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(54) **Title**: DEVICE FOR ADJUSTING THE PENETRATION DEPTH OF A SYRINGE NEEDLE

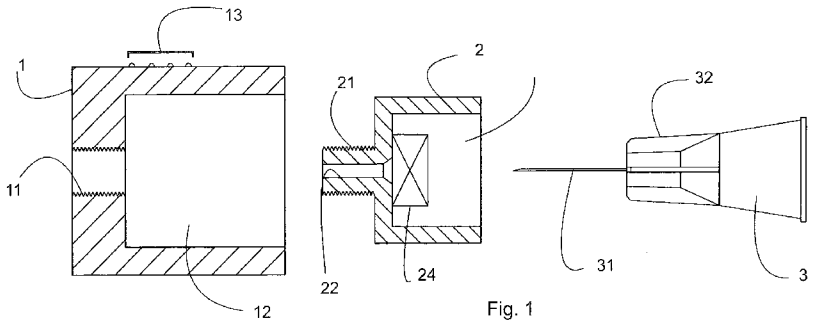


Fig. 1

(57) **Abstract**: Support device for syringe needles, adapted for adjusting the depth of penetration of said needle, comprising two mutually- connectable bodies, one of which is an intermediate member (2) cooperating with the needle-holder (3) of said needle (31) and the other is a container body (1) adapted for receiving said intermediate member, and a passage for the needle through said two bodies; said two mutually- connectable bodies sliding one against the other and being adjustable via coupling means (11, 21) during said sliding.

TITLE:

DEVICE FOR ADJUSTING THE PENETRATION DEPTH OF A SYRINGE NEEDLE

DESCRIPTION

The present invention relates to a support device for syringe needles, in particular for syringes used in the treatment of focal idiopathic hyperhidrosis by means of botulinum toxin type A.

At present, focal idiopathic hyperhidrosis therapy based on use of botulinum toxin type A involves multiple intradermal injections of said toxin in the area to be treated and it is extremely painful, so much so as to require the use of local anaesthetic to reduce the patient's pain.

In fact, the areas treated are extremely sensitive and delicate, particularly the palms of the hands, armpits and soles of the feet.

Furthermore, this treatment has drawbacks linked to the depth of release of the toxin, due to the difficulty of controlling the depth of penetration of the needle and therefore the depth of injection of said toxin; in fact, if said release depth is too great, there is a risk of encouraging the spread of the toxin to the deep muscular layers with the development of transitory hyposthenia, a muscular weakness that can persist for several weeks.

Therefore, the aim of the present invention is to provide a support device for syringe needles to enable and facilitate the control of the depth of penetration of the needle in a simple and effective way, thus reducing the collateral effects linked to transitory hyposthenia.

A further aim of the present invention is to provide a support device for syringe needles that considerably limits the pain felt by the patient so as to reduce or avoid the use of a local anaesthetic.

Another aim of the present invention is to provide a support device for syringe needles that allows successive injections made in the palm of the patient's hand and/or in the sole of the foot to be spaced approximately 1cm apart.

Accordingly, the object of the present invention is a support device for syringe needles comprising a container body having a cavity adapted for receiving a substantially cylindrical intermediate member cooperating with the syringe needle-holder. Said container body and intermediate member slide one inside the other, and their sliding is adjustable through a threaded coupling between said components.

In fact, the container body has a threaded hole which can be coupled with the threaded pin of the intermediate member, and the length by which the needle protrudes from said device is increased or reduced by tightening or unscrewing said intermediate member in relation to the container body.

Furthermore, the threaded pin has a channel running through it lengthwise which is symmetrical to the axis of said threaded pin and which enables the intradermal syringe needle to pass through when the device cooperates with said syringe.

Further advantages and features of the device according to the present invention will emerge from the following description of an embodiment thereof given, by way of a non-limiting example, with reference to the accompanying drawings, in which:

Fig. 1 represents the components of the device according to the present invention;

Fig. 2 represents the device assembled and cooperating with the needle-holder as shown in a first operating configuration.

Fig. 3 represents the device shown in Fig. 2, in a second operating configuration.

Fig. 1 shows the container body 1, the intermediate member 2 and the needle-holder 3. The container body 1 is substantially cylindrical in shape, and it has a cavity 12 adapted for accommodating the intermediate member 2. Said cavity 12 has an opening orthogonal to the axis of symmetry of the container body 1 and communicates with the through-hole 11 of said container body 1. The axis of symmetry of the through-hole 11 coincides with the axis of symmetry of the container body 1, and said through-hole is threaded.

The intermediate member 2 is adapted for being inserted into the cavity 12 of the container body 1, and it has a threaded pin 21 which is screwed into the through-hole 11 to make the container body 1 and the intermediate member 2 firmly connected. Said threaded pin 21 has a channel 23 running through it lengthwise, and said channel 23 is symmetrical to the axis of said threaded pin 21. The intermediate member 2 has a cavity 22 adapted for receiving the needle-holder 3.

Said cavity 22 has an opening orthogonal to the axis of symmetry of said intermediate member 2 and communicates with the channel 23 of the threaded pin 21, so as to make it possible for the needle 31 to pass through said channel 23. The needle-holder 3 has a profile that couples with the member 24 of the intermediate member 2 and, due to this profile, it is possible to screw the intermediate member 2 into the container body 1 by turning the syringe and holding said container body 1 still.

Said container body 1 and intermediate member 2 slide one inside the other, and their sliding is adjustable through the threaded coupling between said components, which enables the depth of penetration of the needle 31 to be adjusted by tightening or unscrewing the needle-holder 3, which rests upon the intermediate member 2, in relation to the container body 1 and thus controlling the relative sliding. Adjustment

of the depth of penetration is made even easier by the graduated scale 13, which enables the extent by which the needle 31 protrudes and therefore what the real depth of penetration will be to be measured .

Fig. 2 shows the device according to the present invention as assembled and ready for use with the maximum protrusion of the needle 31. On the premise that the same numbers correspond to the same parts, from Fig. 2 it can be seen that the length by which the needle 31 protrudes from the container body 1 can be increased or decreased by tightening or unscrewing the intermediate member 2 with respect to the container body 1 by means of the needle-holder 3. Since the base of the container body 1, from which the needle 31 protrudes, is in contact with the area to be treated, it consequently appears to perform a function of support and reference for the operator who is performing the treatment. In particular, the reference is provided by the actual section of the container body 1, which is made so that its base radius is such as to correspond to the distance that the operator must allow between two contiguous injections made within a short space of time between one another. Preferably, the container body has a section with a base radius in the order of 10-15mm.

It is also clear that the depth of penetration of the needle 31 is equal to the length of protrusion of said needle 31, and therefore the ease with which it is possible to adjust the depth of penetration of the needle by varying the length by which it protrudes from the container body 1 is intuitive. This adjustment is made even by the use of a graduated scale 13, which measures the length of protrusion of the needle 31.

This enables the depth of penetration to be adjusted on the basis of the epidermal characteristics of the patient, given that the average thickness of human skin on the

palm of the hand and sole of the foot is on average to 0.5-1mm, and therefore it enables the risk of muscular hyposthenia to be considerably or completely reduced because the possibility of the toxin spreading to the deeper tissues is reduced.

Fig. 3 shows the device with a reduced protrusion of the needle. On the premise that the same numbers correspond to the same parts, from Fig. 3 it can be seen that the length by which the needle 31 protrudes from the container body can be reduced by unscrewing the intermediate member 2 with respect to the container body 1 by means of the needle-holder 3, thus reducing the depth of penetration of said needle 31.

The support device for syringe needles according to the present invention can lower the risk of superficial muscular hyposthenia by adjusting the depth of penetration of the needle and therefore the depth of release of botulinum toxin type A, since it reduces the possibility of spreading said botulinum toxin into the deeper tissues while maintaining high levels of effectiveness in reducing sweating of the treated parts.

Furthermore, due to the specific shape of the container body of said device, it is possible to prevent injections from being performed too close together during the same series of applications, which would result in undesirable effects connected with the excessive quantity of toxin injected into one point with the risk of spreading to the muscles and causing transitory hyposthenia. Moreover, it is possible to prevent injections from being spaced too far apart, which would reduce the effectiveness of the treatment.

Furthermore, said device has the advantage of considerably reducing the pain experienced by the patient and therefore of reducing or eliminating the use of a local anaesthetic, thus enabling both hands to be treated in just one sitting.

CLAIMS

1. Support device for syringe needles, adapted for adjusting the depth of penetration of said needle, comprising two mutually-connectable bodies, one of which is an intermediate member cooperating with the needle-holder of said needle and the other is a container body adapted for receiving said intermediate member, and a passage for the needle through said two bodies; said two mutually-connectable bodies sliding one against the other along a direction parallel to that of the needle and being adjustable via coupling means during said sliding.

2. Support device according to claim 1, wherein the depth of penetration of the needle is adjustable through the coupling means which comprise a screw coupling between said intermediate member and said container body, thus allowing the length by which the needle protrudes from said device to be increased or reduced.

3. Support device according to claim 2, wherein the depth of penetration of the needle is equal to the length by with said needle protrudes from the container body, and it is measurable by means of a graduated scale provided on said container body.

4. Support device according to any one of the preceding claims 1 to 3, wherein said container body has a cavity adapted for receiving the intermediate member, and a threaded through-hole.

5. Support device according to claim 4, wherein said cavity has an opening orthogonal to the axis of symmetry of the container body and communicates with

the threaded through-hole, where the axis of symmetry of said threaded through-hole coincides with the axis of symmetry of the container body.

6. Support device according to any one of the preceding claims 1 to 5, wherein said intermediate member has a threaded pin which can be coupled with the threaded through-hole of the container body, and a cavity adapted for receiving the needle-holder.

7. Support device according to claim 6, wherein said cavity adapted for receiving the needle-holder is provided with a relief extending into said cavity, adapted for cooperating with said needle-holder.

8. Support device according to claim 6 or 7, wherein said threaded pin has a channel running through it lengthwise, and said channel enables the passage of the needle of said intradermal syringe.

9. Support devices according to any of the preceding claims from 1 to 8, wherein said container body is substantially cylindrical in shape, having a base radius corresponding to at least the minimum distance between two adjacent, consecutive injections.

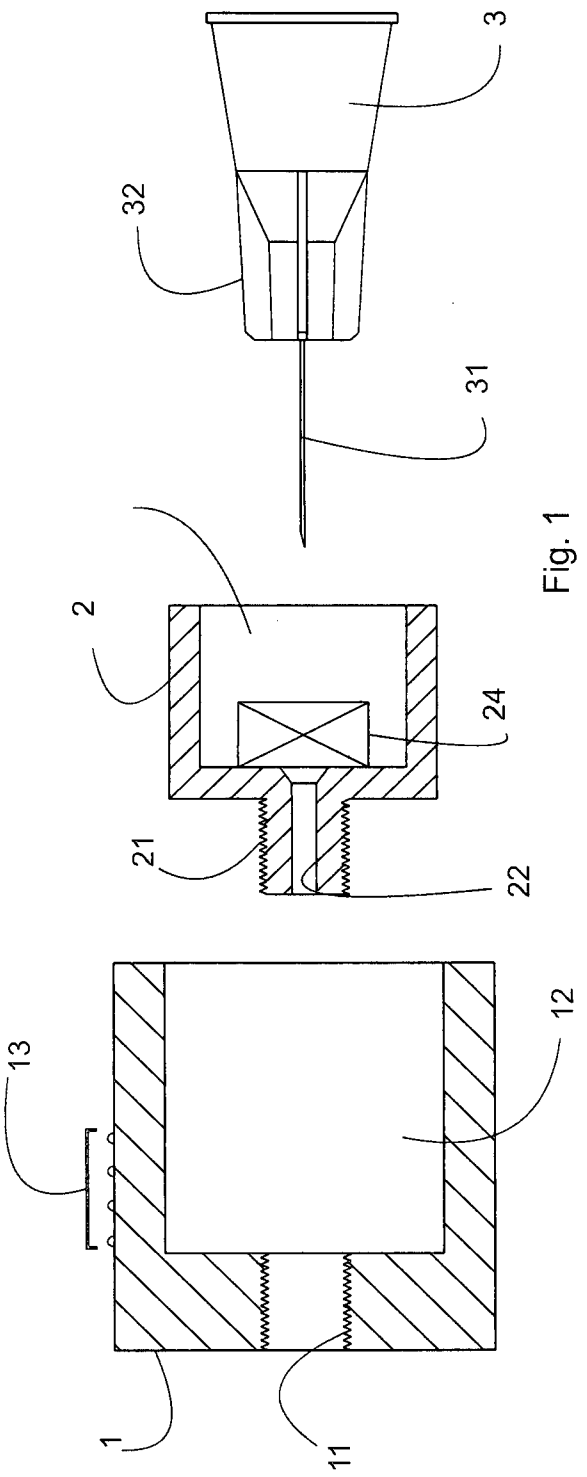


Fig. 1

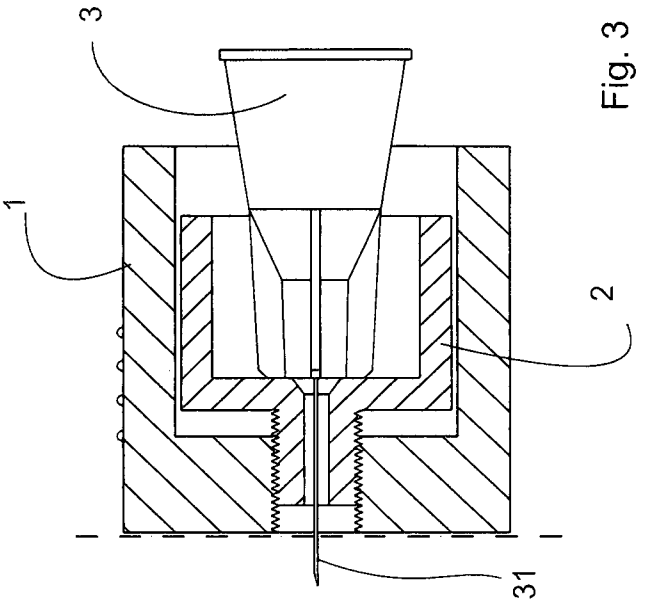


Fig. 3

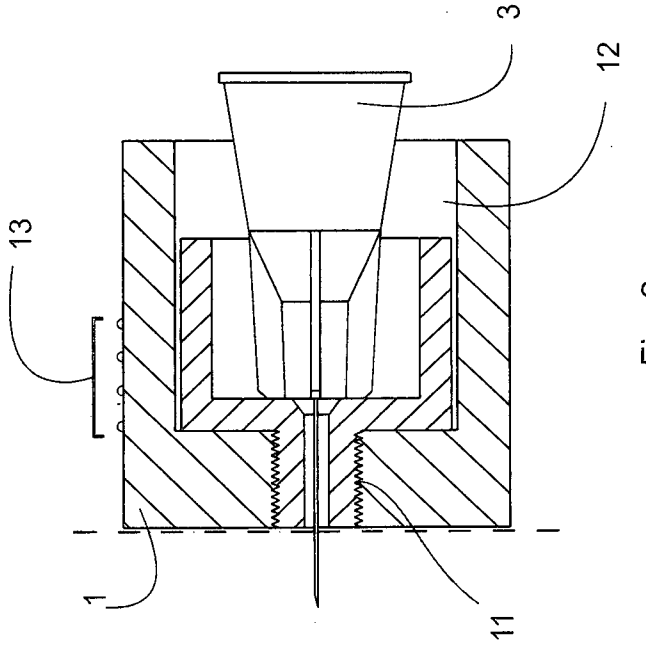


Fig. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2011/000299

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/46
ADD. A61M5/32

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)
A61M

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/27986 A1 (DISETRONIC LICENSING AG [CH]; WICH HORST [US]) 10 June 1999 (1999-06-10) figure 8 page 11, paragraph 3 page 2, paragraph 3 - page 3, paragraph 2 -----	1-9
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X	BE 511 524 A (J.WAUTERS) 14 June 1952 (1952-06-14) the whole document -----	1-9
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 January 2012	03/02/2012

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2011/000299

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

International application No
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