



US 20230158253A1

(19) **United States**(12) **Patent Application Publication**
Lazarof(10) **Pub. No.: US 2023/0158253 A1**(43) **Pub. Date: May 25, 2023**(54) **ANESTHESIA APPLICATORS/INJECTORS
FOR DENTAL AND OTHER APPLICATIONS
AND METHODS OF USE***A61N 1/04* (2006.01)*A61M 5/178* (2006.01)*A61C 5/40* (2006.01)*A61M 19/00* (2006.01)(71) Applicant: **Sargon Lazarof**, Encino, CA (US)(72) Inventor: **Sargon Lazarof**, Encino, CA (US)(21) Appl. No.: **17/878,832**(22) Filed: **Aug. 1, 2022**(52) **U.S. Cl.**CPC *A61M 5/3286* (2013.01); *A61M 5/3287*(2013.01); *A61M 5/422* (2013.01); *A61N**1/36021* (2013.01); *A61N 1/0456* (2013.01);*A61M 5/178* (2013.01); *A61C 5/40* (2017.02);*A61M 19/00* (2013.01); *A61M 2005/3107*

(2013.01)

Related U.S. Application Data

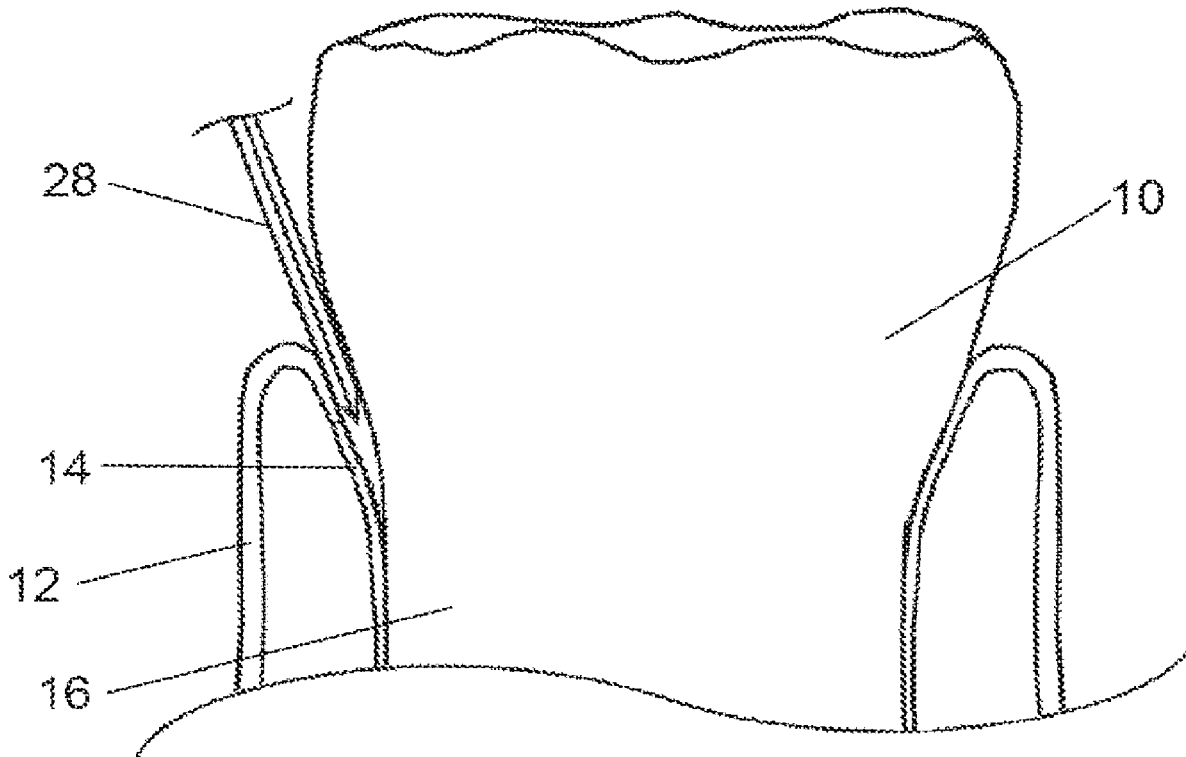
(63) Continuation of application No. 16/512,102, filed on Jul. 15, 2019, now Pat. No. 11,400,235, which is a continuation of application No. 15/632,197, filed on Jun. 23, 2017, now Pat. No. 10,391,265, which is a continuation of application No. 14/679,321, filed on Apr. 6, 2015, now Pat. No. 9,687,606, which is a continuation-in-part of application No. 13/938,686, filed on Jul. 10, 2013, now Pat. No. 9,713,680.

Publication Classification(51) **Int. Cl.***A61M 5/32* (2006.01)*A61M 5/42* (2006.01)*A61N 1/36* (2006.01)

(57)

ABSTRACT

Disclosed are applicators and methods injecting of a liquid anesthetic into a dental patient with no or minimal pain. In accordance with one embodiment the applicator is for intraligamentary injection and includes an elongated, thin member having an open distal free formed of a resilient and somewhat conformable material suitable for producing a substantially fluid-tight interface with the anatomic structures at the gingival sulcus to inject the anesthetic therein. In another embodiment the applicator includes a flexible skirt surrounding a sharpened cannula, with the cannula being movable with respect to the skirt. The skirt is arranged to receive the anesthetic to anesthetize the gum, whereupon the cannula can then pierce the gum to inject the anesthetic into the underlying anatomic structure.



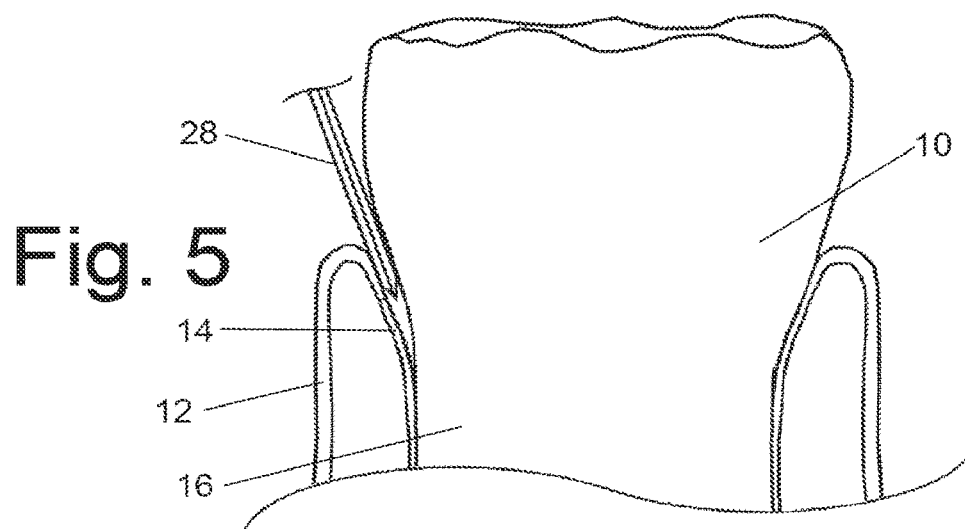
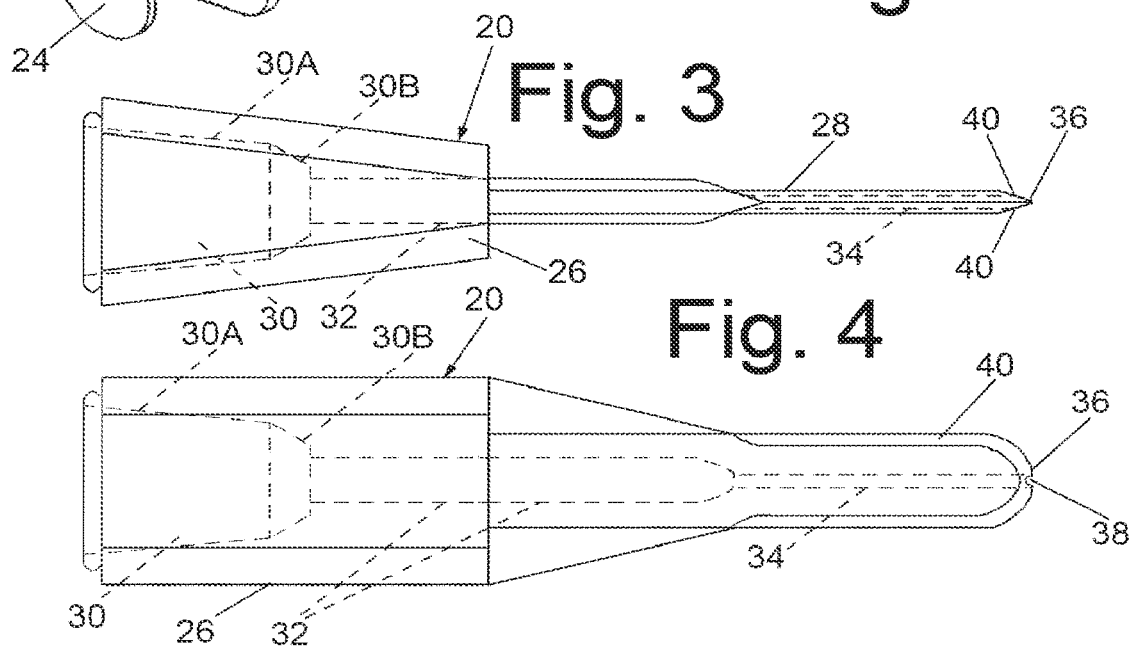
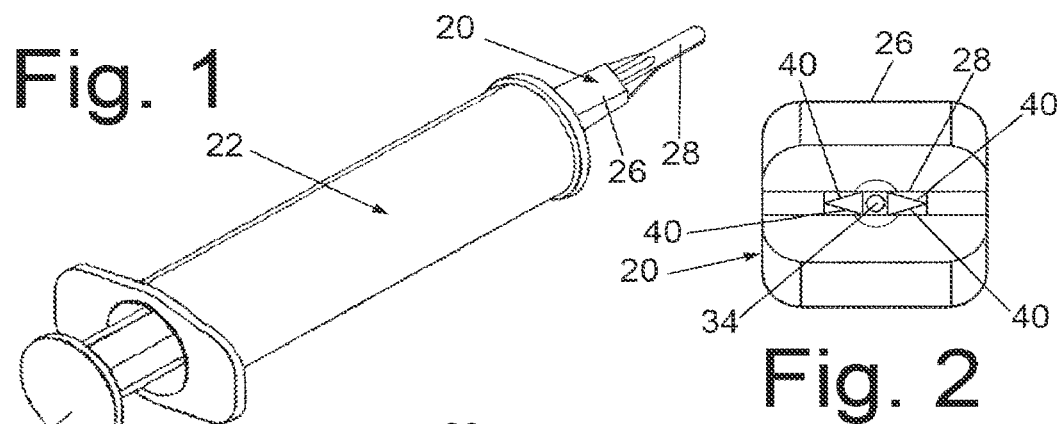


Fig. 6

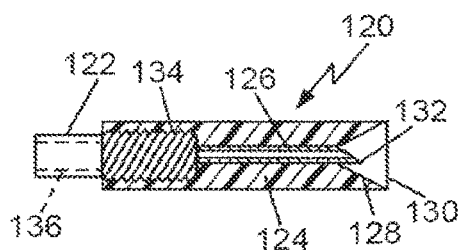


Fig. 7

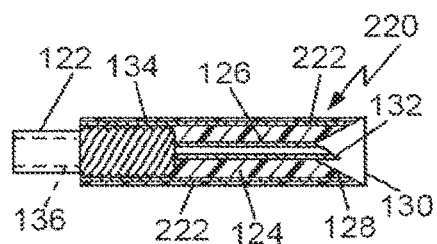
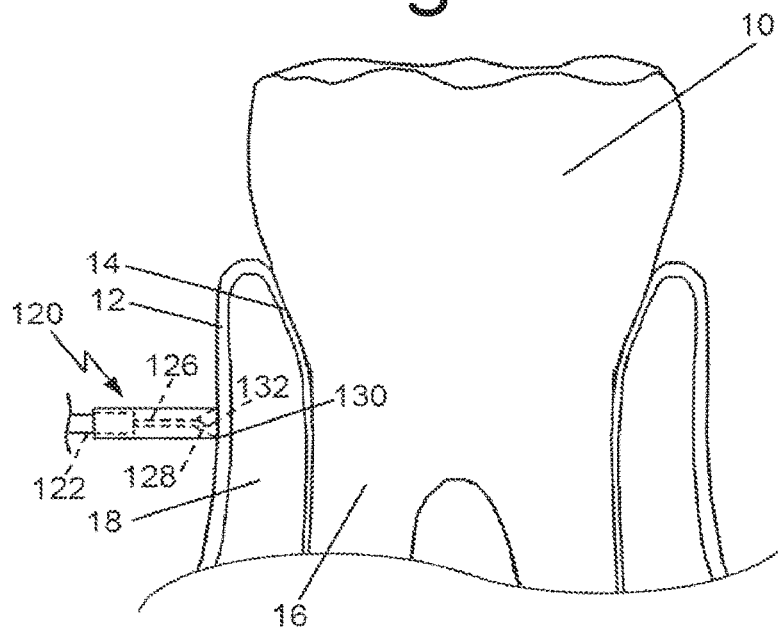


Fig. 8



ANESTHESIA APPLICATORS/INJECTORS FOR DENTAL AND OTHER APPLICATIONS AND METHODS OF USE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation application of U.S. patent application Ser. No. 16/512,102 filed Jul. 15, 2019, entitled “ANESTHESIA APPLICATORS/INJECTORS FOR DENTAL AND OTHER APPLICATIONS AND METHODS OF USE,” which is a continuation application of U.S. patent application Ser. No. 15/632,197 filed Jun. 23, 2017, entitled “ANESTHESIA APPLICATORS/INJECTORS FOR DENTAL AND OTHER APPLICATIONS AND METHODS OF USE,” which is a continuation application of U.S. patent application Ser. No. 14/679,321 filed Apr. 6, 2015, now U.S. Pat. No. 9,687,606, entitled “ARTICULATING APPLICATORS/INJECTORS FOR ADMINISTRATION OF LIQUID ANESTHETIC AND OTHER LIQUID,” which is a continuation-in-part of application of U.S. patent application Ser. No. 13/938,686 filed Jul. 10, 2013, now U.S. Pat. No. 9,713,680, entitled “ANESTHESIA APPLICATORS/INJECTORS FOR DENTAL AND OTHER APPLICATIONS AND METHODS OF USE.” The contents of the aforementioned applications are hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION

[0002] This invention relates generally to dental instruments and more particularly to devices and methods of use for injecting a liquid anesthetic during periodontal or other dental procedures, but which can be used for other procedures involving the injection of a liquid into tissue in the body of a living being.

BACKGROUND OF THE INVENTION

[0003] As is known, the periodontal ligament injection (“PDL”) is an accepted intraligamentary injection modality for primary anesthesia for one or two teeth. It is also used as a supplement to infiltration or block techniques. The PDL technique entails use of a small amount of anesthetic to produce instant anesthesia. In particular, an ultra-short needle is placed in the gingival sulcus on the mesial and distal surfaces and advanced along the root surface until resistance is met. Then the needle is advanced further to make contact and dispense more anesthetic liquid. This allows the numbing of the tooth without the patient feeling the process. The technique’s primary advantage is that it provides pulpal anesthesia for 30 to 45 minutes without an extended period of soft tissue anesthesia. Moreover, because only a small amount of liquid anesthetic is injected at the site of the periodontal ligament (which inherently has limited blood circulation) PDL can be used in patients with bleeding disorders.

[0004] Various syringes and techniques have been proposed and used in the prior art for effecting PDL and there are even computer controlled anesthetic delivery systems, e.g., “The Wand” offered by Milestone Scientific, of Livingston, N.J. Such prior art syringes, techniques and systems, while suitable for their intended purposes, nevertheless leave something to be desired from one or more of the following standpoints: trauma, patient fear of needles, simplicity, cost, ease of use and effectiveness. Thus, a need

exists for a low cost, simple device for readily accomplishing a periodontal ligament injection with minimal, if any patient discomfort. The subject invention addresses that need.

[0005] In addition, the subject invention also provides a device and method of use for injecting a liquid anesthetic into the gum and underlying tissue of a patient with less pain than accomplished with conventional needle syringes.

SUMMARY OF THE INVENTION

[0006] In accordance with one aspect of the invention there is provided an applicator for effecting an intraligamentary injection of a liquid anesthetic into the gingival sulcus of a patient. The applicator basically comprises a body member having an elongated tip. The tip is a generally planar, thin member having an atraumatic free end and a passageway extending therethrough and terminating at the free end of the tip. The applicator is arranged to be secured to a source of liquid anesthetic, whereupon the liquid anesthetic may be selectively introduced into the applicator. The free end of the elongated tip of the applicator is arranged for producing a substantially fluid-tight interface with the anatomic structures at the gingival sulcus, whereupon the liquid anesthetic may be forced from the applicator through the passageway out of the open free end of the tip to enter into the gingival sulcus so that it is directed downward along the root of the adjacent tooth and is prevented from flowing upward and outward.

[0007] In accordance with another aspect of this invention there is provided an applicator for effecting an injection of a liquid anesthetic into the tissue of a person. That applicator basically comprises a coupling, an elongated member having a distal end portion in the form of a hollow skirt having a free edge, and an elongated cannula having an open distal end located within the skirt proximally of the free edge. The open distal end of the cannula is sharp. The coupling is arranged for securing the applicator to a source of liquid anesthetic, whereupon the liquid anesthetic may be selectively introduced within the cannula and from there into the hollow skirt. The hollow skirt is formed of a flexible material suitable for producing a substantially fluid-tight interface with the tissue to locally anesthetize the tissue when the liquid anesthetic is introduced into the hollow skirt. The sharp distal end of the cannula is movable relative to the free edge of the hollow skirt to enable the sharp distal end to penetrate the tissue to inject the liquid anesthetic into the tissue. The applicator may optionally include electrodes forming a portion of a transcutaneous electrical nerve stimulation (TENS) unit.

[0008] In accordance with another aspect of this invention there is provided a method for effecting an intraligamentary injection of a liquid anesthetic into the gingival sulcus of a patient. That method basically entails providing an applicator comprising an elongated member having a hollow interior, an open distal free end, and a portion located proximally of the open distal free end in communication with the hollow interior. The open distal free end of the elongated member is formed of a resilient and somewhat conformable material. The open distal free end of the elongated member is introduced into the gingival sulcus to engage the anatomic structures at the gingival sulcus wherein the resilient and conformable material at the open distal free end produces a substantially fluid-tight interface thereat. A liquid anesthetic is provided into the hollow interior of the elongated member

and through the open distal free end into the gingival sulcus so that the liquid anesthetic is directed downward along the root of the adjacent tooth and is prevented from flowing upward and outward by the fluid-tight interface.

[0009] In accordance with another aspect of this invention there is provided a method for effecting an injection of a liquid anesthetic into the tissue of a person. The method basically entails providing an applicator having a distal end portion in the form of a skirt having hollow interior and a peripheral free edge. The applicator also comprises an elongated cannula having an open distal end located within the skirt proximally of the free edge. The open distal end of the cannula is sharp. The hollow skirt is formed of a flexible material. The free edge of the hollow skirt is placed into engagement with the tissue of the person, whereupon the flexible material at the free end of the skirt produces a substantially fluid-tight interface with the tissue. Liquid anesthetic is provided into the hollow interior of the skirt and into engagement with a portion of the tissue bounded by the peripheral free edge of the skirt to anesthetize the tissue thereat. The sharp distal end of the cannula is moved relative to the free edge of the hollow skirt to cause the sharp distal end to penetrate the portion of the tissue to inject the liquid anesthetic therein. The applicator may optionally include electrodes forming a portion of a transcutaneous electrical nerve stimulation (TENS) unit so that the unit may be operated during the injection procedure. By way of example, but not limitation, instead of providing the liquid anesthetic into the hollow interior of the skirt to anesthetize the tissue thereat, the TENS unit can be operated to anesthetize the tissue, whereupon after the tissue has been anesthetized the cannula may be moved to cause its sharp end to penetrate the tissue. The tissue may comprise the gum and underlying tissue of a dental patient or any other tissue of a person.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is an isometric view of one exemplary syringe including an anesthesia applicator or injector constructed in accordance with this invention for periodontal ligament injection (intraalveolar injection);

[0011] FIG. 2 is an enlarged end view of the applicator shown in FIG. 1;

[0012] FIG. 3 is an enlarged side elevation view of the applicator shown in FIG. 1;

[0013] FIG. 4 is an enlarged top plan view of the applicator shown in FIG. 1;

[0014] FIG. 5 is a greatly enlarged illustration, partially in section, of the exemplary anesthesia applicator/injector of FIG. 1 shown in the process of performing a periodontal ligament injection;

[0015] FIG. 6 is a partial sectional view of an alternative anesthesia applicator/injector constructed in accordance with another aspect of this invention, e.g., an injector for penetrating oral tissue;

[0016] FIG. 7 is a partial sectional view of still another alternative anesthesia applicator/injector constructed in accordance with another aspect of this invention, e.g., a device like that of FIG. 5 but including a electrodes of a transcutaneous electrical nerve stimulation (TENS) unit to facilitate further pain reduction; and

[0017] FIG. 8 is an illustration, similar to the illustration of FIG. 4, but showing the applicator/injector of FIG. 5 in the process of performing an injection of through the gingiva.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0018] Referring now to the various figures of the drawings wherein like reference characters refer to like parts, there is shown in FIG. 1 at **20** an applicator or injector mounted constructed in accordance with one exemplary embodiment of this invention shown mounted on a syringe **22** for use in a periodontal procedure. The applicator can be a separate unit or may form an integral part of the syringe. In either case the applicator is connected to the syringe by means of a coupling. In the exemplary embodiment shown in FIGS. 1-4 the applicator is an integral device which is arranged to be mounted on the syringe. The applicator includes a passageway (to be described later) therethrough for enabling the liquid anesthetic to flow therethrough. The syringe **22** can be of any suitable construction so that a liquid anesthetic can be located within a chamber (not shown) in it to be forced from the chamber through into the applicator when desired. To that end the exemplary embodiment of the syringe **22** includes a plunger **24** which when depressed forces the liquid anesthetic out of the syringe's chamber through a coupling (not shown) and into the applicator **20**.

[0019] It should be pointed out that the applicator **20** may be used with devices, other than a syringe. For example, it can be used with any controlled anesthetic delivery system, like the "The Wand", identified above or with any other equipment, e.g., an electric pump system, arranged to provide a liquid anesthetic under some force.

[0020] As best seen in FIGS. 2-4, the applicator **20** basically comprises a hollow proximally located body section **26** from which an elongated tip **28** projects. The tip **28** is a thin, generally planar member which has a generally rectangular profile in cross-section. The body section includes a proximally located chamber **30** (FIGS. 3 and 4) and a distally located chamber **32**. The chamber **30** is arranged to receive a bolus of the anesthetic from the syringe when the syringe is actuated. The chamber **30** tapers downward in the distal direction in two sections, **30A** and **30B**, with the taper in section **30B** being more severe than the taper of section **30A**. The chamber **32** is in fluid communication with the chamber **30** and is located distally thereof. The chamber **32** serves to produce a jet of the anesthetic liquid from the chamber **30**. To that end, the chamber **32** is of a constant diameter, which is less than the diameter of the chamber **30**. The chamber **32** extends into the proximal portion of the tip **28**.

[0021] The tip **28** is preferably formed of a somewhat flexible material, e.g., polypropylene or polycarbonate or any other suitable plastic or other material. A small diameter passageway **34** extends through the tip **28** from its distal end **36** to the distal end of the chamber **32**, so that the passageway **34** is in fluid communication with the chamber **32**. As best seen in FIG. 4, the distal end **36** of the tip **28** is rounded to be atraumatic and includes a semi-circular shaped cut **38** (FIG. 4) at its distal-most point. The distal end of the passageway **34** terminates at the cut **38** and is in fluid communication therewith.

[0022] As mentioned above the tip **28** has a generally flat profile. More precisely, and in accordance with one exemplary preferred embodiment of the invention, the peripheral edge of the distal end portion of the tip is tapered symmetrically at **40**. This peripheral taper feature, coupled with the fact that the tip is somewhat flexible facilitates atraumatic entry of the tip into the gingival sulcus.

[0023] In one preferred exemplary embodiment of the invention the total length of the applicator **20** is approximately 4 cm (e.g., 2, 3, 4, 5 or 6 cm), with the length of the applicator from its distal end **36** to the proximal end of its chamber **32** being approximately 3 cm (e.g., 1, 2, 3, 4 or 5 cm). The distal portion of the tip **28** is approximately 4 mm (e.g., 2, 3, 4, 5 or 6 mm) wide and 0.5 to 1.0 mm (e.g., 0.5, 0.6, 0.7, 0.8, 0.9 or 1 mm) thick, with the diameter of the passageway **34** being approximately 0.25 mm (e.g., 0.1, 0.2, 0.25, 0.3 or 0.4 mm). The diameter of the chamber **30** at the proximal end of section **30A** is approximately 5.4 mm (e.g., 3.0, 4.0, 5.0, 5.4, 6.0 or 7.0 mm), while the internal diameter of the proximal end of the section **30B** is approximately 3.5 mm (e.g., 2.0, 3.0, 3.5, 4.0 or 5.0 mm). The diameter of chamber **32** is approximately 2.5 mm (e.g., 1.0, 2.0, 2.5, 3.0 or 4.0 mm), while its length is approximately 1.7 cm (e.g., 0.5, 1.0, 1.7, 2.0, 2.5 or 3.0 cm).

[0024] It should be pointed out that the foregoing dimensions are merely exemplary and other shapes and sizes of the applicator **20** are contemplated so long as they enable the distal end of the applicator to be atraumatically introduced into the gingival sulcus along the periodontal ligament to engage the anatomic structures at the gingival sulcus to inject the liquid anesthetic therein.

[0025] Operation of the applicator/injection can best be appreciated by reference to FIG. 5. In particular, as shown therein the tip **28** of the applicator **20** is arranged to be atraumatically introduced into the gingival sulcus between the tooth **10** and the gingiva (gum) **12** along the periodontal ligament **14** to engage the anatomic structures thereat. The periphery of the distal portion of the tip being tapered and somewhat flexible forms or produces a fluid tight seal with the immediately adjacent anatomic structures. Thus, when the plunger **24** of the syringe **22** is pressed inward, a jet of the anesthetic liquid produced in the chamber **32** is forced through the communicating passageway **34** out through its open distal end at the cut **38** so that the anesthetic set is directed downward along the root **16** of the adjacent tooth **10** and is prevented from flowing upward and outward by the fluid-tight interfacial seal formed by the free end of the tip.

[0026] As should be appreciated by those skilled in the art the use of the thin, flexible tip of the applicator **20** enables one to readily deliver an anesthetic solution through the periodontal membrane, thus doing away with the use of needles. However, it is also within the scope of the invention to place the applicator over a conventional needle and deliver the anesthetic solution through the needle and applicator while preventing the needle from contacting the patient.

[0027] Turning now to FIGS. 6-8 there is disclosed another exemplary embodiment of an injector **120** constructed in accordance with this invention. This embodiment and variants encompassed by this invention is primarily arranged for infiltration to numb teeth, which heretofore has been accomplished by use of a sharp cannula to pierce the oral tissue adjacent the roots of the teeth to cause the teeth to numb. To that end, the applicator **120**, like the applicator **20** is arranged to be used with a syringe (e.g., it may be a separate unit arranged to be mounted on a syringe or may be an integral part of the syringe) or may be used with any controlled anesthetic delivery system, like the "The Wand", identified above or with any other device arranged to provide a liquid anesthetic under some force. Unlike the applicator **20** of FIGS. 1-4, the applicator **120** is arranged to

penetrate the gingiva to deliver the liquid anesthetic there-through. However, like the applicator **20**, the applicator injector **120** achieves that end in an atraumatic manner.

[0028] As best seen in FIG. 7, the applicator **120** basically comprises a coupling **122**, an elongated tubular body **124** and an elongated cannula **126**. The elongated tubular body is formed of a somewhat flexible material, e.g., silicone, and has a distal end portion in the form of a hollow skirt **128** having a free edge **130**. The cannula **126** is an elongated tubular member formed of any suitable material, e.g., silicone which is more rigid, than the silicone of the body **124**. The cannula **126** has a sharpened, open distal free end **132**. The cannula **126** extends through the tubular body **124** so that its open free end **132** is in fluid communication with the hollow skirt **128**, e.g., the free end **132** may be located within the hollow skirt **128** (shown) or may be retracted slightly from it but still in fluid communication with it. The hollow body **124** is mounted on the coupling **122** via a threaded engaging portion **134**. The coupling **122** includes a passageway **136** which is in fluid communication with the interior passageway of the cannula and also with the outlet passageway of the chamber in the syringe in which the liquid anesthetic is located.

[0029] The periphery of the free edge **130** of the skirt **128** of the applicator/injector **120** is arranged to be brought into engagement with the surface of the gingiva where the injection is to be made, like shown in FIG. 8, whereupon the free edge **130** of the skirt **128** forms a substantially fluid tight seal with the outer surface of gingiva **12** thereat. Accordingly, when the syringe **22** is operated, e.g., its plunger **26** depressed, the liquid anesthetic is forced out of the syringe's chamber through the coupling's passageway **136**, into the cannula **126** and out the open end **132** of the cannula, whereupon the anesthetic will be within the skirt and thus in engagement with the portion of the gingiva bounded by the periphery of the free edge of the skirt. This initial dose of the anesthetic serves to locally anesthetize the gingiva, so that once that has occurred the cannula can be used to penetrate the gingiva to a desired depth therebelow to deliver a second dose of the anesthesia, without causing the patient to experience any pain or discomfort. To that end, the cannula **126** is arranged to be moved with respect to the free edge **130** of the skirt **128** so that it can extend distally therebeyond to inject the anesthetic through the gingiva into the underlying structure after the gingiva has been locally anesthetized. For example, the cannula may be threadedly coupled to the body **124** so that its sharp free end can be extended beyond the free edge **130** of the skirt and into the underlying structure by merely twisting a portion of the applicator **120**. Alternatively, the cannula may be coupled to the body so that its sharp free end can be extended beyond the free edge of the skirt by a sliding action, instead of a twisting action. In fact, it is even contemplated that the skirt portion **128** of the body **124** may be constructed so that it is collapsible, bendable or otherwise deformable, so that the sharpened free end of the cannula can be extended therebeyond by pushing on the applicator **120** after the free edge of the skirt has engaged the gingiva and the gingiva has been locally anesthetized to cause the skirt to collapse, bend or otherwise deform.

[0030] In any case, the cannula is arranged to move relative to the skirt from a retracted position, like shown in FIGS. 6 and 7, to an extended position (not shown) wherein the sharpened free end of the cannula extends beyond the

free edge **130** of the skirt through the gingiva and into the underlying anatomic structure to a desired depth, e.g., into the bone **18**, after the gingiva has been locally anesthetized by the anesthetic in the hollow skirt. At that point the plunger of the syringe can be depressed again to inject a dose of the anesthetic into that underlying anatomic structure.

[0031] In the interest of making the injection procedure as atraumatic as possible, the distal edge **130**, if not the whole body **124** or skirt **128**, is formed of a resilient and conformable material. Preferably, the distal free end is also somewhat rounded in shape to form an atraumatic end surface.

[0032] In FIG. 7, there is shown an alternative embodiment of an applicator/injector **220**, which is constructed similarly to the applicator **120**. Thus, in the interest of brevity the structural details of the applicator **220** which are the same as those of the applicator **120** will be given the same reference numbers and the details of their construction and operation will not be reiterated. The applicator **220** includes a pair of electrodes **222** which are located within the tubular body **124** and which are connected to a remote TENS unit (not shown) via a pair of electrical conductors (not shown). Thus the TENS unit can be operated to numb the tissue prior to the cannula's penetration of the tissue, thus further lessening the chance that the patient will experience pain during the injection procedure.

[0033] It should be pointed out at this juncture that the embodiments of the applicator/injectors of FIGS. 6 and 7 are not limited to infiltration usage as just described. Hence they can be used for PDL procedures as well. For such usage the applicator has to be appropriately sized and shaped to enter the gingival sulcus. Once the distal end of the applicator/injector **120** or **220** has entered that region the syringe can be operated to inject the liquid anesthetic into the skirt **128**, where it will engage and locally anesthetize the adjacent tissue/anatomic structure. Once that small area has been exposed to the anesthetic for a sufficient time to be numbed, the cannula **126** can then be moved relative to the free edge **130** of the skirt to cause it to penetrate the underlying tissue/anatomic structure, whereupon a second dose of the anesthetic may be injected to numb the tooth.

[0034] Moreover the applicator **120** is not limited to dental use. Thus, it can be used to inject a liquid anesthetic (or any other liquid substance, for that matter) into any tissue of a patient atraumatically.

[0035] It should also be pointed out that the particular materials used to form the applicator/injectors as described above are merely exemplary of various materials which may be used.

[0036] Without further elaboration the foregoing will so fully illustrate my invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

1. (canceled)
2. An apparatus for effecting an intraligamentary injection of a liquid anesthetic into the gingival sulcus proximate a tooth of a dental patient, the apparatus comprising:
 - a body having an elongated, thin and generally planar tip, the tip having an atraumatic free end and a passageway extending therethrough terminating at the free end of the tip, the free end of the tip being arranged for producing a substantially fluid-tight interface with anatomic structures at the gingival sulcus; and
 - an applicator couple with the body and arranged to secure a source of the liquid anesthetic, the applicator being configured to be operated to selectively introduce the liquid anesthetic from the applicator through the passageway through the body and out of the free end of the tip to enter into the gingival sulcus so that it is directed downward along the root of the tooth and is prevented from flowing upward and outward.
3. The apparatus in accordance with claim 2, wherein the tip is formed of a flexible material.
4. The apparatus in accordance with claim 2, wherein the free end of the tip is rounded to be atraumatic.
5. The apparatus in accordance with claim 2, wherein the applicator includes a syringe with a plunger that allows for the selective introduction of the liquid anesthetic.
6. The apparatus in accordance with claim 2, wherein the passageway includes a cannula having a sharp end that extends beyond the free end of the tip.

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