

General Instructions

Clean and sterilize non-sterile instruments in accordance with the validated procedures provided below prior to first use and prior to each reuse.

Cleaning and Sterilization Instructions

Scope

These instructions are applicable to all SS White Dental rotary dental instruments (burs, diamonds, files). They are applicable before initial use, and after each subsequent use. Rotary dental instruments are provided mechanically clean, but not sterile (unless labeled “STERILE”). It is the user’s responsibility to sterilize instruments before the first use and if applicable, before each additional use. Instruments indicated as non-sterile single use should be processed following these guidelines before the initial use only and then properly discarded.

Warnings

1. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Cleaning agents with neutral pH are recommended.
2. Do not use Cold Sterilizing Methods for the sterilization of rotary dental instruments. These agents often contain strong oxidizing chemicals that may dull or weaken rotary dental instruments.
3. Used rotary instruments, damaged sterile packaging and unintentional open packaging shall be considered contaminated. Follow appropriate pre-cautions by utilizing this recommended sterilization guideline.
4. Also, personal protective equipment (PPE) including gloves, mask and eye protection should be worn. Further controls may be required if specific patient risks are present.

Reprocessing Limitations

The end of life is determined by wear and damage in use. Rotary dental instruments should be inspected for defects (i.e. broken tips, broken sections on flutes, etc.) during the cleaning process.

Point of Use

Delay in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.

Containment/ Transportation

Rotary dental instruments can be transported wet or dry and should be protected from damage. If transported wet there is an increased chance of staining or corrosion. Prolonged storage in disinfectant solutions may result in degradation of the product and must be avoided.

Manual Cleaning Procedure

If hand cleaning is the only available option, rotary dental instruments should be cleaned in a sink reserved for cleaning instruments.

Rinse the instrument (and dedicated instrument block, if applicable) under cool running water for at least one (1) minute.

Prepare a fresh bath of neutral-pH cleaning solution. Follow the cleaning agent’s manufacturer’s instructions. Immerse the instrument (and instrument block) and soak for at least ten (10) minutes.

After soaking, and keeping it immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel.

Special care should be taken to clean crevices and other hard-to-reach areas thoroughly. Visually inspect to confirm the removal of debris. Repeat the cycle if needed.

Thoroughly rinse the instrument (and instrument block) under running warm water for at least one (1) minute and until visibly clean.

Dry the instrument using a non-shedding wipe or clean compressed air.

Automated Cleaning Procedure

Rinse the articles under running water to remove excess contamination.
Transfer the test articles into the washer for processing.

STAGE	RECIRCULATION TIME (MINUTES)	TEMPERATURE	DETERGENT TYPE AND CONCENTRATION (IF APPLICABLE)
Pre-wash	02:00	Cold tap water	N/A
Wash 1	02:00	43°C Tap water	Enzymatic or Alkaline detergent prepared at the manufacturer's recommendation
Neutralization Wash	02:00	43°C Tap water	Neutral pH detergent prepared at the manufacturer's recommendation
Rinse 1	01:00	43°C Tap water	N/A
PURW Rinse	01:00	43°C RO/DI water	N/A
Dry Time	10:00	115°C	N/A

Visually inspect to confirm the removal of debris. Repeat the cycle if needed.

Dry the instrument using a non-shedding wipe or clean compressed air.

Inspection Testing

- Carefully inspect each instrument to ensure that all debris has been removed.
- Visually inspect the instrument for damage/ wear that would prevent proper operation.
 - Do not use if the tip is broken.
 - Do not use if there is a broken section of a flute.
 - Do not use if there is evidence of corrosion.

Packaging

Single: Pack the rotary dental instrument in pouches validated for sterilization

In Sets: Place the rotary dental instrument in the dedicated instrument block.

Sterilization

Use the following cycle for steam sterilization

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)
Gravity	30	121°C (250°F)	30
Pre-Vacuum	4	132°C (269°F)	30
Pre-Vacuum	3	134°C (273°F)	30

Ensure that the sterilizer manufacturer's maximum load is not exceeded. The minimum dry time has been validated to ensure that the devices will not be left wet. Failure to achieve the minimum dry time may cause moisture to remain on the burs that could result in corrosion.

Storage

After sterilization, store instruments in a dry, clean, and ambient temperature environment in the sterilization pouch (or instrument block) until required.

Additional Information

These processes have been validated as being capable of preparing SS White Dental rotary dental instruments for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.

Validation

These processes have been validated on SS White Dental rotary dental instruments. Following these instructions along with the instructions of the equipment utilized remains the responsibility of the user. Proper steps should be taken to ensure all equipment is operating safely and properly in accordance with manufacturer's guidelines. Any deviation from these guidelines may require subsequent validation and monitoring for effectiveness and potential risks. Results are maintained by SS White Dental.



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Batch Code

Operating Instructions

Autoclave at specific temperature

Recyclable

Catalog Number

Use by Date

Do not use if package is damaged

Importer

Manufacturer

Do not re-use

Caution

Medical Device

Date of Manufacture

Sterilized using irradiation

Authorized European Representative

Translation

CE 0413