Sartorius Stedim Biotech GmbH, 37070 Göttingen

15. January 2021

Urgent Field Safety Notice
Minisart® NML / Ophthalsart

FSCA ID : FSCA-2021-01-13
Safety measures for Minisart® NML / Ophthalsart

Dear Customer,

Details on affected devices:

We delivered one or more packaging units of syringe filter Minisart® NML / Ophthalsart to you (see list of affected article numbers and lots attached).

Description of the problem:

We identified syringe filters (Minisart® NML / Ophthalsart) that may release fibers and particles (subvisible/visible) into the filtrate. The affected filters may not be suitable for medical device applications e.g. pharmacy admixture applications in a laboratory environment before use for patient care.

Usage of defective filters may result in a release of particles / fibers into the pharmacy admixture, which may be entered into the human body. Depending on the way of access into the body and the size and nature of the particles / fibers this may lead to foreign body reactions, immunological responses as well as pulmonary or cerebral microembolism and thrombosis.

Final impact is currently investigated with the goal to create a final list of affected products and lots. We will inform you as soon as reasonable possible, when additional information is available.

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Registered Office:
Göttingen
Local Court of Registration:
Amtsgericht Göttingen
HRB No. 200266

Managing Directors:
Uwe Becker,
Bettina Berendsen

Chairman of the Supervisory Board:
Dr. Joachim Kreuzburg

Advise on action to be taken by the user:

- Please identify and quarantine all potentially affected filters according to the list attached. We will inform you as soon as possible on a lot basis, whether your lot(s) are indeed affected.
- Please review, if an event occurred after patient treatment associated with usage of the affected products and contact the reference person below if this is the case.
- Please inform us, how many filters you have on stock and how many have already been used by completing the attached form.

Transmission of this Field Safety Notice:

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

Contact reference person:

Iris Traut, Sartorius Stedim Biotech GmbH, August-Spindler-Str. 11, 37079 Gottingen, Phone +49 551 308 3712, Email: iris.traut@sartorius.com

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

We apologize for the related inconvenience.

Best regards
Sartorius Stedim Biotech GmbH

Manager Site Quality	Safety Officer Medical Devices
i.A.	i.A.
Dr. Anna Vreemann	Iris Traut

Field Safety Corrective Action
REPLY

Please complete and return this record by January 31, 2021 to

Sartorius Stedim Biotech GmbH
Iris Traut
August-Spindler-Str. 11
37079 Goettingen
Germany
Email: iris.traut@sartorius.com

Please enter below, which amount of packages of which material and lot number are within your stock and were quarantined following this notice:

Material Number	Lot number	Amount in stock

Please name the application you are using the filter in:

_____

Reply Record Completed By:
(please print name) _____
Title:
(Please print) _____

The above Field Action has been carried out. We have informed all affected customers and have put the respective lot numbers in quarantine.

Return this Response Sheet with the information completed below as confirmation. Objective evidence about the execution of the Field Action is available on demand.

Signature / Date: _____

Name _____

Sales Company / Distributor/
Customer: _____

_____