Product Code – Référence – Artikelnummer – Código – Codice

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

Use by – 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

For single use only – Strict usage unique – Nur zum einmaligen Gebrauch – Válido para un solo uso – Monouso

Read the 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

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

Caution: federal (u.s.a) law restricts this device to sale by or on the order of a physician.

Read the instructions for use

IPH Procedure Kit

Instructions for Use

FOR USE WITH THERMOCHEM™ HT SYSTEMS ONLY

The intended use of the ThermoChem System is to raise the core temperature of the peritoneum to a desired target temperature by continuously lavaging the peritoneum with circulating and warmed Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution. For use with disposable kits IPH-2000, IPH-2000M and IPH 111-2000.

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Instructions for Use

IPH Procedure Kit Contents: (1) Perfusion Kit
(1 to 2) Outflow Drains
(2) Temperature Probes

Information related to the IPH Procedure Kit 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. Contents are provided sterile. Do not use if package is opened or damaged.
3. Non-disposable water lines and connectors are hot and may present a scald hazard. Do not disconnect non-disposable water lines while unit is at operating temperature or powered on with the heater/cooler circulating water.
4. If a malfunction occurs or the patient needs immediate attention, shut off the roller pump, thereby suspending treatment.
5. The ThermoChem unit is designed to work with disposable temperature probes supplied by ThermaSolutions. Use of other probes could result in harm to the patient.
6. Failure to execute the following directions for use in sequence could prevent the ThermoChem system from operating properly.
7. Do not alter or modify otherwise product may not operate as intended.

Directions for Use:

Installation:

1. Ensure the machine is properly set up, water bath is filled and has successfully passed self-test.
2. Visually inspect IPH Procedure Kit to ensure it is sealed and that there is no visible or apparent damage. Open IPH kit.
3. Remove the IPH Table Pack. Pass Table Pack, Temperature Probes and Outflow Drains to the sterile field using proper sterile technique.
4. During assembly of IPH disposable, check that all connections and caps are tight.
5. Place the fluid reservoir in the fluid reservoir holder.
6. Remove the obturator cap from the pressure relief valve on the top of the reservoir.
7. Place the heat exchanger in the heat exchanger holder ensuring the bubble trap is in an upright position.
8. Place the pump boot tubing on one side of the roller pump raceway being sure to match the color band on the tubing to the color mark on the roller pump. Manually advance the roller pump until the tubing is seated.
9. Connect the non-disposable water lines to the heat exchanger.
10. Connect the water lines to the heat exchanger connections on unit being sure to match color caps on the heat exchanger with the color marks on the water connections.
11. Insert the heat exchanger probe into the thermowell of the heat exchanger and lock it in place.
12. (HT-2000 Only) Aseptically attach the pressure sensor to the IPH tubing. Attach to the first Luer connection between the pump and the heat exchanger.
13. Aseptically attach the 3-way stopcock to the top of the reservoir.
14. Optional: Aseptically attach one end of the male/male By-Pass recirculation line to the heat exchanger bubble trap and connect the other end to the 3-way stop cock.
15. Close the clamp on drain line located near the reservoir.
16. Turn the stopcock OFF to the heat exchanger.
17. Touch the **SCREEN** and start water bath circulating.
18. Visually inspect the heat exchanger and tubing to ensure that no fluid is present.

Circuit Priming and Preheating:

1. Hang Lactated Ringers U.S.P. or another physiologically compatible sterile solution from the I.V. hanger.
2. Spike the bag utilizing spikes on the fill tube and allow fluid to drain into the fluid reservoir. Typically 3L is utilized.
3. Clamp spike on fill tube after all fluid is drained into reservoir.
4. Set the water bath temperature to at least 45°C for preheating.
5. Start the roller pump and adjust speed to approximately 500-800 ml/min.
6. Gently hand-tap the heat exchanger to ensure all air has escaped for both the water side and the patient fluid side.

Patient Connection on the Sterile Field:

1. Secure the two inflow cannulas to the inflow wye-tubing. (Inflow wye-tubing is marked with red directional arrows)
2. Select one of the two outflow wye-tubing assemblies. Secure the two outflow drains onto the Y end of the selected outflow tubing. (Tubing is marked with blue directional arrows)
3. Secure temperature probes intracorporeal into the inflow and outflow wye-tubing or to patient per physician preference.
4. Place inflow and outflow assembly into patient and position, temporarily close abdomen per physician preference.
5. Turn off pump on ThermoChem™ HT System and clamp both inflow and outflow lines.
6. Open the sterile tubing loop on the IPH Kit and pass the tubing off to the surgical field using sterile technique.
7. Disengage the quick-connectors on the sterile loop.
8. Connect the inflow tubing to the inflow wye-tubing (marked in red).
9. Connect the outflow tubing to the outflow wye-tubing (marked in blue).
10. Hand the temperature probe cables off the surgical field and connect to the non-disposable temperature probe extension cables.
11. Plug the non-disposable temperature probe extension cables into the appropriate plug on the ThermoChem™ HT System temperature block.

Treatment:

1. Release the clamp on the inflow line. ***(Ensure that clamp on drain line remains closed.)***
2. Increase the roller pump speed control and verify that fluid flows.
3. Place up to 75% of the priming fluid into the patient and ensure no leaks in the inflow portion of the circuit. Do not overfill.
4. Release the clamp on the outflow line to start the circuit and ensure no leaks in the circuit.
5. Adjust pump speed to maintain proper flow nominal volume in the reservoir.
6. Ensure that the **H_2O SET POINT** is set to maintain desired temperature.
7. At the beginning of treatment and periodically throughout, observe the entire circuit to make sure there are no leaks, kinks, or restrictions that would interfere with fluid flow. Monitor patient and fluid temperatures and adjust accordingly to maintain the target temperature.

Flush:

1. Hang Lactated Ringers U.S.P. or other physiologically compatible sterile solution(s) from the I.V. pole.
2. Ensure the clamp on fill tube is closed then spike the bag(s) with the spikes located on fill tube.
3. Place IPH drain tube in proper waste container and open clamp on drain tube.
4. Reduce the roller pump speed when only a small amount of fluid remains in the reservoir.
5. Open the clamp on the fill tubes and allow the flushing fluid to drain into reservoir.
6. Allow all fluid to be pumped from the reservoir and inflow line.
7. When inflow line is empty, STOP the roller pump and clamp the inflow line.
8. When fluid stops flowing out of the drain line, clamp the return AND the drain line.

Disposable Removal:

1. Power down the unit by pressing OFF on the touch screen and follow directions on the screen.
2. Have sterile personnel disconnect inflow and outflow from the patient fluid then pass tubes off the field.
3. Disconnect the patient temperature probes.
4. Remove the heat exchanger probe from the heat exchanger. Do not discard the reusable temperature probe.
5. Disconnect water lines from machine and the disposable. Do not discard the reusable water lines.
6. Remove heat exchanger from machine.
7. Remove the tubing from the roller pump.
8. Remove the fluid reservoir from its holder.
9. Discard the disposables in accordance with hospital disposal policy.