

JMS SysLoc® MINI A.V. Fistula / Apheresis Needle Set

Instruction For Use

INDICATIONS

READ THESE INSTRUCTIONS BEFORE USE.

SysLoc® MINI ARTERIOVENOUS FISTULA NEEDLE SET / SysLoc® MINI APHERESIS NEEDLE is indicated for use in conjunction with procedures requiring access to the blood stream. For example; hemodialysis, hemofiltration, hemodiafiltration and apheresis.

SysLoc® MINI is used as an aid in the prevention of needle stick injuries when removing the needle.

CONTRAINDICATIONS

The use of SysLoc® MINI A.V. Fistula / Apheresis Needle Set (hereinafter referred to as “SysLoc® MINI” for both A.V.Fistula Needle Set and Apheresis Needle Set) is not in itself a medical treatment.

However, contraindication may be inherent in procedures involving access to the bloodstream, generally associated with punctures by needles.

This therefore restricts this device to an order by a physician.

This device should be used as instructed by a physician.

WARNINGS AND PRECAUTIONS

- SINGLE USE**
Single use product. Do not reuse. Reuse may lead to infection or pyrogenic reactions.
- STERILITY**
The single unit packaging of the needle only assures sterility of the blood path. Needles in damaged or improperly sealed unit packages or those with detached or missing protector caps and needle covers may be non-sterile and should not be used.
- All surfaces of the needle set in contact with blood are non-pyrogenic.
- An aseptic technique is required during treatment.
DO NOT TOUCH THE NEEDLE OR THE END SURFACE OF LUER CONNECTOR.
- PERFORMING PUNCTURE**
An aseptic technique is required when preparing SysLoc® MINI for cannulation. Proper cleansing of the access area must be performed to avoid contamination during the needle insertion process.
- An aseptic technique is required to avoid contamination of the blood path when connecting the SysLoc® MINI to the bloodlines / blood collection set. During the first few minutes of operation and at several times during treatment, there should be visual inspections of the needles and connections to detect leaks and avoid blood loss.
- There may be a slight difference in the luer connectors in bloodlines / blood collection set provided by different manufacturers. These differences in size may result in possible blood leakage or separation at the connector. To guard against these possibilities, firmly join the male and female luer connectors to each other. The connection should be visible at all times for visual inspections during treatment. JMS luer lock connectors comply with ISO 594.
- LEAKS**
In spite of great care in production, leaks of fistula needles cannot be excluded absolutely. Some disinfectants may also cause material cracking. Connectors can break or crack under excessive force, resulting in blood loss or aspiration of air into the bloodlines / blood collection set. Air entering the bloodstream can cause an air embolism. Therefore, use air leak detectors at all times. For return of blood to the patient at the termination of treatment, the use of air should be avoided. All critical areas of the extracorporeal circuit / blood collection system should be visually inspected during the treatment.
- The plastics may be incompatible with drugs or disinfectants. (e.g. connectors made of polycarbonate may show cracks when in contact).
- KINKING**
During hemodialysis or other treatment, avoid kinking, twisting or occluding the tubing. Excessive pressure may damage the extracorporeal circuit / blood collection system.
- Place gauze underneath the SysLoc® MINI if a steep angle is observed after cannulating. This is to reduce or prevent possible infiltration.
- Secure Wing Sheath at the access site, prior to release of the external lock.
- Release the external lock and retract needle completely by sliding the hub within wing sheath, encapsulating the entire needle length while applying hemostatic pressure at the puncture site. Do not push the sliding hub towards the access site.
- After use, dispose of the needle immediately into a designated sharp container.
- The user should be careful to avoid accidental needle sticks.
- Do not wipe this device with disinfectant such as alcohol, which may cause loosening of connection with bloodlines / blood collection set, or may cause leakage due to device damage.
- This product contains di-(2-ethylhexyl)phthalate (DEHP). Use for children, pregnant or nursing woman only after careful risk evaluation to physician's instructions.
- SysLoc® MINI (Anti-needle stick protector)
 - Always keep fingers behind back notch of SysLoc® MINI during retraction.
 - Do not attempt to override or defeat the locking safety mechanism.
 - Once retracted, do not push hub/tube in the direction of needlepoint to project needle from SysLoc® MINI.
 - After use, hold SysLoc® MINI with needlepoint upward to prevent blood dripping, and immediately discard the device into a designated sharps container.

REACH information

This product contains DEHP in concentrations > 0.1 mass % according to article 33 and 59 (1, 10) of regulation (EG) Nr. 1907/2006 (“REACH”).

IMPORTANT NOTICE

- STORAGE**
SysLoc® MINI should be stored in the original shipping carton, and in clean, dry and cool location (5°C~30°C, 20% to 80% relative humidity).
PROTECT FROM WETNESS. DO NOT EXPOSE DIRECTLY TO THE SUN.
- SHELF LIFE**
Sterility of the SysLoc® MINI is guaranteed for 60 months. It is necessary to store properly in the original packaging. The expiration date is printed on unit packs and carton labels. The product should be used according to the principle “first-in-first out” (FIFO).

DIRECTIONS FOR USE

- This device should be used aseptically in order to maintain sterility.
- Cleanse the venipuncture access area thoroughly to prevent contamination.
- Follow the open instructions provided. Visually inspect for defects on needle after removing from pack. The caps should remain intact and firmly attached.
- Do not unlock the device prior to cannulation because it is difficult to lock back if it is not centered properly. Visual inspection of locking mechanism should be done prior to cannulation. Tug slightly on the tubing to ensure that the lock is engaged.

- The needle may be flushed with saline (saline may be heparinized).
- At patient's request, local anaesthesia may be used. With a tourniquet applied proximal, select a suitable puncture area.
- Securely fold the wings to obtain a firm grip.
 - Back eye type needles: The hole functions as an additional flow channel to permit sufficient flow rate.
 - Rotating hub type: The black dot on the hub indicates bevel facing up and the red dot indicates down.
- Insert the needle smoothly into the vessel (insert angle 25°~ 45°). If two needles are to be used, it is recommended to place the arterial needle first and then the venous needle. To prevent recirculation, the venous needle must always be at least 15mm downstream from the arterial needle.
- Gently guide the needle into the blood vessel to achieve secure placement.
- Observe pulsation of blood. Clamp the tube.
- Ensure all air is purged from the needle tubing prior to connection.
- Secure the needle alignment and fix wing with tape. Regardless of taping method the needle entry site should remain visible.
- Detach the connector cap and connect to the bloodline / blood collection set aseptically. Do not connect the arterial bloodline to the venous needle and vice versa.
- Needle positions and all connections must be checked carefully prior to and during the first few minutes of operation. During treatment, connections and puncture sites should be visually inspected periodically to detect leaks and avoid blood loss.
- Ensure SysLoc® MINI device and bloodline are properly secured on patients via taping. Avoid taping on patient's clothing and covering of access site by pillow or blanket that may result in entanglement with the device, leading to dislodged needle or loose connection.
- Upon completion of treatment, the operation of SysLoc® MINI safety feature can be activated.
- Secure Wing Sheath at the access site, prior to release of the external lock.
- Release the external lock and retract needle completely by sliding the hub within wing sheath, encapsulating the entire needle length while applying hemostatic pressure at the puncture site. Do not push the sliding hub towards the access site.
- An audible clicking sound is heard or locking force is felt when the needle is fully retracted into the final lock position.
- Discard the device into designated sharps container.
- Refer to pictorial illustration on the operation of SysLoc® MINI safety device.

CAUTION:

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.



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Description of Symbols

 Order Number	 Batch
 Date of Manufacture	 Expiry Date
 Sterile, Sterilized by Ethylene Oxide (ETO)	 Single Use Only
 Manufacturer	 Refer to Instruction for Use
 Authorised representative in the European community	 Keep away from sunlight
 Keep dry	 Units
 Do not use if package is damaged	 Contains phthalate (DEHP)

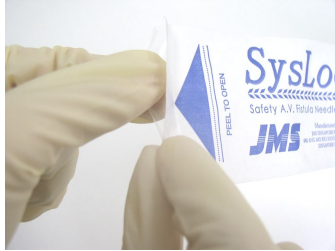
Revision date : 29-07-2010

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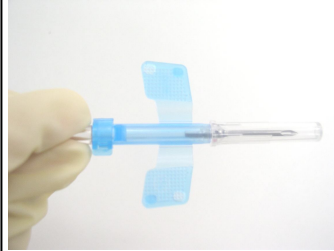
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JMS SysLoc® MINI Safety Feature Operation Manual

Unit Pack Opening & Visual Inspection



Step 1:
Follow open instructions when removing the set from the unit pack.

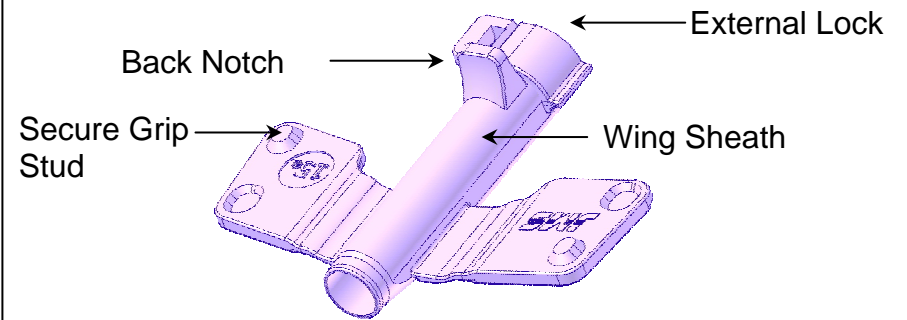


Step 2:
Visually inspect for defects on needle after removing from pack.

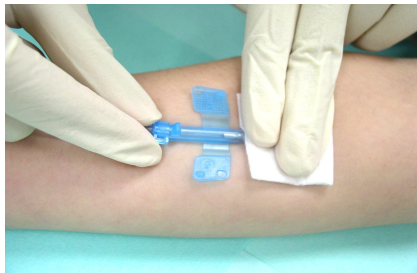


Step 3:
Remove needle cover carefully without damaging the needle tip.

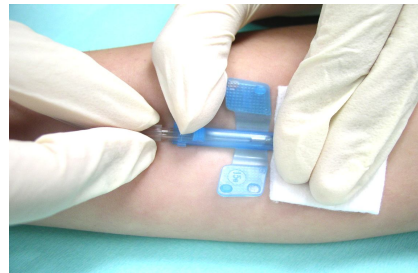
WING ANNOTATION



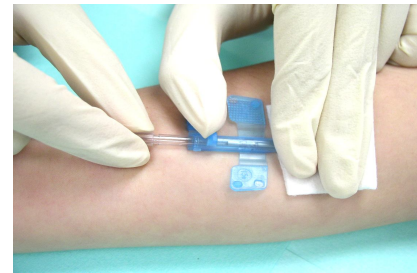
Two-hand Technique



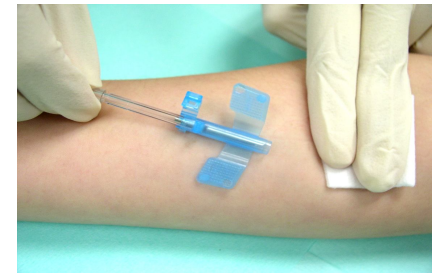
Step 1:
Release the external lock by pinching the lock and the back notch between thumb and index finger.



Step 2:
Place both the index and middle finger on the gauze, and the thumb behind the back notch.

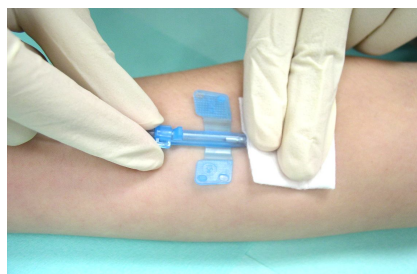


Step 3:
Grasp the tubing with the other free hand. Retract the needle into the hub. Stop pulling when an audible 'click' sound is heard.

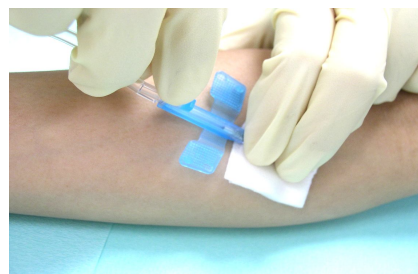


Step 4:
Remove device from the puncture site. Needle is completely encapsulated within the wing sheath and ready for disposal.

One-hand Technique



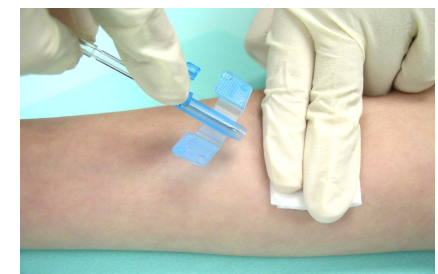
Step 1:
Release the external lock by pinching the lock and the back notch between thumb and index finger.



Step 2:
Place both the index and middle finger of one hand on the gauze and the index finger of the other hand behind the back notch.



Step 3:
Grasp the tubing with the thumb and middle finger. Retract the needle into the hub. Stop pulling when an audible 'click' sound is heard.



Step 4:
Remove device from the puncture site. Needle is completely encapsulated within the wing sheath and ready for disposal.