General Instructions

To protect your scope, please follow these instructions. These instructions are not intended to serve as a guideline for endoscopic surgery or as a training manual. These instructions should be followed for both new scopes and scopes that have been previously used.

- As with any optical device, scopes are fragile and should be handled with care
- Always hold the scopes by its eyepiece or body, never the tube
- Do not bend the tube, or otherwise add mechanical stress
- Avoid contact between the objective and other instruments or surfaces
- If possible, store the scopes individually
- Do not drop the scopes
- As a precaution, scopes that are not used during a particular surgery should be sterilized as well.

Inspection and Care

Before and after each use, scopes should be carefully inspected for damage, scratches, tenacious coagulation encrustations and any other defects. All optical and mechanical surfaces should be inspected.

This scope should also be inspected after cleaning, disinfection and sterilization. It is important that there are no defects such as rough surfaces, sharp edges or other prominent parts. These defects could create severe risk for the end user, patient and third parties. The image quality should be checked to make sure it is clean and free of distortions. Additionally, check the light transmission through the fibers. To do so, hold the light guide connector against alight (not a cold light source). If numerous fibers appear as black spots on the distal end, the light output is insufficient. The black spots are broken fibers. Should any of the above mentioned deviations be found, the scope should be returned to Hayden Medical.

Combinations

To be compatible with other products and allow combinations, make sure that the intended use matches the technical parameters (working length, diameter, connection type, etc) Combinations, accessories or spare parts can be used when they are intended for the application and do not affect the performance and safety standards of this product.

Cleaning and Disinfection

Ultrasonic: ***Scopes MAY NOT be cleaned using ultrasonic.***

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Machine Disinfection and Cleaning:

Machine disinfection and cleaning is appropriate to scopes when using approved cycles. Please follow manufacturers' instructions (please refer to the Machine Cleaning Section).

Water Quality:

Water used for cleaning and rinsing scopes needs to be at least drinking-water quality.

Please note that even drinking water can be hard, and therefore can affect the performance of the scope. We recommend using de-mineralized water.

Cleaning and Disinfection Mediums:

We suggest using solutions and detergents that are recommended by the manufacturers for use with scopes. When preparing these solutions or detergents, please follow the manufacturers' instructions regarding concentration and time. The maximum time for a scopes to remain in a solution is 30 minutes. This should not be exceeded. Extended exposure to cleaning solutions and detergents can damage the scopes.

Manual Cleaning:

1. Manual cleaning is necessary for scopes.
2. The scopes should be cleaned immediately after use, with careful attention paid to blood, secretions and other residues.
3. If immediate cleaning is not possible, the scopes should be immersed in a combined cleaning and disinfection solution.
4. Removable parts, such as light guide connectors and adapters, should be cleaned separately. Stopcocks should be in the open position.
5. When immersing the scopes or instrument in the disinfecting / cleaning solution, make sure all bubbles escape any cavities by rotating or tipping the device. This will ensure that all surfaces are moistened.
6. Encrusted material must be removed carefully, preferably with plastic brushes and soft cloths. Never use sharp instruments to remove debris. This could scratch the scopes, particularly the glass components.
7. Clean the distal and proximal windows, as well as the light post, with a cotton swab moistened in isopropyl alcohol (70 %) or acetone. As an alternative, neutral detergent (such as hand soap) can be used.
8. Please avoid direct contact with other scopes or instruments to protect the optical components from scratches.
9. After cleaning, thoroughly rinse the scopes with de-mineralized water and dry it with soft cloth or compressed air.

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Machine cleaning

Be careful when selecting chemical solutions and corresponding washing machine programs. Only use washing machine programs, washing machines and solutions that are recommended for use with endoscopic instruments by the manufacturer. The risk of damage to the scopes with these cleaning methods is much higher than with cleaning the instruments by hand. Only thermal neutral processes should be used, and they must work in a pH-neutral environment (e.g.enzymatic cleaning solutions). The temperature should not exceed 93 degrees Celsius / 199 degrees Fahrenheit. The machine must be equipped with fixtures securing the instruments so they are not damaged during the washing cycle.

Instruments with channels or stopcocks need to be attached to the corresponding rinsing connections on the machine. It is important that all inner and outer surfaces of the instrument are cleaned and rinsed.

Please Note:

All instruments and scopes need to be removed from the washing machine after cleaning to protect them from damage due to residue. Residue on the fiberoptic surfaces can cause damage to reduce light transmission.

Sterilization:

Scopes need to be cleaned carefully prior to sterilization (see Cleaning and Disinfection). It is essential that the sterilization medium reaches all parts of the scopes or instrument, and is able to penetrate both sides of any cavity to allow full sterilization. Any stopcocks need to be in the open position.

For sterilization, scopes need to be packed in appropriate packaging (e.g. paper bags, sterilization containers). Make sure there is no contact with other instruments or metal surfaces. Such contact would increase localized temperature concentration and could cause severe damage to the instrument.

STERRAD® System

The scopes are compatible with the STERRAD®100S, NX and 100NX sterilization systems. The STERRAD®System utilizes a syngerism between hydrogen peroxide and low temperature gas plasma to produce a rapid, low temperature, low moisture inactivation of microorganisms.

WARNING: Consult STERRAD® labeling for lumen size restrictions.

CAUTION: STERRAD® sterilization may cause cosmetic changes to the device that do not necessarily impact the functionality of the device.

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CAUTION: All scopes must be thoroughly DRIED before loading into the STERRAD®System chamber. Loads containing moisture may cause a cycle cancellation.

CAUTION: Use only STERRAD® Instrument trays in the sterilization chamber. These trays are specially designed to allow the plasma to surround the items.

CAUTION: Use only polypropylene sterilization wrap and polyolefin pouches. Do not use paper pouches or sterilization wraps containing wood pulp or cotton.

CAUTION: Any deviations from the recommended STERRAD® System sterilization parameters must be validated by the user.

Please Note: Instruments that are determined to be compatible with the STERRAD® System sterilization process have been validated with at least one hundred STERRAD® cycles.

1. Clean and thoroughly dry all instruments.

2. Place the scopes in STERRAD® instrument trays, wrapped in polypropylene sterilization wrap or enclose them in polyolefin pouches. Place STERRAD® indicator strips in all trays and pouches.

3. Load the STERRAD® sterilizer, arranging the items such that the hydrogen peroxide plasma can surround them. Do not allow any items to touch the wall of the sterilizer.

4. Please consult the STERRAD® System Operators Manual for detailed instructions for use.

Steam Sterilization:

Endoscopes must be processed according to the hospital's specific regulations for steam sterilization. AED Endoscopes can be autoclaved. The following sterilization method has been validated.

Gravity Displacement - Wrapped
Parameters: 270°- 274° Fahrenheit
Sterilization time: 15 minutes
Dry Time: 30 minutes

Gravity Pre-Vacuum - Wrapped
Temperature: 270° Fahrenheit
Exposure Time: 4 minutes
Dry Time: 30 minutes

After sterilization and prior to opening the packaging, let the instruments cool at room temperature.

Accelerating the cooling process puts stress on the endoscope, which can cause damage and shorten its working life.

Caution: Sudden changes in temperature may fracture the glass components of the endoscope. Do not immediately expose endoscopes to air after removal from the autoclave. Never attempt to cool endoscopes by pouring cool, sterile liquid over them.

Important: Repeated steam autoclaving may have an adverse effect on the optical lens system of the endoscope. It is our recommendation that the endoscopes be inspected after each autoclaving cycle for damage.

The use of "flash" sterilization is not recommended, as it will shorten the life of endoscopy instrumentation.

Vaporized Hydrogen Peroxide (VH2O2) Sterilization Method:

Cycle Type: Non-Lumen / Surface Sterilization
Validation Standard: Validated in accordance with ISO 14937.

Loading Instructions:

This device is validated for use in Vaporized Hydrogen Peroxide sterilization cycles specifically programmed for non-lumen loads.

Ensure the sterilizer cycle selected is intended for surface sterilization of rigid or semi-rigid devices without lumens.

Do not process in cycles intended for long lumens or flexible endoscopes unless the sterilizer manufacturer's compatibility matrix specifically indicates otherwise.

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