Instructions Cerclage Pessary
(Type A unperforated, Type ASQ perforated)

CE 0482
MED/CERT
EN ISO 13485

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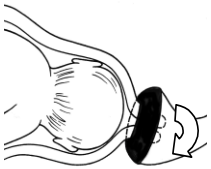
Components and storage: The cerclage pessary consists of high-quality silicone. It can be stored at temperatures from 1 to 30 °C protected from UV radiation without contact to reactive media, gas, ozone or mineral oil.



Indication: The cerclage pessary is designed and registered for the prevention of preterm birth for pregnant women with physical strain, overdistension (polyhydramnios/multiple pregnancy) and/or cervical shortening, but can also be indicated in patients with placenta previa to stabilize the lower uterine segment. Perforated models (ASQ) allow discharge to pass. The pessary does not close the cervix, but rather reduces the cervical tension by changing the utero-cervical angle (Figure). Due to the physiological shortening of the cervix during gestation pessaries are better indicated by centile values instead of strict cut-off values of the cervical length. In patients with a high background risk, the device can be placed at an earlier stage (e.g. centile 25 or 10).
Indication and application should be carried out by an experienced obstetrician who is familiar with the technique but also with the complex syndrome and prevention of preterm birth.-

Sizes: Cerclage pessaries are indexed by
a) outer diameter (65 mm for women without and 70 mm for women with previous vaginal birth), according to
b) height of curvature (17 mm rarely in the 1st trimester, 21 mm for singleton pregnancy, 25 mm for multiple pregnancy, 30 mm rarely for patients with additional genital prolapse)
c) inner diameter (32 mm for any cervical shortening, 35 mm rarely only for patients with a wider cervix and/or U-shaped funnel formation. The size indications are relative and can be modified according to the situation.

Teaching: According to the guidelines of the European and German Workgroup for the Prevention of Preterm Birth we recommend practical and theoretical teaching **before any use. More importantly, the patients should be followed in a cernter with expertise in preterm birth (preterm birth clinic) by a limited number of specialists who are acquainted with follow-up of patients at risk for preterm birth and therefore can better decide how to follow these patients, when to start additional therapies or to indicate hospital admission or removal of the pessary. Physicians in training or without any experience should be supervised.** We recommend to view the "you tube" of Prof. Alfirevic about practical use, to read the FAQs on our home page and to study the following publication before use: Kyvernitakis et al., Position Paper of the Task Force for Obstetrics and Prenatal Medicine (AGG - Section Preterm Birth) on the Placement, Removal and Surveillance of the Arabin Cervical Pessary in Patients at Risk for Spontaneous Preterm Birth. Geburtshilfe Frauenheilkd, 2019. 79(11): p. 1171-75. All teaching material can be viewed on our web site www.dr-arabin.de.

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Usage: The physician places the cerclage pessary while the patient is in a recumbent position**. Increased discharge is a side effect of any pessary therapy and usually not combined with a change of the vaginal microbiome or an "infection".** A bacterial swab is therefore only indicated to know the pattern of the vaginal colonisation. **It is important that the curvature of the pessary with the smaller diameter points upwards**. The pessary is folded before insertion and remains folded until the upper vaginal vault is reached. Then it is carefully pushed cranially as high as possible in the posterior vaginal vault so that the whole cervix is surrounded by the upper ring diameter. By briefly pressing on the anterior edge, the sacral rotation is reinforced (see video and FAQs of our web site or scan you tube). When the patient stands up, she **should feel comfortable without feeling the pessary**. If removal is not otherwise indicated, the pessary remains in place until about 37 weeks. Before removal, the cervix should be pushed back carefully. If a caesarean delivery is planned the pessary can be removed in the operating theatre. In case of preterm rupture of membranes, chorioamnionitis, vaginal bleeding and painful contractions a speculum examination should be performed, and the pessary removed to prevent ascending infections or cervical lesions. If the pessary is stuck in case of oedema, contractions or genital prolapse it should be removed without violence by cutting one side preferably with atraumatic episiotomy scissors.

Follow-up examination and controls during therapy: After the first insertion of the pessary **the patient should be re-examined within one week.** Then the position of the device should be checked, and it must be documented that the cervix is still surrounded by the upper inner diameter. For the duration of the treatment the patient should preferably be cared for by the same physician (team) who is familiar with pessary treatment in patients with imminent preterm birth - preferably in a so-called "preterm birth clinic". Transvaginal sonographic examinations can be performed by positioning the transducer on the upper cervical lip or even on top of the anterior edge of the pessary since the ultrasound waves are absorbed by the silicone. If this is not possible or uncomfortable, the vaginal probe should be directed behind the pessary, but this causes more manipulations. The rotated position of the pessary can easily be determined during a brief clinical examination even without touching the cervix. Further examination intervals and additional treatment strategies in case of imminent preterm birth depend on the severity of the preterm birth syndrome. Follow-up examinations should be carried out be experienced obstetricians. Without severe symptoms patients can be followed in an outpatient setting.

Application: The cerclage pessary is called a therapeutic product and is a **SINGLE USE PRODUCT**. If reused, infections cannot be excluded

Side effects/ complications: Although pessaries are a safe form of treatment, they are a "foreign body". **Therefore, the most frequent side effect is increased discharge which should not be confused with amniotic fluid. Discharge alone is no indication to remove the pessary but to re-assure the patient. In case of doubts, an ultrasound examination and biochemical tests should rule out preterm rupture of membranes.**
During defecation or in case of genital prolapse during pregnancy the pessary can descend and in the worst case dislocate. The patient should be informed that she might palpate the pessary when it descends together with the uterus and that she may push it up again. **In all cases with symptoms of painful contractions, vaginal bleeding, or preterm premature rupture of membranes the patient should immediately consult her physician who has to decide if the pessary can stay or should be removed**. In general, manipulations of the pessary should rather be avoided. In case of a proven rupture of membranes the pessary should be removed because of the risk of chorioamnionitis, exceptions at the border of viability or during maternal transport should be documented. **Of course, the pessary must be removed in case of active contractions, otherwise cervical lesions may occur.**

Duration of treatment: The duration of uninterrupted therapy depends on the week of pregnancy of the first application. It can be > 30 days according to the classification category.
Contraindications: Suspicion of chorioamnionitis, active regular contractions, prolapsed uterus (grade III), uterus bicollis, existing proven preterm premature rupture of membranes.

Warning: In case of fever, suspicion of (preterm) premature rupture of membranes or sepsis, regular contractions, and bleeding the physician in charge must be consulted and the pessary removed. Serious complications should be reported to the manufacturer and, if necessary, to the responsible authorities.

Shelf life: Under normal conditions (see above), the pessary is functionable up to 10 years**.**
Disposal: Used or damaged silicone products are removed in medical facilities. For disposal, the country-specific regulations must be considered.