

MEDICAL SPECULUM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Patent Application Numbers 63/497,172, filed April 19, 2023, entitled “MEDICAL SPECULUM”, and 63/581,468, filed September 8, 2023, entitled “MEDICAL SPECULUM”, the disclosure of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The subject matter described herein relates generally to a medical speculum.

BACKGROUND

[0003] A medical speculum is a medical tool used to provide visualization into a body cavity. Speculums or specula are traditionally used for viewing the vaginal cavity for gynecology patients. The traditional vaginal speculum consists of two bills with a hinge and a handle. The bills are inserted into the body cavity in a closed position and separated by squeezing two pieces of the handle together, thereby dilating the vagina and providing visualization and accessibility of the vagina, the cervix, and surrounding areas. Once opened, the speculum can be locked in an open position using a screw based mechanism so an operator (e.g., physician, nurse, mid-wife, etc.) does not need to continue squeezing the pieces of the handle during the inspection. The operator can then proceed with inspecting the vagina, conducting a Pap smear or any other medical procedures that may need to be provided.

SUMMARY

[0004] Systems, methods, and articles of manufacture, are provided for a vaginal speculum.

[0005] According to some aspects, a speculum has a reduced number of components. The speculum includes: a first unitary body, a second unitary body, a handle cover, and a latch body. The first unitary body includes a lower bill and a forward handle portion extending from the lower bill. The forward handle portion and the lower bill are integrally formed. The second unitary body may be rotatably coupled to the first unitary body. The second unitary body includes: an upper bill, an actuator, and a locking lever including a plurality of teeth. The upper bill, the actuator, and the locking lever are integrally formed. The handle cover defines a rearward handle portion coupled to the forward handle portion. The rearward handle portion

and the forward handle portion define a handle of the speculum. The rearward handle portion and the forward handle portion enclose an interior volume of the handle. The latch body includes a locking receiver configured to engage the plurality of teeth of the locking lever and a locking member. The actuator and the locking member are configured to be manipulated to change a position of the upper bill relative to the lower bill.

[0006] In some aspects, the locking lever extends through an opening of the handle cover.

[0007] In some aspects, the locking lever is curved.

[0008] In some aspects, the second unitary body further includes a window configured to allow a user to view an interior of a cervix of a patient in use. The locking lever extends from a lower portion of the window.

[0009] In some aspects, the speculum further includes a lighting module configured to illuminate a region between the upper bill and the lower bill.

[0010] In some aspects, the upper bill includes a track configured to receive at least a portion of the lighting module. The track is positioned on an interior surface of the upper bill. The interior surface is configured to face the lower bill.

[0011] In some aspects, the speculum includes at least one secondary bill configured to rotate in a lateral direction.

[0012] In some aspects, the at least one secondary bill is positioned between the upper bill and the lower bill.

[0013] In some aspects, the at least one secondary bill includes a keyed bill feature configured to be inserted into a corresponding keyed receiver of the first unitary body when the keyed bill feature and the keyed receiver are aligned.

[0014] In some aspects, the keyed bill feature extends at an angle longitudinally and laterally towards the keyed receiver.

[0015] In some aspects, the keyed bill feature is configured to be coupled with the keyed receiver via a snap-fit arrangement.

[0016] In some aspects, the forward handle portion includes an opening through which the locking member is accessible.

[0017] In some aspects, the locking receiver includes an opening through which at least a portion of the locking lever passes.

[0018] In some aspects, the locking receiver includes a latch bar defining at least a portion of the opening. The latch bar is configured to engage at least one of the plurality of teeth of the locking lever to set a position of the upper bill relative to the lower bill.

[0019] In some aspects, the latch body includes a post receiver configured to receive and engage with a post extending from an inner surface of the forward handle portion. Engagement between the post receiver and the post is configured to lock the position of the upper bill relative to the lower bill.

[0020] In some aspects, the post receiver includes a first prong including a first recess and a second prong including a second recess and spaced apart from the first prong. The first recess and the second recess together form at least a portion of an engagement region. The speculum is in a locked position when the post is positioned within the engagement region.

[0021] In some aspects, the post receiver further includes a post passage extending from the post receiver. The post is configured to slide within the post passage when the speculum is in an unlocked position.

[0022] In some aspects, the post receiver extends from the lock.

[0023] In some aspects, the latch body further includes a biasing member receiver positioned on a rearward portion of the latch body. The biasing member receiver is configured to receive at least a portion of a biasing member such that the biasing member is configured to bias the locking member in a locked position.

[0024] According to some aspects, a method of setting a position of the speculum includes pressing the actuator towards the handle and sliding the locking member away from the lower bill. The sliding causes a post passage of the latch body to slide around a post of the first unitary body to slide.

[0025] In some aspects, the method includes sliding the locking member towards from the lower bill, locking the position of the upper bill relative to the lower bill.

[0026] According to some aspects, a method of assembling a speculum includes providing a first unitary body including: a lower bill and a forward handle portion extending from the lower bill. The forward handle portion and the lower bill are integrally formed. The method also includes coupling at least one lateral bill to the first unitary body. The method also

includes coupling a latch body to the first unitary body by at least positioning a lock portion within an opening of the forward handle portion. The latch body further includes: a locking receiver. The method includes coupling a second unitary body to the first unitary body by at least engaging a locking lever of the second unitary body with the locking receiver. The second unitary body includes: an upper bill, an actuator, and the locking lever including a plurality of locking teeth. The upper bill, the actuator, and the locking lever are integrally formed. The method includes coupling a handle cover defining a rearward handle portion to the forward handle portion to define a handle of the speculum and enclose at least a portion of the latch body within an interior volume of the handle.

[0027] In some aspects, the at least one lateral bill is coupled to the first unitary body via a first toolless attachment. The latch body is coupled to the first unitary body via a second toolless attachment. The second unitary body is coupled to the first unitary body via a third toolless attachment. The handle cover is coupled to the forward handle portion via a fourth toolless attachment.

[0028] In some aspects, the first toolless attachment, the second toolless attachment, the third toolless attachment and/or the fourth toolless attachment includes a snap-fit arrangement.

[0029] In some aspects, the at least one lateral bill includes a keyed bill feature. The first unitary body includes a keyed receiver. The coupling the at least one lateral bill to the first unitary body includes: aligning the keyed bill feature and the keyed receiver and inserting the keyed bill feature into the keyed receiver.

[0030] In some aspects, the upper bill includes a track positioned on an interior surface of the upper bill. The method further includes coupling a lighting module to the upper bill by at least positioning at least a portion of the lighting module within the track.

[0031] In some aspects, a kit including a medical speculum as described herein is provided. In embodiments, the kit includes a sleeve accessory. In embodiments, the sleeve accessory is configured to be positioned on an insertion portion of the speculum, wherein the insertion portion includes the upper bill and the lower bill. In embodiments, the sleeve accessory is disposable.

[0032] In embodiments, the sleeve accessory includes a sleeve body defining a lumen that extends from a proximal end to a distal end of the sleeve body, the sleeve body including: a flared portion extending radially outwardly towards the proximal end of the sleeve body; and

an elongated portion extending from the flared portion towards the distal end of the sleeve body.

[0033] In embodiments, the kit includes an applicator having a flat, oblong shape with a distal end and a proximal end, the proximal end being broader than the distal end; wherein the distal end comprises a first prong and a second prong; and wherein the applicator is configured to slide, by the distal end of the applicator, at least partially into the lumen of the sleeve accessory to facilitate positioning of the sleeve accessory on the insertion portion of the medical speculum.

[0034] In embodiments, the sleeve accessory includes a cylindrical sleeve body comprising an outer surface and an inner surface, the inner surface defining a hollow sleeve channel, and at least one open end; wherein the cylindrical sleeve body is configured to be inserted into a vaginal cavity of a patient; and wherein the sleeve body is configured to receive the insertion portion of the speculum in the hollow sleeve channel subsequent to being inserted into the vaginal cavity. In embodiments, the kit includes an applicator configured to carry the sleeve body and facilitate insertion of the sleeve body into the vaginal cavity.

[0035] In embodiments, the sleeve accessory includes a cylindrical sleeve body having a distal end and a proximal end and including an outer surface, an inner surface, the inner surface defining a hollow sleeve channel, and at least one open end. In embodiments, at least a portion of the proximal end of the sleeve body is configured to extend over at least a portion of a proximal end of the insertion portion of the speculum.

[0036] In embodiments, the sleeve body is configured to receive the upper bill and the lower bill in the hollow sleeve channel configured for visibility and access to a vaginal cavity of a patient by a clinician and wherein the sleeve body is configured to expand from a first state to a second state. In embodiments, when the sleeve body is in the first state the proximal end of the sleeve body comprises a gradual broadening of the sleeve body, the gradual broadening of the sleeve body extending beyond the insertion portion of the medical speculum, the gradual broadening of the sleeve body integrally formed with the sleeve body.

[0037] In embodiments, the kit includes a plurality of speculums. In embodiments, the kit includes 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 15, 18, 20, 24, or more speculums. In embodiments, the kit includes a plurality of sleeve accessories. In embodiments, the kit includes 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 15, 18, 20, 24, or more sleeve accessories. In embodiments, the kit includes a plurality of applicators. In embodiments, the kit includes 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 15, 18, 20, 24, or more applicators.

[0038] In some aspects, methods of using a speculum as described herein are provided. In some aspects, the method includes performing a medical procedure on a female, comprising providing a speculum according to any of the embodiments described herein; inserting the speculum into the vagina of a female patient; and performing the medical procedure. In some aspects, the method includes setting a position of the speculum.

[0039] The details of one or more variations of the subject matter described herein are set forth in the accompanying drawings and the description below. Other features and advantages of the subject matter described herein will be apparent from the description and drawings, and from the claims. While certain features of the currently disclosed subject matter are described for illustrative purposes, it should be readily understood that such features are not intended to be limiting. The claims that follow this disclosure are intended to define the scope of the protected subject matter.

DESCRIPTION OF DRAWINGS

[0040] The accompanying drawings, which are incorporated in and constitute a part of this specification, show certain aspects of the subject matter disclosed herein and, together with the description, help explain some of the principles associated with the disclosed implementations. In the drawings,

[0041] FIG. 1 depicts a rear perspective view of an example medical speculum, consistent with implementations of the current subject matter;

[0042] FIG. 2 depicts a front perspective view of an example medical speculum, consistent with implementations of the current subject matter;

[0043] FIG. 3 depicts a side view of an example medical speculum, consistent with implementations of the current subject matter;

[0044] FIG. 4A depicts a front view of an example medical speculum, consistent with implementations of the current subject matter;

[0045] FIG. 4B depicts a rear view of an example medical speculum, consistent with implementations of the current subject matter;

[0046] FIG. 5 depicts a top view of an example medical speculum, consistent with implementations of the current subject matter;

[0047] FIG. 6 depicts a side cross-sectional view of an example medical speculum, consistent with implementations of the current subject matter;

[0048] FIG. 7 depicts an example unitary body of a medical speculum, consistent with implementations of the current subject matter;

[0049] FIG. 8 depicts a side view of an example medical speculum, consistent with implementations of the current subject matter;

[0050] FIG. 9 depicts a front perspective view of an example medical speculum, consistent with implementations of the current subject matter;

[0051] FIG. 10 depicts a side cross-sectional view of an example medical speculum, consistent with implementations of the current subject matter; and

[0052] FIG. 11 depicts an exploded view of an example medical speculum, consistent with implementations of the current subject matter;

[0053] FIG. 12 depicts an exploded view of an example medical speculum, consistent with implementations of the current subject matter;

[0054] FIG. 13 depicts a rear perspective view of an example medical speculum, consistent with implementations of the current subject matter;

[0055] FIG. 14 depicts a front perspective view of an example medical speculum, consistent with implementations of the current subject matter;

[0056] FIG. 15 depicts a side view of an example medical speculum, consistent with implementations of the current subject matter;

[0057] FIG. 16A depicts a front view of an example medical speculum, consistent with implementations of the current subject matter;

[0058] FIG. 16B depicts a rear view of an example medical speculum, consistent with implementations of the current subject matter;

[0059] FIG. 17 depicts a top view of an example medical speculum, consistent with implementations of the current subject matter;

[0060] FIGS. 18A and 18B depict side cross-sectional views of an example medical speculum in an unlatched position, consistent with implementations of the current subject matter;

[0061] FIGS. 19A and 19B depict side cross-sectional views of an example medical speculum in a latched position, consistent with implementations of the current subject matter;

[0062] FIG. 20 depicts a side view of an example medical speculum, consistent with implementations of the current subject matter;

[0063] FIGS. 21A and 21B depict side cross-sectional views of an example medical speculum in a latched and open position, consistent with implementations of the current subject matter;

[0064] FIG. 22 depicts an exploded view of an example medical speculum, consistent with implementations of the current subject matter;

[0065] FIG. 23 depicts a partial exploded view of an example medical speculum, consistent with implementations of the current subject matter;

[0066] FIG. 24 depicts a rear perspective view of an example medical speculum, consistent with implementations of the current subject matter;

[0067] FIG. 25 depicts a front perspective view of an example medical speculum, consistent with implementations of the current subject matter;

[0068] FIG. 26 depicts a side view of an example medical speculum, consistent with implementations of the current subject matter; and

[0069] FIG. 27 depicts an example process for assembling a medical speculum, consistent with implementations of the current subject matter.

[0070] FIG. 28A is a side perspective view of an applicator carrying an insertable sleeve accessory, according to an exemplary embodiment.

[0071] FIG. 28B is a side perspective view of an applicator carrying an insertable sleeve accessory, according to an exemplary embodiment.

[0072] FIG. 29A is a bottom view of an applicator for a sleeve accessory, in an unfolded position, according to an example embodiment.

[0073] FIG. 29B is a top view of the applicator of FIG. 29A in a folded position and positioned in a sleeve accessory, according to an example embodiment.

[0074] FIG. 30A is a top perspective view of a variation of a sleeve accessory in an uncompressed position, according to an example embodiment.

[0075] FIG. 30B is a top view of the variation of the sleeve accessory of FIG. 30A, in an uncompressed position, according to an example embodiment.

[0076] FIG. 31 is a side view of the sleeve accessory of FIGs. 30A and 30B positioned on a medical speculum, according to one embodiment.

[0077] When practical, similar reference numbers denote similar structures, features, or elements.

DETAILED DESCRIPTION

[0078] Generally, a medical speculum is a medical tool used to provide visualization into a body cavity, such as the vaginal cavity, of a patient. Medical speculums generally include a large number of components. The large number of components can make it difficult to quickly assemble the speculums. The large number of components can also increase the cost of the speculums, as each component can require particular manufacturing processes, may increase the amount of material used for the speculum, and/or the like. Medical speculums can further include a large number of small fasteners used to assemble or retain the large number of components and to ensure that the large number of components do not become disassembled during use, which could be problematic for the patient. When various add-ons, such as lights, adjusters, and/or the like are used with the medical speculums, the number of components can also significantly increase.

[0079] Further, the large number of components of the medical speculums may be used to adjust the medical speculums. However, it can be difficult to easily manipulate and/or adjust the medical speculums in use. This can be problematic for the operator during use. The medical speculums can also produce a significant amount of noise when during adjustments. For example, medical speculums may include complicated and/or noisy adjustment mechanisms. Such noise can make procedures uncomfortable for patients, and can disrupt medical procedures.

[0080] The medical speculum consistent with implementations of the current subject matter includes a reduced number of components that are designed to be easily assembled. In some instances, the components of the medical speculum can be coupled using a toolless arrangement. In other words, the reduced number of components of the medical speculum consistent with implementations of the current subject matter can in some instances be assembled (e.g., hand assembled) without the use of tools. Additionally and/or alternatively,

the medical speculum may be assembled without the use of separate fasteners, such as fasteners that are not integrally formed with the components of the speculum. For example, the various components of the medical speculum described herein may be coupled via a snap-fit arrangement. Thus, the medical speculum may be easily, quickly, and efficiently assembled. The medical speculum may also be more cost effective, as a reduced number of components and/or materials may be used in the assembly of the medical speculum.

[0081] Additionally and/or alternatively, the medical speculum, including the medical speculum 100, the medical speculum 200, and/or the medical speculum 300, consistent with implementations of the current subject matter, may provide an improved experience for the operator. For example, adjustment of a position of the medical speculum may be simpler and faster for the operator compared to conventional speculums. The medical speculum consistent with implementations of the current subject matter may also provide for quieter adjustment of the medical speculum, further improving the experience for the operator and/or the patient.

[0082] The medical speculums 100, 200, 300 are described herein. One or more components, properties, and/or features, as described herein, of the medical speculum 100 may be used with and/or interchanged with one or more components, properties, and/or features of the medical speculum 200 and/or the medical speculum 300. One or more components, properties, and/or features, as described herein, of the medical speculum 200 may be used with and/or interchanged with one or more components, properties, and/or features of the medical speculum 200 and/or the medical speculum 300. One or more components, properties, and/or features, as described herein, of the medical speculum 300 may be used with and/or interchanged with one or more components, properties, and/or features of the medical speculum 100 and/or the medical speculum 200. Accordingly, while the medical speculums 100, 200, 300 refer to examples of a medical speculum, any of the features described herein may be interchanged with and/or used with one another.

[0083] FIGS. 1-12 depict an example of a medical speculum 100 (also referred to herein as the “speculum 100”) consistent with implementations of the current subject matter. The medical speculum 100 may be disposable. In other words, the medical speculum 100 may be a single-use speculum and disposed of after a single use. In other implementations, the medical speculum 100 may be used a limited number of times, such as one, two, three, four, or five times, prior to disposal of the medical speculum. In other implementations, the medical

speculum 100 may be used multiple times. In other words, the medical speculum 100 may be reusable. In embodiments, the medical speculum 100 may be cleaned (e.g., autoclaved) for reuse.

[0084] The medical speculum 100 may be made of one or more materials. For example, the medical speculum 100 may be made of a material that is sufficiently rigid to support tissue of the patient's body, yet soft and/or flexible so as to not cause discomfort to the patient. The one or more materials may include a biomaterial safe to use inside the body. The one or more materials may include at least one of polycarbonate, plastic, metal, titanium, aluminum, stainless steel, acrylic, polyethylene, polyester, polyethyleneaphthlate, polystyrene, polyvinylchloride, polyethersulfone, polyetherimide, polysulfone, polyetheretherketone, polyphenylsulfone, and polymethyl methacrylate. In some implementations, all of the components of the medical speculum 100 are made of the same material. In other implementations, at least some of the components of the medical speculum 100 are made of the same material. In some implementations, the one or more materials are clear or otherwise transparent.

[0085] The medical speculum 100 includes a first unitary body 104, a second unitary body 102, a handle cover 118, a latch body 161, and/or at least one secondary bill 185. The medical speculum 100 may additionally and/or alternatively include an illumination source, such as a lighting module 150 and/or a biasing member 182. Accordingly, the medical speculum 100 may include a limited number of components for easy, quick, and efficient assembly.

[0086] Referring to FIGS. 1-4, the first unitary body 104 includes a lower bill 108 and a forward handle portion 132. The forward handle portion 132 may extend from the lower bill 108 and form a handle 120 with the handle cover 118. The lower bill 108 and the forward handle portion 132 may be integrally formed. For example, the lower bill 108 and the forward handle portion 132 may be formed (e.g., molded, etc.) as a single unitary component having a unitary construction. In some implementations, the lower bill 108 and the forward handle portion 132 cannot be separated without destroying and/or significantly damaging the first unitary body 104.

[0087] The second unitary body 102 includes an upper bill 106, an actuator 110, a locking lever 126, and/or a window 114. The upper bill 106 may be positioned at a forward portion of the second unitary body 102 and the actuator 110, the locking lever 126, and the

window 114 may be positioned at a rearward portion of the second unitary body 102. The forward portion and the rearward portion of the second unitary body 102 may be angled downwardly away from one another. The components of the second unitary body 102, such as the upper bill 106, the actuator 110, the locking lever 126, and/or the window 114 may be integrally formed. For example, the upper bill 106, the actuator 110, the locking lever 126, and/or the window 114 may be formed (e.g., molded, etc.) as a single unitary component having a unitary construction. In some implementations, the upper bill 106, the actuator 110, the locking lever 126, and/or the window 114 cannot be separated without destroying and/or significantly damaging the second unitary body 102.

[0088] The first unitary body 104 and the second unitary body 102 are rotatably coupled. For example, the first unitary body 104 and the second unitary body 102 can rotate with respect to one another. As shown in FIGS. 11 and 12, the first unitary body 104 includes protruding couplers 140 positioned on opposite sides of the first unitary body 104 along a transition portion 104a between the lower bill 108 and the forward handle portion 132. The protruding couplers 140 extend outwardly from the transition portion 140a. The second unitary body 102 includes openings 142 that can receive the protruding couplers 140. The protruding couplers 140 may be inserted into and/or snap into the openings 142. For example, the protruding couplers 140 may each be coupled to a corresponding one of the openings 142 via a toolless attachment. Together, the protruding couplers 140 and the openings 142 may form a hinge that allows the upper bill 106 to rotate with respect to the lower bill 108. This further allows for the speculum 100 to move between a closed position (see FIGS. 1-6) and an opened position (see FIGS. 8-10), as described in more detail below.

[0089] When the speculum 100 is in the closed position, the speculum 100 can be inserted in a patient's vagina. The operator places an end of the upper bill 106 and the lower bill 108 in line with an opening of the vagina and applies a force along a longitudinal axis of the upper bill 106 and the lower bill 108 to push the upper bill 106 and the lower bill 108 into the vagina. The operator may position the speculum 100 at a depth of the vagina to provide a clear view of the cervix when the upper bill 106 and the lower bill 108 of the speculum 100 are opened. The speculum 100 may be inserted so that an end of the upper bill 106 and the lower bill 108 are located below the cervix. Once the upper bill 106 and the lower bill 108 are separated, the cervix may then fall into the viewing window created by the separation of the upper bill 106 and the lower bill 108.

[0090] The upper bill 106 and the lower bill 108 each include an elongated portion of the speculum 100 (see FIGS. 1-6). The elongated portion may have a width that is larger than a height of the elongated portion, creating an oblong shape. Alternatively, the height and width of the elongated portion may be configured in such a way that when the upper bill 106 and the lower bill 108 are closed, a circular cross section is formed. Other configurations are contemplated. At an end of the elongated portion, away from the handle 120, the upper bill 106 and the lower bill 108 may be rounded. A rounded end may provide more comfort to a patient whom will be receiving the speculum 100 in a cavity. The upper bill 106 and the lower bill 108 may also be configured such that when in the closed position, the end of the upper bill 106 and the lower bill 108 may abut one another without any gaps. In other embodiments, the upper bill 106 and the lower bill 108 may be longer than the other to create a gap when the bills are closed, preventing tissue from becoming lodged in between the upper bill 106 and the lower bill 108 during insertion or closing of the bills. The upper bill 106 and the lower bill 108 may have a semi-circular cross section along a length of the upper bill 106 and the lower bill 108, where the flat portions of the semi-circles are moved together when the upper bill 106 and the lower bill 108 are in a closed position. In these implementations, an outer edge and an inner edge of the upper bill 106 and the lower bill 108 may be curved such that when the upper bill 106 and the lower bill 108 are in the closed position, a cross section of the upper bill 106 and the lower bill 108 forms a cylinder shape.

[0091] Referring back to FIGS. 11 and 12, the speculum 100 includes at least one secondary bill 185. The at least one secondary bill 185 aids in retaining side wall tissue of the vagina to maintain a clear viewing window for the operator. The at least one secondary bill 185 includes at least one, two, three, four, five, six or more secondary bills 185. For example, the at least one secondary bill 185 includes a first secondary bill 186 and a second secondary bill 187.

[0092] The first secondary bill 186 and the second secondary bill 187 are positioned opposite one another. The first secondary bill 186 and the second secondary bill 187 may be sized to fit inside the upper bill 106 and the lower bill 108 when in the closed position. The first secondary bill 186 and the second secondary bill 187 are substantially identical opposites of one another. The first secondary bill 186 and the second secondary bill 187 includes arms 186A and 187A, respectively. An exterior of the arms 186A, 187A may be rounded to be more comfortable for the patient and to provide a clear view of the vagina and speculum once inserted by providing support to the side tissue of the vagina.

[0093] The first secondary bill 186 includes a first keyed bill feature 188, such as a keyed protrusion. The second secondary bill 187 includes a second keyed bill feature 189, such as a keyed protrusion. The first keyed bill feature 188 and the second keyed bill feature 189 are configured to couple with a corresponding coupler 144 (e.g., keyed receiver) of the first unitary body 104. The first keyed bill feature 188 and the second keyed bill feature 189 may include a feature extending from an end of a corresponding protrusion that is configured to mate with and/or fit within a corresponding coupler 144 of the first unitary body 104. While the first keyed bill feature 188 and the first secondary bill 186 are described herein, the second keyed bill feature 189 and the second secondary bill 187 include the same (e.g., the same and/or mirrored) features and/or components.

[0094] Referring to FIGS. 11 and 12, the first keyed bill feature 188 is positioned along a length of the first secondary bill 186. For example, a first portion 145 of the first secondary bill 186 is positioned on one side of the first keyed bill feature 188 and a second portion 146 is positioned on the other side of the first keyed bill feature 188. The first portion 145 is longer than the second portion 146. The first portion 145 is configured to contact the tissue of the patient in use, while the second portion 146 is positioned between the upper bill 106 and the lower bill 108. The first portion 145 includes an elongated portion towards an end of the first secondary bill 186 and a flared portion between the end and the second portion 146. The flared portion extends outwardly from the elongated portion. The second portion 146 further extends outwardly from the flared portion. This configuration allows for the at least one secondary bill 185 to easily and comfortably lift and/or retain tissue in use.

[0095] Referring again to FIGS. 11 and 12, the at least one secondary bill 185 includes at least one (e.g., one, two, three, four, five, or more) cutouts 190. The cutouts 190 are positioned on an interior side of the at least one secondary bill 185. The cutouts 190 may reduce an amount of material used for manufacturing. The cutouts 190 also provide for a lightweight speculum, which improves the experience for the operator when using the speculum 100.

[0096] Referring to FIGS. 1-12, the first unitary body 104 includes the lower bill 108 and the forward handle portion 132. The first unitary body 104 may further include the coupler 144, an opening 134, a post 170, and/or coupling features 171, each of which may be integrally formed with the lower bill 108 and the forward handle portion 132 to form the first unitary body 104.

[0097] The coupler 144 includes a coupler corresponding to a respective one of the first keyed bill feature 188 and the second keyed bill feature 189. The coupler 144 similarly includes a keyed feature corresponding to the keyed feature of the first keyed bill feature 188 and the second keyed bill feature 189. The coupler 144 couples to the first keyed bill feature 188 and the second keyed bill feature 189 of the corresponding secondary bill when the keyed feature of the first keyed bill feature 188 and the second keyed bill feature 189 and the corresponding coupler 144 are aligned. The couplers 144 extend (e.g., at an angle) from a transition portion 104a of the first unitary body 104. The couplers 144 are positioned adjacent to couplers 140, which couple the first unitary body 104 to the second unitary body 102.

[0098] The opening 134 receives at least a portion of the locking member 122, such as a surface of the locking member 122 and/or a slider 124. The locking member 122 is accessible to the operator via the opening 134. The locking member 122, as described in more detail below, may be manipulated to lock a position of the upper bill 106 relative to the lower bill 107, and/or the at least one secondary bill 185.

[0099] The coupling features 171 extend inwardly from an edge of the forward handle portion 132 towards an inner surface 172 of the forward handle portion 132. The coupling features 171 are configured to couple to the handle cover 118, such as via a snap-fit arrangement. Thus, the coupling features 171 may couple the handle cover 118 to the first unitary body 104 via a toolless attachment (e.g., without the use of tools).

[0100] The post 170 extends from the inner surface 172 of the forward handle portion 132. The post 170 may be cylindrical, rectangular, square, and/or the like. The post 170 is configured to engage with at least a portion of the latch 160 (discussed in more detail below).

[0101] Referring to FIGS. 1-12, the second unitary body 102 includes the upper bill 106, the actuator 110, and the locking lever 126. The second unitary body 102 may further include a track 136 (see FIG. 7). The track 136 may be positioned on and/or extend from an inner surface of the upper bill 106. The track 136 may be positioned along the inner surface of the upper bill 106 closer to the window 114 than to an end of the elongated portion of the upper bill 106.

[0102] The track 136 may be configured to receive an illumination source, such as a lighting module 150. The lighting module 150 is configured to illuminate the cavity in which the speculum 100 is placed in order to allow better visualization of the cavity and execution of procedures in the cavity. The lighting module 150 provides one or more illumination elements,

such as light emitting diodes (“LEDs”). The configuration of the lighting module 150 provides illumination elements at or near the perimeter of the window 114, so as not to obstruct the view of the user through the window 114. The track 136 may be centered along the inner surface of upper bill 106 to provide centered illumination of the cavity.

[0103] The track 136, integrated with or otherwise integrally formed with the upper bill 106, allows for easy, quick, and efficient assembly and coupling of the lighting module 150 to the second unitary body 102. The track 136 is arranged so that at least a portion of the lighting module 150 can be pressed and/or snapped into the track 136 and so that the track 136 retains the lighting module 150. Accordingly, the lighting module 150 can be coupled to the speculum 100 via a toolless assembly, such as via a snap-fit arrangement.

[0104] The lighting module 150 may include an LED 151 with one or more legs 154, a power source 152, such as one or more batteries (e.g., a one button cell batter, a two button cell battery and/or the like) electrically coupled to the LED 151 (e.g., through in line resistors), and an activation mechanism 153. The power source 152 may have a voltage of about 3.0 V, but batteries having other voltages may also be used. The activation mechanism 153 can be manipulated to cause the LED 151 to go from an "off state to an "on" state. In this example, the activation mechanism 154 includes a pull tab positioned between and/or on (e.g., in contact with) the one or more batteries, thereby preventing discharge of the batteries and keeping the LED 151 "off." The pull tab is configured to be pulled by the operator to dislodge the pull tab from contact with the power source 152, thereby allowing the flow of current and providing power to the LED 151. In some implementations, there is no mechanism for powering the LED 151 off after they have been turned on. In some implementations, the same activation mechanism 154 may be used to power off the LED 151 or there may be a second mechanism for powering off the LED 151.

[0105] Referring again to FIG. 7, the track 136 includes an LED recess 136C, a LED leg passage 136A, and a power source recess 136B. The LED recess 136C may receive and/or retain the LED 151, such as via a press-fit, snap-fit, or the like, arrangement. The LED leg passage 136A may receive and/or retain the legs 154 of the LED 151. For example, the one or more legs 154 may be bent and/or pressed into the LED leg passage 136A. The LED leg passage may be shaped in a “Y” configuration to securely retain the one or more legs 154. The power source recess 136B may receive and/or retain the power source 152, such as via a snap-fit, press-fit, or the like, arrangement. The power source 152 may be coupled to the power

source recess 136B such that at least a portion of the one or more legs 154 is pressed between the power source 152 and the inner surface of the upper bill 106 to more securely retain the lighting module 150. This allows for contact to be maintained between the power source 152 and the one or more legs 154 of the LED 151.

[0106] As shown in FIG. 1, the second unitary body 102 includes a window 114 defined by a window frame along the rearward portion of the second unitary body 102. The window frame extends from the upper bill 106. The window 114 may allow for inspection of the cervix, such as when the upper bill 106 and the lower bill 108 are separated. The window 114 may include a window extension 116 extending from a lower end of the window 114. The window extension 116 may be squared or have another shape. The window extension 116 may extend towards the actuator 110. The window extension 116 may allow for further viewing of the cervix through the viewing window formed between the upper bill 106 and the lower bill 108. The window extension 116 may additionally and/or alternatively allow for viewing of the locking lever 126 through the window 114. The window 114 may be circular, oblong, rectangular, or any other shape that would provide an opening for viewing. The window 114 has a size and shape to allow the user to see the entire opening created when the upper bill 106 and the lower bill 108 are in the open position.

[0107] Referring again to FIGS. 1-12, the actuator 110 may include a thumb tab 112. The actuator 110 may extend from the window 114. The actuator 110 may form at least a part of the rearward portion of the second unitary body 102. The actuator 110, alone, or together with the latch 160, causes opening and closing of the upper bill 106, the lower bill 108, the first secondary bill 186 and the second secondary bill 187. The thumb tab 112 includes a top surface to provide a rigid surface for the operator to apply a force, such as via the operator's thumb while holding the handle 120. A top of the thumb tab 112 has a curvature provided to maintain an ample viewing window for the operator, such as via the window 114. A force is applied by a thumb of the user to the thumb tab 112 and causes the upper bill 106 and the lower bill 108, and/or the first and second secondary bills 186, 187 to open (e.g., separate). In some implementations, a distance the thumb tab 112 moves correlates to a distance the upper bill 106 and the lower bill 108 separate. In this regard, the operator would be able to select a specific distance between the upper bill 106 and the lower bill 108 for each patient. The upper bill 106 and the lower bill 108 may open in a continuous fashion when force is continuously applied to the thumb tab 112. Alternatively, the force applied to the thumb tab 112 may cause

the upper bill 106 and the lower bill 108 to only open a specified distance. Opening and closing of the speculum 100 is described in further detail below.

[0108] The locking lever 126 extends from a lower portion of the window 114, such as from an end of the window extension 116. The locking lever 126 may be curved such that an inner surface 126A faces the inner surface of the second unitary body 102, while an outer surface 126B faces the inner surface of the first unitary body 104. The locking lever 126 is curved towards the latch 160 to engage with the latch 160 as described in more detail herein. The locking lever 126 can include a plurality of teeth 130. The plurality of teeth 130 may engage the latch 160. Each of the plurality of teeth 130 may represent a position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185. For example, the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 can be separated (e.g., opened) by a predetermined amount defined by the spacing between each of the plurality of teeth 130. The plurality of teeth 130 include one, two, three, four, five, six, seven, eight, nine, ten or more teeth.

[0109] Referring again to FIGS. 11 and 12, the handle cover 118 may define a rearward handle portion of the handle 120. The handle cover 118 may couple with the forward handle portion 132 to define the handle 120 of the speculum 100 that may be grasped by the operator in use. The rearward handle portion (e.g., the handle cover 118) may enclose an interior volume in which at least a portion of (e.g., all or substantially all) the latch 160 is positioned. The handle cover 118 includes an opening 138 through which the locking lever 126 may pass to engage with the latch 160 within the interior volume of the handle 120. As the actuator 110 is manipulated by the operator, the locking lever 126 passes in and out of the opening 138. The opening 138 may be positioned towards an end of the handle cover 118 closer to the second unitary body 102. The handle cover 118 includes a plurality of coupling features 135 configured to engage the coupling features 171 of the forward handle portion 132. The plurality of coupling features 135 may be coupled to the coupling features 171 via a snap-fit or other coupling arrangement, such as a toolless assembly arrangement.

[0110] The latch 160 is positioned at least partially within the interior volume of the handle 120. The latch 160 includes a latch body 161. The latch body 161 includes a locking receiver 162 and a locking member 122. The locking receiver 162 may engage with the plurality of teeth 130 of the locking lever 126. For example, the locking receiver 162 includes an opening 164 through which at least a portion of the locking lever 126 passes. At one end,

the locking receiver 162 includes a latch bar 166 defining at least a portion of the opening 164. The latch bar 166 is configured to engage at least one of the plurality of teeth 130 of the locking lever 126. The engagement between the plurality of teeth 130 and the latch bar 166 sets a position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 relative to one another. For example, as shown in FIG. 6, an end portion of the locking lever 126 and/or a first tooth of the plurality of teeth 130 positioned near the end portion of the locking lever 126 engages the latch bar 166 when the speculum 100 is in the closed position. As the locking lever 126 passes further through the opening 164, such as when the actuator 110 is pressed towards the handle 120, the latch bar 166 may engage with at least one of the remaining teeth of the plurality of teeth 130 positioned farther away from the end of the locking lever 126 (see FIG. 10). This increments the position of the upper bill 106, the lower bill 108, and the at least one secondary bill 185 relative to one another such that the upper bill 106, the lower bill 108, and the at least one secondary bill 185 separate.

[0111] The latch body 161 includes a forward side 161A and a rearward side 161B. the forward side 161A of the latch body 161 includes the locking member 122 and the slider 124. The slider 124 extends from the locking member 122 and allows for the locking member 122 to be translated relative to the handle 120 via the opening 134. The locking member 122 may form at least a portion of the forward side 161A. The locking member 122 includes a surface of the forward side 161A that is accessible via the opening 134. The locking member 122 may be manipulated by the operator, such as in conjunction with the actuator 110 to set a position of the speculum 100.

[0112] The latch body 161 may include a post receiver 168 configured to receive and engage with the post 170 of the forward handle portion 132. The post receiver 168 extends from the locking member 122. The engagement between the post receiver 168 and the post 170 is configured to set the position of the speculum 100. For example, the post receiver 168 includes two prongs, such as a first prong 174 and a second prong 176. The first prong 174 and the second prong 176 are spaced apart from one another to define a post passage 178 therebetween. The post passage 178 is configured to receive the post 170 such that the post 170 is permitted to slide within the post passage 178. The post 170 extends from the inner surface 172, into, and/or through the post passage 178.

[0113] The post 170 is configured to slide within the post passage 178, such as when the locking member 122 and/or the slider 124 is pushed towards the lower bill 108. In this

configuration, the speculum 100 may be in an adjustment state in which the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 separate (e.g., open) and/or close freely based on actuation (e.g., pressing on) of the actuator 110 (e.g., the thumb tab 112). In this state, the locking lever 126 passes through the opening 164 without locking a position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185. Thus, in this state, the operator may easily adjust a position of the speculum 100, such as the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 by at least pressing on the actuator 110 (e.g., the thumb tab 112), such as with their thumb, and positioning the locking member 122 in the unlocked position, such as by sliding the slider 124 away from the lower bill 108 (e.g., in a downwards direction).

[0114] Referring again to FIGS. 11 and 12, the first prong 174 includes a first prong recess 175 and the second prong 176 includes a second prong recess 177. The first prong recess 175 and the second prong recess 177 are positioned at and/or adjacent one end of the post passage 178, such an end of the post passage 178 farther away from the locking member 122. The first prong recess 175 and the second prong recess 177 together form a post opening 179 (e.g., an engagement region). The speculum 100 may be in a locked position when the post 170 is positioned within the post opening 179.

[0115] The post opening 179 is configured to receive the post 170, such as when the locking member 122 is in the locked state or locked position. In the locked position, the locking member 122 and/or the slider 124 may be in a neutral position (e.g., centered within the opening 134) and/or pushed in an upwards direction towards the lower bill 108. For example, the latch 160 may slide via manipulation of the locking member 122 and/or the slider 124 such that the post slides from the post opening 179 to the post passage 178. Some force may need to be applied to the locking member 122 and/or the slider 124 to move the latch 160 such that the post 170 passes over a wall separating the post passage 178 from the post opening 179. In this position, the position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 may be set. In other words, the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 may not move relative to one another. In some implementations, in this position, the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 may move relative to one another only when the actuator 110 is actuated (e.g., pressed towards the handle 120).

[0116] For example, in some implementations, in the locked position, the actuator 110 may be actuated to cause the locking lever to slide through the opening 164 such that the latch bar 166 engages a next tooth of the plurality of teeth 130 of the locking lever 126. As an example, in the locked position, the actuator 110 may be pressed towards the handle 120, causing the locking lever 126 to slide through the opening 164 to a next position (e.g., a next tooth). This allows for easy and quick incremental adjustments of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 relative to one another. This also allows for the position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 to be maintained, such as when the actuator 110 is not being actuated.

[0117] The position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 may be reset to the closed position when the locking member 122 and/or the slider 124 are pushed away from the lower bill 108. This releases the post 170 from the post opening 179 and slides the post 170 into the post passage 178 in which the post 170 may slide as the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185 return to the closed position. Accordingly, the latch body 161 and/or the locking lever 126 allows for quick and easy locking and unlocking of the speculum 100 as well as for adjusting a position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185. The latch body 161 and/or the locking lever 126 may allow for locking and unlocking of the speculum 100 as well as for adjusting a position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185, using a single hand. For example, the operator may use their thumb to manipulate the actuator, and another finger, such as an index finger to manipulate the locking member 122 and/or slider 124 to adjust the position of the latch body 161. The latch body 161 and/or the locking lever 126 may also allow for quiet locking and unlocking of the speculum 100 as well as for adjusting a position of the upper bill 106, the lower bill 108, and/or the at least one secondary bill 185. Thus, the latch body 161 and/or the locking lever 126 may provide for an improved experience for the operator.

[0118] In some implementations, the latch body 161 includes a biasing member receiver 180 on the rearward side 161A of the latch body 161. The biasing member receiver 180 may receive and/or secure a biasing member 182, such as a spring or the like. The biasing member 182 may be coupled to the biasing member receiver 180 via a snap-fit, press-fit, or other toolless arrangement. Referring to FIGS. 11 and 12, at least a portion of the biasing member 182 may be positioned within the biasing member receiver 180, and at least another portion of the biasing member 182 may contact the ridges 173. This allows for the biasing

member 182 to bias the latch 160, and thus the locking member 122, in the closed position. For example, the biasing member 182 may bias the latch body 161 and/or the locking member 122 so that the post opening 179 is biased towards retaining the post 170. In this manner, when the locking member 122 and/or the slider 124 is pressed away from the lower bill 108, the biasing member 182 biases the latch body 161 with sufficient force to cause the post 170 to overcome the wall of the post passage 178 and slide into the post opening 179. In some implementations, the handle cover 118 includes a ledge 139 that helps to secure the biasing member 182 and maintain contact between the biasing member 182 and the latch body 161.

[0119] FIGS. 13-23 illustrate an example of a medical speculum 200 (also referred to herein as a speculum 200) consistent with implementations of the current subject matter. As noted, one or more components, features, and/or properties of the speculum 200 may be used with and/or interchanged with one or more components, features, and/or properties of the speculum 100 and/or the speculum 300.

[0120] The speculum 200 includes a first unitary body 204, a second unitary body 202, a handle cover 218, a latch body 261, and/or at least one secondary bill 285. The medical speculum 200 may additionally and/or alternatively include an illumination source, such as a lighting module 250 and/or a biasing member 282. Accordingly, the medical speculum 200 may include a limited number of components for easy, quick, and efficient assembly.

[0121] Referring to FIGS. 13-16B, the first unitary body 204 includes a lower bill 208 and a forward handle portion 232. The forward handle portion 232 may extend from the lower bill 208 and form a handle 220 with the handle cover 218. The lower bill 208 and the forward handle portion 232 may be integrally formed. For example, the lower bill 208 and the forward handle portion 232 may be formed (e.g., molded, etc.) as a single unitary component having a unitary construction. In some implementations, the lower bill 208 and the forward handle portion 232 cannot be separated without destroying and/or significantly damaging the first unitary body 204.

[0122] The second unitary body 202 includes an upper bill 206, an actuator 210, a locking lever 226, and/or a window 214. The upper bill 206 may be positioned at a forward portion of the second unitary body 202 and the actuator 210, the locking lever 226, and the window 214 may be positioned at a rearward portion of the second unitary body 202. The forward portion and the rearward portion of the second unitary body 202 may be angled downwardly away from one another. The components of the second unitary body 202, such as

the upper bill 206, the actuator 210, the locking lever 226, and/or the window 214 may be integrally formed. For example, the upper bill 206, the actuator 210, the locking lever 226, and/or the window 214 may be formed (e.g., molded, etc.) as a single unitary component having a unitary construction. In some implementations, the upper bill 206, the actuator 210, the locking lever 226, and/or the window 214 cannot be separated without destroying and/or significantly damaging the second unitary body 202.

[0123] The first unitary body 204 and the second unitary body 202 are rotatably coupled. For example, the first unitary body 204 and the second unitary body 202 can rotate with respect to one another. As shown in FIGS. 22 and 23, the first unitary body 204 includes protruding couplers 240 positioned on opposite sides of the first unitary body 204 along a transition portion 204a between the lower bill 208 and the forward handle portion 232. The protruding couplers 240 extend outwardly from the transition portion 240a. The second unitary body 202 includes openings 242 that can receive the protruding couplers 240. The protruding couplers 240 may be inserted into and/or snap into the openings 242. For example, the protruding couplers 240 may each be coupled to a corresponding one of the openings 242 via a toolless attachment. Together, the protruding couplers 240 and the openings 242 may form a hinge that allows the upper bill 206 to rotate with respect to the lower bill 208. This further allows for the speculum 200 to move between a closed position (see FIGS. 13-19B) and an opened position (see FIGS. 20-21B).

[0124] When the speculum 200 is in the closed position, the speculum 200 can be inserted in a patient's vagina. The operator places an end of the upper bill 206 and the lower bill 208 in line with an opening of the vagina and applies a force along a longitudinal axis of the upper bill 206 and the lower bill 208 to push the upper bill 206 and the lower bill 208 into the vagina. The operator may position the speculum 200 at a depth of the vagina to provide a clear view of the cervix when the upper bill 206 and the lower bill 208 of the speculum 200 are opened. The speculum 200 may be inserted so that an end of the upper bill 206 and the lower bill 208 are located below the cervix. Once the upper bill 206 and the lower bill 208 are separated, the cervix may then fall into the viewing window created by the separation of the upper bill 206 and the lower bill 208.

[0125] The upper bill 206 and the lower bill 208 each include an elongated portion of the speculum 200 (see FIGS. 13-19B). The elongated portion may have a width that is larger than a height of the elongated portion, creating an oblong shape. Alternatively, the height and

width of the elongated portion may be configured in such a way that when the upper bill 206 and the lower bill 208 are closed, a circular cross section is formed. Other configurations are contemplated. At an end of the elongated portion, away from the handle 220, the upper bill 206 and the lower bill 208 may be rounded. A rounded end may provide more comfort to a patient whom will be receiving the speculum 200 in a cavity. The upper bill 206 and the lower bill 208 may also be configured such that when in the closed position, the end of the upper bill 206 and the lower bill 208 may abut one another without any gaps. In other embodiments, the upper bill 206 and the lower bill 208 may be longer than the other to create a gap when the bills are closed, preventing tissue from becoming lodged in between the upper bill 206 and the lower bill 208 during insertion or closing of the bills. The upper bill 206 and the lower bill 208 may have a semi-circular cross section along a length of the upper bill 206 and the lower bill 208, where the flat portions of the semi-circles are moved together when the upper bill 206 and the lower bill 208 are in a closed position. In these implementations, an outer edge and an inner edge of the upper bill 206 and the lower bill 208 may be curved such that when the upper bill 206 and the lower bill 208 are in the closed position, a cross section of the upper bill 206 and the lower bill 208 forms a cylinder shape.

[0126] Referring back to FIGS. 20-21B, the speculum 200 includes at least one secondary bill 285. The at least one secondary bill 285 aids in retaining side wall tissue of the vagina to maintain a clear viewing window for the operator. The at least one secondary bill 285 includes at least one, two, three, four, five, six or more secondary bills 285. For example, the at least one secondary bill 285 includes a first secondary bill 286 and a second secondary bill 287. In some implementations, the speculum 200 may not include secondary bills. The speculum 300 is an example speculum that does not include secondary bills. Otherwise, the speculum may be the same as the speculum 200.

[0127] The first secondary bill 286 and the second secondary bill 287 are positioned opposite one another. The first secondary bill 286 and the second secondary bill 287 may be sized to fit inside the upper bill 206 and the lower bill 208 when in the closed position. The first secondary bill 286 and the second secondary bill 287 are substantially identical opposites of one another. The first secondary bill 286 and the second secondary bill 287 includes arms 286A and 287A, respectively. An exterior of the arms 286A, 287A may be rounded to be more comfortable for the patient and to provide a clear view of the vagina and speculum once inserted by providing support to the side tissue of the vagina.

[0128] The first secondary bill 286 includes a first keyed bill feature 288, such as a keyed protrusion. The second secondary bill 287 includes a second keyed bill feature (not shown in FIG. 22), such as a keyed protrusion. The first keyed bill feature 288 and the second keyed bill feature are configured to couple with a corresponding coupler 244 (e.g., keyed receiver) of the first unitary body 204. The first keyed bill feature 288 and the second keyed bill feature may include a feature extending from an end of a corresponding protrusion that is configured to mate with and/or fit within a corresponding coupler 244 of the first unitary body 204. While the first keyed bill feature 288 and the first secondary bill 286 are described herein, the second keyed bill feature and the second secondary bill 287 include the same (e.g., the same and/or mirrored) features and/or components.

[0129] Referring to FIGS. 22 and 23, the first keyed bill feature 288 is positioned along a length of the first secondary bill 286. For example, a first portion 245 of the first secondary bill 286 is positioned on one side of the first keyed bill feature 288 and a second portion 246 is positioned on the other side of the first keyed bill feature 288. The first portion 245 is longer than the second portion 246. The first portion 245 is configured to contact the tissue of the patient in use, while the second portion 246 is positioned between the upper bill 206 and the lower bill 208. The first portion 245 includes an elongated portion towards an end of the first secondary bill 286 and a flared portion between the end and the second portion 246. The flared portion extends outwardly from the elongated portion. The second portion 246 further extends outwardly from the flared portion. This configuration allows for the at least one secondary bill 285 to easily and comfortably lift and/or retain tissue in use.

[0130] Referring again to FIG. 22, the at least one secondary bill 285 includes at least one (e.g., one, two, three, four, five, or more) cutouts 290. The cutouts 290 are positioned on an interior side of the at least one secondary bill 285. The cutouts 290 may reduce an amount of material used for manufacturing. The cutouts 290 also provide for a lightweight speculum, which improves the experience for the operator when using the speculum 200.

[0131] Referring to FIGS. 13-23, the first unitary body 204 includes the lower bill 208 and the forward handle portion 232. The first unitary body 204 may further include the coupler 244, an opening 234, and/or coupling features 271, each of which may be integrally formed with the lower bill 208 and the forward handle portion 232 to form the first unitary body 204.

[0132] The coupler 244 includes a coupler corresponding to a respective one of the first keyed bill feature 288 and the second keyed bill feature. The coupler 244 similarly includes a keyed feature corresponding to the keyed feature of the first keyed bill feature 288 and the second keyed bill feature. The coupler 244 couples to the first keyed bill feature 288 and the second keyed bill feature 289 of the corresponding secondary bill when the keyed feature of the first keyed bill feature 288 and the second keyed bill feature and the corresponding coupler 244 are aligned. The couplers 244 extend (e.g., at an angle) from a transition portion 204a of the first unitary body 204. The couplers 244 are positioned adjacent to couplers 240, which couple the first unitary body 204 to the second unitary body 202.

[0133] The opening 234 receives at least a portion of the locking member 222, such as a surface of the locking member 222. The locking member 222 is accessible to the operator via the opening 234. The locking member 222 may be manipulated to lock a position of the upper bill 206 relative to the lower bill 207, and/or the at least one secondary bill 285. The locking member 222 may be a rocker. For example, an upper end of the rocker may be pressed, causing the locking member 222 to pivot about a center of the rocker, to maintain an unlatched position (see FIGS. 18A and 18B, which are described in more detail below). A lower end of the rocker may be pressed, causing the locking member 222 to pivot about the center of the rocker, to maintain a latched position (see FIGS. 19A and 19B, which are described in more detail below). Additionally and/or alternatively, the locking member 222 may be a slider that slides to latch or unlatch the speculum.

[0134] The coupling features 271 extend inwardly an inner surface 272 of the forward handle portion 232 from an edge of the forward handle portion 232. The coupling features 271 are configured to couple to the handle cover 218, such as via a snap-fit arrangement. Thus, the coupling features 271 may couple the handle cover 218 to the first unitary body 204 via a toolless attachment (e.g., without the use of tools).

[0135] Referring to FIGS. 13-23, the second unitary body 202 includes the upper bill 206, the actuator 210, and the locking lever 226. The second unitary body 202 may further include a track 236 (see FIG. 16B). The track 236 may be positioned on and/or extend from an inner surface of the upper bill 206. The track 236 may be positioned along the inner surface of the upper bill 206 closer to the window 214 than to an end of the elongated portion of the upper bill 206.

[0136] The track 236 may be configured to receive an illumination source, such as a lighting module 250. The lighting module 250 is configured to illuminate the cavity in which the speculum 200 is placed in order to allow better visualization of the cavity and execution of procedures in the cavity. The lighting module 250 provides one or more illumination elements, such as light emitting diodes ("LEDs"). The configuration of the lighting module 250 provides illumination elements at or near the perimeter of the window 214, so as not to obstruct the view of the user through the window 214. The track 236 may be centered along the inner surface of upper bill 206 to provide centered illumination of the cavity.

[0137] The track 236, integrated with or otherwise integrally formed with the upper bill 206, allows for easy, quick, and efficient assembly and coupling of the lighting module 250 to the second unitary body 202. The track 236 is arranged so that at least a portion of the lighting module 250 can be pressed and/or snapped into the track 236 and so that the track 236 retains the lighting module 250. Accordingly, the lighting module 250 can be coupled to the speculum 200 via a toolless assembly, such as via a snap-fit arrangement.

[0138] The lighting module 250 may include an LED 251 with one or more legs 254, a power source 252, such as one or more batteries (e.g., a one button cell batter, a two button cell battery and/or the like) electrically coupled to the LED 251 (e.g., through in line resistors), and an activation mechanism 253. The power source 252 may have a voltage of about 3.0 V, but batteries having other voltages may also be used. The activation mechanism 253 can be manipulated to cause the LED 251 to go from an "off state to an "on" state. In this example, the activation mechanism includes a pull tab positioned between and/or on (e.g., in contact with) the one or more batteries, thereby preventing discharge of the batteries and keeping the LED 251 "off." The pull tab is configured to be pulled by the operator to dislodge the pull tab from contact with the power source 252, thereby allowing the flow of current and providing power to the LED 251. In some implementations, there is no mechanism for powering the LED 251 off after they have been turned on. In some implementations, the same activation mechanism may be used to power off the LED 251 or there may be a second mechanism for powering off the LED 251.

[0139] As shown in FIG. 13, the second unitary body 202 includes a window 214 defined by a window frame along the rearward portion of the second unitary body 202. The window frame extends from the upper bill 206. The window 214 may allow for inspection of the cervix, such as when the upper bill 206 and the lower bill 208 are separated. The window

214 may include a window extension 216 extending from a lower end of the window 214. The window extension 216 may be squared or have another shape. The window extension 216 may extend towards the actuator 210. The window extension 216 may allow for further viewing of the cervix through the viewing window formed between the upper bill 206 and the lower bill 208. The window extension 216 may additionally and/or alternatively allow for viewing of the locking lever 226 through the window 214. The window 214 may be circular, oblong, rectangular, or any other shape that would provide an opening for viewing. The window 214 has a size and shape to allow the user to see the entire opening created when the upper bill 206 and the lower bill 208 are in the open position.

[0140] Referring again to FIGS. 13-23, the actuator 210 may include a thumb tab 212. The actuator 210 may extend from the window 214. The actuator 210 may form at least a part of the rearward portion of the second unitary body 202. The actuator 210, alone, or together with the latch 260, causes opening and closing of the upper bill 206, the lower bill 208, the first secondary bill 286 and the second secondary bill 287. The thumb tab 212 includes a top surface to provide a rigid surface for the operator to apply a force, such as via the operator's thumb while holding the handle 220. A top of the thumb tab 212 has a curvature provided to maintain an ample viewing window for the operator, such as via the window 214. A force is applied by a thumb of the user to the thumb tab 212 and causes the upper bill 206 and the lower bill 208, and/or the first and second secondary bills 286, 287 to open (e.g., separate). In some implementations, a distance the thumb tab 212 moves correlates to a distance the upper bill 206 and the lower bill 208 separate. In this regard, the operator would be able to select a specific distance between the upper bill 206 and the lower bill 208 for each patient. The upper bill 206 and the lower bill 208 may open in a continuous fashion when force is continuously applied to the thumb tab 212. Alternatively, the force applied to the thumb tab 212 may cause the upper bill 206 and the lower bill 208 to only open a specified distance. Opening and closing of the speculum 200 is described in further detail below.

[0141] The locking lever 226 extends from a lower portion of the window 214, such as from an end of the window extension 216. The locking lever 226 may be curved such that an inner surface 226A faces the inner surface of the second unitary body 202, while an outer surface 226B faces the inner surface of the first unitary body 204. The locking lever 226 is curved towards the latch 260 to engage with the latch 260 as described in more detail herein. The locking lever 226 can include a plurality of teeth 230. The plurality of teeth 230 may engage the latch 260. Each of the plurality of teeth 230 may represent a position of the upper

bill 206, the lower bill 208, and/or the at least one secondary bill 285. For example, the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 can be separated (e.g., opened) by a predetermined amount defined by the spacing between each of the plurality of teeth 230. The plurality of teeth 230 include one, two, three, four, five, six, seven, eight, nine, ten or more teeth.

[0142] Referring again to FIGS. 22 and 23, the handle cover 218 may define a rearward handle portion of the handle 220. The handle cover 218 may couple with the forward handle portion 232 to define the handle 220 of the speculum 200 that may be grasped by the operator in use. The rearward handle portion (e.g., the handle cover 218) may enclose an interior volume in which at least a portion of (e.g., all or substantially all) the latch 260 is positioned. The handle cover 218 includes an opening 238 through which the locking lever 226 may pass to engage with the latch 260 within the interior volume of the handle 220. As the actuator 210 is manipulated by the operator, the locking lever 226 passes in and out of the opening 238. The opening 238 may be positioned towards an end of the handle cover 218 closer to the second unitary body 202. The handle cover 218 includes a plurality of coupling features 235 configured to engage the coupling features 271 of the forward handle portion 232. The plurality of coupling features 235 may be coupled to the coupling features 271 via a snap-fit or other coupling arrangement, such as a toolless assembly arrangement.

[0143] The latch 260 is positioned at least partially within the interior volume of the handle 220. The latch 260 includes a latch body 261. The latch body 261 includes a locking receiver 262 and a locking member 222. The locking receiver 262 may engage with the plurality of teeth 230 of the locking lever 226. For example, the locking receiver 262 includes an opening 264 through which at least a portion of the locking lever 226 passes. At one end, the locking receiver 262 includes a latch bar 266 defining at least a portion of the opening 264. The latch bar 266 is configured to engage at least one of the plurality of teeth 230 of the locking lever 226. The engagement between the plurality of teeth 230 and the latch bar 266 sets a position of the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 relative to one another.

[0144] For example, FIGS. 18A and 18B show an example of the speculum 200 in an unlatched position (also referred to herein as an adjustment state). In this example, the plurality of teeth 230 of the locking lever 226 do not engage with the latch bar 266 of the latch body 261. Although the speculum is shown as being in the closed position (e.g., the upper and

lower bill are closed, positioned adjacent to one another), the speculum may be opened while in the unlatched position. The unlatched position allows for the speculum to be opened and/or closed freely. In other words, in the unlatched position, the actuator 210 may be manipulated, causing the locking lever 226 to pass through the opening 264 without engaging with the latch body 261. As the locking lever 226 passes through the latch body 261, it passes through the opening 264 without engaging the latch bar 266. This allows for quick and quiet adjustments of the speculum.

[0145] In this configuration, the speculum 200 may be in an adjustment state in which the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 separate (e.g., open) and/or close freely based on actuation (e.g., pressing on) of the actuator 210 (e.g., the thumb tab 212). In this state, the locking lever 226 passes through the opening 264 without locking a position of the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285. Thus, in this state, the operator may easily adjust a position of the speculum 200, such as the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 by at least pressing on the actuator 210 (e.g., the thumb tab 212), such as with their thumb, and positioning the locking member 222 in the unlocked position, such as by sliding the locking member towards the lower bill 208 (e.g., in an upwards direction) and/or by pressing on an upwards end of the locking member 222.

[0146] FIGS. 19A and 19B show an example of the speculum in a latched position (also referred to herein as a locked state). In this example, the plurality of teeth 230 of the locking lever 226 engage with the latch bar 266 of the latch body 261. Although the speculum is shown as being in the closed position (e.g., the upper and lower bill are closed, positioned adjacent to one another), the speculum may be opened while in the latched position. The latched position allows for the speculum to be opened and/or closed in increments, holding the position of the upper bill relative to the lower bill (and/or the secondary bills) via engagement between the teeth 230 and the latch bar 266. In other words, in the latched position, the actuator 210 may be manipulated, causing the locking lever 226 to pass through the opening 264 and engaging with the latch body 261.

[0147] In the locked position, the locking member 222 may be in a neutral position (e.g., centered within the opening 234) and/or pushed in a downwards direction away from the lower bill 208. For example, the latch 260 may slide via manipulation of the locking member 222. In this position, the position of the upper bill 206, the lower bill 208, and/or the at least

one secondary bill 285 may be set. In other words, the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 may not move relative to one another when the actuator is released when the speculum is in the latched position. In some implementations, in this position, the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 may move relative to one another only when the actuator 210 is actuated (e.g., pressed towards the handle 220).

[0148] For example, in some implementations, in the locked position, the actuator 210 may be actuated to cause the locking lever to slide through the opening 264 such that the latch bar 266 engages a next tooth of the plurality of teeth 230 of the locking lever 226. As an example, in the locked position, the actuator 210 may be pressed towards the handle 220, causing the locking lever 226 to slide through the opening 264 to a next position, such as a next tooth (see FIGS. 21A and 21B which show the speculum in the locked position and fully open position with maximum separation between the upper and lower bills 206, 208). In some implementations, an end portion of the locking lever 226 and/or a first tooth of the plurality of teeth 230 positioned near the end portion of the locking lever 226 engages the latch bar 266 when the speculum 200 is in the closed position. As the locking lever 226 passes further through the opening 264, such as when the actuator 210 is pressed towards the handle 220, the latch bar 266 may engage with at least one of the remaining teeth of the plurality of teeth 230 positioned farther away from the end of the locking lever 226 (see FIGS. 21A and 21B). This increments the position of the upper bill 206, the lower bill 208, and the at least one secondary bill 285 relative to one another such that the upper bill 206, the lower bill 208, and the at least one secondary bill 285 separate. Such configurations allow for easy and quick incremental adjustments of the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 relative to one another. This also allows for the position of the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 to be maintained, such as when the actuator 210 is not being actuated.

[0149] The position of the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285 may be reset to the closed position when the locking member 222 is pushed towards the lower bill 208. This releases the engagement between the teeth 230 and the latch bar 266. Accordingly, the latch body 261 and/or the locking lever 226 allows for quick and easy locking and unlocking of the speculum 200 as well as for adjusting a position of the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285. The latch body 261 and/or the locking lever 226 may allow for locking and unlocking of the speculum 200 as well

as for adjusting a position of the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285, using a single hand. For example, the operator may use their thumb to manipulate the actuator, and another finger, such as an index finger to manipulate the locking member 222 to adjust the position of the latch body 261. The latch body 261 and/or the locking lever 226 may also allow for quiet locking and unlocking of the speculum 200 as well as for adjusting a position of the upper bill 206, the lower bill 208, and/or the at least one secondary bill 285. Thus, the latch body 261 and/or the locking lever 226 may provide for an improved experience for the operator.

[0150] Referring again to FIGS. 22 and 23, the latch body 261 includes a forward side 261A and a rearward side 261B. The forward side 261A of the latch body 261 includes the locking member 222. The locking member 222 may form at least a portion of the forward side 261A. The locking member 222 includes a surface of the forward side 261A that is accessible via the opening 234. The locking member 222 may be manipulated by the operator, such as in conjunction with the actuator 210 to set a position of the speculum 200.

[0151] The latch body 261 may include two prongs 274. The prongs 274 are spaced apart from one another to define a passage therebetween. The passage is configured to receive the ledge 270 that is permitted to slide within the passage. The ledge 270 extends from the inner surface of the cover 218.

[0152] In some implementations, the latch body 261 includes a biasing member receiver 280 on the rearward side 261B of the latch body 261. The biasing member receiver 280 may receive and/or secure a biasing member 282, such as a spring, a gasket, or the like. The biasing member 282 may be coupled to the biasing member receiver 280 via a snap-fit, press-fit, or other toolless arrangement. Referring to FIGS. 22 and 23, at least a portion of the biasing member 282 may be positioned within the biasing member receiver 280, and at least another portion of the biasing member 282 may be held in place by the ledge 270. As noted, the biasing member receiver 280 and the ledge 270 can be positioned between the prongs 274. This allows for the biasing member 282 to bias the latch 260, and thus the locking member 222, in the closed position. For example, the biasing member 282 may bias the latch body 261 and/or the locking member 222. In this manner, when the locking member 222 is pressed towards from the lower bill 208, the biasing member 282 biases the latch body 261 with sufficient force to unlatch the latch bar 266 and the teeth 230.

[0153] FIGS. 24-26 illustrate an example of a medical speculum 300 (also referred to herein as a speculum 300) consistent with implementations of the current subject matter. As noted, one or more components, features, and/or properties of the speculum 300 may be used with and/or interchanged with one or more components, features, and/or properties of the speculum 100 and/or the speculum 200. The speculum 300 is an example speculum that does not include secondary bills. Otherwise, the speculum may be the same as the speculum 200 and/or the speculum 100. For example, the speculum 300 may include a first unitary body 304, a second unitary body 302, a handle cover 318, a latch body (not shown), which are respectively similar to or the same as the first unitary body 104 and/or the first unitary body 204, the second unitary body 102 and/or the second unitary body 202, the handle cover 118 and/or the handle cover 218, and/or the latch body 161 and/or the latch body 261, consistent with implementations of the current subject matter. The medical speculum 300 may additionally and/or alternatively include an illumination source, such as a lighting module 350, which is respectively similar to or the same as the lighting module 150 and/or the lighting module 250, consistent with implementations of the current subject matter. Accordingly, the medical speculum 300 may include a limited number of components for easy, quick, and efficient assembly.

[0154] In embodiments, the speculum 300 may be modified compared to one or more components, features, and/or properties of the speculum 100 and/or the speculum 200. For example, the window of speculum 300 may be larger. For example, the window may be large enough to accommodate one or more tools (e.g., gynecologic or obstetric tools). In embodiments, the window may be large enough to accommodate two or more tools (e.g., gynecologic or obstetric tools) at the same time. In embodiments, the bills (e.g., lower bill and upper bill) may be wider than the bills of the speculum 100 and/or the speculum 200.

[0155] FIG. 27 illustrates a process 2700 of assembling a speculum. While the process 2700 refers to the speculum 100, the process can be used to assemble the speculum 200, the speculum 300, and/or a combination thereof. The speculums described herein includes a reduced and/or limited number of components. This allows for easy, quick, efficient, and cheap assembly of the speculum 100. The speculum 100 may also be configured such that the speculum 100 is assembled via a toolless assembly. In other words, the components of the speculum 100 may be designed so that the components may be assembled without the use of tools. For example, the components of the speculum 100 may be coupled via a snap-fit arrangement, a press-fit arrangement, and/or the like. In other implementations, one or more

components of the speculum 100 may be coupled via welding (e.g., laser or sonic welding), an adhesive, or the like, without the use of mechanical fasteners. In yet other implementations, mechanical fasteners may be used.

[0156] At 2702, a first unitary body (e.g., the first unitary body 104) may be provided. The first unitary body may include a lower bill (e.g., the lower bill 108) and a forward handle portion (e.g., the forward handle portion 132) extending from the lower bill. The lower bill and the forward handle portion may be integrally formed.

[0157] At 2704, at least one lateral bill (e.g., the at least one secondary bill 185) may be coupled to the first unitary body. For example, the at least one lateral bill may include a keyed bill feature (e.g., the first keyed bill feature 188 and/or the second keyed bill feature 189), which are configured to align and/or mate with a corresponding coupler 144 (e.g., a keyed receiver) on the first unitary body, such as via a snap-fit arrangement or other toolless assembly arrangement. Thus, the at least one lateral bill may be coupled to the first unitary body by at least aligning the keyed bill feature and the keyed receiver and inserting the keyed bill feature into the keyed receiver.

[0158] At 2706, a latch body (e.g., the latch body 161 of the latch 160) may be coupled to the first unitary body by at least positioning a locking member (e.g., the locking member 122 and/or the slider 124) within an opening (e.g., the opening 134) of the forward handle portion. The latch body may include an opening (e.g., the opening 164).

[0159] At 2708, a second unitary body (e.g., the second unitary body 102) may be coupled to the first unitary body by at least engaging a locking lever (e.g., the locking lever 126) of the secondary unitary body with the opening of the latch body. The second unitary body may include an upper bill (e.g., the upper bill 108), an actuator (e.g., the actuator 110), and the locking lever including a plurality of locking teeth (e.g., the teeth 130). The upper bill, the actuator, and the locking lever are integrally formed.

[0160] In some implementations, the upper bill includes a track (e.g., the track 136). The track may be positioned on an interior surface of the upper bill. A lighting module (e.g., the lighting module 150) may be coupled to the upper bill by at least positioning at least a portion of the lighting module within the track.

[0161] At 2710, a handle cover (e.g., the handle cover 118) may be coupled to the forward handle portion to define a handle (e.g., the handle 120) and enclose at least a portion

of the latch body within an interior volume of the handle. The handle cover may define a rearward handle portion of the handle.

[0162] Consistent with implementations of the current subject matter, the at least one lateral bill is coupled to the first unitary body via a first toolless attachment, the latch body is coupled to the first unitary body via a second toolless attachment, the second unitary body is coupled to the first unitary body via a third toolless attachment, and the handle cover is coupled to the forward handle portion via a fourth toolless attachment. Thus, the components of the speculum 100 may be assembled via a toolless assembly. In some implementations, the first toolless attachment, the second toolless attachment, the third toolless attachment and/or the fourth toolless attachment includes a snap-fit arrangement, among other assembly methods.

[0163] In some aspects, methods of using a speculum as described herein are provided. In some aspects, the method includes performing a medical procedure on a female, comprising providing a speculum according to any of the embodiments described herein; inserting the speculum into the vagina of a female patient; and performing the medical procedure. Some embodiments herein relate to methods of performing obstetric or gynecological procedures utilizing speculum devices having a handle with one or more of the features described herein. Non-limiting examples of such procedures include pelvic exams, pap smears, insemination, IUD insertion/removal. In some embodiments, the methods can include performing a plurality of such procedures in a given period of time, such as an 8 hour or 24 hour period of time, or any sub period of time therein.

[0164] In some aspects, the medical procedure includes an obstetric or gynecological procedure requiring tools. In embodiments, the tools are inserted through the window 114. In embodiments, the window 114 is large enough to accommodate one or more tools (e.g., gynecologic or obstetric tools) at once.

[0165] In some aspects, a kit including a medical speculum as described herein is provided. In embodiments, the kit includes a sleeve accessory. In embodiments, the sleeve accessory is configured to be positioned on an insertion portion of the speculum, wherein the insertion portion includes the upper bill and the lower bill. In embodiments, the sleeve accessory is disposable. In embodiments, the sleeve accessory is insertable, e.g. insertable into the vagina prior to insertion of a medical speculum into the sleeve accessory.

[0166] In embodiments, the sleeve accessory includes a sleeve body defining a lumen that extends from a proximal end to a distal end of the sleeve body, the sleeve body including:

a flared portion extending radially outwardly towards the proximal end of the sleeve body; and an elongated portion extending from the flared portion towards the distal end of the sleeve body.

[0167] In embodiments, the kit includes an applicator having a flat, oblong shape with a distal end and a proximal end, the proximal end being broader than the distal end; wherein the distal end comprises a first prong and a second prong; and wherein the applicator is configured to slide, by the distal end of the applicator, at least partially into the lumen of the sleeve accessory to facilitate positioning of the sleeve accessory on the insertion portion of the medical speculum.

[0168] In embodiments, the sleeve accessory includes a cylindrical sleeve body comprising an outer surface and an inner surface, the inner surface defining a hollow sleeve channel, and at least one open end; wherein the cylindrical sleeve body is configured to be inserted into a vaginal cavity of a patient; and wherein the sleeve body is configured to receive the insertion portion of the speculum in the hollow sleeve channel subsequent to being inserted into the vaginal cavity. In embodiments, the kit includes an applicator configured to carry the sleeve body and facilitate insertion of the sleeve body into the vaginal cavity.

[0169] In embodiments, the sleeve accessory includes a cylindrical sleeve body having a distal end and a proximal end and including an outer surface, an inner surface, the inner surface defining a hollow sleeve channel, and at least one open end. In embodiments, at least a portion of the proximal end of the sleeve body is configured to extend over at least a portion of a proximal end of the insertion portion of the speculum.

[0170] In embodiments, the sleeve body is configured to receive the upper bill and the lower bill in the hollow sleeve channel configured for visibility and access to a vaginal cavity of a patient by a clinician and wherein the sleeve body is configured to expand from a first state to a second state. In embodiments, when the sleeve body is in the first state the proximal end of the sleeve body comprises a gradual broadening of the sleeve body, the gradual broadening of the sleeve body extending beyond the insertion portion of the medical speculum, the gradual broadening of the sleeve body integrally formed with the sleeve body.

[0171] In embodiments, the sleeve accessory is insertable. In embodiments, the sleeve accessory is within an applicator for insertion, e.g. into the vagina. Exemplary applicators are depicted in FIGs. 28A and 28B. The plunger 303 *b* of applicator 303 may include an elongated, cylindrical body configured to fit inside the insertable sleeve 301. By “cylindrical” it is meant here that the body of the plunger 303 *b* has a continuous, longitudinal shape, though the

plunger 303 *b* is not limited to a circular cylinder. As with the sleeve tube 303 *a*, the plunger 303 *b* may instead have a cross-sectional shape that is a triangle, a square, a rectangle, a hexagon, a circle, an oval, and so on. The body of the plunger 303 *b* may be designed to fit the shape of the inner surface of the insertable sleeve 301. For example, the plunger 303 *b* embodied in FIG. 28A has circular cross-section such that it conforms to the circular hollow sleeve channel of the insertable sleeve 301. In other embodiments, however, the plunger 303 *a* may take on a different shape from the insertable sleeve 301. In some embodiments, the plunger 303 *b* further includes a flared end (e.g., an end that distends outward from the cylindrical body of the plunger 303 *b*), shown in FIG. 28A as flared end 310. The flared end 310 may be beneficial to a user by providing the user with a larger area by which to apply a force to the plunger 303 *b* in order to release the insertable sleeve 301 from the applicator 303 once positioned within the patient's vagina. The plunger 303 *b* may be solid throughout the cylindrical body, or the plunger 303 *b* may be hollow. Beneficially, the applicator serves as an additional means of sanitation and comfort for the patient, as the patient knows that an outer portion of the insertable sleeve 301 to be positioned in the patient's vagina has had limited, if any, contact with the hands of anyone handling the insertable sleeve 301 or any other item which may transfer dirt, germs, or otherwise unsanitary elements to an outer surface of the insertable sleeve 301. Furthermore, the applicator 303 allows for a do-it-yourself step before a medical practitioner performs a gynecological or other intrusive medical procedure with a medical speculum. The insertable sleeve 301 thus allows the patient to be more actively involved in the procedure and provides the patient with the opportunity to perform the initial penetration into the body, both desensitizing the tissues and also reducing patient anxiety related to use of the speculum.

[0172] The plunger 503 *b* of the applicator 503 may include an elongated, cylindrical body configured to fit inside the plunger sheath 503 *a*. As shown in FIG. 28B, the plunger 503 *b* has a circular cylindrical body, though in other embodiments the cylindrical body of the plunger 503 *b* may instead have a cross-sectional shape that is a triangle, a square, a rectangle, a hexagon, a circle, an oval, and so on. The body of the plunger 503 *b* may be designed to fit the shape of the inner surface of the plunger sheath 503 *a*. For example, the plunger 503 *b* embodied in FIG. 28B has a circular cylindrical body to fit inside the hollow, circular cylindrical body of the plunger sheath 503 *a*. In other embodiments, however, the plunger 503 *a* may take on a different shape from the plunger sheath 503 *a*. In some embodiments, the plunger 503 *b* may further include a flared end (e.g., an end that distends

outward from the cylindrical body of the sheath **503 a**), shown in FIG. 28B as flared end **510**. Similar to flared end **310** of plunger **303 b**, the flared end **510** may be beneficial to a user by providing the user with a larger area by which to apply a force to the plunger **503 b** in order to release the insertable sleeve **501** from the applicator **503**. The plunger **503 b** may be solid throughout the cylindrical body, or the plunger **503 b** may be hollow. In general, the applicator **503** provides the same benefits as those discussed with respect to applicator **303** above, such as ensuring limited contact with an outer surface of the insertable sleeve **501** during handling and insertion into the patient's vagina so that the insertable sleeve **501** remains sanitary.

[0173] FIGS. 29A-29B illustrate an applicator 700 for a sleeve accessory for applying the sleeve accessory to a medical speculum. According to one embodiment, the applicator 700 is flat and roughly oblong, with a broader proximal end 702 and a narrower distal end 704. The proximal end includes a tab 706 that may be pulled away from the main body of the applicator 700, while the distal end 704 splits into a first prong 708 and a second prong 710. The applicator 700 further includes a first flap 712 and a second flap 714 formed into the sides of the applicator 700, where the first flap 712 is configured to fold at a first fold line 716 and the second flap 714 is configured to fold at a second fold line 718, as shown by the arrows of FIG. 29A. The applicator 700 may be made of a stiff, noncompliant or minimally compliant material or of a flexible, more compliant material. Thus, the applicator 700 may be made of paper, cardboard, paperboard, or corrugated fiberboard. Alternatively, the applicator 700 may be made of natural or synthetic rubbers or of a plastic, such as latex, vinyl, silicone, polyethylene, polyurethane, polypropylene, polycarbonate, or non-degradable or degradable elastomers. In some embodiments, the applicator 700 may be designed for a single use and be disposable. In other embodiments, the applicator 700 may be designed to be reusable (e.g., be designed to be sterilizable for reuse).

[0174] As illustrated in FIG. 29B, the applicator 700 is positioned within the sleeve accessory 801. In an exemplary embodiment, the applicator 700 and the sleeve accessory 801 are packaged together with the applicator 700 pre-inserted into the sleeve accessory 801 as shown in FIG. 29B. However, in other embodiments, a user may need to slide or otherwise position the applicator 700 into the sleeve accessory 801.

[0175] In embodiments, the sleeve accessory 1001 includes an open proximal end 1002 and an open distal end 1004 as shown in FIGs. 30A and 30B. In some embodiments, the proximal end 1002 is framed by an end ring or rib 1007. In embodiments, the sleeve accessory

1001 in at least the unexpanded or uncompressed position may include a flared portion 1020 at the proximal end 1004 and an elongated portion 1022 extending from the proximal end 1004 to the distal end 1002 of the sleeve accessory 1001. The flared portion 1020 may be flared radially outwardly and towards the proximal end 1004 to provide a wider opening.

[0176] FIG. 31 illustrates an example of the sleeve accessory 1001 positioned on the speculum 1200. As shown, the flared portion 1020 of the sleeve accessory has a width or diameter that is wider than a width or diameter of the elongate portion 1022. The flared portion 1020 may beneficially flare radially outwardly from the elongate portion 1022 in a proximal direction to cover one or more portions of the speculum 1200 to protect the patient from the one or more portions of the speculum 1200. The flared portion 1020 (and/or other portions of the sleeve accessory 1001) may expand to conform to the shape of the one or more portions of the speculum 1200 on which the sleeve accessory 1001 is positioned. The flared portion 1020 of the sleeve accessory 1001 may help to protect the patient from pinching by covering at least a hinged area of the speculum, which can often catch tissue or pubic hair, causing discomfort. Thus, at least the flared portion 1020 can help to reduce patient discomfort when the sleeve accessory and speculum are inserted into the patient.

[0177] In embodiments, the kit includes a plurality of speculums. In embodiments, the kit includes 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 15, 18, 20, 24, or more speculums. In embodiments, the kit includes a plurality of sleeve accessories. In embodiments, the kit includes 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 15, 18, 20, 24, or more sleeve accessories. In embodiments, the kit includes a plurality of applicators. In embodiments, the kit includes 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 15, 18, 20, 24, or more applicators.

[0178] Non-limiting examples of sleeve accessories and/or applicators can be found in PCT Pub. Nos. WO2017117313, WO2017117312, and WO 2020/076967, each of which is incorporated herein by reference in its entirety.

[0179] The subject matter described herein can be embodied in systems, apparatus, methods, and/or articles depending on the desired configuration. The implementations set forth in the foregoing description do not represent all implementations consistent with the subject matter described herein. Instead, they are merely some examples consistent with aspects related to the described subject matter. Although a few variations have been described in detail above, other modifications or additions are possible. In particular, further features and/or variations can be provided in addition to those set forth herein. For example, the

implementations described above can be directed to various combinations and subcombinations of the disclosed features and/or combinations and subcombinations of several further features disclosed above. In addition, the logic flows depicted in the accompanying figures and/or described herein do not necessarily require the particular order shown, or sequential order, to achieve desirable results. For example, the logic flows may include different and/or additional operations than shown without departing from the scope of the present disclosure. One or more operations of the logic flows may be repeated and/or omitted without departing from the scope of the present disclosure. Other implementations may be within the scope of the following claims.

[0180] Further, while “upwards”, “downwards,” or other directions are described herein, the directions are referred to as such for ease of description. The directions are not limited to upwards, downwards, and/or the like.

CLAIMS

What is claimed is:

1. A speculum having a reduced number of components, the speculum comprising:
 - a first unitary body comprising: a lower bill; and a forward handle portion extending from the lower bill; wherein the forward handle portion and the lower bill are integrally formed;
 - a second unitary body rotatably coupled to the first unitary body, the second unitary body comprising: an upper bill; an actuator; and a locking lever including a plurality of teeth; wherein the upper bill, the actuator, and the locking lever are integrally formed;
 - a handle cover defining a rearward handle portion coupled to the forward handle portion, wherein the rearward handle portion and the forward handle portion define a handle of the speculum, and wherein the rearward handle portion and the forward handle portion enclose an interior volume of the handle; and
 - a latch body comprising: a locking receiver configured to engage the plurality of teeth of the locking lever; and a locking member, wherein the actuator and the locking member are configured to be manipulated to change a position of the upper bill relative to the lower bill.
2. The speculum of claim 1, wherein the locking lever extends through an opening of the handle cover.
3. The speculum of any one of claims 1 to 2, wherein the locking lever is curved.
4. The speculum of any one of claims 1 to 3, wherein the second unitary body further comprises a window configured to allow a user to view an interior of a cervix of a patient in use; and wherein the locking lever extends from a lower portion of the window.
5. The speculum of any one of claims 1 to 4, further comprising a lighting module configured to illuminate a region between the upper bill and the lower bill.
6. The speculum of claim 5, wherein the upper bill includes a track configured to receive at least a portion of the lighting module, the track positioned on an interior surface of the upper bill, the interior surface configured to face the lower bill.
7. The speculum of any one of claims 1 to 6, further comprising at least one secondary bill configured to rotate in a lateral direction.
8. The speculum of claim 7, wherein the at least one secondary bill is positioned between the upper bill and the lower bill.
9. The speculum of claim 7, wherein the at least one secondary bill comprises a keyed bill feature configured to be inserted into a corresponding keyed receiver of the first unitary body when the keyed bill feature and the keyed receiver are aligned.

10. The speculum of claim 9, wherein the keyed bill feature extends at an angle longitudinally and laterally towards the keyed receiver.

11. The speculum of claim 9, wherein the keyed bill feature is configured to be coupled with the keyed receiver via a snap-fit arrangement.

12. The speculum of any one of claims 1 to 11, wherein the forward handle portion comprises an opening through which the locking member is accessible.

13. The speculum of any one of claims 1 to 12, wherein the locking receiver includes an opening through which at least a portion of the locking lever passes.

14. The speculum of claim 13, wherein the locking receiver includes a latch bar defining at least a portion of the opening, and wherein the latch bar is configured to engage at least one of the plurality of teeth of the locking lever to set a position of the upper bill relative to the lower bill.

15. The speculum of any one of claims 1 to 14, wherein the latch body includes a post receiver configured to receive and engage with a post extending from an inner surface of the forward handle portion, and wherein engagement between the post receiver and the post is configured to lock the position of the upper bill relative to the lower bill.

16. The speculum of claim 15, wherein the post receiver comprises a first prong including a first recess; and a second prong including a second recess and spaced apart from the first prong, wherein the first recess and the second recess together form at least a portion of an engagement region, and wherein the speculum is in a locked position when the post is positioned within the engagement region.

17. The speculum of claim 16, wherein the post receiver further includes a post passage extending from the post receiver, and wherein the post is configured to slide within the post passage when the speculum is in an unlocked position.

18. The speculum of claim 17, wherein the post receiver extends from the lock.

19. The speculum of any one of claims 1 to 18, wherein the latch body further includes a biasing member receiver positioned on a rearward portion of the latch body, wherein the biasing member receiver is configured to receive at least a portion of a biasing member such that the biasing member is configured to bias the locking member in a locked position.

20. A method of setting a position of the speculum of any one of claims 1 to 19, the method comprising:

pressing the actuator towards the handle; and

sliding the locking member away from the lower bill, the sliding causing a post passage of the latch body to slide around a post of the first unitary body to slide within.

21. The method of claim 20, further comprising:

sliding the locking member towards from the lower bill, locking the position of the upper bill relative to the lower bill.

22. A method of assembling a speculum comprising:

providing a first unitary body comprising: a lower bill; and a forward handle portion extending from the lower bill; wherein the forward handle portion and the lower bill are integrally formed

coupling at least one lateral bill to the first unitary body;

coupling a latch body to the first unitary body by at least positioning a lock portion within an opening of the forward handle portion, the latch body further comprising: a locking receiver;

coupling a second unitary body to the first unitary body by at least engaging a locking lever of the second unitary body with the locking receiver, the second unitary body comprising: an upper bill; an actuator; and the locking lever including a plurality of locking teeth; wherein the upper bill, the actuator, and the locking lever are integrally formed; and

coupling a handle cover defining a rearward handle portion to the forward handle portion to define a handle of the speculum and enclose at least a portion of the latch body within an interior volume of the handle.

23. The method of claim 22, wherein the at least one lateral bill is coupled to the first unitary body via a first toolless attachment, wherein the latch body is coupled to the first unitary body via a second toolless attachment, wherein the second unitary body is coupled to the first unitary body via a third toolless attachment, and wherein the handle cover is coupled to the forward handle portion via a fourth toolless attachment.

24. The method of claim 23, wherein the first toolless attachment, the second toolless attachment, the third toolless attachment and/or the fourth toolless attachment includes a snap-fit arrangement.

25. The method of any one of claims 22 to 24, wherein the at least one lateral bill comprises a keyed bill feature, wherein the first unitary body comprises a keyed receiver, and wherein the coupling the at least one lateral bill to the first unitary body comprises: aligning the keyed bill feature and the keyed receiver; and inserting the keyed bill feature into the keyed receiver.

26. The method of any one of claims 22 to 25, wherein the upper bill comprises a track positioned on an interior surface of the upper bill; and wherein the method further comprises coupling a lighting module to the upper bill by at least positioning at least a portion of the lighting module within the track.

27. A method of using a speculum of any one of claims 1-19 in a medical procedure on a female, comprising, providing the speculum; inserting the speculum into the vagina of a female patient; and performing the medical procedure.

28. The method of claim 27, further comprising setting a position of the speculum.

29. The method of claim 28, wherein setting a position of the speculum comprises: pressing the actuator towards the handle; and sliding the locking member away from the lower bill, the sliding causing a post passage of the latch body to slide around a post of the first unitary body to slide within.

30. The method of claim 29, further comprising: sliding the locking member towards from the lower bill, locking the position of the upper bill relative to the lower bill.

31. A kit comprising a speculum of any one of claims 1-19 and a sleeve accessory configured to be positioned on an insertion portion of the speculum, wherein the insertion portion comprises the upper bill and the lower bill.

32. The kit of claim 31, wherein the sleeve accessory comprises a sleeve body defining a lumen that extends from a proximal end to a distal end of the sleeve body, the sleeve body comprising:

a flared portion extending radially outwardly towards the proximal end of the sleeve body; and

an elongated portion extending from the flared portion towards the distal end of the sleeve body.

33. The kit of claim 31 or 32, further comprising an applicator having a flat, oblong shape with a distal end and a proximal end, the proximal end being broader than the distal end;

wherein the distal end comprises a first prong and a second prong; and

wherein the applicator is configured to slide, by the distal end of the applicator, at least partially into the lumen of the sleeve accessory to facilitate positioning of the sleeve accessory on the insertion portion of the medical speculum.

34. The kit of claim 31, the sleeve accessory comprising a cylindrical sleeve body comprising an outer surface and an inner surface, the inner surface defining a hollow sleeve

channel, and at least one open end; wherein the cylindrical sleeve body is configured to be inserted into a vaginal cavity of a patient; and wherein the sleeve body is configured to receive the insertion portion of the speculum in the hollow sleeve channel subsequent to being inserted into the vaginal cavity.

35. The kit of claim 34, further comprising an applicator configured to carry the sleeve body and facilitate insertion of the sleeve body into the vaginal cavity.

36. The kit of any one of claims 31 to 35, the sleeve accessory comprising a cylindrical sleeve body having a distal end and a proximal end and comprising an outer surface, an inner surface, the inner surface defining a hollow sleeve channel, and at least one open end.

37. The kit of claim 36, wherein at least a portion of the proximal end of the sleeve body is configured to extend over at least a portion of a proximal end of the insertion portion of the speculum.

38. The kit of claim 36 or 37, wherein the sleeve body is configured to receive the upper bill and the lower bill in the hollow sleeve channel configured for visibility and access to a vaginal cavity of a patient by a clinician and wherein the sleeve body is configured to expand from a first state to a second state.

39. The kit of claim 38, wherein when the sleeve body is in the first state the proximal end of the sleeve body comprises a gradual broadening of the sleeve body, the gradual broadening of the sleeve body extending beyond the insertion portion of the medical speculum, the gradual broadening of the sleeve body integrally formed with the sleeve body.

40. The kit of any one of claims 31 to 39, comprising a plurality of speculums.

41. The kit of any one of claims 31 to 40, comprising a plurality of sleeve accessories.

42. A kit comprising two or more speculum of any one of claims 1-19.