PA PSRS
Pennsylvania Patient Safety Reporting System

Patient Safety Advisory

Produced by ECRI & ISMP under contract to the Pennsylvania Patient Safety Authority

Mismatching Medical Devices and Accessories

Pennsylvania facilities have submitted reports to PA-PSRS describing injuries to patients from the use of incompatible device parts. For example, one report involved a patient that received deep cuts from a dermatome device in the thigh during harvesting of a skin graft. The facility determined that a cutting blade from a manufacturer other than the dermatome manufacturer was used with the dermatome device to obtain the graft. Another report involved excessive bleeding during circumcision. During the procedure, a Gomco®-type circumcision clamp broke apart. The facility concluded that mismatched parts of different clamps were assembled during the sterilization process.

These reports demonstrate the need for clinical staff to be aware of the compatibility of medical devices and their associated accessories and devices that require assembly prior to use.

The example involving the dermatome is not new. In 1994, ECRI published a Hazard Report and a Hazard Alerts Action Item about a similar incident involving deep lacerations to a patient due to a dermatome blade manufactured by Padgett that was inserted into a Zimmer dermatome device.[1] Though the Padgett blade appeared to fit well into the Zimmer dermatome, there were no identifying marks on the blade as to the manufacturer or the correct blade orientation. The specific shape of the Zimmer blade was such that it could only be installed into the Zimmer dermatome in the correct orientation, unlike the Padgett blade used in this case. The Hazard Report further stated that, in their user manuals, both manufacturers (Zimmer and Padgett) warn against using incompatible manufacturers' blades.

In the circumcision clamp example above, the specific mismatch of parts was not stated in the report submitted to PA-PSRS. However, an example of a mismatch of clamp parts would be the bell or base plate arm from one manufacturer assembled to the base plate of another manufacturer (see Figure 1). Another scenario of an injury occurring during circumcision is using a damaged or worn clamp, which can result in inadequate clamping force.[2,3]

Gomco-type circumcision clamps are used to crush the foreskin distal to the glans penis. The foreskin is then removed without damaging the glans. The bell of the clamp assembly is placed over the glans beneath the foreskin. The bell is positioned through a hole in the base plate. The arm of the plate is used to pull the bell through the hole by adjusting the nut (see Figure 2). A properly assembled, properly applied clamp results in an evenly distributed force around the foreskin between the bell and plate, allowing the foreskin to be removed with a scalpel. If the bell and plate of the clamp are not uniformly positioned around the hole surrounding the foreskin, bleeding from the cut foreskin may occur.

Mismatching parts of devices or devices and associated accessories can have a significant impact on patient safety. Examples of mismatching parts and/or accessories include:[4]

- Mixing devices and parts or accessories from different manufacturers or incompatible parts and accessories from the same manufacturer.
- Attaching an accessory to the wrong connector of a device.
- Cleaning and/or processing different disassembled devices together.
- Using parts or accessories from sources other than the original device manufacturer that may not be completely compatible or that have been modified.

To minimize the likelihood of injuries due to mismatches, some hospitals provide education to users in proper disassembly and reassembly of device parts and accessories and in identifying which accessories are for use with specific medical devices. Other examples of ways to mitigate mismatches are to place unassembled parts of each device in separate instru-

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Mismatching Medical Devices and Accessories (Continued)

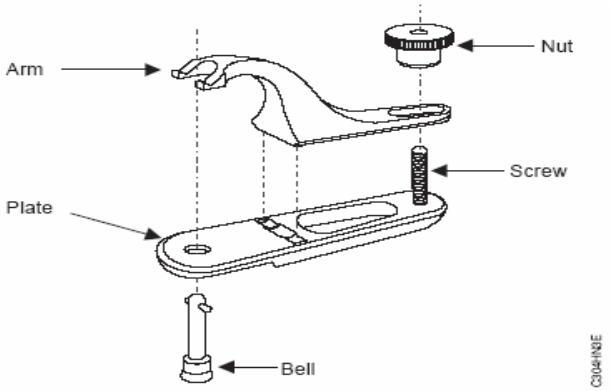

Figure 1. Exploded View of Gomco-type Circumcision Clamp. Source: ECRI. Reprinted with permission.

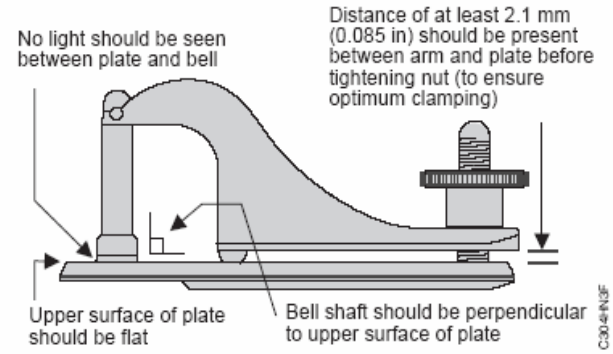

Figure 2. Correctly Assembled Gomco-type Circumcision Clamp. Source: ECRI. Reprinted with permission.

ment sterilization trays or bags, to use pictures of correctly assembled devices to guide device reassembly, and to verify the proper operation of a device after assembly or before use.

Notes

1. ECRI. Use of Incompatible Dermatomes and Blades [Hazard Report]. Health Devices 1994 Apr;23(4):145.

2. ECRI. Incompatibility of Different Brands of Gomco-Type Circumcision Clamps [Hazard Report]. Health Devices 1997 Feb;26 (2):76-77.

3. Food and Drug Administration. Potential for injury from circumcision clamps [online]. 29 Aug 2000. [Cited 21 Feb 2005.] Available from the Internet: http://www.fda.gov/cdrh/safety/circumcision.html.

4. ECRI. Hazards of Mismatched Parts and Accessories [Guidance Article]. Health Devices 1996 Jan;25(1):31.

An Independent Agency of the Commonwealth of Pennsylvania

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority's website at www.psa.state.pa.us.

ECRI is an independent, nonprofit health services research agency dedicated to improving the safety, efficacy and cost-effectiveness of healthcare. ECRI's focus is healthcare technology, healthcare risk and quality management and healthcare environmental management. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, and other organizations worldwide.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a non-punitive approach and systems-based solutions.