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A prefilled syringe for administering buffered lignocaine

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US 3340873
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ABSTRACT

A PREFILLED SYRINGE FOR ADMINISTERING BUFFERED LIGNOCAINE

A prefilled syringe for administering buffered lignocaine comprises a first and second chamber filled with lignocaine and buffer respectively wherein in use by pressing a plunger into the chambers the contents of the chambers are mixed before being expelled and wherein the first chamber has a volume ten times the volume of the second chamber to combine the lignocaine and buffer in a ratio of 10 to 1.

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A PREFILLED SYRINGE FOR ADMINISTERING BUFFERED LIGNOCAINE

FIELD OF THE INVENTION

This invention relates to prefilled syringes for administering buffered lignocaine.

BACKGROUND OF THE INVENTION

Lignocaine (also known as lidocaine) is a common local anaesthetic which many general practitioners and dentists use in their surgeries on a daily basis. Lignocaine is locally injected into a patient before minor surgery. However, during administration of lignocaine patients often experience an unpleasant stinging or burning sensation at the application site.

The stinging sensation associated with lignocaine injections has been attributed to its low pH and increasing its pH by buffering lignocaine with sodium bicarbonate has been shown to reduce this undesirable feeling. However, use of buffered lignocaine, particularly in Australia, is uncommon due to the difficulties associated with its preparation, storage and application.

Lignocaine and sodium bicarbonate when stored separately, have a shelf life of approximately 2 and 3 years respectively. However, once sodium bicarbonate and lignocaine are mixed together the shelf life is reduced to between 1-7 days if stored at room temperature or a maximum of 3 weeks if refrigerated.

Practitioners have been known to prepare a large vial of pre-mixed buffered lignocaine from which they draw out a dosage for each patient. However, given the short shelf life of the pre-mixed solution, vials need to be prepared frequently and much of the mixture is thrown away. This is both labour intensive and results in significant wastage. Further, there is a risk of contaminating the mixture during manual preparation and each time a needle enters the vial the risk of cross

contamination increases. It is these problems that prevent practitioners from using buffered lignocaine.

A two-chambered vial has been developed which contains lignocaine and a buffer in separate chambers and the wall between the two chambers is broken to mix the two solutions when required by bending or twisting the vial. The vial has a stopper for the insertion of a syringe for extraction of the mixture for administration.

However, the outside of such vials is not sterile which is problematic for practitioners who tend to wear sterile gloves to perform injections and in order to maintain sterility of their gloves must either extract mixture without touching the vial or have a second person hold the vial for them. Further, if the stopper has been touched or contaminated and is not cleaned properly then there is a risk of contamination of the needle during insertion into the stopper. This two chambered vial is difficult and time consuming to use.

Therefore, there is a need for an improved device for administering buffered lignocaine.

OBJECT OF THE INVENTION

It is therefore an object of the present invention to provide an improved device for administering buffered lignocaine or at least to provide an alternative to the prior art.

STATEMENT OF THE INVENTION

According to the present invention a prefilled syringe for administering buffered lignocaine comprises a first chamber filled with lignocaine and a second chamber filled with buffer wherein in use by pressing a plunger into the chambers the contents of the chambers are completely mixed before being expelled, the first

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chamber having a volume ten times the volume of the second chamber. It is essential that the contents of both chambers are able to completely mix within the syringe prior to any liquid being expelled out of the tip to enable the neutralising action of the lignocaine and buffer to take full effect.

In one form the chambers are the same length and are located side by side and the syringe has a compartment which can receive a needle tip and encloses one end of the chambers and wherein in use, pressing a plunger into each chamber simultaneously expels the contents of each chamber into the compartment where the contents completely mix before being expelled through the needle tip.

In another form the chambers have substantially the same diameter and are located end to end and are separated by a wall wherein in use, pressing a plunger into the second chamber ruptures the wall separating the two chambers allowing the contents of both chambers to be completely mixed and then expelled.

In yet another form the chambers have substantially the same diameter and are located end to end and are separated by a rubber stopper and the first chamber has an enlarged portion wherein in use, pressing a plunger into the second chamber moves the rubber stopper separating the two chambers into the enlarged portion of the first chamber leaving a space around the plunger through which the contents of the two chambers can be completely mixed before being expelled.

BRIEF DESCRIPTION OF THE DRAWINGS

An embodiment of the invention is now described by way of example only with reference to the accompanying drawings in which:

Fig 1 is a cross section view of a prefilled syringe according to one embodiment of the present invention.

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Fig 2 is a cross section view of a prefilled syringe according to another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

A prefilled syringe for administering buffered lignocaine comprises a first chamber 1 filled with lignocaine and a second chamber 2 filled with buffer said first chamber 1 having a volume ten times the volume of second chamber 2 and wherein in use by pressing a plunger 3 into chambers 1 and 2 the contents of the chambers are completely mixed before being expelled.

In one form, shown in Fig 1, chambers 1 and 2 are located side by side and a compartment 4 encloses one end of the chambers and has an opening which receives a needle tip 5. Chambers 1 and 2 are hollow cylinders of the same length however, chamber 1 has a volume ten times the volume of chamber 2. Therefore the cross section of chamber 1 has an area ten times the area of the cross section of chamber 2.

Since chambers 1 and 2 are of the same length, plungers 3a and 3b can be pressed into each chamber simultaneously to expel the contents of each chamber into compartment 4 where the contents mix completely before being expelled through the opening in compartment 4 and through needle tip 5 into the patient. The plunger for each chamber has a rubber stopper 6a and 6b at one end which are sized to sealably fit within its corresponding chamber. The two plungers 3a and 3b are joined at the opposite end to allow simultaneous insertion of the plungers into chambers 1 and 2. Chambers 1 and 2 each have a wall 7 which seals the contents within the chamber and prevents them from mixing during storage. When plungers 6a and 6b are pressed into the chambers the pressure created ruptures wall 7 allowing the contents to mix in compartment 4 before being expelled. Compartment 4 can be sufficiently large to enable the contents to completely combine therein before being expelled.

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In another form, shown in Fig 2, chambers 1 and 2 are located end to end with a rubber stopper 8 separating the two chambers. Chamber 2 is sealed with another rubber stopper 9 at the end of a plunger 3 and chamber 1 has an opening which receives a needle tip 5. Chambers 1 and 2 are hollow cylinders of substantially the same diameter, however chamber 1 has an enlarged portion 11 of greater diameter. Chamber 1 also has a substantial air pocket such that when plunger 3 is pressed into chamber 2 the air in chamber 1 is expelled until plunger 8, separating the two chambers, reaches enlarged portion 11 leaving a space around plunger 8 through which the contents of the two chambers can mix completely. Plunger 3 can then be pressed into the chambers to expel the buffered lignocaine from needle tip 5 into the patient. The air pocket in chamber 1 also forms an air lock to prevent leakage of the contents from the syringe during storage.

In yet another form plunger 8 separating the two chambers can be replaced with a wall (not shown). An air lock at the tip of the syringe prevents the liquid in chamber 2 from leaking from the syringe during storage. When a plunger is pressed into the second chamber the wall between the two chambers is ruptured due to the pressure build up allowing the contents of the two chambers to mix. Some of the air in the tip of the syringe is expelled which ensures that no solution is accidentally expelled. The plunger can then be pressed into the syringe to expel the buffered lignocaine from the needle into the patient. In this embodiment chamber 1 may have an enlarged portion 11 or may have a constant diameter. Furthermore, in this embodiment, the location of the first and second chambers can be switched such that the plunger is pressed into the first chamber.

Each of the syringes described above can be sold with a needle tip already attached to the syringe, or alternatively can have a cap sealing the opening which is removed before use and a needle tip attached.

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Each syringe will contain 5mls of lignocaine in the first chamber and 0.5 mls of buffer in the second chamber. The buffer is preferably 8.4% sodium bicarbonate solution however an equivalent amount of sodium bicarbonate powder could also be used.

In an alternative embodiment, adrenaline or another suitable adrenoceptor agonist such as epinephrine is combined with the lignocaine in the first chamber of the syringe to reduce bleeding during minor surgical procedures. The syringe can be filled with different concentrations of lignocaine with or without adrenaline and the most frequently used strengths will be 1% lignocaine without adrenaline or combined with 50 micrograms of adrenaline and 2% lignocaine without adrenaline or combined with 62.5 micrograms of adrenaline.

The shelf life of sodium bicarbonate and lignocaine when stored separately in the devices described above is approximately 2 years.

ADVANTAGES

The present invention provides a prefilled syringe for administering buffered lignocaine which significantly reduces the risk of contamination of the product. The present invention provides a syringe that is easy to use and which allows the solutions to be mixed in a single step in a sterile environment.

This device also significantly reduces the time it takes for a practitioner to prepare buffered lignocaine as they do not have to manually measure and mix the two solutions. The separation of the buffer and the lignocaine significantly increase the shelf life of the product which reduces wastage. This increased shelf life also means the product can be mass produced and transported.

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VARIATIONS

It will be realized that the foregoing has been given by way of illustrative example only and that all other modifications and variations as would be apparent to persons skilled in the art are deemed to fall within the broad scope and ambit of the invention as herein set forth.

Throughout the description and claims of this specification the words "comprise" and variations of that word such as "comprises" and "comprising" are not intended to exclude other additives components integers or steps.

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CLAIMS

1. A prefilled syringe for administering buffered lignocaine comprising a first chamber filled with lignocaine, with or without adrenaline, and a second chamber filled with sodium bicarbonate buffer wherein in use by pressing a plunger into the chambers the contents of both chambers are completely mixed within the syringe before being expelled through the needle tip, and where the first said chamber has a volume ten times the volume of the second chamber.

2. The prefilled syringe of claim 1 wherein the chambers are the same length and are located side by side and a compartment which can receive a needle tip encloses one end of the chambers and wherein in use pressing a plunger into each chamber simultaneously expels the contents of each chamber into the compartment where the contents are completely mixed before being expelled through the needle tip.

3. The prefilled syringe of claim 1 wherein the chambers have substantially the same diameter and are located end to end and are separated by a wall wherein in use, pressing a plunger into the second chamber ruptures the wall separating the two chambers allowing the contents of both chambers to be completely mixed prior to being expelled.

4. The prefilled syringe of claim 1 wherein the chambers have substantially the same diameter and are located end to end and are separated by a rubber stopper and the first chamber has an enlarged portion wherein in use pressing a plunger into the second chamber moves the rubber stopper separating the two chambers into the enlarged portion of the first chamber leaving a space around the plunger through which the contents of the two chambers can combine and be completely mixed within the syringe prior to being expelled.

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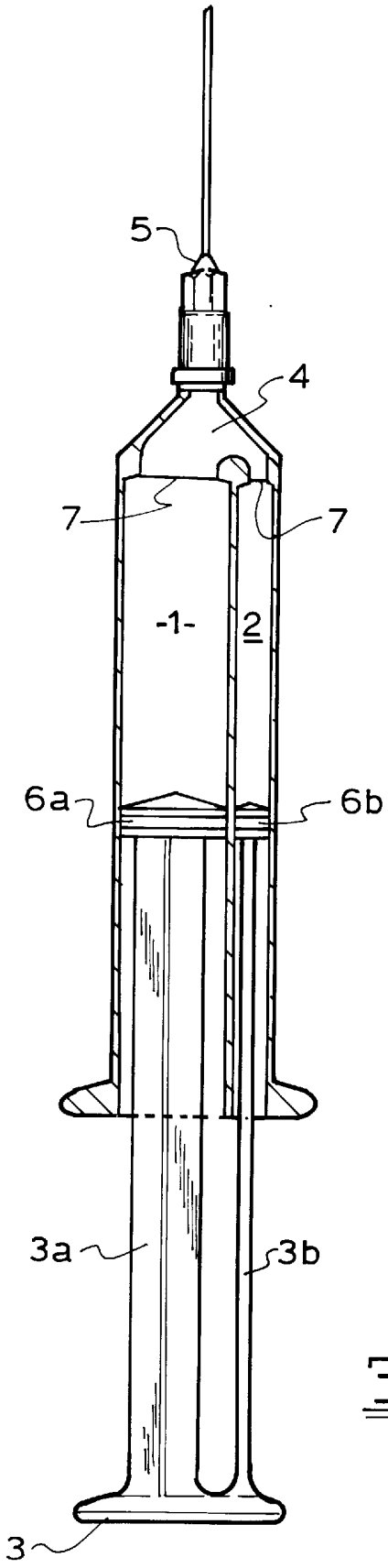

Fig.1.

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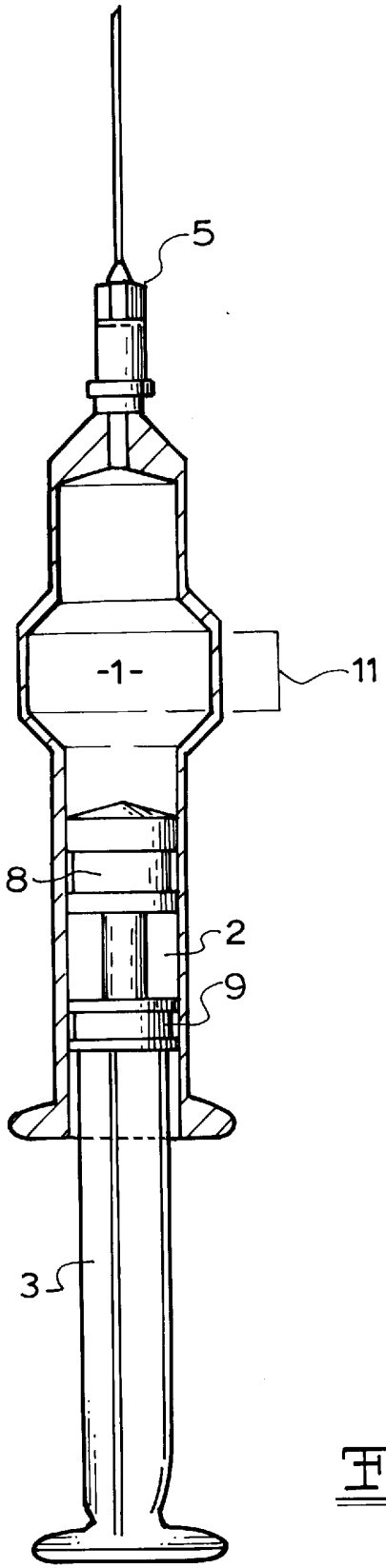

Fig. 2.