CATHETRIX
INNOVATIVE CATHETER SYSTEMS

Foley-Safe

INSTRUCTIONS FOR USE

You must read carefully this IFU in its entirely before using the device.

- Do not use the device if the wrap was compromised.
- Foley-Safe is a Latex-Free device.
- Foley-Safe is a non-sterile device and need not to be re-sterilize.
- Do not cut, modify, sterilize, or reuse device
- Do not intentionally pull catheter to test activation
- Use only with compatible catheter sizes
- Check skin condition daily
- Replace device if adhesion is compromised

Intended Use

Foley-Safe is used as a securement device which is designed to minimize catheter movement and accidental dislodgement, thereby maximizing comfort.

Indication Of Use:

Foley-Safe is a securement device for use with urinary catheters, in which the device is anchored by an adhesive patch to the skin. Foley-Safe is indicated for patients with indwelling urethral catheters, at risk of inadvertent catheter movement and possible extraction. The device can be used by any patient with an indwelling urethral catheter, but it is particularly important for those who are disoriented or have limited body awareness due to long-term catheter use.

General Description:

Foley-Safe is a device that keeps catheters securely in place to help reduce the movements of the catheter within the urethra, reduce the chance for UTI, and reduce unintended catheter accidental dislodgment.

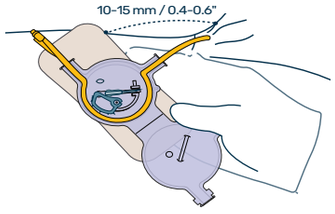
Contraindication:

Foley-Safe is contraindicated in patients with known tape or adhesive allergies. Evaluate skin integrity before application. The device should not be used with 3-way catheters. Device should not be used in cases in which the catheter length outside the urethra is too short to insert into the device. The device should not be used in catheters with a diameter of less than 14 French or with catheters larger than 16 French. It is safe to use the device for up to 14 days.

Placement Technique:

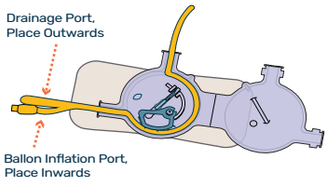
Always secure catheter into Foley-Safe retainer BEFORE applying adhesive patch on skin.
Recommendation : Using permanent marker, write initials and date of application on Foley-Safe anchor patch.

1 Place Catheter Inside the Foley-Safe



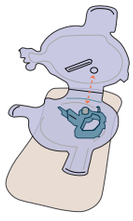
Thread catheter into Foley-Safe. The distance between the urethral meatus and Foley-Safe should be 10-15 mm (about 1 fingers width).

2 Orientation of Foley Catheter Placement



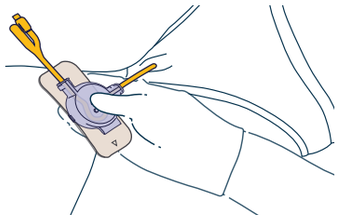
Important: Make sure Balloon Inflation Port is placed inwards towards Foley-Safe center.

3 Closing Technic



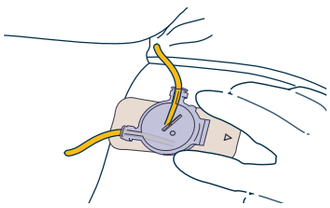
Make sure that the big axis in the middle of the device enters the big hole in the lid.

4 Close Foley-Safe



Close lid by placing your fingers under the Foley-Safe pad and press the lid with your thumb, being careful to avoid pinching the catheter.

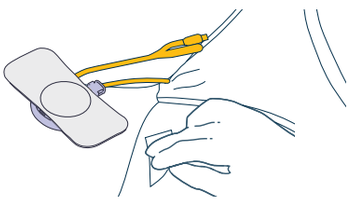
5 Locate a Securement Site



Locate a proper attachment area. Gently lay Foley-Safe straight on the front of the thigh.

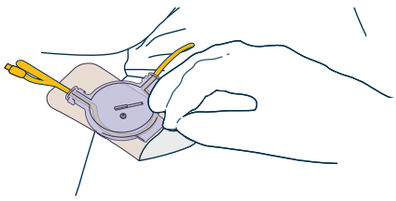
Make sure leg is fully extended.

6 Cleanse & Degrease Securement Site



Shave, Clean and degrease securement site with alcohol and according to institutional practice.
Be sure to clean area larger than securement site.

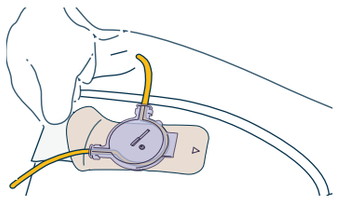
7 Placement



Place Foley-Safe over the securement site. Be sure to leave 30 to 50 mm / 1.5-2" of catheter slack between meatus and the Foley-Safe.

Make sure leg is fully extended.

8 Peal Paper



While holding Foley-safe in place peel away paper backing. One side at a time, and place tension-free on skin.

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Before Activation:

Foley-Safe prevents potential trauma related with accidental pulling on the urethral catheter and/or unintended catheter extraction by utilizing the cutting mechanism.

Activation:

Foley-Safe is activated by pulling the catheter between the Foley- Safe and the urine collection bag.

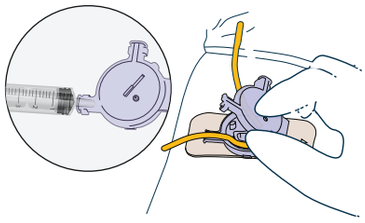
After activation:

1. The severed urtethral catheter needs to be removed by a caregiver.
2. Follow medical instructions to place a new urethral catheter device in case of Foley-Safe replacement.
3. Dispose of the Foley-Safe and place a new one.

② Foley-Safe is single-use device and cannot be re-activated.
There may be rare, extreme cases in which the cutting mechanism fails to cut the catheter.

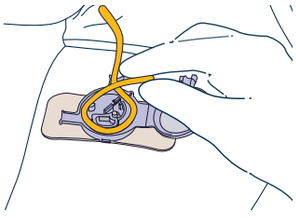
Removal Technique:

1 Disconnecting



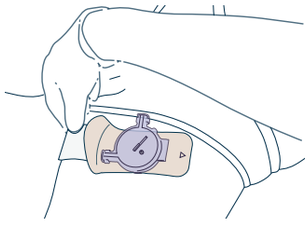
Open Foley-Safe lid with its snap latch on it's ends' by using a plastic injector as a leverage inside the entrance and exit points of the catheter from the device.

2 Remove Catheter



Gently remove catheter from Foley-Safe.

3 Patch Removal



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

Application Instructions

1. Evaluate skin integrity before application.
2. Foley-Safe securement device should be checked daily.
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 Foley-Safe.
5. Consult your healthcare professional about the removal of Foley-Safe 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 general.
The waste should than be buried in a designated area.

Storage Instructions:

18 months when stored at temperature range of 18-28°C and relative humidity range of 45-55%, in original package, out of direct sunlight.

Table of Symbols

	Keep away from sunlight
	Indication of country of origin and manufacturing date
REF	Catalogue/reference number
LOT	Manufacturer Lot No.
MD	Medical Device symbol
NON STERILE	Non sterile
	Dry Keep
	Use by date
②	Single use only

	Consult instructions for use / eIFU Indicator
CE	CE Mark
Rx Only	CE Mark
	Manufacturer's name and address
EC REP	Authorized representative in the European Community
65% 45%	Humidity range
18°c 28°c	Temperature range
	Importer

Contact us

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In case of product activation

What exactly happens upon activation:
When the cutting mechanism is activated, the device severs the catheter lumen proximal to the retention balloon.
This causes the balloon inflation channel to be cut, resulting in passive deflation of the retention balloon. The distal catheter segment (within the bladder) can then be easily removed by withdrawing the catheter through the urethra without resistance or force. Urine drainage will cease immediately upon cutting.

Who is authorized to manage the patient after activation:
Following activation of the cutting mechanism, patient assessment and catheter removal must be performed by a licensed healthcare professional (registered nurse, physician, or qualified clinical staff) in accordance with local institutional protocols. Non-clinical caregivers should not attempt catheter removal and must notify clinical staff immediately.

Is immediate catheter replacement required
Following cutting mechanism activation and catheter removal, the need for catheter replacement must be assessed by the treating clinician based on the patient's clinical indication. Catheter replacement is not automatic and should be performed only when clinically indicated. If urinary retention is a concern, clinical assessment should be performed promptly.

Patient assessment checklist - catheter retention balloon status

1. After the cutting mechanism has been activated and the catheter removed, the patient should be assessed for the following:
2. Bleeding / hematuria: Inspect the urethral meatus and monitor urine output for blood.
3. Pain or discomfort: Evaluate for urethral or suprapubic pain.
4. Urethral or bladder trauma: Assess for signs of injury; consult urology if trauma is suspected.
5. Urinary retention: Monitor for inability to void spontaneously if catheter is not replaced.
6. Balloon deflation confirmation: Verify that the retention balloon has fully deflated prior to catheter withdrawal. If resistance is encountered during removal, do not force — seek clinical guidance.

Should the event be reported
Activation of the cutting mechanism should be documented in the patient's medical record, including the date, time, clinical circumstances, and patient outcome. In accordance with applicable regulations, unintended or unexpected device activation may constitute a reportable adverse event and should be reported to the relevant competent authority and to Cathetrix at contact@cathetrix.com.

Intended function vs. adverse event
Activation of the cutting mechanism is an intended safety function of Foley-Safe, designed to protect the patient from urethral, bladder neck, and bladder trauma in the event of significant accidental catheter traction. It is not considered a device malfunction. However, if activation occurs in the absence of an apparent pulling force, or causes patient harm, this should be treated as an unexpected event and reported accordingly (see Reporting section above).

Intended population:

Primary population: Adult patients with an indwelling urethral Foley catheter, across both acute and long-term care settings (hospitals and nursing homes).

Clinical characteristics:

- Patients requiring urinary bladder drainage via transurethral catheterization
- Patients using Foley catheters of any standard type (Foley, silicone, latex) in sizes 14–16 Fr
- Patients at risk for accidental catheter dislodgment due to mobility, agitation, confusion, or inadvertent traction
- Care settings implied by the document:
  Hospital inpatients
- Nursing home / long-term care residents
  By extension: home care patients with indwelling catheters (not explicitly excluded)

Contraindications:

Known hypersensitivity or allergy to the adhesive patch materials (silicone, acrylic, or latex components, as applicable) risk of skin reaction at the thigh fixation site

Catheters outside the indicated size range (outside 14–16 Fr) — cutting mechanism and holding system are calibrated for this range; efficacy and safety cannot be guaranteed outside it

Non-Foley urinary catheters (e.g., straight/intermittent catheters, condom catheters, nephrostomy tubes) — device is designed exclusively for indwelling balloon-retention Foley catheters

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Warning section:

Cutting Mechanism Activation is Irreversible Once the cutting mechanism has been activated, the catheter cannot be restored. A new catheter must be inserted if ongoing bladder drainage is clinically required. Do not attempt to reconnect or splice the cut catheter. Failure to replace the catheter when clinically indicated may result in urinary retention, bladder distension, and serious patient harm.

Do Not Force Catheter Removal After Activation Following cutting mechanism activation, confirm balloon deflation before attempting catheter withdrawal. If resistance is encountered during removal, do not apply force. Forced removal of a catheter with an incompletely deflated balloon may cause severe urethral laceration, bladder neck injury, or hemorrhage. Seek immediate clinical assessment.

Post-Activation Patient Assessment is Mandatory Following any activation of the cutting mechanism, the patient must be assessed by a licensed healthcare professional for: hematuria, urethral or suprapubic pain, signs of urethral or bladder trauma, urinary retention, and complete balloon deflation. Do not discharge or leave the patient unattended until this assessment is completed.

Not a Substitute for Proper Catheter Securement Practice Foley-Safe is a supplemental safety device. It does not replace the need for correct catheter insertion technique, appropriate balloon inflation volume, or standard clinical monitoring of indwelling catheters. Improper catheter insertion prior to device application may result in device failure or patient injury.

Skin Integrity Risk The adhesive patch must not be applied to broken, irritated, irradiated, or otherwise compromised skin. Application to compromised skin may cause pain, skin tear, or wound disruption upon removal. Assess the thigh application site prior to each use.

Single Use Only Foley-Safe is a single-use device. Do not reuse, reprocess, or resterilize. Reuse may result in device failure, loss of adhesive integrity, failure of the cutting or holding mechanism, and risk of cross-contamination or infection.

Allergy Risk Prior to application, confirm that the patient has no known allergy or hypersensitivity to the adhesive patch components. In the event of skin reaction (redness, blistering, urticaria), remove the device immediately and manage the reaction per institutional protocol.

For Use with Indicated Catheter Types and Sizes Only Use only with indwelling urethral Foley catheters in sizes 14–16 Fr (silicone or latex). Use with catheters outside this range, or with non-balloon-retention catheters, may result in failure of the holding system or cutting mechanism, potentially causing device malfunction and patient injury.

Percautions:

Device Application Must Be Performed by Trained Personnel Foley-Safe should be applied by healthcare professionals or trained caregivers who have read and understood this IFU. Incorrect application may compromise device function and patient safety.

Verify Catheter Seating Before Closing the Lid Ensure the catheter is correctly seated within the device and the lid is fully closed and secured before applying the patch to the patient. Incomplete closure may result in premature or failed activation of the holding or cutting mechanism.

Patch Placement Apply the adhesive patch to clean, dry, intact skin on the patient's thigh. Avoid placement over bony prominences, areas of hair density, or areas subject to excessive moisture. Poor patch adhesion may reduce device efficacy and increase the risk of accidental catheter dislodgment.

Monitor Patch Adhesion During Wear Inspect the patch adhesion site at regular intervals per institutional protocol. If the patch shows signs of lifting, detachment, or reduced adhesion, replace the device. Do not attempt to re-adhere a partially detached patch with tape or additional adhesives.

Document and Report Cutting Mechanism Activation Every instance of cutting mechanism activation must be documented in the patient's medical record. If activation occurred without apparent significant pulling force, or if patient harm resulted, this must be reported to the relevant competent authority and to Cathetrix. See Reporting section.

Catheter Replacement Planning in High-Risk Patients In patients where unplanned catheter removal carries elevated clinical risk (e.g., single functioning kidney, urinary obstruction, post-surgical bladder), a contingency plan for prompt catheter replacement should be in place prior to device application.

Avoid Excessive Tension on the Drainage Tubing After device application, ensure the drainage bag and tubing are positioned and secured to minimize tension on the catheter. The device is designed to absorb accidental pulling forces, but chronic low-grade tension may accelerate mechanism engagement or reduce device lifespan.

Magnetic Resonance Imaging (MRI) Do not use Foley-Safe in MRI procedures. The MRI compatibility of Foley-Safe has not been evaluated. Follow institutional MRI safety protocols before imaging a patient with the device in site.