





Clik-FIX™ Foley Catheter Securement Device (Soft)

REF FCS-1073, FCS-1074, and FCS-1075

Symbols:

 Read Instructions for Use
  Single Patient Use Only
  Do not use if package is damaged
 Product does not contain natural rubber latex
 STERILE EO Sterilized with Ethylene Oxide

R_xonly Federal (U.S.A) Law restricts this device to be sold by or on the order of a physician.

Description: The Starboard Medical Clik-FIX Foley Catheter Securement Device (REF: FCS-1073, FCS-1074, or FCS-1075) is an Engineered Stabilization Device (ESD) designed to provide securement for Foley (Urethral and Suprapubic) Catheters.

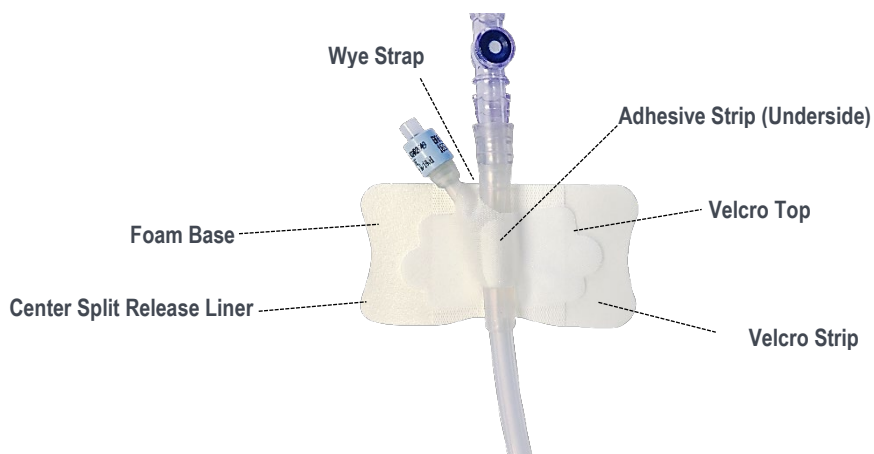
Indications: Clik-FIX Foley Catheter securement is intended to stabilize compatible Foley (Urethral and Suprapubic) Catheters.

Contraindications: Do not use device on compromised skin i.e., open wounds, burns, lesions, rash, other irritation and/or patient's with known tape or adhesive allergies or hypersensitive skin.

Adverse Reactions: Skin irritation

Warning and Pre-Cautions:

- Follow facility protocol when placing and removing the device, observe universal blood and body fluid precautions and infection control guidelines.
- Do not use the Clik-FIX device on patient's who are allergic to adhesives and on non-adherent skin.
- Do not apply alcohol, acetone or other liquid agent directly on the Clik-FIX when in use. These agents can weaken the device.
- During application and removal of the Clik-FIX device take care to minimize manipulation and movement of the catheter.
- Prepare skin surface according to facility protocol. Remove oil and moisture from application area.
- Routinely inspect the Clik-FIX device and catheter position.
- Clik-FIX Securement devices should be monitored daily and replaced when clinically indicated, at least every 7 days.



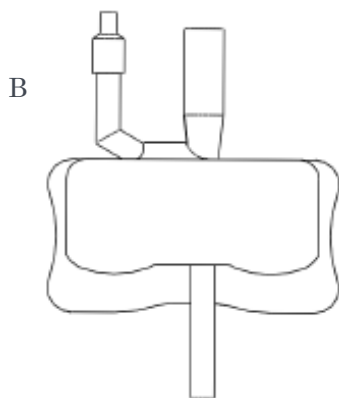
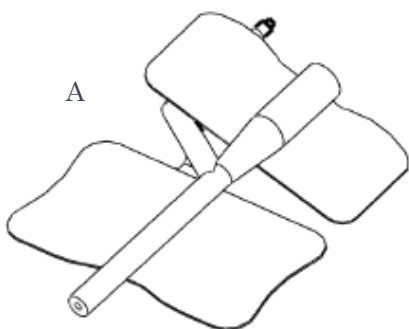
1 PREP

Cleanse the patient's skin at approximate site for placement according to facility protocol. With the patient's leg fully extended, identify the approximate area for securement by gently laying the Clik-FIX Foley Securement Device straight on the front of the patient's thigh or suprapubic area close the the "wye" of the catheter. The best site for securement is usually back up one inch toward the insertion site to allow for slack in the catheter. Prep securement area by cleansing and degreasing the securement site with alcohol or per facility protocol. Be sure to clean area larger than

securement site and allow to dry. Depending on hair growth at the site, you can trim the hair shorter or lay the hair down in the direction of growth using a skin prep pad to assure proper mating of the device with the skin surface. Trimming is preferred for heavier hair growth.

② PLACE FOLEY IN DEVICE

Align the Wye Arms of the Foley Catheter on to the the Foam Base of the Securement Device so that balloon inflation arm is on the side right side when facing the patient. “A” Remove the release paper covering the Adhesive Strip from the Velcro Top and align the Wye Strap so it goes between the balloon inflation arm and main drainage arm of the Foley Catheter. Press the adhesive strap on to the top of the Foley’s main drainage lumen and the Velcro Top down onto the mating Velcro Strips on the Foam Base. The Foley Catheter should now be comfortably stabilized in the securement device. “B”



③ PEEL AND PLACE

Place the Klik-FIX securement device in the area prepped per #1 by removing the center split release liner on the underside of the foam base one side at a time. Make sure that when the leg is fully extended, there is one inch of slack between the insertion site and securement device and the catheter is tension free. Lightly press the foam base down on to the patient’s skin. Using a permanent marker write your initials and date of application on the securement device pad.

④ MAINTENANCE

- Use plastic wrap or water proof dressing while showering
- Skin assessment should be performed prior to application and daily during the duration of use
- Change securement device according to hospital protocol or when visibly soiled, wet, or lifting. Securement device should be changed at least every 7 days.

Removal Technique:

1. To open, lightly detach the Velcro Top from the Velcro hook material on the foam base. Carefully remove the Wye Arms of the Foley Catheter from the device and set to the side. Use caution not to jostle the catheter or create tension when removing.
2. Remove the adhesive pad from the skin by peeling the pad gently away from the skin surface from the outside edge. Follow your facility protocol and clinical best practices for removal of adhesive from skin surface.
3. If difficulty is encountered, apply an alcohol prep pad or adhesive removal pad at the interface between the adhesive and skin to loosen adhesive, continue to carefully remove.
4. Remove device and complete securement device change per facility protocol or if ordered, remove and discard catheter in accordance with your facility protocol.



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US Patent 9526869 other patents pending

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