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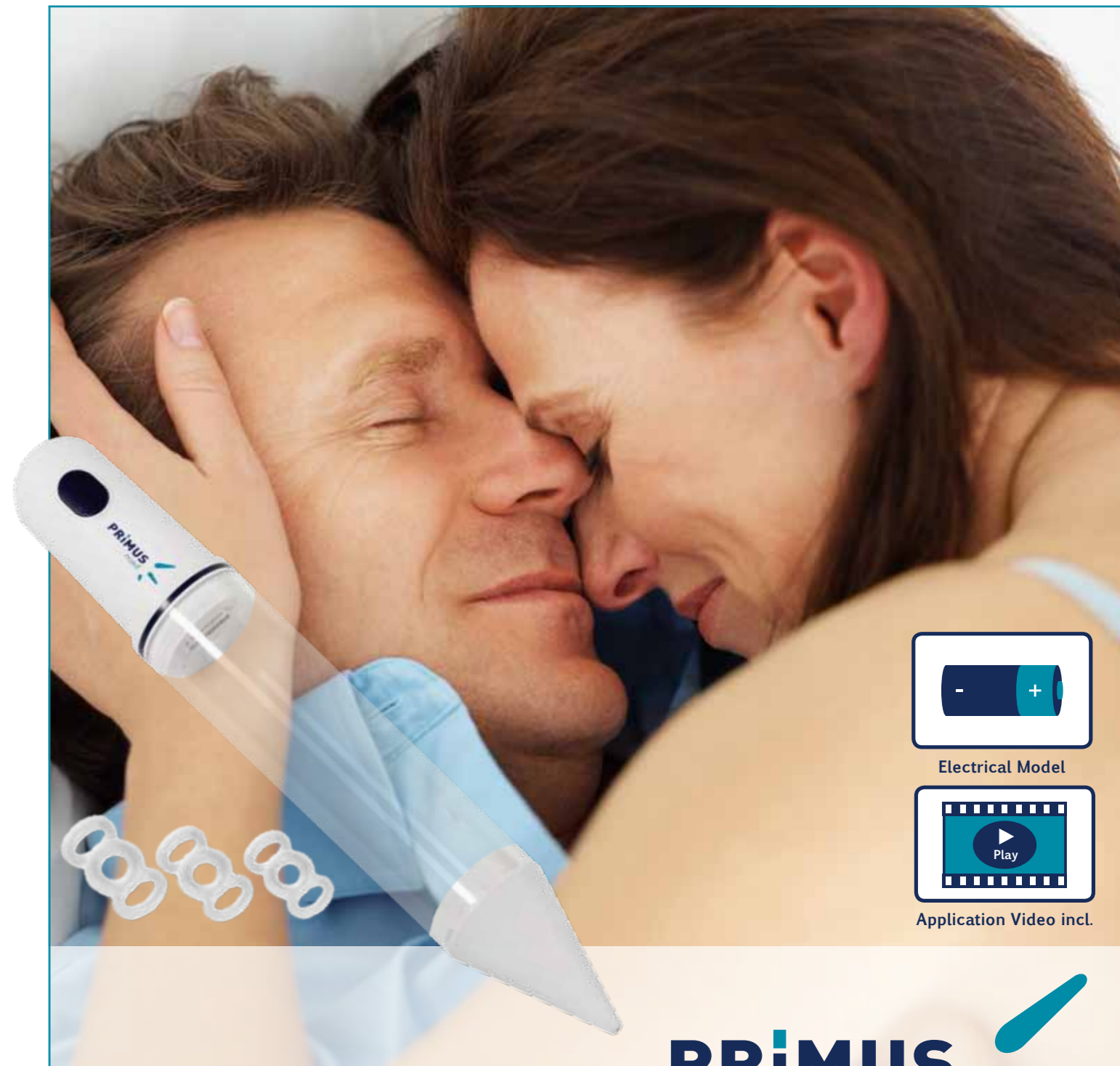
- encourages the restoration of erectile function
- promotes the maintenance of penis length and girth, thereby counteracting atrophy of the corpus cavernosum
- effects proven by many scientific studies
- application is simple, safe and uncomplicated
- can be used as often and for as many years as one likes
- inexpensive alternative to medication, with few side effects
- can be prescribed by doctors as a reimbursable adjuvant (in Germany)
- German brand quality
- modern ergonomic design
- certified medical product
- multilingual user manual and application video, 8 languages



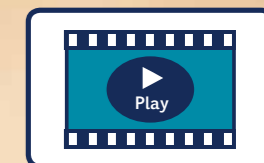
Art.-No.	Scope of delivery
ti1091	PRIMUSmed vacuum erection aid system
ti1092	PRIMUSmed erection ring small, d = 10 mm
ti1093	PRIMUSmed erection ring medium, d = 12.5 mm
ti1094	PRIMUSmed erection ring large, d = 15 mm
ti1096	PRIMUSmed reduction ring small
ti1097	PRIMUSmed reduction ring large
ti1098	PRIMUSmed lubricant 70 ml
-	PRIMUSmed user manual, 8 languages
-	PRIMUSmed application video (DVD), 8 languages
-	PRIMUSmed wash bag
ti6063	1.5 V AA alkaline batteries (set of 3)

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PRIMUS
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A safe, efficient and uncomplicated treatment



PRIMUS med is intended for the treatment of erectile dysfunction resulting from:

- deficiencies in the arterial supply in the area of man's sexual organ
- disorders of the venous/cavernous vascular system (venous leak) when erection rings alone are not sufficiently effective
- damage to the peripheral nervous system resulting in the disorder

Possible causes for erectile dysfunction

vascular diseases, hormonal and mental-health disorders, induration penis plastica, radical pelvis surgery (radical cystectomy, prostatectomy, colectomy), diabetes, hypertonia, heart and circulation diseases, taking medication, alcohol abuse and nicotine consumption.

Overview

The idea of treating erectile dysfunction with a vacuum pump in connection with erection rings stems from the 1960s from D.Osbon. Since 1982, vacuum erection aid systems have been utilised successfully as a mechanical, non-invasive aid for creating an erection. [1, 2]

Operating principle

The PRIMUSmed system consists of an electrically operated vacuum pump, creating a vacuum in a plastic cylinder. Initially, this plastic cylinder is slipped over the penis and then the pumping procedure is initiated. The vacuum created herewith draws venous blood from the pelvic veins into the cavernous body of the penis. The erection is maintained by an erection ring, which was previously applied to the back of the cylinder and is now moved onto the root of the penis. [2]

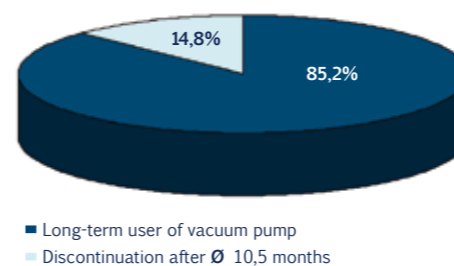
Vacuum pumps counteract atrophy of the corpus cavernosum

A healthy man naturally has four to six erections per night, which serve to maintain the erectile function. After radical prostatectomy in particular, night-time erections are usually absent, due to a lack of nerve connections. In such cases, the erectile dysfunction can lead to hypoxia (insufficient oxygen supply) of the corpus cavernosum and therefore to permanent, irreversible damage to the tissue (fibrotisation). The result of this tissue damage is a process of reduction in the girth and length, as well as decreased rigidity (stiffness), of the penis. The increased oxygen supply delivered to the corpus cavernosum by vacuum therapy counters these processes for the long term (see Table 2). [7, 8]

The latest research even allows us to conclude that vacuum therapy also has positive effects on synaptic facilitation in the area of neural lesions. [9] These approaches indicate the possibility of complete recovery through the use of a vacuum pump.

The cross category success rate of the vacuum therapy is at about 90 % [1]

Fig. 1 Discontinuation rate of the vacuum therapy (n=54)



Study Derouet et al. (1999, Austria) [2]

Method: Clinical monitoring was carried after 0.7 to 6 years by sending 54 vacuum therapy acceptors (age 32-79) a questionnaire and carrying out a clinical follow-up examination.

Results: Patients, who used the vacuum therapy successfully for longer than 4 months, generally continued the therapy. Only 8 of 54 patients discontinued the therapy after on average a period of 10.5 months. (Fig. 1). The reasons for that were loss of the partner, deterioration of health, spontaneous improvement of the erection and only partly the method itself. On average, the patients required 4.3 minutes to create an erection and they could sustain this on average for 13.7 minutes. 73 % of the patients had a sexual climax and for 58.6 % the ejaculation was, in spite of using an erection ring, always or mostly normal. The rate of overall satisfaction of the 46 long-term users was at 98 %, and was thereby slightly higher than for their partners with 85 % (Fig. 2). There were no serious complications. 60 % of the patients reported never having had any side effects.

Fig. 2 Satisfaction rate of the vacuum therapy (n=46)

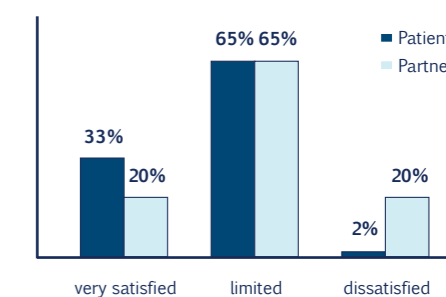


Table 1: Results of further important studies to the vacuum therapy

Author	Publication	Number of Patients	Extent	Results
Nadig et al. [3]	1986	35	8 - 22 months	> 90 % reach an erection sufficient for sexual intercourse 68.6 % satisfaction and regular use of the vacuum pump
Witherington [4]	1989	1517	8,6 months	92 % reach an erection sufficient for sexual intercourse
Cookson et al. [5]	1993 USA	115	29 months	> 90 % satisfaction with the quality of the erection (hardness, length, girth) 84 % patient and 89 % partner satisfaction, 70 % regular application
Baltaci et al. [6]	1995 GB	49	12,8 months	80 % satisfaction rate, 67 % effectivity rate 88 % success rate for arterially caused erectile dysfunction
Lewis et al. [1]	1997 USA	5847	?	83.5 % regular use of the vacuum pump

Table 2: Reduction in penis size after radical prostatectomy with and without the use of a vacuum erection system

Author	Publication	no vacuum therapy, %	with vacuum therapy, %	Follow-up (months)
Munding et al. [10]	2001	71	n/a	3
Savoie et al. [11]	2003	69,3	n/a	3
Zippe et al. [12, 13]	2006/2007	62,8	23	9
Köhler et al. [14]	2007	45,4	12	6
Dalkin [15]	2007	n/a	3,5	3
Monga et al. [16]	2006	62	0,27	12