

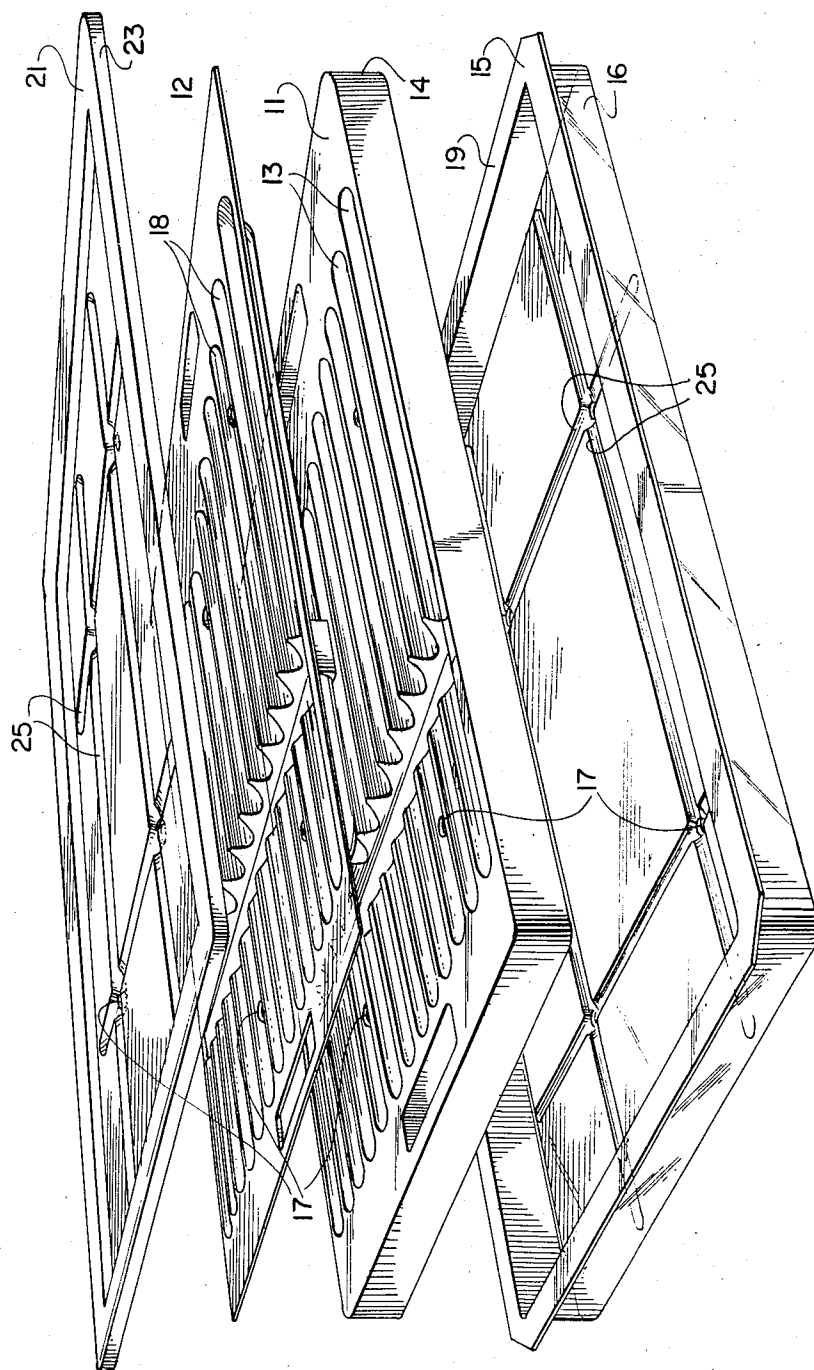
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J. N. KOVALCIK ET AL

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CONTAINER FOR SURGICAL INSTRUMENTS AND APPLIANCES

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INVENTOR

JOHN N. KOVALCIK

BY

ATTORNEYS

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CONTAINER FOR SURGICAL INSTRUMENTS AND APPLIANCES

John N. Kovalcik and Donald B. Hovis, Port Credit, Ontario, Canada, assignors to Medipak Corporation Limited, Toronto, Ontario, Canada
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ABSTRACT OF THE DISCLOSURE

An autoclavable tray for surgical implements having a transparent lid and liner of a plastic material, having a non-sticky non-scratching surface, dimensionally stable at autoclave temperatures, and tending not to provoke an immune reaction when introduced into the human body.

BACKGROUND OF THE INVENTION

This invention relates to storage containers for sterilized items such as surgical instruments and appliances.

Medical and dental instruments, appliances and implements hereinafter referred to for convenience as "surgical implements," which require sterilization, come in a multiplicity of shapes and sizes. These items may be shipped by the manufacturer to hospitals, etc. either individually or as sets in containers having one or more interior spaces formed to fit the particular implement or implements shipped. When the surgical implements reach the hospital, they have to be stored in readily accessible containers suitable for insertion into an autoclave for the purpose of sterilizing the implements contained in the container.

A number of problems have existed both with respect to shipment and with respect to the autoclaving of such surgical implements. In the first place, a metal-to-metal contact between the surgical implements and their container should be avoided because of the possibility of scratching the surgical implements, which sometimes has the effect of creating a crevice within which microbes could lodge without being removed during the autoclaving procedure. Furthermore, materials which tend to provoke an immune reaction mechanism in patients should be avoided for the housing of such surgical implements, because if traces of foreign material adhere to the implements when they are inserted or perhaps implanted in the human body, the foreign material can cause an immune reaction in the human body with detrimental results to the patient, unless the foreign material is accepted by the body. Furthermore, containers suitable for autoclaving must be able to withstand the high temperatures (about 280° to 320° F.) required for sterilizing the contents.

Accordingly, it has been customary for manufacturers of such surgical implements to ship the implements in form-fitting containers e.g. of polyfoam. Following their reception at the hospital, the implements are autoclaved in heat-resistant containers in which they are stored. Representative containers known in the art are described in U.S. Pat. No. 2,018,651 (Bates, Oct. 29, 1935); U.S. Pat. No. 3,261,660 (Wilkinson, July 19, 1966); U.S. Pat. No. 2,472,028 (Son, May 21, 1949); U.S. Pat. No. 3,285,409 (Loran, Nov. 15, 1966) and U.S. Pat. No. 3,437,423 (Mondiadis, Apr. 8, 1969). Of these, all but the Mondiadis patent disclose metal containers. Mondiadis discloses a blow-moulded thermoplastic container made of polypropylene, polycarbonate, polyvinylidene fluoride, polytrifluoroethylene, vinyl chloride-acrylonitrile copolymer, polytetrafluoroethylene or polyphenylene oxide.

A disadvantage associated with all of these heretofore

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known containers is that they are opaque, and thus the contents are not known except by labelling (which is subject to human error). A delay in an operation caused by such incorrect labelling can have adverse consequences to the patient.

SUMMARY OF THE INVENTION

According to the invention, a container suitable for both shipping and autoclaving items such as surgical implements is provided in which at least the lid is transparent so that the contents of the container can be inspected without opening the container. The material which completely surrounds the implements is made of a autoclavable, non-sticky material which does not tend to provoke an immune reaction when introduced into the human body i.e. is non-immune reacting. A number of suitable materials are available, examples being nylon, polycarbonate, polysulfone, and tetrafluoroethylene-hexafluoro-propylene copolymer, commonly referred to as FEP-fluorocarbon. These materials can be made as a transparent or nearly transparent sheet or film. According to the invention that part of the container in contact with the implements is made of such material so as to minimize the risk that the material will enter the human body and to minimize the risk that if the material does enter the body, it will have harmful effects. The shape of the lower part of the container is preferably designed to conform to the shape, configuration and quantity of the contents. Preferably, two or three subcomponents are used rather than a single lower tray. A standard-shaped, structurally rigid lower tray, fitted to the lid, contains at least one insert or liner which is form-fitted to the contents of the container. The lid directly faces and is adjacent the liner, and is replaceable without heat sealing. There may be only one insert, which is in direct contact with the contents of the container, and therefore may, if desired, be made of the same sort of material as the lid. The liner need not necessarily be transparent but must be non-sticky, non-scratchy, and non-immune reacting, and must also be dimensionally stable at autoclave temperatures. The lower supporting tray for the liner need not be made of the same material (because it does not directly touch the contents), but must be made of material capable of withstanding the autoclave temperatures and selected from commercially available materials suitable for providing the required structural strength and economy of manufacture. For example, polypropylene would be satisfactory for this purpose. Finally, there may be two inserts—a lower insert or nest of opaque material, to which suitable labelling may be applied, and an upper transparent liner or film, fitted to the lower insert, and in direct contact with the contents of the container. This variant makes possible an interior labelling without the danger that the surgical implements will be in direct contact with the labelling pigments.

The manufacturer of the implements can design the insert(s) for convenient shipping and display of the contents of the container. The contents can be autoclaved in the container, autoclaving tape being applied to the juncture of the lid and the lower part of the container to seal the container and to indicate that the autoclaving procedure has been followed (because of the colour change of the autoclaving tape). The entire container may in turn be placed inside a conventional permeable dustproof bag, in accordance with usual practice. Of course, if the contents of the tray are to be viewed while it is in the bag, the bag must be transparent as well. The container can then be stored at the hospital or as the case may be, without further autoclaving and without removal of the contents to another container. The container itself, with the lid removed, can be used as the dispenser in the operating room. Use of the tray and liners as a dispenser, with form-fitting recesses in the insert(s) facilitates the correct re-

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placement of implements and also facilitates implement counts following operations. Because the lid is transparent, the contents of the container can readily be ascertained and errors in the operating room heretofore caused by erroneous selection of autoclaved containers due to confusion as to the contents of a particular container (because of the opacity of previously used containers) will tend to be avoided. The transparency feature is particularly advantageous for military field operations. Because the only material in contact with the surgical implements is non-sticky, and non-scratching plastic, there is no danger of scratching the implements. Furthermore, there is minimal danger of provoking the immune reaction mechanism in the human body, because the lid and insert material is selected so that it will be accepted by most human beings without causing the immune reaction. This material is also preferably selected to have excellent release or nonstick characteristics (i.e., foreign material is readily released from the surface of the material during the washing and autoclaving procedures.) The use of transparent material for the surfaces in direct contact with the instruments being autoclaved tends to avoid any possibility that pigment in the material could adhere to the implements. (Such pigments, unlike the basic material, can tend to provoke the immune reaction mechanism.) All materials used must be selected to be highly dimensionally stable at autoclaving temperatures. (This may require low temperature stability for low (freezing) temperature autoclaving.) Finally, the material should preferably be chosen for economy, and thus preferably should be suitable for vacuum or thermal moulding, so that the more expensive blow-moulding and injection-moulding techniques need not be used. A number of suitable plastic materials are known, and others may exist or may be developed which have similar properties, and can be used according to the invention.

SUMMARY OF THE DRAWING

The drawing is an exploded perspective view of an exemplary embodiment of a container according to the invention.

DETAILED DESCRIPTION WITH REFERENCE TO THE DRAWING

The container according to the invention can be made of as few as two components but is preferably made of three or four components, the latter choice being illustrated in the drawing. The lower opaque insert or nest 11 is provided with a plurality of formed recesses 13 each having a size and shape adapted to conform to a particular surgical or dental appliance or instrument, or the like, to be housed in the container. The nest 11 is preferably made of an opaque, dimensionally stable plastic material, such as polypropylene, to which labeling may be applied to identify the manufacturer, the contents, the appropriate hospital operating theatre, or the like. It is sufficiently thick and with sufficient structural rigidity that it gives adequate structural support to the contents of the container. It is provided with side flanges 14 of a height sufficient to accommodate the thickness of the surgical implements to be housed in the container.

The lower tray 15 is moulded to fit the undersurface of the nest 11 so that a reasonably snug fit between the nest 11 and the tray 15 is obtained when the two are pressed together. The tray 15 must, of course, be capable of maintaining dimensional stability at autoclave temperatures. Like the nest 11, the tray 15 may also be made of a material such as polypropylene. The height of side walls 16 of the tray 15 should be chosen to accommodate the full height of flanges 14 of nest 11. Optionally, the tray 15 will be of a standard size and shape (for stacking, etc.) and the height and periphery of flanges 14 of nest 11 will be selected to fit the tray 15. The shape and size of the

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recesses 13 will, of course, vary considerably to fit various surgical implements.

An insert or element in the form of a film or liner 12 is provided having a plurality of recesses 18 which exactly match the recesses 13 in the nest 11. The liner 12 conveniently may be made of transparent plastic material, such as nylon, or polycarbonate or polysulfone of the kind sold by Rowland Products, Inc., Kensington, Conn., or tetrafluoroethylene - hexafluoropropylene copolymer, commonly referred to as FEP-fluorocarbon, sold by E. I. du Pont de Nemours & Company, Wilmington, Del. All of these except polycarbonate and polysulfone are known to tend not to provoke the immune reaction mechanism, and the inventor believes that polycarbonate and polysulfone will also be satisfactory in this regard. Thus the surgical implements come into direct contact not with the opaque (and thus possibly pigmented) nest 11, but with the transparent liner 12. This tends to avoid provoking an immune reaction, and also enables the user to see the labelling, colour coding, etc. of the nest 11. The liner 12 may be of very thin film (perhaps only a few mils thick) and can, if desired, be replaced after each operation, without the necessity of replacing any of the other container components. Whether or not the liner is transparent, it must according to the invention be non-sticky, non-scratchy, non-immune reacting, and dimensionally stable at autoclave temperatures.

The tray 15 is provided with a peripheral horizontal flange 19. This structure is convenient for the fitting of a transparent lid 21 to the tray 15. The lid 21 is preferably made of the same material as the liner 12, but is perhaps .020 inch thick. The lid 21 is replaceable on the tray 15 without heat-sealing. It has a peripheral flange 23, the shape and dimensions of the flange 23 being chosen so that a tight fit of the lid 21 against the inserts 11, 12 and tray 15 occurs. Autoclave tape (not shown) may be applied around the peripheral flanges 19 and 23 when the elements 11, 12, 15 and 21 have been fitted together, so that the container may be sealed and so that the colour change in the autoclave tape can reveal to any person examining the container that the autoclaving procedure has already occurred, in accordance with common practice in the medical arts. The lid 21 is also preferably of a standard size and shape, for convenience in stacking, etc. and also to permit manufacturers and users to change only the inserts when packing or storing a different set of implements.

All three of the elements 11, 15 and 21 are preferably formed by conventional thermal-forming or vacuum-forming techniques. These techniques are commonly understood in the plastics technology and require no further elaboration.

For some purposes, it may be preferable to dispense with the liner 12 altogether, in which case the nest 11 should not be pigmented but should be formed of material of the type previously mentioned as suitable for the liner 12.

Indeed, it is possible to eliminate both of the inserts 11, 12 and have the support tray 15 made of material of the type previously mentioned as suitable for the liner 12, preferably with individual recesses (not shown) such as recesses 13 in nest 11, to accommodate the surgical implements intended to be housed in the container.

However, to enable a standard size of tray and lid to be used, at least one insert is preferred. And for convenience of colour coding or labelling, two inserts as described are desirable.

To improve their structural rigidity, lid 21 and tray 15 may be provided with transverse or longitudinal ridges, or both, exemplary ridges being designated by reference numeral 25 in the drawing.

A plurality of holes 17 may be provided throughout the inserts 11 and 12, the lid 21 and the tray 15 for drainage during washing or flushing, most of which holes may conveniently be located in the recesses for the implements.

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The holes also enable steam or other sterilant to pass between the component elements when they are fitted together in the autoclave.

It is obviously possible to construct a "fishing tackle" type of surgical implement container according to the invention having a plurality of different sizes and shapes of compartments for various surgical implements, but which recesses are not form-fitted to any particular implement, so that the contents of the container may be varied from time to time.

What we claim is:

1. A resterilizable surgical implement storage container, comprising:

a bottom assembly into which the implements may be placed;

a transparent fitting lid for the container replaceable without heat-sealing, whereby the fitting lid and bottom assembly when fitted together completely enclose the contents, the bottom assembly having an element directly facing and adjacent the lid and upon which element rest the contents of the container;

the material of the lid and of the said element being non-sticky, non-scratching, plastic material maintaining dimensional stability at autoclave temperatures and at room temperature, and being non-immune reacting.

2. A container as defined in claim 1, wherein the bottom assembly includes:

a supporting tray, and

the element is a liner which fits into the tray.

3. A container as defined in claim 2, additionally comprising a second insert made of opaque plastic material which nests within the tray and is disposed beneath the liner.

4. A container as defined in claim 1, wherein the plastic material is selected from the following types of material: nylon, polycarbonate, polysulfone, and tetrafluoroethylene-hexafluoropropylene copolymer.

5. A container as defined in claim 4, wherein the bottom assembly and the fitting lid are molded pieces, and the element includes at least one recess fitted to a predetermined surgical implement.

6. A container as defined in claim 5, wherein the lid, and bottom assembly are provided with a plurality of small holes permitting steam or other sterilant to penetrate the container.

7. A container as defined in claim 5, wherein the lid, and bottom assembly have mating peripheral flanges

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suitable for receiving autoclaving tape to seal the container.

8. A resterilizable surgical implement storage container comprising:

a bottom assembly including a tray into which the implements may be placed and which is provided with at least one recess generally corresponding in shape and size to at least one preselected surgical implement;

a transparent lid replaceable without heat-sealing, fitting the tray and with the bottom assembly completely enclosing the contents of the container;

a replaceable liner directly facing and spaced from the lid and mating with the tray for close fitting contact therewith, and upon which the implements rest;

the material of the lid, bottom assembly, tray, and liner being non-sticky, non-scratching plastic material, which maintains its dimensional stability at both autoclave and at room temperatures, and being non-immune reacting.

9. The surgical implement storage container as defined in claim 8, wherein the plastic material is selected from the following types of material: Nylon, polycarbonate, polysulfone, and tetrafluoroethylene-hexafluoropropylene copolymer.

10. The surgical implement storage container as set forth in claim 8, wherein the lid and bottom assembly are provided with a plurality of small holes permitting steam or other sterilant to penetrate the container.

11. A container as defined in claim 8, wherein the lid and bottom assembly have mating peripheral flanges suitable for receiving autoclaving tape to seal the container.

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MORRIS O. WOLK, Primary Examiner

J. T. ZATARGA, Assistant Examiner

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