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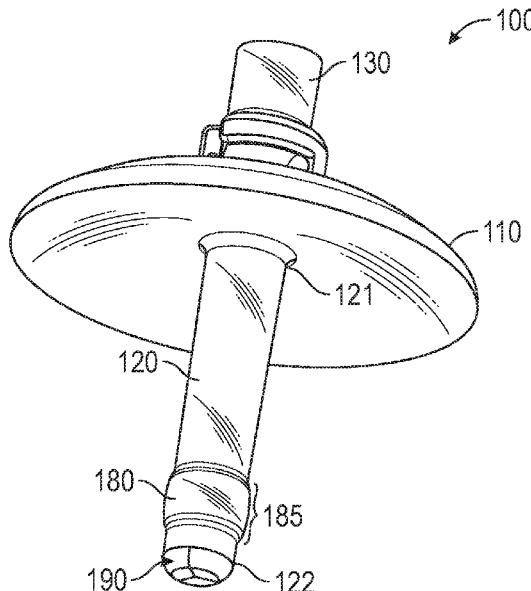


FIG. 1

(57) **Abstract:** A medical device and method for artificial insemination are provided. The medical device has a shield and an arm secured to the shield at one end and extending outwardly from the shield. The arm is inserted into the cervical canal of a patient and the shield covers the external os of the patient. By inserting the medical device into a patient's cervical canal after insemination, a physical barrier that holds a semen sample within the cervical canal and prevents leakage from the cervical canal back into the vaginal cavity is established. The device may have a bore extending through the device for a catheter to pass through. The bore has a valve to allow passage of the catheter and prevent backflow of semen. The arm may have a circumferential bulge to help keep the device in place during use.



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*DEVICE AND METHOD FOR ARTIFICIAL INSEMINATION*

## CROSS REFERENCES

[0001] This application claims priority to PCT Application No. PCT/US2016/064243, filed on November 30, 2016, which application is incorporated herein by reference.

## FIELD OF THE INVENTION

[0002] A preferred implementation of the present invention refers generally to a device and method for artificial insemination.

## BACKGROUND

[0003] Artificial insemination aims to introduce sperm into the reproductive system of a patient to promote pregnancy. Typically, artificial insemination is carried out when it is difficult or impossible for sperm to enter a patient's reproductive system during sexual intercourse. Intracervical insemination, where a semen sample is introduced into a patient's cervical canal, and intrauterine insemination, where a semen sample is introduced into a patient's uterine cavity, are two common artificial insemination procedures currently used. Generally, during such procedures, a patient's vaginal walls are held open by a medical device, such as a speculum. A semen sample is then

introduced into to the patient's cervical canal or uterine cavity, depending on which procedure is being performed, typically via a catheter-syringe assembly. After introduction of the semen sample, the semen is left to take by the patient's reproductive system. However, a portion of the semen sample may be lost by leaking from the cervical canal into the vaginal cavity of the patient due to reflux caused by uterine contractions.

[0004] Some known devices, such as vaginal sponges and cervical caps, attempt to solve the problem of leaking by creating a barrier between the patient's cervical canal and vaginal cavity after the semen sample is introduced. However, these devices merely attempt to blockade the upper region of the patient's vaginal cavity near the patient's cervical canal and may not effectively hold the semen sample within the cervical canal. Thus, the use of vaginal sponges and cervical caps in artificial insemination may not be effective in preventing a reduction in the efficacy of the insemination procedure due to reflux caused by uterine contractions. These devices may also cause patient discomfort when inserted and removed.

[0005] The device disclosed in application PCT/US2016/064243, filed by the present Applicant, attempts to solve the above-outlined problems. This device is designed to be inserted into the cervical canal and remain in place for a period of time during which insemination occurs while preventing leakage of semen from the cervical canal. The device may also allow a catheter to be inserted through a bore extending through the device so that semen may be introduced into the cervical canal or uterine cavity while the device is in place in a patient's cervical canal. However, the device may sometimes become dislodged from the cervical canal during the period of time in which the device is

intended to remain in place to allow insemination to occur, or a small amount of leakage may occur through the bore that extends through the device.

[0006] Accordingly, a need exists in the art for a device for increasing the efficacy of artificial insemination procedures and for a method of using the device. Furthermore, a need exists in the art for a device for increasing the efficacy of artificial insemination procedures without causing significant patient discomfort upon insertion and removal of the device.

## SUMMARY

[0007] The present disclosure provides a device and methods for artificial insemination in accordance with the independent claims. Preferred embodiments of the invention are reflected in the dependent claims. The claimed invention can be better understood in view of the embodiments described and illustrated in the present disclosure, *viz.* in the present specification and drawings. In general, the present disclosure reflects preferred embodiments of the invention. The attentive reader will note, however, that some aspects of the disclosed embodiments extend beyond the scope of the claims. To the respect that the disclosed embodiments indeed extend beyond the scope of the claims, the disclosed embodiments are to be considered supplementary background information and do not constitute definitions of the invention *per se*.

[0008] In one aspect of the present disclosure, a medical device for use during artificial insemination in order to prevent semen sample leakage from the cervical canal of a patient is provided. The medical device may be configured to function as a cervical plug. The medical device has a shield configured to cover an orifice and an arm having a

proximal end and a distal end. The proximal end is secured to the shield, and the distal end is configured to insert into the orifice. For instance, the shield may be configured to cover the orifice between a patient's cervical canal and vaginal cavity ("external os"), and the arm may be configured to insert into the patient's cervical canal. Due to the arm's insertion within the cervical canal and the shield's coverage of the external os, the medical device may effectively secure itself in place during use. The arm may have a circumferential bulge positioned near the distal end of the arm to help keep the device in place with the arm inserted into the cervical canal during use.

[0009] By inserting the medical device through the vaginal cavity and into the cervical canal of a patient such that the arm is inserted into the patient's cervical canal and the shield covers the patient's external os, the medical device may establish a physical barrier that holds a semen sample within the patient's cervical canal and prevents leakage into the vaginal cavity. In this manner, the medical device may be utilized as a cervical plug after a semen sample is introduced into the cervical canal or uterine cavity of a patient to prevent the semen sample from leaking into the vaginal cavity, thereby preventing semen sample loss. Accordingly, the present disclosure may also be directed toward a method for artificial insemination wherein a semen sample is first introduced into a patient's cervical canal or uterine cavity, and the medical device is then inserted into the patient's cervical canal in the manner described above.

[00010] In addition, the medical device may be configured to function as both a cervical plug as well as a guide or cannula for a catheter. The medical device has a shield and an arm having a proximal end and a distal end. The proximal end is secured to the shield, and the distal end is configured to insert into the patient's cervical canal. The medical

device may further have a bore extending longitudinally through the arm and through the shield such that the bore has an opening at the distal end of the arm and an opening on the side of the shield opposite the arm. A valve that is operable between an open position and a closed position may be disposed at the distal end of the arm. The valve comprises a plurality of elastomeric flaps integrally attached to the distal end of the arm. The elastomeric flaps are resiliently biased inwardly toward the center of the bore and against each other when the valve is in the closed position. The elastomeric flaps are sized and shaped to form a substantially fluid-tight seal over the opening at the distal end of the arm when the valve is in the closed position. To use the device, a catheter may be inserted into the opening of the bore on the side of the shield opposite the arm and pushed through the opening at the distal end of the arm. When pushed through the opening at the distal end of the arm, the catheter forces the elastomeric flaps of the valve outward, thereby moving the valve into the open position. In this manner, a catheter may pass through the medical device, deliver a semen sample to a patient's cervical canal or uterine cavity, and then be removed from the medical device while leaving the device in place. When the catheter is removed, the valve moves to the closed position such that the semen sample cannot leak back through the medical device into the vaginal cavity. Accordingly, the present disclosure may also be directed toward a method for artificial insemination wherein the medical device is inserted into a patient's cervical canal in the manner described above, a catheter is inserted into the bore of the medical device, a semen sample is directed through the catheter into the patient's cervical canal or uterine cavity, and the catheter is then removed leaving the medical device in place.

[00011] To insert and remove the medical device, the medical device may have an insert member secured to the shield on the opposite side of the shield as the arm. The insert member may have a string secured thereto in order to facilitate removal of the medical device. To minimize patient discomfort during insertion and removal of the medical device, the shield may be made of a flexible material.

[00012] Additional features and advantages of the present disclosure will be set forth in the description which follows, and will be apparent from the description, or may be learned by practice of the present disclosure. The foregoing general description and following detailed description are exemplary and explanatory and are intended to provide further explanation of the present disclosure.

#### DESCRIPTION OF THE DRAWINGS

[00013] These and other features, aspects, and advantages of the present disclosure will become better understood with regard to the following description, appended claims, and accompanying drawings where:

FIG. 1 shows a perspective view of a device in accordance with the present disclosure.

FIG. 2 shows a perspective view of a device in accordance with the present disclosure.

FIG. 3 shows a perspective view of a device in accordance with the present disclosure.

FIG. 4 shows an elevational view of a device in accordance with the present disclosure.

FIG. 5 shows an elevational view of a device in accordance with the present disclosure.

FIG. 6 shows a partial perspective view of a device in accordance with the present disclosure.

FIG. 7 shows a cross-sectional view of a device in accordance with the present disclosure.

FIG. 8 shows a top plan view of a device in accordance with the present disclosure.

FIG. 9 shows a bottom plan view of a device in accordance with the present disclosure.

FIG. 10 shows an elevational view of a device in accordance with the present disclosure.

FIG. 11 shows a perspective view of a device in accordance with the present disclosure.

FIG. 12 shows a perspective view of a device with a catheter inserted through the device in accordance with the present disclosure.

FIG. 13 shows a perspective view of a device with a catheter inserted through the device in accordance with the present disclosure.

FIG. 14 shows a device in accordance with the present disclosure inserted in a patient's reproductive system, said device being used with a catheter and syringe

#### DETAILED DESCRIPTION

[00014] In the Summary above and in this Detailed Description, and the claims below, and in the accompanying drawings, reference is made to particular features, including method steps, of the invention as claimed. In the present disclosure, many features are described as being optional, e.g. through the use of the verb "may" or the use of parentheses. For the sake of brevity and legibility, the present disclosure does not explicitly recite each and every permutation that may be obtained by choosing from the set of optional features. However, the present disclosure is to be interpreted as explicitly disclosing all such permutations. For example, a system described as having three optional features may be embodied in seven different ways, namely with just one of the three possible

features, with any two of the three possible features, or with all three of the three possible features. It is to be understood that the disclosure in this specification includes all possible combinations of such particular features. For example, where a particular feature is disclosed in the context of a particular aspect or embodiment, or a particular claim, that feature can also be used, to the extent possible, in combination with/or in the context of other particular aspects or embodiments, and generally in the invention as claimed.

[00015] The term “comprises” and grammatical equivalents thereof are used herein to mean that other components, ingredients, steps, etc. are optionally present. For example, an article “comprising” components A, B, and C can contain only components A, B, and C, or can contain not only components A, B, and C, but also one or more other components.

[00016] Where reference is made herein to a method comprising two or more defined steps, the defined steps can be carried out in any order or simultaneously (except where the context excludes that possibility), and the method can include one or more other steps which are carried out before any of the defined steps, between two of the defined steps, or after all the defined steps (except where the context excludes that possibility).

[00017] Turning now to the drawings, Figs. 1-14 illustrate embodiments of a medical device for holding materials in and preventing material leakage from an orifice. The medical device **100** may be designed to function as a cervical plug for holding semen in and preventing semen leakage from the cervical canal **730** of a patient after a semen sample is introduced into the patient’s cervical canal **730** or uterine cavity **740**. The medical device **100** has a shield **110** configured to cover an orifice and an arm **120**

configured to insert into the orifice, wherein one end of the arm **120** is secured to the shield **110**. The shield **110** may be configured to cover a patient's external os **720**, and the arm **120** may be configured to insert into the patient's cervical canal **730**, as illustrated in Fig. **14**. By inserting the medical device **100** through the vaginal cavity **710** and into the cervical canal **730** of a patient such that the arm **120** is inserted into the patient's cervical canal **730** and the shield **110** covers the patient's external os **720**, the medical device **100** may establish a physical barrier between a patient's cervical canal **730** and vaginal cavity **710**. In this manner, the medical device **100** may function as a cervical plug that prevents leakage of a semen sample from the cervical canal **730** into the vaginal cavity **710** after the semen sample has been introduced into the cervical canal **730** or uterine cavity **740** of a patient.

[00018] It should be understood that the medical device may be utilized for covering and plugging other bodily orifices including, but not limited to, the internal orifice of the cervix, without departing from the scope of the present disclosure.

[00019] As illustrated in Figs. **1-5**, the medical device **100** comprises a shield **110** and an arm **120** secured to the shield **110**. To accommodate the contours of the portion of the cervix surrounding a patient's external os **720**, the shield **110** may have a concave shape having a concave side and a convex side, wherein the concave side of the shield **110** faces the external os **720** and the convex side faces the vaginal cavity **710** when the medical device **100** is in place, as shown in Fig. **14**. The shield **110** may be shaped such that the concave side of the shield **110** fits flush against the external os **720** and cervical tissue surrounding the external os of the patient. The curvature of the shield **110** may be adjusted for different patients. The arm **120** may be secured to the concave side of the

shield **110**, as shown in Fig. 1. In addition, the shield **110** may have a generally circular shape, and the arm **120** may be secured to the shield **110** generally at the center of the shield, as shown in Fig. 1. Alternatively, the shield may be of another shape suitable for covering the external os **720** of a patient, such as an elliptical shape.

[00020] The shield **110** may be shaped and sized such that the shield **110** can cover the external os **720** of nulliparous, primiparous, or multiparous women. To minimize pain or discomfort experienced by a patient as the medical device **100** is inserted or removed from the patient's body, the shield **110** may be made of a material that is somewhat flexible such that the material may be deformed by pressure applied by a user of the device but return to its original shape when the pressure is removed. Alternatively, the shield **110** may be made of a material that is substantially rigid or semi-rigid. In addition, the shield **110** may be made of a material that is at least partially translucent or transparent, which may aid a user in inserting the device in the cervical canal. Alternatively, the shield **110** may be made of an opaque material. The shield **110** may comprise medical-grade silicone rubber. However, the shield may be made of any suitable material including, but not limited to, plastic, glass, ceramic, metal, any type of rubber, or any combination thereof.

[00021] The arm **120** of the medical device **100** is configured to insert into the orifice covered by the shield **110** when the medical device **100** is in use. The arm **120** is an elongated member having a proximal end **121** and a distal end **122**. The proximal end **121** is secured to the shield **110**, and the distal end **122** is inserted into the orifice when the device is in use. The arm **120** may be permanently secured to the shield **110**. For instance, the arm **120** and shield **110** may be molded as a unitary piece of material.

Alternatively, the arm **120** may be secured to the shield **110** with an adhesive. To facilitate ease of entry and exit of the arm **120** into and out of a patient's cervical canal **730**, the arm **120** may have a generally cylindrical shape.

[00022] The arm **120** may have a circumferential bulge **180** to help keep the device **100** in place with the arm **120** inserted into the cervical canal **730** during use. The bulge **180** is positioned along a length **185** of the arm **120** between a midway point of the arm (midway between the proximal end **121** and the distal end **122**) and the distal end **122** of the arm, and may preferably be positioned nearer to the distal end **122** of the arm **120** than to the midway point of the arm **120**, as shown in Fig. 1. Once the arm **120** is inserted into the cervical canal **730**, as shown in Fig. 14, the wider diameter of the circumferential bulge **180** provides resistance to removal of the arm **120** from the cervical canal **730**, thereby helping to keep the device **100** in place for a period of time after semen has been introduced into the cervical canal **730** or uterine cavity **740** so that the device **100** prevents leakage of semen from the cervical canal **730** into the vaginal cavity **710**. As shown in Fig. 4, the bulge **180** preferably has a contoured surface to prevent discomfort when inserting the arm **120** into the cervical canal **730**.

[00023] The arm **120** is sufficiently rigid for inserting the arm **120** into the cervical canal **730** of a patient, but the arm **120** may have some amount of flexibility in order to minimize pain or discomfort experienced by the patient as the device **100** is inserted or removed. Alternatively, the arm **120** may be made of a material that is substantially rigid. In addition, the arm **120** may be made of a material that is at least partially translucent or transparent. Alternatively, the arm **120** may be made of an opaque material. The arm **120** may comprise medical-grade silicone rubber. However, the arm may be made of any

suitable material including, but not limited to, plastic, glass, ceramic, metal, any type of rubber, or any combination thereof.

[00024] The shield **110** and the arm **120** may be configured to secure the medical device **100** in place during use, as shown in Fig. 14, such that the shield **110** remains covering an orifice until the medical device **100** is removed by a user. As used herein, the terms “during use” or “in use” refer to any point when the arm **120** of the medical device **100** is inserted into an orifice and the shield **110** of the medical device **100** is covering the orifice. Fig. 14 illustrates the device **100** being used with a syringe **170** and catheter **160** for introducing semen into the reproductive system. However, as discussed below, the syringe **170** and catheter **160** are removed after the introduction of semen, and the device **100** remains in place in the position shown in Fig. 14 for a period of time to prevent leakage of semen into the vaginal cavity **710**. The proximal end **121** of the arm **120** may have a diameter of sufficient size such that when the proximal end **121** of the arm **120** is positioned in the cervical canal **730** of a patient after insertion of the device, a substantially fluid-tight seal is formed between the cervical canal **730** and the vaginal cavity **710** of the patient. The fluid-tight seal formed by insertion of the arm **120** into the cervical canal **730** may facilitate a slight suction between the concave shield **110** and the area of the cervix covered by the shield **110**, thereby further securing the medical device **100** in place. When secured in place, the shield **110** may substantially cover the external os **720** and fit flush against the tissue surrounding the external os **720** such that the shield **110**, in conjunction with the arm **120**, may prevent leakage of a sperm sample around the device **100** and into the vaginal cavity **710**.

[00025] As illustrated in Figs. 3-6, the medical device **100** may further comprise an insert

member **130** secured to the shield **110**. The insert member **130** may function as an aid for inserting the medical device **100** into the cervical canal **730** and removing the device from the cervical canal. The insert member **130** is secured to the opposite side of the shield **110** as the proximal end **121** of the arm **120**. The insert member **130** may be permanently secured to the shield **110**. For instance, the medical device **100** may be molded as a unitary piece of material including the shield **110**, arm **120**, and insert member **130**. Alternatively, the insert member **130** may be secured to the shield **110** with an adhesive. As illustrated in Figs. 4 and 5, the insert member **130** may be secured to the shield **110** such that the insert member **130** forms a generally straight line with the arm **120**.

[00026] The insert member **130** provides a protrusion that may be grabbed using forceps for the purpose of guiding the device to insert or remove the medical device **100**. The insert member **130** may be sufficiently rigid to retain its shape such that it can be grabbed using forceps or a similar device. Alternatively, the insert member **130** may be somewhat flexible. In addition, the insert member **130** may be made of a material that is at least partially translucent or transparent. Alternatively, the insert member **130** may be made of an opaque material. The insert member **130** may comprise medical-grade silicone rubber. However, the insert member may be made of any suitable material including, but not limited to, plastic, glass, ceramic, metal, any type of rubber, or any combination thereof.

[00027] To facilitate removal of the medical device **100** after use, the insert member **130** may optionally have a string **140** attached thereto, as best seen in Figs. 10 and 13. The string **140** may be a medical-grade suture, though any suitable material may be utilized. To facilitate attachment of the string **140** to the insert member **130**, the insert member

**130** may have an annular cavity **200** located on the exterior of the insert member **130**, as best seen in Figs. 6 and 7. The insert member **130** has at least one external opening **210** that provides external access to the annular cavity **200**. Preferably, as best seen in Fig. 5, the insert member **130** has two external openings **210** on opposing sides of the insert member **130**. To secure the string **140** to the insert member **130**, an end of the string **140** may be inserted through the external opening **210** into the annular cavity **200** and around the insert member **130** until the inserted end of the string **140** exits the external opening **210**. The string **140** may then be tied to secure the string **140** to the insert member **130**. As used herein, “tying” the string may include any suitable method of securing the inserted end of the string **140** to a portion of the string after inserting the end through the annular cavity **200** so that the string **140** is secured to the insert member **130**. Fig. 8 shows a top view of the device **100** illustrating the insert member **130** and portions of two external openings **210**.

[00028] The string **140** may be of a sufficient length to extend through the vaginal cavity **710** and outside of the patient’s body when the medical device **100** is inserted in the cervical canal **730**, as seen in Fig. 14. By pulling the string **140**, the medical device **100** may be removed through the vaginal cavity **710** without forceps or a similar device. Alternatively, the string **140** may be permanently attached to the insert member **130**. For instance, the device **100** may be molded such that one end of the string **140** is molded into the insert member **130**.

[00029] As shown in Fig. 7, the medical device **100** may have a bore **150** extending longitudinally through the arm **120** and through the shield **110** such that the bore **150** has an opening **610** at the distal end **122** of the arm **120** and an opening **600** on the side of the

shield **110** opposite the arm **120**. The bore **150** may extend through the insert member **130** such that the opening **600** on the side of the shield **110** opposite the arm **120** is located at the end of the insert member **130**, as shown in Fig. 3. Thus, the bore **150** may extend completely through the device **100** in a generally straight line. When the device **100** is in place during use, as shown in Fig. 14, the bore **150** creates a passageway between the vaginal cavity **710** and the cervical canal **730** or uterine cavity **740** through the device **100**. To use the device **100**, a catheter **160** may be inserted into the opening **600** of the bore **150** on the side of the shield **110** opposite the arm **120** and pushed through the bore **150** and then through the opening **610** at the distal end **122** of the arm **120**, as shown in Figs. 12-14. The bore **150** is of sufficient diameter to allow the catheter **160** to pass therethrough. Accordingly, the medical device **100** may function as a guide or cannula to facilitate passage for the catheter **160**, which may be used as an insemination catheter for introducing a semen sample into a patient's reproductive system. In this manner, the medical device **100** may be utilized during intracervical or intrauterine insemination procedures for introducing a semen sample into the cervical canal **730** or the uterine cavity **740**, as desired. The catheter **160** may then be removed while leaving the device **100** in place.

[00030] The device **100** may further comprise a valve **190** disposed at the distal end **122** of the arm **120**. The valve **190** is operable between an open position, as shown in Figs. 10 and 11, and a closed position, as shown in Figs. 1 and 2. The valve **190** comprises a plurality of elastomeric flaps **195** integrally attached to the distal end **122** of the arm **120**. The elastomeric flaps **195** are resiliently biased inwardly toward the center of the bore **150** and against each other when the valve **190** is in the closed position. The elastomeric

flaps **195** are sized and shaped to form a substantially fluid-tight seal over the opening **610** at the distal end **122** of the arm **120** when the valve **190** is in the closed position. As used herein, the term “elastomeric” refers to any material that is flexible and/or stretchable such that the material can flex and/or stretch and then return to its original position. In this case, the original position refers to the closed position of the valve. Preferably, the valve **190** has three elastomeric flaps **195** each having a generally triangular shape, as best seen in Fig. 2. The three triangular flaps **195** fit together when the valve **190** is in the closed position to form a substantially fluid-tight seal to prevent fluid leakage through the valve **190**. Fig. 9 shows a bottom view of the device **100** with the valve **190** in the closed position.

[00031] During an artificial insemination procedure, an insemination catheter **160** may pass through the entirety of the device **100**. When the catheter **160** is pushed through the opening **610** at the distal end **122** of the arm **120**, as shown in Figs. 12 and 13, the catheter **160** forces the elastomeric flaps **195** of the valve **190** outward, as best seen in Figs. 11 and 12, thereby moving the valve **190** into the open position. In this manner, a catheter **160** may pass through the medical device **100**, deliver a semen sample to a patient’s cervical canal **730** or uterine cavity **740**, and then be removed from the medical device while leaving the device **100** in place. Upon delivery of the semen sample, the insemination catheter **160** may be entirely or partially removed from the medical device **100**. When the catheter **160** is removed, the elastomeric flaps **195** of the valve **190** move to their original position, thereby moving the valve **190** to the closed position. When the valve **190** is in the closed position, the semen sample is prevented from exiting the cervical canal **730** via the bore **150** and thus cannot leak back through the medical device

**100** into the vaginal cavity **710**. Thus, the medical device **100** may effectively function both as a cannula for an insemination instrument and as a cervical plug that prevents semen that has been introduced into the patient's cervical canal **730** or uterine cavity **740** from leaking into the patient's vaginal cavity **710**.

[00032] The present disclosure may also be directed to a method for artificial insemination. The medical device **100** may be configured to function as a cervical plug, as shown in Fig. **14**. A semen sample may first be introduced into a patient's cervical canal **730** or uterine cavity **740**, depending on whether intracervical insemination or intrauterine insemination is utilized. The semen sample may be introduced artificially into the patient's reproductive system or, alternatively, the sample may be introduced into a patient's reproductive system during sexual intercourse. After the semen sample is introduced into the cervical canal **730** or uterine cavity **740**, the medical device **100** may be inserted into the cervical canal **730** of the patient such that the arm **120** extends into the patient's cervical canal **730** and the shield **110** substantially covers the external os **720** of the patient's cervix, as shown in Fig. **14**. As previously noted, Fig. **14** illustrates the device **100** being used with a syringe **170** and catheter **160**, though the device **100** may be used as a cervical plug without the syringe **170** and catheter **160** by inserting the device **100** into the position shown in Fig. **14** and leaving the device in place. If used only as a cervical plug, the bore **150** extending through the device **100** and the valve **190** disposed at the distal end **122** of the arm **120** may be optional features. Once the device **100** is secured in place with the arm **120** inserted into the cervical canal **730** and the shield **110** covering the external os **720**, the shield **110** and the arm **120** of the medical device **100** prevent the semen sample from leaking from the cervical canal **730** into the patient's

vaginal cavity **710**. The circumferential bulge **180** of the arm **120** provides resistance to removal of the arm **120** of the device **100** from the cervical canal **730**, thereby helping to ensure that the device **100** stays in place during use, as shown in Fig. **14**. In this manner, the medical device **100** may increase the efficacy of intracervical or intrauterine insemination by reducing semen sample loss. After a suitable period of time, the device **100** may be removed.

[00033] It is understood that the medical device **100** used within the contemplated method, wherein the medical device **100** is configured to function as a cervical plug, may have some or all of the structural features consistent with the embodiments detailed above. Moreover, it is understood that the method of the present disclosure contemplates methodologies requiring additional or fewer steps dependent upon the presence of such structural features. For instance, the method may further comprise the step of removing the medical device **100** via the insert member **130** using forceps or a similar instrument. Alternatively, the device may be removed by pulling the device **100** through the vaginal cavity **710** via the string **140**.

[00034] The medical device **100** may be configured to additionally function as a guide or cannula for a catheter, as shown in Figs. **12-14**. The medical device **100** has a bore **150** extending therethrough, a valve **190** disposed at the distal end **122** of the arm **120**, and an optional circumferential bulge **180** positioned along a length **185** of the arm **120**. The device **100** may be inserted into the cervical canal **730** of the patient such that the arm **120** extends into the patient's cervical canal **730** and the shield **110** substantially covers the external os **720** of the patient's cervix. A catheter **160** may be inserted into the bore **150** through the opening **600** on the side of the shield **110** opposite the arm **120**. When

inserting the catheter **160** into the bore **150**, the catheter **160** may be pushed through the opening **610** at the distal end **122** of the arm **120**, thereby forcing the valve **190** into the open position, as shown in Fig. **12**, as far as desired for a particular insemination procedure. A semen sample may then be introduced into the patient's cervical canal **730** or uterine cavity **740** via the catheter **160**.

[00035] The catheter **160** may be partially inserted into the bore **150** prior to inserting the device **100** into the cervical canal **730**, and the catheter **160** may then be pushed through the opening **610** and the valve **190** at the distal end **122** of the arm **120** after inserting the medical device **100**. Alternatively, the catheter **160** may be inserted into the bore **150** and through the valve **190** after inserting the medical device **100**, or the catheter **160** may be inserted into the bore **150** such that the catheter **160** is pushed through the opening **610** and the valve **190** at the distal end **122** of the arm **120** prior to insertion of the device **100**, as shown in Figs. **12** and **13**.

[00036] The elastomeric flaps **195** of the valve **190** are resiliently biased against each other when the valve **190** is in the closed position, as shown in Fig. **2**. As the catheter **160** is inserted into the bore **150**, the catheter **160** may be pushed through the opening **610** at the distal end **122** of the arm **120** so that the catheter **160** forces the elastomeric flaps **195** outward, thereby moving the valve **190** to the open position. The catheter **160** may be partially inserted into the bore **150** prior to inserting the device **100** into the cervical canal **730** such that the valve **190** remains in a closed position. The catheter **160** may then be pushed through the opening **610** at the distal end **122** of the arm **120** such that the valve **190** moves to the open position after insertion of the medical device **100** into the cervical canal **730**.

[00037] Once the device **100** is secured in place with the arm **120** inserted into the cervical canal **730**, the shield **110** covering the external os **720**, and the catheter **160** inserted into the bore **150** and through the valve **190**, a semen sample may be introduced into a patient's cervical canal **730** or uterine cavity **740**, depending on whether intracervical insemination or intrauterine insemination is utilized, via the catheter **160**. The sample may be introduced into the cervical canal **730** or uterine cavity **740** by injecting the semen sample through the catheter **160** using a syringe **170**, as shown in Fig. 14. After introduction of the semen sample, the catheter **160** may be removed while leaving the device **100** in place. After removal of the catheter **160**, the resiliently biased elastomeric flaps **195** of the valve **190** return to their original position, as shown in Fig. 2, in which the valve **190** is in a closed position, thereby preventing the semen sample from flowing back through the valve **190** and the bore **150**. With the medical device **100** secured in place, the shield **110** and the arm **120** of the device **100** prevent the semen sample from leaking from the cervical canal **730** around the device **100** and into the patient's vaginal cavity **710**, thereby increasing the efficacy of intracervical or intrauterine insemination by reducing semen sample loss. The circumferential bulge **180** of the arm **120** helps to keep the device **100** secured in place to prevent leakage around the device **100**.

[00038] After a suitable period of time, the device **100** may be removed. The device **100** may be removed via the insert member **130** using forceps or a similar instrument. Alternatively, the device may be removed by pulling the device **100** through the vaginal cavity **710** via the string **140**.

[00039] To ensure the semen sample is introduced into the proper location, the catheter **160** may extend entirely through the medical device **100** such that one end of the catheter

**160** is located in the cervical canal **730** or in the uterine cavity **740** before directing the semen sample through the catheter **160**. Fig. 14 illustrates a catheter **160** extending through the entirety of the device **100** into the uterine cavity **740** of a patient and a syringe **170** for injecting the sample. Alternatively, the semen sample may be directed through the bore **150** of the medical device **100** using a syringe **170** or similar instrument without the aid of a catheter **160**.

[00040] The overall size or specific dimensions of components of the present device **100** may be varied to accommodate different patients. As one example, the device **100** may have the following dimensions: The shield **110** may be circular with a diameter of 22.50 mm; the arm **120** may be cylindrical with a diameter of 3.40 mm; and the circumferential bulge **180** may have a diameter of 4.46 mm at its widest point and extend along a length **185** of the arm **120** of 3.18 mm. These dimensions are illustrative only and are not intended to be limiting.

[00041] The present disclosure may also be directed to an insemination kit, which may be used by a health care provider or by a patient at home. The insemination kit may comprise: a medical device **100** having the features described herein, wherein the medical device **100** functions both as a cervical plug and a guide or cannula for a catheter; a catheter **160**; and a syringe **170** configured to secure to the catheter **160**. The catheter **160** and the syringe **170** of the kit may optionally be permanently attached to each other or molded together as a single component.

[00042] The insemination kit may be supplied to a user with the components pre-assembled such that the catheter **160** is inserted into the bore **150** of the medical device **100**, and the syringe **170** is secured to one end of the catheter **160**. The catheter **160** may

be partially inserted into the bore **150** of the medical device **100** such that the valve **190** is in a closed position upon user receipt. Alternatively, the catheter **160** may be inserted into the bore **150** of the medical device **100** such that the catheter **160** extends through the opening **610** in the distal end **122** of the arm **120** so that the valve **190** is in an open position upon user receipt.

[00043] It is understood that versions of the invention may come in different forms and embodiments. Additionally, it is understood that one of skill in the art would appreciate these various forms and embodiments as falling within the scope of the invention as disclosed herein.

What is claimed is:

- 1) A medical device comprising:
  - a shield configured to cover an orifice;
  - an arm having a proximal end secured to the shield and a distal end configured to insert into an orifice, wherein the shield and the arm are configured to secure the medical device in place during use,
  - wherein the medical device has a bore extending longitudinally through the arm and through the shield such that the bore has an opening at the distal end of the arm and an opening on the side of the shield opposite the arm; and
  - a valve disposed at the distal end of the arm, wherein the valve is operable between an open position and a closed position, wherein the valve comprises a plurality of elastomeric flaps integrally attached to the distal end of the arm, wherein the elastomeric flaps are resiliently biased against each other when the valve is in the closed position, wherein the

elastomeric flaps are each sized and shaped to form a substantially fluid-tight seal over the opening at the distal end of the arm when the valve is in the closed position.

- 2) The medical device of claim 1, wherein the valve has three elastomeric flaps.
- 3) The medical device of claim 1, wherein the arm has a circumferential bulge positioned along a length of the arm between a midway point of the arm and the distal end of the arm.
- 4) The medical device of claim 1, wherein the bore is of sufficient diameter to allow a catheter to pass through the bore.
- 5) The medical device of claim 1, wherein the shield has a concave shape, wherein the proximal end of the arm is secured to the concave side of the shield.
- 6) The medical device of claim 1, further comprising an insert member secured to the shield, wherein the insert member is secured to the opposite side of the shield as the proximal end of the arm.
- 7) The medical device of claim 6, wherein the insert member has an annular cavity, and wherein the insert member has an external opening that provides external access to the annular cavity.
- 8) The medical device of claim 1, wherein the shield is flexible.
- 9) The medical device of claim 1, wherein the shield is translucent.
- 10) A medical device comprising:
  - a shield configured to cover an orifice; and
  - an arm having a proximal end secured to the shield and a distal end configured to

insert into an orifice, wherein the arm has a circumferential bulge positioned along a length of the arm between a midway point of the arm and the distal end of the arm, wherein the shield and the arm are configured to secure the medical device in place during use.

- 11) The medical device of claim 10, wherein the medical device has a bore extending longitudinally through the arm and through the shield such that the bore has an opening at the distal end of the arm and an opening on the side of the shield opposite the arm.
- 12) The medical device of claim 11, further comprising a valve disposed at the distal end of the arm, wherein the valve is operable between an open position and a closed position, wherein the valve comprises a plurality of elastomeric flaps integrally attached to the distal end of the arm, wherein the elastomeric flaps are resiliently biased against each other when the valve is in the closed position, wherein the elastomeric flaps are each sized and shaped to form a substantially fluid-tight seal over the opening at the distal end of the arm when the valve is in the closed position.
- 13) The medical device of claim 10, wherein the bore is of sufficient diameter to allow a catheter to pass through the bore.
- 14) The medical device of claim 10, wherein the shield has a concave shape, wherein the proximal end of the arm is secured to the concave side of the shield.
- 15) The medical device of claim 10, further comprising an insert member secured to the shield, wherein the insert member is secured to the opposite side of the shield as the proximal end of the arm.

- 16) The medical device of claim 15, wherein the insert member has an annular cavity, and wherein the insert member has an external opening that provides external access to the annular cavity.
- 17) The medical device of claim 10, wherein the shield is flexible.
- 18) The medical device of claim 10, wherein the shield is translucent.
- 19) A method for artificial insemination, said method comprising the steps of:
  - providing a medical device comprising:
    - a shield configured to cover the external os of a patient's cervix;
    - an arm having a proximal end secured to the shield and a distal end configured to insert into a patient's cervical canal, wherein the shield and the arm are configured to secure the medical device in place during use, and wherein a bore extends longitudinally through the arm and through the shield such that the bore has an opening at the distal end of the arm and an opening on the side of the shield opposite the arm; and
    - a valve disposed at the distal end of the arm, wherein the valve is operable between an open position and a closed position, wherein the valve comprises a plurality of elastomeric flaps integrally attached to the distal end of the arm, wherein the elastomeric flaps are resiliently biased against each other when the valve is in the closed position, wherein the elastomeric flaps are each sized and shaped to form a substantially fluid-tight seal over the opening at the distal end of the arm when the valve is in the closed position,

inserting the medical device into the cervical canal of a patient such that the arm extends into the patient's cervical canal and the shield substantially covers the external os of the patient's cervix;

providing a catheter;

inserting the catheter into the bore through the opening of the bore on the side of the shield opposite the arm;

pushing the catheter through the opening at the distal end of the arm such that the catheter forces the elastomeric flaps of the valve outward, thereby moving the valve to the open position;

introducing a semen sample into the patient's cervical canal or uterine cavity via the catheter; and

removing the catheter.

- 20) The method of claim 19, wherein the arm has a circumferential bulge positioned along a length of the arm between a midway point of the arm and the distal end of the arm.
- 21) The method of claim 19, wherein the step of inserting the catheter into the bore comprises partially inserting the catheter into the bore prior to the step of inserting the medical device into the cervical canal, and the step of pushing the catheter through the opening at the distal end of the arm is performed after the step of inserting the medical device into the cervical canal.
- 22) The method of claim 19, wherein the semen sample is introduced into the patient's cervical canal or uterine cavity by injecting the semen sample through the catheter using a syringe.

- 23) The method of claim 19, wherein the shield has a concave shape, wherein the proximal end of the arm is secured to the concave side of the shield
- 24) The method of claim 19, wherein the medical device further comprises an insert member secured to the shield, wherein the insert member is secured to the opposite side of the shield as the proximal end of the arm.
- 25) The method of claim 24, wherein the insert member has an annular cavity, and wherein the insert member has an external opening that provides external access to the annular cavity, further comprising the step of securing a string to the insert member by inserting an end of the string into the annular cavity through the external opening and tying the string.
- 26) The method of claim 19, wherein the shield is flexible.
- 27) The method of claim 19, wherein the shield is translucent.
- 28) The method of claim 19, further comprising the step of removing the medical device from the patient after a period of time.

## CLAIMS

What is claimed is:

- 1) A medical device comprising:
  - a shield configured to cover an orifice;
  - an arm having a proximal end secured to the shield and a distal end configured to insert into an orifice, wherein the shield and the arm are configured to secure the medical device in place during use,
  - wherein the medical device has a bore extending longitudinally through the arm and through the shield such that the bore has an opening at the distal end of the arm and an opening on the side of the shield opposite the arm; and
  - a valve disposed at the distal end of the arm, wherein the valve is operable between an open position and a closed position, wherein the valve comprises a plurality of elastomeric flaps integrally attached to the distal end of the arm, wherein the elastomeric flaps are resiliently biased against each other when the valve is in the closed position, wherein the elastomeric flaps are each sized and shaped to form a substantially fluid-tight seal over the opening at the distal end of the arm when the valve is in the closed position.
- 2) The medical device of claim 1, wherein the valve has three elastomeric flaps.
- 3) The medical device of claim 1, wherein the arm has a circumferential bulge positioned along a length of the arm between a midway point of the arm and the distal end of the arm.

- 4) The medical device of claim 1, wherein the bore is of sufficient diameter to allow a catheter to pass through the bore.
- 5) The medical device of claim 1, wherein the shield has a concave shape, wherein the proximal end of the arm is secured to the concave side of the shield.
- 6) The medical device of claim 1, further comprising an insert member secured to the shield, wherein the insert member is secured to the opposite side of the shield as the proximal end of the arm.
- 7) The medical device of claim 6, wherein the insert member has an annular cavity, and wherein the insert member has an external opening that provides external access to the annular cavity.
- 8) The medical device of claim 1, wherein the shield is flexible.
- 9) The medical device of claim 1, wherein the shield is translucent.
- 10) A medical device comprising:
  - a shield configured to cover an orifice; and
  - an arm having a proximal end secured to the shield and a distal end configured to insert into an orifice, wherein the arm has a circumferential bulge positioned along a length of the arm between a midway point of the arm and the distal end of the arm, wherein the shield and the arm are configured to secure the medical device in place during use.
- 11) The medical device of claim 10, wherein the medical device has a bore extending longitudinally through the arm and through the shield such that the bore has an opening at the distal end of the arm and an opening on the side of the shield opposite

the arm.

- 12) The medical device of claim 11, further comprising a valve disposed at the distal end of the arm, wherein the valve is operable between an open position and a closed position, wherein the valve comprises a plurality of elastomeric flaps integrally attached to the distal end of the arm, wherein the elastomeric flaps are resiliently biased against each other when the valve is in the closed position, wherein the elastomeric flaps are each sized and shaped to form a substantially fluid-tight seal over the opening at the distal end of the arm when the valve is in the closed position.
- 13) The medical device of claim 11, wherein the bore is of sufficient diameter to allow a catheter to pass through the bore.
- 14) The medical device of claim 10, wherein the shield has a concave shape, wherein the proximal end of the arm is secured to the concave side of the shield.
- 15) The medical device of claim 10, further comprising an insert member secured to the shield, wherein the insert member is secured to the opposite side of the shield as the proximal end of the arm.
- 16) The medical device of claim 15, wherein the insert member has an annular cavity, and wherein the insert member has an external opening that provides external access to the annular cavity.
- 17) The medical device of claim 10, wherein the shield is flexible.
- 18) The medical device of claim 10, wherein the shield is translucent.

1/7

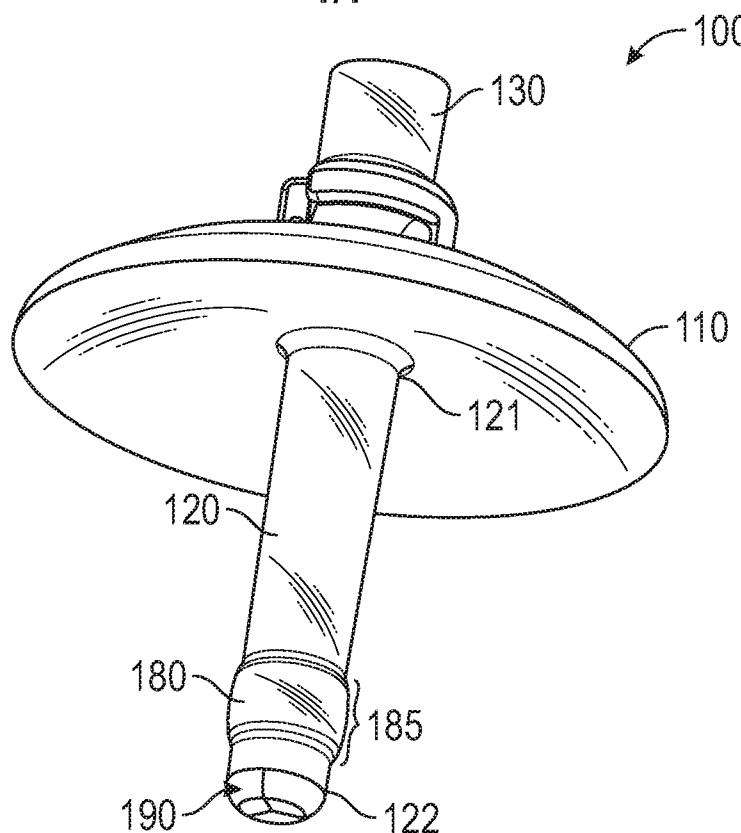


FIG. 1

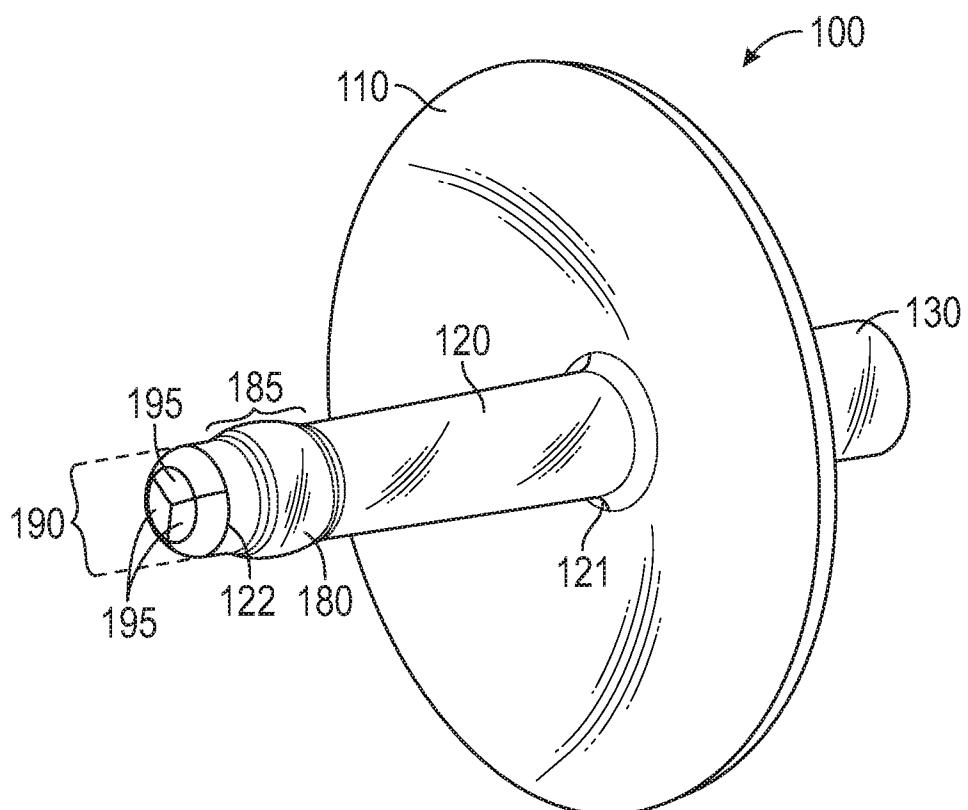


FIG. 2

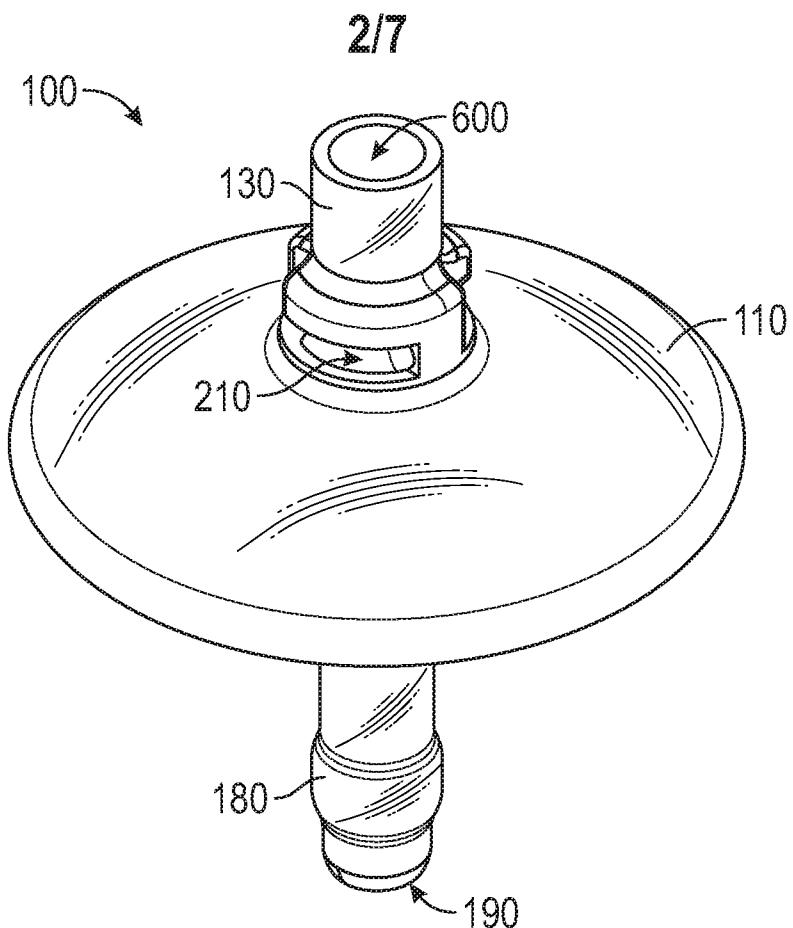


FIG. 3

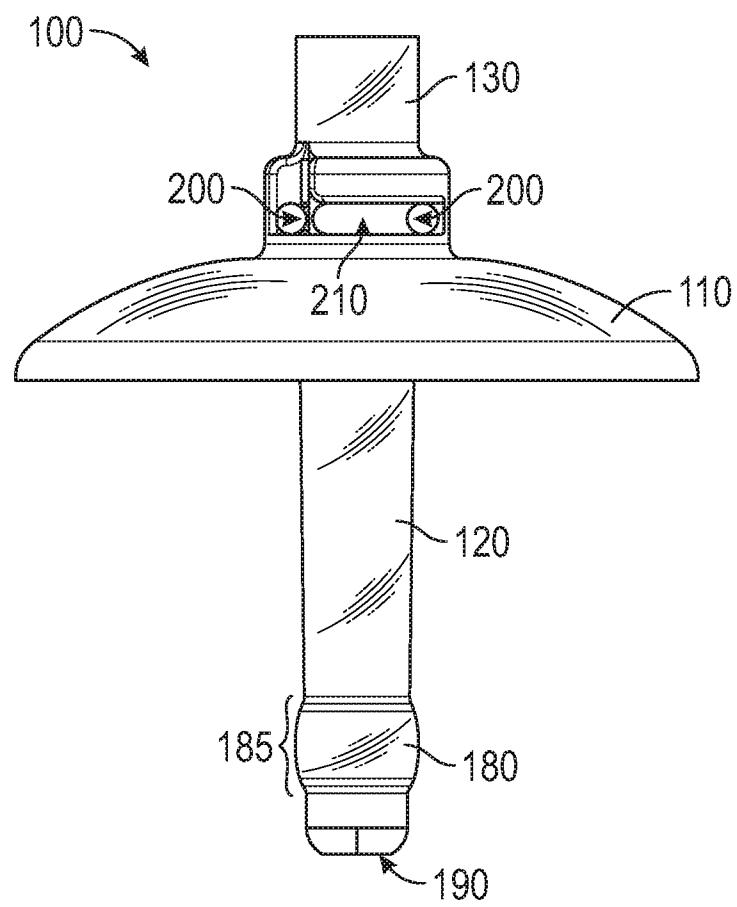


FIG. 4

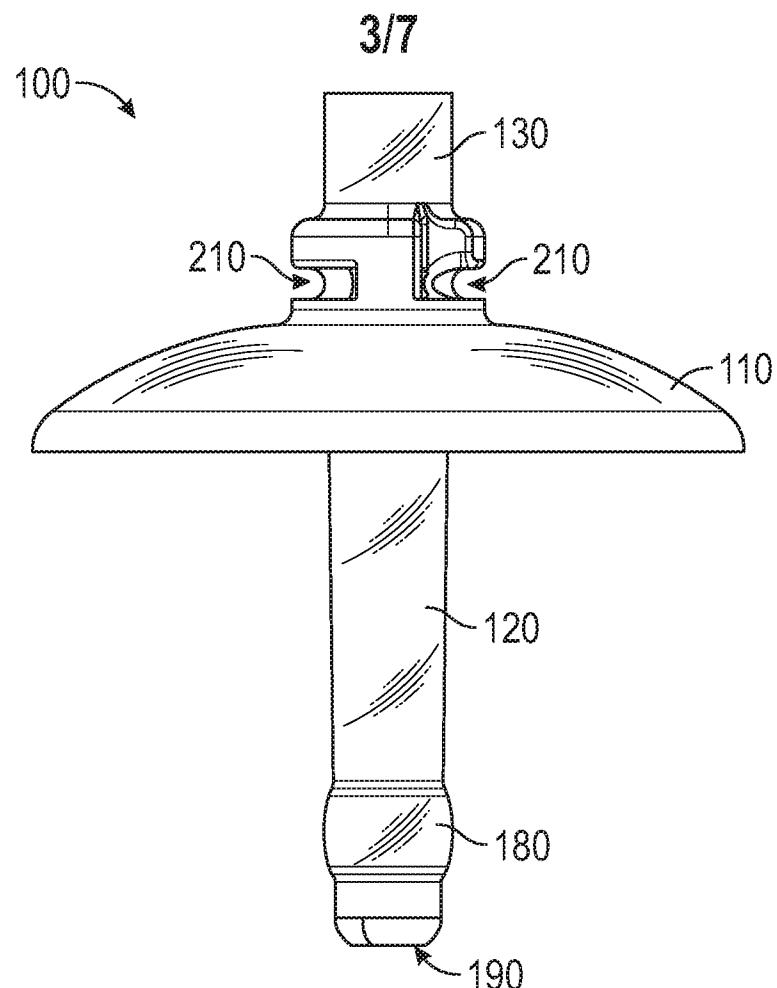


FIG. 5

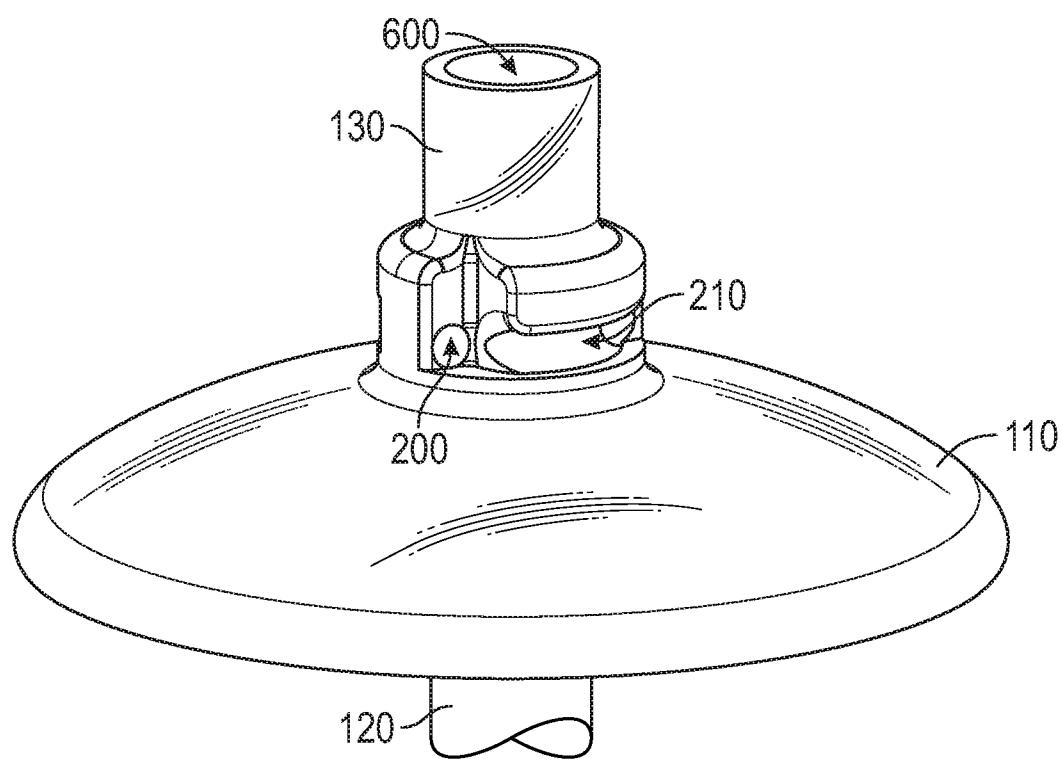


FIG. 6

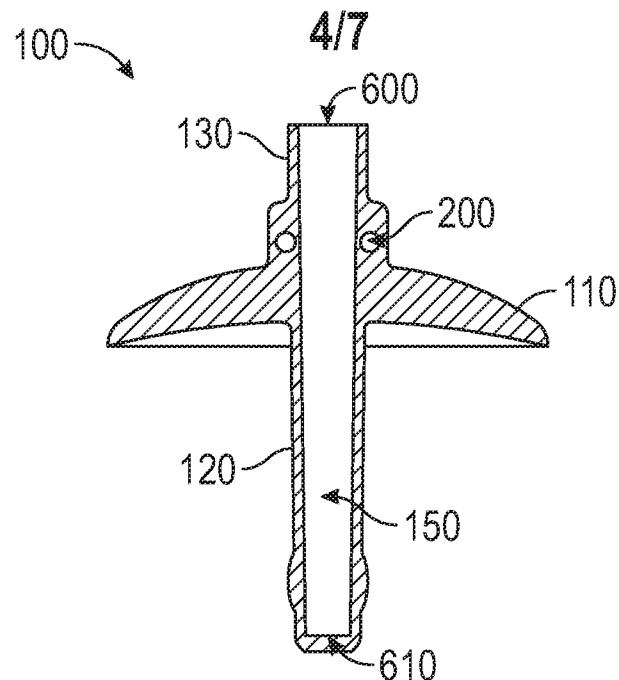


FIG. 7

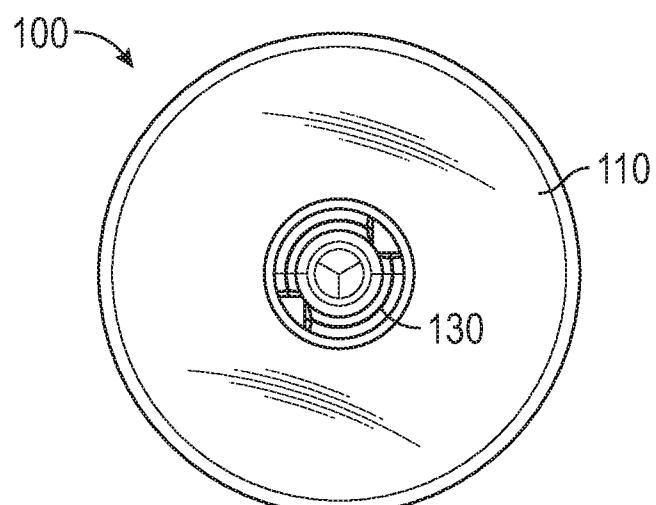


FIG. 8

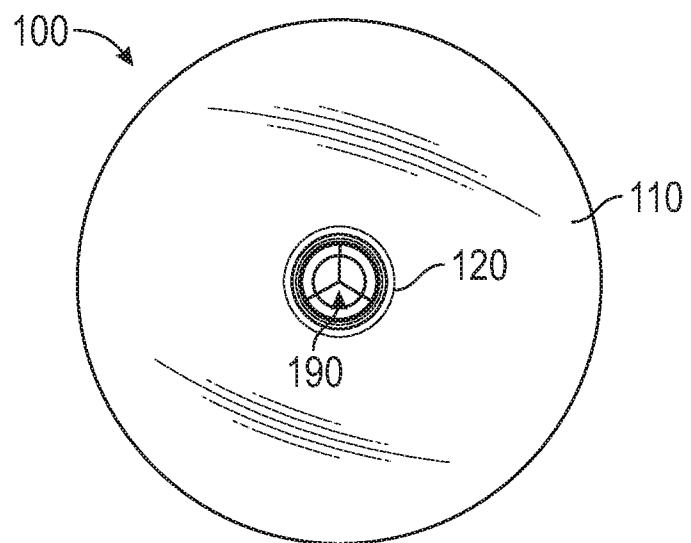
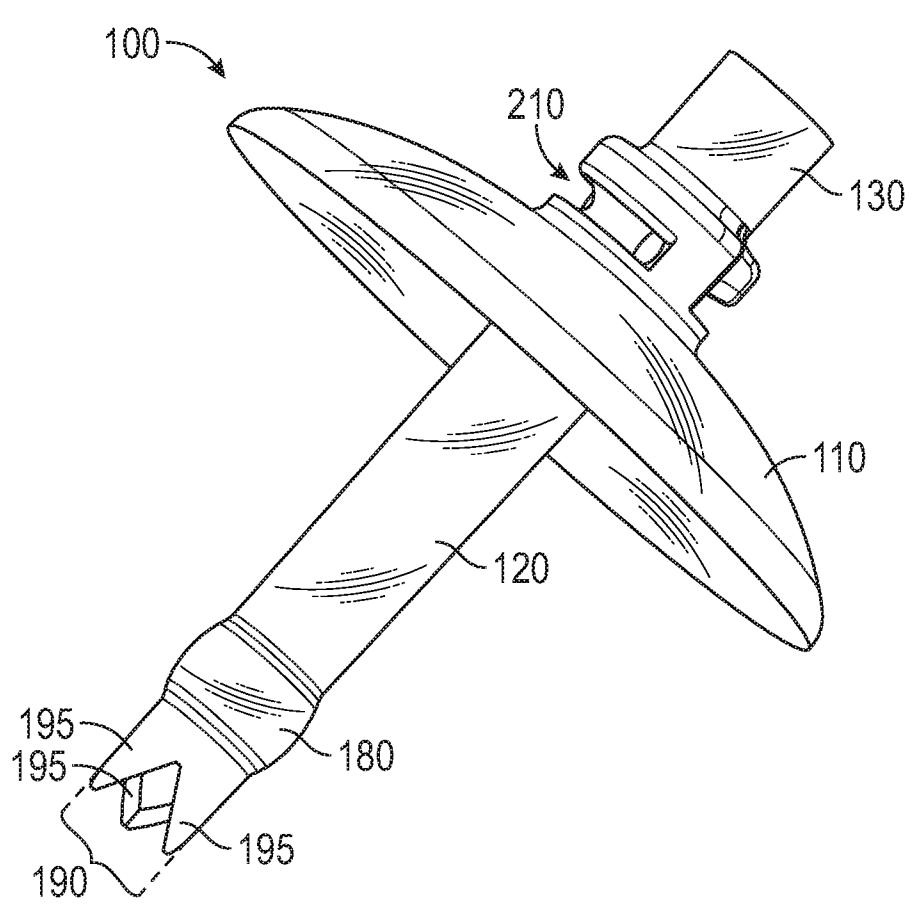
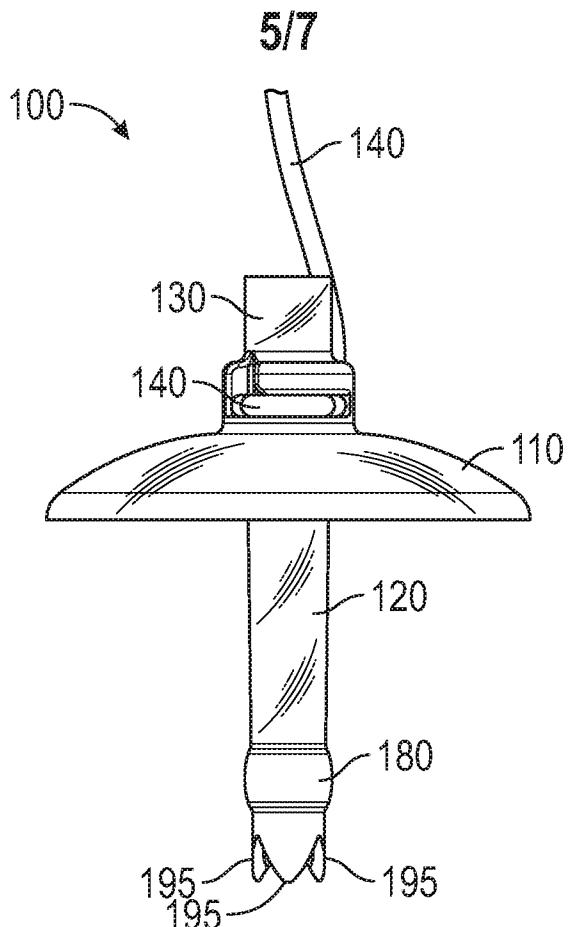


FIG. 9



6/7

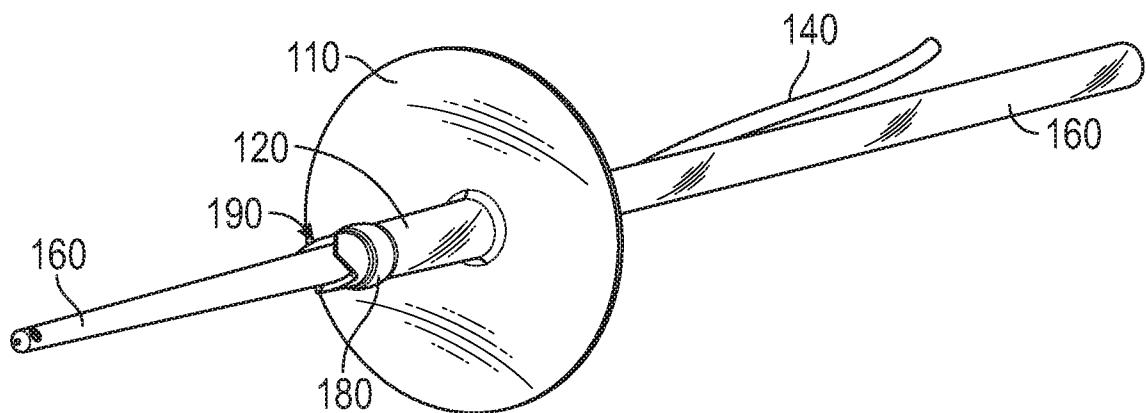


FIG. 12

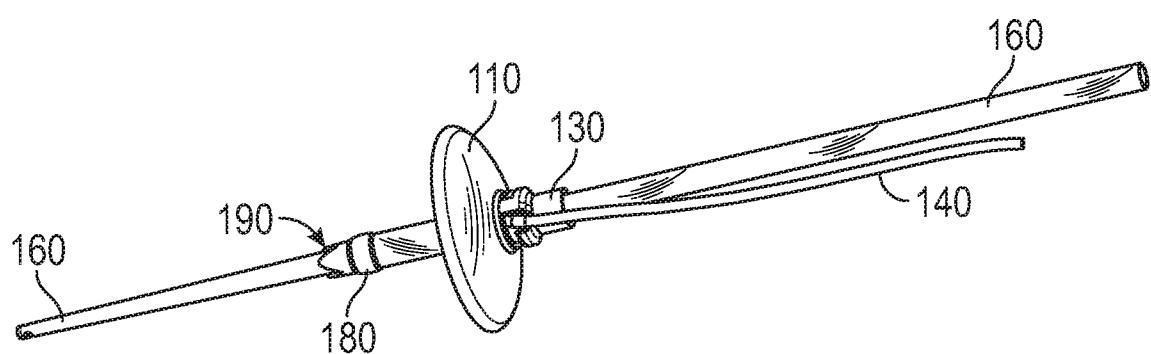


FIG. 13

7/7

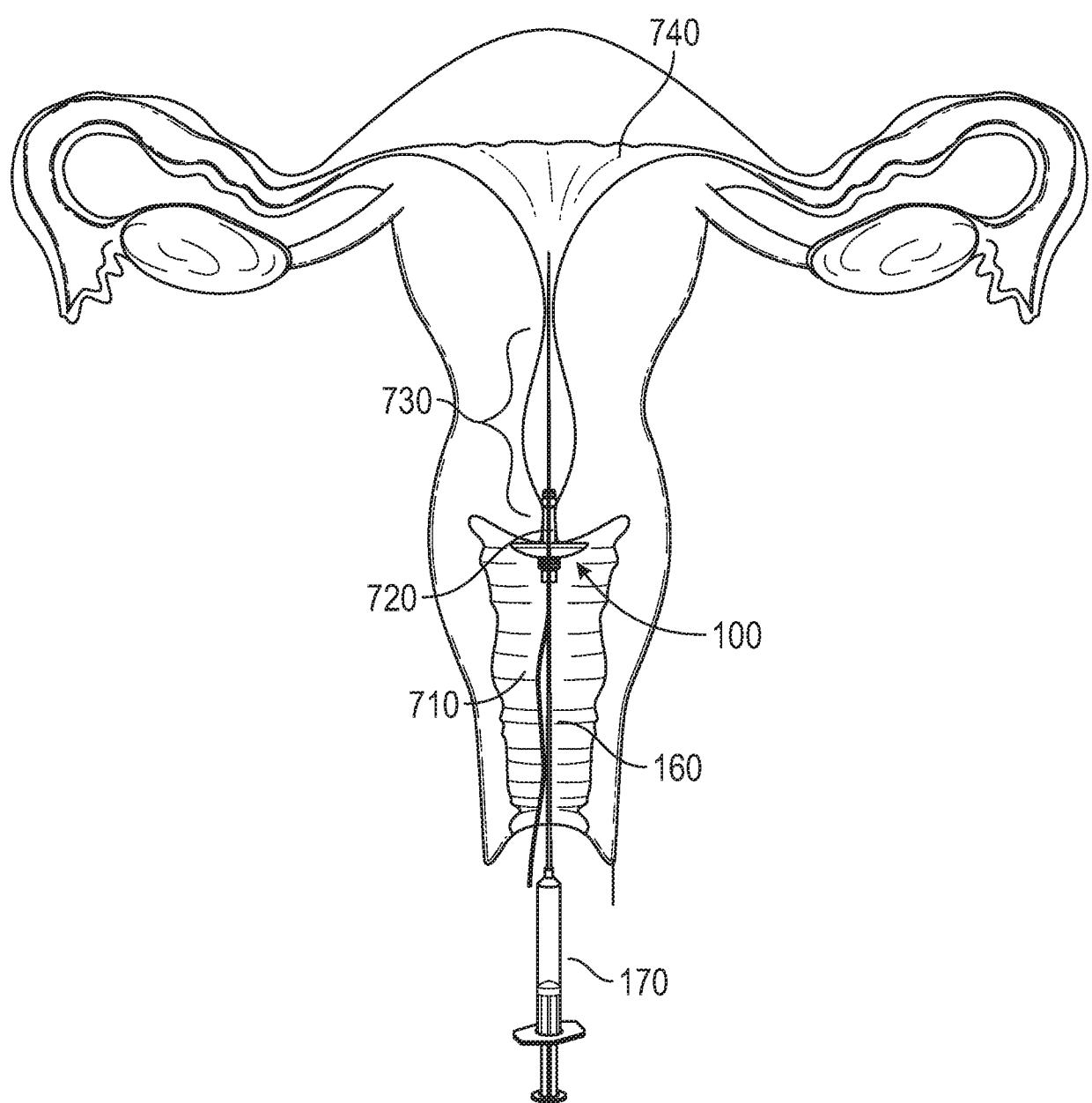


FIG. 14