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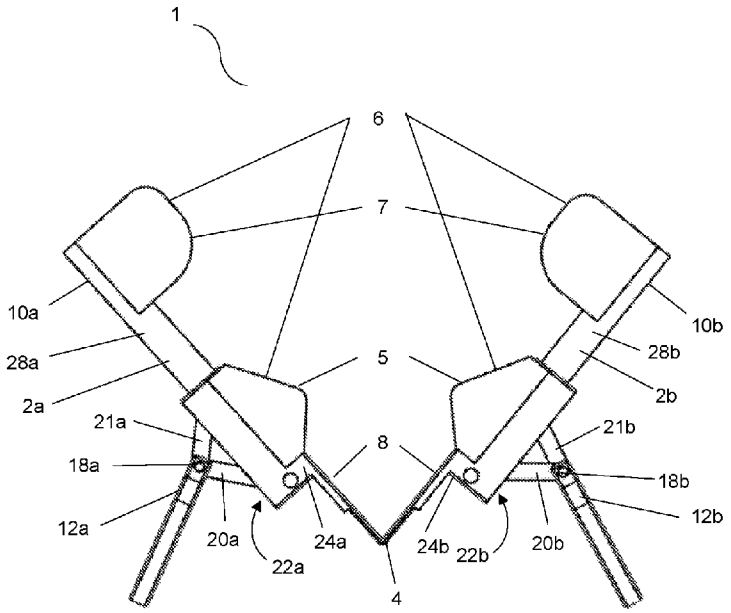

Fig. 1

(57) Abstract: The present disclosure describes a device for preventing and/or minimizing vaginal tears and a method of its use during vaginal delivery. The device comprises a pair of legs joined at one end of each leg at a join, each leg comprising a perineum-facing inner side and an outer side configured to locate a hand of a user, wherein a force provided by the hand of the user helps to urge the legs together.

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DEVICE FOR PREVENTING AND/OR MINIMISING VAGINAL TEARS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to Singapore patent application no. 10202300896X, filed on 31 March 2023, the contents of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure relates generally to gynecological instruments and devices, and methods of use of the same. In particular, the present disclosure relates to devices and the methods of use of the same, for preventing and/or minimizing vaginal tears during vaginal delivery.

BACKGROUND

[0003] The following discussion of the background to the invention is intended to facilitate an understanding of one or more inventions disclosed by the present specification only. It should be appreciated that the discussion is not an acknowledgement or admission that any of the material referred to was published, known or part of the common general knowledge of the person skilled in the art in any jurisdiction as at the priority date of one or more inventions disclosed by the present specification.

[0004] Vaginal delivery is the birth of a mammalian offspring through the vagina. It is the most common method of childbirth worldwide and is considered the preferred method of delivery as there is lower morbidity and mortality than other delivery methods. About 80% of annual births are via vaginal delivery. This is approximately 7.5 million births per year in Southeast Asia alone where the highest birth rates are recorded in Indonesia, Philippines, and Myanmar. Combined with India and China, these equal to an upwards of 33 million vaginal births per year in Asia.

[0005] Over 85% of women undergoing vaginal delivery experience perineal trauma such as spontaneous tears (Kettle, C., & Tohill, S. (2008). BMJ clinical evidence, 2008, 1401). This is often categorized into 4 types: (1) First-degree tears characterised by small tears that are skin-deep having injury to perineal skin only; (2) second-degree tears of skin and muscle such as the perineal skin and muscles but not the anal sphincter; (3) third degree

tears affecting the anal sphincter muscle; and (4) fourth-degree tears affecting both the anal sphincter complex i.e., the external and internal anal sphincter muscle and the anal epithelium along the anal canal. Sutures are required for second degree to fourth degree tears. Spontaneous tears that require suturing happen in about a third of women in US and UK (Kettle, C., & Tohill, S. (2008)). Asian women are 74% more likely to experience severe perineal laceration (third and fourth degree) as compared to non-Asians (Quist-Nelson, *et al.* (2017). The journal of maternal-fetal & neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians, 30(5), 525–528.).

[0006] The consequences of perineal trauma in the short term include bleeding, hematoma, blood loss and infection (Committee on Practice Bulletins-Obstetrics. ACOG Practice Bulletin No. 198: Obstet Gynecol. 2018 Sep;132(3):e87-e102) as well as delayed mother child bonding (Vieira *et al.* Eur J Obstet Gynecol Reprod Biol. 2018 Apr;223:18-25). The consequences of perineal trauma in the long term include urinary, anal incontinence such as faecal and flatal incontinence, pain and Dyspareunia (Rodaki, *et al.* (2022). Maedica, 17(2), 297–305; Ugwu et al. J Obstet Gynaecol Res. 2018 Jul;44(7):1252-1258; and Goh *et al.* Aust J Gen Pract. 2018 Jan-Feb;47(1-2):35-38). Obstetric Anal Sphincter Injuries (OASI) thus may result in pelvic floor dysfunction, faecal incontinence, urinary incontinence, flatus incontinence and/or fistulas. Additionally, the cost of repairing a 3rd or 4th degree vaginal tear may be in the range of about US$1835 – 3035 in Singapore.

[0007] Currently, the most common method of prevention of spontaneous vaginal tears during labour is an episiotomy cut for a controlled tear to occur in a single plane. This will require sutures and still has chances of a high grade tear. Patients as well as some doctors are opposed to episiotomies. Although the ideal angle of the episiotomy cut is 60 degrees away from the downward vertical plane, the positioning of the episiotomy scissors is also highly variable. This makes it harder to standardised the workflow. Episcissors-60 are adapted surgical scissors designed to guide mediolateral episiotomy at an optimal angle. However positioning the Episcissors-60 still has the same issue as it relies on the judgement of practitioners, resulting in significant variability. This makes it difficult to standardise workflow and harder for all practitioners to use. Further this method may not be available to midwives. Recovery from the stiches, while likely to be less painful and cause less damage than a tear between the perineum and the anus, may still be uncomfortable.

[0008] Less commonly used are warm compresses where a warm towel or hot pack is applied to the perineum. This increases blood flow and softens skin and is cheap and easy

to do. However, it is not widely used and while there is evidence that this reduces tears there is no optimal temperature or duration prescribed. This makes it difficult to standardise workflow and harder for all practitioners to use.

[0009] A multicentre randomized controlled trial has been reported where a perineal protection device was inserted to hook around the base of the perineum (T. Lavesson et al. European Journal of Obstetrics & Gynecology and Reproductive Biology, vol. 181, pp. 10–14, 2014). This is a low-cost solution that was demonstrated to reduce tearing, be safe for both the mother and baby, however, as the pads need to be inserted over the edge of the perineum it is hard to insert, prone to fall out and requires manual perineal protection. Further, it redirects pressure in just one direction, which is downwards.

[0010] Some skilled midwives and Gynaecologists are able to reduce tearing by positioning mothers during delivery and using their hands to support the perineum. This is more of an art than a skill and it is not taught or know by many. This makes it difficult to standardise workflow and harder for all practitioners to use. This method may be uncomfortable for mothers.

[0011] Un-proven and less common pre-labour antenatal methods exist such as Antenatal Massage, Pelvic Floor Exercises, or devices that attempt to stretch the perineum known as EPI-NO Childbirth Trainer. These aim to increase skin elasticity and reduce lacerations. These are to be conducted by the mothers rather than practitioners which may be hard to do, uncomfortable and there is currently no statistically significant evidence that any of these methods work.

[0012] There exists a need to reduce the incidence of moderate to severe perineal tears during vaginal deliveries and alleviate at least one of the aforementioned problems.

SUMMARY OF INVENTION

[0013] A device capable of preventing and/or minimizing vaginal tears during vaginal delivery is disclosed herein, including but not limited to a device that is capable to redirect the pressure upward away from the base of the perineum to prevent and/or minimize vaginal tears during vaginal delivery. A method of using the device is also disclosed herein.

[0014] According to an aspect of the present disclosure, there is provided a device for preventing and/or minimize vaginal tears during vaginal delivery comprising a pair of legs

hingedly joined at one end of each leg wherein the join urges the legs towards each, and at least one pad is located on an inner side of each leg.

[0015] According to another aspect of the present disclosure, there is provided a method for preventing and/or minimize vaginal tears during vaginal delivery comprising locating a pair of legs urged together at a join at one end at the base of the perineum when a baby's head is crowning during vaginal delivery, and pushing at least one pad located on the inner side of each leg onto a portion of perineum.

[0016] According to another aspect of the present disclosure, there is provided a device for preventing and/or minimizing vaginal tears during vaginal delivery, the device comprising a pair of legs joined at one end of each leg at a join, each leg comprising a perineum-facing inner side and an outer side configured to locate a hand of a user, and wherein a force provided by the hand of the user helps to urge the legs together.

[0017] In some configurations, the join is configured to urge the legs towards each other.

[0018] In some configurations, the join comprises a hinge.

[0019] In some configurations, each leg comprises a proximal portion adjacent the hinge and a distal portion, wherein the hinge is configured to urge the legs towards each other and the distal portions are configured to urge the legs to move up and out, further spreading out the tension on the sides of the vagina in use.

[0020] In some configurations, the hinge comprises one or more bends. A portion of the bend may be curved.

[0021] In some configurations, the pair of legs and join are integrally formed.

[0022] In some configurations, the device comprises a first wall and a second wall, wherein the perineum-facing inner side is provided on the first wall and the outer side is provided on the second wall, such that the first and second walls form the pair of legs and the join.

[0023] In some configurations, the first and second walls are spaced apart by a cavity. The cavity may comprise a channel extending from one side of the device to another side. The first and second walls may be spaced apart by a plurality of cavities separated by one or more intermediate walls.

[0024] In some configurations, each of the first and second walls comprises a first end region and a second end region, and wherein the first end regions are coupled together and the second end regions are coupled together, wherein the first end regions and the second end regions provide end regions of the pair of legs distal from the join.

[0025] In some configurations, the first wall and/or second wall comprises an elongate wall. The second wall may be longer than the first wall.

[0026] In some configurations, a cross-sectional shape of the first wall corresponds to a cross-sectional shape of the second wall. The device may comprise a C-, V- or U- shaped cross-section. In some configurations, a cross-sectional shape of the first wall is different from a cross-sectional shape of the second wall. The device may comprise a T- or Y-shaped cross-section.

[0027] In some configurations, the first and second walls are integrally formed. The first and second walls may be formed from the same material.

[0028] In some configurations, a portion of the device is compliant or comprises a compliant material. The compliant material may comprise a polymer. The polymer may comprise thermoplastic polyurethane (TPU) and silicone.

[0029] In some configurations, the device further comprises one or more of: a ring defining a finger through hole, a roughened surface finish, a recess and/or a projection provided on the outer side of the pair of legs; or one or more pads located on the inner side of each leg. The one or more pads may comprise an absorbent pad. The one or more pads may comprise high-density foam or silicone or any other material that has a high compressive strength.

[0030] In some configurations, a portion of the device is configured to be heated. The one or more pads may be heated.

[0031] According to another aspect of the present disclosure, there is provided a device for preventing and/or minimizing vaginal tears during vaginal delivery in a patient, the device comprising a first elongate wall configured to engage a perineum of the patient and a second elongate wall couplable to the first elongate wall, the second elongate wall configured to be engaged by a user, wherein in use, the first elongate wall supports a portion of the perineum, and a force applied to the second elongate wall by the user facilitates the support of the perineum by the first elongate wall.

[0032] In some configurations, wherein in use, the first elongate wall distributes pressure across the portion of the perineum.

[0033] In some configurations, the second elongate wall comprises a grip portion.

[0034] In some configurations, a portion of the first elongate wall is spaced apart from a portion of the second wall. The first elongate wall may be spaced apart from the second elongate wall by one or more cavities, the one or more cavities configured to decouple movement of the first elongate wall from the second elongate wall. The one or more cavities may comprise one or more channels extending from one side of the device to another.

[0035] In some configurations, a or the portion of the first elongate wall is spaced apart from a or the portion of the second elongate wall by a first distance, and the portion of the first elongate wall is moveable relative to the second elongate wall such that the moveable portion is capable of being spaced apart from the portion of the second elongate wall by a second distance, wherein the first distance is different from the second distance. The second distance may be less than the first distance.

[0036] In some configurations, the device comprises a pre-formed shape and the second elongate wall comprises two end regions, wherein a central portion of the second elongate wall extends away from the two end regions of the second elongate wall. The second elongate wall may comprise a Y-, C-, V- or U-shaped cross-section.

[0037] In some configurations, the first elongate wall comprises two end regions, wherein a central portion of the first elongate wall extends away from the two end regions of the first elongate wall. The first elongate wall may comprise a C-, V- or U-shaped cross-section. The first elongate wall and the second elongate wall together may provide the device with a Y-shaped cross-section.

[0038] In some configurations, the first and second elongate walls are coupled together at least at one of their two end regions and the coupled end region is configured to additionally support the perineum when in use. The coupled end region may form a partial loop.

[0039] According to another aspect of the present disclosure, there is provided a device for preventing and/or minimizing vaginal tears during vaginal delivery in a patient, the device comprising a first elongate wall configured to engage a perineum of the patient and a second elongate wall engageable by a user to actuate the first elongate wall towards the perineum

of the patient, wherein the first and second elongate walls are configured to be coupled together to form a continuous loop.

[0040] In some configurations, the first elongate wall comprises a compliant material. The compliant material may comprise a polymer, optionally the polymer comprises thermoplastic polyurethane (TPU) and silicone.

[0041] In some configurations, the device comprises a pre-form shape and each of the first and second elongate walls comprises two end regions, wherein the first and second elongate walls are coupled together at their two end regions.

[0042] In some configurations, a central portion of the second elongate wall extends away from the two end regions of the second elongate wall. The second elongate wall may comprise a Y-, C-, V- or U-shaped cross-section.

[0043] In some configurations, a central portion of the first elongate wall extends away from the two end regions of the first elongate wall. The first elongate wall may comprise a C-, V- or U-shaped cross-section. The first elongate wall and the second elongate wall may together provide the device with a Y-shaped cross-section.

[0044] In some configurations, the first and second elongate walls are integral with one another. The first and second elongate walls may be formed of the same material.

[0045] In some configurations, the device comprises a pre-formed shape, and wherein the device comprises a C-, V-, U-, T- or Y- cross-sectional shape.

[0046] Other aspects and features of the present invention will become apparent to those of ordinary skill in the art upon review of the following description of specific embodiments of the disclosure in conjunction with the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0047] In the figures, which illustrate, by way of non-limiting examples only, embodiments of the present disclosure,

[0048] Fig. 1 is a plan view of a first exemplary configuration of a device of the present disclosure that is capable of redirecting pressure upward away from the base of the perineum to prevent and/or minimize vaginal tears during vaginal delivery.

[0049] Fig. 2 is an isometric view of an exemplary configuration of a device of the present disclosure that is capable of redirecting pressure upward away from the base of the perineum to prevent and/or minimize vaginal tears during vaginal delivery.

[0050] Fig. 3 shows an exemplary configuration of a device of the present disclosure in use during vaginal delivery, that is capable of redirecting the pressure upward away from the from the base of the perineum to prevent and/or minimize vaginal tears during the vaginal delivery.

[0051] Figs. 4A to 4E are plan views of alternative embodiments of a device of the present disclosure with different shaped pads capable of redirecting the pressure upward away from the base of the perineum to prevent and/or minimize vaginal tears during vaginal delivery.

[0052] Fig. 5 shows the components of a leg of the device depicted in Fig. 1. Fig. 5A indicate the portion, by a broken lined circle, of the device of Fig. 1 where the leg components shown in Figs. 5(B) to (H) are from. Fig. 5B shows a ring with a finger through hole; Fig. 5C is a bottom isometric view of a proximal portion of the leg adjacent the hinge; Fig. 5D is a side isometric view of the proximal portion of the leg adjacent the hinge; Fig. 5E is a side isometric view of a first arm of a lever; Fig. 5F is a side isometric view of a second arm of the lever; Fig. 5G is bottom isometric view of a distal portion of the leg; and Fig. 5H is a side isometric view of the distal portion of the leg.

[0053] Fig. 6 provides a close-up bottom isometric view of a leg 2b of the device of Fig. 1

[0054] Fig. 7 provides an isometric sectional view of a leg 2b of the device of Fig. 1.

[0055] Fig. 8 provides a rear isometric view of a second exemplary configuration of a device of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery.

[0056] Fig. 9 provides a front isometric view of the device of Fig. 8.

[0057] Fig. 10 provides a planar view of the device of Fig. 8.

[0058] Fig. 11 provides an isometric view of the device of Fig. 8.

[0059] Fig. 12 provides a cross-sectional view of the device of Fig. 8.

[0060] Fig. 13 provides a rear isometric view of a third exemplary configuration of a device of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery.

[0061] Fig. 14 provides a front isometric view of the device of Fig. 13.

[0062] Fig. 15 provides a planar view of the device of Fig. 13.

[0063] Fig. 16 provides an isometric view of the device of Fig. 13.

[0064] Fig. 17 provides a rear isometric view of a fourth exemplary configuration of a device of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery.

[0065] Fig. 18 provides a front isometric view of the device of Fig. 17.

[0066] Fig. 19 provides a planar view of the device of Fig. 17.

[0067] Fig. 20 provides an isometric view of the device of Fig. 17.

[0068] Fig. 21 provides a rear isometric view of a fifth exemplary configuration of a device of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery.

[0069] Fig. 22 provides a front isometric view of the device of Fig. 21.

[0070] Fig. 23 provides a planar view of the device of Fig. 21.

[0071] Fig. 24 provides an isometric view of the device of Fig. 21.

[0072] Fig. 25 provides a rear isometric view of a sixth exemplary configuration of a device of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery.

[0073] Fig. 26 provides a front isometric view of the device of Fig. 25.

[0074] Fig. 27 provides a planar view of the device of Fig. 25.

[0075] Fig. 28 provides an isometric view of the device of Fig. 25.

[0076] Fig. 29 provides a rear isometric view of a seventh exemplary configuration of a device of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery.

[0077] Fig. 30 provides a front isometric view of the device of Fig. 29.

[0078] Fig. 31 provides a planar view of the device of Fig. 29.

[0079] Fig. 32 provides an isometric view of the device of Fig. 29.

[0080] Fig. 33 provides a rear isometric view of an eighth exemplary configuration of a device of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery.

[0081] Fig. 34 provides a front isometric view of the device of Fig. 33.

[0082] Fig. 35 provides a planar view of the device of Fig. 33.

[0083] Fig. 36 provides an isometric view of the device of Fig. 33.

[0084] Fig. 37 shows use of the device of Fig. 29 or Fig. 33 on a patient from a user's viewpoint.

[0085] Fig. 38 provides an perspective view of the device of Fig. 29 or Fig. 33 being used on a patient.

DETAILED DESCRIPTION

[0086] As used herein, the term "(s)" following a noun means the plural and/or singular form of that noun.

[0087] As used herein, the term "and/or" means "and" or "or", or where the context allows both.

[0088] Throughout this document, unless otherwise indicated to the contrary, the terms "comprising", "consisting of", "having" and the like, are to be construed as non-exhaustive, or in other words, as meaning "including, but not limited to".

[0089] Furthermore, throughout the document, unless the context requires otherwise, the word "include" or variations such as "includes" or "including" will be understood to imply

the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

[0090] It is intended that reference to any range of numbers disclosed herein (for example, 1 to 10) also incorporates reference to all rational numbers within that range (for example, 1, 1.1, 2, 3, 3.9, 4, 5, 6, 6.5, 7, 8, 9 and 10) and also any range of rational numbers within that range (for example, 2 to 8, 1.5 to 5.5 and 3.1 to 4.7) and, therefore, all sub-ranges of all ranges expressly disclosed herein are hereby expressly disclosed. These are only examples of what is specifically intended and all possible combinations of numerical values between the lowest value and the highest value enumerated are to be considered to be expressly stated in this application in a similar manner.

[0091] This disclosure may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this disclosure relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

[0092] Throughout the description, it is to be appreciated that the term 'preventing and/or minimizing vaginal tears during vaginal delivery' include stopping, reducing, minimizing tears of the perineum between the vagina and the anus during vaginal delivery.

[0093] As used herein, the term "patient" includes a human patient.

[0094] Unless defined otherwise, all other technical and scientific terms used herein have the same meaning as is commonly understood by a skilled person to which the subject matter herein belongs.

[0095] According to various embodiments there is a device 1 for preventing and/or minimizing vaginal tears during vaginal delivery comprising a pair of legs 2a, 2b hingedly joined at one end at join 4 wherein the join 4 urges the legs 2a and 2b towards each other. The device 1 further comprises at least one pad 6 located on an inner side 8 of each leg 2a, 2b. The at least one pad 6 is optional and may be absent in some examples such as examples provided in Figs. 8 to 36.

[0096] Referring to Figs. 1 to 3, in various embodiments a device 1 (also referred herein as an Ergonomic Pressure Redirection device 1) is depicted comprising a pair of legs 2a, 2b

joined at one end 4 wherein the join 4 urges the legs 2a, 2b towards each other, and comprising at least one pad 6 located on an inner side 8 of each leg 2a, 2b. When the baby's head 11 is pushing on the base of the perineum 3, the legs 2a, 2b of the device 1 when in use are urged together (i.e. towards each other) and upwards (which includes in an anterior direction, in a cephalad direction or in both an anterior and cephalad direction with respect to the patient) by a user's hand 9, with the user's (for example, a doctor's or midwives') hand 9 being located on an outer side 10 of the leg 2a, 2b (see Fig. 3) so that the legs are urged to hold or compress the base of the perineum. In some examples, the join 4 comprises a hinge 4 that is formed by folding a sheet of metal which may act somewhat like a compression spring so that when in use even when the baby's head is pushing on the base of the perineum it is supported or urged together and upwards by the hinge 4 that may act together with the force provided by the user e.g., the user's hand 9 located on an outer side 10 of the leg 2a, 2b (see Fig. 3). The force of the user's thumb and the hinge 4 helps to urge the legs 2a and 2b together and hold or compress the base of the perineum. The device 1 is easy to use requiring very little training or skill to hold the device 1 correctly. The at least one pad 6 located on an inner side of each leg 2a, 2b ensures that the baby's head 11 is protected during vaginal delivery. In various embodiments, two said pads 6 may be provided on each leg 2a, 2b, a lower pad 5 adjacent to the join 4 and an upper pad 7 distal to the join 4 are provided on each leg 2a, 2b, wherein the pair of lower pads 5 support the base of the perineum and the pair of upper pads 7 support another portion of the perineum (see Fig. 1 and Fig. 2). This would have the advantage that when in use during a vaginal delivery, most of the force on the perineum would be redirected to the gap between the lower pads 5 and the upper pads 7. While there may be risk of tearing still overall, the risk of tearing will be significantly reduced with the use of device 1. This may eliminate operator variability to use episiotomy as a method of controlled tearing in a single plane.

[0097] Referring to Fig. 4, alternative devices 1 are depicted each comprising a pair of legs 2a, 2b hingedly joined at one end at join 4 wherein the join 4 may urge the legs 2a, 2b towards each other. Each leg 2a, 2b comprises at least one pad 6 located on the inner side 8 of each leg 2a, 2b. In some examples, the join 4 comprises a hinge 4 that is formed of a bent wire and may act somewhat as a compression spring so that when in use even when the baby's head is pushing on the base of the perineum it is supported or urged together and upwards by the hinge 4 that may act together with the force provided by the user e.g., the user's hand 9 located on an outer side 10 of the leg 2a, 2b. In various embodiments, the at least one pad 6 may be formed in a range of different shapes for example oval and elongate

such as in Fig. 4A; J shaped such as in Fig. 4B; curved and elongate such as in Fig. 4C; rectangular such as in Fig. 4D; or boot shaped such as in Fig. 4E.

[0098] The device 1 comprises one or more grip portions 12, which in various embodiments comprises a lever 12 that is attached to each leg 2a and 2b. When in use the mechanically assisted compression force of the lever 12 provides greater compression force on the base of the perineum with less effort required by a user (e.g. practitioner) to push and position the legs 2a, 2b. In various embodiments each lever 12 comprises a ring 13 defining a finger through hole 14 at a distal end 16 of the lever 12 to allow the user to comfortably push, position and/or hold the device 1 in use. In various embodiments, the lever 12 is connected via a fulcrum 18 to each leg 2a, 2b by a set of arms 20 and 21, wherein first arm 20 in the pair of arms comprises a pair of first arms 20' and 20" (shown as references 20b' and 20b" in Fig. 6) that are pivotably connected at a pivotal connection 22 to a proximal portion 24 proximal the join 4, and the second arm 21 (shown as reference 21b in Fig. 6) in the pair of arms is connected to pivotably connected to knuckle recesses 27 of distal portion 28 of leg 2a, 2b. A part of the distal portion 28 is slidable within a channel 26 that is within a portion of the outer side 10 of each leg 2a, 2b adjacent to and extending away from the pivotable connection 22. This allows the set of arms 20 and 21 to be able to be pushed up and moved away from each other along the legs 2a, 2b to an extended position wherein the arms 20a', 20a", 21a, 20b', 20b" and 21b lie along the legs 2a, 2b respectively when they are fully extended compressing the legs 2a, 2b on the base of the perineum (see Fig. 3). Actuating the set of arms 20, 21 to an extended position also extends the length of the leg 2a, 2b as distal portion 28 slides away from proximal portion 24. In various embodiments, the proximal portion 24 comprises a catch 30 that is attachable to the arms 20', 20" to form the pivotal connection 22. The proximal portion 24 also comprises a stop 32 (Fig. 7) formed on an inner surface of a wall defining a portion of channel 26. The stop 32 limits the movement of the arms 20, 21 away from each other to the extended position, where the pair of first arms 20', 20" abuts against the stop 32 and is prevented from further movement to the extended position. The stop 32 may be provided on one wall or on two opposing walls that define a portion of the channel 26. The stop 32 may be configured to fix the arms 20, 21 in the extended position, which may allow the device 1 to provide continued compression on the base of the perineum even where the user needs to momentarily remove or reposition their hand 9.

[0099] Referring to Fig. 5, in various embodiments. components of the leg 2a, 2b and lever 12 are fitted together wherein a ring 13 defining a finger through hole 14 and having

two small protrusions 15a and 15b are provided at the distal end 16 of the lever 12. A pin can then be passed through a hole on the protrusion 15a, though a hole 20x in one of the pair of the first arm 20', 20'', through a hole 21x in the second arm 21, through a hole 20x of the other of the pair of the first arm 20', 20'' and through a hole on the protrusion 15b as indicated by x to form the fulcrum 18 of the lever 12 whereby the first arms 20', 20'' and the second arm 21 are located between the protrusions 15a and 15b. The proximal portion 24 of each leg 2a, 2b adjacent the join 4 comprises an L shaped ledge 19 for attachment to the join 4 and a hollow portion comprising the channel 26. A hole 20t in each of the first arms 20', 20'' allows a pin to extend through, where the pin is connectable to the catch 30 to form pivotal connection 22. When connected, the catch 30 is located between ends of the pair of first arms 20', 20''. A hole 21y of second arm 21 allows a pin to extend through for a pivotal connection with knuckle recess 27 of distal portion 28. The distal end of proximal portion 24 comprises a pair of indents 31 engageable with a retaining pin 33 that retains a part of the distal portion 28 within channel 26 (as shown in Fig. 7). An end of the knuckle portion 29a, 29b of the distal portion 28 may abut against a stop in the proximal portion 24 to limit its movement within the channel 26. The end of the knuckle portion 29a, 29b comprises a rounded end but other profiles of said end are envisaged. Both the proximal portion 24 of each leg 2a, 2b and the distal portion 28 of each leg 2a, 2b have a recess 23 and 25 for attachment of the pads 5 and 7 to the inner side 8 of each leg 2a, 2b respectively.

[00100] In various embodiments the proximal portion 24 of each leg 2 are urged together by the join 4. The join 4 urges the legs 2a, 2b to move towards each other whilst the distal potion 28 of the legs 2a, 2b urges the legs 2a, 2b to move up and out (i.e. extending the length of each leg 2a, 2b), further spreading out the tension on the sides of the vagina.

[00101] The device 1 is easy to use requiring very little training or skill to hold the device 1 correctly. In use the device 1 has the advantage of guarding the weakest point by directing the force of the baby's head upwards and inwards by pinching the base of the perineum reducing or minimizing tears between the perineal and the anus without obstructing the delivery passage. The baby's head is exerting pressure around the entire circumference of the delivery passage. This is increased by the force of the mother pushing.

[00102] The device 1 lowers rates of tearing between the perineal and the anus which results in less physical and emotional trauma and less medical costs.

[00103] In various embodiments the one or more pads 6 may be formed of high-density foam or silicone or any other material that has a high compressive strength that it is able to

continually provide pressure on the base of the perineum without causing unwanted pressure on the baby's head when in use. In some examples, the one or more pads 6 comprises a thermoplastic, for example thermoplastic polyurethane (TPU). In some examples, the one or more pads 6 comprises a biocompatible material.

[00104] In various embodiments the one or more pad 6 may be heated. This will have the multiple advantages of supporting the base of the perineum, increasing blood flow and softening the skin to reduce tearing between the perineal and the anus.

[00105] According to various embodiments and referencing to Fig. 3, there is a method for preventing and/or minimizing vaginal tears during vaginal delivery comprising locating a device 1 comprising a pair of legs 2a and 2b urged together by a join 4 at one end at the base of the perineum 3 when a baby's head 11 is crowning during vaginal delivery pushing at least one pad 6 on the inner side 8 of each leg 2a, 2b onto a portion of perineum.

[00106] In various embodiments the method may be used with any embodiments of the device described herein.

[00107] The method is easy to use requiring very little training or skill to hold the device 1 and carry out the method correctly. The method has the advantage of guarding the weakest point by directing the force of the baby's head upwards and inwards by pinching the base of the perineum reducing or minimizing tears between the perineal and the anus without obstructing the delivery passage. The baby's head is exerting pressure around the entire circumference of the delivery passage. This is increased by the force of the mother pushing.

[00108] The method lowers rates of tearing between the perineal and the anus which results in less physical and emotional trauma and less medical costs.

[00109] Examples

[00110] [Table 1]: Comparison with the prior art methods.

Qualities	**Antenatal Massage**	**EPI-NO Device**	**Episiotomy**	**Warm Compress**	**MPP**	***Current description***
Ease of use	✓	×	×	✓	×	✓
Reduces rates of tearing	✓	✓	✓	✓	✓	✓
Affordable	×	×	✓	✓	✓	✓
Standardize workflow	×	×	×	×	×	✓
Recommended by doctors	✓	×	×	×	✓	✓
Comfortable for mother	×	×	×	×	✓	✓
Comfortable for user	×	×	×	✓	×	✓

[00111] Figs. 8 to 36 provide exemplary devices of the present disclosure. Unless described as being different below, the features, functionality, alternatives, and uses of the device of Figs. 8 to 36 are as described for device 1 of Figs. 1 to 7, or any of the other described devices. Like reference numbers indicate like parts with the addition of 100 for each exemplary configuration.

[00112] Figs. 8 to 12 show an example of a device 101 of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery. Device 101 comprises a pair of legs 102 which comprises a first leg 102a and a second leg 102b. The legs 102a, 102b are joined at one end of each leg 102a, 102b at a join 104. Each leg 102a, 102b comprises an inner side 108 that faces the perineum when the device 101 is in use, and an outer side 110 that is configured to locate a hand of a user when the device 101 is in use. Accordingly, the inner side 108 of each of the legs 102a, 102b may be herein referred as perineum-facing inner side 108 and outer side 110 of each of the legs 102a, 102b may be

herein referred as a user-facing outer side 110. The legs 102a, 102b may have the same or different lengths.

[00113] The join 104 comprises a hinge 104 in the form of a bend 104. In comparison with the hinge 4 of device 1, the bend 104 comprises multiple axes of rotation. Therefore, a "hinge" as described herein may comprise a single or multiple axes of rotation and "hingedly" as described herein may refer to rotation about single or multiple axes. The hinge 104 may comprise one or more bends. A portion of the bend 104 is curved. The bend 104 may be radiused with a continuous curvature. In some examples, the bend 104 may have portions with different radii of curvature. In some examples, the bend 104 may have one or more non-curved portions. The bend 104 is positioned between the legs 102a, 102b at a substantially central portion of device 101. In some examples, the bend 104 may be closer to the end 128a', 128b' of one of the legs 102a, 102b relative to the end 128a', 128b' of the other leg 102a, 102b. The bend 104 may be configured to urge the legs 102a, 102b towards each other when in use. The device 101 may be pre-formed with the bend 104. In some examples, the bend 104 or a portion thereof, is resilient or comprises a resilient material, and is configured to urge the legs 102a, 102b towards each other when a force is applied to move the legs 102a, 102b apart. The bend 104 may therefore act like a spring. The bend 104 may resist a force separating the legs 102a, 102b. A force (e.g. by a user's hand) applied to the outer sides 110 of the legs 102a, 102b may additionally or alternatively urge the legs 102a, 102b towards each other. A force applied to the outer sides 110 may therefore facilitate the resistance of a resilient bend 104 against any force attempting to separate the legs 102a, 102b. In some examples, the bend 104 or a portion thereof, is compliant or comprises a compliant material. A compliant material can deform under an applied load without breaking or yielding, and can return to its original shape once the load is removed. The bend 104 comprises an inner side 104a that faces the perineum when the device 101 is in use, and an outer side 104b that faces the user and may locate the hand of the user when the device 101 is in use. Accordingly, the inner side 104a of the bend 104 (and accordingly the join 104) may be herein referred as perineum-facing inner side 104a and outer side 104b of the bend 104 (and accordingly the join 4) may be herein referred as a user-facing outer side 104b.

[00114] The inner side 104a of the bend 104 is provided on a portion of a first wall 140 (Figs. 10 and 11) of device 101 and the inner sides 108 of legs 102a, 102b are provided on another portion of the first wall 140. One or more of the inner sides 104a, 108 may have a surface (e.g. a roughened surface or surface with ridges) configured to increase friction between the first wall 140 and the perineum. This is to improve grip of the device 101 on the

perineum. The outer side 104b of bend 104 is provided on a portion of a second wall 150 (Figs. 10 and 11) of device 101 and the outer sides 108 of legs 102a, 102b are provided on another portion of the second wall 150. The first wall 140 therefore forms a portion of the first leg 102a, a portion of the bend 104 and a portion of the second leg 102b. The second wall 150 therefore forms a portion of the first leg 102a, a portion of the bend 104 and a portion of the second leg 102b. The first wall 140 and/or second wall 150 are elongate walls. As used herein, the term "elongate" refers to a portion where one dimension is greater than another dimension, for example the length is greater than the width of that portion. In device 101, the legs 102a, 102b are integral with the bend 104. The legs 102a, 102b and bend 104 may be integrally formed, for example integrally moulded. Device 101 is a unitary device with the first wall 140 and second wall 150 integrally formed. In some examples, the legs 102a, 102b and bend 104 may be separate components that are couplable with one another.

[00115] The first wall 140 is coupled to the second wall 150 by one or more intermediate walls 145. The intermediate wall 145 may be formed of the same material as one or both of the first wall 140 and second wall 150. The intermediate wall 145 may be incompressible or compressible. The intermediate wall 145 may be both compressible and elastic (i.e. capable of stretch). The one or more intermediate walls 245 may be compressible to varying degrees depending on the application. The intermediate wall 145 may be capable of returning to its original shape and size after compression, such that it acts like a cushion between first wall 140 and second wall 150. In some examples, a portion of the first wall 140 is spaced apart by the intermediate wall 145 from a portion of the second wall 150 by a first distance, and the portion of the first wall 140 is moveable relative to the second wall 150 due the compressibility and/or elasticity of the intermediate wall 145, such that the moveable portion is capable of being spaced apart from the portion of the second wall 150 by a second distance, wherein the first distance is different from the second distance. The second distance may be less than the first distance. The one or more intermediate walls 245 may comprise a rigid material. In some examples, the first wall 140, second wall 150 and one or more intermediate walls 145 are integral such that the device 101 is continuous between one or more of the perineum-facing inner sides 108, 104a and one or more of the user-facing outer sides 110, 104b. In such examples, there may not be a physical separation of the first wall 140 and the second wall 150, and the first wall 140 may be a portion of the device 101 that is configured to locate proximate to a patient when the device 101 is in use, and the second wall 150 may be a portion of the device 101 that is configured to locate distal from the patient when the device 101 is in use. Each of the first wall 140 and second wall 150 comprise a first end region and a second end region, where the first end regions are coupled

together and the second end regions are coupled together. The first end regions and the second end regions may be coupled together by the one or more intermediate walls 145. The end regions of the first and second walls 140, 150 provide the end regions of the pair of legs 102a, 102b distal from the join 104, i.e. end regions of the distal portions 128a, 128b. The ends 128a', 128b' of these end regions have a rounded profile (e.g. forming a partial loop) but other profiles such as an angular profile, are envisaged. A rounded profile minimizes any injury to the patient's perineum when the device 101 is in use.

[00116] The device 101 comprises a cavity 160 that separates the first wall 140 and second wall 150. In some examples, the device 101 comprises a plurality of cavities. As shown in Figs. 8 to 12, device 101 comprises a cavity 160 in the form of a channel 160 that separates the first wall 140 and second wall 150. The channel 160 extends through the device 101 from one side to another. The channel 160 also extends from the first leg 102a through bend 104 to the second leg 102b. Various cross-sectional shapes of the channel 160 are envisaged and the channel 160 may have a bent elongate shape (e.g. its length greater than its width), for example a bent rounded rectangle, bent stadium, etc. The one or more cavities 160 is configured to increase the flexibility of a portion of the device 101, for example bend 104 which facilitates movement of the legs 102a, 102b towards and away from one another.

[00117] The device 101 has a pre-formed shape where a central portion of the device 101 extends distally away from a front of the device 101 (i.e. the portion that faces the patient in use). A pre-formed shape is a predetermined shape at rest before any deformation force has been applied. In particular, the device 101 is pre-formed with the bend 104 extending the central portion of the device 101 away from the front of the device 101, such that in use, the distal free ends of the legs 102a, 102b are configured to contact the patient before the inner side 104a contacts the patient.

[00118] The device 101 comprises a grip portion 112 in the form of one or more projections 112 extending from the outer sides 110 of the legs 102a, 102b. The projections 112 are configured to engage a user's digits to allow the user to appropriately grasp and handle the device 101 and actuate the legs 102a, 102b towards each other. The projections 112 comprises a first projection 112', a second projection 112" and a third projection 112"'. Any number of projections 112, for example 1, 2 and 4 are envisaged and the device 101 is not limited to the three projections 112 as shown in Figs. 8 to 12. The one or more projections 112 extend substantially normal to the outer sides 110 of the legs 102a, 102b. First projection 112' and second projection 112" are provided on first leg 102a and the third projection 112"'

is provided on the second leg 102b. However, it will be appreciated that in some examples, the second leg 102b may comprise the same number or have more projections 112 than the first leg 102a. One or more of the projections 112 comprise a recess 114 to allow a user's digit to extend into. The recess 114 may comprise a channel 114' as provided to second projection 112" shown in Fig. 12 which shows a planar cross-section of the device 101. The channel 114' allows a user's digit to extend through the projection 112". The first and third projections 112', 112"' comprise an opening at one end that leads to recess 114 and a blind end at the other end. Projections with blind ends are optional and in some examples, the projections 112 all comprise a channel 114'. In some embodiments, projections 112 are optional and other forms of grip portions 112 are envisaged, some of which are disclosed herein. The projections 112 are integrally formed with the legs 102a, 102b. In some examples, the projections 112 are separate from the legs 102a, 102b and are attachable to the legs 102a, 102b.

[00119] Figs. 13 to 16 show an example of a device 201 of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery. Unless described as being different below, the features, functionality, alternatives and uses of the device 201 are as described for device 1, 101 or any of the other devices described herein.

[00120] Unlike device 101, device 201 includes a plurality of cavities 260 located between and separate the first wall 240 and second wall 250. The cavities 260 are in the form of channels 260 separating the first wall 240 and second wall 250. The channels 260 extend through the device 201 from one side to another. In some examples, one or more cavities 260 comprise recesses that do not extend through the device 201. The channels 260 are arranged from the distal portion 228a of the first leg 202a to the distal portion 228b of the second leg 202b. One or more of the channels 260 has an elongate shape but other shapes are envisaged. The one or more channels 260 may have angular corners unlike the channel 160 in device 101, where the channel 160 has rounded corners which form a rounded end. The cavities or channels 260 are separated by intermediate walls 245 that couple the first wall 240 and the second wall 250 together. The intermediate walls 245 space the first wall 240 and the second wall 250 apart. One or more of the intermediate walls 245 may be incompressible or compressible. The one or more intermediate walls 245 may be both compressible and elastic (i.e. capable of stretch). The one or more intermediate walls 245 may be compressible to varying degrees depending on the application. The one or more intermediate walls 245 may comprise a rigid material.

[00121] The projections 212 are positioned proximate to and aligned with the intermediate walls 245. The projections 212 may however be misaligned with the intermediate walls 245 and placed at a different location on the second wall 250. In examples where one or more intermediate walls 245 is incompressible or minimally compressible, positioning the projections 212 proximate to and aligned with the intermediate walls 245 provide a transmittal of a force applied by a user on the outer side 210 of the legs 202a, 202b at the location of the projections 212, from the second wall 250 to the first wall 240 onto the base of the perineum when the device 201 is in use. This force accordingly provides support to the perineum when the device 201 is in use.

[00122] Figs. 17 to 20 show an example of a device 301 of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery. Unless described as being different below, the features, functionality, alternatives and uses of the device 301 are as described for device 1, 101, 201 or any of the other devices described herein.

[00123] The device 301 comprises a plurality of cavities 360 in the form of channels 360 separating the first wall 340 and second wall 350. The channels 360 extend through the device 301 from one side to another. The channels 360 are arranged from the distal portion 328a of the first leg 302a to the distal portion 328b of the second leg 302b. One or more of the channels 360 has an elongate shape but other shapes are envisaged. Similar to device 101, one of the channels 360 is positioned at a central portion of the device 301 and extends from the first leg 302a through bend 304 to the second leg 302b. Similar as well to device 101, the one or more channels 360 have rounded corners which form rounded ends.

[00124] Figs. 21 to 24 show an example of a device 401 of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery. Unless described as being different below, the features, functionality, alternatives and uses of the device 401 are as described for device 1, 101, 201, 301 or any of the other devices described herein.

[00125] The device 401 comprises a single cavity 460 in the form of a single channel 460 separating the first wall 340 and second wall 350. The channel 460 extends through the device 401 from one side to another. The channel 460 also extends from an end 428a' of the first leg 402a to another end 428b' of the second leg 402b. The thickness of the first wall 440, second wall 450 and walls at the ends 428a', 428b' may be substantially the same. In some examples, these wall thickness may vary, for example, the walls at the ends 328a', 328b' of the device 301 have a greater wall thickness than the first wall 340 and the second wall 350. The thickness of one or more of the first wall 440, second wall 450 and walls at

the ends 428a', 428b' may be in the range of about 1 mm to about 30 mm, optionally about 1mm to about 10 mm, and optionally about 1 mm to about 5 mm. The first wall 440 and the second wall 450 may be spaced apart by a substantially constant distance from one end 428a' to the other end 428b' of the device 401.

[00126] Figs. 25 to 28 show an example of a device 501 of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery. Unless described as being different below, the features, functionality, alternatives and uses of the device 501 are as described for device 1, 101, 201, 301, 401 or any of the other devices described herein.

[00127] Device 501 comprises a pair of legs 502 which comprises a first leg 502a and a second leg 502b. The legs 502a, 502b are joined at one end of each leg 502a, 502b at a join 504. Each leg 502a, 502b comprises an inner side 508 that faces the perineum when the device 501 is in use, and an outer side 510 that is configured to locate a hand of a user when the device 501 is in use.

[00128] The join 504 comprises a hinge 504 in the form of a bend 504. In comparison with the hinge 4 of device 1, the bend 504 comprises multiple axes of rotation. Therefore, the legs 502a, 502b are hingedly joined at one end of each leg 502a, 502b at the bend 504, where the legs 502a, 502b are movably relative to each other about multiple axes of rotation of the bend 504. The hinge 504 may comprise one or more bends. A portion of the bend 504 is curved. The bend 504 may be radiused with a continuous curvature. In some examples, the bend 504 may have portions with different radius of curvature. In some examples, the bend 504 may have one or more non-curved portions. The bend 504 is positioned between the legs 502a, 502b at a substantially central portion of device 501. In some examples, the bend 504 may be closer to the end 528a', 528b' of one of the legs 502a, 502b relative to the end 528a', 528b' of the other leg 502a, 502b. The bend 504 or a portion thereof may be configured to urge the legs 502a, 502b (or a portion of the legs 502a, 502b) towards each other when in use. The device 501 may be pre-formed with the bend 504. In some examples, the bend 504 or a portion thereof, is resilient or comprises a resilient material, and is configured to urge the legs 502a, 502b (or a portion of the legs 502a, 502b) towards each other when a force is applied to move the legs 502a, 502b apart. The bend 504 or a portion thereof is configured to return to its pre-formed shape after the removal of a deformation force. The bend 504 may therefore act like a spring. The bend 504 may resist a force separating the legs 502a, 502b. A force (e.g. by a user's hand) applied to the outer sides 510 of the legs 502a, 502b may additionally or alternatively urge the legs 502a, 502b towards each other. A force applied to the outer sides 510 may therefore facilitate the resistance of

a resilient bend 504 or a resilient portion against any force attempting to separate the legs 502a, 502b. In some examples, the bend 504 or a portion thereof, is compliant or comprises a compliant material. The bend 504 comprises a perineum-facing inner side 504a that faces the perineum when the device 501 is in use, and a user-facing outer side 504b that faces the user and may locate the hand of the user when the device 501 is in use.

[00129] The inner side 504a of the bend 504 is provided on a portion of a first wall 540 of device 501 and the inner sides 508 of legs 502a, 502b are provided on another portion of the first wall 540. One or more of the inner sides 504a, 508 may have a surface (e.g. a roughened surface or surface with ridges) configured to increase friction between the first wall 540 and the perineum. This is to improve grip of the device 501 on the perineum. The outer side 504b of bend 504 is provided on a portion of a second wall 550 of device 501 and the outer sides 508 of legs 502a, 502b are provided on another portion of the second wall 550. The first wall 540 therefore forms a portion of the first leg 502a, a portion of the bend 504 and a portion of the second leg 502b. The second wall 550 therefore forms a portion of the first leg 502a, a portion of the bend 504 and a portion of the second leg 502b. The first wall 540 and/or second wall 550 are elongate walls, where one dimension is greater than another dimension and in particular the length is greater than the width of the wall. The length of the second wall 550 is different from the length of the first wall 540. The second wall 550 is longer than the first wall 540. In some examples, the length of the first wall 540 and the length of the second wall 550 are substantially the same. In some examples, the second wall 550 is shorter than the first wall 540. The legs 502a, 502b are integral with the bend 504. The legs 502a, 502b and bend 504 may be integrally formed, for example integrally moulded. Device 501 is a unitary device with the first wall 540 and second wall 550 integrally formed. In some examples, the legs 502a, 502b and bend 504 may be separate components that are couplable with one another.

[00130] Each of the first wall 540 and second wall 550 comprise a first end region and a second end region, where the first end regions are coupled together and the second end regions are coupled together. The end regions of the first and second walls 540, 550 provide the end regions of the pair of legs 502a, 502b distal from the join 504, i.e. end regions of the distal portions 528a, 528b. The ends 528a', 528b' of these end regions have a rounded profile (e.g. forming a partial loop) but other profiles such as an angular profile, are envisaged. The first wall 540, the second wall 550 and the first and second end regions are integrally formed. In some examples, the first wall 540, second wall 550 and/or first and/or second end regions may be separately formed and are couplable together.

[00131] The device 501 may also be described as a device comprising a first elongate wall 540 configured to engage a perineum of a patient and a second elongate wall 550 couplable to the first elongate wall 540 and is configured to be engaged by a user. In use, the first elongate wall 540 supports a portion of the perineum and a force applied to the second elongate wall 550 by the user facilitates the support of the perineum by the first elongate wall 540. The first elongate wall 540 is configured to distribute pressure across the portion of the perineum.

[00132] The first wall 540 or a portion thereof may be compliant or comprises a compliant material. A compliant first wall 540 can allow the first wall 540 to conform to the contours of the base of the perineum and thereby provide appropriate support when the device 501 is in use. A compliant first wall 540 may be soft to additionally provide comfort to the patient. The first wall 540 may configured to allow torsional rotation without yielding when subjected to a force. The second wall 550 or a portion thereof may be compliant or comprises a compliant material. A compliant second wall 550 can allow a user to easily and comfortably grip and handle the device 501 in use. The second wall 550 may configured to allow torsional rotation without yielding when subjected to a force. The first and second walls 540, 550 may be formed from the same material.

[00133] The device 501 comprises a single cavity 560 that separates the first wall 540 and second wall 550. A portion of the first wall 540 is therefore spaced apart from a portion of the second wall 550 by the cavity 560. In some examples, there are a plurality of cavities separated by intermediate walls as described with reference to devices 101, 201 and 301 herein. The cavity 560 is provided in the form of a channel 560 that separates a portion of the first wall 540 and a portion of the second wall 550. The channel 560 extends through the device 501 from one side to another. The channel 560 also extends from the first leg 502a through bend 504 to the second leg 502b. The channel 560 is configured such that the thickness of the first wall 540, second wall 550 and walls at the ends 528a', 528b' are substantially the same. In such a configuration and having a rounded profile (e.g. forming a partial loop) at the ends 528a', 528b compresses the material at these ends that may increase their stiffness and provide additional support to the sides of the base of the perineum when the device 501 is in use. In some examples, the thickness of the first wall 540, second wall 550 and/or walls at the ends 528a', 528b' are different. Portions of the first wall 540, second wall 550 and/or walls at the ends 528a', 528b' may also vary in thickness, for example, the wall portion at the join 504 on the first wall 540 and/or second wall 550 may be thicker than the other walls. The thickness of one or more of the first wall 540, second

wall 550 and walls at the ends 528a', 528b' may be in the range of about 1 mm to about 30 mm, optionally about 1mm to about 10 mm, and optionally about 1 mm to about 5 mm. The first wall 540, second wall 550 and first and second end regions define the channel 560. The first wall 540 and the second wall 550 are therefore coupled together to form a continuous loop with the channel 560 between them. Various cross-sectional shapes of the channel 560 are envisaged and the channel 560 may have a bent elongate shape, for example a bent rounded rectangle, bent stadium, etc. The cavity 560 is configured to increase the flexibility of a portion of the device 501, for example the legs 502a, 502b and bend 504, which facilitates movement of the first and second walls 540, 550 towards and away from one another. Additionally or alternatively, the channel/cavity 560 and/or the continuous loop structure of device 501 may decouple movement of the first wall 540 from the second wall 550, such that a user is able to manipulate the second wall 550 (for example pinching a portion of the second wall 550 of the first leg 502a and a portion of the second wall 550 of the second leg 502b together to achieve an appropriate grip) without (significantly) affecting the pressure distribution of the first wall 540 across the base of the perineum, and to actuate the second wall 550 towards the first wall 540 to facilitate support of the perineum by the first wall 540. Achieving an appropriate grip for the user may be beneficial to provide the capability to, for example, adjust the pressure applied on the base of the perineum and angles of the device 501 on the base of the perineum while preventing carpal tunnel syndrome for the user. In use, a portion of the first wall 540 is spaced apart from a portion of the second wall 550 by a first distance, and the portion of the first wall 540 is moveable relative to the second wall 550 such that the moveable portion is capable of being spaced apart from the portion of the second wall 550 by a second distance, wherein the first distance is different from the second distance. The second distance may be less than the first distance.

[00134] The device 501 has a pre-formed shape where a central portion of the device 501 extends distally away from a front of the device 501 (i.e. the portion that faces the patient in use). In particular, the device 501 is pre-formed with the bend 504 extending the central portion of the device 501 away from the front of the device 501, such that in use, the distal free ends 528a', 528b' of the legs 502a, 502b are configured to contact the patient before the inner side 504a contacts the patient. The device 501 has a pre-formed shape with the first wall 540 having a central portion and two end regions, where the central portion extends away from the two end regions, as shown in Fig. 27. The first wall 540 may have a C-, V- or U-shaped cross-section. The device 501 also has a pre-formed shape with the second wall 550 having a central portion and two end regions, where the central portion extends away from the two end regions, as shown in Fig. 27. The second wall 550 may have a C-, V- or U-

shaped cross-section. These shapes may be planar cross-sectional shapes. The cross-sectional shape of the first wall 540 corresponds to the cross-sectional shape of the second wall 550. Together, the first and second walls 540, 550 provide the device 501 with a C-, V- or U-shaped cross-section. This C-, V or U-shaped cross-section of device 501 is similarly applicable to devices 101, 201, 301 and 401 described herein. In some examples, the cross-sectional shape of the first wall 540 may be the same as or different from the cross-sectional shape of the second wall 550. The profile (e.g. curvature) of the first wall 540 may be the same or different from the profile of the second wall 550. The first wall 540 has a width W1 and the second wall 550 has a width W2. The widths W1 and/or W2 may be constant the length of the first and/or second walls 540, 550, from the end of the first leg 502a, to the end of the second leg 502b. The width W1 may be the same or different from the width W2. The width W1 may be greater than the width W2. The width W1 may range from about 1.0 cm to about 5.0 cm, optionally about 1.0 cm to about 4.0 cm.

[00135] The device 501 may comprise a grip portion on the outer sides 510 of the legs 502a, 502b and/or the outer side 504b of the bend 504. In an example, the grip portion may extend on the second wall 550, from the first leg 502a through the bend 504 to the second leg 502b. The grip portions may be one or more of a ring defining a finger through hole (e.g. ring 13 of device 1), a roughened surface finish, a recess and a projection.

[00136] The device 501 may comprise one or more pads provided on the inner sides 508 of the legs 502a, 502b. The one or more pads may be removably attached to the legs 502a, 502b. The one or more pads may be a pad 6 of device 1. In some examples, the one or more pads is an absorbent pad configured to absorb fluids. In some examples, the one or more pads, a portion of the device 501 and/or a portion of the first wall 540 is heated. In some examples, the one or more pads comprise a compliant material. The one or more pads may have a surface configured to increase friction between the device 501 and the perineum. This is to improve grip of the device 501 on the perineum. In some examples, the one or more pads is integrally formed with the first wall 540. In some embodiments, the first wall 540 forms the one or more pads.

[00137] Figs. 29 to 32 show an example of a device 601 of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery. Unless described as being different below, the features, functionality, alternatives and uses of the device 601 are as described for device 1, 101, 201, 301, 401, 501 or any of the other devices described herein.

[00138] Device 601 comprises a pair of legs 602 which comprises a first leg 602a and a second leg 602b. The legs 602a, 602b are joined at one end of each leg 602a, 602b at a join 604. Each leg 602a, 602b comprises an inner side 608 that faces the perineum when the device 601 is in use, and an outer side 610 that is configured to locate a hand of a user when the device 601 is in use.

[00139] The join 604 is positioned between the legs 602a, 602b at a substantially central portion of device 601. In some examples, the join 604 may be closer to the end 628a', 628b' of one of the legs 602a, 602b relative to the end 628a', 628b' of the other leg 602a, 602b. The join 604 comprises a perineum-facing inner side 604a that faces the perineum when the device 601 is in use, and a user-facing outer side 604b that faces the user and may locate the hand of the user when the device 601 is in use. The inner side 604a is provided on a portion of a first wall 640 of device 601 and the inner sides 608 of legs 602a, 602b are provided on another portion of the first wall 640. One or more of the inner sides 604a, 608 may have a surface (e.g. a roughened surface or surface with ridges) configured to increase friction between the first wall 640 and the perineum. This is to improve grip of the device 601 on the perineum. The outer side 604b of the join 604 is provided on a portion of a second wall 650 of device 601 and the outer sides 608 of legs 602a, 602b are provided on another portion of the second wall 650. The first wall 640 therefore forms a portion of the first leg 602a, a portion of the join 604 and a portion of the second leg 602b. The second wall 650 therefore forms a portion of the first leg 602a, a portion of the join 604 and a portion of the second leg 602b. The first wall 640 and/or second wall 650 are elongate walls, where one dimension is greater than another dimension and in particular the length is greater than the width of the wall. The length of the second wall 650 is different from the length of the first wall 640. The second wall 650 is longer than the first wall 640. In some examples, the length of the first wall 640 and the length of the second wall 650 are substantially the same. In some examples, the second wall 650 is shorter than the first wall 540. The legs 602a, 602b are integral with the join 604. The legs 602a, 602b and join 604 may be integrally formed, for example integrally moulded. Device 601 is a unitary device with the first wall 640 and second wall 650 integrally formed. In some examples, the legs 602a, 602b and join 604 may be separate components that are couplable with one another.

[00140] The device 601 may be pre-formed with the join 604. The device 601 may be pre-formed such that the portion of the join 604 provided on the first wall 640 is substantially planar and the portion of the join 604 provided on the second wall 650 comprises a bend. In some examples, the join 604 or a portion thereof, is resilient or comprises a resilient material,

such that the resilient join 604 or resilient portion is capable of returning to its shape after being deformed. In some examples, the join 604 or a portion thereof, is compliant or comprises a compliant material. In some examples, the first wall 640 or a portion thereof is compliant or comprises a compliant material. A compliant first wall 640 can allow the first wall 640 to conform to the contours of the base of the perineum and thereby provide appropriate support when the device 601 is in use. A compliant first wall 640 may be soft to additionally provide comfort to the patient. The first wall 640 may configured to allow torsional rotation without yielding when subjected to a force. The second wall 650 or a portion thereof may be compliant or comprises a compliant material. A compliant second wall 650 can allow a user to easily and comfortably grip and handle the device 601 in use. The second wall 640 may configured to allow torsional rotation without yielding when subjected to a force. The first and second walls 640, 650 may be formed from the same material.

[00141] Each of the first wall 640 and second wall 650 comprise a first end region and a second end region, where the first end regions are coupled together and the second end regions are coupled together. The end regions of the first and second walls 640, 650 provide the end regions of the pair of legs 602a, 602b distal from the join 604, i.e. end regions of the distal portions 628a, 628b. The ends 628a', 628b' of these end regions have a rounded profile (e.g. forming a partial loop) but other profiles such as an angular profile, are envisaged. The first wall 640, the second wall 650 and the first and second end regions are integrally formed. In some examples, the first wall 640, second wall 650 and/or first and/or second end regions may be separately formed and are couplable together.

[00142] The device 601 may also be described as a device comprising a first elongate wall 640 configured to engage a perineum of a patient and a second elongate wall 650 couplable to the first elongate wall 640 and is configured to be engaged by a user. In use, the first elongate wall 640 supports a portion of the perineum and a force applied to the second elongate wall 650 by the user facilitates the support of the perineum by the first elongate wall 640. The first elongate wall 640 is configured to distribute pressure across the portion of the perineum. A substantially planar first wall 640 as shown in Fig. 31 may maximise the area that first contacts the base of the perineum to provide quick pressure distribution when the device 601 first contacts the base of the perineum.

[00143] The device 601 comprises a single cavity 660 that separates the first wall 640 and second wall 650. A portion of the first wall 640 is therefore spaced apart from a portion of the second wall 650 by the cavity 660. In some examples, there are a plurality of cavities separated by intermediate walls as described with reference to devices 101, 201 and 301

herein. The cavity 660 is provided in the form of a channel 660 that separates the first wall 640 and second wall 650. The channel 660 extends through the device 601 from one side to another. The channel 660 also extends from the first leg 602a through join 604 to the second leg 602b. The channel 660 is configured such that the thickness of the first wall 640, second wall 650 and walls at the ends 628a', 628b' are substantially the same. In such a configuration and having a rounded profile (e.g. forming a partial loop) at the ends 628a', 628b compresses the material at these ends that may increase their stiffness and provide additional support to the sides of the base of the perineum when the device 601 is in use. In some examples, the thickness of the first wall 640, second wall 650 and/or walls at the ends 628a', 628b' are different. Portions of the first wall 640, second wall 650 and/or walls at the ends 628a', 628b' may also vary in thickness, for example, the wall portion at the join 604 on the first wall 640 and/or second wall 650 may be thicker than the other walls. The thickness of one or more of the first wall 640, second wall 650 and walls at the ends 628a', 628b' may be in the range of about 1 mm to about 30 mm, optionally about 1mm to about 10 mm, and optionally about 1 mm to about 5 mm. The first wall 640, second wall 650 and first and second end regions define the channel 660. The first wall 640 and the second wall 650 are therefore coupled together to form a continuous loop with the channel 660 between them. The channel 660 has a T-shaped cross-section but other shapes of the channel 660 are envisaged. The cavity 660 is configured to increase the flexibility of a portion of the device 601, for example the legs 602a, 602b and join 604, which facilitates movement of the first and second walls 640, 650 towards and away from one another. Additionally or alternatively, the channel/cavity 660 and/or the continuous loop structure of the device 601 may decouple movement of the first wall 640 from the second wall 650, such that a user is able to manipulate the second wall 650 (for example pinching a portion of the second wall 650 of the first leg 602a and a portion of the second wall 650 of the second leg 602b together to achieve an appropriate grip) without (significantly) affecting the pressure distribution of the first wall 640 across the base of the perineum, and to actuate the second wall 650 towards the first wall 640 to facilitate support of the perineum by the first wall 640. Achieving an appropriate grip for the user may be beneficial to provide the capability to, for example, adjust the pressure applied on the base of the perineum and angles of the device 601 on the base of the perineum while preventing carpal tunnel syndrome for the user. In use, a portion of the first wall 640 is spaced apart from a portion of the second wall 650 by a first distance, and the portion of the first wall 640 is moveable relative to the second wall 650 such that the moveable portion is capable of being spaced apart from the portion of the second wall 650 by a second distance, wherein the first distance is different from the second distance. The second distance may be less than the first distance.

[00144] The device 601 has a pre-formed shape with a first wall 640 having a substantially planar central portion that comprises a portion of the join 604, and two end regions that extend away from the front of the device 601, and a second wall 650 having a central portion and two end regions, where the central portion extends away from the two end regions, as shown in Fig. 31. The second wall 650 may have a Y-, C-, V- or U-shaped cross-section which may be a planar cross-sectional shape. The cross-sectional shape of the first wall 640 is different from the cross-sectional shape of the second wall 650. Together, the first and second walls 640, 650 provide the device 601 with a T-shaped cross-section. A pre-formed T-shaped cross-section allows a user to easily grip the second wall 650 of the device 601 between a thumb and a finger(s), and actuate the first wall 640 against the base of the perineum, thereby supporting it during vaginal delivery. A width of the first wall 640 and the second wall 650 may be as described in device 501.

[00145] The device 601 comprise a grip portion 612 on the outer sides 610 of the legs 602a, 602b. In some examples, the grip portion 612 extends on the second wall 650, from the first leg 602a through the join 604 to the second leg 602b. In some examples, the grip portion 612 is provided only on the join 604. The grip portion 612 is provided as a plurality of projections extending from the outer sides 610 of the legs 602a, 602b. Other forms of the grip portion are envisaged as described herein.

[00146] The device 601 may comprise one or more pads provided on the inner sides 608 of the legs 602a, 602b. The one or more pads may be removably attached to the legs 602a, 602b. The one or more pads may be a pad 6 of device 1. In some examples, the one or more pads is an absorbent pad configured to absorb fluids. In some examples, the one or more pads, a portion of the device 601 and/or a portion of the first wall 640 is heated. In some examples, the one or more pads comprise a compliant material. The one or more pads may have a surface configured to increase friction between the device 601 and the perineum. This is to improve grip of the device 601 on the perineum. In some examples, the one or more pads is integrally formed with the first wall 640. In some embodiments, the first wall 640 forms the one or more pads.

[00147] Figs. 33 to 36 show an example of a device 701 of the present disclosure for preventing and/or minimizing vaginal tears during vaginal delivery. Unless described as being different below, the features, functionality, alternatives and uses of the device 701 are as described for device 1, 101, 201, 301, 401, 501, 601 or any of the other devices described herein.

[00148] Device 701 comprises a pair of legs 702 which comprises a first leg 702a and a second leg 702b. The legs 702a, 702b are joined at one end of each leg 702a, 702b at a join 704. Each leg 702a, 702b comprises an inner side 708 that faces the perineum when the device 701 is in use, and an outer side 710 that is configured to locate a hand of a user when the device 701 is in use.

[00149] The join 704 comprises a hinge 704 in the form of a bend 704. In comparison with the hinge 4 of device 1, the bend 704 comprises multiple axes of rotation. Therefore the legs 702a, 702b are hingedly joined at one end of each leg 702a, 702b at the bend 704, where the legs 702a, 702b are movably relative to each other about multiple axes of rotation of the bend 704. The hinge 704 may comprise a one or more bends. A portion of the bend 704 is curved. The bend 704 may be radiused with a continuous curvature. In some examples, the bend 704 may have portions with different radius of curvature. In some examples, the bend 704 may have one or more non-curved portions. The bend 704 is positioned between the legs 702a, 702b at a substantially central portion of device 701. In some examples, the bend 704 may be closer to the end 728a', 728b' of one of the legs 702a, 702b relative to the end 728a', 728b' of the other leg 702a, 702b. The bend 704 or a portion thereof may be configured to urge the legs 702a, 702b (or a portion of the legs 702a, 702b) towards each other when in use. The device 701 may be pre-formed with the bend 704. In some examples, the bend 704 or a portion thereof, is resilient or comprises a resilient material, and is configured to urge the legs 702a, 702b (or a portion of the legs 702a, 702b) towards each other when a force is applied to move the legs 702a, 702b apart. The bend 704 or a portion thereof is configured to return to its pre-formed shape after the removal of a deformation force. The bend 704 may therefore act like a spring. The bend 704 may resist a force separating the legs 702a, 702b. A force (e.g. by a user's hand) applied to the outer sides 710 of the legs 702a, 702b may additionally or alternatively urge the legs 702a, 702b towards each other. A force applied to the outer sides 710 may therefore facilitate the resistance of a resilient bend 704 or a resilient portion against any force attempting to separate the legs 702a, 702b. In some examples, the bend 704 or a portion thereof, is compliant or comprises a compliant material. The bend 704 comprises a perineum-facing inner side 704a that faces the perineum when the device 701 is in use, and a user-facing outer side 704b that faces the user and may locate the hand of the user when the device 701 is in use.

[00150] The inner side 704a of the bend 704 is provided on a portion of a first wall 740 of device 701 and the inner sides 708 of legs 702a, 702b are provided on another portion of

the first wall 740. One or more of the inner sides 704a, 708 may have a surface (e.g. a roughened surface or surface with ridges) configured to increase friction between the first wall 740 and the perineum. This is to improve grip of the device 701 on the perineum. The outer side 704b of bend 704 is provided on a portion of a second wall 750 of device 701 and the outer sides 708 of legs 702a, 702b are provided on another portion of the second wall 750. The first wall 740 therefore forms a portion of the first leg 702a, a portion of the bend 704 and a portion of the second leg 702b. The second wall 750 therefore forms a portion of the first leg 702a, a portion of the bend 704 and a portion of the second leg 702b. The first wall 740 and/or second wall 750 are elongate walls, where one dimension is greater than another dimension and in particular the length is greater than the width of the wall. The length of the second wall 750 is different from the length of the first wall 740. The second wall 750 is longer than the first wall 740. In some examples, the length of the first wall 740 and the length of the second wall 750 are substantially the same. In some examples, the second wall 750 is shorter than the first wall 740. The legs 702a, 702b are integral with the bend 704. The legs 702a, 702b and bend 704 may be integrally formed, for example integrally moulded. Device 701 is a unitary device with the first wall 740 and second wall 750 integrally formed. In some examples, the legs 702a, 702b and bend 704 may be separate components that are couplable with one another.

[00151] Each of the first wall 740 and second wall 750 comprise a first end region and a second end region, where the first end regions are coupled together and the second end regions are coupled together. The end regions of the first and second walls 740, 750 provide the end regions of the pair of legs 702a, 702b distal from the join 704, i.e. end regions of the distal portions 728a, 728b. The ends 728a', 728b' of these end regions have a rounded profile (e.g. forming a partial loop) but other profiles such as an angular profile, are envisaged. The first wall 740, the second wall 750 and the first and second end regions are integrally formed. In some examples, the first wall 740, second wall 750 and/or first and/or second end regions may be separately formed and are couplable together.

[00152] The device 701 may also be described as a device comprising a first elongate wall 740 configured to engage a perineum of a patient and a second elongate wall 750 couplable to the first elongate wall 740 and is configured to be engaged by a user. In use, the first elongate wall 740 supports a portion of the perineum and a force applied to the second elongate wall 750 by the user facilitates the support of the perineum by the first elongate wall 740. The first elongate wall 740 is configured to distribute pressure across the portion of the perineum.

[00153] In some examples, the first wall 740 or a portion thereof is compliant or comprises a compliant material. A compliant first wall 740 can allow the first wall 740 to conform to the contours of the base of the perineum and thereby provide appropriate support when the device 701 is in use. A compliant first wall 740 may be soft to additionally provide comfort to the patient. The first wall 740 may configured to allow torsional rotation without yielding when subjected to a force. The second wall 750 or a portion thereof may be compliant or comprises a compliant material. A compliant second wall 750 can allow a user to easily and comfortably grip and handle the device 701 in use. The second wall 750 may configured to allow torsional rotation without yielding when subjected to a force. The first and second walls 740, 750 may be formed from the same material.

[00154] The device 701 comprises a single cavity 760 that separates the first wall 740 and second wall 750. A portion of the first wall 740 is therefore spaced apart from a portion of the second wall 750 by the cavity 760. In some examples, there are a plurality of cavities separated by intermediate walls as described with reference to devices 101, 201 and 301 herein. The cavity 760 is provided in the form of a channel 760 that separates a portion of the first wall 740 and a portion of the second wall 750. The channel 760 extends through the device 701 from one side to another. The channel 760 also extends from the first leg 702a through bend 704 to the second leg 702b. In Figs. 33 to 36, the device 701 is shown with two portions of the inner surfaces of the first wall 740 and the second wall 750 in contact with one another, thereby transiently separating the channel 760 into three separate channels. However, these inner surfaces are not coupled together and the first and second walls 740, 750 can move apart to provide the channel 760. As described in further detail below, the device 701 has a pre-formed shape. In such a pre-formed shape, portions of the first wall 740 and the second wall 750 may be in contact, but not coupled with one another, as shown in Figs. 33 to 36. The channel 760 is configured such that the thickness of the first wall 740, second wall 750 and walls at the ends 728a', 728b' are substantially the same. In such a configuration and having a rounded profile (e.g. forming a partial loop) at the ends 728a', 728b compresses the material at these ends that may increase their stiffness and provide additional support to the sides of the base of the perineum when the device 701 is in use. In some examples, the thickness of the first wall 740, second wall 750 and/or walls at the ends 728a', 728b' are different. Portions of the first wall 740, second wall 750 and/or walls at the ends 728a', 728b' may also vary in thickness, for example, the wall portion at the join 704 on the first wall 740 and/or second wall 750 may be thicker than the other walls. The thickness of one or more of the first wall 740, second wall 750 and walls at the ends 728a', 728b' may be in the range of about 1 mm to about 30 mm, optionally about 1mm to about 10 mm, and

optionally about 1 mm to about 5 mm. The first wall 740, second wall 750 and first and second end regions define the channel 760. The first wall 740 and the second wall 750 are therefore coupled together to form a continuous loop with the channel 760 between them. The channel 760 has a Y-shaped cross-section but other cross-sectional shapes of the channel 760 are envisaged. The cavity 760 is configured to increase the flexibility of a portion of the device 701, for example the legs 702a, 702b and bend 704, which facilitates movement of the first and second walls 740, 750 towards and away from one another. Additionally or alternatively, the channel/cavity 760 and/or the continuous loop structure of the device 701 may decouple movement of the first wall 740 from the second wall 750, such that a user is able to manipulate the second wall 750 (for example pinching a portion of the second wall 750 of the first leg 702a and a portion of the second wall 750 of the second leg 702b together to achieve an appropriate grip) without (significantly) affecting the pressure distribution of the first wall 740 across the base of the perineum, and to actuate the second wall 750 towards the first wall 740 to facilitate support of the perineum by the first wall 740. Achieving an appropriate grip for the user may be beneficial to provide the capability to, for example, adjust the pressure applied on the base of the perineum and angles of the device 701 on the base of the perineum while preventing carpal tunnel syndrome for the user. In use, a portion of the first wall 740 is spaced apart from a portion of the second wall 750 by a first distance, and the portion of the first wall 740 is moveable relative to the second wall 750 such that the moveable portion is capable of being spaced apart from the portion of the second wall 750 by a second distance, wherein the first distance is different from the second distance. The second distance may be less than the first distance.

[00155] The device 701 has a pre-formed shape where a central portion of the device 701 extends distally away from a front of the device 701 (i.e. the portion that faces the patient in use). In particular, the device 701 is pre-formed with the bend 704 extending the central portion of the device 701 away from the front of the device 701, such that in use, the distal free ends 728a', 728b' of the legs 702a, 702b are configured to contact the patient before the inner side 704a contacts the patient. The device 701 has a pre-formed shape with the first wall 740 having a central portion and two end regions, where the central portion extends away from the two end regions, as shown in Fig. 35. The first wall 740 may have a C-, V- or U-shaped cross-section. The device 701 also has a pre-formed shape with the second wall 750 having a central portion and two end regions, where the central portion extends away from the two end regions, as shown in Fig. 35. The second wall 750 may have a C-, V- or U-shaped cross-section. These shapes may be planar cross-sectional shapes. The cross-sectional shape of the first wall 740 is different from the cross-sectional shape of the second

wall 750. The second wall 750 has a V-shaped cross-section and the first wall 740 has a U-shaped cross-section. Together, the first and second walls 740, 750 provide the device 701 with a Y-shaped cross-section. In some examples, the cross-sectional shape of the first wall 740 may be the same as the cross-sectional shape of the second wall 750. The profile (e.g. curvature) of the first wall 740 may be the same or different from the profile of the second wall 750. A width of the first wall 740 and the second wall 750 may be as described in device 501.

[00156] The device 701 comprise a grip portion 712 on the outer sides 710 of the legs 702a, 702b. In some examples, the grip portion 712 extends on the second wall 750, from the first leg 702a through the join 704 to the second leg 702b. In some examples, the grip portion 712 is provided only on the join 704. The grip portion 712 is provided as a plurality of projections extending from the outer sides 710 of the legs 702a, 702b. Other forms of the grip portion are envisaged as described herein.

[00157] The device 701 may comprise one or more pads provided on the inner sides 708 of the legs 702a, 702b. The one or more pads may be removably attached to the legs 702a, 702b. The one or more pads may be a pad 6 of device 1. In some examples, the one or more pads is an absorbent pad configured to absorb fluids. In some examples, the one or more pads, a portion of the device 701 and/or a portion of the first wall 740 is heated. In some examples, the one or more pads comprise a compliant material. The one or more pads may have a surface configured to increase friction between the device 701 and the perineum. This is to improve grip of the device 701 on the perineum. In some examples, the one or more pads is integrally formed with the first wall 740. In some embodiments, the first wall 740 forms the one or more pads.

[00158] Figs. 37 and 38 show device 601 and 701 in use during vaginal delivery, where the device 601, 701 is configured to prevent and/or minimize vaginal tears during vaginal delivery. A user locates the device 601, 701 at the base of the perineum 3 of the patient such that the first wall 640, 740 contacts the base of the perineum of the patient and/or a portion of a crowning head 11 of a baby. The first wall 640, 740 is configured to support a portion of the perineum 3. The second wall 650, 750 is gripped by a user's hand 9 at the grip portion 612, 712. The user actuates the device 601, 701 against the perineum in an anterior and/or cephalad direction (with respect to the patient), such that the force applied by the user is transmitted from the second wall 650, 750 to the first wall 640, 740 and onto the base of the perineum 3. This force from the user counters a force, for example, from the crowning head 11 of the baby against fourchette and perineum 3, and is distributed across the contact area

of the first wall 640, 740 and the base of the perineum 3 and/or the portion of the crowning baby head 11. This thereby minimizes and/or avoids formation of a pressure point at the fourchette and/or perineum 3, caused by the crowning baby head and/or the patient pushing that increases the risk of obstetric anal sphincter injuries (OASI).

[00159] In the case of device 701, the bend 704 may be resilient such that actuation of the device 701 against the base of the perineum 3 forces the legs 702a, 702b apart, and the resilience of the bend 704 provides a counter force to urge the legs 702a, 702b towards each other. This counter force is an inward force towards a central plane of the device 701, and it counters a force that is separating the vulva as the baby's head 11 is crowning, thereby providing support to the perineum 3 and minimizes and/or avoids formation of a pressure point at the fourchette and/or perineum 3 which increases the risk of obstetric anal sphincter injuries (OASI). In some examples, the first wall 640, 740 may be formed of a compliant material that is configured to conform to the contours of the base of the perineum 3.

[00160] Devices of the present invention may also be used in the same manner as described with respect to devices 601 and 701. For example, device 501 may be used in the same manner except that the user's hand 9 may not be able to achieve a pinch grip as shown in Figs. 37 and 38. Instead, a user using device 501 may conform the hand 9 to the pre-formed shape of the second wall 550 to actuate the device 501 against the base of the perineum 3.

[00161] The device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein may be for single-patient use. In some examples, a portion of the device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein is for single-patient use, and another portion is for multi-patient use, the single-patient use portion and the multi-patient use portion being configured to be removably coupled together.

[00162] A portion of the device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein may be configured to removably attach the device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein to a portion of the perineum 3 in use. For example, the end regions of the distal portion 28, 128, 228, 328, 428, 528, 628 or 728 may be configured to adhere to the base of the perineum 3 in use. This allows momentary removal of the user's hand to allow the use to utilize other medical instruments if needed, without removing the device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein from the patient.

[00163] It should be further appreciated by the person skilled in the art that variations and combinations of features described above, not being alternatives or substitutes, may be combined to form yet further embodiments falling within the intended scope of the disclosure. For example, the device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein may be integrally formed or be formed of separate parts that are coupled together by means known in the art, for example by mechanical couplings, adhesives, welding, insert moulding etc. Such coupling may be a removable coupling. The device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein, or any part thereof, may be formed for example by moulding and additive manufacturing. The device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein may be formed from a single material or from multiple materials. The device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein, or a portion thereof may comprise a polymer such as silicone or a thermoplastic polymer, for example thermoplastic polyurethane (TPU). The device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein, or a portion thereof may comprise a biocompatible material. The device 1, 101, 201, 301, 401, 501, 601, 701 or any of the other devices described herein, or a portion thereof may comprise a material having a Shore A hardness of about 20 A to about 100 A, and such material may be a "compliant material" referred in the present specification. In some examples, a portion of the device 1, 101, 201, 301, 401, 501, 601, 701, for example first wall 140, 240, 340, 440, 540, 640, 740 may be formed from a material (e.g. with a Shore A hardness of 20 A) softer than a material (e.g. with a Shore A hardness of 100 A) of another portion, for example second wall 150, 250, 350, 450, 550, 650, 750. As would be understood by a person skilled in the art, each embodiment, may be used in combination with other embodiment or several embodiments.

CLAIMS

What is claimed is:

1. A device for preventing and/or minimizing vaginal tears during vaginal delivery, the device comprising:

   a pair of legs joined at one end of each leg at a join, each leg comprising a perineum-facing inner side and an outer side configured to locate a hand of a user, and

   wherein a force provided by the hand of the user helps to urge the legs together.

2. The device of claim 1, wherein the join is configured to urge the legs towards each other.

3. The device of claim 1 or 2, wherein the join comprises a hinge.

4. The device of claim 3, each leg comprising a proximal portion adjacent the hinge and a distal portion, wherein the hinge is configured to urge the legs towards each other and the distal portions are configured to urge the legs to move up and out, further spreading out the tension on the sides of the vagina in use.

5. The device of claim 3 or 4, wherein the hinge comprises one or more bends, optionally a portion of the bend is curved.

6. The device of any one of claims 1 to 5, wherein the pair of legs and join are integrally formed.

7. The device of any one of claims 1 to 6, the device comprising a first wall and a second wall, wherein the perineum-facing inner side is provided on the first wall and the outer side is provided on the second wall, such that the first and second walls form the pair of legs and the join.

8. The device of claim 6 or 7, wherein the first and second walls are spaced apart by a cavity, optionally the cavity comprises a channel extending from one side of the device to another side, optionally the first and second walls are spaced apart by a plurality of cavities separated by one or more intermediate walls.

9. The device of claim 8, wherein each of the first and second walls comprises a first end region and a second end region, and wherein the first end regions are coupled together and the second end regions are coupled together, wherein the first end regions and the second end regions provide end regions of the pair of legs distal from the join.

10. The device of any one of claims 6 to 10, wherein the first wall and/or second wall comprises an elongate wall, optionally the second wall is longer than the first wall.

11. The device of any one of claims 6 to 10,

wherein a cross-sectional shape of the first wall corresponds to a cross-sectional shape of the second wall, optionally the device comprises a C-, V- or U- shaped cross-section, or

wherein a cross-sectional shape of the first wall is different from a cross-sectional shape of the second wall, optionally the device comprises a T- or Y-shaped cross-section.

12. The device of any one of claims 6 to 11, wherein the first and second walls are integrally formed, optionally the first and second walls are formed from the same material.

13. The device of any one of claims 1 to 12, wherein a portion of the device is compliant or comprises a compliant material, optionally wherein the compliant material comprises a polymer, optionally the polymer comprises thermoplastic polyurethane (TPU) and silicone.

14. The device of any one of claims A1 to A13, the device further comprising one or more of:

a ring defining a finger through hole, a roughened surface finish, a recess and/or a projection provided on the outer side of the pair of legs; or

one or more pads located on the inner side of each leg, optionally, the one or more pads comprises an absorbent pad, and optionally the one or more pads comprises high-density foam or silicone or any other material that has a high compressive strength.

15. The device of any one of claims 1 to 17, wherein a portion of the device is configured to be heated, optionally, the one or more pads is heated.

16. A device for preventing and/or minimizing vaginal tears during vaginal delivery in a patient, the device comprising:

a first elongate wall configured to engage a perineum of the patient; and

a second elongate wall couplable to the first elongate wall, the second elongate wall configured to be engaged by a user,

wherein in use, the first elongate wall supports a portion of the perineum, and a force applied to the second elongate wall by the user facilitates the support of the perineum by the first elongate wall.

17. The device of claim 16, wherein in use, the first elongate wall distributes pressure across the portion of the perineum.

18. The device of claim 16 or 17, wherein the second elongate wall comprises a grip portion.

19. The device of any one of claims 16 to 18, wherein a portion of the first elongate wall is spaced apart from a portion of the second elongate wall, optionally the first elongate wall is spaced apart from the second elongate wall by one or more cavities, the one or more cavities configured to decouple movement of the first elongate wall from the second elongate wall and optionally the one or more cavities comprise one or more channels extending from one side of the device to another.

20. The device of claim 19, wherein a or the portion of the first elongate wall is spaced apart from a or the portion of the second elongate wall by a first distance, and the portion of the first elongate wall is moveable relative to the second elongate wall such that the moveable portion is capable of being spaced apart from the portion of the second elongate wall by a second distance, wherein the first distance is different from the second distance, optionally the second distance is less than the first distance.

21. The device of any one of claims 16 to 20, the device comprising a pre-formed shape and the second elongate wall comprises two end regions, wherein a central portion of the second elongate wall extends away from the two end regions of the second elongate wall, optionally the second elongate wall comprises a Y-, C-, V- or U-shaped cross-section.

22. The device of claim 21, the first elongate wall comprising two end regions, wherein a central portion of the first elongate wall extends away from the two end regions of the first elongate wall, optionally the first elongate wall comprises a C-, V- or U-shaped cross-section, and optionally the first elongate wall and the second elongate wall together provide the device with a Y-shaped cross-section.

23. The device of claim 22, wherein the first and second elongate walls are coupled together at least at one of their two end regions and the coupled end region is configured to additionally support the perineum when in use, optionally the coupled end region forms a partial loop.

24. A device for preventing and/or minimizing vaginal tears during vaginal delivery in a patient, the device comprising:

a first elongate wall configured to engage a perineum of the patient; and

a second elongate wall engageable by a user to actuate the first elongate wall towards the perineum of the patient,

wherein the first and second elongate walls are configured to be coupled together to form a continuous loop.

25. The device of claim 24, wherein the first elongate wall comprises a compliant material, optionally wherein the compliant material comprises a polymer, optionally the polymer comprises thermoplastic polyurethane (TPU) and silicone.

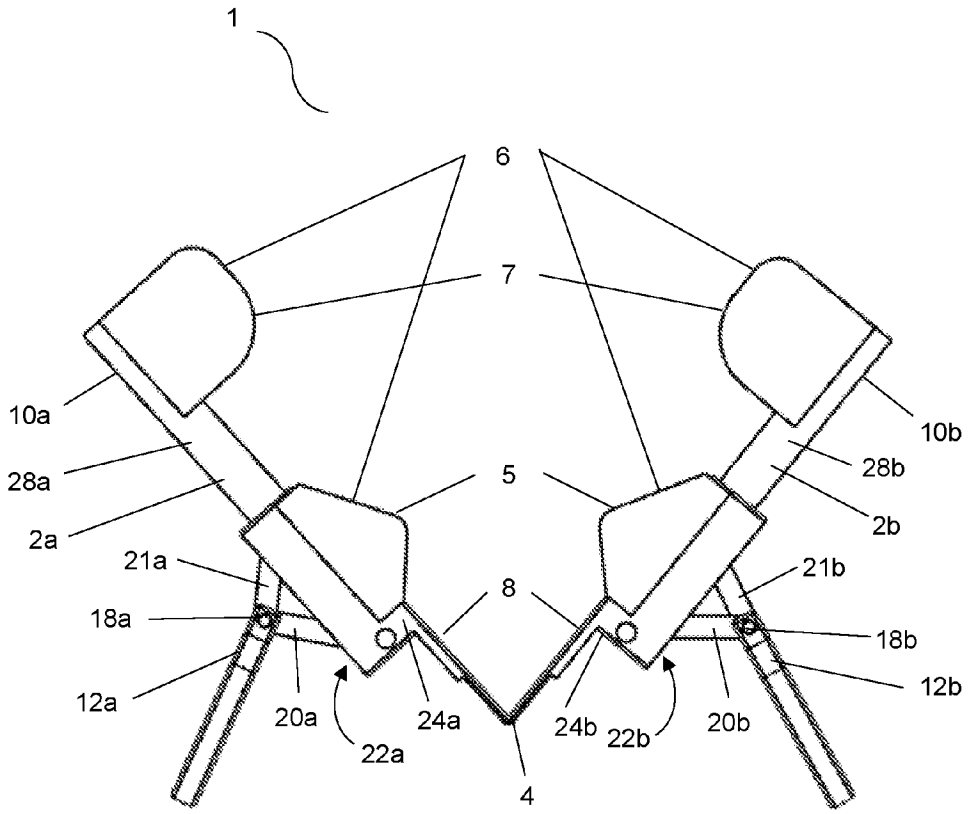
26. The device of claim 24 or 25, the device comprising a pre-form shape and each of the first and second elongate walls comprises two end regions, wherein the first and second elongate walls are coupled together at their two end regions.

27. The device of claim 26, wherein a central portion of the second elongate wall extends away from the two end regions of the second elongate wall, optionally the second elongate wall comprises a Y-, C-, V- or U-shaped cross-section.

28. The device of claim 26 or 27, wherein a central portion of the first elongate wall extends away from the two end regions of the first elongate wall, optionally the first elongate wall comprises a C-, V- or U-shaped cross-section, and optionally the first elongate wall and the second elongate wall together provide the device with a Y-shaped cross-section.

29. The device of any one of claims 26 to 28, wherein the first and second elongate walls are integral with one another, and optionally, the first and second elongate walls are formed of the same material.

30. The device of any one of claims 24 to 29, wherein the device comprises a pre-formed shape, and wherein the device comprises a C-, V-, U-, T- or Y- cross-sectional shape.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24b
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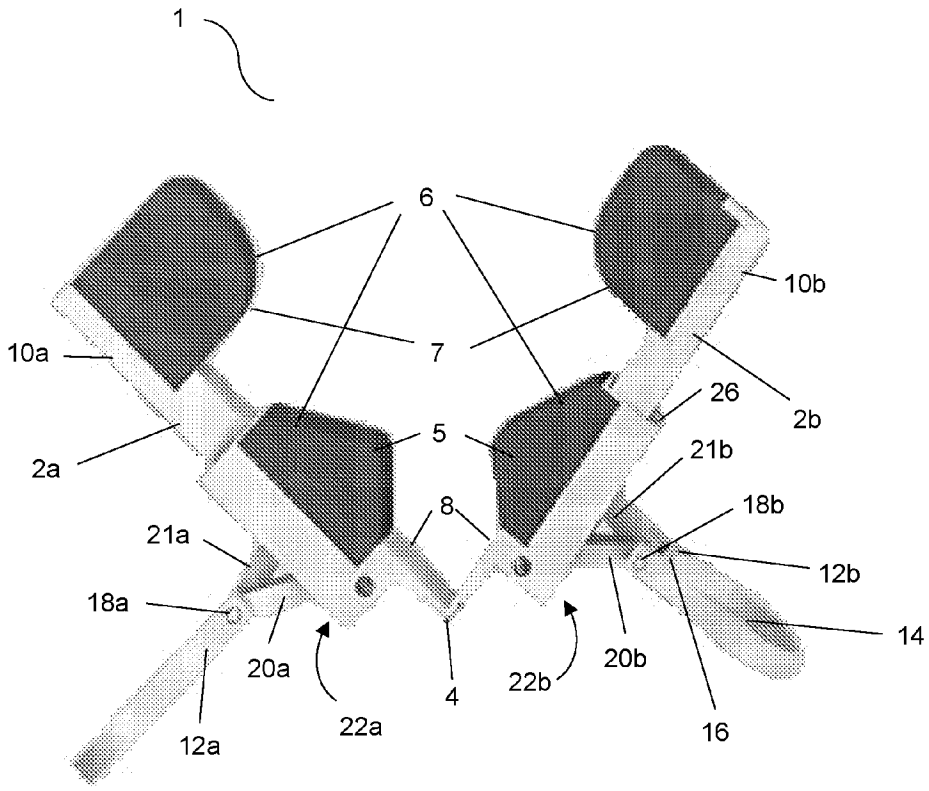
22a
22b
4

Fig. 1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16
12a

Fig. 2

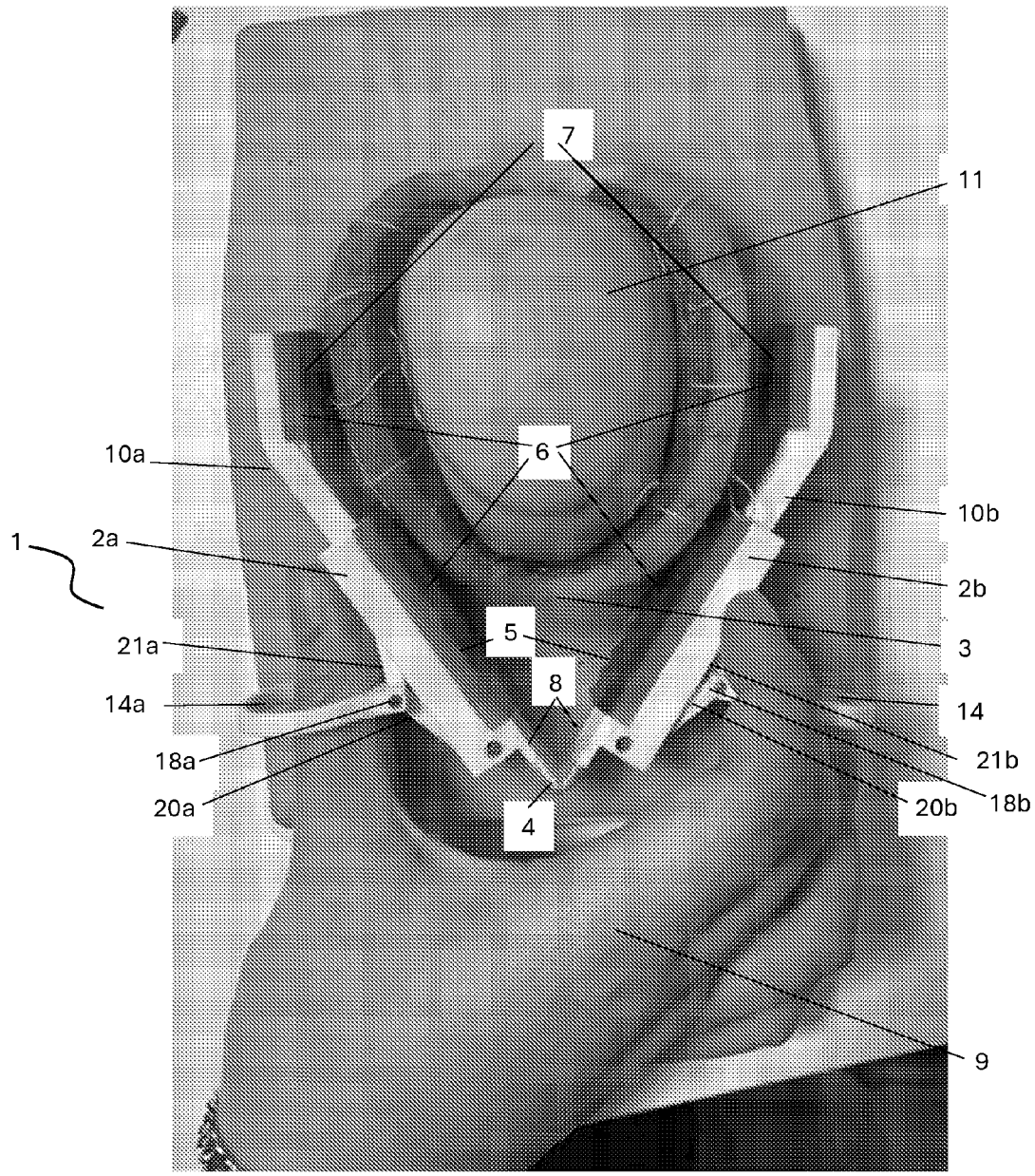


Fig. 3

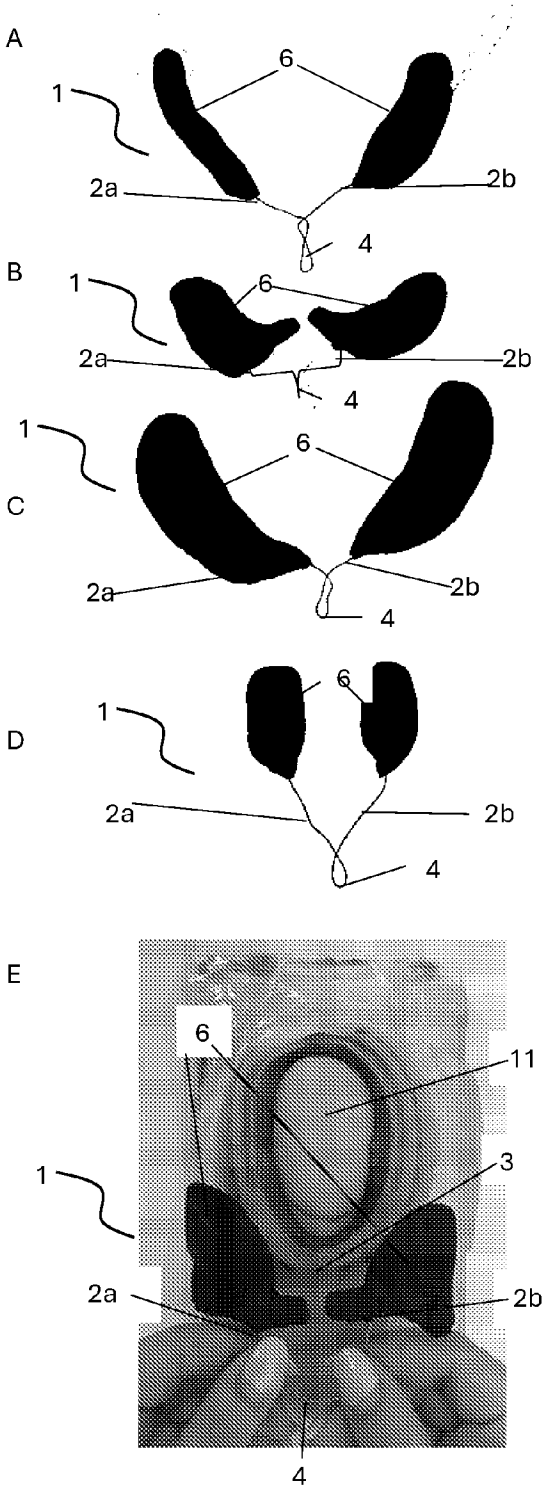
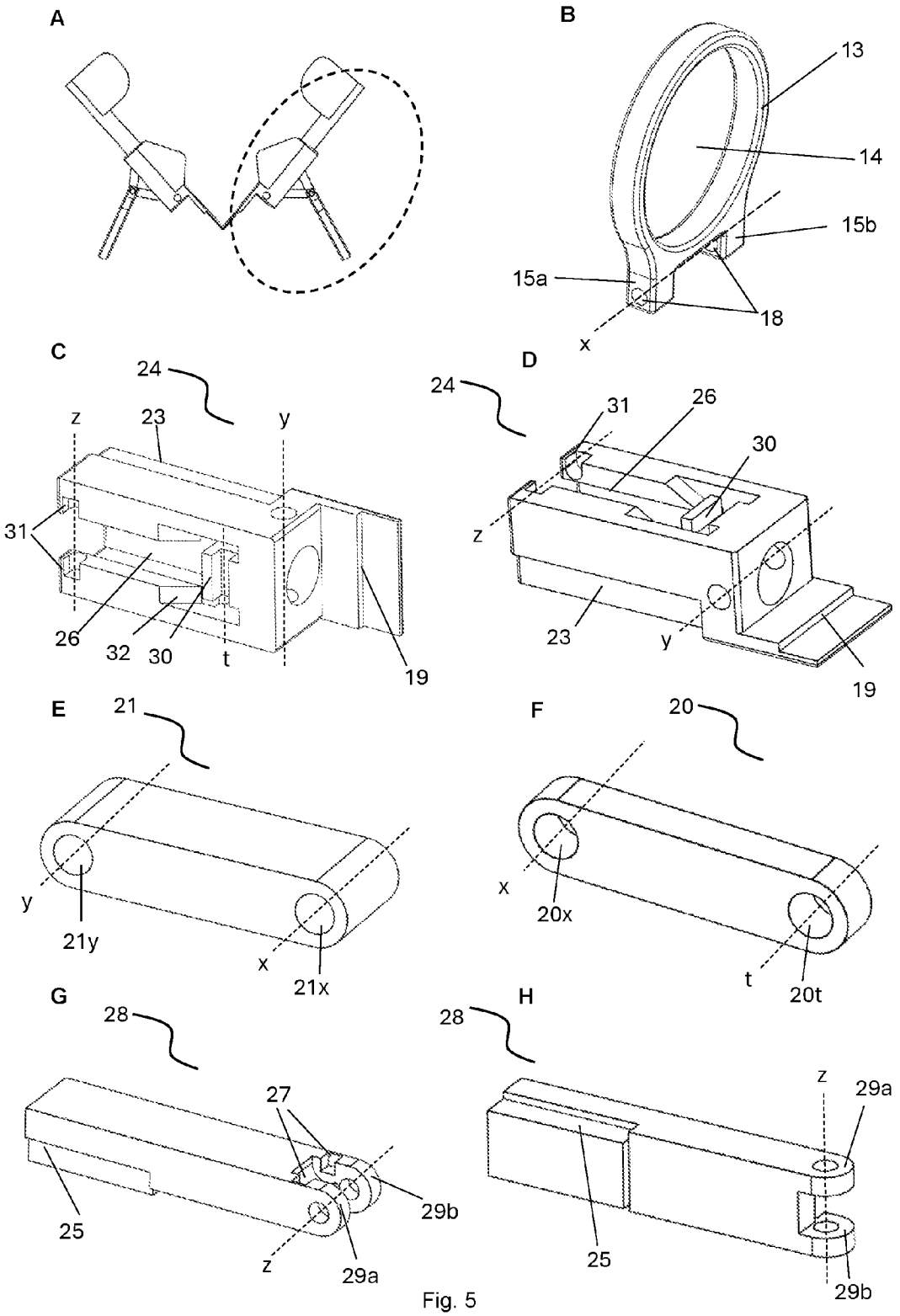


Fig. 4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y
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31
26
30
z
23
y
19
E
21
y
21y
x
21x
F
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Fig. 5

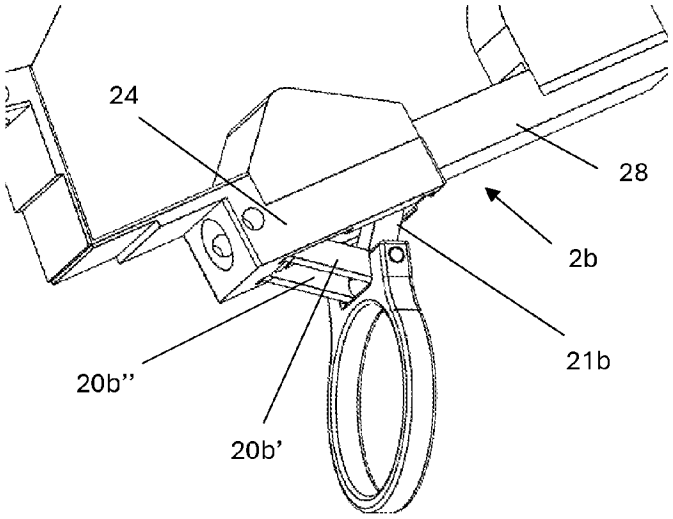

Fig. 6

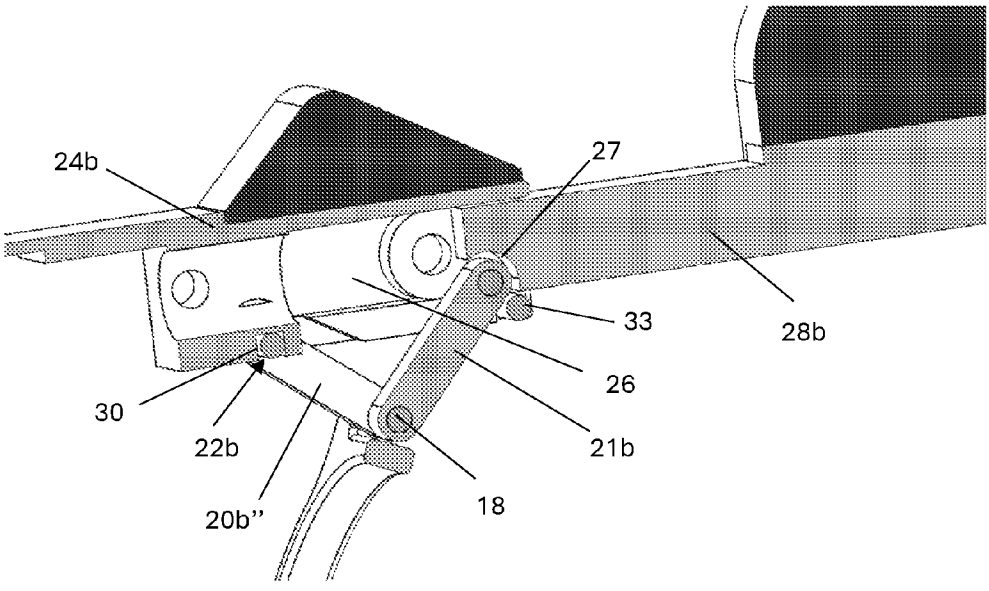

Fig. 7

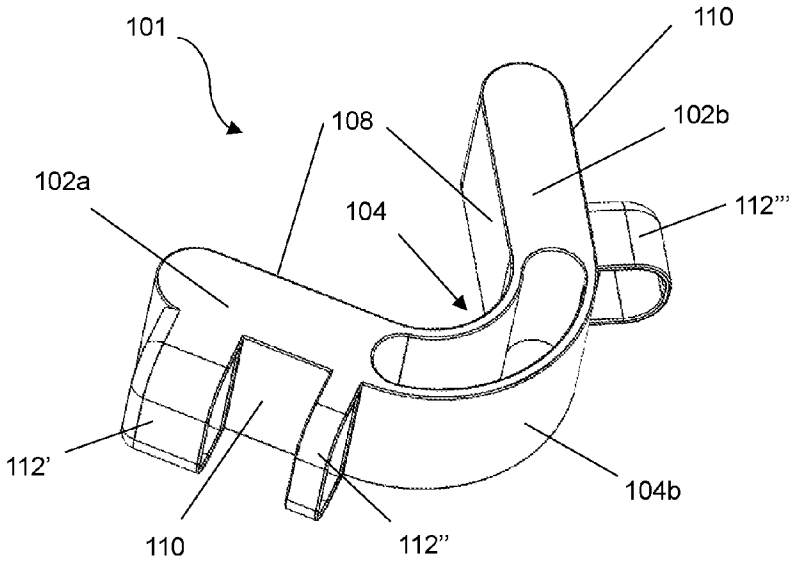
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Fig. 8

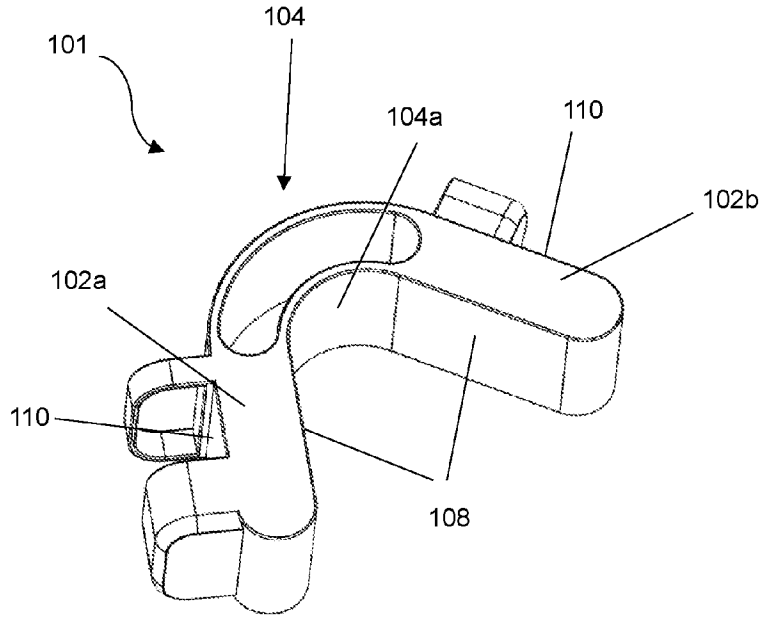
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Fig. 9

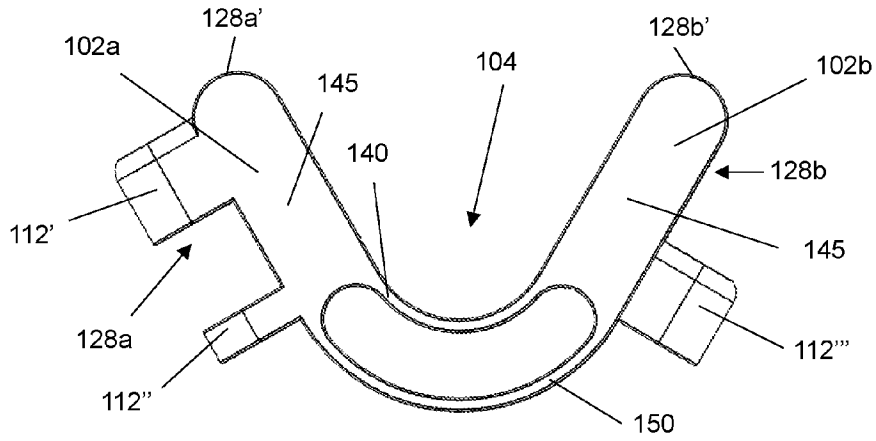

Fig. 10

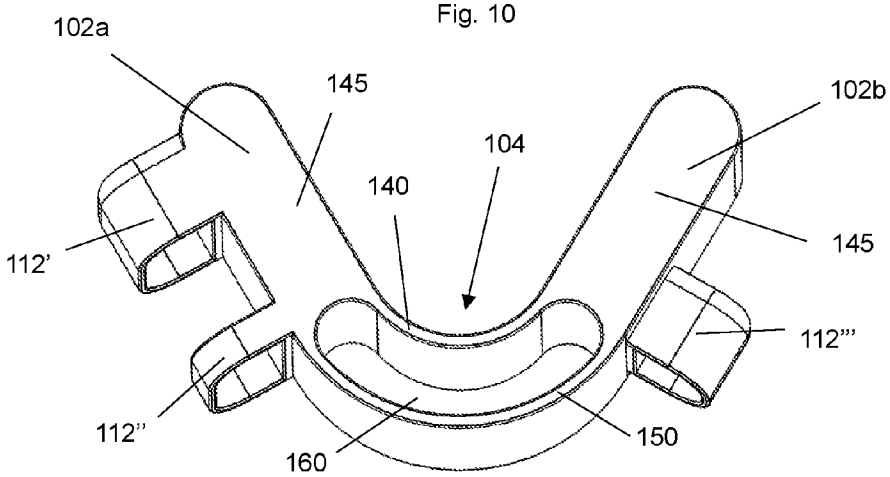

Fig. 11

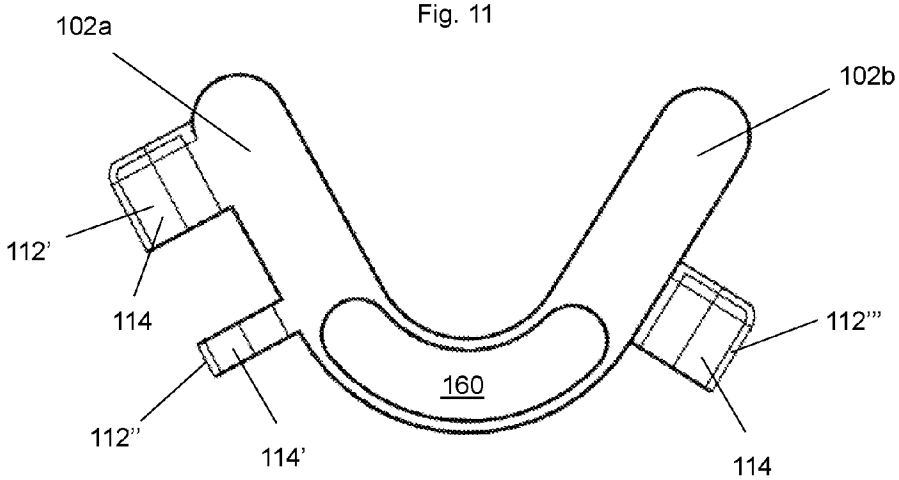

Fig. 12

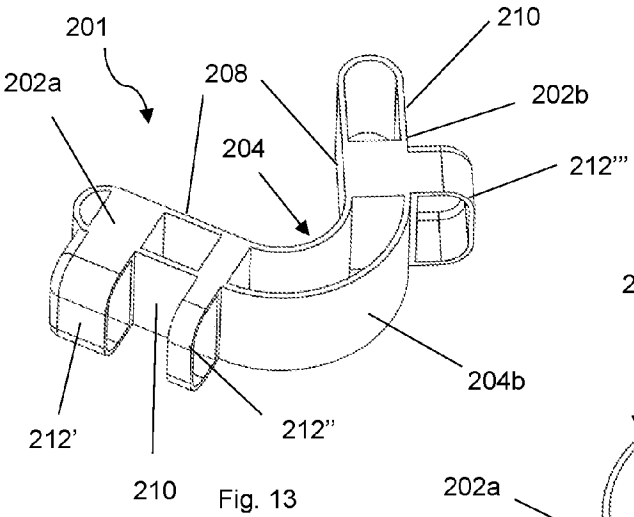

Fig. 13

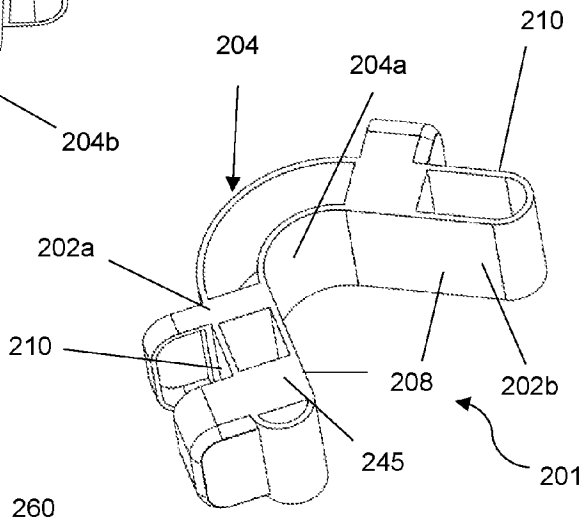

Fig. 14

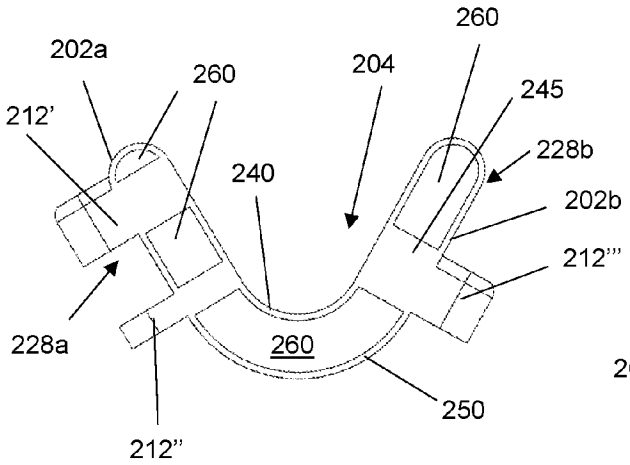

Fig. 15

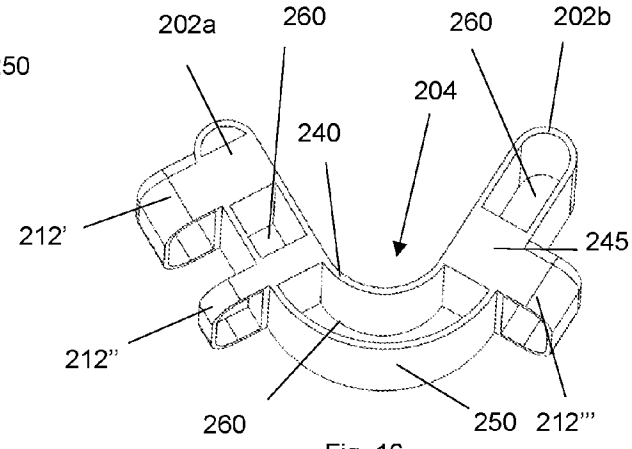

Fig. 16

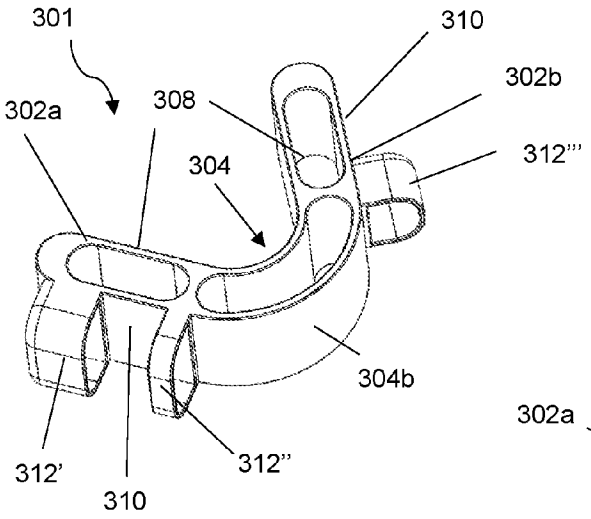

Fig. 17

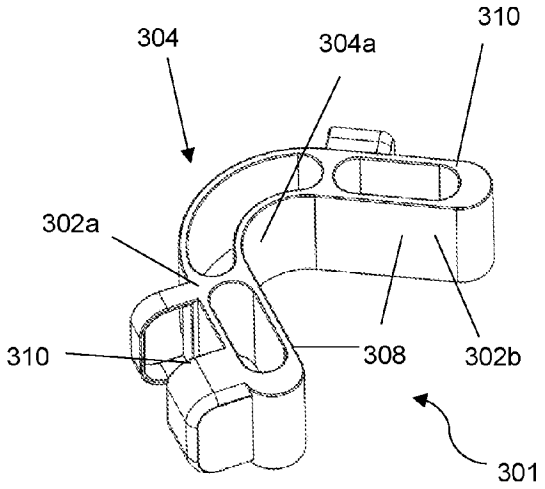

Fig. 18

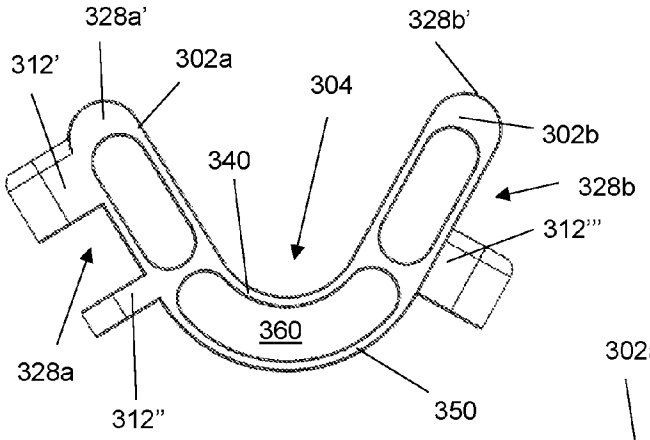

Fig. 19

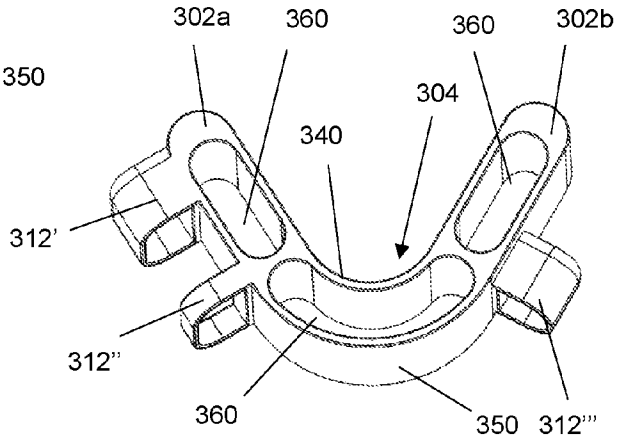

Fig. 20

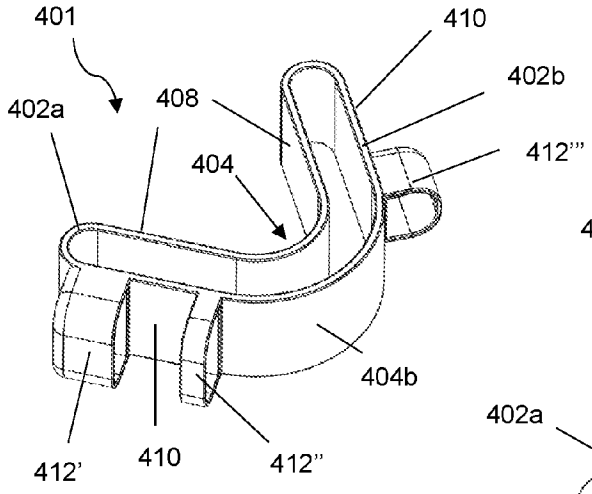

Fig. 21

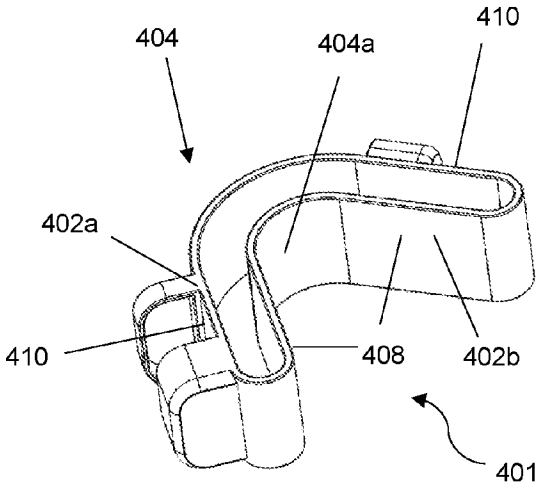

Fig. 22

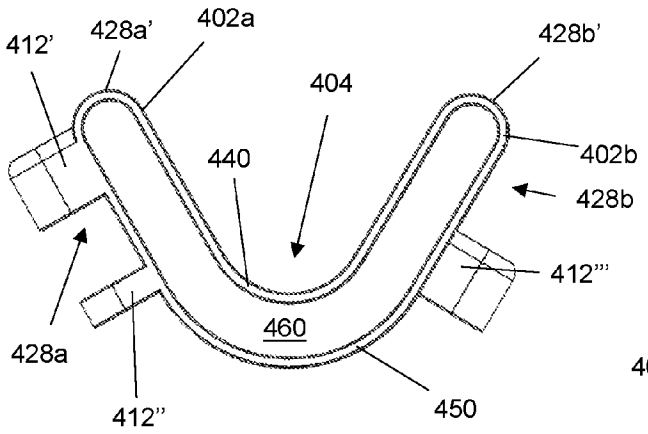

Fig. 23

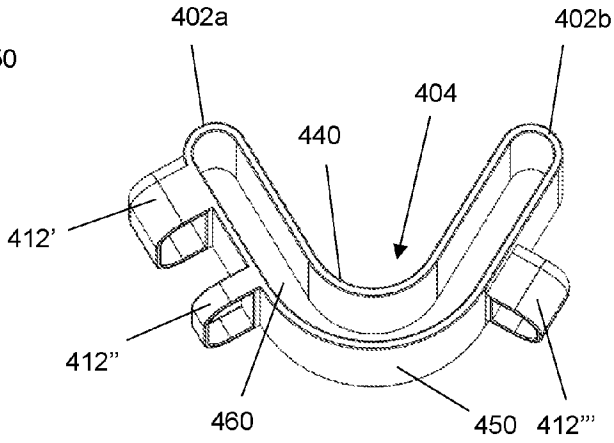

Fig. 24

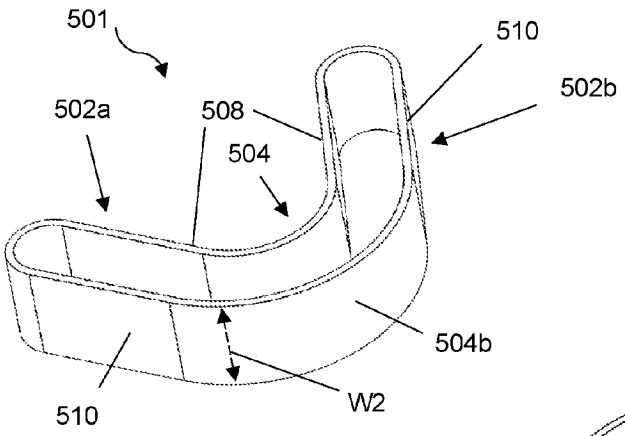

Fig. 25

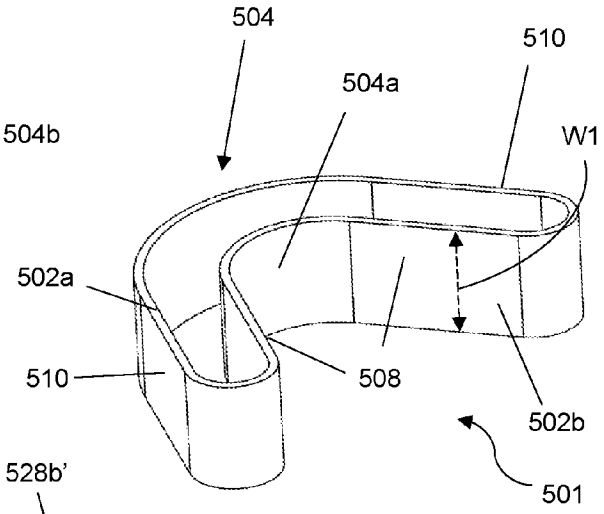

Fig. 26

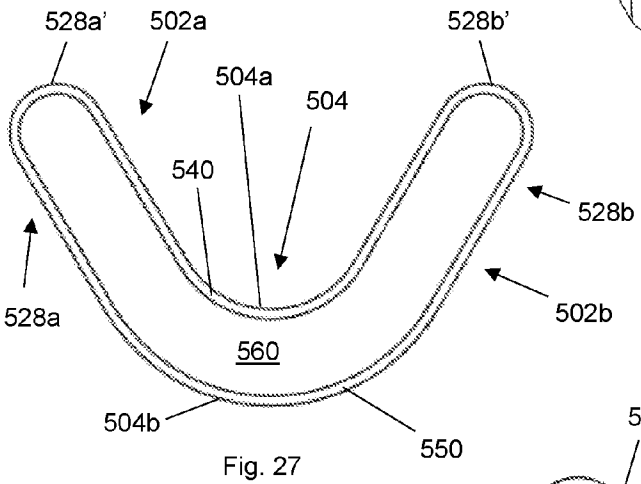

Fig. 27

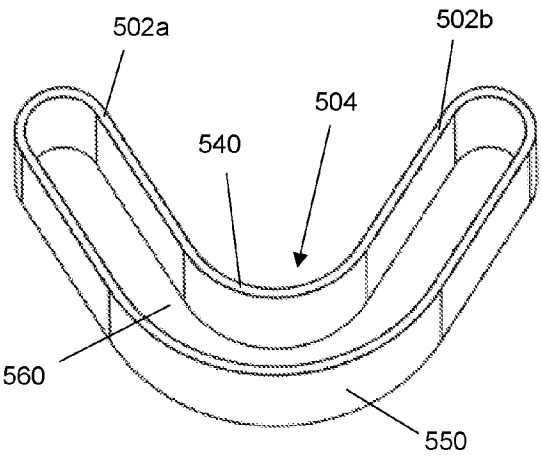

Fig. 28

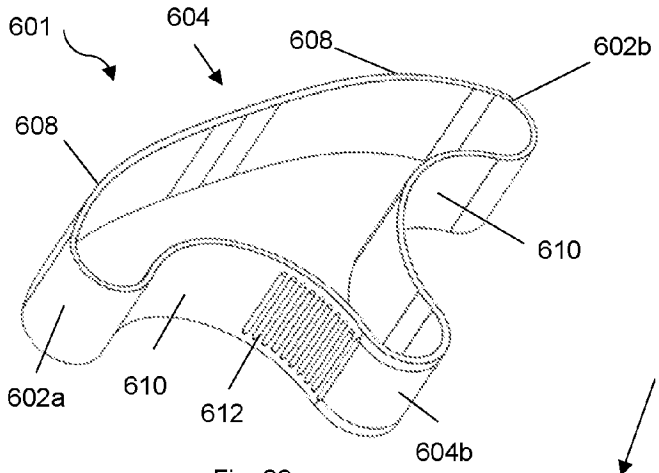

Fig. 29

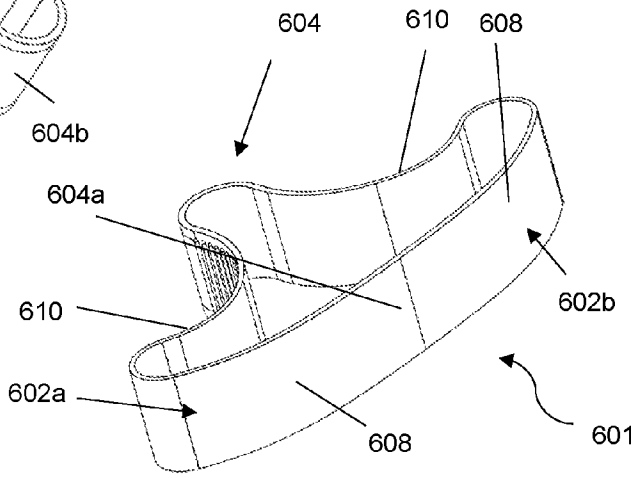

Fig. 30

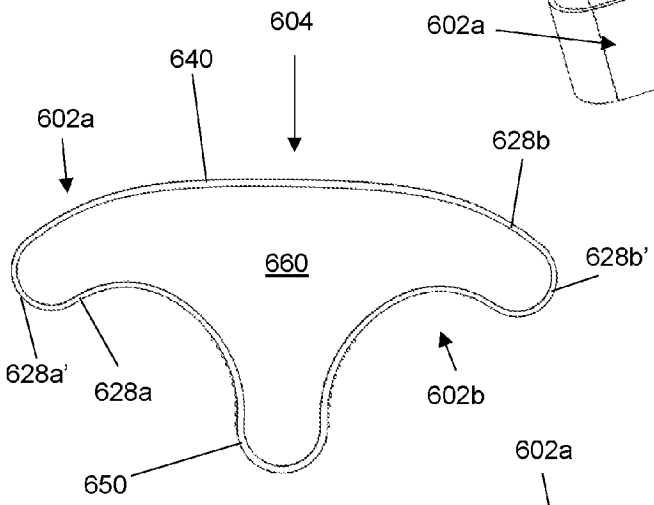

Fig. 31

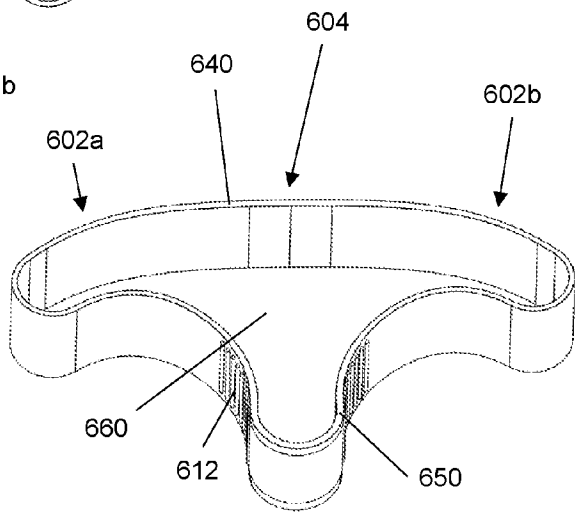

Fig. 32

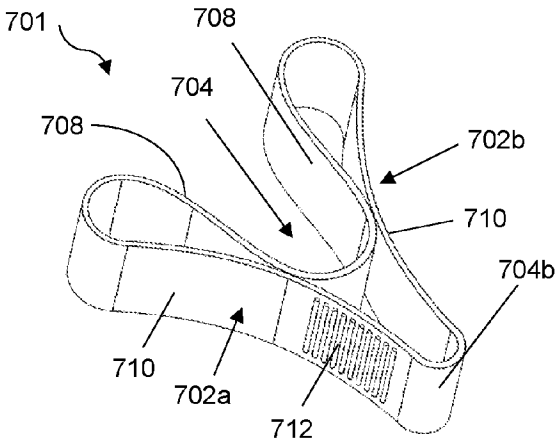

Fig. 33

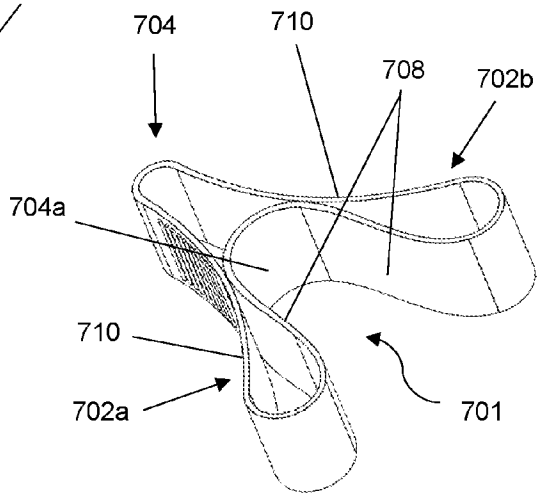

Fig. 34

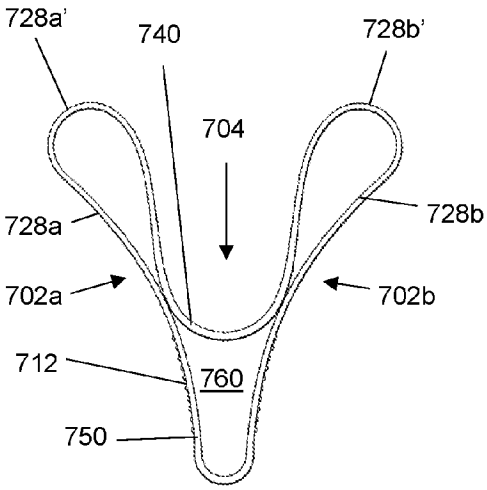

Fig. 35

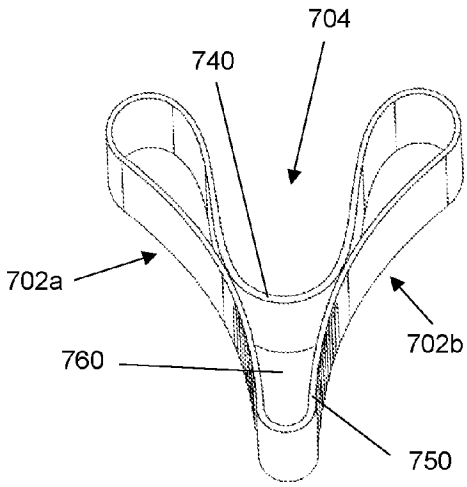

Fig. 36

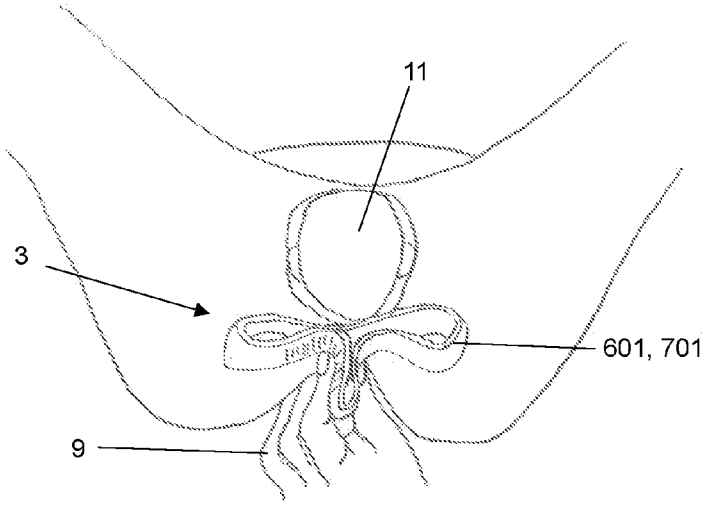

Fig. 37

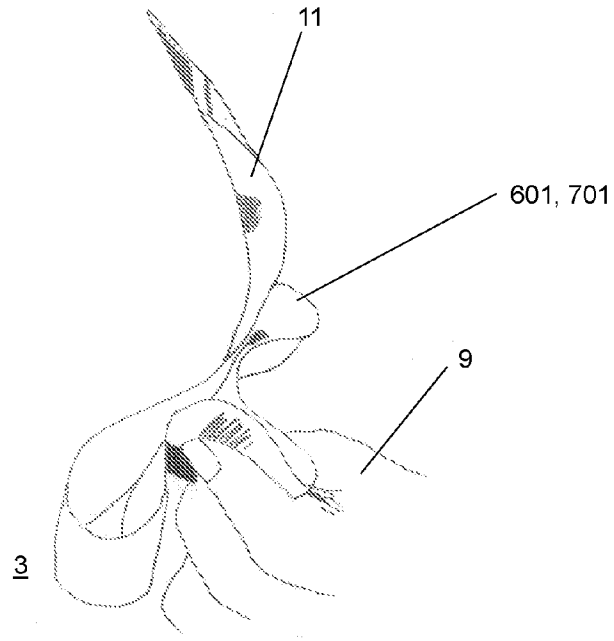

Fig. 38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG2024/050194

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/42 (2006.01)

According to International Patent Classification (IPC)

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

FamPat: perineum, prevent, tear, leg, urge, 会阴，保护，and related terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/198551 A1 (AIR BAG ONE SARL) 15 December 2016 pg 10 ln 1-33, pg 12 ln 3-16, pg 14 ln 16-22, figs 6, 8, 12	1-15
X	US 2016/0249848 A1 (BLURTON, D. D.) 1 September 2016 paras [0029]-[0042], figs 2-3B	1, 6-7, 10-15
X	US 11497640 B1 (BLURTON, D.D. ET AL.) 15 November 2022 col 6 ln 4 – col 9 ln 54, col 12 ln 21-48, col 15 ln 51 – col 17 ln 11, figs 1A-2, 4	1, 6-7, 10-15
X	CN 203138644 U (FAN, A.) 21 August 2013 Whole document of the original non-English language document (a machine translation is enclosed only for your reference)	1, 6-7, 10-15

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

*Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17/05/2024 *(day/month/year)*	21/05/2024 *(day/month/year)*

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG2024/050194

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:

   because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:

   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:

   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please refer to Supplemental Box (Continuation of Box No. III).

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.:

   1-15

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/SG2024/050194

Note: This Annex lists known patent family members relating to the patent documents cited in this International Search Report. This Authority is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2016/198551 A1	15/12/2016	BR 112017023680 A2 EP 3270800 A1 CN 107592800 A AR 101819 A1 AU 2016277456 A1 US 2018/0098790 A1 MX 2017014433 A CA 2969556 A1	17/07/2018 24/01/2018 16/01/2018 18/01/2017 12/10/2017 12/04/2018 10/04/2018 15/12/2016
US 2016/0249848 A1	01/09/2016	NONE	
US 11497640 B1	15/11/2022	US 2023/0130596 A1 WO 2023/076061 A1	27/04/2023 04/05/2023
CN 203138644 U	21/08/2013	NONE	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG2024/050194

Supplemental Box
(Continuation of Box No. III)

This International Searching Authority found multiple inventions in this international application, as follows:

Group 1: Claims 1-15

A device for preventing and/or minimizing vaginal tears during vaginal delivery, the device comprising:

a pair of legs joined at one end of each leg at a join, each leg comprising a perineum facing inner side and an outer side configured to locate a hand of a user, and

wherein a force provided by the hand of the user helps to urge the legs together.

Group 2: Claims 16-30

A device for preventing and/or minimizing vaginal tears during vaginal delivery in a patient, the device comprising:

a first elongate wall configured to engage a perineum of the patient; and

a second elongate wall couplable to the first elongate wall, the second elongate wall configured to be engaged by a user to facilitate the support of the perineum by the first elongate wall

Please refer to **Box No. IV** of Written Opinion of The International Searching Authority (Form PCT/ISA/237) for detailed explanation.