Medex
A Guerbet Group company

Saint Priest, February 02, 2015

Name of the Client
Address
City postal code

To the attention of the Material Vigilance Correspondent
Biomedical Services Department Manager

Material Vigilance Note
Subject: FlowSens injector
Ref. FSN: 15-001

To the attention of: Hospital / Medical practice / General management / Material Vigilance Manager

Dear Sir or Madam,

Although no failure has been observed on the installed base of Flowsens® injectors, internal failure risk data analysis performed on some injector air detector monitoring systems has revealed an injection situation in which a non-recognized air detector failure could result in an anomaly in the automatic purge operation. In rare cases, this anomaly could lead to air being injected.

However, this phenomenon can only occur in a combined risk situation with the following occurring simultaneously:

- ⇨ An unidentified detector failure (occurring during operation).
- ⇨ Use of the filling function (there is no risk with pre-filled ScanBags® by Xenetix®),
- ⇨ During a filling operation,
  - Filling from several successive vials, completed by partial transfer of the last container.
  - And introduction of a volume of air of more than 25 ml in the bag.
- ⇨ Failure by the user to perform a visual check of the purge.

At present, no problem of this type has been reported to us, and the situation described above, although possible in theory is unlikely in standard practice.

Nonetheless, Medex has included a new system which aims to eliminate this risk in its new version of the software, which will be available at the end of February 2015. Our technical services will be in touch with you shortly to upgrade the software version of your injector.

Pending deployment of this corrective action and to avoid the combined risk situation described above, Medex requests that you implement the following measures, which correspond to the most common practices:

- ⇨ **Set the injector to standby regularly (once a day): on restarting, in the event of an unidentified sensor failure, the following message is displayed on-screen: "Dirty sensor"**

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⇨ **During the bag filling operation,**

- For the transfer of each vial, request a **filling volume that is greater than the nominal volume of the original container by 10 ml maximum**
  - Examples:
    - if the bag to be filled is empty and vial volume is 100 ml, request filling to 110 ml maximum (the nominal volume of the vial + 10 ml)
    - if the bag to be filled already contains 200 ml and vial volume is 100 ml, request filling to 310 ml maximum (the volume of liquid already in the bag + nominal vial volume + 10 ml)
- Whenever possible (single patient practice, for example), complete the bag filling operation by **transferring the entire contents of the last original container into the bag.**

⇨ Reminder: follow the instructions for use (section 7.d.7) and best required practices, and **check that the line purge ends** by a continuous flow of liquid flowing out of the end of the line.

Please transmit this information to all those who may be concerned within your organization or any organization to which the device concerned has been transferred.

We confirm that the French local health authorities (ANSM) have been informed of this procedure.

For any additional questions regarding this safety information, please contact your local Medex sales representative or customer service on 04 72 79 20 50 or by email at the internet address cs.medex@guerbet-group.com.

Medex thanks you for your cooperation and we apologize for any inconvenience caused by this procedure.

Catherine Vermeulen
Material Vigilance Correspondent
Regulations and Quality Manager

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