

SAFhandle™

Reusable Scalpel Handle

Care, Handling, Cleaning & Sterilization

The SAFhandle™ reusable scalpel handle is manufactured from the finest German surgical instrument grade stainless steel.



The SAFhandle™ reusable scalpel handle is supplied in a non-sterile condition and must be cleaned and sterilized prior to use in accordance with the processing instructions described in this document and in compliance with local, state and national health & safety regulations. This will ensure that the SAFhandle™ scalpel handle is processed safely and continues to meet its performance specification.

The SAFhandle™ reusable scalpel handle is latex free. It is marked with a unique serial number **[SN]** for identification and traceability.



WARNINGS

The SAFhandle™ reusable scalpel handle is a delicate precision instrument and requires the utmost care and caution whilst handling and reprocessing to prevent damage and misalignment of parts and injury to personnel. The SAFhandle™ reusable scalpel handle is not compatible with reinforced-back blades. The SAFhandle™ reusable scalpel handle is protected during transportation with a plastic guard which must be removed.



Please take the time to familiarize yourself with the scalpel and its correct usage as described in the **INSTRUCTIONS FOR USE**.

SHARPS INJURY PREVENTION GUIDELINES

As per AORN's "Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment," reusable metal scalpel handles should be considered sharp. *Considering a reusable scalpel handle to be sharp minimizes the risk of injury, if a blade has been left on the handle.* Visually check that the blade has not been left on the handle.

OSHA's BBP standard requires that where engineering and work practice controls will reduce employee exposure either by removing, eliminating or isolating the hazard, they must be used. This would include the use of **ultrasonic cleaners and washer-disinfectors** as a form of **engineering control**.

Work practice controls require reusable sharp to be segregated from other instruments and placed in a separate puncture proof container for transportation until properly reprocessed. AORN recommends establishing a separate area to place a reusable sharp for safe handling during the procedure. CDC and OSHA also recommend the use of long-handled brushes (to keep the hand as far away as possible from sharp instruments) for cleaning reusable sharps, to reduce the potential for employee exposure to blood or other potentially infectious materials.

Employees should wear personal protective equipment according to regulations. Employees should not reach into trays, containers or sinks holding sharp instruments that cannot be seen.

CLEANING PRECAUTIONS

Instruments should be kept free of gross soil during surgical procedure. Cleaning and decontamination should occur as soon as possible after instruments are used.

Blood and body fluids, as well as saline, are highly corrosive. Corrosion, rusting, and pitting occur when saline, blood, and debris are allowed to dry in or on surgical instruments. Dried blood and debris can be difficult, if not impossible, to remove from all surfaces during the decontamination process; therefore, subsequent sterilization may not be achieved.

Do not use abrasive detergents, brushes or pads. Use only non-corrosive, low-foaming, neutral pH, non-abrasive, free rinsing enzymatic detergents and preferably 100% biodegradable detergents.

Do not leave in water for long periods. Instruments made from other metals should be processed separately. A tumbling process will damage the delicate instrument and should not be used.

MANUAL CLEANING

Manual cleaning poses occupational health and exposure risk and is therefore not recommended if automated equipment is available.

PRE-SOAKING AND RINSING: Open the handle and saturate the surfaces of the instrument with enzymatic detergent for five (5) minutes. Rinse the instrument with potable water to remove any dislodged debris.

CLEANING: Submerge the instrument in warm water with an appropriate enzymatic detergent for ten (10) minutes.

BRUSHING: Using an autoclavable long handle soft nylon brush designed for surgical instrument cleaning, scrub the instrument with a brushing away-from-the-body and non-splashing action. Brush the instrument in both open and closed positions. Ensure all parts are clean, paying particular attention to hard to reach places.

RINSING: Rinse the instrument thoroughly with soft, high purity water. Ensure that the water reaches all parts of the instrument to remove any dislodged debris.

DRYING: Dry with an industrial hot air dryer or drying oven at ~ 55 deg Celsius, paying particular attention to the space between the two (2) jaws. Visually check that all soil and fluids have been completely removed. If soil or fluid is still visible, repeat the cleaning process again.

ULTRASONIC CLEANING

PRE-SOAKING AND RINSING: Open the handle and saturate the surfaces of the instrument with enzymatic detergent for five (5) minutes. Rinse the instrument with potable water to remove any dislodged debris.

CLEANING: Immerse the device in an open position and without overlapping, in the ultrasonic cleaner with warm water with an appropriate enzymatic detergent prepared according to the manufactures' instructions. Sonicate for ten (10) minutes as per the manufacturers operating instructions.

RINSING: Rinse the instrument thoroughly with soft, high purity water. Ensure that the water reaches all parts of the instrument to remove any dislodged debris.

DRYING: Dry with an industrial hot air dryer or drying oven at ~ 55 deg Celsius, paying particular attention to the space between the two (2) jaws. Visually check that all soil and fluids have been completely removed. If soil or fluid is still visible, repeat the cleaning process again.

WASHER-DISINFECTOR CLEANING

PRE-SOAKING AND RINSING: Open the handle and saturate the surfaces of the instrument with enzymatic detergent for five (5) minutes. Rinse the instrument with potable water to remove any dislodged debris.

CLEANING: Process the handles in a washer-disinfector in the open position and follow the manufacturer's instructions for use, warnings, concentrations and recommended cycles. The cleaning of the instrument with a washer-disinfector has been validated as tabled below:

Washer-Disinfector Parameters

TREATMENT	TIME (MM:SS)	TEMPERATURE	CHEMICAL
Enzymatic Wash	04:00	60°C	Metrex MetriZyme® (1/4 fl. oz. per gallon)
Wash	02:00	Hot Tap Water	Metrex DetergeZyme® (1/4 fl. oz. per gallon)
Rinse	02:00	70°C	N/A
Dry	15:00	80°C	N/A

Visually check that all soil and fluids have been completely removed. If soil or fluid is still visible, repeat the cleaning process again.

INSPECTION

All handles that have been cleaned should be thoroughly inspected. Instruments in disrepair should be tagged or labeled and removed from service until repaired or replaced:

- Visually check the alignment of jaws. There should be a gap between the jaws for the blade. The handle jaw lock should engage.
- Gently check that the pins are not loose or misaligned. Do not force, twist or turn. Check that the screw is not loose and that the jaw stopper pin stops the jaw.
- Check handle for corrosion, stains, pitting, burrs, nicks and cracks.
- Any other defects.

LUBRICATION

Lubricate the handles with a lubricant which is anticorrosive, non-greasy, non silicone-based and is steam permeable and water soluble. Instruments should be clean before lubricant is applied. Applying lubricants to soiled instruments can compound the problem of stiff joints and inhibit smooth movement. Remove excess deposits.

STERILIZATION

Remove all tissue, body fluids and cleaning solutions from the SAFhandle™ scalpel handle prior to sterilization. The scalpel should be dry prior to sterilization.

PACKAGING: Follow recommended practices for the selection and use of packaging systems for sterilization. Place the instrument in a self seal pouch with the handle in the open position to allow the sterilant to contact all exposed surfaces. Ensure that the pack is large enough to contain the instrument without stressing the seals.

The SAFhandle™ reusable scalpel handle should be opened and the tips of the two jaws covered with a vented tip protector which is loose fitting and tested safe for steam sterilization. The tip protector should be used according to the manufacturer's instructions. The tip protectors will help prevent the delicate pins from damage and the tips of the handle from piercing the sterilization pouch.

The SAFhandle™ scalpel handle is validated for sterility by the following cycles: Pre-vacuum steam autoclave, Temperature: 132 deg C (270 deg F), Sterilization time: Four (4) minutes.

STORAGE

Instruments must be dry before storage and stored in dry, clean conditions at an ambient room temperature.

ADDITIONAL INFORMATION

The reprocessor must ensure that reprocessing achieves the required results. If it is necessary to deviate from the instructions provided, the reprocessor must fully evaluate the effectiveness and potential adverse consequences of such deviations.

RETURNING HANDLES TO THE MANUFACTURER

Products returned must have a decontamination certificate identifying the handles unique serial number **[SN]** which testifies that each instrument has been thoroughly cleaned and disinfected.



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