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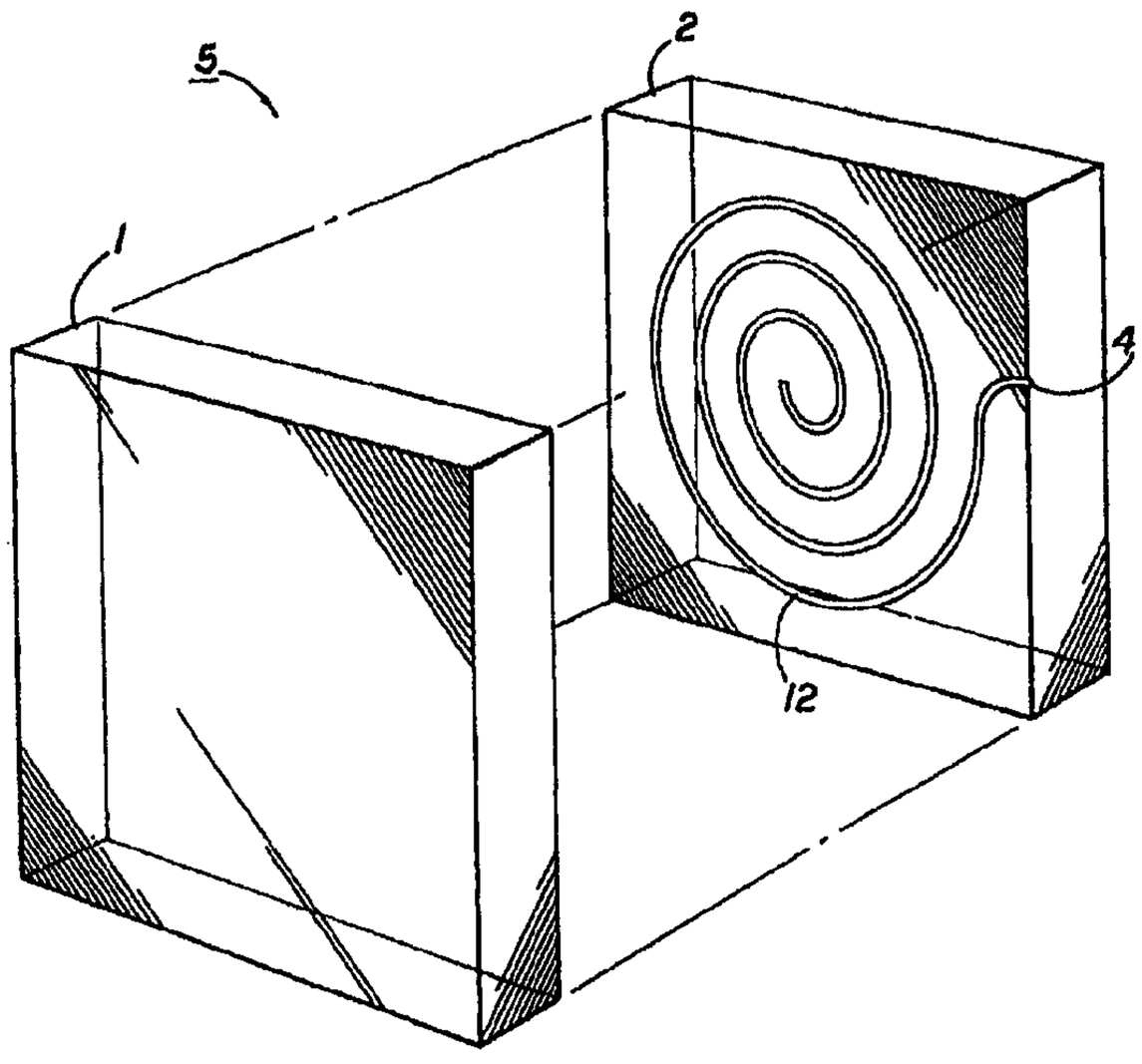
(54) **CONTENANT JETABLE POUR PASTILLES D'IRRADIATION**
(54) **DISPOSABLE CONTAINER FOR IRRADIATION PELLETS**



(57) A disposable safe holds radioactive pellets (8) retrieved from a patient after or during irradiation therapy for the treatment of restenosis, and provides a safety shield for medical personnel. The safe is suitable for couting the radioactive pellets to ensure that all are accounted for, that none are left in the patient, that none are located in patient bedding.

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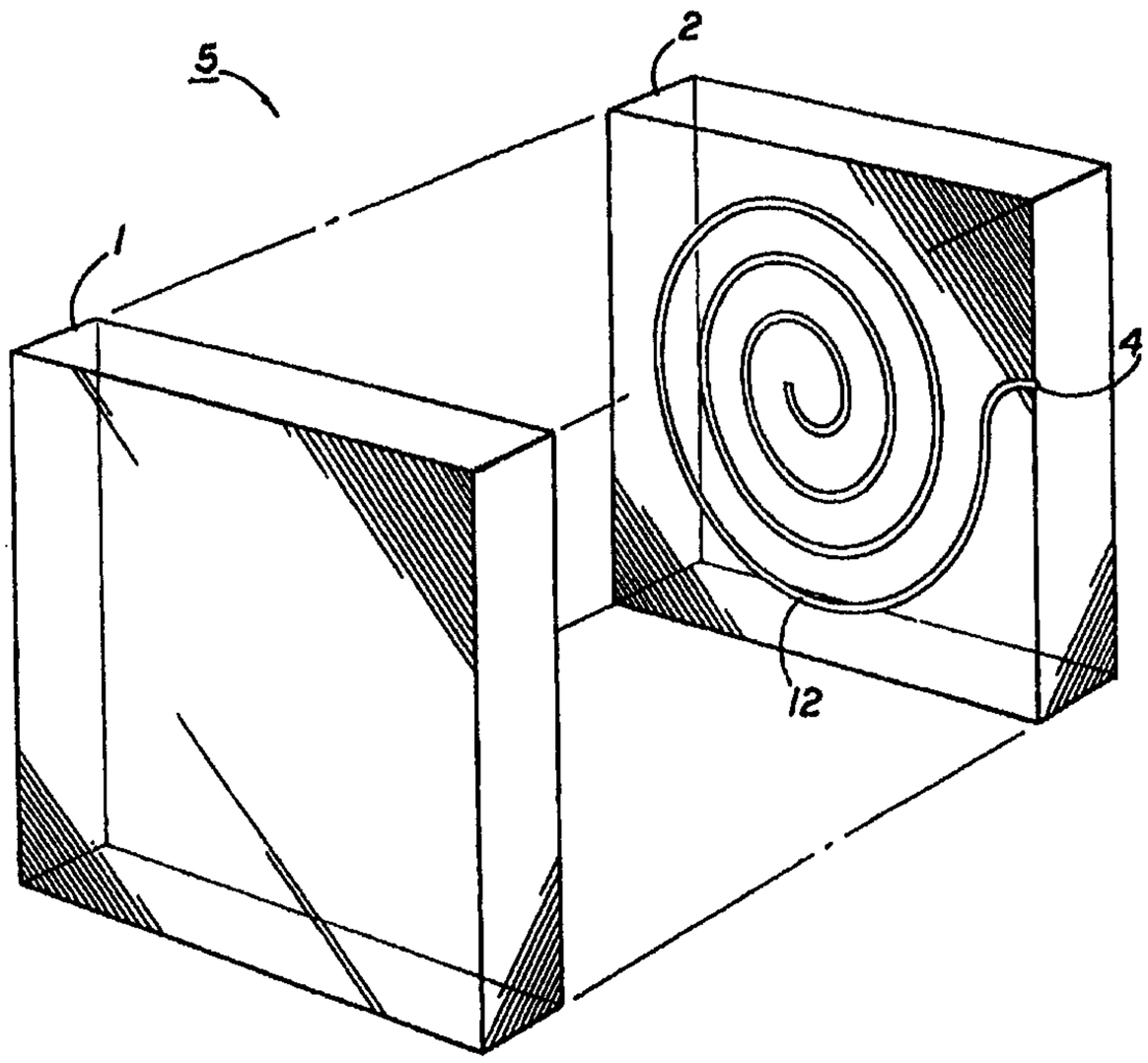


(57) Abstract

A disposable safe holds radioactive pellets (8) retrieved from a patient after or during irradiation therapy for the treatment of restenosis, and provides a safety shield for medical personnel. The safe is suitable for couting the radioactive pellets to ensure that all are accounted for, that none are left in the patient, that none are located in patient bedding.

DISPOSABLE CONTAINER FOR IRRADIATION PELLETS

BACKGROUND OF THE INVENTION

Locally delivered beta irradiation has been shown to be effective in the inhibition of restenosis, a process that occurs after angioplasty. There are two components of restenosis that beta irradiation has been shown to inhibit. One is the proliferation of cells that reside in the outer layer of the artery (adventitia) that occurs within days after vascular injury, the other process is the chronic remodeling that occurs weeks after injury. Trials involving experimental injury in porcine coronaries have conclusively demonstrated the effectiveness of beta irradiation in the treatment of restenosis.

A typical means for delivery of beta irradiation to the vascular vessel is with a catheter, e.g., a tri-lumen, 5-french catheter. The radioactive source is most conveniently a series of pellets. It is not uncommon for the pellets to get undesirably lodged or "stuck" inside the catheter or other delivery means. In such situations, the catheter or other delivery means must be pulled out immediately to remedy the situation. When the radioactive source is more than one pellet, it is essential to visually examine and verify that every pellet is accounted for, and not left behind inside the patient or attached to operating room bedding, or elsewhere.

Applicants provide a disposable container to count the pellets, to provide protection to medical personnel, and to provide ready visual access. The disposable container is typically made of clear plastic, possesses an internal lumen to place the withdrawn catheter containing radioactive pellets, and a radioactive barrier suitable for low level beta irradiation.

The device of the present invention provides the necessary radiation protection to operating room personnel and staff from the radiation originating from the loaded radioactive members within a catheter withdrawn during treatment for restenosis. The device of the present invention allows visual verification of all radioactive sources inside the catheter before the patient is removed from the operating room.

BRIEF DESCRIPTION OF THE INVENTION

A disposable container suitable for radiation members, e.g., pellets, within a catheter for the treatment of restenosis. The container allows medical personnel to confirm that all radioactive sources used have been removed from the patient, by simple visual inspection and counting of the radioactive members.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 schematically illustrates, in one embodiment of the present invention, the disposable safe as two plastic plates, with one plate having a spiral groove on the side intended to be on the inside of the disposable safe.

Figure 2 schematically illustrates, in another embodiment of the present invention, a disposable safe assembled with the plastic plates of Figure 1, showing a catheter with radioactive members about to be inserted into the spiral lumen.

Figure 3 schematically illustrates, in another embodiment of the present invention, an end view or side elevation of the disposable safe as an assembly of two plastic plates, as a cross section of the groove milled according to Figure 2.

Figure 4 schematically illustrates, in another embodiment of the present invention, a side view of the disposable safe as an assembly of two plastic plates, showing a cutaway view of the upper portion of the disposable safe.

Figure 5 schematically illustrates a cross section of the lumen within the plastic assembly, formed of a groove in a round configuration on one plastic plate, without any indentation on the other plastic plate.

Figure 5A schematically illustrates a cross section of the lumen within the plastic assembly, here formed to have a triangular configuration.

Figure 5B schematically illustrates a cross section of the lumen within the plastic assembly, here formed to have a rectangular configuration.

Figure 6 schematically illustrates, in another embodiment of the present invention, the disposable safe as a vessel filled with water, with inner plastic tubing inserted therein.

Figure 7 schematically illustrates the vessel of Figure 6 in cross section.

DETAILED DESCRIPTION OF THE INVENTION

This invention relates to a disposable safe for visually inspecting radioactive members contained therein, without substantial radiation risk to attending personnel, comprising

(a) a plastic section of sufficient thickness to substantially block all irradiation from any radioactive member placed within any lumen of the section, said irradiation consisting of substantially beta irradiation or low-energy gamma irradiation or combination thereof;

(b) one or more lumens within the section, each lumen having an opening suitable for insertion therethrough of radioactive members, said members having been retrieved from a patient undergoing radiation treatment for restenosis via catheterization of the radioactive members.

In one embodiment of the present invention the plastic section of the disposable safe comprises two blocks glued or otherwise attached to each other, with one lumen.

In another embodiment of the present invention the blocks of the disposable safe are glued to each other, and the lumen forms a planar spiral through the plastic section.

In another embodiment of the present invention, the lumen of the disposable safe in cross-section is round, oval, square, triangular, pentagonal or hexagonal, or combination thereof.

The disposable safe is suitable for emergency retrieval of radioactive members during radiation treatment of restenosis, and thereafter the counting of radioactive members.

In another embodiment of the present invention, the clear plastic section of the disposable safe is made of a polymer of methyl methacrylate, forming a clear or translucent solid.

In another embodiment of the present invention, the disposable safe is suitable for counting radioactive members having a radioactive source selected from the group consisting of ^{192}Ir ^{125}I, ^{103}Pd ^{90}Sr ^{89}Sr, ^{90}Y, and ^{32}P.

In another embodiment of the present invention, the disposable safe is suitable for counting radioactive members having a radioactive source producing beta radiation.

In another embodiment of the present invention, the disposable safe for visually inspecting radioactive members contained therein comprises

(a) a plastic bag filled with water of sufficient volume and diameter to substantially block irradiation from any radioactive member placed within a plastic tube within the plastic bag, said irradiation consisting substantially of beta irradiation or low-energy gamma irradiation or combination thereof;

(b) one or more plastic tubes within the plastic bag, each tube having an opening suitable for insertion therethrough of radioactive members, said members having been retrieved from a patient undergoing radiation treatment for restenosis via catheterization of the radioactive members.

In another embodiment of the present invention the plastic bag and plastic tubing of the disposable safe is made of polystyrene or polyethylene, to form a clear or translucent plastic having flexibility without cracking.

In another embodiment of the present invention, the disposable safe is suitable for counting radioactive members having a radioactive source selected from the group consisting of ^{192}Ir ^{125}I, ^{103}Pd ^{90}Sr ^{89}Sr, ^{90}Y, and ^{32}P.

In another embodiment of the present invention, the disposable safe is suitable for counting radioactive members having a radioactive source producing beta radiation.

The disposable safe is made of low cost materials. It permits the counting of radioactive pellets after their removal from a patient undergoing radiation treatment for restenosis, without substantial radiation exposure to attending medical personnel. In some situations emergency retrieval during treatment is required, e.g., when the catheter device kinks during delivery of the radioactive pellets to the target tissue. It is not uncommon to lose one or more of the radioactive pellets, a hazard to both the patient and the attending medical personnel. The present disposable safe permits safe counting of the pellets, an advantageous device suitable for better surgical treatment of restenosis.

The disposable safe of the present invention is suitable for any radiation member having a radioactive source of beta radiation or low-energy gamma radiation. Isotopes typically used for these purposes include, but are not limited to, ^{192}Ir ^{125}I, ^{103}Pd ^{90}Sr ^{89}Sr, ^{90}Y, and ^{32}P. The preferred isotope is ^{90}Sr.

While restenosis is the preferred pathological condition for treatment when using the disposable safe of the present invention, it will be understood that any other condition may be treated provided that the radioactive source is beta radiation or low-energy gamma radiation. This limitation results from the size of the plastic section or water-filled bag needed to block radiation from the radiation pellets contained within the disposable safe.

In one typical embodiment, illustrated in Figures 1 and 2, the disposable safe is an assembly of two plastic plates or blocks. Typical dimensions are about 20 cm in height, about 20 cm in length and about 2.0 cm in width. The thickness of plastic blocking radiation in this instance is about 2.0 cm or more. To block outgoing radiation emitting from the radiation pellets placed therein, the preferred minimum thickness of the plastic is at least about 1.0 cm. Variations in such dimensions are readily apparent to the skilled artisan, e.g., between about 20 cm and about 25 cm in height, between about 20 cm and about 25 cm in length, and between about 2 cm and about 3 cm in width. The assembly need not form from plates or blocks, but may comprise instead two or more plastic sections to be glued together or otherwise attached. Alternatively, the assembly may comprise one piece of clear or translucent solid, with a lumen of appropriate diameter and length drilled out therein.

Such an assembly of plastic plates or blocks requires ready visualization of the radioactive pellets contained therein. The plastic material must be clear or translucent, e.g., a polymer of methyl methacrylate. Any plastic or glass material is suitable, provided that it has a minimum physical density of about 1.2 gm/cc, and is sufficiently clear for the purpose of visualization of the radiation members or pellets lodged therein.

In another typical embodiment, illustrated in Figures 6 and 7, the disposable safe is a plastic bag filled with water or some other suitable liquid. To block outgoing radiation emitting from the radiation pellets placed therein, the preferred minimum thickness of the water is at least about 1 cm. A disposable safe

shaped as a plastic cylinder would then need to have a diameter of about at least 10 cm, or a distance of at least about 1 cm between the diameter of the inner plastic tube and the diameter of the plastic cylinder. Variations in such dimensions are readily apparent to the skilled artisan.

The disposable safe as a plastic bag filled with water and inner tubing must be constructed to allow ready inspection and counting of the radioactive pellets contained therein. The plastic material for this embodiment of the present invention is a clear or translucent plastic having flexibility without cracking. Examples of such plastic compositions include polyethylene plastic bags.

Turning now to the Figures, one embodiment of the present invention is illustrated in Figures **1** and **2**. Plastic block **1** and plastic block **2** are prepared from molds, by milling and sanding, or by any one of a variety of other conventional methods of shaping plastic solids. Plastic block **2** has a spiral groove **12**, with opening **4**. Plastic block **1** has a flat inner surface. When glued together or otherwise attached at their inner surfaces, an assembly or plastic section **5** is formed, as shown in Figure 2, with a lumen **3**. A catheter 7 containing radioactive pellets **8** is inserted by hand **6** (or by machine, not depicted) into the opening **4** and pushed through the lumen **3**. It will be readily apparent to the skilled artisan that the spiral shape of lumen **3** is a preferred configuration, but that other configurations are possible, e.g., a straight configuration within an assembly of long plastic blocks.

Figure 3 illustrates an end view or side elevation of the disposable safe of Figure 2. Depicted are the assembly or plastic section **5**, lumen **3**, and opening **4**. Part of one plate is removed to give the cutaway side view of the assembly in Figure **4**, showing also groove **12**, lumen **3**, and opening **4**.

Figure 5 illustrates, in one embodiment of the present invention, a cross-section through the lumen **3** as shown in Figure 4. Here the lumen **3** is formed of a round groove made on one plate, but not the other. After gluing of the plates, the lumen **3** may now hold the catheter **9** (shown in outline).

Figure 5A illustrates, in another embodiment of the present invention, a second type of cross-section through the lumen **3** as shown in Figure 4. Here the lumen **3** is formed of a triangular groove made on one plate. After gluing of the plates, lumen **3** of triangular cross-section may now hold the catheter **9** (shown in outline).

Figure 5B illustrates, in another embodiment of the present invention, a third type of cross-section through the lumen **3** as shown in Figure **4**. Here the lumen **3** is formed of a square groove made on one plate. After gluing of the plates, the lumen **3** of square cross-section may now hold the catheter **9** (shown in outline).

In another embodiment of the present invention, Figure 6 illustrates a disposable safe as a plastic bag **10** filled with water, with inner plastic tubing **11** inserted therein. The catheter with radioactive pellets (not shown) is inserted through the opening **4** of the proximal end of inner plastic tubing **11**, then counted under the protection of the wall of water already placed in the plastic bag. After counting, the catheter is withdrawn and the bag disposed of in an appropriate fashion.

Figure 7 illustrates the disposable safe of Figure 6 in cross-section. Depicted are the plastic bag **10** in water **13**, as well as the clear plastic tubing **11**.

The radiation delivery system typically used in the treatment of restenosis by radiation with limited penetrating power is a catheter composed of a metal or plastic tubular body. The tubular body has a lumen may be designed to receive one or more guidewires, to assist in the appropriate placement within the blood vessel. A metal sheath optionally covers the tubular body over its entire length, including the distally attached wire assembly, in order to protect the patient from exposure to radiation during deployment of the catheter.

When the catheter of the present invention is positioned at the appropriate place in the body, the precision timer starts and a predetermined amount of radiation is delivered.

EXAMPLE

A. <u>Coronary angioplasty without local irradiation</u>

A 58-year-old man develops chest pain after heavy yard work. He is admitted to the Chest Pain Unit for evaluation. A few days later, the cardiac team decides that the patient needs angioplasty. The angioplasty is completed without any notable incidents. Patient goes home with a list of instructions from his cardiac team. About twelve months later, during a normal follow up session with the cardiac team, he is now diagnosed with a new narrowing of the same cardiac blood vessel, except that it is now more severe. Another angioplasty is needed.

B. Coronary angioplasty with local irradiation

A 63-year-old man develops chest pain after heavy yard work. He is admitted to the Chest Pain Unit for evaluation. A few days later, the cardiac team decides that the patient needs angioplasty. The angioplasty in this case includes the additional protocol of inserting another catheter into the patient through which a train of ^{90}Sr seeds are driven to the site of angioplasty, and thereby locally delivering a predetermined amount of radiation with a precision timer. This modified angioplasty procedure takes a few minutes longer than the conventional procedure, as illustrated in Narrative A above. It is completed without any notable incidents. Patient goes home with a list of instructions from his cardiac team. The patient comes back annually for check ups, but there is no new narrowing of the blood vessel.

While the foregoing specification teaches the principles of the present invention, with examples provided for the purpose of illustration, it will be understood that the practice of the invention encompasses all of the usual variations, adaptations, and modifications, as come within the scope of the following claims and its equivalents.

WHAT IS CLAIMED IS:

1. A disposable safe for visually inspecting radioactive members contained therein, without substantial radiation risk to attending personnel, comprising

(a) a plastic section of sufficient thickness to substantially block all irradiation from any radioactive member placed within any lumen of the section, said irradiation consisting of substantially beta irradiation or low-energy gamma irradiation or combination thereof;

(b) one or more lumens within the section, each lumen having an opening suitable for insertion therethrough of radioactive members, said members having been retrieved from a patient undergoing radiation treatment for restenosis via catheterization of the radioactive members.

2. The disposable safe of claim 1, wherein the plastic section comprises two blocks glued or otherwise attached to each other, with one lumen.

3. The disposable safe of claim 2, wherein the blocks are glued to each other, and the lumen forms a planar spiral through the plastic section.

4. The disposable safe of claim 2, wherein the lumen in cross-section is round, oval, square, triangular, pentagonal or hexagonal, or combination thereof.

5. The disposable safe of claim 1, suitable for emergency retrieval of radioactive members during radiation treatment of restenosis, and thereafter counting the radioactive members.

6. The disposable safe of claim 1, wherein the clear plastic section is made of a polymer of methyl methacrylate, forming a clear or translucent solid.

7. The disposable safe of claim 1, wherein the radioactive members have a radioactive source selected from the group consisting of ^{192}Ir ^{125}I, ^{103}Pd ^{90}Sr ^{89}Sr, ^{90}Y, and ^{32}P.

8. The disposable safe of claim 1, wherein the radioactive members have a radioactive source producing beta radiation.

9. A disposable safe for visually inspecting radioactive members contained therein comprising

(a) a plastic bag filled with water of sufficient volume and diameter to substantially block irradiation from any radioactive member placed within a plastic tube within the plastic bag, said irradiation consisting substantially of beta irradiation or low-energy gamma irradiation or combination thereof;

(b) one or more plastic tubes within the plastic bag, each tube having an opening suitable for insertion therethrough of radioactive members, said members having been retrieved from a patient undergoing radiation treatment for restenosis via catheterization of the radioactive members.

10. The disposable safe of claim 9, wherein the plastic bag and plastic tubing is made of polystyrene or polyethylene, to form a clear or translucent plastic having flexibility without cracking.

11. The disposable safe of claim 9, wherein the radioactive members have a radioactive source selected from the group consisting of ^{192}Ir ^{125}I, ^{103}Pd ^{90}Sr ^{89}Sr, ^{90}Y, and ^{32}P.

12. The disposable safe of claim 9, wherein the radioactive members have a radioactive source producing beta radiation.

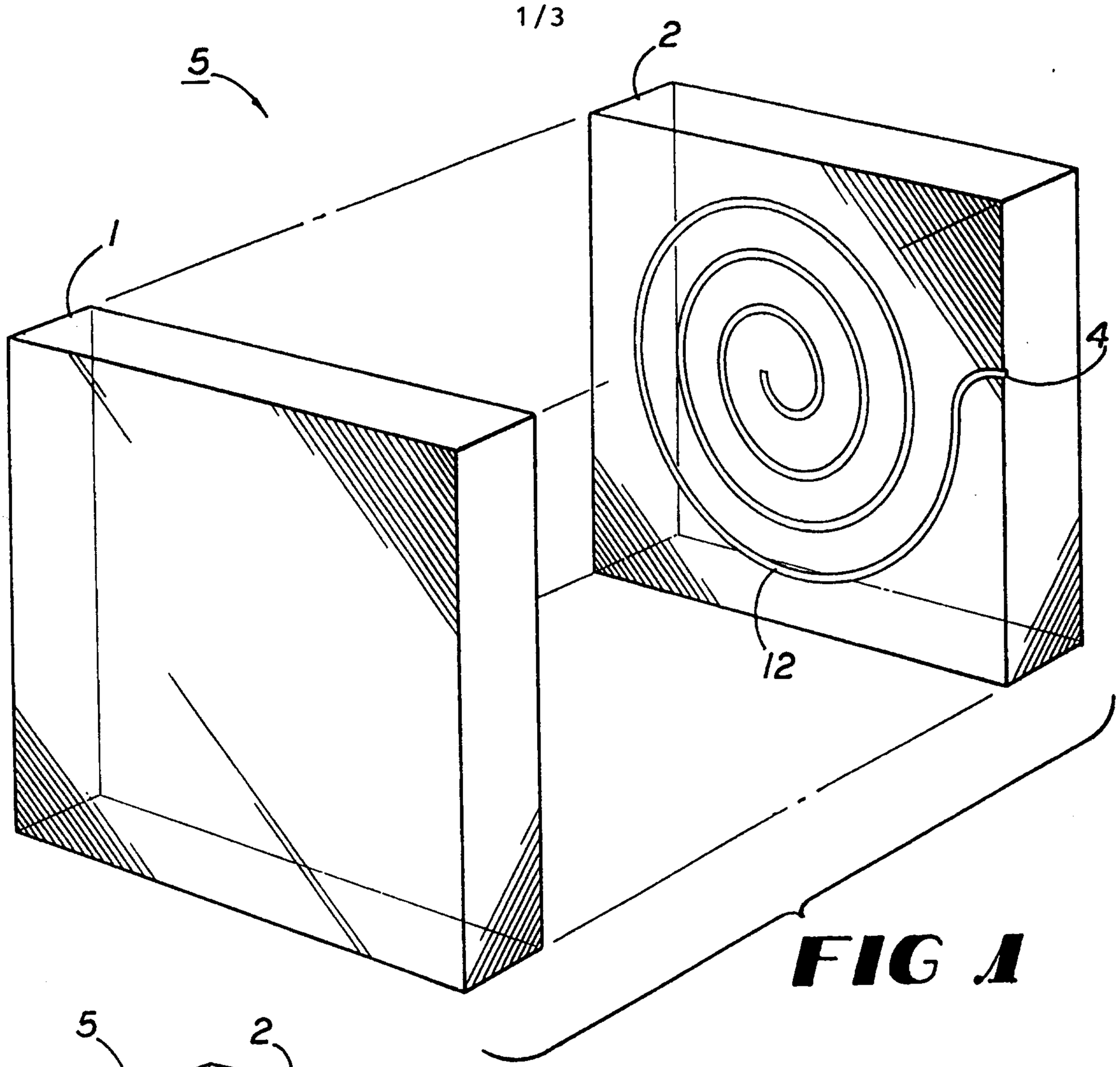


FIG 1

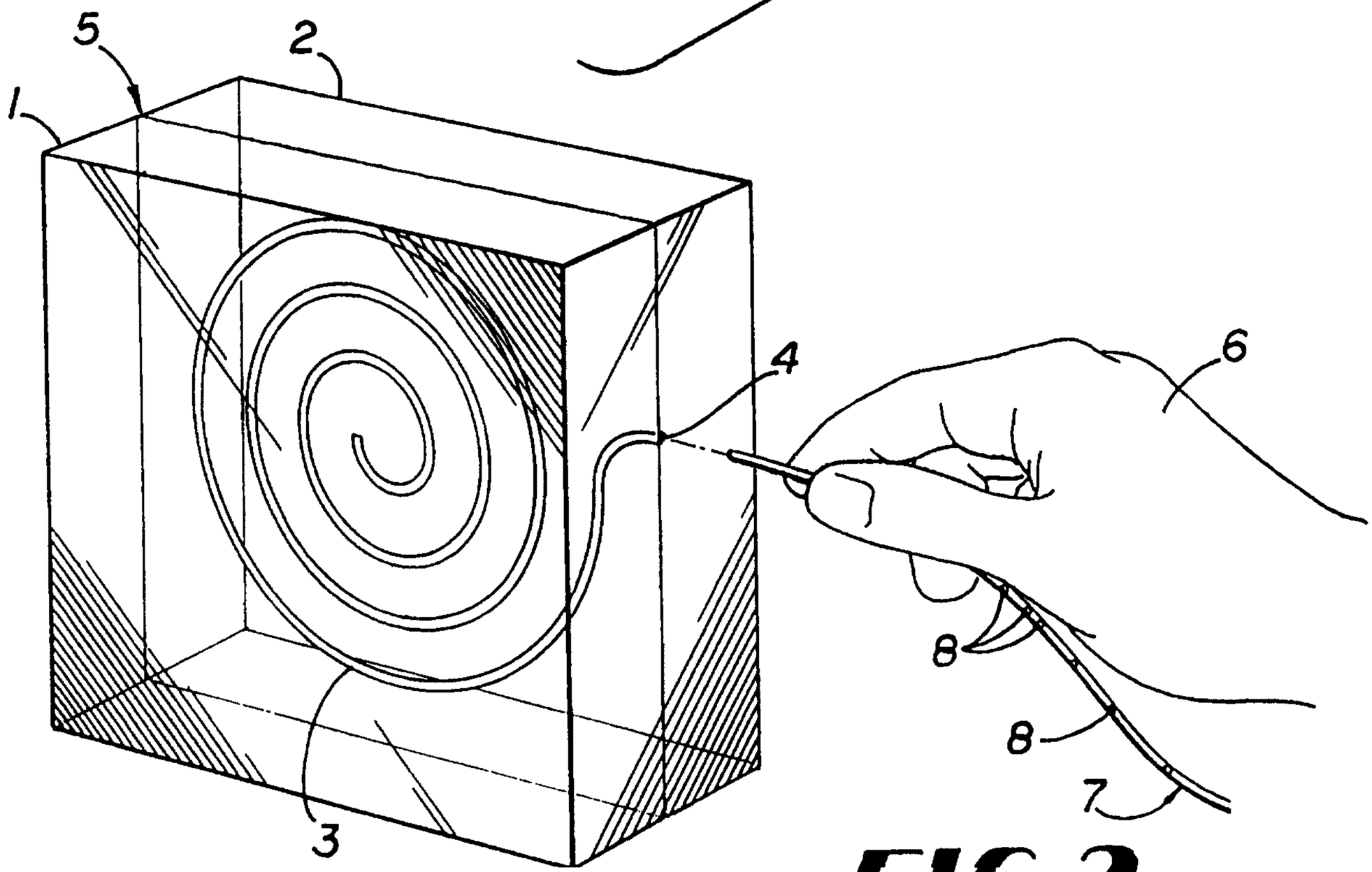


FIG 2

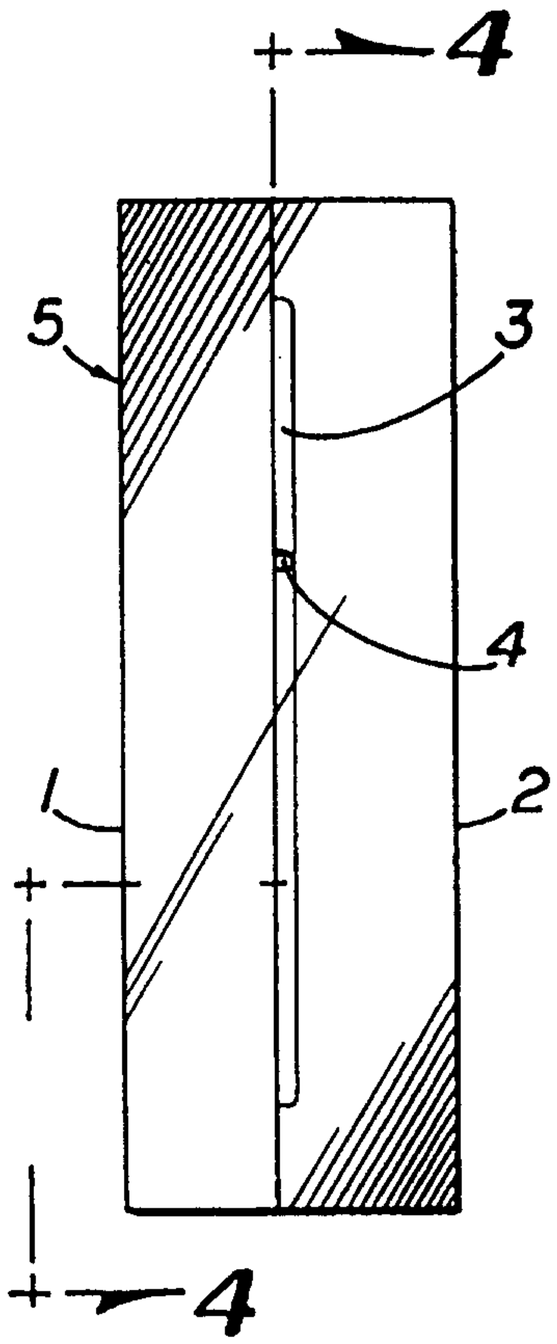


FIG 3

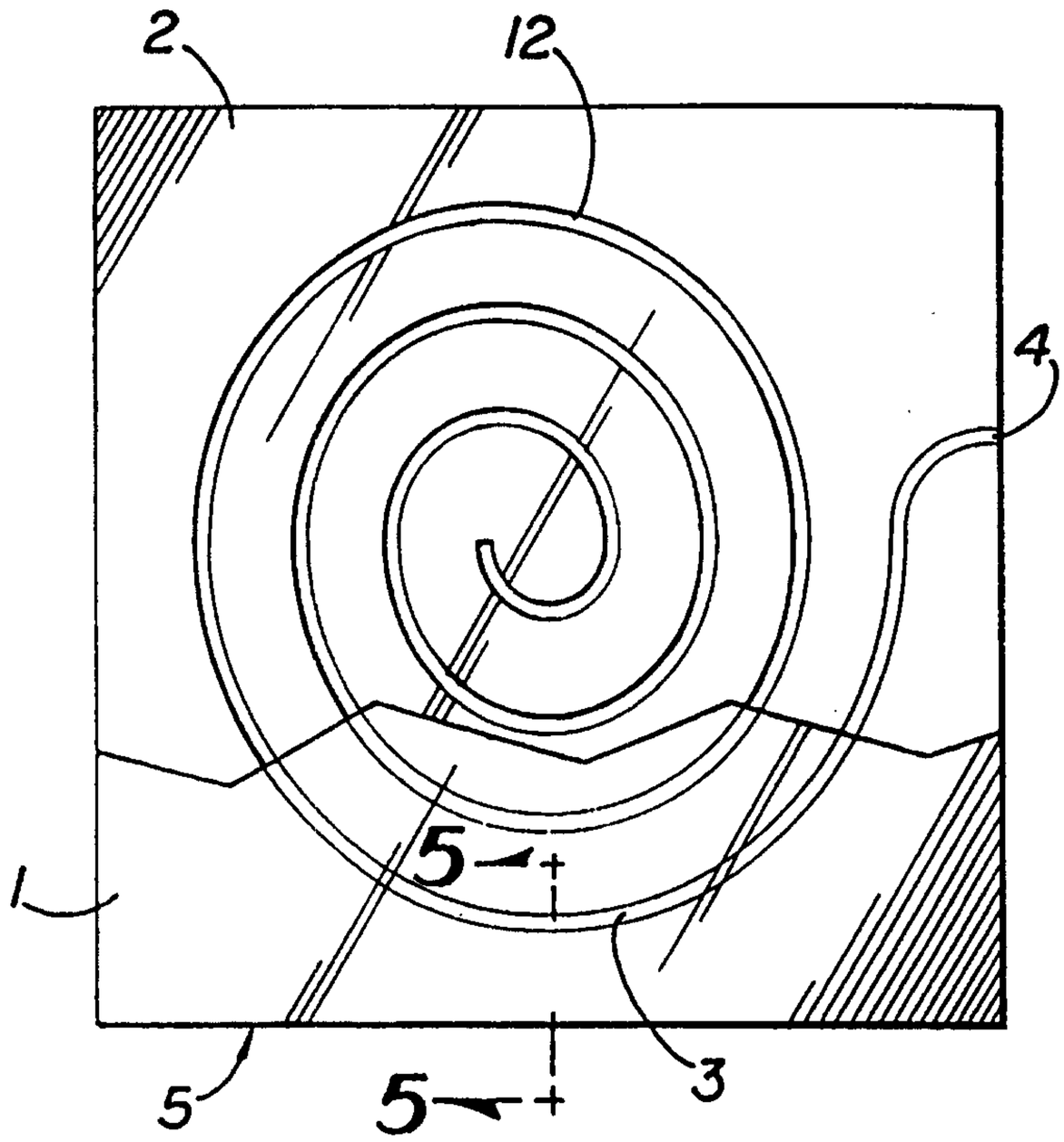


FIG 4

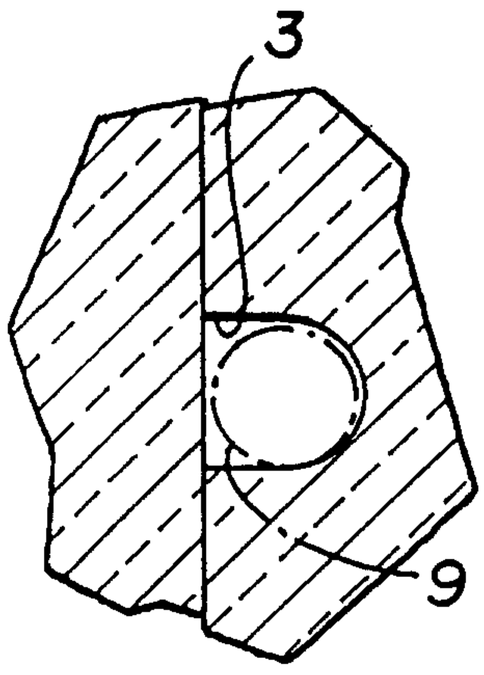


FIG 5

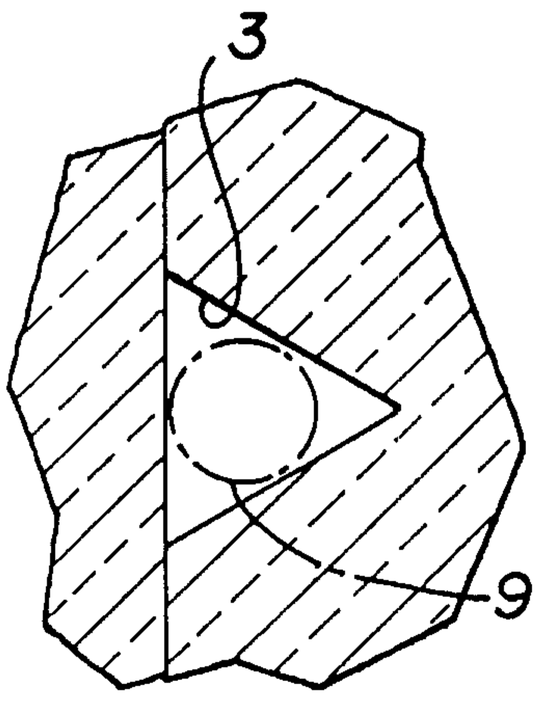


FIG 5A

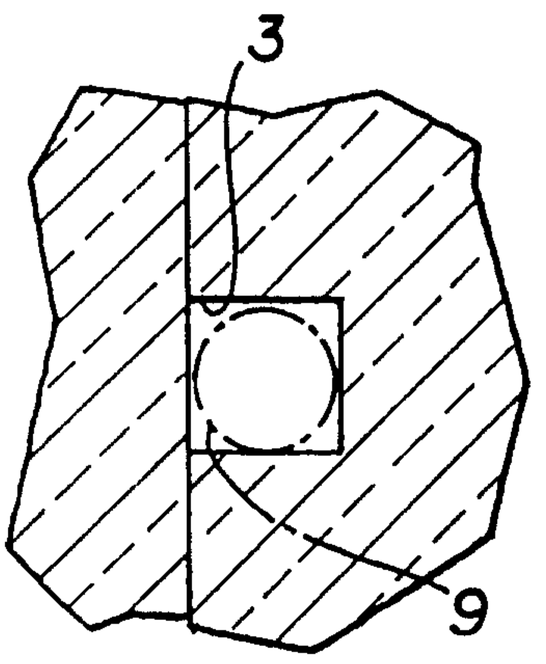


FIG 5B

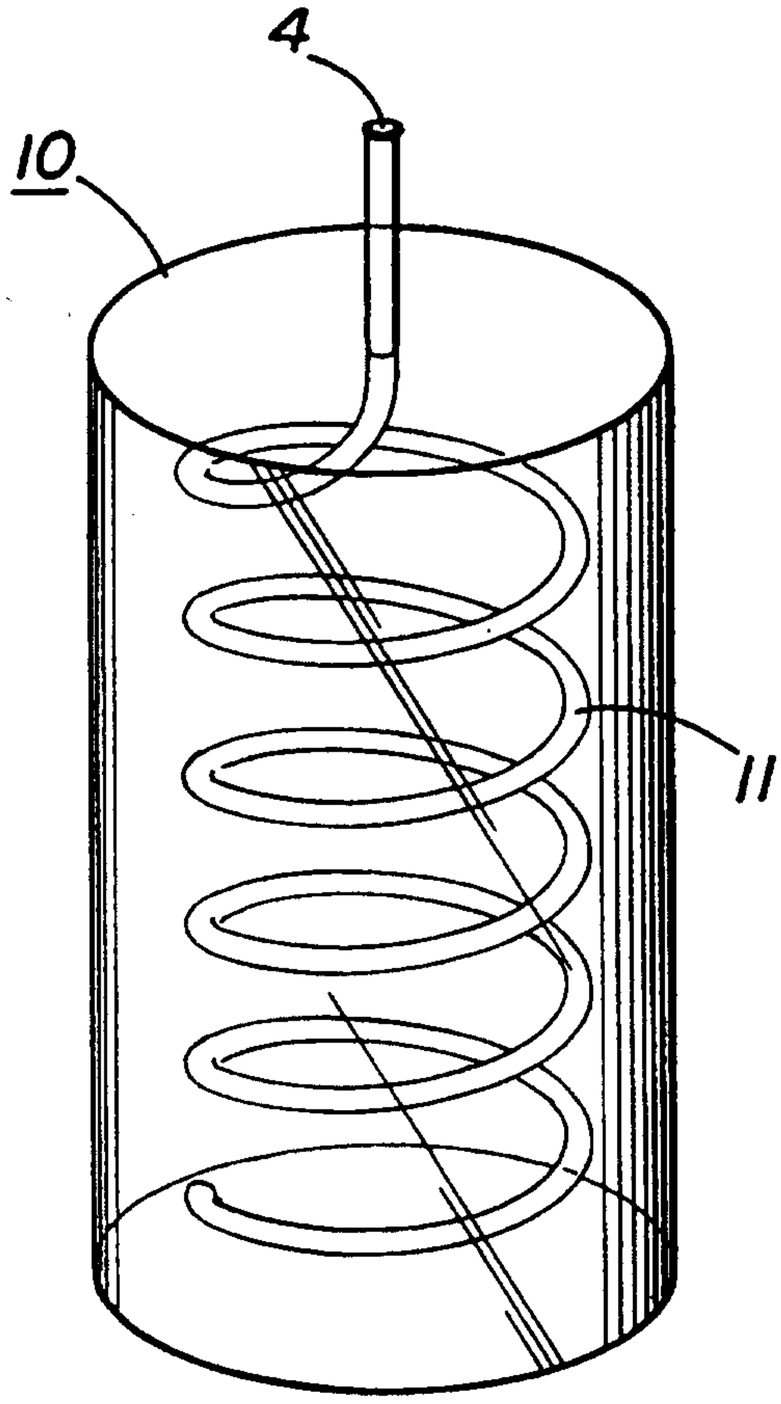


FIG 6

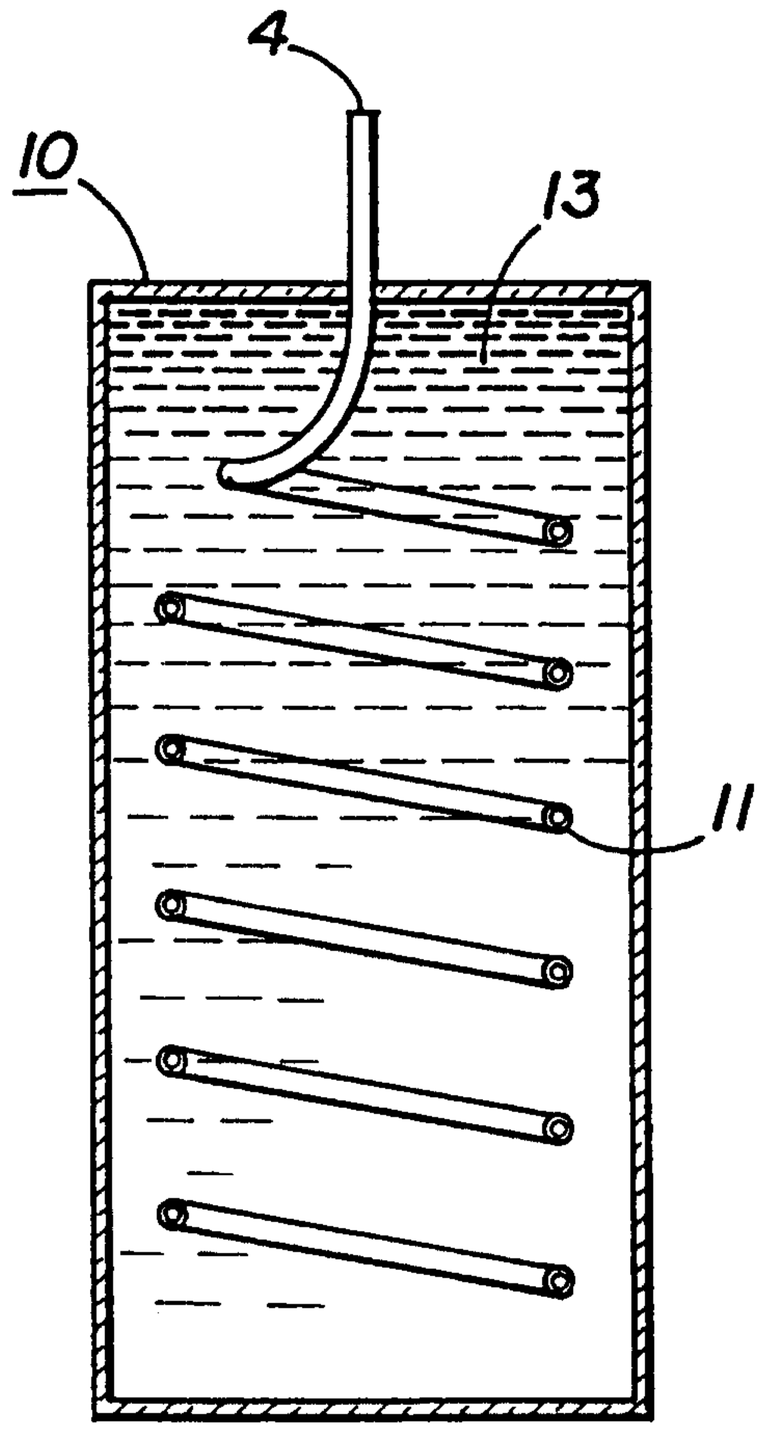
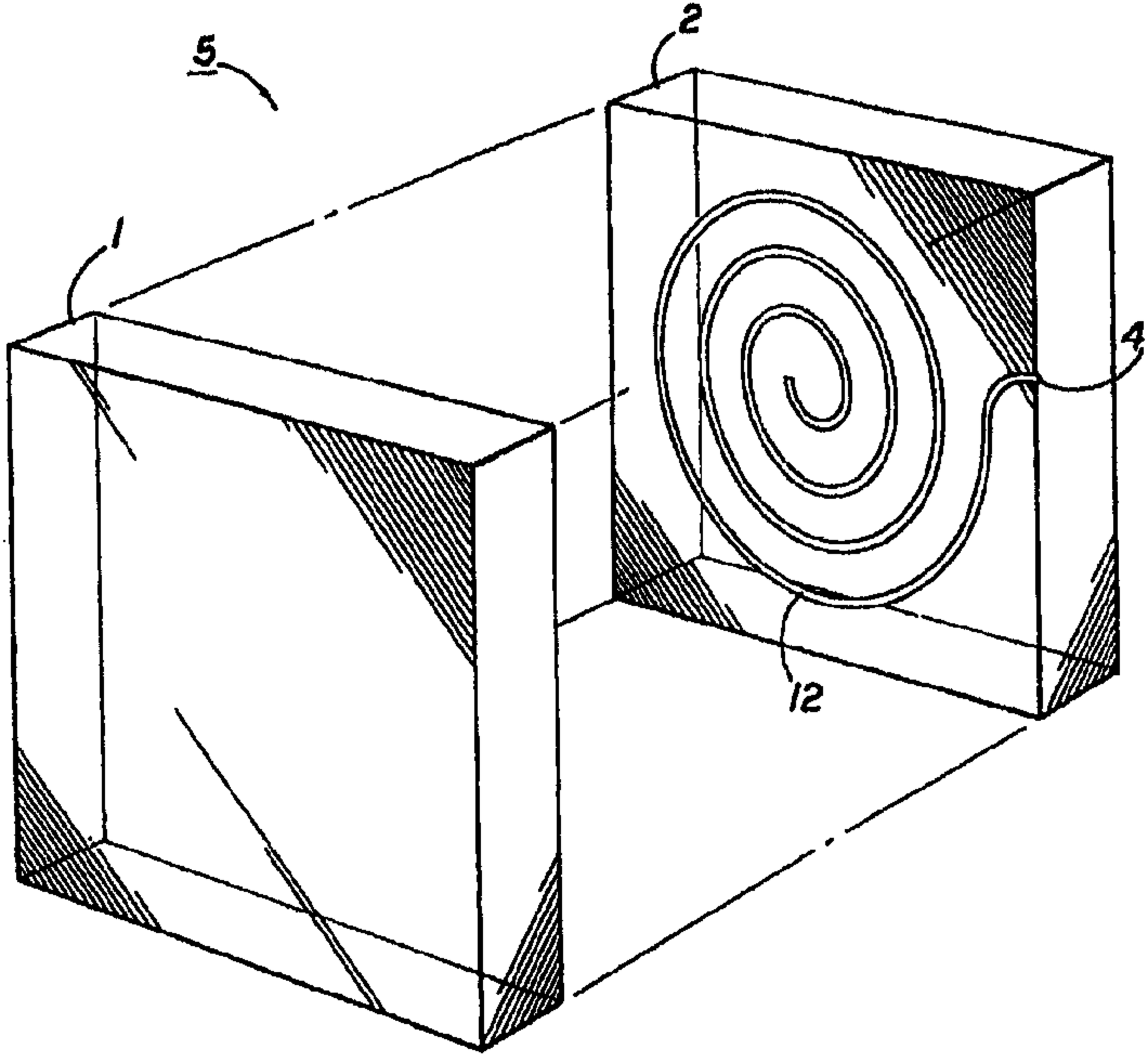


FIG 7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