GETINGE ✳

URGENT – FIELD SAFETY NOTICE

Irrigators GETINGE GSC-K-05 and GSC-K-06 used with the EDS8
## Field Action 2017-02

Date:	**April 26th, 2017**
Product Issue:	**The EDS8 irrigators are intended to dry and store endoscopes in the EDS8 endoscope drying and storage cabinet. It was detected during our manufacturing process that it might be possible to generate particles during assembly of the X component on the silicone tube due to a device design issue with this component.**
Affected Product:	**11 Getinge GSC-K-05 (model number 02190257) and 51 GSC-K-06 (model number 02190258)**
Resolution:	**Getinge proposes to replace the current irrigators with updated irrigators manufactured with a new design of the X component, to make sure all devices present on the market are working effectively and safely.**
Affected Serial Nos.:	**N/A – All irrigators sold up until the shipment hold on January 19th 2017: the 62 units listed.**
Field Correction Notice:	**Scrap current 62 irrigators and replace them with updated irrigators**
Pages:	**3**

Dear Customer:

Our records indicate that you bought one or more EDS8 irrigators of type GSC-K-05 (02190257) or GSC-K-06 (02190258), intended to dry and store endoscopes in the EDS8 endoscope drying and storage cabinet.
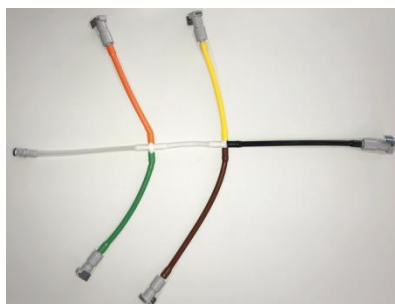
GSC-K-05
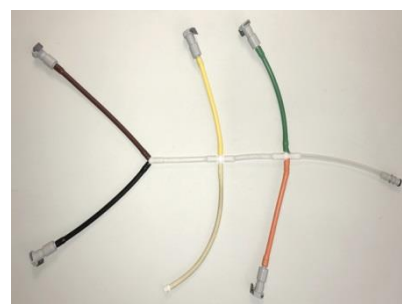
GSC-K-06 (EDS8)

This letter is to inform you of a corrective action that will be performed to prevent a possible failure of the device with a potential hazard to persons.

Due to a device design issue, it was highlighted during manufacturing that **it might be possible to generate particles during assembly of the X component (which is too sharp) on the silicone tube.** If a particle moves from the irrigator to inside the endoscope, it could then theoretically move to the patient's body.
This issue was raised during manufacture of the EDS8 irrigators and we have not received any customer complaint related to this issue.

Internal testing was performed and shows that **the particles stay inside the irrigator when it is connected to the EDS8 during a standard drying/storage cycle.** The particles remain in the irrigator when up to 1 bar of pressure is applied. As the nominal airflow from the EDS8 compressor is 180 mbar and the maximum airflow is no higher than 500mbar (during 1 minute), we do not expect that a particle will move from the irrigator during use of the EDS8.

Although there is no indication or apparent likeliness that a particle might move from the irrigator when connected to the EDS8, we want to correct this flaw and the current irrigators on the market will be replaced with updated irrigators manufactured with a new design of the X component, free of charge.

New component (left) and old component (right)

Next Steps
1. Please make sure that all users of the EDS8 irrigators referenced on the previous page are made aware of this Field Safety Notice and all listed devices at your facility are available to be replaced.

2. Complete and sign the enclosed Customer Response Form and return this form to your local Getinge office. **Note: A Getinge Sales or Service person will contact the person you listed on the Customer Response Form to schedule the replacement of your device, free of charge**.

3. After they are replaced with new irrigators, please return the old irrigators to your local Getinge office to be scrapped. Ask for support from your Getinge contact person if so required.

Transmission of this Field Safety Notice:
This Getinge GSC-K-05 and GSC-K-06 Field Safety Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

Additional Comment
The XX has been informed of this Field Safety Corrective Action.
We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure correct product performance. If you have any further questions or require assistance completing the Customer Response Form, please contact Getinge.

Best Regards,
XX
SSU Quality Manager

Customer Response Form
Field Action 2017-02

Reference: Urgent Field Safety Notice, Getinge GSC-K-05 and GSC-K-06 used with the EDS8

Our records indicate that the GSC-K-05 / GSC-K-06 device shown below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

Designation	Model number
GSC-K-05	02190257
GSC-K-06	02190258

Record the total number of affected device currently located at your facility here please ➔ ___.

Please check the appropriate boxes below:

☐ We have read the GSC-K-05 and GSC-K-06 Field Safety Notice and we understand the communication and the required actions.
  If checked : please provide information where the affected devices are physically located.

Field Safety Notice Receipt and Customer Response Form Completion and Certification		
Current Facility Name		
Contact Name / Title		
Address (no PO boxes, please)		
City, State, Zip		
Phone Number	**Fax:**	
E-Mail Address:		

☐ We have sold/moved our GSC-K-05 and/or GSC-K-06 to another facility.
  If checked : please provide new facility information below.

New Facility Name		
Contact Name / Title		
Address*		
City, State, Zip		
Phone Number	**Fax:**	
E-Mail Address:		

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL	CONTACT
<local SSU address line 1>	*<contact address>*@getinge.com
<local SSU address line 2>	Tel: *<SSU contact phone number>*
<local SSU address line 3>	Fax: *<SSU contact fax number>*
<local SSU address line 4>	