

## Avoiding Patient Injuries from Circumcision Clamps

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In 2000, we issued a warning about the potential for serious injury to patients from circumcision clamps. We were receiving about 20 injury reports per year, including laceration, hemorrhage, urethral damage and penile amputation. We're glad to tell you that the number of reports has gone down since we issued the warning, but they continue to come in, and the injuries, rare as they are, continue to be serious. And so we want to remind you about the steps you can take to avoid these injuries.

The 2000 warning explained what can go wrong with two widely used types of circumcision clamps, the Gomco-type and the Mogen-type. With the Gomco type clamps, the problem generally stems from mismatched parts---that is, from re-assembling the clamp with parts from different manufacturers, or using parts from the same manufacturer that aren't meant to go together, or using parts that have become bent. What makes things difficult here is that the parts may appear to be interchangeable, but often they're not. And so here's what the FDA warning said about how to avoid injuries with Gomco-type clamps:

- \* First, make sure that you reassemble a clamp only from its own parts. Don't mix up parts from different manufacturers, or even from the same manufacturer, unless the manufacturer has assured you that the parts are interchangeable.
- \* Second, if you can't be sure that a clamp component is part of the original clamp, or if any component is damaged, either contact the manufacturer to obtain replacement parts, or discard the entire clamp.
- \* Third, when you request a replacement part, get the manufacturer's assurance that the part you ordered is compatible with the other components of your clamp.
- \* Finally, if you choose to mark the clamp parts to assure that you correctly reassemble them, ask the manufacturer about the best way to do this. Some marking methods may weaken the device or interfere with your ability to sterilize it.

With Mogen-type clamps, problems arise when the jaws of the clamp are too large for the patient. This can allow too much tissue to be drawn through the opening in the clamp, so that an excessive amount of foreskin, or even a portion of the glans penis, is removed. That can happen either because the clamp is not within the manufacturer's specifications, or because the wrong size clamp is selected for the patient. Note that some manufacturers have two sizes of mogen-type clamps, one for infants and the other for adults.

There are two ways to prevent problems with this kind of clamp. First, be sure that the clamp is the correct size for the patient. And second, periodically measure the gap between the clamping jaws to be sure it's within the manufacturer's specifications.

### **Additional Information:**

Potential for Injury from Circumcision Clamps. August 29, 2000.  
<http://www.fda.gov/cdrh/safety/circumcision.html>

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