

Coloplast's Next Generation Inflatable Penile Prosthesis Approved by the FDA – can help millions of men

June 03, 2026

The global leader within intimate healthcare today announced FDA approval of Titan Prime, an inflatable penile prosthesis (IPP) that represents the company's next-generation device and will be available in the U.S. in late 2026.

Around 30 million men in the US experience ongoing difficulty in getting or keeping an erection firm enough for sexual activity*. As an alternative to medication, some benefit from long-term treatment options such as an inflatable penile prosthesis, which is delivered through a single outpatient procedure.

"We are excited to offer Titan Prime IPP, a clinically proven solution that helps men suffering from severe erectile dysfunction take back control of their intimate lives and relationships", says Kevin Hardage, President of Coloplast Interventional Urology.

"This FDA approval advances prosthetic urology and marks an important milestone for patients seeking long-term restoration of erectile function, as well as for clinicians committed to delivering the highest standard of care", says Kevin Hardage.

About Titan Prime Inflatable Penile Prosthesis

Titan Prime IPP is designed to emulate the appearance and performance of a natural erection, supporting device performance for patients, surgeons, and partners. Built with proprietary Bioflex – a polymer engineered for greater strength and durability than silicone – Titan Prime IPP delivers greater material strength than leading silicone competitors and withstands higher pressures to reinforce reliability. ** Titan Prime IPP preserves the rigidity and girth surgeons trust from Titan IPP today, while providing improved flaccid flexibility for comfort and concealability. The result is consistent, predictable outcomes across diverse male anatomies.

Coloplast was founded in 1957 – inspired by a nurse's wish to help her sister and brought to life through the skills of an engineer. From the very beginning, empathy has guided us, and we have grown by learning from the people we serve. Our mission is to make life easier for people with intimate healthcare needs. For decades, we have listened with care and responded with innovation. The Coloplast Group develops products and services that help millions of people live more independent lives, through solutions tailored to their needs. Whether they are adjusting to life after ostomy surgery, learning to breathe or talk with a neck stoma, managing urological or bowel conditions, or healing wounds, – our solutions are designed to empower individuals to live the life they choose.

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Availability

Titan Prime is now FDA-approved and will be available through a phased launch to urologists and health care systems in the United States beginning in late 2026.***

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Notes:

* Nunes KP, Labazi H, Webb RC. New insights into hypertension-associated erectile dysfunction. *Curr Opin Nephrol Hypertens*. 2012;21(2):163-170.

**Coloplast Test Data: *Bioflex Monograph*

*** Titan Prime IPP is approved for use in the United States by the FDA. Coloplast is pursuing regulatory approvals in other countries, where the product is not yet available