

ITL Dental Stainless- Steel Drills, Drivers and Instruments IFU & Cleaning Instructions

Note: ITL Dental has no control over the use of its products, which are the responsibility of the user. ITL Dental assumes no liability whatsoever for damage arising thereof.

These instructions apply to: Stainless Steel drills, drivers and instruments supplied unsterilized by ITL Dental and intended for reprocessing in a dental care clinical setting. All ITL Dental stainless- steel instruments may be safely and effectively reprocessed, by trained personnel, using the cleaning instructions and sterilization parameters provided in this document UNLESS otherwise noted in instructions accompanying a specific instrument. It is the responsibility of the end user/dental care provider to ensure that the instruments are used for the intended use as stated below. The ITL Drills and Drivers are meant to be used with dental implants. End users should follow any additional local and/or international regulations regarding cleaning of stainless- steel instruments.

Cautions/warnings: While the stainless instruments do not stay in the mouth long enough to cause serious health issues, it is possible complications associated with use of the instruments and or procedure could occur, such as allergic reaction to the instruments, temporary pain, swelling, loss of bone or bone is cracked/breaks. In case of damage during the procedure, is it possible that infections, and/or nerve damage could occur.

Step Drills, made of a high- grade stainless steel, are intended to be used in dental surgery to create channels of appropriate depth and diameter in a patient's bone (osteotomy) of the oral cavity to enable the implantation of a dental implant. The step drills are coated to improve the visualization of the score lines and to increase cutting lubricity. They are available in 7 diameters. The sizes are color coded in order for the clinical end user to easily identify the drills. It is recommended that the last drill (yellow) in the sequence is used for dense bone situations. For soft bone, all drills except the last drill in the sequence would be recommended. Drill stops are available and may be used. ITL Dental does not recommend the handpiece source that provides the rotation.

Latch style drivers: A non-powered tool with an ISO 1797-1 connection intended to fit into a screw head for the application of rotation to introduce/remove a screw/dental implant from a patient, in association with a restorative procedure. It may also be used to connect/disconnect a device from another device attached to a patient.

Cleaning instructions: Put on protective clothing, including disposable apron/gown, face shield/mask, and gloves which should be used when cleaning the instruments. Once the cleaning has stopped, dispose of the protective clothing.

Cleaning Process:

- Have a dedicated separate washing and rinsing area preferably with deep sinks located in a designated dirty zone.
- Cleaning of ITL Dental instruments is done manually.
- For instrument cleaning a neutral or near-neutral pH detergent should be used.
- Remove organic materials by rinsing the instruments under warm (not hot) running water.
- Brush instruments carefully with a nylon cleaning brush.
- After scrubbing, rinse instruments thoroughly under running water.
- Use non-shedding and disposable cloths for cleaning and drying equipment.
- Dry instruments to prevent carryover of contaminated wash water into the sterilizer.
- Visually inspect instruments for residual debris or blood after cleaning and repeat if necessary.

IMPORTANT: PRIOR TO USE WITH PATIENTS, FOLLOW THE INSTRUCTIONS TO AUTOCLAVE CLEANED INSTRUMENTS: Reference: ANSI/AAMI TIR12:2010

Type:	<u>Gravity Steam</u>	<u>Gravity Steam</u>	<u>Prevacuum Steam</u>
Exposure Time and Temperature	30 minutes at 121° (250°)	15 minutes at 132°C (270°F)	4 minutes at 132°C (270°F)
Minimum Dry Time	30 minutes	30 minutes	20 minutes

- Do not use ultrasonic devices with torque wrenches
- Do not autoclave for extended periods of time (i.e. overnight)
- Extended autoclaving should not be confused with repeated autoclaving
- Repeated autoclaving will not harm the product