

# ***CDRH Interim Regulatory Policy for External Penile Rigidity Devices***

**This document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.**

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**Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological  
Devices**

**Office of Device Evaluation**

**Document Issued On:**

**September 10, 1997**

*While this document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by writing to Mr. Donald St.Pierre, CDRH, 9200 Corporate Boulevard, HFZ-470, Rockville, MD 20850. For questions regarding the use or interpretation of this guidance, contact Mr. St.Pierre at (301) 594-2194.*

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Center for Devices and Radiological Health**

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**CDRH Interim Regulatory Policy for  
External Penile Rigidity Devices**

**I. Introduction**

External penile rigidity devices (78 LKY, unclassified) are medical devices designed to promote or maintain sufficient penile rigidity for sexual intercourse. These devices may be indicated for either medical uses (e.g., treatment or management of erectile dysfunction/impotence) or sexual pleasure. The class of external penile rigidity devices includes three specific types of products: (i) constriction rings, (ii) vacuum pumps, and (iii) penile splints.

- i. Constriction rings are devices that are placed around the base of the erect penis for the duration of sexual intercourse, to restrict the flow of venous blood leaving the penis. Constriction rings generally consist of loops of a flexible, elastic material, and must be designed to include handles or tabs so that they can be readily removed from the penis by the user.
- ii. Vacuum pumps refer to devices which consist of a cylinder and a vacuum pump (either hand-operated or motorized). By placing the flaccid penis within the cylinder, this device creates an erection by applying a vacuum. This causes blood to enter the penis producing an erection. Once a satisfactory erection is obtained, the user often places a constriction ring around the base of the erect penis prior to removing the vacuum cylinder.
- iii. Penile splints are rigid or flexible support structures intended to be attached to or placed along the penis to hold the penis erect during sexual intercourse.

The purpose of this document is to outline several changes in how FDA regulates external penile rigidity devices:

First, this document clarifies when premarket review is required for new external penile rigidity devices using a uniform approach. In the past, premarket review was required as follows:

- Constriction rings and vacuum pumps required 510(k) review when indicated for the treatment or management of erectile dysfunction/impotence.
- Penile splints required PMA review when indicated for the treatment or management of erectile dysfunction/impotence.

Premarket review was not required for all types of external penile rigidity devices when indicated solely for sexual pleasure.

Additionally, an import alert for constriction rings, vacuum pumps, and penile splints (#78-01, dated 5/18/93) refused admission of these devices into the U.S. unless they have been cleared/approved through either the 510(k) or PMA process.

Second, this new policy allows manufacturers the option of marketing external penile rigidity devices as prescription and/or over-the-counter (OTC) devices. Prior to this document, all external penile rigidity devices that underwent premarket review were required to be labeled as prescription devices. Upon reevaluating this policy, however, the Agency now believes that with adequate labeling, these devices may be safely used when sold OTC.

Until the class of external penile rigidity devices undergoes formal classification procedures, FDA intends to base its regulation of these devices on this new, interim policy, which is described in detail below.

## **II. Requirement for Premarket Review**

As stated in Section I, above, FDA has had a policy of requiring manufacturers of constriction rings and vacuum pumps to submit 510(k)s for their devices based solely on intended use, i.e., 510(k)s were required for those devices that are indicated for the treatment or management of erectile dysfunction/impotence. At the same time, the Agency required PMAs for penile splint devices (none received) since preamendments status had never been demonstrated for this device type and since new types of questions were raised in comparison with predicate constriction rings. Recently, however, FDA became aware that numerous types of external penile rigidity devices, including certain penile splints, were marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments of the Federal Food, Drug, and Cosmetic Act (the Act). The preamendments indications for these devices included both medical claims (i.e., the treatment or management of erectile dysfunction/impotence), and non-medical claims (i.e., sexual pleasure).

A small number of preamendments external penile rigidity devices were capable of injuring either the user or his sexual partner due to their specific design, such as inadequate release mechanism, excessive vacuum pressure, or sharp/hard components that contact the body of the user or his sexual partner. The Agency took a variety of actions against these devices, including seizures, import detention, etc. Based on the inherent risks of this subgroup of external penile rigidity devices, FDA still believes that, regardless of the indication (i.e., either the treatment or management of erectile dysfunction/impotence or sexual pleasure), these unsafe devices are

adulterated. Thus, appropriate regulatory action will be taken when these devices are encountered.

Based on this new information regarding the preamendments status of these devices, FDA is revising its regulatory policy for external penile rigidity devices as follows:

- Constriction rings, vacuum pumps, and penile splint devices affect the structure of the body, and, therefore, are devices.
- For devices with "medical" claims (i.e., for the treatment or management of erectile dysfunction/impotence), premarket clearance is required. Since the preamendments status of constriction rings, vacuum pumps, and penile splints has been established, 510(k)s should be submitted for those devices that require premarket clearance. Those devices that are found substantially equivalent will be categorized as "external penile rigidity devices" (product code LKY; unclassified).
- For devices indicated solely for sexual pleasure, FDA will exercise its enforcement discretion to not require premarket notification, registration, and listing. However, the device remains subject to the remaining adulteration and misbranding provisions of the Act.
- If the device's design presents a potential risk to either sexual partner when used as indicated, taking into account such device characteristics as roughness, sharpness, hardness, stiffness, excessive constriction, lack of protection from over-vacuum, and lack of an easy, reliable means of attachment/release, the Agency may consider the device to be adulterated.

[Device design characteristics that FDA believes do not present a potential risk of injury are use of a soft, pliable material, a smooth shape/surface, non-constricting splint-support of the penis, use of a safe vacuum limit (i.e.,  $\leq 17$  inches of mercury), and a simple, quick method of attaching/releasing the device.]

### **III. Over-the-Counter (OTC) Labeling**

In the past, FDA has required that all external penile rigidity devices indicated for the treatment or management of erectile dysfunction/impotence be labeled as prescription devices. This position was based on the Agency's belief that adequate directions for use could not be written for the layperson. Recently, however, FDA has reevaluated this policy based on the following information: (i) the three known types of external penile rigidity devices (i.e., constriction rings, vacuum pumps, and penile splints) were determined to have been legally marketed OTC prior to May 28, 1976; (ii) there is now sufficient information available regarding the risks, benefits, and use of these types of external penile rigidity devices to enable adequate patient labeling to be written; and (iii) despite their potential for causing harm if misused, very few cases of injury have been reported in either the published literature or FDA's Medical Device Reporting database.

Therefore, manufacturers of external penile rigidity devices may choose to market these devices over-the-counter provided their labeling contain the information described below regarding their safe use and potential risks. For those devices that require premarket notification (as described in Section II of this document), this labeling information will be requested of all 510(k) submitters during FDA review. However, the Agency also encourages manufacturers of the external penile rigidity devices that are not subject to premarket notification requirements to voluntarily follow these labeling recommendations. FDA strongly recommends that manufacturers prepare this patient labeling in consultation with the FDA publication "Write it Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care" (HHS Publication FDA 93-4258), available from the Division of Small Manufacturers Assistance (DSMA) at (301) 443-6597 or their toll free number (800) 638-2041.

#### LABELING RECOMMENDATIONS:

1. Labeling for the external penile rigidity device should include the device name, corporation name, address, telephone number, intended use, disposable/single use status (if applicable), a description of the device (including dimensional specifications), and directions for use.
2. The labeling should include the indications for use and identification of the population(s) for whom the device is appropriate.
3. The directions for use should contain comprehensive instructions on how to size, place, operate, remove, and clean the device.
4. The labeling should include the warning: "If you have symptoms of erectile dysfunction, (i.e., inability to achieve an erection that is sufficient for sexual intercourse), consult your physician prior to using this device to avoid a potentially harmful delay in diagnosing any of the most common causes of this condition, such as diabetes, multiple sclerosis, cirrhosis of the liver, chronic renal failure, or alcoholism."
5. Relevant contraindications, warnings, and precautions should be included in the labeling of the device. Additionally, possible methods of resolution of the problems and risks associated with the use of the device should be stated. The attached "Patient Handout" for vacuum devices and constriction rings, reprinted from the December, 1991, issue of Contemporary Urology, may be useful in this regard. Specifically, we believe that the warning and cautionary statements listed below by device type should be addressed in the labeling for these devices using terminology well-understood by the average layperson.

#### Information Relevant to Constriction Rings:

- a. Consult your physician should any complications present, and discontinue use of the device if such conditions persist.
- b. Use of the device should be restricted to  $\leq 30$  minutes. Do not fall asleep wearing the constriction ring. Prolonged use of the constriction bands (i.e., without removal) may cause permanent injury to the penis.
- c. The user should allow 60 minutes between uses.

- d. Use the least constrictive rings which maintain an erection.
- e. Constriction rings should not be used under the influence of alcohol or drugs.
- f. Constriction rings are not intended for use as a contraceptive/birth control.
- g. Frequent use of constriction rings may result in bruising at the base of the penis (where the shaft of the penis meets the pubic area).

Information Relevant to Vacuum Pumps:

- a. Consult your physician should any complications present, and discontinue use of the device if such conditions persist.
- b. The user should apply the minimum amount of vacuum pressure necessary to achieve an erection.
- c. The user should stop using the vacuum pump if pain occurs.
- d. Vacuum pumps should not be used under the influence of alcohol or drugs.
- e. Use of a vacuum pump may bruise or rupture the blood vessels either immediately below the surface of the skin or within the deep structures of the penis or scrotum, resulting in hemorrhage and/or the formation of a hematoma.
- f. Misuse of a vacuum pump may aggravate already existing medical conditions such as Peyronie's disease, priapism, and urethral strictures.
- g. Misuse of the vacuum pump could result in swelling of the penis and/or serious permanent injury to the penis.
- h. Do not use an electrically powered vacuum pump in or near water.

Information Relevant to Penile Splints:

- a. Consult a physician should any complications present to either yourself or your sexual partner, and discontinue use of the device if such conditions persist.

Consistent with the recommendations of the FDA guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (dated January 10, 1997), sponsors wishing to relabel their external penile rigidity device from prescription to OTC use should submit a new premarket notification for this change since the Agency considers this labeling revision to have a major impact on intended use. A copy of this guidance document is available from either the Internet on FDA's home page (<http://www.fda.gov>), or DSMA.

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*(Updated September 17, 1997)*