

## IPP Improvements-Recent Innovations, Current Iterations, and Developments in the Pipeline

Engy Habashy, MD, Raevti Bole, MD, and Sevan Helo, MD

**Key Words:** Penile Prosthesis; Inflatable Penile Prosthesis; Penile Implant

### INTRODUCTION

Penile prosthesis surgery is an integral part of the management of erectile dysfunction (ED), Peyronie's disease, and gender affirmation surgery. American Urological Association guidelines support the use of a penile prosthesis in men who have failed or do not wish to pursue nonsurgical treatments.<sup>1</sup> Nikolaj A. Bogoraz is credited with the earliest documentation of a penile prosthesis in 1936 using a patient's rib cage and a tubular abdominal flap.<sup>2</sup> The first inflatable penile prosthesis (IPP), the cornerstone of modern surgical management of ED, was introduced by Scott and colleagues in 1973.<sup>3,4</sup> Since its inception the IPP has evolved through subsequent iterations to provide a physiologic erection that is natural-appearing in the flaccid and erect states, with the added advantage of being able to generate an erection on-demand for as long as the patient desires.

Currently, 2 companies manufacture IPP devices that are FDA-approved for use in the United States: Boston Scientific (AMS 700, Minnetonka, MN) (Figure 1) and Coloplast (Titan, Humlebaek, Denmark) (Figure 2). Rigicon (Infla10, Ronkonkoma, NY) and Zephyr (ZSI 475, Geneva, Switzerland) also manufacture IPP devices that are currently approved for use outside the United States (Table 1). Competition within the IPP market continues to fuel innovation as manufacturers pursue the goal of prosthesis perfection. Herein we highlight current and forthcoming innovations in IPP technology that aim to improve functionality, durability, as well as patient and partner satisfaction. All manufacturers were contacted for comment on innovations they are actively pursuing, although most were unable to share proprietary information currently under development.

### CYLINDERS

The corporal cylinders are arguably the most crucial components of the IPP. They must withstand the repetitive axial force of intercourse with sufficient rigidity while maintaining a low profile

in the flaccid state. Boston Scientific AMS 700 is currently available in multiple customizable 3-layer silicone cylinder options: CX (controlled girth expansion 12–24 cm), LGX (length and girth expansion 12–21 cm), and CXR (narrow cylinders 10–18 cm). Cylinder lengths for the CX and LGX devices start at 12 cm and are available in 3 cm increments, whereas the CXR is available in 2 cm increments. Anecdotally, patients are less likely to note “dog-eared” of the device in the flaccid state due to its 3-layer design. All cylinder sizes are available with or without a preconnected pump, in penoscrotal and infrapubic iterations. Snap-fit rear tip extenders (RTEs) are available in 0.5 cm increments (0.5–7.5 cm). The AMS 700 is the only IPP impregnated with an antibiotic coating consisting of Minocycline and Rifampin (InhibiZone) that elutes for up to 14 days after implantation. The exit-tubing of the AMS 700 series are covered with a protective polytetrafluorethylene sleeve surrounding the tubing adjacent to the cylinders to decrease wear. Lastly, Boston Scientific manufactures the only 2-piece IPP device available in the United States. The AMS Ambicor is a pre-filled, pre-connected 2-piece inflatable device that eliminates the need for a separate reservoir.

The Coloplast Titan cylinders are constructed from a single proprietary layer of Bioflex material. Sizes include the standard preconnected penoscrotal and infrapubic iterations (14–22 cm), narrow base (NB 11–18 cm), and disconnected XL (24, 26, and 28 cm). Coloplast RTEs range in size from 1 to 3 cm. Cylinder girth increases with increasing cylinder length, which is an important consideration in patients with longer penile length as a narrower device may not provide adequate axial rigidity. In contrast to the AMS 700 CX and LGX devices, cylinders are available in 2 cm increments minimizing the need for RTEs, which biomechanical studies have shown decreases axial rigidity.<sup>5</sup> Recognizing an increase in the average cylinder length used, Coloplast is expected to release preconnected XL cylinders in the near future.<sup>6</sup> The Titan IPP incorporates a hydrophilic coating that allows the surgeon to use the antibiotic solution of their choice to coat the device. This device also offers a zero-degree tubing angle, which the company asserts decreases tubing wear. The soft molded device tip is designed to reduce palpability when the device is inflated.

The Rigicon Infla10 (launched in 2019) (Figure 3) is currently undergoing its FDA approval process. Cylinders are

Received March 2, 2022. Accepted April 26, 2022.

Department of Urology, Mayo Clinic, Rochester, MN, USA

Copyright © 2022, International Society of Sexual Medicine. Published by Elsevier Inc. All rights reserved.

<https://doi.org/10.1016/j.jsxm.2022.04.011>



**Figure 1.** Boston Scientific AMS 700.

available in 3 sizes, X (girth expansion 12–24 cm), AX (anatomic girth and length expansion 12–24 cm), and NB (narrow body 10–16 cm) in penoscrotal and infrapubic models. The Infla10 cylinders incorporate a proprietary 4th silicone layer which Rigicon contends will increase device integrity. Connect-Secure RTEs (0.5–6.0 cm in 0.5 cm increments) are a feature of the Rigicon IPP that ensures a firm connection of the RTE to the cylinders. Like the Titan device, the Infla10 incorporates a hydrophilic coating and does not require any additional assembly tools for tube connections. The Rigicon Infla10 has a 45° exit tubing that is comparable in diameter to the Coloplast Titan.

The Zephyr ZSI 475 is also not currently available in the US. The device offers the convenience of providing all standard sizes and accessories (minus the dilators) in 1 box. The cylinders range from 13–19 cm, with distal (1–2 cm) and proximal (0.5–3 cm) RTEs. The larger cylinder (21 cm) IPP is offered separately with a larger reservoir. The cylinders attach to the RTEs via a screw-on mechanism. The Zephyr ZSI 475 FtM (available in Europe since 2016) has filled a unique niche as the first IPP designed for phalloplasty. Its single 3-layer silicone cylinder (14–21 cm) incorporates a large base (stainless steel and silicone) for pubic bone fixation and a realistically shaped hard glans.<sup>7</sup>

## PUMP

The IPP pump design is critical as it is the part of the device patients interact with most, and anecdotally the component most likely to generate patient phone calls. It must allow for easy identification as well as facile use of inflation and deflation mechanisms to optimize the utility of the IPP. The newest AMS 700 pump iteration is the Momentary Squeeze (MS), which contains the device's lockout mechanism. The manufacturer confirmed working on a new pump design; however, further details were not provided. They are also actively pursuing an electronic IPP (eIPP) where the scrotal pump would be replaced by a small rechargeable battery operated by the patient's smart device. Coloplast's current pump



**Figure 2.** Coloplast Titan.

iterations are the Classic/Genesis and, more recently, the Titan Touch pump. The newest Titan Touch pump released late 2021 incorporates fewer internal components potentially reducing the incidence of pump malfunction and reportedly requires 22% less force to inflate the device making it more patient-friendly. It is advertised to withstand over 58,000 inflation cycles. The Rigicon RapidPump claims to provide ease in locating and manipulating the pump, primarily due to the lateral location of the release valve. The manufacturer also advertises that it requires fewer pumps to fill the cylinders to desired rigidity, however, no published studies were conducted to validate this claim. The Zephyr's ZSI 475 pump is preconnected to the RTE base which screws on the distal cylinders. The ZSI 475 FtM offers an innovative pump incorporated inside an inflatable prosthetic testicle to create a realistic appearance within the neoscrotum.

## RESERVOIR

The reservoir component of a 3-piece inflatable prosthesis stores saline when the cylinders are deflated. The reservoir can be placed via the inguinal ring into the space of Retzius or in a submuscular location depending on patient surgical history, intraoperative findings, and surgeon preference. Boston Scientific offers the AMS 700 fluid reservoir in original Spherical and newer Conceal Low Profile configurations. The Conceal is a standard size that can be filled from 60 to 100cc. While it is optimized to fit in the space of Retzius, many surgeons commonly choose it for ectopic submuscular placement due to its low-profile design.

Coloplast Titan's Cloverleaf reservoir has a lockout valve to prevent autoinflation. The Cloverleaf is available in 75 mL and 125 mL sizes. It is the only FDA-approved reservoir for ectopic submuscular placement. Neither Boston Scientific nor Coloplast have revealed any upcoming changes to their fluid reservoir designs.

Rigicon products include the Infla10 AdaptiveReservoir. The oblong reservoir comes in 70 mL and 110 mL sizes, though a 65 mL spherical reservoir is also available for cylinders requiring a smaller fill volume (such as the narrow-based or smaller standard sizes). The adaptive material is a proprietary next-generation silicone material which purports to conform better to the body for postoperative comfort. Similar to Coloplast's Cloverleaf, the

**Table 1.** Characteristics of IPP Devices Currently Available.

	AMS 700™ CX/LGX	Titan®	Infla10® X/AX	ZSI 475	ZSI 475 FtM
Manufacturer	Boston Scientific	Coloplast	Rigicon	Zephyr	Zephyr
Approved in the US	Yes	Yes	No	No	No
Cylinder lengths (cm)	12	14	12	13	12
	15	16	15	16	15
	18	18	18	19	18
	21	20	20	22	21
	24 (CX only)	22	22		
		24	24		
		26			
		28			
Rear-tip extenders	0.5 / 1 / 1.5 (stackable) 2 / 3 / 4 / 5 / 6	1 / 1.5 / 2 / 3	0.5 / 1 / 1.5 (stackable) 2 / 3 / 4 / 5 / 6	0.5 / 1 / 2 / 3 (proximal) 1 / 2 (distal)	N/A
Reservoirs (mL)	65/100 (spherical) 60-100 (Conceal™)	75/125 (Cloverleaf)	65 (spherical) 70 / 110 (AdaptiveReservoir™)	80 100	80 100
Coating	InhibiZone®	Hydrophilic	Hydrophilic	Hydrophilic	Hydrophilic
Cylinder layers	Three layers silicone	Single Bioflex®	Four layers silicone	Three layers silicone	Three layers silicone
Offers length expansion	Yes (LGX)	No	Yes (AX)	No	No
Offers narrow device	Yes (CXR)	Yes (NB)	Yes (NB)	No	No
Assembly connector required	Yes	No	No	No	No

**Figure 3.** Rigicon Infla10.

Rigicon AdaptiveReservoir features a lockout valve that is concealed under the reservoir to further minimize autoinflation risk. Zephyr's ZSI 475 comes with an 80 mL reservoir with their standard sizes box or a 100 mL reservoir with their large size box.

## ACCESSORIES

Efficient placement of the IPP requires a selection of specialized tools. In early years, long vascular forceps, snares, and even a cylinder-freezing technique were used to position the device in the corpora.<sup>8,9</sup> In 1978, Dr Furlow at the Mayo Clinic published

a 34-patient series using his novel cylinder insertion device.<sup>7</sup> The modern-day reusable Furlow insertion tool uses a simple Keith needle to thread the suture guide into position. Coloplast has updated the Furlow design by increasing the length 2 cm and engineering a smooth finish instead of notches. The new exterior allows the Furlow to glide more easily and simplifies the cleaning process by reducing the surface area for debris to cling. Rigicon also markets a single-use insertion tool in addition to a standard Furlow for distal cylinder placement.

Positioning the proximal cylinder for a Coloplast device may be facilitated by using the handle of a Debakey forceps within the corporotomy.<sup>10</sup> Boston Scientific's "proximal tool" performs this function with a notch for the exit tubing site and is provided in the AMS 700 accessory kit. Coloplast's response is a new assembly kit that features a shoehorn that can be used to maneuver the proximal end into place and connector tool similar to the AMS Quick Connect Assembly tool.

The experience of soaking a Coloplast penile prosthesis in antibiotic will also be enhanced by new product packaging. The AMS 700 device with its InhibiZone impregnated solution should not be soaked.

Corporal dilation can be performed using the Brooks dilator, which improves upon the Hagar dilator with its blunt end and offset handle.<sup>8</sup> Rigicon's HL dilator, which is used widely outside of the USA, offers 2 different diameter tips in a single tool. The tips are angled allowing the surgeon to grip and use either end. Additionally, the length of the dilator is marked to allow simultaneous dilation and measurement in 1 step. This concept builds upon Dr

F. Brantley Scott's Lone Star Dilamezinsert manufactured by Cooper Surgical (CooperSurgical, Inc, Trumbull, CT).<sup>11</sup>

Zephyr's IPPs offer the advantage of including all the accessories necessary for device placement (except the dilators) in a single box. The box allows the surgeon the ability to construct an IPP that varies in length from 12 to 25 cm. Even if a cylinder is dropped or contaminated during the procedure, the box includes variable size cylinders that can be employed to reconstruct the size of the unusable cylinder.

## CONCLUSION

Since its introduction in 1973, the IPP has undergone multiple modifications; each with the goal of improving device function, decreasing complications, and increasing patient and partner satisfaction. The IPP will undoubtedly continue to play an essential role in the treatment of medication-refractory ED. The future for device innovation is bright as more manufacturers join this technologically advanced surgical space and continue to further the evolution of the IPP to optimize the sexual health of cis and transgender patients.

**Corresponding Author:** Sevan Helo, Department of Urology, Mayo Clinic Minnesota, Rochester, MN, USA; E-mail: [sevanh@mayo.edu](mailto:sevanh@mayo.edu)

*Conflict of Interest:* The authors report no conflicts of interest.

*Funding:* None.

## STATEMENT OF AUTHORSHIP

Conceptualization, E.H., R.B., and S.H. Methodology, E.H., R.B., and S.H.; Investigation, E.H., R.B., and S.H.; Writing —

Original Draft, E.H., R.B., and S.H.; Writing — Review & Editing, E.H., R.B., and S.H.; Supervision, S.H.

## REFERENCES

1. Burnett AL, Nehra A, Breau RH, et al. Erectile dysfunction: AUA guideline. *J Urol* 2018;200:633–641.
2. Schultheiss D, Gabouev AI, Jonas U, et al. Bogoraz (1874–1952): pioneer of phalloplasty and penile implant surgery. *J Sex Med* 2005;2:139–146.
3. Goodwin WE, Scott WW. Phalloplasty. *J Urol* 1952;68:903–908.
4. Scott FB, Bradley WE, Timm GW. Management of erectile impotence. Use of implantable inflatable prosthesis. *Urology* 1973;2:80–82.
5. Thirumavalavan N, Cordon BH, Gross MS, et al. Rear tip extenders and penile prosthesis rigidity: a laboratory study of coloplast prostheses. *J Sex Med* 2018;15:1030–1033.
6. Welliver C, Kottwitz M, Ahmad AE, et al. Manufacturers' data show increasing implanted cylinder sizes and measured corporal lengths in inflatable penile implants. *World J Urol* 2016;34:993–998.
7. Neuville P, Morel-Journel N, Cabelguenne D, et al. First Outcomes of the ZSI 475 FtM, a specific prosthesis designed for phalloplasty. *J Sex Med* 2019;16:316–322.
8. Wilson SK, Delk JR. Historical advances in penile prostheses. *Int J Impot Res* 2000;12(Suppl 4):S101–S107.
9. Furlow WL. Inflatable penile prosthesis: new device for cylinder insertion. *Urology* 1978;12:447–449.
10. Henry GD, Mahle P, Caso J, et al. Surgical techniques in penoscrotal implantation of an inflatable penile prosthesis: a guide to increasing patient satisfaction and surgeon ease. *Sex Med Rev* 2015;3:36–47.
11. Carson CC, Brantley F. Scott: a visionary in the world of urology. *Trends Urol. Men's Health* 2018;9:32–33.