**August 2023 (Fifth Ed.)
* December 2022 (Fourth Ed.)

Medical Device Approval No.: 22800BZI00008000

Classification: Machinery and Equipment (12) Physiotherapeutic Equipment
Highly Controlled Medical Device: Generic Name: Central venous indwelled transdermal body temperature adjustment device system (Code: 44710004)

Biological Product Trade Name: Quattro & Icy IVTM Catheters

(Heat Exchange Catheter Kit)

Do not reuse

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 femoral vein and position it parallel to the vascular wall below the junction of the descending aorta and right atrium. [There is a risk of causing arrhythmia, myocardial erosion or cardiac tamponade in 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. Take measures appropriate to the patient's condition if any abnormalities are observed. [There is a risk of movement of the catheter within the blood vessel or cardiac or vascular puncture.]
- 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.]
- Use in excess of the maximum period of use has caused balloon detachment, thrombus, and other adverse events, so make sure to adhere to the 4 day maximum period of use.

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 diathesis [Blood may not clot]
- Patients with sepsis [Infection may worsen]
- Patients with a platelet count of 30,000/mm^3 or below on catheter insertion [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 height.]

(5) Patients who have hematological diseases that will be made worse with hypothermia e.g. cryoglobulinemia or any hemoglobinopathy in which hemolytic anaemia can be precipitated by cold, including sickle cell disease or thalassemia

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.
[This may cause the polyurethane catheter material to deteriorate.]

Configuration, Structure, Principle

Composition

This product consists of the following:

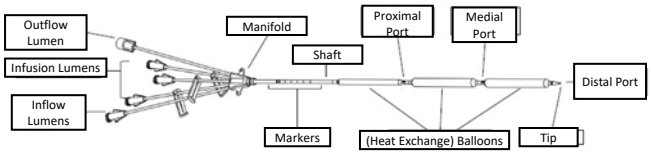
- Heat exchange catheter
  ※Coating: Heparin sodium derived from porcine intestinal mucosa
- Catheter introducer kit
  ※The names and JMDN codes of the relevant components

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

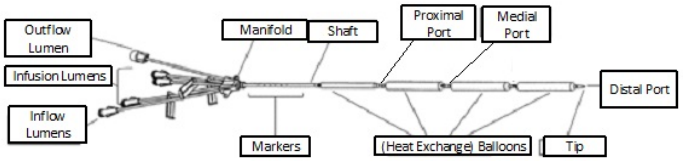
Appearance

The catheter uses a heparin coating (heparin sodium) derived from porcine intestinal mucosa and is available in the two types shown below.

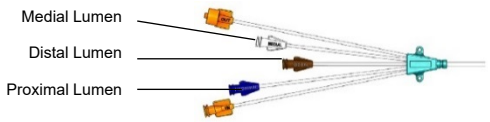
Model: ICY IVTM Catheter



Model Quattro IVTM Catheter



Lumen Enlarged Views



Types

The differences between the two types of catheters are as shown below.

Name	Catheter Number	Start-Up Kit Number
ICY	8700-0782-03	Standard (1.8m): 8700-0784-03 OR Long (EX) (3.0m): 8700-0785-03
Quattro	8700-0783-03	Standard (1.8m): 8700-0784-03 OR Long (EX) (3.0m): 8700-0785-03

Catheter characteristics are shown in the table below.

Name	Catheter		No. of Balloons	No. of Infusion Lumens	Insertion Site	Implant Site
	Effective Length	Diameter				
ICY	38 cm	3.10mm (9.3Fr)	3	3	Femoral vein	Inferior vena cava
Quattro	45 cm	3.10mm (9.3Fr)	4	3	Femoral vein	Inferior vena cava

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Raw Material Composition
The materials of the catheter kit components are shown in the table below.

Component Name		Composition
Heat exchange catheter	Shaft	Polyurethane
	Balloons	Polyurethane Polyethylene terephthalate
	Coating	Heparin sodium derived from porcine intestinal mucosa
Guide wire		Stainless steel
Dilator	Main body	Polyethylene

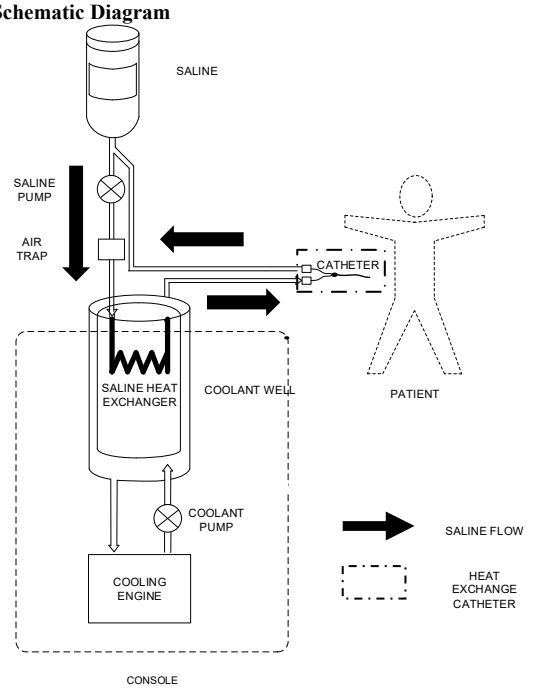
Operating Principles

The heat exchange catheter of the product is used in combination with the start-up kit and console/main unit to provide endovascular heat exchange via a heat exchange catheter in patients requiring body temperature regulation.

In the console/main unit, temperature is electromechanically regulated by circulating saline 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 heat exchange catheter is circulated throughout the body.

The patient's deep body temperature is continuously monitored to provide temperature feedback. The console/main unit brings the patient's body temperature to the target temperature that is set by regulating the temperature of the temperature control reservoir inside of the console, and by controlling the rotation and stoppage of the roller pump to perfuse the saline solution. An overview of the system is shown in the diagram below.

Schematic Diagram



Intended Use, Indications

- Used for temperature management (therapeutic hypothermia) in patients who are post-cardiac arrest & ROSC.
- Used for maintenance of normal body temperature [normothermia] in patients who require a central venous catheter and require temperature management.

Method of Operation or Use

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
Select the appropriate length of the central venous balloon catheter based on individual patient anatomy and the length of the catheter used, as in the case of standard central venous catheters. Insert the catheter through the femoral vein into the inferior vena cava. The maximum period of use is 4 days. Perform standard measures to prevent thrombosis as necessary. Patient body types are provided in the below table.

Name	**Product Number	Length	Number of Balloons	Patient Guide	
				Height ≥135cm<150cm	Height ≥150cm
ICY	8700-0782-03	38cm	3	Y	Y
Quattro	8700-0783-03	45cm	4	N	Y

(1) Select the catheter to be used and 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 Luer.. Do 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 saline solution.

Catheter Insertion Procedure
(1) Sterilize the access site, place the surgical drape over it, and apply local anesthesia.
(2) Insert the puncture needle and insert the guide wire to the desired location. Exercise care to ensure the guide wire does not deviate.
(3) While holding the guide wire to keep it in place, withdraw the sheath of puncture 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 (distal port) 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.
(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 infusion 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 proximal tip of the balloon. Confirm that the balloon is within the vessel.
(9) Use the side wing of the manifold to fix the catheter to the patient.
(10) Attach the suture clip to the catheter as needed. Use the suture thread to suture the suture tab clip or the wing of the catheter 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 luer of the start-up kit to the outflow lumen of the catheter.
(2) Connect the inflow male luer of the start-up kit to the inflow lumen of the catheter.
(3) Check that no air bubbles are visible in the connections.

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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 Related to Method of Use, Etc.

- Do not use a sheath for catheter insertion. [There is a risk of damage to the balloon.]
- Never allow positive pressure in the inflow luer with the outflow luer cap in place. [There is a risk of damage to the balloon.]
- With regards to the puncture needle that is used when inserting the guide wire, do not reinsert the metal internal needle into the cannula. [Doing so may cause damage or breakage of the cannula.]
- If resistance is encountered when attempting to remove the guide wire, withdraw the catheter about 2-3 cm relative to the guide wire and attempt to remove the guide wire. If resistance is again encountered, remove the guide wire and catheter simultaneously. Keep a sufficient length of the guide wire outside the patient at all times. [May cause injury to the vessel, etc., or damage the guide wire.]
- Do not apply excessive force to the guide wire. Exercise sufficient care when inserting. [Using more forward pressure than necessary risks vascular and other damage.]
- Use caution when using the dilator to expand the insertion site. [Using more forward pressure than necessary risks vascular and other damage.]
- Do not directly suture the catheter shaft when affixing it to the catheter insertion site. [Doing so may cause damage to the catheter, leakage of fluid or changes in the flow rate.]
- 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 to quickly 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. Since no more than 30mL is normally needed for blood sampling, use only a 30mL or smaller syringe for blood sampling.
- If saline solution leaks, the air trap 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 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 for use

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

* (1) Patients with abnormal body temperatures requiring intensive care management (accidental hypothermia, heat stroke, burn treatment, hypothermia associated affect surgery.) [It may cause unexpected complications, such as temporary but serious arrhythmia, etc.] Refer to Important basic precaution.

(2) Due to the fact that the following patients were excluded from the Japan trial, exercise care for use.

- Patients with unstable circulatory dynamics [Effect on Circulatory dynamics uncertain]
- Patients with continued bleeding, including intracranial [Effect on bleeding uncertain]
- Drug overdose patients [May effect drug metabolism]
- Stroke patients [Effect on stroke uncertain]

Important basic precautions

- Only insert the catheter from the femoral vein. [Incorrect use may cause serious side effects.]
- Avoid leaving the needle or catheter unattended at the puncture site and take precautions against accidental poor connections. [There is a risk of air embolism.]
- If an allergic reaction occurs after indwelling the catheter, remove the catheter and have a doctor provide appropriate medical treatment.

* •The severe hypothermia patient - Core temperature below 30℃ - Be vigilant when inserting guidewires and catheter, which can cause a significant increase in myocardial irritability and temporary but serious arrhythmia. (It may exacerbate the patient's condition (accidental hypothermia))

- For patients being made hypothermic, the follow may occur, so care should be taken to properly monitor patients during hypothermia and appropriate actions should be taken if the following occur.
  (i) Cardiac rhythm disturbances such as bradycardia and ventricular tachyarrhythmia
  (ii) Disturbances of clotting and coagulation function
  (iii) Blood gas and pH aberrations
  (iv) Depressed immune response and lung function
- Should a fever occur due to infectious and/or non-infectious causes when using this product to mitigate fever, the lack of body temperature changes will reduce the ability to recognize the cause of the new fever. This necessitates meticulous assessment for other signs of infection.
- Make sure that the linkage between the Start-Up Kit and the catheter is implemented correctly.
  [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.]
- During use, regularly confirm that the flow indicator of the start-up kit is rotating during pump operation, the indwelling position of the catheter is correct, and the luers are properly connected. Use the markings on the catheter shaft to verify its position. [There is a risk that the intended results of treatment may not be achieved.]
- Use only sterile saline for priming the catheter and as the circulating fluid inside the catheter.

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- Discontinue operation if blood is observed in the circulating sterile saline. [There is a risk of catheter damage.]
- ZOLL recommends to not use other concomitant devices for temperature management. [May not be able to perform accurate temperature management.]
- Use for clinical subjects should be carefully determined by the treating physician. [In the Japan trial, chilled infusions were used concomitantly] (See Clinical Trial section)
- 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 1.4°C.
The image artifact extends approximately 8 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.

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, acute respiratory distress syndrome, hypoxic ischemic encephalopathy, atrial fibrillation, cardiac arrest
2. Major Malfunctions
Overcooling, overwarming, withdrawal difficult (cut down required)
3. Other Adverse Events
Pseudomembranous colitis, hypoalbuminemia, hyponatremia, spasms, vocal cord paralysis, hypertension, vasculitis of the injection site, increased blood creatine phosphokinase, decreased blood pressure, nosebleed, retention of sputum, constipation
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] (See Clinical Results)

Clinical Results

A clinical study with the following title was performed in Japan.

COOL-ARREST JP: An Evaluation of Therapeutic Hypothermia by means of Intravascular Cooling (Intravascular Temperature Management; IVTM) in Patients who have Undergone Endogenous Cardiac Arrest and Return of Circulation – A Joint, Multicenter, Single-Arm, Prospective Interventional Study

Purpose
The purpose of the trial is to verify that therapeutic hypothermia by means of intravascular cooling using the study device is capable of properly managing body temperature in patients who have undergone endogenous cardiac arrest suspected to be cardiogenic and return of circulation.

Study Type
Non-blinded, single-arm, prospective multicenter study

Subjects
Patients with ROSC following primary cardiac arrest with suspected cardiogenicity

Number of Subjects
Number of registered subjects: 25 (1 discontinued before the start of treatment.)
Number of Subjects Used to Evaluate Efficacy: 24
Number of Subjects Used to Evaluate Safety: 25

Methods
Primary Endpoint
Proportion of subjects achieving the target body temperature within 3 hours from the start of cooling with the study device
[Evaluation of Individual Subjects]
The time at which the deep body temperature reached the target (34.0°C or less) following the start of cooling with the study device was recorded in the case report, and was evaluated to determine whether the target temperature was reached within 3 hours.

Results
Primary Endpoint
The target body temperature was reached within 3 hours of the start of treatment with the study device in all 24 subjects, a target achievement rate of 100% (95% CI: 85.8-100.0%). The deep body temperature at the start of treatment was 36.20 ± 1.11°C, and the time from the start of cooling needed to reach the target body temperature was 54.63 ± 37.46 minutes (IQR 33.0-73.3 minutes).

Safety Endpoints

1) Adverse Events
The incidence of adverse events by seriousness is shown in Table 1. All 5 serious adverse events were “unrelated” to the study device.

Table 1 Incidence of Adverse Event by Seriousness

PT	Serious	Non-Serious
Pneumonia		6 (24.0%)
Pseudomembranous Colitis		1 (4.0%)
Medical Device-Related Infection		1 (4.0%)
Hypoalbuminemia		1 (4.0%)
Hyponatremia		1 (4.0%)
Convulsions		1 (4.0%)
Vocal Cord Paralysis		1 (4.0%)
Hypoxic-Ischemic Encephalopathy		1 (4.0%)
Atrial Fibrillation		1 (4.0%)
Bradycardia		1 (4.0%)
Cardiac Arrest	1 (4.0%)	
Ventricular Fibrillation	3 (12.0%)	
Hypertension		3 (12.0%)
Vena Cava Thrombosis		1 (4.0%)
Acute Respiratory Distress Syndrome	1 (4.0%)	
Nosebleed		1 (4.0%)
Aspiration Pneumonia		2 (8.0%)
Retention of Sputum		1 (4.0%)
Constipation		1 (4.0%)
Gastrointestinal Bleeding		1 (4.0%)
Drug-Induced Liver Disorder		1 (4.0%)
Intramuscular Bleeding		1 (4.0%)
Vasculitis of the Injection Site		1 (4.0%)
Increased Blood Creatine Phosphokinase		2 (8.0%)
Decreased Blood Pressure		1 (4.0%)
Subcutaneous Hematoma		1 (4.0%)

* When multiple events with the same PT have occurred in the same subject, the most serious event is to be used.

Incidence of malfunctions by seriousness is shown in Table 2.

Table 2 Incidence of Malfunctions by Seriousness

PT	Serious	Non-Serious
Pneumonia		1 (4.0%)
Bradycardia		1 (4.0%)
Vena Cava Thrombosis		1 (4.0%)
Increased Blood Creatine Phosphokinase		1 (4.0%)
Decreased Blood Pressure		1 (4.0%)

*When multiple events with the same PT have occurred in the same subject, the most serious event is to be used.

Of the 25 subjects who were registered for this trial, the outcome at the time of the final confirmation was survival in 23 (92%) and death in 2 (8.0%). The 95% confidence interval of the survival rate was 71.6-97.9%. The cause of death was worsening of the primary condition in both of the 2 subjects who died, and the investigator judged there to be no causal relationship between the deaths and the study device. Both subjects died after the discontinuation of the trial.

There were no deaths during the period of the trial. 5 cases of serious adverse

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events other than death were reported in 5 subjects (3 cases of ventricular fibrillation, 1 case of cardiac arrest and 1 case of acute respiratory distress syndrome). Of the serious adverse events, 1 case of ventricular fibrillation and 1 case of cardiac arrest took place before the use of the study device.

2) Study Device Malfunctions
Two study device malfunctions were reported. They consisted of 1 case of failure due to cracking of the start-up kit tube and 1 case of kinking of the guide wire that was included in the catheter kit. Neither malfunction was accompanied by an adverse event.

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.

Name, Address 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
Asahi Kasei ZOLL Medical;
Tel.: 03-6205-4920

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