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

HurriChem Device Kit

Product # PDT-5800

Instructions for use

Intended purpose: The ThermaSolutions HurriChem Device Kit is indicated for use in patients undergoing a laparoscopic procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to lavage blood and tissue debris from the surgical site.

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 patients that are safely undergoing a laparoscopic procedure with pneumoperitoneum and complete visualization of the surgical site established.

Warnings:

1. Read the IFU in its entirety before operating the HurriChem Device Kit. Failure to read the instructions could result in harmful effects to the user, patient, and/or HurriChem Device Kit.
2. The HurriChem Device Kit 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 Kit and notify customer service via the contact information in this IFU.
3. HurriChem Device Kit should only be used by a physician who has been trained in the use of the device.
4. The HurriChem Device Kit should only be operated to a maximum pressure of 300 psi.
5. The HurriChem Device Kit should be used with a liquid injector system that is capable of delivering a flow rate of 42ml /minute.
6. For proper aerosolization, it is recommended that the flow rate 42ml/min (0.7 ml/sec). Flow rates should not exceed a set point that results in pressure of 300psi or greater.
7. If the HurriChem 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 is designed for **SINGLE-USE** only and should not be re-sterilized to avoid risk of biohazard/infection or device failure.
12. **DO NOT** reuse the device. Reuse may result in device failure, 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 irrigation 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 and any injector pump or manual syringe.
2. Store the HurriChem 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 and high-pressure tubing, be certain the entire length of the assembled device can be contained within the cover.
5. Insertion of the HurriChem through a trocar/port should only be done under direct visualization to avoid unintended damage to internal tissue.
6. Only use the HurriChem 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. Precautions should be taken to prevent unintended exposure or inhalation of aerosolized solutions by the patient.

Contraindications:

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 irrigation fluids that are contraindicated for use or contact with medical grade stainless steel.

Instructions for use

Setup:

Using sterile technique, transfer the contents of the HurriChem to the sterile field.

1. Remove the high-pressure tubing from the backer card. Then remove the green bag with the stainless-steel device from the backer card.
2. Separate the HurriChem device from the green bag. The green bag can be discarded.
3. Ensure the connection of the high-pressure tubing to the stainless-steel device is correct and securely tightened. (Tubing comes pre-assembled onto the stainless-steel device)
4. Pull a camera cover over the assembled HurriChem device and tubing.

Functional Test:

5. On the sterile field, fill a syringe with a minimum of 10ml of sterile saline/water.
6. Attach the syringe to the high-pressure tubing.
7. Deliver a minimum of 10ml of fluid through the HurriChem tubing & stainless wand.
8. Ensure the HurriChem device delivers aerosolized fluid.
9. If the device only delivers a stream of fluid, do not use that device. Open another HurriChem Device Kit and repeat the functional test.
10. Remove the syringe and discard the syringe. The HurriChem wand and tubing remain on the sterile field.

Assembly:

11. Affix the camera cover to the stainless-steel device, completely covering the connection of the device to the tubing.
12. Pass the proximal end of the high-pressure tubing and camera cover off the sterile field.
13. 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.
14. Affix the camera cover to the pump or syringe, completely covering the connection of the pump/syringe to the tubing.
15. Under visualization, carefully insert the distal end (nozzle) of the HurriChem device through the access port.
16. The nozzle of the device should extend completely beyond the end of the access port, but no further than 20mm.
17. NOTE: The nozzle of the HurriChem device is approximately 16mm.
18. The device and the camera should be secured so visualization of the nozzle can be maintained during use of the device.
19. NOTE: The nozzle of the device should not have direct contact with tissue during use.
20. The HurriChem is ready for use for irrigation of a surgical site during laparoscopy.
21. After use of the HurriChem is completed, remove the device from the access port under visualization.
22. NOTE: If desired, evacuation of irrigation fluid can be performed using any approved laparoscopic suction device available to the facility. Dispose of any fluid per facility policy.
23. Dispose of the single-use HurriChem per the policy of the facility.