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LactoSorb™ Air Activated Heat Pack

ATTENTION OPERATING SURGEON

DESCRIPTION

The LactoSorb™ Air Activated Heat Pack is a mixture of iron powder, water, salt, activated carbon and vermiculite in a thermal packaging unit for heating LactoSorb™ resorbable implants.

MATERIALS

Iron Powder
Water
Salt
Activated Carbon
Vermiculite
Tyvek/Mylar Thermal Packaging

ACTION

The LactoSorb™ Air Activated Heat Pack is activated by opening the foil chevron pouch and then shaking the heat pack for at least one minute. This agitation allows oxygen to reach the mixture to begin the reaction. As the iron powder oxidizes, the surface temperature of the heat pack increases to optimum temperature, 80-85°C (176-185°F), in approximately 30 minutes.

INDICATIONS

The LactoSorb™ Air Activated Heat Pack is to be used to heat a LactoSorb™ biocompatible resorbable implant 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.

WARNINGS & PRECAUTIONS

1. The LactoSorb™ Air Activated Heat Pack is not for use on skin. If applied to skin, reddening, irritation, blistering, or burns may occur due to the high temperature.
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.
4. Device is single use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.

ADVERSE REACTIONS

Should there be a leak or puncture in the product, avoid contact of the powder mixture with skin since the temperature may be as high as 94°C (201°F). If the mixture contacts skin or eyes, flush immediately with water. Prolonged skin contact may cause irritation. Eye contact or exposure can cause irritation or burns.

DIRECTION FOR USE

NOTE: Allow 30 minutes to reach optimum temperature.

1. The foil package is to be opened and the heat pack dropped into the sterile surgical field.
2. Discard foil packaging.
3. Gently shake the heat pack for one minute to allow ambient oxygen to reach inner mixture to generate heat.
4. Allow 30 minutes to reach optimum temperature.
5. Fold the heat pack in half, with the Tyvek side out, and the shiny plastic side on the inside.

6. Place the implant in the middle of the pack and heat until malleable. Once the implant becomes malleable, shape as desired.
7. Allow the implant to cool until the implant is rigid. The implant is now ready for implantation.

Note: The implant may be reinserted into the heat pack for reshaping. Do not attempt to reshape an implant while it is still in the patient's body. The desired heat is maintained for a minimum of 3 hours. Intermittent shaking of the heat pack may prolong this timeframe. Optimal performance will be achieved when the implant is placed in the middle of the folded pack. To maintain a steady heat, keep pack folded and wrapped in sterile towels.

STERILITY

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

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

SINGLE USE DEVICE – DO NOT REUSE

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