Instructions for Use

XPress BCD® Breast Compression Device

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2.0 XPRESS® BCD INSTRUCTIONS FOR USE

2.1 Front Panel

Breast Compression Device

XPress BCD®

Instructions for Use

2.2 Indications for Use

The Xpress BCD is a reusable device indicated for use with stereotactic biopsy platforms to apply temporary focal mechanical compression to a stereotactic breast biopsy site to achieve hemostasis.

Rx Only. Federal (USA) law restricts this device to sale by or on the order of a physician.

2.3 Contraindications for Use

- Non-sensate skin.
- Anticoagulated patients.

2.4 Warnings

- Use the least amount of compression area and force needed to decrease hematoma formation at the breast biopsy site.
- Anesthesia / analgesia administered for stereotactic breast biopsy can affect patient sensation and feedback of pain associated with device compression.
- Unlike manual compression, device compression does not provide monitoring staff with tactile feedback of the applied compression force.
- Clinical effects of mechanical compression beyond twenty minutes with the XPress device were not evaluated.
- Chronic effects of compression with this device such as pain, fat necrosis, scarring, and changes that obscure imaging signs of malignancy are unknown.
- Close patient supervision during compression with the XPress BCD is required.
- The safety and use of the XPress BCD with anticoagulated patients, other than patients on low dose ASA, has not been assessed.
- As with manual compression of the breast following all minimally invasive breast biopsies, procedures and plans for dealing with excessive or prolonged bleeding are required for the breast intervention suite.

2.5 Precautions

- Avoid dropping the XPress BCD. If dropped, inspect the XPress BCD for damage prior to use.
- If an XPress BCD is damaged in any way, use another XPress BCD or employ manual compression. A damaged device can compromise its appropriate attachment to the stereotactic guidance paddle, or presents a safety concern, such as a sharp edge or fracture. Discontinue use of the device.
- Contact the manufacture via the User Assistance numbers to inform the manufacturer of the XPress BCD damage.

2.6 Device Description

The XPress BCD is a reusable medical device that is a uni-modular unit without movable parts, which is made of Delrin® DuPont polymer and to be used with a single-use Xpress BCD Cover. The XPress BCD Cover is not made with natural rubber latex. The XPress BCD is available in three different geometric configurations provided as a set of three reusable, non-sterile

compression surfaces. XPress BCDs are designed to be used with the biopsy paddles of stereotactic biopsy platforms and have a common paddle-side surface which allow for rapid placement into, and temporary attachment to, the biopsy compression paddles; typically performed in less than 5 seconds. XPress BCDs are designed to apply temporary focal mechanical compression to a stereotactic breast biopsy site to achieve hemostasis and decrease the rate of formation of immediate post-biopsy hematoma (greater than 1cm diameter).

The compressive surface areas of the Spherical and Pyramidal XPress BCD designs average 670 mm^2 (approximately the surface are of two human fingers), while the Flat XPress BCD surface is 2,900 mm^2, essentially matching the size of the biopsy window (2,800 mm^2). The spherical (Figure 1) and pyramidal (Figure 2) designs have nearly identical surface area (approximating two human fingers side-by-side) but differ primarily in the centering of compressive force relative to the center of the biopsy window of the stereo-guide compression paddle. The decision regarding selection of a particular compression surface area may be influenced by a patient's breast size; however, it is primarily determined by the proximity of the biopsy incision site to the chest wall or nipple.

- The **spherical compression surface** has a flattened spherical compression intended for compression of biopsy sites positioned centrally within the biopsy window (Figure 1).
- The **pyramidal compression surface** has its compressive surface offset from the center of the biopsy window to several millimeters from either the top, posterior chest-wall side of the breast, or, if reversed in orientation, to the inferior, nipple side of the biopsy paddle aperture. The device design places focused compression eccentrically within the biopsy window approximately 2 mm from the posterior (chest wall side) or, in 180 degree reverse orientation, 2 mm form the anterior (nipple side) edge of the biopsy window. The pyramidal design is intended to be optimal for compression of post-biopsy sites located far posteriorly or anteriorly within the breast (Figure 2).
- The **flat compression surface** is designed for compression of women with breasts compressing to less the 25 mm, where more focal compression might be uncomfortable (Figure 3).

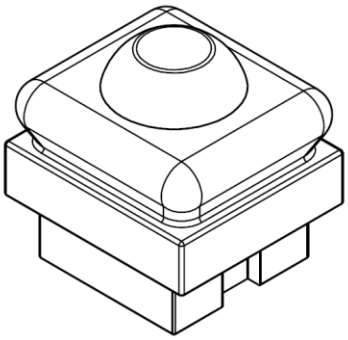

Figure 1.
Spherical
Compression Surface

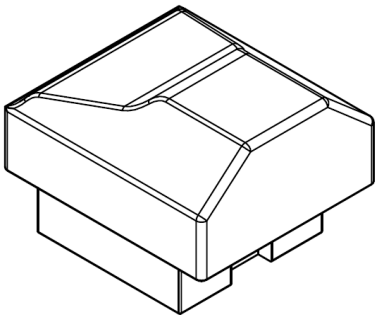

Figure 2.
Pyramidal
Compression Surface

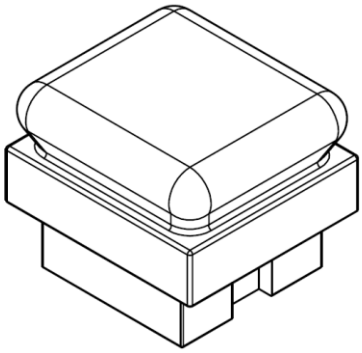

Figure 3.
Flat
Compression Surface

Accessories: The XPress BCD Cover is a sterile device that is a 4" X 5" polyethylene bag with an elastic closure band made of 2 mil polyethylene. XPress BCD Covers are intended to be used to completely cover an Xpress BCD before any patient use of an Xpress BCD. When an XPress

BCD is entirely enclosed within the XPress BCD Cover, the Xpress BCD will not come in direct contact with the patient or the compression paddle. No other accessories are provided.

2.7 Clinical Study Report

A single, investigational device arm only, prospective clinical study was conducted at one investigational site to evaluate the performance of the XPress BCD breast compression device to obtain hemostasis after stereotactic-guided breast biopsy following 120 biopsies in 118 female subjects with mammographic findings that warranted stereotactic biopsy. Five investigators and six assistants participated in this study; the 118 enrolled and treated subjects were eighteen years of age and older and not currently on antithrombotic therapy other than low dose aspirin. Screening excluded subjects who were on any other anti-thrombolytic therapy including, but not limited to, warfarin, clopidogrel and heparin.

XPress BCDs are designed to apply temporary focal mechanical compression to a stereotactic breast biopsy site to achieve hemostasis and decrease the rate of formation of immediate post-biopsy hematoma (greater than 1cm diameter). The primary clinical performance measure of the clinical study was hematoma formation. Hematoma was defined as a new three dimensional mass (> 0.52 cm^3) detected on standard post-biopsy full- field mammography.

Table 1 summarizes demographics and performance measures for 120 biopsy procedures performed on 118 enrolled and treated clinical study patients. Immediate post-compression hematoma was detected by primary investigators in 9/120 biopsies (7.5%). Additional delayed hematomas detected out to one week after biopsy were found following 4/120 (3.2%) of the biopsies. No mammographic evidence of fat necrosis was noted at one-year post-biopsy in a subgroup of 65 subjects who had not been subject to open biopsy or lumpectomy and were evaluated with mammography at one year post-biopsy. All biopsy sites meeting the criteria for evaluation were assessed for mammographic for evidence of fat necrosis by both the primary study and independent mammographers.

Table 1. Demographics and Performance Measures across 118 Patients and 120 Biopsy Sites

Measure	Age (yrs)	Breast Density	Breast Compression (mm)	Calcs/ Other*	Cores	Compression Time (min)	Hematoma	Hematoma Size (cm^3)	Delayed Hematoma	Fat Necrosis
Total				80/ 40			9/120 (7.5%)		4/120 (3.3%)	0/65
Average	57	2	65		9.8	11		4.4		
Range	34-79	1-4	30-103		5-24	10-20		1.0-12.1	Occurred on days 2, 5, 7, 7	

*80 sites were clusters of calcification. 40 sites were other targets, including masses, densities, and sites of architectural distortion.

Table 2 provides the results from two independent mammographers' examinations; one found hematomas on immediate post-biopsy imaging following 7/120 (5.8%) of biopsy procedures and the other in 9/120 (7.5%). Neither noted any mammographic evidence of fat necrosis in the 65 subjects who did not proceed to open biopsy or lumpectomy and for whom mammography at one year post-biopsy was available for review.

Table 2. Independent Imaging Review across 118 Patients and 120 Biopsy Sites

Reviewer	Hematoma	Average Hematoma Size (cm^3)	Fat Necrosis
A	7/120 (5.80%)	5.6	0/65
B	9/120 (7.5%)	5.7	0/65

Of the 120 original biopsy sites, 65 were evaluable for evidence of fat necrosis as surgical biopsy/lumpectomy had not been performed and mammograms were available for review at one year following biopsy and mechanical compression.

Table 3 presents assessments reported by study staff and the 118 subjects. Most assessments are reported per biopsy site (N=120), however, post-study satisfaction was reported per patient (N=118)

Table 3. Staff and Subject Reported Outcomes across 118 Patients and 120 Biopsy Sites

	Staff-Reported Evaluation	Subject-Reported Pain			Subject-Reported Satisfaction		
		Procedure	Compression	Post	0-hour	24-hour	1-7 day
# Biopsy Sites	120	120	120	120	120	115/118 patients	113/118 patients
Average	5	2	0.9	0.3	1.3	1.3	1.2
Criteria Rang	-5= extreme degradation 5= extreme enhancement	0 = no pain 10 = sever pain			1 = great experience 5 = poor experience		

Note: Staff evaluation compared their impressions on the use of mechanical compression on workflow relative to the use of standard manual compression using a 10 point scale (-5 extreme degradation to +5 extreme enhancement of workflow). The effect on workflow closely mirrored staff estimates of net time saved or lost (in minutes) relative to standard manual compression (assuming that they would have been responsible for performing manual breast compression).

2.8 How Supplied

Contents: The XPress BCD kit contains the following components:

- Set of three (3) XPress BCD compression surfaces:
  - 1 - Spherical compression surface
  - 1 - Pyramidal compression surface
  - 1 - Flat compression surface
- 10 - XPress BCD Covers
- 1 – Instructions for Use

XPress BCD compression devices are provided non-sterile, are reusable and have no expiration date. The manufacture date is provided on the Outer Box Label and on each XPress BCD device. No additional equipment is required for installation of the XPress BCD into the stereotactic-guide compression paddle.

XPress BCD Covers are single patient use only devices that are sterilized by gamma radiation. Discard XPress BCD Covers into an appropriate container after use. The XPress BCD Cover is not made with natural rubber latex.

Cleaning and Disinfection: The XPress BCD device, without protective covering, must be cleaned and then disinfected after each procedure between patients, including between biopsies on the same patient, using an EPA-registered disinfectant that achieves intermediate level of disinfection with a tuberculocidal claim. Always follow the disinfectant manufacturer's instructions for cleaning and disinfection of devices. There are no other specific maintenance requirements for the XPress BCD.

The XPress BCD is made of Delrin® acetal homopolymer resin. This material is compatible with Sterilex® Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution. Delrin® is not compatible with oxidizing disinfectants such as Accel TB One-Step Surface Cleaner and Disinfectant.

Storage: The XPress BCD set requires no specific requirements for storage. Extended storage will not affect the performance of the Product.

User assistance: If any questions or problems are encountered associated with the preparation or use of the XPress BCD product, refer to Section 2.10, Customer Assistance, to contact the manufacturer.

2.9 Instructions for Use

1. Select the device with the compression surface design considered optimal for the biopsy site and patient.
2. Visually inspect the selected XPress BCD before each use to ensure that the device has not been damaged. If an XPress BCD is damaged, replace the XPress BCD with an undamaged device or use manual compression.
3. Use sterile technique to handle the XPress BCD sterile covering, placing the sterile covering around the selected XPress BCD with the elastic cover opening facing away from the compression surface.
4. Place the sterilely covered XPress BCD on the physician's sterile field for use after stereotactic biopsy.
5. Complete the stereotactic biopsy with standard post-biopsy clip placement imaging.
6. Withdraw the compression paddle from the breast and immediately wipe the stereotactic guide with an absorbent sterile gauze to remove any gross contamination with blood. Place two twice-folded 4" X 4" sterile gauze pads against the biopsy site skin incision and begin manual breast compression. Ask the patient to report and grade the level of sensation and pain (scale from one/minimal to ten/severe) at the biopsy site prior to mechanical compression.
7. With the free hand, place the attachment side of the XPress BCD (enclosed in sterile covering) into the window of the compression paddle (Figure 4), and move this downward, approximately 3 mm, so the attachment notch engages the dependent lip of the compression paddle. This maneuver takes less than 5 seconds. No tools are required.

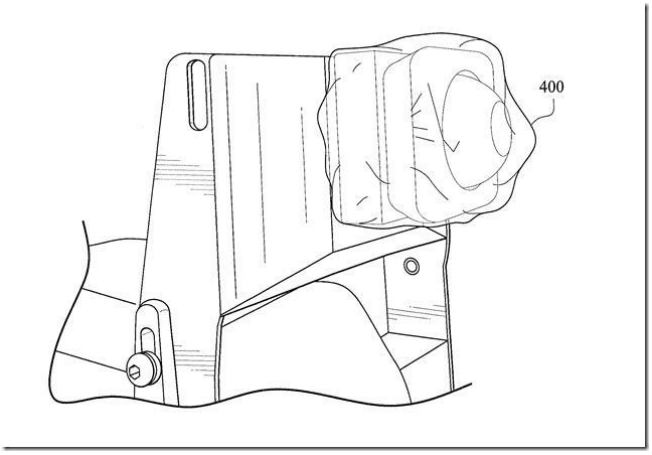

Figure 4. XPress BCD mounted in compression paddle of stereotactic biopsy machine wrapped in sterile covering

8. Interpose a third, unfolded 4” X 4” sterile gauze as further contact and sterile barrier between the covered XPress BCD and the patient’s skin, then advance the paddle to begin mechanical compression with the XPress BCD.
9. Center the compression surface of the XPress BCD device on the needle incision site using the "X" and "Y" controls of the biopsy table needle control.
10. Advance the compression paddle and attached XPress BCD toward the breast using the motorized and/or manual "Z" controls.
11. Apply compression to match standard manual compression, and maintain this compression as for manual compression. The compression should be firm but not painful and should be easily tolerated for up to twenty minutes. Similar to mammography and manual post-biopsy compression, the amount of compression is an interactive process between the patient and technologists as patients have variable tolerance.
12. Attend the patient at all times during the use of the mechanical compression device. If the patient notes significant or increasing pain during compression, release compression and conduct a clinical assessment of the biopsy site.
13. Apply compression for ten minutes in routine cases. As in manual compression, maintain compression for a longer period of time if any of the following are noted: significant bleeding or hematoma development during the biopsy; an unusual amount of suctioned blood during the biopsy or within the biopsy needle guide prior to clip placement; or a hematoma in post-biopsy imaging (post-clip-deployment images). To conduct a direct clinical assessment of the biopsy site, simply withdraw the compression paddle. Clinical effects of mechanical compression beyond twenty minutes with the XPress device were not evaluated.
14. At termination of biopsy site compression, withdraw the compression paddle and XPress BCD and conduct a clinical assessment of the biopsy site. Dress the incision site per individual facility protocol.
15. Perform standard whole field imaging of the breast to confirm accurate lesion targeting, adequate clip placement, and assess the biopsy site and tract for the presence of hematoma or other complications. Conduct additional manual or mechanical compression if clinically warranted.

2.10 Customer Assistance

For more customer assistance contact the XPress BCD Customer Support Department at Carbon Medical Technologies. XPress BCD® is a registered trademark.

Technical Assistance: 651-653-8512

Emergency Assistance: 651-653-8512

2.11 Back Panel

XPress BCD® Breast Compression Device

Manufactured for XPress BCD® by Carbon Medical Technologies, Saint Paul, MN 55110 U.S.A.

IFU part number: BCD-IFU-001

IFU revision number and date: Rev.01 7/12/17