



AUG 28 2000

## 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<sup>1</sup>. 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<sup>2</sup> 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.