Rev 1: April 2022

FSN Ref: 21-004

Date: April 29, 2022

Urgent Medical Device Recall Notice
CERTAIN FLEXIBLE VIDEO CYSTO-URETHROSCOPES (C-VIEW®)

For Attention of: Representatives for medical product safety, users, operators, importers, distributors

Commercial name(s):	Flexible Video Cysto-Urethroscope (C-View)
Device Model/Catalogue/Part Numbers :	11272VUE, 11272VUEK, 11272VUE-R, 11272VUEK-R
Affected serial numbers:	See appendix
FSN Type:	New FSN, Ref.: 21-004

I. Identification of Affected Devices

The endoscopes subject to this Recall Notice are certain serial numbers of the Flexible Video Cysto-Urethroscope (C-View) (hereinafter “C-View Endoscopes”). These devices are used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of the urinary tract including the urethra, bladder, ureters, and kidneys.

II. Reason for the Medical Device Recall Notice

a. Description of the product problem

The product may exhibit temporary loss of image when monopolar electrocautery is activated. Customers who are in possession of the identified scopes should discontinue use of the affected scopes and return them to KARL STORZ for replacement as described below.

b. Background of the issue

KARL STORZ has received complaints about the temporary loss of image when monopolar electrocautery is activated while using the affected scopes. KARL STORZ has adopted manufacturing changes to address the issue in newly manufactured, as well as repaired, devices.

c. Hazard giving rise to the notice

The temporary loss of image when monopolar electrocautery is activated while using the affected scopes creates a risk of patient injury because the loss of image prevents the surgeon from observing the impact of the thermal energy delivered by the electrocautery electrode in real time. The ability to quickly adjust the pressure or timing of electrocautery activation is lost without the image. You should immediately discontinue the use of the affected scopes and follow the instructions of this Recall Notice.

d. Risks to patient/user or third parties

The use of monopolar electrocautery with the affected C-View Endoscopes has the potential to create a situation in which the clinician loses the endoscopic image while the electrocautery energy is being applied to tissue. In the absence of visualization, the clinician may not be able to avoid or prevent an injury to the urinary tract (e.g., a perforation of the bladder or cauterization injury to the

ureteral orifice) or an adjacent organ (e.g., an obturator nerve injury, colon perforation, or vascular injury) or may not be able to identify an injury that occurred during the image loss.

III. Type of action to mitigate the risk

Customers who are in possession of the affected C-View Endoscopes should immediately discontinue the use of the endoscopes and return them to KARL STORZ, as described below.

a. Impact of prior recall related to reprocessing methods

Customers should recognize that the affected C-View Endoscopes are also the subject of a separate Urgent Medical Device Recall Notice initiated by KARL STORZ in April 2022 in connection with a labeling update to correct the instructions for use related to reprocessing methods (the "Reprocessing Methods Recall"). Customers have been notified of that recall separately. Additional information for the Reprocessing Methods Recall may be found at the following link: https://www.karlstorz.com/us/en/voluntarily-recalls.htm.

Please review the Recall Notice and complete the Acknowledgment Form for the Reprocessing Methods Recall before completing the enclosed Acknowledgment Form for the recall described in this notice. Please also refer to steps #5, 6, and 7 below.

b. Action to be taken by the user

1. Confirm that your C-View Endoscope is subject to this recall by comparing the serial number of your device(s) to the serial numbers list in the Appendix below.
2. If you have an affected C-View Endoscope, immediately **discontinue the use of the affected scope** and follow the instructions below to return your device to KARL STORZ for replacement.
3. Ensure that all relevant personnel in your organization review this Recall Notice.
4. If you have sold or donated any affected scope(s) to third parties, please promptly forward this Recall Notice to all such third parties.
5. If you have not already done so, please complete the Acknowledgement Form for the Reprocessing Methods Recall and return it to KARL STORZ.
6. Please legibly complete the enclosed Acknowledgment Form for this recall and return it as soon as possible via the contact information specified on the form. *KARL STORZ will provide you with instructions for returning your endoscopes upon receipt of your completed Acknowledgment Form*.
   If you have already returned any affected scope(s) as part of the Reprocessing Methods Recall, you must still complete the enclosed Acknowledgment Form for this recall and return it as soon as possible via the contact information specified on the form.
7. If your Acknowledgment Form for the Reprocessing Methods Recall indicated that you have access to an appropriate sterilization method to sterilize the affected flexible endoscopes, then you will be eligible to have your C-View Endoscope(s) replaced by KARL STORZ. If you have not returned your Acknowledgment Form for the Reprocessing Methods Recall or if your Acknowledgement Form indicated that you do not have access to an appropriate sterilization method, then KARL STORZ will not be able to replace your C-View Endoscope(s) at this time.

c. Action being taken by the manufacturer

KARL STORZ has identified the affected scopes subject to this Recall Notice in the Appendix below.

Please notify KARL STORZ of any adverse events or quality problems associated with your use of the affected endoscopes. Adverse events or quality problems may also be reported to FDA's MedWatch Adverse Event Reporting program.

If you have any questions regarding this action, please use the contact information provided below for our recall execution partner, Sedgwick:

Telephone: 877-877-0317
Fax: 877-597-9587
E-Mail: karlstorz2935@sedgwick.com

On behalf of KARL STORZ, we thank you for your help and apologize for any inconvenience.

Sincerely,

KARL STORZ Endoscopy-America, Inc.

ACKNOWLEDGMENT FORM

Urgent Medical Device Recall Notice – 21-004

Please complete this form and return it to us by faxing it to 877-597-9587 or emailing it to karlstorz2935@sedgwick.com. Please check all applicable boxes.

☐ I confirm that I have read and understood the Urgent Medical Device Recall Notice and completed all actions requested.

Check one of the two boxes below.

☐ My facility has returned the Reprocessing Methods Recall Acknowledgment Form and has already returned, or is in the process of returning, the affected C-View Endoscope(s) as part of the Reprocessing Methods Recall.

☐ My facility has returned the Reprocessing Methods Recall Acknowledgment Form and retained possession of the affected C-View Endoscope(s) under the terms of that recall. In response to this Urgent Medical Device Recall Notice, my facility will discontinue use of the affected C-View Endoscope(s) and return them.

Number of C-View Endoscopes to be returned: _____

Serial numbers to be returned: _____

_____

Upon receipt of your completed Acknowledgment Form, KARL STORZ will provide you with instructions for returning your endoscopes.

Check one of the two boxes below.

☐ My organization has previously sold or donated one or more of the affected C-View Endoscopes to a third party, and I have forwarded the Urgent Medical Device Recall Notice to all such third parties.

☐ My organization has not sold or donated any of the affected C-View Endoscopes to a third party.

Contact Information:

Facility Name	
Address	
Contact Person & Title	
Signature	
Date	
Phone	
Email	

APPENDIX
Affected C-View Endoscope Serial Numbers

Affected Serial Numbers for Part Numbers 11272VUE and 11272VUEK							
25407	32321	38539	53439	58011	58143	58546	59051
25408	32389	40370	53574	58020	58144	58557	59063
25410	32391	40371	53575	58021	58145	58558	59093
25766	32417	40707	53589	58022	58156	58567	59094
28096	32994	40708	53593	58045	58157	58569	59095
28257	33787	41249	53627	58046	58183	58570	59096
28919	33802	44912	53628	58047	58184	58663	59098
29286	33804	45546	53632	58048	58185	58665	59122
29342	33905	46190	53634	58058	58423	58695	59125
30054	33907	46198	53637	58060	58445	58722	59152
30881	34465	47625	53737	58062	58446	58723	59153
31033	34724	47669	53776	58073	58449	58730	59179
31036	34725	48191	53833	58074	58451	58731	59201
31038	35188	48462	53834	58075	58476	59005	59202
31300	36020	48540	54289	58078	58498	59006	59203
31302	36371	48553	57603	58087	58503	59007	59223
31374	36470	49090	57606	58088	58506	59032	59342
31413	36583	49165	57607	58089	58508	59033	59343
31533	36820	52783	57609	58090	58516	59034	59344
31622	37462	53204	57610	58125	58517	59038	59345
31964	38536	53429	57986	58142	58545	59048	59398

Affected Serial Numbers for Part Numbers 11272VUE and 11272VUEK							
59399	59630	59815	59939	60080	60352	60860	61226
59400	59631	59819	59940	60151	60385	60885	61228
59401	59632	59820	59968	60153	60386	60948	61230
59402	59633	59821	59969	60154	60416	60949	61236
59416	59635	59822	59970	60159	60417	61109	61238
59418	59637	59839	59971	60160	60418	61110	61242
59420	59639	59840	60001	60161	60430	61111	61243
59495	59640	59842	60002	60162	60520	61114	61246
59497	59660	59848	60003	60193	60522	61115	61253
59581	59662	59851	60004	60201	60525	61116	61257
59582	59663	59853	60005	60202	60526	61136	61258
59584	59664	59856	60007	60203	60527	61137	61259
59587	59665	59888	60008	60205	60752	61139	61270
59589	59666	59890	60025	60297	60775	61140	61300
59592	59667	59891	60027	60299	60776	61155	62618
59593	59668	59892	60064	60300	60778	61156	
59594	59692	59896	60066	60301	60780	61190	
59600	59694	59897	60067	60312	60820	61191	
59602	59695	59921	60068	60314	60838	61192	
59603	59699	59935	60076	60315	60839	61193	
59604	59813	59936	60077	60331	60841	61194	
59628	59814	59938	60079	60350	60859	61224	

Affected Serial Numbers for Part Numbers 11272VUE-R and 11272VUEK-R							
25894	37977	48678	58399	59872	60163	60316	60930
25898	38237	49374	58424	59873	60164	60325	61141
27983	38542	49376	58467	59874	60208	60388	61142
30293	40571	51596	58468	59875	60209	60420	61232
31667	40572	55498	58512	59876	60298	60429	61234
31730	40706	57611	58645	60022	60302	60512	61268
32409	44105	58122	58711	60023	60303	60724	61269
34423	46522	58398	59554	60024	60304	60836	62359