**August 2023 (Fourth Ed.)
*March 2023 (Third Ed.)
Medical Device Approval No.: 22700BZI00030000

Classification: Machinery and Equipment (12) Physical Therapy Equipment
Highly Controlled Medical Device, Generic Name: Percutaneous Indwelling Central Venous Thermoregulation System (Code: 44710004)

Trade Name: Cool Line IVTM Catheter

(Start-Up Kit)

Do not reuse

Contraindications/Restrictions

Applicability (Patients)

(1) The following patients who would not be able to tolerate a central venous catheter
- Patients with vena cava filters or other implanted impediments to passage of the catheter [Due to possible inability to place this product in an appropriate position]
- Patients with hemorrhagic risk factors [Blood may not clot]
* - Patients with sepsis [Infection may worsen]
- Patients with a platelet count of 100,000/mm^3 or below on catheter insertion (patients with platelet counts of 50,000 to 100,000/mm^3 on catheter insertion should be evaluated on a case-by-case basis) Blood may not clot]
- Patients with infectious foci at catheter insertion site [Infection may worsen]
- Patients in whom central venous access cannot be established [The catheter may not be able to be placed in an appropriate location]

(2) Patients in whom insertion of a temperature probe may cause injury, etc. and deep temperature monitoring is impossible [Inability to perform deep temperature monitoring will prevent accurate thermoregulation]

(3) Heparin-sensitive patients [heparin is used as a catheter coating agent]

(4) Neonates [The catheters cannot be used in patients less than 100cm in height]

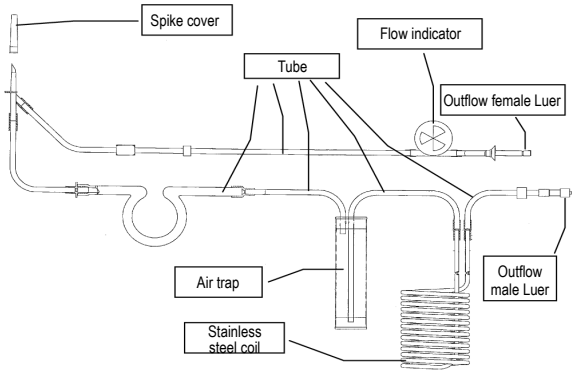
Method of Use

Do not reuse.

Configuration, Structure, Principles

Composition

** The Start-Up Kit is a component part of the System and is composed of the following items.



Types

The start-up kit is available in two types of tubing lengths (standard and long (EX)).

Location	Standard	Long (EX)
From Spike to Outflow Female Luer	3.0m	3.9m
From Coil to Inflow Male Luer	1.8m	2.7m

*

Name	Start-Up Kit Product Number	Start-Up Kit Product Number
Cool Line	8700-0781-03	Standard (1.8m): 8700-0784-03 OR Long (EX) (3.0m): 8700-0785-03

Operating Principles

The Start-Up Kit is used in combination with the console/Main Unit and the heat exchange catheter to provide endovascular heat exchange via a heat exchange catheter in patients requiring body temperature regulation.

The console/Main Unit has a main CPU that comprises a display head and a console. The Start-Up Kit is placed inside the console and connected to a saline bag and the heat exchange catheter.

In the main unit, temperature is electromechanically regulated by circulating saline solution inside the Start-Up Kit. The temperature-regulated saline solution is pumped through the continuous recirculating loop of the heat exchange catheter and then returned to the Start-Up Kit. As blood comes into contact with the surface of the heat exchange catheter, it is sent for recirculation through the entire body.

The patient's deep body temperature is continuously monitored to provide temperature feedback. The following diagram shows how the console/Main Unit regulates the coolant reservoir of the console and rotates and halts the rotary pump which circulates the saline solution to bring the patient’s body temperature to the target temperature.

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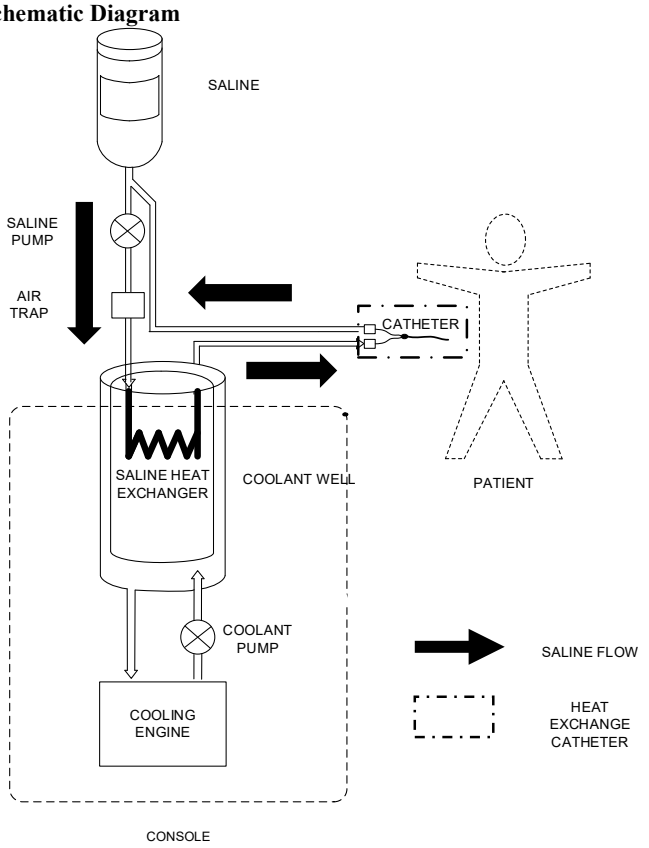
106416-002 Rev. 2

Schematic Diagram



Intended Purpose, Indications

Heat exchange is performed with intravascular blood using a dedicated central venous catheter with heat exchange circulation balloons as an adjunct to antipyretics and cooling blankets for the alleviation of fever burden in ICU patients suffering from fever resulting from severe acute brain damage who require a central venous catheter. (Note, therapeutic hypothermia is excluded).

Method of Use, Etc.

Concomitant Medical Devices

Concomitant Medical Devices

This product is used in combination with the following medical devices.

Brand Name: Thermogard System
Approval No.: 22400BZI00010000
Recipient of Foreign Exceptional Approval: ZOLL Circulation
Designated Marketing Approval Holder: Asahi Kasei ZOLL Medical Corporation

Brand Name: Thermogard XP Console
Approval No.: 22700BZI00039000
Recipient of Foreign Exceptional Approval: ZOLL Circulation
Designated Marketing Approval Holder: Asahi Kasei ZOLL Medical Corporation

Preparation

(1) Prepare a bag containing 500mL of saline solution.
(2) Unseal the Start-Up Kit.
(3) Place the heat exchange coil in the coolant reservoir.
(4) Insert the air trap into the air trap holder.
(5) Attach the pump tube to the rotary pump, and securely close the rotary pump cover.
(6) Connect the spike of the Start-Up Kit to the saline bag.
(7) Remove the air trap from the holder. Then, turn and hold the air trap upside down.
(8) Press and hold down the PRIME switch; check that the pump is rotating slowly, and confirm that the saline solution fills the entire length of the tube, including in the air trap.
(9) Tap the air trap lightly until no air bubbles remain.
(10) When priming is complete, release the PRIME switch.
(11) Once filled with saline solution, re-insert the air trap upright into the air trap holder.

Method of Use

* (1) Connect the primed Start-Up Kit to the inserted catheter.
- Connect the outflow female Luer of the Start-Up Kit to the outflow lumen of the catheter.
- Connect the inflow male Luer of the Start-Up Kit to the inflow lumen of the catheter.
- Make sure there are no air bubbles in the connecting components.

(2) Press the Standby/Run button on the Main Unit to initiate temperature management.
(3) Once initiated, verify that saline solution is flowing into the catheter by making sure that the flow indicator of the Start-Up Kit is rotating.

* **Check for leak**

Check for Start-Up Kit leak:

(1) Check for water in the saline solution bag, loss or leakage of start-up kit, and condensation in the air trap. If the air trap shows signs of condensation, the air trap alarm will sound. Wipe down the air trap and reattach it to the console. If an air trap alarm is present, verify that the air trap alarm is cleared after this procedure.
(2) Carefully check for leaks of saline solution in the path from the saline bag to the console. Check the floor, console, and patient's bed for saline solution.
(3) If there is saline solution on the floor, console, or patient's bed, ensure that there are no cracks or breaks in the lures of the catheter and start-up kit, that the connection (tightness) is sufficient and that there is no leakage.
(4) If the investigation reveals leakage from the start-up kit, replace the start-up kit and check the catheter for leakage as well.
(5) If the investigation shows no leakage from the start-up kit, further confirmation work should be performed because of the possibility of leakage from the catheter (see "Check for catheter leak" below).

Check for catheter leak:

(1) Aseptically remove the start-up kit from the catheter. Connect the outflow female lumen of the start-up kit and the inflow male lumen of the start-up kit to each other, or cap both the catheter and the start-up kit appropriately.
(2) Fill a sterile 10mL slip-tip syringe with sterile saline solution.
(3) Connect the syringe to the catheter's inflow lumen and open the outflow lumen. Inject 10mL of saline solution into the catheter and confirm that the injected saline solution flows out of the outflow lumen. (If the saline does not flow out of the outflow lumen, leakage from the catheter is suspected.)
(4) When the outflow lumen is aseptically blocked and the syringe (3) connected to the inflow lumen is aspirated at 5 mL and held aspirated for at least 10 seconds, confirm that the syringe contains a maximum of 4 mL of saline solution without blood contamination and that decompression can be maintained. (If traces of blood can be seen in the syringe and depressurization cannot be maintained, leakage from the catheter is suspected.
(5) If the investigation shows that the catheter is leaking, replace the catheter.
(6) Replace the saline bag and re-prime the start-up kit.
(7) Verify that there is no loose connection to the start-up kit and no leakage, and continue treatment.

Precautions when Using this Product

- Before connecting the product to a patient, the saline solution circuit must be primed. [During the priming operation, the air-trap alarm is disabled, and if air contaminates the saline line, it might circulate through the indwelling heat exchange catheter.]
- If saline solution leaks, the Fluid Loss Alarm is activated, and the system operation stops. If this alarm is activated, identify its cause immediately. To identify the cause of the leakage, check both the

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catheter and the Start-Up Kit for fluid-tightness.
- If you suspect that the balloon, catheter, or tube may be damaged, take appropriate action, such as immediately replacing the damaged item or removing the catheter.
- When replacing the catheter, always replace the Start-Up Kit.
- Check the tube for damage and for air bubbles inside.

After use

** • When removing the catheter, if necessary, connect the syringe and drain the saline solution.

Precautions

Important Basic Precautions

- Make sure that the Start-Up Kit and catheter are securely connected. [A faulty connection can result in damage to the catheter.]
- Confirm the saline is circulating properly during use.
- Make sure that the linkage between the Start-Up Kit and the catheter is implemented correctly. [Cracking may occur at the contact point of the roller pump of the Console/Main Unit and the tubing.]

Malfunctions and Adverse Events

Other Malfunctions

Damage due to tube wearing out.

Clinical Results

See "Clinical Results" in the package insert for the trade name “Thermogard XP Console.

Storage and Shelf Life

Storage Environment

Store at room temperature, avoiding high temperature, high humidity, and exposure to direct sunlight.

Shelf life

See the expiration date listed on the package and box.

Name of Marketing Authorization Holder and Manufacturer

Holder of Special Foreign Authorization

Name: ZOLL Circulation, Inc. (US)

Foreign Manufacturer

ZOLL Circulation, Inc. (US)

Designated Marketing Authorization Holder

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