

Urgent Field Safety Notice End User

Recall Notification

FSCA-identifier: FSCA-2019-0001

Lausanne, June 19th 2019

Scope: Field Safety Notice – END USERS

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 Injengineering 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
DaySet 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

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

- 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 using, 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 your local BRACCO Affiliate or Distributor.
- Arrange the return of the impacted lots to your local BRACCO Affiliate or Distributor (only unused product should be returned)

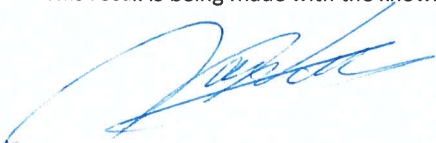
In an effort to ensure continuity of supply and limit the inconvenience to your service, your local BRACCO Affiliate or BRACCO Distributor will replace, free of charge, your products by another lot.

Transmission of this Field Safety Notice

Please forward this information to your radiology staff and biomedical engineers that may use the Day Set III *HP* lot(s) in your healthcare facility.

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
Managing Director
Bracco Injeneering S.A.
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CH - 1004 Lausanne, Switzerland

Urgent Field Safety Notice for End Users
Recall Response Form
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- CT Exprès Day Set III *HP*, Ref. 640060.

Affected Lots:

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

Please populate and sign the appropriate sections below and then email (or fax) the completed form to your local BRACCO Affiliate or Distributor *(Please add Bracco Affiliate/Distributor name, email address and fax number).*

Name/Position	
Institution Name/Department	
Address/Zip/Country	
Telephone Number	
Email Address	

Acknowledgment:	I acknowledge receipt of FIELD SAFETY NOTICE and I have verified that all areas where the affected products could be located have been checked (e.g. shipping/receiving, central supply, radiology, other):	<input type="checkbox"/>
Choose one of the statements:	We do not have any of the affected Day Set III <i>HP</i> at our facility:	<input type="checkbox"/>
	The following affected Day Set III <i>HP</i> is/are being ceased to be used and being returned. Lot number(s): <ul style="list-style-type: none"> • Lot# 2018091403: Number of units (single units): • Lot# 2018092003: Number of units (single units): • Lot# 2018092004: Number of units (single units): • Lot# 2019031101: Number of units (single units): • Lot# 2019031601: Number of units (single units): • Lot# 2019041904: Number of units (single units): 	<input type="checkbox"/>

Note: single units means 1 Day Set III *HP*, 1 box contains 15 single units.

If you have the affected Day Set III *HP* lot, please contact your local BRACCO Affiliate or Distributor to arrange collection and replacement.

Signature:

Date: