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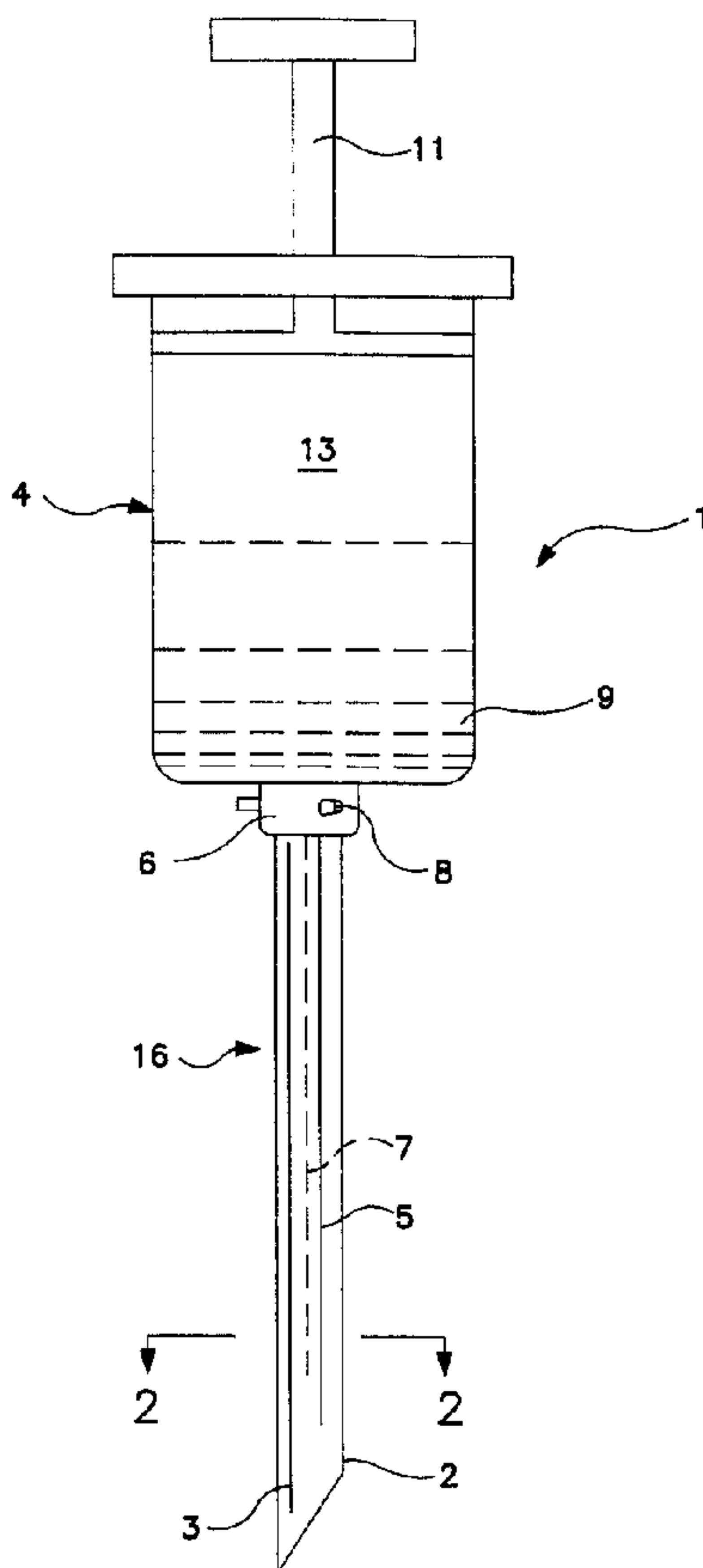
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(54) **DISPOSITIF D'INJECTION MULTIELECTRODE ET AIGUILLE
DE DIAGNOSTIC ET DE TRAITEMENT DE LESIONS ET DE
DOULEURS MUSCULAIRES**

(54) **MULTI-ELECTRODE AND NEEDLE INJECTION DEVICE FOR
DIAGNOSIS AND TREATMENT OF MUSCLE INJURY AND
PAIN**



(57) Un dispositif d'injection multi-électrode et aiguille permet d'identifier et de traiter une douleur musculaire à l'aide de deux enregistrements simultanés d'électromyographie (EMG) par électrodes afin de localiser une zone gâchette active. Les deux électrodes

(57) A multi-electrode and needle injection device for identifying and treating muscle pain using two simultaneous electrode EMG recordings to locate an active trigger point. The two electrodes are displaced so that one electrode detects EMG activity at the trigger



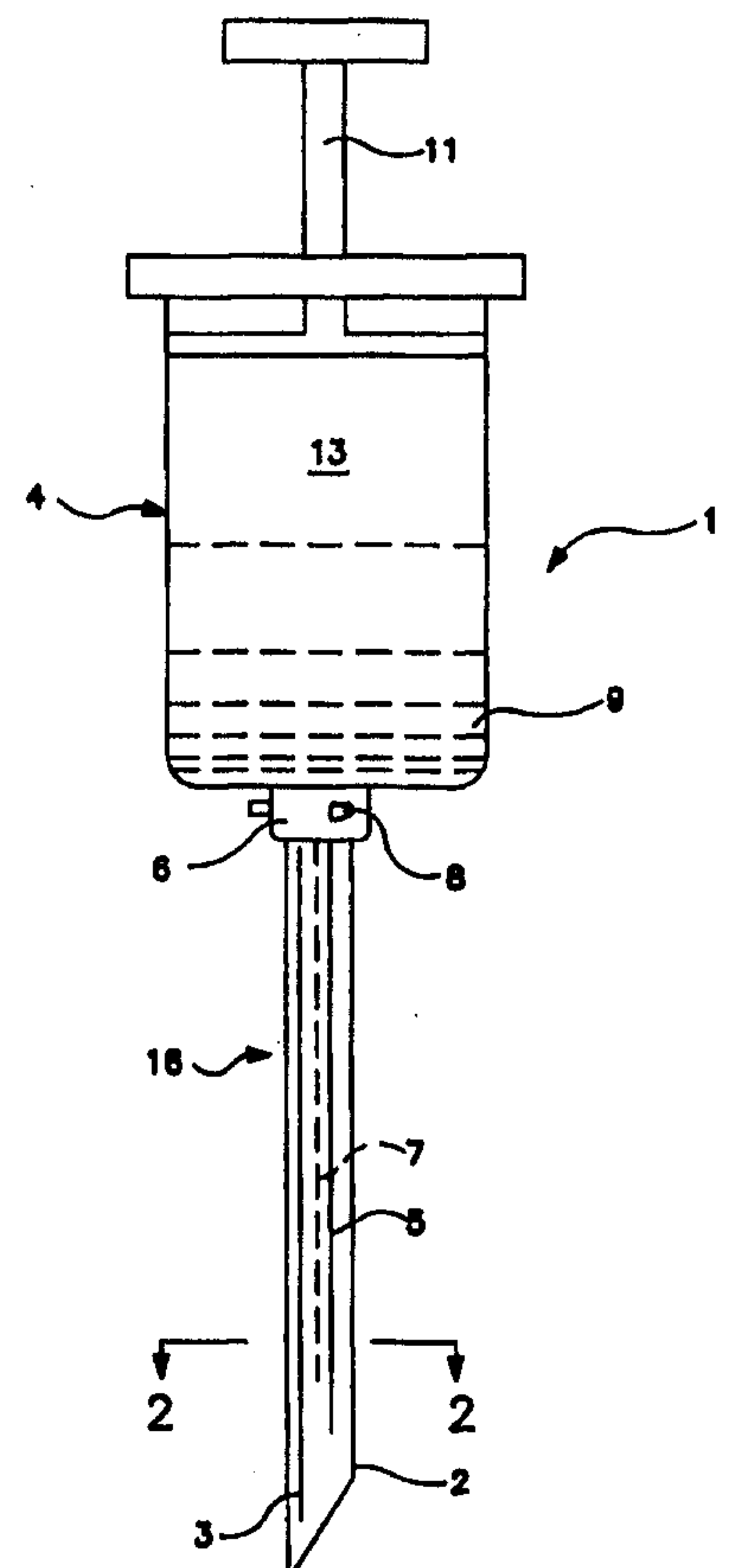
sont déplacées de sorte qu'une électrode détecte une activité EMG au niveau du point gâchette et que l'autre détecte une activité EMG à proximité du point gâchette, dans le même muscle. La combinaison des électrodes avec un système d'administration de médicaments permet à l'utilisateur d'injecter un médicament localement au niveau de la zone gâchette afin de bloquer l'activité de la zone gâchette et de réduire ou d'éliminer la douleur musculaire. Les électrodes se trouvent sur une aiguille hypodermique. L'aiguille est utilisée à la fois pour faciliter la localisation des zones gâchette et pour le traitement par injection d'un médicament dans les zones gâchette.

point and the other one detects EMG activity adjacent to the trigger point, within the same muscle. The combination of the electrodes with a drug delivery system allows the user to inject a medication locally at the trigger point to block the trigger point activity and reduce or eliminate muscle pain. The electrodes are on a hypodermic needle. The needle is used to facilitate both the location of the trigger points and for treatment, by injecting a drug into the trigger points.

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(21) International Application Number: PCT/US97/21885 (22) International Filing Date: 20 November 1997 (20.11.97) (30) Priority Data: 08/752,805 20 November 1996 (20.11.96) US (71) Applicant (for all designated States except US): MYOTECH [US/US]; Suite 100, 3575 Kenyon Street, San Diego, CA 92210 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): HUBBARD, David, R. [US/US]; 2999 Health Center Drive, San Diego, CA 92123 (US). (74) Agents: ZELANO, Anthony, J. et al.; Millen, White, Zelano & Branigan, P.C., Suite 1400, Arlington Courthouse Plaza I, 2200 Clarendon Boulevard, Arlington, VA 22201 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: MULTI-ELECTRODE AND NEEDLE INJECTION DEVICE FOR DIAGNOSIS AND TREATMENT OF MUSCLE INJURY AND PAIN		
(57) Abstract A multi-electrode and needle injection device for identifying and treating muscle pain using two simultaneous electrode EMG recordings to locate an active trigger point. The two electrodes are displaced so that one electrode detects EMG activity at the trigger point and the other one detects EMG activity adjacent to the trigger point, within the same muscle. The combination of the electrodes with a drug delivery system allows the user to inject a medication locally at the trigger point to block the trigger point activity and reduce or eliminate muscle pain. The electrodes are on a hypodermic needle. The needle is used to facilitate both the location of the trigger points and for treatment, by injecting a drug into the trigger points.		



S P E C I F I C A T I O N

MULTI ELECTRODE AND NEEDLE INJECTION DEVICE
FOR DIAGNOSIS AND TREATMENT OF MUSCLE INJURY AND PAIN

BACKGROUND OF THE INVENTION

5 The field of the invention is the diagnosis and treatment of muscle injuries associated with pain and stiffness.

 It is estimated that up to 20% of the adult population in the United States suffers from chronic and recurrent
10 muscle pain. There is currently no FDA-approved or proven effective treatment for these conditions. Treatments now used give only limited temporary relief.

 Chronic and recurring muscle pain is a neuromuscular abnormality typically following a strain injury, and
15 manifested by what has been termed trigger point (TrP) phenomena. As used herein, trigger point means a localized area of tenderness within a muscle associated with spontaneous electromyographic (EMG) activity. Thus, a trigger point is a location of spontaneous EMG activity
20 within a muscle associated with pain. Trigger points may be within muscle spindles. TrPs can be objectively

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diagnosed by identification of spontaneous EMG activity in a trigger point while adjacent muscle fibers are electromyographically quiet. Once the trigger point EMG activity is identified, chronic and recurrent muscle pain associated with this localized EMG activity can be treated through the use of medications including sympathetic blocking agents, as described in U.S. Patent 5,513,661, incorporated herein by reference. This patent describes a method of identifying trigger points in muscle associated with a characteristic spontaneous EMG activity. The activity is then blocked by injecting adrenergic blocking agents. The methods of diagnosis and treatment described in U.S. Patent No. 5,513,661 involves simultaneously measuring both the trigger point activity and the EMG activity adjacent to the trigger point to determine whether the observed trigger point EMG activity is spontaneous localized, and not due to other phenomena such as voluntary contraction. To effectively block sympathetic activity at a trigger point, it is desirable to localize the trigger point as precisely as possible. For effective treatment, the blocking agent should be delivered precisely at the trigger point. Accordingly, there remains a need for a device for simultaneously locating and treating TrP EMG activity.

SUMMARY OF THE INVENTION

To these ends, in a first aspect of the invention, an EMG device for diagnosing chronic and recurrent muscle pain preferably integrates two or more active EMG electrodes and
5 an EMG reference electrode.

In a second aspect of the invention, an EMG device for treating chronic and recurrent muscle pain integrates two or more active EMG electrodes and a reference electrode and includes a drug delivery system.

10 In a third aspect of the invention, a system is provided for analyzing the level of spontaneous EMG activity in trigger points and adjacent muscle tissue.

Other objects and advantages will appear as well hereinafter.

15 BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, wherein similar reference characters denote similar elements, throughout the several views:

Figure 1 is a front elevation view of an EMG needle-injection device according to a first embodiment;

20 Figure 2 is a section view taken along line 2-2 of Figure 1;

Figure 3 is a schematically illustrated view of an EMG needle-injection device with a holder according to a second embodiment;

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Figure 4 is a front elevation view of an EMG needle-injection device, according to a third embodiment;

Figure 5 is a schematically illustrated view of a trigger point analyzer, as used with an EMG Needle-
5 Injection device;

Figure 6 is a schematically illustrated view of the needle shown in Figure 1; and

Figure 7 is a front elevation view of an EMG injection device, according to a fourth embodiment.

10 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In a first aspect of the invention, two or more active EMG electrodes and a reference electrode provide the ability to simultaneously show EMG activity at a trigger point, when adjacent muscle tissue EMG activity is
15 relatively silent. The active electrodes are advantageously spaced apart to avoid having both electrodes sense the same EMG activity. The active electrodes, although spaced apart, are placed in the same muscle. The electrodes are used to locate a trigger point within a
20 muscle. As described in Patent No. 5,513,661, when a trigger point electrode shows active EMG activity, and an adjacent electrode is quiet (indicating the muscle is not contracting), a trigger point has been located. While use of electrodes and cables or wires is contemplated, a fully
25 or partly wireless system maybe used, e.g., EMG with RF,

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infrared, or other wireless link between the sensors and an analyzer. Electrodes, as used here, includes those specifically shown and described, the various known conventional electrodes, as well as all other devices or
5 systems for detecting EMG activity within a muscle.

Referring to Figure 1, the device 1 has needle/electrode unit 16 including a hypodermic needle 2 with a sharp tip for insertion into a patient. The needle/electrode unit 16 is connected to a syringe 4 which contains a drug
10 13. The needle/electrode unit 16 has a hub 6 for connection to the syringe 4. The syringe 4 includes a drug containing vessel or ampoule, and a plunger 11 for containing and dispensing the drug. Various vessels or drug containers may be used in place of a conventional
15 syringe. The needle and syringe are preferably disposable. The syringe body holds enough drug for one or preferably multiple doses. The drug may be phenoxybenzamine, phentolamine, an α agonist, an α_2 agonist, guanethidine or other sympathetic blockers, or a local anesthetic such as
20 lidocaine, or a neuro-muscular blocking agent such as Botulinum Toxin Type A. Other therapeutically effective drugs may of course also be used. For the treatment of muscle pain, for example back muscle pain, the preferred drug is phenoxybenzamine.

25 In the embodiment of Fig. 1, three electrodes, 3, 5 and 7, are provided on the outside wall of the hypodermic

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needle 2. Preferably, the electrode 3 is a trigger point
electrode for identifying the trigger point EMG activity of
the afflicted muscle. The electrode 5 advantageously is an
adjacent electrode for identifying the muscle tissue
5 adjacent to and in the same muscle as the trigger point.
Preferably, the electrode 7 is a reference electrode, used
to provide a common reference voltage for the other two
electrodes 3 and 5. While shown as round in cross section
in Fig. 2, the electrodes may of course have other shapes
10 or arrangements, or may be integral (e.g., etched into
surfaces) of the needle.

All three electrodes are preferably made of a fine
wire or other conductive material and are secured along the
length of the hypodermic needle 2 outer wall as shown in
15 Figure 2. The electrodes 3, 5 and 7 are preferably
insulated along their lengths, except for a small portion
at their lower ends. The uninsulated portion of each
electrode is the electrode's electrical contact, which is
exposed to the patient's muscle tissue. The uninsulated
20 portion of each electrode is positioned to avoid contacting
the hypodermic needle 2 to prevent short-circuiting. As
only a small section of each electrode is exposed,
electrical measurements can be made at specific sites
within a muscle. In a preferred embodiment, electrical
25 connections 8 on the hub 6 provide for electrical

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connection to electromyography (EMG) equipment, such as an oscilloscope or computer monitor.

The electrical contacts of the trigger point electrode 3 and adjacent muscle electrode 5 are displaced from one another to enable the adjacent muscle electrode 5 to electrically contact the muscle fibers, in the same muscle, away from the trigger point area, and to prevent the electrode 5 from being exposed to any spontaneous EMG activity experienced at the trigger point. Typically, the trigger point electrode and the adjacent muscle electrode are spaced apart by about 1-8mm and preferably by about 2-4mm. The reference electrode 7 may be located vertically in between electrodes 3 and 5, as shown in Fig. 1, or further up the needle shaft, above electrode 5. The reference electrode 7 may alternatively be separate from the needle 2. The needle/electrode unit 16 may be provided separately from the drug containing vessel, as shown in Figure 6. The separate needle/electrode unit 16 allows different size vessels to be selected and attached to the needle, and also allows the needle/electrode unit 16 to be reused if desired, after the vessel is empty. The needle/electrode unit 16 and vessel may be joined using Luer fittings or other known techniques.

By monitoring the EMG activity of the adjacent muscle electrode 5 and ensuring that it remains electrically silent, the clinician can verify that any EMG activity

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measured at the trigger point is localized and is not due to voluntary muscle contraction or other generalized contractions (e.g. involuntary splinting or bracing). EMG activity is determined by measuring the electrical potential of the trigger point electrode 3 and adjacent muscle electrode 5, referenced to the reference electrode 7. In this way the adjacent muscle electrode 5 serves as a control, which ensures the specificity of the trigger point electrode EMG readings. In this preferred embodiment, the electrical contacts of the trigger point electrode 3 and adjacent muscle electrode 5 are vertically spaced apart from one another. This allows the electrodes to be attached to a single hypodermic needle, thereby increasing ease of use, disposability and patient comfort. However, the electrodes may be horizontally spaced apart in other embodiments.

In use, the clinician manually palpates the affected muscle to find a trigger point as described in U.S. Patent No. 5,513,661, noting local tenderness and the referral pattern of pain experienced by the patient when pressure is applied to the trigger point. The device 1 is connected to an EMG monitor, such that the trigger point electrode 3 and adjacent muscle electrode 5 are both referenced to the reference electrode 7. The clinician or physician then inserts the needle-electrode combination over the trigger point, slowly advancing it until the localized EMG activity

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at the trigger point is detected by the trigger point electrode 3, while the level of EMG activity from the adjacent electrode 5 remains relatively quiet. If both electrodes 3 and 5 detect significant EMG activity, the muscle is in a contracted condition and no diagnosis or treatment is made. In this situation, the patient is advised to relax the muscle, in an effort to obtain a better reading. If the adjacent electrode 5 shows relatively quiet EMG activity, while the trigger point electrode 3 shows active EMG activity, treatment with medication including sympathetic blocking agents is indicated. Preferably, amplitude and frequency values for the EMG activity are calculated and compared against pre-determined values.

15 The EMG device 1 may be used with an EMG analyzer 31 as shown in Figure 5. In this embodiment, the analyzer 31 can be positioned on a stand or cart 27, and is joined to the device via a cable 29. The EMG analyzer 31 is designed to receive multiple electrical signals from the EMG needle-injection device 1 and continuously compute, display and store values for those signals. The analyzer preferably displays the electrical signals on a CRT or other display 41 and also optionally prints out hard copies of those signals.

25 The EMG analyzer 31 may also provide an audible or visual indication to the clinician when sustained EMG

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activity is occurring at the trigger point and not at the adjacent electrode 5. This can be done using known filtering or analogue-digital conversion and processing to determine when adjacent muscle activity is below a pre-determined level, for example, 13 microvolts (root mean square), and trigger point electrode activity is above a certain level, for example 26 microvolts (root mean square). Depending upon conditions, a difference of about 2:1 or more in EMG activity between a trigger point and the adjacent muscle, indicates a trigger point has been located and treatment by injection is appropriate.

Above threshold activity on the adjacent electrode could be signalled with, for example a steady high-pitched sound from a speaker 43 which would inform the clinician and the patient to relax the patient's muscles. EMG activity in the trigger point electrode could be amplified as a raw voltage signal which would inform the physician that he or she was near (for example within 1-4mm) of the trigger point and would increase in amplitude as the electrode was further advanced into the trigger point.

In a second preferred embodiment, as shown in Figure 3, the preferably disposable EMG needle-injection device is used with a reusable holder 14. The holder 14, vessel 9 and plunger 11 all cooperate to form a drug delivery system. The holder accommodates the disposable EMG needle-injection device 1 and holds the device in place. The

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holder includes a thumb press 15, which acts on the plunger 11, to inject a fixed dosage of drug 13 into the patient. One or more doses, e.g., 5-20 or more doses, may be given from a single disposable EMG device. Alternatively, the dosage may be delivered via an electrically, mechanically or pneumatically powered device associated with or on or in the holder. A holder-needle connector 17 provides electrical connection between the needle electrode connectors 8 and an EMG electrical connector 19 on the holder. The EMG electrical connector 19 connects to an EMG measuring instrument or physiological monitor, such as an oscilloscope via a cable 20.

Preferably, the holder 14 has front and back sections joined at flex or hinge joint and a latch to hold the sections together. The interior of the holder 14 preferably has a recess shaped to receive and position the device 1. The holder-needle connector is positioned within the holder to automatically make contact with the connectors 8 when the holder is closed and latched. The thumb press 15 also automatically aligns with the plunger when the device is seated within the holder 14.

The holder 14 is a hand-held device which allows the user to deliver a fixed dosage of drug 13 to the patient while securing the electrode electrical connections, to minimize interference with the physician's examination. The injection device can be quickly removed from the

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holder, after use, and disposed of, and replaced with a new device. The holder therefore simplifies and expedites patient treatment. The circuitry and features of the analyzer may be miniaturized and included in the holder, eliminating the need for cables and a separate analyzer. The EMG signals may be processed by a microchip on or at the electrodes.

In a third embodiment 24, as shown in Figure 4, an electrically conducting needle 22 is insulated along its entire length except for an uninsulated section 26 at the sharpened tip 28. The needle 22 provides the electrical connection 30 between the uninsulated portion 26 and the connection point 32, although it has no exposed conductive surfaces in between the connection point 32 on the needle hub 34 and the uninsulated portion. The uninsulated portion 26 of the needle 22 serves as a trigger point electrode. The trigger point electrode 26 is connected to an analyzer 31 via a cable. An adjacent muscle electrode 38, in the form of a needle, and a reference skin patch electrode 40 are separately provided and linked to the analyzer 31 by cables 20. In use, the reference electrode 40 is applied to the skin and the electrodes 36 and 38 are separately placed. When trigger point EMG activity is detected, as described above, a drug is injected at the trigger point, using the syringe on the device 24.

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Figure 7 shows a fourth embodiment similar to Figure 4, but having the trigger point electrode 26 and the adjacent muscle electrode 38 on the needle 22. Both electrodes 26 and 38 are connected via a cable 20 to an
5 analyzer 31. The reference electrode 42 is provided as skin patch 45 connected to the analyzer 31 by a cable 46.

Thus, while several embodiments have been shown and described, various modifications may be made without departing from the spirit and scope of the invention. The
10 invention, therefore, should not be restricted, except by the following claims.

WHAT IS CLAIMED IS:

1. An EMG needle injection device for identifying and treating sources of chronic muscle pain in a patient, comprising:

5 a delivery system including a vessel for holding and dispensing a drug;

a hypodermic needle including a hollow needle shaft having a first end and a second end, said drug delivery system attached to and in communication with said needle at
10 the first end thereof, said second end of the needle having a sharpened tip;

a first electrode attached to said hypodermic needle and having an electrical contact located at a first distance from said tip;

15 a second electrode attached to said hypodermic needle, and having an electrical contact located at a second distance from said tip, with said first distance less than said second distance.

2. The device of claim 1, wherein said first
20 distance is about 2-4 mm less than said second distance.

3. The device of claim 1, further comprising:

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a third electrode attached to said hypodermic needle,
said third electrode comprising an electrical contact
located at a third distance from said tip.

4. A device for diagnosis or treatment of muscle
5 pain comprising:

a needle;

a trigger point electrode on the needle;

at least one adjacent electrode on the needle spaced
apart from the trigger point electrode;

10 a reference electrode; and

an analyzer linked to the trigger point, adjacent, and
reference electrodes.

5. The device of claim 4 further comprising means
for delivering a drug.

15 6. The device of claim 5 wherein the means for
delivering includes a syringe attached to the needle.

7. The device of claim 4 wherein the trigger point
electrode is spaced vertically apart from the adjacent
electrode.

20 8. The device of claim 4 wherein there are two or
more adjacent electrodes.

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9. The device of claim 4 wherein the reference electrode is on the needle.

10. The device of claim 6 further comprising a holder including electrical contacts for connecting with the
5 electrodes.

11. The device of claim 10 wherein the holder is reusable and the electrodes, drug vessel, and needle are disposable.

12. The device of claim 6 wherein the syringe and
10 needle are separable.

13. A system for diagnosing or treating muscle pain, comprising:

an EMG device including a trigger point electrode, an adjacent electrode, and a reference electrode on a
15 hypodermic needle;

a holder having electrical contacts for connecting to the electrodes; and

an analyzer connected to the trigger point, adjacent and reference electrode via the contacts in the holder, for
20 detecting EMG activity at the trigger point electrode while

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relatively no EMG activity is detected at the adjacent electrode.

14. The system of claim 13 wherein the trigger point electrode and the adjacent electrode are spaced apart
5 sufficiently for identifying EMG activity localized to a trigger point.

15. The system of claim 13 further comprising means for delivering a drug.

16. The system of claim 13 wherein the trigger point
10 electrode and adjacent electrode are vertically spaced apart by about 2-4mm.

17. The system of claim 13 further comprising a drug holding vessel attached to the needle.

18. The system of claim 17 wherein the drug holding
15 vessel is a syringe.

19. The system of claim 13 wherein the electrodes comprise electrically conductive elements.

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20. The device of claim 13 wherein the first electrode is at a sharp tip on the needle.

21. The device of claim 13 further comprising means for alerting the physician when spontaneous EMG activity at
5 a trigger point exceeds EMG activity in adjacent muscle tissue by a predetermined amount.

22. The device of claim 13 further comprising a display for visually displaying EMG input signals from the electrodes.

10 23. The device of claim 13 further comprising an audio system for communicating EMG activity signals via sound.

24. A device for diagnosing or treating muscle pain comprising:

15 a delivery system including a vessel for holding a drug;

an electrically conducting hypodermic needle insulated along its entire length except for an uninsulated section at the sharp tip of the needle forming a trigger point
20 electrode;

an adjacent muscle electrode;

a reference electrode; and

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an analyzer linked to the trigger point, adjacent, and reference electrode, wherein the trigger point, adjacent muscle and reference electrodes are separate from each other.

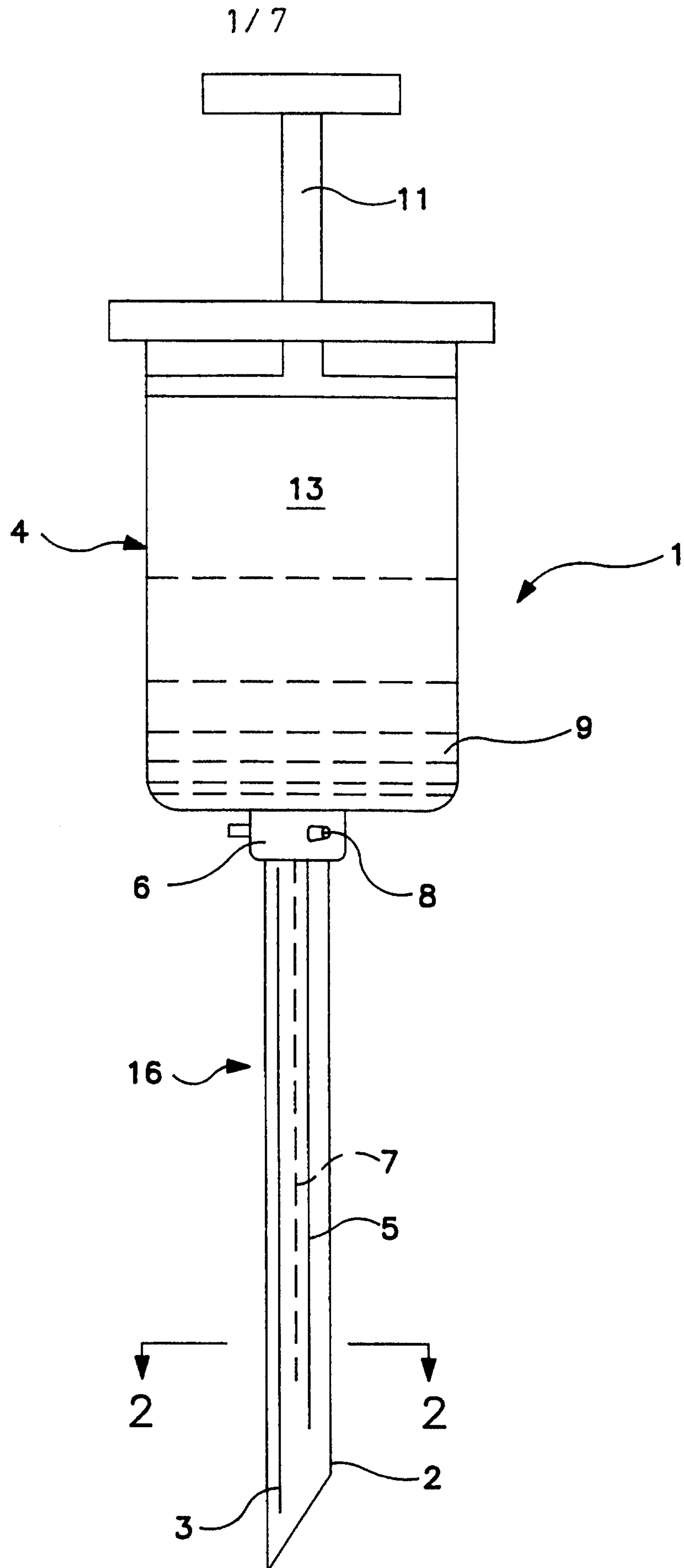


FIG. 1
SUBSTITUTE SHEET (RULE 26)

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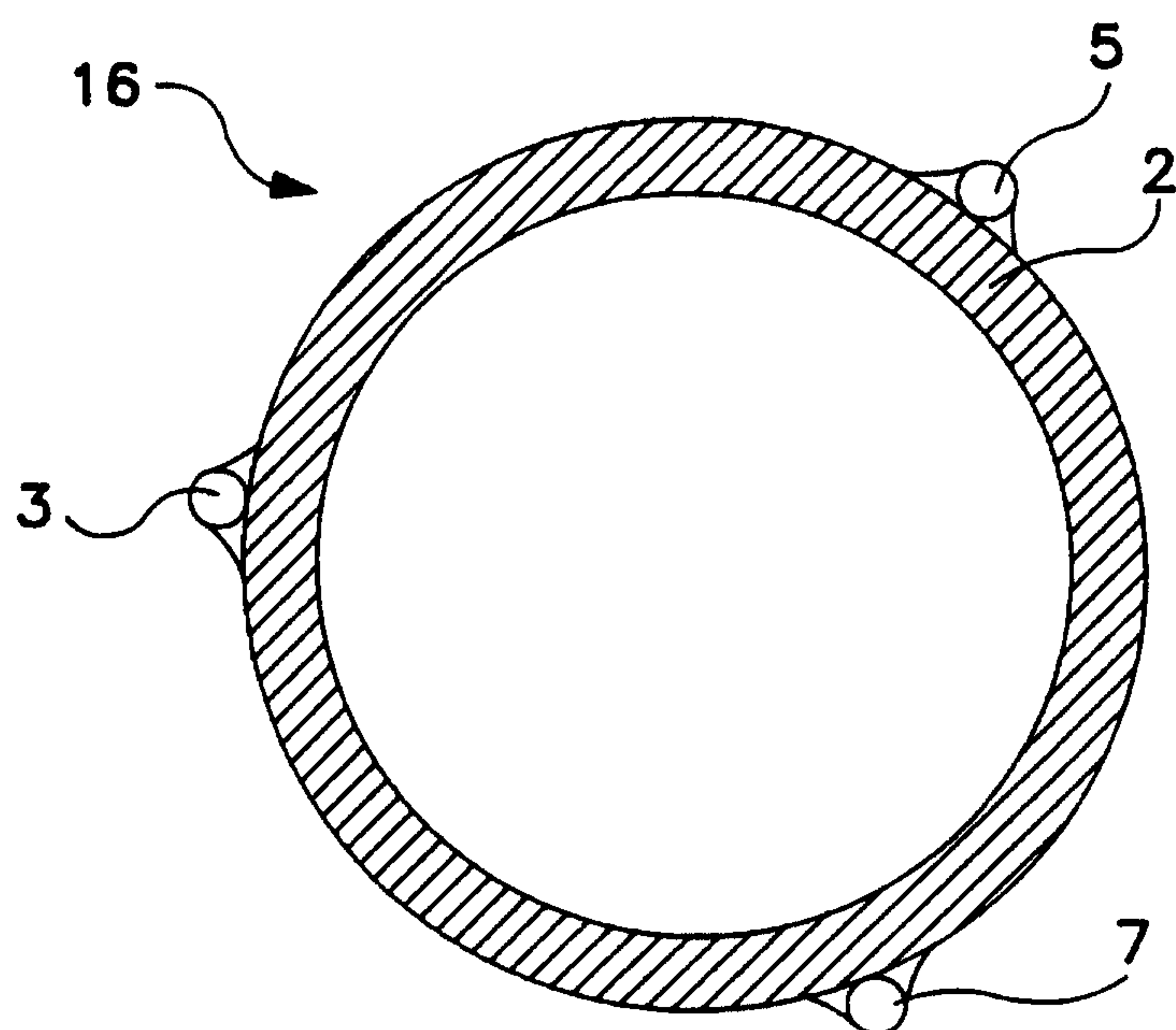


FIG. 2

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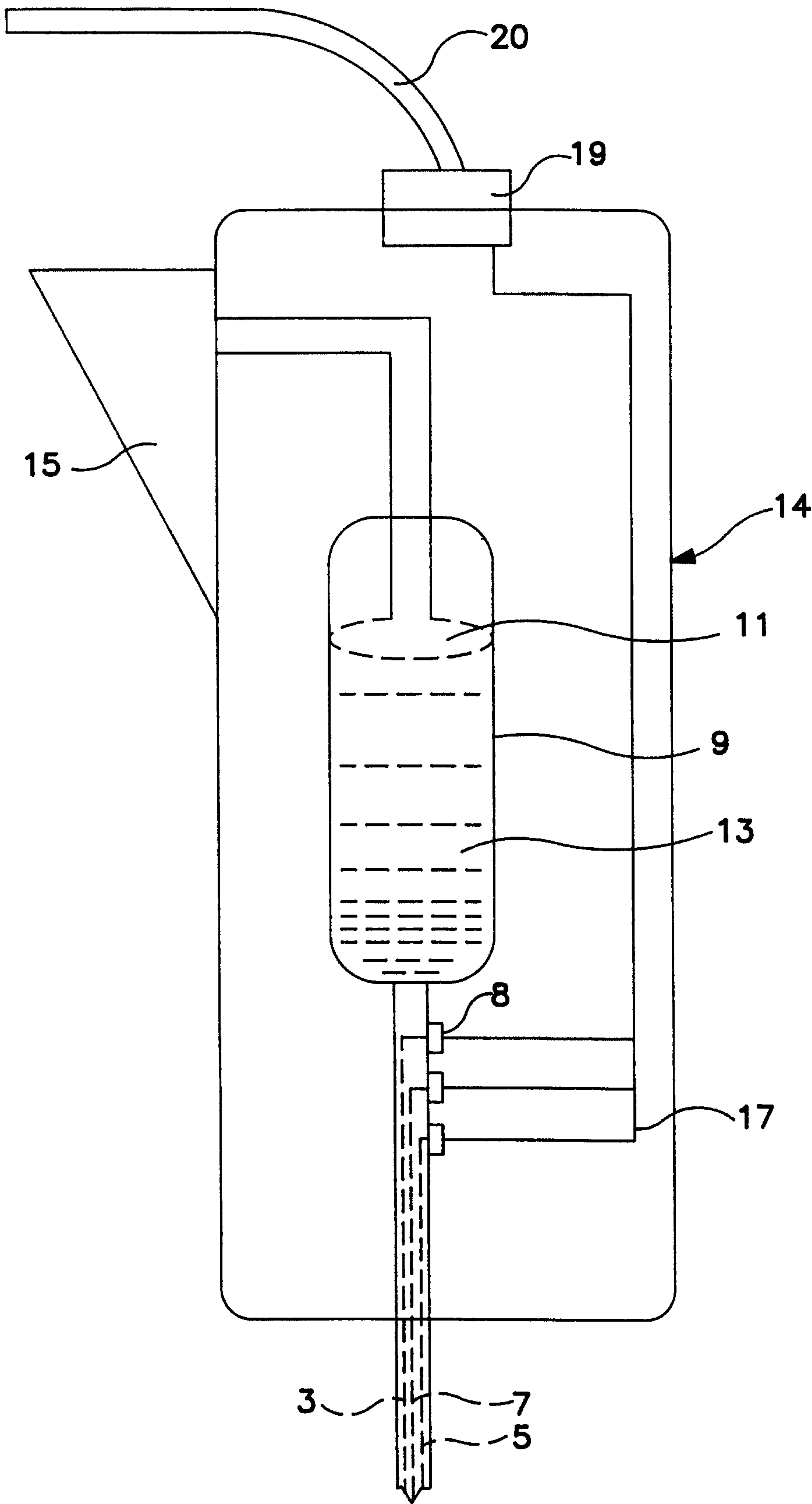


FIG. 3
SUBSTITUTE SHEET (RULE 26)

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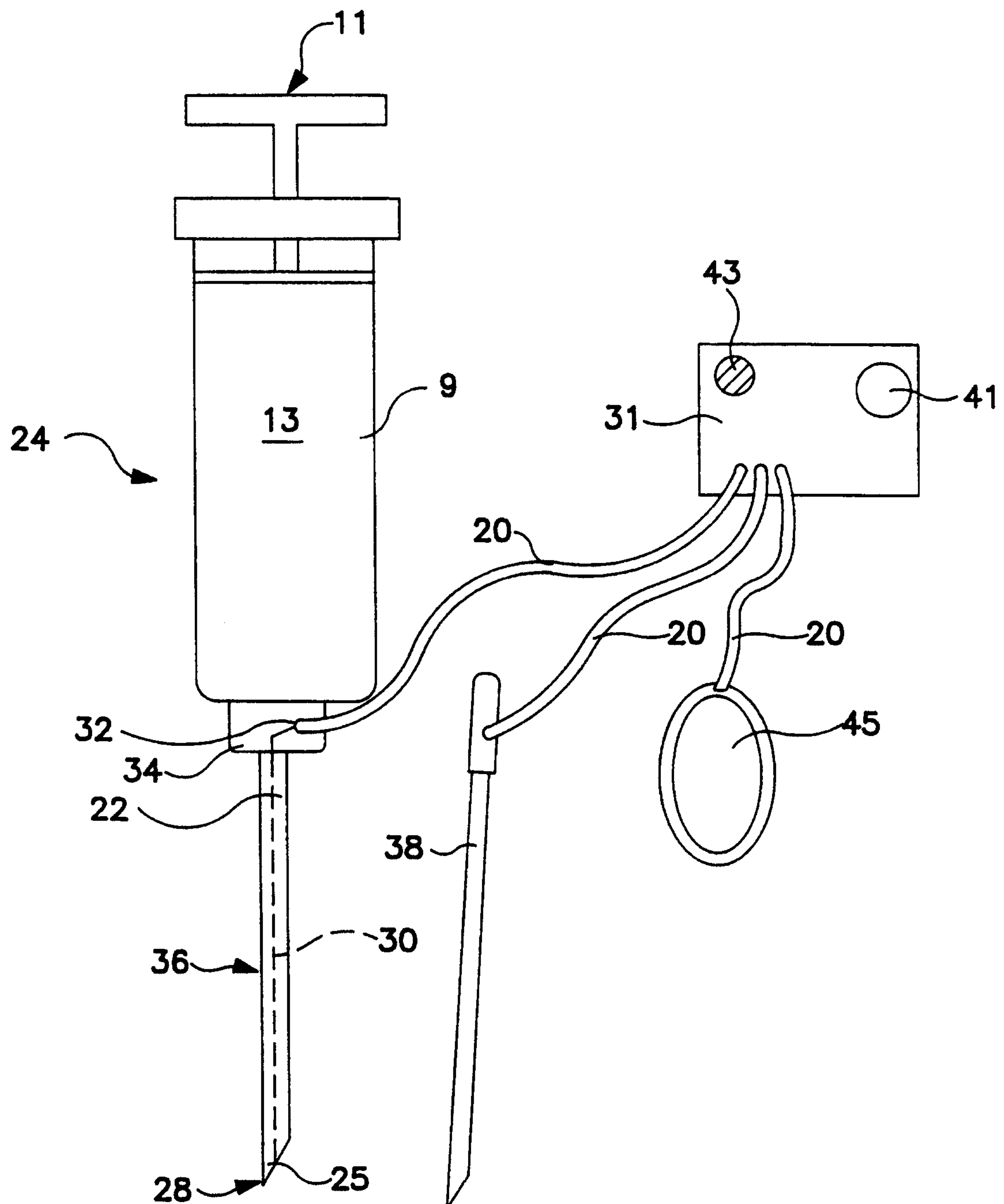


FIG. 4

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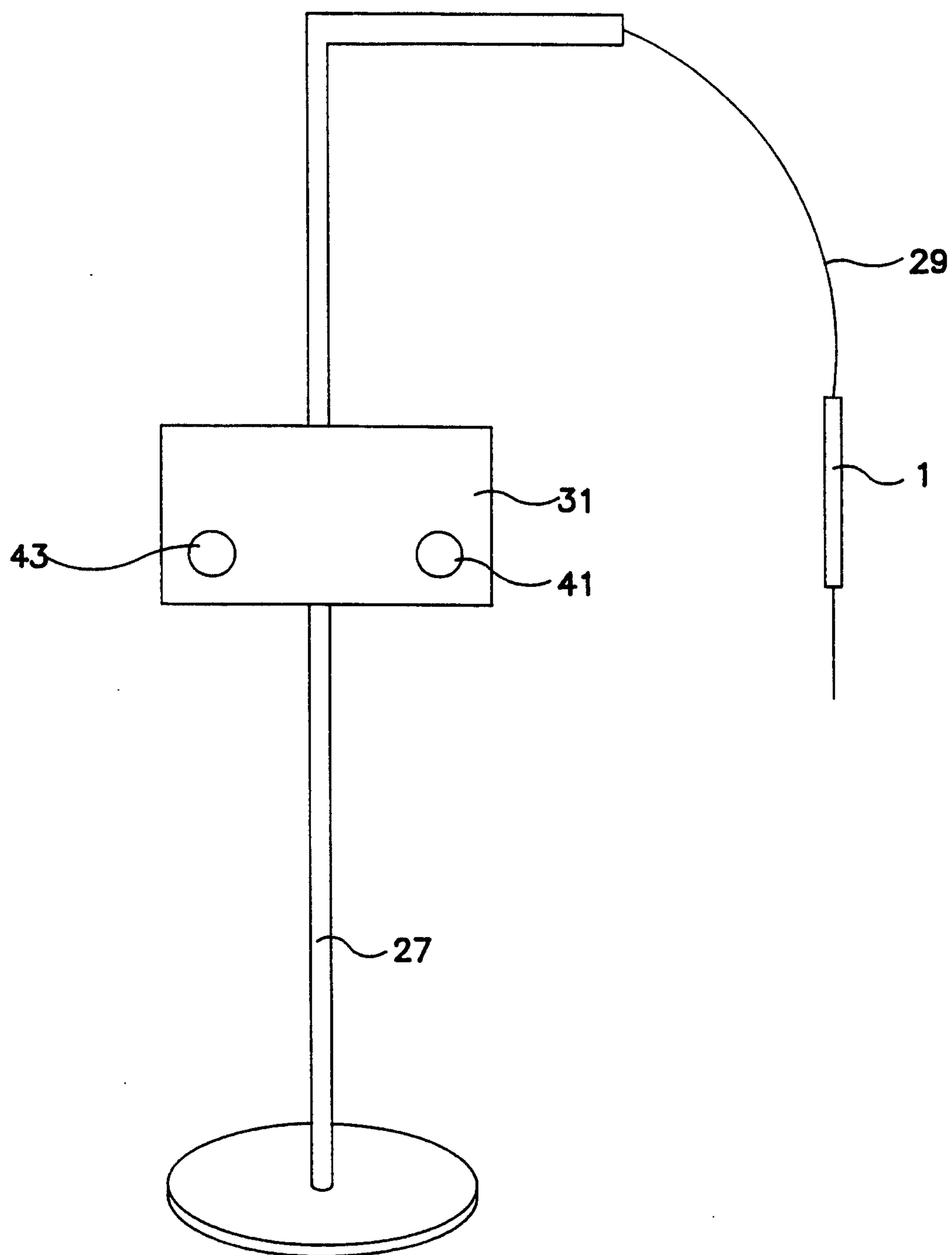


FIG. 5

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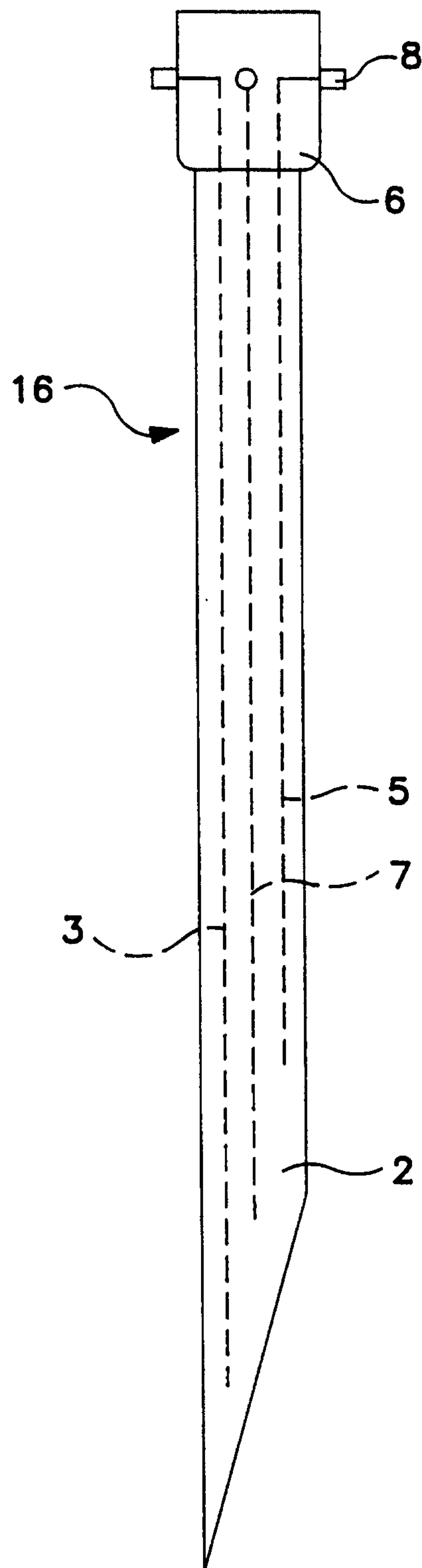


FIG. 6

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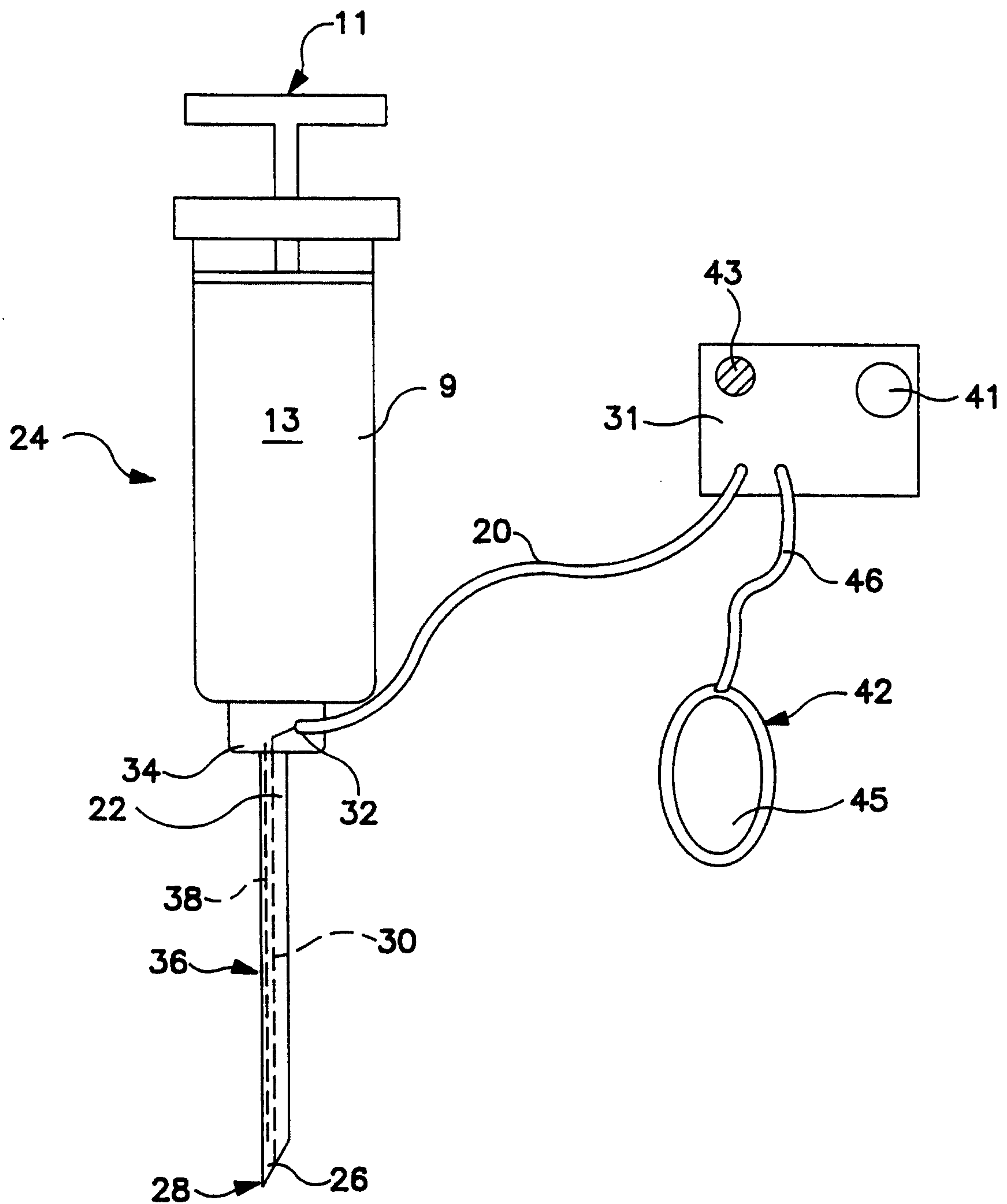


FIG. 7