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(54) Title: TUBES AND THEIR MANUFACTURE

(57) Abstract: An inner cannula for a tracheostomy tube is made from an injection moulded preform (20, 20') of a crystalline or semi-crystalline plastics. The preform is loaded on a mandrel (6, 6') and is heated to soften the plastics. The mandrel is pushed through a die (1, 1') having an opening (2) with a diameter slightly smaller than the external diameter of the preform (20, 20') so that the preform is reduced in diameter and is stretched along the mandrel to the desired dimensions of the inner cannula.

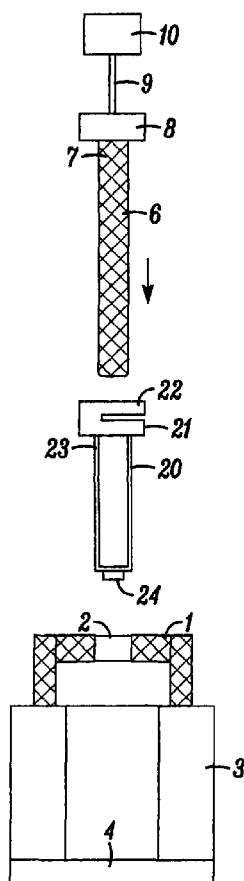


FIG. 1



AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- of inventorship (Rule 4.17(iv))

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TUBES AND THEIR MANUFACTURE

This invention relates to methods of the kind for making a tubular article including the step of providing a tubular preform of a plastics material.

Tracheostomy tube assemblies commonly include an outer tube and an inner tube or cannula that is a removable fit within the outer tube. The inner cannula can be removed and replaced periodically to ensure that the passage through the assembly does not become blocked by secretions. This avoids the need to remove the outer tube frequently.

The inner cannula presents various problems because it must be thin walled and a close fit within the outer tube so as to provide a large bore and thereby limit the resistance to flow of gas along the assembly. Conventional methods of manufacturing thin walled tubes have a number of problems. One method involves injection moulding. The relatively long, thin wall of the tube, however, makes it difficult to inject the fluid plastics material to the extremities of the mould. In order to enable the plastics to flow to all parts of the mould the wall of such tubes are generally made thicker than desired. Another technique often used is blow moulding. In order to achieve a well-controlled wall thickness, the parison used must be extruded or moulded with a very close tolerance. Even, however, if this is done, the blow moulding process itself is uncontrolled during the expansion of the parison until it comes into contact with the wall of the mould. This leads to thick and thin regions in the finished article. In order to ensure that the thinnest part of the tube wall is within the design tolerance it is necessary to make the article with a thicker than ideal wall. The manufacture of inner cannulae for tracheostomy tubes is one example of where these problems are met.

WO94/01156 and WO2004/101048 describe inner cannulae made of PTFE. EP1938857 describes an arrangement of tracheostomy tubes and inner cannulae where the hubs of the inner cannulae of different sizes are shaped differently so that they will only fit in the appropriate tracheostomy tube. EP2224985 describes an arrangement for attaching a hub to the shaft of an inner cannula. GB2056285 describes an inner cannula having a wall with annular corrugations and a longitudinal groove or other reinforcement member traversing at least some of the corrugations. US4817598 describes a smooth-walled inner cannula having a ring-pull formation at its rear, machine

end. US5119811 describes an inner cannula with a flared patient end and formed of two layers of different materials. US5386826 describes an inner cannula with an outer helical filament or layer of low friction material. US5983895 describes an inner cannula with straight sections at opposite ends joined by an intermediate curved section. US6019753 describes an inner cannula with two elongate regions of different flexibility so that the cannula has a plane of preferential bending. US6019753 describes an inner cannula having a shaft formed with slots to make it more flexible, the slots being covered by an outer thin sheath. US6135110 describes a curved inner cannula that is retained with the outer tube by means of a rotatable spring fitting. There are other applications outside the medical field where it is necessary to provide a thin-walled tubular article.

It is an object of the present invention to provide an alternative tubular article, a method of making such an article, and apparatus for use in the method

According to one aspect of the present invention there is provided a method of the above-specified kind, characterised in that the method includes the steps of loading the preform on a mandrel, the external diameter of the preform being slightly larger than the desired external diameter of the tubular article to be formed, heating the preform to allow it to soften, displacing the mandrel and preform relative to a die and through an opening in the die defining the desired external diameter of the tubular article so as to stretch the preform along the mandrel, and subsequently removing the tubular article from the mandrel.

According to another aspect of the present invention there is provided a method for making a tubular article including the step of providing a tubular preform of a plastics material having an initial internal and external diameter and an initial length, characterised in that the method includes the steps of heating the preform to allow it to soften, mechanically forming the preform with a die and mandrel to increase its length and reduce its wall thickness to provide a desired internal and external diameter, and subsequently removing the tubular article from the die and mandrel.

The method may include a preliminary step of injection moulding the preform. The preform is preferably of a crystalline or semi-crystalline plastics material. The method may include the further step of removing a closed end from the tubular article so that it is open at both ends. The preform may

be provided with a hub at one end prior to forming. The mandrel may have a textured surface. The die may be arranged to provide a pattern on the outer surface of the finished article. The die may be arranged to vary the diameter of the opening through the die as the mandrel is displaced relative to the die.

According to a further aspect of the present invention there is provided a tubular article made by a method according to the above one or other aspect of the present invention.

According to a fourth aspect of the present invention there is provided an inner cannula for a tracheostomy tube, the inner cannula being a tubular article made by a method according to the above one or other aspect of the present invention.

According to a fifth aspect of the present invention there is provided apparatus for use in a method according to the above one or other aspect of the present invention.

According to a sixth aspect of the present invention there is provided a tubular article made by apparatus according to the above fifth aspect of the present invention.

It is an object of the present invention to provide an alternative method of making a tubular article, a tubular article made by the method, and apparatus for use in the method.

A method of making an inner cannula for a tracheostomy tube, apparatus used in the method and an inner cannula made by the method, according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a sectional side elevation view of apparatus used in the method at a preliminary stage of the method;

- Figure 2 shows the apparatus of Figure 1 at a later stage of the method;
- Figure 3 is a side elevation exploded view of elements of modified apparatus used in a method to make a tubular article with a curved shape;
- Figure 4 is a side elevation view of a curved tube on a mandrel as made by the apparatus shown in Figure 3; and
- Figures 5A and 5B illustrate two alternative forms of die for making tubular articles with a varying external profile.

With reference first to Figures 1 and 2 there is shown apparatus used to make a straight inner cannula for a tracheostomy tube. The apparatus includes a metal die 1 with a circular aperture 2 defining the outside shape of the inner cannula. The die 1 is supported horizontally by an outer frame 3 above a base plate 4, the height of the die above the base plate being sufficient to accommodate the length of the finished cannula. The apparatus also includes a plug or mandrel 6 having a cylindrical shaft 7 of circular section and with an enlarged head 8 at its upper end. The mandrel could have other sections, such as of ovoid shape. The head 8 is connected to the piston 9 of a ram 10. The mandrel 6 is oriented vertically directly above the aperture 2 in the die 1. The diameter of the mandrel shaft 7 is slightly less than that of the aperture 2 and defines the inner diameter of the inner cannula. In its raised position shown in Figure 1 the lower end of the mandrel 6 is spaced sufficiently above the upper surface of the die 1 to allow a plastics preform 20 to be loaded on the mandrel.

The preform 20 is made by a conventional technique, such as injection moulding, and can be of various thermoplastic materials, preferably crystalline or semi-crystalline such that they will orientate, for example, polyethylene, polypropylene, polyester, nylon or the like. The preform 20 is moulded with an inner diameter equal to the outer diameter of the mandrel shaft 7 and with an outer diameter slightly larger than that of the desired finished inner cannula and slightly larger than the

diameter of the aperture 2 in the die 1. The length of the preform 20 is less than that of the desired finished cannula. The preform 20 may, as shown, be moulded with an integral hub 21 and hinged ring-pull element 22 at one end 23, which will form the machine or rear end of the finished cannula. Other features could be provided at the rear end such as to form a good grip for the cannula. Alternatively, the machine end components 21 and 22 could be joined with the tubular part of the cannula at a subsequent stage. The opposite end 24 of the preform 20 is closed and may be formed with a short leading nose 24.

In the method, the preform 20 is loaded on the mandrel 6 by sliding its upper end 23 upwardly over the lower end of the mandrel shaft 7 until the entire length of the preform is supported on the mandrel. The mandrel 6 is longer than the preform 20 to allow for stretching of the preform during the forming method. The preform 20 is then heated to soften the plastics material, such as by direct contact with a heated surface, by infra-red, radio frequency or by other means. Alternatively, the preform 20 could be heated before it is loaded on the mandrel 6. The ram 10 is then energised to drive its piston 9 and the mandrel 6 vertically down. As the mandrel 6 moves down (shown in Figure 2) it is forced through the aperture 2 in the die 1, pushing the preform 20 with it so as to mechanically form the preform. Instead of moving the mandrel into a stationary die, the die could be moved towards a stationary mandrel, or both the die and mandrel could move together. The wall thickness of the preform 20 emerging through the die 1 is defined accurately by the difference between the diameter of the aperture 2 and the diameter of the mandrel shaft 7. This method stretches the length of the preform 20 upwardly along the mandrel 6. In this way, the wall thickness of the inner cannula is accurately controlled and formed. The ram 10 is then caused to lift the mandrel 6 up out of the die 1 so that the formed inner cannula can be removed from the mandrel. The outer surface of the mandrel 6 may be formed with a texture to facilitate removal of the formed article. Compressed air could be introduced via passages opening on the surface of the mandrel 6 to assist removal of the article.

The lower end of the tube is then trimmed to the desired length and to remove the closed end.

In the method described above the outer diameter of the preform is reduced as it is stretched, whereas its inner diameter remains the same.

It would be possible instead to load a preform initially in the die and then move the mandrel into the preform and through the die. The diameter of the mandrel would be slightly larger than the initial internal diameter of the preform; the difference between the external diameter of the mandrel and the internal diameter of the die defining the desired wall thickness of the finished article, as in the previous method. In this arrangement the preform would, therefore, be selected with the desired external diameter initially and the internal diameter would be enlarged to the desired size as it was stretched by the mandrel.

The method described above may be used to form the finished inner cannula, or other tubular article, or it may provide a preliminary step in a method that includes a subsequent step of treatment, such as a subsequent blow moulding process to enlarge the diameter of the tubular article further.

The tubular article formed does not have to have a circular section and does not have to be straight. The apparatus illustrated in Figures 3 is used to form an inner cannula or other tubular article with a curved shape. The mandrel 6' is curved along its length and is coupled to a ram 10' via a cam arrangement 11' so that the ram moves the mandrel along a curved path. The die 1' is hinged about a central horizontal axis 12' so that it can pivot to align with the mandrel 6' as it is inserted through the die. Figure 4 shows the mandrel 6' and the finished article before it is removed from the mandrel.

The tubular article made by the method of the present invention does not have to have a smooth outer surface but could be formed with a modified surface finish or pattern, such as corrugations. To achieve this, as shown in Figure 5A, the die 100 could include shaped rollers 101 having details that are transferred to the tubular article as the rollers turn during the stretching process. Alternatively, as shown in Figure 5B, the die 200 could have other elements such as retractable pins 201 that are moved into or out of the die such as by a cam or hydraulic mechanism.

The present invention is particularly useful for making thin-walled inner cannulae for tracheostomy tubes but is not confined to these and could be used to form other tubular articles.

CLAIMS

1. A method for making a tubular article including the step of providing a tubular preform (20, 20') of a plastics material, characterised in that the method includes the steps of loading the preform (20, 20') on a mandrel (6, 6'), the external diameter of the preform (20, 20') being slightly larger than the desired external diameter of the tubular article to be formed, heating the preform (20, 20') to allow it to soften, displacing the mandrel (6, 6') and preform (20, 20') relative to a die (1, 1', 100, 200) and through an opening (2) in the die defining the desired external diameter of the tubular article so as to stretch the preform (20, 20') along the mandrel (6, 6'), and subsequently removing the tubular article from the mandrel.
2. A method for making a tubular article including the step of providing a tubular preform (20, 20') of a plastics material having an initial internal and external diameter and an initial length, characterised in that the method includes the steps of heating the preform (20, 20') to allow it to soften, mechanically forming the preform (20, 20') with a die (1, 1', 100, 200) and mandrel (6, 6') to increase its length and reduce its wall thickness to provide a desired internal and external diameter, and subsequently removing the tubular article from the die (1, 1', 100, 200) and mandrel (6, 6').
3. A method according to Claim 1 or 2, characterised in that the method includes a preliminary step of injection moulding the preform (20, 20').
4. A method according to any one of the preceding claims, characterised in that the preform (20, 20') is of a crystalline or semi-crystalline plastics material.
5. A method according to any one of the preceding claims, characterised in that the method includes the further step of removing a closed end from the tubular article so that it is open at both ends.

6. A method according to any one of the preceding claims, characterised in that the preform (20, 20') is provided with a hub (21) at one end prior to forming.
7. A method according to any one of the preceding claims, characterised in that the mandrel (6, 6') has a textured surface.
8. A method according to any one of the preceding claims, characterised in that the die (100, 200) is arranged to provide a pattern on the outer surface of the finished article.
9. A method according to any one of the preceding claims, characterised in that the die (100, 200) is arranged to vary the diameter of the opening through the die as the mandrel (6, 6') is displaced relative to the die.
10. A tubular article made by a method according to any one of the preceding claims.
11. An inner cannula for a tracheostomy tube, characterised in that the inner cannula is a tubular article made by a method according to any one of Claims 1 to 9.
12. Apparatus for use in a method according to any one of Claims 1 to 9.
13. A tubular article made by apparatus according to Claim 12.

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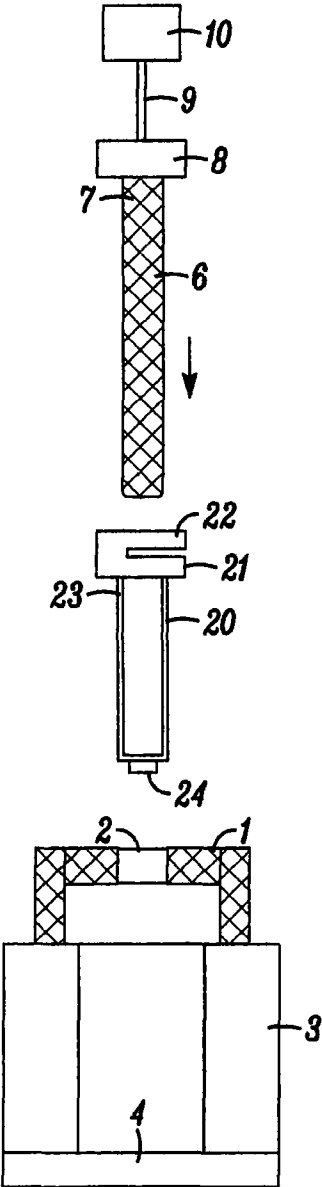


FIG. 1

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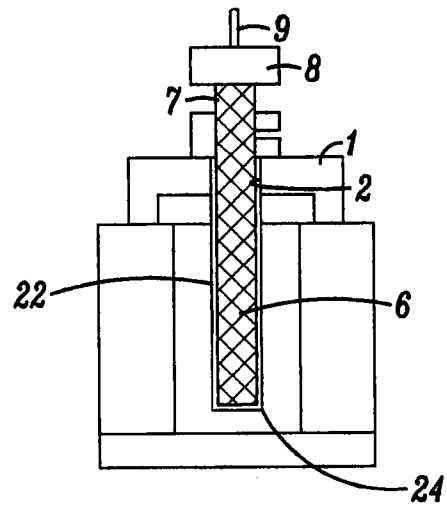


FIG. 2

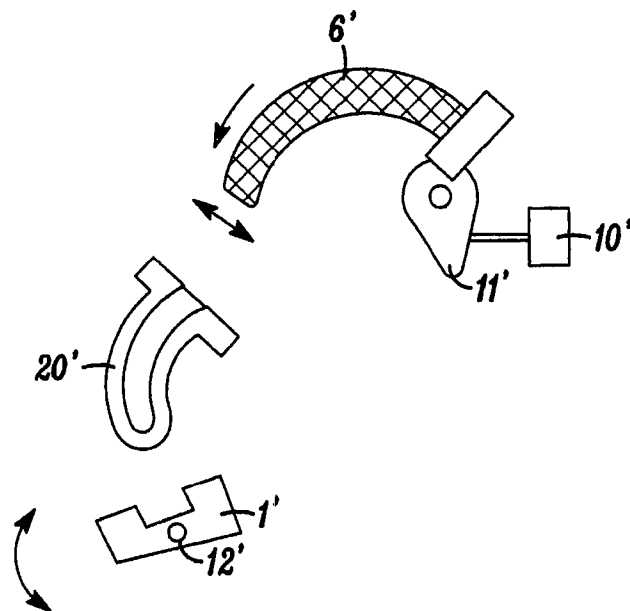


FIG. 3

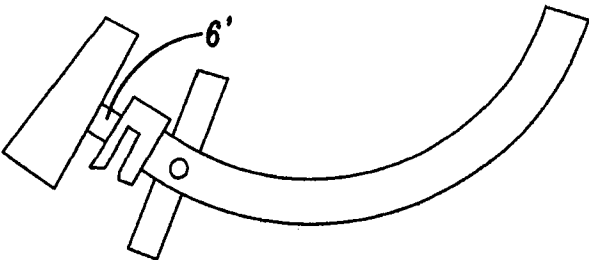


FIG. 4

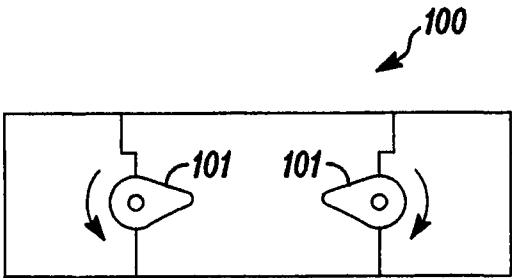


FIG. 5A

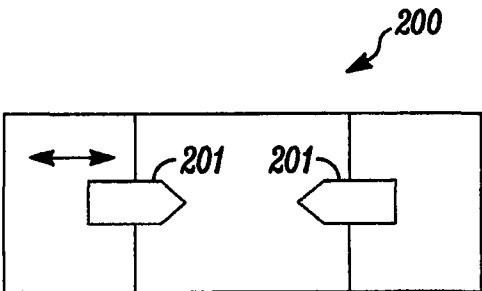


FIG. 5B

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2015/000101

A. CLASSIFICATION OF SUBJECT MATTER

INV. B29C55/30

ADD. B29L23/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 4 565 664 A (IKEHATA SHIGEKI [JP] ET AL) 21 January 1986 (1986-01-21) column 3, lines 48-52 figures 1-6 and relating description -----	1-13



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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