

WARNINGS:

Keep out of reach of children!

This box contains both sterile and non-sterile components.

Non-sterile components (**Ugo Fix Gentle** and **Ugo Fix Leg Bag Straps**) must not be placed on the aseptic field.

Medical symbols for the Ugo Box:

(see individual products for more details)



EC REP

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Sponsor:

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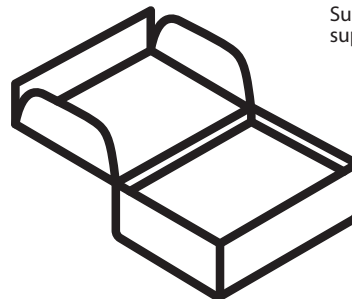
3450-3461-IFU-Sep24-V5.0

THE **ugobox**.™



A fully equipped catheterisation kit supplied in one box.

Suitable for transurethral and suprapubic catheterisation procedures.



The **Ugo Box** must be used in accordance with local policies and procedures and best practice guidance by suitably qualified and competent healthcare practitioners.

INSTRUCTIONS FOR USE

The Ugo Box contains: _____

1x **Ugo Pro** (catheterisation procedure pack)

1x **Ugo Foley Catheter** (all silicone) – size 12CH (Fr), 14CH (Fr) or 16CH (Fr)

1x **OptiPure** (for inflating **Ugo Foley Catheter** balloon)

1x 11 mL **OptiLube** catheterisation jelly syringe OR
11 mL **OptiLube Active CHG Free** catheterisation jelly syringe

1x **Ugo Leg Bag** - **Ugo1C** – short tube (5cm), 500mL, lever tap OR
Ugo2C – long tube (25cm), 500mL, lever tap

1x **Ugo Fix Gentle** (catheter clip)

1x pair of **Ugo Fix Leg Bag Straps**



optimummedical®

Procedure pack producer:

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WHAT IS THE UGO BOX?

The **Ugo Box** is a fully equipped catheterisation kit, designed to be used for the insertion and removal of transurethral or suprapubic catheters.

There are 12 variations of **The Ugo Box**, with a choice of **Ugo Foley Catheter**, **Ugo Leg Bag** and **OptiLube** catheterisation jelly.

Please see table below:

PR Code	Ugo Foley Catheter CH size	Ugo Leg Bag	11mL Catheterisation Jelly Syringe
3450	12CH (Fr)	Ugo 1C	OptiLube Active CHG Free
3451	14CH (Fr)	Ugo 1C	OptiLube Active CHG Free
3452	16CH (Fr)	Ugo 1C	OptiLube Active CHG Free
3453	12CH (Fr)	Ugo 1C	OptiLube*
3454	14CH (Fr)	Ugo 1C	OptiLube*
3455	16CH (Fr)	Ugo 1C	OptiLube*
3456	12CH (Fr)	Ugo 2C	OptiLube Active CHG Free
3457	14CH (Fr)	Ugo 2C	OptiLube Active CHG Free
3458	16CH (Fr)	Ugo 2C	OptiLube Active CHG Free
3459	12CH (Fr)	Ugo 2C	OptiLube*
3460	14CH (Fr)	Ugo 2C	OptiLube*
3461	16CH (Fr)	Ugo 2C	OptiLube*

All **Ugo Foley Catheters** have a 10mL non-integrated balloon.

Note: **OptiLube Active CHG Free** contains lidocaine and is not recommended for use during suprapubic catheterisation procedures.

*For suprapubic catheterisation procedures, select a variation containing **OptiLube**.

All products within **The Ugo Box** can be prescribed as individual items if required.

For ordering information, please visit www.optimummedical.co.uk or email enquiries@optimummedical.co.uk

HOW TO USE THE UGO BOX – STEP BY STEP

Before using **The Ugo Box**, it is important to follow the steps below and read the instructions for use for every product within this kit. The instructions for use for the Ugo Pro are provided in the catheterisation procedure pack pouch. The contents of **The Ugo Box** must be used in accordance with local policies and procedures and best practice guidance by suitably qualified and competent healthcare practitioners.

The contents of **The Ugo Box** are designed to be used together as a kit, not as individual items.

Patients requiring long-term catheters should be continuously assessed and have them removed when not required.

1. Open the **Ugo Pro** (catheterisation procedure pack) pouch packaging and place pack on a clean flat work surface.
2. Open the **Ugo Pro** (catheterisation procedure pack) outer wrapping, touching only the outside corners and spread out to form an aseptic field. Arrange the contents of the **Ugo Pro** (catheterisation procedure pack) on to the aseptic field.
3. Add the remaining sterile products in **The Ugo Box** to the aseptic field:
 - a. **Ugo Foley Catheter.**
 - b. **OptiPure.**
 - c. **11 mL Catheterisation Jelly Syringe.**
 - d. **Ugo Leg Bag.**
4. Please note, do not add non-sterile items to the aseptic field. This includes:
 - a. **Ugo Fix Gentle** (catheter clip).
 - b. pair of **Ugo Fix Leg Bag Straps.**
5. Carry out the catheterisation procedure in line with your local policies and procedures following a full patient assessment and patient consent.
6. Clearly document any relevant information following the procedure, including reason for catheterisation.
7. Dispose of all waste following the procedure in line with your local waste disposal policy.
8. The waste disposal bag may be stored within **The Ugo Box** until it is possible to dispose of it appropriately. Please note that **The Ugo Box** cardboard container is fully recyclable.

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 any of the components contained within **the Ugo Box** should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Ugo.TM
Foley catheter

All silicone Foley catheter (2-way)
with non-integrated 10mL balloon.

The **Ugo Box** has 3 different sizes
of the **Ugo Foley Catheter** to choose from:
12CH (Fr), 14CH (Fr) or 16CH (Fr).



PRODUCT REF / CONTENTS

3350	12CH (Fr)	Ugo Foley Catheter
3351	14CH (Fr)	Ugo Foley Catheter
3352	16CH (Fr)	Ugo Foley Catheter

INTENDED PURPOSE

Ugo Foley Catheter is intended for long term catheterisation of the urinary bladder and is appropriate for both transurethral and suprapubic use.

INDICATIONS FOR USE / INTENDED USER

Ugo Foley Catheter is a medical device indicated for continuous bladder drainage. Catheter insertion should always be carried out by appropriately trained Healthcare Professionals in accordance with local and national best practice policies.

CONTRAINDICATIONS

Do not use the **Ugo Foley Catheter** if the patient is sensitive or allergic to any of the device ingredients.

The **Ugo Foley Catheter** may be contraindicated or not be suitable for individuals who have:

- Acute urethritis
- Acute prostatitis
- Acute epididymitis

WARNINGS AND PRECAUTIONS

- Read all the warnings and instructions before use. Improper use can result in serious or fatal illness or injury.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.
- Do not use the catheter if its damaged or irregularly shaped.
- Do not use after the expiry date.
- For single use only.
- Not compatible with MRI.
- Do not over inflate the balloon. Refer to outer unit pack or funnel of the catheter for balloon capacity.
- Inflate the catheter balloon only with sterile water.
- The **OptiPure** 10mL prefilled syringe with sterile water supplied, is for inflation of the catheter balloon only; not for injection.
- The empty 10mL syringe provided in the **Ugo Pro** catheterisation kit is for the deflation of the catheter balloon prior to removal of the catheter.
- This product is intended for use by trained Healthcare Professionals.
- An aseptic technique must be practice
- Do not use ointments and lubricants with a petroleum base. Use water soluble lubricants.
- Do not clamp catheter shaft. It may damage the catheter and prevent deflation.
- Patients should be regularly monitored as determined by a Healthcare Professional.
- Ensure local cleaning and hygiene protocols are followed to keep the catheter and meatus as clean as possible.
- During long term use, the balloon inflation volume should be regularly monitored in case any clinical signs of deflation occur, such as bypassing of urine or urethral pain. If necessary, the balloon volume should be adjusted.
- The balloon must be completely deflated before catheter removal.
- The retention time of the **Ugo Foley Catheter** should be decided by the medical care professionals according to the actual situation of using.
- **Ugo Foley Catheter** is supplied sterile by ethylene oxide after the packaging process.
- Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in injury, illness or death of the patient. Reuse, reprocessing or resterilisation may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Precautions shall be taken when discarding device and disposal of the device shall be made in accordance with applicable national regulations for biological hazardous waste.
- The **Ugo Foley Catheter** is not made with natural rubber latex.

UNDESIRABLE SIDE EFFECTS

- Reported adverse reactions associated with Foley catheters are (including but not limited to): Septicaemia, Urethritis, Urinary tract infection and encrustations, bladder spasms and abdominal discomfort.

- If difficulty is encountered aspirating the balloon with a syringe, a rare and infrequently reported event, the leg of the catheter with the valve should be cut with a sharp scissors at the bifurcation or rupture the balloon according to established procedures reported in medical literature. Should it be necessary to rupture the balloon, care must be taken to remove all fragments from the patient's bladder.
- Incorrectly positioned catheters can cause urethral damage if the balloon is inflated contrary to instructions within the urethra.
- Irritation of the urethral mucosa, blockage of the catheter due to encrustation and catheter induced infections are documented complications with some catheter materials and patient's. The patient should be routinely monitored in accordance with accepted procedures and the catheter shall be removed after a suitable interval as determined by a Healthcare Professional or other suitably qualified personnel.
- Long term use of catheter has the risk of urinary tract infection, sphincter relaxation and urethral relaxation.

HOW TO USE

Urethral catheterisation:

- With the sterile gloved hand, pick up the catheter from the sterile field.
- Carefully insert the catheter tip into the bladder (normally indicated by urine flow), and then a further 3 cm to ensure balloon is also inside the bladder.
- Inflate the catheter balloon using the **OptiPure** 10mL prefilled sterile water syringe, at the discretion of the Healthcare Professional.
- Slowly retract the catheter until some resistance is felt to ensure that the balloon is correctly located within the bladder, before the bladder neck.
- Connect the catheter to a urine drainage device.
- Observe urine flow.

Suprapubic catheterisation:

- Suprapubic catheter insertion should always be carried out by appropriately trained Healthcare Professionals in accordance with local and national best practice policies.

Catheter removal:

For removal of the catheter, deflate the balloon by inserting the empty syringe into the valve. Release the syringe plunger and allow the balloon to deflate. Only use gentle aspiration, if necessary, to deflate the balloon.

- Discard the catheter according to hospital protocol.

An implant card must be supplied to the patient with the **Ugo Foley Catheter**.

CATHETER CARE

- Ensure local cleaning and hygiene protocols are followed to keep the catheter and meatus as clean as possible.
- Conduct hand hygiene immediately before and after any manipulation of the catheter and the urine drainage system. Wear disposable gloves when handling the system.
- Maintain unobstructed urine flow.
- Ensure that the catheter and collection tube do not kink.

DAY TO DAY CATHETER CARE

Ensure the catheter user understands the importance of correct catheter care. Discuss with the catheter user and ensure they are aware that they must:

- Wash and dry their hands before and after any catheter manipulation.
- Clean the area around the catheter with a mild soap at least twice a day.
- Drink 2 to 3 litres of water per day.
- Regularly drain their urine drainage system.
- Keep the drainage system closed.

STORAGE AND HANDLING

- Store between -15 and 49°C (5-120°F) until expiry date.
- Store in a dark, cool and dry place.
- Keep dry.
- Keep out of direct sunlight.
- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Unopened packs have a 5-year shelf life.
- Do not use after expiry date.
- Catheters should not be stored folded.
- Store in manner preventing crushing.

DISPOSAL

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

REF **UFC12/UFC14/UFC16**



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optipure.™



PRODUCT DESCRIPTION

OptiPure is a sterile, single use syringe, prefilled with 10mL of sterile water (1128).

OptiPure is a clear liquid.

INTENDED PURPOSE

OptiPure is for the inflation of indwelling urinary Foley catheter balloons, to retain the catheter in the bladder.

INDICATIONS FOR USE / INTENDED USER

OptiPure is a medical device intended to be used by Healthcare Professionals when performing an indwelling catheterisation procedure.

CONTRAINDICATIONS

Do not use **OptiPure** if the intended user or the patient are sensitive or allergic to the ingredients.

WARNINGS AND PRECAUTIONS

- It is recommended that **OptiPure** is used by a Healthcare Professional in line with local healthcare policies and procedures.
- Ensure that **OptiPure** is suitable for the intended use and compatible with other medical devices to be used in conjunction with it.
- Always ensure the Foley catheter is fully inserted into the bladder and urine is draining before inflating the balloon using **OptiPure**.
- Always use the volume advised in the Foley catheter instructions for use for inflating the balloon.
- 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.
- **OptiPure** is not made from natural rubber latex.
- Do not use the **OptiPure** syringe if it is damaged or soiled.
- Do not use for injection, reconstitution of drugs, medication dilution or patient rehydration.

HOW TO USE

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

OptiPure does not have a measuring function, do not use for accurate recording.

OptiPure must be used as part of an aseptic technique and in accordance with local healthcare policies and procedures and best practice guidance by suitably qualified and competent Healthcare Professionals.

- Wash hands and open **OptiPure** pouch.

- Visually inspect the contents of each prefilled syringe for clarity, discoloration or leakage prior to use and do not use if any of the above is observed within the syringe.
- Remove the cap from the **OptiPure** syringe and hold the tip of syringe upward and gently depress the plunger to expel any air.
- Attach the syringe tip to the inflation lumen of the Foley catheter.
- Inflate the Foley catheter balloon using the correct volume.

STERILE DEVICES

- **OptiPure** is supplied sterile.
- **OptiPure** is sterilised by gamma radiation after the packaging process.
- Do not re-sterilise.

STORAGE AND HANDLING

- Store between 5-30°C (41-86°F) until expiry date.
- Keep dry and out of direct sunlight.
- Unopened packs have a 3-year shelf life.
- Do not use after expiry date.

DISPOSAL

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



REF 1128

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The **Ugo Box** has 2 types of catheterisation jelly syringes to choose from; **OptiLube 11mL** or **OptiLube Active CHG Free 11mL**

1 x 11mL syringe is suitable for either male or female catheterisation. For suprapubic catheterisation, we would recommend **OptiLube**.

optilube.™ sterile lubricating jelly



PRODUCT DESCRIPTION

OptiLube is a sterile, single-use, pre-filled syringe with water-soluble jelly.

INGREDIENTS

100g of **OptiLube** contains:

- Purified Water;
- Propylene Glycol;
- Hydroxyethylcellulose.

INTENDED PURPOSE

OptiLube is a medical device that has a lubricating effect that helps prevent trauma being caused to the patient during catheterisation procedures.

OptiLube is a clear, water-soluble, petroleum free lubricating jelly.

INDICATION FOR USE

OptiLube is designed for lubrication of the urethra prior to insertion of urethral catheters and other urological medical devices including cystoscopes. It is also suitable for suprapubic catheterisation.

CONTRAINDICATIONS

OptiLube must not be used in patients with known hypersensitivity to any of the ingredients.

Do not use for intravenous (IV) or intramuscular (IM) injections.

Do not use orally. If swallowed, please seek medical advice.

Do not use in eyes. If it comes into contact with the eyes, please seek medical advice.

WARNINGS AND PRECAUTIONS

OptiLube must only be used under the supervision of Healthcare Professionals in accordance with local guidelines, policies and procedures.

Keep out of reach of children.

Ensure **OptiLube** 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.

OptiLube is latex free.

HOW TO USE

Consult your Healthcare Professional for advice before using **OptiLube**. It is recommended that this product is used as part of an aseptic technique.

- Cleanse the opening and surrounding area prior to use;
 - Evenly peel back the paper backing and remove the sterile syringe;
 - Remove the cap from the end of syringe;
 - Apply a drop of jelly to the opening to make initial insertion easier;
 - Insert the nozzle into the opening and press the plunger of the syringe slowly to release the necessary amount of **OptiLube**.
- NOTE:** **OptiLube** should be applied to the urethra or suprapubic opening, not directly onto the device;
- The lubrication characteristics of the jelly start to take effect at the time of application. Do not use if packaging is damaged or unintentionally opened prior to use.

STERILISATION

OptiLube is supplied sterile. Sterilised with gamma radiation after the packaging process. Do not re-sterilise.

STORAGE AND HANDLING

The scale on the syringe is for the orientation of the user. It does not have a measurement function. Store between 5-30°C (41-86°F) until expiry date. Keep dry and out of direct sunlight. Unopened packs have a 3-year shelf life. Do not use after expiry date.

DISPOSAL

OptiLube must be disposed of according to local policies and procedures, including any remaining fluid in the syringe.

optilube.™
active CHG free

sterile
lubricating jelly
with local anaesthetic
(Lidocaine)
for urethral application



OptiLube Active CHG Free contains Lidocaine and is not suitable for use during suprapubic catheterisation procedures.

PRODUCT DESCRIPTION

OptiLube Active CHG Free (with Lidocaine) is a sterile, single-use, pre-filled syringe with water-soluble jelly.

INGREDIENTS

100g of **OptiLube Active CHG Free** contains:

Active Ingredient: • 2g Lidocaine Hydrochloride

Other Ingredients: • Purified Water; • Propylene Glycol; • Hydroxyethyl cellulose.

INTENDED PURPOSE

OptiLube Active CHG Free is a medical device that helps to prevent trauma being caused to the patient during catheterisation procedures or other urethral procedures by effective lubrication. Additionally, **OptiLube Active CHG Free** contains the following ancillary medicinal substance; local anaesthetic (**Lidocaine**) to help reduce pain for the patient.

INDICATION FOR USE

OptiLube Active CHG Free is designed to lubricate the urethra prior to insertion of a urethral catheter.

CONTRAINDICATIONS

OptiLube Active CHG Free must not be used in patients:

- With known allergies or hypersensitivity to any of the ingredients.
- Who have ever had a reaction to **Lidocaine**.
- Who have damaged or bleeding mucous membranes because of the risk of systemic absorption of the **Lidocaine**.

Do not use in children below 2 years of age.

Do not use for intravenous (IV) or intramuscular (IM) injections.

Do not use orally. If swallowed, please seek medical advice.

Do not use in eyes. If it comes into contact with the eyes, please seek medical advice.

Do not use for suprapubic catheterisation procedures.



STERILE R



LATEX FREE



REF 1126

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WARNINGS AND PRECAUTIONS

OptiLube Active CHG Free must only be used under the supervision of Healthcare Professionals in accordance with local guidelines, policies and procedures.

OptiLube Active CHG Free is not suitable if a patient:

- Has a damaged or bleeding urethra.

Care should be taken when using the jelly with patients who:

- Have heart problems or taking medication for treating irregular heartbeat;
- Have liver problems;
- Are epileptic.

OptiLube Active CHG Free must not be used at the same time as other medical devices or medicines containing Lidocaine or other local anaesthetic.

Patients may experience a slight stinging on application of the jelly, but this usually stops once the anaesthetic starts to work. Encourage patients to report any reaction to the jelly.

Keep out of reach of children.

Ensure **OptiLube Active CHG Free** 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.

OptiLube Active CHG Free is latex free.

PREGNANCY AND LACTATION

Only use during pregnancy and breast feeding under the direction of a doctor.

Always ask the patient if they are pregnant prior to using the jelly.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINERY

The ability to drive and operate machinery may be slightly impaired after the use of lubricant jelly with **Lidocaine**. If affected, patients should be advised not to drive or use machinery.

INTERACTIONS OF MEDICINAL SUBSTANCES AND SUBSTANCES THAT ARE ABSORBED

Depending on the absorption of **Lidocaine**, these interactions can be seen when used with the following medications:

Propranolol: Reduction in plasma clearance of **Lidocaine**;

Cimetidine: Reduction in plasma clearance of **Lidocaine**;

Antiarrhythmic products: Increase in the toxicity of **Lidocaine**;

Phenytoin or barbiturates: Reduction in plasma levels of **Lidocaine**.

Specified interactions can be seen in the long-term use and repeated high doses. When administered as recommended, there is no clinically significant interactions reported.

UNDESIRABLE SIDE EFFECTS

Like any medication, **OptiLube Active CHG Free** may cause side effects in some people. Side effects to this product must be documented in patient records. In rare cases local hypersensitivity reactions may occur, such as redness, stinging, blistering or itching and/or systemic reactions to **Lidocaine**. There is also a risk of severe reactions including drop in blood pressure, dizziness, nausea, shortness of breath, bradycardia, convulsions and anaphylactic shock. If this occurs, stop using **OptiLube Active CHG Free** and consult your Healthcare Professional.

DOSAGE

Dosage recommendations:

FOR ADULTS: Max. 800 mg Lidocaine during a 24 hour period (x 3 syringe for 11 mL)

FOR CHILDREN (between 2 and 15 years): Max. 0.3mL gel/kg B.W (≈ 6mg **Lidocaine**/kg) is recommended per procedure and no more than four doses should be administered within 24 hours.

In children below 2 years lubricant gel with Lidocaine must not be used.

OVERDOSE

Excessive dosage or short intervals between doses can result in high plasma levels and serious adverse effects.

OptiLube Active CHG Free must not be used at the same time as any other medical device or medicines containing a local anaesthetic agent.

In the event of excessive absorption of Lidocaine into the bloodstream, symptoms may include central nervous system effects and cardiovascular reactions.

In the event of excessive use or use outside of these guidelines please seek medical advice.

HOW TO USE

It is recommended that this product is used as part of an aseptic technique.

- Cleanse the opening to the urethra and surrounding area prior to use;
- Evenly peel back the paper backing and remove the sterile syringe;
- Remove the cap from the end of syringe;
- Apply a drop of jelly to urethral opening to make initial insertion easier;
- Insert the nozzle into the urethral opening and press the plunger of the syringe slowly to release the necessary amount of **OptiLube Active CHG Free**.

NOTE: OptiLube Active CHG Free should be applied to the urethra, not directly onto the device;

- The lubrication characteristics of the jelly start to take effect at the time of application. The onset of anaesthetic effect takes 3-5 minutes.

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

STERILISATION

OptiLube Active CHG Free is supplied sterile.

Sterilised with gamma radiation after the packaging process.

Do not resterilise.

STORAGE AND HANDLING

The scale on the syringe is for the orientation of the user. It does not have a measurement function.

Store between 5-30°C (41-86°F) until expiry date.

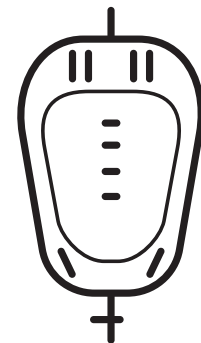
Keep dry and out of direct sunlight.

Unopened packs have a 3-year shelf life. Do not use after expiry date.

DISPOSAL

OptiLube Active CHG Free must be disposed of according to local policies and procedures, including any remaining fluid in the syringe.

ugo.TM
leg bag



The **Ugo Box** has 2 variations of **Ugo Leg Bag** to choose from:
Ugo 1C (5cm short tube, 500mL, lever tap)
or **Ugo 2C** (25cm long tube, 500mL, lever tap)

The **Ugo Leg Bag** can remain attached to your catheter for up to 7 days. The leg bags are sterile pouched packaged and have a needle free sample port.

Only use a **Ugo Leg Bag** if it has been prescribed for you by a healthcare professional and you (or your carer) have the ability to change it, empty it regularly and care for it.

HOW TO ATTACH YOUR UGO LEG BAG TO YOUR CATHETER

- Wash and dry your hands (if a carer is changing the leg bag for you they must apply a clean pair of gloves after drying their hands).
- Remove any straps or sleeve which are supporting your **Ugo Leg Bag** to your leg.
- Open the pouch packaging for a new **Ugo Leg Bag** and remove the protective cap from the leg bag stepped connector.
- Detach the old leg bag from the catheter and immediately insert the stepped connector from the new leg bag ensuring an adequate seal (the leg bag is supplied in the closed position).
- It is important that you do not touch the ends of the catheter or leg bag connector during the change (non touch technique)
- The discarded protective cap from the new **Ugo Leg Bag** can be attached to the stepped connector of the old leg bag.
- Apply your leg bag fixation and support devices and adjust to ensure optimum drainage and comfort. If using the **Ugo Fix Leg Bag Straps** provided, follow the instructions on how to fit overleaf.
- Empty the urine from your old leg bag into the toilet and dispose of the bag as recommended by your nurse.
- Wash and dry your hands.



REF 1168

STERILE R



MD



LATEX FREE

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Şti., Anadolu OSB Mah. 29. Ekim Cad., No: 41 Maliköy, Sincan, Ankara, Turkey

HOW TO EMPTY YOUR UGO LEG BAG

- Wash and dry your hands (if a carer is emptying your bag for you they must apply a clean pair of gloves after drying their hands).
- Hold the outlet tap over a toilet or suitable receptacle.
- Open the tap by sliding the T tap or pushing the lever tap down.
- Allow the bag to drain completely then close the tap.
- Dry the end of the soft silicone outlet tubing with a clean wipe if necessary.
- Wash and dry your hands.

WARNING

**NEVER RECONNECT A USED LEG BAG
KEEP OUT OF REACH OF CHILDREN**

If your urinary drainage system is not draining urine and/or you are in discomfort or feeling unwell, contact your nurse or doctor immediately.

REF.	Product description			
1C/500/ST/L	Ugo 1C	500mL	Short tube (5cm)	lever tap
2C/500/LT/L	Ugo 2C	500mL	Long tube (25cm)	lever tap

REF 1C/500/ST/L **REF 2C/500/LT/L**



EC REP

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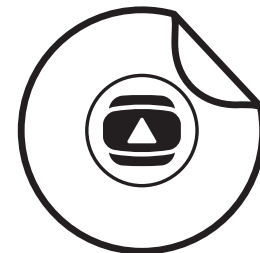


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ugofix.™

gentle



PRODUCT DESCRIPTION

The **Ugo Fix Gentle** catheter clip is a non-sterile, silicone-based securement medical device, used to provide fixation of a 2-way indwelling urinary catheter at the bifurcation of the catheter.

The **Ugo Fix Gentle** features a rotating clip mounted on a re-adhesive silicone gel pad. The rotating catheter clip holds the catheter away from the skin and rotates, allowing the catheter to move naturally with the motion of the body. The re-adhesive silicone gel pad is applied to the skin, providing gentle adhesion.

COMPOSITION

Description	Material Composition
Adhesive silicone	Silicone
Catheter Clip	Polyvinyl Chloride
Release liner	Polyurethane film

INTENDED PURPOSE

The **Ugo Fix Gentle** catheter clip is a medical device intended to provide securement and fixation of 2-way indwelling urinary catheters, size 8CH to 20CH. The fixation of the catheter is intended to provide comfort and help reduce the risk of trauma caused by inadvertent movement of the catheter.

INTENDED USER/S

The intended users of the **Ugo Fix Gentle** catheter clip are patients with a 2-way indwelling urinary catheter, in size 8CH to 20CH, and their carers and/or Healthcare Professionals.

CONTRAINDICATIONS

- Do not use the **Ugo Fix Gentle** catheter clip unless you have been assessed as suitable by a Healthcare Professional and it has been recommended for you.
- Do not use if you are sensitive or allergic to any of the device materials.
- Do not use on skin which is broken or inflamed

WARNINGS AND PRECAUTIONS

- It is recommended that the **Ugo Fix Gentle** catheter clip is used in line with local healthcare policies and procedures following a patient continence assessment by a Healthcare Professional.
- Ensure that the **Ugo Fix Gentle** catheter clip is suitable for the intended use and is compatible with other medical devices to be used in conjunction with it. It may not be compatible with all 2-way indwelling urinary catheters. Check the operating instructions of the catheter in use.
- The **Ugo Fix Gentle** catheter clip is a non-sterile medical device.
- The **Ugo Fix Gentle** catheter clip is not designed to support the weight of a urine

drainage bag. Always support the weight of your urine bag with an appropriate device.

- Do not disconnect your urine drainage bag during fitting of the **Ugo Fix Gentle** catheter clip. It is designed to allow fitting without disconnecting the system
- Do not use moisturisers, moisturising soap, shower gel, wet wipes, baby wipes or talcum powder on the area of skin where the **Ugo Fix Gentle** catheter clip will be positioned, as they may affect the adhesion of the **Ugo Fix Gentle** catheter clip to the skin.
- It is important that you check your skin beneath the **Ugo Fix Gentle** catheter clip regularly, to ensure it remains intact.
- Do not shave where the **Ugo Fix Gentle** catheter clip is to be applied to the skin, as it may cause skin irritation. If necessary, any excess hair can be trimmed.
- It is important to check that your catheter is not twisted prior to insertion into the **Ugo Fix Gentle** catheter clip (see howto use) and to regularly check that your catheter and all drainage tubing are free from obstruction and urine is draining freely (see undesirable side effects)
- Do not use the **Ugo Fix Gentle** catheter clip if it is damaged or soiled
- Do not use if the packaging is damaged or unintentionally opened prior to use.
- Keep out of reach of children.
- The **Ugo Fix Gentle** catheter clip not made with natural rubber latex.
- The device may not be suitable for all skin types.

This is a single-use medical device. Re-use of this medical device may result in patient infection and/or cross-contamination.

Sterilisation, reprocessing, cleaning and/or disinfection, may also compromise the product characteristics, resulting in trauma or infection to the patient.

UNDESIRABLE SIDE EFFECTS

In rare cases local irritation or hypersensitivity may occur. Symptoms of irritation and hypersensitivity include redness, itchiness, or blistering. If this occurs, stop using the **Ugo Fix Gentle** catheter clip and consult your Healthcare Professional and ensure patient records are updated.

There may be an increased risk of complications from wearing the **Ugo Fix Gentle** catheter clip if you have decreased sensation and if the **Ugo Fix Gentle** catheter clip has not been fitted correctly.

Remove the **Ugo Fix Gentle** catheter clip immediately if you experience any of the following during or after use, and seek medical advice:

- Swelling, inflammation or discomfort of the skin.
- Lesions or broken skin.
- Urine not draining into urine bag.
- Cloudy or foul-smelling urine.
- Feeling unwell, high temperature, nausea/vomiting or in any pain/discomfort.

HOW TO USE

Consult your Healthcare professional for advice before using the **Ugo Fix Gentle** catheter clip.

Always wash and dry your hands before and after handling your catheter or drainage tubing. If someone else is handling your catheter or drainage tubing, they must wash and dry their hands and apply a clean pair of gloves on every occasion to avoid cross infection.

The **Ugo Fix Gentle** catheter clip can be used for up to 7 days depending on your lifestyle. We recommend that you change your **Ugo Fix Gentle** catheter clip to suit your personal hygiene and physical needs. Change it sooner if it becomes damaged or soiled or there are signs of degradation.

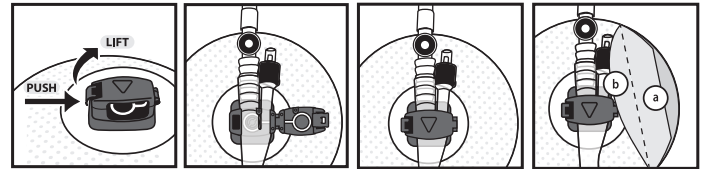
The **Ugo Fix Gentle** catheter clip can be worn in the shower to support your catheter. Ensure the edges are fully adhered to the skin prior to showering and pat dry the **Ugo Fix Gentle** catheter clip with a towel.

Always support the weight of your catheter and/or leg bag when fitting your **Ugo Fix Gentle** catheter clip.

How to Apply the **Ugo Fix Gentle** catheter clip:

Before Applying the **Ugo Fix Gentle** catheter clip to your skin:

It is important that you fix your catheter into the **Ugo Fix Gentle** catheter clip prior to applying to your skin.



Open clip (see illustrations).

1. Push and lift the catch to open the **Ugo Fix Gentle** catheter clip lid.

Insert catheter (see illustrations).

2. Place the bifurcation (the part of the catheter where it splits into two) part of the catheter into the **Ugo Fix Gentle** catheter clip. It will only fit one way.

WARNING - Make sure the catheter is not twisted before placing into the **Ugo Fix Gentle** catheter clip.

3. Once in place, fix the **Ugo Fix Gentle** catheter clip lid closed by gently pressing the lid down.

4. You will sense a click when the clip is closed correctly. Ensure the arrow on the clip is pointing towards your bladder.

APPLICATION OF THE UGO FIX GENTLE CATHETER CLIP TO YOUR SKIN

Now your catheter is fixed into the clip, you are ready to apply the **Ugo Fix Gentle** catheter clip to your skin. Your Healthcare Professional can advise on the most suitable position to place the **Ugo Fix Gentle** catheter clip.

5. Remove backing (A) and apply to skin in desired position.

6. Remove backing (B) and smooth in place.)

IMPORTANT - We recommend an allowance of 2-4cm slack to enable natural movement of the catheter.

If your catheter is pulling when you stand up or move around, you can reposition and reapply as necessary.

REMOVAL OF UGO FIX GENTLE FROM YOUR SKIN AND REPOSITIONING

You may want to reposition the **Ugo Fix Gentle** catheter clip between daytime and bedtime. You can wear your **Ugo Fix Gentle** catheter clip in bed and follow your usual overnight regime. Your Healthcare Professional can advise on regular repositioning of the **Ugo Fix Gentle** catheter clip.

7. Gently lift the edges of the **Ugo Fix Gentle** catheter clip adhesive until it is fully removed taking care not to allow it to stick together.
8. Reapply to skin in new position and smooth down in place.

STORAGE AND HANDLING

Keep dry and out of direct sunlight.

Unopened packs have a 5-year shelf life.

Do not use after expiry date.

DISPOSAL

Ugo Fix Gentle catheter clip must be disposed of according to local policies and procedures, including any accessories or consumables used with the device.

ugofix.™

leg bag straps



DESCRIPTION

The **Ugo Fix Leg Bag Straps** are a single patient, multiple use, non-sterile, medical device for supporting the weight of a urinary leg bag that is attached to an indwelling urinary catheter or male urinary sheath.

The **Ugo Fix Leg Bag Straps** consist of a pair of elasticated straps, which are used to support urinary leg bags to the user's thigh, upper knee or shin, and are secured with a hook and loop fastening. The straps feature silicone strips on the inner surface to help prevent movement on the skin.

The **Ugo Fix Leg Bag Straps** measure 75cm and 45cm. They can be used as a pair or joined to form one strap and are adjustable and can be cut down to fit if necessary. They are suitable for supporting urinary leg bags from 350mL to 750mL volumes, through the eyelet holes in the top and bottom band of the urinary leg bag.

The **Ugo Fix Leg Bag Straps** are washable and reusable.

INGREDIENTS/COMPOSITION

Silicone strip

Nylon hook

Elastic loop (polyester, nylon, spandex)

INTENDED PURPOSE

The **Ugo Fix Leg Bag Straps** provide support for the weight of your urinary leg bag, allowing it to fill whilst worn on the leg, enabling mobility.

This support is intended to provide comfort and reduce the risk of injury from the weight of your urinary leg bag pulling on your catheter or male urinary sheath.

INTENDED USER

The intended users of the **Ugo Fix Leg Bag Straps** are patients with urinary leg bags attached to indwelling urinary catheters or male urinary sheaths, and their Carers and/or Healthcare Professionals.

CONTRAINDICATIONS

- Do not use the **Ugo Fix Leg Bag Straps** unless you have been assessed as suitable by a Healthcare Professional and they have been recommended for you.
- Do not use the if you are sensitive or allergic to any of the device materials.
- Do not use on skin which is broken or inflamed.

WARNINGS AND PRECAUTIONS

- It is recommended that the **Ugo Fix Leg Bag Straps** are used in line with local healthcare policies and procedures following a patient assessment by a Healthcare Professional.
- Ensure that the **Ugo Fix Leg Bag Straps** are suitable for the intended use and are compatible with other medical devices to be used in conjunction with them.
- Do not disconnect your urinary leg bag when fitting your **Ugo Fix Leg Bag Straps**. They are designed specifically to allow fitting without disconnecting the system.

REF 3004



EC REP

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- Always support the weight of your catheter and urinary leg bag when fitting your **Ugo Fix Leg Bag Straps**.
- It is important that your catheter is also secured to prevent inadvertent movement, in addition to using the **Ugo Fix Leg Bag Straps**.
- Ensure you measure around your thigh, upper knee or lower leg at the position you intend to wear your **Ugo Fix Leg Bag Straps** before cutting to length. Allow for shrinkage after washing and drying. If the straps are too short, they can restrict circulation (see How to use).
- Only apply the **Ugo Fix Leg Bag Straps** to skin which is clean and dry with no wounds or sores.
- The **Ugo Fix Leg Bag Straps** are elasticated. It is important that you visually check your skin regularly to ensure it remains healthy and intact and your straps are not too tight and marking your skin.
- It is important to check that your catheter or drainage bag tubing are not twisted prior to applying the **Ugo Fix Leg Bag Straps** to your leg (see how to use) and to regularly check that your catheter and all drainage tubing are free from obstruction and urine is draining freely (see undesirable side effects).
- Do not use the **Ugo Fix Leg Bag Straps** if they are damaged or soiled.
- Do not use if the packaging is damaged or unintentionally opened prior to use.
- Keep out of reach of children.
- The **Ugo Fix Leg Bag Straps** are not made with natural rubber latex.
- The **Ugo Fix Leg Bag Straps** are a non-sterile medical device.
- The **Ugo Fix Leg Bag Straps** are a reusable device. Please refer to 'How to care for your device' to ensure the product performance is maintained.

UNDESIRABLE SIDE EFFECTS

There may be an increased risk of complications from wearing the **Ugo Fix Leg Bag Straps** if you have decreased sensation or changes to your leg circumference (oedema) and if the **Ugo Fix Leg Bag Straps** have not been fitted correctly.

Remove the **Ugo Fix Leg Bag Straps** immediately if you experience any of the following during use and seek medical advice:

- Swelling, inflammation or discomfort of the skin;
- Pressure markings to the skin, lesions or broken skin;
- Discolouration to the skin or oedema;
- Urine not draining into urine bag;
- Urine leaking outside the catheter;
- Cloudy or foul smelling urine;
- Blood in urine;
- Changes to urine colour or volume;
- Feeling unwell, high temperature, nausea/vomiting or in any pain/discomfort.

HOW TO USE

Consult your Healthcare Professional for advice before using the **Ugo Fix Leg Bag Straps**.

Always wash and dry your hands before and after handling your catheter or drainage bag tubing and straps. If someone else is handling your catheter or drainage bag tubing and straps, they must wash and dry their hands and apply a clean pair of gloves on every occasion to avoid cross infection.

We recommend that you change your **Ugo Fix Leg Bag Straps** daily along with your catheter hygiene regime. Only change them sooner if they are damaged or soiled. The **Ugo Fix Leg Bag Straps** are not waterproof; however you can still bathe and shower when wearing them to support your leg bag. Replace the wet **Ugo Fix Leg Bag Straps** with a clean dry pair afterwards.

Identify the best place to wear the **Ugo Fix Leg Bag Straps**.

The **Ugo Fix Leg Bag Straps** can be used to support your urinary leg bag on your thigh, upper knee or lower leg. The position you wear your leg bag will depend on whether you have a urethral or suprapubic catheter, the length of your catheter and leg bag tubing, your leg bag volume and your level of mobility.

Measuring and adjusting the **Ugo Fix Leg Bag Straps** to the correct length

1. Using a tape measure, measure around your leg at the position you intend to wear your **Ugo Fix Leg Bag Straps**.
2. Then using the tape measure, measure the length of the **Ugo Fix Leg Bag Straps**, add at least 5cm for hook and loop overlap and cut to length.

Warning! – Do not cut the **Ugo Fix Leg Bag Straps** whilst being worn and stretched.

How to apply your **Ugo Fix Leg Bag Straps**

FITTING OPTIONS (see page 30):

Method A – Using both straps to attach your urinary leg bag to your thigh or shin.

1. Feed the long **Ugo Fix Leg Bag Strap** (75cm) through the 4 holes in the top of your urinary leg bag and the short **Ugo Fix Leg Bag Strap** (45cm) through the bottom 2 holes.
2. Ensure the silicone line will be facing down onto your skin;
3. Attach the straps around your thigh or shin in the desired position and use the hook and loop tabs to secure in place (it is usually easiest to fit the top strap first).

Method B – Using the long strap to attach your urinary leg bag to your upper knee.

1. Feed the long **Ugo Fix Leg Bag Strap** (75cm) through the 4 holes in the top of your urinary leg bag;
2. Ensure the silicone line will be facing down onto your skin;
3. Take both ends of the **Ugo Fix Leg Bag Strap** and pass around your thigh just above your knee. Cross the strap at the back of the knee;
4. Bring the two ends of the strap to the front of your leg and feed through the bottom 2 holes of your urinary leg bag, attaching with the hook and loop tab behind the bag.

If the long **Ugo Fix Leg Bag Strap** (75cm) is not long enough for Method B, you can attach it to the short **Ugo Fix Leg Bag Strap** (45cm) using the hook and loop tab for extra length before attaching to your leg.

Warning! - Make sure your catheter or drainage bag tubing is not twisted before supporting your urinary leg bag to your leg using the **Ugo Fix Leg Bag Straps**.

Ensure your urinary leg bag is supported, the **Ugo Fix Leg Bag Straps** are not too tight, your catheter is not pulling and that you are able to move around comfortably with it in place.

Removal and repositioning

It is recommended that you remove the **Ugo Fix Leg Bag Straps** at bedtime.

Your Healthcare Professional can advise on regular repositioning of the **Ugo Fix Leg Bag Straps**.

Using your urine drainage bag in conjunction with the **Ugo Fix Leg Bag Straps**

- Empty your urinary leg bag before it reaches 2/3 full.
- It is important that your urinary leg bag is positioned below the level of your bladder and to check regularly that your catheter and drainage tubing are free from obstruction and urine is draining freely.
- To drain your urinary leg bag, it is not necessary to remove the straps, however you may find it easier to do this for optimal drainage.
- Ensure that the tap at the bottom of your urinary leg bag does not touch the floor.

CARING FOR YOUR DEVICE

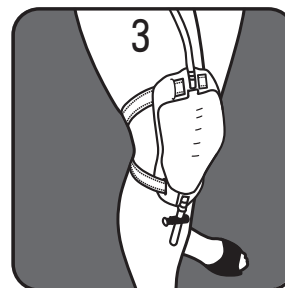
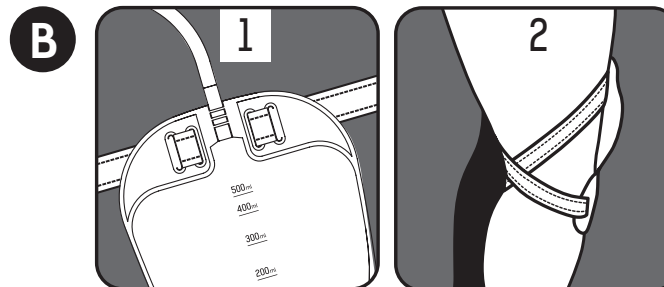
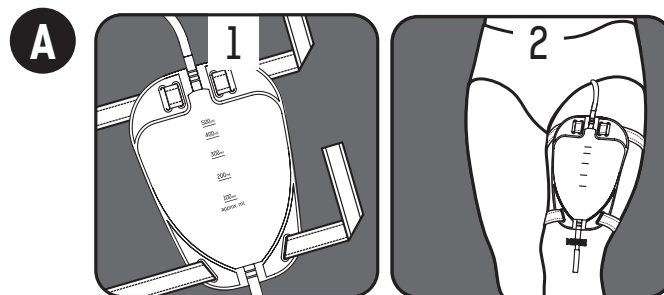
- To maintain optimum performance of the **Ugo Fix Leg Bag Straps** we recommend that you wash the strap at 60°C. Tumble dry. Do not iron. Do not bleach. Do not dry clean.
- Replace your **Ugo Fix Leg Bag Straps** when the elasticity and support is reduced from washing and stretching;
- The **Ugo Fix Leg Bag Straps** should no longer be used if there are any signs of damage or degradation.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight.

DISPOSAL

The **Ugo Fix Leg Bag Straps** must be disposed of according to local policies and waste disposal procedures, including any accessories or consumables used with the device.



REF **3011**



EC REP



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