CAUTION: NON-STERILE. STERILIZE BEFORE USE. NOT RETURNABLE ONCE OPENED.

parkell®

DuraTip®

Curved Perio Slim Magnetostrictive Ultrasonic Insert

Instructions for Use

REF DURA30-PSL, DURA30-PSR

A01257_**revA0525**

MADE IN USA

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Rx Only MD	Product is intended for use by a licensed dental professional.

Device Description

Parkell DuraTip® Curved Perio Slim Magnetostrictive Ultrasonic Inserts are designed for use with all major manufacturer's 30KHz magnetostrictive ultrasonic scalers. DuraTip inserts, unlike any other inserts currently available, are uniquely designed to maintain a consistently high level of efficiency for a full 3 mm of tip wear.

Includes

- (1) DuraTip Curved Perio Slim Insert
- (1) Colored Performance Guide that matches Grip(s)

Indications for Use

Used for ultrasonic procedures including;

- All general supra and subgingival scaling procedures
- Periodontal debridement

Contraindications

- Do not use on amalgams, composites, gold, or porcelain.
- Do not use on white spot lesions.
- Do not use for restorative or endodontic procedures.

Warnings

- Handle all inserts with care. Improper handling may result in injury and/or cross contamination.
- Insert is NOT sterile when shipped and must be autoclaved before first use.
- Failure to follow properly validated sterilization processes may result in cross contamination.
- Inserts with tips that have been bent or reshaped should be discarded to avoid possible in-use breakage.

Precautions

It is the responsibility of the Dental Healthcare Professional to:

- Operate the inserts only at the recommended power settings.
- Avoid contact of the vibrating tip with intraoral tissues.
- Not bend or reshape insert tips. Ultrasonic insert tips that have been bent, reshaped, or otherwise damaged, are susceptible to in-use breakage and should be immediately discarded and replaced.
- Verify that the green O-ring is in place before use. Lubricate the O-ring with water before inserting the insert into the handpiece.
- When inserting the insert into the handpiece, always use a twisting motion.
- Replace any worn or missing O-rings with a Parkell approved replacement part (REF DORING-GR).

Adverse Reactions

None known.

Residual Risks

- Manually bending tips may result in in-use breakage and possible injury.
- Failure to follow proper handling procedures or not properly drying the insert may cause insert to stain, corrode, or clog.
- Improper handling of insert, especially the tip, may result in:
  - Injury to the patient and/or the clinician.
  - Insert damage.
- Failure to follow proper sterilization procedures may result in cross contamination.
- Not properly handling O-rings according to these instructions could potentially cause leaking, and/or inability to properly seat the insert into handpiece.

Unit Power Setting

DuraTip Curved Perio Slim Left and Right inserts may be used up to maximum power.

Operating Instructions

1. Select the proper insert for the teeth/root surfaces being treated.
2. Fill the handpiece with water according to the scaler manufacturer's instructions.
3. Lubricate the O-ring with water.
4. Gently twist the insert while inserting into handpiece until it is fully seated.
5. Begin by always using the lowest power setting based on the patient's clinical condition.
6. Adjust the water (lavage) control for a rapid drip flow or light spray at the tip.
7. Take hold of the insert using a pen or modified pen grip.
8. For stabilization and better control while scaling, always use a suitable intraoral or extraoral finger fulcrum.
9. The insert tip should be adapted so that the point is not directed into the tooth or root surface.
10. Always maintain a light, smooth, gentle pressure (touch) against the tooth surface.
11. Always keep the tip of the insert in motion, using overlapping horizontal and vertical strokes.
12. The inactivated insert tip can also be used to explore and evaluate the tooth surfaces.

Infection Control Procedures

- All devices (including Performance Guide) should be cleaned and sterilized before each use.
- When a three-step process is required, where disinfection is necessary prior to sterilization, all devices must be cleaned, disinfected, and sterilized before use.
- Disinfection alone is not an acceptable method for reprocessing between patients.

Limitations on Processing

- Repeated processing should have minimal effect on the inserts when done correctly.
- Always use neutral pH instrument cleaning or disinfecting detergent solutions. The inserts can be damaged by use of alkaline and acidic detergents.
- Failure to follow the cleaning solution's recommended concentration rates and contact times may result in rapid deterioration of the insert grip as well as other insert components.
- Cold liquid disinfection/sterilization, chemical vapor sterilization, and dry heat sterilization have not been tested or validated and should not be used.

Point of Use (Post-Treatment)

- The ultrasonic insert must be removed from the handpiece before processing.
- Residue or any other form of contamination must not be allowed to dry on the insert. All excess soil/gross debris must be removed by rinsing under running water.
- The insert should be removed from the treatment area and reprocessed, as soon as practical, following use.

Mechanical Cleaning (Ultrasonic Cleaners)

- Follow manufacturer's instructions for instrument cleaning solution, observing concentration rates and contact times.
- May be cleaned using an ultrasonic water bath for up to 15 minutes. May use a non-ammoniated detergent or mild soap.
- When using cassettes, to avoid insert damage, make sure the cassette does not put excessive pressure on the insert stack or tips.
- Remove the instruments from the ultrasonic cleaning bath and rinse under warm running water for 30 seconds to remove any cleaning agents.
- Inspect instruments for visible debris. Manually remove any debris using a nylon brush with a cleaning solution. Rinse the instrument under warm running water for 30 seconds to remove any cleaning agents.
- Dry the insert using a dry, disposable cloth or use a dental instrument dryer. An insert left wet, may stain, corrode, or clog.

Manual Cleaning

- Prepare an enzymatic pH neutral instrument cleaning solution per manufacturer's instructions, paying attention to concentration rates.
- Fully immerse the inserts in the instrument cleaning solution for the recommended contact time.
- Rinse the instrument under warm running water for 30 seconds.
- Inspect instruments for visible debris. Manually remove any debris using a nylon brush with a cleaning solution. Rinse the instrument under warm running water for 30 seconds to remove any cleaning agents.
- Dry the insert using a dry, disposable cloth or use a dental instrument dryer. An insert left wet, may stain, corrode, or clog.

Maintenance, Inspection and Testing

- Visually inspect insert to assure all contamination has been removed.
- Visually inspect O-rings for wear. Replace worn O-rings with Parkell approved parts.
- Lubricate O-rings before use.
- Check for damaged inserts.
- Check for tip wear using the appropriate Performance Guide for the selected insert style and shape.

Sterilization of Insert

Steam Sterilization Cycles	Sterilizing Temperature	Sterilizing Cycle Time
Dynamic Air Removal	270°F/132°C	4 Minutes
Gravity Displacement	270°F/132°C	15 Minutes

Bagged Inserts

- Place an insert in a paper or paper/plastic steam sterilizer pouch. Place the paper side up when using a paper/plastic steam sterilizer pouch. Place the bagged insert(s) into the steam sterilizer and run the cycles listed above based on the type of sterilizer being used. The sterilization cycle is followed by a 20–30-minute drying time.
- To maintain sterility, the insert(s) should remain in the sealed pouch(es) until ready for use.

Unbagged Inserts

- Place the insert(s) on a tray or in a cassette into the steam sterilizer and run the cycles listed above based on the type of sterilizer being used. The sterilization cycle is followed by a 20–30-minute drying time.
- When using cassettes, make sure the cassette does not put excessive pressure on the insert stack or tips that might cause damage.
- Use the insert immediately.

Using The Performance Guide* to Check for Tip Wear

- DuraTip insert Performance Guides (included with every insert) are color coded to correspond to the color of the grip of the insert.
- While DuraTip inserts maintain a consistently high level of efficiency, and provide optimal scaling performance throughout their life, it is always important to regularly check for wear so the insert can be removed from service at the appropriate time. ***The recommended interval for wear measurements is once per week.***

How to Use Performance Guide

1. "Left" or "Right" refers to the direction the tip bends. Hold the insert with the tip point facing away from you—if the bend goes left, it's a LEFT insert; if it goes right, it's a RIGHT insert **(Figure 1)**
2. Position the tip into the Left-Right Performance Guide, being sure the tip lays in the proper cutout. **(Figure 2)**
3. Be sure the tip is flat against the guide.
4. Evaluate the tip for wear. If the end of the insert tip extends beyond the border of the 3 mm measurement groove **(Figure 3)**, it has not yet reached 3 mm of wear and will continue to operate at peak efficiency.
5. If the end of the tip does not extend fully across the 3 mm indicator groove **(Figure 4)** or is flush with the left side of the groove, or is short of the groove, the tip has reached 3 mm of wear and should be removed from service and replaced.

Performance Guide Precautions

- To avoid unintended injury from pointed/sharp insert tips, use appropriate precautions while measuring wear.
- Always keep fingers away from the end of the tip when measuring.
- Do not take measurements post-treatment when the insert tip is contaminated. Measurements should only be taken pre-treatment, when the insert and Performance Guide are removed from their corresponding sterilization pouches.

Performance Guide Maintenance and Reprocessing

- Performance Guides are NOT sterile when shipped and must be autoclaved before first use.
- After each use the Performance Guide can be cleaned of debris with an EPA-registered low-level to intermediate-level hospital disinfectant then placed in a paper or paper/plastic steam sterilizer pouch. Place the paper side up when using a paper/plastic steam sterilizer pouch into the steam sterilizer and run the cycles listed below based on the type of sterilizer being used. The sterilization cycle is followed by a 20–30-minute drying time.
- To maintain sterility, the Performance Guide should remain in the sealed pouch until needed.

Sterilization of Performance Guide

Steam Sterilization Cycles	Sterilizing Temperature	Sterilizing Cycle Time
Dynamic Air Removal	270°F/132°C	4 Minutes
Gravity Displacement	270°F/132°C	15 Minutes

Disposal

Dispose of inserts in accordance with state and local laws.

Fig.1

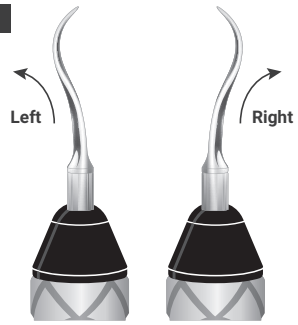
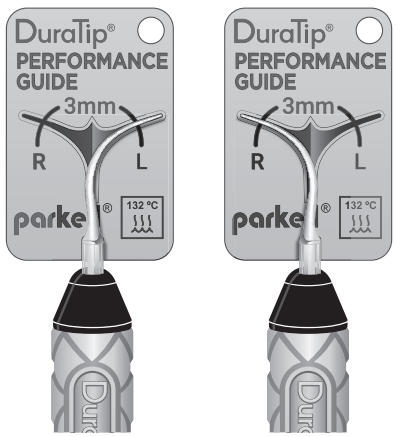


Fig.2



Explanation of Symbols Used

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

Fig.3

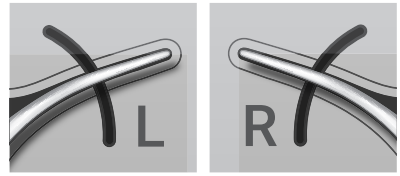
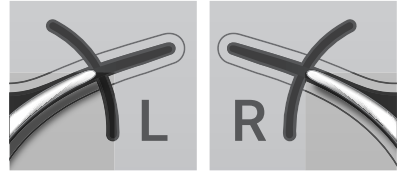


Fig.4



** This Performance Guide is intended for general reference purposes only. It is the responsibility of the user to decide when an insert should be replaced based on their own professional judgement. Measurements obtained with the guide may vary due to variations in manufacturing and user handling of both the insert and the guide. The guide is not suitable for inserts that have been used improperly or have damaged or altered tips.*