RIGID ENDOSCOPES
INSTRUCTIONS FOR CARE, USE AND STERILIZATION

MILLENNIUM SURGICAL
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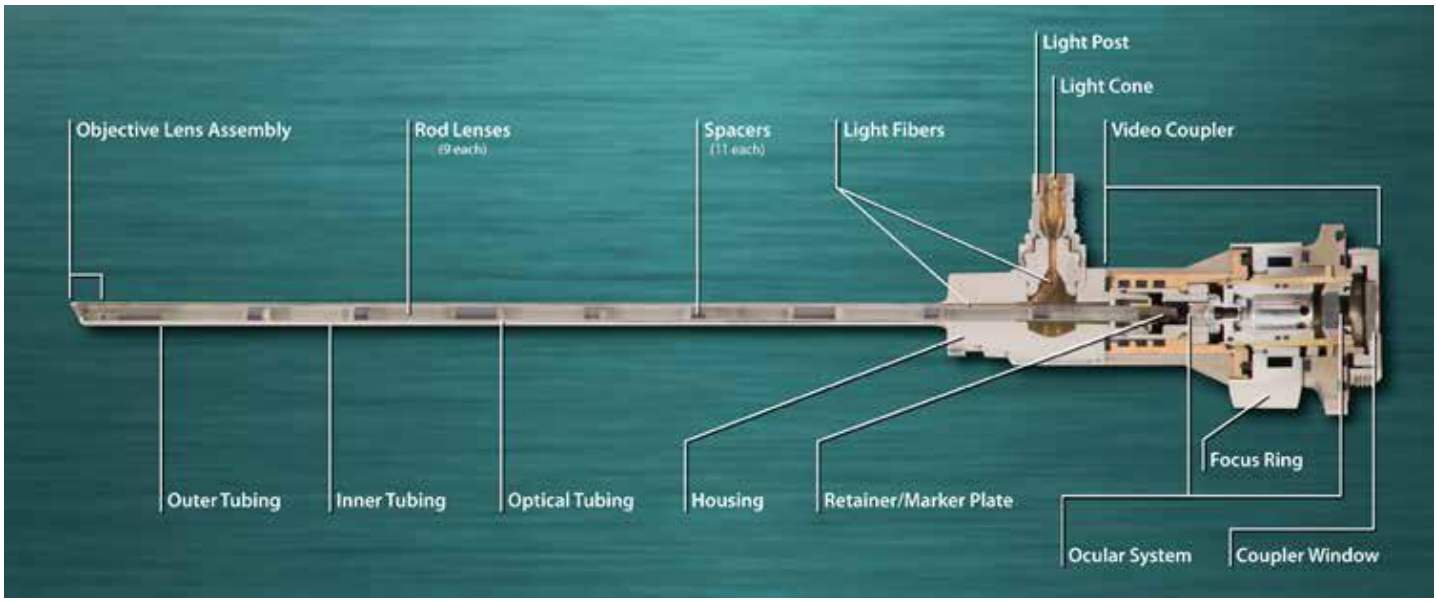
APPLICATION

NOT for use in the central nervous system or cardiovascular system.
Check your endoscope for damage and ensure that it is working properly before every use.
Your endoscope can be adapted for use with all commercially available light sources. The Wolf and Storz fittings can be removed for this purpose. Remember that light is a source of energy that will warm up your endoscope. The duration of use of our endoscopes is limited through the choice of light source (type and wattage). Avoid high temperatures at the distal end of the light source (compare DIN EN 60601-2-1 8). High temperature at the distal end of the light source may harm your patient causing tissue damage. Improper use can cause infection, harm patients or damage your endoscope.

ANATOMY OF A RIGID SCOPE



Eyepiece – At the proximal end of the scope. Can be used to view through the scope or to attach a Camera Coupler.
Ocular Lens Assembly – The focusing lens of the scope located near the proximal end of the scope.
Light Post – Fiberoptic Light Cords attaches to the scope here.
Shaft – Stainless steel tube that houses the Lens Train. The length of the Shaft is called the scopes working length. There is a second or inner tube as well.
Lens Train – A series of glass Rod Lenses and Spacers that transfer the image through the scope.
Objective Lens System – A collection of lenses, windows and/or prisms located at the distal end of the scope. This system captures the image and transfers it to the Rod Lenses.
Distal Window – Flat window that protects the Objective Lens System.
Light Fibers – Glass fibers that carry light from the Light Post to the distal end of the scope.

RIGID ENDOSCOPES

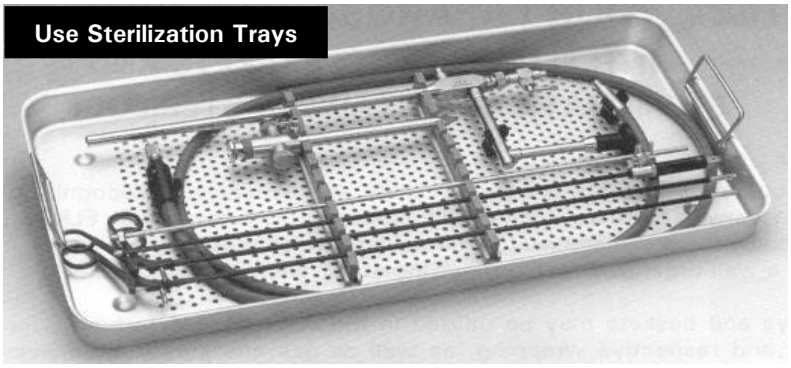
A Rigid Endoscope is a very delicate instrument that allows a surgeon to look into the body and see internal organs. Flexible glass fibers (fiber optics) transmit light for illuminating and viewing without transmitting damaging heat. Usually, a Video Camera is attached to the scope via a Camera Coupler so that the image can be transmitted to a Video Monitor. Endoscopes can be diagnostic, for observation only, or operative, some having channels for irrigation, suction, and the insertion of accessory instruments or Laser fiber. The rigid endoscope comes in a variety of diameters and lengths depending on the requirements of the procedure and/or surgeon.

The rigid endoscope also comes in different viewing angles, The angle of the lens used is determined by the position of the structure to be viewed.

0° degree for forward viewing.
12° degree for forward oblique views
30° degree
45° degree
90° degree and 70° degree for lateral viewing

CARE AND HANDLING

The Rigid Scope is a delicate instrument that must be treated with care if it is to work properly. The quality of the image depends on the integrity of the glass rods that capture the image. Since these Rod Lenses are in a very thin metal shaft, the scope is a very delicate instrument. The smaller the diameter of the scope is and the longer the shaft of the scope, the greater the chance of fracture or misalignment of the small glass rods within the scope. The rigid scope should never be bent or flexed. Whenever possible, the scope should be protected by a scope protector and/or a scope case. If a scope protector or case is not available for transporting the scope, you should grip the instrument so that the ocular lens is in the palm of the hand and the light post protrudes between the index and second fingers. This will minimize the possibility of dropping the endoscope, which could shatter the fragile optical components within the scope. Never transport a rigid scope in your pocket! Cleaning and reprocessing the scope should be done per the manufacturers written instructions.



COMMON COMPLAINTS

Since there are no moving parts in a Rigid Scope, almost all problems with the scope are due to someone doing something to the scope. For a Rigid Scope, this damage is usually done either during or immediately after the procedure.

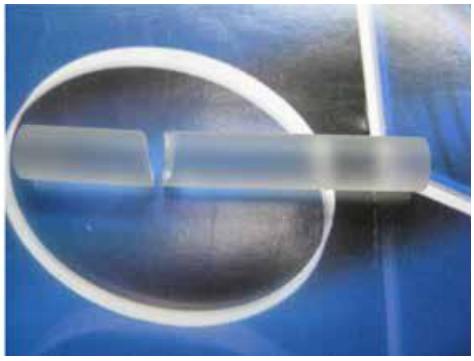
The most common complaint with a Rigid Scope is foggy, cloudy or blurry image. This usually indicates that the Rod Lenses inside the scope are broken or misaligned. While many people believe that the blurry, foggy, cloudy image is due to fluid invasion, this is rarely the case.
Rod Lenses become damaged or misaligned either due to Impact damage, such as dropping the scope, or torqueing the shaft of the scope. There are basically 4 ways that this torqueing occurs:

1. The surgeon uses the scope as a "pry bar" to move tissue or see a different view. This is common in Urology as these scopes tend to be longer and thinner.
2. The surgeon removes the scope from the working sheath at an angle instead of straight out.
3. Following the procedure, the scope is placed on the back table and something heavy is placed on top of it.
4. The scope is transported/cleaned/processed outside of a protective case and something heavy impacts it.

Fluid can get into the scope if the seals fail. This can happen if a non-autoclavable scope is autoclaved or if any scope is Flash Sterilized. A rather common misconception is that if a scope is autoclavable that it can be flash sterilized. Not true. Every manufacturer of autoclavable scopes states that their scope is NOT to be Flash Sterilized. Autoclavable scopes are generally laser welded at the Eyepiece but NOT at the Objective Lens. You cannot laser weld glass, so this end of the scope uses epoxy to seal it. Flash Sterilizing provides very high heat very fast which will cause the metal in the scope to expand. When the metal expands and the glass does not, the epoxy holding the two together gets pulled away from the scope and will allow fluid to enter the scope. If the image of the scope is very clear outside of the patient but tends to cloud up when inserted into the patient, fluid has likely gotten into the scope and is condensing inside the warm body.

Other possible damage to the scope can occur when the orthopedic surgeon hits the Distal End of the Arthroscope with a Shaver during the procedure. A picture of that type of damage is below.

SHAVER DAMAGE **BROKEN ROD LENS**



ELECTRICAL SAFETY

The endoscopes are primarily of metallic construction. The level of electrical isolation is determined by the manufacturer of all equipment used with endoscopes and accessories. Experience with predicate devices has shown no safety hazards.

WORKING CHANNEL

If you have an endoscope with a working channel, please note the following : The working channel is designed for the sole use of non-active surgical Instruments, or if used with High Frequency current, the instrument must be properly insulated per FDA recommendations. **The use of laser instruments is strictly forbidden.** The possible combination of endoscopes with working channel and surgical instruments depends on the length and the diameter of the instruments. The combination should allow safe functioning. The manufacturer is not liable for any immediate or consequential damage due to non-compliance with the instructions for use, inappropriate handling, or improper use of endoscopes. If you have any further questions, do not hesitate to contact the distributor.

CLEANING

Clean your endoscope immediately after use. If this is not possible, place your endoscope in a detergent solution until it can be cleaned. Use demineralized water if possible to avoid damaging the instrument. Never sterilize your endoscope before cleaning it first, as the effectiveness of sterilization depends on the cleanliness of the instrument prior to the sterilization procedure. Before every disinfection or sterilization all residue or grime has to be removed. The endoscope equipped with a working channel has to be cleaned cautiously but thoroughly with an appropriate round brush, List No. 72-5220532 . All visible dirt has to be removed. **Whatever detergents you use, be sure to follow the manufacturer's instructions. If you are using heat sterilization, it is important to make sure that optic parts do not come into contact with hot metal surfaces. Otherwise, conduction may destroy the endoscope material and cause leaks, affecting the entire system.** Carelessness when it comes to cleaning the endoscope encourages the build-up of scale on the optical parts. Be sure to manage all factors likely to affect cleaning, and observe the manufacturer's instructions when using detergents. **Never clean/sterilize endoscope with other instruments.**

AUTOCLAVING METHODS FOR AUTOCLAVABLE SCOPES

STEAM AUTOCLAVING WITH PREVACUUM AND GRAVITY STERILIZERS

If a wrapping method is used, make certain that the instruments are individually wrapped or sealed in a sterile pack. We recommend the following values/parameters, but we also suggest following the manufacturer's instructions for steam sterilization:

Cycle	Sterilizing Temp.	Sterilizing Time	Drying Time
Gravity Displacement	250 - 254°F	30 min	20 min
	270 - 274°F	18 min	20 min
Prevacuum	270 - 274°F	5 - 10 min	20 min

IT IS IMPORTANT THAT THE LONGEST DRYING CYCLE POSSIBLE IS EMPLOYED, TO PREVENT BUILD UP OF MOISTURE INSIDE THE INSTRUMENT. CORROSION, PITTING OR INTERMITTENT OPERATION ARE SIGNS OF A MOISTURE INDUCED CORROSION PROBLEM.

STERRAD STERILIZATION PROCESS INCLUDING STERRAD NX

The sterilization process is a multiple sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to affect sterilization. The Sterrad NX sterilizer can sterilize instruments which have diffusion restricted spaces, such as hinged portions of forceps and scissors.
Adhere to the sterilization instructions provided by the manufacturer. (Advanced Sterilization Products a Johnson & Johnson company).

GAS STERILIZATION

Follow standard hospital procedure for gas sterilization. Place scopes separately from instruments in a container approved for general use with gas sterilization (such as a perforated metal tray), with gauze or loosely woven cloth inserts folded about each item to avoid movement. Following 10:90 ethylene oxide/Oxyfume 2002 sterilization cycle is validated.

IMPORTANT PARAMETERS

Note : These parameters have been validated to ensure sterility. Sterilizer functioning should be monitored at regular intervals with biological indicators to ensure products have been subjected to sterilization conditions.

PRECODITIONING PARAMETERS

Temperature : 55 +/-2C (131 +/- 5F)
Relative Humidity : >/=35%
Vacuum : 21 +/- 1 In Hg
Pre-Conditioning time : 1 hour

STERILIZATION PARAMETERS

Ethylen Oxide Carrier : Oxyfume 2002
Temperature : 55 +/- 2 C (131 +/- 5F)
Relative Humidity : >/= 35%
Pressure (PSIG Start) : 19 +/- 1 PSIG
Ethylene Oxide concentration : 736mg/L
Gas Exposure Time (Full cycle) : 4 hours
Aeration : 11 hour at 54c (129 F) minimum

***** DO NOT FLASH AUTOCLAVE! *****

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