For more information please contact:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015 USA

www.baxter.com

Baxter Healthcare SA
8010 Zurich
Switzerland

Made in France

Definitions of Symbols Used on Labeling of Product

Symbol	Title of Symbol	Description of Symbol
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Date of manufacture	Indicates the date when the medical device was manufactured.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
STERILE EO	Sterilized using ethylene oxide	Indicates the presence of a sterile fluid path within the medical device. The method of sterilization is indicated within the box.
	Manufacturer	Indicates the medical device manufacturer.
Rx Only	Prescription only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Non-Pyrogenic	Indicates a medical device that is non-pyrogenic.
	Defibrillation-proof Type CF Applied Part	Indicates the type of applied part per IEC 60601-1.

Definitions of Expressions Used in this Manual

⚠ **"Warning"** indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ **"Caution"** indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

"Note" is used as a reminder to the user/operator on normal treatment activity and on what is suitable action in a particular situation.

Product Description

- The Blood Warmer Disposable is a disposable circuit for use with the TherMax blood warmer in combination with other PrisMax disposable sets.
- The Blood Warmer Disposable consists of a bag, 2 sections of tubing lines, and luer connectors.
- The Blood Warmer Disposable is a sterile disposable product free of toxics.
- All line Connectors are compatible with the ISO 594 international standards concerning conical fittings.
- The Blood Warmer Disposable is guaranteed sterile and non-pyrogenic.
- The Blood Warmer Disposable is sterilized by ethylene oxide (EO).
- Expiration date: Please refer to product label.
- Not made with natural rubber latex.
- The priming volume of the Blood Warmer Disposable is 27mL +/- 10%.
- The Blood Warmer Disposable is intended for up to 72 hours of use.

Use of the Blood Warmer Accessory with PrisMax requires the installation of the TherMax Blood Warmer Unit on the PrisMax Control Unit; contact your local Baxter representative.

Intended Use

The TherMax Blood Warmer Accessory includes the Blood Warmer Unit and Blood Warmer Disposable. It is intended for use in combination with the PrisMax control unit using Prismaflex blood tubing sets for the warming of blood during extracorporeal blood circulation.

Indication For Use

The TherMax Blood Warmer Accessory is indicated for warming returning blood flow.

Contraindictions

There are no known contraindications when used as intended and within the specified operating conditions.

Cautions and Warnings

Note: *Additional warnings and cautions pertaining to the TherMax Blood Warmer Accessory are included in the PrisMax Control Unit, or in the TherMax Operator's Manual.*

⚠ Cautions

1. Read the TherMax Operator's Manual carefully prior to use.
2. Read the IFU of the Blood Tubing Therapy Set carefully prior to use.
3. Read the IFU of the Blood Warmer Disposable carefully prior to use.
4. Use aseptic technique according to hospital policy.
5. Dispose of the product after use according to clinical and legal regulations.
6. Do not expose to heat or sun.
7. The product should be stored in a cool, dry and dark place.
8. Do not use solvents on the product such as alcohol, ether, acetone, liquid inhalation anaesthesia (e.g. halothan, enfluran, etc.). They can damage the products from the inside and outside.
9. In order to avoid product damage, do not use lubricants, disinfectants, etc. for tube connections.
10. Tubes and Luer Lock connections have to be fixed and fastened by hand only. Other aids can damage the connectors.
11. Once the product has been primed it should be used within hours to minimize the danger of microbiological contamination and/or precipitation in priming fluid.
12. Rx Only.

⚠ Warnings

1. The use of operating procedures, other than those published by the manufacturer, or the use of other devices not recommended by the manufacturer can result in patient injury or death.
2. Sterility is only guaranteed if the packaging is undamaged and unopened.
3. Pay attention to the expiration date.
4. The product must be carefully checked by the user before application for damages and intactness. Do not use if package is damaged, sterilization caps are missing, or lines are kinked.
5. For single use only, due to loss of sterilization, risk of contamination, and decreased performance.
6. Do not resterilize.
7. All products have to be used under aseptic conditions.
8. This product should be used only for medical applications and should only be used under medical supervision and by suitably trained operators.
9. This product must be used as soon as the packaging is removed.

Specifications

Accessory Materials

Component	Material
Bag	Polyurethane (PU)
Tubing	Polyurethane (PU)
Male Luer Fitting	Acrylonitrile Butadiene Styrene (ABS)
Female Luer Fitting	Polyvinyl Chloride (PVC)
Male Luer Cap	Polypropylene (PP)
Female Luer Cap	Polyethylene (PE)

Instructions For Use

Note: *Use the Blood Warmer Disposable by following the detailed on-screen instructions provided by the PrisMax Control Unit. Additional information is available in the PrisMax Operator's Manual.*

Warranty and Limitation of Liability

A) The manufacturer warrants that the TherMax accessory has been manufactured in accordance with its specifications and in compliance with good manufacturing practices, other applicable industry standards and regulatory requirements. If provided with the lot/serial number of the defective product, the manufacturer will, by replacement or credit, remedy manufacturing defects in the TherMax accessory becoming apparent before the expiration date.

B) The warranty under paragraph A) above is in lieu of, and to the exclusion of, any other warranty whether written or oral, express of implied, statutory or otheriwse, and there are no warranties of merchantability or other warranties, which extend beyond those described in paragraph A) above. The remedy set out above for manufacturing defects is the sole remedy available to any person due to defects in the TherMax accessory, and the manufacturer shall not be liable for any consequential or incidental loss, damage, injury, or expense arising directly, or indirectly, from the use of the TherMax accessory, whether as a result of any defect therein or otherwise.

C) The manufacturer shall not be liable for any misuse, improper handling, non-compliance with warnings and instructions, damage arising from events after the manufacturer's release of the TherMax accessory, failure or omission to inspect the TherMax accessory before use in order to ensure that the TherMax accessory is in proper condition, or any warranty given by independent distributors or dealers.