



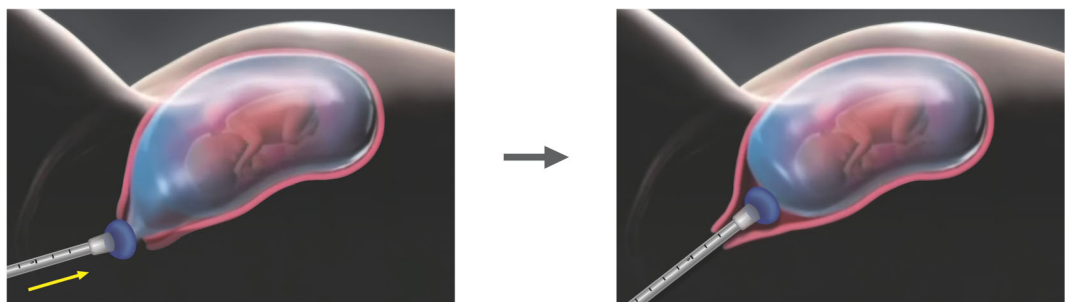
Lee's Cerclage Balloon (Uniconcave Balloon)

Lee's Cerclage Balloon is used for repositioning prolapsed fetal membrane into uterus prior to performing cervical cerclage to prevent still birth or preterm delivery.



① Features of Products

- Soft silicone balloon reduces risk of rupture of fetal membrane during the procedure.
- The range of proper air inflation volume and diameter of inflated balloon are printed on products.
- Depth marking is printed on product for easier measurement of the position of balloon and fetal membrane.



Prod. No	Air Fill Volume (Balloon should be completely deflated prior to inflation)	Diameter of Inflated Balloon	Diameter of Prolapsed Fetal Membrane
AI-001	3 ~ 4 mL	10~16 mm	The length of cervix was measured less than 25mm by ultrasonography although fetal membrane was not prolapsed outside of cervix.
			Less than 10mm
AI-002	6 ~ 10 mL	17~23 mm	Over 10mm ~ Less than 20mm
AI-003	10 ~ 15 mL	25~30 mm	Over 20mm ~ Less than 25mm
AI-004	15 ~ 30 mL	30~40 mm	Over 25mm

Directions for Use

- Select suitable size of device.
- Fill suggested air volume into balloon with needleless syringe and check the air leakage from balloon surface or balloon bonding area or check valve. After leakage test, deflate balloon completely by releasing syringe plunger.
- The procedure was performed under general anesthesia in the Trendelenburg position.
- Transabdominal amniocentesis was performed under ultrasonographic guidance to reduce the amount of amniotic fluid.
- The fetal membrane and the cervix were exposed using 2 Simpson retractors and the cervical edges were gently grasped with 2 atraumatic forceps.
- Fill suggested air volume into balloon with needleless syringe and insert device until the balloon is properly positioned on the prolapsed fetal membrane.
- Gently push the device until prolapsed fetal membrane is repositioned into uterus.
- Perform the cerclage procedure.
- After cerclage procedure, balloon is deflated and the device is removed from the patient.

Warning

- Do not use device if package has been damaged or opened.
- Disposal of the device shall be made in accordance with applicable national regulations for biologically hazardous waste.
- Do not expose the product to high temperature, humid air and ultraviolet ray during storage.
- Do not re-sterilize this device to avoid any potential risk of infection.
- Meticulous and prudent technique is the key to success. In cases of membrane rupturing during rescue cerclage after amnioreduction with this balloon, the operation should be discontinued.
- Vaginal bleeding and fluid leakage after rescue cerclage should be watched.

※ Precise information of instructions for use is inserted into each product package



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