## PRIMARY PACKAGING/ INDIVIDUALLY SEALED CONTAINER

Brand Name or Identity of Manufacturer/Importer

[Drawing of a catheter]

| | |
|---|---|
| LOT | : YY-G-XXM |
| | : YYYY/MM |
| STERILE R | : Sterilized using irradiation |
| LATEX | : Contains natural rubber latex |
| | : Consult instruction for use |
| | : Do not resterilize |
| | : Do not reuse |
| | : Do not use if package is damaged |
| | : Store in a cool dry place |
| | : Keep away from sunlight |
| | : Manufacturer |
| | : Manufacture date |
| EC REP | : Authorized representative in the European Community |
| REF | : Catalogue number |
| MD | : Medical device* |
| | : Single sterile barrier system with protective packaging inside* |
| | : Importer* |
| Type | : Type of catheter |
| Size/Balloon | : Size and balloon of catheter |
| Effective Length | : Effective length of catheter |
| Coating | : Type of coating |

CE mark (minimum height of 5mm with notified body's number)
Any additional marking required by local regulations

## SECONDARY PACKAGING/ CONSUMER BOX

### FRONT PANEL

Brand Name or Identity of Manufacturer/Importer

[Drawing of a catheter]

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.

Store in a cool, dry place away from heat and direct sun light.

| | |
|---|---|
| LOT | : YY-G-XXM |
| | : YYYY/MM |
| | : Manufacture date |
| Effective Length | : Effective length of catheter |
| REF | : Catalogue number |

### LEFT & RIGHT SIDE PANELS

Brand Name or Identity of Manufacturer/Importer
No. of catheters contain in the package
CE mark (minimum height of 5mm with notified body's number)
QUALITY ASSURANCE [logo]

**INSTRUCTION FOR USE**

***FRONT**

## Instructions for use

### Foley-Catheter

**Product description**
Flexible shaft made of multiple-cleansed latex with siliconised or silicone elastomer coated surface

**Intended Purpose**
Sterile, Latex Urethral Foley Balloon Catheters are intended for the drainage and/ or flushing of the bladder. It is to be used by trained medical professional.

**Indications**
- acute and chronic urinary disorders including urinary incontinence and urinary retention
- intra- and postoperative urinary drainage
- urinary drainage for measurement of urine excretion e.g. during intensive care and infusion therapy

**Clinical Benefits**
Relieve discomfort due to bladder dysfunction

**Patient Target Group**
Children, Adults, Both genders

**Directions for use**
- The product is sterile as long as the packaging is sealed and undamaged.
- Remove the catheter from its sterile packaging using aseptic technique.
- Using sterile technique as indicated in published literature, insert the catheter fully into the urethra ensuring that the balloon is beyond the bladder neck.
- Inflate the balloon with sterile water.
  Use sterile water only.
- The capacity of the balloon is indicated on the funnel of the catheter or on the label of the packaging. Do not overinflate.
- To deflate the balloon prior to removal aspirate the syringe gently to remove the inflation fluid.
  Do not use excessive aspiration on the syringe during deflation as this may cause a vacuum collapse of the inflation lumen which may impair normal drainage.
- Maximum recommended indwelling times will vary due to patient specific factors.
- To obtain safe combination with urine bags, urine bags with nominal taper 20% connector is recommended.

**Potential complications**
If difficulty is encountered aspirating the balloon with the syringe, a rare and infrequently reported event, the limb of the catheter with the valve should be cut with sharp scissors at the bifurcation, or the balloon ruptured according to established procedures reported in medical literature. Should it necessary to rupture the balloon, care must be taken to remove all fragment from the patient. Irritation of the urethral mucosa, blockage of the catheter due to encrustation and catheter induced infections are documented complications with some catheter materials and patients.

- The patient should be routinely monitored in accordance with accepted procedures.
- The siliconised catheter should be changed after an appropriate time usually not more than 7 days or as specified by a medical practitioner.
- The silicone elastomer coated catheters should be replaced every 28 days or as specified by a medical practitioner.

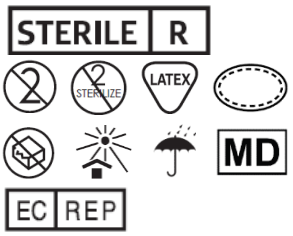
**Warnings and Precautions**
- Product contains natural rubber latex which may elicit allergic responses in latex sensitized individuals.
- Catheters are contraindicated in patients with abnormalities of urethra, including false passages, severe strictures, bleeding or injury.
- Catheters are also contraindicated for patients who undergo urethral surgery and gender reassignment surgery.
- For urological use only.
- Latex Urethral Catheter is packaged for single use.
- Do not re-use or re-sterilise as there is a risk of transmission of body fluids or contaminated tissue between patients. Do not use if pouch is opened or damaged.
- Do not use lubricants or preparations with a petroleum base on products which contain latex.
- Always inflate the balloon with sterile water.
- Never clamp the catheter.
- Never use a syringe to puncture the catheter shaft for urine sampling. There is a danger of needle-stick injury and the catheter may be compromised.
- Excessive aspiration can collapse inflation lumen, preventing balloon deflation.
- Visually inspect the package for any breach of the packaging integrity.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/ or patient is established.

**Paediatric Catheters**
Paediatric catheters include a stylet/stillette to facilitate insertion. Make sure stillette end is properly positioned in the catheter tip and not protruding from the catheter eye during insertion. Remove the stillette once the catheter is positioned correctly before inflating the balloon.

**Storage and Disposal**
These products should be stored in their original box, preferable away from direct and indirect sources of light and heat.
After use, this product may be a potential biohazard. Handle and dispose off in accordance with accepted medical practice and applicable laws and regulations.

***BACK**

CE 0123




**URO TECHNOLOGY SDN. BHD.**
Lot 2491, Batu 39 1/2,
Pontian Besar,
82000 Pontian,
Johor, Malaysia.

**Advena Ltd.**
Tower Business Centre,
2nd Flr. Tower Street,
Swatar, BKR 4013, Malta

| Symbol | Definition |
|---|---|
| | Manufacturer |
| STERILE R | Sterilized using irradiation |
| | Do not reuse |
| | Do not use if package is damaged |
| | Do not resterilize |
| | Keep away from sunlight |
| LATEX | Contains natural rubber latex |
| | Store in a cool dry place |
| EC REP | Authorized representative in the European Community |
| | Consult instruction for use |
| LOT | Batch code |
| | Manufacture date |
| | Use by day |
| REF | Catalogue number |
| MD | Medical device |
| | Single sterile barrier system with protective packaging inside |
| | Importer |

## PRIMARY PACKAGING/ INDIVIDUALLY SEALED CONTAINER

Brand Name or Identity of Manufacturer/Importer

Sterile, 1 Way Urethral Catheter

It is intended for the drainage of the bladder

| | |
|---|---|
| REF | : Catalogue Number |
| Size | : Size of catheter |
| Effective Length | : Effective length of catheter |
| LOT | : YY-G-XXM |
| | : YYYY/MM |
| | : YYYY/MM |
| MD | : Medical device |
| | : Single sterile barrier system |
| STERILE R | : Sterilized using irradiation |
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Any additional marking required by local regulations

**URO TECHNOLOGY SDN. BHD.**
Lot 2491, Batu 39 1/2, Pontian Besar,
82000 Pontian, Johor, Malaysia.

**CE mark**
(minimum height of 5mm with notified body's number)

EC REP **Advena Limited**
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

: **XXX company & address**

UDI UDI or other format [Barcode]