

IVF Hartmann AG, Victor von Bruns-Str. 28, 8212 Neuhausen

Mr Sample	Your ref.	Contact
Company	Your ref.	Mr Sample
27 Colmore Row	Your letter of	Telephone
Birmingham	Date	+49 7321 36
England	Our Ref.	Fax
B3 2EW	Our Ref.	+49 7321 36
	Date	Email
	Date	john.sample@hartmann.info

URGENT: SAFETY NOTICE MedNet syringes contained in HARTMANN sets

Dear Medical Device Safety Officers,

PAUL HARTMANN AG stands for the safety and reliability of its products and also feels responsible for providing information relating to the use of these products.

We are writing to inform you that PAUL HARTMANN AG has initiated a field safety corrective action for HARTMANN sets containing syringes from the manufacturer MedNet, which are listed in the table in Appendix 1.

REASON FOR THE FIELD SAFETY CORRECTIVE ACTION:

MedNet GmbH, Borkstrasse 10, 48163 Münster, Germany, has informed us of an URGENT FIELD SAFETY NOTICE regarding potential contamination in some syringes and particles in the syringes. Particles may not be detectable before use as they may adhere to the syringe seal. In the worst case, their use in patients may therefore lead to embolism.

We at PAUL HARTMANN AG are following this urgent safety information as we use the syringes mentioned in a few sets.

For your information, we have enclosed the original notification from MedNet with this letter.

CORRECTIVE MEASURES:

The HARTMANN surgical sets affected by this safety notice containing the affected lots of these syringes have been blocked and will no longer be delivered. Sets with syringes from other LOTs are available.

NECESSARY STEPS:

Step 1: Please take note of this safety information and inform all users in your facility.

GLN 404 9500 00000 0

Executive Board/Management Board: Britta Fünfstück
(Chairwoman of the Management Board/CEO), François
Georgelin,
Stefan Grote, Oliver Neubrand
Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

Registered office: Heidenheim
Ulm Local Court HRB 661090

Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB
661090

Step 2: Please urgently check your inventory physically and immediately quarantine the affected HARTMANN sets listed in the table in Appendix 1.

Step 3: Please complete the acknowledgement of receipt (Appendix 3) and return it by email as soon as possible, but no later than 21 November 2025. Please indicate the quantity of affected HARTMANN sets in your inventory so that PAUL HARTMANN AG can take the necessary steps regarding returns and replacement deliveries. By confirming, you also confirm that you have received the report and that you have understood and will implement the letter.

Thank you for your cooperation. We apologise for the additional work caused by this FSN.

Kind regards

PAUL HARTMANN AG

Site or department name (if necessary)

Commercial law abbreviation (ppa. / i.V.)

Commercial law abbreviation (p.p. / p.p.)

Name of sender

Name of sender

Appendix 1:

REF (item no.) / REF (item no.)	Trade name	LOT No. / Batch No.			
2336991	CS Irid P3 CPT	400140290	400240297	400341291	500215294
2342001	CS Individual PTA P3 CPT	400334293	400446293	500102297	500208296
2373605	CS Radiology antegrade P2 CPT	400235293			
2915556	CS Carotid P2 CPT	400338291			
2351232	CS Vascular Treatment Set P3 CPT	400538295			
	CS Endovascular Treatment Kit P3 CPT	400448297	500102297		
2356052	CS Vascular Angiography C P2 CPT	400344292	400449294		
2368852	CS Pack ENDO-VASCULAR P2 CPT	400335290	400448297	500104291	
2387181					

GLN 404 9500 00000 0

Executive Board/Management Board: Britta Fünfstück
(Chairwoman of the Management Board/CEO), François
Georgelin,
Stefan Grote, Oliver Neubrand
Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

Registered office: Heidenheim
Ulm Local Court HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB
661090

Appendix 2: UFSN MedNet GmbH

See appendix

Appendix 3: Customer response form

[Enter customer address]

Urgent safety notice for use on site – syringes from MedNet GmbH contained in HARTMANN sets

We hereby confirm receipt of the safety notice and that it has been forwarded to all persons within our organisation or to organisations to which the potentially affected products have been distributed who need to be informed.

The result of a review of our inventory is as follows:

Please specify:

After thorough inspection, there are **no stocks** of the affected products

Existing sets in Stock for exchange and return

REF (item number)	Trade name	LOTs	Stock
"Number"	"Product name" (customer-specific)	"Number"	"Number of primary packaging units"

Date: _____

Signature _____

GLN 404 9500 00000 0

Executive Board/Management Board: Britta Fünfstück
(Chairwoman of the Management Board/CEO), François
Georgelin,
Stefan Grote, Oliver Neubrand
Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

Registered office: Heidenheim
Ulm Local Court HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB
661090