

## THERUPTOR™ NOVO

### 3D Hydrocellular Microbicidal Composite Dressing

- Anti-microbial Chronic Wound Dressing
- 3D Hydrocellular dressing for exudate and moisture management
- Non adherent for easy removal

### INSTRUCTIONS FOR USE

**STERILE** **R**

Gamma Irradiation Sterilized



Medical Device



Do not use if damaged



Do not reuse



Store in dry place, not above 50°C

### PRODUCT DESCRIPTION

Theruptor NOVO is a sterile barrier wound dressing intended for use as a primary dressing for exuding wounds, first and second degree burns, minor wounds and surgical wounds; to secure and prevent movement of a primary dressing; and as a wound packing. The structure of dressing is a 3-Dimensional knitted fabric that act as a hydrocellular structure. It consists of a textile substrate consisting of polyethylene terephthalate (90% w/w) and polyurethane (10%w/w) with a permanently bound “Dimethyl tetradecyl [3-(trimethoxysilyl)propyl] ammonium chloride” (DTAC) at a concentration of 1% w/w. The non toxic DTAC does not leach into skin or out of the dressing. The device acts as a physical barrier to outside contaminants and does not act on the surface or interior of the wound nor does it contain antimicrobial agents that act on the body.

### INDICATIONS

Intended for use as a primary dressing for exuding wound; to secure and prevent the movement of primary dressing; and as a wound packing. It is intended to be used for indications such as

- Minor wounds
- Partial and full thickness wound
- Venous ulcer & pressure ulcer
- Diabetic ulcer
- Chronic vascular ulcers
- Surgical wounds(donor sites and grafts, post Moh's surgery, post laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasion, lacerations, second-degree burns, and skin tears)

### CONTRAINDICATIONS

Theruptor Novo Wound Dressing is contraindicated for use in 3rd degree burns

### CONTAINS

Hydrocellular structure made of Poly ethylene terephthalate, Polyurethane & Dimethyl tetradecyl [3(trimethoxysilyl) propyl] ammonium chloride.

### PRECAUTIONS

- To be used as directed by a trained and registered health care professional
- Theruptor NOVO Wound Dressing is intended for external use only
- Theruptor NOVO Wound Dressing act as a physical barrier to outside contaminants and does not act on the surface or the interior of the wound nor does it contain antimicrobial agent that act on the body
- Theruptor NOVO Wound Dressing is not intended as treatment for clinical infections, if signs are present, please consult a physician
- Theruptor NOVO should not be used on patient's with known sensitivity to quaternary ammonium compound
- If there is a pain while removing the dressing, soak with sterile saline or water until it is removed without difficulty

### DIRECTIONS FOR USE (For Adhesive Dressing Variant)

- Before applying Theruptor NOVO, wound cleansing should be performed according to local clinical protocol.
- A dressing of appropriate size should be chosen for each wound. Make sure that the dressing size is bigger than the wound to get complete coverage of the wound well.
- Remove Theruptor NOVO from the sterile package using an aseptic technique.
- While stabilizing the area where dressing needs to be applied, position the dressing over the wound.
- Beginning at the center of the dressing, grasp one section of the paper carrier and pull toward the outer edge of the dressing exposing the adhesive layer. Repeat this for each of the remaining carrier sections until all paper carrier is removed. Firmly press and conform the adhesive border to the skin.
- Ensure Theruptor NOVO Wound Dressing is in good contact with the wound.
- The dressing may be left in place for up to seven days but might require earlier changing of the dressing if a strike through of exudate occurs.
- Theruptor NOVO is simple and safe to use wound protection device which does not warrant any medical practitioners' guidance for usage and repetitive application.
- Remove Theruptor NOVO Wound Dressing after seven days of application.
- To remove Theruptor NOVO dressing follow the instruction below.
- Lift the Theruptor NOVO dressing starting from the adhesive layer, away from the wound.
- To remove the dressing, soak with sterile saline or water until it is removed without difficulty

### DIRECTIONS FOR USE (For Non Adhesive Dressing Pad variant)

- Before applying Theruptor NOVO, wound cleansing should be performed according to local clinical protocol.
- A dressing of appropriate size should be chosen for each wound. Make sure that the dressing size is bigger than the wound to get complete coverage of the wound well.
- Remove Theruptor NOVO from the sterile package using an aseptic technique.

- Apply the Theruptor NOVO Wound Dressing on the surface of the wound ensuring good contact and secure with a tape or bandage.
- Cut to shape as necessary, appropriate to the wound area if required. Use cotton gauze or adhesive tape as secondary dressing.
- The dressing may be left in place for up to seven days but might require earlier changing of the dressing if a strike through of exudate occurs.
- Theruptor NOVO is simple and safe to use wound protection device which does not warrant any medical practitioners' guidance for usage and repetitive application.
- Remove Theruptor NOVO Wound Dressing after seven days of application.
- To remove Theruptor NOVO dressing follow the instruction below.
- Remove the retention tape or bandage.
- Lift the Theruptor NOVO dressing away from the wound.
- To remove the dressing, soak with sterile saline or water until it is removed without difficulty.

### CHANGE FREQUENCY

Upto 7 days of time or when completely saturated with exudates; whichever occurs first.

### BIOCHEMICAL PROPERTY

Permanently bonded DTAC on the Theruptor NOVO Wound Dressing inhibits the growth of bacteria, fungi and yeast. The summary of the Bio-Chemical Testing results are given below. (ASTM E2315-03)

### Summary of Bio-Chemical Testing Result

S.NO	Test Organisms	% of Reduction			
		1 hour	4 hour	24 hour	48 hour
1.	Staphylococcus aureus ATCC 6538	99.99	99.99	99.9999	99.9999
2.	Listeria monocytogenes ATCC 19115	99.99	99.99	99.9999	99.9999
3.	Enterococcus faecalis ATCC 29212	99.99	99.99	99.9999	99.9999
4.	Escherichia coli ATCC 25922	99.99	99.99	99.9999	99.9999
5.	Pseudomonas aeruginosa ATCC 15442	99.99	99.99	99.9999	99.9999
6.	Klebsiella pneumoniae ATCC 4352	99.99	99.99	99.9999	99.9999
7.	Candida albicans ATCC 10231	90	90	99.9999	99.9999
8.	Aspergillus niger ATCC 6275	90	90	99.9999	99.9999

### AVAILABLE DIMENSIONS

Available Sizes: 7.5 x 7.5cm, 10 x 10cm and 15 x 15cm.

### \*Available in custom sizes

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