April 6, 2022

Dear Customer,

On April 1, 2022, KARL STORZ initiated a voluntary recall and issued an urgent field safety notice to instruct users to sterilize affected urological endoscopes after each use. Per the notice, users are to discontinue use of high-level disinfection for all affected urological endoscopes.

We would like to clarify two important points:

1) This is not a CIDEX® OPA Solution or EVOTECH® Endoscope Cleaner and Reprocessor (ECR) related recall; it is specific to KARL STORZ devices.
2) ASP has determined devices qualified for reprocessing in both the EVOTECH® ECR and a STERRAD® System can continue to be reprocessed in the EVOTECH to ensure proper cleaning as long as the device is then sterilized in a STERRAD® System every time before being used on a patient[1]

Proper precleaning, leak testing, and cleaning are critical to ensure proper endoscope reprocessing.

EVOTECH® ECR was the first system cleared by the United States Food and Drug Administration (FDA) that automatically cleans flexible endoscopes when selecting a cycle that includes a wash stage.

Flexible endoscope models have been qualified for use with the EVOTECH® ECR undergo a stringent qualification process. Endoscope models are tested to ensure they can be effectively processed in the EVOTECH® ECR to Clean and High Level Disinfect. The EVOTECH® ECR is equipped with an endoscope database that includes specific connectors and diagrams. Only qualified endoscopes are included in the EVOTECH® ECR software database. If your endoscope model is listed in the database, when used in conjunction with the instructions for use and connection diagrams, you can be assured the EVOTECH® ECR will effectively reprocess the endoscopes.

You can find additional resources on our Endoscope Reprocessing Resource Hub.

Respectfully,

Advanced Sterilization Products

DocuSigned by:
Chanda Owens
Signer Name: Chanda Owens
Signing Reason: I approve this document
Signing Time: 19-Apr-2022 | 8:10 AM PDT
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[1] 22 of the 30 devices are currently qualified in EVOTECH and all 30 are validated for sterilization in both the STERRAD NX® and STERRAD® 100NX (STERRAD® Systems)

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APPENDIX 1

List of Affected Devices are qualified for reprocessing in both the EVOTECH® ECR and a STERRAD® System (As of April 6, 2022)

Part Number	Product Description
1. 11278V	CMOS Video Ureteroscope
2. 11278AC1	Flexible Ureteroscope
3. 11272VN	Flexible Video Urethro Cystoscope
4. 11272VNU	Flexible Video Urethro Cystoscope
5. 11272V	Flexible CMOS Video Cysto Urethroscope
6. 11272VU	Flexible CMOS Video Cysto Urethroscope
7. 11272VA	K Flexible CMOS Video Cysto Urethroscope
8. 11272C1	Flexible Cysto-Urethroscope Fiberscope
9. 11272CU1	Flexible Cystoscope
10. 11274BCU1	Flexible Cystoscope
11. 11278ACU1	Flexible Ureteroscope
12. 11278AU1	Flexible Ureteroscope
13. 11278A2	Flexible Ureteroscope
14. 11005BC1	Flexible Bronchoscope
15. 11278VSE	Flexible Video-Uretero-Renoscope (FLEX-XC)
16. 11278VSU	Flexible Video-Uretero-Renoscope (FLEX-XC)
17. 11278VU	Flexible Video-Uretero-Renoscope (FLEX-XC)
18. 11278VA	Flexible Video-Uretero-Renoscope (FLEX-XC)
19. 11278VSA	Flexible Video-Uretero-Renoscope (FLEX-XC)
20. 11278VSUA	Flexible Video-Uretero-Renoscope (FLEX-XC)
21. 11278VSUE	Flexible Video-Uretero-Renoscope (FLEX-XC)
22. 11278VUA	Flexible Video-Uretero-Renoscope (FLEX-XC)

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