# Urgent—Field Safety Notice

## Urgent Field Safety Notice

**DEVICE: WORKER™ GUIDEWIRE AMPLATZ, STRAIGHT**
**FSCA: 2019-12-04-1**
**RECALL- Return to Argon Medical Devices, Inc.**

Date: December 9, 2019

**To:** _____
_____
_____

**Re:** RECALL - Worker™ Guidewire Amplatz Straight

Dear Physician, Clinician, or Hospital Administrator,

Argon Medical Devices has received a complaint from and international customer regarding a perceived increase in the stiffness of the soft/floppy end of the Worker Guidewires and reported an issue during a procedure where the guidewire easily perforated tissue during a procedure. The manufacturing process for the guidewire includes trimming of the flexible tip to the specified 3.5 cm length. The affected product was found to have a 1.0 cm tip. Argon has examined all in-house inventories, and the issue is limited only to the two-catalog numbers.

As a precautionary measure, Argon is conducting this recall to notify our customers of this operator error. Theoretically, there is a risk that if product is used with a wrong length dimension, those units could contribute to heightened risk associated with a puncture to a blood vessel or organ. Before using the product, users should double-check the dimension and tactile differentiability at the end tip of the wire. The user should be able to feel the difference in wire stiffness.

Argon has identified the cause in the manufacturing process, and corrective actions and inspections have been implemented to prevent this from happening again in the future.

The voluntary recall is of certain lot numbers of two specific catalog numbers of the Worker Guidewire product listed below. Our distribution records indicate that these devices were shipped to your facility:

In addition to our communications to the field, we will be communicating this issue to the US FDA and other Competent Authorities, as well as our Notified Body.

Our records indicate that we have shipped the following affected units to your organization.

1445 Flat Creek Road
Athens, TX 75751 USA
www.argonmedical.com

# Urgent—Product Recall Notice

**Model** 114135080

| Lot | Manufacture Date | Expiration Date |
|---|---|---|
| 11235895 | 10/23/2018 | 10/23/2023 |
| 11234476 | 10/18/2018 | 10/18/2023 |
| 11237014 | 11/6/2018 | 11/6/2023 |
| 11240602 | 12/10/2018 | 12/10/2023 |

**Model** 114135150

| Lot | Manufacture Date | Expiration Date |
|---|---|---|
| 11248718 | 2/25/2019 | 2/25/2024 |
| 11251204 | 3/19/2019 | 3/19/2024 |
| 11260495 | 5/28/2019 | 5/28/2024 |
| 11268741 | 7/30/2019 | 7/30/2024 |
| 11242667 | 1/8/2019 | 1/8/2024 |
| 11241250 | 12/10/2018 | 12/10/2023 |
| 11239540 | 12/3/2018 | 12/3/2023 |

The inventory sheet at the end of this letter helps us know what product is still in your possession. We request that you complete this form and return it as quickly as possible to our attention. This will allow us to begin staging replacement product to you and minimize interruption to service. All affected product should be returned to our Argon (Athens, TX) facility using RGA#25612, attention Arbee Cummings. The mailing address is listed below:

RGA# 25612
Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens, TX 75751 USA

Argon Medical will ship you replacement devices once we receive your returned product. Your assistance in accounting for the affected devices in your possession is greatly appreciated. If you have any questions about this letter or the recall action it describes please contact me at Beckie.Ellis@argonmedical.com. You may also contact Ms. Arbee Cummings (Arbee.Cummings@argonmedical.com) or Ms. Kimberli Scott at Kimberli.Scott@argonmedical.com.

Argon is committed to providing our customers with high-quality, effective medical devices. We take this commitment seriously and understand that on rare occasion, corrective actions such as this recall may be necessary to uphold that commitment. Thank you for choosing to do business with Argon Medical and we apologize for any inconvenience this action may cause you.

Sincerely,

# Urgent—Product Recall Notice

Beckie Ellis
Vice President, Regulatory Affairs/Quality Assurance
Argon Medical Devices, Inc.

Cc: Kimberli Scott, Quality and Compliance Manager

- *Please proceed to next page to respond to inventory on hand –*

# Urgent—Product Recall Notice

**Argon Recall: Guidewire – tip length**

Argon Medical Devices, Inc.
1445 Flat Creek Road,
Athens, TX 75751 USA
Attn: Ms. Arbee Cummings, Quality Specialist
Arbee.Cummings@argonmedical.com

## RGA# 25612

**Product Recall Report**

**Customer Address:** _____
_____
_____

| Argon Part Number | Shipping Date to your facility | Lot Number | # of units Shipped to your facility (boxes of 10) | # Currently on hand at your facility | Number to be Returned to Argon |
|---|---|---|---|---|---|
| | | | | | |

_____ _____
Signature of Individual Completing Inventory Printed Name

_____ _____
Title Date Signed by Facility Representative

Contact Phone Number: _____ Proposed Date to Return to Argon: _____