FPO Label/UDI

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EC REP

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Schiffgraben 41

0425



Definition Product reference number Batch or Lot code Use-by Date Caution: Federal Law restricts this device to sale by or on the order of a dentist

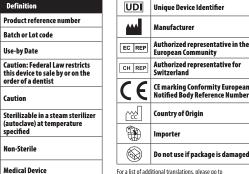
Caution

specified

Non-Sterile

Medical Device

Translations of Symbols



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	BUC° Non-Surgical Ultrasonic Endodontic Instruments							
	930-041		930-04	12	930-043			
e	930-046		930-048		930-049			
-	BUC-E° Non-Surgical Ultrasonic Endodontic Instruments							
4	932-018	93	2-019	932-02	0	932-024		
n er	CPR-E° Non-Surgical Ultrasonic Endodontic Instruments							
	932-001	93	2-002	932-00	3	932-004		
\dashv	932-005	93	2-006	932-00	7	932-008		
d	CPR° Non-Surgical Ultrasonic Endodontic Instruments							
u	930-011	93	0-012	930-01	3	930-014		
	930-015	93	0-016	930-01	7	930-018		

DEE

KiS® Ultra	sonic E	ndodo	ontic Inst	rum	ents
931-011	931-	931-012		931-013	
931-015	931-	931-016		952-614	
KiS-E° Ultr	asonic l	Endod	ontic Inst	rum	ents
932-011		932-01	12	93	2-013
932-014		932-01	15	93	2-016

Obtura Spartan Instructions for Use - Ultrasonic Tips Intended Use

Ultrasonic tips are used by dental professionals for the removal of material from outside or inside of the tooth for endodontic or periodontal applications.

KiS® Ultrasonic Endodontic Instruments

All KiS instruments can be used at an Intensity Setting of Medium - High. It is recommended that new users of these instruments begin use on low to medium power until they become familiar with the cutting efficiency of these instruments.

KiS-1: Angled 80-degrees at the working end, with a 0.5mm diameter x 3.0mm cutting surface. KiS-2D: Similar to the KiS-1, with a 0.7mm diameter x 3.0mm cutting surface for larger diameter roots.

KiS-3D: A double angled, 75-degree instrument designed for use on the buccal root of the mandibular right molar and mesial buccal of the maxillary left molar, 0.5mm diameter of 3.0mm cutting surface.

KiS-4D: A double angled, 110-degree instrument designed for use on the lingual root of the mandibular left molar and distal buccal of the maxillary right molar. 0.5mm diameter x 3.0mm cutting surface.

KiS-5D: A mirror image of the KiS-3D, for use on the buccal roots of the mandibular left molar and mesial buccal of the maxillary right molar, 0.5mm diameter x 3.0mm cutting surface.

KiS-6D: A mirror image of the KiS-4D, for use on lingual roots of the mandibular right molar and distal buccal of the maxillary left molar. 0.5mm diameter x 3.0mm cutting surface.

KiS-1D4: Angled 80-degrees at the working end, with a 0.5mm diameter x 4.0mm cutting surface larger than

Reprocessing Limitations: Tips have been tested to withstand 250 reprocessing cycles per ISO 18397 without deterioration in performance or signs of corrosion both internally and externally. The end of life is determined by the wear and damage in use as well as reprocessing cycles. Ultrasonic Tips should be inspected for defects during the cleaning and sterilization process. Damaged or broken tips should no longer be used.

Disposal: Dispose of damaged or broken ultrasonic tips in a sharps container.



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Obtura Spartan Ultrasonic Tips are designed to function with most ultrasonic scalers that use M3 X 0.6 threading. Obtura Spartan also offers all of their tips with M3 X 0.5 threading in their E series of ultrasonic tips. Refer to your ultrasonic machine owner's manual for further details on the use of these types of devices. Using force to install a tip with improper threading will cause damage to the ultrasonic device. An appropriate ultrasonic tip wrench may assist in securing tips to scalers. Obtura Spartan Ultrasonic Tips are contra-angled for improved procedural access to both anterior and posterior teeth. The following are guidelines for the

various uses of Obtura Spartan Ultrasonic Tips. The

operator should be aware that ultrasonic tips with small

diameters are subject to breakage at any time. To reduce

very light pressure should be applied by the operator, and

the incidence of premature breakage or failure, only a

the suggested intensity settings should be followed.

Sterilization Instructions - Ultrasonic Tips: The Ultrasonic Tip should be kept in original packaging in a dry and dust-free location prior to sterilization. Cleaning and sterilization validated in accordance with ISO 17664-1 and ISO 17665-1 standards. Tips are not sold sterile, and should be cleaned and sterilized prior to each use. Proper Personal Protective Equipment (PPE) should be utilized during cleaning and sterilization as well as normal use and handling of these devices. 1. Cleaning — Prior to cleaning and sterilization, tips should be disconnected from any handpiece to which they are connected. Pre-clean using a high-quality, pH neutral, ultrasonic cleaning solution. Follow solution

manufacturer's instructions. Dry thoroughly with

2. Steam Sterilization — For long-term tip storage,

place the tips to be sterilized in the tip taxi, then in an

autoclave pouch prior to sterilization. The tips do not

immediate use and can be placed solely in the tip taxi

require an autoclave pouch if they are intended for

clean cloth.

following parameters:

BUC-1A Intensity Setting — Medium BUC-2 and BUC-2A Intensity Setting — Medium to High: BUC-3 and BUC-3A Intensity Setting — Low CPR® Non-Surgical Ultrasonic Endodontic for sterilization. Sterilize the handpiece according to the Instruments CPR-1 Intensity Setting — Medium to High

Maximum Dry Time

dust free location

Instruments

Steam Sterilization Parameters for Tips Steam S

Steam Sterilizat	ion Parameters for Tips	DIRECTLY ON A CERAMIC CI
Steam Sterilizer Type	Prevacuum	CPR-2D Intensity Setting – Low to Hid
Temperature	132°C	CPR-3D — CPR-5D Intensity Setting —
Cycle Time	4 minutes	CPR-6 — CPR-8 Intensity Setting — Lov

30 minutes

The Ultrasonic tip should be stored in a dry and

BUC® Non-Surgical Ultrasonic Endodontic

BUC-1 Intensity Setting — Medium to High

△ CAUTION! DO NOT PLACE THE CPR-1 CROWN OR

Low