TSP1016

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 risterilizzare

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

Caution

CE 1639

EC REP

ThermaSolutions Europe BV
Takkebijsters 41
4817 BL Breda
The Netherlands
Phone: +31 76 579 11 44
www.thermasolutions.com
emea@thermasolutions.com

ThermaSolutions

HYPERTHERMIC PERFUSION KIT

FOR USE WITH THE THERMOCHEM™ FAMILY OF DEVICES (HT-2000 and HT-2500)

The hyperthermic perfusion kits are intended to directly administer and/or remove medicinal products, body liquids or other substances to or from the peritoneal cavity.

Distributed by:

ThermaSolutions Europe BV
Takkebijsters 41
4817 BL Breda
The Netherlands
Phone: + 31 76 579 11 44
www.thermasolutions.com
emea@thermasolutions.com

ThermaSolutions
1889.Buerkle Road
White Bear Lake, MN 55110
USA
+1.651.209.3900
Info@thermasolutions.com

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 in 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 Hyperthermic Perfusion 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 the 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 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 (<u>always in this order, not the other way around!</u>).
14. Prime the system in accordance with the manufacturer's instructions for the ThermoChem™ unit.
15. Inspect the system for leaks before initiating intraperitoneal hyperthermia.

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.

TSP1016

Instructions for use

3. Open in the sterile field the connector between the blue and red tubing.
4. Attach the (red) inflow catheter to the connector on this red line.
5. Attach the (blue) outflow catheter to the connector on this blue line.
6. Hand off from the sterile field the ends of the yellow and green lines and attach them to the ports on the reservoir.
7. 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. MNL-2001 HT-2000 Operators Manual or MNL-2500 HT-2500 Operators Manual.

Perfusion Kit 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 <u>non</u>-disposable/kit heat exchanger temperature probe from heat exchanger and control panel.
   b. Disconnect the <u>non</u>-disposable/kit patient temperature probe extension cables from the temperature probes and the control panel.
   c. Disconnect the <u>non</u>-disposable/kit 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 perfusion kit from the ThermoChem™ unit and place into the facility approved waste receptacle:
   a. Disconnect the perfusion kit pressure sensor from the control panel.
   b. Remove kit tubing from roller pump.
   c. Remove the heat exchanger.
   d. Remove fluid reservoir from bracket.
   e. Place the perfusion kit lines and waste bag into the facility approved waste receptacle.
5. Have sterile personnel disconnect the perfusion kit 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 <u>non</u>-disposable/kit components are stowed in the side/back pocket of the ThermoChem™ unit including:
   - Reservoir bracket, non-disposable/kit temperature probe extension cables, non-disposable heat exchanger temperature probe, non-disposable water lines.
7. Discard all perfusion kit 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. **<u>This should be done after every use</u>**. Clean the internal water bath according to procedure (see instructions for use of the device).

ThermaSolutions