Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.....73..... dated 20/4/2022 Regarding NCMDR FSCA of Flexible Endoscopes from (mrf: KARL STORZ SE & Co. KG).

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
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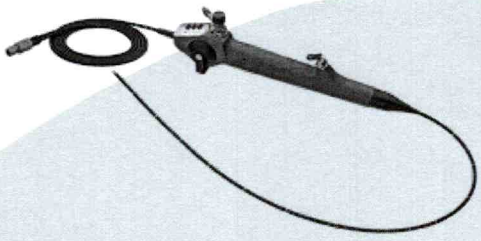
Circular No. 73 / 2022

18 -09-1443 H

20 -04-2022

Field Safety Corrective Action of Flexible Endoscopes from KARL STORZ SE & Co. KG

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16109
Product	Flexible Endoscopes.
Description	Endoscopes
Manufacturer	KARL STORZ SE & Co. KG.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	Refer to "APPENDIX" in the attached FSN.
Reason	The correction is limited to a labeling update to correct the Instructions for Use for certain flexible endoscopes and advise that CIDEX OPA should not be used for manual high-level disinfection.
Action	1. Refer to "Action to be taken by the user" in the attached FSN. 2. The updated Instructions for Use, no longer contain CIDEX OPA as a recommended manual high-level disinfection method. 3. Contact the local agent for remedial action.
Product Picture	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

KARL STORZ SE & Co. KG • PO Box 230 • 78503 Tuttlingen/Germany

Rev 1: March 2022

FSN Ref: 22-0002

Date: 31.03.2022

Urgent Field Safety Notice
Labeling Update
Certain KARL STORZ Flexible Endoscopes

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

Commercial name(s):	See Appendix
Device Model/Catalogue/part numbers :	See Appendix
Affected serial numbers:	All serial numbers of devices listed
FSN Type:	New FSN, Ref.: 22-0002

I. Identification of Affected Devices

The flexible endoscopes subject to the labeling correction are single channel endoscopes with a T-Luer that are intended for different indications for diagnostic and therapeutic use and that contain CIDEX OPA as a recommended method of manual high-level disinfection in their instructions for use.

II. Reason for the Field Safety Corrective Action (FSCA)

a. Description of the product problem

The correction is limited to a labeling update to correct the Instructions for Use for certain flexible endoscopes and advise that CIDEX OPA should not be used for manual high-level disinfection.

b. Background of the issue

Supplemental validation testing of the efficacy of the manual high-level disinfection process using CIDEX OPA as a single step was performed. Testing showed that the required efficacy level of disinfection using CIDEX OPA without any additional process step was not achieved. Because the testing did not validate the process step of disinfection using CIDEX OPA, CIDEX OPA is being removed as a method of manual high-level disinfection from the Instructions for Use of the affected products.

c. Hazard giving rise to the FSCA

As the efficacy of the manual high-level disinfection process using CIDEX OPA as a single step cannot be assured for the affected products, there is a potential that the patient may be exposed to a higher risk of infection.
All manual high-level disinfection with CIDEX OPA should be discontinued. You should consult the Instructions for Use for your products for alternative reprocessing methods.

d. Risks to patient/user or third parties

The use of a flexible endoscope which is incompletely reprocessed with an ineffective disinfection phase has a risk for patient infection.

III. Type of Action to mitigate the risk

a. Action to be taken by the user

1. Immediately discontinue the use of manual high-level disinfection with CIDEX OPA for the affected products
2. Pass on this Urgent Field Safety Notice to all users of the products listed above and all other persons who need to be aware within your organization
3. Ensure that personnel responsible for reprocessing and all other relevant personnel in your organization review this letter and the updated Instructions for Use for affected flexible endoscopes which are available at the following links:
   https://go.karlstorz.com/PFA-22-0002-20
   https://go.karlstorz.com/PFA-22-0002-06
4. Please discard any prior versions of the Instructions for Use for the affected products that you may possess.
5. If you have distributed any of the affected products to third parties, please promptly forward this letter to all such third parties and indicate contact details of the recipient on the Acknowledgement Form
6. Please legibly complete the enclosed Acknowledgment Form and return it to KARL STORZ via the contact information specified on the form.

b. Action Being Taken by the Manufacturer

The updated Instructions for Use, which are made available as described above, no longer contain CIDEX OPA as a recommended manual high-level disinfection method.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please notify KARL STORZ of any adverse events or quality problems associated with your use of these devices. Adverse events or quality problems may also be reported to the national Competent Authority, as this provides important feedback.

Your contact person for this is given below. If you have any questions about this measure, please contact your contact person directly.

APPENDIX

Scope Base Part Number	Scope Kit Number	Product Description	Current IFU
11001RD1	N/A	Rhino-Laryngo-Fiberscope 3.7 x 34	96216006 V6.0 06/2021
11003BC1	N/A	Rhino-Laryngo-Broncho-Fiberscope	96216006 V6.0 06/2021
11005BC1	11005BCK1	Broncho-Fiberscope 2.8 x 70	96216006 V6.0 06/2021
11161C1	11161CK1	Neuro-Fiberscope 2.8 x 40	96216006 V6.0 06/2021
11272CU1	11272CUK1	Cysto-Urethro-Fiberscope	96216006 V6.0 06/2021
11272V	11272VK	CMOS Video Cysto-Urethroscope	96136020 V2.1 02/2018
11272VU	11272VUK	CMOS Video Cysto-Urethroscope	96136020 V2.1 02/2018
11278ACU1	11278ACUK1	Ped. Cysto-Urethro-Fiberscope, FLEX-X	96216006 V6.0 06/2021
11278AU1	11278AUK1	Uretero-Reno-Fiberscope FLEX-X2S	96216006 V6.0 06/2021
11282BN1	11282BNK1	Neuro-Fiberscope, 3.7 x 34	96216006 V6.0 06/2021
11292AD1	11292ADK1	Choledocho-Fiberscope, 7.5 Fr.	96216006 V6.0 06/2021
11292ADU1	11292ADUK1	Choledocho-Fiberscope, 7.5 Fr.	96216006 V6.0 06/2021
11292DE1	11292DEK1	Choledocho-Fiberscope, 15.5 Fr.	96216006 V6.0 06/2021
11001UD1	11001UDK1	Rhino-Pharyngo-Laryngo-Fiberscope 5.2x23	96216006 V6.0 06/2021
11272C1	11272CK1	Cysto-Urethro-Fiberscope	96216006 V6.0 06/2021
11278A1	11278AK1	Uretero-Reno-Fiberscope FLEX-X2S	96216006 V6.0 06/2021
11278AC1	11278ACK1	Ped. Cysto-Urethro-Fiberscope, FLEX-X	96216006 V6.0 06/2021
11272CI1	11272CIK1	Cysto-Urethro-Fiberscope, PDD	96216006 V6.0 06/2021
11272CIU1	11272CIUK1	Cysto-Urethro-Fiberscope, PDD	96216006 V6.0 06/2021
11274AA1	11274AAK1	Uretero-Fiberscope	96216006 V6.0 06/2021
11274AAU1	11274AAUK1	Uretero-Fiberscope	96216006 V6.0 06/2021
11278AI1	11278AIK1	Uretero-Fiberscope, FLEX-X²	96216006 V6.0 06/2021
11278AIU1	11278AIUK1	Uretero-Fiberscope, FLEX-X²	96216006 V6.0 06/2021
11292BD1	11292BDK1	Choledocho-Fiberscope, 11 Fr.	96216006 V6.0 06/2021

Please return the completed acknowledgement form as soon as possible.

Name: local contact
Telephone: local contact
E-Mail: local contact

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
On behalf of KARL STORZ, we thank you for your help and apologize for any inconvenience.

Yours sincerely,

KARL STORZ SE & Co. KG

i. V. Karim Djamshidi
Person Responsible for Regulatory Compliance
Executive Director Global Regulatory Affairs
Global Regulatory Affairs

This document was created electronically and is valid without signature

KARL STORZ—ENDOSKOPE

ACKNOWLEDGMENT FORM

Urgent Field Safety Notice – 22-0002

Please complete this form and return it to us by faxing it to [number] or emailing a copy to [address]. Please check all applicable boxes.

☐ I confirm that I have read and understood the "Urgent Field Safety Notice" for the KARL STORZ flexible endoscopes and completed all actions requested. Specifically:

- ☐ I have ensured that all relevant personnel in my organization review the "Urgent Field Safety Notice" and the Instructions for Use for the flexible endoscopes identified in the appendix.
- ☐ I confirm that we do not use any of the affected products in our facility or that this has already been discarded.

Check one of the boxes below.

- ☐ My organization has previously sold or transferred one or more of the affected flexible endoscopes to a third party, and I have forwarded the "Urgent Field Safety Notice" to all such third parties.
- ☐ My organization has not sold or transferred any of the affected flexible endoscopes to a third party.

Contact Information:

Facility Name	
Address	
Contact Person & Title	
Signature	
Phone	
Email	