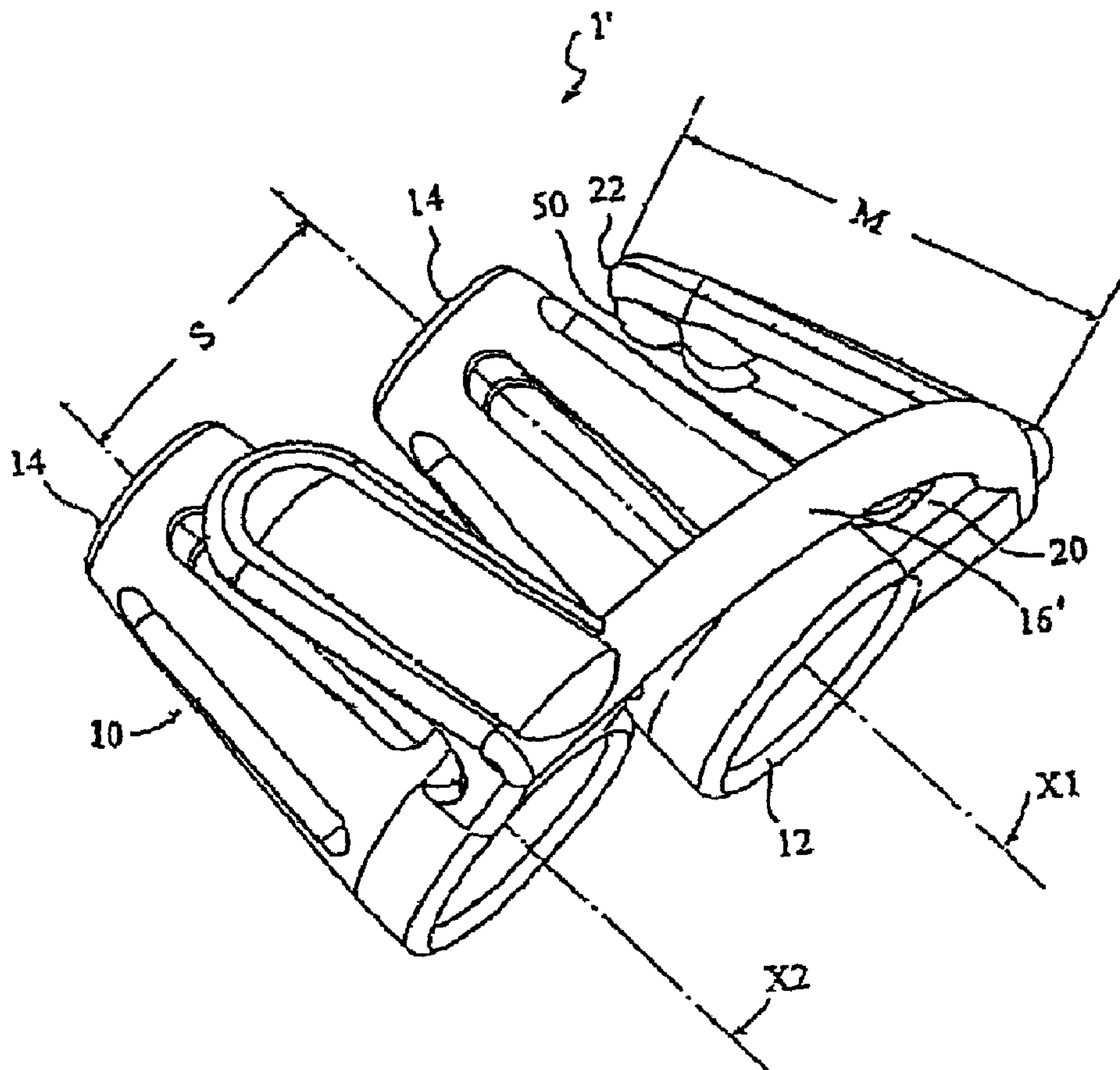




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(54) Title: NASAL CONGESTION AND OBSTRUCTION RELIEF AND BREATHING ASSIST DEVICES



(57) Abrégé/Abstract:

A nasal breathing assist device includes one or two open-ended tubular elements each extending along a central tube axis between a relatively large first end and a relative small second end, and at least one non-resilient tab extends from the first end

(57) **Abrégé(suite)/Abstract(continued):**

toward the second end of the tubular element. In embodiments with two tubular elements, a coupler element extends between the first ends of the tubular elements. Each tubular element may further include a liner-shaped filter having a liner portion extending along a central axis between a relatively large end and a relatively small end, and a filter medium spanning at least one of the relatively large end and the relatively small end. The filter is adapted to snap-fit in the tubular element. The tubular element may further include at least one stiffening element affixed to the tubular element.

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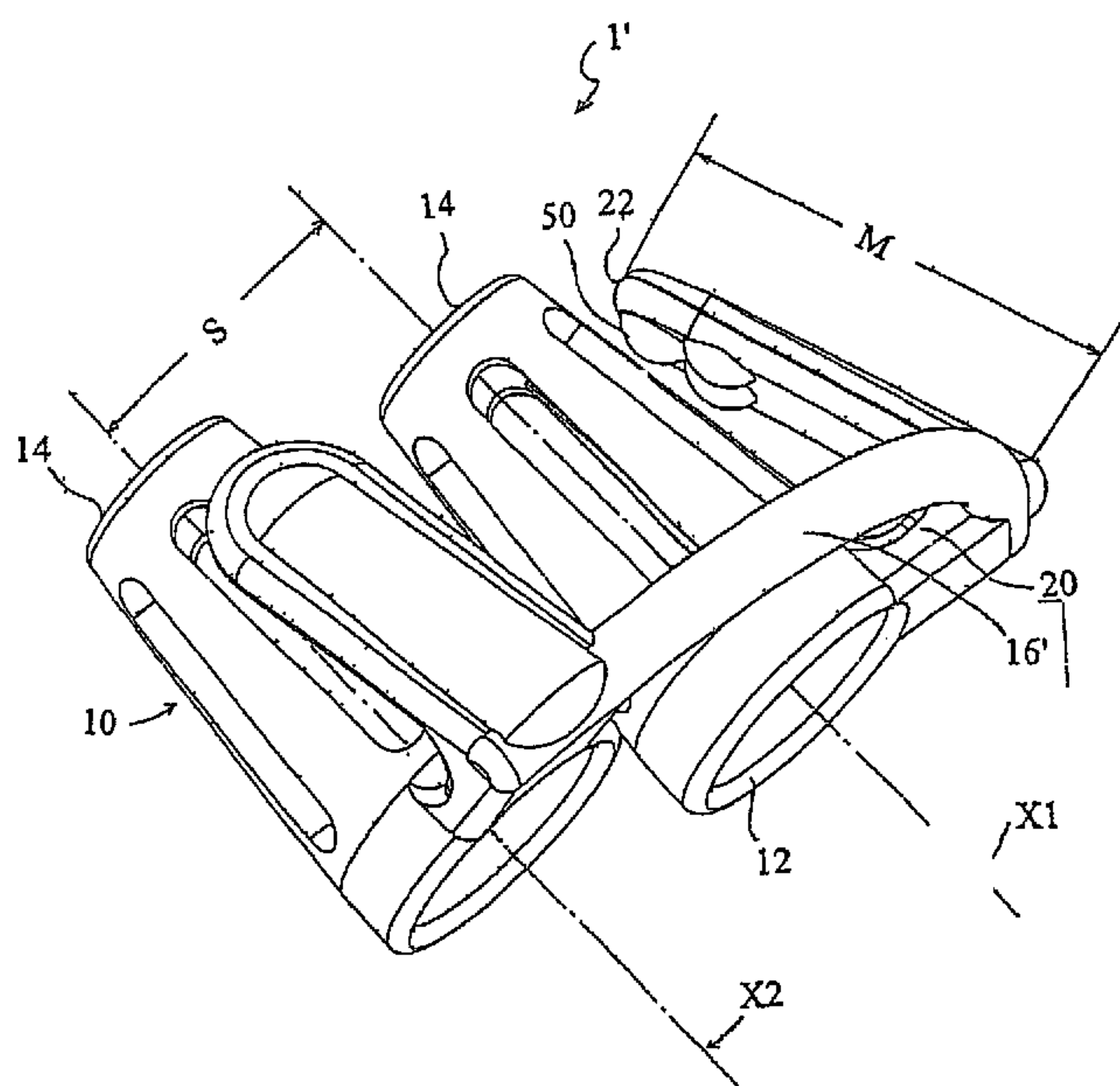
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(54) Title: NASAL CONGESTION AND OBSTRUCTION RELIEF AND BREATHING ASSIST DEVICES



(57) Abstract: A nasal breathing assist device includes one or two open-ended tubular elements each extending along a central tube axis between a relatively large first end and a relative small second end, and at least one non-resilient tab extends from the first end toward the second end of the tubular element. In embodiments with two tubular elements, a coupler element extends between the first ends of the tubular elements. Each tubular element may further include a liner-shaped filter having a liner portion extending along a central axis between a relatively large end and a relatively small end, and a filter medium spanning at least one of the relatively large end and the relatively small end. The filter is adapted to snap-fit in the tubular element. The tubular element may further include at least one stiffening element affixed to the tubular element.

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## NASAL CONGESTION AND OBSTRUCTION RELIEF AND BREATHING ASSIST DEVICES

### 10 **Field of the Invention**

(02) This invention pertains to methods and devices for nasal congestion and obstruction relief and breathing assist devices, and in particular to methods and devices for improving nasal breathing, treatment of sinus conditions, and reducing snoring.

### 15 **Background of the Invention**

(03) Nasal obstruction is characterized by anatomical conditions including nasal valve collapse, nasal valve obstruction, septal deviation, and medium hypertrophy. These conditions obstruct and restrict nasal airflow causing difficulties in breathing through the nose.

(04) Limited or obstructed nasal airflow reduces the normal ventilation of sinuses. Properly ventilated sinuses allow healthy draining for cleaning of the sinuses. Without proper ventilation, sinuses may not drain properly, which can cause infections in the sinuses. Chronic sinusitis is a condition characterized by long lasting sinus infections, which are caused by obstructed or restricted nasal airflow.

(05) Snoring is a condition characterized by rough, loud, rattling breathing, or aspiratory noise in the throat during sleep or deep coma. The characteristic snoring noise is produced by vibration of the soft palate (the soft tissue in the roof of the mouth near the throat)

or vocal chords by inhaled or exhaled air. As the soft palate vibrates, the lips, cheeks, and nostrils may also vibrate, making the snoring louder.

(06) Snoring can be caused by underlying physical or disease conditions that restrict air passages and force the patient to breathe through their mouth with exaggerated force to  
5 move air through narrowed nasal passages. Chronic snoring can be the result of obstruction of nasal airways, septal deviation, or obstructed nasal passages. Temporary snoring, or a sudden onset of snoring can be the result of congestion or swollen nasal mucus membranes, as with a cold or hay fever, or a nasal polyp.

(07) Anatomical deformities in the airway such as septal deviation, medium  
10 hypertrophy, obstructed nasal valves and nasal valve collapse can diminish the airway size. Fat deposits around the nasal passages, as found in obesity, can make the nasal passages smaller. Poor muscle tone in the muscles of the tongue and throat, or medications and foods (such as alcohol) that relax these muscles also increase snoring.

(08) Snoring can cause relationship problems between partners, and lead to a loss of  
15 intimacy and deterioration of relationships. Loss of sleep, or insufficient rest during sleep increases irritability, reduces memory and concentration, and decreases work performance.

(09) A number of methods and devices have been developed to reduce or eliminate snoring. Some devices are external to the patient and include buzzer systems and alarms that wake the patient. Special pillows, neck collars, chin braces and head straps have also been  
20 tested in an effort to control snoring. When nasal obstruction, chronic sinusitis, or snoring is caused by serious deformity, surgery has been performed to remove anatomical obstructions, such as removing tonsils, or correcting medium hypertrophy, or septal deviation. For snoring, occasionally a procedure called UPPP (Uvulopalatopharyngoplasty) is recommended. This procedure acts like an internal facelift, tightening loose tissue. However, the success rate is only  
25 50%. Laser surgery to correct airway defects is also available in some cases.

(10) Other remedies for chronic sinusitis or snoring include prescription antibiotics, herbal and homeopathic rinses, sprays or potions, and OTC medications such as decongestants and anti-histamines. Diet and lifestyle changes may reduce snoring to some degree. Nasal valve collapse is a soft tissue condition that is inoperable. Remedies are limited to rigid and metal spring like products. Use of these type of products is limited due to the discomfort or metal taste.

(11) Various devices have been developed for nasal congestion and obstruction relief and sinus or snore relief that keep the mouth, or nasal passages open, or the tongue depressed. Devices marketed for snoring through the dental channel can be expensive custom-fit, or inexpensive over the counter mouth pieces. Adhesive nasal strips, which are applied externally to either side of the nose, have been developed. While these strips may dilate the nasal passages to small degree, they do not work well in patients with significant anatomical deformities or obstructions in the nose. Air masks that force pressurized air into the mouth and lungs are available. These devices can be cumbersome, unsightly, painful, or expensive, and the patient may abandon these approaches in short time.

(12) Sinusitis is another common nasal disease. Sinusitis is inflammation or infection of the mucous membranes that line the inside of the nose and sinuses. It can be caused by bacteria, viruses, and possibly by allergies. Chronic sinusitis is a prolonged sinus infection which generally last longer than 12 weeks. Chronic sinusitis is difficult to treat because it responds slowly to medications. Conventional treatment for chronic sinusitis includes oral antibiotics, nasal spray, and sinus surgery. These treatments generally cannot get directly to the source of the problem, or may cause side effect, for example, frequently using nasal spray may worsen the symptom.

## **Summary of the Invention**

(13) The object of the present invention is to reduce snoring by increasing the airflow



through the nasal passages. It is a further object to provide devices that relieve nasal congestion and obstruction to improve nasal breathing by increasing airflow through the nasal passages during sleep. It is another object of the present invention to treat chronic sinusitis.

(14) One aspect of the invention provides "dual tube" nasal breathing assist devices  
5 having a pair of open-ended tubular elements connected together by a coupler element. The tubular elements are preferably conic-frustum shaped along a tube axis, having a relatively large first end and a relatively smaller second end, and tapering from the first end to the second end along the tube axis. In some embodiments, each tubular element may have passageways extending through the tubular elements transverse to the tube axis. These passageways may be  
10 elongated, and extend at least in part in the direction of the tube axes.

(15) The coupler element maintains the tubular element in a generally parallel relationship to each other in a common plane and in a spaced-apart relation which corresponds generally to the separation between the user's nostrils.

(16) In one embodiment, the coupler element is a resilient, nominally curved strut  
15 lying in a plane substantially perpendicular to the tube axes, permitting relative angular motion of the tube elements about an axis perpendicular to the tube axes.

(17) In an alternate embodiment, the coupler element is a resilient, nominally curved strut lying in a plane substantially parallel to the tube axes, permitting relative angular motion of the tube element about an axis parallel to the tube axes.

(18) In another embodiment of the invention, a "single tube" nasal breathing assist  
20 device is a single, open-ended, resilient tubular element, adapted for insertion into a user's nostril. The tubular element is conic-frustum shaped, having a relatively large diameter first end and a relatively smaller diameter second end, and a taper extending from the first end to the second end along a tube axis. The tubular element may have passageways extending through  
25 the tubular element transverse to the tube axis. In one form, these passageways may be elongated. The single tube may be used in a user's nostril, and if desired, together with another



single tube in the user's other nostril. In this form, the tubes are not coupled to each other.

(19) In some forms of both the single tube or dual tube embodiments of the invention, the tubular elements have a tab extending from the first (i.e. relatively large) end which extends substantially parallel to the tube axis and is elongated in the direction of the tube axis. In yet  
5 another embodiment, each tube element has a tab support extending radially from the first end in a direction substantially perpendicular to the tube axis. At least one tab extends from the tab support, and is elongated in the direction of the tube axis. The tabs may be resiliently deformable, so as to permit elastic deformation in use, providing a frictional holding force when engaging the nose. Alternatively, the tabs may be non-resiliently deformable, permitting  
10 inelastic deformation, so that a user can "pinch" the tabs so that they capture and hold the nose. The non-resilient tabs are preferably made with a stiffening material embedded in, affixed to, or of plastic or metal, for example, copper, aluminum, but may be made of other materials that may be non-resiliently deformed. The tab preferably includes at least one relatively small protrusion extending from a distal end of the tab. The distal end is distal from the first end of  
15 the tubular element. The relatively small protrusion may also extend from the outer surface of the tubular element opposing the distal end of the tab. The tab and the protrusion help to prevent the device from slipping out of a user's nose.

(20) In another preferred embodiment, the tab has an inner surface, which faces the tubular element and is at least partially coated with adhesive. In use, after the device is inserted  
20 into a user's nostrils, the tab and the outer surface of the tubular element hold the lateral wall of the user's nose, and the adhesive coating increases the friction between the tab and the outer surface of the user's nose, and make the tab to stick to the outer surface of the user's nose, thus increasing the stability of the device within the user's nose.

(21) The tubular element includes, preferably at its large end, an open-faced channel  
25 extending about its tube axis. The device further includes a filter having a peripheral frame contoured to snap-fit in the open-faced channel. The filter includes a filter medium, preferably

but not necessarily, a composite filter of manmade or natural materials, i.e. paper, metal or plastic with or without a coating of absorbent materials, spanning the peripheral frame. In an alternate embodiment, at least one relative small protrusion extends from an inner surface of the channel. The filter is adapted to snap-fit over the protrusion into the channel and is retained  
5 by the protrusion, so that the filter cannot slip out from the channel when the device is in use. In a preferred embodiment, the protrusion extends throughout an inner circumference of the channel. In another preferred form, the filter includes a liner portion extending along a central axis between a relatively large end and a relatively small end, and a filter medium spanning at least one of the relatively large end and the relatively small end. In an alternative form, the liner  
10 portion and the filter medium are integrally constructed from a sheet or composite of a filter medium.

(22) In another preferred embodiment, the device is embedded or coated with a therapeutic agent or further includes at least one carrier, which may or may not be removable, which may include a medium, for example a metal or plastic mesh, or a surface, adapted to bear  
15 a therapeutic agent. The carrier may be a disc, tablet, or a liner that affixes to the inside of the tubular element. These embodiments may include two opposite edges, and can include multi-edged configurations, for example as in a star shape. The tubular element further defines two or more opposing channels on an inner surface of the tubular element. The two or more opposing channels extend in a plane substantially parallel to the central axis and are adapted to  
20 receive the two or more opposite edges of said removable or permanently placed carrier. The therapeutic agent may be medications, for example, antibiotics, for treating chronic sinusitis or other nasal diseases.

(23) In a further preferred embodiment, the tubular element includes at least one substantially annular-shaped stiffening element affixed to the one or two ends of the tubular  
25 element, or to the middle portion of the tubular element. The tubular element may also include stiffening element with other configurations affixed to side wall of the tubular element. The



varying shaped stiffening element is preferably embedded in the tubular element, but also can be attached to the inner or outer surface of the tubular element.

(24) In a further preferred embodiment, the tubular element is made from a shape memory material.

5 Accordingly, in one aspect the present invention resides in a nasal breathing assist device comprising a pair of open-ended tubular elements, wherein each tubular element extends along a respective central tube axis between a first end and a second end, said first end being larger than said second end; wherein said central tube axes of said tubular elements lie in a first plane; and wherein at least one of the tubular elements defines a groove being defined  
10 on a side of a lateral wall that faces an interior of the tubular element; and a coupler element extending between said first ends of said tubular elements, wherein said central tube axis of said tubular elements are spaced apart at said first ends by a distance D, whereby said distance D is selected to correspond to the separation of a user's nostrils, and wherein said coupler element permits rotational motion of the central tube axes of said tubular elements.

15 In another aspect, the present invention resides in a nasal breathing assist device comprising an open-ended tubular element, wherein said tubular element extends along a central tube axis between a first end and a second end, said first end being larger than said second end, wherein said tubular element defines at least one groove along a lateral wall of the tubular element, the groove being defined on a side of the lateral wall that faces the tubular  
20 element interior.

(25) Related objects and advantages of the present invention will be apparent from the following description.

### **Brief Description of the Drawings**

25 (26) The foregoing and other objects of this invention, the various features thereof, as well as the invention itself, may be more fully understood from the following description, when read together with the accompanying drawings, in which:

(27) Figure 1 is a perspective view of one embodiment of the present invention;

(28) Figure 2 shows a side view of the embodiment shown in Figure 1;

30 (29) Figure 3A shows a side view of an alternate embodiment of the invention;

(30) Figure 3B shows a side view of the embodiment of Figure 3A rotated about an axis;

(31) Figure 4A is a perspective view of an alternate embodiment of the invention;



(32) Figure 4B is a perspective view of another alternate embodiment of the invention;

(33) Figure 5A is a perspective view of an alternate embodiment of the invention;

(34) Figure 5B is a perspective view of yet another embodiment of the invention;

5 (35) Figure 5C is a perspective view of another embodiment of the invention;

(36) Figure 5D is a perspective view of another embodiment of the invention;

(37) Figure 5E is a perspective view of another embodiment of the invention;

(38) Figure 6 shows a schematic view of a filter in accordance with one embodiment of the present invention;

(39) Figure 7 shows a cross-sectional view of an alternate embodiment of the invention;

(40) Figure 8 shows the filter of Figure 6 together with the nasal breathing assist device;

5 (41) Figure 9 shows another preferred embodiment of the invention;

(42) Figure 10A shows a schematic view of a filter in accordance with one preferred embodiment of the present invention;

(43) Figure 10B shows a schematic view of a filter in accordance with another preferred embodiment of the present invention;

10 (44) Figure 11A shows a perspective view of another preferred embodiment of the present invention;

(45) Figure 11B shows a perspective view of another preferred embodiment of the present invention; and

(46) Figure 12 is a representation of one embodiment of the invention in use.

15

#### **Description of the Preferred Embodiments**

(47) The nasal breathing assist devices according to the various aspects of the invention are shown in Figures 1 through 10. These devices overcome the deficiencies in the currently available devices. The illustrated devices are small, inconspicuous in use, and require  
20 no special attachments or fittings. The devices are worn inside the nose, so that the nasal passages are kept open from the inside, rather than by external means. This allows the devices to maintain airways in noses where anatomical abnormalities diminish the effectiveness of externally applied strips. The devices can be used alone, or in conjunction with decongestant and antihistamines powders, tablets or liquid medications, other snore-reducing aids, such as  
25 pillows, or medicated nasal sprays.

(48) In the embodiment shown in Figure 1, the nasal breathing assist device 1 comprises generally a pair of open ended tubular elements 10 connected together by a coupler element 16.

(49) The tubular elements 10 are generally circular in cross section and extend a distance along tube axes X1 and X2 from first ends 12 to second ends 14. Preferably the tubular elements taper linearly from a relatively large diameter cross section along the tube axes X1 and X2 to a relatively smaller diameter cross section from the first end 12 to the second end 14. The taper may be other than linear, for example, contoured to correspond generally to the taper inside the user's nostrils. First ends 12 also connect to the coupler element 16. In the illustrated form, the tubular elements 10 are conic-frustums, but other shapes may be used. For example, instead of circular cross sections, the tubular elements could have elliptical or other shaped cross sections. Further, instead of the inner diameter tapering monotonically from the large end to the small end, it could decrease initially, become larger, then decrease again.

(50) The tubular elements 10 may also include at least one passageway 18 extending through the walls of the tubular elements transverse to the tube axes X1 and X2. The passageways 18 may be circular, elliptical, or elongated at least in part in the direction of the tube axes. Alternately, the passageways can be elongated in a direction extending circumferentially around the tube axes.

(51) The coupler element 16 is a resilient, nominally curved strut which maintains the tubular elements spaced apart, with axes X1 and X2 in a substantially parallel relationship, and in substantially a common plane. The coupler element may be made of resilient, semi-rigid, or rigid material.

(52) Grooves 19 inside of tubular elements are an additional feature which may be used to receive medication (nasal cream) before inserting in nasal passage so as not to irritate the skin inside the nasal passage, this allows the medication to be effective without contacting the nasal passage.



(53) As shown in Figure 2, coupler element 16 maintains a nominal distance D between the tubular elements 10 that generally corresponds to the distance between the user's nostrils. In this embodiment, the coupler element extends in a plane that is essentially parallel to tube axes X1 and X2. As shown in Figures 3A and 3B, the resistance of coupler element 16 permits the axes X1 and X2 to be offset from an axis  $X_0$  by angle A. Angle A can be as much as 15° or greater. Furthermore, in this embodiment, coupler element 16 permits relative flexing motion of the device about an axis, substantially perpendicular to the tube axes X1 and X2.

(54) In a preferred embodiment shown in Figure 4A, device 1' has coupler element 16' which extends between first ends 12. The central axis of coupler element 16' lies in a plane that is substantially perpendicular to the tube axes X1 and X2. In this embodiment, coupler element 16' permits relative flexing motion of device 1' so that axes X1 and X2 remain substantially parallel, but separation S of those axes varies to accommodate spacing of the nostrils.

(55) Radially extending tab supports 20 extend from first ends 12 and connect to coupler element 16. Tabs 22 extend from tab supports 20 a distance M in the direction of the central axis to distal ends of the tabs. Tabs 22 are preferably made of non-resiliently deformable materials, for example, metal including copper, aluminum, and etc. The tab supports 20 may be made of the same or different materials as that used for the tabs 22. In use, tabs 22 remain outside the user's nostrils, and, acting as clips, help secure the device in the nostrils. The tabs 22 also function as a stop which prevent the device from being wholly inserted into a user's nostril.

(56) In another preferred embodiment, as shown in Figure. 4B, the tabs 22 are substantially S-shaped, and includes a distal curved portion 23 distal from the first end 12. The distal curved portion 23 defines a relatively small gap G with an outer surface of the tubular element. The tabs 22 are constructed such that the small gap G is adapted to receive a lateral wall of a user's nose, and the tabs 22 are adapted to clip on the lateral wall of the user's nose.

In one preferred embodiment, the tab 22 includes at least one relatively small protrusion 50 extending from the distal curved portion 23 toward the tubular element 10, as best shown in Figure. 4B and Figure. 5B. Alternatively, the relatively small protrusion 50 may extend from the outer surface of the tubular element 10 toward the distal curved portion 23 of the tab 22.

5 In another alternate embodiment, the tab 22 includes protrusions 50 extending from the distal curved portion 23 toward the tubular element 10, and the tubular element 10 also includes protrusions opposing to the protrusions of the tab 22. In the embodiment shown in Figure 4A, the protrusions 50 extends from a distal end of the tab 22 toward the tubular element 10. The small protrusion helps to secure the device in the user's nostrils.

10 (57) Figures 5A –5E show other embodiments of nasal breathing assist devices. In Figure 5A, device 1" has a tubular element 10 extending along a tube axis X between a relatively large diameter first end 12 and tapering toward a relatively smaller diameter second end 14. As previously described, tubular element 10 may have passageways 18 extending through the walls of the tubular elements transverse to tube axis X.

15 (58) As shown in the embodiment in Figure 5B, radially extending tab support 20 extends from first end 12. The substantially S-shaped non-resilient tab 22 extends from tab support 20 a distance M in the direction of axis X toward second end 14. Figure 5C illustrates another preferred embodiment, in which the device includes a stop member 52 extending radially and outwardly from the first end 12 of the tubular element to a distal end. The stop  
20 member 52 is adapted to engage with an open end of a user's nostril to prevent the device from being wholly inserted into the nostril when the device is in use. In an alternate embodiment, as shown in Figure 5D, the stop member may further include a protrusion extending from the distal end of the stop member toward the second 14 of the tubular element 10. In another alternate embodiment, as shown in Figure 5E, the substantially S-shaped non-resilient tab 22,  
25 the tab support 20, and the tubular element 10 are integrally constructed. In use, the protrusion remains outside the user's nostril, and, acting as a clip, helps secure the device in the nostril.



Device 1" of Figures 5A-5E may be used singly or as a pair. The stop member 52 may also be employed in the embodiments having a pair of tubular elements connected by a coupler element.

(59) In another preferred embodiment, the tab 22 has an inner surface, which faces the tubular element and is at least partially coated with adhesive 98, as shown in Figures 10A and 10B. The tab 22 is also preferably non-resiliently deformable. In use, after the device is inserted into a user's nostrils and the tab 22 is pressed against the outer surface the user's nose, the tab 22 keeps in contact with the outer surface of the user's nose. The adhesive coating increases the friction between the tab 22 and the outer surface of the user's nose, and make the tab to stick to the outer surface of the user's nose, thus increasing the stability of the device within the user's nose. The adhesive coating of the inner surface of the tab helps to maintain the device within a user's nose, preventing the device from being knocked off during sleep, sports, or other activities.

(60) Figure 6 shows a filter 30 which may be used with the nasal breathing assist device. The filter 30 includes a filter medium, preferably a paper, a metal or plastic mesh coated with absorbent materials, spanning a frame 32. The frame 32 is preferably contoured to fit in an open-faced inner channel 36 defined in the tubular element 10. In a preferred embodiment, the tubular element 10 includes at least one relatively small protrusion 38 extending radially from an inner surface of the inner channel 36. The frame 32 of the filter 30 is adapted to snap-fit over the protrusion 38 into the inner channel 36 and is retained by the protrusion 38, thereby the filter 30 cannot slip out of the tubular element 10 when the nasal breathing assist device is in use.

(61) Figure 7 illustrates a cross-sectional view of one tubular element 10 in accordance with one preferred embodiment of the invention. As shown in Figure 7, the protrusion 38 extends throughout an inner circumference at the first end 12 (the end with a relatively large diameter) of the inner channel 36. The filter 30 is snap-plugged into the channel



36 from the first end of the channel 36, and because the diameter of the channel 36 tapers from the first end to the second end, the filter can be secured by the inner surface of the channel 36 and the protrusion 38. The protrusion 38 is relatively small, so that the filter 36 can be easily removed and replaced. Figure 8 shows a schematic view of the filters 30 together with a nasal breathing assist device. Each tubular element 10 includes relatively small protrusions 38 securing the filter 30 at the first end of the tubular element 10. The filter 30 is preferably positioned at one of the two ends of the tubular element 10, so that the filter 30 can be easily removed and replaced, but the filter 30 also can be positioned at a place between the two ends and secured by protrusions extending radially adjacent that place.

(62) Figure 9 illustrates another preferred embodiment of the present invention. As shown in Figure 9, The device further includes at least one removable medication carrier 60 which may include a medium adapted to bear a therapeutic agent. The removable carrier 60 preferably includes a frame tapering from a first end to a second end. The frame includes two opposite edges 62. The tubular element 10 further defines two opposing channels 64 on an inner surface of the tubular element 10. The two opposing channels 64 extend substantially in the same direction as the central axis and are adapted to receive the two opposite edges 62 of said removable carrier 60. The frame of the removable medication carrier 60 may be constructed with other shapes, and the tubular element may define corresponding channels or other mechanism for receiving the frame of the carrier 60. The therapeutic agent may be medications, for example, antibiotics, for treating chronic sinusitis or other nasal diseases.

(63) In alternative embodiments, as illustrated in Figures. 10A and 10B, the filter is a liner filter (as denoted by number 80 in Figures. 10A and 10B) including a conic-shaped liner portion 82 extending between two ends 84 and 86. One end has a relatively large diameter and the other end has a relatively small diameter. In the embodiment shown in Figure. 10A, the relatively large end 84 is a closed end having a filter medium spanning the circumference of the end of the liner portion, and the other end 86 is an opened end. In an alternative form, as shown

in Figure. 10B, the filter medium is attached to the relatively small end 86, and the relative large end is an open-faced end.

(64) The liner portion 82, preferably but not necessarily, is constructed by the filter medium. The filter 80 preferably but not necessarily is made from a unitary sheet of a filter medium by a molding process. The filter 80 is sized to fit in the open-faced inner channel 36 defined in the tubular element 10. The tubular element 10 may include at least one relatively small protrusion extending radially from an inner surface of the inner channel 36 at the relatively large end of the tubular element for preventing the liner filter 80 from slipping out of the channel 36 of the tubular element 10. In use, the liner filter 80 is inserted into and retained in the inner channel 36 of the tubular element 10. The liner filter 80 can be easily removed from the inner channel 36, and can be replaced or cleaned.

(65) The filter medium is constructed to filter pollen, dust, mold, and/or other particles that may cause allergic reactions or other diseases or discomfort. In an alternative form, the filter medium is preferably made from a material that can be coated with medications, particularly, medications for treating nasal diseases. Exemplary medications include decongestants, antihistamine, and antibiotic.

(66) The filters as illustrated in Figures. 6-8, the medication carriers shown in Figure. 9, and the liner filters as shown in Figures. 10A and 10B can be used with nasal breathing assist devices, which have one tubular element or have a pair of tubular elements connected by a strut, as described in the previous embodiments. The nasal breathing assist devices can be disposable or reusable. The reusable devices can be easily cleaned by rinsing with soap and water.

(67) The device can be made of rigid, semi-resilient, or resilient materials. In one preferred embodiment, the tubular element 10 includes at least one stiffening element 90 embedded in or attached to the tubular element. The stiffening element 90 is preferably made from a material with a higher hardness value than the rest part of the tubular element 10. In one preferred form, as shown in Figure. 11A, the stiffening element 90 includes two rigid rings 92,



94 extending about the central axis of the tubular element 10 and embedded in the conic wall of the tubular element 10, one of the two rings, for example, the ring 92, preferably embedded at or near the relatively large end of the tubular element 10, and the other (ring 94) embedded at or near the relatively small end of the tubular element 10. The device could include more than two stiffening rings, and/or other shape stiffening parts embedded in the conic wall of the tubular element 10. Alternatively, the stiffening element 90 also can be attached to the inner surface or outer surface of the tubular element 10. The stiffening element prevents the tubular element 10 from collapse when under pressure and maintain opening of the nasal passage in severe cases, for example, pathologic nasal valve collapse, septal deviation, and other types of nasal congestion or obstruction. The stiffening element also increases the resilience of the tubular element 10 and the stability of the tubular element 10 within a user's nostrils.

(68) In another preferred embodiment, as shown in Figure 11B, the stiffening element 90 includes an elongated wire embedded within the tubular element 10 and the tab 22.

(69) In one preferred embodiment, part of the device is made from a non-resiliently deformable material, for example, aluminum. Preferably, the tabs 22 shown in Figures. 4A-5E are made from a non-resiliently deformable material. In another preferred embodiment, as shown in Figure 11B, an elongated metal wire is embedded within the tubular element 10 and the tab 22. In one preferred form, the wire is non-resiliently deformable, enabling the tab 22 non-resiliently deformable. In another preferred form, the wire is made from a resilient material, enabling the tab 22 resiliently deformable. In use, after the device is inserted to a user's nostrils, the user can force the tab 22 toward the outer surface of the user's nose to allow the tab 22 to touch the outer surface of the user's nose. The tab 22 will stay in contact with the outer surface of the user's nose, thus preventing the device from slipping out of the user's nose.

(70) In a further preferred embodiment, at least part of the device is made from a shape memory material. For example, the device may have one shape under room temperature, and after the device is inserted into the user's nostrils, where the temperature is normally higher



than the room temperature, the device returns to its original shape that fit the contour of the inside of the user's nostrils. The device may also be coated, or embedded with medications for treating nasal diseases, or other diseases, such as skin or mucous diseases.

(71) The nasal breathing assist device is inserted in the user's nostrils, as shown in Figure 12, usually at bedtime. The tubular elements maintain open nasal passages during sleeping, which allow the patient to obtain sufficient airflow through the nose only, rather than supplementing the air supply through the mouth. The filters can be made to absorb or hold pollen, dust, particles in smoke and smog fumes, nicotine in tobacco smoke, obnoxious odors, and other irritating elements.

(72) The nasal breathing assist devices can be used to aid in the administration of nasally supplied drugs and medications, either at bedtime or during the day, for example, using a medication carrier inserted in the tubular element to deliver medications through the nose. The nasal breathing assist device can also be used with other conventional devices to supply drugs and medications, for example, the user can insert the device into the nose, and spray a nasal medication, or moisture mist agent into the nose. The passageways in the device act to help circulate the medication or agent within the nasal passageways by keeping the nasal passages open.

(73) The invention may be embodied on other specific form without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered illustrative and not restrictive, the scope of the invention being dictated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

We claim:

1. A nasal breathing assist device comprising:
  - i) a pair of open-ended tubular elements, wherein each tubular element extends along a respective central tube axis between a first end and a second end, said first end being larger than said second end; wherein said central tube axes of said tubular elements lie in a first plane; and wherein at least one of the tubular elements defines a groove being defined on a side of a lateral wall that faces an interior of the tubular element; and
  - ii) a coupler element extending between said first ends of said tubular elements, wherein said central tube axis of said tubular elements are spaced apart at said first ends by a distance D, whereby said distance D is selected to correspond to the separation of a user's nostrils, and wherein said coupler element permits rotational motion of the central tube axes of said tubular elements.
2. The device of claim 1, wherein at least one of said tubular elements further comprises at least one tab extending from said first end toward said second end of said tubular element to a distal end of said tab, wherein said tab is non-resiliently deformable.
3. The device according to claim 2, wherein said tab includes at least one relatively small protrusion extending from said distal end of said tab toward said tubular element.
4. The device according to claim 2, wherein at least one of said tubular element includes at least one relatively small protrusion extending from an outer surface of said tubular element opposing said distal end of said tab.
5. The device according to claim 2, wherein said tab is substantially S-shaped, and comprises a distal curved portion adjacent said distal end, said distal curved portion defining a relatively small gap with an outer surface of said tubular element, said gap being adapted to receive a lateral wall of a user's nose, and said tab being adapted to clip on the lateral wall of the user's nose.
6. The device according to claim 5, wherein said tab includes at least one relatively small protrusion extending from said distal curved portion toward said tubular element.
7. The device according to claim 5, wherein at least one of said tubular element includes at least one relatively small protrusion extending from an outer surface opposing said distal curved portion of said tab.



8. The device according to claim 2, wherein said tab is made of metal.
9. The device according to claim 2, wherein said tab is made of a metal selected from a group consisting of copper and aluminum.
10. The device according to claim 1, wherein said coupler element permits relative rotational motion of said tube axes about an axis substantially perpendicular to said tube axes.
11. The device according to claim 1, wherein said coupler element permits relative rotational motion of said tube axes about an axis substantially parallel to said tube axes.
12. The device according to claim 1, wherein said coupler element is a resilient, nominally curved strut lying substantially in a plane substantially perpendicular to said tube axes.
13. The device according to claim 1, wherein said coupler element is a resilient, nominally curved strut lying substantially in a plane substantially parallel to said tube axes.
14. The device according to claim 1, wherein said central axes of said tubular elements are offset by an angle A and diverge from said first ends thereof.
15. The device according to claim 1, wherein each of said tubular elements includes a lateral wall which defines passageways extending therethrough transverse to said tube axes.
16. The device according to claim 15, wherein said passageways are elongated and extend at least in part in the direction of said tube axes.
17. The device according to claim 1, wherein at least one of said tubular elements includes a filter having a peripheral frame contoured to snap-fit in an open-faced channel defined in said tubular element, said filter having a filter medium spanning said frame.
18. The device according to claim 17, wherein at least one of said tubular element includes at least one relatively small protrusion extending radially from an inner surface of said channel, said peripheral frame of said filter being adapted to snap-fit in said channel and being retained by said protrusion.
19. The device according to claim 18, wherein said protrusion extends throughout an inner circumference of said channel.
20. The device according to claim 1, wherein said groove being adapted to receive



medication.

21. The device according to claim 1, wherein at least one of said tubular element further defines at least one channel on an inner surface of said tubular element, said channel extending in a plane substantially parallel to said central axis, said channel being adapted to receive a removable carrier bearing a therapeutic agent.

22. The device according to claim 1, further comprising at least one removable carrier adapted to bear a therapeutic agent and adapted to be received in said tubular element, said removable carrier comprising two opposite edges, wherein at least one of said tubular element further defines two opposing channels on an inner surface of said tubular element, said two opposing channels extending in a plane substantially parallel to said central axis and being adapted to receive said two opposite edges of said removable carrier.

23. A nasal breathing assist device comprising:

an open-ended tubular element, wherein said tubular element extends along a central tube axis between a first end and a second end, said first end being larger than said second end,

wherein said tubular element defines at least one groove along a lateral wall of the tubular element, the groove being defined on a side of the lateral wall that faces the tubular element interior.

24. The device as claimed in claim 23, wherein said tubular element comprises at least one tab extending from said first end toward said second end of said tubular element to a distal end of said tab, and wherein said tab is non-resiliently deformable.

25. The device according to claim 24, wherein said tab includes at least one relatively small protrusion extending from said distal end of said tab toward said tubular element.

26. The device according to claim 24, wherein said tubular element includes at least one relatively small protrusion extending from an outer surface of said tubular element opposing said distal end of said tab.

27. The device according to claim 24, wherein said tab is substantially S-shaped, and comprises a distal curved portion adjacent said distal end, said distal curved portion defining a relatively small gap with an outer surface of said tubular element, said gap being adapted to receive a lateral wall of a user's nose, and said tab being adapted to clip on the lateral wall of

the user's nose.

28. The device according to claim 27, wherein said tab includes at least one relatively small protrusion extending from said distal curved portion toward said tubular element.

29. The device according to claim 27, wherein said tubular element includes at least one relatively small protrusion extending from an outer surface opposing said distal curved portion of said tab.

30. The device according to claim 24, wherein said tab is made of metal.

31. The device according to claim 24, wherein said tab is made of a metal selected from a group consisting of copper and aluminum.

32. The device according to claim 23, wherein said tubular element includes a lateral wall which defines passageways extending therethrough transverse to said tube axis.

33. The device according to claim 32, wherein said passageways are elongated and extend at least in part in the direction of said tube axis.

34. The device according to claim 23, wherein said tubular element comprises a filter having a peripheral frame adapted to be snap-fitted in an open-faced channel defined in said tubular element.

35. The device according to claim 34, wherein said filter having a filter medium spanning said frame.

36. The device according to claim 34, wherein said tubular element includes at least one relatively small protrusion extending radially from an inner surface of said channel, said peripheral frame of said filter being adapted to snap-fit in said channel and being retained by said protrusion.

37. The device according to claim 36, wherein said protrusion extends throughout an inner circumference of said channel.

38. The device according to claim 23, wherein said groove being adapted to receive medication.

39. The device according to claim 23, wherein said tubular element further defines at least



one channel on an inner surface of said tubular element, said channel extending substantially parallel to said central axis, said channel being adapted to receive a removable medication carrier adapted for bearing a therapeutic agent.

40. The device according to claim 23, further comprising at least one medication carrier adapted to bear a therapeutic agent and adapted to be received in said tubular element, said removable carrier comprising two opposite edges, wherein said tubular element further defines two opposing channels on an inner surface of said tubular element, said two opposing channels extending in a plane substantially parallel to said central axis and being adapted to receive said two opposite edges of said removable carrier.

41. A nasal breathing assist device comprising:

an open-ended tubular element, wherein said tubular element extends along a central tube axis between a first end and a second end, said first end being larger than said second end; and

a medication carrier adapted to bear a therapeutic agent and adapted to be received in said tubular element, wherein said tubular element further defines at least one groove on an inner surface of said tubular element, said groove extending substantially parallel to said central axis, said groove being adapted to receive an edge of said medication carrier.

42. A nasal breathing assist device of claim 1 or 23 further comprising:  
at least one stiffening element affixed to said tubular element.

43. The device according to claim 42, wherein said at least one stiffening element is substantially annular-shaped, extending about said central tube axis and embedded within a lateral wall of said tubular element.

44. The device according to claim 43, wherein said at least one stiffening element comprises two rigid rings, a relatively large ring embedded at or near said relatively large first end of said tubular element, and a relatively small ring embedded at or near said relatively small second end of said tubular element.

45. The device according to claim 42, wherein said tubular element further comprises at least one tab extending from said first end toward said second end of said tubular element to a distal end of said tab.

46. The device according to claim 45, wherein said at least one stiffening element is



affixed to said tubular element and said tab.

47. The device according to claim 45, wherein said at least one stiffening element is a wire and is embedded within said tubular element and said tab.

48. The device according to claim 45, wherein said tab has an inner surface facing an outer surface of said tubular element, wherein said inner surface of said tab is at least partially coated with adhesive.

49. The device according to claim 45, wherein said tab is substantially S-shaped, and comprises a distal curved portion adjacent said distal end, said distal curved portion defining a relatively small gap with an outer surface of said tubular element, said gap being adapted to receive a lateral wall of a user's nose, and said tab being adapted to clip on the lateral wall of the user's nose.

50. The device according to claim 45, wherein said tab is made from a non-resiliently deformable material.

51. The device according to claim 42, wherein said tubular element includes a filter having a peripheral frame contoured to snap-fit in an open-faced channel defined in said tubular element, said filter having a filter medium spanning said frame.

52. The device according to claim 51, wherein said tubular element includes at least one relatively small protrusion extending radially from an inner surface of said channel, said peripheral frame of said filter being adapted to snap-fit in said channel and being retained by said protrusion.

53. The device according to claim 52, wherein said protrusion extends throughout an inner circumference of said channel.

54. The device according to claim 52, wherein said device further includes a filter adapted to fit in an open-faced channel defined in said tubular element, wherein said filter includes a liner portion extending along a central axis between a relatively large first end and a relatively small second end, and a filter medium spanning at least one of the relatively large first end and the relatively small second end.

55. The device according to claim 54, wherein said liner portion is made from said filter medium.

56. The device according to claim 52, wherein said tubular element is made from a shape memory material.

57. A nasal breathing assist device comprising a pair of the devices of claim 52, and further comprising a coupler element extending between said first ends of said tubular elements, wherein said tube axes of said tubular elements are substantially parallel and spaced apart at said first ends by a distance D, whereby said distance D is selected to correspond nominally to the separation of a user's nostrils.

58. The device according to claim 57, wherein said coupler element permits relative rotational motion of said tube axes about an axis substantially perpendicular to said tube axes.

59. The device according to claim 57, wherein said coupler element permits relative rotational motion of said tube axes about an axis substantially parallel to said tube axes.

60. The device according to claim 57, wherein said coupler element is a resilient, nominally curved strut lying substantially in a plane substantially perpendicular to said tube axes.

61. The device according to claim 57, wherein said coupler element is a resilient, nominally curved strut lying substantially in a plane substantially parallel to said tube axes.

62. The device according to claim 57, wherein said central axes of said tubular elements are offset by an angle A and diverge from said first ends thereof.

63. A nasal breathing assist device comprising:

i) a pair of open-ended tubular elements, wherein each tubular element extends along a central tube axis between a first end and a second end, said first end being larger than said second end, wherein the central tube axes of said tubular elements lie in a first plane;

wherein said tubular element further defines a groove along a lateral wall of said tubular element;

wherein each tubular element further comprises at least one stiffening element affixed to said tubular element; and

ii) a coupler element extending between said first ends of said tubular elements, wherein said tube axes of said tubular elements are spaced apart at said first ends by a distance D, whereby said distance D is selected to correspond nominally to the separation of a user's nostrils,



wherein said coupler element permits relative rotational motion of said central tube axes of said tubular elements.

64. The device according to claim 63, wherein each of said tubular element further includes a filter adapted to fit in an open-faced channel defined in said tubular element, wherein said filter includes a liner portion extending along a central axis between a relatively large first end and a relatively small second end, and a filter medium spanning at least one of the relatively large first end and the relatively small second end.

65. The device according to claim 64, wherein said liner portion is made from said filter medium.

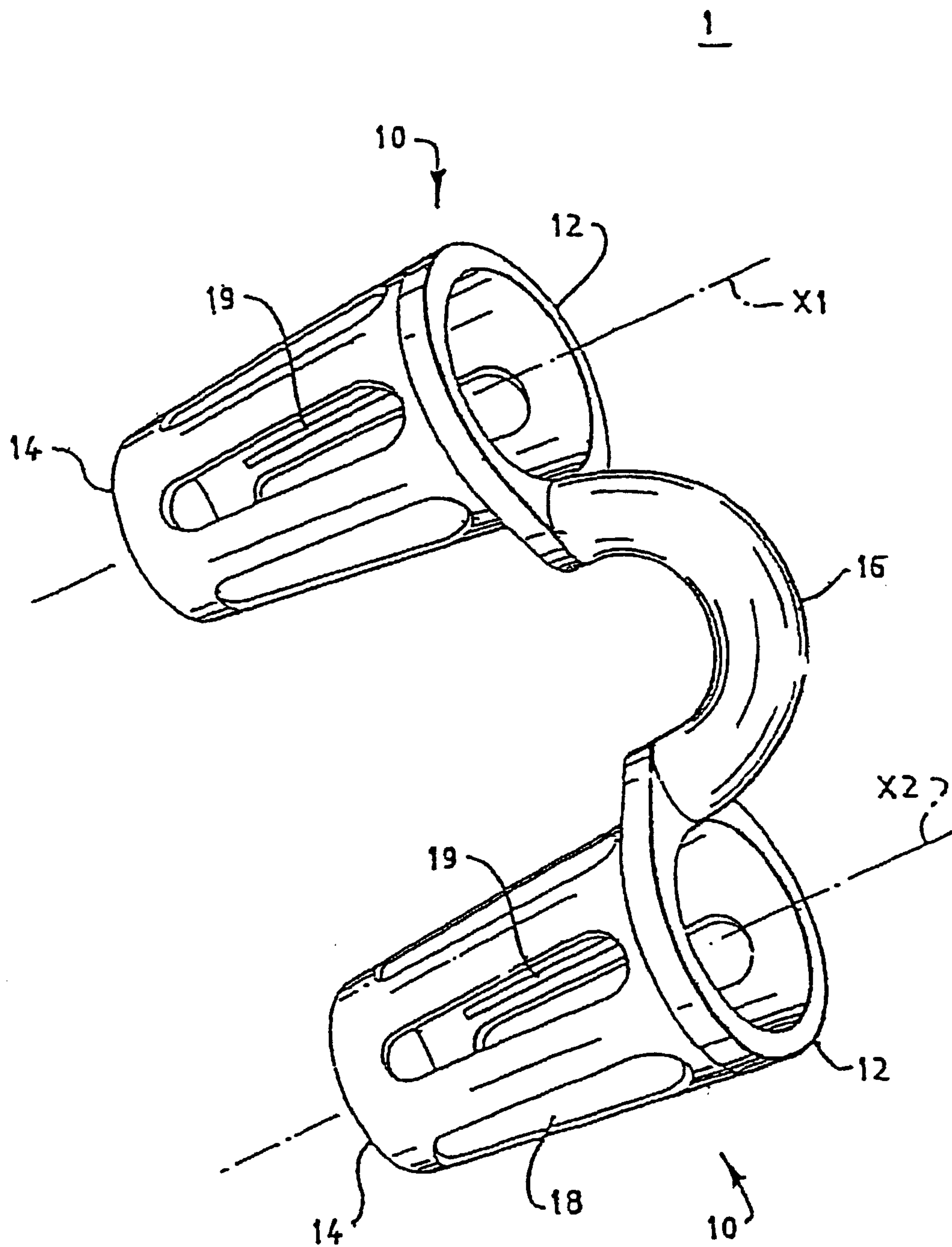
66. The device according to claim 63, wherein said at least one stiffening element is substantially annular-shaped, extending about said central tube axis and affixed to said tubular element.

67. The device according to claim 63, wherein said tubular element further comprises at least one tab extending from said first end toward said second end of said tubular element to a distal end of said tab.

68. The device according to claim 67, wherein said at least one stiffening element is affixed to said tubular element and said tab.

69. The device according to claim 67, wherein said at least one stiffening element is a wire and is embedded within said tubular element and said tab.

70. The device according to claim 67, wherein said tab has an inner surface facing an outer surface of said tubular element, wherein said inner surface is at least partially coated with adhesive.





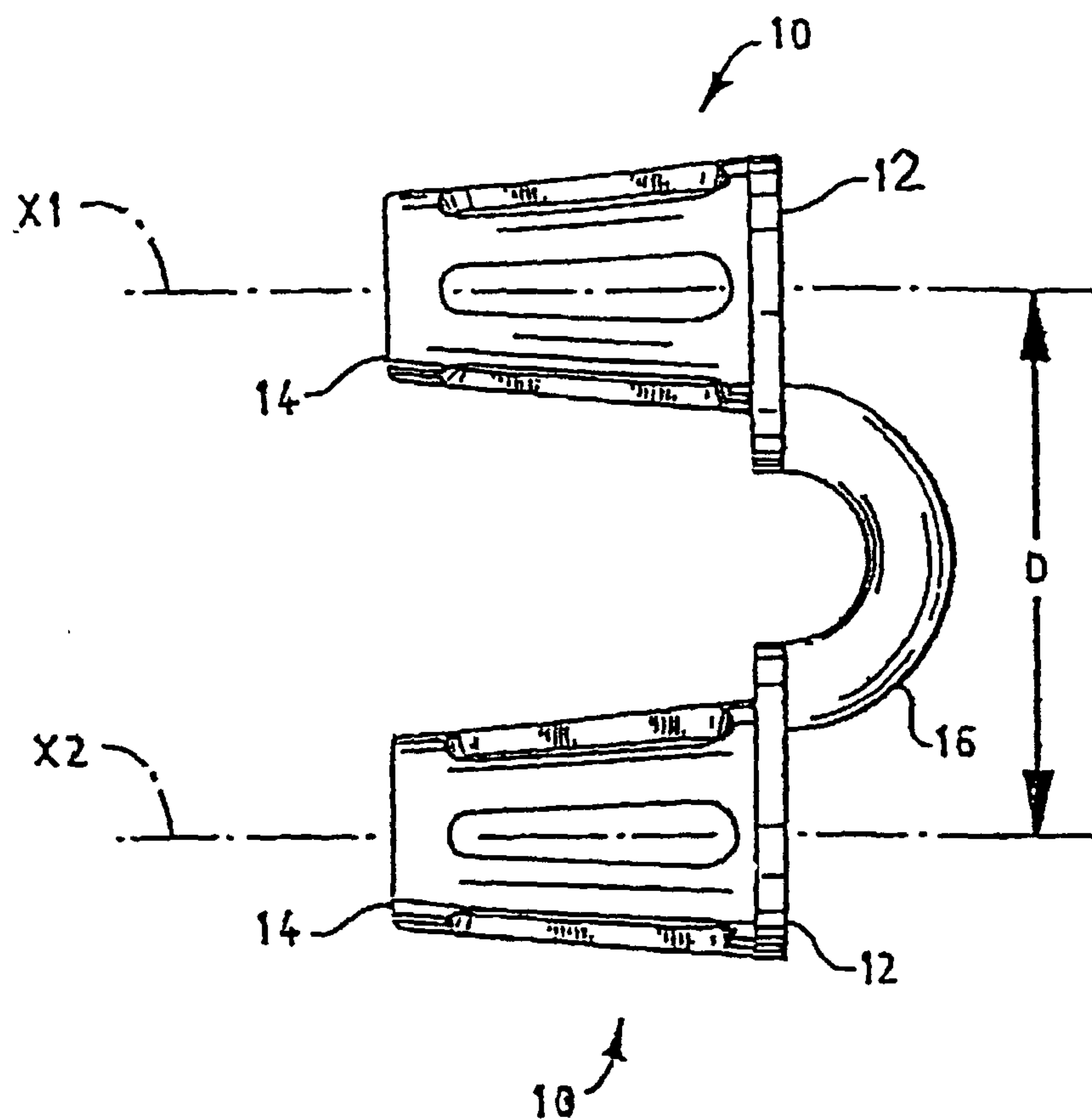


FIG. 2

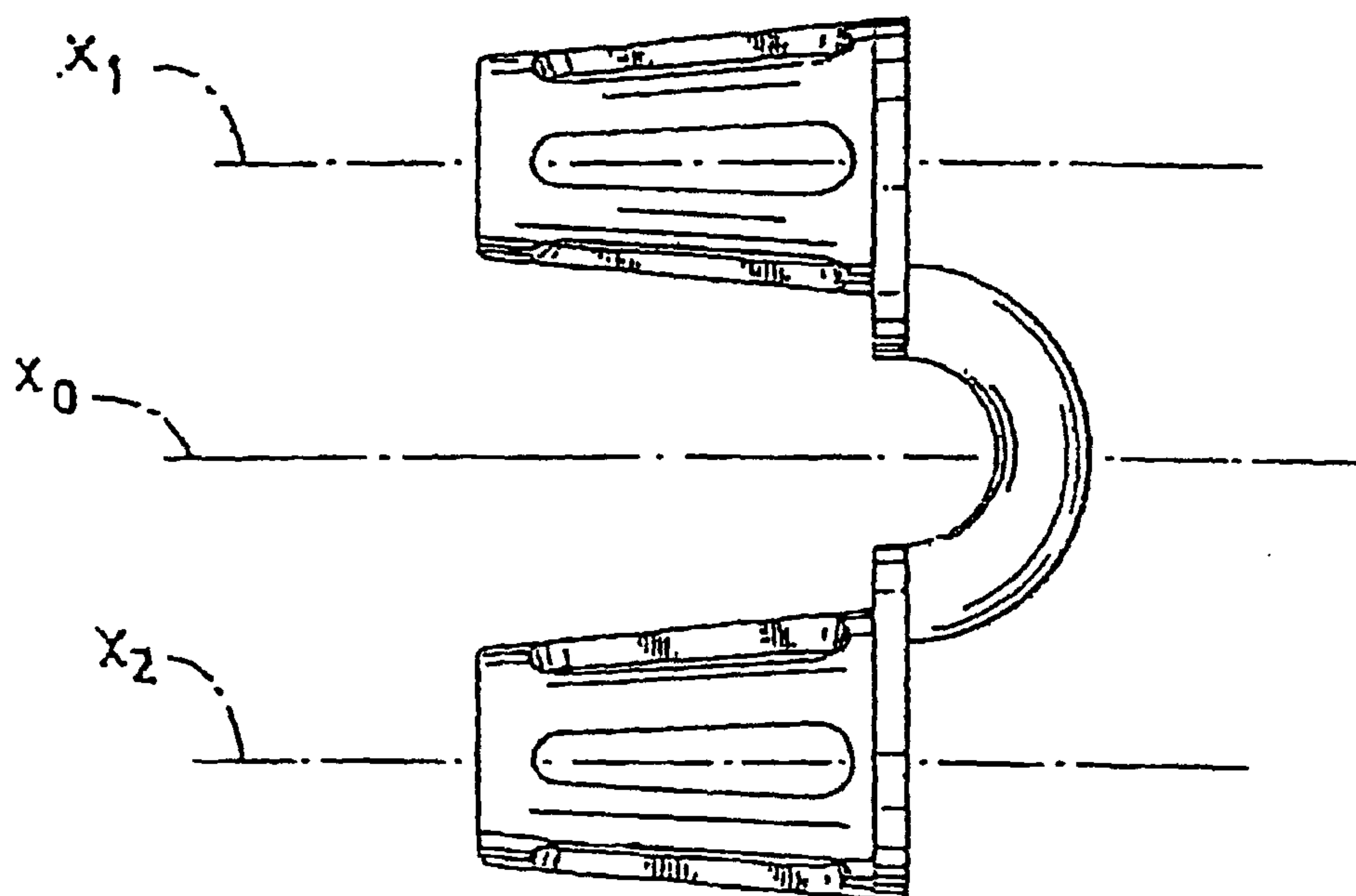


FIG. 3A

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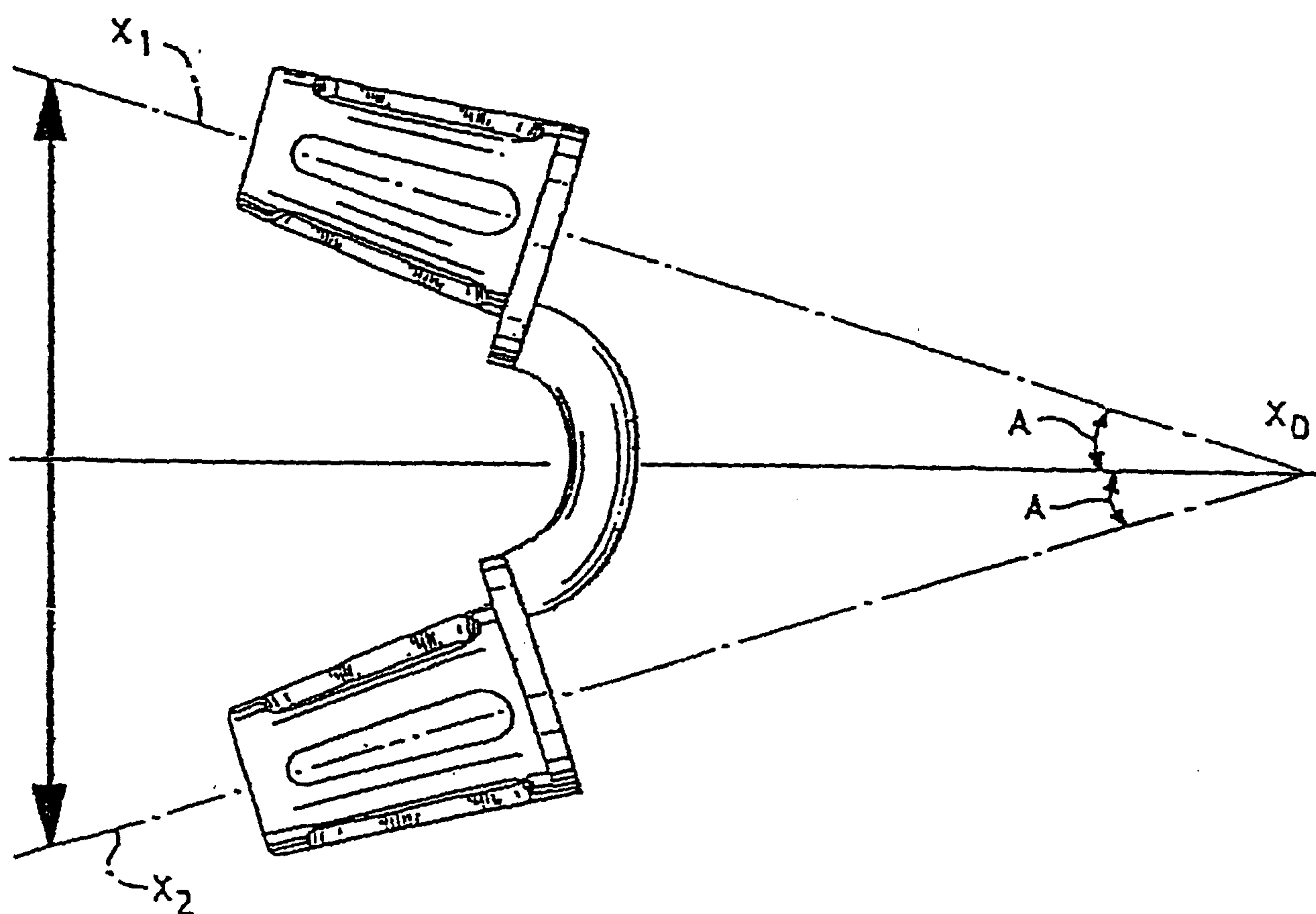


FIG. 3B

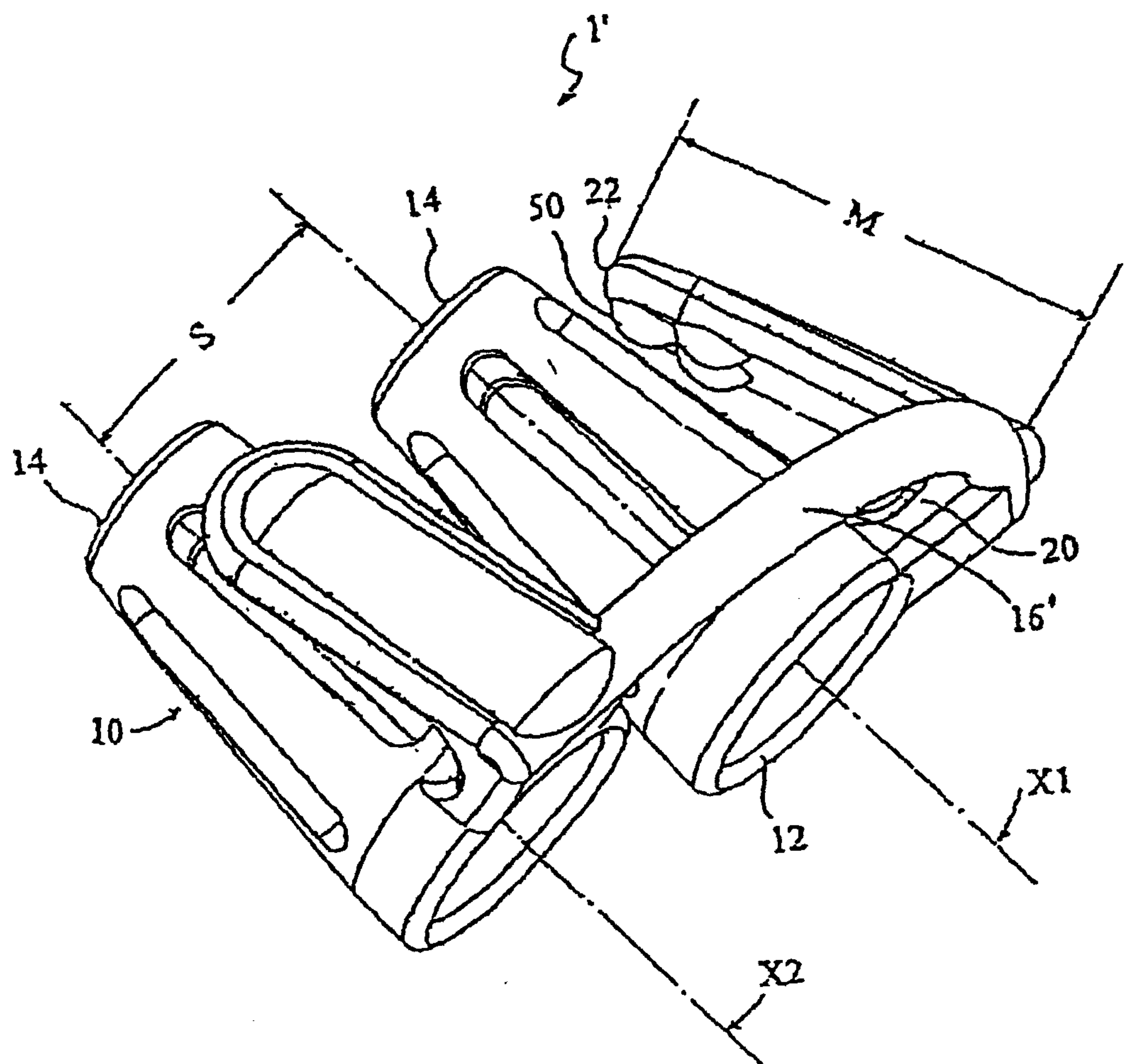


FIG. 4A



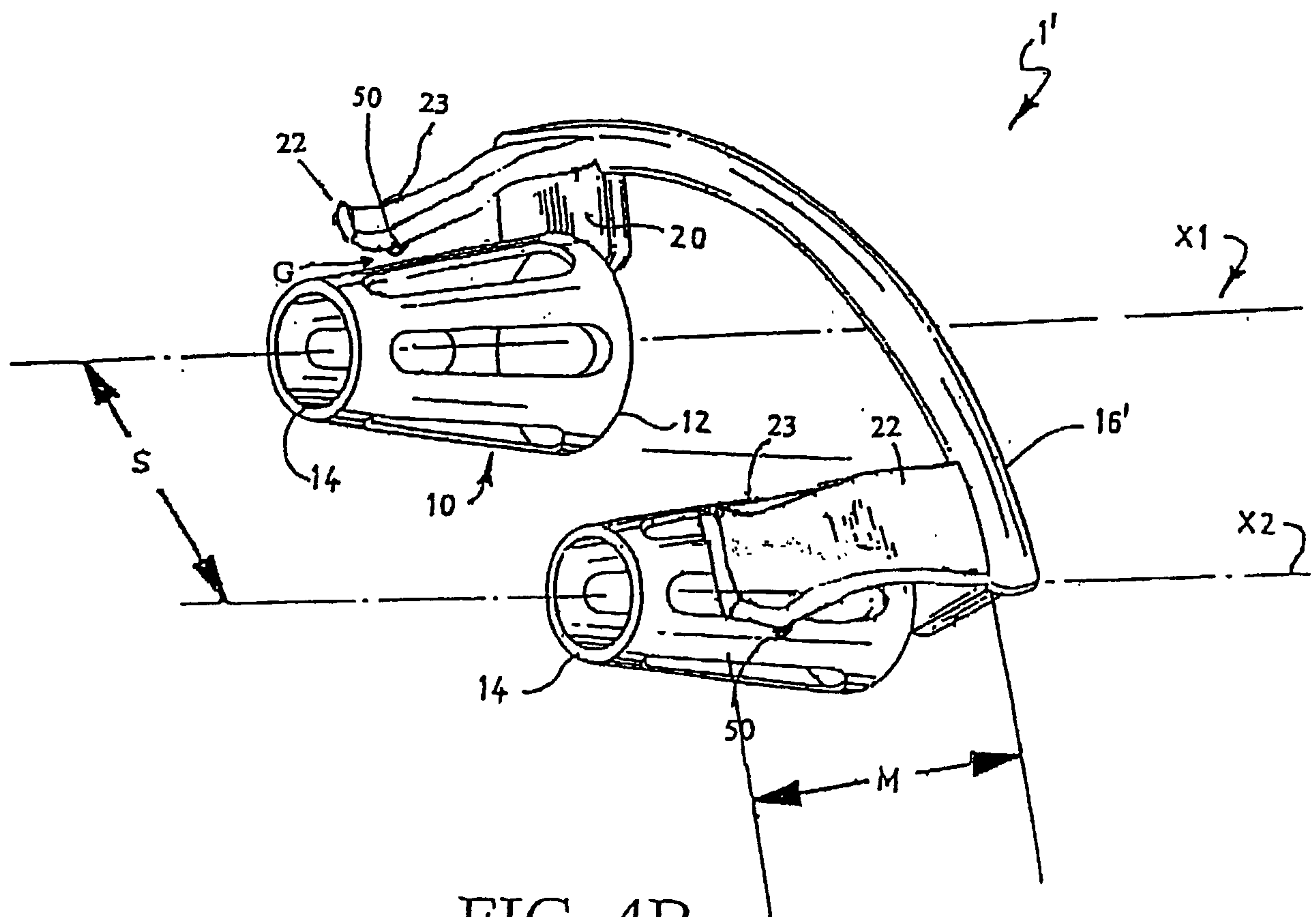


FIG. 4B

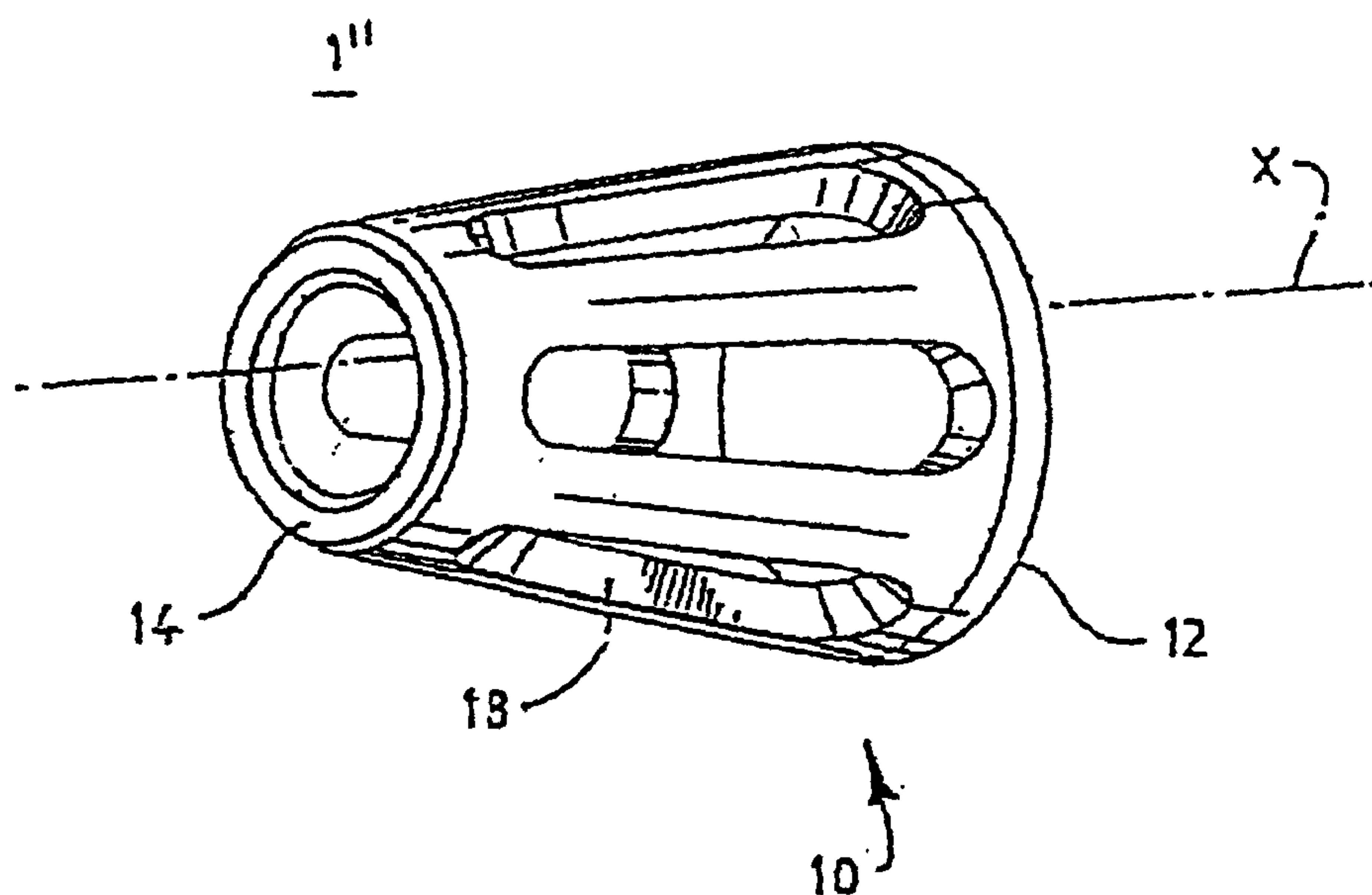


FIG. 5A

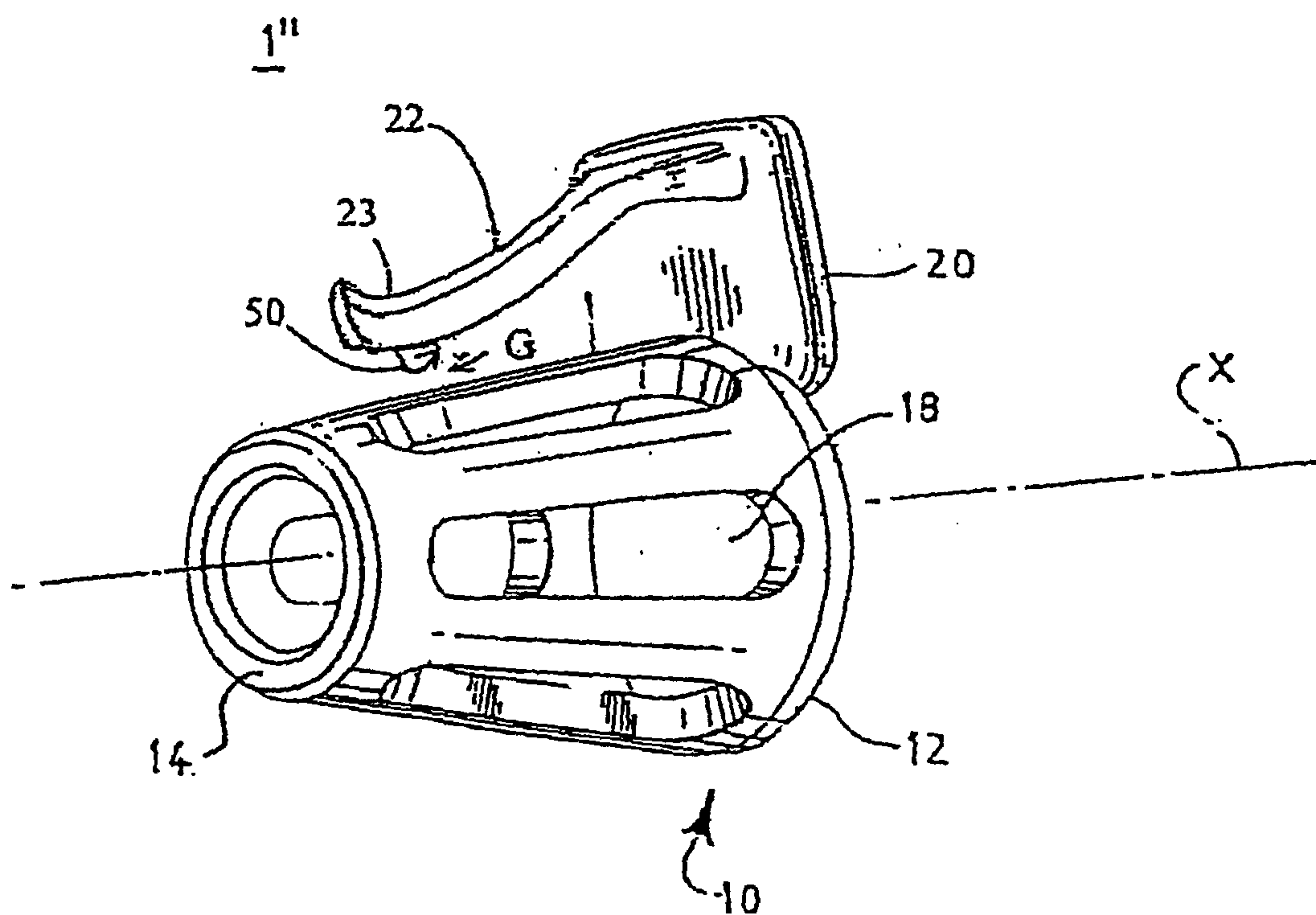


FIG. 5B

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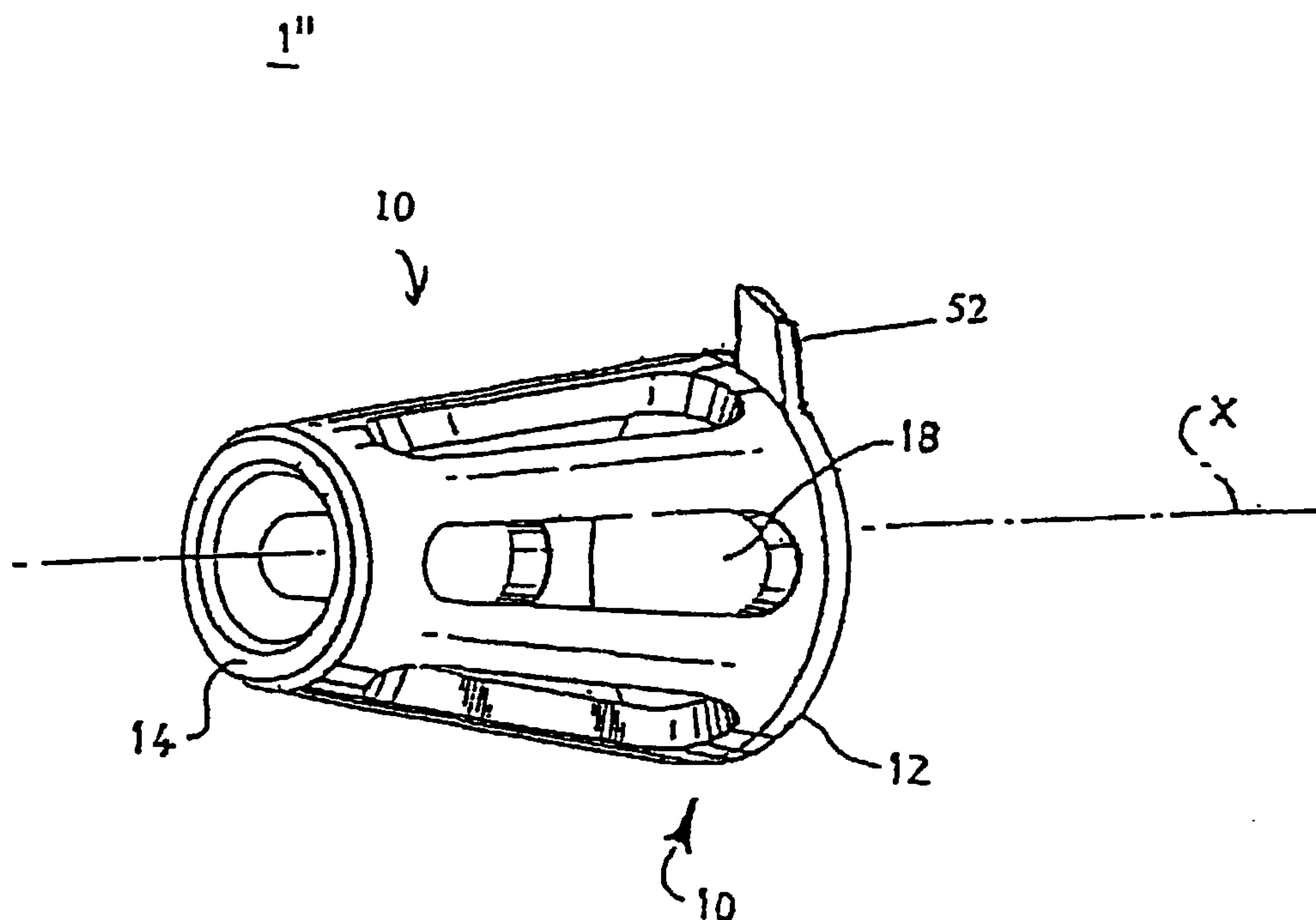


FIG. 5C

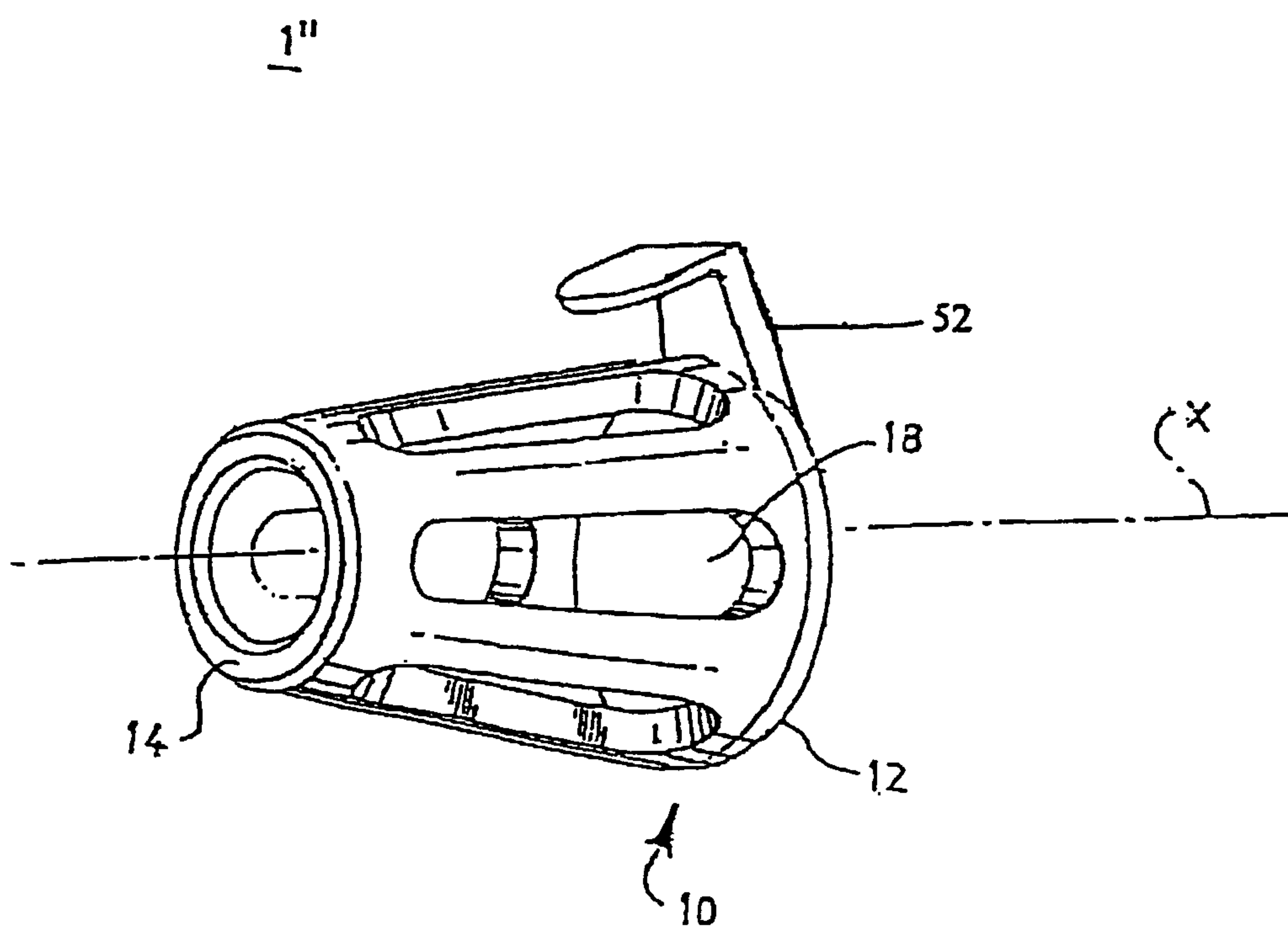


FIG. 5D

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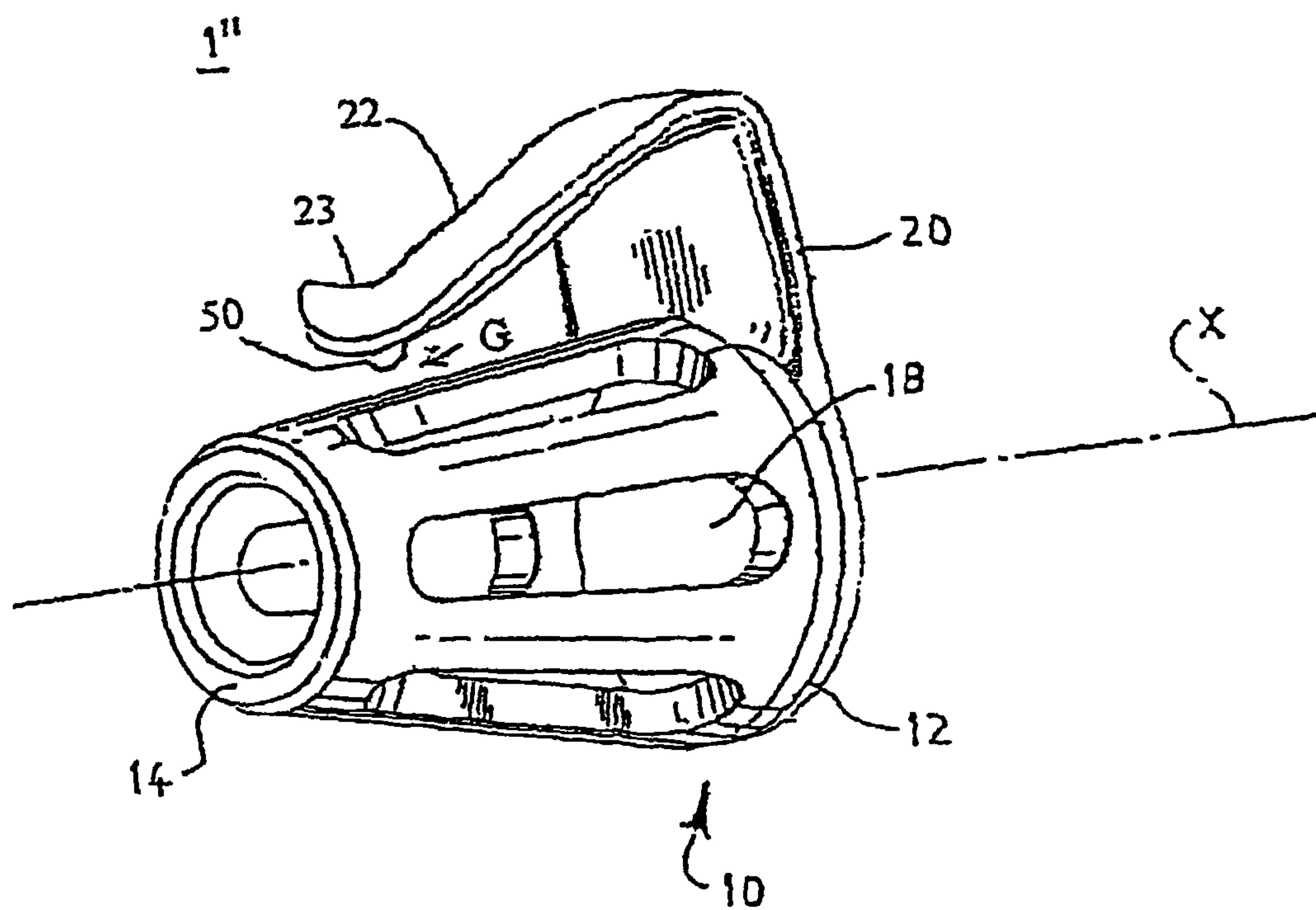


FIG. 5E

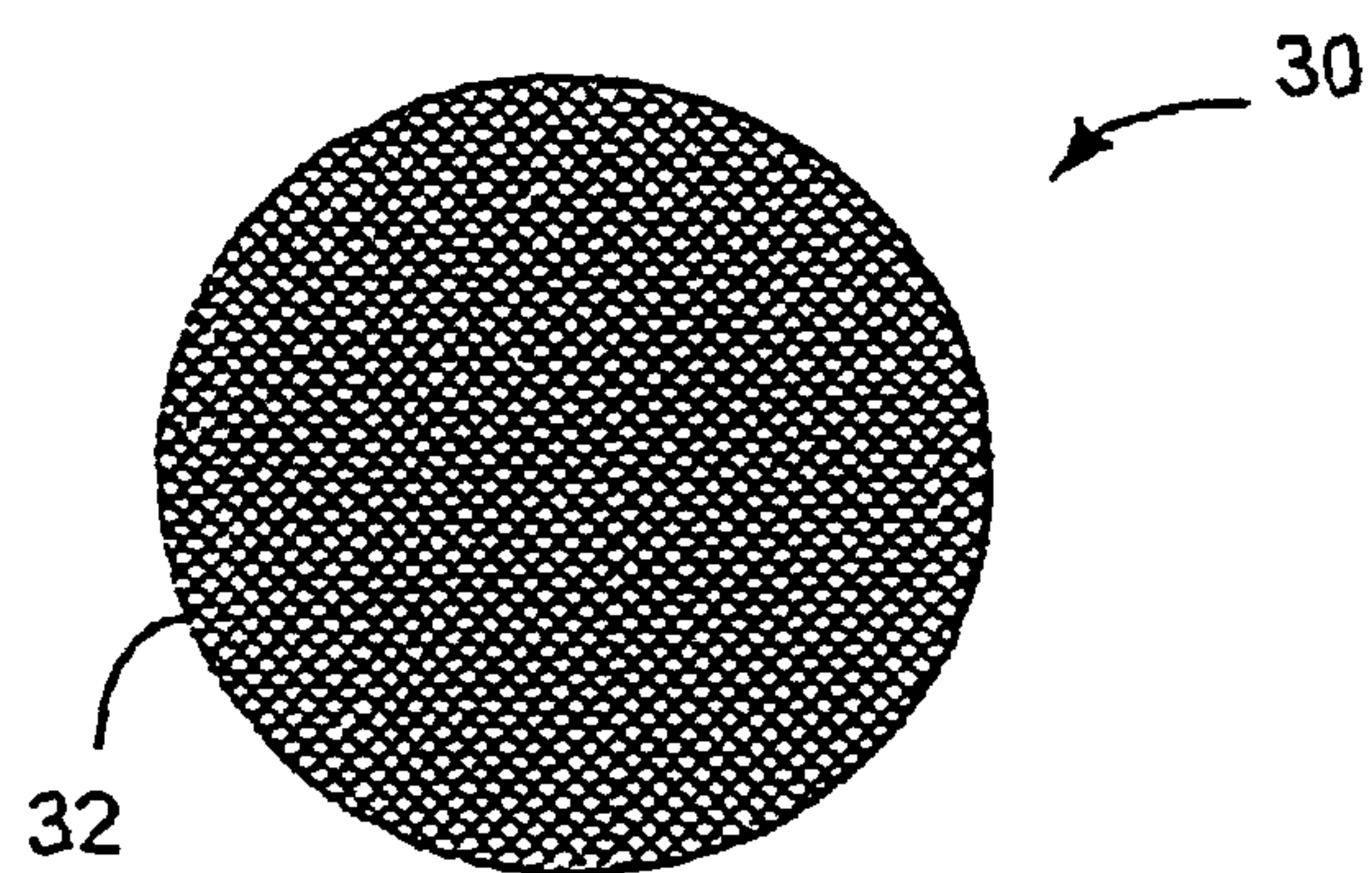


FIG. 6

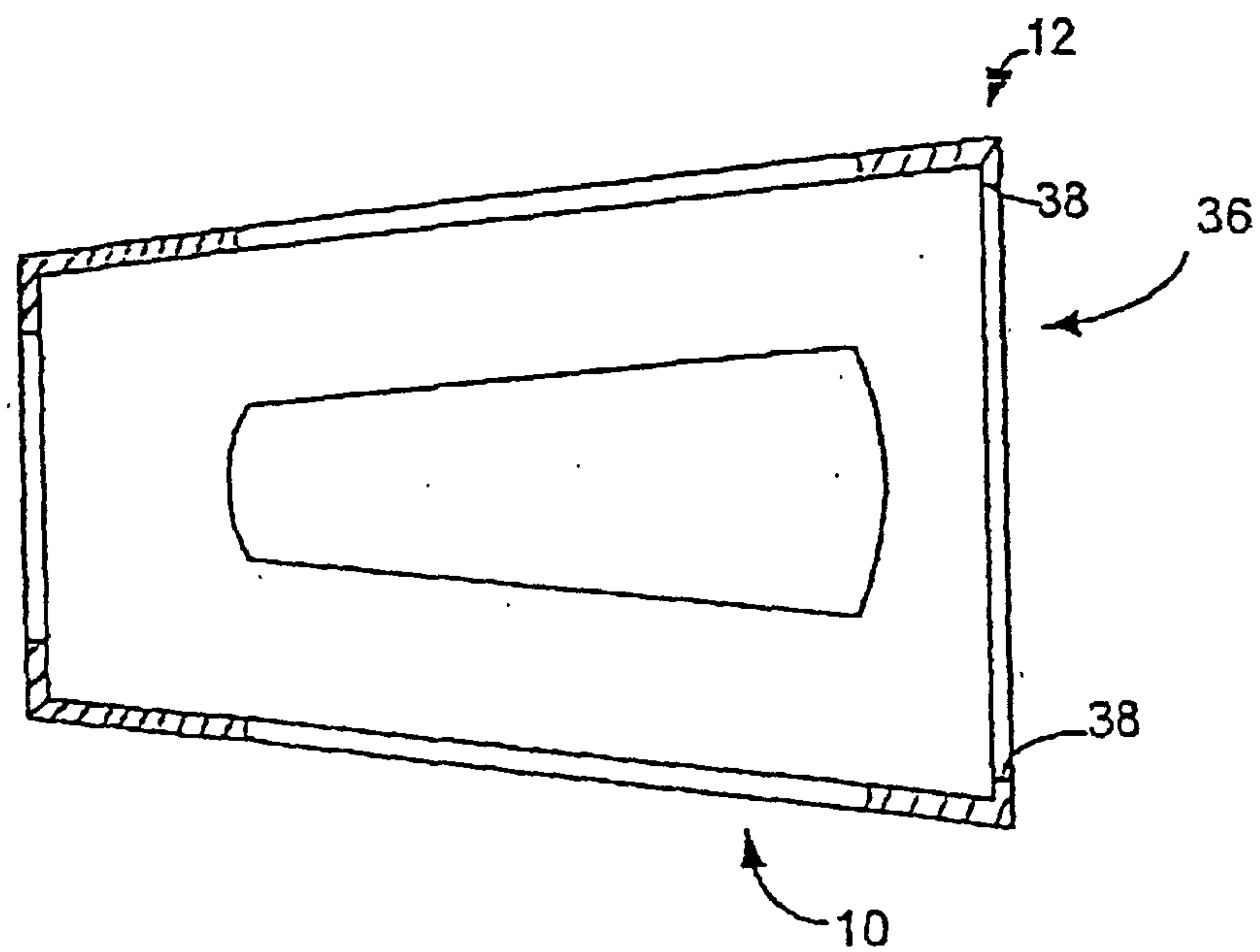


FIG. 7



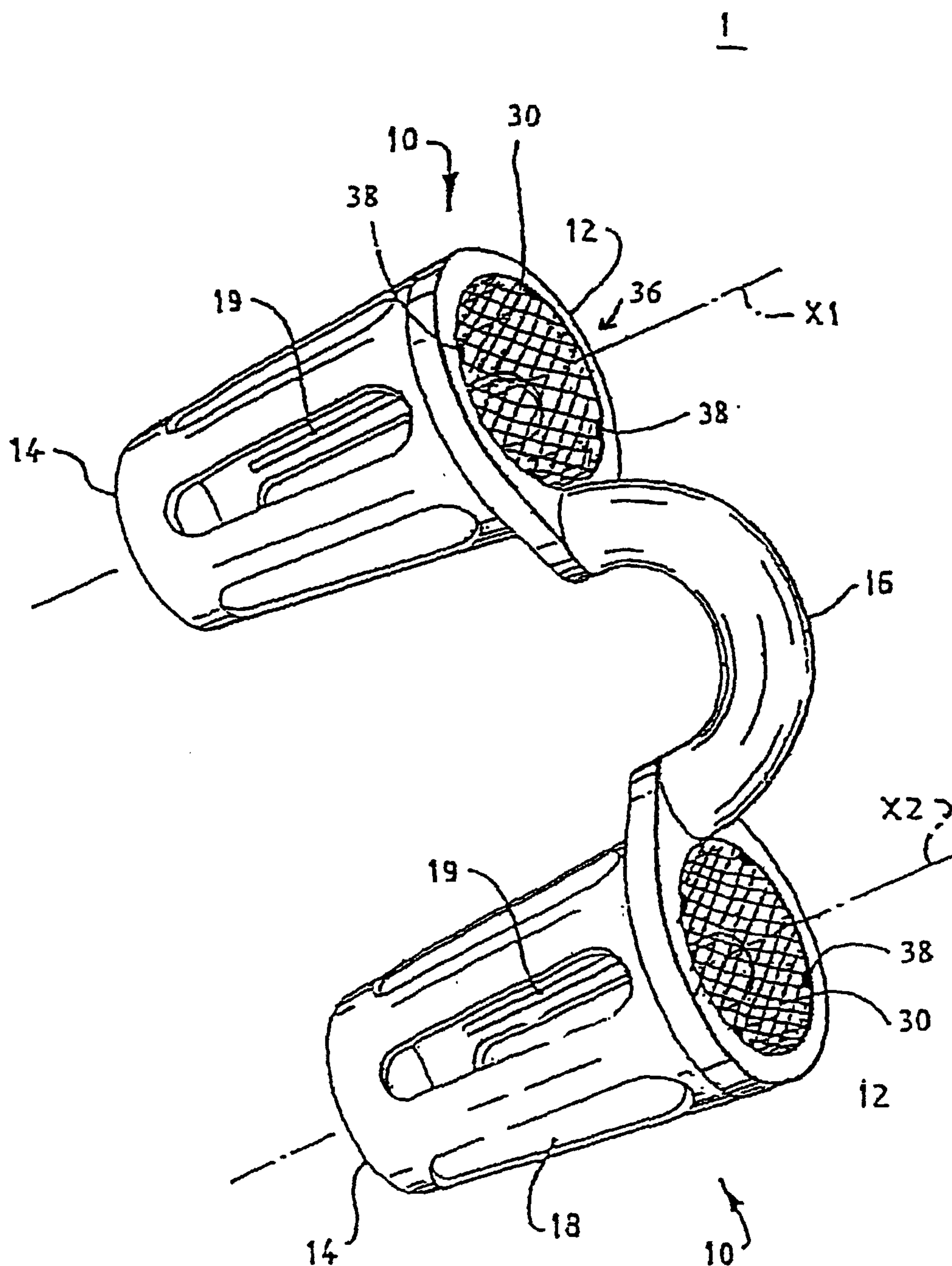


FIG. 8

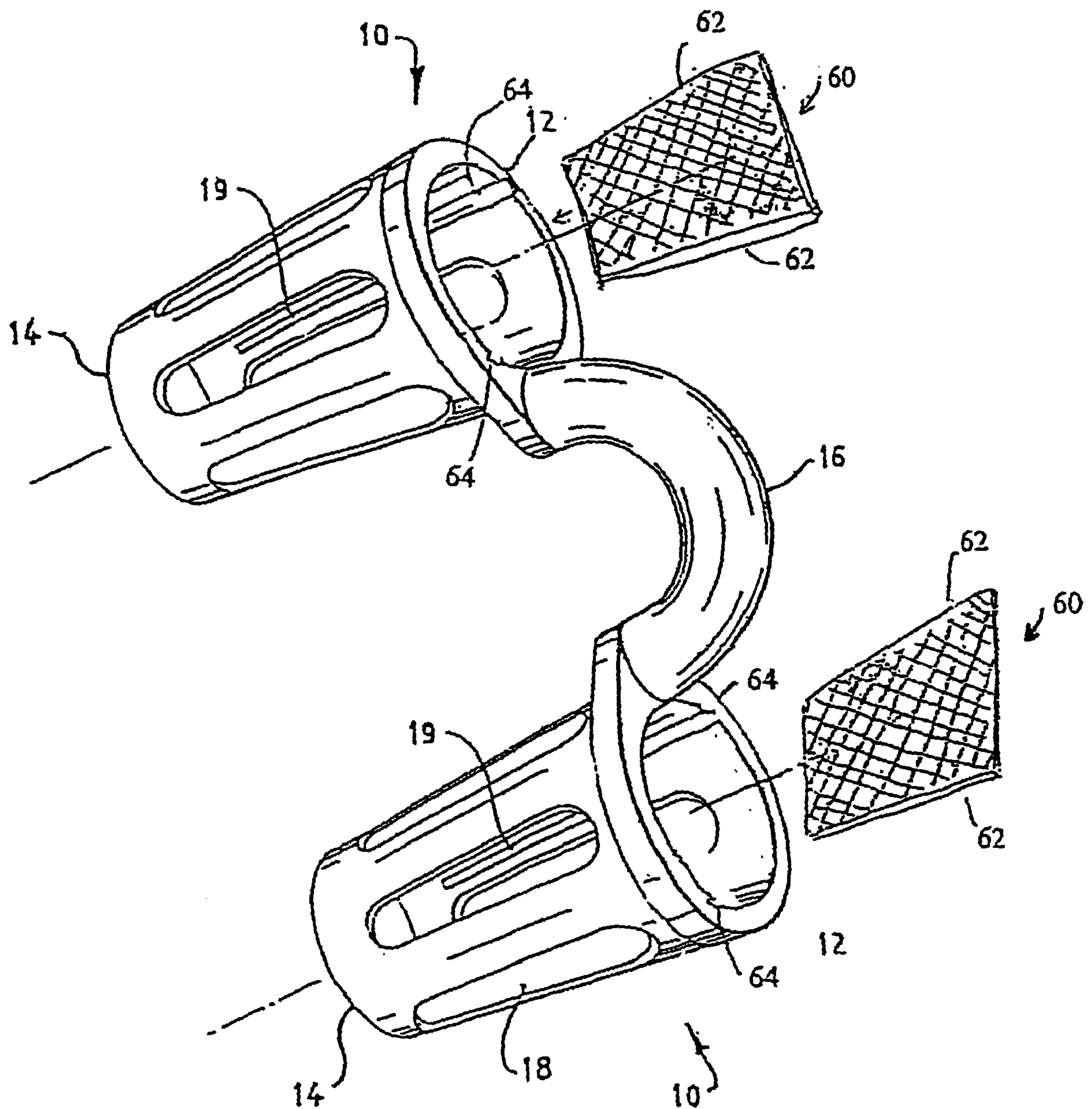
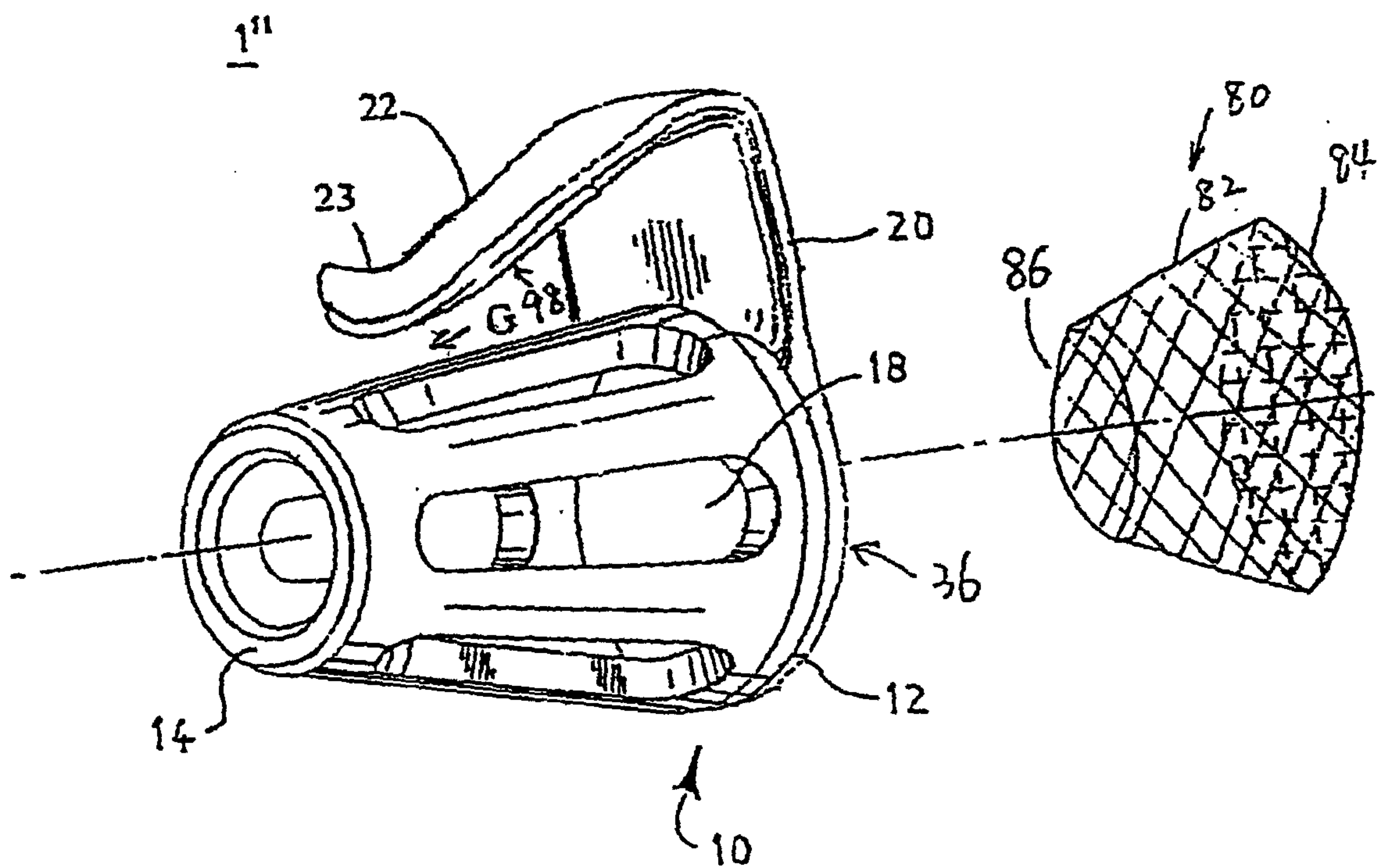


FIG. 9





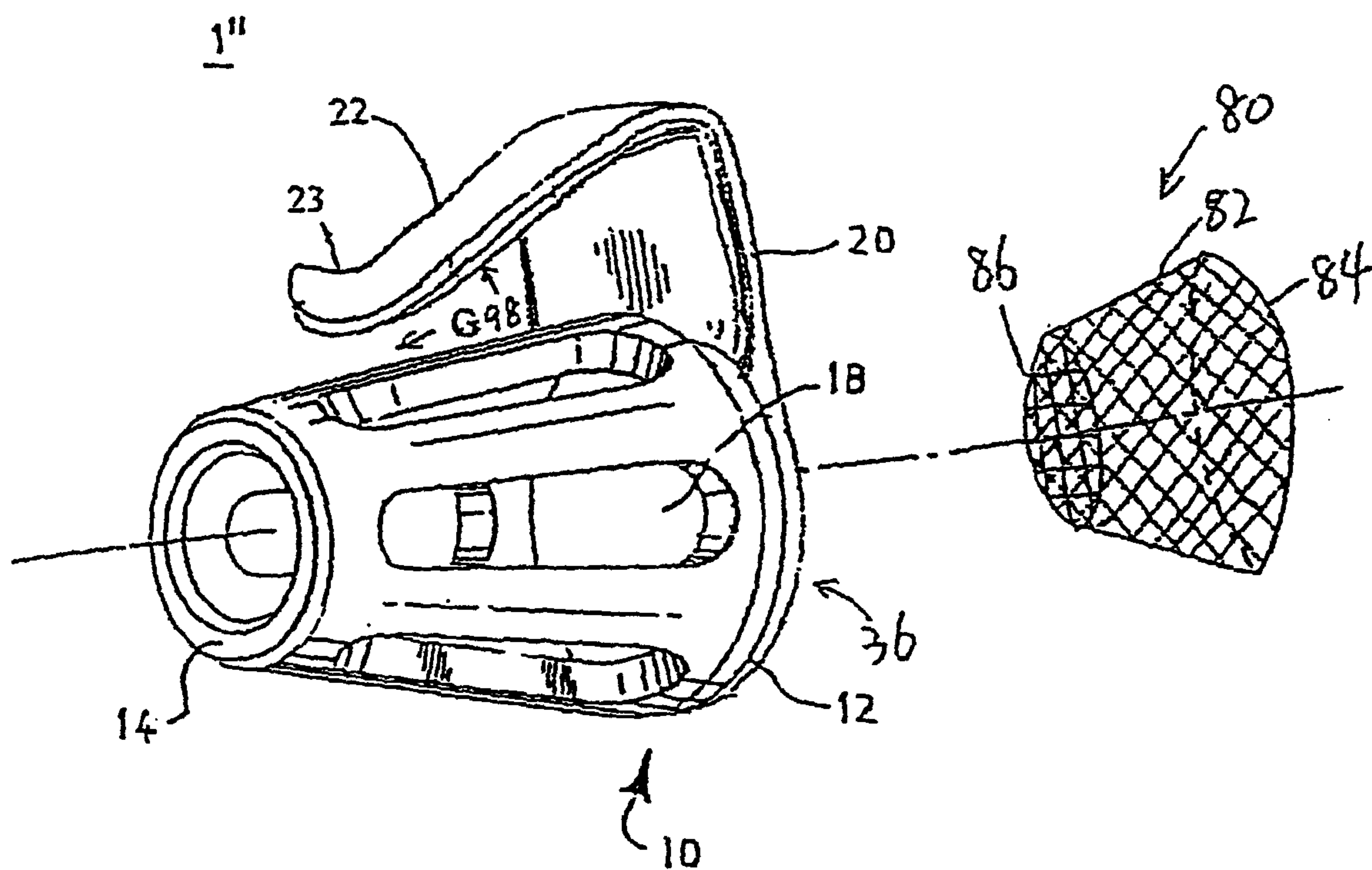


FIG. 10B

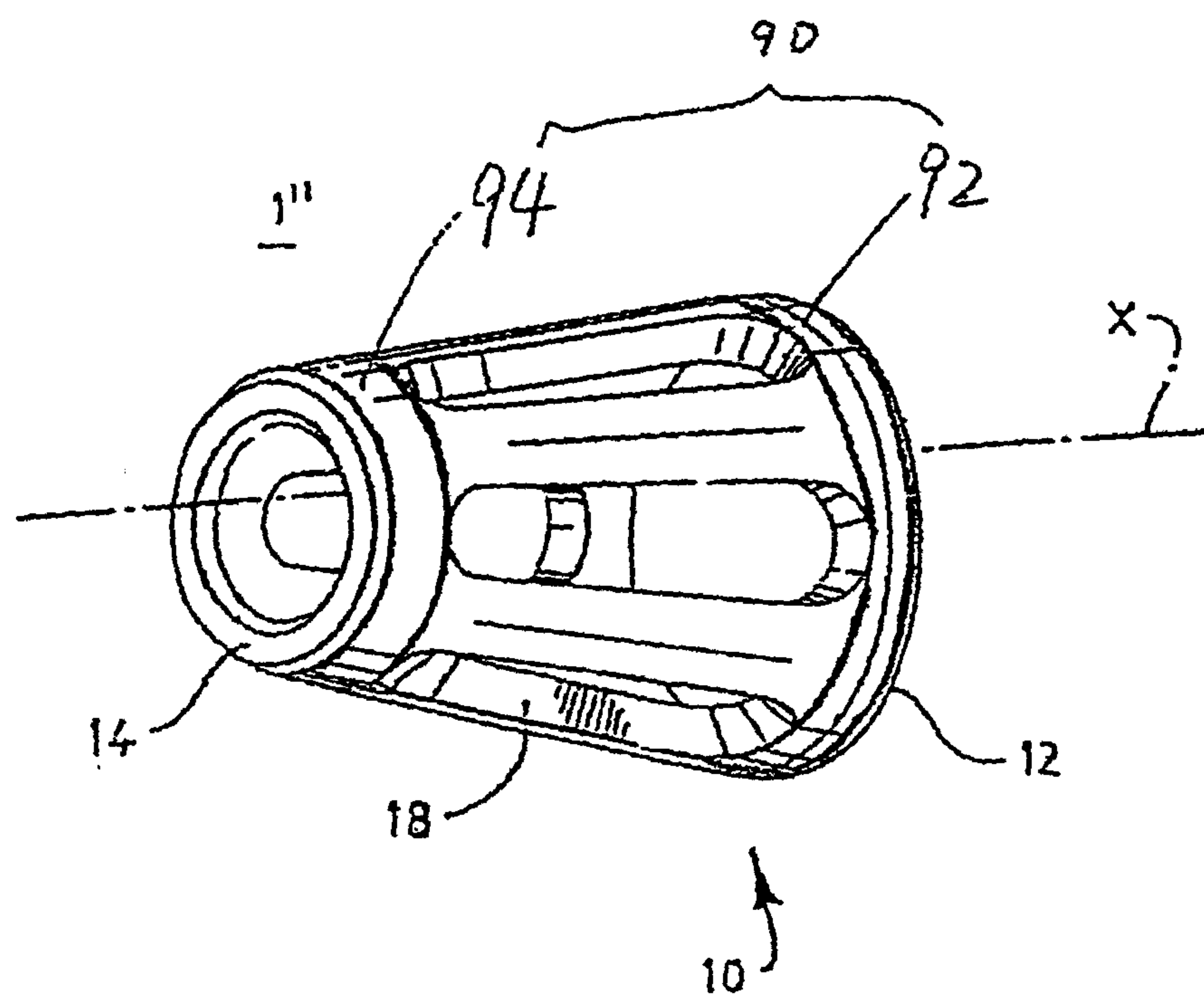
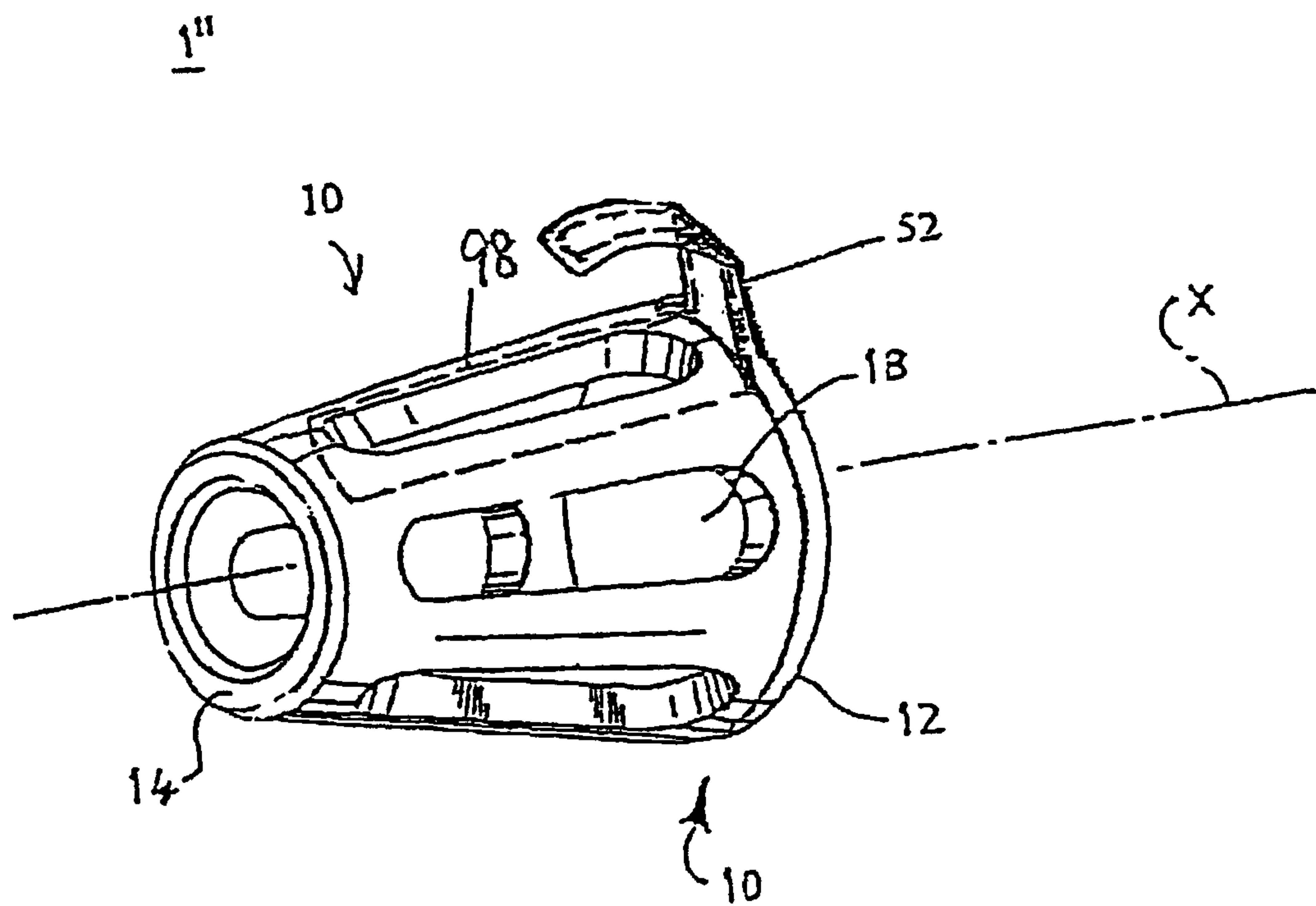


FIG. 11A





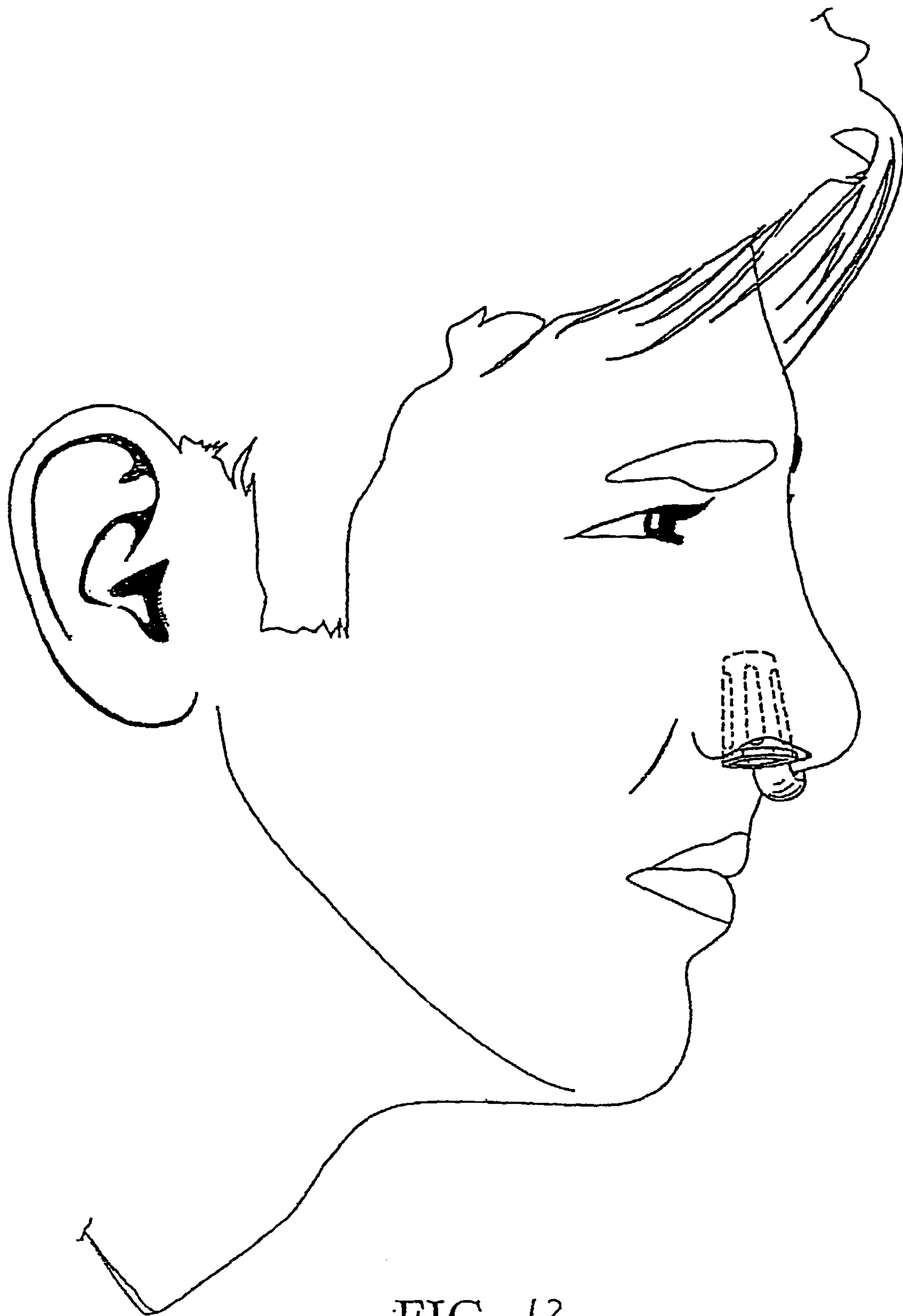


FIG. 12

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