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**Field Safety Notice****Potentially defective seal in aluminium pouch****CPA-17-003****Request for visual inspection of the pouches**

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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.



Kati Marttinen  
QA/RA Director, Inion Oy

Attached:

- List of products and Feedback form

Delivery	Material	Batch	Delivery quantity	SU	Manuf. Date	Expiry date	Current stock (Consign.)
80021263	Australia	TCK-2011	1503039	2 PC	1.3.2015	1.3.2018	
80021435	Australia	ACL-4103	1410005	2 PC	1.10.2014	1.10.2017	
80021083	Australia	ACL-4103	1410005	2 PC	1.10.2014	1.10.2017	
80020609	Bahrain	ACL-4106	1409004	70 PC	1.9.2014	1.9.2017	
80020871	Bahrain	ACL-4106	1409004	50 PC	1.9.2014	1.9.2017	
80021059	Brazil	MRD-3010	1604015	256 PC	1.4.2016	1.4.2019	
80021132	Brazil	MRD-3010	1501011	748 PC	1.1.2015	1.1.2018	
80020399	Brazil	MRD-3010	1501011	4 PC	1.1.2015	1.1.2018	
80021263	Brazil	ACL-4108	1410006	46 PC	1.10.2014	1.10.2017	
80020381	Brazil	ACL-4106	1409004	124 PC	1.9.2014	1.9.2017	
80020765	Brazil	ACL-4102	1409001	53 PC	1.9.2014	1.9.2017	
80020489	China	ACL-4108	1410006	80 PC	1.10.2014	1.10.2017	
80019920	China	ACL-4108	1410006	85 PC	1.10.2014	1.10.2017	
80020032	China	ACL-4102	1409001	7 PC	1.9.2014	1.9.2017	
80020016	Colombia	ACL-4101	1410004	4 PC	1.10.2014	1.10.2017	
80020260	Colombia	ACL-4103	1410005	3 PC	1.10.2014	1.10.2017	
80020381	Czech	ACL-4101	1410004	19 PC	1.10.2014	1.10.2017	
80019813	Czech	ACL-4101	1410004	35 PC	1.10.2014	1.10.2017	
80019765	Czech	ACL-4101	1410004	30 PC	1.10.2014	1.10.2017	
80020016	Czech	ACL-4101	1410004	40 PC	1.10.2014	1.10.2017	
80019194	Czech	ACL-4101	1410004	40 PC	1.10.2014	1.10.2017	
80019485	Czech	ACL-4102	1409001	45 PC	1.9.2014	1.9.2017	
80019362	Egypt	ACL-4103	1410005	20 PC	1.10.2014	1.10.2017	
80019534	Finland	TCK-2011	1606014	1 PC	1.6.2016	1.6.2019	
80019765	Finland	TCK-2011	1606014	1 PC	1.6.2016	1.6.2019	
80019194	Finland	TCK-2011	1505007	1 PC	1.5.2015	1.5.2018	
80018723	Finland	TCK-2011	1503039	1 PC	1.3.2015	1.3.2018	
80018533	Finland	SET-3002	1412016	2 PC	1.12.2014	1.12.2017	
80018653	Finland	SET-3002	1412016	1 PC	1.12.2014	1.12.2017	
80018486	Finland	SET-3002	1412016	2 PC	1.12.2014	1.12.2017	
80018915	Finland	SET-3002	1412016	2 PC	1.12.2014	1.12.2017	
80017912	Finland	SET-3002	1412016	1 PC	1.12.2014	1.12.2017	

80019920	Finland	SET-3002	1412016	1 PC	1.12.2014	1.12.2017
80019484	Finland	SET-3002	1412016	1 PC	1.12.2014	1.12.2017
80020769	Finland	ACL-4101	1410004	1 PC	1.10.2014	1.10.2017
80018991	Finland	ACL-4103	1410005	1 PC	1.10.2014	1.10.2017
80019779	Finland	ACL-4103	1410005	3 PC	1.10.2014	1.10.2017
80018283	Finland	ACL-4103	1410005	3 PC	1.10.2014	1.10.2017
80017758	Finland	ACL-4106	1409004	1 PC	1.9.2014	1.9.2017
80019007	Finland	ACL-4106	1409004	1 PC	1.9.2014	1.9.2017
80020003	Finland	ACL-4102	1409001	1 PC	1.9.2014	1.9.2017
80018340	France	TCK-2011	1505007	11 PC	1.5.2015	1.5.2018
80018408	France	TCK-2011	1503039	8 PC	1.3.2015	1.3.2018
80018440	France	SET-3002	1412016	5 PC	1.12.2014	1.12.2017
80018454	Germany	TCK-2011	1612018	36 PC	1.12.2016	1.12.2019
80018468	Germany	TCK-2011	1612018	20 PC	1.12.2016	1.12.2019
80018647	Germany	TCK-2011	1606014	10 PC	1.6.2016	1.6.2019
80018725	Germany	TCK-2011	1606014	25 PC	1.6.2016	1.6.2019
80018880	Germany	TCK-2011	1606014	10 PC	1.6.2016	1.6.2019
80018919	Germany	TCK-2011	1606014	70 PC	1.6.2016	1.6.2019
80019038	Germany	TCK-2011	1606014	34 PC	1.6.2016	1.6.2019
80018513	Germany	TCK-2011	1604006	10 PC	1.4.2016	1.4.2019
80018702	Germany	TCK-2011	1604006	30 PC	1.4.2016	1.4.2019
80018731	Germany	TCK-2011	1602002	10 PC	1.2.2016	1.2.2019
80018916	Germany	TCK-2011	1602002	23 PC	1.2.2016	1.2.2019
80018931	Germany	TCK-2011	1602002	30 PC	1.2.2016	1.2.2019
80018441	Germany	TCK-2011	1505007	30 PC	1.5.2015	1.5.2018
80018487	Germany	TCK-2011	1505007	27 PC	1.5.2015	1.5.2018
80018382	Germany	TCK-2011	1503039	15 PC	1.3.2015	1.3.2018
80018072	Germany	TCK-2011	1503039	51 PC	1.3.2015	1.3.2018
80018014	India	ACL-4101	1410004	1 PC	1.10.2014	1.10.2017
80017915	Iran	SET-3002	1412016	30 PC	1.12.2014	1.12.2017
80017967	Italy	SET-3002	1412016	1 PC	1.12.2014	1.12.2017
80018055	Italy	ACL-4101	1410004	10 PC	1.10.2014	1.10.2017
80017912	Korea	ACL-4108	1410006	101 PC	1.10.2014	1.10.2017

80017925	Korea	ACL-4102	1409001	30	PC	1.9.2014	1.9.2017
80017927	Norway	TCK-2011	1606014	1	PC	1.6.2016	1.6.2019
80017956	Paraguay	ACL-4101	1410004	10	PC	1.10.2014	1.10.2017
80018016	Romania	TCK-2011	1606014	3	PC	1.6.2016	1.6.2019
80018041	Romania	TCK-2011	1606014	1	PC	1.6.2016	1.6.2019
80018068	Romania	TCK-2011	1604006	2	PC	1.4.2016	1.4.2019
80017928	South Africa	SET-3002	1412016	20	PC	1.12.2014	1.12.2017
80018059	Taiwan	ACL-4101	1410004	18	PC	1.10.2014	1.10.2017
80017745	Taiwan	ACL-4103	1410005	18	PC	1.10.2014	1.10.2017
80017765	Taiwan	ACL-4106	1409004	1	PC	1.9.2014	1.9.2017
80017737	Tunisia	ACL-4108	1410006	4	PC	1.10.2014	1.10.2017
80017758	Tunisia	ACL-4103	1410005	5	PC	1.10.2014	1.10.2017
80017733	USA	TCK-2011	1604006	1	PC	1.4.2016	1.4.2019
80017736	USA	TCK-2011	1505007	3	PC	1.5.2015	1.5.2018
80017748	USA	TCK-2011	1503039	32	PC	1.3.2015	1.3.2018