



**MILLENNIUM  
SURGICAL**

**SURGICALINSTRUMENTS.COM**

UNMATCHED SERVICE · UNLIMITED INSTRUMENTS

822 Montgomery Ave #205  
Narberth, PA 19072  
(800) 600-0428

# Rigid Endoscopes

## Instructions for Use and Care

IFU-2017.01.25

Millennium Surgical Corp. endoscopes are precision instruments. Please treat your endoscope carefully so that it will give you many years of service.

### APPLICATIONS

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.

### 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 of grime must be removed. First the endoscope equipped with a working channel has to be cleaned cautiously but thoroughly with an appropriate round brush, available from Millennium Surgical Corp. All visible dirt must 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

Warning! The use of autoclave settings and cycles other than those indicated may damage your endoscope. Be sure that scope is cleaned thoroughly before sterilizing. The endoscopes should be sterilized or disinfected in a container which secures the instrument in place. Be sure the needle portion does not experience any force or stress which can destroy the delicate optics.

### STERRAD STERILIZATION PROCESS INCLUDING STERRAD NX

The sterilization process is a multiple sterilization process that uses 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 is a Johnson & Johnson company.)



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### 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. Other metal objects should never come in contact with the insulating material of forceps and handles or with RF-connection cables. Such points of contact may cause melting of the insulation.

We recommend the following values/parameters but we also suggest following the manufacturer's instructions for steam

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\*\*\*\***

### CHEMICAL DISINFECTION & STERIS PROCESS

The scope is immersible and should be disinfected using the process obtained from the individual chemical manufacturer. These scopes are materially compatible with the Steris process. The endoscopes should be rinsed after soaking with sterile water and dried with a sterile cloth.

### GAS STERILIZATION

Follow standard hospital procedures 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 :

#### Preconditioning Parameters

Temperature : 55 +/-2C (131 +/- 5F)

Relative Humidity : >=35%

Vacuum : 21 +/- 1 In Hg

Pre-Conditioning time : 1 hour

#### Sterilization Parameters

Ethylene 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



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### 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.

### 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.

### Storage

The scope should be stored with the plastic tip covering the distal working end. This will preserve good optics by protecting the delicate portion. The scope and accessories should be stored either in their shipping box or in a sterilization tray. In either case, proper care should be taken to ensure that the scope is immobile to prevent any damage.

Note : Any mechanical manipulation of the eyepiece may result in seal breakage; therefore do not attempt to remove the eyepiece.

Mechanical wear and tear resulting from bending the shaft, dropping the instrument, or holding it by the distal end may damage or destroy your endoscope. Therefore, please treat your endoscope with the utmost care.

We recommend that you always have a spare endoscope ready in case you need one. This reduces the risk of mishap during surgery and examination and helps avoid error.

### Working Channel

If you have an Millennium Surgical Corp. endoscope with 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.

Millennium Surgical Corp. is not liable for any immediate or consequential damage due to non-compliance with the instructions for use, inappropriate handling, or improper use of Millennium Surgical Corp. endoscopes.

If you have any further questions, please do not hesitate to contact us.

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

**Warning: If this device is/was used in a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!**