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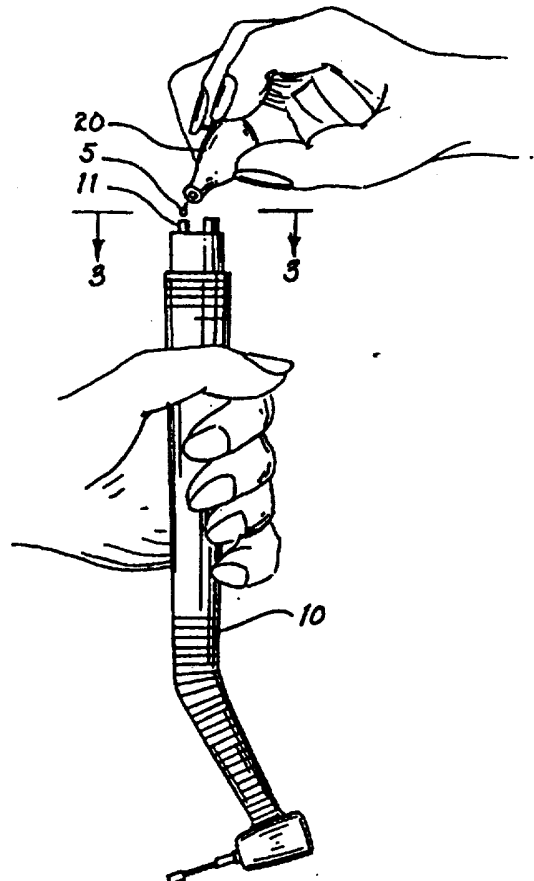
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US95/09749 (22) International Filing Date: 1 August 1995 (01.08.95) (30) Priority Data: 08/283,851 1 August 1994 (01.08.94) US (71)(72) Applicant and Inventor: BROWN, Kenneth, R. [US/US]; Suite #77, 7127 East Becker Lane, Scottsdale, AZ 85254 (US). (74) Agent: LISA, Donald, J.; Law Offices of Donald J. Lisa, Suite #215, 8989 East Via Linda, Scottsdale, AZ 85258-5409 (US).</p>	<p>(81) Designated States: AM, AU, BB, BG, BR, BY, CA, CN, CZ, EE, FI, GE, HU, JP, KG, KP, KR, KZ, LK, LR, LT, LV, MD, MG, MN, MX, NO, NZ, PL, RO, RU, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).</p> <p>Published With international search report.</p>	

(54) Title: DENTAL HANDPIECE HYGIENIC PHARMACEUTICAL STERILIZATION LUBRICANT

(57) Abstract

About 1/2 cc of a sterile composition (5) dropped into the rotor drive air feed line (11) of a dental handpiece (10) while holding the handpiece upside down protects and lubricates the handpiece bearings and turbine during the subsequent auto-clave sterilization process. An additional dosage inserted into the bur hole after the auto-clave process further lubricates the handpiece and inhibits rust from forming on the handpiece bearings and turbine during use. The pre-sterilization dosage and post-sterilization dosage of measured amounts may be separately packaged in disposable capsules (20, 30). The composition (5) is made by heat mixing until sterile about 10 % by volume of a sterile solution of Power-Up™ NNL-690, which is a liquid hydrocarbon boundary lubricant and corrosion inhibitor, with 90 % by volume of pharmaceutical grade mineral oil.



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**DENTAL HANDPIECE HYGIENIC PHARMACEUTICAL STERILIZATION  
LUBRICANT**

**BACKGROUND OF THE INVENTION**

**1. FIELD OF THE INVENTION**

The present invention relates generally to a sterile, pharmaceutical composition inserted into a dental handpiece prior to and after sterilization to lubricate moving parts and to inhibit handpiece corrosion, and, more particularly, to the process of sterilizing such instruments by inserting such compositions prior to auto-claving.

**a. Prior Handpiece Lubricants and Processes**

It is well known that a dental handpiece has to be lubricated periodically to maintain its efficiency and prevent premature failure. The rotor or turbine in the handpiece is supported in bearings which are subjected to severe wear due to the wide range of speeds and torque loads involved in drilling teeth. Typically, the bearings are lubricated by adding oil in a variety of ways, such as from a large oiler connected to the rotor drive air feed line which intermittently drops oil into the inlet air stream where the oil is atomized and then carried to the rotor entrained in the inlet air.

In a method disclosed in Sugai U.S. Patent 4,218,216 an improved system employed a small oiler inserted in the air feed line having a spring loaded check valve overcome by feed air pressure to allow oil to escape into the feed air, be atomized and continuously lubricate the rotor bearings. However, with the onset of AIDS and the need for increased sterilization, such a

1 system did not function during auto-claving and offered no  
2 protection against cross contamination.

3 By 1991, as disclosed in Feldman U.S. Patent 5,131,845, it  
4 was highly recommended that the handpiece be sterilized  
5 frequently, and sterilization of the handpiece between patients  
6 was becoming a recommended procedure. However, increased  
7 sterilization required more frequent lubrication. It was known  
8 to lubricate the handpiece both before and after sterilization.

9 However, the initial lubricants used pre-sterilization and  
10 post-sterilization were generally the same products as were  
11 previously available prior to the need for increased  
12 sterilization. These products did not survive the heat of the  
13 auto-clave process itself and were in effective. Handpiece  
14 failures increased and were replaced at an average unit cost of  
15 about \$150.00.

16 While Feldman developed an improved method of inserting the  
17 oil into the rotor drive air feed line using a squeezable sealed  
18 capsule containing the lubricant and his system further prevented  
19 the transmission of viral and bacterial matter to the patient and  
20 the dentist, it did not advance the art of developing lubricant  
21 compositions that could not only withstand the auto-clave cycle,  
22 but also, protect the handpiece during the auto-clave cycle by  
23 retaining and/or enhancing their boundary lubricating and anti-  
24 corrosion characteristics. Feldman merely disclosed that his  
25 shell 10 was filled with an extremely light, dental grade, FDA  
26 approved, lubricating oil which was required for the handpiece  
27 and widely used in the art. Feldman 7:21-24.

1                   **b. Industrial Product Preservatives**

2           It was also known to add ingredients, such as, an anion  
3 selected from the group consisting of sulfate, acetate and  
4 citrate groups, to aqueous industrial products to inhibit  
5 microbiological degradation in such products resulting from the  
6 growth of micro-organisms which can cause odors, deterioration  
7 and corrosion. Pera U.S. Patent 4,920,107. In an improvement  
8 to Nelson U.S. Patent 5,283,005, the biocidal efficacy of such  
9 additives were enhanced by mixing a known preservative  
10 (pyrithione, used in lubricants) with a known antibiotic  
11 (lipopeptide, for treating superficial infections) to inhibit  
12 notably bacteria and fungi from forming in the composition itself  
13 when used alone or in combination with an inert carrier, such as  
14 water, liquid hydrocarbons, ethanol, isopropanol, or the like.  
15 2:63-67. However, there was no disclosure or suggestion of the  
16 composition of the present invention, that the disclosed  
17 compositions were sterile or could be used as pre-sterilization  
18 lubricants for a dental handpiece, or that the boundary  
19 lubricating or protective quality of the compositions were  
20 enhanced.

21                   **c. Boundary Lubricant Theory**

22           The general theory of how a boundary lubricant works is well  
23 known. When surfaces contact each other during rolling or  
24 sliding contact, wear particles are formed which combine with the  
25 lubricant to form an eutectic film (the new material has a lower  
26 melting point than the original material) which can withstand  
27 high loads and become the sacrificial layer which is worn away

1 and removed instead of the underlying (rotor/bearing) material,  
2 thus, reducing friction.

3 It is an object of the present invention to provide a new,  
4 low coefficient of friction, lubricant composition and process  
5 that allows insertion of the composition into the rotor drive air  
6 inlet prior to the auto-clave cycle, or after, or both, and which  
7 remains effective during the auto-clave cycle and thereafter to  
8 provide improved protection of the handpiece against corrosion,  
9 substantially reduced wear rates and substantially improved  
10 resistance to wear, thereby extending significantly the service  
11 life of the handpiece.

12 It is a further objective of the present invention to  
13 provide a new sterile composition and process that reduces the  
14 risk of cross contamination from viruses and bacteria.

## 15 2. SUMMARY OF INVENTION

16 Set forth below is a brief summary of the invention in order  
17 to achieve the foregoing and other benefits and advantages in  
18 accordance with the purpose of the present invention as embodied  
19 and broadly described herein.

20 One aspect of the present invention is a dental handpiece  
21 lubricant which includes a composition of about 90% by volume of  
22 a liquid hydrocarbon and about 10% by volume of a boundary  
23 lubricant and corrosion inhibitor. This composition is made by  
24 mixing about 10% by volume of a solution of>NNL-690 with about  
25 90% by volume of a pharmaceutical grade mineral oil. Preferably,  
26 the>NNL-690 solution is initially heated at about 250°F for about  
27 one hour or until sterile and the final composition is preferably

1 additionally heated at about 225°F for about one hour or until  
2 sterile and thoroughly mixed.

3 A further aspect of the present invention is the process of  
4 sterilizing a dental handpiece having a rotor supported in a  
5 bearing and a bur hole adapted to receive and hold a bur by  
6 lubricating the handpiece rotor and bearing by inserting a  
7 predetermined amount of the aforesaid composition into the rotor  
8 driven air feed line while holding the handpiece vertically  
9 upside down, and, then, auto-claving the handpiece in a sealed  
10 plastic bag.

11 A further aspect of the invention is protecting the  
12 handpiece in use by inserting a predetermined amount of the  
13 aforesaid composition into the bur hole before each use or during  
14 use.

#### 15 DESCRIPTION OF THE DRAWINGS

16 Fig. 1A is a perspective view of a handpiece of the prior  
17 art.

18 Fig. 1B is a perspective view of a disposable capsule of the  
19 prior art in which the composition of the present invention may  
20 be conveniently packaged.

21 Fig. 1C is a perspective view of the capsule of Fig. 1B with  
22 the head detached.

23 Fig. 2 is a front elevation of the handpiece of Fig. 1A held  
24 vertically upside down and showing the capsule of Fig. 1C  
25 containing the composition of the present invention being  
26 squeezed to insert a measured dosage of the composition into the  
27 air feed inlet passage of the handpiece prior to sterilization.

1           Fig. 3 is a top elevation of Fig. 2.

2           Fig. 4 is a front perspective of the handpiece of Fig. 1A  
3 held right side up and slightly at an angle and showing the  
4 capsule of Fig. 1C containing the composition of the present  
5 invention being squeezed to insert, after sterilization, a  
6 measured amount of the composition into the bur hole of the  
7 handpiece head which houses the turbine, the turbine bearings and  
8 the chuck which holds the bur.

9           Fig. 5 is a right side elevation of Fig. 4.

10                   **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**

11           The composition of the present invention is a specially  
12 formulated, mineral based, hygienic, pharmaceutical lubricant.  
13 It may be packaged individually for use prior to sterilization  
14 of the handpiece without risk of contamination by the lubricant  
15 itself. It may be packaged individually for use after  
16 sterilization of the handpiece without risk of contamination by  
17 the lubricant itself. The pre-sterilization package contains a  
18 measured amount of about 1/2 cc, enough for one application. The  
19 post-sterilization package contains a pre-measured amount of  
20 about ten (10) applications of about 2 drops each.

21           The composition 5 of the present invention comprises a  
22 mixture of liquid hydrocarbons refined from petroleum including  
23 about 90% by volume of a fully refined, pharmaceutical grade,  
24 non-sterile, white mineral oil to which has been added and  
25 thoroughly mixed about 10% by volume of a fully refined, light,  
26 mineral based oil, amber in color, as a boundary lubricant  
27 enhancer and corrosion inhibitor. The composition 5 is

1 manufactured for applicant by Petroleum Products of America of  
2 Scottsdale, Arizona and is sold under applicant's brand name  
3 STERI-LUBE™.

4 The mineral oil used in the present invention meets the  
5 requirements of the United States Pharmacopeia XXII, as well as  
6 the requirements of the Food and Drug Administration per 21  
7 C.F.R. § 172.878.

8 The boundary lubricant enhancer and corrosion inhibitor of  
9 the present invention is a non-sterile petroleum product known  
10 by applicant only by the Power-Up™ designation NNL-690, made and  
11 sold by Power-Up Distribution, Inc. of 6173-6 Street SE, Calgary,  
12 AB, Canada T2H1L9 ("Power-Up"). Power-Up has retained the  
13 specific composition of NNL-690 as a trade secret. However, the  
14 product is commercially available to any buyer and may be  
15 obtained by simply contacting Power-Up at the above location.  
16 Prior to the present invention, it has been known to use NNL-690  
17 as a boundary lubricant enhancer to reduce friction in automotive  
18 engines. Preferably, the enhancer/inhibitor solution of the  
19 present invention is first heated at a temperature of about 250  
20 degrees Fahrenheit for about one hour to sterilize it. The  
21 lubricant enhancer/inhibitor used in the present invention also  
22 complies with the Material Safety Data Sheet ("MSDS")  
23 specifications.

24 The final lubricant composition 5 of the present invention  
25 is made by mixing the 90% by volume mineral oil with the 10% by  
26 volume enhancer/inhibitor and then heating the final mixture at  
27 a temperature of about 225 degrees Fahrenheit for about one hour

1 to sterilize it and assure a complete mixing of the ingredients.

2 Additional characteristics of the final composition 5 of the  
3 present invention are as follows:

- 4 1. Color/odor: Clear - Pleasant, nutty order.
- 5 2. Specific Gravity: < 1.0 @ 15 Deg. C.
- 6 3. Vapor Pressure: < .5mm
- 7 4. Evaporation Rate: Nil @ 25 Deg. C.
- 8 5. Boiling Point: > 230 Deg. C.
- 9 6. Pour Point: >-9 Deg. C.
- 10 7. Flash Point: 193. Deg. C.; > 380 Deg. F.
- 11 8. Solubility in Water: Nil.
- 12 9. pH: N/A.
- 13 10. Viscosity: 100 (SUS)

14 **WORKING EXAMPLE**

15 Take 5.5 gallons of NNL-690 and heat at 250 degrees F. for  
16 1 hour. Mix the resulting liquid with 49.5 gallons of mineral  
17 oil and heat again at about 225 degrees F. for about 1 hour. The  
18 two heating steps may be omitted if a sterile final composition  
19 is not required. Package and ship.

20 The packaging of the invention is conventional. A pre-  
21 sterilization package, such as a capsule 20, may be conveniently  
22 sized to hold an amount of the final composition of the present  
23 invention sufficient to protect the handpiece 10 during the  
24 sterilization process, such as, about 1/2 cc. A post-  
25 sterilization package, such as a capsule 30, may be conveniently  
26 sized as a 1 cc reclosable applicator holding ten individual  
27 applications of about 1/10th cc each. 1/10th cc is the

1 equivalent of about 2 drops. The post-sterilization capsule will  
2 be a reclosable container as is well known in the art.

### 3 PROCESS OF USING

4 The process of using the composition of the present  
5 invention is best understood with reference to the drawings.

6 1. Fig. 1. shows the handpiece 10 of the prior art.  
7 The handpiece 10 is held vertically upside down as shown in Fig.  
8 2. The cap of the capsule 20 containing the sterile pre-auto-  
9 clave composition 5 is removed and the capsule is squeezed to  
10 allow a dosage of about 1/2 cc of the lubricant to enter the main  
11 air hole 11 of handpiece 10.

12 2. Place the handpiece 10 in a sterilization bag (not  
13 shown) and place the bag into a standard auto-clave (not shown).

14 3. Follow the auto-clave instructions.

15 4. When the auto-clave cycle is complete, remove the  
16 bag and handpiece.

17 5. As seen in Fig. 2 hold the handpiece 10 right side  
18 up and at an angle to expose access to the bur hole 12 and then  
19 squeeze capsule 30 allowing two (2) drops of the sterile post-  
20 auto-clave solution 5 to enter into bur hole 12 before use of  
21 handpiece 10.

22 The foregoing description of a preferred embodiment and best  
23 mode of the invention is known to applicant at the time of filing  
24 the application, and has been presented for the purpose of  
25 illustration and description. It is not intended to be  
26 exhaustive or to limit the invention to the precision form  
27 disclosed, and obviously many modifications and variations are

1 possible in light of the above teaching. The embodiment was  
2 chosen and described in order to best explain the principles of  
3 the invention and its practical application to thereby enable  
4 others skilled in the art to best utilize the invention in  
5 various embodiments and with various modifications suited to the  
6 particular use contemplated. It is intended that the scope of  
7 the invention be defined by the claims appended hereto.

I Claim:

1           1.    The process of making a dental handpiece lubricant  
2 characterized by the step of:

3                        mixing about 10% by volume of NNL-690 and about  
4 90% by volume of a pharmaceutical grade mineral oil.

1           2.    The process of claim 1 further characterized by the  
2 step of:

3                        heating the mixture until sterile.

1           3.    The process of claim 2 wherein the heating step is  
2 characterized by the step of heating the mixture at about 225°F  
3 for about one hour.

1           4.    The process of claim 3 further characterized by the  
2 step of:

3                        heating the NNL-690 at about 250°F for about one  
4 hour prior to the mixing step.

1           5.    The process of claim 1 wherein the mixture is  
2 characterized by not more than about 10% by volume of NNL-690 and  
3 not less than about 90% by volume of mineral oil.

1           6.    The process of claim 1 wherein the NNL-690 is  
2 characterized by a liquid hydrocarbon boundary lubricant and  
3 corrosion inhibitor.

1           7.    A dental handpiece lubricant characterized by a mixture  
2 of

3                        about 10% by volume of NNL-690 and about 90% by  
4 volume of a pharmaceutical grade mineral oil.

1           8. The lubricant of claim 7 wherein the solution is  
2 sterile.

1           9. The lubricant of claim 7 wherein the mixture is  
2 characterized by not more than about 10% by volume of NNL-690 and  
3 not less than about 90% by volume of mineral oil.

1           10. The lubricant of claim 7 wherein the NNL-690 is  
2 characterized by a liquid hydrocarbon boundary and corrosion  
3 inhibitor.

1           11. The product made by the process of claim 1.

1           12. The product of claim 11 made by the process of claim  
2 2.

1           13. The product of claim 12 made by the process of claim  
2 3.

1           14. The product of claim 13 made by the process of claim  
2 4.

1           15. The product of claim 11 made by the process of claim  
2 5.

1           16. The product of claim 11 made by the process of claim  
2 6.

1           17. The process of sterilizing a dental handpiece having  
2 a rotor supported in a bearing and a bur hole adapted to receive  
3 and hold a bur characterized by the steps of:

4                   (a) lubricate the rotor and bearing of the  
5 handpiece with a predetermined amount of a composition comprising  
6 a solution of about 90% by volume of a liquid hydrocarbon and  
7 about 10% by volume of a boundary lubricant and corrosion  
8 inhibitor, and

9 (b) insert the handpiece into a sealed bag and  
10 subject the bag to an auto-clave cycle sufficient to sterilize  
11 the handpiece.

1 18. The process of claim 17 wherein the predetermined  
2 amount is about 1/2 cc.

1 19. The process of claim 17 wherein the lubricating step  
2 further characterized by the step of

3 inserting the composition into a rotor drive air  
4 feed line while holding the handpiece vertically upside down.

1 20. The process of claim 17 wherein the composition of the  
2 lubricating step further characterized by:

3 the boundary lubricant and corrosion inhibitor is  
4 NNL-690, and

5 the liquid hydrocarbon includes a pharmaceutical  
6 grade mineral oil.

1 21. The process of claim 20 wherein the composition is  
2 sterile.

1 22. The process of claim 21 further characterized by the  
2 step of:

3 after completing the auto-clave cycle, inserting  
4 a predetermined amount of the composition into the bur hole.

1 23. The process of claim 20 wherein the composition  
2 includes not more than about 10% by volume of NNL-690 and not  
3 less than about 90% by volume of the liquid hydrocarbon.

1 24. The process of claim 17 further characterized by the  
2 step of:

3 after completing the auto-clave cycle, inserting

4 a predetermined amount of the composition into the bur hole.

1 25. The process of protecting a dental handpiece having a  
2 rotor supported in a bearing and a bur hole adapted to receive  
3 and hold a bur is characterized by the step of:

4 lubricating the rotor and bearing of the handpiece  
5 with a predetermined amount of a composition comprising about 10%  
6 by volume of NNL-690 and about 90% by volume of a pharmaceutical  
7 grade mineral oil.

1 26. The process of claim 25 wherein the composition is  
2 characterized by not more than about 10% NNL-690 and not less  
3 than about 90% mineral oil.

1 27. The process of claim 26 wherein the predetermined  
2 amount is about 2 drops.

1 28. The process of claim 25 wherein the composition is  
2 sterile.

1 29. The process of claim 25 wherein the lubricating step  
2 is further characterized by the step of inserting the composition  
3 into the bur hole.

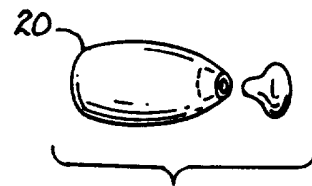
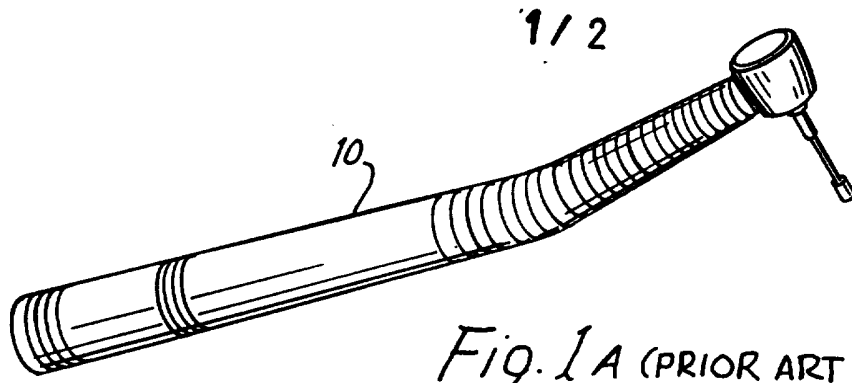
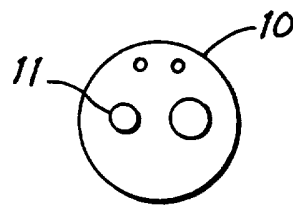
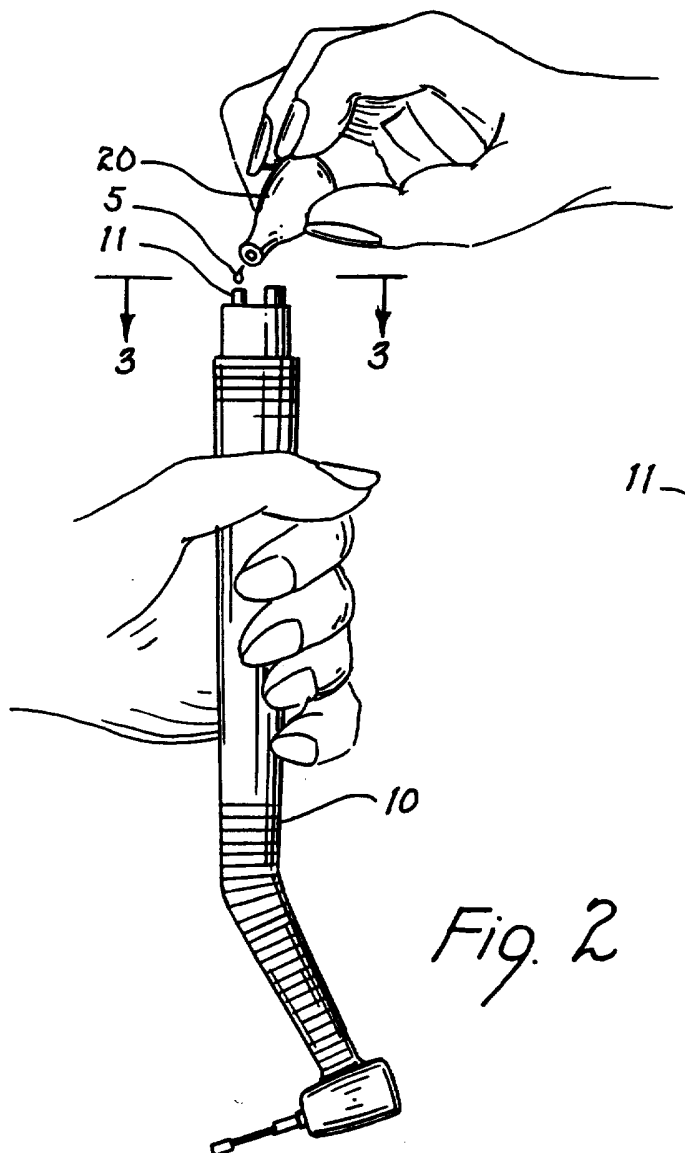
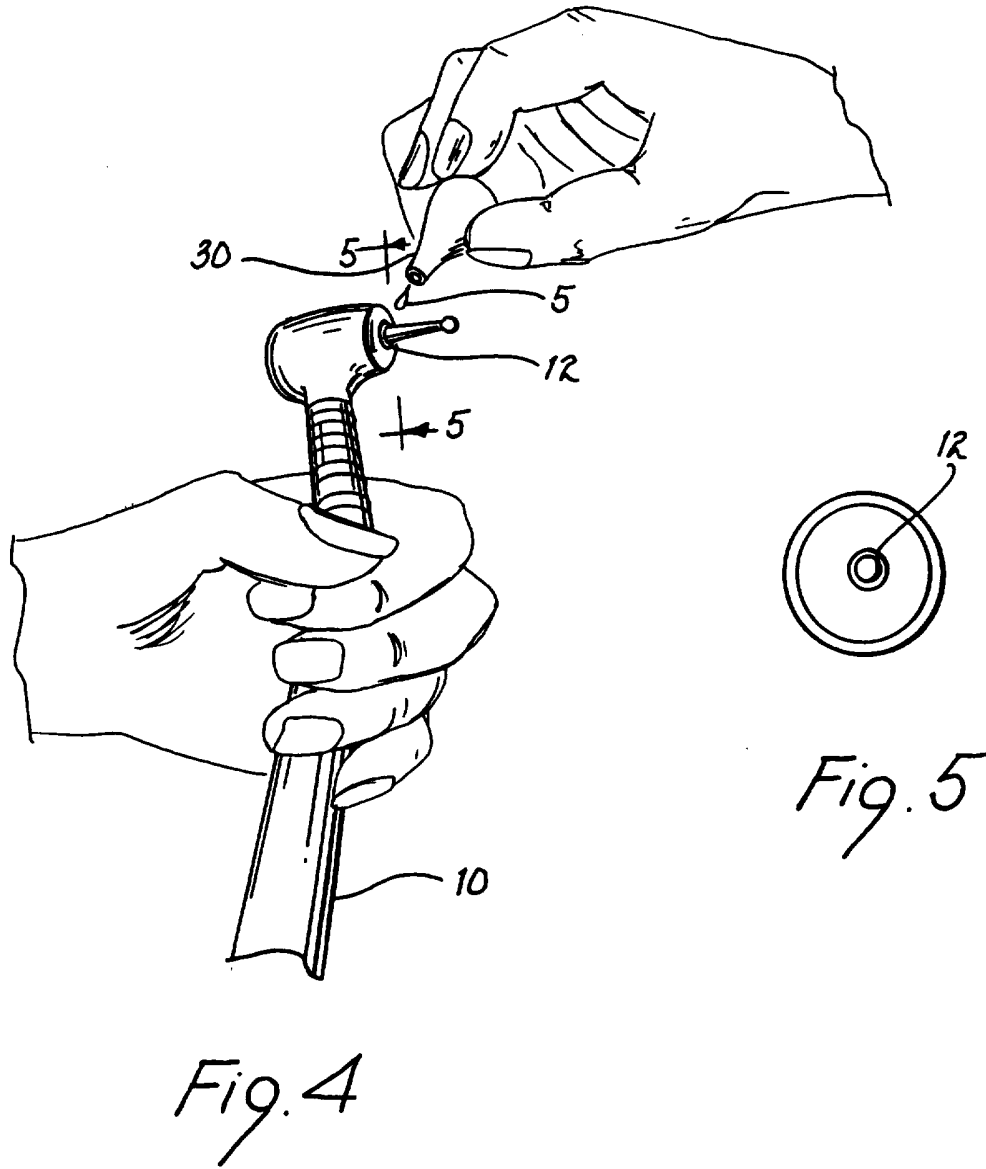


Fig. 1B (PRIOR ART)

Fig. 1c (PRIOR ART)





# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US95/09749

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A61C 1/02  
US CL : 433/104; 422/1, 7, 26, 27, 28, 40; 252/10

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 433/104; 422/1, 7, 26, 27, 28, 40; 252/10

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS  
search terms: NNL-690, lubricants; dental handpieces, sterilize

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,131,845 (FELDMAN ET AL) 21 July 1992, see entire document.	7-10, 17-29
X		----- 1-6, 11-16
Y	US, A, 4,218,216 (SUGAI ET AL) 19 August 1980, see entire document.	1-29
A	US, A, 4,920,107 (PERA ET AL) 24 April 1990, see entire document.	1-29
A	US, A, 5,283,005 (NELSON, JR. ET AL) 01 February 1994, see entire document.	1-29

Further documents are listed in the continuation of Box C.       See patent family annex.

<p>* Special categories of cited documents:</p> <p>*A* document defining the general state of the art which is not considered to be of particular relevance</p> <p>*E* earlier document published on or after the international filing date</p> <p>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>*O* document referring to an oral disclosure, use, exhibition or other means</p> <p>*P* document published prior to the international filing date but later than the priority date claimed</p>	<p>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principles or theory underlying the invention</p> <p>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>*A* document member of the same patent family</p>
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<p>Date of the actual completion of the international search</p> <p style="text-align: center;">26 SEPTEMBER 1995</p>	<p>Date of mailing of the international search report</p> <p style="text-align: center; font-size: 1.5em;">19 OCT 1995</p>
<p>Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231</p> <p>Facsimile No. (703) 305-3230</p>	<p>Authorized officer <i>Krisanne M. Thornton</i> KRISANNE M. THORNTON</p> <p>Telephone No. (703) 308-0196</p>