CLAIMS

WHAT IS CLAIMED IS:

1. A cervical control system comprising:

a body comprising a proximal opening, a distal opening, an inner passageway between the proximal and distal openings, and an inflatable inner cuff disposed on a proximal portion of the body and defining the proximal opening, the inner passageway configured to receive a cervix of a patient therein; and

a positioning balloon disposed on an external surface of the body proximate the distal opening, the positioning balloon surrounding only a portion of a circumference of a distal portion of the body and configured to, when inflated, contact a vaginal wall to adjust an angle of orientation of the cervix; and

an inflation media conduit comprising a first end configured to be in fluid communication with the inflatable inner cuff and/or positioning balloon and a second end opposite the first end and configured to receive an inflation media.

2. The cervical control system of claim 1, wherein the positioning balloon comprises a minor arc shape disposed around less than 180 degrees of the circumference of the distal portion of the body.

3. The cervical control system of claim 1, further comprising: a plurality of cleats positioned on an exterior surface of the inflatable inner cuff.

4. The cervical control system of claim 1, wherein the inflatable inner cuff is configured to compress the cervix closed when expanded.

5. The cervical control system of claim 1, wherein the inflatable inner cuff is configured to pull the cervix away from a uterus of the patient when expanded.

6. The cervical control system of claim 1, wherein the body of the cervical control system is molded in one piece.

7. The cervical control system of claim 1, wherein the inflation media conduit is a bi-lumen inflation media conduit comprising:

a first lumen comprising a first end configured to be in fluid communication with the inflatable inner cuff and a second end configured to receive the inflation media; and

a second lumen comprising a first end configured to be in fluid communication with the positioning balloon and a second end configured to receive the inflation media.

8. The cervical control system of claim 1, further comprising:

a tube configured to be in fluid communication with the second end of the inflation media conduit, the tube being sufficiently long that it extends through the patient's vaginal canal and exits the introitus when the cervical control system is in position within the patient.

9. The cervical control system of claim 1, wherein a degree of expansion or contraction of the inflatable inner cuff and/or the positioning balloon is responsive to at least one of a clinical need, an orientation of the cervix, an orientation of the patient's uterus, a degree of dilation of the cervix, a length of the cervix, a degree of softness of the cervix, a level of amniotic fluid present in the patient's uterus, and an indication of a status of the patient's amniotic sac membrane.

10. The cervical control system of claim 1, the inflatable inner cuff further comprising:

a first recessed portion; and

a second recessed portion, the second recessed portion being positioned approximately one hundred and eighty degrees in opposition to the first recessed portion.

11. The cervical control system of claim 10, further comprising a first expandable portion positioned on a first side of the first recessed portion and a second expandable portion positioned on a second, opposite side of the first recessed portion, wherein, when inflation media is added to the inner cuff, the first and second expandable portions are configured to expand toward the inner passageway and the first and second recessed portions are configured to remain in an uninflated state.

12. The cervical control system of claim 1, wherein the positioning balloon extends around less than ninety five percent of the distal portion of the body.

13. A cervical control system comprising:

a body comprising a proximal opening, a distal opening, an inner passageway between the proximal and distal openings, and an inflatable inner cuff disposed on a proximal portion of the body and defining the proximal opening, the inflatable inner cuff comprising:

an exterior surface;

an interior surface; and

a first inner chamber disposed between the interior surface and the exterior surface;

a positioning balloon disposed on an external surface of the body proximate the distal opening, the positioning balloon surrounding only a portion of a circumference of a distal portion of the body, wherein the positioning balloon comprises a second inner chamber;

a first inflation media conduit, the first inflation media conduit comprising:

a first end in fluid communication with the first inner chamber; and

a second end configured to receive inflation media; and

a second inflation media conduit, the second inflation media conduit comprising:

a first end in fluid communication with the second inner chamber; and

a second end configured to receive inflation media,

wherein the inflatable inner cuff is configured to expand when inflation media is added to the first inner chamber via the first end of the first inflation media conduit, and

wherein the positioning balloon is configured to expand when inflation media is added to the second inner chamber via the second end of the inflation media conduit.

14. The cervical control system of claim 13, wherein at least one of the first inflation media conduit and the second inflation media conduit is in fluid communication with a valve.

15. The cervical control system of claim 14, wherein the valve is resident within a valve housing, the valve housing including a pressure sensor configured to sense pressure within the at least one first inflation media conduit and second inflation media conduit.

16. The cervical control system of claim 15, further comprising:

a tube physically coupled to and in fluid communication with at least one of the first inflation media conduit and the second inflation media conduit, the tube being configured to extend from the patient's body so that is accessible outside a patient's introitus when the patient's cervix is positioned within the inner passageway.

17. A cervical control system comprising:

a body defining an inner passageway configured to receive a cervix of a patient;

an expandable cuff configured to surround at least a portion of the cervix;

a positioning balloon disposed at an exterior surface of the body, wherein the positioning balloon surrounds a portion of a circumference of the exterior surface;

a first inflation media conduit comprising a first end in fluid communication with the expandable cuff and a second end configured to receive inflation media;

a second inflation media conduit comprising a first end in fluid communication with the positioning balloon and a second end configured to receive inflation media; and

a bi-lumen tube dimensioned to extend through the patient’s vaginal canal and exit the introitus when the body is in position within the patient, the bi-lumen tube comprising:

a first lumen having a first end in fluid communication with the second end of the first inflation media conduit, and a second opposing end configured to receive inflation media from outside the patient's body; and

a second lumen having a first end in fluid communication with the second end of the second inflation media conduit and a second opposing end configured to receive inflation media from outside the patient's body,

wherein the expandable cuff and the positioning balloon are configured to expand respectively upon the introduction of inflation media into the second ends of the first and second lumens.

18. The system of claim 17, wherein the second end of the first inflation media conduit or the second inflation media conduit is in fluid communication with a valve, and wherein the valve is configured to transition between an open state to permit flow of inflation media and a closed state to hold inflation media within the respective conduit.

19. The system of claim 17, wherein the positioning balloon is configured to adjust an angle of orientation of the cervix via adjustment of a volume of inflation media therein.

20. A cervical control system comprising:

a cuff comprising an exterior surface defining an internal passageway configured to accept insertion of a cervix, an interior surface, and a first inner chamber disposed between the interior surface and the exterior surface;

an expandable positioning balloon disposed on an exterior surface of the cervical control system and including a second inner chamber;

a first inflation media conduit having a first end in fluid communication with the first inner chamber and a second end;

a second inflation media conduit having a first end in fluid communication with the second inner chamber and a second end; and

a bi-lumen tube configured to extend through the patient’s vaginal canal and exit the introitus, the bi-lumen tube comprising:

a first lumen in fluid communication with the second end of the first inflation media conduit and configured to receive inflation media from outside the patient's body to expand the cuff; and

a second lumen in fluid communication with the second end of the second inflation media conduit and configured to receive inflation media from outside the patient's body to expand the expandable positioning balloon.

21. The system of claim 20, wherein the second end of the first inflation media conduit is in fluid communication with a first valve and the second end of the second inflation media conduit is in fluid communication with a second valve.

22. The system of claim 20, wherein the cuff is configured to compress the cervix, slow or stop a flow of amniotic fluid, or apply traction to the cervix upon expansion of the first inner chamber.

23. The system of claim 20, wherein the positioning balloon is configured to adjust an angle of orientation of the cervix upon expansion.