



ALCIS SARL

Urgent Field Safety Notice

Date: 24 November 2017

For the attention of: Healthcare Professionals and Distributors

Commercial name of the affected product: **Connection Cable – 2069-CE**

Manufacturer: Alcis

Alcis Reference Number: RC 17/083

Type of action: Recall

Details on affected products:

Devices concerned by this recall are the ones listed in the table below and distributed before **08 November 2017**.

Device	Commercial Reference	Lot Number	Quantity
Connection cable 12 contacts	2069-CE12C-150-B-FB5	16/495	7
		16/683	3
		17/148	2
Connection cable 15 contacts	2069-CE15C-150-B-FB5	16/552	8
		17/108	9
Connection cable 18 contacts	2069-CE18C-150-B-FB5	16/549	2
		17/093	7

Description of the problem:

Connection cable (2069-CE) are accessories of depth coagulation electrodes (2069-EPC) manufactured by ALCIS.

ALCIS has been aware of two (2) complaints from healthcare professionals reporting the breakage of the depth coagulation electrode's connector. This breakage occurred while disconnecting the electrode from the connection cable.

This electrode connector breakage made its use impossible and has required a surgical intervention to replace the defective electrode.

Investigations performed have highlighted a default on the connection cable's connector.

Electrical contacts of the connector have a higher tensile strength as usual, inducing a higher strength required by the user to disconnect the two devices.



ALCIS SARL

ALCIS proceeds to the recall and replacement of these connection cables.

Advice on action to be taken by the user:

1. Please review the attached list of affected products and lot numbers and quarantine any affected product.
2. Immediately collect and return all affected products to Alcis.

Alcis
Les hauts du Chazal - Témis Santé
2 rue Paul Milleret– Bat. BIOPARC
25000 BESANCON
France

Please contact our customer service to define pick up arrangement (commercial@alcis.net - +33 (0)3.81.61.69.93).
Returned products will be exchanged as soon as possible.

3. Please complete the enclosed form acknowledging of the receipt of this field safety notice by sending it back by email to regulatory@alcis.net or by fax +33 (0)3.81.53.47.65

Transmission of the field safety notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations 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:

Jean-François Delforge – CEO

Alcis
Les hauts du Chazal - Témis Santé
2 rue Paul Milleret – Bat. BIOPARC
25000 BESANCON
France



ALCIS SARL

Should you have any question, please feel free to contact us for further information (email: regulatory@alcis.net, phone: +33 (0)3.81.61.69.93)

We confirm that this notice has been notified to the appropriate competent authorities.

Jean-François Delforge
ALCIS CEO

Annex: Acknowledgment form



ALCIS SARL

Acknowledgement receipt of this field safety notice referred Alcis RC 17/083

Please complete and return this form to:
email: regulatory@alcis.net or fax: +33 (0)3.81.53.47.65

Please tick off the boxes accordingly:

We hereby confirm that we are aware of this field safety notice concerning the product.
The field safety notice was communicated within our organization, and if required, to
any other organization having affected products

In our facility, we do not have any of the affected products in stock

Or

We have quarantined and will return the following products:

Device	Commercial Reference	Lot Number	Quantity
Connection cable 12 contacts	2069-CE12C-150-B-FB5	16/495	7
		16/683	3
		17/148	2
Connection cable 15 contacts	2069-CE15C-150-B-FB5	16/552	8
		17/108	9
Connection cable 18 contacts	2069-CE18C-150-B-FB5	16/549	2
		17/093	7

Institution (name and address):

Phone:

Name:

Date / Signature: