Urgent Product Safety Information

Recall - FA2021-01

regarding

ICT5011 / i-Cut

20.08.2021

Dear Customer

For A.M.I. the quality and safety of our products are paramount. Therefore, as a precaution, we would like to inform you, that in isolated cases, under unfavorable circumstances, difficulties within the electronic may occur in the LOT mentioned below.

There is a potential risk that the affected product cannot be switched off after usage without removing it from the power.

Sender:	A.M.I. Agency for Medical Innovations GmbH Im Letten 1 6800 Feldkirch, Austria
Addressee:	Distributors, safety officers at clinics and hospitals

Identification of the medical devices concerned:

Article number(s):	ICT5011
Product description:	i-Cut
Product category:	Tissue morcellation system handpiece, line powered
Batch number(s) (LOT):	191878, 200319, 201885, 201944, 210166, 210153
UDI-DI	+EAMIICT50110

Description of the problem including the identified cause:

- The cause of the malfunction that the unit cannot be switched off in very exceptional situations, is due to an electronic fault.
- Inappropriate misconduct by the user could result in possible harm to the patient, so it is advisable to strictly follow the instructions for use:

Warning ⚠	In case of an error of the i-Cut activation button, if the device does not stop, put adjustment wheel into "CLOSED" position and immediately unplug the power cord. Exchange the defective device for a new one.

- For patients who have already been treated with the products, there is no subsequent risk.

What measures are to be taken by the addressee?
According to our records, you have been supplied with at least one of the products/batches listed above and are therefore affected by this action.

Please read this letter carefully and take the following measures:

- Quarantine the affected products. These must not be used.
- Return your inventory of the batches listed to us. Please use the enclosed reply letter. No measures are planned for those products that have already been used.
- Bring this safety information within the organization to everyone who needs to know about it.
- Forward this safety information to any organization or person to whom you have submitted affected products.
- No further action is required for patients who have received treatment.
- Send the completed response form to the fax number, e-mail address, or mailing address on the form by September 27, 2021.

Forward of this information:

This notice must be shared with everyone involved in your organization or others in the organizations that should know, are affected, or to whom you have passed the affected articles.

If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the action has been completed.

The relevant authority in your country have been informed about this “Urgent Product Safety Information”.

Contact:

Philipp Steinert
Head of Product Management
A.M.I. Agency for Medical Innovations GmbH
Tel.: +43 5522 90505-4008 (during business hours)

Thank you in advance for your prompt response to this matter.

Please be informed that we have already optimized the product to ensure that such an error can be excluded with the currently produced quantities.

We apologize for the inconvenience caused to you by this deviation and will immediately replace the returned products.

Sincerely,

Philipp Egle

Head of Quality Management and Quality Assurance
A.M.I.® Agency for Medical Innovations GmbH

Customer response form

Recall - FA2021-01

Article number(s):	ICT5011
Product description:	i-Cut
Product category:	Tissue morcellation system handpiece, line powered
Batch number(s):	191878, 200319, 201885, 201944, 210166, 210153
UDI-DI	+EAMIICT50110
Sender:	A.M.I. Agency for Medical Innovations GmbH Im Letten 1 6800 Feldkirch, Austria

RAN 2021-_____ (please enter the customer-specific RAN here)

We: _____

_____

_____

hereby confirm receipt of the urgent security information / FSN-ID FA2021-01

hereby confirm that the following products will be returned

LOT _____	_____ Piece	LOT _____	_____ Piece
LOT _____	_____ Piece	LOT _____	_____ Piece
LOT _____	_____ Piece	LOT _____	_____ Piece

hereby confirm that the following products have already been used

LOT _____	_____ Piece	LOT _____	_____ Piece
LOT _____	_____ Piece	LOT _____	_____ Piece
LOT _____	_____ Piece	LOT _____	_____ Piece

Name _____

Date _____

Signature _____

Please return the together with the products by fax or e-mail to A.M.I.

A.M.I. Agency for Medical Innovations GmbH
Im Letten 1 . 6800 Feldkirch . Austria . t +43 5522 90505-0 . f +43 5522 90505-4006 e info@ami.at . www.ami.at . FN 176676v . LG Feldkirch