
Field Safety Notice

Potentially defective seal in aluminium pouch

CPA-17-003

Request for visual inspection of the pouches

Date: 24.2.2017

Dear Customer,

Inion has received information of one distributed product, where the aluminium pouch seal was noticed to be partially open before taking into use.

We have inspected the aluminium pouch batch and concluded that as a precaution all products packed in this pouch batch should be visually checked for possible similar defects. The acceptable aluminium pouch seals shall be uniform and intact. We ask you kindly to:

1. Inspect the aluminium pouch seals of products delivered to you (listed on page 2)
2. Inspect the aluminium pouch seals of products delivered to your customer (listed on page 2)
3. Remove any devices with defective seals from sales stocks.
4. Inform us of the outcome using the attached form.

Any devices with defective pouch seals will be sent to Inion for further investigation. We sincerely apologize for the inconvenience. To prevent similar issues in the future, Inion increases quality control activities of purchased pouch components.

Please pass this notice on all those who need to be aware within your organisation / customers' organisations where the devices have been transferred. For further information please contact Mrs. Riitta Juko: riitta.juko@inion.com.

The undersigned confirms that this notice will be distributed to the appropriate Regulatory Agencies.



General Director, Inion Oy

Attached:

- List of products and Feedback form

Material	Batch	Delivery quantity	SU	Manufacturing date	Expiry date
TCK-2011	1612018	20	PC	1.12.2016	1.12.2019
TCK-2011	1606014	10	PC	1.6.2016	1.6.2019
TCK-2011	1606014	25	PC	1.6.2016	1.6.2019
TCK-2011	1606014	10	PC	1.6.2016	1.6.2019
TCK-2011	1602002	10	PC	1.2.2016	1.2.2019
TCK-2011	1503039	15	PC	1.3.2015	1.3.2018