

Biopsy Management Devices ^{REF} BB0023, EZ0023, DX26280, DX26380-5, DX26290, DX26290-5, X23285, X25300, FM2000-B, BP1000, FM2000-W, BP1000W, FM2000-K, BP1000K, FM2000-Y, BP1000Y, BBG100, BBG200, BBG044

FM2000-B	Biopsy Pad, Blue, 1"x1 1/4" (25 x 30 mm), 500/bag
BP1000	Biopsy Pad, Blue, 1"x1 1/4" (25 x 30 mm), 1000/bag
FM2000-W	Biopsy Pad, White, 1"x1 1/4" (25 x 30 mm), 500/bag
BP1000W	Biopsy Pad, White, 1"x1 1/4" (25 x 30 mm), 1000/bag
FM2000-Y	Biopsy Pad, Yellow, 1"x1 1/4" (25 x 30 mm), 500/bag
BP1000Y	Biopsy Pad, Yellow, 1"x1 1/4" (25 x 30 mm), 1000/bag
FM2000-K	Biopsy Pad, Black, 1"x1 1/4" (25 x 30 mm), 500/bag
BP1000K	Biopsy Pad, Black, 1"x1 1/4" (25 x 30 mm), 1000/bag
BB0023	Biopsy Paper, Blue 2" x 3" (51mm x 76mm) PK/500
EZ0023	Bio-Paper, White, 2" x 3" (51mm x 76mm) PK/500
DX26280/-5	Tri-Fold Secure, Blue Biopsy Filter Paper, PK/500, CS/2,500
DX26290/-5	Tri-Fold Secure, White Biopsy Filter Paper, PK/500, CS/2,500
X23285	Vortex Micro (Bi-fold) White Biopsy Filter Paper, PK/500
X25300	Vortex Biopsy (Bi-fold) White Biopsy Filter Paper, PK/500
BBG100	Paper Bio-Bags, White, 7cm x 7cm, CS/600
BBG200	Paper Bio-Bags, White, 7.5cm x 5cm, CS/500
BBG044	Paper Bio-Bags, White, 4cm x 4cm, CS/600
BIO3045W	Biopsy Bags, White, 30 x 50 mm, PK/100
BIO3045WM	Biopsy Bags, White, 30 x 50 mm, CS/1000
BIO3045Y	Biopsy Bags, Yellow, 30 x 45 mm, PK/100
BIO3045B	Biopsy Bags, Blue, 30 x 45 mm, PK/100
BIO4573W	Biopsy Bags, White, 45 x 73 mm, PK/100
BIO7595W	Biopsy Bags, White, 75 x 95 mm, PK/100

Materials Not Included

Products should be placed inside a standard histology cassette, (not included).

Devices Required

Not Applicable.

Storage and Stability

Cancer Diagnostics, Inc. Biopsy Management Devices are to be stored at room temperature (15-30°C).

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In Use Stability

Stable under normal conditions. User discretion should be utilized when determining in-use stability.

Sterility

Cancer Diagnostics, Inc. Biopsy Management Devices are not sterile products.

Warnings/Precautions

Not Applicable.

Infectious Material Status

Cancer Diagnostics, Inc. Biopsy Management Devices do not contain infectious material. All specimens whether fresh or fixed—and any materials exposed to them should be treated as potentially infectious. Handle and dispose of these items using appropriate precautions in accordance with your facility's policies and procedures.

Special Facilities

Cancer Diagnostics, Inc. biopsy management devices should be used in accordance with your facility's established policies, procedures, and safety guidelines.

Specimen Handling

Fresh Tissue Grossing — All specimens should be handled as if they are capable of transmitting infection.

Preparation for Use

- Bio-Paper

Bio-Paper should be folded to fit within a standard cassette so that the cassette can be securely latched. The use of a colored pigment/dye may aid in visualizing specimens on the Bio-Paper. Any colored pigment/dye applied to specimens must be validated at the point of use by the end user.

- Mesh Biopsy Bags

Remove a single bag from the packaging. The bag can be easily opened by gently twisting it between the thumb and forefinger in preparation for loading. Colored bags can be chosen for specimen contrast.

- Biopsy Pads

Biopsy pads must not extend beyond the internal side walls of a cassette and must allow a standard cassette to be securely latched. The combined thickness of the biopsy pad and tissue specimen must not exceed the internal height of a standard cassette (4 mm). To prevent specimen flotation and minimize artifacts, biopsy pads should be pre-saturated in fixative. When soaked in formalin, the pads should fully cover all cassette pores so that, when the cassette is gently moved side to side, all pores remain covered.

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- Tri-Fold Secure, (Blue or White) Biopsy Filter Paper & Vortex (Bi-Fold) Papers
Perforated folding filter paper for containing biopsies during processing.
Papers available in WHITE or BLUE version for optimal biopsy color contrast.
Oval papers (White) for Vortex Biopsy and Vortex Micro. Pre-moisten with water or formalin.
- Paper Bio-Bags
Paper Biopsy Bags provide security for small specimens.

Direction for Use

- Bio-Paper

Remove a single sheet of Bio-Paper from the dispenser pack. Place the biopsy specimen in the center and fold the Bio-Paper several times to fully enclose the tissue. Insert the folded Bio-Paper into a cassette, ensuring it fits entirely within the cassette and allows the lid to close securely. Bio-Paper may be pre-wetted to help prevent drying artifacts.

- Mesh Biopsy Bags

Fixative and specimen may be poured directly into the bag, allowing the fixative to pass through while retaining the biopsies inside. Fold the bag at least once, place it into a cassette, and process as usual. Specimens may also be transferred from a container of fixative into a biopsy bag using forceps. After processing, the bag can be removed and opened to recover the specimen for paraffin embedding.

- Biopsy Pads


Use pads to secure small biopsies during fixation and processing to prevent specimen loss. Samples may also be sandwiched between two foam pads and placed in cassettes with either metal or plastic lids. Contrasting colored pads in relation to biopsy enhance tissue visibility.

- Tri-Fold Secure, (Blue or White) Biopsy Filter Paper

Pre-moisten with water or formalin. Special tri-fold design folds once at perforation and then one more time to secure biopsy completely. Papers fit edge to edge in cassette ensuring proper biopsy security. Easy security at time of grossing, efficient “unwrapping” during embedding. Vortex Papers are bi-fold and fold once onto specimen.

- Paper Bio-Bags

Remove a single paper Bio-Bag. Place the biopsy specimen into Bio-Bag and fold several times to fully enclose the tissue. Insert the folded Bio-Bag into a cassette, ensuring it fits entirely within the cassette and allows the lid to close securely. Bio-Bags may be pre-wetted to help prevent drying artifacts.

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Readiness for Use

Biopsy Handling Devices are ready to use products.

Quality Control

Quality control should be assessed at the point of use.

Expected Results

When used in accordance with the instructions for use, Biopsy Management Devices permit the free flow of fixative and/or processing reagents while securely retaining specimens within the cassette.

Analytical Performance

Cancer Diagnostics, Inc. Biopsy Management Devices do not detect, measure, or analyze any analyte or biological marker. These medical devices are intended solely to securely contain tissue specimens within a cassette during fixation, processing, and handling. Accordingly, analytical performance characteristics—including, but not limited to, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (as derived from trueness and precision), limits of detection and quantitation, measuring range, linearity, and cut-off values—are not applicable to the performance of this system. Likewise, criteria associated with analytical testing, such as determination of specimen collection and handling parameters, control of known endogenous or exogenous interferences, and evaluation of cross-reactivity, do not apply to these devices.

Clinical Performance

Cancer Diagnostics, Inc. Biopsy Management Devices are not intended to detect, diagnose, or indicate any specific disease, pathological process, or physiological state. They function solely as specimen-management accessories used to securely contain tissue samples during fixation and processing. As these devices do not generate diagnostic results, clinical performance metrics—including diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratios, and expected values in normal or affected populations—are not applicable to their use or performance.

Disposal

Dispose of Biopsy Management Devices in accordance with licensed waste-collector sorting instructions and all applicable facility policies and procedures



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