Records processed under FOIA Request 2014-6834; Released 10/23/14

K961158

MAY 23 1996

9. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submitter Information

SATELEC
Z.I. du Phare, BP 216
Avenue Gustave Eiffel
33708 Merignac Cedex
FRANCE

Telephone: 011-33-56-34-06-07

Contact Person: Pascal Dupeyron
Regulatory Affairs

Date Prepared: March 20 , 1996

B. Device Identification

Common/Usual Name: Piezoelectric Ultrasonic Scaling Generator
Proprietary Name: SUPRASSON P5 Booster

C. Identification of Predicate Device(s)

The SUPRASSON P5 Booster is substantially equivalent to its predicate device, SUPRASSON P-MAX (K942139), previously cleared and currently marketed.

D. Device Description

The SUPRASSON P5 Booster ultrasonic scaler consists of three primary components: the scaling instrument (PAM) "handpiece", the control panel case, and the footswitch.

The scaling instrument (PAM) "handpiece" is held in the physician's hand, but can also be stored in the holder located onto the case. The handpiece is connected to the control panel case via a fixed electrical cable connection. Tips are mounted by means of a tip wrench at the extremity of the handpiece. All SUPPRASON P5 Booster tips vibrate in a single plane (vibration from front to rear and along the tip axis) via piezoelectric ultrasonic power. This rectilinear motion provides a more accurate and more comfortable approach to the tooth and gum. The enamel and cement are protected from unnecessary lateral impacts.

The SUPRASSON P5 Booster, similar to its predicate device, SUPRASSON P-MAX (K942139), operates from the action of cavitation, following the propagation of ultrasounds in a frequency spectrum comprised between 27 and 33 kHz and a mechanical effect following vibration of the tips mixing with water within a range of maximum amplitudes varying from 20 to 310 µm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

The portable plastic control panel case includes all control and ultrasonic power generation functions. A visible light diode informs the user when the device is in enable mode; it also serves as an indicator for the power regulation potentiometer knob. The power settings can be varied from 1-14, dependent upon the clinical application.

Housed in the portable case, internal electronics generate electrical signals at the ultrasound frequency in order for the tip screwed at the extremity of the handpiece to vibrate. Irrigation is provided by a water line manually controlled by tap knob which adjusts the spray at the tip of the handpiece, and is located on the flat side of the control panel case.

Connections to the case are all shorter than 3 m:

- the AC mains cable, 3 conductors, fixed, unshielded;
- the PAM cable, 3 conductors, fixed, unshielded;
- the footswitch cable, 2 conductors, fixed, unshielded.

The footswitch pedal has two functions. Pressure on the pedal activates/deactivates piezoelectric ultrasonic power triggering, and enables/disables the flowswitch, located inside the control panel case, for irrigation.

E. Substantial Equivalence

The technical characteristics are almost identical to those of the Satelec SUPRASSON P-Max. Refer to Table A for a comparison with the predicate device. Differences that exist between these devices relating to technical specifications, materials, physical appearance, and control systems do not affect the relative safety or effectiveness of the SUPRASSON P5 Booster relative to its predicate.

The SUPRASSON P-Max and SUPRASSON P5 are intended to provide overall prophylaxis and preservation of soft and hard tissue during the 3 standard dental treatments; Scaling, Periodontics, and Endodontics.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 1996

Ms. Jacqueline E. Masse
Consultant
Satelec
C/O Interactive Consulting, Incorporated
70 Walnut Street
Wellesley, Massachusetts 02181

Re: K961158
Trade Name: Suprasson P5 Booster
Regulatory Class: II
Product Code: ELC
Dated: May 7, 1996
Received: May 13, 1996

Dear Ms. Masse:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Timothy A. Ulatowski
Acting Director
Division of Dental, Infection Control
and General Hopsital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

510(k) Number (if known): **K961158**

Device Name: **SUPRASSON P5 BOOSTER**

Indications For Use:

Scaling
Endodontics
Periodontics

Please refer to the attached listing for a complete description.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

D.G. Swyllton

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K961158/S1

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

INDICATIONS FOR USE
SATELEC SUPRASSON P5 BOOSTER
510(k) NUMBER: K961158

Scaling:

- Interdental junction treatment
- Tooth neck and subgingival treatment
- Treatment of large deposits
- Treatment of coatings and tobacco stains
- Treatment of periodontal pockets
- Interproximal treatment
- Retro Surgery
- Plugging
  - Amalgam plugging
- Loosening
  - Prosthesis Loosening (crown, pivot loosening)
  -
- Inlay/Onlay Condensation:
  - Finish of inlay/onlay restorations

Endodontia:

- Canal preparation
- Canal cleaning
- Canal filling
- Treatment resumption
- Prosthesis:
  - Preparing in luted denture
  - Surface smoothing after burring
- Micro Retro Surgery
- Gutta Condensation:
  - Treatment resumption on gutta percha
  - Post loosening
  - Silver cone loosening
  - Gutta percha condensation

Periodontia:

- Root planing
- Initial therapy
- Treatment of periodontal pockets
- Treatment of furcations
- Maintenance therapy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

D 15

510(K) ROUTE SLIP

510(k) NUMBER K961158 PANEL DE DIVISION DDIG BRANCH DEDB

TRADE NAME SUPRASSON P5 BOOSTER

COMMON NAME PIEZOELECTRIC ULTRASONIC SCALING GENERATOR

PRODUCT CODE ___

APPLICANT SATELEC
SHORT NAME SATELEC
CONTACT JACKIE MASSE
DIVISION C/O INTERACTIVE CONSULTING, INC.
ADDRESS 70 WALNUT ST.
WELLESLEY, MA 02181
PHONE NO. (___) ___-____ FAX NO. (___) ___-____

MANUFACTURER UNKNOWN REGISTRATION NO.

DATE ON SUBMISSION 20-MAR-96 DATE DUE TO 510(K) STAFF 05-JUN-96

DATE RECEIVED IN ODE 22-MAR-96 DATE DECISION DUE 20-JUN-96

DECISION __ DECISION DATE _____

BRANCH 02AUG96
GREG

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	07-MAY-96	13-MAY-96	27-JUL-96	11-AUG-96	

CORRESPONDENCE	SENT	DUE BACK	
C001	25-APR-96	25-MAY-96	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	29-MAR-96	03-APR-96	02-JUN-96		

Is this 510(k) identified as a Class III device ____YES ____NO

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 5/17/96

From: Reviewer(s) - Name(s) D. G. Singleton, DDS

Subject: 510(k) Number K961158/S

To: The Record - It is my recommendation that the subject 510(k) Notification:

- [x] Is substantially equivalent to marketed devices.
- [ ] Requires premarket approval. NOT substantially equivalent to marketed devices.
- [ ] Requires more data.
- [ ] Accepted for review _____ (date)
- [ ] Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	[ ] YES	[x] NO
Is this device subject to the Tracking Regulation?	[ ] YES	[x] NO
Was clinical data necessary to support the review of this 510(k)?	[ ] YES	[x] NO
Is this a prescription device?	[x] YES	[ ] NO

This 510(k) contains:

Truthful and Accurate Statement [ ] Requested [x] Enclosed
(required for originals received 3-14-95 and after)

- [x] A 510(k) summary OR [ ] A 510(k) statement
- [ ] The required certification and summary for class III devices
- [x] The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

[ ] No Confidentiality [x] Confidentiality for 90 days [ ] Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

Review: Susan Runner (Branch Chief) DEDB (Branch Code) 5/17/96 (Date)

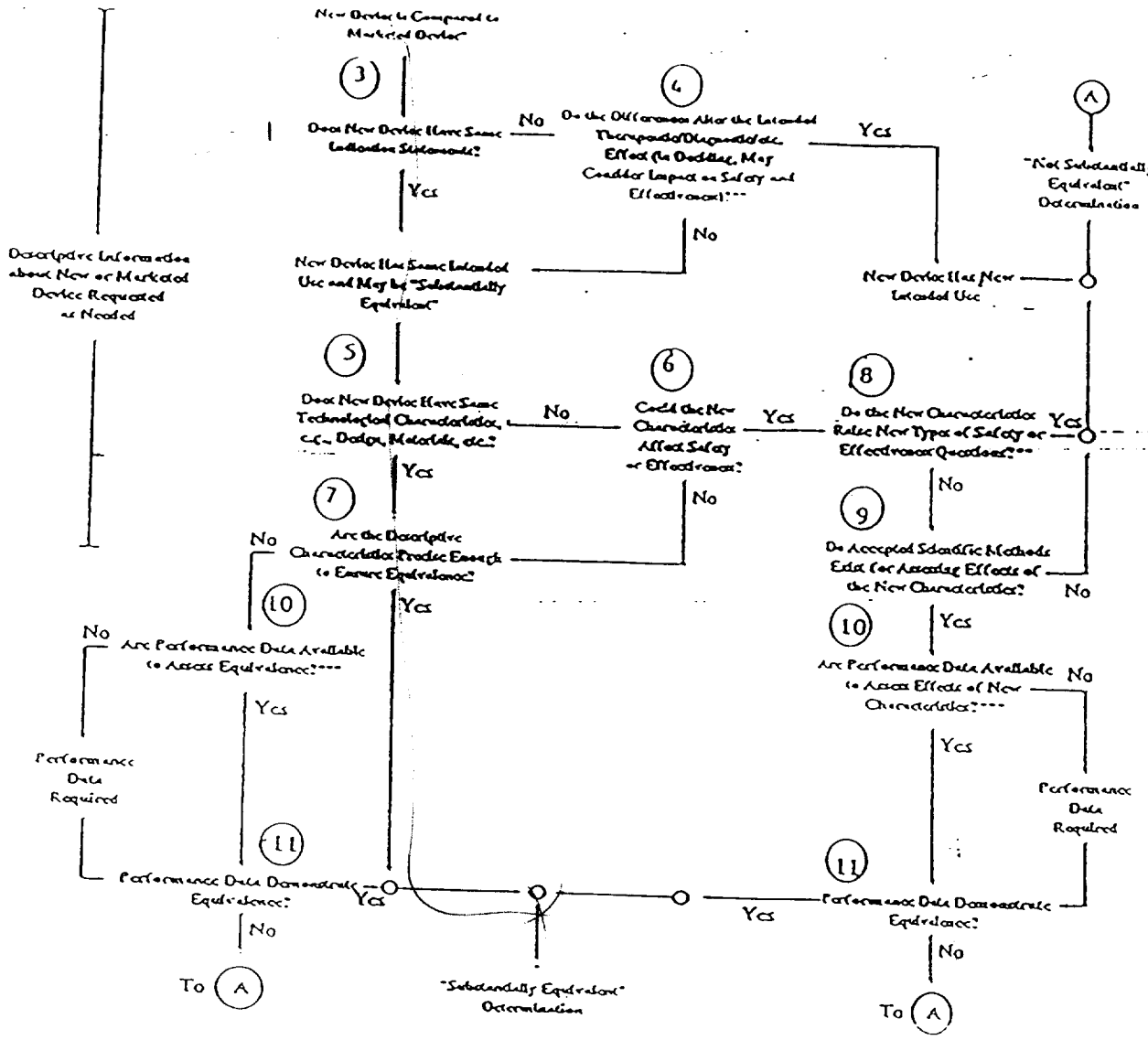
Final Review: [signature] (Division Director) 5/17/96 (Date)

Revised 1-2-96

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

MEMO

To: The record
From: D. Gregory Singleton, D.D.S.
Subject: k961158/S1
Date: May 17, 1996

Summary:

Interactive Consulting has responded to the Center's April 25, 1996 letter that requested new information in the labeling for the Suprasson P5 Booster device to be consistent with the company's labeling for the previously reviewed Suprasson P-MAX device. The new labeling includes a warning statement that the device should not be used if the operator or patient has a pacemaker and that the water lines should be flushed with water f or 20 to 30 seconds after each use.

Review:

The new information has been provided by the submitter in the form of an insert for the device's User's Manual along with placing the information in each Instruction Booklet.

Recommendation:

Based on the new information provided in this supplement, the Suprasson P5 Booster device is substantially equivalent to previously marketed ultrasonic scaling devices such as the Suprasson P-MAX device in terms of indications, materials, safety and effectiveness.

D. Gregory Singleton, D.D.S.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Date: April 3, 1996

From: Senior Dental Officer, DGRD, HFZ-410

Subject: K961158, Suprasson P5 Booster

To: The record

Summary:

Interactive Consulting has provided a submission for an piezoelectric ultrasonic scaling generator to be used in dental applications. The submitter claims that the device is the result of modifications made to and upgrading to a previously marketed device, the Suprasson P-MAX scaler reviewed under k924139. The device would operate at a frequency between 27 and 33 kHz with a maximum amplitude of the tip varying from 20 to 310 micro mm.

The main modifications to the new ultrasonic scaler as compared to the predicate device, other than the smaller exterior dimensions, is the power which rises from 8 watts to 10 watts and vibration amplitude which is slightly greater, 20 to 310 micro mm versus 50 to 250 micro mm of the Suprasson P-MAX. The new device also has an external irrigation line instead of the peristaltic pump found on the P-MAX device. All other specifications of the device are identical to the original device.

The intended use of this device, as described in the labeling, are specifed in three separate areas, scaling, endodontia and periodontia. Included in the scaling area are "retro surgery" and "amalgam plugging". Included with endodontia are "prosthesis: preparing in luted denture", "surface smoothing after burring" and "micro retro surgery". Indications in the periodontia section include all aspects of periodontal treatment including root planing and treatment of furcations

Review:

There were a number of supplements that were required from the submitter before the predicate device, the Suprasson P-MAX was found to be substantially equivalent to previously marketed devices. One of the deficiencies noted by Dr. Mendelsohn in his review of the 510k was that no warning is provided to persons who have pacemakers. The company agreed to place a warning in the labeling as follows: "do not operate the unit if the patient or operator has a pacemaker". This warning does not appear in any of the labeling for the Suprasson P-MAX device and should be included.

The submitter also agreed to place a statement in the labeling that the handpiece lines must be flushed for 20 to 30 seconds with water after each use. No such statement appears in the labeling for this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Recommendation:

Based on the information provided by the submitter, the submitter should be asked to provide revised labeling that include warnings concerning the use of pacemakers and the requirement to flush water lines.

Additional information,

D. Gregory Singleton, D.D.S.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 14, 1996

SATELEC
C/O INTERACTIVE CONSULTING, INC.
70 WALNUT ST.
WELLESLEY, MA 02181
ATTN: JACKIE MASSE

510(k) Number: K961158
Product: SUPRASSON P5 BOOSTER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14 K961158 s

INTERACTIVE CONSULTING

May 7, 1996

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: K961158
SUPRASSON P5 BOOSTER

SPONSOR: SATELEC
c/o Interactive Consulting, Inc.

Dear Sir or madam:

In response to your April 25, 1996 letter, enclosed please find the requested revised labeling for the SUPRASSON P5 Booster device, which includes a warning that the device should not be used if the patient or operator has a pacemaker. An additional precaution has been incorporated stating that the handpiece waterlines must be flushed with water for 20 to 30 seconds after each use.

This revised Labeling has been incorporated in the SUPRASSON P5 Booster User's Manual, as well as each Individual Instruction Booklet. Copies of the pages where the revised labeling are located are attached. Please add these separate pages to our 510(k) Submission filed (K961158) on March 22, 1996.

If you have any questions, or should additional information be required, please contact the submission correspondent at Interactive Consulting, Inc., Mrs. Jackie Masse at (617) 239-8108.

Sincerely,

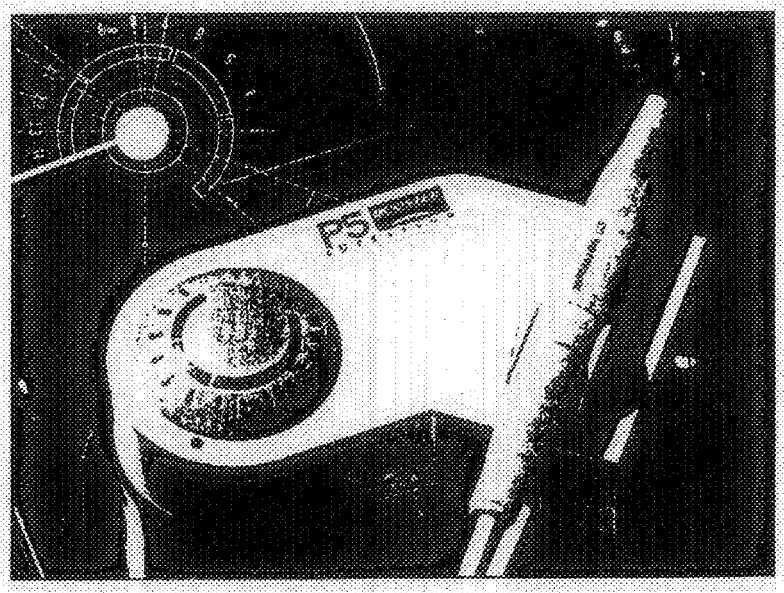
Jacqueline E. Masse

Jacqueline E. Masse
Consultant

Enclosures

70 Walnut Street - Wellesley, Massachusetts 02181 - USA - T: 617 239 8108 F: 617 674 2002
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14



P5 BOOSTER

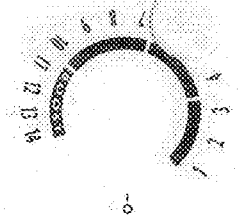
MANUEL D'UTILISATION / USER'S MANUAL
ISTRUZIONI D'USO / BEDIENUNGSANLEITUNG
INSTRUCCIONES PARA EL USO

SATELEC

000001

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14



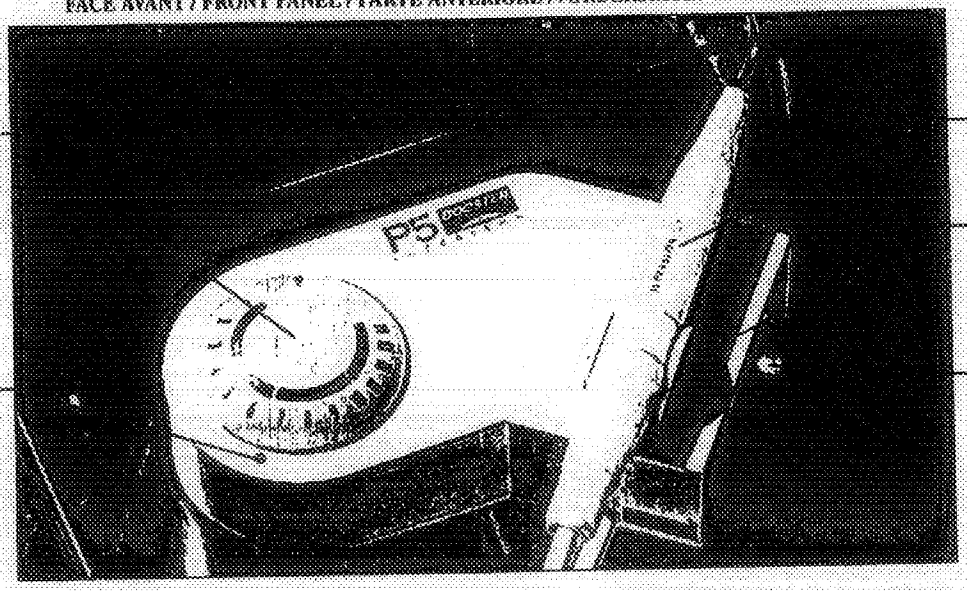
P5 BOOSTER

SUPRASSON

FACE AVANT / FRONT PANEL / PARTE ANTERIORE /VORDERSEITE / PARTE FRONTAL

Réglage de puissance - Power adjustment - Regolazione di potenza - Leistungsregler - Regulador de potencia

Voyant de mise sous tension - Energizing light - Spia di messa sotto tensione - Spannungsanzeige leuchtet auf - Indicador luminoso



Pièce à main - Handpiece - Manipolo - Handstück - Pieza de mano

Support de pièce à main - Handpiece holder - Sopporto del manipolo - Halterung für Handstück - Soporte pieza de mano

Réglage de spray - Spray adjustment - Regolazione dello spray - Sprayeinstellungen - Regulador de spray

WARNING: The SUPRASSON P5 Booster should not be used if patient or operator has a pacemaker.

ATTENTION : La vibration correcte d'un insert implique un serrage parfait qui ne doit pas être forcé au-delà de son point de butée. L'insert doit être démonté, nettoyé et stérilisé avant chaque utilisation.

CAUTION : For correct vibration, the tip must be perfectly tightened without over-torquing beyond its stop point. The tip should be removed, cleaned and sterilised before each using.

ATTENZIONE : La vibrazione corretta di un inserto implica che lo stesso sia stretto perfettamente ma non forzato oltre il punto d'arresto. L'inserto deve essere smontato, puliti i sterilizzazioni prima dell'utilizzo.

ACHTUNG : Die spitze muß perfekt sitzen, damit sie richtig schwingen kann, sie darf jedoch nicht über den anschlag hinaus angezogen werden. Vor jeder Behandlung, spitze mindestens einmal, reinigen und sterilisieren.

IMPORTANTE : La vibración correcta de un insert implica un roscado perfecto, ni demasiado flojo ni demasiado fuerte. El insert debe ser desmontado, limpiado y esterilizado antes de cada utilisacion.

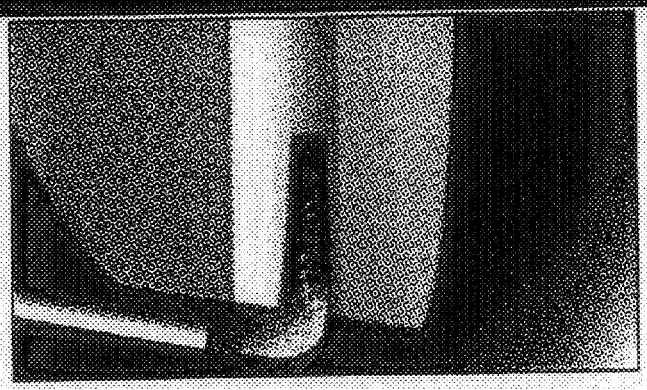
PRECAUTION: The handpiece waterlines must be flushed with water 20 to 30 seconds after each use.

000002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

RETRO CHIRURGIE / RETRO SURGERY



MICRORETROTIPS

NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET

SATELEC

000003

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

OPERATION IN SURGICAL ENDODONTICS

Objectives :

Whenever conventional endodontic treatment by the endo-canal approach fails to provide a proper apical sealing, surgery and sealing by a Retrograde approach are indicated. After peri-apical curettage and apical resection, a Rétrograde cavity can be filled using a biocompatible material (reinforced fast-setting eugenate, gutta percha, cement, etc).

WARNING: The SUPRASSON P5 Booster should not be used if patient or operator has a pacemaker.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

STERILIZATION AND DISINFECTION

Damaged tips (normal wear or accidental damage), must be replaced systematically.

Tip must be cleaned before sterilization

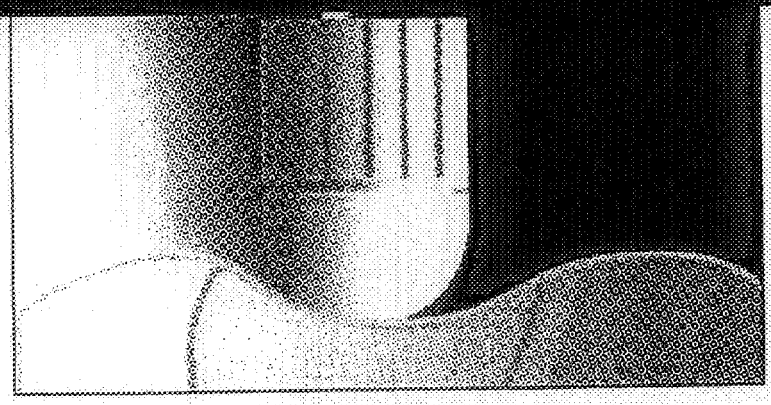
Sterilizing conditions :
Equipment : autoclave, chemiclave
Sterilization : 10 minutes at 134° C at 2 bars (29 Psi)

PRECAUTION: The handpiece waterlines must be flushed with water for 20 to 30 seconds after each use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

CONDENSATION INLAY-ONLAY



PIEZOCEM

NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET

SATELEC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

WARNING: The SUPRASSON P5 Booster should not be used if patient or operator has a pacemaker.

PRECAUTION: The handpiece waterlines must be flushed with water for 20 to 30 seconds after each use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DETARTRAGE / SCALING / ABLAZIONE / ZUR ZAHNSTEIN ENTFERNUNG / DETARTRADOR

SUPRASSON™

NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET / FOGLIETTO ILLUSTRATIVO
BEDIENUNGSANLEITUNG / INSTRUCCIONES DE USO

SATELEC

000008

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

WARNING: The SUPRASSON P5 Booster should not be used if the patient or operator has a pacemaker.

3 - Precautions for fitting tips

- The tips must be screwed in and moderately tightened using their key.

Important : In order to obtain a good vibration of a tip, the latter must be perfectly tightened. For that, it must not be forced beyond the stop point.

NOTE : The tip must be removed at least once a day so that it does not get jammed.

4 - Description of the vibrations

All the SUPRASSON tips have the particularity of vibrating in a single plane (vibrations from front to rear along the axis of the tip). Lateral vibrations common to scalers do not therefore exist. The rectilinear displacement provides a more accurate and more comfortable approach to the tooth and gum. The enamel and cement are protected against pointess impacts. Within this main vibratory plane, the extremity of each tip is driven by tiny vibratory movements.

For maximum performance of the SUPRASSON the operator should take into account these mini-vibrations specific to each tip.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

CLEANING AND STERILIZATION

Tips

Damaged tips (normal wear or accidental damage), must be replaced systematically.
Sterilizing conditions :
Equipment : autoclave, chemiclave
Sterilization : humid conditions
40 minutes at 121°C at 1 bar (247°F) at 1 bar (14.5 psi)
20 minutes at 134°C at 2 bars (29 psi)

Handpieces

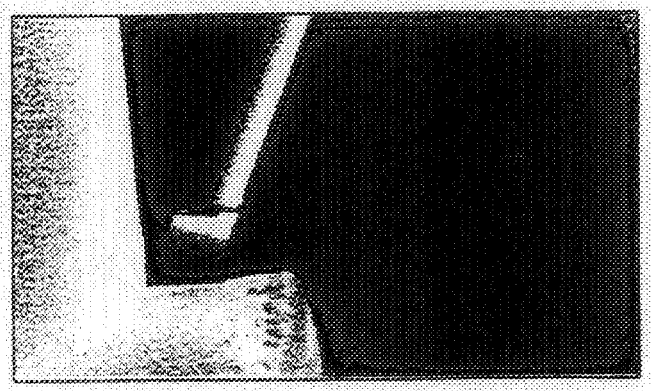
These may be cleaned with alcohol. The screw-thread cavity can be properly cleaned by using a cotton bud soaked in alcohol. Do not clean handpieces in an ultrasonic ultrasonic tank.
Sterilizing conditions :
Equipment : autoclave
Sterilisation : humid conditions
40 minutes at 121°C (247°F) at 1 bar (14.5 psi)
20 minutes at 134°C (273°F) at 2 bars (29 psi).

PRECAUTION: The handpiece waterlines must be flushed with water for 20 to 30 seconds after each use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PROSTHESIS



CHISEL TIPS™

INSTRUCTION BOOKLET

SATELEC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

STERILIZATION AND DISINFECTION

Damaged tips (normal wear or accidental damage), must be replaced systematically.

Sterilizing conditions :

Equipment : autoclave, chemiclave
Sterilization : 10 minutes at 134° C at 2 bars (29 Psi)

PRECAUTION: The handpiece waterlines must be flushed with water for 20 to 30 seconds after each use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

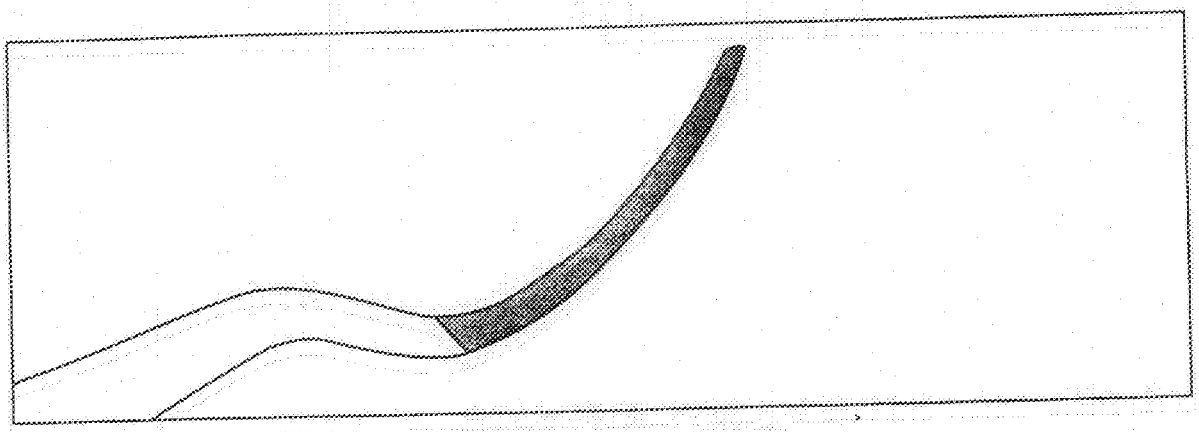
PERSONAL NOTES

WARNING: The SUPRASSON P5 Booster should not be used if patient or operator has a pacemaker.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PARODONTIE / PERIODONTICS



PERIO - KIT

NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET

SATELEC

000014

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

LE SURFACAGE RADICULAIRE

Un traitement parodontal commence toujours par la motivation à l'hygiène accompagné d'un détartrage sus-gingival.

En général, le praticien élimine à l'aide d'un appareil à ultra-sons les dépôts tartriques visibles au-dessus de la gencive. Souvent cela suffit pour une gingivite légère, mais en présence d'une gingivite avancée ou d'une parodontite (poches parodontales plus ou moins profondes) le détartrage sus-gingival ne permet pas l'accès au tartre sous-gingival.

Dans ce cas, le praticien devra pratiquer un détartrage sous-gingival et un polissage de la racine : le surfaçage radiculaire.

ROOT PLANING

A periodontal treatment generally starts by motivating the patient towards oral hygiene followed by supra-gingival scaling.

Ultrasonic scaler is generally used to remove visible calculus and this is often sufficient for dealing with minor gingivitis. With severe gingivitis or periodontitis (deep periodontal pockets) supra-gingival scaling is insufficient to eliminate sub-gingival calculus.

Consequently, a sub-gingival scaling and a root polishing are necessary : the root planing.

WARNING: The SUPRASSON P5 Booster should not be used if the patient or operator has a pacemaker.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PRECAUTIONS

Remplacement des Inserts :

1) H1, H2R, H2L.

Les inserts doivent être changés lorsque la partie diamantée devient lisse et brillante.

2) H3

Cet insert doit être changé lorsque sa partie active est émoussée.

CAUTIONS

Tips replacement :

1) H1, H2R, H2L.

Tips must be replaced when the diamond part becomes smooth and shiny.

2) H3

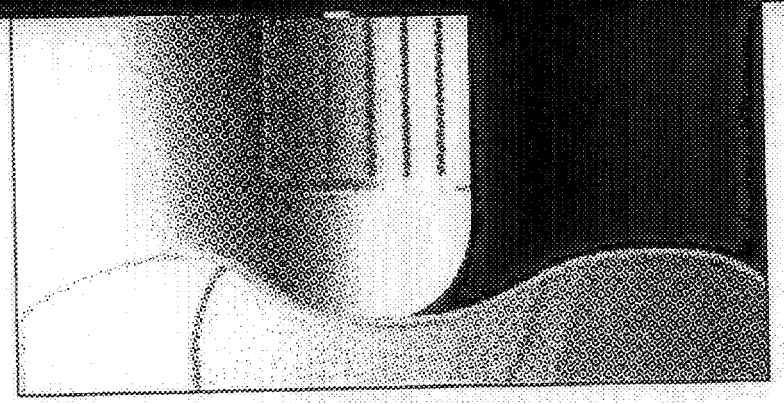
This tip must be changed when the active part becomes blunt.

PRECAUTION: The handpiece waterlines must be flushed with water for 20 to 30 seconds after each use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

CONDENSATION INLAY-ONLAY



PIEZOCEM

NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET

SATELEC

000017

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PRECAUTIONS

Remplacement des Inserts :

1) H1, H2R, H2L.

Les inserts doivent être changés lorsque la partie diamantée devient lisse et brillante.

2) H3

Cet insert doit être changé lorsque sa partie active est émoussée.

CAUTIONS

Tips replacement :

1) H1, H2R, H2L.

Tips must be replaced when the diamond part becomes smooth and shiny.

2) H3

This tip must be changed when the active part becomes blunt.

PRECAUTION: The handpiece waterlines must be flushed with water for 20 to 30 seconds after each use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 1996

Satelec
C/O Ms. Jackie Masse
Consultant
Interactive Consulting
70 Walnut Street
Wellesley, Massachusetts 02181

Re: K961158
Trade Name: Suprasson P5 Booster
Dated: March 20, 1996
Received: March 22, 1996

Dear Ms. Masse:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require revised

(b)(4) [redacted] (b)(4)

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact D. Gregory Singleton, D.D.S. at (301) 594-8879. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Susan Purves

for Timothy A. Ulatowski
Acting Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Satelec
C/O Ms. Jackie Masse
Consultant
Interactive Consulting
70 Walnut Street
Wellesley, Massachusetts 02181

Re: K961158
Trade Name: Suprasson P5 Booster
Dated: March 20, 1996
Received: March 22, 1996

Dear Ms. Masse:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require revised

(b)(4)

[redacted]

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact D. Gregory Singleton, D.D.S. at (301) 594-8879. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Timothy A. Ulatowski
Acting Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ	Singleton	4/25						
HFZ	Rimer	4/25						

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

U.S. GOVERNMENT PRINTING OFFICE 1991-519-771

Records processed under FOIA Request 2014-6834; Released 10/23/14

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-480 DDIGD Division
D.O.

f/t:HFZ-480:DGS:RMD:4/23/96

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 4/17/96

From: Reviewer(s) - Name(s) D. G. Singleton, DDS

Subject: 510(k) Number K961158

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☑ Is substantially equivalent to marketed devices.
- ☐ Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☑ Requires more data.
- ☐ Accepted for review _____ (date)
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☑NO
Is this device subject to the Tracking Regulation?	☐YES	☑NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☑NO
Is this a prescription device?	☑YES	☐NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑A 510(k) summary OR ☐A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

Review: Susan Runner (Branch Chief) DEDB (Branch Code) 4/25/96 (Date)

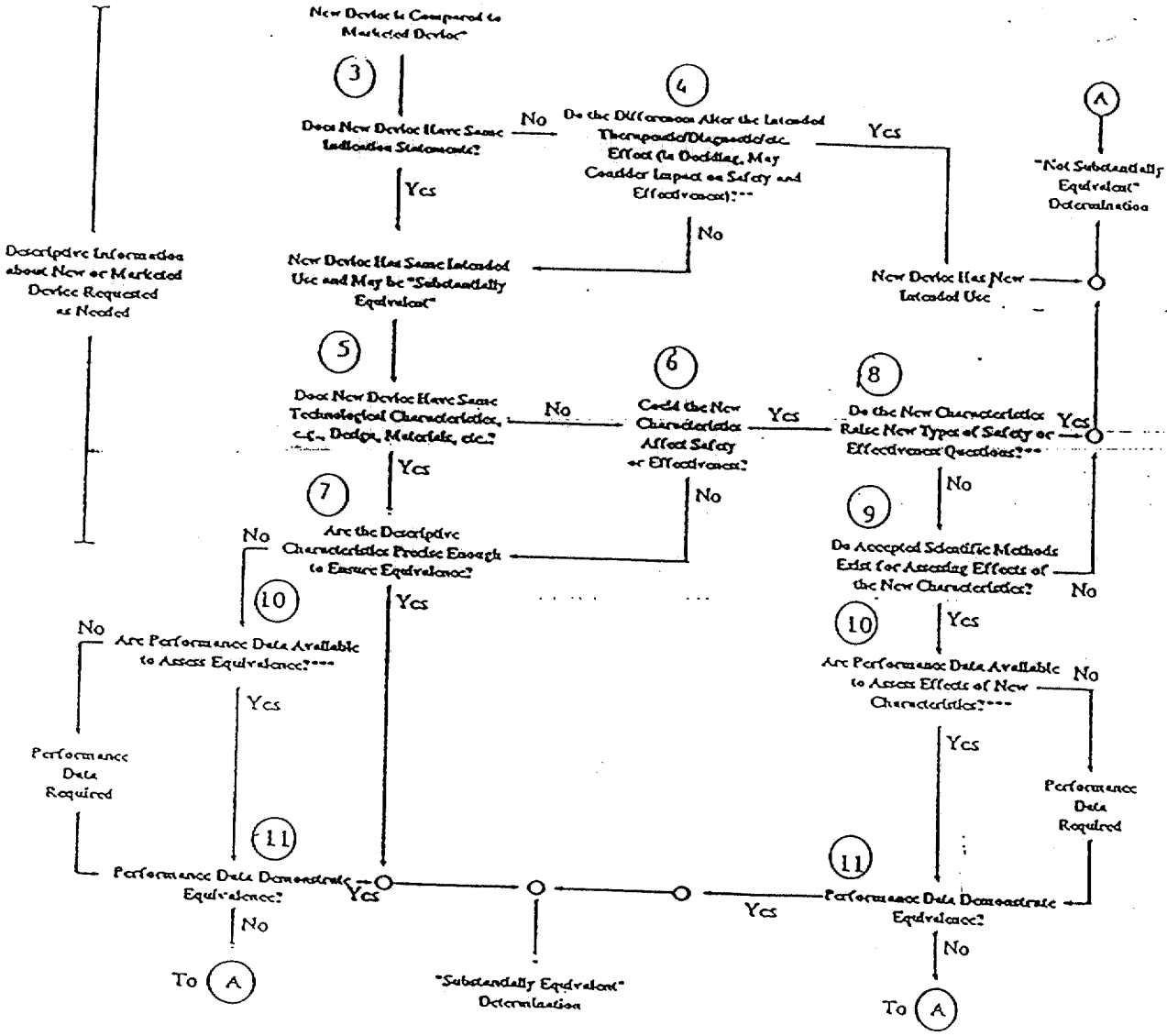
Final Review: Susan Runner (Division Director) 4/25/96 (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Revised: 1-2-96

Records processed under FOIA Request 2014-6834; Released 10/23/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

510(k) Number (if known): **K961158**

Device Name: **SUPRASSON P5 BOOSTER**

Indications For Use:

Scaling
Endodontics
Periodontics

Please refer to the attached listing for a complete description.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

D.G. Singleton _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

INDICATIONS FOR USE
SATELEC SUPRASSON P5 BOOSTER
510(k) NUMBER: K961158

Scaling:

- Interdental junction treatment
- Tooth neck and subgingival treatment
- Treatment of large deposits
- Treatment of coatings and tobacco stains
- Treatment of periodontal pockets
- Interproximal treatment
- Retro Surgery
- Plugging
  - Amalgam plugging
- Loosening
  - Prosthesis Loosening (crown, pivot loosening)
  -
- Inlay/Onlay Condensation:
  - Finish of inlay/onlay restorations

Endodontia:

- Canal preparation
- Canal cleaning
- Canal filling
- Treatment resumption
- Prosthesis:
  - Preparing in luted denture
  - Surface smoothing after burring
- Micro Retro Surgery
- Gutta Condensation:
  - Treatment resumption on gutta percha
  - Post loosening
  - Silver cone loosening
  - Gutta percha condensation

Periodontia:

- Root planing
- Initial therapy
- Treatment of periodontal pockets
- Treatment of furcations
- Maintenance therapy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

K961158 / A 1

INTERACTIVE CONSULTING

RECEIVED
APR 30 1996
FDA/CDRH/OCE/DMC

March 29, 1996

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: K961158
SUPRASSON P5 BOOSTER

SPONSOR: SATELEC
c/o Interactive Consulting, Inc.

Dear Sir or madam:

In response to your March 25, 1996 letter, enclosed please find 2 pages, clearly marked "Indications For Use", in compliance with the new regulations of January 1, 1996. Please add these separate pages to our 510(k) Submission filed (K961158) on March 22, 1996.

If you have any questions, or should additional information be required, please contact the submission correspondent at Interactive Consulting, Inc., Mrs. Jackie Masse at (617) 239-8108.

Sincerely,

Jacqueline E. Masse

Jacqueline E. Masse
Consultant

Enclosures

70 Walnut Street - Wellesley, Massachusetts 02181 - USA - T: 617 239 8108 F: 617 674 2002
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PILOT Division Checklist
for Premarket Notifications [510(k)s]

Device Trade Name: Suprassom P5 Booster	K#: K961158
Submitter Name: Sofalec	
Date Received: MAR 27 1996 90 Day Due Date: 20 Jun 96	
Review Tier (circle one): 1 (2) 3	

Question	Yes	No
A. Is the product a device?	✓	
B. Is the device exempt from 510(k)?		✓
C. Expedited Review Status: Requested by sponsor,		✓
or identified by PILOT Division		
Granted by Pilot Division?		
D. Has this device been the subject of a previous NSE decision?		✓
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		✓
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Decision: ACCEPT ✓ REFUSE TO ACCEPT _____

Administrative Reviewer Signature: Renita L Hood

Date: MAR 27 1996

Supervisory Signature: Susan Runner

Date: 3/28/94

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PILOT Division Screening Checklist
for Premarket Notifications [510(k)s]

ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: Soprasson P5 Booster	
Submitter Name: Satelec	
General Content of a 510(k)	**MISSING INFORMATION**
1.* General Information: a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, i) applicant's name and address. COMMENT:	
2.* Safe Medical Device Act of 1990 Requirements: a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices). COMMENT:	
3.* Proposed Labeling: a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device. COMMENT:	C
4.* Description of Device (or modification): diagrams, engineering drawings, or photographs. COMMENT:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

5.* <u>Comparison Information</u>: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness. COMMENT:	
6. <u>Biocompatibility Data</u>: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use. COMMENT:	
7. <u>Sterilization Information</u>: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method. COMMENT:	
8. <u>Software Validation & Verification</u>: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification. COMMENT:	
9. <u>Information Recommended in FDA Guidance</u>: There is an FDA guidance document for this device that recommends additional data. COMMENT:	
10. <u>Kit Information</u>: see attachment if this device is a kit. COMMENT:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 25, 1996

SATELEC
C/O INTERACTIVE CONSULTING, INC.
70 WALNUT ST.
WELLESLEY, MA 02181
ATTN: JACKIE MASSE

510(k) Number: K961158
Received: 22-MAR-96
Product: SUPRASSON P5 BOOSTER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522 (a) (1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

If you have procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or call me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14 K961158

INTERACTIVE CONSULTING

Jean-Luc Boulnois
President

March 20, 1996

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850

RE: SUPRASSON P5 Booster
510(k) Premarket Notification

Dear Sir or Madam:

Pursuant to the requirements of Section 510(k) of the Safe Medical Devices Act of 1990, which amended the Federal Food, Drug, and Cosmetic Act, notification is made of the intention of the Sponsor, Satelec, to market the SUPRASSON P5 Booster.

The Submission is made by Interactive Consulting, a Wellesley, MA firm, on behalf of Satelec.

The SUPRASSON P5 Booster is a piezoelectric ultrasonic scaling generator used for dental applications. The SUPRASSON P5 Booster is an upgraded model to the Satelec SUPRASSON P-Max (K924139), and incorporates minor modifications to make the device a more compact, lightweight, portable, and cost-effective unit.

Interactive believes that the foregoing information will be sufficient for the Agency to find the SUPRASSON P5 Booster substantially equivalent to SUPRASSON P-MAX (K924139); however, should additional information be required, please contact the submission correspondent at Interactive Consulting Inc., Mrs. Jackie Masse at (617) 239-8108.

Satelec regards its intent to market the SUPRASSON P5 Booster as confidential commercial information and requests that the FDA not disclose the existence of the premarket notification for at least ninety (90) days, or as required.

Sincerely,

Jacqueline E. Masse

Jacqueline E. Masse
Consultant

Enclosures

70 Walnut Street - Wellesley, Massachusetts 02181 - USA - T: 617 239 8108 F: 617 674 2002
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission:

FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

- ☒ New device
- ☐ Other reason (specify):
- ☐ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process

Section B2 — Reason for Submission — PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

Section B3 — Reason for Submission — IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol – feasibility
  - ☐ Protocol– other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

Records processed under FOIA Request 2014-6834; Released 10/23/14

FDA Document Number:

Section C — Product Classification

Product code: ELC

C.F.R. Section: 872.4850

Device class:
- ☐ Class I
- ☒ Class II
- ☐ Class III
- ☐ Unclassified

Classification panel: Dental Panel (DE)

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 ELC	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
- ☒ 510(k) summary attached
- ☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K9242139	1 SUPRASSON P-MAX	1 SATELEC
2	2	2
3	3	3
4	4	4
5	5	5
6	8	8

Section E — Product Information — Applicable to All Applications

Common or usual name or classification name: Piezoelectric Ultrasonic Scaling Generator

Trade or proprietary or model name	Model number
1 SUPRASSON P5 Booster	1 n/a
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling): Scaling, Endodontics, Periodontics

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

FDA Document Number:

Section F — Manufacturing / Packaging / Sterilization Sites

☐ Original ☐ Add ☐ Delete | FDA establishment registration number: | ☐ Manufacturer ☐ Contract manufacturer ☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name:

Division name (if applicable): | Phone number (include area code): ( )

Street address: | FAX number (include area code): ( )

City: | State / Province: | Country: | ZIP / Postal Code:

Contact name:

Contact title:

☐ Original ☐ Add ☐ Delete | FDA establishment registration number: | ☐ Manufacturer ☐ Contract manufacturer ☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name:

Division name (if applicable): | Phone number (include area code): ( )

Street address: | FAX number (include area code): ( )

City: | State / Province: | Country: | ZIP / Postal Code:

Contact name:

Contact title:

☐ Original ☐ Add ☐ Delete | FDA establishment registration number: | ☐ Manufacturer ☐ Contract manufacturer ☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name:

Division name (if applicable): | Phone number (include area code): ( )

Street address: | FAX number (include area code): ( )

City: | State / Province: | Country: | ZIP / Postal Code:

Contact name:

Contact title:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

	FDA Document Number:

Section G **Applicant or Sponsor**

Company / Institution name: SATELEC	FDA establishment registration number: 8044015
Division name (if applicable):	Phone number (include area code): (33) 56 34 06 07
Street address: Z.I. du Phare BP216, Avenue Gustave Eiffel	FAX number (include area code): (33) 56 47 85 52

City:	State / Province:	Country:	ZIP / Postal Code:
Merignac		France	33708

Signature:

Name: Mr. Gilles PIERSON

Title: President

Section H **Submission correspondent (if different from above)**

Company / Institution name: Interactive Consulting, Inc.	
Division name (if applicable):	Phone number (include area code): (617) 239-8108
Street address: 70 Walnut Street	FAX number (include area code): (617) 674-2002

City:	State / Province:	Country:	ZIP / Postal Code:
Wellesley	MA	US	02181

Contact name: Ms. Jackie Masse

Contact title: Consultant

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Date of Application: 03/20/96

SATELEC

510(k) Premarket Notification for SUPRASSON P5 BOOSTER

a Piezoelectric Ultrasonic Scaling Generator

Table Of Contents

	Page
1. Identification	1
2. Establishment Registration Number	1
3. Device Classification	1
4. Performance Standards	1
5. Product Labeling/Promotional Material	2
6. Device Description	2
6.1 General Description	2
6.2 Description of Mechanical Interface	4
6.3 Intended Use	6
7. Statement of Substantial Equivalence	8
7.1 Technical Substantial Equivalence	8
7.2 Clinical Substantial Equivalence	10
7.3 Conclusion of Substantial Equivalence	12
8. Sterilization	12
9. SMDA Summary of Safety and Effectiveness	13
10. Premarket Notification: Truthful and Accurate Statement	16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Appendices

A. Product Labeling

Device Labeling
User's Manual
Individual Instruction Booklets per Dental Treatment

B. Suprasson P5 Booster Advertisements and Promotional Material

Product Brochure
Satelec Tip Book
Tip Information Sheet

C. Diagrams of Device

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

510(k) Premarket Notification for SUPRASSON P5 BOOSTER

a Piezoelectric Ultrasonic Scaling Generator

1. Identification

1.1 Classification Name:	Not Known
1.2 Common/Usual Name:	Piezoelectric Ultrasonic Scaling Generator
1.3 Proprietary Name:	SUPRASSON P5 Booster

2. Establishment Registration Number: 8044015

Manufacturing Facility:	SATELEC Z.I. du Phare, BP 216 Avenue Gustave Eiffel 33708 Merignac Cedex FRANCE

3. Device Classification:

Piezo-electric Ultrasonic Scaling Generators have been reviewed by the FDA Dental Panel. FDA identified such systems as "Scaler, Ultrasonic (ELC)" which are classified as Class II devices.

4. Performance Standards:

Pursuant to Section 514 of the Act and 21 CFR 872, no performance standards presently exists for ultrasonic scalers. However, the SUPRASSON P5 Booster conforms to all applicable requirements of 21 CFR 1010 (Performance Standards for Electronic Products: General). The device also conforms to the following European standards:

- EN60601-1 (1991) and EN60601-1-2 (1993), "Medical Electrical Equipment - General Requirements for Safety"; these standards are European harmonized versions of IEC 601-1(1988).
- IEC 1000-4-5 (1995), which replaces IEC 801-4-5.

As a result, the SUPRASSON P5 Booster is in compliance with:

- EN 55011, Group 1, Class B, for conducted and radiated emissions,
- EN50082-1 for electrostatic discharge immunity (IEC 801-2),
- EN50082-1 for electromagnetic field immunity (IEC 801-3),
- EN50082-1 for electrical fast transient/burst (EFT) immunity (IEC 801-4).

Also the SUPRASSON P5 Booster complies with the European regulations for CE Marking (electromagnetic compliance).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

The SUPRASSON P5 Booster also complies with the requirements of the United Kingdom Department of Health: SATELEC obtained the Manufacturer Registration Scheme No. R0263/ME on March 31, 1995

5. Product Labeling/Promotional Material:

Samples of the proposed device labeling and their locations are included in Appendix A. In addition, a draft of the SUPRASSON P5 Booster User's Manual as well as individual instruction booklets (per dental treatment application) are included in Appendix A.

Appendix B presents examples of all advertisements and/or promotional material for the SUPRASSON P5 Booster, including:

- SUPRASSON P5 Booster Brochure
- Satelec Tip Book
- 2-Page Tip Information Sheet

6 Device Description:

6.1 General Description

The SUPRASSON P5 Booster, a piezoelectric ultrasonic scaling generator, is the 2nd generation device of the SUPRASSON P-Max which received 510(k) clearance for dental applications (K942139) on September 29, 1995. This new model is designed to make the device a more compact, lightweight, portable, and cost-effective unit. The new design preserves the safety and effectiveness of the device. Therefore, the intended use, technical performance, and clinical indications are identical to those of its predicate device, the SUPRASSON P-MAX (K942139).

The SUPRASSON P5 Booster ultrasonic scaler consists of three primary components:

- the scaling instrument (PAM) "handpiece",
- the control panel case, and,
- the footswitch.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Handpiece

The scaling instrument (PAM) "handpiece" is held in the physician's hand, but it can also be stored in the holder located onto the case. The handpiece is connected to the control panel case via a fixed electrical cable connection. It is fitted to the cord socket by means of a simple snap connection. Tips are mounted by means of a tip wrench at the extremity of the handpiece. All SUPPRASON P5 Booster tips vibrate in a single plane (vibration from front to rear and along the tip axis) via piezoelectric ultrasonic power. In this main vibratory plane, each tip end is subject to very small vibratory movements. Therefore, lateral vibrations inherent to other scalers do not exist. This rectilinear motion provides a more accurate and more comfortable approach to the tooth and gum. The enamel and cement are protected from unnecessary impacts.

The SUPRASSON P5 Booster, similar to its predicate device, SUPRASSON P-MAX (K942139), operates from the action of cavitation, following the propagation of ultrasounds in a frequency spectrum comprised between 27 and 33 kHz and a mechanical effect following vibration of the tips mixing with water within a range of maximum amplitudes varying from 20 to 310 μm.

Control Panel Case

The plastic control panel case includes all control and ultrasonic power generation functions. A visible light diode (LED) informs the user when the device is in enable mode; it also serves as an indicator for the power regulation potentiometer knob. The power settings can be varied from 1-14, dependent upon the clinical application.

Housed in the portable case, internal electronics generate electrical signals at the ultrasound frequency in order for the tip screwed at the extremity of the handpiece to vibrate. Irrigation is provided by a water line manually controlled by a tap knob which adjusts the spray at the tip of the handpiece, and is located on the flat side of the control panel case.

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Footswitch

The footswitch pedal has two functions. Pressure on the pedal activates/deactivates piezoelectric ultrasonic power triggering, and enables/disables the flowswitch, located inside the control panel case, for irrigation.

6.2 Description of the Mechanical Interface

The portable case is entirely made of plastic which enhances electrical safety for the patient and the physician. It contains the motherboard generating ultrasound together with the AC filter. On the case are connected:

- on the back panel: the AC cable, the footswitch, connection for water inlet,
- on the front panel: the handpiece cable

The potentiometer controlling the output power and the light diode registering the P5 operation are located on the top face of the case.

The SUPRASSON P5 Booster is an upgraded model of the SUPRASSON P-MAX. In order to upgrade the model, it was modified to make the device more compact, lightweight, portable, and cost effective. But it did not alter the original SUPRASSON P-MAX's technical specifications or intended uses. The modifications do not affect safety or effectiveness and include the following:

6.2.1 Upgraded Electronics

Motherboard

Electric power is generated from the main through a 2X120 V/2 X12V transformer associated with a filter-rectifier unit. The output voltage is used as a command for the transducer. A regulator is used for the switch-mode power supply. The triggering sequence sends an ON/OFF command to the automatic tuning system. Automatic tuning enables locking of the transducer's Voltage Control Oscillator ("VCO") onto the resonant frequency of the handpiece. The VCO, together with the switch-mode power supply, commands the variable power handpiece's transducer through the output transformer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

6.2.2 External Irrigation Line

The predicate device, SUPRASSON P-MAX, comprises a disposable external sterile irrigation line connected to a sterilizable glass bottle located on the device back panel. The irrigation flow rate is controlled via a peristaltic pump. This irrigation line connects onto the handpiece to ensure fluid separation and to keep the whole irrigation line sterile. This sterile irrigation line is replaced after every treatment.

The SUPRASSON P5 Booster employs a built-in irrigation line by which the water inlet is connected directly to the physician's unit located in the dental suite. Water is activated when the foot pedal is used to enable piezoelectric ultrasonic power, and manually controlled by a tap knob which adjusts the spray at the tip of the handpiece, and is located on the flat side of the control panel case.

The above describes the modifications to the SUPRASSON P-MAX to upgrade it to the SUPRASSON P5 Booster. Refer to Table 1 for a comprehensive comparison of the key features and performances of the SUPRASSON P-Max and the SUPRASSON P5 Booster.

TABLE 1
Design Comparison - SUPRASSON P-MAX and SUPRASSON P5 Booster

	SUPRASSON P-MAX	SUPRASSON P5 Booster
Dimensions (mm) Height: Depth: Width:	70 250 166	44 147 117
Weight (g)	1500	640
Main Power Supply	84-264 VAC; 50/60 Hz	90-140 VAC; 50/60 Hz 200-260VAC; 50/60 Hz
Vibration System	Piezoelectric	Piezoelectric
Frequency	27-33 kHz	27-33 kHz
Irrigation System	Peristaltic Pump	External irrigation line
Handpiece Size (mm) Weight (g) Tips Length Range (mm) Decontamination/Sterilization	130 X ∅ 18 65 20-35 Autoclavable	110 X ∅ 18 55 20-35 Autoclavable
Ultrasound Power Output (W)	8	10
Vibration Amplitude Range (µm)	50-250	20-310

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8718

Records processed under FOIA Request 2014-6834; Released 10/23/14

6.3 Intended Use:

As with its predicate device, the SUPRASSON P-Max, the SUPRASSON P5 Booster provides overall prophylaxis and preservation of soft and hard tissue during the 3 standard dental treatments Scaling, Periodontics, and Endodontics.

The standard dental treatments which are performed with the SUPRASSON P5 Booster have been broken down into 3 categories and are described in detail below:

1. **Scaling**:
   - Interdental junction treatment
   - Tooth neck and subgingival treatment
   - Treatment of large deposits
   - Treatment of coatings and tobacco stains
   - Treatment of periodontal pockets
   - Interproximal treatment
   - Retro Surgery
   - Plugging
     - Amalgam plugging
   - Loosening
     - Prosthesis Loosening (crown, pivot loosening)
     -
   - Inlay/Onlay Condensation:
     - Finish of inlay/onlay restorations

2. **Endodontia:**
   - Canal preparation
   - Canal cleaning
   - Canal filling
   - Treatment resumption
   - Prosthesis:
     - Preparing in luted denture
     - Surface smoothing after burring
   - Micro Retro Surgery
   - Gutta Condensation:
     - Treatment resumption on gutta percha
     - Post loosening
     - Silver cone loosening
     - Gutta percha condensation

3. **Periodontia:**
   - Root planing
   - Initial therapy
   - Treatment of periodontal pockets
   - Treatment of furcations
   - Maintenance therapy

The applications for each treatment, tip # choices, and reference information, respectively, are summarized in Table 2, which also presents the respective power settings for the SUPRASSON P5 Booster.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

TABLE 2: DENTAL TREATMENT APPLICATIONS AND POWER SETTINGS FOR SUPRASSON P5 BOOSTER

Dental Treatment Application	Tip #	Ref:	Power Settings
Scaling:			
Scaling	1	F00246	5-8
	2	F00247	8-10
	3	F00248	5-7
	10P	F00253	5-8
Retro Surgery	S12 80°	F00093	8-14
	S12 90°	F00094	8-14
	S12 120°	F00095	8-14
	S12D 80°	F00101	7-9
	S12D 90°	F00102	7-9
	S12D 120°	F00109	7-9
	S13L	F00096	8-14
	S13LD	F00104	7-9
	S13R	F00097	8-14
	S13RD	F00105	7-9
Micro Retro Surgery	P14	F00098	8-9
	P14D	F00196	7-9
	P15L	F00099	8-9
	P15LD	F00107	7-9
	P15R	F00100	8-9
	P15RD	F00108	7-9
Plugging	6A	F00251	5-7
	7A	F00252	5-7
Loosening	5	F00250	10-14
	5AE	F00249	10-14
Gutta Condensation	S04	F88009	7-10
	S07	F88010	7-10
Inlay/Onlay Condensation	C19	F00112	3-5
	C20	F00113	3-5
Endodontics:			
Endondontia	K10 21 mm	F43710	1-3
	K15 21 mm	F43715	2-4
	K25 21 mm	F43725	3-5
	K30 21 mm	F43730	5-6
	K10 25 mm	F43712	1-3
	K15 25 mm	F43717	2-4
	K25 25 mm	F43727	3-5
	K30 25 mm	F43732	5-6
Prosthesis	F1 L	F00116	1-3
	F1 R	F00110	1-3
	F2 L	F00117	1-3
	F2 R	F00111	1-3
Periodontics:			
Periodontia	H1	F00366	1-3
	H2L	F00367	1-3
	H2R	F00368	1-3
	H3	F00369	1-3
	H4L	F00114	1-3
	H4R	F00115	1-3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

In order for the physician to determine which tip and power setting to utilize for the specific dental treatment to be performed, he/she may refer to the individual instructions booklets available (refer to Appendix A) for various applications in:

- Scaling
- Prosthesis - Chisel Tips
- Retro Surgery - MicroRetoTips
- Periodontics - Perio-kit
- Inlay/Onlay Condensation - Piezocem

These instruction booklets, together with the Satelec Tip Book, which has previously been given to the FDA (K942139), provide complete information for the choice of tip and appropriate power setting. Please refer to Appendix B.

7. Substantial Equivalence:

The SUPRASSON P5 Booster is substantially equivalent to its predicate, the SUPRASSON P-MAX (K942139), in terms of its technical specifications and its intended uses. The FDA previously cleared this device for applications in Scaling, Endodontics, and Periodonitics. The equivalence of the SUPRASSON P5 Booster with its predicate device from both a technical and clinical perspective is supported below.

7.1 Technical Substantial Equivalence

The SUPRASSON P5 Booster is an updated version of its predicate device, SUPRASSON P-MAX (K942139), with design modifications of the power supply and irrigation systems making the device more compact, lightweight, portable and cost-effective, at no detriment to either safety or effectiveness. Substantial Equivalence is established by a direct comparison of the technical specifications and performances of the two devices as summarized in Table 3.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

TABLE 3
Technical Substantial Equivalence

	SUPRASSON P-MAX	SUPRASSON P5 Booster
K- Number Class	K942139 II	II
Dimensions (mm) Height: Depth: Width:	 70 250 166	 44 147 117
Weight (g)	1500	640
Main Power Supply	84-264 VAC; 50/60 Hz	90-140 VAC; 50/60 Hz 200-260VAC; 50/60 Hz
Vibration System	Piezoelectric	Same
Frequency	27-33 kHz	Same
Irrigation System	Peristaltic Pump	External irrigation line
Handpiece Size (mm) Weight (g) Tips Length Range (mm) Decontamination/Sterilization	 130 X ∅ 18 65 20-35 Autoclavable	 110 X ∅ 18 55 Same Same
Ultrasound Power Output (W)	8	10
Vibration Amplitude Range (μm)	50-250	20-310

Differences that exist between the above systems relating to technical specifications, materials, physical appearance, and control systems do not affect the relative safety or effectiveness of the SUPRASSON P5 Booster device relative to the SUPRASSON P-Max.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

7.2 Clinical Substantial Equivalence:

Piezoelectric ultrasonic scalers for dental applications have been available as safe and effective devices since October, 1976 when Cavitron received its first Premarket Notification clearance for the "Ultrasonic Dental Prophylaxis Device", (K760805).

The SUPRASSON P5 Booster is used to treat the same clinical dental applications, and utilizes the same 46 tips and reference information as its predicate device, SUPRASSON P-MAX (K942139). A direct comparison establishing the clinical substantial equivalence of the two devices is summarized in Table 4.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Table 4
Clinical Substantial Equivalence

Dental Treatment Application	Tip #	Ref:	Power Settings SUPRASSON P-MAX	Power Settings SUPRASSON P5 Booster*
Scaling:				
Scaling	1	F00246	1-5	5-8
	2	F00247	5-10	8-10
	3	F00248	1-3	5-7
	10P	F00253	1-5	5-8
Retro Surgery	S12 80°	F00093	5-10	8-14
	S12 90°	F00094	5-10	8-14
	S12 120°	F00095	5-10	8-14
	S12D 80°	F00101	4-9	7-9
	S12D 90°	F00102	4-9	7-9
	S12D 120°	F00109	4-9	7-9
	S13L	F00096	5-10	8-14
	S13LD	F00104	4-9	7-9
	S13R	F00097	5-10	8-14
	S13RD	F00105	4-9	7-9
Micro Retro Surgery	P14	F00098	5-9	8-9
	P14D	F00196	4-8	7-9
	P15L	F00099	5-9	8-9
	P15LD	F00107	4-8	7-9
	P15R	F00100	5-9	8-9
	P15RD	F00108	4-8	7-9
Plugging	6A	F00251	1-3	5-7
	7A	F00252	1-3	5-7
Loosening	5	F00250	8-10	10-14
	5AE	F00249	8-10	10-14
Gutta Condensation	S04	F88009	8-10	7-10
	S07	F88010	8-10	7-10
Inlay/Onlay Condensation	C19	F00112	1-3	3-5
	C20	F00113	1-3	3-5
Endodontics:				
Endondontia	K10 21 mm	F43710	1-2	1-3
	K15 21 mm	F43715	1-4	2-4
	K25 21 mm	F43725	3-6	3-5
	K30 21 mm	F43730	5-8	5-6
	K10 25 mm	F43712	1-2	1-3
	K15 25 mm	F43717	1-4	2-4
	K25 25 mm	F43727	3-6	3-5
	K30 25 mm	F43732	5-8	5-6
Prosthesis	F1 L	F00116	1-2	1-3
	F1 R	F00110	1-2	1-3
	F2 L	F00117	1-2	1-3
	F2 R	F00111	1-2	1-3
Periodontics:				
Periodontia	H1	F00366	1-10	1-3
	H2L	F00367	1-10	1-3
	H2R	F00368	1-10	1-3
	H3	F00369	1-10	1-3
	H4L	F00114	1-10	1-3
	H4R	F00115	1-10	1-3

* Note: Micro Retro Surgery and Gutta Condensation are Endodontic applications which can only be accessed through the Scaling Power Mode for the Suprasson P-Max.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

7.3 Conclusion on Substantial Equivalence

As outlined above and in Tables 3 and 4, the Satelec SUPRASSON P5 Booster is similar to its predicate device, the SUPRASSON P-MAX (K924139) in terms of technical specifications, performances, intended use, and methods of application. It has the same properties of safety and effectiveness. Therefore, the SUPRASSON P5 Booster piezoelectric ultrasonic scaler is Substantially Equivalent to its predicate device.

The SUPRASSON P5 Booster is available for the treatments in Scaling, Periodontics, Endodontics, including Retro Surgery, Micro Retro Surgery, Plugging and Loosening, Prosthesis, Gutta Percha Condensation, and Inlay/Onlay Condensation procedures, and should be judged marketable under the provision of Section 510(k) of the Medical Devices Amendments to the Food, Drug and Cosmetic Act.

Substantial Equivalence is summarized in a single format in Section 9 of this Submission entitled "SMDA Summary of Safety and Effectiveness - "510(k) Summary"..

8. Sterilization

The control panel case and handpiece cord are non autoclavable and can be cleaned and disinfected with surgical antiseptic as well as disinfectant towelettes commonly used in dental practice. They are not intended to be in contact with the patient.

The titanium handpiece and stainless steel tips are sterilizable under standard autoclave conditions as described in all the individual instruction/user booklets (i.e. 134°C (273°F), 2.25 bars (29 Psi) for 10 minutes (See Appendix A)).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

9. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submitter Information

SATELEC
Z.I. du Phare, BP 216
Avenue Gustave Eiffel
33708 Merignac Cedex
FRANCE

Telephone: 011-33-56-34-06-07

Contact Person: Pascal Dupeyron
Regulatory Affairs

Date Prepared: March 20 , 1996

B. Device Identification

Common/Usual Name: Piezoelectric Ultrasonic Scaling Generator
Proprietary Name: SUPRASSON P5 Booster

C. Identification of Predicate Device(s)

The SUPRASSON P5 Booster is substantially equivalent to its predicate device, SUPRASSON P-MAX (K942139), previously cleared and currently marketed.

D. Device Description

The SUPRASSON P5 Booster ultrasonic scaler consists of three primary components: the scaling instrument (PAM) "handpiece", the control panel case, and the footswitch.

The scaling instrument (PAM) "handpiece" is held in the physician's hand, but can also be stored in the holder located onto the case. The handpiece is connected to the control panel case via a fixed electrical cable connection. Tips are mounted by means of a tip wrench at the extremity of the handpiece. All SUPPRASON P5 Booster tips vibrate in a single plane (vibration from front to rear and along the tip axis) via piezoelectric ultrasonic power. This rectilinear motion provides a more accurate and more comfortable approach to the tooth and gum. The enamel and cement are protected from unnecessary lateral impacts.

The SUPRASSON P5 Booster, similar to its predicate device, SUPRASSON P-MAX (K942139), operates from the action of cavitation, following the propagation of ultrasounds in a frequency spectrum comprised between 27 and 33 kHz and a mechanical effect following vibration of the tips mixing with water within a range of maximum amplitudes varying from 20 to 310 µm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

The portable plastic control panel case includes all control and ultrasonic power generation functions. A visible light diode informs the user when the device is in enable mode; it also serves as an indicator for the power regulation potentiometer knob. The power settings can be varied from 1-14, dependent upon the clinical application.

Housed in the portable case, internal electronics generate electrical signals at the ultrasound frequency in order for the tip screwed at the extremity of the handpiece to vibrate. Irrigation is provided by a water line manually controlled by tap knob which adjusts the spray at the tip of the handpiece, and is located on the flat side of the control panel case.

Connections to the case are all shorter than 3 m:

(b) (4)

[redacted]

The footswitch pedal has two functions. Pressure on the pedal activates/deactivates piezoelectric ultrasonic power triggering, and enables/disables the flowswitch, located inside the control panel case, for irrigation.

E. Substantial Equivalence

The technical characteristics are almost identical to those of the Satelec SUPRASSON P-Max. Refer to Table A for a comparison with the predicate device. Differences that exist between these devices relating to technical specifications, materials, physical appearance, and control systems do not affect the relative safety or effectiveness of the SUPRASSON P5 Booster relative to its predicate.

The SUPRASSON P-Max and SUPRASSON P5 are intended to provide overall prophylaxis and preservation of soft and hard tissue during the 3 standard dental treatments; Scaling, Periodontics, and Endodontics.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Table A
Comparison Table: Piezoelectric Ultrasonic Scaling Generator Devices

Manufacturer:	**SATELEC**	**SATELEC**
Model	Suprasson P-Max	Suprasson P5 Booster
K-Number	K942139	
Class	II	Request II
Vibration System:		
Ultrasonic System	Piezoelectric	Piezoelectric
Frequency (Khz)	27-33	27-33
Irrigation System:		
Irrigation Method	Peristaltic Pump	External Irrigation Line
Irrigation Rate (ml/mm)	8-30 +/- 20%	
Handpiece:		
Size (mm)	130 X ∅ 18	110 X ∅ 18
Weight (g)	65	55
Tips Length Range (mm)	20-35	20-35
Decontamination	Autoclavable	Autoclavable
Ultrasound Power Output	8W	10W
Vibration Amplitude Range (μm)	50-250	20-310
Unit Characteristics:		
Unit Dimensions (mm)	166 X 250 X 70	147 X 117 X 44
Weight (g)	1000	640
Electrical Requirements	84-264VAC/50-60Hz	90-140VAC/50-60Hz 200-260VAC/50-60Hz
Clinicals:		
Clinical Claims	Scaling Periodontic Treatment Endodontic Treatment	Scaling Periodontic Treatment Endodontic Treatment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

10. Premarket Notification: Truthful and Accurate Statement

Premarket Notification

Truthful and Accurate Statement
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as President of SATELEC, I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been omitted.

Signature

Gilles PIERSON
Typed Name

March 20, 1996
Date

Premarket Notification Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

APPENDIX A

68

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

APPENDIX A

Product Labeling

This appendix includes the following product labeling information for the SUPRASSON P5 Booster:

1. Device Labeling and Locations.
2. SUPRASSON P5 User's Manual.
3. Individual Instruction Booklets for various applications in:
    - Scaling
    - Prosthesis - Chisel Tips
    - Retro Surgery - MicroRetroTips
    - Periodontics - Perio Kit
    - Inlay/Onlay Condensation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

APPENDIX A

SUPRASSON P5 BOOSTER
Device Labeling and Locations

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4) Engineering Drawing

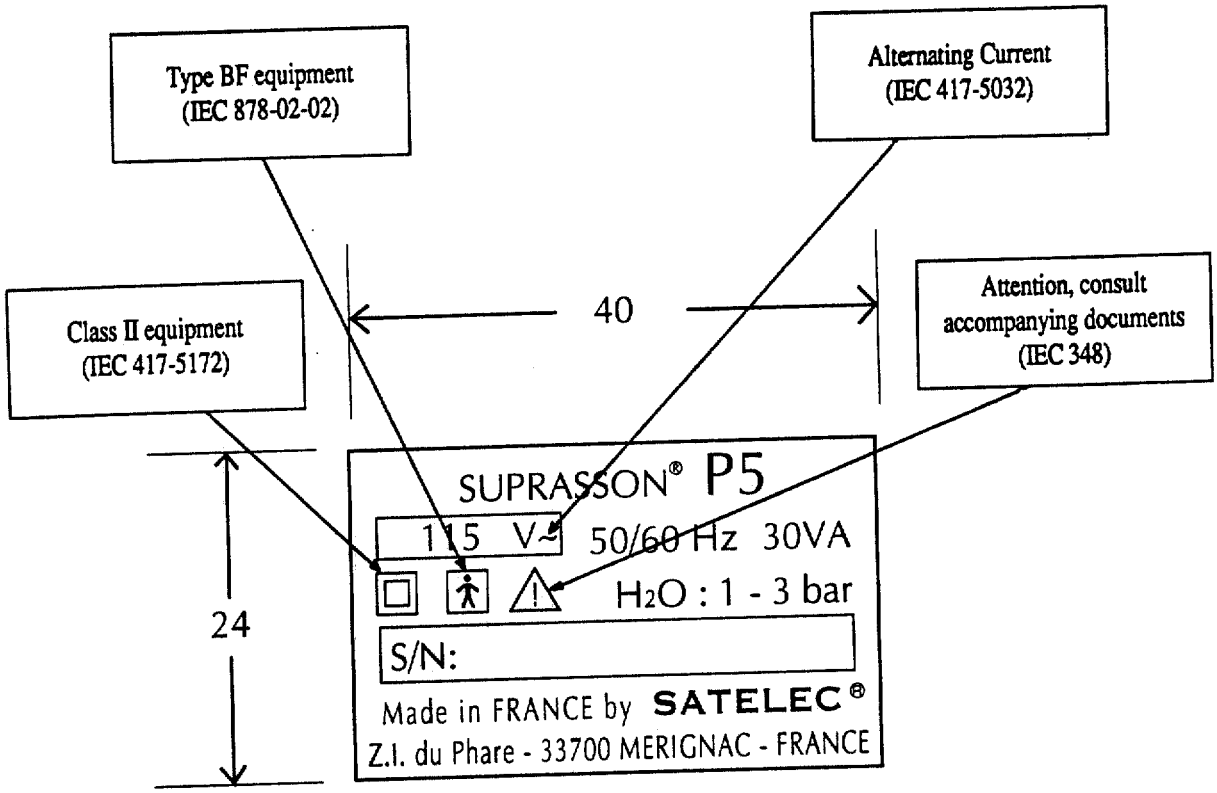
[redacted]

(b) (4)

[redacted]

Records processed under FOIA Request 2014-6834; Released 10/23/14

SYMBOLS ACCORDING TO INTERNATIONAL STANDARD :
IEC 601-1

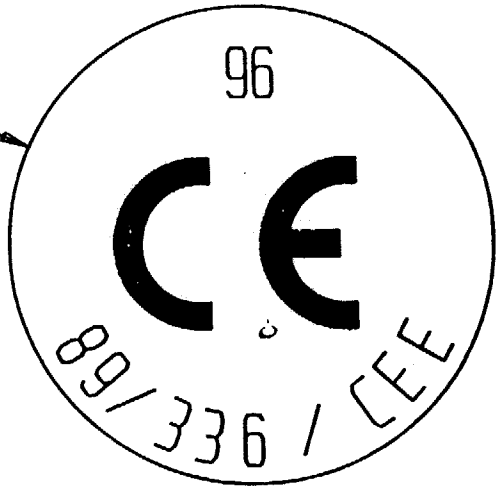


SUPRASSON P5 BOOSTER
IDENTITY PLATE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Diametre de decoupe : 14



Ech 1

NOTA

- C E : impression noire
- Adhesif permanent au verso
- Adherent sur tous type de support propre et sec
  (ex. Aluminium , Plastique , Peinture , Carton)
- Support : PAPIER blanc
- Film fourni par SATELEC

CE MARKING

Rep	Date:	MODIFICATIONS

Tolerances Genérales: ± 0.2	Etat de surface :		
Protection:	Traitement:	Matiere: Voir nota	
Code Article: E 0 0 1 1 0	DESSINE par Ph. T. le 23/11/95	SATELEC	33708 MERIGNAC (56) 34.06.07
Etiquette C E	VERIFIE par le		
	Ech: 5/1	N° E 0 0 1 1 0 B A 0 5 0 0 1 4 A	

Ce document PROPRIETE DE SATELEC ne peut etre utilise, communique ou reproduit sans autorisation prealable ecrite

000022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

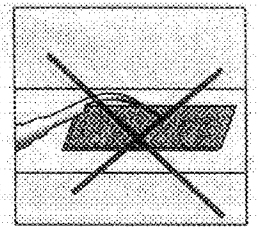
APPENDIX A

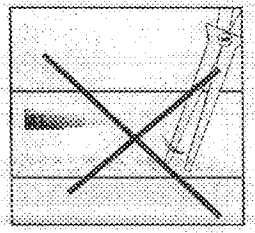
SUPRASSON P5 BOOSTER
User's Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

RECOMMANDATIONS / RECOMMENDATIONS / RACCOMANDAZIONI
EMPFEHLUNGEN / RECOMENDACIONES



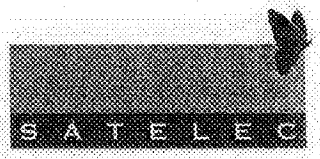


CARACTERISTIQUES TECHNIQUES / TECHNICAL DATA / CARATTERISTICHE TECNICHE
TECHNISCHE DATEN / CARACTERISTICAS TECNICAS

• Poids : 640 g	• Weight : 640 g	• Peso : 640 g	• Gewicht : 640 g	• Peso : 640 g
• Dimensions :	• Dimensions :	• Dimensioni :	• Ausmaße :	• Dimensiones :
- largeur 147 mm,	- width147 mm,	- larghezza 147 mm,	- breite 147 mm,	- ancho 147 mm,
- profondeur 117 mm, -	- depth 117 mm,	- profondità 117 mm, -	- tiefe 117 mm,	- largo 117 mm,
- hauteur 44 mm	- height 44 mm	- altezza 44 mm	- höhe 44 mm	- alto 44 mm
• Freq. : 27-32 Khz	• Freq. : 27-32 Khz	• Freq. : 27-32 Khz	• Freq. : 27-32 Khz	• Freq. : 27-32 Khz
• U. S. : 10 W	• U. S. : 10W	• U. S. : 10 W	• U. S. : 10 W	• U. S. : 10 W
• Puissance max. consommée : 20 VA	• Max. power consumption : 20 VA	• Potenza massima consumata : 20 VA	• Leistungsaufnahme : 20 VA	• Potencia maxima consumida : 20 VA
• Réglage de puissance : 2% → 100%	• Power adjustment : 2% → 100%	• Regolazione di potenza : 2% → 100%	• Leistungsregler : 2% → 100%	• Regulador de potencia : 2% → 100%
• Alimentation : (90-140 et 200-260 VAC 50/60 Hz)	• Power supply : (90-140 et 200-260 VAC 50/60 Hz)	• Alimentazione : (90-140 et 200-260 VAC 50/60 Hz)	• Stromversorgung : (90-140 et 200-260 VAC 50/60 Hz)	•Alimentacion : (90-140 et 200-260 VAC 50/60 Hz)

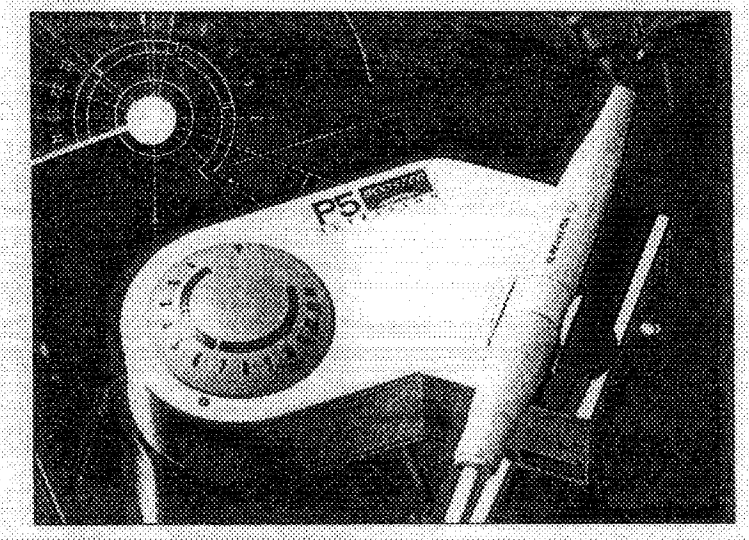
RESPONSABILITÉ / LIABILITY / RESPONSABILITA / GEWÄHRLEISTUNG / RESPONSABILIDAD

- La responsabilité du fabricant ne sera pas engagée en cas d'intervention ou de réparations effectuées par des personnes non autorisées par le constructeur, d'utilisation sur une installation électrique non conforme aux prescriptions de la norme NFC 74-010 (C.E.I publication 601-1), d'utilisations autres que celles spécifiées dans ce manuel.
- The manufacturer accepts no liability in case of : maintenance or repair performed by persons not authorized by the manufacturer, installer or importer, use on an electrical installation not complying with the requirements of standard NFC 74-010 (IEC publication 601-1), uses other than those specified in this manual.
- Il fabbricante declina ogni responsabilità in caso di intervento o riparazione effettuati sull'apparecchio da personale non autorizzato, utilizzo dell'apparecchio su rete elettrica non conforme alle prescrizioni della normativa NFC 74-010 (pubblicazione C.E.I. 601-1), utilizzi diversi da quelli specificati nel presente manuale.
- Der Hersteller haftet nicht : bei Eingriffen und Reparaturen, die nicht durch vom Hersteller, Aufsteller oder Importeur autorisierten Personen durchgeführt worden sind, bei Verwendung mit einer Elektroinstallation, die nicht den Vorschriften der Norm NFC 74-010 (Fassung 601-1) entspricht, bei anderen als in der Bedienungsanleitung angegebenen Verwendungen.
- El fabricante elude cualquier responsabilidad en los siguientes casos : cuando intermienen el aparato, personas no autorizadas por el fabricante, en caso de que la instalacion eléctrica no sea conforme con las prescripciones de la norma NFC 74-010 (CEI publicacion 601-1), cuando el aparato se utilice para otros usos no especificados en este manual.



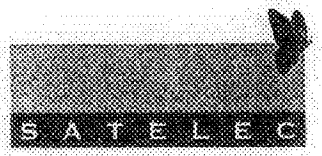
Z.I. du Phare • B. P. 216 • 33708 Mérignac cedex • France • Tél (33) 56 34 06 07 • Fax (33) 56 34 92 92

Ref. : 1 358806 • FN



P5 BOOSTER

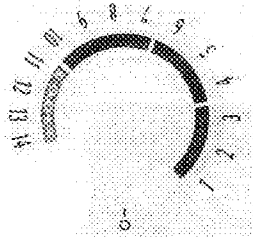
MANUEL D'UTILISATION / USER'S MANUAL
ISTRUZIONI D'USO / BEDIENUNGSANLEITUNG
INSTRUCCIONES PARA EL USO



000024

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

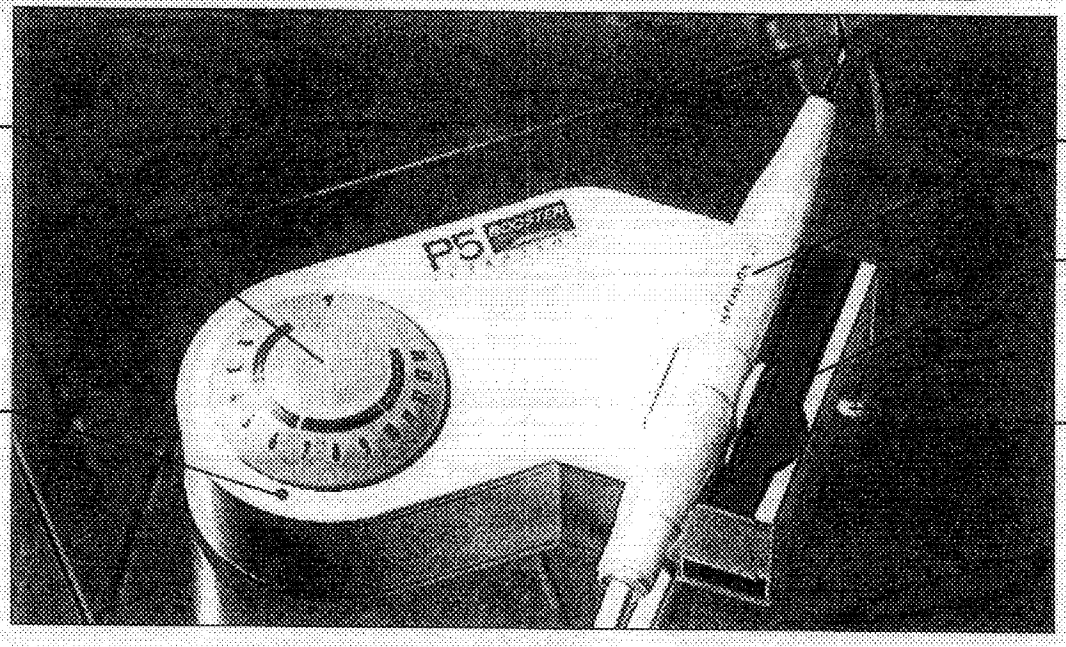


P5 BOOSTER SUPRASON

FACE AVANT / FRONT PANEL / PARTE ANTERIORE /VORDERSEITE / PARTE FRONTAL

Réglage de puissance - Power adjustment - Regolazione di potenza - Leistungsregler - Regulador de potencia

Voyant de mise sous tension - Energizing light - Spia di messa sotto tensione - Spannungsanzeige leuchtet auf - Indicador luminoso



Pièce à main - Handpiece - Manipolo - Handstück - Pieza de mano

Support de pièce à main - Handpiece holder - Sopporto del manipolo - Halterung für Handstück - Soporte pieza de mano

Réglage de spray - Spray adjustment - Regolazione dello spray - Sprayeinstellungen - Regulador de spray

ATTENTION : La vibration correcte d'un insert implique un serrage parfait qui ne doit pas être forcé au-delà de son point de butée. L'insert doit être démonté, nettoyé et stérilisé avant chaque utilisation.

CAUTION : For correct vibration, the tip must be perfectly tightened without over-torquing beyond its stop point. The tip should be removed, cleaned and sterilised before each using.

ATTENZIONE : La vibrazione corretta di un inserto implica che lo stesso sia stretto perfettamente ma non forzato oltre il punto d'arresto. L'inserto deve essere smontato, puliti i sterilizzazioni prima dell'utilizzo.

ACHTUNG : Die spitze muß perfekt sitzen, damit sie richtig schwingen kann, sie darf jedoch nicht üben den anschlag hinaus angezogen werden. Vor jeder Behandlung, spitze mindestens einmal, reinigen und sterilisieren.

IMPORTANTE : La vibración correcta de un insert implica un roscado perfecto, ni demasiado flojo ni demasiado fuerte. El insert debe ser desmontado, limpiadoy y esterilizado antes de cada utilisacion.

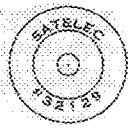
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

FACE ARRIERE / REAR PANEL / PARTE POSTERIORE / RÜCKSEITE / PARTE POSTERIOR

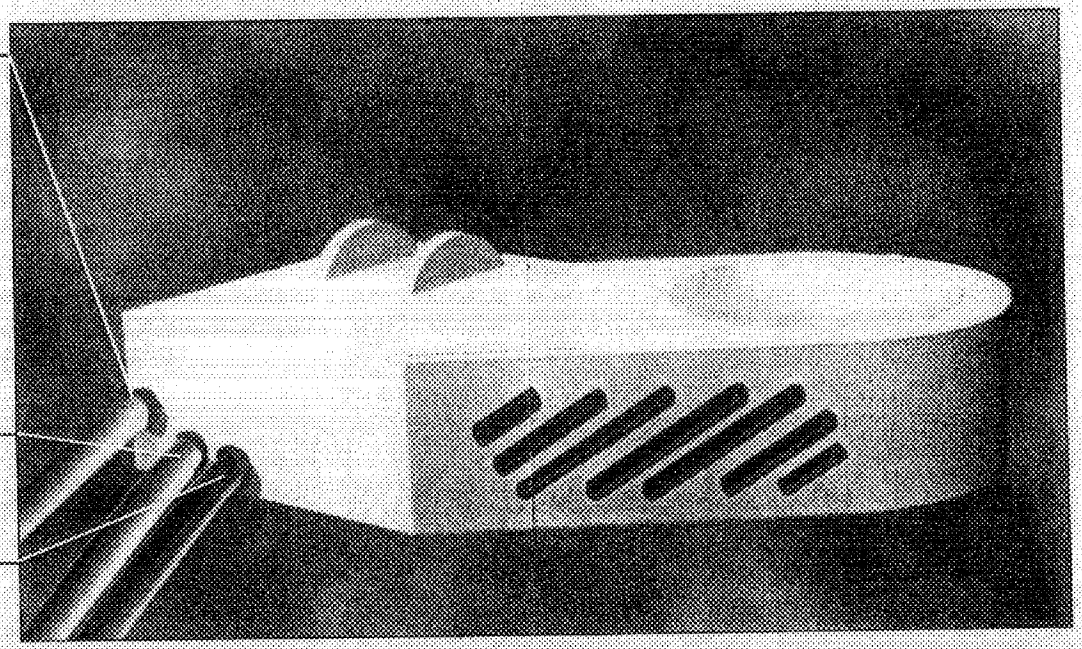
Raccord pour entrée d'eau et connection filtre - Water inlet connector and filter conector - Raccordo entrata acqua e raccordo il filtro - Wasser und Filteranschluß

- Filter KIT option : Ref. F32133
- 10 Filters option - Ref. F32134

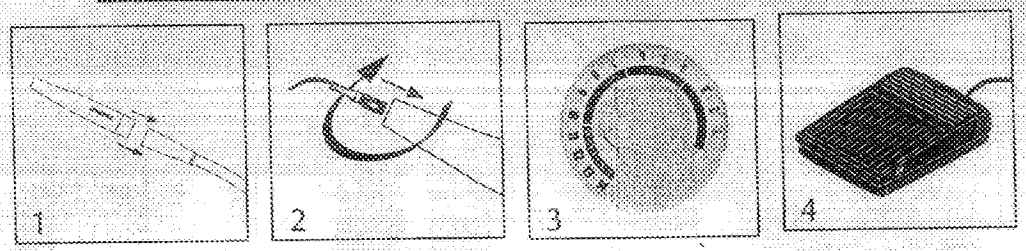


Prise pédale - Pedal power socket - Collegamento pedale - Fußschalterbuchse - Conexion del pedal

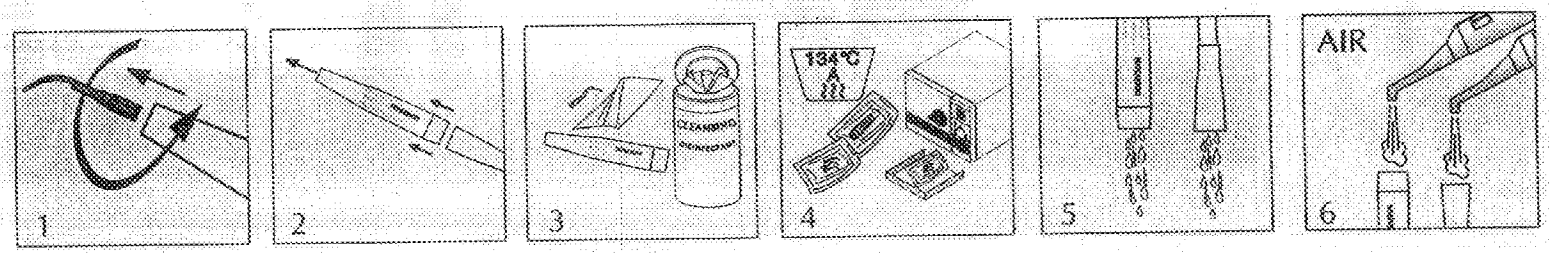
Cordon secteur - Mains cord - Cavo di alimentazione - Netzkabel - Cordon de la red



MONTAGE - FITTING
MONTAGGIO - EINSETZEN
MONTAJE



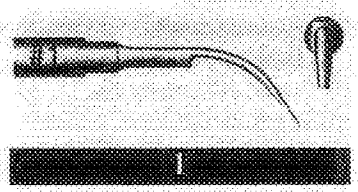
Autoclavable - Autoclavable
Autoclavibilie - Autoklavierbaren
Esterilizable

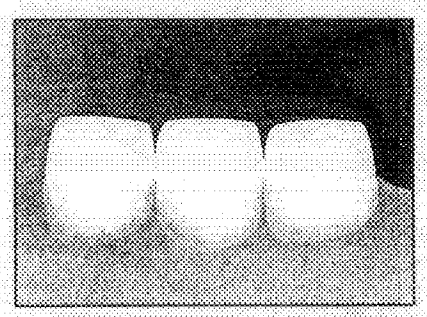


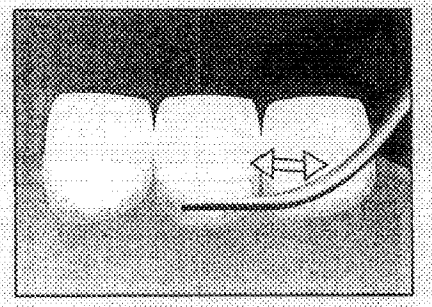
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

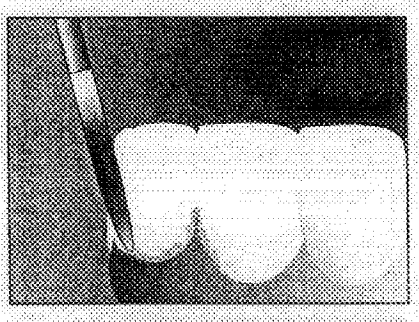
Records processed under FOIA Request 2014-6834; Released 10/23/14

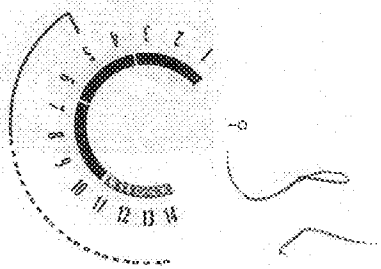
DETARTRAGE / SCALING / ABLAZIONE DEL TARTARO / ZAHNSTEINENTFERNUNG / DETARTRAJE

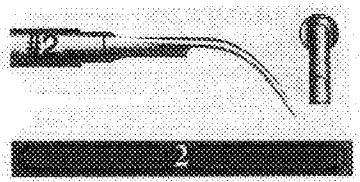


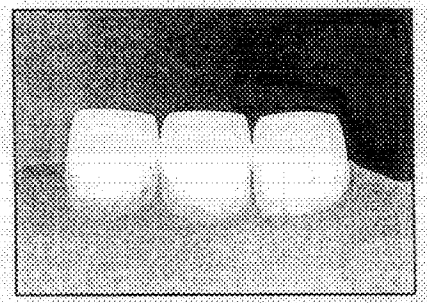


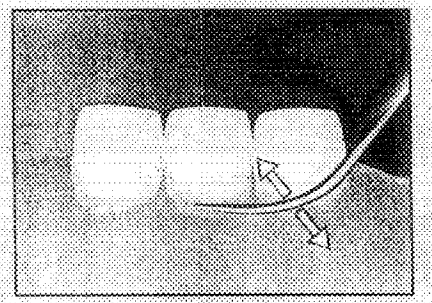


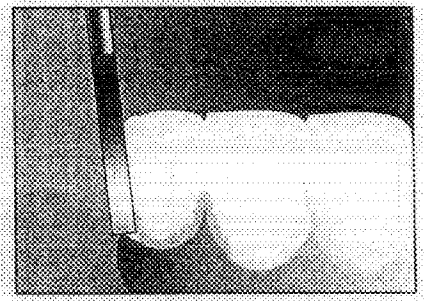


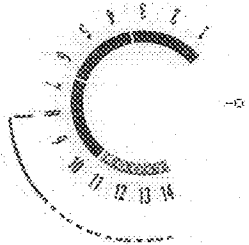


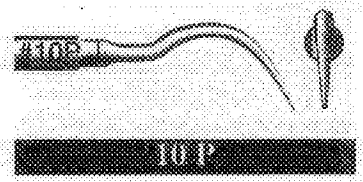


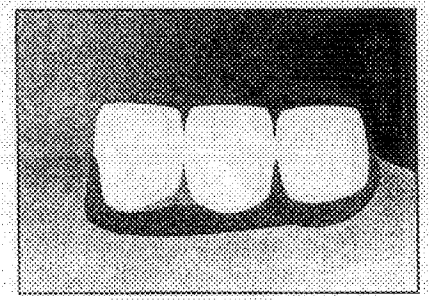


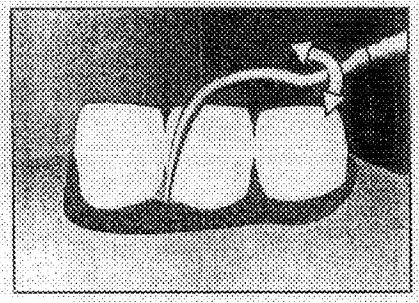


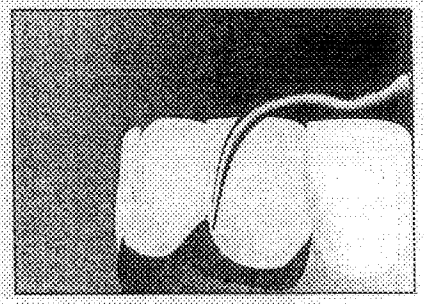


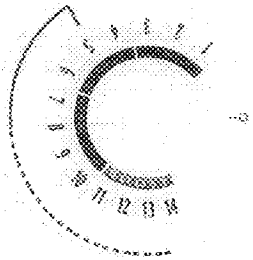












Description des vibrations

Tous les inserts du P5 BOOSTER présentent la particularité de vibrer sur un plan unique (vibrations d'avant en arrière et dans l'axe de leur pointe).
Ainsi, les vibrations latérales propres à d'autres détartreurs sont inexistantes. Ce déplacement rectiligne favorise une approche plus précise et plus confortable de la dent et de la gencive. De ce fait, l'émail et le cément sont préservés des chocs inutiles.

Description of the vibrations

All P5 BOOSTER tips have the particularity of vibrating in a single plane (vibration from front to rear and along the tip axis).
Therefore, lateral vibrations inherent to other scalers do not exist. The rectilinear motion provides a more accurate and more comfortable approach to the tooth and gum. The enamel and cement are protected against useless impacts.

Descrizione delle vibrazioni

Tutti gli inserti del P5 BOOSTER presentano la particolarita' di vibrare su un piano unico (vibrazioni avanti-indietro e lungo l'asse della loro punta). Quindi, le vibrazioni laterali che si verificano su altri ablatori sono inesistenti. Tale spostamento rettilineo favorisce un approccio al dente e alla gengiva più preciso e confortevole. . In questo piano principale di vibrazione, l'estremita' di ogni inserto e' animata da piccoli movimenti vibratori.

Beschreibung der Schwingungen

Alle P5 BOOSTER Arbeitsspitzen schwingen nur in einer Ebene (vorwärts und rückwärts in der Achse der Arbeitsspitze). Deshalb treten keine seitlichen Schwingungen auf, wie bei anderen Zahnsteinentfernern. Die geradlinige Auslenkung ermöglicht eine präzisere Annäherung an den Zahn und an das Zahnfleisch, mit mehr Behandlungskomfort. Schmelz und Zement bleiben vor unnötiger Beanspruchung geschützt.

Descripción de las vibraciones

Todos los inserts del P5 BOOSTER tienen la particularidad de vibrar en un solo plano (vibraciones hacia adelante y hacia atrás y en el sentido del eje del insert).
De este modo, se evitan las vibraciones laterales parásitas propias de otros detartradores. Este movimiento rectilíneo permite un tratamiento mas eficaz y confortable de dientes y encías evitando al esmalte y al cemento la acción de vibraciones inutiles.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

APPENDIX A

Individual Instruction Booklets for various applications in:

- Scaling
- Prosthesis
- Retro Surgery
- Periodontics
- Inlay/Onlay Condensation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

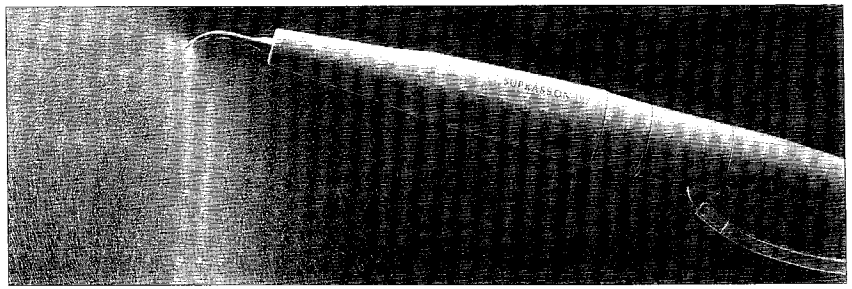
Records processed under FOIA Request 2014-6834; Released 10/23/14

PROPHY MAX
SUPRASSON P-MAX
SUPRASSON PIEZO ENDO
SERVOTOME
PROPHY UNIT S/ENDO
ACTA
TRANS'CARE
LASERSAT CO2
SUNI
X-MIND SYSTEM
SOFTLY

GROUPE SATELEC - PIERRE ROLLAND
Z.I. du Phare - B.P. 216 - 33708 MERIGNAC cédex FRANCE
Tél. (33) 56 34 06 07 - Fax. (33) 56 47 85 52 - Télex SATPR 540 407 F

Ref. 1 12000 - ED

DETARTRAGE / SCALING / ABLAZIONE / ZUR ZAHNSTEIN ENTFERNUNG / DETARTRADOR



SUPRASSON

NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET / FOGLIETTO ILLUSTRATIVO
BEDIENUNGSANLEITUNG / INSTRUCCIONES DE USO

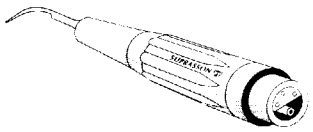
SATELEC

81

000026

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14



- Pièce à main autoclavable
- This handpiece may be sterilized in an autoclave
- Manipolo autoclavabile
- Im autoklaven sterilisierbarem handteil
- Pieza de mano esterilizable en autoclave

SOMMAIRE

	Page
Composition du coffret	4
Mise en service	5-6
-Raccordement de la pièce à main	
- Option STERIJOINT	
- Montage des inserts	
- Description des vibrations	
Nettoyage et stérilisation	7-8
Recommandations	8
Notes personnelles	29

SUMMARY

	Page
Content of the box	9
Start-up	10-11
- Connection of the handpiece	
- STERIJOINT option	
- Precautions for fitting tips	
- Description of the vibrations	
Cleaning and sterilization	12-13
Recommendations	13
Personnal notes	29

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

NOTE PERSONALI / PERSÖNLICHE NOTIZEN / NOTAS PERSONALES

SOMMARIO

	Pagina
Composizione del cofanetto	14
Accensione	15-16
- Connessione del manipolo	
- Montaggio degli inserti	
- Montaggio degli inserti	
- Descrizione delle vibrazioni	
Pulizia e sterilizzazione	17-18
Raccomandazioni	18
Note personali	30

INHALT

	Seite
Inhalt	19
Inbetriebnahme	20-21
- Anschluss des Handstücks	
- Option STERIJOINT	
- Einsetzen der Spitzen	
- Beschreibung der Schwingungen	
Reinigen und Sterilisieren	22-23
Empfehlungen	23
Persönliche Notizen	30

SUMARIO

	Página
Composición del estuche	24
Puesta en servicio	25-26
- Conexión de la pieza de mano	
- Opcion STERIJOINT	
- Montaje de los insertos	
- Descripción de las vibraciones	
Limpiado y esterilización	27-28
Recomendaciones	28
Notas personales	30

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

COMPOSITION DU COFFRET

- 1 ou 2 pièces à main, autoclavables, avec spray.

- 1 série d'inserts avec spray à utiliser avec la pièce à main :
  - n°1 F 00246 - DETARTRAGE
  - n°2 F 00247 - DETARTRAGE
  - n°10P F 00253 - DETARTRAGE
  - n°3 F 00248 - DETARTRAGE
  - n°5AE F 00249 - DESCELLEMENT

- 1 série d'inserts sans spray à utiliser avec la pièce à main :
  - n°5 F 00250 - DESCELLEMENT
  - n°6A F 00251 - FOULAGE D'AMALGAME
  - n°7A F 00252 - FOULAGE D'AMALGAME

NOTES PERSONNELLES / PERSONNAL NOTES

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

LIMPIADO Y ESTERILIZACION

Importante :
- Desconectar el cordon.
- Situar las piezas de mano en un paño o bolsa esterealizable, si es necesario.
- Sacar las piezas de mano del autoclave cuando haya terminado la esterilización.
- Secar las piezas de mano antes de su utilización.

Precauciones :
- Las piezas de mano deben esterilizarse sin los insertos.
- Echar fuera el liquido de irrigación en la pieza de mano con aire comprimido antes de la esterilización.

RECOMENDACIONES

N. B. : Durante la esterilización, las piezas metálicas de naturaleza diferente, no deben tocarse. Cualquier contacto acarrearía la creación de pares electroliticos que provocan una deterioración local. Para evitar ese fenómeno, colocar los objetos en una tela o en una bolsa esterilizable.

Fra

MISE EN SERVICE

1 - Raccordement de la pièce à main

- Le raccordement de la pièce à main sur la douille du cordon s'effectue par simple enfichage. Ne pas effectuer de mouvement de rotation.

2 - Option STERIJOINT

- Le STERIJOINT est très facilement enfichable sur la pièce à main, le cordon venant se connecter sur le STERIJOINT.
- La ligne d' irrigation se raccorde sur l' embout métallique du STERIJOINT.
- Ceci permet une chaine stérile du flacon à l' insert via la pompe péristaltique.
- Ainsi, le STERIJOINT assure une totale stérilité du liquide d' irrigation.
- Le STERIJOINT est stérilisable à 134° C en autoclave.
- Dans le cas d'utilisation d'hypochlorite de sodium, il est impératif d'effectuer un rinçage systématique de toutes les parties en contact avec la solution après chaque patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

MISE EN SERVICE

3 - Montage des inserts

- Les inserts doivent être vissés et serrés modérément avec leur clé.

Important : La vibration correcte d'un insert implique son serrage parfait. Le serrage d'un insert ne doit pas être forcé au-delà de son point de butée.

NOTA : Pour éviter son auto-blocage, l'insert doit être démonté, au minimum une fois par jour.

4 - Description des vibrations

- Tous les inserts du SUPRASSON présentent la particularité de vibrer sur un plan unique (vibrations d'avant en arrière et dans l'axe de leur pointe). Ainsi les vibrations latérales propres à d'autres détartreurs sont inexistantes. Ce déplacement rectiligne favorise une approche plus précise et plus confortable de la dent et de la gencive. De ce fait, l'émail et le cément sont préservés des chocs inutiles.
- Dans ce plan principal de vibration, l'extrêmité de chaque insert est animée de très petits mouvements vibratoires. Pour obtenir les meilleures performances du SUPRASSON, l'opérateur tiendra compte de ces mini-vibrations spécifiques à chaque insert.

LIMPIADO Y ESTERILIZACION

De las piezas desmontables

Proceder sistematicamente al reemplazo de una pieza deteriorada por el desgaste o por un choque accidental (caída...).

Condiciones de esterilización :

Material : autoclave, chemiclave

Esterilización : bajo calor húmedo

40 minutos a 121°C bajo 1 bar - 20 minutos a 134°C bajo 2 bar

De las piezas de mano

Su limpieza puede efectuarse con alcohol. La limpieza de la cavidad del paso de rosca se realiza mediante un bastoncillo empapado en alcohol. No limpie la pieza de mano en una cubeta de ultrasonidos.

Condiciones de esterilización :

Material : autoclave

Esterilización : bajo calor húmedo

40 minutos a 121°C bajo 2 bar - 20 minutos a 134°C bajo 2 bar.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PUESTA EN SERVICIO

3 - Montaje de los insertos

- Los insertos deben ser atornillados y apretados con moderación con su llave.
Importante : La vibración correcta de un inserto implica un apriete perfecto. El apriete de un inserto no debe ser forzado más allá de su tope.
NOTA : Para evitar su autobloqueo, los insertos deben desmontarse por lo menos una vez al dia de la pieza de mano.

4 - Descripción de las vibraciones

- Todos los insertos del SUPRASSON presentan la particularidad de vibrar sobre un plano único (vibraciones de adelante hacia atrás y en el eje de su punta). De este modo, se evitan las vibraciones laterales propias de otros detartradores. Este desplazamiento rectilineo favorece un acercamiento más preciso y más cómodo al diente ya la encia. Así, el esmalte y el cemento están preservados de las choques perjudiciales.
- En este plano principal de vibración, el extremo de cada inserto está animado de muy pequeños movimientos vibratorios. Para obtener los mejores resultados del SUPRASSON el operador tendrá en cuanta estas mini-vibraciones específicas a cada inserto.

NETTOYAGE ET STERILISATION

Des inserts

Procéder systématiquement au remplacement d'un insert qui a subi une détérioration par l'usure ou par un choc accidentel (chute ...).
Conditions de stérilisation :
Matériel : autoclave, chemiclave
Stérilisation : sous chaleur humide
40 minutes à 121°C sous 1 bar - 20 minutes à 134°C sous 2 bars.

Des pièces à main

Leur nettoyage peut s'effectuer à l'alcool. Un nettoyage correct de la cavité du pas de vis est réalisable au moyen d'un coton tige imbibé d'alcool. Ne pas nettoyer la pièce à main dans une cuve à ultrasons.
Conditions de stérilisation :
Matériel : autoclave
Stérilisation : sous chaleur humide
40 minutes à 121° C sous 1 bar - 20 minutes à 134° C sous 2 bars..

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

NETTOYAGE ET STERILISATION

Important :
- Déconnecter le cordon
- Placer les pièces à main dans un tissu ou un sac stérilisable, si nécessairre.
- Sortir les pièces à main de l'autoclave dès la fin de la stérilisation.
- Sécher les pièces à main avant utilisation.

Attention :
- Les pièces a main doivent être stérilisées sans l'insert.
- Chasser tout liquide d'irrigation dans la pièce à main à l'aide d'air comprimé avant stérilisation.

RECOMMANDATIONS

Nota : Pendant la stérilisation, des pièces métalliques de nature différente ne doivent pas se toucher. Tout contact entrainerait la création de couples électrolytiques qui provoqueraient une détérioration locale. Afin d'éviter ce phénomène, placer les objets dans un tissu ou un sac stérilisable.

PUESTA EN SERVICIO

1 - Conexión de la pieza de mano

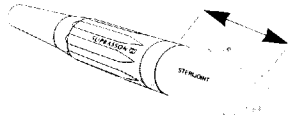
- La conexión de la pieza de mano sobre el casquillo del cordón se efectua sin movimiento de rotación.

2 - Opción STERIJOINT

- El STERIJOINT es fácil acoplamiento a la pieza de mano. El cordón se conecta en el STERIJOINT.
- La línea de irrigación se coloca en la boquilla metálica del STERIJOINT.
- Esto permite crear una cadena estéril, desde el frasco hasta el insert, o pasando por la bomba peristáltica.
- Así, el STERIJOINT asegura una total esterilidad del líquido de irrigación.

El STERIJOINT es esterilizable a 134° C en autoclave.

- En caso de utilizar hipoclorito de sodio, es imprescindible efectuar un enjuague sistematico de todos los elementos en contacto con dicha solucion despues de cada utilizacion.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

COMPOSICION DEL ESTUCHE

- 1 o 2 piezas de mano, esterilizables en autoclave, con spray.

- 1 serie de insertos con spray para emplear con la pieza de mano :
  - n°1 F 00246 - DETARTRADOR
  - n°2 F 00247 - DETARTRADOR
  - n°10P F 00253 - DETARTRADOR
  - n°3 F 00248 - DETARTRADOR
  - n°5AE F 00249 - DESEMPOTRADOR

- 1 serie de insertos sin spray para emplear con la pieza de mano :
  - n°5 F 00250 - DESEMPOTRADOR
  - n°6A F 00251 - CONDENSADOR DE AMALGAMA
  - n°7A F 00252 - CONDENSADOR DE AMALGAMA

CONTENT OF THE BOX

- 1or 2 handpieces, may be sterilized in an autoclave with spray.

- A range of tips with spray to be used with the handpiece :
  - n°1 F 00246 - SCALING
  - n°2 F 00247 - SCALING
  - n°10P F 00253 - SCALING
  - n°3 F 00248 - SCALING
  - n°5AE F 00249 - PROSTHESIS LOOSENING

- A range of tips without spray to be used with the handpiece :
  - n°5 F 00250 - PROSTHESIS LOOSENING
  - n°6A F 00251 - AMALGAM CONDENSATION
  - n°7A F 00252 - AMALGAM CONDENSATION

19

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

START-UP

1 - Connection of the handpiece

- The handpiece is fitted to the cord socket by means of a simple snap connection. Do not attempt to screw.

2 - STERIJOINT option

This is a P-MAX Option.
Not available for the P5
Booster Model

- STERIJOINT can be plugged in the handpiece very easily, the cord being connected to the STERIJOINT.
- The irrigation line is adapted to the STERIJOINT small metallic tube.
- This enables a sterile line from the flask to the tip via the peristaltic pump.
- Thus, STERIJOINT ensures a total sterility of the irrigation liquid.
- STERIJOINT can be sterilized at 134° in an autoclave unit.
- When using sodium hypochlorite, a systematic rinse of every part in contact with the solution is imperative after each patient.

REINIGEN UND STERILISIEREN

Wichtig :
- Kabel ausstecken.
- Zum Sterilisieren, Handstücke in eine Steri-Hülle packen.
- Nach Ende des Sterilisationsvorganges, Handstücke aus den Autoklaven nehmen.
- Vor Gebrauch, Handstücke bitte abtrocken.

Achtung :
- Handstücke und Spitzen immer separat sterilisieren.
- Vor der Sterilisation alle Spüeflüssigkeit im Handstück mit Komprimierter Luft entfernen.

EMPFEHLUNGEN

Anmerkung : Beim Sterilisieren dürfen Teile aus verschiedenartigen Metallen nicht in Kontakt geraten. Dies würde eine elektrolytische Wirkung nach sich ziehen die lokale Schäden hervorrufen könnte. Deshalb Einwickein der Gegenstände in einen Textil oder Sterilisierbeutel

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

REINIGEN UND STERILISIEREN

Einsätze

Ein durch Abnutzung oder einen möglichen Stoß (Sturz...) beschädigter Einsatz muß in jedem Fall ausgewechselt werden.

Sterilisierungsbedingungen :

im Autoklav, chemikalisch

40 Minuten bei 121°C bei 1 Bar - 20 Minuten bei 134°C bei 2 Bar

Handteile

Sie können mit Alkohol gereinigt werden. Zur ordnungsgemäßen Reinigung der Gewinde kann ein mit Alkohol getränktes Wattestäbchen benutzt werden. Ein Handteil darf niemals in einem Ultraschallbehälter gereinigt werden.

Sterlisierungsbedingungen :

im Autoklav

40 Minuten bei 121°C bei 1 Bar - 20 Minuten bei 134°C bei 2 Bar

START-UP

3 - Precautions for fitting tips

- The tips must be screwed in and moderately tightened using their key.

Important : In order to obtain a good vibration of a tip, the latter must be perfectly tightened. For that, it must not be forced beyond the stop point.

NOTE : The tip must be removed at least once a day so that it does not get jammed.

4 - Description of the vibrations

All the SUPRASSON tips have the particularity of vibrating in a single plane (vibrations from front to rear along the axis of the tip). Lateral vibrations common to scalers do not therefore exist. The rectilinear displacement provides a more accurate and more comfortable approach to the tooth and gum. The enamel and cement are protected against pointess impacts. Within this main vibratory plane, the extremity of each tip is driven by tiny vibratory movements.

For maximum performance of the SUPRASSON the operator should take into account these mini-vibrations specific to each tip.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

CLEANING AND STERILIZATION

Tips

Damaged tips (normal wear or accidental damage), must be replaced systematically.

Sterilizing conditions :

Equipment : autoclave, chemiclave

Sterilization : humid conditions

40 minutes at 121°C at 1 bar (247°F) at 1 bar (14.5 psi)

20 minutes at 134°C at 2 bars (29 psi)

Handpieces

These may be cleaned with alcohol. The screw-thread cavity can be properly cleaned by using a cotton bud soaked in alcohol. Do not clean handpieces in an ultrasonic ultrasonic tank.

Sterilizing conditions :

Equipment : autoclave

Sterilisation : humid conditions

40 minutes at 121°C (247°F) at 1 bar (14.5 psi)

20 minutes at 134°C (273°F) at 2 bars (29 psi).

INBETRIEBNAHME

3 - Einsetzen der Spitzen

- Spitze einschrauben und mit dem Schlüssel leicht festziehen.

Wichtig : Die Spitze muß perfekt sitzen damit sie richtig schwingen kann. Sie darf jedoch nicht über den Anschlag hinaus angezogen werden.

ANMERKUNG : Um zu vermeiden, daß sich der Einsatz selbst blockiert, muß er mindestens einmal am Tag demontiert werden.

4 - Beschreibung der Schwingungen

Alle SUPRASSON Arbeitsspitzen schwingen nur in einer Ebene (vorwärts und rückwärts in der Achse der Abeitsspitze). Deshalb treten keine seitlichen Schwingungen auf, wie bei anderen Zahnnsteinentfernern. Die geradlinige Auslenkung ermöglicht eine präzisere Annährerung an den Zahn und an das Zahnfleisch, mit mehr Behandlungskomfort. Schmelz und Zement bleiben vor unnötiger Beanspruchng geschützt.

Die Bewegungen der Spitze in der Hauptschwingungsebene sind sehr klein. Die beste Leistung bringt das SUPRASSON, wenn man die spezifischen Minischwingungen der verschiedenen Spitzen berücksichtigt.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

INBETRIEBNAHME

1 - Anschluss des Handstücks

- Die Verbindung des Handstücks mit dem kabel ist ein einfacher Steckverschluß. Bitte nicht verdrehen (kein Schraubverschluß).

2 - Option : STERIJOINT

- Der STERIJOINT wird zwischen Handstück und Kabel eingesteckt.
- Der Spülschlauch wird am STERIJOINT montiert, was eine sterile Linie von der Flasche bis zur Spitze ermöglicht, angetrieben durch die Peristaltic Pumpe.
- Das garantiert eine hundertprozentige Sterilität der verwendeten Flüssigkeit.
- Der STERIJOINT kann bei 134° C in einem Autoklaven sterilisiert werden.
- Bei Verwendung von Natriumhypochlorit müssen alle Teile, die in Kontakt mit der Lösung waren, nach jedem Patienten systematisch gereinigt werden.

CLEANING AND STERILIZATION

Important :
- Disconnect the cord.
- Put the handpieces in a sterilizable or cloth bag, if needed.
- Take the handpieces out of the autoclave as soon as sterilization is complete.
- Dry the handpieces before using.

Attention :
- Handpieces and tips must always be separated before sterilization.
- Use compressed air to expel any irrigation fluid left in the handpiece before sterilization.

RECOMMENDATIONS

Nota : During sterilization, metal parts of different kinds should not come into contact with each other. Any such contact would create electrolytic torque causing local degradation. To avoid this phenomenon, wrap the objects in a cloth or place them in a sterilizable bag.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

COMPOSIZIONE DEL COFANETTO

- 1 o 2 manipoli, autoclavabili con spray.

- 1 serie d'inserti con spray da utilizzare con il manipolo :
  - n°1 F 00246 - ABLAZIONE
  - n°2 F 00247 - ABLAZIONE
  - n°10P F 00253 - ABLAZIONE
  - n°3 F 00248 - ABLAZIONE
  - n°5AE F 00249 - DECEMENTAZIONE

- 1 serie d'inserti senza spray da utilizzare con il manipolo :
  - n°5 F 00250 - DECEMENTAZIONE
  - n°6A F 00251 - CONDENSAZIONE
  - n°7A F 00252 - CONDENSAZIONE

Deu

INHALT

- 1oder 2 Handstücke, autoklavierbar, mit Spray.

- Ein Satz Spitzen mit Spray, zur Verwendung mit dem Handstück :
  - n°1 F 00246 - ZUR ZAHNSTEIN ENTFERNUNG
  - n°2 F 00247 - ZUR ZAHNSTEIN ENTFERNUNG
  - n°10P F 00253 - ZUR ZAHNSTEIN ENTFERNUNG
  - n°3 F 00248 - ZUR ZAHNSTEIN ENTFERNUNG
  - n°5AE F 00249 - ZUR ABLÖSUNG VON ZAHNERSATZ

- Ein Satz Spitzen ohne Spray, zur Verwendung mit dem Handstück :
  - n°5 F 00250 - ZUR ABLÖSUNG VON ZAHNERSATZ
  - n°6A F 00251 - ZUR AMALGANVERDICHTUNG
  - n°7A F 00252 - ZUR AMALGANVERDICHTUNG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PULIZIA E STERILIZZAZIONE

Importante :
- Staccare il cordone dal manipolo.
- Sistemare il manipolo in una busta per sterilizzazione, se necessario.
- Terminato il ciclo di sterilizzazione, estrarre il manipolo dall'autoclave.
- Asciugare il manipolo prima dell'utilizzo.

Attenzione :
- I manipoli devono sempre essere sterilizzati senza l'inserto.
- Prima della sterilizzazione, eliminare il liquido di irrigazione con uno spruzzo di aria compressa e acqua.

RACCOMANDAZIONI

Nota : Durante la sterilizzazione, pezzi metallici di natura differente, non devono toccarsi. Ogni contatto causerebbe la creazione di coppie elet-trolitiche, il che prove-cherebbe un deterioramento locale. Per evitare questo fenomeno, porre i pezzi in un tessuto o in una busta per sterilizzazione.

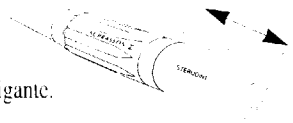
ACCENSIONE

1 - Connessione del manipolo

- La connessione del manipolo al cordone viene effettuata con semplice inserimento. Non effettuare movimenti di rotazione.

2 - Opzione STERIJOINT

- STERIJOINT e' facilmente collegabile al manipolo dato che il cordone di quest' ultimo si innesta anche sullo STERIJOINT.
- Il tubo per l'irrigazione viene collegato sul raccordo metallico dello STERIJOINT.
- Cosi' si viene a creare una "linea sterile", dal flacone all' inserto, passando attraverto la pompa peristaltica.
- In tal modo STERIJOINT assicura la totale sterilita' del liquido di irrigazione.
- STERIJOINT puo' essere sterilizzato in autoclave a 134° C.
- Nel caso si utilizzasse ipoclorito di sodio, al termine di ogni trattamento è importante risciacquare tutte le parti che vengono a contatto con la soluzione irrigante.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

3 - Montaggio degli inserti

- Gli inserti devono essere avvitati e stretti moderatamente con l'apposita chiave.
Importante : La vibrazione corretta di un inserto implica che sia perfettamente fissato ma non deve essere forzato oltre il punto d'arresto.
NOTA : Per evitarne l'auto-bloccaggio, l'inserto deve essere smontato per lo meno una volta al giorno.

4 - Descrizione delle vibrazioni

Tutti gli inserti del SUPRASSON presentano la particolarità di vibrare su un piano unico (vibrazioni avanti-indietro sull' asse della loro punta). Quindi, le vibrazioni laterali che si verificano su altri ablatori sono inesistenti. Tale spostamento rettilineo favorisce un piú preciso e confortevole approccio del dente e della gengiva. Percio ' lo smalto e il cemento sono protetti da urti inutili.
In questo piano principale di vibrazione, l'estremità di ogni inserto è animata con piccoli movimenti vibratori. Per ottenere le massime prestazioni del SUPRASSON, l'operatore terrà conto di queste minivibrazioni specifiche per ogni inserto.

Inserti
Procedere sistematicamente alla sostituzione di un inserto che ha subito un deterioramento a causa dell' usura o a causa di uno urto accidentale (caduta, ecc...)
Sterilizzazione :
Apparecchio : autoclave, chemo-autoclave
Sterilizzazione : calore umido
40 minuti a 121°C a 1 bar - 20 minuti a 134°C a 2 bar

Manipoli
La loro pulizia puo' effettuarsi a mano. Una corretta pulizia della cavità del passo della vite é realizzabile con un bastoncino di cotone imbevuto di alcool. Non utilizzare vaschette ad ultrasuoni.
Sterilizzazione :
Apparecchio : autoclave
Sterilizzazione : calore umido
40 minuti a 121°C a 1 bar - 20 minuti a 134°C a 2 bars

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

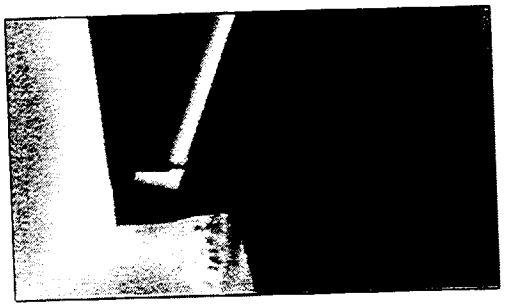
Records processed under FOIA Request 2014-6834; Released 10/23/14

P5 BOOSTER
PROPHY-MAX
SUPRASSON P-MAX
SUPRASSON PIEZO ENDO
PROPHY UNIT S/ENDO
SERVOTOME
ACTA
TRANS'CARE
LASERSAT CO2
SUNI
X-MIND SYSTEM

GROUPE SATELEC - PIERRE ROLLAND
Z.I. du Phare - B.P. 216 - 33708 MERIGNAC cédex FRANCE
Tél. (33) 56 34 06 07 - Fax. (33) 56 47 85 52 - Télex SATPR 540 407 F

Ref. F00209 - F4

PROSTHESIS



CHISEL TIPS™

INSTRUCTION BOOKLET

SATELEC

000027

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

OBJECTIVES

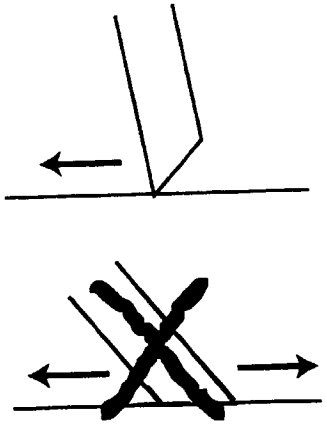
1- Rough surface of the cutting bur can be corrected smooth
2- Square shape irregularities of the shoulder surface can be corrected smooth by rubbing towards the forward direction.
3- When removing free substance while preparing with chamfer, can correct without deviation nor damage.
4- Flares of half crowns and offset portions as well as corrections after providing bevel can be done smooth.
5- Corrections of occlusal inlays and cavity floors close to the pulp can be done without excessive force. Thus pulp does not receive unnecessary stimulation.
6- Adjacent box floor and other hard to reach portions can be corrected without damaging adjacent tooth.

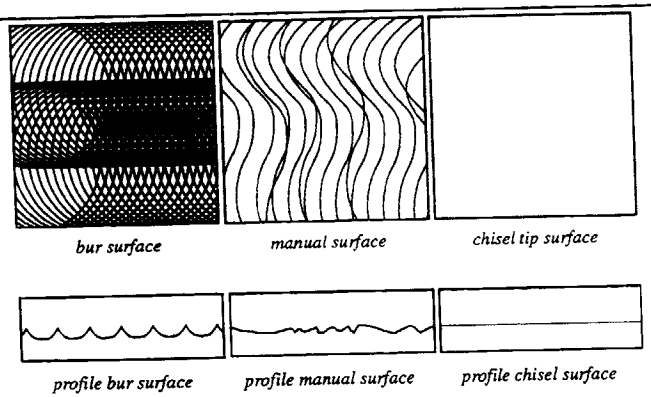
As given above, there are several advantages to this. However, it is not always sufficient merely to draw forward as in the case with planes and adzes.
For instance, in case there are hard enamel substances left in volume, you might have to push forward carefully. It would be inconsiderate to use this for excessively rough surfaces. It must be understood that this is principally for corrections after final finish.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

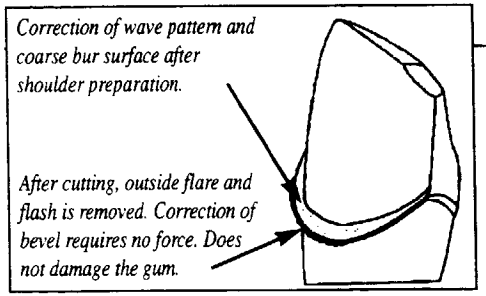
HOW TO USE CHISEL TIP

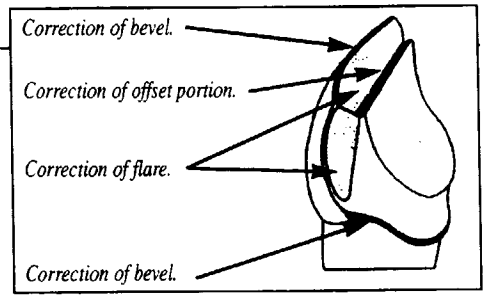


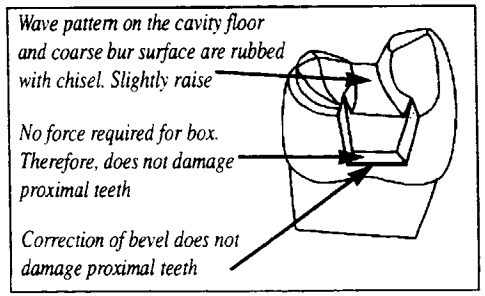


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14







PERSONAL NOTES

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

STERILIZATION AND DISINFECTION

Damaged tips (normal wear or accidental damage), must be replaced systematically.

Sterilizing conditions :

Equipment : autoclave, chemiclave
Sterilization : 10 minutes at 134° C at 2 bars (29 Psi)

OPERATING INSTRUCTIONS

Purpose and usage :

To retouch and correct the final finished surface of total or half crown.

In order to avoid damage of gingiva resulting from overrunning the manual chisel in forward direction, ultrasonic vibration is applied to this and chisel pulled in backward direction to rub and correct the coarse surface. No force is required for doing this and the following points can be accomplished.

1. Correction of the finished line

2. Correction of free dental substances on the chamfer

3. Correction of coarse cavity floor

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

OPERATING INSTRUCTIONS

Application :

By pulling Chisel backwards and rubbing the surface gently, square dent surface can be finished smooth.

Unscrapped portion of chamfer can also be corrected by gently moving the chisel forward or rubbing backwards. Chisel must be handled with both hands as single hand will create rolling motion.

Frequency must also be adjusted depending on time and place of use,

adjust power,

When coarse surface is large or free dental substance rigid, adjust chisel tips to maximun frequency (for removing metal). In general, ultrasonic scaling position (for removing calculu) will suffice.

OPERATING INSTRUCTIONS

Efficacy :

Trial on coarse shoulder surface and bevels proved to be satisfactory. The device has the following efficacies.

1- Can correct coarse surface smooth
2- Square irregularities can be made smooth by pulling the chisel forward and rubbing gently. No force required (fig. 1).
3- When removing free substances for preparing the chamfer, it does not overrun and damage the gingiva.
4- Can correct flares, and offsets of half crowns and finish bevels smooth.
5- Can correct occlusal inlay cavity floors close to pulp without force. Therefore, no unnecessary stimulation on the pulp.
6- Floors of adjacent box hard to reach can be corrected without damaging the proximal tooth (fig. 2).
7- Bevels can be properly corrected for all preparations.

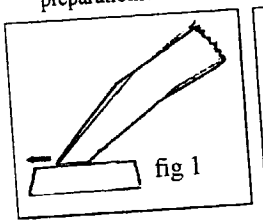


fig 1

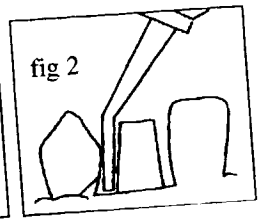


fig 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

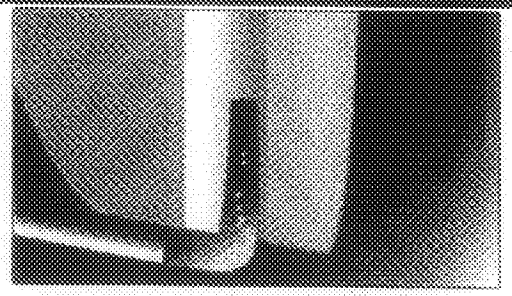
Records processed under FOIA Request 2014-6834; Released 10/23/14

P5 BOOSTER
PROPHY-MAX
SUPRASSON P-MAX
SUPRASSON PIEZO ENDO
SERVOTOME
PROPHY UNIT S/ENDO
ACTA
TRANS'CARE
LASERSAT CO2
SUN1
X-MIND SYSTEM

GROUPE SATELEC - PIERRE ROLLAND
2, r. du Phare - B.P. 116 - 33700 MERIGNAC cedex FRANCE
Tél. (33) 56 34 05 07 - Fax (33) 56 97 85 32 - Télex SATPR 540 497 F

Ref. 1000102 - F4

RETRO CHIRURGIE / RETRO SURGERY



MICRORETROTIPS

NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET

SATELEC

000028

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

F R A N C A I S

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

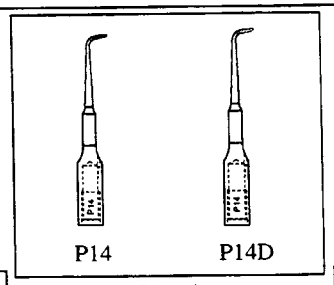


Fig. 4

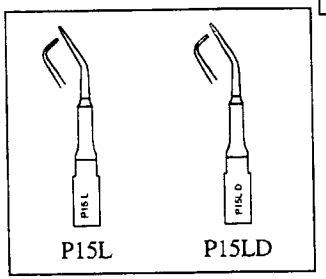


Fig. 5

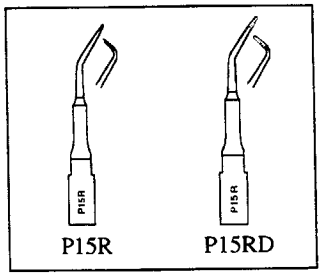


Fig. 6

SOMMAIRE

	Page
Introduction	4
Mode Opératoire	5 - 6
Préparation et Obturation Rétrograde	7 - 9
Entretien et Stérilisation	10
Notes personnelles	11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

INTRODUCTION

Le nouveau kit d'inserts d'endodontie chirurgicale vient compléter la gamme des inserts d'endodontie.

Ces inserts permettent de réaliser des cavités d'obturation rétrograde (péri-apical ou latéroradiculaire) lors des interventions de chirurgie endodontique.

Ils remplacent avantageusement les fraises même montées sur contre-angles miniaturisés, souvent trop volumineuses par rapport à la cavité osseuse.

Ils permettent de préparer des cavités rétrogrades :

- parfaitement dans l'axe du canal,
- étroites et profondes,
- tenant compte de la section du canal,
- sans affaiblir les parois radiculaires.

PERSONAL NOTES

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

STERILIZATION AND DISINFECTION

Damaged tips (normal wear or accidental damage), must be replaced systematically.

Tip must be cleaned before sterilization

Sterilizing conditions :
Equipment : autoclave, chemiclave
Sterilization : 10 minutes at 134° C at 2 bars (29 Psi)

MODE OPERATOIRE

Objectifs :

Lorsque le traitement endodontique conventionnel par voie endocanalaire ne permet pas d'obtenir un scellement apical correct, le recours à la chirurgie et le scellement par voie rétrograde sont indiqués. Après curetage péri-apical et résection apicale, une cavité rétrograde peut être obturée à l'aide d'un matériau biocompatible (eugénate renforcé à prise accélérée, gutta percha, ciment ...).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

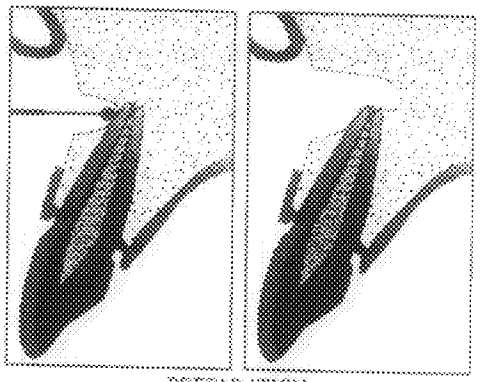
Records processed under FOIA Request 2014-6834; Released 10/23/14

MODE OPERATOIRE

Les étapes de l'intervention :

Le traitement endodontique ou la tentative de traitement devra toujours précéder l'intervention chirurgicale.

- anesthésie adaptée au site et à la durée de l'intervention,
- tracé et élévation du lambeau permettant d'avoir une bonne visibilité sur le site opératoire,
- trépanation osseuse à la fraise boule sous irrigation constante,
- curetage de la lésion,
- repérage et résection limitée de l'apex,
- réalisation de la cavité rétrograde,
- obturation rétrograde,
- suture du lambeau,
- mise en place du pansement chirurgical.



PREPARATION

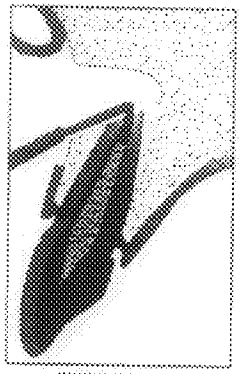
PREPARATION AND Rétrograde FILLING

Comments :

- exert only light pressure on the tip,
- to be retentive, the depth of the canal must exceed its width,
- the final cross-section of the cavity must follow the initial shape of the canal to avoid fragilization of the root.

Filling :
(after checking the bleeding in the bone cavity)

- drying of the Rétrograde cavity (needle fitted to the aspirator, sterile paper points),
- preparation, insertion and condensation of the filling material (mini-spatula and mini-pluggers),
- elimination of all excess material,
- X-ray check on the canal filling before suturing.



CURETTAGE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PREPARATION AND RETROGRADE FILLING

The MicroRetroTips are available in normal or diamond versions with amplified efficacy for enhanced convenience of the practitioner and the patient.

- power settings : scaling power 10, and adjustment for optimal efficiency
- choose the irrigation : physiological serum.
- bring the tip into contact with the root, in alignment with the canal.
- start up at maximum power and under irrigation to avoid heating of the tip and of the root.
- progressively lower the tip end into the canal using a parietal support movement taking into account the cross-section of the canal.

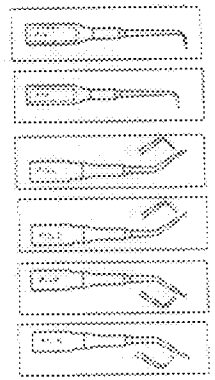
PREPARATION ET OBTURATION RETROGRADE

Préparation : (après curetage apical et résection limitée de l'apex)

- repérer le canal à l'aide d'une sonde courte.
- choisir l'insert selon la zone d'intervention et le type d'intervention

MICRO-RETRO-TIPS :

- insert P14 : insert avec irrigation.
  bloc incisive-canin
- insert P14D : insert avec irrigation.
  bloc incisive-canin diamanté
- insert P15L : pré-molaires et molaires.
  maxillaire gauche et mandibulaire droit
- insert P15LD : pré-molaires et molaires.
  maxillaire gauche et mandibulaire droit diamanté
- insert P15R : pré-molaires et molaires.
  maxillaire droit et mandibulaire gauche
- insert P15RD : pré-molaires et molaires.
  maxillaire droit et mandibulaire gauche diamanté



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PREPARATION ET OBTURATION RETROGRADE

Les MicroRétroTips existent en version normale ou en version diamantée avec une efficacité accrue pour un plus grand confort du praticien et du patient.

- réglage de la puissance: puissance maximum sur la fonction détartrage puis adapter selon le résultat désiré
- choix de l'irrigation : sérum physiologique.
- mettre l'insert en contact avec la racine, dans l'axe du canal.
- mise en marche à puissance maximum et sous irrigation pour éviter l'échauffement de l'insert et de la racine,
- descendre l'extrémité de l'insert dans le canal, par petites touches, en réalisant un mouvement d'appui pariétal tenant compte de la section du canal.

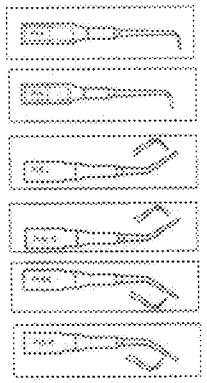
PREPARATION AND RETROGRADE FILLING

Preparation :(after apical curettage and limited resection of the apex)

- locate the canal using a short probe,
- choose the tip according to the area and type of intervention .

MICROSURGICAL-SURGERY :

- tip P14 : tip with irrigation, incisor-canine block .
- tip P14D : tip with irrigation, incisor-canine block diamond treated
- tip P15L : premolars and molars, left maxillary and right mandible
- tip P15LD : premolars and molars, left maxillary and right mandible diamond treated.
- tip P15R : premolars and molars, right maxillary and left mandible
- tip P15RD : premolars and molars, right maxillary and left mandible diamond treated .



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

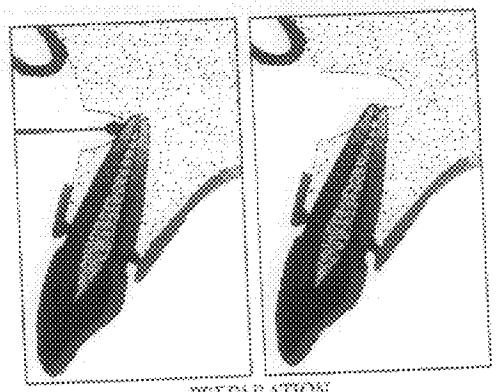
Records processed under FOIA Request 2014-6834; Released 10/23/14

OPERATION IN SURGICAL ENDODONTICS

Stage of surgery :

Endodontic treatment or attempted treatment should always precede surgery.

- anaesthetic adapted to the site and duration of surgery.
- tracing and raising of the flap to provide good visibility of the operative field.
- bone trepanation using a round-headed bur under constant irrigation.
- curettage of the lesion.
- marking and limited resection of the apex.
- preparation of the Rétrograde cavity.
- Retrograde filling.
- suturing of the flap.
- installation of the surgical dressing.



PREPARATION

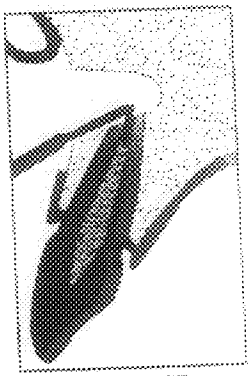
PREPARATION ET OBTURATION RETROGRADE

Remarques :

- la pression exercée sur l'insert doit être légère.
- pour être rétentive la cavité doit être plus profonde que large.
- la section finale de la cavité doit respecter la forme initiale du canal pour ne pas fragiliser la racine.

Obturation :
(après contrôle du saignement dans la cavité osseuse)

- séchage de la cavité rétrograde (aiguille montée sur aspirateur, pointes en papier stériles).
- préparation, insertion et condensation du matériau d'obturation (mini spatules et mini fouloirs).
- élimination des excès de matériau.
- contrôle radiographique de l'obturation canalaire rétrograde avant de suturer.



CURETAGE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

ENTRETIEN ET STERILISATION

Procéder systématiquement au remplacement d'un insert qui a subi une détérioration par l'usure ou par un choc accidentel.

Tout insert doit être nettoyé avant stérilisation.

Conditions de stérilisation de l'insert :
Matériel : autoclave, chemiclave
Stérilisation : 20 minutes à 134° C sous 2 bars

OPERATION IN SURGICAL ENDODONTICS

Objectives :

Whenever conventional endodontic treatment by the endo-canal approach fails to provide a proper apical sealing, surgery and sealing by a Retrograde approach are indicated. After peri-apical curettage and apical resection, a Rétrograde cavity can be filled using a biocompatible material (reinforced fast-setting eugenate, gutta percha, cement, etc).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

SUPRASSON
SUPRASSON PIEZO ENDO
SERVOTOME
PROPHY UNIT
SERVOTORQUE
SERVOLITE
TRANS'CARE
LASERSAT CO2
SUNI

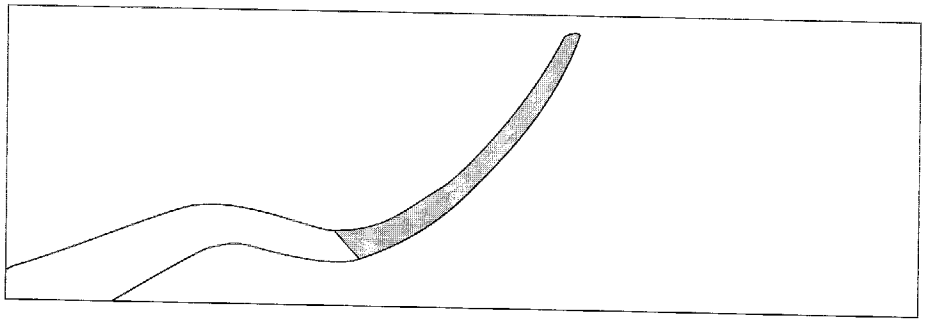
SATELEC

PREND SOIN DE MOI

Z.I. du Phare - B.P. 216 - 33708 MERIGNAC cédex FRANCE
Tél. (33) 56 34 06 07 - Fax. (33) 56 47 85 52 - Télex SATPR 540 407 F

Ref. I00200 - D4

PARODONTIE / PERIODONTICS



PERIO - KIT

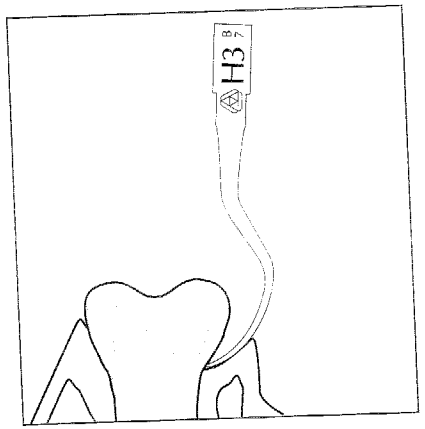
NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET

SATELEC

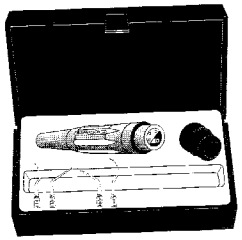
000029

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14



ULTRASONIC TIPS FOR
SUPRASSON
PERIO-KIT H1, H2R, H2L, H3



STERILISATION/DESINFECTION

Pièces à main
Leur nettoyage peut s'effectuer à l'alcool.
Un nettoyage correct de la cavité du pas de vis est réalisable au moyen d'un coton tige imbibé d'alcool.
Ne pas nettoyer la pièce à main dans une cuve à ultrasons.

Conditions de stérilisation dans le cas d'une pièce à main autoclavable :
Matériel : autoclave
Stérilisation : 10 minutes à 134° C sous 2 bars

Attention : les pièces à main doivent toujours être stérilisées séparément des inserts.

Remarques
Les inserts dont la partie diamantée est usée ou les inserts curettes qui sont émoussés peuvent s'utiliser pour enlever le ciment des couronnes temporaires et des bridges.

STERILIZATION/DISINFECTION

Handpiece
These may be cleaned with alcohol.
The screw-thread cavity can be properly cleaned by using a cotton bud soaked in alcohol.
Do not clean handpiece in an ultrasonic tank.

Sterilizing conditions in case of autoclavable handpiece :

Equipment : autoclave
Sterilization : 10 minutes at 134° C at 2 bars

Caution : handpieces and tips must always be separated before sterilization.

Remarks
Tips where diamonds are worn out or curette tips that have become blunt can be used for removing cements of temporary crowns and bridges.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

STERILISATION/DESINFECTION

Stérilisation/Désinfection

A effectuer soit aux désinfectants chimiques soit à l' autoclave.

Inserts

Procéder systématiquement au remplacement d'un insert qui a subi une détérioration par l'usure ou par un choc accidentel.

Conditions de stérilisation :
Matériel : autoclave, chemiclave
Stérilisation : 10 minutes à 134° C sous 2 bars

STERILIZATION/DISINFECTION

Sterilization/Disinfection

To be done either by chemicals or autoclave.

Tips

Damaged tips (normal wear or accidental damage), must be replaced systematically.

Sterilizing conditions :
Equipment : autoclave, chemiclave
Sterilization : 10 minutes at 134° C at 2 bars

SOMMAIRE

	Page
Description	**4**
- Le surfaçage radiculaire	**5 - 10**
- Dessins	**11**
Mode d'emploi	**12 - 15**
Précautions	**16**
- Remplacement des Inserts	**17**
- Stérilisation / Désinfection	**18 - 19**
- Remarques	**20**

SUMMARY

	Page
Description	**4**
- Root planing	**5 - 10**
- Drawings	**11**
Use	**12 - 15**
Cautions	**16**
- Tips replacement	**17**
- Sterilization / Disinfection	**18 - 19**
- Remarks	**20**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

DESCRIPTION

Le nouveau kit d'inserts de parodontie venant compléter la gamme des Inserts SUPRASSON a été développé par le Dr Hiroshi Himeno de l'Université d'Hokkaido (Japon). Ces inserts permettent d'effectuer le surfaçage radiculaire à puissance modérée afin d'éviter tout échauffement du parodonte.

L'insert diamanté H1 s'utilise pour la finition du surfaçage radiculaire.

Les Inserts diamantés H2R, H2L, s'utilisent pour les zones difficiles d'accès (zones étroites interproximales et zones de bifurcation).

L'insert H3 (curette), en raison de sa forme, est utilisé comme une curette manuelle universelle.

DESCRIPTION

The new perio-kit, complement of the range of Suprasson tips, was developped by Dr. Hiroshi Himeno of the Hokkaido University in Japan.These tips allow root planing with reduced power in order to avoid overheating of the periodontium.

Tip H1 is utilized for the finishing of root planing.

The diamond tips H2R and H2L are utilized for areas of difficult approach (narrow interproximal area and furcation area).

H3 tip (curette), thanks to its shape, is utilized in the same way as a manual universal curette.

PRECAUTIONS

Remplacement des Inserts :

1) H1, H2R, H2L.

Les inserts doivent être changés lorsque la partie diamantée devient lisse et brillante.

2) H3

Cet insert doit être changé lorsque sa partie active est émoussée.

CAUTIONS

Tips replacement :

1) H1, H2R, H2L.

Tips must be replaced when the diamond part becomes smooth and shiny.

2) H3

This tip must be changed when the active part becomes blunt.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

PRECAUTIONS

A la fin du traitement parodontal, contrôler et vérifier la surface radiculaire, ainsi que la finition, en utilisant de fines sondes d'exploration.
Etant donné que ces inserts de parodontie sont conçus pour des curetages radiculaires à puissance modérée bien contrôlée, le traitement parodontal peut être fait en toute sécurité sans risque d'endommager les tissus environnants.

Attention :
Respecter la puissance préconisée page 12. L'insert peut se casser si la puissance n'est pas respectée.

CAUTIONS

At the end of the periodontal treatment, check and confirm root surface and finishing, using delicate explorers.

As these periodontic tips are designed for carrying out root planing (URM) with moderate power fully controlled, the periodontic treatment can be done safely without any risk of damaging the tissues around.

Caution :
Respect the power recommended in page 12. The tip may break if power is not respected.

LE SURFACAGE RADICULAIRE

Un traitement parodontal commence toujours par la motivation à l'hygiène accompagné d'un détartrage sus-gingival.

En général, le praticien élimine à l'aide d'un appareil à ultra-sons les dépôts tartriques visibles au-dessus de la gencive. Souvent cela suffit pour une gingivite légère, mais en présence d'une gingivite avancée ou d'une parodontite (poches parodontales plus ou moins profondes) le détartrage sus-gingival ne permet pas l'accès au tartre sous-gingival.

Dans ce cas, le praticien devra pratiquer un détartrage sous-gingival et un polissage de la racine : le surfaçage radiculaire.

ROOT PLANING

A periodontal treatment generally starts by motivating the patient towards oral hygiene followed by supra-gingival scaling.

Ultrasonic scaler is generally used to remove visible calculus and this is often sufficient for dealing with minor gingivitis. With severe gingivitis or periodontitis (deep periodontal pockets) supra-gingival scaling is insufficient to eliminate sub-gingival calculus.

Consequently, a sub-gingival scaling and a root polishing are necessary : the root planing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

LE SURFACAGE RADICULAIRE

I - La pathologie parodontale

L'orsqu'il y a présence de poches, la surface de la racine qui se trouve à l'intérieur de la poche est recouverte de tartre sous-gingival très adhérent et le cément est nécrosé et infiltré par des endotoxines.

Donc, le but du traitement sera de nettoyer cette racine, c'est-à-dire de la surfacer afin d'éliminer les dépôts nuisibles à la réattache de la gencive sur la racine et de polir cette dernière pour obtenir une surface lisse.

Le surfaçage radiculaire sera réalisé à l'aveugle pour les poches inférieures à 5 mm.

ROOT PLANING

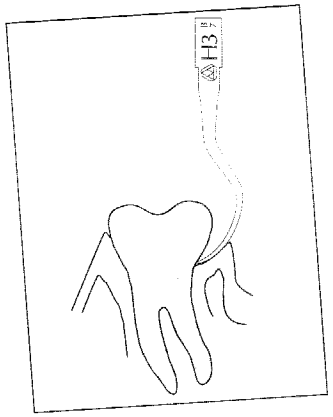
I - Periodontal pathology

When there are periodontal pockets, the root surface inside the pocket is layered with highly adhesive calculus, the cement is necrotic and infiltrated by endo-toxines.

The treatment consists in cleaning the root thouroughly, in surfacing it in order to remove the deposits which prevent gingival reattachment and in polishing the root to give it a smooth finish.

Root planing has to be carried out blindly for pockets of less than 5 mm.

MODE D'EMPLOI



c) Insert Curette H3

Cet instrument est utilisé comme une curette manuelle universelle (c'est-à-dire en remontant verticalement le long de la racine).

Il permet, en outre, un travail beaucoup plus rapide et moins contraignant.

Il sert aussi à enlever le cément nécrosé à la surface de la racine .

USE

c) H3 Curette tip

This tip is to be used in the same way as any normal universal curette (going back up vertically along the root).

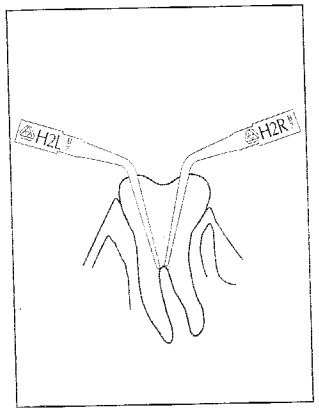
It also makes operating much quicker and easier.

It is also adapted for removing necrotic cement on root surface.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

MODE D'EMPLOI



b) Inserts H2R, H2L diamantés

Les inserts H2R et H2L particulièrement fins ont été conçus pour permettre le surfaçage radiculaire des zones très difficiles d'accès. Il est impératif de les utiliser avec minutie.

* L'insert H2R permet d'accéder à la racine par le côté droit.
* L'Insert H2L permet d'accéder à la racine par le côté gauche.

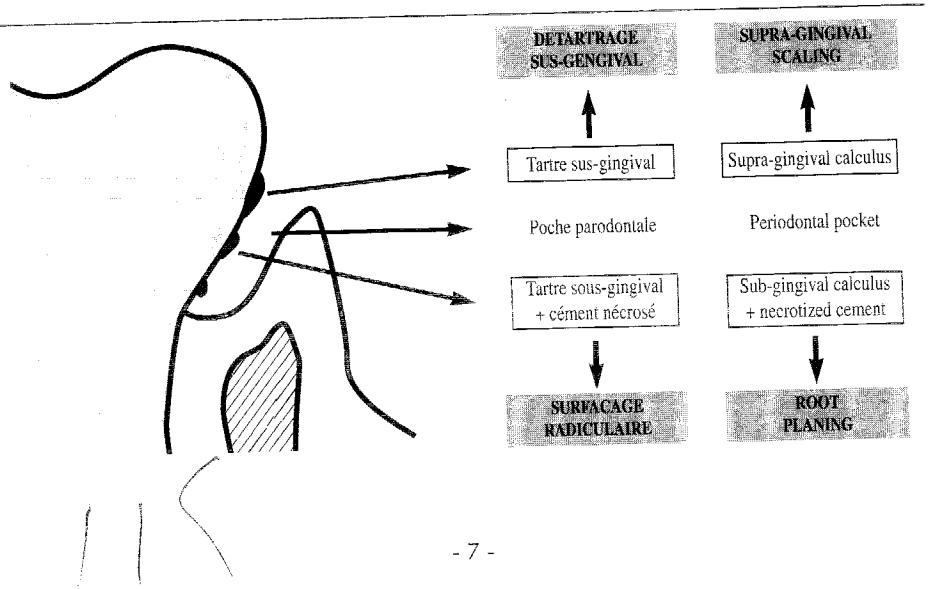
USE

b) H2R, H2L diamond tips

H2R, H2L tips particularly thin are concieved for difficult approach areas. They have been designed to allow delicate root planing. It's very important to manipulate them with great care.

* The H2R tip enables to reach the root by the right side.
* The H2L tip enables to reach the root by the left side.

LE SURFAÇAGE RADICULAIRE / ROOT PLANING



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

LE SURFAÇAGE RADICULAIRE

II - Le surfaçage radiculaire manuel

Définition
C'est l'élimination des dépôts calcifiés des surfaces cémentaires ou dentinaires suivie du polissage de celles-ci.
Objectif de la méthode
Le surfaçage élimine de la paroi dure radiculaire :
* la plaque bactérienne,
* le tartre sous-gingival résiduel,
* le cément infiltré par les endotoxines.
Technique opératoire
Il se pratique à l'aveugle pour des poches inférieures à 5mm.
En présence de poches supérieures à 5mm, le surfaçage radiculaire se fait après élévation d'un lambeau gingival.

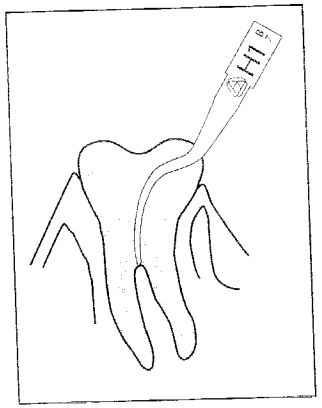
ROOT PLANING

II - Manual root planing :

Definition :
Elimination of calcified deposits on cement or dentine surfaces followed by polishing.
Objectives :
Root planing is used to eliminate from the hard walls of the root :
* deposits of bacterial plaque,
* residual sub-gingival calculus,
* cement infiltrated by endotoxines.
Operating technique :
To be carried out blindly for pockets of less than 5 mm.
With pockets deeper than 5 mm, root planing is used after elevation of a gingival flap.

MODE D'EMPLOI

USE



a) Insert H1 type Universel diamanté

Cet insert permet d'assurer le polissage final de la racine après le passage du H2R ou H2L ou H3.

a) H1 diamond Universal type tip

This tip allows a final polishing of the root after the treatment by H2R or H2L or H3.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

MODE D'EMPLOI

Les inserts de parodontie sont conçus pour être utilisés en douceur à faible puissance :

* Appareils SATELEC ayant une fonction Endo :
- Appareils ayant une touche SOFT : 1 ➔ 3
- Appareils ayant une touche "P" : 1 ➔ 10
- Appareils ayant une fonction ENDO avec le symbole uniquement : 1 ➔ 3

* Pour les appareils n'ayant pas ces touches et sans fonction "ENDO", on n'utilisera pas les inserts.

On tiendra compte des contraintes apportées à l'instrument par le contexte anatomique

USE

The parodontia tips are designed to be used with a soft touch using soft power with the following devices set on :

* SATELEC products having an ENDO function :
- Appliances having a SOFT key : 1 ➔ 3
- Appliances having a P key : 1 ➔ 10
- Appliances having an ENDO function with only the symbol : 1 ➔ 3

* For appliances without any of these keys and without "ENDO" function, we will not use these tips.

Taking into consideration any limitations imposed by the anatomy of the patient

LE SURFAÇAGE RADICULAIRE

Indications
- gingivites,
- parodontites modérées (poches < 5mm),
- parodontites avancées (après élévation d'un lambeau ou en tant que phase initiale du traitement),
- phase de maintenance,
- poche profonde et étroite ,
- lésion inter-radiculaire,
- anatomie radiculaire complexe.

ROOT PLANING

Applications :
- gingivitis,
- moderate periodontitis (< 5 mm pockets),
- advanced periodontitis (either after elevating a flap, or as an initial treatment phase),
- maintenance phase,
- deep, narrow pockets,
- interradicular lesions,
- complex radicular anatomy.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

LE SURFAÇAGE RADICULAIRE

III - Les avantages du surfaçage radiculaire aux ultra-sons

* Les instruments sont réduits en nombre (4 inserts) par rapport à l'instrumentation manuelle,
* de part leur finesse et leur forme, ces inserts sont faciles à positionner même dans des zones difficiles d'accès (bifurcation, zone interproximale étroite, etc...),
* le temps d'intervention est réduit car l'efficacité est plus grande,

* nettoyage du champ opératoire par un spray sous pression (adjonction éventuelle d'un antiseptique).

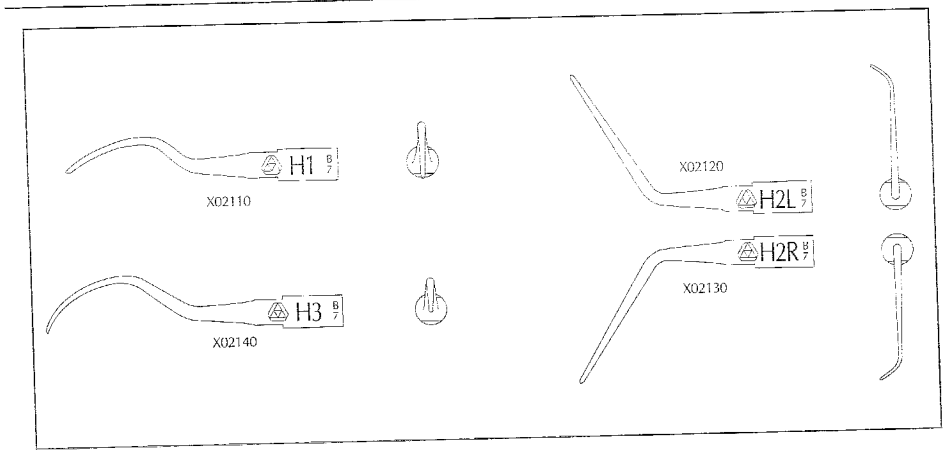
ROOT PLANING

III - Advantages of ultrasound root planing :

* Only a small number of instruments are used (4 tips), as compared to the large number of manual instruments required,
* these tips have the right shape and thin size to be easy to use even in difficult areas (furcations, narrow approximal areas, etc.),

* operating time is much shorter as the instruments are more efficient,
* the operating field is kept clear by a pressurized spray (it is possible to add antiseptic).

DESSINS / DRAWINGS



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

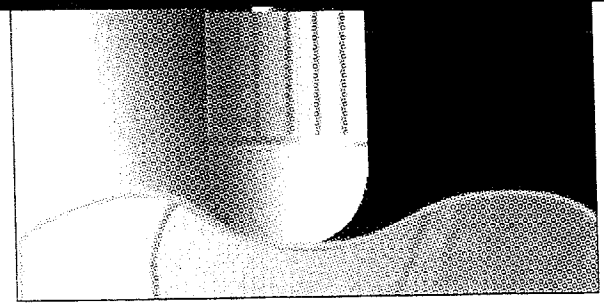
Records processed under FOIA Request 2014-6834; Released 10/23/14

P5 BOOSTER
PROPHY-MAX
SUPRASSON P-MAX
SUPRASSON PIEZO ENDO
SERVOTOME
PROPHY UNIT S/ENDO
ACTA
TRANS'CARE
LASERSAT CO2
SUNI
X-MIND SYSTEM

GROUPE SATELEC - PIERRE ROLLAND
Z.I. du Phare - B.P. 216 - 33708 MERIGNAC cédex FRANCE
Tél. (33) 56 34 06 07 - Fax. (33) 56 47 85 52 - Télex SATPR 540 407 F

Ref. I00103 - F4

CONDENSATION INLAY-ONLAY



PIEZOCEM

NOTICE D'INSTRUCTIONS / INSTRUCTION BOOKLET

SATELEC

123

000030

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

F R A N C A I S

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

SOMMAIRE

	Page
Introduction	4
Mode opératoire	5
Entretien et Stérilisation	7
Notes personnelles	24

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

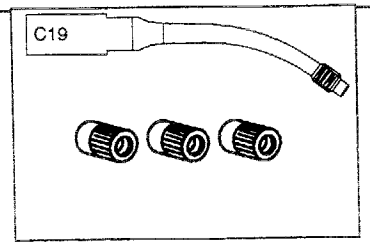
Records processed under FOIA Request 2014-6834; Released 10/23/14

INTRODUCTION

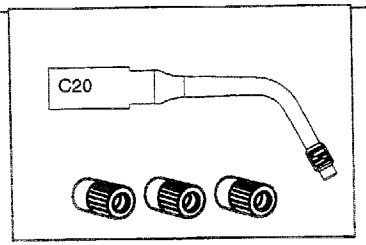
L'insert PIEZOCEM sert à la mise en place d'inlays et d'onlays par l'utilisation de composites de fixation denses avec des propriétés thixotropes.

L'utilisation des ultrasons permet de fluidifier le composite de scellement qui s'épanche totalement dans la cavité, ce qui rend inutile l'application d'un agent de liaison sur l'émail.

L'embout PIEZOCEM est parfaitement étudié pour apporter le plus de confort dans cette opération et éviter le contact métal/céramique (transmissions ultrasons, rayures, échauffement...)



C 19



C 20

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

MODE OPERATOIRE

Fixation de l'insert PIEZOCEM :

• Visser l'insert (2) sur la pièce à main ultrasonore du SUPRASSON et le serrer avec la clé (l'arrivée d'eau est alors automatiquement interrompue).

• Visser fermement à la main l'embout plastique (1) sur l'insert .(Fig. 1)

En cas d'usure, l'embout doit être remplacé.

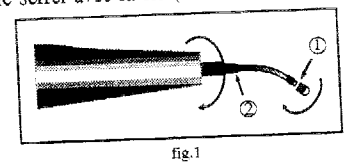


fig.1

Utilisation de l'insert PIEZOCEM :

Après la mise en place de l'inlay/onlay sur la surface de préparation selon les indications du fabricant de composites, presser légèrement avec la pièce à main équipée de l'insert PIEZOCEM (sans ultrason) pour bien engager l'inlay/onlay jusqu'à ce qu'il soit maintenu par le composite de scellement.

• La forme arrondie de l'embout plastique du PIEZOCEM est particulièrement adaptée à cet usage. Pour éviter une fracture éventuelle, il est recommandé d'avoir une épaisseur d'inlay/onlay d'au moins 1,5mm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

MODE OPERATOIRE

Cimentation du composite avec l'insert PIEZOCEM :

- Régler la puissance du générateur d'ultrasons SUPRASSON sur 1 à 3 en position «détartrage» (scaling).
- Appliquer l'insert sur l'inlay/onlay sans exercer de pression.
- Mettre le SUPRASSON en marche en appuyant sur la pédale pendant 2 secondes maximum.

La viscosité du composite se réduit alors considérablement (thixotropie) et l'inlay/onlay peut être complètement inséré pratiquement sans pression.

- Après la mise à l'arrêt des ultrasons, le composite reprend immédiatement sa consistance normale, c'est-à-dire le matériau excédentaire ne coule pas et peut être éliminé sans problème.
- Pour la polymérisation, observer les indications du fabricant de composites.

APPLICATION

Place the tip on the inlay without exerting pressure.

Turn the ultrasonic generator handpiece on (footswich) for a few seconds with power setting scaling 1-3-
the viscosity of the composite drastically reduces (thixotropy) and the inlay can be completely inserted practically without pressure.

After the ultrasonic is turned off, normal consistency is restored to the composite, i.e. material oozing out does not flow away and can be removed without difficulty. The piezocem tip prevents from the scratch , heating, breaks and avoid black metal stains
The special designed shape of the cap is perfectly fitted for this use. It is recommended to work with 1.5 mm inlay/onlay thickness .

You can repeat this process to check whether surplus composite material can still be driven out.

Cure according to the composite manufacturer's information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

ACCESSORY PIEZOCEM SET

The purpose of the PIEZOCEM tip is to insert inlays making use of highly filled adhesion composites with thixotropic properties.

Stérilization :

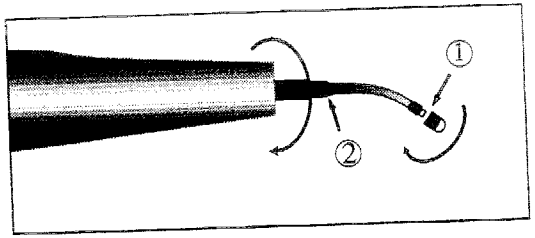
The cap (1) and tip can be sterilized.
Sterilization only in the autoclave at 135° C at 2.1 bars (29 Psi).

Insert PIEZOCEM tip :

- Screw the tip with the key.

- Screw cap firmly on the tip by hand.

If the cap is worn, replace it by a new one.



ENTRETIEN ET STERILISATION

Procéder systématiquement au remplacement d'un insert ou d'un embout qui a subi une détérioration par l'usure ou par un choc accidentel.

L'insert et l'embout sont stérilisables.
Tout insert et embout doivent être nettoyés avant stérilisation.

Condition de stérilisation :
Matériel : autoclave
Stérilisation : 20 minutes à 134°C sous 2 bars.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

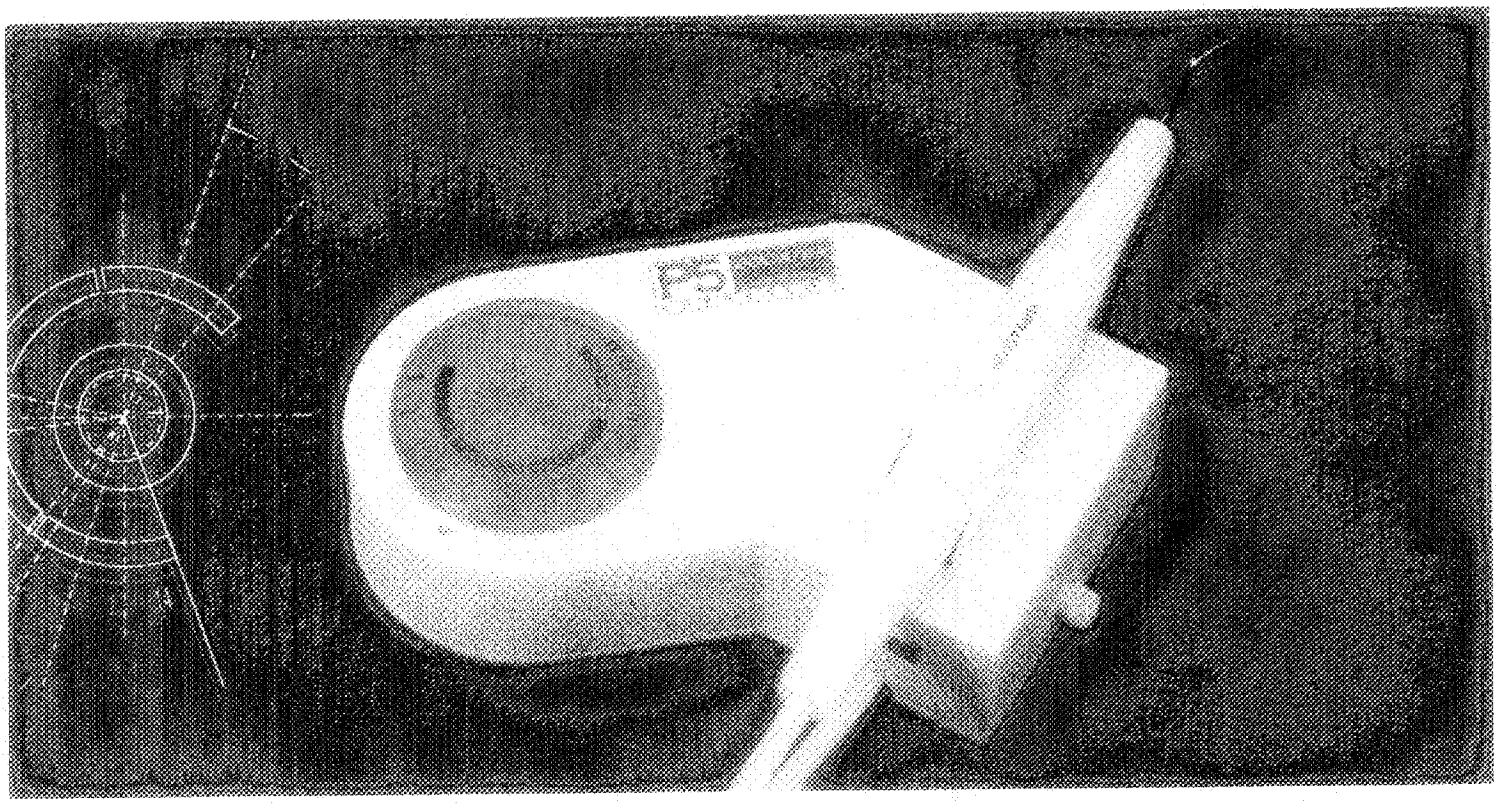
E N G L I S H

CONTENTS

	Page
Accessory PIEZOCEM set	8
Application	9
Personal notes	22

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

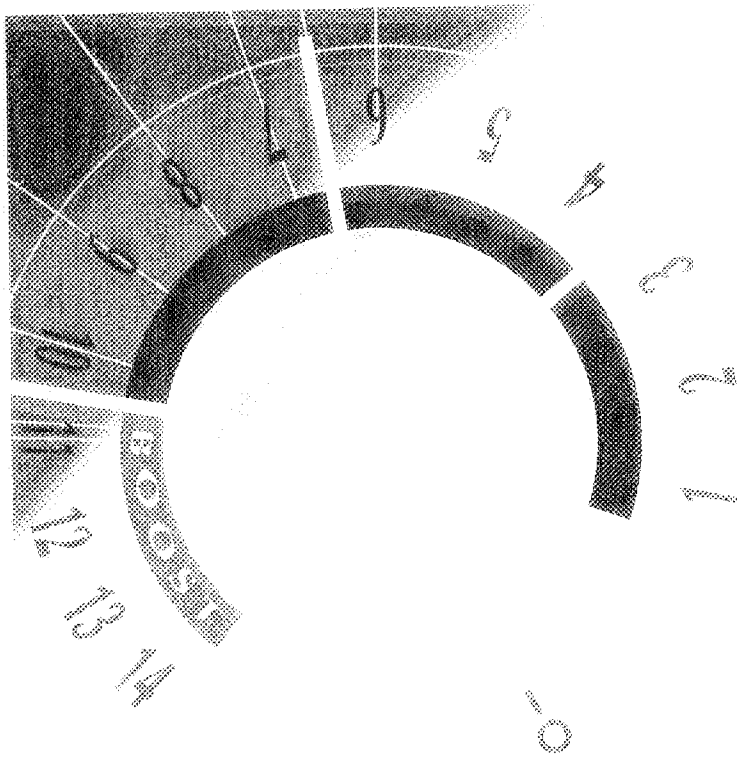


P5 BOOSTER

The world's most compact and most powerful ultrasonic generator

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14



P5 BOOSTER

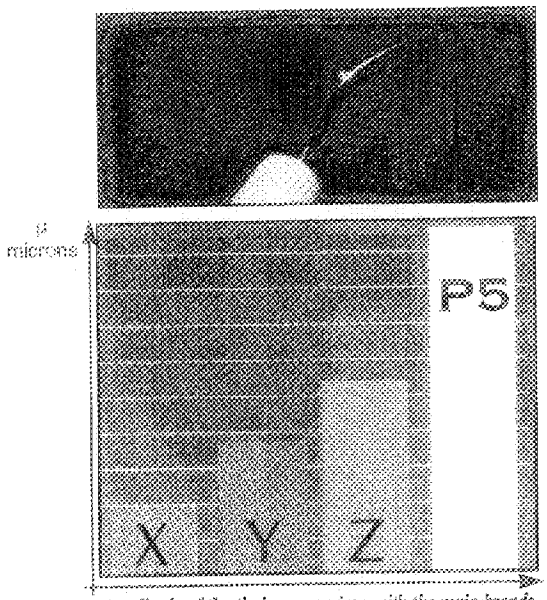
SUPRASSON

The P5 BOOSTER, with its extra wide power range, enables you to adjust scaling from the most delicate to the most powerful..

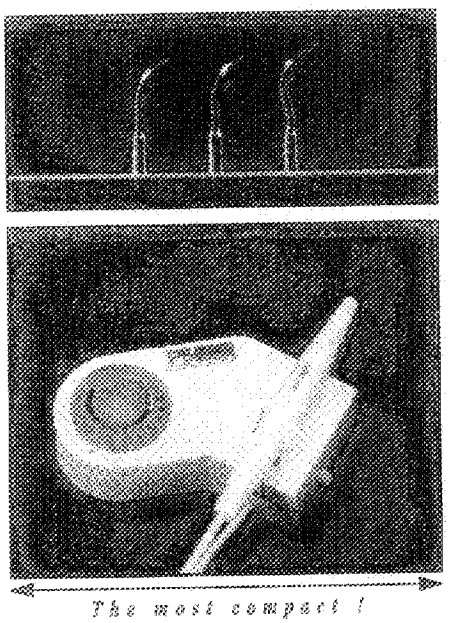
It is the only piezo-electric ultrasonic generator equipped with functions from « supersoft » to « boost »
The P5 BOOSTER is driven by the latest generation of electronics, providing fully controlled power at the tip of the insert.
Compact : it will always be ready on the tray of your unit, in a drawer, or on the counter top.
Simple : a single dial controls 4 operating ranges and 14 powers levels for ultimate precision.
Irrigation : the P5 BOOSTER is equipped with an ajustable spray : no special tools required.
New look design : it is half the size of the smallest generator on the market, and extremely easy to clean due to its smoothed surfaces.

REFERENCES :

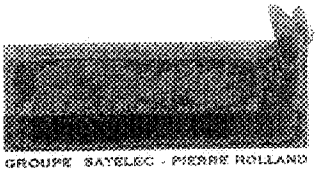
P58600 : P5 + tip (1,2,10p), 1 tipwrench & 1 standard handpiece	/ 230 V
P58601 : P5 + tip (1,2,10p), 1 tipwrench & 1 sterilisable handpiece	/ 230 V
P58602 : P5 + tip (1,2,10p), 1 tipwrench & 1 standard handpiece	/ 110 V
P58603 : P5 + tip (1,2,10p), 1 tipwrench & 1 sterilisable handpiece	/ 110 V



Amplitude of the tip in comparison with the main brands
Scaling function, amplitude, linear movement of the tip and wide range of power, enables unequalled calculus removal in all cases from perio to hard scaling.



The most compact !
Only 15 X 8 cm
The necessary transformer is internally housed within the elegantly styled case.



GROUPE SATELEC - PIERRE ROLLAND
Z.I. du phare • B.P.216 • 33708 MERIGNAC cedex • FRANCE • Fax. (33) 56 34 92 92 • Tél. (33) 56 34 06 07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-0

SATELLITE BOOK

000033

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIST@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

MAX CLINIC WITH SATELEC'S TOP TIPS

SATELEC'S TOP TIPS have been designed with the collaboration of Universities and Clinicians.
The result : Today you have at your fingertips the most precise and well shaped tips, dedicated to Ultrasonic treatment. All tips are optimized to work with the new SUPRASSON sterilisable handpiece. Developing tips requires expertise integrated with experience. Each tip is manufactured by SATELEC of France. We are proud to assist in the daily practice of dentistry. Tips are available in standard format, diamond impregnation and irrigation. All requirements are fully researched to ensure that even the most difficult task can be accomplished with great efficiency, and with user and patient comfort. Now let us start to work with real clinic tips.

MAX CLINIC AVEC LES TOP TIPS DE SATELEC

Les TOP TIPS de SATELEC ont été conçus et dessinés en collaboration étroite avec les Universités et les cliniciens.
Le résultat : vous avez en mains les inserts à ultrasons les plus précis et les plus élaborés pour la dentisterie. Tous les inserts SATELEC sont optimisés pour fonctionner avec la pièce à main stérilisable SUPRASSON. Concevoir et développer des inserts à ultrasons demande expérience et savoir-faire. C'est pour cela que les inserts à ultrasons sont fabriqués directement par SATELEC France. Nous sommes fiers d'aider les praticiens dans leur pratique quotidienne avec une gamme d'inserts standards, diamantés ou avec irrigation. Ainsi les applications, même les plus sophistiquées, peuvent être réalisées avec un grand confort tant pour le praticien que pour le patient. Dès aujourd'hui, réalisez vos traitements ultrasons avec des inserts totalement dédiés à l'art dentaire.

MASSIMA PERFORMANCE CON LE TOP TIP SATELEC

Le TOP TIP di SATELEC sono state progettate e disegnate con la collaborazione di staff Universitari e clinici.
Risultato : Potete ora disporre delle punte più precise ed elaborate esistenti in campo odontoiatrico. Tutte le punte SATELEC sono state elaborate per essere utilizzate con il manipolo sterilizzabile SUPRASSON. Il progetto e lo sviluppo degli inserti ad ultrasuoni sono frutto della vasta esperienza e competenza degli operatori. Ogni punta è fabbricata direttamente dalla SATELEC-Francia. La nostra azienda è orgogliosa di poter contribuire in maniera positiva alla pratica odontoiatrica quotidiana con una gamma di punte in versione standard, diamantata o con irrigazione. Ogni esigenza specifica è stata oggetto di ricerche avanzate per poter dare la possibilità di realizzare i compiti, anche i più difficili, con la massima efficacia ed il massimo confort sia del dentista che del paziente. D'ora in avanti potrete realizzare i Vostri trattamenti ad ultrasuoni con inserti appositamente ideati per la professione odontoiatrica.

MAX CLINIC MIT DEN TOP INSTRUMENTEN VON SATELEC

Die TOP INSTRUMENTE von SATELEC sind in Zusammenarbeit mit Universitäten und Kliniken entstanden.
Das Ergebnis : Sie finden heute bei SATELEC präzise und optimal geformte Instrumente, die speziell für Ultraschallbehandlungen entwickelt wurden. Alle Instrumente wurden für das neue, sterilisierbare Titan-Handstück SUPRASSON optimiert. Dazu braucht man Know-how und Erfahrung. Jedes Instrument wird von SATELEC Frankreich hergestellt. Wir sind stolz, in der täglichen Zahnarztpraxis Hilfestellung leisten zu können. Einige Instrumente sind im Standardformat auch mit Diamantbestückung lieferbar. Sorgfältige Entwicklungsarbeit stellt sicher, daß auch die schwierigsten Arbeiten wirksam und mit hohem Komfort für Zahnarzt und Patienten ausgeführt werden können.

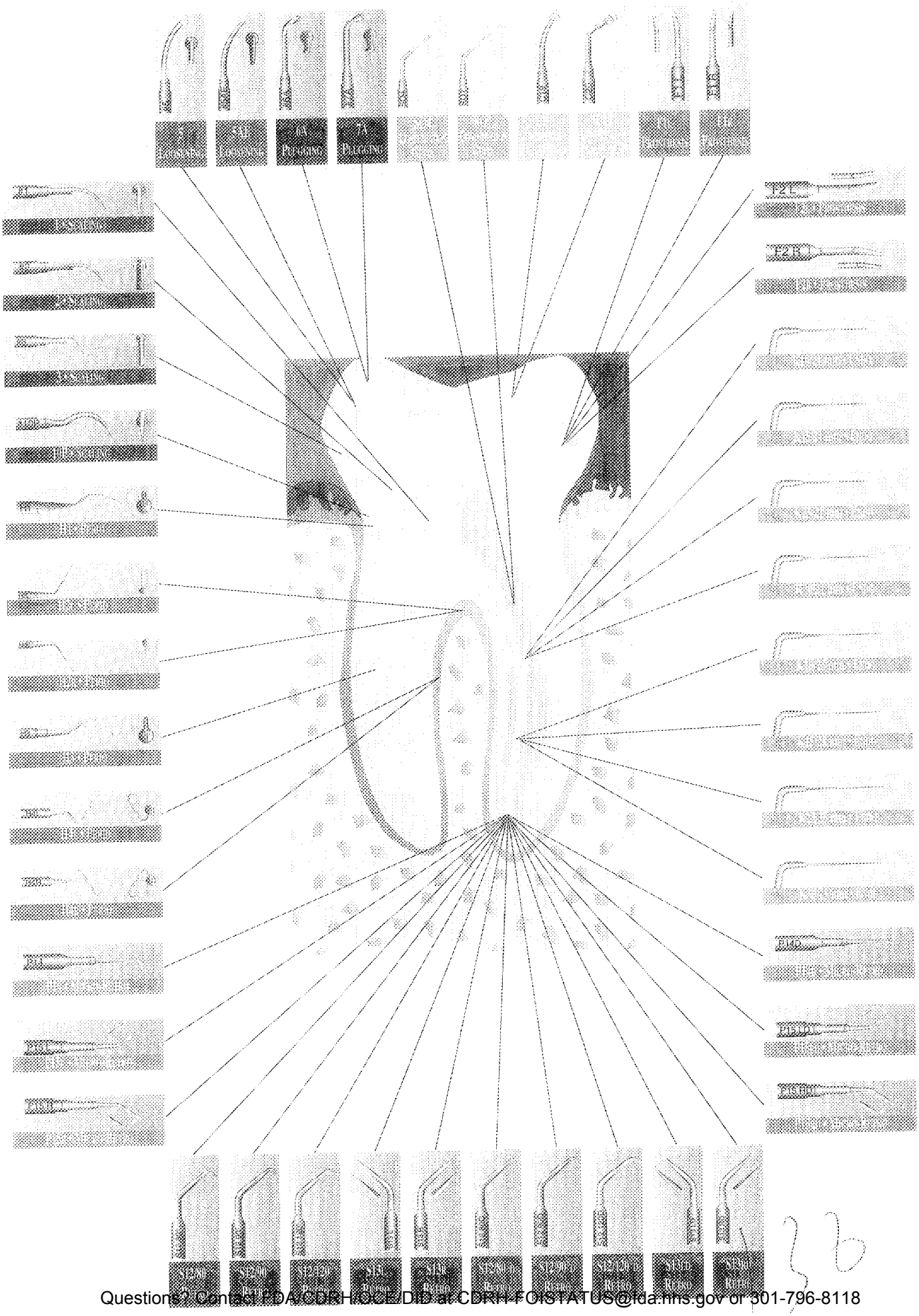
MAX CLINIC CON LOS TOP TIPS DE SATELEC

Los TOP TIPS de SATELEC han sido elaborados con la colaboración de Universidades y de expertos profesionales.
Resultado: hoy, tiene al alcance de la mano los inserts más precisos y los mejor diseñados, concebidos especialmente para el tratamiento por ultrasonidos. Todos los inserts están optimizados para utilizarse con la nueva pieza a mano esterilizable SUPRASSON. El desarrollo y la elaboración de inserts para su uso en ultrasonidos requiere integrar un conocimiento técnico con una gran experiencia. Es por ello, que todos los inserts son fabricados directamente por SATELEC en sus instalaciones centrales en Francia. Nos sentimos orgullosos de aportar nuestra ayuda a la práctica cotidiana de la odontología. Los inserts se encuentran disponibles en formato estándar, con impregnación diamantada y con irrigación. Todas las necesidades han sido objeto de una investigación profunda para asegurarse que es posible llevar a cabo incluso las tareas más difíciles con gran eficacia y con la mayor comodidad del profesional y de su paciente. A partir de ahora, realice sus tratamientos ultrasónicos con verdaderos inserts clínicos.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

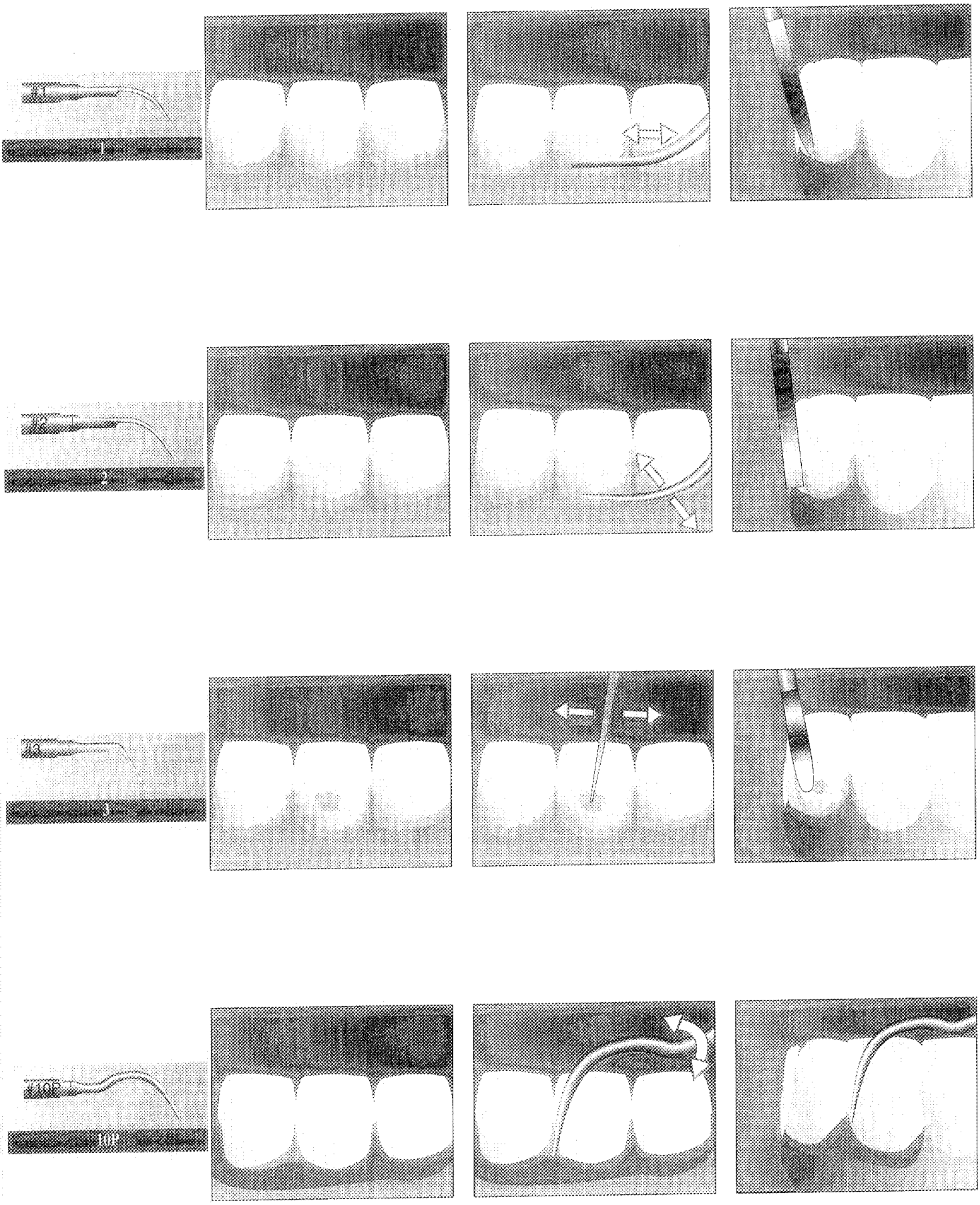
Records processed under FOIA Request 2014-6834; Released 10/23/14

SATELEC CLINICAL LINE WITH ULTRASONIC GENERATORS



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

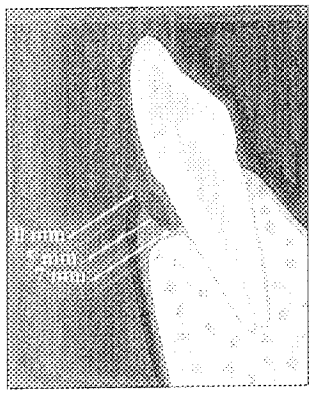


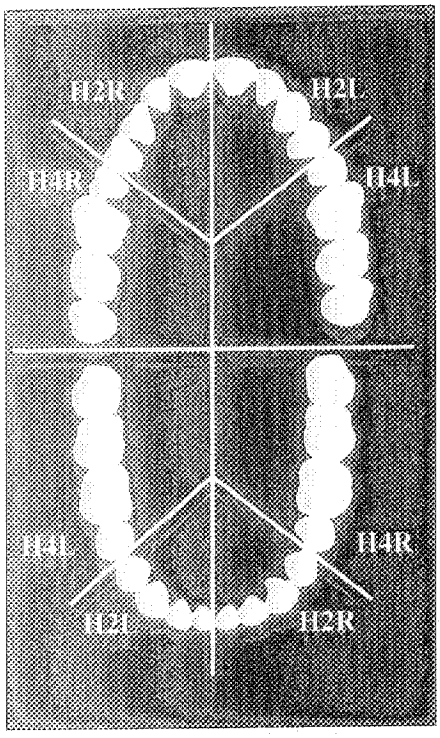
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

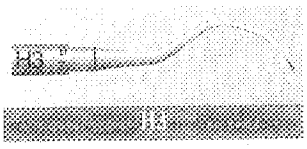
Records processed under FOIA Request 2014-6834; Released 10/23/14

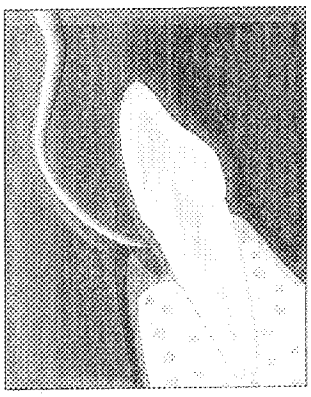
SATELEC CLINICAL LINE WITH ULTRASONIC GENERATORS

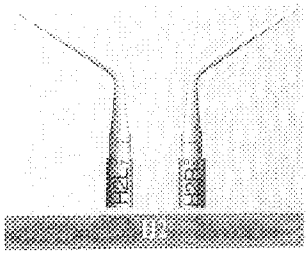
PERIODONTIE / PARODONTIC / PARODONTOLOGIA / PERIODONTIE / PERIOPONCIA

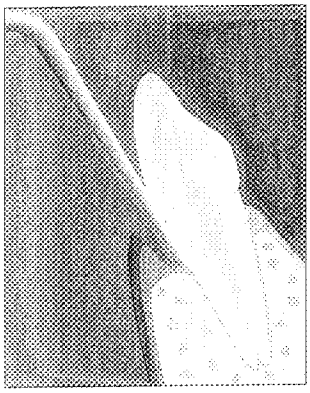


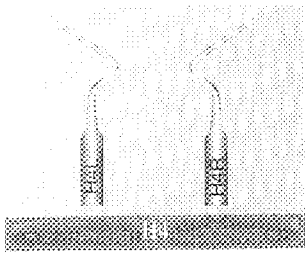


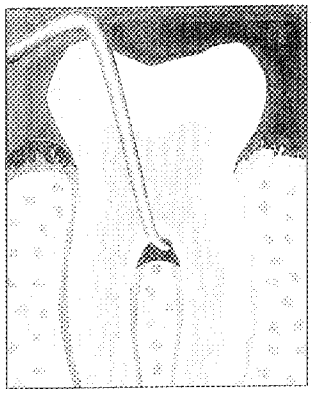


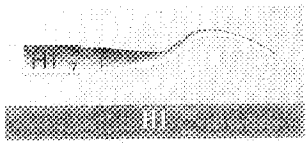


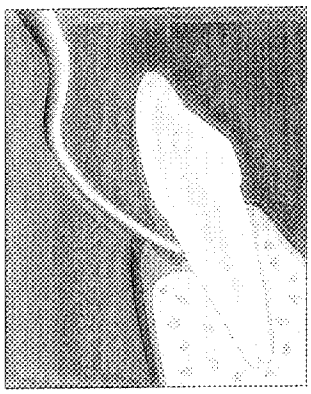








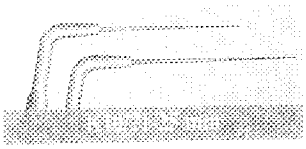


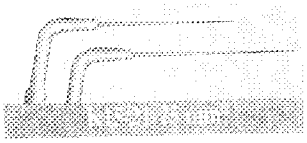


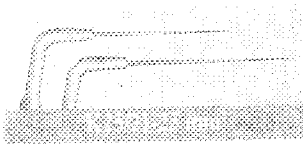
128

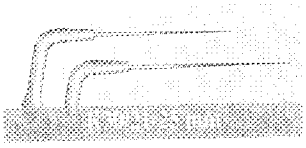
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

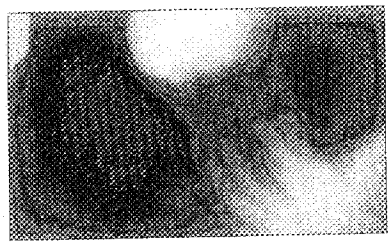
Records processed under FOIA Request 2014-6834; Released 10/23/14

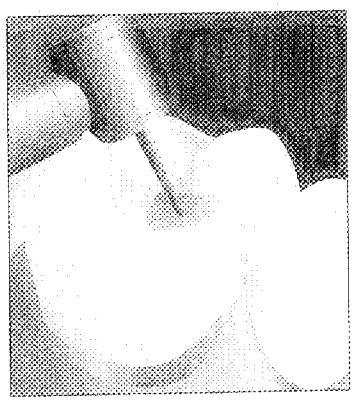


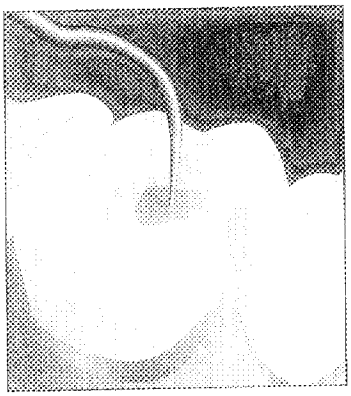


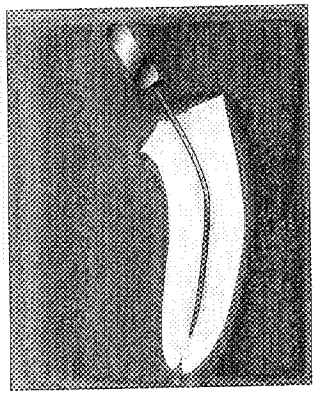


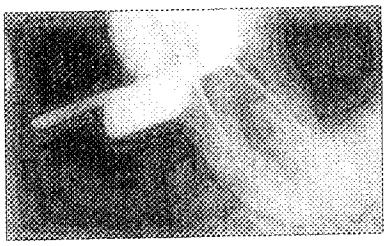


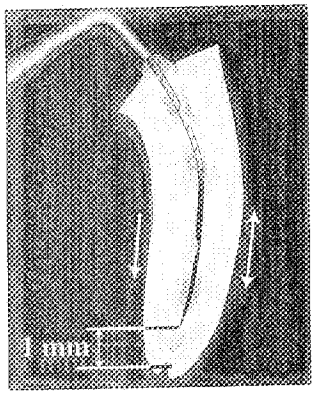


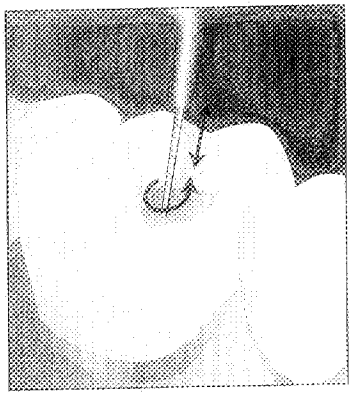


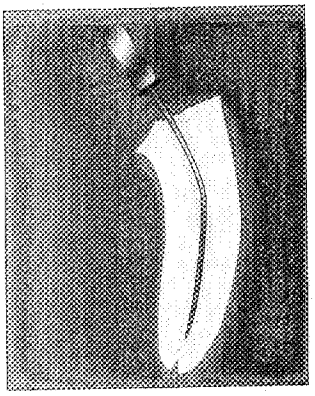


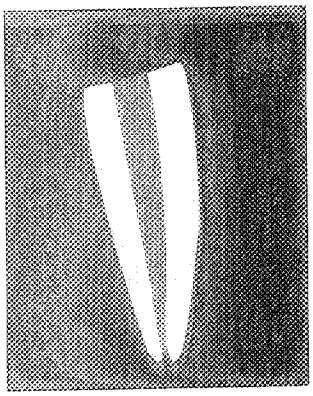












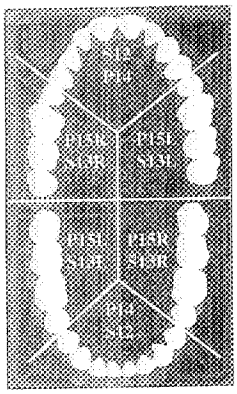
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

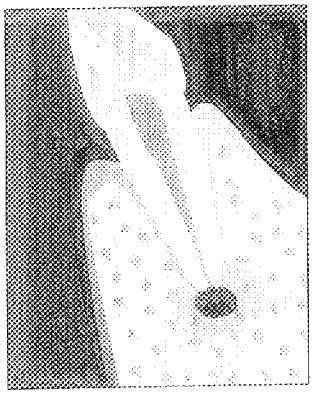
Records processed under FOIA Request 2014-6834; Released 10/23/14

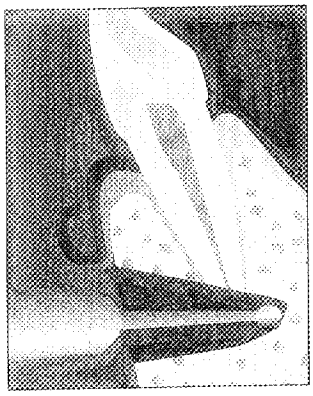
SATELEC CLINICAL LINE WITH ULTRASONIC GENERATORS

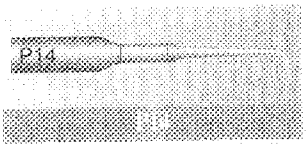
RETRO SURGERY • RETRO CHIRURGIE • CHIRURGIA RETROGRADA • RETRO CHIRURGIE • RETRO CIRUGIA

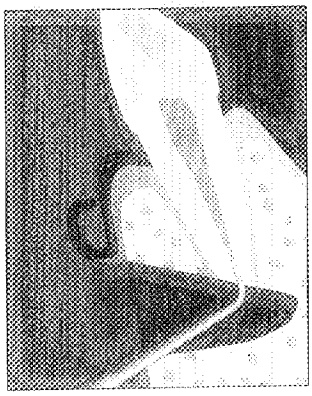
MICRO RETRO SURGERY • MICRORETROCHIRURGIE • MICRO CHIRURGIA RETROGRADA • MICRO RETRO CHIRURGIE • MICRO RETRO CIRUGIA

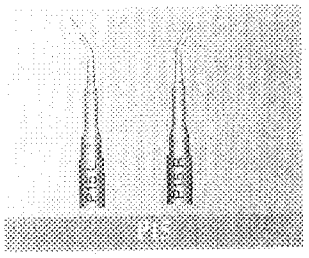


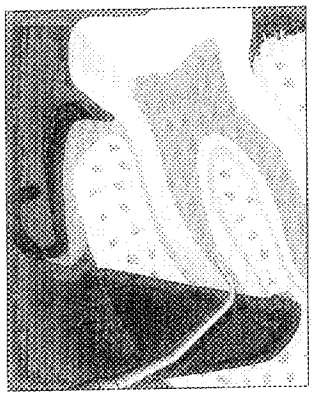


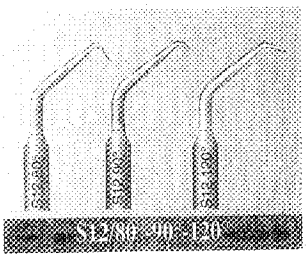


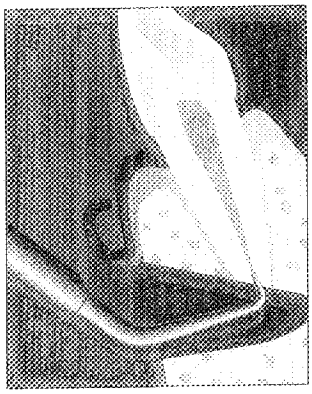


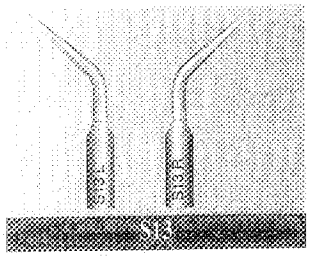


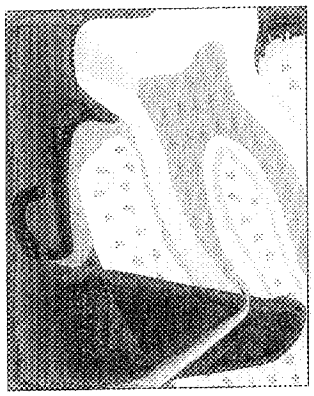








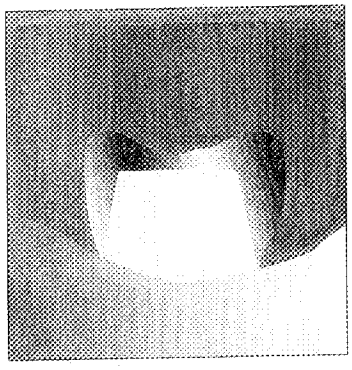


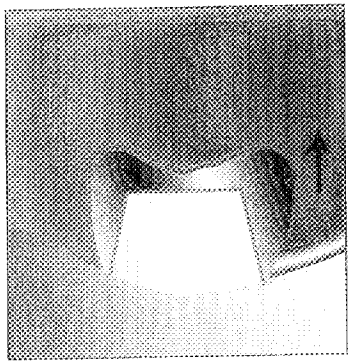


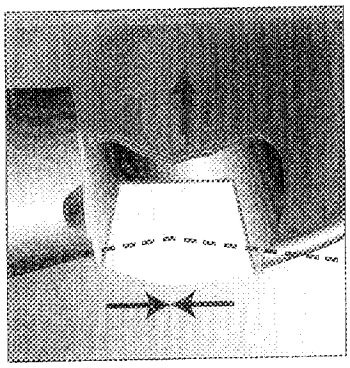
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

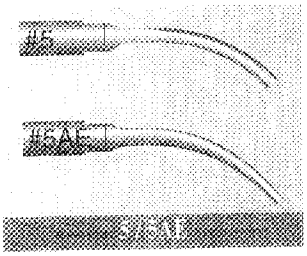
Records processed under FOIA Request 2014-6834; Released 10/23/14

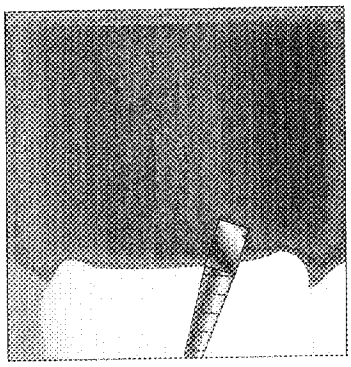
LOOSENING • DÉSOLLEMENT • DECEMENTAZIONE • ABLOSEN • DESEMPOTRAMIENTO

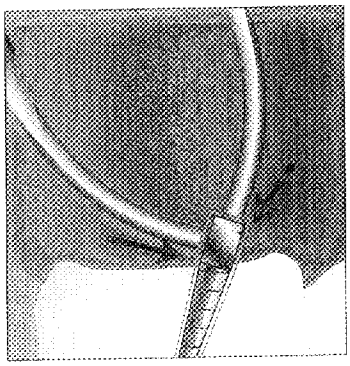


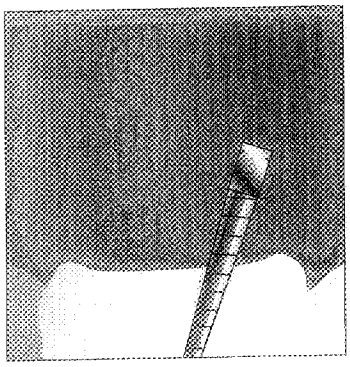




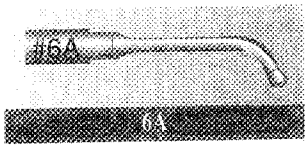


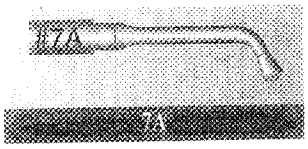


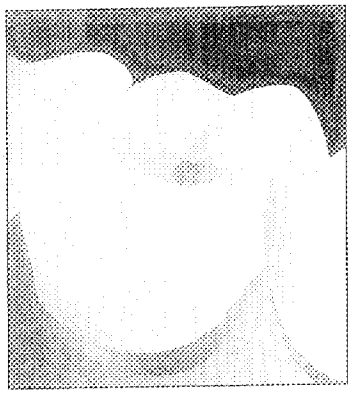


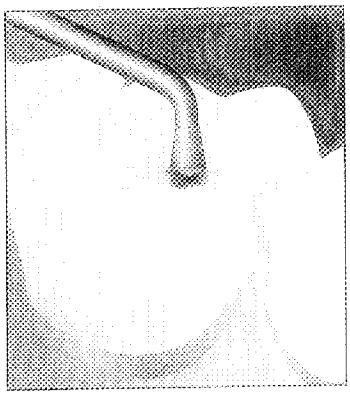


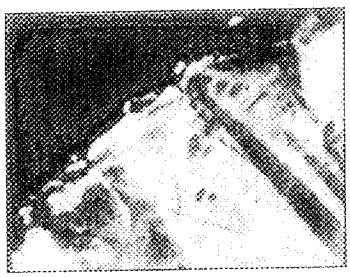
PLUGGING • CONDENSATION • CONDENSAZIONE • VERDICHTUNG • CONDENSACION









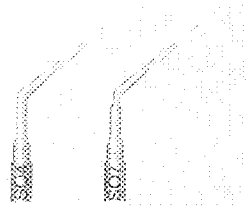


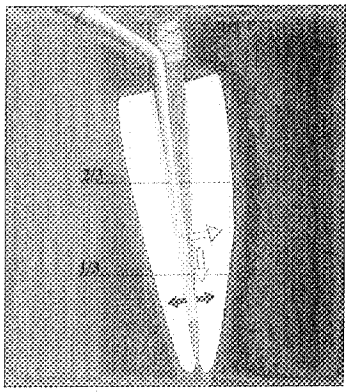
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

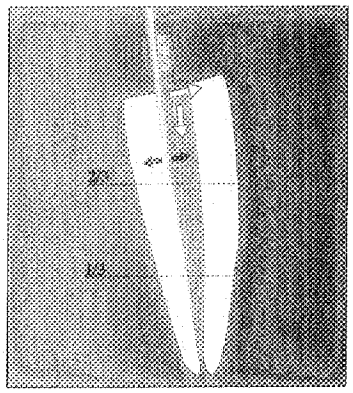
Records processed under FOIA Request 2014-6834; Released 10/23/14

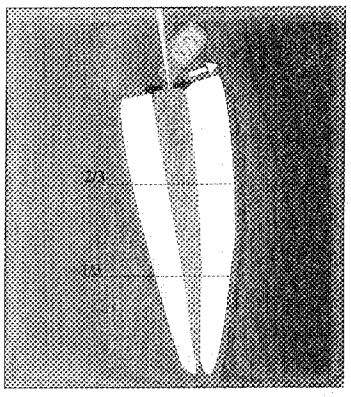
SATELEC CLINICAL LINE WITH ULTRASONIC GENERATORS

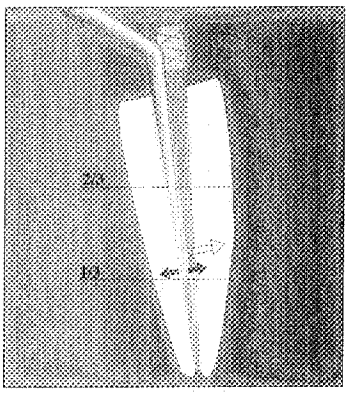
GUTTA CONDENSATION

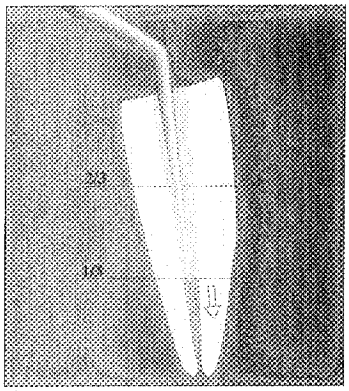


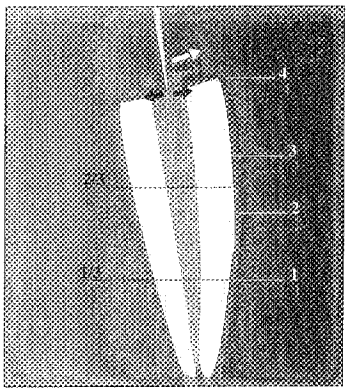


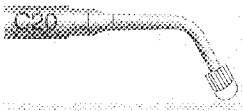


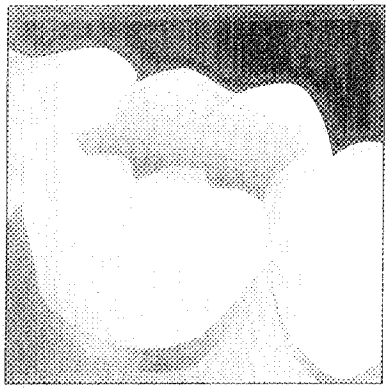


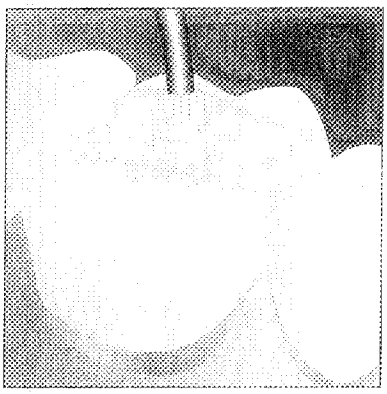


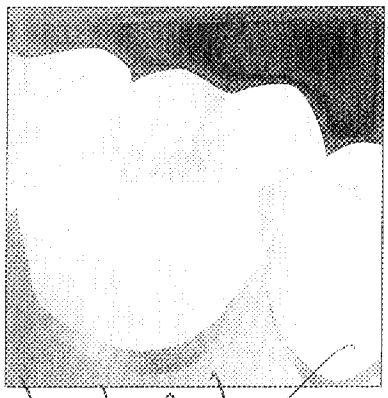






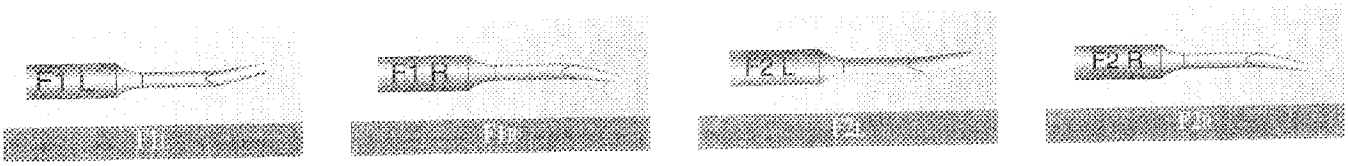


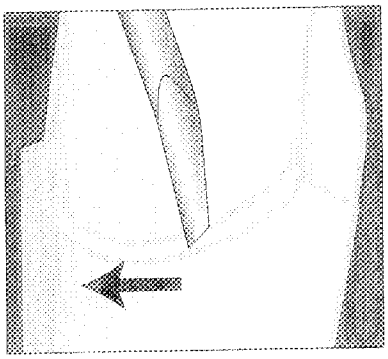


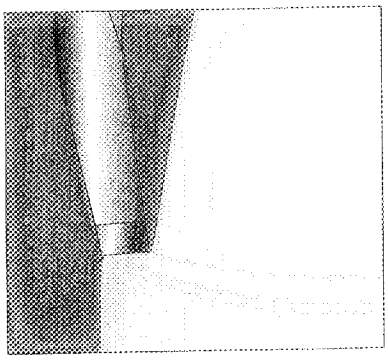


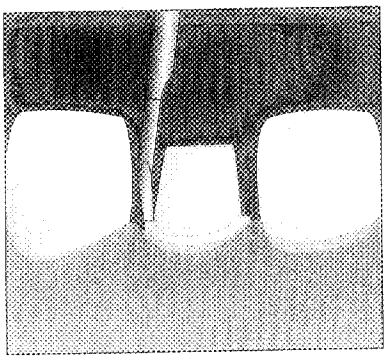
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

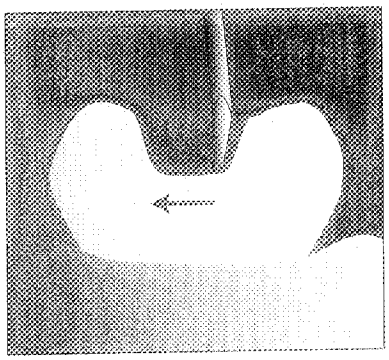
Records processed under FOIA Request 2014-6834; Released 10/23/14

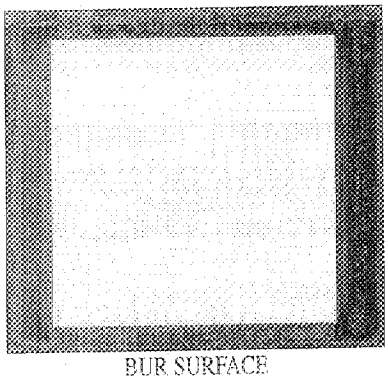




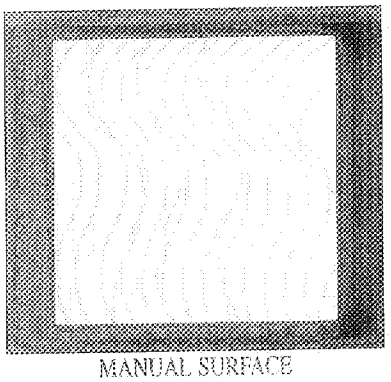




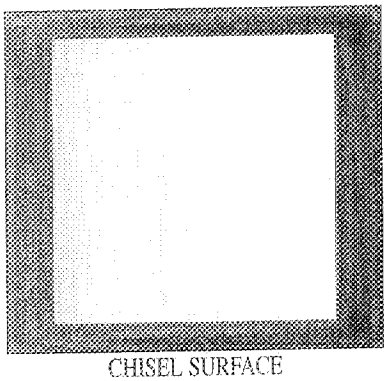




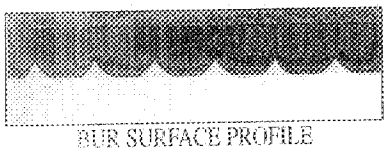
BUR SURFACE



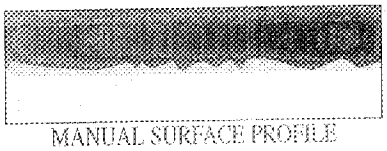
MANUAL SURFACE



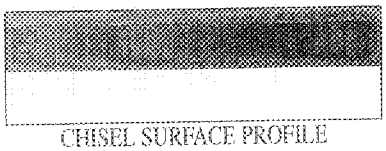
CHISEL SURFACE



BUR SURFACE PROFILE



MANUAL SURFACE PROFILE



CHISEL SURFACE PROFILE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

SATELEC CLINICAL LINE WITH ULTRASONIC GENERATORS

POWER SETTING PER CLINICAL APPLICATIONS • PUISSANCE • POTENZA • LEISTUNG • POTENCIA

APPLICATIONS Applications / Indicazioni Anwendungen / Indicaciónes	TIPS Inserts / Inserti Spitze / Puntas	REF Ref. / Cod. Ref. / Ref.	SP 3055 SP Classic SP PIEZO / ENDO	SP 3055 PROPHY-UNIT EXPERT	SP 4055 B P5	SP 4055 P-MAX	SP 4055 PROPHY-MAX
SCALING Detartrage / Ablazione del tartaro Zahnsteinentfernung / Detartraje	1	F 00246	[illegible]	[illegible]	5 - 8	[illegible]	[illegible]
	2	F 00247			8 - 10		
	3	F 00248			5 - 7		
	10 P	F 00253			5 - 8		
PERIODONTICS Parodontie / Parodontologia Parodontie / Periodoncia	H1	F 00366			1 - 3	1 - 10	1 - 10
	H2L	F 00367			1 - 3	1 - 10	1 - 10
	H2R	F 00368			1 - 3	1 - 10	1 - 10
	H3	F 00369			1 - 3	1 - 10	1 - 10
	H4L	F 00114			1 - 3	1 - 10	1 - 10
	H4R	F 00115			1 - 3	1 - 10	1 - 10
ENDONDONTICS Endodontie / Endodonzia Endodontie / Endodoncia	K10 21mm	F 43710	0 - 2 / 0 - 2		1 - 3	1 - 2 / 1 - 2	
	K15 21mm	F 43715	1 - 4 / 1 - 4		2 - 4	1 - 4 / 1 - 4	
	K25 21mm	F 43725	3 - 6 / 3 - 6		3 - 5	3 - 6 / 3 - 6	
	K30 21mm	F 43730	5 - 8 / 4 - 7		5 - 6	5 - 8 / 5 - 8	
	K10 25mm	F 43712	0 - 2 / 0 - 2		1 - 3	1 - 2 / 1 - 2	
	K15 25mm	F 43717	1 - 4 / 1 - 4		2 - 4	1 - 4 / 1 - 4	
	K25 25mm	F 43727	3 - 6 / 3 - 6		3 - 5	3 - 6 / 3 - 6	
	K30 25mm	F 43732	5 - 8 / 4 - 7		5 - 6	5 - 8 / 5 - 8	
SURGICAL ENDODONTICS Chirurgie endodontique / Chirurgia retrograda Retrochirugie / Retro cirugia	S12 80°	F 00093	[illegible]		8 - 14	[illegible]	
	S12 90°	F 00094			8 - 14		
	S12 120°	F 00095			8 - 14		
	S12D 80°	F 00101			7 - 9		
	S12D 90°	F 00102			7 - 9		
	S12D 120°	F 00103			7 - 9		
	S13L	F 00096			8 - 14		
	S13LD	F 00104			7 - 9		
	S13R	F 00097			8 - 14		
	S13RD	F 00105			7 - 9		
MICRO SURGICAL ENDODONTICS Micro Chirurgie endodontique / Micro chirurgia retrograda Mikro Retrochirurgie / Micro retro cirugia	P14	F 00098	[illegible]		8 - 9	[illegible]	
	P14D	F 00106			7 - 9		
	P15L	F 00099			8 - 9		
	P15LD	F 00107			7 - 9		
	P15R	F 00100			8 - 9		
	P15RD	F 00108			7 - 9		
PLUGGING Pontage / Condensazione / Verdichtung / Condensación	6A	F 00251	[illegible]		5 - 7	[illegible]	
	7A	F 00252			5 - 7		
LOOSENING Desscellement / Decementazione / Ablösen / Desempotramiento	5	F00250	[illegible]		10 - 14	[illegible]	
	5AE	F00249			10 - 14		
GUTTA CONDENSATION Condensation / Condensazione / Kondensation / Condensacion	S04	F 88009	[illegible]		7 - 10	[illegible]	
	S07	F 88010			7 - 10		
PROSTHODONTICS Prothese / Protesi / Prothese / Protesis	F1 L	F 00116	1 - 2 / 1 - 2		1 - 3	1 - 2 / 1 - 2	
	F1 R	F 00110	1 - 2 / 1 - 2		1 - 3	1 - 2 / 1 - 2	
	F2 L	F 00117	1 - 2 / 1 - 2		1 - 3	1 - 2 / 1 - 2	
	F2 R	F 00111	1 - 2 / 1 - 2		1 - 3	1 - 2 / 1 - 2	
INLAY/ONLAY CONDENSATION Condensation / Condensazione / Kondensation / Condensacion	C19	F 00112	[illegible]		3 - 5	[illegible]	
	C20	F 00113			3 - 5		

Identical to keys of our units / Equivalent touches de nos appareils /
Die hier aufgeführten Einstellungen entsprechen den Ziffern / Equivalente de las teclas de nuestros aparatos

Scaling/S/ Endo/E/ Perio/P/

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

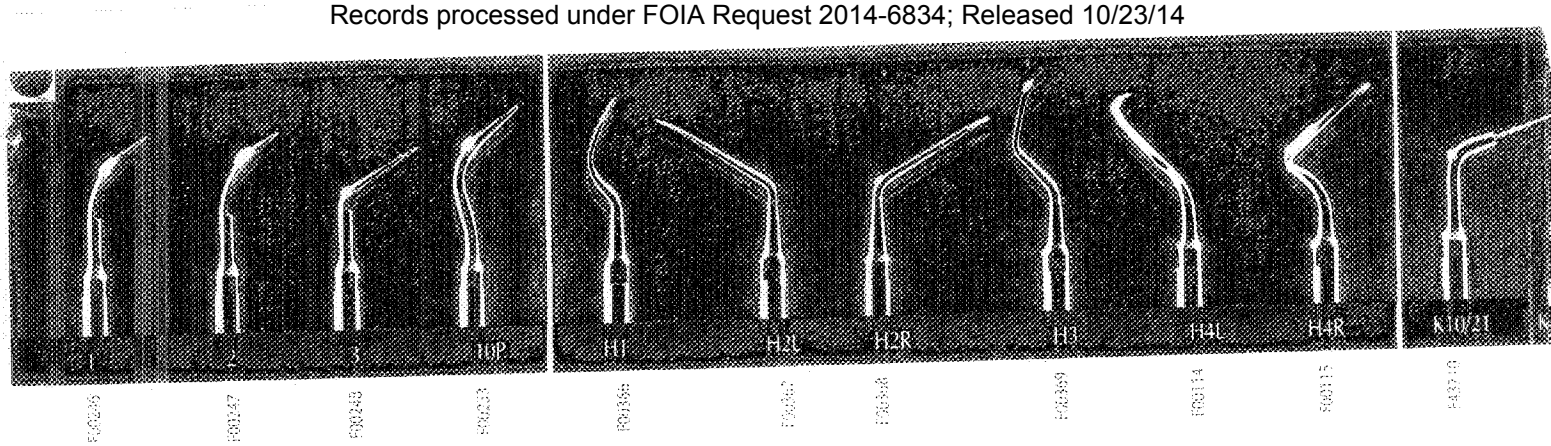
Records processed under FOIA Request 2014-0831 Released 10/23/14

SATELEC

Z.I. du Phare • B.P. 216 • 33708 MERIGNAC cedex • France
Tél : (33) 56 34 06 07 • Fax : (33) 56 47 85 52

3118

Records processed under FOIA Request 2014-6834; Released 10/23/14



MAX' SCALING WITH IRRIGATION

- *Scaling with tip # 1*
  Interdental junction treatment
  Tooth neck and subgingival treatment
- *Scaling with tip # 2*
  Treatment of large deposits
- *Scaling with tip # 3*
  Treatment of coatings and tobacco stains
- *Scaling with tip # 10P*
  Treatment of periodontal pockets
  Interproximal treatment

MAX' PERIODONTIA WITH DIAMOND TIPS AND IRRIGATION

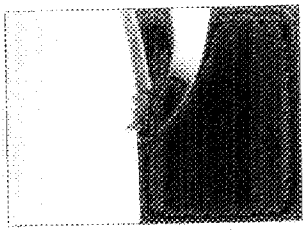
In order to achieve better gingival reattachment onto the tooth, subgingival scale must be removed (root planing) and the root must be polished to obtain a smooth and clean root surface.
Thus, the SUPRASSON P-MAX allows you to work with the H1, H2R and H2L diamond tips and an antiseptic irrigation solution. The efficiency is greater as the intervention time is shorter.

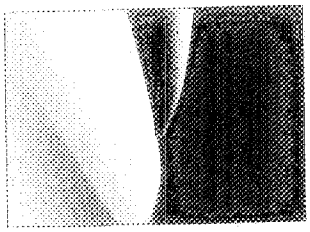
Initial therapy
Initial therapy is the choice treatment in periodontia. After root planing, it allows you to reappraise the situation before resorting to surgery, when necessary.

Treatment of periodontal pockets
- pocket < 5 mm without flap raising (moderate periodontitis).
- pocket > 5 mm with flap raising to allow planing in areas of difficult access (advanced periodontitis).

Treatment of furcations
Owing to their fineness and shape, the tips are easy to use in these areas.

Maintenance therapy
Ultrasonic root planing allows the implementation of the maintenance therapy, thus avoiding relapse of the disease.

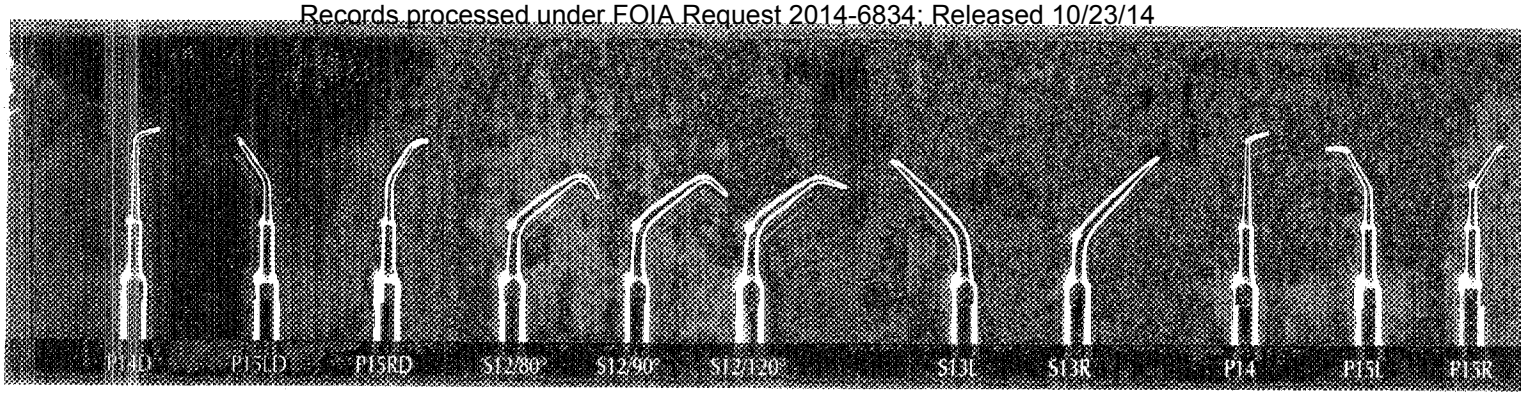




T H E W I D

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14



MAX' Retro Surgery using Retro Tips

Exclusive SATELEC profiles, diamond tips and irrigation

Retro Tips are tips dedicated to retrosurgery. They allow total control of retroapical preparations while achieving the results of ultrasonic treatment and cavitation.

Now, the canal can be easily reached from the best suited angle (80°, 90°, 120°) and at the correct depth, while preserving the canal axis and wall fineness. The apical cavity morphology remains unimpaired.

The tubuli are efficiently cleaned by the combined effects of ultrasonic emission and cavitation.

All these tips are available with aseptic solution irrigation.

The Retro Tips are available in normal or diamond versions with amplified efficacy for enhanced convenience of the practitioner and the patient.

*• Retro surgery tip # S12/80, S12/90, S12/11 and S12/80D, S12/90D, S12/12D**

Universal use and main accesses

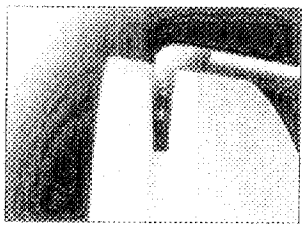
*• Retro surgery tip # S13L and S13LD**

premolars and molars, left maxillary and right mandible

*• Retro surgery tip # S13R and S13RD**

premolars and molars, right maxillary and left mandible

** diamond tip*



MAX' Micro Retro Surgery with Micro Retro Tips

Sophisticated applications and optimized power thanks to the exclusive SATELEC design for Micro Retro Tips

Micro Retro Tips are tips intended for micro retro surgery. They are finer than RetroTips to allow more sophisticated operations in very narrow canals. Micro Retro Tips use all the possibilities of ultrasonic treatment and cavitation, combined with diamond technology and irrigation.

A canal can now be easily reached from the best suited angle and at the correct depth, while preserving the canal axis and wall fineness.

The apical cavity morphology remains fully unimpaired.

The tubuli are efficiently cleaned by the combined effects of ultrasonic emission and cavitation.

All these tips are available with aseptic solution irrigation.

The Micro Retro Tips are available in normal or diamond versions with amplified efficacy for enhanced convenience of the practitioner and the patient.

*• Micro retro surgery tip # P14 and P14D**

tip with irrigation, incisor-canine block

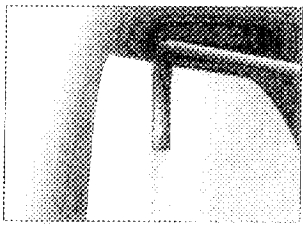
*• Micro retro surgery tip # P15L and P15LD**

premolars and molars, left maxillary and right mandible

*• Micro retro surgery tip # P15R and P15RD**

premolars and molars, right maxillary and left mandible

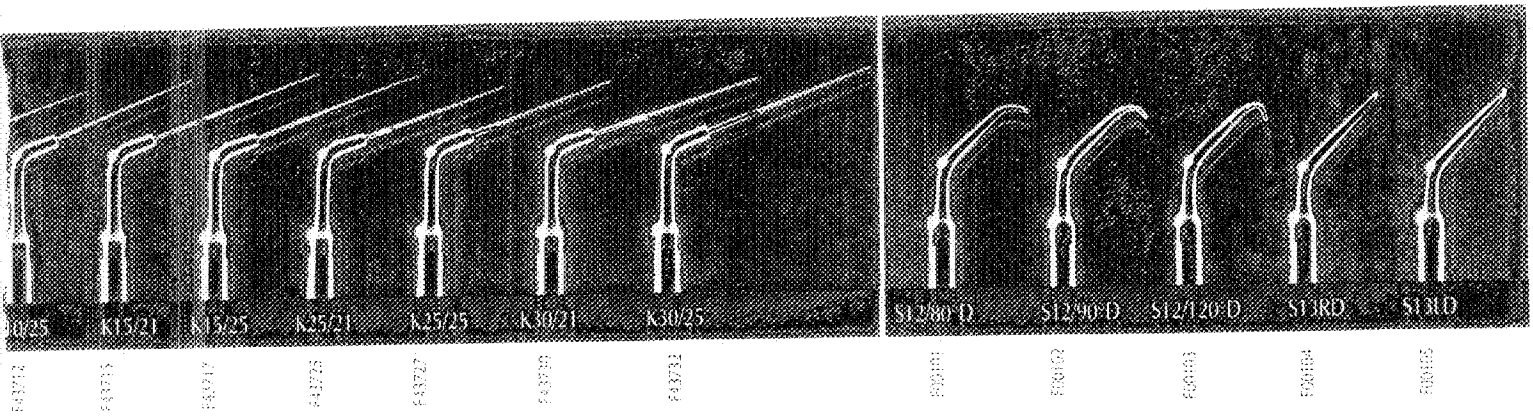
** diamond tip*



F O R M O S T C L I N I C

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

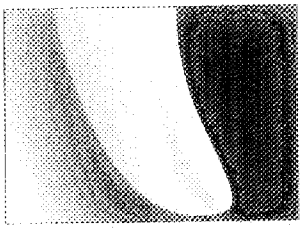


MAX' ENDODONTIA WITH IRRIGATION

Canal preparation : Fast preparation of the canal system. Respect of the initial canal morphology or curves and the apical constriction.

- *Optimal antibacterial activity of the irrigation solution and by the cavitation generated by ultrasonics.*
- *Abundant irrigation without increasing the intracanal pressure (eliminates apiflow risks).*
- *Selection of irrigation by the surgeon (distilled water, hypochlorite, etc.)*
- *Higher quality tooth/filling material junction thanks to the surface condition of the canal walls after ultrasonic cleaning.*

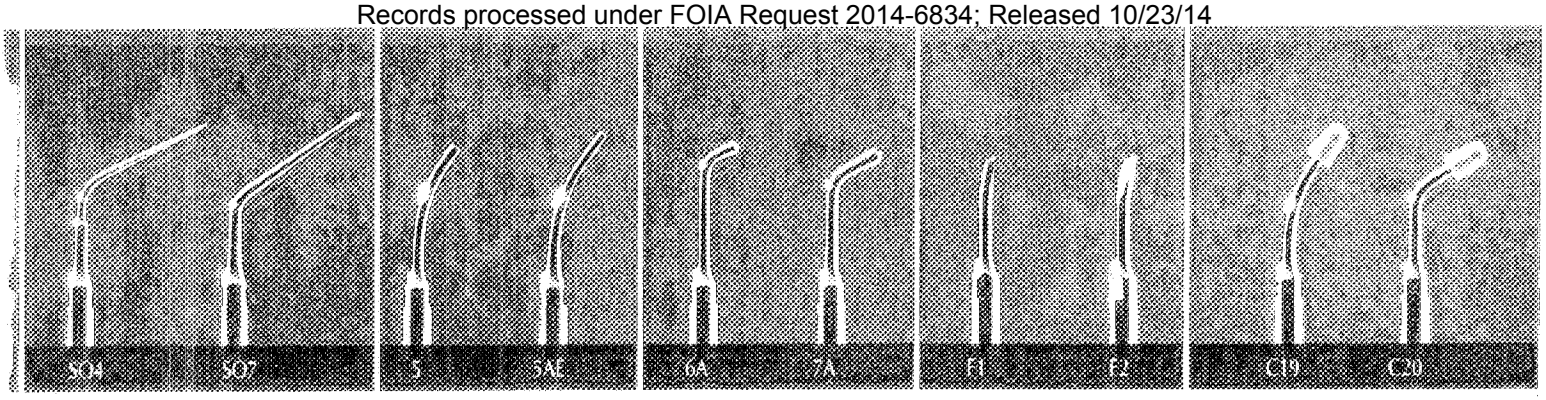
8 types of files for all applications
• 21 mm : K10/21, K15/21, K25/21, K30/21.
• 25 mm : K10/25, K15/25, K25/25, K30/25.



E S T U L T R A S O N J C

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14



MAX' PLUGGING and LOOSENING

• Amalgam plugging with tips n° 6A - 7A
Pluggers 6A and 7A, which vibrate on the cavity walls provide an excellent adaptation to the walls avoiding pulpal lesions.
• Prosthesis loosening with tips n° S - SAE
- Crown loosening;
- Post loosening.

Gutta Percha condensation with the S04 and S07 condensers

• Easy treatment resumption on little or not hardening pastes, more effective on pastes hard to dissolve (e. g. bakelite resins...).
- Treatment resumption on gutta percha.
- Post loosening.
- Silver cone loosening.
• Gutta Percha condensation
The thermal and mechanical effects obtained with a condenser subjected to ultrasounds effectively transforms gutta percha cones into a dense and homogeneous mass.

MAX' PROSTHESIS with CHISEL tips

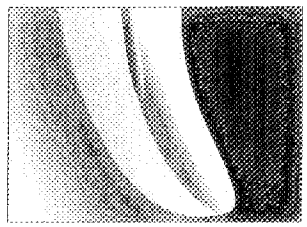
The F1 and F2 tips have been designed for preparation in luted denture, and surface smoothing after burring.
To avoid damage caused by conventional manual preparations, the prosthetic finish tips F1 and F2 are used upside down to ensure perfect surface finish and angular shaping.
Thanks to the specific design of the F1 and F2 tips, you can now correct chamfers and any cavity floor roughness.
Burred surfaces can be smoothed.
Shoulders are corrected with perfect shape control.
Chisel tips also allow :
- smoothing of crown roughness,
- correction of the cavity floor close to the pulp without applying inappropriate pressure. The pulp is thus protected from any adverse stimulation.

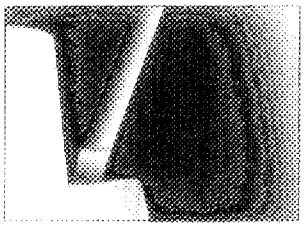
• Tip # F1, concave chisel
• Tip # F2, square chisel

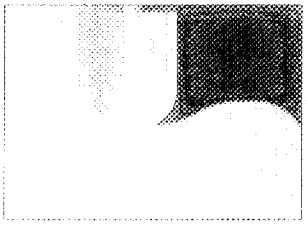
MAX' INLAY-ONLAY CONDENSATION with PIEZOCEM tips

PIEZOCEM tips have been designed to provide perfect finish of inlay/onlay restorations thanks to the thixotropy principle.
The procedure consists in cautiously placing the tips on the inlay and triggering ultrasonic emission. The sealing cement viscosity is strongly reduced and completely flows into the cavity without any pressure or effort.
Once ultrasonic emission is stopped, the sealing cement resumes its normal consistency.
The operation can be repeated until an easily removal excess of sealing.
Of course, the tip and end piece are autoclavable.
SATELEC's PIEZOCEM tips thus provide :
- perfect finish,
- up to now, an unequaled convenience,
- long-lasting restoration,
- double angulation for the different approaches.

• Condensation with tip # C19
• Condensation with tip # C20







115

A L A P P L I C A T I O N S

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

APPENDIX C

Diagrams of the Device

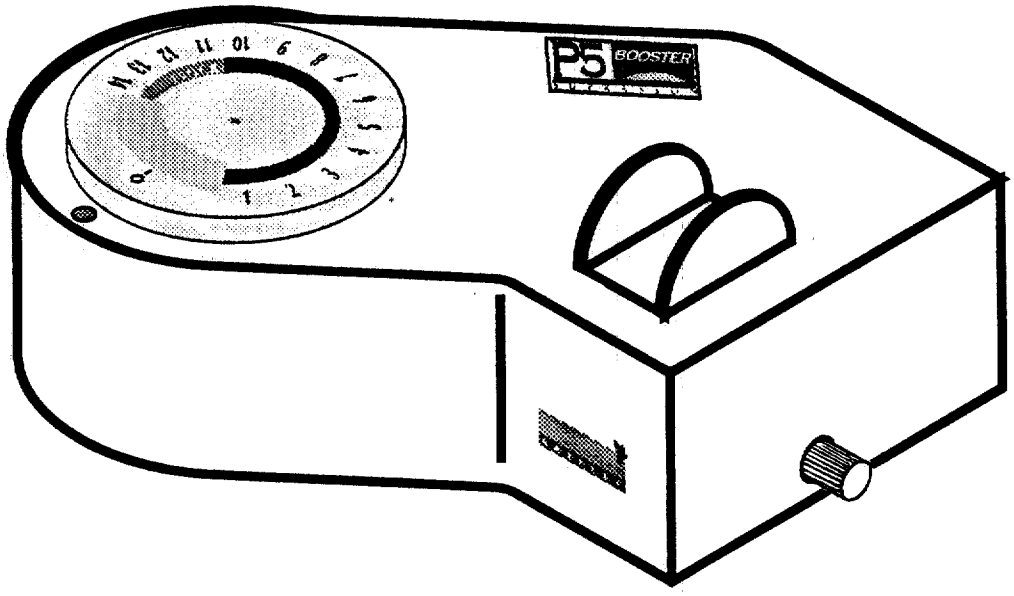
1. Diagram of the Control Panel Case.
2. Diagram of the 3 Connectors
3. Diagram of the Scaling Instrument (PAM) Handpiece

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

SUPRASSON P5

BOOSTER



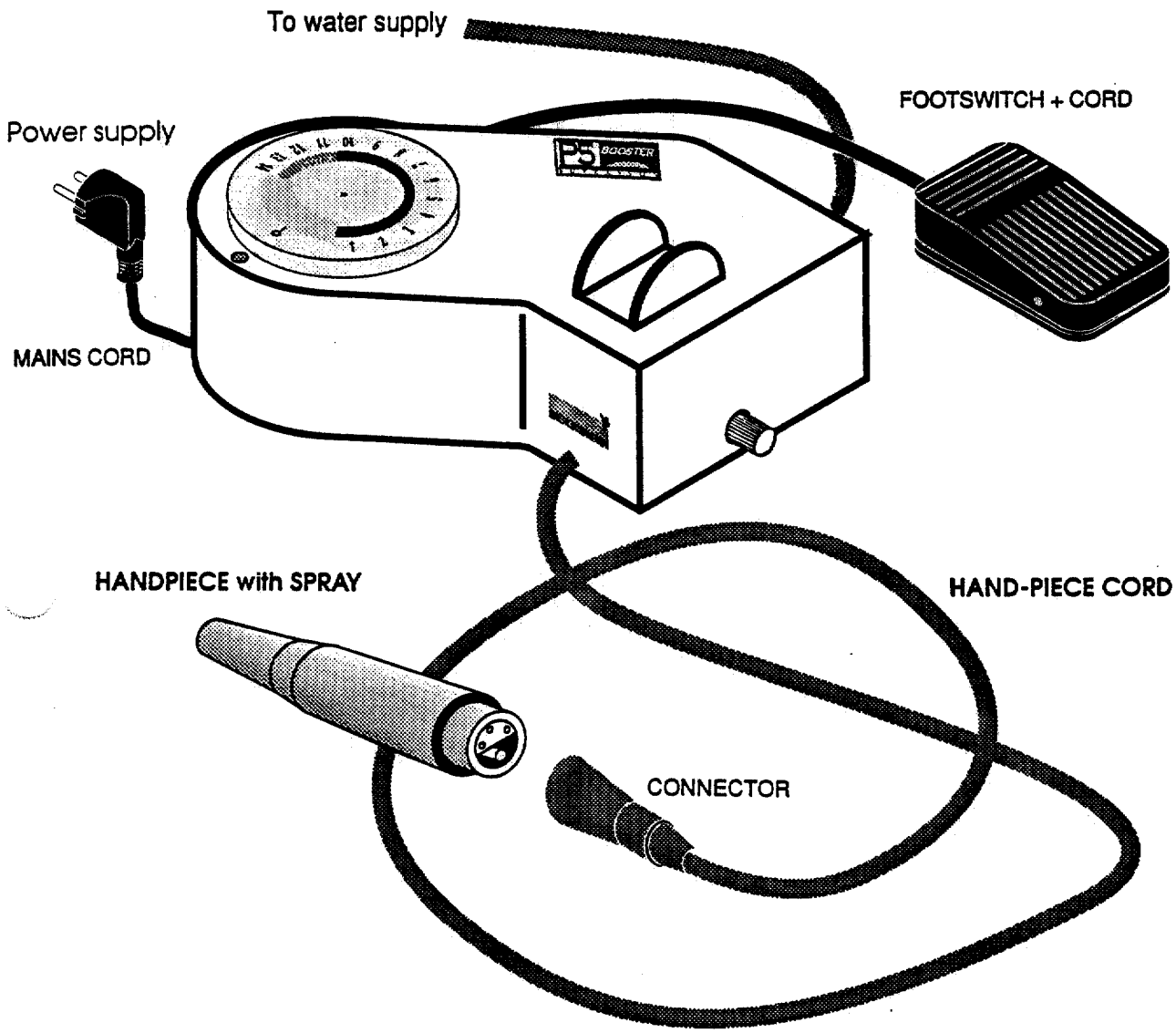
000036

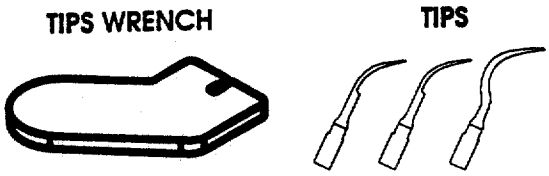
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-6834; Released 10/23/14

SUPRASSON P5

Description





000037

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

[redacted]