

Indication Of Use:

FoleySafe is a securement device for use with a Foley urinary catheter which is device anchored by an adhesive patch. The FoleySafe device indicated for patients at risk of inadvertent Foley catheter extraction, and patients discharge with a foley catheter and may pull their catheter due to irritation. Patients at risk include but are not limited to: Those whose catheter use is long term, demented patients, disoriented patients, patient under the influence of drugs and patients lacking body awareness. Alternatively, any patient with a catheter which nurses and other caregivers estimate can accidentally pull his/her catheter.

FoleySafe to be used with foley catheters only sizes 8 to 22 french, silicone & latex.

General Description:

FoleySafe is a catheter securement device preventing the damages that can be caused by accidental and unintended pulling of a Foley catheter. The FoleySafe cutting action is activated either by pulling the catheter between the FoleySafe and the urine collection bag, or between the FoleySafe and the meatus.

The illustrations reflect Foley Safe placement on the left hip. Placement on the right hip is similar to the placement on the left one, please notice that the cover axis will always face inward and the catheter routing will be always by entering the upper port and exiting the lower one.

Contraindication:

Caution The FoleySafe device is contraindicated in patients with known tape or adhesive allergies. Evaluate skin integrity before application.

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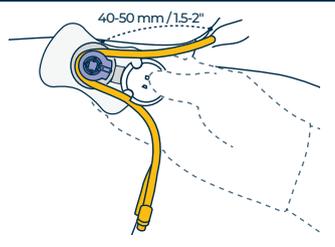
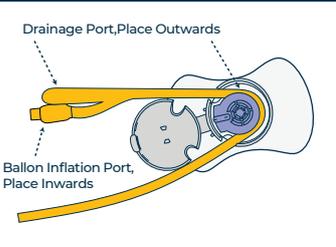
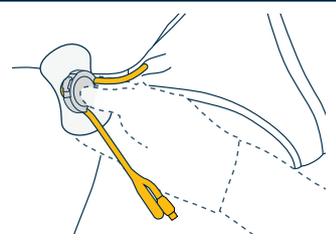
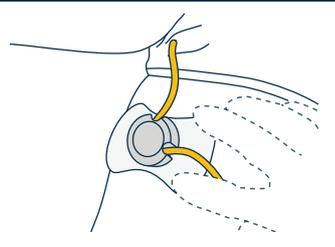
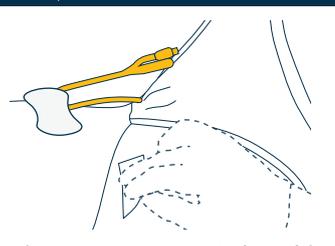
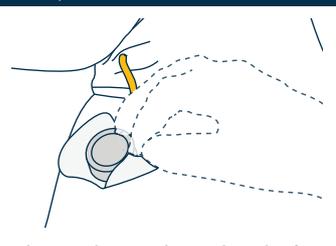
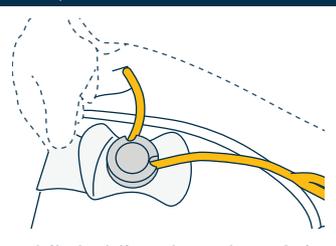
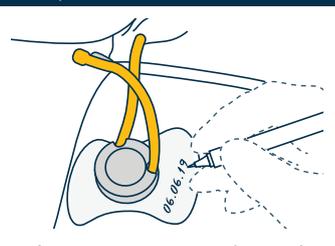






Placement Technique:

NOTE: Always secure catheter into the FoleySafe Stabilization Device retainer BEFORE applying adhesive pad on skin.

<p>1 Place Catheter Inside the FoleySafe</p>  <p>Thread Foley catheter into FoleySafe, the distance between meatus and FoleySafe entrance should be about 40 to 50mm / 1.5"-2".</p>	<p>2 Orientation of Foley Catheter Placement</p>  <p>* Important: Make sure Balloon Inflation Port is placed inwards towards the FoleySafe device center.</p>	<p>3 Close FoleySafe</p>  <p>Close lid by placing your fingers under the FoleySafe and press the lid with your thumb, being careful to avoid pinching the catheter.</p>	<p>4 Locate a Securement Site</p>  <p>Locate proper attachment area by gently laying the FoleySafe securement device straight on the front of the thigh. *Make sure leg is fully extended.</p>
<p>5 Cleanse & Degrease Securement Site</p>  <p>Cleanse securement site with alcohol. Let skin dry. Be sure to clean area larger than securement site.</p>	<p>6 Placement</p>  <p>Place the FoleySafe device over the securement site. Be sure to leave 40 to 50 mm / 1.5-2" of catheter slack between meatus and the FoleySafe. *Make sure leg is fully extended.</p>	<p>7 Peel Paper</p>  <p>While holding the Foleysafe in place peel away paper backing. One side at a time, and place tension-free on skin.</p>	<p>8 Note the Date with a Marker</p>  <p>Using permanent marker, write initials and date of application on FoleySafe anchor pad.</p>

Before Activation:

FoleySafe prevents damage that can be caused by accidental pulling and/or unintended extraction by cutting the urinary Foley catheter and draining the retention balloon.

Activation:

The FoleySafe cutting action is activated either by pulling the catheter between the FoleySafe and the urine collection bag, or between the FoleySafe and the meatus.

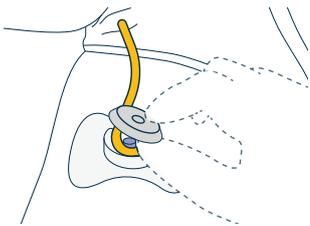
After activation:

- ① The severed Foley catheter needs to be removed by a caregiver.
- ② Place a new Foley catheter according to medical instruction.
- ③ Dispose of the FoleySafe and place a new one.

Ⓚ * **FoleySafe is single-use device and cannot be re-activated.**

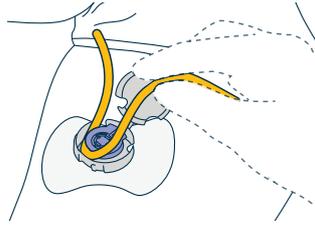
Removal Technique:

1 Disconnecting



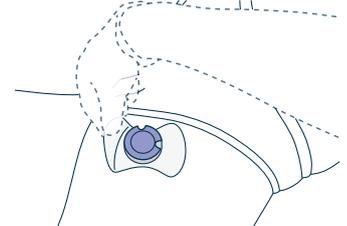
Open FoleySafe lead with its snap latch on its end.

2 Remove Catheter



Gently remove catheter from FoleySafe.

3 Patch Removal



Wipe edge of pad using alcohol pads until a corner lifts. Then continue to wipe under surface of pad, in a back-and-forth motion, by squeezing the alcohol out to dissolve adhesive pad away.

Application Instructions

- ① Evaluate skin integrity before application.
- ② The FoleySafe securement device should be checked daily and remove after ten (10) days.
- ③ If patch becomes soiled, wash with soap, water, saline or hydrogen peroxide.
- ④ Do not use alcohol or prepackaged bathing systems, which could lead to early removal of the FoleySafe.
- ⑤ Consult your healthcare professional about the removal of the FoleySafe stabilization device if you experience any difficulties at removal.

Disposal Instructions:

Follow local state and federal regulations with respect to environmental protection when disposing of general and follow local infectious waste, including all single use device elements, tools, and material that came in contact with the body or bodily fluids should be incinerated / other general waste should be segregated & stored in bins marked properly.

The waste should than be buried in a designated area.

Storage Instructions:

Two years when stored at between **-5°C and 30°C** and **50%** relative humidity, in original package, out of direct sunlight.

