Oct. 24, 1967 B. BRAUN 3,348,544

POLYPROPYLENE CANULA FOR CONTINUOUS INTRAVENOUS INFUSION

Filed July 26, 1962

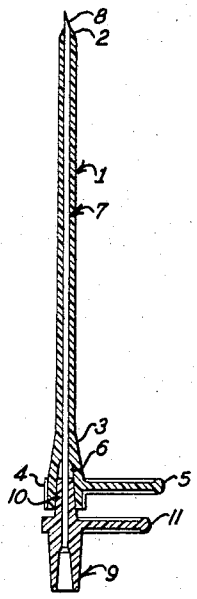

Fig. 1

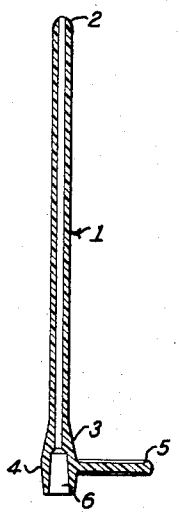

Fig. 2

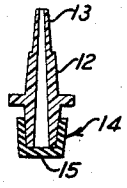

Fig. 3

INVENTOR

BERNHARD BRAUN

BY Burgess DinKlage & Sprung ATTORNEYS

United States Patent Office

3,348,544
Patented Oct. 24, 1967

3,348,544

POLYPROPYLENE CANULA FOR CONTINUOUS INTRAVENOUS INFUSION

Bernhard Braun, 1 An der Trankelucke, Melsungen, Germany

Filed July 26, 1962, Ser. No. 212,696
Claims priority, application Germany, July 29, 1961, B 63,451
2 Claims. (Cl. 128—214.4)

The present invention relates to a therapeutic apparatus and has particular reference to devices adapted especially for the purpose of indefinite continuous introduction of fluids into the vascular system.

Although the device of the invention is intended mainly for use in connection with the introduction of fluids into the vascular system, it may obviously be used for other purposes, as for example, introduction of suitable sounds or catheters for examination of the interior of the heart.

Heretofore, for continuously infusing fluids into the blood veins of the body, metal canulae which were maintained in the veins for an extended period of time have been used. The sharp pointed ends of the canulae, however, tended to irritate the blood vessel interior. This is not only objectionable but often dangerous in that a phlebitis is produced.

To obviate such disadvantage, it has been proposed to use plastic capillaries. One recent proposal consists in a device wherein the capillary is introduced in such a manner that the vein is pierced by a metal canula having its tip or fore-end tapered and having an inside diameter of at least 2 mm. The canula can contain in its bore a second canula having a smaller diameter. The canula is introduced into the vein after which a fine plastic canula is introduced into the pierced blood vessel through the bore of the first canula, if desired, after removal of the second inner canula, and, finally, the outer metal canula is withdrawn over the plastic canula. The plastic canula is provided at its outer end with a wing-shaped metal canula adapted for being fastened to the skin or the plastic canula is otherwise fastened, and it is thereafter connected with an infusion liquid supply line.

Another prior proposal consists in a plastic canula assembly formed in such a manner that canula sections each having a length of about 60 mm. and formed from a hard plastic material, such as rigid P.V.C., are shrunk onto a metal canula having a smaller diameter and being tapered at its tip or fore end in the conventional manner. The tapered or conical forward portion of the short plastic canula extends to the rear end of the beveling of the pointed end of the metal canula, whereby the pointed end of the metal canula gradually assumes the full cross-section of the plastic canula. The plastic canula at its end opposite the pointed end is connected with a second metal canula having a somewhat larger cross-section, being mounted thereon by means of a piece of shrunken tubing also made of plastic and which covers the rear section (Rochester Plastic Needle). Thus, this type of apparatus is provided with more or less short plastic canula sections for the introduction of the fluid into the blood vessel, the sections being provided on a metal canula and introduced with the metal canula into the blood vessel when the vein is pierced. These sections remain in the puncture opening after the subsequent removal of the metal canula. Alternatively, such plastic canula sections are introduced through the bore of the metal canula and remain inserted

in the blood vessel after the metal canula has been removed. In the latter device the injection passage produced by the metal canula has a greater diameter than the plastic canula and, consequently, there exists the danger of bleeding due to the fact that the size of the puncture necessary for the introduction of the apparatus is greater than that of the retained device. Further, because of the inevitable variations in the inner cross-section of the fine plastic capillaries (such variations occurring particularly after heat sterilization), it is repeatedly observed that, after introduction of the plastic canula into the vein, the connection provided for engagement of the infusion tubing does not hold reliably so that the plastic capillaries come loose and pass into the blood stream, and even into the chamber of the heart, from which they can be removed only by serious surgery.

An object of the present invention is to provide an apparatus by which all of the disadvantages referred to above are entirely obviated.

Another object of the present invention is to provide an apparatus which makes possible the installation of a plastic self-retaining canula into a vein for continuous infusion of fluid into the vascular system.

Another object of the invention is to provide a form of canula which, in addition to being an apparatus for introducing fluids into the vascular system, may also be used as a sheath for conducting a sound or catheter of proper form for the purpose of examining the interior of the heart.

Another object of the invention is to provide a form of canula having means forming a part thereof for holding the apparatus firmly in position in the vein, which has been punctured.

With these and other objects in view, the invention comprises various features hereinafter described.

The therapeutic device of the invention is particularly suitable for continuous intravenous infusions and comprises an inner metal canula provided at the tip or fore-end with a tapered portion, a plastic canula having a tapered tip or fore-end and a somewhat larger diameter adapted to receive and carry the metal canula designed so as to accurately fit the canula, and so as to tightly seal off the latter. The tapered or conical portion of the plastic canula terminates at a point just short of the tapered section of the metal canula tip in such a manner as to provide a smooth fit with the metal canula and to avoid the formation of a perceptible shoulder, whereby the plastic canula can be introduced into the blood vessel in an easy sliding manner together with the inner metal canula. At the other end of the plastic canula there is provided a reinforcement formed integrally with the plastic canula proper, the reinforcement having on its free end a recess or opening adapted to receive a cone fitting, such as a Rekord cone and/or Luer cone. The reinforcement at the outermost end of the plastic canula is preferably conical and on its exterior may be provided with a holding plate.

An advantage of the invention resides in that the plastic canula is formed from a flexible physiologically-acceptable plastic material which neither on sterilization nor on extended contact with blood plasma or other fluids becomes brittle or undergoes any other deformation changes.

It is of essential importance to choose a suitable material for the construction of a plastic canula. Rigid polyvinylchloride has been found not to be particularly suitable other than for the reasons already mentioned. Poly-

vinylchloride, as many other plastic materials, often contains plasticizers which are extracted on contact with the blood plasma. The plasticizers, on the one hand, are not always physiologically acceptable and, on the other hand, the mechanical properties of the plastic material are often changed due to the extraction of the plasticizers therefrom so that deformation, embrittling, tearing, etc., occur. It has been found, however, in accordance with the invention that polypropylene, as well as a mixture of high-pressure and low-pressure polyethylenes, as for example in a ratio of 85%:15%, is very satisfactory for forming the plastic canula. A particularly suitable material is the product polypropylene KR1122 Badische Anilin- & Soda-Fabrik A.G., Ludwigshafen am Rhine, Germany.

The inside diameter of the plastic canula of the invention can be so dimensioned as to permit the passage therethrough of a plastic sound or catheter having a smaller diameter and a correspondingly greater length and into the blood vessel, and from there into the auricle. With the aid of such a sound it is possible to introduce fluids directly into the auricle, such introduction being possible during installation of the device for carrying out a continuous intravenous infusion, which infusion can be temporarily interrupted for this purpose without any difficulty or need for the further installation of a second canula.

The therapeutic apparatus of the invention is illustrated in its preferred form in the accompanying drawings, in which.

FIG. 1 is a longitudinal sectional view of a canula assembly according to the invention;

FIG. 2 is a longitudinal sectional view of the plastic canula; and

FIG. 3 is a longitudinal sectional view of a plastic stopper provided with a rubber cover;

Referring more in detail to the drawings, the numeral **7** designates an inner metal canula and **1** an outer plastic canula which is adapted to fit accurately around the metal canula so as to tightly seal it off. Preferably, the plastic canula **1** is made of polypropylene. However, other suitable flexible plastics may be used. The plastic canula **1** has, at its tip or fore-end a taper or conical portion **2** (tapering inwardly to diminish the usual thickness) which is attached to the inner metal canula **7** at the area of the inwardly tapered point **8** to produce a smooth fit with the metal canula, i.e., without a shoulder being formed. As can be seen from the drawing, the conical or tapered surface terminates just short of the end of the metal point. At the opposite end of the plastic canula **1** there is provided an outwardly tapering portion forming an integral conical reinforcement. The reinforcement **3** extends outwardly into a further expanded portion **4**, the outer surface of which is preferably provided with grooves, serrations or otherwise roughened. The reinforcement member **3** may be provided with a holding plate **5** at the expanded portion **4** thereof. The holding plate constitutes a means for securing the apparatus in fixed position until the infusion is completed. A similar holding plate **11** may be provided for the metal canula. The plastic canula **1** is also provided with a conical recess **6** adapted to receive the shoulder of a Rekord cone or a Luer cone.

The metal canula is preferably provided with a stylet which is advantageously a rod or spring wire which is of sufficient diameter so as to be rigid (not shown). The inner metal canula is provided with a plastic member **9** the outer cone of which is seated in the conical recess **6**. The plastic stopper according to FIG. 3 comprises an outer cone **13** having a shoulder portion **12** and the rubber cover **14** with the reinforced portion **15**.

Since the body tissues of older people are apt to be more dehydrated than those of younger individuals and are accordingly difficult to penetrate, it has been found to be of advantage, in order to have a universally applicable device, to assure a sufficient rigidity and relative absence of elasticity of the canula so that the same can be used for both young and old subjects. This can be accomplished in accordance with a still further embodiment of the invention and, namely, by coordinating the Shore hardness of the metal canula insert to the length of the cylindrical insert passage and to the cross-section of the plastic canula. This should be as follows:

(a) Shore hardness of the metal canula having a cross-section of 1 mm. and a thickness of 0.25 mm.	60–62
Length of the metal canula measured from the plastic cone up until the point thereof ___mm__	56
Length of cylindrical part of the plastic canula at a cross-section of 1.8 mm. and a thickness of 0.4 mm. ___mm__	40
(b) Shore hardness of the metal canula having a cross-section of 0.45 mm. and a thickness of 0.15 mm.	60–62
Length of the metal canula measured from the plastic cone up until the point thereof ___mm__	38
Length of cylindrical part of the plastic canula at a cross-section of 1 mm. and a thickness of 0.275 mm. ___mm__	23

For the use the therapeutic apparatus of the invention is enclosed in a plastic bag and sterilized by means of gaseous ethylene oxide. To maintain the sterility the cylindrical part of canula **1** and the plastic member **9** are protected by a tube provided with a cotton filter. Before puncturing the vein the protecting tube is removed from the cylindrical part. The vein is then punctured with a light step. The apparatus is carefully introduced into the vein. If the blood is leaking into the protecting tube of the plastic member **9** the metal canula is pulled out of the plastic canula which remains in the vein and at the same time the plastic canula is pushed further into the vein. The outer cone of a dripping infusion or transfusion tube is then connected with the recess **6** of the plastic canula, the recess **6** being filled completely with blood. To interrupt the infusion or transfusion, the plastic canula can be closed by the sterile plastic stopper of FIG. 3 with the rubber cover. Injections can be made through the rubber and blood removed at any time.

The plastic canulae of the invention has the important advantage that the shoulder portion thereof prevents the canula from disengaging itself and from entering into the vascular system of the patient. Furthermore, the plastic canula is formed of a material not producing irritation on prolonged insertion and which, additionally, is entirely stable. Additionally, in accordance with the invention, the manufacture of the plastic canulae can be undertaken in an economically efficient manner. Due to the construction of the canula of the particular plastic, it can be maintained in position in the vein for long periods since, in contrast to the heretofore employed rigid metal canulae, it does not produce a mechanical irritation of the interior of the blood vessel. Additionally, there is the advantage that, when the canula is in place, the supply of the infusion liquid can be interrupted by detaching the supply line and the canula used for the introduction of a sound or catheter into the auricle. Alternatively, the canula may be used for injection of other materials as, for example, otherwise required in the treatment of the patient's condition.

The plastic canulae, in accordance with the invention, are highly flexible, are capable of repeated sterilization treatments, and serve to handicap the patient only slightly. A patient having such a canula inserted in an arm vein can, for example, eat and drink using the arm. This, in itself, represents a great advantage over the infusion canula heretofore available.

While in the embodiment shown, reinforcement **3** is formed integrally with canula **1** by injection molding, it is, of course also possible to produce these two portions

separately and to thereafter join them as by soldering, taking care only that the bond offers sufficient resistance and security and will not become loosened, deformed or become embrittled in use or in sterilization.

It is believed that the process of my invention, as well as the apparatus for practicing the invention, and the many advantages thereof will be understood from the foregoing detailed description, and it will be obvious that while I have shown and described the process and apparatus in a number of forms only, many changes may be made in the individual method steps and in the parts of the apparatus and in their arrangement without departing from the spirit of the invention defined in the following claims.

I claim:

1. A therapeutic device comprising an inner metal canula having a cutting edge at the forward end portion thereof, a flexible, substantially non-distensible canula formed of a physiologically acceptable polypropylene plastic material positioned about said metal canula coaxial with the same, the forward end of the plastic canula adjacent the insertion end of the metal canula tapering inwardly to substantially the same diameter as the metal canula in order to make a smooth, even, and edge-tight contact therewith and terminating just short of the forward end of said metal canula, said plastic canula defining, as integral parts thereof, a first portion of substantailly uniform outer cross-section and wall thickness extending rearwardly from said forward end, an outwardly tapering second portion of rearwardly increasing wall thickness, extending rearwardly from said first portion,

an enlarged recess adjacent said second portion in communication with the interior of said canula and sidewardly extending finger holding means, rearward of said first portion, said recess defining a seat for connection with other tubings, syringes, and the like.

2. A therapeutic device according to claim **1**, wherein the outwardly extending portion is of conical shape.

References Cited

UNITED STATES PATENTS

2,389,355	11/1945	Goland	128—214
2,483,094	9/1949	Harvey	18—420
2,770,236	11/1956	Utley et al.	128—221
3,021,568	2/1962	Scott	18—55
3,030,953	4/1962	Koehn	128—214
3,050,059	8/1962	Wall et al.	128—218
3,051,994	9/1962	Carozzo	18—55
3,060,509	10/1962	McCubbins	18—20
3,064,653	11/1962	Coanda	128—348
3,082,769	3/1963	Palmer	128—221
3,094,122	6/1963	Gauthier et al.	128—221
3,097,646	7/1963	Scislowicz	128—214
3,204,634	9/1965	Koehn	128—221 X
3,225,762	12/1965	Guttman	128—221 X

FOREIGN PATENTS

605,067	2/1926	France.
1,087,323	8/1960	Germany.

RICHARD A. GAUDET, *Primary Examiner.*

JORDAN FRANKLIN, D. L. TRULUCK, *Examiners.*