



# New Device Approvals

## Mentor Saline-Filled Testicular Prosthesis - P020003

*This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.*

Product Name: Mentor Saline-Filled Testicular Prosthesis  
Manufacturer: Mentor Corporation  
Address: 201 Mentor Drive, Santa Barbara, CA 93111  
Approval Date: July 19, 2002  
Approval Letter: <http://www.fda.gov/cdrh/pdf2/P020003a.pdf>

What is it? This device is a cosmetic replacement for a missing testicle. It is silicone rubber, oval shaped, and contains salt water (saline).

How does it work? A surgeon implants the device in the scrotum of a man or boy. It looks and feels like a natural testicle, but does not have any other function.

When is it used? When a man or boy is missing one or both testicles and wants a cosmetic replacement.

What will it accomplish? It will help restore the shape and feel of a scrotum that is missing one or both testicles.

When should it not be used? Doctors should not implant this device if the patient has an infection or untreated cancer.

Additionally, implantation of the device should be carefully considered if:

- the patient's scrotum is too small or damaged from prior surgery or radiation,
- the patient has uncontrolled diabetes or poor circulation, or
- the patient wants to avoid future surgery to remove it. About 1 in every 30 patients had to have the implant removed in about a year because it moves too much in their scrotum, weakens their skin, or it becomes infected.

**Additional information:**

- Summary of Safety and Effectiveness and labeling are available at:  
<http://www.fda.gov/cdrh/pdf2/P020003.html>
- Information on Testicular Cancer: [http://rex.nci.nih.gov/WTNK\\_PUBS/testicular/side.htm](http://rex.nci.nih.gov/WTNK_PUBS/testicular/side.htm)

(Updated 08/08/2002)