INDICATIONS
READ THESE INSTRUCTIONS BEFORE USE.
SysLoc® MINI ARTERIOVENOUS NEEDLE SET / SysLoc® MINI Apheresis Needle Set is indicated for use in conjunction with procedures requiring access to the blood stream. For example: hemodialysis, hemofiltration, hemodiafiltration and apheresis.

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.

WARNINGS AND PRECAUTIONS
1. SINGLE USE
   Single use product. Do not re-use. Re-use may lead to infection or pyrogenic reactions.
2. STERILITY
   The single unit packing of the needle only assures sterility of the blood path. Needles in damaged or improperly sealed unit packages or those with detached or missing protective caps and needle covers may be non-sterile and should not be used.
3. All surfaces of the needle set in contact with blood are non-pyrogenic.
   DO NOT TOUCH THE NEEDLE OR THE END SURFACE OF LUER CONNECTOR.
5. 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.

6. 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.

7. 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.

8. LEAKS
   In spite of great care in production, leaks of fistula needles cannot be excluded absolutely. Some disinfectants may also cause material cracking. (e.g. connectors made of polycarbonate may show cracks when in contact).

9. KINKING
   During hemodialysis or other treatment, avoid kinking, twisting or occluding the tubing. Excessive pressure may damage the extracorporeal circuit / blood collection system.

10. Place gauze underneath the SysLoc® MINI if a steep angle is observed after cannulating. This is to reduce or prevent possible infiltration.

11. Secure Wing Sheath at the access site, prior to release of the external lock.

12. 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.

13. After use, dispose of the needle immediately into a designated sharp container.

14. The user should be careful to avoid accidental needle stick injuries.

15. Do not use if package is damaged.

16. This product contains di-(2-ethyl hexyl)phthalate (DEHP). Use for children, pregnant or nursing woman only after careful review to physician’s instructions.

17. The needle may be flushed with saline (saline may be heparinized).

18. At patient’s request, local anaesthesia may be used. With a tourniquet applied proximal, select a suitable puncture area.

19. 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. Tag slightly on the tubing to ensure that the lock is engaged.

20. Do not push hub/tube in the direction of needlepoint to project needle from the body.

21. After use, hold SysLoc® MINI with needlepoint upward to prevent blood dripping, and discard the device into a designated sharps container.

22. Reference 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.
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.

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.

This information is not medical advice and is not intended to supplement or replace the advice or information provided by a physician or clinic procedures. Follow your clinic’s policies regarding cannulation and access care.