SurgiChem Dual Injector Pump

ThermaSolutions

A complete treatment solution for PIPAC

Pressurized Intraperitoneal Aerosolized Chemotherapy

with the HurriChem Nebulizer





www.thermasolutions.com

Injector Pump and Monitor

- Adjustable injector arm on rolling stand
- Secured injection position by sensor detecting arm angle
- User-friendly interface with large LCD touch screen
- Wireless touch screen
- Injection pressure display in real time
- Programmable auto-fill volume & flow
- Used with ThermaSolutions disposable syringes
- CE approved disposable syringes (FDA pending)



Injector Pump and Rolling Stand

Injection Specifications

- Flow Rate: 0.1 ml/sec. to 10 ml/sec. in 0.1 ml/sec. increments
- Syringe Capacity: 200ml/syringe
- Preset limit: 300 psi default, user-adjustable between 100 to 300 psi
- Injection Delay: 0 to 3600 seconds in 1 sec. increments
- Protocol Storage Capability: stores 1000 protocols

Device Specifications

Injector Arm and Stand

Class IIA Medical Device
19.5 kg
159 cm x 74 cm x 53 cm

Monitor

4.1 kg
25 cm x 11.5 cm x 32 cm

Electrical Requirements

AC 220V/50Hz/200VA
or
AC 110V/50Hz/200VA



Monitor



Injector Pump with optional IV Pole

Disposable High-Pressure Syringe Kits

For use with
SurgiChem Dual Injector Pump
and HurriChem Nebulizer

Single HP Syringe

Each kit contains:

A - 200ml Syringe (1)
B - 150cm Injection Line (1)
C - Spike (1)

Transfer Set Kit:

D - Single channel transfer set (1)

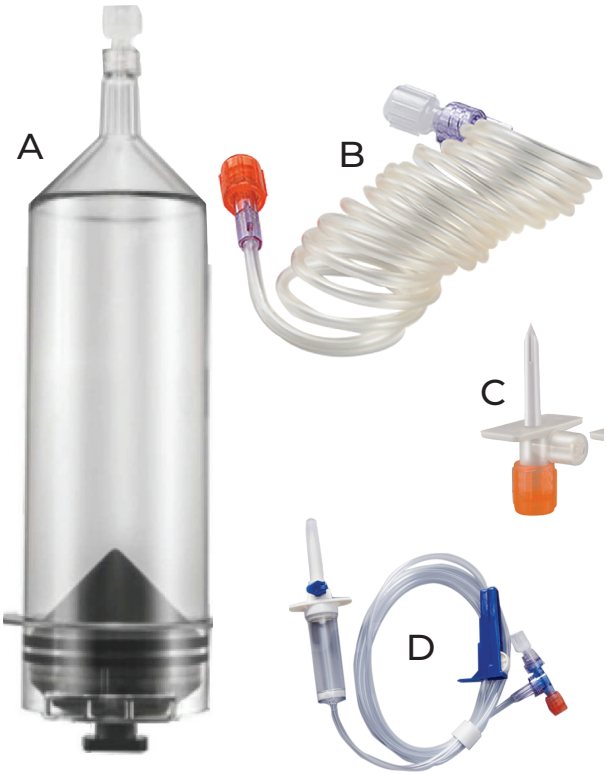
Dual HP Syringe

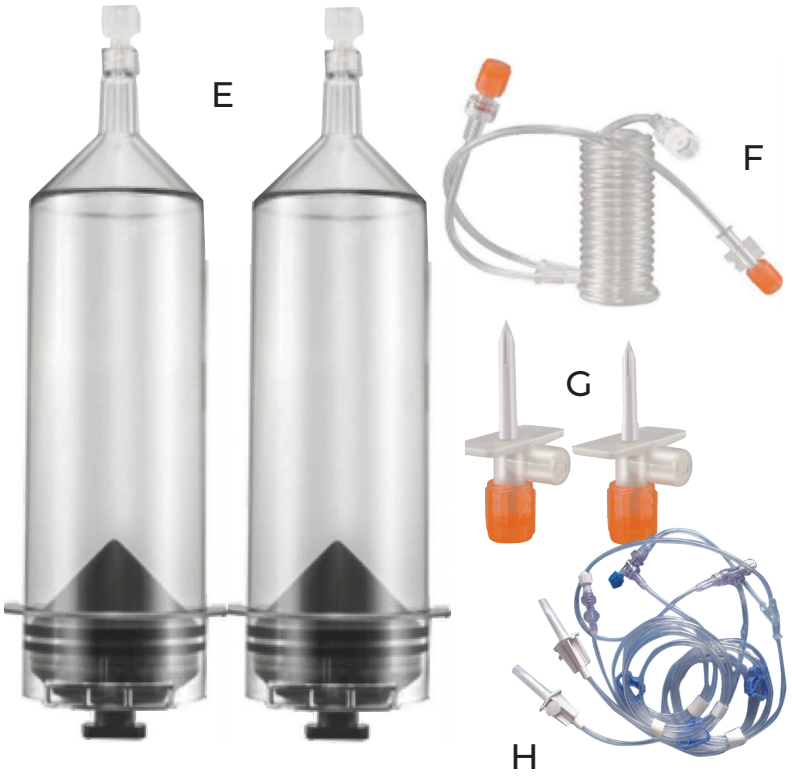
Each kit contains:

E - 200ml syringes (2)
F - 150cm Y Injection Line (1)
G - Spikes (2)

Transfer Set Kit:

H - Double channel transfer set (1)





Ordering Information

SurgiChem Dual Injector Pump:
C-22
Dual HP Syringe kit:
C01-010-10
Single HP Syringe kit:
C01-008-10
Dual channel transfer set:
C04-021-10
Single channel transfer set:
C04-025-10

Packaging

*Blister packaging

*Syringes: quantity per box

25 kits (single syringe)

15 kits (double syringe)

*Sterilization - ETO

Who we are: ThermaSolutions manufactures and sells devices for regional cancer treatment including Pressurized Intraperitoneal Aerosolized Chemotherapy (PIPAC) and Hyperthermic Intraperitoneal Chemotherapy (HIPEC)

Cancers treated:

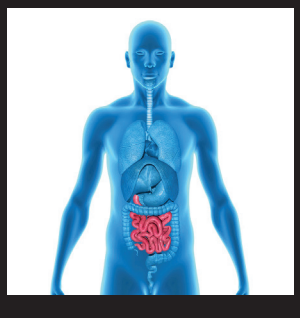
- ☑ Pseudomyxoma Peritonei - A build-up of mucin in the peritoneal cavity
- ☑ Ovarian Carcinoma – Cancer that forms in the tissue of the ovary
- ☑ Mucinous Adenocarcinoma of Appendix - A type of cancer that begins in cells that line the appendix and produces mucin
- ☑ Gastric Carcinoma – Cancer that forms in tissues lining the stomach
- ☑ Colorectal Carcinoma – Cancer that forms in the colon
- ☑ Mesothelioma - A benign (noncancerous) or malignant (cancerous) tumor affecting the lining of the chest or abdomen

We train medical staff on the ThermaSolutions devices and sterile disposables with unparalleled customer service and support.

ThermaSolutions has been intricately and consistently involved in cancer treatment since 1995, partnering with physicians world-wide in 6 continents and over 50 countries.

Authorized Distributor of Seacrown manufactured products

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Contraindications: The system is not to be used for any use for which the device is not indicated. The system is not intended for portable use. User Qualification: The system should be operated only by qualified personnel who: are completely familiar with the unit, have read and understood this User's Manual, and are properly trained in the use of equipment and procedures of this type. Improper use with the system could result in serious injury to the patient or the user. The system should be operated only by qualified personnel who have read and understood this manual or are properly trained in the use of this equipment. The system is not able to check for air in the syringe and tubing. Electric shock hazard! Serious electric shock injury could be caused by contact with the Internal systems. Only professional personnel should open the system case. If any worn or damaged cables are detected, do not use the system. Call ThermaSolutions for assistance. The occurrence of cross-contamination and infection will cause serious harm to the patient! Using aseptic technique, install syringe, connect tube and connect to patient. Syringes may not be used to store fluids for long periods of time. The syringe with fluid in it should be immediately used. Do not remove the plunger to fill the syringe. Disposables whose packaging has been opened or damaged may not be used. All disposables are intended for single patient use only. Do not reuse any disposables. Non-compliant disposables could result in patient injury, operator injury and/or equipment damage. Patient injury could result if the syringe is not properly engaged. Ensure the syringe is properly snapped into the front of the injector arm before injecting. Improper engagement may cause the syringe to leak, become damaged, or to come off during the injection and result in an under-volume delivery. Patient injury may result from a system malfunction. If a system malfunction occurs, immediately remove and disconnect the system from the patient. If a fault message is displayed that cannot be corrected, and/or the system is not operating correctly, do not use the system. Explosion hazard! Patient injury could result from explosion caused by using the system in the presence of flammables. Fire Hazard! Patient injury could result from a fire caused by using incorrect fuses. To avoid an electrical fire, assure the same type of fuse as original is used for replacement. Only use the power cord supplied with the system. Do not plug the power cord into an extension cord or multi-outlet power strip. Material toxicity hazard! Patient injury could result from potentially hazardous system electronic assembly material. Dispose of system components or accessories properly. Follow local regulations for proper disposal or contact ThermaSolutions Service for assistance. Improper medical fluid volume and flow rate may harm patients. Configure the injection fluid volume and flow rate according to the physician direction. Fill syringes only with the minimum amount of fluid required by the procedure to be performed on the patient. Prior to commencing the injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. The system must only be connected to a supply main with protective ground. Failure to use the hand switch could result in Electro Magnetic Emissions not meeting specification. The system is not serviced or maintained while in use with the patient. In order to ensure the system's leakage current and voltage is normal, only the equipment which complies with IEC/EN60601-1 (or IEC/EN60950-1) can be connected to our system. Do not to position the system to make it difficult to operate the disconnection device. If the fluid permeates into the injector arm or accumulates on the piston rod, short circuits can occur, or the movement of the piston rod may be inhibited. Both could cause damage to the system. Be absolutely sure to promptly clear away residual fluids. Place the injector arm in a downward-facing position of the syringe to prevent fluids and other medicinal liquids accessing the injector arm. In the event of water vapor condensation, connecting the power may damage the system's electronic components. System taken indoors from outdoor environments of extreme temperatures should not be immediately used. Only use the system once there is no more water vapor condensation indoors. Incorrect voltage can cause system damage. Check that the power source voltage and frequency are identical to those marked on the system label on the injector arm. When calibrating the touch-screen, do not use sharp objects to make contact with the touch-screen. Failing to carry out routine maintenance may cause system malfunctions. It is recommended that regular maintenance be carried out to ensure the system remains in a well calibrated operational state. For details, please review the manual or contact ThermaSolutions for more information. Do not use strong chemicals such as acetone to clean the system. Warm water and mild disinfectants are sufficient. To avoid damage to the touch-screen, do not directly spray cleaning liquid onto the touch-screen. Wipe it using a non-abrasive cloth or paper towel that has been dipped in soluble cleaning liquid. Improper or careless cleaning methods may result in equipment damage. Do not soak or immerse any part of the system in water. While cleaning any outside portion of the system, avoid allowing any water to leak inside system components. Component damage may occur if not installed properly. Ensure all connections are secure; do not over tighten. This will help minimize leaks, disconnection, and component damage. In circumstances where strong electromagnetic fields generated by wireless electrical transmitters or strong static electricity discharges are present, the system may be unable to operate normally. The use of disposables not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include evidence that the safety certification of the disposables has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard. If any anomalies in the system performance are noticed, identify devices within the immediate area that are capable of producing electromagnetic interference and call a qualified service representative.

CE 0482

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