

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

- 1. The authority citation for part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Amend § 884.5330 by revising the section heading and paragraph (a) to read as follows:

§ 884.5330 Multiple-use female condom.

(a) *Identification.* A multiple-use female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. At the conclusion of coitus, the device can be reused. It is indicated for contraception and prophylactic (preventing the transmission of sexually transmitted infections) purposes.

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- 3. Add § 884.5340 to subpart F to read as follows:

§ 884.5340 Single-use internal condom.

(a) *Identification.* A single-use internal condom is an over-the-counter sheath-like device that lines the vaginal or anal wall and is inserted into the vagina or anus prior to the initiation of coitus. At the conclusion of coitus, it is removed and discarded. It is indicated for contraception and/or prophylactic (preventing the transmission of sexually transmitted infections) purposes.

(b) *Classification.* Class II (special controls). The special controls for this device are:

- (1) Clinical performance testing must evaluate the following:

(i) Rate of clinical failure of the device and rate of individual failure modes of the device based on an acute failure modes study evaluating the intended use (vaginal and/or anal intercourse); and

(ii) Cumulative pregnancy rate when using the device based on a contraceptive effectiveness study (when the device is indicated for vaginal intercourse).

(2) Viral penetration testing must demonstrate the device is an effective barrier to sexually transmitted infections.

(3) Nonclinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Mechanical testing must demonstrate the device can withstand forces under anticipated use conditions, include evaluation of tensile, tear, and burst properties of the device; and

(ii) Compatibility testing with personal lubricants must determine whether the physical properties of the device are adversely affected by use of additional lubricants.

(4) The device must be demonstrated to be biocompatible.

(5) Shelf-life testing must demonstrate that the device maintains its performance characteristics and the packaging of the device must maintain integrity for the duration of the shelf-life.

(6) Labeling of the device must include:

(i) Contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;

(ii) Statement regarding the adverse events associated with the device, including potential transmission of infection, adverse tissue reaction, and ulceration or other physical trauma;

(iii) Expiration date; and

(iv) Statement regarding compatibility with additional types of personal lubricants.

Dated: September 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[Docket No. USCG–2018–0836]

Drawbridge Operation Regulation; Newark Bay, Newark, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Lehigh Valley Bridge across the Newark Bay, mile 4.3, at Newark, New Jersey. The deviation is necessary to replace bridge timber on the lift span. This deviation allows the bridge to remain in the closed-to navigation position during the construction periods.

DATES: This deviation is effective from 6 a.m. on October 14, 2018, to 6 p.m. on November 12, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0836 is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open

Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Judy Leung-Yee, Bridge Management Specialist, First District Bridge Branch, U.S. Coast Guard, telephone 212–514–4336, email Judy.K.Leung-Yee@uscg.mil.

SUPPLEMENTARY INFORMATION: The owner of the bridge, Consolidated Rail Corporation, requested a temporary deviation from the normal operating schedule to replace bridge timber on the lift span. The Lehigh Valley Bridge across the Newark Bay, mile 4.3, at Newark, New Jersey is a lift bridge with a vertical clearance in the closed position of 35 feet at mean high water and 39 feet at mean low water. The existing bridge operating regulations are listed at §§ 117.5 and 117.735.

Under this temporary deviation, the Lehigh Valley Bridge shall remain in the closed position from 6 a.m. on October 14, 2018 to 6 p.m. on October 15, 2018; from 6 a.m. on October 21 to 6 p.m. on October 22, 2018; and from 6 a.m. on October 28, 2018 to 6 p.m. on October 29, 2018. Should inclement weather occur, the following rain dates may be used: (a) From 6 a.m. on November 4, 2018 to 6 p.m. on November 5, 2018; or (b) from 6 a.m. on November 11, 2018 to 6 p.m. on November 12, 2018.

The waterway is transited by recreational and commercial vessels. Coordination with known waterway users has indicated no objection to the closure. Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 21, 2018.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

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