#### (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau





(10) International Publication Number WO 2019/165112 A1

(43) International Publication Date 29 August 2019 (29.08.2019)

(51) International Patent Classification: *A41B 13/06* (2006.01) *A61F 5/37* (2006.01)

(21) International Application Number:

PCT/US2019/019010

(22) International Filing Date:

21 February 2019 (21.02.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/633,529

21 February 2018 (21.02.2018) US

- (71) Applicant: HAPPIEST BABY, INC. [US/US]; 3115 S La Cienega Blvd., Los Angeles, CA 90016 (US).
- (72) Inventors: KARP, Harvey; c/o Happiest Baby, Inc., 3115 S La Cienega Blvd., Los Angeles, CA 90016 (US). LEE,

Angie; c/o Happiest Baby, Inc., 3115 S La Cienega Blvd., Los Angeles, CA 90016 (US).

- (74) **Agent: PASSLER, Mark, D.** et al.; Akerman LLP, 777 S. Flagler Drive, Suite 1100, West Tower, West Palm Beach, FL 33401 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(54) Title: INFANT SLEEP GARMENT

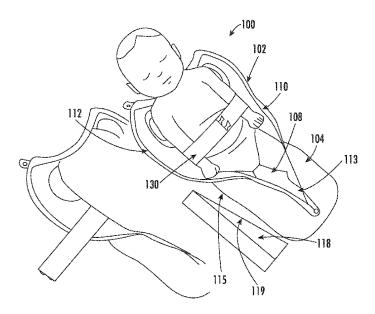


FIG. 1

(57) **Abstract:** An infant sleep garment comprises an enclosure having a first side and a second side. The first side and the second side define an enclosure volume. The enclosure includes a first portion, a second portion, a weight element, and a support element. The first portion is configured to accommodate a lower body of an infant within the enclosure volume. The second portion is located in a superior position relative to the first portion and be configured to accommodate an upper body of the infant. The weight element is couplable to the first side at a location corresponding to an abdominal area of the infant when the infant is enclosed. The support element is couplable to the second side at a location corresponding to the lower body of the infant. The support element is configured to elevate hips and feet of the infant relative to the upper body of the infant.

# 

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

# **Published:**

— with international search report (Art. 21(3))

#### INFANT SLEEP GARMENT

# TECHNOLOGY FIELD

[0001] The present disclosure relates to infant garments, and specifically to garments with infant calming and sleep-aid properties intended to assist in triggering a calming reflex in an infant.

#### **BACKGROUND**

**[0002]** Persistent crying and poor infant sleep are perennial and ubiquitous causes of parent frustration. During the first months of life, babies fuss/cry an average of about two hours/day and wake two to three times a night. One in six infants is brought to a medical professional for evaluation for sleep/cry issues.

[0003] Infant crying and parental exhaustion are often demoralizing and directly linked to marital conflict, anger towards the baby, impaired job performance, and are primary triggers for a cascade of serious/fatal health sequelae, including postpartum depression (which affects about 15% of all mothers and 25-50% of their partners), breastfeeding failure, child abuse and neglect, infanticide, suicide, unsafe sleeping practices, SIDS/suffocation, cigarette smoking, excessive doctor visits, overtreatment of infants with medication, automobile accidents, dysfunctional bonding, and perhaps maternal and infant obesity. Thus, there is a need for improved sleep aids to promote sleep (by reducing sleep latency and increasing sleep efficiency). "Sleep latency" may be defined as the length of time between going to bed and falling asleep. "Sleep efficiency" may be defined as the ratio of time spent asleep (total sleep time) to the amount of time spent in bed.

#### **SUMMARY**

[0004] In one aspect, an infant sleep garment comprises an enclosure having a first side and a second side. The first side and the second side may together define an enclosure volume

therebetween. The enclosure may include a first portion, a second portion, a weight element, and a support element. The first portion may be configured to accommodate at least a portion of a lower body of an infant within the enclosure volume when the infant is enclosed therein. The second portion may be located in a superior position relative to the first portion and be configured to accommodate at least a portion of an upper body of the infant within the enclosure volume when the infant enclosed therein. The weight element may be coupled or couplable to the first side along the second portion at a location corresponding to an abdominal or chest area of the infant when the infant is enclosed within the enclosure volume. The support element may be coupled or couplable to the second side along the first portion at a location corresponding to at least a portion of the lower body of the infant when the infant is enclosed within the enclosure volume. The support element may be configured to elevate hips and feet of the infant relative to the at least a portion of the upper body of the infant.

[0005] In one embodiment, the weight element weighs between 0.5 pounds and 1.5 pounds and the support element includes an arcuate cross-section that extends a distance into the enclosure volume at least 4 inches.

**[0006]** In another aspect, an infant sleep garment includes an enclosure having a first side and a second side. The first side and the second side may together define an enclosure volume therebetween. The enclosure may include a first portion and a second portion. The first portion may be configured to accommodate at least a portion of a lower body of an infant within the enclosure volume when the infant is enclosed therein. The second portion may be located in a superior position relative to the first portion and may be configured to accommodate at least a portion of an upper body of the infant within the enclosure volume when the infant is enclosed therein. The first side may be configured to couple with a weight element along the second portion. The second side may be configured to couple with a support element along the first portion. When coupled with the first side, the weight element may be positioned to apply weight to at least a portion of the upper body of the infant. When coupled with the second side, the support element may be positioned to support the at least a portion of the at least a portion of the lower body of the infant to elevate hips and feet of the infant relative to the at least a portion of the upper body of the infant.

**[0007]** In various embodiments, the first side includes a compartment configured to receive the weight element to thereby couple the weight at the first side. In one embodiment, the first side is configured to couple with the weight element at a location configured to position the weight over a chest or abdominal area of the infant when the infant is enclosed in the enclosure volume to apply pressure to the same when the weight element is received therein. In one example, the weight element weighs between 0.5 and 1.5 pounds.

[0008] In some embodiments, the second side includes a compartment configured to receive the support element. The compartment may be configured to receive the support element and be positioned at a location along the second side corresponding to at least thighs and feet of the infant to underlay the same when the infant is enclosed within the enclosure volume. In one embodiment, the compartment configured to receive the support element is positioned at a location along the second side corresponding to at least hips of the infant to underlay the same when the infant is enclosed within the enclosure volume.

[0009] In various embodiments, when coupled at the second side, the support element extends 4.5 to 5.5 inches into the enclosure volume. In one example, the support element includes a cylindrical cross-section portion that when coupled at the second side extends into the enclosure volume. In a further example, when coupled at the second side, an arcuate cross-section portion of the support element may extend a distance greater than 4 inches or between 4.5 to 5.5 inches into the enclosure volume.

**[0010]** In an embodiment, the first side and the second side are selectively couplable along their respective lateral peripheries extending between the first and second portions. Adjacent lateral peripheries of the first and second sides may include attachment members configured to couple the adjacent lateral peripheries. In one example, the attachment members comprise zipper halves that are matable with adjacent zipper to couple the lateral peripheries.

**[0011]** In some embodiments, the first and second sides may be configured to accommodate an infant sleep sack within the enclosure volume. In one example, the enclosure includes laterally positioned openings to accommodate passage of a sleep sack securing mechanism from the enclosure volume to an exterior of the enclosure for attachment to a moveable sleep platform to thereby indirectly fix the enclosure to movement of the sleep platform.

**[0012]** In one embodiment, the first side includes a compartment configured to receive the weight element to thereby couple the weight at the first side and the second side includes a compartment configured to receive the support element. The compartment configured to receive the weight element may be positioned along the first side at a location corresponding to a chest or abdominal area of the infant when the infant is enclosed within the enclosure volume such that the weight element when received therein applies pressure to the same. The compartment configured to receive the support element may be positioned along the second side at a location to underlay the lower body of the infant when the infant is enclosed within the enclosure volume. When received within the compartment, the support element may extend a distance into the enclosure volume a distance greater than 4 inches or between 4.5 to 5.5 inches.

[0013] In still another aspect, an infant sleep garment comprises an enclosure having a first side and a second side. The first side and the second side may together define an enclosure volume therebetween. The enclosure may include a first portion, a second portion. The first portion may be configured to accommodate at least a portion of a lower body of an infant within the enclosure volume when the infant is enclosed therein. The second portion may be located in a superior position relative to the first portion and be configured to accommodate at least a portion of an upper body of the infant within the enclosure volume when the infant enclosed therein. The enclosure may further include a weight element, a support element, or both. The weight element may be coupled or couplable to the first side along the second portion at a location corresponding to an abdominal or chest area of the infant when the infant is enclosed within the enclosure volume. The support element may be coupled or couplable to the second side along the first portion at a location corresponding to at least a portion of the lower body of the infant when the infant is enclosed within the enclosure volume. The support element may be configured to elevate hips and feet of the infant relative to the at least a portion of the upper body of the infant.

[0014] In one embodiment, the weight element weighs between 0.5 pounds and 1.5 pounds and the support element includes an arcuate cross-section that extends a distance into the enclosure volume at least 4 inches.

[0015] In still another aspect, an embodiment of the present disclosure includes an infant sleep garment comprising a body having a first side, and a second side opposite the first side, the first

and second sides defining an internal volume therebetween, the internal volume comprising: a first portion configured to accommodate at least a portion of an infant's lower body; and a second portion located in a superior position relative to the first portion and configured to accommodate at least a portion of the infant's upper body.

[0016] In an embodiment, the sleep garment may further comprise a first accommodation mechanism connected to the body for receiving a support element, the first accommodation mechanism being located proximate to and inferior relative to the first portion at the second side, and wherein the support element, upon being received at the first accommodation mechanism, is configured to support the infant's legs at an elevated angle relative to the infant's hips.

[0017] In an embodiment, the sleep garment may further comprise a first securing mechanism; wherein the first securing mechanism is connected to the body and configured to fix the sleep garment to a sleep surface;

[0018] In an embodiment, a surface of the support element may be inclined upwardly or downwardly from a proximal end to a distal end. In an embodiment, the surface of the support element may be level, partial inclined, or shaped to have any geometries that may allow the infant to rest in a comfortable position.

[0019] In an embodiment, the support element may comprise a flat portion and an inclined portion, the inclined portion further comprising the inclined surface.

[0020] In an embodiment, the first side may comprise a first coupling mechanism coincident with the sagittal plane of the infant and allowing access to the internal volume

[0021] In an embodiment, a portion of the body may comprise a mesh fabric for allowing air to move therethrough.

[0022] In an embodiment, the elevated angle relative to the infant's hips may be between 30 and 160 degrees.

[0023] In an embodiment, the support element, upon being received at the first accommodation mechanism, may be located outside the interior volume.

[0024] In an embodiment, the support element, upon being received at the first accommodation mechanism, may be located inside the interior volume.

[0025] In an embodiment, the infant sleep garment may further comprise a second securing mechanism. The second securing mechanism may be attached to the body and configured to fix an infant within the interior volume.

[0026] In an embodiment, the infant sleep garment may further comprise a second attachment mechanism. The second attachment mechanism may be configured to receive a weight element at a location proximate to the second portion at the first side of the body, thereby applying pressure to the infant's body.

[0027] In an embodiment, the second attachment mechanism may be connected to the body at the location proximate to the second portion at the first side of the body.

[0028] In an embodiment, the weight element may weigh between 1 ounce and 3 pounds.

**[0029]** In an embodiment, the infant sleep garment may further comprise a first accommodation mechanism connected to a sleep surface for receiving a support element, the first accommodation mechanism being located proximate to and inferior relative to the first portion at the second side; wherein the support element, upon being received at the first accommodation mechanism, may be configured to support the infant's legs at an elevated angle relative to the infant's hips.

**[0030]** In an embodiment of the present disclosure, an infant sleep garment may further comprise: a second attachment mechanism connected to the body. The second accommodation mechanism may be configured to receive a weight element at a location proximate to the second portion at the first side of the body, thereby applying pressure to the infant's body.

[0031] In an embodiment, the sleep garment may further comprise an outer enclosure configured to accommodate a portion of the body therein.

[0032] In an embodiment, the sleep garment may further comprise a first accommodation mechanism connected to the outer enclosure for receiving a support element, the first accommodation mechanism being located proximate to and inferior relative to the first portion at the second side; wherein the support element, upon being received at the first accommodation

mechanism, may be configured to support the infant's legs at an elevated angle relative to the infant's hips.

[0033] In an embodiment, the outer enclosure may comprise a second coupling mechanism extending partially around the periphery of the outer enclosure and allowing accommodation of the body therein.

[0034] In an embodiment, a portion of the outer enclosure may comprise a mesh fabric for allowing air to move therethrough.

[0035] In an embodiment, the sleep garment may be configured to receive a weight element at a location proximate to the second portion at the first side of the body, thereby applying pressure to the infant's body.

[0036] In an embodiment, the second portion of the internal volume may comprise a compartment to receive the weight element at the location proximate to the second portion at the first side of the body.

[0037] In an embodiment, the weight element may be received at the location proximate to the second portion at the first side of the body by connecting the weight element to the second portion.

[0038] In an embodiment, the sleep garment may be configured to receive a weight element at a location proximate to the second portion at the first side of the body, thereby applying pressure to the infant's body; and the outer enclosure further may comprise a second compartment for accommodating the weight element at the location proximate to the second portion at the first side of the body.

[0039] In an embodiment, the weight element may be received at the location proximate to the second portion at the first side of the body by connecting the weight element to the second portion.

[0040] In an embodiment, the second portion of the internal volume may comprise a compartment to receive the weight element at the location proximate to the second portion at the first side of the body.

[0041] In another aspect of the present disclosure, an enclosure for accommodating an infant may comprise: a first side and a second side opposite the first side; a first portion configured to accommodate an infant's legs between the first and second sides; a second portion for accommodating the infant's torso beneath the first side; wherein the first portion may comprise a first accommodation mechanism for receiving a support element configured to support the infant's legs at an elevated angle relative to the infant's hips; and wherein the second portion may comprise a second accommodation mechanism for receiving a weight element configured to apply pressure to the infant's body.

[0042] In an embodiment, portions of the first and second side may comprise a mesh fabric for allowing air to move therethrough.

[0043] In an embodiment, the first and second side may be at least partially connected by a coupling mechanism extending partially around the periphery of the first portion.

[0044] In an embodiment, the first accommodation mechanism may comprise a compartment for receiving the support element therein.

[0045] In an embodiment, the second accommodation mechanism may comprise a compartment for receiving the weight element therein.

[0046] In an embodiment, the first and second sides may be configured to at least partially accommodate an infant sleep garment therebetween.

# BRIEF DESCRIPTION OF THE DRAWINGS

[0047] The novel features of the described embodiments are set forth with particularity in the appended claims. The described embodiments, however, both as to organization and manner of operation, may be best understood by reference to the following description, taken in conjunction with the accompanying drawings in which:

[0048] FIG. 1 is a perspective view illustration of an infant sleep garment according to various embodiments described herein;

[0049] FIG. 2 is a top-down perspective view illustration of the first side of an infant sleep garment according to various embodiments described herein;

[0050] FIG. 3 is a bottom-up perspective view illustration of the second side of an infant sleep garment according to various embodiments described herein;

[0051] FIG. 4 is a left-to-right perspective view illustration of the left side of an infant sleep garment according to various embodiments described herein;

[0052] FIG. 5 is a right-to-left perspective view illustration of the right side of an infant sleep garment according to various embodiments described herein;

[0053] FIG. 6 is perspective view illustration of a sleep surface according to various embodiments described herein;

[0054] FIG. 7 is a perspective view illustration of a first securing mechanism according to various embodiments described herein;

[0055] FIG. 8 is a perspective view of an outer enclosure according to various embodiments described herein;

[0056] FIG. 9 is a perspective view of an outer enclosure according to various embodiments described herein;

[0057] FIG. 10 is a bottom view of an enclosure for accommodating an infant according to various embodiments described herein;

[0058] FIG. 11 is a top view of an enclosure for accommodating an infant according to various embodiments described herein;

[0059] FIG. 12 is a top view of an opened enclosure for accommodating an infant according to various embodiments described herein;

[0060] FIG. 13 is a perspective view of a support element according to various embodiments described herein;

[0061] FIG. 14 is a top view of an enclosure including a first side according to various embodiments described herein;

[0062] FIG. 15 is a bottom view of an enclosure including a second side according to various embodiments described herein;

[0063] FIG. 16 is a top view of an enclosure wherein a first side has been folded down to review an enclosure volume according to various embodiments described herein;

[0064] FIGS. 17A & 17B illustrate a zipper garage feature according to various embodiments described herein;

[0065] FIG. 18A is a top view of an infant positioned within an enclosure volume of an enclosure with a first side of the enclosure folded down according to various embodiments described herein;

[0066] FIG. 18B is a side view of the infant positioned with the enclosure volume of the enclosure shown in FIG. 18A according to various embodiments described herein;

[0067] FIG. 19 is a top view of an infant positioned within an enclosure volume of an enclosure wherein a first side of the enclosure is positioned over the infant according to various embodiments described herein;

[0068] FIG. 20 is a top view of an infant secured within an enclosure volume of an enclosure according to various embodiments described herein;

[0069] FIG. 21A illustrates a securing mechanism pulled through an opening in a side of an enclosure according to various embodiments described herein;

[0070] FIG. 21B illustrates a securing mechanism being pulled from a pocket in a side of the enclosure of FIG. 21A according to various embodiments described herein;

[0071] FIG. 22 is a top view of an infant positioned within an enclosure volume of an enclosure wherein the enclosure and infant are indirectly secured to a platform of a sleep device according to various embodiments described herein; and

[0072] FIGS. 23A & 23B illustrate a neck opening adjustment mechanism according to various embodiments described herein.

# DETAILED DESCRIPTION

[0073] Traditional parenting practices have utilized swaddling, rhythmic motion and certain sounds to soothe fussing infants and promote sleep by reducing sleep latency and increasing sleep efficiency.

**[0074]** Swaddling, rhythmic motion and certain positions and sounds may be utilized to imitate elements of in utero sensory milieu and activate a suite of subcortical reflexes, called the "calming reflex." during the first 4-6 months of a baby's life.

[0075] Swaddling, for example, is a method of snug wrapping with the arms restrained at the sides of the baby. This imitates the confinement and continual touch a baby experienced in the womb. Swaddling also inhibits startling and flailing, which often interrupts sleep and starts/exacerbates crying.

[0076] Rhythmic motions may include jiggling motions that replicate movement a baby experienced as a fetus when the mother was walking. This motion is believed to stimulate the vestibular apparatus in the inner ear. A specific rumbling noise may also be incorporated that imitates the sound created by the turbulence of the blood flowing through the uterine and umbilical arteries. In utero, the sound level a fetus hears has been measured at between 75 and 92 dB.

[0077] Like the children and adults they will grow to become, each baby is an individual that may favor a specific and/or unique mix of motion and sound that most efficiently activates his or her calming reflex. This preferred mix is believed to stay consistent through the first months of life (e.g., babies who respond best to swaddling plus jiggling continue to respond to those modalities over time and do not abruptly switch their preference to swaddling plus sound). In utero, babies are confined in a small space requiring them to flex their hips and knees with the knees pressing against the stomach and arms pressed against the chest.

**[0078]** The calming reflex has several constant characteristics. It is triggered by a stereotypical sensory input; produces a stereotypical behavioral output; demonstrates a threshold phenomenon (i.e. stimuli that are too mild may not be sufficient to activate a response); has a threshold that varies between individuals (i.e. is higher or lower for any given child); the threshold varies by state (e.g. fussing and crying raise the level of stimulation required to exceed threshold and bring about reflex activation); the reflex is universally present and relatively obligatory at birth, but wanes after 3-4 months of age.

[0079] In addition, crib death or SUID (Sudden Unexplained Infant Death) is a leading cause of infant mortality. Approximately 3700 US babies die each year from SUID during the first year of life. The peak occurrence is from 2-4 months of age, with 80% of the victims being under 4 months and 90% being under 6 months of age.

[0080] In the 1990's, a program to reduce SUID deaths called "Back to Sleep" was introduced. At that time, it was discovered that sleeping on the stomach was a key triggering factor in many of the deaths, so caregivers were instructed to place babies on their backs for sleeping. Within less than a decade, the rate of SUID dropped almost in half, however, since 1999, the SUID incidence has barely diminished. Studies have indicated that stomach sleeping may indeed predispose babies to SUID by causing suffocation or by reducing infant arousability and inhibiting breathing.

**[0081]** In addition, many babies fall out of their bassinet during the first 6 months of life. Federal reports reveal that 69% of recent bassinet/cradle incidents have been attributed to falling. All falls resulted in head injury. Alarmingly, 45% of falls occurred in infants five months old or less.

[0082] Therefore, a need exists for an infant garment that constrains the movement of the infant relative to a sleep surface while promoting the calming reflex of the infant.

[0083] In an embodiment of the present disclosure, an infant sleep garment may comprise a body having a first side, and a second side opposite the first side, the first and second sides defining an internal volume therebetween, the internal volume comprising: a first portion configured to accommodate at least a portion of an infant's lower body; and a second portion located in a superior position relative to the first portion and configured to accommodate at least a portion of the infant's upper body.

[0084] In an embodiment, the sleep garment may further comprise a first accommodation mechanism connected to the body for receiving a support element, the first accommodation mechanism being located proximate to and inferior relative to the first portion at the second side, and wherein the support element, upon being received at the first accommodation mechanism, is configured to support the infant's legs at an elevated angle relative to the infant's hips.

[0085] FIG. 1 illustrates an infant sleep garment 100 according to various embodiments described herein. The sleep garment 100 may include a body 102, which may also be referred to herein as a sleep sack, may be configured as a clothing article or an over garment to be worn by an infant. The body 102 may include an infant enclosure region comprising an interior volume. The body 102 may include a coupling mechanism to enclose the infant within the interior volume. The body 102 may be configured to swaddle an infant when within the interior volume thereof. In some embodiments, the body 102 may comprise a sleep sack as described in U.S. Patent Application No. 15/055,077, filed February 26, 2016, titled *Infant Calming/Sleep-Aid and SIDS Prevention Device with Drive System*, or U.S. Patent Application No. 15/336,519, filed October 27, 2016, titled *Infant Calm/Sleep-Aid*, *SIDS Prevention Device*, and Method of Use. The disclosures of both of which are hereby incorporated herein by reference.

**[0086]** With reference to **FIGS. 1-5**, body 102 has first side 104 and second side 106 opposite first side 104, first side 104 and second side 106 defining internal volume 108 therebetween. Internal volume 108 comprises first portion 110 configured to accommodate at least a portion of an infant's lower body. In an embodiment, a width of first portion 110 may be the average width of an infant's hips, or a circumference of first portion 110 may be the average waist circumference of an infant. In an embodiment, first portion 110 may be a material with elastic properties that shrinks or expands to accommodate at least a portion of an infant's lower body, or may be adjustable such that a user may set an appropriate dimension of first portion 110 to accommodate an infant's lower body.

[0087] Internal volume 108 may further define a second portion 112 located in a superior position relative to the first portion 110 and configured to accommodate the infant's upper body. The internal volume 108 may further define a third portion 113 located in an inferior position relative to the first portion 110 and configured to accommodate the infant's feet. In the context of the

present disclosure, a superior position is one relatively further towards the head of an infant, while an inferior position is one relatively further towards the feet of an infant.

[0088] FIG. 2 is a top-down perspective view illustration of the first side 104 of infant sleep garment 100. In the example shown in FIG. 2, the first side 104 may comprise a first coupling mechanism 124 coincident with the sagittal plane of the infant and allowing access to the internal volume 108. A portion of the body 102 may comprise a mesh fabric 126 for allowing air to move therethrough. First coupling mechanism 124 may include but is not limited to any sealable and unsealable mechanism, such as a zipper mechanism, a hook and loop attachment mechanism, a push snap attachment, a magnetic attachment mechanism, fasteners, clips, buttons, or any similar mechanism.

**[0089] FIG. 2** also shows an embodiment of a first securing mechanism 114. First securing mechanism 114 is connected to the body 102 and configured to fix the sleep garment to a sleep surface 116 (shown in FIG. 6). In an embodiment, the first securing mechanism 114 may be any mechanism configured to secure the sleep garment 100 to sleep surface 116 to prevent an infant inside a sleep garment from rolling over or otherwise moving into an unsafe disposition. The first securing mechanism 114 may include but is not limited to any of the following: a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism configured to secure sleep garment 100 to sleep surface 116. An embodiment of a securing mechanism 114 may comprise a sleeve 117 or clip 123 for engaging a corresponding clip or sleeve, which may be connected to the sleep surface 116, e.g., in a manner shown in **FIG. 7**. In an embodiment, the first securing mechanism 114 of the sleep garment 100 may be configured to attach to another garment, or sleep garment 100 may be accommodated within another garment, wherein the other garment is attachable to sleep surface 116, thereby indirectly securing the sleep garment 100 to sleep surface 116.

**[0090]** With particular reference to FIGS. 1-3, a support element 118 may be configured to be received at location 115 that is proximate to and inferior relative to the first portion 110 at the second side 106, thereby supporting the infant's legs at an elevated angle relative to the infant's hips. In an embodiment, support element 118 may be placed at location 115 by a user, without an

attachment mechanism. In the embodiment shown in FIGS. 1-3, support element 118 may be received at first accommodation mechanism 121 located at location 115 that is proximate to and inferior relative to the first portion 110 at the second side 106. The first accommodation mechanism 121 may be connected to the body 102 of sleep garment 100 as shown in **FIG. 3**, or may be connected to the sleep surface 116 of **FIG. 6**, or may be connected to outer enclosure 120 which may receive support element 118, as shown in **FIGS. 8-9**. The first accommodation mechanism 121 may include but is not limited to any mechanism configured to receive support element 118, such as a pocket, an enclosure, a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism configured to receive support element 118.

[0091] It is to be appreciated that the support element 118 may be configured to have different shapes and dimensions in accordance to the principles disclosed there. In an embodiment, a surface 119 of the support element 118 may be flat, inclined upwardly or downwardly, rounded, recessed, partially inclined or any combination thereof. In an embodiment, the surface 119 may be inclined from one end to another end, as shown in FIG. 1. In an embodiment, a support element may comprise a flat surface. In an embodiment shown in FIG. 13, support element 218 may comprise a first portion 230 and a second portion 232, first portion 230 comprising a flat surface and second portion 232 comprising an inclined surface. The incline of the surfaces 119 and 232 may be configured to promote a desired elevated angle between the infant's legs and hips. In an embodiment, the elevated angle relative to the infant's hips may be between 30 and 160 degrees, which is a range that may be effect in comforting certain infants. The raising of an infant's legs to within this range may preferably relax the infant's abdomen muscles, promoting a calming reflex. In an embodiment of a support element, there may be multiple upwardly or downwardly inclined, flat, or otherwise shaped portions from a proximal to a distal end. A support element may comprise other shapes and geometries in accordance to the principles disclosed herein. For example, in an embodiment, a surface of the support element may be contoured to accommodate each leg of an infant separately. In an embodiment, the height of a distal end of the support element may be lower than that of the proximal end.

[0092] In an embodiment, the support element 118, upon being received at the location 115 that is proximate to and inferior relative to the first portion 110 at the second side 106, may be located outside the interior volume 108.

[0093] In an embodiment, the support element 118 may be received at first accommodation mechanism 121 located at location 115 outside the interior volume 108 by connecting the support element 118 to the sleep surface 116. It is to be appreciated that the support element 118 may be connected to the sleep surface 116 by any type of connectors (not shown) in accordance with the principles of the present disclosure. For example, the support element 118 may be connected to sleep surface 116 by a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism configured to connect support element 118 to sleep surface 116. In an embodiment, support element 118 may also be inserted into an accommodation space (not shown) of sleep surface 116.

[0094] In an embodiment, the support element 118 may be received at the location 115 that is proximate to and inferior relative to the first portion 110 at the second side 106 by connecting the support element 118 to the body 102 of the garment 100. Support element 118 may be connected to body 102 at the second side 106 by any type of connectors (not shown) in accordance with the principles of the present disclosure. For example, the support element 118 may be connected to the garment 100 by a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism configured to attach support element 118 to second side 106. In an embodiment, support element 118 may also be inserted into an accommodation space (not shown) defined on the exterior or interior of the second side 106 of the garment 100.

[0095] In an embodiment, the support element 118, upon being received at the location 115 that is proximate to and inferior relative to the first portion 110 at the second side 106, may be located inside the interior volume 108. For example, an accommodation space (not shown) may be defined by a compartment between the first and second sides 104, 106 of the garment 100 for receiving the support element 118 in the interior volume 108.

[0096] In an embodiment, the support element 118, upon being connected to the garment 100, may be located outside the interior volume 108. For example, the garment 100 may further include an outer enclosure 120 for enclosing the support element 118 in a compartment 122 outside the body 102.

[0097] FIG. 8 is a perspective view of an embodiment of the outer enclosure 120. The outer enclosure 120 may be configured to accommodate a portion of the body 102 therein and define an internal compartment 122 for accommodating the support element 118 and the third portion 113 of the body 102. The support element 118, upon being accommodated in the internal compartment 122, may be received at the location 115 that is proximate to and inferior relative to the first portion 110 at the second side 106 and under the third portion 113.

[0098] In FIG. 8, the outer enclosure 120 may comprise a second coupling mechanism 128 extending at least partially around the periphery of outer enclosure 120. In an embodiment, the second coupling mechanism 128 may be a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism configured to seal and unseal outer enclosure 120 to accommodate body 102 therein. At least a portion of the outer enclosure 120 may comprise mesh fabric 126 for allowing air to move therethrough. In an embodiment, at least a surface of the outer enclosure 120 proximate to the second surface may be comprised entirely of a mesh structure. In an embodiment, a majority of the outer enclosure 120 may comprise a mesh structure.

[0099] Referring back to FIG. 1, the infant sleep garment 100 may further comprise a second securing mechanism 130; and the second securing mechanism 130 may be attached to the body 102 and configured to fix an infant within the interior volume 108. The second securing mechanism 130 may include but is not limited to any of the following: a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism configured to fix an infant within the interior volume 108. The second securing mechanism 130 may be located inside the interior volume 108 or may be located outside the interior volume 108, and may be proximate the first portion 110, second portion 112, or third portion 113.

[00100] In FIG. 9, the sleep garment 100 may be configured to receive a weight element 132 at a location 134 proximate to the second portion 112 at the first side 104 of the body 102, thereby applying pressure to the infant's body. In an embodiment, a sleep garment may be configured to receive a weight element at a location to thereby apply pressure to the infant's upper body, lower body, or both upper and lower body simultaneously.

[00101] In an embodiment, the second portion 112 of the internal volume 108 may comprise a compartment (not shown) to receive the weight element 132 at the location 134 proximate to the second portion 112 at the first side 104 of the body 102.

[00102] In an embodiment, the weight element 132 may be received at the location 134 proximate to the second portion 112 at the first side 104 of the body 102 by connecting the weight element 132 to the first side 104 of the body 102 by a connector (not shown) which may include but is not limited to any of the following: a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism.

[00103] In FIG. 9 the outer enclosure 120 further may comprise a second compartment 136 for accommodating the weight element 132 at the location 134 proximate to the second portion 112 at the first side 104 of the body 102.

[00104] In an embodiment, the weight element 132 may weigh between 1 ounce and 3 pounds, preferably between 0.5 and 1.5 pounds, between 1 and 1.5 pounds, or about 5 pounds, about 0.75 pounds, about 1 pound, about 1.25 pounds, or about 1.5 pounds, or about 1.75 pounds. By positioning the weight element 132 at location 134 proximate an infant's chest, the pressure applied by the weight element 132 may elicit a calming response from the infant, aiding in the sleep of the infant. Further, upon being received at location 134, the weight element 132 may be fixed relative to an infant within the sleep garment, and may be prevented from interfering with the sleep of the infant. In an embodiment, the pressure applied by weight element 132 upon being received at location 134 may be distributed over the chest and stomach of the infant. In an embodiment, the pressure from the weight element may be at least partially distributed over the lower body of the infant as well. In an embodiment, the weight element may be received at an

alternate location (not shown) to thereby distribute a portion of the weight over the upper body and a portion of the weight over the lower body.

[00105] In an embodiment, the weight element 132 may be received at the location 134 proximate to the second portion 112 at the first side 104 of the body 102 by connecting the weight element 134 to the second portion 112 by a connector (not shown) which may include but is not limited to any of the following: a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism.

[00106] In an embodiment, the weight element 132 may comprise any weighted material which may include but is not limited to a metal, a plastic, a ceramic, a polymer, gel, liquid, a composite, a natural, or an artificial material. Furthermore, the weight may be flat, round, irregular or any other shape and further may be any size so as to be effective for its functions described herein.

[00107] FIGS. 10-12 illustrate an embodiment of an enclosure 200 for accommodating an infant. FIG. 11 shows a view of first side 204, while FIG. 10 shows a view of second side 202, which is opposite first side 204.

[00108] Enclosure 200 comprises a first portion 206 configured to accommodate an infant's legs between the first side 204 and the second side 202. Enclosure 200 may further comprise a second portion 208 configured to accommodate the infant's torso beneath the first side 204.

[00109] The second side 202 is configured to couple with a support element 210. In **FIG.** 12, first portion 206 comprises a first accommodation mechanism 210 for receiving a support element 212 configured to support the infant's legs at an elevated angle relative to the infant's hips. Furthermore, second portion 208 comprises a second accommodation mechanism 214 for receiving a weight element (not shown) for applying pressure to an infant's torso.

**[00110]** Referring to **FIGS. 10-12**, portions of first side 204 and second side 202 comprise a mesh fabric 216 for allowing air to move therethrough. First side 204 and second side 202 are partially connected by coupling mechanism 218, which extends partially around the periphery of first portion 206.

[00111] In FIG. 12, the first accommodation mechanism 210 comprises a compartment 222 for receiving the support element 212 therein, and second accommodation mechanism 214 comprises compartment 220 for receiving the weight element (not shown) therein. Furthermore, first side 204 and second side 202 are configured to at least partially accommodate an infant sleep garment, such as sleep garment 100, therebetween. When a sleep garment is located between first side 204 and second side 202, the enclosure 200 may accommodate the sleep garment by limiting the second side 202 to second portion 206, as shown in FIG. 10. In an embodiment, enclosure 200 may be configured to attach to a sleep surface, such as sleep surface 116. In an embodiment, upon enclosure 200 accommodating a sleep garment such as sleep garment 100 therewithin, the sleep garment may be configured to attach to a sleep surface such as sleep surface 116, thereby fixing enclosure 200 to the sleep surface. In an embodiment, the enclosure 200 may alternately be configured to attach to another sleep garment through an attachment mechanism, and the other sleep garment may then be secured to a sleep surface, thereby indirectly securing enclosure 200 to the sleep surface. By attaching the enclosure 200 to a sleep surface, an infant accommodated within enclosure 200 may be prevented from rolling over or otherwise moving into an unsafe disposition.

In an embodiment, the enclosure 200 may comprise a first securing mechanism for securing an infant within the enclosure according to the principles disclosed herein. In an embodiment, the enclosure 200 may comprise a second securing mechanism for securing the enclosure 200 to a sleep surface, such as sleep surface 116, according to the principles disclosed herein. The second securing mechanism may prevent an infant accommodated with the enclosure 200 from rolling over or otherwise moving into an unsafe disposition. Furthermore, the attachment mechanisms disclosed herein may be configured to communicate with a control system to detect whether an attachment mechanism is properly secured, and may alert a user or cease some operational function upon detecting that an attachment mechanism is not properly secured.

[00113] Referring to FIGS. 10-12, an infant may be placed proximate to enclosure 200, with the infant's hips adjacent to support element 212 and legs positioned on a top surface of support element 212. A user may then operate coupling mechanism 218, partially sealing first side 204 on top of second side 202, accommodating the infant and support element 212 within compartment 222. First side 204 will then be located above the infant, with compartment 220 positioned proximate to the infant's torso.

[00114] FIG. 13 illustrates an embodiment of support element 212. Support element 212 comprises a first portion 230 and a second portion 232. First portion 230 is flat, while second portion 232 is inclined from a proximal end 236 to a distal end 234. Support element 212 at the first portion 230 is a constant thickness, and has a rounded, bullnose shape at the distal end 234 and a straight edge at the proximal end 236. In embodiments, a support element may include but is not limited to a foam material, a cushion, an air pocket, or any material configured to support an infant's legs in an elevated angle relative to the infant's torso. The support element may further comprise a fabric case (not shown) surrounding the supportive material. The support element may have a resistance to deformation configured to support the infant's legs in the elevated position according to the principles disclosed herein. The support element and/or the fabric case may also be resistant to liquid or biological materials.

[00115] In an embodiment, sleep garment 100 may be configured to accommodate a pillow, gel pad or other type of support (not shown) beneath the head of an infant. In an embodiment, enclosure 200 may be configured to accommodate a pillow, gel pad or other type of support (not shown) beneath the head of an infant.

**FIGS. 14-17B** illustrate an enclosure 300 according to various embodiments. The enclosure 300 may be configured to accommodate an infant, which, in some embodiments, may include all or a portion of a body 102 (see, e.g., **FIG. 1**) further enclosing or swaddling the infant therein.

[00117] The enclosure 300 includes a first side 302 (FIG. 14) and a second side 306 (FIG. 15) that together define an enclosure volume 305 (FIG. 16) between their respective interior surfaces. FIG. 16 illustrates the first side 302 partially separated or detached from the second side 304. The first and second sides 302, 304 may remain attached along a portion of their respective perimeters as shown or along another perimeter portion or may be completely separated (not shown). The enclosure 300 further comprises a first portion 306 configured to accommodate the lower body of an infant within the enclosure volume 305 between the first side 304 and the second side 302. The enclosure 300 may further comprise a second portion 308 configured to accommodate a torso of an infant within the enclosure volume 305 between the first side 304 and the second side 302.

[00118] The enclosure 300 may include one or more areas comprising mesh fabric 316 to provide breathability and reduce overheating. For example, the first side 304, the second side 302, or both may include one or more areas comprising a mesh fabric 316. In the illustrated embodiment, the first side 304 includes an area comprising a mesh fabric 316 along the first portion 306 defining a region of the enclosure volume 305 corresponding to a region for enclosing the legs of an infant. The second side 306 includes one or more areas of fabric mesh 316 along the second portion 308 defining a region of the enclosure volume 305 corresponding to regions for enclosing arms or shoulders of an infant. In an embodiment, at least a surface of the enclosure 300 proximate to the first portion 306 may be comprised entirely of a breathable mesh structure. In a further embodiment, a majority of the enclosure 300 may comprise a breathable mesh structure.

[00119] The enclosure 300 may be configured to include or associated with one or more accommodation mechanisms. The accommodation mechanisms may be similar to the accommodation mechanisms described above with respect to FIGS. 1-13 and elsewhere herein. In the illustrated embodiment, the first side 304 is configured to couple with a weight element 332 and the second side 203 is configured to couple with a support element 312. For example, the enclosure 300 is configured to include or associate with an accommodation mechanism 332 comprising a weight element 332 and an accommodation mechanism 310 comprising a support element 312. As shown, the enclosure 300 is configured to receive a weight element 332 at a location 335 proximate to the second portion 308 at the first side 304. The weight element 332 may be positioned such that it applies weight to the upper body, chest, and/or abdominal area of an infant enclosed in the enclosure 300. In the illustrated embodiment, as best shown in FIG. 16, a compartment 320 comprising a pocket is positioned on the first side 304 for receiving the weight element 332. The compartment 320 is accessible from the interior side of the first side 304. In one embodiment, the first side 304 includes a compartment 320 accessible from its exterior side or that is sewn, adhered, or otherwise closed, with the weight element 332 enclosed therein. In some embodiments, the first side 304 is configured to removably couple with the weight element via snaps, straps, clips, hook and loop, mating structures, or other coupling structures.

[00120] In some embodiment, the weight element 332 may weigh between 1 ounce and 3 pounds, preferably between 0.5 and 1.5 pounds, between 1 and 1.5 pounds, or about 5 pounds, about 0.75 pounds, about 1 pound, about 1.25 pounds, or about 1.5 pounds, or about 1.75 pounds.

By positioning the weight element 332 at location 335, which corresponds to an upper body location proximate a chest of an infant, the pressure applied by the weight element 332 may be applied to a chest or abdominal area and elicit a calming response from the infant, aiding in the sleep of the infant. Further, upon being received at location 335, the weight element 332 may be fixed relative to an infant within the enclosure 300, and may be prevented from interfering with the sleep of the infant. In an embodiment, the pressure applied by weight element 332 upon being received at location 335 may be distributed over the chest and stomach of the infant. In an embodiment, the pressure from the weight element 332 may be at least partially distributed over the lower body of the infant as well. In an embodiment, the weight element 332 may be received at an alternate location (not shown) to thereby distribute a portion of its weight over the upper body and a portion of the weight over the lower body of an infant enclosed in the enclosure 300.

[00121] In some embodiments, the weight element 332 may comprise any weighted material which may include but is not limited to a metal, a plastic, a ceramic, a polymer, gel, liquid, a composite, a natural, or an artificial material. Furthermore, the weight may be flat, round, irregular or any other shape and further may be any size so as to be effective for its functions described herein.

[00122] As introduced above, enclosure 300 also includes a support element 312. The support element 312 may extend within the enclosure volume 305 and include a structure dimensioned to elevate the lower body, legs, and/or feet of an infant, e.g., from between 0 and 8 inches, such as between 3 and 6 inches, between 4 or 4.5 and 5.5 inches, at least or greater than 4 inches, or approximately 5 inches +/- 1/4 inch. The support element 312 may extend from the interior side of the second side 302 so as to underlay the legs of an infant when enclosed in the enclosure volume 305. The support element 312 may include an upper surface 313 positioned to underlay the lower body, legs, and/or feet of the infant and that extends a distance from the second side 302 corresponding to the elevation distance the support element 312 is configured to elevate the lower body, legs, and/or feet. The elevation and operable perimeter surface for contacting an infant's lower body, legs, and/or feet is preferably sufficient to produce a bend in the hips and elevate the feet of the infant. The support element 312 may be configured to support the infant's legs at an elevated angle relative to the infant's hips. In some instances, the hips may also contact the support element 312 or otherwise be elevated.

[00123] The support element 312 may include various dimensions and cross-section shapes. As best shown in **FIG. 16**, the illustrated support element 312 includes a generally cylindrical shape having an arcuate cross-section extending from the second side 302. In one embodiment, the support element 312 includes a planar exterior facing surface, an arcuate interior facing surface, and comprises a general "D" shaped cross-section. In another embodiment, the support element 312 is arcuate around its entire or a majority of its perimeter. In other embodiments, the support element 312 comprises other dimensions and cross-section shapes. For example, the support element 312 may comprise geometric, non-geometric, or free form cross-section shapes. In some embodiments, the support element 312 includes inclined, declined, curved, planar, or undulating surfaces. In one embodiment, the top surface 313 comprises an edge formed by the convergence of two sides that form a peak along a length of the support element 312. In one configuration, the support element 312 is dimensioned and shaped as described above with respect to support element 212. In some embodiments, a support element may include but is not limited to a foam material, a cushion, an air pocket, or any material configured to support an infant's legs in an elevated angle relative to the infant's torso. In the illustrated embodiment, the support element 312 is configured to support legs at an elevated angle relative to the hips. The support element 312 comprises a generally cylindrical foam insert approximately 5 inches high configured to produce bend in hips and elevate feet of an infant. The support element 312 may further comprise a fabric case (not shown) surrounding the supportive material. The support element 312 may have a resistance to deformation configured to support the infant's legs in the elevated position according to the principles disclosed herein. In various embodiments, the support element 312 may include contours such as indentations to nest the legs. For example, the top surface, distal facing surface, or proximal facing surface of the support element 312 may include a first indentation to nest a first leg and a second indentation to nest a second leg. Thus, the surfaces within and/or adjacent to the indentations may rise above a back of a leg. In some embodiments, the surfaces within and/or adjacent to the indentations may contact sides of a leg or provide vertically extending obstructions to lateral leg movement. The indentations may be of a constant width or may tapper to a reduced width within indentation valleys. The indentations may have planar bases or may include rounded or arcuate laterally extending base surfaces. The support element 312 and/or the fabric case may also be resistant to liquid or biological materials. It will be appreciated that height of the support

element 312 or vertical distance the support element 312 extends as described herein is intended to be in reference to the top surface upon which the back or legs or feet are supported.

In support element 312 may be integral or couplable with respect to the second side 302. For example, the enclosure 300 may be configured to receive the support element 312 at a location proximate to the first portion 306 along the second side 302. The support element 312 may be positioned along the first portion 306 such that it elevates the lower body, legs, and/or feet and produces a bend in the hips of an infant enclosed in the enclosure 300. In the illustrated embodiment, as best shown in **FIG. 16**, a compartment 322 comprising a pocket is position on the second side 302 for receiving the support element 312. Thus, the support element 312 may comprise a material insert. The pocket may comprise an envelope enclosure configuration as shown or another configuration. The compartment 322 is accessible from the exterior side of the second side 302. In one embodiment, the second side 302 includes a compartment 322 accessible from its interior side or that is sewn, adhered, or otherwise sealed closed with the support element 312 enclosed therein. In some embodiments, the second side 302 is configured to removably couple with the support element 312 via snaps, straps, clips, Velcro or hook and loop, mating structures, or other coupling structures along the exterior or interior side of the second side 302.

between the exterior or the enclosure and the enclosure volume 305. In the illustrated embodiment, the enclosure 300 includes a coupling mechanism comprising one or more attachment members 318a, 318b for coupling the first side 304 and the second side 302 and thereby selectively open or close first and second apertures 319a, 319b. The selectively openable apertures are located along lateral peripheries of the first and second sides 304, 302. Attachment members 318a, 318b extend along the adjacent lateral peripheries for coupling the first and second sides 304, 302 to close or reveal the enclosed volume 305. As best shown in **FIGS. 14 & 16**, the attachment members 318a, 318b comprise zippers wherein adjacent portions of the first and second sides 304, 302 defining the apertures 319a, 319b include zipper halves. In other embodiments, adjacent portions of the first and second sides 304, 302 defining one or more apertures may include snaps, straps, clips, hook and loop, mating structures, or other coupling structures configured to interact to selectively reveal the enclosure volume 305.

[00126] In other embodiments, the first side 304 couples to the second side 302 via closure of a single aperture. For example, a selectively openable or closable aperture may extend down a right, left, or middle portion of the first or second sides 304, 302. In a further example, a selectively openable or closable aperture extends diagonally across the first or second sides 403, 302. Some embodiments of the enclosure 300 may include more than two selectively openable or closable apertures.

[00127] An infant may be placed within the enclosure 300, with the infant's hips adjacent to support element 312 and legs positioned on upper surface 313 thereof. A user may then operate coupling members 318a, 318b, partially sealing first side 304 to the top of second side 302, accommodating the infant and support element 312 within the enclosure volume 305. First side 304 may then be located above the infant, with compartment 322 positioned proximate to the infant's torso.

[00128] The illustrated apertures 319a, 319b extend through the first portion 306 and the second portion 308 to a bottom region or location corresponding to a region of the enclosure volume 305 configured to be at or beyond the feet of an enclosed infant. In other embodiments, one or more apertures may not be dimensioned to extend beyond a foot region of the enclosure volume 305. For example, an aperture may extend to an ankle or knee region of the enclosure volume 305. In some embodiments, the enclosure 300 may include multiple selectively openable or closable apertures wherein a length of a first aperture is less than a length of a second aperture.

[00129] With particular reference to FIG. 16, decoupling attachment members 318a, 318b allows the first side 304 to be pulled down and moved out of the way to reveal the enclosure volume 305. This configuration provides caregivers maximum visibility for proper positioning of an infant and ease of removal. In another embodiment, the first side 304 and second side 302 may be completely separated to reveal the enclosure volume 305 and may thereafter be coupled with attachment members as described herein.

[00130] Enclosure 300 further defines a neck opening 315 (FIG. 14) between the first and second sides 304, 302. The first side 304 includes a first portion 315a defining a first side of the neck opening 315 and the second side 302 includes a second portion 315b defining a second side of the neck opening 315. When the attachment members 318a, 318b are coupled to close the

apertures 319a, 319b, the first portion 315a and the second portion 315b define the neck opening to allow a neck of an infant to extend from the enclosure volume 305.

[00131] To better protect sensitive skin of an infant, all or a portion of one or more attachment members 318a, 318b may be covered interiorly. FIGS. 17A & 17B illustrate an embodiment of the enclosure 300 wherein a portion of the attachment member 318a is covered by a zipper garage 350 comprising a flap 351 configured to extend over the attachment member 318a along a portion thereof corresponding to the neck opening 315 and an adjacent region. In various embodiments, the flap 351 may include a reinforcement or biasing material configured to cover the attachment member 318a when coupled. In one embodiment, the flap 351 includes a magnet or magnetically attractive structure to attract to the attachment member 318a or a magnet or magnetically attractive structure adjacent to the attachment member 318a. In another example, the flap 351 may include an exteriorly facing attachment member such as a snap configured to mate with an adjacent interiorly facing snap to cover the attachment member 318a. While the zipper garage 350 is shown with respect to attachment member 318a, in some embodiments, a zipper garage is provided for attachment member 318b in addition to or instead of for attachment member 318a. In some embodiments, enclosure 300 does not include a zipper garage 350.

[00132] The enclosure 300 may include additional features. For example, in an embodiment, enclosure 300 may be configured to accommodate a pillow, gel pad or other type of support (not shown) beneath the head of an infant.

**FIGS. 18A-22** illustrate a sleep garment 500 and methods of aiding sleep of an infant 450 utilizing a sleep garment 500. The sleep garment 500 includes an enclosure 300 as described above with respect to **FIGS. 14-17B**. The sleep garment 500 may also include or associate with a sleep sack 400. The sleep sack 400 may comprise a sleep sack as described in U.S. Patent Application No. 15/336,519, filed October 27, 2016, titled Infant Calm/Sleep-Aid, SIDS Prevention Device, and Method of Use. The sleep sack 400 may comprise a body 402, which may be configured similar to body 102 and its various embodiments described herein.

[00134] In one embodiment, a method of aiding sleep of an infant 450 may include positioning an infant 450 with the enclosure volume 305 of the enclosure 300. In a further

embodiment, the method may include positioning the infant 450 in a sleep sack 400 before positioning the infant in the enclosure 300.

Positioning the infant in the enclosure 300 may include laying the enclosure 300 on a surface with the exterior side of the second side 302 down. With the attachment members 318a, 318b decoupled, the first side 304 may be moved or folded down to reveal the enclosure volume 305. For example, in the illustrated enclosure 300, attachment member 318a, 318b zippers may be unzipped all the way down and the first side 304 and weight element 332 may be moved out of the way (e.g., as shown in **FIG. 16**). The weight element 332 may be positioned in the compartment 320 prior to or after folding down the first side 304.

[00136] With the enclosure 300 open, the infant 450 may be positioned on the interior side of the second side 302 within the enclosure volume 305. **FIG. 18A** depicts a top view of the infant 450 positioned within the sleep sack 400 and further positioned on the interior side of the second side 302 within the enclosure volume. **FIG. 18B** depicts a side view of the same.

[00137] The support element 312 is preferably positioned in compartment 322 prior to positioning the infant within the enclosure. The infant 450 may be placed onto the interior side of the second side 302 with the lower body of the infant 450 up against the support element 312 and the lower legs, ankles, or feet of the infant extending over the top surface 313. In some examples, thighs may be over the top surface or the infant 450 may be placed with feet up against the support element 312. From the side view shown in **FIG. 18B**, the hips and feet of the infant 450 are elevated up onto the support element 312 and top surface 313 thereof. The buttocks or thighs of the infant 450 may contact a proximal surface 347 of the support element 312.

[00138] With reference to **FIG. 19**, the first side 304 may be pulled over the infant 450 with the weight element 332 positioned over the chest/abdomen region of the infant 450. The attachment members 318a, 318b may then be coupled, e.g., zipped up, to enclose the infant 450 within the enclosure volume 305 of the enclosure 300 in a manner similar to that shown in **FIG. 20**.

[00139] In embodiments wherein the sleep sack 400 includes one or more securing mechanisms 414, securing mechanism 414 may be extended out from the enclosure volume 305

through laterally positioned side openings 337 formed in the enclosure 300, as shown in **FIG. 21A**, for example. With reference to **FIG. 21B**, the enclosure 300 may also include a pocket 338 adjacent to opening 337 for tucking in the securing mechanism 414 when not in use.

[00140] It should be noted, that in some embodiments the enclosure 300 does not include side openings 337 or includes side openings 337 with attachment members (not shown) to selectively open and close the openings 337. In one embodiment, the enclosure 300 includes securing mechanisms similar to that described herein with respect to sleep sacks or bodies thereof for securing the enclosure 300 to a platform or bassinet. The securing mechanism may be in addition to or instead of securing mechanism 414. In one such embodiment, the enclosure 300 includes a pocket (not shown) for tucking the securing mechanism out of the way when not in use.

To secure the sleep garment 500 to a platform or other structure, such as a bassinet, [00141] mattress, chair, or pad, the securing mechanism 414 may be pulled through the opening 337 or from the pocket 338 (FIGS. 21A & 21B) for coupling to or with respect to the platform or other structure. With reference to FIG. 22, the enclosure may couple to a sleep platform 616 of a sleep device 600, which is a bassinet in the illustrated embodiment. For example, securing mechanism 414 may include clips or sleeves as described above with respect to securing mechanism 114. As shown, the securing mechanism 414 includes sleeves 415a, 415b for receiving clip arms 623a, 623b that are fixed relative to the sleep platform 616. In some embodiments, the attachment mechanism 414 or corresponding attachment mechanism to which attachment mechanism 414 couples may be configured to communicate with a control system to detect whether an attachment mechanism 414 is properly secured, and may alert a user or cease some operational function upon detecting that an attachment mechanism is not properly secured. By attaching the enclosure 300 to a sleep surface platform 616, the infant 450 accommodated within enclosure 300 may be prevented from rolling over or otherwise moving into an unsafe disposition. In various embodiments, attachment mechanism 414 and corresponding attachment mechanisms to which attachment mechanism 414 couples may correspond to attachment mechanisms described in U.S. Patent Application No. 15/336,519, filed October 27, 2016, titled Infant Calm/Sleep-Aid, SIDS Prevention Device, and Method of Use. In one embodiment, the sleep device comprises a sleep device or bassinet having a movable platform as described in U.S. Patent Application No.

15/336,519, filed October 27, 2016, titled Infant Calm/Sleep-Aid, SIDS Prevention Device, and Method of Use.

[00142] It is to be appreciated that embodiments of the sleep garment 500 may include fewer or additional features. For example, in one embodiment, the sleep garment 500 does not include a sleep sack 400. In some such embodiments, the sleep garment 500 may include another sack or swaddling device or may not include an enclosure to enclose the infant in addition to that of the enclosure 300. In some embodiments, the infant may be enclosed in the enclosure 300 without being enclosed in a sleep sack or swaddle. As described above, the sleep garment 500 or enclosure 300 may also be configured with fewer or additional accommodation mechanisms.

[00143] Embodiments of the sleep garment 500 may include modifications to the sleep sack 400, enclosure 300, or both. The modifications may include any of those described herein, including those described with respect to sleep garment 100, body 102, enclosure 200, or outer enclosure 120. For example, the support element 312 may be incorporated under the lower body, legs, or feet of the infant within the interior of the sleep sack 400 or a compartment thereof. The support element 312 may be positioned loosely or unattached with respect to the enclosure 300. The weight element 332 may be attached to or within a compartment of the sleep sack 400. The weight element 332 may be positioned at other locations to apply weight to other regions of the body of the infant.

In an embodiment, the enclosure 300 may be configured to receive a weight element 332 at a location to thereby apply pressure to the infant's upper body, lower body, or both upper and lower body simultaneously. In one embodiment, a sleep sack 400 or body 402 may include an accommodation mechanism, which may be in addition to or instead of one or both of accommodation mechanisms 314, 310. For example, a body 302 may include a weight element, support element, or both, which may be similar to weight element 332 and support element 312. Such elements may be coupled or couplable to the body 302, e.g., elements may be attachable to surfaces via attachment members such as snaps, hook and loop, straps, or the like or may be received within compartments such as a pocket. In some embodiments, one or more accommodation mechanisms may be loosely positioned within the enclosure volume 305 or

exterior thereto and located to elevate the lower body, legs, or feet or apply weight to the chest of an infant in a manner consistent to that described herein.

[00145] As noted above, body 102 described with respect to FIGS. 1-5, may be used to enclose an infant and subsequently be enclosed within the enclosure volume 305 of enclosure 300 (not shown). In one such embodiment, the weight element 332, rather than being received at location 335, may be received on body 102 at location 134 proximate to the second portion 112 at the first side 104 of the body 102 by connecting the weight element 332 to the second portion 112 by a connector which may include but is not limited to any of the following: a strap configured to attach to a clip, an elastic strap, a hook and loop attachment mechanism, a push snap attachment, a zipper mechanism, a magnetic attachment mechanism, or any similar mechanism.

[00146] In an embodiment, sleep garment 500 may be configured to accommodate a pillow, gel pad or other type of support (not shown) beneath the head of an infant.

In some embodiments, the enclosure 300 includes a neck opening adjustment mechanism operable to adjust the size of the neck opening 315. **FIGS. 23A & 23B** illustrate a neck opening adjustment mechanism 360 according to various embodiments. As shown in **FIG. 23A**, adjacent sides of the neck opening 315 include attachment members 360a, 360b, which in this embodiment comprise snaps. The attachment members 360a, 360b may be coupled to decrease the size of the neck opening 315, as exemplified in **FIG. 23B**. For infants with larger necks, attachment members 360a, 360b may be left decoupled to provide a larger neck opening 315. While the neck opening adjustment mechanism 360 is shown with respect to attachment members 360a, 360b comprising snaps, in some embodiments, attachment members 360a, 360b may comprise straps, clips, hook and loop, mating structures, or other coupling structures. Additionally, while the neck opening adjustment mechanism 360 is shown with respect to a single side of the neck opening 315, in various embodiments, the neck opening adjustment mechanism 360 may include adjustment features on a second side of the opening comprising attachment members.

[00148] In various embodiments, a method of aiding sleep with respect to an infant that prefers a side or stomach position, which is unsafe and known to increase incidence of SIDS, includes enclosing the infant within a sleep garment or enclosure as described herein to cause the infant feel as if they are in the fetal position, but while sleeping safely on the back. The method

may similarly be effective to aid sleep of infants that have difficulty sleeping on their back or when not laying on a caregiver's body. The method may also be effective to aid sleep of infants that experience limited sleep duration or those that sleep well in a rock in play, swing or bouncer, but not on their back.

[00149] This specification has been written with reference to various non-limiting and non-exhaustive embodiments. However, it will be recognized by persons having ordinary skill in the art that various substitutions, modifications, or combinations of any of the disclosed embodiments (or portions thereof) may be made within the scope of this specification. Thus, it is contemplated and understood that this specification supports additional embodiments not expressly set forth in this specification. Such embodiments may be obtained, for example, by combining, modifying, or re-organizing any of the disclosed steps, components, elements, features, aspects, characteristics, limitations, and the like, of the various non-limiting and non-exhaustive embodiments described in this specification.

[00150] Various elements described herein have been described as alternatives or alternative combinations, e.g., in a lists of selectable actives, ingredients, or compositions. It is to be appreciated that embodiments may include one, more, or all of any such elements. Thus, this description includes embodiments of all such elements independently and embodiments including such elements in all combinations.

[00151] The grammatical articles "one", "a", "an", and "the", as used in this specification, are intended to include "at least one" or "one or more", unless otherwise indicated. Thus, the articles are used in this specification to refer to one or more than one (i.e., to "at least one") of the grammatical objects of the article. By way of example, "a component" means one or more components, and thus, possibly, more than one component is contemplated and may be employed or used in an application of the described embodiments. Further, the use of a singular noun includes the plural, and the use of a plural noun includes the singular, unless the context of the usage requires otherwise. Additionally, the grammatical conjunctions "and" and "or" are used herein according to accepted usage. By way of example, "x and y" refers to "x" and "y". On the other hand, "x or y" refers to "x", "y", or both "x" and "y", whereas "either x or y" refers to exclusivity.

[00152] Any numerical range recited herein includes all values and ranges from the lower value to the upper value. For example, if a range is stated as 1 to 50, it is intended that values such as 2 to 40, 10 to 30, 1 to 3, or 2, 25, 39 and the like, are expressly enumerated in this specification. These are only examples of what is specifically intended, and all possible combinations of numerical values and ranges between and including the lowest value and the highest value enumerated are to be considered to be expressly stated in this application. Numbers modified by the term "approximately" are intended to include +/- 10% of the number modified.

[00153] The present disclosure may be embodied in other forms without departing from the spirit or essential attributes thereof and, accordingly, reference should be had to the following claims rather than the foregoing specification as indicating the scope of the invention. Further, the illustrations of arrangements described herein are intended to provide a general understanding of the various embodiments, and they are not intended to serve as a complete description. Many other arrangements will be apparent to those of skill in the art upon reviewing the above description. Other arrangements may be utilized and derived therefrom, such that logical substitutions and changes may be made without departing from the scope of this disclosure.

### **CLAIMS**

What is claimed is:

1. An infant sleep garment comprising:

an enclosure having a first side and a second side, the first side and the second side together defining an enclosure volume therebetween, wherein the enclosure comprises:

a first portion configured to accommodate at least a portion of a lower body of an infant within the enclosure volume when the infant enclosed therein; and

a second portion located in a superior position relative to the first portion and configured to accommodate at least a portion of an upper body of the infant within the enclosure volume when the infant enclosed therein:

a weight element coupled or couplable to the first side along the second portion at a location corresponding to an abdominal or chest area of the infant when the infant is enclosed within the enclosure volume;

a support element coupled or couplable to the second side along the first portion at a location corresponding to at least a portion of the lower body of the infant when the infant is enclosed within the enclosure volume, wherein the support element is configured to elevate legs and feet of the infant relative to the at least a portion of the upper body of the infant.

- 2. The infant sleep garment of claim 1, wherein the weight element weighs between 0.5 pounds and 2 pounds, and wherein the support element includes an arcuate cross-section that extends a distance into the enclosure volume at least 4 inches.
- 3. An infant sleep garment comprising:

an enclosure having a first side and a second side, the first side and the second side together defining an enclosure volume therebetween, wherein the enclosure comprises:

a first portion configured to accommodate at least a portion of a lower body of an infant within the enclosure volume when the infant is enclosed therein; and

a second portion located in a superior position relative to the first portion and configured to accommodate at least a portion of an upper body of the infant within the enclosure volume when the infant is enclosed therein;

wherein the first side is configured to couple with a weight element along the second portion and the second side is configured to couple with a support element along the first portion, wherein, when coupled with the first side, the weight element is positioned to apply weight to at least a portion of the upper body of the infant, and wherein, when coupled with the second side, the support element is positioned to support the at least a portion of the at least a portion of the lower body of the infant to elevate hips and feet of the infant relative to the at least a portion of the upper body of the infant.

- 4. The infant sleep garment of claim 3, wherein the first side is configured to couple with the weight element at a location configured to position the weight over a chest or abdominal area of the infant when the infant is enclosed in the enclosure volume to apply pressure to the same when the weight element is received therein.
- 5. The infant sleep garment of any one of claims 4 or 5, wherein the weight element weighs between 0.5 and 1.5 pounds.
- 6. The infant sleep garment of any one of claims 3-5, wherein the weight element weighs about 1 pound.
- 7. The infant sleep garment of any one of claim 3-6, wherein the first side includes a compartment configured to receive the weight element to thereby couple the weight at the first side.
- 8. The infant sleep garment of any one of claims 3-7, wherein, when coupled at the second side, the support element extends 4.5 to 5.5 inches into the enclosure volume.

9. The infant sleep garment of any one of claims 3-8, wherein the support element includes a cylindrical cross-section portion that when coupled at the second side extends into the enclosure volume.

- 10. The infant sleep garment of any one of claims 3-9, wherein, when coupled at the second side, an arcuate cross-section portion of the support element extends 4.5 to 5.5 inches into the enclosure volume.
- 11. The infant sleep garment of any one of claims 3-10, wherein the second side includes a compartment configured to receive the support element.
- 12. The infant sleep garment of claim 8, wherein the compartment configured to receive the support element is positioned at a location along the second side corresponding to at least thighs and feet of the infant to underlay the same when the infant is enclosed within the enclosure volume.
- 13. The infant sleep garment of claim 8, wherein the compartment configured to receive the support element is positioned at a location along the second side corresponding to at least hips of the infant to underlay the same when the infant is enclosed within the enclosure volume.
- 14. The infant sleep garment of any one of claims 3-13, wherein the first side and the second side are selectively couplable along their respective lateral peripheries extending between the first and second portions, and wherein adjacent lateral peripheries of the first and second sides include attachment members configured to couple the adjacent lateral peripheries.
- 15. The infant sleep garment of claim 14, wherein the attachment members comprise zipper halves that are matable with adjacent zipper to couple the lateral peripheries.
- 16. The infant sleep garment of any one of claims 3-15, wherein the first and second sides are configured to accommodate an infant sleep sack within the enclosure volume.
- 17. The infant sleep garment of claim 16, wherein the enclosure includes laterally positioned openings to accommodate passage of a sleep sack securing mechanism from the enclosure volume to an exterior of the enclosure for attachment to a moveable sleep platform to thereby indirectly fix the enclosure to movement of the sleep platform.

18. The infant sleep garment of claim 3, wherein the first side includes a compartment configured to receive the weight element to thereby couple the weight at the first side and the second side includes a compartment configured to receive the support element,

wherein the compartment configured to receive the weight element is positioned along the first side at a location corresponding to a chest or abdominal area of the infant when the infant is enclosed within the enclosure volume such that the weight element when received therein applies pressure to the same,

wherein the compartment configured to receive the support element is positioned along the second side at a location to underlay the lower body of the infant when the infant is enclosed within the enclosure volume, and

wherein, when received within the compartment, the support element extends a distance into the enclosure volume between 4.5 to 5.5 inches.

## 19. An infant sleep garment comprising:

an enclosure having a first side and a second side, the first side and the second side together defining an enclosure volume therebetween, wherein the enclosure comprises:

a first portion configured to accommodate at least a portion of a lower body of an infant within the enclosure volume when the infant is enclosed therein; and

a second portion located in a superior position relative to the first portion and configured to accommodate at least a portion of an upper body of the infant within the enclosure volume when the infant is enclosed therein; and

a weight element, a support element, or both;

wherein the weight element is coupled or couplable to the first side along the second portion at a location corresponding to an abdominal or chest area of the infant when the infant is enclosed within the enclosure volume,

wherein the support element is coupled or couplable to the second side along the first portion at a location corresponding to at least a portion of the lower body of the infant when the infant is enclosed within the enclosure volume, and

wherein the support element is configured to elevate hips and feet of the infant relative to the at least a portion of the upper body of the infant.

20. The infant sleep garment of claim 19, wherein the weight element weighs between 0.5 pounds and 1.5 pounds, and wherein the support element includes an arcuate cross-section that extends a distance into the enclosure volume at least 4 inches.

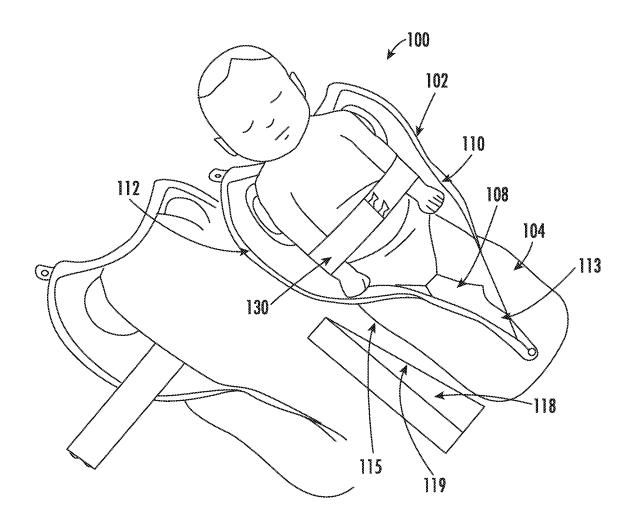
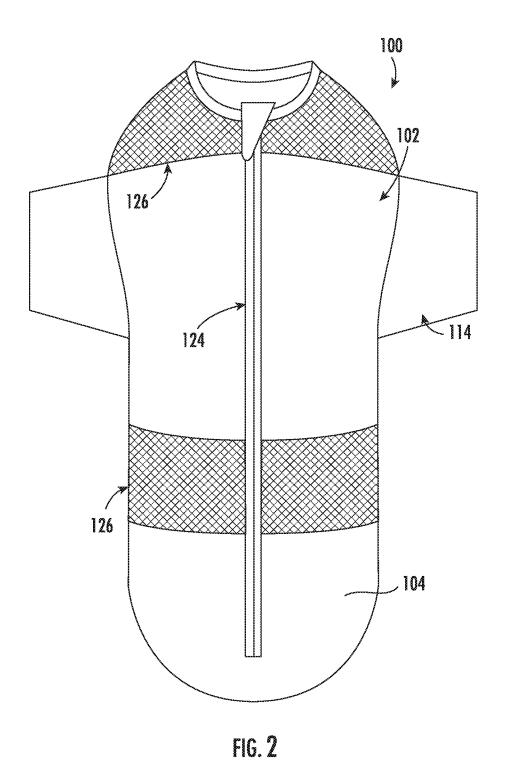
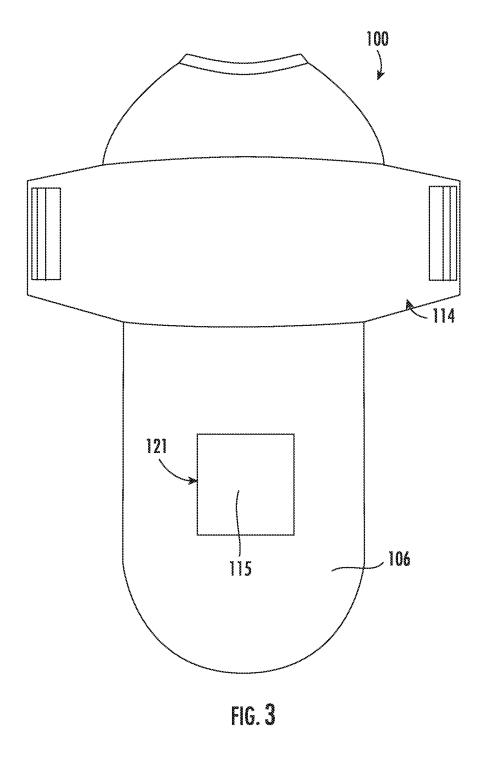
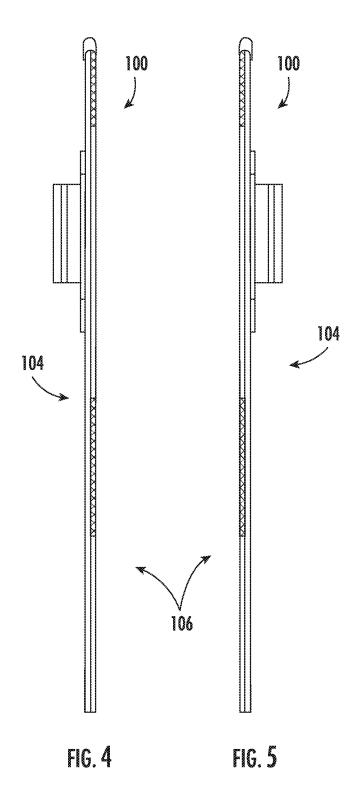


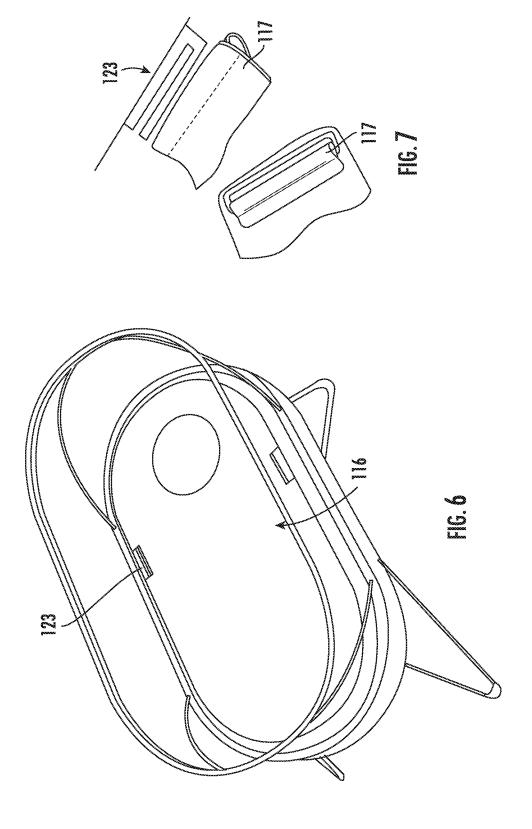
FIG. 1



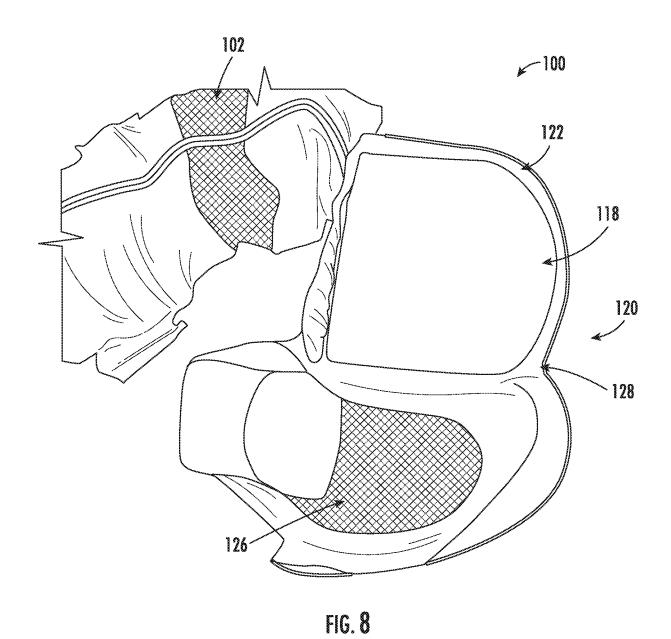


PCT/US2019/019010





SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

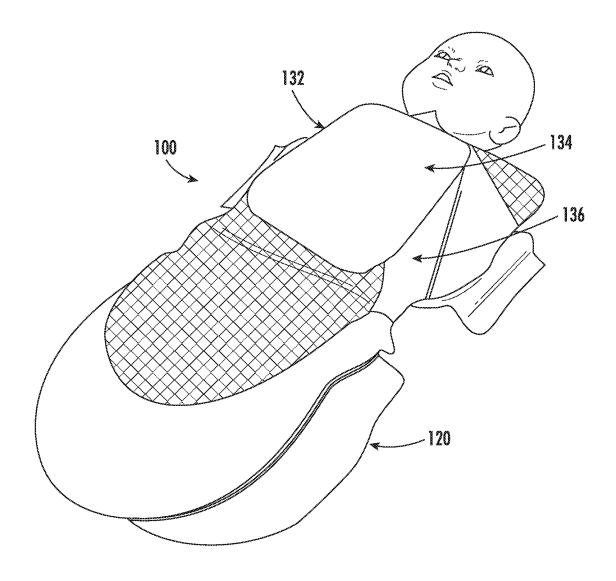
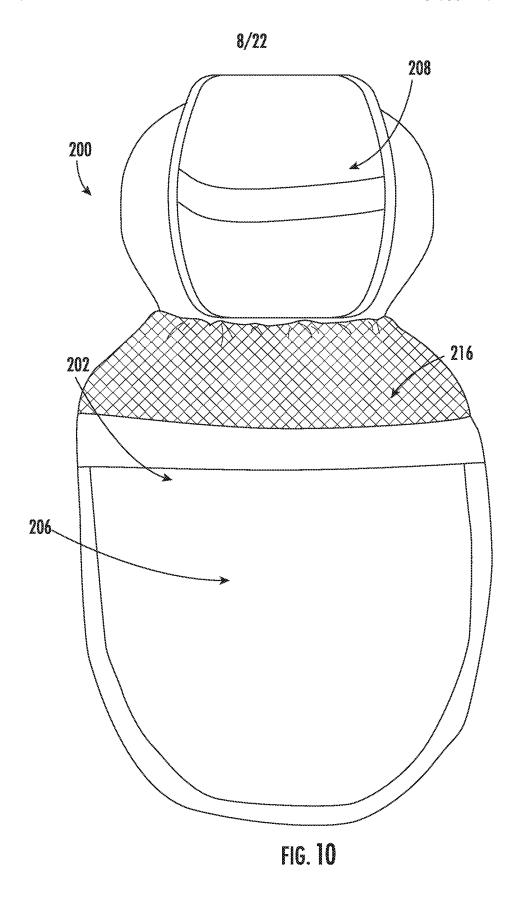
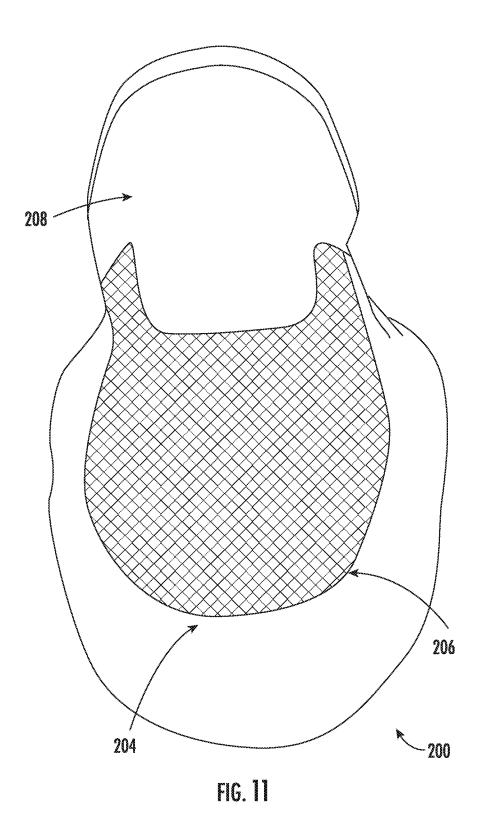


FIG. 9







SUBSTITUTE SHEET (RULE 26)

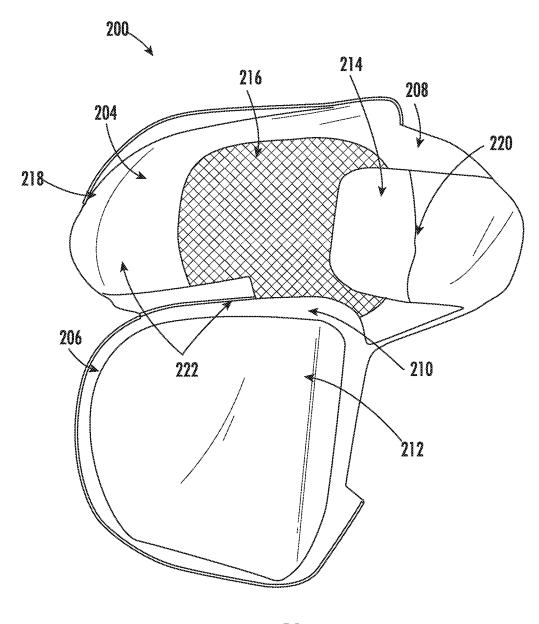


FIG. 12

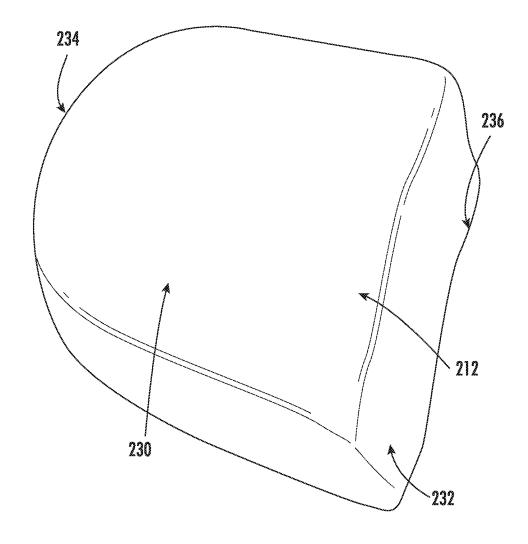


FIG. 13

12/22

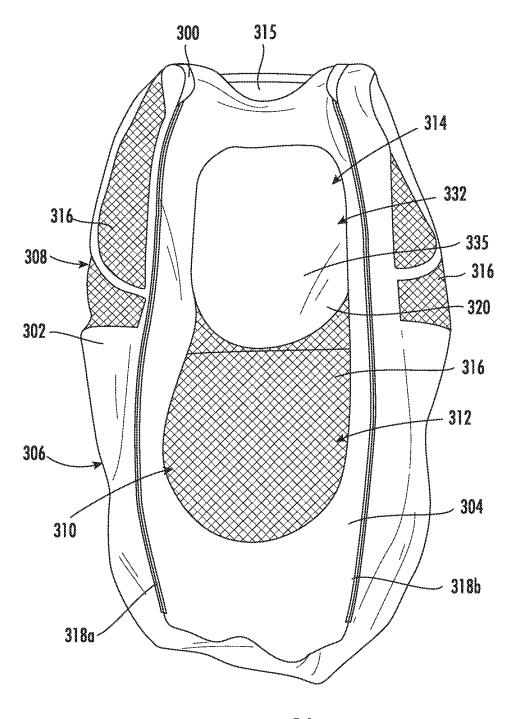
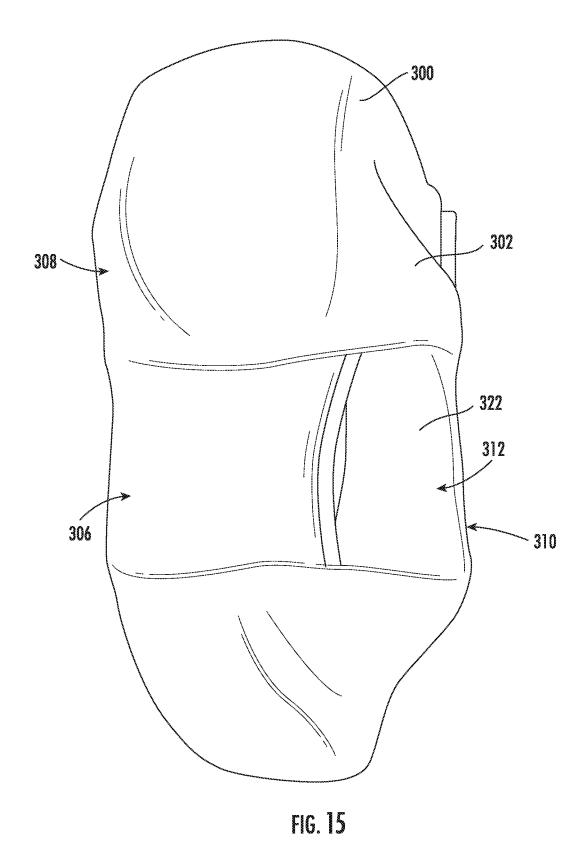
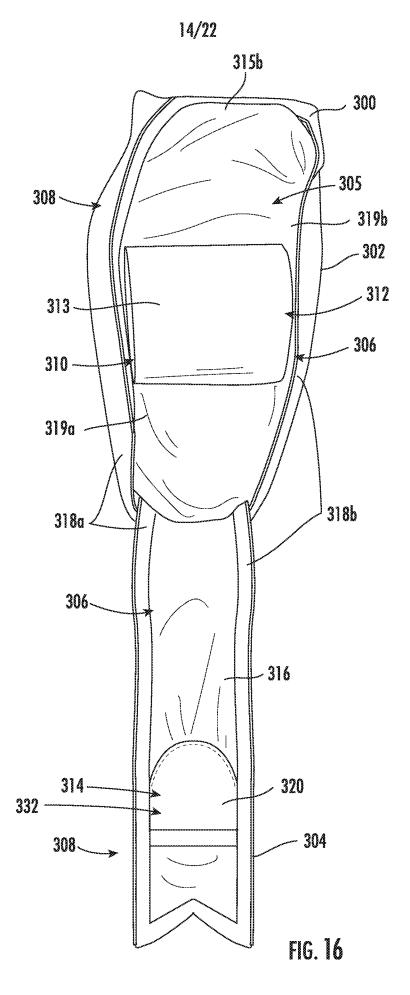
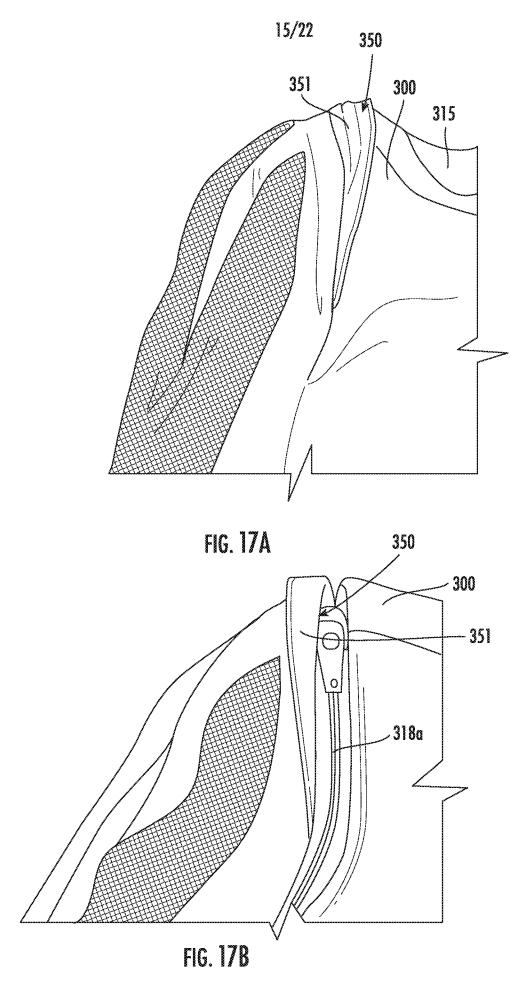


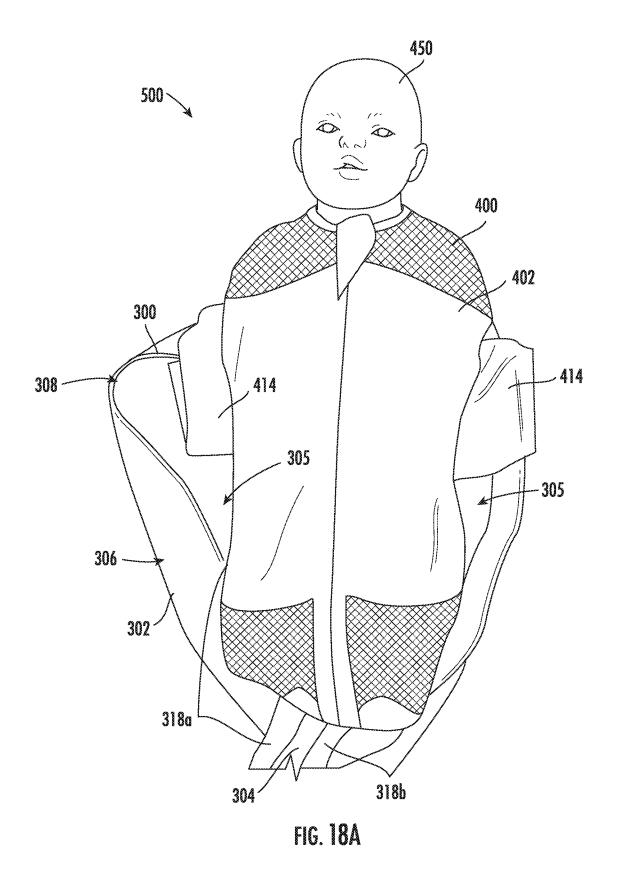
FIG. 14



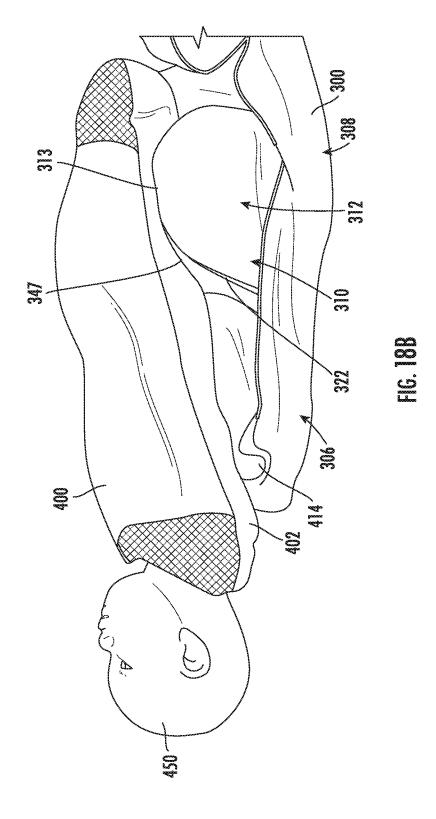


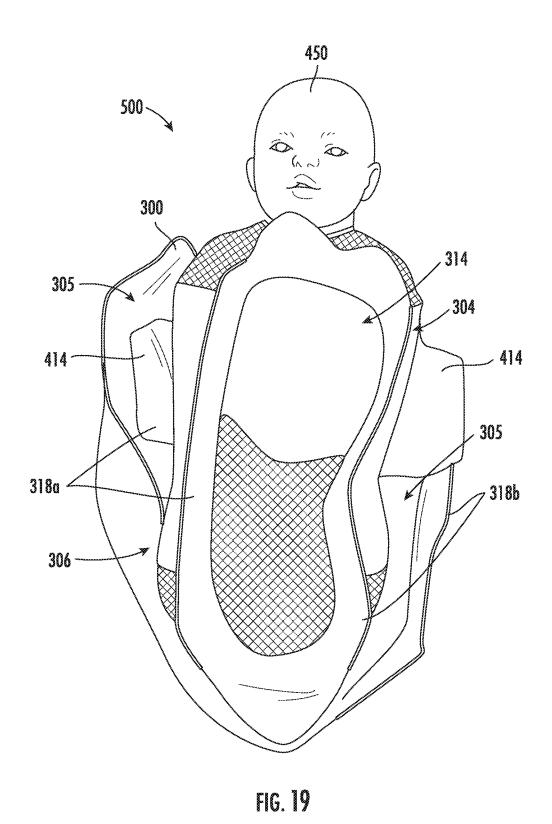
**SUBSTITUTE SHEET (RULE 26)** 





SUBSTITUTE SHEET (RULE 26)







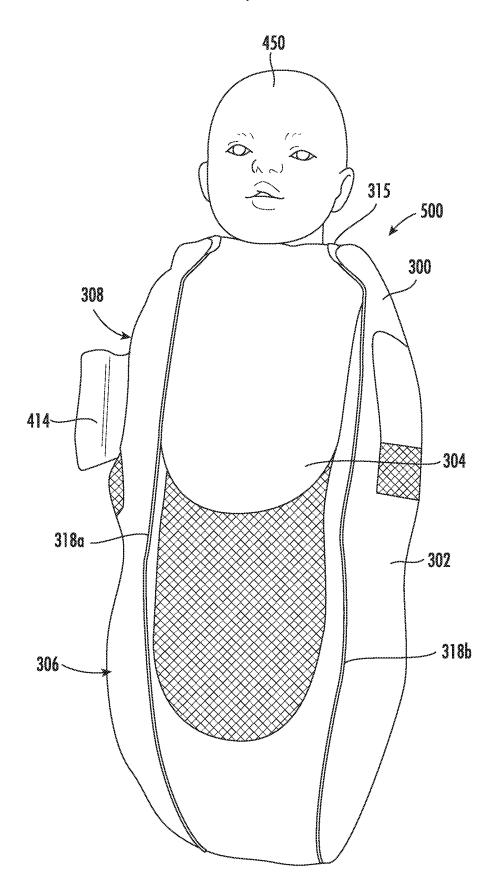
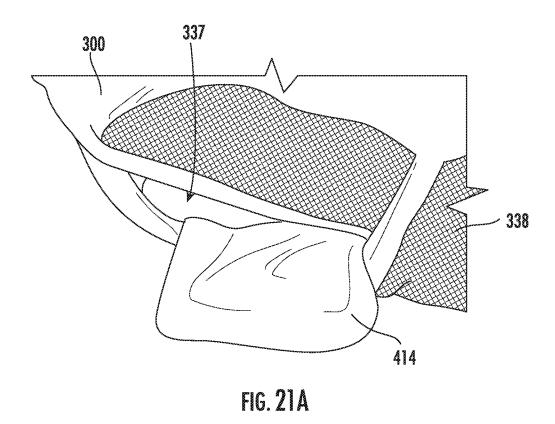
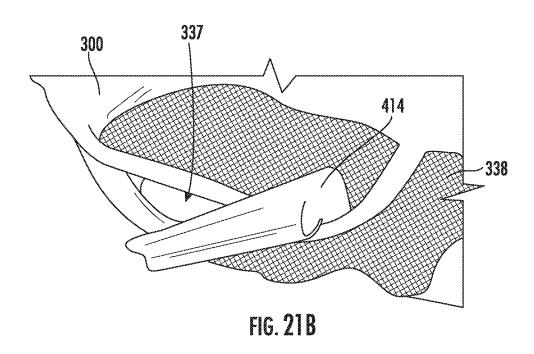


FIG. 20

## 20/22





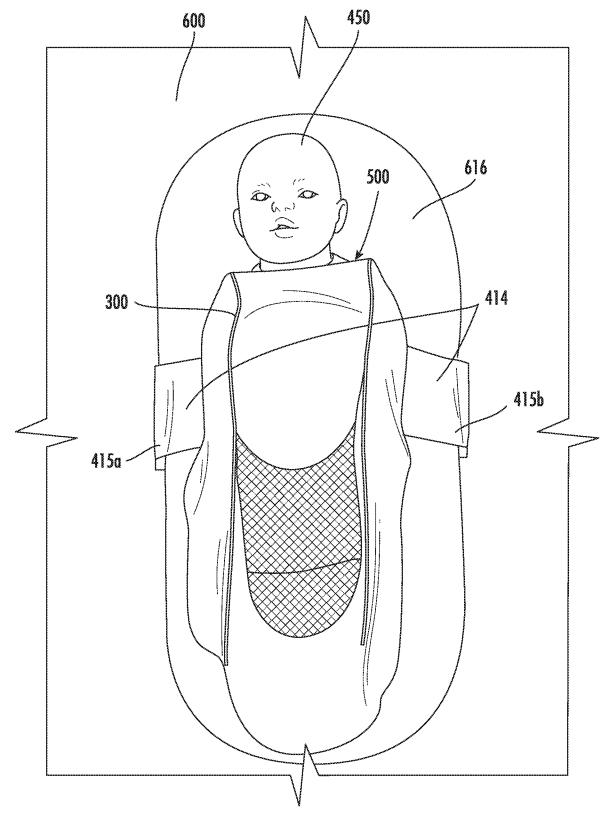
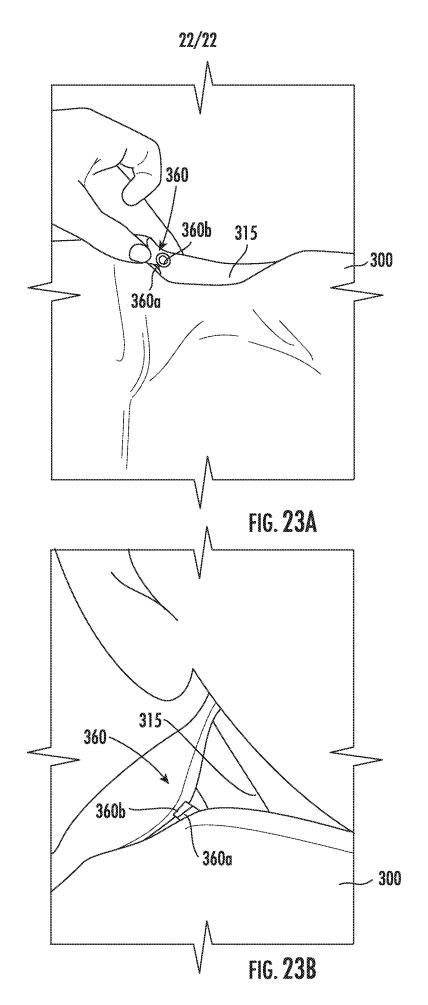


FIG. 22



SUBSTITUTE SHEET (RULE 26)

## INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/19010

IPC - A41B 1	ATION OF SUBJECT MATTER 3/06; A61F 5/37 (2019.01)		
CPC - A41B 1	3/06, 13/065; A41D 13/1272; A61F 5/	37	
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)  See Search History document			
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched See Search History document			
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) See Search History document			
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category* Cita	tion of document, with indication, where appr	opriate, of the relevant passages	Relevant to claim No.
X US 201	1/0277210 A1 (HARDESTY, C.) 17 November	2011; figure 12; paragraph [0067]	19
Y			1
A			2, 18
X US 201	6/0128392 A1 (KRAWCHUK, H.) 12 May 2016	; figure 1, 5; paragraph [0045]	3-4, 19
Y 			1, 5, 20
A			2, 18
Y US 2014/0068834 A1 (SKINNER, C.) 13 March 2014;		paragraph [0024]	5, 20 
A			2
A US 2006/0096031 A1 (FOSTER, M.) 11 May 2006; fig		ure 2	2
A US 2004/0070254 A1 (CONLON, J., et al.) 15 April 20		04; figure 3; paragraph [0034]	2
A US 2015/0026886 A1 (GANGAN, M., et al.) 29 Januar		y 2015; figure 3; paragraph [0027]	18
Further docum	ents are listed in the continuation of Box C.	See patent family annex.	
Special categories of cited documents:     document defining the general state of the art which is not considered to be of particular relevance		"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	
"E" earlier application or patent but published on or after the international filing date		"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive	
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other		step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be	
special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other means		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	
"P" document published prior to the international filing date but later than the priority date claimed		"&" document member of the same patent f	amily
Date of the actual completion of the international search 09 April 2019 (09.04.2019)		Date of mailing of the international search 24 MAY 2019	ch report
Name and mailing address of the ISA/		Authorized officer	
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450		Shane Thomas	
Facsimile No. 571-273-8300		PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774	

Form PCT/ISA/210 (second sheet) (January 2015)

## INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/19010

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)			
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:			
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:			
2. Claims Nos.:  because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:			
3. Claims Nos.: 6-17 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).			
Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)			
This International Searching Authority found multiple inventions in this international application, as follows:			
1. As all required 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 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.:			
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.			