

**Urgent: FIELD SAFETY NOTICE**

**Disposable Automatic Biopsy Gun ABG-2020 / ABG-2040**

**Disposable Semi-Automatic Biopsy Gun SBG-2010**

**Type of Action: Product Recall**

**For Attention of: Users, clinical staff, distributors, and authorized representatives of  
Möller Medical**

**This letter contains important information that requires your **immediate** attention.**

Dear Customer and/or Business Partner,

Möller Medical is conducting a field safety corrective action to recall affected lots of the following products:

- **Disposable Automatic Biopsy Gun ABG-2020 / ABG-2040** and
- **Disposable Semi-Automatic Biopsy Gun SBG-2010**

In Appendix 1 you will find the list of the product reference numbers (REF) and the affected lot numbers (LOT). Information on the products can be found in Table 1.



**Description of the problem:**

Möller Medical was informed that a third-party provider of sterilization services has allegedly intentionally falsified sterilization process records in connection with the processing of Möller Medical products.

Möller Medical has immediately carried out an investigation and determined that the sterility of the products listed in Appendix 1 cannot be guaranteed. For this reason, the product lots listed in Appendix 1 are temporarily blocked for use on patients.

The scope of this product recall includes all lots listed in Appendix 1.

**Table 1:** Disposable Automatic Biopsy Gun ABG-2020 / ABG-2040 and Disposable Semi-Automatic Biopsy Gun SBG-2010

Product	Purpose
<b>Disposable Automatic Biopsy Gun ABG-2020 / ABG-2040</b>	
	Use for taking tissue samples / Sterile single-use product
<b>Disposable Semi-Automatic Biopsy Gun SBG-2010</b>	
	Use for taking tissue samples / Sterile single-use product

### **Clinical effects:**

The use of non-sterile products in a clinical setting can lead to an increased risk of infection, which can cause serious damage or life-threatening conditions. Möller Medical has not received any reports of adverse events or serious patient harm that could be associated with this field safety corrective action. If the product has already been used, no special patient follow-up care is required.

### **Actions to be taken by the customer and / or business partner:**

1. Use Appendix 1 to identify the affected lot numbers (LOT) in your inventory.
2. Discontinue the use of all affected lot numbers (LOT) in your possession.
3. Separate the affected lot numbers (LOT) until the assessment is complete to avoid unauthorized access.
4. Möller Medical will keep you informed on how to proceed.
5. Share this safety alert with anyone in your organization who needs to be informed. If you have passed the products on, please identify the customers concerned, and forward this notification to them immediately.
6. Fill out the answer form on page 4 and send it back to [QM@moeller-medical.com](mailto:QM@moeller-medical.com) **immediately, but no later than March 31, 2021**, so that we can offer you an alternative as soon as possible.

**Corrective action by Möller Medical**

Blocking of the products listed in Appendix 1 for use and sales until further information is provided. The availability of the affected products is still guaranteed, as an alternative sterilization facility is qualified for these products.

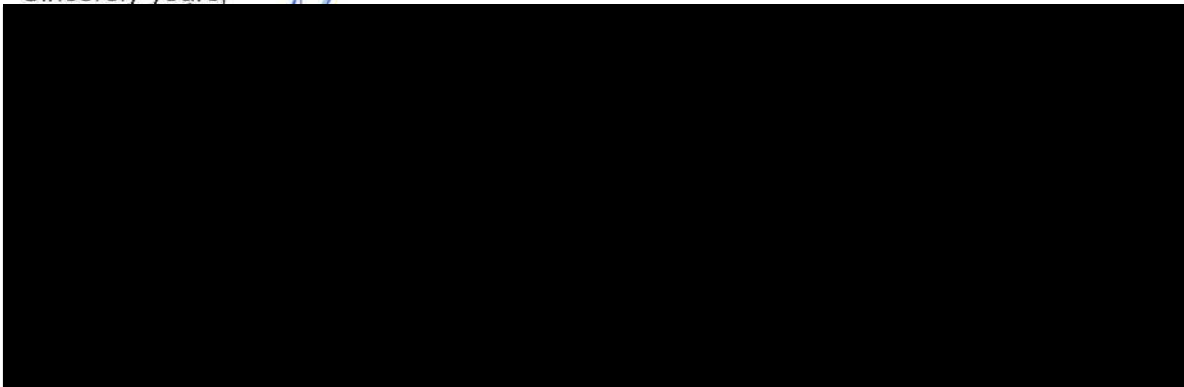
**Contact Person**

If you have any questions, please get in touch with your local contact person or by phone **+49 (0) 661 94195 0** or email [QM@moeller-medical.com](mailto:QM@moeller-medical.com).

We confirm that the responsible authorities have been or will be informed about these activities.

We apologize for the inconvenience this situation may cause and thank you in advance for helping to resolve this matter as quickly and effectively as possible.

Sincerely yours,



## Answer Form

### Disposable Automatic Biopsy Gun ABG-2020 / ABG-2040 and Disposable Semi-Automatic Biopsy Gun SBG-2010

Please read the urgent field safety notice “CAPA 0052-QM” and send the completed and signed form as soon as possible, but no later than **March 31, 2021** to [QM@moeller-medical.com](mailto:QM@moeller-medical.com).

**I confirm that I have read and understood this notice and that all recommended measures have been implemented as required.**

Check the appropriate box below:

We do not have any of the affected products as listed in Appendix 1 in our possession.

or

We have the affected products listed in Appendix 1 and I certify that the following products have been blocked as detailed below.

Product Reference Number (REF)	Lot Number (LOT)	Blocked Quantity	Product Reference Number (REF)	Lot Number (LOT)	Blocked Quantity

<b>Customer / Business Partner Name:</b>	
<b>Department (if applicable):</b>	
<b>Address:</b>	
<b>Postcode, City:</b>	
<b>Contact Name:</b>	
<b>Job Title:</b>	
<b>Contact Phone Number:</b>	
<b>Contact email Address:</b>	
<b>Date, Signature:</b>	

This form must be returned to Möller Medical immediately.

**Appendix 1: Affected Product Reference Numbers (REF) and Lot Numbers (LOT)**

<b>Product Reference Numbers (REF)</b>	<b>Product Description</b>	<b>Lot Numbers (LOT)</b>
ABG-2020-18-0200	Disposable Automatic Biopsy Gun 18G	20051240
ABG-2040-14-0150	Disposable Automatic Biopsy Gun 14G	20041022
ABG-2040-14-0200	Disposable Automatic Biopsy Gun 14G	2003871
ABG-2040-16-0200	Disposable Automatic Biopsy Gun 16G	20061421
ABG-2040-18-0100	Disposable Automatic Biopsy Gun 18G	20092227
ABG-2040-18-0200	Disposable Automatic Biopsy Gun 18G	2003831
SBG-2010-14-0100	Disposable Semi-Automatic Biopsy Gun 14G	2002524
		2003786
SBG-2010-14-0150	Disposable Semi-Automatic Biopsy Gun 14G	20051248
SBG-2010-16-0100	Disposable Semi-Automatic Biopsy Gun 16G	20041100
SBG-2010-16-0150	Disposable Semi-Automatic Biopsy Gun 16G	20092108
SBG-2010-16-0200	Disposable Semi-Automatic Biopsy Gun 16G	2002517
SBG-2010-18-0100	Disposable Semi-Automatic Biopsy Gun 18G	200131
		2002427
SBG-2010-18-0150	Disposable Semi-Automatic Biopsy Gun 18G	200117
		20061466
SBG-2010-18-0200	Disposable Semi-Automatic Biopsy Gun 18G	19123128
SBG-2010-20-0100	Disposable Semi-Automatic Biopsy Gun 20G	20071718
SBG-2010-20-0150	Disposable Semi-Automatic Biopsy Gun 20G	20071713