

Urgent Field Safety Notice

Name of the affected product: Disposable Cleaning Brush

FSCA-identifier: FSCA161031

Type of action : chapter 4.3

Date: 2017-04-06

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 or under the sudden pressure, the tubing will be broken at the last stamping point.

Advise on action to be taken by the user:

Wilson revised the IFU, and the new IFU updated:

Do not fold the tube with big strength.

Please change a new one if the cleaning brush is blocked during cleaning process.

Wilson will use the new IFU from on 25th March 2017 (Lot Number GC25).

Transmission of this Field Safety Notice:

This notice will be informed within WILSON

Only sent it to distributor in Ireland, no other organization need to be aware.

Please accept our apologize for the inconvenience that this situation has caused.

WILSON insist on providing our Customers the highest quality products. Thanks for your patience and support.

If you have any questions or need additional information, please contact WILSON or your local technical support representative.

Contact reference person:

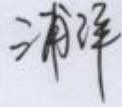
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Signature/date:



2017. 4. 10.