



URGENT FIELD SAFETY NOTICE/ DEVICE RECALL
Dragonfly OpStar™ Imaging Catheter

Abbott Medical GmbH
Betriebsstätte Wetzlar
Schanzenfeldstr. 2
35578 Wetzlar

T: +49 6441-8707 50
www.abbott.de

Commercial Name: Dragonfly OpStar™ Imaging Catheter
FSCA-Identifizier: Dragonfly OpStar April 11, 2022
Manufacturer: Abbott Medical, Westford, MA, USA
SRN: US-MF-000011429
Type of Action: Device Recall

Attention: Risk Manager or Healthcare Professional

Dear Valued Abbott Customer:

Abbott has initiated a field action for specific lots of Dragonfly OpStar™ Imaging Catheter. Our records indicate that affected devices have been shipped to your account.

This action does not affect patients having successfully undergone procedures using these devices.

The proximal marker on devices from these lots may separate from the device. A dislodged marker may require additional intervention, including unplanned additional coronary intervention, or surgery. To date Abbott has received 5 complaints related to this issue, one which resulted in an embolism which required an additional intervention to resolve with no immediate adverse consequences. Potential risks include embolism, cardiovascular injury and myocardial ischemia.

What action should you take?

- Immediately stop using devices from affected lots (see attached)
- Review your inventory, complete, and return the provided Effectiveness Check Form
- Return all unused affected devices to Abbott
- Share this notification with relevant personnel in your organization
- If you have further distributed/transferred the affected products, notify those customers
- Report any occurrence of product performance issues or patient adverse events to Abbott

What action is Abbott taking?

- Abbott has taken immediate action to stop shipping devices from affected lots
- The investigation has determined there are no other affected products or lots in distribution
- Abbott will implement appropriate corrective actions to ensure product performance
- Abbott will work with customers to replace inventory, when available
- The appropriate regulatory agencies have been notified of this action

We regret any inconvenience this may cause you and appreciate your patience. Abbott is committed to providing high quality, compliant products and ensuring customer satisfaction. If you have any questions, please do not hesitate to contact your local Abbott Representative or Customer Service department at **+49(0) 6441-87075738** (Mo.-Fr. from 08 am to 05 pm).

Sincerely,

Abbott Medical GmbH – Betriebsstätte Wetzlar



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Part Numbers and Lot Numbers

Product Identifier/GTIN	Product Description	Model Number	Lot Number	
05415067031129	Dragonfly OpStar™ Imaging Catheter	1014651	8010027	8147191
			8010043	8153815
			8010047	8153816
			8010052	8211505
			8127930	8211506
			8127931	8211507
			8127932	8220671
			8127934	8220672
			8131366	8220673
			8131367	8220675
			8131369	8257085
			8131370	8257087
			8147186	8274128
			8147188	8294077
05415067031112	Dragonfly OpStar™ Imaging Catheter	1014652	8111644	8192796
			8131360	8211508
			8131361	8211509
			8131362	8211510
			8131363	8211511
			8131364	8211512
			8131365	8211513
			8157505	8211514
			8157506	8211515
			8184979	8211516
			8184980	8211517
			8184981	8211518
			8184982	8211519
			8185100	8211520
			8185101	8211521
			8192782	8220680
			8192783	8220681
			8192784	8220684
			8192786	8220685
			8192787	8220686
8192788	8256952			
8192789	8256953			
8192791	8256954			
8192793	8274133			
8192795	8294003			



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Effectiveness Check Form

Customer Account # _____

Account Name _____

Address _____

(Information required for regulatory effectiveness check)

After reviewing your inventory for the affected devices, complete this form and return this form and any affected devices to Abbott per the instructions below.

<p>Check One:</p> <p><input type="checkbox"/> A thorough search for all affected devices has been completed and no affected units remain in inventory. No devices will be returned.</p> <p><input type="checkbox"/> Affected devices have been identified and are being returned</p> <p>RGA Number: _____</p> <p>_____</p> <p>Customer Name/ Job Title (print) Signature Date</p>

This form is to be returned to Abbott

- If returning product, call Abbott Customer Service **+49(0)6441-87075738** to receive RGA number. Record RGA number above.
- Scan and email this form to **WETCustomerService@av.abbott.com** or fax to **+49(0)800-1808193**
- Return a copy of this completed form with returned product.