



The SureSet™ Peripheral IV Device

Instructions for Use

Trademarks and Copyright

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Patent 9,878,129 SSIV-26

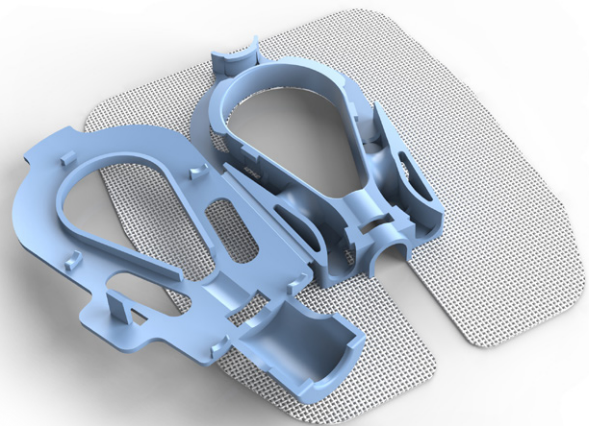
Manufacturer

The SureSet™ Peripheral IV is manufactured by:
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IMPORTANT: Carefully read and understand all instructions, indications, warnings and precautions and directions for use prior to using the SureSet™ Securement device. Failure to do so could result in compromised patient safety, patient complications and/or insufficient treatment.

SSIV-7-1-US-IF-30NOV21





The SureSet™ Peripheral IV Device

Intended use:

The device creates a streamlined step-by-step standard system to reliably stabilize the IV catheter and organize the infusion tubing. The arrangement of the tubing in the SureSet device forms a loop configuration, with multiple areas of tension strain relief, effectively securing the indwelling catheter and IV tubing so that it does not advance or withdraw. It allows care teams to confidently and consistently secure the IV catheter and arrange the tubing, while also allowing easy access to the catheter hub and tube set.

Contraindications:

Known tape or adhesive allergies.

Safety considerations:

Single use only.

Discard if package is damaged.

Training:

MedicaMetrix requires provider training specific to the SureSet Peripheral IV prior to use.

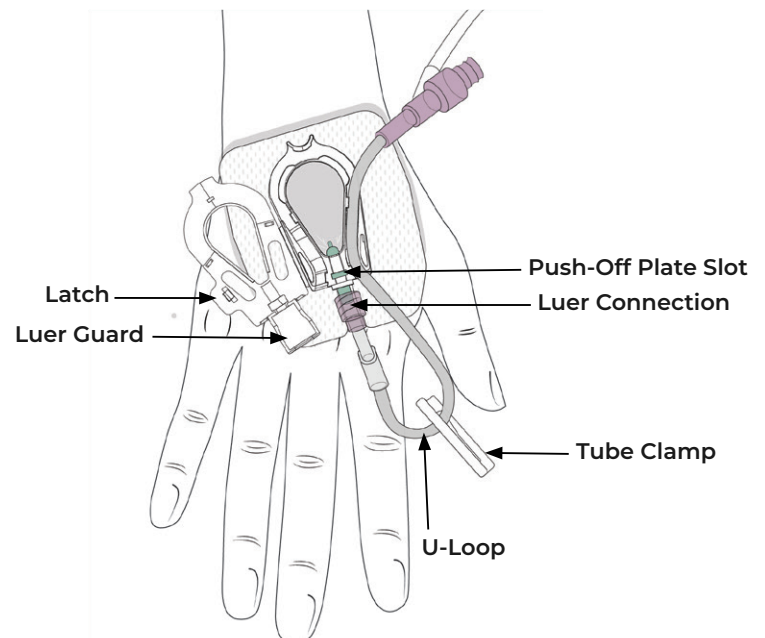
Familiarity with IV procedures:

Users should be familiar with IV procedures and techniques for inserting and managing catheter sites.

Key usage points:

- Prepare the skin: cleanse skin with alcohol wipe and allow to dry completely.
- Affix the device as described on page 4.
- To access the IV tubing, place finger under clasp and lift to open the cover of the SureSet device.
- Remove any residue of the dressing pad adhesive with alcohol after removing the device.
- Remove the device as described on page 4.
- Discard after use.

Device overview:



This section contains important safety information. MedicaMetrix requires that you read and understand all warnings, cautions, precautions and the operator’s manual prior to using the SureSet Peripheral IV.

Warnings and precautions:

- Do not use the device where loss of adhesive could occur, such as non-adherent skin or confused patient.
- Respect infection control guidelines during application and removal of the device, wash hands before use.
- Minimize catheter or tubing manipulation during application and removal of the device.
- Remove any oil and moisturizer from the targeted skin area before application.
- The device and the surrounding area should be routinely inspected.
- The device should be replaced at least every 4 days.
- Use an aseptic technique for application and removal of the device.
- This is a single use device. If reused, the adhesive may not maintain its performance, causing the device to loosen from the skin.
- In case of device loosening or malfunction, the device should be removed and replaced.
- Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury.

Incidents should be reported to the manufacturer.

The following symbols may appear in this manual, on the SureSet device and on the SureSet packaging. Some of the symbols represent standards and compliances associated with the SureSet Peripheral IV device and its use.



Warning



Keep dry



Quantity



Caution



Single use



Consult instructions for use



Date of Manufacture



Do not use if package is damaged



Manufacturer

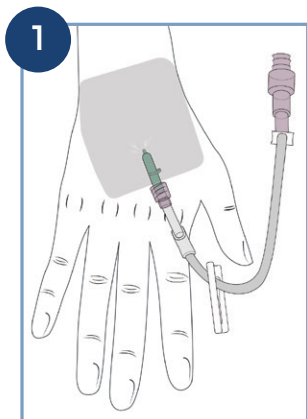


Catalog Number

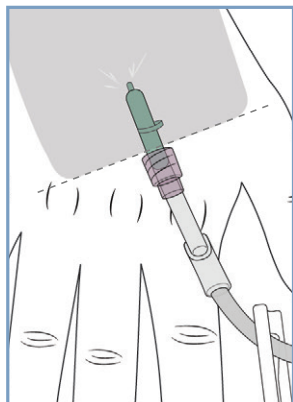


Lot Number

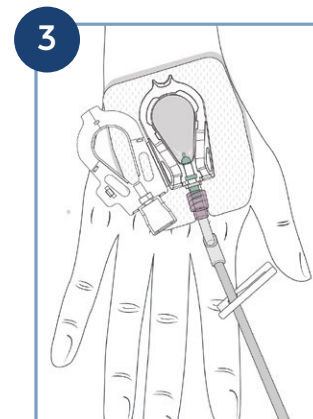
Instructions for Use



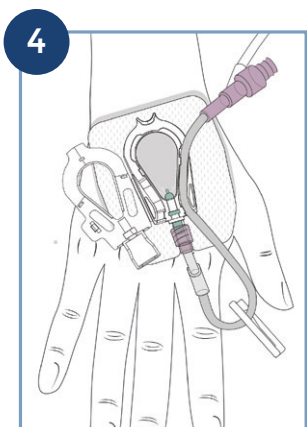
1 Place the protective dressing over the IV catheter hub. Do not cover the Luer connection with the protective dressing.



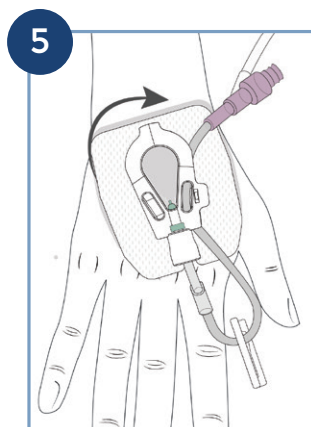
2 Peel off the adhesive cover to reveal adhesive strip on underside of SureSet.



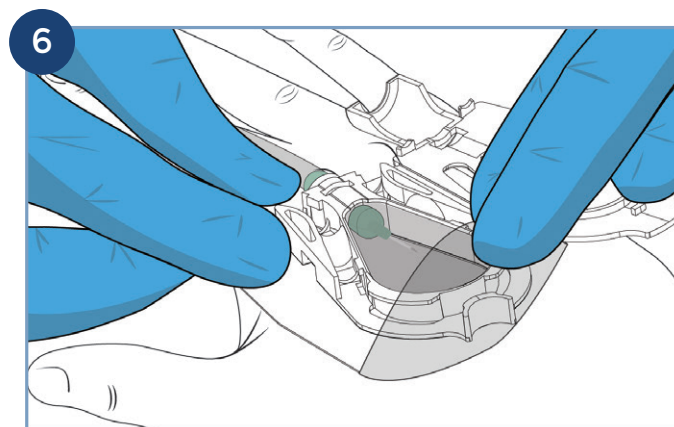
3 Place the device.



4 Press and secure tubing into the side channel.

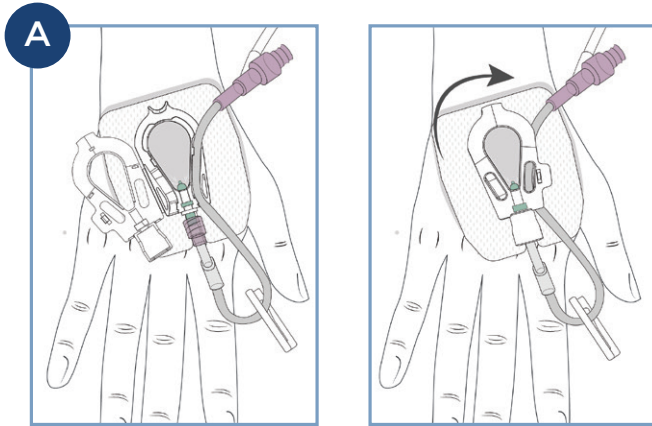


5 Close the device cover. You may hear a click as the device locks.



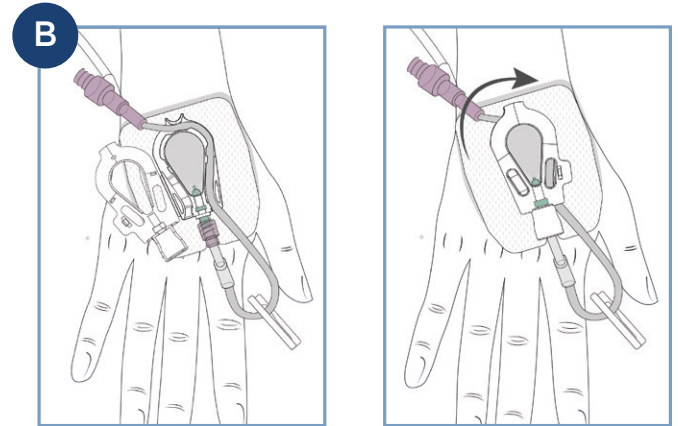
6 To remove, open the cover, gently remove tubing from channel. While holding the catheter in place, peel the protective dressing off the skin. Dispose of device according to hospital protocol.

Additional Configurations



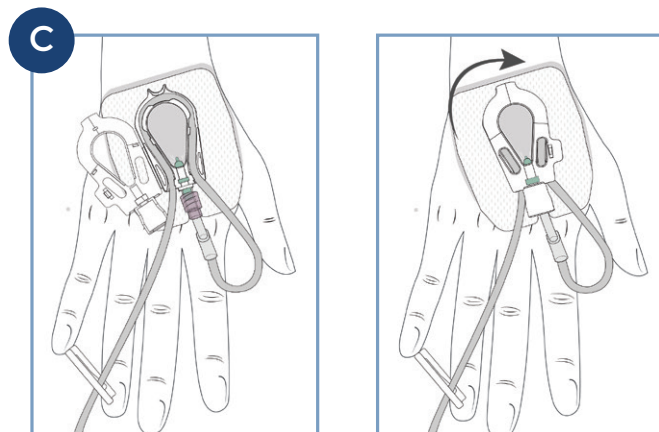
Configuration A

Standard configuration as shown on previous page.



Configuration B

The IV tubing can be directed to the opposite side of the apex bumper to route the tubing in parallel with the catheter flow.



Configuration C

If desired, the tubing can be looped around and configured to exit through the opposite channel.