



## Instructions for Use

Medical device No.: 11550401



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

SilverStream® is a hypertonic buffered solution, with hydrogel properties and a pleasant odor, for wound management and maintenance of wound moisture level. SilverStream® is a clear, colorless solution, protected from microbial contamination by a low concentration of ionic silver and supplied in 100mL, 250mL and 500mL bottles.

### **INTENDED USE AND INDICATIONS FOR USE**

SilverStream® is intended for use under the supervision of a healthcare professional for management and moisturizing of wounds such as stage I-IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, cuts abrasions and minor skin irritations.

### **GENERAL DIRECTIONS FOR USE**

SilverStream® is designed for management and moisturizing of wounds by applying the SilverStream® solution directly from the bottle, by means of a syringe or bulb, spraying onto the wound using a spray bottle, by applying with devices designed to allow for irrigation or lavage, or by soaking a gauze/dressing or sponge.

Apply 1-2 times daily, according to the physician instruction.

Note: The wound may be cleansed if SilverStream® is applied with a 19G needle (application pressure of ~ 10 psi).



### **CAUTIONS AND WARNINGS**

- For external use only. Avoid contact with eyes.
- Use only undamaged bottle.
- Do not use in patients with a history of hypersensitivity to any of the ingredients.
- Discontinue use if irritation develops.
- Avoid usage of turbid or colored solution.
- Protect bottle from direct contact with wound. Bottles that have come into contact with the wound must be discarded after use.
- For single patient use only.
- If the bottle is closed immediately after use and the top of the bottle is protected from contamination, the solution may be reused within 28 days from first opening.
- Store the bottle between 10-30°C
- The empty bottle can be disposed to the regular trash can. A bottle that contains solution should be cleared off to an appropriate site.
- Do not apply more than 700mL of SilverStream® solution within a 24 hour period

### **INGREDIENTS**

Ingredients include purified water, glycerol (glycerin), sorbitan monolaurate (Tween-20), TRIS, menthol and silver nitrate 0.01% (w/v).

**Each package contains twelve (12) bottles of 250mL or 500mL, or twenty four (24) bottles of 100mL and instructions for use leaflet, which is part of the bottle label.**

### **SYMBOLS**

The following provides a description of the graphic symbols that appear on the SilverStream® label:



Caution



Consult instructions for use



Manufacturer



Keep bottles out of direct sunlight



30

10 Temperature Limitation



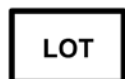
Use by date



Sterilized using aseptic processing techniques



Do not re-sterilize. Re-sterilization may reduce the effectiveness of the product



Batch code / LOT #

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