

## URGENT: FIELD SAFETY NOTICE

Action Identification Number: **2021-001 (QIL 154-004)**

Type of Action: **Field Safety Corrective Action**

Affected Products/Lot numbers:

Product Range	Product Description	Model Name	Part Number	LOT number
Endocuff Vision	ARV110 ENDOCUFF-V M BLUE PK8 ARV120 ENDOCUFF-V L GREEN PK8 ARV130 ENDOCUFF-V S PURPLE PK8 ARV140 ENDOCUFF-V XL ORANGE PK8	ARV110 ARV120 ARV130 ARV140	E0420501 E0420500 E0420502 E0420503	See list below

Lot number					
60496	61662	63310	64848	66023	67819
60780	61664	63314	64850	66146	69141
60862	61678	63316	65172	66148	69144
60865	62007	63542	65173	66150	69148
60867	62009	63544	65340	66154	69150
60869	62011	63582	65342	66361	69256
61168	62013	63584	65344	66363	69258
61171	62146	63586	65390	66365	69260
61176	62149	63606	65391	66367	69282
61285	62151	63611	65392	66634	69478
61287	62405	63746	65464	66636	69480
61539	62407	63750	65465	66638	69554
61541	62469	64132	65466	66640	69556
61543	62471	64134	65489	66705	69628
61557	62473	64141	65490	66763	69774
61559	62650	64263	65491	66765	69776
61560	62652	64265	65496	66767	70089
61561	62781	64268	65497	66910	70478
61562	62783	64533	65498	66912	70480
61563	62787	64535	65499	66914	70482
61564	62976	64537	65519	67019	70524
61578	62978	64674	65521	67021	
61580	63007	64676	65523	67023	
61582	63009	64678	65525	67025	
61595	63011	64738	65527	67181	
61597	63035	64831	66017	67183	
61599	63037	64844	66019	67815	
61601	63039	64846	66021	67817	

Dear Customer,

Olympus has become aware of an issue that requires your urgent attention. This letter refers to the integrity of the sterile packaging of certain Boddingtons Endocuff Vision products which are supplied as sterile single-use devices.

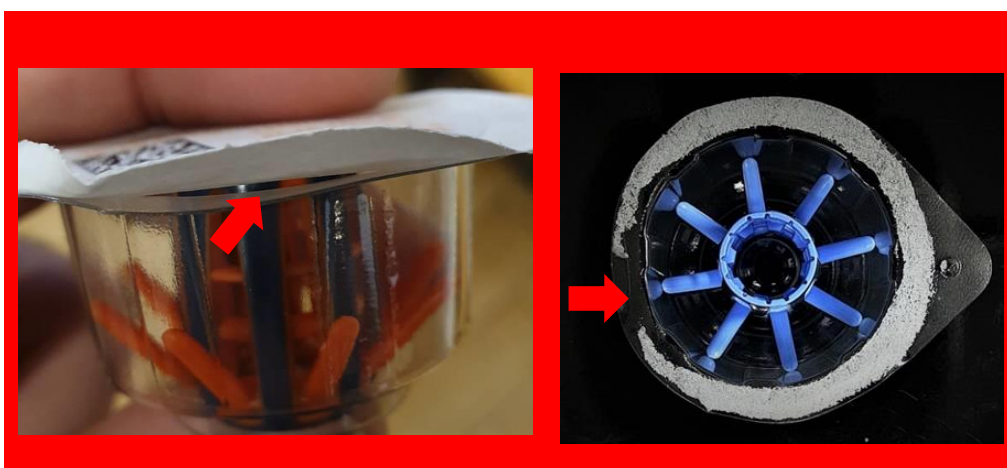
The Endocuff Vision is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy.

Due to an irregularity in the packaging process of the above listed devices, it has been identified that there is a very low probability for a potential packaging seal defect which may allow a breach of the package's sterile barrier. This seal breach can be detected with the naked eye prior to use once the lid has been removed from the plastic package. A breach of the package's sterile barrier might lead to patient infection. However, as the product is intended to be used in the lower gastrointestinal tract this occurrence is considered as extremely improbable.

Olympus have not received any complaints or reports of injuries, infections or required medical intervention as a result of this issue. The defective units have been detected internally by Olympus only. Olympus has determined that users can continue to use the Endocuff Vision in accordance with the Instructions for Use.

### **Olympus requires you to take the following immediate action:**

1. Carefully read the content of this Field Safety Notice.
2. Below are examples of a gap in the seal between the lid and the plastic package.



**Examples of a gap in the seal between the lid and the plastic package**

3. As per the instructions for use, do not use if packaging is damaged. If you observe this packaging anomaly or any other damage to the packaging, please do not use your product and report to your local Olympus representative to get a credit note or replacement for any damaged products.
4. Complete and return the attached reply form confirming you have acknowledged the information in this Field Safety Notice by **DD/MM/2021** to:

*[Contact person name]*

*[Contact person position]*

*[Email: name@olympus.com]*

*[Fax number]*

5. If you have further distributed this product, identify your customers, forward them this Field Safety Notice and appropriately document your notification process.



Your National Competent Authority has been informed of this Field Safety Notice.

We appreciate your cooperation and apologise for any inconvenience this may cause. If you have any questions or would like further information, please do not hesitate to contact the Olympus Customer Care Department on *[please insert local number]* from Monday till Friday or alternatively by e-mail at *[name@olympus.com]*

Yours sincerely,  
*[Contact person name]*  
*[Contact person position]*

Attachment: Field Safety Notice Reply Form

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Endocuff Vision	ARV110 ENDOCUFF-V M BLUE PK8	ARV110	E0420501	Please see list on page 1
	ARV120 ENDOCUFF-V L GREEN PK8	ARV120	E0420500	
	ARV130 ENDOCUFF-V S PURPLE PK8	ARV130	E0420502	
	ARV140 ENDOCUFF-V XL ORANGE PK8	ARV140	E0420503	

Please send the completed and signed reply form by post, fax or a digitally scanned e-mail to:

[\[Contact person name\]](#)[\[Contact person position\]](#)[\[Email: name@olympus.com\]](mailto: name@olympus.com)[\[Fax number\]](#)

Dear Olympus representative,

I acknowledge the receipt of the Field Safety Notice (FSN) and have transferred the information to all affected departments on which this action may have an impact.

 I confirm that I have read and understood this Field Safety Notice.

Name:
Job Title:
Facility Name:
Facility address:
Country:
Email:
Phone: