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[54] **DISPOSABLE GUIDE WIRE**

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[52] **U.S. Cl.** ..... **128/2.05 R**

[51] **Int. Cl.** **A61b 5/02**

[58] **Field of Search**... 128/2.05 R, DIG. 9, 341, 348

[56] **References Cited**

UNITED STATES PATENTS

3,452,740	7/1969	Muller	128/DIG. 9 UX
3,547,103	12/1970	Cook	128/2.05 R
3,612,058	10/1971	Ackerman	128/348

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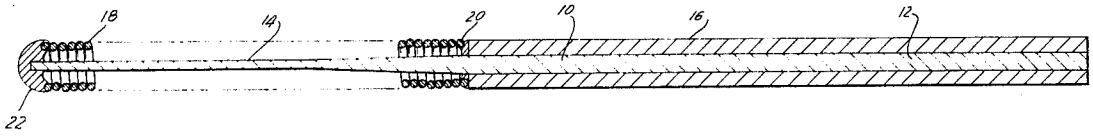
[57] **ABSTRACT**

A stainless steel core wire has a tapered portion at one end and a portion of uniform thickness at another end. A Teflon jacket encloses the portion having uniform thickness to form a proximal end and a flexible stainless steel spring encloses the tapered portion forming a distal end. The spring is secured at both ends to the stainless steel core wire.

10 Claims, 2 Drawing Figures



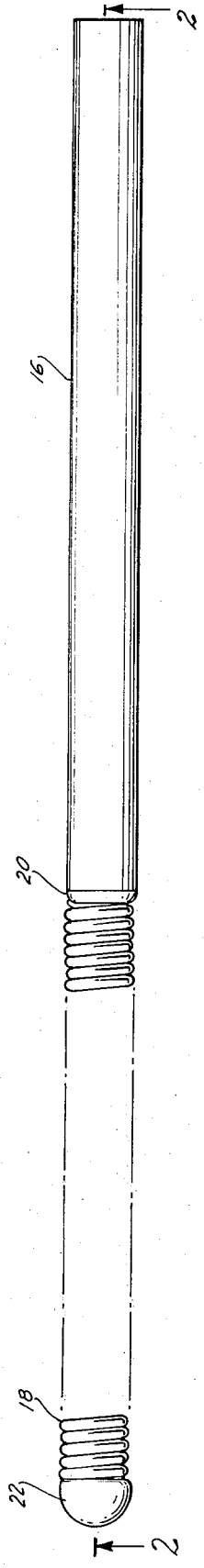


FIG. 1

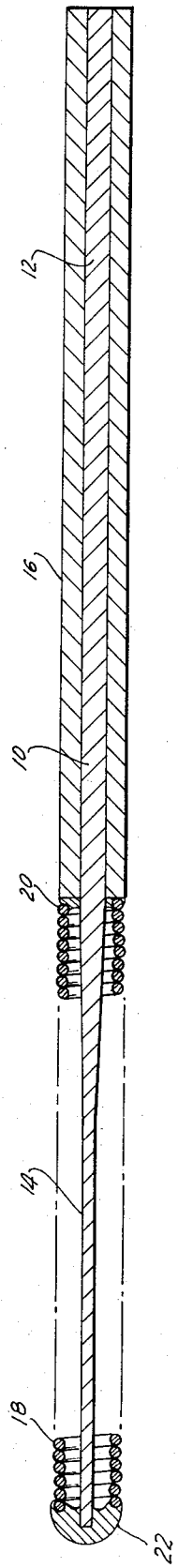


FIG. 2

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DISPOSABLE GUIDE WIRE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to guide wires for vascular manipulations and more particularly to a disposable guide wire having added strength in the proximal portion and flexibility in the distal portion.

2. Description of the Prior Art

The requirements for diagnostic studies of the vascular systems of the human body have increased considerably in recent years with the marked advances in the cardiac and vascular surgery. This increased requirement has led to extensive use of cardiac and vascular catheters that must be inserted over a relatively long distance into internal sites in the body. Extensive manipulation is required to maneuver a relatively long catheter into branch vessels that extend at sharp angles relative to the feeding direction of the catheter.

The most common catherization procedure is the percutaneous technique described in 1953 by Sven Ivar Seldinger. In the practice of this catherization procedure, an area of the skin is antiseptically prepared and a local anthestic is applied after which a nick is made in the skin over the site of a vessel to be catherized. An arterial needle assembly, (inner needle, stylet) is then introduced into the vessel and its introduction is indicated by a back flow of blood to the inner needle. The inner needle is then withdrawn and replaced with a guide wire which is then introduced through the cannula for a distance of approximately 6 to 10 inches. External pressure is then applied to hold the guide wire in place while the cannula is withdrawn after which the guide wire is fed into the vessel to the selected area by fluoroscopy or some other similar technique. Considerable manipulation is required of the guide line to direct it to the desired area. Once the guide wire reaches the selected area, the catheter is passed over the guide wire to the selected area after which the guide wire is withdrawn from the catheter.

Heretofore, guide wires were formed of closely wound stainless steel forming a continuous coil spring having an inner bore which is sealed at the distal end with a rounded cap or tip. Usually an inner core wire is placed within the coil bore, said wire terminating a short distance from the distal tip to provide flexibility at the distal tip and rigidity throughout the remainder of the wire. In most cases, the proximal portion having the core wire was too rigid while the distal tip was so flexible it was practically uncontrollable.

In order to overcome the problems of the devices of the prior art, U. S. Pat. No. 3,528,406 taught the use of two core wires, one extending to the distal tip and the other terminating a distance therefrom. Another embodiment taught by the previously mentioned patent included a heavy gauge core wire throughout the proximal portion, the heavy gauge wire being reduced to a uniform thinner diameter at the distal tip portion to provide greater flexibility.

All the devices heretofore provided had a coil spring extending throughout their entire length and were therefore subject to coil breakage or breakage of the core wire. The coil spring and the core wire were not usually in contact and therefore did not provide mutual support for each other. The coil spring did not provide for good torque transmission because the spring would

tend to bend and turn rather than transmit torque from the proximal portion to the distal tip of the guide wire. This feature made manipulation more difficult and time consuming.

The coil spring also had many other disadvantages, one being the high friction presented between the coils of the spring and the inner surface of the vessel. The spring coils tended to collect blood and were more difficult to clean causing clot formation on the coils. The spring also presented an electrical hazard during cardiovascular catheterization.

SUMMARY OF THE INVENTION

The present invention contemplates a flexible guide wire for use in vascular manipulations. The guide wire is disposable and comprises a stainless steel core wire having a portion of uniform diameter and a tapered portion. The uniform diameter portion is coated with a plastic jacket to form a proximal portion and the tapered portion is enclosed in a stainless steel coil spring to form a distal portion. The spring is fixed at both ends to the inner core by soldering, the solder at the end forming a rounded distal tip.

The stainless steel spring closing the distal portion provides the required flexibility and resiliency while permitting introduction of the guide wire through a stainless steel cannula without the danger of skiving during introduction of the wire. The danger of spring coil breakage is greatly reduced by reducing the spring length and by connecting it to the inner core at both ends. The tapered core wire at the distal portion provides for uniform increase in flexibility between the proximal portion and the distal tip.

The use of the plastic jacket around the proximal portion of the center of core wire provides several advantages. The use of the plastic jacket reduces the length of spring coil required and thereby greatly reduces the cost of the guide wire. Stainless steel spring material is the most expensive component of the guide wire and elimination of substantial length of spring material greatly reduces the cost. The plastic material provides a smooth low friction surface and thereby facilitates the movement of the guide wire through a vessel. The plastic jacket is easier to clean than the spring coil and prevents clotting between the coils of the spring. The plastic jacket is in direct contact with the inner core wire and therefore supports the wire and reduces the possibility of wire breakage while also providing for excellent torque transmission to the distal portion to facilitate manipulation of the guide wire. Use of an insulated plastic jacket eliminates the electrical hazard which was present during cardiovascular catheterization when devices of the prior art were used.

The primary objective of the present invention is to provide a disposable guide wire that need not be cleaned and sterilized after each use.

Another objective of the present invention is to provide a guide wire having better manipulative characteristics than guide wires heretofore provided.

Another objective of the present invention is to provide a guide wire having a low coefficient of friction and good torque transmitting ability.

Another objective of the present invention is to provide a guide wire that prevents clot formation.

Another objective of the present invention is to provide a guide wire that is not prone to breakage.

The foregoing objectives and advantages of the invention will appear more fully hereinafter from a consideration of the detailed description which follows, taken together with the accompanying drawing wherein one embodiment of the invention is illustrated by way of example. It is to be expressly understood, however, that the drawing is for illustrative purposes only and is not to be considered as defining the limits of the invention.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of a flexible guide wire constructed in accordance with the present invention.

FIG. 2 is a sectional view taken along lines 2—2 of FIG. 1.

DESCRIPTION OF THE INVENTION

Referring to the drawings, there is shown a stainless steel wire **10** having a portion **12** of uniform thickness and a tapered portion **14**. Portion **12** is covered by a jacket **16** made of a plastic material such as Teflon which has a smooth low friction outer surface. The plastic coated portion **12** forms a proximal portion of a guide wire.

A stainless steel coil spring **18** extends over tapered portion **14** and is soldered or otherwise connected to wire **10** at a point indicated by numeral **20** which is adjacent the end of jacket **16**. Spring **18** also connected by soldering or otherwise to the end of the tapered portion **14** to form a distal tip **22** having a rounded outer surface.

The outer diameters of spring **18** and jacket **16** are substantially equal and vary from 0.021 to 0.047 of an inch. However, other diameters are contemplated and must be considered to be within the teachings of the present invention.

The guide wire may be manufactured from standard plastic coated stainless steel wire cut to any desired length such as 120 centimeters after which the plastic coating is stripped from the distal portion. The distal portion is then tapered by either a grinding procedure or by the application of a tension force to neck down the distal portion. The stainless steel spring is then positioned over the distal portion and soldered to the stainless steel core wire to form the disposable guide wire.

The flexible guide wire may be used following the standard techniques taught by Seldinger and as previously explained in the background of the invention. The distal portion has a rounded tip **22** and an increased amount of flexibility provided by the tapered core wire **14** while the proximal portion has a greater degree of rigidity provided by the uniform diameter of the core wire and the plastic jacket **16**. The plastic jacket provides a smooth surface with a low coefficient of friction to facilitate insertion of the guide wire into a vessel while the Teflon jacket provides for excellent torque transmission making the guide wire exceptionally maneuverable.

The use of a plastic jacket eliminates the need for the coil spring to extend over the entire length of the guide wire and thus reduces the amount of spring material it required. The cost of the guide wire is substantially reduced as a result of the reduced amount of extensive stainless steel spring material required for the guide wire. Likewise, the tendency towards clot formation is greatly reduced by the smooth surface of the plastic jacket. The possibility of core wire breakage is greatly reduced by the use of the plastic jacket which is in contact with the proximal portion of the core wire and provides reinforcement. The tendency towards spring coil breakage is also reduced by the use of a shorter spring than in those devices heretofore provided. The plastic jacket also provides an additional advantage in that it eliminates the electrical hazard associated with devices of the prior art during cardiovascular catheterization.

It is to be understood that the teachings of the invention are not strictly limited to the materials recited above, but that other compatible materials may be used which are familiar to those skilled in the art.

What is claimed is:

1. A flexible guide wire, comprising:
an elongated inner core wire having a proximal portion and a distal portion;
a coil spring enclosing the distal portion and fixably attached thereto the coil spring including a proximal end and distal end; and
a plastic jacket enclosing and engaging the proximal portion the jacket including a proximal end and a distal end, the jacket distal end terminating at the coil spring proximal end and being substantially equal in diameter to the coil spring such that the jacket forms an extension of the coil spring.

2. A guide wire as described in claim **1**, wherein the proximal portion is of uniform diameter.

3. A guide wire as described in claim **1**, wherein the coil spring is attached to the inner core wire at both ends of the distal portion.

4. A guide wire as described in claim **1**, wherein the inner core wire is made of stainless steel.

5. A guide wire as described in claim **1**, wherein the coil spring is made of stainless steel.

6. A flexible guide wire, comprising:
an elongated inner core wire having a proximal portion and a tapered distal portion;
a coil spring enclosing the distal portion and fixably attached thereto; and
a plastic jacket enclosing and engaging the proximal portion.

7. A flexible guide wire, comprising:
an elongated inner core wire having a proximal portion and a distal portion the proximal portion of the inner core wire being of uniform diameter and the distal portion is tapered;
a coil spring enclosing the distal portion and fixably attached thereto; and
a plastic jacket enclosing and engaging the proximal portion.

8. A guide wire as described in claim **7**, wherein the coil spring is attached to the inner core wire at both ends of the distal portion.

9. A guide wire as described in claim **8**, wherein the inner core wire and the coil spring are formed of stainless steel.

10. A guide wire as described in claim **9**, wherein the coil spring is attached to the inner core wire by soldering and the solder forms a distal tip at one end of the coil spring.

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