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Re: MRI Compatibility and Latex Content

Urgent For Review Please Comment Please Reply Please Recycle

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

MRI COMPATIBILITY

Coloplast's penile prostheses contain components fabricated from metals. The following two sections describe in detail the materials of construction and the evidence demonstrating that Coloplast's penile prostheses are MRI conditional.

Malleable Penile Prostheses

Genesis, Acu-Form[®], and Malleable penile prostheses are composed of silicone, a silver (99.97% pure) coil, and a polypropylene connector. In addition, the Acu-Form and Genesis contain a silver core (99.97% pure) and a polyurethane elastomer.

Inflatable Penile Prostheses

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

Testing

All Genesis, Acu-Form[®], and Malleable penile prostheses are MRI conditional per testing commissioned by Coloplast and undertaken by F. Shellock in July 2007. All Titan, Alpha I, Excel, and Mark II materials are MRI conditional per testing commissioned by Coloplast and undertaken by F. Shellock in December, 2005. The testing resulted in both Malleable and Inflatable penile prostheses being verified as MRI 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) or 3 W/kg for 15 minutes of MR scanning.

In non-clinical testing, the all tested penile prostheses produced temperature rises of less than 0.5 °C at a maximum whole body average specifications absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 Tesla (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) 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.

LATEX CONTENT

Coloplast's penile (malleable and inflatable) prostheses and testicular 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 Urology Help Line at 800-525-8161.

Sincerely,



Yelena Tropsha
Vice President Research and Development
Coloplast