Date: XX.XX.XXXX
Olympus reference: QIL FY24-EMEA-26-FY24-OSTA-07

URGENT FIELD SAFETY NOTICE

RE: Recall of certain lot numbers of EZDilate Fixed Wire Balloon, EZDilate Wire Guided Balloon
Attention: Endoscopy Department, Risk Management Department

Material ID	Material Name	Lot Numbers
EGBD-400P-1080	EZDILATE (FW) 8.5-9.5-10.5	366479, 384325
EGBD-400P-1380	EZDILATE (FW) 11-12-13	369624, 377715
EGBD-400P-1580	EZDILATE (FW) 13.5-14.5-15.5	360911, 367646, 367647, 367648, 383847
EGBD-400P-1880	EZDILATE (FW) 16-17-18	365825, 369028, 376914
EGBD-400P-2080	EZDILATE (FW) 18-19-20	365582, 365586, 375543, 375973, 381391, 377491
EGBD-410X-0855	EZDILATE (WG) 6-7-8	373808, 374005, 379746, 379747, 379835, 379836
EGBD-410X-1055	EZDILATE (WG) 8.5-9.5-10.5	361663, 361664, 365174, 374533, 374533, 374534, 375148, 378070, 386395
EGBD-410X-1355	EZDILATE (WG) 11-12-13	369715, 370108, 370270, 370496, 377814, 378933, 379534, 386461, 386462, 388459
EGBD-410X-1555	EZDILATE (WG) 13.5-14.5-15.5	372741, 373098, 373607, 378932, 380775, 380776, 387128, 389197, 389201, 360767, 360768
EGBD-410X-1855	EZDILATE (WG) 16-17-18	360769, 368258, 368259, 368844, 369417, 387794
EGBD-410X-2055	EZDILATE (WG) 18-19-20	367026, 369509, 370718, 371173, 372147, 374100, 374101, 374810, 386463, 386842, 387130, 387424

Dear Healthcare Professional:

Olympus has become aware of a matter that may require your attention. This recall pertains to specified lots of the above-referenced Olympus EZDilate Fixed Wire Balloon and Wire Guided Balloon.

The EZDilate Fixed Wire Balloon is indicated for endoscopic dilation of strictures of the esophagus in adults and adolescents (>12 years). The EZDilate Wire Guided Balloon is indicated for endoscopic dilation of strictures in the alimentary tract in adults and adolescents (>12 years) as well as endoscopic dilation of the Sphincter of Oddi with or without prior sphincterotomy in adults.

Olympus is taking this recall action after investigating reported complaints about issues inflating, deflating and/or retrieving the devices, as well as reports of bursting and leaking. Olympus has received reported adverse events involving foreign body in patient and prolonged procedure. Although our investigation is still ongoing, Olympus has learned that a misaligned processing aid during manufacturing may be a contributing factor. As a result, Olympus is requesting healthcare facilities return the affected model/lots to Olympus.

A solution has been implemented and so new lots are not impacted.

Risk to Patient Health:

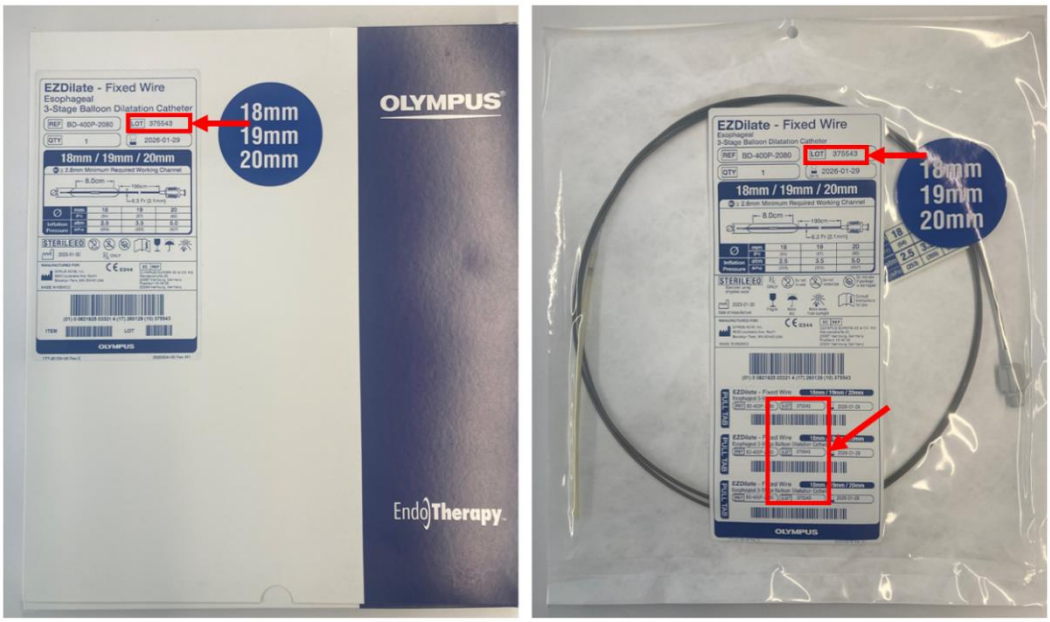
The potential risk associated with this issue includes the potential for foreign body in patient and/or prolonged procedure. Potential harms include hemorrhage/blood loss/bleeding, hematoma, tissue injury, aspiration and/or additional surgery.

Action steps to be taken by the end user:

Our records indicate that you have purchased one or more of the affected products. Olympus requires you to take the following action:

1. Carefully read the content of this Field Safety Notice.

2. Inspect your inventory and identify any models and lots subject to this action. Please check all areas of the hospital to determine if any of these devices remain in inventory. Quarantine and cease use of the affected model/lots. Any models and lots that are not impacted can remain in inventory and be used. The model/lot number can be found on the box or pouch as illustrated below:



3. Contact your Olympus representative at [XXXXXXX] with regard to return and reimbursement procedure. Olympus will issue a credit note to your facility upon return of affected product.

4. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative at [XXXXXXX] latest by [XX.XX.XXXX].

Your competent authority is aware of the actions described in this letter.

Olympus requests that you report complaints to [local facility complaint reporting contact]. [If applicable:] Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at [phone] or at [email] for any additional information or support concerning this matter.

Sincerely,
Name
Title, Department/Region

REPLY FORM – QIL FY24-EMEA-26-FY24-OSTA-07

FIELD SAFETY NOTICE
Recall of certain lots of EZDilate Fixed Wire Balloon, EZDilate Wire Guided Balloon

[Name & Address of Hospital/Medical Facility]

[Dept/Attn]

[Inventory information (Material and Lot Number(s) of EZDilate Fixed Wire Balloon, EZDilate Wire Guided Balloon)]

Model	Lot Number	Quantity per piece

[Date]

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to **[XXXXXXX]**