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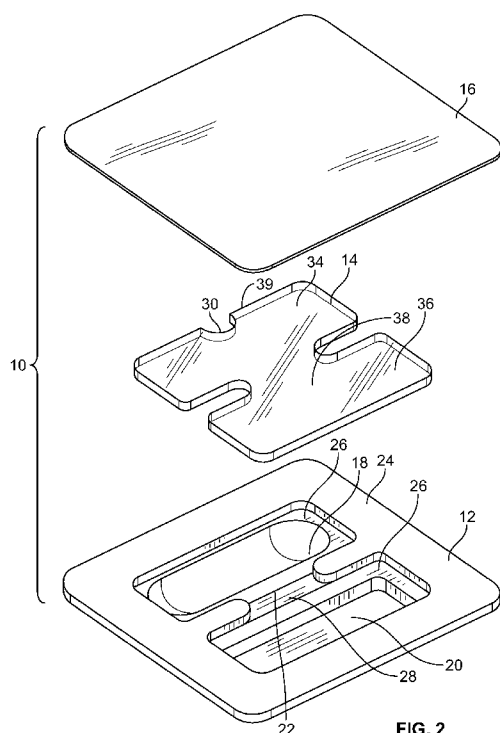
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(54) Title: STERILIZATION PROCESS CHALLENGE PACK



(57) Abstract: A sterilization process challenge pack including a base tray, a first cover, and a second cover is configured to provide a restrictive flow path for gaseous sterilization medium to test the efficacy of a sterilization process. The base tray includes at least one chamber containing a biological indicator and/or chemical indicator. The first cover including a notch is configured to cover the at least one chamber. The second cover is attached to peripheral surfaces of the base tray except at an unsealed portion. A flow path through the unsealed portion and the notch in the first cover provides the only fluid communication between an external environment and the at least one chamber.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/026262

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L2/28
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)
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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 750 184 A (IMBURGIA RICHARD [US]) 12 May 1998 (1998-05-12) figures 1-3	1-14
X	----- EP 0 202 724 A1 (WARNER LAMBERT CO [US]) 26 November 1986 (1986-11-26) page 4, line 26 - page 5, line 16; figure 2	1-14
X	----- US 3 752 743 A (HENSHILWOOD J) 14 August 1973 (1973-08-14) figure 2	1-14
X	----- WO 95/24622 A1 (PROPPER MFG CO INC [US]) 14 September 1995 (1995-09-14) abstract; figure 1; example 1	1-14
	----- -/-	



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

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Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2013/055569 A1 (AMERICAN STERILIZER CO [US]) 18 April 2013 (2013-04-18) abstract; figures 1, 2, 4 -----	1-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/026262

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.:

1-14

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: 1-14

1. A sterilization challenge pack, comprising:
a base tray including at least one chamber and a peripheral surface;
a first cover including a notch and configured to cover the at least one chamber;
a second cover attached to the peripheral surface except at an unsealed portion;
at least one sterilization indicator contained in the at least one chamber;
wherein the only fluid communication between the at least one chamber and an external environment is provided through the unsealed portion and the notch.
2. The sterilization challenge pack of claim 1, wherein the at least one chamber includes a first chamber and a second chamber, wherein the first and second chambers are in fluid communication with each other.
3. The sterilization challenge pack of claim 2, wherein the at least one sterilization indicator includes a biological indicator and a chemical indicator, wherein the biological indicator is contained in the first chamber and the chemical indicator is contained in the second chamber.
4. The sterilization challenge pack of claim 2, wherein the first cover includes a first portion configured to cover the first chamber and the second portion configured to cover the second chamber, wherein the first and second portions are connected by a middle portion.
5. The sterilization challenge pack of claim 4, wherein the base tray includes ledges defined by surfaces recessed from the peripheral surface and arranged between the peripheral surface and the first and second chambers, wherein the first cover is configured such that the notch extends beyond the ledges and into the first chamber when placed on the ledges.
6. The sterilization challenge pack of claim 5, wherein the notch is provided in the first portion proximate an outer peripheral edge, wherein the first cover is arranged on the ledges such that the notch is aligned with the unsealed portion to provide a fluid path into the first chamber through the unsealed portion and notch.
7. The sterilization challenge pack of claim 5...

2. claims: 15-19

15. A sterilization challenge pack, comprising:
a base tray including at least one chamber and a peripheral surface, the peripheral surface being substantially flat and free of any channels, grooves or indentations;
a cover sealingly attached to the peripheral surface except at an unsealed portion; and
at least one sterilization indicator contained in the at

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

least one chamber;

wherein the only fluid communication between the at least one chamber and an external environment is provided through the unsealed portion between the substantially flat peripheral surface and the cover.

16. The sterilization challenge pack of claim 15, wherein the at least one chamber includes a first chamber and a second chamber, wherein the first and second chambers are in fluid communication with each other, wherein the at least one sterilization indicator includes a biological indicator and a chemical indicator, wherein the biological indicator is contained in the first chamber and the chemical indicator is contained in the second chamber.

17. The sterilization challenge pack of claim 15, wherein the unsealed portion extends from an outer periphery of the cover to the at least one chamber, wherein the unsealed portion is configured to provide a path having a width of about 1/32 inch to about 1 inch.

18. The sterilization challenge pack of claim 15, wherein the cover is sealed to the peripheral surface via an adhesive or heat seal, wherein cover is left unsealed to the peripheral surface in the unsealed portion.

19. The sterilization challenge pack of claim 15, wherein the cover is formed from a laminate material having a metal foil layer and a sealing layer, wherein the cover is heat sealed to the peripheral surface except in the unsealed portion.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2019/026262

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5750184	A	12-05-1998	NONE
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