Instructions Cerclage Pessary Perforated (CPP)

Dr. Arabin GmbH & Co KG A. Herrhausen Str. 44, D-58455 Witten-Germany Tel: +49 2302 189214 www.dr-arabin.de info@dr-arabin.de

CE 0482

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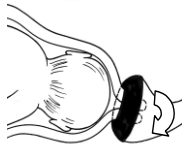

Components and storage: The cerclage pessary consists of high-quality silicone. It can be stored at temperatures from 1 to 50 °C protected from UV radiation without contact to reactive media, gas, ozone or mineral oil.

Indication/Intended Purpose: The cerclage pessary is designed and registered for the **secondary prevention of preterm birth** in singleton and multiple pregnancies between 12 and 34 gestational weeks when cervical shortening and/or funnelling are diagnosed by transvaginal sonography (TVS). Thereby it is recommended to relate the diagnosis to centile values of the cervical length throughout pregnancy (e.g., published by Salomon et al. 2009) and thereby to consider the background risk (history of preterm birth or cervical operation, artificial reproductive techniques, placenta praevia). The perforations allows discharge to pass. The pessary is supposed to reduce the pressure to the lower uterine segment by changing the utero-cervical angle (Figure). The 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. The intended purpose is a prolongation of pregnancy with the intention to improve the neonatal outcome.
Clinical use: The therapy with the cerclage pessary has the goal to postpone preterm birth and can thereby be combined with other methods (e.g., cerclage operation or medical treatment).
Sizes: The indications for sizes are relative and might be individualized. With increasing size the compression forces of our devices increase. The cerclage pessaries are indexed by the following sizes:
a) outer diameter (65 mm for women without and 70 mm for women with previous vaginal birth),
b) height of curvature (17 mm rarely in the 1st trimester, 21 mm for singleton pregnancy, 25 mm for multiple pregnancy and/or symptoms of genital prolapse grade 1-2)
c) inner diameter (32 mm for any cervical shortening, 35 mm only for patients with a wider cervix and/or U-shaped funnel formation.
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. The patients should be followed in a cernter with expertise in preterm birth (preterm birth clinic) by a limited number of specialists who are experienced 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, to indicate hospital admission or removal of the pessary. Physicians in training or without any experience should seek for supervision. We recommend to view the “you tube” of Prof. Alfirevic about practical use, to read the FAQs on our websitee and to study the Position Paper of the German Task Force (AGG - Section Preterm Birth) on Placement, Removal and Surveillance of the Arabin Cervical Pessary in Patients at Risk for sPTB before use: Kyvernitakis et al., Geburtshilfe Frauenheilkd, 2019. 79(11): p. 1171-75. All teaching material can be viewed on our website www.dr-arabin.de.

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Usage: The health care provider places the cerclage pessary while the patient is in a recumbent position**.** The device can be folded and inserted without pain**. It is important that the curvature of the pessary with the smaller diameter points upwards**. The device 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 whereby the position of the device should be determined documented whether its upper diameter still surrounds the cervix. 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 clinics". 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 rare cases, the size of the pessary may be changed. 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 (long time therapy, Class IIb).

Contraindications: Suspicion of infection, chorioamnionitis, normal cervical length, regular contractions, vaginal bleeding, genital prolapse Gr.III-IV,uterus bicollis, premature rupture of membranes, trachelectomy.
Warning: In case of pain, bleeding, regular contractions, suspicion of (preterm) premature rupture of membranes or sepsis the physician in charge must be consulted, a speculum examination performed and the pessary removed. Exceptions at the border of viability or during maternal transport should be documented. Serious complications should be reported to the manufacturer and, if necessary, to the responsible authorities.
Shelf life: Under the described storage conditions, 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.