**August 2023 (Fourth Ed.)
*March 2022 (Third Ed.)

Medical Device Approval No.: 22700BZI00030000

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

Biological Product * Brand Name: Cool Line IVTM Catheter

(Cool Line Catheter Kit (Triple))

Warnings

** **Method of Use**

- Do not insert or place the catheter or guide wire in the right atrium or the right ventricle. Insert the distal tip of the indwelling catheter via the internal jugular vein or the subclavian vein and place it in the superior vena cava above the junction with the right atrium and parallel to the vessel. [There is a risk of causing arrhythmia, myocardial erosion or cardiac tamponade in the patient..]
- Insert the distal tip of the indwelling catheter via the femoral vein and position it parallel to the vascular wall below the junction of the descending aorta and right atrium. [Failure to do so may result in severe injury to or death of the patient.]
- Verify that the catheter is properly placed at the target site by means of x-ray imaging. Verify the positional relationship between the tip of the catheter and the vascular wall with periodic lateral x-ray imaging to ensure that the catheter tip is parallel to the vascular wall. [Improper placement of the catheter may result in damage to the blood vessel and puncture of cardiac vasculature.]
- Consider taking patient-appropriate measures to prevent thrombus. [The heat exchange catheter has been found to have a structural risk of thrombus formation in animal models, etc.]

Contraindications/Restrictions

Applicability (Patients)

(1) The following patients who would not be able to tolerate an 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 the 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 for whom insertion of a temperature probe may cause injury, etc. and deep temperature monitoring is not possible [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 135cm in heightthe System is for use in adults]

Method of Use

* (1) Do not use the catheter line of the system when providing injections or intravenous drips of mannitol at concentrations exceeding 20%. [It may be affected by low temperatures and crystallize.]

(2) For single use only.

(3) Do not use alcohol, acetone, or similar substances to disinfect or clean the catheter.

Configuration, Structure, Principle

Composition

This product is a component part of the System.

* • Heat exchange catheter

*Coating: Heparin sodium derived from porcine intestinal mucosa

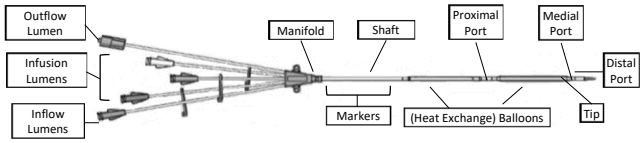
* • Catheter introducer kit

The names and JMDN codes of the relevant components

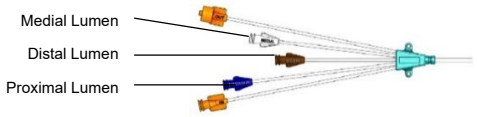
Guidewire	35094103
Dilator	32338000
Puncture needle	70204010
Suture thread	13910000
Suture tab clip	15735000
Scalpel	35130001
Syringe	13929001
Gauze	34655000
Surgical drape	35531000

Appearance

The catheter form is shown below.



Luer Enlarged Views

* 

Name	Catheter 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

*

Catheter characteristics are shown in Table 1.

Table 1

Name	Catheter		No. of Balloons	No. of Infusion Lumens	Insertion Site	Implant Site
	Effective Length	Diameter				
Cool Line	22 cm	3.10mm (9.3Fr)	2	3	Inner jugular vein, subclavian vein, or femoral vein	Superior vena cava, Inferior vena cava

Raw Material Composition

The composition of the catheter kit components are shown in Table 2.

Table 2

Component Name		Composition
Heat exchange catheter	Balloon and Shaft	Polyurethane
	Coating	Heparin sodium derived from porcine intestinal mucosa
Guidewire		Stainless steel
Dilator	Main unit	Polyethylene
Puncture needle	Inner needle	Stainless steel
Scalpel	Blade	Stainless steel

Please read the Instructions for Use

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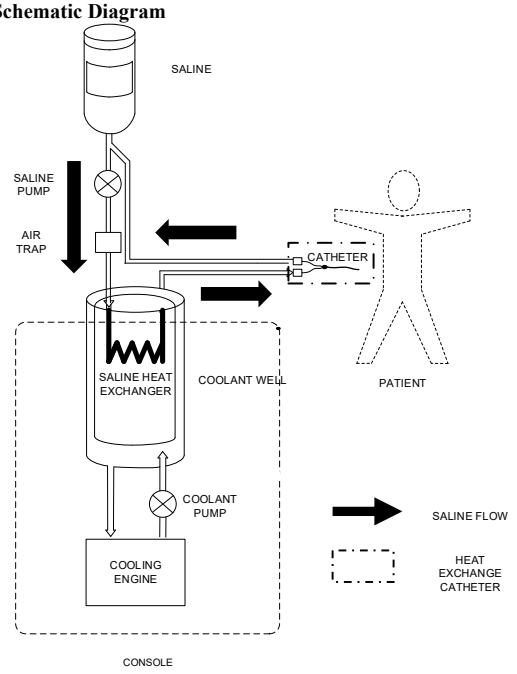
Operating Principles
The heat exchange catheter is used in combination with the Start-Up Kit, and the console/Main Unit to provide endovascular heat exchange via a heat exchange catheter in patients requiring body temperature regulation.

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

In the console/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. Blood that comes into contact with the surface of the central venous balloon catheter is circulated throughout the body.

The patient's deep body temperature is continuously monitored to provide temperature feedback. The following diagram shows how a patient's body temperature is brought to the target temperature set in the console/Main Unit by regulating the temperature of the coolant in the coolant reservoir of the console, and by controlling the action of the rotary pump to perfuse the saline solution.

Schematic Diagram



Intended Use, 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
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

** Brand Name: Thermogard HQ Console
Approval No.: 30500BZI00023000
Recipient of Foreign Exceptional Approval: ZOLL Circulation
Designated Marketing Approval Holder: Asahi Kasei ZOLL Medical Corporation

Insert the catheter using the Seldinger technique. Perform all operations using aseptic technique.

Preparation
* (1) Carefully remove the catheter from the package, leaving on the catheter membrane cover
* (2) Check the inflow lumen and remove the caps. With the catheter cover in place, fill the syringe (5 cc or larger) with sterile saline and attach the syringe to the female IN Luer. Gently inject saline through the catheter until it begins to exit from the OUT LDo not use the catheter if saline solution is leaking from its balloon.
(3) Prime the other lumens with sterile saline solution. Clamp the proximal and medial lumens. Or attach caps to the lures of the proximal and medial lumens. Leave the distal Luer uncapped for guidewire passage.
(4) Remove the cover from the catheter balloon and check for the presence of air bubbles or leakage. If the balloon cover is difficult to remove, introduce saline solution into the balloon cover.
(5) Flush the guide wire dispenser with sterile saline solution.

Catheter Insertion Procedure
(1) Sterilize the access site, place the surgical drape over it, and apply local anesthesia.
(2) Place a needle into the access site. Exercise care that the guide wire does not deviate.
(3) While holding the guide wire to keep it in place, withdraw the needle and insert the dilator. Make a small incision at the access site with the scalpel, if necessary.
(4) After removing the dilator, pass the guide wire through the catheter tip and insert the catheter into the vein with the balloon deflated. Hold the guide wire firmly during this step and advance the catheter into the vein by slightly twisting it. Keep a sufficient length of the guide wire outside the patient's body at all times.
(5) Using the catheter markers, advance the catheter to its final placement site.
(6) Once the catheter reaches the placement site, remove the guide wire while keeping the catheter in place. At this point, confirm the guide wire is free of defects.
(7) After removing the guide wire, attach the syringe to the drug lumen and check for back bleeding. Bind the access port and the catheter together temporarily.
(8) Use fluoroscopy to confirm the catheter is at the targeted site. The fluoroscopic marker shows the tip of the balloon. Confirm that the balloon is within the vessel.
(9) Use the side wing of the manifold to secure the catheter to the patient.
(10) Attach the suture clip to the catheter as needed. Use the suture thread to suture the wind of the suture tab clip to the patient and keep the catheter in place.
* (11) Dress the puncture site per hospital protocol. Maintain the insertion site with regular meticulous redressing using aseptic technique.
* (12) Record on the patient's chart the indwelling catheter length, using the centimeter marks on the catheter shaft as reference. Frequent visual reassessment should be made to ensure that the catheter has not moved.

Connect to Start-Up Kit
* Connect the primed start-up kit to the inserted catheter.
(1) Connect the outflow female lumen of the start-up kit to the outflow lumen of the catheter.
(2) Connect the inflow male lumen of the start-up kit to the inflow lumen of the catheter.
(3) Check that no air bubbles are visible in each connection.

*** Please read the Instructions for Use**

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

Catheter Removal

* (1) Stop the pumping saline trough the catheter.
* (2) Disconnect the Start-Up Kit from the catheter. Uncap or leave uncapped the IN and OUT Luers of the catheter. This allows residual saline within the circuit to be expressed. As the catheter is withdrawn, the balloons are compressed. Saline within the balloons must be free to pass out of the balloon or the balloon will not deflate, making the catheter difficult to remove.
* (3) Optionally, attach a 20 or 25 cc syringe to the catheter IN Luer. Pull and hold a vacuum for 15 seconds to allow residual saline to be removed from the catheter balloon section prior to removing the catheter.
* (4) Place the patient in supine position. Remove the dressing Remove the suture from the suture site.
* (5) Slowly remove the catheter from the patient.As the catheter exits the site, apply pressure with a dressing impermeable to air (e.g. Vaseline gauze).

Precautions when Using this Product

- Do not use a sheath for catheter insertion. [There is a risk of damage to the balloon.]
- Never allow positive pressure in the inflow lumen of the catheter with the outflow lumen cap in place. [There is a risk of damage to the balloon.]
- When inserting the guide wire, do not re-insert the metal needle through cannula. [Doing so may damage or break the cannula.]
- If resistance is encountered when attempting to remove the guide wire, withdraw the catheter relative to the guide wire about 2-3 cm and attempt to remove the guide wire. If resistance is again encountered remove the guide wire and catheter simultaneously. [May cause injury to vessels, etc. or guidewire damage]
- Do not apply excessive force to the guide wire. [Using more forward pressure than necessary risks vascular and other damage.]
- Exercise care when expanding the insertion site using the dilator. [Excessive pushing may damage the vasculature, etc.]
- When affixing the catheter to the insertion site, do not use the suture tab and clip to directly suture the catheter shaft. Also, do not suture tightly. [Doing so may cause catheter damage, liquid leakage, changes in flow volume.]
- Do not use a three-way stopcock or clamp with the inflow lumen and outflow lumen, or obstruct the circuit.• Do not use an automatic contrast media injector and inject contrast medium through the infusion lumen. Use manual infusion if injecting contrast medium through the infusion lumen pressure not to exceed 689kPa (100psi).
- If using the catheter for blood sampling, use the infusion lumen and temporarily halt infusion. Use only a 30mL or smaller syringe for blood sampling.
- If saline solution leaks, the air trap Fluid Loss Alarm is activated and the system operation stops. If the air trap Fluid Loss Alarm alarm is activated, identify its cause immediately. To identify the cause of the leakage, check both the catheter and the Start-Up Kit for fluid-tightness.
- Be sure to monitor the patient's deep body temperature while using this product. [Failure to accurately monitor deep body temperature could lead to inability to accurately control patient temperature.]
- The heat exchange catheters have a risk of infection. Exercise care when using.

** • The start-up kit to be connected differs depending on the console/device body to be used in combination. When used in combination with the "ThermoGuard XP Console" (trade name), the start-up kit for the components of this product must be connected, and when used in combination with the "ThermoGuard HQ Console" (trade name), the start-up kit for the ThermoGuard HQ Console components must be connected.

Precautions

＜Usage Precaution＞ (Exercise care when using in the following patients)

- In a clinical study conducted in the US in patients with subarachnoid hemorrhage and primary traumatic brain injury, the mortality rates according to disease were higher in the study group than the control group (no statistically significant differences.) See “Clinical Results" in the package insert for the console/Main Unit.

Important basic precautions

- Only insert the catheter through the inner jugular vein, the subclavian vein, or the femoral vein. [Incorrect use may cause serious side effects.]
- Exercise care with needles or catheter placement at the puncture site or poor connections. [This may cause air embolism.]
- If a hypersensitive reaction occurs following catheter placement, withdraw the catheter and perform the physician’s appropriate measures.
- Ensure that the Start-Up Kit and the catheter are properly connected. [Failure to do so may result in damage to the catheter or balloon, failure to cool or warm, and/or leakage of the saline solution.]
- Use only sterile saline for priming the catheter and as the circulating fluid inside the catheter.
- Discontinue operation if blood is observed in the circulating sterile saline. [There is a risk of catheter damage.]
- Use immediately once the packaging is opened.

* • Non-clinical studies have shown that this product is MR Conditional. MR tests can be performed safely on patients wearing this product under the following conditions. 【Self-certification】.
    - Static magnetic field strength of 1.5 T or 3 T
    - Maximum spatial gradient field of 4,000 Gauss/cm (40 T/m)
    - Averaged whole body SAR of 2 W/kg for 15 minutes of scanning (normal operation mode)

The maximum temperature rise that can occur in this product during a 15-minute scan time under the above conditions is less than 1.5°C.

The image artifact extends approximately 5 mm that can occur when this product is imaged using the gradient field echo method on a 3T MR system.

T: Tesla, unit of magnetic flux density, 1T=10,000 Gauss

SAR: Absorbed heat per unit tissue mass, unit is W/kg

The catheter must be disconnected from the Thermogard XP console. The Thermogard XP consoles are MR Unsafe. Do not use in the MR Suite.

Please read the Instructions for Use

Malfunctions and Adverse Events

1. Major Adverse Events

There is a risk of the following adverse events when using this product.

Atrial or ventricular perforation, cardiac tamponade, air embolus, catheter embolism, thoracic laceration, bacteremia, sepsis, thrombosis, hematoma formation at the puncture site, hemorrhage, nerve damage, arrhythmia, pneumothorax, infection, pneumonia, pulmonary embolism

2. Major Malfunctions

Overcooling, overwarming, withdrawal difficult (cut down required)

4. Other Malfunctions

- Leakage of saline solution due to damage of the balloon.
- Leakage of saline solution due to a short circuit between the saline circulation lumen and the drug infusion lumen
- Guidewire kinking

<Use in Pregnant Women, Nursing Mothers, and Pediatrics, Etc.>

- If using in children, use with care. [Efficacy and safety in children has not been verified]

Clinical Results

See "Clinical Results" in the package insert for the Main Unit.

Storage, 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.

Usage Period

7 days
(Clinical testing in the United States confirmed safe use for 7 days.)

Name of Marketing Authorization Holder and Manufacturer

Holder of Special Foreign Authorization

ZOLL Circulation, Inc. (US)

Foreign Manufacturer

ZOLL Circulation, Inc.(US)

Designated Marketing Authorization Holder

Asahi Kasei ZOLL Medical
Tel.: 03-6205-4920 (Main No.)

Please read the Instructions for Use