

[54] **NEEDLE**

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[22] Filed: **June 24, 1974**

[21] Appl. No.: **482,746**

[52] U.S. Cl. **128/221; 128/214.4; 128/348**

[51] Int. Cl.² **A61M 05/32; A61M 25/00**

[58] Field of Search **128/214.4, 221, 348**

[56] **References Cited**

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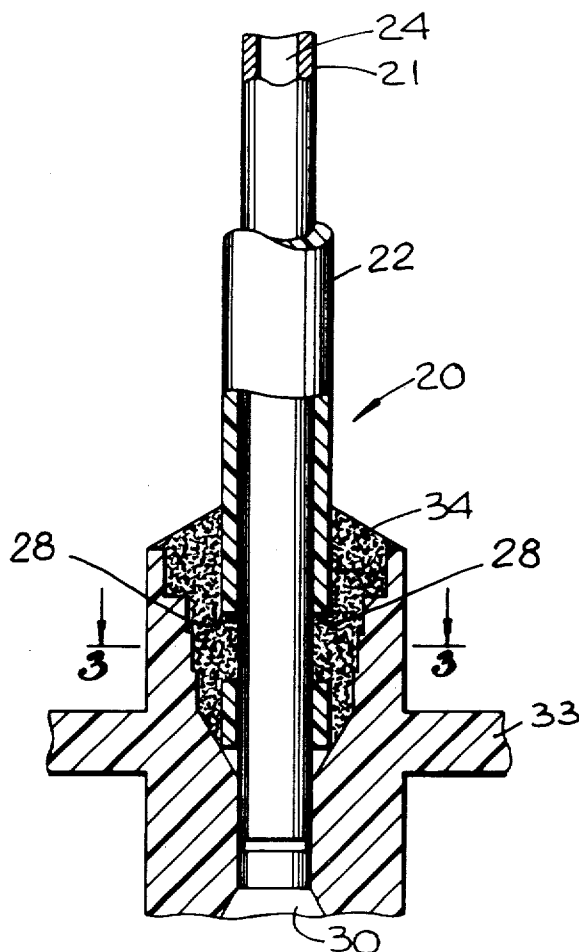
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[57] **ABSTRACT**

A needle adaptable for arterial use which includes an inner cannula, a sheath and a hub. The cannula is open at both ends and has a passageway therethrough. The sheath is disposed in surrounding engagement with a substantial portion of the outer surface of the cannula. The sheath has at least one side opening so as to expose the inner cannula through the opening. The hub has a passageway therethrough and is positioned over one end portion of the cannula and the portion of the sheath containing the side opening. The hub is bonded to the cannula through the side opening so as to hold the cannula and sheath in fixed position with respect to the hub.

11 Claims, 3 Drawing Figures



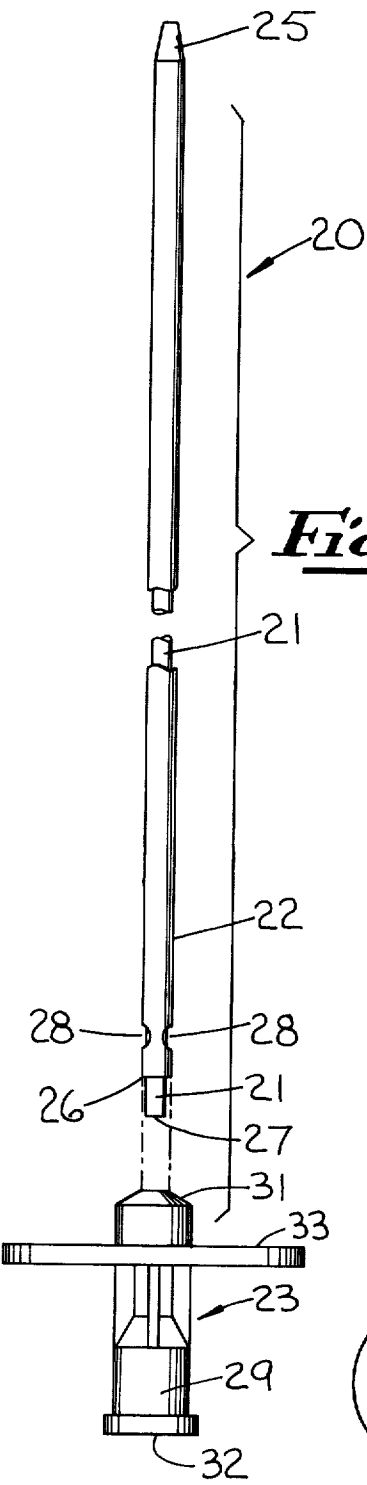


Fig. 1

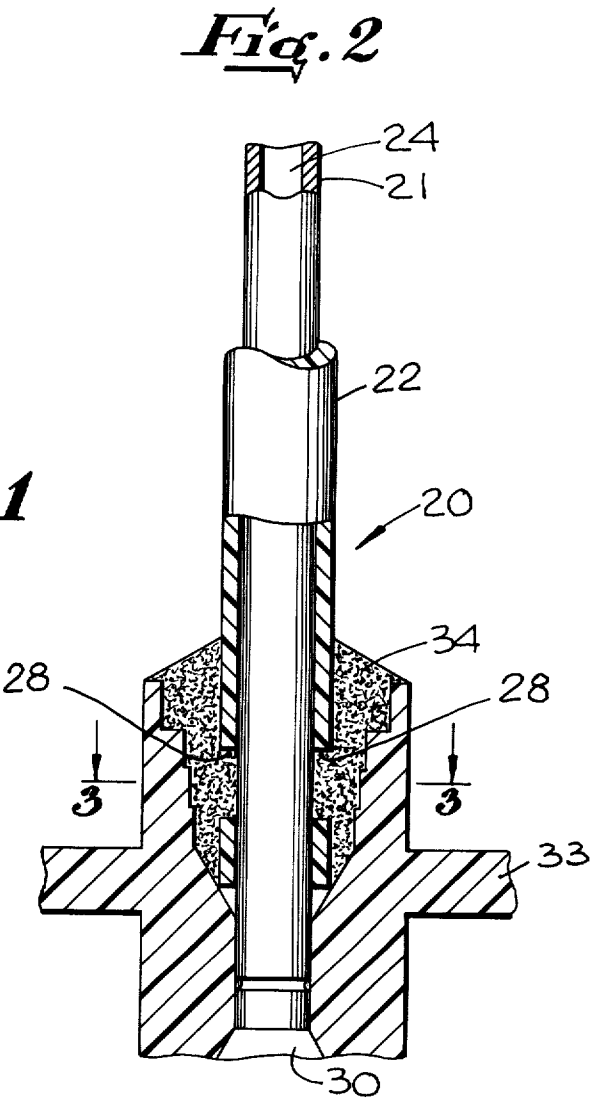


Fig. 2

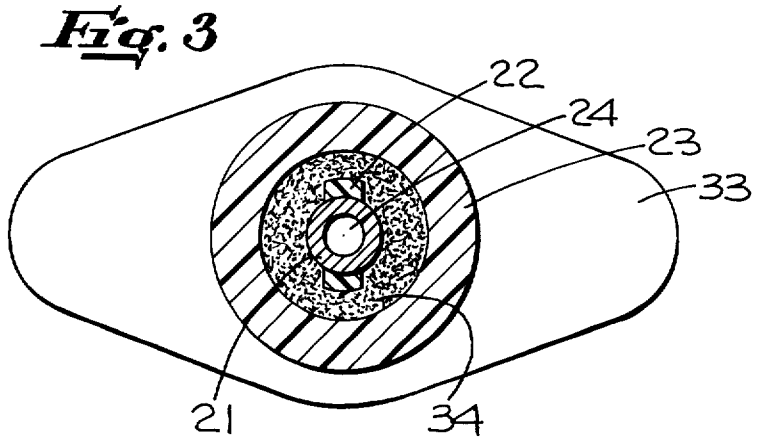


Fig. 3

NEEDLE

BACKGROUND OF THE INVENTION

In construction of needles of the type utilized in the medical profession, it has often been found necessary to interconnect dissimilar materials to form a needle. This creates problems in certain instances where the materials are not readily receptive for connection to one another. In modern day needle structures it is often necessary to interconnect a polytetrafluoroethylene member with a metallic member or a member constructed of a different type of plastic. It is well known that polytetrafluoroethylene is not readily bondable to other materials since it is not receptive to most known epoxies. Consequently, different manufacturing techniques have been attempted and employed. For example, in needles where polytetrafluoroethylene sheaths are positioned on inner cannulas and the resultant subassembly is attached to a hub to form a needle, the sheath is often heat shrunk over the inner supporting cannula and then the subassembly is staked into the hub. This pinching action presses the sheath against the supporting cannula and forcibly secures the subassembly into the hub.

Certain deleterious effects can occur from the above type of manufacturing procedure. For example, the pinching action could have a damaging effect on the polytetrafluoroethylene. Also, the staking operation does not lend itself to the clean assembly required for sterile disposable devices. With this in mind, it is apparent that the medical field is receptive to a needle which is formed in a manner which completely eliminates the danger of the above difficulties.

SUMMARY OF THE INVENTION

With the above background in mind, it is among the primary objectives of the present invention to provide a needle for medical use which permits a sheath to be secured to an inner supporting cannula and the subassembly to be secured to a hub without the danger of possible damage to the sheath. Additionally, the structure permits clean room assembly which is highly desirable in dealing with sterile disposable devices such as needles used in medical environments. The needle formed in this manner and by this process is readily adaptable for use as an arterial needle by the medical profession.

In summary, the needle includes an inner cannula, a sheath and a hub. The inner cannula is open at both ends and has a passageway therethrough. The sheath is disposed in surrounding engagement with a substantial portion of the outer surface of the cannula and has at least one side opening therein so as to expose the inner cannula therethrough. The hub has a passageway therethrough and is positioned over one end portion of the cannula and the portion of the sheath containing the side opening. The hub is bonded to the cannula through the side opening so as to hold the cannula and sheath in fixed position with respect to the hub.

The needle and its method of formation is particularly useful in medical applications such as where a polytetrafluoroethylene sheath is to be interconnected with an inner supporting cannula and a hub to form an arterial needle.

Other medical applications are also readily available. For example, a Teflon catheter can be formed of any desired length with the hub bonded to an inner tubular

base of stainless steel or similar material with the bonding agent extending through openings in the Teflon material to bond the base to the hub and thereby hold the Teflon tube to the hub. Naturally, the base would be provided with a passageway therethrough to retain the continuous passageway through the resultant catheter assembly.

With the above objectives, among others, in mind, reference is had to the attached drawings.

BRIEF DESCRIPTION OF THE DRAWING

In the drawing:

FIG. 1 is an exploded fragmentary plan view of the needle of the invention;

FIG. 2 is an enlarged fragmentary sectional view of the needle of the invention; and

FIG. 3 is a cross-sectional view of the needle taken along the plane of line 3—3 of FIG. 2.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Needle 20 includes an inner supporting cannula 21, outer sheath 22 and a hub 23. When interconnected they form a needle which is particularly adaptable for use in the medical field, for example as an arterial needle.

Inner cannula 21 is tubular in configuration and has a continuous passageway 24 from end to end. Cannula 21 is open at both ends. The cannula can be of stainless steel or any other conventional material having similar properties.

Disposed about a substantial portion of cannula 21 is a sheath 22 which is also of tubular configuration so that it is in substantial concentric relationship with respect to the inner cannula 21. Sheath 22 is of polytetrafluoroethylene material. In this manner, the outer surface of sheath 22 provides the desired self-lubricating surface and inert surface desirable for use in medical insertions into the body. Naturally, other suitable sheath materials can be employed in place of polytetrafluoroethylene. The penetrating forward tip 25 of sheath 22 is tapered to facilitate entrance into a body orifice. Sheath 22 is open at both ends and has a continuous passageway therethrough through which the cannula 21 passes. Sheath 22 and cannula 21 are in close fitting relationship so that the subassembly acts as one element for insertion. The rear end 26 of sheath 22 terminates short of the rear end of cannula 21. This results in a short portion 27 of cannula 21 which is free from the surrounding sheath 22. Adjacent the rear end 26 of sheath 22 are a pair of diametrically opposed apertures or openings 28. These side openings 28 extend through the walls of the sheath so as to expose the outer surface of the inner cannula 21 aligned with the openings. The number of openings about the circumference of sheath 22 is a matter of choice and in the embodiment shown there are two openings 28.

Mounted to the subassembly formed by the inner cannula 21 and the sheath 22 is a hub 23. The hub can be of any conventional hub material such as a plastic like polypropylene. For purposes of the depicted embodiment, polypropylene is the material utilized for hub 23. The hub has a generally tubular elongated housing 29 with a passageway 30 therethrough. The hub is open at forward end 31 and open at rear end 32 so that by means of a passageway 30 a continuous passage is provided through the hub from end to end. In-

intermediate the ends of the housing 29 and extending from the outer surface thereof is a wing projection 33. This projection provides means for gripping the needle during use and also provides an engaging surface for mounting the needle or fastening it in an appropriate manner as commonly done in the medical profession. With the configuration and design of needle 20 shown, the needle is particularly adaptable for use as an arterial needle.

The rear end portion 27 of cannula 21 and the rear portion of sheath 22 including the portion with openings 28 extend within passageway 30 to a seated position in hub 23. Retention of the sheath and cannula within the hub is accomplished by means of an epoxy 34 which adheres to the inner surface of hub 23 where the passageway is formed and adheres to the exposed portion of cannula 21 through openings 28. In this manner, the epoxy need not be bonded to the Teflon and can provide a bonding action between the cannula 21 and the hub 23 so as to retain those two elements in fixed position and also retain the sheath 22 in fixed position since the epoxy extends through openings 28.

By utilization of the epoxy, the sheath can be interconnected with the cannula and the hub without causing damage to the sheath. Additionally, the actual assembly of the elements can be accomplished in a clean room environment resulting in sterile products. Additionally, the components of the assembly are of low cost and the manufacturing process is of low cost resulting in a device which is designed for one-time use and is therefore disposable in nature.

The openings or holes in the sheath 22 permit the epoxy of any comparable adhesive to grip onto the inner cannula. This gripping action holds the cannula to the hub in fixed position and simultaneously holds sheath 22 in position.

In manufacture, a tubular length of cannula 21 is provided and then the sheath is placed in close fitting surrounding relationship to the cannula in a conventional manner such as by a heat shrinking operation. The sheath 22 is preformed of desired length with an appropriate number of openings 28 adjacent the rear end 26 and a beveled tip 25 adjacent the forward penetrating end. The openings 28 and beveling of the forward tip of the sheath can be accomplished in any well known conventional manner. The molded hub 23 can also be formed in a conventional manner with an appropriate configuration for passageway 30 being provided to accomplish the necessary connection procedures. With this in mind, the forward portion of passageway 30 is enlarged to provide the desired spacing between the sheath and the hub surfaces so that the bonding agent can be positioned therebetween. The central portion of passageway 30 is of reduced diameter so that the exposed end 27 of cannula 21 can be placed into frictional engagement with the hub thereby assuring the necessary insertion distance for the cannula and sheath within the hub and assisting in aligning the hub and cannula and sheath in an axial direction. The rear portion of passageway 30 has an appropriate taper to provide an acceptable engaging surface for association with other instruments. Wing flange 33 can be molded in one-piece design with the remainder of the hub and along with the appropriate ribs and reinforcing surfaces on the hub. Bonding is also enhanced by providing a stepped inner surface on the hub in the forward area of

passageway 30 so as to increase the bonding surfaces for engagement with the bonding agent.

The rear end portion of the cannula 21 and sheath 22 are inserted through open forward end 31 of hub 23 until exposed rear portion 27 of cannula 21 is brought into frictional engagement with the reduced diameter central portion of passageway 30. Thereafter, an appropriate supply of bonding agent such as epoxy is placed through opening 31 until it fills the cavity between the sheath and cannula subassembly and adjacent inner surfaces of the hub. The bonding agent 34 will extend through openings 28 into bonding engagement with cannula 21 and thereby bond the subassembly of the cannula and the sheath to hub 23. Needle 20 is then complete and is ready for use with a continuous passageway extending from penetrating tip 25 to the opening 32 in the rear end of hub 23.

It should be kept in mind that other medical devices can be provided with interconnected components in the same fashion as the above discussed needle embodiment. For example, a Teflon catheter can be formed by providing appropriate openings in one end of the catheter and then positioning the catheter between an outer hub and an inner base of bondable material such as stainless steel. The bonding agent can be positioned so as to bond the hub to the base by passing through the openings in the Teflon catheter and retain the catheter in position with respect to the hub. The inner base would be a short length of tubular material which has a passage therethrough to retain the continuous passageway through the completely assembled medical device. In this manner, catheters of any usable desired length can be provided. The catheter tube can extend independently easily as much as several feet beyond the length of the inner base and the outer hub. Needless to say, other types of catheters and needles can be readily envisioned which would employ the above discussed system for interconnecting the sheath to the hub.

Thus, the several aforementioned objects and advantages are most effectively attained. Although several somewhat preferred embodiments have been disclosed and described in detail herein, it should be understood that this invention is in no sense limited thereby and its scope is to be determined by that of the appended claims.

What is claimed is:

1. A needle comprising: an inner cannula open at both ends and having a passageway therethrough, a tubular sheath disposed in surrounding engagement with a substantial portion of the outer surface of the cannula and having at least one side opening therein so as to expose the inner cannula therethrough, a hub having a passageway therethrough and having a cavity in the forward end portion thereof and positioned over one end portion of the cannula and the portion of the sheath containing the side opening in spaced relationship therewith and being bonded to the cannula through the side opening by bonding material located in the cavity and in direct bonding contact with the cannula and the hub so as to hold the cannula and sheath in fixed position with respect to the hub.
2. The invention in accordance with claim 1 wherein the cannula is of stainless steel material, the hub is of polypropylene material, and the sheath is of polytetrafluoroethylene material.

5

3. The invention in accordance with claim 1 wherein there are a plurality of spaced side openings arranged around the circumference of the sheath.

4. The invention in accordance with claim 1 wherein the cannula and hub are bonded by epoxy.

5. The invention in accordance with claim 1 wherein the needle is a disposable arterial needle.

6. A needle comprising; an inner cannula open at both ends and having a passageway therethrough, a tubular sheath disposed in surrounding engagement with a substantial portion of the outer surface of the cannula and having at least one side opening therein so as to expose the inner cannula therethrough, a hub having a passageway therethrough and positioned over one end portion of the cannula and the portion of the sheath containing the side opening and being bonded to the cannula through the side opening so as to hold the cannula and sheath in fixed position with respect to the hub, the sheath extending beyond the other end of the cannula and being tapered to facilitate insertion of the needle, and the cannula at the one end thereof extending beyond the sheath into the hub in position so that the opening in the one end of the cannula is in fluid communication with the passageway through the hub so that a continuous passageway is retained through the needle.

7. A method of forming a needle comprising; providing an inner cannula open at both ends and having a passageway therethrough, disposing a tubular sheath in surrounding engagement with a substantial portion of the outer surface of the cannula and having at least one side opening therein so as to expose the inner cannula therethrough, forming a hub with a passageway therethrough and a cavity in the forward end thereof, positioning the hub over one end portion of the cannula and the portion of the sheath containing the side opening with the side opening in communication with the cavity in the hub and the open end of the inner cannula in communication with the passageway through the hub, and introducing a bonding material into the cavity between the portion of the sheath and cannula and the cavity walls so that the bonding material extends through the side opening in the sheath and bonds the inner cannula directly to the surface of the hub forming the cavity thereby holding the cannula and sheath in fixed position with respect to the hub.

8. The invention in accordance with claim 7 wherein the cannula is of stainless steel material, the hub is of polypropylene material, and the sheath is of polytetrafluoroethylene material, there are a plurality of spaced

6

openings arranged around the circumference of the sheath, and the hub is bonded to the cannula by epoxy.

9. The invention in accordance with claim 7 wherein the sheath extends beyond the end of the cannula distal from the end within the hub and is tapered to facilitate insertion of the needle, and the cannula at the other end thereof extends beyond the sheath into the hub in position so that the opening in one end of the cannula is in fluid communication with the passageway through the hub so that a continuous passageway is retained through the needle and the needle being a disposable arterial needle.

10. A medical cannula device comprising; an inner tubular member having a passageway therethrough, a tubular sheath disposed in surrounding engagement with a substantial portion of the outer surface of the member and having at least one side opening therein so as to expose the inner member therethrough, a hub having a passageway therethrough and having a cavity in the forward end portion thereof and positioned over at least one end portion of the member and the portion of the sheath containing the side opening in spaced relationship therewith and being bonded to the member through the side opening by bonding material located in the cavity and in direct bonding contact with the base and the hub so as to hold the member and sheath in fixed position with respect to the hub.

11. A method of forming a medical cannula device comprising; providing an inner tubular member open at both ends and having a passageway therethrough, disposing a tubular sheath in surrounding engagement with a substantial portion of the outer surface of the member and having at least one side opening therein so as to expose the inner member therethrough, forming a hub with a passageway therethrough and a cavity in the forward end thereof, positioning the hub over one end portion of the member and the portion of the sheath containing the side opening with the side opening in communication with the cavity in the hub and the open end of the inner member in communication with the passageway through the hub, and introducing a bonding material into the cavity between the portion of the sheath and member and the cavity walls so that the bonding material extends through the side opening in the sheath and bonds the inner member directly to the surface of the hub forming the cavity thereby holding the member and sheath in fixed position with respect to the hub.

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