

PAUL HARTMANN AG
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PAUL HARTMANN AG, P.O. Box 1420, 89504 Heidenheim, Germany

Mr Sample
Company
27 Colmore Row
Birmingham
England
B3 2EW

Your ref.	Contact
Your ref.	Mr Sample
Your letter of	Phone
Date	+49 7321 36
Our Ref.	Fax
Our Ref.	+49 7321 36
Date	E-Mail
Date	john.sample@hartmann.info

URGENT: FIELD SAFETY NOTICE - Medical Device Safety Advisory Notice

Kocher forceps, included in the HARTMANN gynaecology and obstetrics sets

Dear Medical device safety officers,

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

With this letter, we would like to inform you that PAUL HARTMANN AG has initiated a field safety corrective action for the HARTMANN Gynecology and Obstetrics sets with Kocher forceps listed in the table in Appendix 1.

REASON FOR THE Field Safety Correction:

After receiving complaints and due to a potential serious incident, PAUL HARTMANN AG has initiated a voluntary field safety corrective action as a matter of precaution.

This action is based on potential serious incidents while using forceps for clamping too large objects compared to the size of the clamp. Peha-instrument Surgical Hemostatic forceps and HARTMANN Surgical Instruments Surgical Hemostatic forceps are intended to be used as surgically invasive, single-use, surgical steel instruments for short-term treatment in the context of medical interventions such as holding and removal of foreign objects, holding and clamp of tissue and tubes, occlusion of vessels, manipulation and removal of tissue on humans used by healthcare professionals. Clamping of umbilical cords may make clamping difficult, and carries the risk that the forceps may come loose or break due to the physical nature of the umbilical cord.

POTENTIAL HAZARDS:

The use of Kocher forceps, included in the HARTMANN gynecology and obstetrics sets listed in the table in Appendix 1, for cord clamping may make clamping difficult, and carries the risk that the forceps may come loose or break due to the physical nature of the umbilical cord.

In fact, such use could result in significant blood loss in the infant, which could have serious consequences.

CORRECTIVE ACTIONS:

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Oliver Neubrand
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

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The HARTMANN OB/GYN procedure trays affected by this field safety notice are no longer being produced with this type of Kocher forceps. The replacement clamps reduce the incidence of breakage and inadvertent opening of the Kocher clamp when used properly with blood vessels.

In addition, we are revising our instructions for use for the affected HARTMANN Kocher forceps, which specify the intended use that excludes clamping of umbilical cords.

Further, the sets that are in the market need to be labelled with respective information that excludes clamping of umbilical cords. These instructions are enclosed as Annex 3 of this letter

REQUIRED ACTION:

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

Step 2: Please check your inventory physically as a matter of urgency and immediately quarantine the affected HARTMANN gynecology and obstetrics sets listed in the table in Annex 1.

Step 3: Please complete the acknowledgement of receipt (Annex 3) and return it by email as soon as possible, but not later than 03 March 2025. Please indicate the quantity of HARTMANN gynecology and obstetrics sets affected in your inventory so that PAUL HARTMANN AG can prepare the required quantity of 'warning labels'. With this acknowledgement, you also confirm that you have received the report and that you have understood and will implement the letter.

Step 4: Your HARTMANN sales representative will relabel the affected products in your inventory. Appointments will be arranged with you shortly to label the boxes of the affected sets.

Step 5: If you no longer have any of the affected products in stock, please complete the acknowledgement of receipt (Annex 3) and return it by email as soon as possible, but no later than 03. March 2025.

With this acknowledgement of receipt, you also confirm that you have received the notification and that you have understood and will implement the letter.

Thank you for your cooperation. We apologise for the additional work that this FSMA has caused you.

Kind regards

PAUL HARTMANN AG

Site or department name (if necessary)

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i.V.

Name of sender

i.V.

Name of sender

Product codes : See Annex 1

Warning Sticker: Annex 2

Feedback Form: Annex 3

Annex 1:

Material	Bezeichnung
2963013	Schleimhautset farbm. P28 st CPT
2962985	Geburtenset farbm. P32 st CPT
2379204	CS Geburten RK P7 CPT
2379205	CS Geburtenset mit Babytuch P15 CPT
2376974	CS Pack Accouchement P3 CPT
2352991	CS Uniforme bevallingset ZNA P6 CPT
2641152	CS Pack suture accouchement P9 CPT
2641065	CS de Suture Accouchement P20 CPT
2641053	CS d'Accouchement P29 CPT
2960503	Geburten-Set Variante I P24 st CPT
2360373	CS Geburten P26 CPT
2965822	Geburts Set Frdst. P36 st CPT
2487822	CS Abnabelung P17 CPT
2646223	CS Geburt-Naht P19 CPT
2550575	CS Geburtshilfe P19 CPT
2367252	CS Entbindung P13 CPT
2664415	CS Dammschnitt P14 CPT
2489813	Geburtsset I G.Kurz P18 CPT

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2962634	Abnabelungsset P40 st CPT
2967722	Abnabelungsset P32 st CPT
2963984	Geburts-Set P28 st CPT
2967652	Naht Set P15 st CPT
2967653	Naht Set P12 st CPT
2916834	CS Cesárea P3 CPT
2916527	CS Cesárea P3 CPT
2902075	CS trousse césarienne P3 CPT
2664653	CS Trousse accouchement P13 CPT
2356601	CS Trousse accoucht P10 CPT
2346841	CS SET PARTO BASE P18 CPT
2374681	CS porodu naturalnego P10 CPT
2362591	CS Zestaw do porodu naturalnego P18 CPT
2362661	CS Zestaw do porodu naturalnego P25 CPT
2384712	CS Zestaw do porodu naturalnego P28 CPT
2353741	CS Zestaw do porodu naturalnego P11 CPT
2643779	CS Zestaw do porodu naturalnego P12 CPT
2355511	CS Zestaw do porodu naturalnego P12 CPT
2365303	CS na incíziu UNLP KUCH P8 CPT
2342241	CS Pôrodný balík NR P8 CPT
2365304	CS na incíziu UNLP KUCH P8 CPT
4756904	Geburts-Set B1777 st CPT
4756808	Geburts-Set
4800641	MS - Naht
4706900	Set d'Accouchement avec Episiotomie
4707005	Set de suture d'épisiotomie
4707006	MS de suture d'épisiotomie
4708785	Set de suture d'épisiotomie
4791291	Set d'accouchement n° B5183 st CPT
4790992	Set d'accouchement B4759
4788443	Set d'accouchement et suture d'épisiotom
4787802	Set accouchement

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4788223	Set d'accouchement
4788502	Set d'accouchement
4783905	Set accouch. champ double poche
4784763	Set suture d'épisiotomie
4783353	Set de suture d'episiotomie
4790563	Set de suture d'épisiotomie
4785213	Set de suture d'episiotomie
4793452	Set d'accouchement
4788633	Set d'accouchement et épisiotomie
4787763	Set d'accouchement
4801071	MS d'accouchement et épisiotomi

Annex 2: Warning Sticker

GLN 404 9500 00000 0

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Safety notice
Do not use Kocher forceps for umbilical cord clamping respectively only under supervision.

Annex 3: – Customer Response Form:

[Enter Customer address]

Urgent Field Safety Notice – Kocher forceps, included in the HARTMANN gynaecology and obstetrics sets

We hereby confirm receipt of the Field Safety Notice and the forwarding to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred.

The result of an examination of our stocks is as follows:

Please indicate:

☐ after thorough examination there is **no stock** of the affected products

GLN 404 9500 00000 0

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☐ **existing Sets on stock must be labeled** as per HARTMANN instructions (fill table below in case, additional products/ labels needed)

REF (article number)	trade name	LOTs	stock quantity	Desired Action for product
„number“	„product name“ (customer individual)	„number “	„Number of primary packs “	“Return / Label / Replacement needed”

Date: _____

Signature: _____

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