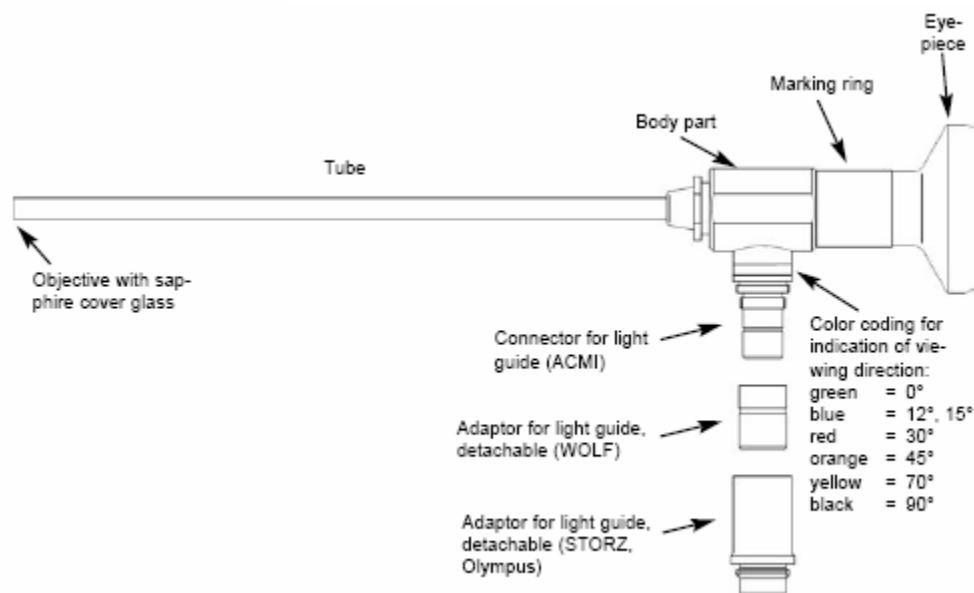




Handling and Maintenance Information for Bryan Rigid Endoscopes

1. General Information



2. Product Description

Bryan Endoscopes are optical instruments using high-quality lens systems. Endoscopes are used to visualize hollow organs and body cavities.

Each Bryan Endoscope has been designed for specific application and may only be used for this application. Surgeons should choose an operating method that is best for their patient's comfort and safety, and is appropriate to their level of knowledge and experience.

All Bryan Endoscopes are reusable and supplied in non-sterile conditions. These scopes can be disinfected, sterilized in a low-temperature or gas-sterilized.

Endoscopes marked "Autoclave" can also be steam-sterilized.

All Bryan Endoscopes are manufactured according to DIN EN 46001 and Medical Device Directive standards, and therefore are marked with the CE sign. Depending on their intended use, Bryan Endoscopes are marked as follows:

Mark:	Use:
CE	Invasive products for temporary use
CE 0123	Invasive and surgical invasive products for short-term use

Interconnections

Bryan Endoscopes are equipped with standard eyepieces. All TV-objectives or camera systems accommodating this standard can be used. The eyepiece consists of a non-conductive material and is therefore sufficiently insulated for the camera system.

Bryan Endoscopes are equipped with light guide adapters according to the chart on the first page. Other adapters are available upon request.

3. General Instructions

To protect your Bryan Endoscope, please follow these instructions. These instructions are not intended to serve as a guideline for endoscopic surgery or as a training manual.

To avoid defects or other limitations of use, please adhere to the following instructions for handling, storage and transport.

These instructions should be followed for both new scopes and scopes that have been previously used.

- **As with any optical device, Bryan Endoscopes are fragile and should be handled with care**
- **Always hold the endoscope 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 endoscopes individually**
- **Do not drop the endoscope**
- **As a precaution, endoscopes that are not used during a particular surgery should be sterilized as well.**

Inspection and Care

Upon receipt, as well as before and after each use, endoscopes 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 a light (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 Bryan Corporation.

Before re-assembling the stopcocks the sliding surfaces have to be treated with very little silicone grease.

All Bryan products must be used for their intended purpose, and only by personnel appropriately trained and qualified.

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.). This Bryan scope should only be used in combinations with approved accessories and/or spare parts listed in our catalogs. Other 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.

4. Cleaning and Disinfection

Ultrasonic:

Bryan Endoscopes **MAY NOT** be cleaned using ultrasonic.

Machine Disinfection and Cleaning:

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

Water Quality:

Water used for cleaning and rinsing endoscopes 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 endoscopes. When preparing these solutions or detergents, please follow the manufacturers' instructions regarding concentration and time. The maximum time for an endoscope to remain in a solution is 30 minutes. This should not be exceeded. Extended exposure to cleaning solutions and detergents can damage the endoscope.

Manual Cleaning:

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

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 endoscope 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 endoscopes 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:

Endoscopes need to be cleaned carefully prior to sterilization (see Cleaning and Disinfection). It is essential that the sterilization medium reaches all parts of the endoscope 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, endoscopes 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.

Gas sterilization

Endoscopes must be processed according to the hospital's specific regulations for gas-sterilization. Each instrument should be packed in appropriate packaging. The following sterilization method has been validated.

Please follow the manufacturer's instructions.

Ethylene Oxide Sterilization Process
DMB-Sterivit-Automatic
Half-Cycle-Process

Gas: 6 % Ethylene Oxide, 94 % Carbon Dioxide
Chamber pressure: 1.7 bar
Temperature : 55 degrees Celsius / 131 degrees Fahrenheit
Sterilization Time: 60 minutes
Packaging: Standard sterilization bags made of paper laminate (Steriking brand)

(Sterilizer: DMB-Sterivit-Automatic, type 30010 VS, version 908.01a, DMB Aparatebau, volume 300)

After sterilization, the endoscopes need to be aerated at room temperature (approximately 20 degrees Celsius / 68 degrees Fahrenheit) for a minimum of 24 hours. Increasing the temperature shortens the aeration time.

Steam Sterilization

Endoscopes must be processed according to the hospital's specific regulations for steam-sterilization. Only scopes marked "Autoclav" can be autoclaved without restriction. The following sterilization method has been validated.

Half-Cycle-Process

Parameters: 134 degrees Celsius / 273 degrees Fahrenheit
Sterilization time: 5 minutes
Packaging In metal containers and sterilization bags made of paper laminate (type Steriking)

Gravity or Vacuum Process

<u>Gravity</u>	<u>Pre-Vacuum</u>
Temperature: 270 to 272	Temperature: 270 to 272
Pressure: 27 psi	Pressure: 27 psi
Exposure Time: 10 to 15 minutes	Exposure Time: 4 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 telescope. Do not immediately expose telescopes to air after removal from the autoclave. Never attempt to cool telescopes by pouring cool, sterile liquid over them.

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

5. Safety Information

Cleaning, Disinfection and Sterilization:

Bryan Endoscopes can be processed by any of the following methods:
Steris™, Sterrad, autoclave (when marked as such), ETO, CIDEX and Henkel-Ecolab Sekumatic FRE

Temperature:

Endoscopes and attached light sources should not be used for more than four hours without a break. Prolonged use could increase the endoscope's surface temperature over the body temperature.

Security Information:

Details about electrical insulation should be provided by the manufacturer of any devices used with Bryan Endoscopes and accessories.

Storage:

Bryan Endoscopes and instruments should be stored using the original packaging or any other sterilization box. Safe and secure storage is essential for protecting the device. Rigid scopes with an outer diameter of less than 3 mm should be protected during storage and transport by protection sleeves to avoid bending or other damage.

Service:

Only Bryan authorized and trained repair facilities are able to perform a high-quality repair using original replacement parts. If a Bryan product is serviced by an unauthorized facility, the safety of the product may be jeopardized.

Warranties on Bryan products, as well as any liability for safety, are voided if the instrument has been repaired or otherwise handled by an unauthorized facility.

Bryan Endoscopes and instruments must be cleaned and sterilized before they are submitted for repair.

6. Contact Information

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