GUIDELINES FOR INSTRUMENT CARE

COMPANY OVERVIEW

Novo Surgical Inc. is a medical device company focusing on a comprehensive line of premium, operating room grade general and specialty surgical instrumentation at industry-leading price points. The company also specializes in manufacture of hard-to-find, discontinued or custom instrument designs.

PRODUCT OVERVIEW

As an instrument-focused brand, Novo Surgical offers among the industry’s most exhaustive selection of instruments across the full range of specialties, including: general surgery, plastic surgery/ent, obstetrics/gynecology, ophthalmology, orthopedics/neuro/spine, cardiothoracic surgery, laparoscopic/arthroscopic surgery, etc. Novo Surgical is proud to offer its customers premium, operating room grade instruments forged from the highest quality German stainless steel. Novo instruments are manufactured at the company’s network of ISO-certified facilities by experienced instrument craftsman to ensure all of the products it sells conform to the highest standards in instrumentation.

FORGINGS

The most important factor in determining the durability and build-quality of an instrument is the material and process used to create the instrument forging, or the raw material from which all instruments are made. The quality of the raw forging (or blank) determines the ability of the instrument to withstand repeated use and sterilization without compromising its integrity or finish. The vast majority of Novo instruments are made with 300-series German stainless steel forgings, which are composed of alloys of an iron ore base with a delicate balance of carbon and chromium. Carbon gives the forging the hardness necessary for surgical applications and the chromium content provides a stainless, anti-corrosive finish. Stainless steel alloy sheets are milled into instrument blanks which are forged, die-cast or molded into pieces of varying size and shape. The pieces are then treated with heat to achieve the requisite spring and temper, providing the flexibility to withstand the stresses of repeated use. Depending on the instrument type, Novo Surgical instrument forgings are made with either 300 or 400 series grade stainless steel. The series of steel for an instrument depends on its intended use and desired malleability. Both of these steel grades are consistent with those used for premium, operating room quality instruments, which undergo repeated sterilization while resisting corrosion and maintaining strength.

Novo only offers a single line of operating room quality instruments, and does not, as many retailers do, offer an ‘economy’ or disposable line of products.

FINISH

Surgical instruments come in a variety of finishes. The vast majority of Novo’s patterns come in a satin, sand-blasted or dull finish, which minimizes glare that may distract surgeons and hinder visibility under operating room lights. This is the standard finish of most instrumentation used in operating rooms today.

Certain instrument patterns are available and stocked in other finishes, including mirror (highly-polished), titanium (mostly...
microsurgical instruments) insulated (blue coated for electrosurgery) and ebonized (black coated for laser surgery). While all of these finishes can be sterilized in a similar fashion to stainless steel instruments, please pay attention to the particular guidelines for these finishes as outlined in this document.

OUR CRAFTSMEN

Much of our instrumentation is hand-finished by skilled craftsmen whose families have apprenticed in the art of instrument-making for generations. Working with such experienced craftsmen and established facilities ensures that our products conform to the highest quality standards. However, as with any process by hand, slight variations in dimension may occur between the actual product and the specifications listed in company literature or the website. Any such variation will be immaterial and never affect the intended functionality of an instrument.

STERILITY

Novo instruments do not typically ship sterile, as is the case for most operating room quality instrumentation (aside from select items such as surgical blades, which always ship sterile). Typically, economy or “floor-grade” instruments are sold sterile, as they are either disposable or can only withstand autoclaving a couple times before their service life is over.

Since Novo Surgical instruments are supplied non-sterile, they must be cleaned, lubricated and sterilized prior to initial use.

PROPER CARE & MAINTENANCE

The single most important factor for maximizing the service life of a surgical instrument aside from the manufacturing material and process is proper and consistent care and maintenance.

ABOUT THIS GUIDE

Many healthcare facilities own tens or hundreds of thousands of dollars of surgical instrumentation. In order to maintain the value of that inventory and ensure optimal performance and safety of these devices in the operating room, instruments must be handled, cleaned and stored properly in a consistent maintenance program. Failure to do so may result in shortened lifespan and/or decreased efficacy of the device(s).

Novo instruments are premium quality products that are intended to undergo repeated sterilization cycles, but their lifecycle depends on the meticulous execution of such a program.

This guide is meant to provide background information as to the handling, storage, cleaning, decontamination, and sterilization of most Novo Surgical products. When combined with proper training and established industry reference books, this guide will allow you to extend the life of your devices while improving safety, performance and service life. The information in this guide is consistent with International Association of Healthcare Central Service Materiel Management (IAHCSMM) guidelines for the care of surgical instruments. This guide is not meant to be exhaustive; it is simply a quick reference guide that will allow you to easily find information on how to best care for your Novo Surgical devices. Always use relevant reference manuals for more complete information. Failure to follow generally accepted instrument care and maintenance
procedures will shorten the service life or instrumentation and may invalidate the manufacturer instrument warranty.

CONTACT US

If you have any questions or concerns regarding this guide or specific maintenance protocols, feel free to contact us using the information below:

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SECTION I – HOLDING & PRE-CLEANING

HOLDING

Please adhere to the following guidelines for effective holding practices:

- Remove debris from surgical instruments with a sponge and sterile water during procedures to prevent drying on of blood and tissue.
- All instruments should be placed in a distilled water bath immediately after a procedure and before leaving the operating room.
- If a bath is not possible, place the instruments into an instrument tray and cover with a towel moistened with sterile water immediately after the procedure. Foam and spray products, specifically intended to pre-treat surgical instruments, are available to keep the soiled instruments moist, as substances like blood and bodily fluids can be highly-corrosive when allowed to dry.
- Instruments should be rinsed, disinfected and cleaned as soon as possible thereafter to prevent the formation of bio film.

PRE-CLEANING (SOAK & RINSE)

Pre-cleaning procedures can make subsequent steps more effective and easier to carry out.

- Place instruments in a neutral presoak enzymatic solution designed for surgical instruments or a solution of distilled water and neutral detergent (pH of 7).
- Separate instruments of dissimilar metals and ensure sharp tips do not come in contact with each other.
- Prepare the enzymatic soak and use per the enzyme manufacturer’s recommendations, paying special attention to instructions for correct dilution, temperature and soak time.
- Immerse instruments fully in the solution in the open, unlocked and/or disassembled position.
- Remove instruments from the enzymatic soak after the time period recommended by the enzymatic solution manufacturer and rinse them thoroughly with distilled water, removing any remaining organic material.

SECTION II – CLEANING

Before true decontamination can take place, devices must be cleaned. Cleaning involves removing all visible and invisible soil from a device and is critical to the sterilization process as it affects all of the steps that follow it. Failure to clean properly can leave foreign material (soil, microorganisms, lubricant, etc.) which may hinder the subsequent sterilization process. Ideally, cleaning should take
place within 15 to 60 minutes after the use of the instrument.

Cleaning can be done either manually or with the aid of a cleaning device. While it is possible to clean devices by hand, Novo Surgical recommends the use of an ultrasonic cleaner or automatic washer as these have proven to be the most effective options. Regardless of the cleaning method chosen, all instruments should be given a cursory wash/rinse before other cleaning methods are used. They should be free from blood, body fluids and tissue prior to sterilization. It is important to remember that disinfected instruments are not yet sterile.

CLEAN WORK AREAS

It is impossible to clean surgical instruments effectively if the work area itself is not clean. Routine cleaning of work spaces should take place per the following:

- Horizontal work surfaces should be cleaned and disinfected at the beginning and end of each shift.
- Spills should be spot-cleaned immediately.
- Floors should be cleaned and disinfected daily.
- Bio-hazardous waste should be removed at frequent intervals.

CLEANING AGENTS & WATER

It is vital to use high-quality and effective cleaning agents when cleaning surgical instruments. Improper or abrasive cleaning agents can adversely affect the patient, employees or the device itself. While Novo Surgical does not endorse specific brands of cleaning agents, we recommend that cleaning agents used on Novo Surgical instruments are:

- Non-abrasive
- Low-foaming
- Neutral (pH of 7)
- Free rinsing (the cleaning agent is completely removed by rinsing)
- Biodegradable
- Allow for rapid soil dispersion
- Non-toxic
- Effective on all types of soil

Water used for cleaning instruments should be clean and distilled. It is important that water used be as close to neutral (pH 7) as possible.

MANUAL CLEANING

It is possible, and in some cases necessary, to clean surgical instruments by hand. For delicate instruments, hand washing is likely required. Devices, especially those that are used in invasive operations such as orthopedic surgery, may need to be hand washed prior to machine-washing to remove the gross amounts of soil that may be contained within them. This is in addition to the rinsing and enzymatic soak required for all surgical instruments. Use manufacturer instructions and your best judgment to determine if a device requires hand washing prior to automatic cleaning. Manual cleaning should be used in most circumstances only as a secondary option.

Follow the guidelines below when cleaning manually:

1. Before hand washing an instrument, it is vital that you ensure your own safety. Soil and fluid proof goggles, gloves, aprons, and shoe covers should always be used.
2. Check your equipment to make sure you are using a neutral (pH 7) detergent.
3. Use distilled water for best results.
4. Follow the detergent manufacturer’s instructions with regard to cleaning time, dilution, etc. Instruments should be fully submerged for the period of time recommended by the manufacturer of the cleaning product. Change solutions frequently, per the solution manufacturer’s recommendations.

5. Carefully and diligently remove all soil from the instrument, paying special attention to hard to reach places such as box locks, instrument jaws and crevices. Instruments should be cleaned in the open (unlocked) position while ensuring sharp instruments don’t touch each other.

6. Using a small, clean, soft-bristled hand-held brush, remove soil and organic material from all surfaces of the instrument while fully immersed in the solution. Brushes should be stiff but not abrasive. Never use abrasives like steel wool, and only specifically-designed wire brushes should be used on particular areas of the instrument (serrations, files, etc.).

7. Remove the soil from the ratchets, jaws, tips, box locks, and/or hinge mechanisms. The box lock and hinge portion of an instrument must be thoroughly cleaned after each use.

8. If applicable, vigorously flush device lumens, channels, and other areas that are not easily accessible with a brush.

9. Thoroughly rinse devices and dry with clean, non-abrasive, soft towels laundered with neutral (pH 7) detergent.

10. Inspect the device carefully to ensure that it maintains a free range of motion, tips are aligned, etc.

11. Proceed to ultrasonic or automated machine-washing as appropriate. Procedures are described below.

ULTRASONIC CLEANING

Novo Surgical recommends the use of an ultrasonic cleaner as it is widely regarded as the most effective way to clean surgical instruments; in particular it is best for removing soil from hard to reach surfaces such as grooves, crevices, hinges, box locks, and other moving parts, etc.

Before using an ultrasonic cleaner, be sure to follow the manual cleaning procedures detailed above if applicable to remove any gross soil such as blood and tissue debris. This will help keep the ultrasonic solution clean.

Please follow these guidelines when using ultrasonic cleaners:

- Use only detergents that have been specifically formulated for ultrasonic cleaners. These detergents should be pH-neutral and low-foaming to avoid inhibiting the cleaning process.
- Follow the recommendations of the ultrasonic manufacturer regarding cycle times, detergents, proper placement of the instrument tray and conditioning (“degassing”) of the cleaning solution.
- Used distilled water for best results.
- Bath temperatures for cleaning instruments should be between 27°C (80°F) and 43°C (109°F). Follow sterilization equipment and solution manufacturer’s recommendations for temperature and cycle time, but note that temperatures above 60°C (140°F) will coagulate protein and make it more difficult to remove.
- Ultrasonic solution should be changed when it is visibly soiled, or at regularly scheduled intervals to prevent the redeposit of soiled particles onto
other instruments, per solution manufacturer recommendations. Solution should be changed more frequently when cleaning devices that might have fatty deposits on them, such as orthopedic instruments. When solution is changed, the tank should be cleaned and the drain checked for debris.

- After solution is changed, the solution must be “degassed.” To degas the solution, close the lid and run the cleaner for 5-10 minutes without any devices in it. This will remove excess bubbles in the solution that may have arisen from the filling process.

- All instruments must be completely submerged in order to ensure cleaning is effective.

- Instruments placed in the ultrasonic cleaner should be in the open or unlocked position. Open or disassemble them as necessary. All instruments should be placed in trays designed specifically for use in the cleaner.

- Separate dissimilar metal instruments during cleaning.

- Do not let sharp instruments touch each other during cleaning.

- Rinse instruments with water after cleaning to remove all remnants of the cleaning solution. This final rinse should be with softened or de-ionized water to better remove detergents and avoiding pitting and staining. All visible residues should be removed at this point.

Items that should not be placed in a sonic cleaner include:

- Chrome plated (mirror finish) or ebonized (black coated) instruments
- Any device made of plastic, glass, cork, or wood
- Endoscopy instruments
- Instruments that include fiber optic cables

All instruments in an ultrasonic cleaner should be of the same type of metal. Most Novo Surgical instruments are made of stainless steel, while some are comprised of titanium.

Note: Stainless steel and titanium or titanium nitride (ceramic coated) instruments have the same cleaning/sterilization instructions, but detergents/cleaners used should be formulated for each specific metal and only like metals should be cleaned/autoclaved together.

Follow all manufacturer instructions for care and use of ultrasonic cleaners.

**AUTOMATED MECHANICAL WASHER**

Another effective cleaning tool is the automated mechanical washer. These devices work on the principle of impingement, or pressure removing soil from a surface similar to a dishwasher. They are also effective because of their ability to use thermal and enzymatic detergents. Please follow the guidelines below when using automated mechanical washers:

1. Before using an automated washer, ensure that racks are not overloaded and that all spray arms can move freely. If instruments are sticking up or are out of their baskets, they must be relocated so as to be out of spray arm paths. Failure to do so could result in damage to the washer, the instruments, or both.

2. Wash like metals together to ensure that there are no adverse effects of machine washing. In general, Novo
Surgical instruments are stainless steel but some include titanium.

3. As with all cleaning methods, ensure that devices are in the open position and they are spaced such that water can reach all parts of the device. Multi-rack storage trays might need to be disassembled to facilitate cleaning.

4. Inspect the racks, trays and especially the washer traps/drains to ensure they are in good working condition and free of debris.

5. Ensure that detergent/lubricant are sufficient prior to beginning the cycle, per the sterilization equipment manufacturer’s recommendations.

6. When selecting a wash cycle for mixed-use loads, the most extensive applicable cycle must be used. The most extensive cycle is generally for surgical instruments. If even one surgical instrument is being included in a load, the surgical instrument cycle must be selected.

7. Follow the manufacturer instructions for your particular washer and select the appropriate cycle.

**FINAL RINSE**

Final rinse should occur after the above processes and must be done thoroughly with softened, de-ionized, or distilled water to prevent mineral deposits. It is necessary to manually rinse items after they are done being washed. This rinsing removes chemical cleaning agents that may damage instruments.

**SECTION III – DECONTAMINATION**

After cleaning is completed, devices must be decontaminated/disinfected in order to make them safe for transport, handling and inspection. The method required for this decontamination is dependent on the type instrument and the procedure it was used for. Decontamination methods include steam sterilization (without pouches), chemical agents, or heat. This section will deal with chemical decontamination agents, as sterilization will be described below. It is vital to understand that decontaminated instruments are not sterilized. Some living organisms may remain on a decontaminated instrument.

There are several factors that affect the efficacy of chemical disinfectants:

- Type and number of microorganisms. Some microorganisms are more difficult to kill than others. The type of procedure that the device was used for determines this.
- Direct contact with the device. An item to be disinfected must come in direct contact with the disinfecting agent for a time specified by the manufacturer of the chemical agent used. If possible, devices should be disassembled to allow for maximum surface contact.
- Temperature of disinfectant
- The pH of the disinfectant. Note that Novo Surgical instruments should only be used with disinfectants that have a pH of 7.
- Hardness of water
- Material compatibility. Make sure to use a disinfectant that is effective on the metal type of the instrument. In most cases, this would be stainless steel.
- Positioning of devices. Devices should be open, not touching, and must have their lumens soaked vertically.
It is important to select a disinfectant that is appropriate for the metal type and pH level required by the specific surgical instrument. In the case of most Novo Surgical devices, this will be stainless steel and 7, respectively.

It is also vital that a disinfectant be selected with the appropriate strength required. Disinfectants are separated into three categories based on how thorough they are:

- High-level disinfectants kill all microbial organisms but not necessarily large numbers of bacterial spores (AAMI TIR No. 7: 1999)
- Intermediate-level disinfectants kill viruses, mycobacteria, fungi and vegetative bacteria, but not bacterial spores (AAMI TIR No. 7: 1999)
- Low-level disinfectants kill vegetative forms of bacteria, some fungi, and lipid viruses (AAMI TIR No. 7: 1999)

Additionally, never mix different types of metals when disinfecting. Keep like metals together and isolated from others.

Based on the information above, choose an appropriate disinfectant and follow all manufacturer instructions to ensure efficacy.

SECTION IV – STERILIZATION

The final step in the sterilization procedure is the sterilization of the instrument itself. Sterilization depends heavily on the correct completion of all preceding steps. It is impossible to sterilize an instrument that has not been properly cleaned and decontaminated. Sterilization, by its nature, demands extreme care and caution. Mistakes during the process could render items contaminated. This results in wasted time and resources or, in a worst-case scenario, adversely affect patient safety. For these reasons, it is imperative that all instructions are adhered to and sterilization is only performed by qualified technicians.

Sterilization by definition requires that there are no living organisms (including bacterial spores) remaining on an instrument. All Novo Surgical instruments should be sterilized, not merely disinfected, to ensure patient safety.

There are two types of sterilization: high and low temperature. This guide will deal mainly with high temperature sterilization, as that is what Novo Surgical recommends for almost all of its products. However, some items such as endoscopes and plastics are not suitable for high temperature sterilization. In this case, low temperature chemical sterilization may be used.

The efficacy of both types of sterilization is affected by several factors:

- The type and number of microorganisms present
- The amount of soil present
- The amount of protection the medical device provides, such as box locks or tubes

Cleaning and disinfection as outlined earlier in this document can dramatically mitigate these factors and make sterilization much more effective.

If devices were sterilized in individual or group sterilization packs, they must be kept in these packs for storage.

Before instruments are wrapped for sterilization, they must be thoroughly dried. Wet instruments wrapped for sterilization are likely to come out of the
sterilizer wet and prone to contamination. Moisture, particularly in box locks and hinges, may result in corrosion that will weaken the instrument and lead to breakage.

LUBRICATION

Some automatic washer sterilizers include a lubrication phase that is built into the cycle – if not, ensure instruments are lubricated per the guidelines below prior to sterilization.

An instrument lubricant (often referred to as instrument milk) that is compatible with the method of sterilization to be used is recommended before instruments are sterilized. Ultrasonic cleaners remove all agents. Thus, instruments cleaned with an ultrasonic cleaner must be lubricated routinely after cleaning and before sterilization.

Some lubricants must be diluted in a solution and used by dipping instruments in the open position, while others may be applied directly into box locks, hinges and other moving parts. Follow the manufacturer’s instructions for proper use.

Proper application of lubricants to joints will keep them moving freely and aid in protecting the entire instrument surface from mineral deposits. Lubrication will prevent metal-on-metal friction, sticking and corrosion, as well as preserve the smooth function of the instrument.

HIGH-TEMPERATURE STERILIZATION

There are two types of high temperature sterilization: flash and terminal. Flash sterilization occurs when sterilizing an item that is not packaged, usually in an emergency situation in the operating room. Terminal sterilization means the item is packaged. Central service departments generally perform terminal sterilization, which is more extensively covered here since it is the preferred method for Novo Surgical instruments.

These procedures are approved for stainless steel, titanium, tungsten carbide, bipolar, nylon-coated, and fiber optic instruments unless otherwise stated. However, nylon coated instruments should not be flash sterilized.

High temperature sterilization is the process of sterilization by using high temperature and pressure steam to kill all microorganisms on a device. Steam is used as it is a much more effective conductor of heat than air. There are several types of steam sterilizers:

- Table top sterilizers use gravity air displacement and are generally used in smaller clinics
- Gravity air displacement sterilizers are small-to-medium size and use the density difference between air and steam to create a pressurized, steam-only environment
- Dynamic air removal sterilizers have vacuum pumps that are used to remove air, ensuring only steam is extant in the sterilization chamber. These devices have a faster sterilization cycle than gravity air displacement machines.
- Steam-flush pressure-pulse sterilizers use a repeated sequence of steam flush and pressure pulse to remove air from the sterilization chamber. This type of sterilizer is not susceptible to air leaks like dynamic air removal machines.
- Special purpose pressure (flash) sterilizers are used for emergency
sterilization of dropped instruments when there is not time for regular sterilization.

It is vital to understand which sterilizer is being used to ensure correct cycle times. The subsequent steps outline the process:

1. As noted previously, before any sterilization process, instruments must be lubricated. Use an approved lubrication agent such as instrument milk. Never use an industrial lubricant such as WD40. Lubricant should not be wiped off instruments prior to autoclaving.

2. Check the autoclave to ensure that it is working correctly.
   a. Cool the chamber before performing any maintenance.
   b. Perform Bowie-Dick tests.
   c. Perform routine cleaning.
   d. Check the steam sterilizer and door gasket.
   e. Follow any other of the sterilization manufacturer instructions to ensure that the autoclave is working properly.

3. Place the items in the autoclave either as a group or individually:
   a. Individual items should be placed in disposable paper or plastic pouches. Make sure that the pouch is large enough for the device to be in the open position. Ensure that the pouch is appropriately sealed, but steam permeable.
   b. Instrument sets can be placed together in specially designed trays with holes to allow for steam or in fabric pouches. Do not hold devices together with rubber bands.
   c. Items such as basins that are capable of capturing condensate should be placed on edge so they may drain.
   d. Make sure all devices are in the open or unlocked position.

4. It is vital that each part of each instrument be in contact with the sterilization agent (steam). This means that all devices must be open, disassembled, and cannot be placed too close together. Close placement could create pockets where steam cannot fully penetrate. In addition, devices cannot be placed in containers that steam cannot penetrate. All sterilization pouches will allow the penetration of steam.

5. Ensure that the autoclave trays/shelves are not overloaded. This could cause pockets where steam cannot fully penetrate.

6. If any fabric is being used for wrapping of instruments, ensure that it is being laundered with neutral (pH 7) detergent as it could otherwise cause damage.

7. Following manufacturer instructions begin the sterilization cycle. Novo Surgical recommends the following exposure times based on temperature and autoclave type:
<table>
<thead>
<tr>
<th>Item</th>
<th>Exposure Time at 121°C (250°F)</th>
<th>Exposure Time at 132°C (270°F)</th>
<th>Exposure Time at 135°C (275°F)</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped Instruments</td>
<td>30 mins</td>
<td>15 mins</td>
<td>10 mins</td>
<td>30 mins</td>
</tr>
<tr>
<td>Textile Packs</td>
<td>30 mins</td>
<td>25 mins</td>
<td>10 mins</td>
<td>30 mins</td>
</tr>
<tr>
<td>Wrapped Utensils</td>
<td>30 mins</td>
<td>15 mins</td>
<td>10 mins</td>
<td>30 mins</td>
</tr>
<tr>
<td>Unwrapped Nonporous Items</td>
<td>N/A</td>
<td>3 mins</td>
<td>3 mins</td>
<td>0-1 mins</td>
</tr>
<tr>
<td>Unwrapped Nonporous Items  (Mixed Load)</td>
<td>N/A</td>
<td>10 mins</td>
<td>10 mins</td>
<td>0-1 mins</td>
</tr>
</tbody>
</table>

8. During the autoclave process, check the pressure and temperature gauges on the autoclave and compare them to a steam table (located on the autoclave or in reference books) to ensure that steam saturation is occurring. If it is not, consult a qualified repair technician to ensure that the device returns to working order. Sterilizations performed by an autoclave not reaching steam saturation are likely not complete.

9. After the cleaning and rinsing cycles are complete, but before the drying cycle begins, open the door of the autoclave about ¾ of an inch, and then run the dry cycle, or per manufacturer instructions. Do not open the door fully before the dry cycle as this can result in wet packs.

10. After the dry cycle is complete, carefully inspect the devices for any wet packs. Wet packs are surgical devices or packs that have condensation inside or outside of them. Wet packs are considered contaminated and must be completely reprocessed. Do not touch the devices.

11. Inspect the devices, looking at any indicators or packs used to ensure that proper sterilization took place. Chemical indicators should clearly change color/shape/size, etc., to show that the proper temperature was reached.

12. Do not handle the devices any more than is required. Any moisture on a sterile instrument pack means that it could be contaminated. Packs only provide adequate barriers against contamination when dry.

13. After devices are removed and stored securely and steriley, perform routine maintenance and cleaning on the autoclave, including clearing out the steam drain to ensure it is ready for the next use. Always wait until the
autoclave has cooled to perform maintenance or cleaning procedures.

LOW TEMPERATURE STERILIZATION

Low temperature sterilization is the process of using low temperature gases or liquids in order to sterilize instruments. In this way, it is similar to disinfection. However, it is important to remember that sterilization means that all organisms have been killed. For this reason, an instrument is only considered sterile by chemical means after it has been submerged (in gas or liquid) for 10 hours. The harsh chemicals and long exposure times are often corrosive to surgical instruments. For this reason, Novo Surgical recommends high temperature sterilization for its products. Low temperature sterilization, however, may be suitable for some products which cannot be autoclaved, including some endoscopes or plastic constructions.

These devices must be sterilized through low temperature means. In some cases, high-level disinfection may even be sufficient.

For endoscopes, proceed with the cleaning steps as described above but do not use ultrasonic cleaners or automated washers, as these can damage the scopes. Instead, hand wash only and use enzymatic cleaners as prescribed by the manufacturer. Do not allow the endoscope to soak for more than 30 minutes in any solution, as moisture can damage it.

In order to use chemical sterilizers, follow a procedure similar to disinfection. Based on the device being used, choose an effective sterilizer and follow the manufacturer instructions. For endoscopes, ethylene oxide sterilization is recommended.

When performing ethylene oxide sterilizations, the endoscope must be completely dry in order to prevent the formation of a harmful byproduct. Temperatures should stay below 60°C (140°F) and pressure below 22 psi.

Note: Do not use solutions containing benzyl aluminum chloride when sterilizing instruments with tungsten carbide inserts, as this will cause irreparable damage. Novo Surgical recommends high temperature sterilization for these instruments.

SECTION V – STORAGE

- Surgical instruments should be stored only once they are decontaminated, sterilized and lubricated. General procedures for decontamination and sterilization are given above. Always consult reference manuals for complete instructions.
- Instruments should be lubricated using a neutral (pH 7) lubricant such as instrument milk. Regular lubrication helps keep the instruments protected and can prevent corrosion by creating a protective layer in a process known as passivation. Some lubricants are concentrated and require dilution before they can be used. Read the lubricant manufacturer instructions to know how to best use the lubricant.
- It is important that surgical instruments are never stacked or piled together. This can cause damage to delicate instruments and can reduce their efficacy. Surgical instruments should be stored by carefully placing them individually in a storage container.
Surgical instruments should be stored in a clearly marked location such as a drawer or cabinet. This location should be kept clean. Ideally this area is kept secure and is out of the way from general workflow. It is essential that this space be kept dry to prevent contamination or water spots. Silica gel packets or other drying agents should be used to keep the area dry.

Surgical instruments should be stored using products such as roll packs. This prevents the instruments from touching one another, which could cause damage. It is inadvisable to keep instruments in a drawer without any protection. It is vital that sterile instruments be stored in their sterilization packs.

Sterile instruments should be stored using a first-in, first-out (FIFO) system. This means that older instruments that have been in storage longer should be removed first. This will help prevent contamination.

Devices should always be stored with their protective tip/edge coverings (where appropriate). These coverings can prevent the instrument from becoming dull and also reduce the risk of injury while handling.

Note: Handling and storing devices with fiber optic cables should be approached extremely delicately. At no point should the cable be bent, kinked, distorted, etc. No heavy or sharp items should be placed on top of or near these cables. The lenses are extremely fragile and must be treated with care. Wipe only with soft gauze to prevent scratching. Never pull or yank on the cables.

**SECTION VI – GENERAL HANDLING & INSPECTION**

Novo Surgical instruments are designed for use and handling only by those with the proper training and certification to do so. Surgical instruments can be fragile and dangerous, and as such should be treated with the utmost care and attention. Anyone who handles surgical instruments must be familiar with their use, assembly, disassembly, and all the risks associated with each device. Any information in this guide should be used only by qualified personnel.

Before and after each use, devices must be thoroughly inspected by a trained and certified technician. The device should be inspected to make sure that (when applicable) its tips are aligned, there are no pits, scratches or scrapes, the device has its full range of motion, there is no soil present, no screws are loose or can become loose during motion, the device is lubricated/disinfected/sterilized, all parts are present, and everything else is in order. Pay particular attention to the following when inspecting instruments:

- Smooth instrument motion
- Condition of moving parts, including tips, box locks, ratchets and cutting edges
- Blade sharpness and cutting ability
- Box lock and ratchet security
- Security of screws during instrument operation
- Tip and/or jaw alignment
Meshing of serrations and/or teeth, w/ no catching

- Missing parts of obvious signs of wear

- Under no circumstances should an instrument identified to be functioning improperly be returned to service prior to repair.

- It is important to ensure that one does not injure oneself when handling surgical instruments. Due to the nature of surgical instruments, they are likely to have sharp or otherwise dangerous edges and points. Combined with the possible presence of dangerous biological material, the utmost precaution must be taken when handling these devices. Most surgical devices have tip or edge protectors that blunt edges and prevent injury. Whenever possible (i.e. when both the device and its protector are sterilized) these protectors should be used. The proper use of these protectors will help prevent injury from handling as well as prolong the lifetime of the devices.

- Whenever one is handling a surgical device, proper personal precautions must be taken. These include wearing fluid resistant surgical gloves, aprons, goggles, shoe covers and masks as appropriate. These items will help prevent both physical injuries and biological hazards. Workers handling surgical equipment should wash their hands/arms and any other body parts that may come in contact with surgical devices frequently and thoroughly. Food and drink should not be allowed in the same areas as surgical equipment.

- Sterile instrument packs should not be handled excessively. Any touching, moving, or contact with the packs should be avoided if possible. Sterile instrument packs should be transported only on carts with solid bottom construction and should never be cradled.

- Immediately after surgical devices are used in an operation, they should be transferred to a tray with towels moistened by sterile distilled water to maintain moisture. As soon as is possible, they should be transferred to an enzymatic bath to soak. These steps will aid in the cleaning process. Follow all instructions provided with enzymatic detergents. This process is described in further detail in Section I (Holding & Pre-Cleaning).

Some general handling guidelines include:

- Avoid overloading of trays
- Protect all sharp tips with tip protectors
- All instruments should be air-dried prior to storing
- Place heavier instruments on the bottom of trays
- Store in a clean and dry environment

**SECTION VII – GENERAL TIPS**

1. There are some substances that Novo Surgical instruments should absolutely never be exposed to for any length of time. These substances are highly corrosive and have the ability to damage the product within seconds:
   a. Aqua regia
   b. Iodine
   c. Ferric chloride
   d. Hydrochloric acid
   e. Sulfuric acid
2. In addition, the following substances can degrade the product over time and contact should be avoided:
   a. Aluminum chloride
   b. Barium chloride
   c. Dichloride of mercury
   d. Calcium chloride
   e. Carbolic acid
   f. Chlorinated lime
   g. Dakin’s sodium
   h. Mercury chloride
   i. Potassium permanganate
   j. Potassium thiocyanate
   k. Saline
   l. Sodium hypochlorite
   m. Stannous chloride
   n. Solutions with a pH \( \leq 5 \) or pH \( \geq 9 \)

3. Always isolate corroding instruments to avoid transferring rust.

4. Always replace protective cutting edges and tip protectors when possible.

5. During nearly every step of the cleaning/disinfecting/sterilizing process, instruments should be grouped with like metals. Remember that most, but not all, Novo Surgical products are stainless steel.

6. Each instrument is designed to perform a specific function, such as cutting, grasping, dissecting, retracting, etc. Instruments should only be used for their designated surgical purpose by trained personnel. It is the responsibility of each healthcare facility to ensure the personnel responsible for transport, cleaning, storage and use of instruments are trained properly.

7. All instruments should be routinely inspected and maintained by a qualified repair technician.

8. Avoid processing dissimilar metals together.

9. Do not use bleach or other corrosive chemicals to disinfect, treat or clean instruments. Only EPA-approved substances designed specifically for use with stainless steel surgical instruments should be used.

SECTION VIII – COMMON ISSUES

This section will allow you to diagnose possible issues with your instruments and take steps toward troubleshooting.

- Wet packs: A wet pack is one that has water condensation after the high temperature sterilization process is complete. Wet packs are considered contaminated because water can allow for the transfer of contaminants that air can’t. Wet packs are most often the cause of improper loading of the autoclave. Either not enough room was allowed between packs, basin-like items were not tilted to allow for draining, or insufficient time was allowed for drying. Moisture inside a pack is indicative of improper positioning of devices that allowed steam to be trapped.
  - Brown stains: Dark brown stains are often the result of detergents containing polysulphates being used. These can lead to the formation of copper deposits. However, dull blue or brown stains result from a different process and can actually be protective.
  - Rust deposits: Surgical grade steel rarely rusts. Ensure that rust is not actually biological matter trapped in tough to clean areas. This can also be the result of “hard” water being used too often, leaving...
mineral deposits on the instrument. This can be resolved by using softened or distilled water whenever possible.

- Black stains: Usually indicative of ammonia staining.
- Light or dark spots: Usually the result of water drying on instruments and leaving mineral deposits. This can be rectified by using treated water whenever possible, especially on the final rinse.
- Blue stains: Usually the result of an improper low temperature sterilization procedure. Make sure to follow all manufacturer instructions, especially with regard to exposure time.
- Pitting: Usually the result of autoclaving with a solution containing chloride or the use of acid-based detergents. Both of these can cause a buildup of hydrochloric acid that causes deterioration. This can be avoided by making sure to use neutral (pH 7) detergent and solutions.

A large portion of corrosion can be tied to exposure to solutions with pH less than 5 or greater than 9. Avoid these substances entirely.

SECTION IX: CONCLUSION & WARRANTY

Thank you for taking the time to read this guide. Proper use of these procedures by trained personnel will go a long way towards the extending the useful life of your instruments.

NOVO SURGICAL WARRANTY

Novo Surgical instruments are unconditionally guaranteed to be free of any defects in materials and/or workmanship when used under normal conditions for their intended surgical purpose. Any Novo Surgical instrument that is determined to be defective will, at Novo Surgical's discretion, be repaired or replaced at no charge. Normal wear and tear and/or instrument misuse, including improper use or inadequate maintenance, are not covered under the manufacturer’s warranty. All Novo Surgical instruments are warranted only to the original purchaser.

Much of our instrumentation is hand-finished by skilled craftsmen. As such, slight variations in dimension may occur between the actual product and the specifications contained herein.

The limited warranty described herein is the only warranty made by Novo Surgical. Novo Surgical makes no other representations, either expressly or implied, beyond the information contained here. Novo Surgical disclaims any implied warranty of merchantability or fitness for a particular purpose. Novo Surgical will not be liable for any incidental, special, consequential or exemplary damages or loss of profits in connection with the use of a Novo Surgical instrument or product. The stated warranty is in lieu of all liabilities or obligations of Novo Surgical arising out of or in connection with the delivery, use or performance of any Novo Surgical instrument. Replacement or repair shall be the sole remedy for all breaches of all warranties and claims.