

Instruction for use

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1 Introduction

These instructions for use and safety recommendations are to be strictly observed. Non-observance of these instructions may lead in increasing the risk of injury and impair the proper function of the devices. The devices are intended for dental use only.

The instruments are sold in unsterile condition and should be cleaned, disinfected and sterilised prior each application.

The instruments are multi use so they can be re-used. However, it is the sole responsibility of the doctor using the instruments to decide whether, depending on the respective case and the potential wear and tear of the products, he can re-use the products and how frequently he uses them.

2 Storage

Prior to the first use, the device should be stored in its original packaging at room temperature in dust and humidity-free conditions. This will maintain the useful life of the devices. As re-usable instruments the useful life depends on their wear and tear.

After sterilisation, the devices need to be stored in sterilisation wrapping in a dry and dust-free place. Please note that the shelf-life of the sterilisation state of the device depends from the validation of the sterilisation wrapping. After expiration of the defined date the devices need to be re-sterilised.

3 Cleaning and disinfecting

Warning:

- Do not use alcohol or solvent for cleaning purposes.
- Do not clean the CSTT in ultrasonic bath with other instruments.

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. A manual procedure (even in case of application of an ultrasonic bath) should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered.

When choosing an appropriate cleaning and disinfecting agent you need to ensure

- fundamental suitability for the cleaning and disinfection of instruments made of metallic/zirconia material.
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA clearance or CE marking) compatible with the used cleaning detergent.
- avoid aggressive products (hydrochloric acid, hydrogen peroxide...), they may corrode the instruments.

Manual Cleaning and disinfection procedure:

Immediately place used instruments in a special anti-corrosive disinfectant bath for a short time.
Clean the instruments in an ultrasonic bath (not with other instruments) or under running water.
Rinse the instruments at least 1 min under running water (temperature < 35°C / 95°F).

Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

Automated cleaning/disinfection (disinfector/ WD (Washer-Disinfector)):

Please consider the following points during selection of the WD:

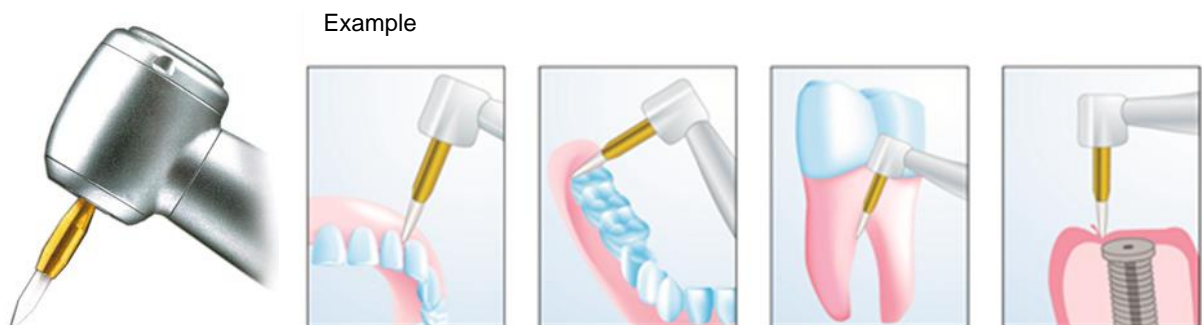
- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA clearance)
- possibility for an approved program for thermal disinfection (A0 value ≥ 3000 or – in case of older devices - at least 5 min at 90°C / 194°F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water - only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

4 Sterilisation

Before sterilization, place the instruments in stands and trays suitable for sterilization.

Sterilize the instruments. Autoclave: 18 min. 134°C, 2 bars.

5 Use



Warning:

To be used without any water / spray cooling.

CSTT (Ceramic Soft Tissue Trimmer) is used under rotation in the air turbine (300'000 – 500'000 min⁻¹). Correctly used the kinetic energy causes a heat-coagulating effect without « burning » the tissue. Do not use under the recommended speeds, lower speeds may cause injury and must be avoided. When using the CSTT, avoid excessive contact to tooth or bone tissue.

Applications

1. CSTT as a soft tissue trimmer

- Gingival modelling
- Laceration of interradicular granulation tissue
- Removal of gingival hyperplasia/papillectomies
- Exposure of intraosseous implant sections and retained teeth

Before using the CSTT any blood and pus must be rinsed away and the area must be dried by a cotton sponge or by the air-syringe. The tip of the CSTT must be moved through the tissue with small «brushstroke» movements in a 30 - 45° degree, not forcing the tip of the trimmer in the tissue or cutting too deep in only one cut.

2. Supplementary application: opening of the sulcus

The CSTT is moved in the sulcus with an even slow sliding motion of the necessary depth. To avoid any tissue loss, it is important to preserve the epithelium of the marginal gingiva.

Using the CSTT correctly, with all its applications, you will find that the CSTT is often able to replace not only electro-surgery and surgical blades, but in many cases also the use of retraction cord.

6 Disposal

Disposal in compliance with national and local legal regulations.