PATENT SPECIFICATION (11) 1 587 764

1 587 764

(21) Application No. 48507/77 (22) Filed 22 Nov. 1977 (19)
(31) Convention Application No. 760 208 (32) Filed 17 Jan. 1977 in
(33) United States of America (US)
(44) Complete Specification published 8 April 1981
(51) INT. CL.³ B65D 53/02
(52) Index at acceptance
B8T CA
F2P 23D

(54) PROTECTIVE DEVICE FOR A TUBE END

(71) We, BAXTER TRAVENOL LABORATORIES INC., a Corporation organised and existing under the laws of the State of Dalaware, United States of America, of One Baxter Parkway, Deerfield, Illinois 60015, United States of America, 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:—

In parenteral solution administration sets and many other types of medical equipment tubular hubs, needle-receiving luers, and the like are utilized which must be sealed in a sterile manner until ready for opening and use.

Accordingly, a semi-rigid tube is provided to fit over the hub or luer as a removable sealing closure, the semi-rigid tube having a bore which may define several spaced annular sealing members. These are generally semicyclindrical in shape, extending in circumferential manner about the axis of the bore. The annular sealing devices are proportioned to press against a rigid, cylindrical surface of the tube to be sealed, providing several annular seal lines when in place, and yet permitting removal by simply twisting and pulling of the rigid sealing tube.

Such an arrangement, however, has the disadvantage that it exhibits a very sensitive tolerance of only one or two thousandths of an inch. In other words, if the sealing devices happen to be made with an inner diameter which is off specification by more than two or three thousandths of an inch, the devices may either not fit on the desired luer or other tube to be sealed, or they will fit so loosely that they will fail to perform the desired sealing function. Similarly, if the outer diameter of the luer to be sealed is out of specification for any reason by two or three thousandths of an inch, the same effect may happen.

The above also indicates that separately-designed and moulded sealing devices must be provided for each type of luer or other tube to be sealed, even if the variation in outer diameter between the various types is only two or three thousandths of an inch.

Furthermore, sealing devices which utilize, in their inner diameter, semi-cylindrical, annular sealing rings may be very difficult to mould. It has been found experimentally that, referring to medical-type tip protection sealing devices exhibiting an inner diameter of about 0.27 inch, it has been exceedingly difficult to mould semi-cylindrical, annular sealing rings which are as much as 0.01 inch in radius, in that such large sealing rings tend to rip as they are being removed from the mould. The only way to accomplish this would be to substantially increase the draft angle of the mould, or to use a much softer plastics moulding material than is customarily used in this type of operation.

An example of a tip protection device using such semi-cylindrical annular sealing rings is shown in U.S. Patent No. 3,889,673. Other annular sealing structures are shown in U.S. Patents 3,101,841; 2,752,059; and 3,583,591.

In accordance with this invention there is provided a device for grippingly engaging a tube to permit protection of an end of the latter, comprising a tubular member which has an open mouth, the interior of the tubular member being provided with a plurality of axially spaced annular sealing rings to grip a tube to be protected, each ring being a flexible projection which is elongate in cross-section and whose longitudinal axis extends in acute angle relationship to the axis of the tubular member towards the open mouth, the length of the projection along its longitudinal axis, as viewed in cross-section, being at least 0.01 inch and the average thickness of the projection being less than said length, the inner diameter of the tubular member between the open mouth and the sealing ring nearest said open mouth being greater than the inner diameter of the tubular member between said nearest sealing ring and the next adjacent sealing ring, and the inner diameter of the tubular member between consecutive sealing rings de-

creasing in the direction inwardly of the tubular member from said open mouth.

The device can be used to seal tubular parts with substantial size variation. In the specific embodiment shown, the tip protection device is capable of sealing tubular parts which vary in outer diameter by up to nine percent. Accordingly, quality control problems in the manufacture of sealed parenteral solution administration sets and similar medical items is greatly simplified, and a single design of tip protection device can be used with varying designs of tubular members to be sealed.

Furthermore, the annular sealing members utilised in this invention may have a length which is substantially greater than 0.01 inch, while being readily mouldable without damaging of the annular sealing rings on removal from the mould, even when a normal draft angle or taper is used on the mould (for example two degrees), and when normally stiff plastics formulations such as low density polyethylene are used for moulding the tip protection devices.

As a result of this, the sealing rings define angularly-related, elongated "gills", rather than the typical semi-cylindrical, annular projections. Because of this, the gill-type sealing rings may be flexible, and bend outwardly when surrounding and gripping a tube to be sealed. Because of this capability to bend outwardly, a significant variation in the relative size of the tube to be sealed is possible without disruption of the sealing capability of the sealing device of this invention.

Furthermore, the structure of this invention can be removed from its mould with a substantially reduced risk of tearing of the sealing rings, despite their increased length over that of the prior art, because of their flexibility.

The inwardly decreasing inner diameter of the tubular member facilitates the folding of the sealing rings flush with the inner surface of the tubular member which is advantageous upon removing of the sealing device of its mould, and also when receiving a relatively large tube to be sealed.

Preferably, the cross-sectional projections of the sealing rings taper to a minimum width at their outer ends, and their outer ends preferably define annular inner surfaces defining an acute angle with the axis of the bore of the tubular sealing member. This provides an annular, innermost edge on the sealing rings which can bear against the tube to be sealed with focussed sealing pressure, for improved sealing characteristics.

The lengths of the longitudinal axes of the cross sectional projections of the sealing rings are preferred to decrease consecutively from the outermost ring, nearest the open mouth, to the innermost sealing ring. However, the annular sealing edges of the separate sealing rings are generally equidistant from the axis of the bore, to provide equal sealing opportunity for each ring.

Referring to the drawings, Figure 1 is a perspective view of a sealing device according to this invention, shown closing and sealing a luer of a parenteral solution administration set;

Figure 2 is a longitudinal sectional view of the sealing device of Figure 1;

Figure 3 is a longitudinal sectional view of the sealing device, shown in sealing relation with respect to a luer as in Figure 1;

Figure 4 is a greatly enlarged, fragmentary, longitudinal sectional view of a portion of the sealing device.

Referring to the drawings, tubular sealing member 10 is shown made out of a semi-flexible plastics material such as low-density polyethylene or the like. Tubular sealing member 10 defines an integral, closed end 12, although, alternatively, end 12 may be open and sealed if desired with a wad of cotton or an air-permeable filtering membrane, if such is desired.

Sealing member 10 defines at its other end an open mouth 14 for receiving a luer 15 or the like to be sealed.

Spaced from open mouth 14 are a plurality of spaced, annular sealing rings 16, 18, 20 which project from the bore of tubular member 10, and extend completely around the axis 22 of the bore in circumferential manner. The cross-sectional projections of rings 16, 18, 20, in turn, define longitudinal axes 24, 26, 28 which incline toward open mouth 14 in acute angle relationship to the axis 22 of the bore of sealing member 10.

The lengths of longitudinal axes 24, 26, 28 may be defined as extending from the inner ends 30 of rings 24, 26, 28, to the intersections 32 of the cylindrical planes 40, 42, 44 of the bore-defining wall 23 and the ends of the respective axes 24, 26, 28, as shown in Figure 4.

The longitudinal axes 24, 26, 28 of each of the cross sectional projections of rings 16, 18, 20 are at least 0.01 inch long, to facilitate the outward flexing of the sealing rings as shown in Figure 3. Preferably, axis 24 may be about 0.043 inch long; axis 26 may be about 0.035 inch long; and axis 28 may be about 0.030 inch long, the lengths of the axes diminishing from axis 24 to axis 28.

The thicknesses of the cross sectional projections of rings 16, 18, 20 preferably taper to a minimum thickness at their inner ends 30, as shown in Figure 4. This minimum thickness may preferably be about 0.01 to 0.15 inch, for example, 0.011 inch. The respective inner and outer sides 34, 36 of the rings can diverge outwardly at an angle of,

for example, fifteen degrees, to provide an increasing thickness as one proceeds from the free inner end 30 to the outer end, which is integral with the rest of sealing member 10.

Sealing rings 16, 18, 20 define flat, annular inner surfaces (or cross-sectional projection ends) 30, positioned in acute angular relationship to axis 22 of the bore, to define an annular, innermost angled edge 38 which, as shown in Figure 4, engages the tube to be sealed, providing a series of focused, annular sealed areas of relatively reduced area and relatively high sealing pressure. Also as shown in Figure 4, rings 16, 18, 20 fold outwardly, and are spaced apart a distance sufficient to permit the unhindered folding of the rings to a position flush with the bore-defining wall 23, when that is required for removal from the mold and for accommodation of a relatively thick tube to be sealed.

The angle of axes 24, 26, 28 is preferably essentially from thirty degrees to sixty degrees to the axis 22 of the bore of sealing member 10. As specifically shown, the angle is substantially forty-five degrees.

It is also preferred for the inner diameter of the bore at area 40 between open mouth 14 and the sealing ring 16 which is nearest to the open mouth, to be greater than the inner diameter of the bore at area 42 between the nearest sealing ring 16 and the next sealing ring 18 adjacent thereto. Similarly, the inner diameter of the bore between all consecutive sealing rings may decrease in the direction inwardly of the sealing member from the open mouth. Specifically, the inner diameter of the bore at area 40 may be about 0.27 inch; at area 42 the inner diameter may be 0.262 inch; and at area 44 the inner diameter may be 0.252 inch; and at area 46 the inner diameter may be 0.238 inch. Alternatively, the inner diameter may not necessarily decrease from between the first and second sealing rings and the second and third rings, and subsequent rings if they are utilized.

Accordingly, the resulting structure provides a tip protector which is capable of sealing the tube to be sealed with a substantial tolerance of relative diameters, the tolerance depending, of course, upon the size of the tip protector and its specific construction. Also, the structures of this invention provide easier moulding characteristics for the elongated, annular sealing rings utilized herein.

WHAT WE CLAIM IS:—

1. A device for grippingly engaging a tube to permit protection of an end of the latter, comprising a tubular member which has an open mouth, the interior of the tubular member being provided with a plurality of axially spaced annular sealing rings to grip a tube to be protected, each ring being a flexible projection which is elongate in cross-section and whose longitudinal axis extends in acute angle relationship to the axis of the tubular member towards the open mouth, the length of the projection along its longitudinal axis, as viewed in cross-section, being at least 0.01 inch and the average thickness of the projection being less than said length, the inner diameter of the tubular member between the open mouth and the sealing ring nearest said open mouth being greater than the inner diameter of the tubular member between said nearest sealing ring and the next adjacent sealing ring, and the inner diameter of the tubular member between consecutive sealing rings decreasing in the direction inwardly of the tubular member from said open mouth.

2. A device according to Claim 1 in which each projection tapers in cross-section to a minimum thickness at its free end.

3. A device according to Claim 1 or 2 in which the said lengths of the projections, as viewed in cross-section, consecutively decrease from that nearest the mouth inwardly.

4. A device according to any preceding Claim in which each projection has an annular inner surface which defines an acute angle with the axis of the tubular member.

5. A device according to any preceding Claim, in which the acute angle of said longitudinal axis of each projection with the axis of the tubular member is substantially from thirty to sixty degrees.

6. A device according to any preceding claim, wherein the end of the tubular member opposite to the open mouth is closed by an element forming an integral part of the device.

7. A device according to Claim 1, for grippingly engaging a tube to permit protection of an end of the latter, constructed substantially as herein described with reference to the accompanying drawings.

8. Medical apparatus including a tubular support portion and a medical implement supported by one end thereof, and a protective device constructed according to any one of the preceding claims and mounted on the tubular support portion to accommodate the implement, the end of the tubular member of the device opposite to the open mouth being closed, the interior of the protective device and the parts shielded thereby being sterile.

ERIC POTTER & CLARKSON,
Chartered Patent Agents,
14 Oxford Street,
Nottingham.

Printed for Her Majesty's Stationery Office by Burgess & Son (Abingdon), Ltd.—1981.
Published at The Patent Office, 25 Southampton Buildings, London, WC2A 1AY,
from which copies may be obtained.

1587764 COMPLETE SPECIFICATION
1 SHEET This drawing is a reproduction of the Original on a reduced scale

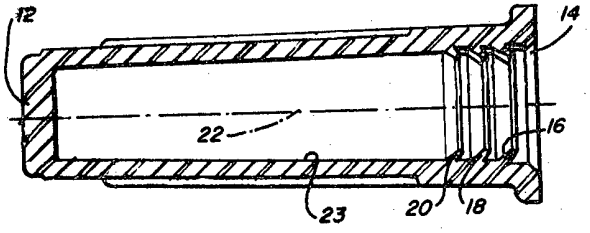
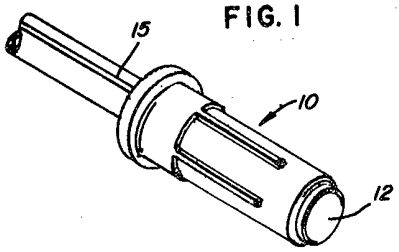


FIG. 2

FIG. 1



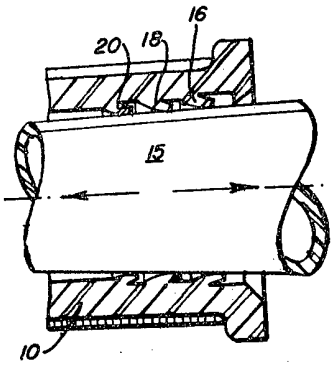


FIG. 3

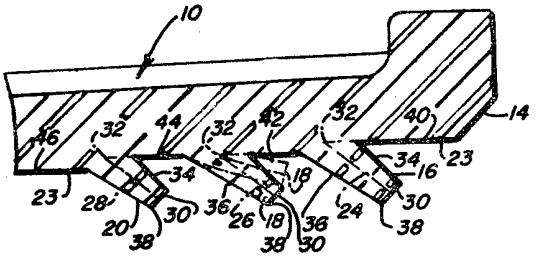


FIG. 4