



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

Commercial Name: Dragonfly OpStar™ Imaging Catheter  
FSCA-Identifier: 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 8088 1765.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jonathan Wood', is written over a light blue horizontal line.

Jonathan Wood  
Regional Director, Vascular, North Europe



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**Dragonfly OpStar™ Imaging Catheter**

**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.**

**Check One:**

- A thorough search for all affected devices has been completed and no affected units remain in inventory. **No devices will be returned.**
- Affected devices have been identified and are being returned

**RGA Number:** \_\_\_\_\_

\_\_\_\_\_  
**Customer Name/ Job Title (print)                      Signature                      Date**

**This form is to be returned to Abbott**

- If returning product, call Abbott Customer Service 8088 1765 to receive RGA number. Record RGA number above.
- Scan and email this form to [maiaavregulatory@abbott.com](mailto:maiaavregulatory@abbott.com) or fax to 8088 1769
- Return a copy of this completed form with returned product.

