



Dr. Arabin
dare to care



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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Plattenspool 2, 20355 Hamburg, Germany


Marcus Harder
Certification Body

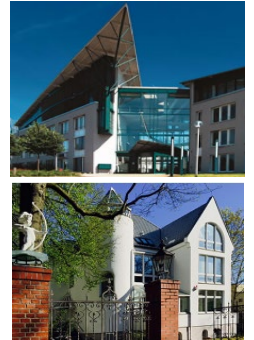
Product Overview 2025 with respect to the MDR

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PRODUCT GROUP A: Urogynecology

Ring-shaped devices/ Pessaries with vacuum effect/Manufactured/Hybrid

PRODUCT GROUP B

Obstetrics /Cerclage pessary



Our Dr. Arabin GmbH & Co KG follows a risk-based approach that relates to products, production, processes and personnel, including modifications and new developments (e.g. Dr. Arabin Hybrid pessary).

The Medical Device Regulation (MDR)/ Regulation (EU) 2017/745 on medical devices aims to increase the **quality and traceability of medical devices** through testing and documentation efforts. In addition to the **ISO 13485 certificate**, our team has received the **MDR certificate** since 2024 (valid until 2028). Our main goal is to integrate the MDR requirements into our development, production and service to **fulfill the requirements for the medical needs of patients**. This requires balancing **our commitments with the requirements of our customers**, consistently fulfilling the quality standards, and digitalizing our QM system to meet global challenges. We strive for appropriate counselling, training and scientific verification of sizes and models.

Our products are made of **biocompatible silicone** and produced by injection molding with subsequent grinding and tempering. We regularly verify and validate our products and processes. Our devices should be used for therapy by one patient only. We try to **strengthen women's health literacy**: Women should be informed about indications, therapeutic effects and the independent changing and cleaning of pessaries. Serious side effects of pessaries are rare when used according to instructions.

The profit of our company supports the Clara Angela Foundation:

<https://clara-angela.info>



CLARA ANGELA FOUNDATION





The main goals of our Group A class IIa are the prevention or treatment of pelvic floor dysfunctions such as genital prolapse/ incontinence. The models and sizes depend on the symptoms. Our devices of this group are stratified into four subgroups that are summarized in four technical documentations.

1. Ring-shaped pessaries for prolapse grade II (require support function of the pelvic floor). All devices are made of the same biocompatible silicone and by the same production process.

Ring pessary with customized compression force, also replaces the thick ring pessary



Size	Item No.	UDI-Code	Indication:
50 mm	R 050	04260245820566	Preferably milder forms of genital prolapse (grade II) and/or stress incontinence. The compression force is adjusted for larger diameters of the ring pessaries, i.e. the thickness of the diameter increases with increasing sizes.
55 mm	R 055	04260245820573	
60 mm	R 060	04260245820580	
65 mm	R 065	04260245820597	
70 mm	R 070	04260245820603	
75 mm	R 075	04260245820610	
80 mm	R 080	04260245820627	
85 mm	R 085	04260245820634	
90 mm	R 090	04260245820641	
95 mm	R 095	04260245820658	
100 mm	R 100	04260245820665	

Bowl pessary



Size	Item No	code	Indication
55	SP	04260245820719	Genital prolapse grade II and/or incontinence. In women with cystocele, the pessary supports the anterior (cystocele) and also the lateral wall defects. The prerequisite is a "still viable" pelvic floor
60	SP	04260245820726	
65	SP	04260245820733	
70	SP	04260245820740	
75	SP	04260245820757	
80	SP	04260245820764	
85	SP	04260245820771	
90	SP	04260245820788	
95	SP	04260245820795	

Sieve bowl pessary



Size	Item No.	UDI- code	Indication
55	SSP 055	04260245820801	Genital prolapse grade II and/or incontinence. In women with cystocele, the device supports additional medial and lateral defects. Compared to the bowl pessary, the sieve bowl pessary facilitates the passage of discharge.
60	SSP 060	04260245820818	
65	SSP 065	04260245820825	
70	SSP 070	04260245820832	
75	SSP 075	04260245820849	
80	SSP 080	04260245820856	
85	SSP 085	04260245820863	
90	SSP 090	04260245820870	
95	SSP 095	04260245820887	

Urethra bowl pessary



Size	Item No.	UDI- code	Indication
55	USP 055	04260245821013	Stress incontinence, with or without genital prolapse. Compared to the urethral pessary, this product dislocates less and remains in place. It can also be used in the case of additional vaginal prolapse
60	USP 060	04260245821020	
65	USP 065	04260245821037	
70	USP 070	04260245821044	
75	USP 075	04260245821051	
80	USP 080	04260245821068	
85	USP 085	04260245821075	
90	USP 090	04260245821082	

Urethra pessary with customized compression force



Size	Item No.	UDI-Code	Indication:
45 mm	UP 045	04260245820894	Stress - incontinence The thickening supports the transition between the bladder and the urethra. Thus it prevents an early opening of the urethra in case of physical stress
50 mm	UP 050	04260245820900	
55 mm	UP 055	04260245820917	
60 mm	UP 060	04260245820924	
65 mm	UP 065	04260245820931	
70 mm	UP 070	04260245820948	
75 mm	UP 075	04260245820955	
80 mm	UP 080	04260245820962	
85 mm	UP 085	04260245820979	
90 mm	UP 090	04260245820986	
95 mm	UP 095	04260245820993	
100 mm	UP 100	04260245821006	

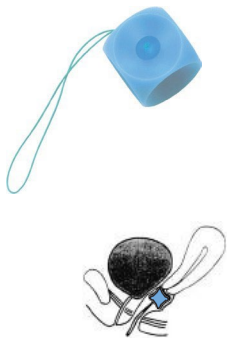
2. Pessaries with a concave wall structure creating a vacuum effect: cube/ tandem pessaries for genital prolapse grade II-III and/or incontinence and club pessaries for genital prolapse grade III-IV. Compared to ring-shaped pessaries, these products are made from a slightly softer, biocompatible silicone and are manufactured in several steps.

Cube and tandem pessaries can be used preoperatively to improve tissue perfusion (e.g. with oestriol cream). The flexibility of the material facilitates self-treatment. For isolated genital prolapse, smaller pessaries are placed in the upper vagina; for cysto- or rectocele, cube or tandem pessaries are placed in the middle or lower vagina respectively.

To guarantee hygienic conditions for self-management at home, we recommend using a storage container that we also offer at the manufacturing price.

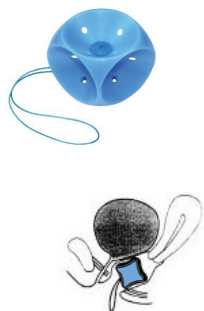
The new club pessaries are easier to change than the previous ones without losing its function.

Cube pessary non-perforated with button



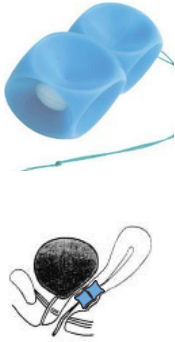
Size	Item No	UDI- code	Indication
25 mm	WP 0	04260245821150	Genital prolapse grade II-III and/or incontinence, regardless of whether the pelvic floor can hold devices or not, even with scars or abnormalities, as the device adapts to the anatomy.
29 mm	WP 1	04260245821167	
32 mm	WP 2	04260245821174	
37 mm	WP 3	04260245821181	
41 mm	WP 4	04260245821198	Compared to the perforated version, the non-perforated form can withstand greater strain on the internal organs, but no discharge can pass it.
45 mm	WP 5	04260245821204	
55 mm	WP 6	04260245821723	All cube pessaries should be routinely removed in the evening and reinserted in the morning or when under stress.
65 mm	WP 7	04260245821730	
70 mm	WP 8	04260245821747	
75 mm	WP 9	04260245821754	

Perforated cube pessary



Size	Item No	UDI- code	Indication
25 mm	WPP 0	04260245821211	Genital prolapse grade III-IV and/or incontinence, regardless of whether the pelvic floor is stable or not, even in the case of scars or abnormalities, as the pessary adapts.
29 mm	WPP 1	04260245821228	
32 mm	WPP 2	04260245821235	
37 mm	WPP 3	04260245821242	
41 mm	WPP 4	04260245821259	Compared to the non-perforated version, the product allows fluorine to run off and is easier to remove as the vacuum effect is less strong.
45 mm	WPP 5	04260245821266	
55 mm	WPP 6	04260245821761	All cube pessaries should be routinely removed in the evening and reinserted in the morning or when under stress.
65 mm	WPP 7	04260245821778	
70 mm	WPP 8	04260245821785	
75 mm	WPP 9	04260245821792	

Tandem pessary with button



Size	Item No	UDI- code	Indication
25 mm	TP0+0 F0	04260245821808	Genital prolapse grade III-IV and/or incontinence if a cube is not sufficient or the tandem pessary better treats pelvic floor dysfunction. The non-perforated form can withstand high loads of the internal organs but is more difficult to change. All tandem pessaries should routinely be removed in the evening and re-inserted in the morning or during physical stress.
25/29 mm	TP0+1 F0	04260245821815	
29/25 mm	TP1+0 F1	04260245821822	
29 mm	TP1+1 F1	04260245821839	
29/32 mm	TP1+2 F1	04260245821846	
32/29 mm	TP2+1 F2	04260245821853	
32 mm	TP2+2	04260245821860	
32/37 mm	TP2+3	04260245821877	
37/32 mm	TP3+2	04260245821884	
37 mm	TP3+3 F3	04260245821891	
37/41 mm	TP3+4 F3	04260245821907	
41/37 mm	TP4+3 F4	04260245821914	
41/45 mm	TP4+5 F4	04260245821938	
45/41 mm	TP5+4 F5	04260245821945	
45 mm	TP5+5 F5	04260245821952	

Tandem pessary perforated with button



Size	Item No	UDI- code	Indication
25 mm	TPP0+0 F0	04260245821969	Genital prolapse grade III-IV and/or incontinence if a cube is not sufficient or the tandem pessary better treats pelvic floor dysfunction. The non-perforated form can withstand even higher loads of the internal organs.
25/29 mm	TPP0+1 F0	04260245821976	
29/25 mm	TPP1+0 F1	04260245821983	
29 mm	TPP1+1 F1	04260245821990	
29/32 mm	TPP1+2 F1	04260245822003	
32/29 mm	TPP2+1 F2	04260245822010	
32 mm	TPP2+2	04260245822027	
32/37 mm	TPP2+3	04260245822034	
37/32 mm	TPP3+2	04260245822041	
37/41 mm	TPP3+4 F3	04260245822065	
41/37 mm	TPP4+3 F4	04260245822072	
41 mm	TPP4+4 F4	04260245822089	
41/45 mm	TPP4+5 F4	04260245822096	
45/41 mm	TPP5+4 F5	04260245822102	

Club pessary soft



Size	Item No	UDI- code	Indication
50	KP 050	04260245820474	Patients with genital prolapse grade III-IV are treated with the club pessary if cube pessaries are too weak to hold the organs or if patients are unable to change cube pessaries regularly.
55	KP 055	04260245820481	
60	KP 060	04260245820498	
65	KP 065	04260245820504	
70	KP 070	04260245820511	
75	KP 075	04260245820528	With the soft silicone the devices are now easier to change – even by patients- and still hold inner organs. .
80	KP 080	04260245820535	
85	KP 085	04260245820542	
90 mm	KP 090	04260245820559	

3. Ovoid Dr Arabin Hybrid Pessaries

Dr. Arabin Hybrid pessaries are **new developments** that treat pelvic floor dysfunction, regardless of the function of the pelvic floor and the age.

The name “Hybrid pessary” is based primarily on two effects: the pessaries lie ventrally on the symphysis pubis creating additional support. The pessaries are laterally characterized by recesses built into the walls. This promotes the formation of a vacuum effect and fixes the device to the vaginal walls. The egg-shaped contour and relatively soft consistency allow the pessary to be changed easily and prevent overstretching of the side walls as compared to round pessaries. Discharge and blood can drain centrally, patients can simultaneously even use a tampon.

The pessary was also developed for lesions of the levator ani muscle that are associated with an enlargement of the hiatus of the vagina (**avulsion**). The defined intended purpose is to support internal organs and relieve pressure or incontinence symptoms. **The pessaries can be used during pregnancy and the postpartum period for prevention and therapy of deterioration of pelvic floor dysfunction.** This is unique, although damage to the pelvic floor mostly occurs during pregnancy and even more during vaginal delivery. early and should then be treated. Therefore, practitioners and patients can choose between firm and soft hybrid pessaries.

Another purpose is the treatment of genital prolapse such as extensive cystocele that is inadequately treated by conventional models (e.g. when a cystocele descends laterally of the sides of cube pessaries. This effect is guaranteed by the supporting effect of the placement on the symphysis pubis.

We supply these pessaries with a storage box to guarantee hygiene during self-management,
We are planning further developments of hybrid pessaries. The present models available are:

Dr Arabin Hybrid Pessary normal



Size Long diameter	Item No	UDI code	Indication:
55	AHYPN 055	04260245829644	Patients with early pelvic floor dysfunction or women who are not satisfied with other models. Hybrid pessaries lie ventrally on the symphysis and are held laterally by recesses built into the walls. The egg-shaped contour prevents less overstretching of the side walls than round pessaries. They are also suitable in the case of cube pessaries with deeper lateral depressions. The severity of the symptoms, the stress in everyday life and the patient's subjective experience determine the consistency.
60	AHYPN 060	04260245829651	
65	AHYPN 065	04260245829668	
70	AHYPN 070	04260245829675	
75	AHYPN 075	04260245829682	
80	AHYPN 080	04260245829699	

Dr Arabin Hybrid Pessary soft



Size diameter	Item	UDI code	Indication:
55	AHYPNS 055	04260245829705	Patients with early pelvic floor dysfunction or women who are not satisfied with other models. Hybrid pessaries lie ventrally on the symphysis and are held laterally by recesses built into the walls. The egg-shaped contour prevents less overstretching of the side walls than round pessaries. They are also suitable in the case of cube pessaries with deeper lateral depressions. The severity of the symptoms, the stress in everyday life and the patient's subjective experience determine the consistency.
60	AHYPNS 060	04260245829712	
65	AHPYNS 065	04260245829729	
70	AHYPNS 070	04260245829736	
75	AHYPNS 075	04260245829743	
80	AHYPNS 080	04260245829750	

4. Special urogynecological pessaries, still manufactured

Urethra pessary with elastic metal inlay and round thickening



Size	Item No.	UDI-Code	Indication:
45 mm	UP 045	04260245822133	Stress incontinence mainly for women who have used this model and do not want to change or women with a small change. The thickening supports the transition between the bladder and the urethra. Thus it prevents an early opening of the urethra in case of physical stress.
50 mm	UP 050	04260245822140	
55 mm	UP 055	04260245822157	
60 mm	UP 060	04260245822164	
65 mm	UP 065	04260245822171	
70 mm	UP 070	04260245822188	
75 mm	UP 075	04260245822195	
80 mm	UP 080	04260245822201	
85 mm	UP 085	04260245822218	
90 mm	UP 090	04260245822225	
95 mm	UP 095	04260245822232	
100 mm	UP 100	04260245822249	

Hodge pessary with flexible metal inlay



This product is now only ordered as a customized product, as it has to be manufactured manually, see order forms on the first page of the website www.dr-arabin.de. Routine production has been discontinued as the original indication for the treatment of retroflexion of the uterus no longer exists.

Customized sizes between 55 and 90 mm can be accepted and requested with the signature of the doctor and patient.

Vaginal dilator for dilating the vagina in the case of malformations, (post-operative) stenoses



Size diameter/length)	Item No	code	Indication
20x120 mm	SD-XS	04260245820672	Vaginal dilators are indicated for narrowing or shortening of the vagina, whether due to malformations, post-operative complications or transsexuality. The treatment can be combined with other therapies (e.g. oestrogen therapy) can be combined. Therapy is usually only offered on an hourly basis but regularly carried out by patients.
25x125 mm	SD-S	04260245820689	
30x125 mm	SD-M	04260245820696	
35x135 mm	SD-L	04260245820702	

Help for beginners with pessary therapy

Adaptation rings (class I

The entire range of fitting rings consists of 3 x 4 rings of different sizes made of extremely soft, flexible silicone. In contrast to the therapeutic ring pessaries, the rings are green in color and are used exclusively for selecting the appropriate size of our urogynecological therapy pessaries. Instructions for using the set and a table showing how these adapter rings also help selecting suitable sizes for cube pessaries are included.

Adaptation sets are validated for sterilization and cleaning so that the rings can be reused in the outpatient clinic. Instructions for use and validation are available at www.dr-arabin.de/downloads.



Set (3 x 4)	Item No	UDI code
Small (45/50/55/60) mm	Adjustment Set	04260245821327
Medium (65/70/75/80) mm	Adjustment Set	04260245821334
Large (85/90/95/100) mm	Adjustment Set	04260245821341

Starter Set

A starter set with 6 individually selectable pessaries in size and model (cube pessaries sizes 6-9, tandem pessaries excluded) for routine outpatient use is available for €60 to help you treat your first patients. Pessaries can then also be reordered from us or pharmacies via prescription using our UDI codes or PZN numbers. The prices for individual products may vary as they are determined by local organizations, intermediaries and health insurance companies.

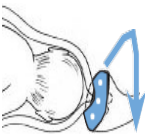


The main objectives of our products group B of class IIb are: Reduction of pressure on the cervix and lower uterine segment, thereby prolonging pregnancy and reducing infant mortality & morbidity

Premature birth is a syndrome with many causes; obstetricians should therefore focus their treatment concepts accordingly. Our products rotate the cervix towards the sacrum, thereby reducing the pressure on the lower uterine segment in cases of incipient or advanced cervical shortening. The aim is to stop the process of further opening of the internal os and shortening of the cervix. In pregnant women with placenta previa, the lower uterine segment is stabilized by such a device.

Our cerclage pessaries are defined by three sizes: the lower diameter (65 or 70 mm) adapted to the size of the vagina, the height (17, 21, 25 mm) adapted to the uterine weight and the upper diameter adapted to the size of the external cervical circumference (32 or 35 mm). On our website, we provide a video for inserting and removing the pessary and support selecting the size. Sizes 65/21/32, 65/25/32 usually fulfil their purpose.

Perforated cerclage pessary



Size	Item	UDI-Code	Indication:
65/17/32	CPP 65/17/32	04260245821501	Supporting the cervix in pregnant women with a risk of preterm birth (short cervix detected by ultrasound).
65/17/35	CPP 65/17/35	04260245821518	
65/21/32	CPP 65/21/32	04260245821525	Training and experience of the supervisors for indication, application, monitoring and removal of the pessary is required.
65/21/35	CPP 65/21/35	04260245821532	
65/25/32	CPP 65/25/32	04260245821549	
65/25/35	CPP 65/25/35	04260245821556	
70/17/32	CPP 70/17/32	04260245821570	
70/17/35	CPP 70/17/35	04260245821587	
70/21/32	CPP 70/21/32	04260245821594	
70/21/35	CPP 70/21/35	04260245821600	
70/25/32	CPP 70/25/32	04260245821617	
70/25/35	CPP 70/25/35	04260245821624	

Conclusions and view into the future

Internal organ prolapse can be caused by weaknesses in the pelvic floor muscle or connective tissue, which can cause various symptoms depending on their location. Surgery cannot always improve symptoms and carries risks such as additional injury or recurrence of symptoms. For this reason, specialist colleagues and international guidelines now consider pessary therapy to be the method of choice (Harvey et al. SOGC CLINICAL PRACTICE GUIDELINE 2021). The group led by R. Thakar in London has found that self-therapy by women is even more successful in most cases than pessary therapy prescribed by a doctor (Bugge et al. Health Technol Assess. 2024). We therefore encourage counseling for empowered patients with pelvic floor problems!

The success of urogynaecological pessary therapy depends on information, the right size, the right model and regular changes. Patients can insert and remove many gynecological pessaries themselves; daily changes are even recommended for cube, tandem and hybrid pessaries. **We therefore recommend hygienic storage in our special boxes.** Pessaries with thicker walls or hard material are often too stiff to handle. By consistently applying compression measurements, **we ensure that all our pessaries can be compressed with normal hand force.**

A threatened preterm birth usually develops gradually and has complex causes (a syndrome with many causes). Pessary therapy primarily treats mechanically caused problems and reduces the pressure on the lower uterine segment by rotating the cervix towards the sacrum. As compared with cerclage surgery or progesterone, the cerclage pessary has no disadvantages, but is more cost-effective and has no side effects (Hezelgrave et al. PLoS Med 2024). Usually, an MFM specialist indicates obstetric pessaries through transvaginal ultrasound examinations detecting a shortening of the cervix and/or placenta previa. Only specialists with experience should insert, monitor and remove pessaries. An Integrity meta-analysis found that only the studies in which experienced obstetricians carried out the therapy (with audit) and who also followed our instructions for the pessary were successful. Other studies can be challenged through the MDR, which has legal implications (Kyvernitakis et al., IJOG 2023). **For every pessary therapy, we recommend:**

- Communicate information about risk factors and pelvic floor disorders or the threat of preterm birth to include patients in treatment options.
- All our products are designed to limit physical inactivity and promote activity.

UROGYNECOLOGY

- Inform your patients that pessary therapy can relieve symptoms of genital prolapse and/or stress incontinence.
- Short- or long-term treatment is recommended to improve quality of life and prevent symptomatic worsening.
- Even complicated forms of organ prolapse up to grade IV can be treated.
- Warn patients that bleeding and pain require medical evaluation.
- Inform patients about self-management, micturition, bowel movements, carrying loads, and coughing.

OBSTETRICS

- Threatening preterm birth is a syndrome with many causes. If the cerclage pessary is used by experienced health care providers considering our instructions for use the treatment is not inferior to other therapies but less invasive and cost-effective. Inform pregnant women using a cerclage pessary therapy in case of regular contractions or suspicion of rupture of membranes to seek medical help possibly to remove the device.
- Propose our Dr. Arabin Hybrid pessary for genital prolapse and/or incontinence during or after pregnancy.

Please do not hesitate to ask us for professional support: info@dr-arabin.de. We will advise you promptly with clinical and scientific expertise according to the motto: