

Nujno varnostno obvestilo

Urgent Field Safety Notice

Address

Sales Division

Lohmann & Rauscher GmbH & Co.KG

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Email: xxx.xxxx@de.LRmed.com

Date: 29.07.2020

Nujno varnostno obvestilo

Urgent Field Safety Notice

zaradi možnosti pretrganja in nitkanja rentgenske kontrastne nitke v kompresah iz gaze (v sestavi KitPack operacijskih setov)
due to breaking and fraying of the x-ray thread in gauze compresses (in KitPack procedure packs)

Spoštovani,

Dear Sir or Madam,

Obveščamo vas o previdnostnem odpoklicu izdelka-komprese iz gaze z kontrastno nitko zaradi možnega pretrganja in nitkanja uporabljene rentgenske nitke. Kompreses iz gaze z rtg-kontrastno nitko so v KitPack op. setih integrirana komponenta seta.

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

Na podlagi povratnih informacij iz treh klinik je postalo znano, da se pod napetostjo rentgenska nit v obremenjenih kompresah iz gaze na posameznih točkah lahko zlomi in na posamičnih točkah tudi zdrobi.

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

Izdelke in serije ki jih je prizadela ta napaka smo nemudoma izločili v karanteno v našem skladišču.

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

Teoretično se lahko pojavijo majhni koščki niti, če se takšna rentgenska nit prekine ali počí. To lahko na primer povzroči vnetje in/ali nastanek granuloma v kolikor ostane 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 te kompreses iz gaze z RK-kontrastno nitko del KitPack operacijskih setov ki so vam bili dostavljeni, morate v interesu varnosti pacientov sprejeti 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, da ne uporabljate prizadetih kompres iz gaze s RK-kontrastno nitko iz KitPack operacijskih setov in jih pred uporabo v operacijski dvorani zavržete. Pred uporabo drugih komponent preverite, ali so morda onesnažene z deli rentgenske niti.

Please do not use the affected gauze compresses with x-ray thread from the Kit-Pack 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 operacijskih posegov in za vzdrževanje nemotene oskrbe pacientov, bomo embalažo KitPack setov 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 s kontrastno nitko. Prosimo, da jih zavržete!

"Attention: Do not use gauze compresses with x-ray thread. Please discard"

To ne bo vplivalo na druge sestavne komponente KitPack operacijskih setov in jih 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.

Prizadete izdelke bo seveda mogoče brezplačno zamenjati ali pa pridobiti dobropis.
The products will of course be exchanged free of charge or credited on request.

V svoji organizaciji zagotovite, da so vsi uporabniki navedenih izdelkov in druge osebe, ki jih bomo obveščali, seznanjeni s tem nujnim varnostnim obvestilom in nam vrnite potrjeno priloženo potrdilo.
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.

V kolikor ste izdelke posredovali tretjim osebam, jim prosimo pošljite kopijo teh podatkov.
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 & Co KG
i.V. / On behalf of LR-SLO

i.V. / On behalf of

29.07.2020
Sales department

XXXYYY
Regional Vigilance Officer

Priloga 1: Nujno varnostno sporočilo zaradi možnosti pretrganja in nitkanja RK-rentgenske kontrastne nitke v kompresah iz gaze (v sestavi KitPack operacijskih setov)

Attachment:

1) Urgent Field Safety Notice due to breaking and fraying of the x-ray thread in gauze compresses (in KitPack proced)

Priloga 1
Enclosure 1

Nujno varnostno sporočilo
Urgent Field Safety Notice!

Date: 29.07.2020

zaradi možnosti pretrganja in nitkanja rentgenske kontrastne nitke v kompresah iz gaze (v sestavi KitPack operacijskih setov)
due to breaking and fraying of the x-ray thread in gauze compresses (in KitPack procedure packs)

(per mail: Tea.Borsic@at.LRMed.com, per Fax an 02634 - 99 xxxx)

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

Adresse:

Opis: Nujno varnostno sporočilo – zaradi možnosti pretrganja in nitkanja rentgenske kontrastne nitke v kompresah iz gaze opremljenih z RK nitjo (v sestavi KitPack operacijskega seta)

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

Ukrepi:
Corrective Actions:

Please do not use the affected gauze compresses with x-ray thread in the KitPack procedure packs anymore.

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.

The undersigned confirms (please tick as appropriate)

Prosimo, da kompres iz gaze s rentgensko kontrastno nitko iz KitPack operacijskih setov navedenih v seznamu na koncu te priloge ne uporabljate!

Prosimo vas, da obvestite vse sodelavce ki uporabljajo te izdelke o tem varnostnem obvestilu in nam potrdite nazaj da teh izdelkov ne uporabljate.

Podpisnik tega obvestila potrjuje, (*prosimo označite s križcem v oklepaju*):

- da ne uporablja prizadetih kompres iz gaze opremljenih s RK-kontrastno nitko iz navedenih KitPack op. setov,
that he will not use the affected gauze compresses with RK thread from the KitPacks,
- da je obvestil vse osebe ki uporabljajo ta izdelek vo tej pomembni varnostni informaciji,
that he has informed all persons involved about this important information
- da navedenih izdelkov nima na zalogi,
that he no longer possesses the mentioned products,
- da navedenih izdelkov ne bo posredoval tretji osebi,
that he has not sold the mentioned products to third parties
- da je v primeru če je tretja oseba dobila od njega navedene izdelke to tudi informiral o vsebini tega varnostnega sporočila in o neuporabi kompres z RK iz KitPack prizadetih op. setov,
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.

