BIOPSYBELL S.R.L. Via Aldo Manuzio 24 - 41037 Mirandola (MO) – Italy
T. +39 0535 27850 - F. +39 0535 33526 - - www.biopsybell.it

URGENT: SAFETY NOTICE – FSN02-2021

Biopsybell medical devices

Type of action: Immediate stop of product use

For the attention of: Distributors, Clinical Personnel, End Users
This letter contains important information that requires your immediate attention.

Dear Customer,

BIOPSYBELL SRL is conducting a Field Safety Corrective Action requesting to STOP with immediate effect using the Biopsybell devices with codes and batches listed in annex to this communication.

Description of the problem

BIOPSYBELL SRL has been informed by one of its sterilization service suppliers of a potential risk of incorrect sterilization of product batches sterilized by this supplier.

As part of the product release procedure, Biopsybell systematically checks all the technical information associated with sterilization of each single batch together with other product manufacturing and test information and formally releases the product on the market only when the outcome is positive.

Due to wilful falsification of the sterilization data and certificates by the supplier, it was not possible to intercept and identify any sterility problems.

This advisory warning applies to the product codes and batches listed in the annex.

Description of the devices involved

The devices involved are all Biopsybell devices with the codes and batches listed in the annex. Biopsybell also uses another supplier for the sterilization service, who is NOT involved in this problem. Therefore, **batches not listed in the annex can be used as they are not impacted by the sterilization problem.**

Clinical impact

The use of non-sterile devices in a clinical environment may lead to an increased risk of infection, which in extreme cases may cause severe harm or potentially lethal conditions.

BIOPSYBELL SRL has to date not received any notification of adverse events or harm to patients, which might be associated with this field safety corrective action.

Request to clinical users:

1. **Immediately stop using all products belonging to the batches listed in the annex still in your possession and contact Biopsybell/Biopsybell Representative for product return/disposal and related replacement.**
2. **Use products with codes and batches not listed in the annex available in your warehouse.**
3. **Contact your local BIOPSYBELL representative to discuss possible product alternatives.**
4. **Contact BIOPSYBELL or your Biopsybell representative in case of urgency or need for immediate replacement.**

Action requested from the local distributor and customer

1. **Circulate this safety notice to anyone in your organisation that needs to be aware of the problem.**
   - **If the product has been distributed further, identify the facilities/organisations involved and immediately forward this notice.**
2. **Place all products of the impacted batches in quarantine, awaiting the product return/disposal and related replacement, then complete the customer response form returning it to international1@biopsybell.it or international2@biopsybell.it, or to your local Biopsybell representative, as soon as possible.**

BIOPSYBELL corrective actions

Biopsybell makes itself available to receive the involved parts still available in your warehouse and to replace them, after completing the form below and prior agreements with Biopsybell.

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Contact person

Should you have any questions on this letter, please contact:

Information	Contact
Technical and commercial information for abroad	e-mail: international1@biopsybell.it telephone: +39-0535-27850 e-mail: international2@biopsybell.it telephone: +39-0535-27850

We wish to underline that BIOPSYBELL's main objectives have always been the safety of patients and operators and the supply of quality products in full compliance with the regulations in force. We regret any inconvenience caused, but are also aware that we have done everything possible to prevent this situation. Nonetheless, as this was a case of wilful falsification by an external third party and we consider ourselves the injured party, we could not have prevented what occurred despite every possible control on our part and on the part of the Competent Bodies in charge of this control at this supplier. Thank you in advance for the support provided to BIOPSYBELL to solve this problem in as fast and effective a way as possible.

MIRANDOLA, 07/04/2021

BIOPSYBELL SRL

VICE PRESIDENT OF THE BOARD OF DIRECTORS

CARLO RICCA PRANDI BELLINI

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Customer response form – FSN02-2021- BIOPSYBELL SRL medical devices

Read together with the safety notice FSN02-2021 and return the completed and signed form as soon as possible to:

international1@biopsybell.it; international2@biopsybell.it

- **I confirm that this communication has been read and understood and that all the recommended actions have been implemented as requested.**

Tick the appropriate box below:

☐ We have none of the impacted devices listed in the annex

OR

☐ We have in our possession units of the impacted devices listed in the annex and confirm that the following units have been placed in quarantine and will NOT be used

CODE	BATCH	QUANTITY IN QUARANTINE

BIOPSYBELL S.R.L. Via Aldo Manuzio 24 - 41037 Mirandola (MO) – Italy
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Facility name:	
Department (*if applicable*):	
Address:	
Postal code:	**City:**
Contact name:	
Professional role within the organisation:	
Contact phone number:	**Contact e-mail address:**
Signature and stamp:	**Date:**

This form must be returned to BIOPSYBELL before this action can be considered closed for your facility.