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

READ THESE INSTRUCTIONS BEFORE USE.

INDICATIONS

Use for temporary cannulation non-implantable (less than 30 days) to vascular access for extra corporeal blood treatment. The device is intended for single use only and has an anti-stick feature integrated as part of the Needle Set which aids in prevention of needle-stick injuries.

CONTRAINDICATIONS

The use of SysLoc® MINI A.V. Fistula / Apheresis Needle Set (hereinafter referred to as "SysLoc® MINI" for A. V. Fistula / Apheresis Needle Set) is not in itself a medical treatment.
However, contraindication may exist for these procedures in which access to the bloodstream, generally associated with punctures by needles or in conjunction with extracorporeal circuit.
This therefore restricts the use of this device by order of and as instructed by a physician.

WARNINGS AND PRECAUTIONS

1. SINGLE USE
   SysLoc® MINI is intended for single use only. DO NOT REUSE. Reuse may lead to infection or pyrogenic reactions.
2. STERILITY
   The single unit packaging of the needle only assure 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.
3. All surfaces of needle set in contact with blood are non-pyrogenic.
4. Aseptic technique is required during treatment.
   DO NOT TOUCH THE NEEDLE AND THE END SURFACE OF LUER CONNECTOR.
5. PERFORMING VENIPUNCTURE
   Aseptic technique is required when preparing SysLoc® MINI for venipuncture.
   Proper cleansing of the vessel access area must be performed to avoid contamination during the needle insertion process.
6. Aseptic technique is required to avoid contamination of the blood path when connecting the SysLoc® MINI to the blood line / blood collection set.
   During the first minute 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.
7. There may be a slight difference in the luer connectors in blood line / 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. Taping assures connection. The connection should be visible at any time for visual inspection during treatment. JMS luer lock connectors comply with ISO 594.
8. LEAKS
   In spite of great care in production, leaking from fistula needles cannot be excluded absolutely. Some disinfectants also may cause material cracks. Connectors break or crack under excessive force. These damaged parts may result in blood loss or aspiration of air into the blood line / blood collection set. Air entering the bloodstream can cause an air embolism. Therefore, use air leak detectors at all time. For return of blood to the patient at the termination of treatment, the use of air should be avoided at all critical areas of the extracorporeal circuit / blood collection system. The system should be visually inspected during the treatment.
9. The plastics may be incompatible with drugs or disinfectants. (e.g. connectors made of polycarbonate may show cracks when in contact.)
10. KINKING
    During hemodialysis or any other treatment, avoid kinking, twisting or occluding of tubing. Excessive pressure may damage the extracorporeal circuit / blood collection system.
11. Place gauze underneath the SysLoc® MINI if a steep angle is observed after cannulating. This is to reduce or / and prevent possible infiltration.
12. Since exposure to blood and blood by-products carries the risk of transfer of infectious disease, for example Hepatitis and HIV, the person performing the venipuncture procedure should avoid direct contact with the patient's blood. Personal protective equipment should be utilized routinely.
13. Secure Wing Sheath at the access site, prior to release of the external lock.
14. 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.
15. After use, exercise caution during disposal of the needle assembly into sharps container to protect against infectious diseases for all concerning persons.
16. User disposing the needles should be careful to avoid accidental needle sticks.
17. Do not wipe this device with disinfectant such as alcohol, which may cause loosening of connection with blood line / blood collection set, or may cause leakage due to device damage.
18. Ensure compatibility with all external devices before usage.
19. 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 the designated sharps container.
20. This product contains di-(-2-ethylhexyl)phthalate (DEHP). Use for children, pregnant or nursing woman only after careful risk evaluation to physician's instructions.

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

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 products should be used according to the principle "first-in-first out".

DIRECTION FOR USE

1. This device should be used aseptically in order to maintain sterility.
2. After thoroughly cleansing the vessel area for puncture, carefully disinfect the site assuring the venipuncture area is not contaminated.
3. When the needle is removed from the unit pack it should be inspected for gross damages or particles in the lumen. The luer cap should be checked and tightened. The needle cover should be carefully removed to avoid touch contamination of the needle.
4. 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.
5. The needle may be flushed with saline (saline may be heparinized).
6. At patient's request, local anaesthesia may be used. With a tourniquet applied proximal, select a suitable puncture area.
7. 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.
8. Insert the needle smoothly into the blood vessel (insert angle 25º~ 45º). 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.
   [Single needle type is punctured one time.]
9. Gently guide the needle into the blood vessel to achieve secure placement.
10. Observing pulsation of blood, fill the tube with blood and saline. Clamp the tube.
11. All air in the products should be eliminated entirely.
12. Secure the needle alignment and fix wing with tape. Regardless of taping method the needle entry site should be remain visible.
13. Detach the connector cap and connect with blood line / blood collection set aseptically. Do not connect the arterial blood line with the venous needle and vice versa.
14. Needle positions and all connections must be checked carefully prior to and during the first minutes of operation. During treatment, connections and puncture sites should be visually inspected periodically to detect leaks and avoid blood loss.
15. Ensure SysLoc® MINI device and blood line 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.
16. Upon completion of treatment, the operation of SysLoc® MINI safety feature can be activated.
17. Secure Wing Sheath at the access site, prior to release of the external lock.
18. 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.
19. An audible clicking sound is heard or a locking force is felt when the needle is fully retracted into the final lock position activating the final locking mechanism.
20. Discard the device into designated sharps container.
21. Refer to pictorial illustration on the operation of SysLoc® MINI safety device.

DISCLAIMER

JMS Singapore is neither liable nor responsible for any failure of the needle set where such failure may occur in whole or in part due to any misuse or modification of the set or its operation, including, and without limitation:

a. failure to have fully-trained and qualified persons performing all operating procedures;
b. failure to use the set with compatible equipment, such as tubing sets or other medical devices;
c. failure to comply in accordance with the precautions, warnings, and instructions contained in this document at all times;
d. needle reuse or use with reused blood line / blood collection set.

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	
REF — Catalogue number	LOT — Batch code
Date of Manufacture	Use-by date
STERILE EO — Sterilized using ethylene oxide	Do not re-use
Manufacturer	Caution
EC REP — Authorized representative in the European Community	Keep away from sunlight
Keep dry	Units
Do not use if package is damaged	PHT/DEHP — Contains phthalate (DEHP)
Consult instructions for use	STERILE EO — Sterilized using ethylene oxide with fluid path

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Revision : D

JMS SysLoc® MINI Safety Feature Operation Manual

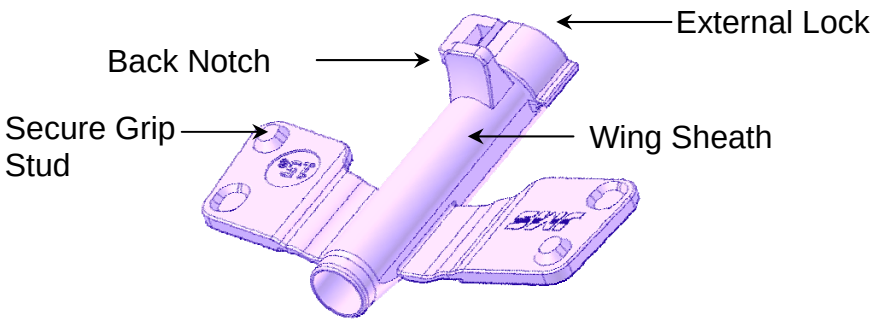
Unit Pack Opening & Visual Inspection

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

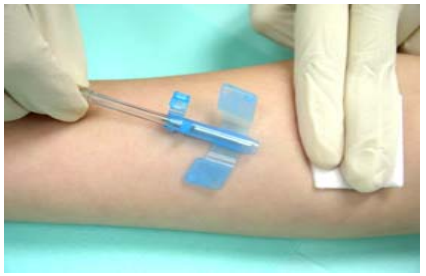


Two-hand Technique

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.

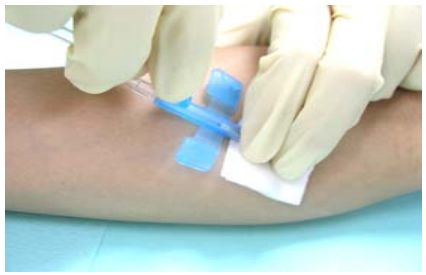
Step 3:
Grasp the tubing with the other free hand. Retract the needle into the hub. Stop pulling when an audible 'click' sound is heard.



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

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 into designated sharp container.