Great Bear®
Healthcare

GB Cath Kit

Instructions For Use

This pack contains:

1x Removal Pack
1x Insertion Pack
1x GB All Silicone Foley Catheter
1x Prefilled Syringe of Sterile Water for Balloon Inflation
1x Catheter Insertion Gel
1x Libra Leg Bag
1x Libra Leg Bag Strap
1x GB Fix-it Catheter Retaining Strap - Long (80cm)

A UK manufacturer committed to Urology.

Catheter Removal Pack

Catheter Removal Pack contains all the necessary equipment to remove a catheter already in-situ.

Item	Qty
Green Drape	1
Disposable Apron	1
Disposal Bag	1
Gloves	1 Pair
Empty Syringe	1
Gauze Squares	3
Rectangular Gallipot	1

1. Wash hands
2. Open the 'Removal Pack' peel pouch and remove the wrapped pack
3. Open the outer green wrapping, taking care only to touch the corners of the wrapping, and place on a flat surface
4. Wash hands and apply the gloves and apron. Place the green modesty drape over the patient
5. Use the empty syringe provided to remove the amount of water instilled in the catheter balloon, and remove the catheter as per the catheter instructions and local clinical guidelines

Catheter Insertion Pack

Catheter Insertion Pack contains all the necessary equipment to insert a catheter.

Item	Qty
Green Drape	1
Gloves	2 Pairs
Fenestrated Drape	1
Disposable Apron	1
Disposal Bag	1
Round Gallipot	1
Non-Woven Balls	5
Gauze Squares	3
Rectangular Gallipot	1
Saline Solution	2

1. Wash hands

2. Open the 'Insertion Pack', remove the wrapped pack and place on a clean, flat surface

3. Open the outer green wrapping, taking care only to touch the corners of the wrapping. The white side of the wrapping is your sterile field

4. Remove the following items from the GB Cath Kit Box:
   - GB All Silicone Foley Catheter
   - Prefilled syringe of sterile water
   - Catheter insertion gel
   - Libra Leg Bag

5. Open each item into your sterile field, maintaining your sterile environment as per local clinical guidelines. The Libra Leg Bag Strap and GB Fix-it Retaining Strap should be placed to the side, not in the sterile field

6. Wash hands and apply the gloves and apron. Place the fenestrated drape over the patient with the opening exposing the catheter insertion site

7. Dispense the saline solution into the circular gallipot. Use saturated gauze swabs to clean the catheter insertion site. Dry the patient with the 3 gauze squares

8. Dispense the lubricating gel into the urethra, as per local clinical guidelines

9. Proceed with catheterisation according to local clinical guidelines

10. Once the catheter is in-situ, connect the Libra Leg Bag to the catheter funnel. To reduce the risk of introducing bacteria, do not touch connector whilst connecting

11. To prevent trauma and/or discomfort, secure the catheter using the GB Fix-it Catheter Retaining Strap provided

12. Dispose of waste as per local clinical guidelines

GB All Silicone Foley Catheter

Product Description

GB All Silicone Foley Catheter is a sterile, single-use product. The catheter has a drainage lumen and inflation channel. It has an integrated balloon towards the tip of the catheter and a funnel with an inflation valve at the bottom of the catheter. The capacity of the balloon can be found on the funnel and on the catheter pack label. GB All Silicone Foley Catheter is made of 100% silicone. The catheter has a nelaton (cylindrical) tip with two opposite drainage eyes. The valve of the catheter is colour coded and can be operated with a luer syringe tip. Each catheter is sterile and double-wrapped to aid in non-touch insertion.

Indications
GB All Silicone Foley Catheter is suitable for drainage of urine from the bladder.

Contra-indications
GB All Silicone Foley Catheter should not be used if the patient has a known allergic reaction to silicone.

Important
Catheterisation with a GB All Silicone Foley Catheter can only be performed by a suitably qualified and trained healthcare professional. The catheter is strictly single-use and must not be reused.

Precautions
- Urethral injury and stricture
- Recent urethral or bladder surgery
- Prior transurethral resection of the prostate with large tissue defect
- Significant symptoms of urinary obstruction prior to treatment
- History of abdominoperineal resection for rectal cancer, rectal stenosis or other major rectal pathology

Catheter Instructions for Use: Insertion

The catheter should be inserted using an aseptic technique

1. Lubricate the catheter using a water-based gel and proceed with catheterisation in line with the normal urethral catheterisation procedure
2. Insert the catheter into the meatus until urine starts to flow
3. Guide the catheter gently 5-8cm beyond the point at which urine begins to flow. The rationale for inserting the catheter further into the bladder ensures the catheter is beyond the neck of the bladder
4. Use the prefilled water syringe and inflate the balloon with the recommended volume into the injection port
5. Retract the catheter until you feel resistance
6. Secure the catheter with a catheter fixation device
7. Attach a drainage bag or catheter valve

The catheter is licensed to be left in-situ for up to 12 weeks. Regular monitoring of the patient should be undertaken to ensure there are no side effects and that the catheter is functioning correctly. Change the catheter according to local clinical policies. This should be no longer than 12 weeks.

Please Note
- Only use water-based lubricants or gels
- Only use a luer slip syringe to inflate the balloon with sterile water
- Fill the balloon slowly, taking care only to instil the amount of water specified on the catheter funnel and packaging

Possible Complications
- Should balloon rupture occur, care should be taken to ensure no fragments are left inside the bladder
- Use of any medical devices carries associated risks. Device failures are rare, however in the event of a device failure following the use of this product, you should contact Great Bear Healthcare using the details provided within this leaflet
- If a failure has resulted in a serious incident, such as significant deterioration of health or death, you should contact Great Bear Healthcare and your local Competent Authority as soon as possible. Details of your local Competent Authority can be found on your local government website

Sterilisation
The GB All Silicone Foley Catheter has been sterilised by Ethylene Oxide (EtO). The expiry date can be found on the sterile pouch. Do not use the catheter if the packaging has been damaged or accidentally opened.

Storage
GB All Silicone Foley Catheters should be stored in their original packaging in a cool, dry place away from direct sunlight.

Disposal
GB All Silicone Foley catheters should be disposed of in line with your local Clinical Policies.

Additional Warnings & Precautions
- Do not use ointments or lubricants with a petroleum base
- Do not use sharp instruments with the GB All Silicone Foley Catheter – sharp instruments could damage the catheter and cause it to malfunction
- It is recommended to drink more water when catheterised – please follow local clinical policies on fluid intake
- Instructions for use shall be read and abided by carefully
- Medical advice shall always be followed depending on patient's clinical symptoms
- Patients with indwelling catheters should be monitored in accordance with local and national clinical policies
- Strict adherence to aseptic technique and hand hygiene are essential to minimise the risk of Catheter Associated Urinary Tract Infections (CAUTI)

Konix Lido C Sterile Catheter Gel

Konix Lido C Sterile Catheter Gel is a sterile water soluble, non-irritating lubricant gel with supportive antiseptic and anesthetic properties used to facilitate the insertion of catheters and other medical instruments (catheterisation, cystoscopy) into the urethra and bladder.

It helps preventing trauma, which may occur during the catheterisation between the urethral mucosa and catheter, by lubricating effect. It reduces infection risk by antiseptic properties of chlorhexidine and helps reducing perioperative pain associated with the procedure by local anesthetic properties of lidocaine. It minimises patient discomfort caused by the procedure.

Ingredients

100 g of Konix Lido C Sterile Catheter Gel contains; Deionized Water, Hydroxyethyl Cellulose (Lubricative), Mono Propylene Glycol (Moisturizer), 2g Lidocaine (Local anesthetic), 0.05g Chlorhexidine Gluconate (Antiseptic), Methyl Hydroxybenzoate (Preservative), Propyl Hydroxybenzoate (Preservative).

Application

1. Wash your hands and prepare an area that is aseptic as possible to perform the operation. Prepare a clean serving tray and place required materials

2. Remove the syringe from its sterile package

3. Lightly press on the plunger before removing the blue cap to provide more even and gentle application

4. Carefully insert the cone of the syringe into the urethral opening and slowly inject the gel by applying gentle and even pressure

5. Apply the remaining gel to the surface of the catheter or to the surface of another medical device

6. Konix Lido C Sterile Catheter Gel shows lubricative effect as soon as the application starts. Its anesthetic effect starts 3-5 minutes later

7. If more gel has to be used, condition of the applied tissue, age of the patient and any adverse condition of the patient which may be related to sensitivity of chlorhexidine must be taken into care by the physician

8. When the whole product is not used, the syringe and the remaining gel

should be evaluated and discarded like other medical wastes

9. Konix Lido C Sterile Catheter Gel should only be used under the supervision of specialist health personnel

Contra-indications
Konix Lido C Sterile Catheter Gel should not be used in patients with hypersensitivity to any of the components or patients with marked bradycardial rhythm disorders. Konix Lido C Sterile Catheter Gel should not be used in patients with severe cardiac insufficiency, severe hepatic and renal dysfunction, traumatic mucosa and / or inflammation / sepsis at the application site, and in patients with a tendency to convulsion (epilepsy, severe shocks). Do not use in children under 2 years.

Warnings and Precautions for Use
• Under anesthesia a lubricant without lidocaine should be used
• Instilllation should only be performed by a physician or by qualified medical personnel
• Patients with glucose-6-phospate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia are more susceptible to drug induced methaemiglobinaemia
• When applying Konix Lido C Sterile Catheter Gel, a temporary burn may occur; patients should be warned in this regard. In this case, cold compress to the applied region can alleviate the burning sensation
• Allergic reactions to lidocaine and / or chlorhexidine may rarely occur. Please consult your doctor if redness, burning and stinging occurs in the applied site
• Irritates eyes and/or skin in case of direct contact. Wash with plenty of water in case of exposure
• If swallowed, seek medical advice
• Keep away from children
• Store in dry and cool places
• Keep away from direct sunlight
• For single use only
• Do not re-sterilize
• Do not use products with damaged packages because of the risk of sterilisation deterioration

Pregnancy and Lactation
Konix Lido C Sterile Catheter Gel can be used during pregnancy and lactation. The risk/benefit assessment should be performed by the physician. Lidocaine passes to placenta and enters breast milk in small quantities;however, therapeutic dose used in Konix Lido C Sterile Catheter Gel does not generally pose a risk to the fetus and infants.

Drug Interaction
Interaction due to absorption of lidocaine may occur when used in combination with the following drugs; Propranolol: Reduction in plasma clearance of lidocaine, Cimetidine: Reduction in plasma clearance of lidocaine, Antiarrhythmic products: Increase in toxicity of lidocaine, Phenytoin or barbiturates: Reduction in plasma levels of lidocaine. The specified interactions can be seen in long-term use and repeated, high doses. No clinically significant interactions have been reported when administered at the recommended doses.

Due to the risk of interaction depending on chlorhexidine, use with the following is not recommended; Chlorhexidine Gluconate (CHX) + Sodium Hypochlorite (NaOCl) Chlorhexidine Gluconate (CHX) + Hydrogen Peroxide (H2O2) Chlorhexidine Gluconate (CHX) + Povidone-Iodine (BTD) According to scientific literatures, CHX + NaOCl interaction is known to produce toxic by-products for humans.

Side Effects
Allergic reactions to lidocaine and chlorhexidine are extremely rare. In the case of hypersensitivity, skin reactions are possible. Skin reactions depending on anaphylaxis (hypersensitivity) may occur due to the use of lidocaine in the damaged mucosa. Systemic adverse reactions to lidocaine are rare and may result from hypersensitivity or diminished tolerance.

Sterilisation
Konix Lido C Sterile Catheter Gel is sterilised with radiation after the packaging. In the case that the packaging is damaged, do not use as sterility may be compromised.

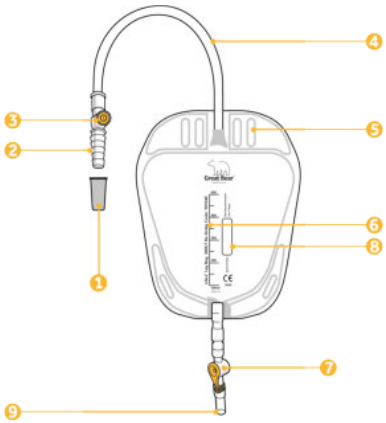
Libra Leg Bag

Instructions for use

- Libra Leg Bags are for the daytime storage and drainage of urine
- Designed to be connected directly to a catheter for continuous drainage
- Libra Leg Bags can also be connected to a Night Bag for overnight drainage (See Overnight Drainage below)
- Libra Leg Bags should be changed every 5-7 days

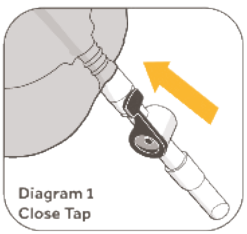
Before Use

1. Wash hands
2. Open peel pouch and remove the Libra Leg Bag from its packaging
3. Ensure the lever on the outlet tap (7) is in the closed position (Diagram 1)
4. Remove the grey protective cap (1) from the Libra inlet connector (2)



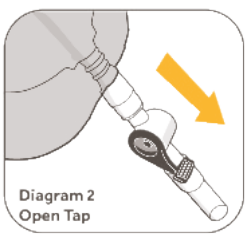
Direct Connection

1. Insert the ridged inlet connector (2) into the end of the Indwelling Catheter. Insert the connector fully to allow a secure connection. To reduce the risk of introducing bacteria, do not touch connector whilst connecting
2. The Libra Leg Bag should be positioned on the thigh or calf, depending on the tube length, and secured appropriately with the leg bag straps provided
3. Feed the leg bag straps through the eyelets (5) on the bag and ensure the wavy silicone lines face onto the leg
4. Make sure the inlet tubing (4) isn't kinked which can restrict the flow of urine



Emptying

1. Empty the Libra Leg Bag by pushing the lever on the outlet tap (7) downwards (Diagram 2)
2. After emptying, wrap the outlet tap with a tissue and pat a number of times before gently wiping around the inside of the valve. This will dislodge any residual urine



3. Remember to close the tap after emptying (Diagram 1)

4. The outlet tap (7) can be twisted to avoid accidental emptying

Overnight Drainage

1. If you require additional drainage for overnight use, a night bag can be connected as part of an overnight link system. When you go to bed, do not disconnect your leg bag from your catheter

2. Insert the connector of your night bag to the silicone sleeve (9) on your leg bag. Insert the connector fully to allow a secure connection

3. Once connected, turn the Libra Leg Bag tap to the open position (Diagram 2) to allow the overnight drainage into the night bag

4. Before disconnecting the night bag in the morning, ensure the Libra Leg Bag tap is in the closed position (Diagram 1)

Storage and Disposal

1. The Libra Leg Bag should be stored at an ambient temperature and allowed to come to room temperature before use

2. Dispose with normal household waste – do not flush down the toilet

Cautions

Ensure you fill in the Data Fitted Box (8) to allow you to monitor how long the Libra Leg Bag has been in use. Change the Libra Leg Bag every 5-7 days.

The Libra Leg Bag should not be reused after disconnection from a catheter due to increased risk of infection.

Keep out of reach of children.

Use of any medical device carries associated risks. Device failures are rare, however in the event of a device failure, you should contact Great Bear Healthcare using the details provided in this leaflet.

If a failure has resulted in a serious incident, such as significant deterioration of health or death, you should contact Great Bear Healthcare and your local Competent Authority as soon as possible. Details of your Competent Authority can be found on your local government website.

How to Order

The GB Cath Kit is available on prescription via Nightingale Home Delivery Service.

To place your order call Freephone 0800 304 7434
or visit www.nightingaledelivery.co.uk.

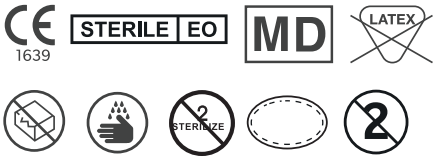
Please ensure you have your GP details to hand and make sure you have at least two weeks' supply before reordering.

Order Codes

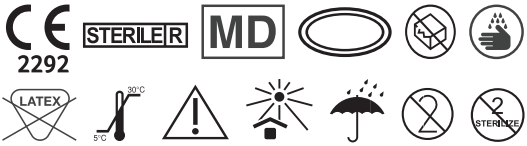
Product Code	Charriere Size	Tube Length	Qty
GBCK12LT	12Ch	Long (30cm)	1
GBCK14LT	14Ch	Long (30cm)	1
GBCK16LT	16Ch	Long (30cm)	1
GBCK12ST	12Ch	Short (10cm)	1
GBCK14ST	14Ch	Short (10cm)	1
GBCK16ST	16Ch	Short (10cm)	1

Manufacturer's Details

Insertion and Removal Packs
Rocialle, Cwm Cynon Business Park (North), Mountain Ash, Rhondda Cynon Taff, South Wales, CF45 4ER, UK
+44 (0)1433 471 300

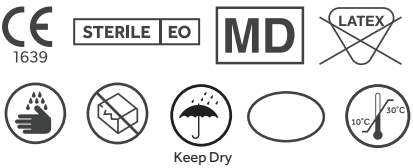


Konix Lido C Sterile Catheter Gel
Turkuaz Medikal
Turkuaz Sağlik Hizmetleri, Medikal, Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.
Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad
No:45/5 34522 Esenyurt/Istanbul/Türkiye
+90 212 428 6848



Libra Leg Bag, Libra Leg Bag Strap and GB Fix-it Catheter Retaining Strap
Great Bear Healthcare Ltd
1 Lambourne Crescent,
Cardiff Business Park, Cardiff,
CF14 5GF, UK
+44 (0)29 2074 7770

Libra Leg Bag

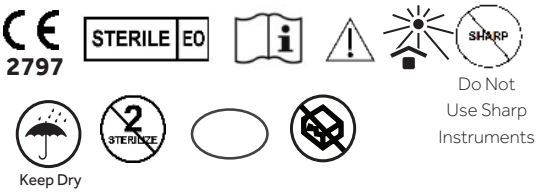


Libra Leg Bag Strap and GB Fix-it Catgeter Retaining Strap

Prefilled Syringe of Purified Water
Well Lead Medical Co. Ltd
C-4 Jinhu Industrial Estate Hualong, 511434
Panyu, Guangzhou, People's Republic of China
+(00)86 20 8475 8878

Phthalate Free

Foley Catheter
Fortune Medical Instrument Corp.
6F, No.29, Sec.2, Jhongjheng E. Road,
Danshuei Dist., New Taipei City, 251, Taiwan
+(00)886 2 2624 2233



Do Not Use Sharp Instruments

The items in this pack are assembled under Article 12 of the MDD 93/42/EEC and Article 22 of the MDR 2017/745.

Great Bear Healthcare Ltd, 1 Lambourne Crescent, Cardiff Business Park, Cardiff, CF14 5GF, UK
T: +44 (0)29 2074 7770
mail@gbhl.co.uk
www.greatbearhealthcare.co.uk
CATHKITIFUV1/2021