

NeoBiotech Cleaning and Sterilization Guide for Surgical Instruments

This document provides detailed instructions on the cleaning and sterilization procedures for NeoBiotech surgical instruments. To prevent damage and corrosion of the instruments and to ensure proper sterilization, the following procedures must be strictly followed.

Precautions When Selecting Cleaning Agents and Disinfectants

When selecting cleaning agents and disinfectants, make sure they do **not** contain the following components:

- Organic acids, inorganic acids, or oxidizing acids (Minimum allowed pH: 5)
- Strong alkalis (Maximum allowed pH: 9; mildly alkaline detergents are recommended)
- Organic solvents (e.g., alcohol, ether, ketones, benzene compounds)
- Oxidizing agents (e.g., hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic or halogenated hydrocarbons
- Heavy metal salts
- Fixatives (e.g., aldehydes)

2. Causes of Damage and Prevention

The following are common causes of instrument damage and how to prevent them:

- Dried blood, pus, or tissue residues can cause corrosion if left on instruments.
- Prolonged exposure to moisture can lead to corrosion.
- Inadequate drying increases the risk of corrosion.
- Using inappropriate cleaning agents or disinfectants can cause stains or discoloration.
- Using metal brushes or steel wool can damage the oxide layer, leading to corrosion.
- Cleaning instruments made of different metals together can cause galvanic (contact) corrosion.
- Cutting edges may be damaged due to impact or usage beyond the recommended lifespan.

3. Before Use

- Coarse contaminants must be removed from the instruments immediately after use (within 1 hour at the latest).

For cleaning purposes, disassemble the components of the instrument (e.g., torque ratchet). The KIT tray should be disassembled in the following order: top plate, middle plate, and bottom plate.

Before each use, carefully inspect the instruments for proper functionality and any signs of damage.

4. Cleaning and Sterilization

All instruments can be cleaned using either automated or manual methods.
During the cleaning and disinfection process, observe the following guidelines:

Water Quality

1. Contaminants or minerals in water can shorten the lifespan of instruments and reduce the effectiveness of cleaning solutions.
2. Always use distilled water for cleaning.
3. For the final rinse, NeoBiotech strongly recommends using fully demineralized and endotoxin-free water.

Detergents

1. Select a detergent suitable for both metal and plastic instruments.
2. Use a detergent that is also compatible with ultrasonic cleaning.
3. Always use freshly prepared cleaning solutions for each cleaning process.
4. Always follow the instructions provided by the detergent manufacturer. The specified concentration and contact time must be strictly followed.

Cleaning Method

Surgical Instruments

- After the procedure, remove all instruments from the tray and soak them in alcohol. Clean using standard methods.
- Rinse with distilled water or equivalent to remove any remaining blood stains or foreign substances. Use a syringe or pipe cleaner to clean hard-to-reach areas.
- Dilute an enzymatic detergent with distilled water (or equivalent) according to the manufacturer's instructions. Perform ultrasonic cleaning for 10 minutes, then rinse with distilled water for 3 minutes.

Tray

- Rinse all debris off the tray using distilled water (or equivalent), and remove remaining substances with a soft brush. Use a syringe or pipe cleaner for hard-to-clean areas.
- Dilute enzymatic detergent with distilled water according to the manufacturer's instructions, soak the tray for 1 minute, and use a soft brush to remove any residual contaminants.
- After cleaning, rinse the tray with distilled water for 3 minutes to remove any remaining detergent.
- Completely remove moisture using a dry cloth or warm air.
- Organize the dried instruments in the KIT case and sterilize them according to the sterilization method.

(Refer to the color codes for easy and correct placement.)

Sterilization Method

1. As these are non-sterile medical devices, perform pre-vacuum sterilization using an autoclave.
2. Before sterilization, remove any inner packaging from the tray and separate any assembled components to enhance sterilization efficiency.
3. Wrap the tray with a surgical drape, seal it with autoclave tape, and proceed with sterilization.

◁Recommended Steam Sterilization Conditionse▷

Cycle Type	Temperature	Pressure	Exposure Time	Dry Time
Pre-vacuum	132 °C (270 °F)	2 bars	4 minutes	30 minutes

To ensure effective high-pressure steam sterilization, regular use of biological indicator should be considered.

1. Steam sterilization conditions of minimum time and temperature to ensure a sterility assurance level of 10^{-6} .

2. If regional or national sterilization conditions specify stricter parameters, follow those instead.

Exceeding the above conditions may damage plastic parts or assembled components. To avoid this, do not exceed the recommended temperature.

Caution

All instruments and cassettes must not be exposed to temperatures exceeding 132°C (270°F).

Always place the KIT on a shelf in the sterilizer and ensure it does not come into contact with the walls of the sterilizer. Do not place the KIT on its side or upside down with the top facing downward.

Do not place corroded or rusty instruments in the KIT for sterilization. Rusty instruments can contaminate the sterilizer's water circulation system with rust particles.

Alternative sterilization methods (such as dry heat, radiation, plasma, formaldehyde, or ethylene oxide sterilization) are not permitted.