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1 BLOWN-IN-PLACE BLOOD GASKET FOR A SAFETY CATHETER

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 The present invention relates, in general,
to intravenous catheter insertion devices, and in
particular pertains to a blood gasket of a blood
chamber for a safety catheter, wherein a cannula
extends through the blood gasket with the assurance of
10 a seal being present therebetween during relative
sliding movement between the cannula and the blood
gasket. Moreover, the invention is directed to a
novel method of forming a blown-in-place gasket for a
safety catheter adapted to slidably receiving a
15 cannula in a sealing engagement therewith in a simple
and inexpensively produced manner.

Pursuant to a specific aspect of the
invention the construction of various types of safety
catheters necessitates the provision of a blood gasket
enabling a catheter, such as in the form of a hollow
20 steel needle, to extend therethrough so as to be
slidable while sealingly engaged therein. Ordinarily,
a component of the intravenous catheter insertion
device, such as a nose or guard element which is
mounted on a housing containing a blood chamber has a
25 through aperture formed therein, including a recessed
well through which the cannula is extended. An
extrusion of plastic material arranged within the nose
and extending about the cannula is positioned within
the well so as to cause an inner bore surface thereof
30 to sealingly contact the periphery of the cannula, and
thereafter the cannula is exercised; in effect,

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1 axially reciprocated within the blood gasket, to
ensure that it can be slidably displaced relative to
the nose element of the catheter insertion device.

5 The utilization of clinical apparatus in
which pointed hollow needles or cannulae are employed
in order to puncture the skin of a patient, and
especially catheters utilizing such needles to
effectuate venipunctures, is well known in the medical
art and is widely practiced by physicians and clinical
10 personnel for the purpose of injecting fluids and
drugs directly into the bloodstream of patients, or to
withdraw blood from the patients. Additionally,
during surgical operations or procedures it may be
frequently required that whole blood transfusions and
15 parenteral fluids be administered to a patient
undergoing such surgical procedures. Basically, as is
well known and has been employed for a considerable
length of time, the introduction of such fluids into
the cardiovascular systems of patients or the
20 withdrawal of blood samples has necessitated the
forming of a venipuncture utilizing a hollow rigid
needle having a proximal attachment site for a fluid
connection which is adapted to interconnect the needle
with a source of intravenously administered fluids.

25 The foregoing method of administering fluids
to patients through venipunctures has been subject to
some rather serious problems in the administration of
fluids to patients in this medical technology. Thus,
a primary concern which had to be addressed resided in
30 the inherent rigidity of the needle, the latter of
which is normally generally constituted of surgical-

1 quality steel, and while inserted into the vein of a
patient, necessitated the needle to be maintained for
reasons of safety in a fixed position at the general
site of the venipuncture throughout the duration of
5 fluid administration or transfusion, whereby such a
procedure could conceivably consume a considerable
length of time. In addition to the foregoing, at
times it has been necessary to periodically draw blood
samples and/or successively administer intravenous
10 fluids to a patient, thus requiring the patient to be
subjected to a series or plurality of venipunctures,
each administered at a specific time and at different
sites on the body, resulting in a relatively traumatic
experience to the patient in view of such repeated and
15 somewhat painful and unpleasant venipunctures.

In order to ameliorate or possibly even
eliminate the foregoing problems, in the medical
technology it has been more recently the practice to
introduce a flexible tubular catheter of a low-
20 friction material, such as a silastic or Teflon into
the vein of a patient and to permit the catheter tube
to remain in such a position over lengthier periods of
time for purposes of; for example, periodically
administering fluids, including parenteral fluids,
25 blood/plasma transfusions, medications in liquid form
and also for the collection of blood samples and the
like. In this manner, the previously encountered
trauma, extravasation, and infiltration caused by
repeated venipunctures have been largely avoided, and
30 the danger and discomfort to a patient of leaving a
rigid needle in the body for a prolonged period of

1 time has been generally overcome. Thus, in order to
position the distal end of such a flexible catheter
tube within the body cavity of a patient, such as a
vascular cavity or vein, there is normally employed a
5 cannula or; in essence, a hollow sharp-tipped needle
for the purpose of forming the venipuncture.
Thereafter, the flexible catheter tube, which is
telescopically and slidably coaxially mounted on the
outer circumference of the cannula or hollow needle so
10 as to extend sleeve-like thereabout is advanced along
the length of the needle into the vein subsequent to
the needle having formed the venipuncture.
Thereafter, the needle is adapted to be withdrawn from
the interior of the catheter tube, while permitting
15 the latter to remain within the body of the patient at
the site of the venipuncture, and the needle is
preferably discarded rather than being reused.

Inasmuch as the needle which has been
previously positioned in the body of the patient upon
20 forming the venipuncture may have been exposed to
infectious agents; for instance, such as a patient
infected with the Acquired Immune Deficiency Syndrome
(AIDS) which is frequently or practically always
ultimately fatal in nature, or other dangerous
25 infectious conditions such as hepatitis, there is
present the danger or hazard that the clinical
personnel may inadvertently or accidentally jab or
stick themselves with the used needle after withdrawal
from the body of the patient, with the possibility of
30 infection or even death resulting therefrom.
Consequently, upon withdrawal of the needle from the

1 body of the patient, the needle is generally retracted
into a protective environment, such as a needle tip
protective housing or structure, and safely disposed
in conjunction therewith.

5 2. Discussion of the Prior Art

Although the utilization of blood gaskets
for safety catheters or the blood chambers thereof
used to collect blood samples is well known, and a
method has been developed for forming in place a
10 plastic blood gasket for a safety catheter, the
currently employed method is somewhat complex and
necessitates the use of either a liquid adhesive or
the employment of ultraviolet curing. Thus, pursuant
to a presently employed method, a cannula; in essence,
15 the hollow steel needle or stylus component, is
assembled into a plastic nose portion of the device,
whereby the nose portion which is normally constituted
of a molded plastic, has a central aperture for
receiving the cannula so as to be slidable relative to
20 the nose portion, and in which a well of larger
diameter coaxial with the central aperture is formed
in the nose portion and traversed by the cannula.
Thereafter, a suitable adhesive composition is poured
into the well to fill the latter, and cured through
25 the intermediary of U.V. heat applied by ultraviolet
ovens, with the cannula being exercised by being
axially reciprocated so as to ensure that the cannula
can be slidable relative to the nose portion of the
device. This particular type of "formed-in-place
30 gasket" necessitates either the use of a liquid
adhesive and/or ultraviolet curing of the gasket

1 material being employed, requiring extensive downtime
and waste in implementing the production process.

SUMMARY OF THE INVENTION

5 Accordingly, in order to improve upon the
currently practiced method of producing a gasket,
particularly such as a blood gasket, placed into a
bore of a nose portion of a catheter insertion device
or safety catheter is an extruded plastic element
10 which is of a generally hollow annular cylindrical
construction, the outer diameter of the extruded
element being dimensional and configured so as to
prevent its being displaced out from of the nose
portion. Thereafter a cannula is slipped into the
nose portion and through the bore of the extrusion,
15 with the bore being somewhat larger than the outer
diameter of the cannula. One end of the cannula is
adhesively fastened to a housing structure which may
be a blood chamber with the other end of the cannula
extending outwardly and having a sharp point or tip
20 for insertion into the body of a patient.

The cannula is induction heated, causing the
inner surface of the extrusion about its bore to foam
and expand radially inwardly in response to the
incorporation of an unactivated blowing agent in the
25 plastic material of the extrusion forming the gasket.
The activation temperature of the blowing agent is
higher than the required extrusion melt for the
extruded component, and is only activated upon induced
heating being applied to the cannula at a temperature
30 which is higher than the extrusion melt temperature.
Ordinarily, prior to the heat being applied the inside

1 or bore diameter of the extrusion for forming the
blood gasket is larger by about .001 to .050 inches
than the outside diameter of the cannula positioned
therein and extending therethrough, such that upon the
5 heating of the cannula to a temperature above the
activation temperature of the blowing agent contained
in the extrudate for the blood gasket and upon the
cannula being exercised; in effect, axially
reciprocated, this creates a thin pliable foam film
10 between the cannula and the extrusion bore surfaces,
thereby producing a good blood seal between the entire
length of the extrusion or gasket bore and the
cannula.

Release agents such as silicones or other
15 lubricants can be incorporated in the extrusion
material or coated on the inside or bore diameter of
the extrusion and/or coated onto the cannula surface
so as to ensure that no foam will adhere to the
cannula.

20 Alternatively, this particular concept in
the method of forming the blown-in-place blood gasket
can be utilized by molding the nose portion itself
with an unactivated foaming agent or a highly
pressurized foam incorporated in the plastic material
25 thereof, whereby the internal aperture or bore surface
of the nose portion engages the surface of the
cannula, thereby eliminating the requirement for a
separate gasket-forming extrusion being positioned
within the nose portion, and thereby simplifying the
30 overall construction by reducing components.

1 According, it is an object to provide a
novel method of forming a blown-in-place blood gasket
for the cannula of a catheter insertion device.

 A more specific object of the present
5 invention is to provide method of forming blood gasket
of the type described whereby an extrusion of a
plastic material located within a nose portion of the
catheter insertion device incorporates a foaming or
blowing agent which, subsequent to the insertion of a
10 cannula in a bore of the extrusion and heating of the
cannula, causes the foaming agent in to be activated
so as to create a foam forming a sealing engagement
with the surface of the cannula while enabling the
cannula to be axially exercised relative to the nose
15 portion and blood gasket.

BRIEF DESCRIPTION OF THE DRAWINGS

 Reference may now be had to the following
detailed description of a preferred embodiment of the
invention, taken in conjunction with the accompanying
20 drawings; in which:

 Figures 1a-1d illustrate various stages in
the method of producing a formed-in-place blood gasket
pursuant to the current state of the technology;

 Figures 2a-2d illustrate various stages in
25 the inventive method for forming blown-in-place blood
gasket for sealingly contacting a cannula of a
catheter insertion device.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

 Referring now in detail to the drawings, and
30 particularly Figures 1a-1d setting form a currently
employed method of forming a blood gasket, illustrated

1 in Figure 1a is a nose portion 10 of a safety catheter
(not shown) which nose portion is constituted of a
generally rigid molded plastic material and which is
adapted to be mounted on the front end 12 of a housing
5 14. A steel cannula 16 is retractable through the
nose portion 10 subsequent to withdrawal of the former
from the body of a patient into the housing 14 so as
to protect clinical personnel or a physician from
needle stick.

10 The rearward end 18 of the cannula 16 which
extends into the housing 16 is fixedly connected to an
end 20 of a blood chamber 22 so as to communicate with
internal space 24 thereof, and is adapted to have an
adhesive extending about the circumference of the
15 cannula 16 so as to permanently secure the cannula 16
to the blood chamber 22 as described hereinbelow.

The nose portion 10 which is fixedly seated
onto the leading or front end 12 of the housing 14,
and which is constituted of a molded plastic element,
20 has a generally cylindrical external configuration 28
possessing a central through aperture or bore 30
through which the cannula is extended so as to be in
slidable contact with a lower portion 32 of the bore
30. The forward end 33 of the nose portion 10 has a
25 larger diameter stepped well 34, 36 formed therein
communicating with the bore portion 32 in which the
cannula 16 is located, and provides an annular space
38, 40 about the cannula 16. As shown in Figure 1b an
adhesive 26 is adapted to be poured into the nose well
30 34, 36 so as to completely fill the space 38, 40 about
the cannula 16. Thereafter, as shown in Fig. 2c, the

1 adhesive 26 is cured by the exposure to heat produced
by ultraviolet ovens 44 while the cannula 16 is
exercised by being reciprocated in a longitudinal
direction along its axial length, as shown by the
5 double-headed arrow A in Fig. 1d, so as ensure that it
can maintain slidability relative to the adhesive 26
while the latter still maintains a seal therewith and
with the surface of well 34, 36 to which it adheres.
This particular method of forming a blood gasket
10 through the introduction and curing of adhesive 26 in
the well 34, 36, which comprises either liquid
adhesives and/or ultraviolet curing of settable
materials requires much downtime and waste in the
manufacturing process.

15 In order to improve upon the foregoing
method in producing a blood gasket, pursuant to the
present invention, as disclosed in Figures 2a-2d
of the drawings, there is produced a so called "blown-
in-place" blood gasket. In this embodiment, elements
20 which are the same or similar to those described with
regard to Figures 1a-1d are identified by the same
reference numerals and no detailed discussion thereof
is deemed to be necessary for an understanding of the
invention.

25 In this inventive embodiment, the nose
portion 50, which is preferably also constituted of
molded plastic material is of generally cylindrical
shape and slightly tapers down towards the front end
53 so as to be somewhat frusto-conical. The interior
30 of the nose portion 50 has a large-diameter through-
bore 54, slightly widening towards the rear end

1 expanding into a conical enclosure 56. The rear end
58 of the nose portion is configured similar to that
of Figs. 1a-1d and is adapted to be mounted on a
housing 14 containing a blood chamber 22. Cannula 16
5 is fastened to the blood chamber by means of adhesive
26 and projects forwardly through the nose portion 50
as shown in Fig. 2b. A plastic extruded member 52 of
generally hollow cylindrical configuration is inserted
into a bore 54 of the nose portion 50. The extruded
10 member 52 has one end 56 towards the rear of the nose
portion 50 radially outwardly chamfered or widened so
as to prevent it from being displaced axially
forwardly in bore 54. As shown, extruded member 52
has a longitudinal includes a central bore 59 through
15 which the cannula 16 which is fastened at one end
thereof to the blood chamber 22 can be slipped through
the nose portion 50 as shown in Figure 2b, with a
circumferential space 60 being provided between
cannula 16 and the wall of bore 59. The internal
20 diameter of the bore 58 of the extruded member 52 is
approximately 0.001 to 0.050 inches larger in diameter
than the external diameter of the steel cannula 16.
Preferably the extruded member 52 which is positioned
within the nose portion 50 is constituted of a
25 suitable plastic material which incorporates a blowing
agent, the latter of which is unactivated at the
extrusion melt temperature of the extruded member 52.
Subsequent to the insertion of the cannula 16 through
the nose portion 50 and the extruded member 52, as
30 shown in Figure 2b, the cannula 16 is heated,
preferably by induction heating means 62, as shown in

1 Figure 2c, to a temperature which is higher than the
activation temperature of the blowing agent and the
plastic material of the extruded member 52 than that
of the nose portion 50. This causes the inner or bore
5 surface 59 of the extruded member 52 to foam and to
form a sealing contact along the length thereof with
the cannula 16, the latter of which is axially
reciprocated or exercised along the direction of
double headed arrow B so as to ensure its
10 displacability within the foamed extruded member 52
and nose portion 50 while maintaining a suitable blood
seal, the latter of which is created by means of a
thin pliable foam film 64 created between the surface
of the cannula 16 and the foamed bore 59 of the
15 extruded member 52.

In order to ensure that no foam from the
extruded member 52 will adhere to and potentially
contaminate the surface of the cannula 16, coated on
the surface of the bore 59 of the extruded member
20 and/or coated on the cannula 16, or, alternatively
incorporated into the plastic material of the extruded
member 52, may be suitable release agents, such as
silicones and other lubricants.

Furthermore, pursuant to a simplified
25 modification of the invention, rather than providing
an extruded member 52 within the nose portion 50, the
latter can be molded from a suitable plastic material
which incorporates the foaming or blowing agent, and
in which the inner or bore diameter of the nose cone
30 50 is proximate to or slightly larger than the
external diameter of the cannula 16, whereby upon the

1 heating of the cannula 16, this will cause the bore of
the nose portion to foam and sealingly close about the
cannula in a manner as described hereinabove. In this
instance, although the method is essentially identical
5 to that described with regard to Figures 2a-2d of the
drawings, there is eliminated the extruded member 52
within the nose cone 50, thereby further simplifying
the construction of the safety catheter so as to
render it more economical to produce.

10 From the foregoing, it becomes readily
apparent that the present inventive method of the
blowing-in-place of a blood gasket for a safety
catheter is extremely simple in nature in comparison
with that currently being employed in the technology
15 and, in an inexpensive manner, produces an excellent
blood seal.

While there has been shown and described
what are considered to be preferred embodiments of the
invention, it will, of course, be understood that
20 various modifications and changes in form or detail
could readily be made without departing from the
spirit of the invention. It is, therefore, intended
that the invention be not limited to the exact form
and detail herein shown and described, nor to anything
25 less than the whole of the invention herein disclosed
as hereinafter claimed.

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1 WHAT IS CLAIMED IS:

1. A method of producing a blood sealing
gasket for a safety catheter, wherein said safety
catheter includes a nose portion having an elongate
5 cannula axially slidably positioned therein, said
cannula having a first end protruding from said nose
portion fixedly connected with a chamber structure for
receiving blood from a patient and including a second
10 end extending from an opposite end of said nose
portion for insertion into a vein of the patient; said
method comprising:

(a) positioning an extruded hollow
cylindrical plastic member in a central bore axially
extending through said nose portion;

15 (b) extending said cannula through an axial
bore in said hollow cylindrical member, said axial
bore of said cylindrical member for receiving said
cannula being dimensioned so as to provide an annular
space about said cannula;

20 (c) imparting heat to said cannula to cause
the material of the inner surface of the axial bore of
said cylindrical member to foam and expand radially
inwardly to sealingly engage the outer surface of said
cannula;

25 (d) and imparting axial reciprocating
movement to said cannula within said foamed bore
surface of the cylindrical member to inhibit binding
between the cannula and cylindrical member enabling
axial displacement of said cannula relative to said
30 nose portion while maintaining sealing contact with



1 the cylindrical member such that the latter forms said blood sealing gasket.

2. A method as claimed in Claim 1, wherein said cylindrical member is constituted of a plastic
5 material incorporating a blowing agent having an activation temperature which is higher than the extrusion temperature for said extruded cylindrical member but lower than the temperature to which the cannula is heated.

10 3. A method as claimed in Claim 1, wherein the inner diameter of said extruded cylindrical member prior to implementing the heating step (c) is about 0.001 to 0.050 inches larger than the outer diameter of said cannula.

15 4. A method as claimed in Claim 1, wherein said foaming of the inner surface of said cylindrical member responsive to heating of said cannula forms a pliable foam film between said cannula and the length of the axial bore in said cylindrical member.

20 5. A method as claimed in Claim 1, wherein said heating of the cannula comprises the application of induction heating.

25 6. A method as claimed in Claim 1, wherein said extruded plastic material of the cylindrical member incorporates release agent means to prevent adherence of the cannula to said cylindrical member.

7. A method as claimed in Claim 6, wherein said release agent means comprises a silicone.

30 8. A method as claimed in Claim 1, wherein said cannula is coated with release agent means to prevent adherence to said cylindrical member.



1 9. A method as claimed in Claim 8, wherein
said release agent means comprises a silicone.

10. A method as claimed in Claim 1, wherein
said nose portion comprises a molded plastic material.

5 11. A method as claimed in Claim 10,
wherein said cylindrical member is integrally molded
with said nose portion.

12. A blood sealing gasket for a safety
catheter, wherein said safety catheter includes a nose
10 portion having an elongate cannula axially slidably
positioned therein, said cannula having a first end
protruding from said nose portion and fixedly
connected with a chamber structure for receiving blood
from a patient and including a second end extending
15 from an opposite end of said nose portion for
insertion into a vein of the patient; said method
comprising:

(a) an extruded hollow cylindrical plastic
member being positioned in a central bore axially
20 extending through said nose portion;

(b) said cannula extending through an axial
bore in said hollow cylindrical member, said axial
bore in said cylindrical member for receiving said
cannula being initially dimensioned so as to provide
25 an annular space about said cannula;

(c) said cannula being subjected to heat
such as that the material of the inner surface of the
axial bore of said cylindrical member is foamed and
expanded radially inwardly to sealingly engage the
30 outer surface of said cannula; whereby said cannula is
axially reciprocated within said foamed bore surface



1 of the cylindrical member to inhibit binding between
the cannula and cylindrical member enabling axial
displacement of said cannula relative to said nose
portion while maintaining sealing contact with the
5 cylindrical member such that the latter forms said
blood sealing gasket.

13. A gasket as claimed in Claim 12,
wherein said cylindrical member is constituted of a
plastic material incorporating a blowing agent having
10 an activation temperature which is higher than the
extrusion temperature for said extruded cylindrical
member but lower than the temperature to which the
cannula is heated.

14. A gasket as claimed in Claim 12,
15 wherein the inner diameter of said extruded
cylindrical member prior to being foamed is about
0.001 to 0.050 inches larger than the outer diameter
of said cannula.

15. A gasket as claimed in Claim 12,
20 wherein said foaming of the inner surface of said
cylindrical member responsive to heating of said
cannula forms a pliable foam film between said cannula
and the length of the axial bore in said cylindrical
member.

25 16. A gasket as claimed in Claim 12,
wherein the cannula is heated by induction heating.

17. A gasket as claimed in Claim 12,
wherein said extruded plastic material of the
cylindrical member incorporates release agent means to
30 prevent adherence of the cannula to said cylindrical
member.



1 18. A gasket as claimed in Claim 17,
wherein said release agent means comprises a silicone.

 19. A gasket as claimed in Claim 12,
wherein said cannula is coated with release agent
5 means to prevent adherence to said cylindrical member.

 20. A gasket as claimed in Claim 19,
wherein said release agent means comprises a silicone.

 21. A gasket as claimed in Claim 12,
wherein said nose portion comprises a molded plastic
10 material.

 22. A gasket as claimed in Claim 21,
wherein said cylindrical member is integrally formed
with said nose portion.

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