Special Answers to Special Problems℠
Health Care Logistics® INC.

Technical Bulletin

SALJET

HCL #13090

Single Dose 30ml Sterile Saline Topical Solution

Manufactured by Winchester Laboratories LLC

Saljet

Easy, safe, convenient, fast, economical method to moisten bandages and cleanse minor wounds, burns and grazes

- **Easy to use**, just twist off top and single dose of 30ml sterile saline is ready for use
- **Safe in use**, Saljet cannot be recapped once opened thereby reducing the risk of using non-sterile saline during a cleansing procedure
- **Convenient**, the sterile saline is contained in a light plastic container, four to six of which would easily fit into a pocket
- **Fast,** reduces visits to nursing stations for equipment and enables several cleansing operations to be carried out in quick succession
- **Economical,** less expensive than other small volume use of sterile saline

SALJET is a blow fill seal presentation of 30ml isotonic (0.9%), sterile saline for use in moistening bandages, cleansing minor wounds, burns and grazes. The product is manufactured in strips of four with forty units to a box and nine boxes to a shipping carton.

Cleansing

TREATING THE PATIENT WITH CARE

Moistening bandages before removal helps to halt debriding of healing wounds. Cleansing small wounds, burns and grazes prior to dressing helps the healing process.

- Conventional swabbing with cotton wool or gauze can leave fibers in the wound.
- To be effective, cleansing must be directional enough to remove infected material and foreign bodies in the desired direction, while being controllable enough to cleanse without trauma, even in the most sensitive areas of the body.

SIMPLE SOLUTIONS ARE BEST

- Sterile Saline is all that is needed to moisten bandages prior to removal.
- Simple cleansing is most desirable for minor wounds, burns and grazes and a 0.9% saline solution is the cleansing agent of choice, as it has been successfully used for over 2,000 years.

Warmth and Pressure

WARMTH IMPROVES COMFORT AND HELPS HEALING

If bandages are moistened prior to removal with warm saline it is more comfortable for the patient. Cleansing minor wounds, burns and grazes with cold saline will lower the temperature of the wound and may delay the healing process.

- It has been shown that a wound will take 40 minutes to regain its original temperature and three hours to reach normal cellular activity after being cleansed with cold saline.
- Below temperatures of 28C, phagocytic and mitotic activity are particularly affected and the lowered availability of oxygen in a chilled wound may reduce fibroblast activity, delaying healing even further.
- Therefore saline should be warmed to body temperature before irrigation takes place.
- Saljet can be warmed by carrying it in the pocket or by simply immersing it in a pitcher of hot water before use- without compromising the saline's sterility.
- Another major benefit of warming Saljet before use is that irrigation is then more comfortable for the patient.

CONTROLLING IRRIGATION PRESSURE

The simple rule is to use the lowest pressure possible to remove a bandage and cleanse a minor wound, burn or graze. The pressure needed will obviously vary according to the site of the wound.

- Syringes offer a variable pressure jet, but even using the ideal combination of a 30ml syringe body and an 18 gauge needle can pose problems of control, and if only a small amount of irrigant is used there will be some unavoidable wastage.

- Aerosol systems can prove bulky to carry and concern has been expressed about "splash back" and cross-contamination.
- Saljet's squeezable single shot saline offers the most effective and convenient method of moistening and cleansing, dispensing streams or drops as required with guaranteed sterility and no waste of materials.
- Sterile saline offers a simple, effective way to improve the healing potential of patients' wounds and Saljet gives an effective, convenient and economical way to dispense it.

Useful features and benefits

All products from Winchester Laboratories will be manufactured using 'Blow Fill Seal' technology, (BFS), which provides an unrivalled ability to design combined packaging and delivery systems for liquid pharmaceuticals which are better suited to

their end use than traditional designs. BFS also provides superb assurance of sterility and both these advantages are achieved in a cost effective way that usually results in cost savings in the order of 25% over traditional methods of manufacture.

These combined capabilities provide well-designed products that are effective and easy to use. Winchester Laboratories' products have the feature of unit-dose presentation that provides preservative free solutions.

Competition

There is no equivalent product on the market specifically marketed for bandage moistening and cleansing of minor wounds, burns and grazes. Rather there is a method used by medical personnel that involves using at least two other products. The

most common practice is for the medical person to extract sterile saline from a one-liter container with a 20ml syringe body, and to use the syringe body to expel the saline solution directly onto the treatment site. It is common practice to use one or

two syringefuls of saline per procedure. It is also common practice to reuse the saline solution from the one liter bottle for the same patient at least twice more, however this is not safe practice as there is no guarantee that the saline will remain sterile after opening.

The cost of this method of wound irrigation is about 58 cents, 26cents for a 20ml syringe body and approximately 32 cents for the saline. (A one-liter bottle of sterile saline costs about $1.29 and is used on average three to four times per bottle.)

What is Blow Fill Seal technology?

Blow Fill Seal technology is a continuous process carried out on one multi-function machine. The starting point is a supply of polymer granules which are fed via a hopper to an extruder operating at high pressure (300 atmospheres), and high temperatures (approximately 165C for polyethylene). Semi molten polymer is extruded in a tube shape, called a parison, until it is the desired length, whereupon the two halves of the mold forming the body of the container to be made, close.

With the aid of vacuum the parison is pulled into shape in the mold and the plastic very quickly cooled by virtue of the coolant flowing through a honeycomb of passageways in the mold segments. At this point filling tubes are lowered and the required dose of product is filled into the container using time/pressure dosing. The filling tubes are withdrawn and the head mold segments close on the still hot upper section of the parison and again with the help of vacuum, the top part of the container is formed.

The whole filling and sealing process takes place in an enclosed volume that is fed with a fast flow of absolute filtered air to provide a sterile environment. The machine itself is also housed in an environmentally controlled room to minimize the bacteriological challenge to the process. Solution to be filled is sterile filtered immediately prior to filling and the air which supports the parison during extrusion is also sterile filtered.

The cycle time is approximately 10 to 12 seconds depending on the size of the container, plastic type and thickness and other variables. Typically for small volume containers in the range 5ml to 30ml, eight to ten will be molded per cycle. The product which leaves the BFS machine has been formed, filled and sealed, and ready for use requiring only labeling, packing and Quality Control release to be ready for sale.

Directions for use

- Tear a single unit from a strip of four, hold the body of Saljet firmly but without squeezing, and twist off the tab.
- Saljet may now be positioned at any angle required to access the area to be moistened or cleansed and pressureapplied to obtain the desired flow rate of sterile, isotonic saline.
- The empty Saljet and its tab may be disposed of for polymer re-cycling.
- Discard any unused portion of saline, Saljet is not designed for resealing or reuse.