

«Nom_de_lEtablissement_» «Nom_du_correspondant»

«Adresse_1» «Adresse_2» «CP_VILLE_»

Quality contact:



Mail ref: 17 0601 «N_de_Chrono»CO/NU

Ecouen, 17th October, 2017

Subject: URGENT: FSN-RECALL

OCTOPUS code 842.312

Dear Madam, Sir,

We have identified a non-systematic potential defect on some devices

OCTOPUS code 842.312 batch 160617AF;

one of the 3 lumens of the extension line may disconnect from its green hub.

For safety reasons, we ask you to withdraw this batch immediately.

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acknowledge receipt of this letter, to complete and return the attached form by indicating the quantities involved withdrawn from your institution.

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

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

Christine OBER - Pharmacist
Postmarket Quality Director



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







URGENT: FSN-RECALL OCTOPUS code 842.312 ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

| Please complete and return this form by fa | x: xxxxxxxxxx or e-mail to : xxxxxxxxxx |
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| | |
| Name and address of the institution : | |
| Full name of the person to contact: | «N_de_Chrono»CO/NU » |
| | « TOWN_» |
| Function : | |
| Phone number : | |
| ூ E-mail : | |
| We acknowledge receipt of the above ESN | and that the information contained in this field safety notice has |
| | f product listed below within your organization. |
| Please tick the appropriate box: | , produce noted below that in your organization. |
| The state of the s | |
| You have OCTOPUS code 842.312 | |
| Lot 160617AF : □Yes □ No If you have uni | ts, number of units removed: |
| Signature and Date: | |
| | |

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



