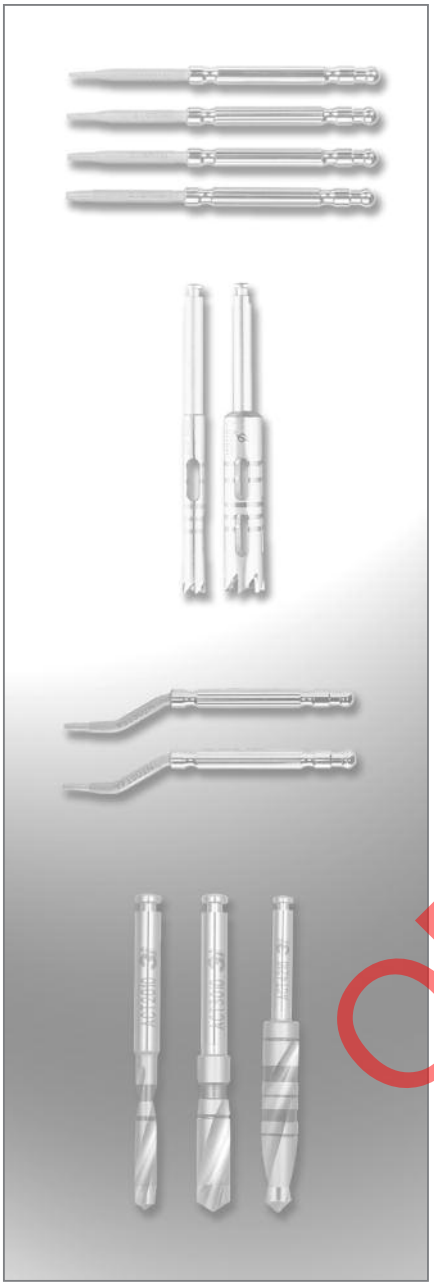
Information And Instructions
Sterilization And Care Of Stainless Steel



Discussion

Surgical grade stainless steel is an alloy of iron, carbon and chromium. Each element provides a specific benefit and is blended based on function. The percentage of carbon steel is related to hardness and the ability to keep a sharp cutting edge throughout repeated use. Chromium enhances corrosion resistance.

While carbon enhances hardness, iron is a key factor in corrosion or rusting problems. Therefore, the surface is treated with passivation and electropolishing processes to reduce corrosion.

Passivation is a chemical process that creates the corrosion resistant properties of stainless steel. Electropolishing, a form of passivation, produces a smooth surface finish, resulting in a chromium oxide surface layer that is highly resistant to corrosion. However, this protective layer can be removed due to use, improper handling and repeated sterilization. The result is rusting or staining. Stainless steel is not stain proof. While it has excellent corrosion resistance, stainless steel may discolor or rust under sterilization procedures or when exposed to a number of chemicals including iodine, stannous fluoride, sodium hypochlorite or even Lysol®.

NOTE: An example of products covered by these instructions include twist drills, osteotomes, trephines, hand drivers and bone profilers.

BIOMET 3i™ Recommended Cleaning And Sterilization Procedures For Surgical Instrumentation

Directions For Use:

To maintain the quality of BIOMET ***3i*** Instrumentation, the following procedures should be followed.

Cleaning	1. After use, place drills and instruments in a beaker of plain water with mild soap or a specialized cleaning solution.
	2. Rinse with tap water for a minimum of two (2) minutes while brushing with a soft bristled brush to remove visible debris. Clean the interior lumen with a thin wire to remove any remaining debris.
	3. Place instruments in an ultrasonic bath containing enzymatic detergent for five (5) minutes*. Scrub instruments again with a soft bristled brush and ream interior lumen to remove any remaining debris.
	4. Rinse and flush instruments for one (1) minute using tap water.
	5. Inspect visually for any remaining bone fragments or debris and scrub as necessary.
Sterilization	6. Remove the bur block from the surgical tray. Scrub the surgical tray and block with a soft bristled brush and mild soap. Rinse thoroughly.
	7. Place components in the surgical tray and pour ethyl alcohol (do not use rubbing alcohol) over the burs and tray to remove soap residue and minerals from the water. This step is important to help prevent corrosion and spotting.
	8. Wrap the surgical tray in paper or autoclave-approved bags twice to prevent a tear in the outer packaging so as to protect from contact with contaminated instruments.
	9. <u>Steam Gravity Sterilization Method</u> **Kits NPSDK0, NCATD0, NCATD0C, SGKIT, SGTIKIT:** **Trays PSDT1, SGTRAY, SGTTRAY:** Minimum forty (40) minutes at a temperature of 270 – 275ºF (132-135ºC) **All other Kits and Trays:** Minimum twenty (20) minutes at a temperature of 270-275ºF (132-135ºC) ***or*** <u>Pre-vacuum Sterilization Method (All Kits)</u> Minimum four (4) minutes (four pulses) at a temperature of 270-275ºF (132-135ºC) **NOTE:** Since BIOMET ***3i*** is not familiar with individual clinical handling procedures, cleaning methods, bioburden levels, and other conditions, BIOMET ***3i*** assumes no responsibility for sterilization of product even if the above guidelines are followed.
	10. Post sterilization, devices should be thoroughly dried to mitigate the risk of stainless corrosion (30 minutes is typical). Please refer to the BIOMET ***3i*** Surgical and Restorative Manual for the remaining care and cleaning steps. **NOTE: Drying times may vary according to load size.**

NOTE: Multiple sterilizations may affect the flow of fluid through internally irrigated burs. After each use, prior to the sterilization cycle, ream burs individually with wire to remove any bone fragments or debris that will prevent the flow of water.

It is very important to not remove drills, instrumentation or the surgical tray from the autoclave until the "dry cycle" is complete.

These guidelines DO NOT apply to the cleaning and sterilization of your powered instrumentation. Please follow your powered instrumentation manufacturer's instruction.

These recommendations have been validated by BIOMET 3i to obtain the following:
Cleaning: An average LOG_{10} reduction in tag spores to 4.58.
Sterilization: A 10^{-6} SAL.
*ENZOL enzymatic detergent was used to validate this process per the manufacturer's dilution recommendation.

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BIOMET 3i™ Recommended Cleaning And Sterilization Procedures For Surgical Instrumentation (continued)

General Observations:	
Cleaning	Prevent blood from drying on the instrument by cleaning it as soon as possible after use. If timely cleaning is not possible, presoak the instrument. Enzymatic cleaners digest blood proteins and tissue faster than ordinary cleaners. Before sterilization, clean the instrument in a non-corrosive, low sudsing neutral detergent; ultrasonic cleaning is preferred. Completely cover instruments in a liquid bath. To prevent spotting, instruments should be rinsed under a steady stream of water after ultrasonic cleaning. All instruments should by dried completely and stored in a moisture-free environment. Failure to do so may result in corrosion or staining.
Handling	A new stainless steel instrument has a thin, highly corrosion resistant layer of chromium oxide. Removal of the layer due to use (i.e. friction) or improper handling (i.e. scratching) can increase the chance of corrosion. End of life for surgical instruments is normally determined by wear and damage. Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid compromising the intended performance of the instrument. Visually inspect each instrument before and after each use for damage and/or wear.
Staining	Staining is the result of a deposit on the instrument, such as spotting from water in the autoclave, or it can develop from within the instrument due to factors such as oxidation. In general, most stains occur during the sterilization cycle and are usually the result of inadequately maintained sterilizers, contact with harsh detergents or chemicals and processing with dissimilar metals.

Ultimately, care and maintenance are directly related to the lifespan of the instrument. As a result, instrument audits are recommended to identify pitting, chips, cracks, scratches and dull cutting edges that can contribute to corrosion and staining.

Do not leave instruments in cleaning or sterilization solution for extended periods of time.

Troubleshooting Guide For Stainless Steel

Problem	Cause	Prevention
Spotting	Insufficient rinsing.	Rinse with running water for one to two minutes.
	Insufficient drying after ultrasonic cleaning.	Rinse with hot water. Follow with alcohol rinse to remove soap residue.
	Contaminated solutions.	Ultrasonic solutions should be changed at least once per day.
	Sterilizer has not been cleaned.	Clean sterilizer weekly. Use only distilled water.
Pitting	Chemical attack on instruments.	Rinse and dry thoroughly. Use approved cleaning solutions only.
	Corrosion from dissimilar metals.	Separate stainless steel, carbon steel and aluminum during cleaning and sterilizing. Dip carbon steel in surgical milk.
	Disruption of oxide layer.	Handle instruments with care. Do not use instruments that show wear.
	Improperly maintained autoclave.	Clean and flush water lines and disinfect inner chamber.
Rust	Contaminated sterilizer.	Clean and flush sterilizer weekly.
	High alkaline detergents.	Use neutral pH solutions.
	Dried blood.	Rinse instruments thoroughly.
	Acid reaction from low pH detergents.	Avoid contact with incompatible solutions.
	Mixing dissimilar metals during cleaning and sterilization.	Separate carbon steel, aluminum and stainless steel.
	Chromium oxide stains from excessive heat.	The protective layer has been damaged and the component should no longer be used.

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