



(86) Date de dépôt PCT/PCT Filing Date: 2000/09/06
(87) Date publication PCT/PCT Publication Date: 2001/03/22
(45) Date de délivrance/Issue Date: 2008/07/08
(85) Entrée phase nationale/National Entry: 2002/03/15
(86) N° demande PCT/PCT Application No.: US 2000/040830
(87) N° publication PCT/PCT Publication No.: 2001/019301
(30) Priorités/Priorities: 1999/09/17 (US09/398,991);
1999/11/05 (US09/434,653); 2000/02/25 (US09/513,432);
2000/02/25 (US09/513,039); 2000/02/25 (US09/513,042);
2000/06/23 (US09/602,141)

(51) Cl.Int./Int.Cl. *A61F 5/56* (2006.01),
A61B 17/24 (2006.01), *A61F 2/02* (2006.01)

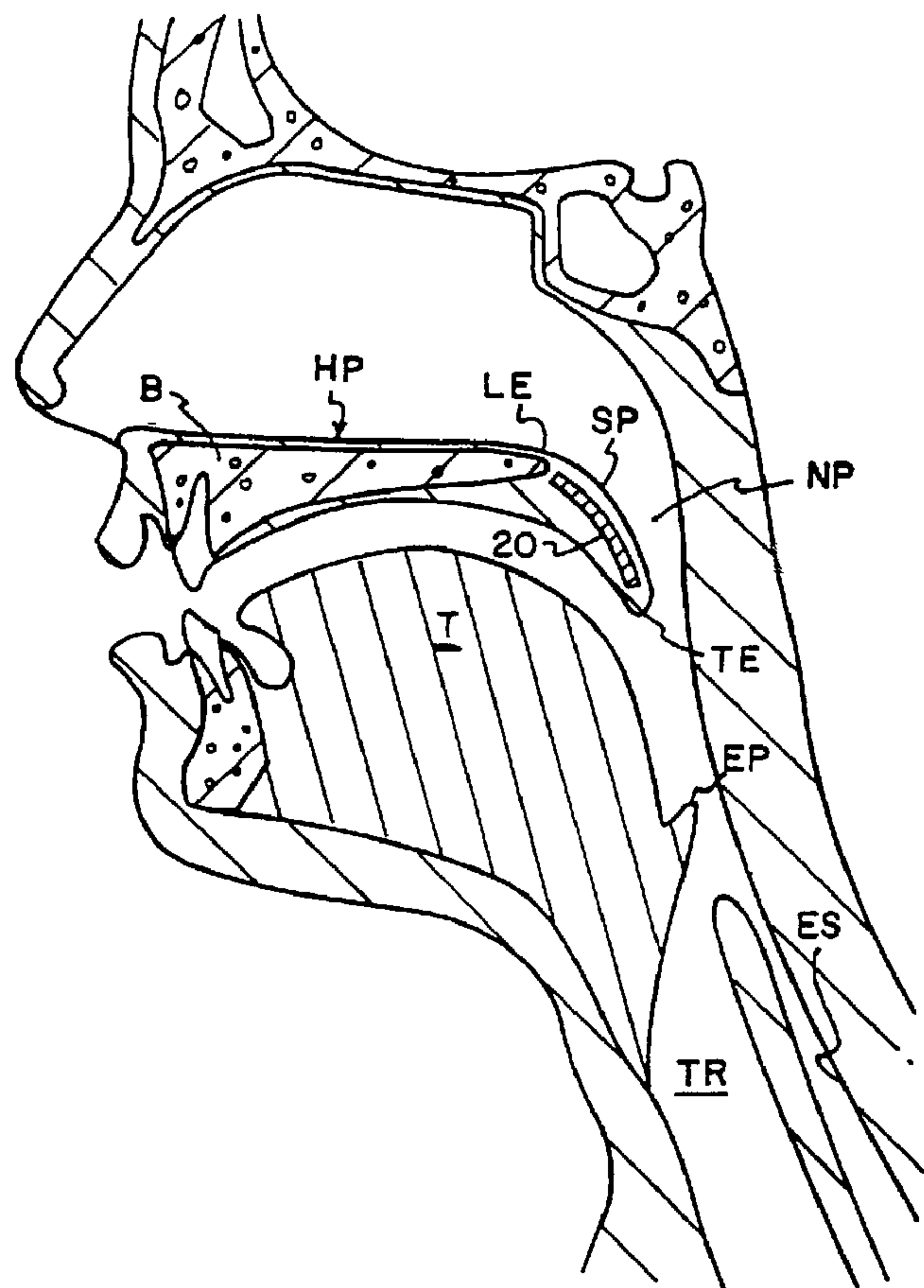
(72) Inventeurs/Inventors:
CONRAD, TIMOTHY R., US;
KNUDSON, MARK B., US;
GRIFFIN, JERRY C., US

(73) Propriétaire/Owner:
RESTORE MEDICAL, INC., US

(74) Agent: SIM & MCBURNEY

(54) Titre : IMPLANTS ET PROCEDES POUR TRAITER LES RONFLEMENTS

(54) Title: IMPLANTS AND METHODS FOR SNORING TREATMENT



(57) Abrégé/Abstract:

An apparatus for use in treating snoring of a patient suffering from snoring includes an implant (20) of bio-compatible material sized to be embedded within the soft palate (SP). When implanted, the implant (20) is able to alter a dynamic response of the soft palate (SP) to airflow past the soft palate (SP).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
22 March 2001 (22.03.2001)

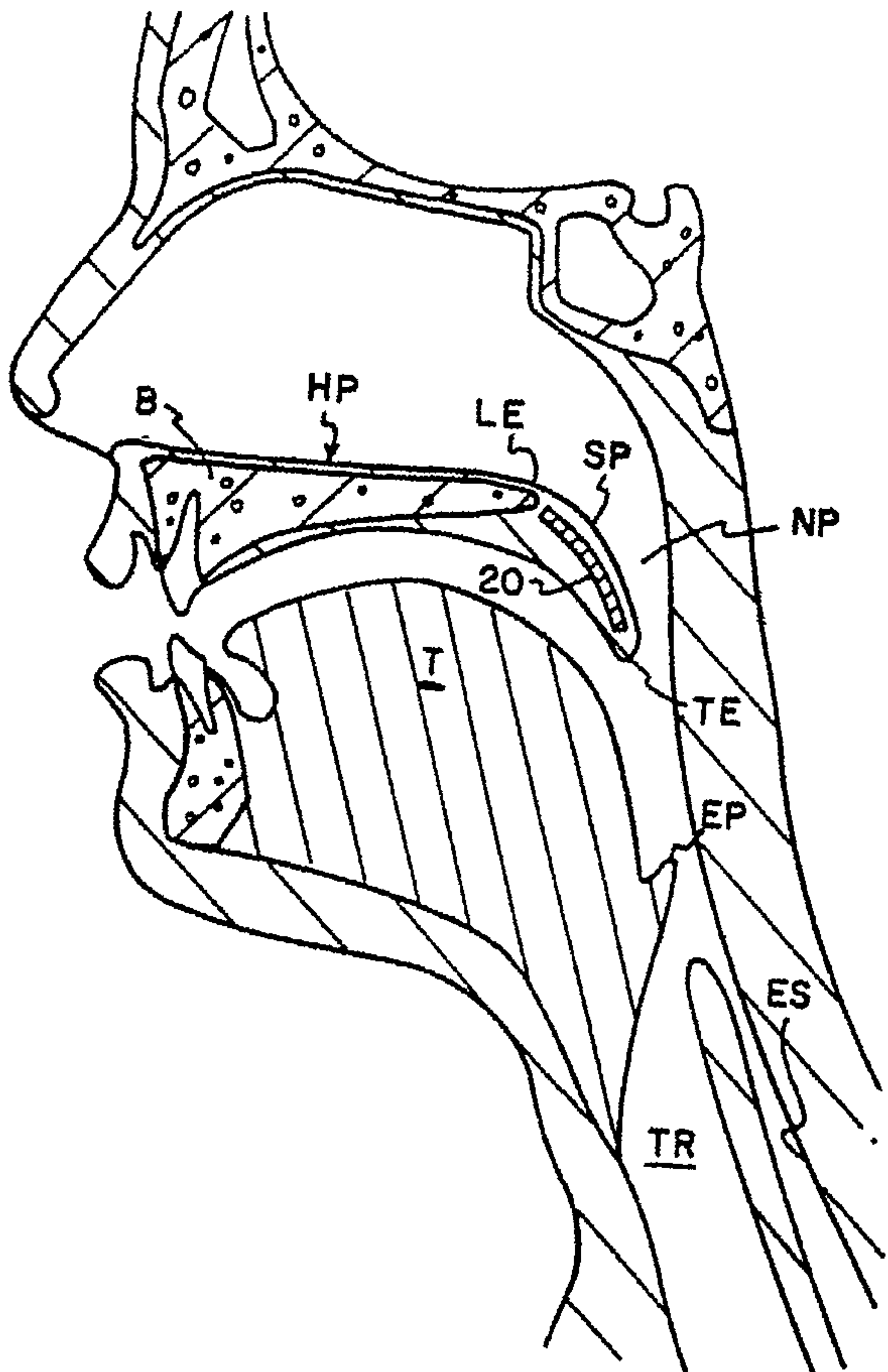
PCT

(10) International Publication Number
WO 01/19301 A1

- (51) International Patent Classification⁷: **A61F 5/56** (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 09/602,141 (CIP)
Filed on 23 June 2000 (23.06.2000)
- (21) International Application Number: PCT/US00/40830
- (22) International Filing Date:
6 September 2000 (06.09.2000) (71) Applicant (for all designated States except US): **PI MEDICAL, INC.** [US/US]; 2800 Patton Road, St. Paul, MN 55113 (US).
- (25) Filing Language: English
- (26) Publication Language: English (72) Inventors; and (75) Inventors/Applicants (for US only): **CONRAD, Timothy, R.** [US/US]; 6903 Ros Emily Lane, Eden Prairie, MN 55344 (US). **KNUDSON, Mark, B.** [US/US]; 1309 West Royal Oaks Drive, Shoreview, MN 55126 (US). **GRIFFIN, Jerry, C.** [US/US]; 1 Miraflores Lane, Tiburon, CA 94920 (US).
- (30) Priority Data:
09/398,991 17 September 1999 (17.09.1999) US
09/434,653 5 November 1999 (05.11.1999) US
09/513,042 25 February 2000 (25.02.2000) US
09/513,039 25 February 2000 (25.02.2000) US
09/513,432 25 February 2000 (25.02.2000) US
09/602,141 23 June 2000 (23.06.2000) US (74) Agent: **BRUESS, Steven, C.**; Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903 (US).

[Continued on next page]

(54) Title: IMPLANTS AND METHODS FOR SNORING TREATMENT



(57) Abstract: An apparatus for use in treating snoring of a patient suffering from snoring includes an implant (20) of bio-compatible material sized to be embedded within the soft palate (SP). When implanted, the implant (20) is able to alter a dynamic response of the soft palate (SP) to airflow past the soft palate (SP).

WO 01/19301 A1

IMPLANTS AND METHODS FOR SNORING TREATMENT

BACKGROUND

1. Field of the Invention

5 This invention is directed to methods and apparatuses for treating snoring.

2. Description of the Prior Art

Snoring has received increased scientific and academic attention.

10 One publication estimates that up to 20% of the adult population snores habitually. Huang, et al., "Biomechanics of Snoring", Endeavour, p. 96-100, Vol. 19, No. 3 (1995). Snoring can be a serious cause of marital discord. In addition, snoring can present a serious health risk to the snorer. In 10% of habitual snorers, collapse of the airway during sleep can lead to obstructive sleep apnea syndrome. Id.

15 Notwithstanding numerous efforts to address snoring, effective treatment of snoring has been elusive. Such treatment may include mouth guards or other appliances worn by the snorer during sleep. However, patients find such appliances uncomfortable and frequently discontinue use (presumably adding to marital stress).

20 Electrical stimulation of the soft palate has been suggested to treat snoring and obstructive sleep apnea. See, e.g., Schwartz, et al., "Effects of electrical stimulation to the soft palate on snoring and obstructive sleep apnea", J. Prosthetic Dentistry, pp. 273-281 (1996). Devices to apply such stimulation are described in U. S. Pat. Nos. 5,284,161 and 5,792,067. Such devices are appliances requiring patient
25 adherence to a regimen of use as well as subjecting the patient to discomfort during sleep. Electrical stimulation to treat sleep apnea is discussed in Wiltfang, et al., "First results on daytime submandibular electrostimulation of suprahyoidal muscles to prevent night-time hypopharyngeal collapse in obstructive sleep apnea syndrome", International Journal of Oral & Maxillofacial Surgery, pp. 21-25 (1999).

implant of bio-compatible material sized to be embedded within the soft palate.
When inserted, the implant is able to alter a dynamic response of the soft palate to
airflow past the soft palate.

Accordingly, in one aspect of the present invention there is provided an
5 apparatus for use in the treatment of snoring, comprising:

an implant of biocompatible material suitable for embedding in a soft
palate of a patient;

the biocompatible material including a fibrosis-inducing material
selected to induce a fibrotic response of tissue in the soft palate following implantation
10 of said implant; and

said fibrosis-inducing material provided in an amount which is sufficient
to induce a fibrotic stiffening of the soft palate following implantation of said implant
to passively and without application of external force alter the dynamic response of said
soft palate to airflow.

15 According to another aspect of the present invention there is provided an
implantation device comprising a needle and the apparatus as described above, the
needle being suitable for implanting said implant into the soft palate.

According to yet another aspect of the present invention there is
provided a pack comprising the apparatus as described above and further including
20 instructions to use the apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will now be described more fully
with reference to the accompanying drawings in which:

25 Fig. 1 is a side sectional view of a portion of a human head showing a
soft palate in a relaxed state and in relation in adjacent anatomical features;

Fig. 2 is a portion of the view of Fig. 1 showing the soft palate in a
flexed state;

Fig. 3 is a front view of an interior of the mouth shown in Fig. 1 and
30 showing an area to be ablated according to a first prior art surgical procedure;

Fig. 4 is the view of Fig. 3 and showing an area to be scarred according
to a second prior art surgical procedure;

Fig. 5 is a schematic representation of a spring-mass system model of
the soft palate;

Fig. 6 is the view of Fig. 1 with the soft palate containing an implant according to a first embodiment of the present invention;

Fig. 7 is the view of Fig. 3 showing the embodiment of Fig. 6;

Fig. 8 is a cross-sectional view of the implant of Fig. 6;

5 Fig. 9 is a first modification of the implant of Fig. 8 having a tissue in-growth layer;

Fig. 10 is a second modification of the implant of Fig. 8 having a smooth outer layer;

10 Fig. 11 is the view of Fig. 6 with the soft palate containing an implant according to a second embodiment of the present invention;

Fig. 12 is the view of Fig. 7 showing the embodiment of Fig. 11;

Fig. 13 is a perspective view of the implant of Fig. 11;

Fig. 14 is a cross-sectional view of the implant of Fig. 13;

15 Fig. 15 is a view of the implant of Fig. 14 with the implant pre-formed to assume the shape of a soft palate in a relaxed state;

Fig. 16 is the view of Fig. 14 with the implant constructed to have greater flexion in a downward direction;

Fig. 17 is an exploded perspective view of first modification of the implant of Fig. 13;

20 Fig. 18 is a perspective view of a modification of a housing of the embodiment of Fig. 17;

Fig. 19 is a side section view of a second modification of the implant of Fig. 13;

46. The use of the implantation device of any one of claims 36 to 42 in the treatment of snoring.

FIG. 7

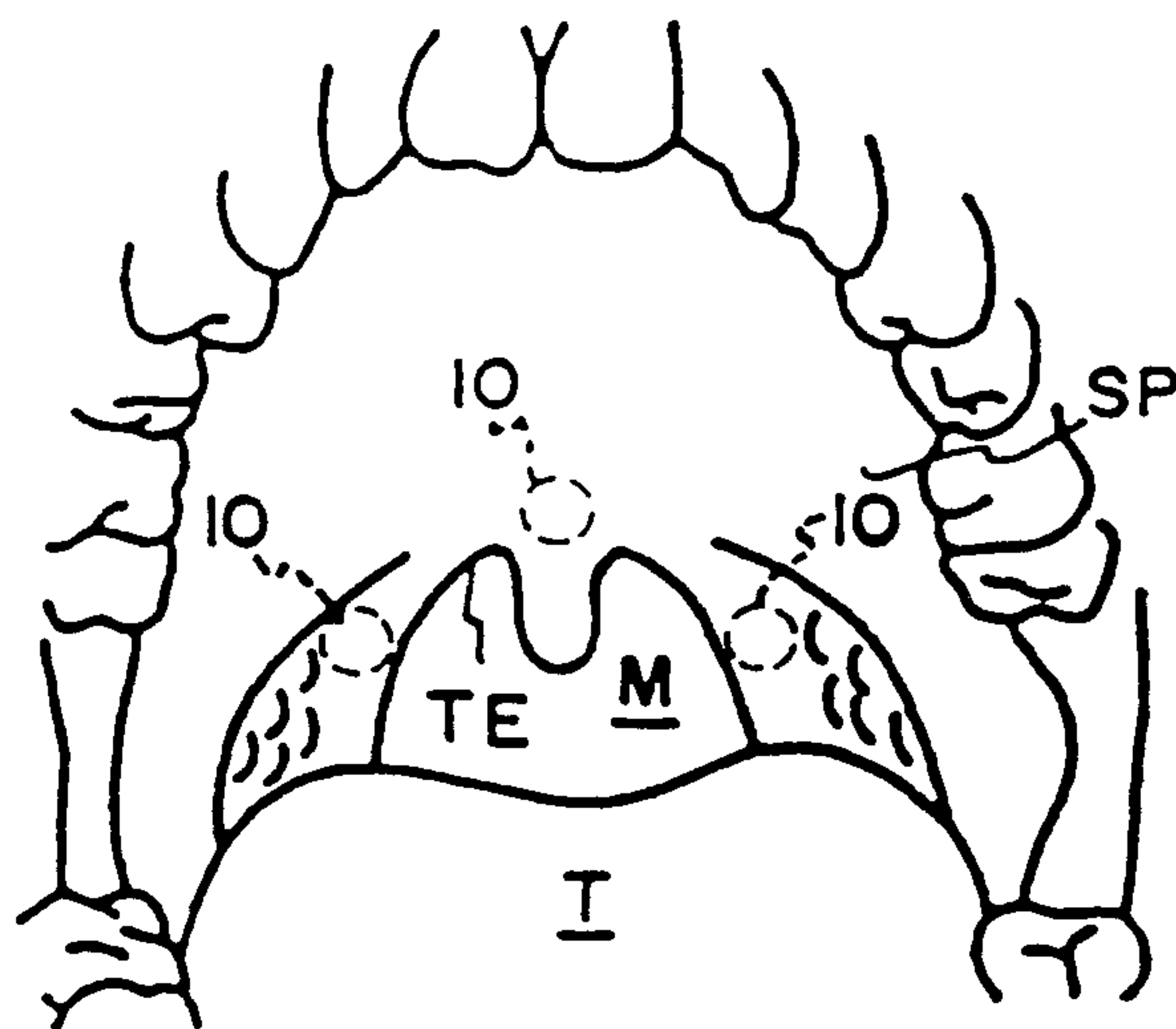


FIG. 8

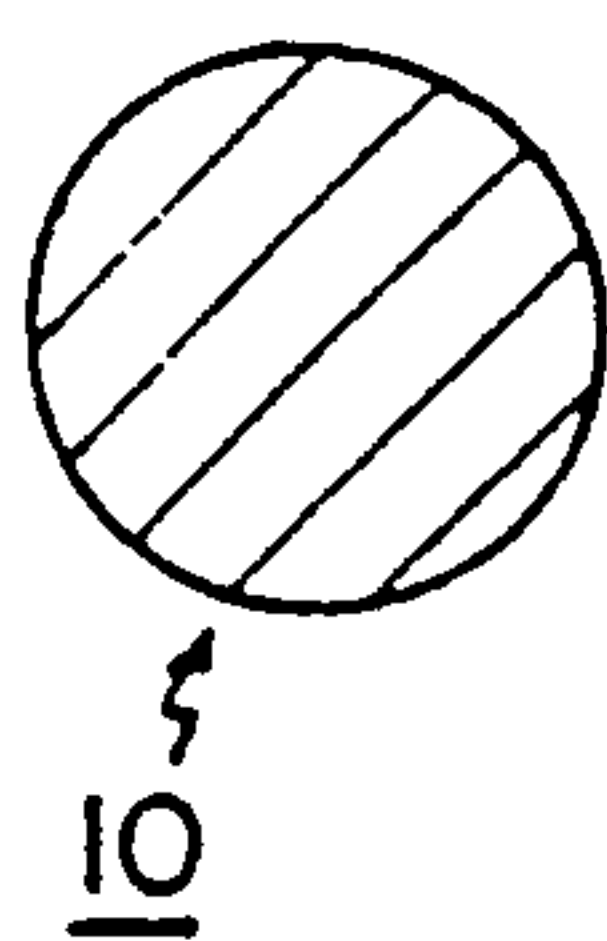


FIG. 9

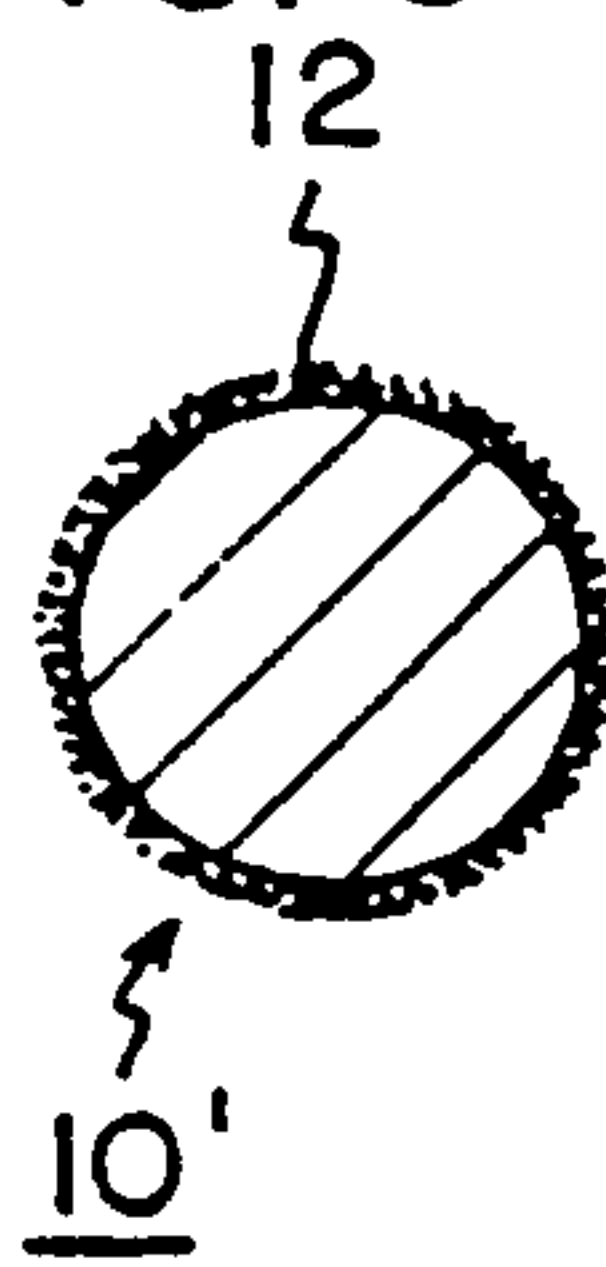


FIG. 10

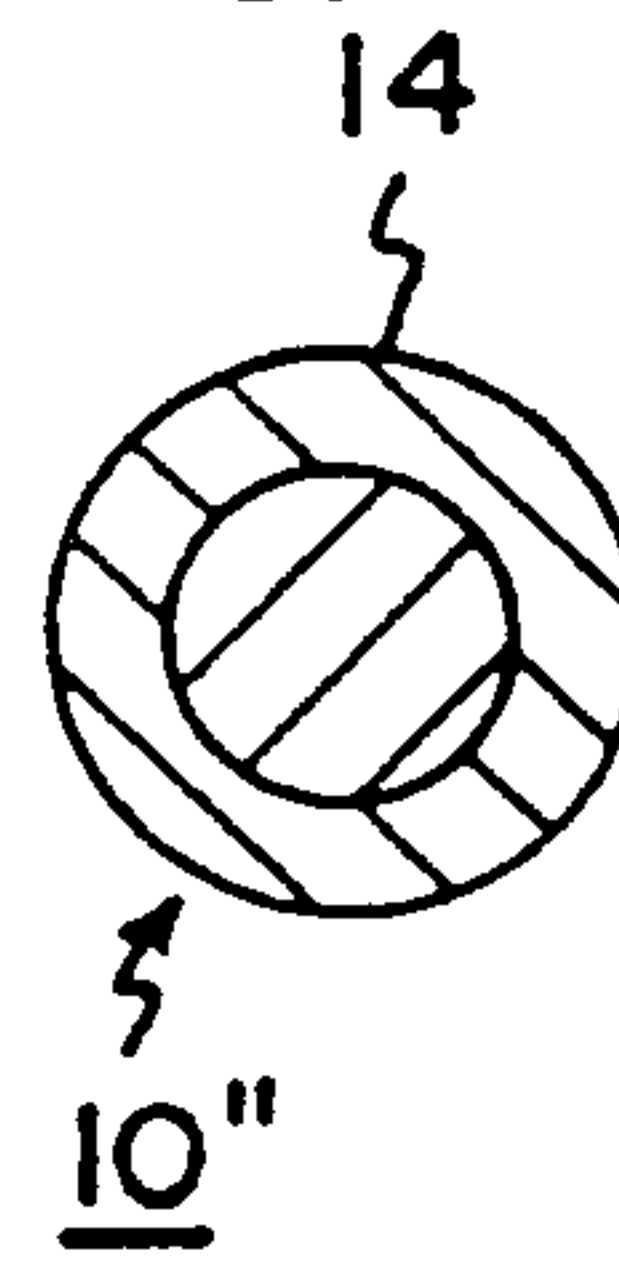


FIG. 12

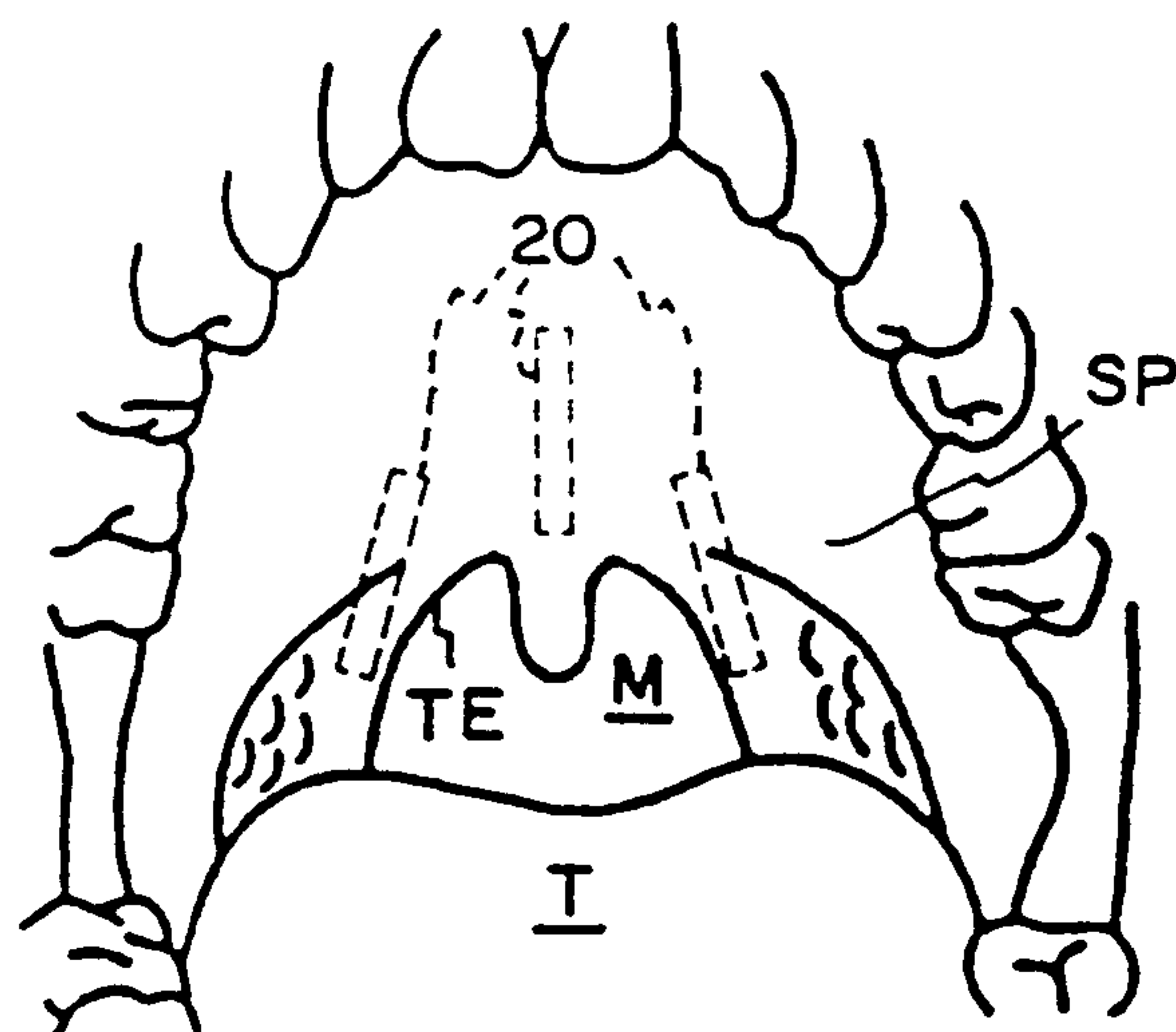


FIG. 13

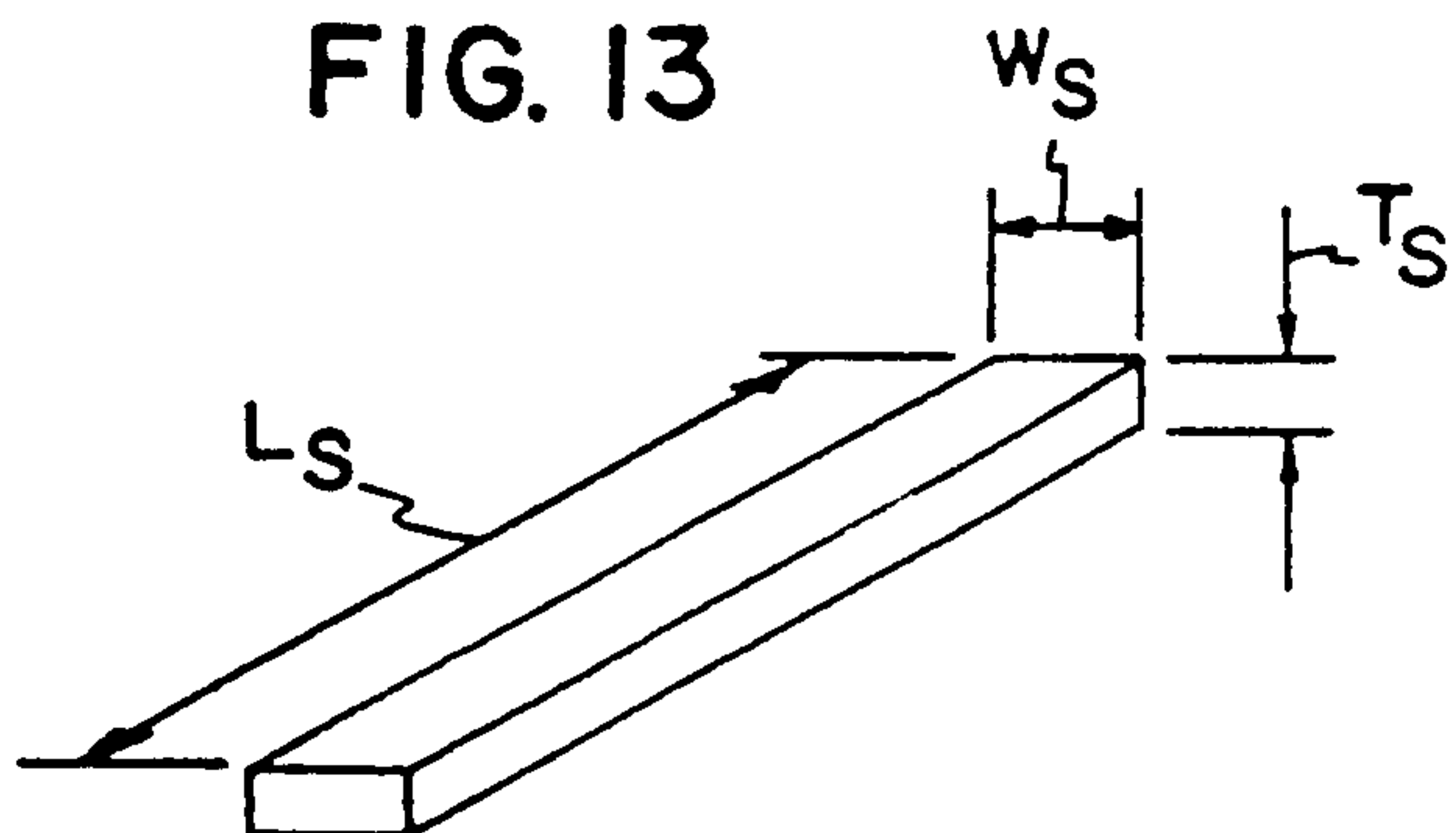


FIG. 14

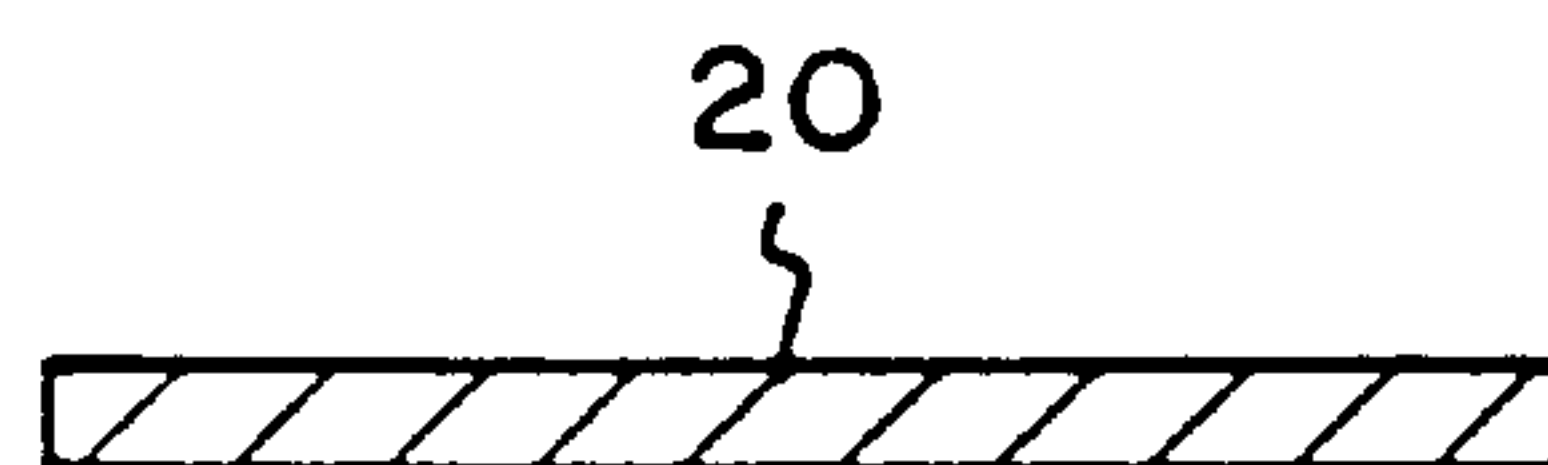


FIG. 15

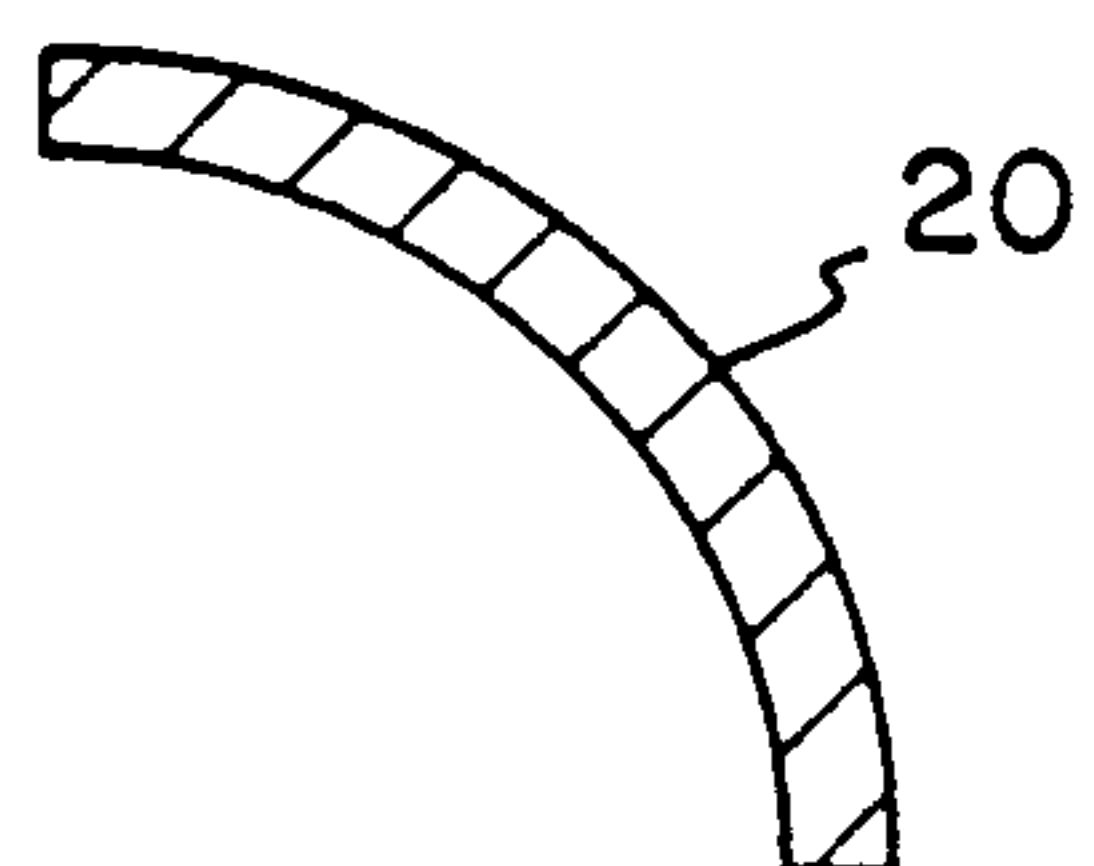


FIG. 16

