

TruLock™ Foley Catheter Securement Device

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Instructions for Use

REF

TLFCP For 2-Way Pediatric Foley Catheter

INDICATIONS FOR USE

The TruLock™ Foley Catheter Securement Device is indicated for the stabilization of compatible Foley catheters.

CONTRAINDICATIONS

- Do not use on patients with known tape or adhesive allergies.

WARNINGS

- Do not use the device on skin where adhesion may be compromised, such as with a confused patient, diaphoretic or non-adherent skin, or when the device is not monitored daily.
- Do not apply to neonate or infant skin. Application to immature and fragile skin may result in irritation, injury, or skin stripping.

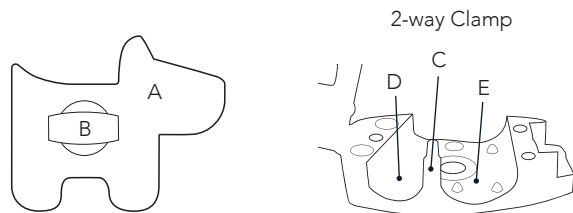
PRECAUTIONS

- Do not use the product if the packaging is opened, damaged, or defective.
- Assess the skin prior to application. Avoid use on areas with thin, immature, or fragile skin to prevent potential skin injury.
- Ensure skin is clean, dry, and free of oils before application. Avoid use on broken, inflamed, or sensitive skin areas.
- Minimize Foley catheter manipulation during securement device application and removal.
- Assess the device daily and change when clinically indicated.
- Avoid using alcohol or prepackaged bathing systems on the device while it is attached to the patient to prevent loss of adhesion.
- When showering/bathing, cover the device with plastic wrap or a waterproof dressing.
- Do not re-sterilize any portion of this device. Single use only.

ADVERSE REACTIONS

None known.

DEVICE COMPONENTS



A. Pediatric Mesh Cloth Base
B. 2-Way Clamp

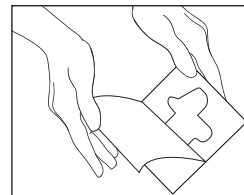
C. Clamp Bifurcation
D. Inflation/Deflation
E. Drainage

STEP-BY-STEP INSTRUCTIONS

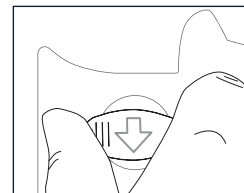
Application

- Remove the device from the packaging.

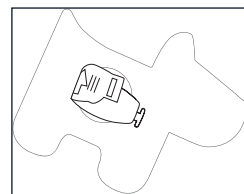
Note: The CliniCare Skin Protectant Wipe will be used in Step 8.



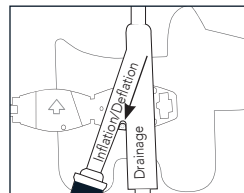
- Open the clamp by pressing the release button inward with the thumb (as shown) or the index finger.



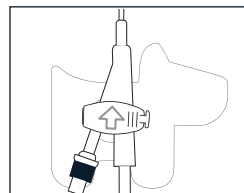
- Rotate the clamp so the arrow is facing towards the Foley catheter insertion site, then gently lift to open.



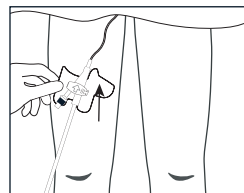
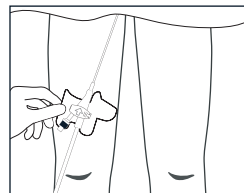
- Seat the Foley catheter into the clamp at the catheter bifurcation—as shown in the image.



- Close the clamp to secure the Foley catheter. Take care to avoid pinching the catheter.

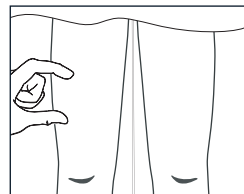


- Identify a skin placement site – see option a or b:
 - Follow facility procedure for Foley catheter securement device placement.
 - Fully extend a leg. Select a location on the inner or outer thigh and extend the catheter along the thigh towards the location (top image). Then, move the device back 1 inch (1") from the location towards the Foley insertion site to create slack for the catheter (bottom image).

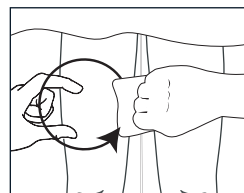


- After selecting the placement site, gently place the device to the side to prepare for skin preparation.

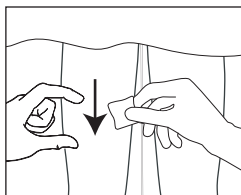
Option: Use the non-dominant hand as a placeholder to mark the placement site.



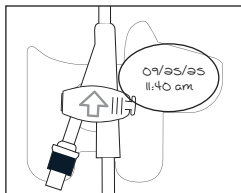
- Cleanse an area larger than the securement device placement site to remove any impurities or substances from the skin that may affect adhesive performance. Follow facility procedure for site cleansing. Allow skin to dry.



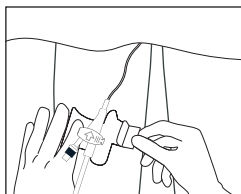
9. Use the CliniCare™ Skin Protectant Wipe to prep the previously cleansed area — wipe in the direction of hair growth. Wait 15 seconds for the skin to dry or until the site is no longer tacky.



10. Use a felt tip marker to label the date and time of application on the securement device.



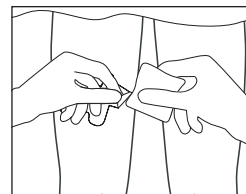
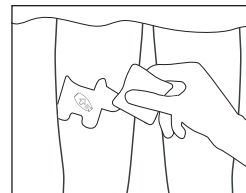
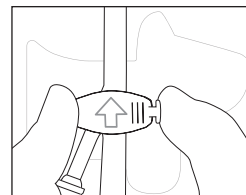
11. The arrow on the clamp points toward the Foley catheter insertion site. Ensure there is adequate slack in the catheter tubing to prevent tension.



Start the device application by pulling back one winged pull tab and applying the exposed adhesive to the prepped skin. Gently rub the adhesive surface, including the edges, to ensure proper adhesion. Repeat for the opposing adhesive tab—do not apply tension.

Removal

1. Open the clamp by pressing the release button inward, then gently lift to open. Remove the Foley catheter from the device.
2. Use an alcohol pad to wipe the surface of one side of the device, saturating the edge until it begins to loosen.
3. Slowly separate the device from the skin, continuing to wipe the skin with alcohol while lifting. Do not pull or force the device. If the device stops peeling easily, switch to a new alcohol pad. Repeat this process until the entire device is removed.



STORAGE

Store products in a dry, clean place at room temperature.

STERILE R

Skin Protectant Wipe

STERILE EO

Securement Device



R_{only}



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