ORIGINAL

ABSTRACT

CONTROLLED DISCHARGE OSTOMY APPLIANCE AND SHIELD THEREFOR

A controlled discharge ostomy appliance assembly comprises (i) a stoma seal that is self-urging with a dynamic damping characteristic that resists changes of seal volume, (ii) a press-fit coupling member displaceable from an unlocked position to a locked position as part of a press-fit process, and (iii) a single-use frangible portion. The assembly further includes a protector shield removably fastened to the appliance forming a combined assembly therewith. The protector shield comprises (i) a seal displacer manipulable for displacing the stoma seal to a non-operative position ready for fitting, (ii) a substantially rigid coupling member guard portion for protecting the state of the coupling member, and (iii) a bracing portion for bracing the single-use frangible portion.

CLAIMS

1. A controlled discharge ostomy appliance assembly, comprising:

(a) a controlled discharge ostomy appliance having a body-facing side for facing towards a stoma in use, the appliance comprising:

a seal support wall;

a flexible seal membrane sealed to the support wall to define a seal chamber;

a resilient device disposed in the seal chamber and configured for generating, in response to compression of the resilient device from the body facing side, a resilient return force for urging the seal membrane in a direction towards the body-facing side to a deployed seal state; and

at least one port communicating with the seal chamber for permitting the transfer of inflation fluid with respect to the seal chamber, said at least one port defining a fluid flow property to effect a dynamic damping characteristic for changes in volume of the seal chamber; and

(b) a seal displacer fastened releasably to the appliance forming a combined assembly therewith, the seal displacer being manipulable by hand to displace the seal membrane against the return force of the resilient device, to place the seal membrane in a non-deployed seal state ready for the appliance to be fitted at a stoma, wherein in the non-deployed seal state the resilient device is substantially compressed, and the seal membrane is displaced to a substantially non-operative position, and whereafter, upon separation of the seal displacer from the appliance, the seal membrane advances progressively towards the deployed seal state by the resilient return force damped by the dynamic damping characteristic.

2. The assembly of claim 1, wherein the seal displacer is disposed on the body-facing side of the appliance.

3. The assembly of claim 1, wherein the seal displacer is displaceable between a first limit position accommodating the seal membrane in an at least partly deployed seal state to which the resilient device urges the seal membrane, and a second limit position corresponding to said non-deployed seal state.

4. The assembly of claim 3, wherein in the first limit position, the seal displacer has a cup shape for receiving at least a portion of the seal membrane.

5. The assembly of claim 4, wherein in the second limit position, the seal displacer has a shape selected from: flattened; a reverse-cup shape of opposite convexity to the first limit position.

6. The assembly of claim 1, wherein the seal displacer is made of molded plastics that (i) has a self-supporting shape, and (ii) is deformable to permit manipulation to deform the seal.

7. The assembly of claim 1, wherein the seal displacer comprises at least one fastener for engaging the appliance to fastener said seal displacer to the appliance releasably.

8. The assembly of claim 7, wherein the at least one fastener engages a periphery of the appliance.

9. The assembly of claim 7, wherein the fastener interfits mechanically with the appliance.

10. The assembly of claim 7, wherein the appliance comprises an ostomy coupling member for securing the appliance in use in an operative position at a stoma, and wherein the fastener engages the appliance at a position distinct from the ostomy coupling member.

11. The assembly of claim 1, comprising a protector shield of which the seal displacer forms an integral part, the protector shield being configured for protecting the body-facing side of the appliance prior to fitting of the appliance at a stoma, and the protector shield being releasably fastened to said appliance to define said releasable fastening between said seal displacer and the appliance, and to define said combined assembly.

12. The assembly of claim 11, wherein the appliance further comprises a frangible single-use element that is configured to (i) provide for attachment of the appliance at a stoma only when the frangible single-use element is intact, and (ii) be torn in use upon removal of the appliance from the stoma the first time, and the protector shield comprises a protector bracing portion for bracing the frangible single-use element to prevent tearing of the frangible single-use element prior to first use of the appliance.

13. The assembly of claim 11, wherein the appliance further comprises an ostomy coupling member for coupling to a body fitment, the coupling member being displaceable relative to a cover of the appliance from a first unlocked position to a second locked position, and wherein the protector comprises a substantially rigid coupling member guard portion for protecting the state of the coupling member prior to first use of the appliance.

14. The assembly of claim 1, wherein the appliance nests within the protector shield.

15. A controlled discharge ostomy appliance assembly, the assembly comprising:

(a) a controlled discharge ostomy appliance having a body-facing side and comprising:

a cover;

a stoma seal disposed within the cover,

a first coupling member for coupling to a body fitment for mounting the appliance in an operative position at a stoma, the first

coupling member being displaceable with respect to the cover from an unlocked position to a locked position; and

(b) a protector shield for protecting the body-facing side of the controlled discharge ostomy appliance, the protector being made of integrally molded plastics and comprising:

a substantially rigid coupling member guard portion for protecting the first coupling member of the appliance from external forces that might otherwise displace the first member from the unlocked position to the locked position, and

a fastener profile for co-operating with the appliance at a location distinct from the first coupling member, to fasten the protector to the appliance releasably to form a combined assembly therewith.

16. The assembly of claim 15, wherein the protector shield further comprises a seal displacer manipulable by a user to displace the stoma seal to a non-deployed position prior to fitting the appliance at a stoma.

17. The assembly of claim 15, wherein:

the appliance further comprises a second member including a frangible portion that is selectively breakable or tearable in use for releasing the appliance from the body fitment; and

(b) the protector shield further comprises

a bracing portion for bracing and supporting the second member of the appliance, to prevent tearing of the frangible portion prior to first use.

18. A controlled discharge ostomy appliance assembly, the assembly comprising:

(a) a controlled discharge ostomy appliance having a body-facing side and comprising:

a stoma seal, and

a member including a frangible portion that is selectively breakable or tearable in use for releasing at least one of (i) the stoma seal from an operative position; and (ii) the appliance from a body fitment; and

(b) a protector shield for protecting the body-facing side of the controlled discharge ostomy appliance, the protector being made of integrally molded plastics and comprising:

a bracing portion for bracing and supporting said member of the appliance, to prevent tearing of the frangible portion prior to first use, and

a fastener profile for co-operating with the appliance, to fasten the protector to the appliance to form a combined assembly therewith.

19. The assembly of claim 18, wherein the protector shield further comprises a seal displacer manipulable by a user to displace the seal of the appliance to a non-deployed position prior to fitting the appliance at a stoma.

20. A protector shield for protecting a body-facing side of a controlled discharge ostomy appliance, the protector being made of integrally molded plastics and comprising:

(i) a seal displacer manipulable by a user to displace a self-urging seal of the appliance to a non-deployed position prior to fitting the appliance at a stoma,

(ii) a substantially rigid coupling member guard portion for protecting a first coupling member of the appliance from external forces that might otherwise displace the first member from an unlocked position to a locked position,

(iii) a bracing portion for bracing and supporting a second member of the appliance, the second member including a frangible portion that is selectively breakable or tearable in use to release the appliance,

(iv) a fastener profile for co-operating with a periphery of the appliance, to releasably fasten the protector shield to the appliance to form a combined assembly therewith.

21. The protector shield of claim 20, wherein the seal displacer is located at a centre of the protector shield.

22. The protector shield of claim 20, wherein the coupling member guard portion comprises a channel shaped fender, the fender extending in a closed loop to define an endless channel.

23. The protector shield of claim 20, wherein the coupling member guard portion extends around the seal displacer.

24 The protector shield of claim 23, wherein the seal displacer and the coupling member guard portion adjoin at a bendable interface portion.

25. The protector shield of claim 20, wherein the bracing portion comprises a step-shaped recess extending around a closed loop shaped path.

26. The protector shield of claim 20, wherein the fastener profile comprises at least one undercut lug.

27. A controlled discharge ostomy appliance for attachment to body-side coupling member of a body fitment, the appliance comprising:

a stoma seal for sealing against a stoma in use;

a first member of closed loop form and including a coupling formation, the coupling formation being deflectable to permit press fit engagement with a said body-side coupling member when pressed in a first direction;

a second member having at least one bracing portion;

wherein the first and second members are relatively displaceable generally parallel to said first direction, from a first unlocked position in which the bracing portion does not substantially brace the coupling formation against said deflexion, to a second locked position for bracing the coupling formation against said deflexion;

wherein the appliance further comprises:

co-operating retainers on the first and second members and configured to:

(i) retain said first and second members initially in said unlocked position with a first retention strength until pressure is applied to cause relative displacement of the first and second members to the locked position; and

(ii) retain said first and second members in said locked position with a second retention strength; and

the appliance further comprising a single-use frangible portion of the second member, for obstructing attachment of the device to the body side coupling member more than once, the frangible portion extending through said bracing portion, and configured such that, to release the appliance, the frangible portion is torn, thereby removing the bracing effect of the bracing portion.

28. The appliance of claim 27, wherein said second retention strength is greater than said first retention strength.

29. A controlled discharge ostomy appliance, the appliance comprising:

a first integrated module comprising: a top wall; a collapsible collector depending from the top wall at a first open end of the collector; and a first member of closed loop shape depending from the collapsible collector at a second open end of the collector; the first module defining a first chamber;

a second integrated module comprising: a second member including a bracing portion for cooperating with the coupling formation of the first member for bracing the coupling formation against outward deflection, the second member including a frangible portion for releasing the bracing effect when the frangible portion is broken; and

a third integrated module comprising: a seal support wall and a seal membrane depending from the seal support wall, the seal support wall and the seal membrane defining a seal chamber in which is disposed a resiliently compressible device; the third module being locatable in an operative position at least partly within in the first chamber of the first module with the seal support wall arranged close to the top wall;

wherein the first, second and third modules are attachable one to another to form an appliance assembly.

30. The appliance of claim 29, wherein the second member has a generally closed loop form, and defines a skirt profile around the first module.

31. The appliance of claim 30, wherein at least a portion of the top wall of the first module is received at a respective aperture of the second member.

32. The appliance of claim 29, wherein the seal support wall carries at least one port for controlling fluid flow into and/or our of the seal chamber.

33. The appliance of claim 32, wherein at least one port comprises a chimney that extends through an aperture in the top wall, and at least a second port communicates with a space between the seal support wall and the top wall.

34. The appliance of claim 29, wherein the top wall of the first module and the seal support wall of the third module together define a flatus vent channel communicating with the first chamber around at least a portion of the periphery of the seal support wall.

35. The appliance of claim 34, further comprising at least one flatus porous element disposed in the flatus vent channel, the at least one flatus porous element being at least one selected from a deodorising filter and a phase separator.

36. The appliance of claim 29 further comprising at least one selected from:

(i) a coupling for retaining the third module in the operative position with respect to the first module;

(ii) a coupling provided between the second module and at least one of the first and third modules, for retaining the modules in assembled condition.

37. A method of preparing a controlled discharge ostomy appliance for fitting at a stoma, the appliance having a body-facing side for facing towards a stoma in use, and the appliance comprising:

a seal support wall;

a flexible seal membrane sealed to the support wall to define a seal chamber;

a resilient device disposed in the seal chamber and configured for generating, in response to compression of the resilient device from

the body facing side, a resilient return force for urging the seal membrane in a direction towards the body-facing side to a deployed seal state; and

at least one port communicating with the seal chamber for permitting the transfer of inflation fluid with respect to the seal chamber, said at least one port defining a fluid flow property to effect a dynamic damping characteristic for changes in volume of the seal chamber;

wherein the method comprises the step of displacing the seal against the return force of the resilient device, to place the seal membrane in a non-deployed seal state ready for the appliance to be fitted at a stoma, wherein in the non-deployed seal state the resilient device is substantially compressed, and the seal membrane is displaced to a substantially non-operative position, from which the seal membrane advances progressively towards the deployed seal state by the resilient return force damped by the dynamic damping characteristic.

Dated this 06/03/2012

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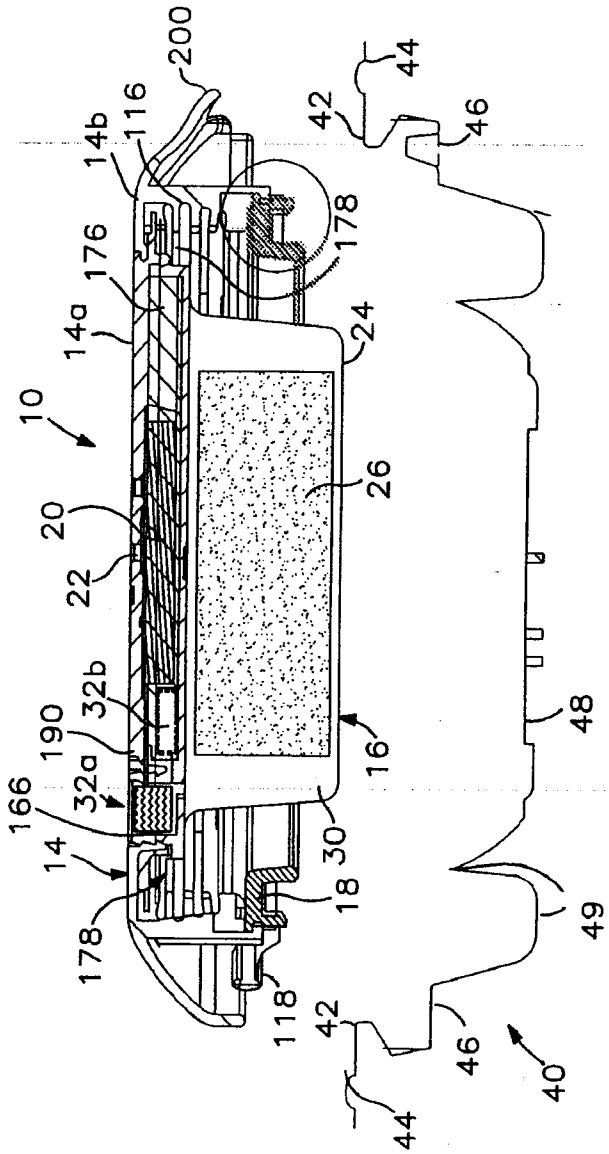

FIG. 1

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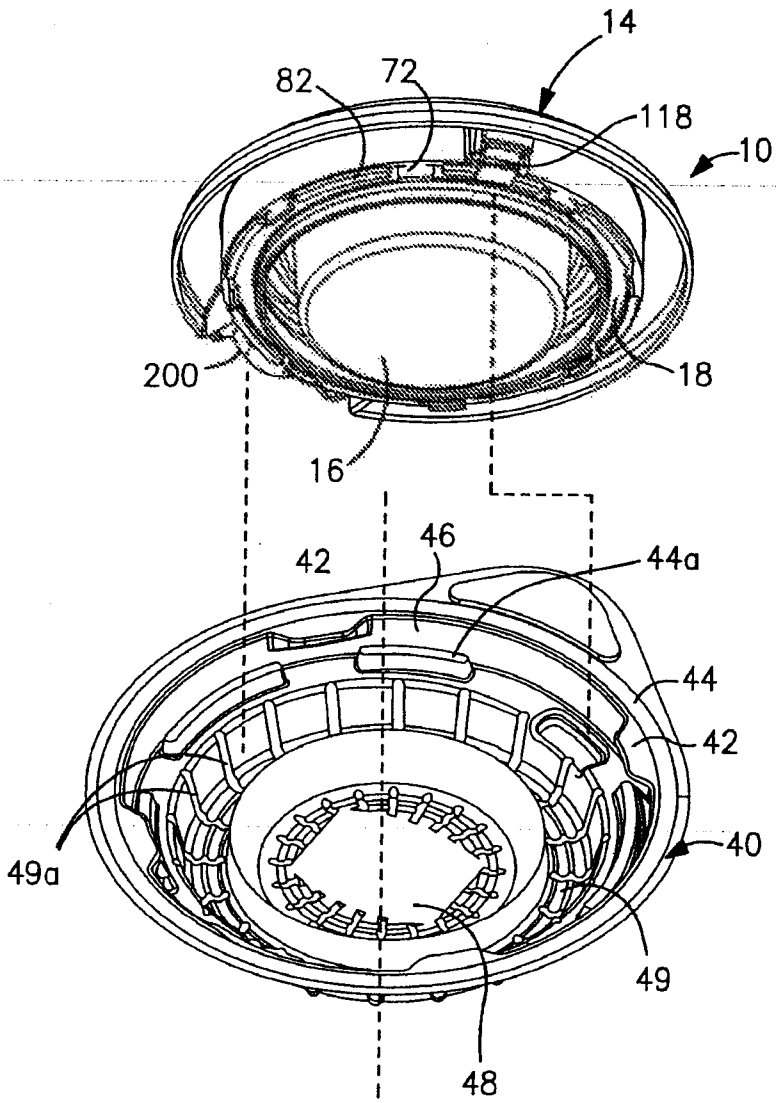

FIG. 2

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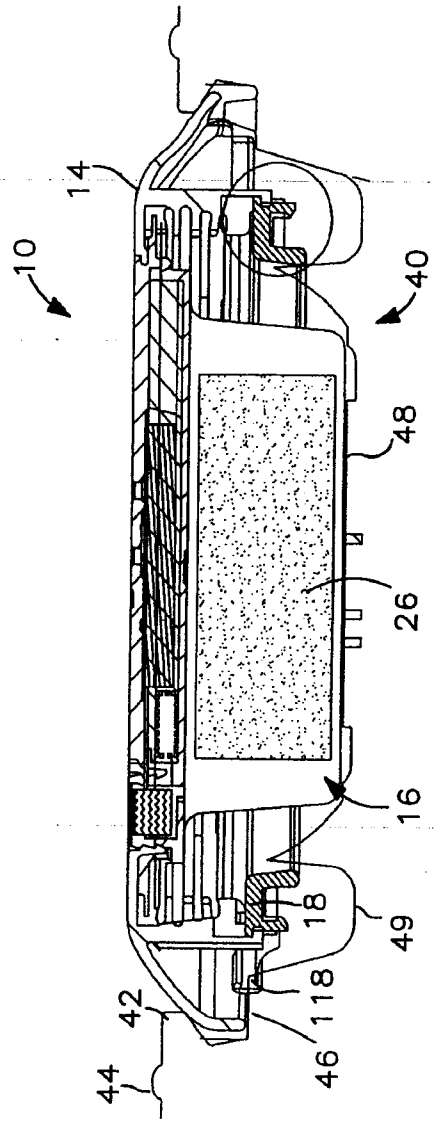

FIG. 3

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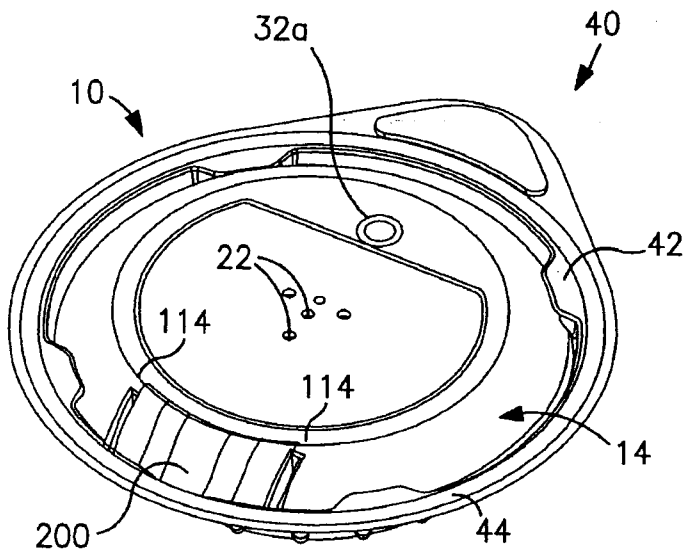

FIG. 4

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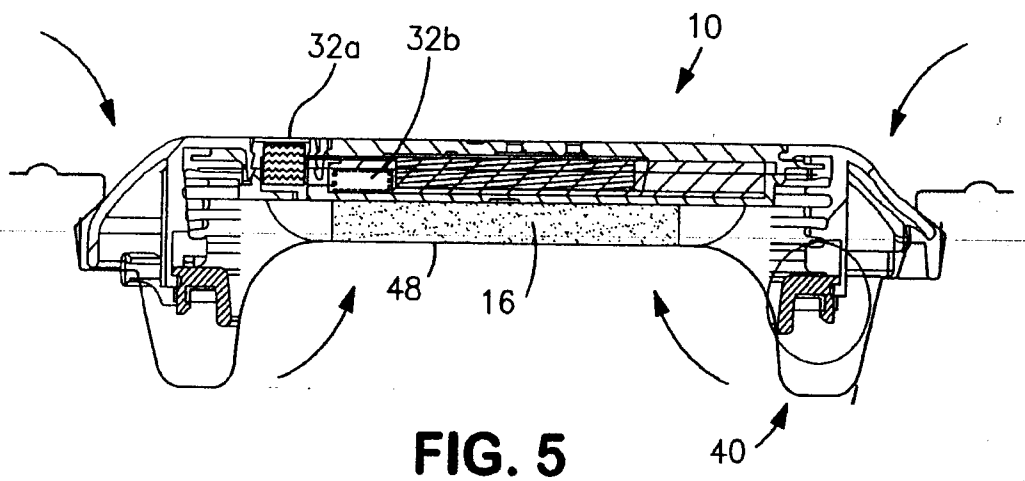

FIG. 5

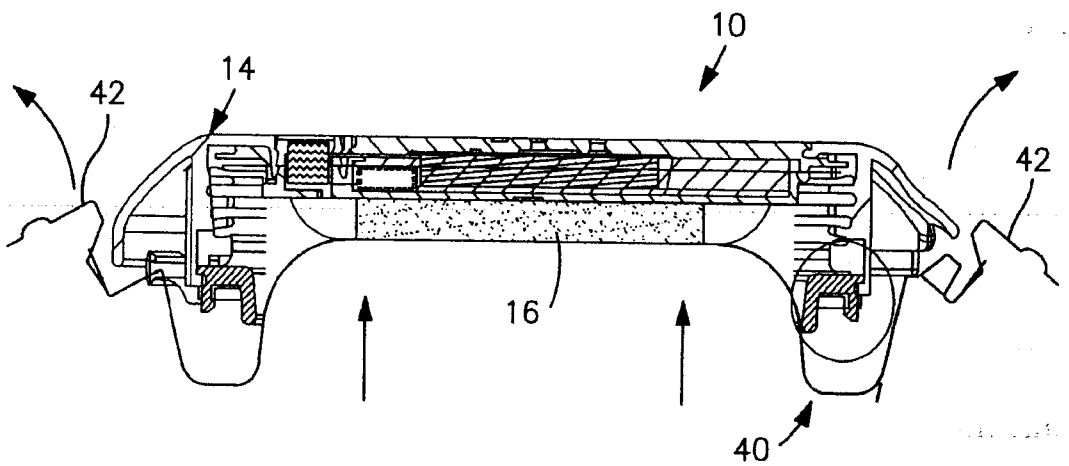

FIG. 6

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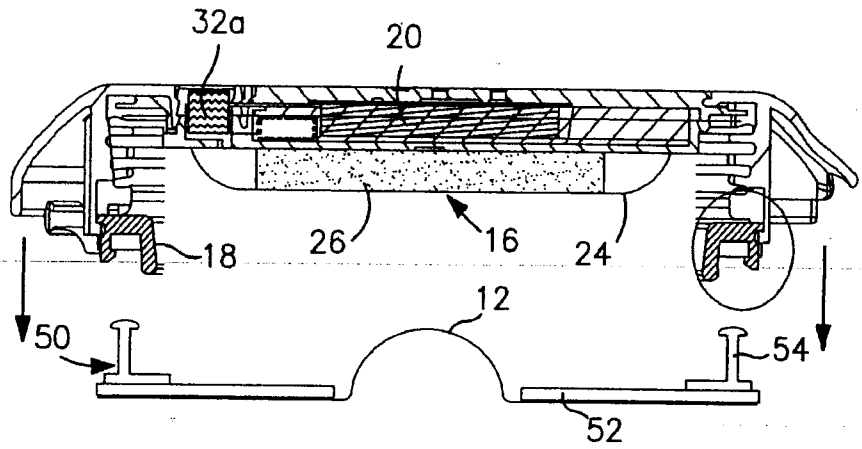

FIG. 7

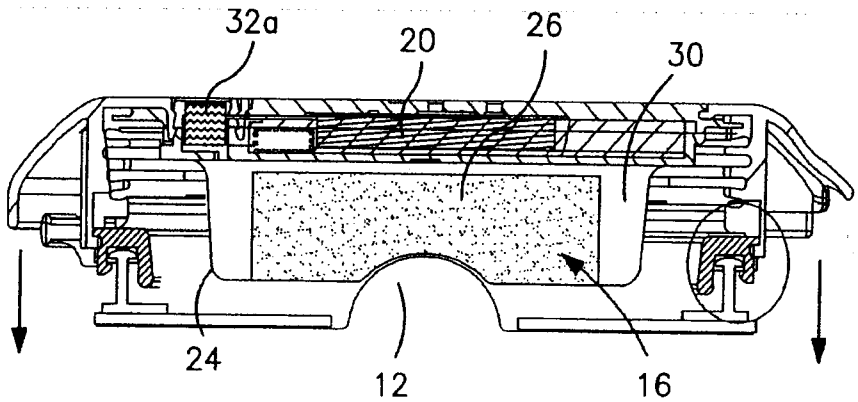

FIG. 8

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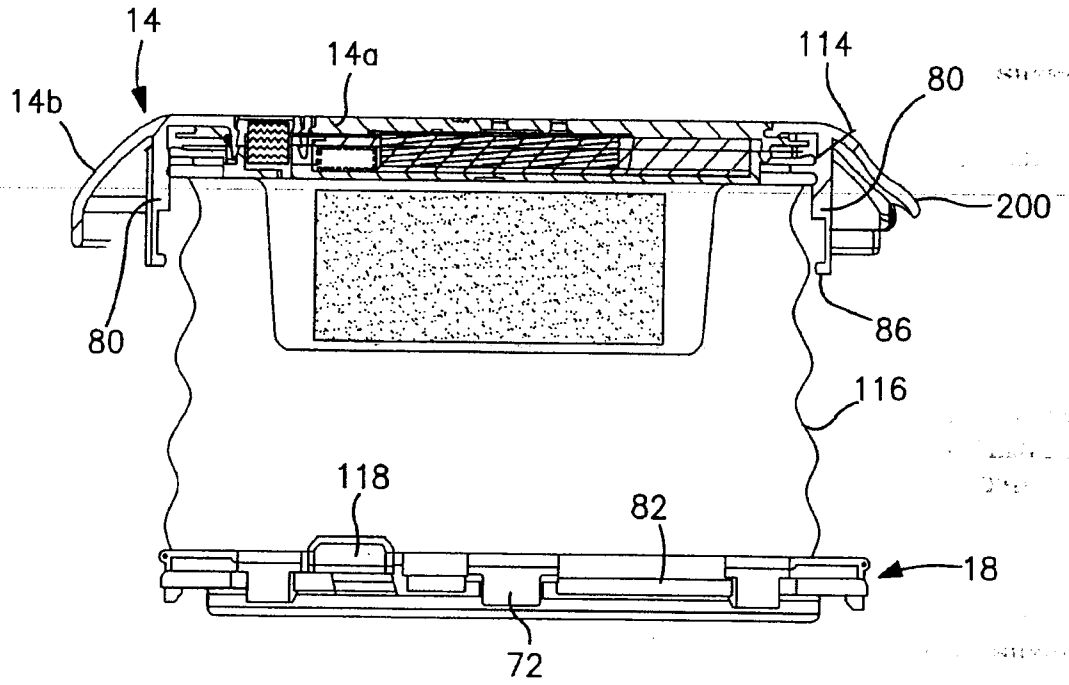

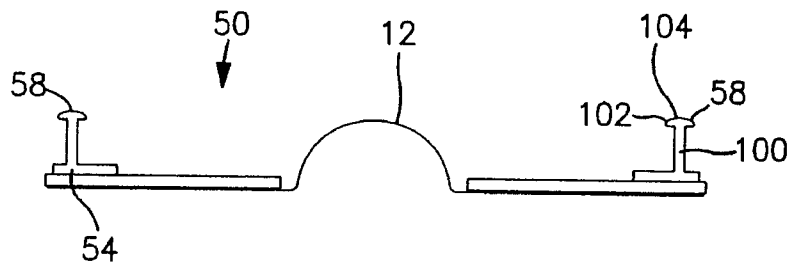

FIG. 9

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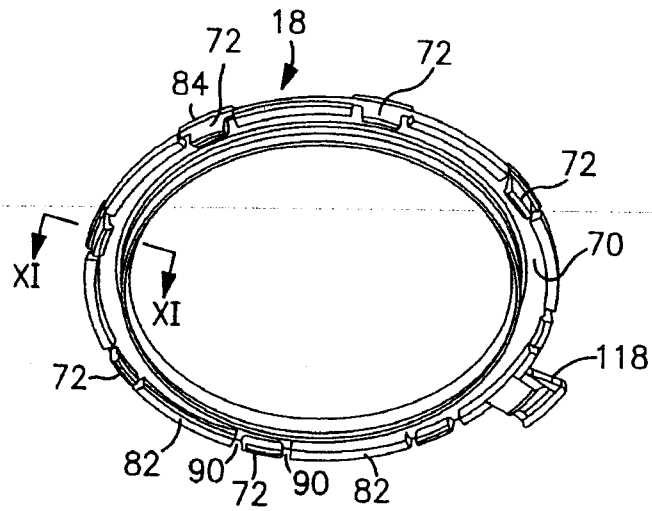

FIG. 10

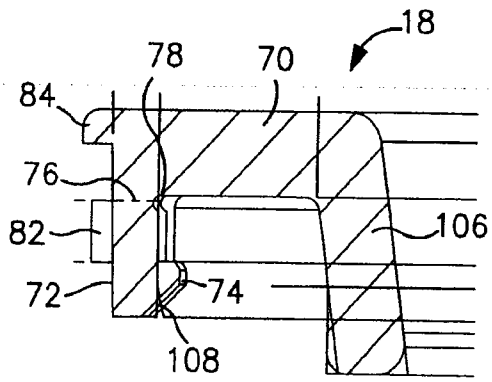

FIG. 11

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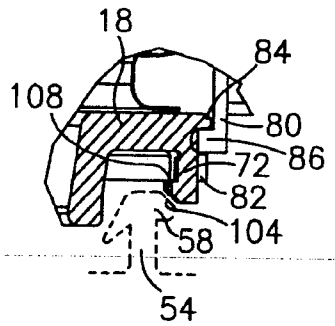

FIG. 12

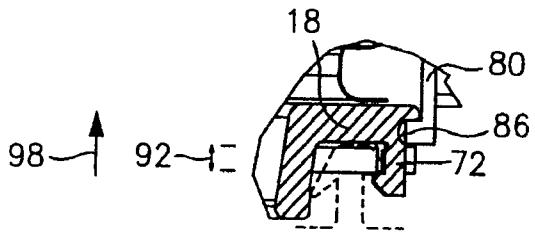

FIG. 13

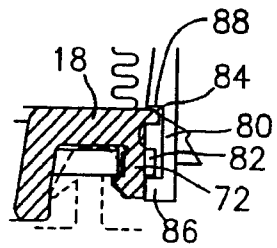

FIG. 14

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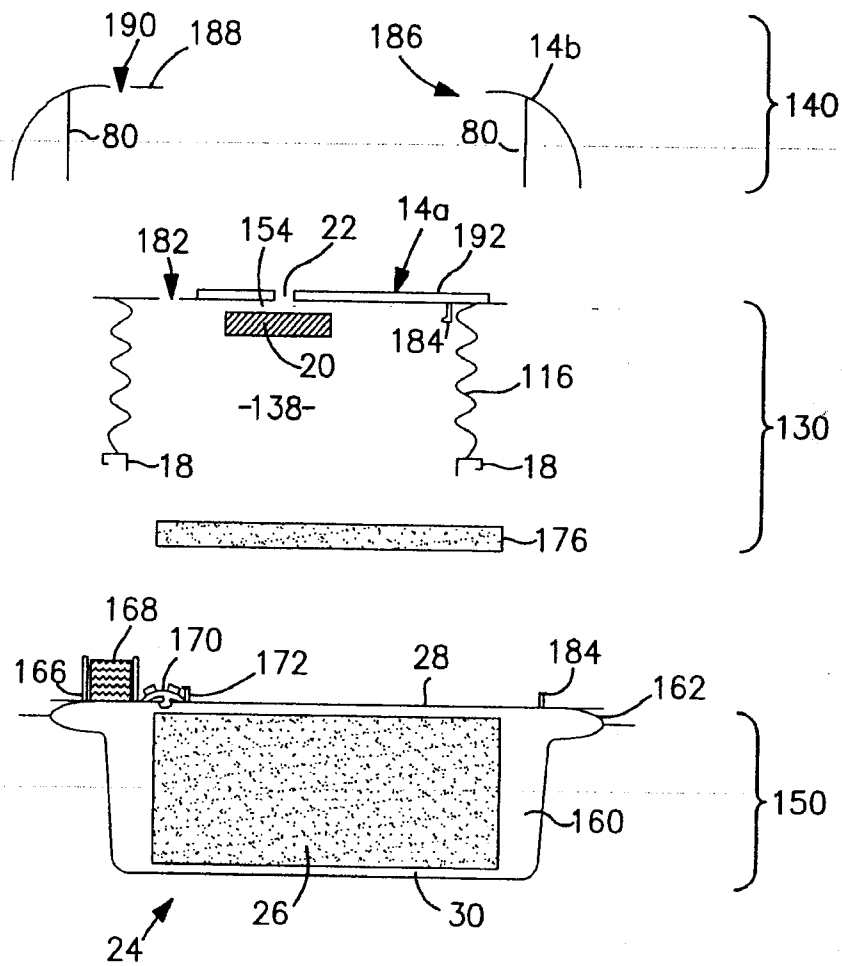

FIG. 15

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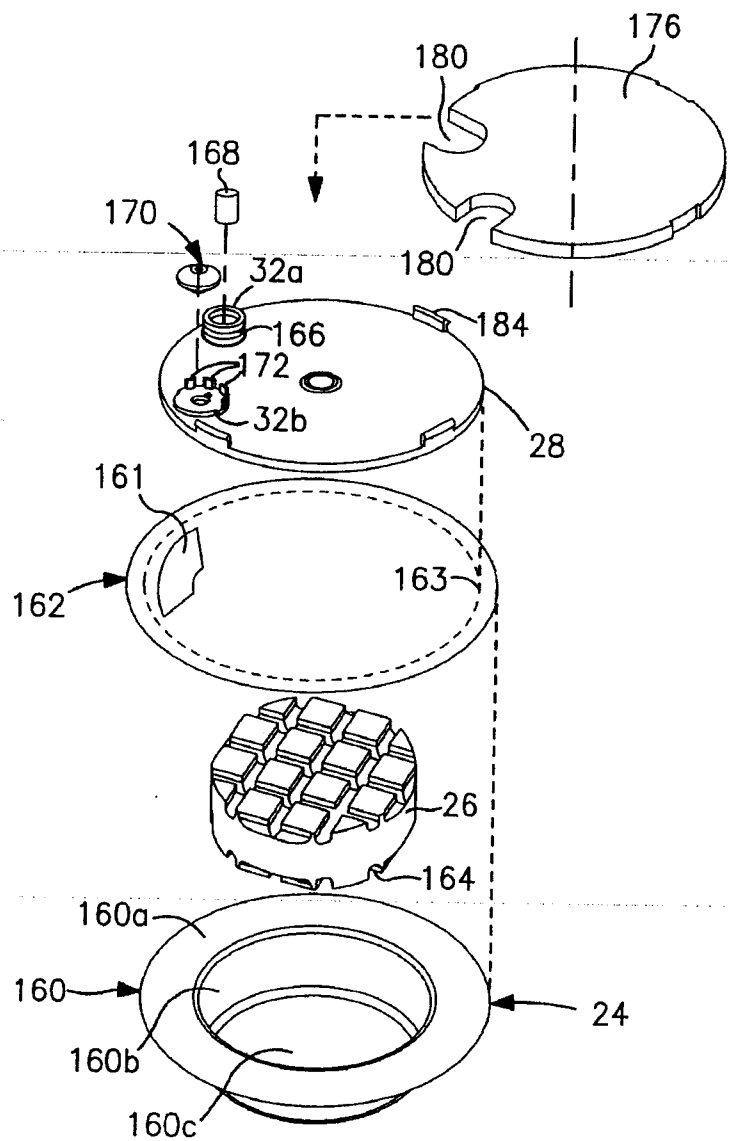

FIG. 16

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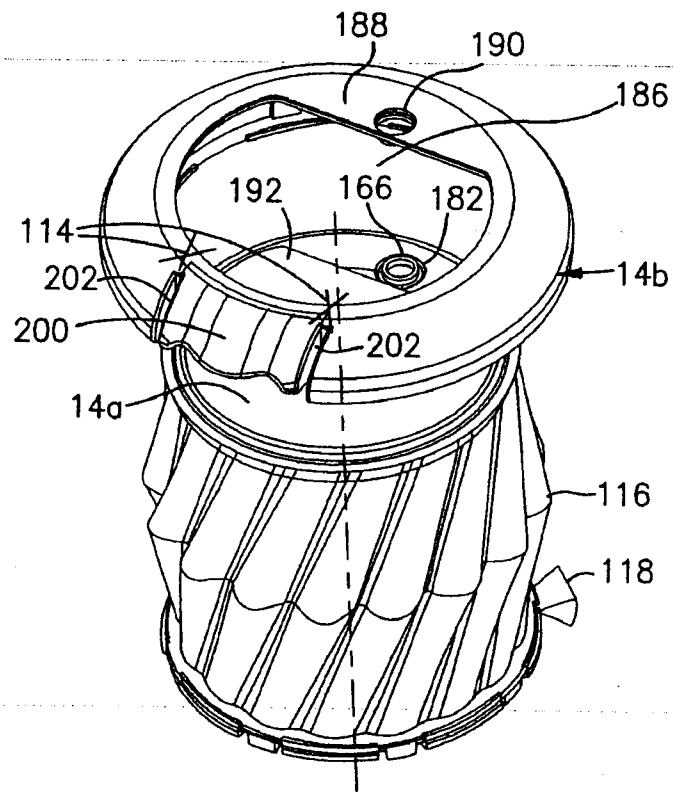

FIG. 17

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