Use by

Sterilized by ethylene oxide

For single use

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician

Do not resterilize

Do not use if packaging is damaged

Please read the instructions prior to use

Non pyrogenic fluid path

LIMITED WARRANTY

This Limited Warranty is in addition to any statutory rights of the Purchaser pursuant to applicable law.
ThermaSolutions warrants that all reasonable care has been taken in the manufacture of this medical device, as required by the nature of the device and the use for which the device is intended. THERMASOLUTIONS warrants that the medical device is capable of functioning as indicated in the current instructions for use when used in accordance with them by a qualified user and before any expiry date indicated on the packaging. However, THERMASOLUTIONS cannot guarantee that the userwill use the device correctly, nor that the incorrect diagnosis or therapy and/or that the particular physical and biological characteristics of an individual patient, do not affect the performance and effectiveness of the device with damaging consequences for the patient, even though the specified instructions for use have been respected. THERMASOLUTIONS, whilst emphasizing the need to adhere strictly to the instructions for use and to adopt all the precautions necessary for the correct use of the device, cannot assume any responsibility for any loss, damage, expense, incidents or consequences arising directly or indirectly from the improper use of this device. THERMASOLUTIONS undertakes to replace the medical device in the event that it is defective at the time of placing on the market or whilst being shipped by ThermaSolutions up to the time of delivery to the final user unless such defect has been caused by mishandling by the purchaser. The above replaces all other warranties explicit or implicit, written or verbal, including warranties of merchantability and fitness for purpose. No person, including any representative, agent, dealer, distributor or intermediary of THERMASOLUTIONS or any other industrial or commercial organization is authorized to make any representation or warranty concerning this medical device except as expressly stated herein. THERMASOLUTIONS disclaims any warranty of merchantability and any warranty of fitness for purpose with regard to this product other than what is expressly stated herein. The purchaser undertakes to comply with the terms of this Limited Warranty and in particular agrees, in the event of a dispute or litigation with ThermaSolutions, not to make claims based on alleged or proven changes or alterations made to this Limited Warranty by any representative, agent, dealer, distributor or other intermediary. The existing relations between the parties to the contract (also in the case that it is not drawn up in writing) to whom this Warranty is given as well as every dispute related to it or in any way connected to it as well as anything related to it or any dispute concerning this Warranty, its interpretation and execution, nothing excluded and/or reserved, are regulated exclusively by the United States law and jurisdiction. The court chosen is the Court of Minnesota.

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ThermaSolutions

IPH Waste Bag

Instructions for Use

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⚠ Please read the instructions prior to use.

Instructions for Use

THERMASOLUTIONS IPH WASTE BAG

FOR USE WITH THERMOCHEM™ HT SYSTEMS ONLY.

CAUTION: FEDERAL (U.S.A) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

IPH Waste Bag Contents: (1) waste bag, non-sterile

Information related to the IPH Waste Bag is provided in this instruction sheet. Refer to the ThermoChem System Operator's Manual for complete instructions on proper installation and use of the ThermoChem System.

Warnings and Precautions

1. For Single use only – do not reuse.
2. Use proper aseptic technique when handling this product.
3. Do not use if package is opened or damaged.
4. Overfilling the Waste Bag may cause it to rupture.
5. After use, dispose of the device in accordance with applicable regulations in force in the country of use.
6. The device must not undergo any further processing.
7. For further information and/or in case of complaints contact ThermaSolutions or authorized local representative
8. Do not alter or modify otherwise product may not work as intended.

Description

The devices are single use, non toxic, non pyrogenic, supplied non sterile and packaged singly. Levels of ethylene oxide residuals in the devices are within the limits established by national regulations in the country of use.

Contraindications

There are no known contraindications when the device is used as intended.

Safety Information

Information intended to attract the attention of the user to potentially dangerous situations and to ensure correct and safe use of the device is indicated in the text in the following way:

WARNING

Indicates serious adverse reactions and potential safety hazards for practitioner and/or patient that can occur in the proper use or misuse of the device, and also the limitations of use and the measures to be adopted in such cases.

Indicates any special care to be exercised by a practitioner for the safe and effective use of the device.

GENERAL SAFETY INFORMATION

The following is general safety information with the aim of advising the operator in preparing to use the device. Also, specific safety information is given in the instructions for use at locations in the text where that information is relevant for correct operation.

- The product must be used in accordance with the instructions for use provided in the manual.
- The product is intended to be used by professionally trained personnel only.
- Do not use the product if it has been torn, dropped or otherwise physically damaged.
- ThermaSolutions is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Keep dry. Store at room temperature.
- For single use and single patient only: during use the device may be in contact with human blood, or body fluids. Due to its specific design it cannot be fully cleaned and disinfected at the end of use. Therefore the reuse on other patients might cause cross-contamination, infection and sepsis. In addition, the reuse increases the probability of product failure.
- The product must not undergo further processing.
- Do not resterilize, after use, dispose of the device in accordance with applicable regulations in force in the country of use.
- The device contains phthalates. Considering the nature of body contact, the limited contact duration, the amount of phthalates which might be released from the device do not raise specific concerns about residual risks. Further information is available by request.
- For further information and/or in case of complaint contact ThermaSolutions or the authorized local representative.
- For a detailed description of the circuits, refer to ThermaSolutions operator's manual.
- Refer to the ThermaSolutions operator's manual for complete instructions on the device.
- Federal law (U.S.A.) restricts this device to the sale by or on the order of a physician.

Setup

- Check the expiry date on the label attached. Do not use the product after the date shown.
- The product must be used immediately after opening the packaging.
- Cary out a visual inspection and carefully check the device before use. Transport and/or storage conditions other than those prescribed may have caused damage to the device.
- Do not use solvents such as alcohol, ether, acetone, etc to prevent damage to the device.
- Do not allow halogenated liquids such a Halothane and Fluothane to come into contact with the polycarbonate parts of the device this could cause damage which may compromise the integrity and proper function of the device.
- Due to the possibility of operator exposure to blood borne pathogens (such as HIV, hepatitis viruses, bacteria, cytomegalovirus, etc.) when handling extracorporeal blood circuits, adequate precautions should be taken at all times to present the exposure to and transmission of such agents.
- Carefully observe this device for leaks before and during use. Leakage my result in loss of fluid. If leakage is observed before or during use, replace the leaking component or appropriately retighten the leaking connection.

General Setup instructions

1. Remove the bag from the packing.
2. Ensure the drain valve on the Waste Bag is securely closed during collection and processing.
3. Using aseptic technique, attach Waste Bag to the 3/8" drain leg of the IPH Procedure Kit using a sterilized 3/8" to 3/8" straight tubing connector.
4. Assure the clamp on the inlet tube of the waste bag is open before collection begins.
5. Follow the instructions for use on the IPH Procedure Kit, section titled: "FLUSH."
6. The maximum rated capacity of the Waste Bag is 10 Liters. Do not overfill.
7. Slide clamp on the inlet tube of the Waste Bag may be sued to plug inlet of the Waste Bag when full.
8. Discard after use.

Disposable Removal:

1. Dispose of device in accordance with facility and governing body regulations.
2. Use caution when handling the bag, as the weight of the bag will increase when filled.
3. Take proper precautions when moving or transporting bag containing waste fluid.
4. Secondary containment should be utilized.

Explanation of the symbols used on labels

REF	Catalogue Number
LOT	Batch Code