




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

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

Quality contact : 

Mail ref: 17 0366 «N\_de\_Chrono»CO/NU

Ecouen, 19<sup>th</sup> 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acknowledge receipt of this letter, to complete and return the attached form by indicating the quantities involved withdrawn from your institution.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.

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.....

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 : 01.39.90.99.37  
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**

<b>Name and address of the institution :</b>	
<b>Full name of the person to contact:</b>	«N_de_Chrono»CO/NU »  « TOWN_ »
<b>Function :</b>	
<b>☎ Phone number :</b>	
<b>✉ E-mail :</b>	

**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:

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  
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