

BARD® TRUGUIDE®



Disposable Coaxial Biopsy Needle

Instructions for Use

Aiguille pour biopsie coaxiale jetable BARD® TRUGUIDE®
Mode d'emploi

BARD® TRUGUIDE® Koaxiale Einweg-Biopsienadel
Gebrauchsanweisung

Ago per biopsia coassiale monouso TRUGUIDE® BARD®
Istruzioni per l'Uso

Aguja de biopsia coaxial desechable BARD® TRUGUIDE®
Instrucciones de uso

BARD® TRUGUIDE® wegwerpbare coaxiale biopsienaald
Gebruiksaanwijzing

Agulha de biopsia coaxial descartável BARD® TRUGUIDE®
Instruções de Utilização

Αναλώσιμη ομοαξονική βελόνα βιοψίας BARD® TRUGUIDE®
Οδηγίες χρήσης

BARD® TRUGUIDE® engangs koaksial biopsikanyle
Brugsanvisning

BARD® TRUGUIDE® koaxial biopsinål för engångsbruk
Bruksanvisning

Kertakäyttöinen koaksiaalinen BARD® TRUGUIDE® -biopsianeula
Käyttöohjeet

BARD® TRUGUIDE® koaksial biopsinål til engangsbruk
Bruksanvisning

Jednorazowa igła współosiowa do biopsji BARD® TRUGUIDE®
Instrukcja użycia

BARD® TRUGUIDE® egyszer használatos koaxiális biopsziás tű
Használati utasítás

Jednorázová koaxiální biotická jehla BARD® TRUGUIDE®
Návod k použití

BARD® TRUGUIDE® Tek Kullanımlık Koaksiyal Biyopsi İğnesi
Kullanım Yönergeleri

BARD® TRUGUIDE® 拋棄式同軸切片針
使用說明

BARD® TRUGUIDE® 일회용 동축 생검 바늘
사용 지침

Одноразовая коаксиальная биопсийная игла
BARD® TRUGUIDE®
Инструкции по применению

Jednorazová koaxiálna ihla na biopsiu BARD® TRUGUIDE®
Návod na použitie

BARD

BIOPSY SYSTEMS

Instructions for Use:

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information and Device Description:

The BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle is a three-part device consisting of an outer cannula with an attached female luer lock hub, an inner stylet with an attached male luer lock hub, and a flexible slip ring style depth stop.

The BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle is designed for use with BARD® disposable biopsy instruments and BARD® disposable biopsy needles.

The depth stop is color coded to match the gauge size of the appropriate BARD® biopsy needle or BARD® biopsy instrument, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge, Green=14 gauge and Light Blue=12 gauge. The outer cannula is only one gauge size larger than the appropriate BARD® biopsy needle, e.g., 19 gauge BARD® TRUGUIDE® Coaxial Biopsy Needle for a 20 gauge BARD® disposable biopsy needle or BARD® disposable biopsy instrument.

B. How Supplied:

The BARD® TRUGUIDE® Coaxial Biopsy Needle is a disposable needle and is available in varying needle gauge sizes and lengths. The product is supplied sterile and nonpyrogenic unless the package has been opened or damaged. **Sterilized using Ethylene Oxide. For single patient use only. Do not reuse. Do not resterilize.**

C. 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.

D. Contraindications:

Not intended for use in bone.

E. 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.

F. 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.

G. 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.

H. Equipment Required:

The BARD® TRUGUIDE® Coaxial Biopsy Needle is designed for use with BARD® disposable MAX-CORE® and MONOPTY® biopsy instruments and BARD® MAGNUM® and BIOPTY-CUT® disposable biopsy needles. Refer to applicable Instructions for Use.

I. Directions for Use:**Needle Preparation:**

Prior to use, determine the appropriate gauge and length of the needle required for the specific biopsy to be performed (See Figure 1). Using aseptic technique, remove the needle from the package and from the protective sheath.

Figure 1

BARD® Biopsy Instrument (MONOPTY®, with 11mm Penetration)	BARD® Biopsy Instrument (MONOPTY®, with 22mm Penetration, and MAX-CORE®)	BARD® TRUGUIDE® Coaxial Biopsy Needle	BARD® Biopsy Needle (BIOPTY-CUT® and MAGNUM®)	BARD® TRUGUIDE® Coaxial Biopsy Needle
Gauge x Length	Gauge x Length	Reorder No.	Gauge x Length	Reorder No.
	12 x 10	C1210A	12 x 10	C1210B
	12 x 16	C1216A	12 x 13	C1213B
14 x 9	14 x 10	C1410A	12 x 16	C1216B
14 x 15	14 x 16	C1416A	14 x 10	C1410B
16 x 9	16 x 10	C1610A	14 x 13	C1413B
16 x 15	16 x 16	C1616A	14 x 16	C1416B
16 x 19	16 x 20	C1620A	16 x 10	C1610B
18 x 9	18 x 10	C1810A*	16 x 13	C1613B
18 x 15	18 x 16	C1816A*	16 x 16	C1616B
18 x 19	18 x 20	C1820A*	16 x 20	C1620B
20 x 9	20 x 10	C2010A*	18 x 10	C1810B*
20 x 15	20 x 16	C2016A*	18 x 13	C1813B*
20 x 19	20 x 20	C2020A*	18 x 16	C1816B*
			18 x 20	C1820B*
			20 x 10	C2010B*
			20 x 13	C2013B*
			20 x 16	C2016B*
			20 x 20	C2020B*

* **Note:** An optional blunt tip stylet is included with all 18 and 20 gauge BARD® TRUGUIDE® Coaxial Biopsy Needles. The blunt tip stylet may be used to manipulate through soft tissue and around vasculature or other organs to minimize the risk of unintentional damage to these areas.

Biopsy Procedure:

The biopsy procedure must be performed using appropriate aseptic technique.

Recommendation: Prior to performing the procedure, ensure the stylet can be separated from the cannula without difficulty by loosening the hubs. Retighten the stylet into the cannula and ensure the stylet is fully seated in the cannula prior to insertion into the patient.

1. Prepare site as required. Adequate anesthesia should be administered prior to incision of the skin.
2. If preferred, place the supplied depth stop at the predetermined placement depth.
3. Determine which stylet is preferred. If the trocar tip stylet is selected, proceed to step number 6.
4. If the blunt tip stylet is selected, hold the guiding cannula needle hub and turn the trocar tip stylet hub counter-clockwise to remove the trocar tip stylet from the outer cannula.
5. Insert the blunt tip stylet into the guiding cannula holding the guiding cannula needle hub and turn the blunt tip stylet needle hub clockwise to engage the outer cannula hub.

Note: For ease of insertion, puncture the skin with a scalpel at the entry site.

6. Using imaging guidance, insert the tip of the BARD® TRUGUIDE® Coaxial Biopsy needle proximal to the lesion to be biopsied using the depth stop as an aid for proper placement and adjust as necessary.

Note: The depth stop should be adjusted so that the needle is in proper position when the depth stop is in contact with the skin. This will help stabilize the BARD® TRUGUIDE® Coaxial Biopsy Needle.

7. Hold the guiding cannula needle hub and turn the stylet hub counterclockwise to remove the stylet from the outer cannula. Leave the cannula in place as a guide for the placement of the BARD® biopsy needle.
8. Place the appropriate BARD® biopsy needle through the guiding cannula to the lesion to be biopsied.
9. Perform the biopsy and remove the biopsy needle from the guiding cannula. Leave the guiding cannula in place.

10. For multiple samples, reinsert stylet and reposition the BARD® TRUGUIDE® Coaxial Needle using imaging guidance. Repeat steps 7, 8, and 9 above.

Recommendation: When collecting multiple samples, wipe the core tissue biopsy needle with sterile moist gauze prior to reinsertion into the TRUGUIDE® cannula. This will aid in the proper movement of the core tissue biopsy needle within the cannula.

11. Reinsert stylet and remove the BARD® TRUGUIDE® Coaxial Biopsy Needle.

ENGLISH

Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular, Inc. to see if additional product information is available.

Assembled in Korea.

 **Manufacturer:**
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA
TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
1-800-440-5376
www.bardbiopsy.com

 **0086** **EC REP**
Authorised Representative
in the European
Community
Bard Limited
Forest House
Tilgate Forest Business Park
Brighton Road, Crawley
West Sussex
RH11 9BP, UK

BAIRD
BIOPSY SYSTEMS

PK1280500 Rev. 0 05/12

Attorney Docket No.: 287107US35

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
POST REGISTRATION SECTION

In re the Registration of:

C. R. BARD, INC.

Registration No.: 3,222,970

Issued: March 27, 2007

Mark: TRUGUIDE

Honorable Commissioner for Trademarks
P.O. Box 1451
Alexandria, Virginia 22313-1451

Dear Commissioner:

COMBINED DECLARATION UNDER SECTIONS 8 AND 15
OF THE TRADEMARK ACT

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this document, declares that C. R. BARD, INC. owns the above identified registration, issued March 27, 2007, as shown by the records in the Patent and Trademark Office; that the mark shown therein has been in continuous use in commerce for five consecutive years from the date of registration to the present, on or in connection with all the goods and/or services listed in the existing registration; that such mark is still in use in commerce on or in connection with said goods and/or services as evidenced by the enclosed facsimile(s) or specimen(s) showing the mark as currently used; that there has been no final decision adverse to the owner's claim of ownership of such mark for such goods/services, or to the owner's right to register the same or to keep the same on the register; that there is no proceeding involving said rights pending and not disposed

of either in the Patent and Trademark Office or in the courts; and that all statements made of his/her own knowledge are true and all statements made on information and belief are believed to be true.

POWER OF ATTORNEY

The undersigned hereby appoints Roberta S. Bren, and the following attorneys of the law firm of OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, L.L.P., as its attorneys with full powers of substitution and revocation, to file and prosecute this application to register, to transact all business in the Patent and Trademark Office in connection therewith:

Norman F. Oblon
Marvin J. Spivak
Gregory J. Maier
Arthur I. Neustadt
Jeffrey H. Kaufman
Roberta S. Bren
Jonathan Hudis

Kathleen Cooney-Porter*
Beth A. Chapman*
Christopher I. Donahue
Kyoko Imai
David H. Aleskow*
Richard D. Kelly
James D. Hamilton

Eckhard H. Kuesters
Robert T. Pous
Charles L. Gholz
Jean-Paul Lavallee
Stephen G. Baxter
Richard L. Treanor
Richard L. Chinn

Members of the Bar of Virginia (except as indicated)
*Member of the Bar other than Virginia

Please address all correspondence to Roberta S. Bren at OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, L.L.P., 1940 Duke Street, Alexandria, Virginia 22314.

C. R. BARD, INC.
Signature: 
Name: Charles A. Krauss
Title/Position: Vice President Government Investigations,
Litigation and Intellectual Property
Date: 2/19/13

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