

[54] **UNITARY CORE FOR MOLDING A
NASAL CANNULA**

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249/175, 176, 177

[56] **References Cited**

UNITED STATES PATENTS

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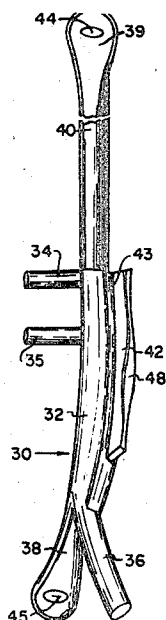
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[57] **ABSTRACT**

A flexible nasal cannula having improved characteristics is produced in a mold cavity incorporating a forming means comprising a transverse core having straight upper portion and a lower portion extending at an angle from the upper portion and a nipple core portion comprising a pair of rod-like extensions located toward the upper end of the upper portion and which extend substantially perpendicular to its axis. In a molding process, the forming means is maintained in spacial relation within a mold cavity, a thermoplastic material is flowed within the cavity around the forming means, cooled sufficiently to set the material and thereafter the cannula is removed from the forming means.

8 Claims, 4 Drawing Figures



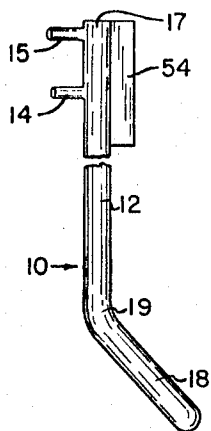


FIG. 1

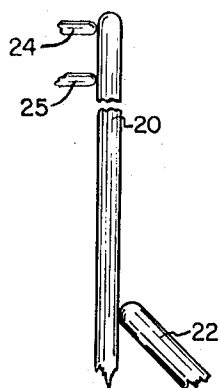


FIG. 2

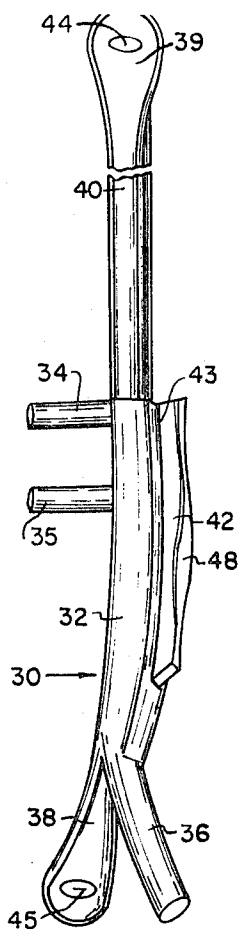


FIG. 3

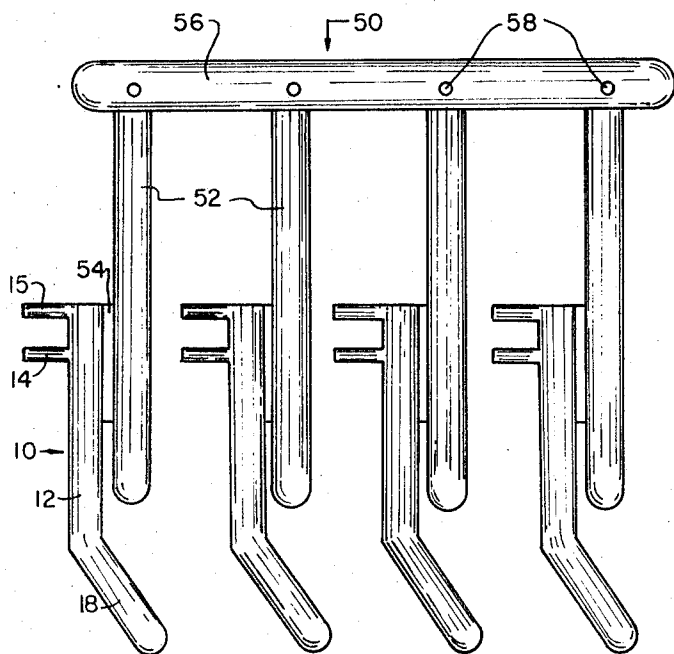


FIG. 4

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UNITARY CORE FOR MOLDING A NASAL CANNULA

BACKGROUND OF THE INVENTION

More recently nasal cannula devices have become very important as a means of administering oxygen to patients. Such devices are known to incorporate a flexible plastic tube which is placed on the patient's upper lip and maintained in such a position by an elastic strap or other retention means extending around the patient's head and attached to the ends of the plastic tube. Such a device also incorporates a pair of extensions, usually referred to as nasal tips which are hollow and join the plastic tube. The nasal tips extend into the patient's nares or nasal passages while oxygen containing therapeutic gases introduced from a supply tube flows into the main tube of the cannula, through the nasal tips and directly into the patient's nasal cavity and pharynx.

Various features have been incorporated into the cannula devices in an effort to improve their efficiency as well as patient comfort. Examples of improved design characteristics include nasal tips curved to conform to the contour of the nares, flattened surface and/or ends which lie against the patient's upper lip and cheek respectively. Such features provide greater patient comfort and maintain the cannula properly on the patient so that the nasal tips will not slip out of the nares.

In certain of the cannula devices presently in use the oxygen supply tube is attached directly to the main tube of the cannula in such a manner that the main tube and the supply tube lie along the same axis at the point of attachment. Such a feature is similar to that shown in U.S. Pat. No. 2,735,432. The major disadvantage of such a construction is that during use, the oxygen supply tube may become twisted which, in turn, causes the main tube of the cannula to rotate. Such rotation in one direction causes the nasal tips to be forced toward the patient's nares. If the rotation is extensive, discomfort to the patient may result due to pressure caused by the tips at the patient's nostrils or in the nares. Excessive twist may even cause collapse or folding of the tips to reduce or cut off oxygen flow. Rotation in the other direction will pull the nasal tips out of the patient's nostrils whereby effective oxygen therapy is eliminated. It will be appreciated by those skilled in the art that in the latter instance, if the patient is unconscious or otherwise disabled to the extent of not being able to again insert the nasal tips into his nostrils, where a constant or necessary oxygen supply to the patient is absent, further injury could ensue.

In order to eliminate cannula rotation caused by twisting of the oxygen supply tube, certain cannula devices have been improved by incorporating hollow angled inlet tube which joins and extends from the main cannula tube and to which inlet tube an oxygen supply tube is attached. Such a feature is illustrated in U.S. Pat. No. 2,868,199. The use of an angled inlet tube, greatly reduces any rotational movement of the cannula device otherwise caused by the twisting of the oxygen supply tube. This feature will be appreciated since any rotation or twisting of the oxygen supply tube will only tend to rotate the angled inlet tube but will not be passed on to the main tube of the cannula which does not lie along the axis of either the oxygen supply

tube or the angled inlet tube. Thus, the force of a twisted oxygen supply tube substantially terminates at the angled inlet tube portion of the cannula.

In molding a nasal cannula of the type described above, it has been the practice to use a plurality of forming means referred to as cores at least one of which is retractable. Thus, separate cores are used in forming the tubular body portion of the cannula and the tube-like hollow nasal tips. Again, these cores are maintained in spacial relationship to the mold cavity within the closed mold while a thermoplastic material is injected into the cavity and around the cores. Thereafter, as the mold is opened, the cores around which the tubular body portion or the hollow nasal tips are formed are retracted leaving the cannula remaining on the unretracted core. The mold operator then peels the cannula from the core.

In producing a cannula having a tubular main body portion and hollow nasal tips without an angled inlet tube portion only two forming cores are required. The core about which the tubular main body is formed is referred to as a transverse core. The cores used to form the hollow nasal tips are nipple cores. In the mold apparatus the transverse and nipple cores are brought together in an attempt to simulate a unitary or integral core at the phase during the molding process in which the material is injected into the mold cavity and around the cores. Thus, the nipple cores comprising two spaced rods will meet and contact the transverse core so that when the injected material flows around these cores the hollow nasal extensions and hollow main tube will join.

It will be appreciated that in attempting to produce a cannula in which the interior passageways for the flow of oxygen or other gases is to be unobstructed, i.e., flow along the main tube and through the nasal tips, the respective cores must be carefully machined so that no spaces are present between the nipple core and transverse core at the junction area. However, as the mold is used these cores become worn at the interfaces and common points of contact. This wear due to friction and abrasion, results in small spacial areas being formed which in turn, allows for the injected material to flow in these small spaces. This material which remains on the finished molded device is referred to as flash. Further, small diameter cores are sometimes deflected by the flowing thermoplastic producing a deformed product, uneven interior and exterior surfaces and flash.

On the exterior of the cannula, flash can be trimmed to improve the appearance of the product. On the other hand, where flash occurs on the interior of the cannula and especially in the tubular or hollow passageways, cannula performance can be significantly altered. Especially troublesome is flash located at the areas where the nasal tips join the main tube. It will be appreciated that significant amounts of flash at those areas will cause restriction in the interior gas passageway and may greatly reduce the amount of gas passing into either or both of the nasal tips and possibly shut them off altogether. Accordingly, the avoidance of flash at the interior joiner areas of the hollow nasal tips and main cannula tube will be appreciated as will the disadvantage of using separate nipple and transverse cores.

In a well known and extensively used cannula device prepared by an injection molding process, an angled inlet tube is present adjacent one end of main cannula tube with the hollow interiors of cannula body portions communicating as previously described. In producing such a device four separate cores are used: two nipple cores for forming the two hollow nasal tips, a transverse core for forming the hollow main tube and an angle core for forming the angled inlet tube. Thus, a further problem of flash on the interior of the cannula device is caused where the angled inlet tube communicates with the main cannula tube, thereby presenting the same problems of possible stoppage or interruption of gaseous flow from the angled inlet tube into the main cannula tube as above noted for the nasal tips. Further, since the transverse core used is substantially a straight rod, the main tube of the cannula has an open end when initially formed which must be plugged so that only the nasal tips and angled inlet tube are opened to the exterior of the cannula device. The plugging of this opening is usually accomplished by hand and obviously requires additional time and effort to complete the device which concomitantly increases production costs.

SUMMARY OF THE INVENTION

In the cannula molding process of the present invention a unitary core is utilized having an angle core portion, an axial transverse core portion and a nipple core portion each of which portions are integral with and a part of the single unitary forming core. In the injection molding process the unitary core is maintained in spacial relationship with the mold cavity, material is injected into the cavity around the core, the mold is opened and the cannula device is removed from the core. Since the core is unitary in construction, no separate cores are used thereby eliminating flash on the interior of the molded cannula device. The device is removed from the core and a lipped slot formed at the bridge where the core is attached to a core support is closed by a radio frequency welding process. The unique forming means or core described herein, in addition to eliminating interior flash, produces a cannula having hollow nasal tips, a hollow main tube and a hollow angled inlet tube. The device has no other tube openings which must be plugged as previously described except for the lipped slot which is sealed and the lips removed. A further embodiment of the invention utilizing multiple cores will be more fully described hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a cannula forming core of the present invention;

FIG. 2 shows cannula forming cores of the type previously used;

FIG. 3 illustrates a cannula device prepared according to the present invention; and

FIG. 4 illustrates a plurality of forming cores as shown in FIG. 1 on a molding rack according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, a forming core shown generally as 10 has an upper portion 12, an angle portion 18 and nipple portions 14 and 15. These portions are integral thus comprising the unitary forming core 10. The nipple portions 14 and 15 are separated rod-like extensions, one located at or near the upper end 17 of the upper portion 12, and the other somewhat lower.

The nipple portions 14 and 15 are spaced apart and extend substantially perpendicular from the axis of the upper portion 12. These nipple core portions 14 and 15 in cooperation with the mold cavity form the nasal tips of the cannula during the molding process. Accordingly, the distance between nasal tips desired for the cannula to be produced are dependent on the distance between the portions 14 and 15. The nipple core portions 14 and 15 may be substantially straight or curved where curved nasal tips are desired. The length of these nipple portions 14 and 15 may also be varied depending on the intended length of the nasal tips of the cannula.

The angle portion 18 extends directly from the upper portion 12 at the joiner area 19 of the upper portion 12 opposite the end 17. The angle at which the angle portion 18 extends from the upper portion 12 may be varied depending on the angle desired for the angled inlet tube of the cannula produced. Generally, angles between about 20° and about 80° are suitable with those between about 30° and about 45° preferred. The length of the angle portion 18 will also depend on the desired length of the angled inlet tube.

The core 10 is attached to a core support, not shown, by bridge member 54 which is preferably flat and extends along a side of the upper portion 12. The location of the bridge member 54 is shown as extending from the end 17 of the upper portion to somewhat below the lower nipple core portion 14, and opposite the nipple core portions 14 and 15. The length of the bridge 54 is important since if it does not extend beyond the lower nasal core portion 14 the cannula can not be easily removed from the core, as will be more fully explained hereinafter.

The location of the bridge 54 along the upper core portion 12 and relative to the nipple core portions 14 and 15 may be varied somewhat depending on the mold cavity and the length of the nipple core portions 14 and 15. Again, as shown, the bridge 54 is preferably opposite the nipple core portions 14 and 15. In that location, as the cannula is removed from the forming core 10, the nipple core portions 14 and 15 can directly exit through a lipped slot of the cannula formed by the bridge 54. However, the bridge 54 may join the upper portion 12 closer to the joiner area as of the nipple cores 14 and 15 with the upper portion 12 other than as shown in FIG. 1.

The shape of the various core portions 12, 14, 15 and 18 are preferably circular in cross-section thus forming a tubular hollow cannula interior. However, other cross-sectional shapes may be used such as rectangular, hexagonal, ellipsoidal and the like.

Referring to FIG. 2 which illustrates a state of the art forming means and by way of distinguishing the unitary forming core of the invention shown in FIG. 1 therefrom, separate transverse core 20, nipple cores 24 and 25 and angle core 22 are shown. The nipple cores

24 and 25 comprise rod-like extensions around which hollow nasal tips of a cannula are formed in a previously used mold apparatus. The transverse core 20 forms the hollow main tube portions of a cannula while the angle core 22 forms the hollow angled inlet tube of the cannula.

In a cannula molding process using a state of the art core assembly as shown in FIG. 2, the individual cores 22 and 26 are maintained in spacial relationship within a hollow cannula mold as thermoplastic material is injected into the mold cavity. Just prior to material injection, the end of the angle core 22 is brought into contact with the side of the transverse core 20. Similarly, the rod-like nipple core extensions 24 and 25 contact the side of the transverse core 20. Each of the cores 20, 22, 24 and 25 are attached to separate core supports and core slides, not shown. When the cores are brought into position, the fluid thermoplastic is injected into the mold cavity and around the separate cores. The thermoplastic is cured and the mold is opened. During the mold opening stroke, the transverse core 20 is retracted by an air cylinder or other retracting means, the angle core 22 is then retracted, and the nipple cores are brought forward from the parting plane or part line of the mold halves. The cannula which is attached to the nipple cores is then peeled off.

The core of the present invention shown in FIG. 1 eliminates the requirement of separate forming cores shown in FIG. 2 thereby simplifying the molding apparatus since only a single unitary core is used. However, even more important is the elimination of internal flash in a cannula produced by the core of the invention as previously explained. Thus, by eliminating the assembly of separate cores 20, 22, 24 and 25 which must contact in order to form the hollow interior of a cannula, flash occurring around the areas of contact of the individual cores is avoided, thereby producing a superior cannula.

A cannula prepared by the use of the forming core of the invention is illustrated in FIG. 3. The cannula 30 includes a hollow main tube portion 32, hollow angled inlet tube 36 joining and extending at an angle from the main tube 32, and hollow nasal tips 34 and 35 extending substantially perpendicular from the axis of the main tube 32. The hollow interior of the main tube 32 communicates with the hollow interior of tips 34 and 35 and angled inlet tube 36.

An elongated portion 40, also part of the cannula body, terminates in a flattened end 39 while a similar flattened end 38 joins the exterior wall of angled inlet tube 36 where the latter joins the main tube 32. It will be noted that the elongated portion 40 and flattened ends 38 and 39 lie generally along the axis of main tube 32. Each of these flattened ends 38 and 39 are for the purpose of maintaining the cannula in a fixed and comfortable position on a patient with the aid of an adjustable elastic strap, not shown, secured through openings 44 and 45 on the respective flattened ends.

Referring to both FIG. 3 and 4 the unitary forming core 10 (FIG. 4) is attached to a core support 52 by a bridge 54, which bridge in cooperation with the mold cavity forms a lipped slot 48 having a lip 42. This slot 48 is simply an elongated opening which enables the removal of the cannula from the forming core. When the mold halves are separated leaving the cannula

formed on the unitary core, the cannula 30 is peeled from the core 10 by pulling the cannula in the area of the nasal tips 34 and 35 away from nipple core portions 14 and 15. Accordingly, the nipple core portions 14 and 15 are pulled through the slot 43 and parting lip 42. Once the nipple core portions 14 and 15 clear the lip 42 the cannula is pulled downward off of core portions 12 and 18 respectively. Thereafter, the lip 42 of the cannula is removed by sealing means which both cuts the lip 42 from the cannula body and seals the slot along seam 43 shown in FIG. 3. If necessary, any exterior flash may be trimmed from the cannula body. A strap is threaded through openings 44 and 45 of the flattened ends 38 and 39 and the cannula is ready for use.

It will be evident that the length of bridge 54 and in turn the lipped slot 48 should be sufficient to permit easy removal of the cannula from the core without exceeding the elastic limits of the thermoplastic material. In other words, the lipped slot 48 should permit withdrawal of the nipple core portions 14 and 15 therethrough without unduly stretching the cannula.

FIG. 4 illustrates a further embodiment of the invention utilizing a plurality of forming cores 10 shown in FIG. 1. The individual unitary forming cores 10 are attached to a removable rack device 50. The rack 50 comprises a primary rod 56 along which extend substantially evenly spaced core support rods 52. Attached along one side of each core support rod 52 is a bridge 54 to which is attached the forming core 10. Such a bridge is preferably flat, and relatively thin. It is the presence of the bridge 54 which causes formation of the lipped slot 48 on the cannula as shown in FIG. 3 and previously described. Pins 58 fit into recesses on a mold apparatus and hold the rack 50 in proper position or alignment until the mold is closed prior to injection of thermoplastic material.

The rack 50 is itself of unitary construction. Its advantage is not only to enable the simultaneous formation of a plurality of molded cannula devices but generally permits improved efficiency in a mold operation. For example, such a rack is removable from the cannula mold by simply disengaging the pins 58 from cooperating mold recesses. This may be done by hand or automatically during the phase when mold halves are opened or opening. Thus, an operator may then peel off the cannulae outside of the mold apparatus which is advantageous from both a convenience standpoint as well as for safety. Where two of such racks are used, a single operator can remove and inspect cannulae while the other rack is engaged in the molding operation. Thus, speed is also facilitated in such an operation.

Although the rack of FIG. 4 engages four forming cores any number may be used depending on the construction of the mold apparatus and the capacity of the machine used in the molding operation. Thus, the invention is not limited to the specific device shown but may incorporate fewer or more forming cores. Similarly, the rack may incorporate equivalent features other than those specifically shown to achieve substantially the same results.

A variety of thermoplastic materials may be used in forming a cannula according to the invention although polyvinyl chloride and polyvinyl acetate are usually

preferred. These as well as alternative embodiments within the purview of the invention will be evident to those skilled in the art.

I claim:

1. In a core for molding a nasal cannula having an elongated tubular body and a pair of nasal tips extending therefrom, the improvement comprising:
a unitary core having
a. an elongated portion terminating at an upper and lower end for forming the tubular body and having the shape of the nasal cannula body interior;
b. a pair of relatively short rods spaced along the length of the elongated portion and extending therefrom, one of the rods being adjacent said upper end, for forming the nasal tips; and
c. a bridge for securing said core to a core support means said bridge extending from approximately the upper end of said elongated portion to

below the rods and forming a slot for removal of the cannula from said unitary mold core, and wherein said elongated portion, rods and bridge comprise an integral forming core.

2. The core of claim 1 wherein the bridge is disposed substantially opposite the rods.
3. The core of claim 1 wherein the elongated portion comprises an upper and lower portion, the latter extending at an angle from the former.
4. The core of claim 1 wherein the rods are straight.
5. The core of claim 1 where the rods are curved.
6. The core of claim 3 wherein the rods extend substantially perpendicular to the axis of said upper portion.
7. The core of claim 3 wherein the angle is between about 20° and about 80°.
8. The core of claim 1 wherein said portions have a substantially circular cross-section.

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