Zaventem, December 18, 2025

FIELD SAFETY NOTICE
VOLUNTARY FIELD SAFETY CORRECTIVE ACTION

Brevera® Breast Biopsy System Disposable 9 Gauge Needle

FSN Ref: MISC-11281-EUR-2101 Rev. 001
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

NOTE: Product is NOT being removed from the field and does not need to be returned.

Dear Valued Hologic Customer,

At Hologic, our top priority is patient and health care provider safety. We continually evaluate our products and processes to improve quality and reliability. Hologic is initiating a Field Safety Corrective Action in the form of a Field Safety Notice (FSN) for all lots of Brevera Breast Biopsy System Disposable 9 Guage 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

An internal review of post-market data for the Brevera® Breast Biopsy System Disposable 9 Gauge Needle identified a 0.016% occurrence rate of particulate generated by the device during normal clinical use. This rate equates to approximately 1.6 incidents per 10,000 uses. Over a three-year period, there were sixteen (16) reported cases in which a device-related particulate was potentially identified or confirmed in patient breast tissue post-biopsy, and in one (1) instance a procedure was aborted.

While the current Instruction for Use (Manual Number: MAN-07918) identifies infection, foreign body reaction, pain and hematoma as potential adverse effects associated with the use of the subject device, it does not describe the specific risk of particulate generation. This FSN is intended to inform users of the potential for particulate generation, which may contribute to these adverse clinical effects, out of an abundance of caution.

Hologic BV - the Corporate Village, Building Caprese 3rd floor, Da Vincilaan 5, 1930 Zaventem, Belgium
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Potential Patient Impact

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

- Foreign body reaction
- Hematoma/hemorrhage
- Infection
- Misdiagnosis
- Pain
- Requirement for additional treatment/imaging
- Delay in treatment

The particulate generated by 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 executed testing which has confirmed that these device materials are biocompatible for their intended use and that the long-term presence of these materials in breast tissue poses a negligible toxicological risk to patients.

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 as well as provide information on the negligible risk confirmed via toxicological risk assessment and biocompatibility testing.
- Assess the clinical significance based on patient symptomatology 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 (contact details below).

Healthcare providers who are planning to treat patients with the subject device should:

- Prior to biopsy, consider discussing with patients the potential risks associated with the issue, while also emphasizing the negligible toxicological risk confirmed with testing.
- Post-procedure, plan to inspect the biopsy site for retained fragments by considering post-biopsy imaging.
- Continue to provide routine follow-up care.
- Report suspected device complaints and/or adverse events to Hologic (contact details below).

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Please take the Following Steps

NOTE: Product is NOT being removed from the field and does not need to be returned.

1. Familiarize yourself with the content of this letter.
2. Forward this notice to anyone in your facility that needs to be informed.
3. Post a copy of this notice in a visible area for awareness and keep a copy for your records.
4. If you are a Hologic customer (including distributors), please acknowledge receipt of this notification. To complete this step, please complete the online Customer Response Form provided by IQVIA (our official partner for this FSCA) within 3 business days of receiving this notice. Replying promptly will confirm your receipt of the notification and prevent you from receiving repeat notices.
5. If you are a distributor, please inform your customers of this Field Safety Notice.

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 appreciate your patience and your willingness to work with us.

Marta Szczerczowska-Katillari
Manager Post Market Surveillance

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