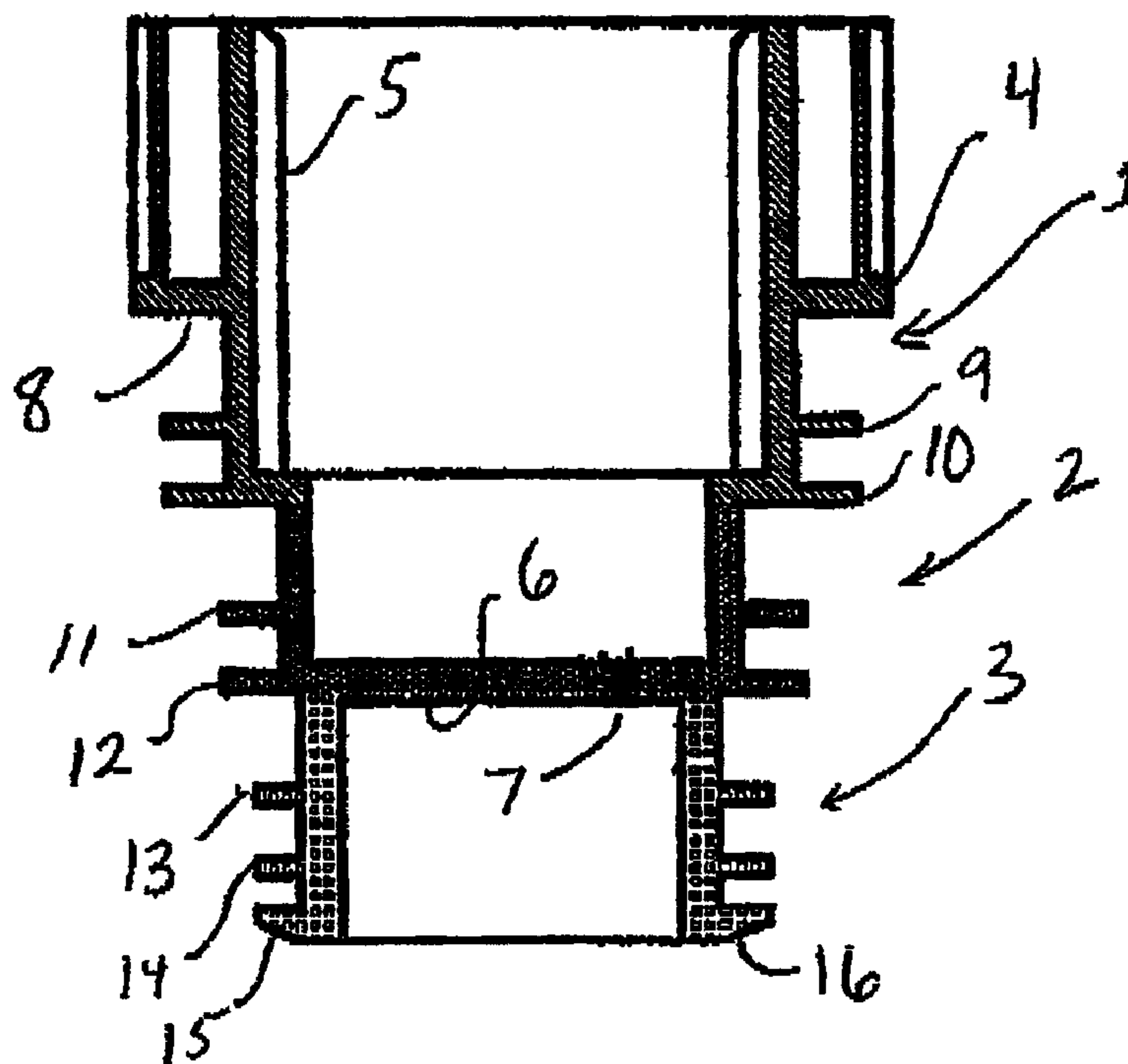




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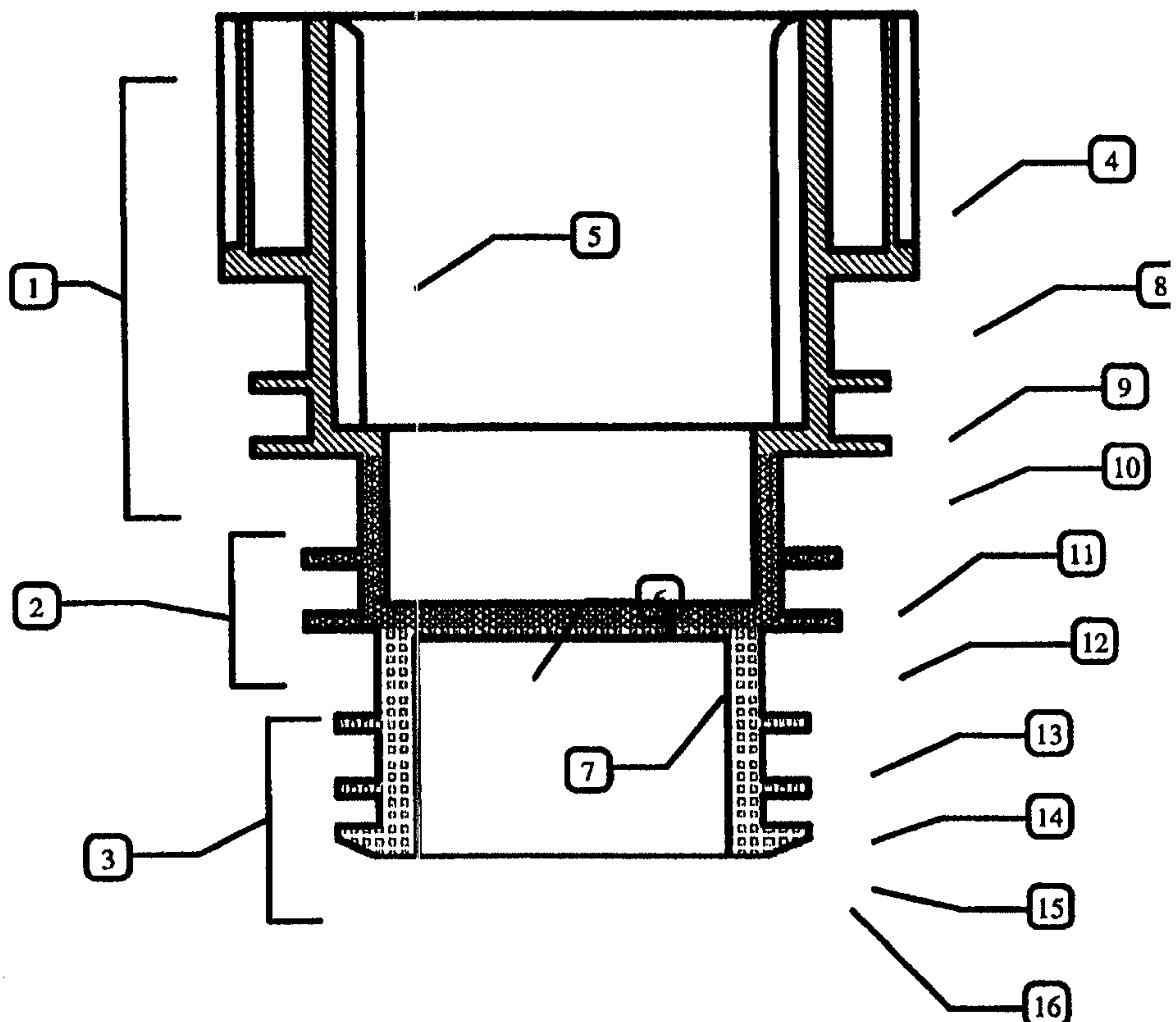
A universal plug which can be used to close various size containers such as those used in health care for collecting and handling human blood, fluids, and the like. The universal plug comprises a plurality of stepped posts (1, 2, 3) each of which comprises at least one ring (9, 10, 11, 12, 13, 14, or 15) for sealing the internal surface of the container. The lowermost ring further comprising a chamber for easy insertion into the container.



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(21) International Application Number: PCT/US97/20447 (22) International Filing Date: 12 November 1997 (12.11.97) (30) Priority Data: 60/030,859 12 November 1996 (12.11.96) US (71) Applicant (for all designated States except US): SMITHKLINE BEECHAM CORPORATION [US/US]; One Franklin Plaza, Philadelphia, PA 19103 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): CONSTABLE, Kevin, N. [US/US]; 503 Providence Avenue, Claymont, DE 19703 (US). (74) Agents: KANAGY, James, M. et al.; SmithKline Beecham Corporation, Corporate Intellectual Property, UW2220, 709 Swedeland Road, P.O. Box 1539, King of Prussia, PA 19406-0939 (US).		(81) Designated States: AL, AU, BA, BB, BG, BR, CA, CN, CZ, EE, GE, HU, ID, IL, IS, JP, KP, KR, LC, LK, LR, LT, LV, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, SL, TR, TT, UA, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: UNIVERSAL PLUG (57) Abstract A universal plug which can be used to close various size containers such as those used in health care for collecting and handling human blood, fluids, and the like. The universal plug comprises a plurality of stepped posts (1, 2, 3) each of which comprises at least one ring (9, 10, 11, 12, 13, 14, or 15) for sealing the internal surface of the container. The lowermost ring further comprising a chamber for easy insertion into the container.		



Universal Plug

Scope of the Invention

This invention covers a universal plug which can be used to close various container diameters of sample containers such as those used in health care for collecting and handling human bloods and the like. This plug is also adapted to use with an automated capping and decapping device to enable the automated processing of said containers.

Area of the Invention

Assaying of samples obtained from patients has become highly automated in terms of aspirating an aliquot of the specimen and subjecting it to an analytical process. Transporting sample specimens to these analytical devices also has seen substantial strides in automation take place. But little has been done in automating the preparing of specimens for introduction onto the transport mechanism or opening them once they are on-line. This is particularly true as regards removing the plug or plug on specimen containers or bottles, and reclosing that orifice once the specimen inside the container has been sampled and processed. Closure is needed so specimens will not become contaminated, sample loss is prevented, or law or regulation requiring they be available for future reference are met.

Specimens can be sampled by removal of the existing closure allowing for free access by the technician. Good laboratory practices or regulations dictate that a new clean closure is used for recapping the specimen. Specimen containers may vary in diameter and require a selection of different closures for recapping. A universal closure (or plug) can provide a quick and cost effective method of providing closure for specimen containers stored and processed within the laboratory.

Consequently what is needed to further automate specimen handling is a decapper/recapper device and a compatible universal plug which can be processed by this machine.

This invention provides a universal plug.

Summary of the Invention

This invention comprises a universal plug which can be used with any size sample container with a diameter of .4" to .58". The universal plug assigns a set of rings to a specific range of diameters. There are three sets of rings located on each hollow

post . Each ring set comprises a zone that will accommodate a subset of the full range of diameters.

Geometrical relationships between the outside diameter of the ring and the outside diameter of the post control the insertion force required and the seal between the closure and container to prevent spills on tipping. Vertical separation between the rings and between each zone of rings provide stability for the plug in the container. The length of the post determines the depth of insertion for each zone. A ring may also provide tapered or chamfered leading edges for locating and ease of insertion.

The knurled cap provides easy grasp for manual or robotic or automatic removal of the plug. The internal flat surface is used to aid in manual or robotic or automatic insertion of the plug. A vent hole in the plug allows for pressure relief during insertion and controlled venting for temperature changes.

Material thickness balances manufacturing costs with strength required for insertion or sealing or gripping. The overall design provides for easy removal or insertion, prevents damage to the container, allows for handling by humans or robots or automatic devices, prevents spills, limits dehydration or contamination of the sample.

Brief Description of the Drawings

The invention will now be described by way of example only with reference to the accompanying drawings.

Figure 1 shows a top view of the plug, looking down into the open core of the device.

Figure 2 shows a cross sectional view of the plug.

Detailed Description of the Invention

The design of this universal plug is intended to allow it to fit securely into the containers or bottles which are currently used in drawing or processing medical specimens. This design works particularly well on containers which have a smooth inner bore. It can be used on any type of container for drawing bloods currently available to the medical profession. These containers have internal diameters ranging in size from about 0.4 to about 0.58 inches. One example is the ubiquitous pre-evacuated blood drawing containers that have a smooth inner bore and are closed with a soft rubber plug that can be penetrated by a needle. Such containers are available commercially. The most commonly available container is the "Vacutainer TM" marketed by Becton Dickinson. These containers, normally three sizes, are de-capped and the specimen sampled or processed by some means. After a sample aliquot is removed the container should be closed to prevent contamination from its surroundings or to prevent

loss of sample if the container should be jostled or tipped over. The original rubber plug could be reused, but this is seldom done. Good laboratory practices or regulations or guidelines dictate discarding the plug when it is removed from the container. This helps to avoid cross contamination of samples should the wrong plug be placed in
5 another container. It also reduces the risk of someone or something coming in contact with the plug and being contaminated by any residue it may carry.

This universal plug provides a means for closing such sample containers. It can be used in all currently available containers. Sample specimens are thus isolated and evaporation is reduced or prevented. It is not intended that samples be shipped with
10 these plugs. That is because the plug was designed with a pressure release hole so air could escape as the plug is inserted into the container. Pressure generated from compressing the air in the container could require substantial effort to seat the plug or push the plug back out of the container. This could make it difficult to process containers rapidly and it might be possible that the pressure needed to seat an unvented
15 plug would break the glass wall of a container.

In general the design of the plug is that of a multiple hollow stepped post. Each post has multiple thin flexible rings, each with a smaller diameter than the previous one. The largest diameter post has an additional thick ring used for gripping the plug by manual or robotic or automatic means. The thin rings are inserted into the container to
20 prevent spillage of the contents. Multiple rings on each post are provided for stability of the inserted plug, better sealing, and ease of insertion.

The first post has the largest diameter. It is essentially round. The inner surface is smooth. The top of the post has a thick outer ring attached by multiple gussets forming a web to support a knurled outer surface, thereby forming a cap. The knurling
25 allows for better gripping by human or robotic or automatic means. Below the knurled cap is a set of thin rings. These rings are inserted into the largest diameter container. The container is seated against the bottom surface of the knurled cap.

The second post has a medium size diameter. It is essentially round. The inner surface is smooth. A medium size set of rings are used to provide sealing of a container
30 when inserted into medium sized containers. The bottom of the post is has an internal cap giving this post a cup like appearance. This cap surface has a vent hole for releasing excess pressure. The last ring of the previous largest diameter post provides a seat for the top of medium sized containers.

The third post has the smallest diameter. It is essentially round. The inner
35 surface is smooth. A small size set of rings are used to provide sealing of a container when inserted into small sized containers. The last ring of the set is smaller and has a chamfer for locating the plug into a small container. The last ring of the previous medium size diameter post provides a seat for the top of small sized containers.

In its preferred form, this plug is designed to fit any opening of any container where that internal diameter (ID) is between 0.4" to 0.58" and the neck forming the opening has essentially parallel walls. These measurements refer to the average ID of the neck opening. In some containers the mouth of the neck curves in slightly just at the top most portion of the opening ; the term burnished is sometimes used to describe this type of rounding. In some containers the top edge of the neck may flare out slightly like a funnel. If this funnel shape is too pronounced, it will probably result in the plug being less firmly seated and in the extreme case no seat will be attained. If the funnel is inverted in the neck the plug should seat readily and be retained.

10 In this plug, two or more flexible annular rings are used to contact the inner surface of the neck. This provides a means for seating the plug and preventing loss of the contents if the container is tilted. As the plug is inserted into the container the rings will deflect upward and cling to the inside of the container effectively sealing it. A minimum of three seals is required to prevent spillage of the contents. One seal is
15 provide by each ring and the last seal is provided by the last ring of the next larger diameter zone.

Another preferred characteristic of this plug is the low insertion force required to seat the plug. An insertion force of about 10 pounds or less, measured as downward force, is preferred. This 10 pound force will permit easy recapping for manual or
20 robotic or automatic means. The insertion force is controlled in several ways. One way is through geometrical relationships between the outside diameter of the ring and the outside diameter of the post. This is the depth of the ring. Preferred depth is 0.035 to 0.055. A second means of affecting insertion force is through material selection. A plastic or rubber or composite material may be chosen. A third means of affecting
25 insertion force is through thickness of the fins. Thickness of the fins is chosen in conjunction with material selection and the requirements of a flexible device.

The plug can be solid, except for the vent hole; or one or more of the posts can be solid and the others made with a hollow core; or all can have a hollow core. A hollow core structure is preferred. Hollow core plugs will have at least one solid bridge
30 positioned in one or more posts so the plug will be sufficiently rigid to withstand insertion force. A solid bridge with a vent hole can be positioned at the shoulder between the small and medium posts. If a post is constructed with a hollow core , the wall thickness can vary. Wall thickness may vary from 0.010" to 0.030".

The overall height of the plug can range from 0.3" to 1". For the medical
35 specimen containers illustrating this invention, plugs should be about 0.5" long. The height of a given post can vary independent of the other posts. A preferred height is about 0.2" for medical specimen containers. For other containers, the overall height of

the plug and the height each post can be varied to meet the requirements of the neck and the opening of a given container.

The annular rings will be made of a deformable material which can be the same as the posts or a more flexible material. Because injection molding is the most cost effective method to make these plugs, it is expected that the device will be of one material. The rings will be relatively thin as needed to be flexible, but not so thin that they tear or have little or no structural integrity. Rings should be placed on the post so as not to contact other rings during insertion or under full deformation.

Venting is accomplished by making a small non-sealing hole which allows for pressure flow from internal to external and external to internal. This hole is sized to prevent medical samples from leaking or moisture from entering. It is approximately a 0.002" diameter hole.

Discussion of the Figures

Figure 1 is a top view of a hollow plug. Figure 2 is a cross-sectional view through the center of the plug. The three posts are signified as (1), (2), and (3). The inner most post (3) is the smallest diameter ring and is sized to fit small diameter tubes. The middle post (2) has is a medium size diameter ring and is sized to fit the middle range diameter of tubes. The outer post (1) is sized to fit the largest size diameter tubes and incorporates the knurled (4) outer surface for gripping. The outer post (1) in conjunction with the knurled (4) outer surface has a honeycomb appearance. The ribs (5) of the honeycomb provide stability and strength to the plug during removal and insertion. Post (3) has a top surface (6) comprising a cup like appearance as shown in Figure 2. The top surface has a vent (7) for pressure release from the tube.

Post (1) has two rings (9) and (10). The bottom of the knurled ring (8) forms a seal on the top of the tube inserted on rings (9) and (10). Rings (9) and (10) are similar diameters. Post (2) has two rings (11) and (12). The bottom of ring (10) forms a seal on the top of the tube inserted on rings (11) and (12). Rings (11) and (12) are similar diameters. Post (3) has three rings (13), (14), and (15). The bottom of ring (12) forms a seal on the top of the tube inserted on rings (13), (14), and (15). Rings (13), (14) and (15) are similar diameters. Ring 15 has a chamfer (16) to provide easy insertion of the plug into a tube.

What is claimed

1. A universal plug which can be used with a medical specimen container which has an opening comprising a neck and an internal diameter of 0.4" to 0.58", the
5 plug being characterized in that it comprises three different diameter posts in step like fashion wherein :

a) a first post is essentially circular and has a knurled exterior and a shoulder that is essentially perpendicular to the vertical axis of the post with at least two annular deformable rings of integral construction with the first post;

10 b) a second post essentially parallel to the vertical axis of the plug and inset from the first post and having a diameter smaller than the diameter of the first post, with at least two annular deformable rings of integral construction with the second post, and wherein the lowest ring is integral to the shoulder of the second post;

c) a third post essentially parallel to the vertical axis of the plug
15 and inset from the second post and having a diameter smaller than the diameter of the second post, with at least two annular deformable rings of integral construction with the third post, and wherein the lowest ring provides locating of the plug into a container; each of the second and third posts having an external diameter adapted to a specific, unique range of container neck internal diameters, and wherein said rings of
20 the second post have an external diameter of about that of the first post and said rings of the third post have an external diameter of about that of the second post, and a cap with a vent hole positioned at about the shoulder between the second and third posts.

2. A plug according to claim 1 characterized in that the annular
25 deformable rings are effective in providing stability of the plug in the container, sealing the container, and easing insertion of the plug into the container.

3. A plug according to claim 1 or 2 characterized in that all the posts have a hollow core.

30

4. A plug according to any one of claims 1 to 3 characterized in that the annular deformable rings are positioned on the posts so as not to contact other rings during insertion or under full deformation.

5. A plug according to any one of claims 1 to 4 characterized in that the lowest ring includes a chamfer.

5 6. A plug according to any one of claims 1 to 5 characterized in that the plug forms a minimum of three seals when the plug is located in the container.

7. A plug according to any one of claims 1 to 6 characterized in that the plug is structured to be inserted into the container with an insertion force less than
10 about ten pounds.

Fig. 1 of 2

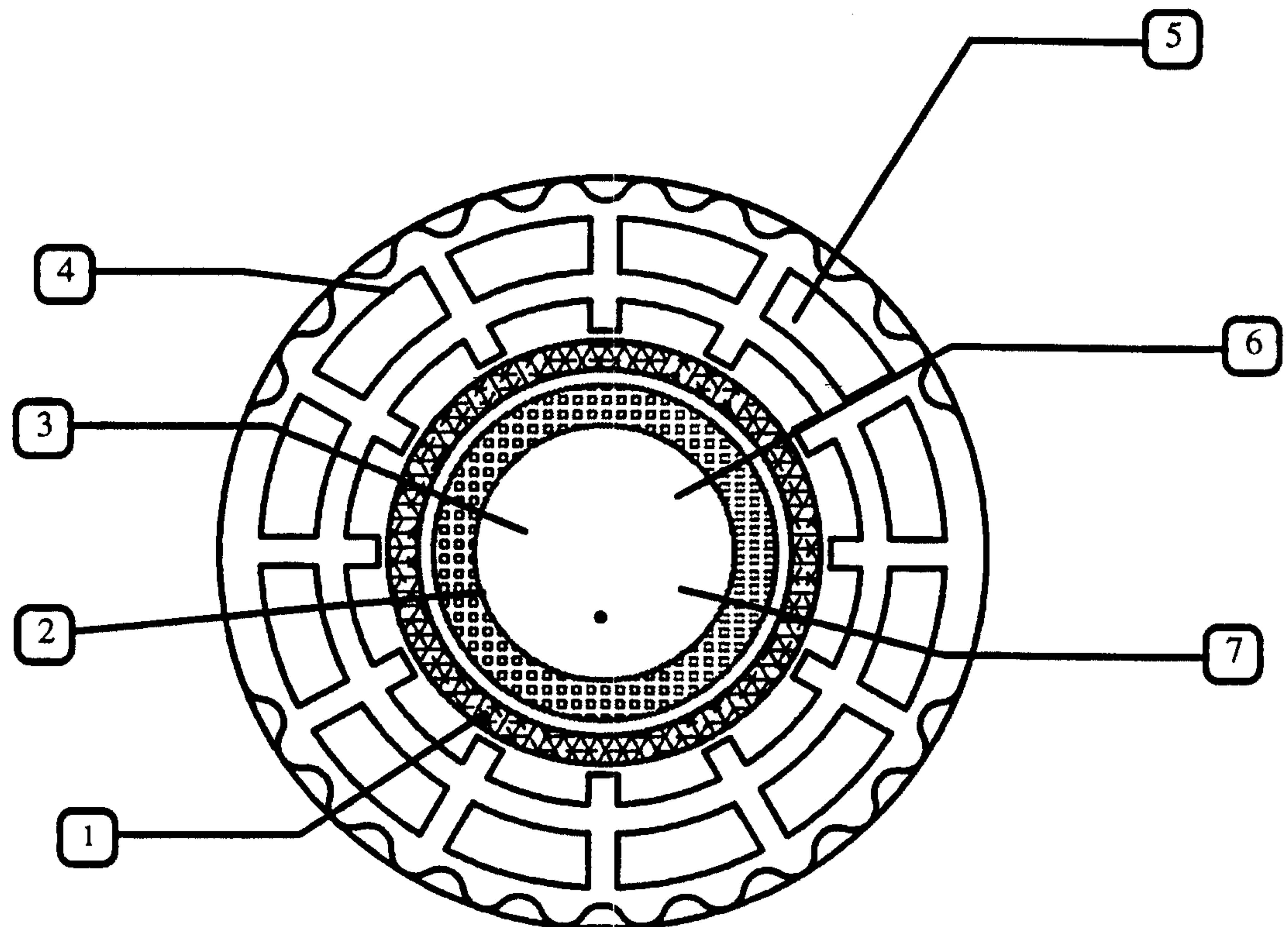


Fig. 2 of 2

