Product Code – Référence – Artikelnummer – Código – Codice

Lot number – Numéro de lot – Chargenbezeichnung – Lote – Numero di lotto

Use by date – A utiliser avant – Verwendbar bis – Caducidad – Data di scadenza

Sterilized by ethylene oxide – Stérilisé à l'oxyde d'éthylène – Sterilisiert mit Ethylenoxid – Esterilizado con óxido de etileno – Sterilizzato con ossido di etilene

Do not reuse – Strict usage unique – Nur zum einmaligen Gebrauch – Válido para un solo uso – Monouso

Consult instructions for use – Lire le mode d'emploi – Lesen Sie die Gebrauchsanweisung – Leer las instrucciones de uso – Leggere le istruzioni per l'uso

Manufactured by – Fabriqué par – Hergestellt von – Fabricado por – Fabbricato da

Date of manufacture– date de fabrication – Herstellungsdatum – Fecha de fabricación – Data produzione

Temperature limitation – Limite de temperature – Temperaturbegrenzung beachten – Limite de temperature – Limite di temperature

Do not use if package is damaged – Ne pasutiliser si l'emballage est endommagé – Bei beschädigter verpackung nicht verwenden – No usar en caso de envase dañado – Non utilizzare in caso di confezione danneggiata

Do not resterilise – Ne pas restériliser – Nicht erneut sterilisieren – No reesterilizar – Non risterilizzare

EC REP

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ThermaSolutions Drains

Products # FLW-0112 and FLW-0120

Instructions for use

Intended purpose: The ThermaSolutions Drains are intended for drainage of the abdomen. The products are referred to as "Drains" in this IFU. This IFU applies to both products.

Mode of action:

The function of the Drains is to drain fluids from the abdomen. The Drains are attached to tubing that will direct the fluid to reservoir or collection receptacle.

Patient population:

The target subject population is composed of patients undergoing lavage of the peritoneum or abdominal surgery, and the ability to tolerate general anesthesia and surgery.

Warnings:

1. Read the IFU in its entirety before operating the Drains. Failure to read the instructions could result in harmful effects to the user, patient, and/or Drains.
2. The Drains are STERILE. If the package is damaged, DO NOT use. Damaged packaging could compromise the sterility of the components. Replace with a new Drain and notify customer service via the contact information in this IFU.
3. Drains should only be used by a physician who has been trained in the use of the device.
4. If the Drains is combined with other equipment (such as the ThermoChem HT-2000, the user should also follow the warnings and cautions of the other device.
5. Inspect the device and sterile package carefully. Do not use if the sterile package and/or device is damaged or suspect.
6. CONFIRM expiration date on device packaging. DO NOT use if the expiration date has been exceeded.
7. The Drains is designed for SINGLE-USE only and should not be re-sterilized to avoid risk of biohazard/infection.
8. DO NOT reuse the device. If it is reused the drain may cause material damage, microbiological contamination, or biohazard/infection.
9. DO NOT modify. Product may not work as intended if altered.
10. Any medicinal substances used with the device are at the discretion of the physician. Off-label use is not promoted.

Cautions:

1. Ensure the Drain is connected properly and securely to connectors or tubing.
2. Store the Drains in a dry and clean environment.
3. Maintain the sterility of the components after removing from the packaging.

Contraindications:

1. The Drains is not indicated for use in any other areas other than the intraperitoneal area.
2. Do not use pharmaceutical or liquid solutions that are contraindicated for use or contact with PVC tubing.

Instructions for use

Setup/Installation:

1. Using sterile technique, transfer the contents of the Drain package to the sterile field.
2. Select the desired Outflow or Inflow Wye Tubing from the Table Pack. The Outflow Wye Tubing is a 10" section of 3/8" tubing with a 3/8" Y connector on one end. The Outflow Connection has BLUE directional arrows. . The Inflow Wye Tubing is a 10" section of 1/4" tubing with a 1/4" Y connector on one end. The Outflow Connection has RED directional arrows.
3. Connect the open end of each Drain to the fitting on the end of the Wye connector. Ensure a complete insertion.
4. The Drain is ready for use.
5. Follow the instructions of the IPH Kit to complete placement of the Outflow & Inflow Tubing (with installed Drain Tubing) to the patient and to the disposable kit.
6. When finished, dispose of the single-use Drains per the policy of the facility.