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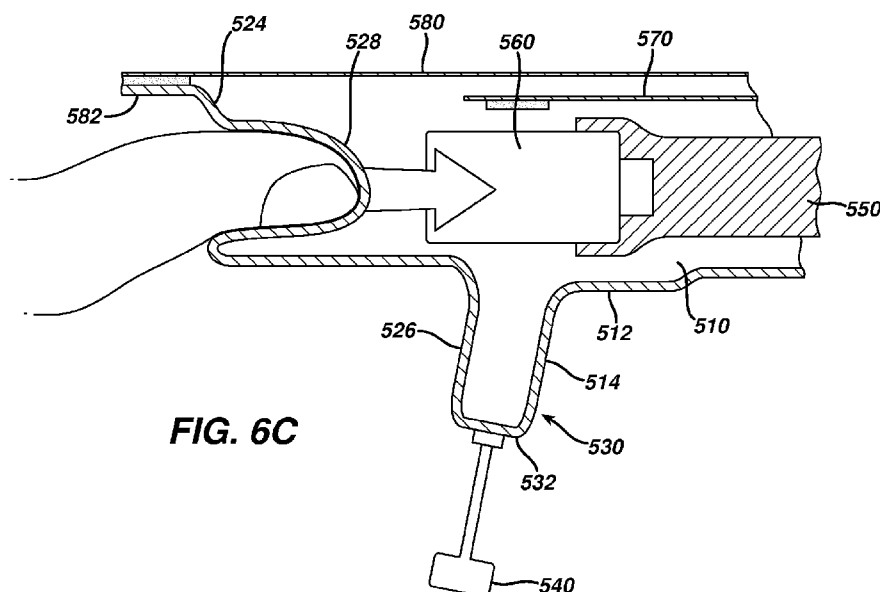
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[Continued on next page]

(54) Title: STERILE PACKAGE SYSTEM FOR MEDICAL DEVICE



(57) Abstract: An apparatus for aseptic insertion includes a container, a first cover, and a second cover. The container includes a first compartment, a second compartment, and a detachable wall disposed between the first compartment and the second compartment. The first cover is sized and configured to attach to the first compartment and the second cover is sized and configured to attach to the container. The detachable wall may defined by a top portion, a portion of a first distal wall of the first compartment, and a portion of a second proximal wall of the second compartment. The detachable wall may be removably attached to the first cover by the top portion of the detachable wall.

**Declarations under Rule 4.17:**

- *as to the identity of the inventor (Rule 4.17(i))*
- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/040088

A. CLASSIFICATION OF SUBJECT MATTER

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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)

A61B A61L

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 practicable, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	US 5 873 814 A (ADAIR) 23 February 1999 (1999-02-23) column 8, line 33 - column 9, line 8; figures 3,5,5(a) -----	1,6,10, 11,13-15 20
Y A	US 2003/205029 A1 (CHAPOLINI) 6 November 2003 (2003-11-06) paragraphs [0044] - [0047], [0049] - [0051], [0058]; figures 1-3,5-8 -----	1,6,10, 11,13-15 20
A	DE 296 08 617 U1 (MEDIMEX HOLFELD) 8 August 1996 (1996-08-08) claims 1,2,4,5; figure ----- -/--	1,4,6, 13-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later 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

"X" 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

"Y" 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

"&" document member of the same patent family

Date of the actual completion of the international search

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Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/040088

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 178 282 A (WILLIAMS) 12 January 1993 (1993-01-12) column 5, lines 37,38; claims 1-3; figures 1,2,4,5	1,5,6
A	----- US 2007/095679 A1 (NAKAMURA) 3 May 2007 (2007-05-03) the whole document	1,6,7, 13-15
A	----- US 5 163 557 A (SOKOLOWSKI) 17 November 1992 (1992-11-17) the whole document	1,6, 13-15
A	----- US 6 622 864 B1 (DEBBS) 23 September 2003 (2003-09-23) column 5, line 8 column 11, lines 8-11; figures 3B,5-7	6-8, 12-14
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A	----- US 5 168 863 A (KURTZER) 8 December 1992 (1992-12-08) abstract; figures	1
A	----- WO 98/06144 A1 (MINNESOTA MINING AND MANUFACTURING COMPANY) 12 February 1998 (1998-02-12) abstract; figures	1
A	----- US 2003/149424 A1 (BARLEV) 7 August 2003 (2003-08-07) abstract; figures	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/040088

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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.:

1-15, 20

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15, 20

An apparatus for aseptic attachment or insertion of an insertable electrical component comprising:

- a container comprising a first compartment, a second compartment, and a detachable wall connected to and disposed between the first and second compartments;
- a first cover removably attachable to the first compartment; and
- a second cover removably attachable to a portion of the container; wherein:

- the detachable wall is removably attached to the first cover; and
- one or both of the first or second covers are configured to cooperate with the container to maintain sterility of a medical device within the container.

Also a method for aseptically inserting an insertable electrical component into a medical device in a package system comprising a container, a first cover, a second cover, a medical device, an insertable electrical component, a first and a second compartments, and a detachable wall, wherein the medical device is contained within the first compartment, wherein the insertable electrical component is contained within the second compartment, wherein the first cover hermetically seals the first compartment, wherein the second cover hermetically seals the container, wherein the detachable wall is defined by a top portion, a first distal wall of the first compartment and a second proximal wall of the second compartment, wherein the top portion of the detachable wall is removably attached to the first cover, and wherein a pull tab is secured to the detachable wall, the method comprising the steps of:

- (a) pulling the pull tab to detach the detachable wall from the first cover;
- (b) inverting the detachable wall to provide clearance between the first compartment and the second compartment; and
- (c) pushing on the second compartment to push the insertable electrical component into the medical device adapted to receive an insertable electrical component.

Problem solved :

Providing an apparatus and a method for aseptically inserting an insertable electrical component into a medical device

2. claims: 16-19

A method of dual sterilization for a package system comprising a container, a first cover, a second cover, a medical device, an insertable electrical component, a first compartment and a second compartments, the method comprising

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

the steps of:

- (a) placing the medical device in the first compartment of the container;
- (b) attaching the first cover to the first compartment of the container, wherein the first cover hermetically seals the first compartment when the first cover is attached;
- (c) sterilizing the container, the medical device, and the first cover by a first sterilization method;
- (d) placing the insertable electrical component into the second compartment of the container; and
- (e) attaching the second cover to the container.

Problem solved :

Providing a method for differently sterilizing a medical device and an insertable electrical component placed within one single container

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/040088

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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