



Au commencement, il y avait un patient...

TO whom is concerned :

PHARMACIEN RESPONSABLE DES DM STERILES

RESPONSABLE MATERIOVIGILANCE DES DM

Adresse
CP_Ville
France

Lissieu, 13/07/2021

N/Réf : DA- **R1910265 – RC19228/C**

Objet : Field Safety Notice Enteral Feeding Tube

Urgent Field Safety Notice

Sir, Madam,

During our post-market surveillance process, we observed in some products a non-uniform yellow color on a portion of the feeding tube. In view of the increasing number of ppm observed and after discussion with ANSM, CAIR LGL has decided to proceed with product safety information on adult and paediatric enteral nutrition tubes (list of references in appendix A):

References : NCE...PU
NCE...AU
NCE...G

This phenomenon is characterized by the appearance of a non-uniform yellow color at different part on the polyurethane tubes of our adult and paediatric nutrition probes. We were aware that the natural oxidation of polyurethane could cause a slight yellow coloration of the polyurethane, but not in the proportions observed.



ISO 9001 - ISO 13485

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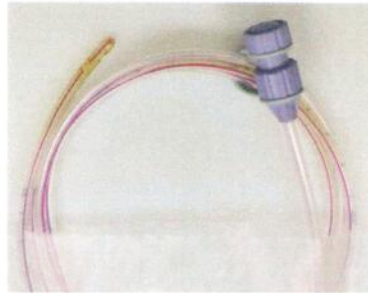
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This defect is detectable as soon as the blister is opened and therefore systematically before placing the probe into the patient. All of our tests show that there is no accelerated degradation of the structure of the polyurethane, but in the absence of knowledge of the consequences on the patient, CAIR LGL recommends not to use feeding tubes with this coloration.

To correct this defect, an action has been taken internally and it is applicable as of now.

At the same time, we ask you to confirm receipt of this information by returning the form attached below.

As this warning follows a materiovigilance procedure, the competent authorities concerned are informed of this decision, and we will keep them informed of the progress of the operation.

We would like to thank you for your collaboration and through this warning, CAIR LGL reaffirms its desire to provide you with secure and efficient products.

Remaining at your entire disposal for any further information, please accept, Madam, Sir, the assurance of our best regards.

Delphine ALLARD
Correspondant Matéiovigilance



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Annex A :

Exhaustive list of references of enteral feeding tubes

NCE04PU	NCE110G	NCE214AU	NCE508G
NCE05NPU	NCE110NG	NCE214G	NCE508NAU
NCE05PU	NCE110PU	NCE306G	NCE508NG
NCE06NPU	NCE112AU	NCE306NPU	NCE510AU
NCE06PU	NCE112G	NCE306PU	NCE510G
NCE08NPU	NCE114AU	NCE308G	NCE512AU
NCE08PU	NCE114G	NCE308NG	NCE512G
NCE104PU	NCE114NAU	NCE308NPU	NCE514AU
NCE105PU	NCE116AU	NCE308PU	NCE514G
NCE106AU	NCE116G	NCE310G	NCE516AU
NCE106G	NCE118AU	NCE310NPU	NCE516G
NCE106NAU	NCE120AU	NCE310PU	NCE518AU
NCE106PU	NCE206AU	NCE312G	NCE520AU
NCE108AU	NCE206G	NCE312NG	NCE520NAU
NCE108G	NCE208AU	NCE312NPU	
NCE108NAU	NCE208G	NCE312PU	
NCE108NG	NCE210AU	NCE314G	
NCE108PU	NCE210G	NCE506AU	
NCE10PU	NCE212AU	NCE506G	
NCE110AU	NCE212G	NCE508AU	



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ACKNOWLEDGEMENT OF RECEIPT FORM SAFETY COMMUNICATION
FSN - DA- R1910265 – RC19228/C

To be completed and returned

Email : FieldAction@cairgl.fr

Fax : 0033 (0)4 37 64 60 09

Establishment (Stamp)

We hereby certify receipt of the safety communication / important notice sent by CAIR LGL on 20/02/2020 and its transmission to everyone needing to be informed of it within our organization.

We certify that we have read and understood the field safety notice

Name / Position of the person who completed the form

Date :

Signature



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Na pažnju

LJEKARNIK ODGOVORAN ZA STERILNE MD

ODGOVORAN ZA MATERIOVIGILNOSTI DM

Adresa
CP_Ville
Francuska

Lissieu, 13.7.2021.

Br./ref.: DA- **R1910265 – RC19228/B**

Predmet: Informacije o upotrebi nutricionističkih sondi

Hitna sigurnosna obavijest za teren

Poštovani,

Tijekom procesa nadzora nakon stavljanja na tržište primijetili smo kod nekih proizvoda neujednačeno žutilo na dijelu sonde. S obzirom na sve veći broj promatranih ppm -a i nakon razgovora s ANSM -om, CAIR LGL odlučio je nastaviti s informacijama o sigurnosti proizvoda na epruvetama za enteralnu prehranu odraslih i djece:

Serijske: NCE...PU
NCE...AU
NCE...G

Ovu pojavu karakterizira pojava neujednačene i neujednačene žute boje na poliuretanskim cijevima naših sondi za prehranu odraslih i dječjih. Bili smo svjesni da prirodna oksidacija poliuretana može uzrokovati blagu žutu boju poliuretana, ali ne u promatranim omjerima.

Ovaj se nedostatak može otkriti čim se alveola otvori i stoga sustavno prije stavljanja sonde na pacijenta. Svi naši testovi pokazuju da ne postoji ubrzana degradacija strukture poliuretana, ali u nedostatku znanja o posljedicama na pacijenta, CAIR LGL preporučuje da se ne koriste hranjive sonde s ovom bojom.



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Kako bi se ovaj nedostatak ispravio, interno je poduzeta radnja koja se primjenjuje od sada.

U vezi s tim vas molimo da potvrdite primitak ovih podataka slanjem obrasca u nastavku.

Budući da je ovo upozorenje rezultat postupka vigilancije medicinskih proizvoda, nadležna su tijela obaviještena o ovoj odluci te ćemo ih i dalje obavještavati tijekom cijelog ovog postupka.

Ovim putem želimo vam zahvaliti na suradnji, a ovim upozorenjem CAIR LGL ponovno potvrđuje svoju želju pružiti vam sigurne i učinkovite proizvode.

Stojimo vam na raspolaganju za sve dodatne informacije i srdačno vas pozdravljamo.

Delphine ALLARD
Korespondentica za vigilanciju medicinskih proizvoda



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OBRAZAC ZA VRAĆANJE I POTVRDU PRIMITKA
FSN - DA- R1910265 – RC19228/

Ispuniti i vratiti po primitku:

Adresa e-pošte: FieldAction@cairgl.fr
Telefaks: 0033 (0)4.78.43.77.07

Ustanova (pečat)

Ovim potvrđujemo primitak važnih podataka o sigurnosti / obavijesti koje je CAIR LGL poslao 22.7.2021. i prenosimo ih svima onima u našoj organizaciji koji o njima trebaju biti obaviješteni.

Podaci o sigurnosti / obavijest pročitani su i primljeni na znanje.

Ime / svojstvo osobe koja je ispunila obrazac:

Datum:

Potpis:



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