

Urgent Field Safety Notice

Commercial name of the affected product: disposable cleaning brush

FSCA-identifier:FSCA161031

Type of action : chapter 4.3

Date:2016-11-2

Attention: N/A

Details on affected devices:

Device Name	Catalog No.	Lot No.	Quantity	Device Mfr Date
Disposable cleaning brush	WS-1523WA(P)/DH	FJ01	6000	2016-09-01

Description of the problem:

WILSON has received a complaint concerning the Disposable Cleaning Brush broken in endoscope. A member of EDU staff was carrying out the manual cleaning of this scope the tip came of the brush and is lodged in the scope. When opened another brush of the same batch the end had fallen off in the packet.

WILSON found that stamping point didn't cover all of the stainless steel wire. When the user used the cleaning brush to clean the endoscope with rough way, the tubing will be broken at the last stamping point.

Furthermore, WILSON found that the proximal end of stainless steel wire close to the handle was very sharp, under the sudden pressure ,the tubing would be broken .When worker pack the products or operator pick it out of the box with rough way, maybe the tubing will be broken at this position.

Advise on action to be taken by the user:

Based on the complaint rate of this device's and factory inspection by WILSON, there is extremely small proportion of broken Disposable Cleaning Brush and it might not lead to scope damage or unanticipated serious deterioration in scope status. In addition, WILSON would like to notice the users when operating brushes:

Please do not fold the tubing close to the brush or handle with hard pressure before use.

Please change the Disposable Cleaning Brush if the brush is block during operation.

Transmission of this Field Safety Notice:

This notice will be informed within WILSON

Because of the products with lot no. FJ01 were only sent to its distributor in Ireland within European Union. Therefore the notice is only need to be sent to this distributor.

*Please accept our apologize for the inconvenience that this situation has caused.
WILSON insist on providing our Customers the highest quality products. WILSON
Thanks for your patience and support.*

*If you have any questions or need additional information, please contact WILSON or its
local distributors.*

Contact reference person:

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Signature/date:

Sophia Nov. 4, 2016