BAAT MEDICAL Products BV
F. Hazemeijerstraat 800
7555 RJ Hengelo
The Netherlands

Field Safety Notice 344

Anterior Resection Plate NC Lot 19-00002

Commercial name of the affected product: AVON Patella Anterior Resection Plate

FSCA-identifier: 344_FSCA_Anterior Resection Plate _NC_Lot 19-00002

Type of action: the return of a MEDICAL DEVICE to the supplier

Details on affected devices

Manufacturer	BAAT Medical Products B.V. www.baatmedical.com
Distributor	STRYKER (Stryker ref: RA2019-2254435)
Product category	AVON Patella Instrument set for STRYKER®
Product name	Anterior Resection Plate
REF	0901601002
UDI-DI (GTIN)	08719425462790
Lot	19-00002
Date of manufacture	May-2019

Description of the problem

The Anterior Resection Plate doesn't fit in the Intercondylar Block as described in the AVON™ Surgical Protocol. As a result, the surgeon is not able to perform a sawing operation in accordance with the surgical protocol.
This is caused by incorrect position of the mating posts (1 small and 1 large) on the Anterior Resection Plate. Due to this switch the resection plate can only be assembled with the Intercondylar block in the reverse direction, making proper functioning limited or impossible.
This nonconformance concerns all 10 parts from lot 19-00002. No other lots are identified with the same nonconformance.

Advise on action to be taken by the user

Hold and return, as soon as reasonably possible, the AVON patella Anterior Resection Plate (0901601002) with lot number 19-00002 to BAAT Medical, by at the latest 1-February-2020.

Confirmation form to be sent back to the manufacturer.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate).
Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (If appropriate)

Contact reference person at Stryker:

Name: Sharun Thavarajan
Position: Senior RAQA Specialist
E-mail: sharunyan.thavarajan@stryker.com
Phone: +44(0)1635 262411
Fax : 01635 580300

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Yours sincerely,

Sharun Thavarajan
Regulatory Affairs and Quality Assurance

Field Safety Notice 344

Acknowledgement form

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I acknowledge receipt of the Field Safety Notice 344 (Stryker ref. RA2019-2254435) and can confirm that:

We have not located any of these devices in our inventory: (please delete if not applicable)			
We have located the following devices:			
Reference	Description	Lot number	Qty
We have further distributed subject devices to the following organisations:			
Facility Name			
Facility Address			
Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL raqa.uk@stryker.com OR FAX 01635 580300