




«Nom_de_lEtablissement_»
«Nom_du_correspondant»

«Adresse_1»
«Adresse_2»
«CP_VILLE_»

Quality contact : 

Mail ref: 17 0366 «N_de_Chrono»CO/NU

Ecouen, 19th July, 2017

Subject : **URGENT: FSN-RECALL**
UMBILICAL CATHETER code 270.03

Dear Madam, Sir,

We have identified a non-systematic wrong marking on our devices **umbilical catheter code 270.03**
lots 241116FR – 281116FR – 071216FR – 151216FR – 211216FR – 050117FR – 060117FR - 150217FR – 230217FR and 280217FR

the first marking from the distal tip may be at 5,5 cm instead of 4 cm.

For safety reasons, we ask you to withdraw these batches 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acknowledge receipt of this letter, to complete and return the attached form by indicating the quantities involved withdrawn from your institution.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.

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 - Pharmacist
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





**URGENT : FSN-RECALL UMBILICAL CATHETER code 270.03
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:	«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 product listed below within your organization.

Please tick the appropriate box: You have UMBILICAL CATHETER code 270.03

Lot 241116FR : Yes No If you have units, number of units removed: _____

Lot 281116FR: Yes No If you have units, number of units removed: _____

Lot 071216FR : Yes No If you have units, number of units removed: _____

Lot 151216FR : Yes No If you have units, number of units removed: _____

Lot 211216FR : Yes No If you have units, number of units removed: _____

Lot 050117FR: Yes No If you have units, number of units removed: _____

Lot 060117FR : Yes No If you have units, number of units removed: _____

Lot 150217FR : Yes No If you have units, number of units removed: _____

Lot 230217FR : Yes No If you have units, number of units removed: _____

Lot 280217FR : Yes No If you have units, number of units removed: _____

Signature and Date:

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