Medical Device Safety Tip: Resectoscopes for Infants and Babies

U.S. Food & Drug Administration

* *Medical Device Safety Tips highlight what can go wrong if labeling is overlooked or not followed, and provide advice on how to mitigate risks. Commonly known as Instruction for Use manuals or package inserts, labeling includes any written material from the manufacturer accompanying medical devices. FDA's goal is to promote awareness of labeling to enhance device safety and prevent patient harm.*

What is the problem?

During cystoscopy and incision of a ureterocele in a 2-month old, the insulation slipped off the sheath and slid over the tip of the catheter exposing the hook electrode. Fortunately, the 2-month old was not injured. It was discovered that improper sequence of assembling the resectoscope was associated with this situation.

How are these devices used?

Resectoscopes are used to remove tissue during endoscopy procedures. The resectoscope in this situation is made by Richard Wolf Medical Instruments Corporation.

What can I do to prevent patient injuries?

- It is important to follow the proper sequence of steps outlined in the manufacturer's user manuals when assembling resectoscopes for endoscopy procedures. For example, the chronological order for assembly of the device used in this situation is:

    1. Prior to use and after each use, inspect all products and accessories for damage, loose or missing parts and rough surfaces; the insulation should be checked with particular care,
    2. Insert obturator into resectoscope sheath,
    3. Insert endoscope into working element,
    4. Insert electrode into working element with endoscope in place,
    5. Once resectoscope sheath with obturator in place is passed into the patient's bladder, leave sheath in place and remove obturator, and
    6. Gently pass endoscope, electrode and working element into sheath, insure all are in a parallel plane.

- Always check the user manual for specific instructions prior to assembly of

any device.
- Contact the manufacturer if further assistance is needed with device assembly.

How can I report problems to FDA?

If you suspect a problem with a medical device, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program [1]. Healthcare personnel employed by facilities that are subject to FDA's user facility reporting requirements [2] should follow the reporting procedures established by their facilities

SOURCE [3]

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[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
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