




«Nom_de_lEtablissement_»
«Nom_du_correspondant»

«Adresse_1»
«Adresse_2»
«CP_VILLE_»

Quality contact : 

Mail ref: 16 1271 «N_de_Chrono»CO/NU

Ecouen, 8th December, 2016

Subject : **FSN-Recall AUTOFLUSH code 5897.01**

Batches 070515EK, 190515EK, 030615EK, 061115EK, 111215EK, 250116EK, 290316EK

Dear Madam, Sir,

We have identified a potential non-systematic leakage defect between female white and male blue luer on needleless valve connector **AUTOFLUSH code 5897.01 for specific lots mentioned below:**

lot 070515EK	lot 250116EK
lot 190515EK	lot 290316EK
lot 030615EK	
lot 061115EK	
lot 111215EK	

This defect may be visually detected.

Therefore, we ask you to withdraw these batches.

We ask you to kindly acknowledge receipt of this letter, to complete and return the attached form by indicating per batch the involved quantities withdrawn from your institution.

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

*For further information, you can directly contact M. **xxxxxxxx**, quality contact, or sales administration phone number **xxxxxxxxxxxx**.*

We apologize for any inconvenience this FSN-Recall may cause.

Christine OBER -
Postmarket Quality Director

Service Qualité
Tél : 01.39.92.63.51
Fax : 01.39.92.64.82
E-mail : quality@vygon.com

Service Clients France
Tél : 01.39.92.63.81
Fax : 01.39.90.29.37
E-mail : commandes@vygon.com

Service Clients Export
Tél : 01.39.92.64.17
Fax : 01.34.29.19.34
E-mail : export@vygon.com





FSN-RECALL AUTOFLUSH Code 5897.01

ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

Please complete and return this form:

by fax: **XXXXXXXXXX** or e-mail to : **XXXXXXXXXX**

Name and address of the institution :

Full name of the person to contact: 16«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.

Please tick the appropriate box:

You have AUTOFLUSH code 5897.01:

- | | | |
|------------------|----------------------------------------------------------|----------------------------------------------------|
| ✓ Lot : 070515EK | <input type="checkbox"/> YES <input type="checkbox"/> NO | If you have units, number of units removal: _____ |
| ✓ Lot : 190515EK | <input type="checkbox"/> YES <input type="checkbox"/> NO | If you have units, number of units removal:: _____ |
| ✓ Lot : 030615EK | <input type="checkbox"/> YES <input type="checkbox"/> NO | If you have units, number of units removal:: _____ |
| ✓ Lot : 061115EK | <input type="checkbox"/> YES <input type="checkbox"/> NO | If you have units, number of units removal:: _____ |
| ✓ Lot : 111215EK | <input type="checkbox"/> YES <input type="checkbox"/> NO | If you have units, number of units removal: _____ |
| ✓ Lot : 250116EK | <input type="checkbox"/> YES <input type="checkbox"/> NO | If you have units, number of units removal:: _____ |
| ✓ Lot : 290316EK | <input type="checkbox"/> YES <input type="checkbox"/> NO | If you have units, number of units removal:: _____ |

Signature and date:

Service Qualité
Tél : 01.39.92.63.51
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