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

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ThermaSolutions

HurriChem™ Device Kit

Product # PDT-5500

Instructions for use

Intended purpose: The HurriChem Device Kit is intended for the minimally invasive administration of aerosolized liquids. It is intended for laparoscopic nebulization of high-pressure drugs for pressurized laparoscopic aerosolization (PLA) treatment. The HurriChem Device Kit is to be used only by physicians trained in the use of this device.

Mode of action:

The function of the HurriChem is to create aerosolized particles via a mechanical action that converts the liquid microscopic droplets. The fluid is ejected from the device as tiny droplets constituting the aerosol.

Patient population:

The target subject population is composed of patients with confirmed peritoneal/pleural carcinomatosis, with tumor progression or reoccurrence after intravenous chemotherapy, and the ability to tolerate general anesthesia and minimally invasive surgery. No demographic exclusion criterion has been identified.

Warnings:

1. Read the IFU in its entirety before operating the HurriChem™ Device Kits. Failure to read the instructions could result in harmful effects to the user, patient, and/or HurriChem™ Device Kits.
2. The HurriChem™ Device Kits is STERILE. If the package is damaged, DO NOT use. Damaged packaging could compromise the sterility of the components. Replace with a new HurriChem™ Device Kits and notify customer service via the contact information in this IFU.
3. HurriChem™ Device Kits should only be used by a physician who has been trained in the use of the device.
4. The HurriChem™ Device Kits should only be operated to a maximum pressure of 200 psi.
5. The HurriChem™ Device Kits should be used with a liquid injector system that is capable of delivering a flow rate of 30ml /minute.
6. For proper aerosolization, it is recommended that the flow rate be 30ml/min. Flow rates should not exceed a set point that results in pressure of 200psi or greater.
7. If the HurriChem™ Device Kit is combined with other equipment, the user should also follow the warnings and cautions of the other device.
8. 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 labeled recommendations of the pharmaceutical manufacturer regarding appropriate protective clothing, handling, and disposal of any contaminated material or products.
9. Inspect the device and sterile package carefully. **DO NOT** use if the sterile package and/or device is damaged or suspect.
10. CONFIRM expiration date on device packaging. **DO NOT** use if the expiration date has been exceeded.
11. The HurriChem™ Device Kit is designed for **SINGLE-USE** only and should not be re-sterilized to avoid risk of biohazard/infection.
12. DO NOT reuse the device. If it is reused the high pressure may cause material damage, microbiological contamination, or biohazard/infection.
13. DO NOT modify. Product may not work as intended if altered.
14. Only use the high-pressure tubing supplied in the HurriChem™.
15. Prior to insertion into the trocar/port, ensure the integrity of the pneumoperitoneum.
16. Any medicinal substances used with the device are at the discretion of the physician. Off-label use is not promoted.
17. Do not use pharmaceutical or liquid solutions that are contraindicated for use or contact with medical grade stainless steel.

Cautions:

1. Ensure the high-pressure tubing is connected properly and securely to both the HurriChem™ Device and any injector pump or manual syringe.
2. Store the HurriChem™ Device Kit in a dry and clean environment.
3. Maintain the sterility of the components after removing from the packaging.
4. When using a camera cover over the HurriChem™ Device and high-pressure tubing, be certain the entire length of the assembled device can be contained within the cover.
5. Insertion of the HurriChem™ Device through a trocar/port should only be done under direct visualization to avoid unintended damage to internal tissue.
6. Only use the HurriChem™ Device Kits under direct visualization to ensure no unintended contact with tissue.
7. The device requires insertion through a trocar or single lumen multi-port device with access for 10 to 12mm laparoscopic devices. The trocar or access port must be able to maintain a secure fix on the abdominal wall throughout the use of the device.
8. Luer lock connections of the liquid injector syringe should be ISO 594-2 compliant.
9. A Closed Aerosol Waste System (CAWS) should be used to remove pressure and aerosolized pharmaceuticals from the insufflated area.
10. The HurriChem™ device should be operated in a direct flow operating room only.
11. Remote operation of the injection system should be used when unintended exposure to aerosolized solutions is to be avoided.
12. Precautions should be taken to prevent unintended exposure or inhalation of aerosolized solutions by the patient.

Contraindications for the HurriChem Device:

1. The HurriChem™ Device Kit is not indicated for use in any other areas other than the intraperitoneal area, during laparoscopic operations.
2. Do not use pharmaceutical or liquid solutions that are contraindicated for use or contact with medical grade stainless steel.

Instructions for use

Setup/Installation:

1. Using sterile technique, transfer the contents of the HurriChem™ Device Kits to the sterile field.
2. Remove the high-pressure tubing from the backer card. Then remove the green bag with the stainless-steel device from the backer card.
3. Separate the HurriChem™ device from the green bag. The green bag can be discarded.
4. Attach the rotating luer connector on the high-pressure tubing to the stainless-steel device. Ensure the connection is correct and firmly tightened.
5. Pull a camera cover over the assembled HurriChem™ device and tubing.
6. Affix the camera cover to the stainless-steel device, completely covering the connection of the device to the tubing.
7. Pass the proximal end of the high-pressure tubing and camera cover off the sterile field.
8. The distal end of the high-pressure tubing should be connected to a syringe assembled onto an injector pump. Ensure the connection is correct and securely tightened.
9. Affix the camera cover to the pump or syringe, completely covering the connection of the pump/syringe to the tubing.
10. Under visualization, carefully insert the distal end (nozzle) of the HurriChem™ device through the access port.
11. The nozzle of the device should extend completely beyond the end of the access port, but no further than 20mm.
12. NOTE: The nozzle of the HurriChem™ device is approximately 16mm.
13. The device and the camera should be secured so visualization of the nozzle can be maintained during use of the device.
14. NOTE: The nozzle of the device should not have direct contact with tissue during use.
15. The HurriChem™ is ready for use.
16. After use of the HurriChem™ device is completed, remove the device from the access port under visualization.
17. Dispose of the single-use HurriChem™ device kit per the policy of the facility.