



MRK HEALTHCARE PVT. LTD.

ELECTRONIC IFU

MALE INCONTINENCE DEVICE (U-DRAIN) - Sterile

DEVICE INTENDED USE:

U-Drain is a male incontinence device that can be used by males who have lost control over urination or by those who need to urinate frequently. It can be used as a partial alternative to catheterization and can be used by bed ridden patients and patients without expert assistance.

DEVICE CATALOGUE NO.:

Variants	Catalogue No.
Male Incontinence Device (U-drain) sterile	UDRLE

BASIC UDI:

8905159UDRLBG

DEVICE SIZES:

Variants	Sizes
Male Incontinence Device (U-drain) sterile	Small / Ex-Small, Medium, Large / Ex-Large

DEVICE VARIANTS:

Male Incontinence Device (U-drain) sterile

TARGET POPULATION:

Male Adults with urinary incontinence

DEVICE SHELF LIFE:

5 years from the date of manufacture printed on the Product label.

DEVICE STORAGE:

It is recommended to store the device in dry place, in the temperature of 5°C to 40°C and to protect them against direct sunlight.

METHOD OF STERILIZATION:

Device is supplied after EO (Ethylene Oxide) sterilization.

INDICATIONS:

U-Drain is a male incontinence device is used by males who have lost control over urination or by those who need to urinate frequently.

WARNINGS AND PRECAUTIONS:

- 1 This product contains natural latex which may cause allergic reaction.
2. Do not reuse Or Single use only.
3. Do not re-sterilize. Re sterilization can compromise product quality.
4. Sterilized by ETO

Rev. No.	A	Rev. Date	25-6-2022	Document NO:	MRK/IFU/MID/S	Page 1 of 4	Device Name	Male Incontinence Device (U-drain) sterile
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MALE INCONTINENCE DEVICE (U-DRAIN) - Sterile

5. Keep in cool and dry place.
6. Keep away from direct sunlight.
7. Sterility guaranteed until package is opened or damaged.

Intended Patient population:

Patient with Urinary Incontinence

Contra Indications:

This product contains natural latex which may cause allergic reaction including Latex Allergy – Anaphylactic if the user is allergic to latex.

Clinical Benefits:

1. Comfortable and secure fit
2. Protecting the skin from contact with urine.
3. Capture the urine that is voided involuntarily.
4. Reduce the risk of developing UTIs.
5. Reduce the incidence of perioperative urethral or bladder perforations.
6. Reduce the risk of complications associated with navigating the barrier protecting the urinary tract from stool.

Residual Risks:

1. Anaphylaxis
2. Urinary tract infection
3. Inflammation
4. Toxic to environment

POTENTIAL ADVERSE EFFECTS:

Latex Allergy, Inflammation, Allergy, Pain, Rashes, Itching, Skin redness, Skin ulceration

INSTRUCTIONS FOR USE:

1. Trim public hair as necessary to avoid entanglement with strap.
2. Place the sheath ½ inch in front of the head of the penis and unroll over the penis.
3. Peel backing from adhesive strap.
4. Starting just behind the glans of the penis, gently spiral the adhesive around the penal shaft

DEVICE SINGLE UNIT PACKAGING (PRIMARY PACK) CONTAINS:

















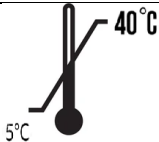


Variant	Single Unit Packaging (Primary pack)
Male Incontinence Device (U-Drain) – Sterile	1 Pc packed in primary pack

DEVICE SALES PACKAGING (SECONDARY PACK) CONTAINS:

Variant	Sales Unit Packaging (Secondary pack)
Male Incontinence Device (U-Drain) – Sterile	50 Pcs in each secondary pack

MALE INCONTINENCE DEVICE (U-DRAIN) - Sterile

SYMBOLS USED IN DEVICE SINGLE UNIT PACKAGING AND SALES PACKAGING

	Manufacturer		Date of Manufacture		Keep away from Sunlight
	Authorized Representative in the European Community/ Authorized representative European Union		Use by Date/ Expiry Date		Keep Dry
	Contains presence of Natural Rubber Latex		Batch Code		Do not Re-use
	Sterilized using Ethylene Oxide		Do not use if package is damaged and consult instructions for use		Caution
	Do not resterilize		Medical Device		Unique Device Identifier
	Single sterile barrier system		Storage Temperature		No: of units
	CE Mark Symbol				

• In case of any adverse event noted, contact manufacturer (MRK Healthcare Pvt Ltd) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs.



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Authorized EU REP

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Rev. No.	A	Rev. Date	25-6-2022	Document NO:	MRK/IFU/MID/S	Page 4 of 4	Device Name	Male Incontinence Device (U-drain) sterile
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