

Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: External Penile Rigidity Devices

Document issued on: [release date of FR Notice]

The draft of this document was issued on March 17, 2004

**This guidance supersedes CDRH Interim Regulatory Policy for External
Penile Rigidity Devices, September 10, 1997**

The information collection provisions in this guidance have been approved under OMB control number 0910-0485. The approval expires 3/31/05. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

For questions regarding this document, contact Janine Morris at 301 594-2194 x117 or by email at JZM@cdrh.fda.gov.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Urology and Lithotripsy Devices Branch
Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation**

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. When submitting comments, please refer to Docket No. _____ Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: [http://www.fda.gov/cdrh/\[specific address\]](http://www.fda.gov/cdrh/[specific address]), or to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (**1231**) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Table of Contents

1.	Background	1
2.	Scope.....	2
3.	Risks to Health	3
4.	Design Features	4
5.	Labeling	6
6.	Limitations of Exemption from Premarket Notification.....	9

Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: External Penile Rigidity Devices

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Background

The Food and Drug Administration (FDA) is designating this guidance as a special control guidance for external penile rigidity devices and is exempting this device from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the Act). FDA is issuing this guidance in conjunction with a Federal Register notice announcing the final rule.

This guidance document describes a means by which external penile rigidity devices may comply with the requirement of Class II Special Controls. Designation of this guidance document as a special control will mean that manufacturers of external penile rigidity devices who follow the recommendations or equivalent measures to address the risks identified in this guidance, before introducing their device into commercial distribution in the United States, will be able to market their device without being subject to the premarket notification requirements of section 510(k) of the Act.

Section 510(m) of the Act provides that FDA may exempt a Class II device from the premarket notification requirements under section 510(k) of the Act if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA may determine that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device if the manufacturer follows the recommendations in this special controls guidance or equivalent measures to address the risks identified in this guidance. Thus, persons who intend to market a device of this type do not need to submit a 510(k) to FDA and receive agency clearance prior to marketing the device, but as a class II device, the device must comply with the general and special controls (Section [513\(a\)\(1\)\(B\)](#) of the Act).

Contains Nonbinding Recommendations

Following the effective date of a final rule exempting the device, manufacturers of external penile rigidity devices will need to address the issues covered in this special control guidance. However, a manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.¹ If a manufacturer does not follow these recommendations or equivalent measures, it will not be exempt from the requirements of 510(k) and will need to submit a 510(k) and receive clearance for its device prior to marketing.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the guidance, **A Suggested Approach to Resolving Least Burdensome Issues**, <http://www.fda.gov/cdrh/modact/leastburdensome.html>

2. Scope

The scope of this document is limited to external penile rigidity devices, which are classified under 21 CFR 876.5020, product code [LKY](#):

§ [876.5020](#) -- External penile rigidity devices.

External penile rigidity devices are devices intended to create or maintain sufficient penile rigidity for sexual intercourse. External penile rigidity devices include vacuum pumps, constriction rings, and penile splints, which are mechanical, powered, or pneumatic devices.

Vacuum pumps

Vacuum pumps consist of a cylinder and a vacuum pump which is either hand-operated or motorized. The cylinder is placed over the flaccid penis and the

¹We recommend that manufacturers document how they address the recommendations of this guidance in their design history file. Manufacturers must maintain design controls, including a design history file, in accordance with [21 CFR 820.30](#).

Contains Nonbinding Recommendations

user applies an external vacuum to cause blood to enter the penis and produce an erection. Once a satisfactory erection is obtained and before removing the vacuum cylinder, the user often places a constriction ring around the base of the erect penis to maintain the erection during intercourse. The vacuum cylinder includes a quick-release mechanism to relieve vacuum suction and/or a separate automatic vacuum mechanism to limit vacuum strength as listed in the design features section of this guidance.

Constriction rings

Constriction rings are placed around the base of the erect penis for the duration of sexual intercourse to restrict venous blood flow leaving the penis. Constriction rings generally consist of loops of flexible, elastic material and a quick-release mechanism to release constriction and remove the ring. When an erection can be achieved but not maintained constriction rings can be used alone, or when creating an erection is not possible, they are used in conjunction with vacuum pumps.

Penile splints

Penile splints are flexible support structures intended to be attached to or placed along the penis to hold the penis erect during sexual intercourse. Penile splints include a quick-release mechanism to enable quick removal.

External penile rigidity devices do not include intended uses such as:

- mechanical penile extenders
- foreskin remodeling or restoration
- penile enhancement, such as penis enlargement
- treatment of diseases or conditions of the penis with respect to curvature and other penis deformities, e.g., Peyronie's Disease.
- prevention or reversal of erectile dysfunction/impotence
- retaining a condom on the penis.

Devices intended for the uses listed above raise new questions of safety and effectiveness and we believe they cannot be found substantially equivalent to the external penile rigidity devices that are described in this guidance document. The Urology and Lithotripsy Devices Branch is available to discuss any questions you may have concerning such devices.

3. Risks to Health

FDA has identified the following risks to health associated with the use of the external penile rigidity devices in the table below. FDA recommends the following measures to mitigate the identified risks in this guidance, as shown in the table below.

Contains Nonbinding Recommendations

Table 1. Identified Risks and Recommended Mitigation Measures

Identified risks	Recommended mitigation measures
Tissue injury, trauma, or infection (user and user's partner)	Design Features (Section 4) Labeling (Section 5)
Aggravation of existing medical conditions such as Peyronie's disease, priapism, and urethral strictures	Labeling (Section 5)

FDA believes that conformance with the recommendations in this guidance document, when combined with the general controls of the Act, will provide reasonable assurance of the safety and effectiveness of the external penile rigidity devices. We recommend that manufacturers evaluate their devices as described below and, where appropriate, document the results in their design history files as a part of the Quality Systems Requirements ([21 CFR 820.30](#)).

4. Design Features

We recommend that external penile rigidity devices have the design features described below. We believe these features will minimize the potential risk of injury to the user.

Design Features for Vacuum Pumps

Manual Safety Mechanism – A vacuum device should include a manually operated mechanism to quickly release the vacuum pressure. The design should not include design features for extended continuous use.

Vacuum Level – Vacuum pumps typically draw a vacuum of less than 17 inches of mercury. If the vacuum range of a new device differs substantially from that specification, manufacturers should conduct studies to establish the acceptability of the vacuum drawn by their device.² The manufacturer should perform tests to verify the maximum vacuum level. The device should include an automatic safety valve to limit vacuum pressure to safe levels.

Shape and Surface Design – Vacuum pumps should have smooth surfaces and shapes. Vacuum pumps should not include design features that promote extended application and use of the device beyond the limited time needed to draw a vacuum and to create an erection.

Electrical Safety – An electrically powered vacuum device should have adequate

² We recommend that manufacturers document how they have addressed the recommendations of this guidance in their design history files; see also [21 CFR 820.30](#).

Contains Nonbinding Recommendations

electrical isolation between the user and the power source of the device. The device leakage current should not exceed a safe limit according to the standard [IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety \(General\)](#).

Design Features for Constriction Rings

Manual Safety Release Mechanism – The device should have a simple and quick method to manually release the device. Quick release mechanisms for constrictive devices should include a sufficiently wide tab, handle, loop, or other means for the user to eliminate continued application of constrictive pressure and remove the device. The design should not include design features for extended continuous use.

Pliable Materials – The materials used in constriction rings should minimize the potential for injury to the user or partner by using soft and pliable materials. The materials used should not cause adverse tissue reaction with respect to cytotoxicity, sensitization, or irritation and should conform to [International Standard Organization Standard \(ISO\) Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"](#) for a limited duration, skin contacting device.

Shape and Surface Design – Constriction rings should include a smooth shape and surface design to minimize protrusions and pressure points to the user and partner. Constriction rings should avoid design features that promote use of the device beyond 30 minutes.

Design Features for Penile Splints

Manual Safety Mechanism – The device should have a simple and quick method to easily release and remove the device manually. The design should not include design features for extended continuous use.

Pliable Materials – Soft and pliable materials should be used in penile splints to help minimize the potential for injury to the user or partner. The materials used should not cause adverse tissue reaction with respect to cytotoxicity, sensitization, or irritation, and should conform to [International Standard Organization Standard \(ISO\) Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"](#) for a limited duration, skin contacting device.

Shape and Surface Design– Penile splints should include a smooth shape and surface design. Penile splints should be designed to not constrict the penis.

5. Labeling³

The following suggestions are aimed at assisting manufacturers in preparing labeling that satisfies the requirements of 21 CFR Part 801.

Instructions for Use

The instructions for use should contain comprehensive instructions with adequate illustrations regarding how to size, place, operate, remove, and clean the device.⁴ The instructions should also include a general descriptive overview of the entire system, including diagrams of the system and its major components and a description of each safety feature. The first page of the instructions for use should include a statement that the user should read the instructions before using the device.

The instructions for use should be written and formatted so as to be easily read and understood by the layperson (i.e., 8th grade reading level) with any medical or technical words either replaced with terms understood by the layperson or defined in a glossary. We recommend that the instructions for use include the following sections:

- a table of contents
- a brief description of the device and its intended use
- a list of all potential risks and hazards associated with using the device
- a list of warning statements and their consequences to emphasize the importance of following them
- comprehensive instructions
- a troubleshooting section (Attachment 1 provides an example of a suggested content and format)
- a glossary of any medical or technical terms used in the instructions.

Warnings

In addition to the information above, FDA recommends that labeling address the warnings as given in the examples below.

³ Labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce.

⁴ External penile rigidity devices are over-the-counter (OTC) devices; however, they are often used in consultation with a physician. Manufacturers may elect to restrict distribution of their devices through professional channels and healthcare providers may actually prescribe these devices to patients. External penile rigidity devices used in consultation with a physician rely on the medical experience and knowledge of the physician in performing an evaluation of the patient, determining whether an external penile rigidity device is appropriate for the patient, and thoroughly discussing any instructions unique to that patient's circumstances.

Contains Nonbinding Recommendations

Delayed Diagnosis of Other Conditions

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.

Use with Impaired Pain Perception

Do not use the device if you have decreased sensation of pain in the area of the penis. (This warning should inform the user that if he cannot feel pain, he may not know whether or not he is being injured by the device.)

Use with Decreased Hand Strength

Do not use the device if you have decreased hand strength because this may make removal of the device difficult.

The labeling should also describe alternative treatments such as counseling, drug therapy, hormonal therapy, vascular surgery, and implanted prosthetic devices. The labeling should advise the device user to contact his physician for more information regarding these alternative treatments.

Labeling for external penile rigidity devices should also include:

- indications for use
- identification of the population(s) for whom the device is appropriate
- warning advising the user and his partner to consult a physician if any complications occur and to discontinue use of the device if complications continue
- warning against using lubricants that may adversely affect the materials of the device along with examples of such lubricants
- other contraindications, warnings, and precautions relevant to your device (See the example in Attachment 1. Sample patient handout for vacuum devices and constriction rings, December 1991, Contemporary Urology reprint)
- disposable or single use status (if applicable).

Contains Nonbinding Recommendations

Additional Labeling for Vacuum Pumps

In addition to the information for all external penile rigidity devices, FDA recommends that labeling for vacuum pumps address the warnings and precautions given in the examples below.

Warnings

- stop using the vacuum pump if pain occurs
- do not use under the influence of alcohol or drugs, since such use may impair the user's judgment and increase the risk of injury to the penis.
- do not use if the user has sickle cell disease, has a history of prolonged erections, or is taking large quantities of aspirin or other blood thinners, as these conditions increase the risk of bruising and hematoma.
- misuse of the vacuum pump could injure the penis.

Precautions

- apply only the minimum amount of vacuum pressure necessary to achieve an erection; excessive vacuum pressure may bruise or injure the penis.
- use of a vacuum pump may bruise or rupture the blood vessels within the penis or scrotum, resulting in petechiae, hemorrhage, or the formation of a hematoma.
- use of a vacuum pump may aggravate already existing conditions such as Peyronie's disease (the formation of hardened tissue in the penis that causes pain, curvature, and distortion, usually during erection); priapism (persistent, usually painful erection of the penis as a consequence of disease and not related to sexual arousal); and urethral strictures (urethral stricture is an area of hardened tissue, which narrows the urethra sometimes making it difficult to urinate).
- if appropriate, the labeling should instruct patients not to use an electrically powered vacuum pump in or near water.

Additional Labeling for Constriction Rings

In addition to the information above for all external penile rigidity devices, FDA recommends that labeling for constriction rings address the warnings and precautions given in the examples below.

Contains Nonbinding Recommendations

Warnings

- do not fall asleep while wearing the constriction ring, since prolonged use of the constriction ring may cause permanent injury to the penis.
- allow at least 60 minutes between uses, as more frequent use may increase the risk of injury to the penis.
- do not use constriction rings under the influence of alcohol or drugs, since such use may impair the user's judgment and increase the risk of injury to the penis.
- misuse of a constriction ring may cause bruising, painful injury, or permanent damage to the penis.
- constriction rings do not prevent pregnancy.

Precautions

- use of a constriction ring may aggravate already existing medical conditions such as Peyronie's disease (the formation of hardened tissue in the penis that causes pain, curvature, and distortion, usually during erection); priapism (persistent, usually painful erection of the penis as a consequence of disease and not related to sexual arousal); and urethral strictures (urethral stricture is an area of hardened tissue, which narrows the urethra sometimes making it difficult to urinate).
- limit use of the constriction ring to no longer than 30 minutes per use (You should box or otherwise make this precaution more prominent than others.)
- prolonged use of the constriction ring (i.e., without removal) may cause permanent injury to the penis (You should box or otherwise make this precaution more prominent than others.)
- device use may bruise or rupture the blood vessels within the penis or scrotum, resulting in petechiae (a small purplish spot on a body surface, such as the skin or a mucous membrane, caused by a minute hemorrhage), hemorrhage (flow of blood from ruptured blood vessels), or the formation of a hematoma (localized swelling filled with blood resulting from a break in a blood vessel).
- use the least constrictive ring size that maintains an erection, since excessive constriction could injure the penis.

6. Limitations of Exemption from Premarket Notification

FDA's decision to exempt a Class II device from the requirement of 510(k) is based on the existing and reasonably foreseeable characteristics of devices within that generic type

Contains Nonbinding Recommendations

that currently are, or have been, in commercial distribution. Section [21 CFR 876.9](#) specifies the limitations to exemption. A device classified as exempt from 510(k) requirements is not exempt, if the device:

- is for an intended use that is different from the intended use of a legally marketed device in that generic type
- operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type.

ATTACHMENT 1 – Troubleshooting Guide

PATIENT HANDOUT

How you can manage common problems with a vacuum device

Problem	Likely cause	Remedy	Comments
No erection	No vacuum because of air leak caused by poor seal	Use more lubricant; apply firm pressure to body; trim pubic hair; check device for air leaks	Problem is most often associated with inexperience; it resolves as you become more adept at using the device
Partial erection	Incorrect cylinder size; incorrect insert or seal ring size; not enough practice sessions	More practice using device; use larger cylinder insert	Problem most often improves with continued use of device
Rapid loss of erection (in less than 5 minutes)	Vacuum lost because of air leak from faulty equipment, poor seal, inadequate lubrication, or excessive pubic hair	Same as for “No erection.” Also: use smaller cylinder insert; use smaller or double tension rings; remove tension band carefully	Requires that you experiment with varying sizes of seal rings, inserts, and tension bands; see your physician if you need help or support to persevere
Delayed loss of erection (after 5 to 10 minutes)	Insufficient tension from bands or rings	Use smaller or combination of tension rings or bands; use the two-step application method (ask your physician about this)	-
Pulling of the skin of the scrotum	Lubricant on scrotum; improper pumping technique; too large insert or seal ring; inexperience with system	Remove lubricant from scrotum; use smaller insert or seal ring; use the modified pumping technique (ask your physician about this); continue with practice sessions; angle cylinder downward during pumping	Problem may disappear as you become more adept at using the device.
Discomfort or pain:			
<ul style="list-style-type: none"> ● During pumping 	Too rapid pumping; pulling of scrotal tissue	Slower pumping; continue to use device	Problem usually resolves as you become more adept at using the device.
<ul style="list-style-type: none"> ● From tension ring 	Tension ring too small; Anxiety	Use larger tension ring; continue to use device	Problem usually resolves as you continue to use the device.
<ul style="list-style-type: none"> ● During intercourse 	Inadequate lubrication; pressure on a sensitive area	More lubrication; position changes	-
<ul style="list-style-type: none"> ● During ejaculation 	Long period of abstinence; infection or inflammation of the prostate gland	Continue to use device	Problem usually resolves as you become more adept at using the device.
Redness, irritation or bruising	Too rapid pumping; over pumping	Slower pumping; fewer pumps	Consult your physician if this problem persists past the first few practice sessions
Penis feels cold (to you or your partner)	Constriction of blood flow to the penis; lubrication	Wash off lubricant or warm lubricant before use	-
Penis pivots on its base	Constriction of blood flow to the penis	If manageable, apply the device after you have a partial erection	-

This instruction sheet may be photocopied without permission of the publisher and given to patients.

“A way to help your patients who use vacuum devices.” Lewis JH, Sidi AA, Reddy PK. Contemporary Urology 1991 Dec;3(12):15; 19-21; 24. Review. PubMed ID: 10148056.