MHRA Ref: 2017/006/006/291/036

NIAIC Ref: ST-14423

Date: 12th June 2017

Field Safety Notice: FSN 593

Xograph Technologies Ltd is investigating an Adverse Incident report received from NIAIC involving an incident during intubation with a difficult airway in which the following product was deemed to be faulty:

Distributor	Product Name and Code	Lot No.	
Armstrong Medical Ltd.	AMT15750 Tracheal Tube Bougie	1215/01	2018/11

Adverse Incident reports that placement of the bougie during a difficult airway procedure was achieved but a crumpling effect happen during the railroading of the Endo Tracheal Tube over the positioned bougie tube.

The report states that multiple attempts was performed which resulted in delayed intubation of the patient.

Action Taken: Xograph Technologies Ltd are investigating this incident, retained samples have been tested under simulation and found to be performing correctly. The investigation is continuing and more information is being sourced and a voluntary batch recall has been initiated.

Xograph can confirm that this reported incident is the first received from this product range since product launch in 2012.

For any additional information please contact:

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