TSP2011

REF — Product Code – Référence – Artikelnummer – Código – Codice

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

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

STERILE EO — 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

Non-pyrogenic – Apyrogéne – Pyrogenfrei – Não pirogénico – Senza pirogeni

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

PHT DEHP — Contains phthalates – Contient des phtalates – Enthält Phthalate – Contiene ftalatos – Contiene ftalati

2 STERILIZE — Do not resterilise – Ne pas restériliser – Nicht erneut sterilisieren – No reesterilizar – Non risterilizzaire

℞ ONLY — Caution: Federal (USA) law restricts this device to sale or on order of a physician

Caution

CE 1639

EC REP

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ThermaSolutions

HYPERTHERMIC PERFUSION KIT

FOR USE WITH THE THERMOCHEM™ HT-1000 AND HT-2000 FAMILY OF DEVICES

Distributed by:

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Instructions for use

Cautions and Warnings:

1. If using any pharmaceutical agents during the procedure please follow the hospital internal guidelines for handling and disposal of any contaminated materials or products, as well as complying with the labelled recommendations of the pharmaceutical manufacturer regarding appropriate protective clothing, handling, and disposal of any contaminated material or products.
2. The tubing pack is made to specifications requested and approved by the user. Therefore the user is responsible for the configuration being appropriate to the procedure for which it is used.
3. The user should satisfy himself that this custom tubing pack is suitable for its intended use.
4. Leakage at any point in the circuit can cause fluid loss. Careful observation of the circuit for leaks before and during circulation is recommended.
5. Do not resterilise and do not reuse the pack or any component of the kit. It is disposable and intended for one time use only.
6. Do not modify. Product may not work as intended if altered.
7. If used on children, pregnant or nursing women, be aware that this device contains DEHP that is presently classified I the European Union as toxic to reproduction. The amount of DEHP that may be released from the device does not raise specific concerns about residual risks.

Installation:

1. Inspect the device and sterile package carefully. Do not use if the sterile package and/or device is damaged.
2. Open the IPH Procedure Kit and check that all connections and caps are tight.
3. Place the reservoir into the holder.
4. Remove the obturator cap from the pressure relief valve.
5. Attach the pressure sensor to both the control panel and the pressure dome (HT-2000); or the pressure dome to a pressure monitor (if available for HT-1000).
6. Insert the pump segment into the pump housing. Be sure that the blue marking is on the side of the reservoir (right) and the red marking on the site of the heat exchanger (left).
7. Connect the end of the pump tubing to the inlet of the heat exchanger observing aseptic technique. Make this a tight connection (high pressure site). In some kits this is already pre connected.
8. Connect the temperature probe into the heat exchanger.
9. Aseptically attach the three way stopcock (tap) to the filtered luer port of the reservoir.
10. Adjust the vacuum line (1/4" line with yellow cap) in the OR to the pressure controlled vacuum system.
11. Connect the waste bag to the waste line using the quick connects and clamp the line.
12. Connect the non-disposable water hoses to the heat exchanger.
13. Next connect the water hoses to the water bath outlets of the ThermoChem™ unit (always in this order, not the other way around!).
14. Close one of the two inflow lines marked yellow.
15. Prime the system in accordance with the manufacturer's instructions for the ThermoChem™ unit.
16. Inspect the system for leaks before initiating intraperitoneal hyperthermia.

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Instructions for use

Patient Connection:

1. Take care for the preparation of the inflow and outflow lines to the sterile field. The pump on the ThermoChem™ should be OFF.
2. Hand over the table pack and the primed tubing loop in a sterile way.
3. Disconnect the red and blue lines in the sterile loop using the quick connector.
4. Connect the red inflow catheter assembly to the quick connect on the red line.
5. Connect the blue outflow catheter assembly to the quick connect on the blue line.
6. Position inflow and outflow catheters and attach temperature probes intracorporeal in patient as desired.

Initiate intraperitoneal hyperthermia in accordance with the manufacturer's instructions for the ThermoChem™ unit.

Disposable Removal:

1. Power down the HT-2000 unit by the software button on the screen. Power down the HT-1000 unit by setting the ON/OFF switch on the back of the unit to OFF.
2. Position facility-approved waste receptacle next to the ThermoChem™.
3. Disconnect non-disposable components from the ThermoChem™ and place in the side pocket of the ThermoChem™ unit.
   a. Disconnect the non-disposable heat exchanger temperature probe from heat exchanger and control panel.
   b. Disconnect the non-disposable patient temperature probe extension cables from the temperature probes and the control panel.
   c. Disconnect the non-disposable water lines from heat exchanger and the ThermoChem™ unit. (**NOTE:** Ensure a collection basin or absorbable material is available to collect water as it drains from the water lines and heat exchanger.)
4. Remove the disposable from the ThermoChem™ unit and place into the facility approved waste receptacle:
   a. Disconnect the disposable pressure sensor from the control panel.
   b. Remove disposable tubing from roller pump.
   c. Remove the heat exchanger.
   d. Remove fluid reservoir from bracket.
   e. Place the disposable lines and waste bag into the facility approved waste receptacle.
5. Have sterile personnel disconnect the disposable inflow and outflow lines and hand them off the sterile field. Place the remainder of the disposable tubing into the approved waste receptacle.
6. Ensure non-disposable components are stowed in the side/back pocket of the ThermoChem™ unit including:
   - Reservoir bracket, non-disposable temperature probe extension cables, non-disposable heat exchanger temperature probe, non-disposable water lines.
7. Discard all disposable components in accordance with the hospital's disposal policy.

Draining the Water Bath

Open the water bath drain to drain the water bath. Drain into a bucket or floor drain. **This should be done after every use**. Clean the internal water bath according procedure (see instructions for use of the device).

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