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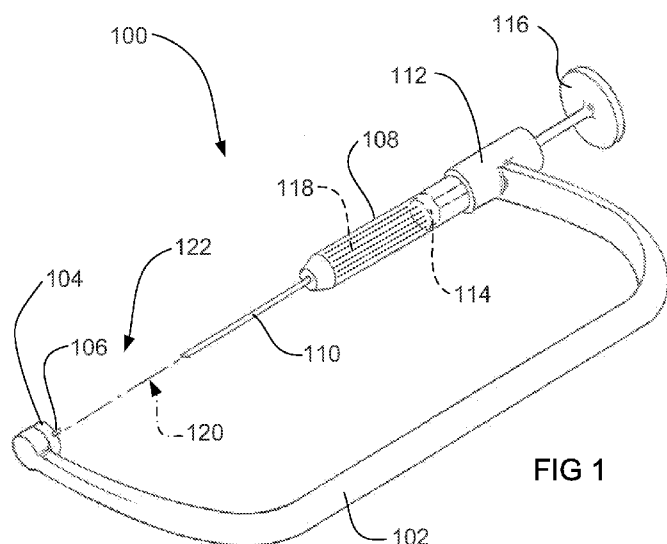


FIG 1

(57) Abstract: An injection guide device for administering a dental anaesthetic injection to a subject has a body portion comprising a light source with an emitter and a syringe retaining region. The syringe retaining region is configured to align a syringe needle with the emitter such that light from the emitter is substantially collinear with the needle. The body portion is configured to receive a portion of the subject's cheek between the syringe needle and the emitter such that operation of the light source produces a luminous indicator on the subject's skin which is alignable with an extra-oral landmark to guide insertion of the needle. In another embodiment the injection guide device comprises a physical locating member. The device is useful for performing the Gow-Gates mandibular block.

A DENTAL INJECTION GUIDE DEVICE AND METHOD FOR USING THE SAME

Field of the invention

The present invention relates to a device for use in guiding an injection for administration of dental anaesthetic to a patient. It also relates to a method for administering anaesthetic using the guide device. The invention relates particularly, but not exclusively, to an injection guide device for use in performing a Gow-Gates mandibular nerve block.

Background to the invention

The mandibular block is one of the most commonly delivered major nerve block injections performed in dentistry. One popular mandibular block is the inferior alveolar nerve block. However, this block, even when performed expertly, does not always result in complete pulpal anaesthesia. Failure rates of up to 20% are relatively common and it is believed that around 90% of general dentists have difficulties with performing inferior alveolar nerve block.

An alternative approach to the inferior alveolar nerve block was developed in the 1970's. Named after the man who developed it, the Gow-Gates technique uses extra-oral and intra-oral landmarks to direct the needle to a higher local anaesthetic deposition point than that used with the inferior alveolar nerve block. The Gow-Gates technique provides sensory anaesthesia to virtually the entire distribution of the trigeminal (5th) (inferior alveolar, lingual, mylohyoid, mental, incisive, auriculotemporal, and buccal nerves) and is therefore considered a true mandibular block. It is a useful alternative to the inferior alveolar nerve block and when performed correctly, has a higher success rate.

A disadvantage associated with use of the Gow-Gates technique is that it has been described as "initially more difficult to learn" than the inferior alveolar nerve block because the positioning and orientation of the needle during insertion is different to that which is required for inferior alveolar nerve block. Thus, until the operator gains sufficient experience with the Gow-Gates technique, the incidence of unsuccessful anaesthesia may be comparable with that of inferior alveolar nerve block.

The Gow-Gates mandibular block requires the insertion of a dental needle into the tissues of the pterygomandibular space where the anaesthetic is deposited and relies on use of intra- and extra-oral landmarks. The landmarks described by Gow-Gates for aligning the needle from the point of insertion to the final resting point are:

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Intra-oral

- The mesiopalatal cusp of the maxillary second molar. Injection height is established by the placement of the needle tip just below this cusp.
- A site just distal to the maxillary second molar at the height established in the preceding step. Penetration of the soft tissues occurs at this site.

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Extra-oral

- The lower border of the tragus of the ear (i.e. the intertragic notch). The precise landmark is the centre of the external auditory meatus, which is concealed by the tragus; its lower border may therefore be adopted as a visual aid.
- The corner of the patient's mouth. The puncture point lies in the plane extending from the lower border of the intertragic notch of the ear, through the corner of the mouth.
- The angle of the ear to the side of the face is used as a guide for assessing the divergence of the ramus of the mandible from the sagittal plane.

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There have been past attempts to develop devices for assisting performance of the Gow-Gates mandibular nerve block. However, their uptake has not been widespread.

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The limited uptake may be at least in part attributable to the need to insert part of the device, an auricular anchor, into the patient's ear. This exacerbates the patient's anxiety and is uncomfortable, not to mention unhygienic.

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It would be desirable to provide an alternative device for guiding dental anaesthesia using the Gow-Gates technique. Such a device may increase the success rate for the procedure, particularly when performed by inexperienced operators, and may give operators more confidence in executing the Gow-Gates technique. Ultimately, this

may lead to an increase in the level of uptake of the technique in performing mandibular nerve block.

The discussion of the background to the invention included herein including reference to documents, acts, materials, devices, articles and the like is intended to explain the context of the present invention. This is not to be taken as an admission or a suggestion that any of the material referred to was published, known or part of the common general knowledge in Australia as at the priority date of any of the claims.

10 **Summary of the invention**

According to one aspect of the present invention, there is provided an injection guide device for administering a dental anaesthetic to a subject, the guide device having a body portion comprising: a light source with an emitter and a syringe retaining region. The syringe retaining region is configured to align a syringe needle with the emitter such that light from the emitter is substantially collinear with the needle. The body portion is configured to receive a portion of the subject's cheek between the syringe needle and the emitter such that operation of the light source produces a luminous indicator on the subject's skin which is alignable with an extra-oral landmark to guide insertion of the needle. Ideally, the luminous indicator is visible to the operator's naked eye.

In one embodiment, the syringe retaining region is configured to removably receive and retain a syringe containing anaesthetic for administration to the subject. Thus, the syringe may be interchangeable so that the guide device is re-useable. In a preferred embodiment, the syringe retaining region is configured to retain a standard syringe of the type which is widely available for use in dental anaesthesia. The syringe retaining region may be adjustable to accommodate different syringe sizes. It is also contemplated that specially designed syringes may be manufactured to be compatible with the guide device, e.g. with corresponding notches and grooves, which are used to retain and release a syringe in the retaining region. Such notches and grooves may provide e.g. a 'twist lock' type coupling.

In an embodiment, the guide device includes a power source for powering the light source. Ideally, the power source is a battery which, in a preferred embodiment, is

removable or receivable within the body portion. This enables spent batteries to be replaced for continued use of the guide device and also permits removal of the battery prior to sterilisation of the body portion. The battery may take any suitable form which is capable of driving the light source. Thus, the battery may be a AAA, AA or even a watch-style battery. Ideally the battery is accommodated in a housing in the body portion, with the housing located in a region that gives rise to good balance within the device when in use. Thus, it is desirable to locate the housing for the battery closer to the operator's hand to minimise moment forces that may cause the device to twist or rotate during use.

Ideally, the light source generates light in the visible spectrum. Light is emitted through the emitter, in alignment with the needle so as to produce a visible luminous indicator which is collinear with the needle. Light may be generated by the light source in any suitable manner as may be known to one of skill in the art, and in any colour. In one embodiment, the light source is a light emitting diode or laser diode which generates luminous emissions in e.g. the yellow, green or red spectra. Orange, blue and other colours are also contemplated. It has been found that emissions in the green spectrum may produce a 'brightness' which is easily observed by the operator at low power and so, to avoid excess heating and power consumption this may be particularly desirable, although any colour light may be used. Preferably the light source emits light at power of less than 50 mW, preferably, less than 20 mW, more preferably less than 10 mW and more preferably still, less than 5mW.

Ideally, the guide device includes a selector means for selecting an operational state of the light source. In its simplest form, the selector means controls operation of the light source enabling it to be switched between "off" and "on" states. In another embodiment, the selector means may control the power or wavelength of luminous emissions from the light source and so, control the colour, intensity and/or size of the luminous indicator which falls incident on the subject's skin during operation of the device. Thus the selector may be e.g. a button, switch, dial or combination of these. Where power and 'focus' controls (governing the size of the light 'dot' on the subject's skin) are available, the selector means may alternatively/additionally comprise a knob or dial. Ideally, the size of the light dot is sufficiently large for the operator to see,

while still being small enough to minimise positional error with regard to identifying the location of the extra-oral landmark.

In one embodiment, the light source has an energy supply (e.g. battery) and control
5 circuitry which are removable from the injection guide device for cleaning and/or
sterilisation. This may be achieved by providing the control circuitry in a housing
having a snap in-snap out type connection with the body portion, or may involve
threaded couplings or the like to receive and remove the housing containing electrical
and electronic components from the device for cleaning or e.g. autoclaving.
10 Alternatively the guide device may be sterilised using other approaches such as
ultraviolet irradiation.

In one embodiment, the guide device includes a mirror attachment for viewing a
reflected image of the visible luminous indicator on the subject's skin surface. This
15 may be useful where the operator is positioned on one side of the subject and the
light source is illuminating an extra-oral landmark on the other side of the patient's
face. In such arrangement it may be difficult for the operator to crane his head
around the patient to inspect whether the luminous indicator is trained onto the extra-
oral landmark. Accordingly, the mirror attachment may aid visibility. The mirror
20 attachment may be removably attachable to the body portion, or it may be a
permanent feature of the guide device.

According to another aspect of the present invention, there is provided an injection
guide device for administering a dental anaesthetic injection to a subject, the guide
25 device having a body portion comprising: a locating member configured to move
along an axis and a syringe retaining region configured to align a syringe needle with
the locating member such that the locating member is substantially collinear with the
needle. The body portion is configured to receive a portion of the subject's cheek
between the syringe needle and the locating member and the locating member is
30 moveable along the axis toward the subject's skin at an extra-oral landmark to guide
insertion of the needle.

In one embodiment, the locating member is a pin which is slidably coupled with the
body portion, e.g. through a sleeve, to permit advancement of the pin along the axis,

collinearly with the needle. This enables the pin to approach or contact the subject's skin at the extra-oral landmark.

In one embodiment, the locating member has a biased condition in which the position
5 of the locating member along the axis is biased toward the subject at the extra oral
landmark. That is, the locating member may be spring-loaded such that the natural
position of the locating member is toward the extra oral landmark to enable the
operator to correctly align the needle with both the intra- and extra-oral landmarks
before advancing the needle into the tissue to administer the anaesthetic. Ideally, the
10 locating member has an atraumatic tip which, if in contact with the subject's skin, will
minimise or avoid perforating, scratching or otherwise harming the subject.

The locating member may also have a retracted condition in which the position of the
locating member along the axis is not biased toward the extra oral land mark. The
15 retracted condition may counteract a biased condition in which the locating member is
spring-loaded, e.g. by having a locking mechanism that maintains a retracted position
of the locating member relative to a sleeve or other part of the body portion with which
the locating member is coupled. A locking mechanism between the sleeve/body
portion and the locating member may comprise e.g. a detent, tooth, peg, frictional,
20 threaded or other form of releasable engagement between the parts.

In one embodiment, the body portion includes a sleeve through which the locating
member moves, and the sleeve and at least portion of the locating member have co-
operable threaded portions. The threaded portions enable the locating member to be
25 engaged with the sleeve when in an advanced condition, wherein the position of the
locating member is toward or in contact with the subject's skin at the extra-oral
landmark. This may be utilised as an alternative to a spring-loaded or other biased
configuration as described above. The locating member may alternatively/
additionally have a threaded portion toward an opposing end for retaining the locating
30 member in a retracted condition.

Preferably, the guide device is sterilisable between uses. It is also contemplated that
the guide device may be disposable and/or that the syringe barrel and needle is

provided as a permanent feature of the device, with the entire unit being disposable after the anaesthetic has been delivered using the guide device and needle.

Ideally, the body portion has a handle region which is gripped by or otherwise
5 contacted by the operator's hand. In one embodiment, the handle region is configured to rest upon the operator's hand during administering the anaesthetic. In such arrangement, handle region may be contoured to accommodate and be supported by at least part of the operator's forefinger and thumb. In another embodiment, there is a handle which is grasped by the operator during use of the
10 device. In this embodiment, the battery may be housed in a cavity in the handle.

In an embodiment, the injection guide device includes a retractor member for retracting at least part of the cheek of the subject during use of the injection guide device. This may help the operator to inspect the oral cavity and locate the intra-oral
15 landmarks prior to puncturing the tissue with the needle.

According to another aspect of the present invention, there is provided a method for using the injection guide device described above for guiding administration of a dental anaesthetic to a subject. The method includes positioning the guide device with the
20 needle tip directed at an intra-oral landmark and, in one embodiment, activating a light source in the device to provide a luminous indicator on the subject's skin, then positioning the guide device with the luminous indicator aimed at an extra-oral landmark and advancing the needle into the subject's tissue while substantially tracking the luminous indicator on the extra-oral landmark. In another embodiment,
25 the method involves advancing a physical locating member toward the subject's skin at the extra-oral landmark and advancing the needle into the subject's tissue while substantially tracking the locating member on the extra-oral landmark. It may be preferable to configure the locating member in a biased condition in which the locating member is biased toward and preferably in contact with the subject's skin at the extra-oral landmark while the needle is located and advanced into the tissue.
30

In a preferred embodiment, the extra-oral landmark is the apex of the intertragic notch of the ear. In one embodiment, the method includes applying a marker to the subject's skin at the apex of the intertragic notch to designate a more precise location

of the extra-oral landmark. This can make tracking the luminous indicator or the locating member onto the landmark easier.

Preferably, the guide device is calibrated before use, ideally before every use, by
5 aligning the syringe needle and the emitter to ensure the needle and the light emitted from the light source are collinear. Alternatively, calibrating the guide device may involve aligning the locating member and the syringe needle prior to use.

Viewed from another aspect of the invention, there is provided an injection guide
10 device for administering a dental anaesthetic to a subject, the guide device including a body portion, a light source with an emitter toward a first end of the body portion and a syringe retainer toward a second end of the body portion, the syringe retainer being configured to receive a syringe with a needle and plunger. The body portion aligns a longitudinal axis of the needle with the light source so as to align and
15 substantially maintain the tip of a syringe needle collinearly with light emitted from the light source as the syringe plunger is advanced into syringe barrel.

Viewed from another aspect still, the present invention provides a guide device for
administering a dental anaesthetic to a subject. The guide device includes a body
20 portion, a locator toward a first end of the body portion and configured to be directed to a target on the subject's skin and a syringe retainer toward a second end of the body portion. The syringe retainer is configured to receive a syringe with a needle and a plunger. The body portion aligns a longitudinal axis of the needle with the locator so as to align and substantially maintain the tip of the syringe needle
25 collinearly with the locator as the syringe plunger is advanced into the syringe barrel during administration of a dental anaesthetic. In one embodiment, the locator comprises a light source with an emitter, wherein operation of the light source produces a luminous indicator that is directable to a target on the subject's skin. In another embodiment, the locator comprises a locating member configured to move
30 along an axis toward the target on the subject's skin.

Brief description of the drawings

The present invention will now be described in greater detail with reference to the accompanying drawings. It is to be understood that the particularity of the

accompanying drawings does not supersede the generality of the preceding description of the invention.

Figure 1 is a schematic illustration of an injection guide device according to an embodiment of the present invention, in which there is a light source.

5 Figure 2 is a schematic illustration of an embodiment of the invention in use, during guiding of a needle during dental anaesthesia according to the Gow-Gates technique.

10 Figure 3 is a schematic illustration showing use of a guide device according to another embodiment of the invention, with a contoured handle region for resting on the operator's thumb and forefinger.

Figure 4 is a schematic illustration showing a guide device according to yet another embodiment of the invention, with a handle region for gripping by the operator during use.

15 Figure 5 is a schematic illustration showing use of a guide device according to another embodiment of the invention, the guide device having a retractor member for retracting part of the cheek.

Figure 6 is a schematic illustration showing use of a guide device according to another embodiment of the invention having a removable battery and light source.

20 Figure 7 is a schematic illustration showing use of a guide device according to yet another embodiment to the invention, the guide device having a mirror for viewing a reflected image of the visible luminous indicator on the subject's skin.

Figure 8 is a schematic illustration of an injection guide device according to an alternative embodiment of the present invention, in which there is a physical locating member.

25

Detailed description

Throughout this specification the embodiments shown in the drawings will be described using reference numbers to assist with identifying the various parts. Throughout the drawings like numerals will be used to refer to like parts.

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Where the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification (including the claims) they are to be interpreted as specifying the presence of the stated features, integers, steps or components, but not precluding the

presence of one or more other features, integers, steps or components or group thereof.

Referring firstly to Figure 1, there is shown an injection guide device 100 according to a first embodiment of the present invention. The injection guide device has a body portion 102 with a light source 104 having an emitter 106 for emitting light which, in use, is incident on the subject's cheek, forming a visible luminous indicator in the form of a dot of light. The dot of light is used to facilitate correct orientation of the needle prior to and during insertion into the soft tissues of the oral cavity. Toward an opposing end of the body portion 102 is a syringe retaining region 112 which holds a syringe 108 with syringe needle 110, plunger 114 and plunger end 116.

To use the device, the subject lies supine with the head back and mouth wide open so that the operator is able to visualise the intra-oral landmarks which designate the needle insertion point. Location of the intra-oral landmarks may be aided by the operator palpating the tissue with a finger, to identify the deep tendon of the temporalis muscle, the needle being inserted medially within 2mm of this structure.

Prior to injecting the subject, the guide device 100 is prepared by inserting the syringe in the syringe retainer 112. In a preferred embodiment, syringe retainer 112 is configured to retain standard syringes which are widely available for use in dental anaesthesia. The means to retain the syringe may comprise a sleeve for receiving the syringe barrel with e.g. a set screw passing through the sleeve and into abutment with the barrel to hold it in place. The sleeve may be adjustable to accommodate different syringe sizes. In another embodiment, the means to retain the syringe may incorporate one or more retaining clips which cradle the syringe barrel in the syringe retainer and frictionally engage it. Ideally, the retaining clips are resiliently biased to a retaining configuration and flex outwardly when a slight force is applied, to receive and remove syringe barrels. A similar arrangement is illustrated in Figure 6 in the form of retaining clips 140 which retain and cradle a removable battery. It is also contemplated that specially designed syringes may be manufactured to be compatible with the guide device, e.g. with corresponding notches and grooves, which are used to retain and release a syringe within the retaining region. Such notches and grooves may provide a 'twist and lock' type coupling.

With the syringe in the syringe retainer 112, the operator places needle 110 and part of syringe 108 in the mouth of the subject. Part of the cheek is positioned within opening 122 with the light source 104 and emitter 106 positioned near but not in contact with the subject's ear. The operator uses the guide device 100 to orient the needle 110 with respect to the intra- and extra-oral Gow-Gates landmarks prior to puncturing the tissue with the needle tip. Figure 2 is a schematic drawing the device of Figure 1 in use, prior to activation of the light source 104 to produce the visible luminous indicator on the skin surface. Here the guide device is being used to aid orientation of the needle within the guide device for a right mandibular block.

Ideally, once the needle insertion site (intra-oral landmark) has been identified, the light source is activated, light 120 is emitted from emitter 106 and a visible luminous indicator appears, in the form of a spot of light, on the subject's skin. Figures 6 and 7 show light beam 120 emitted from the emitter 106, and falling incident on the subject to form a dot of light on the subject's skin surface. The light source may be activated using a switch or trigger as may be known to one of skill in the art. The operator orients the guide device so that the visible luminous indicator is positioned at or "trained onto" the extra-oral landmark designated "A" in Figure 2.

Since the needle 110 and the emitter 106, and hence light emitted from the emitter are aligned, when the visible luminous indicator is positioned over the extra-oral landmark the needle is known to be aligned between the intra- and extra-oral landmarks and is so oriented correctly for administration of anaesthetic using the Gow-Gates technique.

With the guide device positioned as discussed above, the operator advances the needle into the soft tissue, while maintaining the position of the luminous indicator over the extra-oral landmark, until the operator detects that the needle has been inserted to the requisite depth. The requisite depth in most subjects is around 27 mm. This is typically identified when the operator detects that the needle tip has contacted bone (the final resting point at the lateral surface of the condylar neck). The visible luminous indicator incident on the subject's skin surface acts as a guide, which is visible to the operator, for the needle tip trajectory. Once the requisite depth has

been reached, the operator advances the plunger 114 into the syringe 108 and the anaesthetic formulation 118 is released into the tissue.

To assist in maintaining correct needle trajectory, the operator or an assistant may
5 mark the extra-oral landmark on the subject's skin using e.g. a non-permanent marker, adhesive dot or the like as shown at "A" in Figure 2. The marker or dot is ideally used to designate the location of the extra-oral landmark, i.e. the intertragic notch. It may be easier to maintain correct needle trajectory by tracking or training the visible luminous indicator on to a specific visible target of fixed position than would
10 be the case for tracking or training the light dot onto an unmarked anatomical landmark.

In one embodiment, the marker applied to the subject's skin is metallic or magnetic, and the guide device may include means for automatically checking alignment
15 between the needle tip and the extra-oral landmark using e.g. magnetic or electromagnetic field sensing. When alignment goes off track the guide device may include an automatically actuated alert means such as a loud speaker, light or vibrating member to provide audible and/or visible and/or haptic cues for the operator to correct the orientation of the guide device before advancing the needle into the soft
20 tissue. Ideally, a relatively rigid needle is employed during the procedure to minimise deflection from the desired needle tip trajectory. In one most adult cases, a 25 gauge needle is sufficient.

In one embodiment, the guide device and syringe are operable together using one
25 hand only, e.g. by resting the body portion on the operator's forefinger and part of the thumb while using the thumb to advance the plunger end 116 and plunger 114 into the syringe 108. This frees up the operator's other hand e.g. to retract the subject's cheek to provide better line of sight and/or to palpate the tissue around the intra-oral landmark to appropriately position the needle tip before insertion into the soft tissue.
30 Alternatively, the free hand may be useful for comforting or distracting the subject the subject during needle insertion.

Figure 3 is a schematic illustration of an embodiment of the guide device with the body portion 102 having a handle region 124 which is balanced on the operator's

hand 200 during use. In this embodiment, the handle region 124 has contours designed to accommodate at least part of the operator's forefinger and thumb so that the guide device sits comfortably and securely on the hand during use. Contours may be provided on either or both sides of the body portion so that it is comfortable for operation using the right or left or either hand. The weight of the guide device is ideally balanced in such a way that stability of the device is maximised. Thus, heavier components, such as batteries and the like, are ideally located at or toward the handle region of the body portion of the device.

Figure 4 is a schematic illustration showing use of an alternative embodiment of the device, in which the body portion 102 has been modified to provide a handle 134. In use, the handle is grasped or gripped by the operator, during orientation of the guide device and insertion of the needle into the tissue. In this arrangement, the guide device and syringe 108 may also be operable with one hand, with the fingers wrapped around the handle 134 and the thumb operating the plunger end 116. In this arrangement, a battery or power source for the light source 104 may be housed within the handle 134.

Figure 5 is a schematic illustration of yet another embodiment of the invention having a retractor member 136. In this embodiment, the guide device is positioned with the retractor member 136 just inside the subject's cheek, and the retractor member retracts the corner of the mouth and cheek away from the needle so as to open the mouth providing the operator with improved visual access to the intra-oral landmark. Given that the retractor member 136 contacts the subject's face and mouth, it is desirable to sterilise the device between uses, although this is contemplated even for embodiments of the guide device which do not require contact with the subject's face, mouth or skin.

In one embodiment, the guide device is re-useable. Between uses, a battery or other energy source housed within the body portion 102 is ideally removed so that the guide device may be sterilised e.g. by autoclave, washing, ultraviolet radiation or the like. Ideally other circuitry that is required to drive the light source and which is not hermetically sealed within the guide device may also be removed between uses to facilitate sterilisation.

Figure 6 shows another embodiment of the invention in use, with light 120 from light source 104 exiting emitter 106 and falling incident on the subject's skin, at the extra-oral landmark (the intertragic notch, as identified by the operator). An energy source in the form of battery 138 is housed in the body portion 102 toward the plunger and handle region of the guide device. A pair of retaining clips 140 cradle battery 138 within the body portion 102 and in contact with a conductive pathway (not shown) providing electrical contact between the battery 138 and light source 104. Prior to sterilisation, the battery 138 and light source 104 are removed from the guide device and the device is then sterilised as discussed above. In preparation for use, a battery 138 is inserted past the retaining clips 140 forcing the clips to flex outwardly to accommodate passage of the battery into the battery housing, where the clips hold the battery in place. Similarly, light source 104 is coupled to the body portion prior to use of the device. It is to be understood however that any suitable method for retaining the battery may be incorporated, as would be known to one of skill in the art.

The light source 104 may take any suitable form. Ideally the light source is low power, meeting safety standards applicable to the relevant medical device classification. In one embodiment, the light source is a laser light source such as a laser diode or a LED emitting e.g. red, green, yellow, blue, orange, white or other coloured illumination during operation. Given the close proximity of the light source to the subject's face, skin and eyes during use, it is desirable to minimise heat generation and also to minimise the risk of harm to the eyes, although the latter can be dealt with by having the subject (and optionally the operator and assistant if present) wear protective eyewear during the procedure. In one preferred embodiment, the light source emits green laser light at a power of around 5 mW although any colour emission having sufficient brightness and resolution will be sufficient.

Figure 7 shows a further modification of the device having a mirror 142 for viewing a reflected image of the visible luminous indicator (i.e. light dot) on the patient's skin, during use of the guide device for positioning and guiding a needle through the soft tissues for mandibular block using the Gow-Gates technique. In some scenarios it may be difficult for the operator to view the visible luminous indicator because he is

positioned on the opposite side of the subject's body. In some scenarios it may be possible for the operator to crane the neck over the subject to view the skin surface and check the position of the visible luminous indicator relative to the extra-oral landmark. In other scenarios, the operator may be guided by visual cues from an assistant. However where neither are possible, a mirror 142 may be useful. The mirror may be a removal accessory for use with the guide device, or it may be a permanent feature of the guide device.

Figure 8 shows an alternative embodiment of an injection guide device 100. In this embodiment, the light source, power supply and control circuitry have been removed and instead, a physical locating member in the form of a pin 159 is provided. The pin is configured to move along an axis which is collinear between the pin and the needle such that the pin is moveable along the axis toward the subject's skin at the extra-oral landmark, to guide insertion of the needle 110. As in other embodiments, the injection guide device has a body portion 102 and a syringe retaining region 112 which holds a syringe 108 with syringe needle 110, plunger 114 and plunger end 116.

In the illustrated embodiment, pin 159 is slidably coupled with the body portion 102 through a sleeve 158 within which the pin may advance and retract. Pin 159 includes a flange 162 which stops the pin from advancing all the way through and out of the sleeve 158 when advanced toward the extra-oral land mark.

With the syringe in the syringe retainer 112, the operator places needle 110 and part of syringe 108 in the mouth of the subject. Part of the cheek is positioned within opening 122. Ideally, once the needle insertion site (intra-oral landmark) has been identified, the pin is advanced, collinearly with the needle, toward the subject's skin targeting the pin tip 160 onto the extra-oral landmark. Since the needle 110 and pin 159 are aligned, when the pin tip 160 is trained onto or in contact with the extra-oral landmark, the needle is known to be aligned between the intra- and extra-oral landmarks and is so oriented correctly for administration of anaesthetic using the Gow-Gates technique.

In one embodiment, the sliding pin 159 may be biased or spring-loaded e.g. using a mechanism within the sleeve, such that the pin is biased toward the extra-oral target.

The bias means (e.g. spring) urges the pin to advance toward the extra-oral landmark thereby enabling the operator to align the pin with the landmark more effectively. Where there is no bias means, the pin 159 may move freely, sliding within the sleeve 158. In such arrangement, the operator may be aided by a dental assistant who
5 manually slides the pin toward the extra-oral landmark thereby improving correct alignment of the needle prior to and during insertion of the needle. With the guide device positioned as discussed above, the operator advances the needle into the soft tissue, while maintaining the position of the pin tip trained onto the extra-oral landmark, until the operator detects that the needle has been inserted to the requisite
10 depth.

Advantageously a guide device incorporating a physical locating member instead of a light source and illuminated locating aide may be produced and operated at a lower cost since a power source and electronic components are not required. Further, the
15 device incorporating a physical locating member may be more readily sterilisable and cleaned (e.g. by submersing in cleaning fluid) which may produce efficiencies and other cost savings in use.

Ideally the guide device is robust and durable yet relatively light weight and
20 economical to manufacture. Suitable materials may include PEEKTM, PEI (polyethyleneimine), PSU (polysulfone, polyethersulfone) and other injection mouldable polymers, stainless steel, aluminium, other alloys and the like. Ideally the materials used have dimensional stability since effective use of the guide device depends on maintaining alignment between the needle and the emitted light. The
25 guide device may be calibrated, preferably between each use, by manipulating the needle within the syringe while the light source is activated, to ensure alignment between the emitter and hence the visible luminous indicator and the needle when the device is used.

30 Ideally, the syringe and needle is interchangeable so that used syringes can be removed and disposed after a single use. The guide device can then be sterilised e.g. by autoclaving, and prepared with a fresh syringe before the next use. Alternatively, the guide device may be manufactured with the syringe forming part of

the device itself, as a permanent fixture. In such embodiment, the entire guide device and syringe is a one-use only product which is disposed of after use.

Advantageously, the inventive device enables the operator to ensure that the needle
5 is precisely aligned with the extra-oral landmark. The light emitted toward the needle tip can be calibrated easily before use and is then trained onto the extra-oral landmark (the apex of the intertragic notch of the ear, or a mark designating that landmark) while the needle is advanced to the final resting point. This makes
10 alignment of the needle intra-orally with the extra-oral landmark much easier than relying on guesswork alone, and is especially useful for those learning the Gow-Gates technique. Use of the device eliminates the guesswork involved with orienting the needle, and replaces it with precision.

It is to be understood that various modifications, additions and/or alterations may be
15 made to the parts previously described without departing from the ambit of the present invention as defined in the claims appended hereto.

The claims defining the invention are as follows:

1. An injection guide device for administering a dental anaesthetic injection to a subject, the guide device having a body portion comprising:
 - 5 a light source with an emitter; and
 - a syringe retaining region configured to align a syringe needle with the emitter such that light from the emitter is substantially collinear with the needle;
 - wherein the body portion is configured to receive a portion of the subject's cheek between the syringe needle and the emitter such that operation of the light
 - 10 source produces a luminous indicator on the subject's skin which is alignable with an extra-oral landmark to guide insertion of the needle.
2. An injection guide device according to any one of the preceding claims, further including a housing for removably receiving a battery for powering the light source.
- 15 3. An injection guide device according to claim 2, wherein a battery powering the light source is located within or in close proximity to a handle region of the body portion.
- 20 4. An injection guide device according to any one of the preceding claims, wherein the light source emits light in the visible spectrum, preferably in one or more of the yellow, green or red spectra.
5. An injection guide device according to any one of the preceding claims,
- 25 wherein the light source emits light at power of less than 50 mW, preferably, less than 20 mW, more preferably less than 10 mW and more preferably still, less than 5mW.
6. An injection guide device according to any one of the preceding claims, wherein the light source has an energy supply and control circuitry which are
- 30 removable from the injection guide device for cleaning.
7. An injection guide device according to any one of the preceding claims, including a mirror attachment for viewing a reflected image of the visible luminous indicator on the subject's skin.

8. An injection guide device according to any one of the preceding claims including a selector for selecting an operational state of the light source.

5 9. An injection guide device for administering a dental anaesthetic injection to a subject, the guide device having a body portion comprising:

a locating member configured to move along an axis; and

a syringe retaining region configured to align a syringe needle with the locating member such that the locating member is substantially collinear with the needle;

10 wherein the body portion is configured to receive a portion of the subject's cheek between the syringe needle and the locating member; and

wherein the locating member is moveable along the axis toward the subject's skin at an extra-oral landmark to guide insertion of the needle.

15 10. An injection guide device according to claim 9, wherein the locating member is a pin which is slidably coupled with the body portion to permit advancement of the pin along the axis, collinearly with the needle, such that the pin approaches or contacts the subject's skin at the extra-oral landmark.

20 11. An injection guide device according to claim 9 or claim 10, wherein the locating member has a biased condition in which the position of the locating member along the axis is biased toward the extra oral landmark.

25 12. An injection guide device according to any one of claims 9 to 11, wherein the locating member has a retracted condition in which the position of the locating member along the axis is not biased toward the extra oral land mark

30 13. An injection guide device according to any one of claims 9 to 12 wherein the body portion includes a sleeve through which the locating member moves, and wherein the sleeve and at least portion of the locating member include co-operable threaded portions for engaging the locating member in an advanced condition, wherein the position of the locating member is toward or in contact with the subject's skin at the extra-oral landmark.

14. An injection guide device according to any one of claims 9 to 13 wherein the locating member includes an atraumatic tip.

15. An injection guide device according to any one of the preceding claims,
5 wherein the body portion includes a handle region configured to rest upon or to be grasped by an operator administering the anaesthetic.

16. An injection guide device according to claim 15, wherein the handle region is contoured to accommodate and be supported by at least part of the operator's
10 forefinger and thumb.

17. An injection guide device according to any one of the preceding claims, wherein the injection guide device is re-useable and sterilisable.

18. An injection guide device according to any one of the preceding claims further including a retractor member for retracting at least part of the subject's cheek during use of the injection guide device.

19. A method for using the injection guide device of any one of claims 1 to 8, for
20 guiding a needle for administration of a dental anaesthetic to a subject, the method including the steps of:

- (a) positioning the guide device with the needle tip directed at an intra-oral landmark;
- (b) activating the light source to provide a luminous indicator on the subject's skin;
- 25 (c) positioning the guide device with the luminous indicator aimed at an extra-oral landmark; and
- (d) advancing the needle into the subject's tissue while substantially tracking the luminous indicator on the extra-oral landmark.

20. A method according to claim 19 including the steps of:
applying a marker to the subject's skin at the apex of the intertragic notch of the ear, wherein the marker designates the extra-oral landmark; and
advancing the needle into the subject's tissue while substantially tracking the luminous indicator on the marker.

21. A method according to claim 19 or claim 20, including the step of calibrating the device before use, by aligning the syringe needle and light from the emitter.

5 22. A method for using the injection guide device of any one of claims 9 to 18, for guiding a needle for administration of a dental anaesthetic to a subject, the method including the steps of:

a) positioning the guide device with the needle tip directed at an intra-oral landmark;

10 (b) advancing the locating member toward the subject's skin at the extra-oral landmark; and

(c) advancing the needle into the subject's tissue while substantially tracking the locating member on the extra-oral landmark.

15 23. A method according to claim 22, including the step of configuring the locating member in a biased condition in which the locating member is biased toward and preferably in contact with the subject's skin at the extra-oral landmark.

20 24. A method according to any one of claims 20 to 23, wherein the extra-oral landmark is the apex of the intertragic notch of the subject's ear.

25. A method according to any one of claims 20 to 24 for guiding administration of a dental anaesthetic according to the Gow-Gates technique.

25 26. An injection guide device for administering a dental anaesthetic to a subject, the guide device including:

a body portion

a light source with an emitter toward a first end of the body portion; and

a syringe retainer toward a second end of the body portion, the syringe retainer

30 being configured to receive a syringe with a needle and plunger;

wherein the body portion aligns a longitudinal axis of the needle with the light source so as to align and substantially maintain the tip of a syringe needle collinearly with light emitted from the light source as the syringe plunger is advanced into the syringe barrel.

27. A guide device for administering a dental anaesthetic to a subject, the guide device including:

a body portion;

5 a locator toward a first end of the body portion and configured to be directed to a target on the subject's skin; and

a syringe retainer toward a second end of the body portion, the syringe retainer being configured to receive a syringe with a needle and a plunger;

10 wherein the body portion aligns a longitudinal axis of the needle with the locator so as to align and substantially maintain the tip of the syringe needle collinearly with the locator as the syringe plunger is advanced into the syringe barrel during administration of a dental anaesthetic.

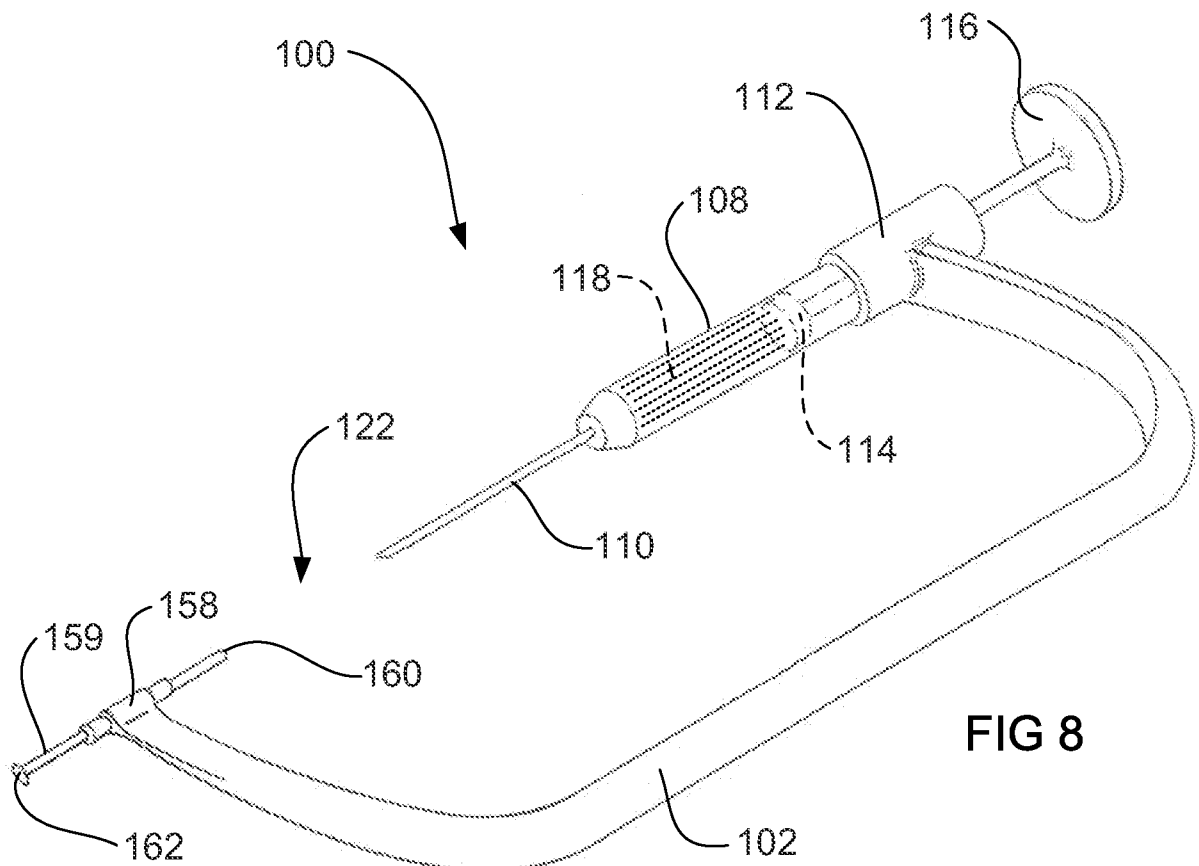
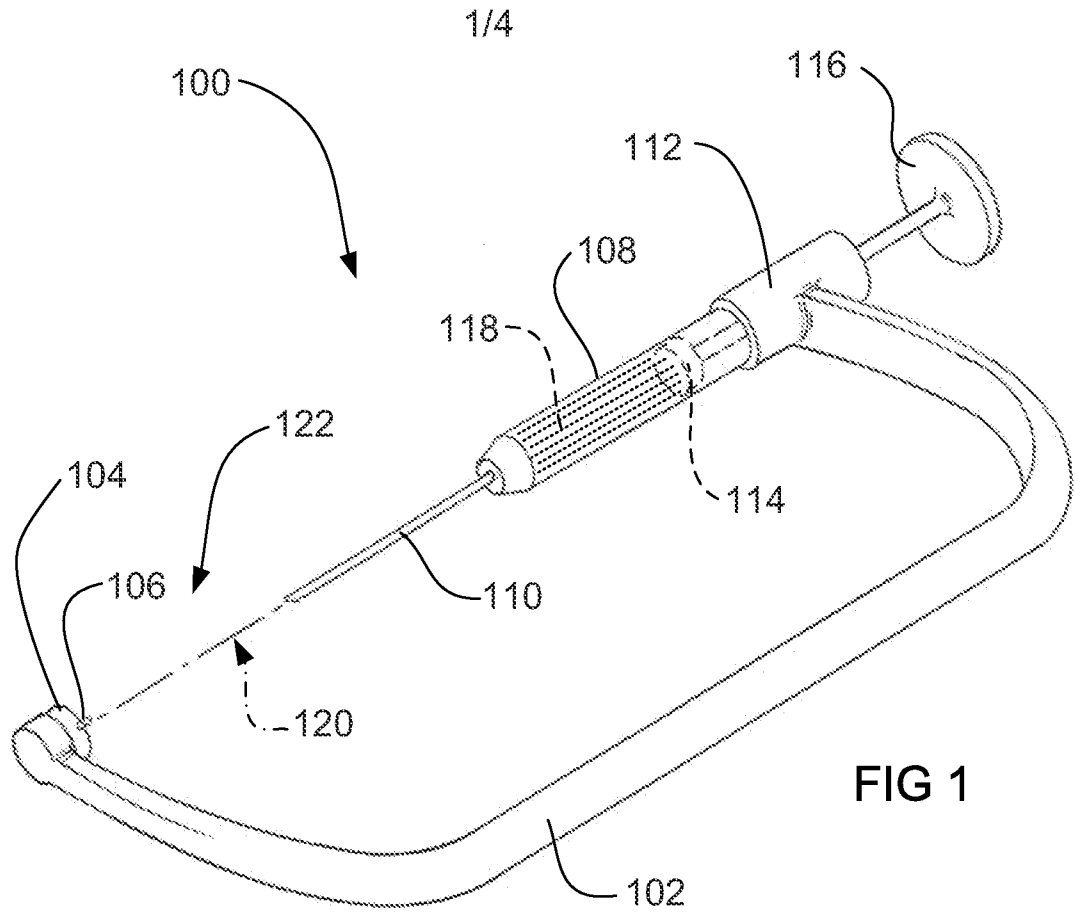
28. A guide device according to claim 27 wherein the locator comprises a light source with an emitter, and wherein operation of the light source produces a luminous indicator that is directable to a target on the subject's skin.

29. A guide device according to claim 27 wherein the locator comprises a locating member configured to move along an axis toward the target on the subject's skin.

20

30. A guide device for administering a dental anaesthetic injection to a subject, the guide device substantially as hereinbefore described with reference to any one of the embodiments illustrated in the accompanying drawings.

25 31. A method for performing dental anaesthetic using the guide device of any one of the preceding claims, the method substantially as hereinbefore described with reference to any one of the embodiments illustrated in the accompanying drawings.



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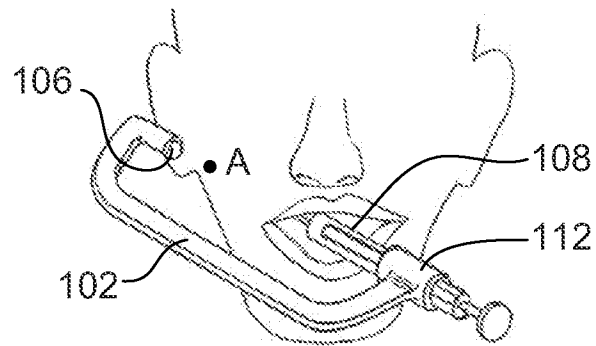


FIG 2

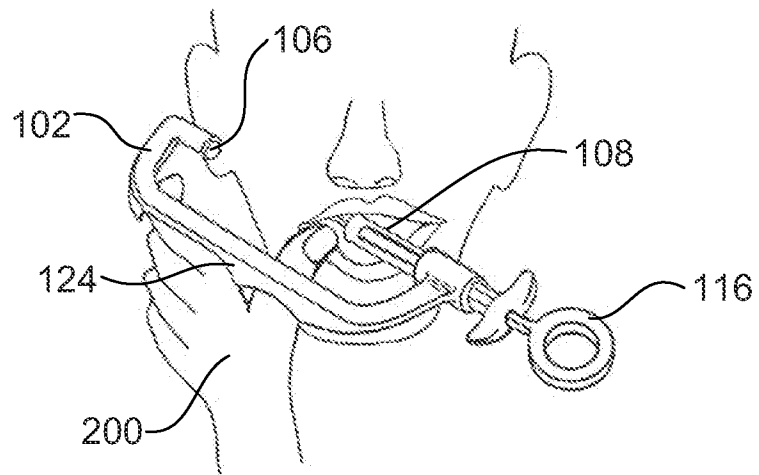


FIG 3

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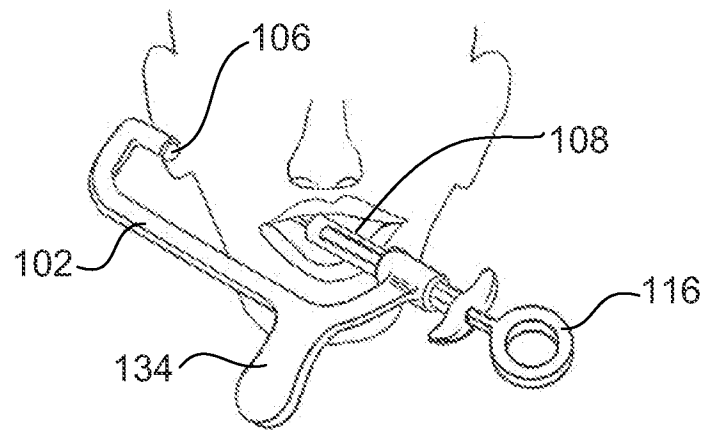


FIG 4

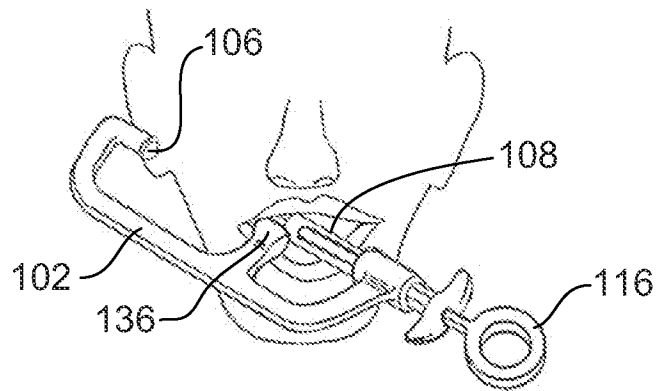


FIG 5

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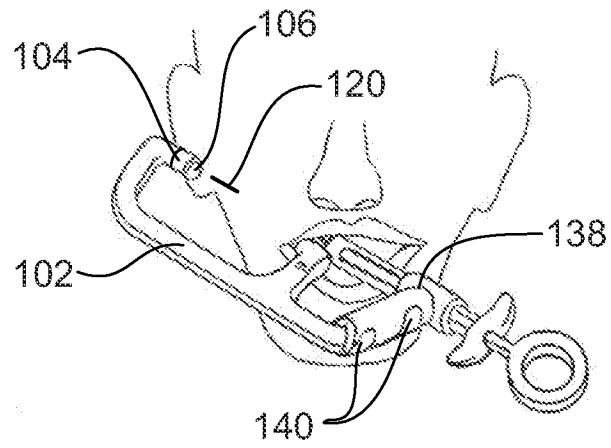


FIG 6

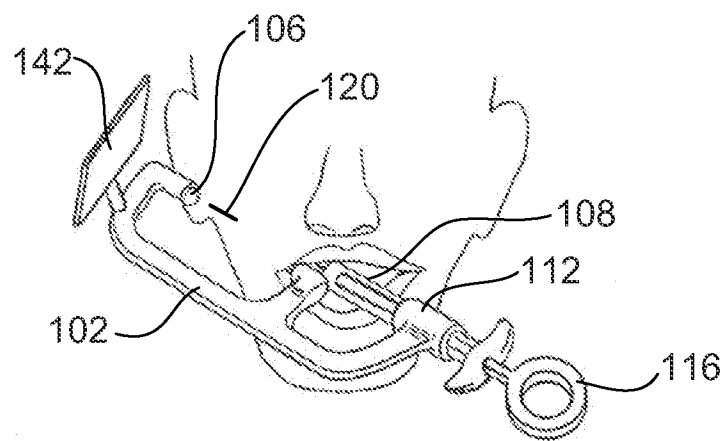


FIG 7

INTERNATIONAL SEARCH REPORT

 International application No.
PCT/AU2012/000361
A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61C 19/08 (2006.01)**A61C 1/00** (2006.01)**A61M 5/32** (2006.01)

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)

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)

WPI, EPODOC, Google Scholar: A61C/-, A61M5/32 & Keywords (Syringe, Inject, Anaesthetic, Alveolar, Block) and like terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2858542 A1 (CAILLIEUX) 11 February 2005 Abstract, Figure 2	27, 29
A	WO 2010/097520 A1 (CAILLIEUX) 2 September 2010 Abstract, Figures 1-2	
A	ZANDI, M. et al., 'Design and Development of a Device for Facilitation of Gow-Gates Mandibular Block and Evaluation of its Efficacy', Oral Maxillofac Surgery, 2008, Vol. 12, Pages 149-153. The whole document	
A	JOFRE, J. et al., 'Design and Preliminary Evaluation of an Extraoral Gow-Gates Guiding Device', Oral Surgery Oral Medicine Oral Pathology, 1998, Vol. 85, Pages 661-664. The whole document	



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"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
 22 May 2012

 Date of mailing of the international search report
 1 June 2012

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2012/000361

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: **30-31**
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 30-31 do not comply with Rule 6.2(a) because they rely on references to the description or drawings.
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Supplemental Box

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No III:

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-8, 19-21 and 26 are directed to an injection guide device for administering a dental anaesthetic injection to a subject. The feature of a light source with an emitter is specific to this group of claims.
- Claims 9-18, 22-25 and 27-29 are directed to an injection guide device for administering a dental anaesthetic injection to a subject. The feature of a locating member moveable along the axis toward the subject's skin is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is an injection guide device including a body portion, a locating member, and a syringe retainer configured to align a syringe needle to be collinear with the locating member. However this feature does not make a contribution over the prior art because it is disclosed in:

(i) FR 2858542 A1 (CAILLIEUX) 11 February 2005

Therefore, in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied, *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2012/000361

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member	
FR	2858542	NONE		
WO	2010097529	EP	2401167	FR 2942428
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.				
END OF ANNEX				