



[Addressee name, address]

Date:

# Urgent Field Safety Notice

Reference: 8043971-2/3/20-001-R

## Purpose

This Field Safety Notice (FSN) is to inform you about a recall due to potential for breach in the sterile barrier.

## Products affected by the issue

Product Name	Part No.	Lot No.	UDI
FLIPCUTTER® III DRILL	AR-1204FF	See below	10818674021446

Scope includes all quantities from the associated batches:

19E01, 19E02, 19E03, 19E05, 19F10, 19F06, 19F05, 19F02, 19E10, 19F01, 19F03, 19F04, 19F07, 19F08, 19F09, 19E11, 19J22, 19J23, 19J21, 19J15, 19J17, 19J18, 19J20, 19J16, 19J19, 19J24, 19J26, 19J29, 19J25, 19K01, 19K03, 19K02, 19J28, 19K09, 19M09, 19M11, 19K11, 19M12, 19M10, 19K12, 19M01, 19M16, 19M15, 19M14, 19M13, 19N06, 19N05, 19M17, 19N02, 19M18, 19M21, 19M22, 19N03, 19N07, 19N08, 19N14, 19N13, 19N11, 19N12, 19N09, 19P03, 19P02, 19P04, 19P05, 19P01, 19P06, 19R07, 19R05, 19R06, 19R04, 19P13, 19P08, 19R02, 19P09, 19P11, 19P12, 19P07, 19R01, 19P10

## Description of the issue

it was discovered by the product surveillance department that there is a trend in complaints for the blister tray comprising the sterile barrier of ar-1204ff having been cracked. an additional trend was observed during supplemental inspection of finished goods inventory where devices contained black particle(s) within the sterile barrier

Risk to patient includes potential contact with non-sterile product.

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

1. Immediately discontinue use, sale and distribution of the product.
2. Please contact Arthrex GmbH Product Surveillance at [complaints@arthrex.de](mailto:complaints@arthrex.de).
3. Our product surveillance specialists are available to answer questions regarding credit for affected devices in your possession.
4. You do not need to notify any patients about this product removal.
5. The attached form must be used and sent back immediately.

## 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 voluntary recall.

## Contact information

Sincerely,

