


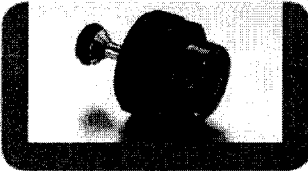


## TO WHOM IT MAY CONCERN

Hamburg, 6 May 2009  
Phone +49-40-56192-0 Fax +49-40-5604213

### Field Safety Notice on the Use of PENTAX Valve Types OF-B136, OF-B140, OF-B163 and OF-B179 in Endoscopy

Dear Sirs,

With this Field Safety Notice we would like to inform you about a field action initiated by HOYA Corporation, PENTAX Tokyo Office relating to the following PENTAX brand suction valves:

	<b>OF-B136</b> (red) Suction valve for FB-V, -X, EB-30, VNL-30 endoscopes (order code 82673)
	<b>OF-B140</b> (red) Suction valve for FB-P, -BS endoscopes (order code 82688)
	<b>OF-B163</b> (blue) Irrigation control valve for ECY-1570(K) endoscopes (order code 86488)
	<b>OF-B179</b> (red) Suction valve for VNL-70(K), EB-70(K) endoscopes (order code 86805)

According to our records you have received a number of the endoscopes affected. Please refer to the reply form stating all details of the endoscopes and valves in question.

**Description of the problem:**

PENTAX Europe GmbH was informed that a certain production lot of suction valves could possibly be subject to impaired functioning during endoscopy. This problem may cause the valve to get stuck in the valve cylinder or the rubber cap to become detached from the valve shaft. As a consequence, this may result in continuous suction.

**Measures to be taken:**

In case the valve gets stuck in the valve cylinder, we strongly recommend to interrupt or to completely turn off suction.

Furthermore, we would like to ask for your assistance to ensure that all valves concerned may be quickly identified and be replaced by PENTAX Europe GmbH. To this end, we are kindly asking you to complete the attached reply form and fax it as soon as possible to the fax number indicated.

We are aware that valves and endoscopes are not necessarily kept as a unit in daily practice. However, as there is no identification method available at the moment, we have decided to replace all "old" valves with new ones at no charge. Therefore, please return the valves withdrawn from your endoscopy section to PENTAX Europe GmbH with no delay in order to prevent any mix-up.

It is important for us to advise you that this action taken is a voluntary and preventative measure and that to date no incident related to this problem has been reported to us by users of our endoscopes.

**Transfer of information described here:**

Please ensure that all users of the above mentioned products in your organisation and all other individuals to be informed will receive this field safety notice. In case you have made these products available to third parties please forward a copy of this information to them or kindly provide us with the new contact data.

This information should at least be kept as long as the field measure has not been completed.

Please note that PENTAX Europe GmbH has notified the Competent Authority about this Field Safety Notice.

**Contact:**

In the event that you have additional queries concerning this measure, please don't hesitate to contact your local PENTAX dealer.

Please accept our apologies for all the inconvenience resulting from this action. The safety of patients and users is our utmost concern and for this reason we decided to replace the valves as timely and effectively as possible. We hope you share our motivation and look forward to a continued trustful cooperation.

Yours faithfully,

**PENTAX Europe GmbH**

  
Dr.   
Quality Affairs

Enclosure: Reply Form

## REPLY FORM

Please be so kind as to complete this form and fax it to :

PE sister or distributor  
**[Contact]**  
 Address  
 Postal code/Place  
 Fax number: xxx

PENTAX needs your help in order to identify and replace all products concerned, so kindly give us the following information.

User's name and address	(to be automatically prepared by PE sister/distributor when sending the letter to the customer)
Person to contact	
Signature	
Telephone number	
Date	

According to our records you have received a number of the endoscopes affected. Please refer to the table below stating all details of the endoscopes and valves in question:

Type of endoscope	Model name	Serial number	Date of installation	Valve concerned
e.g. bronchoscope	EB-1970K	A000111	2009-03-30	OF-B179

User's statement: We have physically checked our complete stock of valves and have identified the following products for replacement:

Valve denomination	Quantity - returned	
OF-B136		
OF-B140		
OF-B163		
OF-B179		

PENTAX is aware that valves and endoscopes are not necessarily kept as a unit in daily practice. However, as there is no identification method available at the moment, it was decided to replace all "old" valves with new ones at no charge.

Thank you for completing and faxing the form to us.

PE sister or distributor/  
 LIFE CARE