

TN-Brush

A Device description

TN-Brush is made of Nickel-Titanium shape memory alloy and stainless steel for single patient use and is attached to a dental hand-piece. It is used during open flap surgery to remove biofilms (plaque and calculus) from the surfaces of dental implants where the surface of the implant is exposed due to peri-implantitis. The TN-Brush mechanically removes the biofilms from the surface of the implants without damaging the integrity of the toughened implant surface.

B Indications

TN-Brush is a debridement instrument for titanium dental implants subjected to perimplantitis. It is indicated for the open debridement of titanium implant surfaces in bone defects caused by peri-implantitis.

C Contraindications

- TN-Brush is contraindicated in clinical situations where dental surgery should NOT be performed.
- TN Brush should not be used on unstable dental implants.

D Caution

- TN-Brush is packaged sterile and must be used immediately after opening of the blister packaging in an aseptic surgical environment.
- The Instrument is for single patient use only.
- TN-Brush is provided being sterilized by gamma radiation. Do not re-sterilize. Reuse of TN-Brush may lead to cross-contamination and / or infection.
- The product should be used in standard dental hand-pieces at a speed of 500-800 rpm.

E Precautions

- TN-Brush must be used by licensed practitioners properly trained in oral Implantology.
- TN-Brush is designed for single patient use. Do NOT re-use. Reuse of TN-Brush may lead to cross contamination and/or infection.
- TN Brush must NOT be used if the sterile package is opened or damaged.
- As with any surgical procedure, Infection is a risk. Use sterile intra-operative technique.
- The following complications are common with the surgical intervention for peri-implantitis and therefore may not be totally excluded: Soft tissue dehiscence, hematoma, pain, Inflammation, Irritated sensitivity and redness.
- When using TN Brush intraorally, always take measures to prevent it from being inhaled or ingested.
- Do not touch or damage the supraconstruction with the device.
- Avoid damaging the bristles prior to use.
- Avoid using a reciprocal hand-piece which oscillates in a front to back motion.
- Caution should be used to minimize contact with hard or soft tissue.
- Please read the instructions carefully prior to the surgery.

F Instruction for use

- 1 Visually inspect the package and its contents for damage before opening the blister. Open the package shortly before surgery to avoid contamination.
- 2 Genoss recommends removing the prosthetic supraconstruction prior to using TN-Brush.
- 3 Remove excessive granulation tissue around the implant with a sterile titanium curette.
- 4 Using sterile intra-operative technique, open the package and remove the TN-Brush with sterilized tweezers. Avoid damaging the bristles.
- 5 Attach TN-Brush to a surgical reciprocal oscillating hand-piece limited to 800 oscillations per minute to avoid damaging the integrity of the titanium surface of the implant. The oscillating motion should be clockwise/ counterclockwise.
- 6 Debride the implant surface using physiological sterile saline solution (NaCl) or Ringer solution to irrigate and cool the treatment site.
- 7 Rinse the treatment site repeatedly with saline solution to wash away the debris.
- 8 If using the TN-Brush in multiple sites, it is recommended to immerse the TN-Brush in a 3% hydrogen peroxide solution and rinse with sterile saline solution between treatment sites.

G Storage & Stability

TN-Brush must be kept in original packaging during storage.

H Symbols

REF	Catalogue number	STERILE R	Sterilized using irradiation
LOT	Batch code	EC REP	Authorized representative in the European Community / European Union
MD	Medical Device		Date of manufacture
UDI	Unique device identifier		Manufacturer
CE 2195	CE Mark		Distributor
	Do not re-use		Consult instructions for use or consult electronic instructions for use
	Do not use if package is damaged and consult instructions for use		Use-by date
	Do not re-sterilize		Single sterile barrier system with protective packaging inside

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