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Profin® LAMINEER TIPS

LTA and EVA Tips
Instructions for Use

CE 2862 MD Rx Only
www.dentatus.com/ifu

EN INSTRUCTIONS FOR USE — ENGLISH

Prior to initial use - always read the instructions for use. These instructions inform the user about the recommended procedures when using the Lamineer Tips with the Profin Directional System. They are intended for use by clinicians with basic training in dentistry. It is the responsibility of the clinician to stay informed, educated and trained. The printed guidelines, including Precautions and Notes, are to be regarded as additions to accepted clinical procedures and protocols. Profin System is a motor driven contra-angle handpiece and tips for mechanical finishing, cleaning and polishing of dental surfaces.

This IFU is available for download on our website: www.dentatus.com/ifu.
Also available on our website are instructions and reprocessing information for the Profin PDX.
Follow the instructions in the instructions for use. The instructions are validated by the manufacturer.

Material	**LTA Tips**: Stainless steel, diamond or tungsten (wolfram) plating, plastic shanks. **EVA Tips**: plastic.
Intended Purpose	**Profin PDX** is a motor driven contra-angle handpiece used with tips for mechanical finishing, cleaning and polishing of dental surfaces, used with: • **LTA Tips**: for finishing and polishing of tooth and dental prosthetic materials. • **EVA tips**: in combination with prophy paste for adjusting and polishing of tooth structure and dental prosthetic materials maintenance.
Intended User	Licensed Dentists and Hygienists.
User Environment/ Clinical Setting	Dental clinic.
Patient Population Group	**Profin PDX** • **LTA tips**: for patients undergoing restorative dental treatment (adolescent and permanent teeth). • **EVA tips**: for patients in need of oral hygiene maintenance or dental implant cleaning (adolescent and permanent teeth).
Expected Clinical Benefit	Profin together with LTA & EVA Tips can be used for shaping, finishing and polishing of natural teeth or dental restorations and cleaning and polishing of dental surfaces and dental implant maintenance.
Performance Charactertistics	**Profin PDX** • **LTA tips**: can be used for shaping, finishing and polishing of natural teeth or dental restorations. • **EVA tips**: can be used together with a polishing paste for cleaning and polishing of dental surfaces and dental implant maintenance.
Indications for Use	**Profin PDX** • **LTA tips**: for restorative dental treatment. • **EVA tips**: for oral hygiene maintenance or dental implant cleaning.
Contraindications	For patients with known allergy to nickel, LTA Tips shall be used with caution.
Safe Disposal	Dull tips shall be disinfected, then can be disposed of in normal waste in the clinic according to local regulations.
Accessories	EVA-60 Plunger.

⚠ Warnings
Any serious incident that occurs in relation to this device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
Allergens
• For patients with known allergy to nickel, LTA Tips shall be used with caution.
Small Objects
• Before starting: check for a secure seating by pulling the tip with your fingers. A firm resistance shall be sensed. If the tip comes out easily, try another tip or send the handpiece in for service.
Vibration
• Discomfort for patient and dentist if speed is lower than 5,000 rpm.
Thermal
• Do not exceed 10,000 rpm.

Precautions
Cross-contamination
• Clean, disinfect and sterilize the handpiece and LTA tips before first use and between uses.The PDX and all LTA tips are delivered factory clean.
• Disinfect the EVA-tips before first use.
• Do not re-use the EVA-tips. They cannot be disinfected properly.
Thermal
• Verify the recommended rpm on the motor before using the handpiece.
• Lubricate the handpiece between each use, debris can cause clogging and excessive friction.
Malfunction
• Do not disassemble any part of the handpiece.
• Lubricate the handpiece between each use, debris can cause clogging and excessive friction.
Working Tips
• LTA & EVA tips are a part of the Profin System and are not intended to be used without the Profin PDX or PDH.
• Use Profin EVA-60 plunger to safely eject the LTA or EVA tips from the Profin head.

Technical Description - *Lamineer Tips*

Movement of working tip	Reciprocating 1,2 mm axial stroke.
Maximum motor speed	10.000 rpm.
Recommended speed	Lamineer & EVA Tips: 5.000-10.000 rpm.
Torque	Depending on the torque of the motor.
Variation of tip movement	*Free-floating:* Self steering for polishing procedures. *Fixed postion:* Locked in piston for more control in creating anatomical corrections to esthetic alignments.

Table 1

LTA Lamineer Tips For Shaping, Finishing And Polishing Of Teeth And Dental Restorations

Catalog No.	Coating	Shank Color	Shape	Description
LTA-150/2	Diamond	Red	Spatula	Removal of gross overhangs and shaping of all restorative material - use tips with large particle size (150-75µ).
LTA-S150/2	Diamond	Red	Knife Edge	
LTA-100/2	Diamond	Green	Spatula	
LTA-S100/2	Diamond	Green	Knife Edge	
LTA-75/2	Diamond	Gold	Spatula	For shaping and polishing all prosthetic materials and enamel (75-50µ).
LTA-S75/2	Diamond	Gold	Knife Edge	
LTA-50/2	Diamond	Yellow	Spatula	
LTA-S50/2	Diamond	Yellow	Knife Edge	
LTA-30/2	Diamond	White	Spatula	Final polishing - use tips with small particle size (30-15µ).
LTA-S30/2	Diamond	White	Knife Edge	
LTA-15/2	Diamond	Violet	Spatula	Tungsten Carbide does not scuff enamel. For final finishing of composite filling margins. (LTA-39 & LTA S36)
LTA-S15/2	Diamond	Violet	Knife Edge	
LTA-39/2	Tungsten	Black	Spatula	
LTA-S36/2	Tungsten	Black	Knife Edge	
LTA-E50/2	Diamond	Yellow	Concave	For occlusal and concave surfaces.
LTA-C50/2	Diamond	Yellow	Shoulder/Bevel	For finishing shoulders, bevels etc.
LTA-D150/2	Diamond	Red	Paddle	For shaping diverging surfaces and incisal edges.
LTA-D100/2	Diamond	Green	Paddle	
LTA-D50/2	Diamond	Yellow	Paddle	
LTA-D30/2	Diamond	White	Paddle	
LTA-T50/2	Diamond	Yellow	Saw Blade	For opening incisal and gingival, approximal areas.
LTA-T30/2	Diamond	White	Saw Blade	

Table 2

EVA Tips For Polishing With Polishing Paste (Single Use Plastic Tips)

EVA-2000/100	Plastic	Green	Universal tips, only used freely rotating. Use with appropriate polishing paste
EVA-5000/100	Plastic	Blue	

Table 3

The LTA Tips are intended for re-use and should be thoroughly cleaned, disinfected, and sterilized after each use. The wearing of the diamond plating is low. Durability is dependent on the circumstances in which they're used. The end of life is determined by wear and damage in use. Tips should be inspected for defects during the cleaning process (under magnification). Carefully inspect each instrument to ensure that all debris has been removed. Visually inspect the instrument for damage/wear that would prevent proper operation. Do not use if the tip is broken. Do not use if there is evidence of corrosion. Do not use if there is evidence of excessive wear (i.e dull).

Lamineer Tips Reprocessing Instructions *(in accordance with ISO 17664-1:2021)*

WARNINGS	Use chemicals suitable for diamond coated stainless steel instruments.	
Limitations on processing	See inspection below.	
INSTRUCTIONS		
Initial treatment at the point of use	Soak in solution. If debris remains use a cleaning stone suitable for the diamond instruments. The maximum period of time between start of use and start of cleaning process shall not exceed 2 hours.	
Cleaning: Manual	*Equipment* *Detergent* *Water Quality* *Instructions*	Soft bristle brush & ultrasonic bath. Enzymatic or low-alkaline (pH≤8) detergent with minimal foaming characteristics. Follow agent manufacturers recommendations for concentration and temperature. Minimum drinking water quality should be used for manual cleaning and distilled or de-mineralized water for ultrasonic bath and final rinse. 1. Immerse tips in freshly prepared cleaning solution as per manufacturer's instructions although maximum 40°C. Clean mechanically with a brush, working beneath the liquid level, until visibly clean. 2. Rinse thoroughly. 3. Clean in an ultrasonic bath for a minimum of 5 minutes at maximum 60°C, using a frequency of 35-45 KHz and power min. 150 W. 4. Rinse thoroughly for min. 30 seconds. 5. Carefully dry tips with lint free wipes or clean compressed air (Class 1 or better, according to ISO 8573-1:2010). 6. Inspect cleanliness. If necessary, repeat from step 1. If debris remains on the tips after cleaning, use a cleaning stone suitable for diamond instruments during step 1.
Disinfection: Manual	*Equipment* *Detergent*	Disinfection bath. Immerse into disinfection solution suitable for instruments of stainless steel. Follow the manufacturer's instruction of disinfection solution for concentration and time.
Cleaning & Disinfection: Automated	*Equipment* *Detergent* *Rinsing Agent* *Water Quality* *Instructions*	Washer-disinfector (validated according to EN ISO 15883-1:2006/Amd 1:2014). Enzymatic or low alkaline, suited for medical devices. Non-corrosive, neutral rinsing agent, suited for medical devices. Follow agent manufacturer's instructions regarding concentration and temperature. Minimum drinking water quality should be used for cleaning and distilled or de-mineralized water for final rinse/disinfection. 1. Load the tips in the washer-disinfector. Use a suitable instrument tray. 2. Run program suited for surgical instruments. Validation performed with following parameters: - Pre-wash in cold water, 2 x 2 min. - Main wash with detergent at minimum 55°C, 10 min. - Rinse in warm water, 2 x 1 min. - Final rinse/disinfection in de-mineralized water at 90°C, minimum 1 min. - Drying at 110°C, minimum 15 min. 3. When unloading, visually confirm that the instruments are clean. If necessary, repeat from step 1 or use manual cleaning.
Inspection and Maintenance	The product should be replaced when its functioning and/or performance no longer satisfies the specifications in this manual. Visually inspect the tips for diamond coating appearance to determine abrasiveness of the tip. Discard the tip when diamond coating is worn out.	
Packaging for Sterilization	Standard packaging pouch. Sterile goods packing according to EN 868-5:2018-5. 1) Place in individual sterilization pouches. 2) Check that the bag is not stretched. 3) Check correct sealing. Place pouches plastic towards plastic and paper towards paper.	
Sterilization	*Caution* *Equipment* *Temperature/ Pressure* *Time* *Vacuum Drying*	The tips must be cleaned and disinfected before sterilization. Steam autoclave (validated according to EN 13060:2014/Amd 1:2018, EN 285:2015/Amd 1:2021, EN 17665-1:2006). Run minimal cycle: Steam temperature/pressure min. 134°C (273°F) / 3.06 bar (27psi). Steam exposure time minimum 3 min. Vacuum drying minimum 6 min.
Storage	Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.	

Table 4

Symbols Glossary

LOT	Lot number	Rx Only	Prescription use – for use by dental clinicians only
⚠	Caution, consult accompanying documents	REF	Reference/catalog number
CE	CE mark		Right revolution (clockwise rotation) at the speed specified
	Consult instructions for use	SN	Serial number
	Date of manufacture	134°C	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Do not reuse		Ultrasonic bath
	Manufacturer	UDI	Unique device identifier
MD	Medical Device		Washer-disinfector for thermal disinfection

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