Sigurnosna obavijest- opoziv

Lohmann & Rauscher d.o.o.
Oreškovićeva 10a · HR-10000 Zagreb
Tel.: 01 6609543 Fax: 01 6609548
Email: info@hr.LRmed.com

Zagreb, 26.05.2015.

Hitna sigurnosna obavijest
Povlačenje proizvoda radi onečišćenja

- **Raucodrape Inzijska folija, 55 x 80 cm, steril**
  Broj LOT-a 444212206 (REF no. 25447; PZN 01400670) (pojedinačni proizvod)

  i

- **pogođeni Setsystems KitPack (sa integriranom incizijskom folijom)**

Poštovane dame i gospodo,

moramo vas u svrhu sigurnosti pacijenata informirati u svezi povlačenja proizvoda koji je gore naveden.

Prilikom provjere 4 Raucodrape incizijske folije iz gore navedenog broja LOT-a ustanovilo se onečišćenje sa krvlju. Primjena na ljudima nije provedena. Onečišćenje je vrlo vjerojatno nastalo prilikom male ozljede radnika prilikom pakiranja. Proizvodi su odmah izdvojeni i blokirana isporuka robe sa skladišta pod tim brojem LOT-a.

Radi toga pozivamo na povrat iz sigurnosnih razloga navedni proizvod sa navedenim brojem LOT-a.

Molimo pošaljite nam proizvode sa navedenim LOT-om nazad i sa ispunjenim formularom. Proizvode ćete naravno dobiti gratis zamijenjene.

Molimo uvjerite se da su u vašoj organizaciji svi koji proizvod primjenjuju informirani u svezi navedenog slučaja i da su dobili **Hitnu sigurnosnu obavijest koju treba ispunjenu poslati nazad na našu adresu.**

U slučaju da ste proizvod predali trećoj osobi, proslijedite kopiju ove informacije dalje.

Ovim putem se želimo ispričati radi nastale neugodnosti i zahvaliti na razumijevanju i kooperaciji.

S poštovanjem

Lohmann & Rauscher GmbH & Co KG
i.V. i.V.

Rukovoditelj Regionalni produkt menađer

Privitak:
Hitna sigusnosna obavijest, Opoziv proizvoda radi nedostatka kvalitete

Hitna sigurnosna obavijest

Opoziv proizvoda radi onečišćenja
(poslati na fax 00 385 1 66 09 548)

Absender: Lohmann & Rauscher GmbH & Co. KG
Westerwaldstr.4
D-56579 Rengsdorf

Adressaten: Globex d.o.o.
Dobrovoljnih davalaca krvi 4
72000 Zenica-BiH

Beschreibung: Opoziv sljedećeg proizvoda radi onečišćenja

- **Raucodrape incizijska folija, 55 x 80 cm, steril**
  LOT broj 444212206 (REF no. 25447; PZN 01400670) (pojedinačni proizvod)
  i
- **pogođeni KitPack kompleti (sa integriranom incizijskom folijom)**

Korekcijske mjere:

Molimo vas da količine koje imate na skladištu više ne koristite i ne proslijeđujete te da nam ih vratite!

Besplatan povratak robe je osiguran s naše strane. Javite se našoj odgovornoj osobi za povrat robe.

Odgovorna osoba: Tel. 00 385 1 6609 543 / Fax. 00 385 1 6609 548

Molimo informirajte svoje djelatnike, koji primjenjuju proizvod, o ovoj hitnoj sigurnosnoj i potvrdite nam da se proizvod više neće koristiti te da ćete nam ga vratiti.

Osoba koja dolje potpisuje potvrđuje (molim označiti):
[ ] da više ne posjeduje gore navedene proizvode,
[ ] da nije predao gore navedene osobe trećim osobama ,
[ ] da je treće, ako su od njega dobili gore navedene proizvode, obavijestio u svezi opoziva,
[ ] da će gore navedene proizvode koji su još u njegovom posjedu ili pojedu treće osobe vratiti Lohmann & Rauscher GmbH & Co. KG.

Molimo unesite proizvode koje vračate sa navodom količine u sljedeću tablicu:

Proizvod (REF)	LOT	Broj vračenih proizvoda
REF 25447 (PZN 01400670)	444212206	
KitPack NN REF NN	NN	

Datum / Potpis: _____

Ime pisano velikim slovima: _____

Pozicija: _____

Odjel / Institucija : _____

Telefon i Email: _____

Field Safety Notice - Recall

Sales Division

Lohmann & Rauscher d.o.o.
Oreškovićeva 10a · HR-10000 Zagreb
Tel.: 01 6609543 Fax: 01 6609548
Email: info@hr.LRmed.com

Zagreb, 26.05.2015.

Urgent Field Safety Notice
Product Recall due to impurity

- **Raucodrape Surgical Incise Drape, 55 x 80 cm, sterile**
  Lot 444212206 (REF no. 25447) (single product)

  and

- **Set systems KitPack concerned (with integratd Incise Drape)**

Dear Sir or Madam,

Today, in terms of patient safety, we would like to inform you about a precautionary product recall of the above mentioned products.

After control of Raucodrape Surgical Incise Drape 55 x 80, Lot 444212206 (REF no. 25447) an impurity on 4 products which could be blood was observed. The product was not used on human beings. The 4 products were separated and our Quality Assurance blocked the goods in our warehouse immediatly.

The assumption is that during the packaging process of RD Surgical Incise Drape a worker has injured a finger of his/her hand unnoticeable. The blood contaminated a part of the products of the lot during the packaging process.

Therefore we perform a precautionary recall of the products in terms of patient safety.

Please send the products of the above mentioned batches with the enclosed form back to us. You will receive a credit note for the returned products in short term.

Please ensure within your organization that all users of the above mentioned products and other relevant persons are aware of this **Urgent Field Safety Notice** and send the enclosed confirmation back to us.

If you have delivered the product to third parties, please forward a copy of that information to them.

We thank you in advance for your cooperation and apologize for any inconvenience.

Yours truly,

Lohmann & Rauscher GmbH & Co KG

i.V. / On behalf of	i.V. / On behalf of
LRHR	Ines Vlahović,dipl.oec/Tvrtko Blaić Milutinović,dipl.ing
Sales department	Regional Vigilance Officer

Attachment:
Urgent Field Safety Notice, Product Recall due to colour bleeding

Urgent Field Safety Notice! **26.05.2015**

Product Recall due to impurity

(via Fax to 01 6609 548)

Sender: Lohmann & Rauscher d.o.o.
Oreškovićeva 10a
HR-10000 Zagreb

Addresse: Globex d.o.o.
Dobrovoljnih davalaca krvi 4
72000 Zenica-BiH

Description: Recall of the following products due to impurity

- **Raucodrape Surgical Incise Drape, 55 x 80 cm, sterile**
  Lot 444212206 (REF no. 25447) (single product)

  and

- **Set systems KitPack concerned (with integratd Incise Drape)**

Corrective Actions:

We ask you not to use the above mentioned products anymore and to send them back to us!

To ensure a free return to us, please contact our returns department:

Ms. Zvonkica Jurić Tel. 01 6609 543 / Fax. 01 6609 548, email: info@hr.LRmed.com

Please inform your employees who use the products of this Field Safety Notice and confirm to us that the product is not used anymore and the products have been returned to us.

The undersigned confirms (please tick):

[ ] that he does not possess the above mentioned products anymore,
[ ] that he has not given the above mentioned products to third parties,
[ ] that if he has given the above mentioned products to employees or third parties, he has informed the employeesand third parties about the recall,
[ ] that he will return the above mentioned products, which have been delivered to him and are still in his possession or in the possession of third parties, to Lohmann & Rauscher

Please enter the returned products with quantity in the following table:

Product (REF)	Batch (LOT)	Quantity of returned products
REF 25447	444212206	

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? Federal Institute for Drugs and Medical Devices, Germany
Type of report (•) Initial report ( ) Follow-up report ( ) Final report
Date of this report 2015-05-26
Reference number assigned by the manufacturer RD_Incise_Drape_6_2015
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable)

2 Information on submitter of the report
Status of submitter (•) Manufacturer ( ) Authorised Representative within EEA and Switzerland ( ) Others: (identify the role)

3 Manufacturer information	new

Name Lohmann & Rauscher GmbH & Co KG	
Contact Name Dr Martin Abel / Dr Annette Koggel	
Address Westerwaldstr. 4	
Postcode 56579	**City** Rengsdorf
Phone 02634 99 6566 02634 99 6941	**Fax** 02634 99 1566 02634 99 1941
E-mail vigilance.int@de.LRmed.com	**Country** DE - Germany

4 Authorised Representative Information

new

Name Lohmann&Rauscher d.o.o.	
Contact Name Tvrtko Blaić Milutinović,Dipl.Ing.	
Address Oreškovićeva 10a	
Postcode 10000	**City** Zagreb
Phone 00 385 1 66 09 543	**Fax** 00 385 1 66 09 548
E-mail info@hr.LRmed.com	**Country** HR - Croatia

5 National contact point information

new

National contact point name Lohmann & Rauscher GmbH & Co KG	
Name of the contact person Dr Martin Abel / Dr Annette Koggel	
Address Westerwaldstr. 4	
Postcode 56579	**City** Rengsdorf
Phone 02634 99 6566 02634 99 6941	**Fax** 02634 99 1566 02634 99 1941
E-mail vigilance.int@de.LRmed.com	**Country** DE - Germany

6 Medical device information

new

Class

- ○ AIMD Active Implants
- ○ MDD Class III
- ○ MDD Class IIb
- ○ MDD Class IIa
- ◉ MDD Class I
- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD Devices for self-testing
- ○ IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
UMDNS (ECRI)	12368

Nomenclature text

Drape, Surgical

Commercial name/ brand name / make

Raucodape Surgical Incise Drape, sterile, 50x80 cm

Model number	**Catalogue number**
	REF No 25447
Serial number(s)	**Lot/batch number(s)**
	single product: 444212206 for KitPack: see enclosure 1b
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

0123

Accessories / associated devices (if applicable)

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

Description of the product:
Raucodrape Surgical Incise Drape is intended for covering the incision area during surgery in order to avoid the penetration of pathogens into the wound. It is a medical device of Class Is in terms of Rule 4 (Council Directive 93/42/EEC concerning medical devices, Annex IX).
see homepage:
http://www.lohmann-rauscher.com/en/products/or-products/raucodrape-or-drape-system/surgical-incise-film.html

Event:
On 13.04.2015 CEMed, Neufra/Germany, reported that during the production process with Raucodrape Surgical Incise Drape 55 x 80, Lot 444212206 (REF no. 25447) they observed an impurity on 4 products which could be blood. The product was not used on human beings. The 4 products were sent to L&R Quality Assurance. After consultation of the Vigilance Officer L&R International QA blocked the goods in our warehouse. The impurity were tested by the forensic medicine, Schleswig-Holstein. On 12.05.2015 the forensic medicine informed us that the impurity is human blood (enclaosures 1a, 1b).

The production of the Lot of Raucodrape Surgical Incise Drape was in Neuwied, Germany. The products are also integrated in KitPack. The assumption is that during the production (packaging) process of RD Surgical Incise Drape a worker has injured a finger of his/her hand unnoticeable. The blood contaminated a part of the products of the lot during the packaging process.

The batch concerned, Lot 444212206, has an amount of 13.260 pieces.
1. 12.003 pieces of the single product were delivered to customers
2. 337 pieces of the single product are in the warehouse
3. 880 pieces of the single product are integrated in set systems KitPack (warehouse: 642 (DE (hospital), AT, FR); delivered: 297 (hospital only, 5 customers); difference: eg two pieces in one KitPack or in one lot of KitPack we integrated different lots of RD Surgical Incise Drape)
4. 40 pieces were a false entry in our warehouse system (information by Logistics).

Countries with quantities for Raucodrape Surgical Incise Drape 55 x 80, Lot 444212206 (Material no. 25447) (without KitPack):
Countries concerned n= 15; total: 12.003 pieces in the market, number of pieces in brackets [ ]:
Austria AT [110]
Bosnia-Herzogovina BA [200]
Czech Rebublic CZ [600]
Germany DE [6013] (hospital: 4303; non-hospital: 1710)
Spain ES [80]
France FR [2200]
Great Britain GB [500[
Kroatia HR [80]
Ireland IE [680]
Italy IT [590]
Marocco MA [200]
Mexico MX [10] (samples only, not in the market)
The Netherlands NL [450]
Poland PL [120]
Slovakia SK [170]

The final list of Customers is enclosed, for Raucodrape Surgical Incise Drape enclosure 2a; for KitPack – enclosure 2b.

Description and justification of the action (corrective / preventive)

Recall of the single product and the ste systems (KitPacks) with integrated single product both products precautionary:
1) To recall the single product Raucodrape Surgical Incise Drape, Lot 444212206.
We will recall the product in the market. The current quantities have to be destroyed and can not be delivered into the market anymore.

2) To recall the set systems (KitPacks) in which Raucodrape Surgical Incise Drapes with Lot 444212206 are integrated,
Recall of the KitPacks due to the risk/hazard for the patients, users or other third party.
The set systems in the warehouse are in quarantine. QMS, production as well as the logistics will re-check the set systems and destroy the Raucodrape Surgical Incise Drape Lot 444212206.

3) Assessment by a hygenist/physician for evaluating the risk for the patient, user and third parties with the recommendation of recalling the product (see enclosure 3).

4) Corrective/preventive actions:
4.1. Quarantine for the products concerned in all store-houses of L&R by Quality Assurance and Logistic (responsible Quality Assurance) (done)
4.2. Evaluation of the customers concerned by QA (done)
4.3. First information of the sales units concerned (done)
4.4. Reporting of the recall to the national authorities concerned by the Regional Vigilance Officers and Vigilance Officers L&R International
4.5. Information of the customers concerning the recall (FSN) by the sales divisions concerned

5) Preventive actions

5.1 Initiation of the CAPA process by Quality Assurance for preventive actions
5.2 Training of the employes (eg packaging process; procedure for adequate handling of injuries during production)
5.3 Identification of possible localisations with a risk of an injury during production (eg sharp edges) for the product and the production in general

Advice on actions to be taken by the distributor and the user

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

We want to end the recall until end of July 015 (final confirmation by the customers).

Attached please find

☒ Field Safety Notice (FSN) in English
☒ FSN in national language
☐ Others (please specify)

FSN Status

○ Draft FSN
◉ Final FSN

examples of FSNs in German and English: see enclosures 4a and 4b

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☐ BE	☐ BG	☐ CH	☐ CY	☒ CZ	☒ DE	☐ DK
☐ EE	☒ ES	☐ FI	☒ FR	☒ GB	☐ GR	☐ HU	☒ IE
☐ IS	☒ IT	☐ LI	☐ LT	☐ LU	☐ LV	☐ MT	☒ NL
☐ NO	☒ PL	☐ PT	☐ RO	☐ SE	☐ SI	☒ SK	☐ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland

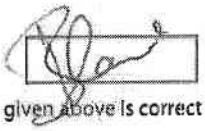
Others:

Bosnia-Herzegovina BA; Italy IT, Marocco MA

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature



I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Lohmann & Rauscher d.o.o.
Oreškovićeva 10a
Z A G R E B