

## Saline-Filled Testicular Prosthesis

**REF** 450-1323, 450-1325, 450-1327, 450-1329

## Patient Information Leaflet en

### What is Torosa?

Torosa Saline-Filled Testicular Prosthesis is a surgically implanted prosthetic device intended for use in males when cosmetic testicular replacement is indicated, such as in the absence or incomplete development of a testicle (agenesis) or following the surgical removal of a testicle.

Torosa is made of silicone elastomer and is concealed entirely within the body. Torosa is available in multiple sizes and is fitted to simulate the weight, shape and size of a natural testicle.

### Is Torosa the right option for me?

Discuss the benefits and risks of a testicular implant with the doctor to determine if Torosa is the best option based on your current health, lifestyle and expectations.

Torosa cannot be implanted if you have a testicular infection or abnormal testicular growth (neoplasm).

Implantation of the prosthesis may be difficult or impossible in patients who have undergone pelvic radiation therapy, have difficulty healing, or have inadequate scrotal tissue to cover the prosthesis. Persistent pain may occur in patients with pre-existing varicoceles (varicose veins within the scrotum).

Torosa is considered a permanent implant, however, as a prosthetic device it may require replacement if surgical, physical, psychological, or mechanical problems occur.

The doctor will provide instructions for surgery, post-operative care, and advise when it is safe to return to usual activities. It is important to attend routine office visits with the doctor to monitor your health and ensure the prosthesis is functioning as intended.

### What are the risks?

Discuss how the following conditions may affect the risks of testicular prosthesis surgery:

- Documented sensitivity to silicone
- Autoimmune disorders (e.g., systemic lupus erythematosus, discoid lupus erythematosus)
- Scleroderma
- Myasthenia gravis

Complications may occur following testicular prosthesis surgery. These risks can include:

- Collection of blood or fluid outside of tissue or vessels (hematoma, seroma)
- Damage or loss of tissue (necrosis)
- Excessive bleeding (hemorrhage)
- Excessive scarring and/or tightening around prosthesis (capsular formation or contracture)
- Foreign body reaction leading to formation of blood clots (thrombosis) or systemic infection (sepsis)

Immediately report complications, or if there are changes in the size, appearance, or firmness of the prosthesis. Failure to report or treat complications may result in infection, pain, or loss of tissue and could result in the removal of the prosthesis.

### Will Torosa interfere with other equipment?

Torosa does not contain material that conducts electricity or magnetic current. The device is considered MR-Safe and will not interfere with airport security equipment or magnetic resonance imaging (MRI) machines.

After surgery you will receive a Patient Implant Card to carry at all times. This card identifies that your device is MR-Safe and provides specific identification details for your device.

### How do I report a serious complication?

You should report all complications to your doctor right away. If the complications are serious and you or your doctor think they are related to the prosthesis, you or your doctor should notify Coloplast A/S, the company that makes Torosa, and the appropriate national authority. You can find contact information for Coloplast A/S on your Patient Implant Card.

If you live in Australia and experience a serious complication, you should report the problem to Coloplast A/S and your national authority, the Therapeutic Goods Administration (TGA). Report the problem online at [www.tga.gov.au](http://www.tga.gov.au) or by calling the Adverse Medicine Events Line at 1300 134 237.