Review Article

Recent technological development of penile prosthesis: a literature review

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Background and Objective: In contemporary Urology, the gold standard for treatment of erectile dysfunction refractory to medical therapy has been implantation with a penile prosthesis. The past 40 years has witnessed evolutions in technology and surgical techniques, which have led to increased patient satisfaction rates and decreased complication and infection rates. This review is an update to a prior review article that evaluates these advancements in the context of patient satisfaction and different rates of complications following surgeries. In addition, the review compares malleable and inflatable prostheses with regard to infection rate, mechanical failure rate, and erosion rate.

Methods: A literature search was conducted using Medline and Google Scholar to examine papers from 1973 to the present day. Keywords, such as, "penile prosthesis surgery", "malleable penile prosthesis", "inflatable penile prosthesis", "two-piece Inflatable Penile Prosthesis (IPP)", and "three-piece IPP" were utilized during the search. A total of 76 papers were included, and all were in English.

Key Content and Findings: Studies on the latest models of each of the three prostheses (malleable, two-piece IPP, three-piece IPP) revealed patient satisfaction ratings at or above 75%. Both types of IPPs were associated with greater satisfaction and lower erosion rates while malleable prostheses were associated with lower mechanical failure rates. Although no significant differences in infection rates were noted between the prosthesis types, a history of diabetes, obesity, and smoking were predictive of infection events.

Conclusions: The three-piece IPP, if indicated for a suitable patient, is generally accepted as the best type of prosthesis given its biological mimicry to an erect human penis.

Keywords: Penile prosthesis surgery; penile implants; inflatable penile prosthesis (IPP); malleable penile prosthesis

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Introduction

In 1936, a Russian surgeon named Nikolaj Bogaraz designed the first autologous penile implant using a patient's rib cartilage (1). A few decades later, the first inflatable penile prosthesis (IPP) and the Small-carrion malleable prosthesis were introduced in 1973 (2). In contemporary times, penile prostheses are the mainstay treatment for male urologic conditions, namely erectile dysfunction (ED) that is refractory to pharmacologic therapy. Penile prostheses are often classified as malleable (also known as semi-rigid), two-piece inflatable, or three-piece inflatable; each necessitating a distinct surgical technique. Of the three classes, the three-piece IPP considered the most technologically advanced implant in the realm of penile prostheses and is used in the majority of penile implant surgeries (3). Prior reviews of penile prostheses have stratified findings based on type of prosthesis (i.e., two-piece) but not by the model type (i.e., Coloplast Titan). The present review is an update to our previously published article, and emphasizes the postoperative outcomes of penile prosthesis procedures by implant type and model (4). We present this article in accordance with the Narrative Review reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-741/rc).

Methods

A literature search was conducted using using Medline and Google Scholar to comprehensively determine penile prosthesis advancements and surgical outcomes from 1973 to 2023. Our search included keywords such as, "penile prosthesis surgery", "malleable penile prosthesis", "inflatable penile prosthesis", "two-piece IPP", and "three-piece IPP" to select relevant papers to discuss in this review. Papers published in languages other than English were excluded. Seventy-six publications were included. Due to their value in comparing metrics (i.e., mechanical failure rate) between penile prosthesis types and models, studies with postoperative outcome data were given priority (*Table 1*).

Findings

Table 2 displays the most popular penile prosthesis models (*Table 2*). *Figure 1* presents a chronological timeline with historical milestones in the development of penile prostheses.

Malleable prostheses

Historical perspective

The penile implants to first gain popularity in modern times were the malleable implants. It became possible to develop a silicon prosthesis that could be implanted through a dorsal penile incision after the introduction of novel polymers in the 1960s (5). Drs. Hernan Carrion and Michael Small were among the first scientists to publish a study on the effective implantation of malleable penile prostheses in 1973 (6). The Small-Carrion came in four lengths ranging from 12 to 15.8 cm and two diameters, 0.9 and 1.1 cm, and was designed with a silicone-sponge interior encased in a medical-grade silicone shell. To obviate possibility of complications with the dorsal technique, Drs. Carrion and Small chose a perineal approach for implantation. Patients who have a malleable prosthesis have a semi-rigid penis that stays the same way permanently, although they are able to superiorly bend the implant during sexual activity.

Technological development of malleable prostheses

In 1980, the Jonas malleable penile prosthesis—which is regarded as the first truly marketable implant, was unveiled (7). This prosthesis featured a flexible core made of silver, which allows for the phallus to remain in a more natural state during times when it is not being used for sexual activity, yet still allows it to project at a proper angle prior to intercourse. Between 1980–1982, literature was published describing the prosthesis' outcomes: 69 patients received the implant via the peno-scrotal approach, and just two incidences of post-operative infections were noted at follow up (8). The 600-model series malleable penile prosthesis was developed in 1983. The silicon rubber-encased stainless steel wire core of the prosthesis had a cone-shaped proximal cylinder and a tapered distal end to fit the patient's crus and glans, respectively (9).

In the initial investigations of patient satisfaction with the Jonas and American Medical Systems (AMS) prostheses implants, data revealed notably high satisfaction rates (~90%) and decreased satisfaction with regard to seclusion and garment fit with the implant in place (~65%) (9). A polyethylene disc exterior encircling a metal cable core made up of the Duraphase II penile prosthesis was created in 1992. This model was created to enhance the mechanical strength, seclusion, and positioning memory of preceding

Table 1 The search strategy summary

Items	Specification
Date of search	The first search was conducted on 11/12/2022, the second search was conducted on 3/18/2023
Databases and other sources searched	PubMed, Google Scholar
Search terms used	Malleable penile prosthesis, Inflatable penile prosthesis, Three-piece Inflatable penile prosthesis, Two-piece Inflatable penile prosthesis, Malleable penile prosthesis AND satisfaction rates, Malleable penile prosthesis AND erosion rates, Malleable penile prosthesis AND infection rates, Malleable penile prosthesis AND mechanical dysfunction rates, Three-piece Inflatable penile prosthesis AND satisfaction rates, Three-piece Inflatable penile prosthesis AND erosion rates, Three-piece Inflatable penile prosthesis AND infection rates, Three-piece Inflatable penile prosthesis AND mechanical dysfunction rates, Two-piece Inflatable penile prosthesis AND satisfaction rates, Two-piece Inflatable penile prosthesis AND erosion rates, Two-piece Inflatable penile prosthesis AND infection rates, Two-piece Inflatable penile prosthesis AND mechanical dysfunction rates
Timeframe	6/1/1973–3/18/2023
Inclusion criteria	Retrospective studies, Case reports, English journals
Selection process	All authors contributed to the selection process

Table 2 Modern penile implants

Implant type	Manufacturer	Model	Antibacterial design	Cylinder lengths (cm)	Cylinder diameters (mm)	Year released
Semi-Rigid	Mentor (Coloplast)	Small carrion prosthesis	–	Discontinued model		1975
	Dacomed	Omniphase/duraphase	–	Discontinued model		1986
	Mentor (Coloplast)	Acu-Form (predecessor to Genesis)	–	Discontinued model		1998
	Coloplast	Genesis™ [2004]	Hydrophilic; polyvinylpyrrolidone coating	14–23; 16–25; 18–27	9.5, 11, 13	2004
	AMS-BSCI	Spectra™ [2009]	None	12, 16, 20	9.5, 12, 14	2009
	BSCI	Tactra	–	Cut to length sizing	–	2019
Two-piece inflatable	Brantley-Scott Inflatable		–	Discontinued model		1973
	Mentor	GFS Mark II	–	Discontinued model		1988
	AMS-BSCI	Ambicor™	None	14, 16, 18, 20, 22	12.5, 14, 15.5	1994
Three piece inflatable	Coloplast	Titan		11, 14–28 (even sizes)	13, 14, 15, 16	1983 first version of 3-piece release
		Titan NB	Hydrophilic	11, 14	11, 12	
		Titan OTR	Polyvinylpyrrolidone coating	11, 14–28 (even sizes)	13–16	
		Titan OTR NB		11, 14	11, 12	
	AMS-BSCI	AMS 700™ CX	Inhibizone™—minocycline and rifampin	12, 15, 18, 21	12–18	1983 first version of 3-piece released
		AMS 700™ CXR		12–18 (even sizes)	9.5–14.5	
		AMS 700™ LGX		12, 15, 18, 21	12–18	

AMS, American Medical Systems; BSCI, Boston Scientific Corporation; AMS-BCSI, American Medical Systems-Boston Scientific Corporation; GFS, Girth-flaccidity-simplicity; NB, Narrow Base; OTR, One-Touch release; OTR NB, One-Touch release Narrow Base; CX, Controlled Expansion; CXR, Controlled Expansion Restricted; LGX, Length and Girth Expansion.

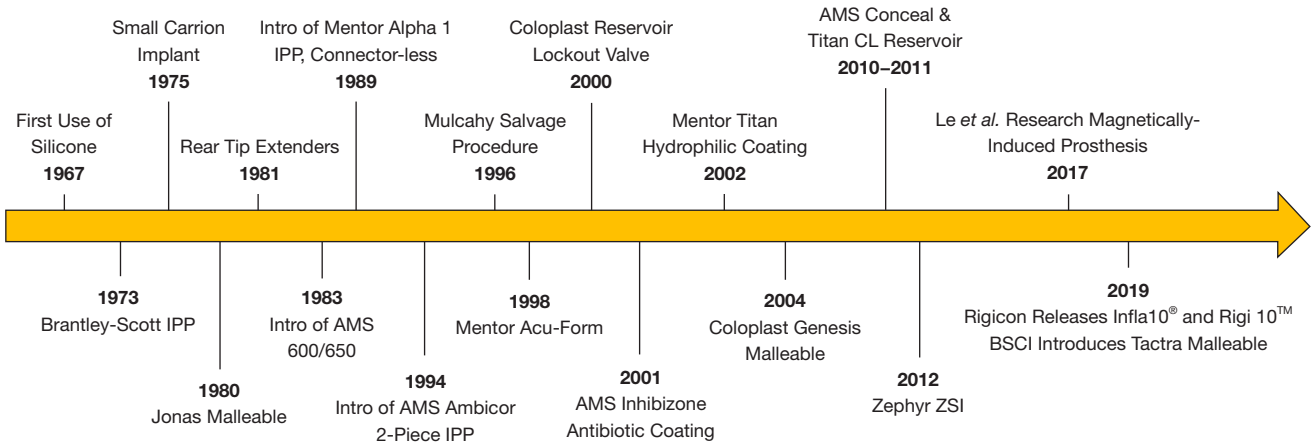


Figure 1 Developmental milestones of modern penile prostheses. IPP, inflatable penile prosthesis; AMS, American Medical Systems; BSCI, Boston Scientific Corporation; ZSI, Zephyr Surgical Implants.

implants. The Duraphase II, AMS 600, and AMS 650 remained a well-liked implants option throughout the 90's.

The Coloplast Genesis and AMS Spectra malleable implants were first offered in 2004 and 2009, respectively. These prostheses are still the most popular malleable implants in America (10). Patients with spinal cord injuries or those who have trouble pumping IPPs frequently receive malleable prostheses (11). The malleable prosthetics can also be utilized in various salvage procedures (12).

New Tactra, Rigi10, and touchless memory shape prostheses

In April 2019, Boston Scientific's new Tactra malleable penile prosthesis received U.S. Food and Drug Administration (FDA) approval (13). The prosthesis includes a unique dual-layer silicone shell covering a Nitinol nickel-titanium alloy core. The prosthesis features external etchings that can be trimmed for corporal size optimization during the operation. In addition, the prosthesis also includes insertion-fit rear tip extenders (RTEs) for secure crural placement. The Tactra prosthesis was designed to be easier to implant, and includes a high level of rigidity for sexual activity, as well as dependable concealment outside of sexual activity. Roughly 140 patients are now participating in post-market clinical trial research for the implant (14).

In April 2019, the FDA granted clearance for Rigicon's new Rigi10™ malleable penile prosthesis. The Rigi10™ is an implant with a stainless-steel interior core that allows for greater durability, flexion, and extension. The Flexible Rod Technology™ in the Rigi10™ permits up to a 135-degree bending angle, allowing for a smaller corporotomy. The implant also has RTE's to allow for optimal placement. Similar to the Coloplast Titan, the Rigi10™ has hydrophilic coating on the exterior (15). Clinical outcomes data on Rigi10™ are limited; However, in data provided from Rigicon, 2,400 patients were implanted between July 2017 and February 2020. Rigicon survey forms documented high levels of patient and surgeon satisfaction. Adverse events in the patients were uncommon, with the revision-free rate being 99% and infection being the most common event (0.34%) (from unpublished document provided by Rigicon—"Rigi10 Malleable Penile Prosthesis A Scientific Assessment of Safety and Effectiveness Profile").

Le and colleagues are currently investigating a novel "touchless" memory shape IPP to simplify current prosthesis technology (16). The prosthesis contains a nickel-titanium alloy (nitinol) exoskeleton, which can be expanded and harden to produce an erection with the use of an external magnetic inducer wand. This process, known as magnetic induction, involves the excitation metal molecules by a magnetic field to generate heat and an electrical current. The nitinol expands into an "erect" condition due to a rise in heat. Initial proof of concept tests compared the device to current inflatable and malleable penile prostheses and discovered a comparable resistance to buckling [2.62 kilogram-force (kgf)] as the traditional inflatable (1.42 kgf) prosthesis (17). Le and colleagues focused on efficacy of device activation in their following experiments. As of recent, they discovered that the IPP may be activated by the magnetic field in under 45 seconds after penetrating the tissue (16). Due to the possibility for tissue injury from internal temperature increases and issues related to

prosthesis activation, experts have expressed doubts about this new technology (18). This novel kind of prosthesis is still in its very early stages of research. Although there are promising benefits such as fewer moving parts, minimally intrusive activation, and possibly less mechanical failure, it remains unclear how much of an impact this new device will have on the prosthesis industry.

Surgical considerations and post-operative results for malleable implants

With the Coloplast Genesis, surgeons may tailor antibiotic coatings due to a hydrophilic coating. This prosthesis is currently the only malleable implant with antibiotic/hydrophilic coating on market (19). No statistically significant differences were found in the 11 criteria listed in the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire between the Genesis and AMS Spectra models (20).

The malleable prostheses are usually implanted using the penoscrotal or Infrapubic approaches. The use of somewhat bigger corporal incisions than those required for inflatable cylinders is important to prevent the possibility of the device bending excessively (21).

The Mulcahy salvage protocol relies on the use of malleable prostheses (22). In order to lessen fibrosis and maintain penile length, a malleable prosthesis is inserted intraoperatively at the time of an IPP removal (23,24). First, the infected prosthesis and removed, followed by extensive debridement of area of infection and thorough washout with combination of antibiotic solutions (25). Some urologists have performed modified versions of the Mulcahy salvage protocol without a washout period and instead using an antibiotic-coated prosthesis for reimplantation; however, this has proven not to be a substitute for the washout period (26). Theoretically, this procedure decreases the likelihood of infection because there are less moving parts and it is more time efficient (7).

A buried penis, defined by reduced visible and functional length usually due to excess pubic fat, can be treated with implantation of a malleable penile prosthesis (27). These prostheses have also been shown to be effective in improving condom catheter usage in spinal cord injury patients who frequently lose their condoms due to a small retractile penis (28).

Numerous studies have investigated the post-operative outcomes and patient satisfaction in patients implanted with malleable prostheses. Reported infection rates range from 1.4% to 8.3%, erosion rates from 1.4% to 5.1%, and mechanical dysfunction rates from 0.5% to 12% (*Table 3*) (11,29-33). Retrospective surveys report patient satisfaction ranging from 69% to 86.6% depending on the type of malleable prosthesis (34). *Table 3* summarizes post-operative results from malleable penile prosthesis implantation surgeries.

Inflatable prostheses

Two-piece IPP

Historical perspective

The history of IPPs dates back to 1985, when Hydroflex inflatable one-piece penile prosthesis was released, followed shortly by release of the AMS Dynaflex in 1990 (35). However, high rates of mechanical failure and explantation were reported for the one-piece IPP; in contrast the survival for multicomponent IPPs was found to be more promising (36,37).

In 1988, the Mentor GFS (Girth, Flaccidity, and Simplicity) two-piece IPP was first introduced and included a combined fluid reservoir and pump implanted in the scrotum (38). Limited papers about this device revealed the patient satisfaction rate of 86% and mechanical malfunctions rates of 14% to 32% (39,40). The Mark II version of the device was subsequently introduced, and removed the need for tubing connectors (41).

Technological development of two-piece prostheses

The Ambicor prosthesis (Boston Scientific), introduced in 1994, was a significant upgrade to the pumping system of the Dynaflex as it had a separate scrotal pump to inflate cylinders, obviating the need to include the reservoir within the penile anatomy (42). Improvements to the prosthesis occurred in 1998, and involved reshaping of the RTE for more secure crural positioning and additional protection to the tubing exiting the pump. In a study of 146 patients with a mean post-operative follow-up time of 38 months, these improvements were investigated. The study reported an overall patient satisfaction of 88% in a modified Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) survey, and 86% of patients noted that they would have the surgery again if needed or recommend the implant to a friend (43).

The most popular two-piece IPP on the market in the US now is the Ambicor two-piece inflatable prosthesis, which consists of parylene-coated cylinders implanted in the corpora and a pump inserted in a scrotal Dartos

Table 3 Malleable IPP implantation surgery results

Author	Year published	Study period	Devices	Patients	Mean follow up (months)	Infection	Mechanical dysfunction	Explantation	Erosion	EDITS score	IIEF	General patient satisfaction	Overall device survival
Chiang *et al.* (29)	2000	1985–1996	AMS 600	156	34.5	4% avg. across models	12% avg. across models	N/A	N/A	N/A	N/A	86.6% avg. across all models	84% 5-year survival
			Duraphase	23	27.5								
			AMS 650	6	34.5								
			Mentor	5	34.5								
			Acu-Form	3	34.5								
Salama (30)	2004	1991–1992	AMS 650	29	7 years	4 total (8%)	N/A	N/A	N/A	N/A	N/A	69%	100% 1-year
			Acu-Form	21	7 years							71%	
Minervini *et al.* (31)	2006	1975–2000	Acu-Form	256	N/A	19 (5.1%)	2 (0.5%)	N/A	19 (5.1%)	N/A	N/A	75% avg across all models	N/A
			Small-Carrion	77									
			AMS 600-650	52									
			Finney	4									
			Jonas	4									
Falcone *et al.* (32)	2013	2010–2012	AMS Spectra	22	24.3	No events during follow-up period	No events during follow-up period	No events during follow-up period	No events during follow-up period	45.2 (at 12 months)	Pre-op 28.5 avg.; post-op 53.9 (at 12 months)	86.4%	N/A
Kim *et al.* (11)	2008	1990–2004	AMS 600	48	11.7 years	4 (8.3%)	N/A	2 (4.2%)	2 (4.2%)	N/A	N/A	79.2%	83% 11.7-year follow-up
Bozkurt *et al.* (33)	2015	2001–2012	AMS 600/650	72	1 year	2 (1.4%)	N/A	N/A	2 (1.4%)	57±8 avg	22.8±1.8	N/A	N/A
			Acu-Form	67									
Rigicon[a]	Unspecified	2017–2020	Rigi10	2,400	N/A	8 (0.34%)	4 (0.17%)	N/A	0 (0.0%)	N/A	N/A	N/A	99.03% (unspecified)

[a], data directly provided by Rigicon. IPP, inflatable penis prosthesis; IIEF, International Index of Erectile Function; N/A, not applicable or directly provided/analyzed in the study; AMS, American Medical Systems.

pouch. The device comes in diameters between 12.5 to 15.5 mm, lengths between 14 to 22 cm, and RTEs between 0.5 to 3 cm that can be added to modify proximal corporal and crural insertion. The pump is squeezed to inflate the cylinder, which is then deflated through activation of a time-pressure valve by bending the penis upward or downward for about 10 seconds. In a review paper in 2018 on two-piece IPPs, overall complication rates were between 2.1% to 11.2% while infection rates ranged from 0.7% to 4.8%, and mechanical failure rates from 0.7–6.1 (41). Patient satisfaction percentages ranged from 75.0% to 86.4% according to a 2018 literature review for Ambicor prosthesis implants placed in the last decade (44).

Surgical considerations and post-operative results for two-piece implants

Two-piece IPP's represent a powerful alternative for a number of patients with ED despite the rising demand for 3-piece IPPs and growing body of research on their technological advances. The two-piece Ambicor IPP only needs 3–6 pumps to harden whereas the 3-piece IPPs can require around 10–14 pumps, making it perfect for patients with limited hand dexterity, such as the older adult population (10). It should be noted that although 2-piece IPPs are easier to pump, they may be more difficult to deflate given the necessity to bend the penis toward the scrotum. Furthermore, patients with retropubic scarring secondary to procedures in the pelvis may be unsuitable for implantation with a 3-piece IPP as the intra-abdominal placement would be challenging (10,45). As of 2022, Ambicor remains the only popular 2-piece IPP option—however, its use is diminishing given the advancements of three-piece IPPs and the specific type of patient that may benefit from the Ambicor IPP (46). Though surgical implantation of the Ambicor IPP may be simpler compared to 3-piece IPPs, it remains more difficult relative to historical 2-piece IPPs (i.e., Uniflate 1000) and is unsuitable for patients with a longer penis given the effect on axial rigidity. With an infection rate of greater than 4%, the Ambicor IPP still faces drawbacks compared to 3-piece IPP's and may be best suitable for those patients with a pelvis that contradicts 3-piece IPP placement (46).

Two-piece IPPs are not recommended for those with Peyronie's disease because the cylinders may not offer the best stiffness against plaque buildup and may be challenging to orient in the tunica albuginea, given its less elastic nature (44). Female to male transgender patients' neophallus construction procedures have been completed with two-piece prostheses, and thus they may continue to play an important role in this population.

For 2-piece IPP implantations, studies on post-operative and patient satisfaction outcomes were analyzed and are shown in *Table 4*. Infection rates are between 0.7% to 7.5% (42,43,45,47). Across all of the analyzed studies, which mostly involved the AMS Ambicor model, four cases of erosion and twelve cases of mechanical dysfunction were found. Across the studies, the average patient satisfaction rates were between 80.0% and 96.4% (34).

Three-piece inflatable prostheses

Historical perspective

In the U.S., over 80% of the market share of penile prostheses are estimated to be 3-piece penile prostheses (3). Therefore, this section will focus on the technological and surgical developments of 3-piece IPPs. The beginning of the 1980's saw the introduction of 3-piece IPP prototypes, which shared the same elements as the current 3-piece IPP models: two intra-corporal inflatable cylinders, scrotal pump, and an abdominal fluid reservoir. Significant technological advances through the 80's and 90's were made in three-piece IPPs, and after a 4-year follow-up, complication rates fell from nearly 50% at its introduction to only 13% (48). Three-piece penile prostheses are inserted via trans-scrotal or infra-pubic routes, each with their own advantages. The benefits of a penoscrotal technique include a decreased chance for dorsal nerve damage, improved corporal visualization, and easier scrotal pump insertion. On the other hand, infra-pubic techniques have been noted to reduce device placement time provide clearer view of reservoir implantation (7).

Technological development of 3-piece prostheses

Cylinder development

The first three-piece IPPs were made of flexible polymer materials, such as silicone. To reduce wear between silicone parts, polytetrafluoroethylene (PTFE) sleeve coverings, were introduced within the AMS 700 model in 1983 (49). New cylinder improvements included increased prosthesis girth, controlled length expansion potential, and more stable RTEs that snap in place, addressing the concern for cylinder separation from the proximal corpora (50).

The AMS 700 CX type was introduced by AMS in 1987 and had a stronger, three-ply material construction with an inner bulk silicone foundation covered by a unidirectional Dacron-Lycra weaving layering (49). Less pressure was

Table 4 Two-piece IPP implantation surgery results

Author	Year published	Study period	Devices	Patients	Mean follow up (months)	Infection	Mechanical dysfunction	Explantation	Erosion	EDITS score	IIEF	General patient satisfaction	Overall device survival
Gentile *et al.* (45)	2016	2005–2013	AMS Ambicor	29	27	2 (4.8%) (all models)	1 (2.4%) (all models)	–	2 (4.8%) (all models)	Not collected	Not collected	~90% satisfaction with sexual function	100% at 27-month follow-up
			Coloplast Excel	13									
Lux *et al.* (43)	2007	1999–2004	AMS Ambicor	146	38	1 (0.7%)	2 (1.4%)	1 (0.7%)	0	88%	Not collected	85% overall	91% at >48 months
Levine *et al.* (42)	2001	1995–1999	AMS Ambicor	131	43.4	6 (4.6%)	3 (2.3%)	2 (1.5%)	0	90.6%	Not collected	96.4%	97% expected at 70 months
Natali *et al.* (47)	2008	1990–2004	AMS Ambicor	98	60	3 (7.5%)	6 (15%)	Not identified	2 (5%)	Not collected	Not collected	81%	Not collected

IPP, inflatable Penis Prosthesis; IIEF, International Index of Erectile Function; N/A, not applicable or directly provided/analyzed in the study; AMS, American Medical Systems.

applied to the patient's corpora during IPP inflation as a result of this unique cylinder design (51). In addition, patients with tunica albuginea problems are also advised to use the dacron-lycra layer in the AMS 700 and a comparable polyurethane layer in the Titan Coloplast implant to minimize the chance of aneurysm formation (52). AMS improved their cylinder's performance in 2001 by including a Parylene microcoating to increase durability and decrease friction between cylinders. When compared to non-coated AMS 700 implants, researchers discovered that the Parylene coating increased 3-year revision-free survival from 78.6% to 87.4% (21).

IPP technology was improved in 1981 with the introduction of RTEs, silicon tips applied to the proximal end of corporal cylinders to enable a more secure placement and reduce cylinder wear (53). The positioning of the cylinder was made more stable in 2006 by improved RTE design. AMS offers snap-fit RTEs in sizes ranging from 0.5 to 6 cm. The use of RTEs in prosthesis surgery has significantly increased from 6% to 8% in 2000 to 93% in 2015 (54).

The Ultrex cylinders, introduced by AMS in 1990, enabled for higher cylinder girth expansion thanks to a bidirectional fabric layer (50). Three years later, in 1993, updated Ultrex—a tougher material that increased device dependability and patient satisfaction—was used to replace the middle fabric layer of the Ultrex IPP. The modified Ultrex showed better 5-year estimates of overall (64.7% *vs.* 77.7%, P=0.23), mechanical (70.7% *vs.* 93.7%, P=0.017), and cylinder survival (77.7% *vs.* 96.2%, P=0.008) relative to the original model in a study from 2002 that compared the modified and older Ultrex models (55). The Ultrex later renamed the Length Girth Expansion (LGX) by AMS. The proximal ends of the cylinders on the LGX model had narrower diameters, allowing for extension with snap-on RTEs. The LGX model is recognized to augment mean post-operative penile length in addition to increasing girth (56). For individuals who have fibrotic corpora or smaller penises, AMS and Colopast also offer narrow cylinders (50). The 700 CXM and CXR versions, which had thinner cylinders, were the first types that AMS released in 1990. The Coloplast Titan One Touch Release (OTR), which became available in 2008, also offers a narrow base model as well as deflation mechanism with release pads (57) (*Figure 2*). For patients with substantial corporal scarring and Peyronie's disease, multi-component prosthesis implantation is advised using both the AMS and Coloplast reduced girth models (58).

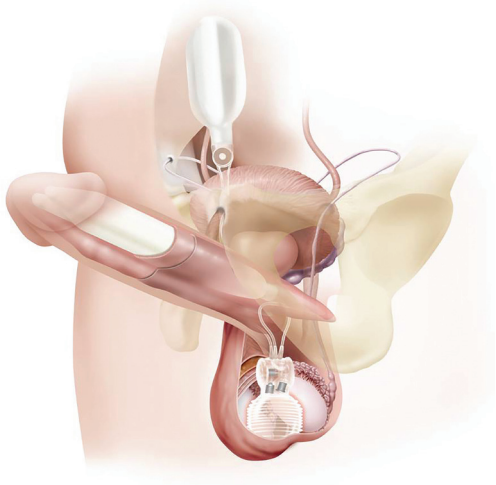


Figure 2 Coloplast Titan. Source: Coloplast (with permission).

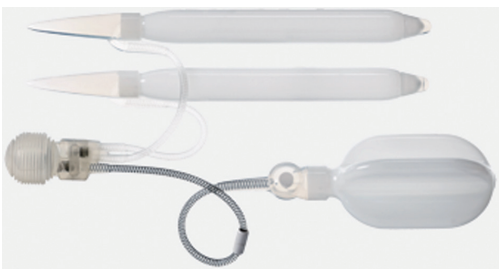


Figure 3 Three-piece inflatable penile prosthesis. Source: Coloplast (with permission).

Antibacterial coatings

Infection is one of the concerns during IPP placement. To reduce the probability of infections, manufacturers began producing IPP implants with hydrophilic material that could absorb antibiotic solutions. Following device implantation, IPP antibacterial coating continue to elite from the device for around two weeks. An inventive feature of implant design is antibacterial distribution via IPPs, which has been shown to lower infection rates from 3–5% to 1–2% (59).

Minocycline hydrochloride and rifampin, a combination that has been found to be highly effective against Staphylococcus, the most prevalent cause of device infection, were combined to create the Inhibizone™ coating, which AMS first used in their implants in 2001 (50). For primary implants, reported infection rates were between 1% to 1.61% (60,61).

Coloplast quickly followed suit in 2002 and added its polyvinylpyrrolidone hydrophilic covering to all of their Titan implants. Prior to implanting, the polyvinylpyrrolidone covering reduces bacterial adhesion and adsorbs any hydrophilic antibiotics (62). Infection rates were shown to be lower in the Titan coated implants (1.06% of 2,357 patients) than in non-coated implants (2.07% of 482) in a study comparing the two types of implants (62). The effectiveness of various adsorption antibacterial mixtures to prevent infection when compared with the AMS Inhibizone™ implant has been the subject of several studies done on the Coloplast titan (63,64). Experts recommend that the Coloplast Titan is coated with an antibiotic solution, such as rifampin/gentamicin mixture, prior to implantation (63,65). A variety of antibiotic combinations have been studied on penile prosthesis tubing. Using modified disk diffusion assays with *E. coli*, *S. aureus*, *S. epidermidis*, and *P. mirabilis*, Chanyi *et al.* found that ampicillin was most effective against both Staphylococcus organisms and ciprofloxacin was most effective against *E. coli* and *P. mirabilis* (66). In a retrospective study of Coloplast Titan implants coated with vancomycin/gentamycin and rifampin/gentamicin, it was found that rifampin/gentamicin produced lower rates of infection (63).

Pump development

The tactile pump, which was made available for 3-piece IPPs in 2004, improved scrotal pump manipulation, increased volumetric fluid per squeeze, and facilitated easier device deflation for patients (*Figure 3*) (50). Patients using the Tactile pump had an easier time finding the pump and deflating it, according to a blinded study comparing the older 700 series pump with the Tactile pump (67). The Momentary Squeeze pump, which allowed for speedier and easier pump deflation, was introduced by AMS in 2006. The earlier variant required continual pump deflation as well as simultaneous cylinder squeezing to fully deactivate the IPP. The momentary squeeze mechanism involves full deflation for 2–4 seconds with a single click of the depressurization button. A lockout valve, as well as a smaller pump body, are also features of the new design. The 10-year survival rates of the AMS 700CX IPPs with the touch pump and the momentary squeeze pumps were analyzed, and the results showed that the rates were 77.6% and 82.5%, respectively. Nearly 91% of the patients kept using the gadget and were able to continue participating in sexual activity (51).

In 2008, Coloplast's OTR pump technology acquired approval. With the addition of "Touch Pads" for deflation on either side of the pump, this modification made it possible to deflate the pump with just one hand. To increase

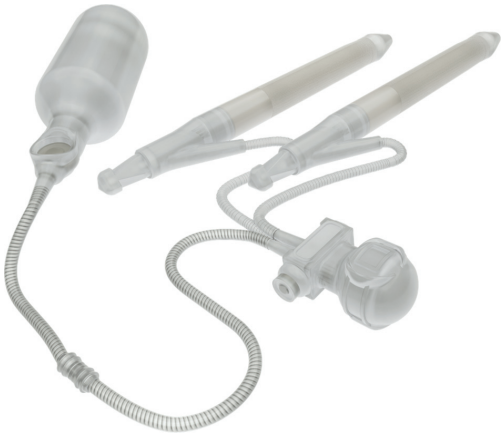


Figure 4 Rigicon Infla10 inflatable penile prosthesis. Source: Rigicon (with permission).

device robustness, the OTR pump was manufactured of a tougher silicone substance and was smaller in size than earlier iterations. A retrospective study found that between 100 cases with the Titan OTR pump and 100 cases with the (classic) Titan Genesis pump, there were no significant differences in short-term post-operative complications and that the OTR pump reduced postoperative teaching sessions to patients. In a study of 138 patients with severe PD undergoing implantation with Coloplast or AMS 700 CX, there were no significant differences in survival between the two implants with regard to mechanical failure (39).

Reservoir development

The development of a tissue capsule surrounding the reservoir is assumed to be the source of IPP complication known as auto-inflation of reservoirs (68). In order to reduce encapsulation by increasing surface area, Coloplast created a textured reservoir in 2000 (50). That same year, Coloplast further improved the reservoir design by adding a Lock-out Valve™, which also intended to prevent auto inflation (49). By using this concept, auto inflation was successfully reduced from 11% in the previous technology to 1.3% in the new technology (36). Even though many instances of auto-inflation that occur after IPP implantation can be viewed as benign complications, more severe occurrences may necessitate a capsulotomy to free up and realign the reservoir (69). Boston Scientific's AMS 700's lock-out valve, on the other hand, is located in the pump rather than the reservoir (70).

Another significant worry for IPP recipients is reservoir palpability, which can be reduced by placing the reservoir in the Space of Retzius, where it is invisible to the patient. It should be noted that the patient is at risk for suffering a bowel, bladder, or vascular injury because installing the reservoir into this region is usually done blindly. Surgeons may decide to place the reservoir in a different, ectopic location to prevent harm (71). Companies have created novel reservoirs (Conceal reservoir, AMS and Cloverleaf reservoir, Coloplast) that would stay flat when filled in an effort to mitigate this concern and reduce reservoir palpability in ectopic regions. The first reservoir to get FDA approval with labeling instructions that involve "ectopic" placements was Coloplast's Cloverleaf reservoir in 2015.

Latest 3-piece IPP developments

The three-piece IPP design has been enhanced through the submission of numerous new patents by Boston Scientific Corporation. The dual poppet valve assembly described in patents #10285815, #9522065, and #9889010 ensures improved pump bulb filling and overall fluid flow throughout the hydraulic system. A piezoelectric pump operated by an external magnetic field is described in patent #9808343. This pump might make it simpler for patients to achieve IPP inflation and may remove any lingering concerns about manually finding the pump and soreness during inflation. However, new developments with these patents remain to be seen.

A more recent three-piece, the Zephyr Surgical Implant (ZSI) 475, is not yet FDA approved. The implant's three-layer construction of silicone (outer and interior layers) and biocompatible polyester (middle layer) gives it additional width, rigidity, and stability. Twenty-eight patients who underwent implantation with the ZSI 475 between 2012 and 2016 reported an average satisfaction rate of 93% at a mean follow-up of 35 months. Three complications were noted: a scrotal hematoma, replacement due to tubing breakage, and reoperation for pump location modification (72).

In 2019, Rigicon released the Infla10® (*Figure 4*), an IPP that includes hydrophilic coating on all external surfaces and the opportunity for length expansion. The implant also contains ConnectSecure™ RTE's for optimal implantation of the device. The Infla10® contains a 4-layer cylinder design for increased durability, including an exclusive silicon layer. Between July 2019 and February 2020, 400 patients received the implant; the revision free rate was 97.7%, with infection being the most common reason for revision or replacement (1.0%) Data on the Infla10® is limited, however, a clinical trial is currently active to assess the long-term safety and efficacy of the implant (From document provided by Rigicon—"Infla10 Three-Piece Inflatable

Penile Prosthesis A Scientific Assessment of Safety And Effectiveness Profile").

Surgical considerations and post-operative results for 3-piece implants

Cylinders

When fibrotic tissue replaces smooth muscle, a condition known as corporal fibrosis, the insertion of IPP cylinders becomes more challenging. History of diabetes, previous intracorporal injections, ischemic priaprism, and PD are a few of the factors leading to corporal fibrosis (58). Cavernotomes, or beveled rasping tools, can be used to core out a tunnel adequate for housing a penile implant in difficult to access fibrotic regions. Wider incisions, numerous incision procedures, and corporal counter incisions are additional strategies that have been investigated to accommodate implants in patients with fibrotic corpora. Due to high infection rate (up to 50%), the use of synthetic grafting materials is no longer widely used in the clinical setting (73). Patients with more severe fibrosis may also get narrow implants, either permanently or to gradually widen the corporal tunnel in preparation for replacement with a bigger prosthesis in the future (58). For prosthetic implantations in PD patients who require adjuvant modeling (bending of the penis against the pathologic curve) treatments during surgery, the AMS 700CX and Coloplast Titan have been investigated. There was no statistically significant difference in prosthesis survival among the 138 PD patients implanted with either the AMS 700 CX (88 patients) or Coloplast Titan (50 patients). Eight needed revision surgery due to device malfunction, while two were removed due to infection (39).

Glans hypermobility, which occurs when a patient's corpora do not fully extend to the distal glands, can be brought on by inadequate sizing or location of the prosthesis cylinder as well as anatomic variance (58). Surgery can be necessary if the problem does not go away during the healing phase. In this procedure, the glans is dissected away from the distal tips of the corpora while the cylinders are inflated, and permanent sutures are applied to fix the glans to the distal tunica albuginea. In this surgery, a hemi-circumcisional incision is made opposing the tilting direction, and the glans is dissected from the distal tips of the corpora while the cylinders are inflated—permanent sutures are placed to anchor the glans to the distal tunica albuginea (58).

The perception of shorter penile size after prosthesis surgery is the most frequent complaint, which in some circumstances may be caused by decreased glans engorgement (74). Studies have been published about intra-operative adjuvant procedures, such as sliding, modified sliding, and multiple slice techniques, for preserving and restoring penile length at the time of prosthesis placement. Peniel degloving, mobilization of the dorsal neurovascular bundle, dissection and separation of corpus spongiosum tissue from the cavernosal bodies, and finally incisions through the Buck's fascia of the corporal bodies to release them and enable penile lengthening were among the more difficult and dangerous steps involved in the surgical procedures (74). Other penile length conservation techniques, such as aggressive cylinder sizing or the "new length measurement NLMT" in conjunction with postoperative rehabilitation inflation protocol, are also being studied for the placement of three-piece IPPs in patients without pre-existing fibrosis, PD, or other corporal defects (75-77). Though these adjuvant maneuvers may help increase stretched penile length (SPL) following surgery, they are complex and have similar outcomes. However, modeling, which involves forcibly bending and holding penis in opposite direction of curvature to split fibrotic plaques and straighten the penis, is the simplest option (78). Techniques during the pre-operative phase may enhance penile length following prosthesis implantation. Vacuum erection devices, which involves application of a constriction band following engorgement of the penis, have been shown to increase SPL in a RCT (n=51) (79). Penile traction therapy, where external penile traction is applied daily for a few months prior to prosthesis placement, has also been shown to increase SPL; however, this technique requires a great amount of patient effort and compliance for success (80).

Infection control

The main causes of implant infections are skin flora (81). The "no touch" technique involves draped fenestration to block contact between the patient's and surgeon's instruments in order to lower the risk for infection. Eid *et al.* examined infection rates associated with devices coated with antibiotics in a single-surgeon study between 2002 and 2011. The "no-touch" method decreased infection rates to 0.46% while antibiotic-coated implants reduced risk from 5.3% to 2.0% (82). Regarding infection rate, there were no statistically significant differences between AMS and Coloplast devices. Dhabuwala *et al.* have investigated the rates of infection following prosthesis implantation with various antibiotic solutions. Titan Coloplast infection rates by antibiotic solution used were 4.4% for vancomycin/

gentamicin and 0% for rifampin/gentamicin; however, no statistically significant differences were noted. The AMS Inhibizone-coated implant had an infection rate of 1.3% (63).

Recent studies on antibacterial coatings for penile prostheses emphasize necessity to choose antibiotic solutions with the possibility of fungal and non-traditional bacterial infections in mind. Despite the fact that gram positive *Staph epidermidis* is thought to be the most prevalent bacterium in infected implants, literature notes that the culprits for IPP biofilms appear to be evolving: namely, notable trends of decreased gram positive bacteria and proliferation of gram negative bacteria and fungi in coated implants at time of revisionary surgery (65,83-85). According to a multi-center study on infections associated with penile prostheses, 14–38% of infections are caused by micro-organisms not covered by current AUA and EUA antibiotic guidelines, underscoring the need for ongoing improvement in surgical technique and medical therapies to prevent infection (86).

Reservoirs

The traditional placement of reservoirs in three-piece IPPs have been in the space of Retzius as they are imperceptible in this location. However, placement into this area comes with higher risk in patients with a history of pelvic surgery or radiation, and thus alternative ectopic locations such as a high submuscular placement are utilized (87,88). In obese patients, ectopic reservoir placements in the subcutaneous region may be adequate (89-91). Although the plan to place the reservoir is usually done pre-operatively, the surgeon may elect to switch to a more suitable site in the intraoperative phase after exposure to the patient's anatomy (52). Although rare, intra- and post-operative reservoir complications can occur, including: inguinal herniation, bowel/bladder erosion, auto-inflation, and infection (87). Patients who have robotic-assisted laparoscopic prostatectomy run a higher risk of these complications because the procedure can damage the space of Retzius (87). Contralateral or ectopic implantation of the reservoir can be used in cases of iatrogenic injury to the bladder during prosthetic placement or post-operative erosion into the bladder (92). With reported frequencies of 0.09% to 1.2% in Space of Retzius placement and 1.4% in other reservoir placements, reservoir migration through the inguinal canal is a rare event (93). A purse-string suture to support the inguinal ring or a higher inguinal canal placement (greater than or equal to 4 inches) are two procedures documented in the literature for treating reservoir herniation, which necessitates either reservoir placement or repositioning through an inguinal incision (94,95). Surgical results from three-piece IPP implantation procedures are presented in *Table 5* (39,51,96-107).

Predictive factors and comparison of IPP and malleable prostheses in infection rates, erosion rates, and mechanical dysfunction

Though the occurrences of infection are rare following prosthesis placement, it can lead to difficult reoperations, leading to decreased patient quality of life (40). A systemic review published by Mahon and colleagues examined the infection rates in different protheses across 97 study arms (108). They found that the studies reporting infection rates for IPPs (n=68) had a wider range of infection rates (range: 0–24.6%) compared to those reporting infection rates for malleable prostheses (n=12; range: 0–9.1%) (108). However, the majority of studies reported an infection rate of less than 5% for both IPPs and malleable prostheses, and small series comparing infection rates between the two did not find statistically significant differences (108). Several risk factors have been predictive for infections, including diabetes, BMI >30 kg/m^2, and history of smoking tobacco (108,109). The risk for infection can be decreased with use of antibiotics on the hydrophilic coating of the prosthesis (109).

Patient satisfaction is often divided into satisfaction with erection or satisfaction with sexual function; however, there is no standard method of evaluating satisfaction rate. One study by Bernal and Henry evaluated patient satisfaction in 79 patients who received the AMS 700 CX (3-piece IPP) and found that 79% of patients reported it improved the quality of their sexual life while 97% stated they would recommend it to someone with ED (110). Çayan *et al.* examined the differences between dissatisfaction rates three-piece IPPs, two-piece IPPs, and malleable prostheses, and found there were no differences between the two- and three-piece IPPs (3.8% and 3.3%, respectively) but malleable prostheses had a significantly higher dissatisfaction rate (11.2%) (111). Though a perceived loss of penile length is associated with dissatisfaction, it should be noted that in many cases there may actually not be a decrease in penile length following IPP implantation (112).

With regard to mechanical failure, no specific factor has been linked to a higher failure rate. However, IPPs, given their increased complexity, have a greater propensity for mechanical failure (31). On the other hand, erosion rates were higher for malleable prostheses compared to IPPs (113).

Table 5 Three-piece IPP implantation surgery results*

Author	Study period	Devices	Patients	Mean follow up	Infection	Mech. dysfunction	Explants	Erosion	EDITS score	IIEF	General patient satisfaction	Overall device survival
Chung *et al.* (39), 2013	2006–2010	AMS 700 CX	88	40.6 months	3 (2%) across both models	7 (5.1%) across both models	3 (2%) across both models	N/A	N/A	N/A	86%	91% (700CX) and 87% (Titan) 5 years est.
		Coloplast Titan	50	35.4 months							90%	
Vitarelli *et al.* (51), 2013	1997–2010	AMS 700 CX/CXR	80	68.7 months	2 (2.5%)	10 (12.5%)	13 (16.25%)	3 (3.75%)	73.11	21.46	87.7%	91.9% (4 years); 77.6% (10 years)
Brinkman *et al.* (96), 2005	1992–1998	AMS 700 Series; Mentor Alpha-1; Mentor Alpha NB	12: AMS; 187: Mentor	N/A	N/A	N/A	N/A	N/A	N/A	N/A	69.3% across all models	N/A
Dhar *et al.* (97), 2006	1986–2004	AMS 700 CX/CXM	380	7.6 years	8 (2%)	39 (10.3%)	N/A	8 (2%)	N/A	N/A	N/A	74.9% (10 years est.)
Enemchukwu *et al.* (98), 2013	1997–2008	AMS 700 CX	39,443	7 years	N/A	5,981 (10.9%)	N/A	N/A	N/A	N/A	N/A	87% avg. (7 years)
		AMS 700 LGX	15,570									
Kim *et al.* (99), 2010	2001–2009	AMS 700 CXM	383	113 months	8	82 (20.6%)	N/A	3 (0.7%)	N/A	N/A	N/A	93.2% (5 years); 78.2% (10 years)
		AMS 700 CX	14									
Lindeborg *et al.* (100), 2014	2008–2011	Coloplast Titan	33	16 months	1 (3%)	3 (9%)	1 (3%)	N/A	85%	N/A	N/A	97% at follow-up
Negro *et al.* (101), 2016	2009–2012	AMS LGX	36	6 months	0	0	0	0	77.8 mean at 12 months	8.3 mean at 12 months	N/A	100% at 6 months
Nehra *et al.* (102), 2012	2001–2007	AMS 700 M/R-coated *vs.* non-M/R models	9,300 (M/R) *vs.* 1,764 (non-M/R)	34.4 (M/R) *vs.* 53.9 months (non-M/R)	233 (2.5%) *vs.* 65 (3.7%)	177 (1.6%) across all models	N/A	211 (2%) across all models	N/A	N/A	N/A	76.% (10 years) *vs.* 71.0% (10 years)
Ohl *et al.* (103), 2012	2007–2009	Titan OTR	113	6 months	4 (3.5%)	2 (1.8%)	5 (4.3%)	1 (0.9%)	N/A	N/A	90% at 12 months.	96% at 12 months
Serefoglu *et al.* (104), 2012	2000–2011	Titan	29,360	11 years	1.4%	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Song *et al.* (105), 2013	2000–2011	AMS 700 CXM/CXR	179	68.3 months	1 (0.6%)	4 (2%)	1 (0.6%)	1 (0.6%)	N/A	20.2	89%	Not evaluated
Thomas *et al.* (106), 2011	1984–2007	AMS 700 Series	38	8.4 years	2 (3.5%)	15 (25%)	N/A	4 (7.1%)	N/A	N/A	65%	81.6% 50 months
Wilson *et al.* (107), 2007	N/A (prospective study)	AMS 700 Series; Mentor Alpha 1; Mentor Alpha 1 NB	2,384	N/A	7% (by 10 years)	20.6% (by 10 years)	N/A	N/A	N/A	N/A	98.1% 10 years est.	68.5% revision free 10 years
Rigicon[a]	2019–2020	Infla10	400	N/A	4 (1.0%)	2 (0.5%)	N/A	1 (0.3%)	N/A	N/A	N/A	97.7% (unspecified)

*, table includes results from AMS and Coloplast prosthesis models published since 2006; [a], data directly provided by Rigicon. AMS, American Medical Systems; N/A, not applicable or directly provided/analyzed; CX, controlled expansion; OTR, One-Touch release; CXM, controlled expansion module; CXR, controlled expansion restricted; LGX, length and girth expansion; M/R, minocycline/rifampin; NB, narrow base; est, estimate.

Conclusions

Since the early 1980s, advancements in technology and surgical techniques have transformed penile prosthetic implants. The unique features of various models of the three types of implants from this review paper are summarized in *Table 6* with associated images (114-122). The use of advanced polymeric prosthetic materials, antibiotic coatings, and increased length and width options have led to

Table 6 Summary of Prostheses

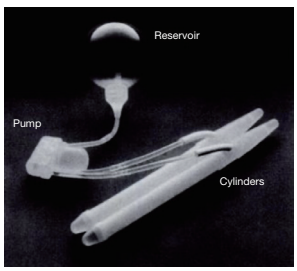
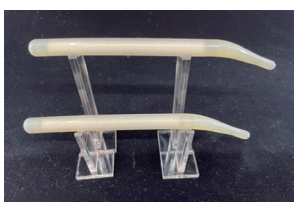
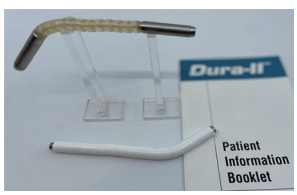
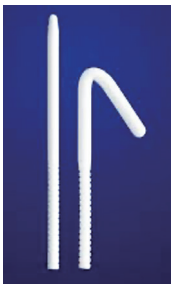
Name of implant	Picture of implant	Notes
Coloplast Genesis (114)		• Only malleable prosthetic that has hydrophilic coating.
Coloplast Titan (115)		• Hydrophilic coat that allows for antibiotics to be absorbed
Mentor GFS (116)		• First two-piece IPP introduced in 1988 • Combined fluid reservoir and pump implanted into scrotum
Small-Carrion (malleable) (117)		• First malleable penile prosthesis on market • Silicone-sponge interior encased in medical-grade silicone shell • Perineal approach commonly used with this implant
Jonas Implant (malleable) (117)		• Malleable silver core, allowing for phallus to hang in dependent fashion
Duraphase II (117)		• Polyethylene disc exterior surrounding a metal cable core • Improved mechanical strength, concealment, and positional memory

Table 6 (*continued*)

Table 6 (*continued*)

Name of implant	Picture of implant	Notes
Rigicon's Rigi10 (118)		• Stainless steel interior that allows for increased durability and flexibility • The Flexible Rod Technology™ with up to 135° degree bending angle • Hydrophilic coating for antibody absorption
Boston Scientific Tactra (119)		• Nitinol nickel-titanium alloy core encased by proprietary dual-layer silicone exterior • Trimmable exterior etchings for corporal size optimization • Insertion-fit Rear Tip Extenders
AMS Spectra (120)		• Useful in patients with limited hand dexterity or those with spinal cord injury
Ambicor Prosthesis (121)		• Pre-filled prosthetic, eliminates the necessity for fluid filled reservoir, only leaving the pump in the scrotum • Parylene-coated cylinders
Boston Scientific AMS 700 (122)		• First three-piece IPP introduced • fluid reservoir, scrotal pump, and dual intra-corporal inflatable cylinders • Polytetrafluoroethylene sleeve coverings to reduce wearing down between silicon parts Can come in four different variations: • AMS 700 LGX works to increase girth and length by 25% • AMS 700 CX offers controlled expansion to maximize girth • AMS 700 CXR provides same features of an IPP, but is used for those requiring smaller cylinders • AMS 700 Ultrex offers increased girth size bidirectionally
AMS 600 model series (malleable)	N/A	• Stainless steel wire core with silicone rubber exterior • Cone-shaped proximal cylinder design and distal tapered end to conform to patients' crus and glans, respectively

AMS, American Medical Systems; GFS, Girth-flaccidity-simplicity; IPP, inflatable penis prosthesis; LGX, length and girth expansion; CX, controlled expansion; CXR, controlled expansion restricted; N/A, not applicable.

improvements in functionality, strength, and device longevity. Concurrently, these advances have also decreased both infections and overall complication rates (123). Studies on the latest models of the three penile prosthetic device types reveal patient satisfaction ratings consistently at or above 75% (42,43,45,110-112). Two- and three-piece IPPs were associated with greater satisfaction, lower erosion rates, and higher failure mechanical rates compared to malleable prostheses. No notable differences in infection rate were found between IPPs and malleable prostheses, though diabetes, obesity, and history of smoking were associated with higher infection rates. Given that a patient is a suitable candidate for a 3-piece IPP, many experts consider this device type to be the highest standard for biological mimicry of an erect human penis.

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Footnote

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