FSN ref. : 2020-01

Date: 2020-11-13

Urgent Field Safety Notice (FSN) regarding Vivostat devices

For the attention of: medical doctors, nurses, perfusionists and medical technicians

For further information and questions related this FSN please contact (please insert name and contact details of local representative)

Information on affected devices

The notice relates to all single use Vivostat products (not specific to any code or batch number). All sets are supplied sterile.

1. Device types and commercial names

Vivostat fibrin set	Vivostat PRF set	Vivostat Obsidian set
		

plus Vivostat application kits (ref appendix 1)

2. Primary clinical purpose of devices

The products are used to achieve hemostasis, tissue sealing and – gluing and support tissue regeneration.

3. Devices catalogue numbers

Please refer to appendix 1 (Vivostat Product list 2020)

Reason for the Field Safety Corrective Action (FSCA)

1. Description of the product problem/Hazard giving rise to the FSCA

Vivostat has become aware of a **sterility problem** of the reagents of one of its sub suppliers due to outstanding revalidation of the sterilization process. The conclusion is relevant to all sterile products manufactured by our supplier over a period of 5 years. The conclusion does not specifically relate to products manufactured for Vivostat but applies to all sterile products manufactured by this Swiss supplier irrespective of the customer. The following sterile reagents for Vivostat are affected by this notice:

- Citrate/TA – fibrin (20 ml vial)
- Citrate/TA – PRF (20 ml vial)
- pH 10 – (5 ml vial)

These reagents are included in **all single use kits and sets** from Vivostat.

2. Probability of problem arising

Every single batch of Vivostat reagents received from Legacy during the last 5 years in question has been tested for sterility by an external lab and none have failed. More than 80% of the reagents manufactured during the 5 year period have already been used in the market and we have received no complaints or been made aware of any unexpected infection that could potentially be related to lack of sterility.

Type of Action to mitigate the risk

We ask your support in ensuring that all affected products are identified and traced and that below actions are performed.

Action to be taken

1) Identify all products and **quarantine all disposable Vivostat products** at your facility. Please make sure none of the affected products are used as the sterility can't be guaranteed.
2) Please fill out the Reply Form in Appendix 2 (Form A) with quantity of identified product. Please sign and email the Reply Form per its instruction within 5 business days.

Action being taken by the Manufacturer

Vivostat has initiated production of new batches of the affected reagents at another of our suppliers. Due to the lead time in receiving raw material and packaging material and the time required to test the raw material prior to manufacturing and test the final product for sterility replacement products will not be available before early December.

General Information

The Competent Authority of your country has been informed about this FSN and received a FSCA report from Vivostat and the Danish Medicines Agency has issued a National Competent Authority Report (NCAR).

2. Follow-up anticipated

We will contact you again as soon as replacement vials are available to arrange an exchange/ replacement. We anticipate this to happen during the first 2 weeks of December

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization/hospital or to any department/ward where the potentially affected devices have been transferred (if relevant).

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action (until affected vials have been exchanged).

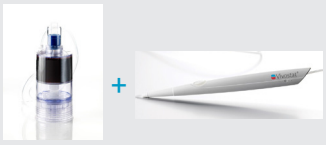
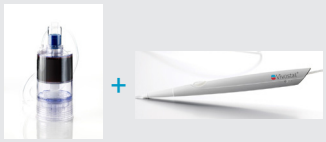
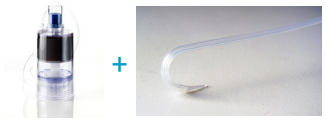
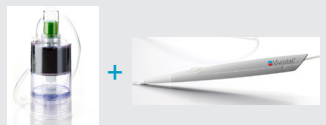
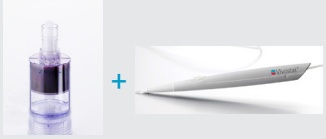
Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

We sincerely apologize to you and your patients and hope for your understanding and continued support to Vivostat and our products.

For questions to this FSN see top for contact details.

Vivostat® Product List 2020

Vivostat®

Ref. no.	Product	Units	Illustration
- Fibrin Set (Preparation Kit and Application Kit)			
VS 302	Fibrin Set	10	
VS 312	Fibrin Set - Concorde	10	
VS 322	Fibrin Set - Co-Delivery	10	
VS 323	Fibrin Set - Endoscopic	10	
- PRF® Set (Preparation Kit and Application Kit)			
VS 400	PRF® Set	10	
VS 410	PRF® Set - Concorde	10	
VS 420	PRF® Set - Endoscopic	10	
VS 422	PRF® Set - Co-Delivery	10	
- OBSiDiAN ASG® Set (Preperation Kit and Application Kit)			
GM 700	OBSiDiAN ASG® Set	10	
GM 720	OBSiDiAN ASG® Set - Endo[1,2]	10	

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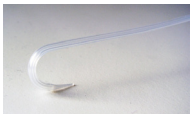
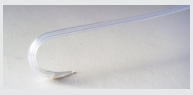
Ref. no.	Product	Units	Illustration
- OBSiDiAN RFT® Set (Preperation Kit and Application Kit)			
GM 740	OBSiDiAN RFT® Endo Straight - Co-delivery Set[2]	10	
- Application Kit (Including all necessary components for Application)			
VS 305	Spraypen® Kit	4	
VS 315	Spraypen® Kit - Concorde	4	
VS 325	Endoscopic Kit[1]	4	
VS 335	Spraypen® Kit - Co-Delivery	4	
VS 345	Endoscopic Kit - Straight[2]	4	
VS 355	Endoscopic Kit - Co-Delivery[1]	4	
- Preparation Kit (Including all necessary components for Preparation)			
VS 306	Fibrin Preparation Kit	10	
VS 406	PRF® Preparation Kit	10	

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Appendix 2

Form A

Return reply: Field Safety Notice regarding vials

1. We have received and understood the FSN ☐ Yes ☐ No

2. We intend to send the FSN to all customers having ordered affected products within the last 24 months

☐ Yes ☐ No

3. We will prepare a list of all customers having ordered Vivostat products within the last 24 months

☐ Yes ☐ No

4. We will ask customers for a return reply and follow-up two times if no reply

☐ Yes ☐ No

5. We intend to replace all affected vials in our country

☐ Yes ☐ No

_____ _____

Country Name

_____

Signature

Please e-mail to: chm@vivostat.com