

Ugo Pro
Catheterisation procedure pack

REF **3400**



Sterile Saline Pod

REF **2405006**



optimummedical®



EU Importer:
Optimum Medical Solutions GmbH,
c/o Warth & Klein Grant Thornton AG,
Ulmenstraße 37-39,
60325 Frankfurt am Main, Germany
Email: enquiries@optimummedical.de

 Optimum Medical Solutions Ltd
Tennant Hall, Blenheim Grove,
Leeds, LS2 9ET, United Kingdom
T: +44(0) 845 643 5479
enquiries@optimummedical.co.uk
www.optimummedical.co.uk

ugopro.TM
catheterisation procedure pack



Instructions for use



PRODUCT REF / CONTENTS

3400

Ugo Pro catheterisation procedure pack

- This is a **Ugo Pro** 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** 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. A 20ml Sterile Saline Pod (0.9% w/v sodium chloride) is conveniently included separately to the procedure pack. 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 Polysoprene Stopper |
| O Drape Waterproof Drape Wrapping Drape | Polyethylene with non-woven backing Polypropylene Polyester |
| Gloves - medium | Nitrile rubber |
| Sterile Saline Pod | Ingredients |
| Saline Pod | Pod: Polyethylene Saline: 99% Distilled Water, 0.9% Sodium Chloride |

INTENDED PURPOSE

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

CONTRAINDICATIONS

Do not use the **Ugo Pro** 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** is used by a Healthcare Professional in line with local healthcare policies and procedures; Ensure that **Ugo Pro** 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** is latex free;
 Do not use the **Ugo Pro** if it is damaged or soiled.

Saline Pod Warnings:

Do not place the saline pod directly on the aseptic field;
 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** 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** 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** pouch packaging and place pack on a clean flat work surface;
- Open the **Ugo Pro** 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** 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 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. |
| Sterile Saline Pod | Indications for use/Rationale |
| 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.

Saline solution is supplied sterile.

Saline solution is sterilised by using an aseptic processing technique; Sterile until opened; Do not re-sterilise.

The exterior of the pod is non-sterile.

- Add any additional sterile medical devices required for the procedure to the aseptic field;
- Carry out the catheterisation procedure using the **Ugo Pro** 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 and out of direct sunlight;

Unopened packs of the **Ugo Pro** catheterisation procedure packs have a 3-year shelf life;

Unopened packs of the Sterile Saline Pod have a 5-year shelf life;

Do not use after expiry date.

DISPOSAL

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

MANUFACTURER INFORMATION

Optimum Medical Solutions Ltd, Tennant Hall, Blenheim Grove, Leeds, LS2 9ET, UK.

Tel: +44 (0) 845 643 5479

Email: enquires@optimummedical.co.uk

Website: www.optimummedical.co.uk

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

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

**10ml Syringe (CE 0123)

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

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

Crest Medical Ltd, 3 Chesford Grange, Woolston, Warrington, WA1 4RQ, UK.

EU IMPORTER INFORMATION

Optimum Medical Solutions Ltd GmbH, c/o Warth & Klein Grant Thornton AG, Ulmenstraße 37-39, 60325 Frankfurt am Main, Germany.

Email: enquiries@optimummedical.de

EU AUTHORISED REPRESENTATIVE / UK RESPONSIBLE PERSON INFORMATION

MT Promedt Consulting GmbH, Altenhofstrasse 80, 66386 St. Ingbert, Germany. Tel: +49 6894 581020

Email: info@mt-procons.com

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

EC REP 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**

EC REP 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**

EC REP CMC Medical Devices & Drugs S.L C/ Horacio Lengo No18, CP29006, Málaga, Spain



