

#### 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)

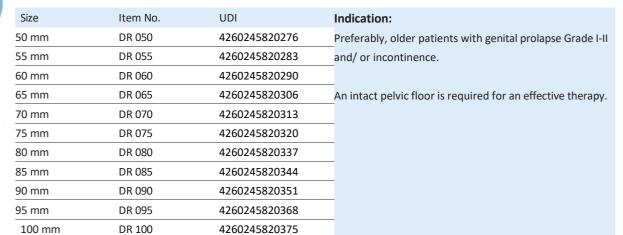
#### New: Adapted compression for handcraft!

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









## **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
70 mm	SP 070	4260245820740	the medial and the lateral defect.
75 mm	SP 075	4260245820757	
80 mm	SP 080	4260245820764	
85 mm	SP 085	4260245820771	An intact pelvic floor is required for an effective therapy
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
70 mm	SSP 070	4260245820832	the medial and the lateral defect.
75 mm	SSP 075	4260245820849	
80 mm	SSP 080	4260245820856	
85 mm	SSP 085	4260245820863	An intact pelvic floor is required for an effective therapy.
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
70 mm	USP 070	4260245821044	better support vaginal walls in case of genital prolapse
75 mm	USP 075	4260245821051	and reduce the risk of displacement.
80 mm	USP 080	4260245821068	
85 mm	USP 085	4260245821075	
90 mm	USP 090	4260245821082	





#### **Urethra Pessary (Class IIa)**

New: Adapted compression for handcraft!

Size	Item No.	UDI	Indication:
45 mm	UP 045	4260245820894	Stress incontinence possibly combined with genital
50 mm	UP 050	4260245822900	prolapse provided the pelvic floor can hold the device.
55 mm	UP 055	4260245820917	
60 mm	UP 060	4260245820924	The thickening supports the transition between bladder
65 mm	UP 065	4260245820931	and urethra, avoiding an opening of the upper urethra
70 mm	UP 070	4260245820948	under conditions of physical stress.
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)**

This device can only be ordered as a customized device, see special order sheet on www.dr-arabin.de.

Routine production was stopped because the original indication to treat retroflexion of the uterus is no longer valid.

Individual sizes can be accepted between 55 and 90 mm.

## 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	WPK 0	4260245821150	Genital prolapse grade III-IV and/ or incontinence,
29 mm	WPK 1	4260245821167	when the pelvic floor is not capable to support a ring
32 mm	WPK 2	4260245821174	pessary, even in the presence of scars or anatomic aberrations
37 mm	WPK 3	4260245821181	—As compared to the perforated version, this device can
41 mm	WPK 4	4260245821198	withstand higher pressure from the inner organs but does
45 mm	WPK 5	4260245821204	not allow passage of fluid.
55 mm	WPK 6	4260245821723	All cube pessaries should be removed in the evening and
65 mm	WPK 7	4260245821730	reinserted in the morning on a daily basis.
70 mm	WPK 8	4260245821747	
75 mm	WPK 9	4260245821754	



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

Item No.

TP4+5 F4

TP5+4 F5

TP5+5 F5

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

Indication:



#### **Tandem Pessary (Class IIa)**

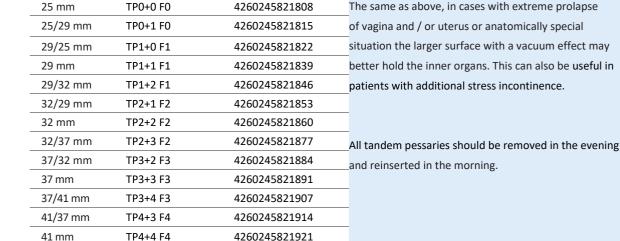
Size

41/45 mm

45/41 mm

45 mm

4	M



4260245821938

4260245821945

4260245821952

UDI





## Tandem Pessary perforated (Class IIa)

	<i>,</i> .		
Size	Item No.	UDI	Indication:
25 mm	TPL0+0 F0	4260245821969	The same as above, in cases with extreme prolapse
25/29 mm	TPL0+1 F0	4260245821976	of vagina and / or uterus or anatomically special
29/25 mm	TPL1+0 F1	4260245821983	situation the larger surface with a vacuum effect may
29 mm	TPL1+1 F1	4260245821990	better hold the inner organs. This can also be useful in
29/32 mm	TPL1+2 F1	4260245822003	patients with additional stress incontinence.
32/29 mm	TPL2+1 F2	4260245822010	
32 mm	TPL2+2 F2	4260245822027	
32/37 mm	TPL2+3 F2	4260245822034	All tandem pessaries should be removed in the evening
37/32 mm	TPL3+2 F3	4260245822041	and reinserted in the morning.
37 mm	TPL3+3 F3	4260245822058	Ů
37/41 mm	TPL3+4 F3	4260245822065	
41/37 mm	TPL4+3 F4	4260245822072	
41 mm	TPL4+4 F4	4260245822089	
41/45 mm	TPL4+5 F4	4260245822096	
45/41 mm	TPL5+4 F5	4260245822102	
45 mm	TPL5+5 F5	4260245822119	

## Club pessary (Class IIa)





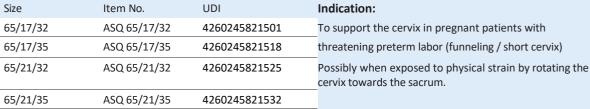
Size	Item No.	UDI	Indication:
50 mm	KP 050	4260245820474	Patients with genital prolapse grade III-IV are treated
55 mm	KP 055	4260245820481	with the club pessary when cube pessaries do not any
60 mm	KP 060	4260245820498	longer stay in place or cannot be handled by patients.
65 mm	KP 065	4260245820504	
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	The pessary is quite stiff which impairs handling of the patient herself. Insertion and removal should be performed with caution and expertise.

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

Our cerclage pessaries are defined by three sizes: the lower diameter (65or 70 mm) adapted to the size of the vagina, the height (17, 21, 25 or 30 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 Type ASQ (perforated) (Class IIb)







,	05/21/32	A3Q 65/21/32	4200245821525	cervix towards the sacrum.
(	65/21/35	ASQ 65/21/35	4260245821532	
_	65/25/32	ASQ 65/25/32	4260245821549	
(	65/25/35	ASQ 65/25/35	4260245821556	
(	65/30/35	ASQ 65/30/35	4260245821563	Training and experience of the health care providers to
	70/17/32	ASQ 70/17/32	4260245821570	insert, follow and remove the device in at least 30
	70/17/35	ASQ 70/17/35	4260245821587	patients is required for a successful therapy.
	70/21/32	ASQ 70/21/32	4260245821594	We also support and recommend continuous care and
	70/21/35	ASQ 70/21/35	4260245821600	surveillance by experienced experts preferably within
	70/25/32	ASQ 70/25/32	4260245821617	preterm birth clinics.
	70/25/35	ASQ 70/25/35	4260245821624	

## **GROUP Ac) SPECIAL GYNECOLOGICAL DEVICES**

ASQ 70/30/35

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

4260245821631

#### Vaginal expanders (Class IIa)

70/30/35



Size	Item No.	UDI	Indication:
20 mm	SD-XS	4260245820672	Vaginal expanders are indicated in patients when an
27 mm	SD-S	4260245820689	expansion of the vagina is a therapeutic effect for
30 mm	SD-M	4260245820696	different reasons such as malformations, obstructions
37 mm	SD-L	4260245820702	due to scars after episiotomies or vaginal operations.
			They can also be combined with estrogen or fatty crèmes.
			The duration of uninterrupted treatment is rarely more
			than the time it is manually used unless patients may wish
			to carry this overnight.

## 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).



Set sizes (4 each)	Item No.	UDI
Small (50/55/60/65 mm)	Adaption set ring Small	42602458 21327
Middlel (65/70/75/80 mm)	Adaption set ring Normal	42602458 21334
Large (85/90/95/10 0 mm)	Adaption set ring Large	42602458 21341

#### **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. 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