A STERILISATION POUCH

Pouches for storing sterile instruments. In particular, a sterilisation pouch comprising a bag having an opening through which an instrument can be inserted into and removed from the bag and means to seal the opening to maintain the instrument in the bag sterile; and a hanger for suspending the bag from a support. The hanger may be attached to be bag by attachment means such as a self-adhesive label. An apparatus for heat sealing and punching holes in a sterilisation bag is also disclosed.
A Sterilisation Pouch

This invention relates to pouches for storing sterile instruments.

Instruments which have to be used in medical or dental operations have to be sterilised prior to use to avoid the risk of transmitting infection to the patient. Standard sterilising pouches have been developed which are formed from clear plastics on one side with a slightly porous or one-way breathable plastics on the reverse side. The pouches are heat sealed together on three sides to form the pouch with a peel-off self-adhesive strip on the fourth side to allow insertion of the instrument to be sterilised.

Before placing in the bag, the instrument is passed through a disinfector which is usually a high specification dishwasher. The instrument is then clean but not sterile. The instrument is then placed in a bag or pouch as indicated above (from a roll of such bags) then sealed using a self-sealing adhesive strip. The bagged instrument then goes into a vacuum autoclave in which the resulting heat treatment sterilises the instrument.

The instruments can be stored in the pouches until they are needed for use but this will normally be for a limited period only. It is important to be able to identify from the pack when the instruments in question were sterilised so that when the pack reaches a date by which the instrument can no longer be safely regarded as being sterile, the instrument can be re-sterilised. Also, it is important to ensure that the oldest sterilised instruments are used first before more recently sterilised instruments, provided of
course that they are still within the period in which they can safely be regarded as being sterile. Once sterile, instruments are allowed to remain in the bags for up to typically 60 days before they have to be re-sterilised.

There is a problem in organising the old stock to be used first before they are out of date and in storing the bagged instruments.

The present invention provides a sterilisation pouch comprising a bag having an opening through which an instrument can be inserted into and removed from the bag and means to seal the opening to maintain the instrument in the bag sterile; and a hanger for suspending the bag from a support.

The present invention is advantageous as it allows the pouches to be hung from a support in an organised manner such that the oldest pouches can be used first.

In one preferred embodiment the hanger is integral with the bag material, the hanger extending from one wall of the bag, the hanger embodying a reinforcing element to stiffen the hanger and enable the pouch holding the instrument to be suspended from a support. This arrangement provides a self contained pouch that requires no assembly.

The hanger preferably comprises a panel for carrying information relating to the contents of the pouch so that the end user can easily ascertain if the instrument is still sterile.
In another preferred embodiment the hanger is attached to the bag by an attachment means. In certain embodiments, this allows standard sterilisation bags to be used, thus removing the need for specially adapted production machinery to produce pouches with integral hangers.

In one embodiment the attachment means comprises heat sealed lines formed in the material of the bag proximate one end of the bag. The heat sealed lines may define an opening for receiving a portion of the hanger. Preferably, the heat sealed lines define a first engagement feature for engaging with a co-operating second engagement feature on the received portion of the hanger.

In another embodiment the attachment means comprises a self-adhesive sealing flap of the bag. This allows standard sterilisation pouches with a sealing flap to be used. Preferably the self-adhesive sealing flap comprises a non-adhesive portion, the non-adhesive portion being arranged to form a loop for receiving a portion of the hanger in use. The non-adhesive area may comprises cut-out portions to allow the hanger to be fixed to the bag by a self-adhesive label if desired.

In a preferred embodiment the bag comprises at least one hole through which a portion of the hanger is received. This helps to prevent the hanger becoming dislodged in use.

The hanger may comprise a downwardly facing open hook shaped element comprising at least one leg, the at least one leg comprising a loop for engaging with the at least one
hole. In this embodiment the pouch is held on the hanger by gravity in use. Alternatively, the loop may be substantially closed such that a first part of the at least one leg contacts a second part of the at least one leg to form a frictional engagement area which prevents the bag slipping off the hanger in use.

In another embodiment the hanger may comprise a downwardly facing open hook shaped element formed integrally with a cross member. In one preferred embodiment the cross member comprises an upset portion, wherein the upset portion helps to prevent the bag from slipping from the hanger in use.

The attachment means preferably comprises an adhesive label for holding the hanger in place in use. The adhesive label may advantageously be capable of carrying information relating to the contents of the pouch and the date of sterilisation of the instrument.

In another aspect the present invention provides a method of making a sterilisation pouch, the method comprising providing a sterilisation bag having an opening through which an instrument can be inserted into and removed from the bag; inserting an instrument into the bag; sealing the opening to maintain the instrument in the bag sterile; providing a hanger for suspending the bag from a support; and attaching the hanger to the sterilisation bag.

The method of providing the sterilisation bag may comprise cutting a length of tubing from a roll of medical
grade tubing; and sealing one of the open ends of the length of tubing to form the bag.

The method preferably comprises punching at least one hole in the sterilisation bag, and attaching the hanger to the sterilisation bag preferably comprises passing a portion of the hanger through the at least one hole.

In a further aspect the present invention provides a kit of parts for making a sterilisation pouch, the kit of parts comprising a sterilisation bag having an opening through which an instrument can be inserted into and removed from the bag and means to seal the opening to maintain the instrument in the pouch sterile; a hanger for suspending the bag from a support; and an attachment means for attaching the hanger to the bag.

In another aspect the present invention provides a kit of parts for making a sterilisation pouch, the kit of parts comprising a roll of medical grade tubing for forming a sterilisation bag; a hanger for suspending the bag from a support; and an attachment means for attaching the hanger to the bag.

The present invention also provides a sterilisation pouch comprising a sterilisation bag containing an instrument, and a hanger for suspending the bag from a support.

In a further aspect the present invention provides a device for sealing a sterilisation pouch comprising a means for heat sealing an opening in the pouch and a means for
punching one or more holes in the pouch. The device is preferably arranged to perform the sealing and punching operations at the same time.

The following is a description of some specific embodiments of the invention, reference being made to the accompanying drawings in which:

Figure 1 is a perspective view of a pair of instrument sterilisation/storage pouches;

Figure 2 is a perspective view of the pouches of Figure 1 supported on rods in a storage container or drawer;

Figure 3 shows a length of pouches formed as a strip to be rolled up prior to use;

Figure 4 is a plan view of an alternative pouch in which a part of a rear wall of the upstanding hanger is exposed for writing on;

Figure 5 is a further alternative pouch in which a folded panel is laminated into the hanger end of the pouch;

Figure 6 shows a further arrangement in which a folded panel is partially encapsulated in the closed end of the pouch;

Figure 7 shows a modification of the Figure 6 arrangement;

Figure 8 shows a schematic exploded view of a further alternative pouch arrangement;

Figure 9 shows a schematic partially exploded view of the pouch of Figure 8;

Figure 10 shows a schematic view of the pouch of Figure 8;
Figures 11A to HE, show schematic illustrations of the initial process steps in producing a further alternative pouch;

Figures 12F to 12H, show schematic illustrations of the subsequent process steps to those shown in Figures 11A to HE;

Figures 13I and 13J, show schematic illustrations of the subsequent process steps to those shown in Figures 12F to 12H;

Figure 14 shows a schematic illustration of a sealing and punching apparatus;

Figure 15 shows a schematic illustration of an alternative hanger arrangement;

Figures 16A and 16B show schematic illustrations of a further alternative hanger arrangement;

Figures 17A to 17C, show schematic illustrations of the process steps in producing a further alternative pouch;

Figures 18A to 18C, show schematic illustrations of the process steps in producing yet a further alternative pouch;

... and

Figures 19A and 19B, show schematic illustrations of the process steps in producing a still further alternative pouch.

Referring firstly to Figure 1 of the drawings, there is shown a pair of sterilisation pouches indicated generally at 10, each comprising a clear plastics wall 11 forming the front face of the pouch and a slightly porous or one way breathable plastics material 12 forming the back of the pouch. The pouches are generally of upright rectangular form and are heat sealed along their side and bottom edges as indicated at 13 to form an open topped pouch.
A peel-off self-adhesive strip 15 is provided for closing the top edge of the pouch to allow insertion of the instrument to be sterilised before the pouch is closed.

The front and rear walls 11, 12 of the pouch are extended at the upper end of the pouch to form a panel 16 which is shaped to create a hanger 17 from which the pouch can be suspended. Stiffening material 18 is laminated between the front and rear walls of the pouch to strengthen the panel 16 and the hanger 17 to support the pouch suspended from a rod or other support. Referring to Figure 2, there is shown a drawer or container 19 having a pair of internal parallel rods 20 on which the two pouches are suspended by their hangers 17.

The panels 16 of the pouches can also be laminated with a sheet of material on which information can be recorded such as the date on which the instruments were sterilised to enable the stored instruments to be monitored. It is usual to have a period in which such instruments must be used or re-sterilised. Typically the period is 60 days. The instruments can therefore be stored so that the oldest sterilised instruments are brought forward first for use and when they are out of time, can be transferred for re-sterilisation.

Thus the extended panel 16 at the top of the pouch provides both a hook shape for supporting the pouch suspended from a rod and provides an area where information can be recorded regarding the instrument and its sterilisation date to enable the instruments stored in the container or drawer to be readily monitored.
The pouches can be formed in lengths held on a roll as indicated in Figure 3 with lines of weakness 22 between each pair of pouches to enable the pouches to be readily-separated from the roll as required for use. In contrast to the pouches 10 shown in Figure 1, the pouches 10' shown in Figure 3 comprise an opening at the bottom of the pouch, at the opposite end to the hanger 17. A peel-off self adhesive strip 15' is provided at the bottom of the pouch for sealing the opening.

The pouches 10, 10' shown in Figures 1 and 3 may be either top or bottom opening. It is preferred that the pouches 10' which are provided in a strip are bottom opening. However, this is not mandatory and the opening may alternatively be located at the top of the pouch beneath the panel 16. Similarly, the pouches 10 of Figure 1 may be bottom opening rather than top opening.

Referring now to Figure 4, there is shown a pouch 50 which is generally similar to the pouches 10, 10' described above. The pouch 50 is of generally rectangular upright form with a hook shaped hanger 57 at its upper end and an opening 51 to receive an instrument to be stored at its lower end. The pouch comprises a front wall 52 formed from a substantially clear plastics film and a rear wall 53 formed from a plasticised paper on which written material can be recorded. The front and rear walls are heat sealed together along a line 54 of heat seal along the sides of the walls and towards the upper ends of the walls to form a pouch having a bottom opening to receive an instrument to be stored in sterile conditions. At the bottom open end of the pouch the rear wall of the pouch forms an extended flap 55
which has a band of adhesive coated on it which is temporarily covered by a protective strip which can be removed to allow the flap is to be folded over and adhered to the front wall of the pouch to close the open end of the pouch.

At the upper end of the pouch the front and rear walls are extended upwardly to form an upstanding panel 56 having a side slot 60 opening into an enlarged central aperture 58 to create a hanger 57 from which the pouch can be suspended. The hanger is reinforced by a pre-formed reinforcement member 59 sandwiched between the front and rear walls and comprising a base 61 extending across the pouch above the closed end of the pouch and a hook shaped element 62 which encircles the central aperture 58. The front and rear walls are heat sealed together along a line of heat seal 63 extending around the entire periphery of the pre-formed reinforcement member 59 to secure the reinforcing element in place. Another part 64 of the upstanding panel 56 is available for written material.

Figure 5 shows a variation of the arrangement of Figure 4 in which the hook shaped reinforcing member is replaced by a folded plastic panel 65 again having a side slot 60 leading into an enlarged aperture 58 to receive a support from which the pouch can be suspended. The folded plastic panel 65 is laminated between the front and rear walls of the upstanding part of the pouch beyond the closed end of the pouch and the front and rear walls are heat sealed together along a line 63 around the periphery of the panel 65. Printed or written information may appear on the area 64 of the panel 65.
Figure 6 shows a further alternative arrangement to that shown in Figure 5 in which only a lower part 66 of the plastic panel 65 is laminated between the front and rear sheets of the pouch leaving an upper part 67 of the panel projecting above the sheets and in which the side slot 60 is formed leading to the aperture 58 to engage over a support. The panel also provides an area 64 on which written material may be recorded. The lower part 66 of the insert panel 65 is partially enclosed by a line of heat seals 63 between the front and rear walls of the pouch to hold the panel in place.

The embodiment of Figure 6 is advantageous if it is not possible to make the stiffening as an integral part of the pouch due to limitations of production machinery. The panel 65 may be supplied separately and slid into the top of the pouch before hanging the pouch. However, the stiffening may work loose or slip out over time when the pouch is holding an instrument. To help prevent this, the pouch and the stiffening can have interengaging male and female elements so that when the weight of the pouch with an instrument in hangs on the stiffening it will stop the stiffening sliding sideways and out of the pocket in the pouch.

Figure 7 shows such an arrangement in the form of a variation in the arrangement of Figure 6. The upper edge of the lower part 66 of the reinforcing panel has a recess 68 positioned centrally of the hook and the line of sealing 63 has a projection 69 to engage in the recess and stop the panel 65 slipping out from between the walls of the pouch.
Referring now to Figure 8, there is shown a sterilisation pouch having a generally rectangular upright form with an opening 121 to receive an instrument to be stored at its lower end. A bag 100 comprises a front wall 122 formed from a substantially clear plastics film and a rear wall 123 formed from a plasticised paper on which written material can be recorded if desired. The front and rear walls are heat sealed together along a line 124 of heat seal along the sides of the walls and towards the upper ends of the walls to form the bag 100 having a bottom opening 121 to receive an instrument to be stored. At the bottom open end of the bag 100 the rear wall 123 of the bag forms an extended flap 125 which has a band of adhesive coating on it which is temporarily covered by a protective strip which can be removed to allow the flap to be folded over and adhered to the front wall of the bag 100 to close the open end of the bag.

Two holes 150 are formed at the upper end of the bag 100. The holes 150 extend through the front 122 and rear 123 walls of the bag. The holes 150 facilitate connection of the bag 100 to the hanger 200 as described below.

The hanger 200 comprises a downwardly facing open hook shaped element 210 which is formed integrally with cross member 215. Referring to Figure 9, the hanger 200 is connected to the bag 100 by placing the cross member 215 in the holes 150. As shown in Figure 10, the hanger 200 is fixed in place by an adhesive label 250 which may carry information relating to the contents of the pouch and the date of sterilisation of the instrument.
The complete pouch 110 is shown in Figure 10. In this example the pouch 110 does not yet contain an instrument. An instrument may be placed into the pouch 110 via the opening 121 and the bag 100 sealed by removing the protective strip from the adhesive coating and folding over the flap. The pouch 110 and contained instrument may then be sterilised. Alternatively, the instrument may be placed into the bag 100 and the bag sealed and sterilised before the hanger 200 and adhesive label 250 are attached.

As an alternative to using single pouches, sterilisation pouches may also be made-up from a roll of medical grade tubing as illustrated in Figures 11 to 13.

Referring to Figure 11A, a roll of tubing 300 comprises a continuous length of plastic film and medical grade paper, heat sealed along its edges to form a continuous pouch without the ends sealed off. An upper sheet 301 of the tubing comprises impervious transparent plastic material and a lower sheet 302 of pervious material comprises medical grade paper. The upper and lower sheets are joined by heat sealing on two sides 303, 304 along the length of the roll 300 to form the tube.

As shown in Figure 11B, the process of forming a made-up pouch from a roll of medical grade tubing 300 comprises feeding the roll of tubing 300 through an automatic pouch cutting and sealing machine 320 such as the Seal 2 automatic pouch sealing device made by W & H (UK) Limited. The machine 320 cuts a length of tubing 325 and heat seals the upper 301 and lower 302 sheets together to form a bag 330. As shown in Figure 11C, the bag 330 has an open end 331 and
a closed end 332. An instrument 310 is inserted into the open end of the bag 330 as illustrated in Figures 11D and HE.

The bag 330 is next sealed by means of a heat sealing apparatus 350 as shown in Figure 12F. The heat sealing apparatus 350 comprises punch elements 360 which are arranged to punch holes 340 in the bag 330. As shown in Figure 12G, the sealed bag 330 comprises an upper seal line 315 and two holes 340 located above the seal line 315. The heat sealing and hole punching steps are preferably performed concurrently to save manufacturing time. However, these processes could alternatively be performed separately from one another by the heat sealing apparatus 350, or by separate heat sealing and punching apparatus (not shown).

Figure 12H shows the sealed and punched bag 330, a hanger 200 and an adhesive label 250. As shown in Figure 13I, the cross member 215 of the hanger 200 is located in the holes 340 and fixed in place by the adhesive label 250 which may carry information relating to the contents of the pouch and the date of sterilisation of the instrument.

The complete pouch 370 is shown in Figure 13J. In this example the pouch 370 and contained instrument 310 has not yet been sterilised. The sterilisation process may take place after the hanger 200 and label 250 are attached to the bag 330. Alternatively, the bag 330 and instrument 310 may be sterilised before the hanger 200 and adhesive label 250 are attached.
Figure 14 shows a schematic plan view of the heat sealing apparatus 350 comprising punch elements 360.

Figure 15 shows an alternative hanger 200' which may be used with any bag suitable for forming a sterilisation pouch which also comprises holes for receiving a hanger. For the purposes of illustration, the bag 100 of Figure 8 is shown in Figure 15. The hanger 200' comprises a downwardly facing hook portion 210' and a cross-bar portion 215'. The cross-bar portion 215' has an upset portion 217 which helps to prevent the bag 100 slipping off the hanger 200' in use. An adhesive label 250 may optionally be used to hold the hanger in place if desired.

Figures 16A and 16B show a further alternative hanger 260 which may be used with any bag suitable for forming a sterilisation pouch which also comprises holes for receiving a hanger. For the purposes of illustration, the bag 100 of Figure 8 is shown in Figures 16A and 16B. The hanger 260 comprises a downwardly facing hook portion 262 and two leg portions 264 which each define a loop 261. Preferably, the top of each loop contacts the upper end of the leg portions 264 to form a frictional engagement 263. In use, the legs 264 pass through the holes 150 of the bag 100 so the bag rests in the loops 261. The frictional engagements 263 help to prevent the bag 100 from slipping from the hanger 260 in use. In an alternative embodiment (not shown) there is no frictional engagement such that the bag resides in the loops 261 of the hanger by virtue of gravity when hung. An adhesive label 250 may optionally also be used to hold the hanger in place if desired.
Referring to Figures 17A to 17C, process steps in producing a further alternative pouch 410 are illustrated. The bag 400 comprises a front wall formed from a substantially clear plastics film and a rear wall formed from a plasticised paper. The front and rear walls are heat sealed together along the sides of the walls and towards the lower ends of the walls to form a bag 400 having a top opening to receive an instrument 405 to be stored. At the top open end of the bag 400 the rear wall of the bag forms an extended flap 425 which has a band of adhesive coating on it which is temporarily covered by a protective strip 428 which can be removed to allow the flap to be folded over and adhered to the front wall of the bag 400 to close the open end of the bag. The lower portion of the flap 425 has an area 427 which is not coated with adhesive. This area forms a hanger engagement loop 426 when the pouch is sealed (described below).

Figure 17B shows the bag 400 with the flap 425 folded over to seal the bag 400. The instrument 405 has been placed in the bag for subsequent sterilisation. As shown in the side perspective view of Figure 17B, the area 427 of the flap 425 not comprising adhesive forms a loop 426 when the bag is closed. The loop 426 receives a cross-bar portion 422 of the hanger 420 to enable the pouch 410 to be suspended from a rail or bar by hook portion 421 in use. In an alternative example (not shown) the cross-bar portion 422 of the hanger may comprise an upturned end to prevent the bag 400 slipping off the hanger in use.

Figures 18A to 18C show a slight variation to the pouch 410 of Figures 17A to 17C. As above, the bag 450 comprises
a front wall formed from a substantially clear plastics film and a rear wall formed from a plasticised paper. The front and rear walls are heat sealed together along the sides of the walls and towards the lower ends of the walls to form a bag 450 having a top opening to receive an instrument 455 to be stored. At the top open end of the bag 450 the rear wall of the bag forms an extended flap 475 which has a band of adhesive coating on it which is temporarily covered by a protective strip 478 which can be removed to allow the flap to be folded over and adhered to the front wall of the bag 450 to close the open end of the bag. The lower portion of the flap 475 has an area 477 which is not coated with adhesive. In addition the area 477 comprises a pair of cut-outs 479. This area forms a hanger engagement loop 476 when the pouch is sealed (described below).

Figure 18B shows the bag 450 with the flap 475 folded over to seal the bag 450. As shown in the side perspective view of Figure 16B, the area 477 of the flap 475 not comprising adhesive forms a loop 476 when the bag is closed. The loop 426 receives a cross-bar portion 472 of the hanger 470 to enable the pouch 460 to be suspended from a rail or bar by hook portion 471 in use. As shown, the cut out portions 479 form cut-out shoulders 481. The cut-out shoulders 481 facilitate engagement of a self adhesive label 480 with the cross-bar portion 472 of the hanger 470. This keeps the hanger 470 in place during use. In an alternative example (not shown) the cut-out portions 479 may be replaced by, or augmented, by an further cut-out in the form of a hole towards the centre of the area 477. Which alternative/additional cut-out would form an
alternative/additional area for the self adhesive label 480 to contact the hanger to keep it in place in use.

Figures 19A and 19B show another variation to the pouch 410 of Figures 17A to 17C. The bag 500 comprises a front wall formed from a substantially clear plastics film and a rear wall formed from a plasticised paper. The front and rear walls are heat sealed together along the sides of the walls and towards the lower ends of the walls to form a bag 500 having a top opening to receive an instrument 505 to be stored. At the top open end of the bag the rear wall of the bag forms an extended flap 525 which has a band of adhesive coating on it which is temporarily covered by a protective strip which can be removed to allow the flap to be folded over and adhered to the front wall of the bag to close the open end of the bag. There is no adhesive free area on the flap 525.

Figure 19B shows the bag 500 with the flap 525 folded over to seal the bag. As shown in the side perspective view of Figure 19B, when the flap 525 is folded over to seal the bag, the flap 525 folds over the cross-bar 522 of a hanger 520 to attach the hanger 520 to the bag to enable the pouch 510 to be suspended from a rail or bar by hook portion 521 in use.
CLAIMS;

1. A sterilisation pouch comprising:
   a bag having an opening through which an instrument can be inserted into and removed from the bag and means to seal the opening to maintain the instrument in the bag sterile; and
   a hanger for suspending the bag from a support.

2. A sterilisation pouch as claimed in claim 1, wherein the hanger is integral with the bag material, the hanger extending from one wall of the bag, the hanger embodying a reinforcing element to stiffen the hanger and enable the pouch holding the instrument to be suspended from a support.

3. A sterilisation pouch as claimed in claim 1 or 2, wherein the hanger comprises a panel for carrying information relating to the contents of the pouch.

4. A sterilisation pouch as claimed in claim 1, wherein the hanger is attached to the bag by an attachment means.

5. A sterilisation pouch as claimed in claim 4, wherein the attachment means comprises heat sealed lines formed in the material of the bag proximate one end of the bag.

6. A sterilisation pouch as claimed in claim 5, wherein the heat sealed lines define an opening for receiving a portion of the hanger.

7. A sterilisation pouch as claimed in claim 6, wherein the heat sealed lines define a first engagement feature for
engaging with a co-operating second engagement feature on the received portion of the hanger.

8. A sterilisation pouch as claimed in claim 4, wherein the attachment means comprises a self-adhesive sealing flap of the bag.

9. A sterilisation pouch as claimed in claim 8, wherein the self-adhesive sealing flap comprises a non-adhesive portion, the non-adhesive portion being arranged to form a loop for receiving a portion of the hanger in use.

10. A sterilisation pouch as claimed in claim 9, wherein the non-adhesive area comprises cut-out portions.

11. A sterilisation pouch as claimed in claim 1 or 4, wherein the bag comprises at least one hole through which a portion of the hanger is received.

12. A sterilisation pouch as claimed in claim 11, wherein the hanger comprises a downwardly facing open hook shaped element comprising at least one leg, the at least one leg comprising a loop for engaging with the at least one hole.

13. A sterilisation pouch as claimed in claim 12, wherein the loop is substantially closed such that a first part of the at least one leg contacts a second part of the at least one leg to form a frictional engagement area.

14. A sterilisation pouch as claimed in claim 11, wherein the hanger comprises a downwardly facing open hook shaped element formed integrally with a cross member.
15. A sterilisation pouch as claimed in claim 14, wherein
the cross member comprises an upset portion, wherein the
upset portion helps to prevent the bag from slipping from
the hanger in use.

16. A sterilisation pouch as claimed in any one of claims 4
or 11 to 15, wherein the attachment means comprises an
adhesive label.

17. A sterilisation pouch as claimed in claim 16, wherein
the adhesive label is capable of carrying information
relating to the contents of the pouch and the date of
sterilisation of the instrument.

18. A method of making a sterilisation pouch, the method
comprising:

- providing a sterilisation bag having an opening through
  which an instrument can be inserted into and removed from
  the bag;

- inserting an instrument into the bag;

- sealing the opening to maintain the instrument in the
  bag sterile;

- providing a hanger for suspending the bag from a
  support; and

- attaching the hanger to the sterilisation bag.

19. The method of claim 18 wherein providing the
sterilisation bag comprises:

- cutting a length of tubing from a roll of medical grade
tubing; and

- sealing one of the open ends of the length of tubing to
  form the bag.
20. The method of claim 18 or 19 further comprising punching at least one hole in the sterilisation bag.

21. The method of claim 20 wherein attaching the hanger to the sterilisation bag comprises:
   passing a portion of the hanger through the at least one hole.

22. A kit of parts for making a sterilisation pouch, the kit of parts comprising:
   a sterilisation bag having an opening through which an instrument can be inserted into and removed from the bag and means to seal the opening to maintain the instrument in the pouch sterile;
   a hanger for suspending the bag from a support; and an attachment means for attaching the hanger to the bag.

23. A kit of parts for making a sterilisation pouch, the kit of parts comprising:
   a roll of medical grade tubing for forming a sterilisation bag;
   a hanger for suspending the bag from a support; and an attachment means for attaching the hanger to the bag.

24. A kit of parts as claimed in claim 22 or 23, wherein the attachment means is an adhesive label.

25. A sterilisation pouch comprising:
   a sterilisation bag containing an instrument, and a hanger for suspending the bag from a support.
26. A device for sealing a sterilisation pouch comprising a means for heat sealing an opening in the pouch and a means for punching one or more holes in the pouch.

27. A device as claimed in claim 26, wherein the device is arranged to perform the sealing and punching operations at the same time.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

<table>
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<th>INV.</th>
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<th>A61B19/02</th>
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**ADD.**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**EPO-Internal**

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
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<td>US 2009/139889 A1 (KYRITIS GEORGE [CA]) 4 June 2009 (2009-06-04) paragraphs [0064], [0065], [0069]; figures 23, 26</td>
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Further documents are listed in the continuation of Box C.

See patent family annex.

- **X** document, member of the same patent family
- **Y** document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- **Z** document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- **T** document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

**Date of the actual completion of the international search**

7 February 2011

**Date of mailing of the international search report**

24/05/2011

Name and mailing address of the ISA:
European Patent Office, P.B. 5018 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, 340-2040
Fax. (+31-70) 340-3016

Authorized officer:
Katsoul as, K
### DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 6 361 010 B1 (GROSSKOPF GLENN A [US] ET AL) 26 March 2002 (2002-03-26) column 1, line 17 - line 21; figures 1,3,5,6 column 6, line 62 - column 8, line 20</td>
<td>3,4, 16-18</td>
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</table>
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. □ Claims Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:
   
2. □ Claims Nos.:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
   
3. □ Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

This International Searching Authority found multiple inventions in this international application, as follows:

   see additional sheet

1. □ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. □ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☑ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

   see additional sheet(s)

Remark on Protest

☐ The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

Form PCT/ISA/21 0 (continuation of first sheet (2)) (April 2005)
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-25

    Independent claims 1 and 25 define a sterilization pouch comprising a bag suitable for containing an instrument and a hanger for the bag.
    Independent method claim 18 defines a method of making said pouch.
    Claims 22 and 23 define kits comprising parts for making said pouch.

2. claims: 26, 27

    Independent claim 26 defines a device for sealing a sterilization pouch comprising heat sealing means and hole punching means.
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