



Premier® Ultrasonic Inserts

US Premier® Ultrasonic Inserts
 ES Boquillas ultrasónicas Premier®
 FR Inserts ultrasoniques Premier®



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Made in U.S.A.

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Premier® Ultrasonic Inserts

Intended Use:

The Ultrasonic Inserts are intended for use by medical professionals during dental cleaning and periodontal therapy to remove calculus and tartar deposits and stains from teeth using the application of an ultrasonically vibrating tip.

Use of any ultrasonic device is not recommended in cases where the operator or the patient has been fitted with a cardiac pacemaker.

Product Description:

Ultrasonic Inserts are precision-crafted instruments designed to facilitate the removal of calculus and tartar from teeth surfaces. With their ergonomic design, these inserts are easy for dental professionals to navigate the contours of teeth, ensuring thorough cleaning even in hard-to-reach areas while minimizing patient discomfort.

Contents:

Big Easy Inserts		Item No.	
Premier® Ultrasonic Inserts	Big Easy®	Thin-Tip 25K	1005320
		Thin-Tip 30K	1005330
		Triple Bend 25K	1005305
		Triple Bend 30K	1005315
		Universal 25K	1005300
		Universal 30K	1005310
Resin Grip Inserts		Item No.	
Premier® Ultrasonic Inserts	Resin Handle	IF-100 - Thin Tip 25K (Red)	1006820
		IF-100 - Thin Tip 30K (Red)	1006920
		IF-1000 - Triple Bend 25K (Red)	1006802
		IF-1000 - Triple Bend 30K (Purple)	1006901
		IF-50 - Universal 25K (Orange)	1006800
		IF-50 - Universal 30K (Yellow)	1006900

Implant Inserts	Item No.
Premier® Ultrasonic Inserts Big Easy® Implant 30K	1005336

Materials:

- Handle Material: Silicone/Resin
- Tip Material: 17-4PH Stainless Steel, PEEK

Contraindications:

Do not use Premier Ultrasonic Inserts in cases of:

- Patients with unshielded pacemakers, communicable diseases, respiratory issues, and other medical conditions.
- Patients with advanced periodontal disease.
- Patients with demineralized teeth or softened tooth structures.
- Not intended to be used as a tool to assist other restorative, surgical, operative, or similar dental procedures.

Precautions:

- Do not use if the product is broken or damaged prior to use.
- Only use the Implant insert on titanium implants or associated prostheses.
- Do not bend or reshape insert tip and or stacks. Inserts should be handled with care at all times.
- Ultrasonic Inserts tips or stacks that have been bent, reshaped or otherwise damaged are susceptible to in-use breakage and should be discarded and replaced immediately.
- Before each use, inspect the ultrasonic insert for any signs of damage, bending, wear, or corrosion.
- Use caution when operating a thin tip insert at excessive amplitude (power).
- Adequate personal protective equipment such as gloves, masks, and eye protection are recommended for both the operator and patient.
- Caution should be exercised when using ultrasonic instruments near dental restorations (crowns, bridges, veneers, implants) to prevent damage.
- Inspect, clean, and sterilize prior to each use.
- Rx only, Prescription device.

WARNINGS:

- Do not use tips which have bent or worn exceeding 2mm per the wear guide.
- Do not use insert which has a bent or distorted stacks.
- Never operate a system without water flowing through the handpiece.
- Do not use ultrasonic inserts on exposed dentin or tooth roots.
- Do not use metal tip inserts on titanium implants or associated prostheses.
- Do not expose inserts to temperatures above 177°C (350°F) exceeding manufacturer's recommendations.

Adverse Reactions:

- Sensitivity and discomfort in the treated area can occur, especially in areas of exposed dentin surfaces or if excessive force is applied.
- Improper use of ultrasonic inserts may cause damage to teeth, gums, or dental restorations.
- Overusing the device in a single area may lead to discomfort or damage to dental tissues.

If a serious incident has occurred in relation to the device, please report the incident to the Manufacturer and/or competent authority of the Member State where the device was used.

Directions for Use:

- Select the appropriate tip design and frequency based on the specific treatment requirements and the patient's condition. Note: Different tips may be required based on the anatomical location, size, and type of deposits.
- When the tip of the ultrasonic insert becomes worn, it prevents effective functioning and becomes susceptible to breakage. Replace inserts if tip wear decreases the size and clinical accessibility from their original state.
- Before usage, it is recommended to flush the water lines leading to the ultrasonic insert and fill the handpiece with water to achieve optimal results.
- Place the Ultrasonic insert into the power unit and ensure the insert is functioning as intended and there is a proper flow of water.
- Position the tip of the ultrasonic insert at the desired angle, keeping it parallel to the tooth surface.
- Gently place the vibrating ultrasonic insert on the tooth surface, angling it at approximately 45 degrees to the tooth axis.
- Apply gentle pressure and utilize a sweeping motion to eliminate calculus and tartar deposits. Avoid prolonged contact with the same spot to prevent enamel damage.
- Periodically rinse the area to remove debris and maintain a clear view of the tooth surface prior to continued use of ultrasonic insert.
- If any O-rings are damaged or torn, it's important to replace them before use.

Proper Placement of Replacement O-Rings:

Proper placement of O-rings will significantly extend the life of the O-rings and provide better ultrasonic scaling. During

installation, the O-ring should be protected from the sharp edges of the insert stack.

- Take a new O-ring and position it on a standard drinking straw with a diameter of 1/4", leaving about 1 inch of straw at the end.
- Carefully slide the straw around the insert stack, starting with the O-ring-end of the straw.
- Gently slip the O-ring from the straw into the designated groove, then discard the straw.
- Before usage, ensure the insert is sterilized. It's important to use the provided O-rings for your ultrasonic inserts as other O-rings might not be the correct size.

Cleaning

After each use, ensure a complete cleaning of the ultrasonic insert.

- Thoroughly rinse the insert to clear away any debris or material.
- If required, utilize a gentle cleaning brush with soapy water to aid in the cleaning process.
- Do not place in ultrasonic bath. Ultrasonic Inserts can be placed within an automated cleaner when placed into a cassette.
- Avoid the use of phenols, bleaching agents, or cold disinfectant solutions.

Sterilization:

Sterilize prior to each use. Use a steam autoclave. Premier® Dental has independently validated their instruments to be sterile when using a pulsed pre-vacuum steam sterilization process for five (5) minutes at 134°C (273°F).

- Do not expose inserts to temperatures above 177°C (350°F) exceeding manufacturer's recommendations.
- Do not use Rapid Heat Transfer (dry heat) sterilization method.
- Do not use the cold sterilization method.
- Do not sterilize in 100% plastic sterilization pouches. Only sterilize in approved sterilization pouches.

Storage:

- Store the ultrasonic insert in a clean and dry environment.
- Avoid storing it in a manner that could lead to contamination or damage.

Warranty:

Premier® Ultrasonic inserts are warranted for 90 days against manufacturer's defect from the date of original purchase. The return must be accompanied by a written description of the claimed defect. In addition, a warranty claim must be accompanied by a dated sales receipt or other appropriate documentation showing the date of purchase. In the event of a warranty claim, it is the responsibility of the user to return the defective insert(s) to Premier Dental Products Co.

For Further Information:

To obtain IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbols:

A full explanation of symbols used on Premier Dental packaging and literature is located at premierdentalco.com/symbol-glossary

Symbols	Symbol Meaning
	Date and Country of Manufacturer
	Manufacturer
	Batch number
	Catalog number
	Caution: See instructions for use
	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Non-Sterile
	Do not use if package is damaged

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Uso previsto:

Las boquillas ultrasónicas están indicadas para que las utilicen profesionales médicos durante la limpieza dental y el tratamiento periodontal para eliminar los depósitos de sarro y las manchas de los dientes mediante la aplicación de una punta vibratoria ultrasónica.

No se recomienda el uso de dispositivos ultrasónicos en casos en los que al operador o al paciente se le haya colocado un marcapasos cardíaco.

Descripción del producto:

Las boquillas ultrasónicas son instrumentos fabricados con precisión y diseñados para facilitar la eliminación de sarro de las superficies de los dientes. Con su dise-

ño ergonómico, estas boquillas facilitan a los profesionales dentales el desplazamiento por los contornos de los dientes, lo cual garantiza una limpieza minuciosa incluso en zonas de difícil acceso, y al mismo tiempo minimiza las molestias al paciente.

Contenido:

Boquillas Big Easy	Número de artículo
Punta fina 25K	1005320
Punta fina 30K	1005330
Triple flexión 25K	1005305
Triple flexión 30K	1005315
Universal 25K	1005300
Universal 30K	1005310

Boquillas de agarre de resina	Número de artículo
IF-100: Punta fina 25K (rojo)	1006820
IF-100: Punta fina 30K (rojo)	1006920
IF-1000: Triple flexión 25K (rojo)	1006802
IF-1000: Triple flexión 30K (morado)	1006901
IF-50: Universal 25K (naranja)	1006800
IF-50: Universal 30K (amarillo)	1006900

Boquillas de implantes	Número de artículo
Boquillas ultrasónicas Premier® Big Easy® Implante 30K	1005336

Materiales:

- Material del mango: silicona/resina
- Material de la punta: acero inoxidable 17-4PH, polietileno tereftalato (PEEK)

Contraindicaciones:

No utilice las boquillas ultrasónicas Premier en casos de:

- Pacientes con marcapasos sin protección, enfermedades contagiosas, problemas respiratorios y otras afecciones médicas.
- Pacientes con enfermedad periodontal avanzada.
- Pacientes con dientes desmineralizados o estructuras dentales ablandadas.
- No está indicado para utilizarse como herramienta para ayudar a otros procedimientos restauradores, quirúrgicos, operatorios o procedimientos dentales similares.

Precauciones:

- No utilice el producto si está roto o dañado antes de utilizarlo.
- Utilice la boquilla de implante únicamente para implantes de titanio o prótesis asociadas.
- No doble ni cambie la forma de la punta ni el caño de la boquilla. Las boquillas deben manipularse con cuidado en todo momento.
- Las puntas o los caños de boquillas ultrasónicas que se hayan doblado, cambiado de forma o dañado de cualquier otro modo pueden romperse durante el uso y deben desecharse y reemplazarse de inmediato.
- Antes de cada uso, inspeccione la boquilla ultrasónica para detectar cualquier signo de daño, doblamiento, desgaste o corrosión.
- Tenga cuidado al utilizar una boquilla de punta fina con una amplitud excesiva (potencia).
- Se recomienda un equipo de protección personal adecuado, como guantes, mascarillas y protección ocular, tanto para el operador como para el paciente.
- Tenga cuidado al utilizar instrumentos ultrasónicos cerca de restauraciones dentales (coronas, puentes, carillas, implantes) para evitar daños.
- Inspeccione, limpie y esterilice antes de cada uso.
- Dispositivo de venta bajo prescripción médica (Rx only).

ADVERTENCIAS:

- No utilice puntas dobladas o desgastadas más de 2 mm según la guía de desgaste.
- No utilice boquillas que tengan caños doblados o deformados.
- Nunca haga funcionar un sistema sin que el agua fluya a través de la pieza de mano.
- No utilice boquillas ultrasónicas en la dentina expuesta ni en las raíces de los dientes.
- No utilice boquillas de punta metálica en implantes de titanio o prótesis asociadas.
- No exponga las boquillas a temperaturas superiores a 177 °C (350 °F) que superen las recomendaciones del fabricante.

Reacciones adversas:

- Pueden producirse sensibilidad y molestias en la zona tratada, especialmente en zonas de superficies de dentina

