



P M H
P R O D U T O S
M É D I C O
H O S P I T A L A R E S

Sociedade Anónima
Capital Social: €3.418.000
NIPC: PT 502 376 899
Reg. na C.R.C. de Benavente
n.º 502 376 899

FSN URGENT FIELD SAFETY NOTE

FROM: PMH,S.A.

DATE: 28/07/2014

REFERENCE: 306.2234

DATE OF FSCA: 23/07/2014

ACTION TYPE: RECALL

DESCRIPTION AND DETAILS ON AFFECTED DEVICES:

306.2234 - V EXTENSION LINE POE/PVC 1.00x3.00mm, WITH A FIXE
Lot - 22 14 05 E
6 boxes – 900 units

DESCRIPTION OF THE PROBLEM: Leakage

The leakage is due to a problem in the bond between the tube and the luer piece – the affected lot has been collected from your hospital.

During the production process, the inspection is done by sampling - in every 100 produced 10 are leakage inspected.

This inspection might not be enough to detect this problem in this specific product - with a 100% inspection in the course of the production process, the quality of the connection between the tube and the luers (male and female) is guaranteed.

ADVISE ON ACTION TO BE TAKEN BY THE USER:

Not use the Lot - 22 14 05 E

Please transmit this notice to all that need to be aware within your organization or to any other entity that could be potentially directly or indirectly affected by this event.

Contact reference person:

Miguel Alves (Quality Director)

E-mail: d.tecnica@pmh.pt

The undersigned confirm that this notice has been notified the appropriate Regulatory Agency.

Signature

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