sureset™
SECUREMENT

SureSet™
Foley Catheter Securement Device

Instructions for Use

Manufactured for:
Alera Medtech LLC
77 Rowe Street, Suite 2C
Auburndale, MA 02466

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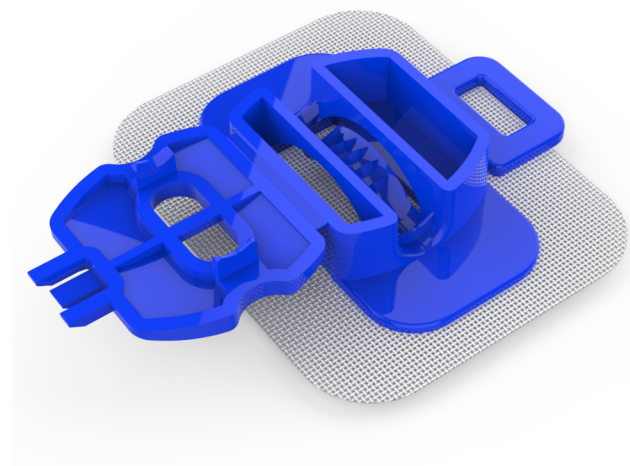
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IMPORTANT: Carefully read and understand all instructions, indications, warnings and precautions and directions for use prior to using the SureSet™ Securement device. Failure to do so could result in compromised patient safety, patient complications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

Trademarks and Copyright

SureSet™
Foley Catheter Securement Device

Intended use The device is intended to secure a Foley catheter to the patient's skin to reduce catheter movement and prevent accidental traction or dislodgement.
Tubing – 14Fr to 18Fr

Contraindications
Known tape or adhesive allergies.

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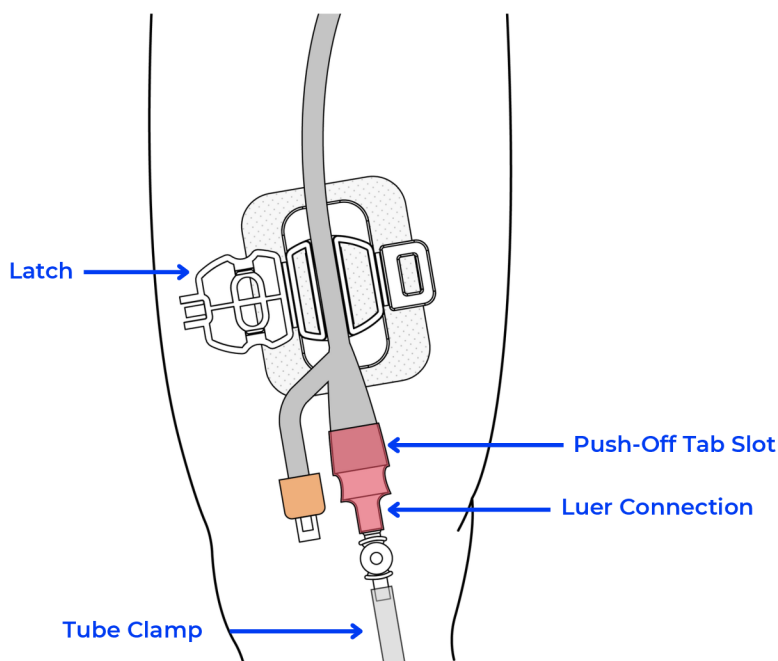Single use only.
Discard if package is damaged.
This device is latex free.

Training Alera offers SureSet Foley Securement Device training for users prior to use. Use the QR code on page 1 to view the training.

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 Foley catheter tubing, place finger under clasp and lift to open the cover of 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

Tube Clamp

This section contains important safety information. Please read and understand all warnings, cautions, and instructions for use prior to using the SureSet Foley Catheter 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.
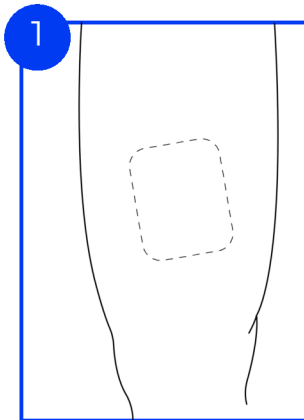
⚠ Cautions

• 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 Foley Catheter and its use.

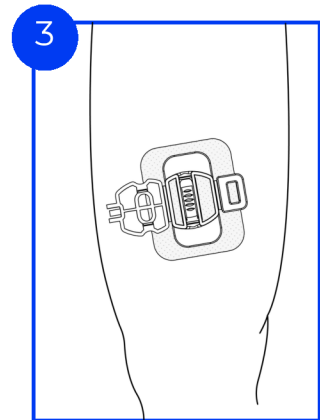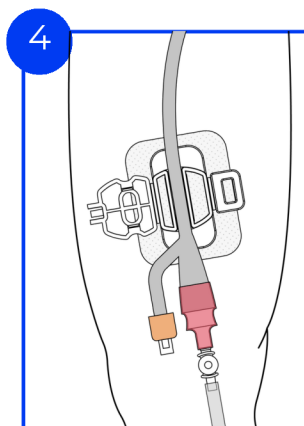|					
⚠	Warning	☂	Keep dry	⚖	Quantity
⚠	Caution	Ⓧ	Single use	📖	Consult instructions for use
	Date of Manufacture		Do not use if package is damaged		Manufacturer
REF	Catalog Number	LOT	Lot Number	STERILE EO	Device is sterile

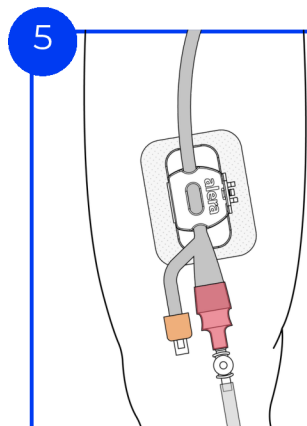1 Clean the site where the device will be affixed

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

3 Place the device over the patient site ensuring it adheres securely
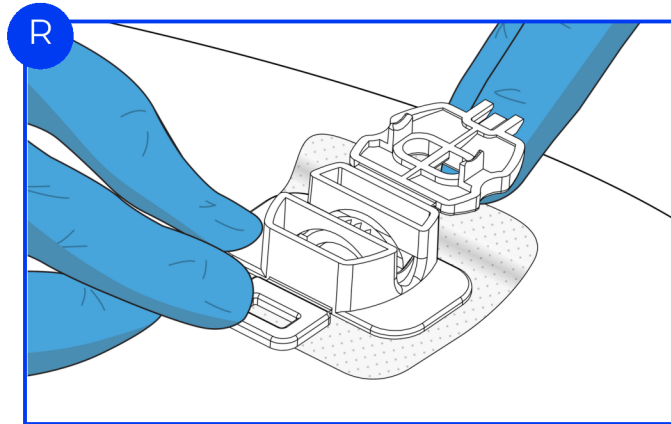

4 Press and secure tubing into channel in the device

5 Close the device cover.Make sure it closes securely

Foley Step Device Removal

Device Removal To remove, open the cover, gently remove tubing from the channel. Peel the SureSet device gently off the skin. Dispose of device according to hospital protocol