



«Nom\_de\_Etablissement\_»  
«Nom\_du\_correspondant»

«Adresse\_1»  
«Adresse\_2»  
«CP\_VILLE\_»

Quality contact : ☎ 00 33 139 926 351  
✉ [nusur@vygon.com](mailto:nusur@vygon.com)

Mail ref : 15 0827 «N\_de\_Chrono»CO/NU  
**Objet : FSN-Field Safety Notice  
Y connector code 884.08**

Ecouen, 25th June, 2015

Dear Madam, Sir,

We have identified, a non-systematic manufacturing defect on **Y connector code 884.08 for specific lot 100315EG**. There is a possibility that the Y connector can be blocked.

This obstruction cannot be visually detected by the end user before use. Therefore we would ask you to inform all end users that these Y connectors could be blocked. It is necessary to check during an initial use its efficiency either through aspiration, suction or administration.

We ask you to kindly acknowledge receipt of this letter, to forward this safety notice to all potential users, then to complete and return the attached form.

*The French health authorities (ANSM) have been informed of this FSN.*

*For further information, you can directly contact **M.xxxx**, quality contact, or sales administration on phone number **xxxxxxxxxx***

We apologize for any inconvenience this FSN may cause,

**Christine OBER - Pharmacist  
Postmarket Quality Director**

Service Qualité  
Tél : 01.39.92.63.51  
Fax : 01.39.92.64.82  
E-mail : [quality@vygon.com](mailto:quality@vygon.com)

Service Clients France  
Tél : 01.39.92.63.81  
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Service Clients Export  
Tél : 01.39.92.64.17  
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E-mail : [export@vygon.com](mailto:export@vygon.com)





Field safety notice CODE 884.08

**ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM**

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Please complete and return this form:

by fax: **XXXXXXXXXX**

or e-mail to : **XXXXXXXXXXXXXX**

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**Name and address of the institution :**

**Full name of the person to contact:** 15«N\_de\_Chrono»CO/NU »

« TOWN\_ »

**Function :**

**Phone number :**

**E-mail :**

**We acknowledge receipt of the above FSN and that the information contained in this field safety notice has been shared with all recipients/ end users of above products within your organization.**

**Signature and Date :**

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Tél : 01.39.92.63.51  
Fax : 01.39.92.64.82  
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