



**Clinical Protocol (bold)**

**CP.XX.xxx**

The objective of this document is to be a resource, not a replacement for institutional specific protocols. It is intended as a template for your perfusion team to edit and adapt into a resource that fits your institutional specific needs. These Clinical Protocols may also be superseded by the judgment of the healthcare professional considering the facts and circumstances of the individual case.

**SUBJECT/TITLE:**                    **HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY UTILIZING THE THERMASOLUTIONS→ MACHINE**

**PURPOSE:**                        The purpose of this policy is to ensure the proper and safest procedure for setting up, priming, and administration of the HIPEC to the patient, using the ThermaSolutions→ machine. This document is a guide that describes the use of a specific medical device. Therefore, the Instructions For Use (IFU) from ThermaSolutions→ supersedes all information provided.

This procedure is used at the sole discretion of the surgeon and is always monitored by a perfusionist. All perfusionists are responsible for maintaining the integrity of the circuit and the safety of the patient.

**TARGET POPULATION:** Patients requiring Hyperthermic Intraperitoneal Chemotherapy with a ThermaSolutions→ machine.

**DEFINITIONS:**                    HIPEC is a type of hyperthermia therapy used in combination with surgery in the treatment of advanced abdominal cancers. In this procedure, warmed anti-cancer drugs are infused and circulated in the peritoneal cavity (abdomen) for a short period of time. The chemotherapeutic agents generally infused during HIPEC are Mitomycin-C and Cisplatin.

**POLICY:**                             Perfusionists shall work closely with surgeons, anesthesiologists, surgical nurses and all other ancillary personnel to ensure a safe and effective HIPEC procedure.

**PERFUSION PUMP CONSIDERATIONS:**

Supplies needed to perform procedure with the ThermaSolutions→ HIPEC Machine are as follows:

1. ThermaSolutions→ HIPEC Machine
2. 3 Clamps
3. 2 Liters of Sterile Water

4. 7 Liters of NaCl
5. IPH Intraperitoneal Hyperthermia Kit & Table pack
6. Waste bag
7. PPE – double gloves, eye wear or shield and gown are recommended
8. Yellow Chemotherapy Disposal bag

## **PROCEDURE:**

### **Preparation**

1. Perfusion to check in at the start of the case, provide circulating nurses with a phone number to call/text when perfusion is needed.
2. Ensure ThermaSolutions→ machine, tubing pack and all supplies are in room and available.
3. Circulating Nurses will provide Cisplatin→, Mitomycin→, or Physician prescribed Chemotherapy from the pharmacy.

### **Priming, Initiation and Termination**

4. Connect 2 Temp probes (provided with the ThermaSolutions→ machine).
5. Fill the ThermaSolutions® machine with 2L of Sterile Water.
6. Set up Disposables & Prime with 3L of warm NaCl.
7. Attach water lines to the bottom of Myotherm→ disposable heater.
8. Attach pressure transducer & temperature probe to Myotherm→ disposable heater.
9. Turn on the water bath and heat exchanger.
10. Set the “Set Temp” to 45° Celsius.
11. Hand off HIPEC tubing pack and packaged white temp probes to the field. This pack contains 29/29 Fr. cannulas and quick connect’s to attach to the loop.
12. Attending Physician will insert cannulas and hand off the white temp probe connections labeled “in” and “out.”

**RED** temp from table **INFLOW** to patient.

**BLUE** temp from table **OUTFLOW** from patient.

Connect these to the ThermaSolutions→ machine.

13. Turn off pump and clamp inlet red line and outlet from patient blue line.
14. Attending physician will make quick-connects to the tubing pack.
15. Once Attending physician is ready, they will tell you to initiate flow.
16. Begin recirculating fluid to the patient at 500-800 ml/min.

17. Turn the set temperature to 47°C to allow fluid to reach a temperature of 43°C. **Do not drain the reservoir.** (It's helpful to transfuse approximately 75% of prime volume into the patient before removing the venous clamp.)
18. Once inflow temperature reaches 42°C, the physician or perfusionist (following institutional specific protocol) will administer the confirmed chemotherapy dose via the side port of the stopcock on the side of the reservoir.
19. Dispose of the syringe in the hospital provided chemotherapy disposal bags.
20. Start timer and begin charting every 10 minutes.
21. Chart should include:
  - a . Set temp/water bath
  - b . In & Out temps
  - c . Line pressure
  - d . Pump Flow
  - e . Patient Temperature
  - f . Timing of chemotherapy dosing
  - g . Volume and concentration of chemotherapy drugs given
22. Depending on the type of Chemotherapy prescribed by the physician, HIPEC runs can range from approximately 90-120 minutes. Once the Physician has ordered termination of the HIPEC recirculation, the perfusion will end. At this point, open drain line and clamp reservoir line and drain to waste bag (set at <200 ml/min). Slow RPM's.
23. Once the reservoir is almost empty, begin to flush the system with 2L NaCl.
24. Continue flushing until the reservoir is empty, stop pump and fill the waste bag until 5 liters of fluid total is removed.
25. Follow institutional specific protocol for waste disposal of this flush volume.
26. Turn off the pump.
27. Once finished, the physician will open the belly and remove cannulas, tubing, and circuit should be disposed of in a designated chemotherapy disposable bag and zip tied.
28. Temperature probes should be wiped down with cleaning wipes. Then, placed in the side pocket of the ThermaSolutions→ machine. Take care as to NOT throw these away!
29. Turn off the ThermaSolutions→ machine.
30. Empty ThermaSolutions→ machine of sterile water into bucket. Empty in the sink.
31. Unplug the machine, wipe down and return to designated storage area.



#### **CLINICAL ASSESSMENT/SCREENING:**

A. Contraindications: None.

#### **RELATED DOCUMENTS:**

A. None

#### **REFERENCES:**

1. Lheureux, Stephanie, et al. "Epithelial ovarian cancer." *The Lancet* 393.10177 (2019): 1240-1253.
2. Lei, Ziyang, et al. "Evaluation of cytoreductive surgery with or without hyperthermic intraperitoneal chemotherapy for stage III epithelial ovarian cancer." *JAMA network open* 3.8 (2020): e2013940-e2013940.
3. Van Driel, Willemien J., et al. "Hyperthermic intraperitoneal chemotherapy in ovarian cancer." *New England Journal of Medicine* 378.3 (2018): 230-240.
4. Verwaal, Vic J. "Long-term results of cytoreduction and HIPEC followed by systemic chemotherapy." *The Cancer Journal* 15.3 (2009): 212-215.

#### **IMPORTANT INFORMATION ABOUT THESE PROTOCOLS:**

If this protocol/process is adopted as is, the AmSECT logo must be removed and replaced with an institution specific logo.

This protocol/process encourages high quality patient care but observing it cannot guarantee any specific patient outcome.

This protocol/process should be reviewed or revised as warranted by institutional specific protocol, taking into account the evolution of technology and practice.

Review period: Review as changes occur or per institutional protocol.

Original hard copies and/or computer copies of this protocol are stored under the supervision of the Chief Perfusionist, Department of Cardiovascular Perfusion.

**APPROVED BY:** *(signature of CMO and CNE only required)*

**Source:** *(originating department/committee)*

**Effective Date:** *(can use 'created date' for this)*

**Version Number:** *(should match # of revisions, use 1.0 if new document)*

**Date Revised:** *MM/YYYY; all dates any content changes were made*

**Date Reviewed:**

**Signatures:**

Date:

*<Insert Name, Title>*

Date:

*<Insert Name, Title>*

Date:

*<Insert Name, Chief Medical Officer >*

Date:

*<Insert Name, Chief Nursing Executive>*