

B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices
34209 Melsungen

Our reference: FSCA-2026-07-30

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Date: July 30, 2026

URGENT Field Safety Corrective Action - RECALL Certofix® protect

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel, Purchasing Managers, Safety Officers

Dear Customers,

The B. Braun Melsungen AG has decided to proactively recall the following article/batch combinations of Certofix® protect from the market.

Article Number	Article Name	Batch
4161211P	CERTOPIX PROTECT DUO V 720	25K25A8551
4162153P-07	CERTOPIX PROTECT TRIO V 715-EU/SA	25K09A8551
4162153P	CERTOPIX PROTECT TRIO V 715	25K11A8551
4162153P	CERTOPIX PROTECT TRIO V 715	25K19A8551
4163214P	CERTOPIX PROTECT TRIO V 720	25K23A8551
4161211P	CERTOPIX PROTECT DUO V 720	25M01A8551
4163214P	CERTOPIX PROTECT TRIO V 720	25K26A8551

Reason for the Recall

During our post-market and quality surveillance activities, B. Braun identified the potential presence of particles in the affected Certofix® protect article/batch combinations listed above. Based on the currently available root-cause analysis, the particles were traced back to excess coating material that was unintentionally introduced into the catheter during the coating process. Internal investigations indicate that the issue is limited to the listed article/batch combinations.

Clinical risk

If an affected device is used, particles may enter the patient's bloodstream during infusion. Depending on the clinical situation, this may lead to particle embolism and, in severe cases, serious patient harm. Based on the identified risk, B. Braun has decided to recall all affected devices from the market.

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Actions to be taken

Our records have shown that your institution has received articles of the affected article batch combinations.

Please take the following actions immediately and with priority:

- Review this Field Safety Notice in full and ensure that all users, clinical personnel and other relevant persons within your organization are informed of this Recall.
- If you are a distributor, forward this Recall notification to all customers and third parties to whom the affected devices were supplied and ensure documented confirmation of downstream notification and completion of the required actions.
- Identify all affected article/batch combinations in your inventory and clinical areas, quarantine the affected devices to prevent further use, and return them according to the instructions provided by your local B. Braun contact.
- Stop using affected devices immediately. For affected catheters that are already in use, assess the clinical situation and replace the catheter as soon as medically feasible in accordance with your institution's clinical procedures.
- Confirm receipt of this information by completing the attached confirmation form and returning it to B. Braun by 2026-07-31 using the contact details provided.

If more information is needed or you require devices for replacement, please contact

Local contact 1

Name

Title

Email

telephone

Local contact 2

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. As a true partner we develop smart solutions and set standards to improve health care. Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

The undersigned confirms that the relevant competent authority has been notified of this Recall.

Yours sincerely,

Jul **XX**, 2026

Field Safety Corrective Action Acknowledgment Form
Certofix® protect

Please complete this form and return to

1. **We hereby confirm that we are aware of the Field Safety Notice from **xx** July 2026 concerning Certofix® protect.**
2. **Please mark accordingly:**
 - ☐ We do not have any of the affected product in stock.
 - ☐ We have the following products on stock and will destroy them.
 - ☐ We have the following products on stock and will return them.

Article Number	Article Name	Batch Number	Quantity to be Destroyed/ Returned
4161211P	CERTOFIX PROTECT DUO V 720	25K25A8551	
4162153P-07	CERTOFIX PROTECT QUATTRO V 820-EU/SA	25K09A8551	
4162153P	CERTOFIX PROTECT TRIO V 715	25K11A8551	
4162153P	CERTOFIX PROTECT TRIO V 715	25K19A8551	
4163214P	CERTOFIX PROTECT TRIO V 720	25K23A8551	
4161211P	CERTOFIX PROTECT DUO V 720	25M01A8551	
4163214P	CERTOFIX PROTECT TRIO V 720	25K26A8551	

Organisation:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	