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TITLE

RELEASE LINERS FOR OSTOMY LEAKAGE SENSING ACCESSORY

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RELEASE LINER FOR OSTOMY LEAKAGE SENSING ACCESSORY**CROSS REFERENCE TO RELATED APPLICATIONS**

[0001] This present application claims the benefit and priority of U.S. Provisional Application No. 63/510,669, entitled RELEASE LINER FOR OSTOMY LEAKAGE DETECTION SYSTEM, filed June 28, 2023, the disclosure of which is incorporated by reference herein in its entirety.

BACKGROUND

[0002] This disclosure is related to an ostomy leakage detection system. More particularly, the present disclosure pertains to a release liner for use with an ostomy sensing accessory of the leakage detection system.

[0003] Ostomy leakage detection systems can include sensors for detecting the presence of ostomy effluent (or leakage) around a stoma of a user. Such sensors can be part of an accessory that attaches to a barrier and surrounds a stoma. The sensing accessories may require mounting the sensing accessory in a particular manner for correct use. For example, the sensing accessory may have sensors on a body-side of the accessory and therefore it must attach the body-side of the accessory around the stoma to detect a leak. Some users of ostomy appliances may encounter challenges or frustration with orienting the sensing accessory in the correct position for placement and use. Users can also experience frustration when removing a release liner for exposure of an adhesive layer for securing the accessory to the user and/or an ostomy barrier. Thus, there is a need in the art to address and mitigate such frustrations and provide an improved and easy-to-use sensing accessory.

[0004] Sensor accessories can also be difficult to package and/or remove from packaging. For

example, different sized sensor accessories can have central openings having differing sizes. Such varying configurations can present challenges in packaging and can require custom packaging designs to accommodate various sizes of the sensor accessories, which can increase costs and production time. In addition, adhesives on the surfaces of the accessory can exude or spread after being applied to the accessory during production. As such, there is a need in the art for a sensing accessory that can be efficiently produced and packaged and to account for potential flow of a hydrocolloid adhesive material after production so as to prevent sensor assemblies from sticking to one another and/or the packaging.

BRIEF SUMMARY

[0005] A sensing accessory for an ostomy leakage detection system is provided according to example embodiments.

[0006] In one aspect, a sensing accessory may include a sensing region comprising a plurality of sensors for detecting a leakage, a skin barrier layer arranged on a body-side of the sensing region for attachment to user's peristomal skin, an inlet opening defined by an inner periphery of the sensing region for receiving a stoma, and a first release liner covering the skin barrier layer. The first release liner may include a first center opening defined by an inner periphery of the first release liner and having a universal width that is less than a width of the inlet opening. The universal width may be configured such that the inner periphery of the first release liner is in contact with a post of a sensing accessory packaging while the inner periphery of the sensing region is arranged at a distance away from the post when the sensing accessory is packaged in the sensing accessory packaging.

[0007] In an embodiment, the first release liner may include printed graphics configured to

illustrate where the skin barrier layer of the sensing accessory is to be mounted.

[0008] In an embodiment, the printed graphics may be further configured to illustrate where not to cut the sensing region.

[0009] In an embodiment, the first release liner may include a first pull tab.

[0010] In an embodiment, the first pull tab may be colored to emphasize a location of the pull tab.

[0011] In an embodiment, the skin barrier layer is formed from a hydrocolloid adhesive.

[0012] In an embodiment, the first release liner extends past at least one edge of the skin barrier layer.

[0013] In an embodiment, the first release liner extends 1mm past an inner periphery of the skin barrier layer.

[0014] In an embodiment, the sensing accessory may further include an adhesive layer arranged on a distal-side of the sensing region and a second release liner arranged to cover the adhesive layer. The second release liner may include a second center opening having a width greater than the universal width.

[0015] In an embodiment, the first release liner may include a first pull tab defining a cutout. The second release liner may include a second pull tab. The first pull tab and the second pull tab may extend past the sensing region at the same location and the second pull tab may extend past the cutout.

[0016] In an embodiment, the first and second release liners may be formed from different materials.

[0017] In an embodiment, the first release liner may be more rigid than the second release liner.

[0018] In an embodiment, the first release liner may be formed from a polyester release liner

and the second release liner is formed from a paper liner.

[0019] In an embodiment, the second release liner may be configured to be removed from the sensing accessory with less force than the first release liner. The second release liner may have a lower release value than the first release liner.

[0020] In another aspect, a sensing accessory for an ostomy leakage detection system may include a sensing region including a plurality of sensors for detecting a leakage, wherein the sensing region has a body-side surface and a distal-side surface. The sensing accessory may further include an inlet opening defined by an inner periphery of the sensing region for receiving a stoma, a first release liner arranged to cover the body-side surface and including a first center opening defined by an inner periphery of the first release liner and aligned with the inlet opening, and a second release liner arranged to cover the distal-side surface and including a second center opening defined by an inner periphery of the second release liner and aligned with the inlet opening. A width of at least one of the first and second center openings may be a universal width that is less than a width of the inlet opening. The universal width is configured such that the inner periphery of the corresponding release liner is in contact with a post of a sensing accessory packaging while the inner periphery of the sensing region is arranged at a distance away from the post when the sensing accessory is packaged in the sensing accessory packaging.

[0021] In an embodiment, the first release liner may include printed graphics configured to illustrate where the body-side surface of the sensing region is to be mounted on a user. The second release liner may include a printed graphics configured to illustrate where the distal-side surface of the sensing region is to be mounted on an barrier appliance of an ostomy bag.

[0022] In an embodiment, at least one of the first and second release liners may include a pull tab.

[0023] In an embodiment, the pull tab may be colored to emphasize a location of the pull tab.

[0024] In an embodiment, the sensing region may include a skin barrier layer defining the body-side surface and formed from a hydrocolloid adhesive, and an adhesive layer defining the distal-side surface.

[0025] In an embodiment, the first and second release liners may extend at least 1mm past peripheries of the skin barrier layer and the adhesive layer.

[0026] In an embodiment, a width of the second center opening of the second release liner may be greater than the universal width.

[0027] In an embodiment, the first release liner may be more rigid than the second release liner.

[0028] In an embodiment, in the sensing accessory packaging, the inner periphery of the first release liner may contact the post while the inner periphery of the second release liner does not contact the post.

[0029] In an embodiment, the second release liner may be configured to be removed from the sensing accessory with a less force than the first release liner. The second release liner may have a lower release value than the first release liner.

[0030] In an embodiment, the first release liner may be formed from a polyester release liner and the second release liner is formed from a paper release liner.

[0031] In an embodiment, a width of the first center opening of the first release liner may be greater than the universal width.

[0032] In an embodiment, the second release liner may be more rigid than the first release liner.

[0033] In an embodiment, in the sensing accessory packaging, the inner periphery of the second release liner may contact the post while the inner periphery of the first release liner does not contact the post.

[0034] In an embodiment, the release liner with the universal width may be more rigid than the other release liner.

[0035] In an embodiment, the first release liner may include a first pull tab defining a cutout. The second release liner may include a second pull tab. The first pull tab and the second pull tab may extend past the sensing region at the same location. The second pull tab may extend past the cutout.

[0036] The foregoing general description and the following detailed description are examples only and are not restrictive of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] The benefits and advantages of the present embodiments will become more readily apparent to those of ordinary skill in the relevant art after reviewing the following detailed description and accompanying drawings, wherein:

[0038] FIG. 1 is an illustration of an ostomy system, according to an embodiment.

[0039] FIG. 2 is an illustration of an ostomy system attached to a user, according to an embodiment.

[0040] FIG. 3 is a body-side view of a sensor circuit, according to an embodiment.

[0041] FIG. 4 is a body-side view of a sensor accessory, according to an embodiment.

[0042] FIG. 5 is a distal-side view of the sensor accessory of FIG. 4.

[0043] FIG. 6 is a schematic exploded cross-sectional illustration to show layers of the sensor accessory of FIG. 4.

[0044] FIG. 7 is a body-side view of a sensor accessory, according to another embodiment.

[0045] FIG. 8 is a body-side view of a sensor accessory, according to another embodiment.

- [0046] FIG. 9 is a distal-side view of the sensor accessory of FIG. 8.
- [0047] FIG. 10 is a body-side view of a sensor accessory, according to another embodiment.
- [0048] FIG. 11 is a body-side view of a sensor accessory, according to another embodiment.
- [0049] FIG. 12 is a distal-side view of a sensor accessory of FIG. 11.
- [0050] FIG. 13 is a schematic exploded cross-sectional illustration to show layers of a sensor accessory, according to another embodiment.

DETAILED DESCRIPTION

[0051] While the present disclosure is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described presently preferred embodiments with the understanding that the present disclosure is to be considered an exemplification and is not intended to limit the disclosure to the specific embodiments illustrated. The words “a” or “an” are to be taken to include both the singular and the plural. Conversely, any reference to plural items shall, where appropriate, include the singular. The words “first,” “second,” “third,” and the like may be used in the present disclosure to describe various information, such information should not be limited to these words. These words are only used to distinguish one category of information from another. The directional words “top,” “bottom,” “up,” “down,” “front,” “back,” and the like are used for purposes of illustration and as such are not limiting. Depending on the context, the word “if” as used herein may be interpreted as “when” or “upon” or “in response to determining.”

[0052] The present disclosure provides a sensing accessory for an ostomy leakage detection system. The ostomy leakage detection system can be configured to detect ostomy effluent leakage under a skin barrier and to alert a user. The ostomy leakage detection system can provide multiple benefits to the user. For example, the system can allow the user to intervene and change a skin

barrier and/or ostomy pouch system before a leak progresses which can cause embarrassment and inconvenience to the user. Further, the ostomy leakage detection system can assist in maintaining a user's skin health by detecting a leakage in its early stage to prevent prolonged skin exposure to ostomy effluent, which can lead to skin health complications. The ostomy leakage detection system can also support a user's emotional well-being by reducing anxiety associated with a risk of leakage. The ostomy leakage detection system may be used with an ostomy barrier of a one-piece pouch system or a faceplate for a two-piece pouch system.

[0053] FIG. 1 illustrates an ostomy two-piece pouch system 10. According to example embodiments shown in FIG. 1, the ostomy system 10 can generally include a sensing accessory 12, an ostomy barrier appliance 14, an ostomy bag 16, a wearable device 18, and a mobile device 20. The sensing accessory 12 can include a sensing region 22, a tail region 24, and a connector region 26. The sensing region 22 can include an inlet opening 28 configured to surround a stoma (not shown). The connector region 26 can include a connector opening 30 configured to engage with the wearable device 18. The ostomy bag 16 may be configured to receive and contain bodily waste and can include a pouch coupling member 32 configured to engage with a barrier coupling member 15 to attach the ostomy bag 16 to the ostomy barrier appliance 14.

[0054] FIG. 2 illustrates the ostomy pouch system 10 mounted to a user. According to example embodiments shown in FIG. 2, the sensing accessory 12 can be mounted to the ostomy barrier appliance 14 and attached to a user using an adhesive, wherein user's stoma may be received through the inlet opening 28. The ostomy pouch 16 can be mounted on the ostomy barrier appliance 14 by engaging the pouch coupling member 32 with the barrier coupling member 15. The wearable device 18 can be attached to the sensing accessory 12 using the connector opening 30. The wearable device 18 can be mounted on a user or attached to the ostomy bag 16 using a

patch or an adhesive.

[0055] According to example embodiments, the ostomy leakage detection system may comprise three subsystems – the sensing accessory 12, the wearable device 18, and a mobile application on the mobile device 20. The sensing accessory 12 may be provided as an accessory for an ostomy pouch system. The sensing accessory 12 can include sensors for detecting the presence of ostomy effluent. The sensing accessory 12 may be configured to communicate leakage detection signals to the wearable device 18.

[0056] The wearable subsystem 18 may be a wearable device configured to perform at least some processing of leakage detection signals and to alert a user of a leakage event. The wearable subsystem 18 may be configured to electronically communicate through a wire or wireless communication system with the mobile application. Such electronic communications may include raw data as acquired from the sensing accessory 12 or a leak status for all or part of the sensing accessory 12. The mobile application may be a digital subsystem installed on the mobile device 20. The mobile application may be configured to further process leak detection data and provide an alert or other information about an ostomy appliance to a user.

[0057] FIG. 3 illustrates a body-side view of a sensor circuit 34. According to example embodiments shown schematically in FIG. 3, the sensor circuit 34 can generally include a conductive sensor 36, a conductive trace 38, and a connection point 40. The conductive sensor 36 can be located on the sensing region 22 and be configured to detect a leak around a stoma. The conductive trace 38 can be located on the tail region 24 and be configured to connect the conductive sensor 36 to the connection point 40. The connection point 40 can be located on the connector region 26 and be configured to connect to the wearable device 18.

[0058] The conductive sensor 36 may be arranged in a predetermined pattern in the sensing

region 22. For example, the conductive sensor 36 may be generally arranged in a circular or semi-circular pattern. Other suitable patterns can be used as well without limitation, such as an oval or oblong pattern, or other closed or substantially closed loop pattern. The conductive sensor 36 in the sensing region 22 may be arranged at one or more radial distances from the inlet opening 28. For example, the sensor circuit 34 may include a plurality of electrically conductive traces arranged at a plurality of different, radial distances from the inlet opening 28.

[0059] The sensor circuit 34 may include conductive traces that may be formed by printing on a circuit substrate using a conductive ink via a conventional printing process, for example, screen printing. The conductive ink may comprise carbon black, graphite, silver(Ag), or a silver and silver chloride blend (Ag/AgCl). Each of the plurality of conductive traces may have a width and arranged to be spaced apart from each other. The parameters of the conductive traces may be configured to provide a particular resistance of a sensor circuit.

[0060] According to example embodiments, the conductive traces may be printed on a circuit substrate using a conductive ink. Suitable materials for the circuit substrate may include, but are not limited to polyester (PET), polyethylene (PE), polyurethane film (PU), or thermoplastic polyurethane (TPU) film. The circuit substrate may be configured to provide an excellent bonding surface for the conductive ink, prevent mechanical damage to the conductive ink, and adhere to a hydrocolloid adhesive layer. According to example embodiments, the circuit substrate and the conductive ink may be configured to provide at least some degree of elasticity to allow stretching of the sensing accessory 12. According to example embodiments, the sensing accessory 12 may comprise a PET circuit substrate having a thickness of about 0.001 inches to about 0.010 inches, preferably about 0.003 inches.

[0061] According to example embodiments, the sensing accessory 12 may be configured to be

molded to conform to the convexity of a convex ostomy barrier. According to example embodiments, the sensing accessory 12 may comprise a stretchable printed circuit system to conform to a convex ostomy barrier. In such embodiments, a circuit substrate, printed conductive traces, and masking layers may be formed from stretchable materials, such as the Dupont INTEXAR system. In another embodiment, the sensing accessory may include slits and voids configured and arranged in a nonstretchable circuit substrate, such as PET, to conform the sensing accessory to a convex barrier.

[0062] Referring now to the figures, FIGS. 4-12 show a sensing accessory 112, 212, 312, 412, 512 according to example embodiments. The sensing accessory 112, 212, 312, 412, 512 can generally include a sensing region 122, 222, 322, 422, 522, a tail region 124, 224, 324, 424, 524, a connector region 126, 226, 326, 426, 526 an inlet opening 128, 228, 328, 428, 528, a connector opening 130, 230, 330, 430, 530 and a sensor circuit 134, 234, 334, 434, 534. The inlet opening 128, 228, 328, 428, 528 can be defined by an inner edge of the sensing region 122, 222, 322, 422, 522. The inlet opening 128, 228 can have a width W_{128} , W_{228} . The connector opening 130, 230, 330, 430, 530 can be located on the connector region 126, 226, 326, 426, 526.

[0063] The sensing region 122, 222, 322, 422, 522 can generally include a conductive sensor 136, 236, 336, 436, 536, an adhesive layer 146, 246, 346, 446, 546, and a release liner 148, 248, 348, 448, 548. A barrier tail region 142, 242, 342, 442, 542 can extend from the sensing region 122, 222, 322, 422, 522 into at least a portion of the tail region 124, 224, 324, 424, 524. The adhesive layer 146 246, 346, 446, 546 may be provided on a body-side surface of the sensing region 122, 222, 322, 422, 522 and can extend to the barrier tail 142, 242, 342, 442, 542. The adhesive layer 146 246, 346, 546 can include an adhesive outer edge 144, 244, 344, 544. The release liner 148, 248, 348, 448, 548 can be provided to cover the adhesive layer 146, 246, 346,

446, 546. The release liner 148, 248, 348, 548 can include a liner inner edge 152, 252, 352, 452, 552 defining an inner opening that may align with the inlet opening 128 and a liner outer edge 154, 254, 354, 554. The liner inner edge 152, 252 can have a width W152, W252. The release liner 148, 248, 348, 448, 548 may include a first pull tab 150, 250, 350, 450, 550. The first pull tab 150, 250, 350, 550 can extend past the liner outer edge 154, 254, 354, 554 so that they can be used to remove the release liner 148, 248, 348, 548.

[0064] In some embodiments, the sensing region 122, 222, 322, 422, 522 may also include a barrier-side release liner 148', 348', 548' including a second pull tab 150', 250', 350', 550'. In some aspects, the barrier-side release liner 148', 348', 548' may be placed against the barrier-side of the sensing region 122, 222, 322, 422, 522 with a portion of the adhesive layer 146, 246, 346, 446, 546 extending outside of the sensing region 122, 222, 322, 422, 522 holding the barrier-side release liner 148', 348', 548' in place, best viewed in FIGS. 6, 7, and 8.

[0065] According to example embodiments, the adhesive layer 146, 246, 346, 446, 546 may be formed from a hydrocolloid adhesive.

[0066] The tail region 124, 224, 324, 424, 524 can generally include a circuit substrate 156, 256, 356, 456, 556, a conductive trace 138, 238, 338, 438, 538, and a first insulator layer 158, 258, 358, 458, 558. The first insulated layer 158, 258, 358, 458, 558 can be located over the conductive trace 138, 238, 338, 438, 538 for insulating the trace.

[0067] The connector region 126, 226, 326, 426, 526 can generally include a connection point 140, 240, 340, 440, 540, a second insulated layer 160, 260, 460, 560, an insulated layer opening 162, 262, 462, 562, a key opening 164, 264, 364, 464, 564, and an aligning opening 166, 266, 366, 466, 566. The second insulated layer 160, 260, 460, 560 can insulate the conductive trace 138, 238, 438, 538 and connection point 140, 240, 440, 540. The second insulated layer 160, 260, 460, 560

can include a stiff surface for handling the connector region 126, 226, 426, 526. The insulated layer opening 162, 262, 462, 562 can be an opening in the second insulated layer 160, 260, 460, 560 for allowing the connection point 140, 240, 440, 540 to make contact with connection pads (not shown) on the wearable device 18. In at least one aspect, the second insulated layer 160, 260, 460, 560 functions as a locating material to help align the wearable device 18 with the sensing accessory 112, during connection of the wearable device 18. For example, the stiff surface of the second insulated layer 160, 260, 460, 560 may help align the wearable device in a correct position. Additionally, the key opening 164, 264, 364, 464, 564 and the aligning opening 166, 266, 366, 466, 566 can allow for the connector region 126, 226, 326, 426, 526 to be connected to the wearable device 18 in the correct position.

[0068] FIG. 4 illustrates a body-side view of the sensing accessory 112. According to example embodiments shown in FIG. 4, the liner inner edge 152 can have an opening width W_{152} . The adhesive outer edge 144 can define a circumference with a width W_{144} . Adhesive layer 146 can include an inner edge defined by the inlet opening 128 with a width W_{128} . Width W_{152} can be less than or equal to the width W_{128} so that the release liner 148 covers the adhesive layer 146. Thus, as shown schematically in FIG. 4, the inner edge of the adhesive layer 146 can be set radially outward from the liner inner edge 152 of the release liner 148. Similarly, the outside edge of the adhesive layer 146 can be set radially inward from the liner outer edge 154 of the release liner 148. The release liner 148 can extend to fully cover the sensing region 122.

[0069] According to example embodiments, the liner inner edge 152 and the liner outer edge 154 of the release liner 148 can extend past the inlet opening 128 and the adhesive outer edge 144 of the adhesive layer 146 to accommodate for potential exuding of adhesive material between production and product use and to prevent sensor assemblies from sticking to each other and/or

the packaging. For example, the liner edges can extend between 1-1.5 mm over, or past, the adhesive edges. In another example, the liner edges can extend 1mm over, or past, the hydrocolloid adhesive edges to capture a majority of flow of the hydrocolloid adhesive and prevent excess hydrocolloid adhesive from seeping out into the packaging.

[0070] According to example embodiments, the tabs 150, 150' can be located near but separate from each other so that they may be individually grasped. The adhesive layer 146 can be mounted to the user so that the inlet opening 128 can surround the stoma and the conductive sensor 136 can detect leaks.

[0071] According to example embodiments, the release liners 148, 148' can be marked to illustrate instructions to a user. For example, the release liners can have the words "body-side" or "barrier-side" to describe what side of the sensing accessory the user is facing. In another example, the release liner can have words "REMOVE LINER" to remind the user to remove the liner before mounting the sensing accessory on the user or barrier.

[0072] FIG. 5 illustrates a distal-side (also referred to as "barrier-side" herein) view of the sensing accessory 112. According to example embodiments shown in FIG. 5, the sensing accessory 112 can also include a barrier-side release liner 148' having a liner inner edge 152' and a liner outer edge 154', a barrier-side first insulator layer 158' and a stiffener layer 160'. As show in FIG. 5, the inner edge of the adhesive layer 146 can be set radially outward from the liner inner edge 152' of the barrier-side release liner 148'. Similarly, the outside edge of the adhesive layer 146 can be set radially inward from the liner outer edge 154' of the release liner 148'. The barrier-side release liner 148' can extend to fully cover the sensing region 122. According to example embodiments, the liner inner edge 152' and the liner outer edge 154' of the release liner 148' can extend past the inlet opening 128 and the adhesive outer edge 144 of the adhesive layer 146 to accommodate for

potential exuding of adhesive material between production and product use and to prevent sensor assemblies from sticking to each other and/or the packaging. For example, the liner edges can extend between 1-1.5 mm over, or past, the adhesive edges. In another example, the liner edges can extend 1mm over, or past, the hydrocolloid adhesive edges to capture a majority of flow of the hydrocolloid adhesive and prevent excess hydrocolloid adhesive from seeping out into the packaging. As shown in FIG. 5, the release liner 148' is adhered to a portion of the adhesive layer 146 that extends past the conductive sensor 136. As discussed above the adhesive layer 146 is placed on the body-side of the conductive sensor 136.

[0073] According to example embodiments, the barrier-side of the sensing accessory 112 can be attached to the ostomy barrier appliance 14. For example, the ostomy barrier appliance 14 can have an adhesive layer to stick to the sensing accessory 112. In an additional or alternative embodiment, the barrier-side of the sensing accessory 112 can include an adhesive layer to stick to the ostomy barrier appliance 14.

[0074] According to example embodiments, the barrier-side release liner 148' can be marked to illustrate instructions to a user. For example, the liner can have the words "barrier side" to describe what side of the sensing accessory the user is facing.

[0075] FIG. 6 is a schematic exploded cross-sectional view of the sensing accessory 112 to illustrate layers of the sensing accessory 112. According to example embodiments shown in FIG. 6, the sensor circuit 134 can be printed on the body-side of the circuit substrate 156. The body-side adhesive layer 146 can be arranged on a body-side surface of the sensing region 122 and barrier tail 142 over the sensor circuit 134. The adhesive layer 146 can extend past the edges of the circuit substrate 156 in the sensing region 122. The body-side release liner 148 can be arranged over the adhesive layer 146. The body-side release liner 148 can extend past the edges of the body-

side adhesive layer 146. The tab 150 can extend from the body-side release liner 148. The first body-side insulator layer 158 can be located on the tail region 124 over the sensor circuit 134. The second body-side insulated layer 160 can be located on the connector region 126 over the conductive trace 138 and the connection point 140. In at least one aspect, the second body-side insulated layer 160 can also function as a locating material to help align the wearable device 18 with the sensing accessory 112, during connection of the wearable device 18. The stiffener layer 160' can be located on the connector region 126. In at least one aspect, the stiffener layer 160' can also function as a locating material to help align the wearable device 18 with the sensing accessory 112, during connection of the wearable device 18. In various aspects, the stiffener layer 160' includes an insulative material.

[0076] The barrier-side release liner 148' can be arranged over the distal-side (also referred to as "barrier-side") of the circuit substrate 156. As shown in FIGS. 5 and 6, the barrier-side release liner 148' attaches to a portion of the adhesive layer 146 on the body-side of the circuit substrate 156 that extends past the sensing region 122 and circuit substrate 156.

[0077] According to example embodiments, the adhesive layers 146 can extend past the inner and outer edges of the circuit substrate 156 in the sensing region 122 so that a portion of the body-side adhesive layer 146 makes direct contact with the barrier-side release liner 148'.

[0078] In an alternative embodiment, a barrier-side adhesive layer can be provided on the distal-side (also referred to as "barrier-side" herein) of sensing region 122 and the barrier tail 142' and over the circuit substrate 156. The barrier-side release liner 148' can be arranged over the barrier-side adhesive layer. In this embodiment, the adhesive layers 146 can extend past the inner and outer edges of the circuit substrate 156 in the sensing region 122 so that the body-side adhesive layer 146 makes direct contact with the barrier-side adhesive layer.

[0079] FIG. 7 illustrates a body-side view of the sensing accessory 212. According to example embodiments shown in FIG. 7, the sensing region 222 can have a larger surface area when compared to the sensing region 122 of the embodiment illustrated in FIG. 4 to accommodate a larger stoma. The release liner 248 can cover the adhesive layer 246 and part of the inlet opening 228.

[0080] According to example embodiments, sensor accessories having varying sizes can be provided while retaining the same sized central interior opening. More particularly, where the size of a sensor accessory and sensing region is enlarged, the outer dimension of the accessory and the area of the adhesive layer can increase proportionally. Notwithstanding such enlargement, the size of the central opening can remain consistent. With reference to FIGS. 4 and 7, widths W144 and W128 (FIG. 4) and W244 and W228 (FIG. 7) can vary based on the sensor accessory size while the width W152 and W252 of a release liner opening defined by the liner inner edge 152, 252 can be consistent to accommodate the utilization of universal packaging. For example, the sensing accessory 112 may be a size 1 and the sensing accessory 212 may be a size 3 with the width W144 being less than the width W244 and the width W152 being equal to the width W252. The width W152 and W252 can be a universal width designed to fit on a center post in a packaging.

[0081] FIG. 8 illustrates a body-side view of a sensing accessory 312. According to example embodiments shown in FIG. 8, the sensing accessory 312 can include a first illustration 368 and a second illustration 370 or other markings, graphics, text, indicia or the like. The first illustration 368 can illustrate or otherwise signify to a user that it should refrain from cutting the sensing accessory 312 or other handling or safety instructions for utilizing the accessory. The second illustration 370 can illustrate a body-side view of the sensing accessory 312 to communicate or identify that the corresponding side is the one that is intended to for adherence to a user's body

around a stoma.

[0082] FIG. 9 illustrates a distal-side view of the sensing accessory 312. According to example embodiments shown in FIG. 9, the sensing accessory 312 can also include a distal-side release liner 348' having a liner inner edge 352' and a liner outer edge 354', a barrier tail 342', a first distal-side insulator layer 358', and a stiffener layer 360'. In at least one aspect, the stiffener layer 360' includes an insulative material. The distal-side release liner may include a first distal-side illustration 368' and a second distal-side illustration 370'.

[0083] According to example embodiments, the first distal-side illustration 368' can illustrate or otherwise signify to a user that it should refrain from cutting the sensing accessory 312 or other handling or safety instructions for utilizing the accessory. The second distal-side illustration 370' can illustrate a distal-side view of the sensing accessory 312 and to communicate or identify that the distal-side of the sensing accessory 312 is intended to be attached to an ostomy barrier appliance 14.

[0084] According to example embodiments, the first tab 350 may be colored a different color than the body-side release liner 348 to emphasise the tab location. In another embodiment, the second tab 350' may be colored a different color than the distal-side release liner 348' and the first tab 350 to emphasise the tab locations.

[0085] FIG. 10 illustrates a body-side view of the sensing accessory 412. According to example embodiments shown in FIG. 10, the sensing accessory 412 can include a first illustration 468, a second illustration 470, a third illustration 471, and a first tab 450 with a tab end 451. The sensing accessory 412 can further include other markings, graphics, text, indica or the like. The first illustration 468 can illustrate or otherwise signify to a user that it should refrain from cutting the sensing accessory 412 or other handling or safety instructions for utilizing the accessory. The

second illustration 470 can illustrate a body-side view of the sensing accessory 412 to communicate or identify that the corresponding side is the one that is intended to for adherence to a user's body around a stoma. The third illustration 471 can illustrate a product identification number, a sensing accessory size and/or other product or sensor accessory information. The tab end 451 that may be formed to have a different color than the rest of the first tab 450 and the release liner 448 to emphasize the tab end location.

[0086] According to example embodiments, the first tab 450 can align with the tail region 424 by extending from the release liner 448 over the tail region 424. The first tab 450 can be pulled away from the tail region 424 while holding onto the tail region 424 to remove the release liner 448.

[0087] According to example embodiments, the first tab 450 can have a width W₄₅₀ similar to a width of the tail region 424 so that the first tab 450 does not require additional space in a packaging and for easier handling of the sensing accessory 412.

[0088] FIGS. 11 and 12 illustrate a body-side view of the sensing accessory 512. According to example embodiments shown in FIG. 12, the sensing accessory 512 may also include a distal-side release liner 548' having a liner inner edge 552' and a liner outer edge 554', a first distal-side insulator layer 558', and a stiffener layer 560'. In at least one aspect, the stiffener layer 560' includes an insulative material.

[0089] According to example embodiments shown in FIGS. 11 and 12, the release liner 548 may include a first pull tab 550 and the release liner 548' may include a second pull tab 550'. The first pull tab 550 may extend past the liner outer edge 554 so that it may be used to remove the release liner 548. The second pull tab 550' may extend past the liner outer edge 554' so that it may be used to remove the release liner 548'. The first pull tab 550 may define a cutout 551. The first

pull tab 550 and the second pull tab 550' may be positioned at the same location on the sensing accessory 512 such that the first pull tab 550 rests against the second pull tab 550'. The second pull tab 550' may extend past the cutout 551 of the first pull tab 550. The cutout 551 may allow a user to pull the second pull tab 550' away from the first pull tab 550, allowing the user to remove the release liner 548'. In some aspects, the cutout 551 can promote the user to pull the second pull tab 550' and remove the release liner 548' before removing the release liner 548. For example, when grabbing the first and second pull tabs 550, 550', the cut out 551 may allow the user to grasp more of the second pull tab 550' promoting the user to pull the second pull tab 550' and the release liner 548' away from the sensing accessory 512. Once the release liner 548' is removed, the first pull tab 550 may be more easily grasped and pulled by the user to remove the release liner 548. In an alternative embodiment, the second pull tab 550' may define a cutout similar to cutout 551 and the first pull tab 550 may not.

[0090] The release liners (e.g. release liners 148, 248, 348, 448, 548, 148', 348', 548') of the sensor accessory (e.g. sensing accessory 112, 212, 312, 412, 512) can be formed from the same material or different materials. Some example suitable materials for the release liner are paper materials (e.g. polyethylene-coated white paper), plastic materials, and polymeric materials (e.g. polyester film). While the two release liners (i.e. the body-side release liner and the barrier-side release liner) of the sensor accessory can be formed from the same material, in some embodiments, there can be some benefits to having two different materials. For example, two different materials can be used to promote a proper order of use steps among users in conjunction with identification marks and/or release liner geometry. For example, the proper step for applying the sensing accessory 12 can be to: first, remove the first release liner or distal release liner (e.g. release liner 148', 348', 548'), second, apply the newly exposed face to an ostomy barrier (e.g. ostomy barrier

appliance 14), third, remove the second release liner or body-side release liner (e.g. release liner 148, 248, 348, 448, 548), fourth, apply the ostomy barrier assembly to the body around the stoma such that the body-side adhesive (e.g. adhesive layer 146, 246, 346, 446, 546) of the sensor accessory may be attached to user's peristomal skin. It is noted that the example steps are one example of potential steps being used for discussion. A different step order, or different steps, is/are possible and appropriate changes can be made to the release liners to promote the desired step order.

[0091] The two release liners can be configured to promote the user removing the release liners in the desired order. For example, the release liners may be configured such that the distal-side release liner may have a lower release value (that is, a lower surface energy for easier removal from an adjacent adhesive layer) when compared to the release value of the body-side release liner to promote removal of the distal-side release liner before the body-side release liner. In some embodiments, one of the release liners may be formed from a more rigid material than the other release liner. For example, the body-side release liner can be formed from a material that is more rigid than the material of the distal-side release liner to promote the distal-side release liner, which is a more pliable release liner, to be removed first. In some embodiments, the release agents (e.g. silicone) of the two release liners can be configured and/or adjusted to provide desired release values to promote removal of one release liner over another as desired. Various properties and characteristics of the release liners (e.g. release values, rigidity, thickness, geometry, and tabs) can be combined as desired when forming the release liners to promote the removal of one release liner before another release liner.

[0092] In one example embodiment, the release liner to be removed first ("first release liner") may be a distal-side release liner (e.g. release liner 148', 348', 548') made of polyethylene-coated

white paper with silicone as a release agent over the polyethylene and the second release liner for removal after the first release liner may be a body-side release liner (e.g. release liner 148, 248, 348, 448, 548) made of polyester with a silicone release agent on one side. The second release liner may include a matte coating on the other side to promote graphics printing as described above regarding FIGS. 8 and 10. In this embodiment, the sensor accessory may be configured such that the first release liner is removed before the second release liner for assembling the sensing accessory 12, 112, 212, 312, 412, 512 with an ostomy barrier appliance 14 before attaching the assembled sensor accessory and ostomy barrier appliance to a user. As such, the release liners may be configured so that the release value of the first release liner can be less than the release value of the second release liner to promote removal of the first release liner before the second release liner. For example, the release value of the first release liner can be 35-135 grams force per inch, and the release value of the second release liner can be 90-150 grams force per inch. As such, the release value of the second release liner can be greater than the release value of the first release liner.

[0093] Additionally, the selection of geometry, material, and releasing agent can be done to promote removal of one release liner over another release liner. For example, due to a particular geometry, the effective release force between an adhesive (i.e., releasing agent) and the second release liner is greater than an adhesive (i.e., releasing agent) and the first release liner. For example, the area of a second adhesive against the second release liner may be greater than the area of a first adhesive against the first release liner. This may allow the line of contact between the second release liner and the second adhesive during peeling to be greater than the line of contact between the first release liner and the first adhesive. The line of contact being less for the first release liner may make the first release liner have a smaller effective release force than the second release liner.

As such, less force may be required to remove the first release liner than the second release line.

This may promote removal of the first release liner before the second release liner.

[0094] For example, referring to FIGS. 11 and 12, the body-side release liner 548 may be adhered to the adhesive layer 546 and the distal-side release liner 548' may be adhered to a portion of the adhesive layer 546 that extends past the conductive sensor 536. Therefore, the surface area of adhesive layer 546 against the distal-side release liner 548' is much less than the surface area of the adhesive layer 546 against the body-side release liner 548. Additionally, the line of contact between the body-side release liner 548 and the adhesive layer 546 during peeling may be greater than the line of contact between the distal-side release liner 548' and the adhesive layer 546. The release liner 548 may have a greater effective release force than the release liner 548', due to the larger line of contact. As such, less force may be required to peel the distal-side release liner 548' away from the sensing accessory 512 than the body-side release liner 548. This may promote removal of the distal-side release liner 548' before the body-side release liner 548.

[0095] The release liner material selections can also be made to provide the user with visual cues to help them remember the order to remove the release liners. For example, the opacity of the release liners can be used to promote the user to remove the correct release liner first. In an example embodiment, the first release liner can be opaque, and the second release liner can be translucent or transparent. This process can provide the user with the visual cue to remove the opaque release liner first. Additionally, once the opaque release liner is removed, the user can then see through the second release liner to apply the newly exposed face to an ostomy barrier. In one embodiment, the first release liner may be a distal release liner (e.g. release liner 148', 348', 548') formed from an opaque material, such as a polyethylene-coated white paper with a silicone release agent, and the second release liner may be a body-side release liner (e.g. release liner 148, 248, 348, 448, 548)

formed from a translucent material, such as a polyester film with a silicone release agent on one side and a matte coating on the other side. This embodiment can provide the benefit of the release values being different and a different opacity between the release liners to promote removal of one release liner over another.

[0096] In some alternative embodiments, the first release liner and the second release liner can both be opaque or translucent/transparent, or the second release liner can be opaque and the first release liner can be translucent or transparent.

[0097] The release liner material selections can also provide the user with at least one tactile cue to help them remember the order to remove the release liners. For example, the rigidity of the release liners can be used to promote the user to remove the correct release liner first. In an example embodiment, the first release liner can be more pliable, and the second release liner can be more rigid. For example, the more pliable release liner can be removed from the sensor accessory easier than the more rigid release liner. Additionally, this material property can provide the user with a tactile cue to remove the pliable release liner first. In one embodiment, the first release liner may be a distal release liner (e.g. release liner 148', 348', 548') formed from an opaque polyethylene-coated white paper with a silicone release agent and the second release liner may be a body-side release liner (e.g. release liner 148, 248, 348, 448, 548) formed from a translucent polyester film with a silicone release agent on one side and a matte coating on the other side, where the second release liner may be more rigid than the first release liner. This embodiment can provide the benefit of the release values being different, the rigidity being different, and a different opacity between the release liners to promote removal of one release liner over another.

[0098] In some embodiments, the release liners may be configured to facilitate removal of a first release liner from the sensor accessory before a second release liner by configuring each

release liner to have a different release value, a different rigidity, a different opacity, or any combination thereof. In an embodiment, the two release liners may be formed from a same base material (e.g. paper or polymeric film) but having different release values to promote removal of one release liner over another release liner.

[0099] While it was discussed removing the first release liner before the second release liner, the sensor accessory may be configured to promote removing the second release liner before the first release liner (e.g. by selecting and forming each release liner from a different release liner material). For example, in another embodiment, the first release liner may be a distal release liner (e.g. release liner 148', 348', 548') made of a polyester film with a silicone release agent on one side and a matte coating on the other side to promote graphics printing, and the second release liner may be a body-side release liner (e.g. release liner 148, 248, 348, 448, 548) made of polyethylene-coated white paper with silicone as a release agent over the polyethylene.

[00100] As discussed above, the release liners (e.g. release liners 148, 248, 348, 448, 548, 148', 348', 548') of the sensor accessory (e.g. sensing accessory 112, 212, 312, 412, 512) can be formed from the same material or different materials. In either instance, it can be beneficial for only one release liner of the two release liners in the sensory accessory to contact a center hole post present in a packaging (e.g. a first protrusion 140 (center post) of a sensor accessory packaging system 110 disclosed in PCT Application No. PCT/US24/31071, which is commonly assigned to the applicant of the present application). For example, either the body-side release liner (e.g. release liner 148, 248, 348, 448) or the distal release liner (e.g. release liner 148', 348', 548') can include a center hole configured to contact the center hole post with the other release liner having a center hole enlarged so as to not contact the center post. In this aspect, the center hole of one release liner may be configured to have a universal width (e.g. width W152 and W252) to accommodate the

universal packaging and the other release liner may have a width larger than the universal width and smaller than the inlet opening (e.g. inlet opening 128, 228, 328, 428, 528). When the release liner materials are different, it can be beneficial to use this approach to specify which release liner contacts the center post based on the material of the release liner. For example, the release liner formed from a more durable material, or a material that minimizes abrasions, or another beneficial material property, can be the release liner to contact the center post. This process can allow the center post of the packaging to selectively interface with one release liner over the other release liner.

[00101] FIG. 13 shows a schematic exploded cross sectional view of a sensing accessory 612 illustrating one release liner having a center hole with a universal width and the other release liner center hole being enlarged. This process can be applied to any of the sensing accessories 112, 212, 312, 412, 512. For example, the sensing accessory 612 may be configured substantially similar to sensing accessories 112, 212, 312, 412, 512. For the sake of brevity, not all similarities will be discussed in detail. The sensing region 622, tail region 624, connector region 626, inlet opening 628, width W628, connector opening 630, sensor circuit 634, adhesive layer 646, release liner 648, first tab 650, width 652, circuit substrate 656, first insulator layer 658, second insulated layer 660, release liner 648', second tab 650', and stiffener layer 660' may be configured similar and function similar to sensing region 122, 222, 322, 422, 522, tail region 124, 224, 324, 424, 524, connector region 126, 226, 326, 426, 526, inlet opening 128, 228, 328, 428, 528, width W128, W228, connector opening 130, 230, 330, 430, 530, sensor circuit 134, 234, 334, 434, 534, adhesive layer 146, 246, 346, 446, 546, release liner 148, 248, 348, 448, 548, first pull tab 150, 250, 350, 450, 550, width W152, W252 circuit substrate 156, 256, 356, 456, 556, first insulator layer 158, 258, 358, 458, 558, second insulated layer 160, 260, 460, 560, release liner 148', 348', 548', second

pull tab 150', 250', 350', 550', and stiffener layer 160', 360', 560', respectively.

[00102] Fig. 13 shows the release liner 648 having a center hole with a width of W652. The release liner 648 may be arranged on the body-side of the sensing accessory 612. The width W652 can match the width W152 and W252, where the width W152, W252, W652 can be a universal width designed to fit on a center post 690 in a packaging (e.g. a first protrusion 140 (center post) of a sensor accessory packaging system 110 disclosed in PCT Application No. PCT/US24/31071, which is commonly assigned to the applicant of the present application). The release liner 648' may have a width W652' that is larger than width W652 allowing only the release liner 648 to contact the center post 690 in the packaging. The width W652 and W652' are both smaller than width W628 of the inlet opening 628 as previously described regarding sensing accessories 112, 212, 312, 412, 512.

[00103] As described above, the release liner 648 can be formed from a different material than release liner 648'. In one embodiment, the release liner 648 may be formed from a polymeric film, such as a polyester film with a silicone release agent on one side and a matte coating on the other side, and the release liner 648' may be formed from a polyethylene-coated paper with silicone as a release agent. In some aspects, the polyester film can be more rigid and durable than the polyethylene-coated paper. In this aspect, the width W652' being larger than the width W652 allows the release liner formed from a more rigid and durable material to contact the center post.

[00104] In some alternative embodiments, the widths W652 may be greater than W652'. This embodiment may allow the release liner 648' to contact the center post 690 instead of the release liner 648. In this embodiment, the width W652' may be the universal width that matches width W652 and W652, and the width W652 may be larger than width W652'.

[00105] In some embodiments, an adhesive layer 646' may be applied to a distal-side of the

circuit substrate 656. In this embodiment, the amount of the adhesive layer 646 against the release liner 648 may be greater than the amount of the adhesive layer 646' against the release liner 648', as illustrated in FIG. 13. In this aspect, the line of contact between the adhesive layer 646 and the release liner 648 during peeling may be greater than the line of contact between the release liner 648' and the adhesive layer 646'. If the adhesives are similar, then the release liner 648 may have a greater effective release force than the release liner 648', due to the larger line of contact. As such, less force is required to peel the release liner 648' away from the sensing accessory 612 than the release liner 648. This may promote removal of the release liner 648' before the release liner 648.

[00106] From the foregoing it will be observed that numerous modifications and variations can be effectuated without departing from the true spirit and scope of the novel concepts of the present disclosure. It is to be understood that no limitation with respect to the specific embodiments illustrated is intended or should be inferred. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

CLAIMS

What is claimed is:

1. A sensing accessory for an ostomy leakage detection system comprising:
a sensing region including a plurality of sensors for detecting a leak;
a skin barrier layer arranged on a body-side of the sensing region configured for attachment to a user's peristomal skin;
an inlet opening defined by an inner periphery of the sensing region for receiving a stoma;
and
a first release liner arranged to cover the skin barrier layer, wherein the first release liner comprises a first center opening defined by an inner periphery of the first release liner and aligned with the inlet opening, wherein a width of the first center opening is a universal width that is less than a width of the inlet opening, wherein the universal width is configured such that the inner periphery of the first release liner is in contact with a post of a sensing accessory packaging while the inner periphery of the sensing region is arranged at a distance away from the post when the sensing accessory is packaged in the sensing accessory packaging.
2. The sensing accessory of claim 1, wherein the first release liner comprises printed graphics configured to illustrate where the skin barrier layer of the sensing accessory is to be mounted.
3. The sensing accessory of claim 2, wherein the printed graphics are further configured to illustrate where not to cut the sensing region.

4. The sensing accessory of any one of claims 1-3, wherein the first release liner comprises a first pull tab.

5. The sensing accessory of claim 4, wherein the first pull tab is colored to emphasize a location of the pull tab.

6. The sensing accessory of any one of claims 1-5, wherein the skin barrier layer is formed from a hydrocolloid adhesive.

7. The sensing accessory of any one of claims 1-6, wherein the first release liner extends past at least one edge of the skin barrier layer.

8. The sensing accessory of any of claims 1-7, wherein the first release liner extends 1mm past an inner periphery of the skin barrier layer.

9. The sensing accessory of any one of claims 1-8, further comprising a second release liner arranged to cover a distal-side of the sensing region opposite the body-side, wherein the second release liner includes a second center opening having a width greater than the universal width, and wherein the second release liner adheres to a portion of the skin barrier layer extending past the sensing region.

10. The sensing accessory of any one of claims 9, wherein the first release liner

comprises a first pull tab defining a cutout, wherein the second release liner comprises a second pull tab, wherein the first pull tab and the second pull tab extend past the sensing region at the same location, and wherein the second pull tab extends past the cutout.

11. The sensing accessory of claim 9, wherein the first and second release liners are formed from different materials.

12. The sensing accessory of claim 11, wherein the first release liner is more rigid than the second release liner.

13. The sensing accessory of claims 11 or 12, wherein the first release liner is formed from a polyester release liner and the second release liner is formed from a paper liner.

14. The sensing accessory of any one of claims 1-13, wherein the second release liner is configured to be removed from the sensing accessory with a less force than the first release liner, and wherein the second release liner has a lower release value than the first release liner.

15. A sensing accessory for an ostomy leakage detection system comprising:
a sensing region comprising a plurality of sensors for detecting a leakage, wherein the sensing region has a body-side surface and a distal-side surface;
an inlet opening defined by an inner periphery of the sensing region for receiving a stoma;
a first release liner arranged to cover the body-side surface and including a first center

opening defined by an inner periphery of the first release liner and aligned with the inlet opening;
and

a second release liner arranged to cover the distal-side surface and including a second center opening defined by an inner periphery of the second release liner and aligned with the inlet opening;

wherein a width of at least one of the first and second center openings is a universal width that is less than a width of the inlet opening, wherein the universal width is configured such that the inner periphery of the corresponding release liner is in contact with a post of a sensing accessory packaging while the inner periphery of the sensing region is arranged at a distance away from the post when the sensing accessory is packaged in the sensing accessory packaging.

16. The sensing accessory of claim 15, wherein the first release liner comprises printed graphics configured to illustrate where the body-side surface of the sensing region is to be mounted on a user, and wherein the second release liner comprises printed graphics configured to illustrate where the distal-side surface of the sensing region is to be mounted on an barrier appliance of an ostomy bag.

17. The sensing accessory of claims 15 or 16, wherein at least one of the first and second release liners comprises a pull tab.

18. The sensing accessory of claim 17, wherein the pull tab is colored to emphasize a location of the pull tab.

19. The sensing accessory of any one of claims 15-18, wherein the sensing region includes a skin barrier layer defining the body-side surface and formed from a hydrocolloid adhesive.

20. The sensing accessory of claim 19, wherein the first and second release liners extend at least 1mm past peripheries of the skin barrier layer.

21. The sensing accessory of any one of claims 15-20, wherein a width of the second center opening of the second release liner is greater than the universal width.

22. The sensing accessory of claim 21, wherein the first release liner is more rigid than the second release liner.

23. The sensing accessory of claims 21 or 22, wherein, in the sensing accessory packaging, the inner periphery of the first release liner contacts the post while the inner periphery of the second release liner does not contact the post.

24. The sensing accessory of any one of claims 15-23, wherein the second release liner is configured to be removed from the sensing accessory with a less force than the first release liner, and wherein the second release liner has a lower release value than the first release liner.

25. The sensing accessory of any one of claims 15-24, wherein the first release liner is formed from a polyester release liner and the second release liner is formed from a paper release liner.

26. The sensing accessory of any one of claims 15-20, wherein a width of the first center opening of the first release liner is greater than the universal width.

27. The sensing accessory of claim 26, wherein the second release liner is more rigid than the first release liner.

28. The sensing accessory of claims 26 or 27, wherein, in the sensing accessory packaging, the inner periphery of the second release liner contacts the post while the inner periphery of the first release liner does not contact the post.

29. The sensing accessory of any one of claims 15-28, wherein the release liner with the universal width is more rigid than the other release liner.

30. The sensing accessory of any one of claims 15-29, wherein the first release liner comprises a first pull tab defining a cutout, wherein the second release liner comprises a second pull tab, wherein the first pull tab and the second pull tab extend past the sensing region at the same location, and wherein the second pull tab extends past the cutout.

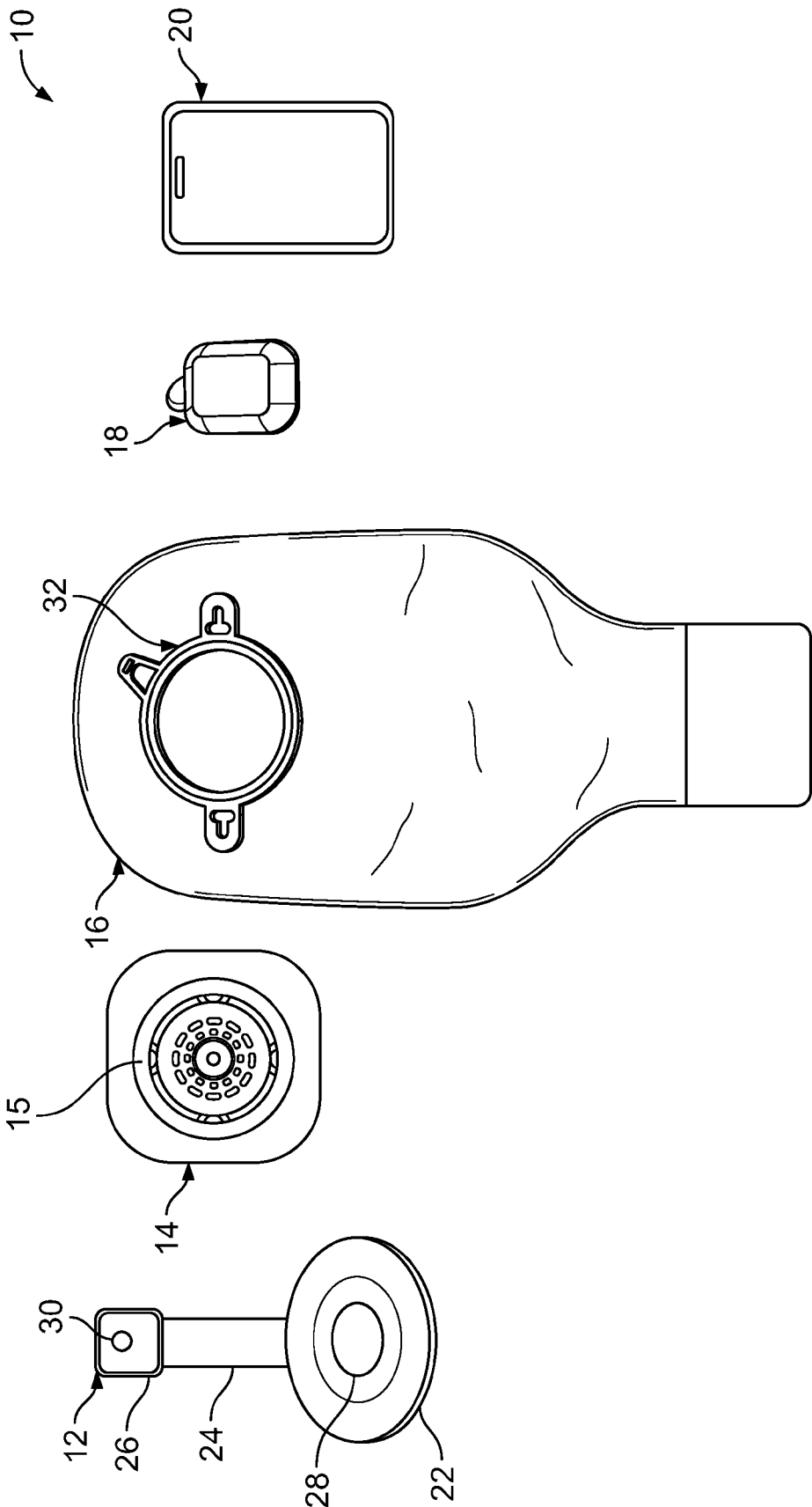


FIG. 1

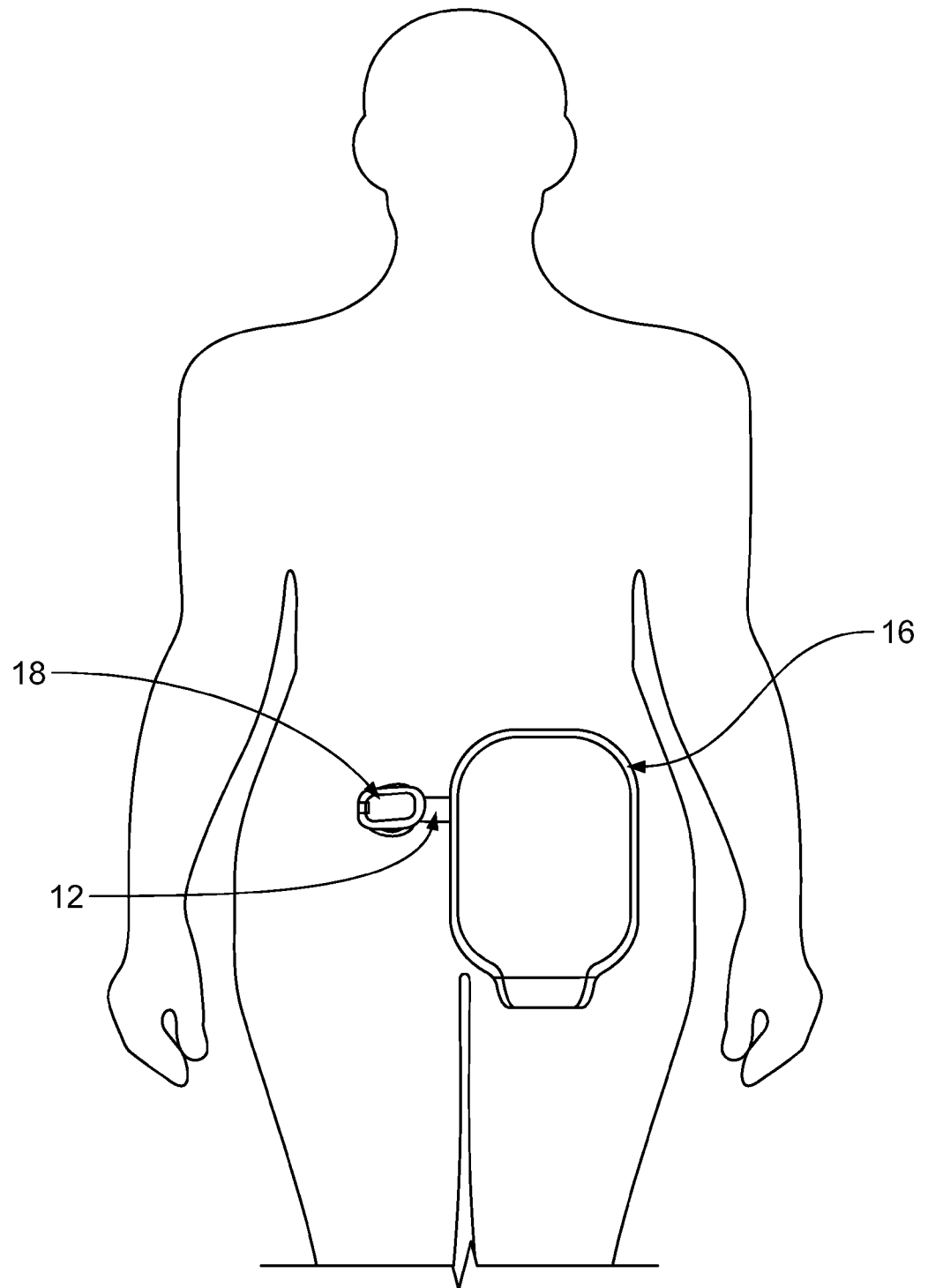


FIG. 2

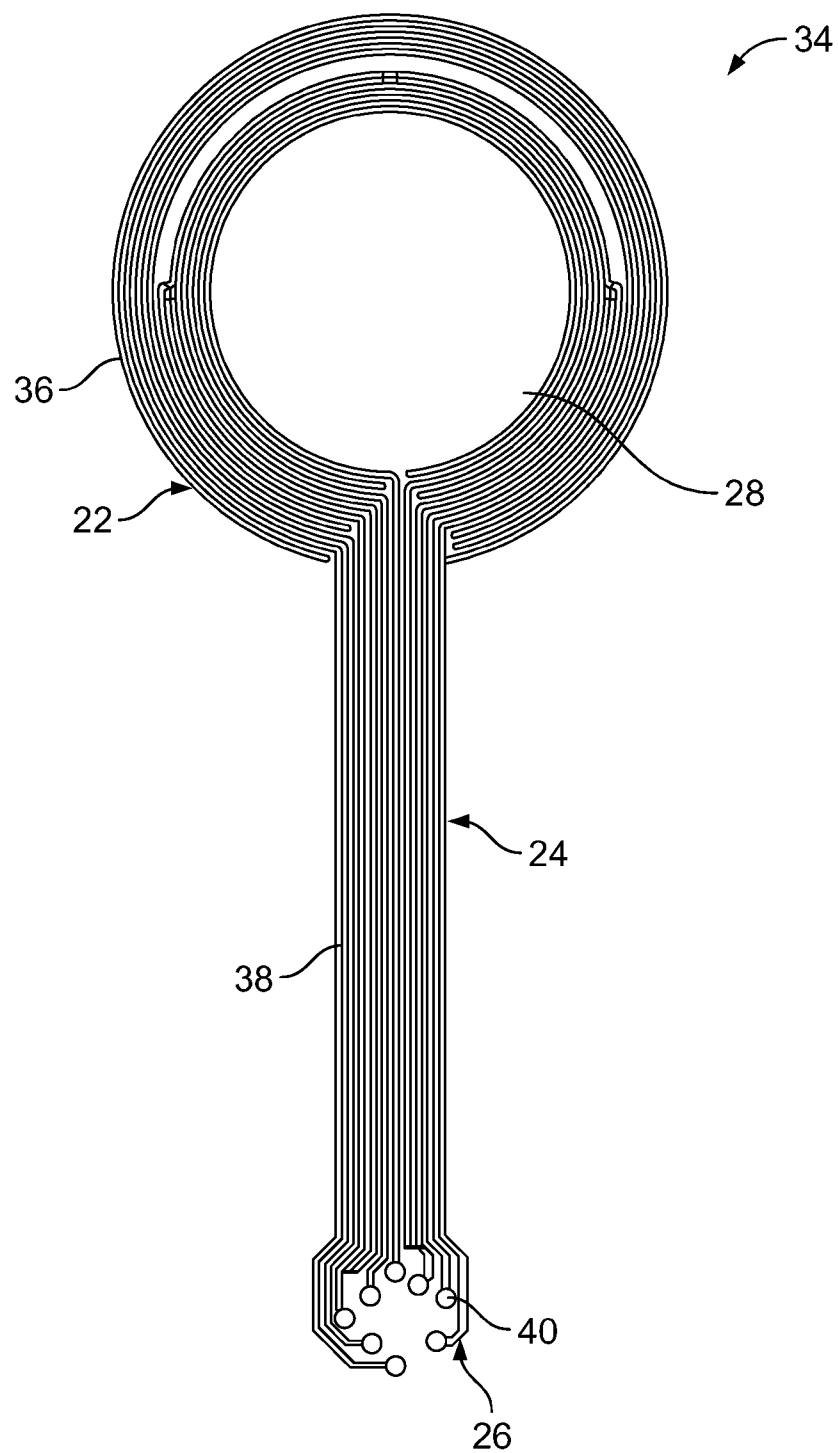
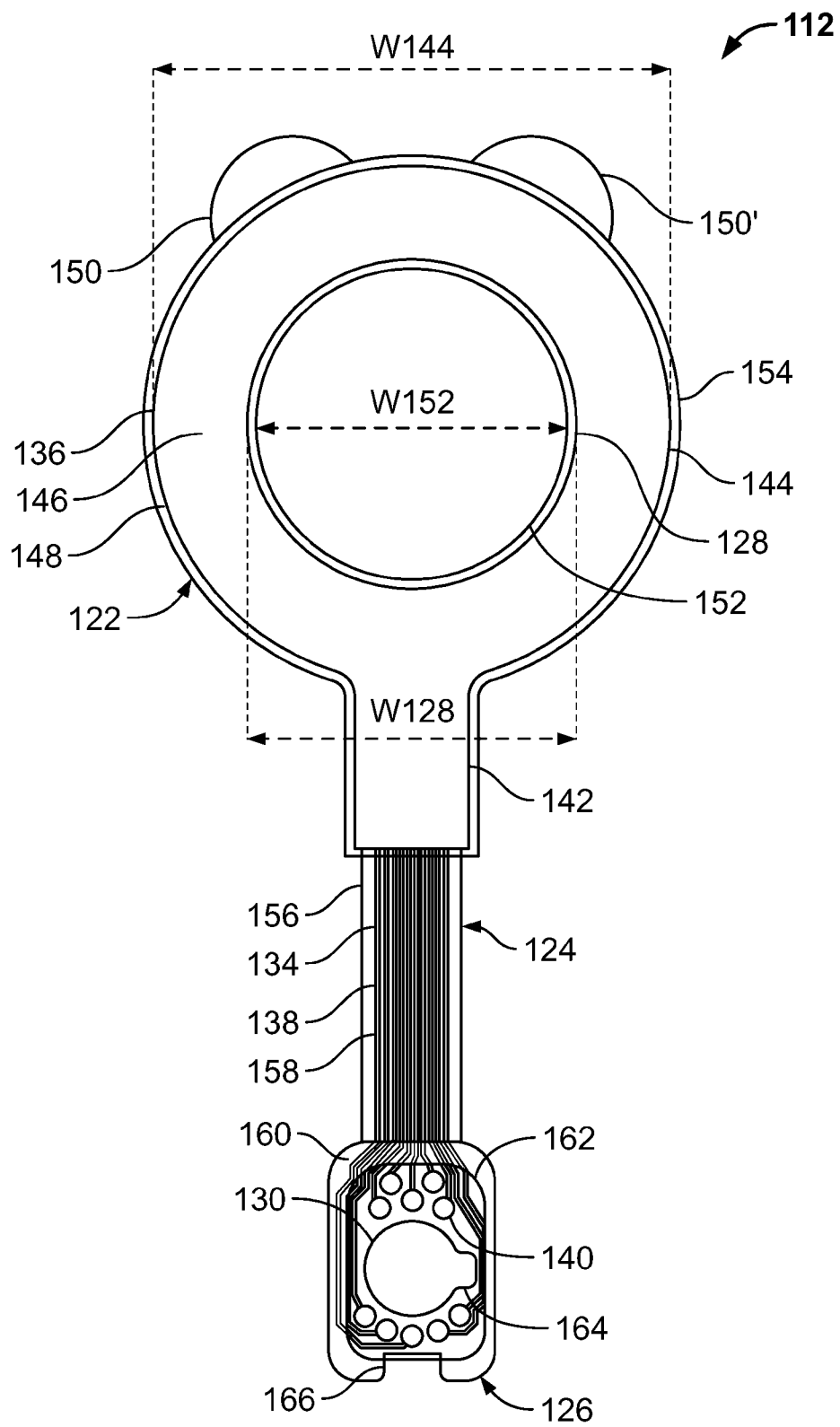
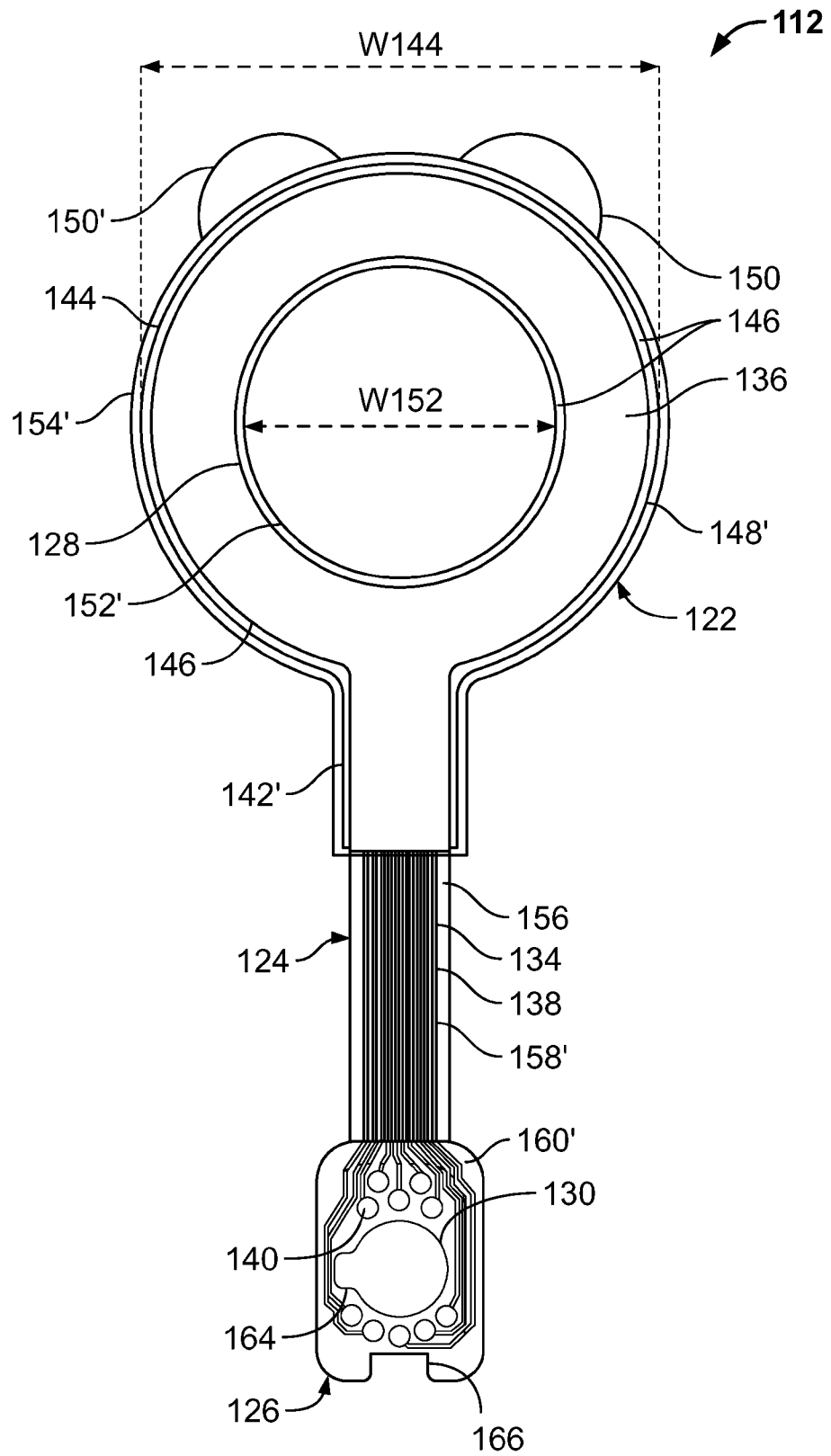


FIG. 3A

**FIG. 4**

**FIG. 5**

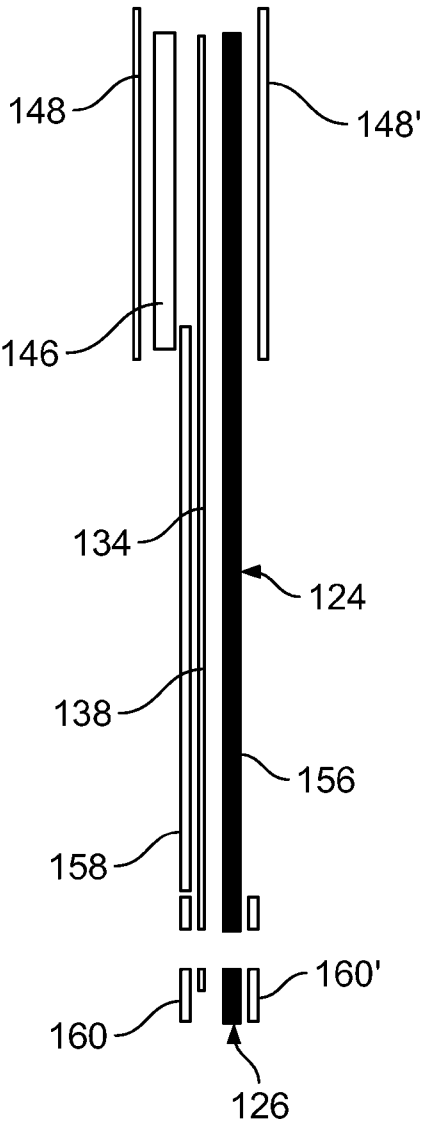
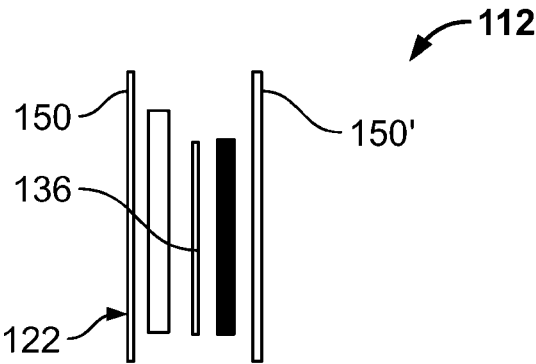


FIG. 6

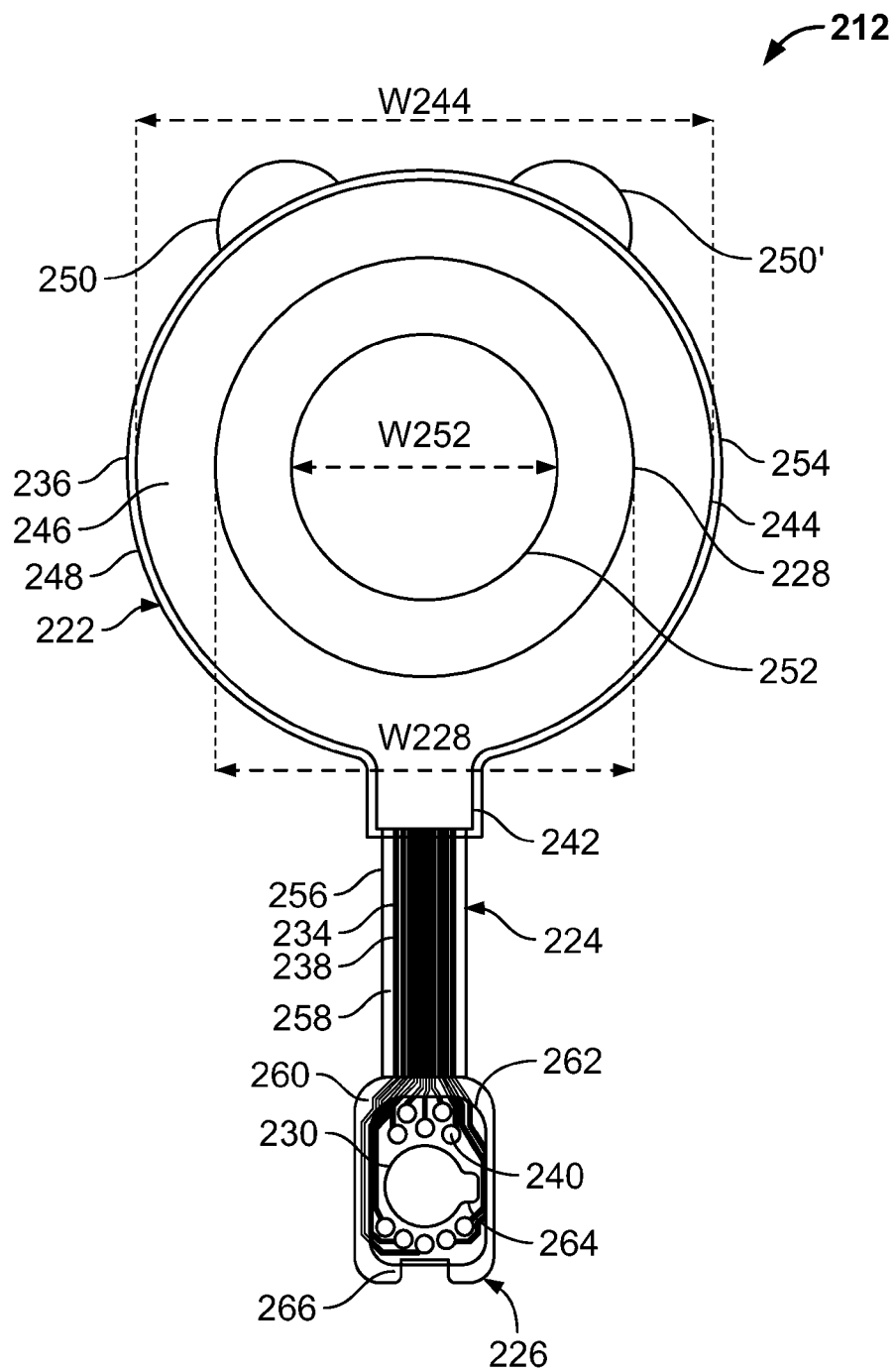


FIG. 7

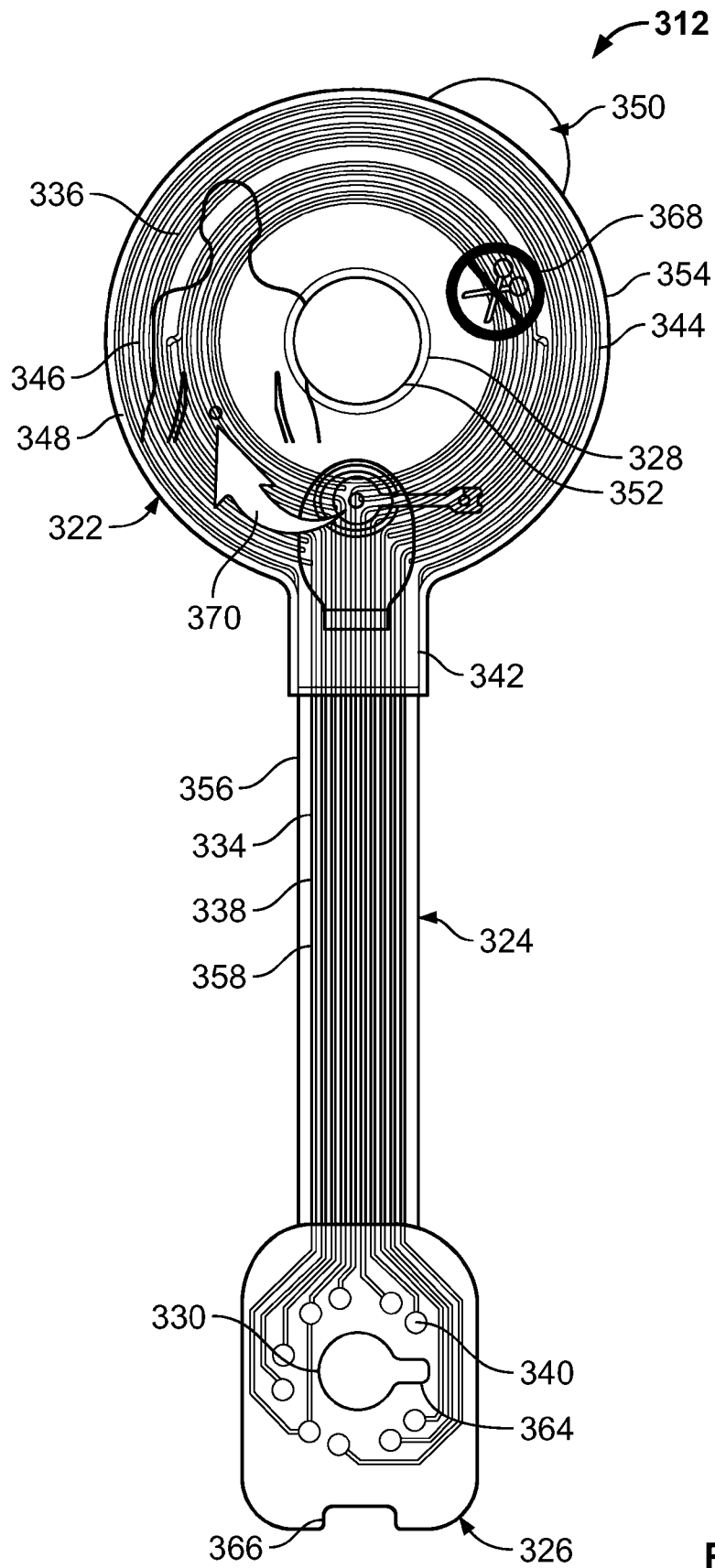


FIG. 8

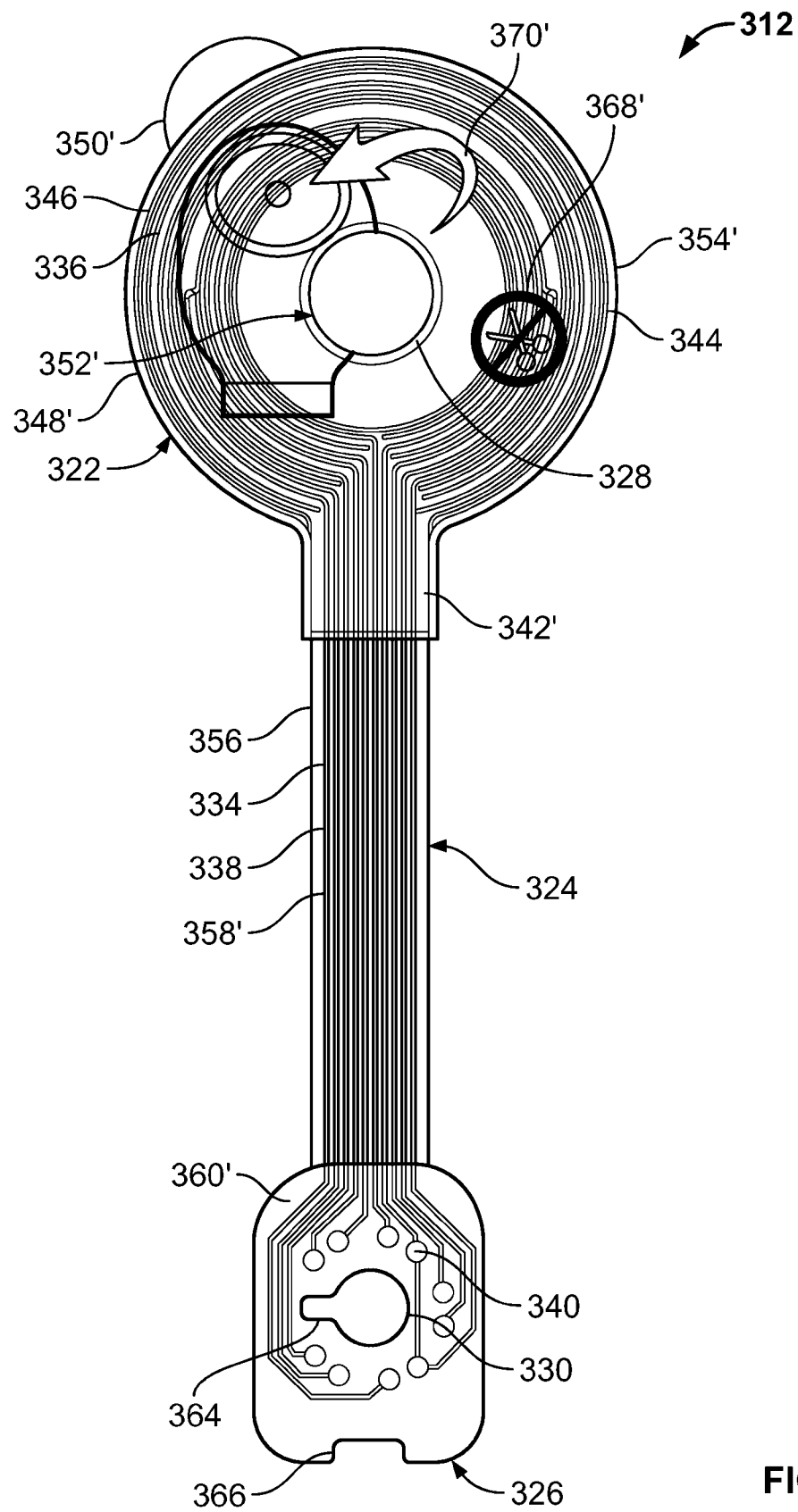


FIG. 9

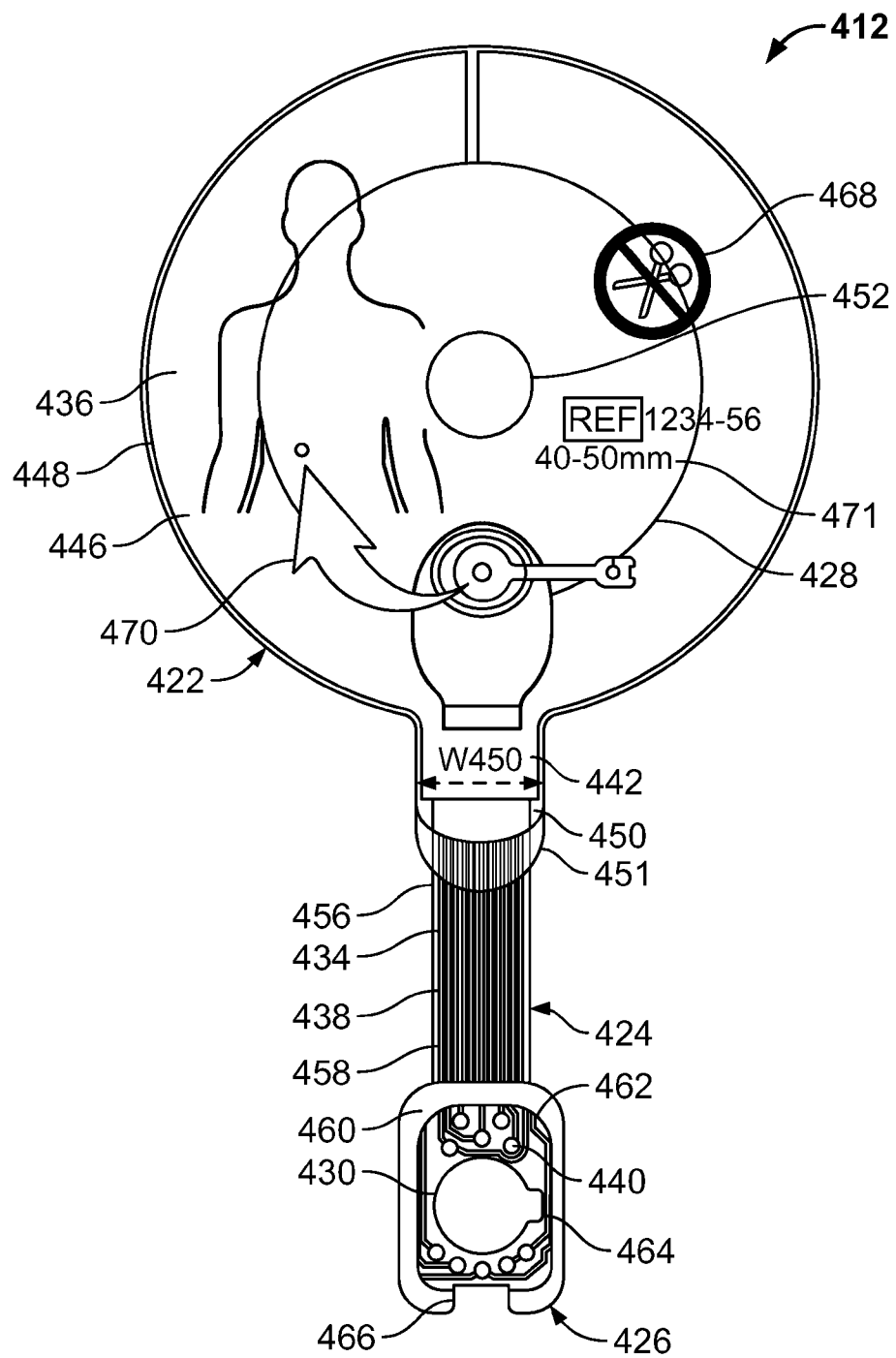


FIG. 10

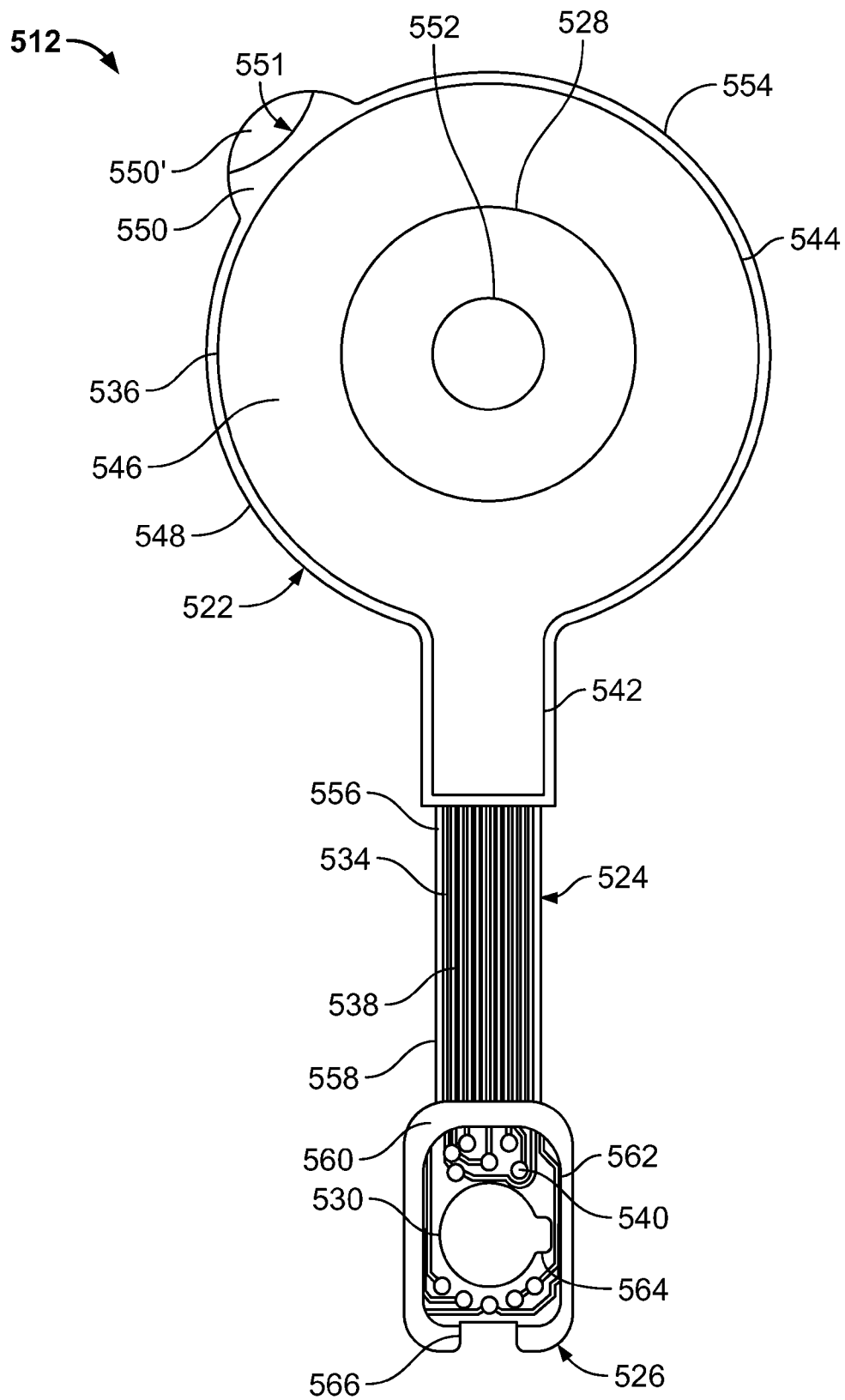


FIG. 11

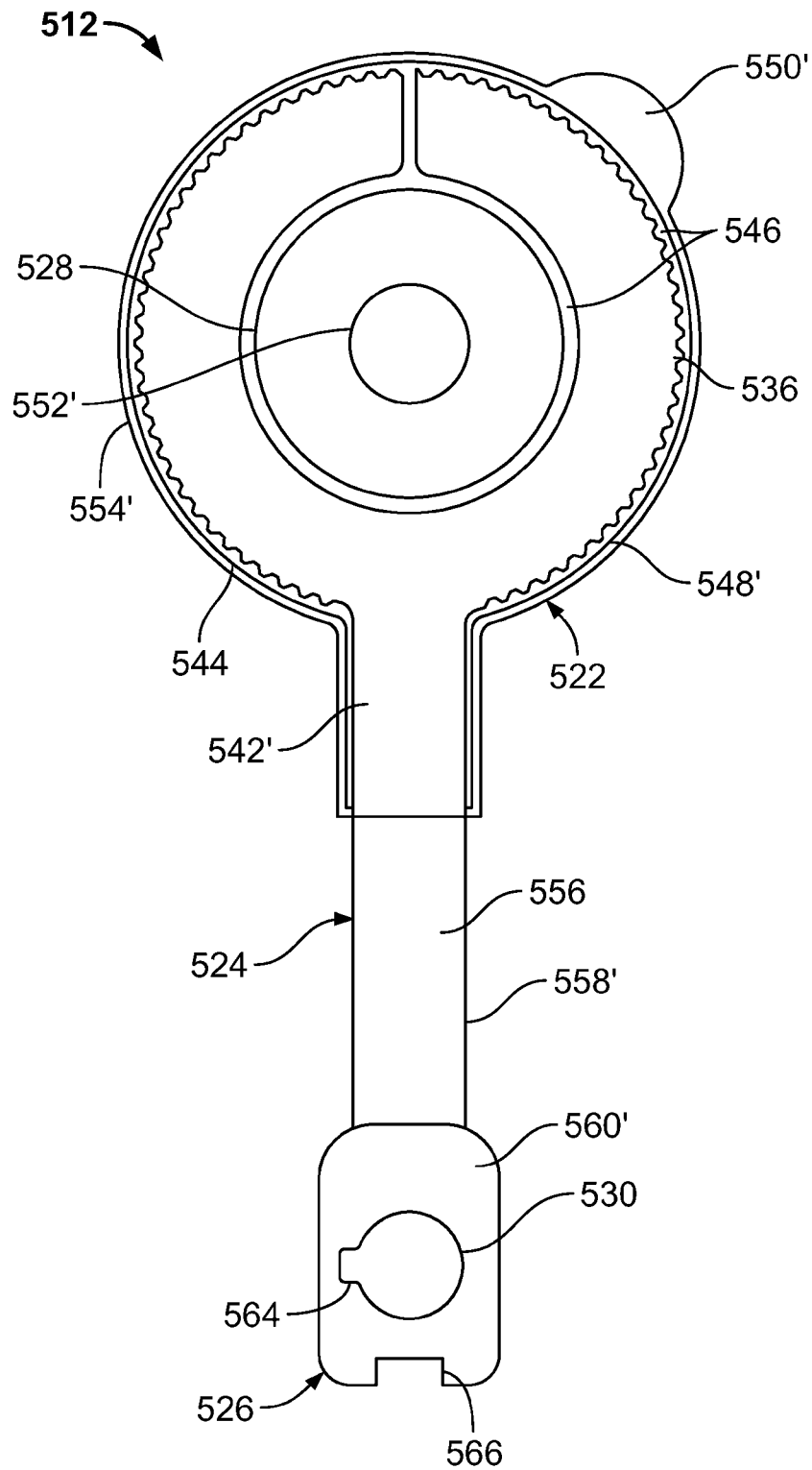


FIG. 12

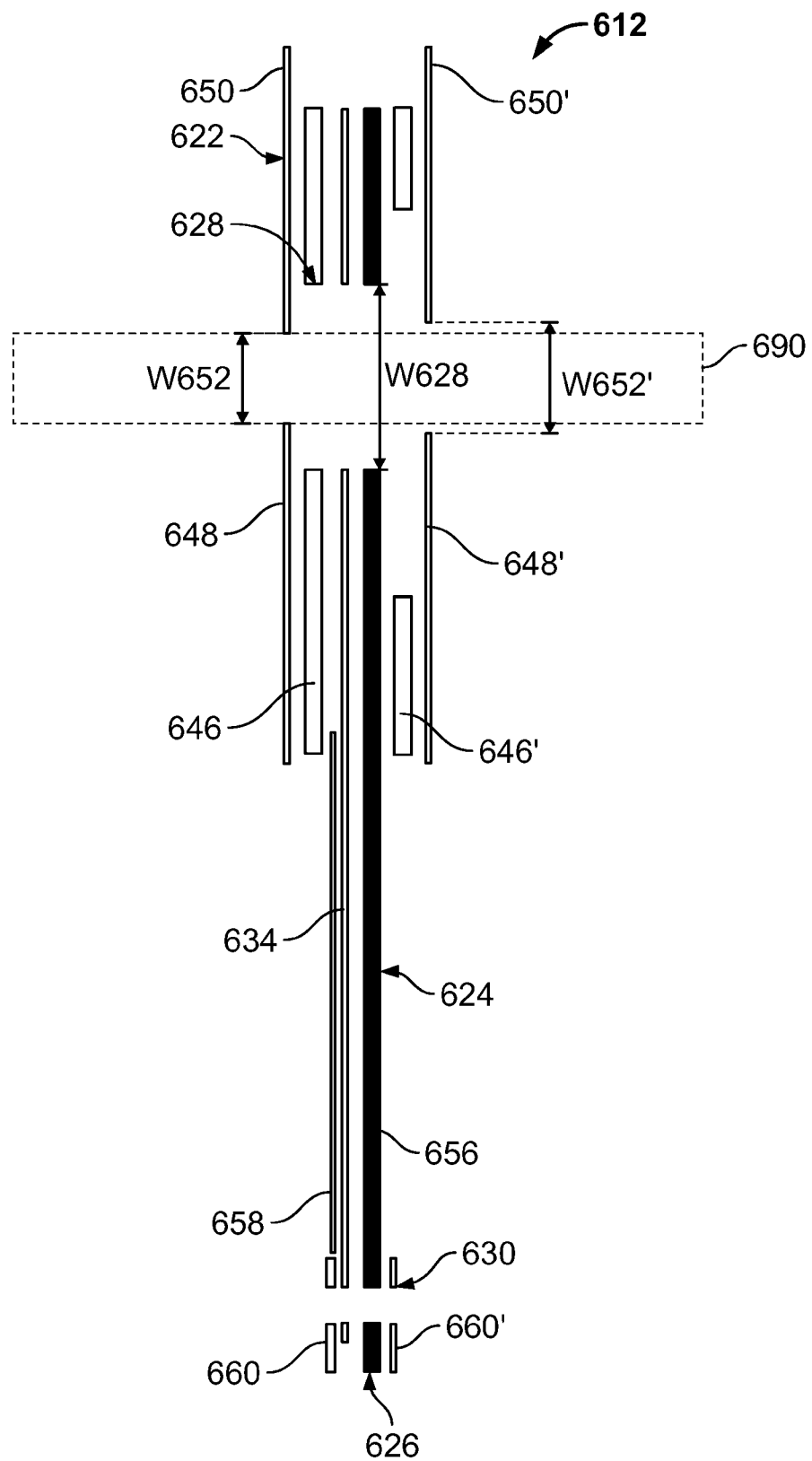


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2024/035945

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F5/44 A61F5/443 A61F5/445
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)

A61F

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**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AU 2020 290 577 A1 (HOLLISTER INC [US]) 20 January 2022 (2022-01-20)	1,2,4-9, 11-14
Y	figures 4, 8, 12 paragraphs [0019], [0065], [0100], [0122] - [0124] -----	3
X	AU 2021 281 459 A1 (HOLLISTER INC) 10 November 2022 (2022-11-10) figure 7 paragraphs [0015], [0077] -----	1,10
Y	EP 1 124 516 B1 (COLOPLAST AS [DK]) 18 May 2005 (2005-05-18) paragraphs [0013], [0014] -----	3
A	JP 2021 161352 A (LINTEC CORP) 11 October 2021 (2021-10-11) paragraphs [0002], [0007] - [0009], [0024] - [0035], [0039], [0044] -----	12-14

☐

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

"&" document member of the same patent family

Date of the actual completion of the international search

23 September 2024

Date of mailing of the international search report

02/12/2024

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Harnack, Hanna

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/035945

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

A sensing accessory for an ostomy leakage detection system comprising: a sensing region including a plurality of sensors for detecting a leak; a skin barrier layer arranged on a body-side of the sensing region configured for attachment to a user's peristomal skin; an inlet opening defined by an inner periphery of the sensing region for receiving a stoma; and a first release liner arranged to cover the skin barrier layer, wherein the first release liner comprises a first center opening defined by an inner periphery of the first release liner and aligned with the inlet opening, wherein a width of the first center opening is a universal width that is less than a width of the inlet opening, wherein the universal width is configured such that the inner periphery of the first release liner is in contact with a post of a sensing accessory packaging while the inner periphery of the sensing region is arranged at a distance away from the post when the sensing accessory is packaged in the sensing accessory packaging.

2. claims: 15-30

A sensing accessory for an ostomy leakage detection system comprising: a sensing region comprising a plurality of sensors for detecting a leakage, wherein the sensing region has a body-side surface and a distal-side surface; an inlet opening defined by an inner periphery of the sensing region for receiving a stoma; a first release liner arranged to cover the body-side surface and including a first center opening defined by an inner periphery of the first release liner and aligned with the inlet opening; and a second release liner arranged to cover the distal-side surface and including a second center opening defined by an inner periphery of the second release liner and aligned with the inlet opening; wherein a width of at least one of the first and second center openings is a universal width that is less than a width of the inlet opening, wherein the universal width is configured such that the inner periphery of the corresponding release liner is in contact with a post of a sensing accessory packaging while the inner periphery of the sensing region is arranged at a distance away from the post when the sensing accessory is packaged in the sensing accessory packaging.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2024/035945

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
AU 2020290577 A1	20-01-2022	AU 2020290577 A1	20-01-2022
		CA 3143202 A1	17-12-2020
		CN 114080204 A	22-02-2022
		EP 3982890 A1	20-04-2022
		US 2022304844 A1	29-09-2022
		WO 2020252458 A1	17-12-2020

AU 2021281459 A1	10-11-2022	AU 2021281459 A1	10-11-2022
		CA 3175645 A1	02-12-2021
		EP 4158298 A1	05-04-2023
		US 2023160771 A1	25-05-2023
		WO 2021242603 A1	02-12-2021

EP 1124516 B1	18-05-2005	AT E295708 T1	15-06-2005
		AU 6465499 A	22-05-2000
		DE 69925376 T2	19-01-2006
		DK 1124516 T3	29-08-2005
		EP 1124516 A1	22-08-2001
		US 6659989 B1	09-12-2003
		WO 0025709 A1	11-05-2000

JP 2021161352 A	11-10-2021	JP 7465136 B2	10-04-2024
		JP 2021161352 A	11-10-2021
