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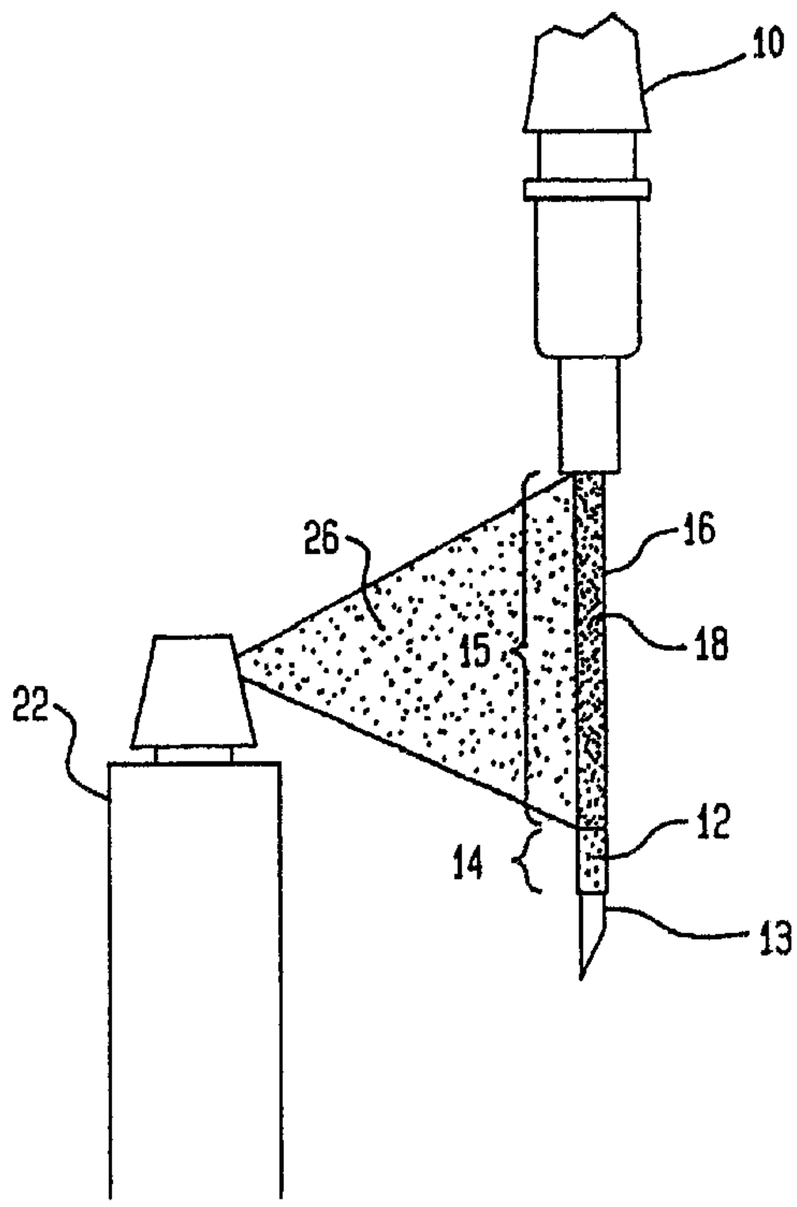
(54) Titre : PROCEDE DE LUBRIFICATION DES CATHETERS COMPORTANT DEUX ETAPES
(54) Title: TWO STEP CATHETER LUBRICATION PROCESS



(57) Abrégé/Abstract:
This invention relates to a novel method for lubricating a catheter in which a tip lubricant is applied to the tip of the catheter and a different shaft lubricant is applied to shaft of the catheter. The preferred tip lubricant used is a solution of polydimethylsiloxane and the preferred shaft lubricant is a solution of moisture curable organosiloxane. The most preferred tip lubricant is a solution of about 0.5% Dow 360 Silicone® by weight and the most preferred shaft lubricant is a solution of about 1.25% Dow MDX 4-4159 by weight and about 2.5% Dow 360 Silicone® by weight.

HB305630787
J&J-002

TITLE: TWO STEP CATHETER LUBRICATION PROCESS

INVENTOR: **JANIE C. TERRY**

ABSTRACT OF THE DISCLOSURE

This invention relates to a novel method for lubricating a catheter in which a tip lubricant is applied to the tip of the catheter and a different shaft lubricant is applied to shaft of the catheter. The preferred tip lubricant used is a solution of polydimethylsiloxane and the preferred shaft lubricant is a solution of moisture curable organosiloxane. The most preferred tip lubricant is a solution of about 0.5% Dow 360 Silicone® by weight and the most preferred shaft lubricant is a solution of about 1.25% Dow MDX 4-4159 by weight and about 2.5% Dow 360 Silicone® by weight.

HB305630787
J&J-002

TITLE: TWO STEP CATHETER LUBRICATION PROCESS

INVENTOR: **JANIE C. TERRY**

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a method and apparatus for lubricating an over the needle catheter thereby optimizing the catheter's insertion performance.

2. Description of the Related Art

A needle catheter is a surgical device for insertion into the tissues of a body cavity. After insertion, fluids can be introduced or removed. The problem of effectively lubricating catheters for ease of insertion into a patient has persisted in the medical community.

One conventional solution for lubricating a catheter is to apply a lubricating gel to the catheter. U.S. Patent No. 4,878,906 describes a kit for use in performing a suctioning procedure with a suction catheter. The kit includes a foil pack or other suitable container for holding a lubricating gel. To use the catheter, the foil package is first torn at one edge and the gel is squeezed onto a sterile field. The catheter tip is inserted into the gel for lubrication. This gel is a water-soluble composition. The use of water-soluble gels has the disadvantage that the gel loses lubricity over time. The loss of lubricant effectiveness during a medical procedure can cause significant discomfort to the patient.

U.S. Patent No. 3,556,294 describes a package for catheters in which the distal end of the catheter is enveloped within a flexible sleeve. Lubricant filled friable capsules are located within the sleeve. The capsules are broken by pressure to release the lubricant. An inert liquid silicone is used in the capsules so as to allow the catheter to remain lubricated for the entire procedure.

U.S. Patent Nos. 4,720,521 and 4,806,430 describes a film forming siloxane composition having a combination of three siloxane polymers chemically crosslinked, and a non-reactive component dispersed therein. The composition is described as useful for lubricating hypodermic needles, razor blades and catheters.

U.S. Patent No. 3,574,673 describes a lubricant for cutting edges, such as razor blades. A composition of a moisture curable amine terminated organosiloxane copolymer is coated onto the razor blades. This composition is referred to as Dow MDX 4-4159®. MDX 4-4159® is a registered trademark of Dow Corning Corporation, Midland, Michigan.

U.S. Patent No. 4,588,398 describes an improved operating surface for catheter entry through skin and venipuncture. The catheter is formed of polyurethane. After molding the catheter, the catheter is dipped in a lubricant having a composition of a solvent consisting of 70 percent freon; 30 percent isopropanol mixed with 2 percent Dow MDX 4-4159® (by weight); and 1.75 percent Dow 360 Silicone®. Dow 360 Silicone® is a registered trademark of

Dow Corning Corporation, Midland, Michigan. The lubricant has a 1,000 CTKS viscosity (by weight).

Of possible general relevance to the invention are U.S. Patent Nos. 3,683,928; 3,726,281; and 4,140,127 which describe assemblies for self-lubricating catheters. In these patents only a single gel type lubricant is used.

A practical solution to the problem of lubricating a catheter with two different lubricants in order to provide improved insertion and shaft drag reduction is not found in the prior art.

SUMMARY OF THE INVENTION

This invention is directed to lubricants for a catheter apparatus in which problems with conventional lubricants are eliminated. A first lubricant is located at the tip portion of the catheter and a second lubricant on at least that portion of the catheter positioned behind the tip. It has now been discovered that the application of a first lubricant on a tip of a catheter and the application of a different second lubricant on the portion of the catheter shaft behind the tip has outstanding properties for ease of penetration and reduction of catheter drag forces.

The lubricant applied to the tip is preferably a solution of polydimethylsiloxane (PMDS). Most preferably, the tip lubricant is a solution of about 0.5% Dow 360 Silicone® by weight. Preferably, the lubricant applied to the shaft is a solution of a moisture curable siloxane and PMDS. Most preferably, the shaft lubricant is a solution of about 2.5% Dow 360 Silicone® and about

1.25% Dow MDX 4-4159® by weight. The lubricants are applied to the catheter during manufacture of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevational view of the catheter and applied lubricants of the present invention.

Fig. 2 is a side elevational view of the method of application of the shaft lubricant by spraying the shaft and the tip with the shaft lubricant.

Fig. 3 is a side elevational view of the method of application of the shaft lubricant by dipping the shaft and the tip into the second lubricant.

Fig. 4 is a side elevational view of the method of application of the shaft lubricant by spraying the portion of the shaft positioned behind the tip with the shaft lubricant.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 is a side elevational view of a catheter 10 which can be used according to the present invention. Catheter 10 can be of the type described in U.S. Patent No. 4,588,398, or manufactured by Johnson & Johnson as OPTICAL CLEAR RADIOPAQUE (OCR) referred to as OCR-470, or can be can be formed of any polyurethane material. It is known that polyurethane is a difficult surface to lubricate and that the lubricant has to be specially formulated to wet the surface.

A tip lubricant 12 is shown applied to the catheter tip 14. The catheter tip 14 is generally defined as the first 0.25 to

0.50 inches of the end of catheter shaft 16. A portion of the shaft 15 is positioned behind the catheter tip 14. Preferably, catheter shaft 16 is a hollow tubular molded polyurethane resin. A needle 13 can be positioned below the catheter tip 14 for aiding penetration of the catheter. Needle 13 can be lubricated with a conventional needle lubricant.

Tip lubricants 12 useful in practice of this invention are fluids including a silicone material. Polydimethylsiloxane (PMDS) can be used as the silicone material.

A preferred tip lubricant 12 is a lubricant having a solvent mixed with Dow 360 Silicone®. Representative solvents are freon, hexane, isopropanol, alkanes, toluene and non-toxic chlorinated or fluorinated hydrocarbons. Hexane is a preferred solvent. It will be appreciated that other solvents which are known in the art can be used. Preferable tip lubricants 12 for practice of this invention are lubricants consisting of about 95.0% to about 99.5 % hexane mixed with about 0.5% to about 5.0% Dow 360 Silicone® (by weight). A most preferred lubricant consists of 99.5% hexane mixed with 0.5% Dow 360 Silicone® (by weight). Dow 360 Silicone® has an inherent high viscosity of 1,000 CTKS to about 100,000 centistokes (CTKS). Preferably, tip lubricant 12 includes Dow 360 Silicone® having a 12,500 CTKS viscosity measured at room temperature. Room temperature is about 20°C to 25°C.

Tip lubricant 12 is applied to the catheter tip 14 by dipping the tip into a solution of the tip lubricant 12. In the

alternative, tip lubricant 12 can be applied by directing a spray of the lubricant onto the tip 14.

Shaft lubricant 18 is a composition of a moisture curable silicone. Silicone compositions when cured have the advantages of: increased adherence of the silicone to the catheter; and, of having the silicone being dry to the touch and thus less likely to trap foreign material such as dust. The increased adherence of the silicone has the advantage that the lubricant does not easily wipe off of the catheter.

A preferred moisture curable silicone is an amine terminated organosiloxane copolymer as described in U.S. Patent No. 3,574,673 and referred to as Dow MDX 4-4159®. Preferably, shaft lubricant 18 is a lubricant consisting of 96.25% to about 99.0% solvent mixed with about 1.0% to about 2.5% Dow 360 Silicone® (by weight) and about 1.0% to about 2.5% Dow MDX 4-4159® (by weight). Viscosity of the shaft lubricant 18 is between 1,000 CTKS to about 100,000 CTKS. The solvent used in shaft lubricant 18 can be chosen from the same solvents described above for use in the tip lubricant 12. A most preferred shaft lubricant 18 consists of 96.5% hexane mixed with 2.5% Dow 360 Silicone® (by weight, 12,500 CTKS) and 1.25% MDX 4-4159® (by weight, 12,500 CTKS).

Figs. 2-4 are side elevational views of the application of the shaft lubricant 18 in three different embodiments. Fig. 2 illustrates a first embodiment. In the first embodiment, shaft lubricant 18 is applied over tip lubricant 12 and to the portion of

the shaft 15. In this embodiment, shaft lubricant 18 is applied to both the tip of the catheter 14 and the portion of the catheter shaft 15 by spraying the total area with shaft lubricant 18. Spray 20 is applied by a conventional spraying device 22 as is known in the art.

Fig. 3 illustrates a second embodiment. In the second embodiment, shaft lubricant 18 is applied by dipping catheter tip 14 and the portion of the catheter shaft 15 into a solution of the shaft lubricant 24. In the third embodiment illustrated in Fig. 4, shaft lubricant 18 is applied only to the portion of the shaft 15 positioned behind the tip lubricant 12. Shaft lubricant 18 is applied by spraying the portion of the shaft 15 behind the tip into the shaft lubricant 18. Spray 26 is applied with the conventional spraying device 22. Spraying device 22 is adjusted to spray the portion of the catheter shaft 15. In all of the above-described embodiments, tip lubricant 12 and shaft lubricant 18 are applied during manufacture of catheter 10. It will be appreciated that other methods for applying lubricants to catheters are known in the art.

A first experiment applied various combinations of tip and body lubricants to a catheter. The tip was dipped into the tip lubricant. The shaft and the tip were sprayed with the shaft lubricant. Penetration testing was performed through a pigskin having a thickness of about 1/16 to about 3/16 of an inch. In the penetration testing, the film is stretched taut and the needle and

catheter are entirely inserted through the film. Force measurements are taken in grams necessary to penetrate the film. Measurements were also performed on catheter shaft drag. Catheter shaft is defined as the force required to drag the catheter through the punctured pigskin when inserting the catheter through the pigskin. The results from the first experiment are summarized in Table 1.

TABLE 1

Run	Tip Lubricant	Shaft Lubricant	Catheter Penetration	Drag
1	0.5% 360	2.5% 360/1.0% MDX	218±34	71±14
2	5.0% 360	2.5% 360/1.0% MDX	215±37	71±13
3	2.0% 360	2.5% 360/1.0% MDX	220±26	71±13
4	0.5% 360	1.0% 360/2.5% MDX	204±31	79±13
5	5.0% 360	1.0% 360/2.5% MDX	217±31	83±14
6	2.0% 360	1.0% 360/2.5% MDX	211±34	82±13
7	0.5% 360	2.5% 360/2.5% MDX	192±37	91±11
8	5.0% 360	2.5% 360/2.5% MDX	211±33	86±11
9	2.0% 360	2.5% 360/2.5% MDX	210±29	83±11
INSYTE®	(Control)		232±33	79±19
Teflon® Jelco	(Control)		261±33	150±26

INSYTE® is a registered trademark of Beckton, Dickenson, Franklin Lakes, New Jersey. Teflon® is a registered trademark of Dupont, Dover, Delaware.

It was found that a tip lubricant having a low level of 0.5% Dow 360 Silicone® in freon, runs 4 and 7, had improved catheter penetration values. Improved drag results were obtained with a shaft lubricant of solution of about 2.5% Dow 360 Silicone® and about 1.0% MDX 4-4159® runs 1, 2 and 3. Accordingly, reducing

the MDX 4-4159® concentration from about 2.5% to about 1.0% indicates an improvement of drag values. However, at a higher MDX 4-4159® concentration an improvement of penetration values was obtained.

In a second experiment, a shaft lubricant of combinations of about 0.5% to about 2.5% Dow 360 Silicone® and of about 0.5% to about 2.5% MDX 4-4159® in hexane was applied to the catheter. The shaft and tip were sprayed with the shaft lubricant. In runs 1, 4, 5, 8, 9, 12 and 13 a tip lubricant was not applied. In runs 2, 6, 10 and 14 about 0.5% Dow 360 Silicone® tip lubricant was applied and in runs 3, 7, 11 and 15 about 2.0% Dow 360 Silicone® tip lubricant was applied. When the tip lubricant is applied the tip was dipped into the tip lubricant.

TABLE 2

	TIP LUBRICANT	SHAFT LUBRICANT		Catheter		Needle
RUN	%360	% 360	%MDX	Penetration	Drag	Penetration
1	0.0	0.5	0.5	285±31	113±16	160±29
2	0.5	0.5	0.5	274±45	159±26	112±23
3	2.0	0.5	0.5	292±52	143±36	130±41
4	0.0	0.5	1.25	274±43	112±15	151±36
5	0.0	0.5	2.5	292±48	119±15	218±49
6	0.5	0.5	2.5	256±35	119±12	108±17
7	2.0	0.5	2.5	286±51	121±16	116±20
8	0.0	1.25	1.25	303±36	124±11	209±61
9	0.0	2.5	0.5	279±47	128±16	195±68
10	0.5	2.5	0.5	286±70	128±26	117±30
11	2.0	2.5	0.5	317±73	131±21	145±57
12	0.0	2.5	1.25	221±27	112±10	156±40
13	0.0	2.5	2.5	249±30	115±12	168±41
14	0.5	2.5	2.5	320±49	127±13	136±34
15	2.0	2.5	2.5	320±50	135±12	141±45

The results show that run 12 having a composition of about 2.5% Dow 360 Silicone® and about 1.25% MDX 4-4159® has the lowest values for catheter penetration and shaft drag. The results indicate that applying a tip lubricant of about 0.5% Dow 360 Silicone® lowers the catheter penetration values.

A third experiment applied a tip lubricant of about 0.5% Dow 360 Silicone® by dipping the catheter into the solution for all runs. Various concentrations of the shaft lubricant of from about 2.5% Dow 360 Silicone®, and about 1.25% MDX 4-4159® to about 2.5% MDX 4-4159® were sprayed on the catheter and the tip.

TABLE 3

	TIP LUBRICANT	SHAFT LUBRICANT		Catheter		Needle
RUN	%360	% 360	%MDX	Penetration	Drag	Penetration
1	0.0	2.5%	2.5%	160±19	79±11	93±22
2	0.0	2.5%	2.5%	158±18	79±8	86±18
3	0.0	2.5%	2.5%	145±18	76±9	87±27
4	0.0	2.5%	1.25%	148±14	72±11	89±20
5	0.5	2.5%	1.5%	134±19	69±11	84±18

The results indicate that reducing the concentration of MDX 4-4159® in the shaft lubricant improves both penetration and drag. The two step process in which the tip of a catheter is first dipped into a solution of about 0.5% Dow 360 Silicone® (12,500 CTSK) and is then sprayed with a solution of about 2.5% Dow 360 Silicone® (12,500 CTKS) and about 1.25% Dow MDX 4-4159® in hexane produced improved penetration and drag values.

The present invention has the advantage of increasing a catheter penetration value and reducing a catheter drag value by

applying a different tip lubricant and shaft lubricant to the catheter. A tip lubricant of a solution of about 0.5% Dow 360 Silicone® by weight and a shaft lubricant of a solution of about 2.5% Dow 360 Silicone® by weight and about 1.25% MDX 4-4159® by weight results in increased performance of both drag and penetration values.

While the invention has been described with reference to the preferred embodiment, this description is not intended to be limiting. It will be appreciated by those of ordinary skill in the art that modifications may be made without departing from the spirit and scope of the invention.

WE CLAIM:

1. A method for lubricating a needle catheter having a tip and a shaft, said method comprising the steps of:

applying a first surface lubricant to said tip for aiding penetration of said tip; and,

applying a second surface lubricant to at least a portion of said shaft for reducing the drag of said shaft.

2. The method according to claim 1 wherein said first surface lubricant comprises a solution of polydimethylsiloxane.

3. The method according to claim 2 wherein said second surface lubricant comprises a solution of a moisture curable organosiloxane copolymer.

4. The method according to claim 3 wherein said first lubricant comprises a solution of about 0.05% to about 5.0% Dow 360 Silicone® by weight.

5. The method according to claim 4 wherein said second lubricant comprises a solution of about 1.0% to about 2.5% Dow 360 Silicone® by weight and about 1.0% to about 2.5% Dow MDX 4-4159® by weight.

6. The method according to claim 5 wherein said first

lubricant comprises a solution of about 0.5% Dow 360 Silicone® by weight and wherein said second lubricant comprises a solution of about 2.5% Dow 360 Silicone® and of about 1.25% Dow MDX 4-4159® by weight.

7. The method according to claim 6 wherein said first lubricant and second lubricant has a viscosity of about 1,000 to about 100,000 centistokes.

8. The method according to claim 7 whereas said first and second lubricants have a viscosity of about 12,500 centistokes.

9. The method according to claim 8 wherein said solution includes a solvent selected from the group of freon, hexane, isopropanol, alkanes, toluene, fluorinated hydrocarbons and chlorinated hydrocarbons.

10. The method according to claim 9 wherein the solvent is hexane.

11. The method according to claim 10 wherein said first lubricant is applied by dipping said tip into said first lubricant.

12. The method according to claim 11 wherein said second

lubricant is applied by dipping said portion of said shaft and said tip into said second lubricant.

13. The method according to claim 11 wherein said second lubricant is applied by spraying said second lubricant on at least said portion of said shaft.

14. The method according to claim 13 wherein said second lubricant is applied to said portion of said shaft and said tip.

15. The method of claim 14 wherein said first and second lubricants are applied to the catheter during manufacture of the catheter.

16. A needle catheter comprising:

an elongated shaft, said shaft having a tip portion at one end thereof;

a first lubricant adhered to said tip for aiding penetration of said tip; and

a second lubricant adhered to said at least a portion of said shaft for reducing drag of said shaft.

17. The catheter of claim 16 wherein said shaft is a hollow tubular molded polyurethane resin.

18. The catheter according to claim 17 wherein said second lubricant comprises a solution of a moisture curable organosiloxane copolymer.

19. The catheter according to claim 18 wherein said first lubricant comprises a solution of about 0.05% to about 5.0% Dow 360 Silicone® by weight.

20. The catheter according to claim 19 wherein said second lubricant comprises a solution of about 1.0% to about 2.5% Dow 360 Silicone® by weight and about 1.0% to about 2.5% Dow MDX 4-4159® by weight.

21. The catheter according to claim 20 wherein said first lubricant comprises a solution of about 0.5% Dow 360 Silicone® by weight and wherein said second lubricant comprises a solution of about 2.5% Dow 360 Silicone® and of about 1.25% Dow MDX 4-4159® by weight.

22. The catheter according to claim 21 wherein said first lubricant and second lubricant has a viscosity of about 1,000 to about 100,000 centistokes.

23. The catheter according to claim 22 whereas said first and second lubricants have a viscosity of about 12,500

centistokes.

24. The catheter according to claim 23 wherein said solution includes a solvent selected from the group of freon, hexane, isopropanol, alkanes, toluene, fluorinated hydrocarbons and chlorinated hydrocarbons.

25. The catheter according to claim 24 wherein the solvent is hexane.

26. The catheter according to claim 25 wherein said first lubricant is adhered to said tip by dipping said tip into said first lubricant.

27. The catheter according to claim 26 wherein said second lubricant is adhered to said portion of said shaft by dipping said portion of said shaft and said tip into said second lubricant.

28. The catheter according to claim 27 wherein said second lubricant is adhered to said portion of said shaft by spraying said second lubricant on at least said portion of said shaft.

29. The catheter according to claim 26 wherein said second lubricant is adhered to said portion of said shaft and said tip.

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FIG. 1

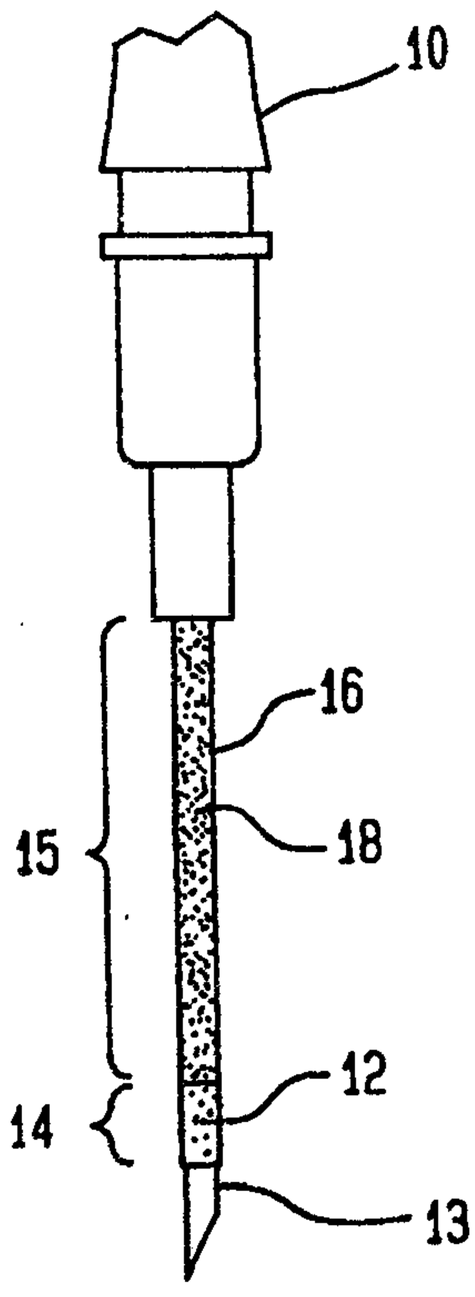

FIG. 2

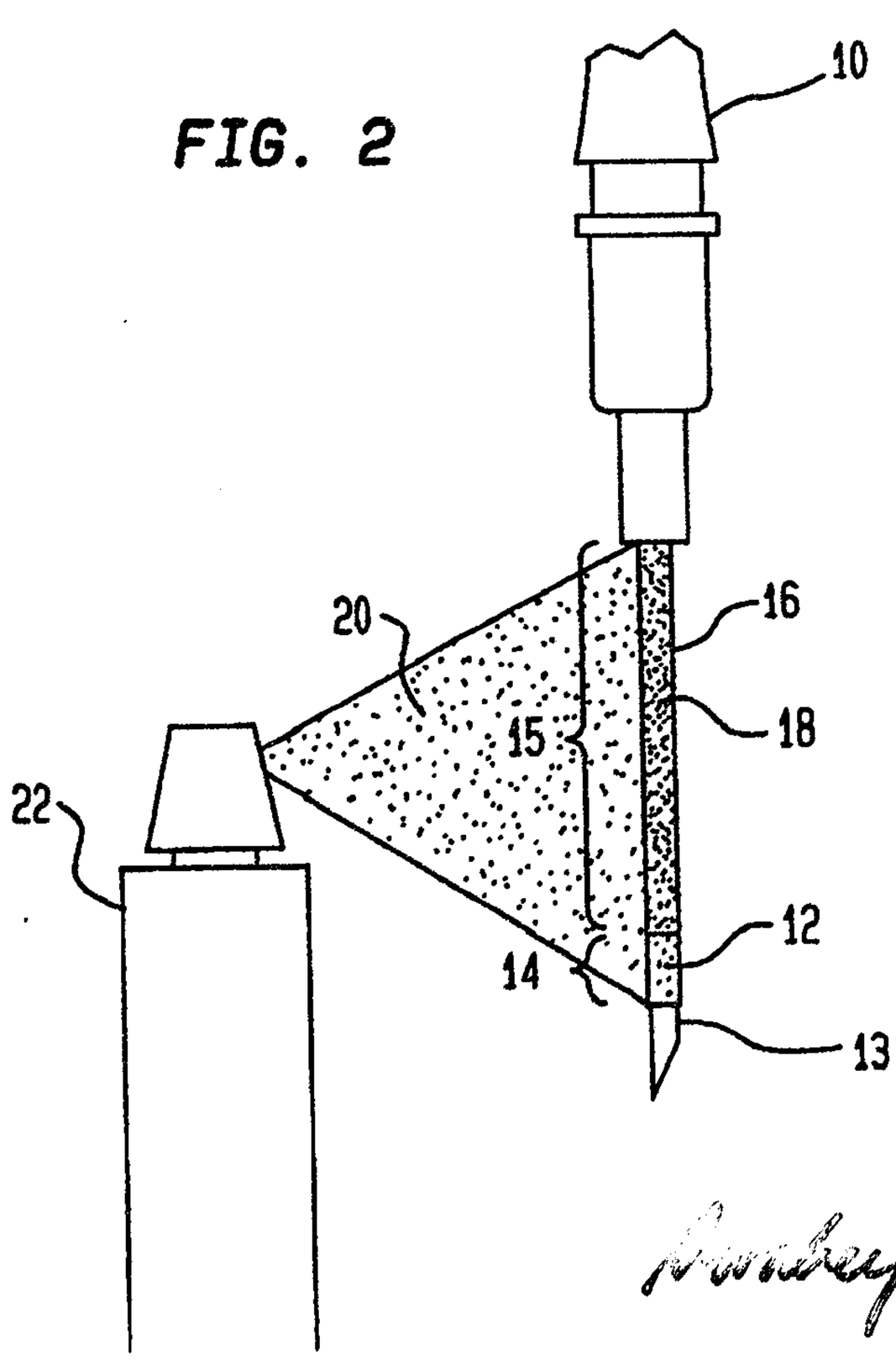

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FIG. 3

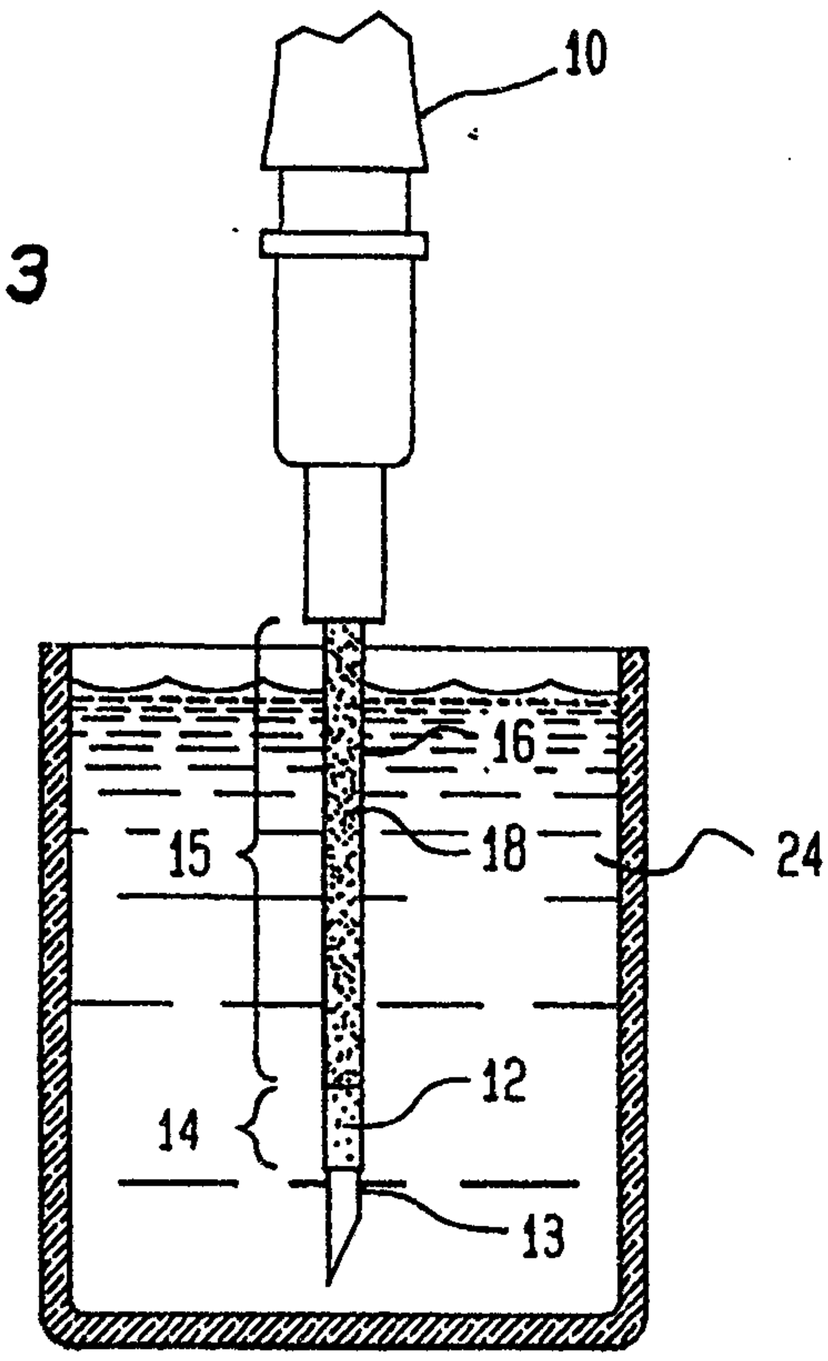
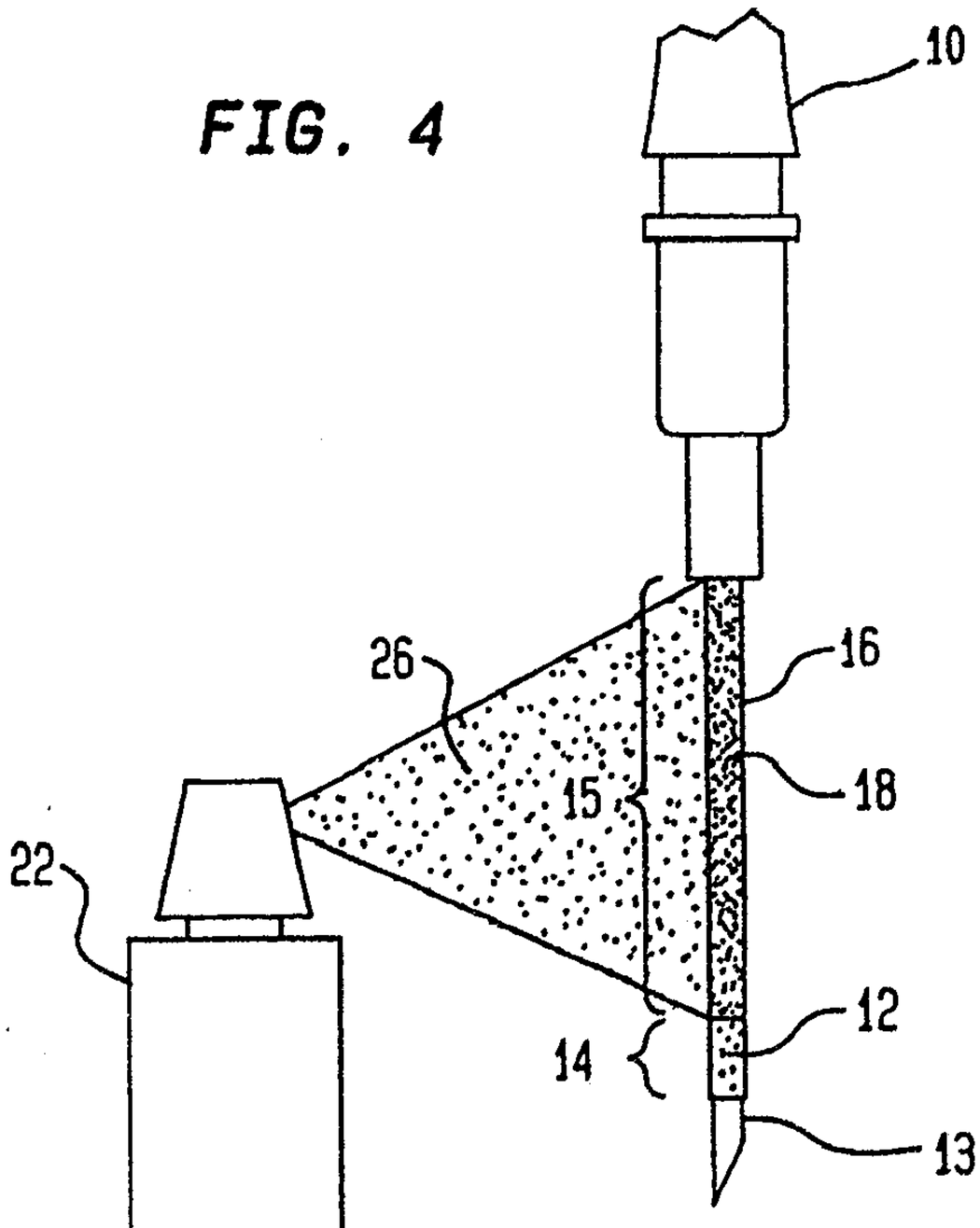


FIG. 4



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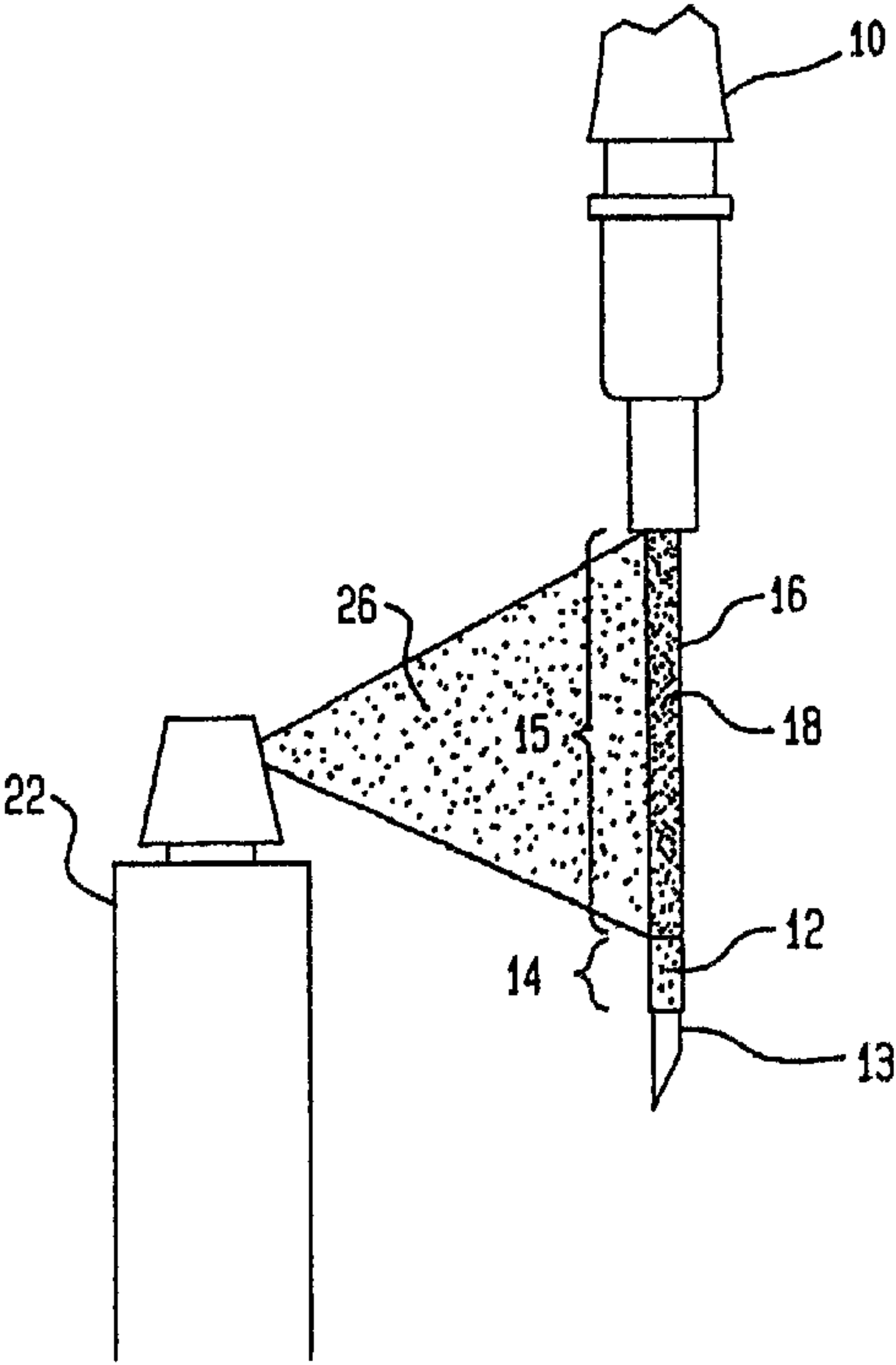
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