GENERAL INSTRUCTIONS FOR USE

Warning:
GerMedUSA manufactures surgical instruments for the use of medical practitioners. We do not take any responsibility for the damage, bending, breaking, or any harm to the instruments if they are misused or improperly handled.

Cautions:
Different instruments may have different manufacturing materials, so do not follow the same maintenance method unless you are completely sure. We do suggest adopting the most suitable and recommended cleaning, disinfecting, and sterilization methods according to the material of the instruments.

Important:
Improper handling and reprocessing can damage the instruments or may result in patient injury. To prevent cross-contamination, avoid reusing the instrument that has been used on the patient who has CJD. Properly clean, inspect, disinfect, and sterilize each instrument before going for any surgical procedure.

Note:
Our instruments are packaged non-sterile, but they are steam sterilizable. The effects of regular, repetitive usage on our instruments are minimal. Normal wear and damage from usage decide when a product reaches its end of life.

General Instructions:

Always follow instructions and precautions while handling and reprocessing surgical instruments. Below are some common instructions that every user of surgical instruments should thoroughly read before going for the procedure.

- Do not forget to wear protective clothing, gloves, and eyewear when cleaning, disinfecting, and sterilizing surgical instruments.
- Carefully handle surgical instruments featuring delicate tips to prevent damage or breakage.
- Use a non-fibrous sponge while removing blood stains and debris from the surgical instruments.
- Instruments forged with different materials should be prepared separately to prevent electrolytic action between the metals.
- Do not apply too much pressure on the joints, locks, or jaws of the surgical instruments, otherwise they will be cracked or misaligned.

- To prevent scratches and the loss of the ebonized coating, keep ebonized instruments apart from stainless steel-made tools.
- Follow the specific restrictions on the number of reprocessing cycles for a specific instrument.
- Check all working parts of the instruments, including blades, locks, points, stops, ratchets, screws, etc. Tools with any sign of corrosion or damage must be replaced or repaired prior to use.

Important Note: Do not sterilize any surgical instrument until it is completely cleaned and disinfected; otherwise, the tool will get stained, and we will not be responsible for any complications.

Decontamination Process

The complete decontamination of the surgical instruments includes cleaning, disinfecting, and sterilization.

Caution- Instruments with different materials should be processed separately.
Do not follow the same method for all the instruments with different materials.

Mostly, the cleaning and disinfecting procedures are similar for different materials, but still, the user has to follow the cautions strictly. The sterilization process can vary for instruments made up of different materials. In case of any mishap, we will not be responsible.

Pre-Cleaning Instructions

- Strictly follow the warnings and caution before choosing disinfectants and cleaning agents for the instruments.
- Always prefer detergents with a neutral pH.
- Do not use mineral acids or abrasive agents.
- Carefully disassemble the instrument prior to cleaning and sterilization if needed.
- Properly clean joints, jaws, and serrations. Try to swiftly open and close the jaws.
- Do not use chlorinated or saline solutions for rinsing instruments. Rinse each instrument thoroughly.
- Use lukewarm/cool water with a temperature not exceeding 35º C (95º F) to remove gross contaminations.
- In any solution, do not soak instruments for more than 2 hours. Also, avoid soaking instruments in antiseptics, alcohol, hot water, alcohol, or disinfectants to prevent blood, mucous, or fluid coagulation.
- Steel wool, wire brushes, pipe cleaners, or abrasive detergents are not recommended for cleaning surgical instruments.

Authorized Cleaning Agents

Here's the list of authorized cleaning agents ideal for cleaning surgical instruments.

- Isopropyl (rubbing) alcohol
- Non-abrasive polish
- Alkaline chlorinated cleaners
- Mild detergents
- White Vinegar
- Windex
- Clean (distilled) water with a pH of 7
- Sodium Bicarbonate/Baking soda
- Hospital-grade (bleach-free) disinfectants
- Non-chloride cleaners

Non-Recommended Cleaning Agents

Users should avoid applying the following chemicals and agents for the cleaning purpose of the surgical instruments otherwise the health of the tools will be affected and we will not be responsible for any kind of complications.

- HCL/Muriatic Acid
- Ammonia
- Cl-containing compounds
- Quaternary Salts
- Hard Water / PH above 7
- Bleach
- Abrasive cleaners

Cleaning Material

Besides selecting the authorized cleaning chemicals for instruments, it is crucial to use the recommended cleaning material, otherwise the instruments can get scratches on them, which will definitely reduce their working efficiency.

Authorized Cleaning Materials

While cleaning the surgical instruments, prefer the following authorized materials:

- Soft-bristle brush
- Soft-bristle toothbrush
- Non-abrasive cleaning pad

Non-Recommended Cleaning Materials

- Metal or Plastic Scrapers
- Abrasive Pads
- Wire Brushes
- Steel Wool Pads

Automated Cleaning Process

- Only use low-foaming and non-ionizing cleaning products and detergents during automated cleaning.
- Use only approved washer-disinfector systems.
- Pay attention to the cautions, concentrations, and suggested cycles.
- Load instruments carefully. Leave the box locks and hinges open to let the opening of the instruments drain easily.
- Be careful not to overload the wash baskets.
- Do not place heavy instruments on delicate ones.
- Adjust the curved-surface instruments downward to prevent water from pooling.
- Instruments featuring channels and lumens must be flushed using proper cleaning supplies.
- Use highly purified and soft water for the final rinse.

Caution:
Automated cleaning may not be suitable for all lumens and channels. In this case, use a water jet and suitable brushes to manually clean the instruments' parts. After being manually cleaned, all instruments should go through an automatic cleaning cycle to ensure disinfection.

Manual Cleaning Process

During manual cleaning of surgical instruments, follow the following instructions.

- Use a double sink system that is not used for hand washing. Make sure the water temperature does not exceed 35º C (95º F).
- In the first sink, keep the instrument completely immersed. Apply a validated cleaning solution to all surfaces. Use a suitable-sized autoclavable soft nylon brush to thoroughly remove the dirt.
- Always brush away from the body and avoid splashing.
- Pay special attention to serrations, hinges, ratchets, teeth, and box locks.
- To remove dirt, carefully flush all channels and lumens with a cleaning solution using a big syringe or a water jet.
- In the second sink, clean the instruments with soft, highly purified water that has been bacterial endotoxin-controlled and make sure that water reaches every portion of the instrument.

- Carefully hand-dry the instruments or use a drying cabinet.

Note:
Avoid going for manual cleaning if an automatic washer-disinfector is available.

Visual Inspection:

It is important to visually inspect the instruments after completing the cleaning process. Make sure all surfaces of the instrument, including ratchets, channels, box locks, holes, and lumens, are free from contaminants.
Repeat the decontamination process if any debris or fluid is still visible on the instrument.

Drying

Prior to sterilization, make sure the instruments are free of any remaining moisture. External surfaces of instruments should be dried with an absorbent towel or soft cloth.

Lubrication

To ensure the smooth functioning of instruments, it's necessary to apply non-silicone and water-soluble lubricants to the moving parts of the instruments.

Function Testing

- Check all parts of the instruments and make sure they are working properly.
- Make sure different parts of the instrument have proper alignment, and there is no bending or wearing.
- Do not sterilize instruments that are blunt, worn out, flaking, fractured, corroded, stained, discolored, or damaged.

Disinfecting:

After cleaning, surgical instruments need enzymatic soaking to completely remove proteins and blood. In this process,

- Immerse the tools in an EPA-approved disinfectant for 10 to 15 minutes.
- Rinse the instruments with sterile distilled water.

Sterilization

General Instructions

The most suitable way to sterilize surgical instruments is to autoclave them in accordance with the manufacturer's instructions. Although it is not advised, some facilities utilize ethylene

oxide gas sterilization. While performing EtO sterilization extreme caution must be used, and the manufacturer's instructions must be strictly adhered to.
Due to the potential danger of instrument damage from the prolonged chemical activity needed for cold sterilization, it is also not advised. Utilizing only FDA-approved Sterilization Pouches, instruments should be sterilized in the open or unlocked position.

Precautions!
Specifications for sterilization may be changed according to load size, the atmosphere, and other factors. The manufacturer of the sterilization equipment's instructions should be followed while opening or disassembling instruments and properly preparing them for sterilization.

Autoclaving/Steam Sterilization

- Use a validated, properly maintained, and error-free steam sterilizer.
- When utilizing the autoclaving process, ensure the instrument is sealed and covered in a sterile bag.
- Other objects should not be in contact with the RF cables or any handle made with insulating material.
- Do not exceed **140° C (284° F)** during the sterilization cycle.
- Follow the steam cycle listed below to ensure an efficient sterilization process.

Autoclave Cycle	**Minimum Temp.**	**Pressure (psi) Above Atmospheric Pressure**	**Minimum Exposure Time**
For Unwrapped Instruments	134°C (273°F)	30 psi	3-4 Mins.
For Wrapped Instruments	121°C (250°F)	15 psi	30 Mins.

While the temperatures and sterilization times remain the same for both prevacuum and gravity displacement cycles for stainless steel surgical instruments, the drying times can differ due to their air removal methods.

*Dry time for Prevacuum Cycle: **15-30 minutes**
*Dry time for Gravity Displacement Cycle: **30-45 minutes**

Note: Get a manual or confirmation from the manufacturer of the steam autoclave to set the appropriate temperatures and sterilization times.

In case:

The WHO recommends the longest exposure times when instruments have contamination from HIV, TSE, or CJD. The user must determine the type of contamination on the instruments and the most suitable procedure to ensure proper sterilization.

Marking:

While marking the instruments, do not stretch tape or place it in a location that hinders the instrument's function.

Packaging

Carefully wrap and pack surgical instruments following local procedures.

Handling and Storage:

When using, transporting, cleaning, sterilizing, and storing, extreme caution must be exercised. Damage to the instrument's function and safety may occur if it is handled roughly or inappropriately or if it is used for something other than its intended purpose.

When the sterilization process is completed, store the instruments in a dry and clean environment at ambient room temperature after wrapping them with the sterilization wrap.

Material-Wise Processing

Most of our instruments are made up of surgical-grade stainless steel. We also manufacture instruments with titanium coatings and tungsten carbide inserts. Be careful while processing our plasma-coated instruments.

Warning:
Do not sterilize instruments made of different materials together. Follow the method that is best suitable for a particular material.

Stainless Steel Instruments:

Stainless steel offers considerable, but not complete, resistance against rust and corrosion. Organic compounds left behind after usage, chloride ions, ordinary salts, and other impurities in tap water are the most harmful elements for stainless steel.
The users cannot overstate the using appropriate cleansers, disinfectants, and distilled water.

After properly cleaning and disinfecting the stainless steel instruments, follow any of the following procedures to sterilize them.

- Ethylene Oxide (EtO) Sterilization
- Steam Autoclaving

Warning:

We do not take any responsibility for the contaminants to which the user will expose the stainless steel surgical instruments. It's the users' choice to select the cleaning and sterilizing methods that they find the best fit for the instruments. They may require some additional steps as there are several methods for cleaning and sterilizing these instruments. We only recommend the authorized ones.

Titanium-Coated Surgical Instruments

Titanium instruments are usually anodized blue for color identification. With the passage of time, these instruments may lose their color through normal use and reprocessing. They can be taken care of and maintained the same as stainless steel instruments.

Users have to follow the most appropriate and recommended protocol to make these instruments long-lasting.

Note:
Instruments should only be used for the purpose they are manufactured. When used improperly, even the strongest instrument might be harmed.

Cleaning Instructions

The user should take great care while selecting the cleaning agents, materials, and methods; otherwise, the structure as well as the overall efficiency of the titanium-coated instruments, can be affected.

Disinfecting

After cleaning, disinfect titanium-coated instruments according to the procedure listed above.

- Double-check the disinfecting process prior to starting with it.
- Do not expose instruments to corrosive chemicals or bleach to prevent any kind of damage/harm.
- Make sure all foreign materials are eradicated before going for sterilization.

- ### Sterilization

Proper sterilization and reprocessing of Titanium-Coated Instruments make them reusable for surgical procedures.

There are multiple methods to sterilize these instruments; choose the most suitable one according to the material of the instrument.

We recommend:

- Ethylene Oxide (EtO) Sterilization
- Steam Autoclaving

During autoclaving, ensure that the instruments are sealed and wrapped in a sterile pack.

Warning:

Do not use corrosive/not recommended methods, chemicals, or materials to decontaminate titanium instruments. We only recommend authorized methods.

Tungsten Carbide Inserted Instruments

Important

Although Tungsten carbide-inserted instruments are three times harder than stainless steel-forged surgical tools, they still need proper care and maintenance to last for years. Make sure that you use the recommended cleaning, disinfecting, and sterilization processes. Otherwise, the instruments can get scratches on the surface, which will definitely reduce their working efficiency.

Steam Autoclaving:

When using this method for autoclaving, ensure that the instruments are sealed and wrapped in a sterile pack. The other objects should not be intact with the RF cables or handles made of insulating material.

Warning:

Do not use glutaraldehyde/cold sterilization as this solution/method is harmful to the instruments with tungsten carbide inserts/edges.

Storage

Tungsten Carbide Inserted instruments feature non-degradable material, so store them under recommended conditions to ensure longer shelf life.

Plasma-Coated Instruments

The color-coated instruments are intended to make it easier for medical professionals to identify and select a specific tool for its unique color. Except for that, the functional benefits

of the plasma coatings range from biocompatibility, reduced friction/corrosion, wear resistance, and excellent durability over a number of cleaning and autoclave cycles.

Caution: Although plasma-coated instruments are biocompatible and corrosion-resistant, they still need great care and maintenance to keep them functional at their optimum level. Improper handling, cleaning, and sterilization can affect the health of color-coated instruments.

Decontamination Of Plasma Coated Instruments

Like other surgical instruments, color-coated medical equipment also needs proper cleaning, disinfecting, and sterilization to prolong its shelf life.

Warning

Do not use the below-listed chemicals and detergents for cleaning the color-coated instruments as they are corrosive and will harm the instruments when exposed.

- HCL/Muriatic Acid
- Ammonia
- Cl containing compounds
- Quaternary Salts
- Hard Water / PH above 7
- Bleach
- Abrasive cleaners

Cleaning

Plasma-coated instruments can be run through automated as well as manual cleaning processes.

Precaution: During machine-cleaning, color-anodized surfaces of the instruments may lose their color, but it will not affect their function.

Choose the best suitable method at your convenience.

Warning: Do not use scalpel blades, wire brushes, or steel wool to remove the tool's contaminants because they can cause damage.

Disinfecting:

It is crucial to remove the debris and contamination from the plasma-coated instruments by immersing them in an EPA-approved disinfectant and rinsing them again after disinfecting.

Attention:

Disinfecting the plasma-coated tools does not make them sterile. So, it is advised not to expose them to corrosive chemicals or bleach because such chemicals and solutions can damage the instruments.

Double-check during the cleaning procedure to make sure all foreign materials are eradicated.

Sterilization

There are multiple methods to sterilize plasma-coated surgical instruments.

Note: Prefer steam autoclaving for color-coated instruments to get optimum results. And for this procedure, follow the cycles mentioned above.

Warning:
Do not clean, disinfect, or sterilize the plasm-coated instruments with other instruments. Process them separately to avoid any kind of complication.

Instruments With Phenolic Handles - Instruments with phenolic handles may be maintained and processed in the same way as the material used for these instruments.

Returns and Refunds

We fully support the return and refund policy based on our terms and conditions. Instruments manufactured with different materials have different warranty times.

Stainless Steel Instruments

All GerMedUSA surgical instruments are guaranteed for life against manufacturing defects, provided that the instrument is used for its intended surgical purpose. GerMedUSA will either repair or replace the instrument without charge at our discretion. Our liability under this guarantee shall be limited to the repair or replacement of defective merchandise. Our guarantee is unqualified because our own quality control inspectors check GerMedUSA surgical instruments.

- Our instruments are carefully examined by our surgical instrument experts.
- No instrument is shipped unless it meets our standards.
- Tungsten carbide instruments are included except for jaw inserts, and Gold handles by a separate warranty

Instruments with Tungsten Carbide Inserts

GerMedUSA surgical instruments with tungsten carbide inserts are warranted for five full years of normal use.
During this warranty period, if any adjustments become necessary, GerMedUSA will repair, sharpen (for TC scissors), or replace the instrument. A nominal charge will be made for repairs once the warranty period has expired.
The non-TC portion of the instrument is guaranteed under GerMedUSA's Lifetime Warranty.

Note:

GerMedUSA's experts will examine the tool and decide whether it can be repaired or replaced. In case of a return, instruments must be properly sterilized, and the user should have documented evidence of purchase.

Our Accreditations

We manufacture our surgical instruments strictly following the FDA guidelines. All our instruments are FDA-approved, and we are an ISO 13485-certified manufacturer and supplier of surgical instruments.

ADDRESS: 2417 Jerichco Turnpike, #333, Garden City Park, NY 11040 (USA).
PHONE: 800-330-1322 | +1(516) 997-2180
FAX: 800-260-7177 | +1(516) 358 2182
EMAIL: sales@GerMedUSA.com