

08 December 2021

Urgent Field Safety Notice

concerning

Sterile disposable bipolar forceps cable

Sender:

Seemann Technologies GmbH
Thomas Seemann – Managing Director
Panoramastraße 20
D-78583 Böttingen
Germany

Addressee:

The Safety Notice targets users and distributors

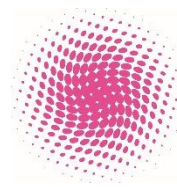
Identification of the affected medical devices:

Sterile disposable bipolar forceps cable
Item Nos ST-99-401 – ST-99-404

Description of the problem and of the root cause:

In the course of a certification audit by the Notified Body, it was noticed that the company Seemann Technologies GmbH markets sterile disposable bipolar forceps cables with HF connection separately as individual products.

The sterile disposable bipolar forceps cables are listed on the EC Directive certificate of the Notified Body not as a Class I sterile product, but as “accessories” to the sterile bipolar forceps with HF connection. Therefore, the sterile disposable bipolar forceps cables with HF connection must not be placed on the market as individual products.



The aforementioned sterile disposable bipolar forceps cables may therefore be used only together with sterile bipolar forceps with HF connection by Seemann Technologies GmbH. Due to the sale of the individual sterile disposable bipolar forceps cables, it cannot be ruled out that these Seemann forceps cables are used together with HF forceps by another manufacturer. This must be ruled out.

Should an unauthorised combination of Seemann forceps cables with HF forceps by another manufacturer have taken place, the risk to patients, users or third parties is considered low, as the sterile disposable bipolar forceps cables can indeed be used with suitable HF forceps by another manufacturer. This does not reduce or limit the function of the HF forceps by another manufacturer. This can be proven by the fact that no complaints or reports of malfunctions have been received by Seemann Technologies GmbH to date which would have indicated this.

There is no risk to patients who have already been treated with the affected products. This can be proven by the fact that no complaints or reports of malfunctions have been received by Seemann Technologies GmbH to date which would have indicated this.

Corrective actions:

The inventory of sterile disposable bipolar forceps cables at Seemann Technologies GmbH was immediately blocked and quarantined, so that further placing on the market is excluded.

Customers are requested in writing and by telephone to return individual sterile disposable bipolar forceps cables with any of the item Nos: ST-99-401 – ST-99-404 to Seemann Technologies GmbH. The individual sterile disposable bipolar forceps cables are withdrawn from the market and no longer marketed.

Actions to be taken by the addressees:

This Safety Notice is to be immediately forwarded by the addressees to their customers. Customers are requested to return all sterile disposable bipolar forceps cables with any of the item Nos: ST-99-401 – ST-99-404 to Seemann Technologies GmbH. This must be confirmed in writing on the return form.

Time schedule for the implementation:

The return must be completed by calendar week 03/2022.

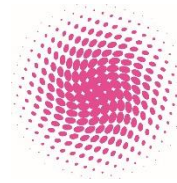
Contact:

Thomas Seemann – Managing Director
Tel: +49-7429-9300388
Fax: +49-7429-9300390
Email: thomas@seemann-technologies.com

We ask for your understanding for this measure and thank you for your support.

Yours sincerely,

Customer address



SEEMANN
TECHNOLOGIES

08 December 2021

URGENT Field Safety Notice: Medical Device Recall

Reference: Sterile disposable bipolar forceps cable

Affected product: Sterile disposable bipolar forceps cable
Item Nos ST-99-401 – ST-99-404

Ladies and Gentlemen:

With the present letter, we would like to inform you that Seemann Technologies GmbH needs to issue a product recall due to a regulatory error.

The affected products were shipped with the item Nos ST-99-401 – ST-99-404.

This field measure is carried out with the knowledge of the competent regulatory authorities.

Actions	<ol style="list-style-type: none">1. Check your inventory and block any unused affected products immediately.2. Return the blocked products to us.3. Send the completed Return Form by fax or email to Seemann Technologies GmbH Fax: +49-7429-9300390 Email: thomas@seemann-technologies.com4. Please ensure that this Safety Notice is forwarded within your organisation to all persons who need to know about it.5. In order to ensure effectiveness of the field measure, please keep track of this information and the resulting actions until completion of the measure.
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For any questions pertaining to this field measure, please contact us at:

Seemann Technologies GmbH
Thomas Seemann – Managing Director
Panoramastraße 20
D-78583 Böttingen, Germany
Tel.: +49-7429-9300388
Fax: +49-7429-9300390
Email: thomas@seemann-technologies.com

Return Form

Please fill in this form sheet and send it to the above contact (this avoids repeated requests)

We hereby confirm that we are aware of the Safety Notice regarding the sterile disposable bipolar forceps cable. The Safety Notice was forwarded within our organisation.

Please tick as appropriate:

- There are no affected products in stock at our facility.
- Shipping of products to non-European countries
- We are returning the following products:

Item	Description	Qty	Batch / Lot	Invoice No	Date	Quantity returned

Facility: _____

Name: _____

Date / Signature: _____