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(54) Title: SEALING CASE FOR FILTER CASSETTE

(57) Abstract: A sealing case for a filtration cassette that reliably prevents leaks after assembly and installation into a filtration system. The sealing case fits on the filtration cassette and provides a fluid-tight seal between the sealing case and around at least one port in the filtration cassette when installed in a filtration system. The sealing case may comprise two halves that mate together, and each half may be identical. The internal surface of the sealing case is flat or substantially flat.

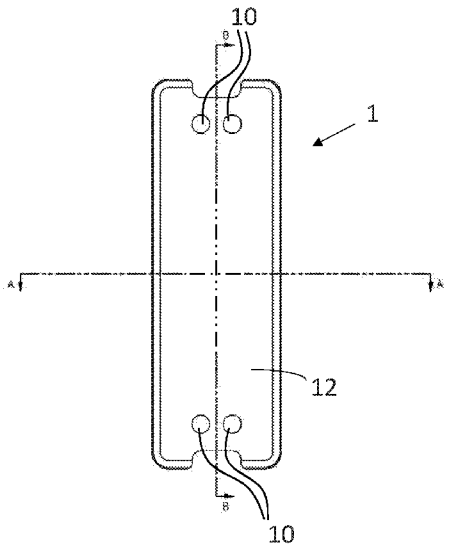

FIG. 1A

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RELEVANT FIELD

[0001] Devices for filtering fluids such as pharmaceutical fluids and gaskets for sealing the devices.

BACKGROUND

[0002] Tangential Flow Filtration (TFF) is a separation process that uses membranes to separate components in a liquid solution or suspension on the basis of size or molecular weight differences. Applications include concentration, clarification, and desalting of proteins and other biomolecules such as nucleotides, antigens, and monoclonal antibodies; buffer exchange; process development; membrane selection studies; pre-chromatographic clarification to remove colloidal particles; depyrogenation of small molecules such as dextrose and antibiotics; harvesting, washing or clarification of cell cultures, lysates, colloidal suspensions and viral cultures; and sample preparation.

[0003] Conventional TFF devices are constructed by layering sheets of filtration membranes and woven screens. The TFF device can be contained in a cassette format. Separate sealing gaskets are placed on both sides of the cassette and this assembly is installed in a filtration system between a set of top and bottom manifolds or holders. The manifolds or holders serve to distribute the filtration fluid stream across the multiple flow paths within the TFF device. The manifolds or holders are clamped together and provide a mechanical constraint against the TFF device and gaskets to achieve the desired fluid sealing. A typical filtration system can comprise many cassettes and therefore many gaskets. However, the installation of many cassettes and gaskets is not only tedious for the user, but it is also prone to problems with gaskets falling out during installation, repair or replacement. Furthermore, even one improperly aligned or improperly seated gasket can result in a system leak. If a leak occurs, the whole system of cassettes and gaskets needs to be removed and the installation repeated.

[0004] A need exists to simplify the installation and use of filtration cassettes in a reliable manner that avoids the problems of improper assembly and leaking.

SUMMARY

[0005] Described herein is a sealing case for a filtration cassette that reliably prevents leaks after assembly and installation into a filtration system. Unlike prior art devices that depend on bonding, overmolding and/or using adhesives to join a sealing gasket to a filtration device to obtain a fluid-tight seal, the present invention avoids these cumbersome and problematic

steps by providing a sealing case that fits on the filtration cassette and provides a fluid-tight seal between the sealing case and around at least one port in the filtration cassette when installed in a filtration system.

[0006] The basic shape of a typical TFF filtration cassette is essentially a rectangular cuboid. The filtration cassette having two major surfaces (that may be referred to as front and back surfaces) and four lateral side surfaces. In one embodiment, the sealing case surrounds at least the two major surfaces and at least one lateral surface. In another embodiment, the sealing case surrounds at least four, five or all six sides of the filtration cassette, wherein at least two of the sides that are surrounded by the sealing case includes the front and back surfaces.

[0007] In another embodiment, the sealing case has an internal surface that is flat or substantially flat. For example, the internal surface does not have protrusions or raised areas that align with a port hole in the filtration cassette.

[0008] In another embodiment, the sealing case comprises two halves that mate together. For example, in a particular embodiment, the two halves of the sealing case are identical. In another embodiment, the two halves of the sealing case are not identical.

[0009] In one embodiment, the sealing case is an elastomeric material. In a particular embodiment, the sealing case is a thermoplastic elastomeric material. In another embodiment, the sealing case is a thermoset material.

[00010] As further described herein, the sealing case can be used with a filtration cassette such as a tangential flow filtration (TFF) cassette.

[00011] Also provided herein is a filtration device comprising both a filtration cassette and a sealing case as described above and further described below. Furthermore, a filtration system is also provided that comprises one or more of the described filtration devices and a pair of manifolds or holders, wherein the filtration devices have a fluid-tight seal when installed in the filtration system.

BRIEF DESCRIPTION OF THE DRAWINGS

[00012] The drawings are provided to illustrate certain embodiments of the present invention and are not to be construed as limiting the scope of the claims.

[00013] FIG. 1A is a top view of one half of a sealing case for a small filtration cassette.

[00014] FIG. 1B is a side view along line A—A in FIG. 1A.

[00015] FIG. 1C is a side view along line B—B in FIG. 1A.

[00016] FIG. 2A is a top view of one half of a sealing case for a large filtration cassette.

[00017] FIG. 2B is a side view along line A—A in FIG. 2A.

[00018] FIG. 2C is a side view of the sealing case in FIG. 2A in an inverted position.

[00019] FIG. 2D is a side view along line B—B in FIG. 2A.

DETAILED DESCRIPTION

[00020] FIG. 1A shows one half of a sealing case 1 suitable for using with a filtration cassette of similar size and shape. As will be appreciated, the dimensions of a sealing case can be adapted to any suitable size such that the case can be fitted onto a filtration cassette of interest. Examples of filtration cassettes that are commercially available include Pellicon®2 ultrafiltration cassettes (EMD Millipore Corporation, Billerica MA), as well as others known in the industry.

[00021] The sealing case is preferably formed of an elastomeric material, such as a thermoplastic elastomer, which can be selected according the needs. For example, the choice of material may for compatibility with the fluid being handled, chemical stability, expected service life (*e.g.*, single-use, multiple-use, under continuous or repeated clamping pressure for longer or shorter periods of time), *etc*. Suitable materials include, but are not limited to, thermoplastic elastomers which can be formed of styrenic block copolymers, blends of ethylene-propylene-diene monomer (EPDM) and polypropylene and the like and which are sold under brand names such as Santoprene® polymer, Kraton® thermoplastic elastomer and Dynaflex® elastomer, EPDM rubber, thermosets, silicone, and rubbers, either natural or synthetic. In one embodiment, the sealing case may be made of two or more materials. For example, the sealing case can comprise a rigid thermoplastic component and an elastomeric material, such as a thermoplastic elastomer. For example, one or more surfaces may comprise a rigid thermoplastic component with the sealing surfaces comprising an elastomeric material. The rigid thermoplastic component may provide structural integrity, for example. The elastomeric material can be overmolded onto the rigid thermoplastic component using art standard techniques.

[00022] The sealing case has one or more openings 10 that correspond and align with at least one or more ports in a filtration cassette (not shown) to which the sealing case is to be fitted. The sealing case is fitted to a filtration cassette by mating two halves of the sealing case 1. In particular, the sealing case is fitted to the filtration cassette without use of an adhesive or other bonding method. For example, the case is not overmolded onto a filtration cassette. Instead, two halves of the sealing case 1 are placed around a filtration cassette and mated together. Many configurations may be used to mate the two halves of the sealing case together as will be appreciated by those of skill in the art. For example, as illustrated more particularly in FIG. 1B, the edges of the sealing case may have a two-step

indentation 14a designed to fit a complementarily shaped 14b counterpart in the other half of the sealing case.

[00023] Both halves of the sealing case can be identical. FIG. 1B exemplifies one design of this embodiment where one half of a sealing case is identical to its complementary half. A similar design is exemplified in FIG. 2B. The two identical halves of a sealing case can be suitably mated by inverting one sealing case half and rotating 180° relative to the other sealing case half. While this may be one preferred embodiment, it is equally contemplated that the two halves of a sealing case are not identical, but which are still complementary such that the two halves can be mated together.

[00024] In addition to the two-step indentation, other configurations for mating two halves of a sealing case can be used. For example, "ball and socket" projections and indentations, where the ball may be spherical, cuboid, rhomboid, or other such shapes. Alternatively, a variety of ridges and grooves may be used. Still further, two halves may be joined by a mating strip that joins to each half together (e.g., through complementary grooves or indentations) around the perimeter of each half. These and other "snap-fit" combinations are known in the art. It will also be appreciated that more than one mating configuration may be used.

[00025] In one embodiment, the two halves of the sealing case are separate before fitting onto a filtration cassette. In another embodiment, the two halves of the sealing case are joined, for example at one edge with a hinge, before fitting onto a filtration cassette.

[00026] As particularly shown in FIG. 1C and FIG. 2D, the internal surface 12 of the sealing case, which is the side of the case that will be adjacent to the filtration cassette once assembled, is flat or essentially flat. That is, the internal surface is without raised projections, edges or rings, particularly at or near the one or more openings 10. Specifically, the internal surface 12 of the sealing case 1 does not protrude either partially or completely into a corresponding port of a filtration cassette after fitting the sealing case 1 to the filtration cassette. While a flat or essentially flat internal surface 12 is preferred, it may be contemplated that the internal surface adjacent the openings 10 may have a raised edge or ring that does not protrude either partially or completely into a corresponding port of a filtration cassette, but surrounds the opening 10.

[00027] Indentations 16 in the sealing case shown in FIG. 2A and 2C, correspond and align with similar indentations on a filtration cassette (not shown). The indentations 16 in the sealing case and the filtration cassette accommodate the use of tie rods, threaded pins or bolts or other such clamping devices as conventionally used with the manifolds or holders to

align the filtration cassettes and secure the assembly of the filtration system. The filtration system may comprise one or more filtration cassettes, each fitted with a sealing case. Once assembled, the clamping holder and clamping device exerts pressure on the filtration cassettes fitted with the sealing case such that a fluid-tight seal is formed around the one or more ports on each of the filtration cassette.

[00028] Advantageously, the sealing case provides a fluid-tight seal without the need for separate gaskets and without the need to bond a gasket to the filtration cassette. The use of a sealing case as described herein reliably prevents leaks after assembly and installation into a filtration system. The assembly is efficient and is less labor-intensive for the user. The sealing case may be provided as a pre-sterilized unit with the filtration cassette. The sealing case and filtration cassette can be disposed after a single use and need not be reused, thus eliminating a need for additional dismantling and re-sterilization steps.

[00029] While this invention has been particularly shown and described with reference to example embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims. It should also be appreciated that the various technical features of the described devices may be combined in various ways to produce alternative and additional embodiments.

[00030] The teachings of all patents, published patent applications, and references cited herein are incorporated by reference in their entirety.

CLAIMS

What is claimed is:

1. A filtration device comprising a filtration cassette and a sealing case that is not bonded or overmolded to the filtration cassette, wherein the sealing case surrounds the filtration cassette on at least a front and back surface of the filtration cassette and at least one side surface of the filtration cassette, the sealing case further comprising at least one opening that aligns with at least one port in the filtration cassette, wherein the internal surface of the sealing case is substantially flat, the filtration device having a fluid-tight seal between the sealing case and around the at least one port in the filtration cassette when installed in a filtration system.
2. The filtration device of claim 1, wherein the sealing case comprises two halves that mate together.
3. The filtration device of claim 2, wherein the two halves of the sealing case are identical.
4. The filtration device of any one of the preceding claims, wherein the sealing case is an elastomeric material.
5. The filtration device of claim 4, wherein the elastomeric material is a thermoplastic elastomer.
6. The filtration device of any one of the preceding claims, wherein the filtration cassette is a tangential flow filtration (TFF) cassette.
7. A sealing case for a filtration cassette, wherein the sealing case when positioned on the filtration cassette surrounds at least four sides of the filtration cassette and forms a fluid-tight seal between the sealing case and around at least one port in the filtration cassette when installed in a filtration system, the sealing case comprising two halves that mate together and having an internal surface that is substantially flat.
8. The sealing case of claim 7, wherein the two halves of the sealing case are identical.
9. The sealing case of any one of claims 7-8, wherein the sealing case is an elastomeric material.
10. The sealing case of claim 9, wherein the sealing case is a thermoplastic elastomeric material.
11. The sealing case of any one of claims 7-10, wherein the filtration cassette is a tangential flow filtration (TFF) cassette.

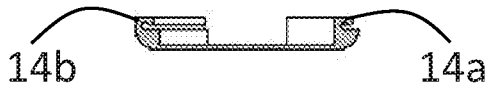

FIG. 1B

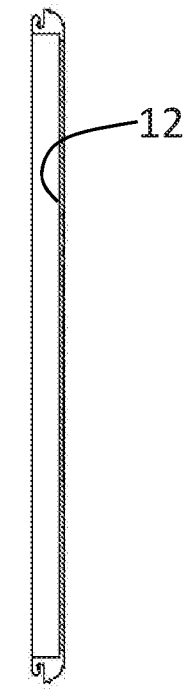

FIG. 1C

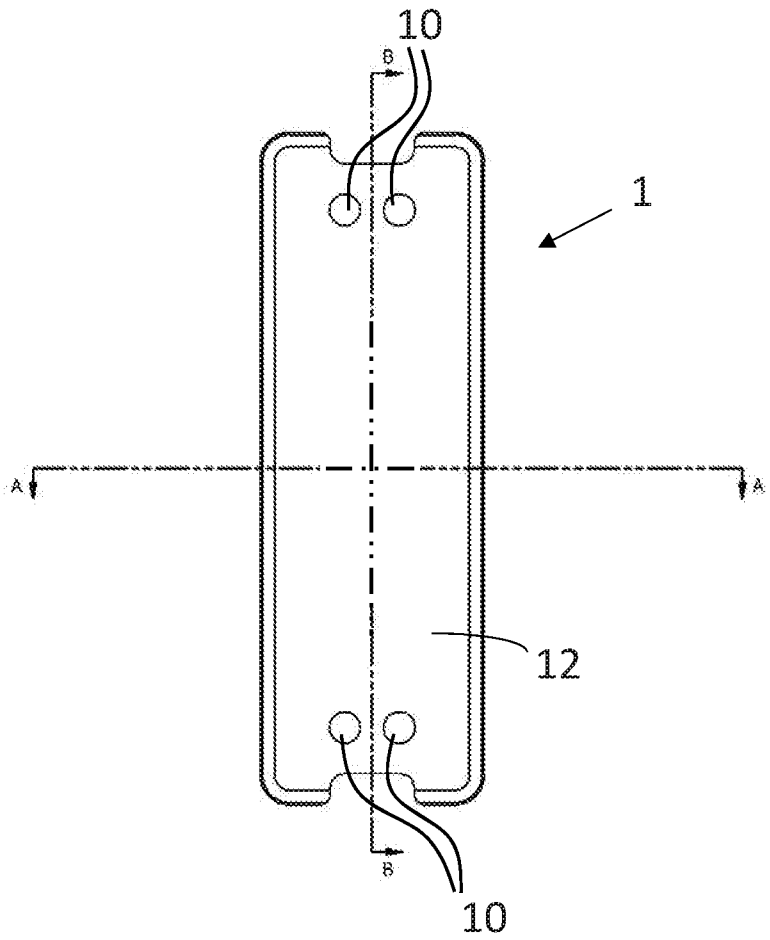

FIG. 1A

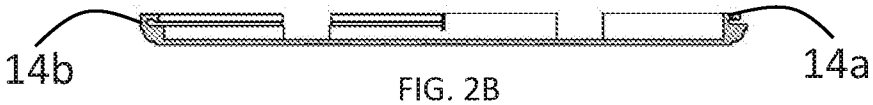

FIG. 2B

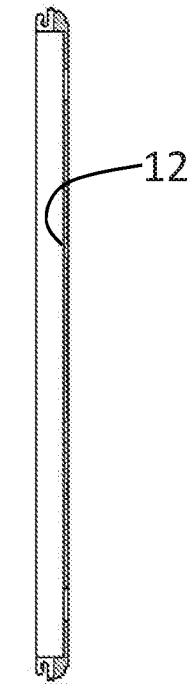

FIG. 2D

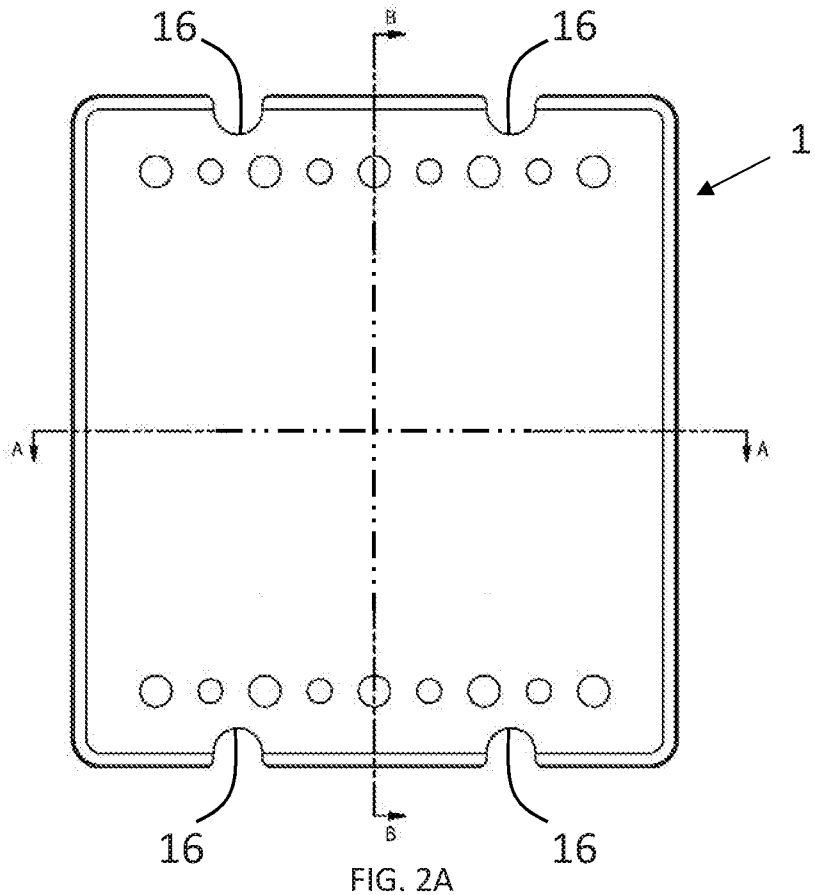

FIG. 2A

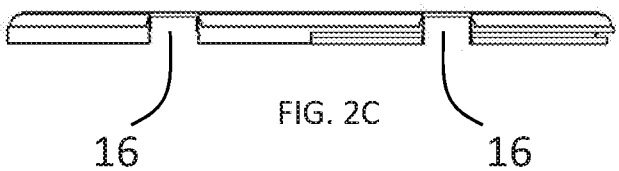

FIG. 2C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/035133

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.: 6, 11
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:

1. ☐ As all required addtional 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 any 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.:

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.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/035133

A. CLASSIFICATION OF SUBJECT MATTER

B01D 61/08(2006.01)I, B01D 61/10(2006.01)I

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)
B01D 61/08; B01D 25/00; B01D 25/12; F16J 15/50; B01D 63/08; B01D 61/10

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords:filtration device, sealing case, cassette, hole, fluid-tight seal, tangential flow filtration(TFF)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0174711 A1 (MORRISSEY, MARTIN et al.) 21 July 2011 See paragraphs [0013], [0015]-[0019]; claim 3; and figure 2.	1-5,7-10
A	US 2002-0139741 A1 (KOPF III, HENRY) 03 October 2002 See paragraphs [0021], [0024]; claim 1; and figures 3A, 4, 10.	1-5,7-10
A	CN 203750238 U (YUNNAN YUNJING FORESTRY & PULP MILL CO., LTD.) 06 August 2014 See abstract; claims 1-4; and figure 1.	1-5,7-10
A	US 2006-0125187 A1 (BARTLETT, ANDREW et al.) 15 June 2006 See paragraphs [0039]-[0041]; and figures 3-4.	1-5,7-10
A	US 2008-0257813 A1 (PROULX, STEPHEN P. et al.) 23 October 2008 See abstract; and claims 1-8.	1-5,7-10

☐ 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	Date of mailing of the international search report
29 August 2016 (29.08.2016)	**30 August 2016 (30.08.2016)**

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2016/035133

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		WO 00-78429 A3	18/10/2001
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