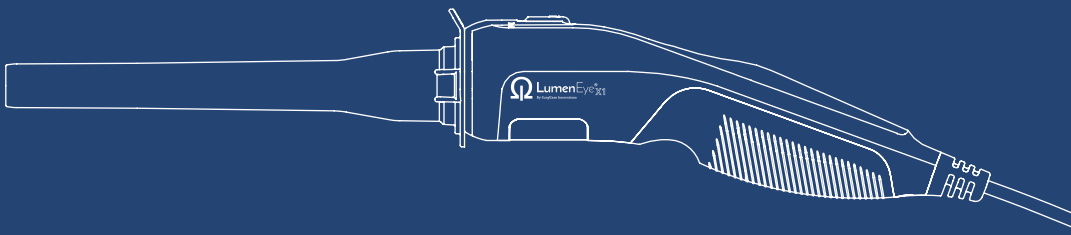
LumenEye® X1

Instructions for Use



SurgEase INNOVATIONS

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1. CE Markings

CE The CE mark on these products indicate conformance with the provisions of Medical Device Regulation 2017/745.

Trademarks

LumenEye® is a European registered trademark of SurgEase (registration number 017947970).

Manual Overview

This manual applies to the LumenEye® X1 system; catalogue ref: LX1-PCK-201 (USB-C), LX1-PCK-202 (USB-A)

The LumenEye® X1 system which includes thefollowing components:

- LumenEye® X1 endoscope medical device, catalogue ref: LX1-SCP-201 (USB-C), LX1-SCP-202 (USB-A)
- Portable docking case & tablet; catalogue ref: LX1-DCK-201 (USB-C), LX1-DCK-202 (USB-A)
- Lumened manifold with sheath & obturator consumable set; catalogue ref: LX1-CSB-201
- Lumened manifold with sheath, obturator and camera cover consumable set; catalogue ref: LX1-CCS-201

Please contact SurgEase directly to report any incidents and concerns regarding safety, performance, and for general feedback and enquiries. Please direct all complaints to the manufacturer or authorised distributor. In the event of a serious incident resulting from the use of the device, the relevant competent authority should be notified immediately.

Manufacturer
SurgEase Innovations Ltd,
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Nelson, Lancashire
BB9 9BT
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+44 (0)330 043 6989
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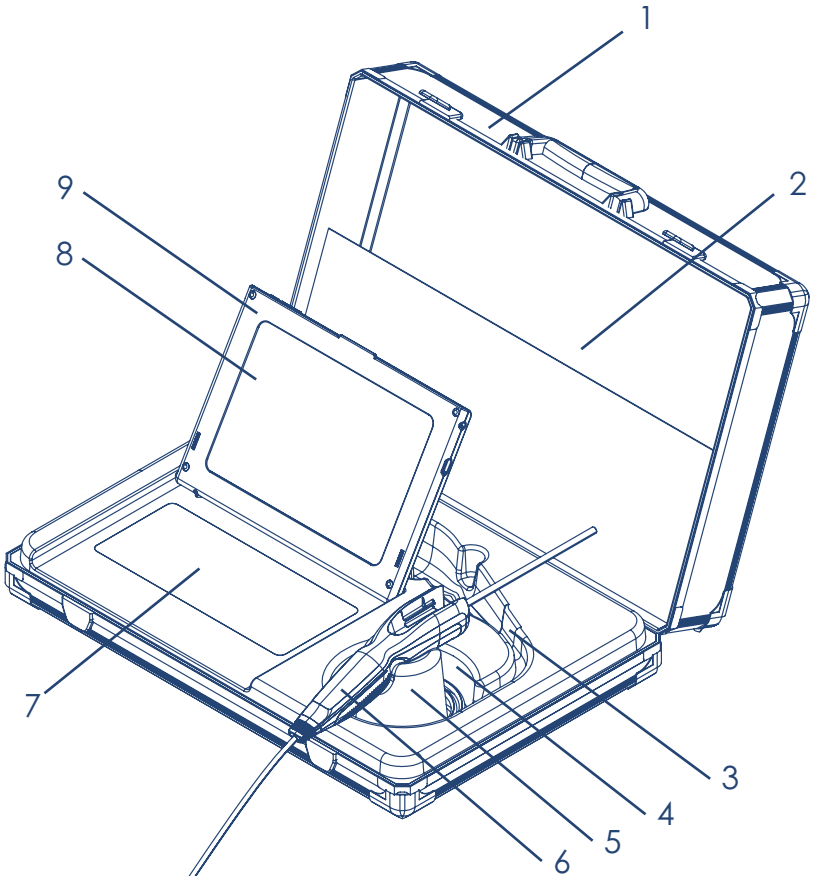
Authorised Distributor

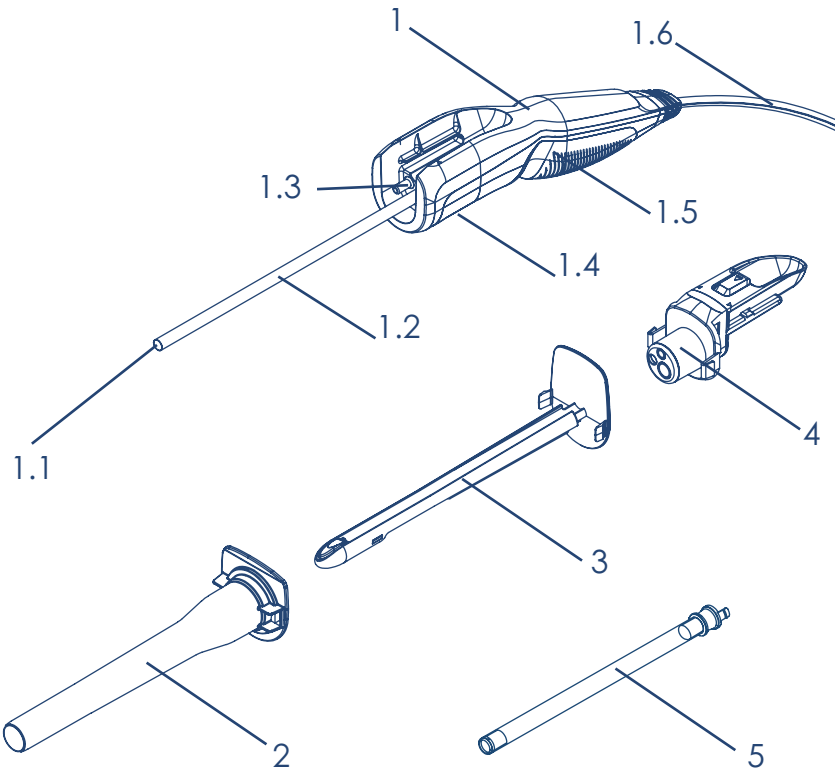
2. LumenEye® X1 system



LumenEye® X1 system Components

1 LumenEye® X1 portable docking case
2 Storage for LumenEye® X1 consumables and tablet charger
3 LumenEye® X1 storage recess
4 LumenEye® X1 cable-tidy recess
5 LumenEye® X1 device mount
6 LumenEye® X1 handheld endoscope
7 Integrated keyboard
8 Touch screen tablet
9 Tablet case

3. LumenEye® X1 Medical Device



LumenEye® X1 Medical Device Parts List

1 LumenEye® X1 handheld endoscope
- 1.1 Camera and LEDs
- 1.2 Stainless steel camera tube
- 1.3 Air barb
- 1.4 Compliance label
- 1.5 Insufflation bellows
- 1.6 USB connector

2 Sheath (single-use, applied part)
3 Obturator (single-use)
4 Manifold (single-use)
5 Camera Cover (single-use, optional part)

4. Intended Use

The intended use of the LumenEye® X1 system is:

- Examination of patients experiencing symptoms of peri-anal discomfort and rectal bleeding.
- Detection of anal disease, rectal polyps, haemorrhoids, cancerous growths and related bowel conditions affecting the rectum and anus.
- Surveillance of anorectal disease.

The device permits views of the anorectum and supports a clinician's examination so a diagnosis can be reached. Following an examination, further investigations may be performed. The LumenEye® X1 manifold is a single-patient use component which houses a channel to permit mucosal biopsy of growths and lesions when clinically indicated. The device does not provide a diagnosis and should not therefore be considered a diagnostic tool.

A typical rectoscopy procedure lasts up to 5 minutes. Total patient interaction time is not likely to exceed 30 minutes. This may vary according to clinical need.

Caution: Users of the LumenEye® X1 should have suitable training on rigid sigmoidoscopy techniques.

Caution: Users must read these instructions in full and ensure they have a reasonable understanding of the procedure prior to using the device. Questions should be directed to the manufacturer or the local account manager.

Caution: The LumenEye® X1 device requires a single patient use manifold, sheath and obturator. These components must not be re-used and be discarded in clinical waste once a procedure is completed. Components must only be purchased from SurgEase or an approved distributor. Do not attempt to use the LumenEye® X1 with other single-use components.

Caution: Do not attempt to insert a sheath without the obturator. Attempting to do so may cause injury.

Caution: Each hospital or practice should maintain a robust system for individual LumenEye® X1 traceability and ensure that cleaning and disinfection audits are conducted regularly (see section 12 & 13 for detailed cleaning and disinfection instructions).

5. Contraindications & Warnings

Using the LumenEye® X1 in patients with BSE/TSE, HIV, Hepatitis C or other communicable pathogens transmittable through direct physical contact should be undertaken in consideration of local standard operating procedures on infection control. Please see section 12 & 13 for further details on cleaning and disinfection.

Users of the LumenEye® X1 must be suitably trained on performing rigid sigmoidoscopy and proctoscopy. Users must read these instructions and ensure they have an adequate understanding of the procedure prior to using the device. Any questions should be directed to the manufacturer or the local representative.

Warnings:

- Do not attempt to use the LumenEye® X1 with other commercially available proctological single-use devices.
- Please inspect the LumenEye® X1 between uses. Particular attention should be given to the camera lens to ensure there are no cracks or signs of physical damage.
- Do not use biopsy forceps larger than 3mm.
- Only insufflate air with the bellows until adequate views are achieved with consideration of patient comfort.
- If the LumenEye® X1 or portable docking case and tablet become soiled, they should be cleaned according to the instructions detailed in sections 10,12 and 13 of this document or notify the manufacturer if it cannot be suitably cleaned. Do not use if there is uncertainty of the cleaning robustness.
- If water enters the integrated bellows in the handle, do not use, and notify the manufacturer.
- **Do not attempt to dismantle or repair the device. This will void the warranty.**
- Do not use defibrillation equipment whilst the device is in contact with the patient. This may damage the camera and the electrical circuits.
- Do not attempt to modify the equipment.
- Avoid use in oxygen-rich environments and do not use in the presence of flammable agents.
- If the equipment is used adjacent to, or stored alongside other electronic equipment, the device should be observed carefully to verify normal operation.
- Do not attempt to open the LumenEye® X1 scope or repair the electronics. Opening the device may cause damage and will void the warranty.
- There are no user serviceable parts in the handheld unit or the components.
- The user should check to ensure the view observed through the device provides a live image (rather than a stored one) and has the correct image orientation.

6. Caution

The LumenEye® X1, docking case and tablet should never be stored or operated in areas where they can become wet or be exposed to extreme environmental conditions like high temperature, humidity, direct sunlight and dust.

Do not autoclave, sterilise, or immerse this device in liquid or use caustic or abrasive cleaning and disinfection agents. Please contact the manufacturer to discuss suitable sterilisation options.

If this device fails to perform as intended, please contact the manufacturer. Do not attempt to service this device.

This equipment complies with IEC 60601-1-2:2001 for Electromagnetic Compatibility (EMC) concerning medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the growing number of radiofrequency transmitting equipment and the general electrical noise in healthcare environments, it is possible that high levels of such interference from close proximity or strength of transmissions could disrupt the performance of the device. Medical electrical equipment requires special precautions concerning EMC, and all equipment must be installed and placed into service according to the EMC information specified in this Instructions for Use. The device should not be connected to any other medical device. If a user opts to do so, then the obligation is on them to ensure the connected device also complies with IEC 60601-1-2:2001. EMC results are available upon request.

In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact SurgEase regarding return or recycling of the LumenEye® X1.

Do not disassemble, heat above 100°C (212°F) or incinerate.

If any serious incident occurs in relation to the device, the user should report the incident to the manufacturer and relevant competent authority.

7. Principle of Operation

The LumenEye® X1 is comprised of an integrated CMOS camera and LED ring which provide views and illumination of the anorectum. The integrated bellows insufflates the rectum to provide unobstructed views. The manifold is a sliding attachment which has a biopsy channel allowing endoscopic biopsy and retrieval of tissue. Existing 3mm endoscopic biopsy forceps should be used for this function. Larger diameter forceps will not fit the channel and should not be used.

The intended users of the LumenEye® X1 should be trained healthcare professionals. Users of the system are expected to have a pre-requisite level of medical knowledge and experience in order to review and analyse the captured data.

8. Symbols

Indicates name and address of the legal manufacturer

Prefixes date of manufacture

The product is a medical device as defined by Medical Device Regulation 2017/745

Serial number

Lot number

REF description should state “catalogue reference”

Refer to instruction manual
Note: This symbol is blue on the product label

Direct current power
Voltage: 5V DC
Current: 500mA

Cautions and Warnings

Equipment providing a particular degree of protection (isolation) against electric shock particularly regarding allowable leakage currents having a BF type (floating) applied part

Particulate and water ingress
Device handle: IP 23
Camera Housing: IP 67

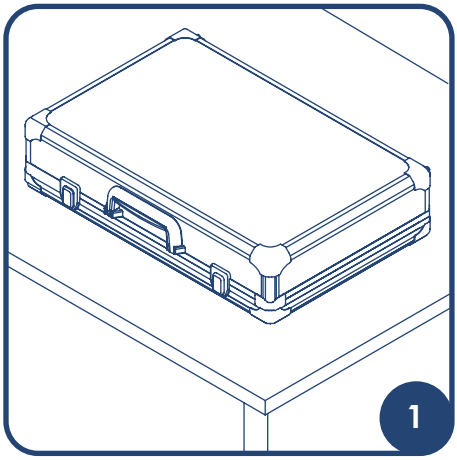
Keep the system dry when packaged for storage and transportation

Please store between 10°C and 40°C

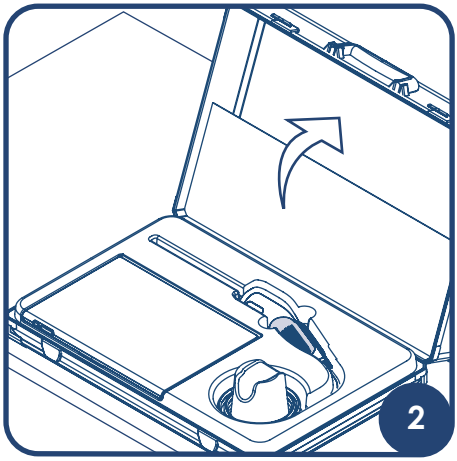
Note: All labels are printed in black

9. Docking Case - Getting Started

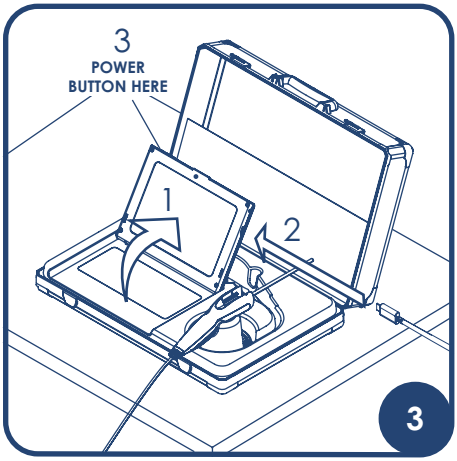
Setting Up



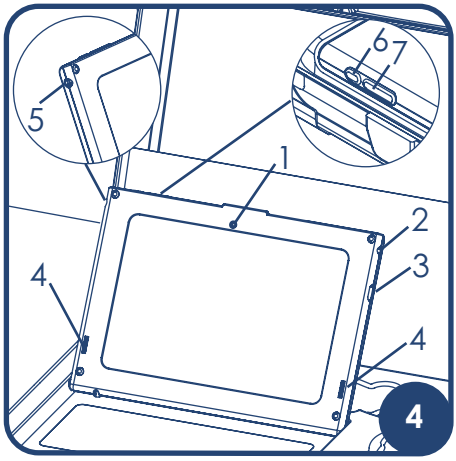
Ensure the docking case is placed on a solid, flat and clean surface before opening.



Open the docking case lid to a fully retracted position and remove all packaging.



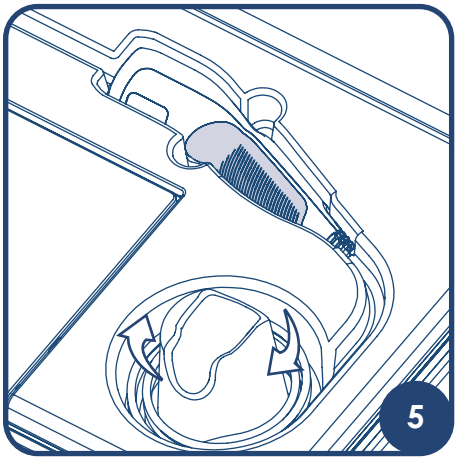
Open the tablet screen to preferred angle (1), connect the LumenEye® X1 to the USB port (2), press the 'power on' button (3) and refer to 'IFU-401' for CHiP software instructions. (Please note: the tablet is controlled via a touch screen interface. Please use the integrated keyboard for typing).



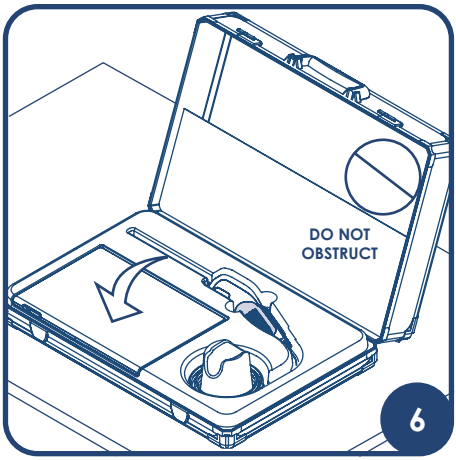
Tablet Feature List

1 Integrated front-facing webcam
2 Power adapter port
3 LumenEye® X1 USB port
4 Speakers
5 Headphone port
6 Power on/off
7 Volume control (-/+)

Storage

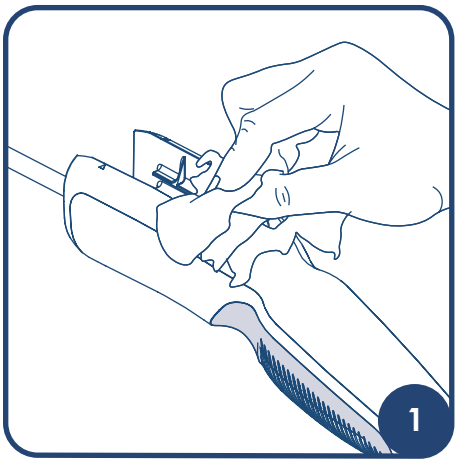


To prevent unnecessary damage, ensure the LumenEye® X1 is packed in the dedicated storage recess and the cable is wrapped in the cable-tidy recess as shown.

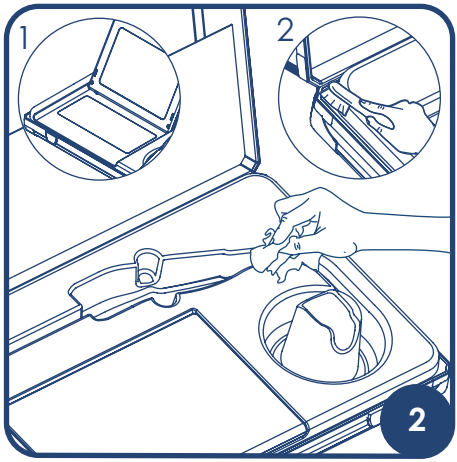


Ensure that the tablet is fully switched off and the tablet screen is placed in the closed position before shutting the case lid. **Ensure there is no obstruction of the mount when closing the case lid.**

10. Docking Case - Cleaning, Disinfection and Maintenance

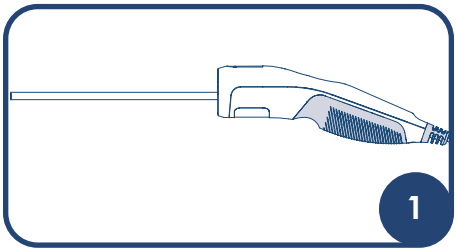


Prior to using and storing the LumenEye® X1 please ensure the device has been cleaned in accordance with the cleaning and disinfection instructions in section 12 & 13.

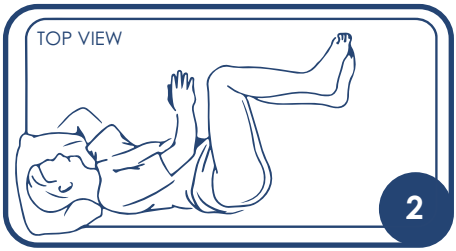


Before and after using the docking case please ensure that all internal surfaces have been cleaned with isopropyl wipes including the tablet screen (1), keyboard (1) and corners (2). A soft-bristled brush may be used to manually clean any crevices.

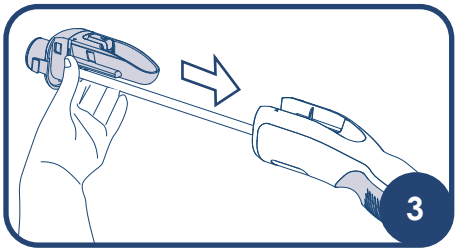
11. LumenEye® X1 - Assembly & Use



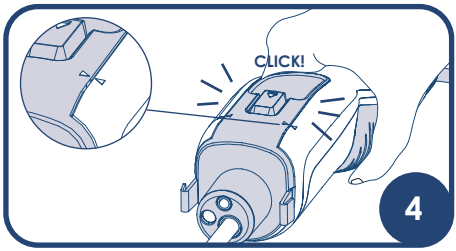
Perform a visual inspection to ensure the device is clean. Check for visible cracks or physical damage. Connect the camera to the tablet, check all LEDs are illuminating sufficiently and confirm the camera feed is working.



The patient should preferably be examined in the left lateral position.

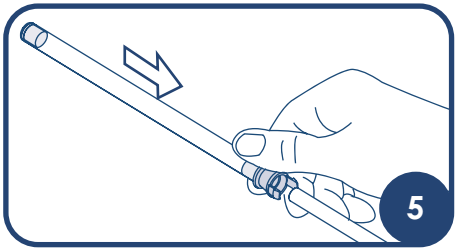


Remove the disposable manifold from the packaging and slide it over the LumenEye® X1 camera tube via the opening marked with a camera symbol.

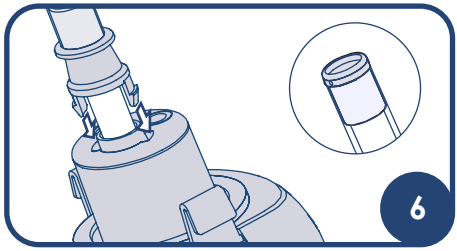


Ensure the manifold is fully in place. An audible click will be heard and the arrows on the manifold will align with those on the LumenEye® X1 handset indicating full engagement.

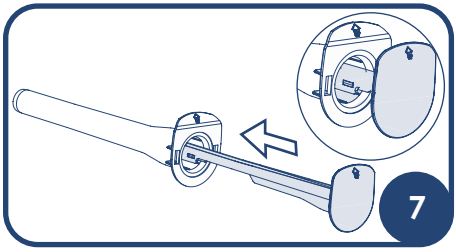
If your consumable pack does not contain a camera cover please move to step 7.



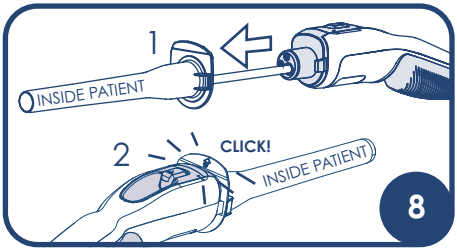
Remove the camera cover from the packaging and slide the connector over the LumenEye® X1 camera tube.



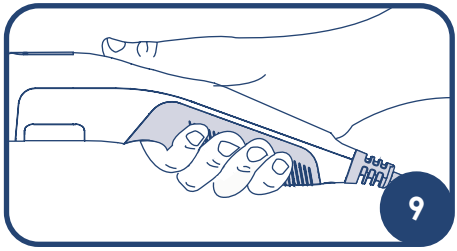
Push the camera cover into the slots firmly until an audible snap is heard. Ensure secure fitting by testing integrity with a gentle pull.



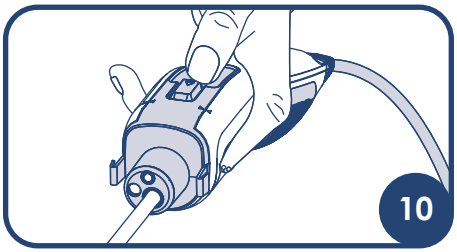
Push the obturator fully into the sheath then carefully insert into the patient. Please note that the arrow on the sheath and obturator should be facing 12 o'clock when insertion is attempted.



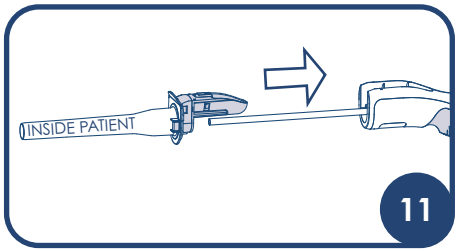
Once inserted, **remove the obturator whilst leaving the sheath inside the patient** and insert the LumenEye® X1 through the sheath. Engage the manifold clips onto the sheath until an audible click is heard.



Insufflate the appropriate amount of air by squeezing the bellows firmly.



Upon completion of the examination, push the release button on the manifold to disengage the LumenEye® X1 from the sheath.



Remove the LumenEye® X1 from the sheath and manifold, leaving the sheath and manifold inside the patient. Air will escape through the camera opening as soon as the LumenEye® X1 is removed. Allow sufficient time for all insufflated air to escape.

Carefully remove the sheath and manifold from the patient and discard in clinical waste.

12. LumenEye® X1 - Cleaning & Disinfection: Preparation

Caution: Ensure the LumenEye® X1 is disconnected during ANY cleaning and disinfection cycle.

Caution: Do not attempt to reprocess this device by autoclave.

Caution: Before use, the LumenEye® X1 must be visually inspected & cleaned with an isopropyl wipe to ensure the device is clean and ready to use.

Caution: After use, cleaning and high-level disinfection of the LumenEye® X1 must be carried out after each use.

What you will need:

1) Tristel Trio Wipes system comprising of:

- **Tristel Pre-Clean Wipes** for the cleaning step. Tristel Pre-Clean Wipes are impregnated with a low-foaming surfactant and a triple enzymatic detergent.
- **Tristel Sporicidal Wipes and Activator Foam** for high-level disinfection. Tristel Sporicidal Wipe is activated with Tristel Activator Foam. Activated Sporicidal Wipe is a high-level disinfecting wipe utilising Tristel's chlorine dioxide chemistry.
- **Tristel Rinse Wipes** for the rinsing step. Tristel Rinse Wipes are sterile and impregnated with deionized water.

2) Moistened Gauze Pad x 2

3) Soft bristled brush

4) Wet lint free cloth

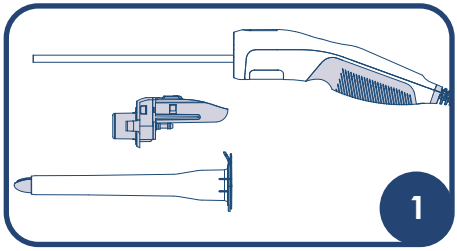
5) Q Tip x 3

Cleaning Notes:

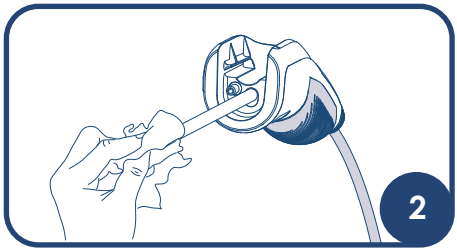
Do not re-use cloths or wipes. Soap, detergents or enzymatic cleaners should be used in accordance with the manufacturer's instructions. SurgEase is not responsible for damage incurred during the cleaning process with products where no material compatibility evaluation has been performed.

Where heavy faecal soiling has occurred and water irrigation is required, be careful not to expose the handle to moisture or liquids. If the functionality of the device has been compromised or there are water ingresses in the handle, please contact the manufacturer.

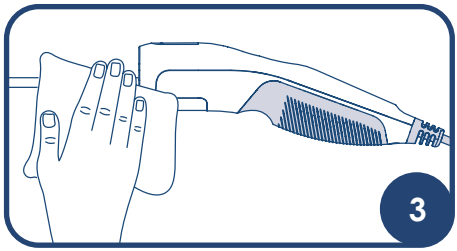
13. LumenEye® X1 - Cleaning & Disinfection: Instructions



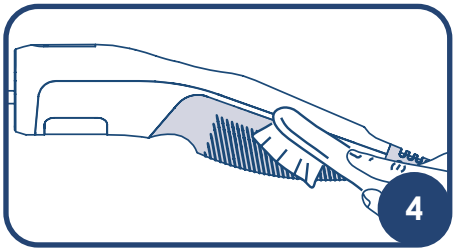
After use, remove and discard the sheath and manifold from the LumenEye® X1. Single use parts should be disposed as clinical waste.



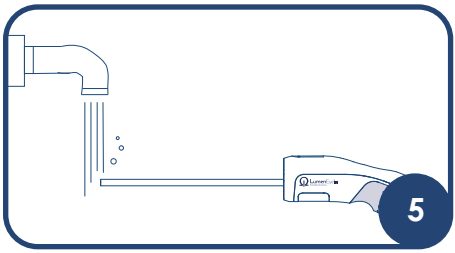
After each examination, ensure all lubricant gel is wiped completely from the camera tip. The device should not be left soaking in gel.



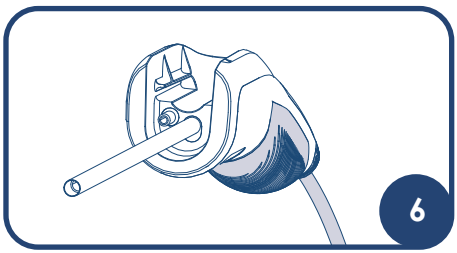
Remove visible debris as much as possible using a moistened gauze pad. Exchange the gauze pad if it becomes soiled.



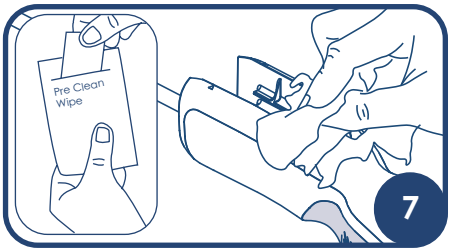
A soft-bristled brush may be used to manually clean any crevices, parting lines, or irregular surfaces.



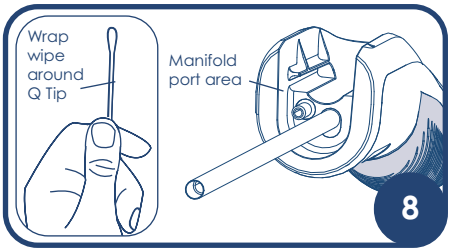
If necessary, run only the endoscope tip under running water and wash the handle with a wet lint-free cloth.



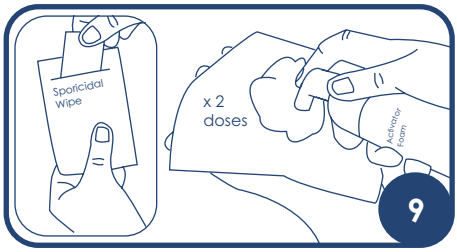
Verify that the handset is in working order prior to cleaning.



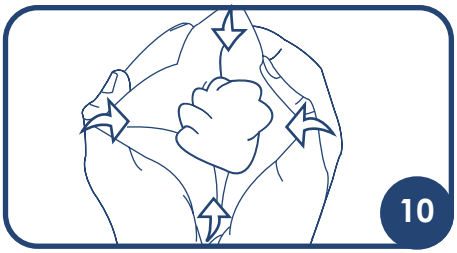
Remove a Tristel Pre-Clean Wipe from the sachet and unfold it in the palm of your hand. Fully wipe the device including cable, starting from the handle to the tip of the camera. Ensure all visible soiling is removed. Pay particular attention to indentations and ridges.



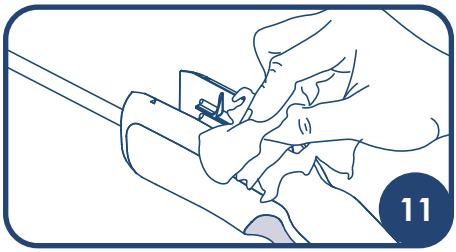
Thoroughly wipe the indentations in the manifold port. Wrap the wipe around a Q Tip and use this to reach every corner. Squeeze liquid from the wipe onto the device to ensure sufficient coverage, if required.



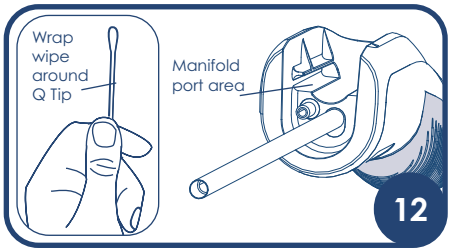
Take a Tristel Sporicidal Wipe and unfold it in the palm of your hand. **Do not shake the Activator Foam bottle.** Dispense 2 full doses of Tristel Activator Foam onto the Sporicidal Wipe.



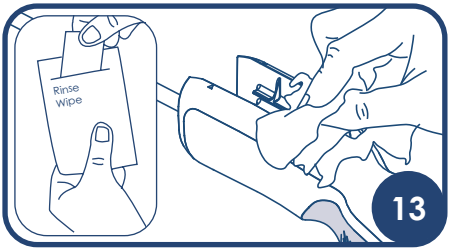
Fold the Sporicidal Wipe in on itself (corners to middle) and scrunch for 15 seconds to generate chlorine dioxide. Ensure that the wipe is completely covered in foam, but do not squeeze out the liquid.



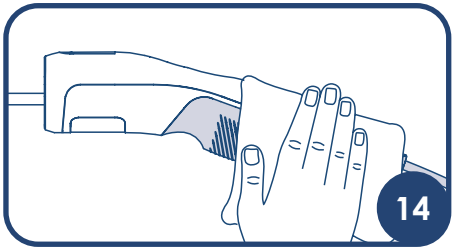
Fully wipe the device including cable with the activated Tristel Sporicidal Wipe starting from the handle to the tip of the camera, ensuring all surfaces are visibly wet and sufficient fluid has been passed from the wipe to device. Pay particular attention to indentations and ridges.



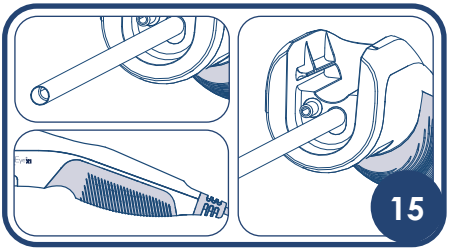
Please repeat step 8 using the Tristel Sporicidal Wipe.



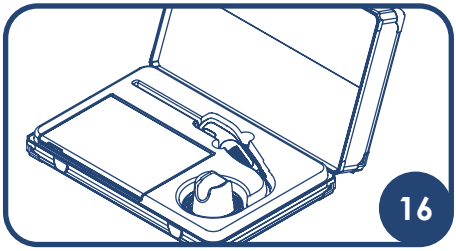
Fully wipe the device including cable with the Tristel Rinse Wipe. Ensure all surfaces are wetted once and foam and other residues from the previous steps are removed.



Use a lint-free soft dry cloth to thoroughly dry the LumenEye® X1.



Perform a visual inspection of the device and verify it is clean following use and before storing away. If the device is not visibly clean, repeat cleaning steps 1-14.



Place the LumenEye® X1 into the docking case for storage (see section 9) ensuring the docking case is also clean, disinfected and maintained according to the procedures detailed in section 10.

14. Charging Instructions

Caution: The device should only be charged if it is not in use (i.e. not connected to a patient)

Caution: Any charger used to charge the tablet must comply with the requirements of the IEC 60601-1

The LumenEye® X1 device does not require any charging and is powered by the tablet.

Note: The tablet used with the LumenEye® X1, must be charged following the manufacturer's instructions.

15. Software Compatibility

The LumenEye® X1 is intended to be used with the CHiP software which has been developed by SurgEase. The LumenEye® X1 can be used with other commercially available camera-feed processing software. Using alternative software is done so at the user's own risk.

16. Warranty

SurgEase warrants LumenEye® X1, when new, to be free from defects in material and workmanship and to perform in accordance with the manufacturer's specifications for a period of one year from the date of first use when purchased from SurgEase or any of the authorised distributors or agents. After this period, it should be sent back to the manufacturer for servicing. SurgEase will either repair or replace any components found to be defective or at variance from the manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return the LumenEye® X1 to SurgEase or an authorised distributor, agent, or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. This warranty is also void if the instrument is not used in accordance with the manufacturer's recommendations or if it is repaired by any agent other than SurgEase or an authorised agent. First-use date determines warranty requirements. No other express warranty is given. Further technical information is available from the manufacturer.

17. Life of Product & Servicing

All single-use consumables have a shelf-life of 2 years.

The expected service life of the LumenEye® X1 system is 1 year.

Under no circumstances should you attempt to repair or service the device yourself. Inspection and repair should only be performed by SurgEase or an authorised agent.

If your device requires repair, please contact us on: +44 (0)1282 690090

18. Disposal

This product is required to comply with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC. It is marked with the following symbol:

This symbol indicates that the product should not be disposed of in household waste, according to the WEEE Directive (2002/96/EC) and State Law. This product should be returned to the manufacturer when the warranty expires.

Improper handling of waste may negatively impact the environment and human health. Full co-operation with appropriate disposal advice improves the use of natural resources.

For more information about recycling this product, contact SurgEase.

19. Troubleshooting

Condition	Description and Corrective Action
Interrupted Feed	If the video feed is lost or frozen, ensure that the USB connector is securely in the correct port. If this issue continues, ensure that there are no other electronic devices in proximity that could cause interference.
Unclear Feed	If the video is foggy or unclear ensure that the camera is clean. (wipe it according to **Section 13.0, page 13**)
LumenEye® X1 not recognised	Ensure that the cable is fully inserted in the dedicated port on the tablet.
Manifold removal difficulty	Press down on the button of the manifold and slide away from the endoscope. Make sure the button is pressed firmly with no interference (as seen in **Section 11.10, page 11)**
Video feed dark	If you notice any LED failure around the camera, please contact our technical support team.
Lack of air pressure	Ensure the Manifold is properly engaged with both the Sheath and endoscope. Follow instructions in **Section 11, page 10**.
Cable damage	If you notice any damage on the cable, do not use and contact the manufacturer.
Manifold or Sheath engagement issues	Ensure the manifold and sheath have been mounted on the device in the correct orientation using the arrows as visual cues. Use instructions in **Section 11, page 10.**
Obturator removal difficulty	Use instructions in **Section 11, page 10.**

For any enquiries, please contact technical support on: +44 (0) 330 043 6989
For any troubleshooting associated with the tablet, please refer to manufacturer's instructions.

20. Environmental Information

Condition	Temperature Range	Relative Humidity	Atmospheric Pressure
Operating	+10 °C to +40 °C (+50 °F to +104 °F)	30% to 75% (non-condensing)	700 hPa to 1060 hPa
Storage and Transport	+10 °C to +40 °C (+50 °F to +104 °F)	20% to 95% (non-condensing)	700 hPa to 1060 hPa

SurgEase INNOVATIONS

CE

INDICATION FOR USE

LumenEye® X1 is indicated for use in diagnostic and interventional endoscopic procedures to provide illumination and visualisation of the anorectum. Should only be used by suitably trained healthcare professionals.

IFU-101-1.0