

ITL Dental IFU for Stainless Steel Drills and Reusable Dental Instruments

Warning: Dental instruments sold by ITL Dental are to be used only by the clinician (dentists, doctors and/or operators) trained in the usage of said instruments. ITL Dental assumes no responsibility for incorrect usage of said instruments and any harm it may cause due to misuse. It is the clinician's responsibility to determine whether or not a particular product is suitable for a particular application and circumstance. ITL Dental disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages arising out of any errors in professional judgment or practice in the use of ITL Dental products. Users are advised and obliged to study the latest industry news and training regarding the use of the instruments.

These instructions apply to: Stainless Steel reusable instruments and accessories which are supplied unsterilized by ITL Dental and intended for usage in a dental care clinical setting. All ITL Dental stainless steel instruments and accessories may be safely and effectively reprocessed using the cleaning instructions and sterilization parameters provided in this document UNLESS otherwise noted in instructions accompanying a specific instrument and/or per the recommendation of the manufacturer of the sterilizer.

It is the responsibility of the end user/dental care provider to ensure that reprocessing is performed using the appropriate equipment, materials and that personnel have been adequately trained. In addition, any maintenance instructions, included with the instrumentation, should be followed to assure safe and effective usage. End users should follow any additional local and/or international regulations regarding cleaning of stainless steel instruments.

EU Representative:

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Contraindications: Include but are not limited to: hypersensitivity and/or an allergic reaction to the material (stainless steel) uncontrolled diabetes, clotting disorders, anti-coagulant therapy, metabolic bone disease, chemotherapy or radiation therapy, chronic periodontal inflammation, insufficient soft tissue coverage, metabolic or systemic disorders associated with wound and/or bone healing, use of pharmaceuticals that inhibit or alter natural bone remodeling, any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene.

1. General Suggestion Cleaning Preparation

- Before cleaning the instruments, the staff-in-charge should put on the following protective clothing:
- Disposable apron/gown/gloves
- Face shield or face mask
- Household gloves

2. Suggestion Cleaning Process:

- Brush instruments carefully with a nylon cleaning brush with soap and water or use a disinfectant wipe.
- 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.
- Steam sterilize for 20 minutes at 135°C (275°F)

3. Cautions:

- Do not exceed 275° F (135° C)
- Do not submerge in any solution
- Do not use ultrasonic devices
- 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