

Patient Safety Advisory

Veterans Health Administration Warning System Published by VA Central Office

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Item: Reprocessing of resectoscope system's working elements (used in urology)

NOTE: The Specific Incident and Background sections below reference a specific manufacturer's resectoscope system's working element (part of a certain type of rigid cystoscope); however, this Patient Safety Advisory APPLIES TO ALL RESECTOSCOPE SYSTEM'S WORKING ELEMENTS USED IN UROLOGY, regardless of manufacturer or model.

Specific Incident: During their SPD Healthcare Failure Mode and Effects Analysis (HFMEA™) on rigid cystoscopes, a VA Medical Center identified they were improperly reprocessing Karl Storz model 27050E resectoscope working elements. The device manufacturer's instructions indicate the working element cannot be sterilized in a STERRAD® sterilization system, which was currently being used for sterilization.

Background: A contributing factor to the improper sterilization of the resectoscope system's working element is the manufacturer's reprocessing instructions that may be open to misinterpretation. The manufacturer's instructions indicate sterilization using a STERRAD® sterilization system can be used for sterilization of Karl Storz's resectoscope working elements; however, an asterisk (*) – which could be easily overlooked – indicates that STERRAD® sterilization system cannot be used for the 27050 series of Karl Storz resectoscope working elements.

Reliance on instructions provided with reprocessor's (sterilization) equipment – to determine if a device can be reprocessed using their reprocessing equipment – could also contribute to improper reprocessing. For example, the resectoscope working element discussed in this Patient Safety Advisory has multiple lumens and holes having different inside diameters that are constructed from different materials (e.g., stainless steel, Teflon). Without a thorough knowledge of all of the lumens and holes that exist (some of which are not obvious and easily overlooked – see Attachment 2), a facility could easily come to the incorrect conclusion (based on reprocessing information from STERRAD®) that sterilization using a STERRAD® sterilization system would be acceptable for the Karl Storz resectoscope working element 27050E.

General Information: Resectoscope working elements are part of resectoscope systems and are used in Urology in the transurethral resection of tissue; including the ablation or cutting of prostate tissue (as in transurethral resection of the prostate [TURP]) and superficial bladder tumors, and to cauterize minor bleeding in the prostate and bladder. An example of a resectoscope system's working element is shown in Attachment 1.

- Recommendations:**
1. Review and follow the specific resectoscope manufacturer's instructions for reprocessing your resectoscope system and its working elements.
 2. If the resectoscope manufacturer's instructions indicate that a particular type of reprocessing (e.g., a particular kind of sterilization) is not to be used, do not use that type of reprocessing, regardless of what the sterilization equipment's instructions may seem to indicate.
 3. If utilizing reprocessing guidance from sterilization equipment manufacturers or their documentation, pay particular attention to the internal diameters, lengths, and materials of ALL the lumens and holes of the resectoscope system's working element. If any of the lumens or holes cannot be reprocessed in a particular manner (and the device cannot be taken apart), then the entire device cannot be reprocessed in that manner.
 4. If there is any ambiguity at all with the manufacturer's instructions for the resectoscope, contact the device manufacturer to get clarification, in writing.

Source: A VA Medical Center

Contact: For additional information or questions, please contact:
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Attachment 1

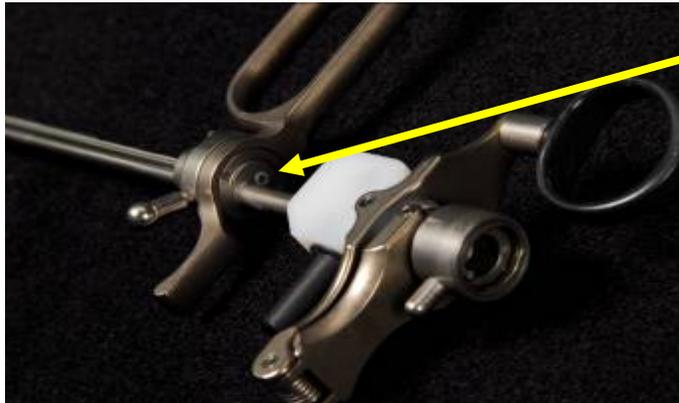
Photograph of an example incident resectoscope system's working element.



Photograph courtesy of St. Joseph Mercy Hospital, Ann Arbor, MI

Attachment 2

Examples of a less obvious cannula and hole on a resectoscope system's working element.



A cannula within the resectoscope system's working element that could be easily overlooked when cleaning and determining proper reprocessing for the device.



A hole within a Teflon block that is part of the resectoscope system's working element. While not obvious to the user, this hole comes into play when determining the reprocessing for this device.

Photographs courtesy of St. Joseph Mercy Hospital, Ann Arbor, MI