



«Nom_de_lEtablissement_»
«Nom_du_correspondant»

«Adresse_1»
«Adresse_2»
«CP_VILLE_»

Quality contact :



Mail ref: 17 0331 «N_de_Chrono»CO/NU

Ecouen, 4th July, 2017

Subject : URGENT: FSN-RECALL

STERNUM GUARD code 409010, 409011 and 409012

Dear Madam, Sir,

We have identified a wrong expiry date on our devices **STERNUM GUARD**

- code 409010 lots 190716VA and 060617VA
- code 409011 lot 200716VA
- and code 409012 lots 200716VA, 200217VA, 080317VA and 020517VA,

the shelf life of these devices is 18 month, it is not yet exceeded.

We ask you to withdraw this batch.

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kindly acknowledge receipt of this letter, to complete and return the attached form by indicating involved quantities withdrawn from your institution.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



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 STERNUM GUARD code 409010, 409011 and 409012
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 above products within your organization.

Please tick the appropriate box: You have STERNUM GUARD

code 409010 Lot 190716VA : ☐ Yes ☐ No If you have units, number of units removed: _____

code 409010 Lot 060617VA : ☐ Yes ☐ No If you have units, number of units removed: _____

code 409011 Lot 200716VA : ☐ Yes ☐ No If you have units, number of units removed: _____

code 409012 Lot 200716VA : ☐ Yes ☐ No If you have units, number of units removed: _____

code 409012 Lot 200217VA : ☐ Yes ☐ No If you have units, number of units removed: _____

code 409012 Lot 080317VA : ☐ Yes ☐ No If you have units, number of units removed: _____

code 409012 Lot 020517VA : ☐ Yes ☐ No If you have units, number of units removed: _____

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