

THE UGO BOX PROCEDURE PACK PRODUCER INFORMATION

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***Components of the Ugo Pro** (catheterisation procedure pack)

 Dansu-China Health Care Co., Ltd, No. 366, Pengjialing,
Yongfeng Street, Hanyang District, 430050 Wuhan, People's Republic of China.

 Shanghai International Holding Corp. GmbH,
Eiffestraße 80, 20537 Hamburg, Germany
UK responsible person: Share Info Ltd, 14 Castle Walk, Lower Street,
London-Stanstead, CM24 8LY, UK

****10mL Syringe (CE 0123)**

 Weigao Medical International Company Ltd, No.1 Weigao Road,
High-tech Industrial Development Zone, 264210 Weihai, Shandong Province, China.

 MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany
UK responsible person: Medimap Ltd, 2 The Drift, Suffolk, Thurston, IP31 3RT, UK

***** Sterile Saline Pod (CE 1639)**

 Roosin Medical Co., Ltd, No. 8 Yuandong Road, Kouan Town Gaogang, Taizhou City, Jiangsu
Province, P.R. China

 Prolinx GmbH, Brehmstr. 56, 40239, Dusseldorf, Germany

ugopro.TM
catheterisation procedure pack



Ugo Pro (catheterisation procedure pack)

REF 3400



LATEX FREE

STERILE EO

MD



optimummedical®

3400-IFU-Nov23-V4.0



Instructions for use



PRODUCT REF / CONTENTS3400 **Ugo Pro** (catheterisation procedure pack)

- This is a **Ugo Pro** (catheterisation procedure pack) product information leaflet for the user.
- Read all of the product information leaflet prior to use and retain for your information.
- Use as prescribed. If you are unsure about how to use this product, please seek advice.

PRODUCT DESCRIPTION

The **Ugo Pro** (catheterisation procedure pack) is a sterile, single use catheterisation procedure pack and contains all the essential and routine components required for the removal and/or insertion of a urinary catheter. See 'How to use' for full list of components and indications for use.

INGREDIENTS/COMPOSITION

| Ugo Pro (catheterisation procedure pack) | Ingredients |
|---|---|
| Plastic Tray Waste Bag Apron | Polyethylene |
| Non-woven Balls Non-woven Swabs | Non-woven material: Polypropylene Polyester |
| 10ml Syringe | Polypropylene barrel and plunger Polyisoprene Stopper |
| O Drape Waterproof Drape Wrapping Drape | Polyethylene with non-woven backing Polypropylene Polyester |
| Gloves - medium | Nitrile rubber |
| Saline Pod | Polyethylene pod Saline containing 0.9% Sodium Chloride |

INTENDED PURPOSE

Ugo Pro (catheterisation procedure pack) provides a prewrapped aseptic field and essential routine components for the safe and effective aseptic removal and /or insertion of a urinary catheter. Additional sterile medical devices required for the procedure can be added to the aseptic field.

INTENDED USER

Ugo Pro (catheterisation procedure pack) is a procedure pack intended to be used by Healthcare Professionals to perform a catheterisation procedure.

CONTRAINDICATIONS

Do not use the **Ugo Pro** (catheterisation procedure pack) if the intended user or the patient are sensitive or allergic to any of the device ingredients.

WARNINGS AND PRECAUTIONS

It is recommended that the **Ugo Pro** (catheterisation procedure pack) is used by a Healthcare Professional in line with local healthcare policies and procedures; Ensure that **Ugo Pro** (catheterisation procedure pack) is suitable for the intended use and compatible with other medical devices to be used in conjunction with it; This is a single-use device. Re-use of this device may result in patient infection / cross-contamination. Re/sterilisation, reprocessing, cleaning and disinfection may also compromise the product characteristics, resulting in trauma or infection to the patient; Keep out of reach of children; Ensure that any additional medical devices placed on the aseptic field are sterile; The **Ugo Pro** (catheterisation procedure pack) does not contain natural rubber latex; Do not use the **Ugo Pro** (catheterisation procedure pack) if it is damaged or soiled.

Saline Pod Warnings:

For irrigation only;
Not for injection;
Do not use unless the solution is clear, and the unit is intact;
Discard any unused product;
Do not re-use.

UNDESIRABLE SIDE EFFECTS

Advise the patient that in rare cases, local irritation/hypersensitivity reactions may occur such as redness, itching or blistering. If this occurs, the patient must inform the Healthcare Professional and patient records updated.

Any serious incident or malfunction that has occurred in relation to the **Ugo Pro** (catheterisation procedure pack) should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

HOW TO USE

Do not use if packaging is damaged or unintentionally opened prior to use.

- **Ugo Pro** (catheterisation procedure pack) must be used in accordance with local policies and procedures and best practice guidance by suitably qualified and competent Healthcare Professionals;
- Wash and dry your hands;
- Open the **Ugo Pro** (catheterisation procedure pack) pouch packaging and place pack on a clean flat work surface;
- Open the **Ugo Pro** (catheterisation procedure pack) pack outer wrapping touching only the outside corners and spread out to form an aseptic field. Arrange the contents onto the aseptic field (the contents may be used in the order presented, to assist with technique);

- Hold saline pod upright and open by twisting off the top;
- Empty the contents of the saline pod, directly from the pod, over non-woven balls in tray compartment – do not touch the nozzle;
- Add any additional sterile medical devices required for the procedure to the aseptic field;
- Carry out the catheterisation procedure using the **Ugo Pro** (catheterisation procedure pack) essential routine components as indicated for use in table below and in line with your local policies and procedures following a full patient assessment and patient consent.

| Ugo Pro (catheterisation procedure pack) components | Indications for use/Rationale |
|---|---|
| Outer wrapper * | <ul style="list-style-type: none"> • To wrap the sterile products; • Create aseptic field for the components to be placed upon. |
| Apron * | <ul style="list-style-type: none"> • For personal protection; • Assists with aseptic technique. |
| Grey waterproof drape * | <ul style="list-style-type: none"> • To be placed under the patient with grey side facing down and absorbent side up; • Protects the bed from spilt fluids during procedure; • Assists with aseptic technique. |
| Blue waterproof drape * | <ul style="list-style-type: none"> • To be placed over the patient with blue side facing down and absorbent side up; • Assists with dignity during the procedure. |
| Waste bag * | <ul style="list-style-type: none"> • For all waste to be collected throughout the procedure. |
| 10ml syringe ** | <ul style="list-style-type: none"> • To remove fluid from prefilled Foley catheter balloon prior to catheter removal. |
| 6 non-woven swabs * | <ul style="list-style-type: none"> • To assist with the removal of Foley catheter; • To assist with general catheterisation procedural technique. |
| Clear tray with 2 compartments * | <ul style="list-style-type: none"> • Holds components for procedure; • Holds cotton balls and saline cleansing solution in small compartment during procedure; • Large compartment can be used as a urine receiver during catheterisation. |

| | |
|---|--|
| 5 non-woven balls * | <ul style="list-style-type: none"> • For cleansing the catheter insertion site during procedure once coated in saline cleansing solution. |
| 3 pairs of medium nitrile Ugo Pro gloves * | <ul style="list-style-type: none"> • 3 pairs of gloves to support an aseptic technique - to be used for the following aspects of the procedure: <ol style="list-style-type: none"> 1. Removal of catheter; 2. Cleaning of the catheter insertion site, instillation of lubricating gel; 3. Insertion of a new catheter. |
| 20ml saline pod (0.9% w/v sodium chloride) *** | <ul style="list-style-type: none"> • Empty contents over non-woven balls in tray compartment; • Cleanse catheter insertion site during procedure. |

- Document clearly any relevant information following the procedure including reason for catheterisation.

STERILE DEVICES

Ugo Pro (catheterisation procedure pack) is supplied sterile;
Ugo Pro (catheterisation procedure pack) is sterilised by ethylene oxide; Sterile until opened; Do not re-sterilise.

- Add any additional sterile medical devices required for the procedure to the aseptic field;
- Carry out the catheterisation procedure using the **Ugo Pro** (catheterisation procedure pack) essential routine components as indicated for use in table above and in line with your local policies and procedures following a full patient assessment and patient consent.

STORAGE AND HANDLING

Keep dry;
 Keep out of direct sunlight
 Unopened packs of the **Ugo Pro** (catheterisation procedure packs) have a 3-year shelf life; Do not use after expiry date.

DISPOSAL

Ugo Pro (catheterisation procedure pack) must be disposed of according to local policies and waste disposal procedures, including any accessories / consumables used with the device.

