

In response to your request for information, please review the following:

Magnetic Resonance Imaging (MRI) COMPATIBILITY

Coloplast's penile prostheses contain components fabricated from metals. The following three sections describe in detail the materials of construction and the MR conditions to avoid patient or product injury.

Section 1

Titan Inflatable Penile Prosthesis

Titan IPP with Classic Pump, Titan IPP with Touch Pump, Titan Prime IPP with Press Pump, and Titan Prime IPP with Classic Pump are composed of polyurethane, silicone, polysulfone, nylon and MP35N. Titan IPP devices may also contain a small amount of glass fiber.

Testing

All Titan penile prostheses are MR conditional per testing commissioned by Coloplast and undertaken by MED Institute in July 2025 (VV-0655315).

MRI Safety Information A patient with a Titan portfolio IPP may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient. A patient implant card stating that the device is MR Conditional is included in the package and should be completed and provided to the patient.	
Name/Identification of Device	Titan or Titan Prime IPP with Classic Pump, Touch Pump, or Press Pump
Nominal Value(s) of Static Magnetic Field	1.5 or 3 Tesla (T)
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	No restriction on transmit-receive coils
Operating Mode	Normal
Maximum Whole Body Specific Absorption Rate (SAR)	2.0 W/kg
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact
In non-clinical testing, the Titan portfolio IPPs produced a temperature rise of less than 1.9°C at a maximum whole body. If information about a specific parameter is not included, there are no conditions associated with that parameter.	

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Section 2

Malleable Penile Prosthesis

Genesis, Acu-Form®, and Malleable penile prostheses are composed of silicone, a silver (99.97% pure) coil, polyurethane and a polypropylene connector.

Legacy Inflatable Penile Prosthesis

Titan OTR, Alpha I®, Excel™, and Mark II® inflatable penile prostheses are composed of polyurethane, silicone, polysulfone, nylon and MP35N. The Alpha I, Titan OTR, and Excel devices also contain a small amount of glass fiber.

Testing

All Genesis, Acu-Form, and Malleable penile prostheses are MR conditional per testing commissioned by Coloplast and undertaken by F. Shellock in July 2007 (VV-0041910). All Titan OTR, Alpha I, Excel, and Mark II materials are MR conditional per testing commissioned by Coloplast and undertaken by F. Shellock in December 2005 (VV-0032634) and February 2011 (VV-0016100). Testing resulted in both Malleable and Inflatable penile prostheses being verified as MR conditional to:

- Static field of 3 Tesla or less
- Spatial gradient field of 720 gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning

In non-clinical testing, all the tested penile prostheses produced temperature rises of less than 1.9 °C at a maximum whole body average specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 Tesla MR scanner. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the prosthesis. Therefore, it may be necessary to optimize MR imaging parameters for the presence of the penile implant.

Section 3

LATEX CONTENT

Coloplast's penile (malleable and inflatable) prostheses are fabricated from materials that do not contain latex. Additionally, latex gloves are not worn by employees that manufacture these products.

For further information, please contact the Coloplast Surgical Support department at 800-258-3476.

Sincerely,



Joseph DuPay III
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Coloplast Interventional Urology