Potential for Injury from Circumcision Clamps

(You are encouraged to copy and distribute this information)

Dear Colleague:

This letter is to alert you to the potential for injury from two commonly used circumcision clamps, the Gomco®/gomco-type and Mogen®/mogen-type clamps. Both are widely used during circumcision to remove the foreskin while protecting the glans penis.

Although research suggests that circumcision is generally a safe procedure, we are concerned that some serious device-related complications have occurred. We received 105 reports of injuries involving circumcision clamps between July 1996 and January 2000[1]. These have included laceration, hemorrhage, penile amputation, and urethral damage.

We are providing recommendations below that can help avoid these complications.

Nature of the Problem

Gomco® and Gomco-type Clamps

The use of Gomco® and gomco-type clamps that have been reassembled by users with parts from different manufacturers, or that have bent parts or mismatched components, has led to clamps breaking, slipping, falling off during use, tearing penile tissue or failing to make a tight seal. Please note that although Gomco® and gomco-type clamps may appear to have interchangeable parts, these parts may not always be safely interchanged because they may vary slightly in dimensions.

Mogen® and Mogen-type Clamps

The use of Mogen® and mogen-type clamps that have jaw gap dimensions greater than those in the manufacturer's specifications, or use of clamps inappropriately sized for patients, has led to patient injuries. In such cases, the clamp may allow too much tissue to be drawn through the opening of the device, thus facilitating the removal of an excessive amount of foreskin and in some cases, a portion of the glans penis.

Recommendations

General:

Before performing a circumcision procedure, examine the clamp to determine that all parts are available, undamaged, and within the manufacturer's specification.

Gomco® and Gomco-type clamps:

- If you cannot be certain that a clamp component is part of the original clamp or if the clamp has stripped threads, a warped or bent base plate, a bent arm, twisted forks, or a scored or nicked bell, either contact the device manufacturer to obtain replacement parts[2] or *discard the clamp*.

- When requesting a replacement part, obtain the assurance of the manufacturer or supplier that the part ordered is compatible with the other components of your device. Do not substitute parts from different clamp manufacturers.

- Make sure that you reassemble a clamp from *only its own parts.* Do not mix up parts from different clamps, even from the same manufacturer, unless the manufacturer has assured you that the parts are interchangeable.

- If you choose to mark clamp parts to assure that you correctly reassemble them, ask the manufacturer about the best way to do this, because some marking methods may weaken the device or compromise your ability to sterilize it.

Mogen® and Mogen-type clamps:

- Ensure that the clamp being used is appropriate for the patient size. Some manufacturers have two sizes of clamps, one for adults and the other for infants.

- Periodically measure the gap between the device's clamping jaws to ensure that it is within the manufacturer's specification.[3] Using a device with an inappropriate jaw gap could allow the tip of the penis to be drawn through the clamp with the foreskin and inadvertently severed or injured.

Reporting Adverse Events to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. This means that if the use of a Gomco/gomco-type clamp or a Mogen/mogen-type clamp result in a death or serious injury, you must report that event. We request that you follow the procedures established by your facility for such mandatory reporting.

If a circumcision clamp malfunctions, you can report this directly to the manufacturer. Alternatively, you can report directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch four ways: online to http://www.accessdata.fda.gov/scripts/medwatch/ by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178, or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting More information

If you have questions regarding this letter, please contact the Issues Management Staff, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a voice mail message may be left at 301-594-0650, and your call will be returned as soon as possible.

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html . Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. Subscribe at http://list.nih.gov/cgi-bin/wa?SUBED1=dev-alert&A=1
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Sincerely yours,

David W. Feigal, Jr., MD, MPH
Director
Center for Devices and Radiological Health
Food and Drug Administration

References and Additional Information:

1. FDA MedWatch Reports, July 1992 through January 2000.

2. IPM Procedure: Circumcision Clamps, Health Devices 2000 January; 29(1):22-3.

3. Hazard: Routine inspection needed for scissors-type circumcision clamps, Health Devices 1999 Mar; 28(3):115-6.

4. Hazard: Incompatibility of different brands of Gomco-Type circumcision clamps. Health Devices 1997 Feb; 26(2):76-7.

5. Hazard: Amputations with use of adult-size scissors-type circumcision clamps on infants. Health Devices 1995 Jul; 4(7):286-7.

6. Hazard: Damaged Allied Healthcare Products Gomco circumcision clamp. Health Devices 1993 Mar; 22(3):154-5.