parkell' Turbo**V**ue.

Instructions for Use

Light-Transmitting Ultrasonic Insert

A00768revE0123

Parkell, Inc., 300 Executive Dr., Edgewood, NY 11717 USA +1-800-243-7446 • www.parkell.com

C E 1639

EN

CAUTION: INSERTS AS PACKAGED ARE NOT STERILE AND MUST THEREFORE BE STERILIZED BEFORE FIRST 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 TurboVue® Light-Transmitting Ultrasonic Inserts will only provide the benefit of a bright white light to the operating field when used with Parkell's TurboVue® Ultrasonic Scaler.

TurboVue® inserts may also function in other 30K insert comparable scalers but will lose their illumination feature. Compatibility with non-Parkell scalers is not guaranteed.

Device Description:

Parkell's 30K TurboVue® magnetostrictive ultrasonic inserts are designed for illumination of the treatment site when used in conjunction with a TurboVue scaler.

Indications for Use:

- All general supra and subgingival scaling procedures.
- · Periodontal debridemetnt.

Contraindications:

• Do not use any type of ultrasonics on amalgams, composites, gold, or porcelain.

- Do not use any type of ultrasonics on white spot lesions.
- · Do not use for restorative procedures.

Scaler Power Settings for TurboVue[®] Inserts:

Up to maximum power:

- TurboVue® Triple-Bend (EF DLH30TRI)
- TurboVue® Universal Tip V (REDLH30U)
- TurboVue® Burnett Power-Tip V (№ DLH30T)

Up to medium power:

• TurboVue® Straight Perio Tip V (I DLH30P)

Precautions:

- Do not bend or reshape insert. Inserts should always be handled with care. Ultrasonic insert tips that have been bent, reshaped, or otherwise damaged are susceptible to in-use breakage and should be discarded and replaced immediately. Changing the original shape of the insert voids the warranty.
- Make sure the insert's green O-ring is in place before each use and lubricate it with water prior to inserting into the handpiece using a "twisting" motion. Replace worn, damaged, or missing O-rings with Parkell (@DORING-GR)
- During scaling procedures, all intra-oral soft tissues should be protected to avoid contact with the vibrating tip.
- To avoid gouging the tooth, keep the tip parallel to (not perpendicular to) the tooth's long axis. Use a controlled wiping motion, with copious water irrigation.
- Do Not attempt to poke the insert through the sterilization bag after autoclaving. This could bend the stack and will affect the performance.

Cleaning and Sterilization:

Inserts must be carefully scrubbed to remove debris. 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 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 detergent or dishrectants. Rinse the Insert again under warm running water for 30 seconds to remove any residual soap and blot dry with a dry lint-free towel. Wipe Insert with a lintfree towel that has been saturated in an EPA-approved, hospital-grade intermediate or high-level disinfectant (minimum 2.5% Glutaraldehyde solution), following the instructions for use provided by the disinfectant wanufacture. Drv Insert with a dry lint-free towel.

Sterilize in a steam autoclave only. Place bagged instruments into the steam autoclave, paper side up when using a paper/plastic pouch.

Pouch should be compliant with ISO 11140-1 Type 4 and ISO 11607-1 standards. Once items are sterilized, adhere to the shelf-life specified by the pouch manufacturer.

Suggested Cycles:

- Gravity Displacement: 15 minutes @ 132 +/-2°C; 15 minutes cool down.
- Prevacuum: 4 minutes @ 132 +/-2°C; 15 minutes cool down.

Warranty and Terms of Use:

For full Warranty and Terms of Use information, please go to 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
\mathbf{O}	Follow instructions for use
1	Temperature limit
*	 Store product tightly sealed away from direct sunlight.
112 ++ 2°C	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
X	 Do not dispose this product into the ordinary municipal waste or garbage system
NON	Non-Sterile
	Package contents
SN	Serial number
LOT	Batch code
REF	Catalogue / stock number
UDI	Unique Device Identifier
MD	Medical Device
$\textcircled{\begin{subarray}{c} \hline \hline$	Do not use if package is damaged
	• Manufacturer