General Guidelines to **the Management of Surgical Tools**

1/ All surgical tools are delivered in a non-sterile condition, and therefore must be cleaned, disinfected and sterilized before use.

WARNING

Incorrect cleaning, disinfection or sterilization of tools may lead to damage or corrosion, and the use of such tools may cause secondary contamination.

2/ The recommended drill cycle life is 20-30 cycles based on the bone thickness. Drill must be replaced when there is distortion or wear on the blades.

WARNING

Drilling the bone with a defected or damaged drill can lead to thermal necrosis.

3/ Mask and gloves must always be worn when handling surgical tools to prevent infection.

Before Sterilization

1/ Immediately soak in antiseptic solution after use, to prevent the attachment of blood, tissue or bone residue on the tool surface.

2/ When using antiseptic solution, check the concentration and soaking time based on the instructions provided by the manufacturer to prevent corrosion and discoloration.

CHECK

Concentration : Make sure to fully dissolute the concentrated solution before soaking the tools.
Soaking time : Do not leave the tools in the solution for more than 24 hours.

3/ Fully immerse the tools into the solution.

4/ Replace the antiseptic solution daily in order to prevent corrosion and low disinfection performance.

Before Rinsing

Tools must be rinsed under cold running water to prevent drying or clotting of protein on the surface at 45°C or above.

WARNING

Clean the tools immediately after pre-rinsing.

1 Disinfection

1/ Only use CE certified or FDA approved sterilizing fluids and comply with the guidelines or instructions provided by the manufacturer.

2/ Use of antiseptic or cleaning solution is recommended for all metal tools.

3/ Wear protective gear such as gloves, goggles and mask for safety and personal protection.

4/ The user is responsible for the sterilization and management of tools.

5/ Limits and restrictions in in the use of reusable tools:

· Regular cleaning can shorten the lifespan of surgical tools and may cause defects such as fractures, distortion, corrosion or discoloration of the markings. Such defects indicate that the tool no longer qualifies for its purpose, and does not meet the required safety standards.

· Products that are labeled as disposable, CANNOT be reused.

· Tools composed of tungsten, carbide bur, plastic or NiTi can be damaged from contact with hydrogen peroxide, while aluminium tools can be damaged from caustic soda solution.

· Do not use PH<6 acid solution or PH>8 alkali solution.

WARNING

Risk of corrosion is high for tools that have contaminants such as blood or bone residue remaining on the surface. Therefore, disassemble all tools before initiating the cleaning process.

2 Cleaning & Drying

1/ Use a soft brush to remove all contaminants and dirty substances.
(Do not put too much pressure onto the surface while brushing, and do not use wire or stainless brushes)

2/ Immerse the product into the antiseptic solution according to the cleaning purpose and use a UC for ultrasonic cleaning.
BUT, do not clean with other tools that are different material to avoid damage.(To avoid the risk of damage to tools from contact or collusion if cleaned together)

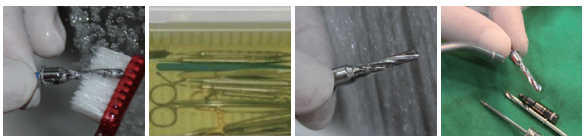
3/ Any dirty or foreign substance should be not be visible to the naked eye after cleaning is completed.

- **Fractured or distorted products must be disposed.**
- **Users must comply with the general recommended guidelines regarding concentration and soaking time provided by the manufacturer.**
- **To prevent the corrosion of tools, the sanitizing fluid must not contain any aldehyde or Di-or triethanolamine components.**

4/ Rinse the tools with distilled or desalted water for more than 1 minute after washing.
(If the sterilizing fluid contains corrosion inhibitors, it is recommended that tools are rinsed before inserting them into the autoclave)

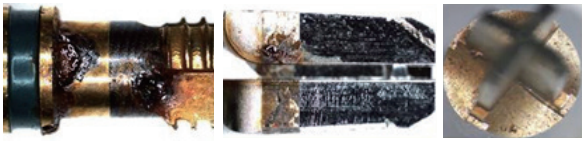
5/ Dry the tools completely by using a drying cabinet or filtered compressed air to prevent water stains or corrosion.

6/ Fill up the sanitizing fluid tank daily to avoid corrosion, contamination and low disinfection performance.



WARNING

If the tools are not rinsed properly and have residue substances remaining on the surface, or are not dried completely, there may be discoloration or corrosion during the next steam sterilization process. Therefore, it is important to redo the whole procedure again in order to prevent damage to the tools.



WARNING

Corrosion may occur if residual substances such as blood or bone residue is not completely removed after use of tool.
Clean the tools immediately after use and completely remove any residual substances on the surface.

CHECK

Check the tools and drill flutes for any fractures, distortions or corrosions.
Assemble the tools if necessary.
Re-clean and sterilize tools that are contaminated or dirty.
Tools that are distorted (bent or curved), damaged (fractured or corroded) or defected (discoloration or fading of the markings) and can have impact on the safety, performance or tolerance of the tool must be disposed.

3 Packaging

1/ Check if the tools are completely dried and pack them in a sterilization packaging.

2/ Attach a sterilization indicator label to the packaging to check the sterilization status and date.
Check the expiry date of the sterilization packaging provided by the manufacturer. The packaging must be resistant to up to 140°C according to the EN ISO11607 requirements

4 Steam Sterilization

1/ Steam sterilization must be conducted in compliance to the instructions provided by the manufacturer.
※4-18 mins at 134°C for autoclave sterilization.

2/ Tools and plastic components must be steam sterilized according to the packaging label.
- Autoclaves must comply with the EN13060 and EN285 requirements.
- The maintenance and steam sterilization procedures must comply with the instructions provided by the manufacturer.
- Manage the efficiencies such as proper packaging, no humidity, color change in the autoclave gauge etc.

WARNING

- **The product must not touch the inside surfaces of the autoclave, and the steam sterilization temperature must be below 150°C.**
- **Tools that are not cleaned or dried properly can be corroded. Disassemble the tools or remove the connections of parts that are not cleaned or dried properly or are corroded. (Do not sterilize the corroded tools with the other tools together)**
- **Only use salt free water or distilled water for the sterilization solution. (Do not use tap water)**

5 Stock

Tools must be kept in a sterilized container and stored in a dry and clean environment. The sterilization status of the tool may be at risk if the packaging is torn or damaged.