



# U.S. Department of Health & Human Services

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**Food and Drug Administration**

## SAVE REQUEST

**USER:** (kml)

**FOLDER:** K133948 - 383 pages

**COMPANY:** BARD PERIPHERAL VASCULAR, INC. (BARDPERIVASCB)

**PRODUCT:** INSTRUMENT, BIOPSY (KNW)

**SUMMARY:** Product: BARD(R) MONOPTY(R) DISPOSABLE CORE BIOPSY INSTRUMENT, BARD(R) MAX-CORE

**DATE REQUESTED:** Nov 2, 2015

**DATE PRINTED:** Nov 2, 2015

**Note:** Printed



**510(k) Summary**

**21 CFR 807.92**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (l)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

**1. Submitter Information:**

Applicant: Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, Arizona 85281  
Phone: 480-638-2954  
Fax: 480-449-2546  
Contact: Sarah McCartney, Regulatory Affairs Specialist  
Date: January 23, 2014

**2. Subject Device:**

Device Trade Name: Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® Disposable Core Biopsy Instrument  
Common or Usual Name: Core Biopsy Instrument  
Classification: Class II  
Classification Name: Instrument, Biopsy (Product Code KNW)  
Review Panel: Gastroenterology / Urology  
Regulation Number: 21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

**3. Predicate Device:**

The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument, K922939, cleared February 16, 1993.

**4. Summary of Change:**

This Special 510(k) provides an updated file to FDA including several changes that have occurred to the subject device since the predicate submission. These changes include updates to the labeling and the addition of a needle gauge size, addition of needle lengths, and addition of performance specifications.

## 5. Subject Device Description:

### Bard® Monopty® Disposable Core Biopsy Instrument

The Bard® Monopty® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge, and Light Blue = 12 gauge.

### Bard® Max-Core® Disposable Core Biopsy Instrument

The Bard® Max-Core® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge.

## 6. Indications for Use of Device:

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.

## 7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Same patient-contacting materials
- Same fundamental scientific technology

- Same patient population
- Same sterility
- Similar packaging configuration

When reviewing the changes from the predicate submission, the subject devices and the predicate device are different in the following manner:

- Updated labeling
- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications

#### **8. Performance Testing Summary:**

To verify that the device design met its functional and performance requirements, representative samples of the device underwent bench testing (dimensional, sample quality, durability, needle to device tensile strength, and echogenicity). Results of this testing demonstrate that the design outputs continue to meet the design inputs and user need requirements.

#### **9. Conclusion:**

Bard Peripheral Vascular, Inc. considers the subject devices to be substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 21, 2014

Bard Peripheral Vascular, Inc.  
Sarah McCartney  
Regulatory Affairs Specialist  
1625 West 3rd Street  
Tempe, AZ 85281

Re: K133948  
Trade/Device Name: Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument  
Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument  
Regulation Number: 21 CFR§ 876.1075  
Regulation Name: Gastroenterology-urology biopsy instrument  
Regulatory Class: II  
Product Code: KNW  
Dated: January 27, 2014  
Received: January 28, 2014

Dear Sarah McCartney,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K133948

Device Name: Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® 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.

Prescription Use    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use    
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner-S

2014.02.21 11:51:08 -05'00'



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

February 21, 2014

Bard Peripheral Vascular, Inc.  
Sarah McCartney  
Regulatory Affairs Specialist  
1625 West 3rd Street  
Tempe, AZ 85281

Re: K133948  
Trade/Device Name: Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® Disposable Core Biopsy Instrument  
Regulation Number: 21 CFR§ 876.1075  
Regulation Name: Gastroenterology-urology biopsy instrument  
Regulatory Class: II  
Product Code: KNW  
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

  
Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Concurrence & Template History Page**  
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: **K133948/S002 – Bard Peripheral Vascular, Inc.**

For Office of Compliance Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=318](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318)

For Office of Surveillance and Biometrics Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=423](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423)

Digital Signature Concurrence Table	
Reviewer Sign-Off	Shanil P. Haugen-S 2014.02.21 12:10:59 -05'00'
Branch Chief Sign-Off	 2014.02.21 12:18:00 -05'00'
Division Sign-Off	Herbert P. Lerner-S 2014.02.21 12:24:47 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 <sup>st</sup> page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format

cc: DCC – sign-off & original  
ODE/DRGUD/ULDB – (Shani Haugen)

Final: KAS:kas: 2/21/2014

## Indications for Use

510(k) Number (if known): K133948

Device Name: Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® 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.

Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner-S  
2014.02.21 11:51:08 -05'00'

**Bard Peripheral Vascular, Inc.**  
C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062

K133948

FDA CDRH DMC  
DEC 23 2013  
Received

**BARD**

December 20, 2013

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: **Special 510(k)**  
**Trade Name:** Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument  
Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument  
**Common Name:** Core Biopsy Instrument  
**Predicate Device:** Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument  
(K922939)

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, Bard Peripheral Vascular, Inc. (BPV), a division of C.R. Bard, Inc., is submitting one paper copy and one eCopy of a Special 510(k) notification for the Bard<sup>®</sup> Monopty<sup>®</sup> and Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instruments. The eCopy is an exact duplicate of the paper copy. There have been no prior formal submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence for this device.

The Bard<sup>®</sup> Monopty<sup>®</sup> and Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instruments are Class II products. The Product Code for these devices is KNW (Instrument, Biopsy). The Review Panel for this Product Code is Gastroenterology / Urology (Medical Specialty No. 78). The Device Classification Regulation Number is 21 CFR §876.1075.

This submission seeks FDA concurrence on the use of the subject device in a broader list of soft tissue organs for promotional purposes. The enumeration of this list represents the original intent of the indications for use statement. There is no change to the intended use or indications for use of the subject device, and the promotional change does not alter the fundamental scientific technology of the device. This modification complies with the requirements for a Special 510(k) submission as outlined in "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance", issued March 20, 1998.

**Bard Peripheral Vascular, Inc.**

C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062



The terms "substantially equivalent", "similar", and related terms and descriptions in this notification are terms or words of art defined by the Food and Drug Administration in the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

This document contains a Medical Device User Fee Cover Sheet and a completed CDRH Premarket Review Submission Cover Sheet following this cover letter. A checklist for Special 510(k)s can be found on Page 4 corresponding to the FDA guidance document, "Refuse to Accept Policy for 510(k)s," dated December 31, 2012, which also denotes where each required element outlined in this guidance can be found in this submission. Furthermore, this document contains a signed Truthful and Accuracy Statement on Page 30, Indications for Use Statement on Page 75, and Declaration of Conformity with Design Controls on Page 92. The 510(k) Summary can be found on Page 26.

BPV requests that the FDA keep and maintain confidential both the existence and the contents of this premarket notification in accordance with 21 CFR §807.95(b). BPV also requests that the FDA keep and maintain confidential the contents of this letter.

Please do not hesitate to contact me if you have any questions or need any additional information. I can be reached via telephone at 480-638-2954, fax at 480-449-2546, or by e-mail at [sarah.mccartney@crbard.com](mailto:sarah.mccartney@crbard.com).

Sincerely,

A handwritten signature in blue ink that reads "Sarah McCartney". The signature is written in a cursive, flowing style.

Sarah McCartney  
Regulatory Affairs Specialist  
Bard Peripheral Vascular, Inc.



**Bard® Monopty® Disposable Core Biopsy Instruments and  
Bard® Max-Core® Disposable Core Biopsy Instruments**

**Special 510(k)**

**20 December 2013**

**CONFIDENTIALITY STATEMENT**

This document contains information that is confidential and proprietary property of C. R. Bard, Inc. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without the proper written consent of Bard Peripheral Vascular, Inc.

**Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, AZ 85281**

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  BARD PERIPHERAL VASCULAR 1625 WEST 3RD STREET P O BOX 1740 TEMPE AZ 85281 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0297		2. CONTACT NAME Tim Williams 2.1 E-MAIL ADDRESS tim.williams@crbard.com 2.2 TELEPHONE NUMBER (include Area code) 480-303-2539 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 480-449-2546	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm</a> <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice			
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number.			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm</a> for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		18-Oct-2013	

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 12/20/2013	User Fee Payment ID Number <b>(b) (4)</b>	FDA Submission Document Number (if known)
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30 day Supplement <input type="checkbox"/> 30 day Notice <input type="checkbox"/> 135 day Supplement <input type="checkbox"/> Real time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Request for Feedback</b> <input type="checkbox"/> Pre Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Bard Peripheral Vascular, Inc.		Establishment Registration Number (if known) 2020394	
Division Name (if applicable)		Phone Number (including area code) 480 638 2954	
Street Address 1625 West 3rd Street		FAX Number (including area code) 480 449 2546	
City Tempe	State / Province Arizona	ZIP/Postal Code 85281	Country U.S.A.
Contact Name Sarah McCartney			
Contact Title Regulatory Affairs Specialist		Contact E mail Address sarah.mccartney@crbard.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name N/A			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E mail Address	

**SECTION D1**

**REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D2**

**REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol Feasibility <input type="checkbox"/> Protocol Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA  <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
	<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D3**

**REASON FOR SUBMISSION - 510(k)**

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason ( <i>specify</i> ):  This submission seeks FDA concurrence on the use of the subject device in a broader list of soft tissue organ examples that represents the original intent of the indications for use statement.		

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed

1	KNW	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- 510 (k) summary attached  
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K922939	Bard® Monopty® Disposable Core Biopsy Instrument	Bard Peripheral Vascular, Inc.
2			
3			
4			
5			
6			

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name

Core Biopsy Instrument

	Trade or Proprietary or Model Name for This Device	Model Number
1	Bard® Monopty® Disposable Core Biopsy Instrument	1 See attached list
2	Bard® Max Core® Disposable Core Biopsy Instrument	2 See attached list
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)

1	K922939	2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

 Laboratory Testing Animal Trials Human Trials**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code KNW	C.F.R. Section (if applicable) 876.1075	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Gastroenterology / Urology		

Indications (from labeling)

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.

**Note:** Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4)

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4)

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4)

## SECTION I

## UTILIZATION OF STANDARDS

**Note:** Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	5 40	ISO	Medical devices Application of risk management to medical devices	14971	08/20/2012
2	2 179	ISO	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	10993 1	03/16/2012
3	14 278	AAMI/ANSI/ISO	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	10993 7	01/15/2013
4	14 228	AAMI/ANSI/ISO	Sterilization of health care products Ethylene oxide Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices	11135 1	03/16/2012
5	14 360	AAMI/ANSI	Bacterial endotoxins Test methods, routine monitoring, and alternatives to batch testing	ST72	01/15/2013
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

**Please include any additional standards to be cited on a separate page.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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 Paperwork Reduction Act (PRA) Staff  
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ATTACHMENT – Section F, Product Information, Continued

Trade or Proprietary or Model Name for This Device	Model Number
Bard® Monopty® Disposable Core Biopsy Instrument	211410, 211416, 211610, 211616, 211620, 211810, 211816, 211820, 212010, 212016, 212020, 121210, 121216, 121410, 121416, 121610, 121616, 121620, 121810, 121816, 121820, 122010, 122016, 122020
Bard® Max-Core® Disposable Core Biopsy Instrument	MC1410, MC1416, MC1610, MC1616, MC1810, MC1816, MC1820, MC1825, MC2010, MC2016, MC2020

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 14971:2007, Medical devices - Application of risk management to medical devices

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 14971:2007, Medical devices - Application of risk management to medical devices

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER 3	SECTION TITLE General requirements for risk analysis	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 4	SECTION TITLE Risk analysis	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER See Attachment 1	SECTION TITLE See Attachment 1	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------------------	-----------------------------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

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Rockville, MD 20850

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ATTACHMENT 1 – Conformance with Standard Sections, Continued

<b>EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE</b>			
STANDARD TITLE ISO 14971:2007, Medical devices - Application of risk management to medical devices			
<b>CONFORMANCE WITH STANDARD SECTIONS</b>			
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
5	Risk evaluation	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
6	Risk control	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
7	Evaluation of overall residual risk acceptability	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
8	Risk management report	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
9	Production and post-production information	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A

Department of Health and Human Services  
Food and Drug Administration  
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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-179

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation..."

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2	Biological evaluation tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦  
Study of relevant experience and actual testing.

DESCRIPTION  
See Attachment 2.

JUSTIFICATION  
See Attachment 2.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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<b>EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE</b>
--

<b>STANDARD TITLE</b>
-----------------------

ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
--

<b>CONFORMANCE WITH STANDARD SECTIONS</b>
---

(b) (4)



Department of Health and Human Services  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-278

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

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Does this standard include acceptance criteria? .....       
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Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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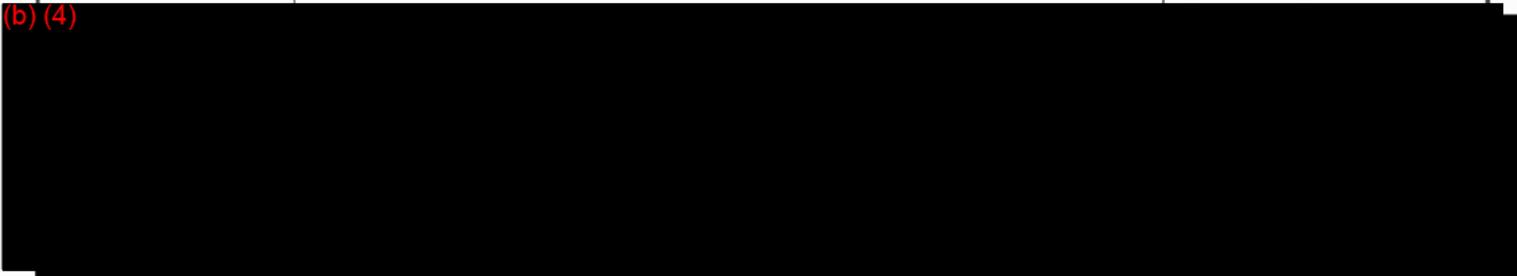
<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4.6.2	Exhaustive Extraction (alternative acceptable method)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A



SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services  
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**STANDARDS DATA REPORT FOR 510(k)s**  
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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for the...

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

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Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for the...

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER See Attachment 3	SECTION TITLE See Attachment 3	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------------------	-----------------------------------	---

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER See Attachment 3	SECTION TITLE See Attachment 3	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------------------	-----------------------------------	---

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

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Office of Chief Information Officer  
1350 Piccard Drive, Room 400  
Rockville, MD 20850

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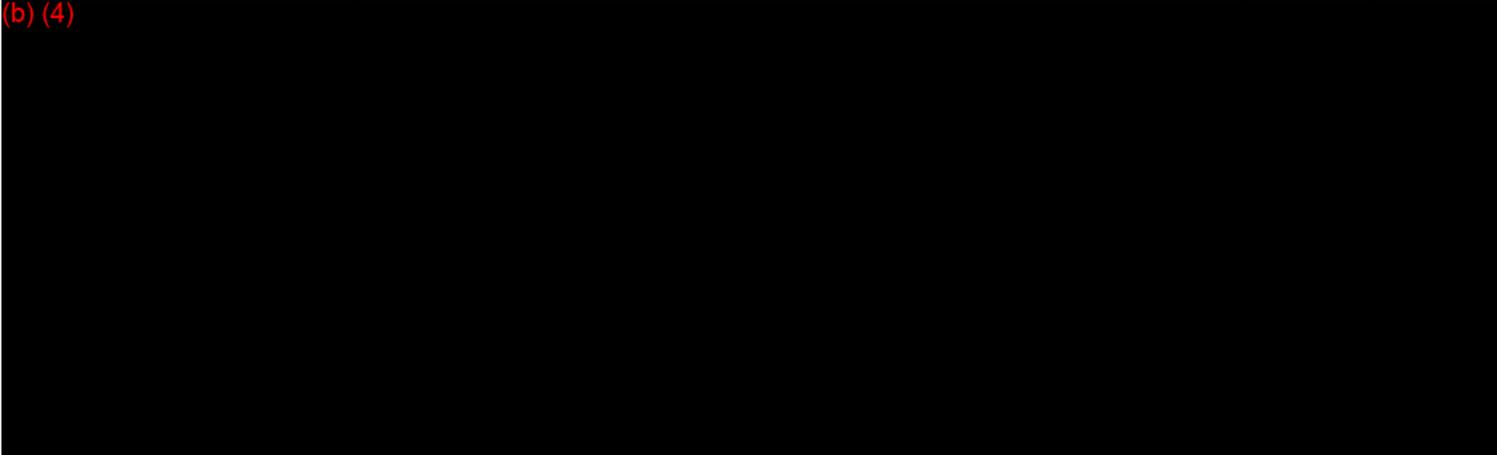
**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

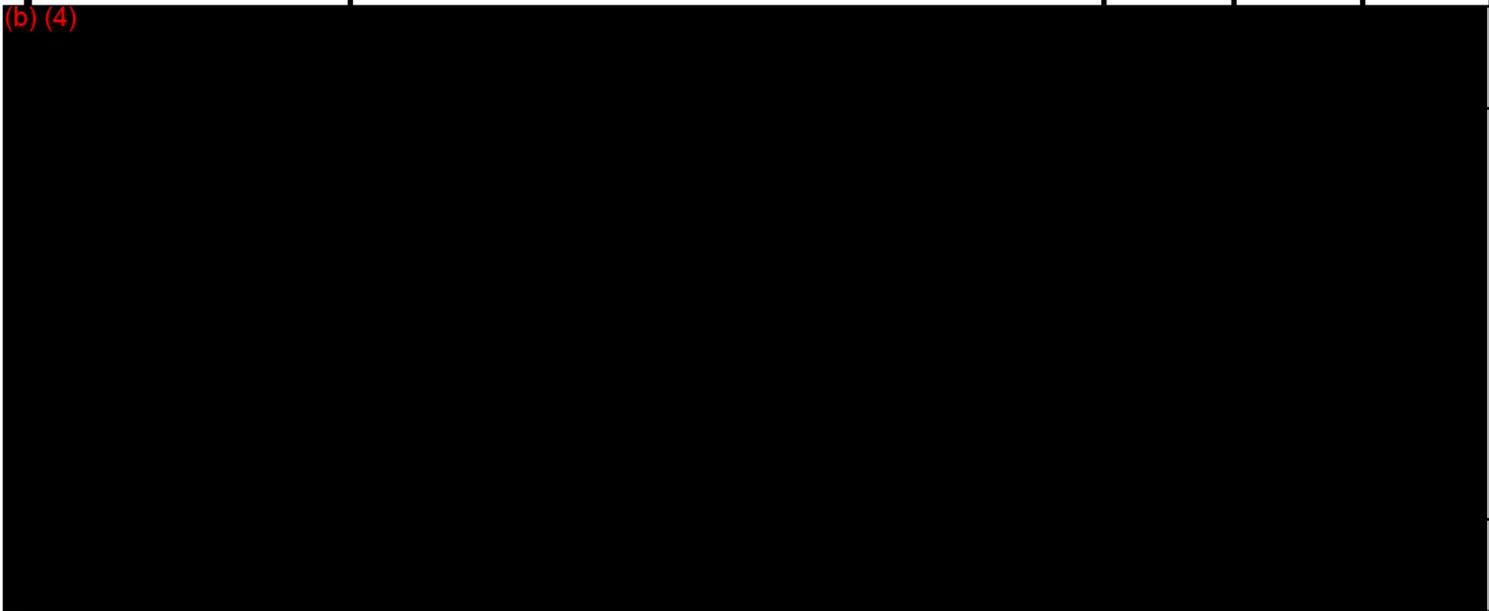
AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products -- Ethylene Oxide -- Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

**CONFORMANCE WITH STANDARD SECTIONS**

SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
9.3.2	Performance qualification - Microbiological	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A



SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
9.3.3	Performance qualification - Physical	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A



Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI ST72:2011 "Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing"

Please answer the following questions	Yes	No
Is this standard recognized by FDA <sup>2</sup> ? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number <sup>3</sup> .....	#14-360	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? ..... If no, complete a summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? ..... If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include more than one option or selection of tests? ..... If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard?..... If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup> ? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?..... If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusions from the standard? ..... If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: "Pyrogens and Endotoxins Testing: Questions and Answers" (June 2012)		

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI ST72:2011 "Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing"

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Selection of technique	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A



SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with  
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Bard Peripheral Vascular, Inc./Sarah McCartney	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Dec 20, 2013
3. ADDRESS (Number, Street, State, and ZIP Code)  1625 West 3rd Street Tempe, AZ 85281	4. TELEPHONE AND FAX NUMBERS (Include Area Code)  (Tel.) 480-638-2954  (Fax) 480-449-2546

**PRODUCT INFORMATION**

5. <b>FOR DRUGS/BIOLOGICS:</b> Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) <b>FOR DEVICES:</b> Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)  Common Name: Core Biopsy Instrument  Classification: Class II  Trade Name: Bard® Monopty® Disposable Core Biopsy Instrument Bard® Max-Core® Disposable Core Biopsy Instrument	Model Numbers: 211410, 211416, 211610, 211616, 211620, 211810, 211816, 211820, 212010, 212016, 212020, 121210, 121216, 121410, 121416, 121610, 121616, 121620, 121810, 121816, 121820, 122010, 122016, 122020, MC1410, MC1416, MC1610, MC1616, MC1810, MC1816, MC1820, MC1825, MC2010, MC2016, MC2020
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**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

**CERTIFICATION STATEMENT / INFORMATION**

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation) <input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial. <input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies. <input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary) NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.  
**Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)  	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Sarah McCartney (Title) Regulatory Affairs Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)  1625 West 3rd Street Tempe, AZ 85281	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 480-638-2954 (Fax) 480-449-2546
	15. DATE OF CERTIFICATION Dec 20, 2013

## Instructions for Completion of Form FDA 3674

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**  
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

**Box A** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

**Box B** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

**Box C** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

### Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

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1350 Piccard Drive, Room 400  
Rockville, MD 20850

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**Refuse To Accept (RTA) Checklist for Special 510(k)s**

**Section 1: Special 510(k) Criteria**

Criteria	Location in 510(k)
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	Cover Letter & Page 10
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	Page 14
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	Page 16
4. The submission includes only summary-level information (i.e., NO test reports with performance data).	Throughout

**Section 2: Organizational Elements**

Organizational Item	Location in 510(k)
a. Submission contains Table of Contents	Page 2
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	Throughout
c. All pages of the submission are numbered	Throughout
d. Type of 510(k) is identified – traditional, abbreviated, or special	Cover Letter and Header

**Section 3: Elements of a Complete Submission (RTA Items)**

Element		Location in 510(k)
<b>A.</b>	<b>Administrative</b>	
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	Throughout
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):	
	a. Device trade name or proprietary name	Cover Letter
	b. Device common name	Cover Letter
	c. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	Cover Letter
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109)	Appendix 5
4.	Submission contains 510(k) Summary or 510(k) Statement	
	a. Summary contains all elements per 21 CFR 807.92	Appendix 1
	b. Statement contains all elements per 21 CFR 807.93	N/A
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k)	Appendix 2
6.	Submission contains Class III Summary and Certification	N/A

	7.		If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	FDA Form 3654
	8.		The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	Cover Letter
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed	N/A
<b>B. Device Description</b>				
	9.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	N/A (Page 11)
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	Page 12-19
	10.		Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:	
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	Page 12-19
		b.	A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	Page 12-19
		c.	A list and description of each model for which clearance is requested.	Page 8-9
	11.		A description of all device modification(s) including rationale for each modification.	Page 14-15
	12.		Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	Appendix 3
	13.		If device is intended to be marketed with multiple components, accessories, and/or as part of a system,	N/A
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	
		b.	Submission includes a description (as detailed in item #12.a. and b. and 14 above) of each component or accessory.	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	
<b>C. Substantial Equivalence Discussion</b>				
	14.		Submitter has identified a predicate(s) device	

	a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendment status.	Page 8
	b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing	Throughout
15.		Submission includes a comparison of the following for the predicate(s) and subject device	
	a.	Indications for use	Page 18
	b.	Technology, including features, materials, and principles of operation	Page 18-19
16.		Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise difference questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act)	Page 14-17
<b>D. Design Control Activities</b>			
17.		Design Control Activities Summary includes all of the following:	
	a.	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	Page 20
	b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	N/A (Page 20)
	c.	Declaration of conformity with design controls, including:	Appendix 7
	i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.	
	ii.	Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30	
	iii.	Statement is signed by the individual responsible for these activities	
<b>E. Proposed Labeling (see also 21 CFR part 801)</b>			
18.		Submission includes proposed labels, and labeling (e.g., instructions for use, package insert, operator's manual), that include a description of the device, its intended use, and the directions for use	Appendix 4
	a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	N/A (Page 13-14)
19.		Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	Page 14

## 1. Executive Summary

The purpose of this Special 510(k) submission is to seek FDA concurrence on the use of the subject devices in a broader list of soft tissue organ examples. This change is consistent with the current intended use / indications for use and does not constitute a new intended use / indications for use. The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument (K922939). This device was cleared on February 16, 1993. The following product configurations, described below, were cleared under K922939:

Gauge x Length	Penetration Depth
14 g x 10 cm	11 mm or 22 mm
14 g x 16 cm	11 mm or 22 mm
16 g x 10 cm	11 mm or 22 mm
16 g x 16 cm	11 mm or 22 mm
16 g x 20 cm	11 mm or 22 mm
18 g x 10 cm	11 mm or 22 mm
18 g x 16 cm	11 mm or 22 mm
18 g x 20 cm	11 mm or 22 mm
20 g x 10 cm	11 mm or 22 mm
20 g x 16 cm	11 mm or 22 mm
20 g x 20 cm	11 mm or 22 mm

The current indications for use statement for the predicate device and subject devices is: “The core biopsy instrument 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.” We had originally provided examples of soft tissue organs in the indications for use statement. These examples were not intended to be exhaustive. It has always been our intention to use the predicate device in a broader list of soft tissues; however, we believe it is prudent at this time to further enumerate this list of soft tissue organ examples for which the subject devices, Bard® Monopty® Disposable Core Biopsy Instrument and Bard® Max-Core® Disposable Core Biopsy Instrument, can be used (refer to Section 3.6). This broader list of examples represents the original intent of the indications for use statement.

**Note: There are no changes proposed to the design, materials, performance specifications, packaging, labeling or sterilization of the currently marketed Bard® Monopty® Disposable Core Biopsy Instrument and Bard® Max-Core® Disposable Core Biopsy Instrument as a result of this submission.**

## 2. Required Information

### 2.1 Predicate Device Information

The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument, K922939, cleared February 16, 1993.

### 2.2 Subject Device Information

#### 2.2.1 Device Name

**Device Trade Name:** Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® Disposable Core Biopsy Instrument

**Common Name:** Core Biopsy Instrument

**Classification Name:** Instrument, Biopsy

The Bard® Monopty® Disposable Core Biopsy Instrument and Bard® Max-Core® Disposable Core Biopsy Instrument will be referred to as “Core Biopsy Instrument(s)” throughout this submission.

#### 2.2.2 Catalogue Numbers

A list of the Core Biopsy Instrument catalogue numbers is provided in Tables 1 and 2.

**Table 1: Bard® Monopty® Disposable Core Biopsy Instrument Catalogue Numbers**

Catalogue Number	Gauge x Length	Penetration Depth
121210	12 g x 10 cm	22 mm
121216	12 g x 16 cm	22 mm
121410	14 g x 10 cm	22 mm
121416	14 g x 16 cm	22 mm
121610	16 g x 10 cm	22 mm
121616	16 g x 16 cm	22 mm
121620	16 g x 20 cm	22 mm
121810	18 g x 10 cm	22 mm
121816	18 g x 16 cm	22 mm
121820	18 g x 20 cm	22 mm
122010	20 g x 10 cm	22 mm

Catalogue Number	Gauge x Length	Penetration Depth
122016	20 g x 16 cm	22 mm
122020	20 g x 20 cm	22 mm
211410	14 g x 9 cm	11 mm
211416	14 g x 15 cm	11 mm
211610	16 g x 9 cm	11 mm
211616	16 g x 15 cm	11 mm
211620	16 g x 19 cm	11 mm
211810	18 g x 9 cm	11 mm
211816	18 g x 15 cm	11 mm
211820	18 g x 19 cm	11 mm
212010	20 g x 9 cm	11 mm
212016	20 g x 15 cm	11 mm
212020	20 g x 19 cm	11 mm

**Table 2: Bard® Max-Core® Disposable Core Biopsy Instrument Catalogue Numbers**

Catalogue Number	Gauge x Length	Penetration Depth
MC1410	14 g x 10 cm	22 mm
MC1416	14 g x 16 cm	22 mm
MC1610	16 g x 10 cm	22 mm
MC1616	16 g x 16 cm	22 mm
MC1810	18 g x 10 cm	22 mm
MC1816	18 g x 16 cm	22 mm
MC1820	18 g x 20 cm	22 mm
MC1825	18 g x 25 cm	22 mm
MC2010	20 g x 10 cm	22 mm
MC2016	20 g x 16 cm	22 mm
MC2020	20 g x 20 cm	22 mm

### 2.2.3 Addresses and Facility Registration Numbers

The addresses and registration numbers for the manufacturer, contract manufacturer and contract sterilizers of the Core Biopsy Instruments are noted below:

Manufacturer:

Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, AZ 85281  
USA  
Establishment Registration Number: 2020394

(b)(4) Contract Manufacturer



(b) (4) is the design center responsible for design control activities affecting the Core Biopsy Instruments.

### 2.2.4 Device Class

**Device Classification:** Class II

**Classification Name:** Instrument, Biopsy ( Product Code KNW)

**Review Panel:** Gastroenterology / Urology

**Regulation Number:** 21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

Please note all of the information above is identical to the predicate device.

The following FDA guidance document is applicable to these devices:

- Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology, dated prior to February 27, 1997.

### **2.3 Performance Standards**

Performance standards have not been established under Section 514 of the Food, Drug and Cosmetic Act for gastroenterology-urology biopsy instruments.

### **2.4 510(k) Summary**

The 510(k) Summary is provided in Appendix 1.

### **2.5 Truthful and Accuracy Statement**

The signed Truthful and Accuracy Statement is provided in Appendix 2.

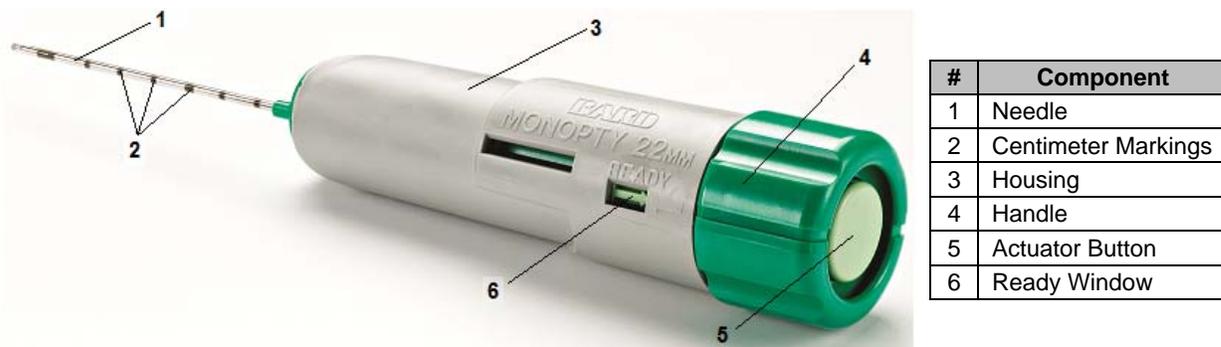
### 3. Device Description and Comparisons

The purpose of this submission is to seek FDA concurrence on the use of the subject devices in a broader list of soft tissue organ examples which represents the original intent of the indications for use statement. **There are no changes proposed to the currently marketed Core Biopsy Instruments.** For ease of review, a brief description of the devices is provided below.

#### 3.1 Device Description

##### Bard® Monopty® Disposable Core Biopsy Instrument

The Bard® Monopty® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths (refer to Table 1 for currently offered product configurations). The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge, Green = 14 gauge, and Light Blue = 12 gauge. A picture of the 14 gauge device is provided in Figure 1.



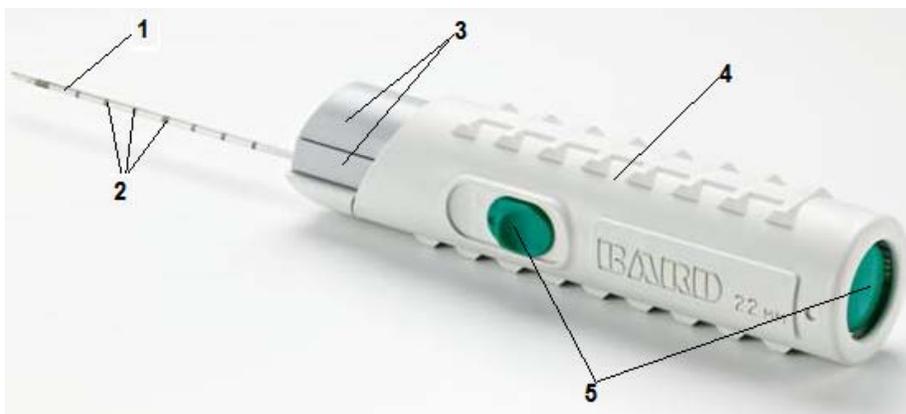
**Figure 1: Bard® Monopty® Disposable Core Biopsy Instrument (14 Gauge)**

##### Bard® Max-Core® Disposable Core Biopsy Instrument

The Bard® Max-Core® Disposable Core Biopsy Instrument was released via a Letter to File on August 15, 1995. The Bard® Max-Core® Disposable Core Biopsy Instrument is an ergonomic enhancement of the Bard® Monopty® Disposable Core Biopsy Instrument. The device provides no new needle gauge sizes (outside the previously cleared range), no significant changes in performance specifications, no new performance claims, no

changes regarding indications for use or contraindications, and no significant changes regarding warnings or precautions. Please refer to Section 3.5, History of Changes, for additional information.

The Bard® Max-Core® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths (refer to Table 2 for currently offered product configurations). The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge. A picture of the 14 gauge device is provided in Figure 2.



#	Component
1	Needle
2	Centimeter Markings
3	Cocking Slides
4	Handle
5	Actuator Buttons

Figure 2: Bard® Max-Core® Disposable Core Biopsy Instrument (14 Gauge)

### 3.2 Engineering Drawings

There are no changes proposed to the engineering drawings of the currently marketed Core Biopsy Instruments. Engineering drawings are provided in Appendix 3.

### 3.3 Labeling, Intended Use and Indications for Use

There are no changes proposed to the labeling of the currently marketed Core Biopsy Instruments. Labels and Instructions for Use for the subject devices are provided in Appendix 4.

The Intended Use and the Indications for Use of the subject devices, as described in its labeling, are the same as the Intended Use and the Indications for Use of the predicate device.

The Indications for Use Statement is provided in Appendix 5.

### 3.4 Materials

There are no changes proposed to the materials of the currently marketed Core Biopsy Instruments. Tables 3 and 4 detail the patient contacting materials of the Core Biopsy Instruments. Body contact and duration are defined per ISO 10993-1:2009, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.”

**Table 3: Bard® Monopty® Disposable Core Biopsy Instrument Patient-contacting Materials**

Component	Material	Body Contact, Duration
(b)(4) Product Specs		Tissue/bone/dentin, Limited
		Tissue/bone/dentin, Limited
		Breached/compromised, Limited
		Breached/compromised, Limited

**Table 4: Bard® Max-Core® Disposable Core Biopsy Instrument Patient-contacting Materials**

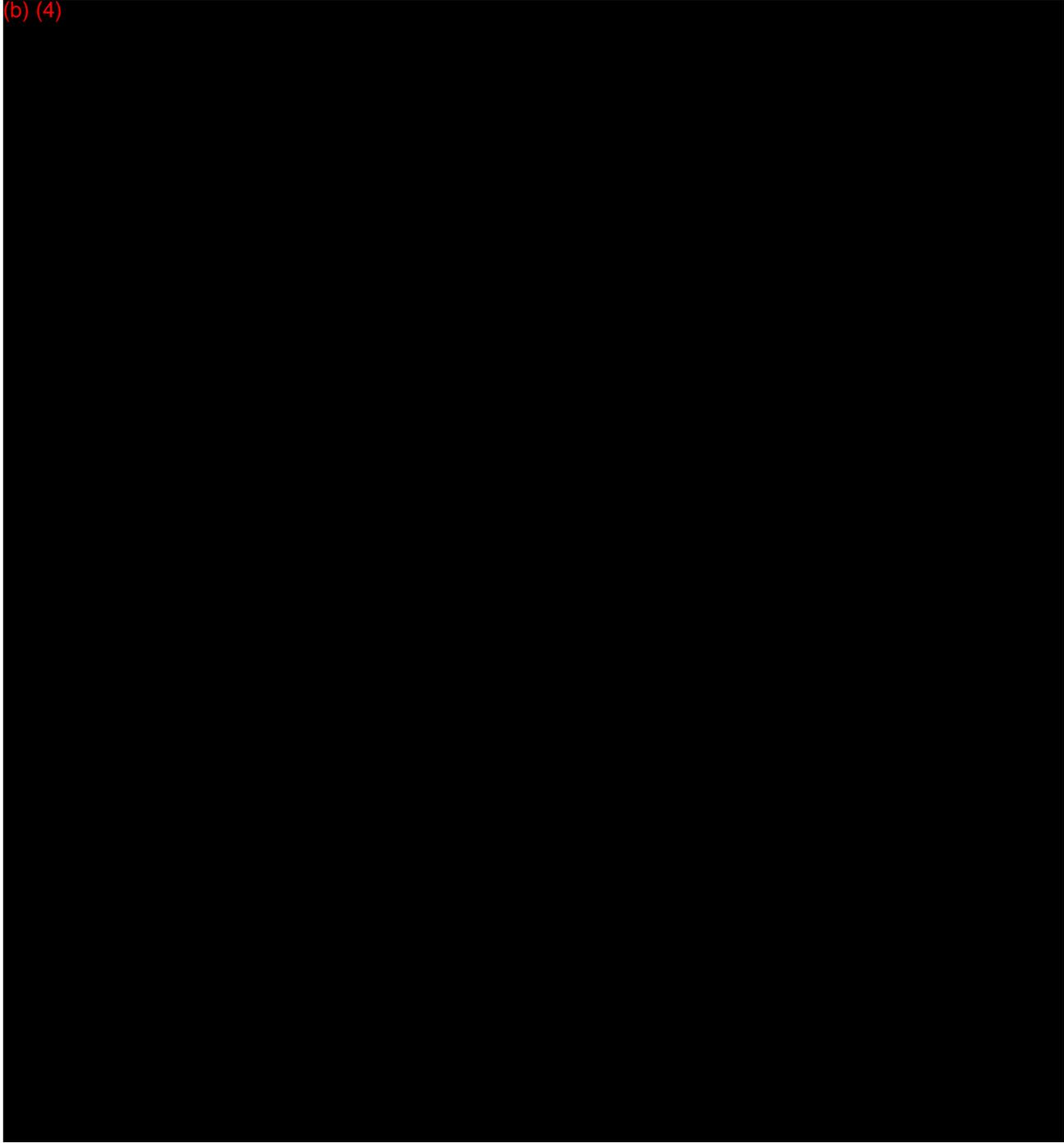
Component	Material	Body Contact, Duration
(b)(4) Product Specs		Tissue/bone/dentin, Limited
		Tissue/bone/dentin, Limited

### 3.5 History of Changes

There have been several changes implemented since the previous submission. Please refer to Table 5 for a list of changes that have been implemented since the previous submission. The changes are listed in the order that they were implemented. These changes did not constitute a new intended use, did not affect safety and effectiveness, did not raise different questions of safety and effectiveness, and did not alter the

fundamental scientific technology of the device; therefore, these changes did not require a new 510(k) submission.

(b) (4)



### 3.6 Predicate and Subject Device Comparison

The predicate device referenced in this submission is the Bard® Monopty® Disposable Core Biopsy Instrument (K922939, cleared February 16, 1993).

This Special 510(k) seeks FDA concurrence on the use of the subject devices in a broader list of soft tissue organ examples. The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Similar patient-contacting materials
- Same fundamental scientific technology
- Same patient population
- Same sterility
- Similar packaging configuration

There are no changes proposed to the design, materials, performance specifications, packaging, labeling or sterilization of the currently marketed Core Biopsy Instruments as a result of this submission. When reviewing the changes since the predicate submission, the subject devices and the predicate device are different in the following manner:

- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications
- Enumeration of a broader list of soft tissue organ examples

These changes do not constitute a new intended use, do not affect safety and effectiveness, do not raise different questions of safety and effectiveness, and do not alter the fundamental scientific technology of the device. The addition of needle gauge size, needle lengths, and performance specifications are described in Section 3.5. Enumerating a broader list of soft tissue organ examples in which the subject devices can be used will be for promotional purposes and does not affect the safety or effectiveness of the device. This broader list of examples represents the original intent of the indications for use statement. This does not represent a change to the intended use or indications for use. For biopsy needles, the physician chooses the needle gauge size and length based upon the type of tissue to be sampled and in the size of the patient. Since the indications for use statement of the subject and predicate device states "...obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors," BPV wants to clarify that moving forward promotional material and sales training will include information regarding the use of the Core Biopsy Instruments in multiple soft tissue organs, including, but not limited to, the liver, kidney, prostate, spleen, lymph nodes, abdomen, thyroid, testes, bladder, lung, breast, all of which are considered soft tissue organs. This list is not meant to be exhaustive; the Core Biopsy Instrument is (and always has been) intended to be used to obtain soft tissue samples. Providing an exhaustive list of all soft tissues in which this device is intended to be used would be burdensome and could make the Instructions for Use difficult or confusing for the user to read and expensive to print. Refer to Table 6 for a comparison of the predicate and subject devices, including those changes detailed in Section 3.5 and described above. The differences are noted in **bold**.

Table 6: Comparison Summary

Attribute	PREDICATE DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (K922939)	SUBJECT DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (Currently Marketed)	SUBJECT DEVICE Bard® Max-Core® Disposable Core Biopsy Instrument (Currently Marketed)
Regulation Number	21 CFR 876.1075 (Class II)	Same as predicate	Same as predicate
Intended Use	<i>The core needle biopsy device is intended to obtain soft tissue samples for diagnostic and histological analysis of soft tissue abnormalities.*</i>	Same as predicate	Same as predicate
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.	Same as predicate	Same as predicate
Soft Tissue Organ Examples	Soft tissue organs such as liver, kidney, prostate, spleen, lymph nodes	Soft tissue organs such as liver, kidney, prostate, spleen, lymph nodes, <b>abdomen, thyroid, testes, bladder, lung, breast</b>	Soft tissue organs such as liver, kidney, prostate, spleen, lymph nodes, <b>abdomen, thyroid, testes, bladder, lung, breast</b>
Design, including:	Single-use, sterile, disposable	Same as predicate	Same as predicate
- Needle Gauge	14, 16, 18, 20 gauge	<b>12, 14, 16, 18, 20 gauge</b>	Same as predicate
- Needle Length	10, 16, 20 cm	<b>9, 10, 15, 16, 19, 20, 25 cm</b>	10, 16, 20, <b>25 cm</b>
- Penetration Depth	11 or 22 mm	Same as predicate	22 mm (Subset of Predicate)
- Sample Notch	7 or 17mm	Same as predicate	<b>18 mm</b>

Attribute	PREDICATE DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (K922939)	SUBJECT DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (Currently Marketed)	SUBJECT DEVICE Bard® Max-Core® Disposable Core Biopsy Instrument (Currently Marketed)
· Number of Samples	One or more	Same as predicate	Same as predicate
· Mechanics of Action	Spring operated	Same as predicate	Same as predicate
· Mode of Action	Single puncture and sample*	Same as predicate	Same as predicate
Energy Used / Delivered	(b)(4) Product Specs	Same as predicate	Same as predicate
Patient-Contacting Materials	(b)(4) Product Specs		
Patient Population	Individuals requiring biopsy for sampling of soft tissue abnormalities*	Same as predicate	Same as predicate
Visualization Techniques	X-ray, ultrasound, CT, etc.	Same as predicate	Same as predicate
Performance Specifications	Sample quality	Same as predicate	Same as predicate
	N/A	<b>Durability</b>	<b>Durability</b>
	N/A	<b>Needle to device tensile strength</b>	<b>Needle to device tensile strength</b>
Sterility	Ethylene oxide, SAL of 10 <sup>-6</sup>	Same as predicate	Same as predicate
Packaging Configuration	6 blister packs with Tyvek lids or 10 Tyvek to film pouches in a cardboard shelf box with the IFU	<b>5</b> or <b>10</b> blister packs with Tyvek lids in a cardboard shelf box with the IFU	<b>5</b> blister packs with Tyvek lids in a cardboard shelf box with the IFU

\* This information is not clearly stated, but is implied from the predicate submission.

\*\* These materials are unchanged from the predicate device, only the patient contact was re-evaluated (additional biocompatibility testing was not required due to the change to patient contact for these components)

## 4. Design Control Activities

### 4.1 Risk Analysis

(b) (4)



### 4.2 Packaging

The predicate device is packaged in either a blister pack with Tyvek lid or Tyvek to film pouch. Sealed blister packs or sealed pouches are placed in a cardboard shelf box with the Instructions for Use.

The subject device is packaged in a blister pack with Tyvek lid similar to the predicate device. Sealed blister packs are placed in a cardboard shelf box with the Instructions for Use. **There are no changes proposed to the packaging of the currently marketed Core Biopsy Instruments.**

### 4.3 Biocompatibility

**There are no changes proposed to the biocompatibility of the currently marketed Core Biopsy Instruments.** The currently marketed subject device is considered biocompatible for its intended use as stated in K922939 and as discussed in Section 3.5, History of Changes. Refer to Table 7 for a list of the testing performed / adopted for the subject device.

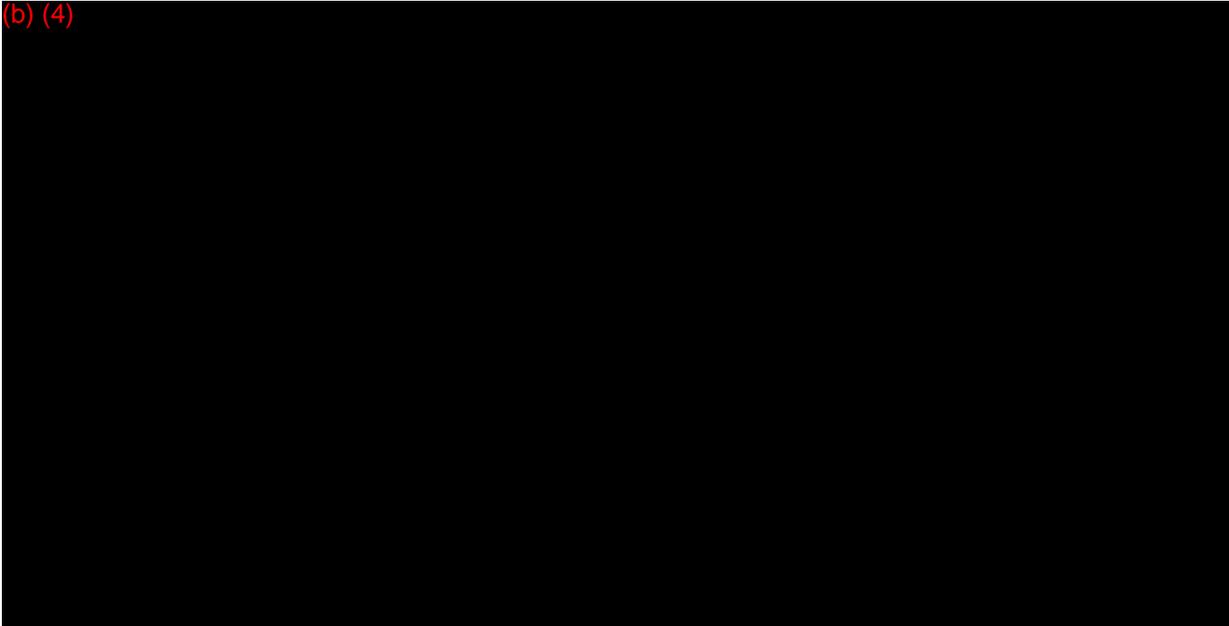
Table 7: Biocompatibility Testing

Test	Results
(b) (4)	

4.4 Sterilization

(b) (4)

(b) (4)



#### 4.5 Shelf-Life

There are no changes proposed to the shelf-life of the currently marketed Core Biopsy Instruments. The subject device is qualified for a 3 year shelf life.

#### 4.6 Declaration of Conformity with Design Controls

The Declaration of Conformity with Design Controls is provided in Appendix 7.

## 5. Statement of Substantial Equivalence

The predicate device referenced in this submission is the Bard® Monopty® Disposable Core Biopsy Instrument (K922939, cleared February 16, 1993).

This Special 510(k) seeks FDA concurrence on the use of the subject device in a broader list of soft tissue organ examples. The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Similar patient-contacting materials
- Same fundamental scientific technology
- Same patient population
- Same sterility
- Similar packaging configuration

There are no changes proposed to the design, materials, performance specifications, packaging, labeling or sterilization of the currently marketed Core Biopsy Instruments as a result of this submission. When reviewing the changes since the predicate submission, the subject device and the predicate device are different in the following manner:

- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications
- Enumeration of a broader list of soft tissue organ examples

As previously noted, a review of the Risk Assessment and DFMEA of the subject device is conducted in accordance with internal procedures based on ISO 14971:2007, to assure that the risks posed by the modified device are acceptable. The outcome of the risk management activities demonstrate the Core Biopsy Instruments present an acceptable level of risk when used within its intended use and that the design outputs continue to meet the design inputs and user need requirements. Therefore, the currently marketed subject devices are substantially equivalent to the legally marketed predicate device.

**Appendix 1: 510(k) Summary**

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**510(k) Summary**

**21 CFR 807.92**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (l)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

**1. Submitter Information:**

Applicant: Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, Arizona 85281

Phone: 480-638-2954

Fax: 480-449-2546

Contact: Sarah McCartney, Regulatory Affairs Specialist

Date: December 20, 2013

**2. Subject Device:**

Device Trade Name: Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® Disposable Core Biopsy Instrument

Common or Usual Name: Core Biopsy Instrument

Classification: Class II

Classification Name: Instrument, Biopsy ( Product Code KNW)

Review Panel: Gastroenterology / Urology

Regulation Number: 21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

**3. Predicate Device:**

The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument, K922939, cleared February 16, 1993.

**4. Summary of Change:**

This Special 510(k) seeks FDA concurrence on the use of the subject devices in a broader list of soft tissue organ examples that represents the original intent of the indications for use statement.

## 5. Device Description:

### Bard® Monopty® Disposable Core Biopsy Instrument

The Bard® Monopty® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge, and Light Blue = 12 gauge.

### Bard® Max-Core® Disposable Core Biopsy Instrument

The Bard® Max-Core® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge.

## 6. Indications for Use of Device:

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.

## 7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Similar patient-contacting materials
- Same fundamental scientific technology

- Same patient population
- Same sterility
- Similar packaging configuration

When reviewing the changes from the predicate submission, the subject devices and the predicate device are different in the following manner:

- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications
- Enumeration of a broader list of soft tissue organ examples

#### **8. Performance Testing Summary:**

The use of the subject devices in the additional soft tissue organs described in this submission does not affect the design of the device and no new or increased risks have been identified, therefore additional bench performance testing was not warranted.

#### **9. Conclusion:**

The subject devices are substantially equivalent to the predicate device.

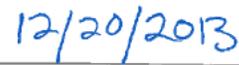
## Appendix 2: Truthful and Accuracy Statement

### Truthful and Accuracy Statement

Pursuant to 21 CFR 807.87(k), I certify that, in my capacity as Regulatory Affairs Specialist of Bard Peripheral Vascular, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been knowingly omitted.



Sarah McCartney  
Regulatory Affairs Specialist

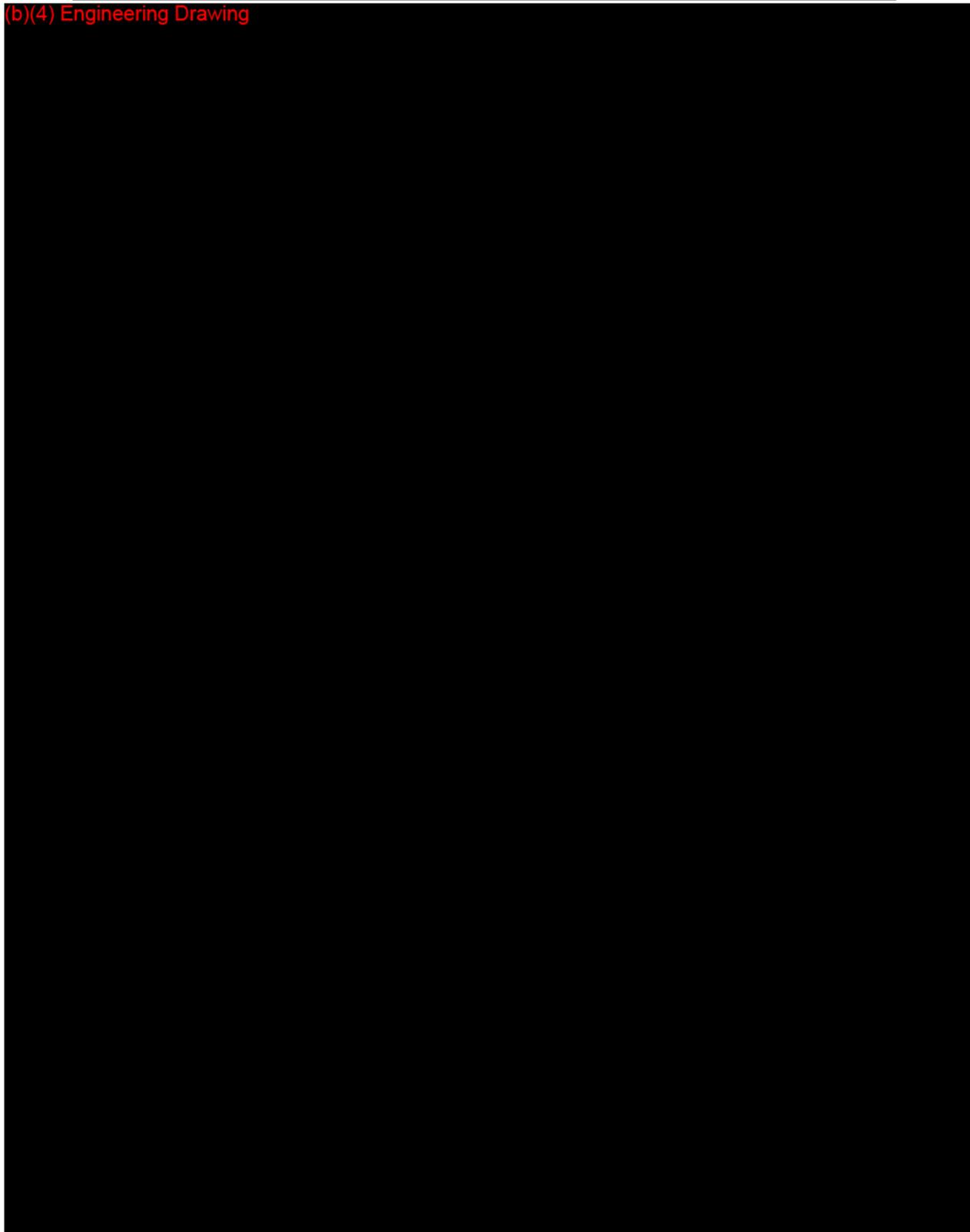


Date

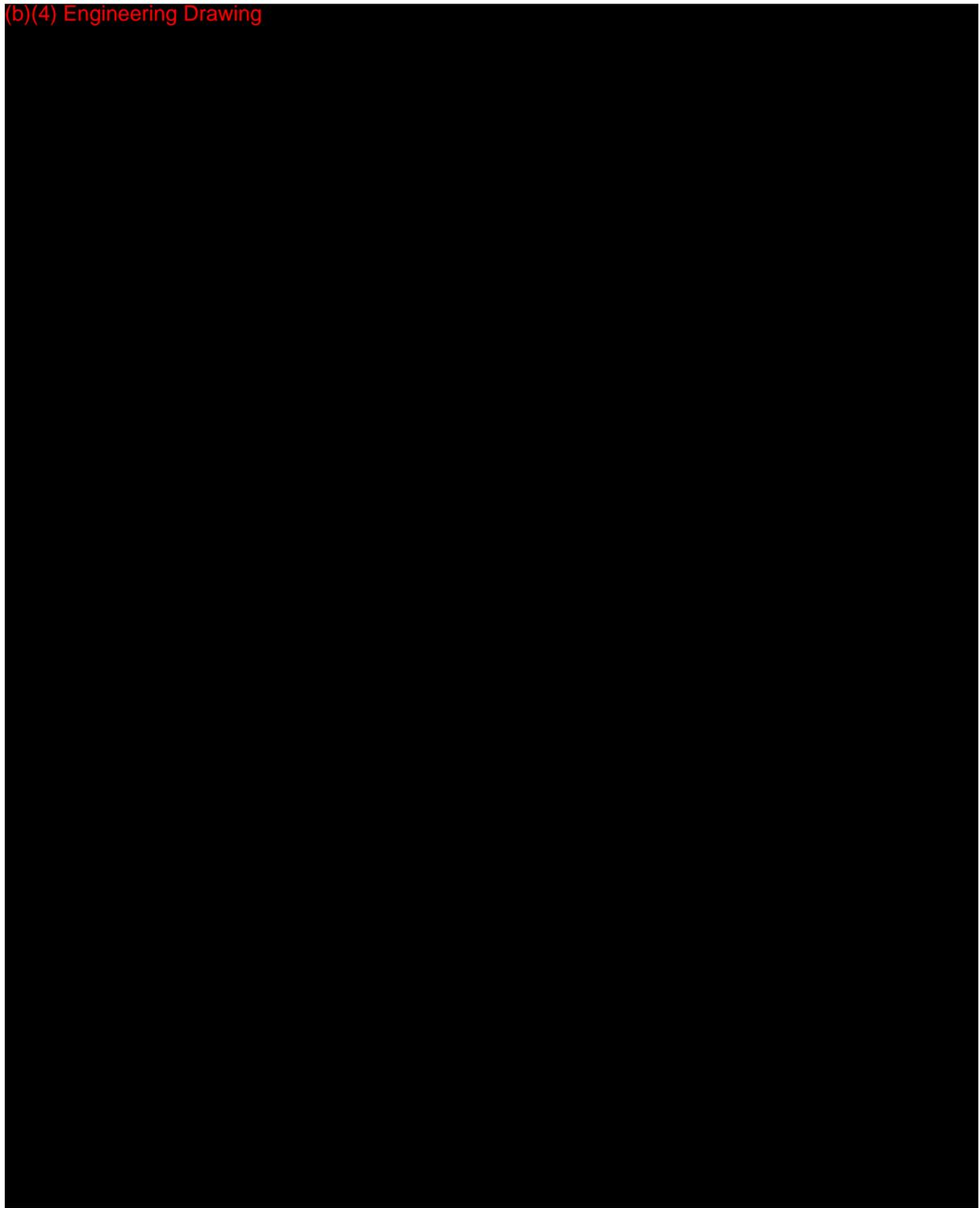
### Appendix 3: Engineering Drawings

**Bard® Monopty® Disposable Core Biopsy Instrument**

(b)(4) Engineering Drawing



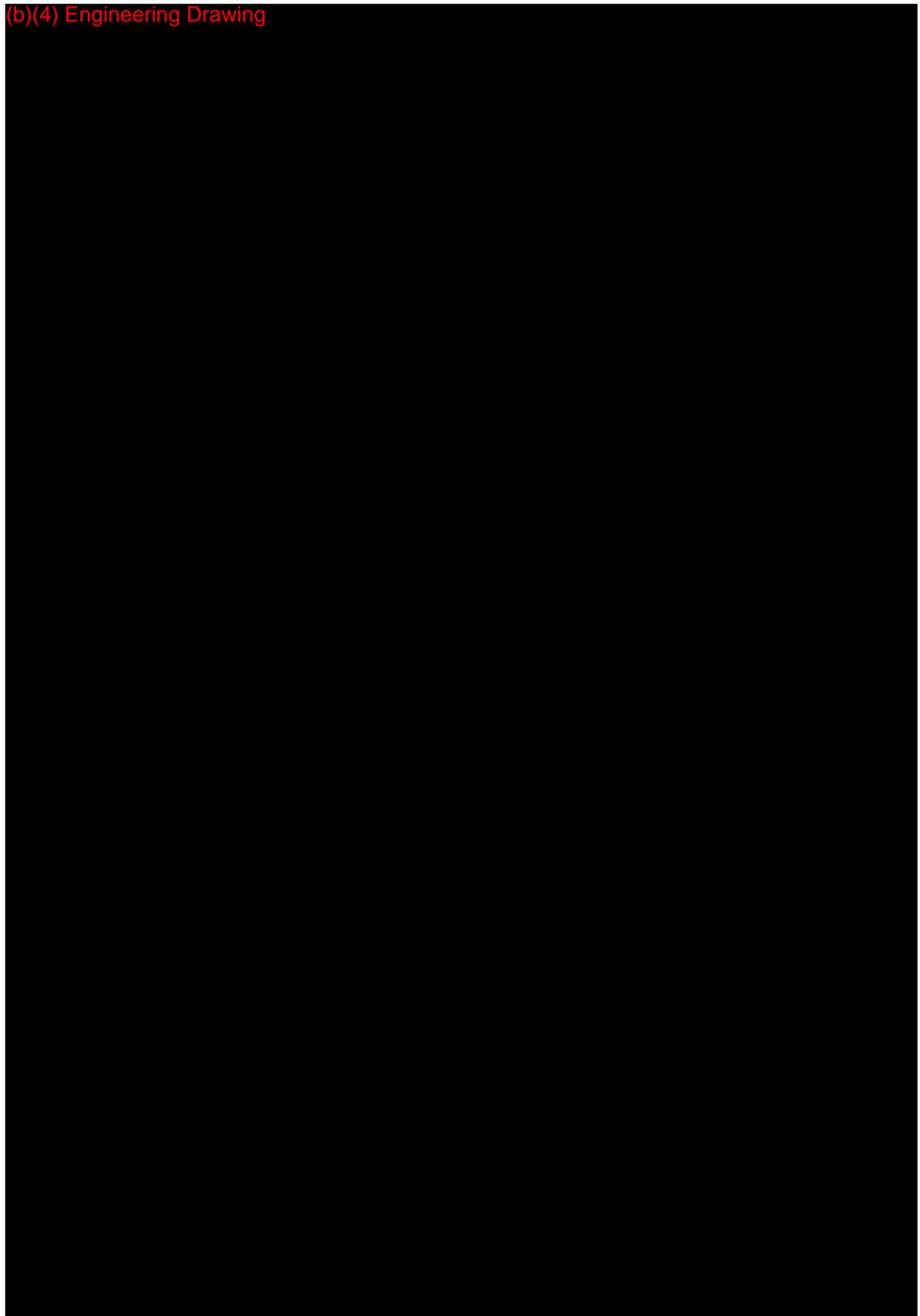
(b)(4) Engineering Drawing



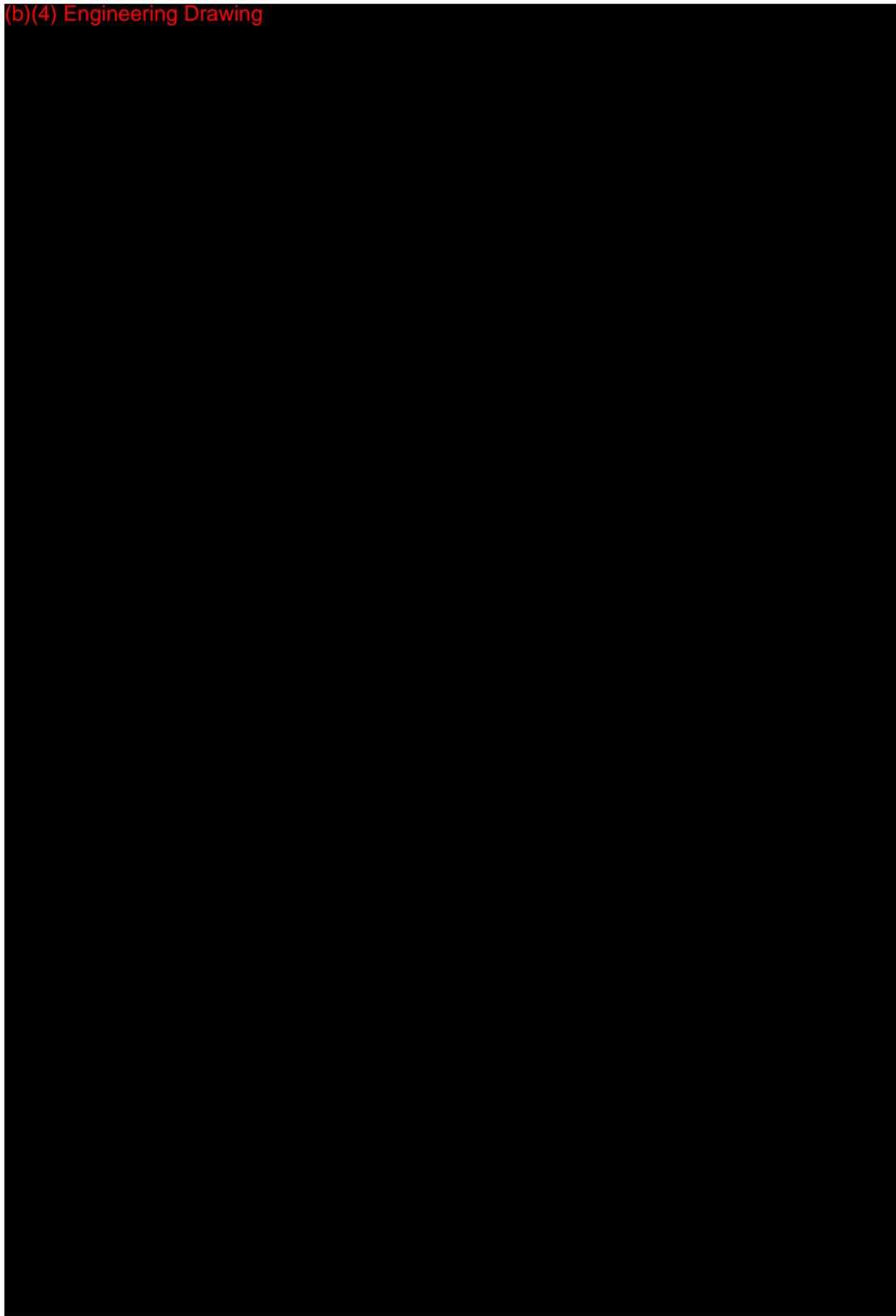
(b)(4) Engineering Drawing



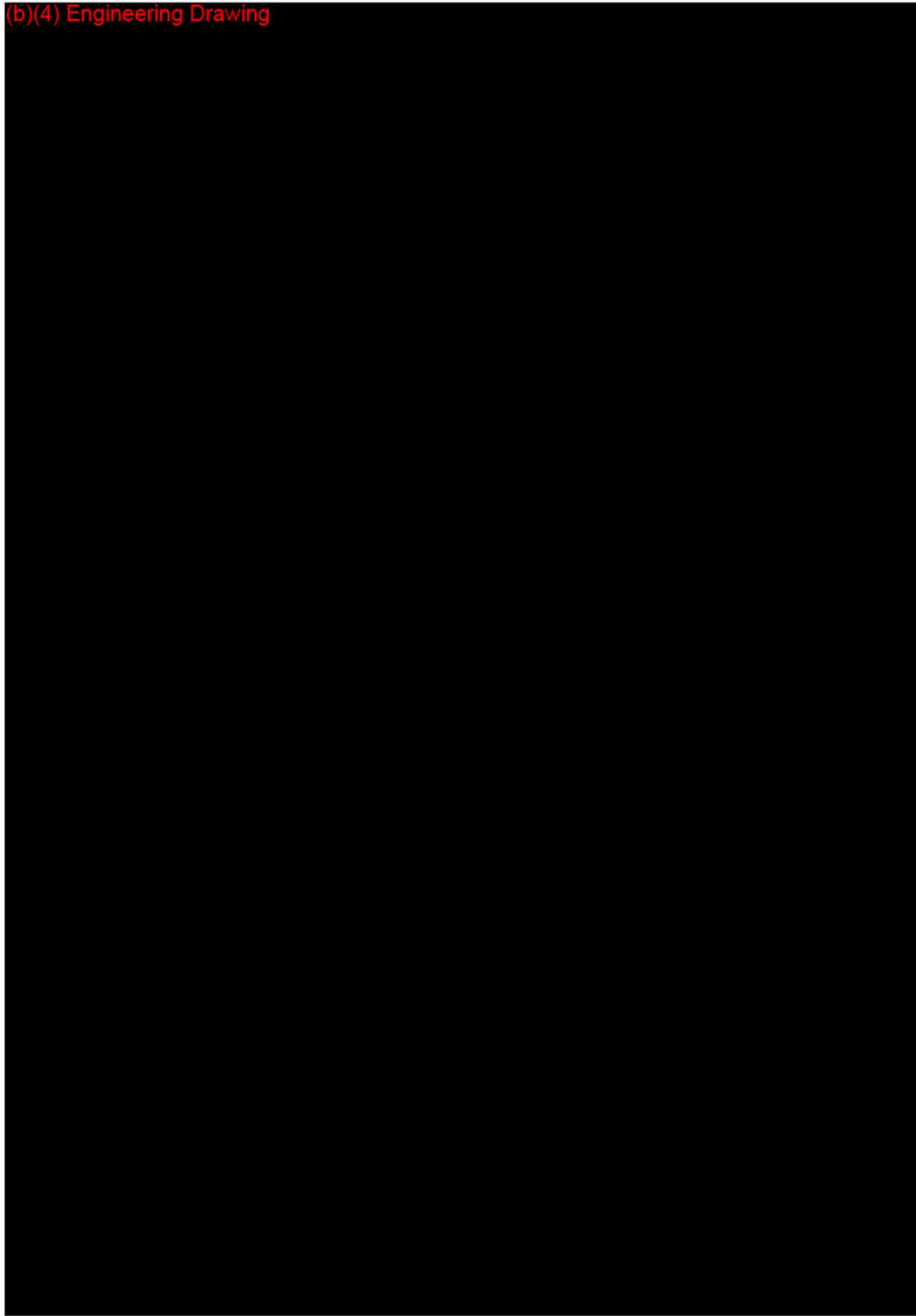
(b)(4) Engineering Drawing



(b)(4) Engineering Drawing

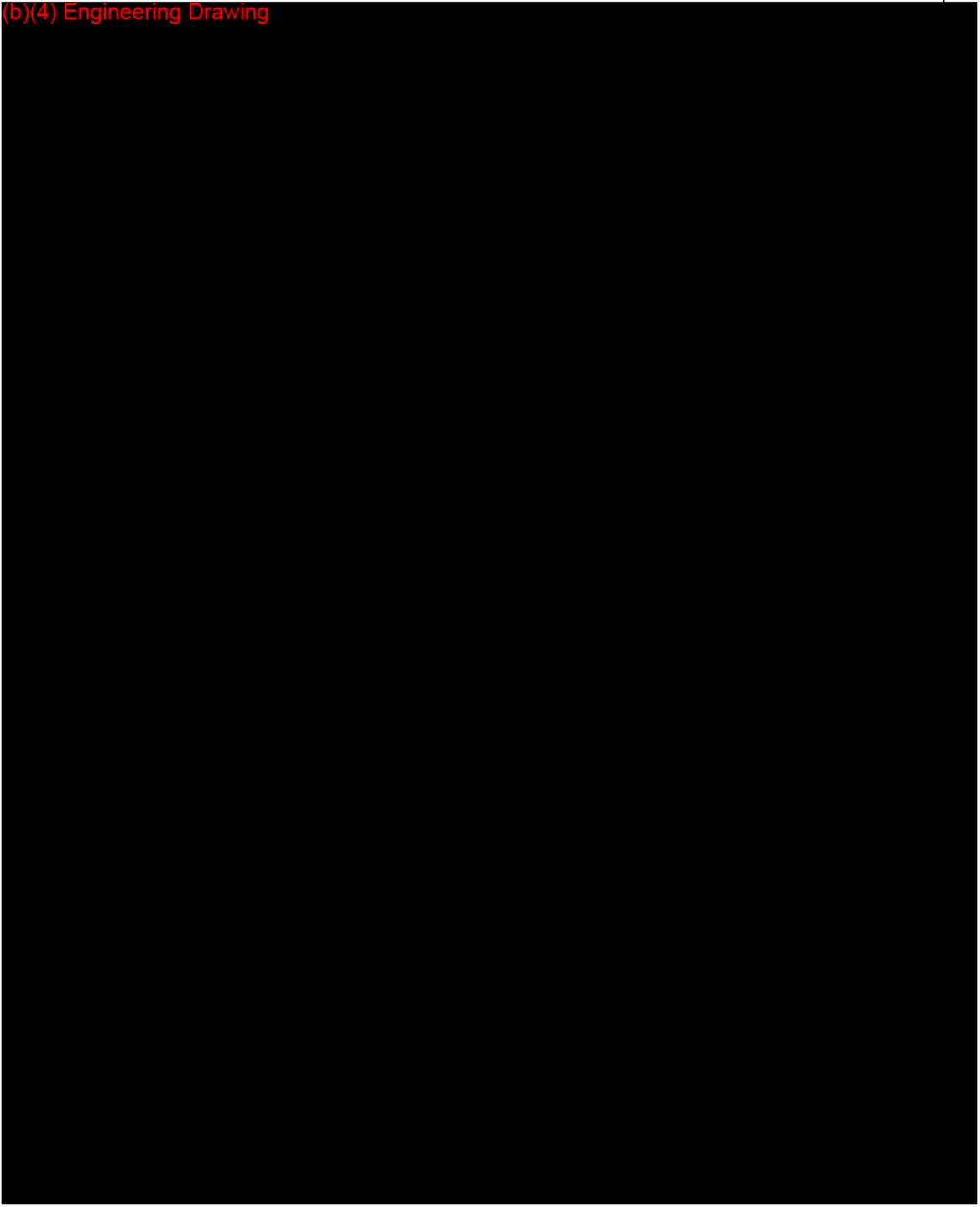


(b)(4) Engineering Drawing



**Bard® Max-Core® Disposable Core Biopsy Instrument**

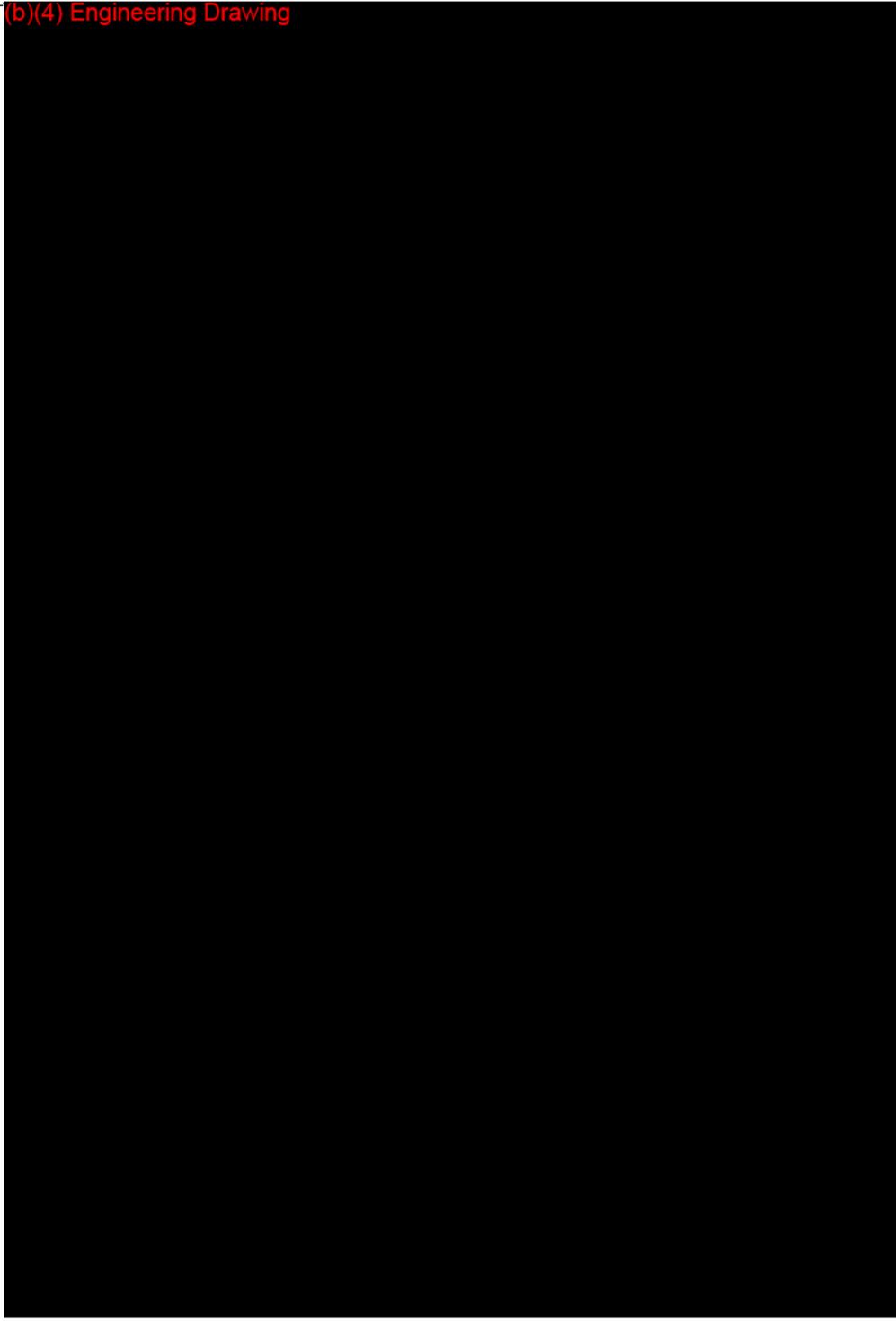
(b)(4) Engineering Drawing



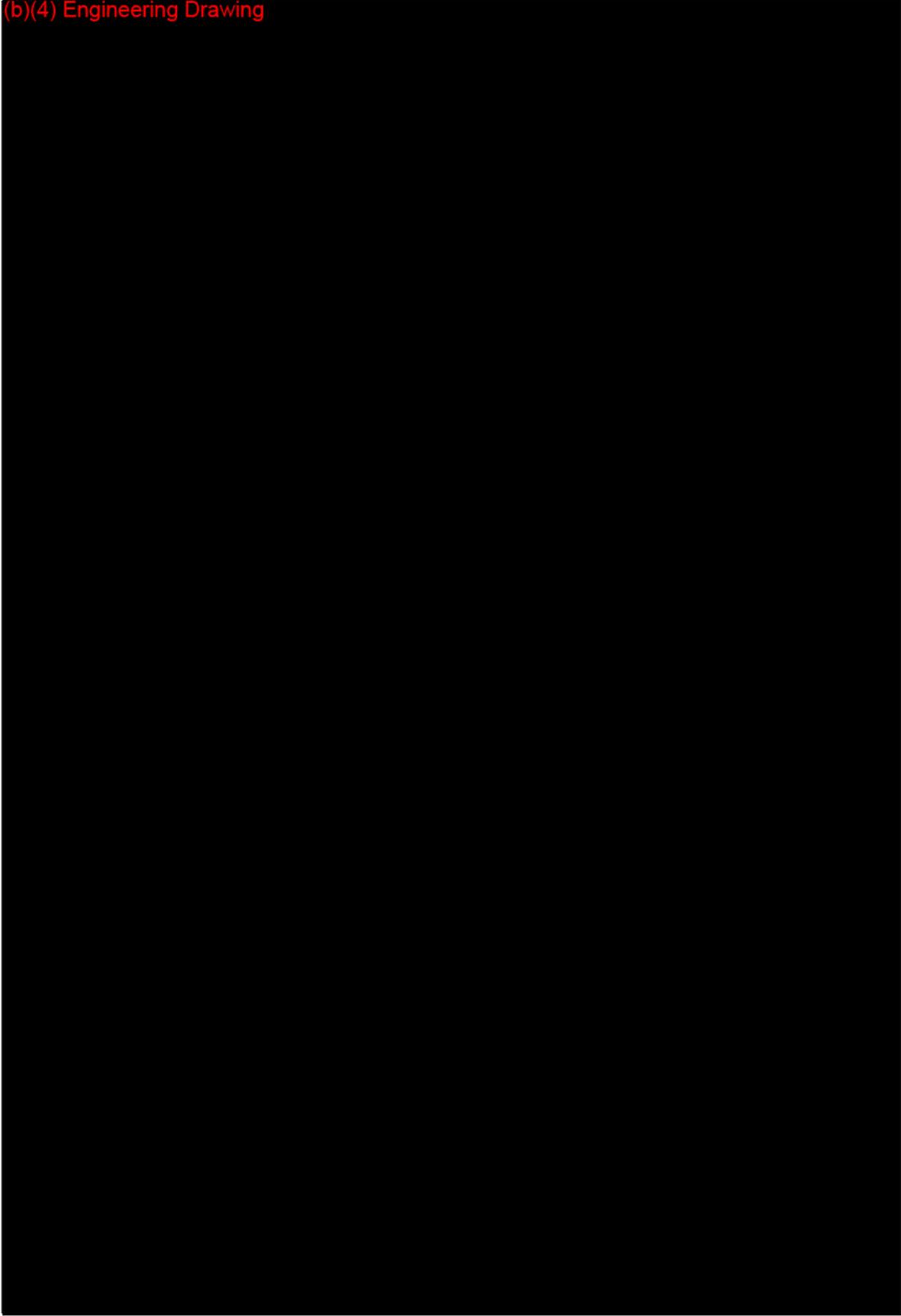
(b)(4) Engineering Drawing



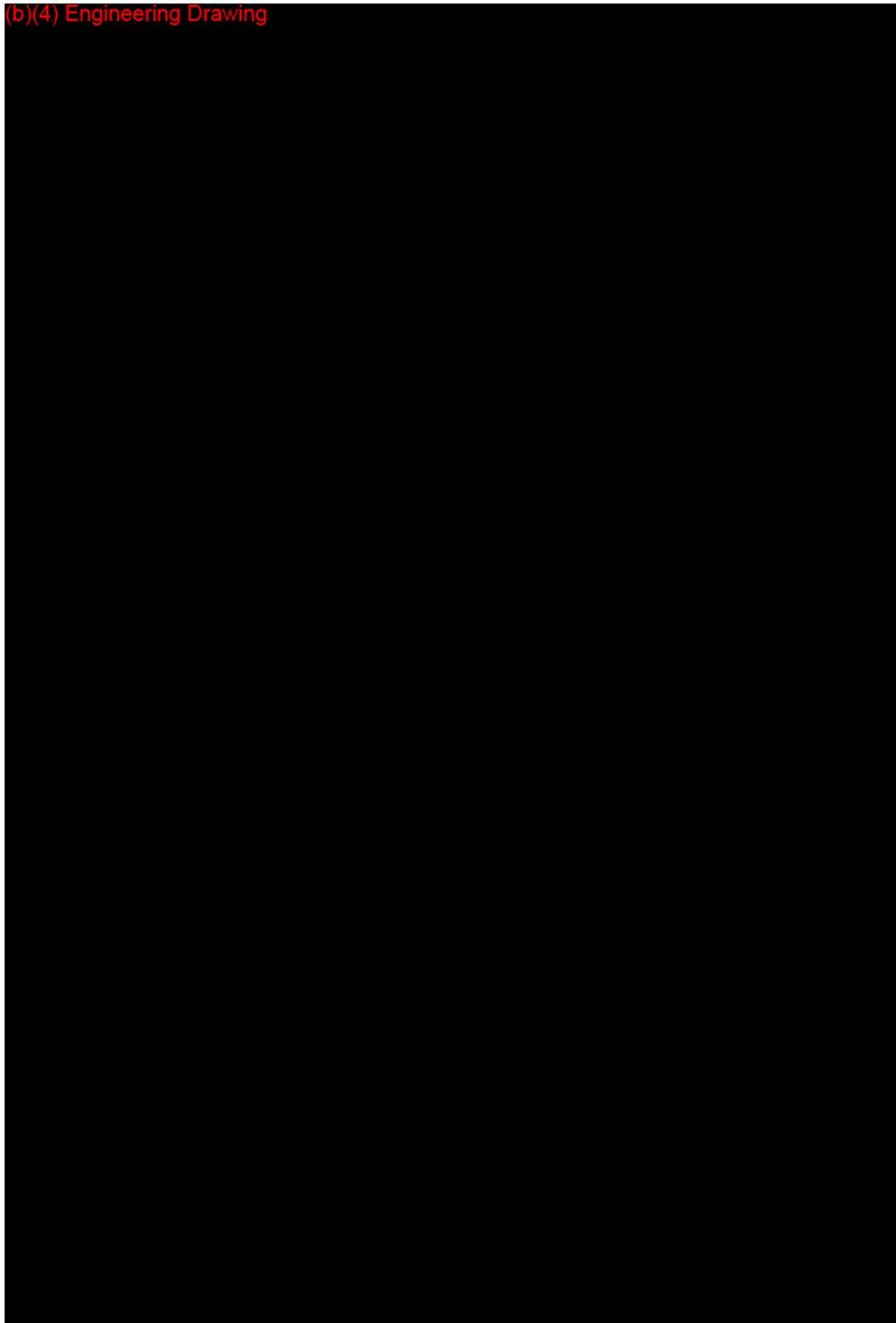
(b)(4) Engineering Drawing



(b)(4) Engineering Drawing



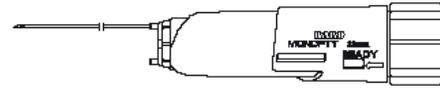
(b)(4) Engineering Drawing



## Appendix 4: Subject Device Labeling

**Bard® Monopty® Disposable Core Biopsy Instrument (English Only)**

## BARD® MONOPTY® Disposable Core Biopsy Instrument Instructions for Use



Instrument de biopsie tissulaire jetable  
BARD® MONOPTY®  
Mode d'emploi

Kertakäyttöinen BARD® MONOPTY®  
-paksuneulabiopsiainstrumentti  
Käyttöohjeet

BARD® MONOPTY® Core-Biopsie-  
Instrument für den Einmalgebrauch  
Gebrauchsanweisung

BARD® MONOPTY® engangsinstrument  
til kjernebiopsi  
Bruksanvisning

Strumento per agobiopsie  
BARD® MONOPTY®  
Istruzioni per l'uso

Jednorazowy przyrząd BARD® MONOPTY®  
do biopsji gruboigłowej  
Instrukcja użycia

Instrumento desechable para biopsia  
core BARD® MONOPTY®  
Modo de empleo

BARD® MONOPTY® eldobható  
core-biopsziás eszköz  
Használati útmutató

BARD® MONOPTY® wegwerpbaar  
hollenaaldbiopsie-instrument  
Gebruiksaanwijzing

Jednorázový nástroj BARD® MONOPTY®  
pro punkční biopsii  
Návod k použití

Instrumento de biopsia por agulha  
grossa descartável BARD® MONOPTY®  
Instruções de utilização

BARD® MONOPTY® Tek Kullanımlik  
Kor Biyopsi Cihazı  
Kullanma Talimatı

Αναλώσιμο εργαλείο βιοψίας με  
κόπτουσα βελόνα BARD® MONOPTY®  
Οδηγίες χρήσης

BARD® MONOPTY® 拋棄式  
空芯切片器械  
使用說明

BARD® MONOPTY® engangs-  
instrument til grovnålsbiopsi  
Bruksanvisning

BARD® MONOPTY® 일회용  
총생검 기구  
사용 지침

BARD® MONOPTY® engångsnål  
för kärnbiopsi  
Bruksanvisning

Одноразовый инструмент  
для толстоигльной биопсии  
BARD® MONOPTY®  
Инструкции по применению

**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® MONOPTY® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge, Green=14 gauge, and Light Blue=12 gauge.

Catalog Number	Gauge Size and Needle Length	Length of Sample Notch	Penetration Depth
121210	12g (2.8mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121216	12g (2.8mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121410	14g (2.1mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121416	14g (2.1mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121610	16g (1.7mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121616	16g (1.7mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121620	16g (1.7mm) x 20cm (200mm)	1.7cm (17mm)	22mm
121810	18g (1.2mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121816	18g (1.2mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121820	18g (1.2mm) x 20cm (200mm)	1.7cm (17mm)	22mm
122010	20g (0.9mm) x 10cm (100mm)	1.7cm (17mm)	22mm
122016	20g (0.9mm) x 16cm (160mm)	1.7cm (17mm)	22mm
122020	20g (0.9mm) x 20cm (200mm)	1.7cm (17mm)	22mm

211410	14g (2.1mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211416	14g (2.1mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211610	16g (1.7mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211616	16g (1.7mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211620	16g (1.7mm) x 19cm (190mm)	0.7cm (7mm)	11mm
211810	18g (1.2mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211816	18g (1.2mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211820	18g (1.2mm) x 19cm (190mm)	0.7cm (7mm)	11mm
212010	20g (0.9mm) x 9cm (90mm)	0.7cm (7mm)	11mm
212016	20g (0.9mm) x 15cm (150mm)	0.7cm (7mm)	11mm
212020	20g (0.9mm) x 19cm (190mm)	0.7cm (7mm)	11mm

(1)

ENGLISH

**B. How Supplied:**

The product is supplied sterile and non-pyrogenic unless the package has been opened or damaged. Sterilized using Ethylene Oxide. **For single use only. Do Not Reuse. Do Not Resterilize.**

**C. 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.

**D. Contraindications:**

Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have bleeding disorders.

**E. 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. 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.
3. 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. 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® MONOPTY® Disposable Core Biopsy Instrument. 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:** If collecting multiple samples, inspect the needle for a damaged point, bent shaft or other imperfections after each sample is collected. Do not use the needle if any imperfection is noted.

**Note:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices 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.)

(2)

3. Never test the product by firing into the air. Damage may occur to the needle/cannula tip and/or patient/user injury.
4. 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.
5. Unusual force applied to the stylet or unusual resistance against the stylet while extended out of the supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with the needle function.

**G. 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.

**H. Equipment Required:**

- Appropriate imaging modality accessories
- Surgical gloves and drapes
- Local anesthetic as needed
- BARD® TRUGUIDE® Coaxial cannula (optional)
- Scalpel
- Sample collection container
- Other equipment as necessary

**I. Directions for Use:**

**BARD® MONOPTY® Disposable Core Biopsy Instrument preparation:**

Before using, inspect the needle for a damaged point, bent shaft or other imperfections that would prevent proper function. If the needle is damaged or bent, DO NOT USE.

1. Using aseptic technique, remove the instrument from its package.
2. Prepare the Monopty® instrument for biopsy by twisting the rotational mechanism at the end of the instrument. One-half turn will withdraw the cannula and lock it into place. An additional one-half turn will withdraw the stylet and lock it into place. The instrument is ready to fire. The arrow must be visible in the ready window prior to insertion into the patient.

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

**Biopsy Procedure:**

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Prepare the site as required. Adequate anesthesia should be administered prior to incision of the skin.
2. Verify instrument is energized (cocked).
3. Insert the tip of the needle prior to the lesion to be biopsied.
4. While maintaining the instrument's position and the needle orientation, depress the actuator button to cause both the stylet and the cannula to automatically advance.

ENGLISH

5. Remove needle from patient and rotate the end of the instrument one-half turn to withdraw the cannula and expose the biopsy specimen. Remove the specimen.
6. If additional biopsies of the same organ are required, withdraw the stylet by rotating the end of the instrument an additional one-half turn and repeat the procedure.

**Warranty:**

Bard Peripheral Vascular, Inc. 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.

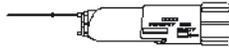
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Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and 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 to see if additional product information is available.

Assembled in Mexico.

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**BARD® MONOPTY® Disposable Core Biopsy Instrument**

Instrument de biopsie tissulaire jetable BARD® MONOPTY®  
BARD® MONOPTY® Einweg-Stanzbiopsieinstrument  
Strumento usa-e-getta per agobiopsie BARD® MONOPTY®  
Instrumento para biopsia de núcleo desechable BARD® MONOPTY®  
BARD® MONOPTY® wegwerpbaar kernbiopsie-instrument  
Dispositivo descartável para biopsia por punção tecidual BARD® MONOPTY®  
Αναλώσιμο εργαλείο βιοψίας με κόπτιουσα βελόνα BARD® MONOPTY®  
BARD® MONOPTY® kernbiopsieinstrument til engangsbrug  
BARD® MONOPTY® kambiopsieinstrument för engangsbruk  
Kertakäyttöinen BARD® MONOPTY® -paksuneulabiopsialaite  
BARD® MONOPTY® engangsinstrument til kjemebiopsi  
Jednorazowy przyrząd BARD® MONOPTY® do biopsji gruboigłowej  
BARD® MONOPTY® egyszer használatos vastagtű-biopsziás eszköz  
Jednorázový bioptický nástroj BARD® MONOPTY® pro „core” biopsii  
BARD® MONOPTY® Tek Kullanımlık Kor Biyopsi Cihazı  
BARD® MONOPTY® 拋棄式空芯切片器械  
BARD® MONOPTY® 일회용 총생검 기구  
Одноразовый инструмент для толстоигльной биопсии BARD® MONOPTY®



**Attention, See Instructions For Use**

Attention, voir le mode d'emploi  
Achtung! Siehe Gebrauchsanweisung  
Attenzione, leggere le istruzioni per l'uso  
Atención: consulte las instrucciones de uso  
Let op, zie Gebruiksaanwijzing  
Atenção, consultar as instruções de utilização  
Προσοχή, βλ. Οδηγίες χρήσης  
Bemærk, Se brugsvejledningen  
Obs! Se bruksanvisningen  
Huomio! Lue käyttöohjeet  
NB! Se bruksanvisningen  
Uwaga: Należy zapoznać się z instrukcją użycia  
Figyelem, lásd a használati utasítást!  
Pozor, viz návod k použití  
Dikkat, Kullanım Talimatları'na bakınız  
注意・請參閱使用說明書  
주의, 사용 지침 참조  
Внимание! См. инструкции по применению



**Catalogue Number**

Numéro de catalogue  
Katalognummer  
Numero di catalogo  
Número de catálogo  
Catalogusnummer  
Número do catálogo  
Αριθμός καταλόγου  
Katalognummer  
Artikelnummer  
Luettelonumero  
Katalognummer  
Numer katalogowy  
Katalógusszám  
Katalogové číslo  
Katalog Numarası  
目錄編號  
카탈로그 번호  
Номер по каталогу



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**Do Not Resterilize**

Ne pas restériliser  
Nicht resterilisieren  
Non risterilizzare  
No reesterilizar  
Niet opnieuw steriliseren  
Não reesterilizar  
Μην επαναποστειρώνετε  
Må ikke resteriliseres  
Får ej omsteriliseras  
Et saa sterioida uudestaan  
Må ikke resteriliseres  
Nie sterylizować ponownie  
Ujrsterilizálni liios  
Neprovádějte resterilizaci  
Tekrar steriilize etmeyiniz  
請勿重複消毒  
재멸균하지 마십시오.  
Повторная стерилизация запрещена



**Lot Number**

Numéro de lot  
Chargennummer  
Numero di lotto  
Número de lote  
Lotnummer  
Número do Lote  
Αριθμός παρτίδας  
Lotnummer  
Lotnummer  
Eränumero  
Partinummer  
Numer partii  
Sorozatszám  
Číslo šarže  
Lot Numarası  
批號  
로트 번트  
Номер партии



**Use By**

Date limite d'utilisation  
Verwendbar bis  
Utilizzare entro  
Usar antes de  
Te gebruiken vóór  
Prazo de validade  
Ημερομηνία λήξης  
Arvendes før  
Utgångsdatum  
Käytettävä ennen  
Brukes innen  
Termin ważności  
Felhasználható  
Datum použitelnosti  
Son Kullanım Tarihi  
有效期限  
유효기한  
Использовать до



**Single Use**

A usage unique  
Nur zum Einmalgebrauch  
Monouso  
Un solo uso  
Voor eenmalig gebruik  
Utilização única  
Πα μία χρήση μόνο  
Engangsbrug  
Engångsbruk  
Kertäkäyttöinen  
Til engangsbruk  
Tylko do jednorazowego użytku  
Egyszer használatos  
K jednorázovému použití  
Tek Kullanım İçindir  
僅供一次性使用  
1회 사용  
Однократного применения



**Sterilized Using Ethylene Oxide**

Stérilisé à l'oxyde d'éthylène  
Mit Ethylenoxid sterilisiert  
Sterilizzato con ossido di etilene  
Esterilizado con óxido de etileno  
Gesteriliseerd met behulp van ethylenoxide  
Esterilizado por óxido de etileno  
Αποστειρωμένο με οξείδιο του αιθυλενίου  
Steriliseret ved ethylenoxid  
Steriliserad med etylenoxid  
Steriloitu etylenoksidilla  
Steriliseret med etylenoksid  
Produkt sterylizowany tlenkiem etylenu  
Etilénoxidál sterilizálva  
Sterilizováno etylenoxidem  
Etilen Oksit Kullanılarak Sterilize Edilmiştir  
使用環氧乙烷消毒  
산화에틸렌으로 멸균 처리됨  
Стерилизовано этиленоксидом



**Manufacturer**

Fabricant  
Hersteller  
Produttore  
Fabricante  
Fabrikant  
Fabricante  
Κατασκευαστής  
Producent  
Tillverkare  
Valmistaja  
Produsent  
Produceant  
Gyártó  
Výrobce  
Üretici  
製造商  
제조사  
Производитель



**Non-Pyrogenic**

Apyrogène  
Pyrogenfrei  
Apirógeno  
Apirógeno  
Niet-pyrogeen  
Apirogénico  
Μη πυρετογόνο  
Pyrogenfri  
Pyrogenfri  
Pyrogeeniton  
Pyrogenfri  
Apirogenny  
Pirogénmentes  
Apyrogenní  
Pirojenik deðildir  
無熱原  
비발열성  
Апирогенно



**Peel to Open**

Peler pour ouvrir  
Zum Öffnen abziehen  
Per aprire staccare qui  
Retirar para abrir  
Trekken om te openen  
Descolar para abrir  
Αποκολλήστε για να ανοίξει  
Trækkes af for at åbne  
Riv upp för att öppna  
Repáise auki  
Trek av for å åpne  
Zerwać w celu otwarcia  
A kinyitáshoz húzza szét  
Otevířete stržením krycí fólie  
Soyarak Açınız  
撕下即可開啟  
벗겨서 개봉하십시오.  
Потянуть для открытия



**Gauge Size and Needle Length**

Diamètre et longueur de l'aiguille  
Größe (Gauge) und Nadellänge  
Calibro e lunghezza dell'ago  
Tamaño de calibre y longitud de aguja  
Naald dikte en -lengte  
Calibre e comprimento da agulha  
Μέγεθος gauge και μήκος βελόνας  
Gauge-størrelse og nålelængde  
Gaugestørlek och nållängd  
G-koko ja neulan pituus  
Gaugestørrelse og nålelengde  
Rozmiar i długość igły  
Vastagság és tűhosszúság  
Průměr a délka jehly  
Kalibre Βυγύκλιόγυ ve İğne Uzunluđu  
規格尺寸和針長  
게이지 크기 및 바늘 길이  
Калибр и длина иглы



**Length of Sample Notch**

Longueur d'encoche d'échantillonnage  
Länge der Probenkerbe  
Lunghezza dell'incavo per il campione  
Longitud de la muesca de la muestra  
Lengte van inkeping  
Comprimento do entalhe da amostra  
Μήκος εγκοπής δείγματος  
Længde af prøverille  
Provsårans längd  
Näyteloven pituus  
Lengden på prøvetakingshakket  
Długość wcięcia próbki  
Mintavévo horony hossza  
Délka drážky na vzorek  
Ömek Çentik Uzunluđu  
樣本切口長度  
샘플 노치 길이  
Длина выемки для образца



**Penetration Depth**

Profondeur de pénétration  
Penetrationstiefe  
Profondità di penetrazione  
Profundidad de penetración  
Penetratiediepte  
Profundidade de penetração  
Βάθος διείσδυσης  
Penetrationsdybde  
Penetrationsdjup  
Penetraatiosyvyys  
Penetrasjonsdybde  
Głębokość penetracji  
Behatolási mélység  
Hĺoubka průniku  
Giriş Derinliđi  
穿刺深度  
침투 깊이  
Глубина проникновения



**Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised**

Ne pas utiliser si la barrière de stérilisation ou l'emballage du produit est endommagé  
Bei beschädigter oder offener Sterilverpackung nicht verwenden  
Non utilizzare se la barriera di sterilizzazione del prodotto o la confezione sono compromessi  
No utilizar si la barrera de esterilización del producto o su envase están dañados  
Niet gebruiken wanneer de sterilisatiebarrière van het product of de verpakking is aangetast  
Não utilizar se a barreira de esterilização do produto ou respectiva embalagem estiverem comprometidas  
Μη χρησιμοποιείτε το προϊόν εάν έχει παραβιαστεί ο φραγμός αποστείρωσης ή η συσκευασία του  
Må ikke anvendes, hvis produktets steriliseringsbarriere eller emballagen er kompromitteret.  
Använd inte om produktens sterila barriär eller dess förpackning är skadad  
Ei saa käyttää, jos tuotteen steriloimisuojaus tai pakkaus on vaurioitunut  
Bruk ikke produktet hvis den sterile barrieren eller emballasjen er brutt  
Nie używać, jeśli naruszono sterylność produktu lub jego opakowanie  
Ne használja, ha a termék védő steril zár vagy a csomagolás sérült  
Nepoužívejte výrobek s narušenou sterilizační ochranou nebo porušeným obalem.  
Ürün Steril Bariyeri veya Ambalajı zarar görmüşse kullanmayın  
如果產品消毒屏障或包裝受損，請勿使用  
제품의 멸균 장벽이나 포장에 손상을 경우 사용하지 마십시오.  
Запрещается применять изделие, если стерильная упаковка или внешняя упаковка повреждена



**Authorised Representative in the European Community**

Représentant autorisé au sein de la Communauté européenne  
Bevollmächtigter in der Europäischen Gemeinschaft  
Rappresentante autorizzato nella Comunità Europea  
Representante autorizado en la Comunidad Europea  
Gemachtigde binnen de Europese Gemeenschap  
Representante autorizado na Comunidade Europeia  
Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα  
Autoriseret repræsentant i Det Europæiske Fællesskab  
Auktoriserad representant inom EG  
Valtuutettu edustaja Euroopan yhteisössä  
Autorisert representant i EU  
Autoryzowany przedstawiciel na terenie Unii Europejskiej  
Meghatalmazott képviselő az Európai Közösségekben  
Autorizovaný zástupce v Evropské unii  
Avrupa Topluluğuna Yetkili Temsilcisi  
歐洲共同體的授權代表  
유럽 공동체 내의 인증받은 대리업체  
Уполномоченный представитель в Европейском сообществе



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FAX: 1-480-966-7062  
1-800-440-5376  
[www.bardbiopsy.com](http://www.bardbiopsy.com)



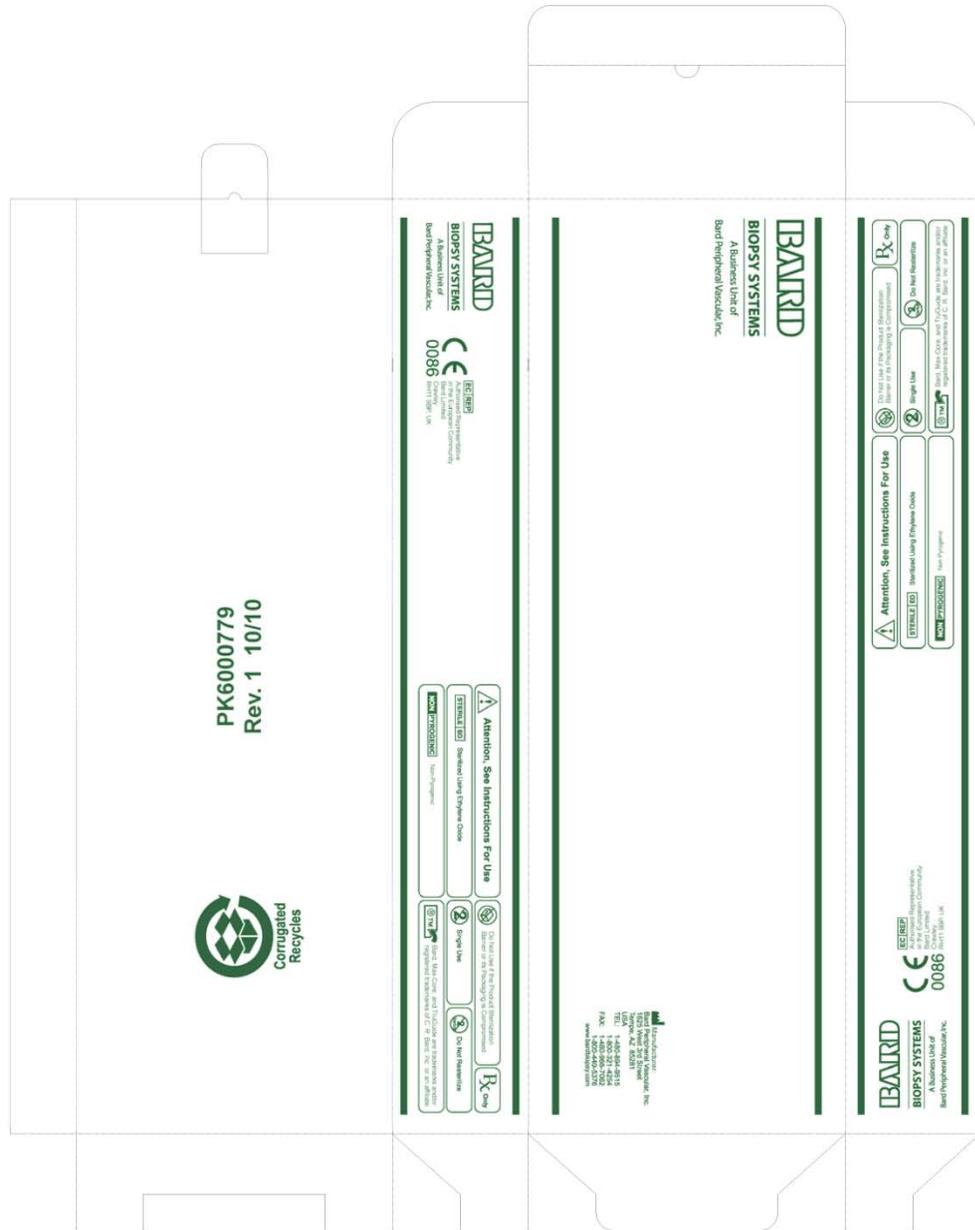
**Authorised Representative  
in the European Community  
Bard Limited**

Forest House  
Tilgate Forest Business Park  
Brighton Road, Crawley  
West Sussex  
RH11 9BP, UK

**BAIRD**

**BIOPSY SYSTEMS**

PK1280000 Rev. 0 05/12



Box (1212XX Codes)

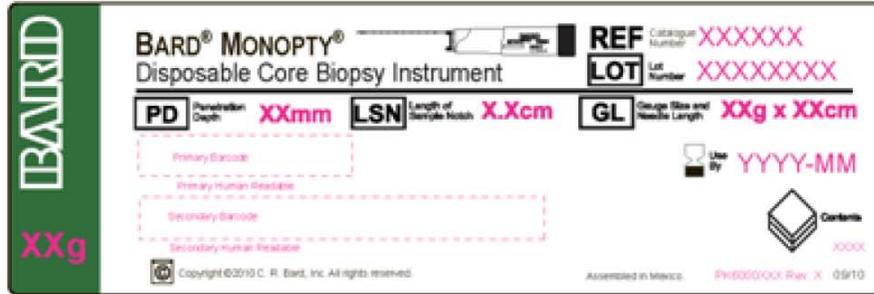


Box ( 1214XX-1220XX, 21XXXX Codes)



Tray Lid

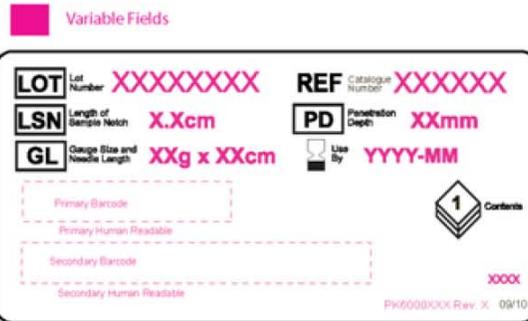
**Variable Fields**



Box Label



Multi-language Label



Tray Lid Label

**Bard® Max-Core® Disposable Core Biopsy Instrument (English Only)**

**BARD® MAX-CORE®**  
**Disposable Core Biopsy Instrument**  
**Instructions for Use**



BARD® MAX-CORE® Instrument pour biopsie à usage unique  
Mode d'emploi

BARD® MAX-CORE® Einweg-Biopsieinstrument  
Gebrauchsanweisung

BARD® MAX-CORE® Strumento Usa-e-Getta per Agobiopsia  
Istruzioni per l'Uso

BARD® MAX-CORE® Instrumento de Biopsia Desechable  
Instrucciones de uso

BARD® MAX-CORE® Biopsie-instrument voor eenmalig gebruik  
Gebruiksaanwijzing

BARD® MAX-CORE® Instrumento de Biopsia Descartável  
Instruções de Utilização

BARD® MAX-CORE® Αναλώσιμο εργαλείο βιοψίας δια βελόνας  
Οδηγίες χρήσης

BARD® MAX-CORE® Biopsiinstrument til engangsbrug  
Brugervejledning

BARD® MAX-CORE® Biopsiinstrument för engångsbruk  
Bruksanvisning

Kertakäyttöinen BARD® MAX-CORE® -paksuneulabiopsialaite  
Käyttöohjeet

BARD® MAX-CORE® biopsiinstrument til éngangsbruk  
Bruksanvisning

Przyrząd do biopsji jednorazowego użytku BARD® MAX-CORE®  
Instrukcja użycia

BARD® MAX-CORE® Egyszer Használatos Biopsziás Eszköz  
Használati utasítás

BARD® MAX-CORE® Jednorázový nástroj pro biopsii  
Pokyny k použití

BARD® MAX-CORE® Tek Kullanımlık Kor Biyopsi Aleti Biyopsi Aygıtı  
Kullanma Talimatı

BARD® MAX-CORE® 拋棄式空芯切片器械  
使用說明

BARD® MAX-CORE® 일회용 총생검 기구  
사용 지침

Одноразовый инструмент для толстоигольной биопсии BARD® MAX-CORE®  
Инструкции по применению

Jednorázový nástroj na hrubohlovú biopsiu BARD® MAX-CORE®  
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® Max-Core® Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge and Green=14 gauge.

Catalogue Number	Gauge Size and Needle Length	Length of Sample Notch	Penetration Depth
MC1410	14g (2.1mm) x 10cm (100mm)	1.9cm (19mm)	22mm
MC1416	14g (2.1mm) x 16cm (160mm)	1.9cm (19mm)	22mm
MC1610	16g (1.7mm) x 10cm (100mm)	1.9cm (19mm)	22mm
MC1616	16g (1.7mm) x 16cm (160mm)	1.9cm (19mm)	22mm
MC1810	18g (1.2mm) x 10cm (100mm)	1.8cm (18mm)	22mm
MC1816	18g (1.2mm) x 16cm (160mm)	1.8cm (18mm)	22mm
MC1820	18g (1.2mm) x 20cm (200mm)	1.8cm (18mm)	22mm
MC1825	18g (1.2mm) x 25cm (250mm)	1.8cm (18mm)	22mm
MC2010	20g (0.9mm) x 10cm (100mm)	1.8cm (18mm)	22mm
MC2016	20g (0.9mm) x 16cm (160mm)	1.8cm (18mm)	22mm
MC2020	20g (0.9mm) x 20cm (200mm)	1.8cm (18mm)	22mm

**B. How Supplied:**

The product is supplied sterile and non-pyrogenic unless the package has been opened or damaged. **Sterilized using Ethylene Oxide. For single use only. Do Not Reuse. Do Not Resterilize.**

**C. 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.

**D. Contraindications:**

Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding problem.

**E. 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. 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.
3. The Bard® Max-Core® Biopsy Instrument 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 indeterminate 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.
4. Do not resterilize the Bard® Max-Core® Biopsy Instrument. 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:** If collecting multiple samples, inspect the needle for damaged point, bent shaft or other imperfections after each sample is collected. Do not use needle if any imperfection is noted.

**Note:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and with 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.)
3. Never test the product 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 supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with the needle function.

**G. 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 signs or symptoms of air embolism.

ENGLISH

**H. Equipment Required:**

- Appropriate imaging modality accessories
- Surgical gloves and drapes
- Local anesthetic
- BARD® TRUGUIDE® Coaxial Cannula (optional)
- Scalpel
- Sample collection container
- Other equipment as necessary

**I. Directions for Use:**

**BARD® MAX-CORE® Biopsy Instrument preparation:**

Before using, inspect the needle for damaged point, bent shaft or other imperfections that would prevent proper function. If the needle is damaged or bent, DO NOT USE.

1. Using aseptic technique, remove the Instrument from its package. See Figure 1.

**Note:** To remove the protective needle sheath and yellow guard, you must energize (cock) Instrument.

2. Energize (cock) Instrument by pulling back on the top slide to withdraw the cannula and lock in place. See Figure 2. Then pull back on the bottom slide to withdraw the stylet and lock in place. See Figure 3. Remove protective needle sheath and yellow guard. Instrument is ready to fire when both slides are locked back.

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

**Biopsy Procedure:**

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Prepare site as required. Adequate anesthesia should be administered prior to incision of the skin.
2. Verify Instrument is energized (cocked). See Figure 3.

**Note:** Do not place fingers in front of cocking slides once Instrument is energized (cocked). Impeding cocking slides' movement will impact functionality.

3. Insert tip of needle to the point to be biopsied.
4. While maintaining Instrument's position and the needle orientation, depress the rear actuator button, or push the side actuator forward (direction of arrow), to cause both stylet and cannula to automatically advance.
5. Remove needle from patient and pull back on the top slide to withdraw the cannula and expose the biopsy specimen (See Figure 2). Remove the specimen.
6. If additional biopsies are required, pull back on the bottom slide to withdraw the stylet and repeat the procedure.

Figure 1



- As Packaged (Protective Needle Sheath and Yellow Guard Not Shown)
- Instrument **Not** Energized (Cocked)
- **Not** Ready to Fire

Figure 2



- Top Slide Locked Back
- Biopsy Sample Notch Exposed

Figure 3



- Top Slide and Bottom Slide Locked Back
- Instrument Energized (Cocked)
- Ready to Fire

**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.

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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 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 to see if additional product information is available.

Assembled in Mexico.

 **Bard® Max-Core® Disposable Core Biopsy Instrument**  
 Bard® Max-Core® Instrument pour biopsie à usage unique  
 Bard® Max-Core® Einweg-Biopsieinstrument  
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 Одноразовый инструмент для толстоигольной биопсии  
 Bard® Max-Core®  
 Jednorázový nástroj na hruboihlovi biopsii Bard® Max-Core®



**Attention, See Instructions For Use**

Attention, voir le mode d'emploi  
 Achtung! Siehe Gebrauchsanweisung  
 Attenzione, leggere le istruzioni per l'uso  
 Atención: consulte las instrucciones de uso  
 Let op, zie Gebruiksaanwijzing  
 Atenção, consulte as Instruções de Utilização  
 Προσοχή, Βλ. Οδηγίες Χρήσης  
 Bemærk, Se brugervejledning  
 Obs! Se bruksanvisningen  
 Huomio! Lue käyttöohjeet  
 OBS, se Bruksanvisning  
 Uwaga: Należy zapoznać się z instrukcją użytkowania  
 Figyelem, lásd a használati utasítást  
 Pozor, viz pokyny k použití  
 Dikkat, Kullanma Talimatına Bakınız  
 注意，請參閱使用說明書  
 주의, 사용 지침 참조  
 Внимание! См. инструкции по применению  
 Pozor, pozri návod na použitie



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**REF Catalogue Number**

Número de catalogue  
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 Numero di catalogo  
 Número de catálogo  
 Catalogusnummer  
 Número do catálogo  
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 Номер по каталогу  
 Katalógové číslo



**Gauge Size and Needle Length**

Taille de la jauge et longueur de l'aiguille  
 Größe (Gauge) und Nadellänge  
 Calibro e lunghezza dell'ago  
 Tamaño de calibre y longitud de aguja  
 Gauge-maat en naaldlengte  
 Calibre e comprimento da agulha  
 Μέγεθος gauge και μήκος βελόνας  
 Gauge-størrelse og nålelængde  
 Gaugestorlek och nållängd  
 G-koko ja neulan pituus  
 Nålens diameter og lengde  
 Rozmiar i długość igły  
 Vastagság méret és tű hosszúság  
 Průměr a délka jehly  
 Gauge Büyüklüğü ve İğne Uzunluğu  
 規格尺寸和針長  
 게이지 크기 및 바늘 길이  
 Калибр и длина иглы  
 Velikost a délka ihly



**Length of Sample Notch**

Longueur d'encoche d'échantillon  
 Länge der Probenkerbe  
 Lunghezza dell'incavo per il campione  
 Longitud de la muesca de la muestra  
 Lengte van inkeping  
 Comprimento do entalhe da amostra  
 Μήκος εγκοπής δείγματος  
 Længde på prøverille  
 Provsårens længd  
 Näyteloven pituus  
 Lengde på prøveinnsnitt  
 Długość karbu próbki  
 Mintavéó horony hossza  
 Délka drážky pro vzorek  
 Ömek Çentik Uzunluğu  
 樣本切口長度  
 샘플 notch 길이  
 Длина выемки для образца  
 Dĺžka priestoru pre vzorku



**Penetration Depth**

Profondeur de pénétration  
 Penetrationstiefe  
 Profondità di penetrazione  
 Profundidad de penetración  
 Penetratediepte  
 Profundidade de penetração  
 Βάθος διείσδυσης  
 Penetrationsdybde  
 Penetrationsdjup  
 Penetraatiosyvyys  
 Penetreringsdybde  
 Głębość penetracji  
 Behatolási mélység  
 Hlubka průniku  
 Penetrasyon Derinliği  
 穿刺深度  
 침투 깊이  
 Глубина проникновения  
 Hĺbka penetrácie



**Lot Number**

Número de lot  
 Lot Nummer  
 Numero di lotto  
 Número de lote  
 Lotnummer  
 Número do lote  
 Αριθμός παρτίδας  
 Lot-number  
 Lot-number  
 Eränumero  
 Lot-number  
 Numer serii  
 Tételszám  
 Číslo šarže  
 Parti Numarası  
 批號  
 로트 번호  
 Номер партии  
 Číslo šarže



**Use By**

À utiliser avant  
Verwendbar bis  
Utilizzare entro  
Usar antes de  
Te gebruiken vóór  
Prazo de validade  
Ημερομηνία λήξης  
Anvendes før  
Utgångsdag  
Käyttävä ennen  
Brukes innen  
Termin ważności  
Felhasználható  
Datum použití  
Son Kullanma Tarihi  
有効期限  
유효기한  
Использовать до  
Spotrebovat' do



**Do not use if the product sterilization barrier or its packaging is compromised**

Ne pas utiliser si la barrière de stérilisation ou l'emballage du produit sont endommagés  
Bei beeinträchtigtem Sterilschutz oder beschädigter Verpackung des Produkts nicht verwenden  
Non usare il prodotto se la barriera sterile è compromessa o la confezione è danneggiata  
No utilice el producto si la barrera de esterilización o su envase no están en perfecto estado  
Niet gebruiken wanneer de sterilisatiebarrière van het product of de verpakking is aangetast  
Não utilizar se a barreira de esterilização do produto ou respectiva embalagem estiverem comprometidas  
Μη χρησιμοποιείτε το προϊόν εάν έχει παραβιαστεί ο φραγμός αποστείρωσης ή η συσκευασία του  
Må ikke bruges, hvis produktets sterilisationsbarriere eller emballage er beskadiget  
Använd inte produkten om sterilbarriären är bruten eller förpackningen öppnad eller trasig  
Ei saa käyttää, jos tuotteen sterilointisuojaus tai pakkaus on vaurioitunut  
Bruk ikke produktet hvis den sterile barrieren eller emballasjen er brutt  
Nie używać, jeśli naruszono sterylność produktu lub jego opakowanie  
Ne használja, ha a termékét védő steril zár vagy a csomagolás sérült  
Pokud je narušena sterilní ochrana nebo poškozen obal, výrobek nepoužívejte  
Urun steril bariyeri veya ambalajı zarar görmüşse kullanmayın  
如果產品消毒屏障或包裝受損，請勿使用  
제품의 멸균 장벽이나 포장에 손상된 경우 사용하지 마십시오.  
Запрещается применять изделие, если его стерильная упаковка или внешняя упаковка повреждены  
Nepoužívajte, ak je sterilná bariéra produktu alebo jeho obal porušený



**Sterilized Using Ethylene Oxide**

Stérilisé à l'oxyde d'éthylène  
Sterilisiert mit Ethylenoxid  
Sterilizzato mediante ossido di etilene  
Esterilizado mediante óxido de etileno  
Gesteriliseerd met behulp van ethyleenoxide  
Esterilizado por óxido de etileno  
Αποστειρωμένο με αιθυλενοξείδιο  
Steriliseret med ethylenoxid  
Steriliserad med etylenoxid  
Steriloitu etyleenioksidilla  
Sterilisert med etylenoksid  
Produkt sterylizowany tlenkiem etylenu  
Etilén-oxiddal sterilizálva  
Sterilizovano etylenoxidem  
Etilen Oksit ile Sterilize Edilmiştir  
使用環氧乙烷消毒  
산화에틸렌으로 멸균 처리됨  
Стерилизовано этиленоксидом  
Sterilizované etylénoxidom



**Non-Pyrogenic**

Apyrogène  
Pyrogenfrei  
Apirogeno  
Apirógeno  
Niet-pyrogeen  
Apirogénico  
Μη πυρετογόνο  
Apyrogen  
Pyrogenfri  
Pyrogeeniton  
Pyrogenfri  
Apirogenny  
Pirogénmentes  
Apyrogenní  
Pirojenik deǵildir  
無熱原  
비발열성  
Апирогенно  
Nepyrogénne



**Single Use**

À usage unique  
Nur zum Einmalgebrauch  
Monouso  
Un solo uso  
Voor eenmalig gebruik  
Utilização única  
Για μία χρήση μόνο  
Engangsbrug  
Engångsbruk  
Kertakäyttöinen  
Éngangsbruk  
Tylko do jednorazowego użytku  
Egyszerhasználatos  
K jednorázovému použití  
Tek Kullanım İçindir  
僅供一次性使用  
1회 사용  
Однократного применения  
Na jednorazové použitie



**Manufacturer**

Fabricant  
Hersteller  
Fabricante  
Fabricante  
Fabrikant  
Fabricante  
Κατασκευαστής  
Productent  
Tillverkare  
Valmistaja  
Fabrikant  
Producent  
Gyártó  
Výrobce  
Uretici  
製造商  
제조사  
Производитель  
Výrobca



**Do Not Resterilize**

Ne pas restériliser  
Nicht resterilisieren  
Non risterilizzare  
No reesterilizar  
Niet opnieuw steriliseren  
Não reesterilizar  
Μη επαναποστειρώνετε  
Må ikke resteriliseres  
Får ej omsteriliseras  
Ei saa steriloida uudestaan  
Skal ikke resteriliseres  
Nie sterylizować ponownie  
Ne sterilizálja újra  
Neprovádajte resterilizaci  
Tekrar Sterilize Etmeyin  
請勿重複消毒  
재멸균하지 마십시오.  
Повторная стерилизация запрещена  
Nesterilizujte opakovane



**Lift Here**

Soulevre ici  
Hier anheben  
Sollevare qui  
Levantar aquí  
Hier optillen  
Levantar aqui  
Ανασηλώστε εδώ  
Løft her  
Lyft här  
Nosta tästä  
Løft her  
Przy podnoszeniu chwycić tutaj  
Itt emelje föl  
Zde zdvihněte  
Buradan Kaldırın  
掀起此處  
여기를 들어 올리십시오  
Поднять здесь  
Tu nadvihnite



**Authorized Representative in the European Community**

Représentant autorisé au sein de la Communauté européenne  
Bevollmächtigter in der Europäischen Gemeinschaft  
Rappresentante autorizzato nella Comunità Europea  
Representante autorizado en la Comunidad Europea  
Gemachtigde binnen de Europese Gemeenschap  
Representante autorizado na Comunidade Europeia  
Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα  
Autoriseret repræsentant i Det Europæiske Fællesskab  
Auktoriserad representant inom EG  
Valtuutettu edustaja Euroopan yhteisössä  
Autorisert representant i EU  
Autoryzowany przedstawiciel na terenie Unii Europejskiej  
Meghatalmazott képviselő az Európai Közösségekben  
Autorizovaný zástupce v Evropské unii  
Avrupa Topluluğu Yetkili Temsilcisi  
歐洲共同體的授權代表  
유럽 공동체 내의 인증받은 대리업체  
Уполномоченный представитель в Европейском сообществе  
Oprávněný zástupca v Európskom spoločenstve



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 **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](http://www.bardbiopsy.com)

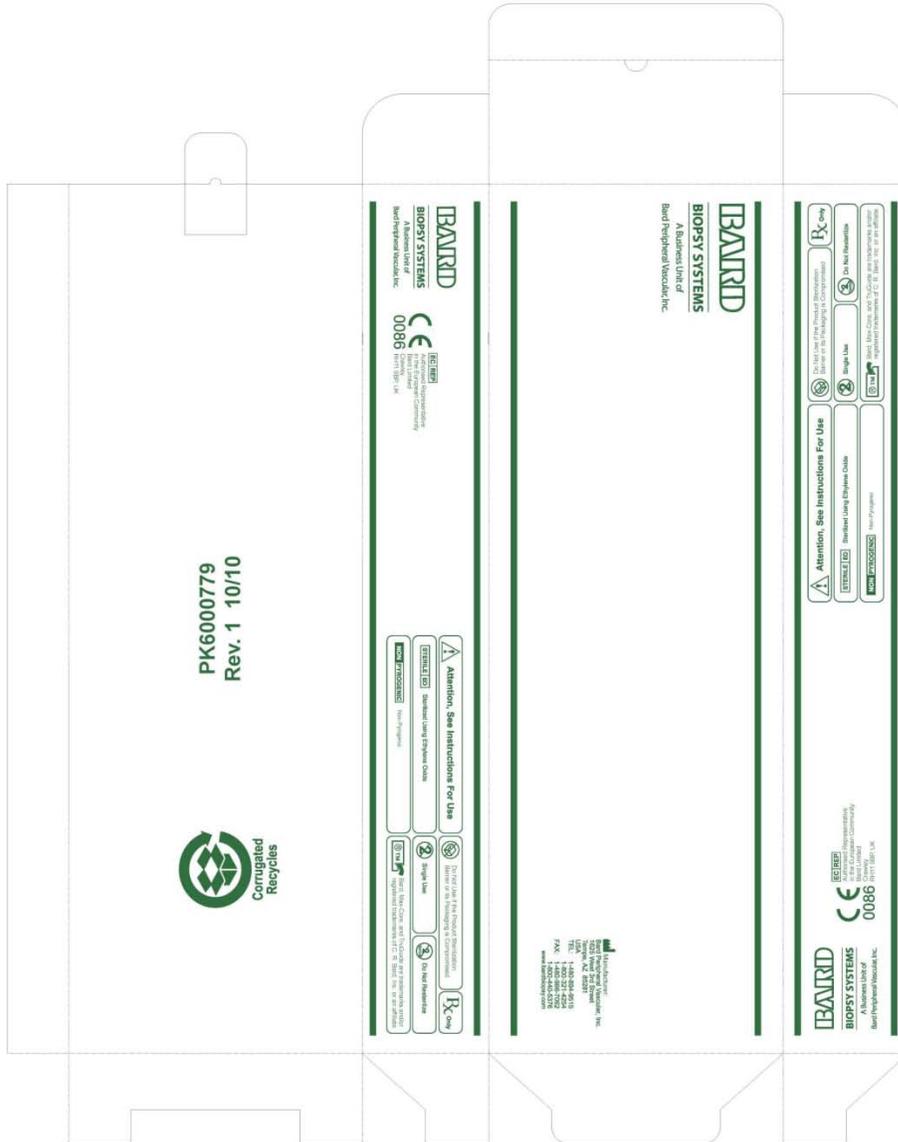
 **EC REP**  
**Authorised Representative  
in the European  
Community**  
**Bard Limited**  
Forest House  
Tilgate Forest Business Park  
Brighton Road, Crawley  
West Sussex  
RH11 9BP, UK

**BAIRD**  

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**BIOPSY SYSTEMS**

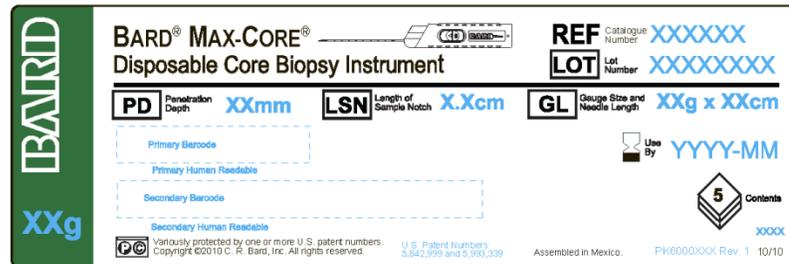
PK1279900 Rev. 0 05/12



Box



Variable fields

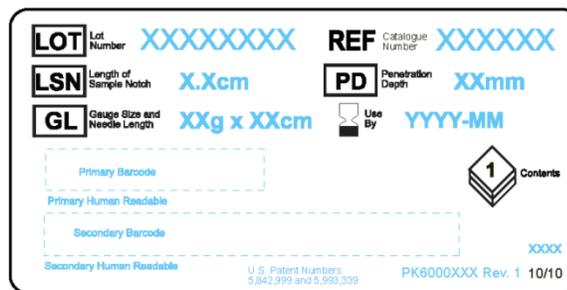


Box Label



Multi-language Label

Variable fields



Tray Lid Label

## Appendix 5: Indications for Use Statement

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name:

Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® 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.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

## Appendix 6: FDA Communication

**Addition of Needle Lengths Letter (dated June 26, 1995)**  
**and FDA Concurrence Letter (dated July 26, 1995)**

C. R. Bard, Inc.  
8195 Industrial Blvd.  
Covington, GA 30209

**BARD**

June 26, 1995

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
510(k) Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

Attention: Ms. Laura Byrd, DRAERD, Urology Branch

Re: #K922939: Addition of 25cm and 30cm needle lengths to Bard®  
Monopty® Disposable Biopsy Instrument product line

Per conversations between Laura Byrd of FDA and Steven Mercereau of C.R. Bard, Inc. on March 14, 1995 and between Laura Byrd of FDA and Donna Wilson of C.R. Bard, Inc. on May 16, 1995, this letter is being submitted as an amendment to a concurred 510(k) file, #K922939. This 510(k) referenced needles in lengths of 10, 16 and 20cm. We would like to add the lengths of 25 and 30cm to the product line. Therefore, we ask that you consider the information included in this letter, make a determination as to whether a new 510(k) is required for this change, and if no new 510(k) is required that you include a copy of this letter in the 510(k) file as notice of the additional needle lengths. We also request that you provide us with written notification of your decision.

Per our interpretation, the April 1994 draft guidance document regarding when to file a 510(k) states that the addition of product sizes (dimensions) outside the previously cleared, via 510(k), ranges would require the submission of a new 510(k) for the new dimensions. However, we feel that this document may allow some flexibility in that it seems reasonable to assume that the requirement for filing a new 510(k) when going outside the previously cleared dimensional ranges would apply only to the more critical

device dimensions for which a change could significantly effect device performance in terms of safety or effectiveness.

(b) (4)



Bard intends to market Monopty and Max•Core™ Disposable Biopsy Instruments with needles in lengths of 25cm and 30cm for the 16 gauge and 18 gauge needle lines only as these are the needles sizes for which additional length would be useful to the physician (see attached Equivalency Table, Part IX). This addition would be for the entire line of Monopty Disposable Biopsy Instruments and Max•Core Disposable Biopsy Instruments.

(b) (4)



biopsy instrument offers ergonomic enhancement in terms of potential one-handed cocking of the device, an additional firing button or trigger to allow firing with either thumb or finger and changes to the outer shape of the device that will prevent it from rolling off hard surfaces.

It should be noted that there are no new claims or new indications for use associated with the longer length biopsy needles and no changes in materials of construction. Medical risk assessments, engineering reviews and FMEAs (Failure Modes and Effects Analyses) confirm that lengthening the 16 gauge and 18 gauge needles to 25cm or 30cm does not significantly effect device safety or effectiveness.

C.R. Bard, Inc. has not publicly disclosed or acknowledged that fact of its intent to market the longer needles to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. Per 21 CFR 807.95(b), C. R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

Should you have any questions regarding this letter, please call me at 404-784-6135.

Sincerely,



Donna J. Wilson  
Director, Regulatory Affairs

Enclosure

CERTIFIED MAIL

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Max•Core is a trademark of C.R. Bard, Inc. or an affiliate.

CONFIDENTIAL

Equivalency Table  
 Comparison Charts of Some Currently Marketed Products  
 and Proposed Bard Product

Current Bard Product Part I #K922939

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A		N/A	N/A	N/A			N/A	N/A		N/A	N/A
13 Gauge	N/A													
14 Gauge				X				X	X					
15 Gauge	N/A													
16 Gauge				X				X	X					
18 Gauge				X				X	X					
19 Gauge	N/A													
20 Gauge				X				X	X					

BIP Company Product Part II #K934370

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A			N/A	N/A			N/A		N/A		N/A
13 Gauge					X			X						
14 Gauge				X	X			X	X					
15 Gauge	N/A													
16 Gauge				X	X			X	X		X			
18 Gauge				X	X			X	X		X		X	
19 Gauge	N/A													
20 Gauge				X	X			X	X					

Biopsy Needle Co. Product Part III

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A		N/A	N/A	N/A			N/A	N/A		N/A	N/A
13 Gauge	N/A													
14 Gauge				X				X						
15 Gauge	N/A													
16 Gauge	N/A													
18 Gauge				X				X	X			X		
19 Gauge	N/A													
20 Gauge				X				X	X					

Boston Scientific Corp. Product Part IV

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
					N/A						N/A		N/A	
13 Gauge	N/A													
14 Gauge				X		X								
15 Gauge						X								
16 Gauge	N/A													
18 Gauge				X		X				X				
19 Gauge	N/A													
20 Gauge						X								

Cook Inc. Product Part V

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
				N/A	N/A		N/A	N/A		N/A	N/A	N/A	N/A	
13 Gauge	N/A													
14 Gauge		X	X			X			X					
15 Gauge		X	X			X			X					
16 Gauge		X	X			X			X					X
18 Gauge		X	X			X			X					X
19 Gauge		X	X			X			X					X
20 Gauge		X	X			X			X					

CONFIDENTIAL

Equivalency Table  
 Comparison Charts of Some Currently Marketed Products  
 and Proposed Bard Product

Inrad Product

Part VI

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge						X							
15 Gauge	N/A												
16 Gauge						X		X					
18 Gauge						X		X			X		
19 Gauge	N/A												
20 Gauge						X		X					

Manan Medical Products, Inc. Product

Part VII

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X	X					
15 Gauge	N/A												
16 Gauge			X				X	X					
18 Gauge			X				X	X			X		
19 Gauge	N/A												
20 Gauge			X				X	X					

Medical Device Technologies, Inc. Product

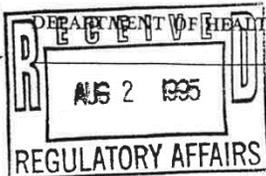
Part VIII

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X						
15 Gauge	N/A												
16 Gauge			X				X	X					
18 Gauge			X				X	X			X		
19 Gauge	N/A												
20 Gauge							X	X					

Proposed Bard Product

Part IX

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X	X					
15 Gauge	N/A												
16 Gauge			X				X	X			X	X	
18 Gauge			X				X	X			X	X	
19 Gauge	N/A												
20 Gauge			X				X	X					



JUL 26 1995

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Donna J. Wilson  
Director, Regulatory Affairs  
C. R. Bard, Inc.  
8195 Industrial Boulevard  
Covington, Georgia 30209

Re: K922939  
Addition of 25cm and 30cm Needle  
Lengths to Bard® Monopty® Disposable  
Biopsy Instrument Product Line  
Dated: June 26, 1995  
Received: June 30, 1995

Dear Ms. Wilson:

We have reviewed the information dated June 26, 1995, regarding the 510(k) notification K922939 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Addition of Echogenicity Claim Letter (dated July 18, 1996)**  
**and FDA Concurrence Letter (dated September 3, 1996)**

Bard, Inc.  
195 Industrial Blvd.  
Covington, GA 30209

July 18, 1996

**BARD**

Ms. Laura Byrd  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
DRAERD, Urology Branch (HFZ-470)  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: #K922939: Bard Monopty Disposable Biopsy Instrument Product Line -  
Echogenic claim

Dear Ms. Byrd:

Per conversations between Laura Byrd of FDA and Donna J. Wilson of C. R. Bard, Inc. on January 19, 1996, voice mail message from Laura Byrd of FDA the week of May 6, 1996, and subsequent conversations between FDA and Bard, this letter is being submitted as an amendment to a concurred 510(k) file, #K922939. This 510(k) referenced

(b) (4)

C. R. Bard, Inc. intends to market Monopty Disposable Biopsy Instruments (including the ergonomically enhanced Max-Core models) with the same needle dimensions (gauge and length) and made using the same materials as described in #K922939 and the June 16, 1995, letter to file. (b)(4) Product Specs

(b) (4)

(b) (4)

(b) (4)

The Indications for Use remain the same but the description of the needles and associated marketing claims would contain the words "echogenic" and "enhanced echogenicity", "significantly more visible" and similar terms indicating enhanced visualization during ultrasound procedures.

Therefore, we ask that you consider the information included in this letter, make a determination as to whether a new 510(k) is required for this change, and if no new 510(k) is required that you include a copy of this letter in the 510(k) file (#K922939) as notice of the Bard Monopty/Max-Core Disposable Biopsy Instrument Product Line echogenic needle claim. We also request that you provide us with written notification of your decision.

It should be noted that other than a claim of echogenicity or enhanced visualization during ultrasound procedures there are no new claims or new indications for use associated with the echogenic needles and no significant changes in materials of construction. No changes in design that could significantly affect safety or effectiveness have been made since

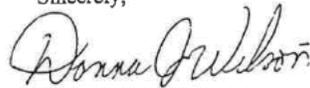
(b)(4) Product Specs

(b) (4)

C. R. Bard, Inc. has not publicly disclosed or acknowledged that fact of its intent to market the Bard Monopty and Max-Core product lines with an echogenic claim to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. Per 21 CFR 807.95(b), C. R. Bard Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

Should you have any questions regarding this letter, please call me at 770-784-6135.

Sincerely,



Donna J. Wilson  
Director, Regulatory Affairs

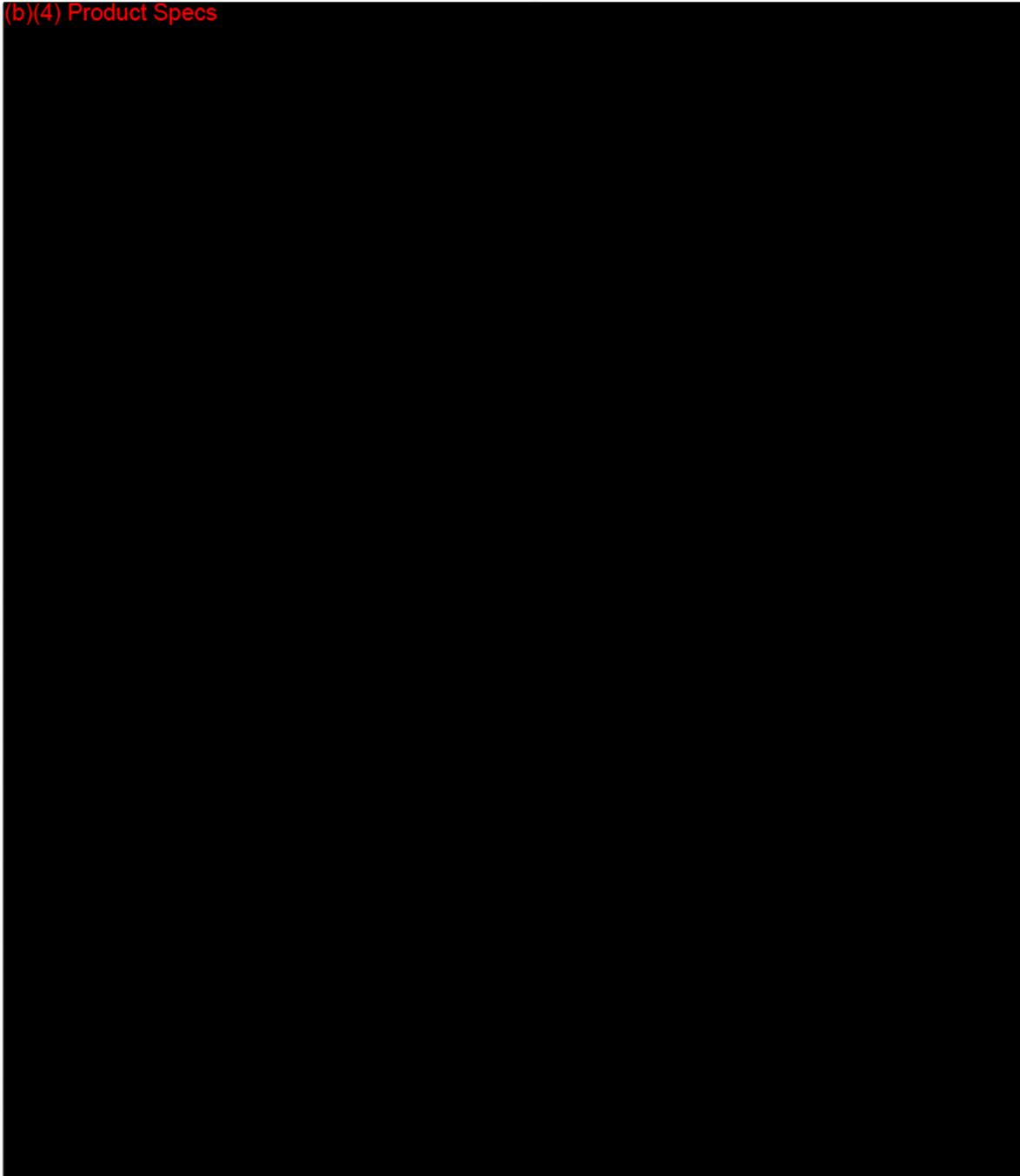
Enclosure

CERTIFIED MAIL

(b) (4)



(b)(4) Product Specs



(b)(4) Product Specs





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850



SEP 3 1996

Ms. Donna J. Wilson  
Director, Regulatory Affairs  
C.R. Bard, Inc.  
8195 Industrial Boulevard  
Covington, Georgia 30209

Re: K936194; K922939; K934370; and K910720  
Coaxial Biopsy Needle; Bard Monopty Disposable Biopsy  
Instrument Product Line; BIP [Bard Magnum] Biopsy Needles;  
and Bard Biopsy-Cut Biopsy Needles  
Dated: July 18, 1996

Dear Ms. Wilson:

We have reviewed the information dated July 18, 1996, regarding the 510(k) notifications K936194, K922939, K934370, and K910720 previously submitted for the devices referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the designs, components, methods of manufacture, or intended use of the devices referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the devices or their labeling could significantly affect the devices' safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

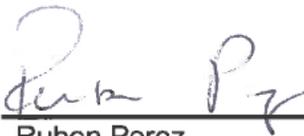
Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Appendix 7: Declaration of Conformity with Design Controls**

## Declaration of Conformity with Design Controls

**Verification and Validation Activities:** As required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



Ruben Perez  
Staff Engineer  
Bard Peripheral Vascular, Inc.

12-19-13

Date

**Manufacturing Facility:** The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.



Scott Neal  
Director of Quality Assurance  
Bard Peripheral Vascular, Inc.

12-19-13

Date



# COVER SHEET MEMORANDUM

Food and Drug Administration  
Office of Device Evaluation &  
Office of In Vitro Diagnostics and  
Radiological Health

**NOTE: This form is REQUIRED for holds and for final decisions.**

Reviewer Name Shani Haugen

510(k) Number K133948-S2

**Please list CTS decision code:**     SE - Substantially Equivalent

Hold (Additional Information or Telephone Hold)                      Hold Date

Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Incomplete Response - Convert Supplement to Amendment (attach email sent to firm)

Add to File

(review staff should follow the instructions and complete the memo/routing sheet at:  
[http://eroom.fda.gov/eRoom/CDRH3/CDRHPremarketNotification510kProgram/0\\_3bba7](http://eroom.fda.gov/eRoom/CDRH3/CDRHPremarketNotification510kProgram/0_3bba7). DCC should refer to that documentation for the close-out code and mail any provided letter.)

The remainder of this form must be filled out for close-outs only

<b>Class:</b>	II
<b>Regulation Number:</b>	876.1075
<b>Product Code:</b>	KNW
<b>Additional Product Codes:</b>	

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page ( <i>Attach IFU</i> )	X	
510(k) Summary or 510(k) Statement ( <i>Attach Summary</i> )	X	
Truthful and Accurate Statement ( <i>Must be present for a Final Decision</i> )	X	
Is the device Class III?		X
Is this a combination product?		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X

2/21

Neonate/Newborn (Birth to 28 days)		×
Infant (29 days to < 2 years)		×
Child (2 years to <12 years)		×
Adolescent (12 years to <18 years)		×
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		×
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		×
Is this device subject to the Tracking Regulation? ( <a href="#">Medical Device Tracking Guidance</a> )		×

**Digital Signature Concurrency Table**

(Not all signatures may be required)

Branch Chief Sign-Off	 <p>2014.02.21 11:36:44 -05'00'</p>
Division Sign-Off	<p>Herbert P. Lerner -S</p> <p>2014.02.21 11:50:29 -05'00'</p>

**Bard Peripheral Vascular, Inc.**  
C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062

FDA CDRH DMC

JAN 03 2014

Received

K133948/S001

**BARD**

January 2, 2014

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: **Special 510(k)**      **K133948**  
**Trade Name:**      **Bard® Monopty® Disposable Core Biopsy Instrument**  
                                 **Bard® Max-Core® Disposable Core Biopsy Instrument**  
**Common Name:**      Core Biopsy Instrument  
**Predicate Device:** Bard® Monopty® Disposable Core Biopsy Instrument  
                                 (K922939)

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, Bard Peripheral Vascular, Inc. (BPV), a division of C.R. Bard, Inc., is submitting one paper copy and one eCopy of a Special 510(k) notification for the Bard® Monopty® and Bard® Max-Core® Disposable Core Biopsy Instruments. The eCopy is an exact duplicate of the paper copy. There have been no prior formal submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence for this device. This updated submission provides responses to the FDA RTA deficiencies indicated for K133948 dated January 2, 2014. For ease of review, both the FDA RTA Checklist questions/requests and Bard's Responses are provided in Attachment 1 of this cover letter.

The Bard® Monopty® and Bard® Max-Core® Disposable Core Biopsy Instruments are Class II products. The Product Code for these devices is KNW (Instrument, Biopsy). The Review Panel for this Product Code is Gastroenterology / Urology (Medical Specialty No. 78). The Device Classification Regulation Number is 21 CFR §876.1075.

This submission provides an updated file to the FDA including several changes that have occurred to the subject device since the predicate submission. There is no change to the intended use or indications for use of the subject device, and the minor changes do not alter the fundamental scientific technology of the device. This modification complies with the requirements for a Special 510(k) submission as outlined in "The New 510(k) Paradigm – Alternate Approaches to

**Bard Peripheral Vascular, Inc.**

C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062



Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance”, issued March 20, 1998.

The terms “substantially equivalent”, “similar”, and related terms and descriptions in this notification are terms or words of art defined by the Food and Drug Administration in the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

This document contains a Medical Device User Fee Cover Sheet and a completed CDRH Premarket Review Submission Cover Sheet following this cover letter. A checklist for Special 510(k)s can be found on Page 4 corresponding to the FDA guidance document, “Refuse to Accept Policy for 510(k)s,” dated December 31, 2012, which also denotes where each required element outlined in this guidance can be found in this submission. Furthermore, this document contains a signed Truthful and Accuracy Statement on Page 30, Indications for Use Statement on Page 75, and Declaration of Conformity with Design Controls on Page 92. The 510(k) Summary can be found on Page 26.

BPV requests that the FDA keep and maintain confidential both the existence and the contents of this premarket notification in accordance with 21 CFR §807.95(b). BPV also requests that the FDA keep and maintain confidential the contents of this letter.

Please do not hesitate to contact me if you have any questions or need any additional information. I can be reached via telephone at 480-638-2954, fax at 480-449-2546, or by e-mail at [sarah.mccartney@crbard.com](mailto:sarah.mccartney@crbard.com).

Sincerely,

A handwritten signature in blue ink that reads "Sarah McCartney". The signature is fluid and cursive, with the first name being more prominent than the last.

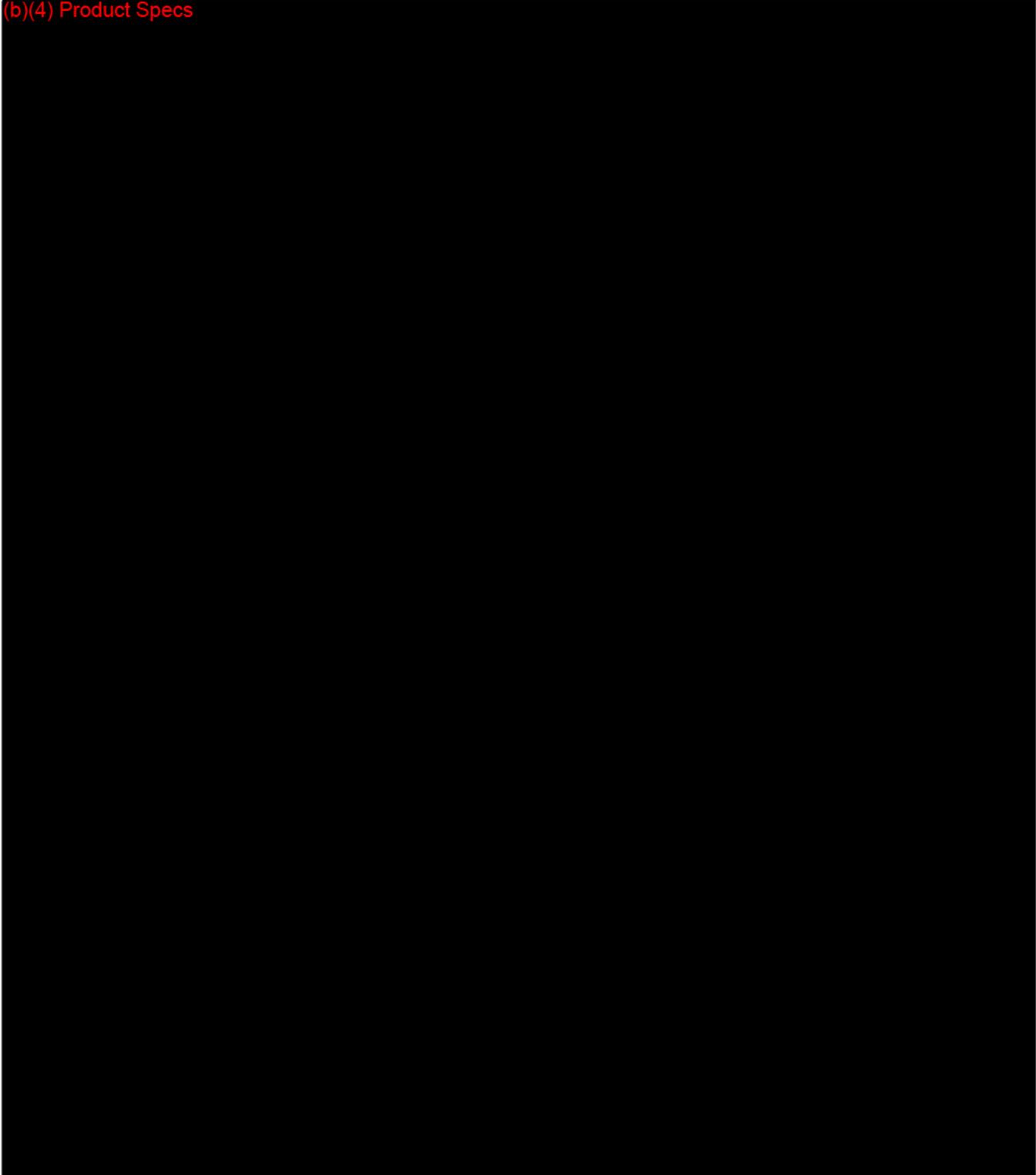
Sarah McCartney  
Regulatory Affairs Specialist  
Bard Peripheral Vascular, Inc.

**Bard Peripheral Vascular, Inc.**

C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062



(b)(4) Product Specs

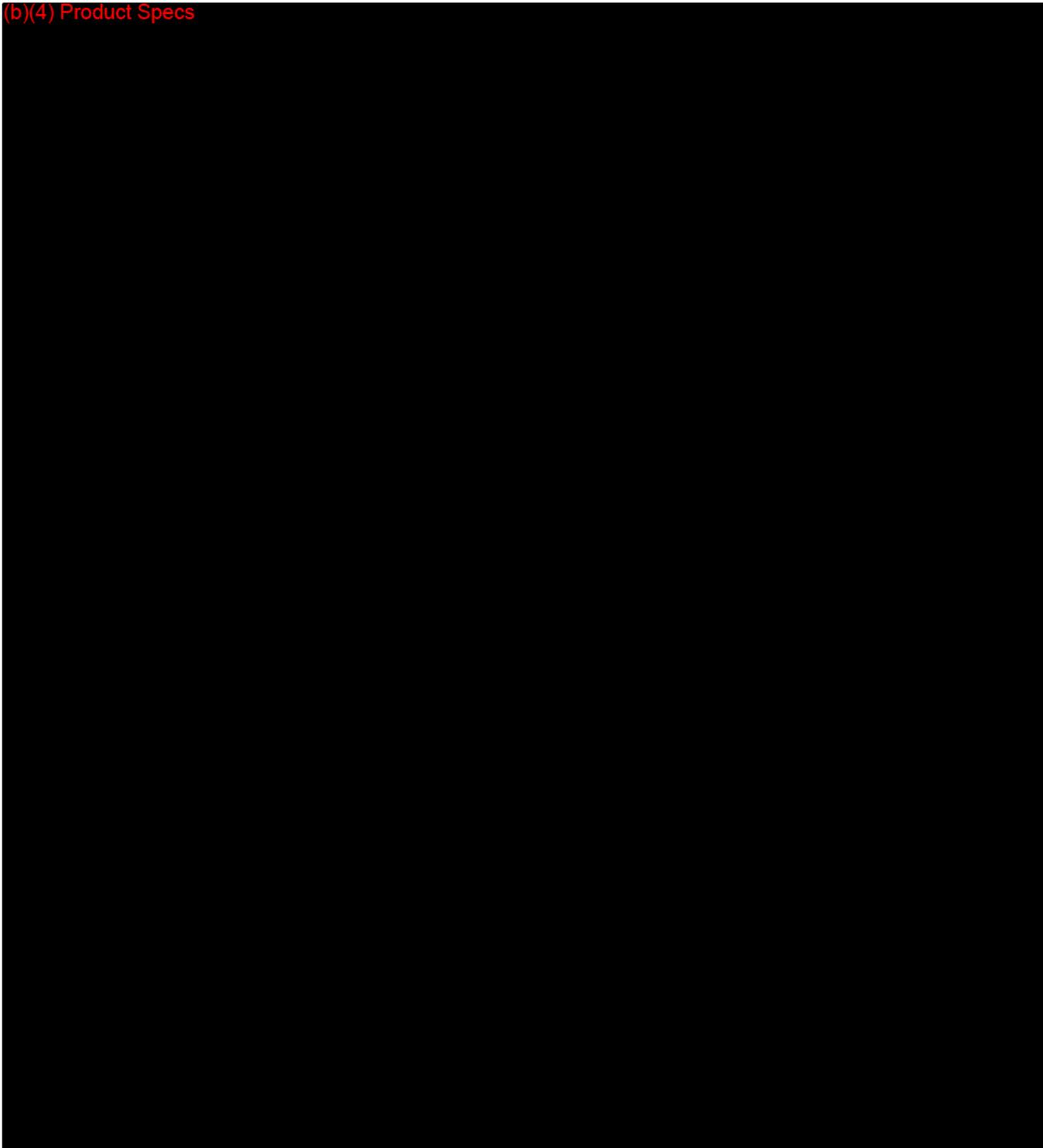
A large, solid black rectangular redaction box covers the majority of the page content, starting below the contact information and ending above the page number. The text "(b)(4) Product Specs" is written in red at the top left corner of this redacted area.

**Bard Peripheral Vascular, Inc.**

C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062



(b)(4) Product Specs

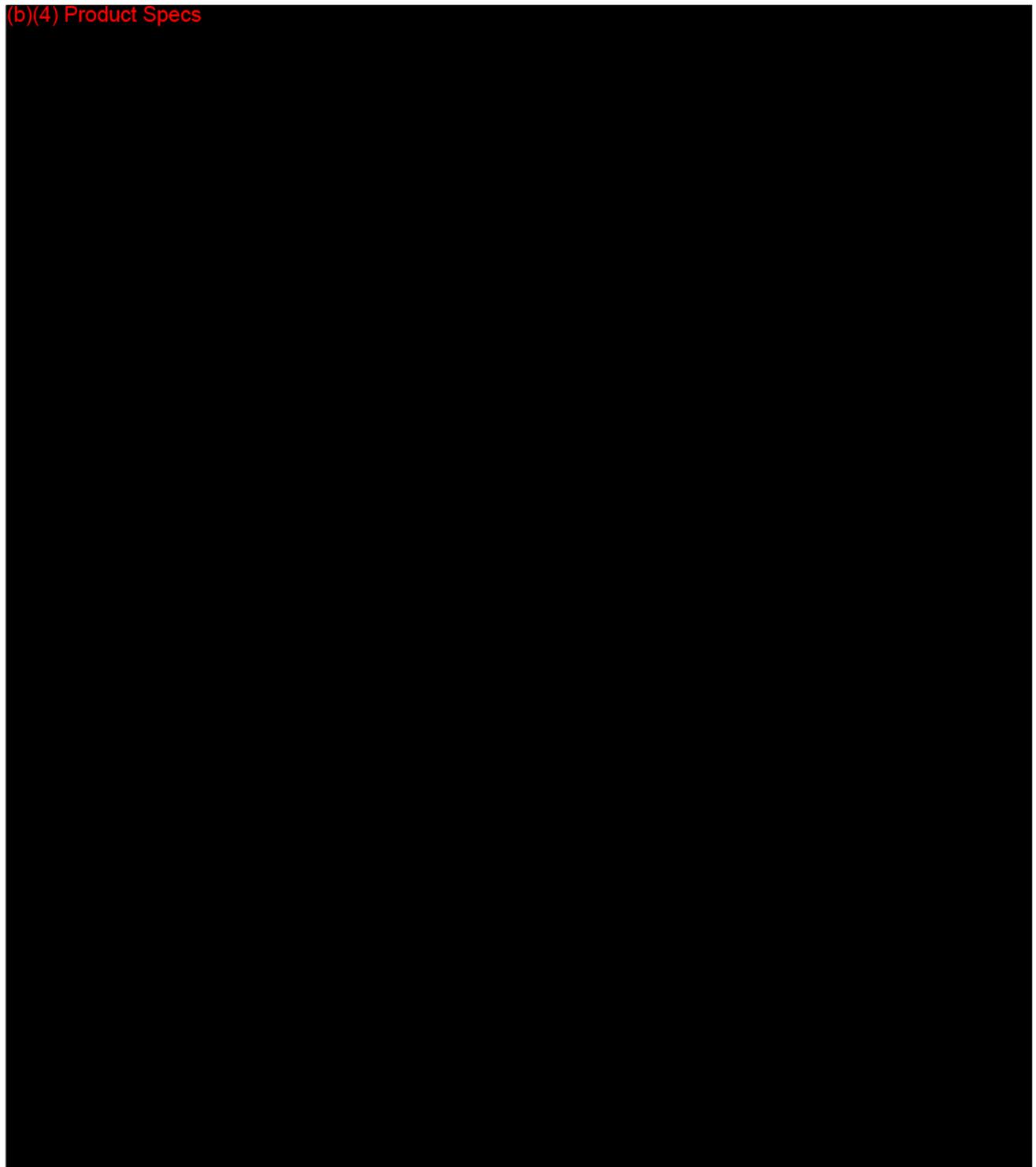


**Bard Peripheral Vascular, Inc.**

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1625 West 3rd Street  
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Tel: (800) 321-4254  
(480) 894-9515  
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(b)(4) Product Specs

A large, solid black rectangular redaction box covers the majority of the page's content, starting below the contact information and ending above the page number.

**Bard Peripheral Vascular, Inc.**

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1625 West 3rd Street  
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(480) 894-9515  
Fax: (480) 966-7062



(b)(4) Product Specs

A large, solid black rectangular redaction box covers the majority of the page's content, starting below the contact information and ending above the page number.



**Bard® Monopty® Disposable Core Biopsy Instruments and  
Bard® Max-Core® Disposable Core Biopsy Instruments**

**Updated Special 510(k): K133948**

**2 January 2014**

**CONFIDENTIALITY STATEMENT**

This document contains information that is confidential and proprietary property of C. R. Bard, Inc. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without the proper written consent of Bard Peripheral Vascular, Inc.

**Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, AZ 85281**

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  BARD PERIPHERAL VASCULAR 1625 WEST 3RD STREET P O BOX 1740 TEMPE AZ 85281 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0297		2. CONTACT NAME Tim Williams 2.1 E-MAIL ADDRESS tim.williams@crbard.com 2.2 TELEPHONE NUMBER (include Area code) 480-303-2539 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 480-449-2546	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm</a> <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice			
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number.			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm</a> for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		18-Oct-2013	

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 01/02/2014	User Fee Payment ID Number <b>(b) (4)</b>	FDA Submission Document Number (if known) K133948
----------------------------------	--	--

**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30 day Supplement <input type="checkbox"/> 30 day Notice <input type="checkbox"/> 135 day Supplement <input type="checkbox"/> Real time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Request for Feedback</b> <input type="checkbox"/> Pre Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Bard Peripheral Vascular, Inc.		Establishment Registration Number (if known) 2020394	
Division Name (if applicable)		Phone Number (including area code) 480 638 2954	
Street Address 1625 West 3rd Street		FAX Number (including area code) 480 449 2546	
City Tempe	State / Province Arizona	ZIP/Postal Code 85281	Country U.S.A.
Contact Name Sarah McCartney			
Contact Title Regulatory Affairs Specialist		Contact E mail Address sarah.mccartney@crbard.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name N/A			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E mail Address	

**SECTION D1****REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D2****REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol Feasibility <input type="checkbox"/> Protocol Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA  <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Other Reason ( <i>specify</i> ):	

**SECTION D3****REASON FOR SUBMISSION - 510(k)**

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason ( <i>specify</i> ): This submission provides an updated file to FDA including several changes that have occurred to the subject device since the predicate submission.		

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	KNW	2		3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K922939	Bard® Monopty® Disposable Core Biopsy Instrument	Bard Peripheral Vascular, Inc.
2			
3			
4			
5			
6			

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name  
Core Biopsy Instrument

	Trade or Proprietary or Model Name for This Device	Model Number
1	Bard® Monopty® Disposable Core Biopsy Instrument	1 See attached list
2	Bard® Max Core® Disposable Core Biopsy Instrument	2 See attached list
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)

1	K922939	2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission  
 Laboratory Testing       Animal Trials       Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code KNW	C.F.R. Section (if applicable) 876.1075	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Gastroenterology / Urology		

Indications (from labeling)  
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.

**Note:** Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

K133948

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4) Contract Manufacturer

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4) Contract Manufacturer

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4) Contract Manufacturer

## SECTION I

## UTILIZATION OF STANDARDS

**Note:** Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	5 40	ISO	Medical devices Application of risk management to medical devices	14971	08/20/2012
2	2 179	ISO	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	10993 1	03/16/2012
3	14 278	AAMI/ANSI/ISO	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	10993 7	01/15/2013
4	14 228	AAMI/ANSI/ISO	Sterilization of health care products Ethylene oxide Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices	11135 1	03/16/2012
5	14 360	AAMI/ANSI	Bacterial endotoxins Test methods, routine monitoring, and alternatives to batch testing	ST72	01/15/2013
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

**Please include any additional standards to be cited on a separate page.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
 Food and Drug Administration  
 Office of Chief Information Officer  
 Paperwork Reduction Act (PRA) Staff  
 1350 Piccard Drive, Room 400  
 Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

ATTACHMENT – Section F, Product Information, Continued

Trade or Proprietary or Model Name for This Device	Model Number
Bard® Monopty® Disposable Core Biopsy Instrument	211410, 211416, 211610, 211616, 211620, 211810, 211816, 211820, 212010, 212016, 212020, 121210, 121216, 121410, 121416, 121610, 121616, 121620, 121810, 121816, 121820, 122010, 122016, 122020
Bard® Max-Core® Disposable Core Biopsy Instrument	MC1410, MC1416, MC1610, MC1616, MC1810, MC1816, MC1820, MC1825, MC2010, MC2016, MC2020

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 14971:2007, Medical devices - Application of risk management to medical devices

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 14971:2007, Medical devices - Application of risk management to medical devices

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER 3	SECTION TITLE General requirements for risk analysis	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 4	SECTION TITLE Risk analysis	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER See Attachment 1	SECTION TITLE See Attachment 1	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------------------	-----------------------------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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ATTACHMENT 1 – Conformance with Standard Sections, Continued

<b>EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE</b>			
STANDARD TITLE			
ISO 14971:2007, Medical devices - Application of risk management to medical devices			
<b>CONFORMANCE WITH STANDARD SECTIONS</b>			
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
5	Risk evaluation	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
6	Risk control	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
7	Evaluation of overall residual risk acceptability	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
8	Risk management report	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
9	Production and post-production information	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-179

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation..."

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2	Biological evaluation tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦  
Study of relevant experience and actual testing.

DESCRIPTION  
See Attachment 2.

JUSTIFICATION  
See Attachment 2.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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ATTACHMENT 2 – Conformance with Standard Sections, Continued

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

**CONFORMANCE WITH STANDARD SECTIONS**

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

6.2

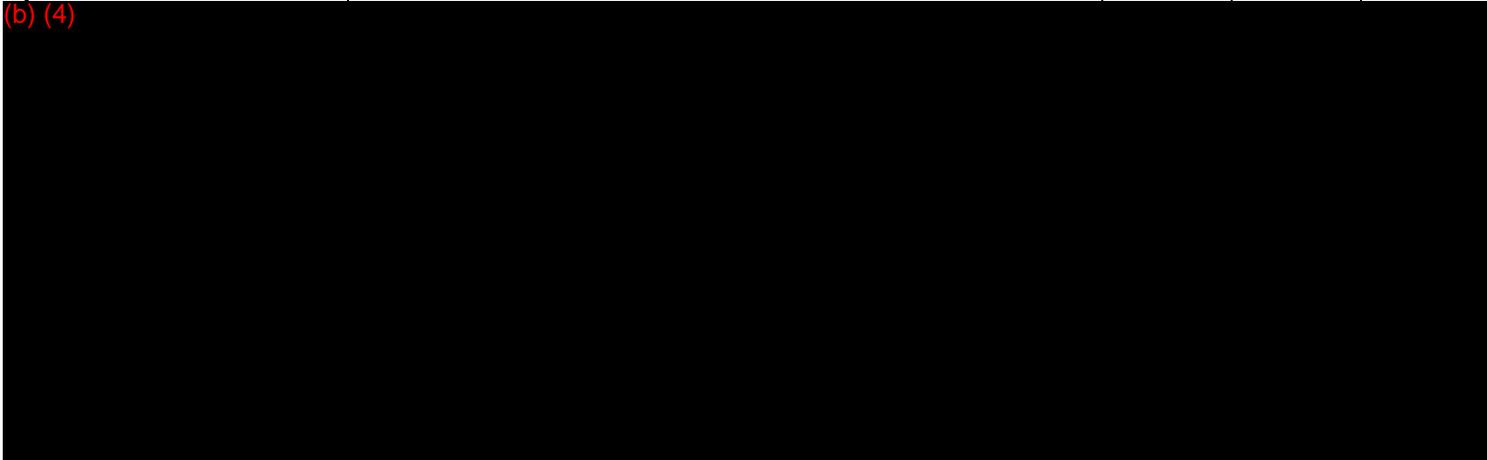
Biological evaluation tests

Yes

No

N/A

(b) (4)



Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-278

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4.6.2	Exhaustive Extraction (alternative acceptable method)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

(b) (4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services  
Food and Drug Administration  
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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for the...

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
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Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
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If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for the...

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER See Attachment 3	SECTION TITLE See Attachment 3	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------------------	-----------------------------------	---

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER See Attachment 3	SECTION TITLE See Attachment 3	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------------------	-----------------------------------	---

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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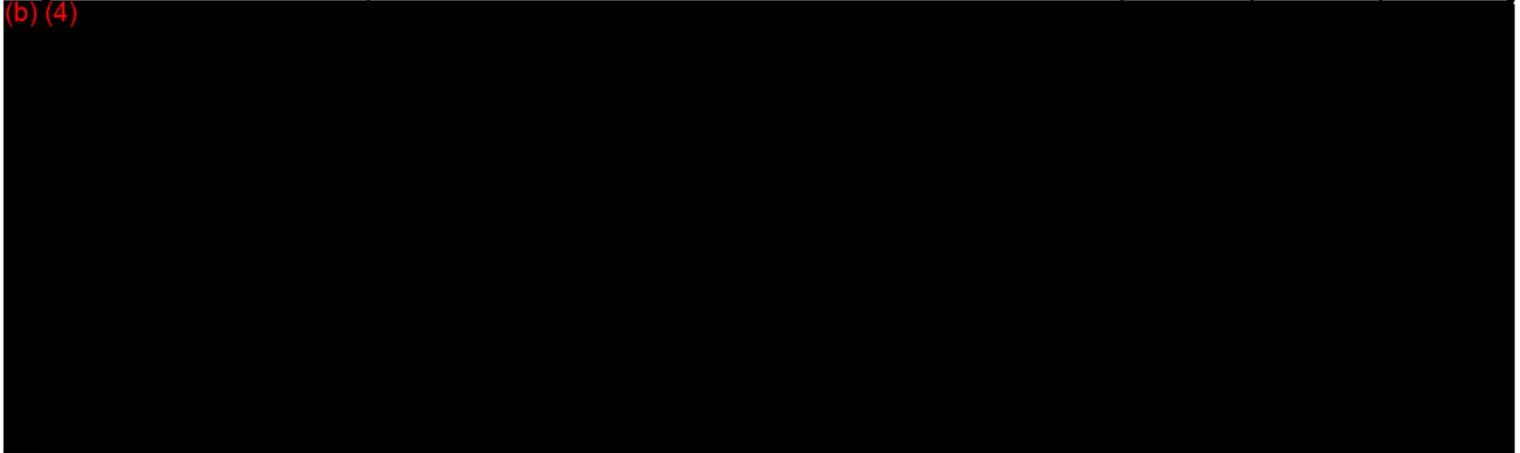
**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

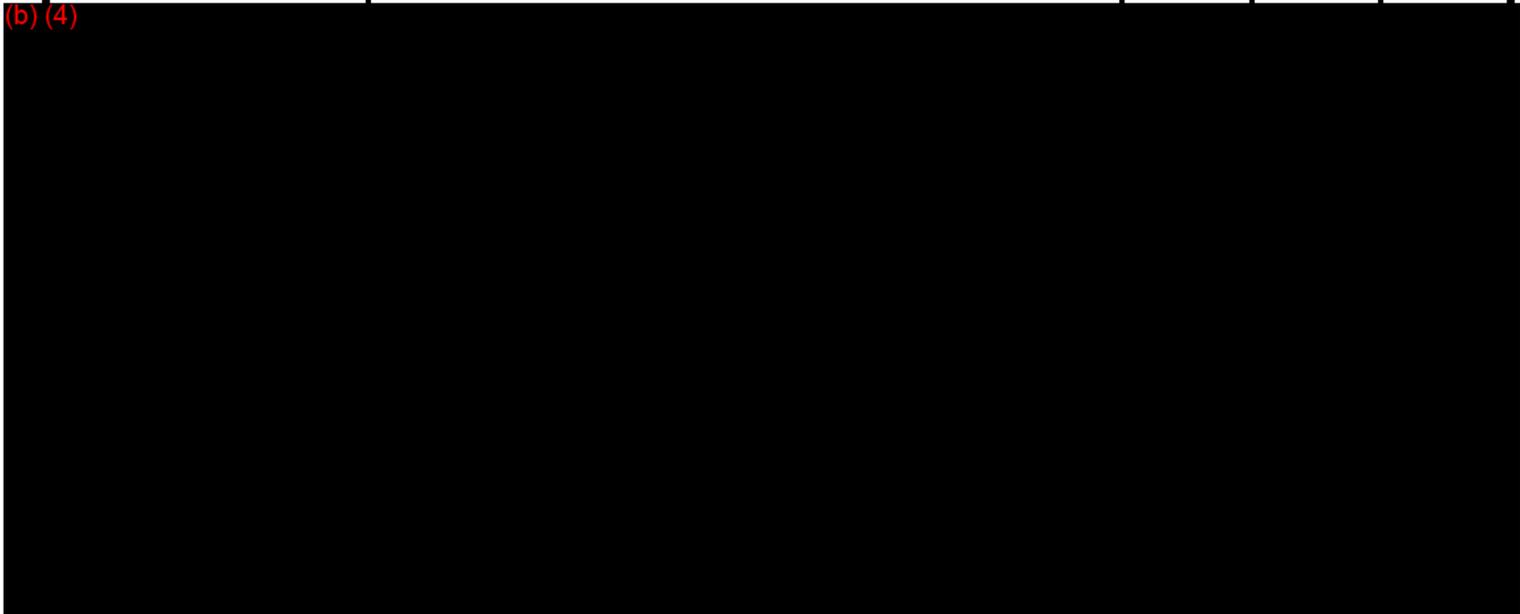
AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products -- Ethylene Oxide -- Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

**CONFORMANCE WITH STANDARD SECTIONS**

SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
9.3.2	Performance qualification - Microbiological	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A



SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
9.3.3	Performance qualification - Physical	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A



Department of Health and Human Services  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI ST72:2011 "Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing"

Please answer the following questions	Yes	No
Is this standard recognized by FDA <sup>2</sup> ? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number <sup>3</sup> .....	#14-360	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup> ? .....	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: "Pyrogens and Endotoxins Testing: Questions and Answers" (June 2012)		

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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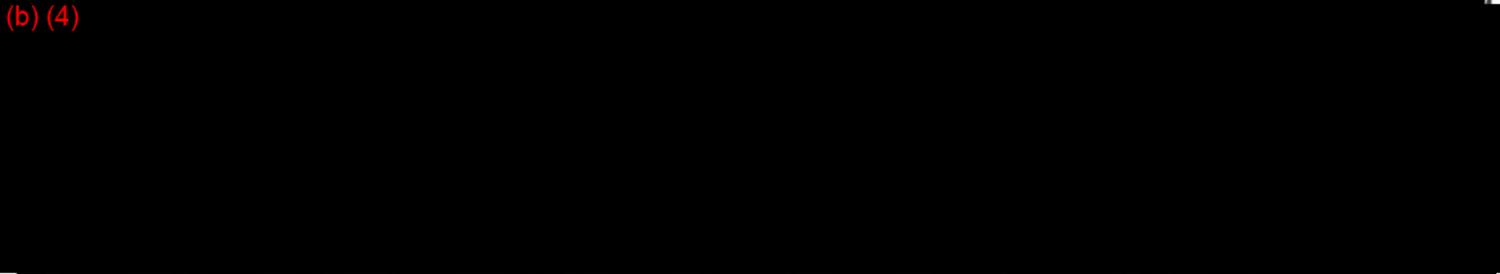
<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI ST72:2011 "Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing"

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Selection of technique	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A



SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
1350 Piccard Drive, Room 400  
Rockville, MD 20850

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with  
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Bard Peripheral Vascular, Inc./Sarah McCartney	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Jan 2, 2014
3. ADDRESS (Number, Street, State, and ZIP Code)  1625 West 3rd Street Tempe, AZ 85281	4. TELEPHONE AND FAX NUMBERS (Include Area Code)  (Tel.) 480-638-2954  (Fax) 480-449-2546

**PRODUCT INFORMATION**

5. <b>FOR DRUGS/BIOLOGICS:</b> Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) <b>FOR DEVICES:</b> Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)	
Common Name: Core Biopsy Instrument	Model Numbers: 211410, 211416, 211610, 211616, 211620, 211810, 211816, 211820, 212010, 212016, 212020, 121210, 121216, 121410,
Classification: Class II	121416, 121610, 121616, 121620, 121810, 121816, 121820, 122010, 122016, 122020, MC1410, MC1416, MC1610, MC1616, MC1810,
Trade Name: Bard® Monopty® Disposable Core Biopsy Instrument Bard® Max-Core® Disposable Core Biopsy Instrument	MC1816, MC1820, MC1825, MC2010, MC2016, MC2020

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned) K133948
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

**CERTIFICATION STATEMENT / INFORMATION**

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)
<input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
<input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
<input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary) NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.  
**Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)  	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11  (Name) Sarah McCartney  (Title) Regulatory Affairs Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)  1625 West 3rd Street Tempe, AZ 85281	14. TELEPHONE AND FAX NUMBERS (Include Area Code)  (Tel.) 480-638-2954  (Fax) 480-449-2546
	15. DATE OF CERTIFICATION  Jan 2, 2014

## Instructions for Completion of Form FDA 3674

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**  
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

**Box A** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

**Box B** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

**Box C** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

### Paperwork Reduction Act Statement

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**Refuse To Accept (RTA) Checklist for Special 510(k)s**

**Section 1: Special 510(k) Criteria**

Criteria	Location in 510(k)
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	Cover Letter & Page 10
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	Page 13
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	Page 15
4. The submission includes only summary-level information (i.e., NO test reports with performance data).	Throughout

**Section 2: Organizational Elements**

Organizational Item	Location in 510(k)
a. Submission contains Table of Contents	Page 2
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	Throughout
c. All pages of the submission are numbered	Throughout
d. Type of 510(k) is identified – traditional, abbreviated, or special	Cover Letter and Header

**Section 3: Elements of a Complete Submission (RTA Items)**

Element		Location in 510(k)
<b>A.</b>	<b>Administrative</b>	
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	Throughout
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):	
	a. Device trade name or proprietary name	Cover Letter
	b. Device common name	Cover Letter
	c. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	Cover Letter
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109)	Appendix 5
4.	Submission contains 510(k) Summary or 510(k) Statement	
	a. Summary contains all elements per 21 CFR 807.92	Appendix 1
	b. Statement contains all elements per 21 CFR 807.93	N/A
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k)	Appendix 2
6.	Submission contains Class III Summary and Certification	N/A

	7.		If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	FDA Form 3654
	8.		The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	Cover Letter
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed	N/A
<b>B. Device Description</b>				
	9.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	N/A (Page 11)
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	Page 11-18
	10.		Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:	
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	Page 11-18
		b.	A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	Page 11-18
		c.	A list and description of each model for which clearance is requested.	Page 7-8
	11.		A description of all device modification(s) including rationale for each modification.	Page 13-14
	12.		Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	Appendix 3
	13.		If device is intended to be marketed with multiple components, accessories, and/or as part of a system,	N/A
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	
		b.	Submission includes a description (as detailed in item #12.a. and b. and 14 above) of each component or accessory.	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	
<b>C. Substantial Equivalence Discussion</b>				
	14.		Submitter has identified a predicate(s) device	

	a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendment status.	Page 7
	b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing	Throughout
15.		Submission includes a comparison of the following for the predicate(s) and subject device	
	a.	Indications for use	Page 17
	b.	Technology, including features, materials, and principles of operation	Page 17-18
16.		Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise difference questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act)	Page 13-18
<b>D. Design Control Activities</b>			
17.		Design Control Activities Summary includes all of the following:	
	a.	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	Page 19
	b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	N/A (Page 19)
	c.	Declaration of conformity with design controls, including:	Appendix 7
	i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.	
	ii.	Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30	
	iii.	Statement is signed by the individual responsible for these activities	
<b>E. Proposed Labeling (see also 21 CFR part 801)</b>			
18.		Submission includes proposed labels, and labeling (e.g., instructions for use, package insert, operator's manual), that include a description of the device, its intended use, and the directions for use	Appendix 4
	a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	N/A (Page 13-14)
19.		Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	Page 13

## 1. Required Information

### 1.1 Predicate Device Information

The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument, K922939, cleared February 16, 1993.

### 1.2 Subject Device Information

#### 1.2.1 Device Name

**Device Trade Name:** Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® Disposable Core Biopsy Instrument

**Common Name:** Core Biopsy Instrument

**Classification Name:** Instrument, Biopsy

The Bard® Monopty® Disposable Core Biopsy Instrument and Bard® Max-Core® Disposable Core Biopsy Instrument will be referred to as “Core Biopsy Instrument(s)” throughout this submission.

#### 1.2.2 Catalogue Numbers

A list of the Core Biopsy Instrument catalogue numbers is provided in Tables 1 and 2.

**Table 1: Bard® Monopty® Disposable Core Biopsy Instrument Catalogue Numbers**

Catalogue Number	Gauge x Length	Penetration Depth
121210	12 g x 10 cm	22 mm
121216	12 g x 16 cm	22 mm
121410	14 g x 10 cm	22 mm
121416	14 g x 16 cm	22 mm
121610	16 g x 10 cm	22 mm
121616	16 g x 16 cm	22 mm
121620	16 g x 20 cm	22 mm
121810	18 g x 10 cm	22 mm
121816	18 g x 16 cm	22 mm
121820	18 g x 20 cm	22 mm
122010	20 g x 10 cm	22 mm

Catalogue Number	Gauge x Length	Penetration Depth
122016	20 g x 16 cm	22 mm
122020	20 g x 20 cm	22 mm
211410	14 g x 9 cm	11 mm
211416	14 g x 15 cm	11 mm
211610	16 g x 9 cm	11 mm
211616	16 g x 15 cm	11 mm
211620	16 g x 19 cm	11 mm
211810	18 g x 9 cm	11 mm
211816	18 g x 15 cm	11 mm
211820	18 g x 19 cm	11 mm
212010	20 g x 9 cm	11 mm
212016	20 g x 15 cm	11 mm
212020	20 g x 19 cm	11 mm

**Table 2: Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument Catalogue Numbers**

Catalogue Number	Gauge x Length	Penetration Depth
MC1410	14 g x 10 cm	22 mm
MC1416	14 g x 16 cm	22 mm
MC1610	16 g x 10 cm	22 mm
MC1616	16 g x 16 cm	22 mm
MC1810	18 g x 10 cm	22 mm
MC1816	18 g x 16 cm	22 mm
MC1820	18 g x 20 cm	22 mm
MC1825	18 g x 25 cm	22 mm
MC2010	20 g x 10 cm	22 mm
MC2016	20 g x 16 cm	22 mm
MC2020	20 g x 20 cm	22 mm

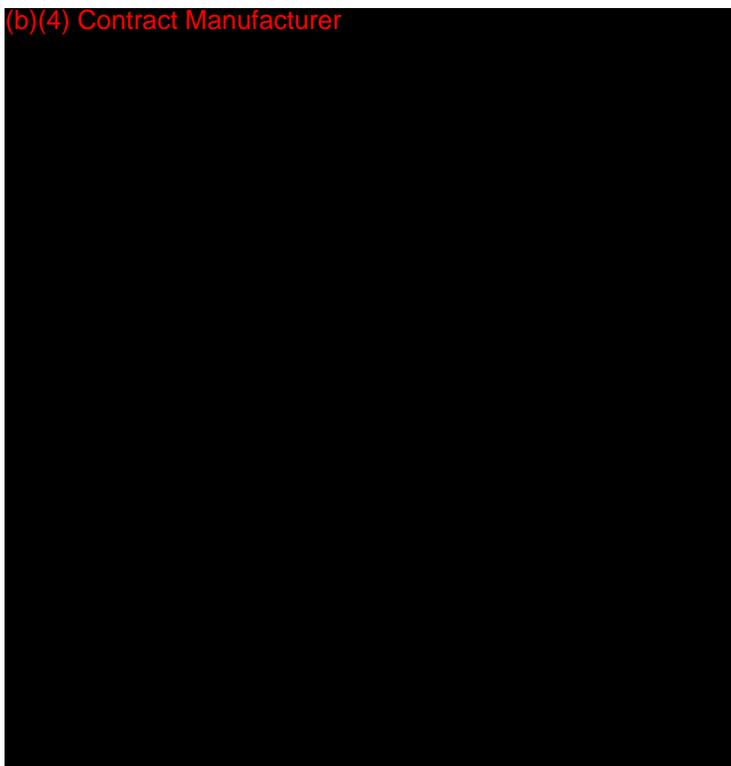
### 1.2.3 Addresses and Facility Registration Numbers

The addresses and registration numbers for the manufacturer, contract manufacturer and contract sterilizers of the Core Biopsy Instruments are noted below:

Manufacturer:

Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, AZ 85281  
USA  
Establishment Registration Number: 2020394

(b)(4) Contract Manufacturer



(b) (4) is the design center responsible for design control activities affecting the Core Biopsy Instruments.

### 1.2.4 Device Class

**Device Classification:** Class II  
**Classification Name:** Instrument, Biopsy ( Product Code KNW)  
**Review Panel:** Gastroenterology / Urology

**Regulation Number:** 21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

Please note all of the information above is identical to the predicate device.

The following FDA guidance document is applicable to these devices:

- Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology, dated prior to February 27, 1997.

### **1.3 Performance Standards**

Performance standards have not been established under Section 514 of the Food, Drug and Cosmetic Act for gastroenterology-urology biopsy instruments.

### **1.4 510(k) Summary**

The 510(k) Summary is provided in Appendix 1.

### **1.5 Truthful and Accuracy Statement**

The signed Truthful and Accuracy Statement is provided in Appendix 2.

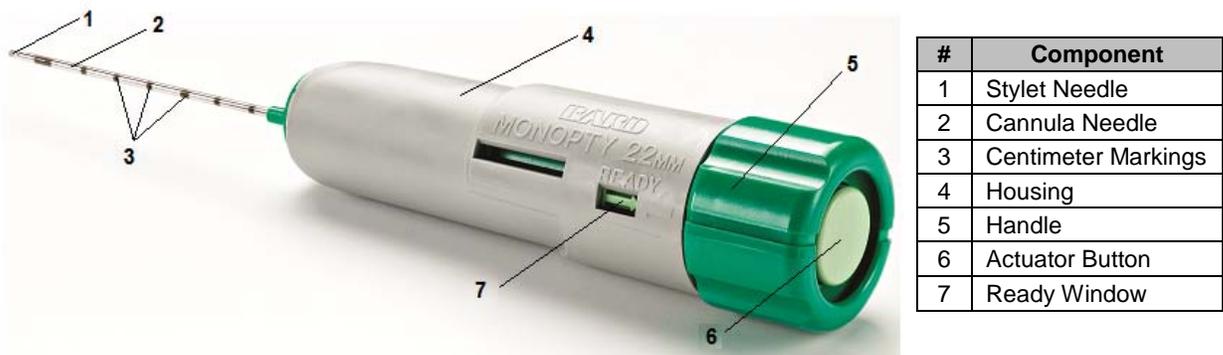
## 2. Device Description and Comparisons

There are no changes proposed to the currently marketed Core Biopsy Instruments. For ease of review, a brief description of the devices is provided below.

### 2.1 Device Description

#### Bard® Monopty® Disposable Core Biopsy Instrument

The Bard® Monopty® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths (refer to Table 1 for currently offered product configurations). The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge, Green = 14 gauge, and Light Blue = 12 gauge. A picture of the 14 gauge device is provided in Figure 1.



**Figure 1: Bard® Monopty® Disposable Core Biopsy Instrument (14 Gauge)**

#### Bard® Max-Core® Disposable Core Biopsy Instrument

The Bard® Max-Core® Disposable Core Biopsy Instrument was released via a Letter to File on August 15, 1995. The Bard® Max-Core® Disposable Core Biopsy Instrument is an ergonomic enhancement of the Bard® Monopty® Disposable Core Biopsy Instrument. The device provides no new needle gauge sizes (outside the previously cleared range), no significant changes in performance specifications, no new performance claims, no changes regarding indications for use or contraindications, and no significant changes

regarding warnings or precautions. Please refer to Section 3.5, History of Changes, for additional information.

The Bard® Max-Core® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths (refer to Table 2 for currently offered product configurations). The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge. A picture of the 14 gauge device is provided in Figure 2.

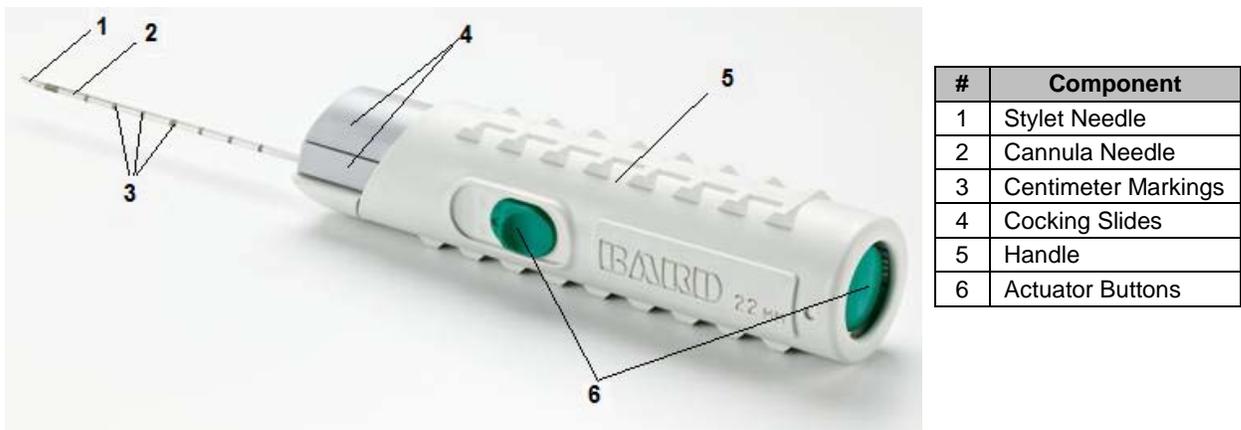


Figure 2: Bard® Max-Core® Disposable Core Biopsy Instrument (14 Gauge)

## 2.2 Engineering Drawings

There are no changes proposed to the engineering drawings of the currently marketed Core Biopsy Instruments. Engineering drawings are provided in Appendix 3.

## 2.3 Labeling, Intended Use and Indications for Use

There are no changes proposed to the labeling of the currently marketed Core Biopsy Instruments. Labels and Instructions for Use for the subject devices are provided in Appendix 4.

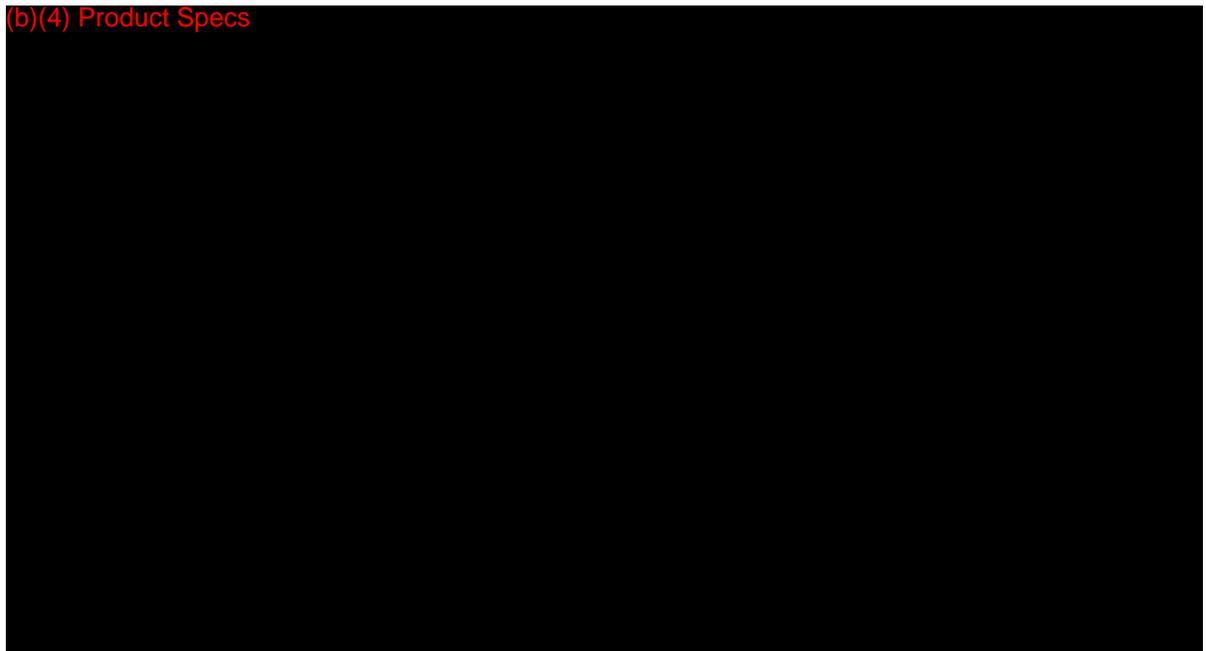
The Intended Use and the Indications for Use of the subject devices, as described in its labeling, are the same as the Intended Use and the Indications for Use of the predicate device.

The Indications for Use Statement is provided in Appendix 5.

## 2.4 Materials

**There are no changes proposed to the materials of the currently marketed Core Biopsy Instruments.** Tables 3 and 4 detail the patient contacting materials of the Core Biopsy Instruments. Body contact and duration are defined per ISO 10993-1:2009, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.”

(b)(4) Product Specs



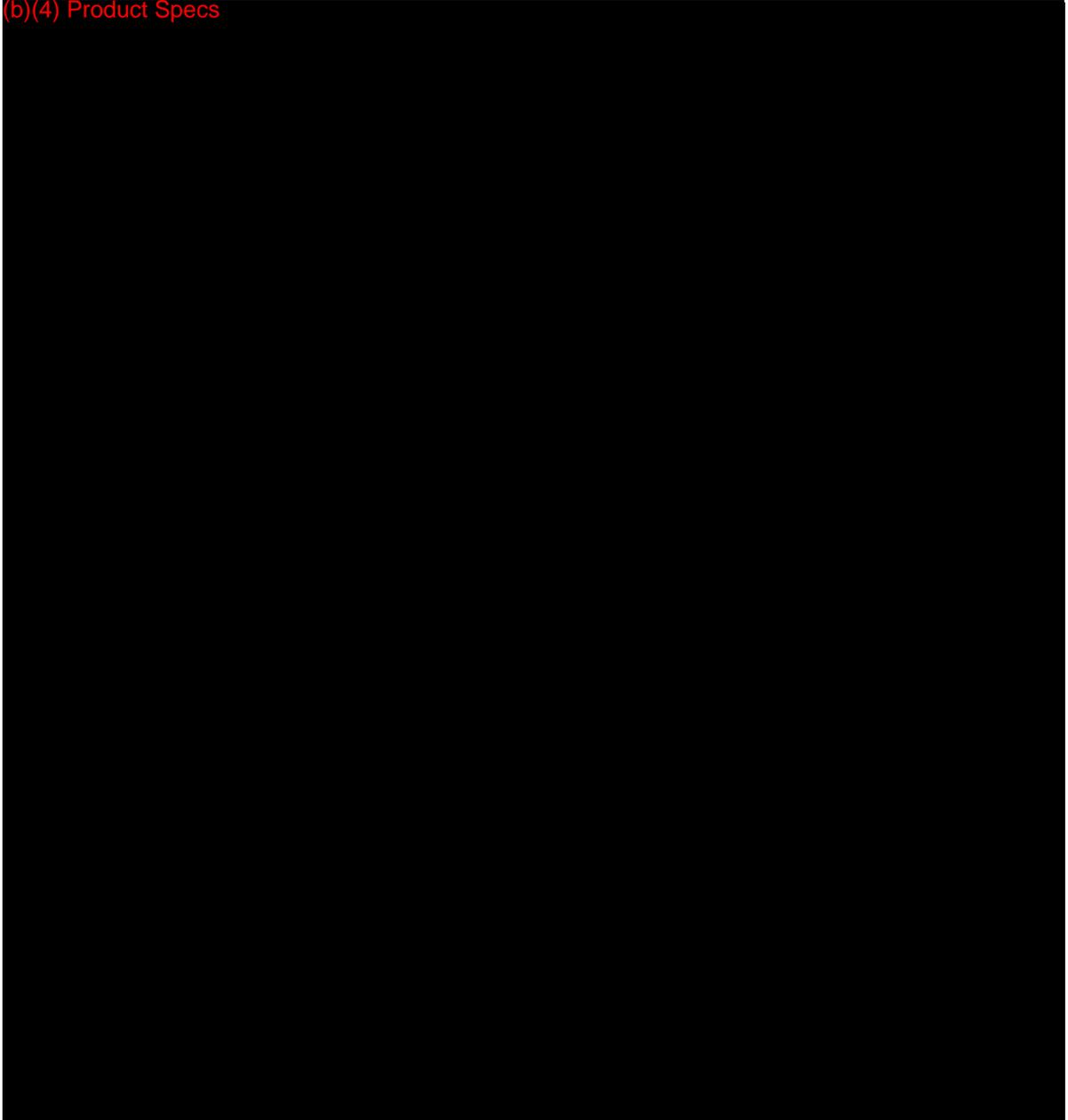
## 2.5 History of Changes

There have been several changes implemented since the previous submission. Please refer to Table 5 for a list of changes that have been implemented since the previous submission. The changes are listed in the order that they were implemented. These changes did not constitute a new intended use, did not affect safety and effectiveness, did not raise different questions of safety and effectiveness, and did not alter the

fundamental scientific technology of the device; therefore, these changes did not require a new 510(k) submission.

**Table 5: History of Changes**

(b)(4) Product Specs



## 2.6 Predicate and Subject Device Comparison

The predicate device referenced in this submission is the Bard® Monopty® Disposable Core Biopsy Instrument (K922939, cleared February 16, 1993).

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Similar patient-contacting materials
- Same fundamental scientific technology
- Same patient population
- Same sterility
- Similar packaging configuration

There are no changes proposed to the design, materials, performance specifications, packaging, labeling or sterilization of the currently marketed Core Biopsy Instruments as a result of this submission. When reviewing the changes since the predicate submission, the subject devices and the predicate device are different in the following manner:

- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications

These changes do not constitute a new intended use, do not affect safety and effectiveness, do not raise different questions of safety and effectiveness, and do not alter the fundamental scientific technology of the device. Refer to Table 6 for a

comparison of the predicate and subject devices, including those changes detailed in Section 3.5 and described above. The differences are noted in **bold**.

Table 6: Comparison Summary

Attribute	PREDICATE DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (K922939)	SUBJECT DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (Currently Marketed)	SUBJECT DEVICE Bard® Max-Core® Disposable Core Biopsy Instrument (Currently Marketed)
Regulation Number	21 CFR 876.1075 (Class II)	Same as predicate	Same as predicate
Intended Use	<i>The core needle biopsy device is intended to obtain soft tissue samples for diagnostic and histological analysis of soft tissue abnormalities.*</i>	Same as predicate	Same as predicate
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.	Same as predicate	Same as predicate
Design, including:	Single-use, sterile, disposable	Same as predicate	Same as predicate
· Needle Gauge	14, 16, 18, 20 gauge	<b>12</b> , 14, 16, 18, 20 gauge	Same as predicate
· Needle Length	10, 16, 20 cm	<b>9</b> , 10, <b>15</b> , 16, <b>19</b> , 20, <b>25</b> cm	10, 16, 20, <b>25</b> cm
· Penetration Depth	11 or 22 mm	Same as predicate	22 mm (Subset of Predicate)
· Sample Notch	7 or 17mm	Same as predicate	<b>18 mm</b>
· Number of Samples	One or more	Same as predicate	Same as predicate
· Mechanics of Action	Spring operated	Same as predicate	Same as predicate
· Mode of Action	<i>Single puncture and sample*</i>	Same as predicate	Same as predicate

Attribute	PREDICATE DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (K922939)	SUBJECT DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (Currently Marketed)	SUBJECT DEVICE Bard® Max-Core® Disposable Core Biopsy Instrument (Currently Marketed)
Energy Used / Delivered	(b)(4) Product Specs	Same as predicate	Same as predicate
Patient-Contacting Materials	(b)(4) Product Specs		
Patient Population	<i>Individuals requiring biopsy for sampling of soft tissue abnormalities*</i>	Same as predicate	Same as predicate
Visualization Techniques	X-ray, ultrasound, CT, etc.	Same as predicate	Same as predicate
Performance Specifications	Sample quality	Same as predicate	Same as predicate
	N/A	<b>Durability</b>	<b>Durability</b>
	N/A	<b>Needle to device tensile strength</b>	<b>Needle to device tensile strength</b>
Sterility	Ethylene oxide, SAL of 10 <sup>-6</sup>	Same as predicate	Same as predicate
Packaging Configuration	6 blister packs with Tyvek lids or 10 Tyvek to film pouches in a cardboard shelf box with the IFU	<b>5</b> or <b>10</b> blister packs with Tyvek lids in a cardboard shelf box with the IFU	<b>5</b> blister packs with Tyvek lids in a cardboard shelf box with the IFU

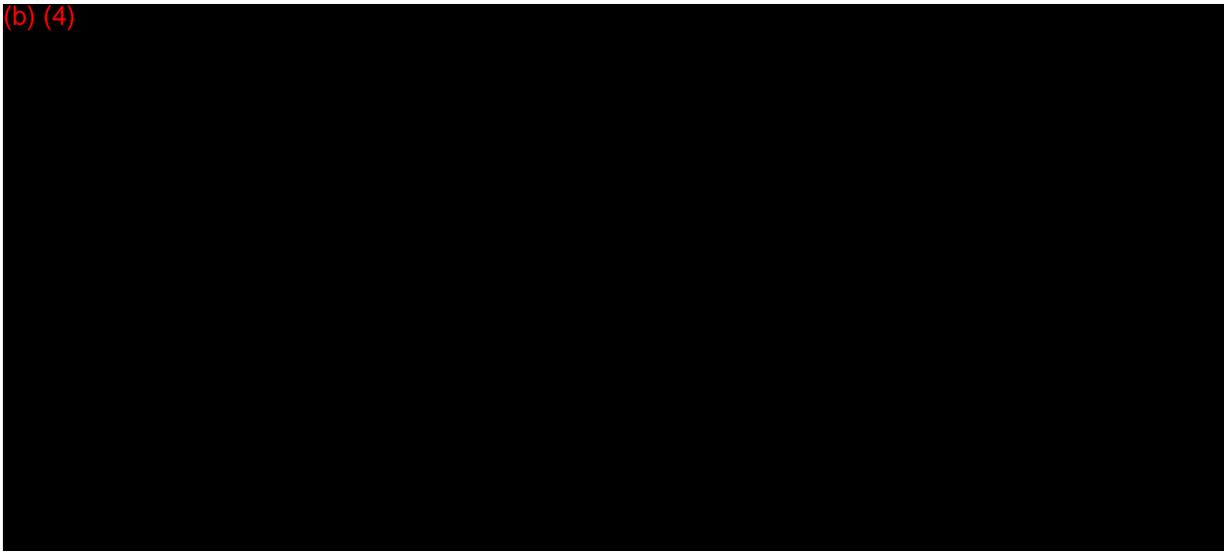
\* This information is not clearly stated, but is implied from the predicate submission.

\*\* These materials are unchanged from the predicate device, only the patient contact was re-evaluated (additional biocompatibility testing was not required due to the change to patient contact for these components)

### 3. Design Control Activities

#### 3.1 Risk Analysis

(b) (4)



#### 3.2 Packaging

The predicate device is packaged in either a blister pack with Tyvek lid or Tyvek to film pouch. Sealed blister packs or sealed pouches are placed in a cardboard shelf box with the Instructions for Use.

The subject devices are packaged in a blister pack with Tyvek lid similar to the predicate device. Sealed blister packs are placed in a cardboard shelf box with the Instructions for Use. **There are no changes proposed to the packaging of the currently marketed Core Biopsy Instruments.**

#### 3.3 Biocompatibility

**There are no changes proposed to the biocompatibility of the currently marketed Core Biopsy Instruments.** The currently marketed subject devices are considered biocompatible for its intended use as stated in K922939 and as discussed in Section 3.5, History of Changes. Refer to Table 7 for a list of the testing performed / adopted for the subject devices.

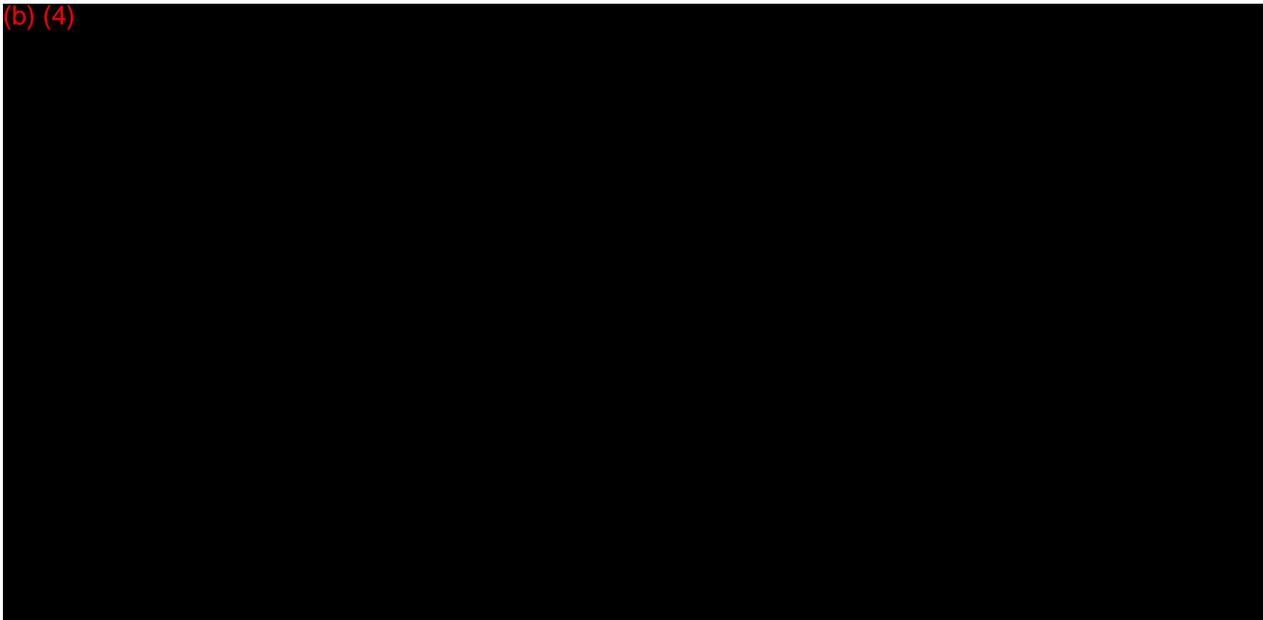
Table 7: Biocompatibility Testing

Test	Results
(b) (4)	

### 3.4 Sterilization

(b) (4)

(b) (4)



### 3.5 Shelf-Life

There are no changes proposed to the shelf-life of the currently marketed Core Biopsy Instruments. The subject devices are qualified for a 3 year shelf life.

### 3.6 Declaration of Conformity with Design Controls

The Declaration of Conformity with Design Controls is provided in Appendix 7.

#### 4. Statement of Substantial Equivalence

The predicate device referenced in this submission is the Bard® Monopty® Disposable Core Biopsy Instrument (K922939, cleared February 16, 1993).

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Similar patient-contacting materials
- Same fundamental scientific technology
- Same patient population
- Same sterility
- Similar packaging configuration

There are no changes proposed to the design, materials, performance specifications, packaging, labeling or sterilization of the currently marketed Core Biopsy Instruments as a result of this submission. When reviewing the changes since the predicate submission, the subject devices and the predicate device are different in the following manner:

- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications

As previously noted, a review of the Risk Assessment and DFMEA of the subject devices is conducted in accordance with internal procedures based on ISO 14971:2007, to assure that the risks posed by the modified devices are acceptable. The outcome of the risk management activities demonstrate the Core Biopsy Instruments present an

acceptable level of risk when used within its intended use and that the design outputs continue to meet the design inputs and user need requirements. Therefore, the currently marketed subject devices are substantially equivalent to the legally marketed predicate device.

**Appendix 1: 510(k) Summary**

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## 510(k) Summary

### 21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (l)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

#### 1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, Arizona 85281

Phone: 480-638-2954

Fax: 480-449-2546

Contact: Sarah McCartney, Regulatory Affairs Specialist

Date: January 2, 2014

#### 2. Subject Device:

Device Trade Name: Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® Disposable Core Biopsy Instrument

Common or Usual Name: Core Biopsy Instrument

Classification: Class II

Classification Name: Instrument, Biopsy ( Product Code KNW)

Review Panel: Gastroenterology / Urology

Regulation Number: 21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

#### 3. Predicate Device:

The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument, K922939, cleared February 16, 1993.

#### 4. Summary of Change:

This Special 510(k) provides an updated file to FDA including several changes that have occurred to the subject device since the predicate submission.

## 5. Device Description:

### Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument

The Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge, and Light Blue = 12 gauge.

### Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument

The Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge.

## 6. Indications for Use of Device:

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.

## 7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Similar patient-contacting materials
- Same fundamental scientific technology

- Same patient population
- Same sterility
- Similar packaging configuration

When reviewing the changes from the predicate submission, the subject devices and the predicate device are different in the following manner:

- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications

#### **8. Performance Testing Summary:**

There are no changes proposed to the currently marketed devices as described in this submission and no new or increased risks have been identified, therefore additional bench performance testing is not warranted.

#### **9. Conclusion:**

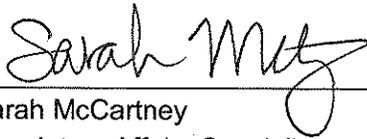
The subject devices are substantially equivalent to the predicate device.

## Appendix 2: Truthful and Accuracy Statement

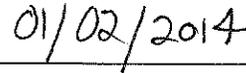
## Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Specialist of Bard Peripheral Vascular, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Sarah McCartney  
Regulatory Affairs Specialist



Date

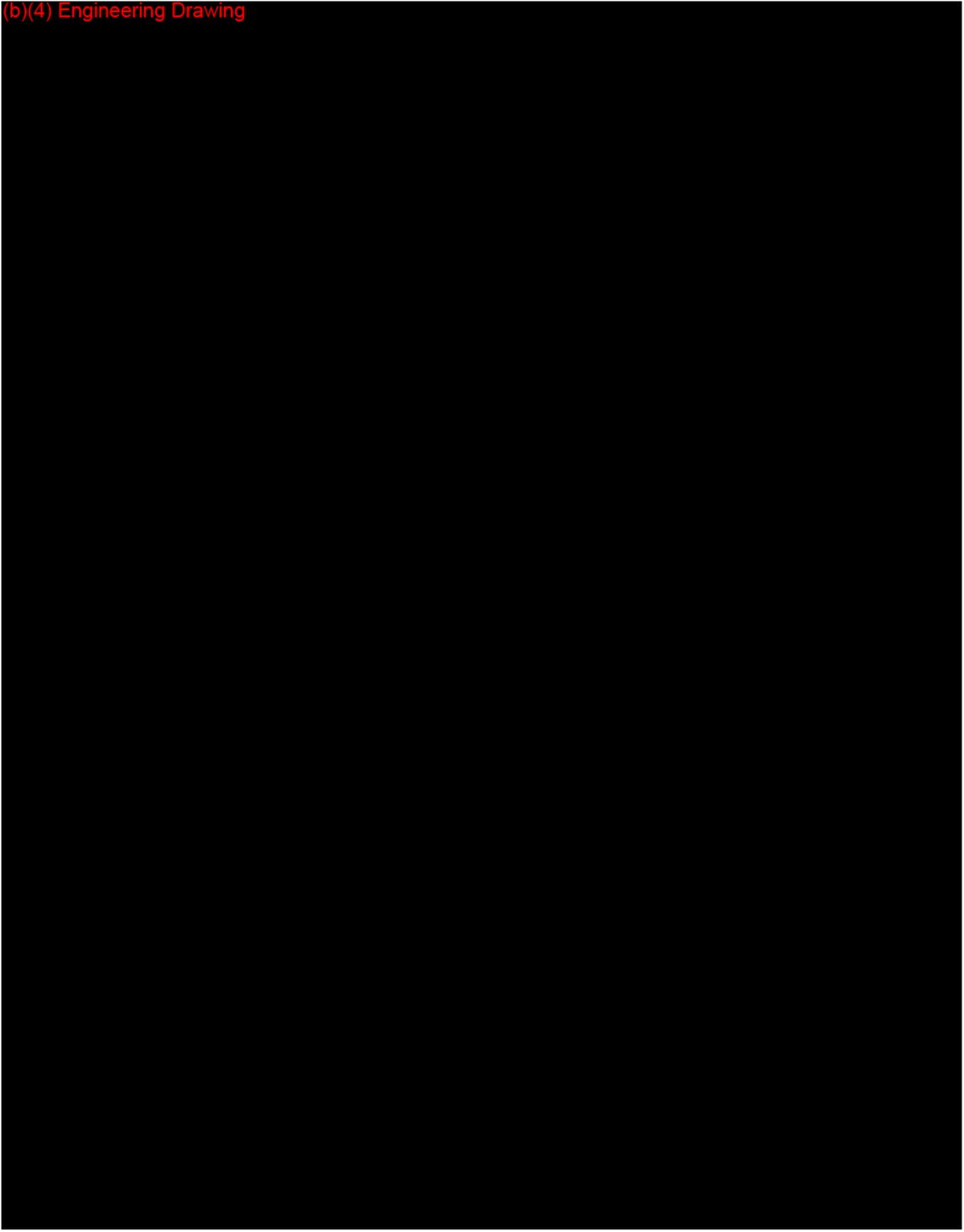
K133948

510(k) Number (if known)

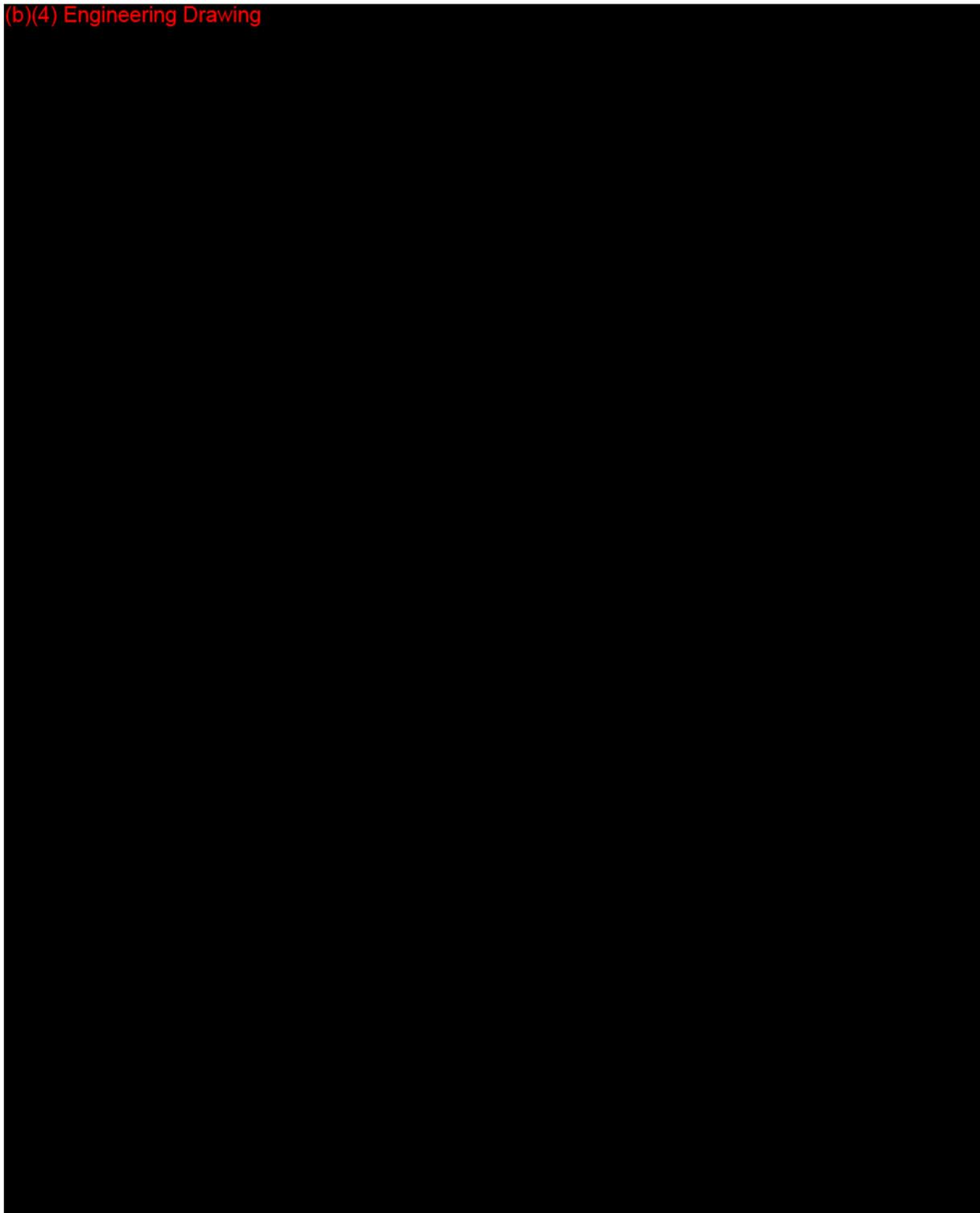
### Appendix 3: Engineering Drawings

**Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument**

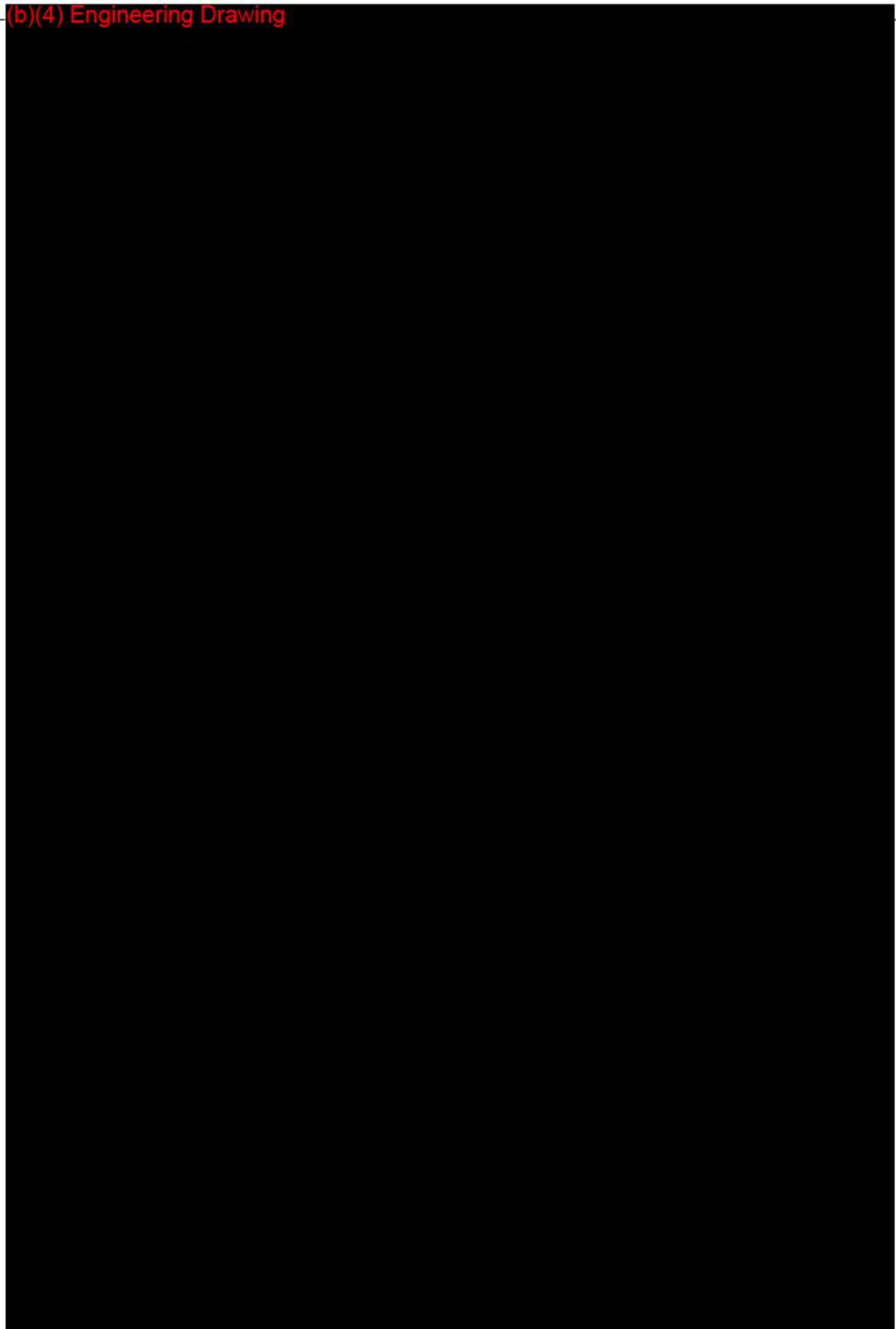
(b)(4) Engineering Drawing



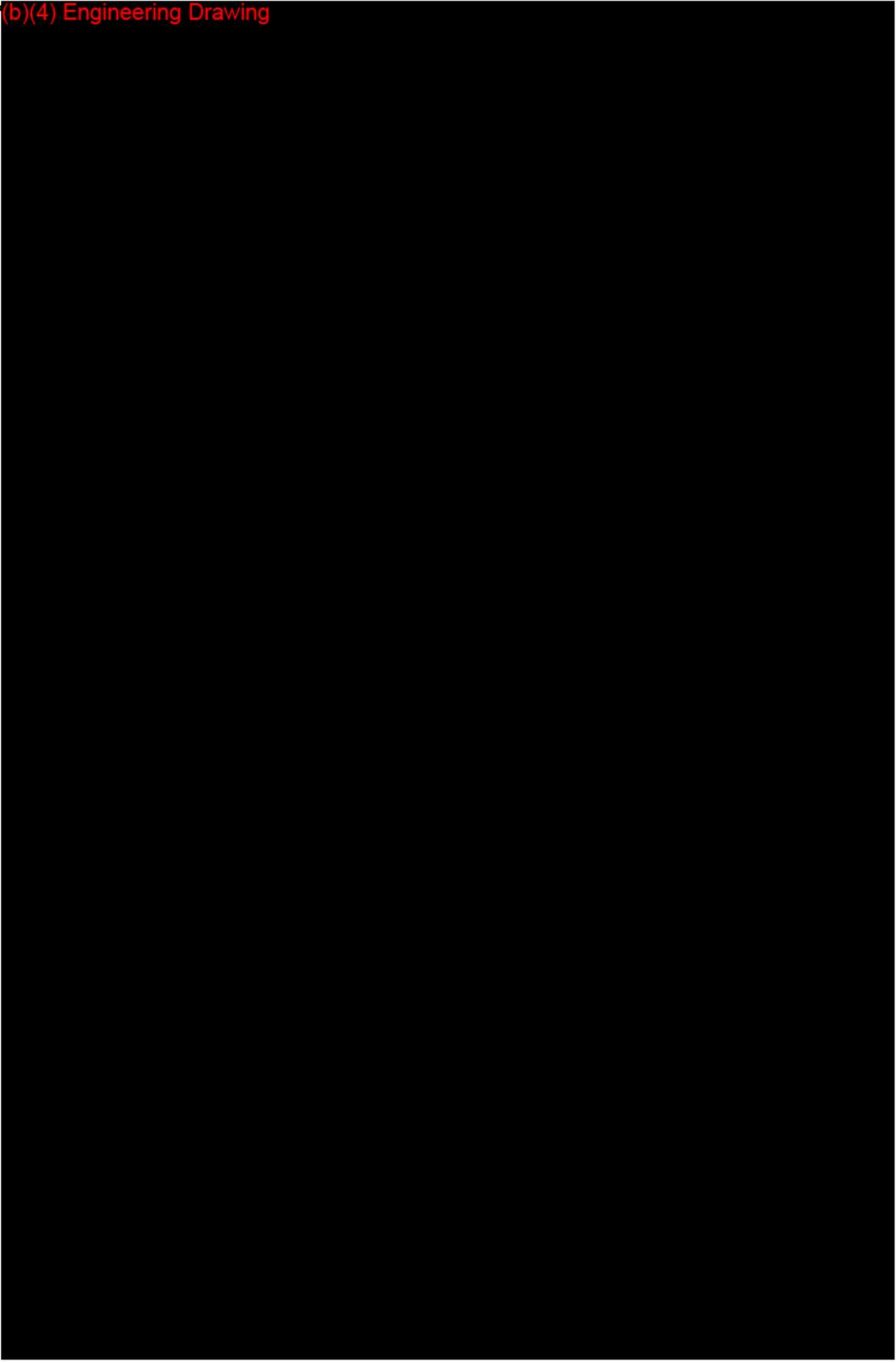
(b)(4) Engineering Drawing



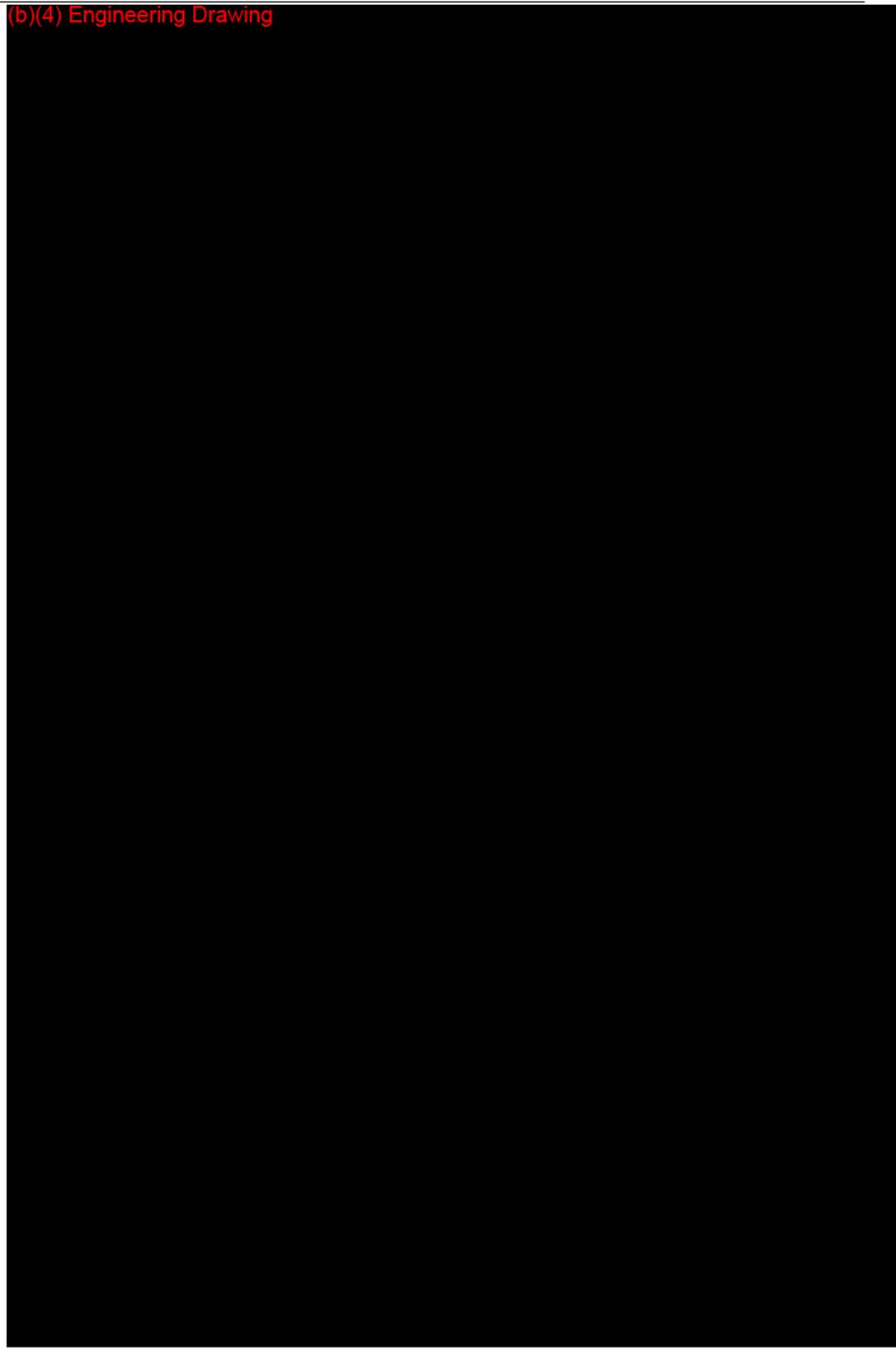
(b)(4) Engineering Drawing



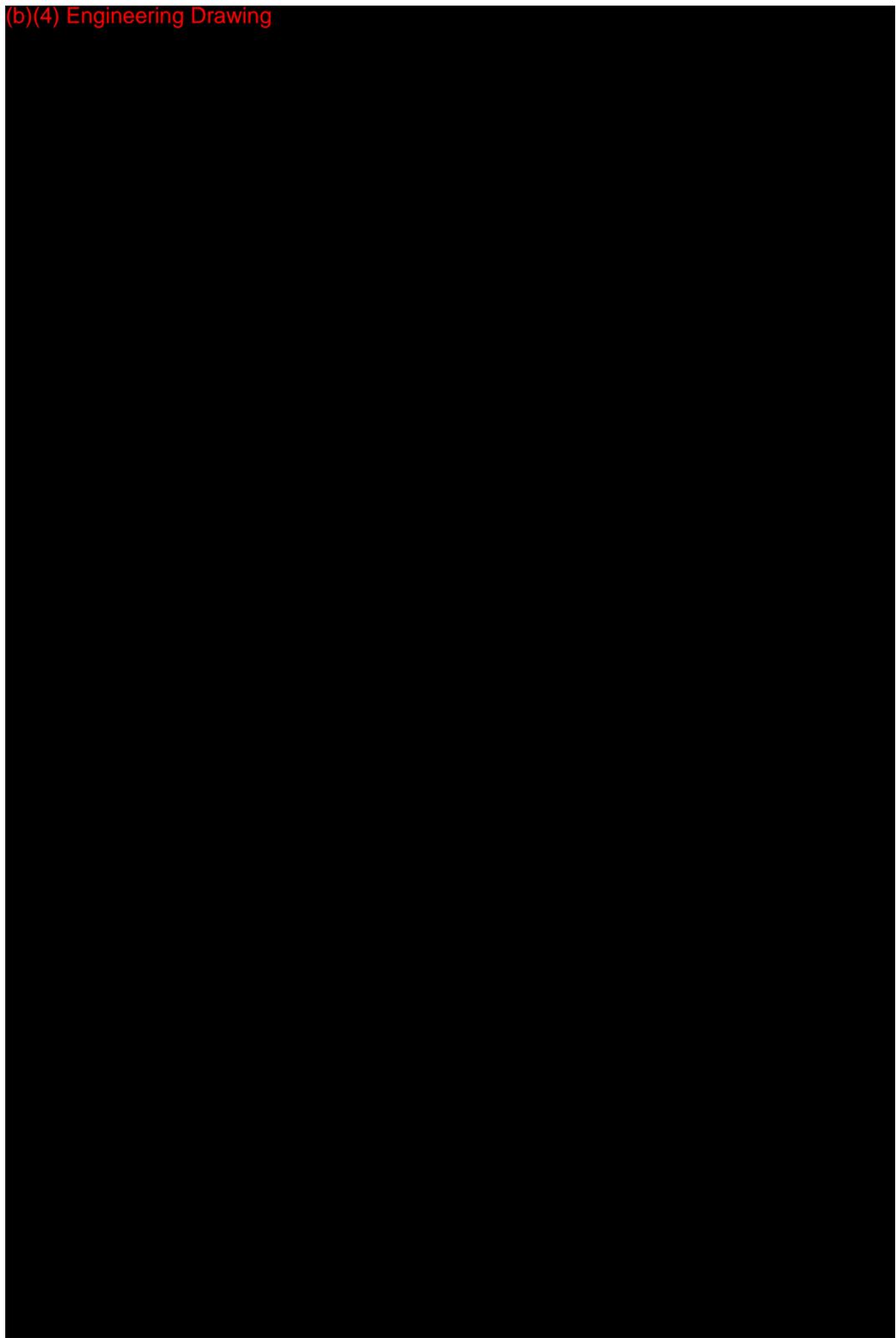
(b)(4) Engineering Drawing



(b)(4) Engineering Drawing

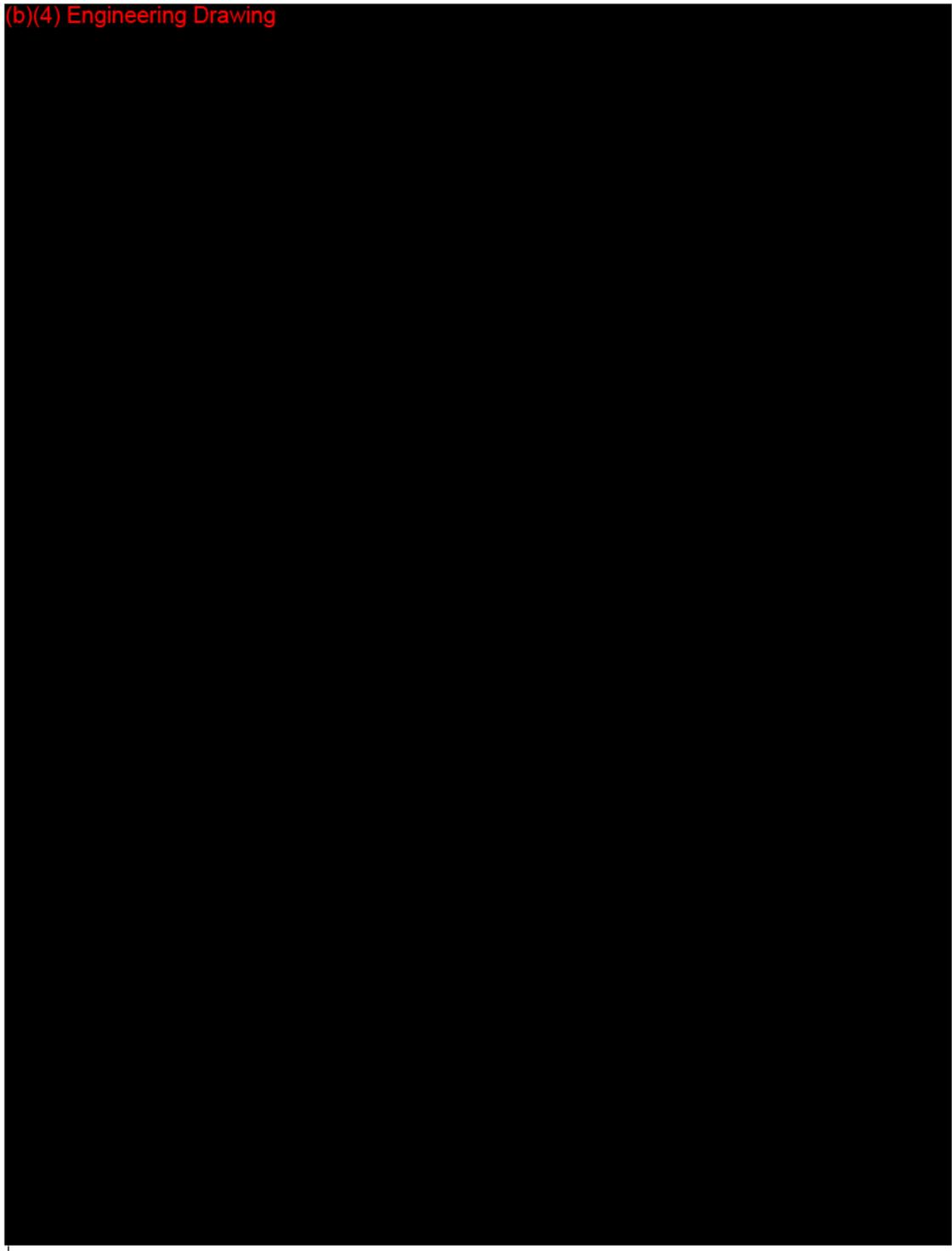


(b)(4) Engineering Drawing

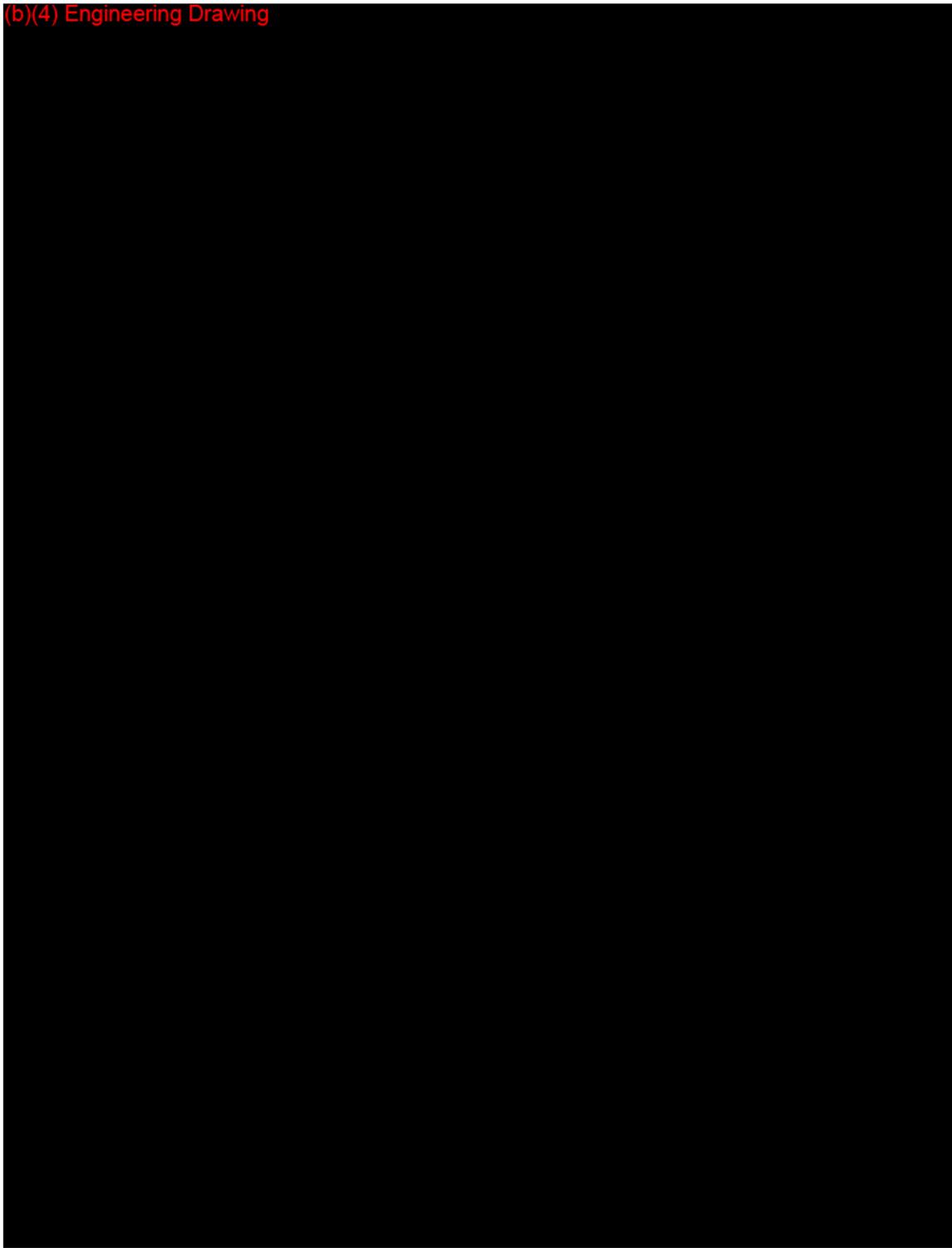


**Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument**

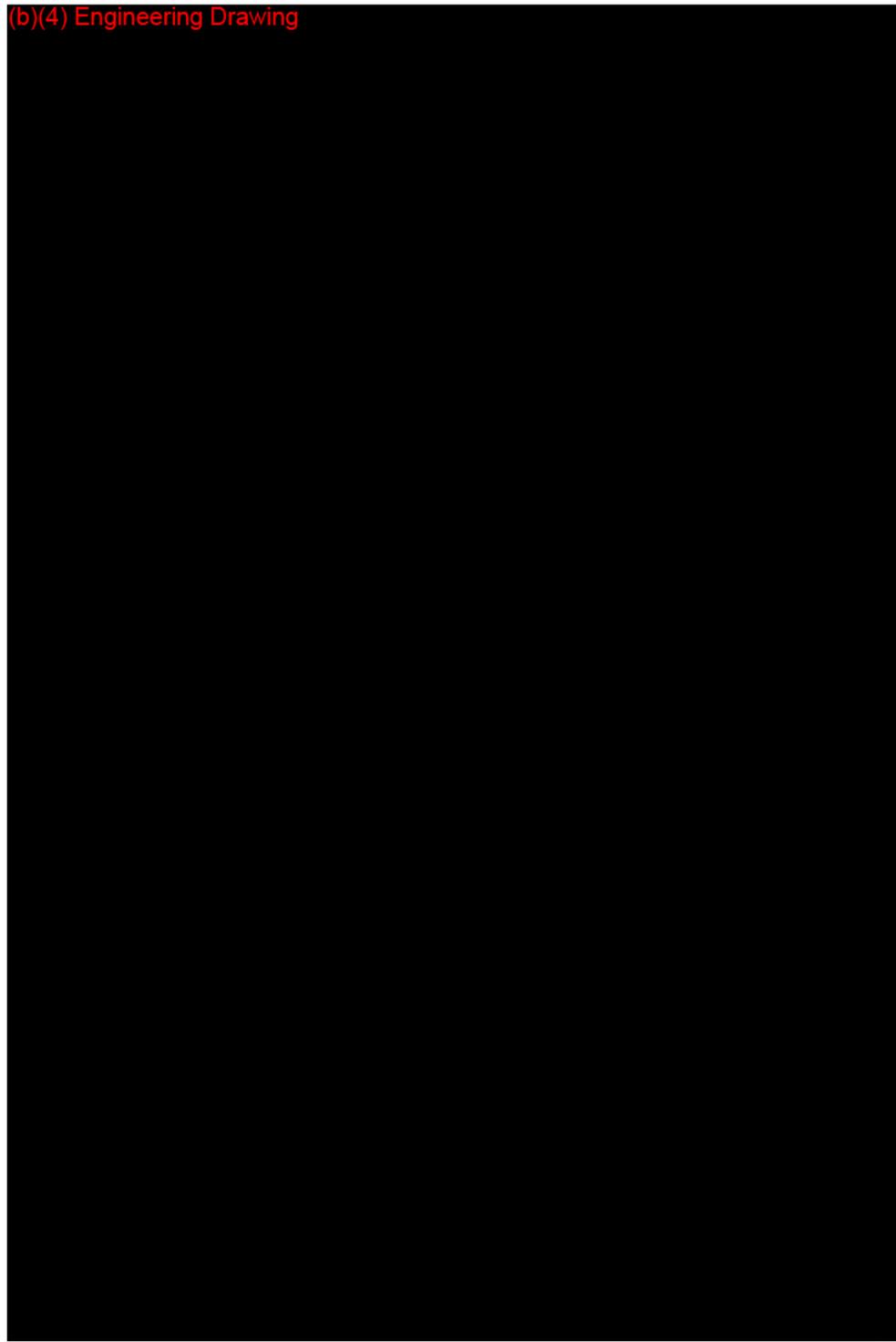
(b)(4) Engineering Drawing



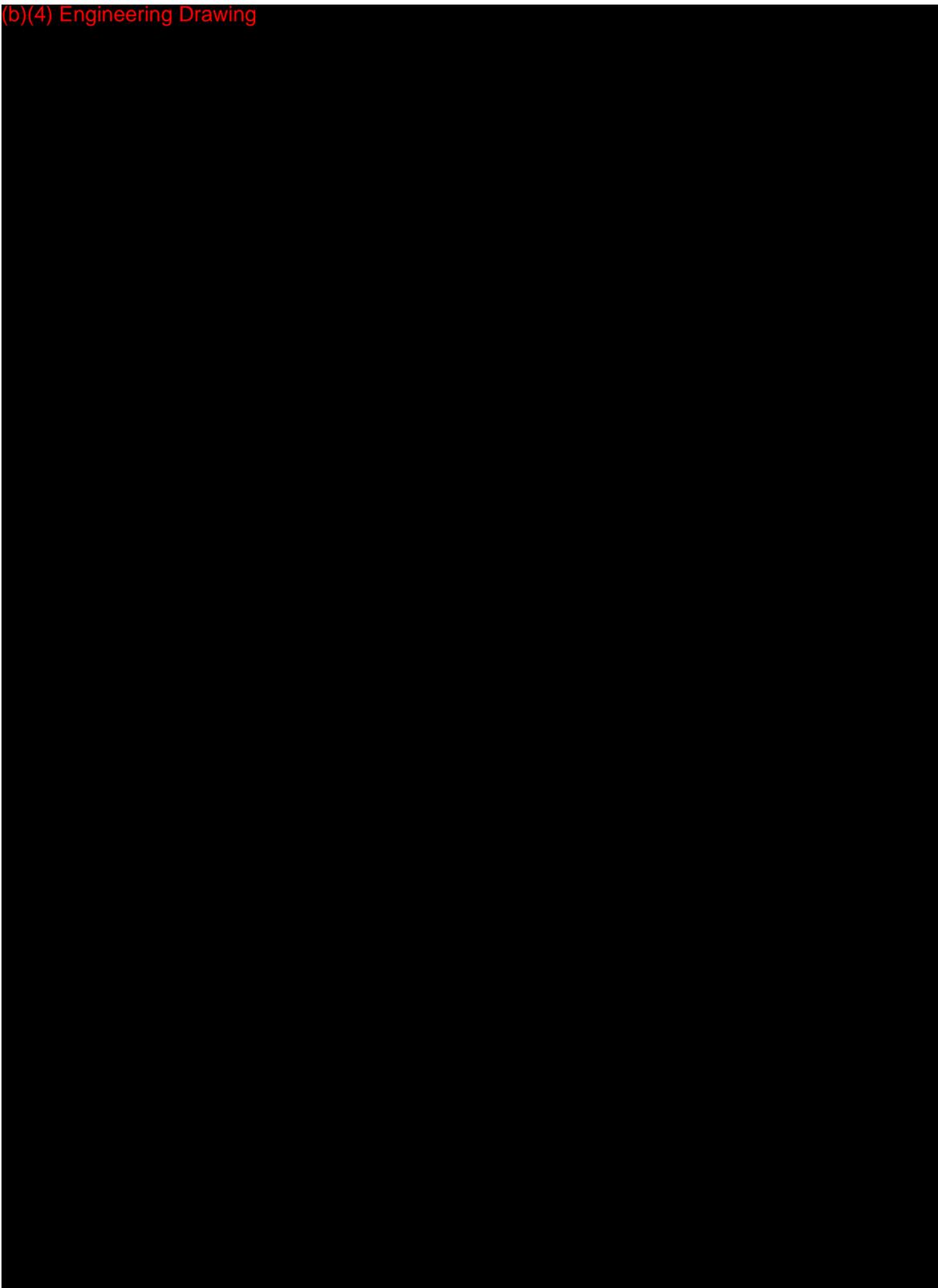
(b)(4) Engineering Drawing



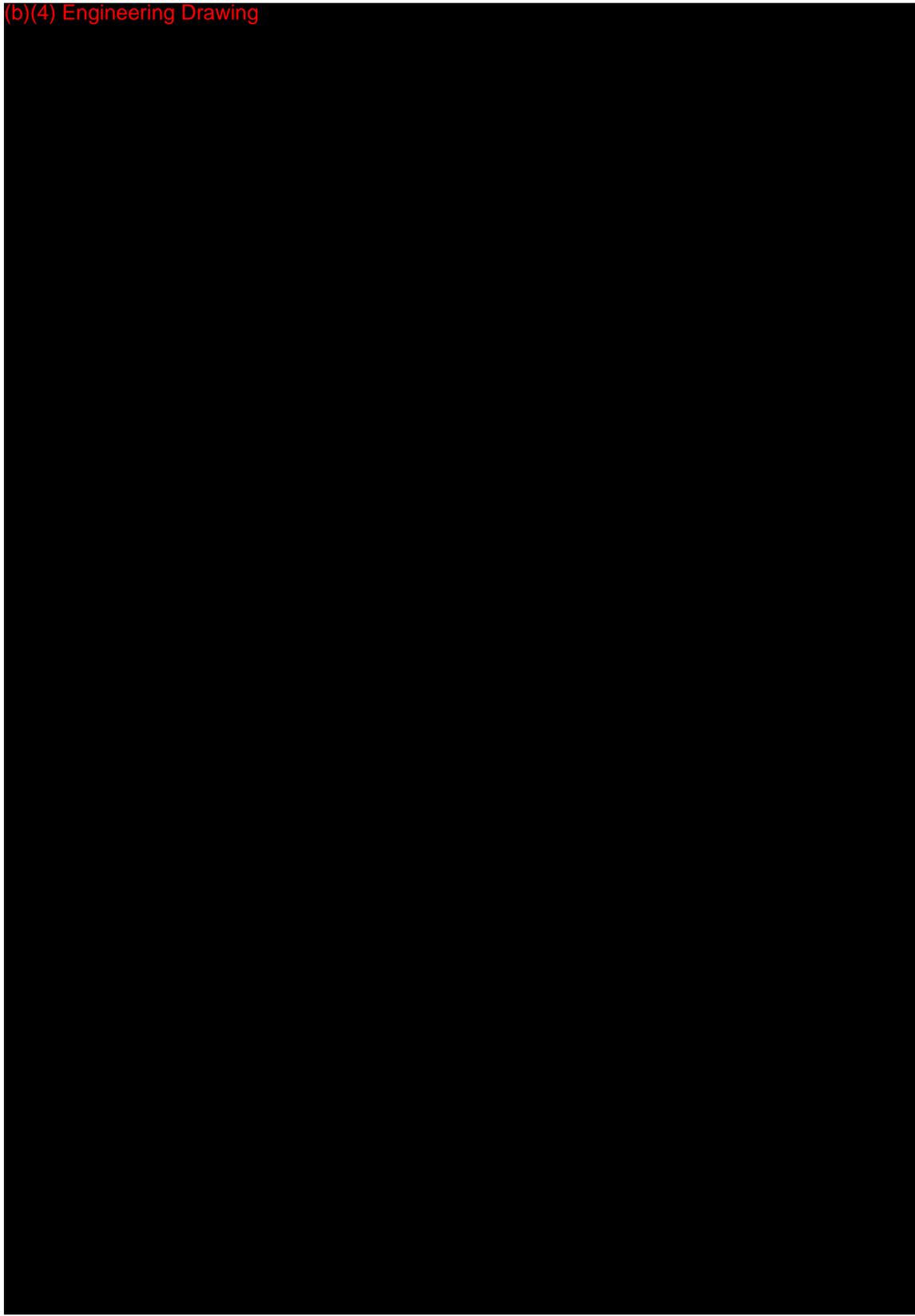
(b)(4) Engineering Drawing



(b)(4) Engineering Drawing



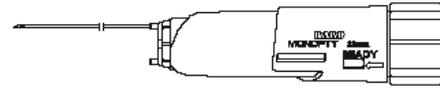
(b)(4) Engineering Drawing



## Appendix 4: Subject Device Labeling

**Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument (English Only)**

## BARD® MONOPTY® Disposable Core Biopsy Instrument Instructions for Use



Instrument de biopsie tissulaire jetable  
BARD® MONOPTY®  
Mode d'emploi

Kertakäyttöinen BARD® MONOPTY®  
-paksuneulabiopsiainstrumentti  
Käyttöohjeet

BARD® MONOPTY® Core-Biopsie-  
Instrument für den Einmalgebrauch  
Gebrauchsanweisung

BARD® MONOPTY® engangsinstrument  
til kjernebiopsi  
Bruksanvisning

Strumento per agobiopsie  
BARD® MONOPTY®  
Istruzioni per l'uso

Jednorazowy przyrząd BARD® MONOPTY®  
do biopsji gruboigłowej  
Instrukcja użycia

Instrumento desechable para biopsia  
core BARD® MONOPTY®  
Modo de empleo

BARD® MONOPTY® eldobható  
core-biopsziás eszköz  
Használati útmutató

BARD® MONOPTY® wegwerpbaar  
hollenaaldbiopsie-instrument  
Gebruiksaanwijzing

Jednorázový nástroj BARD® MONOPTY®  
pro punkční biopsii  
Návod k použití

Instrumento de biopsia por agulha  
grossa descartável BARD® MONOPTY®  
Instruções de utilização

BARD® MONOPTY® Tek Kullanımlik  
Kor Biyopsi Cihazı  
Kullanma Talimatı

Αναλώσιμο εργαλείο βιοψίας με  
κόπτουσα βελόνα BARD® MONOPTY®  
Οδηγίες χρήσης

BARD® MONOPTY® 拋棄式  
空芯切片器械  
使用說明

BARD® MONOPTY® engangs-  
instrument til grovnålsbiopsi  
Bruksanvisning

BARD® MONOPTY® 일회용  
총생검 기구  
사용 지침

BARD® MONOPTY® engångsnål  
för kärnbiopsi  
Bruksanvisning

Одноразовый инструмент  
для толстоигольной биопсии  
BARD® MONOPTY®  
Инструкции по применению

**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® MONOPTY® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge, Green=14 gauge, and Light Blue=12 gauge.

Catalog Number	Gauge Size and Needle Length	Length of Sample Notch	Penetration Depth
121210	12g (2.8mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121216	12g (2.8mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121410	14g (2.1mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121416	14g (2.1mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121610	16g (1.7mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121616	16g (1.7mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121620	16g (1.7mm) x 20cm (200mm)	1.7cm (17mm)	22mm
121810	18g (1.2mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121816	18g (1.2mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121820	18g (1.2mm) x 20cm (200mm)	1.7cm (17mm)	22mm
122010	20g (0.9mm) x 10cm (100mm)	1.7cm (17mm)	22mm
122016	20g (0.9mm) x 16cm (160mm)	1.7cm (17mm)	22mm
122020	20g (0.9mm) x 20cm (200mm)	1.7cm (17mm)	22mm

211410	14g (2.1mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211416	14g (2.1mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211610	16g (1.7mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211616	16g (1.7mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211620	16g (1.7mm) x 19cm (190mm)	0.7cm (7mm)	11mm
211810	18g (1.2mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211816	18g (1.2mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211820	18g (1.2mm) x 19cm (190mm)	0.7cm (7mm)	11mm
212010	20g (0.9mm) x 9cm (90mm)	0.7cm (7mm)	11mm
212016	20g (0.9mm) x 15cm (150mm)	0.7cm (7mm)	11mm
212020	20g (0.9mm) x 19cm (190mm)	0.7cm (7mm)	11mm

(1)

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**B. How Supplied:**

The product is supplied sterile and non-pyrogenic unless the package has been opened or damaged. Sterilized using Ethylene Oxide. **For single use only. Do Not Reuse. Do Not Resterilize.**

**C. 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.

**D. Contraindications:**

Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have bleeding disorders.

**E. 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. **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.**
3. **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. 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® MONOPTY® Disposable Core Biopsy Instrument. 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:** If collecting multiple samples, inspect the needle for a damaged point, bent shaft or other imperfections after each sample is collected. Do not use the needle if any imperfection is noted.

**Note:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices 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.)

(2)

3. Never test the product by firing into the air. Damage may occur to the needle/cannula tip and/or patient/user injury.
4. 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.
5. Unusual force applied to the stylet or unusual resistance against the stylet while extended out of the supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with the needle function.

**G. 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.

**H. Equipment Required:**

- Appropriate imaging modality accessories
- Surgical gloves and drapes
- Local anesthetic as needed
- BARD® TRUGUIDE® Coaxial cannula (optional)
- Scalpel
- Sample collection container
- Other equipment as necessary

**I. Directions for Use:**

**BARD® MONOPTY® Disposable Core Biopsy Instrument preparation:**

Before using, inspect the needle for a damaged point, bent shaft or other imperfections that would prevent proper function. If the needle is damaged or bent, DO NOT USE.

1. Using aseptic technique, remove the instrument from its package.
2. Prepare the Monopty® instrument for biopsy by twisting the rotational mechanism at the end of the instrument. One-half turn will withdraw the cannula and lock it into place. An additional one-half turn will withdraw the stylet and lock it into place. The instrument is ready to fire. The arrow must be visible in the ready window prior to insertion into the patient.

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

**Biopsy Procedure:**

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Prepare the site as required. Adequate anesthesia should be administered prior to incision of the skin.
2. Verify instrument is energized (cocked).
3. Insert the tip of the needle prior to the lesion to be biopsied.
4. While maintaining the instrument's position and the needle orientation, depress the actuator button to cause both the stylet and the cannula to automatically advance.

ENGLISH

5. Remove needle from patient and rotate the end of the instrument one-half turn to withdraw the cannula and expose the biopsy specimen. Remove the specimen.
6. If additional biopsies of the same organ are required, withdraw the stylet by rotating the end of the instrument an additional one-half turn and repeat the procedure.

**Warranty:**

Bard Peripheral Vascular, Inc. 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.

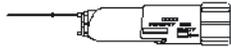
**TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO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

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An issue or revision date and 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 to see if additional product information is available.

Assembled in Mexico.

(4)



**BARD® MONOPTY® Disposable Core Biopsy Instrument**

Instrument de biopsie tissulaire jetable BARD® MONOPTY®  
BARD® MONOPTY® Einweg-Stanzbiopsieinstrument  
Strumento usa-e-getta per agobiopsie BARD® MONOPTY®  
Instrumento para biopsia de núcleo desechable BARD® MONOPTY®  
BARD® MONOPTY® wegwerpbaar kernbiopsie-instrument  
Dispositivo descartável para biopsia por punção tecidual BARD® MONOPTY®  
Αναλώσιμο εργαλείο βιοψίας με κόπτιουσα βελόνα BARD® MONOPTY®  
BARD® MONOPTY® kernbiopsieinstrument til engangsbrug  
BARD® MONOPTY® kambiopsieinstrument för engångsbruk  
Kertakäyttöinen BARD® MONOPTY® -paksuneulabiopsialaite  
BARD® MONOPTY® engangsinstrument til kjemebiopsi  
Jednorazowy przyrząd BARD® MONOPTY® do biopsji gruboigłowej  
BARD® MONOPTY® egyszer használatos vastagtű-biopsziás eszköz  
Jednorázový bioptický nástroj BARD® MONOPTY® pro „core“ biopsii  
BARD® MONOPTY® Tek Kullanımlık Kor Biyopsi Cihazı  
BARD® MONOPTY® 拋棄式空芯切片器械  
BARD® MONOPTY® 일회용 총생검 기구  
Одноразовый инструмент для толстоигльной биопсии BARD® MONOPTY®



**Attention, See Instructions For Use**

Attention, voir le mode d'emploi  
Achtung! Siehe Gebrauchsanweisung  
Attenzione, leggere le istruzioni per l'uso  
Atención: consulte las instrucciones de uso  
Let op, zie Gebruiksaanwijzing  
Atenção, consultar as instruções de utilização  
Προσοχή, βλ. Οδηγίες χρήσης  
Bemærk, Se brugsvejledningen  
Obs! Se bruksanvisningen  
Huomio! Lue käyttöohjeet  
NB! Se bruksanvisningen  
Uwaga: Należy zapoznać się z instrukcją użycia  
Figyelem, lásd a használati utasítást!  
Pozor, viz návod k použití  
Dikkat, Kullanım Talimatları'na bakınız  
注意・請參閱使用說明書  
주의, 사용 지침 참조  
Внимание! См. инструкции по применению



**Catalogue Number**

Numéro de catalogue  
Katalognummer  
Numero di catalogo  
Número de catálogo  
Catalogusnummer  
Número do catálogo  
Αριθμός καταλόγου  
Katalognummer  
Artikelnummer  
Luettelonumero  
Katalognummer  
Numer katalogowy  
Katalógusszám  
Katalogové číslo  
Katalog Numarası  
目錄編號  
카탈로그 번호  
Номер по каталогу



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**Do Not Resterilize**

Ne pas restériliser  
Nicht resterilisieren  
Non risterilizzare  
No reesterilizar  
Niet opnieuw steriliseren  
Não reesterilizar  
Μην επαναποστερωθείτε  
Må ikke resteriliseres  
Får ej omsteriliseras  
Et saa sterioida uudestaan  
Må ikke resteriliseres  
Nie sterylizować ponownie  
Ujraesterilizálni tilios  
Neprovdávajte resterilizaci  
Tekrar steriilize etmeyiniz  
請勿重複消毒  
재멸균하지 마십시오.  
Повторная стерилизация запрещена



**Lot Number**

Numéro de lot  
Chargennummer  
Numero di lotto  
Número de lote  
Lotnummer  
Número do Lote  
Αριθμός παρτίδας  
Lotnummer  
Lotnummer  
Eränumero  
Partinummer  
Numer partii  
Sorozatszám  
Číslo šarže  
Lot Numarası  
批號  
로트 번트  
Номер партии



**Use By**

Date limite d'utilisation  
Verwendbar bis  
Utilizzare entro  
Usar antes de  
Te gebruiken vóór  
Prazo de validade  
Ημερομηνία λήξης  
Arvendes før  
Utgångsdatum  
Käyttätävä ennen  
Brukes innen  
Termin ważności  
Felhasználható  
Datum použitelnosti  
Son Kullanım Tarihi  
有效期限  
유효기한  
Использовать до



**Single Use**

A usage unique  
Nur zum Einmalgebrauch  
Monouso  
Un solo uso  
Voor eenmalig gebruik  
Utilização única  
Πα μία χρήση μόνο  
Engangsbruk  
Engångsbruk  
Kertäkäyttöinen  
Til engangsbruk  
Tylko do jednorazowego użytku  
Egyszer használatos  
K jednorázovému použití  
Tek Kullanım İçindir  
僅供一次性使用  
1회 사용  
Однократного применения



**Sterilized Using Ethylene Oxide**

Stérilisé à l'oxyde d'éthylène  
Mit Ethylenoxid sterilisiert  
Sterilizzato con ossido di etilene  
Esterilizado con óxido de etileno  
Gesteriliseerd met behulp van ethyleenoxide  
Esterilizado por óxido de etileno  
Αποστερωμένο με οξείδιο του αιθυλενίου  
Steriliseret ved ethylenoxid  
Steriliserad med etylenoxid  
Steriloitu etyleenoksidilla  
Steriliseret med etylenoksid  
Produkt sterylizowany tlenkiem etylenu  
Etlénoxidáal sterilizálva  
Sterilizováno etylenoxidem  
Etilen Oksit Kullanılarak Sterilize Edilmiştir  
使用環氧乙烷消毒  
산화에틸렌으로 멸균 처리됨  
Стерилизовано этиленоксидом



**Manufacturer**

Fabricant  
Hersteller  
Produttore  
Fabricante  
Fabrikant  
Fabricante  
Κατασκευαστής  
Producent  
Tillverkare  
Valmistaja  
Produsent  
Produceant  
Gyártó  
Výrobce  
Üretici  
製造商  
제조사  
Производитель



**Non-Pyrogenic**

Apyrogène  
Pyrogenfrei  
Apirogeno  
Apirógeno  
Niet-pyrogeen  
Apirogénico  
Μη πυρετογόνο  
Pyrogenfri  
Pyrogenfri  
Pyrogeeniton  
Pyrogenfri  
Apirogenny  
Pirogénmentes  
Apyrogenní  
Pirojenik deðildir  
無熱原  
비발열성  
Апирогенно



**Peel to Open**

Peler pour ouvrir  
Zum Öffnen abziehen  
Per aprire staccare qui  
Retirar para abrir  
Trekken om te openen  
Descolar para abrir  
Αποκολλήστε για να ανοίξει  
Trækkes af for at åbne  
Riv upp för att öppna  
Repáise auki  
Trek av for å åpne  
Zerwać w celu otwarcia  
A kinyitáshoz húzza szét  
Otevířete stržením krycí fólie  
Soyarak Açınız  
撕下即可開啟  
벗겨서 개봉하십시오.  
Потянуть для открытия



**Gauge Size and Needle Length**

Diamètre et longueur de l'aiguille  
Größe (Gauge) und Nadellänge  
Calibro e lunghezza dell'ago  
Tamaño de calibre y longitud de aguja  
Naald dikte en -lengte  
Calibre e comprimento da agulha  
Μέγεθος gauge και μήκος βελόνας  
Gauge-størrelse og nålelængde  
Gaugestorlek och nållängd  
G-koko ja neulan pituus  
Gaugestørrelse og nålelengde  
Rozmiar i długość igły  
Vastagság és tűhosszúság  
Průměr a délka jehly  
Kalibre Βυγύκλιόγυ ve İğne Uzunluđu  
規格尺寸和針長  
게이지 크기 및 바늘 길이  
Калибр и длина иглы



**Length of Sample Notch**

Longueur d'encoche d'échantillonnage  
Länge der Probenkerbe  
Lunghezza dell'incavo per il campione  
Longitud de la muesca de la muestra  
Lengte van inkeping  
Comprimento do entalhe da amostra  
Μήκος εγκοπής δείγματος  
Længde af prøverille  
Prøvsårans längd  
Näyteloven pituus  
Lengden på prøvetakingshakket  
Długość wcięcia próbki  
Mintavévo horony hossza  
Délka drážky na vzorek  
Ömek Çentik Uzunluđu  
樣本切口長度  
샘플 노치 길이  
Длина выемки для образца



**Penetration Depth**

Profondeur de pénétration  
Penetrationstiefe  
Profondità di penetrazione  
Profundidad de penetración  
Penetratiediepte  
Profundidade de penetração  
Βάθος διείσδυσης  
Penetrationsdybde  
Penetrationsdjup  
Penetraatiosyvyyys  
Penetrasjonsdybde  
Głębokość penetracji  
Behatolási mélység  
Hĺoubka průniku  
Girış Derinliđi  
穿刺深度  
침투 깊이  
Глубина проникновения



**Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised**

Ne pas utiliser si la barrière de stérilisation ou l'emballage du produit est endommagé  
Bei beschädigter oder offener Sterilverpackung nicht verwenden  
Non utilizzare se la barriera di sterilizzazione del prodotto o la confezione sono compromessi  
No utilizar si la barrera de esterilización del producto o su envase están dañados  
Niet gebruiken wanneer de sterilisatiebarrière van het product of de verpakking is aangetast  
Não utilizar se a barreira de esterilização do produto ou respectiva embalagem estiverem comprometidas  
Μη χρησιμοποιείτε το προϊόν εάν έχει παραβιαστεί ο φραγμός αποστείρωσης ή η ακεραιότητα του  
Må ikke anvendes, hvis produktets steriliseringsbarriere eller emballagen er kompromitteret.  
Använd inte om produktens sterila barriär eller dess förpackning är skadad  
Ei saa käyttää, jos tuotteen steriloimisuojaus tai pakkaus on vaurioitunut  
Bruk ikke produktet hvis den sterile barrieren eller emballasjen er brutt  
Nie używać, jeśli naruszono sterylność produktu lub jego opakowanie  
Ne használja, ha a termék védő steril zár vagy a csomagolás sérült  
Nepoužívejte výrobek s narušenou sterilizační ochranou nebo porušeným obalem.  
Ürün Steril Bariyeri veya Ambalajı zarar görmüşse kullanmayın  
如果產品消毒屏障或包裝受損，請勿使用  
제품의 멸균 장벽이나 포장에 손상을 경우 사용하지 마십시오.  
Запрещается применять изделие, если стерильная упаковка или внешняя упаковка повреждена



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Bevollmächtigter in der Europäischen Gemeinschaft  
Rappresentante autorizzato nella Comunità Europea  
Representante autorizado en la Comunidad Europea  
Gemachtigde binnen de Europese Gemeenschap  
Representante autorizado na Comunidade Europeia  
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Autoriseret repræsentant i Det Europæiske Fællesskab  
Auktoriserad representant inom EG  
Valtuutettu edustaja Euroopan yhteisössä  
Autorisert representant i EU  
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Meghatalmazott képviselő az Európai Közösségekben  
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Tempe, AZ 85281  
USA

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1-800-321-4254  
FAX: 1-480-966-7062  
1-800-440-5376  
[www.bardbiopsy.com](http://www.bardbiopsy.com)



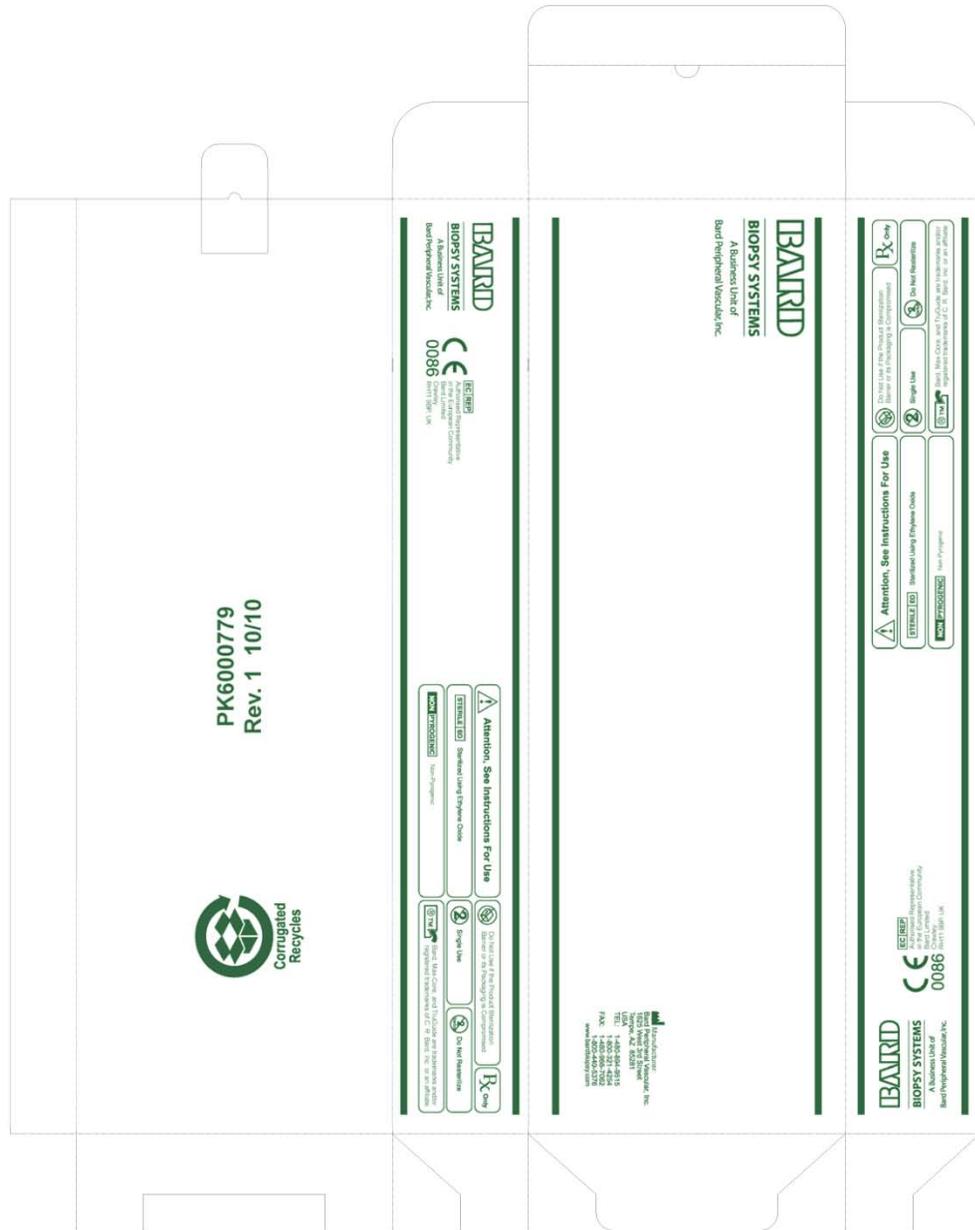
**Authorised Representative  
in the European Community  
Bard Limited**

Forest House  
Tilgate Forest Business Park  
Brighton Road, Crawley  
West Sussex  
RH11 9BP, UK

**BAIRD**

**BIOPSY SYSTEMS**

PK1280000 Rev. 0 05/12



Box (1212XX Codes)

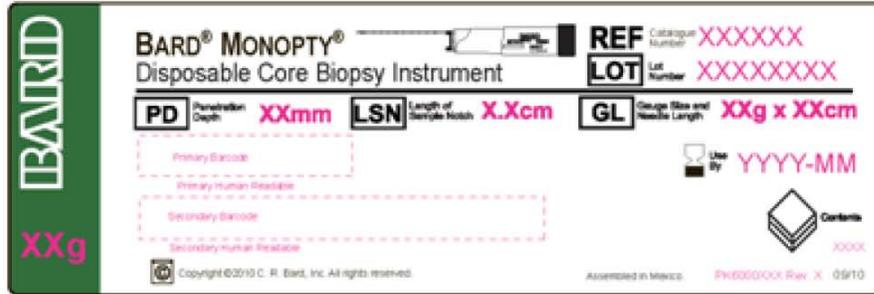


Box ( 1214XX-1220XX, 21XXXX Codes)



Tray Lid

Variable Fields



Box Label



Multi-language Label

Variable Fields



Tray Lid Label



All Products > Core Needle Biopsy Products > BARD® MONOPTY® Disposable Core Biopsy Instrument

COMPLEMENTARY PRODUCTS

MAX-CORE Disposable Core Biopsy Instrument

CONTACT US

I Want To Order

I Need More Information

INDICATIONS FOR USE

Download IFU



THE CONVENIENCE OF A DISPOSABLE WITH CONSISTENTLY ACCURATE CORE SAMPLES

- Ease of single use combined with the security that comes with a Bard product
- Penetration depths of 11mm or 22mm offer you maximum procedural versatility
- Lightweight handle provides you greater handling and control
- Color coding promotes accurate needle gauge identification
- Compatibility with BARD® TRUGUID® Coaxial Biopsy Needle enhances efficiency and accuracy



22mm PENETRATION DEPTH	GAUGE x LENGTH (cm)	COAXIAL LENGTH (cm)	COAXIAL ORDER NO.
● 121210	12 x 10	7.8	C1210A
● 121216	12 x 16	13.8	C1216A
● 121410	14 x 10	7.8	C1410A
● 121416	14 x 16	13.8	C1416A
● 121610	16 x 10	7.8	C1610A
● 121616	16 x 16	13.8	C1616A
● 121620	16 x 20	17.8	C1620A
● 121810	18 x 10	7.8	C1810A
● 121816	18 x 16	13.8	C1816A
● 121820	18 x 20	17.8	C1820A
● 122010	20 x 10	7.8	C2010A
● 122016	20 x 16	13.8	C2016A
● 122020	20 x 20	17.8	C2020A

11mm PENETRATION DEPTH	GAUGE x LENGTH (cm)	COAXIAL LENGTH (cm)	COAXIAL ORDER NO.
● 211410	14 x 9	7.8	C1410A
● 211416	14 x 15	13.8	C1416A
● 211610	16 x 9	7.8	C1610A
● 211616	16 x 15	13.8	C1616A
● 211620	16 x 19	17.8	C1620A
● 211810	18 x 9	7.8	C1810A
● 211816	18 x 15	13.8	C1816A
● 211820	18 x 19	17.8	C1820A
● 212010	20 x 9	7.8	C2010A
● 212016	20 x 15	13.8	C2016A
● 212020	20 x 19	17.8	C2020A

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**Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument (English Only)**

**BARD® MAX-CORE®**  
**Disposable Core Biopsy Instrument**  
**Instructions for Use**



BARD® MAX-CORE® Instrument pour biopsie à usage unique  
Mode d'emploi

BARD® MAX-CORE® Einweg-Biopsieinstrument  
Gebrauchsanweisung

BARD® MAX-CORE® Strumento Usa-e-Getta per Agobiopsia  
Istruzioni per l'Uso

BARD® MAX-CORE® Instrumento de Biopsia Desechable  
Instrucciones de uso

BARD® MAX-CORE® Biopsie-instrument voor eenmalig gebruik  
Gebruiksaanwijzing

BARD® MAX-CORE® Instrumento de Biopsia Descartável  
Instruções de Utilização

BARD® MAX-CORE® Αναλώσιμο εργαλείο βιοψίας δια βελόνας  
Οδηγίες χρήσης

BARD® MAX-CORE® Biopsiinstrument til engangsbrug  
Brugervejledning

BARD® MAX-CORE® Biopsiinstrument för engångsbruk  
Bruksanvisning

Kertakäyttöinen BARD® MAX-CORE® -paksuneulabiopsialaite  
Käyttöohjeet

BARD® MAX-CORE® biopsiinstrument til éngangsbruk  
Bruksanvisning

Przyrząd do biopsji jednorazowego użytku BARD® MAX-CORE®  
Instrukcja użycia

BARD® MAX-CORE® Egyszer Használatos Biopsziás Eszköz  
Használati utasítás

BARD® MAX-CORE® Jednorázový nástroj pro biopsii  
Pokyny k použití

BARD® MAX-CORE® Tek Kullanımlık Kor Biyopsi Aleti Biyopsi Aygıtı  
Kullanma Talimatı

BARD® MAX-CORE® 拋棄式空芯切片器械  
使用說明

BARD® MAX-CORE® 일회용 총생검 기구  
사용 지침

Одноразовый инструмент для толстоигольной биопсии BARD® MAX-CORE®  
Инструкции по применению

Jednorázový nástroj na hrubohlovú biopsiu BARD® MAX-CORE®  
Návod na použitie

**BARD**  
**BIOPSY SYSTEMS**

ENGLISH

**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® Max-Core® Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge and Green=14 gauge.

Catalogue Number	Gauge Size and Needle Length	Length of Sample Notch	Penetration Depth
MC1410	14g (2.1mm) x 10cm (100mm)	1.9cm (19mm)	22mm
MC1416	14g (2.1mm) x 16cm (160mm)	1.9cm (19mm)	22mm
MC1610	16g (1.7mm) x 10cm (100mm)	1.9cm (19mm)	22mm
MC1616	16g (1.7mm) x 16cm (160mm)	1.9cm (19mm)	22mm
MC1810	18g (1.2mm) x 10cm (100mm)	1.8cm (18mm)	22mm
MC1816	18g (1.2mm) x 16cm (160mm)	1.8cm (18mm)	22mm
MC1820	18g (1.2mm) x 20cm (200mm)	1.8cm (18mm)	22mm
MC1825	18g (1.2mm) x 25cm (250mm)	1.8cm (18mm)	22mm
MC2010	20g (0.9mm) x 10cm (100mm)	1.8cm (18mm)	22mm
MC2016	20g (0.9mm) x 16cm (160mm)	1.8cm (18mm)	22mm
MC2020	20g (0.9mm) x 20cm (200mm)	1.8cm (18mm)	22mm

**B. How Supplied:**

The product is supplied sterile and non-pyrogenic unless the package has been opened or damaged. **Sterilized using Ethylene Oxide. For single use only. Do Not Reuse. Do Not Resterilize.**

**C. 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.

**D. Contraindications:**

Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding problem.

**E. 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. 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.
3. The Bard® Max-Core® Biopsy Instrument 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 indeterminate 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.
4. Do not resterilize the Bard® Max-Core® Biopsy Instrument. 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:** If collecting multiple samples, inspect the needle for damaged point, bent shaft or other imperfections after each sample is collected. Do not use needle if any imperfection is noted.

**Note:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and with 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.)
3. Never test the product 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 supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with the needle function.

**G. 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 signs or symptoms of air embolism.

**H. Equipment Required:**

- Appropriate imaging modality accessories
- Surgical gloves and drapes
- Local anesthetic
- BARD® TRUGUIDE® Coaxial Cannula (optional)
- Scalpel
- Sample collection container
- Other equipment as necessary

**I. Directions for Use:**

**BARD® Max-Core® Biopsy Instrument preparation:**

Before using, inspect the needle for damaged point, bent shaft or other imperfections that would prevent proper function. If the needle is damaged or bent, DO NOT USE.

1. Using aseptic technique, remove the Instrument from its package. See Figure 1.

**Note:** To remove the protective needle sheath and yellow guard, you must energize (cock) Instrument.

2. Energize (cock) Instrument by pulling back on the top slide to withdraw the cannula and lock in place. See Figure 2. Then pull back on the bottom slide to withdraw the stylet and lock in place. See Figure 3. Remove protective needle sheath and yellow guard. Instrument is ready to fire when both slides are locked back.

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

**Biopsy Procedure:**

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Prepare site as required. Adequate anesthesia should be administered prior to incision of the skin.
2. Verify Instrument is energized (cocked). See Figure 3.

**Note:** Do not place fingers in front of cocking slides once Instrument is energized (cocked). Impeding cocking slides' movement will impact functionality.

3. Insert tip of needle to the point to be biopsied.
4. While maintaining Instrument's position and the needle orientation, depress the rear actuator button, or push the side actuator forward (direction of arrow), to cause both stylet and cannula to automatically advance.
5. Remove needle from patient and pull back on the top slide to withdraw the cannula and expose the biopsy specimen (See Figure 2). Remove the specimen.
6. If additional biopsies are required, pull back on the bottom slide to withdraw the stylet and repeat the procedure.

Figure 1



- As Packaged (Protective Needle Sheath and Yellow Guard Not Shown)
- Instrument **Not** Energized (Cocked)
- **Not** Ready to Fire

Figure 2



- Top Slide Locked Back
- Biopsy Sample Notch Exposed

Figure 3



- Top Slide and Bottom Slide Locked Back
- Instrument Energized (Cocked)
- Ready to Fire

**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.

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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 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 to see if additional product information is available.

Assembled in Mexico.



**Bard® Max-Core® Disposable Core Biopsy Instrument**  
 Bard® Max-Core® Instrument pour biopsie à usage unique  
 Bard® Max-Core® Einweg-Biopsieinstrument  
 Bard® Max-Core® Strumento Usa-e-Getta per Agobiopsia  
 Bard® Max-Core® Instrumento de Biopsia Desechable  
 Bard® Max-Core® Biopsie-instrument voor eenmalig gebruik  
 Bard® Max-Core® Instrumento de Biopsia Descartável  
 Bard® Max-Core® Αβαλώσιμο εργαλείο βιοψίας δια βελόνας  
 Bard® Max-Core® Biopsieinstrument til engangsbrug  
 Bard® Max-Core® Biopsieinstrument för engångsbruk  
 Kertakäyttöinen Bard® Max-Core® -paksuneulabiopsialaite  
 Bard® Max-Core® biopsieinstrument til engangsbruk  
 Przyrząd do biopsji jednorazowego użytku Bard® Max-Core®  
 Bard® Max-Core® Egyszer Használatos Biopsziás Eszköz  
 Bard® Max-Core® Jednorázový nástroj pro biopsii  
 Bard® Max-Core® Tek Kullanımlık Kor Biyopsi Aleti Biyopsi Aygıtı  
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 Bard® Max-Core® 일회용 총생검 도구  
 Одноразовый инструмент для толстоигольной биопсии  
 Bard® Max-Core®  
 Jednorázový nástroj na hruboihlovi biopsii Bard® Max-Core®



**Attention, See Instructions For Use**  
 Attention, voir le mode d'emploi  
 Achtung! Siehe Gebrauchsanweisung  
 Attenzione, leggere le istruzioni per l'uso  
 Atención: consulte las instrucciones de uso  
 Let op, zie Gebruiksaanwijzing  
 Atenção, consulte as Instruções de Utilização  
 Προσοχή, Βλ. Οδηγίες Χρήσης  
 Bemærk, Se brugervejledning  
 Obs! Se bruksanvisningen  
 Huomio! Lue käyttöohjeet  
 OBS, se Bruksanvisning  
 Uwaga: Należy zapoznać się z instrukcją użytkowania  
 Figyelem, lásd a használati utasítást  
 Pozor, viz pokyny k použití  
 Dikkat, Kullanma Talimatına Bakınız  
 注意，請參閱使用說明書  
 주의, 사용 지침 참조  
 Внимание! См. инструкции по применению  
 Pozor, pozri návod na použitie



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**GL Gauge Size and Needle Length**  
 Taille de la jauge et longueur de l'aiguille  
 Größe (Gauge) und Nadellänge  
 Calibro e lunghezza dell'ago  
 Tamaño de calibre y longitud de aguja  
 Gauge-maat en naaldlengte  
 Calibre e comprimento da agulha  
 Μέγεθος gauge και μήκος βελόνας  
 Gauge-størrelse og nålelængde  
 Gaugestorlek och nållängd  
 G-koko ja neulan pituus  
 Nålens diameter og lengde  
 Rozmiar i długość igły  
 Vastagság méret és tű hosszúság  
 Průměr a délka jehly  
 Gauge Büyüklüğü ve İğne Uzunluğu  
 規格尺寸和針長  
 게이지 크기 및 바늘 길이  
 Калибр и длина иглы  
 Velikost a délka ihly



**LSN Length of Sample Notch**  
 Longueur d'encoche d'échantillon  
 Länge der Probenkerbe  
 Lunghezza dell'incavo per il campione  
 Longitud de la muesca de la muestra  
 Lengte van inkeping  
 Comprimento do entalhe da amostra  
 Μήκος εγκοπής δείγματος  
 Længde på prøverille  
 Provsårens langd  
 Näyteloven pituus  
 Lengde på prøveinnsnitt  
 Długość karbu próbki  
 Mintavető horony hossza  
 Délka drážky pro vzorek  
 Ömek Çentik Uzunluğu  
 樣本切口長度  
 샘플 notch 길이  
 Длина выемки для образца  
 Dĺžka priestoru pre vzorku



**PD Penetration Depth**  
 Profondeur de pénétration  
 Penetrationstiefe  
 Profondità di penetrazione  
 Profundidad de penetración  
 Penetratiediepte  
 Profundidade de penetração  
 Βάθος διείσδυσης  
 Penetrationsdybde  
 Penetrationsdjup  
 Penetraatiosyvyys  
 Penetreringsdybde  
 Głębość penetracji  
 Behatolási mélység  
 Hlubka prúniku  
 Penetrasyon Derinliği  
 穿刺深度  
 침투 깊이  
 Глубина проникновения  
 Hĺbka penetrácie



**LOT Lot Number**  
 Numéro de lot  
 Lot Nummer  
 Numero di lotto  
 Número de lote  
 Lotnummer  
 Número do lote  
 Αριθμός παρτίδας  
 Lot-number  
 Lot-number  
 Eränumero  
 Lot-number  
 Numer serii  
 Tételszám  
 Číslo šarže  
 Parti Numarası  
 批號  
 로트 번호  
 Номер партии  
 Číslo šarže



**Use By**

À utiliser avant  
 Verwendbar bis  
 Utilizzare entro  
 Usar antes de  
 Te gebruiken vóór  
 Prazo de validade  
 Ημερομηνία λήξης  
 Anvendes før  
 Utgångsdag  
 Käyttävä ennen  
 Brukes innen  
 Termin ważności  
 Felhasználható  
 Datum použití  
 Son Kullanma Tarihi  
 有効期限  
 유효기한  
 Исползовать до  
 Spotrebovat' do



**Do not use if the product sterilization barrier or its packaging is compromised**

Ne pas utiliser si la barrière de stérilisation ou l'emballage du produit sont endommagés  
 Bei beeinträchtigtem Sterilschutz oder beschädigter Verpackung des Produkts nicht verwenden  
 Non usare il prodotto se la barriera sterile è compromessa o la confezione è danneggiata  
 No utilice el producto si la barrera de esterilización o su envase no están en perfecto estado  
 Niet gebruiken wanneer de sterilisatiebarrière van het product of de verpakking is aangetast  
 Não utilizar se a barreira de esterilização do produto ou respectiva embalagem estiverem comprometidas  
 Μη χρησιμοποιείτε το προϊόν εάν έχει παραβιαστεί ο φραγμός αποστείρωσης ή η συσκευασία του  
 Må ikke bruges, hvis produktets sterilisationsbarriere eller emballage er beskadiget  
 Använd inte produkten om sterilbarriären är bruten eller förpackningen öppnad eller trasig  
 Ei saa käyttää, jos tuotteen sterilointisuojaus tai pakkaus on vaurioitunut  
 Bruk ikke produktet hvis den sterile barrieren eller emballasjen er brutt  
 Nie używać, jeśli naruszono sterylność produktu lub jego opakowanie  
 Ne használja, ha a termékét védő steril zár vagy a csomagolás sérült  
 Pokud je narušena sterilní ochrana nebo poškozen obal, výrobek nepoužívejte  
 Urun steril bariyeri veya ambalajı zarar görmüşse kullanmayın  
 如果產品消毒屏障或包裝受損，請勿使用  
 제품의 멸균 장벽이나 포장이 손상된 경우 사용하지 마십시오.  
 Запрещается применять изделие, если его стерильная упаковка или внешняя упаковка повреждены  
 Nepoužívajte, ak je sterilná bariéra produktu alebo jeho obal porušený



**Sterilized Using Ethylene Oxide**

Stérilisé à l'oxyde d'éthylène  
 Sterilisiert mit Ethylenoxid  
 Sterilizzato mediante ossido di etilene  
 Esterilizado mediante óxido de etileno  
 Gesteriliseerd met behulp van ethyleenoxide  
 Esterilizado por óxido de etileno  
 Αποστειρωμένο με αιθυλενοξείδιο  
 Steriliseret med ethylenoxid  
 Steriliserad med etylenoxid  
 Steriloitu etyleenioksidilla  
 Sterilisert med etylenoksid  
 Produkt sterylizowany tlenkiem etylenu  
 Etilén-oxidál sterilizálva  
 Sterilizovano etylenoxidem  
 Etilen Oksit ile Sterilize Edilmiştir  
 使用环氧乙烷消毒  
 산화에틸렌으로 멸균 처리됨  
 Стерилизовано этиленоксидом  
 Sterilizované etylénoxidom



**Non-Pyrogenic**

Apyrogène  
 Pyrogenfrei  
 Apirogeno  
 Apirógeno  
 Niet-pyrogeen  
 Apirogénico  
 Μη πυρετογόνο  
 Apyrogen  
 Pyrogenfri  
 Pyrogeeniton  
 Pyrogenfri  
 Apirogenny  
 Pirogénmentes  
 Apyrogenní  
 Pirojenik deǵildir  
 無熱原  
 비발열성  
 Апиrogenно  
 Nepyrogénne



**Single Use**

À usage unique  
 Nur zum Einmalgebrauch  
 Monouso  
 Un solo uso  
 Voor eenmalig gebruik  
 Utilização única  
 Για μία χρήση μόνο  
 Engangsbrug  
 Engångsbruk  
 Kertakäyttöinen  
 Éngangsbruk  
 Tylko do jednorazowego użytku  
 Egyszerhasználatos  
 K jednorázovému použiti  
 Tek Kullanım İçindir  
 僅供一次性使用  
 1회 사용  
 Однократного применения  
 Na jednorazové použitie



**Manufacturer**

Fabricant  
 Hersteller  
 Fabricante  
 Fabricante  
 Fabrikant  
 Fabricante  
 Κατασκευαστής  
 Producent  
 Tillverkare  
 Valmistaja  
 Fabrikant  
 Producent  
 Gyártó  
 Výrobce  
 Uretici  
 製造商  
 제조사  
 Производителъ  
 Výrobca



**Do Not Resterilize**

Ne pas restériliser  
 Nicht reesterilisieren  
 Non risterilizzare  
 No reesterilizar  
 Niet opnieuw steriliseren  
 Não reesterilizar  
 Μη επαναποστειρώνετε  
 Må ikke reesteriliseres  
 Får ej omsteriliseras  
 Ei saa steriloida uudestaan  
 Skal ikke reesteriliseres  
 Nie sterylizować ponownie  
 Ne sterilizálja újra  
 Neprovádajte reesterilizaci  
 Tekrar Sterilize Etmeyin  
 請勿重複消毒  
 재멸균하지 마십시오.  
 Повторная стерилизация запрещена  
 Nesterilizujte opakovane



**Lift Here**

Soulevre ici  
Hier anheben  
Sollevare qui  
Levantar aquí  
Hier optillen  
Levantar aqui  
Ανασηρώστε εδώ  
Løft her  
Lyft här  
Nosta tästä  
Løft her  
Przy podnoszeniu chwycić tutaj  
Itt emelje föl  
Zde zdvihnete  
Buradan Kaldırın  
掀起此處  
여기를 들어 올리십시오  
Поднять здесь  
Tu nadvihnite



**Authorized Representative in the European Community**

Représentant autorisé au sein de la Communauté européenne  
Bevollmächtigter in der Europäischen Gemeinschaft  
Rappresentante autorizzato nella Comunità Europea  
Representante autorizado en la Comunidad Europea  
Gemachtigde binnen de Europese Gemeenschap  
Representante autorizado na Comunidade Europeia  
Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα  
Autoriseret repræsentant i Det Europæiske Fællesskab  
Auktoriserad representant inom EG  
Valtuutettu edustaja Euroopan yhteisössä  
Autorisert representant i EU  
Autoryzowany przedstawiciel na terenie Unii Europejskiej  
Meghatalmazott képviselő az Európai Közösségekben  
Autorizovaný zástupce v Evropské unii  
Avrupa Topluluğu Yetkili Temsilcisi  
歐洲共同體的授權代表  
유럽 공동체 내의 인증받은 대리업체  
Уполномоченный представитель в Европейском сообществе  
Oprávněný zástupca v Európskom spoločenstve



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Bard, Max-Core a TruGuide sú ochranné známky a/alebo registrované ochranné známky spoločnosti C. R. Bard, Inc. alebo jej pridruženej spoločnosti.



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 **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](http://www.bardbiopsy.com)

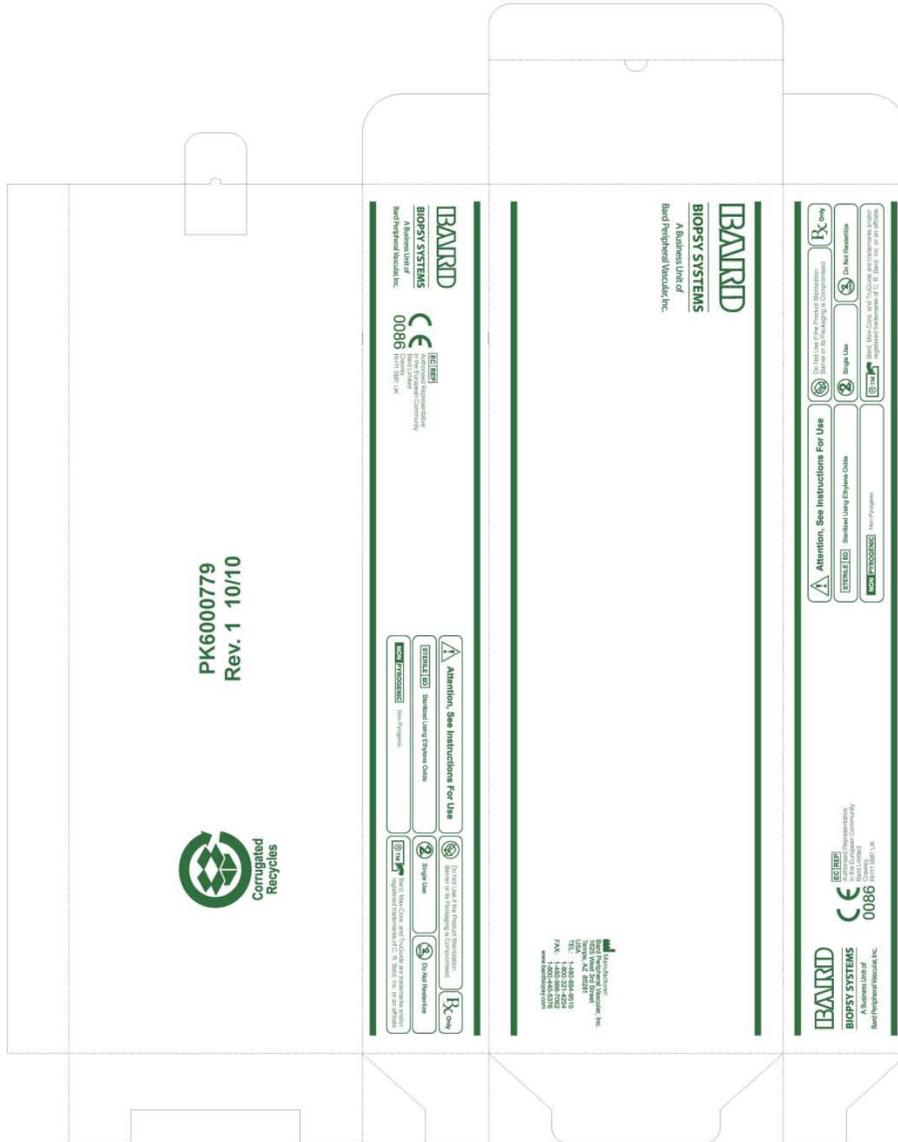
 **EC REP**  
**Authorised Representative  
in the European  
Community**  
**Bard Limited**  
Forest House  
Tilgate Forest Business Park  
Brighton Road, Crawley  
West Sussex  
RH11 9BP, UK

**BAIRD**  

---

**BIOPSY SYSTEMS**

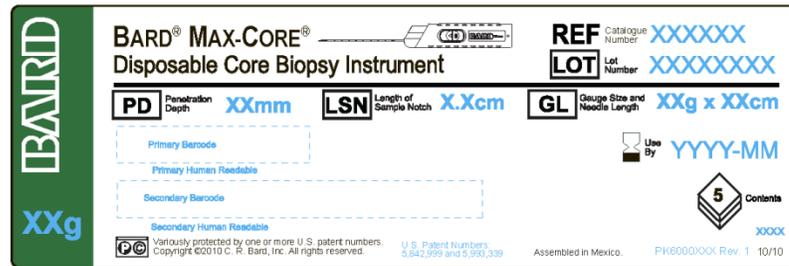
PK1279900 Rev. 0 05/12



Box



Variable fields

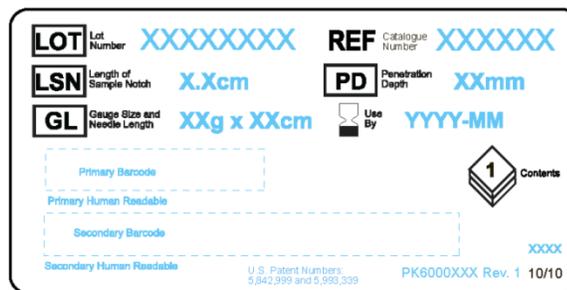


Box Label



Multi-language Label

Variable fields



Tray Lid Label



All Products > Core Needle Biopsy Products > BARD® MAX-CORE® Disposable Core Biopsy Instrument

COMPLEMENTARY PRODUCTS

[Coaxial Biopsy Needles](#)

[CONTACT US](#)

[I Want To Order](#)

[I Need More Information](#)

[INDICATIONS FOR USE](#)

[Download IFU](#)



**THE CONVENIENCE OF A DISPOSABLE. THE EASE OF ONE-HANDED COCKING.**

- One-handed cocking and lightweight ergonomic design improve both handling and control
- Features 22mm 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



ORDER NUMBER	GAUGE x LENGTH (cm)	COAXIAL LENGTH (cm)	COAXIAL ORDER NO.
● MC1410	14 x 10	7.8	C1410A
● MC1416	14 x 16	13.8	C1416A
● MC1610	16 x 10	7.8	C1610A
● MC1616	16 x 16	13.8	C1616A
● MC1810	18 x 10	7.8	C1810A
● MC1816	18 x 16	13.8	C1816A
● MC1820	18 x 20	17.8	C1820A
● MC1825	18 x 25	----	----
● MC2010	20 x 10	7.8	C2010A
● MC2016	20 x 16	13.8	C2016A
● MC2020	20 x 20	17.8	C2020A

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<http://www.bardbiopsy.com/products/max-core.php>

1/2/2014

## Appendix 5: Indications for Use Statement

## Indications for Use

510(k) Number (if known): K133948

Device Name: Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument  
Bard<sup>®</sup> 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.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

## Appendix 6: FDA Communication

**Addition of Needle Lengths Letter (dated June 26, 1995)  
and FDA Concurrence Letter (dated July 26, 1995)**

C. R. Bard, Inc.  
8195 Industrial Blvd.  
Covington, GA 30209

**BARD**

June 26, 1995

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
510(k) Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

Attention: Ms. Laura Byrd, DRAERD, Urology Branch

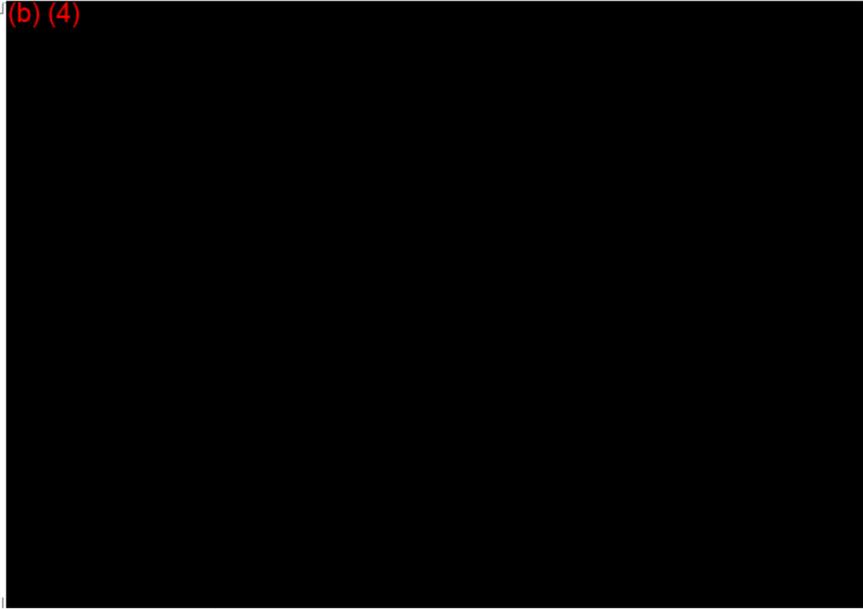
Re: #K922939: Addition of 25cm and 30cm needle lengths to Bard®  
Monopty® Disposable Biopsy Instrument product line

Per conversations between Laura Byrd of FDA and Steven Mercereau of C.R. Bard, Inc. on March 14, 1995 and between Laura Byrd of FDA and Donna Wilson of C.R. Bard, Inc. on May 16, 1995, this letter is being submitted as an amendment to a concurred 510(k) file, #K922939. This 510(k) referenced needles in lengths of 10, 16 and 20cm. We would like to add the lengths of 25 and 30cm to the product line. Therefore, we ask that you consider the information included in this letter, make a determination as to whether a new 510(k) is required for this change, and if no new 510(k) is required that you include a copy of this letter in the 510(k) file as notice of the additional needle lengths. We also request that you provide us with written notification of your decision.

Per our interpretation, the April 1994 draft guidance document regarding when to file a 510(k) states that the addition of product sizes (dimensions) outside the previously cleared, via 510(k), ranges would require the submission of a new 510(k) for the new dimensions. However, we feel that this document may allow some flexibility in that it seems reasonable to assume that the requirement for filing a new 510(k) when going outside the previously cleared dimensional ranges would apply only to the more critical

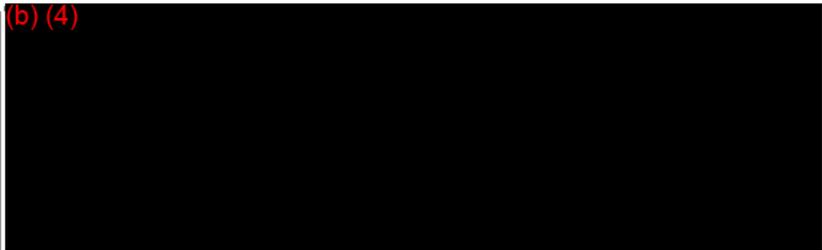
device dimensions for which a change could significantly effect device performance in terms of safety or effectiveness.

(b) (4)



Bard intends to market Monopty and Max•Core™ Disposable Biopsy Instruments with needles in lengths of 25cm and 30cm for the 16 gauge and 18 gauge needle lines only as these are the needles sizes for which additional length would be useful to the physician (see attached Equivalency Table, Part IX). This addition would be for the entire line of Monopty Disposable Biopsy Instruments and Max•Core Disposable Biopsy Instruments.

(b) (4)



biopsy instrument offers ergonomic enhancement in terms of potential one-handed cocking of the device, an additional firing button or trigger to allow firing with either thumb or finger and changes to the outer shape of the device that will prevent it from rolling off hard surfaces.

It should be noted that there are no new claims or new indications for use associated with the longer length biopsy needles and no changes in materials of construction. Medical risk assessments, engineering reviews and FMEAs (Failure Modes and Effects Analyses) confirm that lengthening the 16 gauge and 18 gauge needles to 25cm or 30cm does not significantly effect device safety or effectiveness.

C.R. Bard, Inc. has not publicly disclosed or acknowledged that fact of its intent to market the longer needles to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. Per 21 CFR 807.95(b), C. R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

Should you have any questions regarding this letter, please call me at 404-784-6135.

Sincerely,



Donna J. Wilson  
Director, Regulatory Affairs

Enclosure

CERTIFIED MAIL

Bard and Monopty are registered trademarks of C.R. Bard, Inc. or an affiliate.

Max•Core is a trademark of C.R. Bard, Inc. or an affiliate.

CONFIDENTIAL

Equivalency Table  
 Comparison Charts of Some Currently Marketed Products  
 and Proposed Bard Product

Current Bard Product Part I #K922939

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A		N/A	N/A	N/A			N/A	N/A		N/A	N/A
13 Gauge	N/A													
14 Gauge				X				X	X					
15 Gauge	N/A													
16 Gauge				X				X	X					
18 Gauge				X				X	X					
19 Gauge	N/A													
20 Gauge				X				X	X					

BIP Company Product Part II #K934370

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A			N/A	N/A			N/A		N/A		N/A
13 Gauge					X			X						
14 Gauge				X	X			X	X					
15 Gauge	N/A													
16 Gauge				X	X			X	X		X			
18 Gauge				X	X			X	X		X		X	
19 Gauge	N/A													
20 Gauge				X	X			X	X					

Biopsy Needle Co. Product Part III

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A		N/A	N/A	N/A			N/A	N/A		N/A	N/A
13 Gauge	N/A													
14 Gauge				X				X						
15 Gauge	N/A													
16 Gauge	N/A													
18 Gauge				X				X	X			X		
19 Gauge	N/A													
20 Gauge				X				X	X					

Boston Scientific Corp. Product Part IV

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
					N/A						N/A		N/A	
13 Gauge	N/A													
14 Gauge				X		X								
15 Gauge						X								
16 Gauge	N/A													
18 Gauge				X		X				X				
19 Gauge	N/A													
20 Gauge						X								

Cook Inc. Product Part V

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
				N/A	N/A		N/A	N/A		N/A	N/A	N/A	N/A	
13 Gauge	N/A													
14 Gauge		X	X			X			X					
15 Gauge		X	X			X			X					
16 Gauge		X	X			X			X					X
18 Gauge		X	X			X			X					X
19 Gauge		X	X			X			X					X
20 Gauge		X	X			X			X					

CONFIDENTIAL

Equivalency Table  
 Comparison Charts of Some Currently Marketed Products  
 and Proposed Bard Product

Inrad Product

Part VI

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge						X							
15 Gauge	N/A												
16 Gauge						X		X					
18 Gauge						X		X			X		
19 Gauge	N/A												
20 Gauge						X		X					

Manan Medical Products, Inc. Product

Part VII

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X	X					
15 Gauge	N/A												
16 Gauge			X				X	X					
18 Gauge			X				X	X			X		
19 Gauge	N/A												
20 Gauge			X				X	X					

Medical Device Technologies, Inc. Product

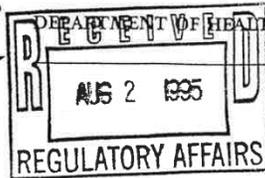
Part VIII

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X						
15 Gauge	N/A												
16 Gauge			X				X	X					
18 Gauge			X				X	X			X		
19 Gauge	N/A												
20 Gauge							X	X					

Proposed Bard Product

Part IX

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X	X					
15 Gauge	N/A												
16 Gauge			X				X	X			X	X	
18 Gauge			X				X	X			X	X	
19 Gauge	N/A												
20 Gauge			X				X	X					



JUL 26 1995

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Donna J. Wilson  
Director, Regulatory Affairs  
C. R. Bard, Inc.  
8195 Industrial Boulevard  
Covington, Georgia 30209

Re: K922939  
Addition of 25cm and 30cm Needle  
Lengths to Bard® Monopty® Disposable  
Biopsy Instrument Product Line  
Dated: June 26, 1995  
Received: June 30, 1995

Dear Ms. Wilson:

We have reviewed the information dated June 26, 1995, regarding the 510(k) notification K922939 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Addition of Echogenicity Claim Letter (dated July 18, 1996)  
and FDA Concurrence Letter (dated September 3, 1996)**

Bard, Inc.  
195 Industrial Blvd.  
Covington, GA 30209

July 18, 1996

**BARD**

Ms. Laura Byrd  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
DRAERD, Urology Branch (HFZ-470)  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: #K922939: Bard Monopty Disposable Biopsy Instrument Product Line -  
Echogenic claim

Dear Ms. Byrd:

Per conversations between Laura Byrd of FDA and Donna J. Wilson of C. R. Bard, Inc. on January 19, 1996, voice mail message from Laura Byrd of FDA the week of May 6, 1996, and subsequent conversations between FDA and Bard, this letter is being submitted as an amendment to a concurred 510(k) file, #K922939. This 510(k) referenced

(b) (4)

C. R. Bard, Inc. intends to market Monopty Disposable Biopsy Instruments (including the ergonomically enhanced Max-Core models) with the same needle dimensions (gauge and length) and made using the same materials as described in #K922939 and the June 16, 1995, letter to file. (b)(4) Product Specs

(b) (4)

(b) (4)

(b) (4)

The Indications for Use remain the same but the description of the needles and associated marketing claims would contain the words "echogenic" and "enhanced echogenicity", "significantly more visible" and similar terms indicating enhanced visualization during ultrasound procedures.

Therefore, we ask that you consider the information included in this letter, make a determination as to whether a new 510(k) is required for this change, and if no new 510(k) is required that you include a copy of this letter in the 510(k) file (#K922939) as notice of the Bard Monopty/Max-Core Disposable Biopsy Instrument Product Line echogenic needle claim. We also request that you provide us with written notification of your decision.

It should be noted that other than a claim of echogenicity or enhanced visualization during ultrasound procedures there are no new claims or new indications for use associated with the echogenic needles and no significant changes in materials of construction. No changes in design that could significantly affect safety or effectiveness have been made since

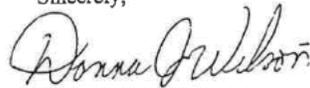
(b)(4) Product Specs

(b) (4)

C. R. Bard, Inc. has not publicly disclosed or acknowledged that fact of its intent to market the Bard Monopty and Max-Core product lines with an echogenic claim to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. Per 21 CFR 807.95(b), C. R. Bard Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

Should you have any questions regarding this letter, please call me at 770-784-6135.

Sincerely,



Donna J. Wilson  
Director, Regulatory Affairs

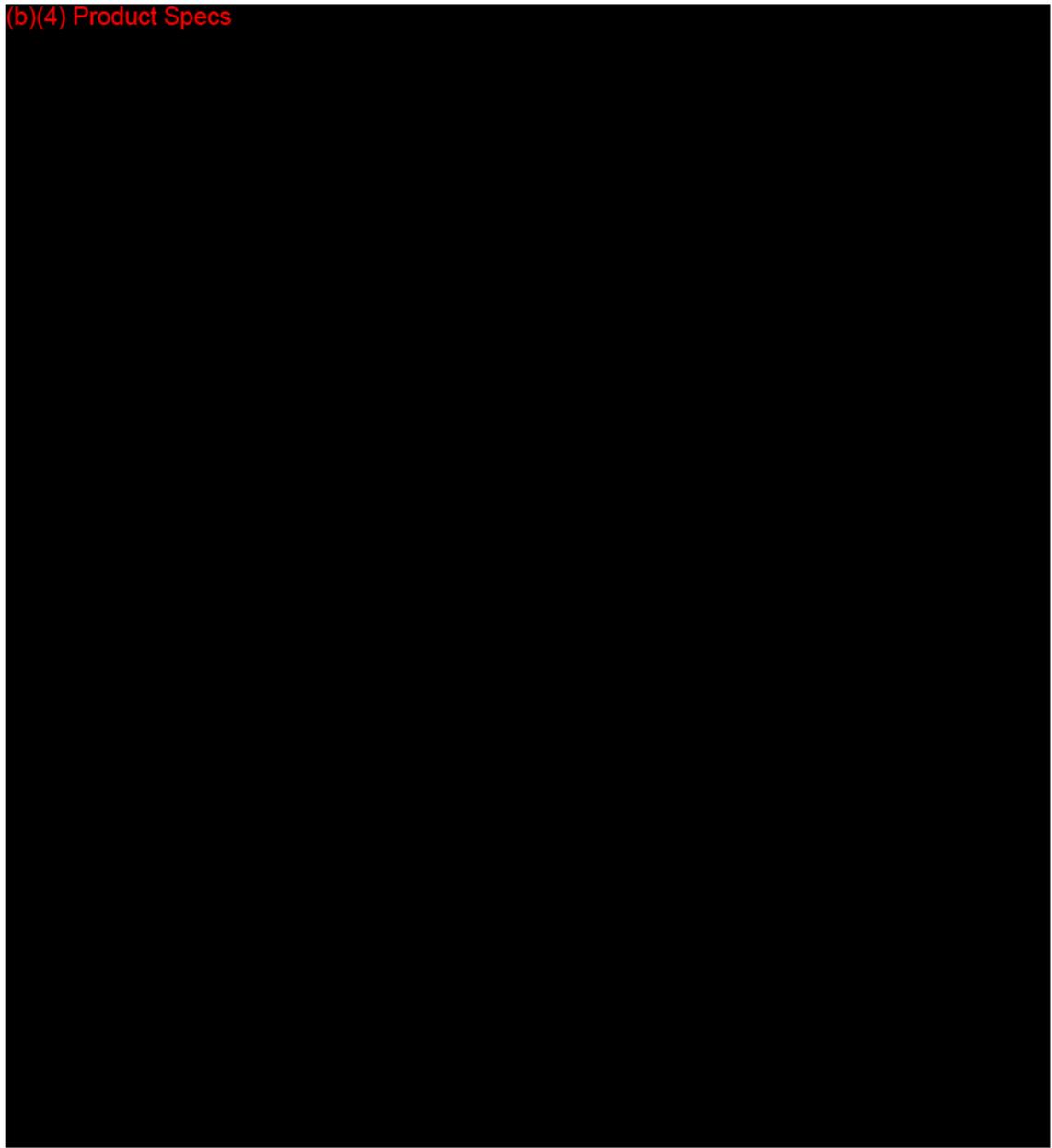
Enclosure

CERTIFIED MAIL

(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850



SEP 3 1996

Ms. Donna J. Wilson  
Director, Regulatory Affairs  
C.R. Bard, Inc.  
8195 Industrial Boulevard  
Covington, Georgia 30209

Re: K936194; K922939; K934370; and K910720  
Coaxial Biopsy Needle; Bard Monopty Disposable Biopsy  
Instrument Product Line; BIP [Bard Magnum] Biopsy Needles;  
and Bard Biopsy-Cut Biopsy Needles  
Dated: July 18, 1996

Dear Ms. Wilson:

We have reviewed the information dated July 18, 1996, regarding the 510(k) notifications K936194, K922939, K934370, and K910720 previously submitted for the devices referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the designs, components, methods of manufacture, or intended use of the devices referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the devices or their labeling could significantly affect the devices' safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Appendix 7: Declaration of Conformity with Design Controls**

## Declaration of Conformity with Design Controls

**Verification and Validation Activities:** As required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

  
\_\_\_\_\_  
Ruben Perez  
Staff Engineer  
Bard Peripheral Vascular, Inc.

12-19-13  
\_\_\_\_\_  
Date

**Manufacturing Facility:** The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

  
\_\_\_\_\_  
Scott Neal  
Director of Quality Assurance  
Bard Peripheral Vascular, Inc.

12-19-13  
\_\_\_\_\_  
Date

**Bard Peripheral Vascular, Inc.**  
C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062

FDA CDRH DMC

JAN 28 2014

Received

K133948/S002

**BARD**

January 27, 2014

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: **Special 510(k)**      **K133948/S002**  
**Trade Name:**      **Bard® Monopty® Disposable Core Biopsy Instrument**  
                                 **Bard® Max-Core® Disposable Core Biopsy Instrument**  
**Common Name:**      Core Biopsy Instrument  
**Predicate Device:**      Bard® Monopty® Disposable Core Biopsy Instrument  
                                 (K922939)

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, Bard Peripheral Vascular, Inc. (BPV), a division of C.R. Bard, Inc., is submitting one eCopy of a Special 510(k) notification for the Bard® Monopty® and Bard® Max-Core® Disposable Core Biopsy Instruments to address the eCopy Hold Letter received January 27, 2014. This updated eCopy is an exact duplicate of the paper copy sent by BPV on January 23, 2014. There have been no prior formal submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence for this device. This updated eCopy submission provides responses to the FDA RTA deficiencies indicated for K133948 dated January 17, 2014. For ease of review, both the FDA RTA Checklist questions/requests and Bard's Responses are provided in Attachment 1 of this cover letter.

The Bard® Monopty® and Bard® Max-Core® Disposable Core Biopsy Instruments are Class II products. The Product Code for these devices is KNW (Instrument, Biopsy). The Review Panel for this Product Code is Gastroenterology / Urology (Medical Specialty No. 78). The Device Classification Regulation Number is 21 CFR §876.1075.

This submission provides an updated file to the FDA including several changes that have occurred to the subject device since the predicate submission including updates to the labeling and the addition of a needle gauge size, addition of needle lengths, and addition of performance specifications. There is no change to the intended use or indications for use of the subject device, and the minor changes do not alter the fundamental scientific technology of the device. This modification complies with the requirements for a Special 510(k) submission as outlined in "The

**Bard Peripheral Vascular, Inc.**

C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062



New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance”, issued March 20, 1998.

The terms “substantially equivalent”, “similar”, and related terms and descriptions in this notification are terms or words of art defined by the Food and Drug Administration in the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

This document contains a Medical Device User Fee Cover Sheet and a completed CDRH Premarket Review Submission Cover Sheet following this cover letter. A checklist for Special 510(k)s can be found on Page 4 corresponding to the FDA guidance document, “Refuse to Accept Policy for 510(k)s,” dated December 31, 2012, which also denotes where each required element outlined in this guidance can be found in this submission. Furthermore, this document contains a signed Truthful and Accuracy Statement in Appendix 2, Indications for Use Statement in Appendix 5, and Declaration of Conformity with Design Controls in Appendix 7. The 510(k) Summary can be found in Appendix 1.

BPV requests that the FDA keep and maintain confidential both the existence and the contents of this premarket notification in accordance with 21 CFR §807.95(b). BPV also requests that the FDA keep and maintain confidential the contents of this letter.

Please do not hesitate to contact me if you have any questions or need any additional information. I can be reached via telephone at 480-638-2954, fax at 480-449-2546, or by e-mail at [sarah.mccartney@crbard.com](mailto:sarah.mccartney@crbard.com).

Sincerely,

A handwritten signature in blue ink that reads "Sarah McCartney". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Sarah McCartney  
Regulatory Affairs Specialist  
Bard Peripheral Vascular, Inc.

K133948/S002

**Bard Peripheral Vascular, Inc.**  
C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062

FDA CDRH DMC

JAN 24 2014

Received

**BARD**

January 23, 2014

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: **Special 510(k)**      **K133948/S001**  
**Trade Name:**      **Bard® Monopty® Disposable Core Biopsy Instrument**  
                                 **Bard® Max-Core® Disposable Core Biopsy Instrument**  
**Common Name:**      Core Biopsy Instrument  
**Predicate Device:** Bard® Monopty® Disposable Core Biopsy Instrument  
                                 (K922939)

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, Bard Peripheral Vascular, Inc. (BPV), a division of C.R. Bard, Inc., is submitting one paper copy and one eCopy of a Special 510(k) notification for the Bard® Monopty® and Bard® Max-Core® Disposable Core Biopsy Instruments. The eCopy is an exact duplicate of the paper copy. There have been no prior formal submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence for this device. This updated submission provides responses to the FDA RTA deficiencies indicated for K133948 dated January 17, 2014. For ease of review, both the FDA RTA Checklist questions/requests and Bard's Responses are provided in Attachment 1 of this cover letter.

The Bard® Monopty® and Bard® Max-Core® Disposable Core Biopsy Instruments are Class II products. The Product Code for these devices is KNW (Instrument, Biopsy). The Review Panel for this Product Code is Gastroenterology / Urology (Medical Specialty No. 78). The Device Classification Regulation Number is 21 CFR §876.1075.

This submission provides an updated file to the FDA including several changes that have occurred to the subject device since the predicate submission including updates to the labeling and the addition of a needle gauge size, addition of needle lengths, and addition of performance specifications. There is no change to the intended use or indications for use of the subject device, and the minor changes do not alter the fundamental scientific technology of the device. This modification complies with the requirements for a Special 510(k) submission as outlined in "The New 510(k) Paradigm – Alternate Approaches to

**Bard Peripheral Vascular, Inc.**

C. R. Bard, Inc.  
1625 West 3rd Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062



Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance”, issued March 20, 1998.

The terms “substantially equivalent”, “similar”, and related terms and descriptions in this notification are terms or words of art defined by the Food and Drug Administration in the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

This document contains a Medical Device User Fee Cover Sheet and a completed CDRH Premarket Review Submission Cover Sheet following this cover letter. A checklist for Special 510(k)s can be found on Page 4 corresponding to the FDA guidance document, “Refuse to Accept Policy for 510(k)s,” dated December 31, 2012, which also denotes where each required element outlined in this guidance can be found in this submission. Furthermore, this document contains a signed Truthful and Accuracy Statement in Appendix 2, Indications for Use Statement in Appendix 5, and Declaration of Conformity with Design Controls in Appendix 7. The 510(k) Summary can be found in Appendix 1.

BPV requests that the FDA keep and maintain confidential both the existence and the contents of this premarket notification in accordance with 21 CFR §807.95(b). BPV also requests that the FDA keep and maintain confidential the contents of this letter.

Please do not hesitate to contact me if you have any questions or need any additional information. I can be reached via telephone at 480-638-2954, fax at 480-449-2546, or by e-mail at [sarah.mccartney@crbard.com](mailto:sarah.mccartney@crbard.com).

Sincerely,

A handwritten signature in blue ink that reads "Sarah McCartney". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Sarah McCartney  
Regulatory Affairs Specialist  
Bard Peripheral Vascular, Inc.



**Bard® Monopty® Disposable Core Biopsy Instruments and  
Bard® Max-Core® Disposable Core Biopsy Instruments**

**Updated Special 510(k): K133948/S001**

**23 January 2014**

**CONFIDENTIALITY STATEMENT**

This document contains information that is confidential and proprietary property of C. R. Bard, Inc. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without the proper written consent of Bard Peripheral Vascular, Inc.

**Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, AZ 85281**

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  BARD PERIPHERAL VASCULAR 1625 WEST 3RD STREET P O BOX 1740 TEMPE AZ 85281 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0297		2. CONTACT NAME Tim Williams  2.1 E-MAIL ADDRESS tim.williams@crbard.com  2.2 TELEPHONE NUMBER (include Area code) 480-303-2539  2.3 FACSIMILE (FAX) NUMBER (Include Area code) 480-449-2546	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm</a> Select an application type:			
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER  3.2 Select one of the types below Supplement Types: <input checked="" type="checkbox"/> Original Application <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number.			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm</a> for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		18-Oct-2013	

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 01/23/2014	User Fee Payment ID Number <b>(b) (4)</b>	FDA Submission Document Number (if known) K133948
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Request for Feedback</b> <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Bard Peripheral Vascular, Inc.		Establishment Registration Number (if known) 2020394	
Division Name (if applicable)		Phone Number (including area code) 480-638-2954	
Street Address 1625 West 3rd Street		FAX Number (including area code) 480-449-2546	
City Tempe	State / Province Arizona	ZIP/Postal Code 85281	Country U.S.A.
Contact Name Sarah McCartney			
Contact Title Regulatory Affairs Specialist		Contact E-mail Address sarah.mccartney@crbard.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name N/A			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

**SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software/Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (*specify*):

**SECTION D2 REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent/Applicant <input type="checkbox"/> Design/Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA  <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (*specify*):

**SECTION D3 REASON FOR SUBMISSION - 510(k)**

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
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Other Reason (*specify*):

This submission provides an updated file to FDA including several changes that have occurred to the subject device since the predicate submission. These changes include updates to the labeling and the addition of a needle gauge size, addition of needle lengths, and addition of performance specifications.

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	KNW	2		3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K922939	Bard® Monopty® Disposable Core Biopsy Instrument	Bard Peripheral Vascular, Inc.
2			
3			
4			
5			
6			

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name  
Core Biopsy Instrument

	Trade or Proprietary or Model Name for This Device	Model Number
1	Bard® Monopty® Disposable Core Biopsy Instrument	1 See attached list
2	Bard® Max-Core® Disposable Core Biopsy Instrument	2 See attached list
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)

1	K922939	2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- Laboratory Testing       Animal Trials       Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code KNW	C.F.R. Section (if applicable) 876.1075	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Gastroenterology / Urology		

Indications (from labeling)

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.

**Note:** Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

K133948

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4) Contract Manufacturer

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4) Contract Manufacturer

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

(b)(4)

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  Repackager / Relabeler

(b)(4) Contract Manufacturer

## SECTION I

## UTILIZATION OF STANDARDS

**Note:** Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	5-40	ISO	Medical devices - Application of risk management to medical devices	14971	08/20/2012
2	2-179	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	10993-1	03/16/2012
3	14-278	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	10993-7	01/15/2013
4	14-228	AAMI/ANSI/ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices	11135-1	03/16/2012
5	14-360	AAMI/ANSI	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	ST72	01/15/2013
6					
7					

**Please include any additional standards to be cited on a separate page.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
 Food and Drug Administration  
 Office of Chief Information Officer  
 Paperwork Reduction Act (PRA) Staff  
 1350 Piccard Drive, Room 400  
 Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

ATTACHMENT – Section F, Product Information, Continued

Trade or Proprietary or Model Name for This Device	Model Number
Bard® Monopty® Disposable Core Biopsy Instrument	211410, 211416, 211610, 211616, 211620, 211810, 211816, 211820, 212010, 212016, 212020, 121210, 121216, 121410, 121416, 121610, 121616, 121620, 121810, 121816, 121820, 122010, 122016, 122020
Bard® Max-Core® Disposable Core Biopsy Instrument	MC1410, MC1416, MC1610, MC1616, MC1810, MC1816, MC1820, MC1825, MC2010, MC2016, MC2020

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 14971:2007, Medical devices - Application of risk management to medical devices

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number<sup>3</sup> ..... #5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 14971:2007, Medical devices - Application of risk management to medical devices

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER 3	SECTION TITLE General requirements for risk analysis	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 4	SECTION TITLE Risk analysis	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER See Attachment 1	SECTION TITLE See Attachment 1	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------------------	-----------------------------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
1350 Piccard Drive, Room 400  
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

ATTACHMENT 1 – Conformance with Standard Sections, Continued

<b>EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE</b>			
STANDARD TITLE			
ISO 14971:2007, Medical devices - Application of risk management to medical devices			
<b>CONFORMANCE WITH STANDARD SECTIONS</b>			
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
5	Risk evaluation	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
6	Risk control	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
7	Evaluation of overall residual risk acceptability	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
8	Risk management report	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
SECTION NUMBER	SECTION TITLE	CONFORMANCE?	
9	Production and post-production information	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA <sup>2</sup> ? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number <sup>3</sup> .....	#2-179	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? ..... If no, complete a summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? ..... If no, include the results of testing in the 510(k).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this standard include more than one option or selection of tests? ..... If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard?..... If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup> ? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?..... If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusions from the standard? ..... If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: <u>Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation..."</u>		

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  
<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>  
<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.  
<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2	Biological evaluation tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦  
Study of relevant experience and actual testing.

DESCRIPTION  
See Attachment 2.

JUSTIFICATION  
See Attachment 2.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

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Rockville, MD 20850

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ATTACHMENT 2 – Conformance with Standard Sections, Continued

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

**CONFORMANCE WITH STANDARD SECTIONS**

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

6.2

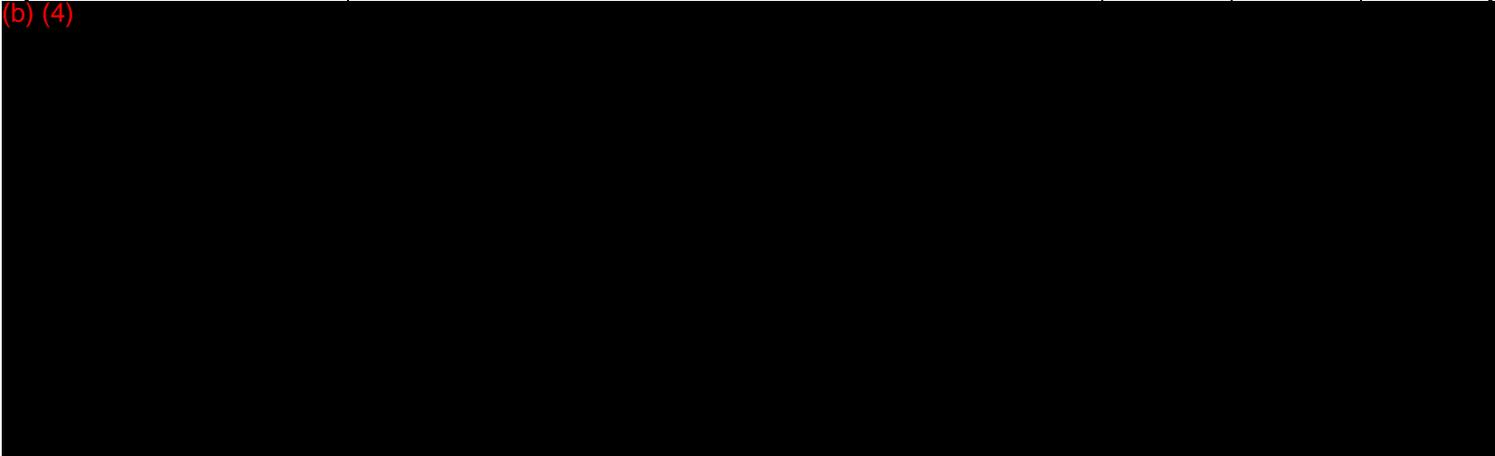
Biological evaluation tests

Yes

No

N/A

(b) (4)



Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-278

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4.6.2	Exhaustive Extraction (alternative acceptable method)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

(b) (4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for the...

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for the...

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
See Attachment 3	See Attachment 3	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
See Attachment 3	See Attachment 3	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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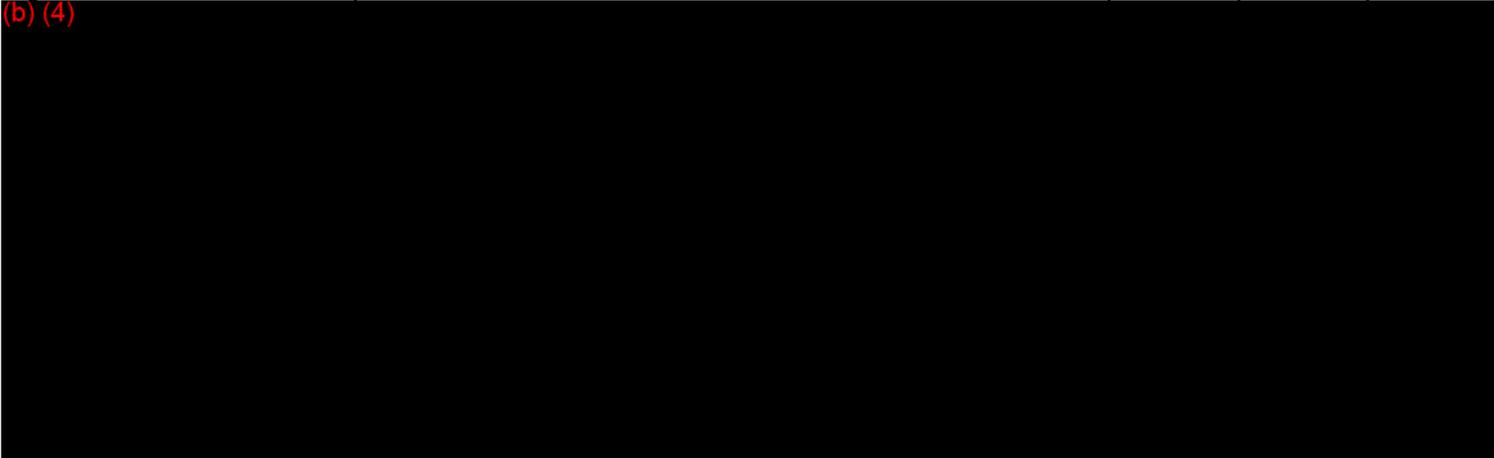
**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

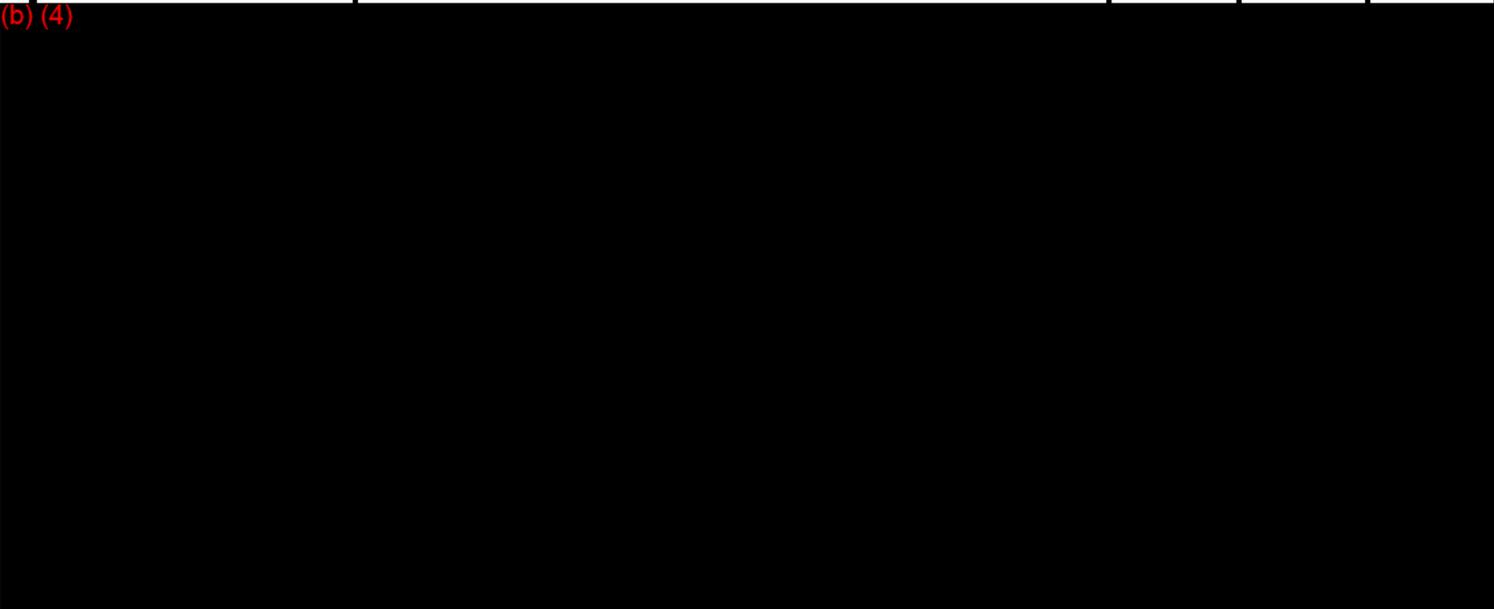
AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products -- Ethylene Oxide -- Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

**CONFORMANCE WITH STANDARD SECTIONS**

SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
9.3.2	Performance qualification - Microbiological	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A



SECTION NUMBER	SECTION TITLE	CONFORMANCE?		
9.3.3	Performance qualification - Physical	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A



Department of Health and Human Services  
Food and Drug Administration  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI ST72:2011 "Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing"

Please answer the following questions	Yes	No
Is this standard recognized by FDA <sup>2</sup> ? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number <sup>3</sup> .....	#14-360	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? ..... If no, complete a summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? ..... If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include more than one option or selection of tests? ..... If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard?..... If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup> ? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?..... If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusions from the standard? ..... If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: "Pyrogens and Endotoxins Testing: Questions and Answers" (June 2012)		

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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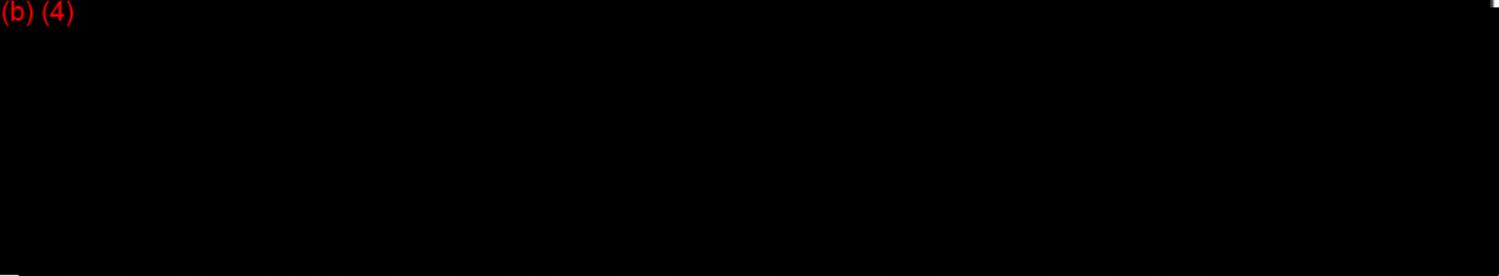
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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI ST72:2011 "Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing"

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Selection of technique	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A



SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with  
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Bard Peripheral Vascular, Inc./Sarah McCartney	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Jan 23, 2014
3. ADDRESS (Number, Street, State, and ZIP Code) 1625 West 3rd Street Tempe, AZ 85281	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 480-638-2954 (Fax) 480-449-2546

**PRODUCT INFORMATION**

5. <b>FOR DRUGS/BIOLOGICS:</b> Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) <b>FOR DEVICES:</b> Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)	
Common Name: Core Biopsy Instrument	Model Numbers: 211410, 211416, 211610, 211616, 211620, 211810, 211816, 211820, 212010, 212016, 212020, 121210, 121216, 121410,
Classification: Class II	121416, 121610, 121616, 121620, 121810, 121816, 121820, 122010, 122016, 122020, MC1410, MC1416, MC1610, MC1616, MC1810,
Trade Name: Bard® Monopty® Disposable Core Biopsy Instrument Bard® Max-Core® Disposable Core Biopsy Instrument	MC1816, MC1820, MC1825, MC2010, MC2016, MC2020

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned) K133948
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

**CERTIFICATION STATEMENT / INFORMATION**

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)
<input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
<input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
<input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary) NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.  
**Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Sarah McCartney (Title) Regulatory Affairs Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 1625 West 3rd Street Tempe, AZ 85281	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 480-638-2954 (Fax) 480-449-2546
	15. DATE OF CERTIFICATION Jan 23, 2014

## Instructions for Completion of Form FDA 3674

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**  
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

**Box A** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

**Box B** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

**Box C** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

### Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

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Rockville, MD 20850

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**Refuse To Accept (RTA) Checklist for Special 510(k)s**

**Section 1: Special 510(k) Criteria**

Criteria	Location in 510(k)
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	Cover Letter & Section 1.2.3
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	Section 2.4
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	Section 2.7
4. The submission includes only summary-level information (i.e., NO test reports with performance data).	Throughout

**Section 2: Organizational Elements**

Organizational Item	Location in 510(k)
a. Submission contains Table of Contents	Page 2
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	Throughout
c. All pages of the submission are numbered	Throughout
d. Type of 510(k) is identified – traditional, abbreviated, or special	Cover Letter and Header

**Section 3: Elements of a Complete Submission (RTA Items)**

Element		Location in 510(k)
<b>A.</b>	<b>Administrative</b>	
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	Throughout
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):	
	a. Device trade name or proprietary name	Cover Letter
	b. Device common name	Cover Letter
	c. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	Cover Letter
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109)	Appendix 5
4.	Submission contains 510(k) Summary or 510(k) Statement	
	a. Summary contains all elements per 21 CFR 807.92	Appendix 1
	b. Statement contains all elements per 21 CFR 807.93	N/A
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k)	Appendix 2
6.	Submission contains Class III Summary and Certification	N/A

	7.		If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	FDA Form 3654
	8.		The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	Cover Letter
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed	N/A
<b>B. Device Description</b>				
	9.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	N/A (Section 1.3)
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	Section 1.2.4 and Section 2
	10.		Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:	
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	Section 2
		b.	A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	Section 2
		c.	A list and description of each model for which clearance is requested.	Section 1.2.2
	11.		A description of all device modification(s) including rationale for each modification.	Sections 2.4 – 2.7
	12.		Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	Appendix 3
	13.		If device is intended to be marketed with multiple components, accessories, and/or as part of a system,	N/A
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	
		b.	Submission includes a description (as detailed in item #12.a. and b. and 14 above) of each component or accessory.	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	
<b>C. Substantial Equivalence Discussion</b>				
	14.		Submitter has identified a predicate(s) device	

	a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendment status.	Section 1.1
	b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing	Throughout
15.		Submission includes a comparison of the following for the predicate(s) and subject device	
	a.	Indications for use	Section 2.7
	b.	Technology, including features, materials, and principles of operation	Section 2.7
16.		Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise difference questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act)	Sections 2.4 – 2.7
<b>D. Design Control Activities</b>			
17.		Design Control Activities Summary includes all of the following:	
	a.	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	Section 3.1
	b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	Section 3.1
	c.	Declaration of conformity with design controls, including:	Appendix 7
	i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.	
	ii.	Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30	
	iii.	Statement is signed by the individual responsible for these activities	
<b>E. Proposed Labeling (see also 21 CFR part 801)</b>			
18.		Submission includes proposed labels, and labeling (e.g., instructions for use, package insert, operator's manual), that include a description of the device, its intended use, and the directions for use	Appendix 4
	a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	Section 2.4
19.		Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	Section 2.4

## 1. Required Information

### 1.1 Predicate Device Information

The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument, K922939, cleared February 16, 1993.

### 1.2 Subject Device Information

#### 1.2.1 Device Name

**Device Trade Name:** Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® Disposable Core Biopsy Instrument

**Common Name:** Core Biopsy Instrument

**Classification Name:** Instrument, Biopsy

The Bard® Monopty® Disposable Core Biopsy Instrument and Bard® Max-Core® Disposable Core Biopsy Instrument will be referred to as “Core Biopsy Instrument(s)” throughout this submission.

#### 1.2.2 Catalogue Numbers

A list of the Core Biopsy Instrument catalogue numbers is provided in Tables 1 and 2.

**Table 1: Bard® Monopty® Disposable Core Biopsy Instrument Catalogue Numbers**

Catalogue Number	Gauge x Length	Penetration Depth
121210	12 g x 10 cm	22 mm
121216	12 g x 16 cm	22 mm
121410	14 g x 10 cm	22 mm
121416	14 g x 16 cm	22 mm
121610	16 g x 10 cm	22 mm
121616	16 g x 16 cm	22 mm
121620	16 g x 20 cm	22 mm
121810	18 g x 10 cm	22 mm
121816	18 g x 16 cm	22 mm
121820	18 g x 20 cm	22 mm
122010	20 g x 10 cm	22 mm

Catalogue Number	Gauge x Length	Penetration Depth
122016	20 g x 16 cm	22 mm
122020	20 g x 20 cm	22 mm
211410	14 g x 9 cm	11 mm
211416	14 g x 15 cm	11 mm
211610	16 g x 9 cm	11 mm
211616	16 g x 15 cm	11 mm
211620	16 g x 19 cm	11 mm
211810	18 g x 9 cm	11 mm
211816	18 g x 15 cm	11 mm
211820	18 g x 19 cm	11 mm
212010	20 g x 9 cm	11 mm
212016	20 g x 15 cm	11 mm
212020	20 g x 19 cm	11 mm

**Table 2: Bard® Max-Core® Disposable Core Biopsy Instrument Catalogue Numbers**

Catalogue Number	Gauge x Length	Penetration Depth
MC1410	14 g x 10 cm	22 mm
MC1416	14 g x 16 cm	22 mm
MC1610	16 g x 10 cm	22 mm
MC1616	16 g x 16 cm	22 mm
MC1810	18 g x 10 cm	22 mm
MC1816	18 g x 16 cm	22 mm
MC1820	18 g x 20 cm	22 mm
MC1825	18 g x 25 cm	22 mm
MC2010	20 g x 10 cm	22 mm
MC2016	20 g x 16 cm	22 mm
MC2020	20 g x 20 cm	22 mm

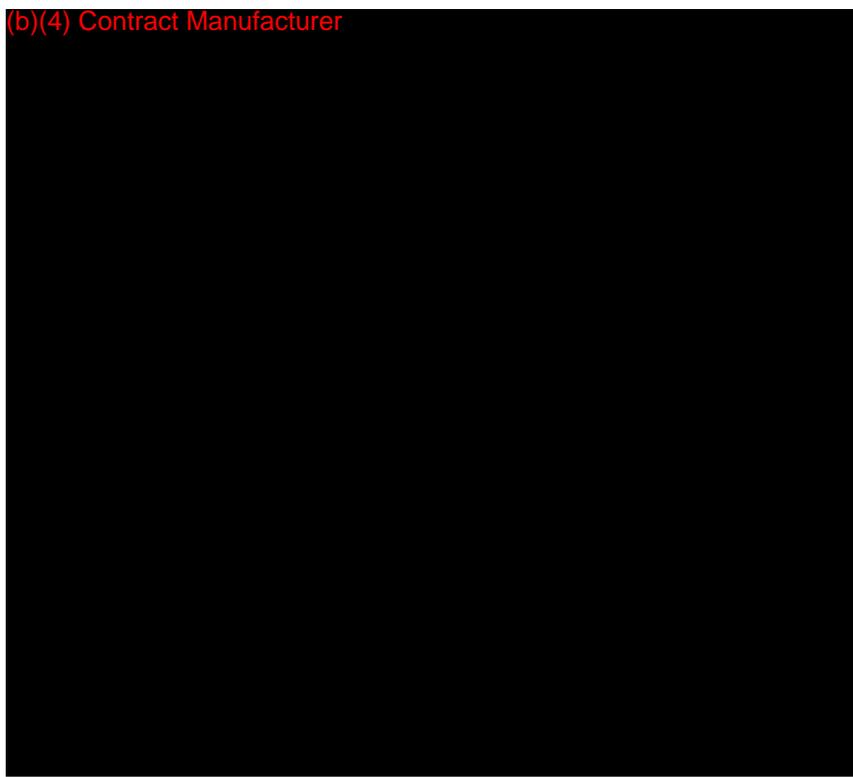
### 1.2.3 Addresses and Facility Registration Numbers

The addresses and registration numbers for the manufacturer, contract manufacturer and contract sterilizers of the Core Biopsy Instruments are noted below:

Manufacturer:

Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, AZ 85281  
USA  
Establishment Registration Number: 2020394

(b)(4) Contract Manufacturer



(b)(4) Product Specs is the design center responsible for design control activities affecting the Core Biopsy Instruments.

### 1.2.4 Device Class

**Device Classification:** Class II  
**Classification Name:** Instrument, Biopsy ( Product Code KNW)  
**Review Panel:** Gastroenterology / Urology

**Regulation Number:** 21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

Please note all of the information above is identical to the predicate device.

The following FDA guidance document is applicable to these devices:

- Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology, dated prior to February 27, 1997.

### **1.3 Performance Standards**

Performance standards have not been established under Section 514 of the Food, Drug and Cosmetic Act for gastroenterology-urology biopsy instruments.

### **1.4 510(k) Summary**

The 510(k) Summary is provided in Appendix 1.

### **1.5 Truthful and Accuracy Statement**

The signed Truthful and Accuracy Statement is provided in Appendix 2.

## 2. Device Description and Comparisons

For ease of review, a brief description of the predicate and subject devices is provided below.

### 2.1 Predicate Device Description

The predicate device, the Bard® Monopty® Disposable Core Biopsy Instrument, is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge, and Green = 14 gauge. A picture of the 14 gauge device is provided in Figure 1.

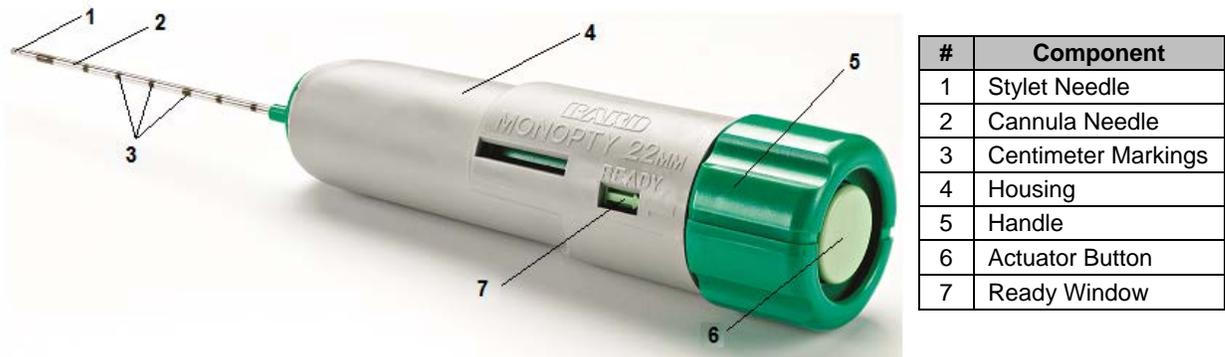
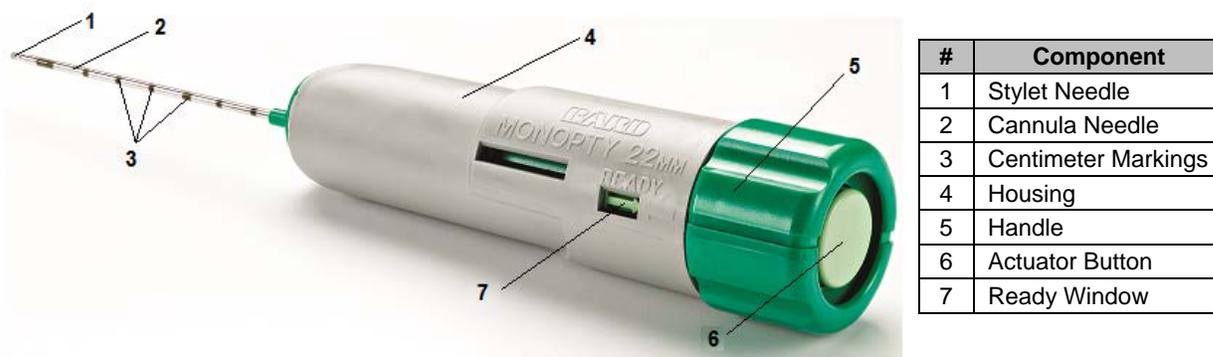


Figure 1: Bard® Monopty® Disposable Core Biopsy Instrument (14 Gauge)

## 2.2 Subject Device Descriptions

### Bard® Monopty® Disposable Core Biopsy Instrument

The subject device, the Bard® Monopty® Disposable Core Biopsy Instrument, is a single use core biopsy device. It is available in several needle gauge sizes and lengths (refer to Table 1 for product configurations) including the new product configurations created by the changes described in Section 2.6, History of Changes. The new product configurations are the 12 G x 10 cm and the 12 G x 16 cm. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge, Green = 14 gauge, and Light Blue = 12 gauge. A picture of the 14 gauge device is provided in Figure 2.



**Figure 2: Bard® Monopty® Disposable Core Biopsy Instrument (14 Gauge)**

### Bard® Max-Core® Disposable Core Biopsy Instrument

The subject device, the Bard® Max-Core® Disposable Core Biopsy Instrument, was released via a Letter to File on August 15, 1995. The Bard® Max-Core® Disposable Core Biopsy Instrument is an ergonomic enhancement of the Bard® Monopty® Disposable Core Biopsy Instrument. The device provides no new needle gauge sizes (outside the previously cleared range), no significant changes in performance specifications, no new performance claims, no changes regarding indications for use or contraindications, and no significant changes regarding warnings or precautions. Please refer to Section 2.6, History of Changes, for additional information.

The Bard® Max-Core® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths (refer to Table 2 for product configurations) including the new product configuration created by the changes described in Section 2.6, History of Changes. The new product configuration is the 18 G x 25 cm. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge. A picture of the 14 gauge device is provided in Figure 3.

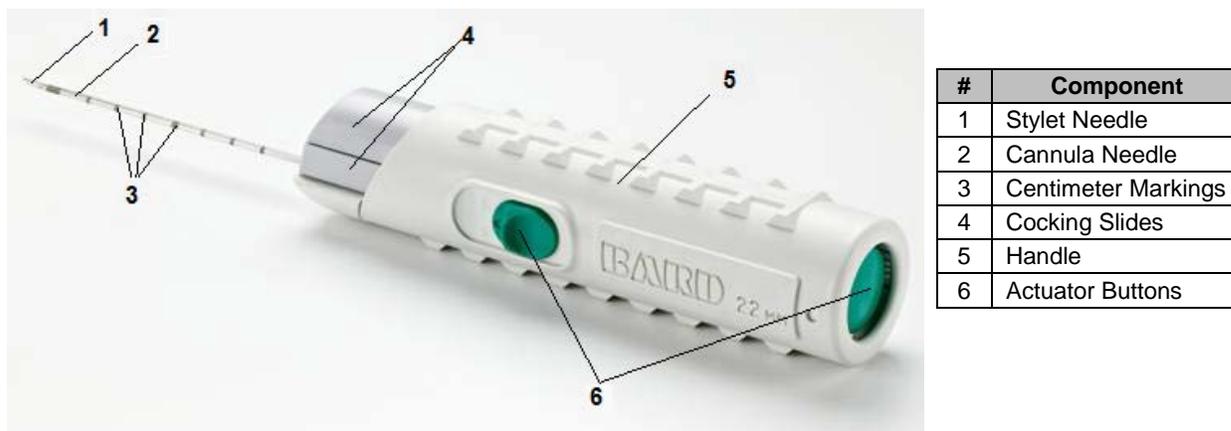


Figure 3: Bard® Max-Core® Disposable Core Biopsy Instrument (14 Gauge)

### 2.3 Engineering Drawings

Engineering drawings are provided in Appendix 3.

### 2.4 Labeling, Intended Use and Indications for Use

The Intended Use and the Indications for Use of the subject devices, as described in its labeling, are the same as the Intended Use and the Indications for Use of the predicate device. Labels and Instructions for Use (IFU) for the subject devices are provided in Appendix 4. The Indications for Use Statement is provided in Appendix 5. Please note, the Indications for Use of the predicate device, as described in its labeling, was updated at the request of the FDA during the review of K922939 per a deficiency letter dated September 16, 1992. This deficiency letter along with the response is provided in Appendix 6.

The proposed significant changes to the labeling of the Bard® Monopty® Disposable Core Biopsy Instrument are highlighted in yellow in Appendix 4. In addition, the IFU was reorganized and reformatted to further align with FDA General Program Memorandum #G91-1, "Device Labeling Guidance" (dated March 8, 1991). These changes along with revisions to the labels are detailed in Table 3.

**Table 3: Changes to the Subject Device Labeling**

Labeling Change	Justification
Correction to the needle lengths provided on the labeling of the Monopty® 11 mm product configurations (from 10 to 9 cm, 16 to 15 cm, and 20 to 19 cm) (highlighted in yellow)	(b)(4) Product Specs
Indications for Use revised from phrase to statement (highlighted in yellow)	
Revision to single use and sterility statements in the Warning section (highlighted in yellow)	
Update to Potential Complications (highlighted in yellow)	
Throughout (not highlighted) - clarification to wording, addition of Equipment Required section (IFU only), and added languages/symbols with definitions	
Reorganization of statements (not highlighted)	

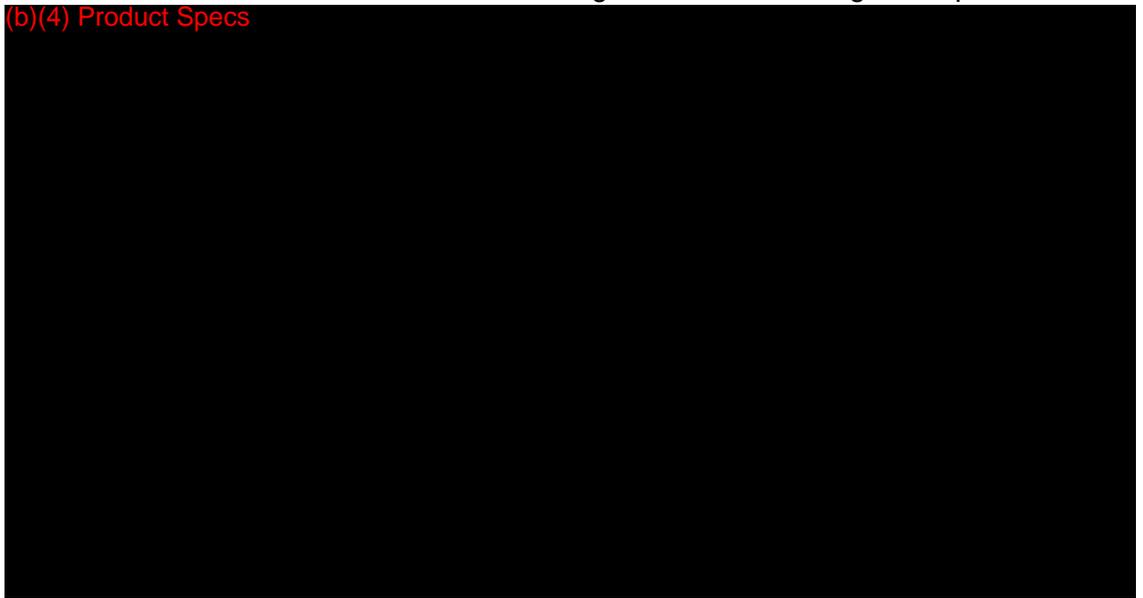
The proposed changes to the Bard® Max-Core® Disposable Core Biopsy Instrument labeling when compared to the predicate device are minimal and are strictly made to provide necessary information related to the directions for use of the ergonomically enhanced device. All changes described in Table 3 were also applied to the IFU and labels for the Bard® Max-Core® Disposable Core Biopsy Instrument.

The changes to the subject device labeling as described in this section were considered improvements to ensure maximum safe and effective use of the subject devices and therefore a 510(k) notification was not required prior to effecting the change.

## 2.5 Materials

Tables 4 and 5 detail the patient contacting materials of the Core Biopsy Instruments. Body contact and duration are defined per ISO 10993-1:2009, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.”

(b)(4) Product Specs

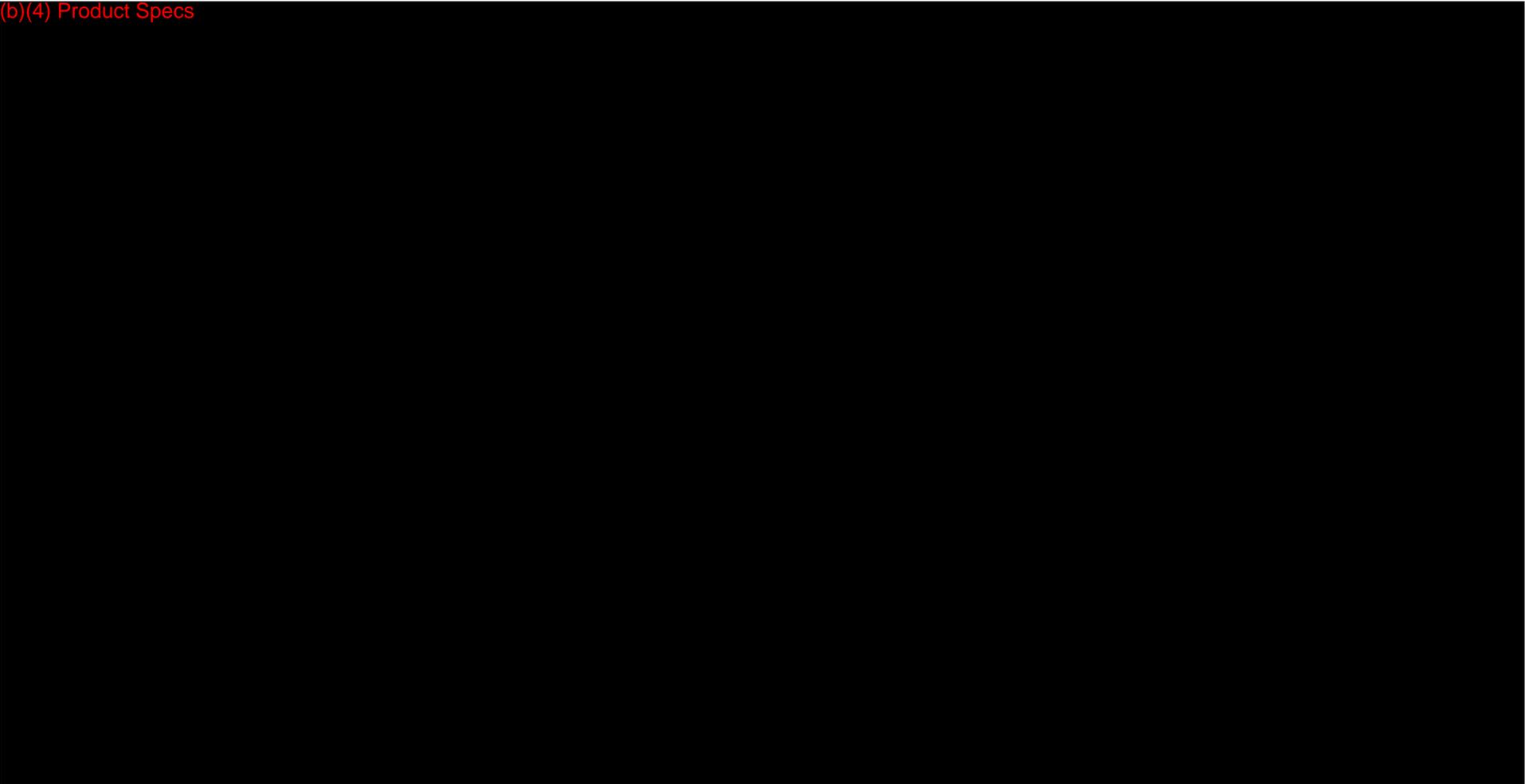


There have been no changes to the patient-contacting materials of the subject devices when compared to the predicate device. Please note, the additional patient-contacting materials described for the Bard® Monopty® Disposable Core Biopsy Instrument are unchanged from the predicate device, only the patient contact was re-evaluated (additional biocompatibility testing was not required due to the change to patient contact for these components as historical data was already on file).

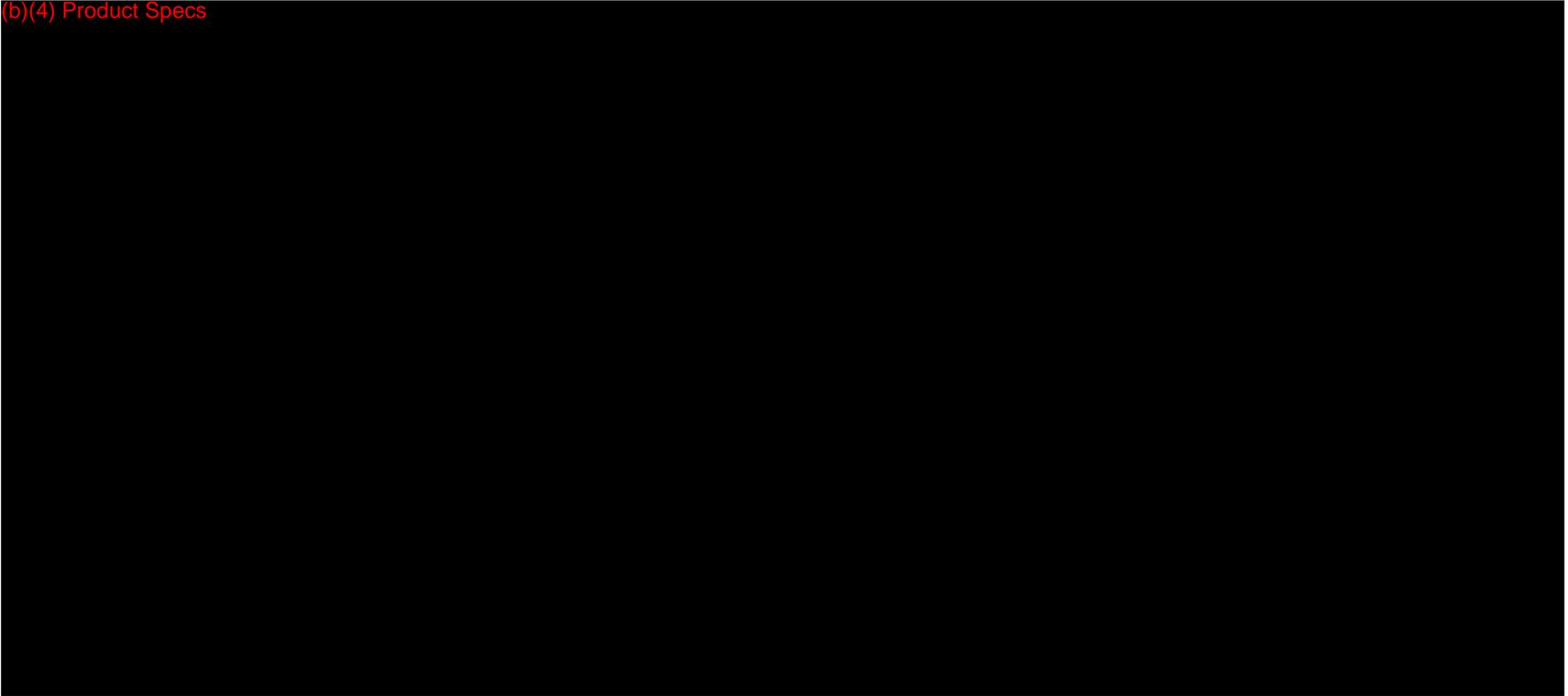
## 2.6 History of Changes

There have been several changes implemented since the predicate submission. Please refer to Table 6 for a list of changes that have been implemented since the predicate submission. The changes are listed in the order that they were implemented. These changes did not constitute a new intended use, did not affect safety and effectiveness, did not raise different questions of safety and effectiveness, and did not alter the fundamental scientific technology of the device; therefore, these changes did not require a new 510(k) submission.

(b)(4) Product Specs



(b)(4) Product Specs



## 2.7 Predicate and Subject Device Comparison

The predicate device referenced in this submission is the Bard® Monopty® Disposable Core Biopsy Instrument (K922939, cleared February 16, 1993).

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Same patient-contacting materials
- Same fundamental scientific technology
- Same patient population
- Same sterility
- Similar packaging configuration

When reviewing the changes since the predicate submission, the subject devices and the predicate device are different in the following manner:

- Updated labeling
- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications

These changes do not constitute a new intended use, do not affect safety and effectiveness, do not raise different questions of safety and effectiveness, and do not alter the fundamental scientific technology of the device. Refer to Table 6 for a comparison of the predicate and subject devices, including those changes detailed in Section 2.6. The differences are noted in **bold**.

Table 6: Comparison Summary

Attribute	PREDICATE DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (K922939)	SUBJECT DEVICE Bard® Monopty® Disposable Core Biopsy Instrument	SUBJECT DEVICE Bard® Max-Core® Disposable Core Biopsy Instrument
Regulation Number	21 CFR 876.1075 (Class II)	Same as predicate	Same as predicate
Intended Use	<i>The core needle biopsy device is intended to obtain soft tissue samples for diagnostic and histological analysis of soft tissue abnormalities.*</i>	Same as predicate	Same as predicate
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.	Same as predicate	Same as predicate
Design, including:	Single-use, sterile, disposable	Same as predicate	Same as predicate
· Needle Gauge	14, 16, 18, 20 gauge	<b>12</b> , 14, 16, 18, 20 gauge	Same as predicate
· Needle Length	10, 16, 20 cm	<b>9</b> , 10, <b>15</b> , 16, <b>19</b> , 20 cm	10, 16, 20, <b>25</b> cm
· Penetration Depth	11 or 22 mm	Same as predicate	22 mm (Subset of Predicate)
· Sample Notch	7 or 17mm	Same as predicate	<b>18 mm</b>
· Number of Samples	One or more	Same as predicate	Same as predicate
· Mechanics of Action	Spring operated	Same as predicate	Same as predicate
· Mode of Action	<i>Single puncture and sample*</i>	Same as predicate	Same as predicate

Attribute	PREDICATE DEVICE Bard® Monopty® Disposable Core Biopsy Instrument (K922939)	SUBJECT DEVICE Bard® Monopty® Disposable Core Biopsy Instrument	SUBJECT DEVICE Bard® Max-Core® Disposable Core Biopsy Instrument
Energy Used / Delivered	(b)(4) Product Specs	Same as predicate	Same as predicate
Patient-Contacting Materials	(b)(4) Product Specs		
Patient Population	<i>Individuals requiring biopsy for sampling of soft tissue abnormalities*</i>	Same as predicate	Same as predicate
Visualization Techniques	X-ray, ultrasound, CT, etc.	Same as predicate	Same as predicate
Performance Specifications	Sample quality	Same as predicate	Same as predicate
	N/A	<b>Durability</b>	<b>Durability</b>
	N/A	<b>Needle to device tensile strength</b>	<b>Needle to device tensile strength</b>
Sterility	Ethylene oxide, SAL of 10 <sup>-6</sup>	Same as predicate	Same as predicate
Packaging Configuration	6 blister packs with Tyvek lids or 10 Tyvek to film pouches in a cardboard shelf box with the IFU	<b>5</b> or <b>10</b> blister packs with Tyvek lids in a cardboard shelf box with the IFU	<b>5</b> blister packs with Tyvek lids in a cardboard shelf box with the IFU

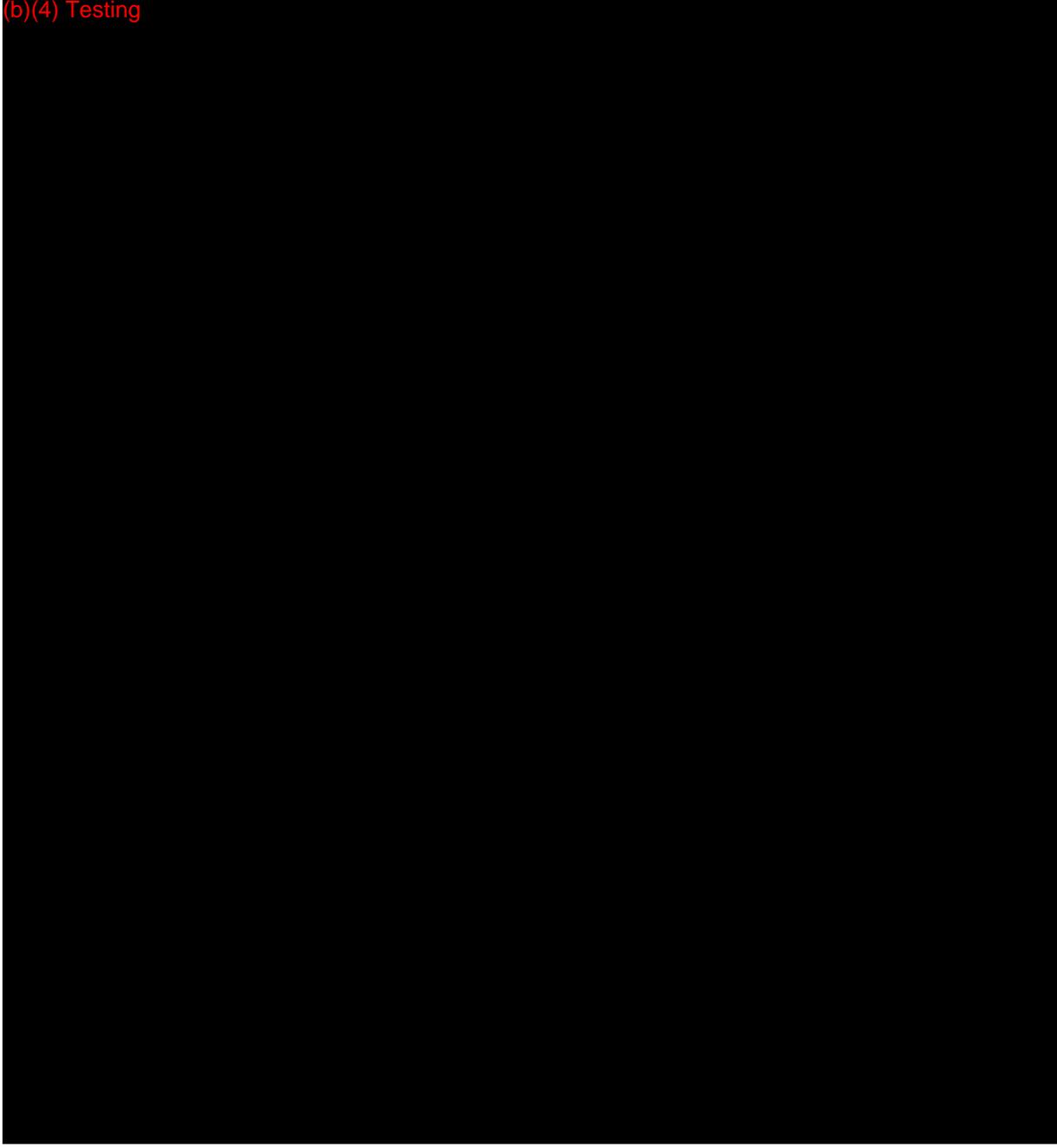
\* This information is not clearly stated, but is implied from the predicate submission.

\*\* These materials are unchanged from the predicate device, only the patient contact was re-evaluated (additional biocompatibility testing was not required due to the change to patient contact for these components)

**3. Design Control Activities**

**3.1 Risk Analysis**

(b)(4) Testing



(b) (4)



### 3.2 Packaging

The predicate device is packaged in either a blister pack with Tyvek lid or Tyvek to film pouch. Sealed blister packs or sealed pouches are placed in a cardboard shelf box with the Instructions for Use.

The subject devices are packaged in a blister pack with Tyvek lid similar to the predicate device. Sealed blister packs are placed in a cardboard shelf box with the Instructions for Use.

### 3.3 Biocompatibility

(b)(4) Testing

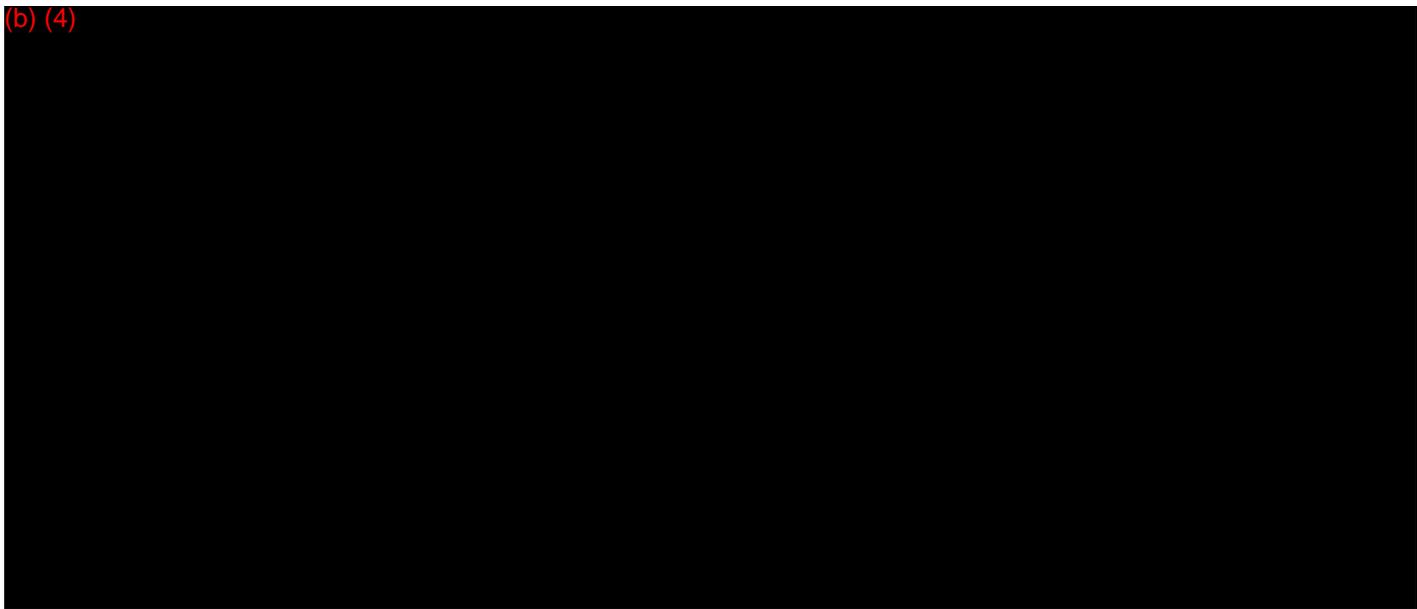


(b)(4) Testing



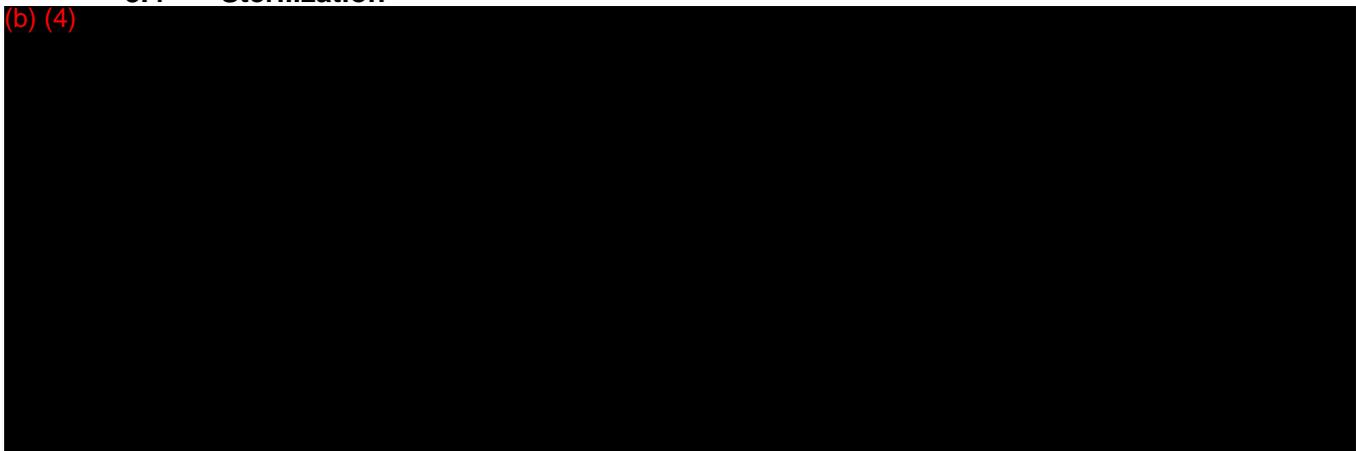
**Table 8: Biocompatibility Testing**

(b) (4)

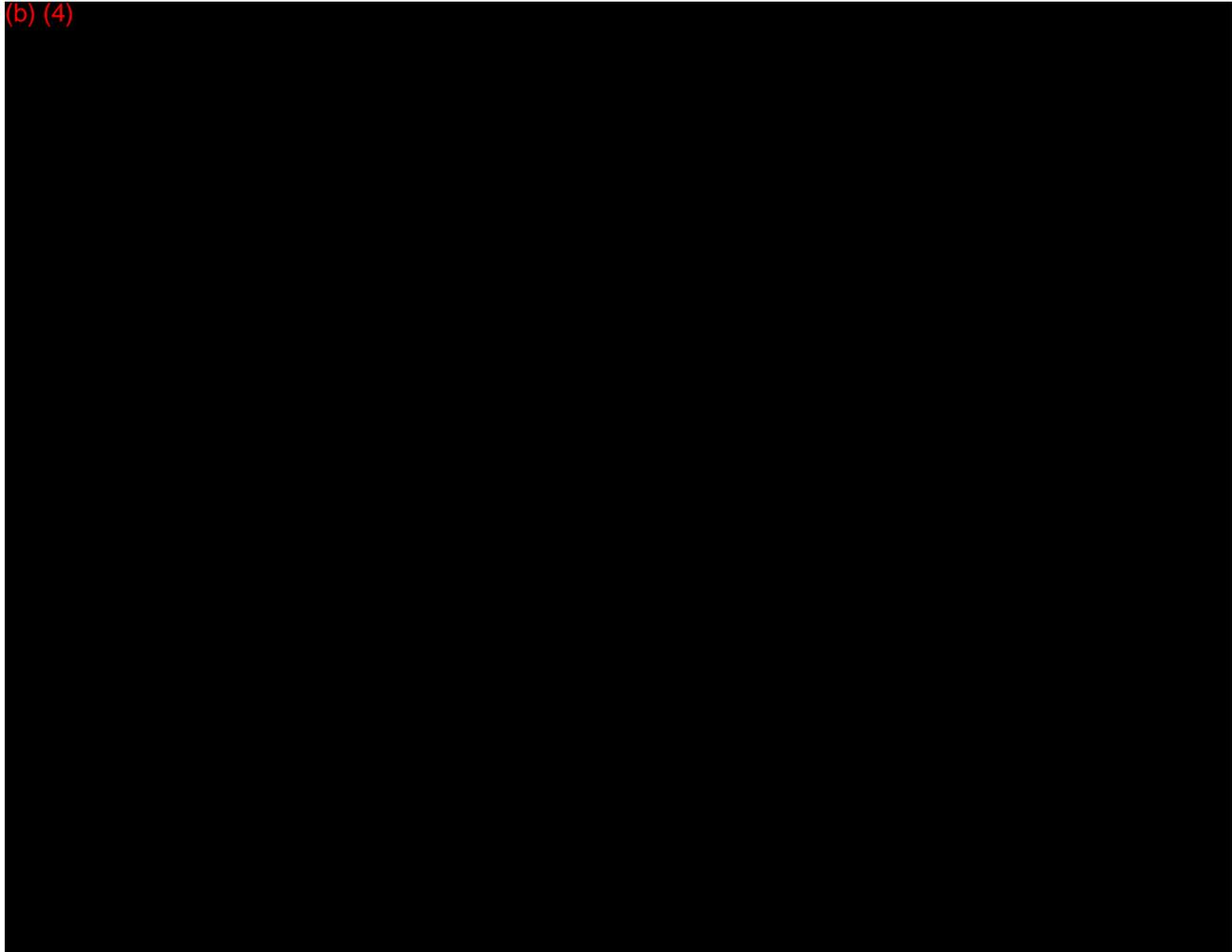


### 3.4 Sterilization

(b) (4)



(b) (4)



### **3.5 Shelf-Life**

The subject devices are qualified for a 3 year shelf life.

### **3.6 Declaration of Conformity with Design Controls**

The Declaration of Conformity with Design Controls is provided in Appendix 7.

#### 4. Statement of Substantial Equivalence

The predicate device referenced in this submission is the Bard® Monopty® Disposable Core Biopsy Instrument (K922939, cleared February 16, 1993).

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Same patient-contacting materials
- Same fundamental scientific technology
- Same patient population
- Same sterility
- Similar packaging configuration

When reviewing the changes since the predicate submission, the subject devices and the predicate device are different in the following manner:

- Updated labeling
- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications

As previously noted, a review of the Risk Assessment and DFMEA of the subject devices was conducted in accordance with internal procedures based on ISO 14971:2007, to assure that the risks posed by the devices are acceptable. The outcome of the risk management activities demonstrate the Core Biopsy Instruments present an acceptable level of risk when used within their intended use and that the design outputs

continue to meet the design inputs and user need requirements. Therefore, Bard Peripheral Vascular, Inc. considers the subject devices to be substantially equivalent to the legally marketed predicate device.

**Appendix 1: 510(k) Summary**

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**510(k) Summary**  
**21 CFR 807.92**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (l)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

**1. Submitter Information:**

Applicant: Bard Peripheral Vascular, Inc.  
1625 West 3<sup>rd</sup> Street  
Tempe, Arizona 85281

Phone: 480-638-2954

Fax: 480-449-2546

Contact: Sarah McCartney, Regulatory Affairs Specialist

Date: January 23, 2014

**2. Subject Device:**

Device Trade Name: Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® Disposable Core Biopsy Instrument

Common or Usual Name: Core Biopsy Instrument

Classification: Class II

Classification Name: Instrument, Biopsy (Product Code KNW)

Review Panel: Gastroenterology / Urology

Regulation Number: 21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

**3. Predicate Device:**

The predicate device is the Bard® Monopty® Disposable Core Biopsy Instrument, K922939, cleared February 16, 1993.

**4. Summary of Change:**

This Special 510(k) provides an updated file to FDA including several changes that have occurred to the subject device since the predicate submission. These changes include updates to the labeling and the addition of a needle gauge size, addition of needle lengths, and addition of performance specifications.

## 5. Subject Device Description:

### Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument

The Bard<sup>®</sup> Monopty<sup>®</sup> Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge, and Light Blue = 12 gauge.

### Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument

The Bard<sup>®</sup> Max-Core<sup>®</sup> Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge and Green = 14 gauge.

## 6. Indications for Use of Device:

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.

## 7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject devices are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same indications for use
- Similar penetration depth
- Similar sample notch
- Same number of samples
- Same mechanics of action
- Same mode of action
- Same energy used / delivered
- Same patient-contacting materials
- Same fundamental scientific technology

- Same patient population
- Same sterility
- Similar packaging configuration

When reviewing the changes from the predicate submission, the subject devices and the predicate device are different in the following manner:

- Updated labeling
- Addition of needle gauge size
- Addition of needle lengths
- Addition of performance specifications

#### **8. Performance Testing Summary:**

To verify that the device design met its functional and performance requirements, representative samples of the device underwent bench testing (dimensional, sample quality, durability, needle to device tensile strength, and echogenicity). Results of this testing demonstrate that the design outputs continue to meet the design inputs and user need requirements.

#### **9. Conclusion:**

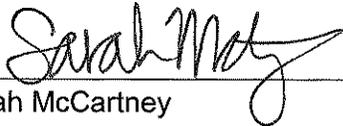
Bard Peripheral Vascular, Inc. considers the subject devices to be substantially equivalent to the predicate device.

## Appendix 2: Truthful and Accuracy Statement

## Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Specialist of Bard Peripheral Vascular, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Sarah McCartney  
Regulatory Affairs Specialist

01/23/2014

Date

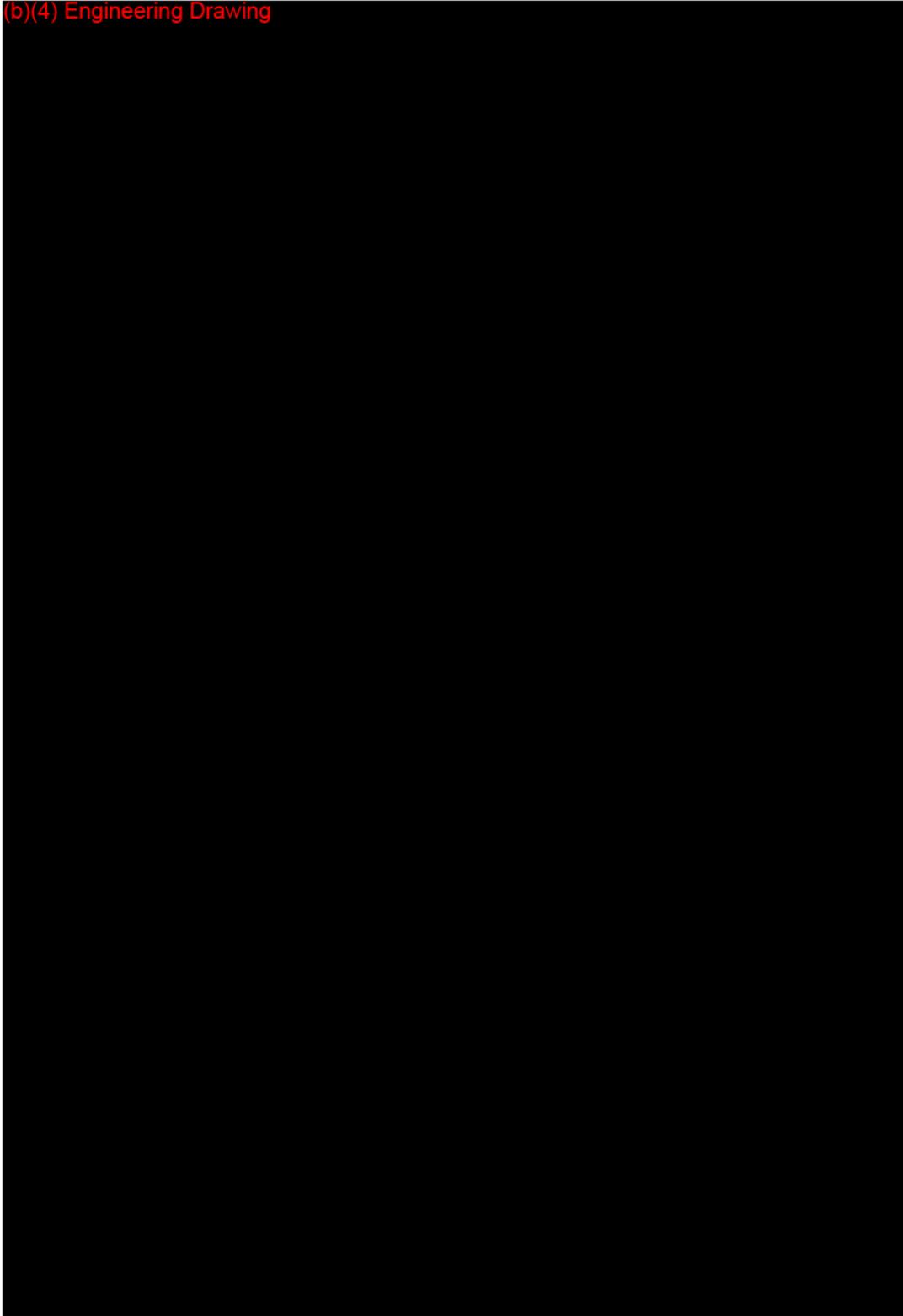
K133948

510(k) Number (if known)

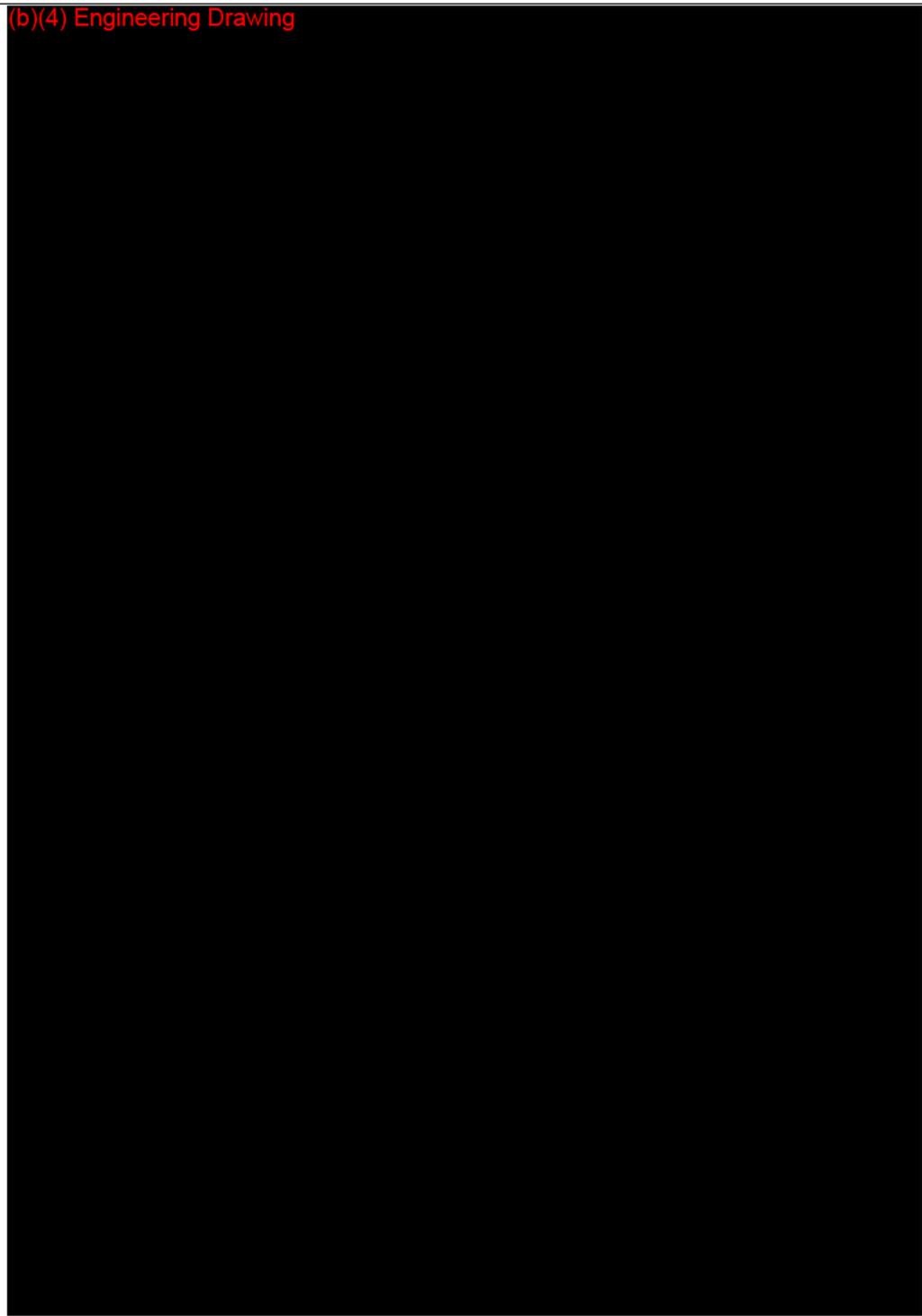
### Appendix 3: Engineering Drawings

**Bard® Monopty® Disposable Core Biopsy Instrument**

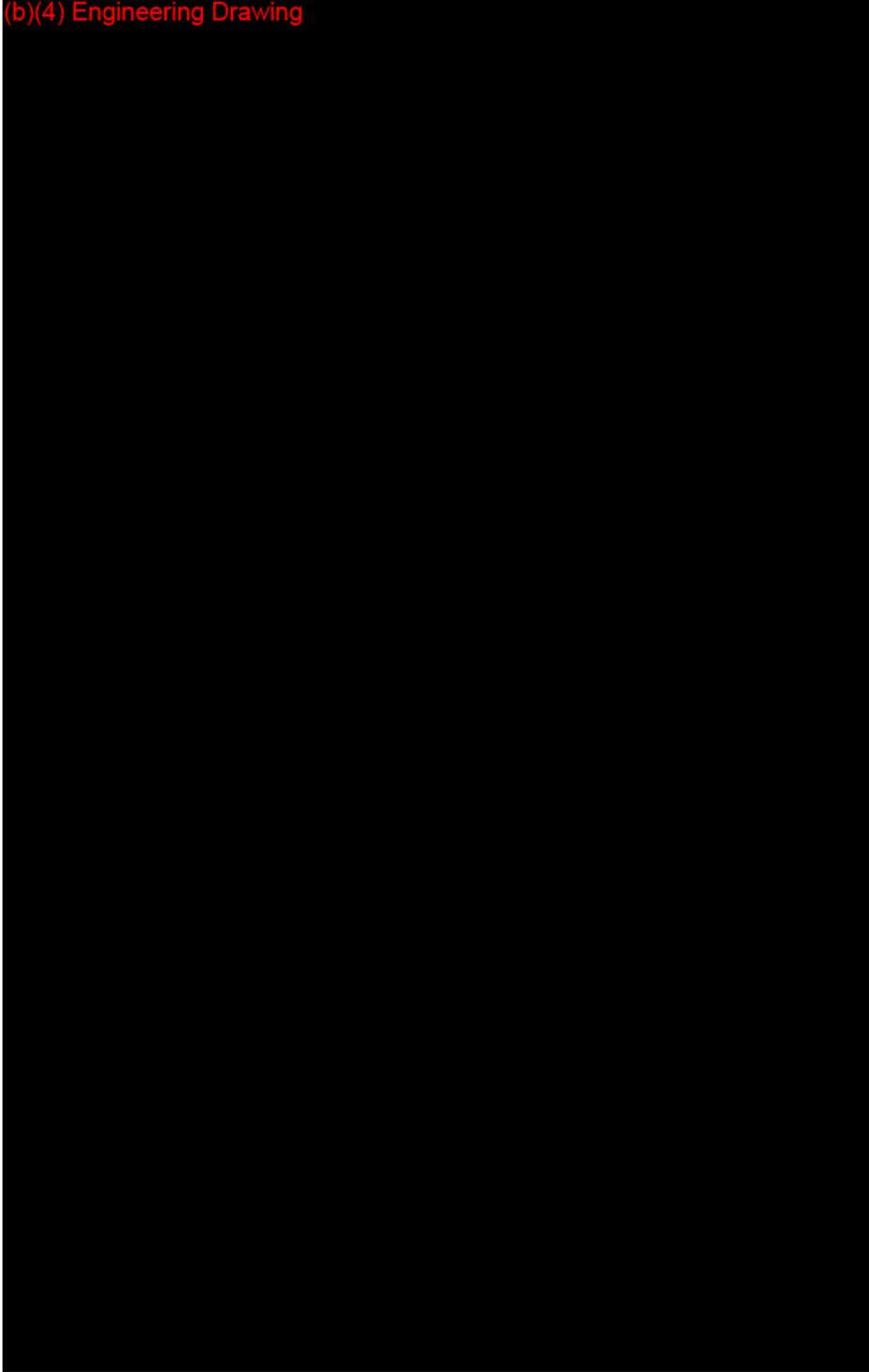
(b)(4) Engineering Drawing



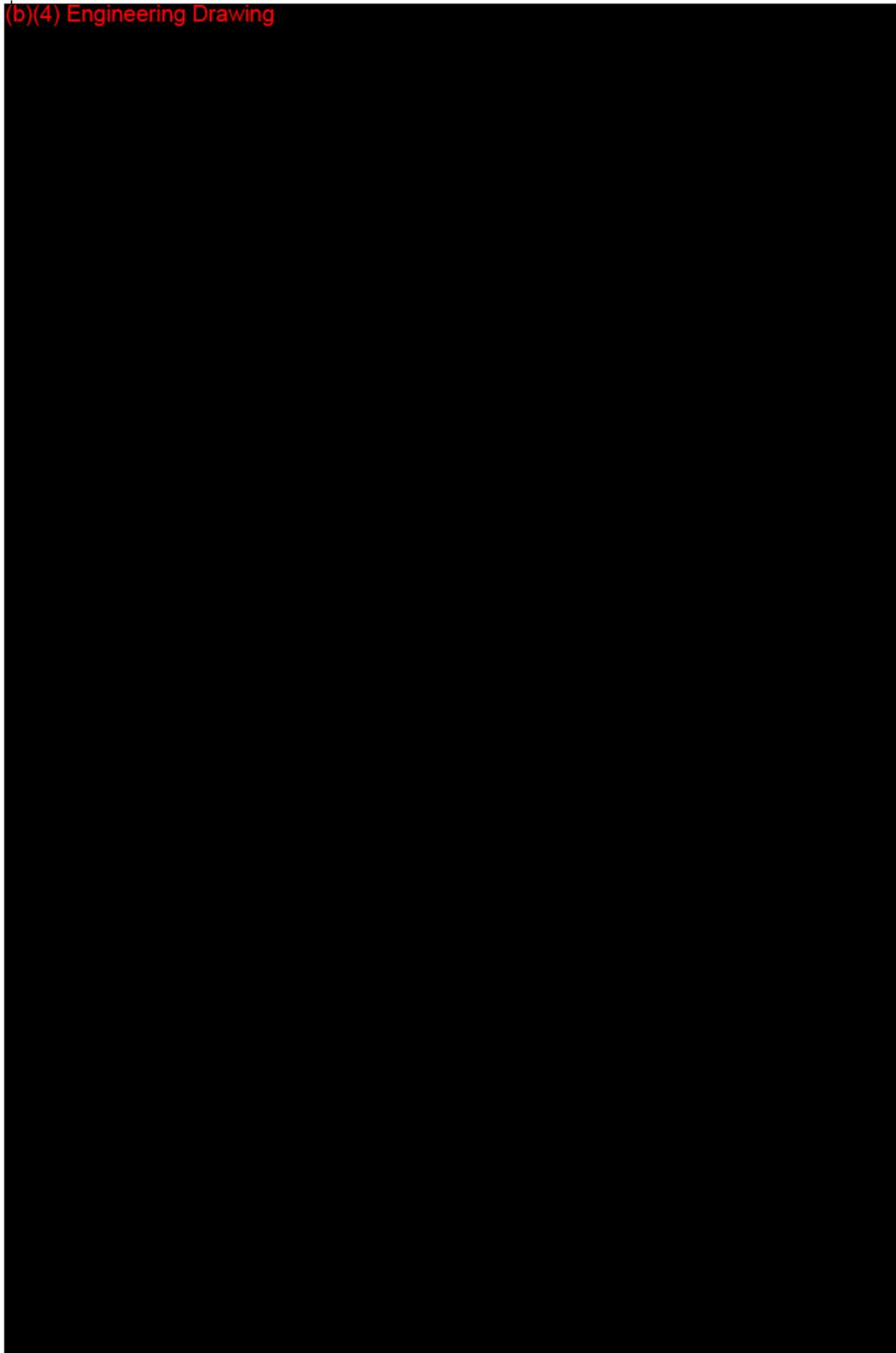
(b)(4) Engineering Drawing



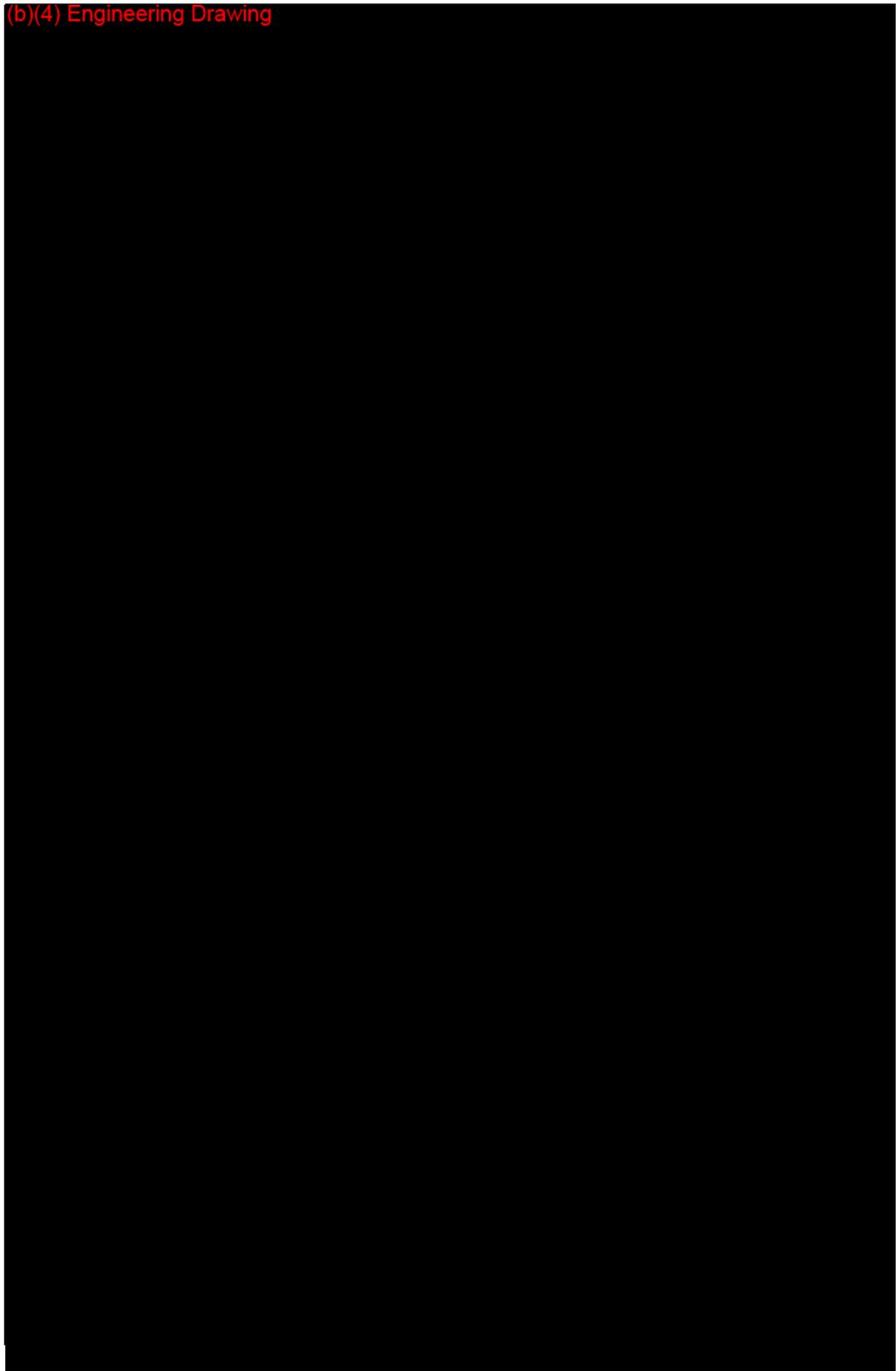
(b)(4) Engineering Drawing



(b)(4) Engineering Drawing



(b)(4) Engineering Drawing

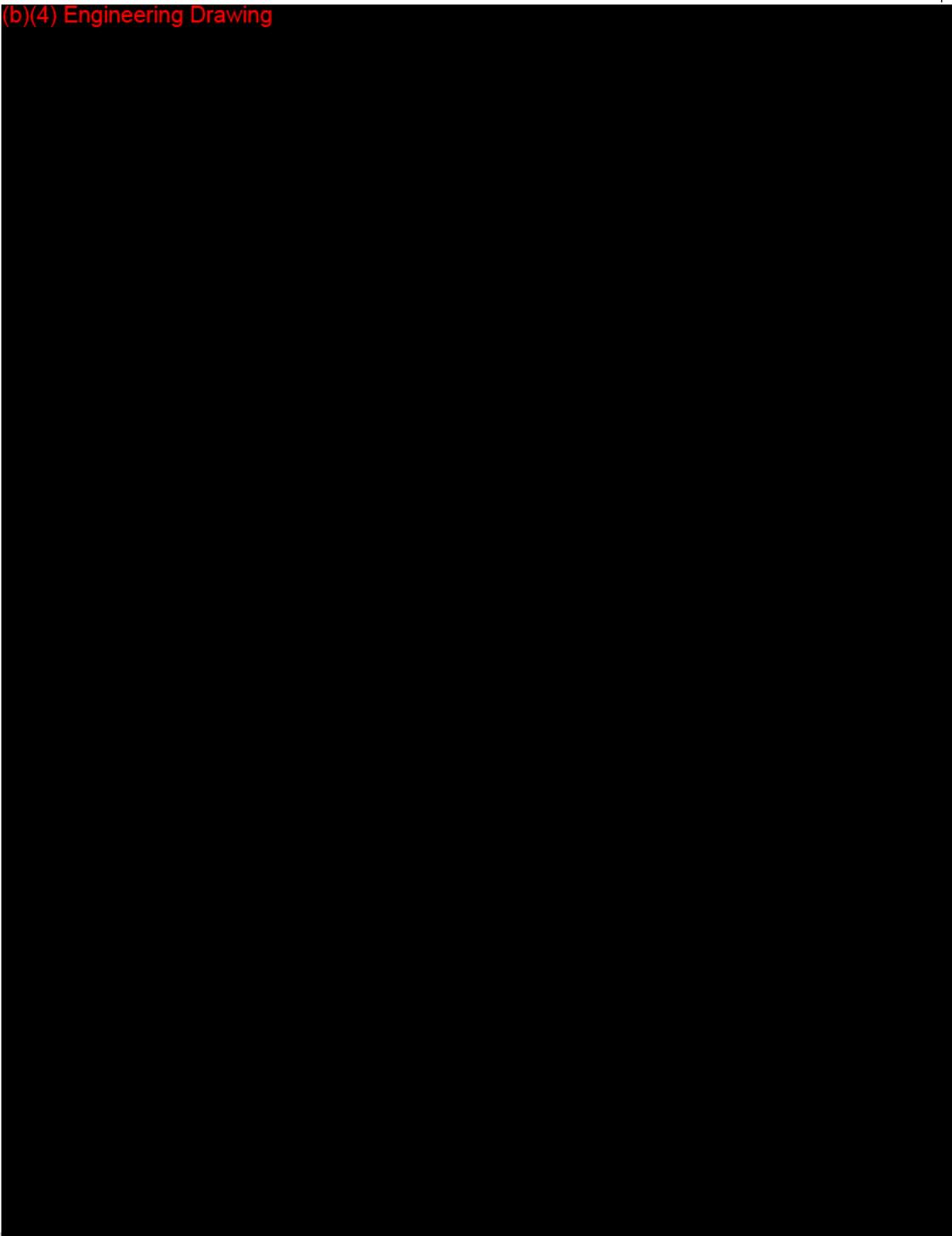


(b)(4) Engineering Drawing

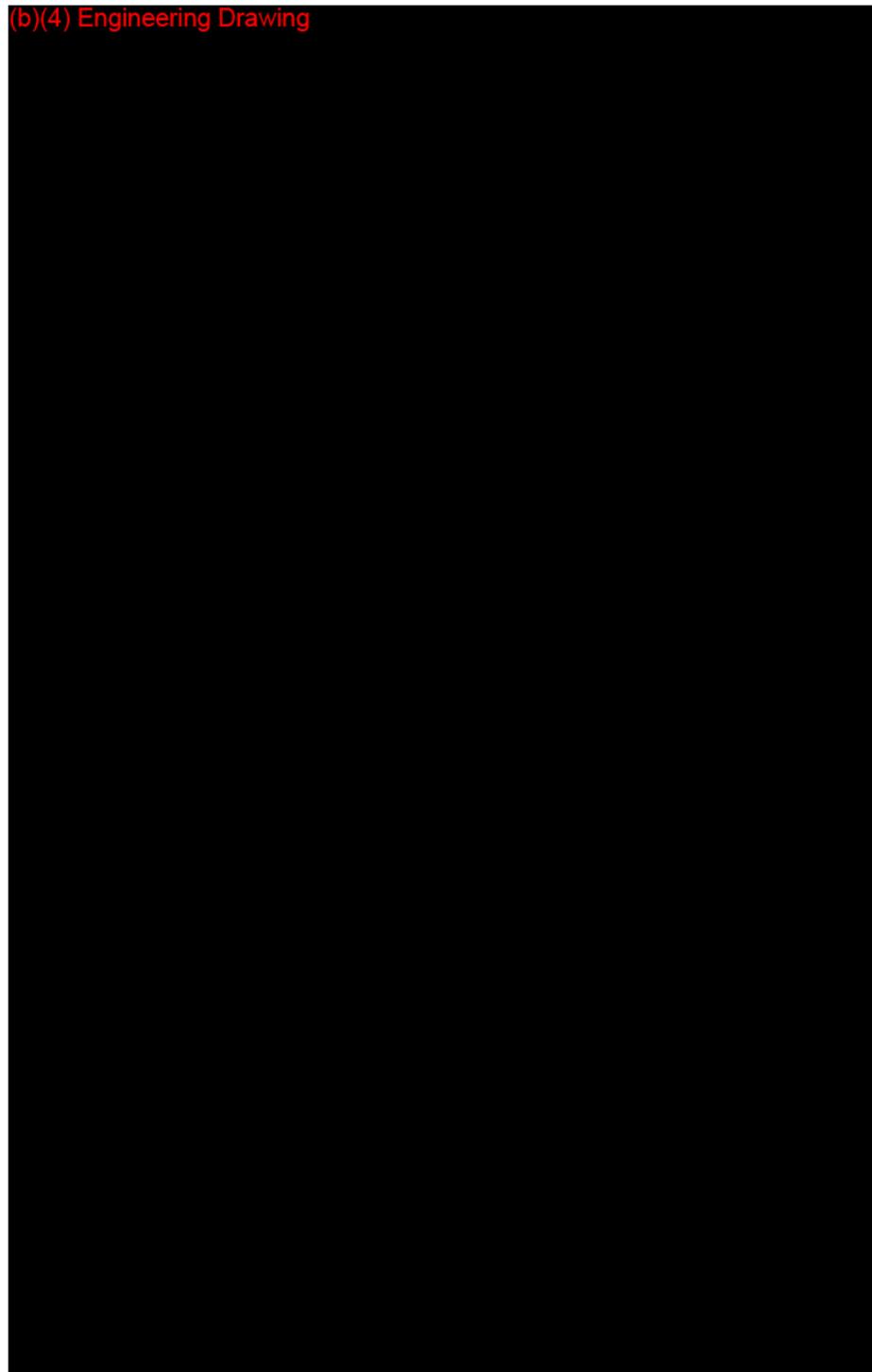


**Bard® Max-Core® Disposable Core Biopsy Instrument**

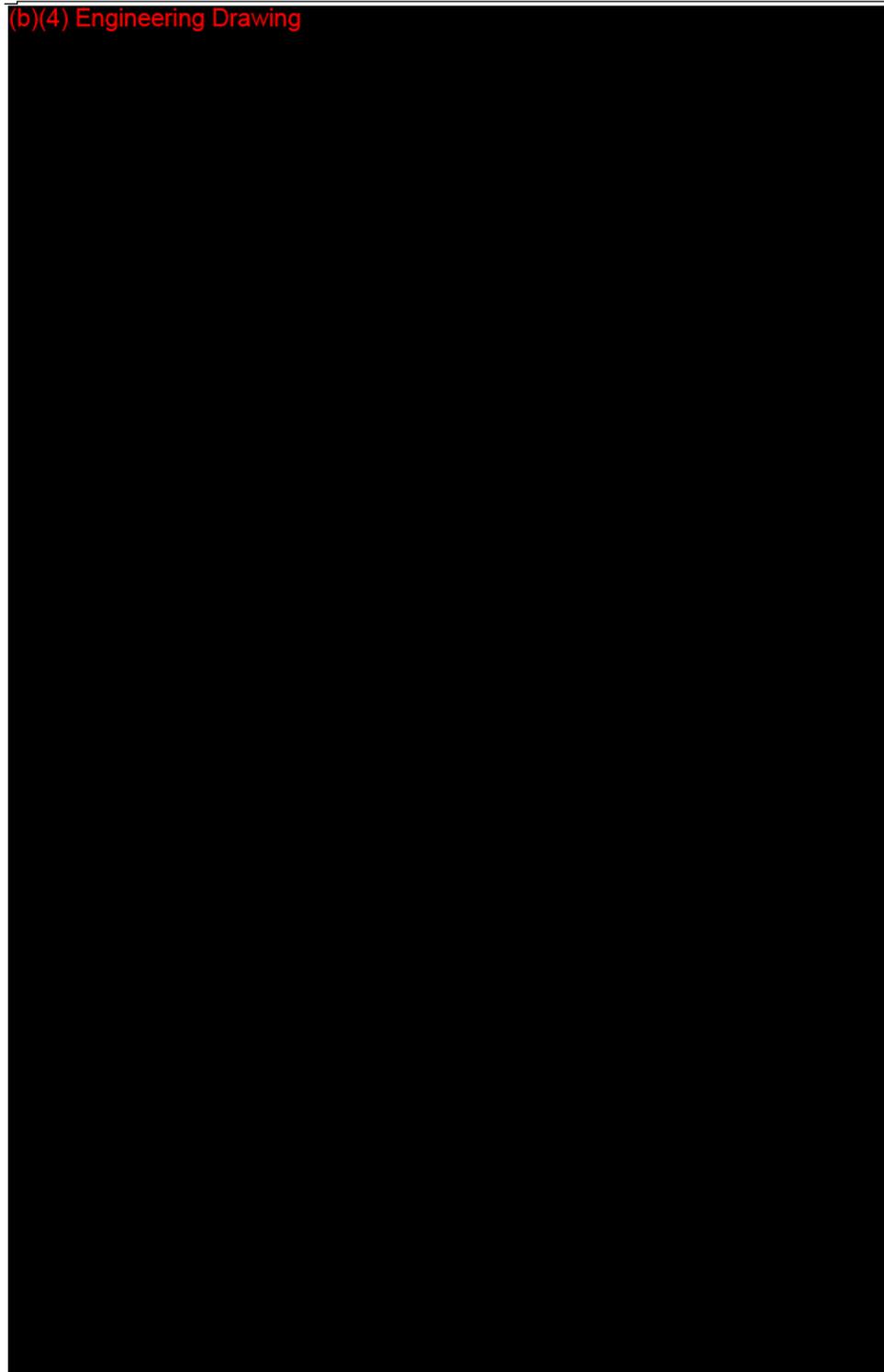
(b)(4) Engineering Drawing



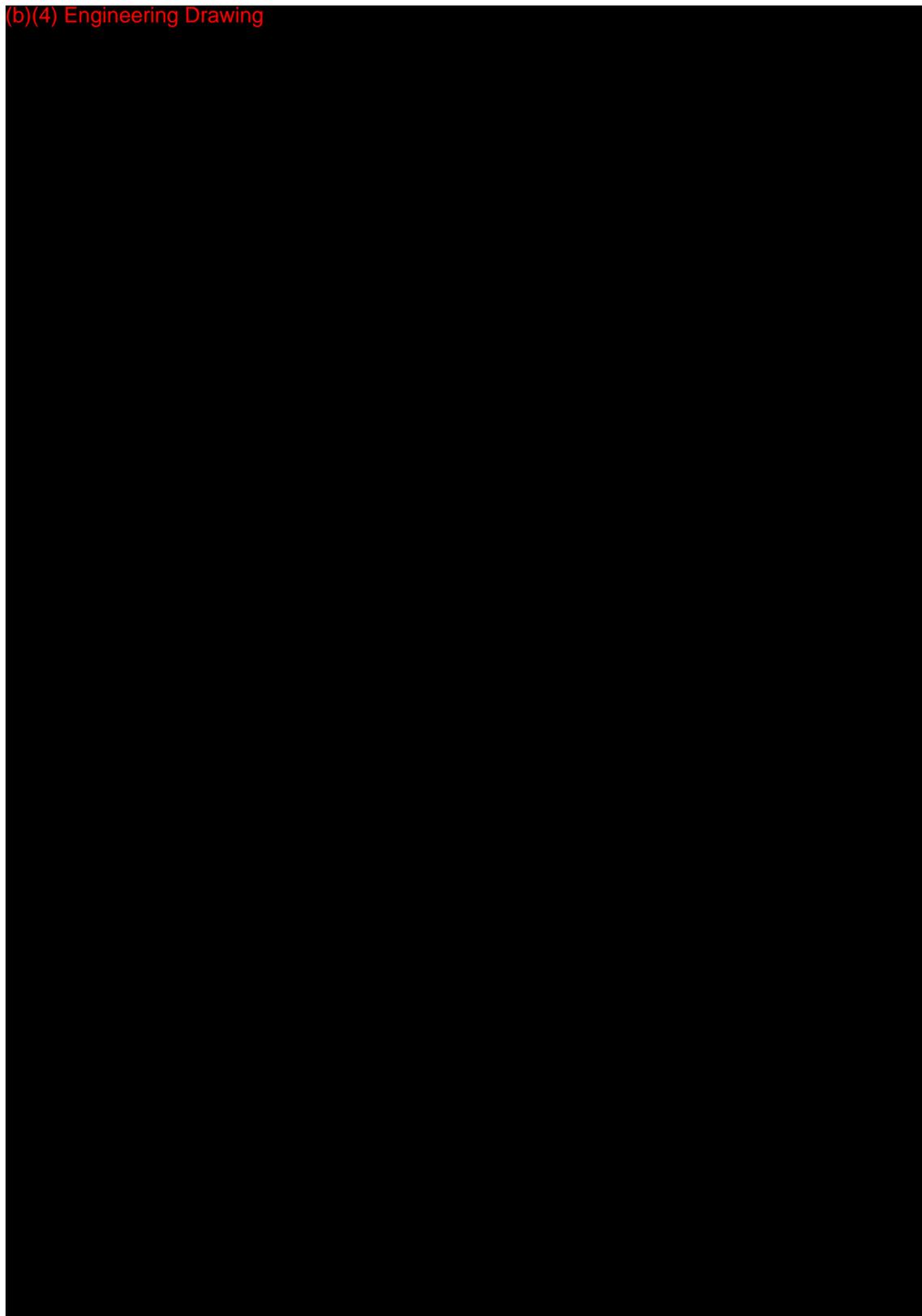
(b)(4) Engineering Drawing



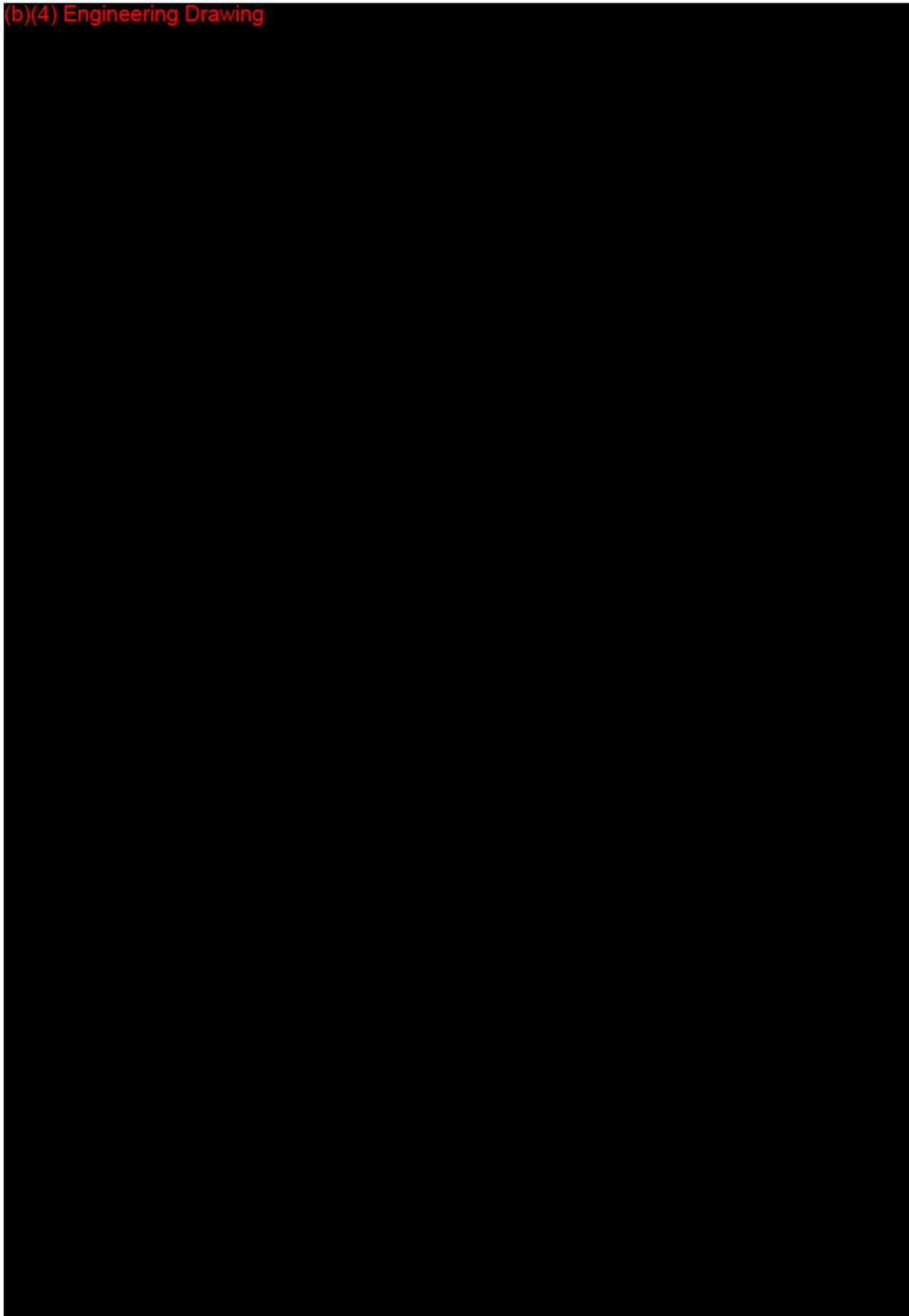
(b)(4) Engineering Drawing



(b)(4) Engineering Drawing



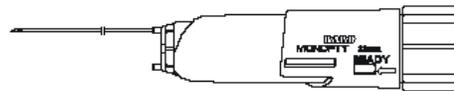
(b)(4) Engineering Drawing



## Appendix 4: Subject Device Labeling

**Bard® Monopty® Disposable Core Biopsy Instrument (English Only)**

## BARD® MONOPTY® Disposable Core Biopsy Instrument Instructions for Use



Instrument de biopsie tissulaire jetable  
BARD® MONOPTY®  
Mode d'emploi

Kertakäyttöinen BARD® MONOPTY®  
-paksuneulabiopsiainstrumentti  
Käyttöohjeet

BARD® MONOPTY® Core-Biopsie-  
Instrument für den Einmalgebrauch  
Gebrauchsanweisung

BARD® MONOPTY® engangsinstrument  
til kjernebiopsi  
Bruksanvisning

Strumento per agobiopsie  
BARD® MONOPTY®  
Istruzioni per l'uso

Jednorazowy przyrząd BARD® MONOPTY®  
do biopsji gruboigłowej  
Instrukcja użycia

Instrumento desechable para biopsia  
core BARD® MONOPTY®  
Modo de empleo

BARD® MONOPTY® eldobható  
core-biopsziás eszköz  
Használati útmutató

BARD® MONOPTY® wegwerpbaar  
hollenaaldbiopsie-instrument  
Gebruiksaanwijzing

Jednorázový nástroj BARD® MONOPTY®  
pro punkční biopsii  
Návod k použití

Instrumento de biopsia por agulha  
grossa descartável BARD® MONOPTY®  
Instruções de utilização

BARD® MONOPTY® Tek Kullanımlık  
Kor Biyopsi Cihazı  
Kullanma Talimatı

Αναλώσιμο εργαλείο βιοψίας με  
κόπτουσα βελόνα BARD® MONOPTY®  
Οδηγίες χρήσης

BARD® MONOPTY® 抛棄式  
空芯切片器械  
使用說明

BARD® MONOPTY® engangs-  
instrument til grovnålsbiopsi  
Bruksanvisning

BARD® MONOPTY® 일회용  
총생검 기구  
사용 지침

BARD® MONOPTY® engångsnål  
för kärnbiopsi  
Bruksanvisning

Одноразовый инструмент  
для толстоигльной биопсии  
BARD® MONOPTY®  
Инструкции по применению

**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® MONOPTY® Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The actuator button and arrow in the ready window are color coded according to the various gauge sizes, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge, Green=14 gauge, and Light Blue=12 gauge.

Catalog Number	Gauge Size and Needle Length	Length of Sample Notch	Penetration Depth
121210	12g (2.8mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121216	12g (2.8mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121410	14g (2.1mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121416	14g (2.1mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121610	16g (1.7mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121616	16g (1.7mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121620	16g (1.7mm) x 20cm (200mm)	1.7cm (17mm)	22mm
121810	18g (1.2mm) x 10cm (100mm)	1.7cm (17mm)	22mm
121816	18g (1.2mm) x 16cm (160mm)	1.7cm (17mm)	22mm
121820	18g (1.2mm) x 20cm (200mm)	1.7cm (17mm)	22mm
122010	20g (0.9mm) x 10cm (100mm)	1.7cm (17mm)	22mm
122016	20g (0.9mm) x 16cm (160mm)	1.7cm (17mm)	22mm
122020	20g (0.9mm) x 20cm (200mm)	1.7cm (17mm)	22mm

211410	14g (2.1mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211416	14g (2.1mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211610	16g (1.7mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211616	16g (1.7mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211620	16g (1.7mm) x 19cm (190mm)	0.7cm (7mm)	11mm
211810	18g (1.2mm) x 9cm (90mm)	0.7cm (7mm)	11mm
211816	18g (1.2mm) x 15cm (150mm)	0.7cm (7mm)	11mm
211820	18g (1.2mm) x 19cm (190mm)	0.7cm (7mm)	11mm
212010	20g (0.9mm) x 9cm (90mm)	0.7cm (7mm)	11mm
212016	20g (0.9mm) x 15cm (150mm)	0.7cm (7mm)	11mm
212020	20g (0.9mm) x 19cm (190mm)	0.7cm (7mm)	11mm

(1)

**B. How Supplied:**

The product is supplied sterile and non-pyrogenic unless the package has been opened or damaged. Sterilized using Ethylene Oxide. **For single use only. Do Not Reuse. Do Not Resterilize.**

**C. 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.

**D. Contraindications:**

Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have bleeding disorders.

**E. 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. 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.
3. 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. 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® MONOPTY® Disposable Core Biopsy Instrument. 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:** If collecting multiple samples, inspect the needle for a damaged point, bent shaft or other imperfections after each sample is collected. Do not use the needle if any imperfection is noted.

**Note:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices 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.).

(2)

3. Never test the product by firing into the air. Damage may occur to the needle/cannula tip and/or patient/user injury.
4. 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.
5. Unusual force applied to the stylet or unusual resistance against the stylet while extended out of the supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with the needle function.

#### G. 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.

#### H. Equipment Required:

- Appropriate imaging modality accessories
- Surgical gloves and drapes
- Local anesthetic as needed
- BARD® TRUGUIDE® Coaxial cannula (optional)
- Scalpel
- Sample collection container
- Other equipment as necessary

#### I. Directions for Use:

##### **BARD® MONOPTY® Disposable Core Biopsy Instrument preparation:**

Before using, inspect the needle for a damaged point, bent shaft or other imperfections that would prevent proper function. If the needle is damaged or bent, DO NOT USE.

1. Using aseptic technique, remove the instrument from its package.
2. Prepare the MONOPTY® instrument for biopsy by twisting the rotational mechanism at the end of the instrument. One-half turn will withdraw the cannula and lock it into place. An additional one-half turn will withdraw the stylet and lock it into place. The instrument is ready to fire. The arrow must be visible in the ready window prior to insertion into the patient.

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

##### **Biopsy Procedure:**

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Prepare the site as required. Adequate anesthesia should be administered prior to incision of the skin.
2. Verify instrument is energized (cocked).
3. Insert the tip of the needle prior to the lesion to be biopsied.
4. While maintaining the instrument's position and the needle orientation, depress the actuator button to cause both the stylet and the cannula to automatically advance.

(3)

ENGLISH

5. Remove needle from patient and rotate the end of the instrument one-half turn to withdraw the cannula and expose the biopsy specimen. Remove the specimen.
6. If additional biopsies of the same organ are required, withdraw the stylet by rotating the end of the instrument an additional one-half turn and repeat the procedure.

**Warranty:**

Bard Peripheral Vascular, Inc. 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.

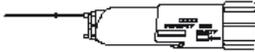
**TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO 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 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 to see if additional product information is available.

Assembled in Mexico.

(4)



**BARD® MONOPTY® Disposable Core Biopsy Instrument**

Instrument de biopsie tissulaire jetable BARD® MONOPTY®  
BARD® MONOPTY® Einweg-Stanzbiopsieinstrument  
Strumento usa-e-getta per agobiopsie BARD® MONOPTY®  
Instrumento para biopsia de núcleo desechable BARD® MONOPTY®  
BARD® MONOPTY® wegwerpbaar kernbiopsie-instrument  
Dispositivo descartável para biopsia por punção tecidual BARD® MONOPTY®  
Αναλώσιμο εργαλείο βιοψίας με κόπτιουσα βελόνα BARD® MONOPTY®  
BARD® MONOPTY® kemebiopsieinstrument til engangsbrug  
BARD® MONOPTY® kambiopsieinstrument för engångsbruk  
Kertakäyttöinen BARD® MONOPTY® -paksuneulabiopsialaite  
BARD® MONOPTY® engangsinstrument til kjembebiopsi  
Jednorazowy przyrząd BARD® MONOPTY® do biopsji gruboigłowej  
BARD® MONOPTY® egyszer használatos vastagtű-biopsziás eszköz  
Jednorázový bioptický nástroj BARD® MONOPTY® pro „core“ biopsii  
BARD® MONOPTY® Tek Kullanımlık Kor Biyopsi Cihazı  
BARD® MONOPTY® 拋棄式空芯切片器械  
BARD® MONOPTY® 일회용 총생검 기구  
Одноразовый инструмент для толстоигльной биопсии BARD® MONOPTY®



**Attention, See Instructions For Use**

Attention, voir le mode d'emploi  
Achtung! Siehe Gebrauchsanweisung  
Attenzione, leggere le istruzioni per l'uso  
Atención: consulte las instrucciones de uso  
Let op, zie Gebruiksaanwijzing  
Atenção, consultar as instruções de utilização  
Προσοχή, βλ. Οδηγίες χρήσης  
Bemærk, Se brugsvejledningen  
Obs! Se bruksanvisningen  
Huomio! Lue käyttöohjeet  
NB! Se bruksanvisningen  
Uwaga: Należy zapoznać się z instrukcją użycia  
Figyelem, lásd a használati utasítást!  
Pozor, viz návod k použití  
Dikkat, Kullanım Talimatları'na bakınız  
注意，請參閱使用說明書  
주의, 사용 지침 참조  
Внимание! См. инструкции по применению



**Catalogue Number**

Numéro de catalogue  
Katalognummer  
Numero di catalogo  
Número de catálogo  
Catalogusnummer  
Número do catálogo  
Αριθμός καταλόγου  
Katalognummer  
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目錄編號  
카탈로그 번호  
Номер по каталогу



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**Do Not Resterilize**

Ne pas restériliser  
Nicht reesterilisieren  
Non risterilizzare  
No reesterilizar  
Niet opnieuw steriliseren  
Não reesterilizar  
Μην επαναποστειρώνετε  
Må ikke reesteriliseres  
Får ej omsteriliseras  
Ei saa steriloida uudestaan  
Må ikke reesteriliseres  
Nie sterylizować ponownie  
Újraesterilizálni tilos  
Neprovádějte reesterilizaci  
Tekrar sterilize etmeyiniz  
請勿重複消毒  
재멸균하지 마십시오.  
Повторная стерилизация запрещена



**Lot Number**

Numéro de lot  
Chargennummer  
Numero di lotto  
Número de lote  
Lotnummer  
Número do Lote  
Αριθμός παρτίδας  
Lotnummer  
Lotnummer  
Eränumero  
Partinummer  
Numer partii  
Sorozatszám  
Číslo šarže  
Lot Numarası  
批號  
로트 번호  
Номер партии



**Use By**

Date limite d'utilisation  
Verwendbar bis  
Utilizzare entro  
Usar antes de  
Te gebruiken vóór  
Prazo de validade  
Ημερομηνία λήξης  
Anvendes før  
Utgångsdatum  
Käytettävä ennen  
Brukes innen  
Termin ważności  
Felhasználható  
Datum použitelnosti  
Son Kullanım Tarihi  
有效期限  
유효기한  
Использовать до



**Single Use**

A usage unique  
Nur zum Einmalgebrauch  
Monouso  
Un solo uso  
Voor eenmalig gebruik  
Utilização Única  
Για μία χρήση μόνο  
Engangsbrug  
Engangsbruk  
Kertäkäyttöinen  
Til engangsbruk  
Tylko do jednorazowego użytku  
Egyszer használatos  
K jednorázovému použití  
Tek Kullanım İçindir  
僅供一次性使用  
1회 사용  
Однократного применения



**Sterilized Using Ethylene Oxide**

Stérilisé à l'oxyde d'éthylène  
Mit Ethylenoxid sterilisiert  
Sterilizzato con ossido di etilene  
Esterilizado con óxido de etileno  
Gasteriliseerd met behulp van ethyleenoxide  
Esterilizado por óxido de etileno  
Αποστειρωμένο με οξείδιο του αιθυλενίου  
Steriliseret ved ethylenoxid  
Steriliserad med etylenoxid  
Steriloitu etyleenioksidilla  
Steriliseret med etylenoksid  
Produkt sterylizowany tlenkiem etylenu  
Etilénoxidal sterilizálva  
Sterilizováno etylenoxidem  
Etilen Oksit Kullanılarak Sterilize Edilmiştir  
使用環氧乙烷消毒  
산화에틸렌으로 멸균 처리됨  
Стерилизовано этиленоксидом



**Manufacturer**

Fabricant  
Hersteller  
Produttore  
Fabricante  
Fabrikant  
Fabricante  
Κατασκευαστής  
Producent  
Tililverkare  
Valmistaja  
Produsent  
Producent  
Gyártó  
Výrobce  
Uretici  
製造商  
제조사  
Производитель



**Non-Pyrogenic**

Apyrogène  
Pyrogenfrei  
Apirógeno  
Apirógeno  
Niet-pyrogeen  
Apirogénico  
Μη πυρετογόνο  
Pyrogenfri  
Pyrogenfri  
Pyrogeeniton  
Pyrogenfri  
Apirogenny  
Pirogénmentes  
Apyrogenní  
Pirojenik deǵildir  
無熱原  
비발열성  
Апирогенно



**Peel to Open**

Peler pour ouvrir  
Zum Öffnen abziehen  
Per aprire staccare qui  
Retirar para abrir  
Trekken om te openen  
Descolar para abrir  
Αποκολλήστε για να ανοίξει  
Trækkes af for at åbne  
Riv upp för att öppna  
Repäise auki  
Trek av for å åpne  
Zerwać w celu otwarcia  
A kinyitáshoz húzza szét  
Otvěrite stržením krycí fólie  
Soyarak Açınız  
撕下即可開啟  
벗겨서 개봉하십시오.  
Потянуть для открытия



**Gauge Size and Needle Length**

Diamètre et longueur de l'aiguille  
Größe (Gauge) und Nadellänge  
Calibro e lunghezza dell'ago  
Tamaño de calibre y longitud de aguja  
Naaldikte en -lengte  
Calibre e comprimento da agulha  
Μέγεθος gauge και μήκος βελόνας  
Gauge-størrelse og nålelængde  
Gaugestørlek och nållängd  
G-koko ja neulan pituus  
Gaugestørrelse og nålelengde  
Rozmiar i długość igły  
Vastagság és tűhosszúság  
Průměr a délka jehly  
Kalibre Büyüklüğü ve İğne Uzunluğu  
規格尺寸和針長  
게이지 크기 및 바늘 길이  
Калибр и длина иглы



**Length of Sample Notch**

Longueur d'encoche d'échantillonnage  
Länge der Probenkerbe  
Lunghezza dell'incavo per il campione  
Longitud de la muesca de la muestra  
Lengte van inkeping  
Comprimento do entalhe da amostra  
Μήκος εγκοπής δείγματος  
Længde af prøverille  
Provskårans längd  
Näyteloven pituus  
Lengden på prøvetakingshakket  
Długość wcięcia próbki  
Mintavető horny hossza  
Délka drážky na vzorek  
Ömek Çentik Uzunluğu  
樣本切口長度  
샘플 노치 길이  
Длина выемки для образца



**Penetration Depth**

Profondeur de pénétration  
Penetrationstiefe  
Profondità di penetrazione  
Profundidad de penetración  
Penetratiediepte  
Profundidade de penetração  
Βύθος διείσδυσης  
Penetrationsdybde  
Penetrationsdjup  
Penetraatiosyvyys  
Penetrasjonsdybde  
Głębokość penetracji  
Behatólási mélység  
Hĺoubka průniku  
Ginç Derinliđi  
穿刺深度  
침투 깊이  
Глубина проникновения



**Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised**

Ne pas utiliser si la barrière de stérilisation ou l'emballage du produit est endommagé  
Bei beschädigter oder offener Sterilverpackung nicht verwenden  
Non utilizzare se la barriera di sterilizzazione del prodotto o la confezione sono compromessi  
No utilizar si la barrera de esterilización del producto o su envase están dañados  
Niet gebruiken wanneer de sterilisatiebarrière van het product of de verpakking is aangetast  
Não utilizar se a barreira de esterilização do produto ou respectiva embalagem estiverem comprometidas  
Μη χρησιμοποιείτε το προϊόν εάν έχει παραβιαστεί ο φραγμός αποστείρωσης ή η συσκευασία του  
Må ikke anvendes, hvis produktets steriliseringsbarriere eller emballagen er kompromitteret.  
Använd inte om produktens sterila barriär eller dess förpackning är skadad  
Ei saa käyttää, jos tuotteen steriloitinsuojaus tai pakkaus on vaurioitunut  
Bruk ikke produktet hvis den sterile barrieren eller emballasjen er brutt  
Nie używać, jeśli naruszono sterylność produktu lub jego opakowanie  
Ne használja, ha a termék védő steril zár vagy a csomagolás sérült  
Nepoužívejte výrobek s narušenou sterilizační ochranou nebo porušeným obalem.  
Ürün Steril Bariyeri veya Ambalajı zarar görmüşse kullanmayın  
如果產品消毒屏障或包裝受損，請勿使用  
제품의 멸균 장벽이나 포장에 손상이 손상을 경우 사용하지 마십시오.  
Запрещается применять изделие, если стерильная упаковка или внешняя упаковка повреждена



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Représentant autorisé au sein de la Communauté européenne  
Bevollmächtigter in der Europäischen Gemeinschaft  
Rappresentante autorizzato nella Comunità Europea  
Representante autorizado en la Comunidad Europea  
Gemachtigde binnen de Europese Gemeenschap  
Representante autorizado na Comunidade Europeia  
Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα  
Auktoriseret repræsentant i Det Europæiske Fællesskab  
Auktoriserad representant inom EG  
Valtuutettu edustaja Euroopan yhteisössä  
Autorisert representant i EU  
Autoryzowany przedstawiciel na terenie Unii Europejskiej  
Meghatalmazott képviselő az Európai Közösségben  
Autorizovaný zástupce v Evropské unii  
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**Manufacturer:**

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Tempe, AZ 85281  
USA

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1-800-321-4254  
FAX: 1-480-966-7062  
1-800-440-5376  
[www.bardbiopsy.com](http://www.bardbiopsy.com)



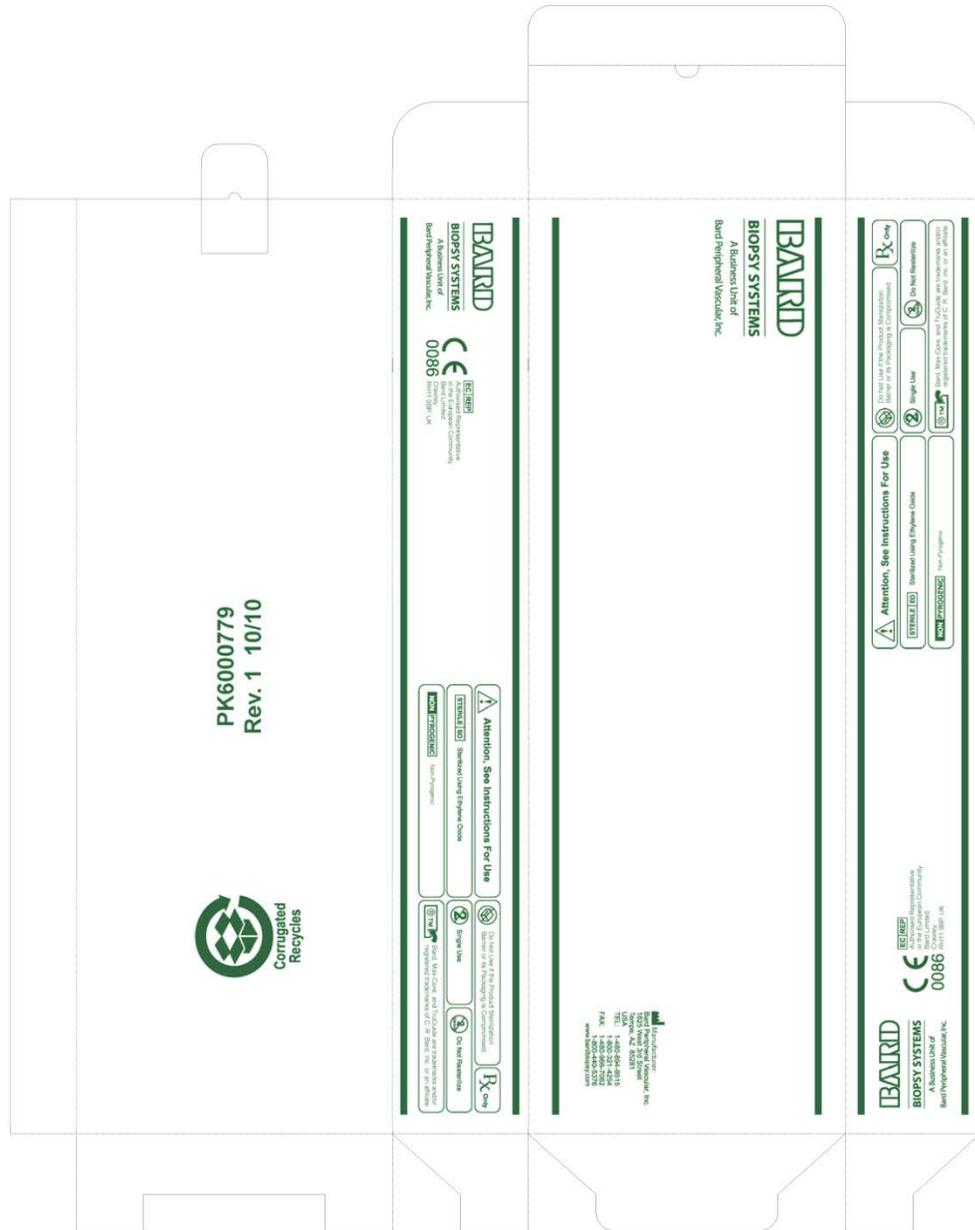
**Authorised Representative  
in the European Community  
Bard Limited**

Forest House  
Tilgate Forest Business Park  
Brighton Road, Crawley  
West Sussex  
RH11 9BP, UK

**BAIRD**

**BIOPSY SYSTEMS**

PK1280000 Rev. 0 05/12



Box (1212XX Codes)

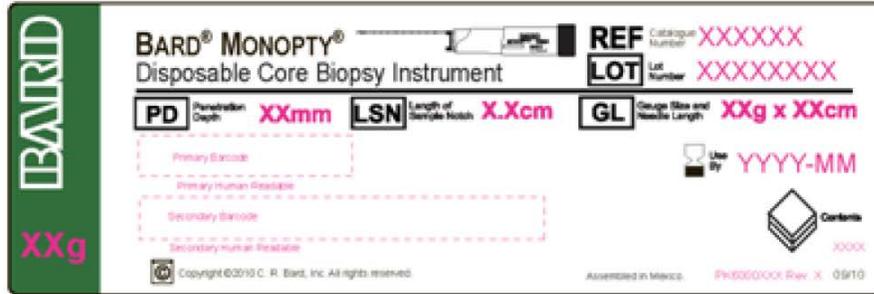


Box ( 1214XX-1220XX, 21XXXX Codes)



Tray Lid

Variable Fields



Box Label



Multi-language Label

Variable Fields



Tray Lid Label



All Products > Core Needle Biopsy Products > BARD® MONOPTY® Disposable Core Biopsy Instrument

COMPLEMENTARY PRODUCTS

MAX-CORE Disposable Core Biopsy Instrument

CONTACT US

I Want To Order

I Need More Information

INDICATIONS FOR USE

Download IFU



THE CONVENIENCE OF A DISPOSABLE WITH CONSISTENTLY ACCURATE CORE SAMPLES

- Ease of single use combined with the security that comes with a Bard product
- Penetration depths of 11mm or 22mm offer you maximum procedural versatility
- Lightweight handle provides you greater handling and control
- Color coding promotes accurate needle gauge identification
- Compatibility with BARD® TRUGUID® Coaxial Biopsy Needle enhances efficiency and accuracy



22mm PENETRATION DEPTH	GAUGE x LENGTH (cm)	COAXIAL LENGTH (cm)	COAXIAL ORDER NO.
● 121210	12 x 10	7.8	C1210A
● 121216	12 x 16	13.8	C1216A
● 121410	14 x 10	7.8	C1410A
● 121416	14 x 16	13.8	C1416A
● 121610	16 x 10	7.8	C1610A
● 121616	16 x 16	13.8	C1616A
● 121620	16 x 20	17.8	C1620A
● 121810	18 x 10	7.8	C1810A
● 121816	18 x 16	13.8	C1816A
● 121820	18 x 20	17.8	C1820A
● 122010	20 x 10	7.8	C2010A
● 122016	20 x 16	13.8	C2016A
● 122020	20 x 20	17.8	C2020A

11mm PENETRATION DEPTH	GAUGE x LENGTH (cm)	COAXIAL LENGTH (cm)	COAXIAL ORDER NO.
● 211410	14 x 9	7.8	C1410A
● 211416	14 x 15	13.8	C1416A
● 211610	16 x 9	7.8	C1610A
● 211616	16 x 15	13.8	C1616A
● 211620	16 x 19	17.8	C1620A
● 211810	18 x 9	7.8	C1810A
● 211816	18 x 15	13.8	C1816A
● 211820	18 x 19	17.8	C1820A
● 212010	20 x 9	7.8	C2010A
● 212016	20 x 15	13.8	C2016A
● 212020	20 x 19	17.8	C2020A

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**Bard® Max-Core® Disposable Core Biopsy Instrument (English Only)**

**BARD® MAX-CORE®**  
**Disposable Core Biopsy Instrument**  
**Instructions for Use**



BARD® MAX-CORE® Instrument pour biopsie à usage unique  
Mode d'emploi

BARD® MAX-CORE® Einweg-Biopsieinstrument  
Gebrauchsanweisung

BARD® MAX-CORE® Strumento Usa-e-Getta per Agobiopsia  
Istruzioni per l'Uso

BARD® MAX-CORE® Instrumento de Biopsia Desechable  
Instrucciones de uso

BARD® MAX-CORE® Biopsie-instrument voor eenmalig gebruik  
Gebruiksaanwijzing

BARD® MAX-CORE® Instrumento de Biopsia Descartável  
Instruções de Utilização

BARD® MAX-CORE® Αναλώσιμο εργαλείο βιοψίας δια βελόνας  
Οδηγίες χρήσης

BARD® MAX-CORE® Biopsiinstrument til engangsbrug  
Brugervejledning

BARD® MAX-CORE® Biopsiinstrument för engångsbruk  
Bruksanvisning

Kertakäyttöinen BARD® MAX-CORE® -paksuneulabiopsialaite  
Käyttöohjeet

BARD® MAX-CORE® biopsiinstrument til éngangsbruk  
Bruksanvisning

Przyrząd do biopsji jednorazowego użytku BARD® MAX-CORE®  
Instrukcja użycia

BARD® MAX-CORE® Egyszer Használatos Biopsziás Eszköz  
Használati utasítás

BARD® MAX-CORE® Jednorázový nástroj pro biopsii  
Pokyny k použití

BARD® MAX-CORE® Tek Kullanımlık Kor Biyopsi Aleti Biyopsi Aygıtı  
Kullanma Talimatı

BARD® MAX-CORE® 拋棄式空芯切片器械  
使用說明

BARD® MAX-CORE® 일회용 총생검 기구  
사용 지침

Одноразовый инструмент для толстоигольной биопсии BARD® MAX-CORE®  
Инструкции по применению

Jednorázový nástroj na hrubohlovú biopsiu BARD® MAX-CORE®  
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® Max-Core® Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes, e.g., Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge and Green=14 gauge.

Catalogue Number	Gauge Size and Needle Length	Length of Sample Notch	Penetration Depth
MC1410	14g (2.1mm) x 10cm (100mm)	1.9cm (19mm)	22mm
MC1416	14g (2.1mm) x 16cm (160mm)	1.9cm (19mm)	22mm
MC1610	16g (1.7mm) x 10cm (100mm)	1.9cm (19mm)	22mm
MC1616	16g (1.7mm) x 16cm (160mm)	1.9cm (19mm)	22mm
MC1810	18g (1.2mm) x 10cm (100mm)	1.8cm (18mm)	22mm
MC1816	18g (1.2mm) x 16cm (160mm)	1.8cm (18mm)	22mm
MC1820	18g (1.2mm) x 20cm (200mm)	1.8cm (18mm)	22mm
MC1825	18g (1.2mm) x 25cm (250mm)	1.8cm (18mm)	22mm
MC2010	20g (0.9mm) x 10cm (100mm)	1.8cm (18mm)	22mm
MC2016	20g (0.9mm) x 16cm (160mm)	1.8cm (18mm)	22mm
MC2020	20g (0.9mm) x 20cm (200mm)	1.8cm (18mm)	22mm

**B. How Supplied:**

The product is supplied sterile and non-pyrogenic unless the package has been opened or damaged. **Sterilized using Ethylene Oxide. For single use only. Do Not Reuse. Do Not Resterilize.**

**C. 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.

**D. Contraindications:**

Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding problem.

**E. 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. 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.
3. The Bard® Max-Core® Biopsy Instrument 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 indeterminate 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.
4. Do not resterilize the Bard® Max-Core® Biopsy Instrument. 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:** If collecting multiple samples, inspect the needle for damaged point, bent shaft or other imperfections after each sample is collected. Do not use needle if any imperfection is noted.

**Note:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and with 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.)
3. Never test the product 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 supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with the needle function.

**G. 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 signs or symptoms of air embolism.

ENGLISH

**H. Equipment Required:**

- Appropriate imaging modality accessories
- Surgical gloves and drapes
- Local anesthetic
- BARD® TRUGUIDE® Coaxial Cannula (optional)
- Scalpel
- Sample collection container
- Other equipment as necessary

**I. Directions for Use:**

**BARD® MAX-CORE® Biopsy Instrument preparation:**

Before using, inspect the needle for damaged point, bent shaft or other imperfections that would prevent proper function. If the needle is damaged or bent, DO NOT USE.

1. Using aseptic technique, remove the Instrument from its package. See Figure 1.

**Note:** To remove the protective needle sheath and yellow guard, you must energize (cock) Instrument.

2. Energize (cock) Instrument by pulling back on the top slide to withdraw the cannula and lock in place. See Figure 2. Then pull back on the bottom slide to withdraw the stylet and lock in place. See Figure 3. Remove protective needle sheath and yellow guard. Instrument is ready to fire when both slides are locked back.

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

**Biopsy Procedure:**

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Prepare site as required. Adequate anesthesia should be administered prior to incision of the skin.
2. Verify Instrument is energized (cocked). See Figure 3.

**Note:** Do not place fingers in front of cocking slides once Instrument is energized (cocked). Impeding cocking slides' movement will impact functionality.

3. Insert tip of needle to the point to be biopsied.
4. While maintaining Instrument's position and the needle orientation, depress the rear actuator button, or push the side actuator forward (direction of arrow), to cause both stylet and cannula to automatically advance.
5. Remove needle from patient and pull back on the top slide to withdraw the cannula and expose the biopsy specimen (See Figure 2). Remove the specimen.
6. If additional biopsies are required, pull back on the bottom slide to withdraw the stylet and repeat the procedure.

Figure 1



- As Packaged (Protective Needle Sheath and Yellow Guard Not Shown)
- Instrument **Not** Energized (Cocked)
- **Not** Ready to Fire

Figure 2



- Top Slide Locked Back
- Biopsy Sample Notch Exposed

Figure 3



- Top Slide and Bottom Slide Locked Back
- Instrument Energized (Cocked)
- Ready to Fire

**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.

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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 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 to see if additional product information is available.

Assembled in Mexico.

 **Bard® Max-Core® Disposable Core Biopsy Instrument**  
 Bard® Max-Core® Instrument pour biopsie à usage unique  
 Bard® Max-Core® Einweg-Biopsieinstrument  
 Bard® Max-Core® Strumento Usa-e-Getta per Agobiopsia  
 Bard® Max-Core® Instrumento de Biopsia Desechable  
 Bard® Max-Core® Biopsie-instrument voor eenmalig gebruik  
 Bard® Max-Core® Instrumento de Biopsia Descartável  
 Bard® Max-Core® Αβαλίστιμο εργαλείο βιοψίας δια βελόνας  
 Bard® Max-Core® Biopsieinstrument til éngangsbrug  
 Bard® Max-Core® Biopsieinstrument för éngångsbruk  
 Kertakäyttöinen Bard® Max-Core® -paksuneulabiopsialaite  
 Bard® Max-Core® biopsieinstrument til éngangsbruk  
 Przyrząd do biopsji jednorazowego użytku Bard® Max-Core®  
 Bard® Max-Core® Egyszer Használatos Biopsziás Eszköz  
 Bard® Max-Core® Jednorázový nástroj pro biopsii  
 Bard® Max-Core® Tek Kullanımlık Kor Biyopsi Aleti Biyopsi Aygıtı  
 Bard® Max-Core® 拋棄式空芯切片器械  
 Bard® Max-Core® 일회용 총생검 도구  
 Одноразовый инструмент для толстоигольной биопсии  
 Bard® Max-Core®  
 Jednorázový nástroj na hrubohľovú biopsiu Bard® Max-Core®



**Attention, See Instructions For Use**  
 Attention, voir le mode d'emploi  
 Achtung! Siehe Gebrauchsanweisung  
 Attenzione, leggere le istruzioni per l'uso  
 Atención: consulte las instrucciones de uso  
 Let op, zie Gebruiksaanwijzing  
 Atenção, consulte as Instruções de Utilização  
 Προσοχή, Βλ. Οδηγίες Χρήσης  
 Bemærk, Se brugervejledning  
 Obs! Se bruksanvisningen  
 Huomio! Lue käyttöohjeet  
 OBS, se Bruksanvisning  
 Uwaga: Należy zapoznać się z instrukcją użytkowania  
 Figyelem, lásd a használati utasítást  
 Pozor, viz pokyny k použití  
 Dikkat, Kullanma Talimatına Bakınız  
 注意，請參閱使用說明書  
 주의, 사용 지침 참조  
 Внимание! См. инструкции по применению  
 Pozor, pozri návod na použitie



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**Gauge Size and Needle Length**  
 Taille de la jauge et longueur de l'aiguille  
 Größe (Gauge) und Nadellänge  
 Calibro e lunghezza dell'ago  
 Tamaño de calibre y longitud de aguja  
 Gauge-maat en naaldlengte  
 Calibre e comprimento da agulha  
 Μέγεθος gauge και μήκος βελόνας  
 Gauge-størrelse og nålelængde  
 Gaugestorlek och nållängd  
 G-koko ja neulan pituus  
 Nålens diameter og lengde  
 Rozmiar i długość igły  
 Vastagság méret és tű hosszúság  
 Průměr a délka jehly  
 Gauge Büyüklüğü ve İğne Uzunluğu  
 規格尺寸和針長  
 게이지 크기 및 바늘 길이  
 Калибр и длина иглы  
 Velikost a délka ihly



**Length of Sample Notch**  
 Longueur d'encoche d'échantillon  
 Länge der Probenkerbe  
 Lunghezza dell'incavo per il campione  
 Longitud de la muesca de la muestra  
 Lengte van inkeping  
 Comprimento do entalhe da amostra  
 Μήκος εγκοπής δείγματος  
 Længde på prøvenille  
 Provsårens langd  
 Näyteloven pituus  
 Lengde på prøveinnsnitt  
 Długość karbu próbki  
 Mintavető horony hossza  
 Délka drážky pro vzorek  
 Ömek Çentik Uzunluğu  
 樣本切口長度  
 샘플 notch 길이  
 Длина выемки для образца  
 Dĺžka priestoru pre vzorku



**Penetration Depth**  
 Profondeur de pénétration  
 Penetrationstiefe  
 Profondità di penetrazione  
 Profundidad de penetración  
 Penetratiediepte  
 Profundidade de penetração  
 Βάθος διείσδυσης  
 Penetrationsdybde  
 Penetrationsdjup  
 Penetraatiosyvyyys  
 Penetreringsdybde  
 Głębość penetracji  
 Behatolási mélység  
 Hlubka průniku  
 Penetrasyon Derinliği  
 穿刺深度  
 침투 깊이  
 Глубина проникновения  
 Hĺbka penetrácie



**Lot Number**  
 Numéro de lot  
 Lot Nummer  
 Numero di lotto  
 Número de lote  
 Lotnummer  
 Número do lote  
 Αριθμός παρτίδας  
 Lot-number  
 Lot-number  
 Eränumero  
 Lot-number  
 Numer serii  
 Tételszám  
 Číslo šarže  
 Parti Numarası  
 批號  
 로트 번호  
 Номер партии  
 Číslo šarže



**Use By**

À utiliser avant  
 Verwendbar bis  
 Utilizzare entro  
 Usar antes de  
 Te gebruiken vóór  
 Prazo de validade  
 Ημερομηνία λήξης  
 Anvendes før  
 Utgångsdag  
 Käyttävää ennen  
 Brukes innen  
 Termin ważności  
 Felhasználható  
 Datum použiti  
 Son Kullanma Tarihi  
 有效期限  
 유효기한  
 Исползовать до  
 Spotrebovat' do



**Do not use if the product sterilization barrier or its packaging is compromised**

Ne pas utiliser si la barrière de stérilisation ou l'emballage du produit sont endommagés  
 Bei beeinträchtigtem Sterilschutz oder beschädigter Verpackung des Produkts nicht verwenden  
 Non usare il prodotto se la barriera sterile è compromessa o la confezione è danneggiata  
 No utilice el producto si la barrera de esterilización o su envase no están en perfecto estado  
 Niet gebruiken wanneer de sterilisatiebarrière van het product of de verpakking is aangetast  
 Não utilizar se a barreira de esterilização do produto ou respectiva embalagem estiverem comprometidas  
 Μη χρησιμοποιείτε το προϊόν εάν έχει παραβιαστεί ο φραγμός αποστείρωσης ή η συσκευασία του  
 Må ikke bruges, hvis produktets sterilisationsbarriere eller emballage er beskadiget  
 Använd inte produkten om sterilbarriären är bruten eller förpackningen öppnad eller trasig  
 Ei saa käyttää, jos tuotteen sterilointisuojaus tai pakkaus on vaurioitunut  
 Bruk ikke produktet hvis den sterile barrieren eller emballasjen er brutt  
 Nie używać, jeśli naruszono sterylność produktu lub jego opakowanie  
 Ne használja, ha a termékét védő steril zár vagy a csomagolás sérült  
 Pokud je narušena sterilní ochrana nebo poškozen obal, výrobek nepoužívejte  
 Urun steril bariyeri veya ambalajı zarar görmüşse kullanmayın  
 如果產品消毒屏障或包裝受損，請勿使用  
 제품의 멸균 장벽이나 포장에 손상된 경우 사용하지 마십시오.  
 Запрещается применять изделие, если его стерильная упаковка или внешняя упаковка повреждены  
 Nepoužívajte, ak je sterilná bariéra produktu alebo jeho obal porušený



**Sterilized Using Ethylene Oxide**

Stérilisé à l'oxyde d'éthylène  
 Sterilisiert mit Ethylenoxid  
 Sterilizzato mediante ossido di etilene  
 Esterilizado mediante óxido de etileno  
 Gesteriliseerd met behulp van ethyleenoxide  
 Esterilizado por óxido de etileno  
 Αποστειρωμένο με αιθυλενοξείδιο  
 Steriliseret med ethylenoxid  
 Steriliserad med etylenoxid  
 Steriloitu etyleenioksidilla  
 Sterilisert med etylenoksid  
 Produkt sterylizowany tlenkiem etylenu  
 Etilén-oxidál sterilizálva  
 Sterilizovano etylenoxidem  
 Etilen Oksit ile Sterilize Edilmiştir  
 使用环氧乙烷消毒  
 산화에틸렌으로 멸균 처리됨  
 Стерилизовано этиленоксидом  
 Sterilizované etylénoxidom



**Non-Pyrogenic**

Apyrogène  
 Pyrogenfrei  
 Apirogeno  
 Apirógeno  
 Niet-pyrogeen  
 Apirogénico  
 Μη πυρετογόνο  
 Apyrogen  
 Pyrogenfri  
 Pyrogeeniton  
 Pyrogenfri  
 Apirogenny  
 Pirogénmentes  
 Apyrogenní  
 Pirojenik deǵildir  
 無熱原  
 비발열성  
 Апиrogenно  
 Nepyrogénne



**Single Use**

À usage unique  
 Nur zum Einmalgebrauch  
 Monouso  
 Un solo uso  
 Voor eenmalig gebruik  
 Utilização única  
 Για μία χρήση μόνο  
 Engangsbrug  
 Engångsbruk  
 Kertakäyttöinen  
 Éngangsbruk  
 Tylko do jednorazowego użytku  
 Egyszerhasználatos  
 K jednorázovému použiti  
 Tek Kullanım İçindir  
 僅供一次性使用  
 1회 사용  
 Однократного применения  
 Na jednorazové použitie



**Manufacturer**

Fabricant  
 Hersteller  
 Fabricante  
 Fabricante  
 Fabrikant  
 Fabricante  
 Κατασκευαστής  
 Producent  
 Tillverkare  
 Valmistaja  
 Fabrikant  
 Producent  
 Gyártó  
 Výrobce  
 Uretici  
 製造商  
 제조사  
 Производителъ  
 Výrobca



**Do Not Resterilize**

Ne pas restériliser  
 Nicht reesterilisieren  
 Non risterilizzare  
 No reesterilizar  
 Niet opnieuw steriliseren  
 Não reesterilizar  
 Μη επαναποστειρώνετε  
 Må ikke reesteriliseres  
 Får ej omsteriliseras  
 Ei saa steriloida uudestaan  
 Skal ikke reesteriliseres  
 Nie sterylizować ponownie  
 Ne sterilizálja újra  
 Neprovádajte reesterilizaci  
 Tekrar Sterilize Etmeyin  
 請勿重複消毒  
 재멸균하지 마십시오.  
 Повторная стерилизация запрещена  
 Nesterilizujte opakovane



**Lift Here**

Soulevre ici  
Hier anheben  
Sollevare qui  
Levantar aquí  
Hier optillen  
Levantar aqui  
Ανασηλώστε εδώ  
Løft her  
Lyft här  
Nosta tästä  
Løft her  
Przy podnoszeniu chwycić tutaj  
Itt emelje föl  
Zde zdvihněte  
Buradan Kaldırın  
掀起此處  
여기를 들어 올리십시오  
Поднять здесь  
Tu nadvihnite



**Authorized Representative in the European Community**

Représentant autorisé au sein de la Communauté européenne  
Bevollmächtigter in der Europäischen Gemeinschaft  
Rappresentante autorizzato nella Comunità Europea  
Representante autorizado en la Comunidad Europea  
Gemachtigde binnen de Europese Gemeenschap  
Representante autorizado na Comunidade Europeia  
Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα  
Autoriseret repræsentant i Det Europæiske Fællesskab  
Auktoriserad representant inom EG  
Valtuutettu edustaja Euroopan yhteisössä  
Autorisert representant i EU  
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Meghatalmazott képviselő az Európai Közösségekben  
Autorizovaný zástupce v Evropské unii  
Avrupa Topluluğu Yetkili Temsilcisi  
歐洲共同體的授權代表  
유럽 공동체 내의 인증받은 대리업체  
Уполномоченный представитель в Европейском сообществе  
Oprávněný zástupca v Európskom spoločenstve



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1-800-440-5376  
[www.bardbiopsy.com](http://www.bardbiopsy.com)



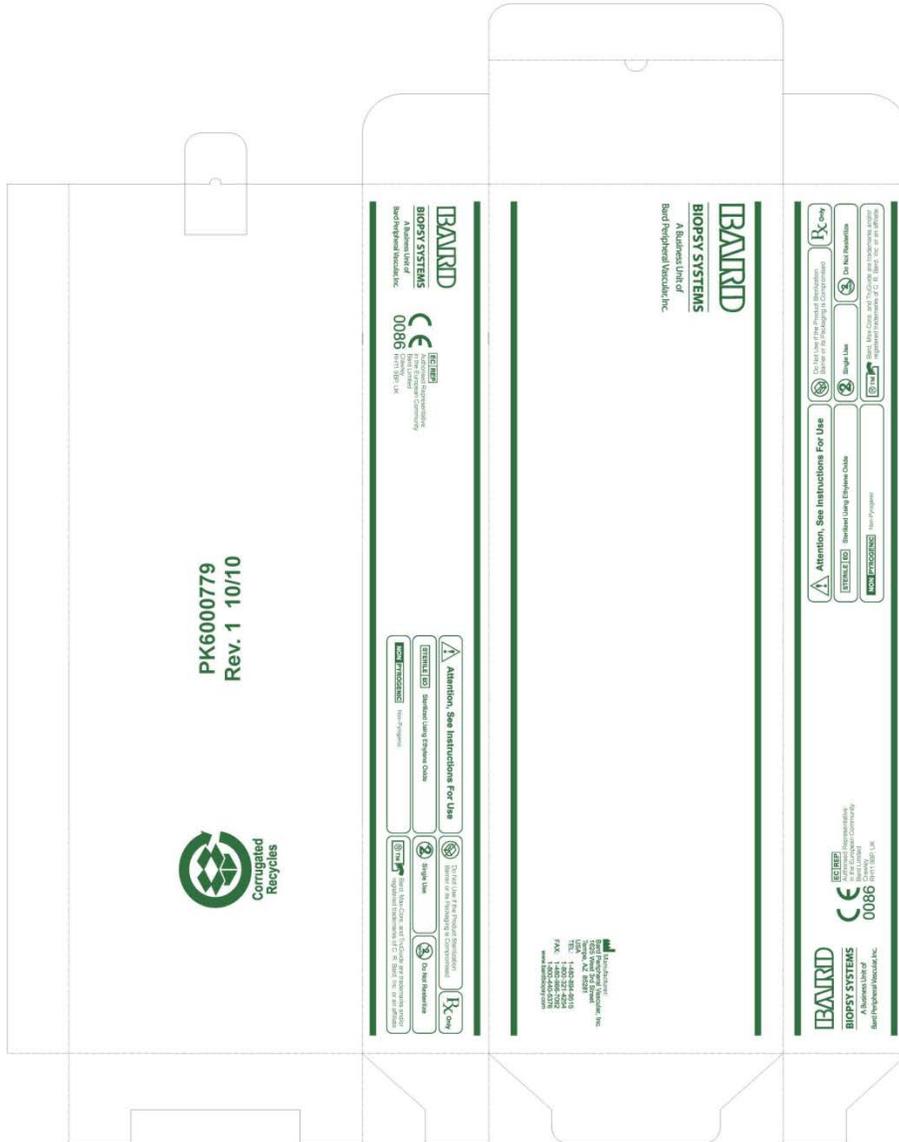
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**BAIRD**

**BIOPSY SYSTEMS**

PK1279900 Rev. 0 05/12

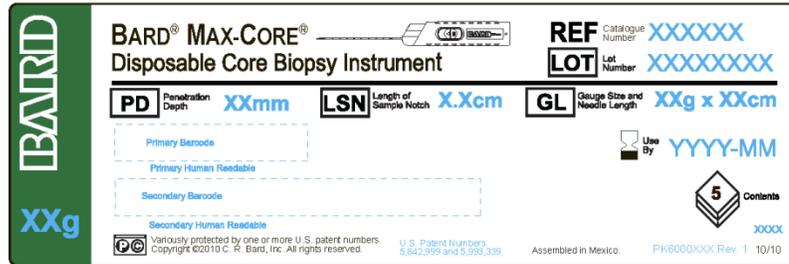


Box



Tray Lid

Variable fields

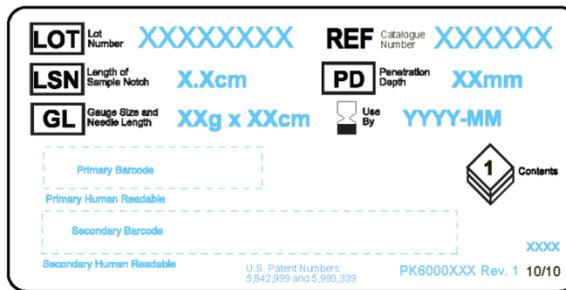


Box Label



Multi-language Label

Variable fields



Tray Lid Label



All Products > Core Needle Biopsy Products > BARD® MAX-CORE® Disposable Core Biopsy Instrument

COMPLEMENTARY PRODUCTS

[Coaxial Biopsy Needles](#)

[CONTACT US](#)

[I Want To Order](#)

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[INDICATIONS FOR USE](#)

[Download IFU](#)



**THE CONVENIENCE OF A DISPOSABLE. THE EASE OF ONE-HANDED COCKING.**

- One-handed cocking and lightweight ergonomic design improve both handling and control
- Features 22mm 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



ORDER NUMBER	GAUGE x LENGTH (cm)	COAXIAL LENGTH (cm)	COAXIAL ORDER NO.
● MC1410	14 x 10	7.8	C1410A
● MC1416	14 x 16	13.8	C1416A
● MC1610	16 x 10	7.8	C1610A
● MC1616	16 x 16	13.8	C1616A
● MC1810	18 x 10	7.8	C1810A
● MC1816	18 x 16	13.8	C1816A
● MC1820	18 x 20	17.8	C1820A
● MC1825	18 x 25	----	----
● MC2010	20 x 10	7.8	C2010A
● MC2016	20 x 16	13.8	C2016A
● MC2020	20 x 20	17.8	C2020A

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<http://www.bardbiopsy.com/products/max-core.php>

1/2/2014

## Appendix 5: Indications for Use Statement

## Indications for Use

510(k) Number (if known): K133948

Device Name: Bard® Monopty® Disposable Core Biopsy Instrument  
Bard® Max-Core® 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.

Prescription Use  X  AND/OR Over-The-Counter Use  \_\_\_\_\_   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

## Appendix 6: FDA Communication

**K922939 FDA Deficiency Letter (dated September 16, 1992)  
and Bard Response Letter (dated October 16, 1992)**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 23 1992

SEP 16 1992

Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850

Ms. Donna J. Wilson  
Regulatory Affairs Manager  
Bard Urological Division  
C.R. Bard, Inc.  
8195 Industrial Blvd.  
Covington, Georgia 30209

Re: K922939  
Bard® Monopty® Disposable Core  
Biopsy Instrument with  
Centimeter Markings  
Dated: June 10, 1992  
Received: June 18, 1992

Dear Ms. Wilson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine whether the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information:

1. Your Directions for Use must include a specific indications for use statement, as stated in your premarket notification: "percutaneous biopsy of liver, kidney, prostate, spleen, lymph nodes, soft tissue and different tumors."
2. You must provide the certification stated below since your device involves a kit:

I certify that the following components of my kit are either (1) legally marketed pre-Amendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemptions from Section 510(k) of the act (e.g., 862.9)), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., I am not claiming or causing a new use for the component(s)).

I further certify that these components are not purchased in "bulk", but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-Amendments, exemption, or premarket notification criteria and status.

If you cannot make the above referenced certification statement (first paragraph) for each component of your kit, you must itemize the components without a pre-Amendments, exemption, or premarket notification status. In this case we will continue our premarket notification review of these components of your kit.

If you cannot make the above referenced certification statement (second paragraph) for each component of your kit, you must itemize these components, state whether they are pre-Amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterile, package/repackage, label/relabel, etc.).

Page 2 - Ms. Donna J. Wilson

If the device kit contains components which are subject to regulation as drugs, a substantially equivalent determination will not apply to the drug component(s) of the device. For information on applicable Agency requirements for marketing the drug component(s) in the kit, it is suggested that you contact the Center for Drug Evaluation and Research's Division of Drug Labeling Compliance at (301) 295-8063.

The additional information should be submitted in duplicate, referencing the 510(k) number, to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
1390 Piccard Drive  
Rockville, MD 20850

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data, if needed, to establish substantial equivalence. Clinical investigations for this device must be conducted in accordance with the Investigational Device Exemption (IDE) regulation.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Laura J. Byrd at (301) 427-1194. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



for Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Bard Urological Division  
C. R. Bard, Inc.  
8195 Industrial Blvd.  
Covington, GA 30209

**BARID**

October 16, 1992

Office of Device Evaluation  
510(k) Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850

Re: Bard® Monopty® Disposable Core Biopsy Instrument with  
Centimeter Markings No. K922939 - Amendment

Ref: 115-GK

Dear Sir/Madam:

Attached is an Amendment to #K922939 in response to the Agency's request for a revised Directions for Use, as well as for a certification statement with regard to kit components.

C. R. Bard, Inc., certifies pursuant to 21 CFR 807.95 (b) that it has not divulged the fact of its intention to market this product to any individuals outside the employ of the company other than paid consultants in advertising or law firms, pursuant to commercial agreements, with appropriate safeguards for secrecy. Therefore, this amendment to the above 510(k) submission should be held confidential until such time as the product is put into commercial distribution.

Should you have additional questions, please call Donna Wilson at 404-784-6135.

Respectfully,

*Pamela D. Woome*

Pamela D. Woome  
Regulatory Affairs Specialist  
Bard Urological Division

Attachment

CERTIFIED MAIL

480-06

The purpose of this Amendment to #K922939 is to address the issues presented by the Agency in the September 16, 1992 letter to Donna Wilson, Regulatory Affairs Manager, C. R. Bard, Inc., Urological Division, with respect to Directions for Use and kit certification.

Issue #1: Directions for Use.

Response #1: The following statement will be revised on the Directions for Use:

Under Indications for Use, the current statement reads:

For core biopsy of various organs or tumors.

The new statement will read:

The Bard® Monopty® Disposable Core Biopsy Instrument 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.

(b) (4)

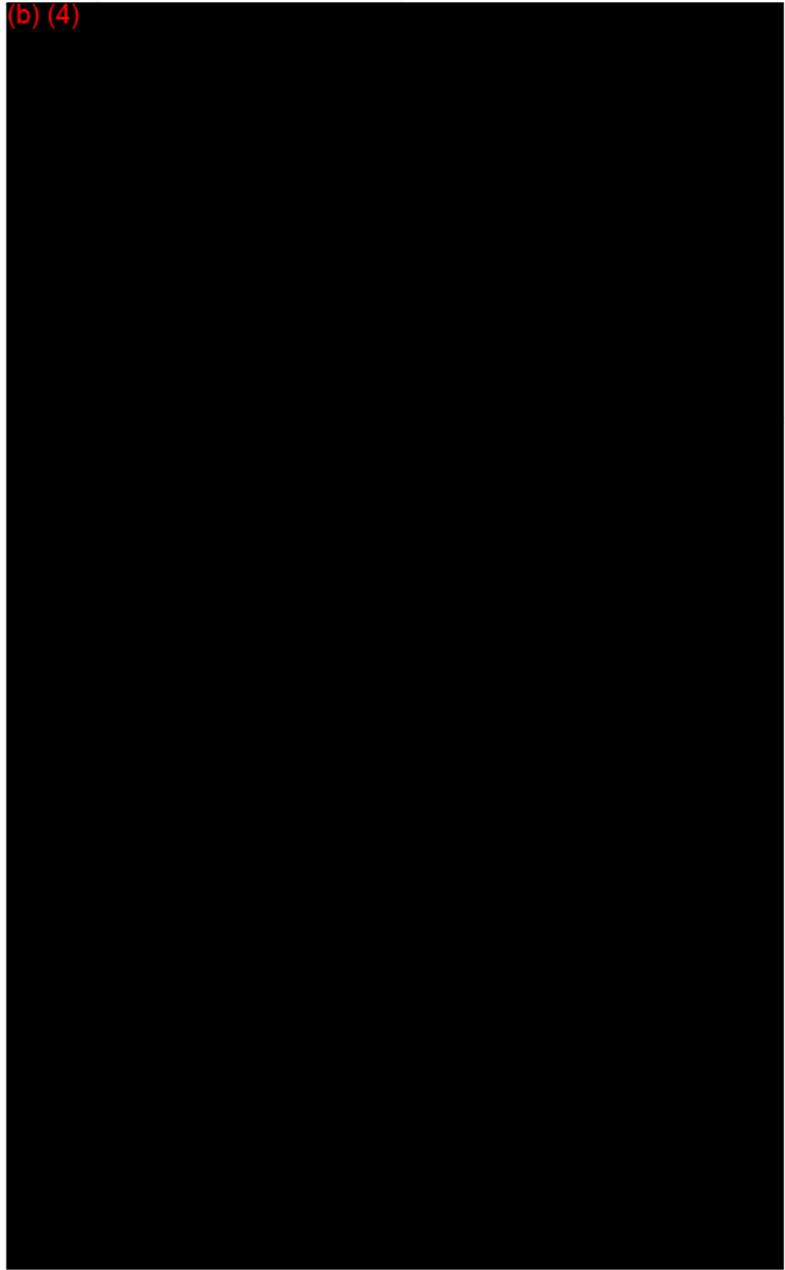
This revised statement is intended to replace the Indications For Use statement presented in Section II of the original 510(k) submission.

Issue #2: Kit Certification.

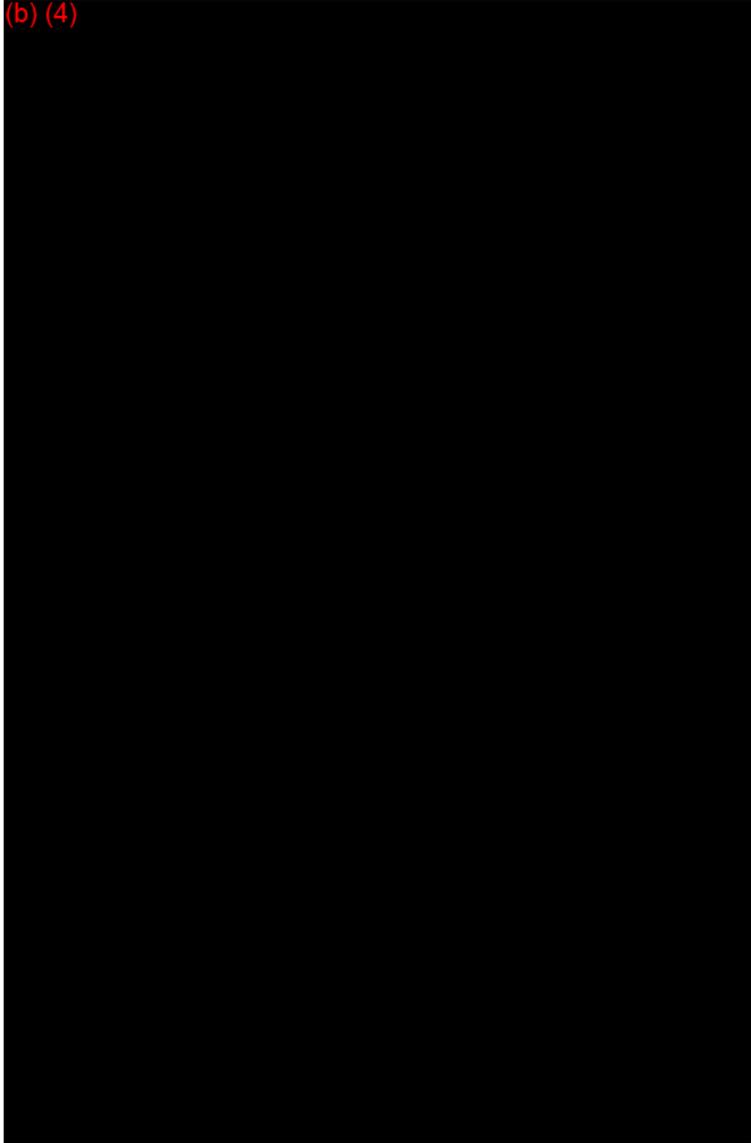
Response #2: We certify that we have been in communication with the suppliers of our components and that these suppliers state that the kit components we purchase from them are either (1) legally marketed preamendment devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemptions from Section 510 (k) of the act, or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended [i.e., we are not claiming or causing a new use for the component(s)].

(b) (4)

(b) (4)



(b) (4)



(b)(4) Product Specs



**Addition of Needle Lengths Letter (dated June 26, 1995)  
and FDA Concurrence Letter (dated July 26, 1995)**

C. R. Bard, Inc.  
8195 Industrial Blvd.  
Covington, GA 30209

**BARD**

June 26, 1995

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
510(k) Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

Attention: Ms. Laura Byrd, DRAERD, Urology Branch

Re: #K922939: Addition of 25cm and 30cm needle lengths to Bard®  
Monopty® Disposable Biopsy Instrument product line

Per conversations between Laura Byrd of FDA and Steven Mercereau of C.R. Bard, Inc. on March 14, 1995 and between Laura Byrd of FDA and Donna Wilson of C.R. Bard, Inc. on May 16, 1995, this letter is being submitted as an amendment to a concurred 510(k) file, #K922939. This 510(k) referenced needles in lengths of 10, 16 and 20cm. We would like to add the lengths of 25 and 30cm to the product line. Therefore, we ask that you consider the information included in this letter, make a determination as to whether a new 510(k) is required for this change, and if no new 510(k) is required that you include a copy of this letter in the 510(k) file as notice of the additional needle lengths. We also request that you provide us with written notification of your decision.

Per our interpretation, the April 1994 draft guidance document regarding when to file a 510(k) states that the addition of product sizes (dimensions) outside the previously cleared, via 510(k), ranges would require the submission of a new 510(k) for the new dimensions. However, we feel that this document may allow some flexibility in that it seems reasonable to assume that the requirement for filing a new 510(k) when going outside the previously cleared dimensional ranges would apply only to the more critical

device dimensions for which a change could significantly effect device performance in terms of safety or effectiveness.

(b) (4)



Bard intends to market Monopty and Max•Core™ Disposable Biopsy Instruments with needles in lengths of 25cm and 30cm for the 16 gauge and 18 gauge needle lines only as these are the needles sizes for which additional length would be useful to the physician (see attached Equivalency Table, Part IX). This addition would be for the entire line of Monopty Disposable Biopsy Instruments and Max•Core Disposable Biopsy Instruments.

(b) (4)



biopsy instrument offers ergonomic enhancement in terms of potential one-handed cocking of the device, an additional firing button or trigger to allow firing with either thumb or finger and changes to the outer shape of the device that will prevent it from rolling off hard surfaces.

It should be noted that there are no new claims or new indications for use associated with the longer length biopsy needles and no changes in materials of construction. Medical risk assessments, engineering reviews and FMEAs (Failure Modes and Effects Analyses) confirm that lengthening the 16 gauge and 18 gauge needles to 25cm or 30cm does not significantly effect device safety or effectiveness.

C.R. Bard, Inc. has not publicly disclosed or acknowledged that fact of its intent to market the longer needles to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. Per 21 CFR 807.95(b), C. R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

Should you have any questions regarding this letter, please call me at 404-784-6135.

Sincerely,



Donna J. Wilson  
Director, Regulatory Affairs

Enclosure

CERTIFIED MAIL

Bard and Monopty are registered trademarks of C.R. Bard, Inc. or an affiliate.

Max•Core is a trademark of C.R. Bard, Inc. or an affiliate.

CONFIDENTIAL

Equivalency Table  
 Comparison Charts of Some Currently Marketed Products  
 and Proposed Bard Product

Current Bard Product Part I #K922939

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A		N/A	N/A	N/A			N/A	N/A		N/A	N/A
13 Gauge	N/A													
14 Gauge				X				X	X					
15 Gauge	N/A													
16 Gauge				X				X	X					
18 Gauge				X				X	X					
19 Gauge	N/A													
20 Gauge				X				X	X					

BIP Company Product Part II #K934370

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A		N/A	N/A	N/A			N/A		N/A	N/A	N/A
13 Gauge					X			X						
14 Gauge				X	X			X	X					
15 Gauge	N/A													
16 Gauge				X	X			X	X		X			
18 Gauge				X	X			X	X		X		X	
19 Gauge	N/A													
20 Gauge				X	X			X	X					

Biopsy Needle Co. Product Part III

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
		N/A	N/A		N/A	N/A	N/A			N/A	N/A		N/A	N/A
13 Gauge	N/A													
14 Gauge				X				X						
15 Gauge	N/A													
16 Gauge	N/A													
18 Gauge				X				X	X			X		
19 Gauge	N/A													
20 Gauge				X				X	X					

Boston Scientific Corp. Product Part IV

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
					N/A						N/A		N/A	
13 Gauge	N/A													
14 Gauge				X		X								
15 Gauge						X								
16 Gauge	N/A													
18 Gauge				X		X				X				
19 Gauge	N/A													
20 Gauge						X								

Cook Inc. Product Part V

Diameter	Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
				N/A	N/A		N/A	N/A		N/A	N/A	N/A	N/A	
13 Gauge	N/A													
14 Gauge		X	X			X			X					
15 Gauge		X	X			X			X					
16 Gauge		X	X			X			X					X
18 Gauge		X	X			X			X					X
19 Gauge		X	X			X			X					X
20 Gauge		X	X			X			X					

CONFIDENTIAL

Equivalency Table  
 Comparison Charts of Some Currently Marketed Products  
 and Proposed Bard Product

Inrad Product

Part VI

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge						X							
15 Gauge	N/A												
16 Gauge						X		X					
18 Gauge						X		X			X		
19 Gauge	N/A												
20 Gauge						X		X					

Manan Medical Products, Inc. Product

Part VII

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X	X					
15 Gauge	N/A												
16 Gauge			X				X	X					
18 Gauge			X				X	X			X		
19 Gauge	N/A												
20 Gauge			X				X	X					

Medical Device Technologies, Inc. Product

Part VIII

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X						
15 Gauge	N/A												
16 Gauge			X				X	X					
18 Gauge			X				X	X			X		
19 Gauge	N/A												
20 Gauge							X	X					

Proposed Bard Product

Part IX

Length	6cm	9cm	10cm	13cm	15cm	15.5cm	16cm	20cm	21cm	24cm	25cm	30cm	48cm
Diameter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13 Gauge	N/A												
14 Gauge			X				X	X					
15 Gauge	N/A												
16 Gauge			X				X	X			X	X	
18 Gauge			X				X	X			X	X	
19 Gauge	N/A												
20 Gauge			X				X	X					



JUL 26 1995

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Donna J. Wilson  
Director, Regulatory Affairs  
C. R. Bard, Inc.  
8195 Industrial Boulevard  
Covington, Georgia 30209

Re: K922939  
Addition of 25cm and 30cm Needle  
Lengths to Bard® Monopty® Disposable  
Biopsy Instrument Product Line  
Dated: June 26, 1995  
Received: June 30, 1995

Dear Ms. Wilson:

We have reviewed the information dated June 26, 1995, regarding the 510(k) notification K922939 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Addition of Echogenicity Claim Letter (dated July 18, 1996)  
and FDA Concurrence Letter (dated September 3, 1996)**

Bard, Inc.  
195 Industrial Blvd.  
Covington, GA 30209

July 18, 1996

**BARD**

Ms. Laura Byrd  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
DRAERD, Urology Branch (HFZ-470)  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: #K922939: Bard Monopty Disposable Biopsy Instrument Product Line -  
Echogenic claim

Dear Ms. Byrd:

Per conversations between Laura Byrd of FDA and Donna J. Wilson of C. R. Bard, Inc. on January 19, 1996, voice mail message from Laura Byrd of FDA the week of May 6, 1996, and subsequent conversations between FDA and Bard, this letter is being submitted as an amendment to a concurred 510(k) file, #K922939. This 510(k) referenced

(b) (4)

C. R. Bard, Inc. intends to market Monopty Disposable Biopsy Instruments (including the ergonomically enhanced Max-Core models) with the same needle dimensions (gauge and length) and made using the same materials as described in #K922939 and the June 16, 1995, letter to file.

(b) (4)

(b) (4)

(b) (4)

The Indications for Use remain the same but the description of the needles and associated marketing claims would contain the words "echogenic" and "enhanced echogenicity", "significantly more visible" and similar terms indicating enhanced visualization during ultrasound procedures.

Therefore, we ask that you consider the information included in this letter, make a determination as to whether a new 510(k) is required for this change, and if no new 510(k) is required that you include a copy of this letter in the 510(k) file (#K922939) as notice of the Bard Monopty/Max-Core Disposable Biopsy Instrument Product Line echogenic needle claim. We also request that you provide us with written notification of your decision.

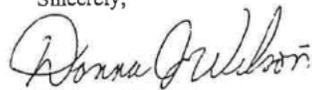
It should be noted that other than a claim of echogenicity or enhanced visualization during ultrasound procedures there are no new claims or new indications for use associated with the echogenic needles and no significant changes in materials of construction. No changes in design that could significantly affect safety or effectiveness have been made since

(b) (4)

C. R. Bard, Inc. has not publicly disclosed or acknowledged that fact of its intent to market the Bard Monopty and Max-Core product lines with an echogenic claim to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. Per 21 CFR 807.95(b), C. R. Bard Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

Should you have any questions regarding this letter, please call me at 770-784-6135.

Sincerely,

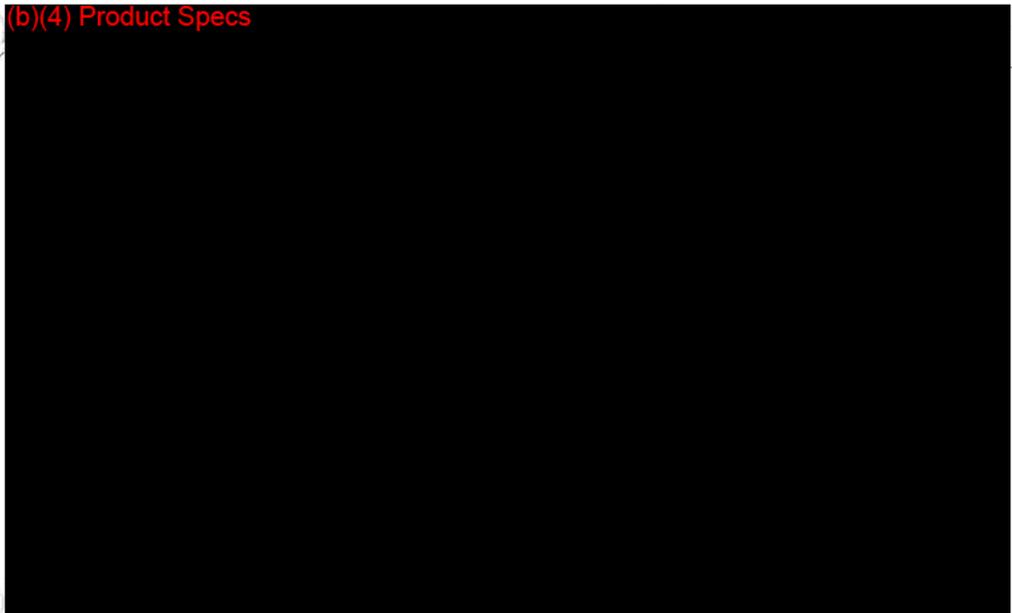


Donna J. Wilson  
Director, Regulatory Affairs

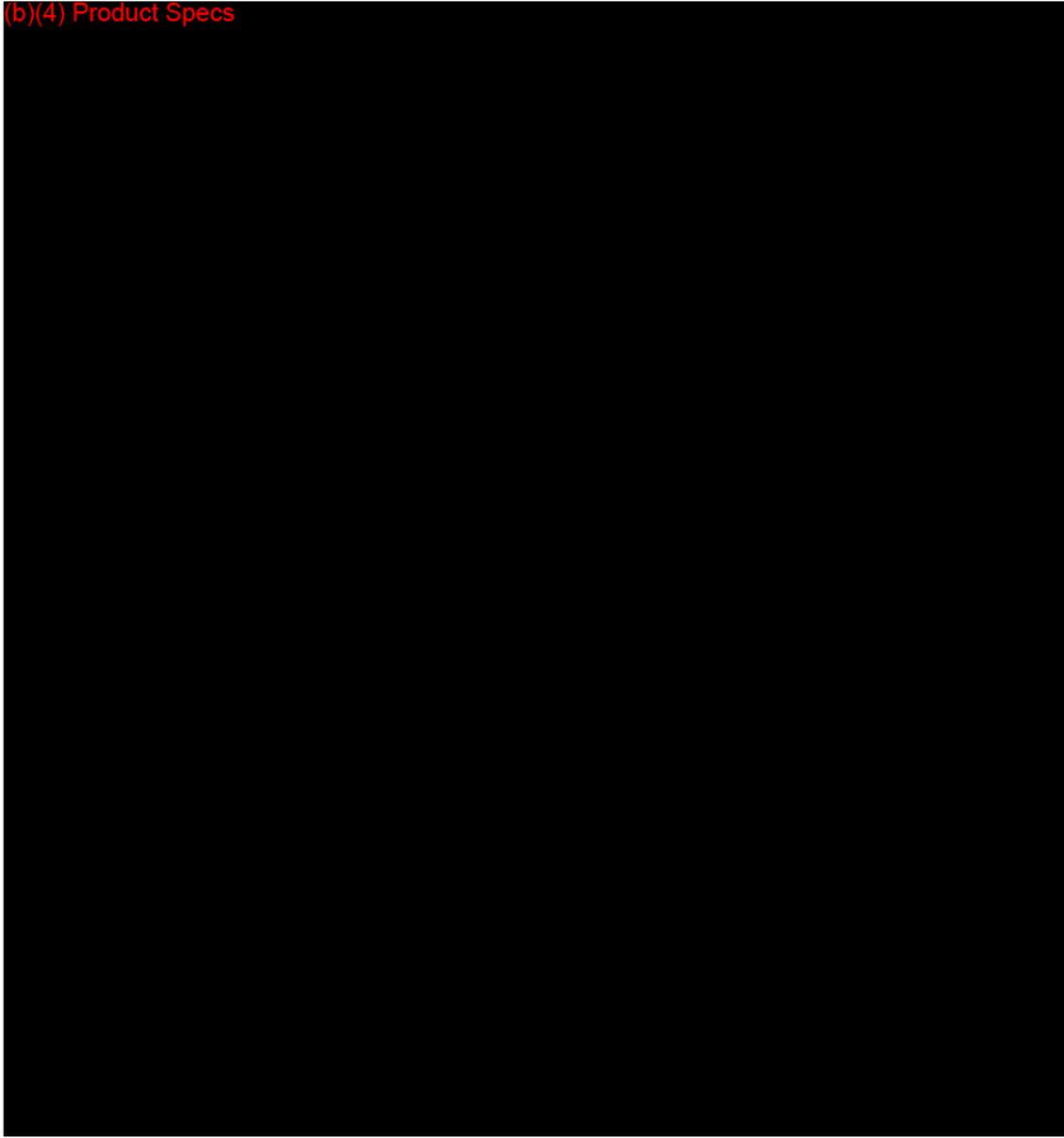
Enclosure

CERTIFIED MAIL

(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850



SEP 3 1996

Ms. Donna J. Wilson  
Director, Regulatory Affairs  
C.R. Bard, Inc.  
8195 Industrial Boulevard  
Covington, Georgia 30209

Re: K936194; K922939; K934370; and K910720  
Coaxial Biopsy Needle; Bard Monopty Disposable Biopsy  
Instrument Product Line; BIP [Bard Magnum] Biopsy Needles;  
and Bard Biopsy-Cut Biopsy Needles  
Dated: July 18, 1996

Dear Ms. Wilson:

We have reviewed the information dated July 18, 1996, regarding the 510(k) notifications K936194, K922939, K934370, and K910720 previously submitted for the devices referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the designs, components, methods of manufacture, or intended use of the devices referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the devices or their labeling could significantly affect the devices' safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Appendix 7: Declaration of Conformity with Design Controls**

106 106  
Smm 01/23/14

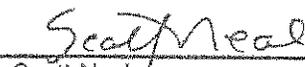
## Declaration of Conformity with Design Controls

**Verification and Validation Activities:** As required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

  
Ruben Perez  
Staff Engineer  
Bard Peripheral Vascular, Inc.

12-19-13  
Date

**Manufacturing Facility:** The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

  
Scott Neal  
Director of Quality Assurance  
Bard Peripheral Vascular, Inc.

12-19-13  
Date