

This memo provides responsive information to inquiries on the use of hyperbaric oxygen therapy for patients with the Titan® Inflatable Penile Prosthesis (IPP) and Torosa® Testicular Prosthesis. It includes relevant data from approved product labeling, testing data, and published literature.

Product Labeling

Please refer to the Titan IPP Instructions for Use (IFU) and Torosa Prothesis IFU for information about approved uses and important safety information. ^{1,2} There are no warnings, precautions, or contraindications in Titan labeling or Torosa labeling about high pressure environments.

Product Testing Data

External pressure testing was conducted to examine the residual effects of overpressurization for the Titan implant, Titan Touch implant, and Torosa prosthesis. Testing found that device performance was unaffected after being subjected to simulated in vivo pressures of up to 73.5 PSI (5 atm), which surpasses typical hyperbaric therapy pressures of 15 to 30 psi and aligns with intensive hyperbaric therapies reaching 73.5 psi and lasting up to two hours.³ Coloplast does not have data on the functioning of these devices during overpressurization.

Published Literature

Search Strategy

The Coloplast Medical Affairs team performed a literature search in PubMed in February 2025. The search strategy included terms for Titan, penile prosthesis, Torosa, testicular implant, and hyperbaric therapy. It excluded nonhuman studies, non-English publications, and publications older than 10 years. Additional relevant publications were also evaluated for content and references.

Search Results

The search identified a single publication where the authors reported using hyperbaric therapy (2.4atm) to treat a patient with glandular ischemia one month after inflatable penile prosthesis implant.⁴ There were no reported complications.

If you need additional information, please contact MUMedicalAffairs@Coloplast.com.

Disclaimers

Medical Information

This information is intended to inform clinical decision making, support the safe and effective use of Coloplast products, and foster scientific exchange. It is not intended to be medical advice or offer recommendations inconsistent with product labeling.

Limitations of Medical Research

The information derived from our literature searches should not be considered comprehensive, as medical literature databases are inherently selective.



How to Report an Adverse Event

To report a patient adverse event or product complaint, please submit information to your local Coloplast representative or contact complaints@coloplast.com.

References

Coloplast sponsors clinical research and may have provided financial support to the studies described in these articles. Please review individual articles for disclosures of financial support.

Please inform us if you would like a copy of cited literature. Reprints are reportable as a transfer of value in compliance with the federal Open Payments / Physician Payments Sunshine Act.

- 1. Titan and Titan Touch Instructions for Use (North America) 70003006 Rev. A. . Humlebaek, DK: Coloplast A/S.; July 2024.
- 2. Torosa Saline-Filled Testicular Prostheses Instructions for Use (North America) 70002200 Rev. B. Humlebaek, DK: Coloplast A/S; October 2021.
- 3. Coloplast. Titan data on file. VV-0342048 v1.0.
- 4. Garrido-Abad P, Estéve-Sánchez DA, Fernández-Arjona M. Superficial glans ischemia after penile prosthesis successfully treated by conservative treatment. *Rev Int Androl.* Oct-Dec 2021;19(4):281-284. doi:10.1016/j.androl.2020.04.001