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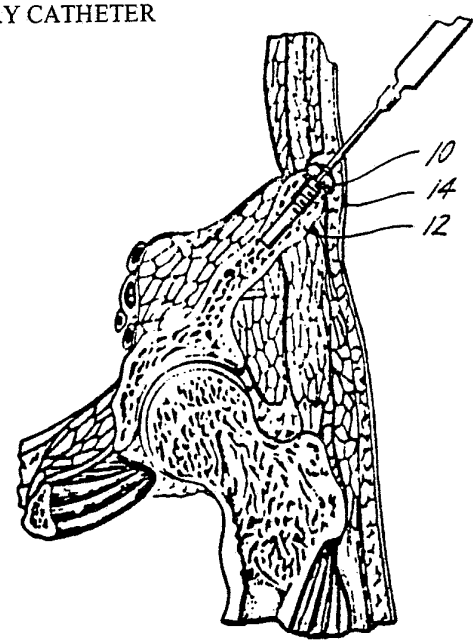
(54) Title: INTRAMEDULLARY CATHETER



(57) Abstract

An intramedullary catheter (10) is provided which is attached to a bone (12) to permit the infusion of drugs, fluids, or the like, directly into the bone marrow for subsequent dispersion to the vascular system. The present invention contemplates an intramedullary catheter, method of implanting such a catheter, and a method of fluid delivery to the vascular system through the bone marrow. The intramedullary catheter preferably includes a threaded conduit, a head attached to one end of the conduit, and a sealing membrane in the head overlying the conduit. The intramedullary catheter is implanted in a bone, such as the iliac crest, with the conduit threadingly engaging the bone and the surrounding skin (19) closed over the head and membrane. Fluids are delivered by inserting a needle through the membrane into communication with the conduit for transport to the bone marrow. The present invention is particularly appropriate for patients who require long-term administration of medications as an alternative to intravenous delivery.

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INTRAMEDULLARY CATHETER

1. Field of the Invention

This invention relates to a device for delivering fluids to the vascular system through the bone marrow cavity, a method of implanting such a device, and a method of using such a device. In particular, the device comprises an intramedullary catheter which is implanted in a bone and covered by the skin, providing access for the administration of fluids through the bone marrow into the vascular system.

2. Description of the Relevant Art

Intravenous devices are commonly used for the delivery of fluids, such as drugs or the like, directly to the vascular system. Most hospital patients are fitted with an intravenous device to provide the physician with easy access to the vascular system for the administration of such fluids. The advantages of intravenous devices for

quickly delivering medication to the vascular system are readily apparent, there are, however, a number of disadvantages.

In using intravenous devices, for example, infection of the surrounding tissue (celulitis) and systemic infection (bacteremia) can sometimes occur. Further, clotting of the vein (thrombosis) and accidental injection of the medication outside of the vein – causing extensive tissue destruction – also occur with some regularity. Perhaps the greatest problem with such intravenous devices is simply the procedure involved in inserting such devices. Often, locating the vein in which such an intravenous device can be placed is difficult, subjecting the patient to a painful ordeal as the doctor or nurse probes the area under the skin in an attempt to find a vein. All of these problems are particularly magnified in those patients requiring long-term (e.g. greater than two weeks) administration of medication.

As an answer to the well known deficiencies of conventional intravenous devices, several systems have been developed for use as an alternative. One such device is the Hichman Broviac silastic catheter which is tunneled under the skin, usually in the chest, and inserted into a large vein, usually the subclavian vein. Other such systems include the Port-a-cath Infus-a-port (sold by Infasaid), and the Mediport (sold by Norfolk) which are essentially cavity structures which are implanted under the skin and have a self-sealing septum. Medication is injected through a needle inserted through the skin and septum into the cavity. A catheter leads from the cavity to the vein to deliver the medication to the vein.

While such implant devices are sometimes a desirable alternative to an intravenous device, a number of problems still exist. For example, infection and clotting in the vein and catheter are still major problems. Further, these implant devices require minor surgery for insertion, and are nevertheless difficult to implant in children. Further, the bulge caused by such implant devices are cosmetically unappealing.

Perhaps the greatest difficulty with such implant devices is that because of the many complications that can arise, many such implant devices must be prematurely removed from the patient. Thus, while such implant devices are often a desirable alternative to intravenous devices, in practice many problems exist with such implant devices.

The problems outlined above are in large measured solved by the method and device of the present invention. That is, the intramedullary catheter hereof provides convenient access to the vascular system without the major infection, clotting, cosmetic, and insertion problems associated with intravenous devices and such implant devices. The intramedullary catheter of the present invention is particularly appropriate where the patient requires long-term administration of medication.

Broadly speaking, the present invention contemplates a device, alternatively known as an intramedullary catheter or osteoport, which is attached to a bone for providing access for fluid delivery to the vascular system. The device includes a tubular conduit which is inserted through a bore in the bone in communication with the bone marrow cavity. A head is attached to one end of the conduit to lay adjacent the bone such that the sur-

rounding skin can be closed about the head. The head includes a seal mechanism which overlies the conduit and permits the insertion of a needle through the seal mechanism to deliver the fluid or other medication to the conduit for transport to the bone marrow. It has been found that many medications delivered to the bone marrow are rapidly dispersed throughout the vascular system.

The present invention also contemplates a method of fluid or drug delivery to the vascular system of a patient which includes such an intramedullary catheter. In the method of fluid delivery, the intramedullary catheter is implanted in a bone with the conduit in communication with the bone marrow cavity by drilling a bore into the bone and inserting the conduit into the bore. Preferably, the bore in the bone is tapped with threads and the conduit has threads along a portion such that the catheter is screwed (threadingly secured) into the bore. The drug or other fluid is injected through the overlying skin into the conduit for delivery to the bone marrow and transport to the vascular system. The present invention additionally contemplates a method of implanting a drug delivery device such as the intramedullary catheter of the present invention.

FIGURE 1 represents a fragmentary anatomical sectional view of the iliac crest with the intramedullary catheter of the present invention implanted therein;

FIGURE 2 is a sectional view of the intramedullary catheter of the present invention;

FIGURE 3 is a top plan view of the head of the intramedullary catheter taken along line 3-3 of FIGURE 2; and

FIGURE 4 is an elevational view of the intramedullary catheter of the present invention with the sealing mechanism exploded for clarity.

Turning now to the drawing, FIGURE 1 illustrates an intramedullary catheter 10 implanted in a bone 12 such as the anterior iliac crest, with the skin and surrounding tissue 14 overlying the catheter 10. As shown in FIGS. 2-4, the intramedullary catheter 10 broadly includes an elongated tubular conduit portion 16 and a head portion 18.

As can be seen readily from FIGURE 2, the conduit 16 is elongated and needle-like to define a passage 20. The outer portion of the conduit 16 includes a mechanism for attaching the conduit 16 to bone 12, which in the preferred embodiment comprises the threads 22. The distal end of the conduit 16 (remote from the head 18) is simply a flat surface, but in alternative embodiments may comprise the sharpened point.

The head 18 comprises an enlarged circular saucer 30 concentrically attached to the conduit 16 and preferably defining a cylindrical cavity 32. Structure defining a truncated cone-shaped bore 34 connects the cavity 32 with the passage 20. The outer periphery of the saucer 30 includes a plurality of circumferentially spaced apart notches 36 (see FIGS. 3 and 4).

A seal mechanism 40 is interfitted into the cavity 32 as shown in FIGURE 2. The seal mechanism includes a silastic self-sealing membrane 42 which is complementally dimensioned for sliding reception into the cavity 32. As can be appreciated from FIGURE 2, the membrane 42 is slightly enlarged relative to the cavity 32 so that the

perimeter of the membrane 42 sealingly engages the internal walls of the saucer 30 defining the cavity 32, causing the central portion of the membrane 42 to outwardly bulge as shown in FIGURE 2. An annular retaining washer 44 is interfitted in an annular groove in the saucer walls defining the cavity 32. The washer 44 overlys the membrane 42, retaining the membrane 42 in position in the cavity 32.

The catheter 10 can be implanted in many different bones in the skeletal structure with the iliac crest 12 shown in FIGURE 1 a preferred entry location. In the method of implanting the catheter 10, a small incision in the skin 14 is made in the region of the iliac crest 12 and the iliac crest 12 positively identified through the incision. After identification of the iliac crest, a bore is drilled through the bone 12 into communication with the marrow cavity as shown in FIGURE 1. An internal thread is tapped into the iliac crest 12 utilizing a thread size and tap used routinely in orthopedic practice for inserting pins in bones.

The catheter is inserted through the incision in the skin 14, with the distal end of the conduit 16 disposed in the threaded bore in the iliac crest 12. The catheter 10 is then screwed into the iliac crest 12 such that the catheter 10 is secured in the bone 12 by the threads 22. In the preferred method of implantation, a driving tool (not shown) is fitted to the catheter 10 and includes four spaced apart lugs which interfit into the notches 36, such that rotation of the driving tool screws the catheter 10 into the bone 12.

As can be seen in FIGURE 1, with the catheter 10 fully inserted in the bone 12, the head 18 abuts the

external surface of the bone 12 and the skin 14 is closed over the head 18.

The use of the catheter 10 contemplates a fluid delivery method to the vascular system through the bone marrow cavity. As used in the present application, the term "fluids" is used broadly to include drugs and other medications. To deliver the fluids to the catheter 10, the region of the skin 14 surrounding the catheter 10 is prepped and the needle on the end of a conventional intravenous tubing is inserted through the skin 14 and into the membrane 42. Preferably, the distal tip of the needle is inserted through the membrane 14 and positioned somewhere in the region of the passage 20 proximate the bore 34. Typically, the needle includes a threaded or luer-type hub that can be connected to a variety of external delivery systems. Normally, the needle is connected by tubing to an infusion bottle.

In use, the drugs or other fluids are administered through the catheter 10 into the bone marrow cavity. It has been found that where drugs are injected into bone marrow cavity, that the drugs are rapidly absorbed from the marrow cavity. In many instances, the drugs are delivered as rapidly to the vascular system through the marrow cavity as in direct infusion into a vein.

In practice, it is believed that the catheter 10 and methods of implantation and use offer many advantages over conventional drug delivery procedures. For example, there are no clotting problems in that the catheter 10 is not located in a vein, and similarly, the probability of infection is dimensioned. Once the catheter 10 is inserted, there are no cosmetic disfigurations and little or no chance for occlusion or migration of the catheter

10. The cost of inserting the catheter 10 is minimal, and it can be easily inserted in historically more difficult patients such as infants and geriatrics or other long term care patients. Finally, there is no chance for pneumothorax and no chance for leakage of toxic drugs outside of the desired location, as is possible with intravenous devices.

In summary, it is believed that the catheter 10 and methods of implantation and drug delivery offer a notable advance over the art. In particular, the catheter and methods of the present invention represent a significant advance for patients requiring long term administration of fluids.

CLAIMS:

1. A method of fluid or drug delivery into the vascular system of a patient, comprising the steps of:

providing a device having an elongated, tubular conduit, and a head attached to one end of the conduit defining a cavity;

implanting the device into a bone with the conduit in operable communication with the bone marrow, including the substeps of -

drilling a bore into the bone,

inserting the conduit into the bore,

closing the skin adjacent the device to overlay the head; and

injecting a fluid through said overlying skin into the cavity for delivery through the conduit into the bone marrow and transport to the vascular system.

2. The method according to claim 1, including the steps of:

providing the device with a sealing mechanism disposed in the cavity to overly the conduit; and

injecting the fluid through the sealing mechanism into the conduit.

3. The method according to claim 1, including the steps of:

providing the device with threads along a portion of the external surface of the conduit; and

the implanting step including the substeps of -

tapping a set of threads in the bone, and

screwing the conduit into the bore to connect the device to the bone.

4. The method according to claim 1, wherein the device is implanted in the iliac crest.

5. A device attachable to a bone for providing access for fluid delivery to the vascular system, the device comprising:

an elongated, tubular conduit insertable in a bore in the bone;

means coupled to the conduit for attaching the conduit to the bone with the conduit in the bore; and

a head attached to one end of the conduit such that with the other end of the conduit inserted in the bore the head is disposed adjacent the bone, the heading including -

seal means overlying the conduit to permit insertion of a needle through the seal means to deliver fluid to the conduit for transport to the bone marrow and subsequent dispersion to the vascular system.

6. The device according to claim 5, wherein the attaching means comprises a plurality of threads along a portion of the exterior surface of the conduit.

7. The device according to claim 5, wherein the head comprises an enlarged circular saucer defining a cavity therein.

8. The device according to claim 7, wherein the seal means comprises a silastic self-sealing membrane disposed within the cavity of the head.

9. The device according to claim 8, wherein the head includes a washer adjoining the membrane for retaining the membrane in the cavity.

10. The device according to claim 5, wherein the head comprises a circular saucer concentrically oriented relative to the conduit and oriented generally perpendicular to the longitudinal axis of the conduit.

11. The device according to claim 5, wherein the head includes a plurality of spaced apart notches adapted for engaging a tool for screwing the device.

12. A method of implanting a drug-delivery structure in a bone comprising the steps of:

incising the skin overlying the bone;

drilling an elongated bore into the bone in communication with the bone marrow cavity;

tapping a thread in a portion of the bore;

screwing an elongated, threaded conduit into the bore; and

closing the skin over the conduit.

13. The method according to claim 12, wherein the elongated, threaded conduit is attached to a head, and screwing the conduit and head into the bore until the head abuts the bone.

14. The method according to claim 13, the closing step including closing the skin over the head.

Fig. 1

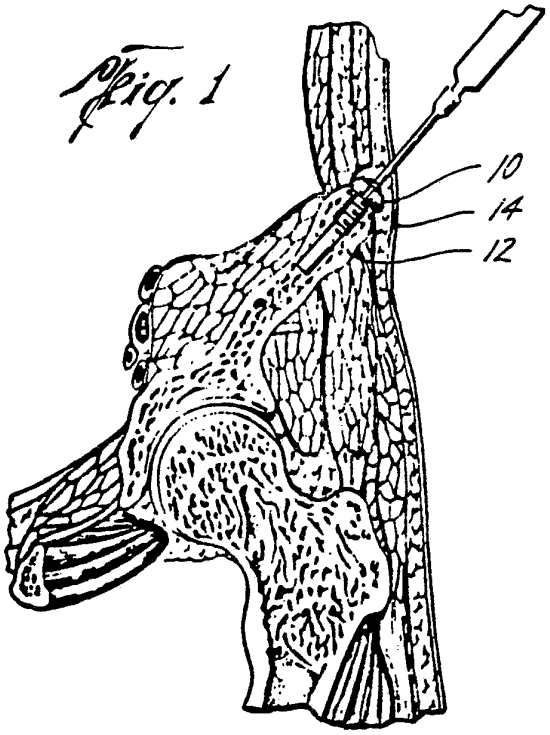


Fig. 3

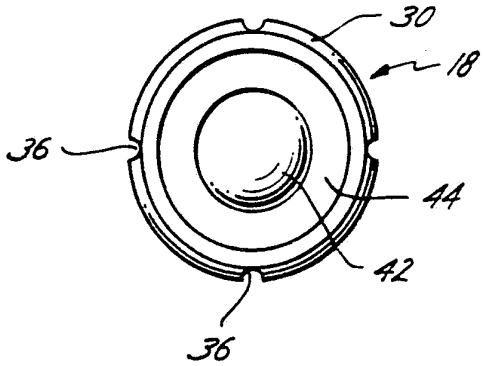


Fig. 4

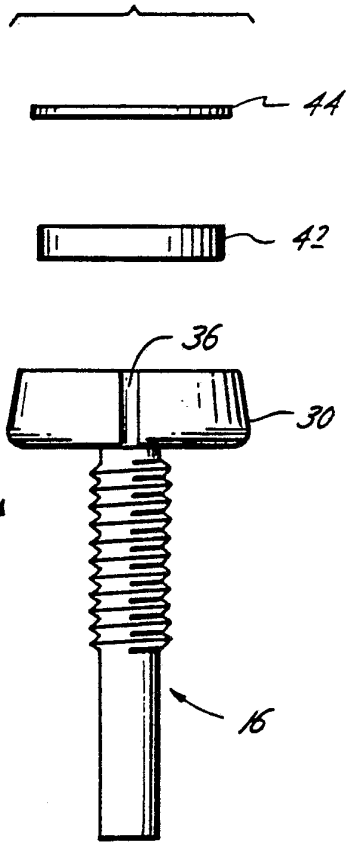
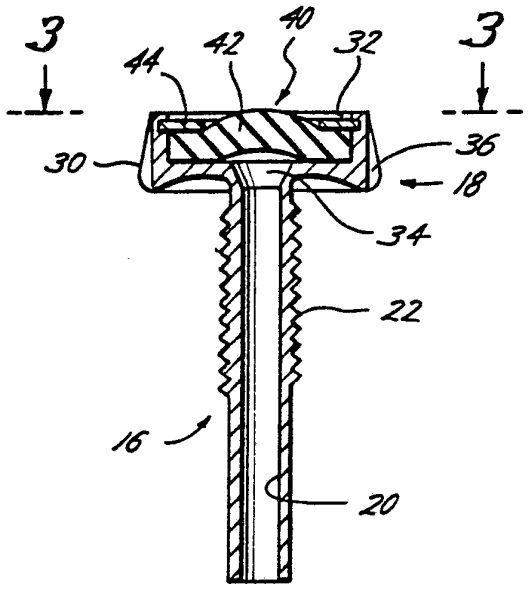


Fig. 2



INTERNATIONAL SEARCH REPORT

International Application No PCT/US 88/02391

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 M 1/00; A 61 M 37/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
E,X	US, A, 4772261 (VON HOFF et al.) 20 September 1988 see the whole document	1-4
E,X	WO, A, 88/06023 (DRAENERT) 25 August 1988 see figure 4; claim 13	1,3,4
A		6,7,11-14
A	US, A, 3750667 (PSHENICHNY) 7 August 1973 see figure 5; column 1, lines 3-6	1,5,12
A	US, A, 2426535 (TURKEL) 26 August 1947 see column 1, lines 1-8	1-6
A	US, A, 4494535 (HAIG) 22 January 1985 see column 1, lines 24-32	1,5,12

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* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
30th May 1989	28 JUN 1989
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G VAN DER PUTTEN

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	EP, A, 0103081 (CULLOR et al.) 21 March 1984 see figures 10-13	1,5,12
A	EP, A, 0134745 (MERIAUX) 20 March 1985 see abstract	1,5,12

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 8802391 SA 27387

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 19/06/89
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO-A- 8806023	25-08-88	EP-A- 0305417	08-03-89
US-A- 3750667	07-08-73	None	
US-A- 2426535		None	
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