

A STERILISATION CONTAINER, METHOD OF STERILISATION AND STERILISATION APPARATUS

FIELD OF THE INVENTION

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The present invention relates to a single use/disposable impervious sealable container for sterilising items that is capable of retaining a vacuum for an extended period, a sterilisation process using the container and a sterilisation system suitable for use with the container.

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BACKGROUND OF THE INVENTION

In a healthcare facility it is necessary that all equipment and materials used for treating patients are safe for use; the chance of spreading infection should be minimal. As is well known, articles used in the operating room, such as surgical instruments, must be sterilised before each use.

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The current steam sterilization industry best practice packaging using porous materials has a contestable and identified risk associated for the patient, by transference of infection and the risk of re-contamination of the sterilized items from airborne micro-organisms.

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Currently used medical packaging (with the exception of irradiation methods) typically requires a porous section to facilitate the removal of air and the introduction and removal of sterilant and moisture. This porous section is then relied on as the barrier after processing. Variations in temperature and pressure can result in air being drawn into the sterilised article with the potential for recontamination.

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Notwithstanding the substantial research and investment in breathable sterile barrier systems the necessity of the barrier material to be breathable during the

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sterilisation process/cycle in the steriliser chamber and then conversely an impervious barrier system after sterilisation is extremely unlikely. This conflicting demand of the breathable barrier system poses a dilemma for most current products.

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The dichotomy of the sterile barrier system persists in current practices and the challenge for the packaging suppliers and users is that the sterile barrier system must be porous or breathable to facilitate air removal and sterilant penetration/removal during the sterilisation process within the steriliser and then crucially at the completion of a successful sterilisation process, provide impervious protection as a viral and liquid barrier until aseptic release at point of use.

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In current practice at the end of a correct sterilisation process, articles inside the steriliser chamber are sterile. The air in the room where the steriliser is installed contains dust particles, which may carry microorganisms; therefore the potential exists when taking out the load from the steriliser that it may be contaminated again.

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Additionally sterile articles are usually stored for quite some time before use and moreover they are transported through the healthcare facility to the place they are to be used. It is thus obvious that when not protected the goods may be re-contaminated by the time they are used.

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Articles therefore must be placed in a packaging to prevent recontamination after sterilisation and at the same time the packaging should be suitable to allow sterilisation of the articles it contains within a steriliser chamber. Packaging is essential for maintaining sterility; moreover the packaging must protect its load against damage during handling and transport.

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Current practices of packaging depending on the use, storage and transportation, dictates that a sterile article should be packaged in one or more packaging layers. The inner primary packaging endeavours to prevent recontamination of the articles after sterilisation and hopes to provide an effective microbial barrier whilst it must allow the passage of air and the sterilant. The secondary layer is applied to facilitate proper storage and transport protection of the articles whilst it must allow the passage of air and the sterilant and in addition the combination of the packaging layers must allow the passage of air and the sterilant. The 'barrier' to microbiologic ingress is thus defined as a tortuous path.

The combination of the packaging layers therefore strives to function as a sterile barrier system that enables medical articles to be sterilised, maintain sterility and ensure the articles sterility until the time of use or the packaging expiry date. The ISO definition of a sterile barrier system is "a minimum package that prevents ingress of micro-organisms and allows aseptic presentation of the product at the point of use".

Due to current sterilisation practices the sterile barrier system is required to be "breathable" and sterile packaging is the single biggest challenge to successful sterilisation. Due to the requirement of the packaging to act as a barrier once sterile – it is inherently difficult to extract air, insert steam and subsequently extract the resultant condensate to leave the load dry, through this barrier system. Advances in non-woven wraps with their more effective barrier construction have contributed to compounding this problem.

Fundamental to air extraction is the rate at which the air to be removed from the pack can physically pass through the barrier. No allowance for load sizing or service (water pressure/steam supply) variance or time-based extraction is implemented. A common problem with today's sterilisers is the vacuum system is too efficient and the vacuum stages cycle faster than the air can get out through the barrier (A common symptom of this is packs 'blowing up' under vacuum).

Conversely the pressure stages that are supposed to force steam into the packs are also too efficient and the steam simply cannot penetrate effectively in the time allowed due to the multiple layers (torturous path) of the porous wrap.

- 5 This very typical problem encountered with breathable sterile barrier systems is made even worse by lightly loaded cycles or mixed loads where some porous packs are in with non-porous instrument cases etc. and results in inadequate air removal, steam penetration failure and non-sterile packs within the loads.
- 10 Traditionally packaging materials were reusable but due to their inadequate microbial barrier properties most of these traditional materials do not meet the requirements for primary sterile packaging anymore. Presently non-wovens, laminated film pouches, paper bags and containers are used as primary packaging materials. These include muslin wraps, various paper wraps and non-
15 woven wraps, or alternatively laminated film pouches or sterilisation containers. The wraps are typically secured by autoclavable tape which may become detached during processing or in the handling of a package leading to rejection of the package. An important feature of fabric is its “breathability” or the ability of the fabric construction to allow the passage of air and water vapour (i.e. steam).
20 Current practices where breathable packaging is required to allow the passage of the sterilant (water vapour/steam) in and out of the package during the sterilisation process places huge demands on the breathable packaging at the conclusion of the sterilisation process to then act as a viral and liquid barrier to ensure impervious protection of the terminally sterile load. The sterilised package should
25 be constructed so that it may be easily opened without the packaging contaminating the contents.

The minimum requirement of any packaging configuration is that it will maintain sterility of the package load until aseptic presentation at the point of use.

Due to the many variables sterilisation services practitioners are faced with everyday new standards are evolving and the International Organisation for Standardisation (ISO) is working globally to coordinate standards.

5 The most recently published standard ANSI/AAMI ISO 11607:2008 section titled
“Packaging for terminally sterilised medical devices” has two parts namely; Part1:
Requirements for materials, sterile barrier systems and packaging systems, and
Part2: Validation requirements for forming, sealing and assembly processes. The
emphasis is clearly on patient safety regardless of where or how the product is
10 sterilised.

Packaging utilized for sterilisation and forming a barrier system for subsequent
storage and transportation is typically comprised of non-woven wraps, paper and
plastic pouches or rigid metal and plastic vented containers.

15 Rigid containers offer another option for enabling sterilisation of medical
instruments and items. They are usually re-usable and come in a variety of sizes
and materials.

20 The containers consist of a receiving body, often with a perforated base, over
which perforations a filter of porous material is fitted and located in place with a
retainer. A separate lid, with a similar perforated area, filter and retainer is latched
and locked onto the base. The lid has a silicon seal fitted around the top for sealing
to the base. The items to be sterilised are typically loaded into a removable basket
25 or tray that is lowered into the container.

Rigid containers being reusable are susceptible to damage over time and must
be carefully inspected before each use. Correct placement of the filter is essential
and the filter material must be of the manufacturers approved type.

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- Unfortunately this visual inspection methodology is very subjective and there is no qualitative way of determining the biological barrier integrity of the locked container post sterilisation in an autoclave. Small dents in the base or lid mating areas or nicks in the seal are likely to mean the seal is unable to form a barrier.
- 5 Defects in or incorrect fitment of the filters and retainers can expose the perforations and provide a path for contamination. Clinicians therefore have less confidence in the efficacy of the container's sterile barrier and the sterility of the contents the older the container gets.
- 10 Re-use requires decontamination and proper cleaning of the containers and lids. This means additional resources for the hospital both in staffing and services such as steam, water and detergents.
- 15 Servicing of the containers is an ongoing and real cost including the requirement to purchase additional containers whilst damaged containers are off site for repair.
- 20 The applicant's prior application published as WO2007/055595 discloses a sterilisation method and apparatus in which items to be sterilised may be sterilised within a plastic bag whilst the exterior of the sterilisation bag is maintained at atmospheric pressure. The applicant's prior application WO2010/093265 discloses an improved bag. The disclosure of these applications is hereby incorporated by reference.
- 25 It is an object of the invention to provide an improved sterilisation container, system and apparatus or to at least provide the public with a useful choice.

SUMMARY OF THE INVENTION

There is thus provided a rigid or semi-rigid single use/disposable container having:

- 5 a. a base and side walls of non-porous material defining a cavity for containing an item or items during steam sterilisation and isolating it from its surroundings after sterilisation;
- b. a rim extending outwardly from the walls; and
- c. a sealable conduit configured and arranged so that, in use, steam sterilant may be introduced into the container and steam sterilant and
10 condensate may be removed from the container via the conduit.

There is further provided a method of steam sterilisation comprising:

- a. providing a rigid or semi-rigid container having an opening for receiving an item to be sterilised and a sealable conduit located at or near the base
15 of the container extending away from the container;
- b. placing an item to be sterilised within the cavity;
- c. applying a cover over the opening;
- d. removing fluid from the container;
- e. introducing steam sterilant into the container through the conduit and
20 around the container to provide the required sterilisation;
- f. extracting fluid in the container via the conduit; and
- g. sealing the conduit.

There is also provided a steam steriliser comprising:

- 25 a. a sterilisation chamber having a cavity dimensioned to receive one or more rimmed containers to be sterilised;
- b. one or more top plate adapted to clamp against each rim during sterilisation;
- c. one or more ports providing a fluid path from within the chamber to the
30 exterior of the chamber;
- d. a vacuum for extracting fluid from the chamber via the one or more port;

- e. a steam source for supplying steam sterilant via the one or more port;
and
- f. a sealing device for sealing the conduit of the container.

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BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described by way of example with reference to the accompanying drawings in which:

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Figure 1 shows an exploded view of a container, tray, tray lid and cover;

Figure 2 shows a perspective view of a container with a container lid applied;

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Figure 3 shows an end view of a container, cover, tray and tray lid;

Figure 4 shows a perspective view of a steam steriliser, a container to be sterilised and container spacers;

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Figure 5 shows a perspective view of a container partially within the steam steriliser; and

Figure 6 shows an end view of a container within a steam steriliser.

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DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

5 In response to the challenges encountered by those of skill in the art, and from the following description, it will be evident that the requirements listed below are desirable:

One time use disposable container

10 A single use container avoids the performance and maintenance issues associated with reusable containers.

Enabling sterilisation

15 The packaging will allow fluid that is in the packaging to be evacuated and the sterilant or sterilising agent to be introduced to reach all surfaces of its contents.

Compatible with the sterilisation process

The combination of the apparatus and packaging will be able to withstand the conditions that occur during the sterilisation process such as pressure changes, high temperature and humidity.

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Ensure product integrity and patient safety

25 The sterilisation container/sterilisation process will not affect the item(s) in any other way, which may affect the quality of the item(s) or which might endanger the patient or process on which the sterile item(s) will be used, subject to the item(s) to be processed being rated for the sterilisation temperature and pressure.

Maintaining Sterility

After taking the sealed and vacuum packed sterile load/item(s) out of the apparatus it/they will remain sterile during handling, transportation and storage until use, whilst package seal integrity is intact.

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Packaging authentication

Authentication of the packaging prior to sterilisation of item(s) is desirable to ensure an authenticated and validated sterilisation container is derived from tested and approved film to facilitate most appropriate functionality with respect to sterilisation process, sealing integrity, handling, transportation and shelf-life.

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Tracking and traceability

The apparatus and packaging may desirably process individual loads/trays with each load/tray incorporating a unique identification code written to a RFID tag or similar (attached to the load) and captured in a database to facilitate data logging of process parameters per individual package and to facilitate full tracking and traceability of individual loads throughout its lifecycle.

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Indicator

Transparent sealed packaging facilitates visual verification of sterilisation process indicators.

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Facilitate aseptic opening and presentation

Simple opening of a sealed vacuum packed sterile load/item(s) facilitating aseptic opening and direct access to the sterile load.

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Visible and tactile indication that packaged has been opened or breached

Subjecting the package to a vacuum state whence sealed after load sterility is achieved enables immediate visible indication of package vacuum loss due to either a fault of seal integrity loss, package integrity breach or package opening under normal controlled aseptic opening of terminally sterilised package. In the

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event that the package has lost its vacuum as a result of a failure the package may be immediately be deemed contaminated and no longer sterile.

Referring now to Figures 1 to 3 an exemplary container will be described.

5 Container 1 is a rigid or semi-rigid container having a base 2, and side walls 3 to 6 with a rim 7 around the top of the container. The container also includes a sealable conduit 8 having a pair of spaced apart side walls 9 and 10 forming an elongate opening which in this case extends along the entire length of side 3. The conduit 8 is configured and arranged so that, in use, steam sterilant may be
10 introduced into the container and steam sterilant and condensate may be removed from the container via the conduit. The two opposing side walls 9 and 10 may then be sealed together to seal the conduit 8.

Conduit 8 is desirably provided at or near the base 2 of container 1 to facilitate
15 draining of fluid (gas or liquid) from the container. Whilst in this embodiment the conduit is shown extending laterally from container 1 it could also be provided in base 2 extending downwardly. The conduit 8 is preferably elongate in cross section and generally parallel to the base 2 so as to provide steam sterilant throughout the container and provide effective draining. The conduit preferably
20 extends along at least half the length of a side wall of the container, and preferably along the entire length, to ensure good steam distribution within the container. The conduit side walls 9 and 10 are preferably greater than 50mm in length (the x dimension in figure 1), and more preferably greater than 150mm in length. In preferred embodiments the side walls are between 50mm and 1800mm in length, more preferably between 150mm and 600mm in length. The conduit side walls 9
25 and 10 preferably extend at least 5mm away from the body of the container (the y dimension in Figure 1) to facilitate heat sealing, and more preferably greater than 10mm. The spacing between the side walls 9 and 10 is preferably between 5 and 25mm (the z dimension in Figure 1). Whilst these ranges are preferred, in
30 other applications the length could be up to or greater than 10m. For a container that has a side wall that is 50 mm long with a spacing between conduit side walls

9 and 10 of 25 mm the aspect ratio along the conduit (viewed in direction y) will be 2:1. This is an extreme example and the aspect ratio will typically be much greater. For example for a more standard sized container having a side wall that is 150mm long and a spacing between conduit side walls 9 and 10 of 25 mm will result in an aspect ratio of 6:1. The typical aspect ratio will be higher than this as the 25mm spacing is greater than will typically be employed.

Handles 11 (an identical handle is provided on the opposite side) facilitate handling of the container and in combination with locating elements 12 (identical on the opposite side) assist in locating spacing elements discussed below.

Container 1 needs to be formed of a material providing an effective microbiological barrier and capable of withstanding internal steam sterilisation process temperatures. Depending on the sterilisation regime selected this may be exposure to steam at a temperature of at least 115 degrees Celsius for at least 40 minutes; a temperature of at least 121 degrees Celsius for at least 15 minutes; or a temperature of at least 138 degrees Celsius for at least 3.5 minutes. The material will also desirably withstand external steam sterilisation process temperatures of up to 180 degrees Celsius.

The container 1 may be formed of a suitable plastics material that provides the required microbial, oxygen and vapour barriers and can withstand sterilisation conditions. Suitable materials may include polypropylene (PP), linear low-density polyethylene (LDPE), high density polyethylene (HDPE) and Biax Nylon (BOPA) PET-AIOx/PP (Aluminium Oxide coated PET such as Barrialex) or EVOH.

Articles to be sterilised may be conveniently placed in perforated tray 13 with perforated lid 14 covering perforated tray 13. The tray 13 may then be placed within the container 1 and a cover 15 applied over the container 1 with the cover extending to cover at least part of rim 7 so that it may be sealed thereto.

The cover may be formed of a stretch or non-stretch material that provides the required microbial, oxygen and vapour barriers and can withstand sterilisation conditions. Certain vacuum skin packaging materials will be suitable. Thermoformable materials such as metalised stretch film or Easypeel PET-AIOx/PP (Aluminium Oxide coated PET such as Barrialex) or EVOH may be suitable. Suitable non-stretch materials include polyethylene or polypropylene. The cover 15 may be sealed to rim 7 in a variety of ways as will be discussed below.

10 The cover 15 or container 1 may include a filtered vacuum release mechanism 16 to facilitate opening. The vacuum release mechanism 16 allows the ingress via a microbiological filter of external fluid to make it easier remove cover 15 from container 1. A vacuum indicator 17 may also be provided in container 1 or cover 15 to indicate that an adequate internal vacuum has been maintained up to the point of opening.

In order to maintain an effective microbial and gaseous barrier the materials used for the container 1 and cover 15 should provide a vapour barrier of less than 0.03 g/m²/hr.

20 A rigid lid 18 may be applied over cover 15 to provide protection for cover 15 and to provide a shape suitable for stacking. The rigid lid may be provided in a non-porous form that is sealed to container 1 to provide an additional barrier as will be described below. In some applications no lid will be required.

25 An identification device 19, such as an RFID tag, holographic indicia, bar code, QR code etc. may be applied to the container 1, cover 15 or lid 18. This identification device may be utilised for tracking as well as for authentication of packaging prior to sterilisation.

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Referring now to figures 4 to 6 a steam steriliser suitable for use with the container described above is shown. The sterilisation chamber 20 has a cavity dimensioned to receive one or more containers to be sterilised. As seen in figure 4 a plurality of containers 1 may be sterilised at the same time. It will be appreciated that
 5 containers of different sizes may be sterilised simultaneously in the same sterilisation chamber so that a range containers of different size may be provided to accommodate different loads. Spacers 21 are placed between and at either end of containers 1 and locate with handles 11 and locating elements 12. The spacing elements provide a suitable anvil at the ends of the containers to enable
 10 the top plate 24 to clamp cover 15 against the rim 7. Doors 22 and 23 are provided at either end of chamber 20 so that containers may be fed in at one end and out the other. Of course just a single door could be provided and the containers could be fed in and out through the same door.

Figure 5 shows a container with spacer 21 attached being fed into chamber 20. Referring now to Figure 6 a cross-sectional view shows a container within sterilisation chamber 20. Once containers 1 are properly located within sterilisation chamber 20 the doors 22 and 23 are closed and the sterilisation chamber is sealed from the external atmosphere. A top plate 24 is then forced
 15 against cover 15 so that cover 15 is clamped to rim 7. The cover 15 may be sealed to container 1 prior to steam sterilisation but may also be sealed to rim 7 when the top plate 24 forces the cover 15 and rim 7 together.

The cover 15 may be secured to the rim 7 of container 1 either prior to entering
 25 sterilisation chamber 20 or within sterilisation chamber 20 using a number of techniques including by an adhesive (self bonding adhesive or a pressure adhesive), welding (e.g. heat sealing, ultrasonic welding, microwave welding or laser welding) or other suitable methods.

The sterilisation chamber 20 includes a port 26 providing a fluid path via conduit
 30 33 from within the chamber to a vacuum 27 for extracting fluid from the chamber

and a steam source 28 for supplying steam sterilant via the port 26. Port 26 extends along almost the entire length of sterilisation chamber 20 to mate with conduit 8 of container 1. The mating is sufficiently loose that there is a fluid path from port 26 to the exterior of container 1 also.

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In the first stage of sterilisation identification device 19 may be read to ensure the container has a valid ID. After validation a vacuum 27 is activated and extracts fluid from within and around container 1. Providing conduit 8 at or near the base of container 1 facilitates the removal of liquids from container 1.

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In the next stage the vacuum 27 is deactivated and steam source 28 supplies steam to port 26 and via conduit 8 to container 1 so that the entire contents of container 1 are exposed to steam sterilant. Due to the loose coupling between port 26 and conduit 8 the exterior of container 1 is also exposed to steam sterilant. Steam is also supplied to channels 29 and 30 (only one of each indicated) to heat the base and side walls of sterilisation chamber 20 and top plate 24. Due to the close contact between the side walls of the sterilisation chamber 20 and top plate 24 this ensures that there is effective thermal contact with the container.

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Different sterilisation regimes may be used depending upon the requirements of a particular application and the materials employed. There is a trade off between material cost and the time required to perform sterilisation. Preferred sterilisation regimes are:

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1. providing steam sterilant of a temperature of at least 115° C to the interior of the container for at least 40 minutes.
2. providing steam sterilant of a temperature of at least 121° C is supplied to the interior of the container for at least 15 minutes.
3. providing steam sterilant of a temperature of at least 134° C is supplied to the interior of the container for at least 3.5 minutes.

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At the completion of steam sterilisation, steam source 28 is closed and vacuum source 27 connected to port 26 to extract fluid from container 1 and its surrounds. Again having conduit 8 located at or near the base of container 1 facilitates the extraction of liquid condensate from the container 1.

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Once a required vacuum is achieved conduit 8 is sealed. In this embodiment heat sealing is performed by heat sealing device 31 being heated and forced against anvil 32 to seal the conduit 8 of container 1 so that the container is entirely sealed from the external atmosphere. Whilst heat sealing is shown in this embodiment other techniques to seal conduit 8 include ultrasonic welding, adhesive bonding or mechanical closure using a suitable clamping mechanism.

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Once the container is sealed a door or both doors 22, 23 of sterilisation chamber 20 may be opened and the container removed. A rigid lid 18 may then be placed over the cover 15 and secured to container 1 to facilitate stacking and transport. The rigid lid 18 may also be sealed to the container 1. This may be performed in an inert gas (e.g. Nitrogen) environment maintained at or above atmospheric pressure when the lid is sealed to the container. This provides an additional inert barrier should there be any failure with the cover seal.

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There is thus provided a non-porous single use impervious and puncture resistant sealable container for steam sterilisation that is capable of retaining a vacuum for an extended period and providing an effective microbiological barrier.

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By providing a rigid container in a lightweight disposable plastic form with the contents sealed in a partial vacuum the barrier integrity status can be immediately determined by visual and tactile confirmation of vacuum remaining therein.

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The container may be transparent and constructed of a plastics material that is able to withstand steam processing temperatures of up to 180°C without degrading, losing shape or structural integrity.

There is thus provided a container that is easy to use, stackable, allows simple article loading, continuous push through processing of containers and easy opening by virtue of the vacuum release mechanism and easily removed cover.

5 The integrity of vacuum is also easily determined by visual inspection of packaging or of an indicator.

10 The container facilitates thorough sterilisation due to effective drainage through the conduit, good contact with the heated walls of the steam steriliser, and effective circulation of sterilant within the container.

15 The non-porous (non-contestable) barrier provides extended shelf life and the ability to withstand pressure and temperature variations during storage or transport without ingress of contamination.

20 Due to the steam steriliser providing steam sterilant within and around the container pressure differential avoided allowing the use of a wider range of materials such as an easy peel cover. The steam steriliser design also allows sterilisation to be performed on conventional or hybrid packaging (with containers and pouches).

A single fluid supply to both the container and sterilisation chamber simplifies the steam steriliser design and improves steam steriliser space utilisation.

25 While the present invention has been illustrated by the description of the embodiments thereof, and while the embodiments have been described in detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. Therefore, the invention in its broader aspects is not limited to the specific details,
30 representative apparatus and method, and illustrative examples shown and

described. Accordingly, departures may be made from such details without departure from the spirit or scope of the applicant's general inventive concept.

5 As disclosed herein are the following concepts:

1. A rigid or semi-rigid single use/disposable container having:
 - a. a base and side walls defining a cavity for containing an item during steam sterilisation and isolating it from its surroundings after sterilisation;
 - b. a rim extending outwardly from the walls; and
 - 5 c. a sealable conduit configured and arranged so that, in use, steam sterilant may be introduced into the container and steam sterilant and condensate may be removed from the container via the conduit.
- 10 2. A container of concept 1 wherein the conduit is provided at or near the base to facilitate draining of the container.
3. A container of concept 1 wherein the conduit is provided in the base to facilitate draining of the container.
- 15 4. A container of any one of concepts 1 to 3 wherein the conduit is elongate in cross section.
5. A container of concept 4 wherein the conduit is elongate in a plane generally parallel to the base.
- 20 6. A container of concept 4 or concept 5 wherein the aspect ratio along the conduit is greater than 2:1.
7. A container of concept 4 or concept 5 wherein the aspect ratio along the conduit is greater than 6:1.
- 25 8. A container of any one of the preceding concepts wherein the conduit includes two opposing side walls that may be sealed together to seal the conduit.
- 30 9. A container of concept 8 wherein the conduit side walls are greater than 50mm in length.

10. A container of concept 8 wherein the conduit side walls are greater than 150mm in length.
- 5 11. A container of concept 8 wherein the conduit side walls are between 50mm and 600mm in length.
12. A container of concept 8 wherein the conduit side walls are between 150mm and 300mm in length.
- 10 13. A container of any one of concepts 8 to 12 wherein the spacing between the side walls is between 5mm and 25mm.
- 15 14. A container of any one of concepts 8 to 13 wherein the conduit side walls extend outwardly from the body of the container more than 5mm.
- 15 15. A container of any one of concepts 8 to 13 wherein the conduit side walls extend outwardly from the body of the container more than 10mm.
- 20 16. A container of any one of the preceding concepts wherein the conduit extends along more than half the length of a side wall of the container.
- 25 17. A container of any one of the preceding concepts wherein the container is formed of a material providing an effective microbiological barrier ANSI/AAMI ISO 11607:2008 or subsequent revisions.
- 30 18. A container of concept 17 formed of a material capable of withstanding internal steam sterilisation process temperatures up to 115 degrees Celsius for at least 40 minutes.

19. A container of concept 17 formed of a material capable of withstanding internal steam sterilisation process temperatures up to 121 degrees Celsius for at least 15 minutes.
- 5 20. A container of concept 17 formed of a material capable of withstanding internal steam sterilisation process temperatures up to 138 degrees Celsius for at least 3.5 minutes.
- 10 21. A container of any one of concepts 18 to 20 capable of withstanding external steam sterilisation process temperatures of up to 180 degrees Celsius.
22. A container of any one of concepts 17 to 21 providing a vapour barrier of less than 0.03 g/m²/hr.
- 15 23. A container of any one of the preceding concepts formed of plastics.
- 20 24. A container of concept 23 formed of a material selected from polypropylene (PP), linear low-density polyethylene LDPE), high density polyethylene (HDPE), Biax Nylon (BOPA) PET-AIOx/PP (Aluminium Oxide coated PET such as Barrialex) or EVOH.
- 25 25. A container of any one of the preceding concepts including an identification device.
26. A container of concept 25 wherein the identification device is selected from an RFID tag, holographic indicia, bar code and QR code.
- 30 27. A container of any one of the preceding concepts having a cover sealed to the rim to seal an open end of the container.
28. A container of concept 27 wherein the cover is fused to the rim of the container.

29. A container of concept 27 or concept 28 wherein the cover is formed of vacuum skin packaging.
- 5 30. A container of concept 29 wherein the cover is formed of a thermoformable material.
- 10 31. A container of concept 30 wherein the thermoformable material is selected from metalised stretch film or Easypeel PET-AIOx/PP (Aluminium Oxide coated PET such as Barrialex) or EVOH.
32. A container of concept 27 wherein the cover is formed of a non-stretch material.
- 15 33. A container of concept 32 wherein the non-stretch material is polyethylene or polypropylene or PET-AIOx/PP (Aluminium Oxide coated PET such as Barrialex) or EVOH.
- 20 34. A container of any one of concepts 27 to 33 wherein the cover or container may include a filtered vacuum release mechanism.
35. A container of any one of concepts 27 to 34 wherein the cover or container include a vacuum indicator.
- 25 36. A container of any one of concepts 27 to 35 having a rigid lid provided over the cover.
37. A container of any one of the preceding concepts having integrally formed handles in side walls of the container.
- 30 38. A container of any one of the preceding concepts including a tray located within the container containing items to be sterilised.

39. A container of concept 38 wherein the tray has a tray lid.

40. A method of steam sterilisation comprising:

- 5 a. providing a rigid or semi-rigid container having an opening for receiving an item to be sterilised and a sealable conduit located at or near the base of the container extending away from the container;
- b. placing an item to be sterilised within the cavity;
- c. applying a cover over the opening;
- 10 d. removing fluid from the container;
- e. introducing steam sterilant into the container through the conduit and around the container to provide the required sterilisation;
- f. extracting fluid in the container via the conduit; and
- g. sealing the conduit.

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41. A method of concept 40 wherein the conduit is sealed by heat sealing walls of the conduit together.

20 42. A method of concept 40 wherein the conduit is sealed by adhesive bonding of the walls of the conduit together.

43. A method of any one of concepts 40 to 42 wherein the cover is secured to the container by welding.

25 44. A method of concept 43 wherein the welding process is selected from heat sealing, ultrasonic welding, microwave welding or laser welding.

45. A method of any one of concepts 40 to 44 wherein the cover is secured to the container by an adhesive.

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46. A method of concept 45 wherein the adhesive is a self bonding adhesive or a pressure adhesive.
- 5 47. A method of any one of concepts 40 to 46 including placing a rigid lid over the cover to facilitate stacking and transport.
48. A method of concept 47 wherein the lid is sealed to the container.
- 10 49. A method of concept 48 wherein the pressure between the lid and cover is maintained at above atmospheric pressure when the lid is sealed to the container.
- 15 50. A method of concept 49 wherein an inert gas environment is maintained between the lid and cover prior to sealing the lid to the container.
- 20 51. A method of any one of concepts 40 to 50 wherein steam sterilant of a temperature of at least 115° C is supplied to the interior of the container for at least 40 minutes.
- 25 52. A method of any one of concepts 40 to 50 wherein steam sterilant of a temperature of at least 121° C is supplied to the interior of the container for at least 15 minutes.
- 30 53. A method of any one of concepts 40 to 50 wherein steam sterilant of a temperature of at least 134° C is supplied to the interior of the container for at least 3.5 minutes.
54. A method of any one of concepts 40 to 53 wherein fluid is extracted from the container by application of a vacuum to the conduit.

55. A method of any one of concepts 40 to 54 wherein the container includes an identification device and the validity of an identification code associated with the identification device is validated prior to processing.
- 5 56. A steam steriliser comprising:
- a. a sterilisation chamber having a cavity dimensioned to receive one or more rimmed containers to be sterilised;
 - b. one or more top plate adapted to clamp against each rim during sterilisation;
 - c. one or more ports providing a fluid path from within the chamber to the exterior of the chamber;
 - d. a vacuum for extracting fluid from the chamber via the one or more port;
 - e. a steam source for supplying steam sterilant via the one or more port; and
 - f. a sealing device for sealing the conduit of the container.
- 10 57. A steam steriliser of concept 56 wherein the one or more ports include an elongate port adapted to couple with a conduit of a container during sterilisation.
58. A steam steriliser of concept 57 wherein the elongate port is greater than 50mm length.
- 20 59. A steam steriliser of concept 58 wherein the elongate port is between 50mm and 1800mm in length.
60. A steam steriliser of concept 59 wherein the elongate port is greater than 150mm in length.
- 25 61. A steam steriliser of concept 60 wherein the elongate port is between 150mm and 600mm in length.
- 30 62. A steam steriliser of any one of concepts 57 to 61 wherein the width of the elongate port is between 5mm to 30mm.

- 5 63. A steam steriliser of any one of concepts 57 to 62 wherein the sterilisation chamber has top, bottom and side walls forming a generally tubular chamber with doors at either end allowing the entry and removal of containers.
64. A steam steriliser of concept 63 including lower anvils along each side wall to support rims of containers within the chamber.
- 10 65. A steam steriliser of concept 64 including one or more spacers for placement between containers under end rims of containers.
66. A steam steriliser of concept 64 or concept 65 including a sealing unit located above the anvils and one or more spacers to seal a cover to rims of a container.
- 15 67. A steam steriliser of concept 66 wherein the sealing unit is a heat sealing unit, ultrasonic welder, or clamping mechanism.
68. A steam steriliser of any one of concepts 63 to 67 including a heating unit in the bottom of the sterilisation chamber.

WHAT WE CLAIM IS:

1. A rigid or semi-rigid single use/disposable container having
 - a. a base and side walls defining a cavity for containing an item during steam sterilisation and isolating it from its surroundings after sterilisation;
 - b. a rim extending outwardly from the walls; and
 - c. a sealable conduit that is elongate in cross section and configured and arranged to allow, in use, steam sterilant to be introduced into the container and steam sterilant and condensate to be removed from the container via the conduit;wherein the sealable conduit includes two opposing side walls that extend outwardly from the body of the container.
2. A container as claimed in claim 1 wherein the elongate conduit is provided at near or in the base to facilitate draining of the container.
3. A container as claimed in claim 1 or claim 2 wherein the aspect ratio of the cross-section of the elongate conduit is greater than 2:1.
4. A container as claimed in any one of the preceding claims wherein the two opposing side walls are greater than 50mm in length and may be sealed together to seal the elongate conduit.
5. A container as claimed in claim 4 wherein the spacing between the side walls of the elongate conduit is between 5mm and 25mm.
6. A container as claimed in claim 4 or claim 5 wherein the elongate conduit side walls extend outwardly from the body of the container more than 5mm.
7. A container as claimed in any one of the preceding claims wherein the elongate conduit extends along more than half the length of a side wall of the container.

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8. A container as claimed in any one of the preceding claims formed of a material capable of withstanding internal steam sterilisation process temperatures of at least 115 degrees Celsius for at least 40 minutes.
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9. A container as claimed in any one of the preceding claims formed of a material selected from polypropylene (PP), linear low-density polyethylene LDPE), high density polyethylene (HDPE), Biax Nylon (BOPA) PET-AlOx/PP (Aluminium Oxide coated PET such as Barrialex) or EVOH.
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10. A container as claimed in any one of the preceding claims including a cover fused to the rim of the container formed of a thermoformable material or a non-stretch plastics material.
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11. A method of steam sterilisation comprising:
- a. providing a rigid or semi-rigid container having an opening for receiving an item to be sterilised and a sealable conduit that is elongate in cross section and located at or near the base of the container, wherein the sealable conduit includes two opposing side walls that extend outwardly from the body of the container;
 - b. placing an item to be sterilised within the cavity;
 - c. applying a cover over the opening;
 - d. removing fluid from the container;
 - e. introducing steam sterilant into the container through the elongate conduit
 - 25 and around the container to provide the required sterilisation;
 - f. extracting fluid in the container via the elongate conduit; and
 - g. sealing the elongate conduit.
- 30
12. A method as claimed in claim 11 wherein the elongate conduit is sealed by heat sealing walls of the elongate conduit together or by adhesive bonding of the walls of the elongate conduit together.

13. A method as claimed in claim 11 or claim 12 wherein the cover is secured to the container by heat sealing, ultrasonic welding, microwave welding or laser welding.

5 14. A method as claimed in any one of claims 11 to 13 wherein steam sterilant of a temperature of at least 115° C is supplied to the interior of the container for at least 40 minutes.

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