Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit
Instructions for Use
Model SL-2593 (8700-0793-01)

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

Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit includes:

Quantity	Description.
1	Solex 7 Intravascular Heat Exchange Catheter 9.3 French x 26cm Triple Infusion Luer Extension Line Clamps Radiopaque Shaft Applause Heparin Coating
2	Guidewires 0.032" (0.81 mm) x 65 cm
1	Vessel Dilator 10.5 F x 0.038" (3.6 mm x 1.0 mm)
1	Detachable Suture Tab & Clip
1	18 ga x 2 ½" (1.3 mm x 6.3 cm) Radiopaque OTN Catheter
1	000 Silk Suture
1	Chloraprep® Applicator 3 mL
6	4" x 4" (10 cm x 10 cm) Gauze Sponges
1	Retractable Scalpel
1	3 cc Syringe and 25 ga x 1" (0.5 mm x 2.5 cm) Needle
2	5 cc Syringes & 22 ga x 1 ½" (3.8 cm) Needles
1	Fenestrated Drape 40" x 62" (1 m x 1.5 m)
1	18 ga x 2 ¾" (7.0 cm) Needle
1	Needle Disposal Cup
1	SilvaSorb® Site Antimicrobial Dressing
1	SureSite Transparent Film Dressing

Device Description

The Solex 7 Catheter is a sterile, single-use, flexible 9.3 F catheter designed for placement in the superior vena cava from an insertion site in the jugular or subclavian vein. The Solex 7 Catheter serpentine balloon provides a heat exchange surface for the cooling or rewarming of the patient's blood. The serpentine balloon has a cross sectional area of 54 mm^2, which is approximately equal to the cross sectional area of an 8 mm outer diameter (OD) standard cylindrical balloon. The Solex 7 Catheter is intended for connection to a single-use, disposable Coolgard 3000®/Thermogard XP® Start-Up Kit (supplied separately) and the Coolgard 3000 or Thermogard XP System. A YSI-400 Temperature probe is required for the operation of the Coolgard 3000 or Thermogard XP. A dilator and guidewire are required for the percutaneous insertion of the Solex 7 Catheter. Three (3) ports are available for infusion and sampling.

Infusion Port	Flow Rate	Priming Volume
Proximal Port (blue)	1300 ml/hr	0.3 cc
Medial Port (white)	1300 ml/hr	0.3 cc
Guidewire Port (brown)	1900 ml/hr	0.4 cc

The Solex 7 Catheter blood contact surfaces (tip, balloon, and shaft) are treated with an anti-thrombotic Applause heparin coating.

Sterility

Ethylene oxide sterilized. The Solex 7 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 20-25ºC. Avoid freezing and excessive heat above 40ºC

Indications for Use

The Solex 7 Intravascular Heat Exchange Catheter connected to the Coolgard 3000/Thermogard XP Thermal Regulation System is indicated for use:

- In cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care *(Maximum use period: 4 days)*
- To induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care *(Maximum use period: 4 days)*
- 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. (Maximum use period: 7 days)

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. A randomized controlled trial of endovascular cooling in patients with fever associated with subarachnoid hemorrhage and primary traumatic brain injury has shown increased mortality as compared to patients receiving standard of care.

Contraindications

1. The risks of the catheter are essentially those of a central venous 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 which will not accommodate a catheter, including patients with vena cava filters or other implanted impediments to passage of the catheter.
6. Patients for whom the required temperature monitoring cannot be established.
7. Hypothermia is contraindicated in patients who have hematological diseases that will be made worse with hypothermia e.g. any disease that produces cryoglobulinemia, any hemoglobinopathy in which hemolytic anemia can be precipitated by cold including Sickle Cell Disease or Thalassemia.
8. Not intended for pediatric or neonatal use.

Warnings and Precautions

WARNING: The Solex 7 Catheter and Start-Up Kit could potentially misconnect with other devices with small bore connectors. Such connection errors could result in patient injury or death.

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

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CAUTION: The custom Luers contained on the Solex 7 Catheter and Start-Up Kit 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 Start-Up Kits to these and other medical device applications.
CAUTION: Ensure that the Solex Catheter and/or Start-Up Kit are not connected to an IV or other medical devices.

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.

USE JUGULAR OR SUBCLAVIAN VEIN APPROACH ONLY

Do not attempt to insert another catheter into the same vessel(s) as the Solex 7 Catheter if its tip will reside in the superior vena cava.

If another catheter is to occupy the same vessel(s) as the Solex 7 Catheter, you MUST

- Place both guidewires at the same time, and
- Insert the Solex 7 Catheter AFTER the other catheter to prevent entrapment of the other catheter within the serpentine balloon of the Solex 7 Catheter.

Entrapment of another catheter within the serpentine balloon of the Solex 7 Catheter should be regarded as a surgical emergency.

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.

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

1. Ensure that the Solex 7 Catheter and/or Start-Up Kit are not connected to an IV or other medical devices.
2. **Caution: The use of an introducer sheath is NOT recommended with the Solex 7 Catheter.**
3. 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.
4. 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.
5. 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.
6. Use of a syringe smaller than 10 ml to irrigate or declot an occluded catheter may cause intraluminal leakage or catheter rupture.
7. If blood is observed within the saline circuit, stop the procedure.
8. The catheter is coated with Heparin. This may induce or aggravate pre-existing Heparin induced thrombocytopenia (HIT).
9. 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.
10. All Luer-Lock connections and covers must be securely tightened to prevent air embolism or fluid or blood loss.
11. 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.
12. Passage of the guidewire into the right heart can cause dysrhythmias, right bundle branch block, vessel wall, atrial or ventricular perforation.
13. Use only sterile saline for catheter priming. It is the circulating fluid in the catheter.
14. The catheter should be routinely inspected for flow rate, security of dressing, correct catheter position and for secure Luer-Lock connection. Use centimeter markings to identify if the catheter position has changed.
15. 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 the catheter tip position.
16. For blood sampling, temporarily shut off remaining infusion ports through which solutions are being infused.
17. Use only a 30 cc or smaller syringe for blood sampling.
18. Use only the ZOLL suture tab and clip provided in the kit to prevent catheter damage.
19. Do not infuse into the orange “IN” (IN) and “OUT” (OUT) Luer-Lock connections.
20. Use care when infusing drugs that may be affected by cool temperatures (as low as 4ºC). Solutions containing mannitol are temperature-sensitive and must not be delivered through the Solex 7 Catheter except for a rapid push of a solution of up to 20% mannitol, followed by a saline flush. Higher than a 20% concentration of mannitol or a drip or infusion pump delivery of mannitol must be done via a separate line.
21. **WARNING: When connecting infusion sets/injection systems to ZOLL Catheters do not exceed 100 psi/689 kPa.**
22. For patients being made hypothermic, the hypothermia itself may exacerbate some disease states. Care should be taken to properly monitor patient homeostasis during hypothermia.
    - Cardiac rhythm disturbances – both bradycardia and ventricular tachyarrhythmia.
    - Clotting and coagulations function. Patients at risk for disturbances of their clotting or coagulation function should be closely monitored during hypothermia.

- Blood gas and pH analysis. Hypothermia modifies resting pH and $PaCO_2$. Physicians should be aware that of the effect of temperature upon the result.
- Prolonged hypothermia depresses the immune response and lung function.

WARNING: When using the Solex 7 Catheter for fever reduction, do not select a target temperature below 36.5ºC.

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).

To check the integrity of the catheter

1. Stop operation of the Coolgard 3000 or Thermogard XP System.
2. Disconnect the Start-Up Kit from the catheter and 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 this for at least 10 seconds. Approximately 4 ml of saline (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 peristaltic (roller) pump 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.

Additional warnings and cautions are located in following instructions.

Materials Required

Quantity	Description
1	Solex 7 Catheter Kit for percutaneous introduction
1	500 cc bag of sterile saline (not provided)
1	CoolGard 3000/Thermogard XP Start-Up Kit (provided separately) • 6 ft (183 cm) Standard Tubing or • 9 ft (274 cm) Extended Tubing **Note**: For convenience, a 20 or 25 cc syringe is included with the Start-Up Kit package. Hang the syringe bag on the saline hook on the Thermogard XP console until ready to use. Discard after each patient.
1	Coolgard 3000 or Thermogard XP System (provided separately)
1	YSI-400 Temperature Probe (not provided)

Catheter Preparation and Insertion

Note: The Solex 7 Catheter has radiopaque marker bands to assist in identification of the catheter during and after insertion when viewed using x-ray equipment. The tip has one marker band and contains barium sulfate to make it radiopaque. The other end of the balloon has one marker band. The proximal port is located 3.5 cm proximal to the proximal marker band.

Catheter Preparation Procedure

1. Using sterile technique remove the Solex 7 Catheter from the kit.
   Caution: Do not prime the heat exchange circuit of the Solex 7 Catheter. The heat exchange balloon is provided fully deflated. There is minimal air within the heat exchange circuit. It is not possible to force fluid through the collapsed balloon. DO NOT REMOVE THE PROTECTIVE TUBE THAT COVERS THE BALLOON UNTIL IMMEDIATELY PRIOR TO INSERTION.

   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.

   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.
2. Remove caps from the IN and OUT Luers

   WARNING: Never inject positive pressure into the IN Luer with the OUT Luer cap in place.
3. Using 5 cc or larger syringe, flush the distal, proximal and medial infusion Luers with sterile saline. Clamp or attach injection caps to the proximal and medial infusion Luers. Leave the distal Luer uncapped for guidewire passage.

WARNING: Do not cut the catheter to alter length.

Catheter Insertion:

WARNING: Use jugular or subclavian vein approach only.

1. Place the patient in a slight Trendelenburg position as tolerated to reduce the risk of air embolism.
2. Prep and drape the puncture site as required.

Caution: Always prime the catheter infusion Luers before inserting the catheter into the patient.

3. Obtain jugular or subclavian venous access using standard percutaneous techniques. Access should be maintained with a .032" (0.81 mm) guidewire. See instructions for guidewires.

   Caution: Do not use a guidewire larger than .032" (0.81 mm) with the Solex 7 Catheter.

   WARNING: Do not attempt to re-insert a partially or completely withdrawn OTN (over the needle) introducer needle from its introducer 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 cutting edge of 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 risk of possible vessel wall perforation.**

6. Remove the catheter membrane cover.

7. Thread the tip of the Solex 7 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. Continue to advance the catheter over the guidewire, placing your fingers just proximal to the balloon.

8. 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.

9. 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.

   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 infusion Luer and aspirate until a free flow of venous blood is observed. Connect the infusion Luer to the appropriate Luer-Lock line as required. The unused infusion port may be "locked" through the injection cap using standard hospital protocol. A slide clamp is provided on the tubing to occlude flow through the infusion Luer during line and injection cap changes.

    Caution: To minimize risk of damage to the tubing from excessive pressure, the clamp must be opened prior to infusing through the Luer.

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

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

13. Verify the catheter tip position by chest x-ray immediately after placement. The x-ray exam must show the catheter located in the SVC with the distal end of the catheter parallel to the vena cava wall. If the catheter tip is mal-positioned, reposition and reverify.

14. The proximal radiopaque marker indicates the proximal end of the balloons. Ensure that the balloon and proximal port reside completely in the vessel. If the catheter is mal-positioned, reposition and re-verify.

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

16. 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.

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

    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.

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

18. 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.

19. 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 (labeled "OUT") of the Solex 7 Catheter. White "ZOLL" tags are fitted loosely to the IN and OUT extension tubes to help identify them.

20. 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.

21. 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.

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

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

22. 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 as described in the system operation manual.

Disconnecting the Catheter from Coolgard 3000/Thermogard XP System

1. Stop circulating 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 Coolgard 3000/Thermogard XP System

1. Remove the Luer caps from the Luer connectors of the catheter and Start-Up Kit. Discard the Luer caps or disconnect the 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.
3. **WARNING: Failure to connect the Start-Up Kit correctly to the catheter could result in catheter failure.**
4. **WARNING: DO NOT use the IN and OUT Luer fittings for standard central line infusion ports. They are for connection to the Coolgard 3000/Thermogard XP System ONLY.**
5. 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.
6. **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

Note: For convenience, a 20 or 25 cc syringe is included with the Start-Up Kit package. Hang the syringe bag on the saline hook on the Thermogard XP console until ready to use. Discard after each patient.

1. Stop pumping saline through the catheter.
2. Place the patient in a supine position. Remove the dressing. Remove the sutures from the suture site.
3. Disconnect the Start-Up Kit from the catheter. Uncap or leave uncapped the saline IN and OUT Luers of the catheter. 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.
4. 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 starting to remove the catheter.
5. If desired, close off the catheter OUT Luer to create negative pressure for a secondary deflation of the balloon.
6. Slowly remove the catheter from the patient. Rotation of the catheter during removal may reduce resistance. As the catheter exits the site, apply pressure with a dressing impermeable to air, e.g. Vaseline gauze.
7. **WARNING: Do not remove the catheter if resistance is felt. If resistance is felt, repeat the deflation procedure 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 Solex 7 catheter is MR Conditional. A patient with this device can be scanned safely in an MR system meeting the following conditions

- Static magnetic field of 1.5 T and 3 T
- Maximum spatial gradient field 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 Solex 7 catheter is expected to produce a maximum temperature rise of 2ºC 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.

In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Solex 7 catheter when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system.

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Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit
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Model SL-2593 (8700-0793-01)

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 the 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.

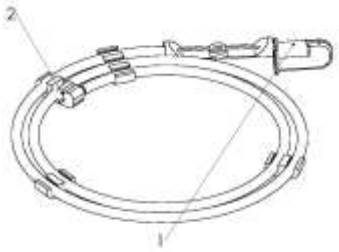
Because of the delicate and fragile nature of guidewires, extra care in handling must be taken. Avoid bending or kinking. Do not use damaged guidewires.

Sufficient guide-wire 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 its shape when removed from the product dispenser.



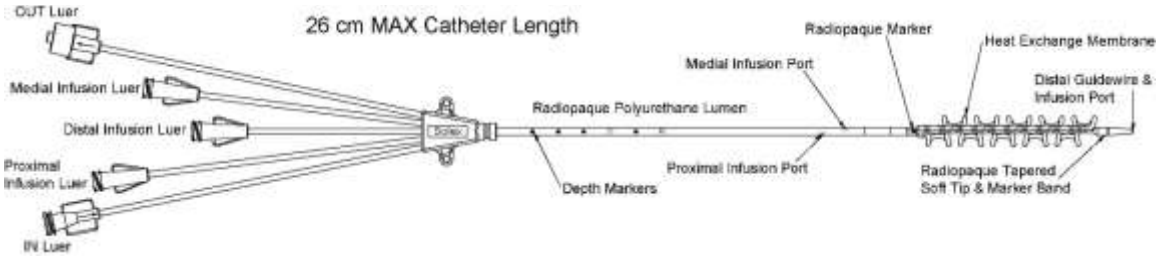
1 = Guidewire protector cap
2 = Guidewire anti-migration clip

Inspection

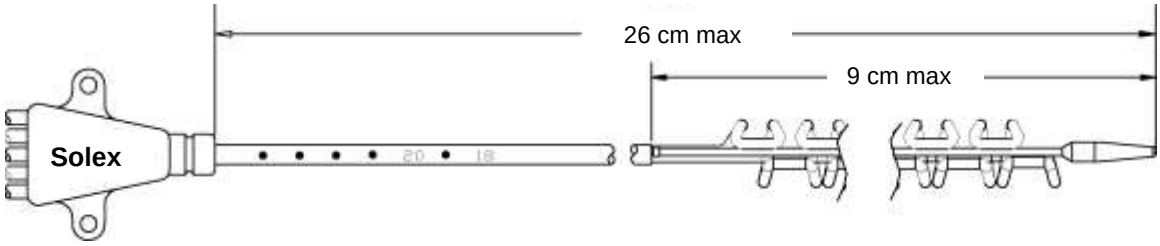
Inspect the guidewire prior to use and discard if any deformities are present in the guidewire. Guidewire placement should be routinely monitored by x-ray or fluoroscopic procedure.

Technique

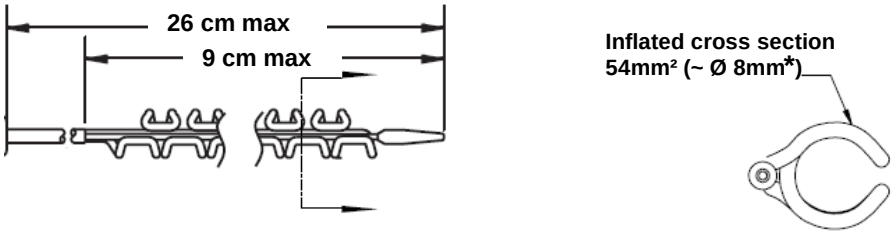
1. Puncture the vessel.
2. Insert the guidewire into the needle hub and gently advance 5-10 cm of the guidewire into the punctured vessel. Navigate the guidewire to the desired position.
3. **Caution: Avoid rough or overly vigorous manipulation of the guidewire to prevent damage to the guide or the vessel.**
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.



Solex 7 Intravascular Heat Exchange Catheter



Solex 7 Intravascular Heat Exchange Catheter Manifold and Distal Configuration



Solex 7 Intravascular Heat Exchange Catheter Serpentine Balloon and
Cross Section of the Inflated Solex 7 Serpentine Balloon.*

* The serpentine balloon has a cross sectional area of 54 mm^2, which is approximately equal to the cross sectional area of an 8 mm OD standard cylindrical balloon.

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.**

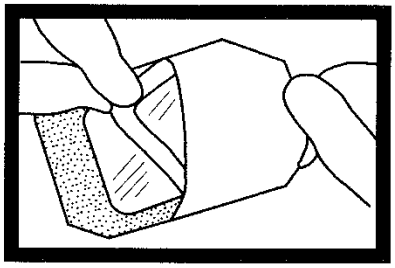
Immuno-compromised patients and diabetic patients may require extra supervision. Care should be taken to avoid skin damage from repeated applications on patients with thin or fragile skin.

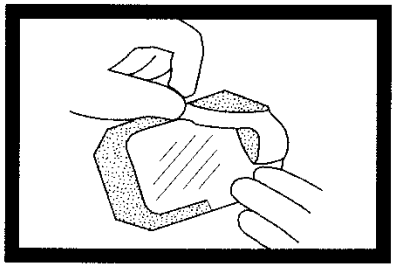
Sterile. Single use. Do not use contents if package is opened or damaged. Store at room temperature, 59-86°F.

Ordering Information:

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

Made in USA for: Medline Industries, Inc.,
Mundelein, IL 60060 USA 1-800-MEDLINE RI04PCI





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 peal 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.

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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

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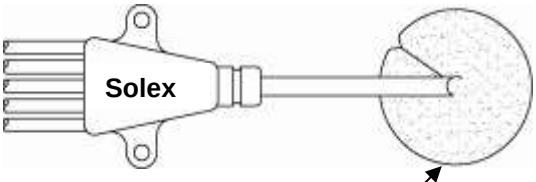

Silva Sorb Site Dressing