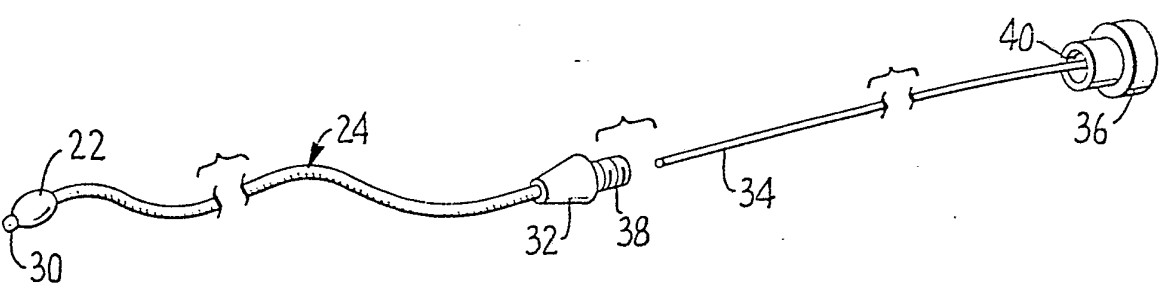


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(54) Title: FLEXIBLE CALIBRATOR 		
(57) Abstract A flexible calibrator which is used to measure the diameter of the lumen in a stenotic segment of a blood vessel, a handle (20), a calibrator oval (22) a flexible shaft or carrier (24) and a relatively stiff but flexible wire stiffener (34). Prior rigid calibrator instruments did not allow advancement of the instrument through sharply winding segments of a vessel.		

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FLEXIBLE CALIBRATOR

Background of the Invention

This invention relates to a flexible calibrator which is used to measure the diameter of the lumen in a stenotic segment of blood vessel when the vessel proximal to the stenosis is highly tortuous. At its distal end the calibrator is provided with a bulb-shaped or oval member which is used as a gauge member to determine the lumen size of the vessel.

The prior art known to me consists of the presently used calibrator instruments. They are provided with lumen-sizing ovals but are rigidly constructed. Their rigidity prevents them from being advanced through sharply winding segments of a vessel in order to reach and measure the desired area of stenosis.

Summary of the Invention

A principal object of the invention is to provide a calibrator with a flexible shaft which enables the calibrator oval to be advanced through tortuous segments of a vessel in order to reach a given area of stenosis.

A further object of the invention is to provide a calibrator having an elongated carrier having variable stiffness and flexibility characteristics.

These objects are attained by providing the carrier with a flexible sheath member and a stiffener core member, the latter being withdrawable during use of the instrument so that an unstiffened, flexible portion of the sheath member may be passed through sharply winding segments of the vessel.

Brief Description of the Drawing

Fig. 1 is a view in perspective of the flexible calibrator of the invention.



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Fig. 2 shows the calibrator initially positioned for passage through a tortuous segment to a stenotic segment of a vessel.

Fig. 3 is a similar view showing the instrument
5 traversing the tortuous segment of the vessel.

Fig. 4 is a similar view showing the calibrator oval of the instrument in sizing disposition to the stenotic segment of the vessel.

Fig. 5 is a view in elevation and in section of the
10 preferred embodiment of the subject calibrator.

Fig. 6 is a broken-away view in elevation of a further embodiment of the subject calibrator.

Description of the Invention

A vessel 10 is provided with a proximal incision 12,
15 an intermediate tortuous segment 14, and a distal stenotic segment 16 having a lumen 18 which is to be sized by use of the calibrator.

The calibrator comprises a handle 20, a calibrator oval 22 and a shaft or carrier 24 interconnecting the handle and oval. The shaft comprises a flexible sheath 26 formed of wound wire 28. The ends of the coiled wire 28 are suitably attached, as by soldering and cementing, to a rounded tip member 30 and to handle member 32. The carrier 24 further comprises a relatively stiff but flexible wire stiffener 34
25 for the flexible sheath 26. The stiffener wire is attached to handle member 36. Handle members 32 and 36 are adapted to be connected together as by threads 38 and 40. When the handle members 32 and 36 are connected together the distal end of wire 34 fits within socket 40 of tip member 30. The oval
30 member 22 is formed of a soft, pliable material such as silicone.

The manner of use of the calibrator is shown in Figs. 2-4. In Fig. 2, the instrument has been introduced into the vessel 10 through the incision 12 and moved along the vessel
35 to a point adjacent the tortuous segment 14. The wire 34



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occupies the full length of the shaft or carrier 24. The stiffness of the shaft 24 is such that further movement of the instrument is resisted by the proximal end of the tortuous segment 14. The operator therefore backs the handle member 36 off of handle member 32 to withdraw enough of the length of the wire stiffener 34 from the flexible sheath 26 to enable the distal, unstiffened portion of sheath 26 to pass through the tortuous segment 14 as the instrument is fed along the vessel by movement of the handle member 32 toward incision 12. The oval 22 becomes finally positioned in the lumen 18 of stenotic segment 16. It typically requires the use of several such instruments, each with a calibration oval of a slightly different size, to correctly calibrate lumen 18.

The calibrator may be used with the wire stiffener 34 fully in place for the calibration of the lumen of a stenotic segment of a non-tortuous vessel. It may be used, as above described, when the vessel proximal to the stenosis is highly tortuous, sufficient length of the stiffener or stylet 34 being withdrawn from the shaft 24 in order to position the pliable calibrator oval 22 as shown in Fig. 4.

A preferred construction of the instrument is shown in Fig. 5. The turns of wire 28 are wound tightly upon each other throughout the length of sheath 26 except for that portion of the sheath which is contained within the oval 22. Here the turns of wire are spaced apart from each other such that the silicone material seeps into the lumen of the guide wire body during molding process, thereby insuring that the oval 22 will not slip off of the guide wire during use of the calibrator.

A further embodiment of the instrument is shown in Fig. 6. Here the core of the oval 22 is formed of tightly wound turns of larger diameter of wire 28. The wire core of oval 22 is then covered with a thin plastic or silicone skin 44. The corrugated surface of the wire core of the oval serves as a good anchor for the skin 44.



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What is Claimed is:

1. A device for measuring the degree of stenosis of arterial vessels comprising a flexible tubular shaft, a lumen-sizing member at the distal end thereof, and a flexible stiffener member extending along said shaft and selectively
5 slidable relative thereto to vary the degree of flexibility of the distal portion of said shaft.

2. The device of Claim 1, further comprising handle means at the proximal end of said shaft comprising a pair of interfitting members, one of said members being
10 attached to said shaft and the other of said members being attached to said stiffener member.

3. The device of Claim 1, said flexible shaft comprising a helically wound spring wire member, said lumen-sizing member being formed of a molded material which extends
15 between turns of said wire member.

4. The device of Claim 3, the turns of said wire member being normally in abutting relation with each other but being in spaced relation with each other within said lumen-sizing member.

20 5. The device of Claim 1, said flexible shaft comprising a helically wound spring wire member, said lumen-sizing member being generally oval in shape and being formed by said helically wound spring wire member, and a flexible, resilient coating of plastic material over said lumen-sizing
25 member.



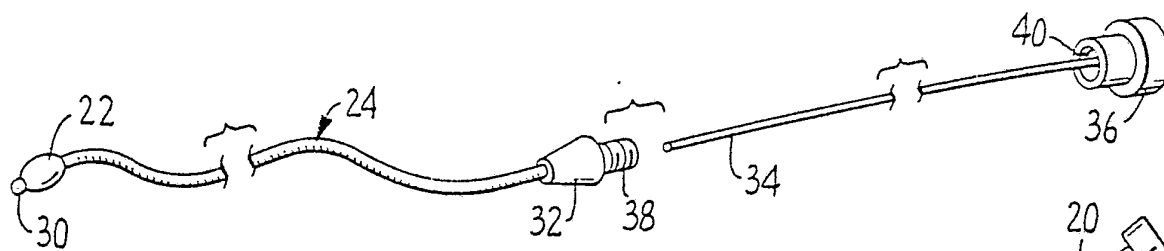


FIG. 1.

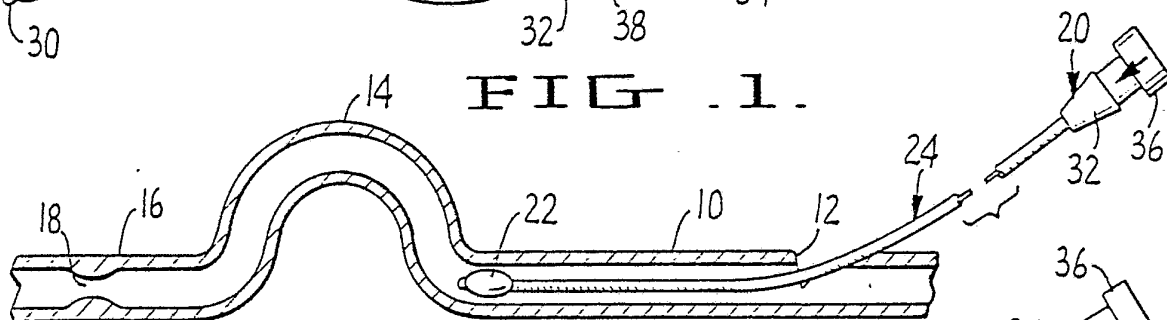


FIG. 2.

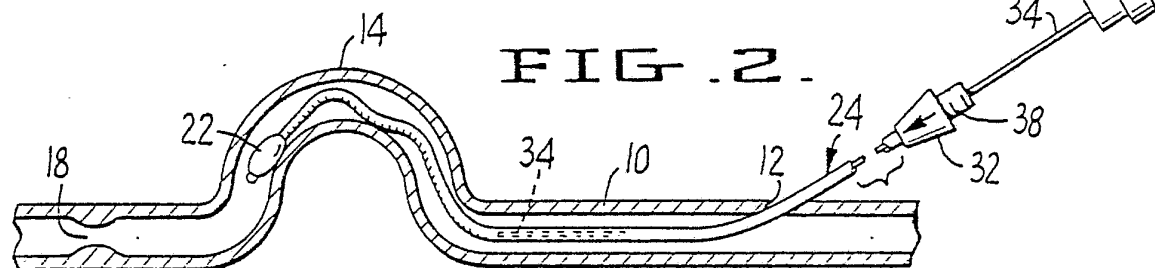


FIG. 3.

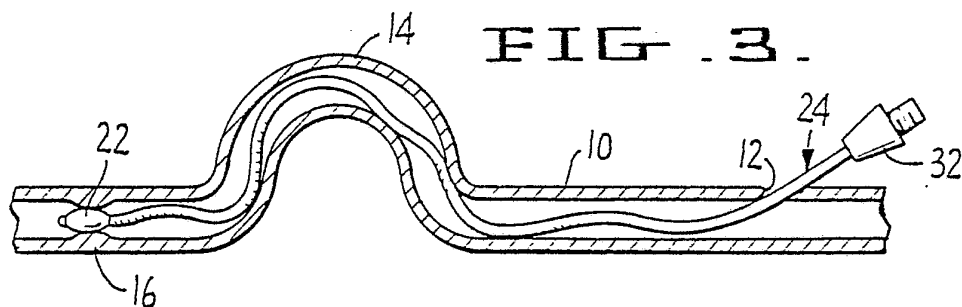


FIG. 4.

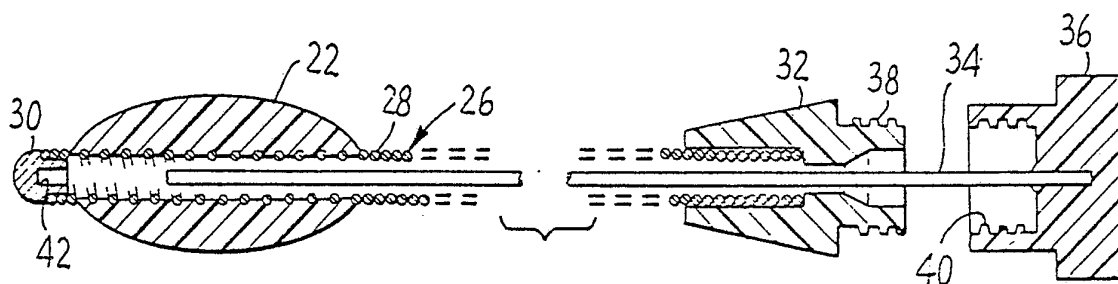


FIG. 5.

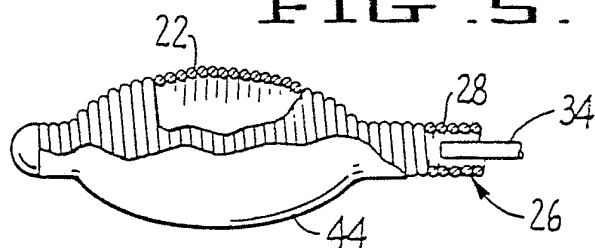


FIG. 6.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US81/00086

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ³		
According to International Patent Classification (IPC) or to both National Classification and IPC		
INT. CL. A61B 5/10		
U.S. CL. 128/774		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
U.S.	128/772, 774, 778, 780, 775, 341, 343, 344, 328, 348, DIG. 9 33/178F, 178R, 174D 15/104, 3SN, 104.165	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁶		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category ⁸	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X	US, A, 1,858,997, Published 17 May 1932 Lewin	1-5
X	US, A, 2,221,138, Published 12 November 1940 Hendrickson	1-5
X	US, A, 3,973,556, Published 10 August 1976, Fleischhacker et al.	1-5
X	US, A, 3,867,945, Published 25 February 1975, Long	1-5
X	US, A, 3,661,148, Published 09 May 1972, Kolin	1-5
A	US, A, 3,938,504, Published 17 February 1976, Dickinson, III, et al.	1-5
A	US, A, 2,887,703, Published 26 May 1959, Williams	1-5
A	US, A, 4,020,829, Published 03 May 1977, Willson et al.	1-5
A	US, A, 2,244,735, Published 10 June 1941, Silverman	5
A	US, A, 1,638,766, Published 09 August 1927, Grosvold	5
A	FR, A5,516,301, Published 16 April 1921	1-5
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²		Date of Mailing of this International Search Report ²
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