypropylene).

The safety and effectiveness of FibDex have not been established on pregnant or breast-feeding women or patients outside the age range of 18-75 years.

The product has not been tested on sensitive skin areas, such as the facial area, the genital area or mucous membranes or on second- or third-degree burns, or on chronic or acute wounds extending to tendons or bones.

### Storage

Store in normal room temperature in dry and clean conditions avoiding sunlight.

### List of materials

Wound dressing: wood cellulose, polypropylene

Sterile barrier pouch: Polyethylene Terephthalate/Polypropylene (PET/PP) and medical special paper

Outer packaging: bleached paperboard

### Safe disposal

Packaging materials and used wound dressings should be disposed of in accordance with local regulations and procedures.

### Contact information

For more information or instructions on how to use the product contact the distributor. Any serious incident that has occurred in relation to the device should be reported to the distributor and/or manufacturer.

Please provide feedback on FibDex by filling out a feedback form at [www.fibdex.com/feedback](http://www.fibdex.com/feedback).

### Symbols

	Consult instructions for use		Caution		Do not re-use
<b>Rx-Only</b>	The US Federal law restricts this device to sale by or on the order of a physician		Manufacturer		Do not re-sterilize
<b>STERILE</b>	Sterilized using steam		Do not use if package is damaged		Keep away from sunlight
	Temperature limit 35°C / 95°F 18°C / 64°F		Keep dry	<b>LOT</b>	Batch code
	Use-by date		Date of manufacture	<b>REF</b>	Catalogue number
<b>CE 0044</b>	Product fulfills the European legislation requirements on medical devices.	<b>MD</b>	Medical device	<b>Rx-only</b>	US, Caution: Federal law restricts this device to sale by or on the order of a physician
	Single sterile barrier system with protective packaging outside		Single sterile barrier system		Contains nano materials

BIOMED-545 rev 3.0

UPM-Kymmene Corporation  
 UPM Biomedicals  
 P.O. Box 380  
 Alvar Aallon katu 1,  
 FI-00101 Helsinki, Finland

[www.fibdex.com](http://www.fibdex.com)

**Rx-only** 0044