parkell GentleClean™ 30KHz Soft-Grip Ultrasonic Insert

Instructions for Use

■ DSG30GC, DSG30GCW, DSG30GCT



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CAUTION: NON-STERILE, STERILIZE BEFORE USE.

Rx Only-product is intended for use by a licensed dental professional. This manual, in whole or in part. should not be considered a substitute for formal training in ultrasonic scaling.

NOT RETURNABLE IF OPENED.

If necessary to return insert, please use a shipping box, not an envelope or padded mailer.

IMPORTANT: Parkell's ultrasonic Inserts are designed to operate with Parkell-compatible magnetostrictive ultrasonic scalers.

Description:

Parkell's GentleClean™ Ultrasonic Insert is designed for cases where traditional metal tips may cause damage or discomfort. It delivers moderate cleaning power through a single-use, disposable tip, which is threaded onto the insert. The tips must be autoclaved before use. The tip wrench must be autoclaved between patients. The tip will not remove hard, longstanding deposits from teeth. For that, a conventional metal-tipped insert should be used.

Indications for Use:

For plague and light calculus deposit removal around:

- Metal implants and implant abutments
- · Orthodontic wires, brackets, and bands
- Inflamed edematous tissue of highly sensitive patients

Warnings:

· Never run a GentleClean insert without ample water. This may result in overheating and/or disposable tip breakage.

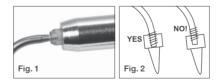
 NEVER reuse disposable tips. They are for single patient use only. Discard after use.

Cautions

- Do not use the GentleClean insert above scaler's "medium" power setting.
- · The GentleClean insert has been designed for use with Parkell's disposable tips. Do not use tips from other manufacturers
- · While scaling, avoid direct contact between the tip and lips, cheek, and tongue. Failure to do so may result in injury or slight burn of soft tissue.

Attaching the Tip:

Place an autoclaved GentleClean Tip into the autoclaved tip-changing wrench (Fig. 1) and thread it clockwise onto the working end of the insert until the threads are almost entirely covered (Fig. 2). Do not over-tighten, which may strip the plastic threads. To remove, turn the tip counterclockwise with the wrench, withdraw it from the insert, and properly dispose of the tip.



Cleaning and Sterilization:

· Autoclaving does not remove debris that has accumulated on the GentleClean Insert. Failure to adequately remove debris will result in inadequate sterilization. Rinse the Insert under warm running water for 30 seconds to remove any external or internal soil or debris. Using a soft soapy cleaning

brush to assist in the cleaning, if necessary, Use non-ammoniated detergent or dishwashing soap. Do not use ammoniated cleansers or disinfectants. Rinse the devices again under warm running water for 30 seconds to remove any residual soap and blot dry with a dry lint-free towel. Wipe the Insert with a lint-free towel that has been saturated in an EPA-approved, hospital-grade intermediate or highlevel disinfectant (minimum 2.5% Glutaraldehyde solution), following the instructions for use provided by the disinfectant manufacturer. Dry the devices with a dry lint-free towel.

 The GentleClean Insert, disposable tips and tip wrench may be sterilized in any conventional steam autoclave following manufacturer's instructions. A typical steam sterilization cycle is 132 +/- 2°C for 4 mins. (Vacuum) or 132 +/ -2°C for 15 mins. (Gravity). followed by a 15 minute minimum cool-down period. Use a steam sterilization pouch that is compliant with ISO 11140-1 Type 4 and ISO 11607-1 standards. Once items are sterilized, adhere to the shelf-life specifed by the pouch manufacturer. After sterilization. inspect the device in the autoclave bag for integrity. If suspicion about the item exists, discard it and order a replacement from Parkell or your dealer.

Warranty and Terms of Use:

For full Warranty and Terms of Use information, please go to www.parkell.com, Safety Data Sheets (SDS) are available at www.parkell.com. Parkell's Quality System is certified to ISO 13485.

Questions?

Please e-mail our Technical Support Service at: techsupport@parkell.com

Explanation of Symbols Used:

R	Professional use only
1	Follow instructions for use
1	Temperature limit
*	Store product tightly sealed away from direct sunlight.
132 4/- 2°C	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
*	• Keep dry
Z	Do not dispose this product into the ordinary municipal waste or garbage system
NOW STEARLE	Non-Sterile
	Package contents
SN	Serial number
LOT	Batch code
REF	Catalogue / stock number
UDI	Unique Device Identifier
MD	Medical Device
	Do not use if package is damaged

