United States Patent

[11] **3,575,225**

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[54] **STERILE SPECIMEN CONTAINER FOR ATTACHMENT TO A SURGICAL TABLE AND FOR OTHER USES**
13 Claims, 5 Drawing Figs.

[52] **U.S. Cl.** **150/8,** 4/110, 128/292, 128/Dig. 24, 150/12
[51] **Int. Cl.** **A61b 19/00,** A47k 11/12, B65d 33/16
[50] **Field of Search** ..... 150/1, 12, 8, (Digest 1); 248/99; 128/292, (Digest 24); 4/274, 110; 99/(Inquiry)

[56] **References Cited**
UNITED STATES PATENTS

3,192,091	6/1965	Hey et al.	156/308
3,021,001	2/1962	Donofrio	206/56(AB)
2,999,387	9/1961	Andelin	128/(Dig.24)
2,991,031	7/1961	Sederquist	248/99
1,458,640	6/1923	Chase	4/110
700,733	5/1902	Buettner	4/259

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ABSTRACT: A heat-resistant, sterile specimen container having a rigid handle, a rigid hinged rim, and a flexible, transparent, graduated bag which is used as a collection and storage receptacle in surgery. The container may also be used in cooking prepackaged frozen foods. The receptacle bag portion is made of pliable heat-resistant plastic. The handle and rim support are made of hard heat-resistant plastic or of metal or of fiberboard.

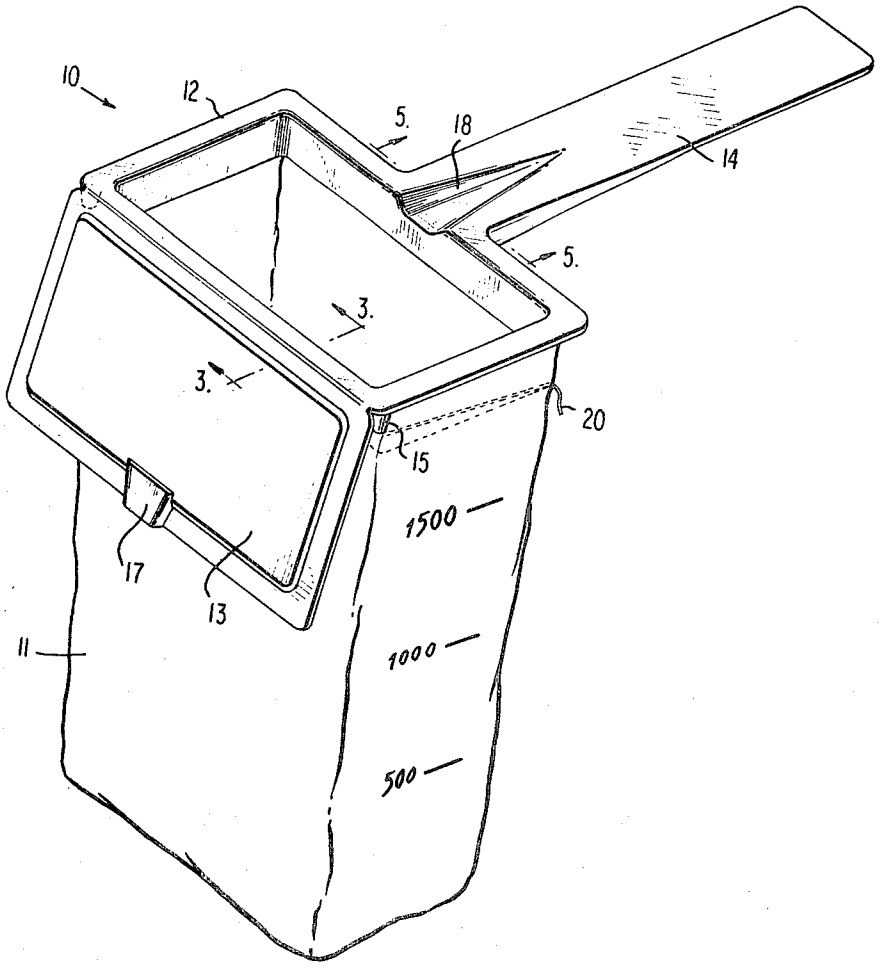


FIG. 1

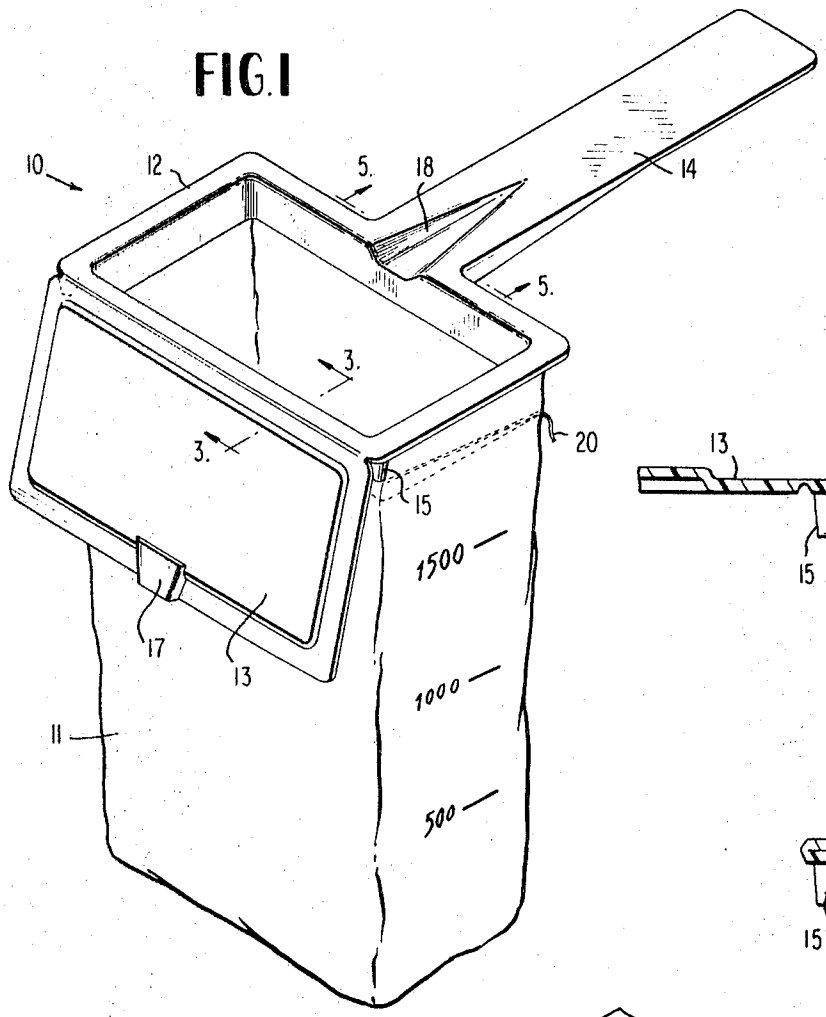


FIG. 3

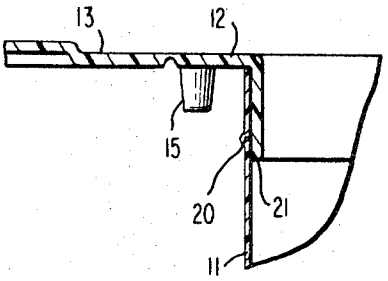


FIG. 4

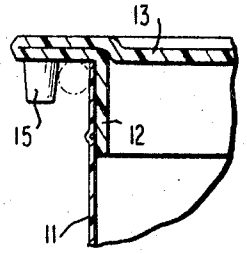
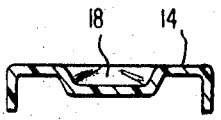


FIG. 5



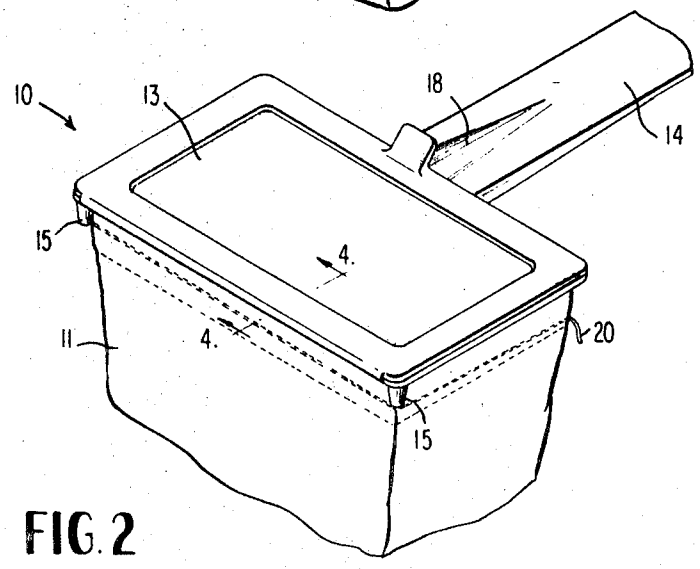


FIG. 2

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STERILE SPECIMEN CONTAINER FOR ATTACHMENT TO A SURGICAL TABLE AND FOR OTHER USES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a surgical drain bag of the type which is supported on a surgical table, such as may be used by a physician or surgeon during obstetric, gynecologic, proctologic and urologic surgery. In medical examinations and operations of these types, the patient reclines on a table which can be positioned laterally and/or horizontally with the physician or surgeon working at one end of the table facing the particular area of the patient for special examination or surgical treatment. It is essential to obtain specimens for later examination in the pathological laboratory or in other departments of the hospital or medical service in order to report immediately concerning the characteristics of the fluids and specimens which have been taken from the patient.

Heretofore, the surgical drain bags have been made part of the table structure, or a makeshift utensil has been used. The present invention relates to a new solution to the problem which is based upon convenience for mounting of the container, economy in construction, and efficiency in sterilization in the collecting and storing of body fluids or specimens.

The invention also fulfills a need in the cooking of prepackaged frozen foods since, without modification, it can store predetermined portions of frozen foods for diet-conscious persons and be used very conveniently by immersing in boiling water, the immersion and withdrawal after cooking being facilitated by an insulated handle which projects beyond the cooking utensil.

2. Description of the Prior Art

A typical approach to solving the problem of providing surgical drainage in convenient form is described in Brenner et al. U.S. Pat. No. 3,386,444, dated Jun. 4, 1968 and entitled "Surgical Drain Bag and Support Therefor." This Brenner et al. patent describes the combination of a surgical drain bag and special support means at the end of the table, which is especially adapted for KUB tract examination.

The purposes of the present invention can be understood in comparing the special novel features which go beyond the objectives of the surgical drain bag-support of Brenner et al.

Automatic high-speed methods of making the novel surgical specimen container, of the type set forth in the present invention, are available to achieve a superior product at lower cost than that which is shown in the drain bag of Brenner et al. The handle and rigid hinged rim portion are formed of a plastic part capable of being readily molded by injection molding techniques, and this part is easily sealed to the flexible bag portion of the container by using known high-speed sealing methods. An example of such high-speed sealing method is shown in U.S. Pat. No. 3,192,091 to Hey et al. granted Jun. 29, 1965, who seal a rigid portion of a container to a flexible portion. Another example of a high-speed method of manufacture is shown in U.S. Pat. No. 3,021,001 to T. F. Donofrio granted Feb. 13, 1962. This Donofrio patent shows a plurality of rigid members being formed and sealed in a single operation, and then the individual containers broken away.

The design of the present rigid handle portion represents a significant change in the manufacture of hinged tops in comparison with the method available for the manufacture of sputum containers of U.S. Pat. No. 700,733 to Buettner et al. granted May 27, 1902.

SUMMARY OF THE INVENTION

The surgical drain bag of this invention has three parts: the lid, the rim support, the receptacle bag held by the rim support. The lid and the support constitute a single unit and are preferably made of the same hard, heat-resistant plastic. Each part has special features pertinent to the effectiveness of the overall unit, as indicated below.

1. The lid is made of hard, heat-resistant plastic, and is attached to the rim of the surgical drain bag and opens away from the handle. Placement in this position avoids interference with the hands of the user. The lid is affixed to the rim by a plastic piano-type hinge. It has a tab opener which snaps into a groove on the handle, thereby closing the bag, and a spout in the handle vents the bag. There is ample space on the top of the lid to label the contents.

2. The rim support is made of rigid, hard, heat-resistant plastic and includes a rigid handle portion which is molded as a unit with the rim. The rim support provides the opening to the receptacle bag, allowing easy access for filling and removing the contents. Two small anchor tabs extend down from the rim on the hinge corners. These tabs allow the bag to be placed securely inside another vessel for laboratory or cooking use. The handle has a tapered groove into which the tab on the lid snaps shut. This groove also provides a channel into the receptacle bag and a vent when the bag is used in the cooking of frozen foods. The location of the handle with respect to the rim and the lid permits the container to be handheld in a surgical situation, and also permits the container to be self-supporting when inserted between the patient and the surgical table. The specific advantages of this feature are explained below in the section pertaining to rectoperineal procedures.

3. The receptacle is a pliable bag made of heat-resistant plastic, either transparent or translucent. The bag receptacle may be bonded permanently to the underside of the rim support during manufacture or may be secured by a permanently tacky, pressure-sensitive, releasable adhesive which permits the bag to be removed from the rim and to be securely closed without contamination for storage or for later examination. The bag is calibrated on the outside or on the inside for accurate measurement of the contents. The bag receptacle can be folded under the support for easy packaging and storage.

In a preferred embodiment, the measurements of the surgical drainage bag are as follows:

Lid –5 inches × 8½ inches
Rim –5 inches × 8½ inches × ⅜ inch
Handle –8 inches × 2 inches × ⅜ inch
Groove in handle–2 inches × ¼ inch (at deepest point)
Interior opening–4 inches × 7½ inches
Receptacle capacity–500 cc., 1,000cc., 1,500 cc., 2,000 cc.

MEDICAL APPLICATIONS 1,000

The surgical drainage bag of this invention is designed for the collection of tissue, specimens, and body fluids in medical-surgical situations. Because it can be prepackaged and sterilized in a tear-back cover, it is most useful during aseptic procedures. Advantages are as follows:

1. Materials are collected, sealed, identified, measured, dispatched, or disposed of in one unit.
2. Contamination of specimens is prevented.
3. Loss of contents is reduced.
4. Accurate measurement of contents is made easy.
5. Spread of infection from contaminated material is reduced.
6. Hospital cost of processing linens and basins is reduced.
7. The time of personnel is saved.
8. Fewer materials are needed.

In general surgery, the container can be hand-held by an assistant while the material is being collected. However, in surgery involving the rectoperineal area and in obstetrics, there are other specific advantages that make the surgical drain bag of this invention most practical. They are as follows:

1. The handle of the bag can be inserted through the opening of the drape sheet between the table and the mattress. The weight of the patient's pelvis secures the container in a fixed position, low enough to avoid interference with the operational field.
2. The surgeon can secure the container at his discretion.

3. Tissues and specimens are scooped directly into the bag, reducing the change of spillage, loss, and contamination of the material.

4. An assistant to hold a basin is no longer necessary, thus reducing possible contamination of the surgical field and providing an unobstructed area for performance of the surgeon's tasks.

5. Blood and fluids drain into the container and are not "lost" in the drapes and buckets. The surgical field stays cleaner and the measurement of the fluids is more accurate.

Specific procedures for suggested medical uses are as follows:

1. Amniotomy: Amniotic fluids are collected for measurement and laboratory study. The recommended size of the bag is 500 cc. to 2,000 cc.

2. Blood loss: Good obstetrical practice requires the measurement of blood loss for all mothers at the time of delivery. Current methods require the transfer of blood collected into a measuring utensil, and blood is "lost" in the linens. A far more accurate measurement can be made with the bag of this invention. The recommended size is 1,000 cc.

3. Placenta: The placenta, or "afterbirth" must be disposed of in some manner. The placenta is bulky, blubbery, slippery, and has a somewhat unpleasant odor. Many are sent to the laboratory for studies. Some hospitals freeze placentas and send them to drug manufactures for the extraction of hormones. Currently, the placentas are collected in a basin and transferred to another container. In some cases, they are wrapped for freezing. With the bag of this invention, the collection and disposal of the placenta is a one-step procedure. The recommended size is 2,000 cc.

4. Hydatidiform mole: These are products of conception requiring laboratory examination. They are often quite large. The recommended size is 1,500 cc.

Recommended bag size for procedures in the field of gynecology are as follows:

1. Spontaneous or therapeutic abortion–1,500 cc.
2. Vaginal hysterectomy–1,000 cc.
3. Dilatation and currettage–500cc.
4. Drainage of Bartholin abscess–1,000 cc.
5. Hymenotomy–500cc.

Recommended bag size for procedures in the field of urology are as follows:

1. Transurethral resection–500cc.
2. Removal of cysts and bladder stones–500cc.
3. Transurethral prostatectomy–100cc.

Recommended bag size for procedures in the field of proctology are as follows:

1. Hemorrhoidectomy–500cc.
2. Rectal fistula and drainage of abscess–1,500 cc.

Recommended bag sizes in the field of general surgery are as follows:

1. Cholecystectomy–500 cc.
2. Gastectomy–1,000 cc.
3. Mastectomy–1,500 cc.

The following nonsterile medical applications are described:

The surgical drain bag of this invention can be packaged in bulk in unsterile boxes for general use in the following manner:

1. Emesis basin: It enables the patient or nurse to handhold the container, measure the contents accurately, and remove it from the patient without spilling.

2. Waste receptacle: As a container for dressings, wipes, and tissues, the bag can be affixed to the bed or examining table and held in place, as in surgery, by the weight of the patient. The lid helps prevent contamination of the environment by enclosing the contents.

OBJECTS OF THE INVENTION

An object of the invention is to provide a container consisting of a receptacle and a lid therefor whereby material may be readily placed therein or removed therefrom in a sanitary and expeditious manner without loss or contamination of such material.

Another object of the invention is to provide a container for the collection of tissue, specimens and body fluids during and for medical-surgical functions, such as during aseptic procedures.

Another object of the invention is to provide a container of such character as to prevent contamination or loss of material in its use.

A still further object of the invention is to provide a container adapted for the preparation and packaging therein of frozen foods. Such foods are frozen, cooked and served in the same container.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the surgical, sterile drain bag of the invention with the lid open.

FIG. 2 is a view of the surgical, sterile drain bag of the invention with the lid closed.

FIG. 3 is a view along section line 3–3 of FIG. 1 showing projected elements under the lid which serve as hooks for attachment over a bar at an end of a surgical table.

FIG. 4 is a view along section line 4–4 of FIG. 2 showing the bar of the table in dotted outline.

FIG. 5 is a view along section line 5–5 of FIG. 1 illustrating the drainage spout facilitating entry of liquids into the pliable container.

In FIGS. 1—5 of the drawings herein, the reference numeral 10 designates the sterile specimen container in its entirety, the container comprising a flexible, transparent or translucent bag receptacle portion 11 which is closed at the bottom and is open at the top. The open top of the bag is fastened to a generally horizontal rigid plastic rim 12. To the one side of the rim 12 opposite the handle portion 14, a lid 13 is hingedly attached by a piano-type hinge so that, in closing, it will lie on the rim 12. From the side of the rim which is opposite the hinged side, there extends a flat handle member 14 which lies substantially in the plane of the rim. The relative locations of the handle and rim are such that the container can be handheld during surgery with no danger of contamination; and it is also possible, at will, for the container to be self-supporting by inserting the handle between the patient and the surgical table, the patient's weight holding the container in position.

As shown in sectional view in FIG. 5 and in perspective view in FIGS. 1 and 2, a vertically tapering and horizontally flaring spout 18 is formed at the handle portion and serves to drain the body fluids from the patient down the inclined channelway to the widened mouth at a line below the upper edge of the rim 12 and to discharge the fluids into the receptacle bag 11.

As shown in FIGS. 3 and 4, mounting buttons 15 project from the underside of the corners of the rectangular-shaped rim 12 to serve as hook elements for engaging a rod which may be used at the laboratory examining station. In use, the sterile specimen container has the handle portion 14 with the rigid rim and flexible bag and when the unit containing the specimen is sent to the pathology laboratory for examination, it must be properly supported pending examination. The buttons 15 may hook over a transverse rod which is provided on the pathology laboratory ringstand apparatus, this rod being a standard feature of all such apparatus. The buttons 15 may be integrally molded with the rim or may be secured by other suitable means, such as a rivet, fastener with adhesive, etc.

The lid and the rim are preferably made of hard, heat-resistant plastic, such as polypropylene, nylon, polyethylene terephthalate, polycarbonate (DELRIN), impact-resistant polystyrene-rubber blends which are commercially available from the U.S. Rubber Company under the name of KRALASTIC (blend of butadiene acrylonitrile copolymer and styrene acrylonitrile copolymer), thermosetting acrylic

polymers, and the like, and the lid and rim are preferably molded as a unit during the manufacture thereof. All of the above polymers are available in injection molding grade for mass production.

The preferred material of the flexible bag 11 is a heat-resistant, transparent or translucent, pliable, heat-resistant plastic, such as high molecular weight polyethylene, polyvinylidene chloride (SARAN), rubber hydrochloride, cellulose acetate, polyethylene terepthalate (MYLAR), butadiene-acrylonitrile copolymer films, or vinyl acetate-acrylic ester copolymer. The bag is calibrated, as at 16, on the outside or on the inside for accurate measurement of the contents. Because the bag material is pliable and the support material is hard and rigid, the bag can be easily folded under the rim of the support for easy packaging and storing.

The handle 14 has a tapered groove 18 as a spout which is broader at the rim junction and into which a tab 17 on the lid snaps tightly to close the receptacle securely. This spout provides a body fluid conducting channel into the bag and also serves as a vent when the bag is used for cooking frozen foods.

When used for medical purposes, the specimen is deposited directly from the patient into the receptacle and is measured, sealed, identified, dispatched or disposed of in one unit, thus preventing loss, contamination, or spread of infection, and also providing a labor-saving arrangement.

The lid and handle portions of the device of the invention may be made of stainless steel, fiberboard or aluminum. Whether of plastic, fiberboard or of metal, the device is easily sterilized by known thermal methods (steam) or by chemicals, and can be reused with a fresh bag. The preferred materials all withstand autoclaving.

This arrangement has obvious advantages in the cooking of frozen foods since the cooking utensils are used only for boiling water and no cleaning is necessary.

An important feature of the invention which adapts the flexible bag portion of the container for easy removal from the rigid handle portion is the string means 20 which is used for quickly opening the top edges of the bag portion 11. As shown in the preferred form in FIG. 1, the string surrounds all four sides of the receptacle 10 at a location beneath the rim 12; and the string is encased within flexible bag 11 in such a manner that the free end 20 projects from the bag at a corner of the receptacle further below the rim than does the rest of the string. The string thus defines an ascending spiral which is adhesively held between the inner top edge portion of the flexible bag 11 and the outer portion of the lower flange of the rim 12.

Tab 17 of the lid 13 enables the nurse or doctor to easily flip the lid into open position when the handle 14 is placed below the patient on the surgical table and the patient's body and weight holds the handle and receptacle in the proper position for collecting the body specimen.

After the specimen has been collected and a volumetric reading has been taken, if necessary, the flexible bag portion 11 can be stripped from the lid 12 and handle 14 by pulling the string upwardly and around the four corners. This is a very easy movement for the doctor or nurse because of the manner in which the specimen is taken and the lower positioning of the end of the string, and one which prevents contamination of the specimen to facilitate more accurate pathological examination and diagnosis.

In an alternative form, the bag 11, with or without the string, may be secured to the rim by pressure-sensitive adhesive between the bag and the vertical flange 12. Of course, during manufacture, it is simple to heat seal the bag 11 to the rim and thereby produce a disposable specimen container good for a single use; but it is preferred to utilize the adhesive bond so that the sterile character of the bag 11 may be maintained and so that the tacky adhesive at the upper edge of the bag may serve to close the top edge of the bag, with the specimen therein, to preserve the sterile condition after collection. In this form, the bag may be sent to the pathology laboratory for further examination or it may be stored under appropriate storing conditions and later examined.

When the container of the invention is used for cooking, the buttons 15 adapt the container to be hooked over the side of a pot which is used for boiling water. In the form of the invention used for cooking, the buttons 15 and the pressure-sensitive adhesive which come into contact with the heated metal pot must be resistant to temperatures higher than those encountered during pasteurization and sterilization.

Accordingly, the pressure-sensitive, permanently tacky adhesives which are useful retain their adhesive properties at elevated temperatures and are preferably based upon mixtures of temperature-resistant rubbers, such as polyisobutylene rubber, or heat-resistant polyvinyl ethers with tackifying resins, such as an ester of hydrogenated rosin, these being modified, if desired, with heat-resistant polymers of butyl acrylate or copolymers of butyl acrylate-butyl methacrylate. Other tackifying agents, well known in the art, may be used instead of the above-mentioned rosin, such as coumarone-indene resin or terpene resin.

I claim:

1. A heat-resistant specimen container adapted to be supported on a surgical table below a patient during diagnosis and treatment and also adapted for cooking frozen foods therein, comprising: a rigid hinged rim provided with a handle portion projecting from a side of the rim opposite the hinge and with a lid which swings from said hinge to open and close the container; a flexible, heat-resistant bag formed of pliable plastic secured at its top to said rim; and a tapered, grooved spout formed in said handle portion which is broadened at the rim junction to provide a body fluid conducting channel terminating below the upper edge of the rim and serving as a vent when the closed container is used in boiling water for cooking frozen food therein.

2. A container as claimed in claim 1, wherein said bag receptacle is adhesively attached to said rim.

3. A container as claimed in claim 2, wherein said adhesive is a pressure-sensitive, permanently tacky adhesive selected from the group consisting of polyisobutylene rubber, heat-resistant polyvinyl ethers with tackifying resins, polyisobutylene rubber modified with heat-resistant polymers of butyl acrylate, polyisobutylene rubber modified with copolymers of butyl acrylate-butyl methacrylate, heat-resistant polyvinyl ethers with tackifying resins modified with heat-resistant polymers of butyl acrylate, and heat-resistant polyvinyl ethers with tackifying resins modified with heat-resistant copolymers of butyl acrylate-butyl methacrylate, these adhesives adapting the bag to be sealed to the rim and after separation of the bag from the rim, to reseal opposing faces of the bag.

4. A container as claimed in claim 1, wherein said rim is provided with buttons projecting from the underside which serve as hooks to adapt the container for additional support at the edge of a pot when used for cooking or on a ringstand.

5. A container as claimed in claim 1, wherein, during the manufacturing process, a tear string is placed between the bag and the rim in an ascending spiral pattern around all sides of the bag and rim, with the free end of said string being exposed to permit quick tearing of the bag away from the rim, said free end being located at the lowest point of said spiral.

6. A container as claimed in claim 5, wherein said bag is heat-sealed to said rim and said bag cannot be resealed.

7. A container as claimed in claim 5, wherein said bag is adhesively sealed to said rim with a heat-resistant, permanently tacky, pressure-sensitive adhesive which adapts the bag to be resealed after separation from said rim.

8. A container as claimed in claim 1, wherein said lid is provided with a locking means cooperating with said handle to lock said lid over said bag.

9. A container as claimed in claim 1, wherein said bag is provided with indicia.

10. A container as claimed in claim 1, wherein said handle is generally flat, said rim and bag are generally rectangular in

shape, and said handle extends rearwardly from said rim to adapt holding the container and contents in the hand.

11. A container as claimed in claim **1**, wherein said rim and handle are made of heat-resistant fiberboard.

12. A container as claimed in claim **1**, wherein said rim and handle are made of heat-resistant plastic.

13. A container as claimed in claim **1**, wherein said rim and handle are made of metal.