



Precautionary Statement (01-50-1082A)

Biomet Sports Medicine, Inc. 01-50-1082A

56 East Bell Drive

Date: 04/07

Airport Industrial Park

Warsaw, IN 46581 USA

LactoSorb™ Heat Pack

Description

The LactoSorb™ Heat Pack is a purified calcium chloride thermal heating device activated by water.

MATERIALS:

Calcium Chloride Pellets

Polyester Foam

Polyvinyl Chloride (PVC) Pouch

ACTION

The LactoSorb™ Heat Pack containing calcium chloride is activated by injecting sterile water into the heat pack port. The pack is manipulated for one minute to aid dissolution of the calcium chloride crystals. As the crystals dissolve, the surface temperature of the heat pack is increased to approximately 90°C (194°F) and it maintains a temperature range of 70-90° (158-194°F) for approximately 20 minutes.

INDICATIONS

The LactoSorb™ Heat Pack is used to heat LactoSorb® implants to a temperature where the implant becomes malleable.

CONTRAINDICATIONS

1. DO NOT apply to the body or to an implanted part.
2. DO NOT use on infant heels.
3. DO NOT use to raise veins for venipuncture on infants, children, or adults.

PRECAUTIONS

1. The LactoSorb™ Heat Pack is not for use on skin. If applied to the skin, reddening, irritation, or discomfort caused by the heat may occur.
2. Do not heat or reshape LactoSorb® screws by any means.
3. The effects of using LactoSorb™ heat packs with resorbable implants made by manufacturers other than Biomet and its subsidiaries are unknown.

ADVERSE REACTIONS

Should there be a leak or puncture in the product, the leaking solution should not contact skin since temperatures may be as high as 94°C (201°F). If the solution or calcium chloride pellets do

contact skin or eyes, flush immediately with water. Prolonged skin contact may cause irritation. Eye contact overexposure causes irritation or burns.

DIRECTIONS FOR USE

1. Open heat pack packaging in the sterile surgical field.
2. Using a sterile syringe, inject approximately 236 milliliters (8 fl. oz.) of sterile water through the injection port. While keeping the syringe attached to the pack, pull back on the syringe plunger to collect residual air trapped within the bag produced by the reaction. Remove syringe from port.
3. Vigorously shake the heat pack for approximately one minute to mix the sterile water with the calcium chloride to generate heat.
4. Fold the heat pack in half to create a pocket for the implant. Place the implant in the middle of the pocket and heat for 1-2 minutes or until malleable.
5. Once the implant becomes malleable, shape as desired, and allow it to cool until the implant becomes rigid. The implant is now ready for implantation.

NOTE: The implant may be reinserted into the heat pack pocket for reshaping. Do not attempt to reshape an implant while it is still in the patient's body. The desired heat is maintained for approximately 20 minutes and is optimum when the implant is placed in the middle of the folded pack. To prolong the optimum heat for the length of the surgery, keep pack folded and wrapped in sterile towels.

STERILITY

The LactoSorb™ Heat Pack is sterilized using a minimum dose of 25 kGy of gamma irradiation. Do not resterilize. Do not use after expiration date.

SINGLE USE DEVICE - DO NOT REUSE

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept, Biomet, P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-1683

LactoSorb is a registered trademark of Biomet Manufacturing Corp. in the United States.

U.S. Patent No.: 5263991, foreign patents pending.

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