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Learning Objectives

1. Explain the purpose of instrument lubrication.
2. Define criteria for selection of instrument lubricants.
3. Discuss how instrument lubricants affect sterilization processes.

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The optimal selection and use of surgical instrument lubricants

by Carol A. Barnett, senior scientist, STERIS Corporation

Professionals responsible for the care and maintenance of surgical instruments often overlook the significance of selecting the appropriate lubricant for processing hand-held, non-powered surgical instruments. A surgical instrument lubricant is a valuable tool and an important variable in the instrument care process. When carefully selected, lubricants can do much more than reduce friction and wear; they can lengthen the useful life of an instrument.

Lubricants for medical equipment and invasive surgeries have obvious health and safety requirements. For example, hygiene and environmental regulations require lubricants to be discreet, non-toxic and effective. However, there are other factors affecting lubricant selection that hospitals and medical professionals need to be concerned with. The use of an inappropriate lubricant can lead to inadequate sterilization of surgical instruments and can ultimately affect surgical outcomes.

The value of instrument lubrication

The Association of periOperative Registered Nurses (AORN) recommends that all decontaminated equipment with moving parts be bathed in a preserved water-soluble lubricant after each mechanical processing, unless the manufacturer advises otherwise. AORN Recommended Practices state that:

"Surgical instruments should be checked for function after cleaning. Those with moving parts may require lubrication according to manufacturers' instructions." Water soluble lubricants should be applied to those instruments that require lubrication. Instruments should be cleaned before the lubricant is applied. Cleaning, particularly ultrasonic cleaning, removes lubricants from instruments. Lubricants decrease friction between working surfaces. Unless otherwise specified, lubricants should be water soluble to allow steam penetration during sterilization; oil-based products cannot be penetrated."¹

It is important to see the lubrication step not merely as an add-on but as a proactive step in the instrument care process that provides a film of protection against wear from

metal-upon-metal friction of moving joints. If carefully selected, lubricants can lengthen the life of surgical instruments by:

1. Reducing wear and friction
2. Preventing staining and rusting during sterilization and storage
3. Contributing to ease of use
4. Preventing corrosion due to friction

The amount and type of lubricant on sliding surfaces has a profound effect on the amount of friction that occurs. Friction can be 200 times less for a lubricated instrument than that between the same surfaces with no lubricant.² After thoroughly cleaning and disinfecting instruments, proper application of lubricants to joints, hinges, locks, threads, or friction surfaces of instruments will keep them moving freely and aid in protecting the surface from mineral deposits. Lubrication will help to preserve the function of the instrument and help avoid the corrosion that can occur from friction. In addition, routine use of lubricating agents on thoroughly cleaned instruments will prevent hinged and other movable parts from sticking.

Choosing the right lubricant

There are few regulations pertaining to lubricants for non-implant medical devices. Generally, the best lubricant for a medically or precisely engineered device is one that is formulated for the instrument's application, operating environment and sterilization process. How do you choose the best lubricant for a medical device? With the myriad of lubricant products on the market today, understanding the differences in lubricant chemistries and the advantages and disadvantages of each can be a challenge.

With the exception of a few devices, most instrument manufacturers recommend using a water-based instrument lubricant made specifically for surgical instruments. Surgical devices coated with lubricants containing mineral oil or silicone oil should never be processed because it might adversely affect the instruments' functionality and because these oils can coat microorganisms and organic soils on instrument surfaces and prevent the penetration of steam or ethylene oxide, thereby preventing sterilization.³ These

oils are difficult to remove and the oily residues can make instruments difficult for medical staff to handle. Many instrument manufacturers actually specify that oil-based lubricants, particularly mineral oil and silicone oil, not be used as lubricants.

Temperature can also affect instruments that have been lubricated with some types of oil-based lubricants. Heat or cold can cause the viscosity of the oil to move beyond the acceptable range, resulting in instruments that may be too stiff or too loose. If viscosity is too low, the contact surfaces will not be separated and excessive wear will occur. If the lubricant viscosity is too thick it will make the instruments hard to operate.

Lubricants formulated with synthetic, inert polymers are an excellent alternative to oil-based lubricants. These compounds are manufactured under controlled conditions to meet strict specifications and are used to formulate lubricants with excellent thermal stability, high flash points, low toxicity and excellent biodegradability, and generally do not contain the naturally occurring impurities or variations that mineral oils may have.

Instruments that are routinely exposed to the heat of steam sterilization benefit from synthetic lubricants. Even in less severe conditions, parts lubricated with a synthetic vs. mineral oil lubricant generally last longer. Water-based synthetic lubricants also have greater stability under varying temperature conditions. Oil-based lubricants, particularly mineral oils, often have oxidation problems at operating temperatures above 100° C. Synthetic lubricants do not generally contain compounds that readily oxidize at high temperatures. Furthermore, synthetic lubricants are more chemically homogenous, which makes them more consistent, more predictable and more robust. The uniform molecular structure of many synthetic lubricants also gives them higher film strength than mineral oils. It is the "film" or coating of a lubricant on an instrument that reduces friction and prevents wear.

When making a selection among lubricants, there are a few important features and conditions to look for, including:

1. Physiological inertness/toxicity. It is wise to use lubricants with base oils and additives that are non-toxic.
2. Compatibility with instrument materials, especially plastics and elastomers. Make sure your lubricant is designed specifically for use with your device.
3. The presence of additives to boost anti-corrosion, adherence, lubricity, antioxidant and other capabilities. Emulsifiers are chemicals that are added to the formula to

form a stable mixture. Without emulsifiers, the liquid would separate into two phases, lubricant and water. Additives are mixed in small concentrations to enhance

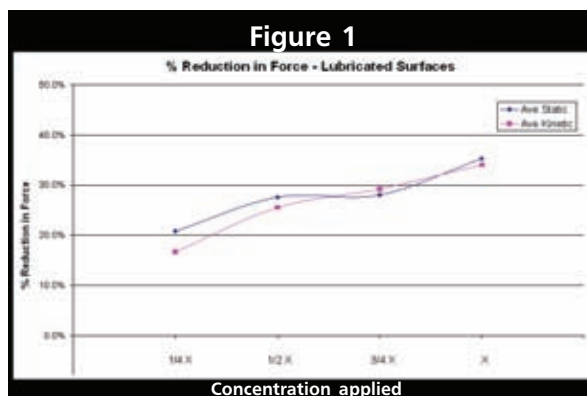
critical performance properties of a lubricant.

4. Ability to withstand sterilization temperatures. Under extreme conditions, any number of chemical transformations may occur to the lubricant that can result in alterations to its lubricating ability.
5. Addition of a preservative or bacteriostatic agent to prevent lubricant contamination after mixing with water. It is important that the expiration date specified by the manufacturer is adhered to for both stock and use-dilution concentrations.
6. Stability. The viscosity should remain stable during exposure to sterilization temperature and pressure extremes. The product should not separate when mixed with water.
7. Suitability for steam sterilization and vapor-permeable. Some lubricant formulations can leave residues that are incompatible with steam or ethylene oxide processes.

SPD professionals should also look for any available data that provides additional detail or information about the lubricant's capabilities and proper use. Reputable manufacturers will have completed a considerable amount of performance testing during the development phase of a product, and they should be willing to discuss laboratory test data related to the lubricant such as:

1. *Effect of the lubricant on the reduction of metal-on-metal friction.* Dependable mechanical action of hinged surgical instruments is critical while the instruments are in use during surgical procedures. Inadequate lubrication of instruments can cause metal-on-metal friction leading to sticking and eventually freezing of the box locks. Studies should be performed by the manufacturer to measure the coefficient of friction between two contacting test surfaces that have been lubricated. For example, the graph in Fig. 1 indicates that at the lowest concentration, 1/4 X, the instrument lubricant reduced static force by 21% and kinetic force by 17% when compared to untreated surfaces. At the highest concentration of lubricant, X, static force was reduced by 35% and kinetic force was

reduced by 33%. A study should indicate that the coefficient of friction is reduced by the use of a lubricant, which will ultimately reduce instrument wear and tear.



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2. *Cytotoxicity.* In surgery, it is possible that sterile tissue may have prolonged contact with lubricant residue found on surgical instruments. This exposure is generally not a concern unless the exposure is to neural and ocular tissue, which can be particularly susceptible to chemical complications. For this reason, testing must demonstrate that the lubricant is not cytotoxic.
3. *Substrate compatibility.* Studies should be performed by the lubricant manufacturer to determine the compatibility of a lubricant with a variety of commonly used surgical instrument substrates such as metals and plastics.
4. *Effect of the lubricant on sterilization processes.* Not all instrument lubricants are suitable for use in steam and ethylene oxide sterilization. It is important to read the label before use. Certain lubricants create a film that is resistant to steam and/or ethylene oxide penetration. The manufacturer should be able to present and discuss testing performed to verify that the lubricant does not inhibit sterilization by steam or ethylene oxide.

How lubricants affect sterilization

There is a great deal of literature discussing the importance of lubricating surgical instruments prior to sterilization, but little information about the effect lubricants can have on the outcome of some sterilization processes. Using a lubricant that is not formulated and labeled specifically for surgical instruments can be detrimental to the sterilization process and ultimately to patient health and safety.

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Lubricants can affect the most commonly used processes for sterilization of surgical instruments: steam and ethylene oxide. However, lubricants can potentially affect other methods of sterilization as well. Any sterilization cycle should be validated using instruments that have been cleaned and lubricated according to written procedures, to assure adequate cycle times for sterilant penetration.

Sterilization is the final step in the surgical instrument processing cycle. To be effective, steam sterilization requires control of four parameters: time, contact, temperature, and high pressure. The ethylene oxide sterilization process requires the simultaneous control of four interdependent parameters: gas concentration, temperature, relative humidity, and exposure time. However, even if these conditions are met and a successful cycle is run, lubricants can interfere with the sterilization process by “shielding” any remaining organic soil or bioburden not removed during the cleaning process and preventing penetration by steam, ethylene oxide or other sterilants.

The inhibitive effect of organic debris and lubricants

Sterilization cannot be assured, even with longer sterilization times, unless all organic matter remaining on the instruments is removed during the cleaning process. Residual soils on the instruments could “protect” microorganisms during the sterilization process, which can result in contaminated instruments.³ Organic material forms a coagulated mass that coats the live microbes and protects them from the sterilization process. Once bacteria and organic residues have adhered to the surface of a medical device, they become more difficult to remove.

The surface properties and texture of the device also influence how soils will adhere to them. In general, bacterial adherence increases as the surface materials become more hydrophobic and more textured or porous, which is the case with many complex instruments.

Left alone, blood and other debris can dry and coagulate or harden on the surfaces of surgical instruments very rapidly, making cleaning nearly impossible. Residual tissue and body fluids can accumulate and result in layers of organic material, which in turn can be exacerbated by the formation of biofilm, an accumulation of bacteria and extracellular material. Biofilm tightly adheres itself to the surface of the instruments and cannot easily be removed. Biofilm and organic material can become fixed *in situ* and

can resist subsequent cleaning, disinfection and sterilization efforts. This is why it is so important to pre-soak instruments as soon as possible after use or maintain them in a moist environment by using adequately designed instrument transport products.

To make matters worse, using water that is too hot in the pre-cleaning step or in the mechanical washer can denature blood proteins and add another challenge to the cleaning process. Residual soil/proteins remaining on instruments will harden during thermal disinfection in washer/disinfectors and potentially make complete removal a problem. Heat from excessively long exposure to ultrasonic cleaning can also denature blood.

Peptone, albumin, nucleic acids, sugars and starch can all form a protective shield for soils at certain concentrations.⁴ It is well known that proteins in particular have a protecting effect on microorganisms. Protein debris can harden and contribute to the formation of biofilm on a potentially contaminated surface. Furthermore, heat can cause proteins on surgical instruments to encapsulate pathogens and protect them from the sterilizing process. For example, ethylene oxide will not penetrate dried protein material.⁵

Damaged instrument surfaces are another concern. Blood, tissue, body fluid residue, synovial fluid, peritoneal fluid, pus, bile, urine, and gastric acids contribute to pitting, staining, corrosion, and discoloration of the surgical instruments. These damaging conditions leave “pockets” for organic soil to settle into. In addition, corrosion on instruments creates an extra layer that may take steam and ethylene oxide longer to penetrate and make sterilization harder to achieve.

Debris on a device, even if it has been through a sterile processing cycle, can also interfere with the instrument's function. It can also lead to a foreign-body or pyrogenic reaction in a patient if any soil dislodges and is introduced into the body during an invasive procedure. This “sterile” dirt can also increase adhesion formation, increase the immune response and delay healing.⁶

It has also been noted that microorganisms encapsulated in water-insoluble crystals can be resistant to ethylene oxide and moist heat. Studies have shown that spores protected by crystals were not sterilized by standard exposures to either steam or ethylene oxide. Although crystals are not typical in the clinical environment, calcium carbonate (water hardness) and iron oxide/hydroxide (rust) are, and they have been shown to occlude spores and require longer sterilization times. Occluded spores were found to be about 900

times more resistant than non-occluded spores to moist heat at 121° C. The crystalline matrix impeded the diffusion of steam to the spores, and the spores died only when moist steam saturated the spore. In addition, occluded spores of *Bacillus subtilis* could not be inactivated with ethylene oxide.^{7,8}

The clinical importance of an occasional bacterial spore that remains viable after sterilization is still under debate. However, its heat resistance is relevant because the spore forms of bacteria have higher resistance to heat than vegetative forms, and therefore they pose a greater challenge for any steam sterilization process. An instrument cycle that can kill spores can certainly kill the less resistant vegetative organisms and may also kill those that are somewhat protected.

Not only can the presence of organic material act as a shield to microorganisms during sterilization, but many oil-based lubricants can also shield the soil or debris, which may also contain pathogens. It has been known for more than 85 years that microorganisms in oils show a higher resistance to heat. In fact, studies have shown that both vegetative and spore forms of bacteria in oils are capable of resisting heating conditions that would be lethal in aqueous solutions. When spores suspended in buffer are compared to spores in oil, the data confirms the increased heat resistance of spores in oil, and the difference becomes more evident as the temperature is increased.⁹

Lubricant dilution and application

Not only is it important to choose the proper instrument lubricant, but it is also critical to dilute and apply lubricants properly. If the lubricant is over-diluted, it will not be effective. Conversely, if a lubricant is too concentrated or too heavily applied, it will result in slippery instruments that are difficult to handle. Devices may also be mistakenly identified as being wet after sterilization if they have concentrated lubricant on them.

An instrument lubricant should be prepared according to the manufacturer's instructions. Generally, diluting with distilled or soft water is recommended. Diluting with tap water might leave crystals that could interfere with sterilization, as mentioned earlier.

Instruments can be immersed in a water-based lubricant solution either mechanically or manually. Instruments should be opened and dipped into the lubricant solution, but not allowed to soak. Too much lubricant can cause a buildup which, after repeated use, can cause a “sticking” of joints due to a multiplying effect. For convenience, some automated washers have a pre-programmed lubrication cycle to facilitate routine lubrication.

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Proper lubrication matters

Reusable surgical instruments constitute a significant investment for any healthcare facility, so maintaining their full useful life is a cost-driven priority. Although keeping surgical instruments in their optimal condition requires significant time and resources, the cost pales in comparison to expensive repairs and replacements, as well as the potential for patient harm.

When reprocessing instruments and preparing them for sterilization, it is critical to use lubricants specifically formulated and labeled for surgical instruments. This can help assure that the lubricants are formulated to allow sterilants to contact instrument surfaces, and will give confidence that they are compatible with the method of sterilization being used. Synthetic lubricants offer a number of advantages over oil-based lubricants and may prove to be a superior and more effective product for the sterile processing department.

It is also critical to thoroughly clean each device to remove any soils, biofilm, vegetative and spore forms of organisms, oils, and any other residues that can impair sterilization. Applying heat to these residues can affix them more tightly to the surfaces and make the instruments even harder to sterilize. This leaves the potential for critical instrumentation to remain contaminated and ultimately to cause infection.

Preserving surgical instrumentation has a significant benefit, since replacing worn and damaged instruments can cost hundreds of thousands of dollars per month. Poorly maintained equipment also jeopardizes surgeon satisfaction. When all the risk factors are considered, lubricants are a very cost-effective way of maintaining and getting the best performance from life-saving instruments. **HPN**

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The optimal selection and use of surgical instrument lubricants

Circle the one correct answer:

- Lubricants lengthen the life of surgical instruments by:**
 - Reducing wear and friction
 - Preventing staining and rusting during storage
 - Preventing corrosion due to friction
 - All of the above
- AORN recommends the use of:**
 - Water-soluble lubricants
 - Mineral Oil
 - Silicone Oil
 - b and c
- The best lubricant to use for surgical instruments is:**
 - Formulated to be the cheapest on the market
 - Formulated for the instruments' application, operating environment and sterilization process
 - Formulated to smell the best
- Lubricants containing mineral oil or silicone oil can coat microorganisms and organic soils on instruments and prevent adequate sterilization.**
 - True
 - False
- Reputable manufacturers should be willing to share lubricant performance data with their customers.**
 - True
 - False
- All lubricants are suitable for steam and ethylene oxide sterilization.**
 - True
 - False
- Sterilization cannot be assured unless all organic matter on instruments is removed during cleaning.**
 - True
 - False
- Which of the following can act as a shield to microorganisms?**
 - Proteins
 - Oil-based lubricants
 - Water-insoluble crystals
 - b and c
 - All of the above
- Use of an inappropriate lubricant can negatively affect:**
 - Sterilization of surgical instruments
 - Wear due to friction
 - Patient health and safety
 - All of the above
- Proper dilution and application of lubricants is critical.**
 - True
 - False

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