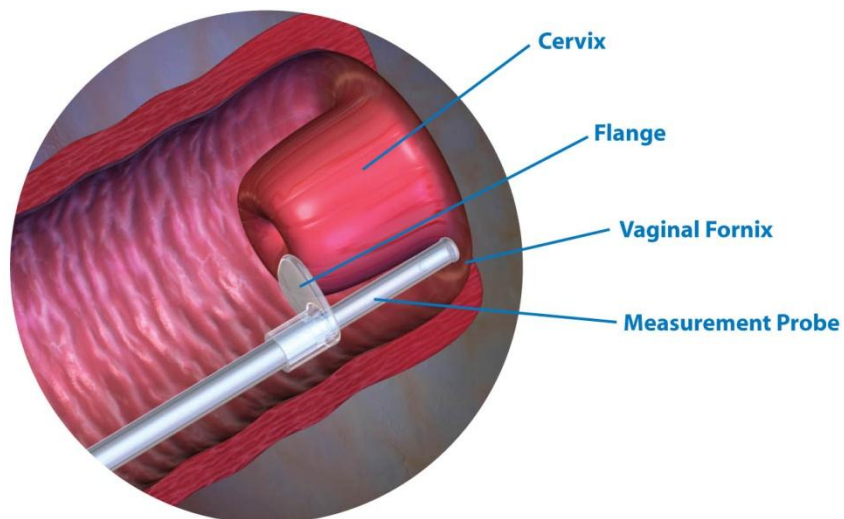


CerviLenz® is a single use device intended to measure vaginal cervical length during pregnancy. The measurement probe has calibrated markings that correspond to vaginal cervical length.



2 DO NOT RE-USE

Rx ONLY

Release Date: 04.06.2010

Directions for Use
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CerviLenz[®] Directions for Use

Any medical professional trained to do a speculum exam can use CerviLenz. To measure vaginal cervical length using CerviLenz, please carefully follow the steps below.

1. Insert a vaginal speculum according to normal protocol and ensure that lighting is adequate.
2. **Visualize the cervix.** To measure accurately, it is important to clearly visualize the cervix.
3. Insert CerviLenz into the vagina toward the cervix, leading with the measurement probe extended beyond the flange.
 - a. Orient the device with the measurement probe at 3 or 9 o'clock, to the right or left of the cervix.
 - b. **Do not insert the measurement probe into the cervical os.**
4. Advance the measurement probe along the lateral wall of the cervix until there is slight resistance at the vaginal fornix.

For an accurate measurement:

 - a. The probe should slide directly along the cervical wall rather than at an angle or away from the cervix.
 - b. The probe should advance only until it is just touching the back of the vagina.
5. Advance the flange until it rests gently on the cervix.

For an accurate measurement, the flange should lay flat on the cervix.
6. Lock the measurement probe by pressing the button on the handle.
 - a. If unsure that the probe was positioned optimally, another measurement can be taken without removing the device from the vagina. Alternatively, the probe can be removed and inserted again.
 - b. Unlock the probe by pressing the button from the opposite side of the handle; reposition the probe and flange for another measurement; re-lock.
7. Remove CerviLenz.
8. Read the scale and record the CerviLenz measurement.
9. Dispose in an appropriate waste container.
10. Remove speculum.

Caution

- DO NOT USE CERVILENZ IF YOU CANNOT VISUALIZE THE CERVIX
- DO NOT INSERT THE MEASUREMENT PROBE INTO THE CERVICAL OS
- DO NOT FORCE THE MEASUREMENT PROBE INTO THE VAGINAL FORNIX
- DO NOT EXERT EXCESSIVE PRESSURE ON THE CERVIX WITH THE FLANGE