

March 25, 2017


URGENT FIELD SAFETY NOTICE - DEVICE RECALL NOTIFICATION

Affected product: CT Exprès Contrast Injection System, Temperature Maintainer Model
FSCA-identifier: FSCA-2017-0001, CA-identifier: CA-2017-0009
Type of action: Voluntary recall (return of a medical device to the supplier and device exchange)

Dear valued customer,

Bracco Injeneering S.A. has initiated a voluntary medical device Field Safety Corrective Action, FSCA (recall) of the CT Exprès Contrast Injection System, Temperature Maintainer Model.

Details on affected devices:

Reference	Product Name	Serial Numbers
650207	CT Exprès™ 3D Contrast Media, Temperature Maintainer Model	The following serial numbers affected are T0030016-0516 to T0030299-0117. The serial numbers of the injector unit for the Temperature Maintainer Models are prefixed with a 'T'. These are visible on the back of the Injector Unit.
650208	CT Exprès™ 4D Contrast Media, Temperature Maintainer Model	

This voluntary recall only affects the CT Exprès Contrast Injection System, Temperature Maintainer Model. Any CT Exprès Contrast Injection System, Classic Model that you may have is not affected by this recall.

Description of the Problem:

Bracco Injeneering S.A. is recalling the above mentioned serial numbers of CT Exprès, Temperature Maintainer Model, due to the possibility that they may develop a failure (hardware-related) leading to over-delivery of contrast media or saline followed by inadvertent air administration.

There have been no reports of patient injury in the few customer complaints received. However Bracco Injeneering S.A. is recalling these serial numbers in an effort to provide our customers and their patients with the highest quality product possible.



Actions to be taken:

Consistent with this voluntary recall, we are requiring the return of all products bearing the serial numbers listed above.

Please examine your inventory immediately to determine if you have any of the serial numbers listed. If so, cease use and immediately remove the affected products from your supply, quarantine them and keep them in a secure location to prevent further or future usage.

In an effort to ensure continuity of supply and limit the inconvenience to your service as best we can we propose the following:

If you have an affected product, your local BRACCO Affiliate or BRACCO Distributor will arrange a visit from an engineer to replace, free of charge, your CT Exprès Contrast Injection System Temperature Maintainer Model:

- with a CT Exprès Contrast Injection System Classic Model,
or
- with an EmpowerCTA+ Contrast Injection System

Your local BRACCO representative will contact you to discuss the matter and the options we can offer but in the meantime if you have any questions, please contact your local BRACCO Affiliate or BRACCO Distributor.

Please complete the attached DEVICE REMOVAL ACTION RESPONSE FORM to acknowledge that you have received this Bracco Injengineering S.A. URGENT FIELD SAFETY NOTICE and, if applicable, indicate on the form the serial numbers and quantity of affected products. Please email (or fax) the completed form to your local BRACCO Affiliate or Distributor in the first instance, and in addition email Bracco Injengineering S.A at BINJ.CustomerSupport@bracco.com

Transmission of this Field Safety Notice:

If you act as a BRACCO Affiliate or Distributor for any of the serial numbers listed, please immediately contact your customers and advise them of this recall, and have them return affected products to you.

If you are the End-User, forward this information to your radiology staff and biomedical engineers that may use the CT Exprès Contrast Injection System Temperature Maintainer Model in your healthcare facility.

The undersigned confirms that this Field Safety Notice will be notified to all affected competent authorities by Bracco Injengineering S.A.

Bracco Injengineering S.A. is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience or disruption to your service this action may cause. If you have any other questions, feel free to contact your local BRACCO representative. Thank you for your cooperation and immediate assistance.

Michael Edwards, Quality Assurance & Regulatory Affairs Director
Bracco Injengineering S.A.