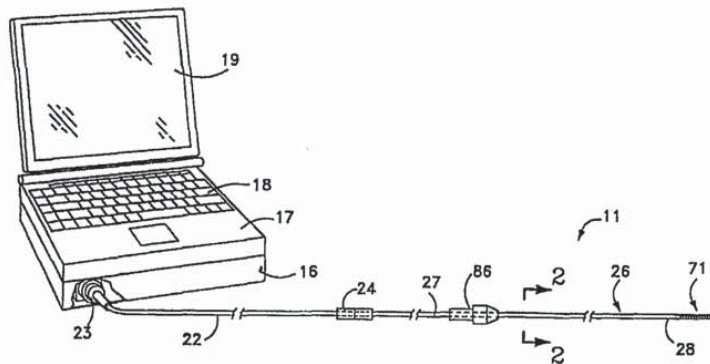




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<p>(21) International Application Number: PCT/US99/30126 (22) International Filing Date: 16 December 1999 (16.12.99) (30) Priority Data: 09/216,628 16 December 1998 (16.12.98) US (71) Applicant: FOX HOLLOW TECHNOLOGIES, INC. [US/US]; 3355 Edison Way, Menlo Park, CA 94025 (US). (72) Inventors: ORMSBY, Theodore, C.; 2357 Dubois Street, Milpitas, CA 95035 (US). VAN BLADEL, Kevin, H.; 1407 Carlisle Drive, San Mateo, CA 94402 (US). IMRAN, Mir, A.; 26641 Laurel Lane, Los Altos, CA 94025 (US). (74) Agents: HOHBACH, Harold, C. et al.; Flehr, Hohbach, Test, Albritton & Herbert LLP, 4 Embarcadero Center, Suite 3400, San Francisco, CA 94111-4187 (US).</p>	<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>	

(54) Title: GUIDEWIRE HAVING SIDEWISE LOOKING IMAGING CAPABILITIES AND METHOD



(57) Abstract

This invention is a guidewire (11) having sidewise ultrasonic imaging capabilities for deployment across a complex lesion in a vessel formed by a wall comprising of flexible elongate tubular member (26) having proximal, distal extremities, and having a lumen (29) extending from the proximal extremity (27) to the distal extremity (28). The proximal extremity (27) of the flexible elongate tubular member (26) is adapted to be grasped by the human hand for rotating the flexible elongate tubular member (26). A sidewise looking ultrasonic transducer (46) is carried by the distal extremity (28) of the flexible elongate tubular member (26), and is mounted therein for rotational movement as the proximal extremity (27) of the flexible elongate tubular member (26) is rotated. Electrical conductors (56) are connected to the ultrasonic transducer (46), and extend to the proximal extremity (27). A flexible coil is secured to the distal extremity (28) of the flexible elongate tubular member (26) to provide a floppy tip (71).

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GUIDEWIRE HAVING SIDEWISE LOOKING
IMAGING CAPABILITIES AND METHOD

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This invention relates to a guidewire having sidewise looking imaging capabilities with over the wire catheters.

Guidewires with imaging capabilities have heretofore been provided as for example in U.S. Patent No. 5,558,093. Such
5 guidewires have utilized an ultrasonic transducer assembly, at least a part of which must be rotated independent of rotation of the guidewire. The provision of such independent rotational capabilities has made it difficult to provide guidewires which have a sufficiently small diameter so that they can be readily
10 used in small vessels as for example arterial vessels in the heart. There is therefore a need for a new and improved guidewire which overcomes these deficiencies.

In general, it is an object of the present invention to provide a guidewire having sidewise looking capabilities which
15 can be utilized in manufacture of small diameter guidewires to permit use of the same in a method for treatment of stenoses in small vessels with over-the-wire catheters.

Another object of the invention is to provide a guidewire of the above character which has a small profile in cross-
20 section from the proximal extremity to the distal extremity.

Another object of the invention is to provide a guidewire of the above character which has a flexible tip which can function in the same manner as the flexible tip of conventional guidewires and which can have the same feel as the flexible tips
25 of conventional guidewires.

Another object of the invention is to provide a guidewire of the above character which can be economically manufactured.

Another object of the invention is to provide a guidewire of the above character which has good torque transmission while
30 retaining flexibility and kink resistance.

Another object of the invention is to provide a guidewire of the above character in which more than one ultrasonic transducer is utilized.

Another object of the invention is to provide a guidewire
5 of the above character in which a plurality of ultrasonic transducers are provided which are spaced apart circumferentially.

Another object of the invention is to provide a guidewire of the above character in which the transducers are spaced apart
10 longitudinally.

Another object of the invention is to provide a guidewire of the above character in which the provision of the ultrasonic transducer in the guidewire does not substantially interfere with the flexibility and feel of the flexible tip of the
15 guidewire.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

Figure 1 is a side elevational view of a guidewire incorporating the present invention coupled into a conventional computer and ultrasonic power supply and receiver.

Figure 2 is a cross-sectional view taken along a line 2-2 of Figure 1.

Figure 3 is an enlarged cross-sectional view of the distal extremity of the guidewire shown in Figure 1.

Figure 4 is a cross-sectional view of the distal extremity of another embodiment of a guidewire incorporating the present invention.

Figure 5 is a cross-sectional view of the distal extremity of still another embodiment of a guidewire of the present invention.

Figure 6 is a cross-sectional view taken along the line 6-6 of Figure 5.

Figure 7 is a cross-sectional view taken along the line 7-7 of Figure 5.

In general, a guidewire is provided which has sidewise ultrasonic imaging capabilities for deployment across a complex lesion in a vessel formed by a wall and normally having a lumen extending therethrough and for use with over-the-wire catheters. A flexible elongate tubular member is provided which has proximal and distal extremities and has a lumen extending from the proximal extremity to the distal extremity. Means is carried by the proximal extremity of the flexible elongate tubular member adapted to be grasped by the human hand for rotating the flexible elongate tubular member. A sidewise looking ultrasonic transducer is carried by the distal extremity of the flexible elongate tubular member and is mounted thereon for rotational movement therewith as the guidewire is rotated. Electrical conductors are provided within the lumen of the flexible elongate tubular member and are utilized for supplying electrical energy to the ultrasonic transducer and for receiving electrical energy from the ultrasonic transducer. A flexible coil is secured to the distal extremity of the flexible elongate tubular member.

More in particular as shown in Figure 1 of the drawings, the sidewise looking ultrasonic imaging guidewire 11 of the present invention is coupled to an ultrasonic power supply 16 which has associated therewith a notebook or laptop computer 17 of a conventional type which is provided with a keyboard 18 and a screen 19 in the form of an LCD panel. The proximal extremity of the guidewire 11 is coupled into the ultrasonic power supply 16 and the computer 17 through a coupling assembly 21 through an electrical cable 22 to a conventional shaft encoder 23 mounted in the ultrasonic power supply 16 and the computer 17.

The guidewire 11 consists of a flexible elongate tubular member 26 having proximal and distal extremities 27 and 28 and having a lumen 29 extending therethrough from the proximal

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