Medline International France
Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh
44 110 Châteaubriant

Facility
Service
Address
Address
ZipCode City
Country

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

Châteaubriant, Date

ATTENTION: Pharmacist/Risk Manager responsible for medical device vigilance and the Biomedical/Engineering Department

Security information regarding Kocher Forceps included in Medline Delivery Sets

Medline Reference:	**FSN-24/04**
MoH Reference:	**R2420949**
Product description:	**Kocher Forceps included in Medline Delivery Sets**
Legal Manufacturer SRN:	**FR-PR-000003713**
Action type:	**Field Safety Corrective Action**
Product codes:	**See Annex 1 *(page 5)***

Dear Customer,

The purpose of this letter is to inform you that Medline International France S.A.S. has initiated a field safety corrective action, regarding the Medline Delivery Sets containing Medline International France Kocher Forceps, listed in the table in **Annex 1** *(page 5)*.

REASON FOR THE FSN:

Following the receipt of a complaint, and although no serious incident has been reported and in order to be cautious, Medline has initiated a field safety corrective action.
This action follows a potential unintended use of these Kocher Forceps. Indeed, these Kocher Forceps are intended to hold medical devices such as swabs or suturing needle and not to clamp the umbilical cord.

POTENTIAL RISKS:

The use of Kocher Forceps, included in the Medline Delivery Sets listed in the table in **Annex 1** *(page 5*), to clamp umbilical cords, may not only make clamping more difficult, but may also present the risk of the forceps unclipping after clamping.
Indeed, such use could result in significant blood loss for the infant, leading to serious consequences.

CORRECTIVE ACTIONS:

The Medline Delivery Sets impacted by this FSN-24/04 will no longer be manufactured with this type of Kocher forceps. They will be replaced by an alternative, designed for clamping umbilical cords.

In addition, an instruction for use was created for these concerned Medline Kocher Forceps, indicating their intended use, which excludes umbilical cord clamping. This instruction is attached on the last page of this letter.

ACTIONS REQUIRED:

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

Step 2: Urgently physically check your stock and promptly put in quarantine the concerned Medline Delivery Sets listed in the table of the **Annex 1** *(page 5).*

Step 3: Please complete the Acknowledgement Receipt *(page 4)* and return it by email as soon as possible, **but no later than August 2nd, 2024,** and indicate the quantity of impacted Medline Delivery Sets in your stock, in order for Medline to prepare the necessary quantity of "warning stickers".

Step 4: Your Medline sales representative will take in charge the relabelling of the affected products in your stock.

Step 5: If you no longer have any of the impacted products in stock, please complete the Acknowledgment Receipt *(page 4)* and return it by email as soon as possible **but no later than August 2nd, 2024**.

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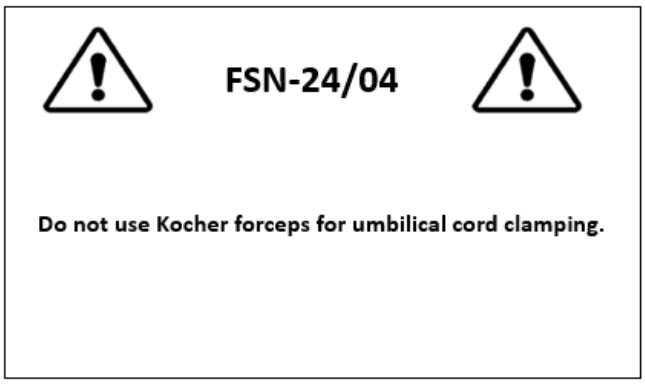
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

WARNING STICKER:



Thank you for your cooperation; Medline apologizes for the inconvenience caused.

The relevant competent authorities have been informed of this safety notice.

Please proceed to the following page to acknowledge receipt of this notice.

Please contact us at the email provided below if you have any questions.

Yours sincerely,

Audrey Barraud,
Quality Director, Medline Europe

This urgent safety information is only addressed to facilities that have received the products concerned.

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Please email the Acknowledgement Receipt to the following email address: GMB-EU-FSN-FSCA-CHBT@medline.com

Medline Reference: FSN-24/04

Please complete the Acknowledgement Receipt and send it back by email as soon as possible, **but no later than August 2nd, 2024**.

The Medline Delivery Sets, where Kocher Clamps impacted by FSN-24/04 are included, are listed in the table in **Annex 1** *(page 5).*

Quantity of warning stickers needed: _____

By completing and signing the document, I confirm that I have read and I understood the instructions provided.
I acknowledge receipt of the FSN-24/04 by signing this document and returning it to Medline.
I also agree to further distribute and communicate this important information within my facility as required.

If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

If you are **a dealer, wholesaler, distributor/reseller**, that distributed any affected products to other facilities: per Medical Device Regulation 2017/745, Article 14, part 4, please distribute this notification to your customers and provide confirmation to Medline that your customers have been notified by completing the information below and returning it to Medline at the address listed above.

Date: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

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Annex 1 :

References	Lot numbers					
KER70023B	232333	233168	239201	241587	244436	253879
	281163	290733				
KER71407	222682	225660	232227	232933	238674	243048
	245227	248899	254505	268468	270616	270624
	270635	279794	287538	295367	295368	45037984
	45037996					
KER71447	231593	233608	238721	241000	244731	252251
	257852					
KER71447B	270485	272178	272189	278897	283770	283886
	289795	45038755	45038761			
KER71462	244458	247441	249012	258056	270484	273393
KER71464	248401	250797	261490	270866	271979	271994
	275977	277728	285316	290967	297959	45038470
KER71471	257504	260834	269100	275236	283990	292155
	45038392					
KER71477	258317	261656	281982	285216	288758	297933
KER71478	260212	261764	269314	271606	277051	287704
	296909					
KER71484	262852	268467	269504	270480	274928	276498
	281417	285523	291119	294785	45038752	45038756
KER71485	268527	277919	281209	285254	287730	291056
KER71495	274740	277989	281082	287670	45038792	45038793
KER72453	291050	45039199	45039208	45039214		
KER72459	293324	297459	45039377			

Références	Numéros de Lot
ST01-KER72451	289331
ST02-KER72451	45288159
1484241-13	243971
1495021-4	254936
1495628-6	258465
1495632-3	258466
1495636-2	268411

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REF 08-18-500
REF 08-14-500

CE UKCA

en Instructions for use

Intended Use: These metallic forceps are intended to hold medical devices such as swabs or suturing needle during non-invasive procedures.
Warning: These forceps are not validated to clamp umbilical cord. Reuse of single use devices creates a potential risk for the patient or user. It may cause contamination and/or impairment of function; which may lead to injury, illness and/or death of a patient. If a serious incident has occurred in relation to the device, it should be reported to Medline and the competent authority of the Member State in which the user and/or patient is established.
Disposal instructions: Precautions should be taken when discarding this device and disposal of the device shall be made in accordance with applicable hospital or national regulations for biologically hazardous waste.

de Gebrauchsanweisung

Anwendungsbereich: Diese Metallpinzette ist zum Halten von Medizinprodukten wie Tupfern oder Nähnadeln bei nicht-invasiven Verfahren bestimmt.
WARNUNG: Diese Pinzette ist nicht für das Abklemmen der Nabelschnur zugelassen. Das Wiederverwenden von zur einmaligen Verwendung bestimmten Produkten stellt ein potentielles Risiko für Patient und Anwender dar. Es kann zu einer Kontamination und/oder Beeinträchtigung der Funktion kommen, was zu Verletzungen, Krankheit und/oder Tod eines Patienten führen kann. Wenn ein schwerwiegender Vorfall in Bezug auf das Produkt aufgetreten ist, sollte dies Medline und der zuständigen Behörde des Mitgliedstaats, in dem der Benutzer und / oder Patient niedergelassen ist, gemeldet werden.
Entsorgungshinweise: Wenn das Produkt entsorgt wird, sind Vorsichtsmaßnahmen zu treffen, die den geltenden Krankenhaus- oder nationalen Vorschriften für kontaminierte Abfälle entsprechen.

fr Mode d'emploi

Utilisation prevue: Ces clamps métalliques sont destinés à tenir des dispositifs médicaux tels que des compresses ou aiguilles de suture pendant des procédures non-invasives.
Attention: Ces dispositifs ne sont pas validés pour clamper un cordon ombilical. La réutilisation de dispositifs à usage unique est dangereuse pour le patient ou l'utilisateur. Ils peuvent être contaminés et/ou ne plus fonctionner correctement, ce qui peut entraîner blessures, maladies et/ou mort du patient. Si un incident grave est survenu en lien avec le dispositif, il doit être reporté à Medline et à l'autorité compétente de l'État membre dans lequel l'utilisateur et/ou le patient est établi.
Instructions d'élimination: Des précautions doivent être prises lors de la mise au rebut de ce dispositif. L'élimination de celui-ci doit être faite conformément aux réglementations hospitalières et nationales applicables aux déchets biologiquement dangereux.

nl Gebruiksaanwijzing

Beoogd gebruik: Deze metalen tang is bedoeld om medische hulpmiddelen zoals wattenstaafjes of hechtnaalden vast te houden tijdens niet-invasieve procedures.
Waarschuwing: Deze tang is niet gevalideerd om navelstrengen af te klemmen. Wanneer voor eenmalig gebruik bestemde hulpmiddelen opnieuw worden gebruikt, kan dit risico voor de patiënt of gebruiker opleveren. Dit kan verontreiniging veroorzaken en/of de werking aantasten, hetgeen letsel, ziekte en/of overlijden van de patiënt tot gevolg kan hebben. Als zich een ernstig incident heeft voorgedaan met betrekking tot het hulpmiddel, moet dit worden gemeld aan Medline en de bevoegde autoriteit van de lidstaat waarin de gebruiker en / of patiënt is gevestigd.
Instructies voor verwijdering: Voorzorgsmaatregelen moeten worden genomen bij het weggooien van dit hulpmiddel en de verwijdering van het hulpmiddel moet worden uitgevoerd in overeenstemming met de bestaande ziekenhuis- of nationale regelgeving voor biologisch gevaarlijk afval.

it Istruzioni per l'uso

Destinazione d'uso: Questa pinza metallica è destinata a tenere dispositivi medici come tamponi o ago da sutura durante le procedure non invasive.
Avvertenza: La pinza non è validata per clampare il cordone ombelicale. Il riutilizzo di dispositivi monouso determina un rischio potenziale per il paziente o l'utilizzatore. Può causare contaminazione e/o compromissione della funzione, con conseguenti lesioni, malattie e/o decesso del paziente. Se si verifica un grave incidente in relazione al dispositivo, deve essere segnalato a Medline ed all'autorità competente dello Stato Membro in cui l'utilizzatore e / o il paziente è stabilito.
Istruzione per lo smaltimento: È necessario adottare delle precauzioni quando si scarta questo dispositivo e lo smaltimento deve essere effettuato in conformità alle normative nazionali o ospedaliere per lo smaltimento dei rifiuti biologicamente pericolosi.

es Instrucciones de uso

Indicción de uso: Esta pinza forceps metálica está indicada para sujetar dispositivos médicos como hisopos o agujas de sutura durante procedimientos no invasivos.
Advertencia: Este forceps no está validado para pinzar el cordón umbilical. Reutilizar un producto de un solo uso crea un riesgo potencial para el paciente o usuario. Puede causar contaminación y / o deterioro de la función; que puede conducir a lesión, enfermedad y / o muerte de un paciente. Si se ha producido un incidente grave en relación con el producto, debe notificarse a Medline y a la autoridad competente del Estado miembro en el que está establecido el usuario y / o el paciente.
Instrucciones de eliminación: Se deben tomar precauciones al desechar este producto y la eliminación del producto debe realizarse de acuerdo con las normativas nacionales o del hospital aplicables para desechos biológicamente peligrosos.

pt Instruções para Uso

Utilização prevista: Esta pinça metálica destina-se a segurar dispositivos médicos, como cotonetes ou agulhas de sutura, durante procedimentos não invasivos.
Aviso: Esta pinça não é validada para pinçar o cordão umbilical. A reutilização de dispositivos de uso único cria um risco potencial para o paciente ou usuário. Pode causar contaminação e / ou comprometimento da função; o que pode levar a lesões, doenças e / ou morte de um paciente. Se ocorrer um incidente grave em relação ao dispositivo, este deve ser reportado à Medline e à autoridade de saúde competente do Estado em que o usuário e / ou o paciente se encontram.
Instruções relativas à eliminação: Devem ser tomadas precauções ao eliminar este dispositivo e seguir as normas e directrizes hospitalares e nacionais aplicáveis aos resíduos biologicamente perigosos.

Medline International France SAS
5 rue Charles Lindbergh, 44110 Châteaubriant, France

UK representative and importer in UK:
Medline Industries Ltd, WA4 6HL, UK

CH REP **CH Rep and importer:** Medline International Switzerland SARL,
c/o MN & Associés SA, 1 Place de Longemalle, 1204 Genève, Switzerland

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