

DECLARATION OF ROGER LOPEZ

I, Roger Lopez, pursuant to 28 U.S.C. § 1746 and 37 C.F.R. § 1.68, hereby declare as follows:

1. I am a Translator for Morningside Translations.
2. I submit this declaration to certify the accuracy of the English translation of Chinese Utility Model Patent CN 2225227Y to Liang et al.
3. I am qualified to perform Chinese to English translations and certify the accuracy of Chinese to English translations.
4. My statements are based on personal knowledge and my review of Chinese Utility Model Patent CN 2225227Y to Liang et al. and its Chinese to English translation. If called as a witness about the facts contained in these statements, I could testify competently based on such personal knowledge and the investigation I have conducted.
5. Attached as **Exhibit A** is a true and accurate copy of Chinese Utility Model Patent CN 2225227Y to Liang et al.
6. Attached as **Exhibit B** is a true and accurate copy of an English translation of Chinese Utility Model Patent CN 2225227Y to Liang et al. (hereinafter, "Liang '227 Translation"), which I prepared based on Exhibit A and my personal knowledge of the Chinese and English languages.
7. Liang '227 Translation is a true and accurate translation of Chinese Utility Model Patent CN 2225227Y to Liang et al. from Chinese to English.
8. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true.

9. I have been warned and am aware that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

10. I understand that by submitting this declaration I may be asked to appear for a deposition asking me questions limited to the material in my declaration. With my signature below, I agree to make reasonable efforts to make myself available for such a deposition at a reasonable place and time.

* * *

I declare under the penalty of perjury that the foregoing is true and correct. Executed on

20/12/2023 in Missouri.

Roger Lopez
Roger Lopez

Exhibit A



[12] 实用新型专利说明书

[21] ZL 专利号 95216733.6

[51]Int.Cl⁶

A61B 17/36

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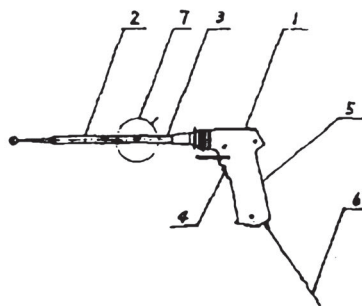
权利要求书 1 页 说明书 3 页 附图页数 3 页

[54]实用新型名称 射频治疗仪中的电极—射频枪

[57]摘要

本实用新型涉及射频治疗仪中的一种射频枪。

由探头、枪柄管、枪手柄、开关、导线组成的射频枪，探头与枪柄管用弹性夹持或螺纹连接为可装卸式连接或探头与枪柄管为不可装卸的一整体结构，插头有多种形式：A、治疗头为球体的弯形探头；B、治疗头为球体状的直形探头；C、治疗头为立方体；D、治疗头为圆锥帽状；E、治疗头顶面为半环形，这种射频治疗仪可用于五官科、妇科、肛肠外科、皮肤科等多种疾患的治疗。



权 利 要 求 书

1、一种射频治疗仪中的射频枪，是由治疗探头（2）、枪柄管（3）、金属导线（6）、开关（4）和枪手把（5）组成，其特征是探头（2）与枪柄管（3）用弹性夹持或螺纹连接为可装卸式连接，或探头（2）与枪柄管（3）固定为不可装卸的一整体，探头（2）的形状有A治疗头为球体状，探头套管（12）为弯曲的弯形探头；或B治疗头（11）为球体状的直形探头；或C治疗头（11）为立方体；或D治疗头（11）为与一平面连接的圆锥帽状，锥端为球面；或E治疗头（11）顶面为半环形。

说明书

射频治疗仪中的电极——射频枪

本实用新型属于射频治疗仪器中零部件的一个元件连接结构及状态的调整。

中国发明专利CN 1067387 A公开了一种用于治疗肛肠疾患的射频痔疮治疗仪。此发明由广州医疗器械厂实施，其产品名称为SHP—I射频痔疮治疗仪。SHP—I主机部分包括了CN 1067387 A中所述的电源、射频信号发生器、功放电路、定时装置、功率调节电路等电器部分，发明专利中所述的电极在产品中是通过一种形似手枪式的所谓射频枪来实施的。这种射频枪由一个金属的治疗探头、枪柄管、开关、枪手柄、金属导线组成，射频枪通过金属导线与SHP—I主机接通。SHP—I射频痔疮仪主机产生的射频电磁波通过金属导线传导给治疗探头，探头的治疗头与病患组织接触产生内热效应，温度达60—80℃，从而使蛋白组织热凝而脱水、萎缩、硬化、形成血栓并逐渐平复消失或坏死脱落而达到治疗的目的。但SHP—I射频痔疮治疗仪中配用的射频枪，其治疗探头与枪柄管是固定为一个整体，不能装卸的，且探头的形式和开关仅是单一直形的一种，治疗头的端面为 $\Phi 8\text{ mm}$ 的圆形，所以只能应用于肛肠外科，且治疗探头的清洁和消毒很不方便。

本实用新型的目的在于扩大射频治疗仪的治疗范围，如可用于五官科方面治疗鼻血管瘤、鼻息肉、声带结节、耳朵上的小肉瘤；妇科方面的宫颈炎、息肉及皮肤科的尖锐湿疣等诸种疾患。

本实用新型提供的一种射频枪仍是由治疗探头2、枪柄管3、

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金属导线 6、开关 4 和枪手把 5 组成。而其探头 2 和枪柄管 3 之间用弹性夹持或用螺纹连接为可装卸式连接，这样可根据临床病灶的位置、形状大小来更换不同构形的探头，或将探头 2 与枪柄管 3 制成固定的不可装卸的一个整体，即每一种构形的治疗探头制成一把射频枪。治疗探头的构形、尺寸大小可根据临床需要来设计。本实用新型设计的治疗探头有如下几种形式：A、治疗头 1 1 为球体状，探头套管 1 2 为弯曲状的弯形探头；B、治疗头 1 1 为球体状的直形探头；C、治疗头 1 1 为立方体；D、治疗头 1 1 为与一平面连接的圆锥帽状，锥端为球面；E、治疗头 1 1 顶面为半环形。

本实用新型的优点是射频治疗仪可一机多用，扩大治疗范围，根据病灶的位置、形状、大小来选用不同形状的探头的射频枪，或更换治疗探头，这种探头可装卸的射频枪又便于清洁消毒更符合医疗器械的卫生要求。

以下结合实施例附图对本实用新型具体说明：

图 1 射频治疗仪的结构示意图。

图中：1 射频枪、2 治疗探头、3 枪柄管、4 开关、5 枪手把、6 金属导线、7 探头与枪柄管的连接处。其连接可用弹性夹持（见附图 2）或用螺纹连接（见附图 3）或探头与枪柄用焊接等方式固定为一个整体不可装卸的连接。

图 2 治疗头和枪柄管弹性夹持连接的结构图。

图 3 治疗头与枪柄管螺纹连接的结构图。

见图 2、图 3，图中 8 插头、9 插座、10 螺母、3 枪柄管、6 金属导线。

图 4 各款治疗探头的形状图。

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图中 1 1 治疗头、1 2 探头套管、9 插头。

探头 A、治疗头为球状体，其大小以 $\Phi 1 \sim 5 \text{ mm}$ 为最佳，探头套管为弯曲形，弯曲半径 R 为 $25 \sim 30 \text{ mm}$ 。内弯角为 $100^\circ \sim 125^\circ$ 为最佳的弯形探头。

探头 B、治疗头为球状体的直形探头，球体大小以 $\Phi 1 \sim 5 \text{ mm}$ 为佳。

探头 C、治疗头为立方体，可以是正四方体，也可以是长方体、边长以 $2 \sim 6 \text{ mm}$ 为妥。

探头 D、治疗头与一平面连接的圆锥帽状，锥端为球面，以圆锥度 $16^\circ \sim 25^\circ$ ，锥长 $13 \sim 20 \text{ mm}$ 为佳。

探头 E、治疗头顶面为半环形，以外圆 $R 10 \sim 12 \text{ mm}$ ，内圆 $R 4 \sim 6 \text{ mm}$ 为佳。

在探头套管 1 2 中有一金属导线，两端分别与治疗头 1 1 及插头 9 焊接并固定在探头套管里，在探头套管的外部包有绝缘塑料层。

说明书附图

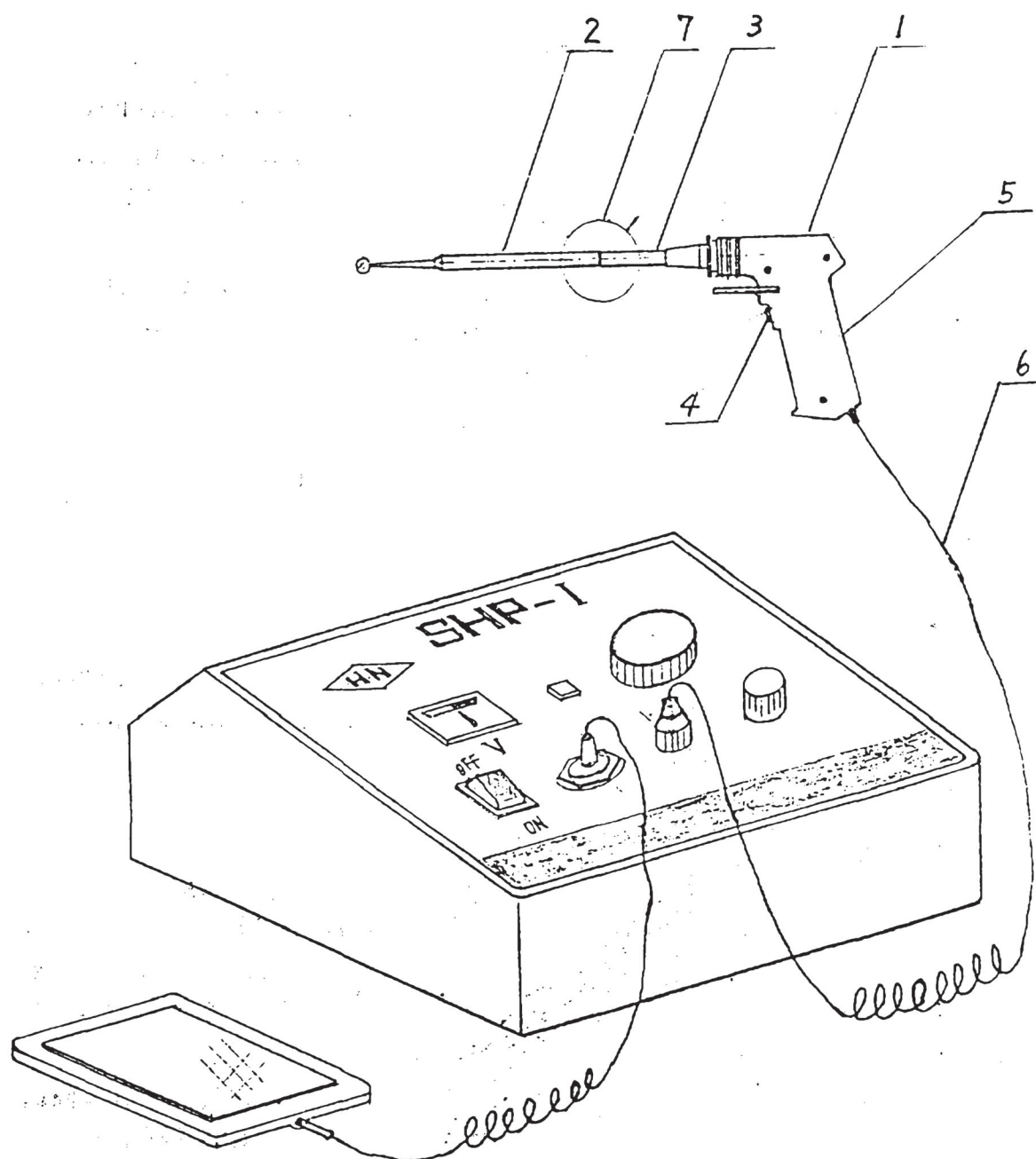


图 1

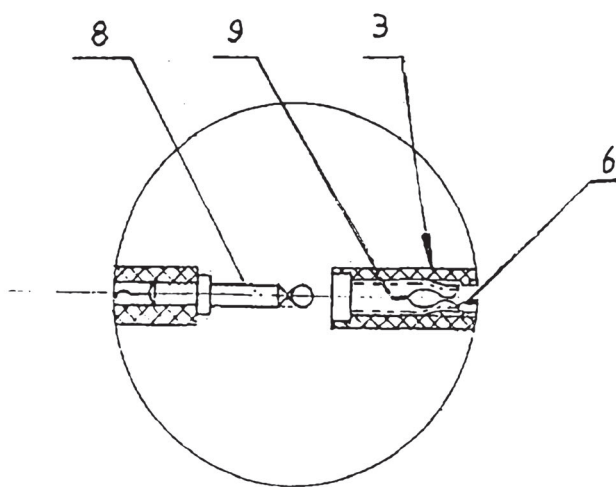


图2

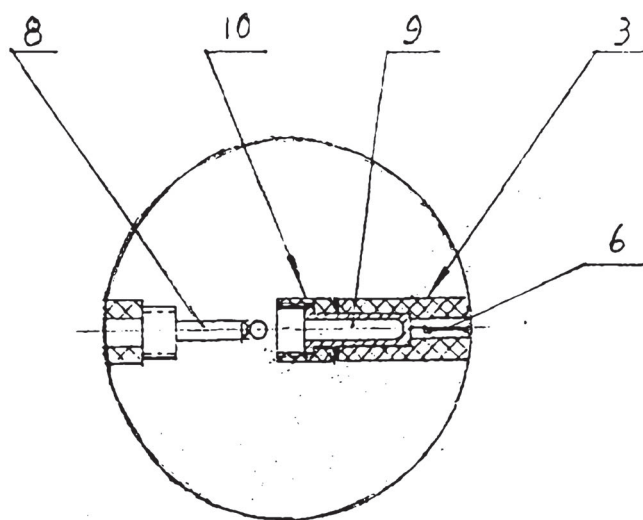


图3

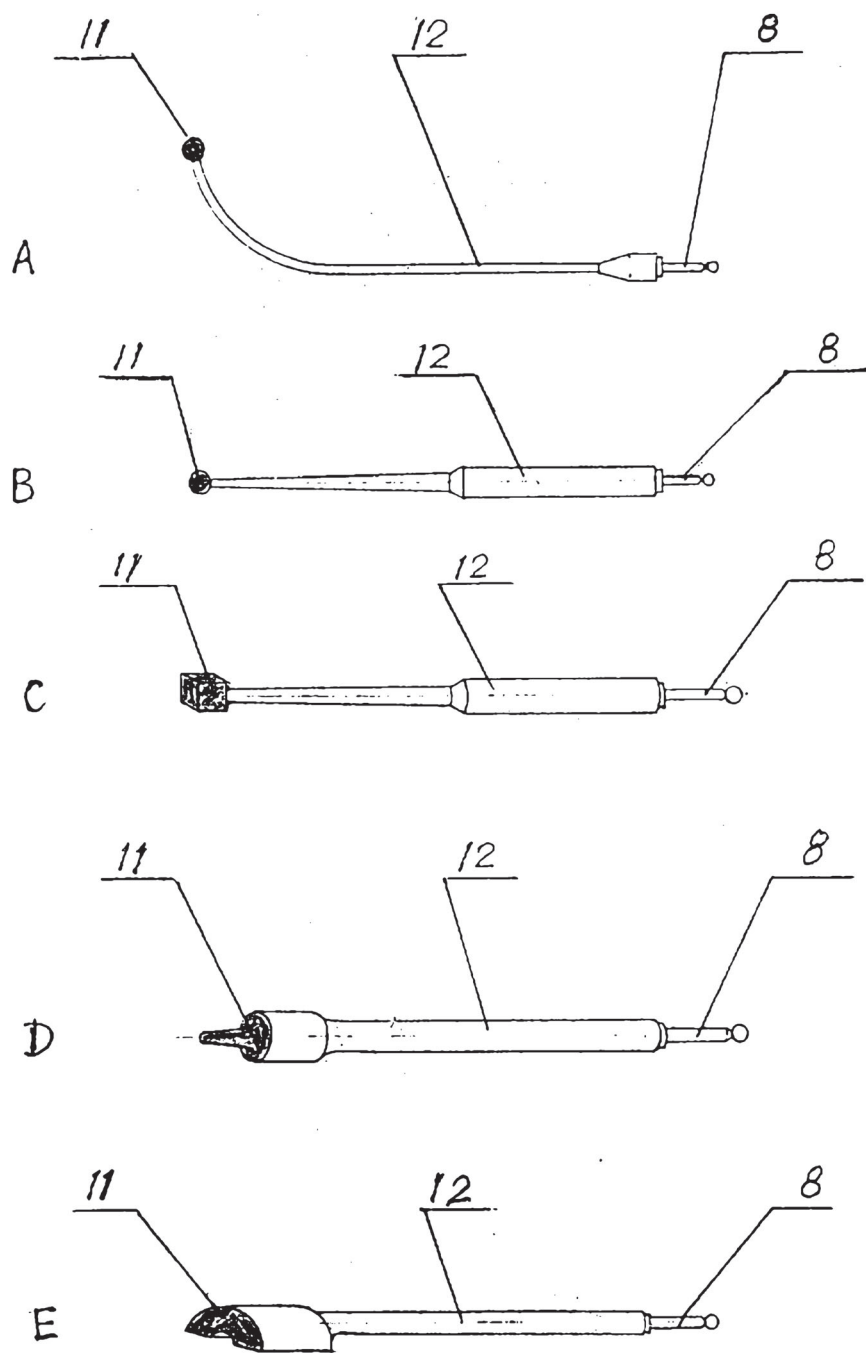


图4

Exhibit B



[12] Utility New Model Patent Description

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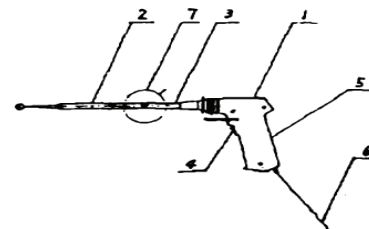
Patent claims: 1 page; Description: 3 pages; Figures:
3 pages

[54] Name of utility new model: Electrode in radiofrequency therapy
device - Radiofrequency gun

[57] Abstract

The present utility new model relates to a radiofrequency gun in
a radiofrequency treatment device.

A radiofrequency gun comprises of a probe, a gun barrel, a gun
handlebar, a switch, and a wire, wherein the probe is elastically clamped
or thread connected to the gun barrel to form a detachable connection,
or the probe forms a non-detachable integral structure with the gun
barrel, the plug comes in various forms: A. a curved probe with a
spherical treatment head; B. a straight probe with a spherical treatment
head; C. a cubic treatment head; D. a treatment head in a conical cap
shape; E. a treatment head with a semi-circular top shape. The
radiofrequency treatment device can be used for the treatment of
various diseases such as in the department of facial organs, gynecology,
anorectal surgery, and dermatology.



CLAIMS

1. A radiofrequency gun in a radiofrequency treatment device, comprising a treatment probe (2), a gun barrel (3), a metal wire (6), a switch (4), and a gun handlebar (5), wherein the probe (2) is elastically clamped or thread connected to the gun barrel (3) to form a detachable connection, or the probe (2) is fixed to the gun barrel (3) for form a non-detachable integral unit, the probe (2) comes in the shape of: A. the treatment head is spherical, and the probe sleeve (12) is a curved probe; B. the treatment head (11) is a spherical straight probe; C. the treatment head (11) is a cube; D. the treatment head (11) is a conical cap connected to a plane, with a spherical cone end; or E. the top surface of the treatment head (11) is semi-circular.

DESCRIPTION

Electrode in radiofrequency treatment device - Radiofrequency gun

The present utility new model belongs to the adjustment of the connection structure and state of a component in the radiofrequency treatment device.

The Chinese invention patent CN1067387A discloses a radiofrequency hemorrhoid treatment device for treating anal and rectal diseases. The invention was implemented by Guangzhou Medical Device Factory, and the product name is SHP-I radiofrequency hemorrhoid treatment device. The main unit of the SHP-I treatment device includes the power supply, radiofrequency signal generator, power amplifier circuit, timing device, power adjustment circuit, and other electrical components as described in CN1067387A. The electrode described in the invention patent is implemented in the product via a so-called radiofrequency gun, like a pistol. The radiofrequency gun consists of a metal treatment probe, a gun barrel, a switch, a gun handlebar, and a metal wire. The radiofrequency gun is in continuity with the SHP-I main unit via the metal wire. The radiofrequency electromagnetic waves generated by the main unit of the SHP-I radiofrequency hemorrhoid treatment device are transmitted to the treatment probe via the metal wire. The treatment head of the probe comes into contact with the patient's tissues to produce an internal thermal effect at a temperature up to 60°C - 80°C, which causes protein tissues to heat coagulate, dehydrate, shrink, harden, form blood clots, and gradually subside or disappear, leading to necrosis and detachment, achieving the purpose of treatment. However, the radiofrequency gun used in the SHP-I radiofrequency hemorrhoid treatment device has a treatment probe and gun barrel fixed as a whole, which cannot be installed or removed, and the form of the probe and the switch are only in a single straight shape, and the end face of the treatment head is circular in ϕ 8 mm, so it can only be used in anal and rectal surgery, and the cleaning and disinfection of the treatment probe are very inconvenient.

The purpose of the present utility new model is to extend the treatment range of the radiofrequency treatment device, such as use for the treatment of nasal hemangiomas, nasal polyps, vocal cord nodules, and small sarcoma on the ear in the field of facial organs; and various gynecological diseases such as cervicitis, polyps, and genital warts in dermatology.

The radiofrequency gun provided by the present utility new model is still composed of a treatment

DESCRIPTION

probe 2, a gun barrel 3, a metal wire 6, a switch 4, and a gun handlebar 5. The probe 2 and the gun barrel 3 are elastically clamped or thread connected to form a detachable connection, which allows the replacement of the probe with different shapes based on the location, shape, and size of clinical lesions, or the probe 2 and the gun barrel 3 are manufactured to form a fixed, non-detachable whole structure, that is, the treatment probe of each shape is made in a radiofrequency gun. The shape and size of the treatment probe can be designed according to clinical needs. The treatment probe designed by the present utility new model has the following forms: A. The treatment head 11 is spherical, and the probe sleeve 12 is a curved probe with a curved shape; B. The treatment head 11 is a spherical straight probe; C. The treatment head 11 is a cube; D. The treatment head 11 is in a conical cap shape connected to a plane, with a spherical conical end; E. The top surface of the treatment head 11 is semi-circular.

The advantage of the present utility new model is that the radiofrequency treatment device can be used for multiple purposes, with the treatment range extended, and probes in different shapes can be selected for the radiofrequency gun according to the location, shape, and size of the lesion, or the treatment probe can be replaced. The radiofrequency gun with detachable probes is also convenient for cleaning and disinfection, which better meets the hygiene requirements for medical devices.

The present utility new model is specifically described below in conjunction with the figures for the embodiments:

Figure 1 shows the schematic diagram of the structure of the radiofrequency treatment device.

Legends in the figure: 1. Radiofrequency gun; 2. Treatment probe; 3. Gun barrel; 4. Switch; 5. Gun handlebar; 6. Metal wire; 7. Connection between the probe and the gun barrel. They can be elastically clamped (refer to Figure 2) or thread connected (refer to Figure 3), or the probe and the gun handlebar can be fixed in modes such as by welding to form a non-detachable connection as a whole.

Figure 2 shows the structural diagram of the elastic clamping connection between the treatment head and the gun barrel.

Figure 3 shows the structural diagram of the threaded connection between the treatment head and the gun barrel.

Legends in Figures 2 and 3: 8. Plug; 9. Socket; 10. Nut; 3. Gun barrel; 6. Metal wire.

Figure 4 shows the shape diagrams of various treatment probes.

DESCRIPTION

Legends in the figure: 11. Treatment head; 12. Probe sleeve; 9. Plug.

Probe A: The treatment head is spherical, preferably with a size of ϕ 1-5 mm; the probe sleeve is curved, with a bending radius R of 25-30 mm. The optimal curved probe is one with an internal bending angle of 100°-125°.

Probe B: The treatment head is a spherical straight probe, and the size of the sphere is preferably ϕ 1-5 mm.

Probe C: The treatment head is a cube, which can be a square or a rectangular shape preferably with a side length of 2-6 mm.

Probe D: The treatment head is in a conical cap shape connected to a plane, with a spherical conical end, preferably with a cone degree of 16°-25° and a cone length of 13-20 mm.

Probe E: The treatment head surface is semi-circular, preferably with an outer circle of R 10-12 mm and an inner circle of R 4-6 mm.

There is a metal wire in the probe sleeve 12, which is welded to the treatment head 11 and the plug 9 at both ends and fixed in the probe sleeve. The outer part of the probe sleeve is wrapped with an insulating plastic layer.

Figures

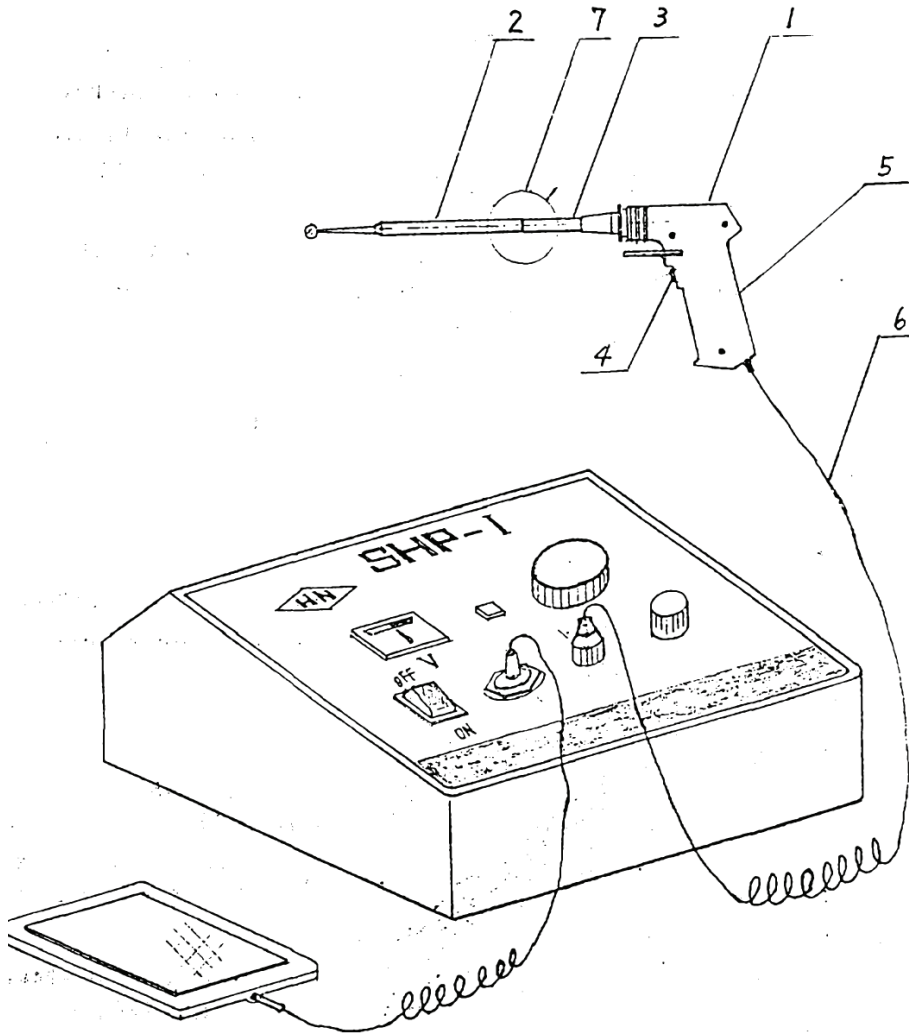


Figure 1

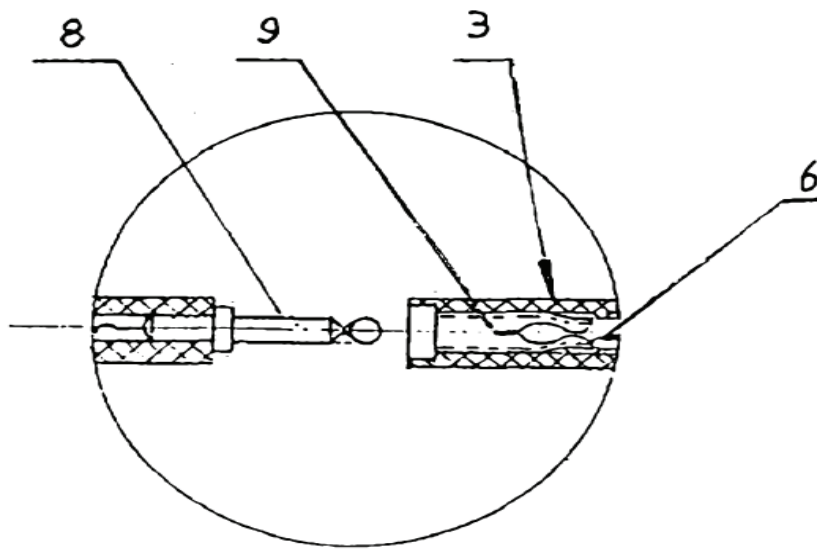


Figure 2

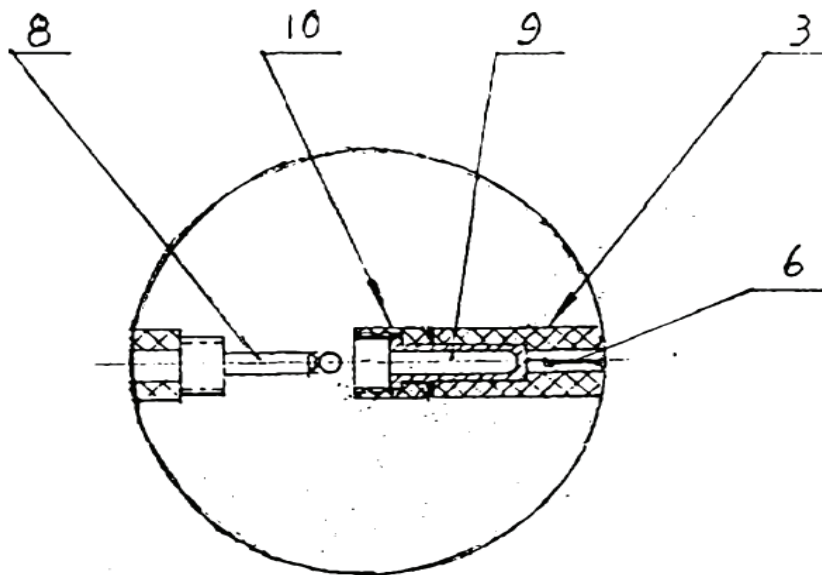


Figure 3

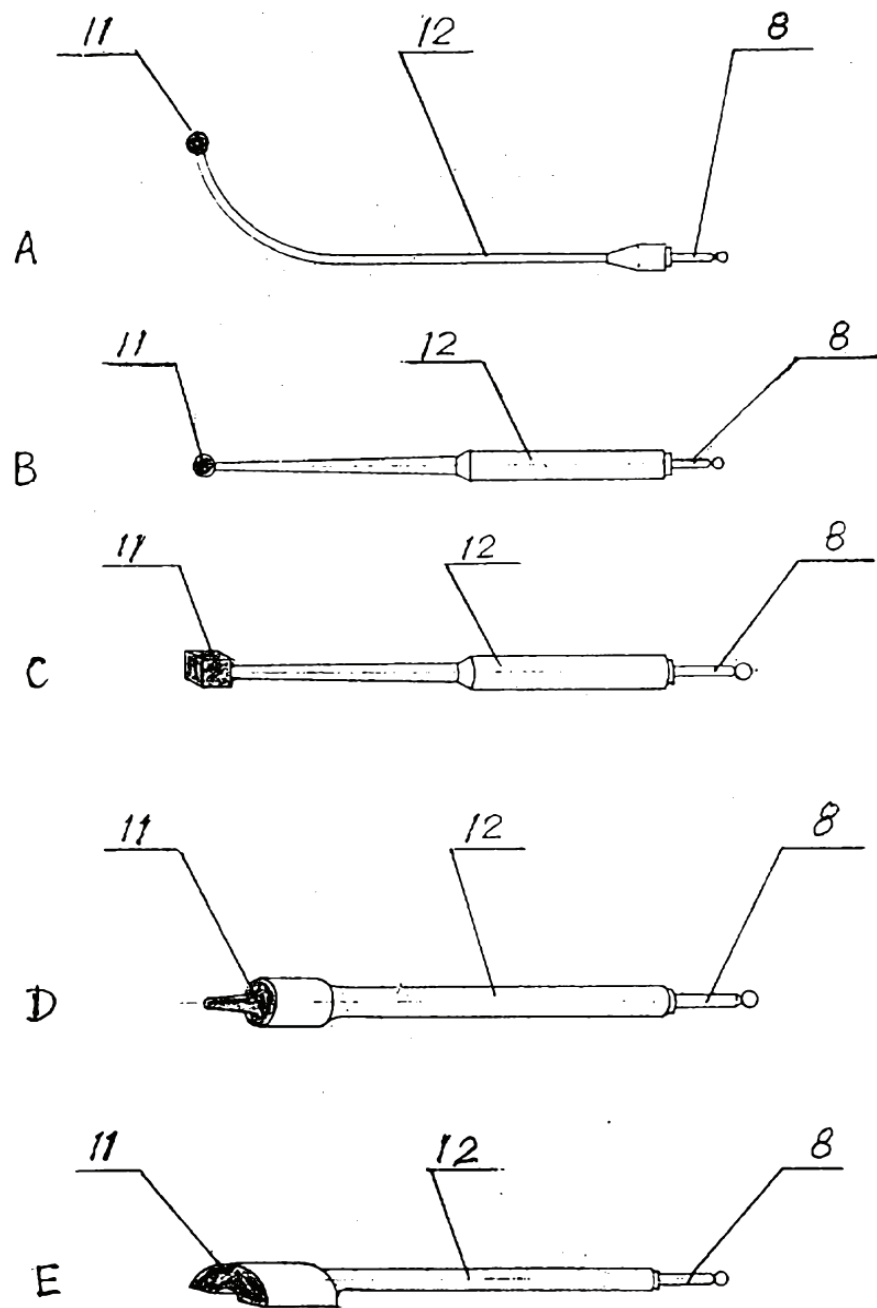


Figure 4