Ultrasonic Insert

Replacement for Cavitron®

by Johnson-Promident

Sterilize before using.

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Caution: U.S. Federal law restricts this device to sale by or on order of a dentist

Warranty for three (3) months from purchase date of this product against manufacturing defects.

Johnson-Promident Ultrasonic Scaler Inserts

DEVICE DESCRIPTION

J-P Ultrasonic inserts are accessory inserts designed for use with magnetostrictive scaler units, (see specifications) that generate a frequency of either 25KHz or 30KHz.

A Range of tip designs are available to suit different clinical conditions. Finger-grips are either plastic or metal and the water channel is either of internal or external design.

These inserts are designed to be used in magnetostrictive ultrasonic scalers only by professionally trained operators such as Dental Hygienists to perform general supra and subgingival scaling procedures.

Internal water channel with plastic finger-grip

Tip Design	Application
#3 Flat	Heavy to moderate supragingival deposits on buccal and lingual surfaces.
#10 Universal #100	Heavy to moderate supragingival deposits, light to moderate subgingival deposit on all surfaces
#1000 3 Bend	Light to moderate supragingival deposits especially interproximally.

External water channel with metal finger-grip

Tip Design	Application
#10 Universal	Heavy to moderate supragingival deposits, light to moderate subgingival deposit on all surfaces
#100 Universal	Light supragingival deposits on all surfaces.

WATER FLOW

An adequate water flow setting, indicated by a small spray or rapid drips, should be selected for the power setting used, so as to prevent overheating of the insert tip during function, and to prevent possible injury.

INSTRUCTIONS FOR USE

Ensure that the frequency (25K or 30K) of the scaler unit is suitable for this insert. Always sterilize prior to each use (see sterilization instructions). Always use a light, smooth, gentle touch with a well positioned stable intraoral or extraoral fulcrum. The lateral surface of the insert is normally used for clinical procedures.

In the event that this insert is dropped or damaged or becomes bent, discard the insert and replace with a new insert. Inserts with high usage, which exceed the warranty period, should be discarded to avoid in-use breakage and possible injury. these inserts should not be used for other procedures including condensation of amalgam.

Care must be excercised to avoid iatrogenic results from the use of ultrasonics in the presence of dental restorations. Mote that the tip end or other sharp aspect of an insert can scratch or otherwise modify the surface of gold or amalgam restorations. Thin porcelain veneers and composite margins can be cracked or crazed by activated ultrasonic tips.

Normal wear of the tip occurs during function. When approximately 2 mm of the tip has worn, the insert may lose up to 50% efficiency, and should be discarded. Contact with composite restorations will cause more rapid attrition of ultrasonic inserts.

O-RINGS

Before placing inserts into the handpiece performing the following steps will increase "O" ring life.

1. Fill entire handpiece with water.
2. Lubricate o-ring (black or green material) with water
3. Gently twist the insert down into the handpiece until fully seated.

UNIT POWER SETTINGS

#100 inserts should be used with minimum power setting only on the unit
#10, 1000 & #10 inserts should be used on low - medium power setting.
#3 inserts may be used on medium - high power setting.
As a rule the power setting on the unit should always be set at the minimum and increased only as directed by clinical requirements.

STERILIZATION

This J-P Ultrasonic Scaling Insert should be autoclaved at 134°C for 7 min. at 2.1 Bar, before initial use and after treatments. This procedure has been validated according to USP 24 and ISO 11135 standards. Suitable autoclaving packaging is recommended to preserve this item sterile until required for use. As the heat distribution in commercial autoclaves can vary, it is recommended to place the insert on a shelf that is not located next to the autoclave heating element. Cold liquid disinfection/sterilization and rapid heat transfer (dry heat) sterilization methods will adversely affect the insert and may void the warranty. Inserts should be scrubbed either manually or cleaned in an ultrasonic bath to remove debris, and dried thoroughly prior to autoclaving.

SPECIFICATIONS

These inserts are designed for 25k or 30k magnetostrictive scaler handpieces with: Internal diameter of 7.3mm.
Internal length of no less than 125mm.

CE DECLARATION (CE 0344)

This unit meets the provisions of the Council Directive 93/42EEC concerning medical devices. It is classified as a Class IIa device according to rule 5 of annex IX of the MDD.
Conformity assessment was according to Annex VII and is marked CE0344 certified by KEMA.

LIMITED WARRANTY

This ultrasonic insert has been manufactured to meet stringent quality assurance requirements. If, in normal use, any insert is found to be defective in material or workmanship within a period of ninety (90) days from the date of original purchase, it will be replaced, or at J-P's option, the purchase price will be refunded.

The limited warranty stated herein is the sole and exclusive warranty with respect to the insert, and J-P hereby disclaims any and all other warranties,expressed or implied, including, without limitation, any statutory warranties or any warranties of merchantability, fitness for use or fitness for any particular purpose. J-P will not be responsible for any inconvenience, loss, injury, or direct, indirect, tort, exemplary, punitive, special incidental or consequential damage arising from the possession or use of the insert. In no event will J-P's liability exceed the purchase price of the insert.

Tampering, abuse, misuse, neglect, alteration, accidental damage, failure to follow manufacturer's instructions, improper disinfection or sterilization procedures, bending, re-grinding or re-shaping, or lack of reasonable care with respect to the insert will void this warranty. Use of the insert by anyone other than a licensed dental practitioner or qualified hygienist will void this warranty.

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 Johnson-Promident.

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