# The Development of Modern Penile Implants



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#### ABSTRACT

**Introduction:** Modern penile implants were introduced to the marketplace more than 40 years ago and were the first effective treatment of organic erectile dysfunction. The original devices were effective in restoring erections but were prone to early malfunction.

Aim: This article describes the penile implants tested in clinical trials and chronicles the changes implemented by penile implant vendors in perfecting their products to improve device longevity, ease of use, and patient satisfaction.

**Methods:** The narrative is divided into six sections, three for inflatable implants and three for the semirigid rod-type devices. The inflatable category includes the three-piece inflatable, the two-piece inflatable, and unitary or self-contained inflatable prostheses. The semirigid rod types consist of soft semirigid, malleable, and mechanical implants.

Main Outcome Measures: These include ease of use, longevity of function, and patient and partner satisfaction. These parameters determine the success or failure of a particular product.

**Results:** Those devices producing the best rigidity and flaccidity (ie, the three-piece inflatables) have increased in popularity and hold the largest market share. Implants not performing well in providing these two qualities have a smaller sales volume or have been discontinued.

**Conclusion:** Penile implants have provided a predictable and reliable way for restoring erections in those patients in whom more conservative measures have failed. Vendors have reinforced or eliminated areas of these devices that were prone to wear and have made them easier to operate. The currently available models have very good durability and patient satisfaction.

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## INTRODUCTION

Penile implants have been a very effective treatment of erectile dysfunction (ED) for more than 40 years. Since their introduction in the early 1970s, they have provided a predictable and reliable means of treating all types of ED. The satisfaction rates in patients receiving these devices and their partners have been very high, in fact, higher than for any of the other means of restoring erections.<sup>1</sup> Previously, there were some implanted devices that could be called "penile stiffeners," which were not very effective and were not marketed widely. Patients with ED suffered in silence and most cases were classified as of psychogenic origin. The early implants were plagued with mechanical problems, with repair rates as high as 50% in 5 years.<sup>2</sup> Vendors

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reinforced or eliminated areas that were prone to premature wear and introduced more reliable and appealing products. Prosthetic urologists developed improved insertion and repair techniques and with experience could decrease infection rates and improve mechanical longevity. Sales of penile implants increased exponentially each year during the 1980s and early 1990s and reached a peak of approximately 33,000 units sold worldwide in 1996. In 1996, Ian Eardley presented the positive effects on patients' erections of a compound, sildenafil citrate, being studied as treatment at a podium session at the annual American Urological Association Meeting in Orlando, Florida. Implant sales plummeted the following year to approximately 12,000 worldwide as patients waited to see whether this new wonder drug would solve their erectile problems. Sildenafil citrate and other phosphodiesterase type 5 inhibitors are effective in restoring erections in most men but not universally. Because this was appreciated, men whose medical treatment of their ED had failed would chose a penile implant and annual sales gradually increased to approach peak levels and have recently reached

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**Figure 1.** Original American Medical Systems 721 penile implant. A pump to inflate was placed in one scrotal cavity and a pump to deflate was placed in the other scrotal cavity. Figure 1 is available in color online at www.smr.jsexmed.org.

a plateau in the range of 28,000 worldwide. As awareness of penile implants increased and patient satisfaction scores became evident shortly after their introduction, the number of vendors of these products wishing to gain market share also increased. At one point there were six companies selling or testing these devices in the United States market. This review relates the experience of the author who completed urology residency in the mid-1970s, quickly became involved with prosthetic urology, and participated as an investigator in the clinical trials of most of these products.

### THREE-PIECE INFLATABLE IMPLANTS

The original three-piece inflatable penile prosthesis (IPP) was developed by Dr F. Brantley Scott and Dr Gerald Timm, an engineer, with the assistance of Dr William Bradley, a neurologist.<sup>3</sup> The prototype device consisted of a pump placed in each hemiscrotum, two cylinders, and a fluid reservoir. Squeezing one pump inflated the device and squeezing the other pump resulted in flaccidity of the penis (Figure 1). The pumping mechanism



**Figure 2.** Reservoir inserter developed by Dr F. Brantley Scott. Figure 2 is available in color online at www.smr.jsexmed.org.



**Figure 3.** Seamed reservoir of American Medical Systems inflatable penile implant. Figure 3 is available in color online at www.smr.jsexmed.org.

was soon changed to a single pump containing an inflate and a deflate mechanism. The parts were supplied in a box, were placed in the autoclave for 20 minutes, and then brought to the operative field. The implant was filled with isotonic radiographic



**Figure 4.** The reinforcing rod against the silicone cylinder caused wear and a defect in the cylinder wall. Figure 4 is available in color online at www.smr.jsexmed.org.

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