

Urgent Field Safety Notice

Ref 10268 Extension line 1x2 mm, 150 cm

Ref 10269 Extension line 1x2 mm, 200 cm

FSCA-identifier : 2018-04-12

Type of action: Device destruction

Date: 2018-05-08

Attention: All wards using extension lines 10268 and 10269

Details on affected devices:

Ref 10268 Extension line 1x2 mm, 150 cm

Lot numbers: 6117117F, 6130717G, 6144914F, 6148117H, 6189817K, 6210815K and 6262717N

Ref 10269 Extension line 1x2 mm, 200 cm

Lot numbers: 1612616H, 6008318A, 6042216C, 6069716D, 6098516E, 6145014F, 6217117L and 6267917N

These products are micro tubing extension lines made of DEHP-free PVC.

Description of the problem:

We have received number of complaints for these two references due to leakages. The root cause for these leakages is found to be caused by improper fitment of tube, on either of the connectors. Beside leaks, this may also cause air to enter to tube, depending on procedure. Leaks may lead to situation where patient isn't getting enough medication. Air entering to tube could possibly lead to air embolism.

Advise on action to be taken by the user:

- Stop use of affected devices. Meaning ref's 10268 and 10269, LOT's listed above,
- Identify, segregate and eventually scrap the affected devices,
- Send acknowledgement to local OneMed representative,
- Contact local OneMed representative for compensation.

Transmission of this Field Safety Notice:

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

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Local sales representative in Denmark: Jonna Kilpatrick,
tel: +45 87 425 675,
mail: Jonna.kilpatrick@onemed.com

For general information of these field safety actions please contact:

Mats Nilsson Category Manager tel: +46 70 405 2009 mail: mats.nilsson@onemed.com	Tommi Karjalainen Quality Engineer tel. +358 50 408 1613 mail: tommi.karjalainen@onemed.com
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The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Signature:  _____ date: 2018.05.08
Julien Rolland
Sourcing director