

13

AN ACCESS PORT FORMING DEVICE AND A METHOD OF FORMING
AN ACCESS OPENING

5 The invention relates to a device for forming an access port or opening in a wall of a flexible, resilient plastics material, and to a method of forming such part or opening.

10 US Patent 2,902,036 discloses a disposable ostomy bag having a pre-formed opening through which an internal clamping member may be inserted and then frictionally connected to an outer clamping member. The passage through the inner clamping member is sized to provide a fluid-tight seal with the outer surface of a catheter inserted therethrough. A catheter may therefore extend through the wall of the bag without disrupting the integrity of the bag as a fluid collecting device.

20 Problems associated with such a construction include the need for utilising a special bag having a pre-formed opening for attachment of the clamping rings and the requirement that only catheter tubes of certain size be used if an effective seal is to be formed between the catheter and the clamping assembly. The latter problem has been reduced in commercial constructions by utilising a gradually tapered tubular nipple formed of elastic material that may be cut anywhere along its length to form a catheter-receiving opening of selected size. However, in the use of such a product, the nipple is adhesively secured to the wall of a bag after an opening is manually formed therein. Although the use of a bag having a pre-formed single-size opening is eliminated, such a construction introduces additional complexities and problems in manually forming an opening of the proper size in the wall of a bag, ensuring that the outer surface of the bag about the

35

opening is dry so that an effective adhesive seal may be formed, adhering the nipple to that outer surface, and preferably framing the area of adhesive attachment with waterproof tape to reduce the possibilities of fluid leakage and/or detachment. Even when such precautions are taken, the possibility remains that separation along the area of adhesive attachment may occur during use.

Other US patents illustrative of the state of the art are 3,893,446, 3,830,235, and 4,084,590.

Accordingly, it is an object of this invention to provide a port-forming device and method which may be used with flexible thermoplastic films and, in particular, with the film materials commonly used for wound covers, surgical covers, and pouches of the type widely available as collection appliances, and which result in a secure and highly effective leakproof attachment that dispenses with the use of adhesives and sealing agents.

The invention provides an access port forming device comprising an internal coupling ring having a tubular side wall and an outwardly-projecting flange at one end thereof; the internal coupling ring being, in use, extended through an opening in a wall of flexible, resilient thermoplastic material such that the wall of the thermoplastic material engages said flange and defines an axially-turned collar extending about the said wall of said ring; a tubular nipple of elastomeric material having a proximal end portion dimensioned to fit about the side wall of the ring and having a reduced distal end portion, and an external coupling ring adapted to extend about said internal ring to clamp said proximal end portion of said nipple and said collar therebetween, said

external ring including locking means engageable with said flange for anchoring said internal and external rings together.

5 The invention also provides a device for forming an access opening in a wall of thin, flexible, and resilient plastics material, comprising an internal coupling ring having a tubular side wall; a piercing element having a body section frictionally
10 received within said ring and having a generally conical section extending therebeyond; said piercing element and said ring being adapted for piercing said wall of plastics material and causing an annular collar of stretched plastics material to be formed externally about said ring; an elastomeric tubular
15 nipple having a resilient proximal skirt portion adapted to receive said ring and collar and having a distal portion extending axially beyond said proximal skirt portion; an external ring adapted to extend about said proximal skirt portion for clamping said
20 proximal skirt portion and collar between said internal and external rings; and locking means integral with said internal and external rings for locking said internal and external rings against axial displacement.

25 The invention further provides a method of forming an access opening in a wall of thin, flexible, stretchable thermoplastic material comprising the steps of placing a coupling ring about the body section of a piercing element having a
30 generally conical portion extending axially beyond said ring; piercing said wall with said conical portion and advancing said element and ring to cause an annular axially-directed collar of stretched material to be positioned externally about said ring;
35 positioning the resilient annular skirt portion of a

-3a-

5 tubular elastomeric nipple about said ring and collar; and then locking said resilient skirt portion tightly against said collar to seal said collar against both said skirt portion and said ring by fitting a second coupling ring about said first coupling ring to clamp said skirt portion and collar therebetween.

Other features, objects, and advantages of

the invention will become apparent from the specification and drawings.

5 The invention will now be described, by way of example, with reference to the accompanying diagrammatic drawings, in which:

Figure 1 is an exploded perspective view illustrating the components of an access port forming device embodying this invention;

10 Figure 2 is a perspective view showing the external locking ring and tubular nipple in preassembled condition;

Figure 3 is a perspective view illustrating the internal support ring and piercing element in preassembled condition;

15 Figure 4 is a sectional side view illustrating commencement of a film-piercing operation;

20 Figure 5 is a sectional view similar to Figure 4 but illustrating the parts upon completion of a film-piercing operation;

Figure 6 is a sectional view showing the subsequent step of coupling the external locking ring and nipple to the internal support ring and pierced thermoplastic film;

25 Figure 7 is a sectional view similar to Figure 6 but depicting the parts following attachment of the access device and after removal of the piercing element;

30 Figure 8 is an enlarged fragmentary sectional view illustrating the locking relationship between the parts of a completed assembly;

Figures 9a, 9b, 9c and 9d illustrate four alternative nipple configurations that may be used in the method and device of this invention; and

35 Figures 10, 11 and 12 illustrate variations

18

in the steps of the method when using a nipple of the type exemplified by Figure 9a.

5 The illustrated port-forming device 10 according to this invention has three primary components: a support ring or internal coupling ring 11, a locking ring or external coupling ring 12 and an elastomeric nipple 13. A further component, a piercing element 14, is used in piercing the plastics film of a pouch (or other article) and coupling other parts thereto, after which it is removed and may be discarded. To the extent that the coupling rings and nipple become permanently affixed to the film or sheet, that film or sheet also becomes a component of the final combination.

15 While this device may be used to form an access port in, and a sealing connection with, any suitable film or sheet material, it is specifically useful for forming an access port in the wall of a thermoplastic pouch for the purpose of inserting a catheter or other conduit therethrough. The term "pouch" is used herein to mean any protective or collective pouch having an opening adapted to be secured about a wound or stoma for protecting the patient and for collecting exudate. Reference may be had to co-owned US patents 3,954,105, Re. 29,319, 4,203,445, and 4,213,458 for disclosures of various pouches intended for such purposes. The dimensions and constructions of such pouches vary depending on the precise uses for which they are intended; however, such pouches are typically formed of flexible thermoplastic sheet materials composed or treated to provide vapour barrier properties as well as liquid barrier properties. For example, one commercial material comprises low-density polyethylene coextruded with a polyvinylidene

chloride core, is commercially available under the trade mark "Saranex"^(R.T.M.) from Dow Chemical, Midland, Michigan. It is to be understood, of course, that the panels of such a pouch may be formed from any of a variety of other suitable thermoplastic materials having similar properties.

The coupling rings 11, 12 and piercing element 14 are formed of a tough, durable, and relatively rigid polymeric material such as high-density polyethylene or polypropylene, although other materials might be used.

The internal coupling ring 11 has a preferably slightly tapered side wall 15 open at opposite ends and provided with an outwardly-projecting annular flange 16 at its proximal end (its lower end, when viewed as depicted). In the embodiment of Figures 1-8, the ring 11 is generally cylindrical with a slight upward or distal taper. The outermost surface 16a of the flange 16 is preferably rounded, and the upper surface of the flange 16 (i.e. the surface facing towards the bevelled upper end 15a of the ring 11), is provided with an annular channel or groove 16b (Figure 8). It will be noted that at its upper or reduced distal end, the internal support ring is provided with a downwardly and outwardly inclined or bevelled surface 15a (Figure 8).

The piercing element 14 has a body portion 17 and a flange portion 18. The body portion 17 includes a cylindrical section 17a of a length approximating the axial dimension of the internal coupling ring 11 and a diameter matching, or slightly greater than, the smallest inside diameter of the ring 11. As a result, when the body portion 17 of the piercing element 14 is inserted into the opening

of the ring 11, the outer surface of cylindrical section 17a will frictionally engage the internal surface of the ring 11 adjacent the upper end 15a (Figure 8). Consequently, when the parts are fitted together as illustrated in Figure 3, they will remain in connected condition unless sufficient force is exerted to overcome the frictional resistance in the area of contact near the bevelled end 15a. As already indicated, the wall 15 of the internal coupling ring 11 is preferably tapered, one purpose being to provide only limited frictional engagement between the piercing element 14 and the ring 11 so that excessive force will not be necessary to separate the parts following piercing and coupling operations as described hereinafter. Another purpose for tapering the wall 15 of the ring 11 is to define the shape of the collar of film or sheet material formed over it, so that the collar may be readily captured between the rings 11 and 12.

The body portion 17 of the piercing element 14 also includes a conical upper portion 17b terminating in a bevelled blade-like tip 17c. Figures 3 and 8 reveal that when the ring 11 and element 14 are preassembled, the sloping surface of the end 15a of the ring 11 serves as a continuation of, or at least avoids sharp departure from, the sloping outer surface of conical portion 17b.

It is to be noted from Figure 1 that the outer surface of the conical upper portion 17b is textured, in contrast to being polished, glossy, slick, or exceptionally smooth. The texturing may take the form of dense craters and projections of microscopic size that give the surface what is commonly known as a frosted finish, or the texturing may be more substantial, taking the form of surface

undulations (of either regular or random pattern) that may be readily discerned by the naked eye. A frosted finish formed by texturing the mould used for forming the piercing element has been found particularly effective, but other texturing techniques may be used. The purpose in any event is to prevent the conical surface of the upper portion 17b from sticking to the collar of thermoplastic film or sheet material as that collar is being formed, creating a resistance to sliding movement that exceeds the tear strength of the film or sheet material.

The tip 17c takes the form of a small-diameter cylindrical extension of the conical upper portion 17b having a heel or bevelled end surface 17d (Figure 1). The bevel results in a sharp piercing edge that is easily urged into and through a film or sheet to initiate collar formation. It has been found that the bevelled surface 17d should either merge with the surface of the conical portion 17b or should be in close proximity to that surface, so that immediately following the piercing of an opening through a film or sheet, the opening so formed is forced to become enlarged and to develop the characteristic collar, as hereinafter explained.

An annular flange portion 18 of the piercing element 14 includes inner and outer sections 18a and 18b, respectively. The inner section 18a has a diameter less than the outside diameter of the flange 16 of the ring 11. The integral outer section 18b is stepped below section 18a and preferably has an outside diameter substantially larger than the flange 16 of the ring 11, and extension 27 of the ring 12 to facilitate insertion and removal of the piercing element 14 with respect to internal coupling

ring 11 and external coupling ring 12.

5 The nipple 13 is formed of thermoplastic rubber, latex, or any other suitable elastomeric material, and includes a proximal skirt portion 13a and a distal tapered portion 13b. In the embodiment illustrated in Figures 1-8, the skirt portion 13a is generally cylindrical, preferably having a slight taper corresponding with the taper of the ring 11 and, in an unstretched state, has inside dimensions approximately the same as, or slightly larger than, the outer surface of the side wall 15 of the ring 11 (Figure 8). An annular bead 20 of rounded cross-sectional configuration projects downwardly from the skirt portion 13a about the open lower end thereof, and is dimensioned to be received within the annular channel or groove 16b of the flange 16. An external rib 21 extends about the lower end of the nipple 13 and provides an upwardly facing shoulder 21a for locking engagement with the external ring 12. An annular external recess 22 extends about the skirt portion 13a at the upper end thereof, and is similarly adapted for interlocking engagement with the external coupling ring 12.

25 The upper portion 13b of the nipple of the form depicted in Figures 1-8 progressively diminishes in internal and external dimensions, the taper being incremental rather than smooth or uninterrupted. Specifically, the upper portion is stepped to provide a plurality of coaxial cylindrical wall portions 23 of incrementally diminishing size in an upwardly-extending series. Such cylindrical wall portions 23 have generally cylindrical inner surfaces of incrementally diminishing size, the sizes corresponding generally to the range of catheter sizes that might be used with the assembly. In the

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illustration given, the nipple 13 is closed at its upper end 13c, although it may, if desired, be supplied to the user with an opening having a diameter corresponding to the inside diameter of the smallest cylindrical wall portion 23 of the series.

The external coupling ring 12 has a side wall 12a whose internal surface conforms generally with the outer surface contour of the skirt portion 13a of the nipple 13. Specifically, the external coupling ring 12 has an inwardly-projecting annular flange or rib 25 adapted to be received within external recess 22 of the nipple's skirt portion 13a (Figure 8). An internal annular indentation 26 near the lower end of the skirt portion 13a receives the rib 21 at the lower end of the nipple 13. In addition, the external coupling ring 12 includes a downwardly-extending annular extension 27 that continues downwardly beyond the nipple's skirt portion 13a (when the parts are assembled as shown in Figure 8) and is provided with an annular internal channel 28 for receiving the rounded periphery of the flange 16 of the internal coupling ring 11. The extension 27 projects below the flange 16 and also inwardly beneath that flange, defining an opening at the lower end of the ring 12 that is smaller than the maximum diameter of the channel 28 and the outside diameter of the flange surface 16a. Therefore, when the parts are assembled as depicted in Figure 8, a snap fit develops between the flange 16 of the ring 11 and the internally-grooved extension 27 of the ring 12 to resist subsequent axial separation of the parts.

The steps of using the device of Figures 1-3 are illustrated in Figures 4-7. Assuming that the piercing element 14 and internal ring 11 are not

supplied in preassembled form, the user first joins such parts as shown in Figure 3 and then directs the pointed tip of the piercing element 14 into and through flexible wall W as represented in Figures 4 and 5. The action is essentially a piercing and drawing operation rather than a cutting operation, with the result that as an opening develops in the wall W and is enlarged by advancement of the textured, conical piercing element 14 (and the internal ring 11 carried by it), the material of the wall W folds upwardly to form an upwardly-projecting collar 30 that tightly encircles the wall 15 of the internal ring 11 when the piercing and drawing step is completed (Figure 5). Although the piercing operation is initiated by the bevelled tip 17d of the piercing element 14, and becomes a stretching and enlarging operation as the conical surface 17b progresses through the opening in the wall, a transition occurs near the end of the piercing and stretching steps, with the collar 30 being directed from the conical portion 17b on to the generally cylindrical wall 15 of the ring 11. The bevelled end surface 15a of the ring 11 helps to ensure a smooth transfer of the collar 30 from the conical surface 17b of the piercing element 14 to the outer surface of the ring 11.

The outer ring 12 and nipple 13 are preassembled, as shown in Figure 2, either by the manufacturer or the user. The assembly is fitted over the protruding conical portion of the piercing element 14, and snapped about the flange of the inner ring 11, in the manner depicted in Figures 6 and 8. As the subassemblies are brought together, the material of the wall W is directed about the

flange 16 of the internal ring 11 and is formed into the annular groove 16b provided by that flange. With the external ring 12 snapped in place, the thermoplastic wall is firmly clamped between the rounded outer surface 16a of the flange 16 and the curved inner surface of the channel 28. In addition, the skirt portion 13a of the resilient, elastomeric nipple 13 is held in tight sealing engagement with the collar 30 of the wall W and with that portion of the wall W received within the annular groove 16b. The result is that the wall W, coupling rings 11, 12, and nipple 13 are not only immobilised with respect to each other, but the resilient skirt of the nipple 13 is utilised to ensure a fluid (liquid and gas) tight seal between such parts.

Following the coupling operation, the piercing element 14 is simply withdrawn from the internal ring 11, and the stepped end portion of the nipple 13 is cut transversely to expose a cylindrical opening of a size that will slidably and sealingly engage the outer surface of a selected catheter C (or other conduit or conductor). Although the tip of the catheter might be inserted through the nipple opening in the direction shown in Figure 7, it is generally easier to draw the catheter upwardly through the nipple 13 in a reverse direction. A suitable lubricant may be applied to the nipple 13 and/or catheter to facilitate such insertion.

Figures 9a to 9d depict certain variations in the nipple construction and configuration for use with modified procedures and equipment. Thus, in a case where the catheter or other conduit with which the assembly is to be used is of a specialised size and configuration, as where the catheter is a multi-lumen catheter of a distinctive non-circular

cross-sectional outline, the elastomeric nipple may assume the shape illustrated in Figure 9a. Skirt portion 113a of nipple 113 is preferably slightly tapered to fit between internal and external rings 11 and 12, respectively. Instead of having an elongate, tapered distal portion as in the preceding embodiment, nipple 113 has a reduced distal portion 113b with a non-circular opening 113d dimensioned for sealingly but adjustably receiving a plural-lumen catheter of non-circular external shape.

The elastomeric tubular nipple 113 cooperates with the internal ring 11 and external ring 12, and with film W, in the manner already described except for one difference in operating procedure. Because of the relatively short axial length of the nipple 113, the piercing element 14 must be withdrawn from the internal ring 11 after the film W is pierced and before the external ring 12, with nipple 113 coupled thereto, is secured in place. The sequence is indicated in Figures 10-12 where it will be seen that the film is first pierced (Figure 10) as already described but then, before coupling the internal and external rings together with the film W and skirt 113a clamped therebetween, the piercing element 14 is separated from the internal ring 11 (Figure 11). Thereafter, the external ring 12, preassembled with the nipple 113, is coupled to the internal ring 11 (Figure 12). With the coupling completed, the plural-lumen catheter C' may be inserted through the opening 113d of the elastomeric nipple 113 with a fluid-tight seal preferably being formed between the outer surface of the catheter C' and the inner surface of the nipple 113 within the opening 113d.

Whether the piercing element 14 remains attached to the internal ring 11 during the coupling

step depends partly on the relative axial dimensions of the piercing element and the nipple and partly on the preferences of the user. In general, it is advantageous to keep the piercing element attached to the internal ring until after the internal and external rings have been snapped together (with the film material W and the skirt of the nipple clamped therebetween) if the axial dimension of the nipple, at least in a stretched state, is sufficient to accommodate the tapered portion of the piercing element 14. However, there may be instances in which a user would find it preferable to separate the piercing element from the internal ring prior to the coupling step even if the internal dimensions of the nipple were large enough to accommodate the tapered portion of the piercing element. For example, Figure 6 has been described in connection with a procedure in which the piercing element 14 is not separated from the internal ring 11 until after the external ring 12 is snapped into the position shown. While such a procedure represents the preferred method of operation, it is to be understood that even though the nipple 13 is large enough to accommodate the tapered portion of the piercing element, in some instances, a user might elect to detach the piercing element 14 from the internal ring 11 after the piercing operation of Figures 4 and 5 is completed and before the internal and external rings are coupled together.

Figures 9b, 9c, and 9d show further variations of the elastomeric nipple suitable for different purposes or applications. Nipple 213 of Figure 9b is basically the same as nipple 13 of Figure 1 except that the stepped tapered portion 213b is eccentrically located and an integral tubular

portion 40 is disposed alongside the tapered portion 213b. Such a nipple may be used where, in addition to catheter access through the tapered portion 213b, it is desirable to insert a suction tube or an irrigation tube through the tubular portion 40 of the nipple 213, or simply to provide a vent opening for the purpose of equalising pressure during evacuation or irrigation procedures.

Figure 9c shows a further modification wherein a nipple 313 has a pair of stepped and tapered portions 313b to accommodate a pair of catheters or other conduits. The skirt portion 313a of the nipple 313 is oval but in other respects is similar to the skirt portions 13a, 113a, and 213a of the previous embodiments. In each embodiment, the skirt portion of the nipple is designed to co-operate with an internal ring 11, an external ring 12, and a wall or film W of plastics material, in the manner illustrated in Figure 8.

Figure 9d shows an elastomeric nipple 413 in inverted position for use as a drain tube for a thermoplastic pouch. The nipple may be equipped with a captive cap 41 attached to the nipple by an integral strap 42, the cap 41 being dimensioned to seal the distal portion 413b of the nipple in the manner indicated in broken lines. As with the other embodiments, the nipple 413 has a tapered skirt portion 413a which is capable of co-operating with internal and external rings 11 and 12, and with the wall W of the pouch, as previously discussed in connection with Figure 8.

29



-16-

CLAIMS

1. An access port forming device comprising an internal coupling ring having a tubular side wall and an outwardly-projecting flange at one end thereof;
5 the internal coupling ring being, in use, extended through an opening in a wall of flexible, resilient thermoplastic material such that the wall of the thermoplastic material engages said flange and defines an axially-turned collar extending about the
10 said wall of said ring; a tubular nipple of elastomeric material having a proximal end portion dimensioned to fit about the side wall of the ring and having a reduced distal end portion, and an external coupling ring adapted to extend about said
15 internal ring to clamp said proximal end portion of said nipple and said collar therebetween, said external ring including locking means engageable with said flange for anchoring said internal and external rings together.
- 20 2. A device according to Claim 1 in which said locking means comprises an extension of said external ring having an internal channel dimensioned to receive a peripheral portion of said flange.
- 25 3. A device according to Claim 2 in which said extension defines an opening at one end of said external ring having a diameter smaller than the outside diameter of said flange.
- 30 4. A device according to Claim 2 in which said external ring is provided with an inwardly-directed annular rib at the end of said external ring opposite from said extension; said tubular nipple having an external annular recess at the proximal end thereof for receiving and interlocking with said rib.
- 35 5. A device according to Claim 1 in which said nipple is provided with an outwardly-projecting annular flange at said proximal end; said external



30

-17-

ring having an internal annular indentation for receiving said flange of said nipple and for restraining relative axial movement of said external ring and nipple.

5 6. A device according to Claim 1 in which said tubular nipple is provided with a plurality of coaxial and generally cylindrical wall portions of progressively increasing diameter, thereby incrementally tapering said nipple in a direction
10 towards said distal end.

7. A device according to Claim 1 in which said reduced distal end of said tubular nipple is provided with an axial opening for receiving and slidably but sealingly engaging the outer surface of
15 a tubular conduit adapted to extend through said nipple.

8. A device according to Claim 7 in which said opening of said nipple is non-circular in cross-section.

20 9. A device according to Claim 1 in which said nipple includes a plurality of said reduced distal ends, each of tubular construction and communicating with said proximal end.

10. A device according to any one of Claims 1
25 to 9 in which a piercing element is co-operatively associated with said internal ring; said piercing element having a body section and a generally conical section; said body section being frictionally receivable within said internal ring with the conical
30 section of said element extending axially beyond said internal ring.

11. A device according to Claim 10 in which said piercing element also includes a flange portion projecting outwardly from the end of said body
35 section opposite from said conical section; said flange of said piercing element being engageable with

(31)



-18-

said flange of said internal ring for limiting the extent of insertion of said piercing element into and through said internal ring.

5 12. A device according to Claim 10 in which said conical section of said piercing element has a textured outer surface.

13. A device according to Claim 12 in which said conical section terminates in a tip having a bevelled surface defining a sharp cutting edge.

10 14. A device for forming an access opening in a wall of thin, flexible, and resilient plastics material, comprising an internal coupling ring having a tubular side wall; a piercing element having a body section frictionally received within said ring and
15 having a generally conical section extending therebeyond; said piercing element and said ring being adapted for piercing said wall of plastics material and causing an annular collar of stretched plastics material to be formed externally about said
20 ring; an elastomeric tubular nipple having a resilient proximal skirt portion adapted to receive said ring and collar and having a distal portion extending axially beyond said proximal skirt portion; an external ring adapted to extend about said
25 proximal skirt portion for clamping said proximal skirt portion and collar between said internal and external rings; and locking means integral with said internal and external rings for locking said internal and external rings against axial displacement.

30 15. A device according to Claim 14 in which said locking means includes an outwardly-projecting flange at one end of said internal ring; and an extension of said external ring having an internal channel dimensioned for receiving said flange to form
35 a snap fit therewith.



32

-19-

16. A device according to Claim 14 in which said piercing element also includes a flange portion projecting outwardly from the end of said body section opposite from said conical section; said
5 flange of said piercing element being engageable with the flange of said internal ring for limiting the extent of insertion of said piercing element into and through said internal ring.
17. A device according to Claim 14 in which
10 said external ring is provided with an inwardly-directed annular rib; said proximal skirt portion of said nipple having an external annular recess for receiving and interlocking with said rib.
18. A device according to Claim 14 in which
15 said proximal skirt portion includes an outwardly-projecting annular flange; said external ring having an internal annular indentation for receiving said flange of said nipple and for restraining axial movement of said external ring and nipple.
- 20 19. A device according to Claim 14 in which said internal ring has a bevelled end surface adjacent said conical portion of said piercing element; said bevelled surface providing a
25 continuation of the surface of said conical portion.
20. A device according to Claim 14 in which
said distal portion of said nipple is provided with a plurality of coaxial and generally cylindrical wall portions of progressively decreasing diameter, thereby providing an incremental tapering of said
30 nipple.
21. A device according to Claim 14 in which said conical section of said piercing element has a textured outer surface.
22. A device according to Claim 21 in which
35 said conical section terminates in a spike tip having



a bevelled surface defining a sharp cutting edge.

23. A device according to Claim 22 in which said bevelled surface has a heel portion in close proximity to the surface of said conical portion.

5 24. A method of forming an access opening in a wall of thin, flexible, stretchable thermoplastic material comprising the steps of placing a coupling ring about the body section of a piercing element having a generally conical portion extending axially
10 beyond said ring; piercing said wall with said conical portion and advancing said element and ring to cause an annular axially-directed collar of stretched material to be positioned externally about said ring; positioning the resilient annular skirt
15 portion of a tubular elastomeric nipple about said ring and collar; and then locking said resilient skirt portion tightly against said collar to seal said collar against both said skirt portion and said ring by fitting a second coupling ring about said
20 first coupling ring to clamp said skirt portion and collar therebetween.

25. A method according to Claim 24 in which there is the further step of removing said piercing element from said first coupling ring; said step of
25 removing said piercing element occurring after said locking step.

26. A method according to Claim 24 in which there is the further step of removing said piercing element from said first coupling ring; said removing
30 step occurring after said piercing step and before said positioning step.

27. A method according to Claim 24 in which said first-mentioned coupling ring includes an outwardly-projecting flange and said second coupling
35 ring is provided with an internal channel adapted to



34

-21-

receive an interlock with said flange; said locking step including advancing said coupling rings to cause said flange of said first ring to be received within said channel of said second ring.

5 28. A method according to Claim 24 in which said nipple includes a tapered portion extending axially from said skirt portion; said tapered portion including a plurality of coaxial cylindrical wall portions of progressively decreasing diameter; and
10 transversely cutting one of said cylindrical wall portions to provide an opening dimensioned to receive a conduit of selected external diameter.

29. A method according to Claim 28 in which
15 there is the further step of inserting said conduit through said opening by cutting said nipple to form a tight seal between the inner surface of said cylindrical portion and the outer surface of said conduit.

30. A device according to Claim 1 constructed,
20 arranged and adapted to operate substantially as herein described with reference to, and as shown in, the accompanying drawings.

31. A device according to Claim 14 constructed,
25 arranged and adapted to operate substantially as herein described with reference to, and as shown in, the accompanying drawings.

32. A product including a device according to any one of Claims 1 to 23, 30 or 31.

33. A method according to Claim 24
30 substantially as herein described with reference to the accompanying drawings.
