



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (szs)
FOLDER: K905188 - 95 pages
COMPANY: TELEDYNE WATER PIK (TELEWATEPIK)
PRODUCT: UNIT, ORAL IRRIGATION (EFS)
SUMMARY: Product: PERIO PIK

DATE REQUESTED: Oct 4, 2011

DATE PRINTED: Oct 4, 2011

Note: Printed





FEB 15 1991

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850Donald Ruehmann
Official Correspondent
Teledyne Water Pik
1730 East Prospect Street
Fort Collins, CO 80553-0001Re: K905188
Perio Pik
Dated: November 16, 1990
Received: November 19, 1990
Regulatory Class: I
21 CFR 872.6510

Dear Mr. Ruehmann:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Pre-market Approval) it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments 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 anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of OB-GYN, ENT,
and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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Memorandum

Date

From

REVIEWER(S) - NAME(S)

Carolyn A. Tylanda

Subject

510(k) NOTIFICATION

K905188

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

2-11-91 spoke with Mr. Don Ruchmann, Official Correspondent WaterPik about composition of device parts that will be in contact with irrigating fluid. - see review

2-12-91 spoke with Ms. Hannah Rusek, quality engineer, WaterPik, about plunger system, possible contact of compressed air with oral tissues, and advantages of this device compared to use of a manual syringe, or use of other WaterPik oral irrigators. Also discussed claims. - see review. C.A. Tylanda DMD, PhD

The submitter requests under 21 CFR 5807.95:

Predicate Product Code w/Panel and class: CFR 872.6510

No Confidentiality

EFS/DE class ~~unclassified~~ I

Confidentiality for 90 days

Additional Product Code(s) w/Panel (optional):

Continued Confidentiality exceeding 90 days

REVIEW:

Louis Novak
(BRANCH CHIEF)

2/12/91
(DATE)

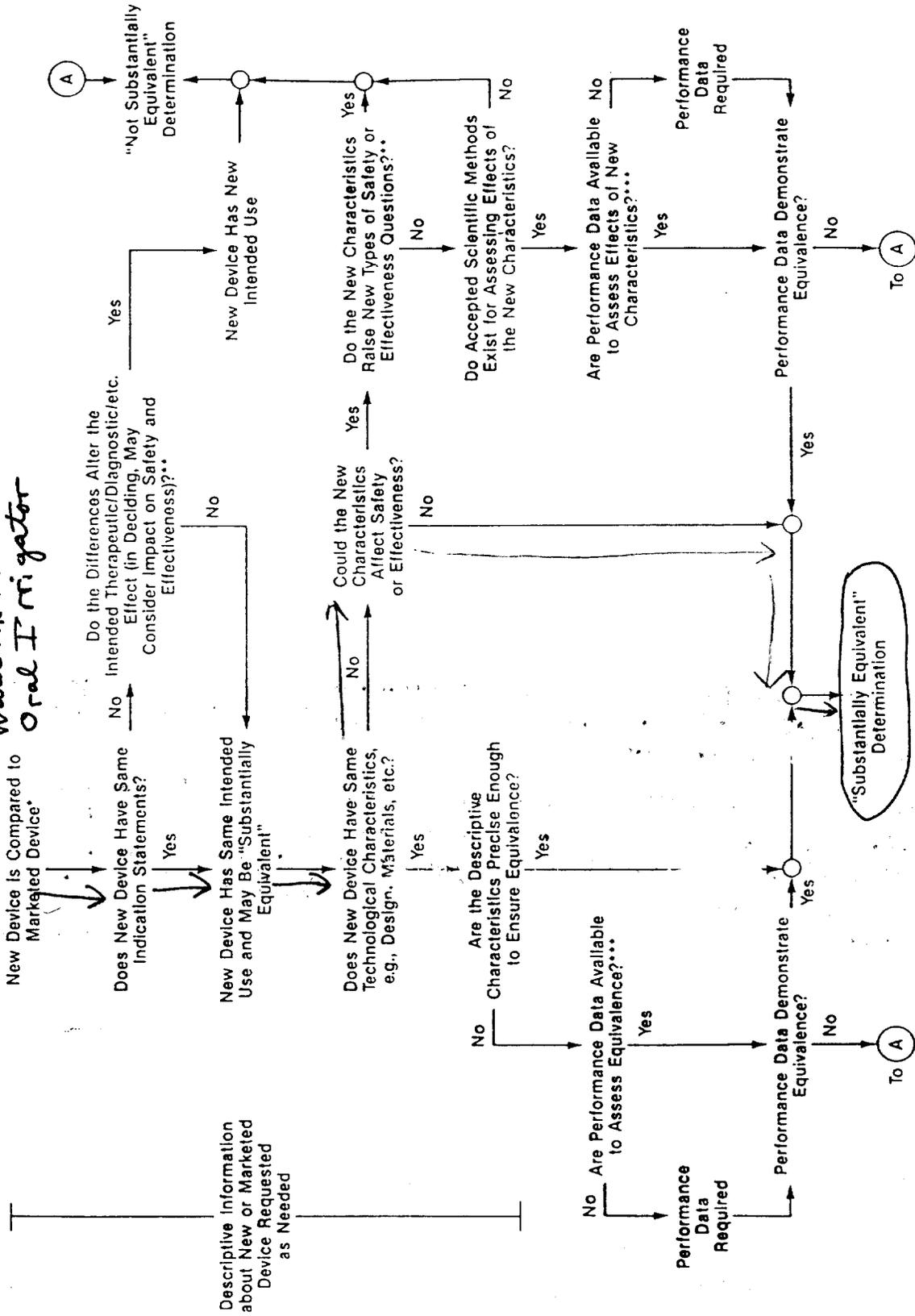
FINAL REVIEW:

D. G. Singleton, DDS
David A. Segerson
(DIVISION DIRECTOR)

2/13/91
2/14/91
(DATE)

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)

K 84-0721
Waters Pik Model XP-7W
Oral Irrigator



* 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.

K 905188

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

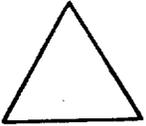
REVIEWER: C.A. Tylenda

DIVISION/BRANCH: DOED/ENTO

TRADE NAME: Perio Pik

COMMON NAME: oral irrigator

PRODUCT TO WHICH COMPARED: K 840721 Water-Pik Model XP-7W
(510(k) NUMBER IF KNOWN) Oral Irrigator

- | | | | |
|--|-------------------------------------|--|---|
| | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO | |
| 1. IS PRODUCT A DEVICE? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - IF NO STOP |
| 2. DEVICE SUBJECT TO 510(k)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - IF NO STOP |
| 3. SAME INDICATION STATEMENT? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - IF YES GO TO 5 |
| 4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS? | <input type="checkbox"/> | <input type="checkbox"/> | - IF YES STOP  |
| 5. SAME TECHNOLOGICAL CHARACTERISTICS? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | - IF YES GO TO 7 |
| 6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | - IF YES GO TO 8 |
| 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - IF NO GO TO 10
- IF YES STOP  |
| 8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS? | <input type="checkbox"/> | <input type="checkbox"/> | - IF YES STOP  |
| 9. ACCEPTED SCIENTIFIC METHODS EXIST? | <input type="checkbox"/> | <input type="checkbox"/> | - IF NO STOP  |
| 10. PERFORMANCE DATA AVAILABLE? | <input type="checkbox"/> | <input type="checkbox"/> | - IF NO REQUEST DAT. |
| 11. DATA DEMONSTRATE EQUIVALENCE? | <input type="checkbox"/> | <input type="checkbox"/> |  |

 NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE: _____

2. EXPLAIN WHY NOT SUBJECT TO 510(k): _____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: _____

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE: _____

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: *The power source is compressed air, in comparison to electricity, the power source for the predicate device.*

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: *Use of compressed air to control fluid syringe release from the device does not affect safety or effectiveness. The design of the device is such that compressed air does not ~~see~~ come in contact with ~~and~~ the irrigating fluid, nor could it be forced into tissue.*

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NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE:

Perio Pik™ is an oral irrigator intended for delivery of fluids to subgingival areas. It is powered by compressed air from the dental operator's dental unit.

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain a drug or biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties and toxicology profile if important.

SUMMARY

Teledyne Water Pik is seeking clearance to market Perio Pik™, an oral irrigator intended for use in a dental operator for subgingival delivery of fluids. Selection of fluids for irrigation is the decision of the dental professional. The device consists of a polypropylene syringe barrel (reservoir) and a ethylene propylene/polypropylene plunger attached to a handpiece that connects to the compressed air source at the dental unit. Volume of the reservoir is 15 ml. The handpiece contains a regulator to control air pressure, and a flow indicator. The unit is intended to operate between 40 and 80 psi. When the foot pedal (not part of the device; standard equipment on any dental unit) is pressed, compressed air enters the handpiece, forcing the plunger to expel the irrigating solution at a constant rate. Fluid flow ceases when the foot pedal is released. When the syringe barrel is emptied of fluid, the plunger is pressed against the tip of the barrel, preventing any compressed air from exiting the device. While the predicate device, Water Pik oral irrigator model XP-5, is electrically powered, use of a compressed air source in this device does pose a safety risk. As mentioned above, the compressed air is not in direct contact with the irrigating fluid, and, because of the device design, cannot be forced into tissue.

According to Hannah Russel (telephone conversation 2-12-91), Teledyne Water Pik quality engineer, dental practitioners would normally use 30 ml of fluid to irrigate an oral cavity. This translates to two reservoir volumes. According to Ms. Russel, an advantage of the device is that it can be located chairside, i.e., attached to the unit as one would attach a dental handpiece, making it easily accessible to the dentist. Another advantage is that carpal tunnel syndrome from repeated pressure on the hand through

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manual expulsion of fluids from a syringe is avoided. When asked about the absence of claims for this product, Ms. Russel replied that no claims will be made other than those already allowed for Water Pik oral irrigators.

In a telephone conversation on 2-11-91 with Mr. Don Ruehmann, Official Correspondent, Teledyne Water Pik he noted that, of the device parts that contact irrigating fluid, the plunger and pump are composed of the same material as the oral irrigator in K840721. Materials which compose other device parts in contact with fluid pose no safety concern.

RECOMMENDATION

This device, Perio Pik Model XP-7W, is substantially equivalent to K840721 Water Pik oral irrigator.

C. A. Tylenko PMP, Ph.D
2-15-91

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)
1390 Piccard Drive
Rockville, Maryland 20850

NOVEMBER 21, 1990

TELEDYNE WATER PIK
ATTN: DONALD RUEHMANN
1730 EAST PROSPECT STREET
FORT COLLINS, CO 80553

D.C. Number : K905188
Received : 11-19-90
90th Day : 02-17-91
Product : PERIO PIK

-- The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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K905188

TELEDYNE
WATER PIK

2E

RECEIVED

19 Nov 90 14 17

1730 EAST PROSPECT STREET
FORT COLLINS, COLORADO 80553-0001
(303) 484-1352 TWX (910) 930-9002
FAX (303) 221-8715

FDA/CDRH/ODE/DMC

November 16, 1990

CERTIFIED MAIL

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

Reference: K840721 (Perio Pik™ Subgingival Irrigation Kit)

Subject: Premarket Notification, 510(K) for Redesign of Perio
Pik™ Subgingival Irrigation Kit, Including Change in
Power Source. Model XP-7W

Attention: Document Control Clerk

Teledyne Water Pik is requesting marketing clearance for a
redesigned version of the XP-5. Said redesign is designated Model
XP-7W. The premarket notification information required by
21CFR807.87 is as follows:

Classification Name: None

Common/Usual Name: Subgingival Irrigation Kit

Proprietary Name: Perio Pik™

Establishment Registration Number: 1712259

Owner Operator I.D. Number: 9920024

Classification: None

Performance Standards: None

Labels, Labeling, Advertisement and Instructions: Final
draft copies enclosed herewith.

Substantial Equivalence: The Model XP-7W subgingival
irrigation kit is manufactured by Teledyne Water Pik. In our
opinion this kit is substantially equivalent to the XP-5 kit
which was cleared for marketing under premarket notification
K840721 (reference copy enclosed herewith). The basis for
this conclusion is further indicated in the description of
Model XP-7W and referenced documents enclosed herewith.

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Food and Drug Administration
November 16, 1990
Page 2

Certain information and data contained in this notification is considered by Teledyne Water Pik to be proprietary and/or confidential information exempt from public disclosure. In the event a Freedom of Information Act request is received by the Agency asking for disclosure of information and/or data contained in this notification, Teledyne Water Pik requests that it be consulted prior to any decision by the Agency as to whether the information/data is disclosable.

Sincerely yours,



Donald W. Ruehmann
Official Correspondent

DWR/pk

Enclosures

November 16, 1990



TELEDYNE WATER PIK

PREMARKET NOTIFICATION 510(K)

FOR MODEL XP-7W SUBGINGIVAL IRRIGATION KIT

RECEIVED

19 NOV 90 14 17

FDA/CDRH/ODE/DMC

TELEDYNE WATER PIK

November 16, 1990

TELEDYNE WATER PIK
Premarket Notification 510(K)
For Model XP-7W Subgingival Irrigation Kit

CONTENTS

Section

1. Premarket Notification, 510(K), Letter to FDA
2. Description of Model XP-7W
3. Instructions and Labeling
4. Reference Copy of K840721 (Model XP-5)

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1



1730 EAST PROSPECT STREET
FORT COLLINS, COLORADO 80553-0001
(303) 484-1352 TWX (910) 930-9002
FAX (303) 221-8715

November 16, 1990

CERTIFIED MAIL

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

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Food and Drug Administration
November 16, 1990
Page 2

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Sincerely yours,



Donald W. Ruehmann
Official Correspondent

DWR/pk

Enclosures

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2

DESCRIPTION OF PERIO PIK™ SUBGINGIVAL IRRIGATING KIT

MODEL XP-7W

1. This product is intended for professional use only. It is to be used for precision subgingival irrigation and irrigation with antimicrobial irrigants selected by the professional.

2. Contents of Kit

<u>Item</u>	<u>Quantity</u>
Regulator	1
Reservoir	4
Plunger	4
Retractor	2
Lubricant	1
Cannula (24GA)	10
Fill Bottle	1
Pump, Fill Bottle	1
Instruction Book	1

3. Change in Power Source

The XP-5 is electrically powered from a common 120V, 60Hz wall receptacle.

The XP-7W is powered from a 40 to 80 P.S.I. compressed air source available at a standard dental operatory work station.

4. Materials in Contact with Irrigant

Reservoir - Polypropylene, Phillips Petroleum Company, Marlex^(R) HGN-200

Plunger - Ethylene Propylene/Polypropylene, Monsanto, Santoprene 271-80
color Color Concentrate, Reed Plastics Corp., C-TPR-00417

Filling Bottle - Thermoplastic Polyester, Kodak, Kodapak PET 5302, DMF 055823. Bottle manufactured by Plasicon Company

11/16/90 - 04/19/92

Description of Perio Pik™
Subgingival Irrigating Kit
Model XP-7W
November 16, 1990
Page 2 of 2

4. Materials in Contact with Irrigant - cont'd

Closure - Polypropylene, KERR Packaging Products Division,
DMF-2256

Lining - Polypropylene, KERR Packaging Products Division,
DMG-2457

Pump - Manufactured by CALMAR, Inc.
Acetal, HOECHST CELANESE, CELCON M90-CF2001
Stainless Stainless Steel grades 302 and 303
Buna N rubber, KYOWA KOKO, COMPOUND
KN 70126-1 (21CFR177.2600)

Lubricant - Silicone Grease, General Electric, G-661,
NSF Standard 42, 21CFR178.3570

Cannula - MAX-I-PROBE, purchased completely packaged from
MPL Hypo Division, subsidiary of Affiliated Hospital
Products, Inc.

5. Performance Comparison

The graphs on the following page compare the XP-5 and XP-7W output pressure and output flow under expected variations of input power source. Unit controls were set on maximum. All testing was done with 24GA. cannulas. Graphs also show performance of XP-7W with regulator set on low. This indicates the range of control available.

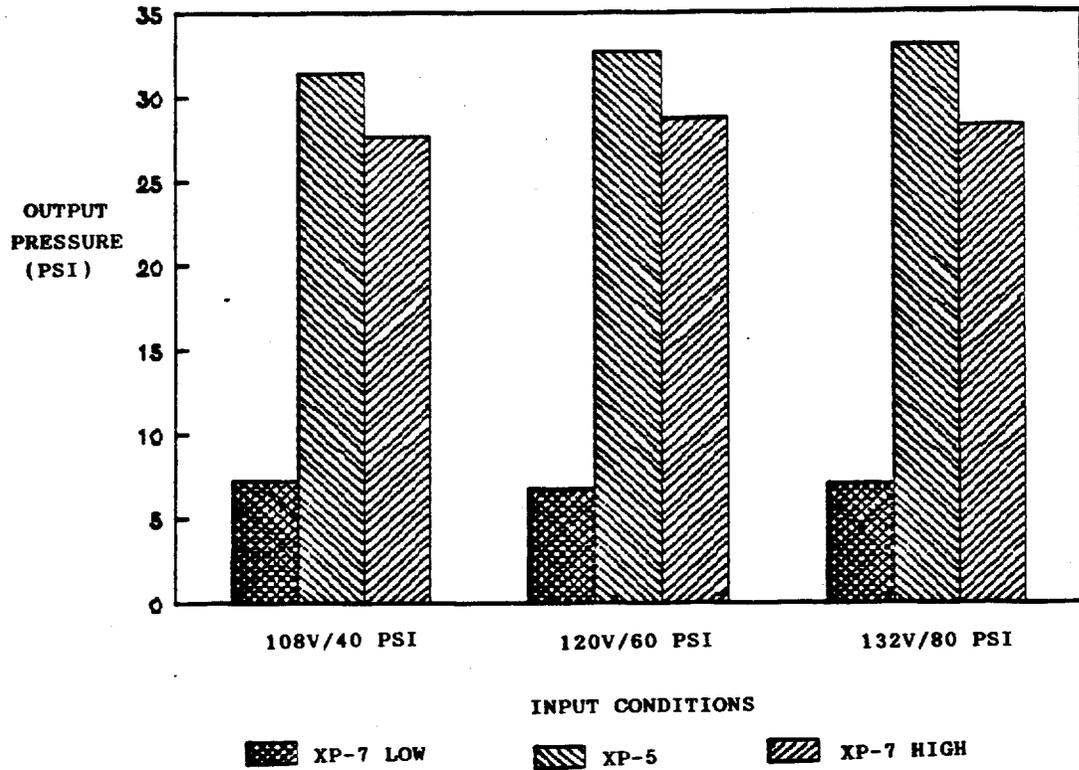
DWR/pk

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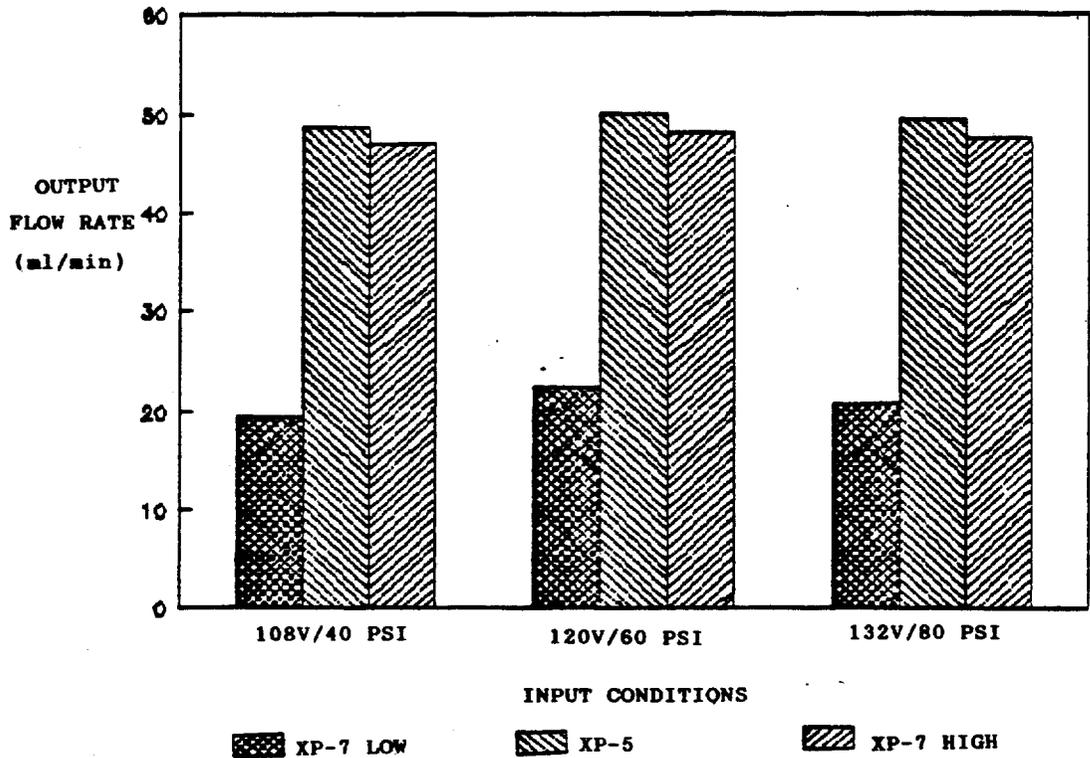
61

XP-5 vs XP-7 Output Fluid Pressure

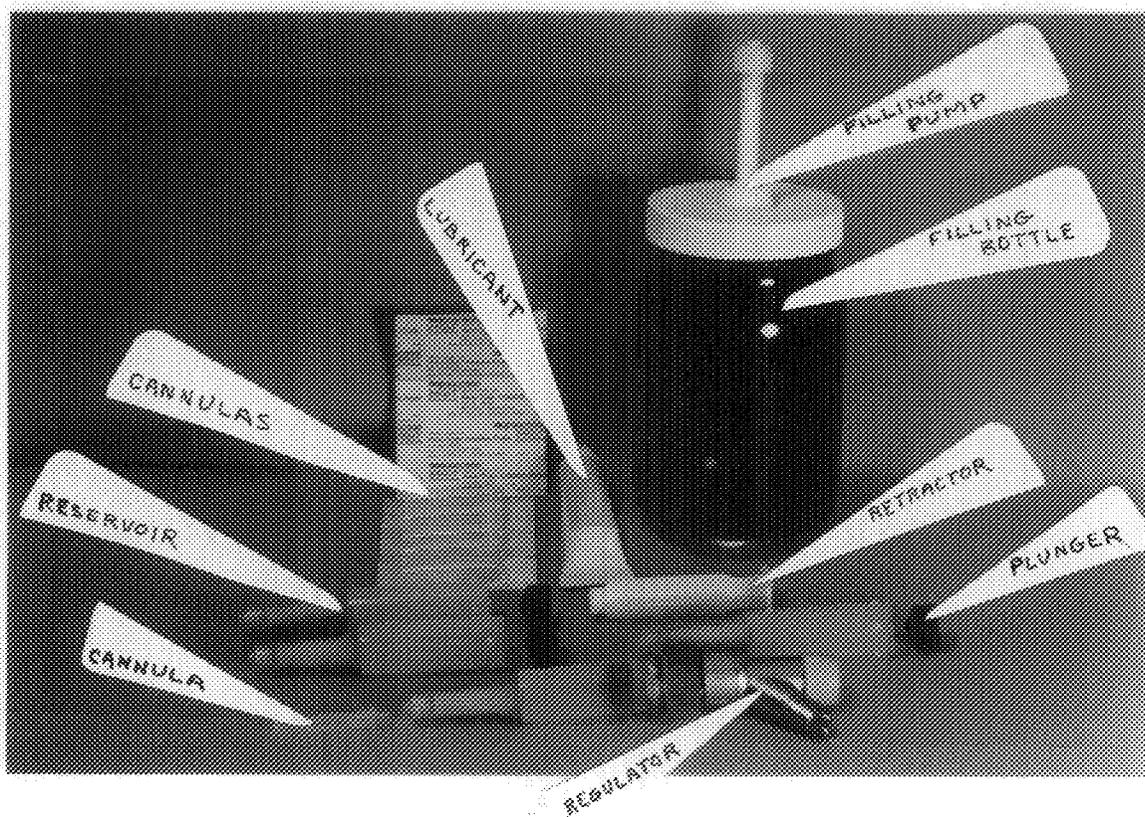
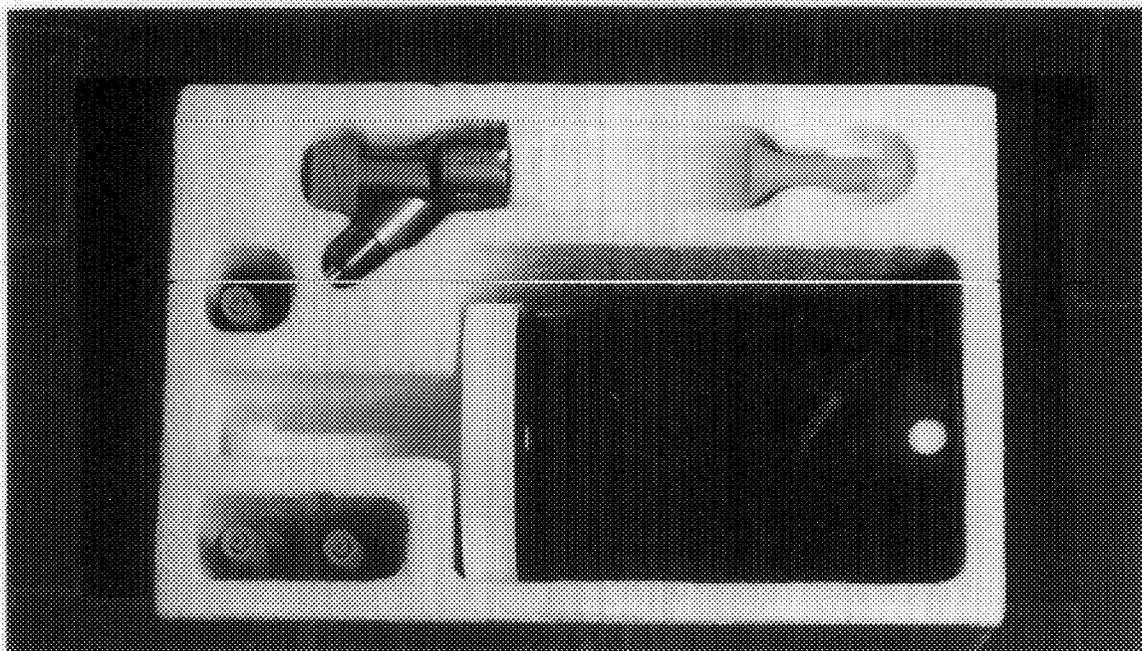


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XP-5 vs XP-7 Output Flow Rate

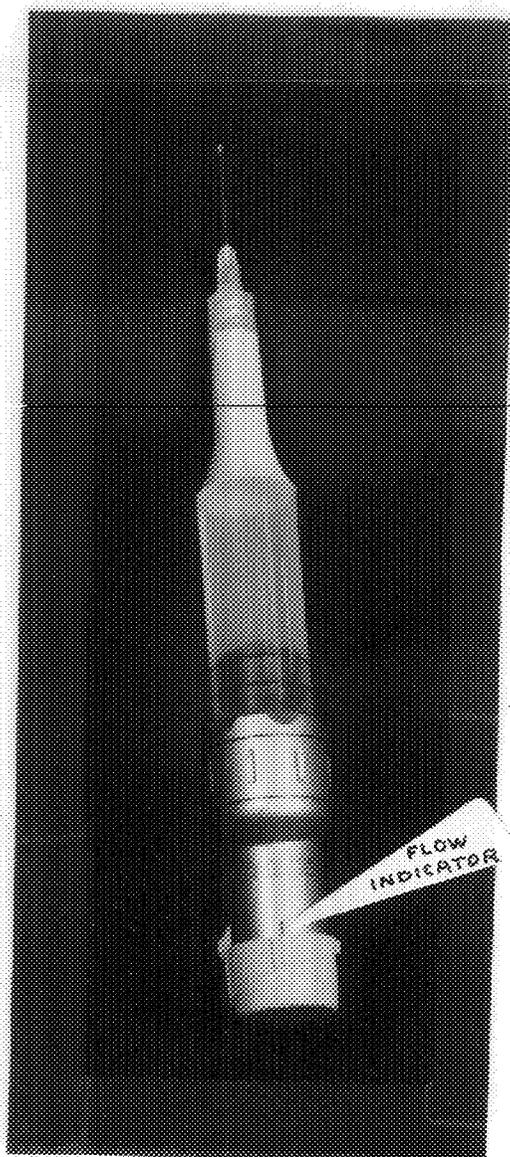
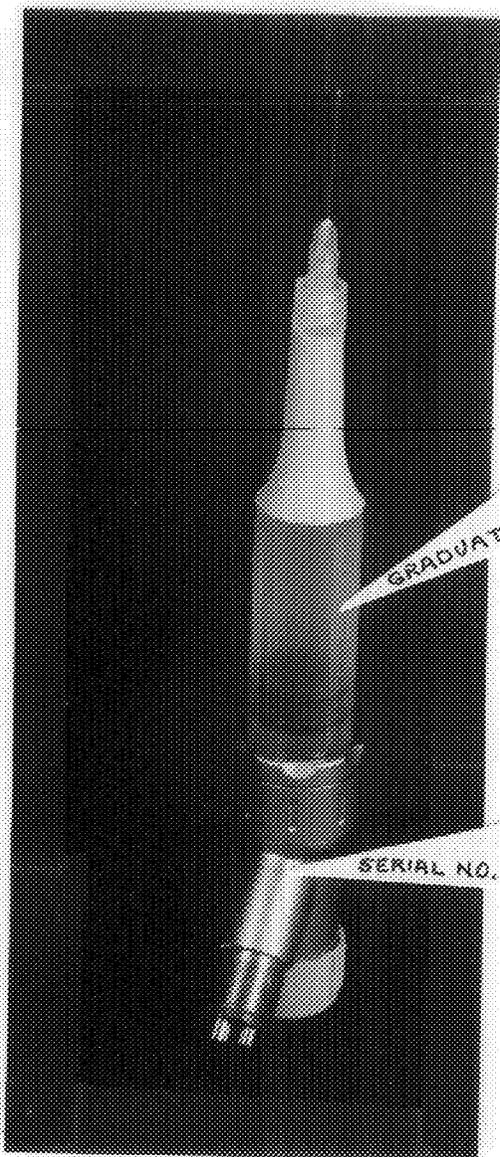


PACKAGED KIT & CONTENTS

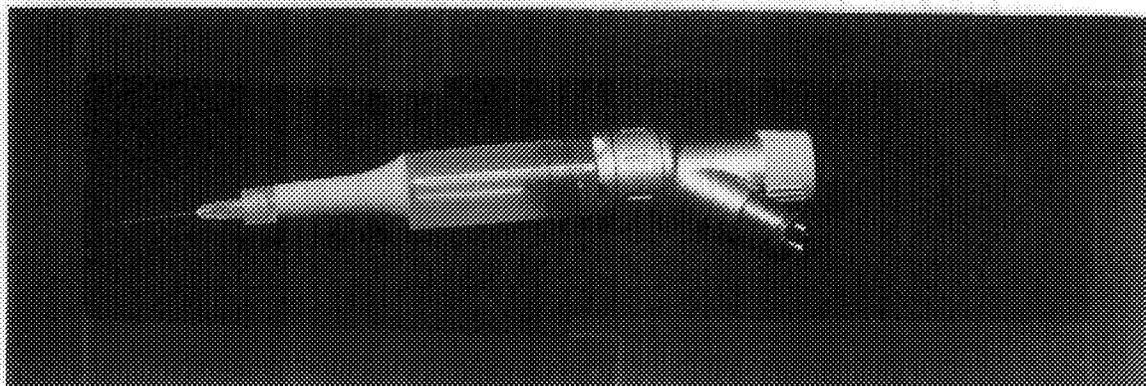


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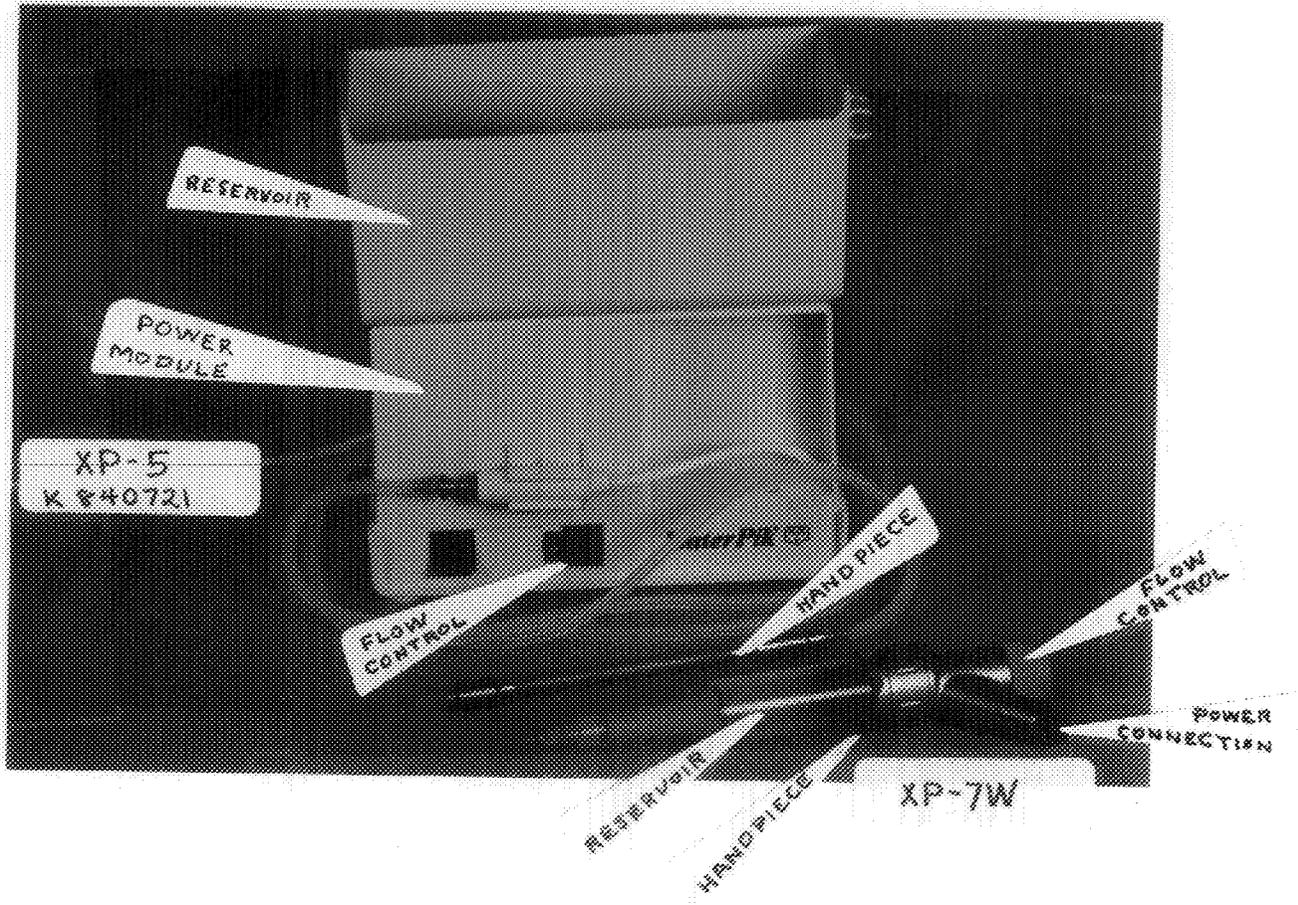
VIEWS OF COMPLETE HANDPIECE



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XP-5/XP-7W COMPARISON



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22

3

APPROVALS

S.O.P. B1-05

PRODUCT XP-7
 TITLE XP-7 Fill Bottle Copy
 MP # WP-36-90 ADD C
 DATE 11/5/90
 ORIGINATOR Susan Peterson
 REV. 1 _____
 REV. 2 _____
 REV. 3 _____
 REV. 4 _____

PROJECT LEADER	J. Jennings	<i>JJA</i>	DATE	11-6-90
* REGULATORY AFF. MGR.	D. Ruehmann	<i>DR</i>		11-7-90
* PRODUCT ENGINEER	J. Baum	<i>JWB</i>		11-7-90
PROD. MRKG. MGR.	C. Ross	<i>CR</i>		11-7-90
BUSINESS UNIT MGR.	M. Codd	<i>MC</i>		11-7-90
OTHER	_____			
* EXEC. VICE PRES.	A. Hupper	<i>AH</i>		11-7-90
COMPANY PRES.	M. Cruger	<i>MC</i>		11-7-90
* COMPLIANCE	_____			

Copy approval for Perio Pik™ Subgingival Irrigation System copy on fill bottle.

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Perio Pik™ Reservoir Filling Bottle

FILLING INSTRUCTIONS:

- 1) Prime pump each time filling bottle is refilled or emptied.
- 2) Use the stem of the pump to push the plunger into a forward and ready to fill position.
- 3) Connect the luer lock fitting of the reservoir to the valve on the pump by threading the reservoir clockwise onto the valve until it is secure.
- 4) Hold the reservoir and filling bottle firmly and push down several times until the reservoir is filled with desired amount of irrigant. To avoid spillage, do not fill reservoir beyond 15 ml/cc graduation mark.
- 5) Disconnect the reservoir from the valve. Expel any air from the filled reservoir by pushing the plunger forward slightly. The filled reservoir is now ready to be engaged to the air regulator.

REMINDER: To ensure optimum infection control, use a sterile reservoir every time you fill a reservoir or require additional irrigating solution.

(flying T) Teledyne Water Pik
Part No. XXXXX
Form No. 04XP7FB-1190

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APPROVALS

S.O.P. B1-05

PRODUCT XP-7
TITLE XP-7 Lubricant Tube Copy
MP # WP-36-90 ADD D
DATE 11/7/90
ORIGINATOR Susan Peterson
REV. 1 _____
REV. 2 _____
REV. 3 _____
REV. 4 _____

		DATE
PROJECT LEADER	J. Jennings <i>[Signature]</i>	11-7-90
* REGULATORY AFF. MGR.	D. Ruehmann <i>[Signature]</i>	11-8-90
* PRODUCT ENGINEER	J. Baum <i>[Signature]</i>	11-7-90
PROD. MRKG. MGR.	C. Ross <i>[Signature]</i>	11-7-90
BUSINESS UNIT MGR.	M. Codd <i>[Signature]</i>	11-7-90
OTHER	_____	_____
* EXEC. VICE PRES.	A. Hupper <i>[Signature]</i>	11-8-90
COMPANY PRES.	M. Cruger <i>[Signature]</i>	11/8/90
* COMPLIANCE	_____	_____

To receive copy approval for the XP-7 Lubricant Tube Copy.

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CAUTION!
Eye Irritant
See Back

Perio Pik™
by Teledyne Water Pik

Silicone Lubricant

Net Wt. 28g. (1 oz.)

(flying T) Teledyne Water Pik
1730 E. Prospect
Ft. Collins, CO 80553-0001
1-800-523-2020

Part No. xxx
Form No. xxx

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CAUTION!

Product contact may irritate the eyes. Avoid contact with eyes. In case of contact, flush with water for 15 minutes. If irritation persists, seek medical attention. Keep out of reach of children.

For professional use with Perio Pik™ Subgingival Irrigation System.

DIRECTIONS:

- 1) Apply thin film of lubricant to the outside surface of the plunger to optimize performance and extend life of reservoir and plunger.
- 2) Apply thin film of lubricant to outside surface of the reservoir seal for easier tightening of the reservoir, with retaining ring, to air regulator.

(Copy will be in English and French)

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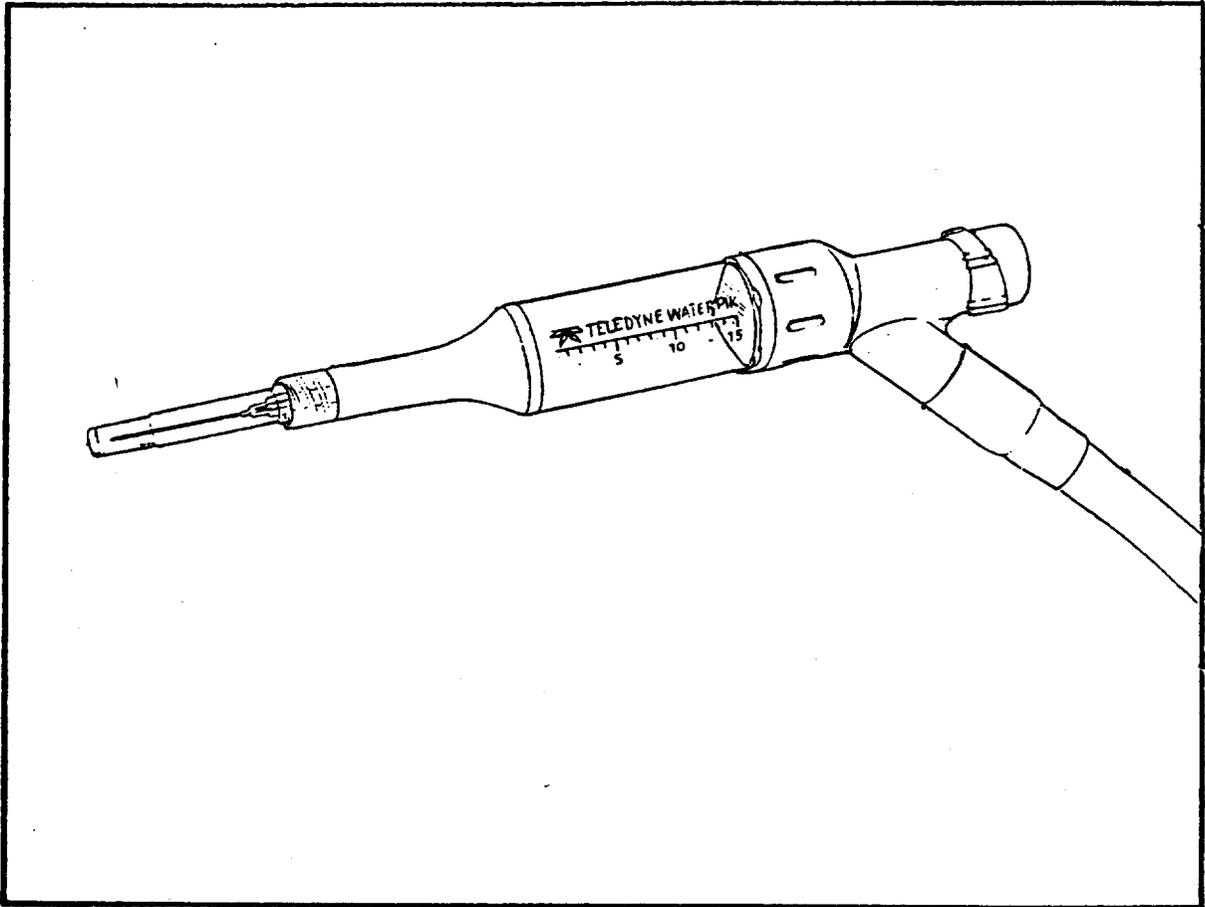
APPROVALS

S.O.P. B1-05

PRODUCT XP-7
TITLE XP-7 INSTRUCTION BOOK
MP # WP-36-90
DATE 10-29-90
ORIGINATOR SUSAN PETERSON
REV. 1 _____
REV. 2 _____
REV. 3 _____
REV. 4 _____

PROJECT MANAGER: J. JENNINGS *JJA* DATE 10/29
* REGULATORY AFF. MGR. D. RUEHMANN *[Signature]* 10/21/90
* PRODUCT ENGINEER J. BAUM *JWB* 10-30-90
PROD. MRKG. MGR. *CR* C. ROSS / C. JANZ
BUSINESS UNIT MGR. M. CODD *[Signature]* 11/2/90
OTHER _____
EXEC. VICE PRES. A. HUPPERT *[Signature]* 11/6
COMPANY PRES. M. CRUGER *[Signature]* 11/6
* COMPLIANCE

Final copy approval for XP-7 Instruction Book



PerioPikTM
by TELEDYNE WATER PIK

Subgingival Irrigation Handpiece
Model XP7-W

READ AND SAVE THESE INSTRUCTIONS

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Important Safeguards

Read All Instructions Before Using

WARNING

Personal injury may result if the following warning statements are not followed:

Use this product only as intended for intraoral subgingival irrigation of teeth and gums.

With the exception of the cannulas, use only attachments recommended by Teledyne Water Pik.

Do not attach to an air supply greater than 80 psi. (5.4 bar)

If any cracks appear over time in the reservoir, replace reservoir immediately.

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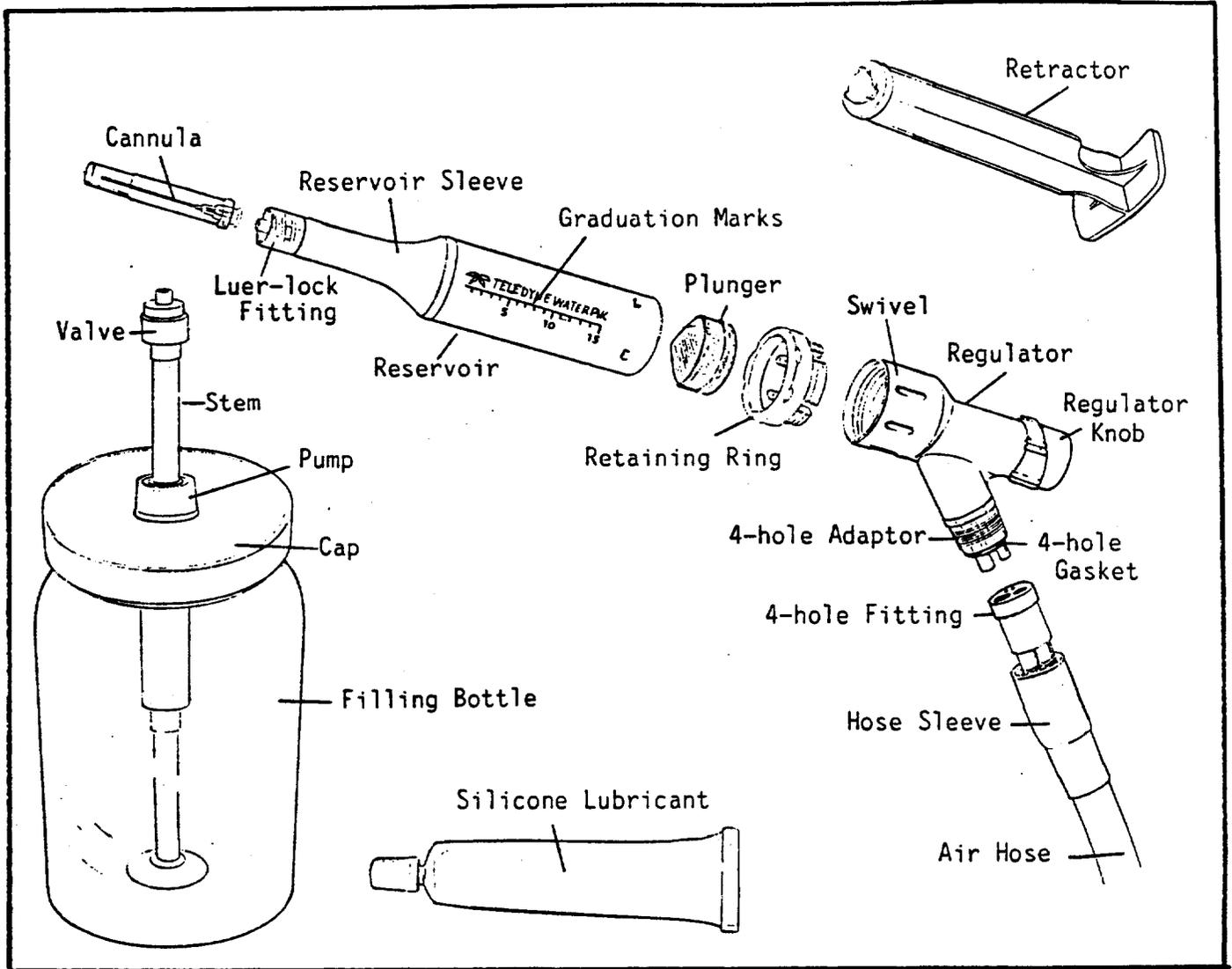


Illustration 1

The Perio Pik™ Subgingival Irrigation Handpiece includes:

- Four Reservoirs
- Four Plungers
- One Air Regulator With 4-hole Adaptor, Swivel, Retaining Ring and 4-hole Gasket
- Two Retractors
- One Filling Bottle and Pump Assembly
- 1 Ounce Tube of Silicone Lubricant
- Ten 24 Gauge (Side Port) Cannulas
- Registration Card/Owner Warranty Card
- Reorder Form
- Instruction Book

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INSTALLATION

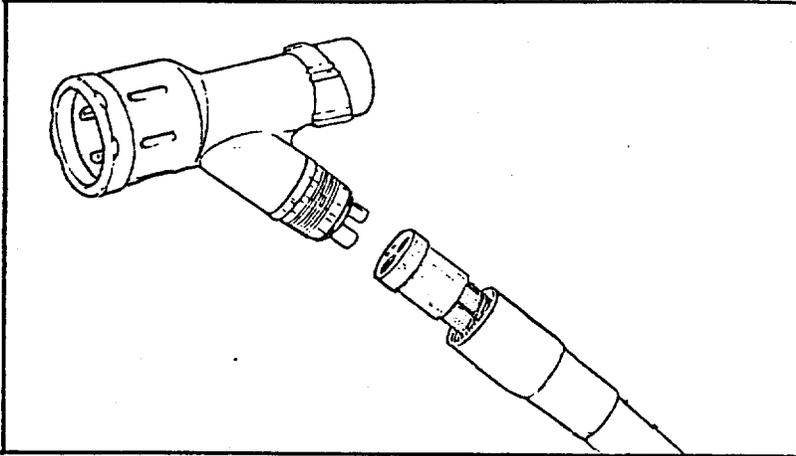


Illustration 2

Connect the air regulator to the available air supply by inserting the 2 metal tubes into the 4-hole fitting. Make sure the 4-hole gasket is in place. Thread the hose sleeve onto the air regulator's 4-hole adaptor.

NOTE: Reservoirs must be pre-conditioned before initial use.

PRE-CONDITIONING RESERVOIRS BEFORE INITIAL USE

Reservoirs must be pre-conditioned to provide for maximum product efficiency and minimize plunger lubrication.

Steam autoclave or MDT® Harvey® Chemiclave to sterilize reservoirs and plungers before initial use.

Lubricate the plunger with the enclosed silicone lubricant.

Spread a thin film of lubricant on the outside surfaces of the plunger.

Insert the lubricated plunger into the large open end of the reservoir.

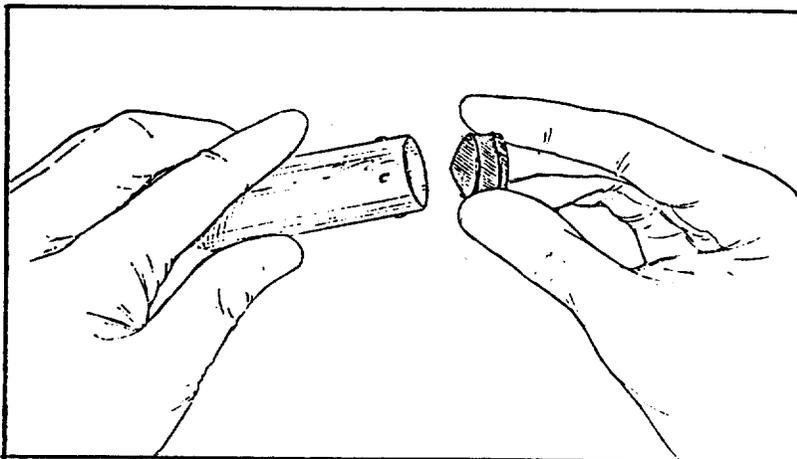


Illustration 3

Use the retractor to engage the plunger by pushing the retractor into the plunger and turning it clockwise. To overcome the tight fit and the initial resistance, force the plunger completely forward into the reservoir.

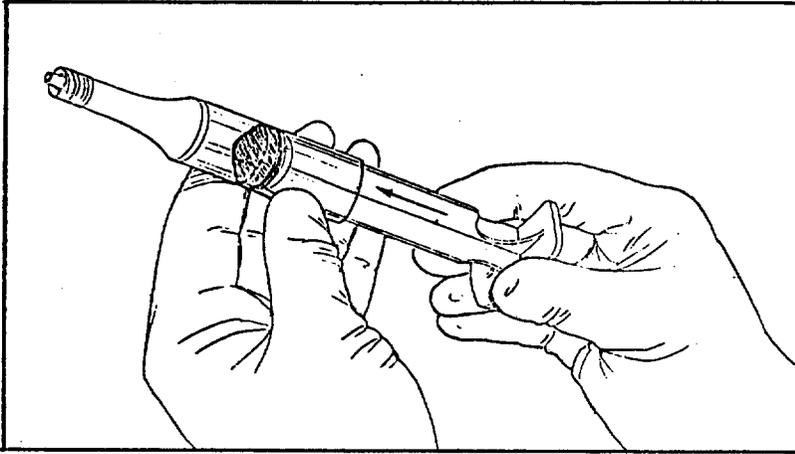


Illustration 4

Withdraw the plunger from the reservoir by twisting the plunger clockwise as you pull the retractor back. The plunger should now slide smoothly inside the reservoir.

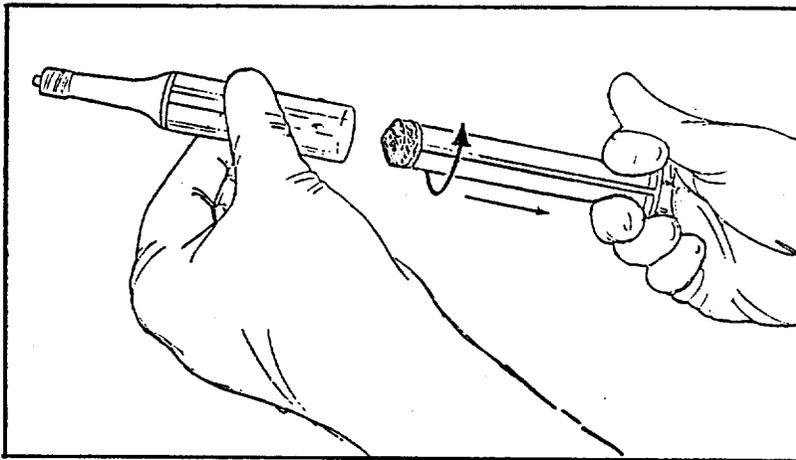


Illustration 5

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SETUP

Your Perio Pik™ Subgingival Irrigation Handpiece comes with two convenient methods of filling the reservoir; a filling bottle for pumping irrigating solution into the reservoir and a retractor for drawing the irrigating solution into the reservoir.

METHOD I

First, insert the sterilized plunger into the large, open end of the sterilized reservoir. Due to repeated autoclaving, the plunger will require occasional lubrication for optimal product performance and extended life of the plunger and reservoir. Use the silicone lubricant supplied with the product as described in maintenance instructions.

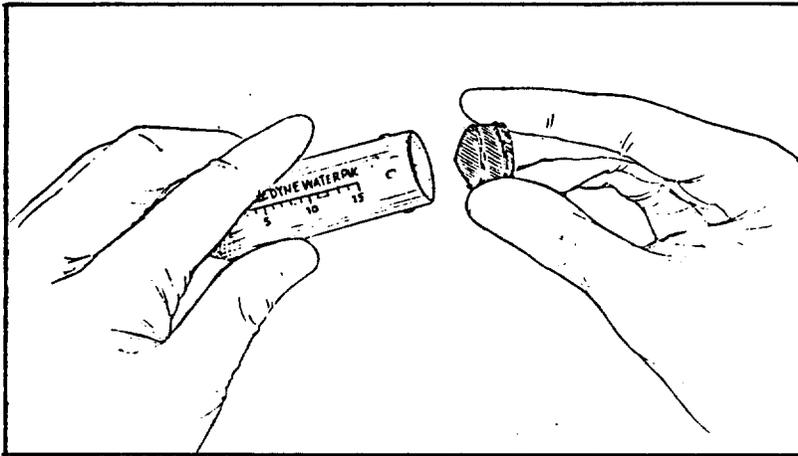


Illustration 6

Use the stem of the pump to push the plunger into a forward and ready position for filling.

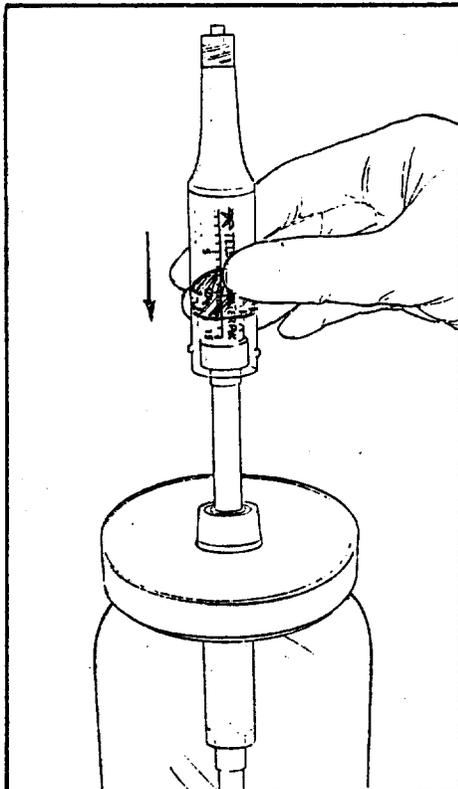


Illustration 7

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Remove the cap and pump from the filling bottle and pour your irrigating solution into the filling bottle. Be sure to label the bottle with the type of irrigating solution being used. Thread the cap back onto the bottle.

To prime the pump, grasp the valve on the pump and connect the luer-lock fitting of the reservoir to the valve by threading the reservoir clockwise until it secures in place. Hold the reservoir and bottle firmly and push down several times until the solution begins to flow into the reservoir. The pump is now primed and ready for filling reservoirs.

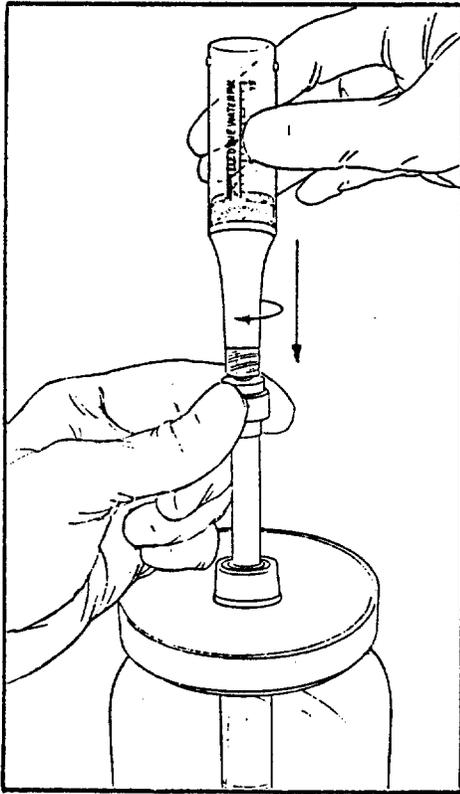


Illustration 8

NOTE: Each time you refill or empty the bottle, the pump will have to be primed.

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To fill reservoirs, connect the luer-lock fitting of the reservoir to the valve on the pump by threading the reservoir clockwise onto the valve until it secures in place.

Hold the reservoir firmly and push down several times until the reservoir is filled with the desired amount of irrigant. The reservoirs are provided with 0, 5, 10 and 15 ml/cc graduation markings.

Do not fill the reservoir beyond the 15 ml/cc marking. Overfilling the reservoir will cause the irrigating solution to spurt out from the reservoir when engaging it to the air regulator.

After reservoir is filled, expell any air from the reservoir by pushing the plunger forward slightly.

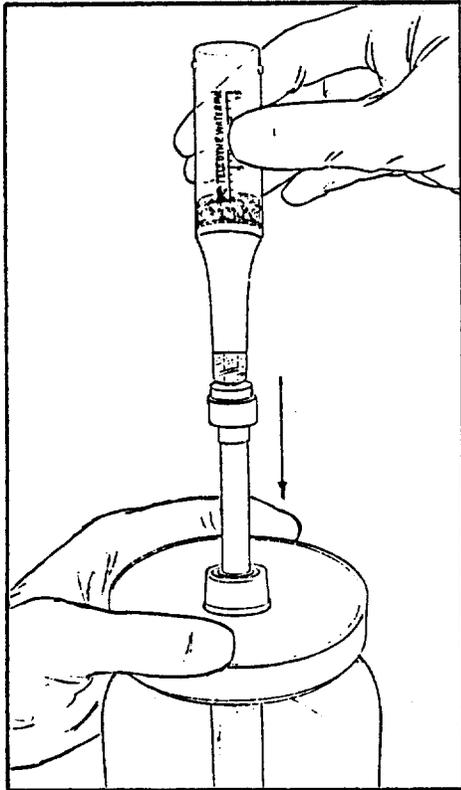


Illustration 9

Reminder: To ensure optimum infection control, use a sterile reservoir every time you fill a reservoir.

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Method II

Use the retractor to position the plunger into a forward and ready position for filling. Insert sterilized plunger into the large, open end of the sterilized reservoir. Use the retractor to push the plunger into the forward ready-to-fill position.

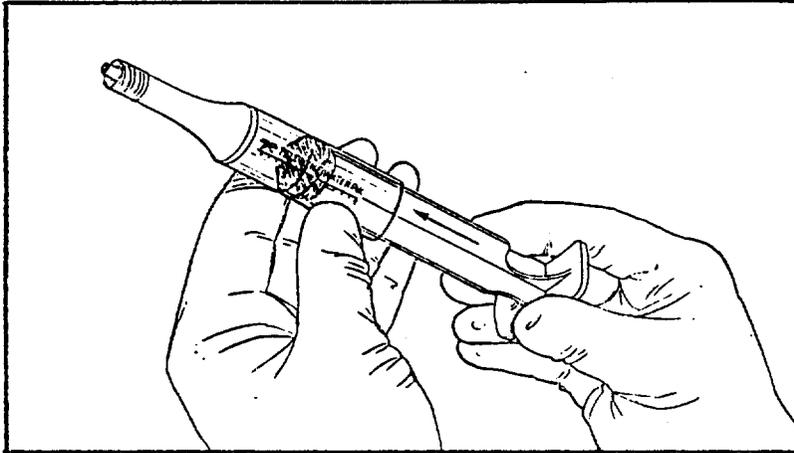


Illustration 10

Rotate the retractor clockwise to engage the plunger. Pull the retractor back to draw the solution from a small cup or beaker. After reservoir is filled, expell any air before use by pushing the plunger forward. Disconnect the retractor by rotating counterclockwise.

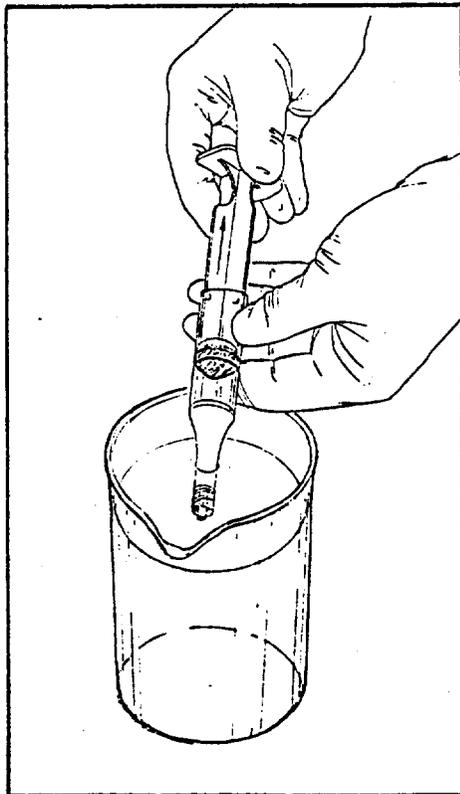


Illustration 11

You may find it more convenient and time-saving to fill multiple reservoirs during one set-up.

To heat the irrigating solution prior to use, you may warm the solution while it is in the reservoir by letting the filled reservoir stand in warm water. You may heat the solution in the reservoir by microwaving for approximately 10 seconds. Check with the manufacturer of the irrigating solution for microwave recommendation.

Now that you have filled the reservoir, you are ready to engage it to the air regulator. Remove the reservoir retaining ring from the air regulator by turning the retaining ring counterclockwise to unthread.

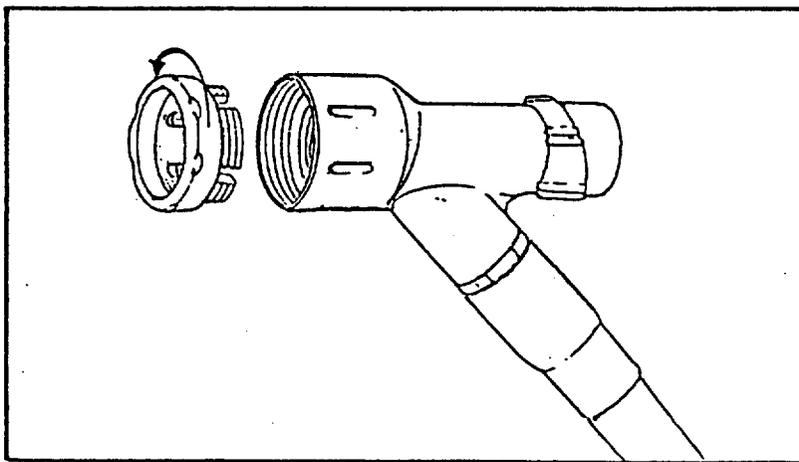


Illustration 12

Slide the reservoir retaining ring over the reservoir so the four posts on the reservoir slide into the four slots in the retaining ring.

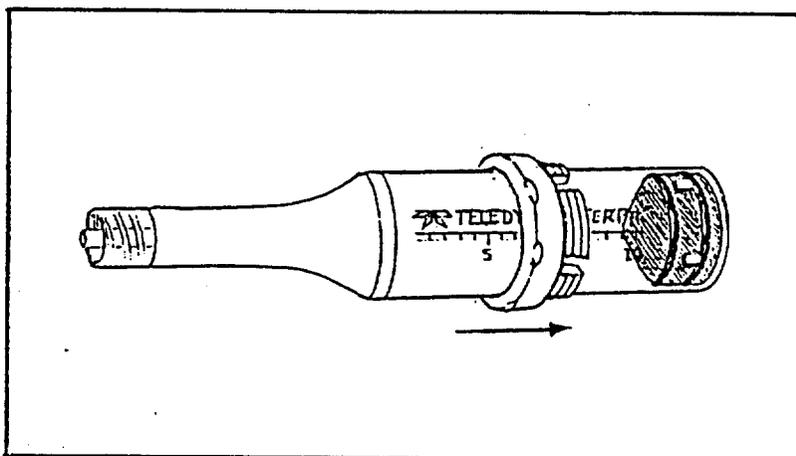


Illustration 13

Make sure the reservoir seal is in place and lubricated with the supplied silicone lubricant as described in the maintenance instructions. Reattach the reservoir retaining ring with the reservoir to the air regulator by threading the reservoir retaining ring clockwise. Secure tightly to prevent leaking. An air leak at this joint is a warning that the reservoir retaining ring and air regulator are not properly assembled or may be coming loose.

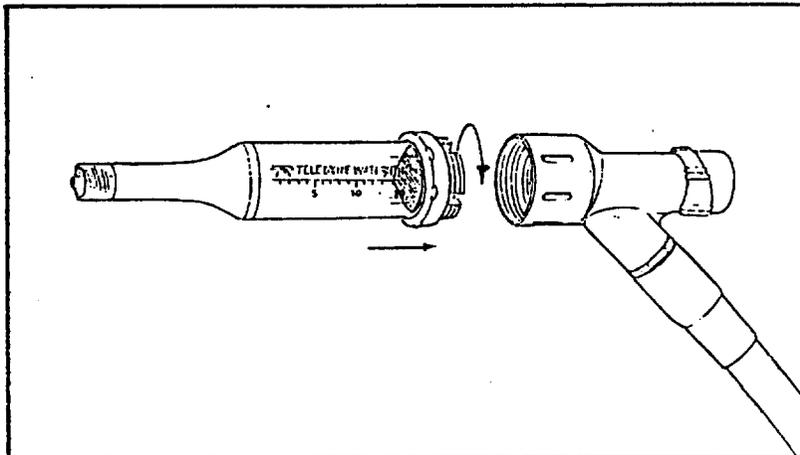


Illustration 14

Hold the sterile cannula by its protective sheath and attach cannula to the luer-lock fitting of the reservoir by threading clockwise until the cannula is secured in place. Save the sheath for disassembly.

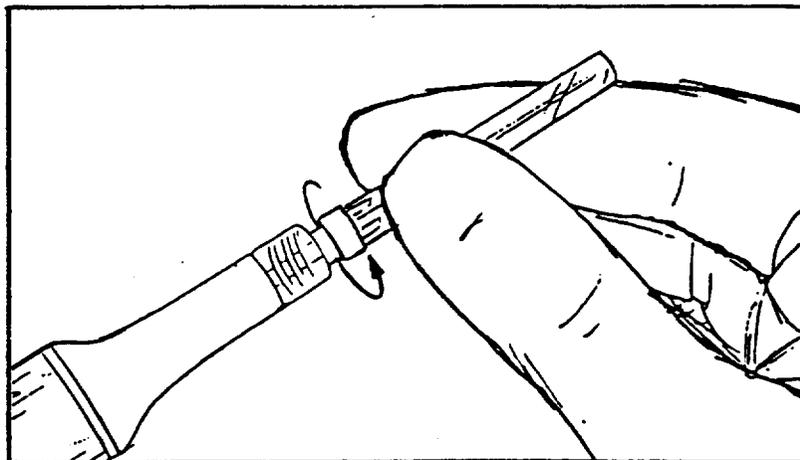


Illustration 15

To adjust flow, turn the control knob clockwise from the indicator line on the air regulator for increased flow and counterclockwise for less flow.

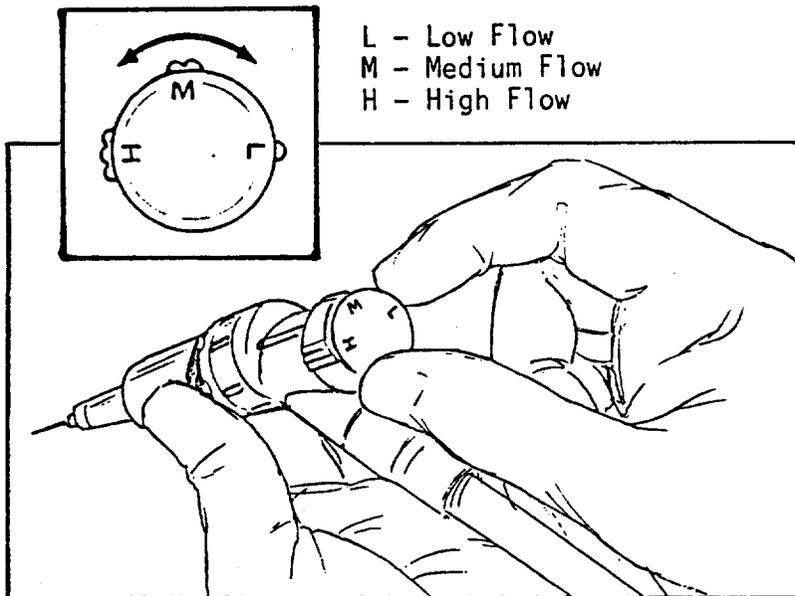


Illustration 16

Depending on the viscosity of the irrigating solution, it may be necessary to vary the size (gauge) of the side port cannula to get the proper flow. The size of the cannula and the flow control setting will affect the rate of flow.

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PROCEDURE

The Perio Pik™ Subgingival Irrigation Handpiece is a high quality, technologically advanced instrument designed to enhance the benefits of professional treatment. The Perio Pik™ Subgingival Irrigation Handpiece provides a time-efficient and precise method for delivering a variety of irrigants including antimicrobial or therapeutic agents.

The irrigator attaches easily to the four-hole air supply connection. Cannulas which are rounded and have side ports create safe and comfortable solution delivery at low pressure. Reusable, autoclavable reservoirs provide for an aseptic system.

1. Position your patient at a comfortable angle to minimize solution flowing down the throat. Utilize evacuation.

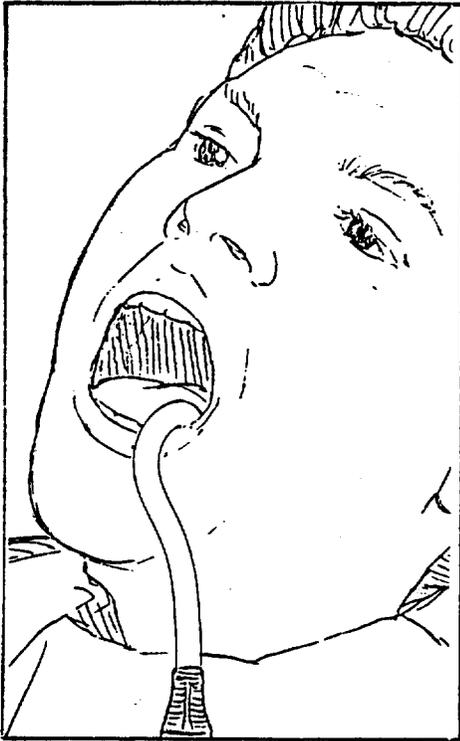


Illustration 17

2. Place the desired gauge cannula on the end of reservoir. Make sure the luer-lock fitting is securely locked into place. The cannula may be gently bent to an angle to ensure accuracy and ease of placement.

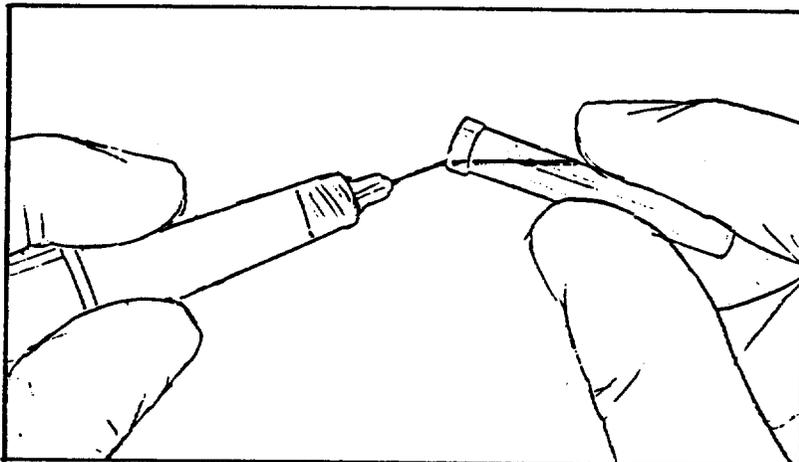


Illustration 18

3. Adjust your flow rate according to the viscosity of the irrigant. Example: Water or Peridex® have very little viscosity - therefore, lower settings should be sufficient for a desired rate of flow.
4. Establishing a fulcrum, hold irrigator as you would a handpiece.

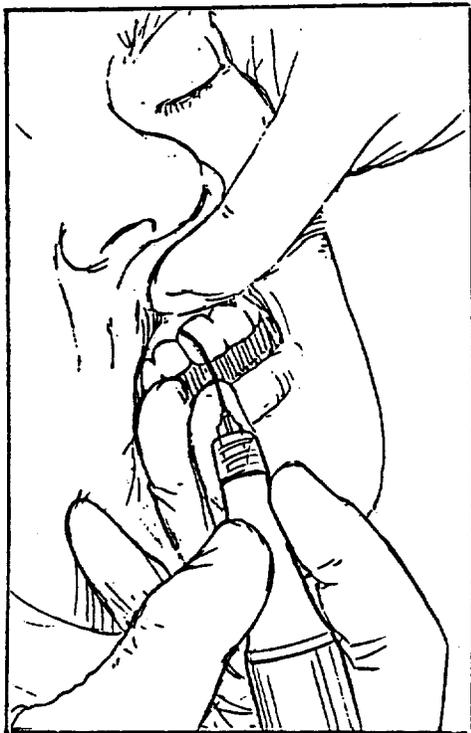


Illustration 19

5. Insert cannula below the gingival margin at the selected site. Release irrigant by stepping on the rheostat. When fluid flows back out of pocket, lift foot from rheostat (1-2 seconds).

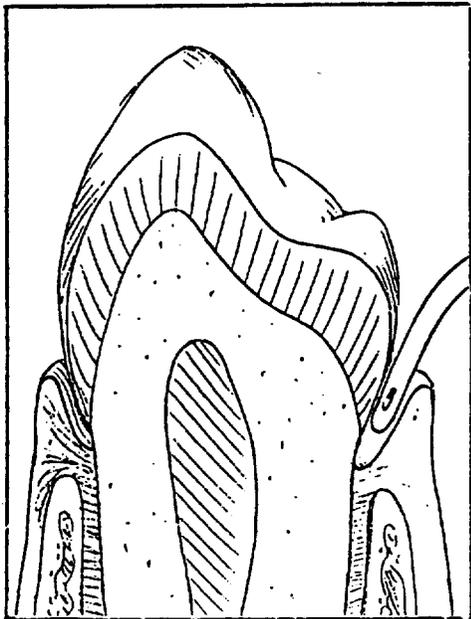


Illustration 20

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6. Irrigate both from the facial and lingual surfaces.

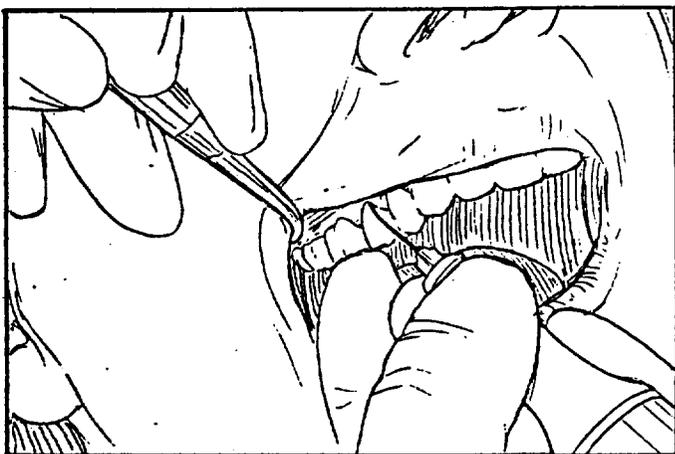


Illustration 21

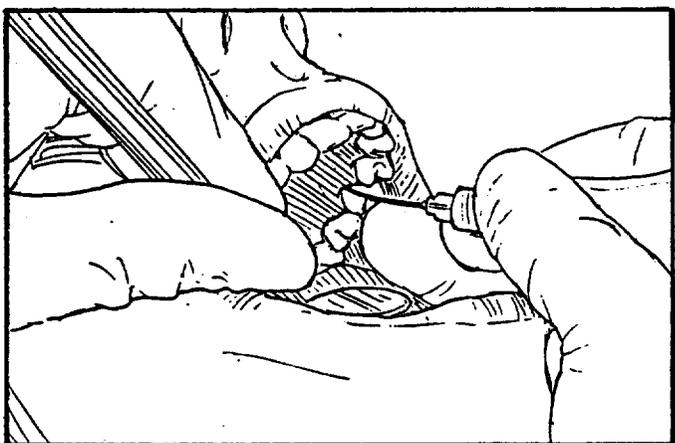


Illustration 22

7. Use periodontal charting to determine sites for irrigation.
8. Monitor amount of irrigant and type used for future reference.

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CLEANING

To disconnect the reservoir from the air regulator, turn the reservoir retaining ring counterclockwise until the threads completely disengage. Remove the reservoir retaining ring from the reservoir and reattach the reservoir retaining ring to the air regulator.

To clean the reservoir, use the retractor to purge any unused solution from the reservoir and to withdraw the plunger for cleaning.

Engage the retractor to the plunger with a quarter turn clockwise.

Push the retractor forward to purge solution.

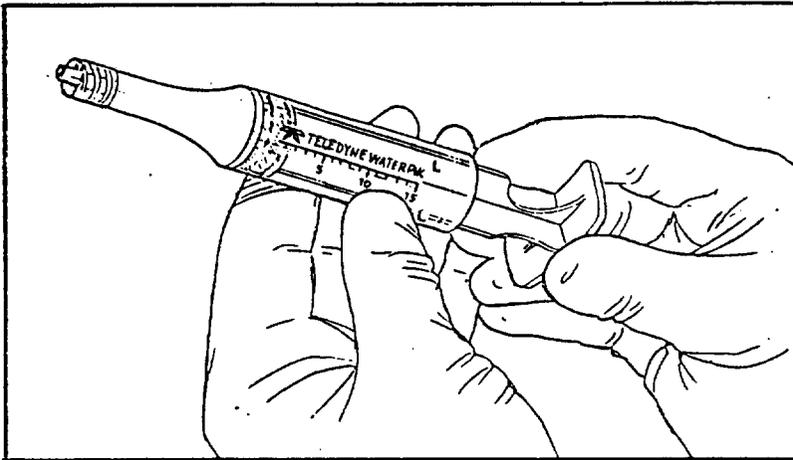


Illustration 23

While the retractor is engaged with the plunger, pull the retractor back to withdraw the plunger from the reservoir. Rinse the reservoir plunger and retractor.

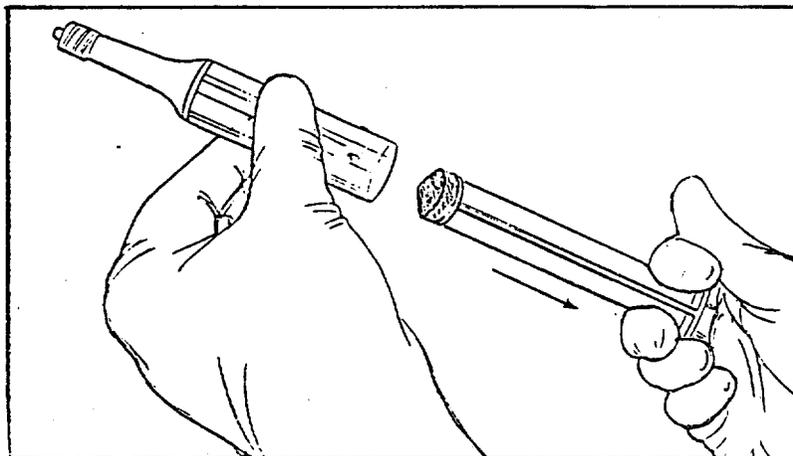


Illustration 24

The reservoir, plunger, and retractor are now ready for sterilization. Do not autoclave or store the reservoir with the plunger installed.

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Disconnect the air regulator from the air hose by unthreading it from the hose sleeve.

The air regulator is now ready for sterilization.

Make sure the flow adjustment knob on the air regulator is set on low prior to sterilization.

STERILIZATION

We recommend steam autoclave or MDT® Harvey® Chemiclave sterilization. Do not sterilize in temperature exceeding 270°F (no dry heat). Do not lay heavy pieces of equipment on or tightly pack the plastic reservoirs/plungers in the autoclave. Plastic will distort. Allow to cool before use to prevent deformation.

The filling bottle may be wiped down with a disinfectant. Thoroughly rinse the inside of the filling bottle. To purge any unused irrigating solution from the pump you can either fill the bottle with a rinsing solution or water and pump it through the pump using a reservoir or engage the reservoir to the valve and hold the pump upside down to drain the pump. Do this procedure over the sink.

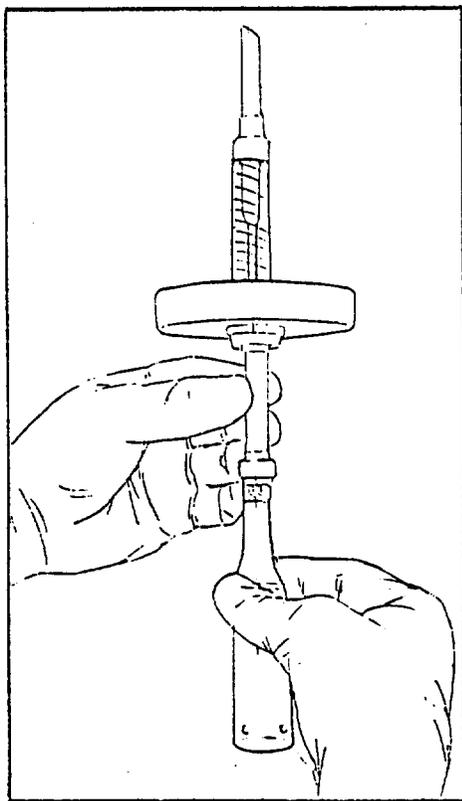


Illustration 25

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MAINTENANCE

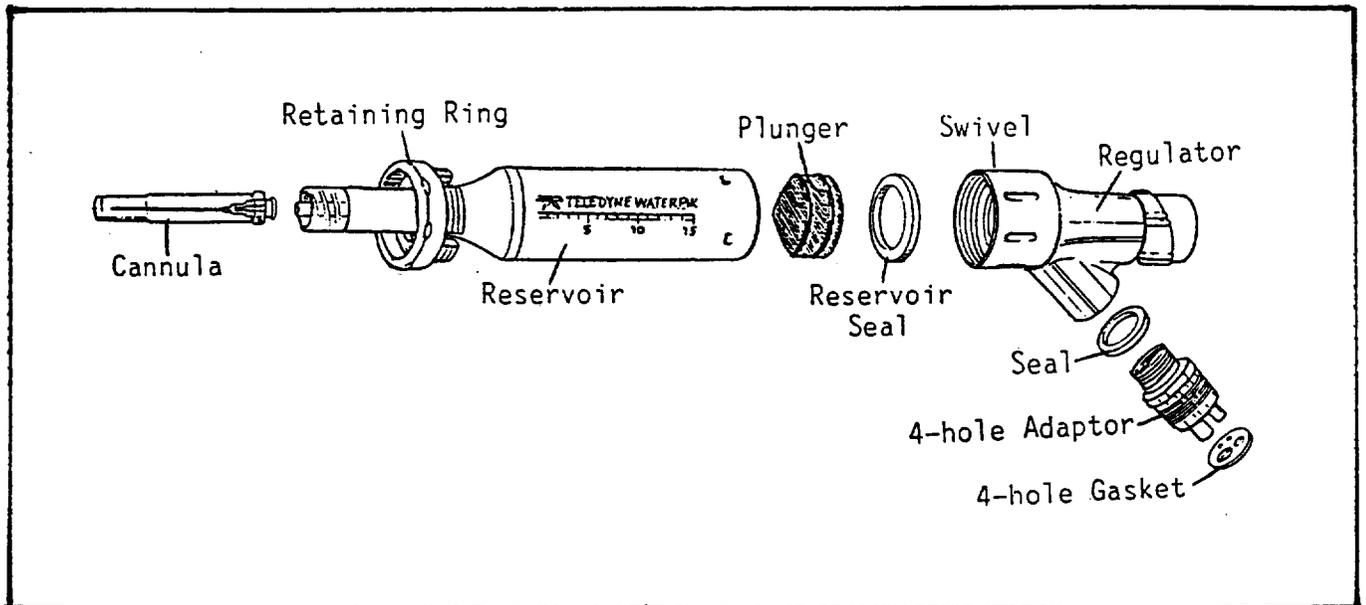


Illustration 26

Replace seals and 4-hole gasket if cracked or damaged. See reorder form for additional seals and 4-hole gasket.

Lubricate plunger when the plunger becomes tight in the reservoir. Lubricate with Teledyne Water Pik recommended silicone lubricant. Apply a thin film of lubricant to the outside surface of the plunger. Frequency depends on solution exposure and type/number of autoclave cycles.

Lubricate the reservoir seal when it becomes difficult to tightly secure the reservoir with the retaining ring, to the air regulator. Lubricate the reservoir seal with the supplied silicone lubricant. Apply a thin film of lubricant to the outside surface of the reservoir seal.

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TROUBLESHOOTING GUIDE

<u>Problem</u>	<u>Cause</u>	<u>Corrective Action</u>
● No fluid expelled when unit is actuated	● Clogged cannula ● Inadequate pressure or not sealed to connections ● Viscosity of solution too thick for highest pressure setting ● Air leak ● Plunger needs lubrication	● Replace cannula ● Check connections for leaks. Check air supply system pressure ● Dilute solution or select different gauge cannula ● Check seals for defects ● Lubricate with TWP supplied silicone lubricant
● Plastic pieces deform slightly	● Parts were under heavier items in the autoclave	● Place in autoclave/Harvey® Chemiclave again, without restrictions
● Too much flow	● Gauge of cannula ● Pressure setting	● Change gauge of cannula ● Adjust unit to lower flow setting
● Run-on	● Air leak in hose or footswitch ● Kink in air hose ● Air bubble in reservoir	● Call your serviceperson ● Expell air from reservoir with retractor
● Noise (whistle)	● Sleeve on hose not tight enough ● Valve chatter	● Tighten sleeve to regulator ● Adjust knob slightly
● Difficult to tighten reservoir with retaining ring to air regulator	● Dry reservoir seal ● Damaged reservoir seal	● Lubricate seal with supplied silicone lubricant ● Replace seal. See maintenance instructions

Professional Toll-Free Hotline (for Dental Professional Use): 1-800-525-2020.

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SUPPLEMENTAL THERAPY

Use of the Perio Pik™ Subgingival Irrigation Handpiece is just the first step in adjunctive irrigation therapy. Home irrigation has been established as providing a therapeutic benefit. Recently, the American Dental Association has approved the use of the Water Pik® Oral Irrigator when used as an adjunct to brushing, flossing, and regular professional care, for the reduction of gingivitis and associated bacteria. Assessment of the patient's gingival health on a routine basis may determine the types of oral irrigation tips recommended. Two different methods of home irrigation therapy are available to recommend to your patients.

- The Water Pik® Professional Dental System (WP-32W or WP-33W) includes the new Pik Pocket® tip, new Pik Pocket® reservoir as well as the standard jet tip and standard reservoir. The Pik Pocket® tip allows for easier access to subgingival space and more targeted delivery of antimicrobial or therapeutic solutions.

The Pik Pocket® tip is designed to ensure low pressure, low flow delivery regardless of setting. The flexible rubber tip provides greater comfort and, therefore, increases patient compliance.

The Pik Pocket® reservoir is designed for ease of measurement and economical use of all of the solution.

- The Water Pik® Dental Systems (Models WP-20W, WP-21W, WP-30W, WP-31W, WP-50W and WP-51W) offer delivery of a greater volume in irrigating. With 1200 pulsating bursts per minute, these units, as adjuncts to brushing and flossing, have shown clinical significance in reducing inflammation, and gingival bleeding. Its pulsating action helps by reducing bacteria and bacterial by-products and reduces gingivitis with water alone or with an antimicrobial agent.

All of these Water Pik® Dental Systems can handle any solution without deleterious effects to the pumping mechanism.

Recommend irrigation therapy for your patients' home care routine as an adjunct to regular professional techniques. Prevention of disease and maintenance of periodontal therapy may be enhanced by the utilization of both professional and home oral irrigation.

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Limited 3-Year Warranty

Teledyne Water Pik warrants to the owner of this new Perio Pik™ Subgingival Irrigation Handpiece, with the exception of the reservoir, the filling bottle, retractor and the plunger, that it will be free from defects in materials and workmanship. If, within three years from date of purchase, this product proves to be defective, return it prepaid to Teledyne Water Pik, Customer Service Department, 1730 East Prospect Street, Fort Collins, CO 80553-0001, for repair or replacement at no charge.

The serial number is located on the air inlet of air regulator.

This warranty covers use only as described in the instructions. It does not cover damage caused by abuse or misuse.

This warranty gives you specific legal rights. You may also have other rights which may vary from state to state. Be sure to complete your ownership registration card and mail it without delay. The return of the ownership registration card is not a condition precedent to warranty coverage and performance. It merely helps us to serve you better.



1730 East Prospect
Fort Collins, CO 80553-0001

Part No.
Form No. 02XP7W-1190

Made in U.S.A.
Printed in U.S.A.

Professional Toll-Free Hotline (for Dental Professional use): 1-800-525-2020.

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Peridex is a registered trademark of the Proctor and Gamble Company.

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INSTRUCTION SHEET FOR ACCESSORY RESERVOIRS
MODEL XR-1

NOTE: Reservoirs must be pre-conditioned before initial use.

PRE-CONDITIONING RESERVOIRS
BEFORE INITIAL USE

Reservoirs must be pre-conditioned to provide for maximum product efficiency and minimize plunger lubrication.

Steam autoclave or MDT® Harvey® Chemiclave to sterilize reservoirs and plunger before initial use.

Lubricate the plunger with the enclosed silicone lubricant.
Spread a thin film of lubricant on the outside surfaces of the plunger.
Insert the lubricated plunger into the large open end of the reservoir.

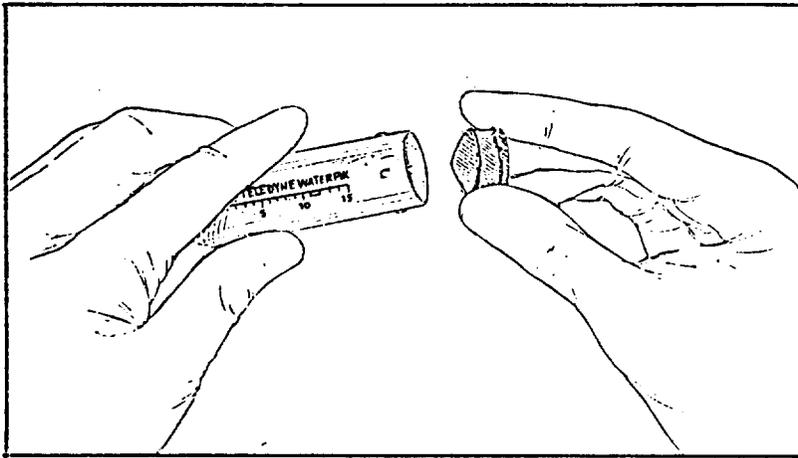


Illustration 1

Use the retractor to engage the plunger by pushing the retractor and turning it clockwise. To overcome the tight fit and the initial resistance, force the plunger completely forward into the reservoir.

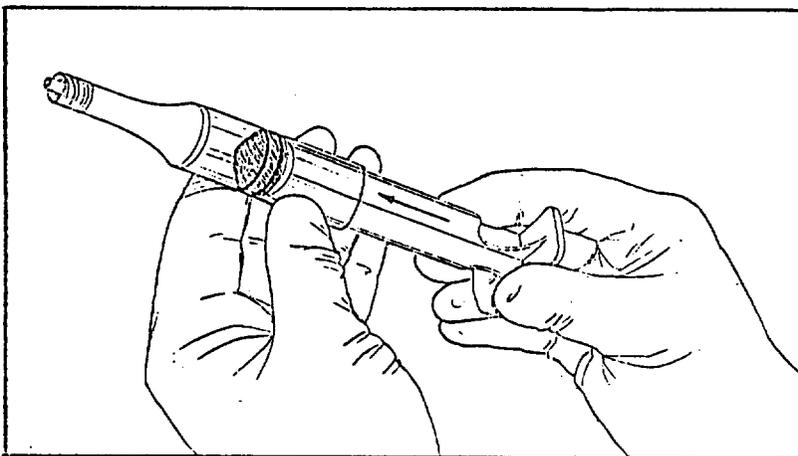


Illustration 2

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Withdraw the plunger from the reservoir by twisting the plunger clockwise as you pull the retractor back. The plunger should now slide smoothly inside the reservoir.

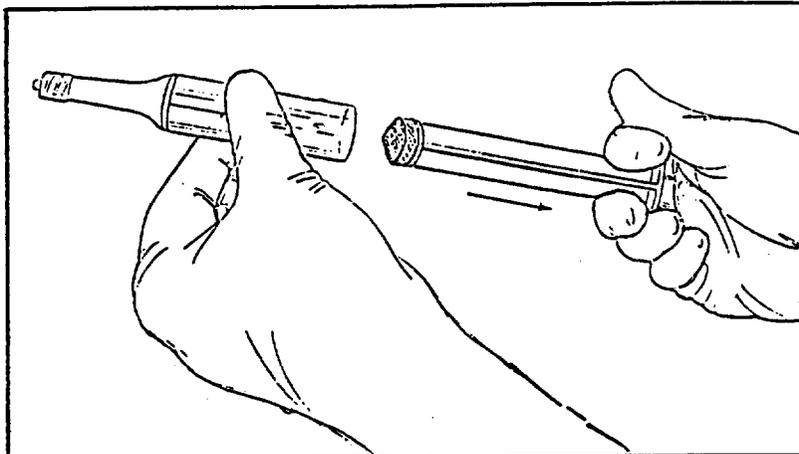


Illustration 3

Professional Toll-Free Hotline (for Dental Professional use): 1-800-525-2020.

 **TELEDYNE WATER PIK**

1730 East Prospect
Fort Collins, CO 80553-0001

Part No.
Form No. 03XR1-1190

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 30

Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

Mr. Donald W. Ruehmann
Manager, Regulatory Affairs
Teledyne Water Pik
1730 East Prospect Street
Fort Collins, Colorado 80525

Re: K840721
Perio Pik™

Dated: February 13, 1984
Received: February 17, 1984

RECEIVED
APR 30 1984
QUALITY ASSURANCE
DEPARTMENT

Dear Mr. Ruehmann:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and Radiological Health

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CERTIFIED MAIL

February 13, 1984

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Reference: Document No. A177906 (copy attached)

Subject: 510-K Notification

Attention: Document Control Clerk

Teledyne Water Pik is requesting marketing clearance for its subgingival irrigating kit to be manufactured by Teledyne Densco. The premarket notification information required by 21CFR807.87 is as follows:

Classification Name:	None
Common/Usual Name:	Subgingival Irrigating Kit
Proprietary Name:	Perio Pik™
Establishment Registration Number:	1712259
Owner Operator I.D. Number:	9920024
Classification:	None
Performance Standards:	None
Labels, Labeling, Adver- tisements, and Instructions:	Final draft copies attached

Document Control Clerk -- FDA
February 13, 1984
Page Two

Substantial Equivalence: The Teledyne Water Pik Perio Pik™ subgingival irrigation kit is manufactured by Teledyne Densco, Denver, Colorado 80207. Teledyne Densco manufactures the Perio Pik™ according to specifications prepared by Teledyne Water Pik. In our opinion, this kit is substantially equivalent to components in general use prior to enactment of the medical device amendments of May 28, 1976.

Reference: Dental Developments Services, Inc.
Establishment No. 1525521
Document No. A 11522
Document No. K 792578

Stram, Inc.
Establishment No. 1419839

MPL, Inc.
Subsidiary of Affiliated Hospital
Products, Inc.
Establishment No. 1412902
Document No. K 840237

We consider our intent to market this device as confidential commercial information and request that it be considered as such by the FDA until February 20, 1984. At that time, we intend to announce it at a trade show.

We would appreciate your earliest attention to this 510-K submission as we would like to introduce it in commerce by April 10, 1984. If you require any further information, please contact me at (303) 484-1352.

Sincerely yours,



Donald W. Ruehmann
Manager, Regulatory Affairs

DWR/rs

Enclosures: Literature & Packaging Copy
Description of Perio Pik™
Photos
Copy of Document No. K 840237 (MPL, Inc.)
Device Listing Document No. A 177906 (Submitted 2/13/84)

cc: H. Gilstrap
Teledyne, Inc.
J. Bennet
Teledyne Densco
J. Jervis

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SWR

DESCRIPTION OF PERIO PIK™ SUBGINGIVAL IRRIGATING KIT

SWR

Handpiece -- Stainless steel, ~~surgical~~ grade 303

Hose Assembly: Tubing -- Silicone rubber, medical grade

Couplings -- Stainless steel, ~~surgical~~ grade 303

O-Ring -- Silicone rubber, medical grade, 70 Shore A Durometer

Cannula, 21 GA (.032 O.D.), Pyrogen Free, MAX-I-PROBE™:

Purchased completely packaged from: MPL, Inc.
1820 West Roscoe Street
Chicago, Illinois 60657

Cannula, 24 GA (.022 O.D.), Pyrogen Free, MAX-I-PROBE™:

Purchased completely packaged from: MPL, Inc.
1820 West Roscoe Street
Chicago, Illinois 60657

Cannula, 28 GA (.014 O.D.), Pyrogen Free, MAX-I-PROBE™:

Purchased completely packaged from: MPL, Inc.
1820 West Roscoe Street
Chicago, Illinois 60657

Clip, Thermoplastic, adhesive-foam backing

Instruction Book

Tray -- 20 mil thickness, white PVC

Cover -- 20 mil thickness, clear PVC

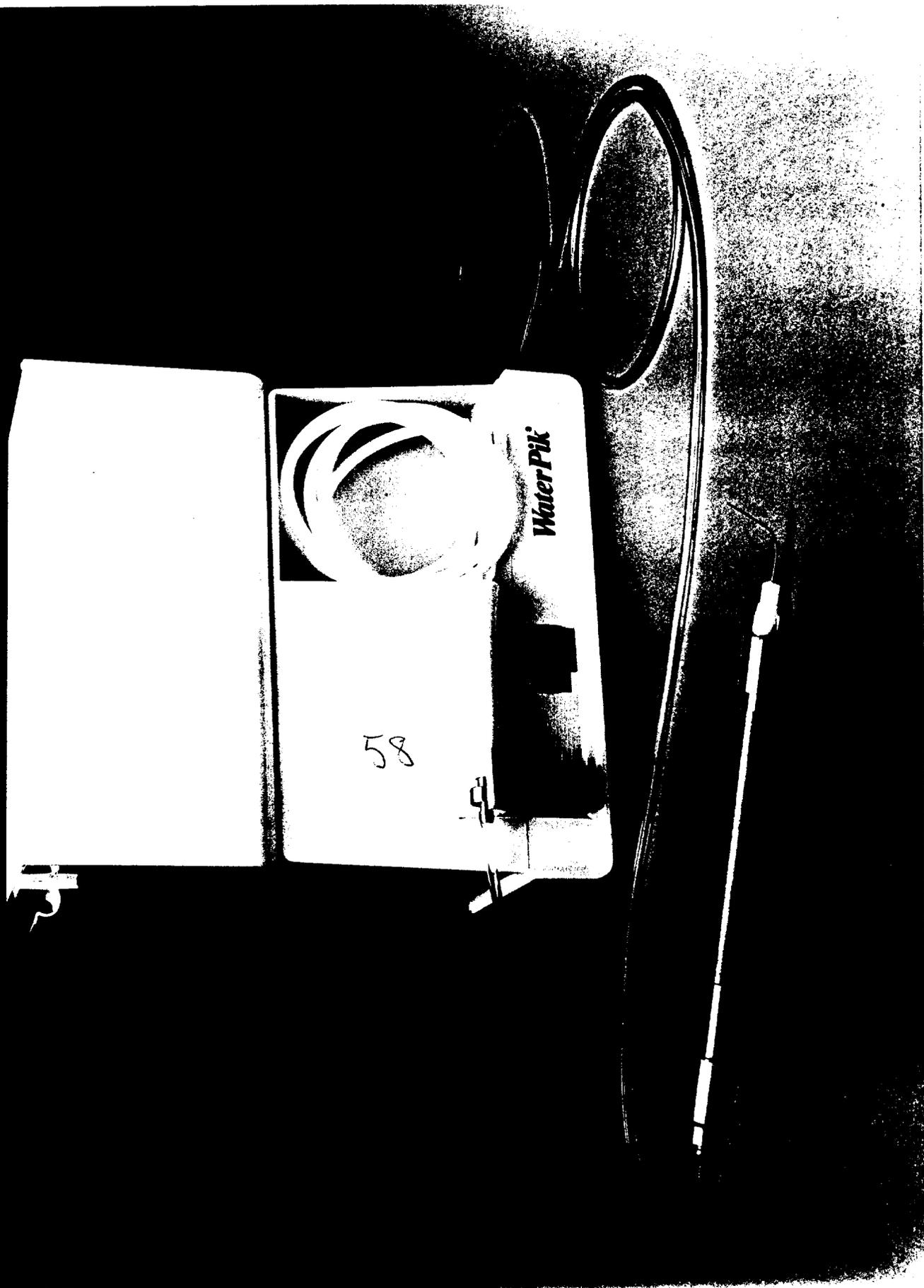
Shipper -- 200 lb. corrugate carton

Card, Reorder -- 3" x 5"

BEST COPY AVAILABLE

57

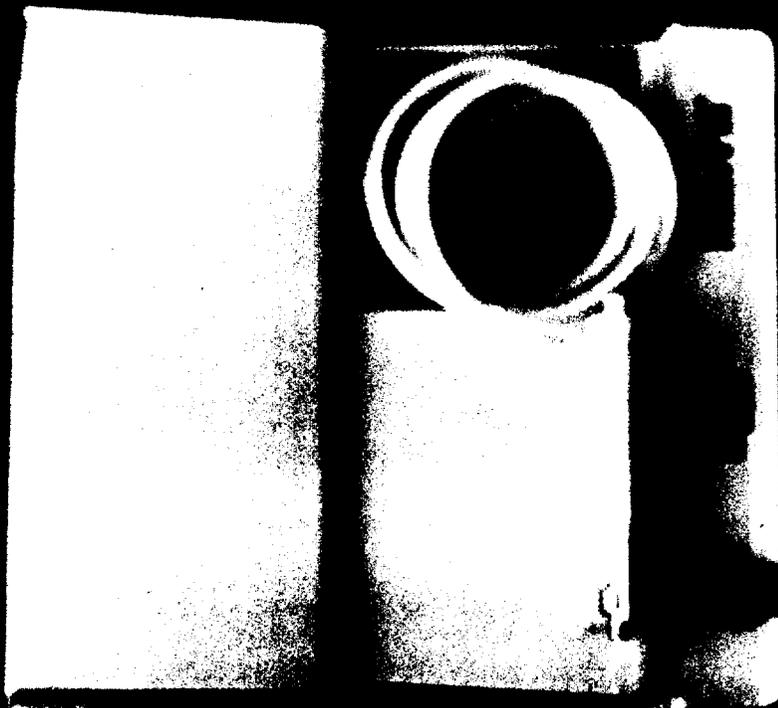
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58

Water Pik

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Marketing Services Department

RECEIVED

FEB 08 1984

QUALITY ASSURANCE DEPARTMENT

APPROVALS S.O.P.# BI-05

Description: _____

Date: _____ MP.# _____

Originator: _____ Date: _____

P. Anello: _____

E.R. Wood: _____

D. Bruno: _____ 2/7/84

Compliance: _____
A.E. Huppert: _____ 2/7/84

Other: John Jerni 2/7/84

John Jerni 2/7/84

PRODUCT PERIO PIK™
 TITLE Sell Sheet
 MP# _____
 DATE 2/2/84 JGS
 REV. 1 2/7/84 JGS
 REV. 2 _____
 REV. 3 _____
 REV. 4 _____

HEAD

INTRODUCING

PERIO PIK™ Subgingival Irrigation Kit
by Teledyne Water Pik

Black and white photo
PERIO PIK™ attached to
WATER PIK®

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Head

THE STATE-OF-THE-ART DELIVERY SYSTEM
FOR SUBGINGIVAL IRRIGATION
FOR PROFESSIONAL USE ONLY

As always, you can trust Teledyne Water Pik to produce the best in oral hygiene equipment. The PERIO PIK combines quality components with functional design to create a superior system for subgingival irrigation.

- o Balanced, instrument quality, stainless steel hand-piece with a convenient luer-lock fitting. Precision machined with a finely knurled grip for comfortable, accurate usability.
- o Transparent, autoclavable hose designed for durability and dependable performance with stainless steel snap-fit connectors.



Marketing Services Department

- Color-coded MAX-I-PROBE™ cannulas with luer-lock hubs, rounded tips, and side windows for optimal safety and patient comfort. Six precisely crafted, disposable cannulas, two each in 21, 24, and 28 gauge, provided in a sample set for your convenience.
- Complete, clearly written instructions for PERIO PIK™ assembly and maintenance.
- Additional PERIO PIK™ components quickly available. Easy-to-use order cards included.

smaller print beneath
cannula graphic

Smoothly rounded and closed tips with side-window effusion creates safe and comfortable fluid movement into periodontal pockets and beneath pericoronal tissue flaps.

Copy

The PERIO PIK™ is designed for use with the WATER PIK® Oral Hygiene Appliance, Model 301-M, also manufactured by Teledyne Water Pik--manufacturers of the best in periodontal irrigation equipment.

lighter print

The complete PERIO PIK™ system for professional subgingival irrigation is available now from Teledyne Water Pik. Please call our toll-free hot line (1-800-525-2020), or write to Teledyne Water Pik, Professional Services Department, 1730 East Prospect, Fort Collins, Colorado 80525, to order your PERIO PIK™.

Model Number	Description	Price
--------------	-------------	-------

	The complete PERIO PIK™ system including: handpiece, hose with connectors, 6-cannula sample set in 3 gauges, handpiece	
--	--	--

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Model Number	Description	Price (cont.)
-----------------	-------------	---------------

holding clips, instruction
sheet and order cards.

Individual PERIO PIK™ components:

- Handpiece
- Hose with connectors
- 6-cannula sample set in 3 gauges
- U.L. listed foot pedal switch

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PRODUCT PERIO PIK™
 TITLE Instruction Book
 MP# _____
 DATE 1/31/84 JGS
 REV. 1 2/1/84 JGS
 REV. 2 2/7/84 JGS
 REV. 3 _____
 REV. 4 _____

APPROVALS S.O.P.# BI-05

Description: _____
 Date: _____ M.P.# _____
 Originator: _____ Date: _____
 P. Anello: _____
 E.R. Wood: _____
 D. Bruno: _____ 2/7/84
 Compliance: _____ 2/7/84
 A.E. Huppert: _____
 Other: John Duric 2/7/84
W. J. ... 2/7/84

COVER

Logo

Black and white photograph of the system connected to the 301

Copy across bottom

INSIDE

Heading

Black and white photograph of the system connected to the 301 with callouts

Head

Copy

PERIO PIK™ Subgingival Irrigation Kit
by Teledyne Water Pik

FOR PROFESSIONAL USE ONLY

Instructions for PERIO PIK™ for professional subgingival irrigation by Teledyne Water Pik

Initial Preparation

The PERIO PIK™ has been designed for use with the WATER PIK® Oral Hygiene Appliance, Model 301-M.

1. As with any use of the WATER PIK Appliance, remove the appliance cover and turn it over to form the reservoir. Center the reservoir over the base and push down to lock in place.
2. Remove the protective strips from the two adhesive-backed clips provided with the PERIO PIK. Position

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clips A and B on a clean surface as indicated in the illustration. Clip A will hold your PERIO PIK handpiece above the fluid level of the reservoir, thus preventing solution siphoning when the reservoir is full.

For ease of operation, the use of a U.L listed foot pedal switch is suggested. The PERIO PIK may be operated with any suitable foot switch, or appropriate foot switches may be ordered directly from Teledyne Water Pik (see enclosed card).

3. Insert the plug of the WATER PIK Appliance into the foot switch. Insert the plug of the foot switch into the wall outlet.
4. Turn the WATER PIK Appliance to the ON (1) position. When using the foot switch, the appliance should remain switched to the ON position; it will operate only when the foot switch is depressed. (Without a foot switch, the appliance must be operated manually using the ON/OFF (1/0) switch (D).)

Head

Assembly of the PERIO PIK™

Although all components of the PERIO PIK are carefully packaged under clean conditions, the hose and handpiece should be autoclaved before first use.

5. Snap the male stainless steel hose connector to the handle of the WATER PIK Appliance (C).
6. Snap the female stainless steel hose connector to the handpiece of the PERIO PIK (F).

Head

Start-Up Routine

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7. Fill the WATER PIK Appliance reservoir with the irrigating solution of your choice.
8. Holding the PERIO PIK handpiece over the reservoir, activate the WATER PIK Appliance until the system is primed. (Increasing the pressure setting may speed the priming time.)
9. Once primed, turn the pressure control dial to the lowest setting.

THE PERIO PIK™ SHOULD ALWAYS BE OPERATED IN THE LOWEST PRESSURE SETTING WHEN IRRIGATING SUBGINGIVALLY.

10. Select the desired gauge of MAX-I-PROBE™ cannula. Attach the cannula to the luer fitting on the PERIO PIK handpiece, twist to lock (G).

Teledyne Water Pik recommends the use of the MAX-I-PROBE™ cannula for optimal safety and patient comfort. Six cannulas in three gauges have been included in this package for your convenience. For reorder quantities, see enclosed card.

11. Break the seal on the sterile cannula, and remove the protective sheath. Check flow of the irrigating solution. The cannula may be bent to the desired angle for easy access to any location in the mouth.
12. Your PERIO PIK is now ready for use.

Head

Disassembly and Maintenance

1. Before disassembly, flush the system with water to remove all traces of irrigating solutions from the WATER PIK Appliance and the PERIO PIK.
2. Using the protective sheath, remove the cannula from the

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handpiece; twist to unlock. Cannulas should be disposed of after each use.

3. Unsnap the handpiece from the hose connector. Unsnap the hose from the WATER PIK Appliance handle.
4. For maintenance of the WATER PIK Appliance, follow instructions supplied with that unit.

NOTE: The PERIO PIK handpiece and hose with stainless steel connectors are autoclavable. The MAX-I-PROBE cannulas are disposable.

See the enclosed cards for reordering MAX-I-PROBE cannulas or for ordering additional components for your PERIO PIK.



Marketing Services Department

PRODUCT PERIO PIK™
 TITLE Order Card TWP
 MP# _____
 DATE 2/9/84 JGS
 REV. 1 _____
 REV. 2 _____
 REV. 3 _____
 REV. 4 _____

APPROVALS S.O.P.# BI-05

Description: _____

Date: _____ M.P.# _____

Originator: _____ Date: _____

P. Anello: _____

E.R. Wood: _____

D. Bruno: _____

Compliance: _____
A.E. Huppert: [Signature] 2/13/84

Other: [Signature] 2/13/84

[Signature] 2/13/84

Address Side - Copy

First Class Permit No. xxxxxx
Fort Collins, Colo. 80521

BUSINESS REPLY MAIL

No Postage Stamp Necessary if Mailed in the United States

Postage will be paid by

TELEDYNE WATER PIK

Professional Services Department

1730 East Prospect Street

Fort Collins, Colorado 80525

Information Side - Copy

PERIO PIK™ Subgingival Irrigation Kit
by Teledyne Water Pik

I would like to order the following:

Model

Number	Description	Price	Quantity
XP-5	The complete PERIO PIK™ Kit including: handpiece, hose with connectors, 6-cannula sample set in 3 gauges,	xx.xx	

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Marketing Services Department

PRODUCT PERIO PIK™
 TITLE Shipping Stamp Copy
 MP# _____
 DATE 2/9/84 JGS
 REV. 1 _____
 REV. 2 _____
 REV. 3 _____
 REV. 4 _____

APPROVALS S.O.P.# BI-05

Description: _____

Date: _____ M.P.# _____

Originator: _____ Date: _____

P. Anello: _____

E.R. Wood: _____

D. Bruno: _____ 2/12

Compliance: _____ 2/13/84

A.E. Huppert: _____

Other: Schiffman 2/13/84

[Signature] 2/13/84

To be stamped on the outside of the shipping carton

FOR PROFESSIONAL USE ONLY

CONTENTS: 1 PERIO PIK™ Kit

Model XP-5

Assy. 26408-1

Qty. 1

Date of Manufacture Code: This number will vary according to the day, month and year of assembly. The code is written as follows:

- a. Digits 1 and 2 are the month assembled.
- b. Digits 3 and 4 are the day assembled.
- c. Digits 5 and 6 are the year assembled, followed with a dash.
- d. Digits 7 and 8 are the assembly line number, followed with a dash.
- e. Digit 9 is the same number as the Engineering Serial No. Change Digit.

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handpiece holding clips,
instruction sheet and
order cards.

Individual PERIO PIK™ components:

XP-4	- Handpiece	xx.xx
XP-3	- Hose with connectors	xx.xx
XP-2	- 6-Cannula sample set in 3 gauges	xx.xx
XP-1	- U.L. listed foot pedal switch	xx.xx

Please send my order to: Name _____
 Street _____
 City _____
 State _____ Zip _____

Bill me for the full amount, including applicable taxes and handling charges.

Charge my VISA account.

Charge my Master Card account.

Enclosed is my check for the full amount including applicable taxes and handling charges.

Credit Card Number _____

Expiration Date _____

Interbank Number (Master Card only) _____

Signature _____

(Required if payment is not enclosed.)

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Marketing Services Department

Sales tax is charged on ship-to location. All WA orders add 7% sales tax; all MN and CA orders add 6% sales tax, except San Francisco, Los Angeles, Alameda & Contra Costa County residents add 6-1/2% sales tax; all TX and FL orders add 5% sales tax; all NC and VA orders add 4% sales tax; all CO orders add 3-1/2% sales tax; all KS orders add 3% sales tax.

For each ship-to location add:	Subtotal _____
Subtotal less than \$15.00 add \$1.00	
Subtotal \$15.00 to \$24.99 add \$1.50	Taxes _____
Subtotal \$25.00 to \$39.99 add \$2.00	
Orders over \$40.00 shipped prepaid.	Shipping & Handling _____
	Total _____

Part No. xxxxx
Form No. xxxxx

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3 copies

MAX-I-PROBE
PERIODONTAL/IRRIGATION PROBE

510-K NOTIFICATIONS

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MPL, Inc.
A subsidiary of Affiliated Hospital Products, Inc.
1820 West Roscoe Street, Chicago, Illinois 60657
(312) 248-3810



January 10, 1984

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Springs, MD 20910

Re: 510K Notification

Attention: Document Control Clerk

This is to notify you of the intention by MPL, Incorporated, a subsidiary of Affiliated Hospital Products, Incorporated, to import, distribute and market the following device,

Classification Name: Although this product, to the best of our knowledge, has not been formally classified, we believe it should be classified as the common/usual name.

Common/Usual Name: Periodontal, Endodontic Irrigating Needle

Proprietary Name: Max-I-Probe Periodontal, Endodontic Probe

Establishment Registration Number: 1412902

Classification: Please refer to your #K792578- "Epic Cannula" which was submitted December 8, 1979 by Dental Developments Services, Inc. (Establishment #1525521), Document #All522.

Stram, Inc. also has filed and received an approved 510-K notification number on this same product line, but we do not know the reference number. The establishment number of Stram is #1419839.

Promotional Material: Draft copies of packaging and label are enclosed (See Exhibit I). We are in the process of preparing selling literature for our marketing use which will be equivalent to selling sheets from Stram, Incorporated. (See Exhibit II).

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Food and Drug Administration
January 10, 1984

Page 2

Substantial Equivalence:

This product is similar in design, composition and function to the periodontal, endodontic irrigating probe which was manufactured in India and distributed by Stram, Incorporated, in the United States.

Stram, Incorporated does have an approved 510K Notification on file with the bureau.

The same probe will now be manufactured by Nissho Corporation of Japan and marketed by MPL, Incorporated.

This product is also similar in design, composition and function to irrigating needles currently manufactured and distributed in the United States by:

1. Sherwood Medical Industries
1381 Olive Street
St. Louis, Missouri 63104
Brand Name - Monoject
2. Pro Pulse, Incorporated
(Distributor of Monoject Blunt Needles
for use in periodontal irrigation).
235 Matthews Street
Fort Collins, Colorado 80524
3. Stram Dental
Division of Stram Incorporated
655 Academy Drive
Northbrook, Illinois 60062
Brand Name - Imax

To the best of our knowledge, the product is similar in design and function to irrigating needles which were marketed prior to May 28, 1976. Promotional materials for these products are attached. (See Exhibit II).

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.../

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Food and Drug Administration
January 10, 1984

Page 3

We are hopeful to meet a scheduled new product release by March 1, 1984. We appreciate and look forward to your early response to our request.

Sincerely,

MPL, INC.

Thomas F. Willer

Thomas F. Willer, Ph.D.
Regulatory Compliance Manager

TFW/jsd

enclosures
copy: FDA (3)

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MAX-I-PROBE
PERIODONTAL/IRRIGATING PROBE

PACKAGING COPY

EXHIBIT I

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MAX-I-PROBE

PERIO-ENDO DENTAL IRRIGATING PROBE PRODUCT LINE

<u>GROUP</u>	<u>CATALOG NO.</u>	<u>DESCRIPTION</u>	<u>PACKAGING</u>	<u>COLOR CODE</u>
D58	MIP211	Max-I-Probe 21 Ga X 1" Perio-Endo Dental Irrigating Probe (100/Bx)	100/Bx	Light Green
D58	MIP231	Max-I-Probe 23 Ga X 1" Perio-Endo Dental Irrigating Probe (100/Bx)	100/Bx	Light Blue
D58	MIP241	Max-I-Probe 24 Ga X 1" Perio-Endo Dental Irrigation Probe (100/Bx)	100/Bx	Med. Purple
D58	MIP251	Max-I-Probe 25 Ga X 1" Perio-Endo Dental Irrigation Probe (100/Bx)	100/Bx	Light Orange
D58	MIP281	Max-I-Probe 28 Ga X 1" Perio-Endo Dental Irrigation Probe (100/Bx)	100/Bx	Light Red
D58	MIP301	Max-I-Probe 30 Ga X 1" Perio-Endo Dental Irrigation Probe (100/Bx)	100/Bx	Dark Blue

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MAX-I-PROBE
Periodontal/Endodontic Irrigating Probe
100 Pak Box Design

Color -

325U

Box Top -

Racing Stripe - 325U/50% Screen.
Three stripes. Drawing of needle in
Racing Stripe with reversed out square
at needle tip highlighting open slot.
(Same as used in the Max-I-Probe Logo).
Copy: U.S. Patent No. 4,276,880

Copy -

Max-I-Probe (Logo)
Periodontal/Endodontic Irrigating Probe

Maximum Safety - Effectiveness-Efficiency

MPL(Logo) Hypo Division, a
subsidiary of Affiliated Hospital
Products, Inc.

Box Front -

Copy -

Max-I-Probe (Logo)
Periodontal/Endodontic Irrigating Probe

Drawing 1

Drawing 2

(Drawing of
Periodontal
Irrigation in Box)

(Drawing of
Endodontic Irrigatic
in Box)

- . Probe-like safety, precision and feel.
- . Moderates velocity of irrigating stream.
- . Side-discharge for turbulent cleansing
- . Safe, effective cleaning of the full depths of gingival sulci and apical third of root canal preparations.
- . Luer lock connectors for quick, secure attachment and removal.

Box Left Side -

Copy -

Directions for Use (Single Use Only)

Sterile unless individual probe
package is opened or damaged.

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1. (Drawing) Peel apart individual package to expose hub.
2. (Drawing) Pushing hub onto syringe or handpiece rotate until seated and locked.
3. (Drawing) Remove paper package. To remove sheath, pull straight off. Do not twist to remove.
4. Max-I-Probe may be bent for convenient access.

Retain sheath to remove probe after use and destroy.

Box Right Side -

Racing stripe - 325U/50% Screen
on right 1/4 of panel. Copy in stripe:
Sterile - Non-Toxic - Non-Pyrogenic

Copy -

Max-I-Probe (Logo)
Periodontal/Endodontic Irrigating Probe

Quantity: (Stamp in Amount)

Gauge & Length: (Stamp In)

Reorder No.: (Stamp In)

Sterile Lot No.: (Stamp In)

Single Use Only

For Professional use only

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Page 3

Box Back Panel -

Copy -

(Heading) Endodontic Irrigation

Standardized Root Canal Instrument	Max-I-Probe Logo		
	Gauge	O.D. Nominal	Color Code
#30	30	.012	Dk.Blue
#40	28	.014	Lt.Red
#50	25	.020	Lt.Orange
#60	24	.022	Med.Purple
#70	23	.025	Lt.Blue
#80	21	.032	Lt.Green

(Heading) Periodontal Irrigation

Periodontal measuring probes range from .012 - .032 O.D. Select the appropriate Max-I-Probe (Logo) gauge according to individual patient needs.

Manufactured for
MPL, Incorporated
1820 W. Roscoe Street
Chicago, Illinois 60657-1079

Box Bottom Panel -

Copy -

Japan

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MAX-I-PROBE
PERIO/ENDO IRRIGATING PROBE
PEEL PACK COPY

21 Ga X 1"

Color Code - Panetone 354-U
Copy - Max-I-Probe (Logo)
21 Ga X 1"
(0.80X25mm)

Sterile Single Use
Perio/Endo Irrigating Probe
Cat. No. MIP 211
Non Toxic. Pyrogen Free

Mfg. for MPL, Inc.
Chicago, IL 60657

Japan

23 Ga X 1"

Color Code - Panetone 325-U
Copy - Max-I-Probe (Logo)
23 Ga X 1"
(0.60X25mm)

Sterile Single Use
Perio/Endo Irrigating Probe
Cat. No. MIP231
Non Toxic. Pyrogen Free

Mfg. for MPL, Inc.
Chicago, IL 60657

Japan

24 Ga X 1"

Color Code - Panetone 265U
Copy - Max-I-Probe (Logo)
24 Ga X 1"
(0.55X25mm)

Sterile Single Use
Perio/Endo Irrigating Probe
Cat. No. MIP241
Non Toxic. Pyrogen Free

Mfg. for MPL, Inc.
Chicago, IL 60657

Japan

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MAX-I-PROBE
PERIO/ENDO IRRIGATING PROBE
PEEL PACK COPY

25 Ga X 1"

Color Code -

Panetone 144-U

Copy -

Max-I-Probe (Logo)
25 Ga X 1"
(0.50X25mm)

Sterile Single Use
Perio/Endo Irrigating Probe
Cat. No. MIP251
Non Toxic. Pyrogen Free

Mfg. for MPL, Inc.
Chicago, IL 60657

Japan

28 Ga X 1"

Color Code -

Panetone 200-U

Copy -

Max-I-Probe (Logo)
28 Ga X 1"
(0.35X25mm)

Sterile Single Use
Perio/Endo Irrigating Probe
Cat. No. MIP281
Non Toxic. Pyrogen Free

Mfg. for MPL, Inc.
Chicago, IL 60657

Japan

30 Ga X 1"

Color Code -

Panetone - Process Blue

Copy -

Max-I-Probe (Logo)
30 Ga X 1"
(0.30X25mm)

Sterile Single Use
Perio/Endo Irrigating Probe
Cat. No. MIP301
Non Toxic. Pyrogen Free

Mfg. for MPL, INC.
Chicago, IL 60657

Japan

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 **MAX-i-PROBE**

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MAX-I-PROBE

PERIODONTAL/IRRIGATING PROBE

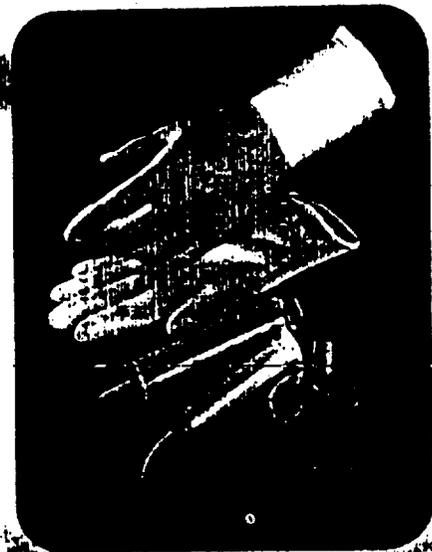
SUBSTANTIAL EQUIVALENCE

EXHIBIT II

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83

PRODUCTS OF EXCELLENCE FOR THE DENTAL PROFESSION



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84

Monoject is proud to offer a line of Dental Products specifically designed to save you time and labor while providing greater safety and comfort for your patients. Monoject Products are ready to use when you need them, quick and easy to discard after use. With single-patient use, there's no need to clean, inspect and sterilize ever — no danger of cross contamination.

Our reputation for quality . . . in raw materials, in manufacturing processes and in finished product and packaging . . . has made Monoject the leading manufacturer of dental needles. Starting in 1959, when we introduced the first Monoject disposable dental needle, we have continually set the standard for safety and convenience in single-patient use products. Through extensive research and development, we have greatly expanded our line of quality products and will continue to meet the needs of the dental profession for safe, convenient and economical products in the years ahead.

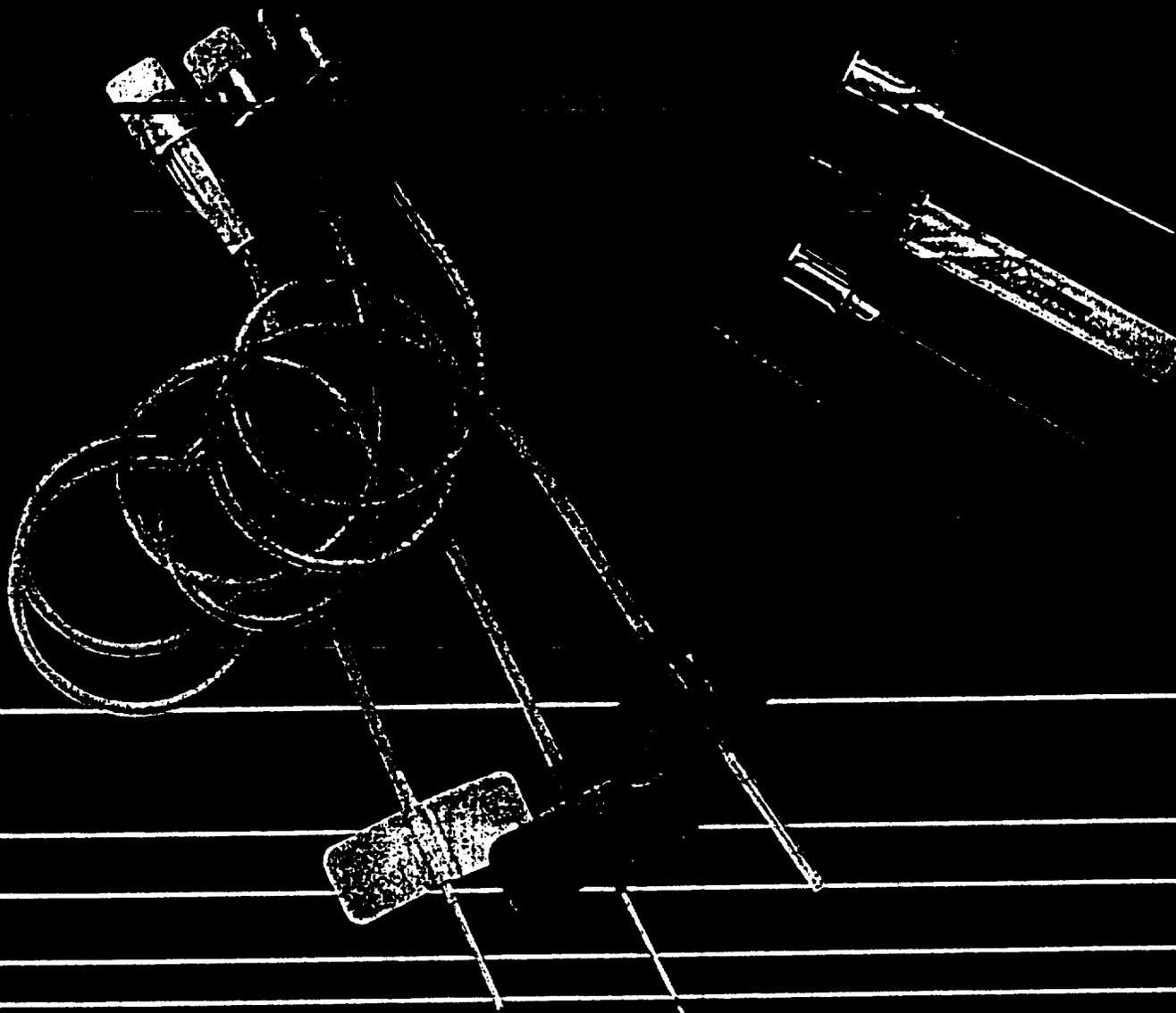
MONOJECT

DIVISION OF SHERWOOD MEDICAL

ST. LOUIS, MO. 63103 U.S.A.

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argyle® Medi-Wing™
INFUSION SETS

- Provides greater safety and convenience for intravenous infusion procedures.
- Sharp, short bevel, thin wall needle is safer, less traumatic to patients.
- Textured wing surface provides secure grip during insertion.
- Luer-lock adapter assures secure connection with luer lock and luer slip devices.
- Sterile packaged 20 per dispenser box, 5 boxes per case.

BLUNT NEEDLES

- For general flushing and irrigating and connecting syringes to plastic tubing.
- Metal luer lock hub fits all luer syringes.
- Sterile, individually packaged, 25 per box, 100 per case.

Order No.	Needle Gage and Length	Tube Length	Fluid Capacity
8888-111716	19TW* x 1/2"	12"	0.6ml
8888-111724	21TW* x 1/2"	12"	0.6ml
8888-111732	23TW* x 1/2"	12"	0.6ml
8888-111740	25TW* x 1/2"	12"	0.6ml

*Thin Wall Needle

Order No.	Needle Gage and Length	O.D.
8881-202314	15 x 1 1/2"	.072"
8881-202330	17 x 1 1/2"	.058"
8881-202363	20 x 1 1/2"	.035"
8881-202389	22 x 1 1/2"	.028"

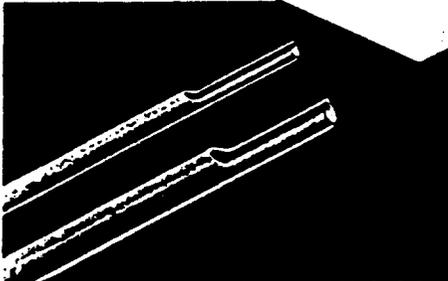
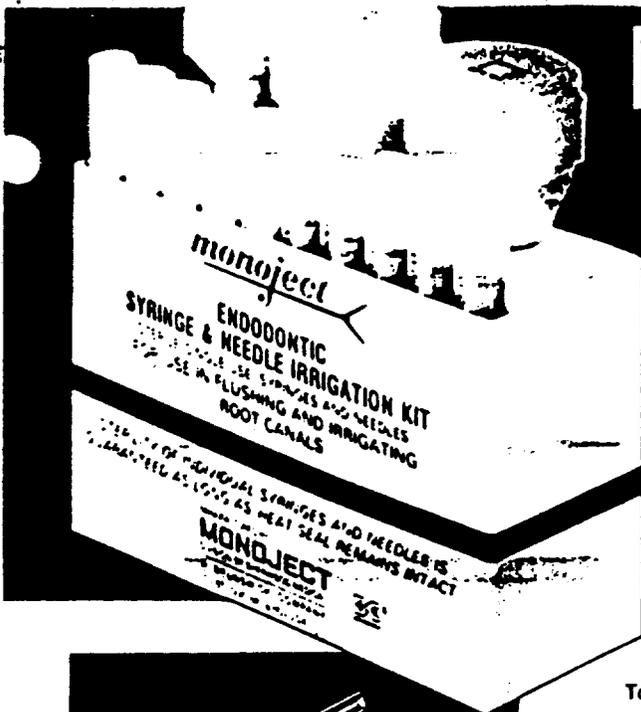
BEST COPY AVAILABLE

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NEW *monoject*

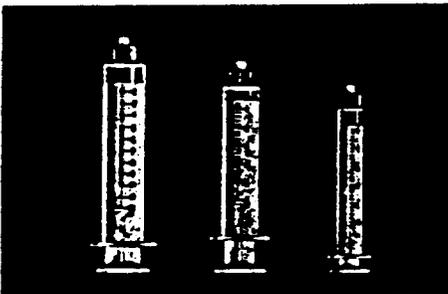
ENDODONTIC SYRINGE AND NEEDLE IRRIGATION KIT

Offers a choice of three different size luer lock syringes . . . plus two different sizes of endodontic notched tip needles.



Notched Tip Needles

Alleviates hydraulic pressure . . . choice of new 27 gage or standard 23 gage needle.



Luer Lock Syringes

Holds needles securely on syringe . . . choice of 3cc, 6cc, or 12cc size.

To optimize flushing and irrigating of root canals, use the syringe and needle best fitted to the particular procedure. Choose 3cc, 6cc, or 12cc luer lock syringes for use with a 27 or 23 gage by 1/4" endodontic needle. Convenient kit offers you MONOJECT quality plus these special features.

- Unique notched tip on needles alleviates hydraulic pressure . . . virtually eliminates danger of rupturing peridental membrane at apex of tooth.
- Luer lock syringes and needles assure positive seating . . . no danger of needle separating from syringe during use.
- Sterile, single-use, individually packaged components . . . eliminates cross contamination.

To use, simply remove the syringe from the hard pack and the cap from the needle; then using the needle guard as a wrench, securely attach needle to luer lock syringe with a push-twist motion. Use needle guard to bend needle as desired. Use each needle and syringe once and then destroy.

For convenience with a choice, order the handy kit.

Product	Order No.	Contents
Endodontic Syringe and Needle Irrigation Kit	8881-470101	1 each — 3cc, 6cc and 12cc luer lock syringes. 5 each — 27 gage x 1/4" Endodontic Needles 5 each — 23 gage x 1/4" Endodontic Needles

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**SEPARATE
ENDODONTIC NEEDLES
AND
LUER LOCK SYRINGES
ALSO AVAILABLE**

Endodontic needles in both 27 and 23 gage as well as 3cc, 6cc, and 12cc luer lock syringes are now available separately. For your higher volume requirements, order the individual products as desired and enjoy extra economy plus the same MONOJECT quality and special features.

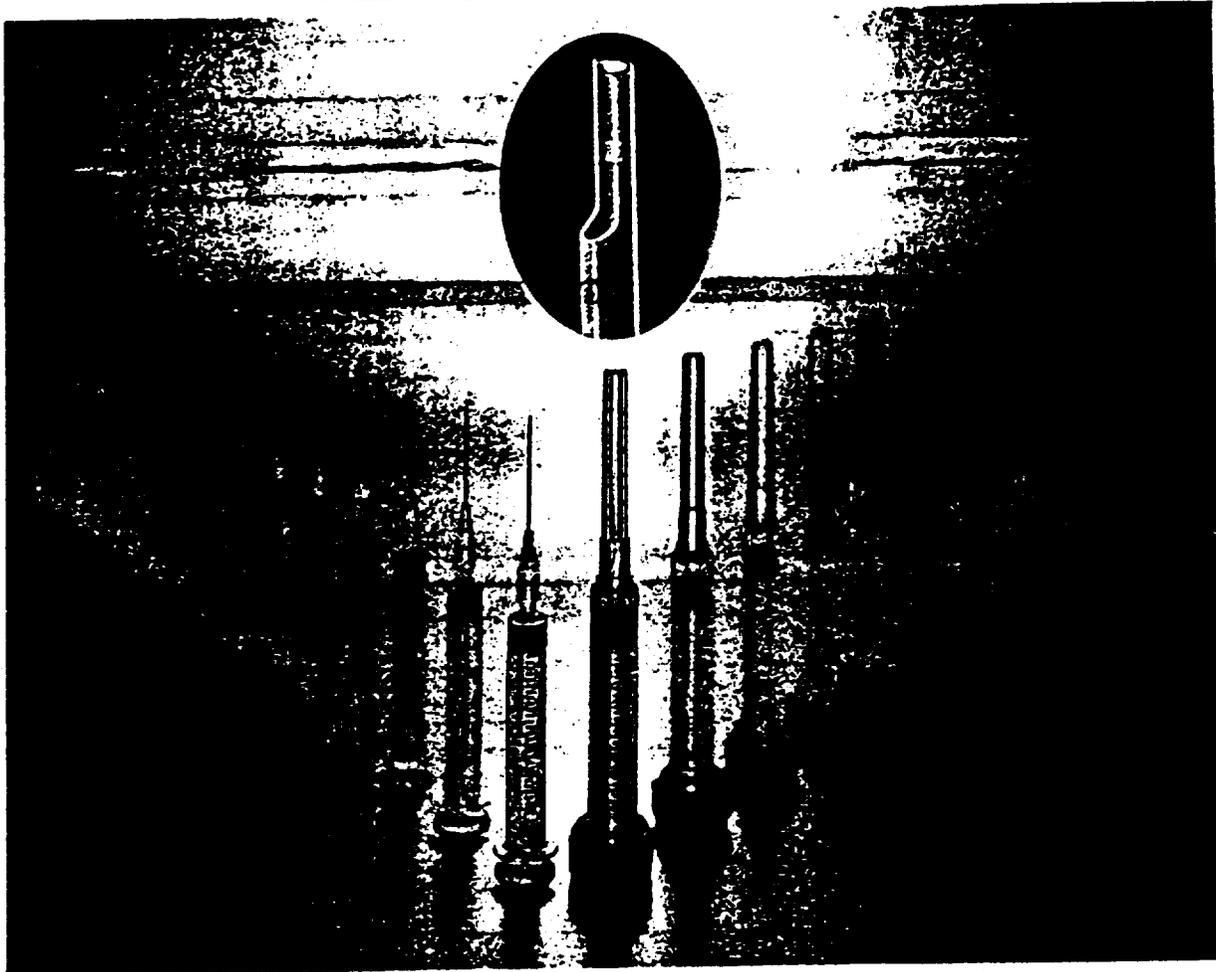
Product	Order No.	Description	Quantity per box
Endodontic Needles with notched tip	8881-471273	27 gage x 1/4" For use with file size 40-60	25
	8881-471232	23 gage x 1/4" For use with file size 70-140	25
Syringes with luer lock connectors	8881-503497	3cc Capacity	100
	8881-506151	6cc Capacity	50
	8881-512175	12cc Capacity	50

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OUR CHOICE OUR FAVORITE

monoject

ENDODONTIC SYRINGE WITH NEEDLE



Specially designed for safe flushing and irrigation of root canals.

- *Preassembled syringe with needle saves time — single use eliminates clean up.*
- *Popular size combination . . . 3cc syringe with 23 gage by 1 1/2" endodontic needle meets most dental needs.*
- *Notched tip needle alleviates hydraulic pressure which could possibly rupture the peridental membrane at the apex of the tooth.*
- *Sterile, individually packaged, single patient use product . . . no danger of cross infection.*

To use, simply remove syringe with needle guard in place from hard pack; seat the needle securely by pushing the needle straight on to the syringe and pulling the needle guard straight off. The needle guard can then be used to bend the needle to the desired position.

Product	Order No.	Quantity Per Box
3cc syringe with 23 gage x 1 1/2" Endodontic Needle	8881-503471	100



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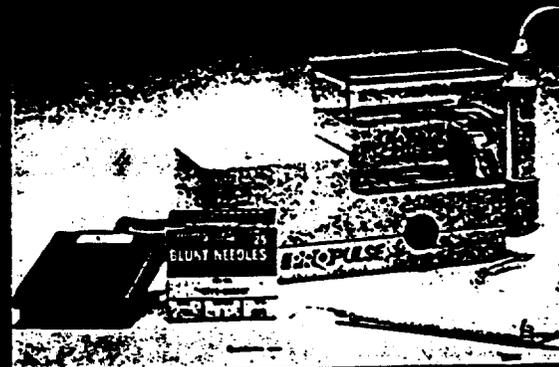
88



ANNOUNCING THE BIGGEST BREAKTHROUGH IN ORAL IRRIGATION IN 20 YEARS



The ProPulse™ Periodontal Irrigating System for your operatory



Developed in conjunction with The International
Dental Health Foundation for use in the Keyes
Perio-Therapy Program

Helps provide accurate placement and delivery of
antibacterial agents to the base of the periodontal pocket

Complete operatory unit includes
Pro Pulse™ Periodontal Irrigator,
periodontal irrigating syringe
handpiece with luer fitting, 6 foot
hose and foot switch for remote
operation, sterile disposable
Monoject® Irrigating tips.

PRO PULSE™

Visit us at the Greater
New York Dental Meeting

Pro Pulse, Inc. • 235 Mathews Street • Fort Collins, Colorado 80524
Toll Free (800) 847-9774 • In Colorado (303) 221-1221

INTRODUCTORY OFFER SAVE \$97.50

Purchase 6 Model 7616 Periodontal
Irrigators for Patient Home Use at
\$26.50 per Unit (See Ad Next Page)
Receive Model 7620 Periodontal
Irrigating System Free

Reg Price	Save	Intro Price	Total
171.00		171.00	
97.50	97.50	0	
268.50	97.50	171.00	

Reg Price	Save	Intro Price	Total

All shipping charges paid by Pro Pulse, Inc.

DDS DMD RDH

Name _____

Address _____

City _____

State _____

Zip _____

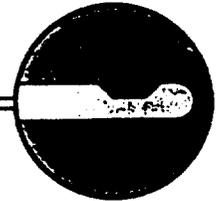
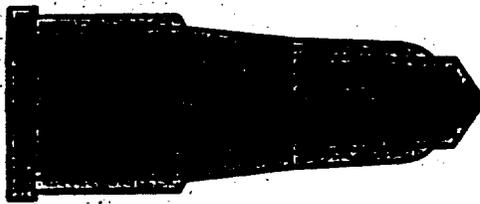
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IMAX



An Idea Whose Time Has Come



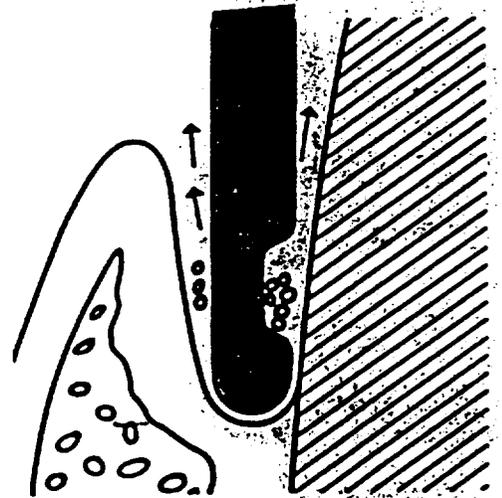
The IMAX Cannula. A simple concept to solve many complex problems of irrigation and medication. A cannula with a smooth rounded and closed end with a side window near the tip. A cannula may be bent for ease of access. Available in a choice of color coded gauges for total versatility.

Periodontal Disease Treatment
IMAX is a unique irrigation and medicating instrument for the most effective treatment of periodontal disease. The versatile cannula may be used with a choice of delivery systems by professionals and auxiliaries to provide the ultimate in periodontal care for the patient.

Probe-like Access Without Risk of Tissue Laceration

The smooth, rounded and closed tip of IMAX provides gentle access into periodontal pockets and beneath pericoronal tissue flaps for convenient irrigation and medication. The cannula may be bent at a suitable angle for ease of access in the mouth. Optimum dispersion of irrigants is achieved through the "side window" at the tip without damaging soft tissue. The IMAX cannula may be used in progressively smaller sizes as the healing process begins in the periodontal pockets.

The unique design of IMAX also facilitates effective application of oxygenating agents and topical medications. Fluoride gels can be precisely placed beneath the free gingiva to combat root caries.



Endodontic Irrigation and Cleansing
The IMAX cannula has been designed for the ultimate in safety and efficacy in the irrigation and cleansing of root canal preparations. The cannula may be used with a choice of irrigation systems and solutions and can be bent for ease of access.

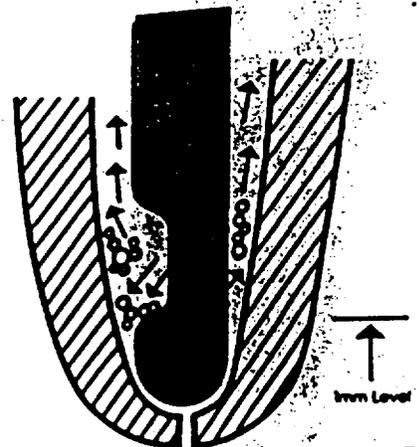
Cleanse the Apical Third!
The greatest danger with endodontic irrigation procedure is the possibility of the irrigation pressure forcing bacteria, debris and solution through the apex. The IMAX has been designed to minimize the axial pressure and guard the apical foramen against injection specialty while irrigating in the apical third. A 30 gauge cannula provides access to even the smallest canal.

Endodontic Aspiration

After irrigation procedure, the same cannula may be used with the aspirator for suction of solution and debris from the preparation and minimize the need for paper cones.

The cannula may be used corresponding to the instrument size used.

Instrument Size	IMAX Cannula	Color Code
#30	30 Gauge	Green
#40	27 Gauge	White
#50	25 Gauge	Blue
#60	23 Gauge	Yellow
#80	21 Gauge	Gray



STRAM DENTAL

Division of Stram Incorporated
655 Academy Drive
Northbrook, Illinois 60062

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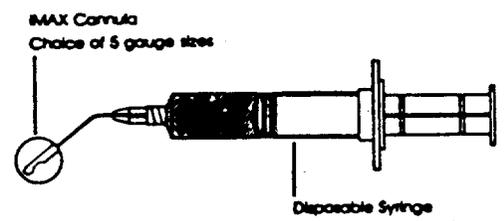
U.S. Patent Number 4,276,880

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Versatility! The Cannula That Fits Your Need

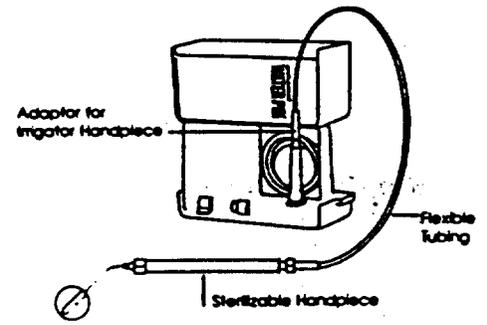
IMAX Irrigator/Medicator

For subgingival irrigation and easy placement of medications and gels. Luer-lock connection permits positive attachment of cannula to the syringe.



IMAX Pulsator

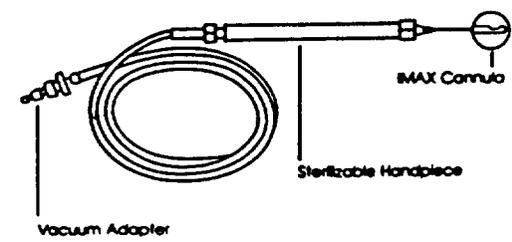
For irrigation with the combined advantages of the IMAX Cannula and the Water Pik® Model 76M.* The system permits pulsating lavage through the IMAX Cannula. Flexible tubing and sterilizable handpiece provide ease of access.



Optional Foot Control Switch

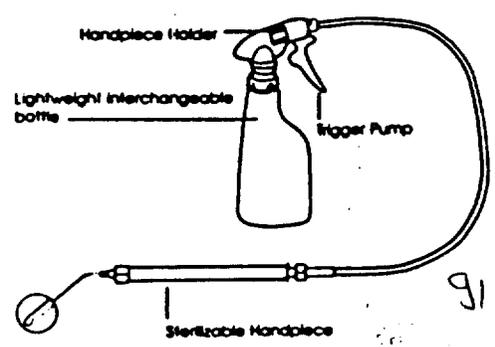
IMAX Aspirator

For suction of solution and debris from the root canal preparation after irrigation. Attaches easily to the vacuum source and the handpiece may be sterilized.



IMAX Bottle Irrigation System

For irrigation with ease of access and handpiece convenience. Permits convenient storage of desired irrigants in the bottle. Handpiece may be changed between patients and sterilized.



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*Water Pik® Model 76M available from Teledyne Water Pik, Fort Collins, Colorado

IMAX

**STRAM DENTAL**

Product	Description	Code	Unit Price
IMAX Irrigator/Medicator	Kit includes: 4 Each 23, 25, 27 & 30G IMAX cannulas and 16 assorted disposable syringes	12000	\$26.95
IMAX Bottle Irrigation System	Dispenser bottle with trigger pump; tubing assembly; 2 hand- pieces; and 4 each 23, 25, 27 & 30G IMAX cannulas	13000	\$44.85
IMAX Pulsator For use with Water Pik® Model 76M	Adaptor for Water Pik® Irrigator handle, tubing assembly, 2 handpieces, 4 each 21, 23 & 25 gauge IMAX Cannulas	13500	\$35.75
	Foot Control Switch w/cord	13602	\$16.75
IMAX Cannulas Color coded, luer hub, disposable packaged 50 per unit	21 Gauge x 1" (Grey)	20200	\$43.50
	23 Gauge x 1" (Yellow)	20201	\$43.50
	25-Gauge x 1" (Blue)	20202	\$43.50
	27 Gauge x 1" (White)	20203	\$43.50
	30 Gauge x 1" (Green)	20204	\$48.50
IMAX Syringes Luer lock, disposable	12cc 50/unit	11020	\$11.30
	6cc 50/unit	11021	\$10.25
	3cc 100/unit	11022	\$19.00
IMAX Irrigation System Components	Dispenser bottle with trigger pump 6/unit	13101	\$35.75
	Tubing assembly with luer lock connectors 6/unit	13102	\$22.50
	Handpiece assembly with luer lock ends 12/unit	13103	\$30.50
	Adaptor for Water Pik® 6/unit	13601	\$19.50
IMAX Aspirator	Aspirator tubing assembly with vacuum adaptor and 1 each 23, 25, 27 & 30G IMAX cannulas	11016	\$17.85

Detach Here

IMAX™

U.S. Patent Number 4,276,880

**Order Form****STRAM DENTAL**

All orders shipped prepaid:
check or money order must
accompany order. Enclose
payment and mail to:

Division of Stram Inc.
655 Academy Drive
Northbrook, Illinois 60062
312/272-5260

Code	Quantity	Price

Name _____

Address _____

City _____ State _____ Zip _____

Telephone _____

Illinois residents add 6% sales tax

Amount Enclosed _____

Additional Price Lists Packed With Each Order

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1000'S



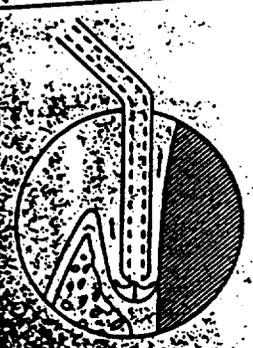
...tical and as readily soldered
...standards with certain other
...entation. Price \$3.95 (obtain
...lling toll-free 1-800-431-3967
...203-265-7397 collect from Con
...necticut or outside the continental
...United States)
...Generic Gold Co.
...for more facts, circle 22 on card

periodontal irrigation medication cannulas



Designed for subgingival irrigation
and medication procedures in the
PerioTip, Pocket Care, PerioTip
are pre-bent cannulas that afford con-
venient, probe-like access to peri-
odontal pockets and pericoronal
tissue flaps. Offered in three gauge
sizes (21, 24, and 27), their ends are

60 years of dedication
to improving dental
x-ray techniques and
procedures.



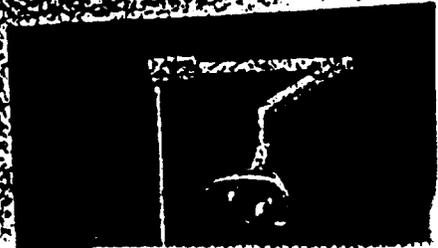
smooth and smooth to avoid tissue
injury during pocket and flap
entry. The sterilizable cannulas are
packaged individually and feature
color-coded finger-locking hubs for at-
tachment to syringes or other delivery
systems. Disposable syringes in 3-
6-cc and 12-cc sizes also are offered.

Siram Dental, Inc.

For more facts, circle 22 on card.

dental chair

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE LISTING

Complete and return to:
Food and Drug Administration
Bureau of Medical Devices (HFK-124)
8757 Georgia Avenue
Silver Spring, MD 20910

Note: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(g)(2)) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER FA 177906		2. INITIAL DOCUMENT NUMBER		3. REASON FOR SUBMISSION B			4. ACTIVITY DATE MO DAY YR.			5. REPORT DATE MO DAY YR.		
										02 06 84		
6. OWNER/OPERATOR NAME L TELEDYNE INDUSTRIES, INC.							7. OWNER/OPERATOR ID NO. 9920024					
8. CLASSIFICATION NAME NONE - DENTAL 76							9. CLASSIFICATION NO.					
10. PROPRIETARY NAME PERIO PIK™												
11. COMMON OR USUAL NAME SUBGINGIVAL IRRIGATING KIT												
12. IS THE ABOVE LISTED DEVICE THE SUBJECT OF ANY PERFORMANCE STANDARD ESTABLISHED PURSUANT TO SECTION 514 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT OR SECTION 358 OF THE RADIATION CONTROL FOR HEALTH AND SAFETY ACT?							324 <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
120. ENTER THE APPROPRIATE NAME AND SECTION NUMBER FROM CHAPTER 21 OF THIS CODE OF FEDERAL REGULATIONS. NAME:							325 328 329 334 SECTION PARA.					
13. IS THE ABOVE LISTED DEVICE THE SUBJECT OF A PREMARKET APPROVAL PURSUANT TO SECTION(S) 505, 507 OR 515 OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT?							335 <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
130. IDENTIFY ANY APPROVED PREMARKET APPLICATION BY ITS ASSIGNED FDA NUMBER:							336 345					
14. IS THE DEVICE, AS LABELED, INTENDED FOR DISTRIBUTION TO AND USE BY THE GENERAL PUBLIC?							346 <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
28 30 31		37		15. EST. REG. NUMBER			16. ESTABLISHMENT NAME			38 39 40 41 42 43 44		
SEQ		EST. REG. NUMBER		ESTABLISHMENT NAME			17. EST. TYPE					
S01		1712259		TELEDYNE WATER PIK			D F I M P R					
S02												
S03												
S04												
S05												
S06												
18. SIGNATURE							19. TYPED OR PRINTED NAME HOWARD GILSTRAP					

TELEDYNE INDUSTRIES, INC.
1901 Avenue of the Stars
Los Angeles, California 90067

LIST OF COMPONENTS IN PERIO PIK™ (KIT)

- 1 Handpiece, stainless steel
- 1 Hose assembly, silicone rubber, medical grade
- 2 Clips (handpiece holding)
- 2 Cannulas, 21 ga. (.032 dia.), MAX-I-PROBE™, pyrogen free
- 2 Cannulas, 24 ga. (.022 dia.), MAX-I-PROBE™, pyrogen free
- 2 Cannulas, 28 ga. (.014 dia.), MAX-I-PROBE™, pyrogen free
- 1 Instruction Book

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