HOLOGIC®

Zaventem, January 7, 2026

# FIELD SAFETY NOTICE
# VOLUNTARY FIELD SAFETY CORRECTIVE ACTION

**Brevera® Breast Biopsy System Disposable 9 Gauge Needle**

**FSN Ref: MISC-11281-EUR-2101 Rev. 002**
**FSCA Ref: FA-00291**
**Manufacturer SRN: US-MF-000045852**

**Products Subject to this Field Safety Notice**

| Part Number | Description | Lots | UDI Impacted |
|---|---|---|---|
| BREVDISP09 | Brevera® Breast Biopsy System Disposable 9 Gauge Needle | All | 15420045512863 |

Dear Valued Hologic Customer,

Hologic is initiating a Field Safety Correction Action (FSCA) to remove all lots of **Brevera Breast Biopsy System Disposable 9 Gauge Needle**. The **Brevera® Breast Biopsy System Disposable 9 Gauge Needle** is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities.

Our records show that your facility received one or more of the subject products. Please review this notice carefully and follow the instructions below in response to this Field Safety Notice.

## Reason for the Field Safety Corrective Action

The subject device is being removed because there is a risk of metal and plastic particles being dislodged from the device during use. An internal review of post-market data, covering a three-year period during which 677,307 **Brevera® Breast Biopsy System Disposable 9 Gauge Needles** were shipped, revealed that one hundred eight (108) complaints were received related to this issue. Sixteen (16) of these reported cases had confirmed particles in patient breast tissue and/or tissue sample post-biopsy, and in one (1) instance a procedure was aborted.

The particulate originating from the device may include 304 stainless steel small fragments from a broken needle or Ultra High Molecular Weight Polyethylene from the cut block in the needle.


Hologic BV - the Corporate Village, Building Caprese 3rd floor, Da Vincilaan 5, 1930 Zaventem, Belgium
T: +32 2 711 46 80 | F: +32 2 725 20 87 | Hologic.com
BNP PARIBAS FORTIS - IBAN BE75 2100 8769 7651 - BIC BEBABEBB - BTW: BE 0445 434 787 - RPR Brussels: 0445 434 787

## Potential Impact

If particulate originating from the device is left behind in a patient post-biopsy or if particulate enters a biopsy specimen, the following potential adverse effects may arise:

**Patient:**

- Foreign body reaction
- Hematoma/haemorrhage
- Infection
- Remote risk of vascular embolization
- Migration and tissue erosion
- Acute and/or chronic inflammatory tissue reaction
- Delay in diagnosis or treatment of a potentially life-threatening condition
- Pain
- Requirement for additional imaging, biopsy procedure, or surgical procedure to remove a retained fragment or biopsy
- Diagnostic imaging artifacts

Small, 304 stainless-steel fragments in breast tissue pose a risk of localized heating or MRI interference. Additionally, the incidence, severity, and duration of any breast imaging artifact caused by the foreign body in the breast is unknown.

**User:**

- Remote risk of soft tissue injury to the clinician if a retained fragment is encountered during surgical and/or pathological manipulation
- Additional biopsy procedure may be required due to sampling error

## Recommendations for Healthcare Providers

Healthcare providers who have treated patients using the subject device and who have identified potential device fragments left in a patient (e.g. through post-biopsy imaging) should:

- Inform the patient of the issue and potential risks.
- Assess the significance based on clinical findings and risk of complications.
- Determine the appropriate clinical management (i.e. conservative monitoring in the asymptomatic patient or, if indicated clinically, surgical removal).
- Continue to provide routine follow-up care ensuring that the patient has clear instructions on seeking further treatment (signs & symptoms that may indicate complications).
- Report suspected device complaints and/or adverse events to Hologic.


Hologic BV - the Corporate Village, Building Caprese 3rd floor, Da Vincilaan 5, 1930 Zaventem, Belgium
T: +32 2 711 46 80 | F: +32 2 725 20 87 | Hologic.com
BNP PARIBAS FORTIS - IBAN BE75 2100 8769 7651 - BIC BEBABEBB - BTW: BE 0445 434 787 - RPR Brussels: 0445 434 787

SIGNATURES ON FILE

HOLOGIC®

## Actions to be taken by all users following this FSN

1. Do not use **Brevera® Breast Biopsy System Disposable 9 Gauge Needles**.
2. Please segregate and count how many units of the subject product are currently in your inventory.
3. Please quarantine all units of the subject product.
4. Forward this notice to anyone in your facility that needs to be informed.
5. Post a copy of this notice in a visible area for awareness and keep a copy for your records.
6. If any of the subject product have been forwarded to another facility, contact that facility and provide them with this notice.

**Additional information for Direct Hologic customers:**

1. Please follow the above instructions (points 1-6).
2. Please discard all units in your inventory.
3. Please confirm receipt of this notification:
   - Complete and submit the online Customer Response Form provided by IQVIA.
   - Complete and submit the online Customer Response Form even if you no longer have the affected product in inventory.
   - Provide your organization details.
   - Provide quantity of units discarded. Please note that you will be issued credit for those units.
   - Signing the form acknowledges receipt of this notification, as well as **confirms destroying** of all remaining inventory of the affected product.

**Additional information for Hologic Distributors or Resellers:**

1. If you are a distributor or reseller, please inform your customers of this Field Safety Notice.
2. Request your customers, who received **Brevera® Breast Biopsy System Disposable 9 Gauge Needles** to: do not use the product & quarantine the remaining inventory.
3. Ask your customers to provide you written response with confirmation of number of units remaining in their stock.
4. **Align with your customer on discard or return to your facility for disposal**.
5. Please confirm receipt of this notification:
   - Complete and submit the online Customer Response Form provided by IQVIA.
   - Complete and submit the online Customer Response Form even if you no longer have the affected product in inventory.
   - Provide your organization details.
   - Provide quantity of units discarded (including units reported by your customers). Please note that you will be issued credit for those units.
   - Signing the form acknowledges receipt of this notification, as well as **confirms destroying** of all remaining inventory of the affected product.

**IQVIA** is Hologic official partner for this FSCA. Hologic has partnered with IQVIA to conduct follow up communications should no response be received to this letter. Replying promptly will confirm your receipt of the notification and prevent you from receiving repeat notices.


Hologic BV - the Corporate Village, Building Caprese 3rd floor, Da Vincilaan 5, 1930 Zaventem, Belgium
T: +32 2 711 46 80 | F: +32 2 725 20 87 | Hologic.com
BNP PARIBAS FORTIS - IBAN BE75 2100 8769 7651 - BIC BEBABEBB - BTW: BE 0445 434 787 - RPR Brussels: 0445 434 787

SIGNATURES ON FILE

HOLOGIC®

For additional support, please contact Hologic's Technical Support (information below).

**Direct Markets (Contact for Customers)**

| Country | Phone Number | email |
|---|---|---|
| Austria | 0800 29 1919 or local +43 720 710 811 | TSbsh@hologic.com |
| Germany | 0800 589 1635 or local +49 3222 109 65 91 | TSbsh@hologic.com |
| Italy | 800 786308 or local +390694801337 | TSbsh@hologic.com |
| Spain | 900988004 or local +34932204047 | TSbsh@hologic.com |
| Switzerland | 0800 29 8921 or local +41 215 880 145 | TSbsh@hologic.com |
| United Kingdom | 0800 323318 or local +441617681658 | TSbsh@hologic.com |

**Indirect Markets (Contact for Distributors)**

| Country | Phone Number | email |
|---|---|---|
| EMEA | +32 2 711 45 45 | Be-techsupport@hologic.com |

Regulatory Authorities of your country have been notified of this Field Safety Notice – if applicable.

We apologize for any inconvenience that this may cause and appreciate your patience and your willingness to work with us.

Marta Szczerczowska-Katillari
Manager Post Market Surveillance


Hologic BV - the Corporate Village, Building Caprese 3rd floor, Da Vincilaan 5, 1930 Zaventem, Belgium
T: +32 2 711 46 80 | F: +32 2 725 20 87 | Hologic.com
BNP PARIBAS FORTIS - IBAN BE75 2100 8769 7651 - BIC BEBABEBB - BTW: BE 0445 434 787 - RPR Brussels: 0445 434 787