



Nephro-Safe

INSTRUCTIONS FOR USE

IFU-2026

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Indication Of Use:

Nephro-Safe is a stabilization device which anchors the nephrostomy tube by an adhesive patch to the skin. The **Nephro-Safe** is indicated for stabilization of indwelling nephrostomy tubes. It is used with percutaneous nephrostomy tubes to prevent tube movement and possible tissue trauma when the tube is inadvertently pulled by patient or caregiver. It is suitable for patients with temporary or long-term nephrostomy tubes, particularly those who are disoriented, have limited mobility, or require extended tube use.

General Description:

Nephro-Safe is a device that keeps the nephrostomy tube secure in place to prevent injuries and complications caused by accidental pulling. It secures the external portion of the nephrostomy tube without impeding internal urine flow, reducing the risk of dislodgement, pain, bleeding, infection, or skin pressure sores.

Intended Use

The **Nephro-Safe** device is used as a securement device to minimize tube movement and accidental dislodgement, thereby maximizing patient comfort and mobility while lowering the risk of skin pressure injuries.

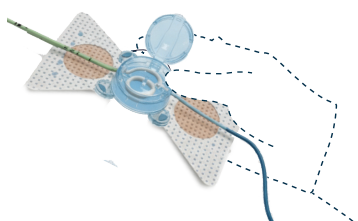
Contraindication:

The **Nephro-Safe** device is contraindicated in patients with known tape or adhesive allergies. Evaluate skin integrity before application. The device should not be used in cases in which the tube length outside the body is too short to insert into the device. Consult healthcare provider for compatibility with specific tube sizes or patient conditions.

Placement Technique:

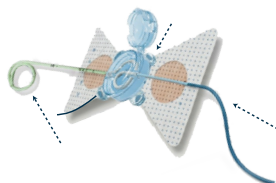
Always secure the nephrostomy tube into the **Nephro-Safe** stabilization device retainer BEFORE attaching the adhesive pad onto the skin.

1 Place Tube inside the Nephro-Safe



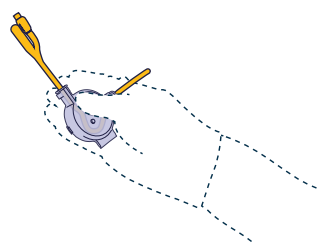
Thread nephrostomy tube into **Nephro-Safe**. The distance between the **Nephro-Safe** and the skin entry site should be about 10 mm to allow slack.

2 Orientation of Nephrostomy



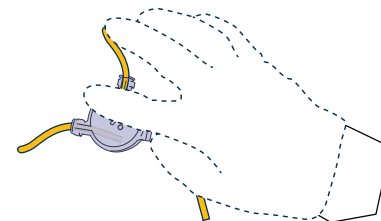
Ensure drainage port is aligned with the **Nephro-Safe** device retainer for proper urine flow.

3 Close Nephro-Safe



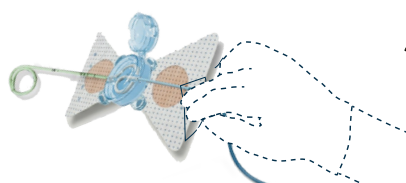
Close lid by placing your fingers under the **Nephro-Safe** pouch thumb, being careful to avoid pinching.

4 Locate a Securement Site



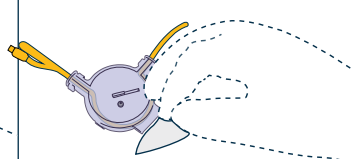
Locate a proper attachment area. Gently lay the **Nephro-Safe** on the flank near the entry site. Make sure the body is positioned comfortably.

5 Shave & Cleanse Securement Site



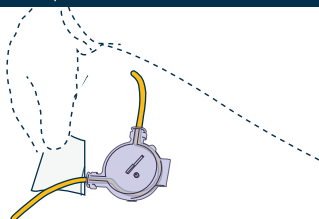
Shave, clean and degrease securement site with alcohol. Let skin dry. Be sure to clean site larger than securement site.

6 Nephro-Safe Placement



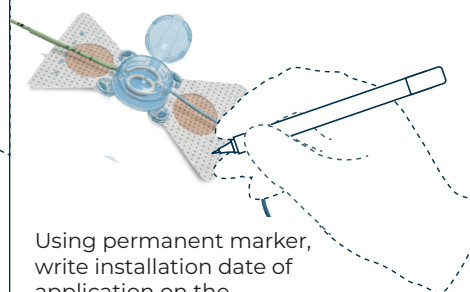
Place over the securement site. Be sure to leave a 10mm slack between entry site and the **Nephro-Safe** when fully extended.

7 Peel Paper



While holding in place peel away paper backing. One section at a time, press firmly for adhesion tension-free on skin.

8 Note the placement date with Marker



Using permanent marker, write installation date of application on the **Nephro-Safe** device.

TubeX Nephro-Safe

INSTRUCTIONS FOR USE

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Before Use:

Nephro-Safe prevents potential trauma related with accidental pulling on the nephrostomy tube by utilizing a secure anchoring mechanism that distributes pressure evenly and reduces concentrated force on the skin.

After Use:

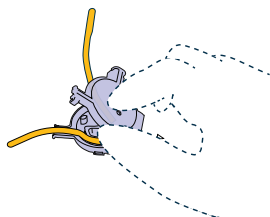
- 1 The stabilized tube needs to be monitored by a caregiver.
- 2 Follow medical instructions to place a new nephrostomy tube device in case of **Nephro-Safe** replacement.

- 3 Dispose of the **Nephro-Safe** and place a new one.

- 2 **Nephro-Safe is a single-use device that can be replaced with a new one.**

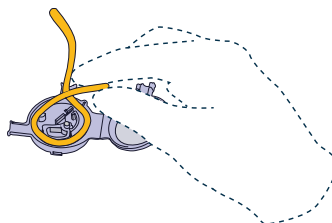
Removal Technique:

1 Disconnecting



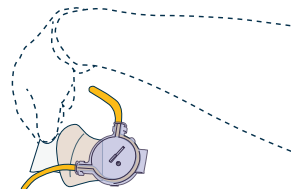
Open **Nephro-Safe** lid with snap latch on its ends.

2 Remove Tube



Gently remove nephrostomy tube from **Nephro-Safe**.

3 Patch Removal



Wipe edge of pad using alcohol pad, in a back-and-forth motion, squeezing the adhesive pad away.

When the patch has finished its activity or becomes soiled, the product may be replaced with a new one without replacing the indwelling tube. The same tube remains in place, and a new Nephro-Safe can be installed. Nephro-Safe can also allow replacement of the nephrostomy tube without replacing the stabilizer, depending on design compatibility.

Application Instructions

- 1 Evaluate skin integrity before application.
- 2 Replace the **Nephro-Safe** securement patch if it becomes soiled or loses adhesion.
- 3 Clean the site with soap, water, saline, or hydrogen peroxide.
- 4 Do not use alcohol or prep solutions that could lead to skin irritation prior to removal of the **Nephro-Safe**.
- 5 Contact your healthcare provider if you experience any difficulties with removal of the **Nephro-Safe** stabilization device.

- 6 Inspect drainage systems regularly.

- 7 Consult your healthcare provider.

Disposal Instructions:

Follow local, state, and federal regulations for environmental protection when disposing of the device as general medical waste. Materials contaminated with bodily fluids should be disposed of in designated biohazard bins.

Storage Instructions:

Store in original packaging at a temperature range of 18°-28°C, in a dry place out of direct sunlight. Shelf life is 18 months under these conditions.

Table Of Symbols

	Keep away from sunlight		Consult instructions for use / eIFU Indicator
	Indication of country of origin and manufacturing date:		CE mark
	Catalogue/reference number		Prescription only
	Manufacturer Lot No.		Manufacturer's name and address
	Medical Device symbol		Authorized representative in the European Community
	Non-sterile		Humidity range
	Dry Keep		Temperature range
	Use-by date		Importer
	Single use only		

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