Urgent Field Safety Notice for Distributor

Recall Notification

FSCA-identifier: FSCA-2019-0001

Lausanne, June 19th 2019

Scope: Field Safety Notice – DISTRIBUTOR

Affected product:

- CT Exprès Day Set III *HP*, Ref. 640060.

Affected Lots:

- Lot# 2018091403
- Lot# 2018092003
- Lot# 2018092004
- Lot# 2019031101
- Lot# 2019031601
- Lot# 2019041904

Dear Customer,

This is to inform you that Bracco Injeneering S.A. is voluntarily recalling six (6) lots of CT Exprès Day Set III *HP* from the market as a precautionary measure.

Day Set III *HP* is a sterile disposable kit designed for use with CT Exprès Injector Systems. It is used to intravenously facilitate the administration of contrast media and flushing solutions into the human vascular systems.

The information related to the lots being recalled is as follows:

Product Name	Product Reference	Lot Number	Unique Device Identification (UDI)	Expiration Date
Day Set III *HP*	640060	2018091403	(01) 1763003930071 (17) 210914 (11) 180914 (10) 2018091403	2021/09/14
		2018092003	(01) 1763003930071 (17) 210920 (11) 180920 (10) 2018092003	2021/09/20
		2018092004	(01) 1763003930071 (17) 210920 (11) 180920 (10) 2018092004	2021/09/20
		2019031101	(01) 1763003930071 (17) 220311 (11) 190311 (10) 2019031101	2022/03/11
		2019031601	(01) 1763003930071 (17) 220316 (11) 190316 (10) 2019031601	2022/03/16
		2019041904	(01) 1763003930071 (17) 220419 (11) 190419 (10) 2019041904	2022/04/19

(01) Device Identification (17) Expiration Date (11) Manufacturing Date (10) Batch Number

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Description of the Problem

The affected devices are being removed from the market as there is the potential for saline leakage in the saline line of the Day Set III *HP* due to lower than nominal Cellene tubing length. This defect could result in the replacement of the Day Set III *HP* and in some situation to an under delivery of contrast media.

There has been no report of illness or injury to-date. However, Bracco Injeneering S.A. is recalling these lots in an effort to provide our customers and their patients with the highest quality product possible. We take this matter very seriously and we are committed to ensuring our products meet the highest quality and safety standards.

Actions to be taken:

- For each lot, provide to Bracco Injeneering S.A. (BINJ.Regulatory@bracco.com) the full traceability (customer/Hospital names and address).
- Update the RECALL RESPONSE FORM with your contact information
- If required, translate the FIELD SAFETY NOTICE and the RECALL RESPONSE FORM in appropriate language.
- Implement the Field Safety Corrective Action sending to all end users/customers the FIELD SAFETY NOTICE and the RECALL RESPONSE FORM according to your internal procedure.
- Collect from your end users/customers the RECALL RESPONSE FORM duly filled in and provide to Bracco Injeneering S.A. (BINJ.Regulatory@bracco.com) the raw data using the template provided (Excel File).
- Collect from your end users/customers the returns of the IMPACTED LOTS.
- Arrange the product returns to ACIST EUROPE Argonstraat 3, 6422 PH Heerlen, Netherland referring to the FSCA identifier "FSCA-2019-0001".

For devices currently in your stock (affiliate/distributor level):

- Please examine your inventory immediately to determine if you have any of the lot(s) listed.
- If you have any product from lot(s) mentioned above, stop shipping, immediately quarantine and keep them in a secure location to prevent further usage.
- Complete the attached RECALL RESPONSE FORM to acknowledge that you have received this Bracco Injeneering S.A. URGENT FIELD SAFETY NOTICE and, if applicable, indicate on the form the lots and quantity of affected products.
- The RECALL RESPONSE FORM shall be completed even if there is no inventory.
- Email (or fax) the completed form to BRACCO Injeneering.
- Arrange the product returns to ACIST EUROPE Argonstraat 3, 6422 PH Heerlen, Netherland referring to the FSCA identifier "FSCA-2019-0001".

We sincerely regret any inconvenience this may cause and appreciate your cooperation with this matter.

This recall is being made with the knowledge of National Competent Authorities.

Wouter Vlaanderen
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