



**Dr. Arabin**  
dare to care

**Dr. Arabin GmbH & Co. KG**

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# Product Overview



The team of the Dr. Arabin GmbH & Co KG has defined a quality policy in the QM Handbook according to DIN ISO 13485-2016. Thereby, quality should relate to the demands of customers by fulfilling the medical needs of patients in the best professional way. The main goals are defined as:

**Prevention and treatment of pelvic floor disease such as genital prolapse and incontinence.** These diseases frequently already arise or become obvious throughout pregnancy and delivery and therefore affect women in their early and late life cycle.

**Prevention of infant mortality and morbidity through secondary prevention of preterm birth.** Preterm birth is a syndrome with many causes and obstetricians should therefore base their treatment concepts accordingly. Our devices rotate the cervix, reduce funneling and elongate the cervical length in those patients where cervical softness and pressure are etiologic.

The quality of our products is the basis of our activities. This requires:

- the precise coordination of our delivery promises with the requirements of our customers,
- consistent fulfillment of the defined quality standards,
- to review of the medical goals to face the challenges of further developments as well as globally different needs,
- appropriate advice, training and scientific review where required.

Our therapeutic devices are made of biocompatible silicone and can be used by one patient only.

We strive for health literacy of women who should be educated to know about the indication, therapeutic effects, how to change and clean pessaries by themselves according to the included instructions.

Serious side effects of pessaries are rare, when used according to instructions. Therefore, **our gynecological devices are class IIa products** (uninterrupted use < 30 days).

Patients should be instructed to be involved in the change of the devices to decide for a less invasive, cost-efficient, and yet effective therapy.

Our **obstetric pessaries to prevent preterm birth are class IIb products** (uninterrupted use > 30 days) to avoid unnecessary manipulations of the cervix.

## GROUP Aa) GENITAL PROLAPSE GRADE I-II AND/OR INCONTINENCE

### (treated by ring-shaped devices to prevent pressure to the pelvic floor)

The ring-shaped pessaries need some kind of intact pelvic floor, which still holds the device. Different models are indicated considering whether isolated genital prolapse and/ or incontinence are predominant symptoms.

#### Ring Pessary (Class IIa)

Adapted compression for handcraft!



Size	Item No.	UDI	Indication:
50 mm	R 050	4260245820566	Preferably mild problems of genital prolapse Grade I-II and/ or a mild form of incontinence.
55 mm	R 055	4260245820537	
60 mm	R 060	4260245820580	An intact pelvic floor is required for an effective therapy.
65 mm	R 065	4260245820597	
70 mm	R 070	4260245820603	
75 mm	R 075	4260245820610	
80 mm	R 080	4260245820627	
85 mm	R 085	4260245820634	The compression force is adapted by increasing diameters of the ring.
90 mm	R 090	4260245820641	
95 mm	R 095	4260245820658	
100 mm	R 100	4260245820665	

#### Thick Ring Pessary (Class IIa)

The ring pessary with adapted handcraft compression (see above) will slowly replace this device



Size	Item No.	UDI	Indication:
50 mm	DR 050	4260245820276	Preferably, older patients with genital prolapse Grade I-II and/ or incontinence.
55 mm	DR 055	4260245820283	
60 mm	DR 060	4260245820290	An intact pelvic floor is required for an effective therapy.
65 mm	DR 065	4260245820306	
70 mm	DR 070	4260245820313	
75 mm	DR 075	4260245820320	
80 mm	DR 080	4260245820337	
85 mm	DR 085	4260245820344	
90 mm	DR 090	4260245820351	
95 mm	DR 095	4260245820368	
100 mm	DR 100	4260245820375	



### Bowl Pessary (Class IIa)

Size	Item No.	UDI	Indication:
55 mm	SP 055	4260245820719	Genital prolapse grade I-II and/ or incontinence.
60 mm	SP 060	4260245820726	
65 mm	SP 065	4260245820733	In patients with a cystocele the pessary supports both the medial and the lateral defect.
70 mm	SP 070	4260245820740	
75 mm	SP 075	4260245820757	
80 mm	SP 080	4260245820764	An intact pelvic floor is required for an effective therapy
85 mm	SP 085	4260245820771	
90 mm	SP 090	4260245820788	
95 mm	SP 095	4260245820795	



### Sieve Bowl Pessary (Class IIa)

Size	Item No.	UDI	Indication:
55 mm	SSP 055	4260245820801	Genital prolapse grade I-II and/ or incontinence.
60 mm	SSP 060	4260245820818	
65 mm	SSP 065	4260245820825	In patients with a cystocele the pessary supports both the medial and the lateral defect.
70 mm	SSP 070	4260245820832	
75 mm	SSP 075	4260245820849	
80 mm	SSP 080	4260245820856	An intact pelvic floor is required for an effective therapy.
85 mm	SSP 085	4260245820863	
90 mm	SSP 090	4260245820870	
95 mm	SSP 095	4260245820887	



### Urethra Bowl Pessary (Class IIa)

Size	Item No.	UDI	Indication:
55 mm	USP 055	4260245821013	Stress incontinence possibly combined with genital prolapse provided the pelvic floor can hold the device.
60 mm	USP 060	4260245821020	
65 mm	USP 065	4260245821037	As compared to the Urethra pessary, the bowl may better support vaginal walls in case of genital prolapse and reduce the risk of displacement.
70 mm	USP 070	4260245821044	
75 mm	USP 075	4260245821051	
80 mm	USP 080	4260245821068	
85 mm	USP 085	4260245821075	
90 mm	USP 090	4260245821082	



### Urethra Pessary (Class IIa)

Adapted compression for handcraft!



Size	Item No.	UDI	Indication:
45 mm	UP 045	4260245820894	Stress incontinence possibly combined with genital prolapse provided the pelvic floor can hold the device.
50 mm	UP 050	4260245822900	
55 mm	UP 055	4260245820917	
60 mm	UP 060	4260245820924	The thickening supports the transition between bladder and urethra, avoiding an opening of the upper urethra under conditions of physical stress.
65 mm	UP 065	4260245820931	
70 mm	UP 070	4260245820948	
75 mm	UP 075	4260245820955	
80 mm	UP 080	4260245820962	
85 mm	UP 085	4260245820979	
90 mm	UP 090	4260245820986	
95 mm	UP 095	4260245820993	
100 mm	UP 100	4260245821006	



### Hodge Pessary (Class IIa)

Within Europe, this device can only be ordered as a customized device, see special order sheet on [www.dr-arabin.de](http://www.dr-arabin.de).

Routine production was stopped because the original indication to treat retroflexion of the uterus is no longer valid. Orders from outside Europe and individual sizes can be accepted between 55 and 90 mm in 5 mm steps.

## GROUP Ab) GENITAL PROLAPSE GRADE III –IV AND/OR INCOTNTINENCE (treated by different forms to re-dispose the prolapse)

Cube and tandem pessaries can be used before surgery in order to improve the tissue circulation (e.g. application with estriol cream). The flexibility of the material facilitates self-treatment. For isolated genital prolapse, smaller pessaries are placed in the proximal vagina, for additional cysto-rectocele, larger sizes (or Tandem pessaries) are placed in the medium vagina. In patients with severe prolapse where the cube or tandem pessaries do not hold or cannot be changed on a regular basis, a club pessary is indicated.



### Cube Pessary with button (Class IIa)

Size	Item No.	UDI	Indication:
25 mm	WP 0	4260245821150	Genital prolapse grade III-IV and/ or incontinence, when the pelvic floor is not capable to support a ring pessary, even in the presence of scars or anatomic aberrations As compared to the perforated version, this device can withstand higher pressure from the inner organs but does not allow passage of fluid. All cube pessaries should be removed in the evening and reinserted in the morning on a daily basis.
29 mm	WP 1	4260245821167	
32 mm	WP 2	4260245821174	
37 mm	WP 3	4260245821181	
41 mm	WP 4	4260245821198	
45 mm	WP 5	4260245821204	
55 mm	WP 6	4260245821723	
65 mm	WP 7	4260245821730	
70 mm	WP 8	4260245821747	
75 mm	WP 9	4260245821754	



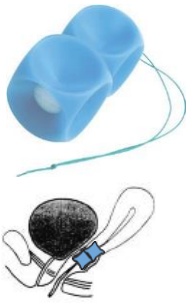
### Cube Pessary perforated with button (Class IIa)

Size	Item No.	UDI	Indication:
25 mm	WPP 0	4260245821211	Genital prolapse grade III-IV and/ or incontinence, when the pelvic floor is not capable to support a ring pessary, even in the presence of scars or anatomic aberrations As compared to the non-perforated version, this device allows drainage of fluid (blood or discharge). All cube pessaries should be removed in the evening and reinserted in the morning on a daily basis.
29 mm	WPP 1	4260245821228	
32 mm	WPP 2	4260245821235	
37 mm	WPP 3	4260245821242	
41 mm	WPP 4	4260245821259	
45 mm	WPP 5	4260245821266	
55 mm	WPP 6	4260245821761	
65 mm	WPP 7	4260245821778	
70 mm	WPP 8	4260245821785	
75 mm	WPP 9	4260245821792	

### Tandem Pessary (Class IIa)

Size	Item No.	UDI	Indication:
25 mm	TP0+0 F0	4260245821808	The same as above, in cases with extreme prolapse of vagina and / or uterus or anatomically special situation the larger surface with a vacuum effect may better hold the inner organs. This can also be useful in patients with additional stress incontinence. All tandem pessaries should be removed in the evening and reinserted in the morning.
25/29 mm	TP0+1 F0	4260245821815	
29/25 mm	TP1+0 F1	4260245821822	
29 mm	TP1+1 F1	4260245821839	
29/32 mm	TP1+2 F1	4260245821846	
32/29 mm	TP2+1 F2	4260245821853	
32 mm	TP2+2 F2	4260245821860	
32/37 mm	TP2+3 F2	4260245821877	
37/32 mm	TP3+2 F3	4260245821884	
37 mm	TP3+3 F3	4260245821891	
37/41 mm	TP3+4 F3	4260245821907	
41/37 mm	TP4+3 F4	4260245821914	
41 mm	TP4+4 F4	4260245821921	
41/45 mm	TP4+5 F4	4260245821938	
45/41 mm	TP5+4 F5	4260245821945	
45 mm	TP5+5 F5	4260245821952	





### Tandem Pessary perforated (Class IIa)

Size	Item No.	UDI	Indication:
25 mm	TPP0+0 F0	4260245821969	The same as above, in cases with extreme prolapse of vagina and / or uterus or anatomically special situation the larger surface with a vacuum effect may better hold the inner organs. This can also be useful in patients with additional stress incontinence.  All tandem pessaries should be removed in the evening and reinserted in the morning.
25/29 mm	TPP0+1 F0	4260245821976	
29/25 mm	TPP1+0 F1	4260245821983	
29 mm	TPP1+1 F1	4260245821990	
29/32 mm	TPP1+2 F1	4260245822003	
32/29 mm	TPP2+1 F2	4260245822010	
32 mm	TPP2+2 F2	4260245822027	
32/37 mm	TPP2+3 F2	4260245822034	
37/32 mm	TPP3+2 F3	4260245822041	
37 mm	TPP3+3 F3	4260245822058	
37/41 mm	TPP3+4 F3	4260245822065	
41/37 mm	TPP4+3 F4	4260245822072	
41 mm	TPP4+4 F4	4260245822089	
41/45 mm	TPP4+5 F4	4260245822096	
45/41 mm	TPP5+4 F5	4260245822102	
45 mm	TPP5+5 F5	4260245822119	

### Club pessary (Class IIa)

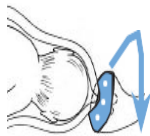
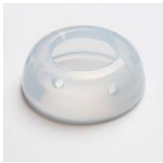


Size	Item No.	UDI	Indication:
50 mm	KP 050	4260245820474	Patients with genital prolapse grade III-IV are treated with the club pessary when cube pessaries do not any longer stay in place or cannot be handled by patients.
55 mm	KP 055	4260245820481	
60 mm	KP 060	4260245820498	
65 mm	KP 065	4260245820504	
70 mm	KP 070	4260245820511	
75 mm	KP 075	4280245820528	
80 mm	KP 080	4260245820535	
85 mm	KP 085	4260245820542	
90 mm	KP 090	4260245820559	

## GROUP B) OBSTETRIC DEVICES TO PREVENT PRETERM BIRTH (treated by dome-shaped devices to release pressure to the cervix)

Our perforated 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 sizes of the outer cervical circumference. On our website, we provide a video how to insert and remove the devices as well as a model for choosing the right sizes. In general, sizes like 32/21/65 or 32/25/65 or 70 fulfill the task.

### Cerclage Pessary Perforated (Class IIb)



Size	Item No.	UDI	
65/17/32	CPP 65/17/32	4260245821501	<p><b>Indication:</b> To support the cervix in pregnant patients with threatening preterm labor (funneling / short cervix) by rotating the cervix towards the sacrum.</p> <p>It is recommended that experience in at least 30 patients is required for a successful therapy.</p> <p>We also support and recommend continuous care and surveillance by experienced experts preferably within preterm birth clinics.</p>
65/17/35	CPP 65/17/35	4260245821518	
65/21/32	CPP 65/21/32	4260245821525	
65/21/35	CPP 65/21/35	4260245821532	
65/25/32	CPP 65/25/32	4260245821549	
65/25/35	CPP 65/25/35	4260245821556	
70/17/32	CPP 70/17/32	4260245821570	
70/17/35	CPP 70/17/35	4260245821587	
70/21/32	CPP 70/21/32	4260245821594	
70/21/35	CPP 70/21/35	4260245821600	
70/25/32	CPP 70/25/32	4260245821617	
70/25/35	CPP 70/25/35	4260245821624	

## GROUP Ac) SPECIAL GYNECOLOGICAL DEVICES

(to dilate or enlarge the vagina in case of malformation, stenosis or post-operative care)

### Vaginal expanders (Class IIa)

Size	Item No.	UDI	Indication:
15x120 mm	SD-XXS	4260245822287	Vaginal expanders are indicated in patients for different reasons such as malformations, obstructions due to scars after episiotomies or vaginal operations. They can also be combined with estrogen or fatty crèmes.
20x120 mm	SD-XS	4260245820672	
25x125 mm	SD-S	4260245820689	The duration of uninterrupted treatment is rarely more than some hours /day and surely less than 12 hours of uninterrupted use.
30x125 mm	M	4260245820696	
35x135 mm	L	4260245820702	

## Special arrangements/advice for beginners in pessary treatment

### Adaption Set Ring (Class I)

The whole range of adaption rings consists of 3 x 4 rings made out of extremely soft flexible silicone. In contrast to the therapeutic ring pessaries rings for adaption have a green color and serve exclusively to choose the appropriate size of our urogynecological therapeutic pessaries. Instructions for use of each pessary and a table how these adaption rings help to choose even cube sizes are applied.

In opposite to all other gynecological devices adaption sets are validated for sterilization and cleaning so that the rings can be re-used within outpatient units (see [www.dr-arabin.de/downloads](http://www.dr-arabin.de/downloads)).



Set sizes (4 rings each)	Item No.	UDI
Small (45/50/55/60 mm)	Adaption set <b>Small</b>	4260245821327
Medium (65/70/75/80 mm)	Adaption set <b>Normal</b>	4260245821334
Large (85/90/95/100 mm)	Adaption set <b>Large</b>	4260245821341

### Starter Set

A starter set with 6 pessaries of individual choice of size and model for the routine outpatient setting is available for 50 €, provided that prescriptions will follow.

All other prices may vary because they depend on local facilities, transport and registration policy.



## Conclusions

For all **gynecological devices**, we recommend pessaries with the smallest diameter, which still stays in place to avoid unnecessary enlargement of vaginal walls. The success depends on proper information, indication of the right size and model and on a regular removal and re-insertion. Patients can insert and remove most gynecological devices themselves; this is even required when daily removal is recommended as in the case of the soft cube or tandem pessaries. If pessaries increase in wall size, they become stiffer and need a stronger handgrip to be compressed. Nevertheless, all our devices are within the normal range of handgrip, which allows self-management.

For **obstetric pessaries**, self-management is obsolete. Only a specialist in obstetrics, who can assure that the upper diameter of the device surrounds the complete cervix, should insert obstetric pessaries.

A prolapse and even threatening preterm birth evolve slowly and therapy is rarely an emergency. The use of a pessary (continuous or discontinuous) can improve discomfort and symptoms associated with prolapse and threatening preterm birth. Therefore, we advise:

- **Transmit clear information on risk factors and the evolution of genital prolapse or preterm birth to re-assure the patient and involve her in the treatment presenting options.**
- **Inform her that the use of a pessary and/or additional treatments can improve the discomfort and symptoms associated with prolapse, threatening preterm birth or both.**
- **Continuous or discontinuous treatment for prolapse is only necessary if discomfort is proven by impaired life quality, or in the event of a complicated form of prolapse.**
- **Bleeding and pain require consultation in obstetric and gynecological patients.**
- **Provide therapeutic education in voiding, defecation, carrying loads and in cough control.**
- **All devices should help to limit physical inactivity and to promote physical activity.**

**PLEASE DO NOT HESITATE TO CONTACT US FOR ANY PROFESSIONAL SUPPORT: [info@dr-arabin.de](mailto:info@dr-arabin.de)**