

Raising the level of core needle biopsy since 1987

# Proven. Powerful. Precise.





Product type	Product name	Kit option	Penetration depth	Penetration depth Advanced echogenic technology	Available gauge sizes			Available needle lengths								
					12 g	14 g	16 g	18 g	20 g	6 cm	10 cm	13 cm	16 cm	20 cm	25 cm	30 cm
Automatic and Semi-Automatic	MARQUEE <sup>®</sup> Disposable Core Biopsy Instrument	•	18 mm and 25 mm (adjustable)	•	•		۰	٠	•		٠	•	•	•	۰	
Semi-Automatic	MISSION <sup>®</sup> Disposable Core Biopsy Instrument	•	10 mm and 20 mm (adjustable)	•		•	٠	٠	٠	•	٠		•	•	٠	
Automatic	MAX-CORE <sup>®</sup> Disposable Core Biopsy Instrument		22 mm			•	٠	٠	٠		٠		•	•	٠	
	MONOPTY <sup>®</sup> Disposable Core Biopsy Instrument		11 mm or 22 mm		•	•	٠	٠	٠		9 cm 10 cm		15 cm 16 cm	19 cm <b>20 cm</b>		
	MAGNUM <sup>®</sup> Biopsy System		15 mm and 22 mm (adjustable)		•	•	٠	•	•		•	•	•	•	٠	•

	Specialty needles	Available gauge sizes	Available needle lengths
Coaxial biopsy needle	TRUGUIDE® Disposable Coaxial Biopsy Needle	11 g 13 g 15 g 17 g 19 g	7.8 cm 13.8 cm 17.8 cm 17.8 cm 17 cm
Fine needle aspiration biopsy	VACU-CUT <sup>®</sup> Disposable Aspiration Biopsy Needle	18 g 19.5 g 21 g 22 g	10 cm 15 cm 20 cm
Bone biopsy	Ostycut <sup>®</sup> Disposable Bone Biopsy Needle	14 g 15 g 16 g 17 g	5 cm 7.5 cm 10 cm 12.5 cm 15 cm

Core Capabilities: Innovations inspired by your procedural challenges

# Automatic and Semi-Automatic BARD<sup>®</sup> MARQUEE<sup>®</sup> Disposable Core Biopsy Instrument

# A comprehensive core needle that provides unparalleled procedural versatility

### Performance

- Enhanced Needle Tip available on 12 g and 14 g needles designed for ease of insertion
- Advanced Echogenic Technology enhanced the visibility of both the instrument and the coaxial cannula in ultrasound

## Versatility

- Adjustable penetration depth of 18 mm and 25 mm
- Automatic and semi-automatic firing modes





Adjustable Penetration Depth



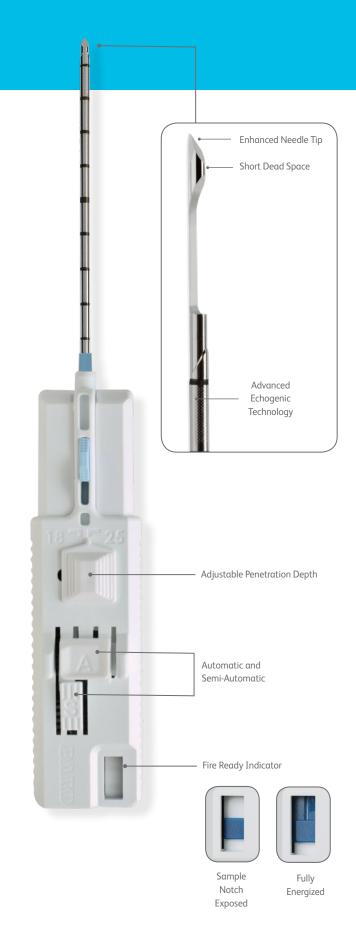
## Security

- Short dead space minimizes tip to sample notch distance
- Fire Ready indicator may help reduce the risk of premature instrument firing

## Convenience

• Complete kit option ensures coaxial compatibility with biopsy needle gauge and length and convenient ordering





	Instrument only order number*	Kit order number	Gauge size and needle length
12 -	MQ1210	MQK1210	12 g x 10 cm
12 g	MQ1213	MQK1213	12 g x 13 cm
	MQ1410	MQK1410	14 g x 10 cm
14 g	MQ1413	MQK1413	14 g x 13 cm
	MQ1416	MQK1416	14 g x 16 cm
16 g	MQ1610	MQK1610	16 g x 10 cm
	MQ1616	MQK1616	16 g x 16 cm
	MQ1620	MQK1620	16 g x 20 cm
	MQ1810	MQK1810	18 g x 10 cm
4.0	MQ1816	MQK1816	18 g x 16 cm
18 g	MQ1820	MQK1820	18 g x 20 cm
	MQ1825	MQK1825	18 g x 25 cm
	MQ2010	MQK2010	20 g x 10 cm
20 g	MQ2016	MQK2016	20 g x 16 cm
	MQ2020	MQK2020	20 g x 20 cm

### BARD® MARQUEE® Disposable Core Biopsy Instrument

\* Instrument only.

+ Kit includes instrument and compatible coaxial biopsy needle.

5 instruments per case.

## Semi-Automatic BARD<sup>®</sup> MISSION<sup>®</sup> Disposable Core Biopsy Instrument

# Semi-automatic instrument with visual status indicators and excellent ultrasound visibility

## Simplicity

- Lightweight compact instrument is designed to easily fit in the CT gantry
- Unique ergonomic grip design provides multiple ways to use the device
- Convenient adjustable throw of 10 mm and 20 mm

## Security

- Penetration depth indicator displays the primed penetration depth
- Visual Fire Ready Indicator confirms the sample notch is fully advanced
- Optional Coaxial Blunt Tip Stylet helps reduce the risk of damage to vasculature or other organs
- 10 mm Adapter attaches to coaxial cannula for accurate biopsy needle positioning when primed to the 10 mm penetration depth



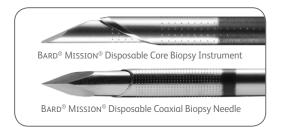


Coaxial Blunt Tip Stylet

### 10 mm Adapter

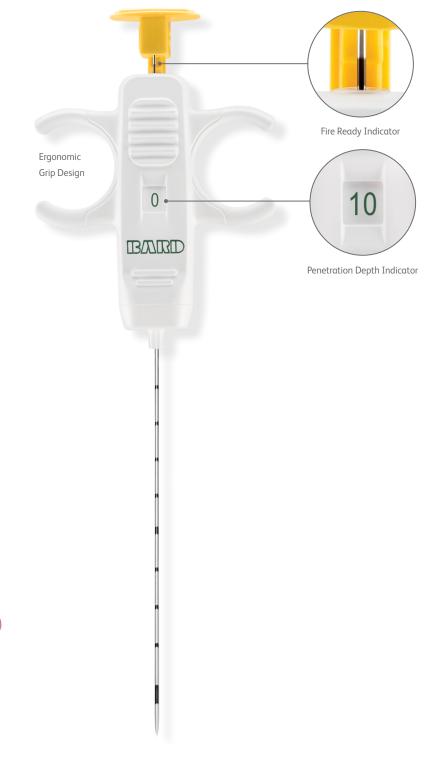
### Speed

- Compatible with BARD® TRUGUIDE® Disposable Coaxial **Biopsy Needle**
- Advanced Echogenic Technology offers excellent ultrasound visibility of the needle



### Complete

- Complete kit option, available in 14 g, 16 g, 18 g, and 20 g sizes, includes:
- BARD<sup>®</sup> MISSION<sup>®</sup> Disposable Core Biopsy Instrument
- Compatible coaxial
- 10mm Adapter
- Trocar stylet
- Unique blunt tip stylet
- Depth stop



### BARD<sup>®</sup> MISSION<sup>®</sup> Disposable Core Biopsy Instrument

Order number	Gauge size and needle length
1406MS	14 g x 6 cm
1410MS	14 g x 10 cm
1416MS	14 g x 16 cm
1606MS	16 g x 6 cm
1610MS	16 g x 10 cm
1616MS	16 g x 16 cm
1806MS	18 g x 6 cm
1810MS	18 g x 10 cm
1816MS	18 g x 16 cm
1820MS	18 g x 20 cm
1825MS	18 g x 25 cm
2006MS	20 g x 6 cm
2010MS	20 g x 10 cm
2016MS	20 g x 16 cm
2020MS	20 g x 20 cm

5 instruments per case.

### BARD<sup>®</sup> MISSION<sup>®</sup> Disposable Core Biopsy Instrument Kit

Order number	BARD <sup>®</sup> MISSION <sup>®</sup> gauge size and needle length	Disposable coaxial biopsy gauge size and needle length
1410MSK	14 g x 10 cm	13 g x 7.8 cm
1416MSK	14 g x 16 cm	13 g x 13.8 cm
1610MSK	16 g x 10 cm	15 g x 7.8 cm
1616MSK	16 g x 16 cm	15 g x 13.8cm
1810MSK	18 g x 10 cm	17 g x 7.8 cm
1816MSK	18 g x 16 cm	17 g x 13.8 cm
1820MSK	18 g x 20 cm	17 g x 17.8 cm
1825MSK	18 g x 25 cm	17 g x 22.9 cm
2010MSK	20 g x 10 cm	19 g x 7.8 cm
2016MSK	20 g x 16 cm	19 g x 13.8 cm
2020MSK	20 g x 20 cm	19 g x 17.8 cm

5 instruments per case.

## **Automatic** BARD<sup>®</sup> MAX-CORE<sup>®</sup> **Disposable Core Biopsy Instrument**

BARD 22 M

# Automatic BARD<sup>®</sup> MONOPTY<sup>®</sup> Disposable Core Biopsy Instrument

# The convenience of a disposable, the ease of one-handed cocking

- One-handed cocking and ergonomic handle designed to improve both handling and control
- 22 mm penetration depth
- Two firing buttons accommodate your preference
- Color coding promotes accurate needle gauge identification
- Compatibility with BARD® TRUGUIDE® Coaxial Biopsy Needle enhances efficiency and accuracy

### BARD® MAX-CORE® Disposable Core Biopsy Instrument

	Order number	BARD <sup>®</sup> MAX-CORE <sup>®</sup> gauge size and needle length	Compatible BARD <sup>©</sup> TRUGUIDE <sup>®</sup> Coaxial order number
1/ ~	MC1410	14 g x 10 cm	C1410A
14 g	MC1416	14 g x 16 cm	C1416A
16 g -	MC1610	16 g x 10 cm	C1610A
	MC1616	16 g x 16 cm	C1616A
	MC1810	18 g x 10 cm	C1810A
10 ~	MC1816	18 g x 16 cm	C1816A
18 g	MC1820	18 g x 20 cm	C1820A
	MC1825	18 g x 25 cm	—
	MC2010	20 g x 10 cm	C2010A
20 g	MC2016	20 g x 16 cm	C2016A
	MC2020	20 g x 20 cm	C2020A

Instrument only. Compatible TRUGUIDE® Disposable Coaxial Biopsy Needles sold separately. 5 instruments per case.

The convenience of a disposable. The versatility of two penetration depth options.

- 11 mm or 22 mm penetration depths
- Color coding promotes accurate needle gauge identification
- Compatibility with BARD® TRUGUIDE® Coaxial Biopsy Needle enhances efficiency and accuracy
- Visual Fire Ready Window displays an arrow when instrument is ready to fire



### BARD® MONOPTY® Disposable Core Biopsy Instrument 22 mm penetration depth

Order number	BARD <sup>®</sup> MONOPTY <sup>®</sup> gauge size and needle length	Compatible BARD <sup>®</sup> TruGuIDE <sup>®</sup> Coaxial order number
121210	12 g x 10 cm	C1210A
121216	12 g x 16 cm	C1216A
121410	14 g x 10 cm	C1410A
121416	14 g x 16 cm	C1416A
121610	16 g x 10 cm	C1610A
121616	16 g x 16 cm	C1616A
121620	16 g x 20 cm	C1620A
121810	18 g x 10 cm	C1810A
121816	18 g x 16 cm	C1816A
121820	18 g x 20 cm	C1820A
122010	20 g x 10 cm	C2010A
122016	20 g x 16 cm	C2016A
122020	20 g x 20 cm	C2020A
	121210 121216 121410 121416 121610 121616 121620 121810 121816 121820 122010 122016	Order number gauge size and needle length   121210 12 g x 10 cm   121216 12 g x 16 cm   121410 14 g x 10 cm   121410 14 g x 10 cm   121410 14 g x 10 cm   121416 14 g x 16 cm   121610 16 g x 10 cm   121610 16 g x 20 cm   121810 18 g x 10 cm   121816 18 g x 16 cm   121820 18 g x 20 cm   122010 20 g x 10 cm

BARD® MONOPTY® Disposable Core Biopsy Instrument 11 mm penetration depth

	Order number	BARD <sup>®</sup> MONOPTY <sup>®</sup> gauge size and needle length	Compatible BARD <sup>®</sup> TRUGUIDE <sup>®</sup> Coaxial order number
1/. a	211410	14 g x 9 cm	C1410A
14 g	211416	14 g x 15 cm	C1416A
	211610	16 g x 9 cm	C1610A
16 g	211616	16 g x 15 cm	C1616A
	211620	16 g x 19 cm	C1620A
	211810	18 g x 9 cm	C1810A
18 g	211816	18 g x 15 cm	C1816A
	211820	18 g x 19 cm	C1820A
	212010	20 g x 9 cm	C2010A
20 g	212016	20 g x 15 cm	C2016A
	212020	20 g x 19 cm	C2020A

Instrument only. Compatible TRUGUIDE® Disposable Coaxial Biopsy Needles sold separately. 12G needles contain 5 instruments per case. 14G-20G needle contain 10 instruments per case.

## **Biopsy Systems** BARD<sup>®</sup> MAGNUM<sup>®</sup> Reusable Core Biopsy Instrument

# Coaxial Bard<sup>®</sup> TruGuide<sup>®</sup> Disposable Coaxial Biopsy Needle

# High power instrument with one-handed cocking



MAGNUM

BAIRD

- Biopsy system comprised of a reusable biopsy instrument and disposable biopsy needles
- Adjustable penetration depths of 15 mm or 22 mm
- Compatibility with BARD® TRUGUIDE® Coaxial Biopsy Needle enhances efficiency and accuracy

### BARD® MAGNUM® Reusable Core Biopsy Instrument Order number MG1552

Instrument only. Biopsy needles sold separately. 1 instrument per case.

### BARD<sup>®</sup> MAGNUM<sup>®</sup> Disposable Core Biopsy Needle

		Compatible
Order number	Bard <sup>®</sup> Magnum <sup>®</sup> gauge size and needle length	BARD <sup>®</sup> TRUGUIDE <sup>®</sup> Coaxial order number
MN1210	12 g x 10 cm	C1210B
MN1213	12 g x 13 cm	C1213B
MN1216	12 g x 16 cm	C1216B
MN1220	12 g x 20 cm	_
MN1410	14 g x 10 cm	C1410B
MN1413	14 g x 13 cm	C1413B
MN1416	14 g x 16 cm	C1416B
MN1420	14 g x 20 cm	_
MN1610	16 g x 10 cm	C1610B
MN1613	16 g x 13 cm	C1613B
MN1616	16 g x 16 cm	C1616B
MN1620	16 g x 20 cm	C1620B
MN1810	18 g x 10 cm	C1810B
MN1813	18 g x 13 cm	C1813B
MN1816	18 g x 16 cm	C1816B
MN1820	18 g x 20 cm	C1820B
MN1825	18 g x 25 cm	_
MN1830	18 g x 30 cm	—
MN2010	20 g x 10 cm	C2010B
MN2013	20 g x 13 cm	C2013B
MN2016	20 g x 16 cm	C2016B
MN2020	20 g x 20 cm	C2020B
	MN1210 MN1213 MN1216 MN1220 MN1410 MN1410 MN1413 MN1416 MN1420 MN1610 MN1610 MN1610 MN1613 MN1616 MN1620 MN1813 MN1816 MN1813 MN1816 MN1820 MN1825 MN1820 MN1825 MN1830 MN18213 MN2010	needle length   MN1210 12 g x 10 cm   MN1213 12 g x 13 cm   MN1216 12 g x 16 cm   MN1210 12 g x 20 cm   MN1220 12 g x 20 cm   MN1410 14 g x 10 cm   MN1410 14 g x 13 cm   MN1413 14 g x 13 cm   MN1416 14 g x 20 cm   MN1416 14 g x 20 cm   MN1416 16 g x 10 cm   MN1610 16 g x 13 cm   MN1613 16 g x 13 cm   MN1614 14 g x 20 cm   MN1615 16 g x 13 cm   MN1616 16 g x 20 cm   MN1810 18 g x 13 cm   MN1810 18 g x 13 cm   MN1813 18 g x 20 cm   MN1816 18 g x 20 cm   MN1825 18 g x 20 cm   MN1825 18 g x 30 cm   MN1830 18 g x 30 cm   MN2010 20 g x 10 cm   MN2013 20 g x 13 cm

Needles only. MAGNUM® Reuseable Core Biopsy Instrument and Compatible TRUGUIDE® Disposable Coaxial Biopsy Needles sold separately. 10 needles per case.

# Innovative and lightweight

- Provides a clear path to work through when performing multiple biopsies in the same area
- Engineered compatibility with BARD<sup>®</sup> Biopsy Instruments enhances efficiency and accuracy
- Sized just one gauge larger than corresponding BARD® Core Tissue **Biopsy Needles**
- Color-coded depth stops conveniently match the gauge color

### BARD<sup>®</sup> TRUGUIDE<sup>®</sup> Disposable Coaxial Biopsy Needle

For use with BARD<sup>®</sup> MAX-CORE<sup>®</sup>, BARD<sup>®</sup> MONOPTY<sup>®</sup>, or BARD® MISSION® Biopsy Instruments

Order number	BARD <sup>®</sup> TRUGUIDE <sup>®</sup> gauge size and total cannula length	Compatil BARD <sup>®</sup> gauge size needle len
C1210A	11 g x 7.8 cm	12 g x 10
C1216A	11 g x 13.8 cm	12 g x 16
C1410A	13 g x 7.8 cm	14 g x 10
C1416A	13 g x 13.8 cm	14 g x 16
C1610A	15 g x 7.8 cm	16 g x 10
C1616A	15 g x 13.8 cm	16 g x 16
C1620A	15 g x 17.8 cm	16 g x 20
C1810A	17 g x 7.8 cm	18 g x 10
C1816A	17 g x 13.8 cm	18 g x 16
C1820A	17 g x 17.8 cm	18 g x 20
C2010A	19 g x 7.8 cm	20 g x 10
C2016A	19 g x 13.8 cm	20 g x 16
C2020A	19 g x 17.8 cm	20 g x 20

Coaxial needles only. Compatible biopsy needles sold separately. 5 needles per case.



- cm cm
- cm

BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle For use with BARD<sup>®</sup> MAGNUM<sup>®</sup>, or BARD<sup>®</sup> BIOPTY<sup>®</sup> Biopsy Instruments

Order number	BARD <sup>®</sup> TRUGUIDE <sup>®</sup> gauge size and total cannula length	Compatible BARD® gauge size and needle length
C1210B	11 g x 7.0 cm	12 g x 10 cm
C1213B	11 g x 10.0 cm	12 g x 13 cm
C1216B	11 g x 13.0 cm	12 g x 16 cm
C1410B	13 g x 7.0 cm	14 g x 10 cm
C1413B	13 g x 10.0 cm	14 g x 13 cm
C1416B	13 g x 13.0 cm	14 g x 16 cm
C1610B	15 g x 7.0 cm	16 g x 10 cm
C1613B	15 g x 10.0 cm	16 g x 13 cm
C1616B	15 g x 13.0 cm	16 g x 16 cm
C1620B	15 g x 17.0 cm	16 g x 20 cm
C1810B	17 g x 7.0 cm	18 g x 10 cm
C1813B	17 g x 10.0 cm	18 g x 13 cm
C1816B	17 g x 13.0 cm	18 g x 16 cm
C1820B	17 g x 17.0 cm	18 g x 20 cm
C2010B	19 g x 7.0 cm	20 g x 10 cm
C2013B	19 g x 10.0 cm	20 g x 13 cm
C2016B	19 g x 13.0 cm	20 g x 16 cm
C2020B	19 g x 17.0 cm	20 g x 20 cm

Coaxial needles only. Compatible biopsy needles sold separately. 5 needles per case.



# Self-aspirating for effective and simple fine needle aspiration

- Winged hub designed to provide procedural control
- Self-aspiration capability that permits the creation of a vacuum to draw sample into the cannula when stylet is withdrawn



# Performance, control and a wide range of sizes

- Two-part needle design
- Self-locking aspiration syringe
- Kit Includes:
- Flat threaded cannula
- Trocar point stylet
- 10 cc luer tipped aspiration syringe

- Ring obturator

## VACU-CUT<sup>®</sup> Disposable Aspiration Biopsy Needle

	Order number	Gauge size and needle length
18 g	1764-0050	18 g x 10 cm
	1764-0070	18 g x 15 cm
	1764-0080	18 g x 20 cm
19.5 g	1762-0050	19.5 g x 10 cm
	1762-0070	19.5 g x 15 cm
	1762-0080	19.5 g x 20 cm
21 g	1761-0050	21 g x 10 cm
	1761-0070	21 g x 15 cm
	1761-0080	21 g x 20 cm
22 g	1760-0050	22 g x 10 cm
	1760-0070	22 g x 15 cm
	1760-0080	22 g x 20 cm

10 needles per case.

### Ostycut<sup>®</sup> Disposable Bone Biopsy Needle

	Order number	Gauge size and needle length
14 g	1786-0010	14 g x 5 cm
	1786-0020	14 g x 7.5 cm
	1786-0050	14 g x 10 cm
	1786-0060	14 g x 12.5 cm
	1786-0070	14 g x 15 cm
15 g	1784-0010	15 g x 5 cm
	1784-0020	15 g x 7.5 cm
	1784-0050	15 g x 10 cm
	1784-0060	15 g x 12.5 cm
16 g	1784-0070	15 g x 15 cm
	1782-0010	16 g x 5 cm
	1782-0020	16 g x 7.5 cm
	1782-0050	16 g x 10 cm
	1782-0060	16 g x 12.5 cm
	1782-0070	16 g x 15 cm
17 g	1780-0010	17 g x 5 cm
	1780-0020	17 g x 7.5 cm
	1780-0050	17 g x 10 cm
	1780-0060	17 g x 12.5 cm
	1780-0070	17 g x 15 cm

1 needle per case.

### MARQUEE® Disposable Core Biopsy Instrument

INDICATIONS FOR USE: The Bard® Marquee® Disposable Core Biopsy Instrument and Kit are intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone. **CONTRAINDICATIONS:** None known. **WARNINGS:** 1. Good medical judament should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding problem. 2. Post-biopsy patient care may vary with the biopsy technique utilized and the individual patient's physiological condition. Observation of vital signs and other precautions should be taken to avoid and/or treat potential complications that may be associated with biopsy procedures. 3. The collection of multiple core biopsy samples may help to ensure the detection of any cancer tissue. A "negative" biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma. 4. The Instrument and Kit have been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. 5. Do not resterilize the Instrument or Kit. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/ or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. Note: Inspect Instrument and Kit needle components for damaged point, bent shaft or other imperfections prior to use and after each sample is collected. DO NOT USE the device if any imperfection is noted. Note: After use, the Instrument and Kit may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations. PRECAUTIONS: 1. The Instrument and Kit should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of core needle biopsy, in particular, those relating to the specific tissue being biopsied. 2. The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT, etc.). Note: This product has not been tested for MR Imaging compatibility. 3. Never test the Instrument by firing into the air. Damage may occur to the Instrument needle tip and could result in patient and/or user injury 4. Unusual force applied to the stylet or unusual resistance against the stylet while extended out of the cutting cannula may cause the stylet to bend at the sample notch. A bent sample notch may interfere with needle function. POTENTIAL **COMPLICATIONS:** Potential complications associated with core biopsy procedures are site specific and may include, but are not limited to: hematoma; hemorrhage; infection; adjacent tissue injury; pain; bleeding; hemoptysis; hemothorax; non-target tissue, organ or vessel perforation; pneumothorax; and air embolism. Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

### MISSION<sup>®</sup> Disposable Core Biopsy Instrument

INDICATIONS FOR USE: The Bard® Mission® Disposable Core Biopsy Instrument and Kit is intended for use in obtaining biopsy samples from soft tissues such as from the lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors. **CONTRAINDICATIONS:** Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding problem. It is not intended for use in bone. WARNINGS: 1. Post-biopsy patient care may vary with the biopsy technique utilized and the individual patient's physiological condition. Observation of vital signs and other precautions should be taken to avoid and/ or treat potential complications that may be associated with biopsy procedures. 2. When used for breast biopsy, the product is for diagnosis only. 3. The collection of multiple core biopsy samples may help to ensure the detection of any cancer tissue. A "negative" biopsy in the presence of suspicious radiographic findings does not preclude the presence of

carcinoma. 4. The Instrument and Kit have been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. 5. Do not resterilize the Instrument or Kit. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/ or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. Note: Inspect the Instrument and Kit needle components for damaged point, bent shaft or other imperfections prior to use and after each sample is collected. DO NOT USE the device if any imperfection is noted. Note: After use, the Instrument and Kit may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations. **PRECAUTIONS:** 1. The Instrument and Kit should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of core needle biopsy, in particular, those relating to the specific tissue being biopsied. 2. The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT, etc.). Note: This product has not been tested for MR Imaging compatibility. 3. Never test the Instrument by firing into the air. Damage may occur to the needle/cannula tip and could result in patient and/or user injury. 4. Unusual force applied to the stylet or unusual resistance against the stylet while extended out of the cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with needle function. POTENTIAL **COMPLICATIONS:** Potential complications associated with core biopsy procedures and coaxial guided biopsy procedures are site specific and may include, but are not limited to: hematoma; hemorrhage; infection; adjacent tissue injury; pain; bleeding; hemoptysis; hemothorax; non-target tissue, organ or vessel perforation; pneumothorax; hematuria; dysphagia; dysphonia; edema; pseudoaneurysm; vasovagal reaction; vertebral puncture; carotid injury; tracheal puncture; nerve injuries; and air embolism. Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

### MAX-CORE<sup>®</sup> Disposable Core Biopsy Instrument

**INDICATIONS FOR USE:** The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone. **CONTRAINDICATIONS:** Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding problem. WARNINGS: 1. The collection of multiple needle cores may help to ensure the detection of any cancer tissue. A "negative" biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma. 2. The BARD® MAX-CORE® Biopsy Instrument has been designed for single use only. 3. Do not resterilize the BARD® MAX-CORE® Biopsy Instrument. **PRECAUTIONS:** 1. This product should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of core needle biopsy in particular those relating to the specific organ being biopsied. 2. The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.). POTENTIAL COMPLICATIONS: Potential complications associated with core biopsy procedures are site specific and include, but are not limited to: hematoma; hemorrhage; infection; adjacent tissue injury; pain; bleeding; hemoptysis; hemothorax; non-target tissue, organ or vessel perforation; and air embolism. Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits sians or symptoms of air embolism.

#### MONOPTY<sup>®</sup> Disposable Core Biopsy Instrument

**INDICATIONS FOR USE:** The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone. **CONTRAINDICATIONS:** Good medical iudament should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have bleeding disorders. WARNINGS: 1. The collection of multiple needle cores may help to ensure the detection of any cancer tissue. A "negative" biopsy in the presence of suspicious radiographic finding does not preclude the presence of carcinoma. 2. The BARD® MONOPTY® Disposable Core Biopsy Instrument is not intended for use in bone. 4. The BARD® MONOPTY® Disposable Core Biopsy Instrument has been designed for single use only. **PRECAUTIONS:** 1. This product should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of core needle biopsy, in particular, those relating to the specific organ being biopsied. 2. The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.). POTENTIAL **COMPLICATIONS:** Potential complications associated with core biopsy procedures are site specific and include but are not limited to: hematoma: hemorrhage: infection: adjacent tissue injury; pain; bleeding; hemoptysis; hemothorax; non-target tissue, organ or vessel perforation; pneumothorax; and air embolism. Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

#### MAGNUM<sup>®</sup> Core Biopsy System

**INDICATIONS FOR USE:** The MAGNUM<sup>®</sup> Biopsy System (instrument and needles) is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue tumors. **CONTRAINDICATIONS:** Not intended for use in bone. WARNINGS: 1. Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding disorder. 2. The collection of multiple needle cores may help to ensure the detection of any cancer tissue. 3. A "negative" biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma. 5. The MAGNUM® Disposable Core Biopsy Needle with spacer has been designed for single use only. 6. Do not resterilize the MAGNUM® Disposable Core Biopsy Needle with spacer. **PRECAUTIONS:** 1. Use only BARD® MAGNUM® Biopsy Needles with the BARD® MAGNUM® Biopsy Instrument. We cannot recommend the use of biopsy needles made by other manufacturers. 2. This product should be used by a physician who is completely familiar with the indications contraindications, limitations, typical findings and possible side effects of core needle biopsy, in particular, those relating to the specific organ being biopsied. 3. The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.). POTENTIAL COMPLICATIONS: Potential complications associated with core biopsy procedures are site specific and include, but are not limited to: hematoma: hemorrhage; infection; adjacent tissue injury; pain; bleeding; hemoptysis; hemothorax; non-taraet tissue, organ or vessel perforation; pneumothorax; and air embolism. Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

### **OSTYCUT®** Disposable Bone Biopsy Needle

INDICATIONS FOR USE: The OSTYCUT® Disposable Bone Biopsy Needle is intended for use in bone biopsy procedures. **CONTRAINDICATIONS:** Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding disorder. **PRECAUTIONS:** 1. The OSTYCUT<sup>®</sup> Disposable Bone Biopsy Needle should be used by a physician who is completely familiar with the indications, contraindications, precautions, limitations, typical findings and possible side effects of bone biopsy. **POTENTIAL COMPLICATIONS:** Potential complications of bone biopsy are hematoma, hemmorrhage, infection and pain.

### VACU-CUT<sup>®</sup> Disposable Aspiration Biopsy Needle

INDICATIONS FOR USE: The VACU-CUT® Disposable Aspiration Biopsy Needle is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone. **CONTRAINDICATIONS:** Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding disorder **PRECAUTIONS:** The Vacu-Cut® Disposable Aspiration Biopsy Needle should be used by a physician who is completely familiar with the indications, contraindications, precautions, limitations, typical findings and possible side effects of aspiration biopsy. **POTENTIAL COMPLICATIONS:** Some potential complications of aspiration biopsy are hematoma, hemorrhage, infection and pain.

#### **TRUGUIDE®** Disposable Coaxial Biopsy Needle

INDICATIONS FOR USE: The coaxial biopsy needle guide is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, spleen, lymph nodes and various soft tissue lesions. CONTRAINDICATIONS: Not intended for use in bone. WARNINGS: 1. Good medical judgement should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have bleeding disorders. 2. Post-biopsy patient care may vary with the biopsy technique utilized and the individual patient's physiological condition. Observation of vital signs and other precautions should be taken to avoid and/or treat potential complications that may be associated with biopsy procedures 3. The collection of multiple needle cores may help to ensure the detection of any cancer tissue. A "negative" biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma. 4. The Bard® TruGuide® Disposable Coaxial Biopsy Needle has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. 5. Do not resterilize the Bard® TruGuide® Disposable Coaxial Biopsy Needle. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. Note: After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations. **PRECAUTIONS:** 1. This product should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of core needle biopsy. in particular, those relating to the specific organ being biopsied. 2. The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.). Note: This product has not been tested for MR Imaging compatibility. 3. Before using, inspect the needle for damaged point, bent shaft or other imperfections that would prevent proper function. If the needle components are damaged or bent, DO NOT USE. POTENTIAL **COMPLICATIONS:** Potential complications of coaxial guided biopsy are site specific and may consist of hematoma; hemorrhage; infection; adjacent tissue injury; pain; bleeding; hemoptysis; hemothorax; non-target tissue, organ or vessel perforation; and pneumothorax.

Please consult product labels and inserts for complete indications, contraindications, hazards, warnings, precautions and directions for use.

1.800.323.9088

### crbard.com/biopsy

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