



SureSet™ Foley Catheter Securement Device

Instructions for Use

Manufactured for:

Alera Medtech LLC
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USA

Made in India
CDSCO License Number: MFG/MD/2023/001035

To report any quality issues or concerns,
please contact us at:

+1 (888) 70ALERA

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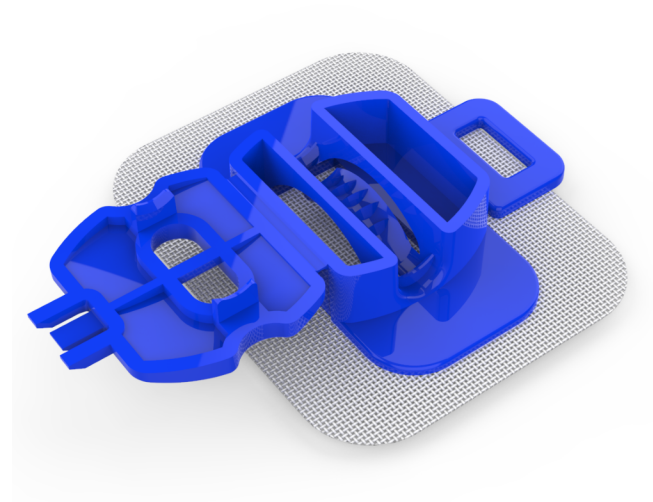
customerservice@alera-medtech.com

www.suresetsecure.com

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 US 2025/0065034 A1



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website to
learn more

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

Safety considerations

Single use only.

Discard if package is damaged.

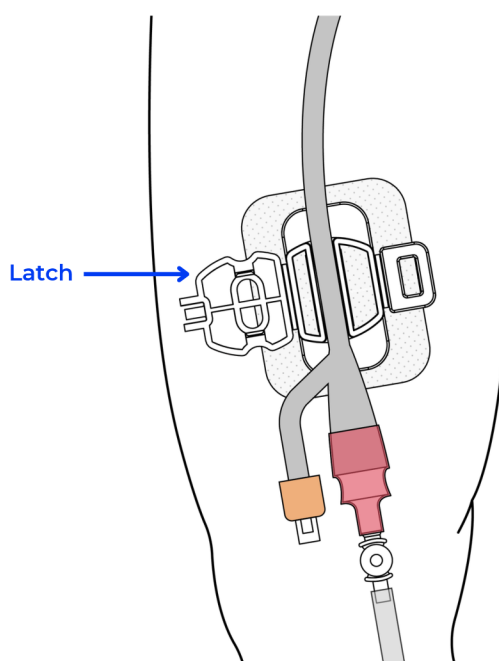
Training

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

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



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

Warnings

- Do not use the device where loss of adhesive could occur, such as non-adherent skin or confused patient.
- Use aseptic technique for application and removal of the device.
- In case of device loosening or malfunction, the device should be removed and replaced.

Precautions

- Read all package insert warnings 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.
- The Foley securement device is to be used with 500ml bags or smaller.

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



Catalog Number

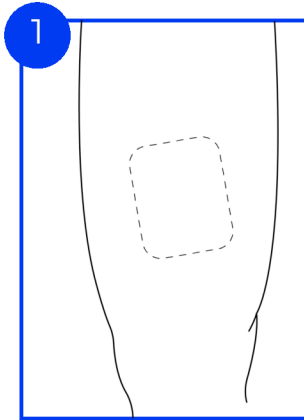


Lot Number



Device is sterile

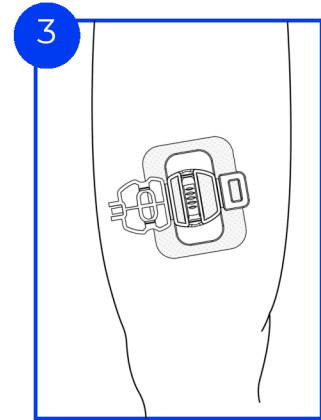
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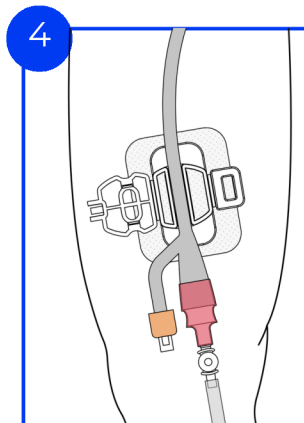
1
Clean the site where the device will be affixed



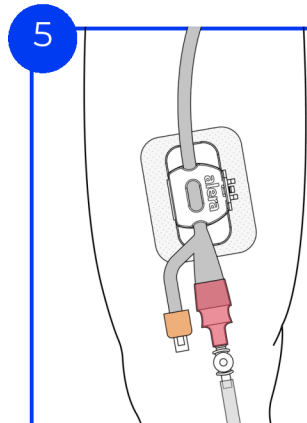
2
Peel off the adhesive cover to reveal adhesive strip on underside of SureSet.



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

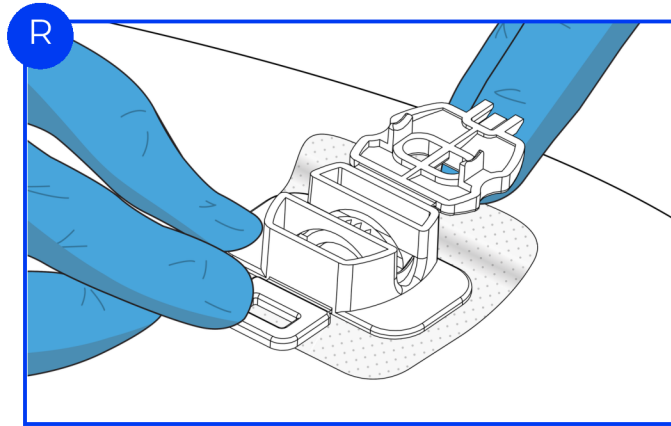


4
Press and secure tubing into channel in the device (supported tubing size - 14 - 18F)



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