IVF HARTMANN AG
Victor-von-Bruns-Strasse 28
Postfach 634
CH-8212 Neuhausen

+41 52 674 31 11
+41 52 672 74 41
info@ivf.hartmann.info
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Indirizzo
Indirizzo
Indirizzo
Indirizzo
Indirizzo

09 ottobre 2020

Rif. Customer Service Hospital
E-mail ivf.hospital@hartmann.info
Tel. +41 52 674 32 31
Fax +41 52 674 34 86

Informativa urgente di sicurezza relativa a CombiSets®, contenenti aghi ipodermici sterili MEDOJECT di CHIRANA T. Injecta

Egregi signori,

Con la presente vi inoltriamo un'informativa di sicurezza riguardante i nostri CombiSets® contenenti il o gli aghi ipodermici MEDOJECT. Il nostro fornitore CHIRANA T. Injecta ci ha informati di una Field Safety Corrective Action (richiamo volontario del prodotto) riguardante gli aghi ipodermici sterili MEDOJECT.

Per i particolari relativi alla motivazione, è possibile consultare l'informativa urgente di sicurezza nell'allegato 2.

Gli aghi ipodermici sterili MEDOJECT di CHIRANA T. Injecta sono utilizzati come componenti nei CombiSets® di HARTMANN.

Al fine di garantire l'assistenza ai pazienti, adotteremo le seguenti misure correttive per tutti i CombiSets® disponibili presso i nostri clienti e a magazzino: applicazione da parte di PAUL HARTMANN AG di un'appropriata avvertenza (vedere **allegato 4**) riguardante l'obbligo di identificare, rimuovere e smaltire immediatamente il o i componenti interessati (aghi ipodermici MEDOJECT) prima di utilizzare il CombiSets®. Tutti gli altri componenti non sono interessati e possono essere utilizzati.

Vi invitiamo pertanto ad adottare le seguenti misure correttive:

Controllate immediatamente le vostre scorte degli articoli riportati nell'allegato 1 e sospendete l'uso dei CombiSets® indicati nell'elenco fino a quando non sarà applicata la relativa avvertenza.

Il vostro referente abituale del Servizio Clienti HARTMANN si metterà in contatto con voi per garantire l'applicazione corretta e completa dell'avvertenza da parte di PAUL HARTMANN AG e per eseguire tale procedura presso la vostra azienda.

Una volta applicata l'avvertenza sui CombiSets®, sarà possibile riprenderne l'utilizzo. Vi preghiamo di identificare, rimuovere e smaltire immediatamente il o i componenti interessati durante la preparazione della sala operatoria. Tutti gli altri componenti non sono interessati e possono essere utilizzati come di consueto.

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Vi preghiamo di prendere nota e confermare il ricevimento della presente informativa di sicurezza utilizzando il modulo prestampato di risposta qui accluso (vedere l'**allegato 3 Conferma del cliente di ricezione e inoltro**) entro **venerdì 23 ottobre 2020.**

In caso di domande, potete contattare il vostro Area OP Manager competente di IVF HARTMANN AG.

Vi ringraziamo per la collaborazione e la comprensione

Cordiali saluti

IVF HARTMANN AG

p.i. René Ampler
Head of Sales Inpatient

p.p. Dr.ssa Regina Bruggisser
Head of Reg. Affairs, Quality and R&D

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Allegato 1

Data 09.10.2020

Allegato 1: Elenco degli articoli

REF (Codice articolo)	Nome commerciale	N° del lotto interessato
2360363	Naht-Set	000215299
2361161	Lasertherapie-Set	000214292
2362983	BAA-Set Triemli	000214292
2364711	Hand-Set	000212298
2369571	MAP Set 70cm	000216296
2370982	ORL-Kit	000114295
2372151	Set à pansement 6.5 B	000218290 000324298
2372171	Set à pansements 7.0 B	000216296 000323291
2374082	Ohr/ Lochtuch-Set	000109291
2375192	Pack Exzision HNO	000108294
2375333	Notfall-Set KSNW	000109291 000224291
2376492	Sectio-Set	000214292 000319294 000423298 000524292
2377082	Urologie-Set	000119290
2379543	Mamma-Set	000209298 000325295 000429290
2379913	Orthopädie-Set	000315296
2379931	Bariatrie-Set	000115292
2380261	Scarless Facelift Set	000109291
2381971	Sectio-Set	000119290
2382262	MIS-Set	000312295 000416290 000623292
2383701	Laparoskopie-Set- Rückenlage	000226295
2383891	Laparoskopie-Set / mod. SSL	000234290
2384311	Set Cesareo	000108294
2384321	Set Chirurgia	000109291
2384601	Set Laparoscopia	000114295
2384661	Set Base Dr Sohani	000114295
2386661	Vaginal gross	000119290
2387151	WV-Set mit Nahtmöglichkeit	000121293
2387181	Pack ENDO-VASCULAIRE	000125291
2387891	AOZ Lochtuch-Set	000126298
2388231	Midline-Set	000130295
2480195	Arthroskopie-Set Knie	000212298 000324298 000427296
2481492	Augen-Set	000109291
2484915	Varizen-Set	000119290 000225298
2620925	Port-a-Cath-Set	000112291

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		000225298
2620934	LSC Gastric Bypass-Set	000124294 000227292
2621495	Gynäkologie-Set	000110297
2621564	LSC Abdominal-Perineal	000107297 000212298 000326292
2622121	Universal Dermatologie Set	000119290
2624812	Combiset Notfall SZO	000213295 000324298 000429290
2626171	Universal Set	000214292 000316293
2626525	Laparoskopie Set	000216296 000324298
2628964	Rektum-Set	000113298
2628984	Universal-Set	000106290 000216296 000319294 000425292
2628993	Arthroskopie-Set	000109291 000217293 000321297
2629204	HNO-Set	000115292
2629213	TUR-Set	000111294
2629214	TUR-Set	000130295
2629223	Extremitäten-Set	000109291 000217293 000320290
2629233	Hand-Set	000211291 000317290 000420297
2629243	Micro HIP- Set	000127295
2640642	Wundabdeckung klein	000112291
2641011	Knie-Punktions-Set	000109291 000212298
2641042	Hüft-Punktions-Set	000108294 000226295
2645871	Set d'Antalgie	000108294 000314299 000417297
2646473	Kocher'sche Keilexzision	000115292
2646761	Set Urgence Hôpital Pays-d'E	000129299
2648262	Abdomino Perineal Set KSM	000108294 000215299 000327299
2663853	Lid Set	000216296
2665589	Neck Set	000209298 000319294 000428293
2666057	WV-Set HNO OP	000216296 000323291
2667027	ORL-Set	000218290 000325295
2667734	Pack Voie Basse CGB	000219297 000323291
2677015	Set de main	000209298

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		000325295 000425292
2691722	Röntgen-Set (TV-1)	000214292 000315296
2908028	Schlitztuch-Set	000117296
2960961	Orthopädie Set	000617253
2962203	Notfall Standard-Set	000914253
2963242	Wundversorgungs- Set	000719254
2964841	Infiltration-Set Radiologie	000633253
2966793	Set pose cathéter	000818254 000927253
2966803	Set pose cathéter	000836258
2967191	Notfall WV klein	000525251 000736251
2967411	Universal-set SZZ	000934251
2967481	Infiltrations Set universal	000625258 000625258

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Allegato 4

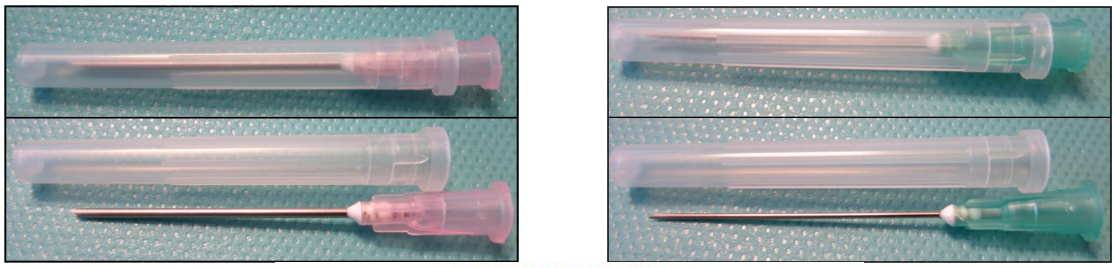
Attenzione - Avvertenza!

Rimuovere e smaltire l'ago ipodermico sterile MEDOJECT contenuto nel CombiSet®!

Gentile cliente,
In data 08.10.2020 Paul HARTMANN AG Le ha inviato un'informativa di sicurezza riguardante i CombiSets® contenenti aghi ipodermici sterili; sono interessati gli articoli e i numeri di lotto definiti (per i dettagli vedere l'informativa di sicurezza, allegati inclusi).

Questo CombiSet® contiene uno o entrambi gli aghi ipodermici sterili MEDOJECT riportati nell'immagine. Questi **non devono essere utilizzati** e **devono essere smaltiti**.

Gli aghi ipodermici di CHIRANA T. Injecta sono contenuti in un sacchetto bianco di carta nel CombiSet®; prestare attenzione alla corrispondente codifica cromatica degli aghi ipodermici per identificarli chiaramente (rosa chiaro o turchese - vedere immagine).



80088210 Kanüle
Aussendurchmesser: 18 = 1,20 Gauge=mm
Länge: 40 = 1 1/2" mm=Inch

80088150 Kanüle
Aussendurchmesser: 21 = 0,80 Gauge=mm
Länge: 40 = 1 1/2" mm=Inch

Per evitare restrizioni di approvvigionamento e per garantire l'assistenza ai pazienti, il CombiSets® rimane comunque a vostra disposizione. Vi preghiamo di prestare attenzione all'avvertenza e di applicarla per un utilizzo sicuro del CombiSets®:

Identificare l'ago o gli aghi ipodermici MEDOJECT, rimuoverli dal CombiSet® e NON utilizzarli.

Vi ringraziamo per il vostro supporto e la vostra collaborazione!

Heidenheim, 08.10.2020
PAUL HARTMANN AG

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Allegato 3 Conferma del cliente di ricezione e inoltro 09.10.2020:

"Indirizzo cliente"
"Indirizzo cliente"
"Indirizzo cliente"
"Indirizzo cliente"
"Indirizzo cliente"

Conferma del cliente di ricezione e inoltro

➔ **si prega di inoltrare entro venerdì 23.10.2020 tramite fax o per e-mail**

Fax: +41 52 674 34 86
E-mail: ivf.hospital@hartmann.info

Informativa urgente di sicurezza

CombiSets® contenenti aghi ipodermici sterili MEDOJECT di CHIRANA T. Injecta, secondo l'allegato 1

Con il presente confermiamo di avere ricevuto l'informativa urgente di sicurezza di PAUL HARTMANN AG del 08.10.2020 riguardante gli articoli sopra indicati (aghi ipodermici sterili MEDOJECT e corrispondenti unità di trattamento (CombiSet®)) e di avere trasmesso tale informativa a tutte le persone e le organizzazioni coinvolte.

Si prega di contrassegnare:

☐ Dopo accurata verifica, non abbiamo rilevato nessuna giacenza a magazzino

☐ Le giacenze sono costituite da quanto segue:

Prodotti riguardanti la vostra istituzione:

REF (codice articolo)	Nome commerciale	Lotto	Quantità in giacenza

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Con la presente confermiamo che su tutte le giacenze di questi articoli (unità di trattamento (CombiSet®) contenenti aghi ipodermici sterili MEDOJECT) è stata applicata l'apposita avvertenza da IVF HARTMANN AG e che il o i componenti interessati (aghi ipodermici sterili MEDOJECT) saranno identificati, rimossi e immediatamente smaltiti prima di utilizzare il CombiSets®.

Direzione OP	**Acquisti**
Data:	Data:
Timbro:	Timbro:
Firma:	Firma:

Date: 11.09.2020

Urgent Field Safety Notice
Sterile hypodermic needle – MEDOJECT
Sterile blunt fill needle - MEDOJECT

For Attention of*: Distributors and users in the countries where these batches were sold.

Rev 1: September 2018
FSN Ref: 2020-CH-09 FSCA Ref: 2020-CH-09

Urgent Field Safety Notice (FSN)
Sterile hypodermic needle – MEDOJECT
Sterile blunt fill needle - MEDOJECT

The observation that the needle surface gives black color when touched by white tissue may potentially rise some concerns about safety of medical device by users and patients. In order to eliminate any such concerns, we decided to make a voluntary recall of all 5 affected batches.

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Sterile hypodermic needle – MEDOJECT, Sterile blunt fill needle - MEDOJECT
1.	2. Commercial name(s)
	Sterile hypodermic needle – MEDOJECT, Sterile blunt fill needle - MEDOJECT
1.	3. Unique Device Identifier(s) (UDI-DI)
	-
1.	4. Primary clinical purpose of device(s)*
	Sterile hypodermic needle MEDOJECT – injection and taking off a blood and other liquids at patients Sterile blunt fill needle MEDOJECT - to be attached to a syringe in order to aspiration fluids from vials or ampules during the preparation of medications
1.	5. Device Model/Catalogue/part number(s)*
	CH21112, CH18112SB, CH18112F, CH15112
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	CH21112 (0,8(21G) x40mm) - LOT 180608, 180705 CH18112SB (1,2(18G) x40mm) - LOT 190920 CH18112F (1,2(18G) x40mm) - LOT 200110 CH15112 (1,8(15G) x40mm) - LOT 190920
1.	8. Associated devices
	Within context of the FSCA

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	Appearance of black spots after puncture or wiping needles by white paper towel. The observation that the needle surface gives black color when touched by white tissue may potentially rise some concerns about safety of medical device by users and patients. In order to eliminate any such concerns, we decided to make a voluntary recall of all 5 affected batches.
2.	2. Hazard giving rise to the FSCA*
	Based on all gathered information there is no fact that the sterile needles MEDOJECT create any risk to patient and user. Test of In vitro toxicity proved that the surface of the needle is non- toxic and there are no particles of surface black deposit formed in terms of embolism. These needles fully comply to standards EN ISO 7864:2016, EN ISO 9626:2016 and ISO 15510:2014 and are in fact safe for use.
2.	3. Probability of problem arising
	More than 350 million needles sold in the last 5 years. This is the first reported problem of this type for needles.

2.	4. Predicted risk to patient/users
	Based on all gathered information there is no fact that these sterile needles MEDOJECT create any risk to patient and user. Test of In vitro toxicity proved that the surface of the needle is non- toxic and there are no particles of surface black deposit formed in terms of embolism.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	We received information about incident from customer in Slovenia with following description: “When the puncture site on the sachet of infusion solution is punctured with a needle, a black spot is formed on the puncture site. When the needle is taken out of the plastic tube and the needle is wiped with a paper towel (white), a black mark/trace remains on the tissue.” We declare that Sterile needles Medoject are made, tested and comply with listed standards: EN ISO 7864:2016 - Sterile hypodermic needles for single use, EN ISO 9626:2016 - Stainless steel needle tubing for the manufacture of medical devices and ISO 15510:2014 - Stainless steels - Chemical composition. Cannulas are made of stainless-steel SUS304. The harmless of used materials has been confirmed by complex biocompatibility testing according to EN ISO 10993 standards. During in vitro cytotoxicity testing has been used for extraction medications-containing medium, in addition during most of biocompatibility tests performed acc. to EN ISO 10993 standards was used for sample extraction 0,9% sodium chloride solution (NaCl saline solution) and no interaction with the needle occurred, all tests are compliant. In theory based on literature review the black spots after puncture or wiping by white paper towel could be the: • Iron oxide (Fe3O4) or some other oxides created as a reaction between metal elements in steel and oxygen or aqueous solution like electrolyte (Fe3O4 is harmless to patient, it is used also as intravenous compound for anemia treatment). • Carbon from stainless steel. Higher electrochemical “dissolution” of elements from steel making higher concentration of carbon on the surface. • Other factors not known. We assume that black color can be result of presence of some ferric oxides as the results of the processing of the stainless-steel tubes. The effect may vary, and it is not perfectly controlled. Additionally, to that the following cleaning process efficiency may cause that some deposit remains on the surface as powder or substance layer which may be wiped off mechanically. We selected the worst-case of returned samples of needles in term of the occurrence of black trace on white paper towel after needles wiping - needle 1,2x40mm (CH18112SB), LOT: 190920. These samples were tested on: • In vitro cytotoxicity test in the independent external accredited laboratory according to EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Test report No. 3/20/129 from 20th July 2020) • particulate contamination: sub-visible particles in accordance with EuPh 2.9.19 (Test protocol No. 561/2020 from 20th August 2020). The tests were showing that such needles are not toxic, and they do not contain the particles of size more than 125µm and contain only small amount of particles of smaller size (2-25µm).
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.
3.	2. By when should the action be completed? — 31st October 2020
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None - Start with voluntary recall of listed 5 LOTs of needles (from 16th September 2020) - Implementation of batch release quality control test for cleanliness with the procedure of wiping the surface by white tissue. (LOTs produced from 11th September 2020) - Further investigation of manufacturing process to identify the cause of the problem and implement necessary measures to eliminate the cause. (long-term action, starting from 11th September 2020)
3	6. By when should the action be completed? — Specify where critical to patient/end user safety
3.	7. Is the FSN required to be communicated to the patient /lay user? — No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item. Choose an item.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	3. For Updated FSN, key new information as follows:	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	CHIRANA T.Injecta, a.s.
	b. Address	Nám. Dr. A. Schweitzera 194 Stará Turá, 916 01 Slovakia
	c. Website address	www.t-injecta.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * State Institute for Drug Control, Bratislava, Slovakia	
4.	9. List of attachments/appendices:	
4.	10. Name/Signature	PaedDr. Zdenka Klbečková Regulatory Affairs Manager

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.