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(54) **METHOD OF TREATING AN INTRAOSSEOUS NERVE**
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(56) **References Cited**
U.S. PATENT DOCUMENTS

3,565,062 A	2/1971	Kuris
3,822,708 A	7/1974	Zilber
3,845,771 A	11/1974	Vice
3,920,021 A	11/1975	Hiltebrandt
3,938,502 A	2/1976	Born
3,997,408 A	12/1976	Barba et al.
4,044,774 A	8/1977	Corgin et al.
4,116,198 A	9/1978	Roos
4,311,154 A	1/1982	Sterzer et al.

(Continued)

FOREIGN PATENT DOCUMENTS

DE	43 23 585 A1	1/1995
EP	0 040 658 A2	12/1981

(Continued)

OTHER PUBLICATIONS

Bogduk, N., The anatomy of the lumbar intervertebral disc syndrome, Med J. Aust. 1976, vol. 1, No. 23, pp. 878-881.

(Continued)

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(57) **ABSTRACT**

This invention relates to a method of straddling an intraosseous nerve with an energy transmitting device to improve the therapeutic treatment of the nerve.

5 Claims, 32 Drawing Sheets

Related U.S. Patent Documents

Reissue of:

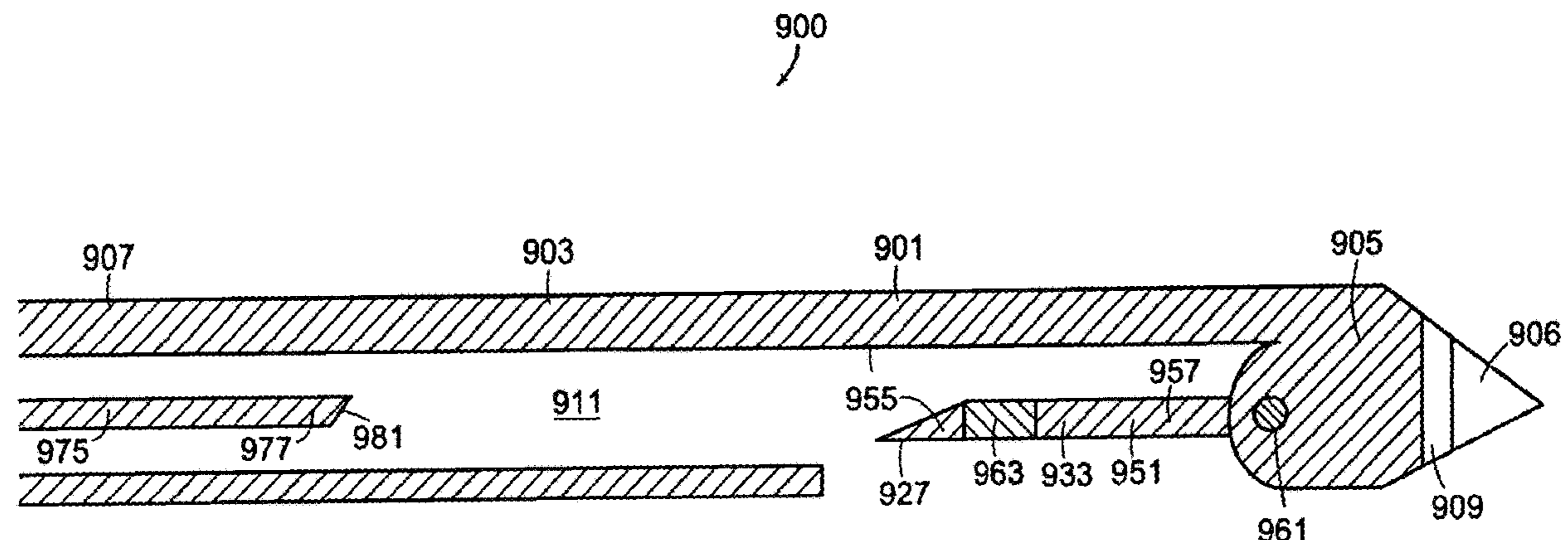
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(56)

References Cited

U.S. PATENT DOCUMENTS

4,312,364 A	1/1982	Convert et al.	5,292,321 A	3/1994	Lee
4,378,806 A	4/1983	Henley-Cohn	5,295,484 A	3/1994	Marcus et al.
4,448,198 A	5/1984	Turner	5,300,085 A	4/1994	Yock
4,449,528 A	5/1984	Auth et al.	5,304,214 A	4/1994	DeFord et al.
4,462,408 A	7/1984	Silverstein et al.	5,305,756 A	4/1994	Entrekin et al.
4,528,979 A	7/1985	Marchenko et al.	5,314,463 A	5/1994	Camps et al.
4,530,360 A	7/1985	Durate	5,320,617 A	6/1994	Leach
4,569,351 A	2/1986	Tang	5,324,255 A	6/1994	Pasafaro et al.
4,573,448 A	3/1986	Kambin	5,325,860 A	7/1994	Seward et al.
4,586,512 A	5/1986	Do-huu	5,342,292 A	8/1994	Nita et al.
4,601,296 A	7/1986	Yerushalmi	5,342,357 A	8/1994	Nardella
4,612,940 A	9/1986	Kasevich et al.	5,342,409 A	8/1994	Mullett
4,657,017 A	4/1987	Sorochenko	5,344,435 A	9/1994	Turner et al.
4,662,383 A	5/1987	Sogawa et al.	5,345,940 A	9/1994	Seward et al.
4,671,293 A	6/1987	Shalov	5,348,554 A	9/1994	Imran et al.
4,676,258 A	6/1987	Inokuchi et al.	5,350,377 A	9/1994	Winston et al.
4,679,561 A	7/1987	Doss	5,351,691 A	10/1994	Brommersma
4,681,122 A	7/1987	Winters et al.	5,366,443 A	11/1994	Eggers et al.
4,750,499 A	6/1988	Hoffer	5,366,490 A	11/1994	Edwards et al.
4,754,757 A	7/1988	Feucht	5,368,031 A	11/1994	Cline et al.
4,757,820 A	7/1988	Itoh	5,368,035 A	11/1994	Hamm et al.
4,774,967 A	10/1988	Zanakis et al.	5,368,557 A	11/1994	Nita et al.
4,800,899 A	1/1989	Elliott	5,368,558 A	11/1994	Nita
4,813,429 A	3/1989	Eshel et al.	5,370,675 A	12/1994	Edwards et al.
4,841,977 A	6/1989	Griffith et al.	5,370,678 A	12/1994	Edwards et al.
4,907,589 A	3/1990	Cosman	5,372,138 A	12/1994	Crowley et al.
4,924,863 A	5/1990	Sterzer	5,374,265 A	12/1994	Sand
4,936,281 A	6/1990	Stasz	5,383,876 A	1/1995	Nardella
4,950,267 A	8/1990	Ishihara et al.	5,385,148 A	1/1995	Lesh et al.
4,951,677 A	8/1990	Crowley et al.	5,385,544 A	1/1995	Edwards et al.
4,955,377 A	9/1990	Lennox et al.	5,391,197 A	2/1995	Burdette et al.
4,959,063 A	9/1990	Kojima	5,391,199 A	2/1995	Ben-Haim
4,961,435 A	10/1990	Kitagawa et al.	5,405,376 A	4/1995	Mulier et al.
4,963,142 A	10/1990	Loertscher	5,411,527 A	5/1995	Alt
4,966,144 A	10/1990	Rochkind et al.	5,417,719 A	5/1995	Hull et al.
4,967,765 A	11/1990	Turner et al.	5,419,767 A	5/1995	Eggers et al.
4,976,711 A	12/1990	Parins et al.	5,421,338 A	6/1995	Crowley
4,977,902 A	12/1990	Sekino et al.	5,423,811 A	6/1995	Imran et al.
5,000,185 A	3/1991	Yock	5,431,649 A	7/1995	Mulier et al.
5,002,058 A	3/1991	Martinelli	5,433,739 A	7/1995	Cosman et al.
5,002,059 A	3/1991	Crowley et al.	D361,555 S	8/1995	Bettin et al.
5,007,437 A	4/1991	Sterzer	5,437,661 A	8/1995	Rieser
5,025,778 A	6/1991	Silverstein et al.	5,441,499 A	8/1995	Fritsch
5,031,618 A	7/1991	Mullett	5,443,463 A	8/1995	Stern
5,061,266 A	10/1991	Hakky	5,447,509 A	9/1995	Millis et al.
5,070,879 A	12/1991	Herres	5,449,380 A	9/1995	Chin
RE33,791 E	1/1992	Carr	5,454,373 A	10/1995	Koger et al.
5,078,736 A	1/1992	Behl	5,458,596 A	10/1995	Lax et al.
5,080,660 A	1/1992	Buelna	5,458,597 A	10/1995	Edwards et al.
5,084,043 A	1/1992	Hertzmann et al.	5,471,988 A	12/1995	Fujio et al.
5,090,414 A	2/1992	Takano	5,472,441 A	12/1995	Edwards et al.
5,098,431 A	3/1992	Rydell	5,474,530 A	12/1995	Passafaro et al.
5,106,376 A	4/1992	Mononen et al.	5,484,432 A	1/1996	Sand
5,108,404 A	4/1992	Scholten et al.	5,486,170 A	1/1996	Winston et al.
5,131,397 A	7/1992	Crowley et al.	5,501,703 A	3/1996	Holsheimer et al.
5,147,355 A	9/1992	Friedman et al.	5,505,730 A	4/1996	Edwards
5,156,157 A	10/1992	Valenta, Jr. et al.	5,514,130 A	5/1996	Baker
5,158,536 A	10/1992	Sekins et al.	5,524,624 A	6/1996	Tepper et al.
5,161,533 A	11/1992	Press et al.	5,526,815 A	6/1996	Granz et al.
5,167,231 A	12/1992	Matsui	5,529,580 A	6/1996	Hagino et al.
5,186,177 A	2/1993	O'Donnell et al.	5,540,679 A	7/1996	Fram et al.
5,190,540 A	3/1993	Lee	5,540,681 A	7/1996	Strul et al.
5,190,546 A	3/1993	Jervis	5,540,684 A	7/1996	Hassler, Jr.
5,201,729 A	4/1993	Hertzmann et al.	5,545,161 A	8/1996	Imran
5,207,672 A	5/1993	Martinelli et al.	5,560,362 A	10/1996	Silwa, Jr. et al.
5,209,748 A	5/1993	Daikuzono	5,565,005 A	10/1996	Erickson et al.
5,222,953 A	6/1993	Dowlatshahi	5,569,242 A	10/1996	Lax et al.
5,226,430 A	7/1993	Spears et al.	5,571,088 A	11/1996	Lennox et al.
5,242,439 A	9/1993	Larsen et al.	5,571,147 A	11/1996	Sluijter et al.
5,255,679 A	10/1993	Imran	5,575,772 A	11/1996	Lennox
5,271,408 A	12/1993	Breyer et al.	5,575,788 A	11/1996	Baker et al.
5,273,026 A	12/1993	Wilk	5,588,432 A	12/1996	Crowley
5,281,213 A	1/1994	Milder et al.	5,596,988 A	1/1997	Markle et al.
5,281,215 A	1/1994	Milder et al.	5,601,526 A	2/1997	Chapelon et al.
5,282,468 A	2/1994	Klepinski	5,606,974 A	3/1997	Castellano et al.
			5,609,151 A	3/1997	Mulier et al.
			5,620,479 A	4/1997	Diederich
			5,628,317 A	5/1997	Starkebaum et al.
			5,630,426 A	5/1997	Shmulewitz et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

5,630,837 A	5/1997	Crowley	5,904,681 A	5/1999	West, Jr.
5,643,319 A	7/1997	Green et al.	5,906,613 A	5/1999	Mulier et al.
5,643,330 A	7/1997	Holshiemer et al.	5,916,213 A	6/1999	Haissaguerre et al.
5,647,361 A	7/1997	Damadian	5,916,214 A	6/1999	Cosio
5,647,871 A	7/1997	Levine et al.	5,919,188 A	7/1999	Shearon et al.
5,658,278 A	8/1997	Imran et al.	5,931,805 A	8/1999	Brisken
5,672,173 A	9/1997	Gough et al.	5,935,123 A	8/1999	Edwards et al.
5,681,282 A	10/1997	Eggers et al.	5,938,582 A	8/1999	Ciamacco et al.
5,683,366 A	11/1997	Eggers et al.	5,941,722 A	8/1999	Chen
5,685,839 A	11/1997	Baker et al.	5,941,876 A	8/1999	Nardella et al.
5,687,729 A	11/1997	Schaetzle	5,944,715 A	8/1999	Goble et al.
5,688,267 A	11/1997	Panescu	5,948,007 A	9/1999	Starkebaum et al.
5,693,052 A	12/1997	Weaver	5,948,008 A	9/1999	Daikuzono
5,697,281 A	12/1997	Eggers et al.	5,954,716 A	9/1999	Sharkey et al.
5,697,536 A	12/1997	Eggers et al.	5,964,727 A	10/1999	Edwards et al.
5,697,882 A	12/1997	Eggers et al.	5,967,988 A	10/1999	Briscoe et al.
5,697,909 A	12/1997	Eggers et al.	5,976,105 A	11/1999	Marcove et al.
5,697,927 A	12/1997	Imran et al.	5,983,141 A	11/1999	Sluijter et al.
5,700,262 A	12/1997	Acosta et al.	5,997,497 A	12/1999	Nita et al.
5,718,231 A	2/1998	Chen et al.	6,001,095 A	12/1999	de la Rama et al.
5,720,286 A	2/1998	Chapelon et al.	6,007,533 A	12/1999	Casscells et al.
5,720,287 A	2/1998	Chapelon et al.	6,007,570 A	12/1999	Sharkey et al.
5,722,403 A	3/1998	McGee et al.	6,012,457 A	1/2000	Lesh
5,725,494 A	3/1998	Brisken	6,014,588 A	1/2000	Fitz
5,728,062 A	3/1998	Brisken	6,016,452 A	1/2000	Kasevich
5,730,706 A	3/1998	Garnies	6,016,809 A	1/2000	Mulier et al.
5,733,315 A	3/1998	Burdette et al.	6,017,356 A	1/2000	Frederick et al.
5,735,280 A	4/1998	Sherman et al.	6,019,776 A	2/2000	Preissman et al.
5,735,811 A	4/1998	Brisken	6,022,334 A	2/2000	Edwards et al.
5,735,846 A	4/1998	Fleischman et al.	6,024,733 A	2/2000	Eggers et al.
5,735,847 A	4/1998	Gough et al.	6,024,740 A	2/2000	Lesh et al.
5,738,680 A	4/1998	Mueller et al.	6,030,374 A	2/2000	McDaniel
5,741,249 A	4/1998	Moss et al.	6,030,402 A	2/2000	Thompson et al.
5,743,904 A	4/1998	Edwards	6,032,673 A	3/2000	Langberg et al.
5,746,737 A	5/1998	Saadat	6,032,674 A	3/2000	Eggers et al.
5,752,969 A	5/1998	Cunci et al.	6,033,411 A	3/2000	Preissman et al.
5,755,663 A	5/1998	Johnson et al.	6,035,238 A	3/2000	Ingle et al.
5,762,066 A	6/1998	Law et al.	6,038,480 A	3/2000	Hrdlicka et al.
5,762,616 A	6/1998	Talish	6,045,532 A	4/2000	Eggers et al.
5,766,153 A	6/1998	Eggers et al.	6,046,187 A	4/2000	Berde et al.
5,766,231 A	6/1998	Erickson et al.	6,047,214 A	4/2000	Mueller et al.
5,776,092 A	7/1998	Farin et al.	6,050,995 A	4/2000	Durgin
5,785,705 A	7/1998	Baker	6,053,172 A	4/2000	Hovda et al.
5,800,378 A	9/1998	Edwards et al.	6,053,909 A	4/2000	Shaddock
5,800,429 A	9/1998	Edwards	6,063,078 A	5/2000	Wittkamp
5,800,432 A	9/1998	Swanson	6,063,079 A	5/2000	Hovda et al.
5,807,237 A	9/1998	Tindel	6,066,134 A	5/2000	Eggers et al.
5,807,391 A	9/1998	Wijkamp	6,066,139 A	5/2000	Ryan et al.
5,807,392 A	9/1998	Eggers	6,068,642 A	5/2000	Johnson et al.
5,807,395 A	9/1998	Mulier et al.	6,071,279 A	6/2000	Whayne et al.
5,810,764 A	9/1998	Eggers et al.	6,073,051 A	6/2000	Sharkey et al.
5,817,021 A	10/1998	Reichenberger	6,074,352 A	6/2000	Hynynen et al.
5,824,021 A	10/1998	Rise	6,086,585 A	7/2000	Hovda et al.
5,840,031 A	11/1998	Crowley	6,090,105 A	7/2000	Zepeda et al.
5,843,019 A	12/1998	Eggers et al.	6,095,149 A	8/2000	Sharkey et al.
5,843,021 A	12/1998	Edwards et al.	6,099,499 A	8/2000	Ciamacco
5,844,092 A	12/1998	Presta et al.	6,099,514 A	8/2000	Sharkey et al.
5,846,218 A	12/1998	Brisken et al.	6,102,046 A	8/2000	Weinstein et al.
5,849,011 A	12/1998	Jones et al.	6,104,957 A	8/2000	Alo et al.
5,855,576 A	1/1999	LeVeen et al.	6,105,581 A	8/2000	Eggers et al.
5,860,951 A	1/1999	Eggers et al.	6,106,454 A	8/2000	Berg et al.
5,865,788 A	2/1999	Edwards et al.	6,109,268 A	8/2000	Thapliyal et al.
5,865,801 A	2/1999	Houser	6,112,122 A	8/2000	Schwardt et al.
5,868,740 A	2/1999	LeVeen et al.	6,113,597 A	9/2000	Eggers et al.
5,871,469 A	2/1999	Eggers et al.	6,117,101 A	9/2000	Diederich et al.
5,871,470 A	2/1999	McWha	6,117,109 A	9/2000	Eggers et al.
5,871,481 A	2/1999	Kannenberget al.	6,117,128 A	9/2000	Gregory
5,873,855 A	2/1999	Eggers et al.	6,120,467 A	9/2000	Schallhorn
5,873,877 A	2/1999	McGaffigan et al.	6,120,502 A	9/2000	Michelson
5,876,398 A	3/1999	Mulier et al.	6,122,549 A	9/2000	Sharkey et al.
5,888,198 A	3/1999	Eggers et al.	6,126,682 A	10/2000	Ashley et al.
5,891,095 A	4/1999	Eggers et al.	6,137,209 A	10/2000	Dahlberg et al.
5,895,370 A	4/1999	Edwards et al.	6,139,545 A	10/2000	Utley et al.
5,902,272 A	5/1999	Eggers et al.	6,142,992 A	11/2000	Cheng et al.
5,902,308 A	5/1999	Murphy	6,143,019 A	11/2000	Motamedi et al.
			6,146,380 A	11/2000	Racz et al.
			6,149,620 A	11/2000	Baker et al.
			6,159,194 A	12/2000	Eggers et al.
			6,159,208 A	12/2000	Hovda et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

6,161,048 A	12/2000	Sluijter et al.	6,368,292 B1	4/2002	Ogden et al.
6,164,283 A	12/2000	Lesh	6,379,351 B1	4/2002	Thapliyal et al.
6,165,172 A	12/2000	Farley et al.	6,383,190 B1	5/2002	Preissman
6,168,593 B1	1/2001	Sharkey et al.	6,391,025 B1	5/2002	Weinstein et al.
6,169,924 B1	1/2001	Meloy et al.	6,416,507 B1	7/2002	Eggers et al.
6,171,239 B1	1/2001	Humphrey	6,416,508 B1	7/2002	Eggers et al.
6,176,857 B1	1/2001	Ashley	6,423,059 B1	7/2002	Hanson et al.
6,179,824 B1	1/2001	Eggers et al.	6,426,339 B1	7/2002	Berde et al.
6,179,836 B1	1/2001	Eggers et al.	6,428,491 B1	8/2002	Weiss
6,179,858 B1	1/2001	Squire et al.	6,432,103 B1	8/2002	Ellsberry et al.
6,183,469 B1	2/2001	Thapliyal et al.	6,436,060 B1	8/2002	Talish
6,190,381 B1	2/2001	Olsen et al.	6,436,098 B1	8/2002	Michelson
6,190,383 B1	2/2001	Schmaltz et al.	6,447,448 B1	9/2002	Ishikawa et al.
6,193,715 B1	2/2001	Wrublewski et al.	6,451,013 B1	9/2002	Bays et al.
6,203,542 B1	3/2001	Ellsberry et al.	6,454,727 B1	9/2002	Bubank et al.
6,206,842 B1	3/2001	Tu et al.	6,461,350 B1	10/2002	Underwood et al.
6,210,393 B1	4/2001	Brisken	6,461,354 B1	10/2002	Olsen et al.
6,210,402 B1	4/2001	Olsen et al.	6,464,695 B2	10/2002	Hovda et al.
6,210,415 B1	4/2001	Bester	6,468,270 B1	10/2002	Hovda et al.
6,216,704 B1	4/2001	Ingle et al.	6,468,274 B1	10/2002	Alleyne et al.
6,221,038 B1	4/2001	Brisken	6,470,220 B1	10/2002	Kraus et al.
6,224,592 B1	5/2001	Eggers et al.	6,478,793 B1	11/2002	Cosman et al.
6,228,046 B1	5/2001	Brisken	6,482,201 B1	11/2002	Olsen et al.
6,228,078 B1	5/2001	Eggers et al.	6,485,271 B1	11/2002	Tack
6,228,082 B1	5/2001	Baker et al.	6,487,446 B1	11/2002	Hill et al.
6,231,516 B1	5/2001	Keilman et al.	6,491,893 B1	12/2002	Babich
6,231,528 B1	5/2001	Kaufman et al.	6,493,592 B1	12/2002	Leonard et al.
6,231,571 B1	5/2001	Ellman et al.	6,494,902 B2	12/2002	Hoey et al.
6,231,615 B1	5/2001	Preissman	6,500,173 B2	12/2002	Underwood et al.
6,233,488 B1	5/2001	Hess	6,505,075 B1	1/2003	Weiner
6,235,020 B1	5/2001	Cheng et al.	6,508,839 B1	1/2003	Lambrecht et al.
6,235,024 B1	5/2001	Tu	6,524,261 B2	2/2003	Talish et al.
6,238,391 B1	5/2001	Olsen et al.	6,537,306 B1	2/2003	Burdette et al.
6,238,393 B1	5/2001	Mulier et al.	6,527,759 B1	3/2003	Tachibana et al.
6,241,665 B1	6/2001	Negus et al.	6,540,741 B1	4/2003	Underwood et al.
6,241,725 B1	6/2001	Cosman	6,544,261 B2	4/2003	Ellsberry et al.
6,245,064 B1	6/2001	Lesh	6,557,559 B1	5/2003	Eggers et al.
6,246,912 B1	6/2001	Sluijter et al.	6,558,385 B1	5/2003	McClurken et al.
6,248,345 B1	6/2001	Goldenheim et al.	6,558,390 B2	5/2003	Cragg
6,254,553 B1	7/2001	Lidgren et al.	6,560,486 B1	5/2003	Osorio et al.
6,254,599 B1	7/2001	Lesh et al.	6,562,033 B2	5/2003	Shah et al.
6,254,600 B1	7/2001	Willink et al.	6,575,968 B1	6/2003	Eggers et al.
6,258,086 B1	7/2001	Ashley et al.	6,575,969 B1	6/2003	Rittman, III et al.
6,259,952 B1	7/2001	Sluijter	6,575,979 B1	6/2003	Cragg
6,261,311 B1	7/2001	Sharkey et al.	6,578,579 B2	6/2003	Burnside et al.
6,264,650 B1	7/2001	Hovda et al.	6,582,423 B1	6/2003	Thapliyal et al.
6,264,651 B1	7/2001	Underwood et al.	6,585,656 B2	7/2003	Masters
6,264,652 B1	7/2001	Eggers et al.	6,589,237 B2	7/2003	Woloszko et al.
6,264,659 B1	7/2001	Ross et al.	6,592,559 B1	7/2003	Pakter et al.
6,267,770 B1	7/2001	Truwit	6,595,990 B1	7/2003	Weinstein et al.
6,270,498 B1	8/2001	Michelson	6,599,288 B2	7/2003	Maguire et al.
6,277,112 B1	8/2001	Underwood et al.	6,602,248 B1	8/2003	Sharps et al.
6,277,122 B1	8/2001	McGahan et al.	6,604,003 B2	8/2003	Fredricks et al.
6,280,441 B1	8/2001	Ryan	6,607,502 B1	8/2003	Maguire et al.
6,283,961 B1 *	9/2001	Underwood et al. 606/41	6,607,529 B1	8/2003	Jones et al.
6,287,114 B1	9/2001	Meller et al.	6,608,502 B2	8/2003	Aoki et al.
6,287,272 B1	9/2001	Brisken et al.	6,622,731 B2	9/2003	Daniel et al.
6,287,304 B1	9/2001	Eggers et al.	6,632,193 B1	10/2003	Davison et al.
6,290,715 B1	9/2001	Sharkey et al.	6,632,220 B1	10/2003	Eggers et al.
6,292,699 B1	9/2001	Simon et al.	6,645,202 B1	11/2003	Pless et al.
6,296,619 B1	10/2001	Brisken et al.	6,648,883 B2	11/2003	Francischelli et al.
6,296,636 B1	10/2001	Cheng et al.	6,659,106 B1	12/2003	Hovda et al.
6,296,638 B1	10/2001	Davison et al.	6,663,627 B2	12/2003	Francischelli et al.
6,305,378 B1	10/2001	Lesh et al.	6,673,063 B2	1/2004	Brett
6,309,387 B1	10/2001	Eggers et al.	6,689,086 B1	2/2004	Nita et al.
6,309,420 B1	10/2001	Preissman	6,689,125 B1	2/2004	Keith et al.
6,312,408 B1	11/2001	Eggers et al.	6,692,450 B1	2/2004	Coleman
6,312,426 B1	11/2001	Goldberg et al.	6,699,240 B2	3/2004	Francischelli
6,319,241 B1	11/2001	King et al.	6,699,242 B2 *	3/2004	Heggeness 606/41
6,322,549 B1	11/2001	Eggers et al.	6,709,432 B2	3/2004	Ferek-Patric
6,348,055 B1	2/2002	Preissman	6,718,208 B2	4/2004	Hill et al.
6,355,032 B1	3/2002	Hovda et al.	6,723,087 B2	4/2004	O'Neill et al.
6,356,790 B1	3/2002	Maguire et al.	6,726,684 B1	4/2004	Woloszko et al.
6,361,531 B1	3/2002	Hissong	6,736,810 B2	5/2004	Hoey et al.
6,363,937 B1	4/2002	Hovda et al.	6,736,835 B2	5/2004	Pellegrino et al.
			6,745,079 B2	6/2004	King
			6,746,447 B2	6/2004	Davison et al.
			6,749,604 B1	6/2004	Eggers et al.
			6,758,846 B2	7/2004	Goble et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

6,770,071 B2	8/2004	Woloszko et al.	7,708,733 B2	5/2010	Sanders et al.
6,772,012 B2	8/2004	Ricart et al.	7,738,968 B2	6/2010	Bleich
6,773,431 B2	8/2004	Eggers et al.	7,740,631 B2	6/2010	Bleich et al.
6,795,737 B2	9/2004	Gielen et al.	7,749,218 B2	7/2010	Pellegrino et al.
6,827,715 B2	12/2004	Francischelli et al.	7,749,220 B2	7/2010	Schmaltz et al.
6,827,716 B2	12/2004	Ryan et al.	7,819,826 B2	10/2010	Diederich et al.
6,832,996 B2	12/2004	Woloszko et al.	7,819,869 B2	10/2010	Godara et al.
6,837,887 B2	1/2005	Woloszko et al.	7,824,398 B2	11/2010	Woloszko et al.
6,837,888 B2	1/2005	Ciarrocca et al.	7,824,404 B2	11/2010	Godara et al.
6,852,091 B2	2/2005	Edwards et al.	7,846,156 B2	12/2010	Malis et al.
6,863,672 B2	3/2005	Reiley et al.	7,850,685 B2	12/2010	Kunis et al.
6,875,219 B2	4/2005	Arramon et al.	7,857,813 B2	12/2010	Schmitz et al.
6,881,214 B2	4/2005	Cosman et al.	7,896,870 B2	3/2011	Arless et al.
6,896,674 B1	5/2005	Woloszko et al.	7,901,403 B2	3/2011	Woloszko et al.
6,896,675 B2	5/2005	Leung et al.	7,909,827 B2	3/2011	Reiley et al.
6,907,884 B2 *	6/2005	Pellegrino et al. 128/898	7,914,526 B2	3/2011	Lehmann et al.
6,915,806 B2	7/2005	Pacek et al.	7,917,222 B1	3/2011	Osorio et al.
6,922,579 B2	7/2005	Taimisto et al.	7,918,849 B2	4/2011	Bleich et al.
6,923,813 B2	8/2005	Phillips et al.	7,918,874 B2	4/2011	Siegel
6,936,046 B2	8/2005	Hissong et al.	7,945,331 B2	5/2011	Vilims
6,955,674 B2	10/2005	Eick et al.	7,951,140 B2	5/2011	Arless et al.
6,960,204 B2	11/2005	Eggers et al.	7,963,915 B2	6/2011	Bleich
6,962,589 B2	11/2005	Mulier et al.	7,969,634 B2	6/2011	Sennett
6,974,453 B2	12/2005	Woloszko et al.	8,021,401 B2	9/2011	Carl et al.
6,980,849 B2	12/2005	Sasso	8,025,688 B2	9/2011	Diederich et al.
6,989,010 B2	1/2006	Francischelli et al.	8,034,052 B2	10/2011	Podhajsky
6,997,941 B2	2/2006	Sharkey et al.	8,062,290 B2	11/2011	Buysse et al.
7,048,743 B2	5/2006	Miller et al.	8,066,702 B2	11/2011	Rittman, III et al.
7,065,408 B2	6/2006	Herman et al.	8,083,736 B2	12/2011	McClurken et al.
7,081,122 B1	7/2006	Reiley et al.	8,100,896 B2	1/2012	Podhajsky
7,090,672 B2	8/2006	Underwood et al.	8,128,633 B2	3/2012	Linderman et al.
7,104,989 B2	9/2006	Skarda	8,162,933 B2	4/2012	Francischelli et al.
7,131,969 B1	11/2006	Hovda et al.	8,172,846 B2	5/2012	Brunnett et al.
7,177,678 B1	2/2007	Osorio et al.	8,182,477 B2	5/2012	Orszulak et al.
7,179,255 B2	2/2007	Lettice et al.	8,192,424 B2	6/2012	Woloszko et al.
7,186,234 B2	3/2007	Dahla et al.	8,192,435 B2	6/2012	Bleich et al.
7,192,428 B2	3/2007	Eggers et al.	8,265,747 B2	9/2012	Rittman, III et al.
7,201,731 B1	4/2007	Lundquist et al.	8,282,628 B2	10/2012	Paul et al.
7,201,750 B1	4/2007	Eggers et al.	8,292,887 B2	10/2012	Woloszko et al.
7,211,055 B2	5/2007	Diederich et al.	8,323,279 B2	12/2012	Dahla et al.
7,217,268 B2	5/2007	Eggers et al.	8,348,946 B2	1/2013	McClurken et al.
7,250,048 B2	7/2007	Francischelli et al.	8,355,799 B2	1/2013	Marion et al.
7,258,690 B2	8/2007	Sutton et al.	8,361,067 B2	1/2013	Pellegrino et al.
7,270,659 B2	9/2007	Ricart et al.	8,414,509 B2	4/2013	Diederich et al.
7,270,661 B2	9/2007	Dahla et al.	8,414,571 B2	4/2013	Pellegrino et al.
7,276,063 B2	10/2007	Davison et al.	8,419,730 B2	4/2013	Pellegrino et al.
7,294,127 B2	11/2007	Leung et al.	8,419,731 B2	4/2013	Pellegrino et al.
7,305,264 B2	12/2007	Larson et al.	8,425,507 B2	4/2013	Pellegrino et al.
7,306,596 B2	12/2007	Hillier et al.	8,444,640 B2	5/2013	Demarais et al.
7,318,823 B2	1/2008	Sharps et al.	8,454,594 B2	6/2013	Demarais et al.
7,326,203 B2	2/2008	Papineau et al.	8,475,449 B2	7/2013	Werneth et al.
7,331,956 B2	2/2008	Hovda et al.	8,486,063 B2	7/2013	Werneth et al.
7,331,957 B2	2/2008	Woloszko et al.	8,504,147 B2	8/2013	Deem et al.
RE40,156 E	3/2008	Sharps et al.	8,535,309 B2	9/2013	Pellegrino et al.
7,346,391 B1	3/2008	Osorio et al.	8,579,903 B2	11/2013	Carl
7,386,350 B2	6/2008	Vilims	8,597,301 B2	12/2013	Mitchell
7,387,625 B2	6/2008	Hovda et al.	8,613,744 B2	12/2013	Pellegrino et al.
7,393,351 B2	7/2008	Woloszko et al.	8,617,156 B2	12/2013	Werneth et al.
7,422,585 B1	9/2008	Eggers et al.	8,623,014 B2	1/2014	Pellegrino et al.
7,429,262 B2	9/2008	Woloszko et al.	8,628,528 B2	1/2014	Pellegrino et al.
7,435,247 B2	10/2008	Woloszko et al.	8,644,941 B2	2/2014	Rooney et al.
7,435,250 B2	10/2008	Francischelli et al.	8,657,814 B2	2/2014	Werneth et al.
7,442,191 B2	10/2008	Hovda et al.	8,676,309 B2	3/2014	Deem et al.
7,468,059 B2	12/2008	Eggers et al.	8,690,884 B2	4/2014	Linderman et al.
7,480,533 B2	1/2009	Cosman et al.	8,747,359 B2	6/2014	Pakter et al.
7,502,652 B2	3/2009	Gaunt et al.	8,747,398 B2	6/2014	Behnke
7,503,921 B2	3/2009	Siegel	8,758,349 B2	6/2014	Germain et al.
7,507,236 B2	3/2009	Eggers et al.	8,771,276 B2	7/2014	Linderman
7,546,164 B2	6/2009	King	8,774,913 B2	7/2014	Demarais et al.
7,553,307 B2	6/2009	Bleich et al.	8,774,924 B2	7/2014	Weiner
7,553,309 B2	6/2009	Buysse et al.	8,795,270 B2	8/2014	Drake
7,555,343 B2	6/2009	Bleich	8,808,161 B2	8/2014	Gregg et al.
7,593,778 B2	9/2009	Chandran et al.	8,808,284 B2	8/2014	Pellegrino et al.
7,645,277 B2	1/2010	McClurken et al.	8,821,488 B2	9/2014	Stewart et al.
7,678,111 B2	3/2010	Mulier et al.	8,845,631 B2	9/2014	Werneth et al.
			8,864,760 B2	10/2014	Kramer et al.
			8,882,755 B2	11/2014	Leung et al.
			8,882,759 B2	11/2014	Manley et al.
			8,882,764 B2	11/2014	Pellegrino et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

8,894,658 B2	11/2014	Linderman et al.	9,351,739 B2	5/2016	Mahoney et al.
8,915,949 B2	12/2014	Diederich et al.	9,358,067 B2	6/2016	Lee et al.
8,926,620 B2	1/2015	Chasmawala et al.	9,358,396 B2	6/2016	Holley
8,968,288 B2	3/2015	Brannan	9,364,286 B2	6/2016	Werneth et al.
8,989,859 B2	3/2015	Deem et al.	9,370,348 B2	6/2016	Tally et al.
8,992,522 B2	3/2015	Pellegrino et al.	9,370,392 B2	6/2016	Sharonov
8,992,523 B2	3/2015	Pellegrino et al.	9,370,398 B2	6/2016	Ladtkow et al.
9,017,325 B2	4/2015	Pellegrino et al.	9,375,274 B2	6/2016	Reid
9,023,038 B2	5/2015	Pellegrino et al.	9,375,275 B2	6/2016	Lee et al.
9,028,488 B2	5/2015	Goshayeshgar	9,375,278 B2	6/2016	Robert et al.
9,028,538 B2	5/2015	Paul et al.	9,375,279 B2	6/2016	Brannan
9,039,701 B2	5/2015	Pellegrino et al.	9,375,283 B2	6/2016	Arts et al.
9,044,245 B2	6/2015	Condie et al.	9,381,024 B2	7/2016	Globerman et al.
9,044,254 B2	6/2015	Ladtkow et al.	9,381,045 B2	7/2016	Donner et al.
9,044,575 B2	6/2015	Beasley et al.	9,381,050 B2	7/2016	Lee et al.
9,095,359 B2	8/2015	Robert et al.	9,381,359 B2	7/2016	Parramon et al.
9,113,896 B2	8/2015	Mulier et al.	9,387,094 B2	7/2016	Manrique et al.
9,113,911 B2	8/2015	Sherman	9,393,416 B2	7/2016	Rooney et al.
9,113,925 B2	8/2015	Smith et al.	9,398,931 B2	7/2016	Wittenberger et al.
9,119,647 B2	9/2015	Brannan	9,399,144 B2	7/2016	Howard
9,119,650 B2	9/2015	Brannan et al.	9,403,038 B2	8/2016	Tyler
9,125,671 B2	9/2015	Germain et al.	9,409,023 B2	8/2016	Burdick et al.
9,131,597 B2	9/2015	Taft et al.	9,414,884 B2	8/2016	Faehndrich et al.
9,151,680 B2	10/2015	Brannan	9,421,064 B2	8/2016	Pellegrino et al.
9,155,895 B2	10/2015	Wacnik et al.	9,421,123 B2	8/2016	Lee et al.
9,161,735 B2	10/2015	Bradford et al.	9,421,371 B2	8/2016	Pless et al.
9,161,805 B2	10/2015	Isenberg	9,421,378 B2	8/2016	Lian et al.
9,161,814 B2	10/2015	Brannan et al.	9,439,693 B2	9/2016	Childs et al.
9,168,078 B2	10/2015	Linderman et al.	9,439,721 B2	9/2016	Werneth et al.
9,168,085 B2	10/2015	Juzkiw	9,445,859 B2	9/2016	Childs et al.
9,173,676 B2	11/2015	Pellegrino et al.	9,446,229 B2	9/2016	Omar-Pasha
9,173,700 B2	11/2015	Godara et al.	9,446,235 B2	9/2016	Su et al.
9,179,970 B2	11/2015	Utley et al.	9,452,286 B2	9/2016	Cowan et al.
9,186,197 B2	11/2015	McKay	9,456,836 B2	10/2016	Boling et al.
9,192,308 B2	11/2015	Brannan et al.	9,457,182 B2	10/2016	Koop
9,198,684 B2	12/2015	Arthur et al.	9,468,485 B2	10/2016	Wittenberger et al.
9,226,756 B2	1/2016	Teisen et al.	9,468,495 B2	10/2016	Kunis et al.
9,237,916 B2	1/2016	Crainich et al.	9,474,906 B2	10/2016	Sachs et al.
9,238,139 B2	1/2016	Degiorgio et al.	9,486,279 B2	11/2016	Pellegrino et al.
9,241,729 B2	1/2016	Juntz et al.	9,486,447 B2	11/2016	Peterson et al.
9,241,760 B2	1/2016	Godara et al.	9,486,621 B2	11/2016	Howard et al.
9,247,992 B2	2/2016	Ladtkow et al.	9,492,657 B2	11/2016	Gerber
9,247,993 B2	2/2016	Ladtkow et al.	9,492,664 B2	11/2016	Peterson
9,248,278 B2	2/2016	Crosby et al.	9,504,372 B2	11/2016	Kim
9,248,289 B2	2/2016	Bennett et al.	9,504,518 B2	11/2016	Condie et al.
9,254,168 B2	2/2016	Palanker	9,504,530 B2	11/2016	Hartmann et al.
9,254,386 B2	2/2016	Lee et al.	9,504,818 B2	11/2016	Moffitt et al.
9,259,241 B2	2/2016	Pellegrino et al.	9,511,229 B2	12/2016	Bradley
9,259,248 B2	2/2016	Leuthardt et al.	9,511,231 B1	12/2016	Kent et al.
9,259,269 B2	2/2016	Ladtkow et al.	9,517,200 B2	12/2016	Bleier
9,259,569 B2	2/2016	Brounstein et al.	9,526,507 B2	12/2016	Germain
9,259,577 B2	2/2016	Kaula et al.	9,526,551 B2	12/2016	Linderman
9,265,522 B2	2/2016	Pellegrino et al.	9,532,828 B2	1/2017	Condie et al.
9,265,557 B2	2/2016	Sherman et al.	9,549,772 B2	1/2017	Carl
9,277,969 B2	3/2016	Brannan et al.	9,550,041 B2	1/2017	Bedell
9,282,988 B2	3/2016	Goshayeshgar	9,555,037 B2	1/2017	Podhajsky
9,289,607 B2	3/2016	Su et al.	9,566,449 B2	2/2017	Perryman et al.
9,295,517 B2	3/2016	Peyman et al.	9,572,976 B2	2/2017	Howard et al.
9,295,841 B2	3/2016	Fang et al.	9,572,986 B2	2/2017	Moffitt
9,301,723 B2	4/2016	Brannan et al.	9,579,518 B2	2/2017	Gertner
9,301,804 B2	4/2016	Bonn	9,597,148 B2	3/2017	Olson
9,302,117 B2	4/2016	De Vincentiis	RE46,356 E	4/2017	Pellegrino
9,308,036 B2	4/2016	Robinson	9,610,117 B2	4/2017	Germain
9,308,045 B2	4/2016	Kim et al.	9,649,116 B2	5/2017	Germain
9,314,252 B2	4/2016	Schaller et al.	9,687,255 B2	6/2017	Sennett et al.
9,314,613 B2	4/2016	Mashiach	9,724,107 B2	8/2017	Pellegrino et al.
9,314,618 B2	4/2016	Imran et al.	9,724,151 B2	8/2017	Edidin
9,333,144 B2	5/2016	Baxter et al.	9,730,707 B2	8/2017	Sasaki et al.
9,333,339 B2	5/2016	Weiner	9,770,280 B2	9/2017	Diederich et al.
9,333,361 B2	5/2016	Li et al.	9,775,627 B2	10/2017	Patel et al.
9,333,373 B2	5/2016	Imran	9,782,221 B2	10/2017	Srinivasan
9,339,655 B2	5/2016	Carbunaru	9,795,802 B2	10/2017	Mohamed et al.
9,345,530 B2	5/2016	Ballakur et al.	9,848,944 B2	12/2017	Sutton et al.
9,345,537 B2	5/2016	Harrison et al.	10,028,753 B2	7/2018	Pellegrino et al.
9,345,538 B2	5/2016	Deem et al.	10,111,704 B2	10/2018	Pellegrino et al.
			10,265,099 B2	4/2019	Pellegrino et al.
			10,272,271 B2	4/2019	Diederich et al.
			10,357,258 B2	7/2019	Patel et al.
			10,390,877 B2	8/2019	Heggeness et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

10,456,187 B2	10/2019	Edidin	2004/0116922 A1	6/2004	Hovda et al.
10,463,380 B2	11/2019	Purdy et al.	2004/0120891 A1	6/2004	Hill et al.
10,463,423 B2	11/2019	Sutton et al.	2004/0133124 A1	7/2004	Bates et al.
10,470,781 B2	11/2019	Purdy et al.	2004/0162559 A1	8/2004	Arramon
10,478,246 B2	11/2019	Pellegrino et al.	2004/0186544 A1	9/2004	King
10,517,611 B2	12/2019	Patel et al.	2004/0193151 A1	9/2004	To et al.
10,588,691 B2	3/2020	Pellegrino et al.	2004/0220577 A1	11/2004	Cragg et al.
10,589,131 B2	3/2020	Diederich et al.	2004/0225228 A1	11/2004	Ferree
10,603,522 B2	3/2020	Diederich et al.	2004/0230190 A1	11/2004	Dahla et al.
2001/0001314 A1	5/2001	Davison et al.	2005/0004634 A1	1/2005	Ricart et al.
2001/0001811 A1	5/2001	Burney et al.	2005/0010095 A1	1/2005	Stewart et al.
2001/0020167 A1	9/2001	Woloszko et al.	2005/0010203 A1	1/2005	Edwards et al.
2001/0023348 A1	9/2001	Ashley et al.	2005/0010205 A1	1/2005	Hovda et al.
2001/0025176 A1	9/2001	Ellsberry et al.	2005/0055096 A1	3/2005	Serhan et al.
2001/0025177 A1	9/2001	Woloszko et al.	2005/0177210 A1	8/2005	Leung et al.
2001/0027295 A1	10/2001	Dulak et al.	2005/0177211 A1	8/2005	Leung et al.
2001/0029370 A1	10/2001	Hodva et al.	2005/0182417 A1	8/2005	Pagano
2001/0029373 A1	10/2001	Baker et al.	2005/0192564 A1	9/2005	Cosman et al.
2001/0029393 A1	10/2001	Tierney et al.	2005/0209659 A1	9/2005	Pellegrino et al.
2001/0032001 A1	10/2001	Ricart et al.	2005/0234445 A1	10/2005	Conquergood et al.
2001/0047167 A1	11/2001	Heggeness	2005/0261754 A1	11/2005	Woloszko
2001/0049522 A1	12/2001	Eggers et al.	2005/0267552 A1	12/2005	Conquergood et al.
2001/0049527 A1	12/2001	Cragg	2005/0278007 A1	12/2005	Godara
2001/0051802 A1	12/2001	Woloszko et al.	2005/0283148 A1	12/2005	Janssen et al.
2001/0053885 A1	12/2001	Gielen et al.	2006/0004369 A1	1/2006	Patel et al.
2001/0056280 A1	12/2001	Underwood et al.	2006/0052743 A1	3/2006	Reynolds
2002/0016600 A1	2/2002	Cosman	2006/0064101 A1	3/2006	Arramon
2002/0019626 A1	2/2002	Sharkey et al.	2006/0095026 A1	5/2006	Ricart et al.
2002/0026186 A1	2/2002	Woloszko et al.	2006/0095028 A1	5/2006	Bleich
2002/0049438 A1	4/2002	Sharkey et al.	2006/0106375 A1	5/2006	Werneth et al.
2002/0095144 A1	4/2002	Carl	2006/0106376 A1	5/2006	Godara et al.
2002/0052600 A1	5/2002	Davison et al.	2006/0122458 A1	6/2006	Bleich
2002/0068930 A1	6/2002	Tasto et al.	2006/0129101 A1	6/2006	McGuckin
2002/0095151 A1	7/2002	Dahla et al.	2006/0178670 A1	8/2006	Woloszko et al.
2002/0095152 A1	7/2002	Ciarrocca et al.	2006/0206128 A1	9/2006	Conquergood et al.
2002/0099366 A1	7/2002	Dahla et al.	2006/0206129 A1	9/2006	Conquergood et al.
2002/0111661 A1	8/2002	Cross et al.	2006/0206130 A1	9/2006	Conquergood et al.
2002/0115945 A1	8/2002	D'Luzansky et al.	2006/0206132 A1	9/2006	Conquergood et al.
2002/0120259 A1*	8/2002	Lettice A61B 18/148 606/32	2006/0206133 A1	9/2006	Conquergood et al.
			2006/0206134 A1	9/2006	Conquergood et al.
			2006/0206166 A1	9/2006	Weiner
			2006/0229625 A1	10/2006	Truckai et al.
			2006/0253117 A1	11/2006	Hovda et al.
			2006/0259026 A1	11/2006	Godara et al.
			2006/0264957 A1	11/2006	Cragg et al.
			2006/0264965 A1	11/2006	Shaddock et al.
			2006/0265014 A1	11/2006	Demarais et al.
			2006/0276749 A1	12/2006	Selmon et al.
			2007/0027449 A1	2/2007	Godara et al.
			2007/0055316 A1	3/2007	Godara et al.
			2007/0118142 A1	5/2007	Krueger et al.
			2007/0129715 A1	6/2007	Eggers et al.
			2007/0142791 A1	6/2007	Yeung et al.
			2007/0142842 A1	6/2007	Kreuger et al.
			2007/0149966 A1	6/2007	Dahla et al.
			2007/0179497 A1	8/2007	Eggers et al.
			2007/0213584 A1	9/2007	Kim et al.
			2007/0213735 A1	9/2007	Saadat et al.
			2007/0260237 A1	11/2007	Sutton et al.
			2008/0004621 A1	1/2008	Dahla et al.
			2008/0004675 A1	1/2008	King et al.
			2008/0009847 A1	1/2008	Ricart et al.
			2008/0021447 A1	1/2008	Davison et al.
			2008/0021463 A1	1/2008	Georgy
			2008/0058707 A1	3/2008	Ashley et al.
			2008/0065062 A1	3/2008	Leung et al.
			2008/0091207 A1	4/2008	Truckai et al.
			2008/0114364 A1	5/2008	Goldin et al.
			2008/0119844 A1	5/2008	Woloszko et al.
			2008/0119846 A1	5/2008	Rioux
			2008/0132890 A1	6/2008	Woloszko et al.
			2008/0161804 A1	7/2008	Rioux et al.
			2008/0275458 A1	11/2008	Bleich et al.
			2008/0281322 A1	11/2008	Sherman et al.
			2008/0294166 A1	11/2008	Goldin et al.
			2009/0030308 A1	1/2009	Bradford et al.
			2009/0054951 A1	2/2009	Lauthardt et al.
			2009/0069807 A1	3/2009	Eggers et al.
			2009/0105775 A1	4/2009	Mitchell et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2009/0112278	A1	4/2009	Wingeier et al.	2014/0243943	A1	8/2014	Rao et al.
2009/0118731	A1	5/2009	Young et al.	2014/0257265	A1	9/2014	Godara et al.
2009/0131867	A1	5/2009	Liu et al.	2014/0271717	A1	9/2014	Goshayeshgar et al.
2009/0131886	A1	5/2009	Liu et al.	2014/0276728	A1	9/2014	Goshayeshgar et al.
2009/0149878	A1	6/2009	Truckai et al.	2014/0276744	A1	9/2014	Arthur et al.
2009/0222053	A1	9/2009	Gaunt et al.	2014/0288544	A1	9/2014	Diederich et al.
2009/0312764	A1	12/2009	Marino	2014/0288546	A1	9/2014	Sherman et al.
2010/0010392	A1	1/2010	Skelton et al.	2014/0296850	A1	10/2014	Condie et al.
2010/0016929	A1	1/2010	Prochazka	2014/0316405	A1	10/2014	Pellegrino et al.
2010/0023006	A1	1/2010	Ellman	2014/0324051	A1	10/2014	Pellegrino et al.
2010/0023065	A1	1/2010	Welch et al.	2014/0336630	A1	11/2014	Woloszko et al.
2010/0082033	A1	4/2010	Germain	2014/0336667	A1	11/2014	Pellegrino et al.
2010/0094269	A1	4/2010	Pellegrino et al.	2014/0364842	A1	12/2014	Werneth et al.
2010/0114098	A1	5/2010	Carl	2015/0005614	A1	1/2015	Heggeness et al.
2010/0145424	A1	6/2010	Podhajsky et al.	2015/0005767	A1	1/2015	Werneth et al.
2010/0179556	A1	7/2010	Scribner et al.	2015/0045783	A1	2/2015	Eddidin
2010/0185082	A1	7/2010	Chandran et al.	2015/0057658	A1	2/2015	Sutton et al.
2010/0185161	A1	7/2010	Pellegrino et al.	2015/0065945	A1	3/2015	Zarins et al.
2010/0211076	A1	8/2010	Germain et al.	2015/0073515	A1	3/2015	Turovskiy et al.
2010/0222777	A1	9/2010	Sutton et al.	2015/0141876	A1	5/2015	Diederich
2010/0261989	A1	10/2010	Boseck et al.	2015/0157402	A1	6/2015	Kunis et al.
2010/0261990	A1	10/2010	Gillis et al.	2015/0164546	A1	6/2015	Pellegrino et al.
2010/0298832	A1	11/2010	Lau et al.	2015/0196358	A1	7/2015	Goshayeshgar
2010/0324506	A1	12/2010	Pellegrino et al.	2015/0216588	A1	8/2015	Deem et al.
2011/0022133	A1	1/2011	Diederich et al.	2015/0231417	A1	8/2015	Metcalf et al.
2011/0034884	A9	2/2011	Pellegrino et al.	2015/0272655	A1	10/2015	Condie et al.
2011/0040362	A1	2/2011	Godara et al.	2015/0297246	A1	10/2015	Patel et al.
2011/0077628	A1	3/2011	Hoey et al.	2015/0335349	A1	11/2015	Pellegrino et al.
2011/0087314	A1	4/2011	Diederich et al.	2015/0335382	A1	11/2015	Pellegrino et al.
2011/0118735	A1	5/2011	Abou-Marie et al.	2015/0342660	A1	12/2015	Nash
2011/0196361	A1	8/2011	Vilims	2015/0342670	A1	12/2015	Pellegrino et al.
2011/0206260	A1	8/2011	Bergmans et al.	2015/0359586	A1	12/2015	Heggeness
2011/0264098	A1	10/2011	Cobbs	2015/0374432	A1	12/2015	Godara et al.
2011/0276001	A1	11/2011	Schultz et al.	2015/0374992	A1	12/2015	Crosby et al.
2011/0295261	A1	12/2011	Germain	2015/0374995	A1	12/2015	Foreman et al.
2011/0319765	A1	12/2011	Gertner et al.	2016/0000601	A1	1/2016	Burger et al.
2012/0029420	A1	2/2012	Vilims	2016/0001096	A1	1/2016	Mishelevich
2012/0136346	A1	5/2012	Condie et al.	2016/0002627	A1	1/2016	Bennett et al.
2012/0136348	A1	5/2012	Condie et al.	2016/0008593	A1	1/2016	Cairns
2012/0172858	A1	7/2012	Harrison et al.	2016/0008618	A1	1/2016	Omar-Pasha
2012/0172859	A1	7/2012	Condie et al.	2016/0008628	A1	1/2016	Morries et al.
2012/0196251	A1	8/2012	Taft et al.	2016/0016012	A1	1/2016	Youn et al.
2012/0197344	A1	8/2012	Taft et al.	2016/0022988	A1	1/2016	Thieme et al.
2012/0203219	A1	8/2012	Evans et al.	2016/0022994	A1	1/2016	Moffitt et al.
2012/0226273	A1	9/2012	Nguyen et al.	2016/0024208	A1	1/2016	MacDonald et al.
2012/0239050	A1	9/2012	Linderman	2016/0029930	A1	2/2016	Plumley et al.
2012/0265186	A1	10/2012	Burger et al.	2016/0030276	A1	2/2016	Spanyer
2012/0330180	A1	12/2012	Pellegrino et al.	2016/0030408	A1	2/2016	Levin
2012/0330300	A1	12/2012	Pellegrino et al.	2016/0030748	A1	2/2016	Edgerton et al.
2012/0330301	A1	12/2012	Pellegrino et al.	2016/0030765	A1	2/2016	Towne et al.
2013/0006232	A1	1/2013	Pellegrino et al.	2016/0051831	A1	2/2016	Lundmark et al.
2013/0006233	A1	1/2013	Pellegrino et al.	2016/0059007	A1	3/2016	Koop
2013/0012933	A1	1/2013	Pellegrino et al.	2016/0074068	A1	3/2016	Patwardhan
2013/0012935	A1	1/2013	Pellegrino et al.	2016/0074279	A1	3/2016	Shin
2013/0012936	A1	1/2013	Pellegrino et al.	2016/0074661	A1	3/2016	Lipani
2013/0012951	A1	1/2013	Linderman	2016/0081716	A1	3/2016	Boling et al.
2013/0079810	A1	3/2013	Isenberg	2016/0095721	A1	4/2016	Schell et al.
2013/0231654	A1	9/2013	Germain	2016/0106985	A1	4/2016	Zhu
2013/0103022	A1	10/2013	Sutton et al.	2016/0106994	A1	4/2016	Crosby et al.
2013/0261507	A1	10/2013	Diederich et al.	2016/0113704	A1	4/2016	Godara et al.
2013/0324994	A1	12/2013	Pellegrino et al.	2016/0115173	A1	4/2016	Bois et al.
2013/0324996	A1	12/2013	Pellegrino et al.	2016/0136310	A1	5/2016	Bradford et al.
2013/0324997	A1	12/2013	Pellegrino et al.	2016/0144182	A1	5/2016	Bennett et al.
2013/0345765	A1	12/2013	Brockman et al.	2016/0144187	A1	5/2016	Caparso et al.
2014/0031715	A1	1/2014	Sherar et al.	2016/0158551	A1	6/2016	Kent et al.
2014/0039500	A1	2/2014	Pellegrino et al.	2016/0166835	A1	6/2016	De Ridder
2014/0046245	A1	2/2014	Cornacchia	2016/0175586	A1	6/2016	Edgerton et al.
2014/0066913	A1	3/2014	Sherman	2016/0199097	A1	7/2016	Linderman et al.
2014/0088575	A1	3/2014	Loeb	2016/0213927	A1	7/2016	McGee et al.
2014/0148801	A1	5/2014	Asher et al.	2016/0220393	A1	8/2016	Slivka et al.
2014/0148805	A1	5/2014	Stewart et al.	2016/0220638	A1	8/2016	Dony et al.
2014/0171942	A1	6/2014	Werneth et al.	2016/0220672	A1	8/2016	Chalasanani et al.
2014/0221967	A1	8/2014	Childs et al.	2016/0228131	A1	8/2016	Brockman et al.
2014/0236144	A1	8/2014	Krueger et al.	2016/0228696	A1	8/2016	Imran et al.
2014/0243823	A1	8/2014	Godara et al.	2016/0235471	A1	8/2016	Godara et al.
				2016/0235474	A1	8/2016	Prisco et al.
				2016/0243353	A1	8/2016	Ahmed
				2016/0246944	A1	8/2016	Jain et al.
				2016/0250469	A1	9/2016	Kim et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2016/0250472 A1 9/2016 Carbanaru
 2016/0262830 A1 9/2016 Werneth et al.
 2016/0271405 A1 9/2016 Angara et al.
 2016/0278791 A1 9/2016 Pellegrino et al.
 2016/0278846 A1 9/2016 Harrison et al.
 2016/0279190 A1 9/2016 Watts et al.
 2016/0279408 A1 9/2016 Grigsby et al.
 2016/0279411 A1 9/2016 Rooney et al.
 2016/0279441 A1 9/2016 Imran
 2016/0302925 A1 10/2016 Keogh et al.
 2016/0310739 A1 10/2016 Burdick et al.
 2016/0317053 A1 11/2016 Srivastava
 2016/0317211 A1 11/2016 Harrison et al.
 2016/0317621 A1 11/2016 Bright
 2016/0324541 A1 11/2016 Pellegrino et al.
 2016/0324677 A1 11/2016 Hyde et al.
 2016/0325100 A1 11/2016 Lian et al.
 2016/0339251 A1 11/2016 Kent et al.
 2016/0354093 A1 12/2016 Pellegrino et al.
 2016/0354233 A1 12/2016 Sansone et al.
 2016/0367797 A1 12/2016 Eckermann
 2016/0367823 A1 12/2016 Cowan et al.
 2016/0375259 A1 12/2016 Davis et al.
 2017/0001026 A1 1/2017 Schwarz et al.
 2017/0007277 A1 1/2017 Drapeau et al.
 2017/0014169 A1 1/2017 Dean et al.
 2017/0027618 A1 2/2017 Lee et al.
 2017/0028198 A1 2/2017 Degiorgio et al.
 2017/0028201 A1 2/2017 Howard
 2017/0035483 A1 2/2017 Crainich et al.
 2017/0036009 A1 2/2017 Hughes et al.
 2017/0036025 A1 2/2017 Sachs et al.
 2017/0036033 A9 2/2017 Perryman et al.
 2017/0042834 A1 2/2017 Westphal et al.
 2017/0049503 A1 2/2017 Cosman
 2017/0049507 A1 2/2017 Cosman
 2017/0049513 A1 2/2017 Cosman
 2017/0050017 A1 2/2017 Cosman
 2017/0050021 A1 2/2017 Cosman
 2017/0050024 A1 2/2017 Bhadra et al.
 2017/0266419 A1 2/2017 Goshayeshgar
 2017/0119461 A1 5/2017 Godara et al.
 2017/0128080 A1 5/2017 Torrie
 2017/0135742 A1 5/2017 Lee et al.
 2017/0181788 A1 6/2017 Dastjerdi et al.
 2017/0202613 A1 7/2017 Pellegrino et al.
 2018/0021048 A1 1/2018 Pellegrino et al.
 2018/0042656 A1 2/2018 Edidin
 2018/0103964 A1 4/2018 Patel et al.
 2018/0153604 A1 6/2018 Ayvazyan et al.
 2018/0161047 A1 6/2018 Purdy et al.
 2018/0193088 A1 7/2018 Sutton et al.
 2019/0029698 A1 1/2019 Pellegrino et al.
 2019/0038296 A1 2/2019 Pellegrino
 2019/0038343 A1 2/2019 Sutton et al.
 2019/0038344 A1 2/2019 Pellegrino
 2019/0038345 A1 2/2019 Pellegrino
 2019/0090933 A1 3/2019 Pellegrino et al.
 2019/0110833 A1 4/2019 Pellegrino et al.
 2019/0118003 A1 4/2019 Diederich et al.
 2019/0118004 A1 4/2019 Diederich et al.
 2019/0118005 A1 4/2019 Diederich et al.
 2019/0282268 A1 9/2019 Pellegrino et al.
 2019/0290296 A1 9/2019 Patel et al.

FOREIGN PATENT DOCUMENTS

EP 0040658 12/1981
 EP 0584959 3/1994
 EP 0597463 5/1994
 EP 0880938 12/1998
 EP 1 013 228 A1 6/2000
 EP 1013228 6/2000
 EP 1 059 067 A1 12/2000
 EP 1059067 12/2000

EP 1059087 12/2000
 EP 2913081 1/2017
 JP 6-47058 2/1994
 JP 6-47058 A 2/1994
 JP 10-290806 11/1998
 JP 2001-037760 2/2001
 JP 2005-169012 6/2005
 WO 9636289 A1 11/1996
 WO WO96/36289 11/1996
 WO 98-27876 A1 7/1998
 WO WO98/27876 7/1998
 WO WO98/34550 8/1998
 WO WO99/19025 4/1999
 WO WO99/44519 9/1999
 WO WO99/48621 9/1999
 WO WO00/21448 4/2000
 WO WO00/33909 6/2000
 WO WO00/49978 8/2000
 WO WO00/56237 9/2000
 WO WO00/67648 11/2000
 WO WO00/67656 11/2000
 WO WO01/01877 1/2001
 WO WO01/45579 6/2001
 WO 0157655 A2 8/2001
 WO WO01/57655 8/2001
 WO WO02/05699 1/2002
 WO WO02/05897 1/2002
 WO 0228302 A1 4/2002
 WO WO02/28302 4/2002
 WO WO2002/026319 4/2002
 WO 02054941 A2 7/2002
 WO WO02/054941 7/2002
 WO 02-067797 A2 9/2002
 WO WO02/067797 9/2002
 WO WO02/096304 12/2002
 WO WO 2009/124192 10/2009

OTHER PUBLICATIONS

A Novel Approach for Treating Chronic Lower Back Pain, Abstract for Presentation at North American Spine Society 26th Annual Meeting in Chicago, IL on Nov. 4, 2011.
 Antonacci, M. Darryl et al.; Innervation of the Human Vertebral Body: A Histologic Study; Journal of Spinal Disorder, vol. 11, No. 6, pp. 526-531, 1998 Lippincott Williams & Wilkins, Philadelphia.
 Arnoldi, Carl C.; Intraosseous Hypertension—A Possible Cause of Low Back Pain?; Clinical Orthopedics and Related Research, No. 115, Mar.-Apr. 1976.
 Bailey, Jeannie F., “Innervation Patterns of PGP 9.5-Positive Nerve Fibers within the Human Lumbar Vertebra, Journal of Anatomy”, (2011) 218, pp. 263-270, San Francisco, California.
 Bergeron et al., “Fluoroscopic-guided radiofrequency ablation of the basivertebral nerve: application and analysis with multiple imaging modalities in an ovine model,” Thermal Treatment of Tissue: Energy Delivery and Assessment III, edited by Thomas P. Ryan, Proceedings of SPIE, vol. 5698 (SPIE, Bellingham, WA, 2005) pp. 156-167.
 Bogduk, Nikolai, et al.; Technical Limitations to the efficacy of Radiofrequency Neurotomy for Spinal Pain; Neurosurgery vol. 20, No. 4, 1987.
 Choy, Daniel SS.J. et al.; Percutaneous Laser Disc Decompression, A New Therapeutic Modality; Spine vol. 17, No. 8, 1992.
 Cosman, E.R. et al., Theoretical Aspects of Radiofrequency Lesions in the Dorsal Root Entry Zone. Neurosurgery, vol. 1, No. 6, 1984, pp. 945-950.
 Deardorff, Dana L. et al.; Ultrasound applicators with internal cooling for interstitial thermal therapy; SPIE vol. 3594, 1999.
 Dupuy, D.E. et al. Radiofrequency ablation of spinal tumors: Temperature distribution in the spinal canal AJR, vol. 175, pp. 1263-1266, Nov. 2000.
 Dupuy, Damian E.; Radiofrequency Ablation: An Outpatient Percutaneous Treatment; Medicine and Health/Rhode Island vol. 82, No. 6, Jun. 1999.

(56)

References Cited

OTHER PUBLICATIONS

- Deramond, H. et al., Temperature Elevation Caused by Bone Cement Polymerization During Vertebroplasty, *Bone*, Aug. 1999, pp. 17S-21S, vol. 25, No. 2, Supplement.
- Diederich, C. J. et al., "IDTT Therapy in Cadaveric Lumbar Spine: Temperature and thermal dose distributions, Thermal Treatment of Tissue: Energy Delivery and Assessment," Thomas P. Ryan, Editor, *Proceedings of SPIE* vol. 4247:104-108 (2001).
- Diederich, Chris J. et al.; *Ultrasound Catheters for Circumferential Cardiac Ablation*; SPIE vol. 3594 (1999).
- Esses, Stephen I. et al.; *Intraosseous Vertebral Body Pressures*; *Spine* vol. 17 No. 6 Supplement 1992.
- FDA Response to 510(k) Submission by Relievant Medsystems, Inc. submitted on Sep. 27, 2007 (date stamped on Oct. 5, 2007) and associated documents.
- Fras M.D., Christian et al., "Substance P-containing Nerves within the Human Vertebral Body: An Immunohistochemical Study of the Basivertebral Nerve", *The Spine Journal* 3, 2003, pp. 63-67.
- Goldberg, S.N. et al., Tissue ablation with radiofrequency: Effect of probe size, gauge, duration, and temperature on lesion volume, *Acad. Radiol.*, vol. 2, pp. 399-404 (1995).
- Hanai, Kenji et al.; *Simultaneous Measurement of Intraosseous and Cerebrospinal Fluid Pressures in the Lumbar Region*; *Spine* vol. 10, No. 1, 1985.
- Heggeness, Michael H. et al., *The Trabecular Anatomy of Thoracolumbar Vertebrae: Implications for Burst Fractures*, *Journal of Anatomy*, 1997, pp. 309-312, vol. 191, Great Britain.
- Heggeness, Michael H. et al. *Discography Causes End Plate Deflection*; *Spine* vol. 18, No. 8, pp. 1050-1053, 1993, J.B. Lippincott Company.
- Hoopes et al., "Radiofrequency Ablation of the Basivertebral Nerve as a Potential Treatment of Back Pain: Pathologic Assessment in an Ovine Model," *Thermal Treatment of Tissue: Energy Delivery and Assessment III*, edited by Thomas P. Ryan, *Proceedings of SPIE*, vol. 5698 (SPIE, Bellingham, WA, 2005) pp. 168-180.
- Haupt, Jonathan C. et al.; *Experimental Study of Temperature Distributions and Thermal Transport During Radiofrequency Current Therapy of the Intervertebral Disc*; *Spine* vol. 21, No. 15, pp. 1808-1813, 1996. Lippincott-Raven Publishers.
- Kleinstueck, Frank S. et al.; *Acute Biomechanical and Histological Effects of Intradiscal Electrothermal Therapy on Human Lumbar Discs*; *Spine* vol. 26, No. 20, pp. 2198-2207; 2001, Lippincott Williams & Wilkins, Inc.
- Kopecky, Kenyon K. et al. "Side-Exiting Coaxial Needle for Aspiration Biopsy"—*AJR*—1996; 167, pp. 661-662.
- Lehmann, Justus F. et al.; *Selective Heating Effects of Ultrasound in Human Beings*; *Archives of Physical Medicine & Rehabilitation* Jun. 1966.
- Letcher, Frank S. et al.; *The Effect of Radiofrequency Current and Heat on Peripheral Nerve Action Potential in the Cat*; U.S. Naval Hospital, Philadelphia, PA. (1968).
- Lundskog, Jan; *Heat and Bone Tissue—/an experimental investigation of the thermal properties of bone tissue and threshold levels for thermal injury*; *Scandinavian Journal of Plastic and Reconstructive Surgery Supplemental 9*, From the Laboratory of Experimental Biology, Department of anatomy, University of Gothenburg, Gothenburg, Sweden, Goteborg 1972.
- Martin, J.B. et al., *Vertebroplasty: Clinical Experience and Follow-up Results*, *Bone*, Aug. 1999, pp. 11S-15S, vol. 25, No. 2, Supplement.
- Massad, Malek M.D. et al.; *Endoscopic Thoracic Sympathectomy: Evaluation of Pulsatile Laser, Non-Pulsatile Laser, and Radiofrequency-Generated Thermocoagulation*; *Lasers in Surgery and Medicine*; 1991; pp. 18-25.
- Mehta, Mark et al.; *The treatment of chronic back pain*; *Anaesthesia*, 1979, vol. 34, pp. 768-775.
- Nau, William H., *Ultrasound interstitial thermal therapy (USITT) in the prostate*; *SPIE* vol. 3594, Jan. 1999.
- Rashbaum, Ralph F.; *Radiofrequency Facet Denervation A Treatment alternative in Refractory Low Back Pain with or without Leg Pain*; *Orthopedic Clinics of North America*—vol. 14, No. 3, Jul. 1983.
- Rosenthal, D.I., *Seminars in Musculoskeletal Radiology*, vol. 1, No. 2., pp. 265-272 (1997).
- Ryan et al., "Three-Dimensional Finite Element Simulations of Vertebral Body Thermal Treatment," *Thermal Treatment of Tissue: Energy Delivery and Assessment III*, edited by Thomas P. Ryan, *Proceedings of SPIE*, vol. 5698 (SPIE, Bellingham, WA, 2005) pp. 137-155.
- Shealy, C. Norman; *Percutaneous radiofrequency denervation of spinal facets Treatment for chronic back pain and sciatica*; *Journal of Neurosurgery*/vol. 43/Oct. 1975.
- Sherman, Mary S.; *The Nerves of Bone*, *The Journal of Bone and Joint Surgery*, Apr. 1963, pp. 522-528, vol. 45-A, No. 3.
- Solbiati, L. et al. *Hepatic metastases: Percutaneous radio-frequency ablation with cooled-tip electrodes*. *Interventional Radiology*, vol. 205, No. 2, pp. 367-373 (1997).
- Stanton, Terry, "Can Nerve Ablation Reduce Chronic Back Pain?" *AAOS Now* Jan. 2012.
- The AVAmox System—Cardinal Health Special Procedures*, Lit. No. 25P0459-01—www.cardinal.com (copyright 2007).
- Tillotson, L. et al. *Controlled thermal injury of bone: Report of a percutaneous technique using radiofrequency electrode and generator*. *Investigative Radiology*, Nov. 1989, pp. 888-892.
- Troussier, B. et al.; *Percutaneous Intradiscal Radio-Frequency Thermocoagulation A Cadaveric Study*; *Spine* vol. 20, No. 15, pp. 1713-1718, 1995, Lippincott-Raven Publishers.
- Ullrich, Jr., Peter F., "Lumbar Spinal Fusion Surgery" Jan. 9, 2013, *Spine-Health* (available via wayback machine Internet archive at <http://web.archive.org/web/20130109095419/http://www.spine-health.com/treatment/spinal-fusion/lumbar-spinal-fusion-surgery>).
- Osteocool Pain Management Brochure*, Baylis Medical, copyright 2011.
- Gehl, J., "Electroporation: theory and methods, perspectives for drug delivery, gene therapy, and research", *Acta Physiol. Scand.*, vol. 177, pp. 437-447 (2003).
- Modic MT et al.; "Degenerative disk disease: assessment of changes in vertebral body marrow with MR imaging", *Radiology*, vol. 166, pp. 193-199 (1988).
- Weishaupt, D et al.; "Painful Lumbar Disk Derangement: Relevance of Endplate Abnormalities at MR Imaging", *Radiology*, vol. 218(2), pp. 420-427 (2001).
- E.R. Cosman et al. *Theoretical aspects of radiofrequency lesions in the dorsal root entry zone*. *Neurosurgery*, vol. 15, No. 6, pp. 945-950 (1984).

* cited by examiner

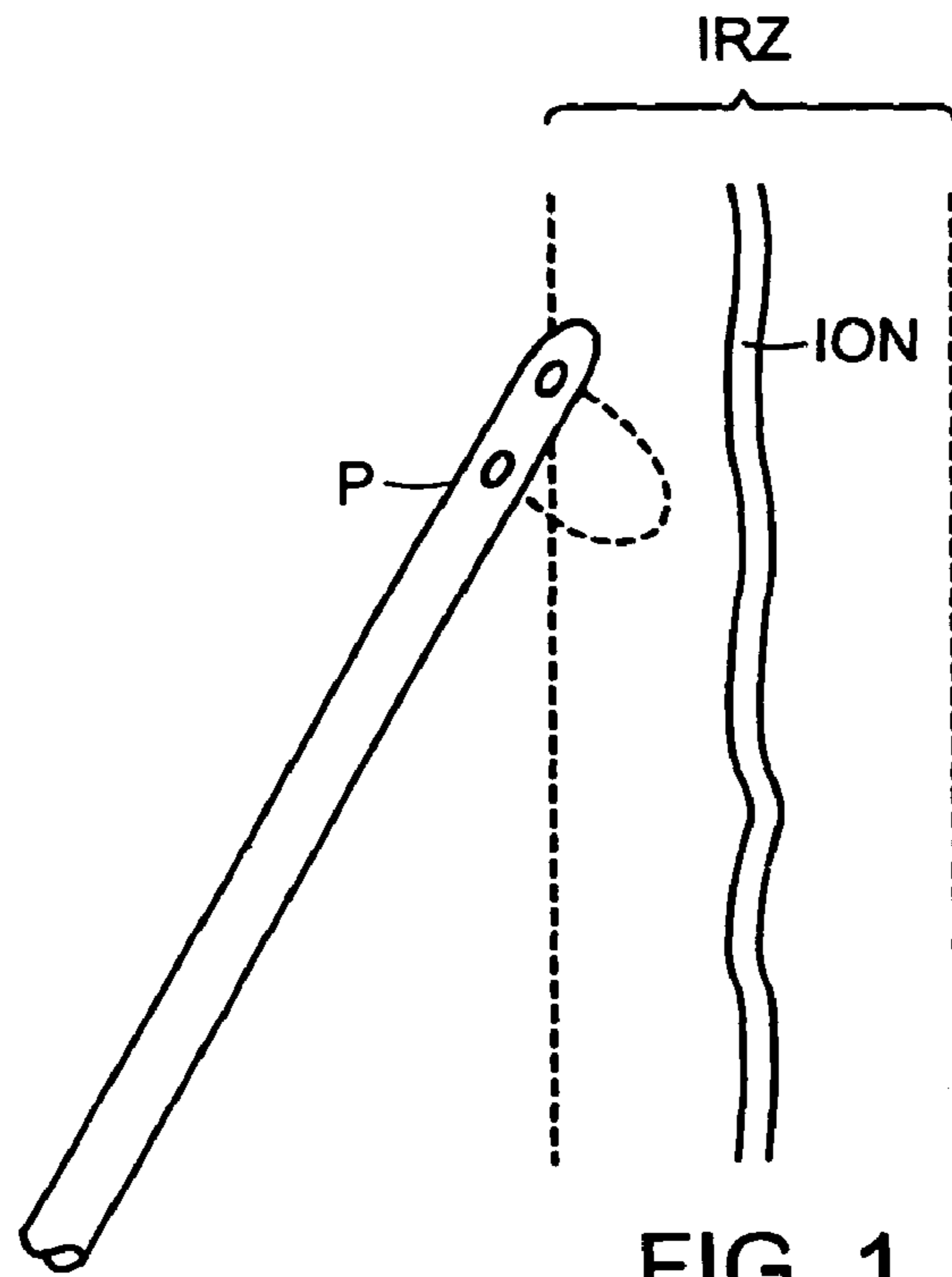


FIG. 1
PRIOR ART

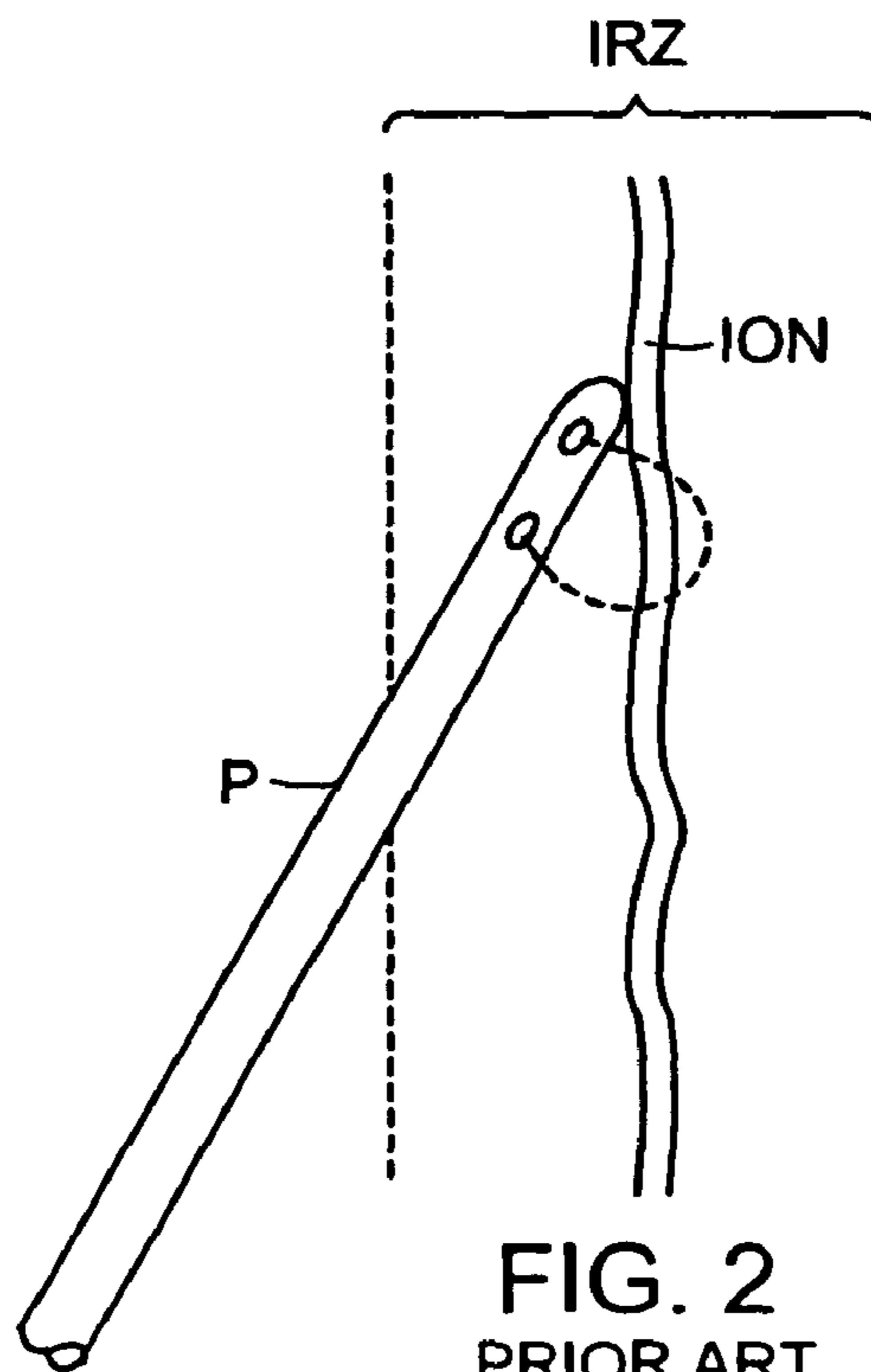


FIG. 2
PRIOR ART

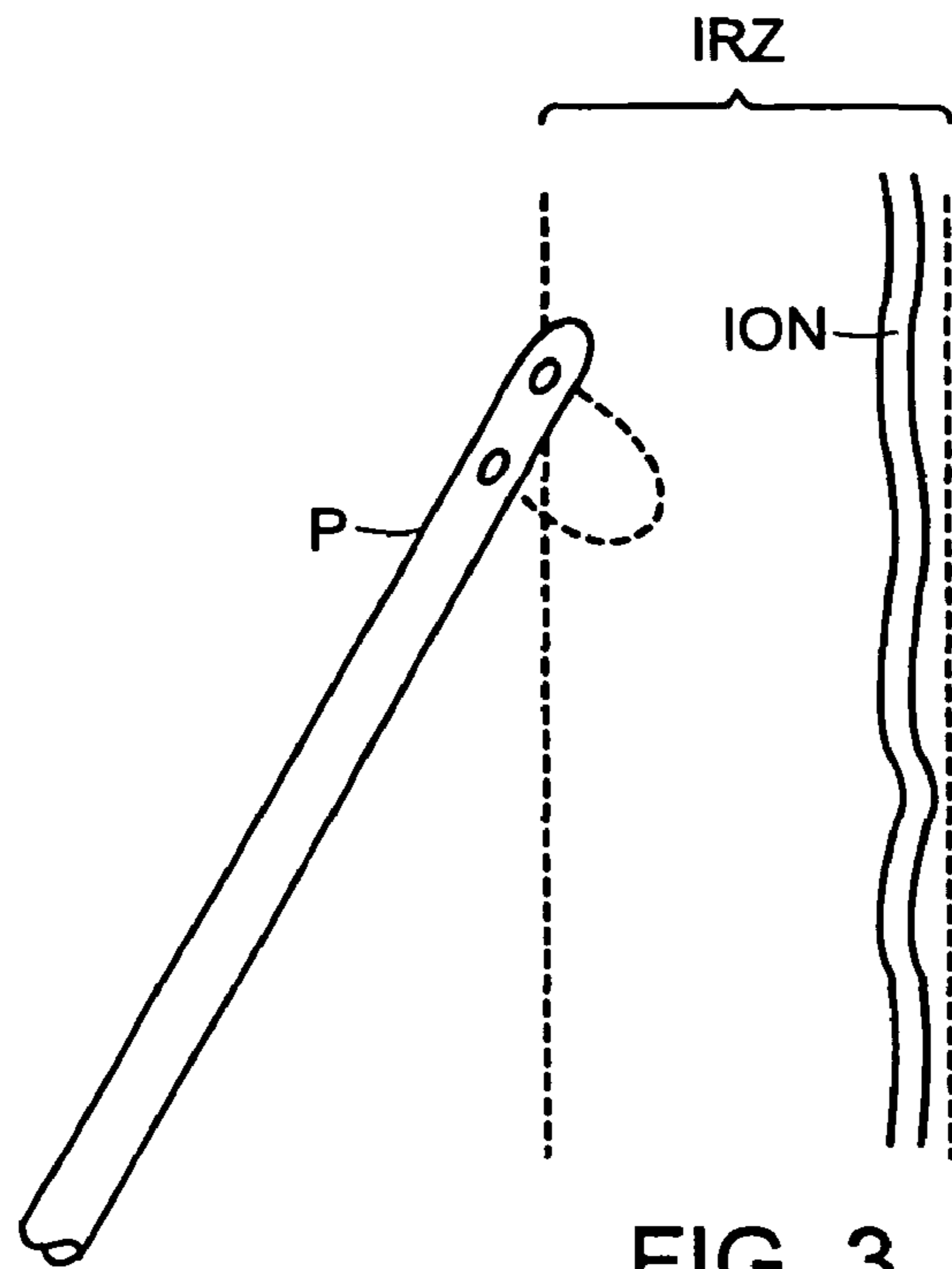


FIG. 3
PRIOR ART

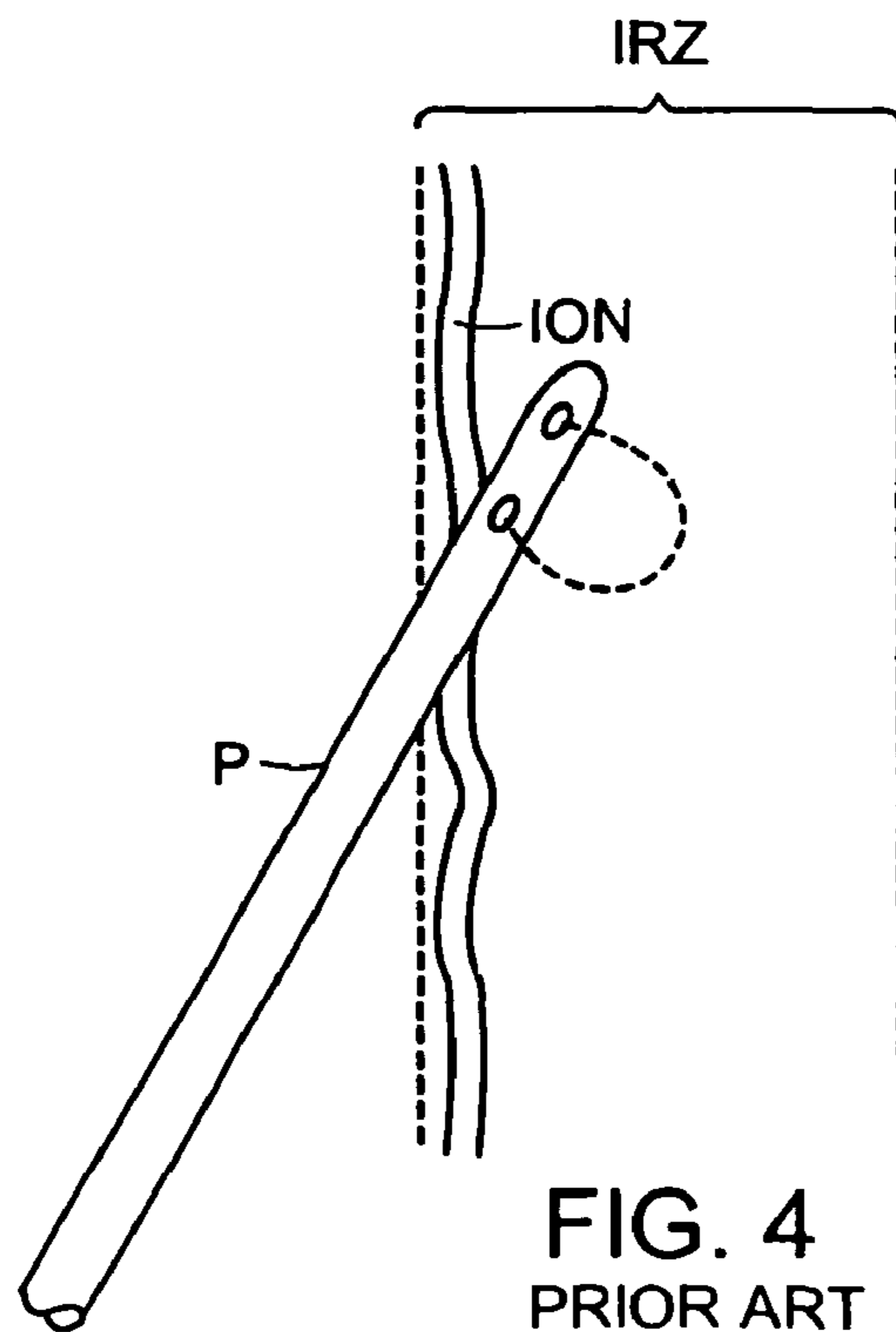


FIG. 4
PRIOR ART

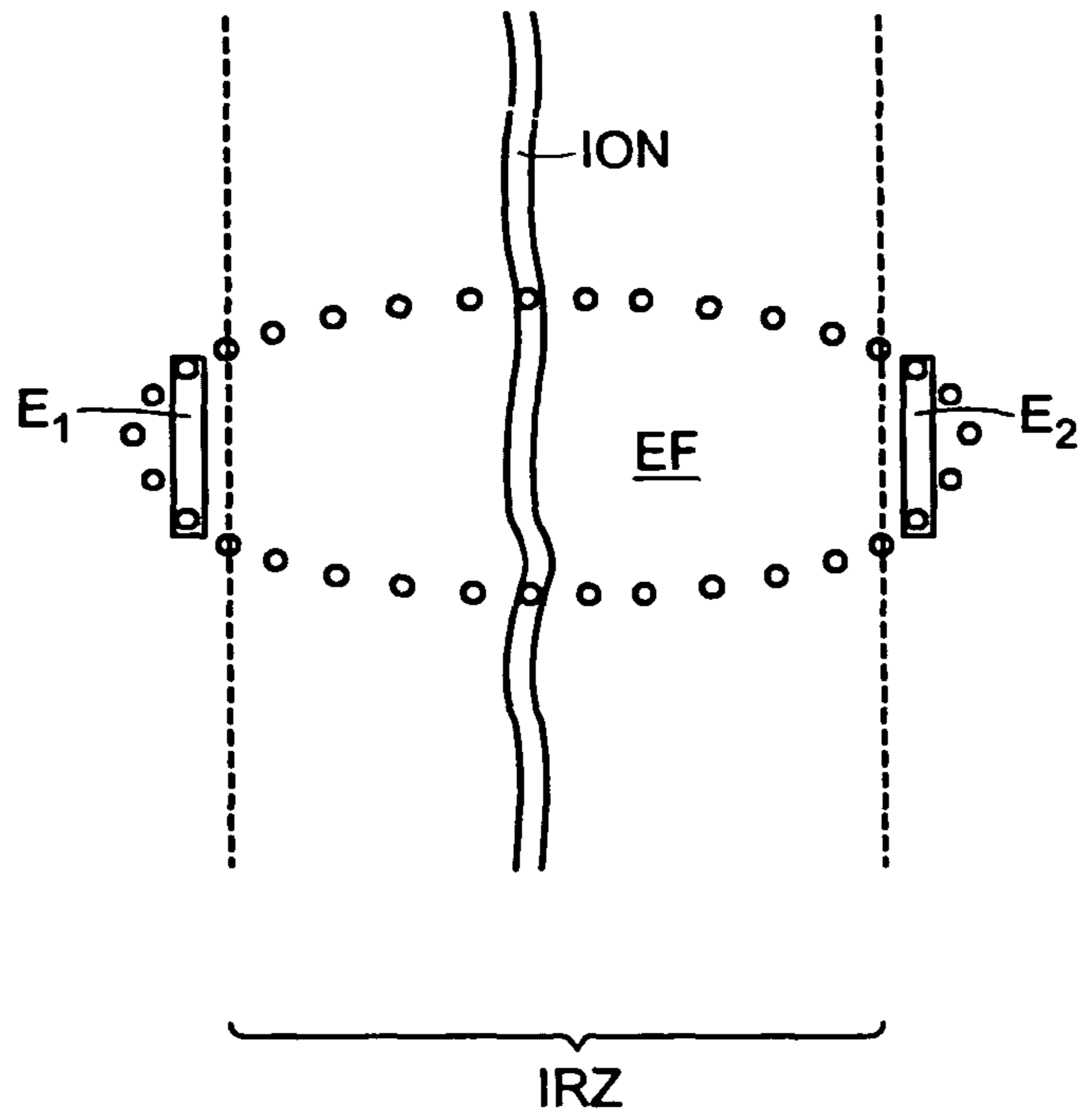


FIG. 5

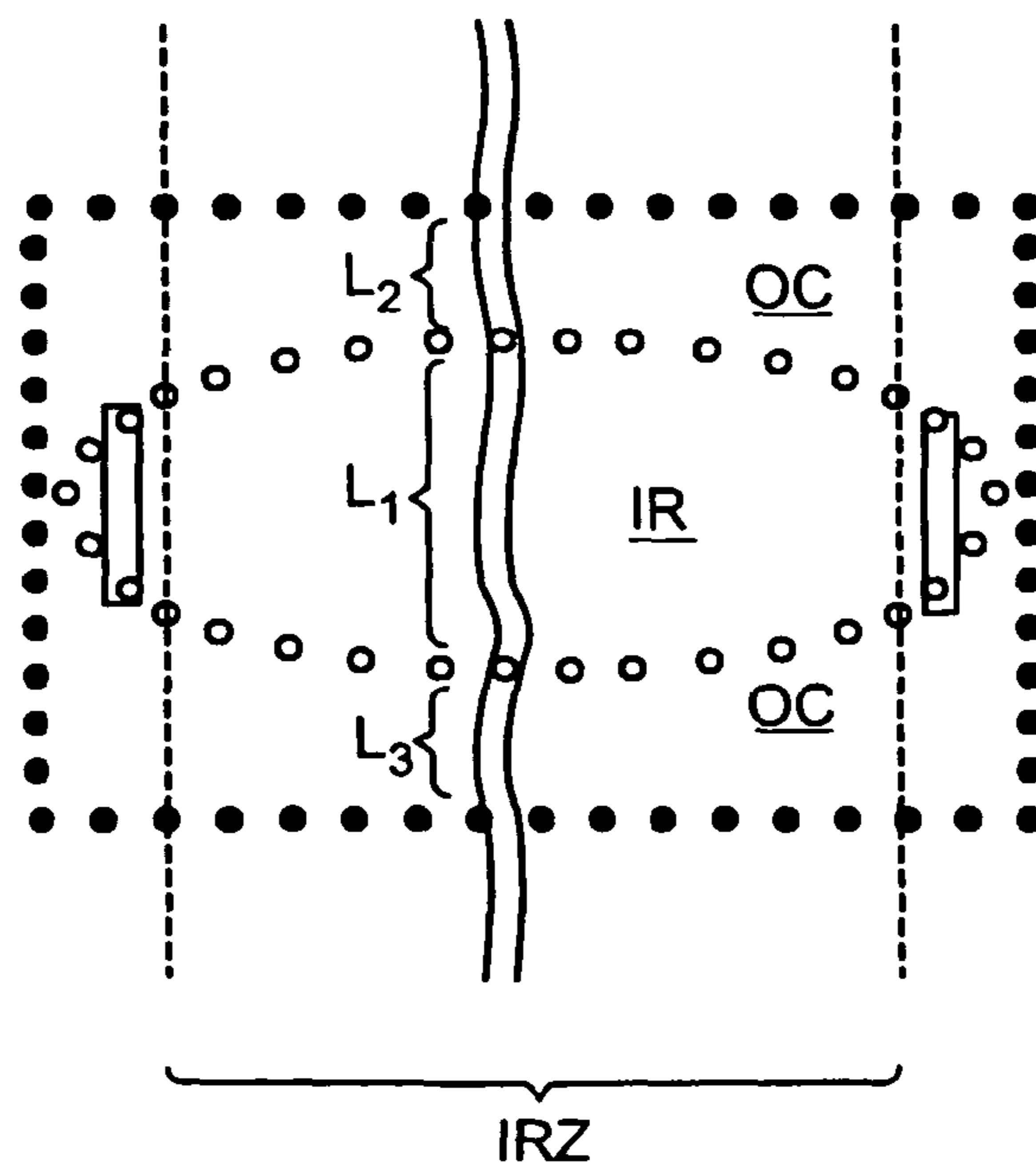


FIG. 6

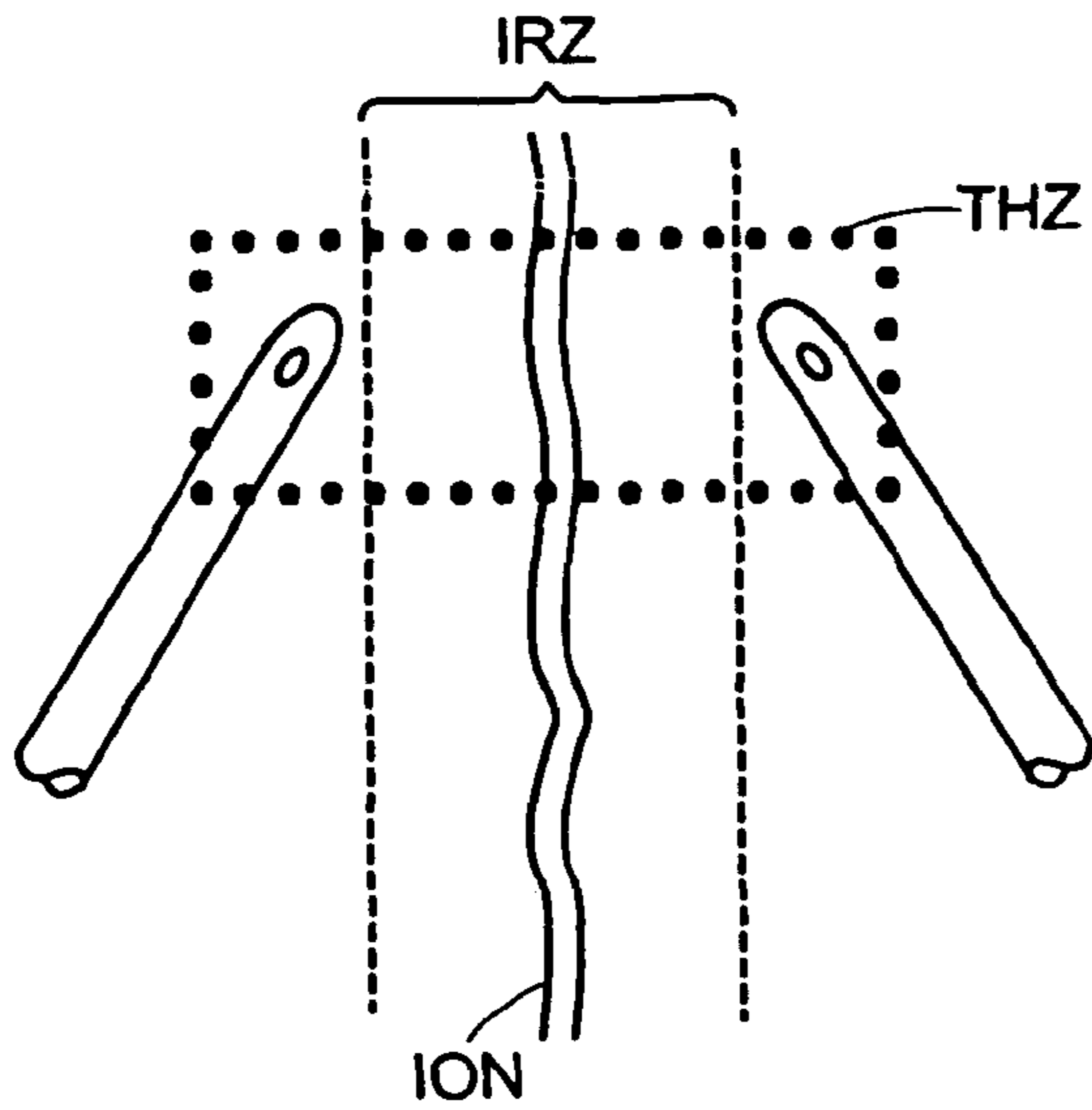


FIG. 7

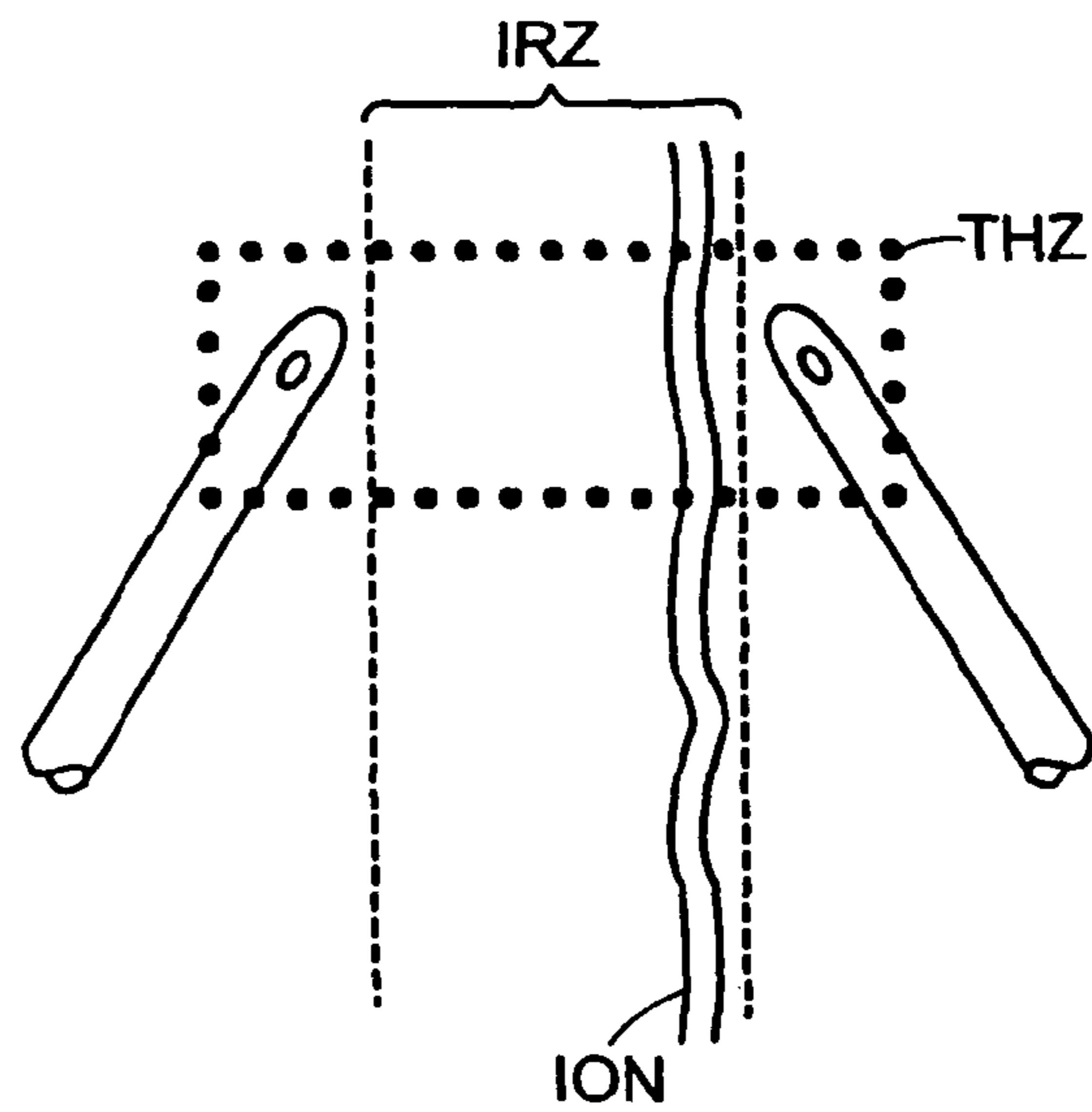


FIG. 8

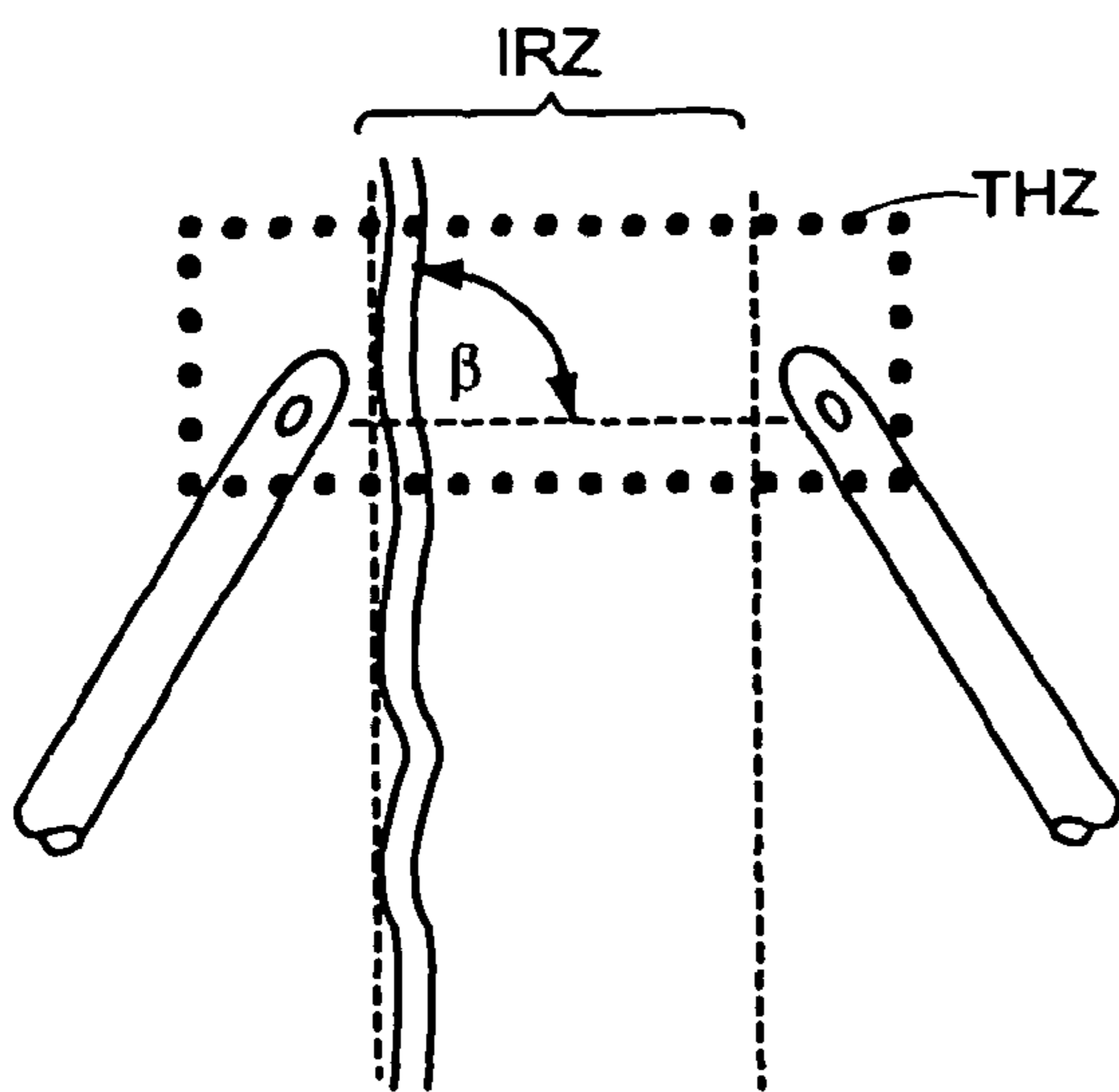


FIG. 9

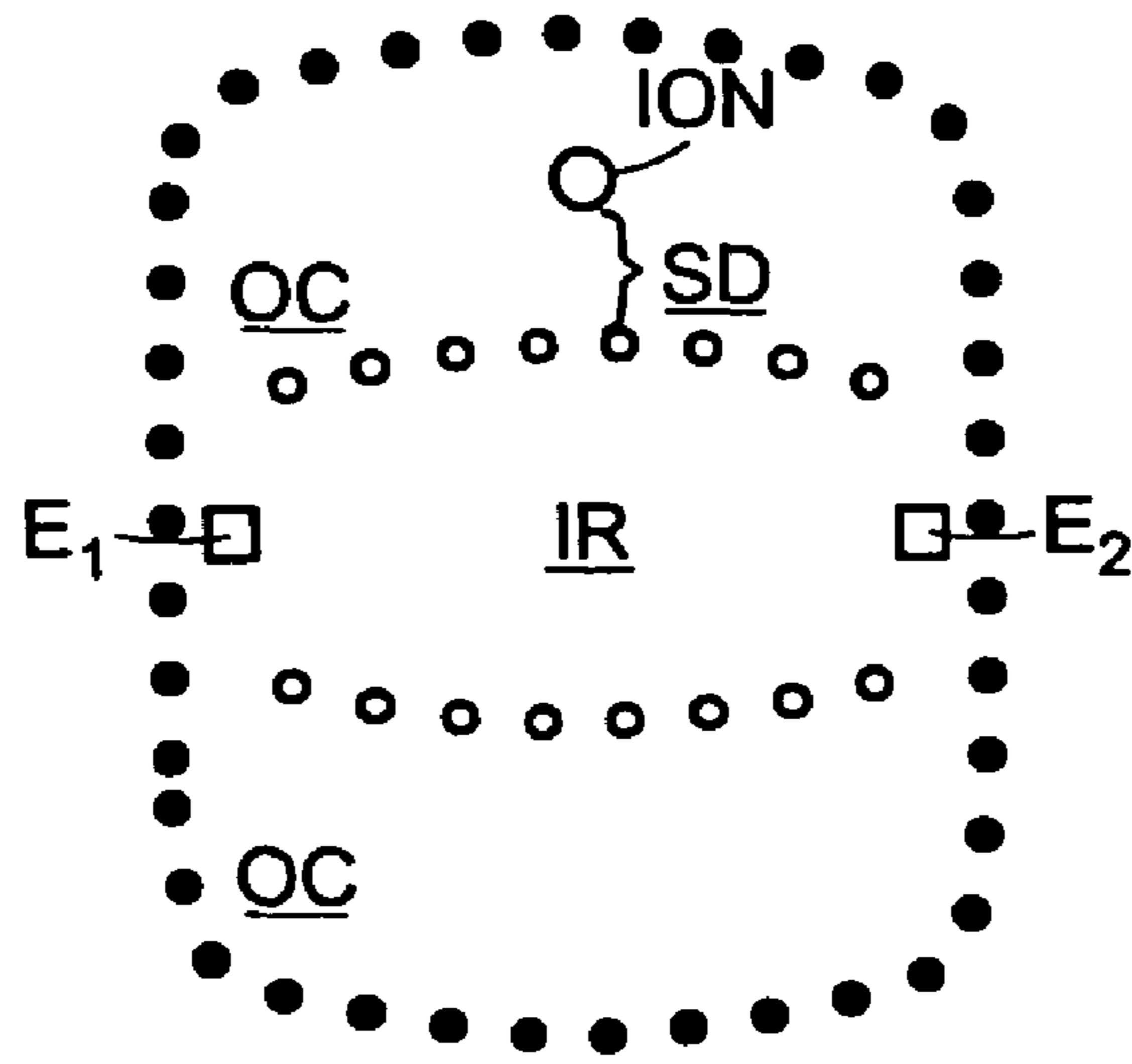


FIG. 10A

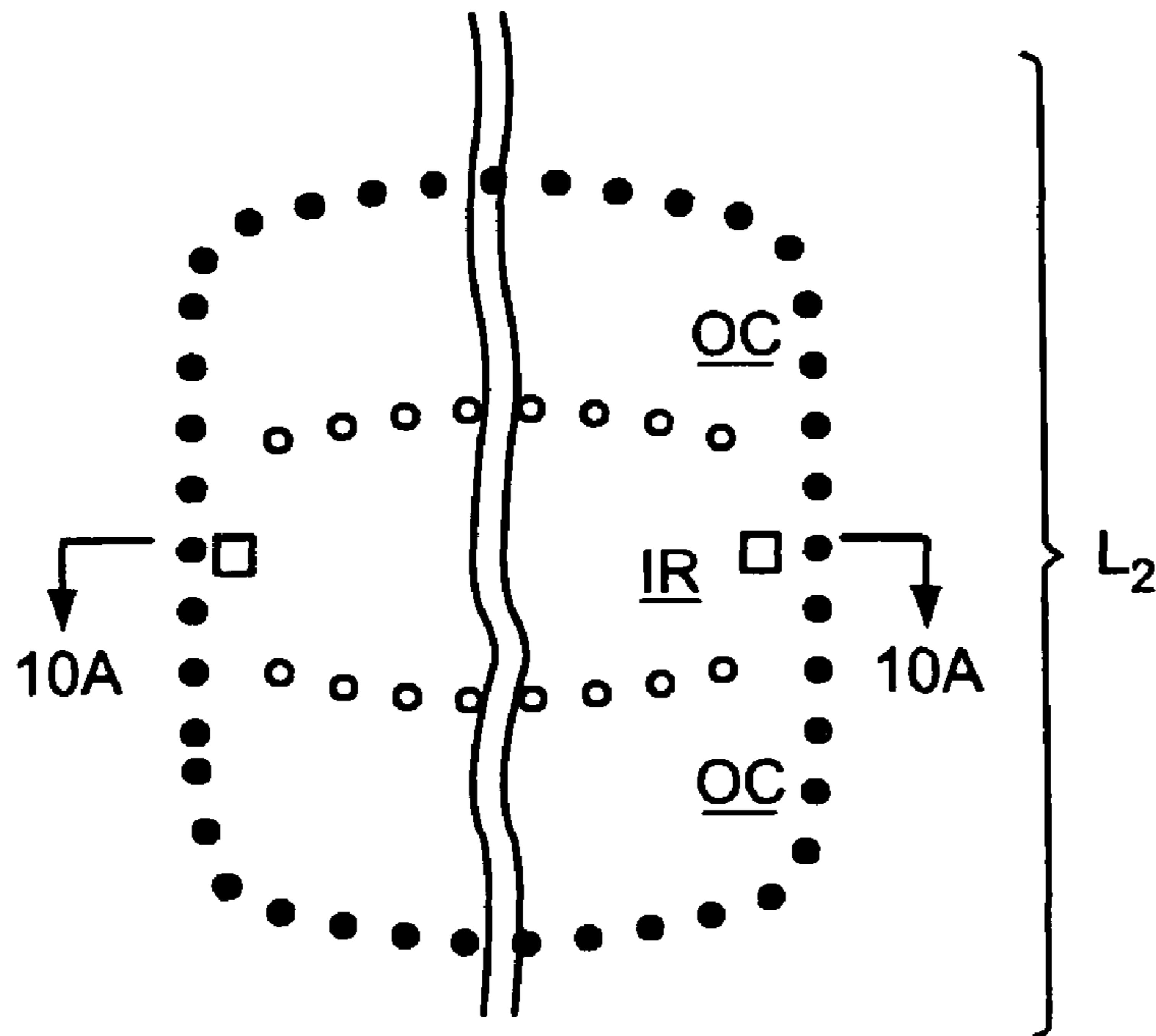


FIG. 10B

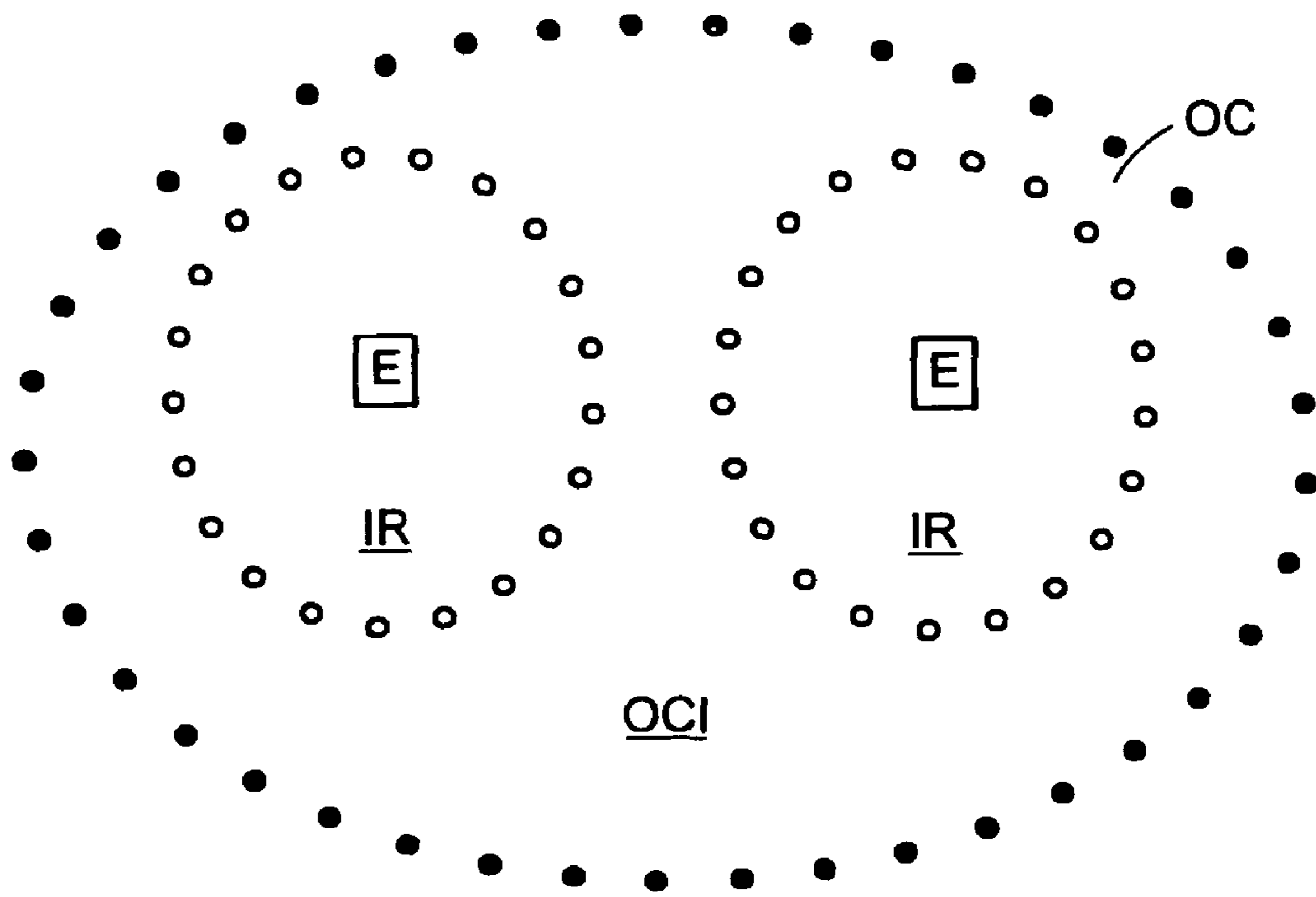


FIG. 11

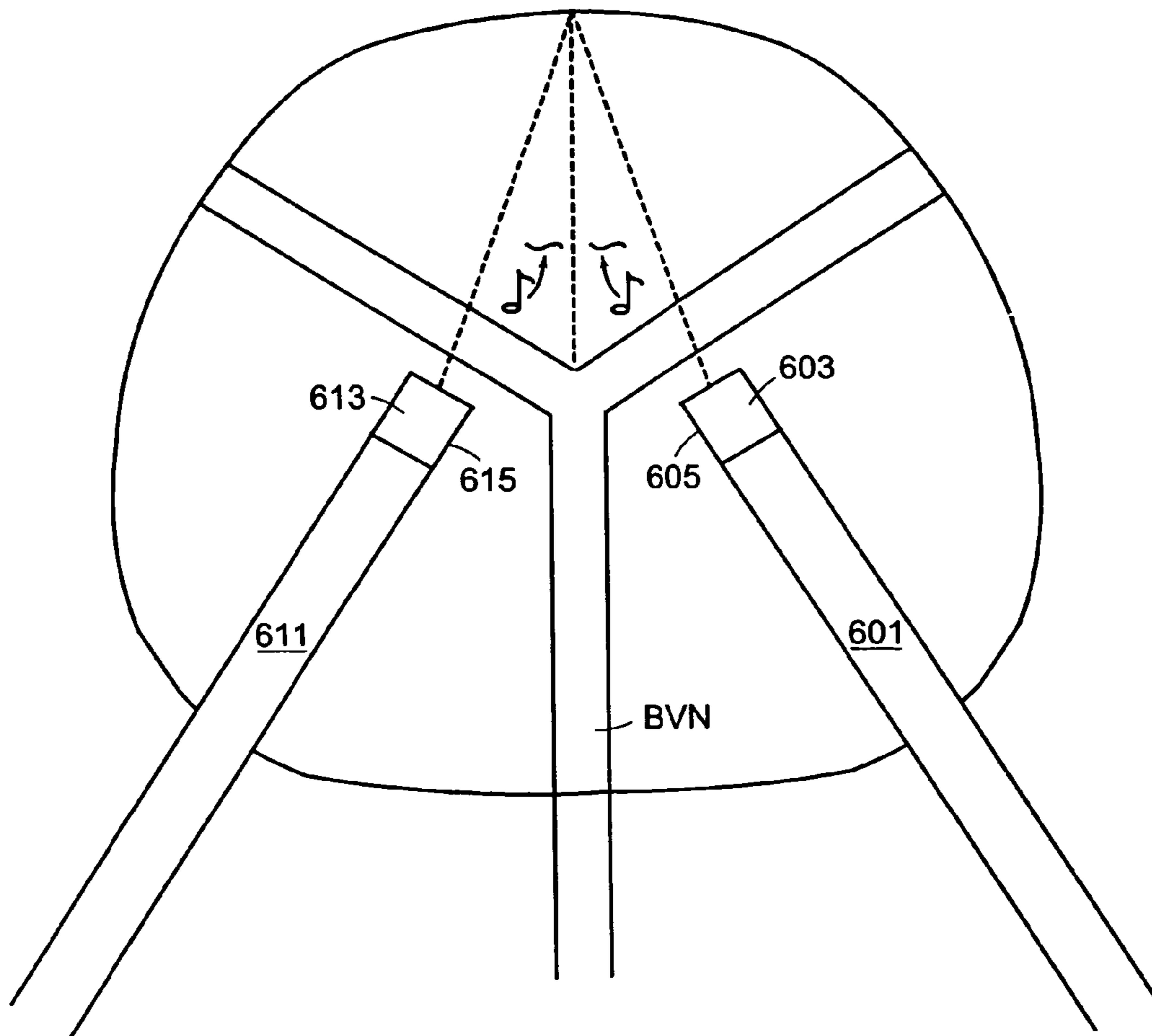


FIG. 12

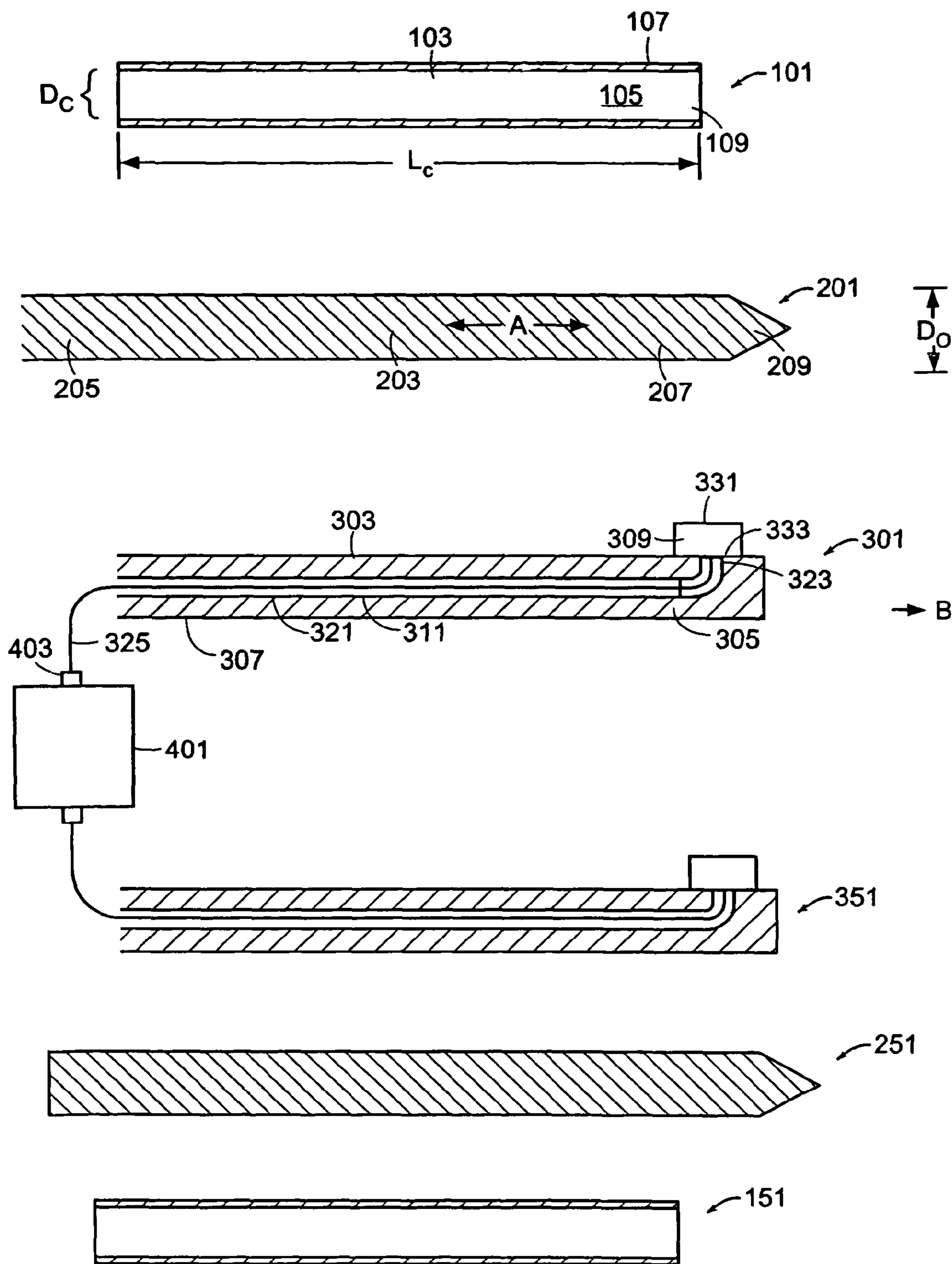


FIG. 13

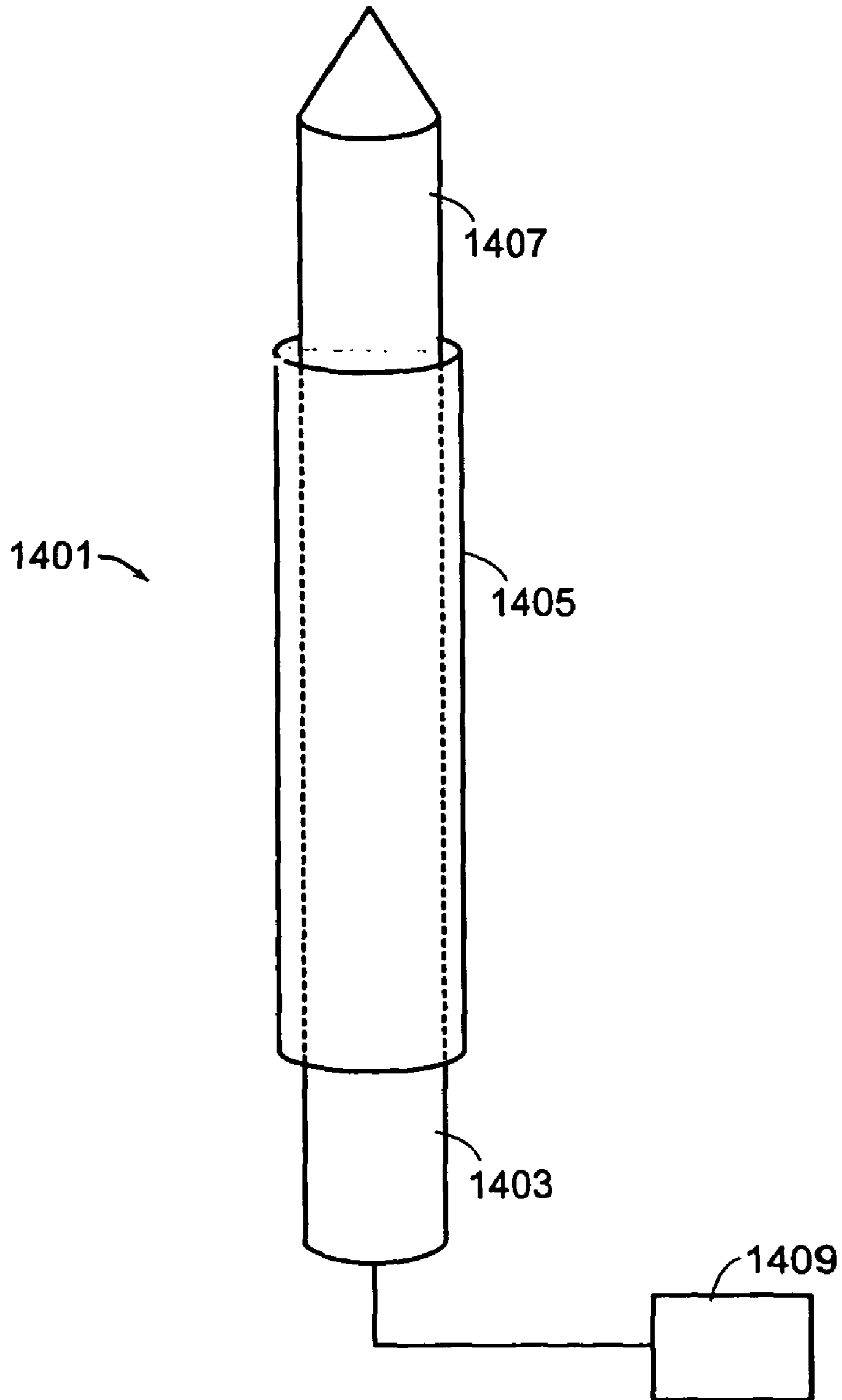


FIG. 14

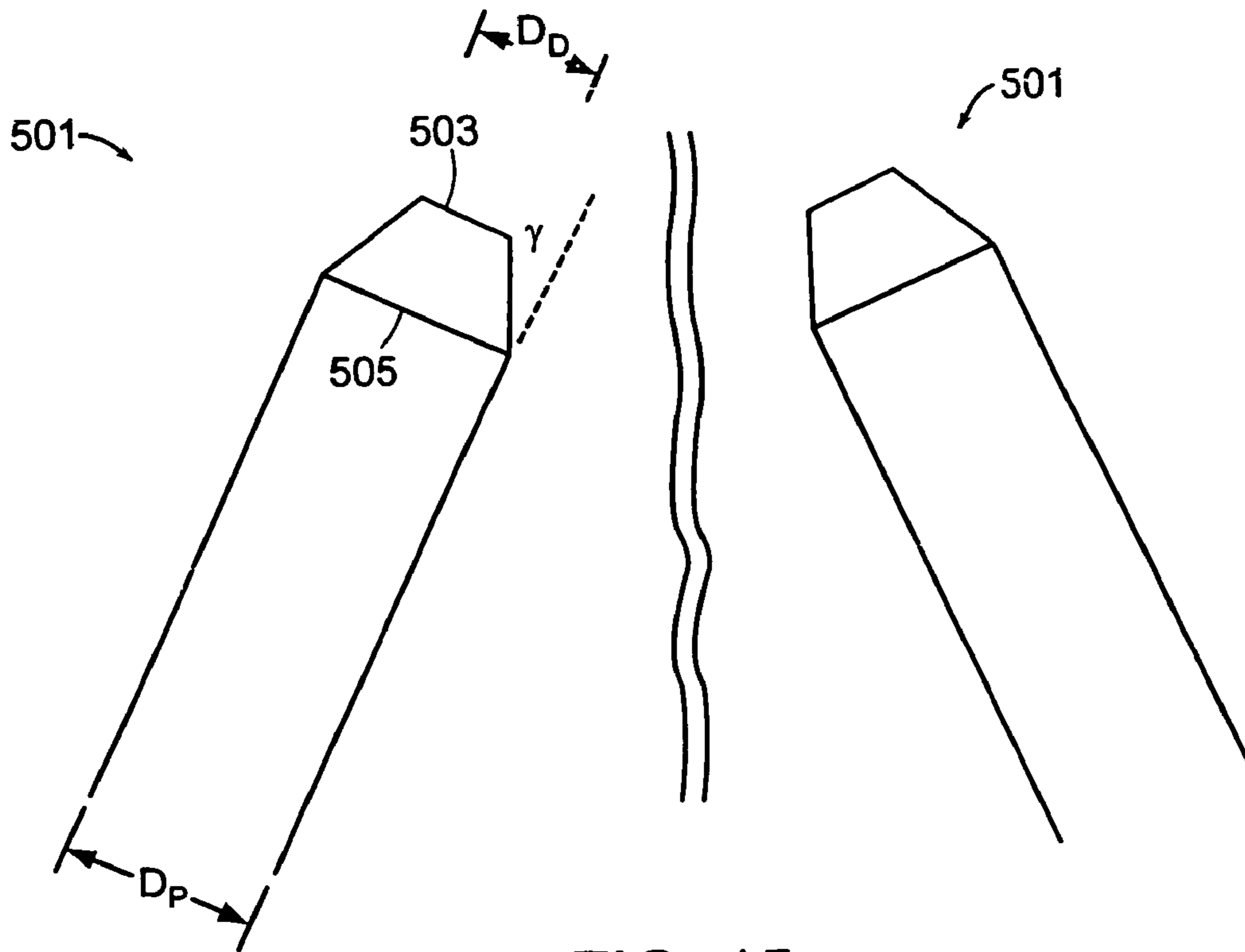


FIG. 15

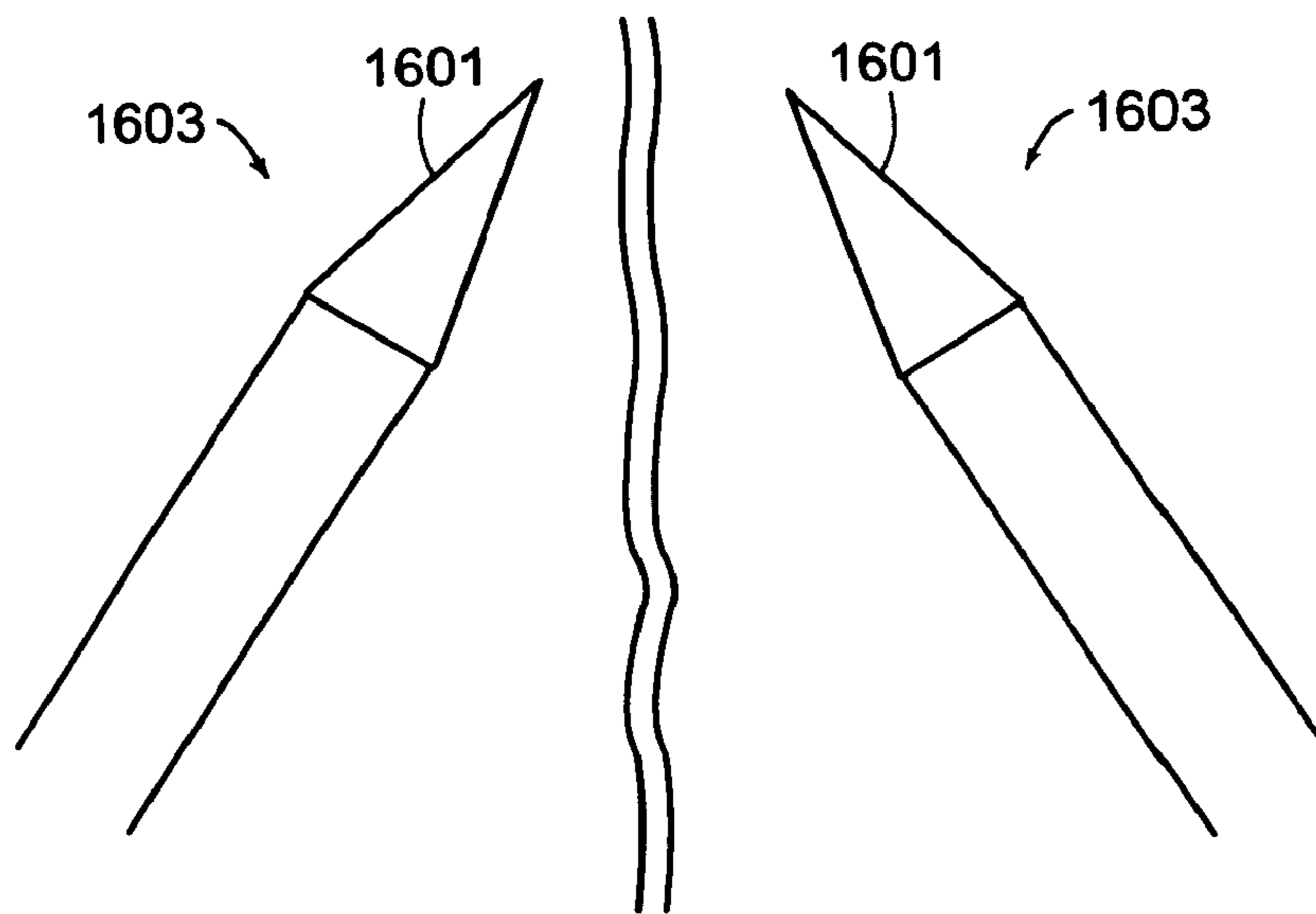


FIG. 16

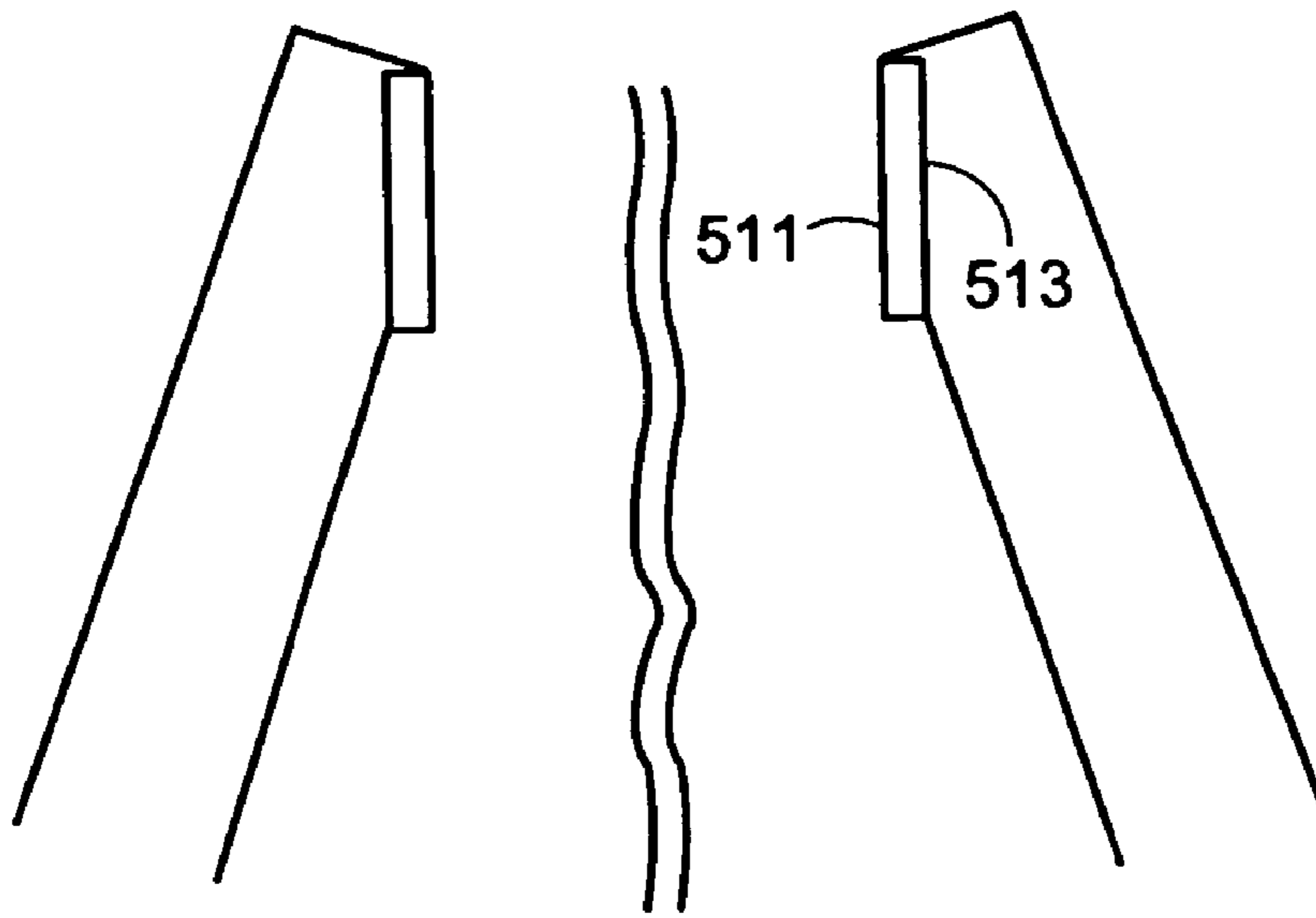


FIG. 17

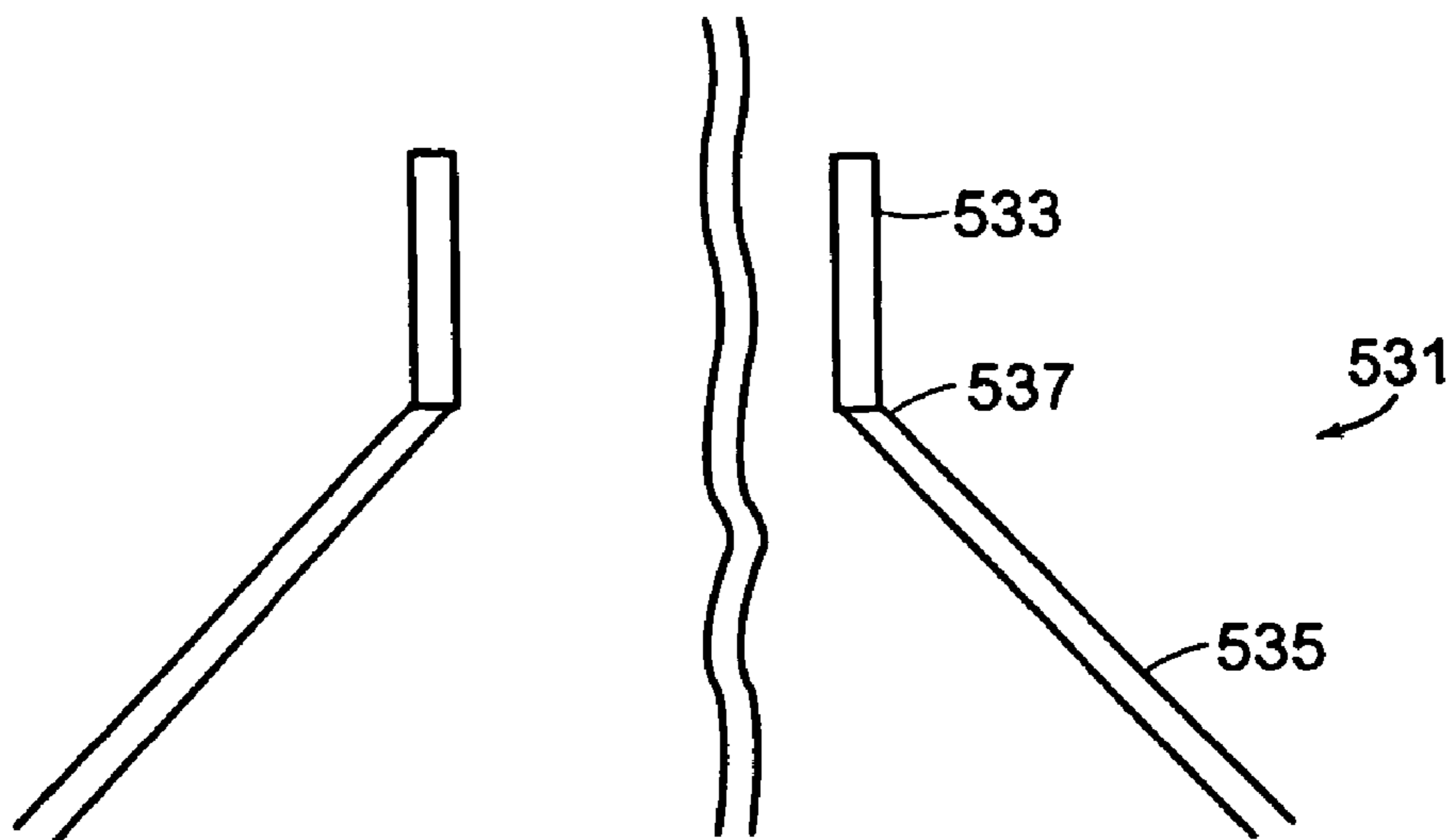


FIG. 18

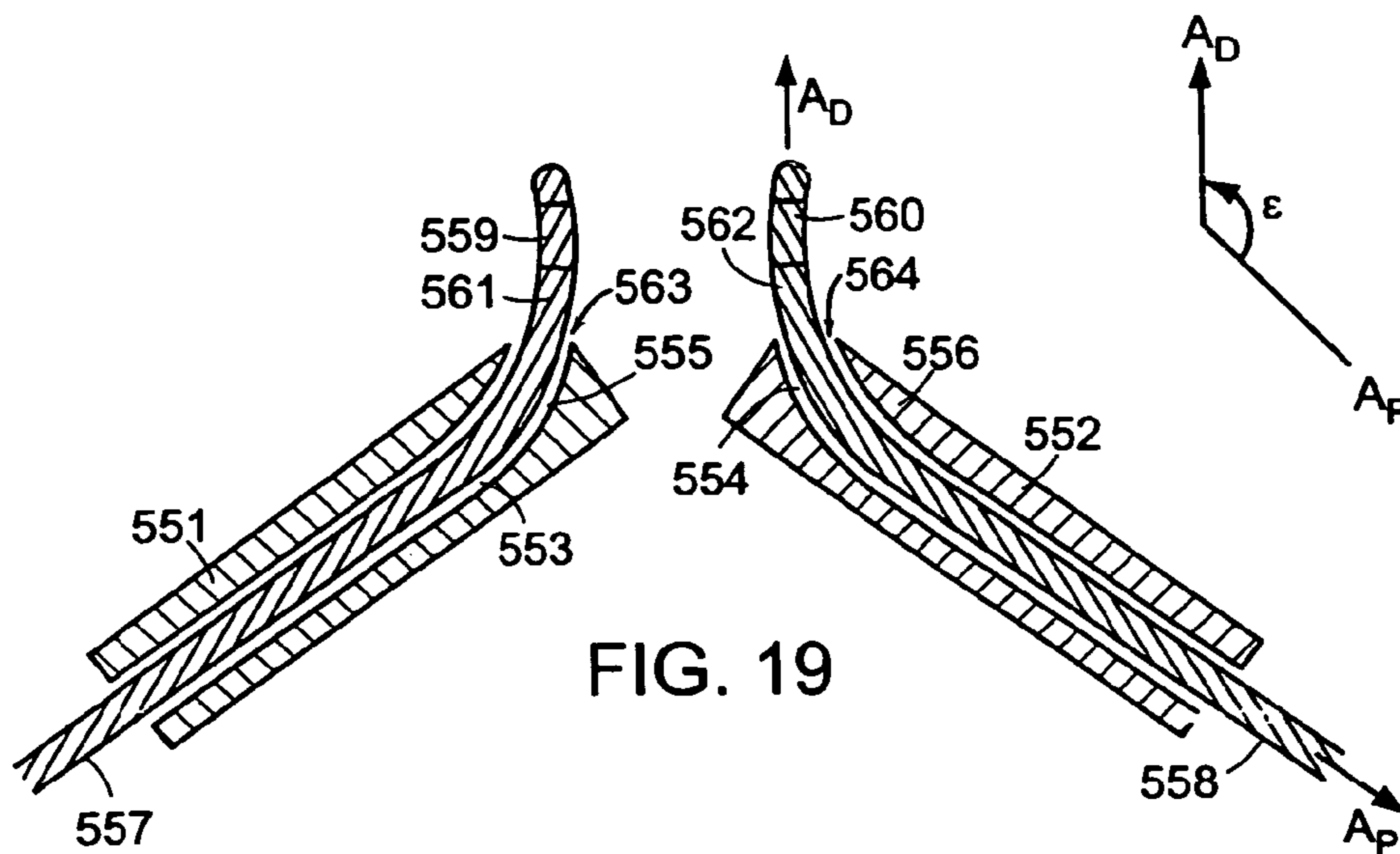


FIG. 19

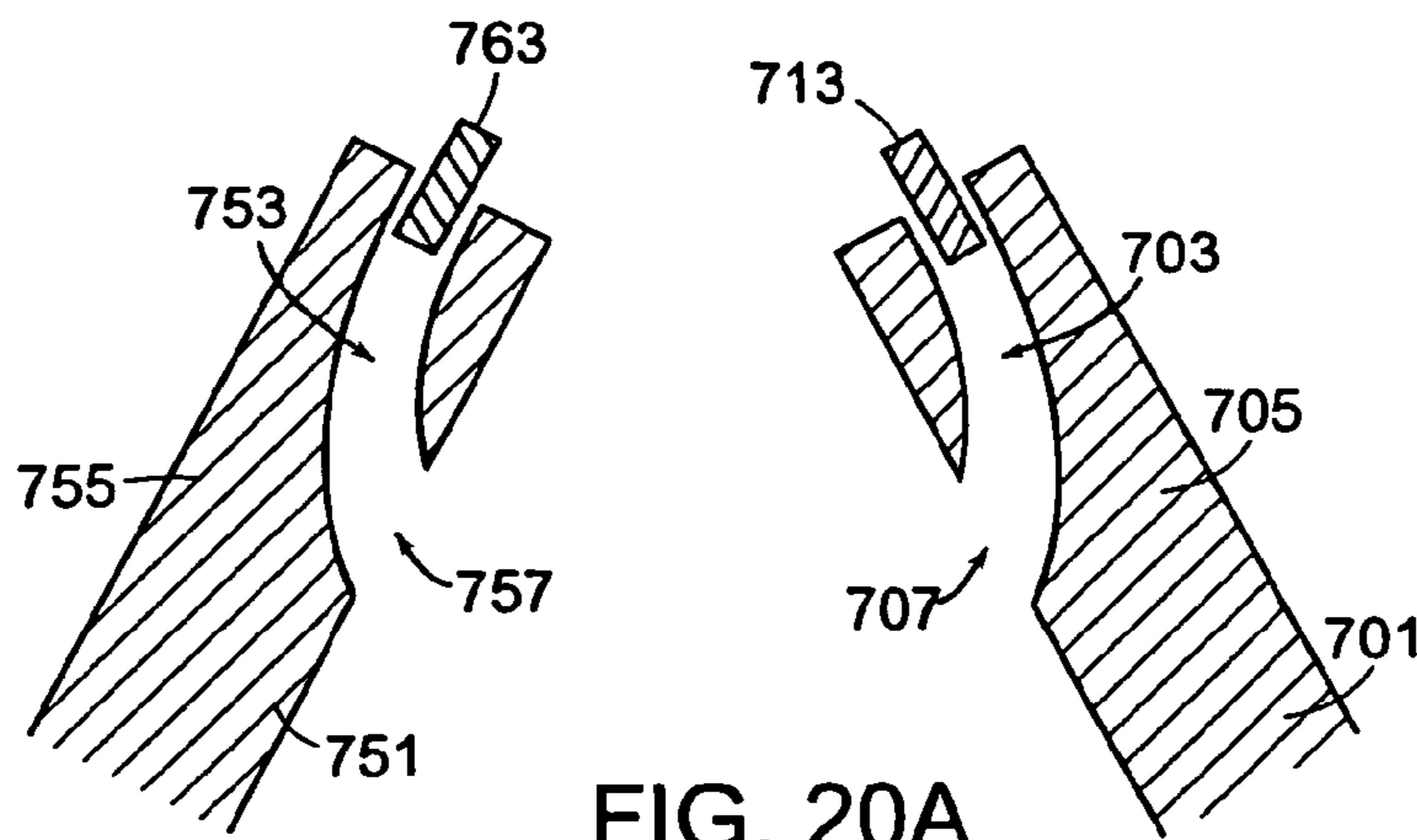


FIG. 20A

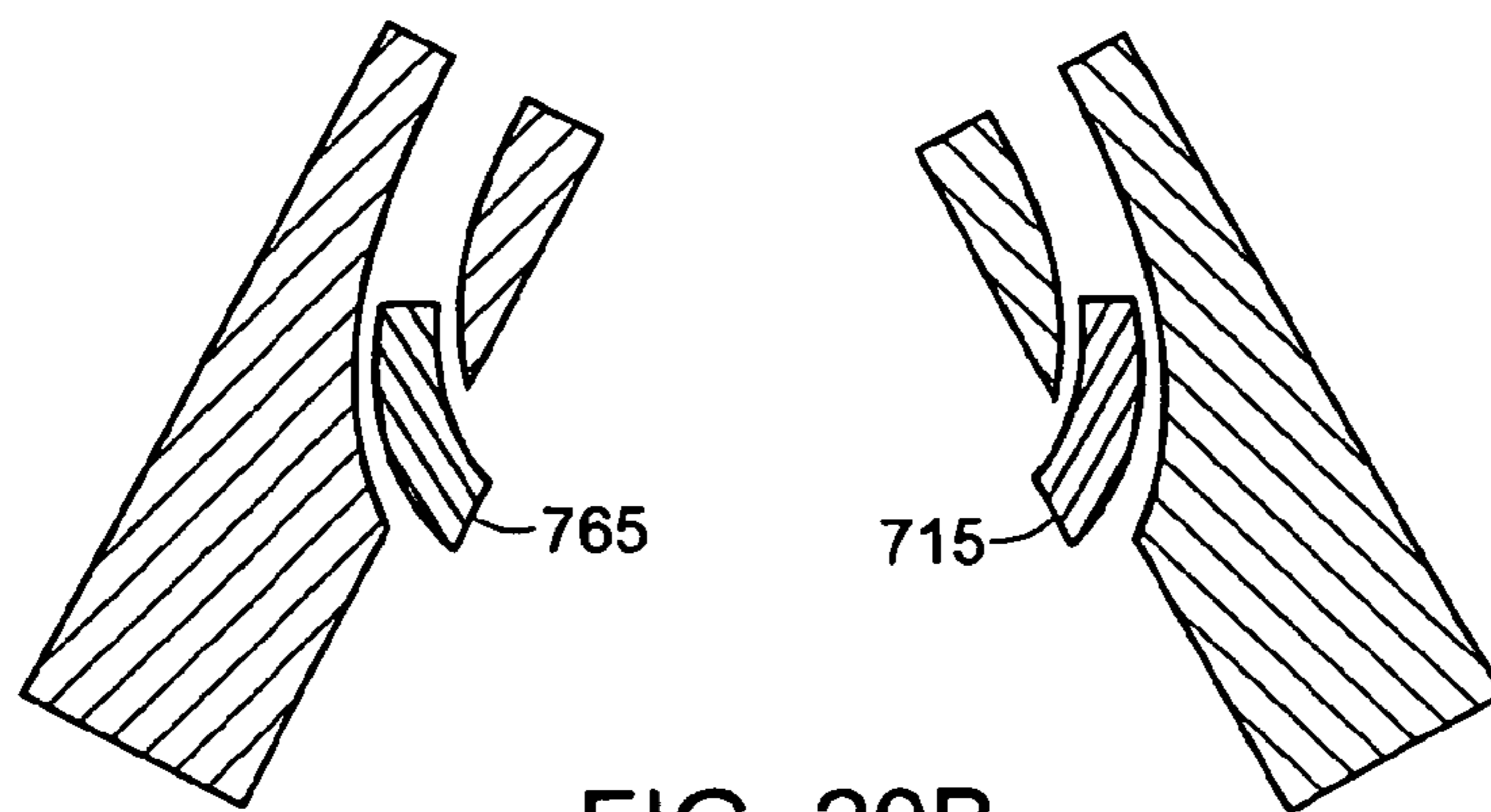


FIG. 20B

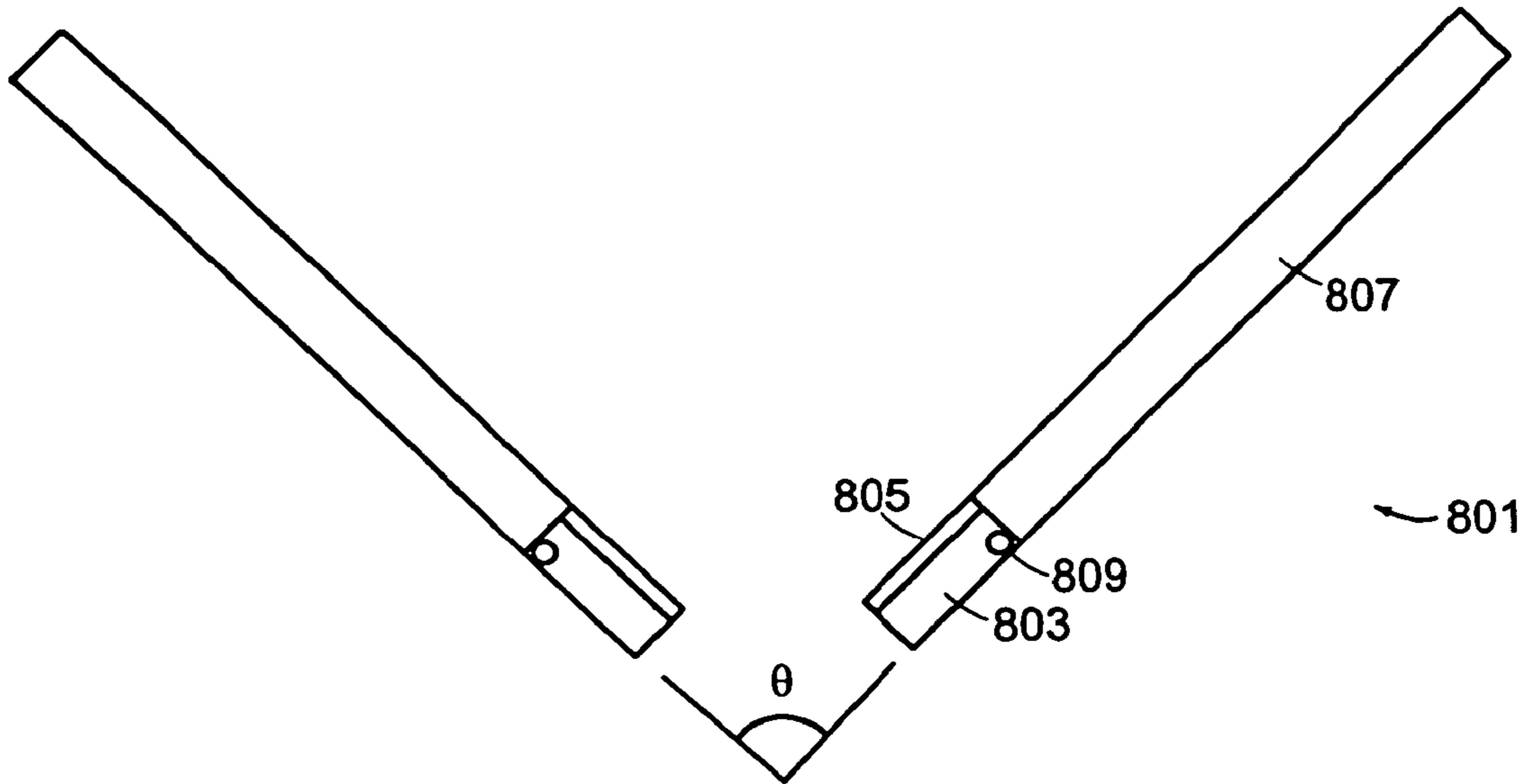


FIG. 21A

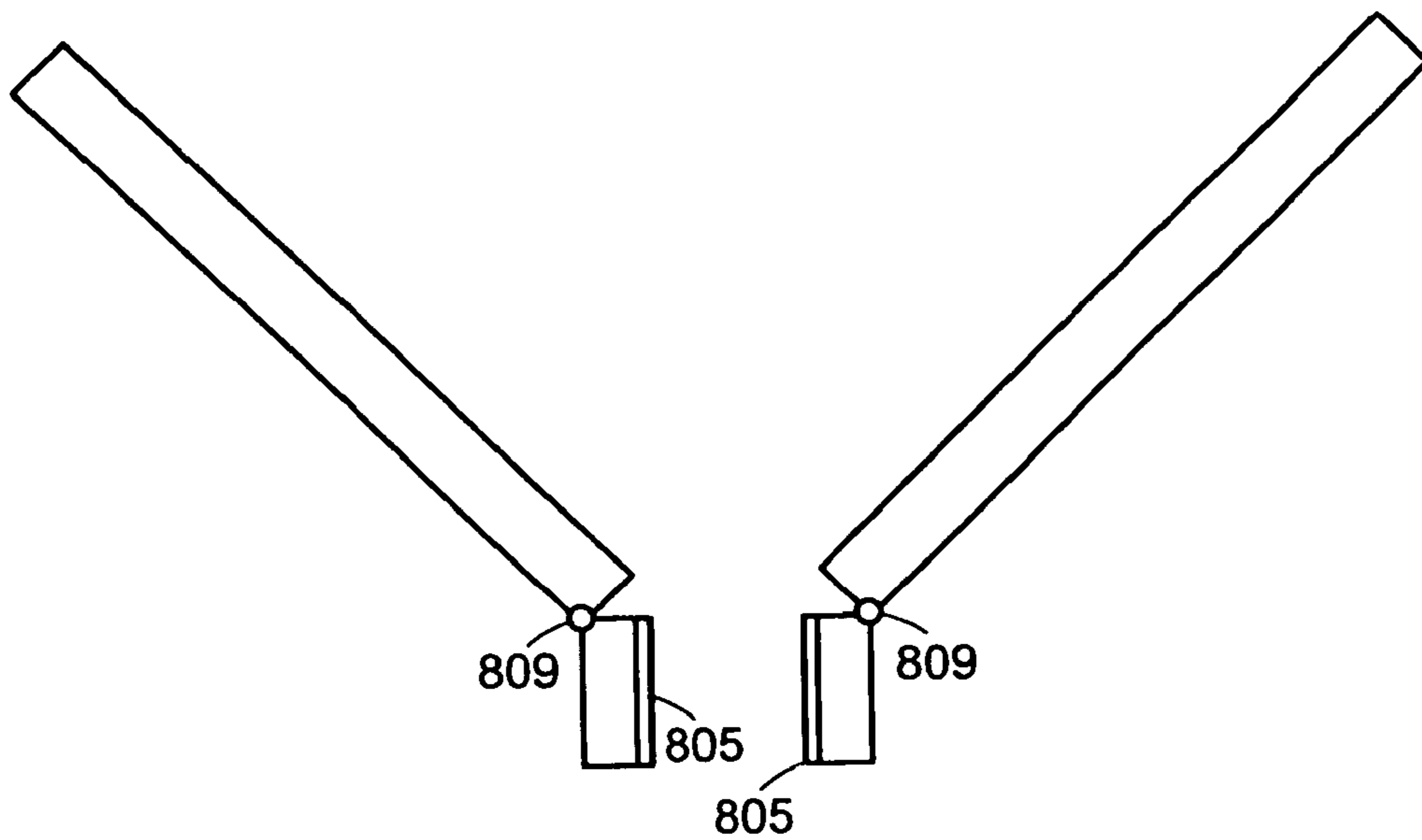


FIG. 21B

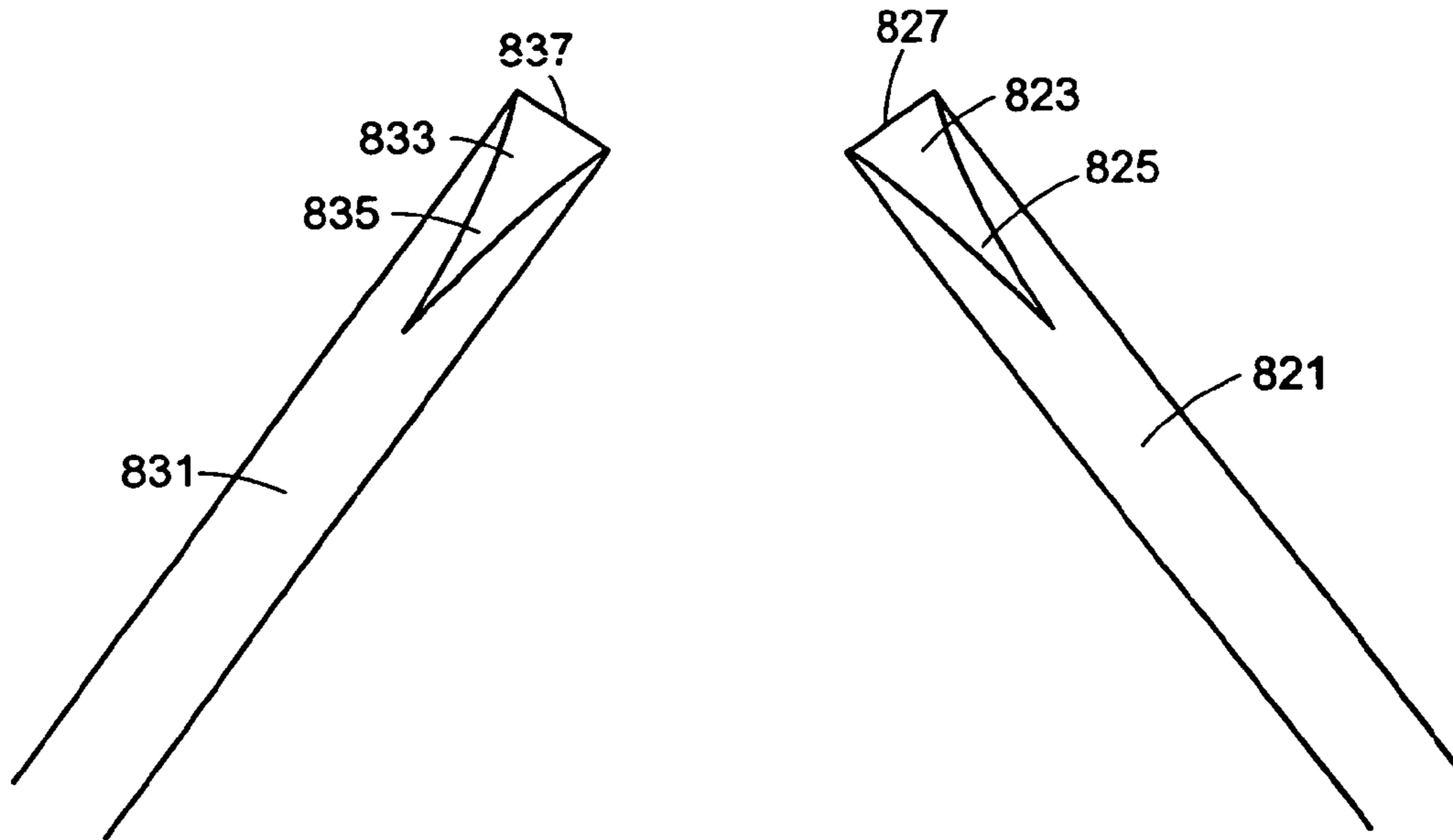


FIG. 22

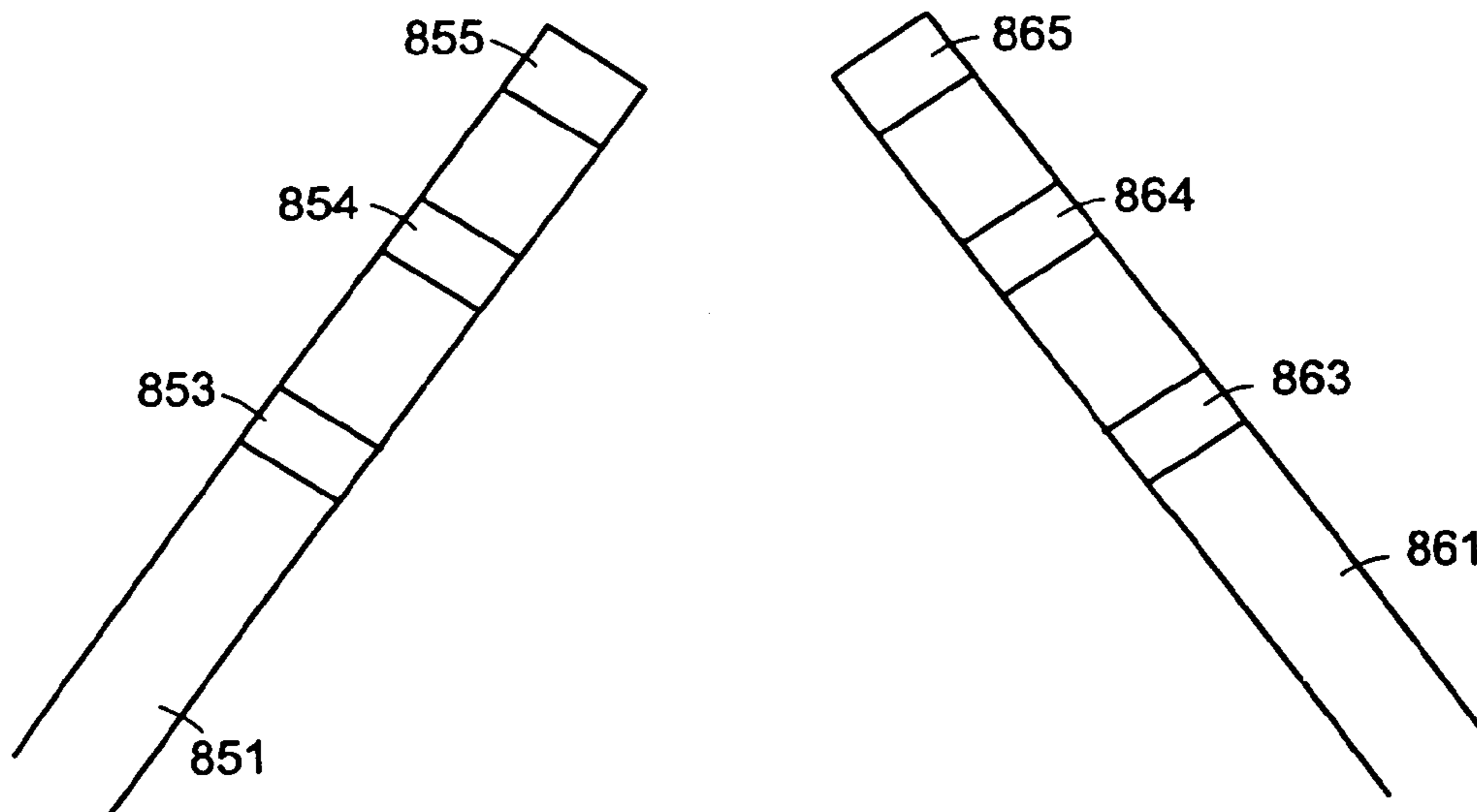


FIG. 23

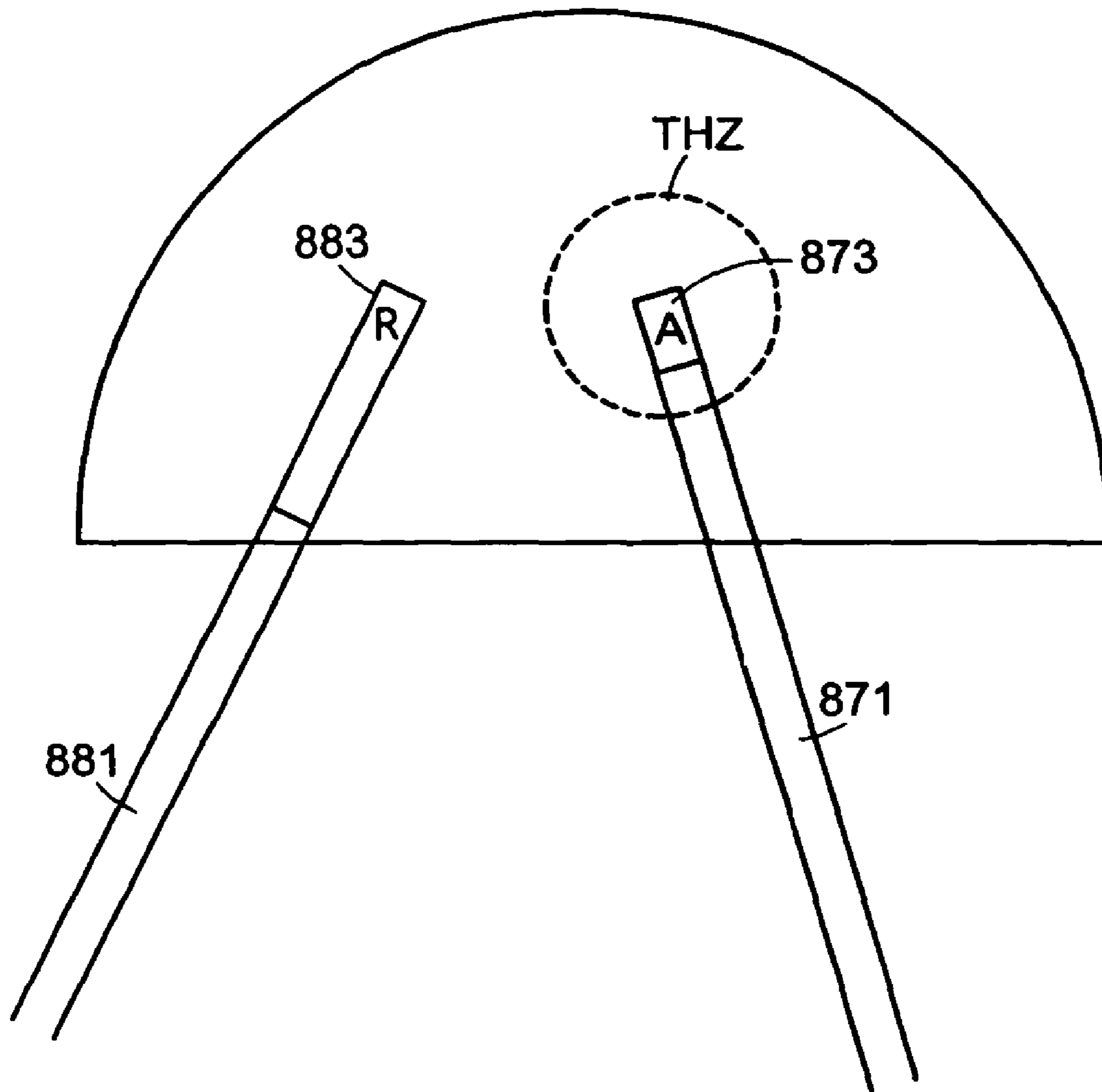


FIG. 24

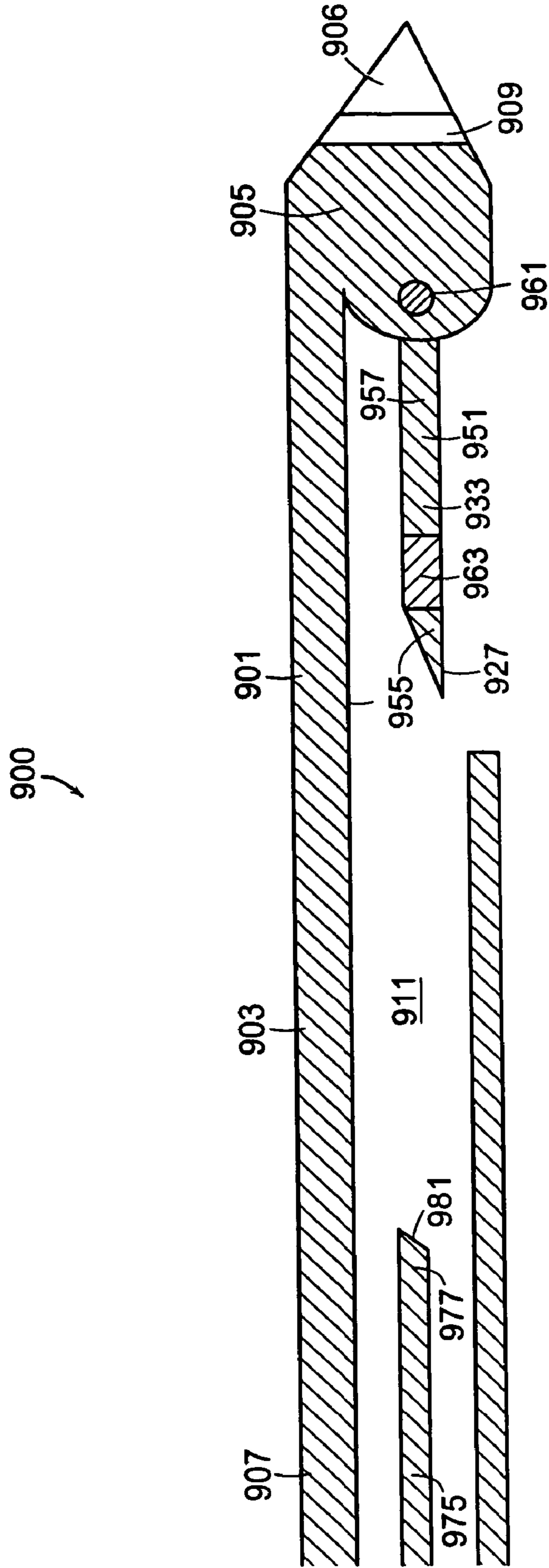


FIG. 25

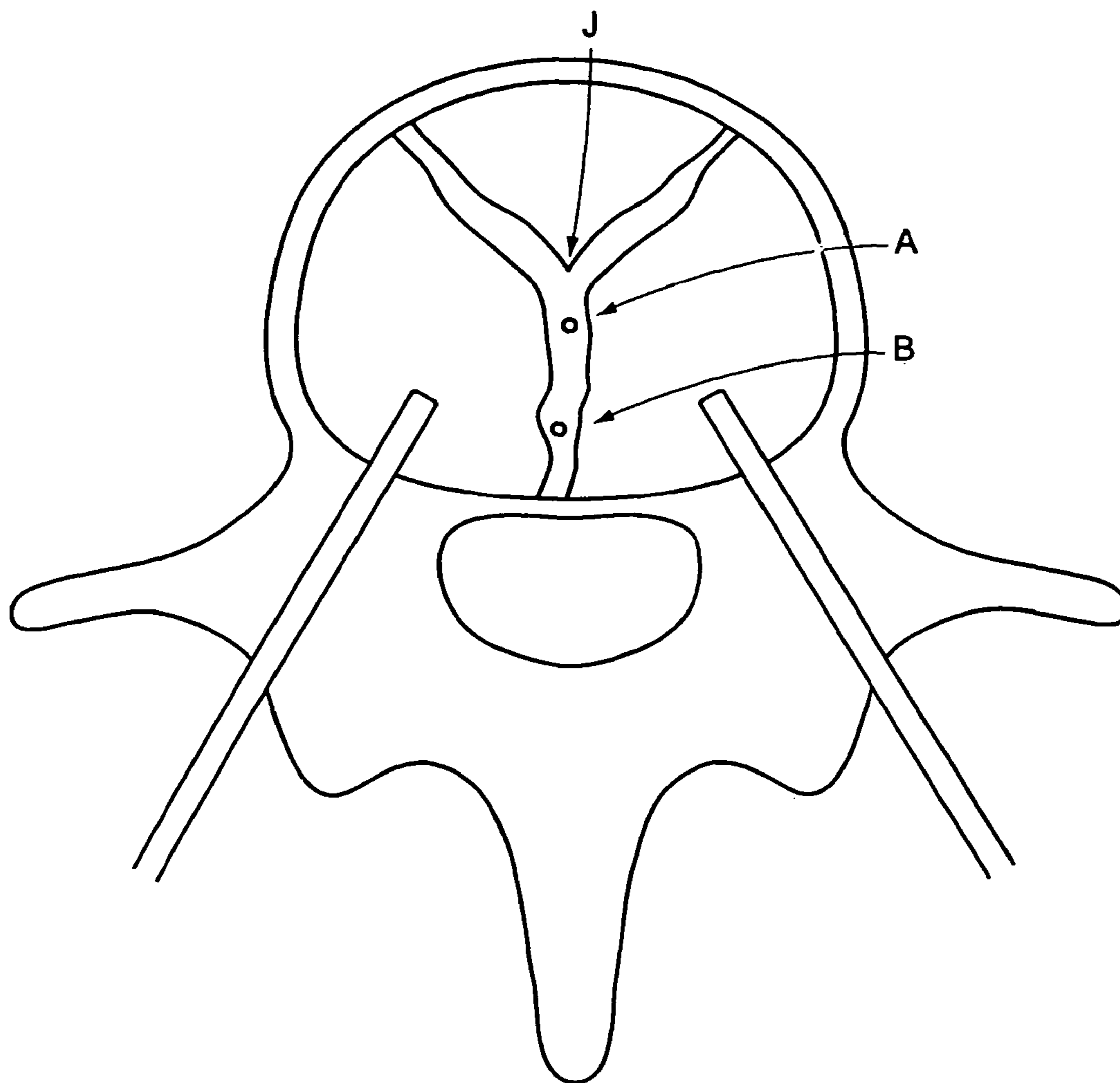


FIG. 26

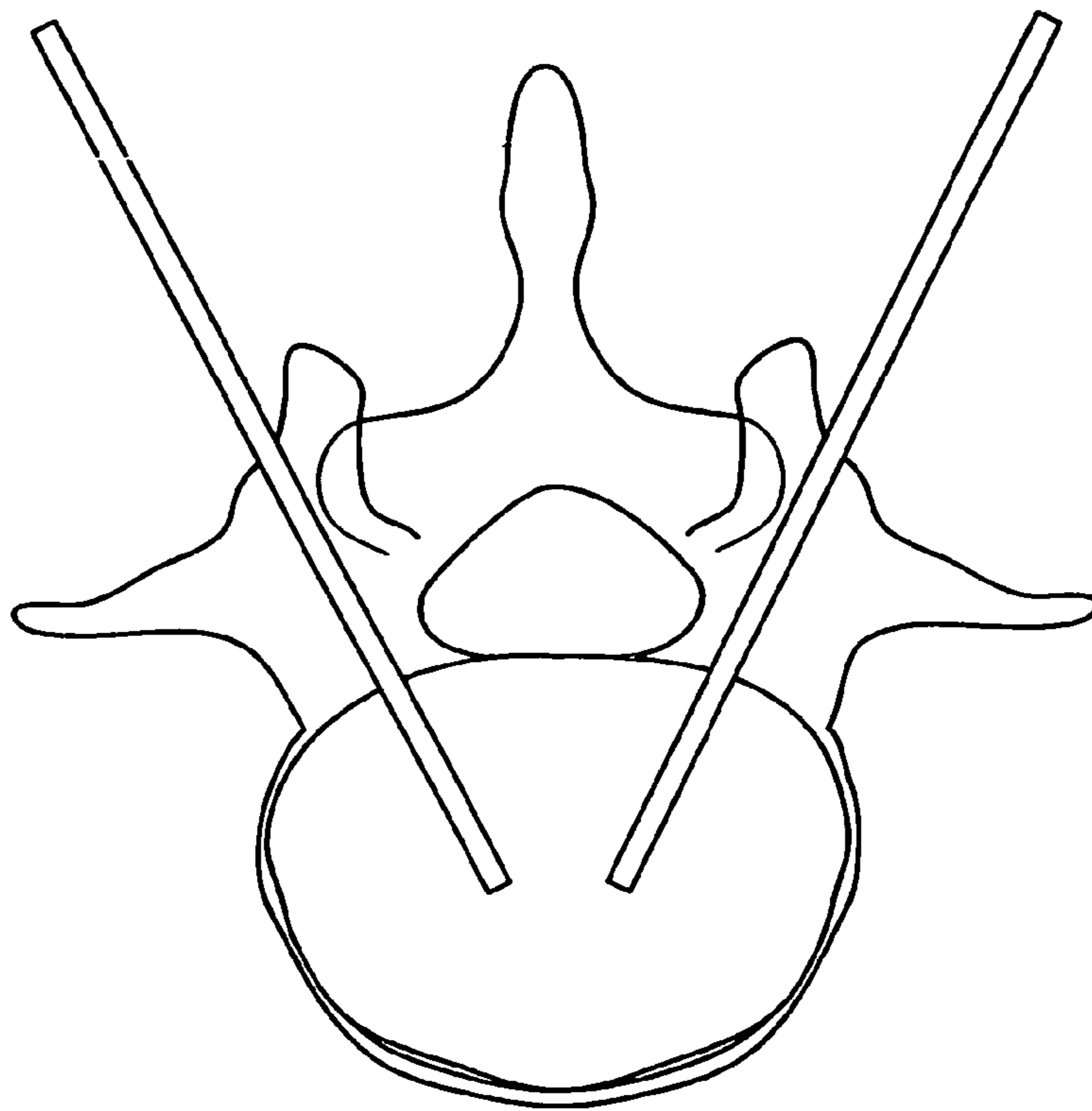


FIG. 27A

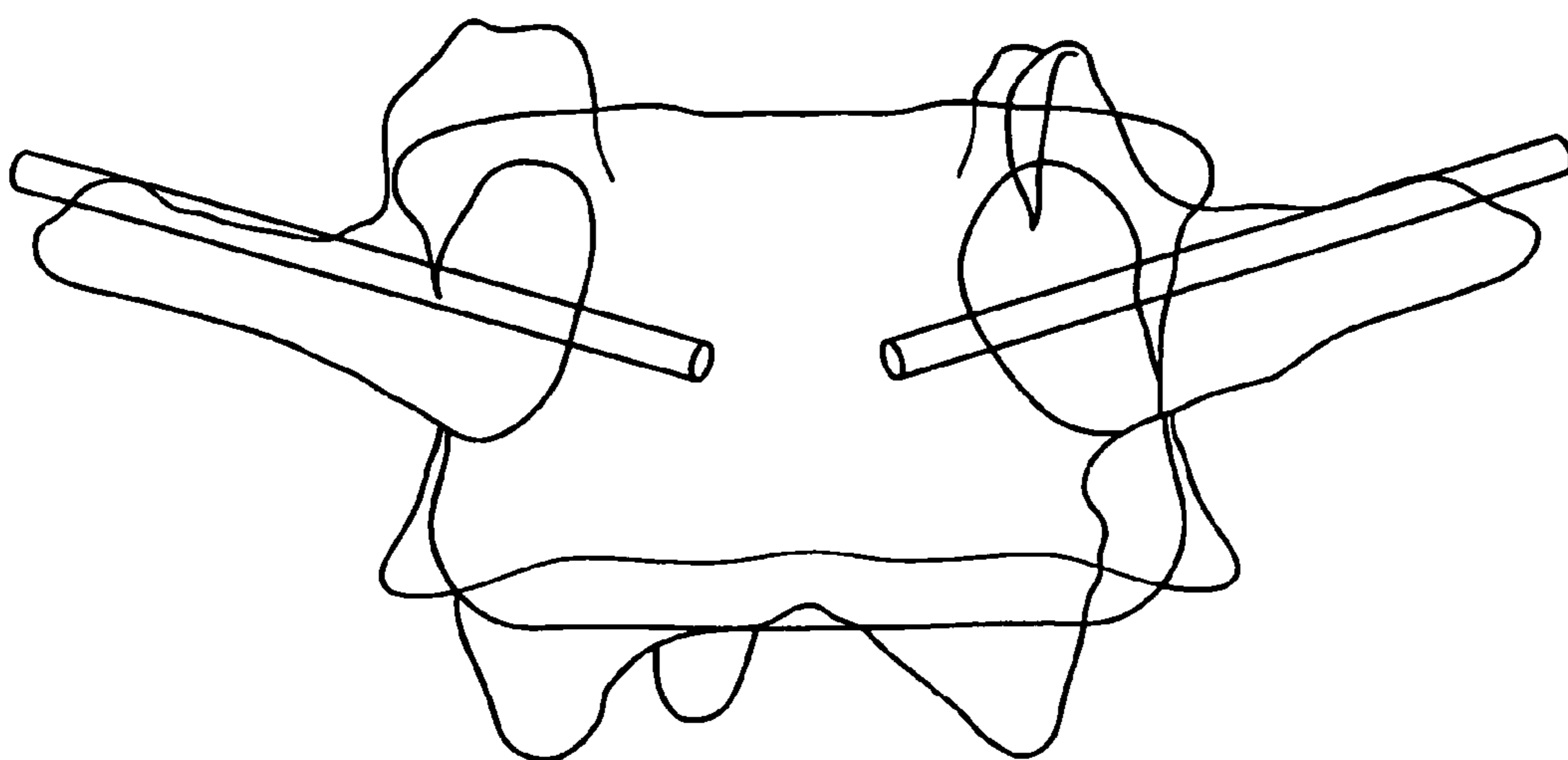


FIG. 27B

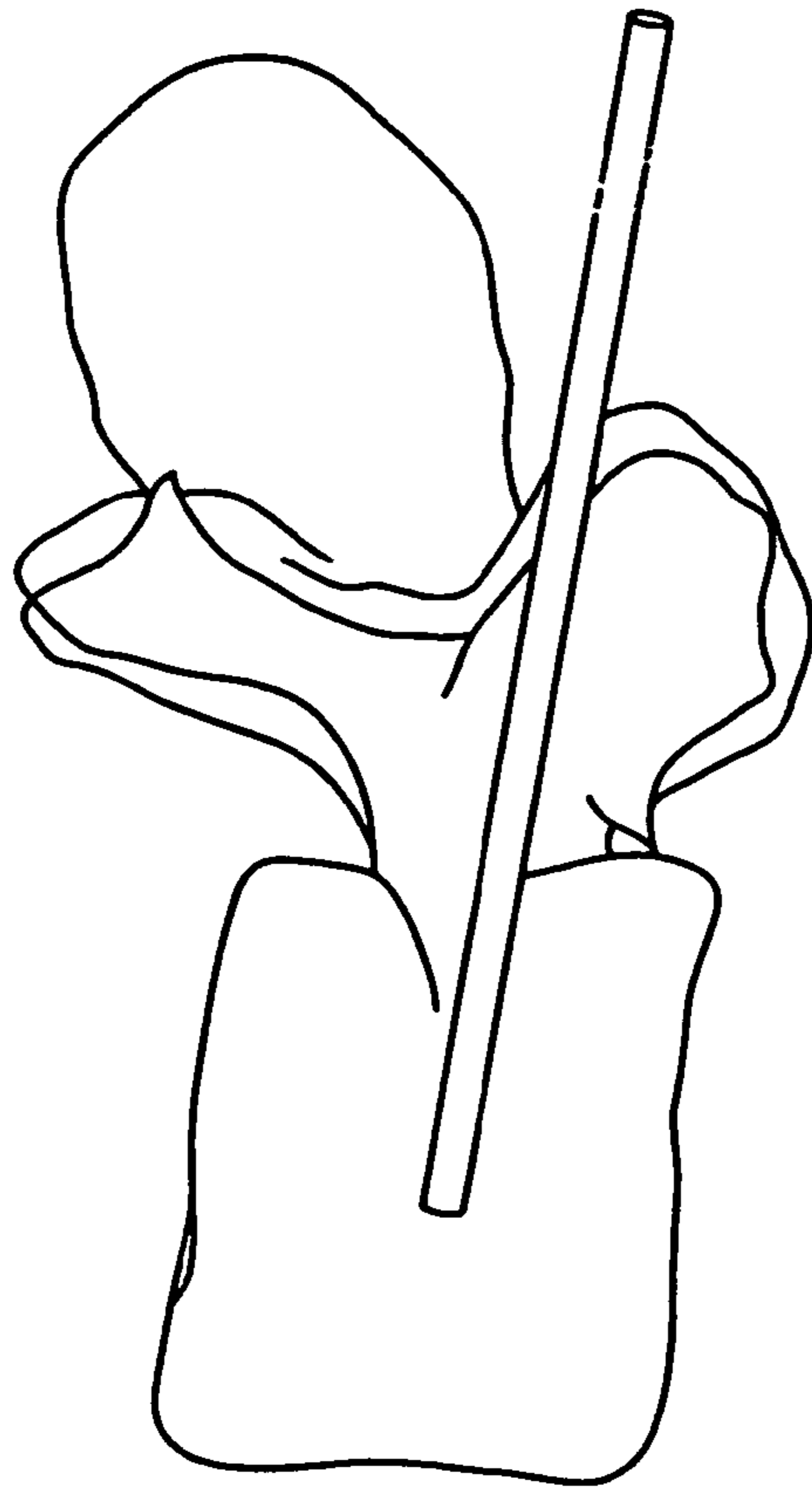


FIG. 27C

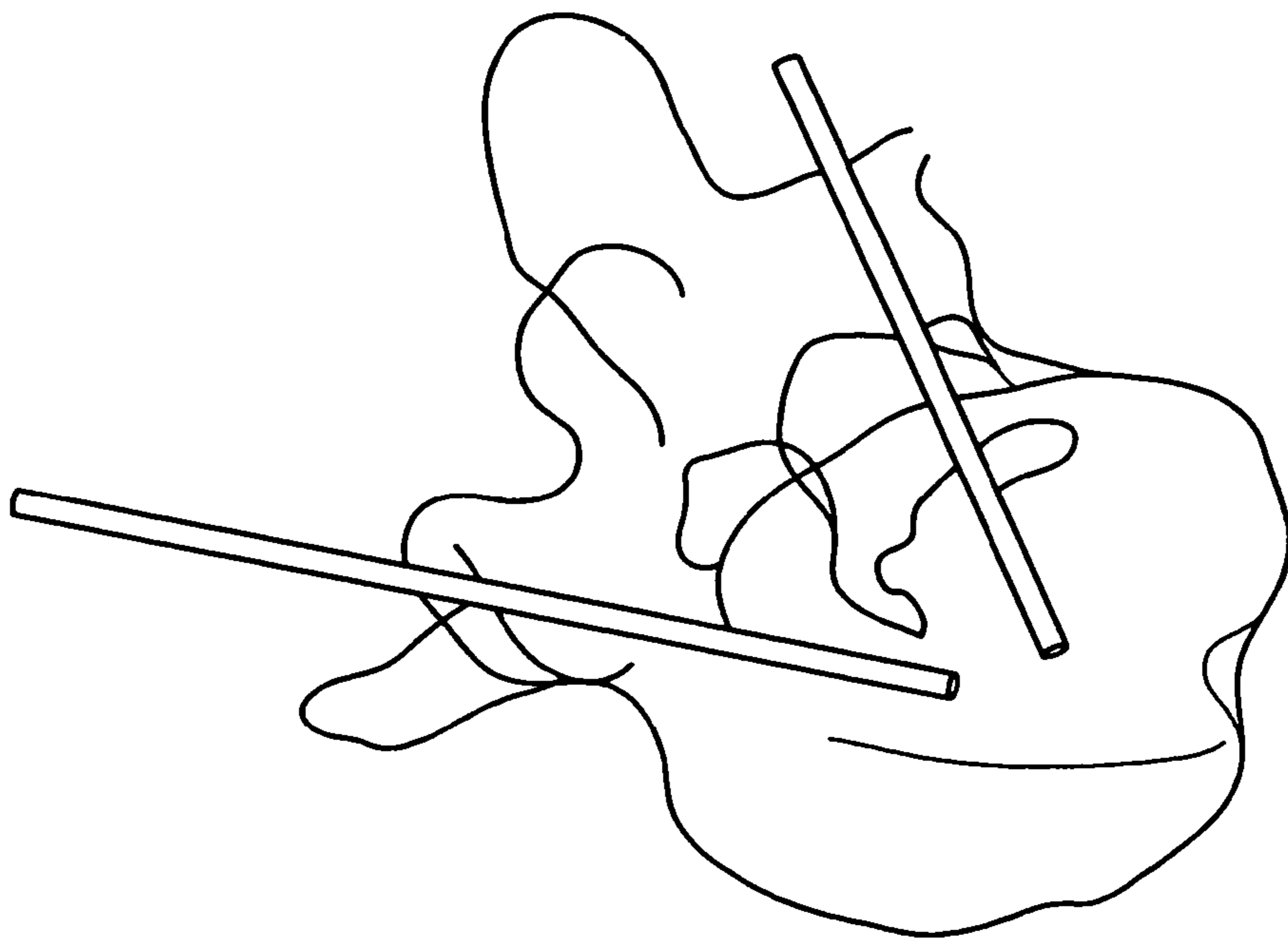


FIG. 27D

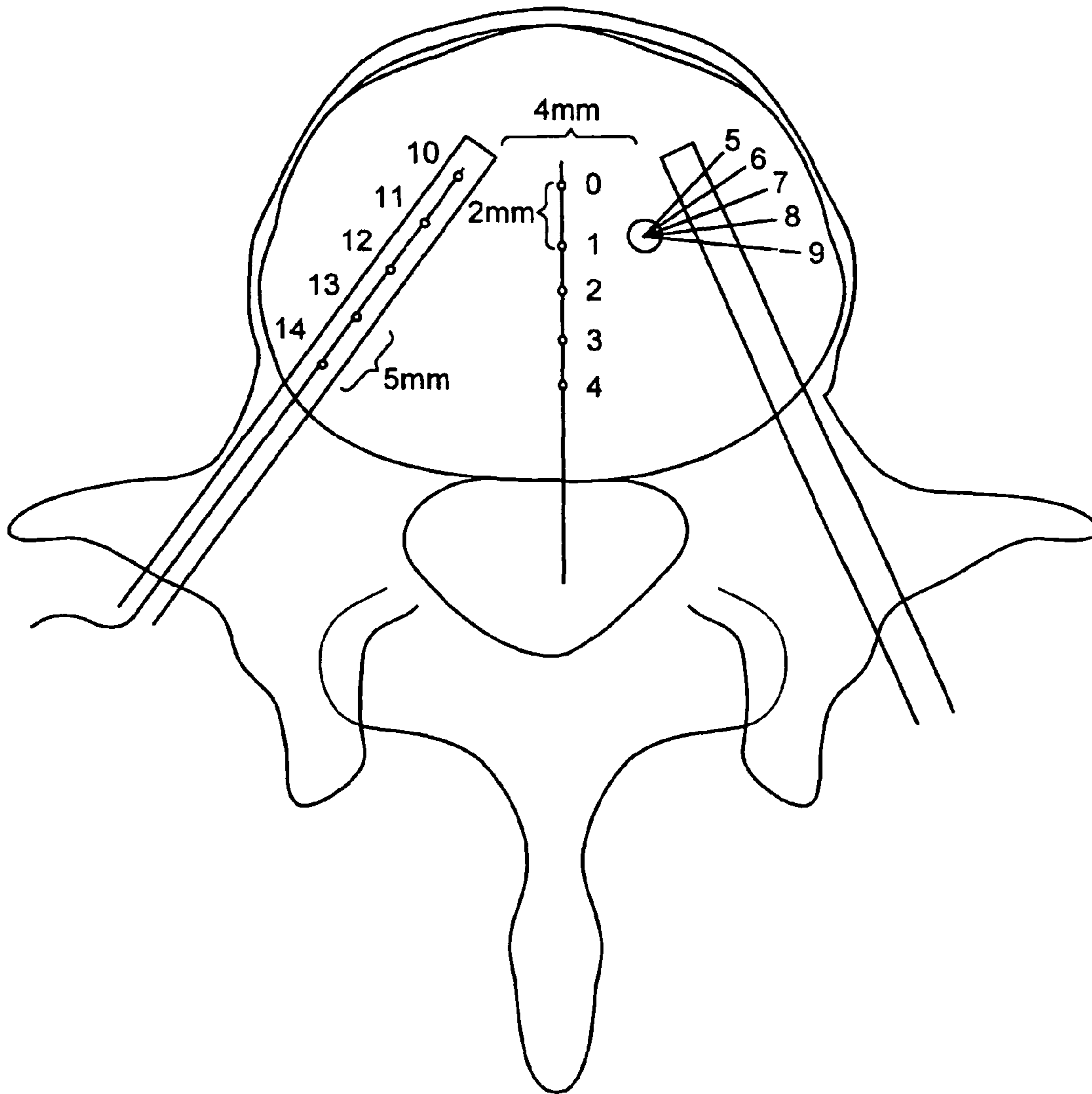


FIG. 28A

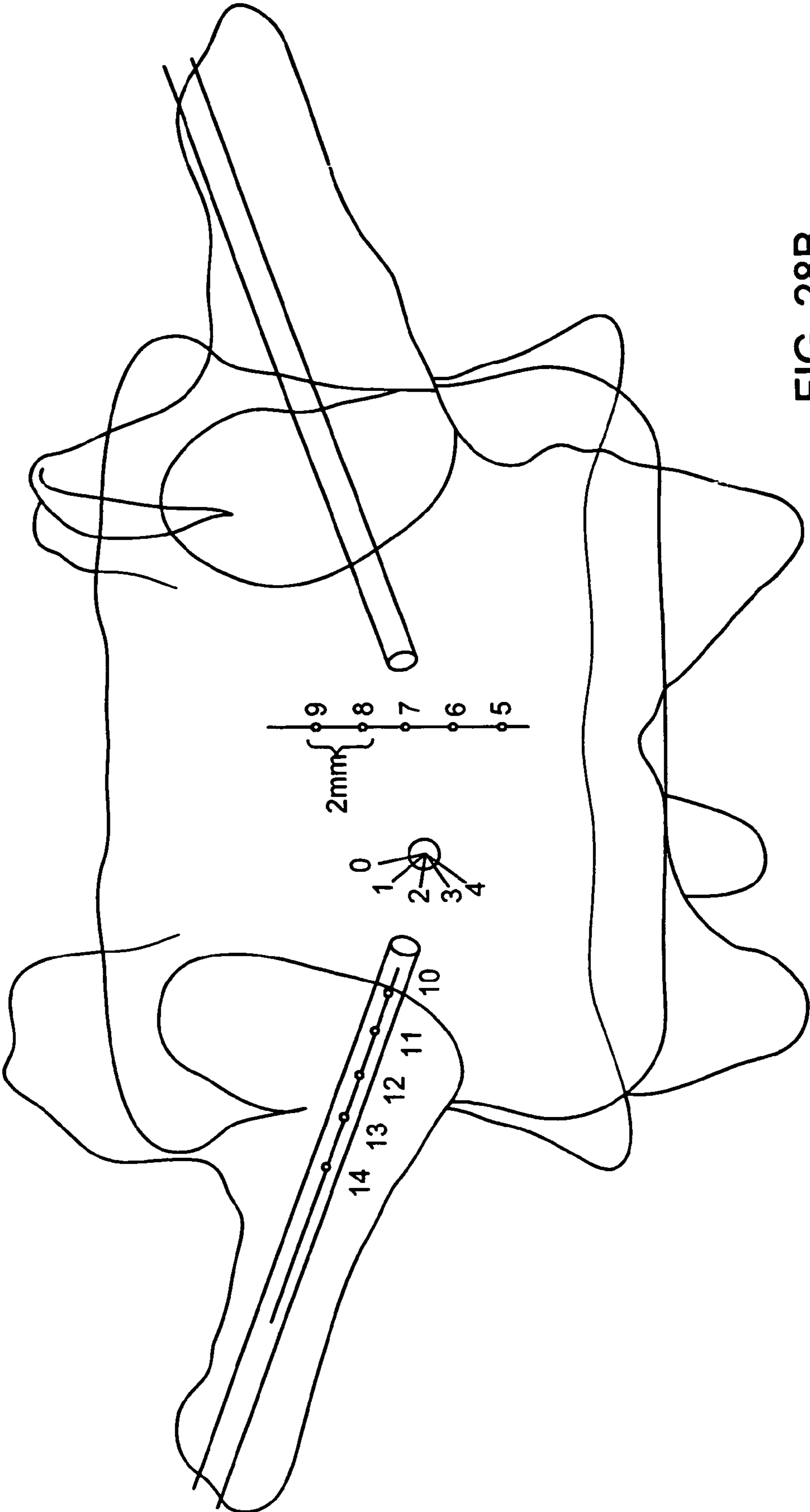


FIG. 28B

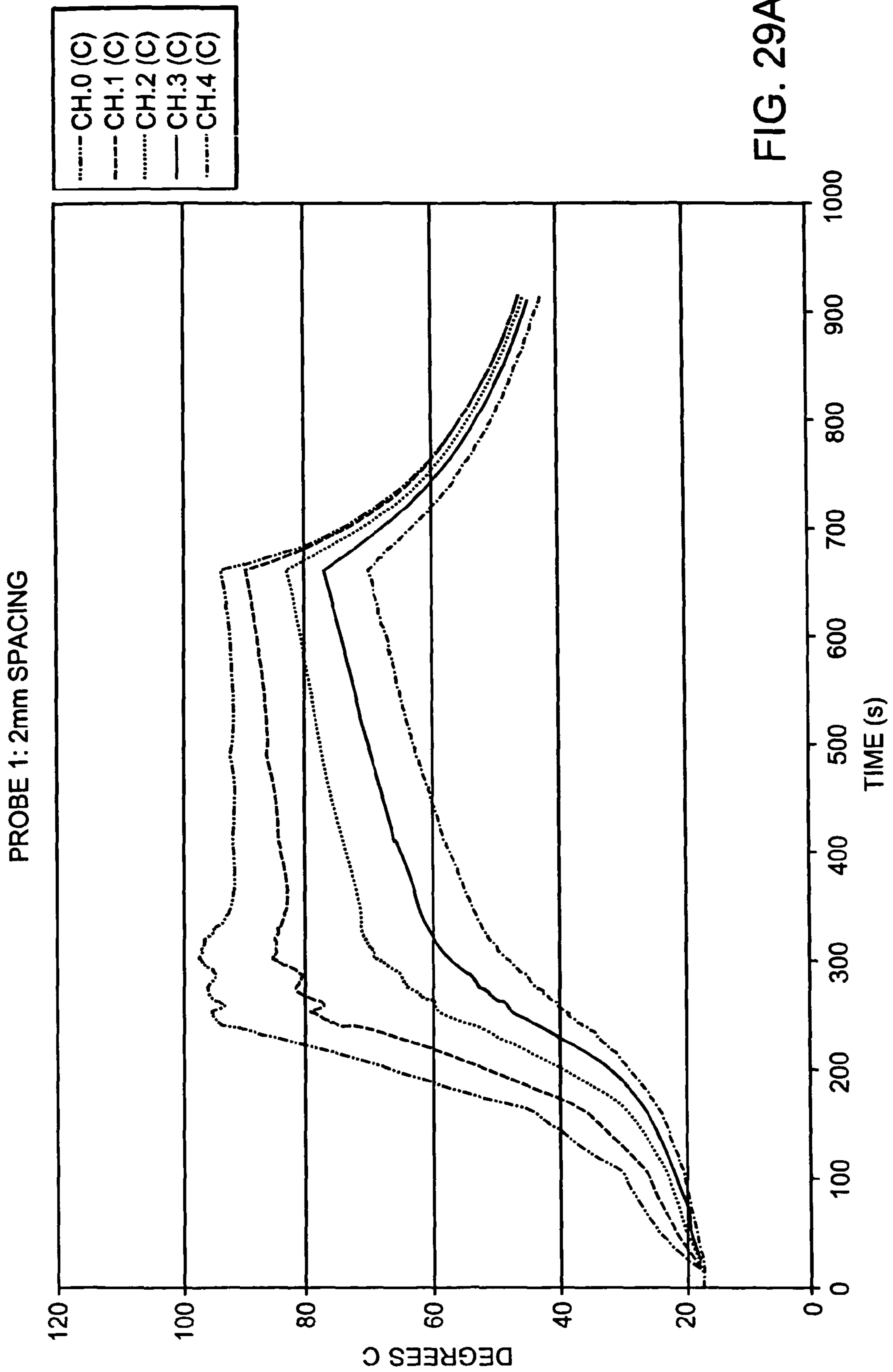


FIG. 29A

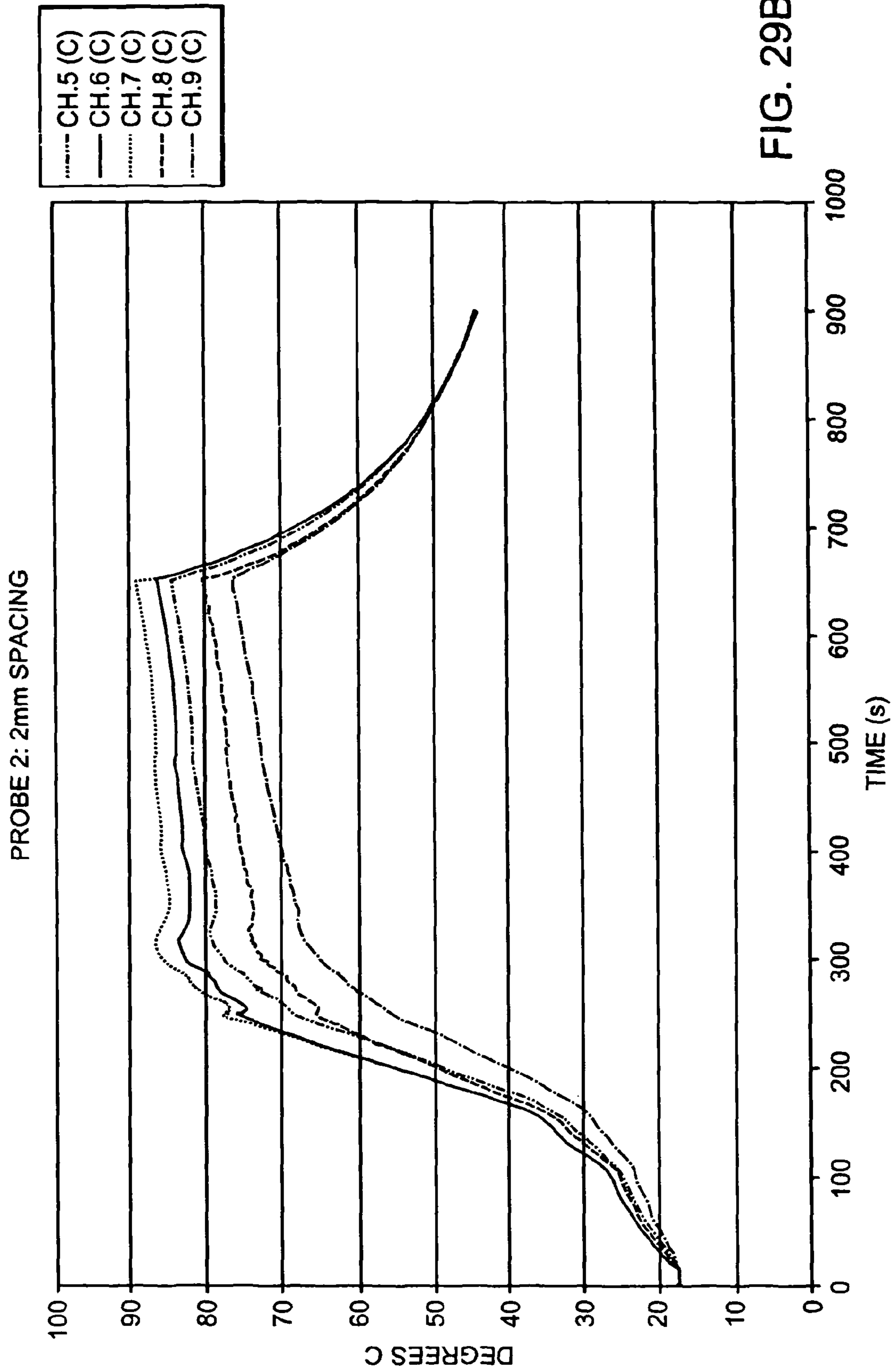


FIG. 29B

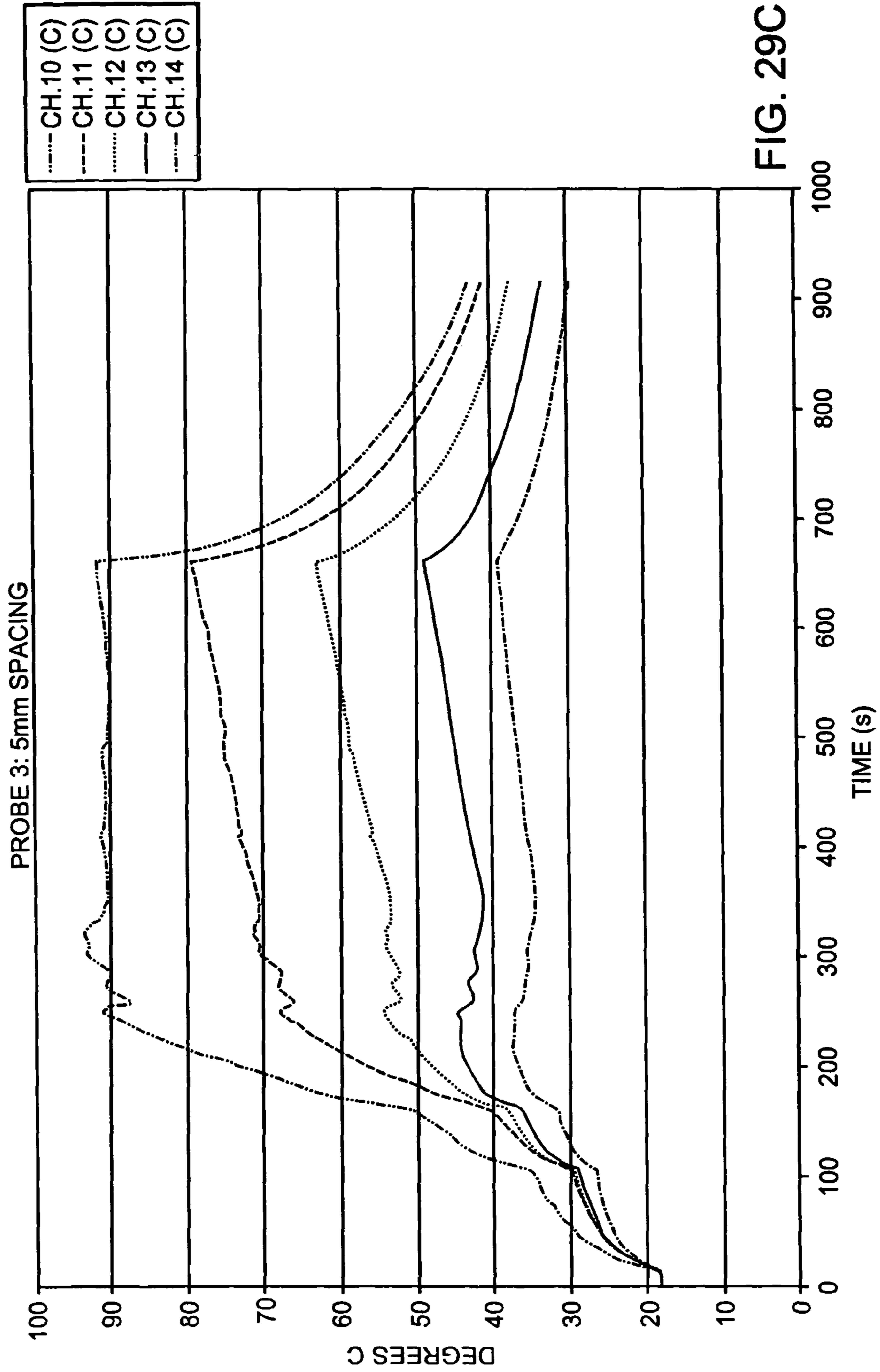


FIG. 29C

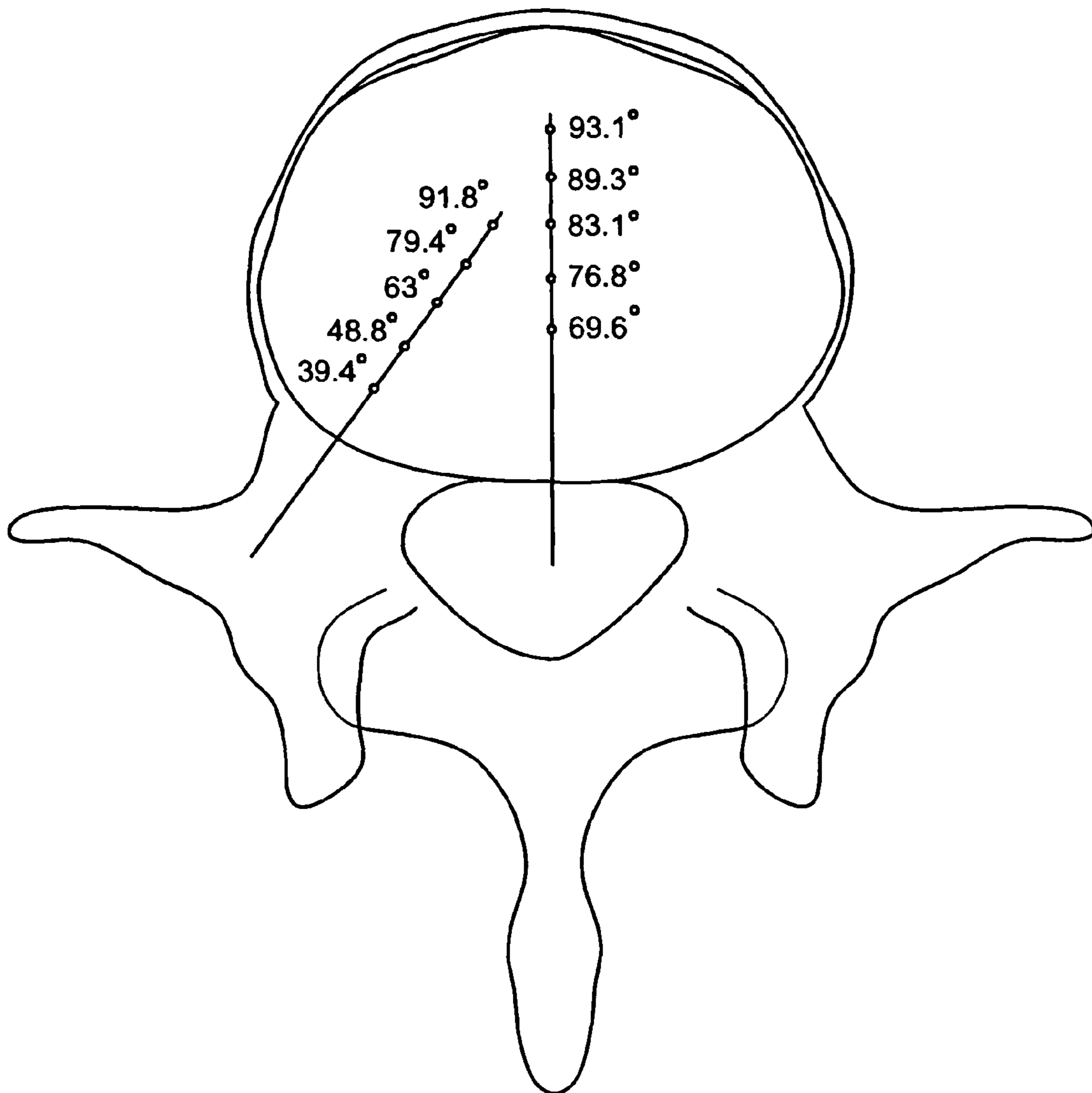


FIG. 30A

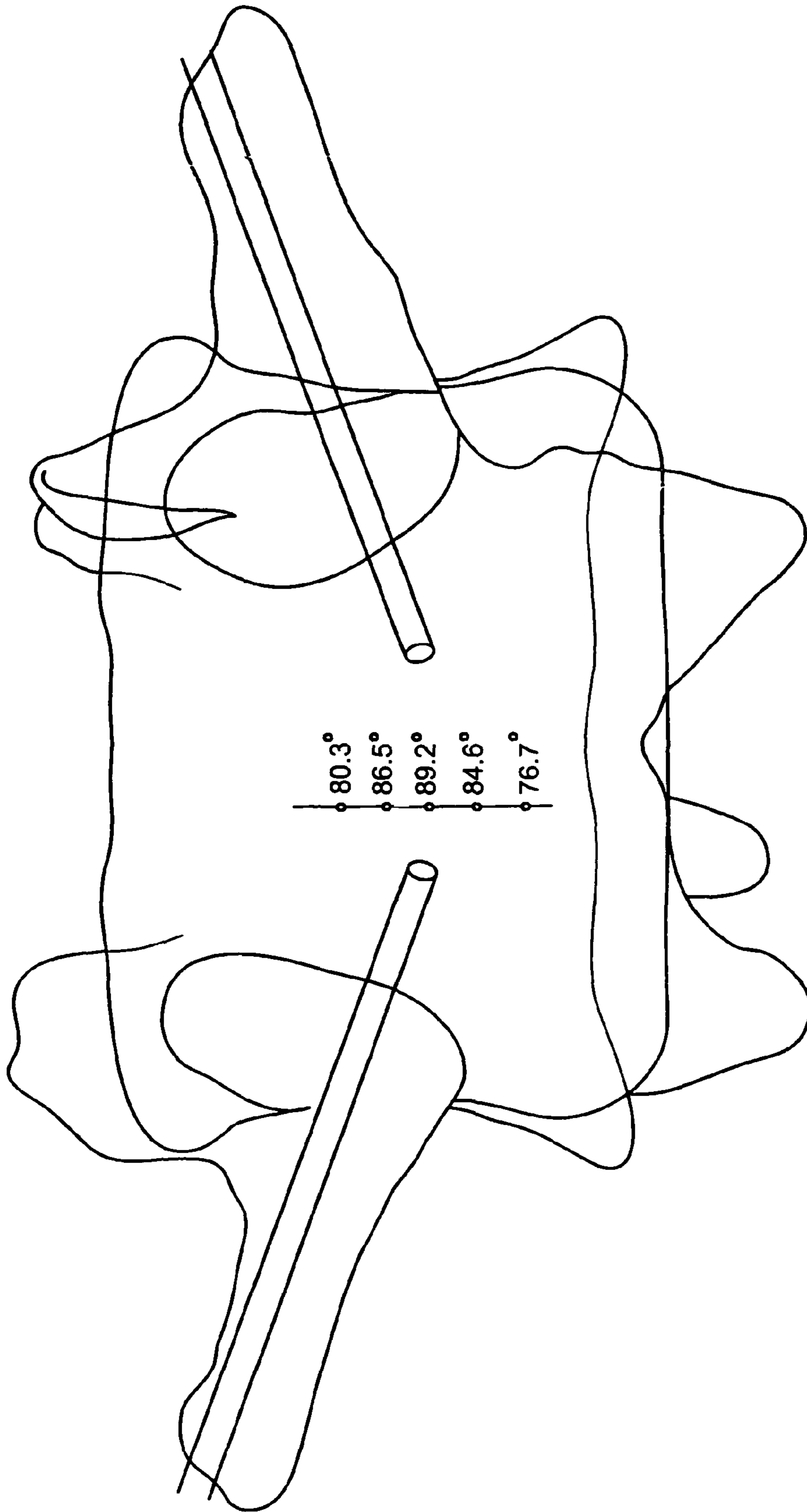


FIG. 30B

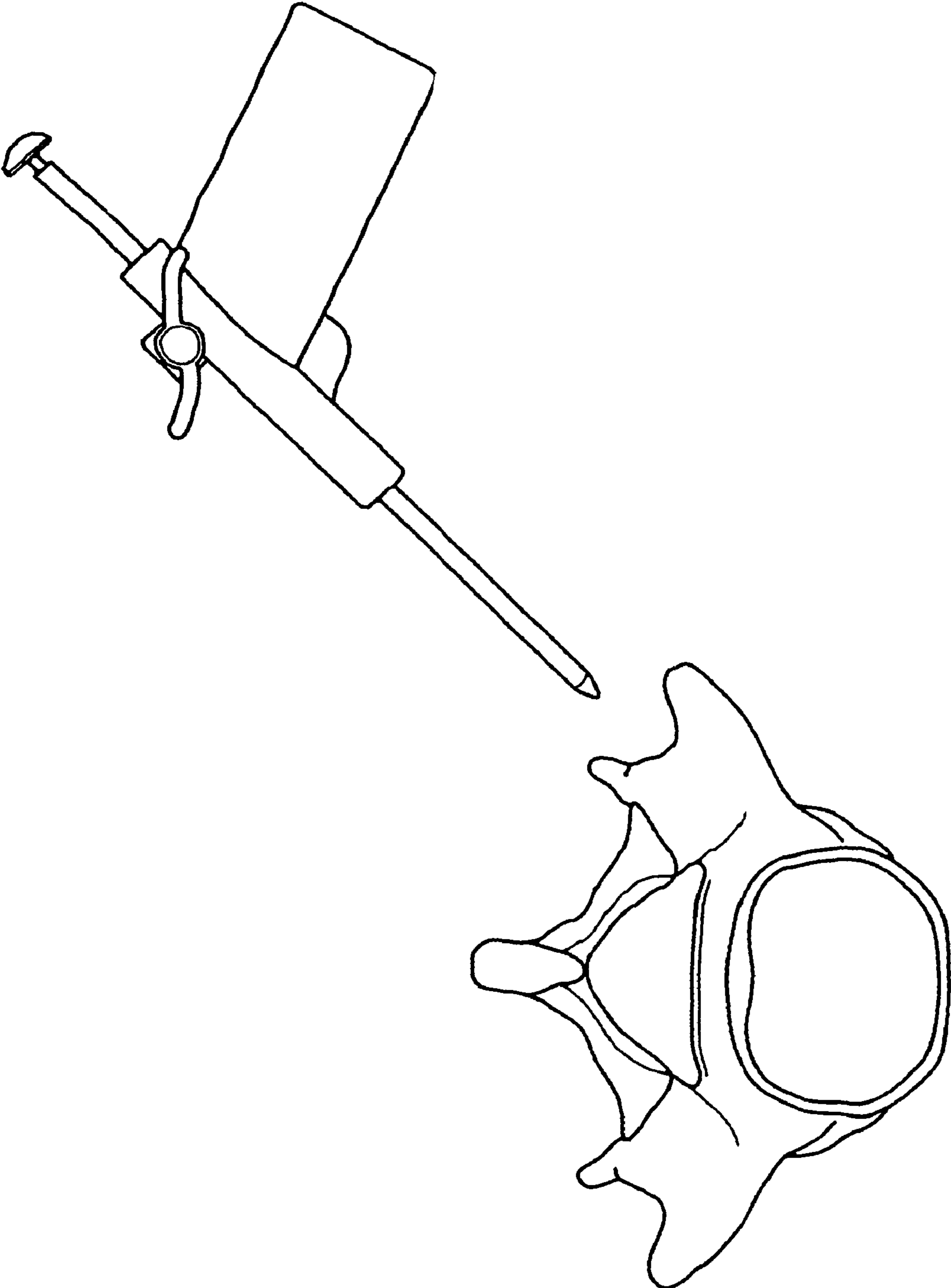


FIG. 31A

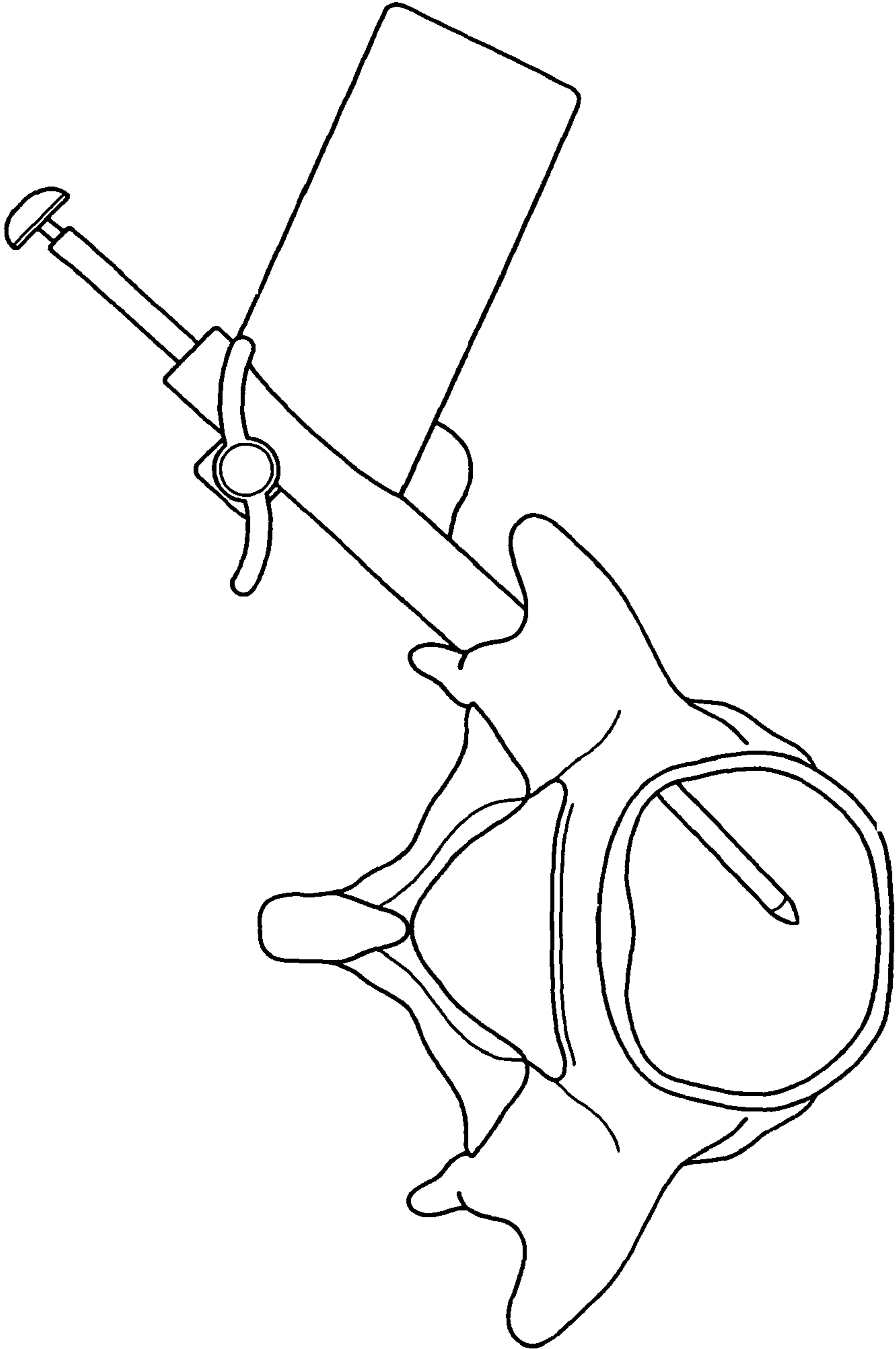


FIG. 31B

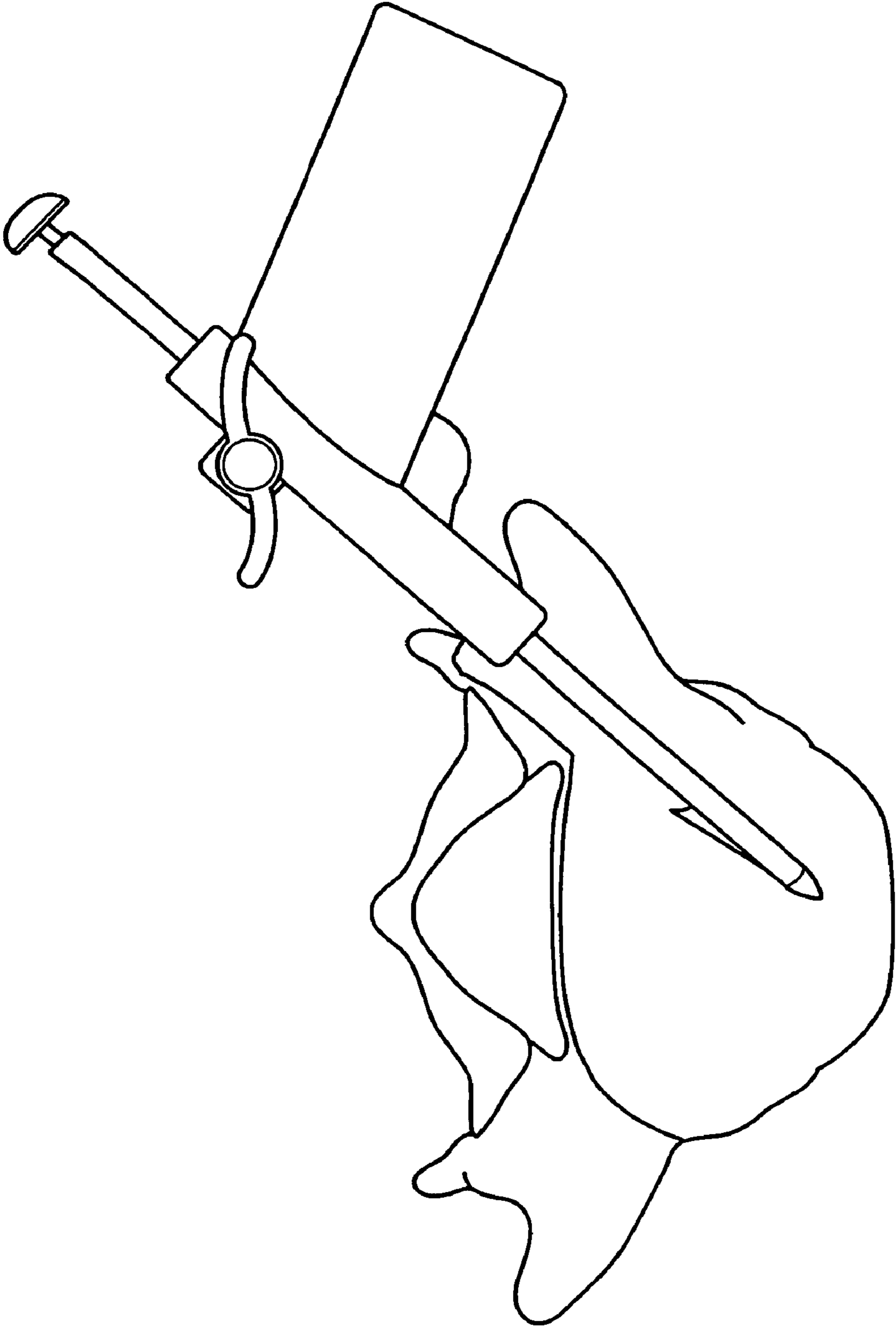


FIG. 31C

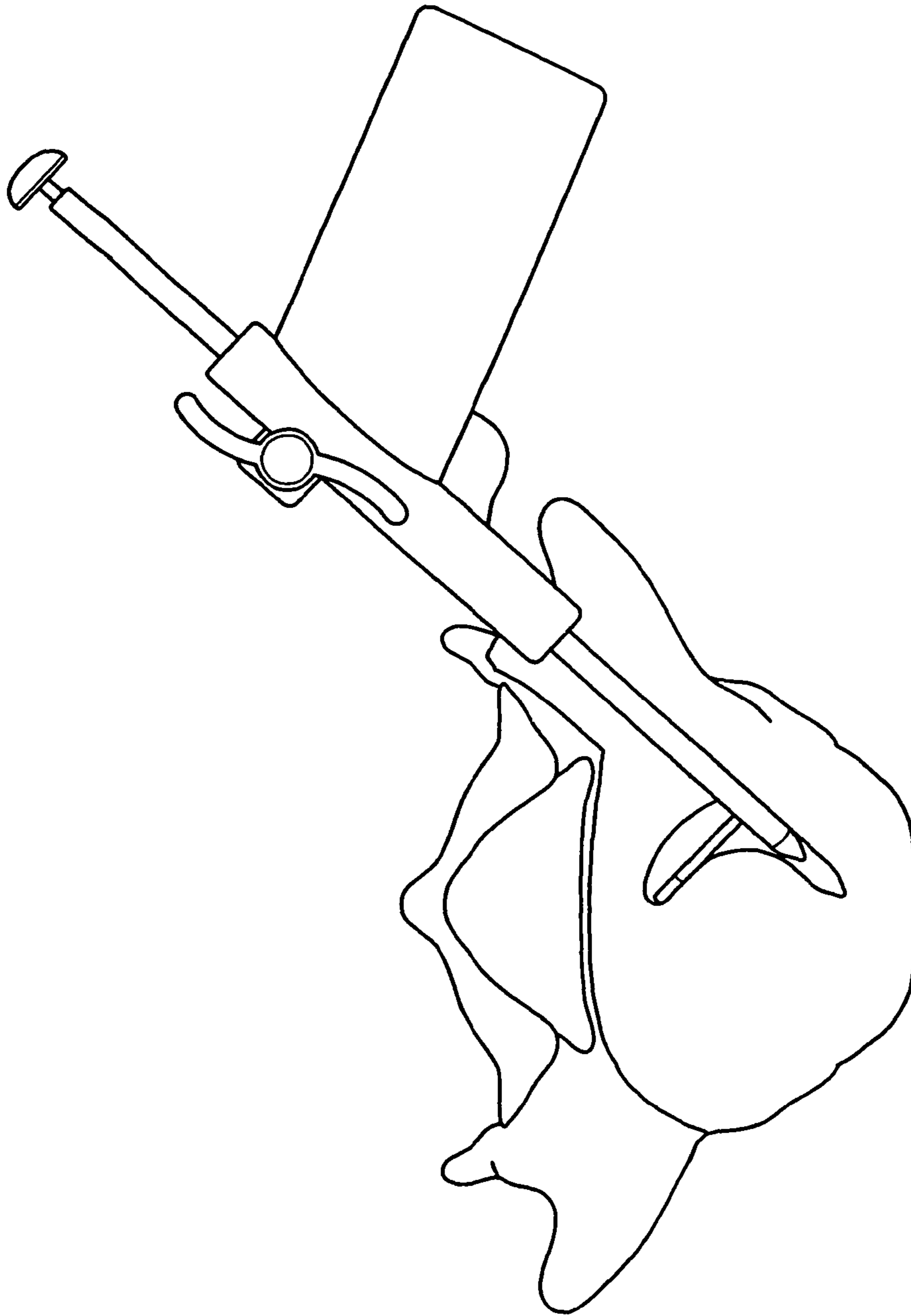


FIG. 31D

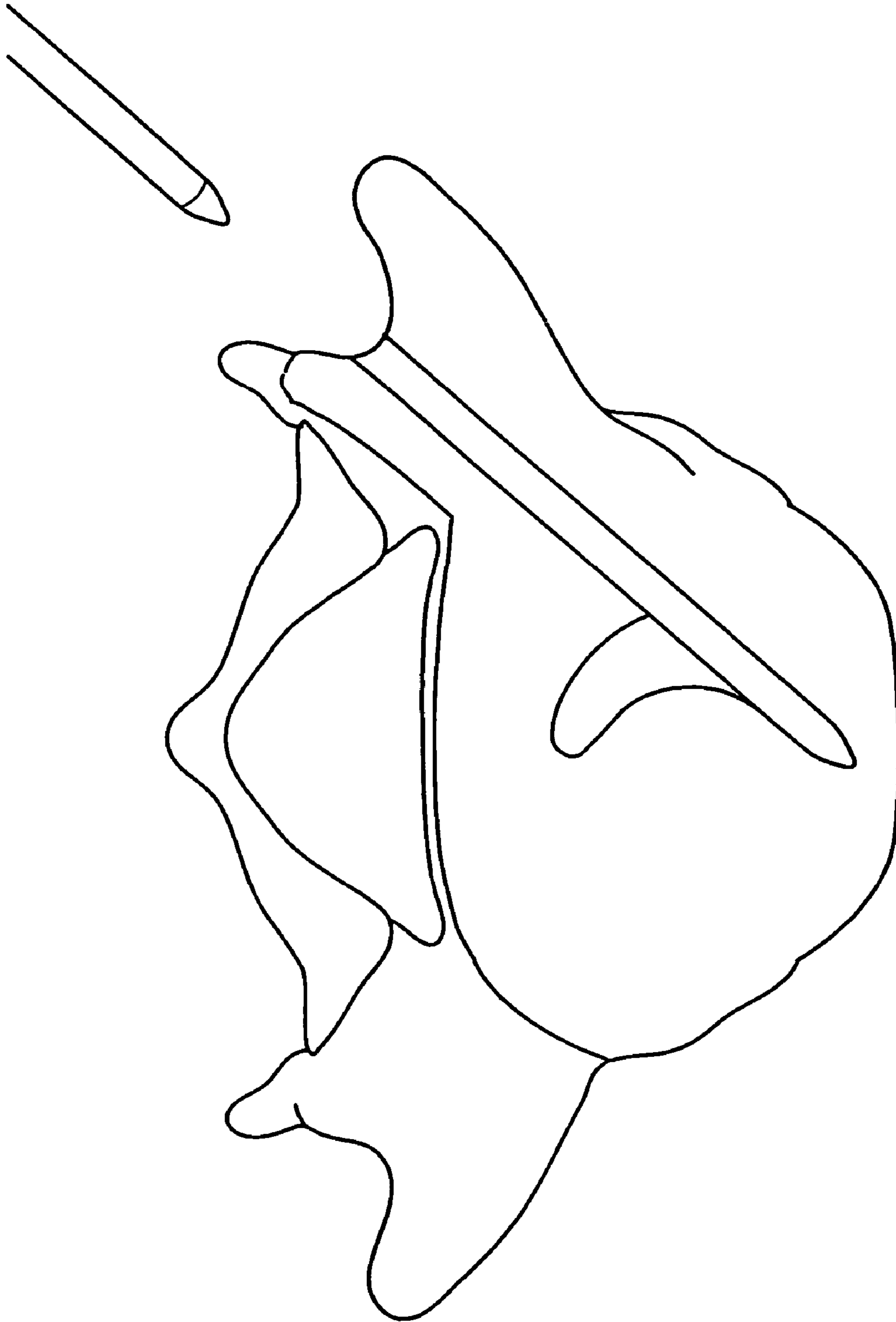


FIG. 31E

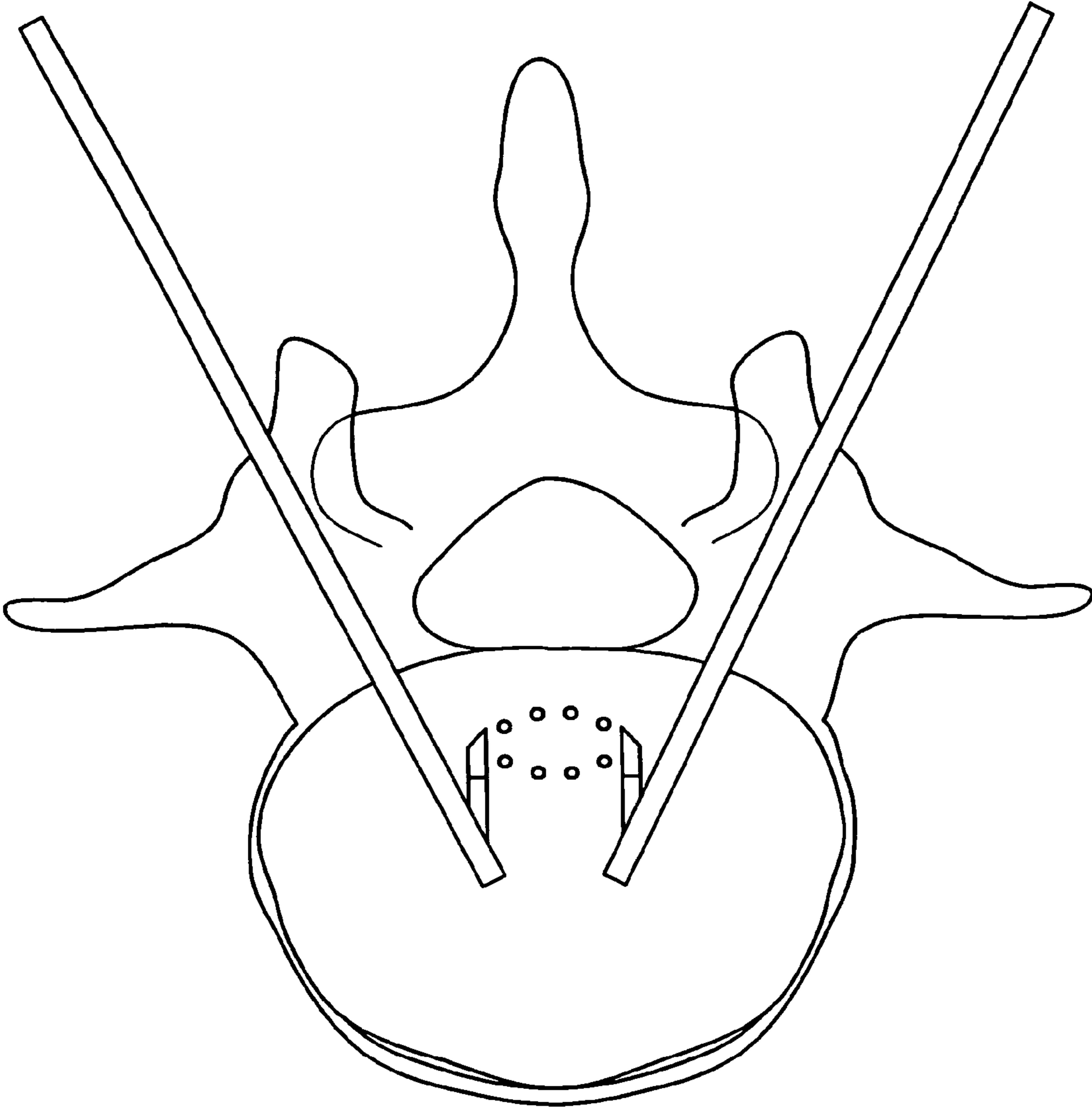


FIG. 32

**METHOD OF TREATING AN
INTRAOSSEOUS NERVE**

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

RELATED APPLICATIONS

This application is a *divisional reissue application of U.S. patent application Ser. No. 13/541,591, filed on Jul. 3, 2012, which is an application for reissue of U.S. Pat. No. 7,749,218, which issued Jul. 6, 2010 from U.S. patent application Ser. No. 11/123,766, which is a divisional of U.S. patent application Ser. No. 10/260,879, filed Sep. 30, 2002, entitled "Method of straddling an intraosseous nerve", now issued as U.S. Pat. No. 6,907,884, the specification of which is incorporated by reference.*

Notice: More than one reissue application has been filed for the reissue of U.S. Pat. No. 7,749,218. The reissue applications include the present divisional reissue application and U.S. application Ser. No. 13/541,591, filed on Jul. 3, 2012, which is a reissue application of U.S. Pat. No. 7,749,218.

BACKGROUND OF THE INVENTION

In an effort to reduce back pain through early intervention techniques, some investigators have focused upon nerves contained within the vertebral bodies which are adjacent the problematic disc.

For example, PCT Patent Publication No. WO 01/0157655 ("Heggeness") discloses ablating nerves contained within the vertebral body by first boring into the vertebral body with a nerve ablation device, placing the tip of the device in close proximity to the nerve, and then ablating the nerves with the tip. Heggeness discloses using laser devices, electricity transmitting devices, fluid transmitting devices and thermal devices, and devices for carrying either chemotherapeutic or radioactive substances as candidate nerve ablation devices.

In describing techniques using electricity transmitting devices, Heggeness discloses "raising the temperature of tip 24 such that the intraosseous nerve is ablated by the heat generated by electrical current passing through tip." See Heggeness at 8,28.

Heggeness further discloses multiple methods of accessing the intraosseous nerve (ION). However, each of these methods essentially disclose either i) boring a straight channel into the vertebra such that placement of an electrode tip near the end of that channel will bring the electrode tip sufficiently close to the ION to effect its ablation, or ii) accessing the basivertebral nerve (BVN) via the vertebral foramen. None of these techniques recognize how to effectively carry out nerve ablation when the precise locations of the ION is unknown, or when the electrode tip can not be maneuvered relatively close to the ION.

EPO Patent Published Patent Application No. EP 1 059067 A1 ("Cosman") discloses ablative treatment of metastatic bone tumors, including those within the spine. Pain relief is reportedly achieved by penetrating the bone wall with a suitable probe, and applying heat through the probe to ablate either the bone tumor or the tissue near the

bone tumor. Cosman teaches the use of both monopolar and bipolar probes in this application. Cosman also teaches that the treatment may also be used to ablate the nerves and nerve ramifications in and/or around the bone to desensitize them against further tumor encroachment. See Cosman at col. 11, lines 7-11.

However, monopolar approaches require the use of a grounding pad beneath the patient and allows energy to flow from the probe and to dissipate in the surrounding tissue. Because the path by which the energy flows from a monopolar probe to its corresponding pad is uncontrolled, the energy may undesirably flow through sensitive tissue, such as the spinal cord. Since this method may cause undesired local muscle or nerve stimulation, it may be difficult or dangerous to operate in sensitive areas of the human body.

Cosman discloses devices whose electrodes can deviate from the axis of the access channel. In particular, Cosman discloses steerable tips, spring-like electrodes that take a straight shape within the catheter and then curve upon exiting the catheter. Cosman discloses that the curved portion of the electrode may be a rigid and rugged permanent curve, or it may be a flexible configuration so that it can be steered, pushed or guided by the clinician to be positioned at various location. See Cosman at col. 8, lines 40-50). Cosman discloses that electrodes may comprise tubing made of elastic or super-elastic metal such as a spring steel or nitinol tubing so that the electrode can be inserted into straight segments of the cannula and still describes a curved path when the curved portion emerges from the opening. See Cosman at col. 10, lines 11-16. Cosman also discloses an electrode having a flexible but steerable tip which can define an arc, as set by the physician. See Cosman at col. 14, line 3.

In sum, Heggeness and Cosman disclose methods of treating that assume the tip of the electrode can be directed substantially to the target tissue.

A few investigators have examined the effectiveness of heating bone with monopolar RF electrodes. DuPuy, AJR: 175, November 2000, 1263-1266 noted decreased heat transmission at a 10 mm distance from the electrode through cancellous bone in ex vivo studies. DuPuy notes that local heat sinks from the rich epidural venous plexus and cerebrospinal fluid pulsations may account for the decreased heat transmission in cancellous bone. Tillotson, Investigative Radiology, 24:11, November 1989, 888-892, studied the percutaneous ablation of the trigeminal ganglion using RF energy, and found that bone marrow necrosis was limited to a sphere of about 1 cm in diameter, regardless of the probe size and duration of heating. Tillotson further reports that Lindsog showed that the transmission of heat within bone is sharply limited by blood flow, and that lethal temperatures cannot be sustained over great distances.

In sum, these investigators appear to report that the well-vascularized nature of bone appears to limit the heating effect of RF electrodes to a distance of less than about 0.5 cm from the tip.

U.S. Pat. No. 6,312,426 ("Goldberg") discloses a system of RF plate-like electrodes for effecting large, uniform, and extended ablation of the tissue proximate the plate-like electrodes. In some embodiments, the plate-like electrodes are placed on the surface of the body tissue, where the ablation is desired, and are configured to lie approximately parallel or opposing one another, such that they make a lesion by coagulating most of the body tissue volume between them. Goldberg appears to be primarily directed to the treatment of tumors. Goldberg states that one advantage of the system is that the surgeon need not determine the

precise position of the tumor. See Goldberg at col. 3, line 59-60. Goldberg does not appear to specifically discuss the treatment of nerves.

U.S. Pat. No. 6,139,545 ("Utley") discloses a facial nerve ablation system including at least two spaced apart bi-polar probe electrodes spanning between them a percutaneous tissue region containing a facial nerve branch. Utley teaches that the size and spacing of the electrodes are purposely set to penetrate the skin to a depth sufficient to span a targeted nerve or nerve within a defined region. See col. 5, lines 44-47. Utley further teaches that the system makes possible the non-invasive selection of discrete motor nerve branches, which are small and interspersed in muscle, making them difficult to see and detect, for the purpose of specifically targeting them for ablation. See col. 2, lines 20-24. Utley does not disclose the use of such a system for the treatment of IONS, nor rigid probes, or deployable electrodes. The probes of Utley

SUMMARY OF THE INVENTION

In attempting to place an electrode in close proximity to the BVN, the present inventors have found the approaches disclosed in the teachings of the art to be somewhat problematic. In particular, although the location of the BVN is somewhat well known, the BVN is radiolucent and so its precise location cannot be easily identified by an X-ray. Since the BVN is also extremely thin, knowingly placing the electrode in close proximity to the BVN may be problematic. Moreover, since conventional RF electrodes appear to heat only a fairly limited volume of bone, misplacement of the electrode tip vis-à-vis the BVN may result in heating a volume of bone that does not contain the BVN.

For example, and now referring to FIGS. 1 and 2, there is provided a representation of a treatment scheme involving the placement of a conventional bipolar electrode device in close proximity to the ION. In these FIGS., the ION is represented by the solid line identified as ION, while the vertically-disposed dotted lines identify the edges of the zone within which the practitioner believes the ION likely resides (i.e., the ION residence zone, or "IRZ"). As shown in FIGS. 1 and 2, if the ION is substantially in the center of the ION residence zone, then placement of the bipolar electrode either on the left hand boundary of the ION residence zone (as in FIG. 1) or substantially in the middle of the ION residence zone (as in FIG. 2) satisfactorily locates the electrodes in a region that allows the current flowing from the electrodes to flow across the ION. Since the current flowing across the ION may resistively and conductive heat the local bone tissue and the ION will be heated to therapeutically beneficial temperatures, these scenarios may provide beneficial treatment of the ION.

However, and now referring to FIG. 3, if the ION is substantially at the right edge of the ION residence zone, then placement of the bipolar electrodes on the left hand side of the ION residence zone fails to locate the electrodes in a region that allows the current flowing from the electrodes to flow across the ION. Accordingly, current flowing across the electrodes can not resistively heat the ION. Moreover, since bone is a heat sink that effectively limits the heat transport to about 0.5 cm, the heat produced by the electrodes may be effectively dissipated before it can reach the ION by conduction.

Similarly, and now referring to FIG. 4, if the ION is substantially at the left edge of the ION residence zone, then placement of the bipolar electrodes in the middle of the ION residence zone fails to locate the electrodes in a region that

allows the current flowing from the electrodes to flow across the ION. Again current flowing across the electrodes can not resistively heat the ION, and the heat sink quality of bone may effectively dissipate the heat produced by the electrodes before it can reach the ION by conduction.

Moreover, even if the precise location of the BVN were known, it has been found to be difficult to access the posterior portion of the BVN from a transpedicular approach with a substantially straight probe.

Therefore, the present inventors set out to produce a system that allows the practitioner to heat the BVN without having to know the precise location of the BVN, and without having to precisely place the electrode tip next to the portion of the BVN to be treated.

The present invention relates to the production of a large but well-controlled heating zone within bone tissue to therapeutically treat an ION within the heating zone.

Now referring to FIGS. 5-6, there is provided a representation of an embodiment of the present invention in which electrodes E1 and E2 respectively disposed probes (not shown) therapeutically treat the ION. FIG. 5 provides a schematic representation of the electric field EF produced in the bone tissue by activation of the electrodes. In this case, the electric field is relatively thin. FIG. 6 provides a schematic representation of the total heating zone THZ produced by the electric field of FIG. 5 including both an inner resistive heating zone IR (represented by open circle) and an outer conductive heating zone OC (represented by closed circles). In this case, the inner resistive zone is produced by the joule heating of bone tissue disposed within the electric field EF, while the outer conductive zone is heated by conduction of heat from the resistive heating zone.

Still referring to FIG. 6, the present inventors have found that positioning the active and return electrodes of an energy-transmitting device in a manner that allows the electrodes to straddle the ION residence zone IRZ provides a large but well-controlled total heating zone (IR+OC) within bone tissue to therapeutically treat the ION within the heating zone. Since the total heating zone is large and the electrodes straddle the IRZ, there is a high level of confidence that a portion of the ION will be present within the total heating zone. Since the total heating zone is well controlled, there is no danger (as with monopolar systems) that current flowing from the active electrode will undesirably affect collateral tissue structures.

Now referring to FIG. 7, if the ION is in fact substantially in the center of the ION residence zone, then placement of the bipolar electrodes in a manner that straddles the ION residence zone allows the production a total heating zone between the electrodes that includes a portion of the ION therein.

Moreover, the present invention allows the practitioner to therapeutically treat the ION even when the ION is in fact located at the edges of the ION residence zone IRZ. Now referring to FIGS. 8 and 9, if the ION is located substantially at the right edge (as in FIG. 8) or the left edge (as in FIG. 9) of the ION residence zone IRZ, then placement of the bipolar electrodes in a manner that straddles the ION residence zone still allows the production a total heating zone between the electrodes that includes a portion of the actual ION therein.

Therefore, the straddling of the ION residence zone by the present invention satisfactorily locates the electrodes so that the total heating zone produced by the electrode activation includes the ION irrespective of the actual location of the ION within the ION residence zone IRZ, thereby guaran-

5

teering that the electrodes will always heat the ION to therapeutically beneficial temperatures.

Therefore, in accordance with the present invention, there is provided a method of therapeutically treating a bone having an intraosseous nerve ION defining first and second sides of the bone, comprising the steps of:

- a) inserting an energy device having an active and a return electrode into the bone,
 - b) placing the active electrode on the first side of the bone and the return electrode on the second side of the bone to define a total heating zone therebetween, and
- applying a sufficiently high frequency voltage between the active and return electrodes to generate a current therebetween to resistively heat the total heating zone sufficient to denervate the ION.

In addition, the present invention provides a very controlled total heating zone which exists substantially only between the paired electrodes. The ability of the present invention to both therapeutically heat the BVN with substantial certainty and to minimize the volume of bone tissue affected by the heating appears to be novel in light of the conventional bone-related technology.

Accordingly, the present invention is further advantageous because it allows the clinician to create a sufficiently large heating zone for therapeutically treating the ION without requiring direct access to the ION.

Thus, in preferred embodiments, the present invention is advantageous because:

- 1) it does not require knowing the precise location of the ION,
- 2) it does not require directly accessing the ION, and
- 3) its controlled heating profile allows the clinician to avoid heating adjacent structures such as the healthy adjacent cancellous bone tissue, the spinal cord or opposing vertebral endplates.

Accordingly, there is also provide a method of therapeutically treating a vertebral body having a BVN defining first and second sides of the vertebral body, comprising the steps of:

- a) determining a BVN residence zone within which the BVN likely resides, the BVN residence zone having a first side and a second side,
- b) inserting an energy device having an active and a return electrode into the vertebral body,
- c) placing the active electrode on the first side of the residence zone and the return electrode on the second side of the residence zone to define a total heating zone therebetween, and
- d) applying a sufficiently high frequency voltage between the active and return electrodes to generate a current therebetween to resistively heat the total heating zone to a temperature sufficient to denervate the BVN.

DESCRIPTION OF THE FIGURES

FIGS. 1 and 2 depict the treatment of the BVN with a conventional bipolar electrode.

FIGS. 3 and 4 depict the difficulty of treating a BVN with a conventional bipolar electrode.

FIGS. 5 respectively depict top views of an electric field and a total heating zone produced within bone tissue by an embodiment of the present invention.

FIGS. 7-9 depict the treatment of the BVN with a bipolar electrode apparatus of the present invention.

FIGS. 10a and 10b disclose anterior and upper cross-sectional views of a straddled ION that extends in a plane above the electrodes but within the total heating zone.

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FIG. 11 is a cross-sectional anterior view of an embodiment of the present invention in which the total heating zone has dumb-bell type resistive heating zones.

FIG. 12 depicts a top view of the treatment of the BVN with a bipolar electrode apparatus of the present invention wherein the distal ends of the probes are located substantially at the midline of the vertebral body.

FIG. 13 discloses cross-sections of components of a preferred dual probe apparatus according to the present invention.

FIG. 14 discloses an embodiment of the present invention in which a portion of the probe shaft acts as an electrode.

FIGS. 15-18 discloses four embodiments of the present invention in which at least a portion of the electrode faces thereof are disposed in a substantially parallel relation.

FIG. 19 discloses a cross-sectional view of an apparatus of the present invention in which the cannula has a bore having a distal bend and a lateral opening.

FIGS. 20a and 20b disclose cross-sectional views of an apparatus of the present invention in which the cannula has a proximal bend.

FIGS. 21a and 21b disclose cross-sectional views of an apparatus of the present invention in which the probe has a pivoted portion containing an electrode.

FIG. 22 discloses a probe of the present invention having reverse conical electrodes.

FIG. 23 discloses a probe of the present invention having a plurality of active electrodes and a corresponding plurality of return electrodes.

FIG. 24 discloses a bipolar probe of the present invention in which the return electrode has a relatively large surface area.

FIG. 25 presents a cross-sectional view of an articulated probe of the present invention having both active and return electrodes.

FIG. 26 discloses the treatment of a posterior portion of the BVN with a bipolar electrode apparatus of the present invention. FIGS. 27a-d disclose respective top, anterior, lateral and perspective views of the placement of a bipolar electrode apparatus of the present invention within a vertebral body.

FIGS. 28a and 28b show the location of thermocouples T0-T14 within the vertebral body.

FIG. 29a-c present the temperatures recorded by thermocouples T0-T14.

FIG. 30a-b present the peak temperatures recorded by thermocouples T0-T14 within the vertebral body.

FIGS. 31a-e present top views of a preferred use of the articulated probe of FIG. 25.

FIG. 32 presents a dual articulated needle embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

For the purposes of the present invention, the "resistive heating zone" is the zone of bone tissue that is resistively heated due to an energy loss incurred by current travelling directly through the bone tissue. Resistive heating, "joule" heating and "near-field" heating may be used interchangeably herein. The "conductive heating zone" is the zone of bone tissue that is heated due to the conduction of heat from an adjacent resistive heating zone. The total heating zone THZ in a bone tissue includes both the resistive heating zone and the conductive heating zone. The border between the conductive and resistive heating zones is defined by the locations where the strength of the electric field is 10% of

the maximum strength of the electric field between the electrodes. For the purposes of the present invention, the heating zones encompass the volume of bone tissue heated to at least 42° C. by the present invention. For the purposes of the present invention, the “first and second sides” of a vertebral body are the lateral-lateral sides intersected by the BVN.

The therapeutic treatment of the ION may be carried out in accordance with the present invention by resistive heating, conductive heating, or by hybrid heating.

In some embodiments, the therapeutic heating of the ION is provided by both resistive and conductive heating. In some embodiments thereof, as in FIG. 6, the electrodes are placed such that the ION passes through resistive heating zone IR, so that length L_1 of the ION is therapeutically heated by bone tissue in the resistive heating zone IR and lengths L_2 and L_3 of the ION are therapeutically heated by the bone tissue in the conductive heating zone OC.

In embodiments wherein the therapeutic heating of the ION is provided substantially by both resistive and conductive heating, it is preferred that the length L_1 of the ION treated by resistive heating comprise at least 25% of the total therapeutically treated length of ION, more preferably at least 50%. In many embodiments, the peak temperature in the resistive heating zone IR is between 40° C. and 60° C. greater than the peak temperature in the conductive heating zone OC. Preferably, the peak temperature in the resistive heating zone IR is no more than 15° C. greater than the peak temperature in the conductive heating zone OC, more preferably no more than 10° C., more preferably no more than 5 degrees.

Now referring to FIGS. 10a and 10b, in some embodiments, the therapeutic heating of the ION is provided essentially by the conductive heating zone OC. This may occur when the ION is in fact located substantially far from the middle of the ION residence zone IRZ. In such an instance, the electrodes are placed such that the ION passes only through the conductive heating zone, so that length L_2 of the ION is therapeutically heated by bone tissue in the conductive heating zone OC.

In preferred embodiments thereof, it is desired that the separation distance SD between the ION and the resistive heating zone IR be no more than 1 cm. This is desired because the closer the ION is to the resistive heating zone, the higher the temperature experienced by the ION length L_2 . More preferably, the separation distance is no more than 0.5 cm, more preferably no more than 0.2 cm.

In some embodiments, as in FIG. 10, the electric field is sufficiently strong to be located substantially continuously between the two electrodes. This typically occurs when the electrodes are very close together (i.e., no more than 5 mm apart). In others, however, as in FIG. 11, the electric field is relatively weak and so resides substantially only in the vicinity of the two electrodes. In such cases, and now referring to FIG. 11, inward energy flow from the resistive heating zones IR conductively heats the intermediate area of the conductive heating zone OC₁. Preferably, the peak temperature in the resistive heating zone IR is no more than 15° C. greater than the peak temperature in the intermediate conductive heating zone OC₁, more preferably no more than 10° C., more preferably no more than 5° C.

In preferred embodiments, the present invention is carried out via a dual probe system. In particular, the present invention preferably comprises an energy delivery device comprising a first probe having an active electrode and a second probe having a return electrode. Now referring to FIG. 12, this dual probe embodiment allows the surgeon to

approach the BVN from separate sides of the vertebral body to easily straddle the IRZ with the electrodes. With such a device, the surgeon can place the first probe 601 having an active electrode 603 on a first side of the vertebral body and the second probe 611 having a return electrode 613 on a second side of the vertebral body, and then align the paired electrodes so that their activation produces a total heating zone that straddles the IRZ and therefore the BVN therein.

Since aligning the electrodes of such an apparatus to straddle the ION merely requires advancing the probes into the vertebral body, no complicated navigation is required. The present inventors have appreciated that, even if the location of the BVN were precisely known, conventional methods of accessing the BVN require either i) the BVN to be naturally located within the vertebral body so as to intersect the axis of the pedicle (Heggeness), or require a complicated probe configuration or navigation (such as those described by Cosman). Because the dual probe approach simply requires substantially linear advance of a pair of substantially straight probes, it is much simpler and/or much more robust than the conventional methods of accessing nerves in bone. Indeed, with this embodiment of the present invention, the clinician may now desirably access the vertebral body through the pedicles with substantially straight probes and have a high confidence that their activation can therapeutically treat the BVN.

Therefore, in accordance with the present invention, there is provided a method of therapeutically treating a vertebral body having a BVN, comprising the steps of:

- a) providing an energy device having an active electrode having a first face and a return electrode having a second face into the vertebral body, and
 - b) placing the active electrode in the vertebral body to face a first direction,
 - c) placing the return electrode in the vertebral body to face a second direction, the first and second faces defining an angle 2δ of no more than 60 degrees, and
- applying a sufficiently high frequency voltage difference between the active and return electrodes to generate a current therebetween to produce a total heating zone to therapeutically heat the BVN.

Therefore, in accordance with the present invention, there is provided a method of therapeutically treating a vertebral body having a BVN, comprising the steps of:

- a) providing an energy device having an active electrode and a return electrode,
- b) placing the active and return electrodes in the vertebral body to define an electrode axis, the axis forming an angle β of between 50 and 90 degrees with the BVN, and
- c) applying a sufficiently high frequency voltage difference between the active and return electrodes to generate a current therebetween to produce a total heating zone to therapeutically heat the BVN.

Now referring to FIG. 13, there is provided a preferred dual probe apparatus according to the present invention comprising first 101 and second 151 cannulae, first 201 and second 251 stylets, first 301 and second 351 probes, and a power supply 401 in electrical connection with the probes. For simplicity, only a single cannula, stylet and probe will be further described. However, the skilled artisan will appreciate that preferred embodiments use two sets of such devices.

Now referring to FIG. 13, cannula 101 comprises a shaft 103 having a longitudinal bore 105 therethrough defining an inner diameter D_c . Distal opening 109 of the cannula provides a working portal for the probe. It is further sized to allow the distal end of the probe to advance past the distal

end **107** of the cannula. The length L_c of the cannula is sized to reach from the patient's skin to a location within the cancellous bone region of the target bone. Preferably, the cannula is made of a material selected from the group consisting of metal and polymer, and is preferably polymer. In many embodiments, the cannula is made of an insulating material in order to prevent stray current from the probe from contacting non-targeted tissue.

In some embodiments, the cannula is shaped so as to guide the probe towards the midline of the vertebral body. This inward guidance will help move the electrodes closer to the BVN. In some embodiments, at least a portion of the cannula bore is curved. In some embodiments, at least half of the length of the cannula bore is curved. In other embodiments, substantially only the distal end portion of the cannula bore is curved.

Stylet **201** comprises a shaft **203** having a longitudinal axis A and a proximal **205** and distal end **207**. Disposed at the distal end of the shaft is a tip **209** adapted for boring or drilling through cortical bone. The outer diameter D_o of the stylet shaft is preferably adapted to be received within the inner diameter D_c of the cannula.

For the purposes of the present invention, the combination of the cannula and the stylet is referred to as a "cannulated needle". In some embodiments, access to the vertebral body is gained by first placing the stylet in the cannula to produce a cannulated needle, piercing the skin with the cannulated needle, and advancing the cannulated needle so that the stylet tip reaches a target tissue region within the cancellous portion of the vertebral body, and then withdrawing the stylet. At this point, the cannula is conveniently located at the target tissue region to receive a probe of the present invention.

Probe **301** comprises a shaft **303** having a longitudinal axis B, a distal end portion **305** and a proximal end portion **307**. Disposed near the distal end portion of the probe is first electrode **309** having a first face **331** and a connection face **333**. The probe is designed so that the connection face of the first electrode is placed in electrical connection with a first lead **403** of the power supply. In this particular embodiment, the shaft has a longitudinal bore **311** extending from the proximal end portion up to at least the first electrode. Disposed within the bore is a wire **321** electrically connected at its first end **323** to the first electrode and having a second end **325** adapted to be electrically connected to a first lead of a power supply.

Therefore, in accordance with the present invention, there is provided an intraosseous nerve denervation system, comprising:

- a) a cannula having a longitudinal bore,
- b) a stylet having an outer diameter adapted to be received within the longitudinal bore and a distal tip adapted to penetrate cortical bone, and
- c) a first probe comprising:
 - i) an outer diameter adapted to be received within the longitudinal bore, and
 - ii) a first electrode, and
 - iii) a lead in electrical connection with the first electrode.

In some embodiments, the outer surface of the probe is provided with depth markings so that the clinician can understand the extent to which it has penetrated the vertebral body.

In some embodiments in which a cannulated stylet is first inserted, the stylet is removed and the cannula remains in place with its distal opening residing in the target tissue while the probe is inserted into the cannula. In this embodiment, the cannula provides a secure portal for the probe,

thereby insuring that the probe can enter the bone safely. This embodiment is especially preferred when the probe is made of a flexible material, or is shaped with an irregular cross-section that could undesirably catch on the bone during probe advancement into the bone.

In the FIG. **13** probe disclosed above, probe **301** has a blunt tip. In other embodiments, however, the probe carrying an electrode can be configured to possess a sharp distal tip having sufficient sharpness to penetrate cortical bone. With such a tip, the clinician can eliminate steps in the procedure that are related to either the stylet or the cannulated stylet, and thereby save time.

Now referring to FIG. **14**, in some embodiments, the electrode may include a portion of the probe shaft. For example, in the case of probe **1401**, the probe comprises:

- a) an inner electrically conductive shaft **1403** in electrical connection with a power supply **1409**, and
- b) an outer insulating jacket **1405** wrapped around a portion of the shaft.

In this configuration, the placement of the jacket provides a distal uninsulated shaft portion **1407** that could be used as an electrode. Preferably, the distal uninsulated portion of the shaft has a length of between 3 mm and 8 mm, and is more preferably about 5 mm. In preferred embodiments thereof, the insulation is selected from the group consisting of polyimide tape, PTFE tape, and heat shrink tubing. Preferred thickness of the insulation range from about 0.00025 to 0.0005 inches.

In other embodiments using insulating jackets, the jacket has either a longitudinally extending slit or slot that exposes a longitudinal surface area of the underlying shaft, thereby producing either an essentially linear or an essentially planar electrode. In such embodiments, the distal end of the shaft may preferably be insulated. In other embodiments using insulating jackets, the insulated portion may comprise a proximal jacket and a distal jacket positioned to provide a space therebetween that exposes a surface area of the underlying shaft to produce the electrode. In some embodiments, the proximal and distal jacket substantially encircle the shaft to provide an annular electrode therebetween.

In some embodiments in which a cannulated stylet is used, both the stylet and the cannula are removed, and the probe is inserted into the hole created by the cannulated stylet. In this embodiment, the hole provides a large portal for the probe. This embodiment conserves the annulus of bone removed by the cannula, and so is preferred when the probe has a relatively large diameter (e.g., more than 8 mm in diameter).

In some embodiments in which a cannulated stylet is used, the cannula comprises at least one electrode. In this embodiment, the cannula acts as the probe as well. With this embodiment, the clinician can eliminate steps in the procedure that are related to introducing a body into the cannula. In some embodiments, the outer surface of the cannula is provided with depth markings so that the clinician can understand the extent to which the cannula has penetrated the vertebral body.

In some embodiments in which a cannulated stylet is first inserted, the stylet comprises at least one electrode. In this embodiment, the stylet acts as the probe as well. With this embodiment, the clinician can eliminate steps in the procedure that are related to removing the stylet and introducing a body into the cannula. In some embodiments, the outer surface of the stylet is provided with depth markings so that the clinician can understand the extent to which it has penetrated the vertebral body.

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In conducting initial animal experiments with a dual probe embodiment, the present inventors used a bipedicle approach as shown in FIG. 12, so that each probe approached the ION at angle δ of 45 to about 55 degrees. Since both the probes and the electrodes disposed thereon were essentially cylindrical, the inner faces **605**, **615** of the electrodes produced an angle 2δ . Subsequent testing of the configuration of FIG. 12 revealed somewhat higher temperatures at the distal portion of the electrodes and somewhat lower temperatures near the proximal portions of the electrodes. Without wishing to be tied to a theory, it is believed that the shorter path between the distal regions produced a lower resistance region (as compared to more proximal inter-electrode regions) and so caused current to preferentially follow the path of the least resistance between the distal portions. Accordingly, the present inventors sought to improve upon the relatively uneven temperature profile produced by the electrode design of FIG. 12.

In accordance with the present invention the present inventors modified its electrode design to reduce the angle 2δ produced by the inner faces, so that the distance between the proximal end of the electrodes is more equal to the distance between the proximal end of the electrodes (i.e., the faces are more parallel). When the electrodes are provided in such a condition, their orientation reduces the significance of any path of least resistance, and so current flows more evenly across the face of each electrode, thereby providing even heating and greater control over the system.

Therefore, in accordance with the present invention, there is provided an intraosseous nerve denervation device, comprising:

- a) a first probe having an active electrode and a first lead,
- b) a second probe having a return electrode and a second lead,
- c) means for creating first and second bores within a bone for accommodating the first and second probes,
- d) a power supply capable of generating a voltage difference between the active and return electrodes, the supply having third and fourth leads,

wherein the first and third leads are in electrical connection, and the second and fourth leads are in electrical connection.

Preferably, the electrodes are disposed so that the angle 2δ produced by the inner faces is less than 60 degrees, more preferably no more than 30 degrees. Still more preferably, the angle is less than 1 degree. Most preferably, the inner faces are substantially parallel.

Now referring to FIG. 15, in some embodiments, substantially parallel electrodes are provided by using conical electrodes **501** that taper distally. In this FIG. 15, each cone electrode **501** has a distal end **503** having a diameter D_D and a proximal end **505** having a diameter D_P , wherein the distal end diameter D_D is larger than the proximal end diameter D_P . Preferably, the angle γ of the cone taper is substantially equal to the angle δ . In this condition, the inner faces of the conical electrodes will be essentially parallel to each other.

Therefore, in accordance with the present invention, there is provided intraosseous nerve denervation system comprising:

- a) a first probe having a first electrode and a first lead in electrical connection with the first electrode, wherein the first electrode has a proximal end having a proximal diameter and a distal end having a distal diameter, and the proximal end diameter is less than the distal end diameter, and
- b) a second probe having a first electrode and a first lead in electrical connection with the first electrode,

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wherein the first electrode has a proximal end having a proximal diameter and a distal end having a distal diameter, and the proximal end diameter is less than the distal end diameter, and

wherein the first and second electrode are disposed so that the electrodes are parallel.

In FIG. 10, the conical shapes are frustoconical (i.e., they are portions of a cone). Frustoconical electrodes are desirable in situations where tissue charring needs to be avoided, as the relatively large diameter of the distal end of the electrode can not provide an avenue for high current density (relative to the proximal end of the electrode). Frustoconical electrodes are also desirable in situations where the probes are disposed at a relatively high angle δ , wherein the use of sharp tipped electrodes would substantially shorten the distance between the distal tips of the electrodes and thereby create an undesirable path of significantly less resistance.

In some embodiments, the frustoconical electrode is shaped so that the diameter of its distal end D_D is between about 10% and 25% of the diameter of its proximal end D_P . In some embodiments, the frustoconical nature of the electrode is provided by physically severing the sharp distal end of the electrode. In others, the frustoconical nature of the electrode is provided by insulating the sharp distal end of an electrode.

As noted above, when the probes are placed such that their corresponding electrodes are parallel to each other, the electric field produced by electrode activation is substantially uniform between the distal and proximal portions of the electrodes. However, as the probes are oriented at an angle from parallel, the electric field becomes strongest where the electrodes are closer together. In order to compensate for this non-uniform electric field, in some embodiments of the present invention, the distal ends of the electrodes are tapered. In this tapered state, the regions of the electrodes that are closer together (e.g., the tip) also have a smaller surface area (thereby reducing the electric field in that region), while the regions of the electrodes that are farther apart (e.g., the trunk) have a larger surface area (thereby increasing the electric field in that region). Typically, the effect is largely determined by the cone size, electrode spacing and tissue type therebetween.

In some preferred embodiments of the tapered electrode, and now referring to FIG. 16, the distal end of the electrode terminates in a sharp tip, so that the electrode has a more completely conical shape. Preferably, the conical electrode is shaped so that the diameter of its distal end is no more than 20% of the diameter of its proximal end, more preferably no more than 10%, more preferably no more than 1%. In addition to compensating for non-uniformity in the electric field, the sharp tip may also be adapted to penetrate the cortical shell of the vertebral body.

Now referring to FIG. 17, in some embodiments, current flows through an electrode having only a portion of the conical or frusto-conical shape. When electrodes of this embodiment, termed "sectored cones" face each other, their use is advantageous because they insure that current will flow the least distance, and so provide efficiency. The sectored cones of this embodiment can be produced by first manufacturing planar electrodes **511** and placing the planar electrode upon a conveniently angled probe surface **513**. Alternatively, this embodiment can be produced by first manufacturing the conical electrode configuration of FIG. 15, and then masking a portion of the conical electrode with an insulating material. Unlike the embodiment of FIG. 15, this sectored cone embodiment requires careful alignment of

the electrode faces and may require in vivo rotation of the electrodes to achieve the desired alignment.

Now referring to FIG. 18, in other embodiments, substantially parallel electrodes can be provided by using elbowed probes 531. The elbowed probes have a distal end 533 and a proximal end 535 meeting at an elbow 537. In some embodiments, the elbow may be produced during the manufacturing process (thereby requiring a smaller diameter probe in order to fit through the cannula). In other embodiments, the elbow is produced in vivo, such as through use of a pull-wire, a pivot or a memory metal disposed within the probe.

Now referring to FIG. 19, in some embodiments, first 551 and second 552 cannulae are each provided with a curved bore 553, 554 forming distal lateral openings 563, 564 in their respective distal end portions 555, 556. When flexible probes 557, 558 containing an electrode 559, 560 are passed through the curved bore, the distal end 561, 562 of the probe likewise conforms to the curved bore, thereby forming an intra-probe angle ϵ determined by the proximal A_P and distal A_D axes of the probe. Preferably, this intra-probe angle is between 90 and 135 degrees. Preferably, the intra-probe angle is selected so that the distal axes A_D of the probes exiting the cannulae form an angle of no more than 30 degrees, preferably no more than 10 degrees, more preferably form a substantially parallel relation.

Therefore, in accordance with the present invention, there is provided an intraosseous nerve denervation system, comprising:

- a) a cannula having a longitudinal bore defining a first axis,
- b) a stylet having an outer diameter adapted to be received within the longitudinal bore and a distal tip adapted to penetrate cortical bone, and
- c) a first probe comprising:
- d) an outer diameter adapted to be received within the longitudinal bore, and
 - i) a first electrode, and
 - ii) a lead in electrical connection with the first electrode.

Now referring to FIGS. 20a and 20b, in some embodiments, first 701 and second 751 cannulae are each provided with a curved bore 703, 753 in their respective distal portions 705, 755, wherein each bore has a proximal lateral opening 707, 757. The apparatus further comprises first and second probes 711, 761, each containing an electrode 713, 763. In some embodiments, the probe may sit in a distal region of the bore (as in FIG. 20a) during advance of the cannula. Once the target tissue region is reached, then probes are moved proximally (by, for example, a pull wire not shown) and exit the proximal lateral openings so that the inner faces 715, 765 of the electrodes face other.

Therefore, in accordance with the present invention, there is provided an intraosseous nerve denervation system, comprising:

- a) a cannula having a longitudinal bore defining a first axis,
- b) a stylet having an outer diameter adapted to be received within the longitudinal bore and a distal tip adapted to penetrate cortical bone, and
- c) a first probe comprising:
 - i) an outer diameter adapted to be received within the longitudinal bore, and
 - ii) a first electrode, and
 - iii) a lead in electrical connection with the first electrode.

Now referring to FIGS. 21a and 21b, in some embodiments, at least one probe 801 comprises i) a distal portion 803 having an electrode 805 and ii) a proximal portion 807, the distal portion being pivotally attached to the proximal portion by pivot 809. In some embodiments, two probes

having such pivotally attached electrodes are introduced through the cannulae in a first linear mode (shown in FIG. 21a) to produce an angle θ between the electrodes. Next, the respective pivots are actuated (by for example, a pull wire—not shown) to produce the angled configuration shown in FIG. 21b which reduces the angle θ between the electrodes. Preferably, the pivoting brings the electrodes into a substantially parallel relation.

Therefore, in accordance with the present invention, there is provided an intraosseous nerve denervation system comprising:

- a) a first probe having:
 - i) a distal portion having a first electrode,
 - ii) a proximal portion comprising a first lead in electrical connection with the first electrode, and
 - iii) a pivot pivotally connecting the proximal and distal portions of the probe.

In some embodiments, relatively even heating is provided by providing current density gradients. Now referring to FIG. 22, in some embodiments, first 821 and second 831 probes have first 823 and second 833 electrodes having a reverse conical shape. In particular, each electrode has a relatively thick distal portion 827, 837 and a relatively thin proximal portion 825, 835. When this probe is activated, it is believed that the current density of this electrode will vary axially, with a relatively high current density present at the proximal portion of each electrode (due to the smaller surface area) and a relatively low current density present at the distal portion of the electrode (due to the larger surface area). This current density gradient should provide a more even heating zone when the electrodes themselves are oriented at a significant angle, as the preference for tip heating (caused by the angled orientation of the electrodes) is substantially balanced by the higher current density at the proximal portions of the electrodes.

Therefore, in accordance with the present invention, there is provided an intraosseous nerve denervation system comprising:

- a) a first probe having a first electrode and a first lead in electrical connection with the first electrode, wherein the first electrode has a proximal end having a proximal diameter and a distal end having a distal diameter, and wherein the proximal end diameter is less than the distal end diameter.

Current density gradients can also be produced by providing a plurality of electrodes on each probe. Now referring to FIG. 23, in some embodiments, first and second electrodes each have a plurality of electrodes. In particular, first probe 851 has first 853, second 854 and third 855 active electrodes, while second probe 861 has first 863, second 864 and third 865 return electrodes. The voltage across the probes can be selected so that there is increasing voltage (and therefore current) across the more widely spaced electrodes (i.e., $V_{855-865} < V_{854-864} < V_{853-863}$). In some embodiments, the probes of FIG. 23 are driven by multiple voltage sources (i.e., a first voltage source for providing voltage between first active electrode 853 and first return electrode 863, etc.).

Therefore, in accordance with the present invention, there is provided a method of therapeutically treating a vertebral body having a BVN, comprising the steps of:

- a) providing a first energy device having distal and proximal active electrodes,
- b) providing a second energy device having distal and proximal return electrodes,

c) placing the first and second energy devices in the vertebral body to define a first distance between the distal active electrode and the distal return electrode, and a second distance between the proximal active electrode and the proximal return electrode, wherein the first distance is less than the second distance,

d) applying a first high frequency voltage between the distal active and distal return electrodes, and applying a second high frequency voltage between the proximal active and proximal return electrodes, wherein the first high frequency voltage is less than the second high frequency voltage.

Because multiple voltage sources may add complexity to the device, in other embodiments, the differences in voltage may be provided by a single voltage source by using a poorly conductive electrode. In particular, in some embodiments thereof, the probe comprises an electrically conductive probe shaft and a plurality of spaced apart insulating jackets wherein the spacing produces the electrodes of FIG. 23. In this jacketed embodiment, the probe shaft can be made of a material that is a relatively poor electrical conductor (such as tantalum) so that, when a single driving force is applied between the jacketed probes, the voltage is highest at the proximal electrode 853, but loss due to the poor conductance produces a substantially lower voltage at distal electrode 855. This jacketed embodiment eliminates the need for multiple voltage sources.

In another dual probe approach, in some embodiments, and now referring to FIG. 24, there is provided an apparatus having first probe 871 having an active electrode 873, and a second 881 probe having a return electrode 883, wherein the ratio of the surface area of the active electrode to the surface area of the return electrode is very high, i.e., at least 2:1 (more preferably at least 5:1). In this condition, the current density will be very high at the active electrode and very low at the return electrode, so that the total heating zone THZ will occur essentially only around the active electrode. Since this device heats essentially only at the active electrode, this device substantially mimics the heating profile of a monopolar electrode, but provides the desirable safety feature of locally directing the current to the return electrode.

Therefore, in accordance with the present invention, there is provided an intraosseous nerve denervation system comprising:

- a) a first probe having:
 - i) an active electrode having a first surface area, and
 - ii) a first lead in electrical connection with the first electrode,
- b) a second probe having:
 - i) a return electrode having a first surface area, and
 - ii) a second lead in electrical connection with the second electrode,

wherein the first surface area is at least two times greater than the second surface area, and, means for creating first and second bores within a bone for accommodating the first and second probes.

Although the dual probe approach has many benefits, in other embodiments of the present invention, an articulated probe having both active and return electrodes may be used in accordance with the present invention.

Now referring to FIG. 25, there is provided a preferred articulated device according to the present invention. In preferred embodiments, this device 900 comprises a fixed probe 901 and a pivotable probe 951.

Fixed probe 901 comprises a shaft 903 having a longitudinal axis and a distal end portion 905 comprising sharpened distal tip 906 and a proximal end portion 907. Disposed near

the distal end portion of the probe is first electrode 909. The fixed probe is designed so that the first electrode is placed in electrical connection with a first lead of a power supply. In this particular embodiment, the shaft has a longitudinal bore 911 running from the proximal end portion up to at least the first electrode. Disposed within the bore is a first wire (not shown) electrically connected at its first end to the first electrode and having a second end adapted to be electrically connected to a first lead of a power supply (not shown). The fixed probe also comprises a recess 927 forming a lateral opening in the shaft and designed to house the pivotable probe when in its undeployed mode.

Pivotable probe 951 comprises a shaft 953 having a longitudinal axis, a distal end portion 955, and a proximal end portion 957 pivotally attached to the fixed probe by pivot 961. The pivot allows the pivoting probe to pivot about the fixed probe. Disposed near the distal end portion of the pivotable probe is second electrode 963. The probe is designed so that the second electrode is placed in electrical connection with a second lead of the power supply.

The pivotable probe has an undeployed mode and a deployed mode. In the un-deployed mode, the pivotable probe is seated within the recess of the fixed probe so that the axis of its shaft is essentially in line with the axis of the fixed probe shaft. In this state, the pivotable probe essentially hides within the fixed probe. In the deployed mode, the pivotable probe extends at a significant angle from the fixed probe so that the axis of its shaft forms an angle of at least 10 degrees with the axis of the fixed probe shaft.

In some embodiments, a pusher rod is used to deploy the pivotable probe. Pusher rod 975 comprises a proximal handle (not shown) for gripping and a distal end portion 977 having a shape for accessing the bore of the fixed probe. Distal end portion has a tip 981 having a shape which, when advanced distally, can push the distal end portion of the pivotable probe laterally out of the recess.

Therefore, in accordance with the present invention, there is provided a device for denervating an ION in a bone, comprising:

- a) a fixed probe having a first electrode thereon in electrical connection with the powder supply, and
- b) a pivotable probe comprising a second electrode having a proximal portion pivotally engaged to the fixed probe.

In some embodiments, the pivotable device has both an active and a return electrode, and the device is introduced through a single pedicle. The location of these electrodes may vary depending upon the use of the pivotable device. For example, when the active electrode is located on the pivotable probe, the return electrode may be positioned in a location selected from the group consisting of:

- a) a location on the fixed probe distal of the pivot (as in FIG. 25);
- b) a location on the fixed probe proximal of the pivot;
- c) a location on the pivotable probe located nearer the pivot; and
- d) a location on the pusher rod.

In other embodiments, the locations of the active and return electrodes are reversed from those described above.

In general, it is desirable to operate the present invention in a manner that produces a peak temperature in the target tissue of between about 80° C. and 95° C. When the peak temperature is below 80° C., the off-peak temperatures may quickly fall below about 45° C. When the peak temperature is above about 95° C., the bone tissue exposed to that peak temperature may experience necrosis and produce charring. This charring reduces the electrical conductivity of the charred tissue, thereby making it more difficult to pass RF

current through the target tissue beyond the char and to resistively heat the target tissue beyond the char. In some embodiments, the peak temperature is preferably between 86° C. and 94° C.

It is desirable to heat the volume of target tissue to a minimum temperature of at least 42° C. When the tissue experiences a temperature above 42° C., nerves within the target tissue may be desirably damaged. However, it is believed that denervation is a function of the total quantum of energy delivered to the target tissue, i.e., both exposure temperature and exposure time determine the total dose of energy delivered. Accordingly, if the temperature of the target tissue reaches only about 42° C., then it is believed that the exposure time of the volume of target tissue to that temperature should be at least about 30 minutes and preferably at least 60 minutes in order to deliver the dose of energy believed necessary to denervate the nerves within the target tissue.

Preferably, it is desirable to heat the volume of target tissue to a minimum temperature of at least 50° C. If the temperature of the target tissue reaches about 50° C., then it is believed that the exposure time of the volume of target tissue to that temperature need only be in the range of about 2 minutes to 10 minutes to achieve denervation.

More preferably, it is desirable to heat the volume of target tissue to a minimum temperature of at least 60° C. If the temperature of the target tissue reaches about 60° C., then it is believed that the exposure time of the volume of target tissue to that temperature need only be in the range of about 0.01 minutes to 1.5 minutes to achieve denervation, preferably 0.1 minutes to 0.25 minutes.

Typically, the period of time that an ION is exposed to therapeutic temperatures is in general related to the length of time in which the electrodes are activated. However, since it has been observed that the total heating zone remains relatively hot even after power has been turned off (and the electric field eliminated), the exposure time can include a period of time in which current is not running through the electrodes.

In general, the farther apart the electrodes, the greater the likelihood that the ION will be contained within the total heating zone. Therefore, in some embodiments, the electrodes are placed at least 5 mm apart, more preferably at least 10 mm apart. However, if the electrodes are spaced too far apart, the electric field takes on an undesirably extreme dumbbell shape. Therefore, in many preferred embodiments, the electrodes are placed apart a distance of between 5 mm and 25 mm, more preferably between 5 mm and 15 mm, more preferably between 10 mm and 15 mm.

In some embodiments, it is desirable to heat the target tissue so that at least about 1 cc of bone tissue experiences the minimum temperature. This volume corresponds to a sphere having a radius of about 0.6 cm. Alternatively stated, it is desirable to heat the target tissue so the minimum temperature is achieved by every portion of the bone within 0.6 cm of the point experiencing the peak temperature.

More preferably, it is desirable to heat the target tissue so that at least about 3 cc of bone experiences the minimum temperature. This volume corresponds to a sphere having a radius of about 1 cm.

In one preferred embodiment, the present invention provides a steady-state heated zone having a peak temperature of between 80° C. and 95° C. (and preferably between 86° C. and 94° C.), and heats at least 1 cc of bone (and preferably at least 3 cc of bone) to a temperature of at least 50° C. (and preferably 60° C.).

Therefore, in accordance with the present invention, there is provided a method of therapeutically treating a vertebral body having a BVN, comprising the steps of:

- a) providing an energy device having an active and a return electrode,
- a) inserting the active electrode into the vertebral body,
- b) inserting the return electrode into the vertebral body, and
- c) applying a sufficiently high frequency voltage difference between the active and return electrodes to generate a current therebetween to produce a total heating zone having a diameter of at least 0.5 cm and a steady state temperature of at least 50° C.

As noted above, a peak temperature below about 100° C. is desirable in order to prevent charring of the adjacent tissue, steam formation and tissue popping. In some embodiments, this is accomplished by providing the power supply with a feedback means that allows the peak temperature within the heating zone to be maintained at a desired target temperature, such as 90° C. In some embodiments, between about 24 watts and 30 watts of power is first supplied to the device in order to rapidly heat the relatively cool bone, with maximum amperage being obtained within about 10-15 seconds. As the bone is further heated to the target temperature, the feedback means gradually reduces the power input to the device to between about 6-10 watts.

If the active electrode has no active cooling means, it may become be subject to conductive heating by the heated tissue, and the resultant increased temperature in the electrode may adversely affect performance by charring the adjacent bone tissue. Accordingly, in some embodiments, a cool tip active electrode may be employed. The cooled electrode helps maintain the temperature of the electrode at a desired temperature. Cooled tip active electrodes are known in the art. Alternatively, the power supply may be designed to provided a pulsed energy input. It has been found that pulsing the current favorably allows heat to dissipate from the electrode tip, and so the active electrode stays relatively cooler.

The following section relates to the general structure of preferred energy devices in accordance with the present invention:

The apparatus according to the present invention comprises an electro surgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. In some embodiments, a return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft

In preferred embodiments, the electrosurgical probe or catheter will comprise a shaft or a handpiece having a proximal end and a distal end which supports one or more electrode terminal(s). The shaft or handpiece may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will

usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft.

Preferably, the shaft may be a rigid needle that is introduced through a percutaneous penetration in the patient. However, for endoscopic procedures within the spine, the shaft will have a suitable diameter and length to allow the surgeon to reach the target site (e.g., a disc) by delivering the shaft through the thoracic cavity, the abdomen or the like. Thus, the shaft will usually have a length in the range of about 5.0 to 30.0 cm, and a diameter in the range of about 0.2 mm to about 10 mm. In any of these embodiments, the shaft may also be introduced through rigid or flexible endoscopes.

The probe will include one or more active electrode(s) for applying electrical energy to tissues within the spine. The probe may include one or more return electrode(s), or the return electrode may be positioned on the patient's back, as a dispersive pad. In either embodiment, sufficient electrical energy is applied through the probe to the active electrode(s) to either necrose the blood supply or nerves within the vertebral body.

The electrosurgical instrument may also be a catheter that is delivered percutaneously and/or endoluminally into the patient by insertion through a conventional or specialized guide catheter, or the invention may include a catheter having an active electrode or electrode array integral with its distal end. The catheter shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode or electrode array. The catheter shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode or electrode array and the return electrode to a connector at the proximal end of the catheter shaft. The catheter shaft may include a guide wire for guiding the catheter to the target site, or the catheter may comprise a steerable guide catheter. The catheter may also include a substantially rigid distal end portion to increase the torque control of the distal end portion as the catheter is advanced further into the patient's body. Specific deployment means will be described in detail in connection with the figures hereinafter.

In some embodiments, the electrically conductive wires may run freely inside the catheter bore in an unconstrained made, or within multiple lumens within the catheter bore.

The tip region of the instrument may comprise many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy is achieved by connecting each individual electrode terminal and the return electrode to a power source having independently controlled or current limited channels. The return electrode(s) may comprise a single tubular member of conductive material proximal to the electrode array. Alternatively, the instrument may comprise an array of return electrodes at the distal tip of the instrument (together with the active electrodes) to maintain the electric current at the tip. The application of high frequency voltage between the return electrode(s) and the electrode array results in the generation of high electric field intensities at the distal tips of the electrode terminals with conduction of high frequency current from each individual electrode terminal to the return electrode. The current flow from each

individual electrode terminal to the return electrode(s) is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the surrounding conductive fluid while minimizing energy delivery to surrounding (non-target) tissue.

Temperature probes associated with the apparatus may preferably be disposed on or within the electrode carrier; between the electrodes (preferred in bipolar embodiments); or within the electrodes (preferred for monopolar embodiments). In some embodiments wherein the electrodes are placed on either side of the ION, a temperature probe is disposed between the electrodes or in the electrodes. In alternate embodiments, the deployable portion of the temperature probe comprises a memory metal.

The electrode terminal(s) are preferably supported within or by an inorganic insulating support positioned near the distal end of the instrument shaft. The return electrode may be located on the instrument shaft, on another instrument or on the external surface of the patient (i.e., a dispersive pad). The close proximity of the dual needle design to the intrasosseous nerve makes a bipolar design more preferable because this minimizes the current flow through non-target tissue and surrounding nerves. Accordingly, the return electrode is preferably either integrated with the instrument body, or another instrument located in close proximity thereto. The proximal end of the instrument(s) will include the appropriate electrical connections for coupling the return electrode(s) and the electrode terminal(s) to a high frequency power supply, such as an electrosurgical generator.

In some embodiments, the active electrode(s) have an active portion or surface with surface geometries shaped to promote the electric field intensity and associated current density along the leading edges of the electrodes. Suitable surface geometries may be obtained by creating electrode shapes that include preferential sharp edges, or by creating asperities or other surface roughness on the active surface(s) of the electrodes. Electrode shapes according to the present invention can include the use of formed wire (e.g., by drawing round wire through a shaping die) to form electrodes with a variety of cross-sectional shapes, such as square, rectangular, L or V shaped, or the like. Electrode edges may also be created by removing a portion of the elongate metal electrode to reshape the cross-section. For example, material can be ground along the length of a round or hollow wire electrode to form D or C shaped wires, respectively, with edges facing in the cutting direction. Alternatively, material can be removed at closely spaced intervals along the electrode length to form transverse grooves, slots, threads or the like along the electrodes. In other embodiments, the probe can be sectored so that a given circumference comprises an electrode region and an inactive region. In some embodiments, the inactive region is masked.

The return electrode is typically spaced proximally from the active electrode(s) a suitable distance. In most of the embodiments described herein, the distal edge of the exposed surface of the return electrode is spaced about 5 to 25 mm from the proximal edge of the exposed surface of the active electrode(s), in dual needle insertions. Of course, this distance may vary with different voltage ranges, the electrode geometry and depend on the proximity of tissue structures to active and return electrodes. The return electrode will typically have an exposed length in the range of about 1 to 20 mm.

The application of a high frequency voltage between the return electrode(s) and the electrode terminal(s) for appropriate time intervals effects modifying the target tissue.

The present invention may use a single active electrode terminal or an array of electrode terminals spaced around the distal surface of a catheter or probe. In the latter embodiment, the electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive fluids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the catheter to form a single wire that couples to a power source.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said instrument and is connected to a power source which is isolated from each of the other electrode terminals in the array or to circuitry which limits or interrupts current flow to the electrode terminal when low resistivity material (e.g., blood) causes a lower impedance path between the return electrode and the individual electrode terminal. The isolated power sources for each individual electrode terminal may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered. By way of example, the isolated power source may be a user selectable constant current source. In this embodiment, lower impedance paths will automatically result in lower resistive heating levels since the heating is proportional to the square of the operating current times the impedance. Alternatively, a single power source may be connected to each of the electrode terminals through independently actuable switches, or by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the instrument, connectors, cable, controller or along the conductive path from the controller to the distal tip of the instrument. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode terminal(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

In a preferred aspect of the invention, the active electrode comprises an electrode array having a plurality of electrically isolated electrode terminals disposed over a contact surface, which may be a planar or non-planar surface and which may be located at the distal tip or over a lateral surface of the shaft, or over both the tip and lateral surface(s). The electrode array will include at least two and preferably more electrode terminals, and may further comprise a temperature sensor. In a preferred aspect, each electrode terminal will be connected to the proximal connector by an electrically isolated conductor disposed within the shaft. The conductors permit independent electrical coupling of the electrode terminals to a high frequency power supply and control system with optional temperature monitor for operation of the probe. The control system preferably incorporate active and/or passive current limiting structures, which are designed to limit current flow when the associated electrode terminal is in contact with a low resistance return path back to the return electrode.

The use of such electrode arrays in electrosurgical procedures is particularly advantageous as it has been found to limit the depth of tissue necrosis without substantially reducing power delivery. The voltage applied to each electrode terminal causes electrical energy to be imparted to any body structure which is contacted by, or comes into close proximity with, the electrode terminal, where a current flow through all low electrical impedance paths is preferably but not necessarily limited. Since some of the needles are hollow, a conductive fluid could be added through the needle and into the bone structure for the purposes of lowering the electrical impedance and fill the spaces in the cancellous bone to make them better conductors to the needle.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the catheter shaft to a power source of high frequency current. Alternatively, the instrument may incorporate a single electrode that extends directly through the catheter shaft or is connected to a single lead that extends to the power source. The active electrode(s) may have ball shapes, twizzle shapes, spring shapes, twisted metal shapes, cone shapes, annular or solid tube shapes or the like. Alternatively, the electrode(s) may comprise a plurality of filaments, rigid or flexible brush electrode(s), side-effect brush electrode(s) on a lateral surface of the shaft, coiled electrode(s) or the like.

The voltage difference applied between the return electrode(s) and the electrode terminal(s) will be at high or radio frequency, typically between about 50 kHz and 20 MHz, usually being between about 100 kHz and 2.5 MHz, preferably being between about 400 kHz and 1000 kHz, often less than 600 kHz, and often between about 500 kHz and 600 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 10 volts to 200 volts, often between about 20 to 100 volts depending on the electrode terminal size, the operating frequency and the operation mode of the particular procedure. Lower peak-to-peak voltages will be used for tissue coagulation, thermal heating of tissue, or collagen contraction and will typically be in the range from 50 to 1500, preferably 100 to 1000 and more preferably 120 to 400 volts peak-to-peak. As discussed above, the voltage is usually delivered continuously with a sufficiently high frequency (e.g., on the order of 50 kHz to 20 MHz) (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the sine wave duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is preferably on the order of about 100% for the present invention, as compared with pulsed lasers which typically have a duty cycle of about 0.0001%.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from several milliwatts to tens of watts per electrode, depending on the volume of target tissue being heated, and/or the maximum allowed temperature selected for the instrument tip. The power source allows the user to select the power level according to the specific requirements of a particular procedure.

The power source may be current limited or otherwise controlled so that undesired heating of the target tissue or surrounding (non-target) tissue does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in

the range of 10 uH to 50,000 uH, depending on the electrical properties of the target tissue, the desired tissue heating rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in U.S. Pat. No. 5,697,909. Additionally, current limiting resistors may be selected. Preferably, microprocessors are employed to monitor the measured current and control the output to limit the current.

The area of the tissue treatment surface can vary widely, and the tissue treatment surface can assume a variety of geometries, with particular areas and geometries being selected for specific applications. The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) or electrode terminal(s) will be formed at the distal tip of the electro surgical instrument shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical instrument shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in endoscopic procedures.

The devices of the present invention may be suitably used for insertion into any hard tissue in the human body. In some embodiments, the hard tissue is bone. In other embodiments, the hard tissue is cartilage. In preferred embodiments when bone is selected as the tissue of choice, the bone is a vertebral body. Preferably, the present invention is adapted to puncture the hard cortical shell of the bone and penetrate at least a portion of the underlying cancellous bone. In some embodiments, the probe advances into the bone to a distance of at least $\frac{1}{3}$ of the cross-section of the bone defined by the advance of the probe. In some embodiments, the present invention is practiced in vertebral bodies substantially free of tumors. In others, the present invention is practiced in vertebral bodies having tumors.

Therefore, in accordance with the present invention, there is provided a method of therapeutically treating a healthy vertebral body having a BVN, comprising the steps of:

- a) providing an energy device having an active and a return electrode,
- b) inserting the active electrode into the healthy vertebral body,
- c) inserting the return electrode into the healthy vertebral body,
- d) placing the active electrode on a first side of the healthy vertebral body and the return electrode on a second side of the healthy vertebral body, and

applying a sufficiently high frequency voltage difference between the active and return electrodes to generate a current therebetween to produce a total heating zone to therapeutically heat the BVN.

In some embodiments using two separate probes, the device of the present invention enters the hard tissue (preferably bone, more preferably the vertebral body) through two access points. In preferred embodiments, the pair of separate probes is adapted to denervate the BVN and enter through separate pedicles transpedicularly. In other embodiments, the pair of separate probes each enters the vertebral body extrapedicularly. In other embodiments, a first of the pair of separate probes enters the vertebral body extrapedicularly and the second enters the vertebral body transpedicularly. In embodiments using a single articulated device, the device enters via a single pedicle.

Now referring to FIG. 26, in some embodiments, the target region of the BVN is located within the cancellous

portion of the bone (i.e., to the interior of the outer cortical bone region), and proximal to the junction J of the BVN having a plurality of branches. Treatment in this region is advantageous because only a single portion of the BVN need be effectively treated to denervate the entire system. In contrast, treatment of the BVN in locations more downstream than the junction require the denervation of each branch.

Therefore, in accordance with the present invention, there is provided a method of therapeutically treating a vertebral body having an outer cortical bone region and an inner cancellous bone region, and a BVN having a trunk extending from the outer cortical bone region into the inner cancellous region and a branches extending from the trunk to define a BVN junction, comprising the steps of:

- a) inserting an energy device into the vertebral body, and
- b) exclusively depositing energy within the inner cancellous bone region of the vertebral body between, but exclusive of the BVN junction and the outer cortical bone region, to denervate the BVN.

Typically, treatment in accordance with this embodiment can be effectuated by placing the electrodes in the region of the vertebral body located between 60% (point A) and 90% (point B) of the distance between the anterior and posterior ends of the vertebral body, as shown in FIG. 26.

EXAMPLE I

This prophetic example describes a preferred dual probe embodiment of the present invention.

First, after induction of an appropriate amount of a local anesthesia, the human patient is placed in a prone position on the table. The C-arm of an X-ray apparatus is positioned so that the X-rays are perpendicular to the axis of the spine. This positioning provides a lateral view of the vertebral body, thereby allowing the surgeon to view the access of the apparatus into the vertebral body.

Next, a cannulated stylet comprising an inner stylet and an outer cannula are inserted into the skin above each of the respective pedicles so that the distal tip of each stylet is in close proximity to the respective pedicle.

Next, the probe is advanced interiorly into the body so that the stylet tips bores through the skin, into and through the pedicle, and then into the vertebral body. The stylet is advanced until the tips reach the anterior-posterior midline of the vertebral body.

Next, the stylet is withdrawn and probe is inserted into the cannula and advanced until the first and second electrodes thereof each reach the midline of the vertebral body. The location of the two probes is shown from various perspectives in FIG. 27a-d.

Next, the power supply is activated to provide a voltage between the first and second electrodes. The amount of voltage across the electrodes is sufficient to produce an electric current between the first and second electrodes. This current provides resistive heating of the tissue disposed between the electrodes in an amount sufficient to raise the temperature of the local portion of the BVN to at least 45° C., thereby denervating the BVN.

EXAMPLE II

This example describes the efficacy of heating a large zone of a vertebral body with a bipolar energy device.

A pair of probes were inserted into a vertebral body of a porcine cadaver so that the tips of the electrodes were located substantially at the midline and separated by about

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4 mm. Each electrode had a cylindrical shape, a length of about 20 mm, and a diameter of about 1.65 mm² (16 gauge) to produce a surface area of about 100 mm².

Next, and now referring to FIGS. 28a and 28b, thermocouples 0-14 were placed within the vertebral body at the 15 locations. Thermocouples 0-4 were placed halfway between the electrode tips and were separated by a distance of 2 mm. Thermocouples 5-9 were placed about at the midpoint between the probe tips, and were vertically separated by a distance of 2 mm. Thermocouples 10-14 were placed along the distal portion of the probe and were separated by a distance of 5 mm.

Next, about 57 volts of energy was applied across the electrodes, and the temperature rise in the tissue was recorded at the thermocouple sites. These temperatures are provided in FIGS. 29a-c. In general, the temperature at each site rose somewhat steadily from about 22° C. to its peak temperature in about 200-300 seconds, whereupon feedback controls maintained the peak temperatures.

FIGS. 30a and 30b provide the peak temperatures recorded by each thermocouple. Analysis of the results in FIGS. 17a and 17b reveals that peak temperatures of between about 80° C. and 95° C. were able to be sustained over substantial distances. In particular, a temperature of 79.4 degrees was reached about 10 mm along the electrode (T11); temperatures of between 76.7 and 80.3° C. were reached at a depth of about 4 mm within the tissue (T5 and T9); and a temperature of 76.8° C. was reached about 10 mm along the electrode (T3).

The positive results provided by this example has great significance to the problem of therapeutically heating IONs, and the BVN in particular. In particular, the results of thermocouples T5-9 indicates that if an ION were located along the z-axis within 2 mm of the presumed center of the IRZ, then the ION could be sufficiently treated to at least 80° C. Similarly, the results of thermocouples T0-4 indicates that as much as a 16 mm length of ION could be sufficiently treated to at least 80° C. Lastly, the results of thermocouples T 10-14 indicate that the ION could be off-center laterally in the IRZ by as much as 2 mm and at least about 10 mm of its length could be sufficiently treated to at least 80 C.

EXAMPLE III

This embodiment describes a preferred articulated probe embodiment of the present invention.

The initial steps described above in Example I are carried out so that the articulated probe is poised on the patient's skin and held in place by a ratchet type gun. See FIG. 31a.

Next, the distal end of the articulated probe is inserted into the skin above a pedicle so that the distal end of the fixed probe is in close proximity, to the pedicle.

Now referring to FIG. 31b, the probe is advanced interiorly into the body so that the distal tip bores through the skin, into and through the pedicle, and then into the vertebral body. The distal tip is advanced until it reaches about 30% beyond the anterior-posterior midline of the vertebral body.

Now referring to FIG. 31c, the distal end of the pusher rod is inserted into the bore of the fixed probe and advanced until the angled portion of the pusher rod contacts the angled portion of the pivotable probe, thereby nudging the pivotable probe out of the recess. The pivotable probe is now in a partially deployed mode.

Now referring to FIG. 31d, the apparatus is slightly withdrawn from the body. As this occurs, the bone disposed between the pivotable and fixed probes prevents the pivotable probe from withdrawing along with the fixed probe, but

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rather forces open the pivoting means, thereby bringing the axis of the pivotable probe to a position substantially normal to the axis of the fixed probe. The pivotable probe is now in extended mode.

Next, the power supply is activated to provide a voltage between the first and second electrodes. The amount of voltage across the electrodes is sufficient to produce an electric current between the first and second electrodes. This current provides resistive heating of the tissue disposed between the electrodes in an amount sufficient to raise the temperature of the local portion of the BVN to at least 45° C., thereby denervating the BVN.

Next, the fixed probe is pushed forward to bring the pivotable probe back into the recess.

Now referring to FIGS. 31e, the probe is removed from the body.

EXAMPLE IV

Now referring to FIG. 32, there is provided a dual articulated needle embodiment of the present invention, wherein the articulated needles are each advanced down the pedicles of the vertebral body, and each of the pivotable probes are deployed at an angle of less than 90 degrees, so that the electrodes thereon align themselves in an essentially parallel relationship. Because the electric field produced by this embodiment is relatively even between the electrodes, the resulting total heating zone is also desirably homogeneous. Because the electrodes deploy in the central posterior portion of the vertebral body, the BVN is desirably denervated near its trunk.

We claim:

[1. A method of therapeutically treating a vertebral body having an outer cortical bone region, an inner cancellous bone region, and a basivertebral nerve BVN, comprising the steps of:

- providing a probe configured to deploy an energy device having an electrode;
- the probe comprising a longitudinal bore extending from a proximal end of the probe toward a distal end of the probe;
- the probe comprising a recess in communication with said bore, said recess forming a lateral opening at or near the distal end of the probe;
- the probe further comprising a pivotable member;
- the pivotable member having a fixed end pivotably secured to the probe at a distal location within the recess of the probe, and a free end configured to be seated in said recess;
- wherein the pivotable member comprises an undeployed mode where the free end extends proximally from the fixed end within said recess, and a deployed mode where the free end is configured to pivot about said fixed end and extend outward from said probe;
- articulating the pivotable member from the undeployed mode to the deployed mode to facilitate delivery of the energy device along a path associated with the free end of the pivotable member into the cancellous bone region of the vertebral body; and
- applying a sufficiently high frequency voltage to the electrode to heat the BVN.]

[2. A method as recited in claim 1, the BVN having a trunk extending from the outer cortical bone region and into the inner cancellous bone region and branches extending from the trunk to define a BVN junction, wherein therapeutically heating the BVN comprises:

depositing therapeutic energy within the inner cancellous bone region of the vertebral body.]

[3. The method of claim 2, wherein the therapeutic energy is deposited in a region of the vertebral body located between 60% and 90% of the distance between the posterior and anterior ends of the vertebral body.]

[4. The method of claim 3, wherein said therapeutic energy is deposited in a region of the vertebral body located between 60% and 90% of the distance from the anterior wall to the posterior wall of the vertebral body.]

[5. The method of claim 2, wherein said therapeutic energy deposited includes a region that is proximal of the BVN junction.]

[6. The method of claim 2, wherein said therapeutic energy is deposited within a region that is at least 1 cm in diameter.]

[7. The method of claim 2, wherein said therapeutic energy deposited comprises a steady-state heated zone having a peak temperature of between 80 degrees C. and 95 degrees C.]

[8. The method of claim 7, wherein said steady-state heated zone heats at least 1 cc of bone to a temperature of at least 50 degrees C.]

[9. The method of claim 2, wherein the method is performed to treat pain in a patient diagnosed with pain.]

[10. The method of claim 1, wherein the method is performed to treat pain in a patient diagnosed with pain.]

[11. The method of claim 1, wherein the pivotable member in the undeployed mode is entirely contained within said recess.]

[12. The method of claim 1, wherein articulating the pivotable member from the undeployed mode to the deployed mode comprises advancing a member distally along said bore to push the free end of the of the pivotable member laterally out the recess.]

[13. The method of claim 1, wherein the free end of the pivotable member deploys pivotably outward from the recess into the cancellous bone region.]

14. A method of therapeutically treating a vertebral body having an outer cortical bone region, an inner cancellous bone region, and a basivertebral nerve BVN, comprising the steps of:

providing a probe configured to deploy an energy device comprising an electrode;

the probe comprising a longitudinal bore extending from a proximal end of the probe toward a distal end of the probe;

the probe comprising a recess in communication with said bore, said recess forming an opening at or near the distal end of the probe;

the probe further comprising a pivotable member;

the pivotable member having a fixed end secured to the probe at a location within the recess of the probe, and a free end configured to be extended out of the opening of the probe;

wherein the pivotable member comprises an undeployed mode where the free end is not in an articulated configuration, and a deployed mode where the free end is configured to extend outward from the opening of said probe into the articulated configuration;

articulating the pivotable member from the undeployed mode to the deployed mode to facilitate delivery of the energy device along a path associated with the free end of the pivotable member into the cancellous bone region of the vertebral body; and

applying a sufficiently high frequency voltage to the electrode to heat the BVN to a temperature between 80 degrees Celsius and 95 degrees Celsius and sufficient to denervate the BVN,

wherein the frequency of the voltage is between 400 kHz and 600 kHz,

wherein the probe comprises a sharp distal tip, and wherein the probe comprises a temperature sensor.

15. The method of claim 14, wherein the electrode comprises an active electrode and wherein the probe further comprises a return electrode.

16. The method of claim 14, wherein the applied high frequency voltage is configured to form a heating zone having a diameter of between 0.5 cm and 2.0 cm.

17. The method of claim 14, wherein the probe has a length between 5 and 30 cm and a diameter between 0.2 mm and 10 mm.

18. The method of claim 14, further comprising:
piercing skin of a patient with a cannulated needle, the cannulated needle comprising a cannula and a stylet inserted within the cannula until a distal tip of the stylet extends beyond a distal opening of the cannula;
advancing the cannulated needle so that the distal tip of the stylet enters within the cancellous bone region of the vertebral body;
withdrawing the stylet from the cannula; and
inserting at least a distal portion of the probe through a bore of the cannula and out of the distal opening of the cannula.

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