Cool Line® Intravascular Heat Exchange Catheter (Custom Luer)
Instructions for Use
CL-2295A/8700-0781-01

Caution: Federal law restricts this device to sale by or on the order of a physician.

Model CL-2295A/8700-0781-01 (Also referred to as CL-2295) includes:

Quantity	Description
1	Cool Line® Catheter 9.3 French x 22 cm Tri Infusion Luer Extension Line Clamps Radiopaque Shaft Applause Heparin Coated
2	Guidewires .032" (0.81 mm) x 65 cm
1	Vessel Dilator 10.5F x 0.38" (3.6 mm x 1.0 mm)
1	Detachable Suture Tab & Clip
1	18 ga x 2 ½" (1.3 mm x 6.4 cm) Radiopaque PTFE OTN Catheter
1	000 Silk Suture
1	Chloraprep® Triple Swabstick Prep Pack
6	4" x 4" (10 cm x 10 cm) Gauze Sponges
1	No. 11 Surgical Blade w/ long handle
1	3 cc Syringe and 25 ga x 1" (0.5 mm x 2.5 cm) Needle
2	5 cc Syringes and 22 ga x 1 ½" (0.7 mm x 38 mm) Needles
1	Fenestrated Drape
1	18 ga x 2 ¾" (1.3 mm x 67 mm) Needle
1	Needle Disposal Cup
1	SilvaSorb® Site Antimicrobial Dressing
1	Suresite® Transparent Film Dressing

Device Description

The Cool Line Intravascular Heat Exchange Catheter ("Cool Line Catheter" or "catheter") is a sterile, single use flexible 9.3 F catheter designed for placement in the central venous circulation from an insertion site in the jugular, subclavian, or femoral veins. The Cool Line Catheter is to be connected to a single use, disposable Coolgard 3000®/Thermogard XP® Start-Up Kit (supplied separately) and the Coolgard 3000/Thermogard XP System. A dilator and guidewire are required for the percutaneous insertion of the Cool Line Catheter. Three Luers are available for infusion, measuring central venous pressure or sampling.

Infusion Port	Size	Flow Rate	Priming Volume
Proximal Port (blue)	18 Ga	1400 ml/hr	0.3 cc
Medial Port (white)	18 Ga	1200 ml/hr	0.3 cc
Guidewire Port (brown)	16 Ga	2100 ml/hr	0.4 cc

Insertion size:

Model CL-2295	9.3F

The Cool Line Catheter blood contact surfaces (tip, balloon, and shaft) are treated with an anti-thrombotic Applause heparin coating.

Sterility

Ethylene oxide sterilized. The Cool Line Catheter is supplied sterile for single use only and should not be resterilized. The package should be inspected prior to use to ensure that the sterility barrier has not been compromised.

Storage

Store between 20-25°C. Avoid freezing and excessive heat above 40°C.

Indications for Use

The Cool Line Catheter Model CL-2295A, when used with the ZOLL Thermal Regulation System is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in adult patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

Mortality by Diagnosis (ITT analysis)

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the clinical trial results, refer to the Physician's Manual – "Normothermia for the Neuro- critically Ill stroke patient".

Safety and Efficacy Considerations

Central venous catheterization should only be performed by well-trained personnel well-versed in anatomical landmarks and safe technique. Personnel should also have knowledge of potential complications. The product is designed for single use only. Do not resterilize or reuse. Do not reinsert, once removed from the patient. Do not alter the catheter in any way.

Potential risks with reuse of a single-use device include but are not limited to

- Potentially life threatening infection
- Toxic shock due to degradation of materials
- Increased risk of thrombosis
- Reduced heat exchange power
- Device failures

WARNING: Do not allow the catheter to be placed into the right atrium or right ventricle. Placement in the right atrium or right ventricle can result in severe patient injury or death.

Contraindications

1. The risks of the catheter are essentially those of a central line. The catheter should not be used in patients for whom central line placement is not indicated.
2. Bleeding diathesis.
3. Active sepsis.
4. Infection or active bleeding at the site of catheter insertion.
5. Patients with no vascular access, or a vascular system will not accommodate a catheter. Patients for whom the required temperature monitoring cannot be established.

6.

Warnings and Precautions

WARNING: The catheter and Start-Up Kit could potentially misconnect with other devices with small bore connectors. Such misconnection errors could result in patient injury or death.

CAUTION: The custom Luers on the catheter and SUK may reduce the risk of misconnections but still have the potential for misconnections with these specific medical device applications: Breathing Systems & Driving Gases applications, Enteral & Gastric applications, Urethral & Urinary applications, Limb Cuff Inflation applications, Neuraxial applications, and Intravascular or Hypodermic applications. Always use caution when connecting ZOLL catheters and SUK's to these and other medical device applications.

CAUTION: Ensure that the catheter and/or Start-Up Kit are not connected to an IV or other medical device.

1. **SINGLE USE ONLY.** The product is designed for single use only. Do not resterilize or reuse. Do not reinsert, once removed from the patient. Do not alter the catheter in any way. Maximum use period: 7 days.
2. The use of intravascular cooling devices controls fever, including fever due to sepsis. Care must be taken to assess patients for sepsis.
3. Alcohol and acetone can weaken the structure of the shaft material. Care should therefore be taken when infusing drugs containing alcohol or when using alcohol or acetone when performing routine catheter care and maintenance. Alcohol should not be used to declot the catheter.
4. Use of a syringe smaller than 10 ml to irrigate or declot an occluded catheter may cause intraluminal leakage or catheter rupture.
5. **Caution: If blood is observed within the sterile saline circuit, stop the procedure.**
6. The catheter is coated with heparin. This may induce or aggravate pre-existing heparin-induced thrombocytopenia (HIT).
7. Central venous catheterization should only be performed by well-trained personnel well-versed in anatomical landmarks and safe technique. Personnel should also have knowledge of potential complications.
8. The catheter should be placed via a jugular, subclavian, or femoral vein approach only.
9. Do not allow the catheter to be placed into the right atrium or right ventricle. If placed via the jugular or subclavian veins, the catheter should be positioned so that the distal tip of the catheter is in the superior vena cava above its junction with the right atrium and parallel to the vessel wall. X-ray examination should be used to ensure that the catheter is not in the right atrium or ventricle. The distal tip of the catheter should be positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.
10. If placed via the femoral vein, the catheter should be positioned so that its distal tip is in the inferior vena cava, below its junction with the right atrium and parallel to the vessel wall.
11. Possible complications with central venous catheters include: atrial or ventricular perforation, cardiac tamponade, air embolism, catheter embolism, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, hematoma formation, hemorrhage, nerve damage and dysrhythmias.
12. All Luer-Lock connections and covers must be securely tightened to prevent air embolism or fluid or blood loss.
13. Never use excessive force in moving the catheter or guidewire. If resistance is encountered, an x-ray should be performed to identify the reason for the resistance.
14. Passage of the guidewire into the right heart can cause dysrhythmias, right bundle branch block, vessel wall, atrial or ventricular perforation.
15. Use only sterile normal saline for catheter priming. It is the circulating fluid in the catheter.
16. The catheter should be routinely inspected for flow rate, security of dressing, correct catheter position and for secure Luer-Lock connections. Use the centimeter markings to identify if the catheter position has changed.
17. Only x-ray examination can ensure that the catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If the catheter position has changed, perform an x-ray examination to confirm catheter tip position.
18. For blood sampling, temporarily shut off remaining infusion ports through which solutions are being infused.
19. Use only a 30 cc or smaller syringe for blood sampling.
20. Use care when infusing drugs that may be affected by cool temperatures (as low as 4ºC). Mannitol-containing solutions are temperature sensitive and must not be delivered through the catheter except for a rapid push of up to a concentration of 20% mannitol solution, followed by saline flush. Higher than a 20% concentration of mannitol or drip or infusion pump delivery of mannitol must be done via a separate line.
21. Do not infuse into the orange Luer-Lock connections.
22. Use only the ZOLL suture tab and clip provided in the kit to prevent catheter damage.
23. Not intended for pediatric or neonatal use.
24. Cardiac Tamponade: Placement of indwelling catheters in the right atrium is a practice that may lead to cardiac perforation and tamponade. Practitioners placing central venous catheters must be aware of this potentially fatal complication before advancing the catheter too far relative to patient size. The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion. Central venous catheters should not be placed in the right atrium unless specifically required for special relatively short-term procedures, such as aspiration of air emboli during neurosurgery. Such procedures are nevertheless risk prone and should be closely monitored and controlled.
25. When connecting infusion sets/injection systems to ZOLL catheters, do not exceed 100 psi/689 kPa.

WARNING: INTRALUMINAL LEAKAGE Intraluminal leakage between the saline Luer and infusion Luers is an uncommon but potential catheter failure. In the event of such a failure, sterile saline from the cooling circuit will be introduced into the patient. Intraluminal leakage will usually be associated with a fluid loss alarm, which will stop the system. ALWAYS INVESTIGATE FLUID LEVEL ALARMS. The cooling circuit is a closed loop system – usually fluid loss alarms indicate a breach somewhere in this closed loop. With any fluid loss alarm, check both the integrity of the catheter and the Start-Up Kit (see below).

Cool Line® Intravascular Heat Exchange Catheter (Custom Luer)
Instructions for Use
CL-2295A/8700-0781-01

To check the integrity of the catheter

1. Stop operation of the Coolgard 3000/ Thermogard XP System.
2. Disconnect the Start-Up Kit from the catheter. Properly cap both the catheter and Start-Up Kit using an aseptic technique.
3. Fill a sterile 10 ml slip tip syringe with sterile saline.
4. Connect the syringe to the IN Luer of the catheter and disconnect the OUT cap. Infuse the 10 ml of saline– it should flow out the OUT Luer.
5. Cap the OUT Luer and pull 5 cc of vacuum. Sustain for at least 10 seconds. Approximately 4 ml of saline, but not blood, should enter the syringe and you should be able to maintain the vacuum.
6. Ease the vacuum and recap the IN Luer.

To check the integrity of the Start-Up Kit

1. Look for obvious leakage.
2. Remove the tubing from the pump raceway and inspect for damage (return it to position if not damaged).
3. Check along the tubing from the pump to the patient for sources of fluid loss.
    - Look for damage to the tubing and/or the presence of air within the tubing.
    - Inspect, and tighten as necessary, each Luer fitting (do not use instruments to tighten Luer fittings).
    - Note: Condensation on the exterior of the tubing is normal.
4. Similarly, check the tubing that returns to the pump from the patient. Examine the saline bag to ensure that it has not been accidentally compromised (for example, the spike may have damaged the bag wall).
5. Trace the tubing from the saline bag back to the pump.

More warnings and precautions are located in following instructions.

Materials Required

Quantity	Description
1	Cool Line Kit for percutaneous introduction
1	500 cc bag of sterile normal saline
1	Coolgard 3000/Thermogard XP Start-Up Kit (provided separately) • 6 ft (183 cm) Standard Tubing or • 9 ft (274 cm) Extended Tubing
1	Coolgard 3000/Thermogard XP System

Catheter Preparation and Insertion

Note: The catheter has a radiopaque marker band to assist in identification of the catheter during and after insertion when viewed using x-ray equipment. The proximal end of the proximal balloon has one marker band. The tip of the catheter contains barium sulfate to make it radiopaque.

Use sterile technique.

1. **Caution: Use jugular, subclavian, or femoral vein approach only.**
2. **Caution: The IN and OUT Luer-Locks on the catheter are custom manufactured and are intended to connect only with the ZOLL Start Up Kits listed in Materials Required. They are not intended to connect to standard Luer-Lock syringes or other standard Luer-Lock connectors.**
3. Place the patient in a slight Trendelenburg position as tolerated to reduce the risk of air embolism. If a femoral approach is used, place the patient in a supine position.
4. Prep and drape the puncture site as required.
5. **Caution: Always prime the catheter before it is inserted into the patient.**
6. Carefully remove the catheter from the package, leaving on the catheter membrane cover.

Catheter Preparation Procedure

1. Remove the caps from the IN and OUT Luers. With the catheter cover in place, fill a 5 cc or larger syringe with sterile saline and attach the syringe to the female IN Luer.
2. **Warning: Never inject positive pressure into the IN Luer with the OUT Luer cap in place.**
3. Gently inject saline through the catheter until it begins to exit from the OUT Luer.
4. Using a 5 cc or larger syringe, flush the distal and proximal infusion Luers with sterile saline. Clamp or attach injection caps to the proximal infusion Luer. Leave the distal Luer uncapped for guidewire passage.
5. Remove the catheter membrane cover. If there is resistance in removing the membrane cover from the catheter, flush the membrane cover with sterile saline. Inspect the catheter to ensure that air has been purged from the heat exchange membrane. Inspect the catheter for leaks.
6. **Caution: Avoid excessive wiping of the coated catheter. Avoid wiping the catheter with dry gauze, as this may damage the catheter coating. Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the catheter, because this may cause unpredictable changes in the coating, which could affect the device safety and performance.**
7. **Warning: Do not cut the catheter to alter length.**

Catheter Insertion

1. Obtain jugular, subclavian, or femoral venous access using standard percutaneous techniques. Access should be maintained with a .032" (0.81 mm) guidewire. See Special Instructions for Guidewires**.**
2. **Warning: Do not attempt to re-insert a partially or completely withdrawn OTN (over the needle) introducer needle from its catheter.**
3. **Caution: Do not use a guidewire larger than .032" (0.81 mm) with the Cool Line catheter.**
4. Holding the guidewire in place, remove the introducer catheter. **Caution: Maintain a firm grip on the guidewire at all times.**
5. Enlarge the cutaneous puncture site with the cutting edge of the scalpel positioned away from the guidewire. **Warning: Do not cut the guidewire.** Use a vessel dilator to enlarge the site as required. Do not leave the vessel dilator in place as an indwelling catheter to minimize the risk of vessel wall perforation

6. Thread the tip of the catheter over the guidewire. Maintain a sufficiently firm grip on the guidewire during catheter insertion. Grasping the catheter tip near the skin, advance the catheter into the vein with a slight twisting motion. Continue to advance the catheter over the guidewire, placing your fingers just proximal to the balloon.

7. Using centimeter marks on the catheter as positioning reference points, advance the catheter to at least the 18 cm mark, to ensure the proximal infusion port is in the vessel.

8. Hold the catheter at the desired depth and remove the guidewire. If resistance is encountered when attempting to remove the guidewire after catheter placement, the guidewire may be kinked at the tip of the catheter. If resistance is encountered, withdraw the catheter relative to the guidewire about 2-3 cm and attempt to remove the guidewire. If resistance is encountered again, remove the guidewire and catheter simultaneously.

9. Caution: Do not apply undue force to the guidewire.

10. Verify that the guidewire is intact upon removal.

11. Check catheter placement by attaching a syringe to the distal and proximal infusion Luers and aspirate until a free flow of venous blood is observed. Connect infusion Luers to appropriate Luer-Lock line(s) as required. Unused infusion port(s) may be "locked" through injection cap(s) using standard hospital protocol. Slide clamps are provided on the tubing to occlude flow through the infusion Luers during line and injection cap changes. **Caution**: To minimize risk of damage to the tubing from excessive pressure, each clamp must be opened prior to infusing through that Luer.

12. **Caution: Do not clamp or occlude the IN or OUT lines. This can cause line blockage and possible failure**.

13. Secure and dress the insertion site and catheter temporarily.

14. If subclavian or jugular access is used, verify the catheter tip position by chest x-ray immediately after placement. The x-ray exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall. The catheter distal tip must be positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized. If the catheter tip is malpositioned, reposition and reverify.

15. If femoral access is used, x-ray examination must show the catheter located in the IVC with the distal end of the catheter parallel to the vena cava wall. If the catheter tip is malpositioned, reposition and reverify.

16. The proximal radiopaque marker indicates the proximal end of the balloon. Ensure that the balloon and proximal port reside completely in the vessel. If the catheter is malpositioned, reposition and reverify.

17. Secure the catheter to the patient. Use the juncture Luer side wings as the primary suture site to minimize the risk of catheter migration.

18. The ZOLL suture tab and clip can also be used as an additional attachment point. Ensure that the catheter body is secure and does not slide.

19. Caution: Use only the ZOLL suture tab and clip provided in the kit. Catheter damage may result if other tabs or clips are used.

20. Caution: Do not suture directly to the outside diameter of the catheter to minimize the risk of cutting or damaging the catheter or impeding catheter flow.

21. Dress the puncture site per hospital protocol. Maintain the insertion site with regular meticulous redressing using aseptic technique.

22. 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.

23. Attach a primed Start-Up Kit to the catheter by connecting the male Luer of the Start-Up Kit to the female IN Luer of the catheter (labeled "IN") and the female Luer of the Start-Up Kit to the male OUT Luer of the catheter (labeled "OUT"). White "ZOLL" tags are fitted loosely to the IN and OUT extension tubes to help identify them.

24. The Start-Up Kit IN and OUT Luers are only intended to connect to the catheter IN and OUT Luers and are not intended to connect to standard Luer Lock syringes. They have ZOLL custom fittings and are orange in color for easy identification.

25. Ensure that a sufficient amount of sterile saline is present at the ends of the Luers to make an air-free connection. **Refer to the operation manual.**

26. **Warning: Failure to connect the Start-Up Kit correctly to the catheter could result in catheter failure. Do not attach the Start-Up Kit (orange) Luers to the dark blue, white or brown infusion Luers.**

27. **Caution: Do not place any stopcocks in line that may be inadvertently shut off. This can cause line blockage and possible failure.**

28. Pump saline through the Start-Up Kit and catheter to ensure that all connections are secure and that there is no leaking. Allow any remaining air in the system to be purged out.

Disconnecting the Catheter from the System

1. Stop circulation of saline through the catheter.

2. Disconnect the Start-Up Kit from the catheter.

3. To maintain sterile connections, immediately cap off the Luer connectors of both the catheter and Start-Up Kit using sterile Luer caps or connect the IN and OUT Luers together.

Reconnecting the Catheter to the System

1. Remove the Luer caps from the Luer connectors of the catheter and Start-Up Kit. Discard the Luer caps or disconnect IN and OUT Luers from each other.

2. Attach the Start-Up Kit to the catheter by connecting the male Luer of the Start-Up Kit to the female IN Luer of the catheter and the female Luer of the Start-Up Kit to the male OUT Luer of the catheter. The Start-Up Kit and catheter IN and OUT Luers are orange in color. Ensure that a sufficient amount of sterile saline is present at the ends of the Luers to make an air-free connection.

   Warning: Failure to connect the Start-Up Kit correctly to the catheter could result in catheter failure.

3. Warning: DO NOT confuse the IN and OUT Luer fittings for standard central line infusion ports. They are for connection to the Coolgard 3000/Thermogard XP System ONLY.

4. The Start-Up Kit IN and OUT Luers are only intended to connect to the catheter IN and OUT Luers and are not intended to connect to standard Luer Lock syringes. They have ZOLL custom fittings and are orange in color for easy identification.

5. **Caution: Do not place any extra stopcocks in line that may be inadvertently shut off. This can cause line blockage and possible failure.**

Catheter Removal

1. Stop pumping saline through the catheter.
2. Disconnect the Start-Up Kit from the catheter. Uncap or leave uncapped the IN and OUT Luers of the cooling circuit (cooling circuit ONLY). This allows residual saline within the circuit to be expelled. 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 saline IN Luer. Pull and hold a vacuum for 15 seconds to allow residual saline to be removed from the catheter balloon section prior to the start of removing the catheter.
4. For convenience, a 20 or 25 cc syringe is included with the Start-Up Kit package. Hang it on the saline hook on the console until ready for use. Discard after each patient.
5. Place the patient in a supine position. Remove the dressing. Remove the sutures from the suture site.
6. Slowly remove the catheter from patient. As the catheter exits the site, apply pressure with a dressing impermeable to air, e.g. Vaseline gauze.
7. **Warning: Do not move the catheter if resistance is felt. Check to ensure that the IN and OUT Luers of the cooling circuit are NOT capped. If they are capped, uncap them, deflate the balloon, and try removing the catheter again. If resistance is still encountered, an x-ray should be performed to identify the reason for the resistance.**

MRI Safety Information

Non-clinical testing has demonstrated that the Cool Line catheter is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 720 gauss/cm (7.2 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Cool Line catheter is expected to produce a maximum temperature rise of less than 2º C after 15 minutes of continuous scanning.

WARNING: The ZOLL Coolgard 3000 and Thermogard XP Consoles are MR Unsafe. Do not use in the MR Suite.

ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131 USA
+1-408-541-2140 (main)
+1 (408) 541-1030 (fax)
Reorder USA only: +1-978-421-9655

GuideWire Instructions for Use

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

Note: This information applies only to the use of guidewires in the Seldinger technique of catheter placement in the vasculature.

Warnings

The supplied guidewire is designed for single use only. Do not resterilize or reuse. Do not reinsert, once removed from patient.

Should resistance occur during insertion or withdrawal, DO NOT continue to move the guidewire. Determine the cause under fluoroscopy and take action as needed.

Use extreme caution when moving a guidewire through a stent. Use of a guidewire in stented vessels creates additional patient risk.

Cautions

Avoid withdrawing the guidewire through metal needles; the guidewire may shear.

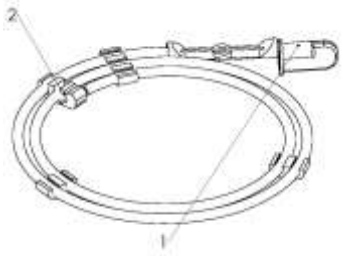
Because of the delicate and fragile nature of guidewires, extra care in handling must be taken. Avoid bending or kinking. Do not use damaged guidewires.

Sufficient guidewire length must remain exposed to maintain firm grip on the guidewire at all times.

Dispenser

Every guidewire is provided in a dispenser package. Remove the guidewire anti-migration clip before dispensing the guidewire. Remove the guidewire protective cap immediately prior to guidewire use. Prepare the guidewire prior to insertion. It is recommended that the dispenser be filled with heparinized solutions (e.g. saline or dextrose) to bathe the guidewire during insertion.

The preformed “J” guidewire will resume shape when removed from the product dispenser.



1 = Guidewire protector cap

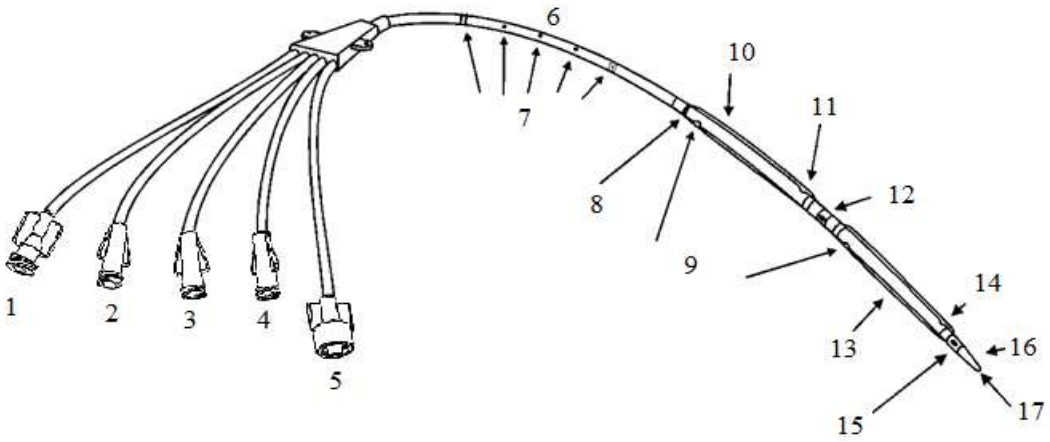
2 = Guidewire anti-migration clip

Inspection

Inspect the guidewire prior to use and discard if any deformities are present in the guidewire. Guidewire placement should be routinely monitored by x-ray or fluoroscopic procedure.

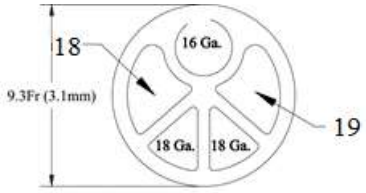
Technique

1. Puncture the vessel.
2. Insert the guidewire into the needle hub and gently advance 5-10 cm of the guidewire into the punctured vessel. Navigate the guidewire to the desired position.
3. **Caution: Avoid rough or overly vigorous manipulation of the guidewire to prevent damage to the guide or the vessel.**
4. Remove the needle from the guidewire.
5. Dilate the tissue and vessel with the dilator using a slight rotary motion.
6. Remove the dilator. (The vessel dilator is intended for vascular dilation only.)
7. Introduce the catheter by sliding it over the guidewire.
8. Remove the guidewire.



1. IN
2. Medial Infusion Lumen
3. Distal Guidewire and Infusion Lumen
4. Proximal Infusion Lumen
5. OUT
6. Radiopaque Shaft
7. Depth Markers
8. Radiopaque Marker
9. Cold Saline Return Port
10. Balloon
11. Cold Saline Supply Port
12. Proximal Infusion Lumen Side Port
13. Balloon
14. Cold Saline Supply Port
15. Medial Infusion Lumen Side Port
16. Radiopaque Tapered Soft Tip
17. Distal Guidewire and Infusion Port

Cool Line CL-2295 Catheter



18. IN
19. OUT

Catheter Cross Section

Cat No. 260103 **NDC 054365-400-08** **DIN 02160757**

ChloraPrep® Triple Swabsticks

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 5.25-mL Applicator
WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.
DO NOT USE WITH ELECTROCAUTERY PROCEDURES.

Drug Facts

Active ingredients	Purpose
Chlorhexidine gluconate 2% w/v	Antiseptic
Isopropyl alcohol 70% v/v	Antiseptic

Use for the preparation of the patient's skin prior to surgery or injection. The maximum treatment area when using three swabsticks is approximately 5 in. x 7 in.

Warnings

For external use only. Flammable: keep away from fire or flame.

Do not use with electrocautery procedures

Do not use

- in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption
- on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a physician

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- tear at notch. Pull across package to expose the ends of the swabsticks. Do not touch foam when removing swabsticks from pouch. Place foam flat side down on the treatment area.
- **dry surgical sites** (such as abdomen or arm): Use repeated back-and-forth strokes of the swabsticks for approximately **30 seconds**. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately 30 seconds. Do not blot or wipe away.
- **moist surgical sites** (such as the inguinal fold): Use repeated back-and-forth strokes of the swabsticks for approximately **2 minutes.** Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately one (1) minute. Do not blot or wipe away.
- discard the swabsticks after a single use

Other information ■ store between 20–25 °C (68–77 °F)
■ avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients ■ USP purified water

Questions? Call **1-800-523-0502** (M-F 8 a.m.–5 p.m. CST) ■ **www.chloraprep.com**

Single Use

Medi-Flex, Inc. Leawood, KS 66211

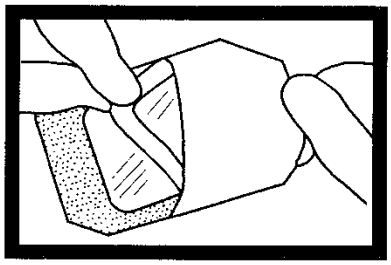
Precautions for Use
Suresite Window may be used on clinically infected wounds if the following precautions are followed:
- The patient should be under medical/clinical supervision.
- The dressing should be changed daily.
- The patient should be receiving suitable systemic treatment.

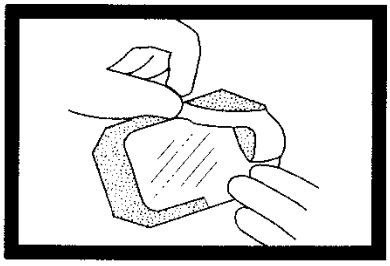
Immuno-compromised patients and diabetic patients may require extra supervision. Care should be taken to avoid skin damage from repeated applications on patients with thin or fragile skin.

Sterile. Single use. Do not use contents if package is opened or damaged. Store at room temperature, 59-86°F.

Ordering Information:

Item Number	Description	Pkg.
MSC2302	2 3/8" x 2 3/4"	100/bx
MSC2304	4" x 4 3/4"	50/bx





MEDLINE latexfree

Suresite® Window

Transparent Film Dressing

Description
Suresite® Window Transparent Film Dressing consists of a polyurethane film with acrylic adhesive. The dressing is moisture vapor permeable, thus allowing oxygen and moisture vapor to pass through the dressing. When properly applied, Suresite is impermeable to liquids and bacteria.

Indications:
Suresite dressings are intended for minor abrasions, skin tears and to help prevent skin breakdown. May also be used on pressure ulcers (stages I & II) with minimal drainage, partial-thickness wounds, clean, closed surgical incisions, first and second degree burns and for autolytic debridement. Also indicated for the management of peripheral and central I.V. catheter sites.

Contraindication:
Suresite is contraindicated for use as a primary dressing on moderately to heavily draining wounds.

Application:
1. Prepare the site according to facility guidelines. Clip any excess hair at the site. Shaving is not recommended. Allow any skin preparation to dry completely.
2. Peel the liner from the dressing, exposing the adhesive surface.
3. Position the dressing over the site. If securing over an I.V., center the slit portion of the frame over the catheter hub.
4. Gently remove the paper frame, smoothing the dressing down as you pull the frame away.
5. For I.V. catheter sites, seal the dressing around and under the catheter hub.
6. Firmly smooth dressing from the center toward the edges.
7. Date and initial the label and apply to edge of dressing if desired.

Removal:
1. Gently grasp the edge and slowly peel the dressing from the skin in the direction of hair growth or grasp one edge of the dressing and gently pull it straight out to stretch and release adhesion.
2. An adhesive solvent can be used to facilitate dressing removal.

SilvaSorb® Site Dressing

Antimicrobial Silver Percutaneous Site Dressing

PRODUCT DESCRIPTION

SilvaSorb Site Dressing is a 1" circular pad with a 4 mm center saddle and radial slit. This size and style of dressing is designed to wrap snuggly around vascular and non-vascular percutaneous devices such as IV catheters, central venous lines, arterial catheters, external fixator pins and others, providing an antimicrobial environment for up to 7 days.

SilvaSorb Site dressing is composed of super-absorbent polyacrylate and utilizes MicroLattice® patented technology to deliver antimicrobial, ionic silver continuously for up to 7 days. Easy to use, this dressing is self-regulating, requiring no wetting or rewetting to activate. It also provides broad spectrum bioburden control without cytotoxicity and no skin staining. Non-adherent material provides pain-free removal at dressing changes and is transparent to permit insertion-site visualization.

INDICATIONS FOR USE

SilvaSorb® Silver Antimicrobial is an effective barrier to bacterial penetration and is effective against a broad range of micro-organisms and may help reduce infection in partial and full thickness wounds. Suggested applications include vascular and non-vascular percutaneous sites such as:

- IV Catheters, such as PICC sites
- Central Venous Lines
- Arterial Catheters
- External Fixator pins

CONTRAINDICATIONS

- Individuals with known sensitivity to silver.

DIRECTIONS FOR USE

1. Prepare the skin surrounding the site according to facility's protocol. Be sure any skin preparations or cleansers are completely dry before the next step.
2. Remove the SilvaSorb Site dressing from the foil pouch, and peel the dressing from the blue release liner.
3. Gently wrap the round patch snuggly around the percutaneous device, placing either side of the dressing down against the skin. The two sides of the radial slit can then be brought back together and overlapped if necessary and should align beneath the device hub such as an IV Catheter. The slit edges must approximate each other to maximize efficacy.
4. Secure the catheter and SilvaSorb Site dressing to the skin with Suresite Transparent Film dressing.
5. Change the SilvaSorb Site dressing as necessary, in accordance with your facility's protocol or at a minimum of every 7 days. Dressing changes may be more frequent on highly exudating sites.
6. To remove the Suresite transparent film dressing, lift one edge and stretch the film laterally to the skin surface, while holding the catheter securely in place. Stretch, lift and peel away the dressing gently. The SilvaSorb Site dressing should lift away along with the film dressing.

STORAGE INFORMATION

- Dressings are photosensitive and will darken with prolonged exposure to light. This does not affect the performance of the dressing.
- Store at room temperature.
- Do not resterilize.
- Do not use if package is damaged or opened.
- Single patient use only.

STERILE | R

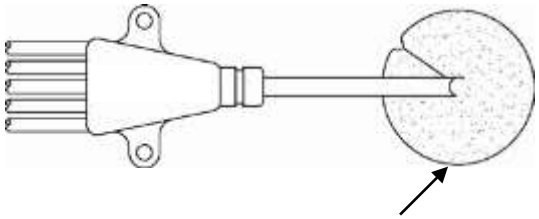
Federal law restricts this device to sale by or on the order of a physician.

REORDER INFORMATION

Item	Number Description	Pkg.
MSC9310	SilvaSorb Site Dressings 1" circular pad with 4 mm saddle and radial slit	10/bx, 6 bx/cs

www.medline.com SilvaSorb is a registered trademark of AcryMed, Inc., US Patent# 6605751. Patents Pending. Manufactured in USA for: Medline Industries, Inc., Mundelein, IL 60060 USA 1-800-MEDLINE RL04ACM

L-95



SilvaSorb