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Urgent Summarized Field Safety Notice/Zusammengefasster Sicherheitshinweis vor Ort

Dear customer,

As manufacturers of the **BIOPSY NEEDLES** listed in this document, we hereby notify you of the issue of a Field Safety Corrective Action relating to the products described (Annex 1 – List of the Impacted batches in German Market).

Sehr geehrter Kunde,

*Als Hersteller der in diesem Dokument aufgeführten **BIOPSY-NADELN** informieren wir Sie hiermit über das Problem einer Korrekturmaßnahme für die Feldsicherheit in Bezug auf die beschriebenen Produkte (Anhang 1 - Liste der betroffenen Chargen auf dem deutschen Markt).*

Explanation of the problem

GTA S.r.l. is a manufacturer of class IIa and IIb medical devices.

The devices are marketed in sterile form, after having undergone an ethylene oxide sterilization process performed by the company Steril Milano Srl.

We have received communication from the sterilizer about the falsification of the process parameters of the sterilization cycles.

So, we conducted a thorough investigation accompanied by sterility tests and residue eto, with positive feedback on all the involved products.

As a precaution, we decide to recall the devices (listed in Annex 1) in stock at our distributors.

With regard to hospitals and health services, the immediate quarantine and segregation of the same devices listed in Annex 1 present in the structure is required.

In Annex no. 1 you can find the list of the affected lots.

Erklärung des Problems

GTA S.r.l. ist Hersteller von Medizinprodukten der Klassen IIa und IIb.

Die Geräte werden in steriler Form vermarktet, nachdem sie einem

Ethylenoxid-Sterilisationsverfahren unterzogen wurden, das von der Firma Steril Milano Srl durchgeführt wurde.

Wir haben vom Sterilisator eine Mitteilung über die Fälschung der Prozessparameter der Sterilisationszyklen erhalten.

Daher führten wir eine gründliche Untersuchung durch, die von Sterilitätstests und Rückstands-Eto begleitet wurde, mit positivem Feedback zu allen beteiligten Produkten.

Als Vorsichtsmaßnahme beschließen wir, die in Anhang 1 aufgeführten Geräte bei unseren Händlern zurückzurufen. In Bezug auf Krankenhäuser und Gesundheitsdienste ist die sofortige Quarantäne und Trennung derselben Geräte erforderlich, die in Anhang 1 der Struktur aufgeführt sind.

In Anhang Nr. 1 finden Sie die Liste der betroffenen Lose.

Clinical impact

The use of non-sterile devices may lead to an increased risk of patient infection.

We would like to specify that GTA Srl has never been notified of adverse events or damage to patients potentially attributable to the problem covered by this report.

There are no specific follow-up actions for patients, where the product has already been used.

Klinische Auswirkungen

Die Verwendung nicht steriler Geräte kann zu einem erhöhten Infektionsrisiko für den Patienten führen.

Wir möchten darauf hinweisen, dass GTA Srl niemals über unerwünschte Ereignisse oder Schäden an Patienten informiert wurde, die möglicherweise auf das in diesem Bericht behandelte Problem zurückzuführen sind.

Es gibt keine spezifischen Folgemaßnahmen für Patienten, bei denen das Produkt bereits verwendet wurde.

All batches of potentially non-sterile devices supplied to your company are listed in Annex 1 "List of Impacted batches"

Actions required to distributors and economic operators

1. Immediately suspend deliveries, identify and quarantine all the items in your possession which are listed in Annex no. 1 "List of Impacted batches".
2. Share this Field Safety Notice within your organization with all interested parties. If you have distributed the products covered by this FSN to third parties, identify these subjects and forward this letter to them immediately, communicating to each hospital the detailed list of the goods subject to this action that have been supplied by you, using the template of the Annex no. 2 "Letter of the Distributor to Hospitals" – Table A1 (making sure to fill in Table A1 with the detail of the article codes and the lots destined for that hospital).
3. Fill in and sign the attached Annex no. 3 "Acknowledgment of the distributor" specifying the quantity of the quarantined goods, including their lot number, their code and inform GTA Srl by sending an email to qa@gta-medical.com and info@gta-medical.com as soon as possible / within 10 days of receipt of this letter.
4. GTA Srl will contact you to organize the collection of the goods. GTA Srl will replace the goods as soon as possible.

Actions required of hospitals and health facilities

1. Immediately discontinue use, identify and quarantine all items listed in Table A1, that are still present at your facility, that are new, unused, and still in their original packaging.
2. Fill in and sign the attached Annex no. 4 "Acknowledgement of hospitals and health facilities" specifying the quantity of the goods placed in quarantine, including their lot number, their code and inform your dealer and GTA Srl by sending an email to qa@gta-medical.com and info@gta-medical.com as soon as possible and in any case within 10 days of receipt of this letter.
3. Wait for information from the distributor and GTA Srl for the handling of the involved goods.

Corrective Actions in place

GTA Srl is completing the qualification of a new supplier for the sterilization process.

Contacts

For further information regarding this FSN please contact GTA Srl at +39.347.2441014 or by email at the address qa@gta-medical.com or info@gta-medical.com and your distributor.

We confirm that the relevant competent authorities have been notified of the actions described herein. We would like to mean that the safety of our devices is a primary objective for us, in issuing this FSN GTA we wanted to maintain a prudent and collaborative approach, we trust to manage the planned actions in the best possible way.

We apologize for any inconvenience this situation may cause. We are available for any clarification.

Yours faithfully,

Maria Vittoria Avaltroni
 QA/RA Manager
 GTA S.r.l.

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Annex1-List of Impacted batches Medical technologies

Name	Description	Code	Lot #	Company
PROCUT	Biopsy Needles	PAG 1820	GT0056/20	
PROCUT	Biopsy Needles	PAG 1820	GT0151/20	
PROCUT	Biopsy Needles	PAG 1825	GT0152/20	
PROCUT	Biopsy Needles	PAG 1825	GT0227/20	
TOTAL 404pcs				