

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. AND AVAILABLE SIZES:

Catalogue No.	Sizes
UDRLE	Small / Ex-Small, Medium, Large / Ex-Large

BASIC UDI:

8905159UDRLBG

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 product 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) Sterile.

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 including anaphylaxis if the user is allergic to latex
2. Do not use if the Package is opened or damaged. Use of product whose package is opened or damaged may cause inflammation.
3. Do not reuse. Reuse of the device may cause urinary tract infection.
4. Do not re-sterilize. Re sterilization can compromise product quality.
5. Device should not be stored in direct sunlight.
6. Device disposable should be done as per local regulations. Failing to do so may lead to toxic to environment.

Intended Patient population:

Patient with Urinary Incontinence

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MRK HEALTHCARE PVT. LTD.

ELECTRONIC IFU

MALE INCONTINENCE DEVICE (U-DRAIN) - Sterile

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.

POTENTIAL ADVERSE EFFECTS:

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

















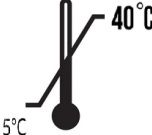


DIRECTION FOR USE:

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

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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 with notified body number				

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MRK Healthcare Pvt. Ltd.

S. No. 153/P& 310, Panch Pippal,
Hansapur, Runi, Unjha-Patan Road, Patan – 384265, Gujarat, India.



Authorized EU REP

OBELIS S.A

Bd. Général Wahis, 531030 Brussels, Belgium

Revision History

Rev. No.	Date	Reason for Revision
A	25-06-2022	Initial Release
B	15-09-2022	Warning & precaution updated with residual risk as per TR comments
C	31-10-2022	Notified body no. included under the CE symbol.