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## **URGENT FIELD SAFETY NOTICE**

**Cousin Biotech FSN # 2017-01-04**

**Date:** 04 January 2017

### **Concerned product references:**

GCBCYSTOSU (BIOMESH® SOFT PROLAPS)  
GCBINSOFTU (SOFT LIFT®)  
GCBINLIFTU (LIFT®)  
GCBRECTOSU (BIOMESH® SOFT PROLAPS)  
GCBINSLXLU (SOFT LIFT®)

The BIOMESH®SOFT PROLAPS devices are designed to be used for support purposes in the surgical treatment of genital prolapse via vaginal approach. The LIFT® and SOFT LIFT® devices are designed for the surgical treatment of female stress incontinence.

- **This Field Safety Notice concerns the references listed above (packaged kits in blisters) with batch numbers strictly less than 163172 for which the expiry date is still valid.**
- **It does not concern the other sterile urogenital implants which are packaged in double pouches.**

### **Description of the issue:**

This field safety corrective action (FSCA) has been initiated due to simulation tests during transport in critical conditions on GCBCYSTOSU products according to Program 13 of ASTM D4169. For some products, it has been observed that the PETG product support plate can unclip after significant, excessive and repeated impacts and then can damage the sterile barrier. In this case, there is a potential risk of sterility loss.

It is important to note that our Post-Market Surveillance data did not show any customer complaints relative to this kind of issue. This has never happened and the occurrence of this situation can be considered as unlikely because the shocks must be serious, excessive and repeated.

As a precaution, Cousin Biotech has decided to inform the customers of the risk detected and on the importance to respect the below recommendations.

### **Actions by the manufacturer Cousin Biotech:**

We decided to review the packaging design by adding a fixing system in the packaging to prevent any movement of the support plate. This solution will be validated thanks to simulation tests during transport. The urogenital implants packaged in blisters with batch numbers greater than or equal to 163172 are not concerned by the field safety notice

### **Actions to be taken by customer (user):**

#### **WARNINGS AND RECOMMENDATIONS**

As it is written in the current Instructions For Use provided by Cousin Biotech, the user must “Inspect the packaging to be sure it is intact (do not use if protective packaging is damaged). Do not use if the device is damaged or out of date.”

Before beginning the surgical procedure (implantation of one of the product references listed above), the customer must inspect the kit and its packaging in order to check that the PETG support plate is well clipped.

If the PETG support plate is well clipped, the kit can be used and the product can be implanted (see Figures 1 and 2 below).

If the PETG support plate is unclipped, the kit cannot be used and the product must not be implanted (see Figure 3 below). In this case, please follow the waste disposal rules of your health centre.



**Figure 1 – PETG support plate well clipped**



Clipped

THE KIT CAN  
BE USED

**Figure 2 – PETG support plate well clipped**



Unclipped

THE KIT  
CANNOT BE  
USED

**Figure 3 – PETG support plate unclipped**

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to end users, on to all those who need to be aware within your organisation or to any organisation (healthcare centres) where the potentially affected devices have been sent.

Please forward this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Contact reference person:**

If you have any additional questions, please send an email to [f.pelletier@cousin-biotech.com](mailto:f.pelletier@cousin-biotech.com)

The undersigned confirms that the relevant National Competent Authorities have been advised of the FSCA.



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Franck Pelletier  
Regulatory Affairs Director  
Vigilance Correspondent

# **URGENT FIELD SAFETY NOTICE**

Cousin Biotech FSN # 2017-01-04

**YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED BY E-MAIL TO THE FOLLOWING ADDRESS: [n.domingues@cousin-biotech.com](mailto:n.domingues@cousin-biotech.com)**

**A response is required 15 calendar days after receipt of this Field Safety Corrective Action (FSCA) letter.**

1. I have read and understood the field safety corrective action instructions provided in this letter.

Yes     No

2. Do you have one of the following product references (GCBCYSTOSU, GCBINSOFTU, GCBINLIFTU, GCBRECTOSU, GCBINSLXLU) at your facility? (If no, please sign and return this document)

Yes     No

If you have products concerned at your facility:

3. Do you understand the instructions provided by Cousin Biotech and have you forwarded the instructions to the end users?

Yes     No

Company Representative:

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First Name

Last Name

---

Organization Name

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Email Address

Telephone Number

---

Signature

Date