



New Device Approvals

Mentor Alpha I Inflatable Penile Prosthesis- P000006

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 Alpha I Inflatable Penile Prosthesis
Manufacturer: Mentor Corporation
Address: 201 Mentor Drive, Santa Barbara, CA 93111
Approval Date: July 14, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000006a.pdf>

What is it? This device is implanted in a man's penis to help him have an erection. It is made from silicone and polyurethane rubber. It has four parts that are put into the body by a doctor during surgery:

- Two tubes (penile cylinders) in the penis,
- A pump in the scrotum, and
- A container (reservoir) in the lower abdomen

How does it work? To get his penis erect, a man squeezes the pump to send fluid from the container to the tubes until his penis is stiff. To make his penis soft, he squeezes the pump base (release bar) to open a valve and let fluid flow back to the container.

When is it used? This device is used when a man is not able to get an erection normally and is not satisfied with other treatments, such as medications or devices worn on the outside of the penis.

What will it accomplish? It will allow a man to get and keep an erection long enough to have sex.

When should it not be used? This device should not be used by men who:

- Have active infections, or
- Have problems with urinating normally, or
- Lack the strength or ability to pump the device, or
- Expect to get back their normal ability to have an erection, or
- Expect to play contact sports.

What serious problems may some men have? A man may need to have surgery to have the device taken out or fixed. This may happen because:

- His penis gets infected,
- His penis is injured by the device rubbing on the inside of it,
- He has too much pain, or

- The device does not work right

Additional information: Summary of Safety and Effectiveness is available at:

<http://www.fda.gov/cdrh/pdf/p000006.html>

Other: NIH Consensus Document: http://odp.od.nih.gov/consensus/cons/091/091_statement.pdf

NIDDK Site, Impotence: <http://www.niddk.nih.gov/health/urolog/pubs/impotnce/impotnce.htm>

(Updated 4/03/01)