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Field Safety Notice

Possible contamination of NeoContactAgent

October 19, 2021

Manufacturer:	**Sentec AG,** Kantonsstrasse 14, 7302 Landquart, Switzerland
Affected products:	Sentec EIT System for neonates and infants
Product name:	NeoContactAgent, NeoContactAgent Kit
REF:	1ST230-100, 1ST232-100
UDI-DI:	+EIT11ST2301000, +EIT11ST2321000
LOT:	all

Dear valued customer,

An issue has been identified with the NeoContactAgent (sold as NeoContactAgent Kit) which could pose a potential risk to patients.

With this field safety notice, we would like to inform you that in approximately 2% of the NeoContactAgent visible contamination was detected. The following species were identified:

- *Penicillium scabrosum*
- *Aspergillus glaucus*
- *Aspergillus niveoglaucus*
- *Aspergillus pseudoglaucus*
- *Aspergillus ruber*
- *Cladosporium cycadicola*
- *Cladosporium sphaerospermum*

Risks:

Based on available data from the literature the following risks have been identified concerning these species:

All of the identified species are naturally widespread and occur in soils, on food from agriculture, and to some extent in living spaces.

Individual cases of infections, most of which were skin or sinus infections have been described (*Aspergillus pseudoglaucus, Aspergillus ruber, Cladosporium sphaerospermum*). Skin infections can be treated with local measures (topic anti-mycotica).

Very few cases of meningitis/brain infections (*Aspergillus glaucus, Cladosporium sphaerospermum*) or lung infections (*Cladosporium sphaerospermum*) have been reported in relation to paper, wood, or agricultural industry. If present in sufficient concentration, these species may enter the circulation via the lungs and from there the brain. It is considered extremely unlikely that a sufficient concentration of these species is reached in the air given the mode of application of NeoContactAgent if a contaminated bottle may have been used. This route of transmission is excluded in patients receiving high-flow oxygen, CPAP, or invasive ventilation.

Please note that according to Sentec's post-market data no incidents of infections related to NeoContactAgent have been reported to date.

Actions to be taken:
The use of NeoContactAgent (all LOTs) shall be stopped immediately and removed from patients on which it is currently used.

Available bottles of NeoContactAgent shall be removed from use and placed in quarantine.

If patients that NeoContactAgent was used on are still in care and develop infections, molds should be considered as a potential cause.

Pass on this information to all who need to be aware of it within your organization.

Confirm receipt of this communication and the implementation of the actions above by returning the signed confirmation page of this notice.

Sentec is currently investigating the root cause and working diligently to replace your existing stock with non-contaminated NeoContactAgent.

Please contact your local Sentec representative, or Sentec Landquart (info-eit@sentec.com) if you have any questions on this field safety corrective action.

We sincerely apologize for the inconvenience and will provide further information and instructions within the next several days. We will also inform you as soon as possible by when replacement of NeoContactAgent will be available.

Yours sincerely,

[redacted]
Branch Manager

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Confirmation

I hereby declare that I have received and understood this information.

In addition, I confirm that I have quarantined all NeoContactAgent, removed LuMon™ Belts wetted with NeoContactAgent from patients, and safely disposed of those belts.

Organization:	
Street, street number:	
City, zip code:	Country:
Name:	Title:
Place, date:	Signature:

Please send a signed copy to info-eit@sentec.com.