

December 2nd 2018
Our Réf: 18 0660

Subject: URGENT : FSN-Recall

DUALSTOP stoppers codes: 9888.00, 9888.001, 9888.002 and 9889.000

Dear Sir/ Madam

We have identified a potential manufacturing defect on some **DUALSTOP stoppers codes 9888.00, 9888.001, 9888.002 and 9889.000 for specifics lots mentioned below**. This non-systematic defect can lead to a leakage.

DUALSTOP red stoppers:code 9888.00

Lots : 120617FD-160617FD-200917FD-250917FD-270917FD-061117FD-211117FD-301117FD-141217FD-090118FD-150118FD-310118FD-200218FD-080318FD-140318FD-260318FD-290318FD-110418FD-130418FD-260418FD-070518FD-180518FD-310518FD-050618FD-200718FD-300718FD-070918FD,

Code 9888.001

Lots : 130917FD-161117FD-111217FD-190118FD-010318FD-140518FD-240518FD-130818FD,

DUALSTOP white stoppers code 9888.002

Lots : 300517FD-081117FD-030118FD-250118FD-130218FD-190318FD-050418FD-180418FD-020518FD-090718FD-220818FD-300818FD,

DUALSTOP- blue stoppers code 9889.000 : lot 100718FD

For this reason, we ask you to immediately withdraw these batches from services and to return them in-line with our instructions below.

Please acknowledge receipt of this letter and complete and return the attached form by indicating the quantities withdrawn from your institution.

The French health authorities (ANSM) have been informed of this Field Safety Notice, FSN.

For further information, should you require it, please contact Denis Coakley at 086-2551148 or dcoakley@vygon.ie

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



Christine OBER -

Postmarket QA/RA Director

ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

Please complete and return this form:

By fax: 01-4105721 or e-mail to: vigilance@vygon.ie

Name and address of the institution :	
Full name of the person to contact:	
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 our organization.

Signed

Reconciliation Record

According to our records you have received the following affected Lots.

Can you withdraw any remaining product of these Lots and enter in the below table the quantities remaining.

Can you return this to us and we will arrange replacement with unaffected Product

Date	Invoice number	Product	Lot Number	Quantity	Quantity Remaining