TOROSA® Saline-Filled Testicular Prosthesis

BRIEF STATEMENT
Physician Facing

Indications
The Coloplast TOROSA Saline-Filled Testicular Prosthesis is intended for use when cosmetic testicular replacement is indicated i.e., in the case of agenesis or following the surgical removal of a testicle.

Contraindications
The implantation of testicular prostheses is contraindicated in the presence of infection or untreated neoplasm.

Warnings
This device contains solid silicone elastomer. The risks and benefits of implanting this device in patients with lupus (e.g., SLE or DLE), scleroderma (e.g., progressive systemic sclerosis), myasthenia gravis, or documented sensitivity to silicone should be carefully considered. The issue of the possible relationship between silicone and various diseases has been and continues to be the subject of scientific and medical debate.

Sepsis or hemorrhage may result from the placement of any foreign object in the body.

Excessive fibrous capsular formation or contracture may occur around any implant placed in contact with soft tissues.

Precautions
Each prosthesis should be checked for patency prior to surgery and continuously monitored throughout the surgical procedure to ensure that the structural integrity of the implant is not compromised in any way.

The action of drugs (such as antimicrobials, chemotherapy agents or steroids) in contact with the prosthesis has not been tested by the manufacturer, and their use cannot be recommended. Each physician who chooses to use drugs in combination with this prosthesis must assure compatibility of the drug with silicone elastomer.

A thorough preoperative consultation should include a discussion between the patient and physician of all available treatment options and their risks and benefits.

Implantation of the TOROSA Saline-Filled Testicular Prosthesis may be difficult or impossible in patients with inadequate scrotal tissue to cover the prosthesis, patients who have undergone prior pelvic radiation therapy, or patients whose wound healing abilities are compromised (e.g., uncontrolled diabetes, poor circulation).

Potential Complications
Potential complications include pain and discomfort.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to this product's Instructions for Use. Alternatively, you may contact a Coloplast Representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Minneapolis, MN
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