For Attention of: Person responsible of Medical Devices safety / vigilance.
Passed on to all user departments and users

Quality Dept.: ☎

Ecouen, 27th June 2023.

Reference: FSN 23 0203

Object : URGENT FIELD SAFETY NOTICE

Kocher forceps in delivery sets

Dear Madam, Sir,

Vygon the legal manufacturer, informs you about this Field Safety Notice concerning **Kocher forceps included in delivery sets for the listed codes below.**

We would like to inform you about the advice and precaution as follows:

When Kocher forceps are used for clamping the umbilical cord, a permanent monitoring must be ensured to prevent them from unclamping. The Kocher forceps should be replaced as soon as possible by a Bahr clamp on newborn side, to prevent any inadvertently opening.

An unclamping of the Kocher forceps without monitoring could lead to a serious risk for the patient with a potential haemorrhage of the newborn's umbilical cord.

The following products codes are involved:

000722501	0007255087	0007255258	0007255369	V09772503	V09772545
0007235062	0007255107	0007255262	0007255396	V09772506	V09772546
0007235072	0007255128	0007255287	0007255413	V09772510	V09772551
0007235110	0007255170	0007255289	0007255424	V09772519	
0007235174	0007255184	0007255331	0007255440	V09772529	
0007255012	0007255197	0007255334	096930656	V09772542	
0007255032	0007255236	0007255353		V09772543	

Accueil
Tél : 01.39.92.63.63
Fax : 01.39.92.64.44
E-mail : questions@vygon.com

Service Clients France
Tél : 01.39.92.63.81
Fax : 01.39.90.29.37
E-mail : commandes@vygon.com

Service Clients Export
Tél : 01.39.92.64.15
Fax : 01.34.29.19.34
E-mail : export.orders@vygon.com

Service Comptabilité
Clients : Tél : 01.39.92.63.65
Fournisseurs : Tél : 01.39.92.63.64
Fax : 01.39.92.64.44

ISO 14001:2015

Adresse postale : 8 rue de Paris 95440 Ecouen - France
Siège social : 5 rue Adeline 95440 Ecouen - France
www.vygon.com

We ask you to kindly acknowledge receipt of this Field Safety Notice, to complete and return the attached Customer reply form.

The National Competent Authority has been informed of this Field Safety Notice, FSN.

If you should require further information, please contact your local Vygon distributor via telephone number detailed below.

We apologize for any inconvenience this FSN may cause.

Yours sincerely,

Christine OBER -

Postmarket QA/RA Director

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	23 0203
FSN Date	27th June 2023
Product/ Device name	**Kocher forceps in delivery sets**
Product Codes	**000722501, 0007235062, 0007235072, 0007235110, 0007235174, 0007255012, 0007255032, 0007255087, 0007255107, 0007255128, 0007255170, 0007255184, 0007255197, 0007255236, 0007255258, 0007255262, 0007255287, 0007255289, 0007255331, 0007255334, 0007255353, 0007255369, 0007255396, 0007255413, 0007255424, 0007255440, 096930656, V09772503, V09772506, V09772510, V09772519, V09772529, V09772542, V09772543, V09772545, V09772546, V09772551**

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number*	
Email*	
Fax	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	No affected devices are available	

Account Number	
Print Name	
Signature	
Date	

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Adress	
Fax	
Deadline for returning the customer reply form	Under 15 days

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective action.