Feb. 13, 1968 G. A. BRUNO ET AL 3,369,121

RADIOACTIVE PACKAGE AND CONTAINER THEREFOR

Filed April 6, 1966 3 Sheets-Sheet 1

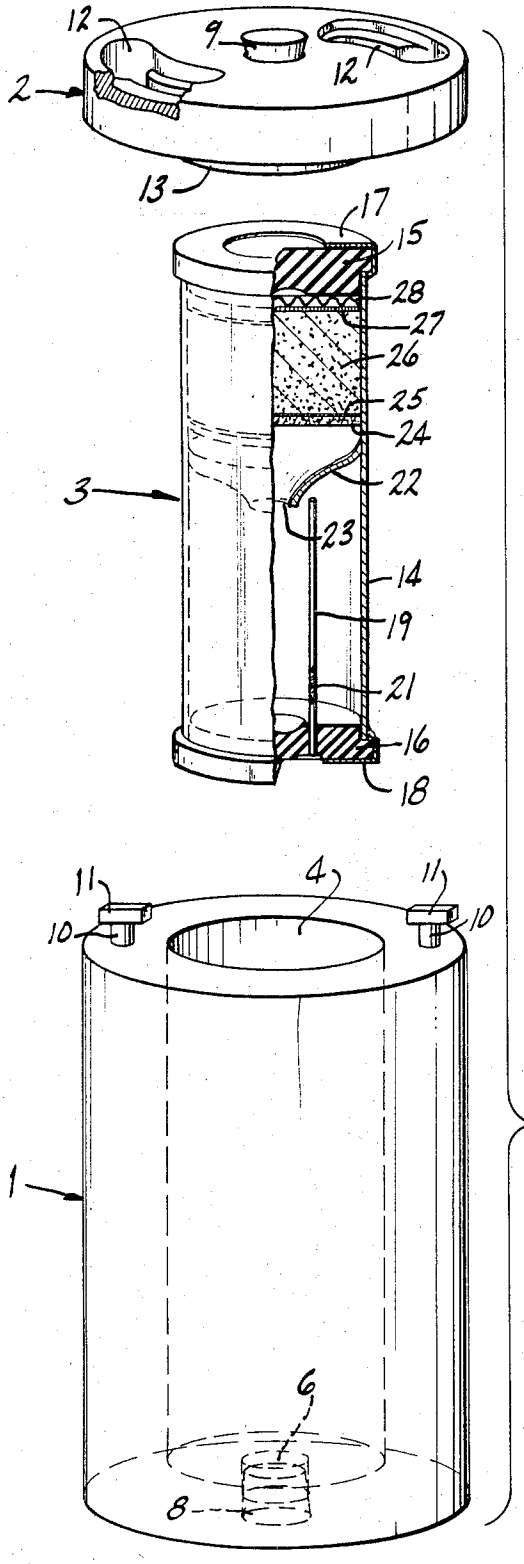

FIG-1

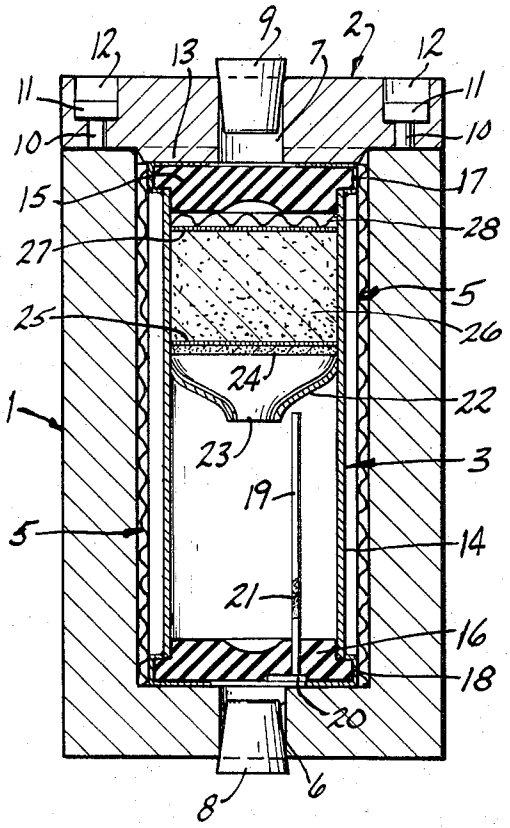

FIG-2

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RADIOACTIVE PACKAGE AND CONTAINER THEREFOR

Filed April 6, 1966 3 Sheets-Sheet 2

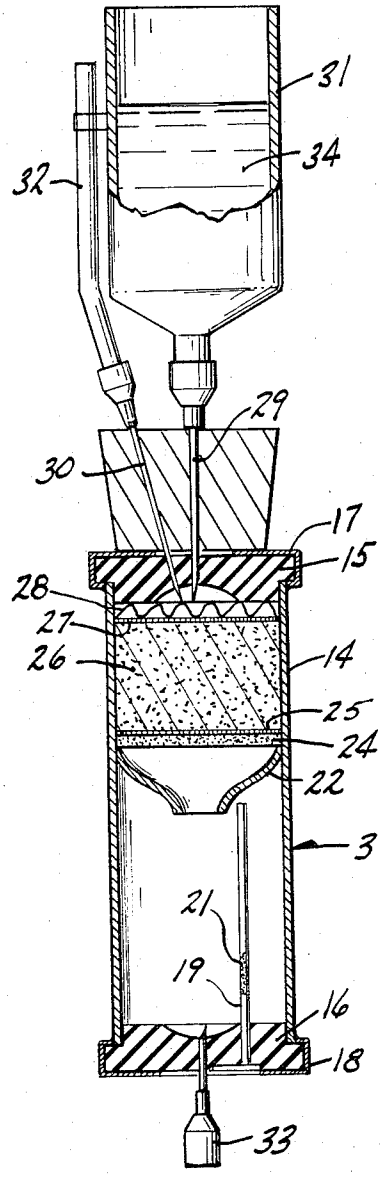

FIG - 3

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RADIOACTIVE PACKAGE AND CONTAINER THEREFOR

Filed April 6, 1966 3 Sheets-Sheet 3

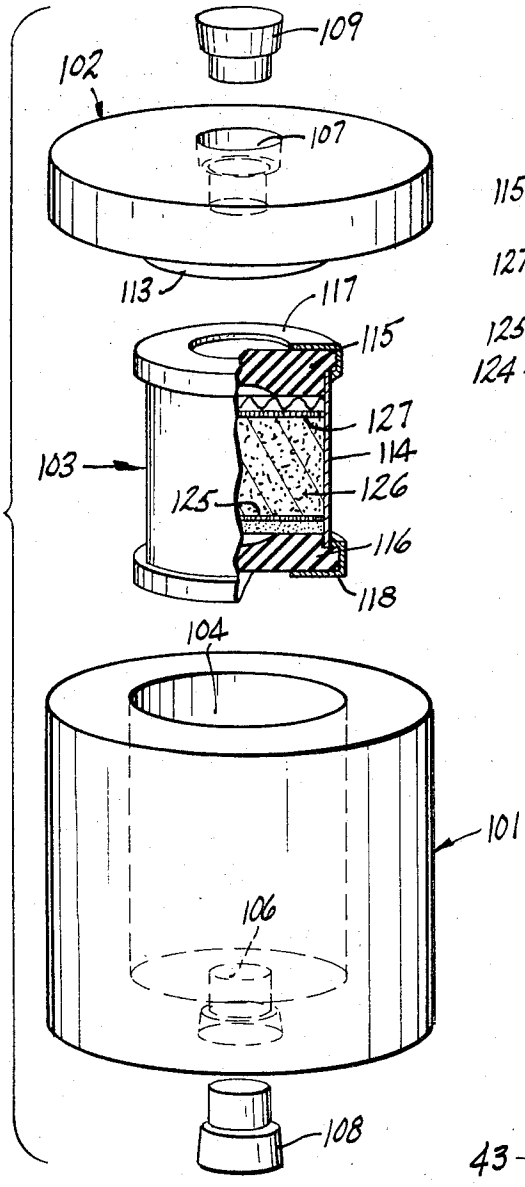

FIG-4

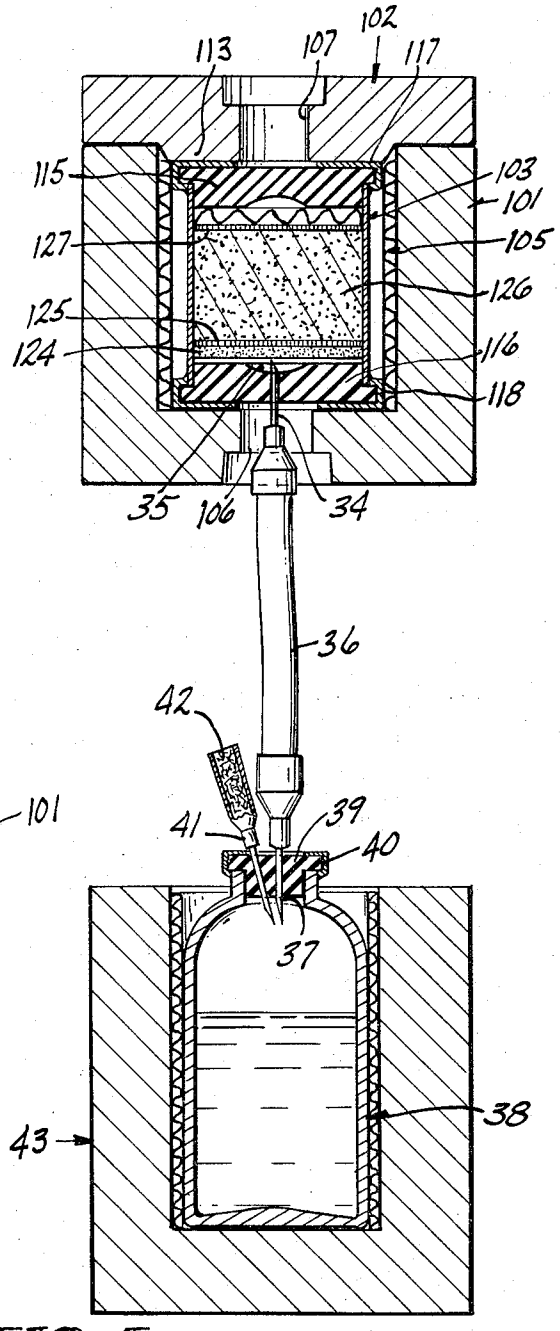

FIG-5

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United States Patent Office 3,369,121 Patented Feb. 13, 1968

3,369,121

RADIOACTIVE PACKAGE AND CONTAINER THEREFOR

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Filed Apr. 6, 1966, Ser. No. 540,689
10 Claims. (Cl. 250—106)

ABSTRACT OF THE DISCLOSURE

This invention relates to a new device for containing a column of elutable radioactive material. The device comprises a hollow body, in which the column of radioactive material is contained, closed at its two ends by pierceable closures, preferably made from resilient material. In this manner a closed system is achieved which can be sterilized and remains sterile in use. The device is preferably shipped in a shielding container having a removable closure. The removable closure and the bottom of the container are both apertured so that access can be had to the interior of the container without removing the closure. By use of a closed system consisting of a hypodermic syringe containing the eluting solution, a hypodermic needle therefor that is used to pass through the aperture in the closure and pierce the top of the device so that the solution can be introduced into the top of the column, a tube containing hypodermic needles at both ends, one needle of which is inserted through the aperture in the bottom of the column into the bottom of the device and the other needle through the closure of an empty sealed vial which is also pierced by another hypodermic needle open to the atmosphere through a sterile plug of cotton, a sterile system for eluting the column and recovering the eluate containing the desired radioactive material is achieved. The preferred radioactive material contains the element Mo^{99} yielding radioactive technetium as the eluted radioactive material.

This invention relates to packages containing radioactive material and containers therefor and, more particularly, to a package of a sterile column containing a radioactive material and a shielding container therefor and to the sterile column itself.

The use of radioactive isotopes for the diagnosis and treatment of various medical conditions is well known. Unfortunately, however, certain radioactive isotopes have so short a half-life that they cannot be economically shipped from the manufacturer to the attending physician. This has made it necessary for the physician to prepare such isotopes as and where they are to be used. One such isotope is the 99m isotope of technetium which is used for the localization of brain tumors, for example. For a more detailed discussion of the subject, reference is made to an article by Smith in the Journal of Nuclear Medicine, vol. 5, p. 871–882 (1964). This isotope has a half-life of six hours and is obtained as the daughter product of molybdenum Mo^{99}. It is separated in the form of the pertechnetate ion from Mo^{99}, absorbed on an alumina column, by elution with dilute hydrochloric acid or saline. Since maximum growth of radioactivity of the Tc^{99m} occurs in about 23 hours, a column containing Mo^{99} may be eluted daily to yield Tc^{99m}. Because of its high radioactivity, such column must be shielded at all times to prevent unnecessary exposure to its radioactivity.

Prior to this inventinon, such columns were in the form of open ended cylinders and were shipped in shielding containers, made of lead or a lead salt or other material used as a gamma ray shielding agent. In use, such columns were either removed from the containers, or, if a container having removable closures on both ends was employed, retained in the container during elution. The eluate was collected in a collecting container, such as a beaker or vial, and had to be sterilized prior to use. This necessitated the sterilization of a radioactive substance thereby increasing both the hazard and difficulty in using such a generator system.

It is an object of this invention, therefore, to provide a novel column for radioactive material, whereby the column can be eluted to yield a sterile, non-pyrogenic radioactive eluate.

It is another object of this invention to provide a novel package containing a novel column for radioactive material enclosed in a radioactive shielding container of such design that the sterile eluate obtained from the column may be removed from the package without removing the column from the container.

These objects are achieved by the columns and containers of this invention, preferred embodiments of which are illustrated in the accompanying drawing wherein:

FIGURE 1 is a perspective view of the separated components that comprise one embodiment of the package of this invention;

FIGURE 2 is an axial section view of the package shown in FIGURE 1, with the components assembled and the package closed;

FIGURE 3 is an elevational view showing the equipment used to load and wash the column of the package of FIGURE 1 of this invention;

FIGURE 4 is a perspective view of the separated components that comprise a second embodiment of the package of this invention; and

FIGURE 5 is an axial section view of the package shown in FIGURE 4, showing the package in use.

Considering the embodiment shown in FIGURES 1, 2 and 3 of the drawings, the package of this invention comprises generally a container having a body 1, a removable top closure 2, and a radioactive column 3 positioned inside the body 1. Since the principal purpose of the container is to store radioactive material, the container is fabricated of lead or other material used as a gamma ray shielding material, such as a lead-antimony alloy iron, or a lead salt, such as lead carbonate or lead sulfide, embedded in plastic. The body 1 is of generally cylindrical shape having a hollow center 4 preferably of circular cross-section and of greater diameter than that of column 3. When the column is placed inside the container, the space between the column and the inner wall of body 1 is preferably filled with a shock absorbant packing material 5, such as corrugated paper, foam plastic or a plastic sleeve.

To permit access through the bottom of the container and limited access through the top of the container, without removing top closure 2, both the bottom wall and the top closure have centrally positioned apertures 6 and 7, sealed by removable plugs 8 and 9, which are also fabricated of gamma shielding materials.

After column 3 has been placed in the body of the container, the container is closed at its top by means of removable closure 2. In the embodiment shown in the drawing, the closure is retained on the body by means of a pair of lugs 10, 10, having enlarged heads 11, 11. The closure 2 is equipped with a pair of arcuate keyhold shaped slots 12, 12, the enlarged openings of which are of greater diameter than are the heads 11. These slots are countersunk so that the outer portions thereof are of sufficient width to accomodate the heads, whereas the inner portions thereof are of width smaller than the heads 11, but of sufficient width to accomodate the shank portions of lugs 10. The closure is also fabricated of lead or other material relatively impervious to radioactivity and,

to insure a tight fit with body **1**, the closure is equipped on its inner surface with a circular projection **13** having a circumference slightly less than the circumference of the hollow center.

Although in the preferred embodiment, the closure **2** is retained on the body by means of lugs and keyhole shaped slots, other means may be used to removably connect the closure to the body. Thus, the closure may be simply taped or stapled to the body, or threading may be used.

The column **3** is preferably made principally of glass or a transparent plastic material and is composed of a cylindrical tube **14** closed at its top and bottom by means of stoppers **15** and **16**. These stoppers are preferably fabricated of resilient material, such as rubber, that can be pierced by a hypodermic needle, and are held permanently in place by means of a pair of annular aluminum discs **17** and **18** that pass over the outer edges of the stoppers, the sides of the stoppers and are then crimped to the adjacent walls of tube **14**, as shown in FIGURE 2. To permit easy access by air to the inside of tube **14**, the bottom stopper **16** is equipped with a breather tube **19** that passes through stopper **16** to about half the height of tube **14**. So that the outside end of the breather tube **19** is in communication with the atmosphere, (after removal of plug **8**,) even when the column **3** is seated in body **1**, the bottom stopper **16** is equipped on its outer surface with a groove **20** extending at least from the outer end of breather tube **19** to aperture **6**. To assure sterility the breather tube **19** is equipped with a plug **21** of cotton or similar material.

The tube **14** is equipped with a partition **22** which divides the tube **14** into an upper and a lower portion. This partition is preferably integral with the tube **14** along its outer end and tapers downward towards the bottom of tube **14** so as to provide a restricted opening **23** at its lower end. The partition can be and preferably is fabricated of the same material as tube **14**. Although the exact position of the partition in tube **14** is not critical, it is preferably positioned in the upper half of tube **14** in such a way that the restricted opening **23** is slightly below the upper end of breather tube **19**.

Seated on the upper end of partition **22** is a perforated disc **24** (preferably a glass fritted disc) on which preferably rests a filter pad **25**. Resting on top of disc **24**, or the filter pad **25**, if one is used, is a granulation **26** of a radioactive containing alumina, and optionally also a cation exchange resin, such as Dowex–50×–8, to prevent passage of the alumina through the tube during elution.

The granulation **26** can be retained in place either by use of a perforated disc (prefereably a cloth disc **27** retained in place by a retaining ring **28**), as shown in the drawing, or merely by means of stopper **15**.

To prepare the column **3** for use, the granulation **26** is packed into the top portion of the column, the stoppers **15** and **16** are inserted and crimped into place by means of aluminum discs **17** and **18**. As shown in FIGURE 3, the top stopper **15** is then pierced by two hollow needles **29** and **30**, one of which is connected to a reservoir **31** and the other to a tube **32** open at its other end to the atmosphere. A third hollow needle **33** is inserted through bottom stopper **16** to allow for drainage.

To load the column, the reservoir **31** is filled with a source of radioactivity, such as an aqueous solution of radioactive (Mo^{99}) ammonium molybdate, and the solution is permitted to drip through needle **29** onto and through granulation **26**. Most of the radioactive molybdenum is adsorbed in the granulation. The excess molybdenum and water pass through the column and are removed through drainage needle **33**. The column is then washed with acid and saline to remove any non-adsorbed molybdenum, the needles **29**, **30** and **33** are removed, and the column is sterilized, as by autoclaving.

The column **3** is inserted into body **1**. The closure **2** is then so positioned over the top of body **1** that the lugs pass through the enlarged portions of slots **9**, and rotated

to firmly connect the closure to said body. The package is then ready for shipment.

When the package is to be used, the plugs **8** and **9** are removed and the column **3** is then eluted, by injecting a sterile, non-pyrogenic eluting solution, such as sterile, non-pyrogenic isotonic saline, through the top stopper **15** into the upper portion of tube **14**. The injection is accomplished by passing the needle of a hypodermic syringe containing the eluting solution through aperture **7** and through stopper **15**. The eluate, containing the radioactive material, is collected and maintained in the bottom of tube **14**. When the eluate is to be used, it is removed from tube **14** by piercing the stopper **16** with a sterile hypodermic needle (connected to a syringe) by passing the needle through aperture **6** and stopper **16**.

Considering now the embodiment shown in FIGURES 4 and 5 of the drawings, the package of this embodiment of the invention differs from the first embodiment primarily in the omission of the lower chamber in the column. It comprises generally a container having a body **101**, a removable top closure **102**, and a radioactive column **103** positioned inside the body **101**. The body **101** and closure **102** are fabricated from gamma ray shielding material as described hereinbefore. The body **101** is of generally cylindrical shape having a hollow center **104** preferably of circular cross-section and of greater diameter than that of column **103**. When the column is placed inside the container, the space between the column and the inner wall of body **101** is preferably filled with a shock absorbant packing material **105**, such as corrugated paper, foam plastic or a plastic sleeve.

To permit access through the bottom of the container and limited access through the top of the container, without removing top closure **102**, both the bottom wall and the top closure have centrally positioned apertures **106** and **107**, sealed by removable plugs **108** and **109**, which are also fabricated of gamma shielding materials.

After column **103** has been placed in the body of the container **101**, the container is closed at its top by means of removable closure **102**. This may be done by positioning the closure **102** on the container **101** and affixing it by means of a strip of adhesive tape (not shown) or other means. To assure a tight fit, the closure **102** is equipped on its inner surface with a circular projection **113** having a circumference slightly less than the circumference of the hollow center.

The column **103** is preferably made principally of glass or a plastic material and is composed of a cylindrical tube **114** closed at its top and bottom by means of stoppers **115** and **116**. These stoppers are preferably fabricated of resilient material, such as rubber, that can be pierced by a hypodermic needle and are held permanently in place by means of a pair of annular aluminum discs **117** and **118** that pass over the outer edges of the stoppers, the sides of the stoppers and are then crimped to the adjacent walls of tube **114**, as shown in FIGURE 5.

Positioned in the tube **114**, preferably spaced from but near the bottom thereof, is a perforated disc **124** (preferably a glass fritted disc) on which preferably rests a filter pad **125**. Resting on top of disc **124**, or the filter pad **125** if one is used, is a granulation **126** of the same material used in the first embodiment. The granulation **126** can be retained in place either by use of a perforated disc **127**, as shown in FIGURES 4 and 5 of the drawing, or merely by means of stopper **115**.

The column is prepared for use by the same method used in the first embodiment of this invention, as shown by FIGURE 3. The loaded column **103** is then inserted into body **101** and the closure **102** is positioned over the opening in body **101** and retained thereon by means of an adhesive strip or other means. The package is then ready for shipment.

When the package is to be used, the plugs **108** and **109** are removed and the column **103** is eluted, by injecting a sterile, non-pyrogenic eluting solution, such as

sterile, non-pyrogenic isotonic saline, through the top stopper **115** into the upper portion of tube **114**. The injection is accomplished by passing the needle of a hypodermic syringe (not shown) containing the eluting solution through aperture **107** and through stopper **115**. The eluate, containing the radioactive material, is withdrawn from the bottom of tube **114** by means of a hypodermic needle **34**. This needle **34** passes through aperture **106** and bottom stopper **116** into the space between perforated disc **124** and stopper **116**. To increase this space, stopper **116** is preferably fabricated to have a concave center portion **35**.

The under end of needle **34** is connected through tubing **36** to a second hypodermic needle **37** that passes into a sterile empty vial or other container **38** through a rubber stopper **39** closing the vial and retained thereon by means of a crimped annular aluminum disc **40**. To permit the air in the vial to escape as the eluate flows into the vial, the stopper **39** is also pierced by a third hypodermic needle **41**, exposed to the atmosphere. To assure sterility of the system, needle **41** is equipped with a plug **42** of cotton or similar material. To minimize the exposure to radiation, vial **38** is retained in a shield **43** of gamma ray shielding material.

In use, the eluate passes from column **103** through needle **34**, tubing **36**, and needle **37** into vial **38**. When the eluate is to be used, it is removed from vial **38** by piercing the stopper **39** with a sterile hypodermic needle (connected to a syringe).

Although in both embodiments of this invention, the closures **2** and **102** are designated as top closures, the columns **3** and **103**, respectively, can of course be introduced upside down into the body **1** and **101**, in which case the top closure becomes a bottom closure.

By use of the packages of this invention it is possible to carry out the entire elution operation under sterile conditions without ever removing the column **3** or **103** from the protective shield, thereby minimizing the possibility of exposure to the relatively high radioactivity of the column. Furthermore, since the whole eluting operation is carried out under sterile conditions, the need to sterilize the radioactive eluate prior to use is obviated.

The invention may be variously otherwise embodied within the scope of the appended claims.

What is claimed is:

1. A column containing a sterile, non-pyrogenic elutable radioactive material to be utilized for diagnosis and treatment of medical conditions, which comprises a hollow portable body, closed at its top and bottom by pierceable autoclavable closures and having positioned therein and spaced from the bottom thereof a source of sterile, non-pyrogenic elutable short-lived medical radioactive material whereby a sterile non-pyrogenic eluate immediately ready for utilization is delivered from the column on elution.

2. The column of claim **1**, wherein the pierceable closures are permanently affixed to said hollow body to seal said body.

3. The column of claim **2** wherein the pierceable closures are fabricated of resilient material.

4. The column of claim **3**, wherein the source of the radioactive material contains the element Mo^{99}.

5. The column of claim **3** wherein the pierceable closure at the bottom contains a tube extending through said closure.

6. The column of claim **5** wherein the body is equipped with a hollow partition equipped with means for retaining said source of elutable material on the upper edge of said partition.

7. A package comprising a shielding container and a column containing a sterile non-pyrogenic elutable radioactive material positioned therein; said container having side and bottom walls, said bottom wall containing a restricted aperture therein; and said column comprising a hollow portable body closed at its top and bottom by pierceable autoclavable closures and having positioned therein and spaced from the bottom thereof a source of sterile, non-pyrogenic elutable short-lived medical radioactive material whereby a sterile non-pyrogenic eluate immediately ready for utilization is delivered from the column on elution.

8. The package of claim **7** wherein the container has a removable closure for the top, said closure having a restricted aperture therein.

9. The package of claim **7**, wherein the pierceable closures are fabricated of resilient material and permanently affixed to said body to seal said body.

10. The package of claim **9**, wherein the source of the radioactive material contains the element Mo^{99}.

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