

Nujno varnostno obvestilo Urgent Field Safety Notice –

Address:

Customer 1

Sales Division
Lohmann & Rauscher GmbH & Co.KG
Westerwaldstr. 4 · D-56579 Rengsdorf
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Email: Hannes.Schober@at.LRmed.com

Date: 23.04.2022

Nujno varnostno obvestilo **Urgent Field Safety Notice**

zaradi lomljenja in obrabe rentgenske niti v kompresah iz gaze (v Kitpack operacijskih setih)
due to breaking and fraying of the x-ray thread in gauze compresses (in Kitpack procedure packs)

Dear Sir or Madam,

Obveščamo vas o previdnostnem ukrepu oz. odpoklicu kompres iz gaze z rentgensko kontrastno nitjo zaradi možnega lomljenja ali obrabe uporabljene rentgenske niti.

Today we would like to inform you about the precautionary product recall of gauze compresses with X-ray thread due to a possible breaking or fraying of the x-ray thread used.

Prizadete komprese iz gaze z rentgensko kontrastno nitko so integrirane v operacijske sete Kitpack.

The affected gauze compresses with x-ray thread are integrated in Kitpack procedure packs.

Na podlagi povratnih informacij s trga je postalo znano, da se lahko v nekih slučajah rentgenska nit v teh kompresah iz gaze pod napetostjo zlomi in na posameznih točkah pretrga.

Based on feedback from the market, it has become known that the x-ray thread in the affected gauze compresses can break under tension and fray at individual points.

Zaradi dveh dodatnih poročil dveh različnih klinik v Švici je bilo odločeno, da se razširi obseg prejšnjega odpoklica.

Due to two additional reports from two different clinics in Switzerland it was decided to extend the scope of a former recall.

Izdelki in serije, ki jih je prizadela ta napaka, so bili takoj dani v karanteno v našem skladišču.

The products and batches affected by this defect were immediately quarantined in our warehouse.

Teoretično bi se lahko v primeru da se rentgenska nit zlomi ali strga pojavili majhni koščki niti, ki bi lahko na primer povzročili vnetje in/ali nastanek granulomov v kolikor ostanejo v telesu.

Theoretically, small pieces of thread could occur when the x-ray thread breaks or frays. This could, for example, lead to inflammation and/or granuloma formation when remaining in the body.

Ker so komprese iz gaze z rentgensko nitjo sestavni del setov za op. posege Kitpack, ki so vam bili dostavljeni, je potrebno zaradi varnosti pacientov izvesti naslednje ukrepe:

Since the gauze compresses with x-ray thread are part of the Kitpack procedure packs delivered to you, the following measures must be taken in the interest of patient safety:

Prosimo, ne uporabljajte prizadetih kompres iz gaze z rentgensko nitjo iz Kitpack seta za op.posege in te izdelke zavržite pred uporabo v operacijski dvorani. Pred uporabo drugih komponent preverite, ali so kontaminirane z deli rentgenske niti.

Please do not use the affected gauze compresses with x-ray thread from the Kitpack procedure packs and please discard these products before use in the operating theatre. Before using the other components, please check whether they are contaminated by parts of the x-ray thread.

Da ne bi ogrozili operacij in da bi ohranili neposredno oskrbo pacientov, bomo pakete za op.posege Kitpack, v kolikor so še na zalogi, označili z naslednjimi dodatnimi informacijami:

In order not to endanger the operation and to maintain direct patient care, we will label the Kitpack procedure packs still in stock with the following additional information:

"Pozor: Ne uporabljajte kompres iz gaze z rentgensko nitjo. Prosimo, zavrzite"
"Attention: Do not use gauze compresses with x-ray thread. Please discard"

To ne vpliva na druge komponente v Kitpack operacijskih setih in te je mogoče uporabljati kot običajno.
The other components of the respective Kitpack procedure packs are not affected by this and can be used as usual.

Izdelke bomo seveda v kolikor so navedene šarže pri stranki v zalogi brezplačno zamenjali ali pa na zahtevo izstavili dobropis.
The products will, of course, be exchanged free of charge or credited on request.

V svoji organizaciji poskrbite, da bodo vsi uporabniki spodaj navedenih izdelkov in druge osebe, ki jih je treba obvestiti, seznanjeni s tem nujnim varnostnim obvestilom in nam prosimo vrnite priloženo potrdilo izpolnjeno z vapše strani in podpisano.
Please ensure in your organisation that all users of the products listed below and other persons to be informed are aware of this Urgent Field Safety Notice and return the enclosed confirmation to us completed.

Če ste izdelke posredovali tretjim osebam, jim posredujte kopijo teh informacij.
If you have passed on the products to third parties, please forward a copy of this information to them.

V naprej se vam zahvaljujemo za sodelovanje in se opravičujemo za morebitne nevšečnosti.
We thank you in advance for your cooperation and apologize for any inconvenience.

With best regards,

Lohmann & Rauscher GmbH
i.V. / On behalf of

i.V. / On behalf of

23.04.2022
LR Graz & LR-SLO

Hannes Schober
Regional Vigilance Officer

Priloga:

Attachment:

- 1) *Nujno varnostno obvestilo zaradi lomljenja in obrabe rentgenske niti v kompresah iz gaze (v Kitpack operacijskih setih)*
- 1) Urgent Field Safety Notice due to breaking and fraying of the x-ray thread in gauze compresses (in Kitpack procedure packs)

Priloga 1
Enclosure 1

Nujno varnostno obvestilo
Urgent Field Safety Notice!

Date: 23.04.2022

zaradi lomljenja in obrabe rentgenske niti v kompresah iz gaze (v Kitpack operacijskih setih)
due to breaking and fraying of the x-ray thread in gauze compresses (in Kitpack procedure packs)

via Fax to LR: 0043-316 682345

Pošiljatelj:

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

Naslovnik:

Addressee: customer 1
& all users who use the below mentioned products.
& vsi uporabniki, ki uporabljajo spodaj navedene izdelke.

Opis: *Nujno varnostno sporočilo zaradi lomljenja in obrabe rentgenske niti v kompresah iz gaze (v Kitpack operacijskih setih)*

Description: **Field Safety Notice due to breaking and fraying of the x-ray thread in gauze compresses (in Kitpack procedure packs)**

Korektivni ukrepi:

Corrective Actions:

Prosimo, ne uporabljajte več prizadetih kompres iz gaze z rentgensko nitjo v teh Kitpack setih za op.posege
Please do not use the affected gauze compresses with x-ray thread in the Kitpack procedure packs anymore.

Prosimo, obvestite vse zaposlene, ki uporabljajo te izdelke, o tem varnostnem obvestilu in potrdite, da ne uporabljate prizadetih kompres iz gaze z rentgensko nitjo.

Please inform all employees who use the products about this Field Safety Notice and confirm that you are not using the affected gauze compresses with x-ray thread.

Podpisani potrjuje (prosimo, ustrezno označite)

The undersigned confirms (please tick as appropriate)

- that he will not use the affected gauze compresses with x-ray thread from the Kitpacks /*da ne bo uporabljal prizadetih kompres iz gaze z rentgensko nitjo iz op. setov*
- that he has informed all persons involved about this important information *da je o tej pomembni informaciji obvestil vse uporabnike/vpletene osebe*
- that he no longer possesses the mentioned products *da omenjenih izdelkov ne poseduje več*
- that he has not sold the mentioned products to third parties *da omenjenih izdelkov ni prodal tretjim osebam*
- that he has informed third parties, if they have received the mentioned products from him, of the Field Safety Notice and non-use of the gauze compresses concerned with x-ray thread from the Kitpack procedure packs / *da je obvestil tretje osebe, če so od njega prejele omenjene izdelke o varnostnem obvestilu in o neuporabi kompres iz gaze z rentgensko nitjo iz Kitpack op. setov.*

Please name a contact person in your company: *(Navedite kontaktno osebo v vaši ustanovi)*

Contact Person for Lohmann & Rauscher within your facility:

Kontaktna oseba za Lohmann & Rauscher v vaši ustanovi:

Name *(ime in priimek)* _____ Function *(funkcija)* _____

Telephone number: _____ Email: _____

*Lohmann & Rauscher will get in touch with the named contact person

Adaption on the customer orders

Please enter the products with quantity in the following table:

REF	Product	Lot number (batch)	Quantity (at 25.4.2022)
230907	Kitpack Osnovni OP univerzalni set	193428907, 194158907, 200418907, 201648907, 202518907, 202948907, 204058907, 205048907	0
234369	Kitpack Neurokir. kranio set	194618369	0
234370	Kitpack Set za op. križnih vezi	200758370, 202238370, 203328370	0
236346	Kitpack Laparoskopski set	193448346, 200638346, 201448346, 202918346, 203338346	0
236366	Kitpack Set proteze kolka	299338366, 201138366, 202528366, 204318366, 210628366	0
243089	Kitpack Set laparoskopski	193438089, 202128089, 202838089, 203218089, 204348089	0
249240	Kitpack Set za TUR	195028240, 201258240, 204558240	0
249242	Kitpack Set za kirurgijo roke	201018242, 204548242, 204558242, 204618242	0
249549	Kitpack Žilni set	201148549, 204548549, 204558549, 204618549	0
257819	Kitpack Set za rektum	202018819, 202258819, 204458819	0
15102	Setpack Mullkompresen 10x20/12	20281A091A	0

Customer address data, signature

Date/Signature (datum/podpis): 25.04.2022 podpis : _____

Printed Name (ime tiskano): _____

Position: _____

Department / Institution: _____

Phone and Email: _____