Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).
Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to an elastic plug assembly for use on a medical device, such as a catheter, that can be penetrated by a needle and that will reseal after removal of the needle. This invention is particularly adapted for use on a catheter having a Y-site connector. Although this invention will be discussed in connection with a catheter having a Y-site connector, it is to be understood that this invention may be used in conjunction with any device which requires a needle to pass through an elastic member that must reseal when the needle is removed.

[0002] Intravenous catheters may have Y-site connectors connected to their proximal end to allow first and second flows of liquids into a patient. The first inlet of a Y-site connector may be sealed with an elastic plug that can be penetrated by a needle to allow a healthcare worker to inject liquid such as medication into the patient when needed. The second inlet to the Y-site connector may be placed in communication with another liquid such as a standard saline solution to provide a continual flow of fluid to a patient. The needle passing through the elastic plug in the first inlet is removed after the proper dosage of medication is provided to the patient. If multiple doses of medication are required, the healthcare worker may subsequently cause a needle to be penetrated through the elastic plug of the Y-site connector to continue the delivery of medication.

[0003] Prior art plugs generally perform well. However, it has been found that the material of these plugs may take a set to the needle, particularly if the needle remains in the plug for a considerable period of time. Thus, when the needle is removed from the plug, a hole in the plug remains where the needle had been. Subsequent needles penetrated through the plug are unlikely to enter the small hole left by the previous needle. Thus, the small hole will remain in communication with ambient atmosphere and can cause leakage, evaporation or contamination. Any contamination that may result typically will be caused by ambient atmosphere communicating with either the liquid being administered or with bodily fluids. However, a possibility may exist for bodily fluids escaping through the hole in the elastic plug to contaminate people working in or near the patient to whom the Y-site connector is connected. The potential for these problems becomes greater each time a needle is removed and replaced, since the number of holes remaining in the elastic plug will increase. This problem is encountered not only with Y-site connectors, but in other situations where elastic plugs are periodically penetrated by needles.

[0004] US patent no. 3,030,955 relates to a plastic container. The container has an entry pad, and in the embodiment of figure 7, the entry pad has a body obliquely attached to the container wall along an anular area. The attached body is provided with a passage closed by a rubber pad. The rubber pad is compressed by a rigid ring and is held in place by a ledge. The rigid ring is held in place by the body by an annular boss.

[0005] US patent no 4,289,129 is concerned with an injection site apparatus adapted to be attached to a continuous unbroken portion of a flexible tube of an intravenous delivery set. The apparatus is provided with a recessed channel for supporting and bending a portion of the flexible tube. The apparatus is provided with a piercable closure and a needle guide which are axially aligned with a portion of the recess channel. The piercable closure and needle guide align a hypodermic needle in axial alignment with the center of said flexible tube to prevent interference therewith.

[0006] It is an object of this invention to provide an elastic plug assembly for a medical device such as a catheter that can be penetrated by a needle and that will not leak after the needle has been withdrawn.

SUMMARY OF THE INVENTION

[0007] According to the present invention, there is provided an elastic plug assembly for penetration penetration by a needle comprising:

- a rigid plug retainer;
- a housing securely engaged around said rigid plug retainer, portions of said inner surface of said housing engaging said rigid plug retainer being formed from an elastic material for resiliently engaging said rigid plug retainer;

and

- a compressible solid cylinder elastic plug compressed within the rigid plug retainer and being surrounded by the rigid tubular cylinder plug retainer to assure that the plug is sealed after removal of a needle inserted therein;

wherein

- said rigid plug retainer consists of a tubular cylinder having opposed inner and outer cylindrical surfaces along its entire length and said inner surface of said rigid plug retainer defines an inner cylindrical surface with a selected cross-sectional dimension;
- said housing has an inner surface of selected diameter; and
- said elastic plug has a cylindrical outer surface, which, in an uncompressed condition of said plug, defines a cross-sectional dimension greater than said internal cross-sectional dimension of said rigid plug retainer with said cylindrical outer surface of said plug being in abutting face-to-face relationship with said cylindrical inner surface of said rigid plug retainer, the elastic plug being radially compressed to a cross-sectional dimension equal to between 60% to 85% of said cross-sectional dimension of said plug in said uncompressed condition in order for the elastic plug to be held captive by engage-
ment of the cylindrical outer surface of the elastic plug with the cylindrical inner surface of the rigid plug retainer.

[0008] The elastic plug assembly of this invention includes an elastic plug that is held in compression by a rigid plug retainer. The rigid plug retainer in turn may be held captive within an elastic material that may function as the catheter hub. The elastic plug and the rigid plug retainer both may be substantially cylindrical. The rigid plug retainer preferably defines a cross-sectional dimension of between 60% and 85% of the non-compressed cross-sectional dimension of the elastic plug. Thus, the elastic plug must be radially compressed by approximately 15%-40% for insertion into the rigid plug retainer.

[0009] The above and any other objects and advantages of the invention will be apparent upon consideration of the drawings and the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The preferred embodiments are illustrated in the drawings in which like reference numerals refer to like elements and in which:

FIG. 1 is an exploded perspective view of the elastic plug assembly of this invention in conjunction with a Y-site connector on an intravenous catheter;
FIG. 2 is an end elevational view of the elastic plug shown in FIG. 1;
FIG. 3 is an end elevational view of the rigid plug retainer shown in FIG. 1;
FIG. 4 is an end elevational view of the catheter hub shown in FIG. 1; and
FIG. 5 is a perspective view, partly in section, of the elastic plug assembly of this invention in conjunction with a Y-site connector on an intravenous catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0011] An elastic plug assembly in accordance with the subject invention is identified generally by the numeral 10 in FIGS. 1 and 5. Elastic plug assembly 10 includes an elastic plug 12, a rigid plug retainer 14 and a catheter hub 16.

[0012] With reference to FIGS. 1 and 2, plug 12 is formed from an elastomeric material to define a solid cylinder with an outer cylindrical surface 18 defining a diameter "A". Polysisoprene or latex could be used to form plug 12. Preferably, polysisoprene is used. Plug retainer 14 is formed from a non-elastic rigid material and defines a tubular cylinder with an inner cylindrical surface 20 and an opposed outer cylindrical surface 22. Polycarbonate, ABS or stainless steel could be used to form plug retainer 14. Preferably, stainless steel is used. Inner cylindrical surface 20 of plug retainer 14 has an inside diameter "B" selected such that "B" approximately equals 60% to 85% of diameter "A." Outer cylindrical surface 22 of plug retainer 14 defines an outside diameter "C".

[0013] Catheter hub 16 is formed from an elastomeric material such as polyurethane and includes a first inlet 24, a second inlet 26 and an outlet 28 that extends to the catheter cannula. 3 First inlet 24 and outlet 28 are substantially collinear with one another to facilitate passage of a needle continuously through catheter hub 16, as shown in FIG. 5. Catheter hub 16 further includes a pair of flexible planar wings 30 and 32 projecting outwardly from substantially diametrically opposite sides of outlet 28. Wings 30 and 32 are flexible relative to outlet 28 and can be urged into substantially abutting face-to-face relationship with one another to facilitate gripping and maneuvering of catheter hub 16 during insertion of the catheter into a patient. Alternatively, wings 30 and 32 can be urged into a substantially coplanar orientation as shown in FIGS. 1 and 5 for taping catheter hub 16 in a fixed position on a patient. First inlet 24 of fitting 16 defines an inside diameter "D" which is equal to or slightly less than outside diameter "C" of rigid plug retainer 14.

[0014] Plug assembly 10 is assembled into the condition shown in FIG. 5 by initially compressing plug 12 radially approximately 15% to 40%, preferably 30%, so that the outside diameter of plug 12 is reduced approximately to dimension "B". This compression of plug 12 may be simultaneous along the length thereof or may be gradual, beginning at one end and continuing to the other. Plug 12, in its compressed condition, is then inserted into the central aperture of plug retainer 14, such that inner circumferential surface 20 of plug retainer 14 securely engages outer circumferential surface 18 of plug 12 along at least a major portion of the respective lengths. Thus, plug retainer 14 securely retains plug 12 in a state of radial compression where plug 12 defines a diameter equal to approximately 70% of its initial non-compressed diameter.

[0015] The subassembly of plug 12 and plug retainer 14 is then inserted into inlet 24 of catheter hub 16. This insertion requires an outward stretching of the elastomeric material of inlet 24. However, the elastomeric material of inlet 24 is resiliently urged toward an unbiased condition, and hence securely grips the subassembly comprising plug 12 and plug retainer 14 in catheter hub 16.

[0016] Plug assembly 10 may be used in the conventional manner by inserting a needle 34 approximately axially through plug 12 for communication with a patient. Needle 34 may be removed when necessary and may be replaced with a new needle. Removal of needle 34 from plug 12 permits the elastic material of plug 12 to return toward an unbiased condition in which the cylindrical aperture that had been occupied by needle 34 is substantially filled. This sealing of plug 12 after removal of needle 34 is positively assured by the radial compres-
sion of plug 12 achieved and maintained by plug retainer 14. [0017] Thus, it is seen that needles may be passed through the compressed elastic plug in the conventional manner, and may be removed and reinserted as necessary. The retention of the elastic plug in the compressed state by the rigid plug retainer ensures that the elastic material of the plug will not take a permanent set to the needle, even when the needle has been in the elastic plug for a considerable time. Thus, the radially compressed elastic material of the plug will resiliently return toward a less compressed condition when the needle is removed to completely fill the space that had been occupied by the needle. New needles may be penetrated through the elastic plug and may be removed without adversely affecting the sealing capabilities of the plug. Additionally, the radial compression of the elastic plug has no practical effect on the ability of a health care worker to urge the needle through the plug.

Claims

1. An elastic plug assembly (10) for penetration by a needle comprising:

   a rigid plug retainer (14);
   a housing (24) securely engaged around said rigid plug retainer (14), portions of said inner surface of said housing (24) engaging said rigid plug retainer (14) being formed from an elastic material for resiliently engaging said rigid plug retainer (14);
   and
   a compressible solid cylinder elastic plug (12) compressed within the rigid plug retainer (14) and being surrounded by the rigid tubular cylinder plug retainer (14) to assure that the plug (12) is sealed after removal of a needle inserted therein;

wherein said rigid plug retainer (14) consists of a tubular cylinder having opposing inner and outer cylindrical surfaces (20,22) along its entire length and said inner surface (20) of said rigid plug retainer (14) defines an inner cylindrical surface with a selected cross-sectional dimension; said housing (24) has an inner surface of selected diameter; and said elastic plug (12) has a cylindrical outer surface (18), which, in an uncompressed condition of said plug (12), defines a cross-sectional dimension greater than said internal cross-sectional dimension of said rigid plug retainer (14) with said cylindrical outer surface (18) of said plug being in abutting face-to-face relationship with said cylindrical inner surface (20) of said rigid plug retainer (14), the elastic plug (12) being radially compressed to a cross-sectional dimension equal to between 60% to 85% of said cross-sectional dimension of said plug in said uncompressed condition in order for the elastic plug (12) to be held captive by engagement of the cylindrical outer surface (18) of the elastic plug with the cylindrical inner surface (20) of the rigid plug retainer (14).

2. The elastic plug retainer (14) of Claim 1, wherein said elastic plug (12) is compressed to a cross-sectional dimension equal to approximately 70% of said cross-sectional dimension of said plug in said uncompressed condition.

1. Elastische Stopfenbaugruppe (10) zum Durchstechen mit einer Nadel, die folgendes umfaßt:

   einen starren Stopfenhalter (14),
   ein Gehäuse (24) in sicherem Eingriff um den starren Stopfenhalter (14), wobei die Abschnitte der Innenfläche des Gehäuses (24), die in Eingriff mit dem starren Stopfenhalter (14), sind, aus einem elastischen Material geformt werden, um elastisch mit dem starren Stopfenhalter (14), ineinanderzugreifen, und einen zusammendrückbaren massiven elastischen Zylinderstopfen (12), der innerhalb des starren Stopfenhalters (14), zusammenge- drückt wird und vom starren rohrförmigen Zylinderstopfenhalter (14), umschlossen wird, um zu sichern, daß der Stopfen (12) nach dem Entfernen einer in denselben eingeführten Nadel abgedichtet wird, bei welcher der starre Stopfenhalter (14) aus einem rohrförmigen Zylinder besteht, der gegenüberliegende innere und äußere zylindrische Flächen (20, 22) über die gesamte Länge desselben hat, und die Innenfläche (20) des starren Stopfenhalters (14), eine innere zylindrische Fläche mit einer gewählten Querschnittsabmessung definiert,
   das Gehäuse (24) eine Innenfläche mit einem gewählten Durchmesser hat, und
   der elastische Stopfen (12) eine zylindrische Außenfläche (18), hat, die in einem nicht-zusammengedrückten Zustand des Stopfens (12), eine Querschnittsabmessung definiert, die grö-
ßer ist als die innere Querschnittsabmessung des starren Stopfenhalters (14), wobei sich die zylindrische Außenfläche (18) des Stopfens in einer direkten Stoßbeziehung mit der zylindrischen Innenfläche (20) des starren Stopfenhalters (14) befindet, wobei der elastische Stopfen (12) in Radialrichtung auf eine Querschnittsabmessung zusammengedrückt wird, die zwischen 60% und 85% der Querschnittsabmessung des Stopfens im nicht-zusammenge- drückten Zustand gleichkommt, damit der Stopfen (12) durch den Eingriff der zylindrischen Außenfläche (18) des elastischen Stopfens mit der zylindrischen Innenfläche (20) des starren Stopfenhalters (14) festgehalten wird.

2. Starrer Stopfenhalter (14) nach Anspruch 1, bei dem der elastische Stopfen (12) auf eine Querschnittsabmessung zusammengedrückt wird, die 70% der Querschnittsabmessung des Stopfens im nicht-zusammenge- drückten Zustand gleichkommt.

Revendications

1. Assemblage de bouchon élastique (10) dans lequel peut pénétrer une aiguille, comprenant :

un élément de retenue rigide du bouchon (14);
un boîtier (24) engagé fermement autour dudit élément de retenue rigide du bouchon (14), des parties de ladite surface interne dudit boîtier (24) s'engageant dans ledit élément de retenue rigide du bouchon (14) étant composées d'un matériau élastique en vue d'un engagement élastique dans ledit élément de retenue rigide du bouchon (14);

et

un bouchon élastique cylindrique solide compréssible (12) comprimé dans l'élément de retenue rigide du bouchon (14) et entouré par l'élément de retenue rigide tubulaire cylindrique du bouchon (14) pour assurer le rétablissement de l'étanchéité du bouchon (12) après le retrait de l'aiguille qui y a été insérée ;
ledit élément de retenue rigide du bouchon (14) étant constitué par un cylindre tubulaire comportant des surfaces cylindriques interne et externe opposées (20, 22) le long de l'ensemble de sa longueur, ladite surface interne (20) dudit élément de retenue rigide du bouchon (14) définissant une surface cylindrique interne ayant une dimension de section transversale sélectionnée ;
ledit boîtier (24) comportant une surface interne de diamètre sélectionné ; et
ledit bouchon élastique (12) comportant une surface cylindrique externe (18), définissant,

dans un état non comprimé dudit bouchon (12), une dimension de section transversale supérieure à ladite dimension interne de la section transversale dudit élément de retenue rigide du bouchon (14), ladite surface cylindrique externe (18) dudit bouchon butant contre ladite surface cylindrique interne (20) dudit élément de retenue rigide du bouchon (14), le bouchon élastique (12) étant comprimé radialement à une dimension de section transversale représentant 60% à 85% de ladite dimension de section transversale dudit bouchon dans ledit état non comprimé pour bloquer le bouchon élastique (12) par suite de l'engagement de la surface cylindrique externe (18) du bouchon élastique dans la surface cylindrique interne (20) de l'élément de retenue rigide du bouchon (14).

2. Élément de retenue rigide du bouchon (14) selon la revendication 1, dans lequel ledit bouchon élastique (12) est comprimé à une dimension de section transversale représentant environ 70% de ladite dimension de section transversale dudit bouchon dans ledit état non comprimé.