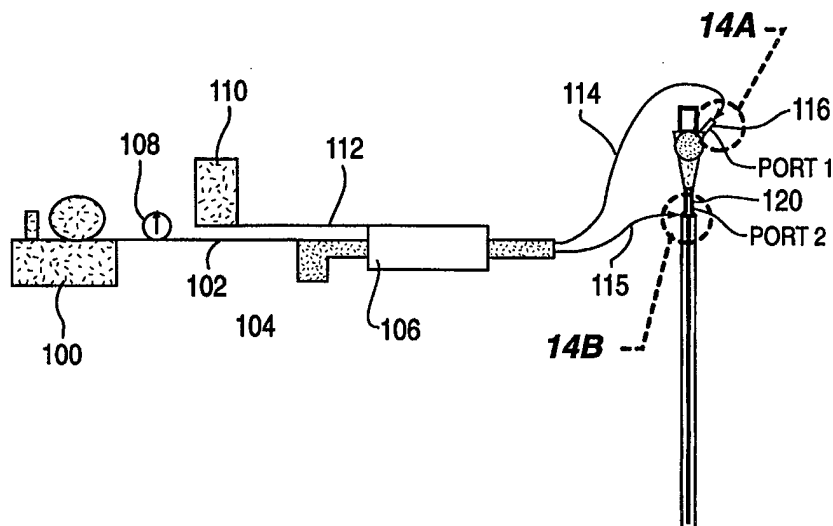




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<b>(21) International Application Number:</b> PCT/US98/11401 <b>(22) International Filing Date:</b> 11 June 1998 (11.06.98) <b>(30) Priority Data:</b> 08/880,662      23 June 1997 (23.06.97)      US <b>(71) Applicant:</b> PRINCETON TRADE AND TECHNOLOGY, INC. [US/US]; 1 Wall Street, Princeton, NJ 08540 (US). <b>(72) Inventors:</b> LABIB, Mohamed, Emam; 650 Ewing Street, Princeton, NJ 08540 (US). LAI, Ching-Yue; 124 Review Avenue, Lawrenceville, NJ 08648 (US). <b>(74) Agent:</b> MORRIS, Birgit, E.; 5 Tall Timbers Drive, Princeton, NJ 08540 (US).		<b>(81) Designated States:</b> CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** CLEANING COMPOSITION AND APPARATUS FOR REMOVING BIOFILM AND DEBRIS FROM LINES AND TUBING AND METHOD THEREFOR

**(57) Abstract**

Biofilm/debris is removed from interior and exterior surfaces of small bore tubing by passing an aqueous cleaning solution of water, one or more surfactants and preferably a hydrogen peroxide source, optionally including small inert solid particles, together with a gas under pressure, to create a turbulent flow within the tubing which loosens the biofilm/debris so it can be flushed from the tubing. When the exterior tubing surfaces are cleaned, the tubing is inserted in a sleeve fitted with an adaptor providing a pressure-tight seal between the tubing and the sleeve. The figure schematically shows an apparatus for cleaning interior and exterior walls of endoscopy tubing: Compressor (100) carries air in line (102) through pulsation control nozzle (104) to mixing chamber (106); air flow is controlled by pressure regulator (108). Chamber (110) stores cleaning solution, passing it through line (112) to mixing chamber (106), and the resultant turbulent mixture passes through line (114) to adaptor (116) providing a pressure-tight fitting to a port of tubing (120), while line (115) carries cleaning solution to the exterior tubing surfaces.

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CLEANING COMPOSITION AND APPARATUS FOR REMOVING  
BIOFILM AND DEBRIS FROM LINES AND TUBING AND METHOD THEREFOR

This invention relates to a mixed-phase cleaning  
solution and method for removing bacteria with pathogenic  
5 potential and other microorganisms, debris, tissue, food  
particles and the like from lines and tubing, and to an  
apparatus that delivers the mixed-phase cleaning solution  
under pressure to the lines and tubing to be cleaned.

BACKGROUND OF THE INVENTION

10 Small bore tubing that delivers ordinary running  
water, purified or not, to fixtures such as dental units,  
develop bacterial and fungal growth from the water on their  
interior surfaces, as is well known. Bacteria present in the  
water strongly adhere to tubing surfaces and then grow  
15 laterally, forming what is known as biofilm. Biofilm is  
apparent to the touch as a slimy film which has been  
analyzed and found to be bacterial growth.

Several prior art workers have identified various  
bacteria included in these biofilms, which include several  
20 bacteria having pathogenic potential, such as  
Flavobacterium, Moraxella, Achromobacter, Pseudomonas,  
Alcaligenes, Micrococcus and Legionella. All of these  
bacteria have the potential to cause infections in humans,  
and legionella, which is highly resistant to antibiotics, is  
25 of particular concern since infection can be fatal.  
Organisms such as legionella can also be inhaled from  
contaminated water spray during dental or other medical  
treatment.

Dental unit tubing that carries rinse water to the mouth of patients has been determined to contain over one million ( $1 \times 10^6$ ) colony forming units of bacteria per milliliter of water (CFU/ml) after one week of use. Thus these water lines and tubing must be periodically cleaned to ensure the removal of this biofilm on the walls of the tubing to prevent infection. The potential for infection of immuno compromised patients is also a major concern. If the patient has any open wounds in the mouth, the danger of infection is of course much higher.

Biofilms are very difficult to remove from tubing however. The biofilm is strongly adherent to smooth tubing surfaces, whether the tubing is made from natural or synthetic materials such as rubber-based materials, polyethylene, polytetrafluoroethylene and the like. Treatment with disinfectant and biocidal agents may kill the bacteria and so remove the biofilm. However, these agents do not readily diffuse into the biofilm which strongly adheres to the tubing walls, and thus removal is generally only partial and the biofilm returns quite rapidly. Reduction of the level of bacteria present in water delivery systems to below 200 CFU/ml has been suggested by the American Dental Association.

Other applications employing small bore tubing that must be periodically cleaned include internal endoscopy tubing, catheter tubing, sterile filling ports, and tubing used for sterile manufacturing, food processing and the like. These types of tubing may contain, in addition to

biofilm, food particles, tissue particles, mucous, blood and the like, which is referred to hereinafter as "debris". Such tubing also must be thoroughly cleaned, these between each and every use, to prevent infection from one patient to another.

Guidelines for cleaning gastrointestinal endoscopy units promulgated by the American Society for Gastrointestinal Endoscopy include a multi-step method for cleaning tubing between patients to prevent infection.

First, mechanical cleaning with a brush is performed, using a detergent solution, soon after use. The tubing is then rinsed with water and then a sterilization is carried out using a disinfecting solution such as a gluteraldehyde solution. The tubing is then rinsed with water again and then dried with forced air.

Other applications for the present invention are respirators, both neonatal and adult, which must be cleaned about every 8 hours or so. Such cleaning is expensive, but necessary.

Thus an improved cleaning composition and method for removing biofilm and debris from interior and external tubing surfaces in a cost effective manner and for preventing or delaying biofilm reoccurrence, and an apparatus to deliver these cleaning solutions to the lines and tubing that have become contaminated, would be highly desirable.

#### SUMMARY OF THE INVENTION

In accordance with the present invention, a

combination of pressurized gas and a suitable aqueous cleaning solution is used to create a turbulent environment on or in a tubing having a biofilm or debris on interior or exterior surfaces, that completely removes the biofilm and debris. A suitable aqueous cleaning solution comprises water and a surfactant. An oxidizing agent and a biocidal agent can also be added. Inert particles that can provide a scrubbing action can also be added advantageously to the aqueous cleaning solution. This aqueous cleaning composition is delivered to the tubing to be cleaned by means of compressed gas, thus making a mixed-phase system, that provides a turbulent flow along the walls of the tubing that aids in loosening the biofilm and debris from the surfaces of the tubing, and aids in flushing the loosened materials from the tubing.

The invention also includes an apparatus for delivering the above mixed-phase cleaning solution to the interior of small bore tubing and lines and combining it with a gas under pressure. The compressed gas-aqueous cleaning solution combination develops turbulent flow inside the tubing that aids in loosening the biofilm from the interior surfaces of tubing so that it can be readily removed by flushing and rinsing with water.

The invention also includes an apparatus for delivering the above cleaning solution to the exterior surfaces of small bore tubing and lines, by encapsulating the tubing in a pressure-resistant sleeve having an adaptor that provides a pressure-tight seal between the cleaning solution-

pressurized gas mixture and the tubing. The apparatus includes a mixing chamber for mixing the aqueous solution, optional solid particles and a gas under pressure for delivery to the lines and tubing to be cleaned.

5

## BRIEF DESCRIPTION OF THE DRAWING

Fig. 1 is a schematic view of an aqueous cleaning composition delivery system of the present invention.

Fig. 2 is a high magnification photomicrograph of the inside wall of tubing having a biofilm thereon used in a dental unit, which biofilm is about one year old.

10

Fig. 3 is a photograph of an overall view of the interior wall of dental tubing after cleaning in accordance with the invention.

15

Fig. 4 is a photograph of the interior wall of another dental tubing prior to treatment according to the invention.

Fig. 5 is a photograph of an overall view of the interior wall of the dental tubing of Fig. 4 after treatment according to the invention.

20

Fig. 6 is a photograph of an overall view of the interior wall of another dental tubing prior to treatment according to the invention.

Fig. 7 is a photograph of the interior wall of a portion of the dental tubing of Fig. 6 after treatment.

25

Fig. 8 is a photograph of still another dental tubing prior to treatment according to the invention.

Fig. 9 is a photograph of the wall of Fig. 8 after treatment in accordance with the invention.

Fig. 10 is a photograph of a closeup view of another

portion of dental tubing prior to treatment.

Fig. 11 is a photograph of a closeup view of the tubing of Fig. 10 after treatment in accordance with the invention.

5           Fig. 12 is a photograph of the interior wall of still another dental tubing prior to treatment.

Fig. 13 is a photograph of the interior wall of Fig. 12 after treatment with a control cleaning solution.

10           Fig. 14 is a schematic view of an apparatus used to remove biofilm and debris from the internal and external surfaces of endoscopy tubing.

Fig. 14A is a magnified view of a port leading to the interior of the endoscopy tube.

15           Fig. 14B is a magnified view of a port connecting the exterior wall of the endoscopy tube with a sleeve.

Fig. 15 is a photograph of the interior of an endoscopy tube prior to cleaning.

Fig. 16 is a photograph of the interior of an endoscopy tube after cleaning in accordance with the invention.

20           Fig. 17 is a photograph of the exterior of an endoscopy tube prior to cleaning.

Fig. 18 is a photograph of the exterior of an endoscopy tube after cleaning in accordance with the invention.

#### DETAILED DESCRIPTION OF THE INVENTION

25           The aqueous cleaning solution useful herein contains water and a surfactant that, when mixed under pressure with a gas such as air, acts to loosen organic residues from tubing surfaces so they can be rinsed away. Since the



cleaning solution is water-based, environmental problems relating to waste disposal are reduced or non-existent.

The aqueous cleaning solution can comprise water and a surfactant alone, but preferably includes an oxidizing agent, such as a hydrogen peroxide source.

Suitable surfactants can be nonionic, anionic or cationic, or mixtures thereof. Any surfactant that is compatible with water or aqueous solutions can be used, generally in a concentration of up to about 5% by weight of the cleaning solution.

Suitable anionic surfactants include for example alkyl sulfates and sulfonates such as sodium dodecyl sulfate. Nonionic surfactants can be added to increase the wetting of the organic material to be removed, and to improve the quality of the foam generated when the aqueous surfactant-containing solution is mixed with a gas under pressure.

Cationic surfactants, such as quaternary amines, have a strong interaction with glycoproteins and bacterial cell walls present in biofilms, and thus solubilize the bacterial and fungal matter in the biofilm. Cationic surfactants are also known that have disinfectant properties.

These surfactants provide a foaming action to the aqueous solution which helps to provide a turbulent flow in the tubing to be cleaned, and also aids in loosening the biofilm or debris from the tubing surface. In particular, quaternary amine surfactants produce small bubbles in solution that further aid in forming a turbulent flow in the gas-cleaning solution mixture during cleaning, adding a

scrubbing action against the biofilm that aids in its effective and efficient removal.

The presence of an oxidizing agent is also believed to aid in loosening the biofilm from the interior and exterior walls of tubing and lines. Suitable oxidizing agents include aqueous hydrogen peroxide solutions, or peroxy compounds such as perborates, periodates and peroxy-carboxylic acids that produce hydrogen peroxide in situ in an aqueous solution. Solid oxidizing agents, such as peroxy-carbonates and the like, may also provide a further scrubbing action.

Further, oxidizing agents have biocidal properties that not only aid in efficiently reducing bacterial material from tubing walls, but also reduce the re-occurrence of biofilm. Mixing a peroxide-surfactant solution with compressed air produces a thick froth, enhanced by the peroxide, in the tubing which removes biofilm more effectively than water and air alone. The oxidizing agents are suitably present in amounts of up to about 15% by weight of the aqueous solution, preferably about 3-15% by weight.

Inert particles can also be added advantageously to the aqueous cleaning solution of the invention to provide a further scrubbing action to the tubing walls. Hard insoluble particles, such as of silica, alumina and titania, will provide the most effective scrubbing action together with surfactant foams. Soft insoluble inert particles such as calcium carbonate, preferably having a small particle size such as 10-300 microns, can advantageously be used. These materials are normally used already as abrasives for

cleaning teeth or removing plaque and for polishing teeth and gums. Water soluble particles, such as sodium bicarbonate, can also be added. Since removal of biofilm takes place rapidly in accordance with the invention, some scrubbing action by the water soluble particles is obtained prior to their dissolution. The fact that the particles are water soluble means that they dissolve during the rinsing or flushing step, so that the particles are removed from the tubing surfaces in solution, thus reducing the number of solid particles that must be flushed out of the tubing after cleaning.

A sufficient amount of inert, insoluble particles can be added to the above cleaning solution to provide increased erosion of the biofilm by impact of the particles on the walls of the tubing to be cleaned in a turbulent environment. However, in order to remove biofilm, the particle size of the inert particles should be on the order of 10-300 microns, which may be somewhat larger than particles used in tooth pastes for example. The particle shape is not critical, but may be adjusted to maximize the effectiveness of the present process. For example, an irregularly shaped particle may be preferred to a smooth walled particle to increase the scrubbing action of the mixture. The particles preferably are hydrophobic so that they can be carried along in the cleaning solution by air bubbles. For example, generally up to about 20% by weight of inert particles are suitably added to the cleaning solution.

The temperature of use of the cleaning mixture of the

invention can vary from about 0-50°C.

The cleaning solution and the inert particles used herein are safe and non-toxic. Most of the ingredients are already used in present-day dental practices and thus present no danger to patients. The cleaning solution can be discharged into municipal sewage systems. The cleaning solution is also safe, i.e., non-toxic and non-carcinogenic, and is non-corrosive to commonly available plastics such as polyvinylchloride, polyolefin and polytetrafluoroethylene tubing.

The cleaning solution is used together with a pressurized gas that provides turbulence of the cleaning solution inside the tubing. Although the invention is hereinafter described using air as the gas, other gases can be substituted such as oxygen, nitrogen, carbon dioxide, noble gases such as argon and the like. Such gases may be stored under pressure in cylinders, or available from in-house gas sources.

The mixture charged to the tubing to be cleaned preferably includes a surfactant that produces bubbles or froth in the aqueous solution, a surfactant that produces a foaming action to the aqueous solution, and air under pressure. This mixed-phase mixture is charged to the small bore tubing to be cleaned in a sufficient volume to loosen and remove biofilm in a short time, i.e., about 3-10 minutes. The volume of the mixed-phase cleaning solution can thus be maximized for various applications.

To further increase the scrubbing action of the above

mixture, the pressurized air can be pulsed.

The air or other pressurized gas is delivered under a pressure of above about 25 psi, preferably at a pressure of about 30 to 60 psi for dental tubing. However, the pressure range is not critical and can be adjusted to be higher according to the tubing diameter.

After the small bore tubing has loosened the biofilm and/or debris, water alone, together with pressurized air, can be used to remove all solid materials from the tubing. This flushing step generally takes another 3 or more minutes.

The invention will be first described in the Examples in terms of cleaning dental tubing that supplies cleaning water under pressure. The pressure is supplied by an air compressor that can continuously supply up to 80-100 psi of compressed air. This pressure is stepped down to about 30-60 psi prior to entry of the cleaning composition to the hand cleaning syringe used by the dental practitioner. As a comparison, water is generally delivered by municipal water systems at a pressure of about 25 psi.

Fig. 1 is a schematic diagram of a modified coolant and irrigation apparatus for use by a dental practitioner. The conventional system includes an air compressor 12, an air line 13, a pressure regulator 14, a water line 16 for adding water or other aqueous solution to the compressed air in line 13, an air adaptor 18 and a water adaptor 19 to permit the dental practitioner to adjust the volumes of air in line 20 and water in line 21 delivered to a hand held fixture 22.

In accordance with the present invention, the conventional apparatus is modified to deliver the present cleaning solution to water line 21 to clean it.

5 A three way valve 24 is used to direct the pressurized air to air line 13A. A solenoid valve 26 is inserted into line 13A to impart a pulsing action to the pressurized air.

10 A pressurized container 28 that is refillable stores the cleaning solution of the invention. An air tight cap (not shown) permits the cleaning solution to be replaced and line 13A permits pressurized air to enter the container 28. The outlet line 30 is connected to a mixing chamber 32.

15 The mixing chamber 32 is connected to the pressurized air line 13A and to the cleaning solution outlet line 30. The cleaning solution and pressurized air are mixed in the mixing chamber 32 to create a turbulent mixture or froth depending on the ratio of air to cleaning solution, which can be adjusted.

20 Additional pressurized containers can be included. As shown in Fig. 1, a container 34 is connected to water line 16 and can include a biocide for example. The outlet from the container 34 can be directly connected to water line 16 or can be connected to the mixing chamber 32 for addition to the cleaning solution mixture.

25 A water source can be connected to the water line 16 or to the mixing chamber 32 to flush the dental water line 21 with water subsequent to cleaning with the cleaning solution of the invention.

A conventional control panel (not shown) can be used to

regulate the air pressure in the system, to turn the solenoid valve 26 to impart a pulsating action to the compressed air, to control the temperature of the solutions, to control the three-way valves during regular dental unit operation, during cleaning and during flushing operations, to add biocide solution from the chamber 34 and the like. An alert light can be included to alert attendants that it is time to clean the dental tubing. The above system can be enclosed in a suitable housing if desired.

Thus during the cleaning cycle, the top water line 36 is shut off via valve V1 and compressed air is directed to the container 28 via valve V2. The solenoid valve 26 is activated to create a pulsating action to the compressed air which is passed to the container 28, and to the additional container 34 if required. A froth is formed in the mixing chamber 32 and is forced into the dental unit adaptor 19 to the dental tubing water line 21.

During the rinsing or flushing cycle, cleaning solution is shut off in line 30 via valve V3 and biocide or an alkaline peroxide solution and water can be directed to the mixing chamber 32 together with pulsating compressed air through line 13A. The pressurized water is passed through the dental tubing 21 to flush out cleaning solution, loosened biofilm and any solid particles or debris remaining in the tubing 21. The addition of a biocide and/or a peroxide may increase the time period that elapses before biofilm starts to re-form.

At the end of the flushing cycle, normal operation of

the dental unit is resumed, using tap water alone or tap water including a biocide stored in container 34.

The cleaning, flushing and normal operation cycles are each continued for a certain period of time, as  
5 predetermined by the manufacturer or the practitioner.

The turbulent flow in the mixing chamber 32 provides bubbles or froth patterns by manipulating the ratio of air:liquid:particles and the flow speeds of the cleaning solution and compressed air. The compressed air creates  
10 liquid droplets, or suspends any solid particles in the cleaning solution, and thus produces an effective method of eroding the biofilm via a dynamic impact of the solution and froth or inert particles on the tubing walls.

As an example, air forced through a 1.8 mm diameter  
15 tubing, using 30-60 psi air pressure, has a Reynolds number between about 9700 and 15,000, which is considered to be turbulent in a pipe-type geometry. The addition of inert particles or liquid droplets to the cleaning solution further increases the cleaning effectiveness of the  
20 solution. When the biofilm has a thickness of 5-10 microns, the relationship between the applied air pressure and the friction force can be estimated in accordance with known one dimensional energy equations.

Calculated and measured velocities in an 8 foot long  
25 dental tubing 1.8 mm in diameter were in good agreement with each other.

Further, the fact that some dental tubing is continuously curled is an excellent geometry for the present



cleaning method because it causes random impact of the air, solid particles and solution against the tubing walls to loosen and erode the biofilm rapidly and completely.

The invention will be further described in the following Examples 1-6 with respect to cleaning dental tubing, but the invention is not meant to be limited to the details described therein. In the Examples, percent is by weight unless otherwise noted.

#### Example 1

A portion of dental tubing having a biofilm about one year old on its interior surface is shown in Fig. 2. The biofilm completely covers the interior surface of the tubing and consists of about 200,000 colonies/cm of bacteria.

A three foot section of the tubing was treated in accordance with the invention using a cleaning solution of 3% aqueous hydrogen peroxide containing 5% by weight of inert particles of calcium carbonate 50-100 microns in size, and surfactants including about 2% of an anionic surfactant, sodium dodecyl sulfate, and about 1% of a nonionic surfactant. The cleaning solution was added to the mixing chamber 28 of Fig. 1 and air was added to the mixing chamber from a 1 HP air compressor regulated at 30-60 psi, the air being continuously pulsed. The amount of air and the pulse rate were regulated to optimize mixing of the ingredients and the turbulence generated inside the tubing. The mixture was passed to the dental tubing to permit turbulent cleaning of the tubing.

The tubing was then flushed with distilled water. The

interior surface of the cleaned tubing is shown in Fig. 3. It is apparent that the biofilm has been completely removed.

The cleaned tubing was tested for bacteria by scraping the interior surface of a section of the tubing 2.5 cm long and collecting water in that portion of the tube as follows. The tubing was cut in half, about 1.25 cm in length, and three pieces were stored at 4°C. The lumen of each piece was scraped 15 times with the tip of a sterile scalpel blade to remove any bacteria and the scalpel and the tubing were agitated in water for one minute to suspend any bacteria present. The resultant suspension was diluted 10 fold and spread onto dilute peptone agar plates using distilled water. The water in the tubing was also diluted and plated. The plates were incubated for two weeks at 25°C and the bacteria colonies counted and identified according to conventional practice, including Gram strain calitose reaction, oxidase and glucose fermentation tests. The total number of bacteria and the total number of viable bacteria were counted according to the procedure of Hobbe et al, Applied & Environmental Microbiology, May, 1977 pp 1225-1228; and Kogure et al, Can. J. of Microbiology Vol. 25, pp 415-420 (1979).

The cleaned tubing had only 280 colonies/cm of tubing, whereas untreated tubing had about 200,000 colonies/cm of tubing. Thus a reduction in bacterial count of one thousand times was obtained. The large white particles in Fig. 4 are believed to be deposits due to water hardness that accumulate over a long period of time.

Example 2

A cleaning solution was made by mixing 50 grams of calcium carbonate particles having a particle size of 10-100 microns into 450 ml of a solution containing 3% by weight of hydrogen peroxide solution, 2% by weight of a surfactant, sodium dodecyl sulfate and 1% of a nonionic surfactant.

The above mixture was introduced into a used dental tubing 3 feet long and 1.8 mm in diameter having a biofilm thereon, as shown in Fig. 4, together with air supplied by a compressor set between 30 and 60 psi. The cleaning composition was flushed through the tubing for about 3 minutes.

The tubing was then flushed with 200 ml of distilled water.

The number of bacterial colonies in the tubing decreased from an initial value of  $7.15 \times 10^5$  per linear cm of tubing down to zero after cleaning. The CFU/ml of water flowing in the tube was reduced from an initial value of  $3.19 \times 10^6$  to zero after cleaning.

The SEM photograph of Fig. 5 is an overall view of the interior wall of the tubing after treatment. Fig. 5 shows a complete removal of biofilm in the lumen of the tubing. The bare surface of the tubing was free of any debris or biofilm.

Example 3

576 Milliliters of 3% by weight of aqueous hydrogen peroxide solution was admixed with 2% by weight of sodium dodecyl sulfate surfactant. The cleaning reagent was

introduced into used dental tubing with air supplied by a compressor set at a pressure of 30 to 60 psi. After treatment for three minutes, the tubing was flushed with 200 ml of water.

5           The number of bacterial colonies per cm of tubing after culture decreased from an initial value of  $1 \times 10^5$  to zero. The CFU/ml of the water decreased from an initial value of  $3.01 \times 10^6$  to zero.

10           Fig. 6 is a photograph of the interior wall of the tubing prior to treatment. Fig. 7 is a photograph of the interior wall of the tubing after treatment.

          Thus in the presence of hydrogen peroxide, surfactant and air under a preselected pressure, complete cleaning was achieved even in the absence of solid particles.

15           Example 4

          The procedure of Example 2 was followed except substituting distilled water for the hydrogen peroxide solution.

20           The CFU/cm decreased from an initial value of  $4 \times 10^5$  to zero. Thus a mixture of water, surfactant, abrasive particles and air under a preselected pressure was sufficient to remove the biofilm from the tubing.

          Fig. 8 is a photograph of the interior surface of the tubing prior to treatment.

25           Fig. 9 is a photograph of the interior surface of the tubing after treatment according to this example.

Example 5

          A cleaning solution was made from 193 ml of 3% by

weight of hydrogen peroxide, 3% by weight of sodium dodecyl sulfate surfactant and 50-100 grams of water soluble sodium bicarbonate particles. The solution was brought to 600 grams with distilled water.

5           The cleaning solution was introduced into used dental tubing along with air from a compressor set at 30-60 psi for three minutes. The tubing was then flushed with distilled water.

10           The CFU/cm decreased from an initial value of  $5.5 \times 10^4$  to zero and the CFU/ml was reduced from an initial value of  $3 \times 10^6$  to zero. SEM photograph of Fig 10 shows the presence of biofilm prior to treatment, and a complete removal of the biofilm from the lumen of the tubing after treatment, as can be seen in Figs. 11.

15           Example 6

          A mixture of 5% of sodium dodecyl sulfate surfactant and peroxycarbonate and 1% of polyphosphate was mixed with water to a total of 600 ml. The mixture was introduced into used dental tubing with air under pressure supplied by a  
20           compressor set at 30 to 60 psi for three minutes. The tubing was then flushed with 200 ml of water.

          The CFU/cm was reduced from an initial value of  $1.25 \times 10^5$  to zero and the CFU/ml was reduced from an initial value of  $3 \times 10^6$  to zero.

25           Control

          As a control, water alone was mixed with air from a compressor set at 30-60 psi and passed through used dental tubing for three minutes.

The CFU/cm was reduced from an initial value of  $7.5 \times 10^4$  to  $3.5 \times 10^4$ . However, the CFU/ml of water was reduced only from  $2.5 \times 10^6$  and was  $2.38 \times 10^6$  after treatment.

The SEM photograph of Fig. 12 shows the presence of  
5 biofilm prior to the Control treatment and Fig. 13 shows a reduction of only about 30% in the biofilm after treatment.

Thus physical force of air and water alone is not sufficient to adequately remove biofilm from tubing.

In order to adequately maintain dental or medical  
10 tubing without substantial biofilm accumulation, the above treatment should be repeated at least about every 100 hours.

As biofilm ages, bacteria colonies not only multiply, but they become more adherent to the surface of the tubing.  
15 Thus, if treatment is repeated often, e.g., every 4-5 days, the biofilm remains comparatively easy to remove with the composition and process of the invention.

The present cleaning solutions and method can also be used to remove other contaminants in addition to biofilm  
20 from tubing, such as organic films, mucous or solid debris, e.g., tissue, loose cells, food particles and the like, that adhere to tubing walls.

A major application for such cleaning is endoscopy tubing, which in accordance with the present invention can  
25 be cleaned on both interior and exterior walls. Fig. 14 is a schematic view of a cleaning apparatus that can be used to clean both the interior walls of an endoscopy tube and the exterior walls.

An air compressor 100 carries air in line 102 through a compressed air pulsation control nozzle 104 to a mixing chamber 106. A pressure regulator 108 controls the air flow. A chamber 110 for the storage of cleaning solution passes the cleaning solution to the mixing chamber 106 through a line 112. The resultant turbulent mixture of pressurized air and cleaning solution is passed via line 114 to an adaptor 116 (see Fig. 14A) that provides a pressure-tight fitting to the port 118 of the endoscopy tube 120. Fig. 14A is a magnified view of the adaptor 116 and the endoscopy port 118.

Fig. 14B is a magnified view of an external port 122 that fastens a pressure-tight sleeve 124 by means of an adaptor 126 to accommodate the line 115 carrying cleaning solution to the external surfaces of the endoscopy tube. The sleeve 124 can be made of any flexible plastic such as cellulose materials, polyolefins and polyesters.

Using the apparatus of Figs. 14, Fig. 14A and Fig. 14B, the following examples were carried out to clean endoscopy tubing.

#### Example 7

A flexible tubing having a length of about 6 feet and an internal channel diameter of about 0.110 cm was partially filled with a debris mixture of food residue including carbohydrates (starch), proteins and sugars and allowed to dry overnight. This residue was designed to simulate debris remaining after an endoscopy procedure. The debris can be clearly seen in Fig. 15, which is a low magnification view.

In a first step, the internal channels were filled with water for 5-10 minutes to soften the debris residue.

A mixture of cationic surfactants of 0.05% octyldecyldimethyl ammonium chloride, 0.025% dioctyldimethyl ammonium chloride and 0.025% didecyldimethyl ammonium chloride and about 1% of nonionic and anionic surfactants mixed with 4% of hydrogen peroxide were used as the cleaning solution. 500 Ml of this solution was mixed with air up to 80 psi pressure and passed through the channel over a 5 minute period.

The channels were then flushed with one liter of water.

The channels were then disinfected using 200 ml of a solution of 3-7% hydrogen peroxide together with pressurized air. The channels were then dried in air for five minutes. The interior walls of the tubing were cleaned of all debris, as shown in Fig. 16.

#### Example 8

The procedure of Example 7 was repeated except the cleaning solution contained a mixture of both anionic and nonionic surfactants at up to 2% concentration in a solution of 3% hydrogen peroxide. All debris was removed.

#### Example 9

The procedure of Example 7 was repeated except the cleaning solution was made by first dissolving the surfactants in distilled water. All debris was removed.

#### Example 10

The procedure of Example 7 was repeated except that 5% of calcium carbonate particles having a particle size of 50-



200 microns was dispersed in the cleaning solution. All debris was removed.

#### Example 11

5 The procedure of Example 8 was repeated except that 5% of calcium carbonate particles having a particle size of 50-200 microns was dispersed in the cleaning solution. All debris was removed.

10 Water soluble particles, such as sodium bicarbonate, can be substituted for the water insoluble calcium carbonate particles.

#### Example 12

15 The external surface of an endoscopy tube about 7 feet long and having an external diameter of 1.1 cm was immersed in a mixture of debris as in Example 7 and allowed to dry overnight. The photograph of Fig. 17 clearly shows the adhered debris on the external surface of the tubing.

20 The stem of the tube was inserted into a flexible cellulose polymer sleeve having a diameter of 1.4 cm. The sleeve and the tube were connected together by means of a pressure-tight adaptor. The cleaning solution (500 ml) of Example 7 was mixed with air at up to 100 psi pressure and passed into the sleeve for five minutes. A water flushing cycle, disinfecting cycle and drying cycle were carried out as in Example 7. All debris was removed from the external  
25 surface of the tubing as can be seen in Fig. 18.

The present cleaning solution can also be sprayed under pressure onto a surface to be cleaned, such as prosthesis implants and respirators for both adults and for neonatal

care.

Although the invention has been described in terms of specific embodiments, the invention is not meant to be so limited. The invention is only to be limited by the scope of the appended claims.

## CLAIMS:

1. An aqueous cleaning solution that removes biofilm and debris from the walls of tubing for dental and medical uses comprises water and a surfactant admixed with air under pressure.
- 5 2. A composition according to claim 1 wherein said solution additionally includes a source of hydrogen peroxide.
3. A composition according to claim 2 wherein said hydrogen peroxide is present in an amount of up to about 15% by weight.
- 10 4. A composition according to claim 1 wherein said solution additionally includes inert particles having a particle size of from 10-100 microns.
5. A composition according to claim 1 wherein said inert particles are present in an amount of up to about 10% by weight of said solution.
- 15 6. A composition according to claim 1 wherein said surfactant is present in an amount up to about 5% by weight.
7. A method of removing biofilm from the interior surfaces of tubing exposed to aqueous solutions comprising mixing an aqueous solution of water and a surfactant with a gas under pressure so as to form a turbulent mixture in said tubing for a time sufficient to loosen said biofilm, and flushing the tubing to remove the biofilm.
- 20 8. A method according to claim 7 wherein said aqueous solution further includes a source of hydrogen peroxide.
- 25 9. A method according to claim 7 wherein said aqueous solution further includes up to 10% by weight of inert solid particles.

10. A method according to claim 7 wherein said gas under pressure is pulsed at intervals of about 0.5 to 1 second.

11. In a dental unit comprising a source of compressed air, a source of water, and a small bore tubing that passes said water and air to a nozzle for delivery of the pressurized air and water to a patient, the improvement which comprises a mixing container for mixing a cleaning solution of water and a surfactant with the pressurized air and delivering the pressurized cleaning solution to said tubing.

12. A dental unit according to claim 11 wherein said cleaning solution further includes a source of hydrogen peroxide.

13. A method of cleaning the interior surface of endoscopy tubing comprising

a) forming a cleaning solution from water, up to 5% of a surfactant and up to 15% of a source of hydrogen peroxide,

b) mixing the cleaning solution with a gas under pressure of up to about 100 psi,

c) providing an adaptor to pass the mixture to the internal surfaces of the tubing, and

d) passing said pressurized cleaning solution to the internal surfaces of said tubing.

14. A method according to claim 13 wherein said surfactants include a cationic surfactant.

15. A method according to claim 14 wherein said surfactants include nonionic and anionic surfactants.

16. A method according to claim 13 wherein prior to step a), the interior surfaces of the tubing are soaked in water.

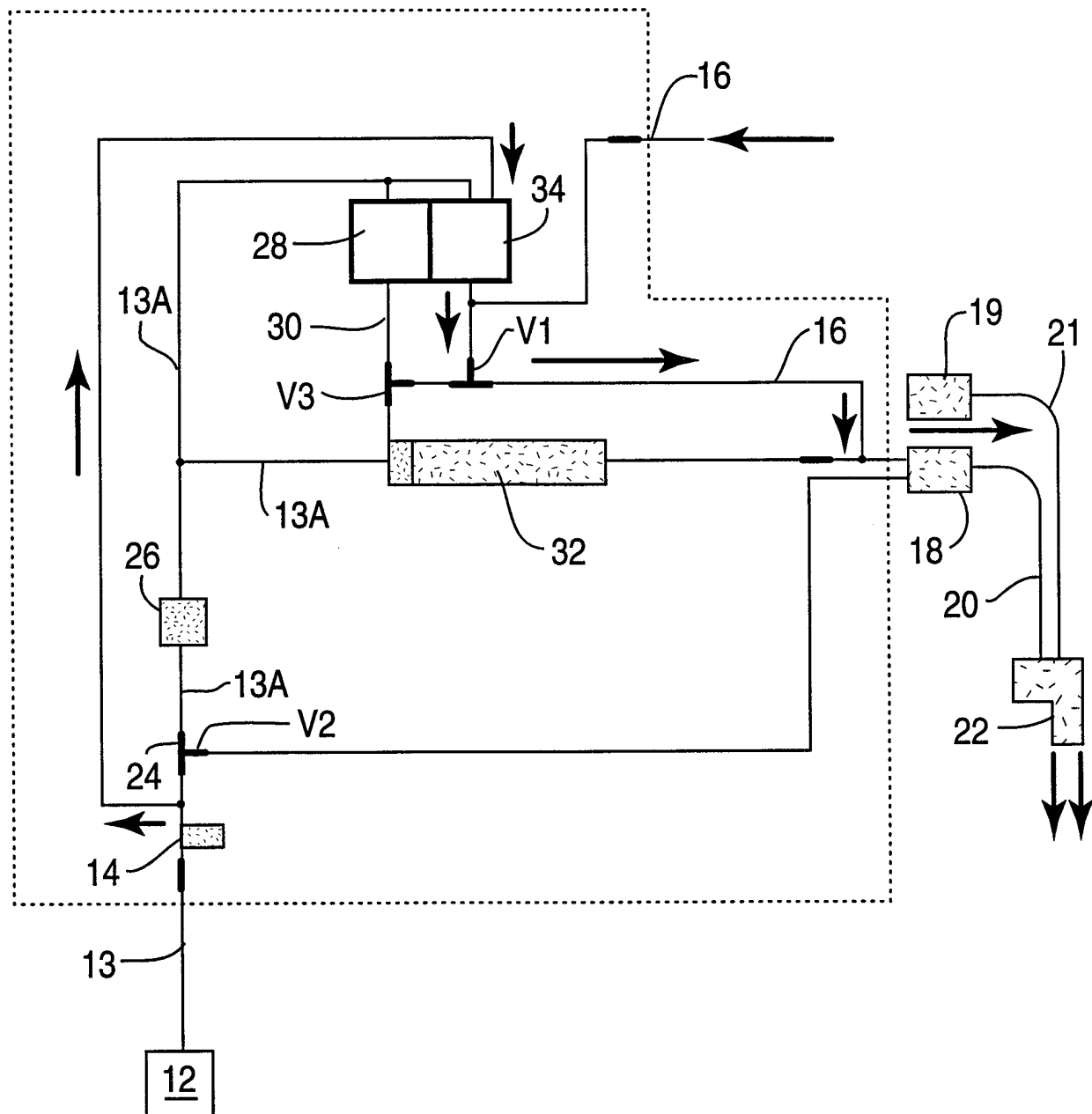
17. A method of cleaning the exterior surfaces of endoscopy tubing comprising

a) encapsulating said tubing in a sleeve fitted with an adaptor to provide a pressure-tight seal between the tubing and the sleeve,

b) forming a cleaning solution comprising water, up to 5% by weight of a surfactant and up to 15% by weight of a source of hydrogen peroxide,

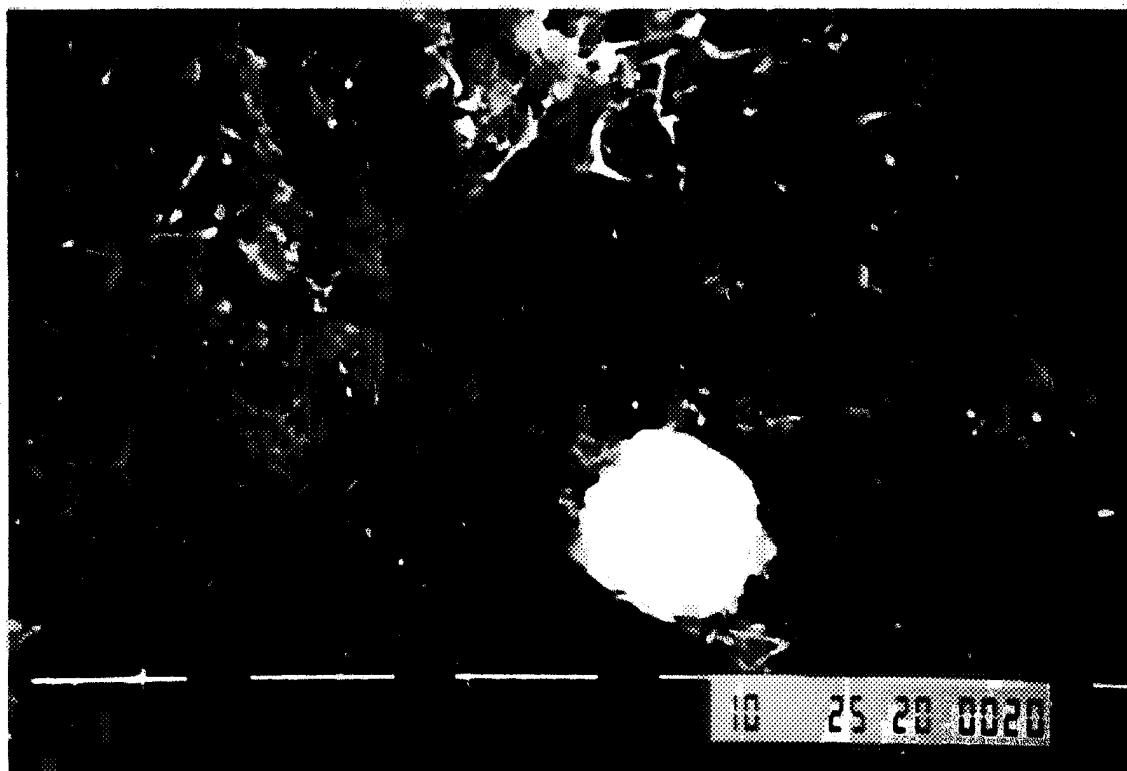
c) mixing said cleaning solution with a gas under pressure of up to about 100 psi, and

d) passing the pressurized cleaning solution between the exterior surface of the tubing and said sleeve.

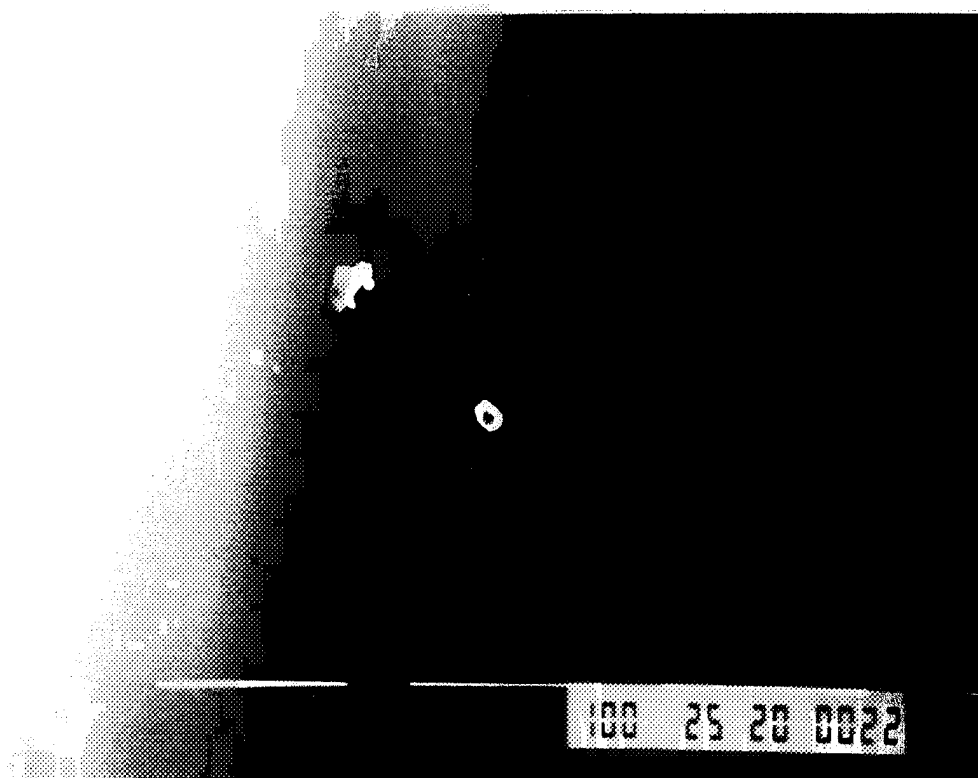


**FIG. 1**

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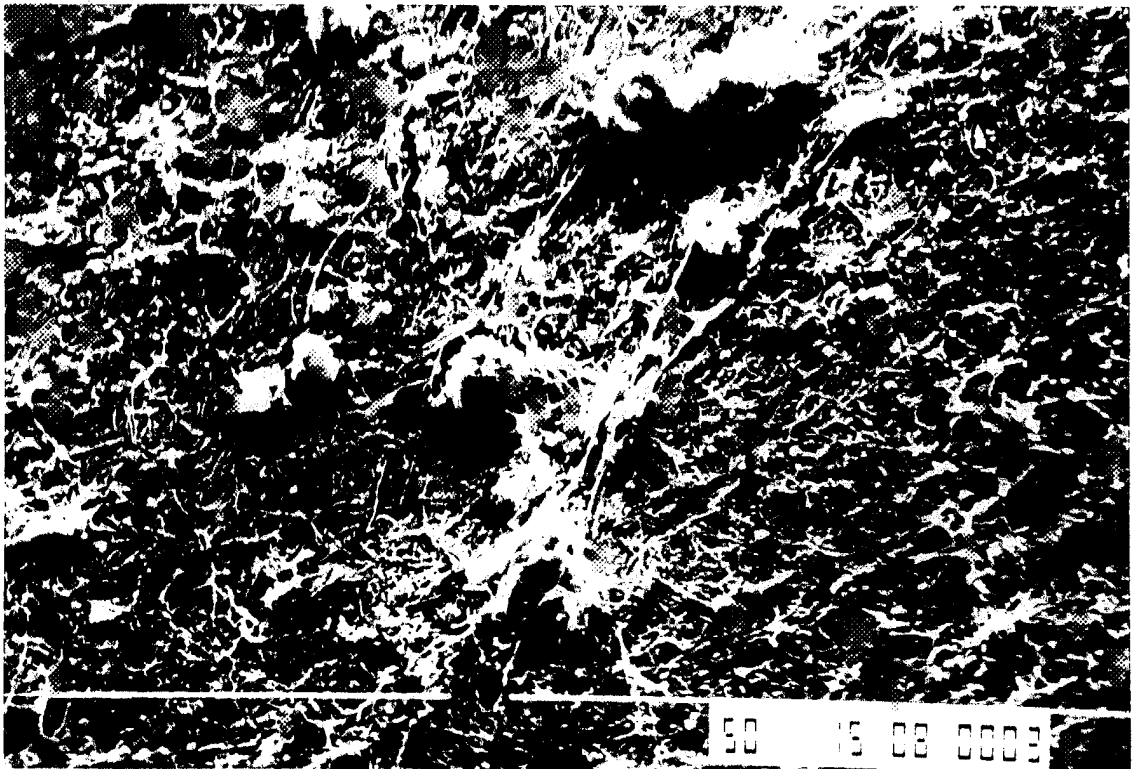


**FIG. 2**

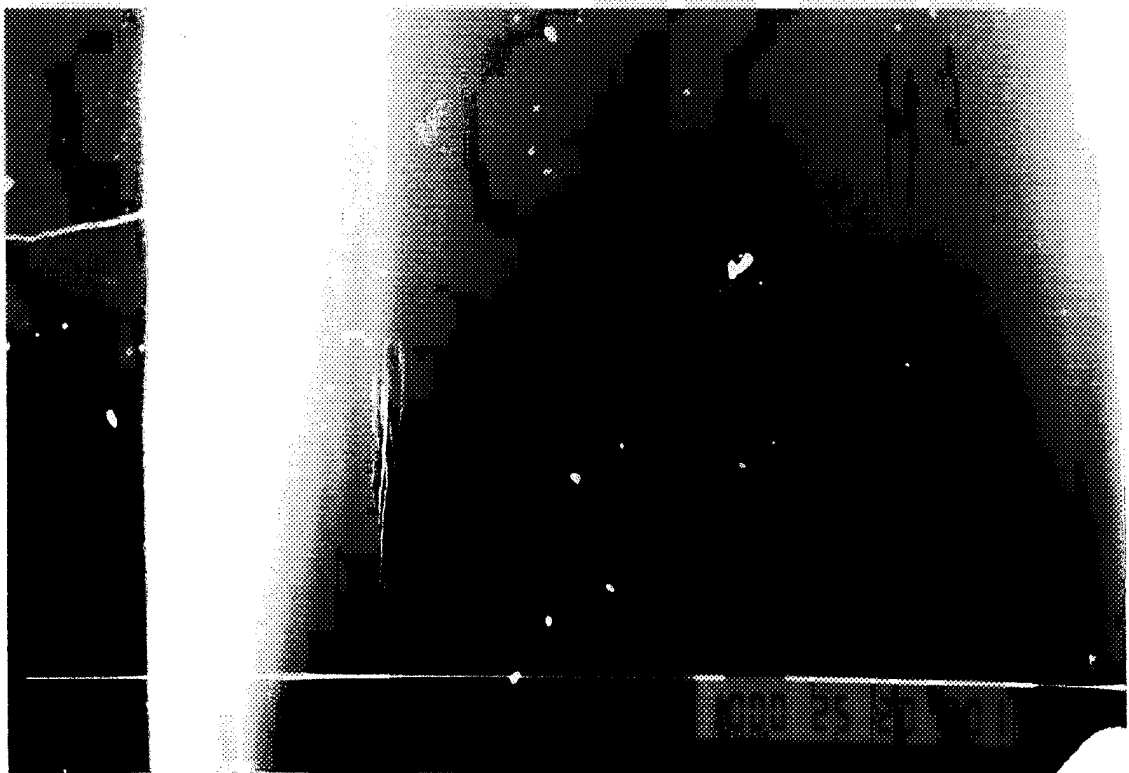


**FIG. 3**

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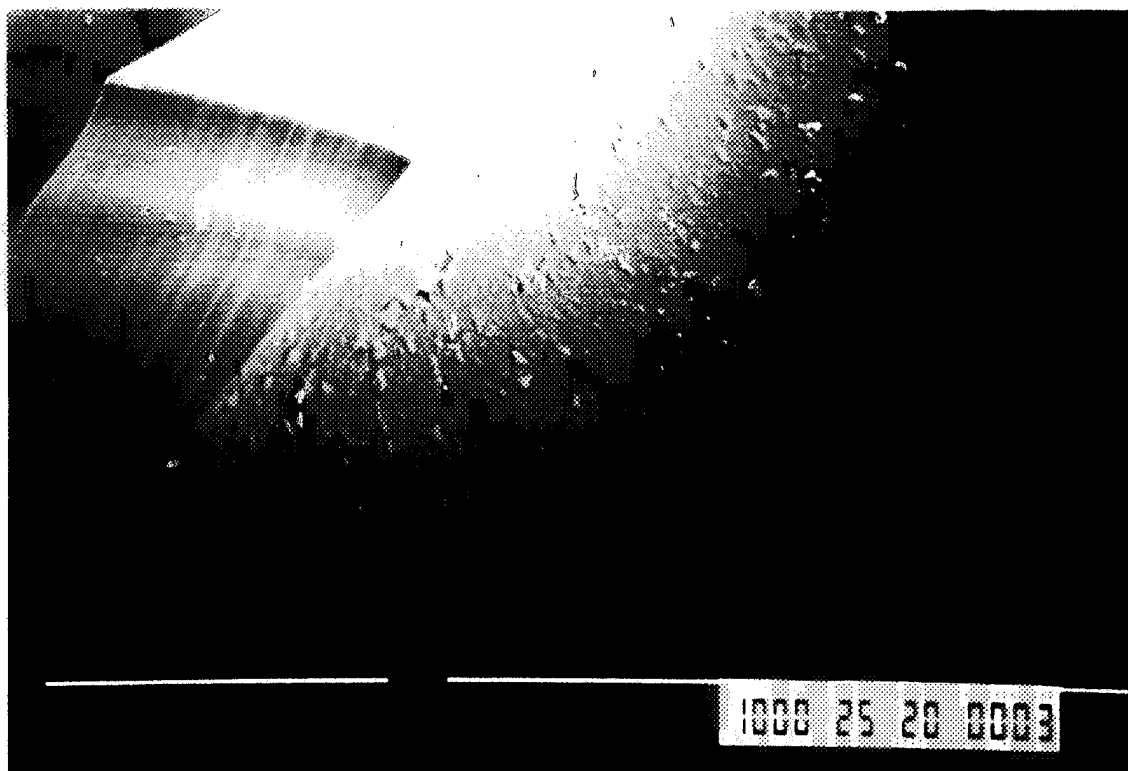
**FIG. 4**



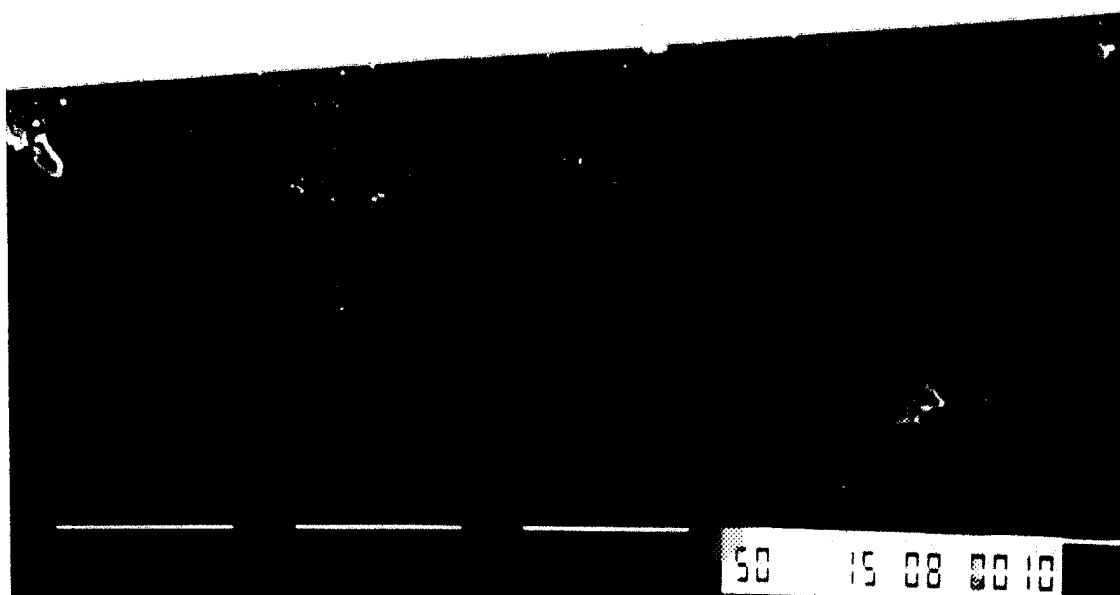
**FIG. 5**



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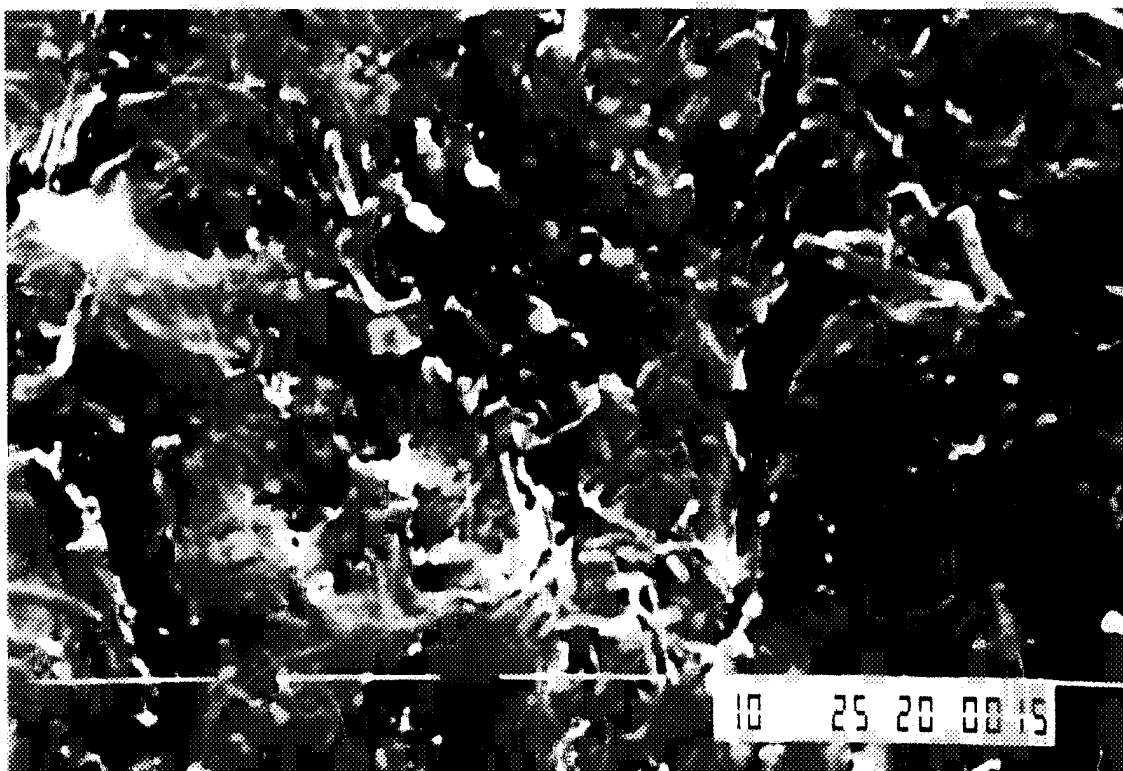


**FIG. 6**

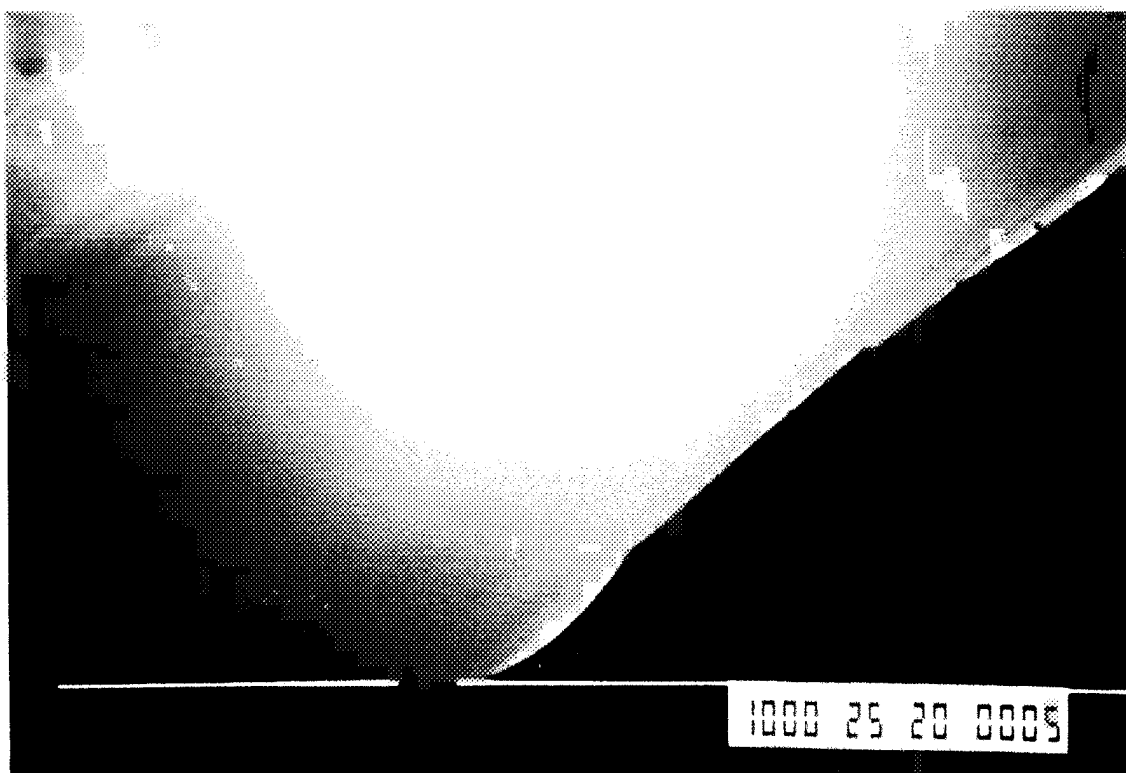


**FIG. 7**

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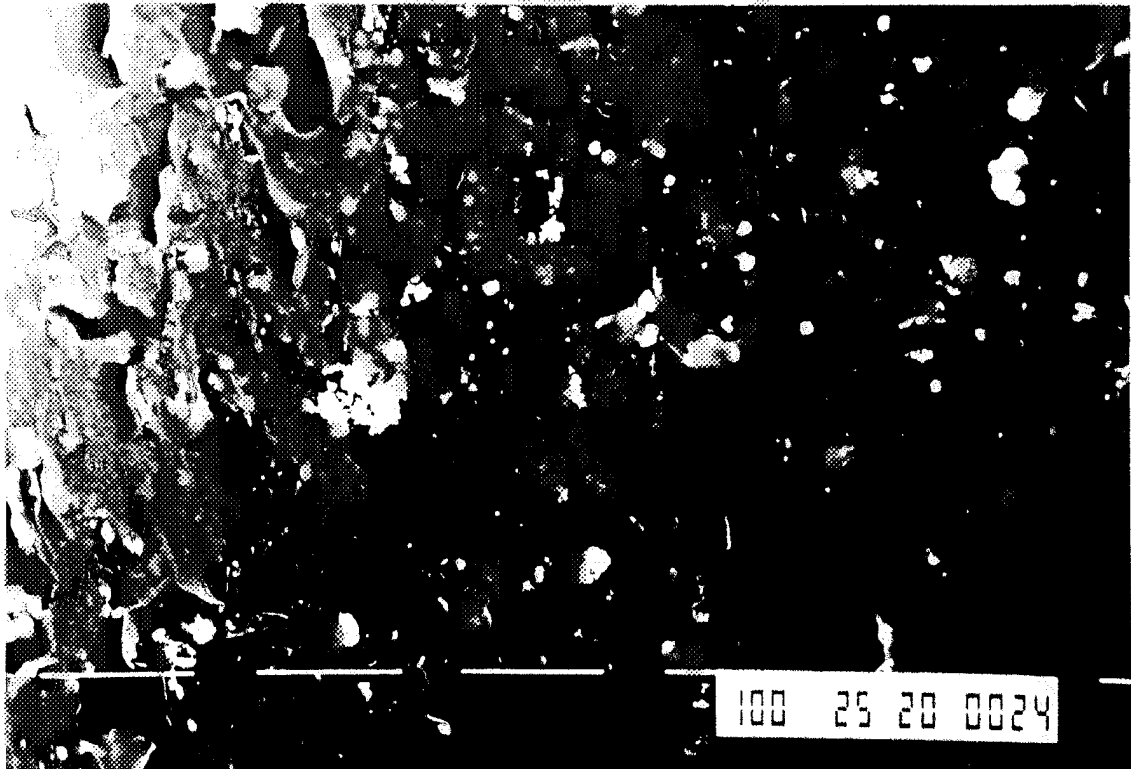


**FIG. 8**

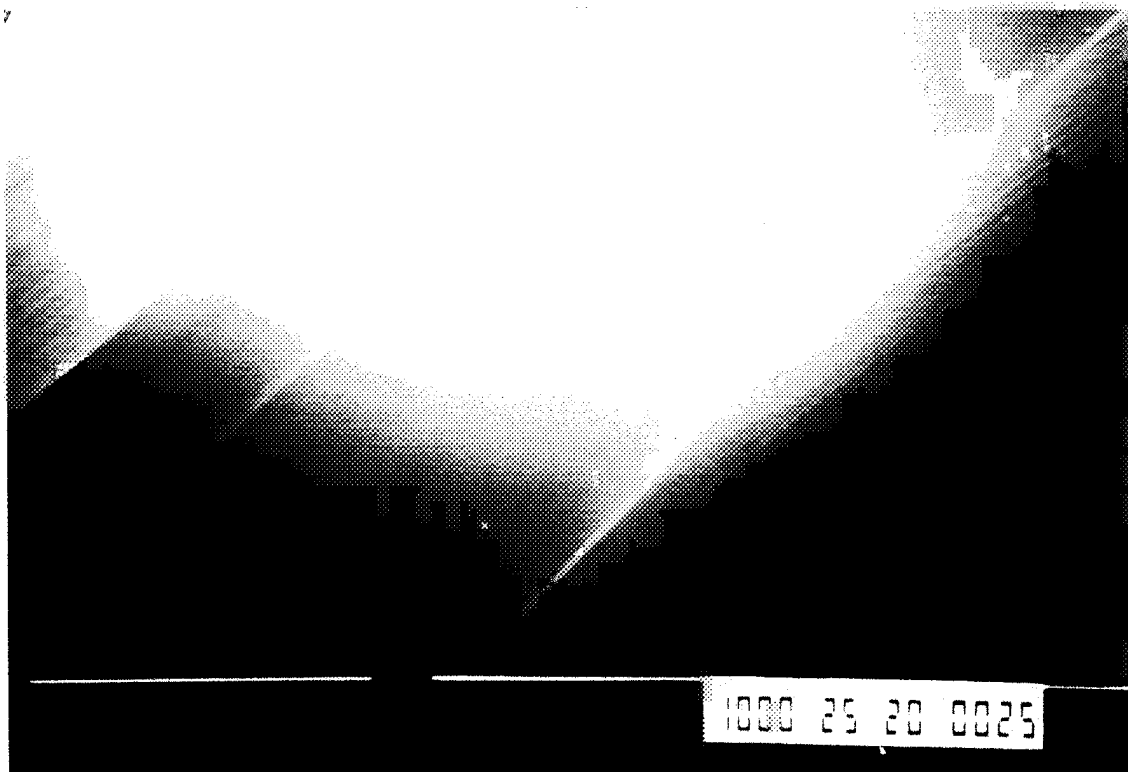


**FIG. 9**

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**FIG. 10**

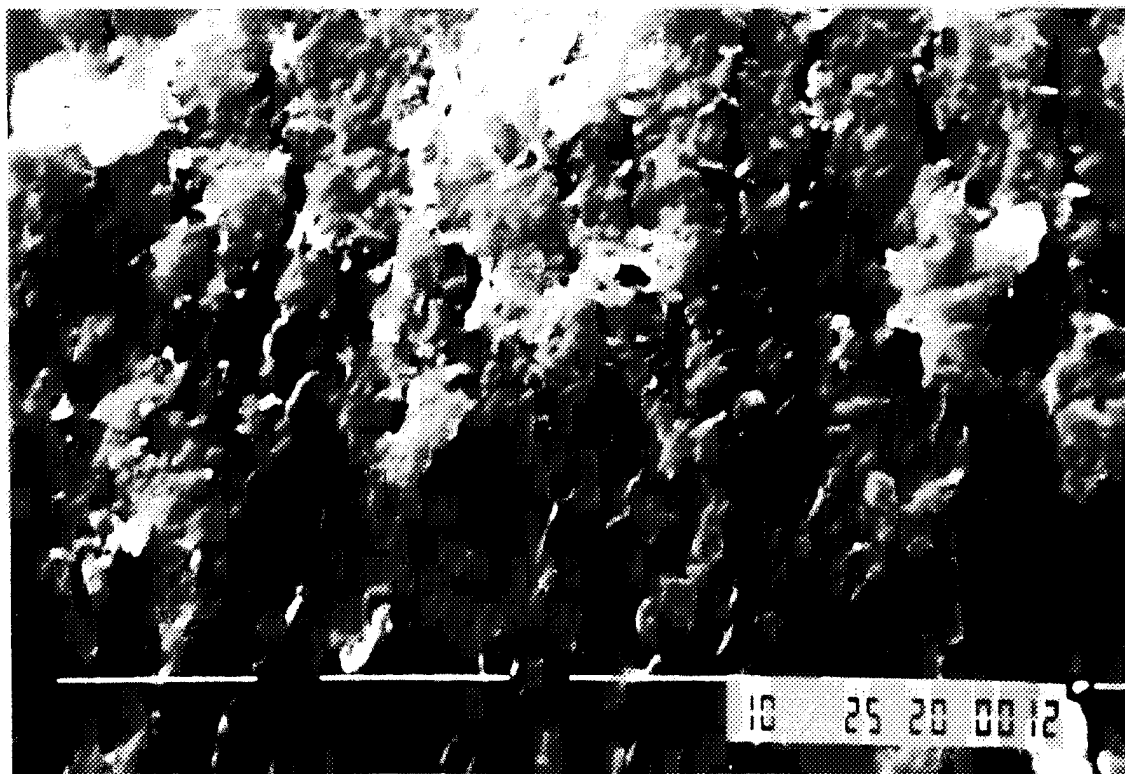


**FIG. 11**

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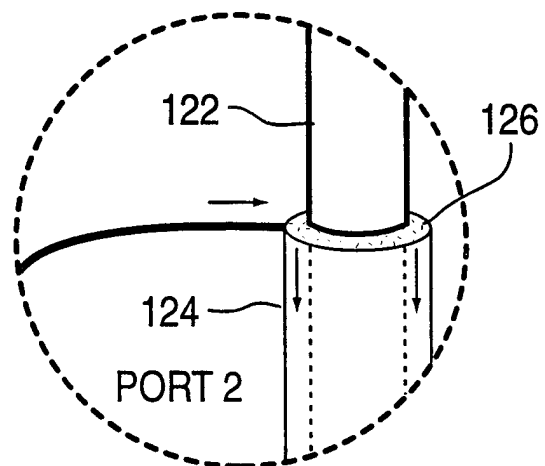
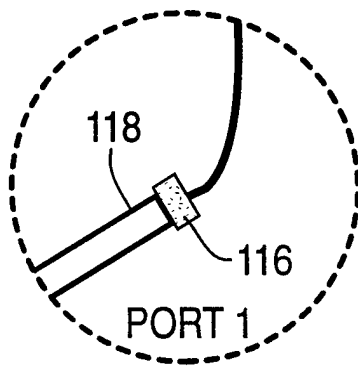
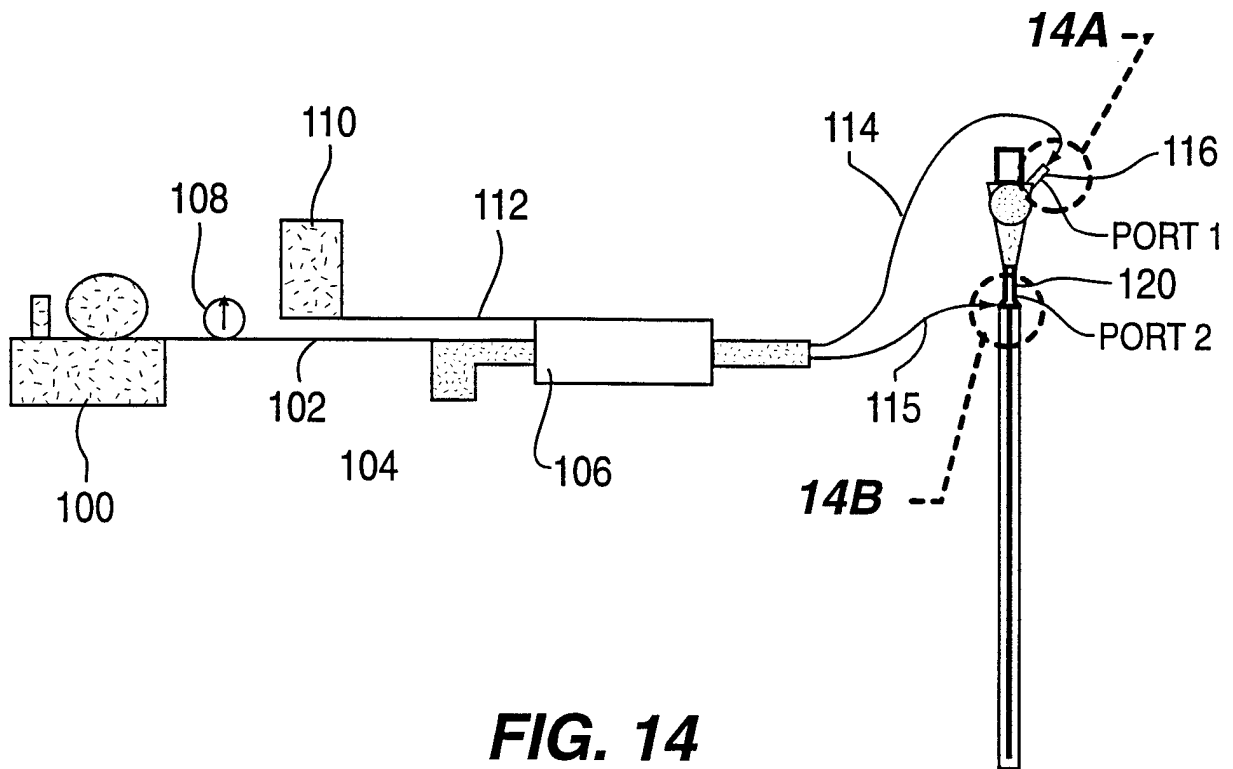


**FIG. 12**

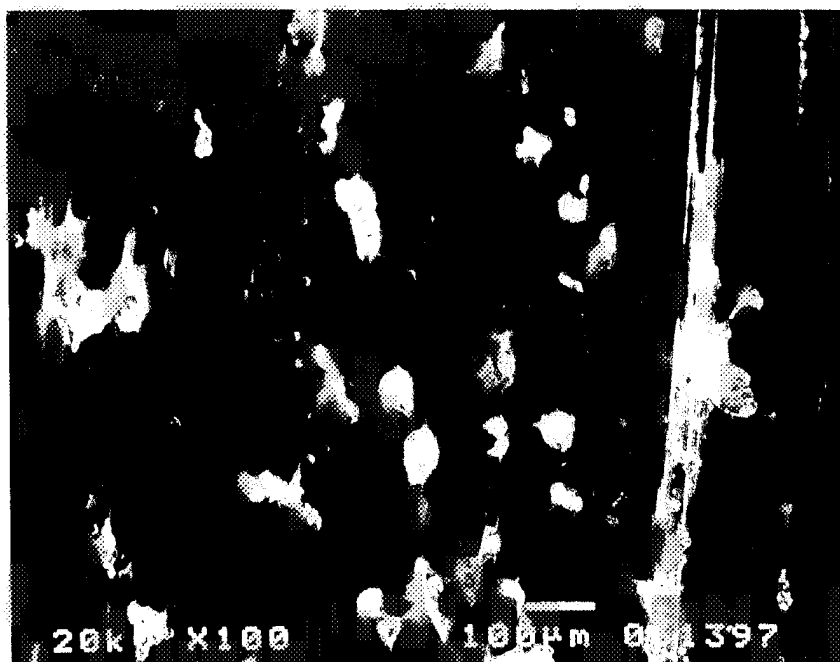


**FIG. 13**

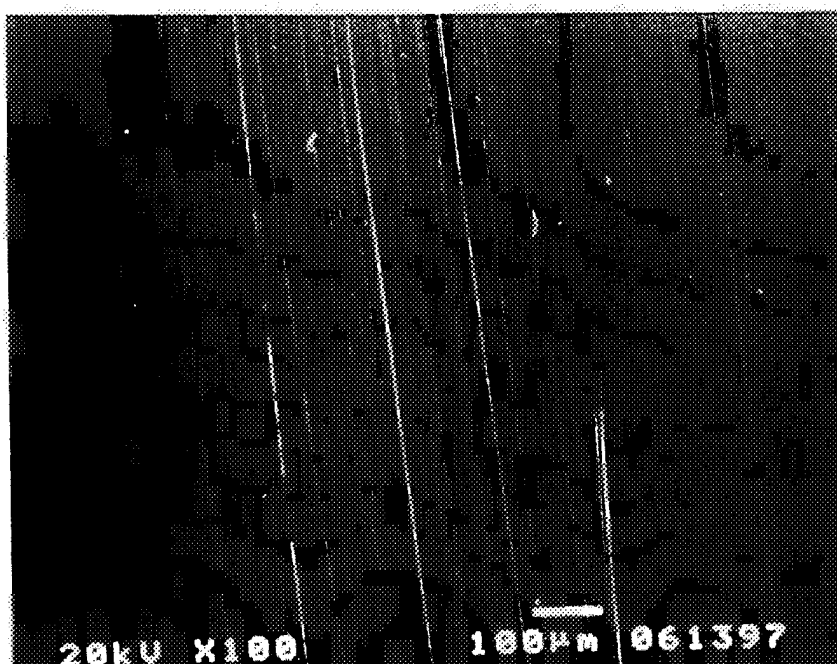
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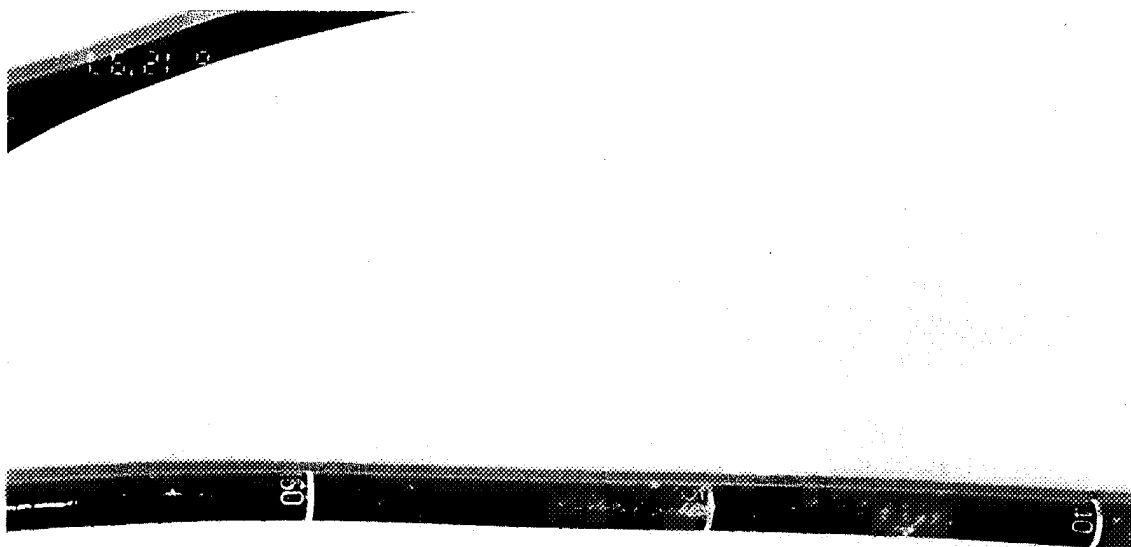


**FIG. 15**



**FIG. 16**

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**FIG. 17**



**FIG. 18**

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/11401

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61K 17/02; B08B 3/08; 9/02; C11D 3/14, 3/395, 17/00; C23G 1/00.

US CL : 134/2, 14, 22.12, 34, 42; 433/85; 510/161, 369, 372.

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. : 134/2, 14, 22.12, 34, 42; 433/85; 510/161, 369, 372.

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, DIALOG

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,219,333 A (HARRIS) 26 August 1980, see Example I bridging cols. 14-15.	1-6
Y	US 5,244,468 A (HARRIS) 14 September 1993, see abstract, especially last 3 lines; col. 2, lines 26-61, especially lines 56-61; col. 5, lines 39-44.	1-6
Y	US 5,425,815 A (PARKER et al.) 20 June 1995, see abstract; Fig. 1; col. 3, lines 39-47, 55-63; col. 4, lines 26-32, 41-49, 53-58.	7-10, 13-17
Y	US 4,311,618 A (SCHAFER-BURKHARD) 19 January 1982, see col. 1, lines 12-31; col. 1, line 63 - col. 2, line 2; col. 2, line 50; col. 4, lines 12-53, 59-64.	7-10, 13-17

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

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier document published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 16 AUGUST 1998	Date of mailing of the international search report 08 OCT 1998
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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/11401

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,077,008 A (KRAVOLIC et al.) 31 December 1991, see abstract; col. 2, lines 6-12; col. 4, lines 53-64.	8, 13-17
X	US 3,625,231 A (LITTRELL, JR.) 07 December 1971, see entire document in general, especially "Background and Objects" section	11, 12
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Y	in col.1	11, 12
Y	US 4,710,233 A (HOHMANN et al.) 01 December 1987, see col. 1, lines 7-10; col. 2, lines 34-38; col. 4, lines 50-55; col. 5, lines 3-4.	11, 12
Y	US 4,477,438 A (WILLCOCKSON, deceased et al.) 16 October 1984, see col. 1, lines 12-15; col. 2, lines 21-59, especially ingredients (1), (4) & (5).	11, 12