Arthrex GmbH | Erwin-Hielscher-Str. 9 | 81249 Munich | Germany
Clinic / Company
Street
Zip Code City

your contact
Jane Doe

E-Mail
Jane.Doe@arthrex.com

date
DD.MM.YYYY

# Field Safety Notice

**Reference: A328**

## Purpose

This Field Safety Notice (FSN) is issued to inform you about a recall concerning the AR-1678-02-RU 3.4 mm Drill Bit for SwiveLock® 4.75 mm, Reusable.

The device is intended to help with bone preparation before the implantation of 4.75mm anchors.

## Products affected by the issue

| Product Number | Product Name |
|---|---|
| AR-1678-02-RU | 3.4 mm Drill Bit for SwiveLock® 4.75 mm, Reusable |
| **Batch** | |
| 914305, 914314, 916729, 919384, 9164022420, 9167292431 | |

## Description of the issue

It was identified that the device includes an incorrect laser marking of “2.7mm” which is not part of the device specification and does not reflect the actual diameter of 3.4mm.

To date, Arthrex has received one complaint related to the affected device. The complaint was identified upon receipt, with no patient involvement.

If the incorrect marking is not recognized by the user, there is a potential risk that the device could be misidentified as a smaller diameter drill bit (e.g., 2.7 mm) and used accordingly. In such a scenario, a larger bone tunnel than intended may be created.
This could result in unintended surgical outcomes, such as reduced implant fixation or damage to surrounding anatomical structures. The worst credible harm associated with this issue is bone or joint damage due to improper tunnel sizing.

## Advice on action to be taken by the addressee of this notice

1. Immediately discontinue use, sale, and distribution of the affected product.

2. Immediately identify and quarantine all the indicated product/batch numbers you have in your control.

3. Please contact your local responsible Arthrex Representative.

4. Please complete the “Arthrex customer’s response form” and fax it back to +49 (89) 90 90 05 52 01 or email to vigilance@arthrex.de.

## Transmission of this Field Safety Notice

Please forward this Field Safety Notice (FSN) to all those who need to be aware of it within your organization or to any organization where the potentially affected devices have been transferred.

The relevant National Competent Authorities have been advised of this recall.

## Contact information

Product Surveillance GmbH:
Sarah Merkle
Manager Vigilance & Product Surveillance
Phone +49 89 90 90 05 52 40
E-Mail: vigilance@arthrex.de

Product-specific questions:
Jörg Mietzner
Manager Product Group Distal Extremities EMEA
Phone +49 (89) 909005 - 4119
E-Mail: Joerg.Mietzner@arthrex.de

Sincerely,

Sarah Merkle
Manager Vigilance & Product Surveillance

Arthrex GmbH
Oskar-von-Miller-Str. 6
85235 Odelzhausen
Phone: +49 89 90 90 05 52 40
Fax: +49 89 90 90 05 52 01
Email: vigilance@arthrex.de

# Arthrex customer's response form

## Field Safety Notice

Reference: A328

| Return To | |
|---|---|
| **To** | **Arthrex GmbH**<br>Product Surveillance<br>Oskar-von-Miller-Str. 6<br>85235 Odelzhausen<br>Germany |
| **E-Mail** | vigilance@arthrex.de |
| **Fax** | +49 89 90 90 05 52 01 |

| From | |
|---|---|
| **Facility Name** | |
| **Address**<br>**City** | |
| **Name** | |
| **Title** | |

Please complete the form as follows and return it by fax or email to the addressee above:

☐ The products in question of the field safety notice are not on our stock

☐ We are returning the following products (please specify quantity) **to our local responsible Arthrex Distributor:**

| Part Number | Batch Number | Quantity |
|---|---|---|
| AR-1678-02-RU | | |

Date Signature