SURESET™
SECUREMENT

SureSet™
Loop IV Securement Device (Paediatric)

Instructions for Use

Manufactured for:
Alera Medtech LLC
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Auburndale, MA 02466

To report any quality issues or concerns, please contact us at:
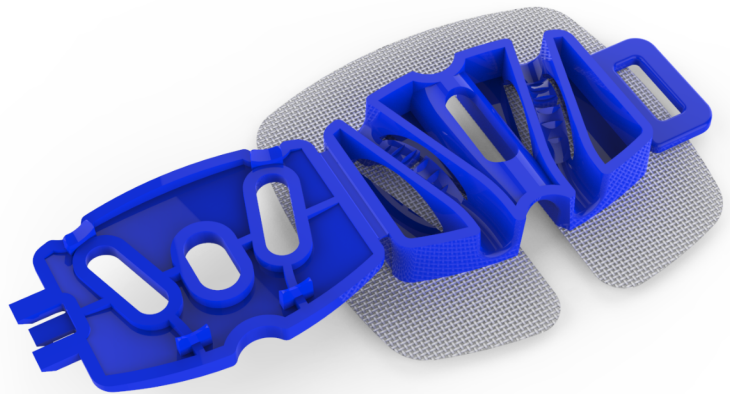
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IMPORTANT: Carefully read and understand all instructions, indications, warnings and precautions and directions for use prior to using the SureSet™ Securement device. Failure to do so could result in compromised patient safety, patient complications and/or insufficient treatment.

Trademarks and Copyright
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Patent 9,878,129

SureSet™
Loop IV Securement Device Adult (Paediatric)

Intended use The device is intended to secure a range of compatible IV catheters including but not limited to peripheral IV to reduce catheter movement and help prevent unintentional dislodgement.
Tubing – 16G to 30G

Contraindications
Known tape or adhesive allergies.

Safety considerations
Single use only.
Discard if package is damaged.
This device is latex free.

Training Alera offers SureSet Loop IV training for users prior to use. Use the QR code on page 1 to view the training.
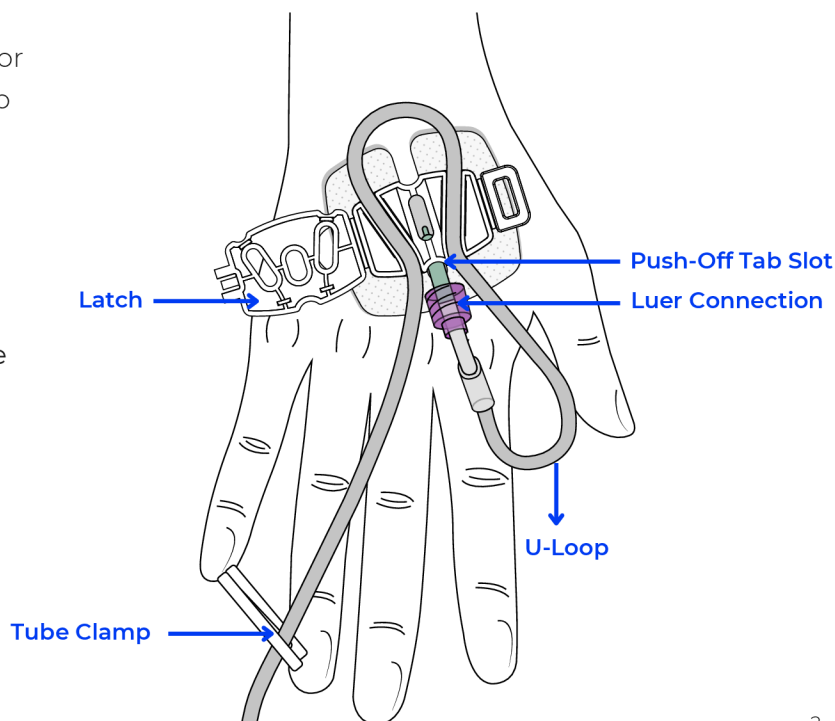
Familiarity with IV procedures
Users should be familiar with IV procedures and techniques for vascular access device care and management.

Key usage points
• Prepare the skin: cleanse skin with antiseptic 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 5.

• Discard after use.

Device overview

Latch
Push-Off Tab Slot
Luer Connection
U-Loop
Tube Clamp

This section contains important safety information. Please read and understand all warnings, cautions, and instructions for use prior to using the SureSet Loop IV Securement Device.

⚠ Warnings

•Donot use the device where loss of adhesive could occur, such as non-adherent skin or confused patient.
•Use an aseptic technique for application and removal of the device. •Incase of device loosening or malfunction, the device should be removed and replaced.
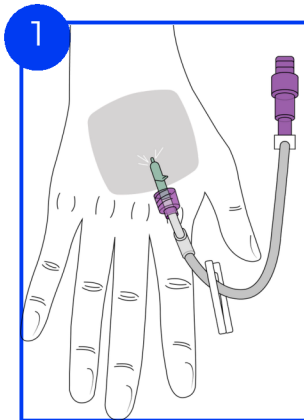
⚠ Cautions

• Read all package insert warnings, precautions, and instructions prior to use.
• The device and the surrounding area should be routinely inspected.
• Minimize catheter or tubing manipulation during application and removal of the device.
• Remove any oil and moisturizer from the targeted skin area before application.
• Respect infection control guidelines during application and removal of the device, wash hands before use.
• This is a single use device. Do not reuse. If reused, the adhesive may not maintain its performance, causing the device to loosen from the skin.

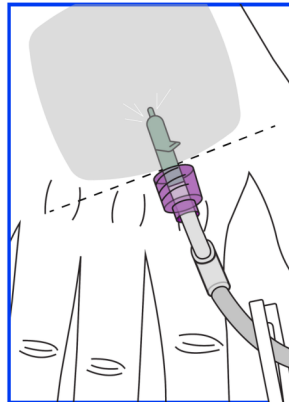| Incidents should be reported to the manufacturer. |
| --- |

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

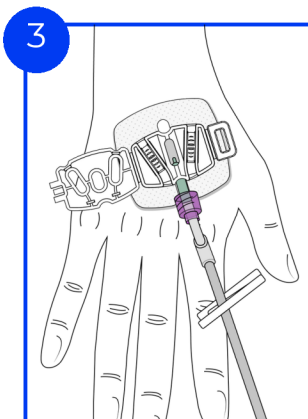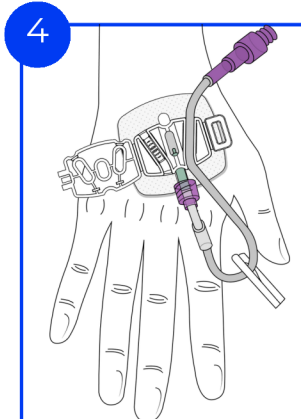|					
⚠	Warning	☂	Keep dry	⚖	Quantity
⚠	Caution	②	Single use	📖	Consult instructions for use
Date of Manufacture		Do not use if package is damaged		Manufacturer	
REF	Catalog Number	LOT	Lot Number	STERILE EO	Device is sterile

Instructions for Use

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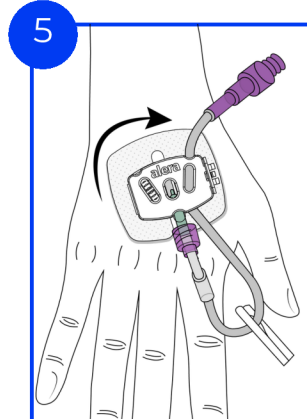

2 Peel off the adhesive cover to reveal adhesive strip on underside of SureSet.

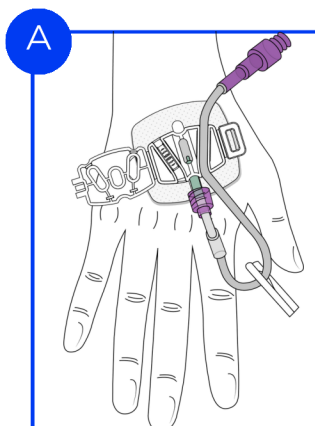**3** Place the device over the protective dressing, ensuring it adheres securely.
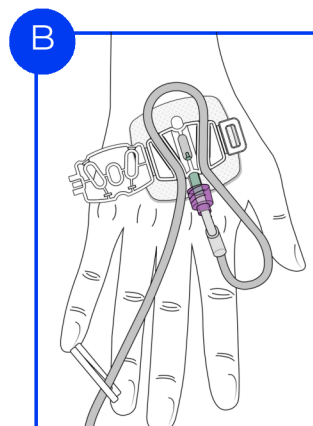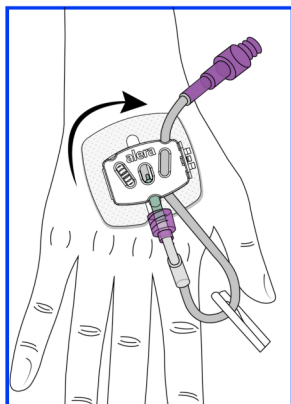

4 Press and secure tubing into the side channel.

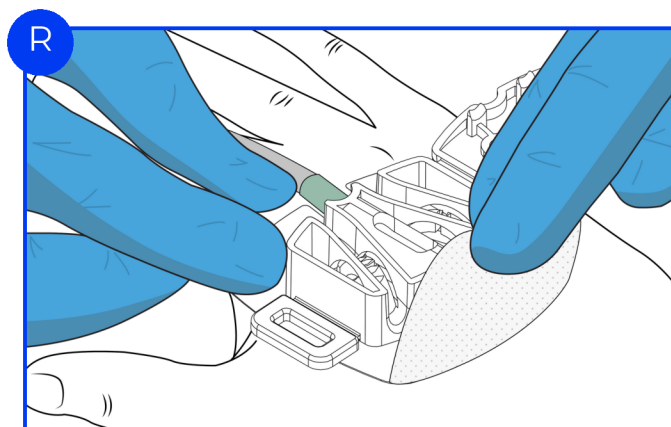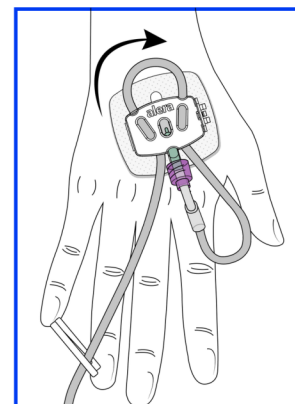**5** Close the device cover. Make sure it closes securely.

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.

Device Removal To remove, open the cover, gently remove tubing from the channel. While holding the catheter in place, peel the protective dressing off the skin. The catheter, protective dressing and SureSet device may then be removed in one motion. Dispose of device according to hospital protocol.