

The Care and Handling of Flexible Endoscopes



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The Care and Handling of Flexible Endoscopes

Study Guide #4

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Description of Study Guide Topic

Flexible endoscopy has become tremendously popular today as less invasive procedures are preferred, advancements in endoscopic technology continue to evolve, and endoscopic techniques are constantly being refined. Health care professionals must understand the importance of proper care and handling of flexible endoscopes to promote patient safety and to ensure cost efficiency. This study guide will discuss the trends driving endoscopy today, the types and parts of flexible endoscopes, and the care and handling of these devices.

Overall Purpose of the Study Guide

To discuss endoscopy technology and the care and handling of endoscopes.

Objectives

Upon completion of this study guide program, the participant should be able to:

1. Compare the different types of flexible endoscopes and their anatomy.
2. Discuss how to reprocess a flexible endoscope, including care and handling tips.

Intended Audience

This study guide is a self-study program intended for use by endoscopy suite nurses, endoscopy staff members, perioperative nurses, surgical technologists, central service staff members, infection prevention nurses, and other health care professionals interested in this topic.

Introduction

Flexible endoscopy has become tremendously popular today as this technology continues to evolve as endoscopic techniques are constantly being refined. Through a flexible endoscope, diagnosis and treatment can be performed in a less invasive manner as compared to an open surgical procedure.

Some of the recognized trends involving flexible endoscopy today include:

- > Increased popularity and acceptance of endoscopy technology (by patients, physicians, nurses, staff members)
- > Increased demand for new, innovative, and less invasive procedures
- > Flexible endoscopy is being performed in less threatening and invasive environments
- > Proper care and handling of endoscopes minimize repair costs and will also foster patient safety

The art of endoscopy has become part of the education included in medical schools and residency programs today; therefore, more physicians are appreciating the value, benefits, and advantages of this amazing tool called the endoscope. With this increased popularity and growing expertise in endoscopy, the volume of flexible endoscopic procedures continue to steadily climb. Older established endoscopic techniques are being refined while new and innovative methods are being introduced.

The sites for performing flexible endoscopy are also expanding. Flexible endoscopy has evolved from the traditional operating room environment to endoscopy suites within a hospital to ambulatory surgery centers, ambulatory care units, medical endoscopy departments, free-standing ambulatory surgery centers, free-standing

endoscopy suites specifically built for endoscopic procedures, and even physicians' offices. Patients prefer to have their endoscopic procedures performed in comfortable, less invasive environments.

In today's healthcare arena, managed care and capitation are becoming the controlling forces for reimbursement and survival. Healthcare professionals are challenged to provide cost efficient and cost effective services. Less invasive procedures, such as endoscopic applications, are usually more economic but require a capital expenditure outlay and ongoing operating expenses. Proper care and handling of endoscopes and endoscopy equipment minimize the expense of repairs and prolongs the life of endoscopic devices and accessories.

The bottom line is by keeping endoscopes healthy (in the proper and ideal working order), patient safety is promoted along with cost efficiency. The cost of a nosocomial infection caused by an endoscope not adequately reprocessed or the expense of a patient injury from a damaged endoscope can become exorbitant. These unnecessary expenses and injuries can easily be avoided.

With this ever growing and ever changing endoscopic technology, healthcare professionals must understand endoscopy and the importance of proper care and handling of flexible endoscopes to promote patient safety and to ensure cost efficiency.

Types of Endoscopes

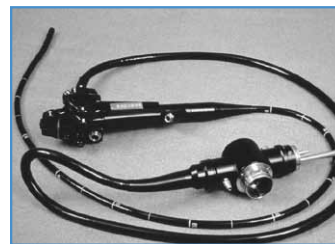
There are two types of flexible endoscopes on the market today:

- > Fiberscopes (fiberoptic endoscopes)
- > Videoscopes



Picture 1

The fiberscope was the first flexible endoscope to be introduced to the health care market. You can easily identify a fiberscope by noting the presence of an eyepiece (**See picture 1**). Through the eyepiece the operator can visualize the target site. A camera attachment (also called a video convertor) can be placed on the eyepiece to transmit the image to a monitor so more people can view the anatomic or targeted site.



Picture 2

Videoscopes became very popular in the early 1990s. A videoscope doesn't have an eyepiece as the image of the target site is directly transmitted to the monitor (**See picture 2**). Physicians have learned the art and skill of performing diagnostic and/or therapeutic procedures through indirect visualization of the anatomical area as it appears on the monitor.

Anatomy of a Flexible Endoscope

Advancements in flexible endoscopy have rapidly progressed this technology into the next level of sophistication. Complex endoscopes and accessories have expanded the capabilities of performing surgery and treatments in a less invasive manner.

When examining a cross section of a flexible endoscope, the internal complexities are evident. These intricate structures consist of wires, metals, glass, plastics, and other polymers that expand

the capabilities of this tool. A flexible endoscope is like a Swiss Army knife that is brilliantly designed into a compact device that includes a suction channel, light and image guides, irrigation channels, and biopsy channels capable of passing instruments through.

The complexities of a flexible endoscope are often not appreciated or even realized by health care professionals using these tools or maintaining them. By understanding the components of an endoscope, proper care and handling can be promoted while troubleshooting can be performed in a logical analytical manner. The four major components of an endoscope are:

- > Control body
- > Insertion tube
- > Bending section / distal tip
- > Light guide connector

Also within the flexible endoscope are three major systems that may extend from one component area to another. These systems include:

- > Mechanical system (i.e., the angulation system that allows the distal tip to be rotated in different directions so that the target site can be optimally visualized)
- > Plumbing system (i.e., water can be conducted to the target site for irrigation while suction can be activated to remove excess fluids, air, or surgical smoke)
- > Illumination system (i.e., conducts the image back to the eyepiece or monitor so that diagnostic and/or therapeutic procedures can be performed or treatments can be provided)

Control Body

The first major component within a flexible endoscope is the control body. Within the control body the plumbing system has outlets to control the instillation of air or water and to provide suction. Also instruments can be introduced through the control body biopsy port so that tissue can be biopsied, cut, coagulated, excised, removed, or ablated.

The control body also houses the control knobs that rotate the distal tip via a complex angulation system. In the control body there is a dry lubricant called mollycoat that allows the internal components to move freely as needed. If water or other solutions invade the internal structures of an endoscope and combines with mollycoat, a gritty substance results that can easily harm these internal components.

The bending section of the endoscope is angulated by turning the control knob which is attached to a wire that is connected to the distal tip. Angulation systems can either have a chain drive or a pulley wire design. If the endoscope angulation system is not moving the endoscope tip to the appropriate angle, then an angulation adjustment may need to be performed or the wires may need to be replaced.

At the juncture of the control body housing and the insertion tube, the endoscope may become stressed through repeated external flexing and bending. A strain relief boot reinforces this area to prevent major injuries resulting from bending the endoscope insertion tube at a right angle to the control body housing. Even with this boot in place to prevent overextension, injuries to the scope can occur with repeated abuse.

Insertion Tube

Another major component of a flexible endoscope is the insertion

tube that usually takes a lot of abuse and wear and tear. For example, a patient could bite through the external surface of a gastroscope if a bite block is not in place. Teeth marks along the insertion tube of an endoscope should be assessed to determine if the outer surface has been punctured causing fluid invasion to occur. Another needless injury to the insertion tube can occur if the lid of the transportation case or a drawer or closet door is closed on the insertion tube. These accidents can become very expensive.

A wavelike appearance (buckles) on the external surface of the insertion tube or bending section indicate problems underneath the surface. Buckles on an endoscope should be assessed and repaired early to prevent more costly repair.

Wires, glass bundles, and channels are found within the endoscope insertion tube. These complex and delicate structures transmit the image and light, provide a pathway for the irrigants, and provide channels for suction and instrument insertion. The illumination system provides the light needed to illuminate the target site. The origination of the light is found at the end of the light guide connector. Light is conducted through thousands of tiny glass fibers, even smaller than a strand of hair. If these light fibers are traumatized, they can fracture, thus decreasing the amount of light provided to illuminate the target area. Ultrasonic cleaners must not be used on fiberoptic scopes or light carrier cords as the minute vibratory motion of the sound waves can fracture these tiny glass fibers.

Fiberscopes conduct the image of the target to the eyepiece also through tiny glass fibers -many more fibers than is needed to conduct the light. If a number of these glass fibers are fractured, then the image will not be conducted by those specific fibers and visibility problems will be noted.

Videoscopes (do not have an eyepiece) conduct the image directly to the monitor without the use of an eyepiece. A CCD (charged coupled device) chip at the distal tip of the endoscope produces an electrical message of the image that is conducted to the monitor for visualization. Since tiny glass fibers are not required, broken fibers are not an issue. However, if the CCD chip in the distal tip is damaged, the entire chip may have to be replaced which is a very expensive repair.

Throughout the length of the insertion tube, ports and channels are present to conduct air, water, solutions, gases, instruments, and accommodate suction. The biopsy port is used to pass instruments to assist with a procedure. Earlier endoscope models used gortex material for this channel as it was extremely flexible. Studies have shown how porous gortex really is and that pathogens can be easily harbored in this material. Therefore, the FDA recommended to the endoscope manufacturers to replace gortex with another material, such as teflon, which provides an easy-to-clean surface.

Manufacturers then began to use teflon for the biopsy port material. The problem with teflon is that it easily can kink if bent too sharply - like a plastic soda straw would do. This has presented problems with flexible endoscopes especially if they are manipulated excessively. Repair companies have addressed this problem by reinforcing the stressed areas along the teflon length with coiled wire that is molded within the teflon tubing.

Another problem that tends to damage the internal surfaces of the biopsy channel is the insertion of instruments or cleaning tools that are damaged or have sharp edges. If the flexible endoscope is even slightly angulated during the passage of a damaged instrument, the internal lining of the channel can be punctured or ripped.

Bending Section/Distal Tip

Another component of a flexible endoscope is the bending section and distal tip. The bending section of an endoscope tends to be the site of most repairs as it is the most manipulated and angulated section of the

endoscope. Most fluid invasion damage occurs along the bending section.

A cross section view of the bending section shows metal coils reinforced with braided wires above the coils. Sometimes, through repeated usage, the braided wires may start to unravel and can puncture through the outer surface of the endoscope causing a leak and fluid invasion.

The distal tip of the endoscope houses the terminal ends of the following:

- > Biopsy port (which is large enough to accommodate instrumentation)
- > Air/water port (there is a nozzle at the air/water port that directs the flow of the irrigant over the image lens to keep it clean and free from debris)
- > Lens covering the image system
- > Lens covering the light or illumination fiberoptic system (there may be one or two of these)

A damaged lens in the distal tip can be caused by mishandling, banging or striking the distal tip which can lead to a costly repair.

Light Guide Connector

The last component of a flexible endoscope is the light guide connector that attaches to the light source. Other ports may be connected at the distal tip of the light guide connector including suction, water, air, and CO₂. Since the post on the light guide connector is attached and detached from the light source regularly, this post may become loose (**See picture 3**). Care must be taken to ensure that the connector post is always tight because if this juncture is loose, fluid invasion can easily occur.



Picture 3

Within a videoscope, the light guide connector is designed with exposed electrical pins that, when connected, conduct the electrical impulse needed to transmit the image. These electrical pins must be covered by a moisture cover (also called soaking

cap) when immersing the endoscope in solutions to prevent fluid invasion. There are also electrical pins on the fiberoptic light guide connector which is the part of the scope that is inserted into the processor/light source.

Reprocessing a Flexible Endoscope

Reprocessing an endoscope requires a skill level and knowledge base not only of the endoscope components but a thorough understanding of reprocessing practices and hazards. Improper reprocessing can compromise patient safety and can damage and actually destroy an endoscope. The endoscope manufacturer must provide detailed instructions on appropriate reprocessing.

The next step in reprocessing a flexible endoscope is cleaning. Precleaning the endoscope always takes place wherever the endoscopic procedure is being performed. When the scope exits the body, gross debris is wiped off the outside surface while fluid is pulled through the channels. Precleaning should always be done to remove and loosen debris before manual cleaning is performed in the reprocessing room.

Leak Testing

The first step is cleaning and flushing at the procedure site. The second step of reprocessing a flexible endoscope involves leak testing. This critical step is often overlooked or avoided, thus leading to more costly repairs from progressive fluid invasion. Healthcare professionals can no longer ignore the problems caused by fluid invasion. Early identification of a leak can prevent major repair bills and will remove an endoscope from service that could potentially harm the next patient. Even a very tiny hole in an endoscope can allow fluid entry which will accumulate during repeated uses and processings. Leak testing is such an easy and quick procedure that it must become a routine step in the proper reprocessing and maintenance of an endoscope.

Some causes of fluid invasion include:

- > Damaged scopes being processed without proper leak testing being performed first. (Damaged scopes can provide entry points for fluid, e.g. through a hole on the outside or inside of the scope, through worn gaskets, through loose lenses at the distal tip, etc.)
- > Energies used through the endoscope (for example, laser energy transmitted out of a fiber that's still recessed inside the endoscope's biopsy port can burn a hole in the biopsy channel causing an entry point for fluid invasion.)
- > Mishandling (for example, sharp biopsy forceps that are placed on top of an endoscope for cleaning can puncture the endoscope's outer sheath.)
- > Inappropriate repairs
- > Faulty or improper leak testing (for example, inadequate leak testing may not identify a damaged area where fluid could invade the endoscope.)

An example of an entry point where fluid can invade an endoscope could be a loose light guide connector post. This post should be checked regularly to make sure it's screwed on tightly. Another example that could cause fluid invasion would be if the endoscope insertion tube is damaged when the shipping case was closed on it. A tear can occur if a sharp biopsy forceps is forced through the biopsy channel of an endoscope thus allowing fluid to enter. Worn seals or gaskets around the control body knobs used for angulation could later foster fluid invasion.

The impact of fluid invasion can be disastrous. Fluid invasion can cause any of the following:

- > Damage to components
- > Reaction with mollycoat (The dry lubricant that is used on the internal components of an endoscope. When mollycoat is exposed to fluid, a sandy, gritty-like substance is formed that can easily damage the internal structures of the endoscope.)
- > Image distortion (Fluid invasion causes images to be distorted. Spider web-like appearances or multi-colored shadows can appear on the monitor screen.)
- > Harbors pathogens (Fluid trapped anywhere in an endoscope can foster the growth of pathogenic materials that can't easily be removed.)

- > Costs (Fluid invasion definitely increases the expense of maintaining an endoscope as repairs are needed to prevent further, more extensive damage.)
- > Rust and corrosion from fluid invasion can form on those metal parts that aren't made of stainless steel.

Leak testing and inspection are the only ways for early identification of fluid invasion. Leak testing is performed by pressurizing the inside of the endoscope to assess the presence of any leaks. The definition of leak testing is “pressurization of the flexible endoscope to determine the integrity of the endoscopes’s seals and demonstrate that no damage has occurred to either the outer coating or to the inner channels during use.”

Pressurization occurs within the internal endoscope spaces. When air is introduced into these areas, any hole, rip, or defect can allow this air to enter into the different channels or escape to the outside of the endoscope.

The basic supplies needed for leak testing are as follows:

- > Leak tester (manual or powered)
- > Water-resistant cap (for a videoscope)
- > Syringe (optional)
- > Basin of water (or large sink)

There are a variety of manual leak testers available today. After the manual leak tester is attached to the endoscope, the bulb is pumped until the needle reaches the indicated area on the gauge. Special attention must be paid to make sure that the needle does not fall during the leak testing process as a depressurized endoscope will allow fluid invasion.

Some people do a dry leak test on their endoscopes. This can only be done with a manual leak tester. After pressurizing the endoscope, the needle is observed closely. If the pressure begins to fall as indicated by the needle dropping, then a leak is present. This method of dry leak testing does not always identify leaks so it is not recommended for regular endoscope assessment.

A powered leak tester is attached to a small power unit that provides a constant flow of air to pressurize a flexible endoscope. The connector that attaches to the endoscope should be checked regularly. At the end of this connector is a pin that can be depressed to check the flow of air while the powered unit is on. Air should escape if the leak tester is functioning properly.

The powered leak tester unit itself also should be checked periodically to make sure it is working appropriately and producing an adequate amount of air. The manufacturer’s written instructions can be referenced for the proper maintenance of the powered leak tester. If the leak tester does not produce enough air flow, then leaks may not be identified.

After making sure the leak tester is working properly, leak testing begins with attaching the leak tester to the endoscope. A videoscope is attached to a leak tester using a water-resistant cap (also called moisture cap).

The water-resistant cap must also be inspected regularly to make sure that it will function appropriately. The gasket or seal within the cap must be properly positioned to prevent fluid invasion. If you note fingerlike projections from the seal protruding outwards, then the seal needs to be replaced or fluid invasion can occur at this site. If there are no fingerlike projections protruding, the seal is seated appropriately to prevent fluid invasion. A functioning water-resistant

cap will provide an adequate seal during the leak testing process.

The first step in the actual leak testing process is to disassemble the endoscope. The buttons that are detachable should be removed before leak testing is performed. If using a powered leak tester, the leak tester is attached to the endoscope and the endoscope is pressurized. If using a manual leak tester, the leak tester is attached to the endoscope and the bulb is compressed until the proper amount of pressure is produced within the endoscope (as noted on the gauge).



Picture 4

After the endoscope is pressurized, the bending section of the endoscope is immersed in the water (See **picture 4**). Warm water is usually used as bubbles tend to form easier in warm water.

The distal tip of the endoscope is angulated in different directions to note if any air bubbles are created. The tip is angulated in every direction to expose even a tiny hole. Air bubbles are formed since the

internal structure of the endoscope is pressurized and any hole or defect will cause the internal pressurized air to escape, thus causing bubbles to be noted. Special attention is paid to the integrity of the bending section since most leaks occur at this site. The scope is angulated to open up any leak area. An analogy to this is like having a paper cut on a joint of your finger. If your finger is straight, it doesn't hurt, but as soon as you bend your finger, it begins to hurt because you've opened up the cut. A hole in the bending section of an endoscope is very similar.

Some people do an abbreviated version of leak testing and stop at this point if no leak is identified. This is not an ideal situation but better than performing no leak testing at all. Manufacturers do not endorse this abbreviated version as other leaks cannot be identified.

The next step is to completely immerse the endoscope in the water while the endoscope remains pressurized. A 20 or 30 cc syringe full of water may be used to flush the air out of all of the lumens so trapped air doesn't form bubbles that may incorrectly be identified as a leak.

With the entire endoscope underwater, the operator patiently waits to note if any air bubbles form. Many endoscope manufacturers recommend that the control knobs be turned while the endoscope is completely submerged to identify any leaks from worn or damaged gaskets or seals. The instruction manual that accompanies each endoscope lists scope specific leak testing instructions.

If an air bubble is noted, that is the site of the endoscope leak. If an internal channel has a leak, then the air bubble usually appears at the distal tip of the endoscope. The site of an air bubble formation should be documented when the endoscope is sent for repair. The hand held leak tester is never immersed with the endoscope during this step of the leak testing process.

After no bubbles have been identified, the endoscope is removed from the water. It's extremely important to NEVER disconnect the leak tester (which depressurizes the endoscope) while the endoscope is immersed.

After the scope is removed, the powered leak tester is turned off to release the pressure (or with manual leak testers, the pressure is released by turning the screw). After the scope has been completely depressurized (which may take 2 or more minutes depending on type of scope), the leak tester can be disconnected from the endoscope.

The results of the endoscope leak testing can go in three different directions:

- > No leak - proceed with the cleaning process
- > Leak is noted - proceed with cleaning while the endoscope is pressurized
- > Major leak is noted - may not be able to proceed with cleaning

If no leak is noted, then the cleaning process can begin. The endoscope needs to be depressurized first and then the endoscope placed back into the water for cleaning. Some people perform the cleaning process while the endoscope is pressurized but since the bending section is inflated, damage to this section can easily occur.

If a leak is noted, the endoscope must remain pressurized during the entire cleaning process so that no further fluid invasion can occur. According to regulations by the Department of Transportation and the Postal Service, the endoscope must be at least decontaminated before returning it for repair and if it can't be decontaminated, other actions must be employed that will be discussed in more detail later in this study guide.

The powered leak tester is preferred when cleaning an endoscope while pressurized as this system provides a constant flow of air to maintain the internal endoscope pressure. As long as the leak tester unit is functioning properly, no fluid can invade the endoscope. If a manual leak tester is used, extreme diligence must be exercised in watching the needle on the gauge. As the needle starts to fall, the hand bulb needs to be compressed to maintain adequate pressure inside the endoscope. If the pressure is allowed to escape during the cleaning process, fluid will easily invade the endoscope and much more costly damages can occur.

If a large leak is noted, or if any leak is noted and cleaning cannot be done, the endoscope can be shipped to the repair company as biohazardous since decontamination has not been accomplished. There are specific steps that must be followed when shipping a biohazardous or uncleaned device through the mail. First the device must be packaged or contained appropriately. If the endoscope is not cleaned, then it needs to be packed in two containers with one container being leak and puncture resistant. Usually endoscopes are sent to the repair company in their original transportation suitcase. The contaminated endoscope can first be placed in a red biohazardous bag and then carefully fitted into the foam within the transportation suitcase.

The outer package needs to be labeled "biohazardous" so the receiver knows that special care needs to be taken when unpacking the contaminated device. This information also is needed by the shipping company. The carrier or shipper needs to be contacted to inform them that the package contains biohazardous material and to ask about any further instructions required for shipping. The U.S. Postal Service and Federal Express will handle biohazardous packages but specific details must be followed. The cost to ship biohazardous material is much greater than normal shipping.

The specific steps for handling biohazardous materials are not recommendations but are laws within the Department of Transportation (DOT) and Postal regulations. If contaminated materials are not handled according to these laws, a hefty fine and even imprisonment can be levied. Other agencies that address the handling of biohazardous materials are OSHA, CDC, AAMI, and the FDA. Some of their recommendations are mandated while others are suggestions in handling biohazardous materials.

Cleaning

The endoscope is then transferred to the reprocessing room. Appropriate detergents and enzymatic solutions must be chosen that are compatible with flexible endoscopes. Product labels must be read to determine this appropriateness. The endoscope manufacturer's

written instructions also will provide details on acceptable solutions to be used for cleaning. Appropriate protective attire should be worn when reprocessing an endoscope. According to Dr. Earl Spaulding, thorough cleaning is extremely important because an endoscope cannot be disinfected or sterilized without adequate cleaning. When brushing the lumens of an endoscope, the endoscope should be submerged under water to prevent aerosolization.

After cleaning the endoscope, thorough rinsing must be performed to remove any detergent residuals that could affect sterilization or disinfection. If the water contains minerals, such as iron, calcium, or magnesium, distilled water should be used for the final rinse as mineral deposits can harm an endoscope.

Thorough cleaning may remove up to 99% of the bioburden thus rendering the endoscope decontaminated. If bioburden is left within or on an endoscope, this debris can act like a foreign body if deposited in the next patient. This "sterile dirt" can increase adhesion formation, increase the immune response, and even delay healing.

The next step in the reprocessing cycle is to determine what is appropriate - disinfection or sterilization. Dr. Spaulding developed a classification system for patient care items based on the risk that is present when the instrument is used. The Spaulding's classifications are as follows:

- > Critical items - Devices that enter sterile tissue or the vascular system. Examples of critical devices are hemostats, scissors, snares, sphincterotomes, injectors, or biopsy forceps. These items need to be sterilized.
- > Semi-critical items - Devices and equipment that come in contact with intact mucous membranes. An example of a semi-critical device is an endoscope that is used for diagnosing a condition. The preferable choice of reprocessing is sterilization but high-level disinfection is acceptable.
- > Non-critical items - Devices and equipment that come in contact with intact skin but not with mucous membranes. Examples of non-critical items are bed pans, blood pressure cuffs, and stethoscopes. The choice of reprocessing is decontamination.

Disinfection

For years, disinfection with glutaraldehyde immersion has been an acceptable method of reprocessing for high-level disinfection. Glutaraldehyde is a protein fixative agent and will harden and cement any leftover debris within the lumens or on the surfaces of an endoscope. Thus through repeated processings, this debris becomes even harder to remove.

Before immersion in glutaraldehyde, the endoscope must be thoroughly cleaned, rinsed, and dried. The endoscope must be dry so that excess water in the lumens or on the surfaces of the endoscope do not dilute the glutaraldehyde solution. Test strips are used to determine the effectiveness for the glutaraldehyde concentration so that a solution that is too diluted is not used.

In the early 1990s the FDA required glutaraldehyde manufacturers to label their products recommending a 45 minute soak time with the solution being heated to 25°C. This recommendation was based on research showing that some pathogens could only be destroyed at this soak time and temperature (this study was based on uncleaned devices). Professional organizations have contested this recommendation and have written guidelines suggesting that devices be soaked for 20 minutes at room temperature if the devices have been thoroughly cleaned. The FDA's response is that devices are not always thoroughly cleaned and there is no way to validate appropriate cleaning has been performed. Therefore, the FDA

continues to promote the 45 minute soak time. As this controversy gains momentum, the end-users remain confused. Because of this debate, many health care facilities have totally eliminated glutaraldehyde and have resorted to the other methods such as liquid chemical sterilization.

Many hazards have been associated with glutaraldehyde including:

- > Skin and mucous membrane hazards
- > Ingestion hazards
- > Chronic exposure hazards
- > Respiratory hazards

Respiratory hazards are such a concern that the following levels of glutaraldehyde exposure have been set:

- > 0.04 ppm odor is detected
- > 0.2 ppm exposure level (set by OSHA)
- > 0.3 ppm the glutaraldehyde fumes become an irritant
- > 0.4 ppm occurs when mixing, pouring, or breaking the surface tension of the glutaraldehyde solution when immersing devices to soak (this is twice the exposure level permitted by OSHA.)

OSHA doesn't mandate glutaraldehyde exposure monitoring but it can penalize facilities if the breathing areas exceed the exposure level for glutaraldehyde. Glutaraldehyde soaking bins must be centralized. At least 10 air exchanges per hour are recommended in the decontamination area. The glutaraldehyde tub should be positioned near the ventilation outlet (that connects with outside air that is not recirculated).

A corneal injury can occur from glutaraldehyde exposure if an unprotected eye is splashed with glutaraldehyde. Glutaraldehyde bonds protein together, therefore, the protein within the cornea can be coagulated easily and quickly after an accidental splash. If contact lenses are being worn when a glutaraldehyde splash occurs to the eye, the contact lens should not be removed as the lens may become adhered to the corneal surface. The eye should be thoroughly flushed with saline or water and the contact lens should be removed by an eye specialist. Eye wash stations should be located in close proximity (within 30 meters) of the glutaraldehyde soaking tub.

Alternative solutions have gained acceptance for high level disinfection of flexible endoscopes. The manufacturer's instructions must be closely followed when using these products.

Sterilization

Many healthcare facilities have switched to sterilization of their flexible endoscopes since therapeutic modalities (cutting, ablation, excision, coagulation, etc.) are often performed during the endoscopy procedure. If the blood system is invaded, during a biopsy, according to the Spaulding Classification, the devices should be sterile.

There are two acceptable sterilization methods that are appropriate for flexible endoscopes, including ethylene oxide and liquid chemical sterilization with peracetic acid. Gas plasma sterilization has not been approved yet for flexible endoscopes but can be used

on rigid endoscopes with lumens greater than 1/8" in diameter and less than 16" in length. Adaptors for smaller diameters and longer lumens are being reviewed for FDA approval.

Ethylene oxide sterilization (EO) has been the sterilization method of choice for heat and moisture sensitive medical devices for years but misunderstandings about this type of sterilization have led some hospitals to remove all of their EO sterilization systems. The ethylene oxide is not the problem; the problem is what has

been combined with EO to make it less flammable. The CFCs (chlorofluorocarbons) and the HCFCs (hydrochlorofluorocarbons) that make EO less flammable tend to destroy the ozone layer.

In 1986 when industrialized countries met to discuss global warming, a treaty was signed to eventually eliminate those compounds that are destroying the ozone layer. This affected the mixtures of EO with CFC. Today the solution to this ban is to convert to the 100% EO sterilization system.

When preparing devices for EO sterilization, they first must be washed, thoroughly rinsed, and then dried. If any water remains, the EO can combine with the water and form ethylene glycol (antifreeze) which would be hazardous if accidentally instilled into a patient during endoscopy.

The effectiveness of EO sterilization depends on several factors, including gas concentration, relative humidity, temperature, and contact time. A relative humidity of at least 35 to 85% is required for sterilization to be effective. Humidity is necessary to allow the EO to penetrate the cellular membranes. Moisture will swell the microbial cell which will aid in the killing of microbes.

Ethylene oxide sterilization progresses through several phases from preconditioning through exposure to detoxification or aeration when the toxic EO is removed so that the instruments and devices can be used or stored. Complete aeration is extremely important to ensure that all of the residual ethylene oxide is removed so that skin irritation or burns will not occur.

To ensure quality, physical monitoring (noting if the sterilization parameters have been met on the printouts or round charts), chemical monitoring, and biological monitoring (with *Bacillus atrophaeus*) can be performed.

The advantages of EO sterilization include:

- > Effective sterilization for heat and moisture sensitive devices
- > EO readily diffuses at low temperatures
- > No lumen restrictions
- > Compatible with most materials
- > Low cost

The limitations of EO sterilization include:

- > Cycle length and aeration (longer cycle length than other methods of sterilization)
- > CFC and HCFC blends cause ozone depletion (CFC has been phased out. HCFC will be phased out in the near future)
- > Cost of EO blend mixtures may be high

- > Installation requirements add to the expense of installation (i.e., ventilation of system)
- > Flammability (of the EO)
- > Toxicity (of the EO)
- > Cost of ensuring safety may be high

- > JITTM for use (Just In Time-sterile devices are ready for use immediately following the cycle)
- > Variety of trays and containers available to accommodate many endoscope and accessory designs
- > Specific Quick Connects and Instructions
- > Diagnostic Cycle for daily testing of processor
- > Ventilation not required, closed system (the end product of the process, which are acetic acid, water and oxygen are safely disposed of in normal sanitary sewers without environmental concerns)

Liquid chemical peracetic acid sterilization was introduced in the mid 1980s to provide a rapid, safe, low temperature destruction of microorganisms on surgical and medical devices and instrumentation. This process enables sterile processing of devices Just In Time™ for use, thus minimizing device downtime between patient procedures. The entire process takes place within a tabletop microprocessor-controlled device, in which the sterile process is performed, controlled and monitored.

As with any reprocessing method, effective sterile processing requires proper cleaning, preparation and placement of devices. Instructions for appropriate methods of cleaning and decontaminating are located in the operator manuals provided by the endoscope manufacturers.

After the endoscope has been cleaned, leak tested and rinsed it is ready for placement within the processor. Specially designed Quick Connect and instructions have been developed to ensure proper flow of internal lumens and surfaces. Prior to processing any device the operator should make sure the he/she fully understands and follows all reprocessing instructions provided by both the device manufacturer and the manufacturer of the reprocessor. Connecting the endoscope to the sterilizer with the proper connectors, using the recommended steps to make these attachments and following manufacturer's and sterilization company's written guidelines will minimize operator errors. (Mathias, J.) Processing instructions are provided by the company and must be followed correctly to guarantee sterilization of devices. Instructions can be found in the operator manual and Quick Connect manuals. The company can also be contacted for further assistance or additional training.

Each sterilization cycle requires a cup of STERIS 20® sterilant concentrate, which is made up of a proprietary combination of buffers and detergents and a small portion of the active ingredient, 35% peracetic acid. After the lid to the processor has been closed and the cycle started, the sterilant concentrate is automatically mixed with water to form a .2% use dilution. After an exposure period of 12 minutes, the devices are rinsed with sterile water during 4 consecutive cycles. The total cycle takes approximately 30 minutes.

Monitoring of the cycle can be done several ways:

- > Operator Observation
- > Parametric Monitoring
- > Diagnostic Cycle
- > Biological Monitoring
- > Chemical Monitoring

The advantages of liquid chemical sterilization using peracetic acid:

- > Standardized cycle
- > Short cycle time

The limitations of liquid chemical sterilization:

- > Items must be immersible
- > Processes 1 scope at a time
- > No shelf life with processed devices
- > Variable cycle times (dependent on incoming temperature, pressure and condition of water)

Storage of Endoscopes

Storage of endoscopes is extremely important to prevent storage damage or growth of pathogens. Flexible endoscopes should not be stored in the transportation suitcases. If the scope is the least bit wet, bacteria can begin to grow and colonize in the endoscope and foam packing. Flexible endoscopes should be stored with the control body securely positioned on a special hanger allowing the insertion tube to hang vertically (See picture 5). Endoscopes should be stored with no valves or buttons in place so that the circulation of air through the channels is fostered.

Preventive Maintenance

Preventive maintenance is extremely important to routinely assess the flexible endoscope. Some endoscope repair companies will provide free preventive maintenance to their customers. Preventive maintenance usually involves checking the angulation of the endoscope to see if the distal tip can flex within 20 degrees of the specifications given by the manufacturer (See picture 6). Preventive maintenance also includes leak testing, checking the air/water flow, and evaluating the patency of the biopsy port. An overall assessment of the cosmetic appearance is usually performed along with an evaluation of the video or imaging capabilities. By routinely assessing the endoscope, early damage or injury to the scope can be repaired before a major service is needed.

Troubleshooting

Everyone who uses or reprocesses a flexible endoscope should understand troubleshooting. Many times troubleshooting can manage a malfunction quickly, prevent major repairs, and promote optimal functioning of the endoscope. This, in turn, often decreases the procedure time thus benefitting the patient.

The owner's manual provides a great source for troubleshooting tips. For example, if the suction appears sluggish, a suggested tip to flush water through the system may help to unclog the suction channel or port.

Returning an Endoscope for Repair

So what needs to be done when an endoscope is sent out for repair? First, the original manufacturer or a reputable repair company should

be chosen to repair a defective endoscope.

The criteria for selecting an appropriate repair company include the following:

- > Component inventory
 - What type, quality, and number of components does the repair company have in its inventory?
 - Are these different components readily available or will the customer have to wait while these components are ordered?
- > Technicians
 - What is the skill level of the technicians who will be doing the repairs?
- > Types of repairs
 - What types of repairs are done - major and minor?
 - If both minor and major repairs are done, are the minor repairs done by the company and the major repairs outsourced to yet another company?
 - Are the types of glues and bonding materials used for repairs able to withstand the various methods of reprocessing?
- > Representatives in the field
 - Are the field representatives educated on endoscope repair?
 - Are they attentive to your endoscope repair needs?
 - Do they help ship the endoscopes out that need repair?
- > Preventive maintenance services
 - Are preventive maintenance services available and conducted regularly by the representatives in the field?
 - What is involved with preventive maintenance?
 - Is there a charge for preventive maintenance?
- > Turnaround time
 - How long does the repair company take to repair and return an endoscope?
- > Tracking of repairs
 - Does the repair company help track repairs on the endoscopes? This information will help to note any repair trends on the endoscopes.
- > Warranty return rate
 - What percentage of endoscopes returned to the customer are sent back to the repair company with the same problems while the warranty is still in effect? This warranty return rate should be less than 5%.
- > Value added services
 - Is the field representative able to perform the needed preventive maintenance on the endoscopes?
 - Does the repair company offer educational sessions on the proper care and handling of endoscopes to minimize repairs?

- > Pricing
 - Is the pricing competitive with the other companies who do similar quality work?
- > Full service
 - Does the repair company only perform repairs on flexible endoscopes or on both flexible and rigid endoscopes?
 - What endoscopes can the company repair - Olympus, Pentax, Fujinon?
- > Reputation
 - What is the reputation of the repair company?

In sending a flexible endoscope for repair, first the transportation suitcase must be located. The suitcase for that specific endoscope type needs to be found as the foam packing has been designed to firmly hold that endoscope model in place.

Loading the decontaminated and dry endoscope into the suitcase is sometimes quite a challenge. The control body of the endoscope needs to be placed in the appropriate area (usually the larger hole within the foam packing). The two extensions from the control body, the light guide connector and the insertion tube, need to be placed in the packing next. The light guide connector is placed firmly into the foam packing slots, then the insertion tube is pushed down into the foam padding. Care is taken to make sure that the entire endoscope fits snugly into the foam padding. Small diameter insertion tubes (such as bronchoscopes) often pop out of the foam packing just when the lid is ready to be closed.

Documentation needs to accompany the endoscope needing repair. Complete documentation is extremely valuable to the repair company. Documentation should include:

- > Date of cleaning
- > Was the scope cleaned, disinfected, or sterilized? (Sometimes endoscopes are actually sterilized before sending for repair. For example, after decontamination, an endoscope with a leak can be sterilized in an ethylene oxide sterilizer. Or an endoscope without a leak that's needing an angulation adjustment can be sterilized by liquid chemical sterilization.)
- > Who performed the process? (Who actually did the cleaning of the endoscope?)
- > Procedure being performed when the endoscope malfunctioned? (For example, during a gastroscopy, was an electrosurgery probe used to coagulate a biopsy site?)
- > Possible damage to endoscope? (What problems have been noted with the endoscope? For example, during the leak testing, bubbles were noted around the angulation knobs. This could indicate a gasket that may need to be replaced.)

The transportation suitcase is often packed within a shipping box to provide a double container system. A mailing label is placed on the outside of the outer container with the appropriate addressee and return address information. The healthcare facility then sends the securely packed endoscope to the shipping department or sends the endoscope directly out after proper packing and documentation have been completed.

When the endoscope is returned from repair, the endoscope should be immediately examined to make sure no damage has occurred during shipping. If certain repairs, such as angulation adjustment or replacement, have been done, the end-user (physician) should be notified so he or she will understand that the endoscope may perform differently (i.e., will not need to be angulated as severely since the angulation mechanism has been changed).

Any preventive maintenance and service should be documented so that the life expectancy of the endoscope can be predicted by following the endoscope's history. These trends also will be very beneficial when budgeting for capital expenditures to increase and replace endoscopes.

Summary

The future of flexible endoscopy depends on the dedication of the endoscopy team members, including the physician, nurse, technologist, reprocessing technician, and other healthcare professionals, to provide optimal care and handling of endoscopes to promote safety, minimize hazards, and maintain the health of the endoscope. Flexible endoscopes are amazing tools that need tender loving care - let's keep them that way!

References

1. Ball, K, Endoscopic Surgery, 1997, St. Louis, C V Mosby.
Mathias, J., "Another wakeup call on scopes," OR Manager, Sept. 1999, Vol 15, No 9, p.5-7.
2. Infection Control Sourcebook, 1997, Atlanta, American Health Consultants.
3. Meeker, M and Rothrock, J, Alexander's Care of the Patient in Surgery, 11th edition, 1998, St. Louis, C V Mosby.
4. Reichert, M and Young, J, Sterilization Technology for the Health Care Facility, 1993, Gaithersburg, MD, Aspen Publishers, Inc.

Review Questions

- The two types of flexible endoscopes are:
 - Flexible and rigid
 - Fiberscope and videoscope
 - Olympus and Pentax
 - Fiberscope and fiberoptics endoscope
- The four main components of a flexible endoscope are the control body, insertion tube, bending section / distal tip, and _____ .
 - Light attachment
 - Light, suction, gas attachment
 - Light guide connector
 - Fiberoptic carrier
- The component that is most frequently damaged is:
 - Control body
 - Angulation system
 - Internal channels
 - Bending section / distal tip
- The three flexible endoscope systems include:
 - Mechanical system, illumination system, plumbing system
 - Angulation system, lighting system, air/water system
 - Control body, insertion tube, light guide connector
 - Fiberoptic system, angulation system, image system
- Gortex is used for biopsy channels today as this material is more pliable and is easier to clean.
 - True
 - False
- Only the bending section of the flexible endoscope needs to be assessed for leaks since this is the area where most leaks occur.:
 - True
 - False
- When preparing a leaking endoscope for shipment to a repair facility:
 - A powered leak tester should be connected to pressurize the endoscope during the cleaning process.
 - The cleaned endoscope must be labeled biohazardous since it hasn't been sterilized.
 - The endoscope must always be disinfected or sterilized before shipping.
 - OSHA and JCAHO are the only organizations that address the shipping of a contaminated endoscope for repair.
- Preventive maintenance may involve checking the angulation of the endoscope to see if the distal tip can flex within _____ degrees of the specifications given by the manufacturer.
 - 75
 - 50
 - 20
 - 2
- Sterile dirt can
 - Increase adhesion formation
 - Increase the immune response
 - Delay healing
 - All of the above
- The FDA recommends that glutaraldehyde manufacturers label their products requiring a 45 minute soak time with the solution being heated to 25°C.
 - True
 - False

Answers to Review Questions & Section Sources:

1.	B	(Types of Endoscopes)
2.	C	(Anatomy of a Flexible Endoscope)
3.	D	(Bending Section/Distal Tip)
4.	A	(Anatomy of a Flexible Endoscope)
5.	B	(Insertion Tube)
6.	B	(Leak Testing)
7.	A	(Leak Testing)
8.	C	(Preventive Maintenance)
9.	D	(Cleaning)
10.	A	(Disinfection)

Evaluation Form

Study Guide 4: The Care and Handling of Flexible Endoscopes

Last Name

First Name/M.I.

RN/LPN/LVN License Number (Circle one: RN - LPN - LVN)

Non-RN: License or Social Security Number

Health Care Facility

Health Care Facility Street Address	City	State	ZIP Code
Current Home Street Address	City	State	ZIP Code
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Area Code /Telephone Number	E-Mail Address
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- Please check here if you want the certificate to be mailed to the address above.
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To receive continuing education credit, please complete the evaluation form and mail, fax or e-mail the completed form to STERIS Corporation.

Rate on a scale of: 1=low 5=high

To what extent did the study guide meet the 2 stated objectives below?

- | | | | | | |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| 1. Discuss the major components of a flexible endoscope. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 2. Discuss the critical steps required to reprocess flexible endoscope. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 3. To what extent is this learning method easy-to-use? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 4. How much time was required to read the content, take the test, compare your answers and complete the evaluation form? | _____ hours _____ minutes | | | | |
| 5. Has the provider disclosed the conflict of interest or lack thereof declared by the planners and content specialist? | Yes _____ No _____ (Review inside cover page) | | | | |
| 6. Was the content presented without bias of any commercial product or drug? | Yes _____ No _____ | | | | |

I have completed all the requirements for this entire activity (please sign and date).

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STERIS Corporation
Education Department
5960 Heisley Road
Mentor, Ohio 44060-1834
Fax: 440-392-8902
E-mail: clinicaleducation@steris.com

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STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834
USA
800-548-4873
www.steris.com