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(54) IMPROVEMENT IN OR RELATING TO METHODS OF HOLE-FORMING IN PLASTICS WORKPIECES AND PRODUCTS MANUFACTURED USING SUCH METHODS

(71) We, SMITHS INDUSTRIES LIMITED, a British Company of Cricklewood, London N NW2 6JN, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:–

This invention relates to methods of hole-forming in plastics workpieces, and products manufactured using such methods.

According to one aspect of the present invention there is provided a method hole-forming in a plastics workpiece, wherein a smooth-surfaced tool-element is inserted in a pierced aperture of the workpiece to contact the rim of the aperture the tool element being rotated such as to cause frictional heating and consequent flow of the material of said workpiece and thereby smooth out the rim contour.

The method of the present invention is especially applicable to hole-forming in thin plastics material, but more particularly to the forming of lateral holes in plastics tubing of small diameter. The method is of notable advantage in the manufacture of medico-surgical items, and in particular, or laterally-ported cannulae of small diameter such as used, for example, for epidural anaesthesia.

In the latter respect, an epidural cannula is commonly formed of plastics tubing having a closed distal end and one or more lateral ports or eyes near that end opening from the tube lumen. The eyes are of small diameter and there is difficulty in forming them satisfactorily.

More especially, it is present practice to form each eye by punching out a small sector of the tube-wall using a punch that impinges on the tube along a transverse path that is offset from the tube axis to an extent dependent on the cross-sectional area of eye required. There is however considerable difficulty in maintaining uniformity of eye cross-section from one cannula to another with this method, because of the problem of accurate location of the tube relative to the punch. Furthermore, there is also the considerable disadvantage that the punched-out eye is usually rough around its rim.

Epidural cannulae are introduced into the epidural cavity through a hollow metal needle having a sharp pointed tip. The needle is used to puncture the skin and underlying tissue and form a passageway to the epidural cavity, the distal end of the cannula being introduced to the cavity by pushing through the bore of the needle. The needle is subsequently withdrawn by sliding along the cannula. To ensure easy insertion of the cannula through the needle and into the cavity it is important that the rim contour of the lateral eyes in the cannula be as smooth as possible. Furthermore, there is the tendency in unskilled users to push and pull the distal end of the cannula through the introducing needle to overcome the slight frictional resistence of the cannula in the bore of the needle. This can be dangerous since the sharp end of the needle may catch on the cannula and could completely sever the tip from the rest of the cannula. The risk that the end of the needle will catch on the cannula is especially great around the rim of the lateral eyes and it is therefore important that the contour of these rims be as smooth as possible to avoid any such catching. It is important also that the rim of the eyes have a smooth contour to ensure non-irritant placement, as well as free-flow characteristics for fluid passing through the eye.

With the method of the present invention eye formation in a cannula can be achieved simply and accurately with smooth contour even though the cannula and the eye are both of small diameter. In this respect and according to another aspect of the present invention a method of forming a hole in the wall of a cannula comprises the steps of piercing the wall of the cannula with a needle to form an aperture therein, withdrawing the needle from the aperture, driving the needle to rotate at high speed about its longitudinal axis, inserting the rotating needle in the aperture to contact the rim of the aperture such as to cause frictional heating and consequent flow of the material of the workpiece and thereby smooth out the rim contour.

Drive to rotate the tool-element or needle may be applied only up to the time of insertion of the tool-element or needle in the pierced aperture.

A cannula and a method of manufacture thereof utilising the hole-forming process of the present invention, will now be described by way of example, with reference to the accompanying drawing, in which:–

Figure 1 shows the finished cannula;

Figure 2 illustrates the form of tooling utilised in the manufacture of the cannula of Figure 1; and

Figure 3 illustrates at (i) to (iv) successive steps in use of the tooling of Figure 2 in manufacture of the cannula of Figure 1.

Referring to Figure 1, the finished cannula is formed of nylon tubing 1 having an external diameter of 0.8255 mm and a wall thickness of 0.1778 mm. A conventional Luer connector 2 is coupled into the open, proximal end 3 of the tubing 1, whereas the distal end 4 is occluded, communication from the tubing bore or lumen 5 at the end 4 being provided via three lateral holes or eyes 6. The eyes 6 are spaced from one another longitudinally of the tubing 1 by 3.715 mm and are distributed symmetrically with respect to one another about the tubing circumference. Each eye 6 has a diameter of 0.3556 mm and has a smoothly-contoured rim so as to ensure, in particular, that there is no projection or external roughness to interfere with fluid flow through the eye or insertion of the cannula into, or withdrawal of it from, the epidural cavity or the introducing needle.

The formation of the eyes 6 with smooth contour is achieved by a process that is performed on the tubing 1 before the fitting of the connector 2 and following a heat-sealing step for occluding and rounding-over the end 4. The three eyes 6 are formed simultaneously, and for this the end 4 is inserted into a cylindrical bush, in which it is a close fit, to be held securely at that end throughout a length of some 19 mm. An air-operated tool is provided at each of the three locations along the bush where the longitudinally and angularly spaced eyes 6 are to be formed in the inserted tubing 1. The three tools are operated together and in their operation and structure are identical to one another. In this latter context the structure and operation of only one of the three tools will be described; tool structure and operation are illustrated in Figures 2 and 3 respectively.

Referring to Figure 2, the tool is in the form of a hardened-steel needle 10 which has a diameter of 0.3556 mm, and which at its pointed tip 11 has an apex angle of 60 degrees. The needle 10 is mounted for movement longitudinally back and forth through an aperture 12 in the wall of the cylindrical bush 13. An air-powered motor 14 is coupled to the needle 10 to drive it in this way so that the needle tip 11 can be selectively caused to enter from the aperture 12 a limited, but adjustable, distance into the central cylindrical-cavity 15 of the bush 13 and then withdrawn completely into the aperture 12 again. An air-powered turbine 16 is also coupled to the needle 10 for selectively driving it in rotation about its longitudinal axis.

The occluded end 4 of the tubing 1 is inserted into the cavity 15 and the motor 14 operated to drive the needle 10 to pierce through the wall of the tubing 1 within the bush 13, as illustrated at (i) of Figure 3. The turbine 16 is not operated at this time so that the needle 10 does not rotate during the piercing operation.

The turbine 16 is operated only after the needle 10 has been withdrawn as illustrated at (ii) of Figure 3 and leaving a raggedly-contoured aperture in the tubing wall. The needle 10 is driven to a rotation speed of some 70,000 revolutions per minute and the motor 14 is again operated to advance the needle 10 as illustrated at (iii) of Figure 3. Drive of the turbine 16 ceases just as the needle tip 11 is about to re-enter the aperture in the wall of the tubing 1, so that rotation continues during the re-insertion by virtue of the stored rotational energy alone. Contact of the rotating needle 10 with the ragged rim of the aperture produces frictional heating that serves to cause plastic flow smoothing out the eye contour around the needle 10. The energy of the needle 10 is dissipated so that it comes to rest, before being withdrawn as illustrated at (iv) of Figure 3. A lateral eye is thereby formed having the same diameter as that of the needle 10, and being smoothly contoured to ensure that free flow can be achieved from the tube lumen and that there is no roughness to obstruct insertion or cause irritation during cannulation.

WHAT WE CLAIM IS:–

1. A method of hole-forming in a plastics workpiece, wherein a smooth-surfaced tool-element is inserted in a pierced aperture of the workpiece to contact the rim of the aperture the tool element being rotated such as to cause frictional heating and consequent flow of the material of said workpiece and thereby smooth out the rim contour.

2. A method of hole-forming in a plastics workpiece, comprising the steps of forcing a smooth-surfaced tool-element into the workpiece to pierce an aperture therein, with-drawing said tool-element from the aperture, applying drive to rotate the tool-element, inserting the rotating tool-element in the pierced aperture to contact the rim of the aperture such as to cause frictional heating and consequent flow of the material of said workpiece and thereby smooth out the rim contour.

3. A method of hole-forming according to Claim 1 or 2 wherein said tool-element is in the form of a needle having a pointed tip.

4. A method of hole-forming according to any one of the preceding claims wherein drive to rotate the tool-element is applied only up to the time of insertion of the tool-element in the pierced aperture.

5. A method of hole-forming according to any one of the preceding claims wherein said tool-element is withdrawn from said aperture only after the tool-element has ceased to rotate.

6. A method of hole-forming according to any one of the preceding claims wherein said tool-element is rotated by means of a gas-driven turbine.

7. A method of hole-forming according to any one of the preceding claims wherein said tool-element is forced into said workpiece by a gas-driven motor so as to form said pierced aperture.

8. A method of hole-forming according to any one of the preceding claims wherein said work-piece is plastics tubing and said aperture is formed laterally in the wall of said tubing.

9. A plastics workpiece including a hole formed by a method according to any one of the preceding claims.

10. A method of forming a hole on the wall of a cannula comprising the steps of piercing the wall of the cannula with a needle to form an aperture therein, withdrawing the needle from the aperture, driving the needle to rotate at high speed about its longitudinal axis, inserting the rotating needle in the aperture to contact the rim of the aperture such as to cause frictional heating and consequent flow of the material of said workpiece and thereby smooth out the rim contour.

11. A method of forming a hole in the wall of a cannula substantially as hereinbefore described with reference to the accompanying drawings.

12. A cannula including a hole in the wall thereof formed by a method according to any one of Claims 1 to 8, 10 or 11.

For the Applicants

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1580924 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

Fig.1.

Fig.2.

Fig.3.