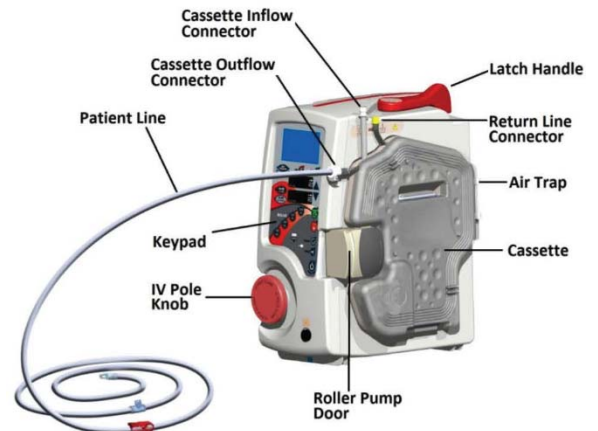




PNC-1200



ThermaCor® 1200 Disposable Sets are indicated for use only with the ThermaCor® 1200 Rapid Thermal Infusion System.

See the Operator Manual for complete instructions on installation and use of this system.

Installing the Disposable Cassette and Priming Instructions

1. Turn on the pump by pressing the Power ON button. The Self-Test will then automatically begin and take a few seconds to complete. Following a successful Self-Test, a message will appear stating "NO CASSETTE".
2. Unpack the Cassette from packaging using aseptic technique, while retaining sterility of fluid connections.
3. Visually inspect and verify that two (2) pads are in place on the Air Trap. These pads are spaced 3/4" apart.
4. Open the Roller Pump Door and move the Latch Handle all the way to the right to the fully LOCKED (Ⓐ) position and then back to the LOAD (Ⓣ) position.
5. Place the Cassette bottom into the lower metal bar at a 45 degree angle, and push the top of the Cassette toward the Pump until the top metal bar engages the Cassette.
6. Move the Latch Handle to the fully LOCKED (Ⓐ) position.
7. Insert the Cassette roller pump tubing into the roller pump. **Ensure that the roller pump tubing is fully pushed into the back surface of the roller pump.**
8. Close the Roller Pump Door.
9. Connect the Inflow, Return and Outflow lines. Close the pinch clamps on the Inflow spike lines. Spike bag(s) and open respective pinch clamp(s).
10. Press and release the PRIME button to run the Auto-Priming cycle. Following Auto-Prime, press and release (allow 15 sec of manual priming) or press and hold the PRIME button to continue Manual Priming until all air is removed. Inspect that the patient line is free of air bubbles.
11. Using aseptic technique, connect patient Outflow line without entrapping air. Select the appropriate settings and press START to begin infusing.

WARNINGS

The patient outflow line must be completely free of air before fluid is administered.

Practice standard precautions when handling blood products. Treat all blood as if it were infected and clean up all spills immediately.

Do not alter or change any part of the Cassette. Any changes or alterations to the Cassette may endanger the patient or damage the system.

Warming plasma with this device may result in loss of von Willebrand factor activity (vWF:RCo) up to 29% in the infused plasma.

Store the Cassette according to manufacturer's recommendations for temperature and humidity.

CAUTIONS

Federal (USA) law restricts this device to sale by or on the order of a physician.

Use aseptic techniques.

DO NOT USE if caps are not in place.

DISPOSE in accordance with local and state regulations regarding medical waste disposal.

THIS PRODUCT IS SINGLE USE ONLY, it cannot be adequately cleaned or sterilized for reuse.

Patent Info: www.SCP-IP.net



INDICATIONS AND CONTRAINDICATIONS

Indications for Use

The Smisson-Cartledge Biomedical ThermaCor® 1200 Rapid Thermal Infusion System is indicated for use over a full range of flow rates from slow feed to rapid, high flow infusion of: crystalloid, colloid, or blood product, including packed red blood cells [not in additive solutions and stored up to 21 days with anticoagulants], as volume replacement for patients suffering from blood loss due to trauma or surgery; warmed fluid to rewarm patients after surgery or for hypothermia; and warmed fluid for irrigation in urology procedures.

Contraindications

The ThermaCor® 1200 Rapid Thermal Infusion System should not be used in situations requiring a flow rate below 10 mL/hour or above 1200 mL/minute; for warming of platelets, cryoprecipitates or granulocyte suspension; or for administration of drugs. The ThermaCor® 1200 System is contraindicated for use in situations for which rapid infusion is medically contraindicated.

NOTE: The Disposable must be replaced after 24 hours of use.



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EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem The Netherlands



0086

UK Responsible Person (UKRP)

EMERGO Consulting (UK) Limited
c/o Cr 360 – UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ
UNITED KINGDOM



Smisson-Cartledge Biomedical, LLC

Macon, GA 31201 USA
www.ThermaCor1200.com
1-478-744-9992
1-866-944-9992