
Urgent Field Safety Notice

Potential defect in sterile barrier sealing
Inion Thermo™ Drape
INION CPA-19-005

Date: 25.11.2019

Dear Customer,

We have identified a defect in the Tyvek pouch sealing of 2 pcs of Inion Thermo™ Drape, where the end-seal has been left unsealed. This represents currently 0,1% of the batch.

REF: ACC-9802 LOT: 1805002

UDI-DI: M224ACC980210 (single pouch) / M224ACC980211 (outer package, 5-pack).

An unsealed pouch may cause loss of sterility of the drape and the product shall not be used. In this case it is easy to notice the defective pouch as the end-seal is completely open.

Please do the following:

1. Check all remaining products at your stock and at your customers' stocks using the attached picture as reference. Fill the results on the attached feedback form and return the form to Inion by email.
2. Unpack and discard the defective products. Inion will provide a replacement product.

To prevent similar issues in the future, we will take corrective action with the packaging subcontractor. We will inform the concerned medical device authorities about this field safety action in accordance with regulatory requirements.

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.

We sincerely apologize for the inconvenience and time which needs to be taken for this action.

Kati Marttinen
Vice General Manager Quality/Regulatory
Inion Oy

Attached: Feedback form