

Urgent Field Safety Notice

FA 2012 003

Getinge Lancer SA, Toulouse, France

Date

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Handled by

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Source: MEDDEV 2.12-1 rev 6, Annex 5

Model:	Channel separator LFC-S-05 used with Fibrocleaners, Poka Yoke, Ed FLOW
Type of action:	Field Safety Corrective Action (FSCA)
FSCA identifier:	48676

Details on affected devices:

This Field Safety Notice (FSN) refers to Getinge Lancer Channel separators LFC-S-05 used with Lancer endoscopes reprocessors (Fibrocleaner, Poka Yoke, ED FLOW) and FUJINON G5 ENDOSCOPY endoscopes. All separators LFC-S-05 are concerned

Description of the problem:

Following a vigilance report concerning repeated contamination of colonoscope FUJINON EC 530 WM, GETINGE LANCER has detected a problem of washing/disinfection efficiency of the "FUJINON G5 Endoscopy" range in washers ED FLOW, POKA YOKE and FIBROCLEANER.

Investigations has highlighted an adequacy issue between Channel Separator LFC-S-05 and the "FUJINON G5 Endoscopy" range. Channel Separator LFC-S-05 has been validated with the previous FUJINON endoscopes range and the suction cage of "FUJINON G5 Endoscopy" range has a different design. GETINGE LANCER was not aware of this design modification.

The Channel Separator LFC-S-05 has a specific pin that spreads the flow in the suction cage (see fig 1). In "FUJINON G5 Endoscopy" range, the flow is not compatible with this pin.

GETINGE LANCER has decided to change the design of the Separator LFC-S-05 for all the GETINGE LANCER AER by removing the pin (see fig 2). Tests in laboratory has demonstrated an improvement of 1log reduction of disinfection with this new separator.

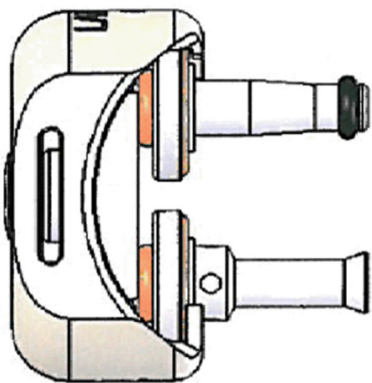


Fig 1 LFC-S-05

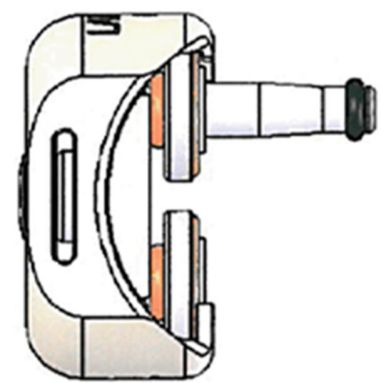


Fig 2 new LFC-S-10

Description of Potential Risk

15883-4 §4.4.2.4 requires 6log reduction minimum. Tests performed in laboratory (ref C.001.LAN.99.179.fr) showed 5,2log reduction with colonoscope EC 530 WM.
There is a risk of lack of disinfection of endoscopes processed in Getinge Lancer Automatic Endoscope Reprocessor.
Potential consequence is the transmission of residual contamination to the next patient.

Advise on action to be taken by the SSU and end customer:

Identifying the device:
LFC-S-05 are marked "FUJI G5" on top of plastic cap. Every batch of LFC-S-05 produced since 02 nov 2005 is concerned.



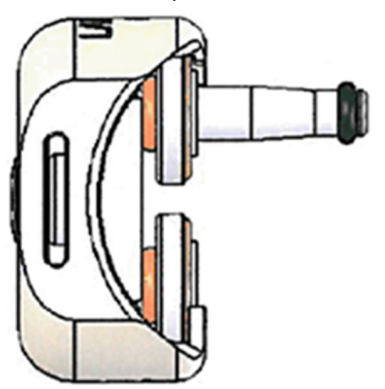
Waiting for new separators you will receive for replacement, you shall verify the microbiological quality of your endoscopes in the range "FUJINON G5 ENDOSCOPY" and use manual reinforced washing procedure for the contaminated endoscopes until full decontamination achieved.

In addition to modified separator, we advise the use of a detergent/disinfectant in the pre-wash bath used before endoscope reprocessing in washer.

Field Correction Kit

Kit description (include parts, special tools, and instructions; specify)

Kit is channel separator LFC-S-10



Kit assembly strategy (purchase vs. make parts; define how kits are to be assembled)

Channel separator LFC-S-10 replaces channel separator LFC-S-05

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The undersign confirms that this Field Safety Notice has been notified to the appropriate Regulatory Agency.

Name
Title
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