

LENS 4K Camera Head



LENS 4K Camera Head

NON-STERILE



Preface

The Smith & Nephew LENS 4K Camera Head is part of a family of products specifically designed for multimodal sterilization including autoclave, STERRAD® 100S Short Cycle, STERRAD NX® Standard Cycle, STERRAD® 100NX Express Cycle, STERRAD® 100NX Standard Cycle or STERRAD® 100NX DUO Cycle Sterilization Systems. It may also be sterilized with V-PRO 1 PLUS/V-PRO maX Non-Lumen Cycle (12 minute exposure), or STERRAD® 100NX All Clear Express Cycle, STERRAD® 100NX All Clear Standard Cycle, STERRAD® 100NX All Clear Duo Cycle, or STERRAD NX® All Clear Standard Cycle Sterilization Systems.

Prior to using the equipment, read these instructions thoroughly. Pay particular attention to the Warnings and Precautions. These instructions will familiarize the user with the camera head and the steps required for proper setup and maintenance.

Device Description

The camera head is a state-of-the-art, 4K video camera head designed for use in arthroscopic and endoscopic surgical procedures. It is compatible with the LENS 4K Camera Control Unit REF 72205059 – LENS 4K Camera Control Unit, Wi-Fi; REF 72205185 – LENS 4K Camera Control Unit, non-Wi-Fi).

Compatible Endoscopes and Couplers (Must have an industry standard 1.00 - 32 UN 2B C-mount thread.)

Arthroscopes:	1.9, 2.7, and 4.0 mm sizes
Laparoscopes:	5.0, 5.5, and 10 mm size
Hysteroscopes:	4.0, 5.0, 5c, and 8.0 mm
Thorascopes:	2.8 mm

Smith & Nephew surgical equipment is designed for use only by medical professionals who are thoroughly familiar with the appropriate surgical techniques and video procedures.

Intended Use

The LENS 4K Camera Control Unit and Camera Head are intended to provide illumination, visualization and capture of still and motion pictures of surgical sites.

Indications for Use

The LENS 4K Camera Control Unit and Camera Head are used in diagnostic and operative procedures for arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of surgical sites within articular cavities, body cavities, hollow organs and canals. Additionally, the LENS 4K Camera Control Unit and Camera Head are indicated for use in endoscopic surgical procedures in the thoracic cavity when used with an appropriately indicated thoracoscope.

Contraindications

None known.

Warnings

- The camera head is shipped non-sterile. It must be cleaned and sterilized before the first use. It must be cleaned and sterilized before every subsequent use.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions completely prior to use.
- Read the Operations/Service Manual for the applicable camera control unit and the Instructions for Use for other components used in the procedure.
- To prevent patient burns, do not place the camera head on the patient when it is not in use. The camera head contains heat-generating components that raise its surface temperature higher than that of the surrounding environment. Prolonged contact with the patient may cause burns.
- **DANGER:** Risk of explosion if used in the presence of flammable anesthetics.
- Do not use this device in oxygen rich environments (>25%).
- To prevent electric shock, do not disassemble the camera head. There are no user-serviceable parts. Dismantling the equipment will void the warranty.
- The camera head is autoclavable and compatible with only one chemical sterilant throughout its lifetime. Once a sterilant has been used, continue to use that same sterilant for the lifetime of that specific camera head. Do not apply multiple chemical sterilants during the lifetime of any single camera head. Use only chemical sterilants from the list of acceptable chemical sterilants.
- Do not modify this equipment. Attempts to modify this equipment will void the warranty.
- The LENS 4K Camera head is not compatible with any Liquid Chemical sterilant processes.

Precautions

R_{ONLY} U.S. Federal law restricts this device to sale by or on the order of a physician.

- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- This product may be sterilized with chemical sterilants STERRAD® 100S Short Cycle, STERRAD NX® Standard Cycle, STERRAD® 100NX Express Cycle, STERRAD® 100NX Standard Cycle or STERRAD® 100NX DUO Cycle Sterilization Systems. It may also be sterilized with V-PRO 1 PLUS/V-PRO maX Non-Lumen Cycle (12 minute exposure), or STERRAD® 100NX All Clear Express Cycle, STERRAD® 100NX All Clear Standard Cycle, STERRAD® 100NX All Clear Duo Cycle, or STERRAD NX® All Clear Standard Cycle Sterilization Systems. The product may be sterilized with any of the above-specified chemical sterilization methods. Failure to comply with this caution may result in damage to the product and will void the warranty.
- The camera head cannot be sterilized with Steris 1E™ or any other wet sterilant.
- To avoid fogging during surgery, ensure that the VideoArthroscopes™ or coupler and the camera head are entirely free of moisture prior to connecting them.
- Use ENZOL™ to clean the camera head. If ENZOL is not available in your facility a neutral pH cleaner can be used. Non-neutral pH cleaners may cause residue buildup, which may cause interference or damage the optical seals. Such damage will result in internal fogging and image discoloration.
- **US Customers:** Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).
- Handle all endoscopic instruments with care. If the camera head is dropped or damaged in any way, it must be returned immediately for service.
- Electrical safety testing should be performed by a biomedical engineer or other qualified service person.
- Do not point the camera head toward direct sunlight, extremely bright lights, or laser beams for prolonged periods as damage may occur.
- Do not plug the camera cable connector into the camera control unit if wet. Moisture on the camera cable connector, including the gold fingers, on the card edge of the camera head cable will damage the circuitry and void the warranty. Ensure that the camera cable connector is completely dry prior to plugging the camera head into the camera control unit.
- Do not sterilize damaged equipment, as further damage may result. Clean and disinfect the camera head prior to returning it to Smith & Nephew.
- Ensure that there are no deposits on the optical surfaces prior to sterilization.
- Allow the camera head to cool to room temperature after it has been autoclaved.
- Extreme caution must be taken to dry out mating portions of both the scope and camera head; otherwise trapped moisture may condense on glass surfaces, blurring the image.
- Carry and store the cable in loose coils to prevent kinks and stress on the internal wires. Do not carry the camera head by the cable.
- Do not pinch or damage the camera head cable (i.e., rolling heavy equipment over it, securing with clamps, pinching in doors, etc.).
- Do not modify this equipment. Attempts to modify this equipment will void the warranty.
- To minimize any reciprocal interference from or to the System, use a dedicated power outlet during any RF treatment or investigation.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional policy relating to obsolete electronic equipment.
- For information regarding electrical emissions and immunity testing, guidance separation, and precautions, refer to the camera control unit's Operations/Service Manual.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
- This product contains Nickel (Ni) which may cause allergic reactions.

Unpacking and General Inspection

Carefully unpack and inspect all of the components shipped with the camera head. You should have received the following:

- 1 ea. LENS 4K Camera Head and Cable (REF 72205058)
- 1 ea. LENS 4K Camera Head Instructions for Use (REF 10601349)

If any parts are missing or damaged, contact an authorized Smith & Nephew representative. Save the carton and packing materials in the event that a component needs to be returned or repaired.

Button Function

Table 1, Live Video Functions and Table 2, OSD (On screen Display) Menu Functions summarize the default button functions for the camera head for both the Live Video and OSD Menu modes. Table 3 provides Optional Programmable Button Functions. Refer to the Operations/Service Manual for the LENS 4K camera control unit (REF 10601350) for more information regarding default and customized button settings and a complete list of the associated functions.

Camera Head Control	Short Press (<1.0 seconds)	Long Press (>1.0 seconds)
Left Button	Frame Capture (Single from Primary)	Light Mode
Middle Button	Brightness (Up/Down)	Menu Access
Right Button	Zoom	White Balance

Table 1. Live Video Functions

Camera Head Control	Default Button Function
Left Button	Move the cursor UP to highlight a menu choice
Middle Button	SELECT the highlighted menu choice
Right Button	Move the cursor DOWN to highlight a menu choice

Table 2. OSD Menu Functions

Function	Effect
BRIGHTNESS	Control the luminance level of the video output
ENHANCEMENT	Enhance the sharpness of the displayed video
ZOOM	Digital zoom of field of view
ALT PAUSE	Pause the video while recording to a device connected to a rear panel port
PAUSE VIDEO	Pause the video from camera head
ALT VIDEO	Start or stop video capture from the secondary input source and save to the Tablet Application or USB
ALT FRAME	Capture a still picture from the secondary input source and save to the Tablet Application
FRAME CAPTURE	Capture a still picture from the endoscopic field of view and save to the Tablet Application or USB
LIGHT MODE	Activates and deactivates the illumination device on the control unit
VIDEO CAPTURE	Start or stop video capture from the endoscopic field of view and save to the Tablet Application or USB
LAST IMAGE	Displays the last known frame captures to the Tablet Application for review
MENU ACCESS	Access the graphical menu system of the control unit [MAIN MENU]
WHITE BALANCE	Correct for ambient color temperature
Peripheral Port 1 (Top port)	Triggers the accessory connected to the top port
Peripheral Port 2 (Bottom port)	Triggers the accessory connected to the bottom port

Table 3. Optional Programmable Button Functions*

* **Note:** Software updates to either the LENS 4K Camera Head or Camera Control Unit, may reset the button-mappable functions to the factory settings.

Instructions for Use

The camera head buttons perform a different set of functions depending upon whether the On Screen Display (OSD) Menu or Live Video is displayed on screen (Tables 1 and 2). When the OSD menu is displayed, use the camera head buttons to navigate through the menus.

When Live Video is displayed, each of the camera head buttons is assigned to default or customized functions for short (less than 1 second) or long (>1 second) presses. The default functions can be changed using the CUSTOMIZE PROCEDURE SETTINGS menu. Each registered press of a button is followed by a beep from the LENS 4K camera head. The beep is the same for both short and long presses.

Note: The camera head is not specific to any single LENS 4K camera control unit. It is interchangeable among multiple System control units.

Refer to the Operations/Service Manual for the applicable LENS 4K control unit for more information regarding the setup of the control unit and the LENS 4K camera head.

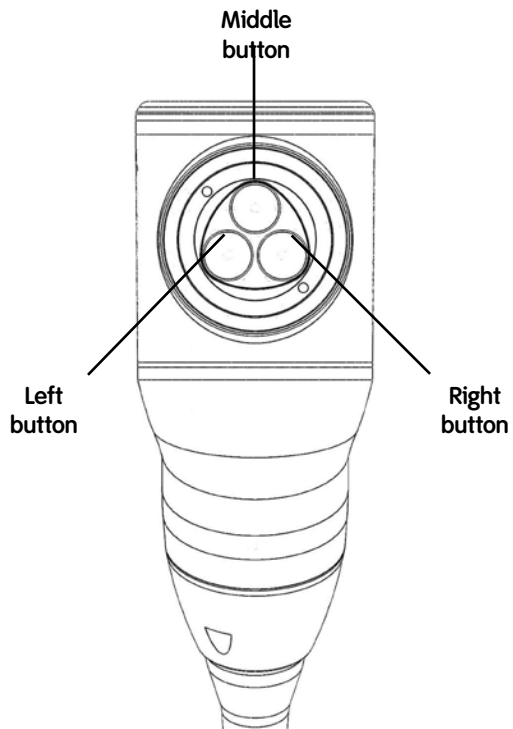


Figure 1. LENS 4K Camera Head

Connect the Camera Head

CAUTION: Do not plug the camera cable connector into the camera control unit if wet. Moisture on the camera cable connector, including the gold fingers, on the card edge of the camera head cable will damage the circuitry and void the warranty. Ensure that the camera cable connector is completely dry prior to plugging the camera head into the camera control unit.

To connect the camera cable connector to the control unit, plug the card edge connector into the appropriate receptacle on the front of the camera control unit and push in firmly (Figure 2).

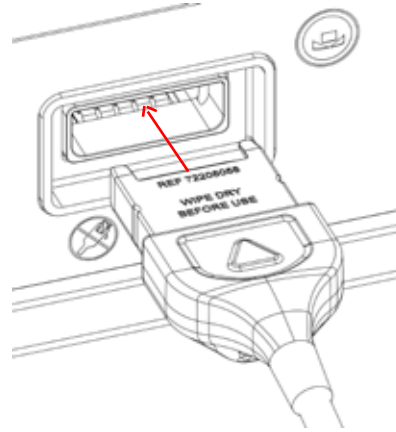


Figure 2. Connect the camera head to the control unit

Endocoupler focal length determines the image size on the monitor. For optimal image size use the LENS Coupler, 19.5 (72200315).

Service Life Checklist

Before each case begins, check the following items to ensure that they function properly and the system is ready to use:

- Confirm that the video works correctly and that visualization is correct.
- Check for any damage to the camera head and receptacle (cracks, corrosion, buildup or damage to the card edge receptacle).
- Check that the labeling information on the camera head connector is still readable.
- Ensure there are no deposits, scratches, or fogging/humidity on the front window of the camera head.
- Check for any damage to the cable (cuts or ruptured).
- Check that all camera head buttons are functioning properly by pressing each button.

White Balance the Camera

When a procedure is selected from the LENS 4K System STARTUP menu, the system automatically starts the White Balance procedure to ensure proper color rendition. The scope and the fiber optic light guide should already be connected in order to perform the White Balance procedure.

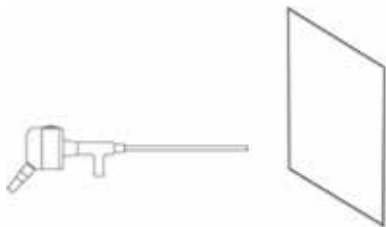


Figure 3. White Balance the camera

1. Point the end of the scope at a white object (a 4" x 4" gauze pad or flat white piece of paper) and focus. Fill as much of the screen as possible with the white object, but do not hold the scope close enough to touch the white object.
2. Select the desired procedure from the STARTUP menu. The monitor will display the message **WHITE BALANCE IN PROGRESS**.
3. Hold the gauze pad or paper in front of the scope until the monitor displays the message **WHITE BALANCE COMPLETE** and a long tone sounds.

If an error occurs during White Balance, the message **WHITE BALANCE INCOMPLETE** will appear on the display and a chirping tone sounds. To White Balance without restarting system, select **WHITE BALANCE** from the MAIN MENU or press the **WHITE BALANCE** button on the front panel of the control unit.

Cleaning and Sterilization

Notes:

- Disinfection is not a substitution for sterilization. Always inspect for damage and debris prior to sterilization.
- The camera head requires sterilization because it is used in the sterile field. No protection is needed for the camera head connector during cleaning and sterilization. The camera head connector must be dry prior to plugging into the camera control unit.

CAUTION: *US Customers: Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).*

WARNING: The camera head is autoclavable and compatible with only one chemical sterilant throughout its lifetime. Use only chemical sterilants from the list of acceptable chemical sterilants. Once a sterilant has been used on the camera head, continue to use that same sterilant for the lifetime of that specific camera head. The use of multiple chemical sterilants during the lifetime of any one camera head will reduce the service lifetime of that camera head.

CAUTION: *Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.*

CAUTION: *Use ENZOL™ to clean the camera head. If ENZOL is not available in your facility a neutral pH cleaner can be used. Non-neutral pH cleaners may cause residue buildup, which may cause interference or damage the optical seals. Such damage will result in internal fogging and image discoloration.*

CAUTION: *To avoid fogging during surgery, ensure that the VideoArthroscope or coupler and the camera head are entirely free of moisture prior to connecting them.*

CAUTION: *Do not plug the camera cable connector into the camera control unit if wet. Moisture on the camera cable connector, including the gold fingers, on the card edge of the camera head cable will damage the circuitry and void the warranty. Ensure that the camera cable connector is completely dry prior to plugging the camera head into the camera control unit.*

CAUTION: *Do not sterilize damaged equipment, as further damage may result. Clean and disinfect the camera head prior to returning it to Smith & Nephew.*

Cleaning and sterilization requires four steps in the following order:

- Cleaning
- Equipment inspection
- Equipment preparation
- Sterilization

Preparations at the point of use prior to processing

Keep instruments moist after use to prevent soil from drying on them.

Follow Universal Precautions for handling and transporting contaminated instruments to the designated cleaning area. Contaminated instruments should be transported to the area for cleaning in a way that avoids contamination of personnel and hospital.

Prior to cleaning, remove visible debris from the surfaces of the device. Dried-on soil is difficult and sometimes impossible to remove with automatic washing.

Clean instruments as soon as possible after use to prevent blood from drying on the devices.

Approved Cleaners/Pre cleaners

Use ENZOL a neutral pH enzymatic cleaner to clean or preclean the camera head. If ENZOL is not available in your facility a neutral pH cleaner can be used.

Water Quality

Warm tap water is recommended for cleaning the camera head assembly. Distilled water is recommended for rinsing the camera head assembly.

Cleaning

Immediately after a procedure, manually clean the camera head to make it safe for further handling. The following steps constitute a general guideline for routine cleaning of the camera head and other equipment.

1. Turn the camera control unit off.
2. Disconnect the light guide from the endoscope and light source.
3. Unplug the camera head cable and unplug any remote controls that were used in the sterile field. Detach the endoscope or endocoupler from the camera head.
4. Contain contaminated instruments for transportation to the cleaning area and preparation for manual cleaning.
5. Do not use germicides or any other agents containing benzene or phenol derivatives. This will damage the camera head cable and will void the warranty.

To clean the camera head

Manual cleaning

1. Rinse the camera head assembly in cold tap water for a minimum of 1 minute.
2. Soak in ENZOL™ a neutral pH solution for a minimum of 2.5 minutes to prevent coagulation and help remove protein materials and other resistant debris. If ENZOL is not available in your facility a neutral pH cleaner can be used.
3. Clean manually using soft cloths, soft bristled brushes or sponges for a minimum of 1 minute.
 - To prevent the scratching of lenses and electrical components, limit the number of items in the sink at any one time.
 - Never use scouring pads or abrasive powders.
 - Pay particular attention to the button area. To avoid scratching lenses, wipe them in one direction; do not scrub.

Note: It is the responsibility of the hospital to ensure adequate cleaning of the brushes between each use.
4. Rinse in purified water for a minimum of 1 minute.
5. Use isopropyl alcohol on the lens for a minimum of 1 minute. Do not allow the exposed lenses and glass surfaces to air dry. Use a cotton applicator dipped in 70% isopropyl alcohol to remove stubborn spots, streaks, and residual debris.
6. Dry thoroughly with a clean applicator. Do not allow to air dry.
7. Repeat the cleaning process until the device is visually clean.

Automated cleaning

1. Place the camera directly on the washer rack being careful to arrange the cables so they have full exposure to the washing/rinsing action of the washer.
2. Run the automatic washer cycle. The minimum automatic washer parameters are:
 - Five (5) minute cold prewash (<43 °C)
 - Five (5) minute enzyme wash (neutral pH cleaner)
 - Two (2) minute rinse hot water
 - One (1) minute final rinse with purified water (90° C)

To clean the coupler

For information about how to clean and sterilize the coupler, refer to the Instructions for Use provided with that product.

To clean the card edge connector:

1. Use a soft-bristled brush to manually remove debris from the card edge connector and cable. Never use abrasive powders.

Note: It is the responsibility of the hospital to ensure adequate cleaning of the brushes between each use.
2. If residue is visible on the metal housing of the card edge connector, use a mildly abrasive plastic scrubbing pad to gently scrub both sides of the metal housing. Ensure that all visible debris is removed.

DO NOT scrub the gold fingers on the end of the card edge connector as this will damage the electronic connections and cause the camera head to fail. Figure 4 indicates which areas to scrub and which to avoid.

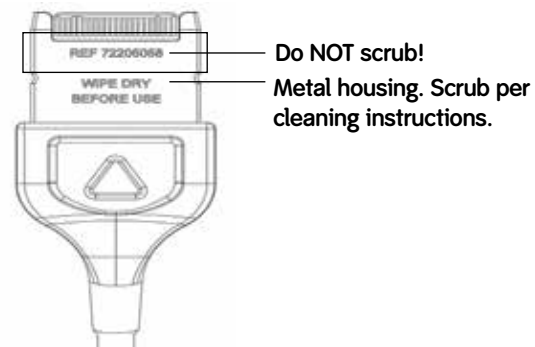


Figure 4. Card edge connector

3. Use distilled water to thoroughly rinse off any residue. Do not use saline as salt can increase pitting or corrosion of surfaces.
4. Use a soft, lint-free cloth to thoroughly dry the connector.
5. Wipe the camera head cable connector with isopropyl alcohol and air dry or dry thoroughly with a sterile, lint-free cloth. Ensure that the connector is completely dry. If moisture is present in the connector, use compressed air to blow out any fluid within the connector.
6. Visually inspect the device to ensure all visible tissue and debris have been removed. If not, repeat steps 1–5.

Note: Do not lubricate the camera head or cables.
7. Repeat the cleaning process until the device is visually clean.

Equipment Inspection

Prior to each use, inspect the camera head to ensure the following:

Camera head cable jacket: There are no burn holes, cracks, tears, swelling, etc.

Camera head cable connector: There is no corrosion, damaged card edge, etc.

Glass window: There are no scratches and no deposits.

If any of the listed conditions are present, contact Smith & Nephew as directed in the **Warranty** section of this Instructions for Use. The use of damaged equipment could compound the damage, harm interfacing equipment, or void the warranty.

Equipment Preparation

After every use, ensure that the camera head has been thoroughly cleaned, inspected, and sterilized according to the directions in this document.

Note: The camera head can be autoclaved as part of a visualization system or individually. A visualization system consists of a camera head, camera coupler, light guide, endoscope and adaptor.

Sterilization

READ ALL WARNINGS AND CAUTIONS BEFORE STERILIZING.

WARNING: The camera head is autoclavable and compatible with only one chemical sterilant throughout its lifetime. Once a sterilant has been used, continue to use that same sterilant for the lifetime of that specific camera head. Do not apply multiple chemical sterilants during the lifetime of any single camera head. Use only chemical sterilants from the list of acceptable chemical sterilants.

CAUTION: This product may be sterilized with chemical sterilants STERRAD® 100S Short Cycle, STERRAD NX® Standard Cycle, STERRAD® 100NX Express Cycle, STERRAD® 100NX Standard Cycle or STERRAD® 100NX DUO Cycle Sterilization Systems. It may also be sterilized with V-PRO 1 PLUS/V-PRO maX Non-Lumen Cycle (12 minute exposure), or STERRAD® 100NX All Clear Express Cycle, STERRAD® 100NX All Clear Standard Cycle, STERRAD® 100NX All Clear Duo Cycle, or STERRAD NX® All Clear Standard Cycle Sterilization Systems. The product may be sterilized with any of the above-specified chemical sterilization methods. Failure to comply with this caution may result in damage to the product and will void the warranty.

CAUTION: Ensure that there are no deposits on the optical surfaces prior to sterilization.

CAUTION: Allow the camera head to cool at room temperature after it has been autoclaved.

CAUTION: Extreme caution must be taken to dry out mating portions of both the scope and camera head; otherwise trapped moisture may condense on glass surfaces, blurring the image.

Notes:

- Disinfection is not a substitute for sterilization.
- Always inspect for damage and debris prior to sterilization.

For sterilization instructions for light guides, couplers, and endoscopes, refer to the Sterilization section of the respective product's Instructions for Use.

Sterilization Methods

WARNING: The camera head is autoclavable and compatible with only one chemical sterilant throughout its lifetime. Once a sterilant has been used, continue to use that same sterilant for the lifetime of that specific camera head. Do not apply multiple chemical sterilants during the lifetime of any single camera head. Use only chemical sterilants from the list of acceptable chemical sterilants.

Use one of the following methods to sterilize the camera head:

WARNING: The LENS 4K Camera head is not compatible with any Liquid Chemical sterilant processes.

Autoclave (Steam Sterilization Parameters)

Method	Cycle	Exposure Temperature	Exposure Time (minutes)	Dry Time (minutes)
Steam (wrapped)	Prevacuum	270 °F (132 °C)	4	30
Steam (wrapped)	Gravity	270 °F (132 °C)	15	30

CAUTION: Allow the camera head to cool to room temperature after it has been autoclaved.

Non US Customer

Autoclave (Steam Sterilization Parameters)

Method	Cycle	Exposure Temperature	Exposure Time (minutes)	Dry Time (minutes)
UK Cycle (wrapped)	NA	134 °C	3	30
World Health Organization (WHO)	NA	135 °C	18	30

Note: The UK cycle is not an FDA cleared sterilization cycle and only for use Internationally.

Note: The WHO cycle is not an FDA cleared sterilization cycle and only for use Internationally.

CAUTION: Allow the camera head to cool to room temperature after it has been autoclaved.

Chemical Sterilization

Sterilize the device using any one of the sterilization systems. The device load is the same for all sterilization systems listed.

Device Load: The LENS 4K camera should be wrapped in a FDA cleared sterilization wrap individually or as part of a visualization system.

Note: A visualization system consists of a camera head, camera coupler, light guide, endoscope and adaptor.

List of Sterilization System:

- STERRAD® 100S Short Cycle
- STERRAD® 100NX All Clear Duo Cycle
- STERRAD® 100NX All Clear Express Cycle
- STERRAD® 100NX All Clear Standard Cycle
- STERRAD® 100NX DUO Cycle
- STERRAD® 100NX Express Cycle
- STERRAD® 100NX Standard Cycle
- STERRAD NX® All Clear Standard Cycle
- STERRAD NX® Standard Cycle
- STERIS V-PRO 1 PLUS
- STERIS V-PRO maX Non-Lumen Cycle

Follow all recommended directions and warnings included with the sterilization system.

CAUTION: *The camera head cannot be sterilized with Steris System 1E™ or any other wet sterilant.*

Notes:

- The camera head can be used immediately after chemical sterilization.
- These parameters have been validated to ensure sterility.
- The camera head is validated for sterilization assurance using the sterilant manufacturer's instructions.

Storage

To prevent damage, ensure that camera heads remain immobile while stored.

Service



WARNING: Do not modify this equipment. Attempts to modify this equipment will void the warranty.

There are no user-serviceable components in the camera head. Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers.

If service becomes necessary, call an authorized Smith & Nephew Customer Service Representative prior to returning the device and request a Return Authorization (RA) number. A representative can also explain the available Service Replacement and Repair programs.

Service items should be carefully cleaned and disinfected, repackaged, and returned postpaid to Smith & Nephew. Smith & Nephew Customer Service or an authorized representative can provide additional instructions.

Note: Product that has been returned that is found to have been serviced by an unauthorized third party repair facility and/or sterilized with a sterilization method other than the ones approved for it by Smith & Nephew will incur additional costs, regardless of warranty status.

Maintenance

Recommended Annual Performance Checks

Smith & Nephew recommends that Dielectric Strength Testing be performed annually to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications IEC 60601-1:2005 + A1:2012, IEC 60601-2-18:2009, IEC 60601-1-2:2014.

CAUTION: *Electrical safety testing should be performed by a biomedical engineer or other qualified service person.*

CAUTION: *For information regarding electrical emissions and immunity testing, guidance separation, and precautions, refer to the camera control unit's Operations/Service Manual.*

Note: Service life is determined by adherence to general maintenance procedures.

Camera Head Specifications*

Equipment Classification	Protection against electrical shock Class 1, type CF equipment
Video Sensor Technology	4K 3-Chip MOS
Video Data Transmission	High-speed, low-voltage differential serial (LVDS), digital transmission via 12-foot camera cable
Video Output Format	Full UHD 2160p, 100% compatible with SMPTE ST 425-5 when used with the LENS 4K Camera Control Unit
Video Field Rate	60 Hz
Transport Shock and Vibration Compliance	ISTA 3A
Camera Head Dimensions	1.7" W x 2.0" H x 3.5" L 43.18 mm W x 50.8 mm H x 88.9 mm L
Camera Head Weight	1.5 lbs (0.7 kg)
Camera Head Cable	12 ft (366 cm)
Lens Mount	1.00 - 32 UN 2B C-mount thread
Compatible Control Units	Smith & Nephew LENS 4K Camera Control Unit
Compliance	Complies with IEC 60601-1:2005 + A1:2012, IEC 60601-2-18:2009, IEC 60601-1-2:2014
Modes of Operation	Continuous

*Specifications subject to change without notice.

Environmental Conditions

	Transport and/or Storage Use	Use
Ambient Temperature	-20 – +140 °F -29 – +60 °C	+50 –77 °F +10 –25 °C
Relative Humidity	15–85%	30–75%
Atmospheric Pressure	70–106 kPa	70–106 kPa
Operating Altitude	3000 meters maximum	3000 meters maximum

Ordering Information

REF 72205058 Smith & Nephew LENS 4K Camera Head
 REF 10601349 Smith & Nephew LENS 4K Camera Head Instructions for Use (all countries)

Warranty

Smith & Nephew products are warranted to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

This limited warranty is restricted to repair or replacement by Smith & Nephew, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user will result in additional charges and may void the warranty. This includes but is not limited to normal use related damage, any attempted repairs by unauthorized service providers, use of a sterilization method not approved by Smith & Nephew, and use of the product in a way that is not intended by Smith & Nephew. All warranties apply to the original buyer only and are not transferable. In no event shall Smith & Nephew be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

Service Replacement Units Warranty

Smith & Nephew service replacement units are warranted to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.










For Further Information






If further information on this product is needed, contact Smith & Nephew Customer Service at +1 800 343 5717 in the U.S., or an authorized Smith & Nephew representative.

All trademarks acknowledged.

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Glossary of Symbols

	Non-sterile
	CE Mark
	Caution
	Manufacturer
	Date of Manufacture
	Batch Code
	Catalog Number
	Serial Number
	Use by date

	Consult instructions of use
	EU: Not for general waste
	Type CF Equipment
	Temperature Limitation
	Humidity Limitation
	Do not plug in wet
	Keep Dry
	MR Unsafe
	Atmospheric Pressure



Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810
USA

www.smith-nephew.com

+1 978 749 1000 Telephone
+1 978 749 1108 Fax
+1 800 343 5717 U.S. Customer Service



Smith & Nephew Orthopaedics GmbH
Alemannenstraße 14
78532 Tuttlingen
Germany
ec.rep@smith-nephew.com

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