



Fabio v. Zeppelin
Safety Officer

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Urgent Safety Notice regarding MSI Biopsy Instruments / Product Recall

EN-FSN_FSCA_012019_MI001

To whom it may concern,

this safety information is intended for users, operators and distributors of the above-mentioned medical devices. Please make the following information available to all other employees for whom this notification is relevant. It is important that the meaning of this notification is understood.

The following MSI Biopsy Instruments are affected:

Art. Nr. MSI 08 Batch No. FS, LT, FV, ES, 00890960, JR, JL

Art. Nr. MSI 02 Batch No. 056548, JL

Art. Nr. MSI 04 Batch No. KQ, CV

Art. Nr. MSI 04/SA1 Batch No. KJ

Art. Nr. MSI 04/SA2 Batch No. LR

Art. Nr. MSI 04/SVS Batch No. LR

Art. Nr. MSI 04-190 Batch No. KJ

Art. Nr. MSI 06-190 Batch No. IL

Art. Nr. MSI 06/SA1 Batch No. KJ

Art. Nr. MSI 12-190 Batch No. 0707-07, 0807-07

adeor medical AG recalls all MSI biopsy instruments placed on the market due to their classification in a risk class that is too low. According to current knowledge, incorrect application of the classification regulations has led to the incorrect classification described above.



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From our point of view, there is currently no increased risk for patients, users or third parties when continuing to use the product. However, please discontinue the use of the affected products immediately. From our point of view, there is currently no increased risk for patients who have already been treated with affected products. No special recommendations for patients or the treatment/aftercare of patients treated with affected products are necessary.

Our sales department or field staff will contact you directly in the coming days to coordinate and carry out the recall of the affected products with you. We will do our best to minimize the negative consequences of this recall for you.

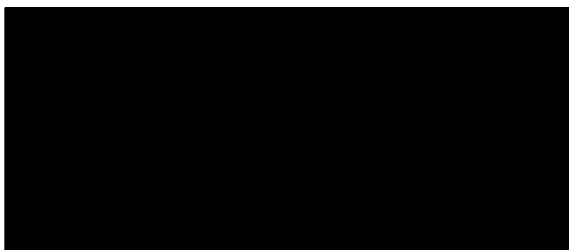
We plan to implement the described measure within the next 4 weeks.

If you have any questions about this product recall, please contact:

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Please excuse the inconveniences caused by this product recall.

Best regards,



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Annex 1 – FSCA Proof - FSN_FSCA_012019_MI001

Customer	Products	Date	Signature

This is to confirm that all products still available at the respective customer and affected by the FSCA have been withdrawn from circulation.

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