Zeleno. Dotakni me nežno.

TIK d.o.o.
Proizvodnja medicinskih pripomočkov

Goriška cesta 5b,
5222 Kobarid, Slovenija

T: +386 (0)5 389 07 00
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URGENT FIELD SAFETY NOTICE

Medical device brand name: Tikanila 2- IV cannula with injection valve

Number of field safety notice: 15-2019

Nature of measure: Preventive action – voluntary recall

Date: 6.6.2019

Subject: Voluntary recall of medical device – Tikanila 2

Detailed data for affected medical devices:

- Id. (catalogue number) **53951** – Tikanila 2, **G18** – IV cannula with injection valve, batch no. **809549**
- Id. (catalogue number) **53952** – Tikanila 2, **G20** – IV cannula with injection valve, batch no. **805059, 805839, 806549**
- Id. (catalogue number) **53953** – Tikanila 2, **G22** – IV cannula with injection valve, batch no. **806399, 807749, 809539, 811369**
- Id. (catalogue number) **53954** – Tikanila 2, **G24** – IV cannula with injection valve, batch no. **805049, 808899**

Intravenous cannula with injection valve is used for intermittent peripheral intravenous procedures such as:

- Administration of liquid substances and medicines
- Administration of blood or blood products
- Blood sampling

It is marketed in sterile state.

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Potential nonconformity on the products' primary packaging was observed. This can potentially influence the integrity of medical device sterile barrier (primary packaging).

Under certain conditions, seal on the packaging can loosen, consequently not ensuring full protection against medical device contamination before use.

If the device is used according to instructions for use, it does not represent any additional risks for patients or users.

Devices from affected batches shall not be used. If a product with damaged primary packaging is used, potential risk of nonsterile product is present.

Above mentioned batches of medical devices shall be immediately **quarantined** to prevent use of potentially nonconforming products.

Products in question shall be **returned to suppliers** through distributors **or properly discarded.**

At the moment, such complications are not detected. In case of complications (vigilance cases), it is necessary to report them to National Competent Authority.

This instruction shall be forwarded to **all customers for devices in** question, in whole distribution chain, down to end users.

Our company policy binds us to ensuring safety for patients and users of all our products. Therefore, our actions are always directed towards care for user safety. We sincerely apologize for any inconvenience this event has caused.

Thank you for your cooperation and understanding.

Reference person for contacts:

Maja Faletič

Goriška cesta 5b

5222 Kobarid

00386 5 389 07 02

maja.faletic@tik.si

Signature below confirms that Slovenian National Competent Authority (JAZMP) was informed on this safety notice.

Signature:

Petra Borovinšek, general manager

TIK d.o.o.

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Form for customer/user – confirmation of acquaintance with content and instructions:

Company or institution	
Country	
Address	
Contact person	
E-mail	
Telephone	
Signature	
Date	

Signature above confirms that we are acquainted with the content of the notice, we understand it and (circle the suitable indent):

- We destroyed all products from affected series of medical devices
- We returned all products from affected batches to our supplier
- We confirm that products from affected batches were never present in our institution/company.

List of affected medical devices' inventory:

Destroyed devices		Returned devices	
Batch	Qty.	Batch	Qty.

Return signed and filled form to info@tik.si within 7 days after receipt (subject: Voluntary recall).

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