EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Becton, Dickinson and Company Limited

Main Site: Pottery Road, Dun Laoghaire, Co. Dublin, Ireland

Product Category:

- Closed system drug-transfer device

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
41319062-03

Initial Certification Date:
24 July 2012

Certificate Valid from:
9 June 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

9 June 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

BIOPSIJOS

INSTRUMENTAI IR ADATOS

Padeda Jums gauti kokybiškesnius ir patikimesnius branduolio mėginius.

BARD | MEDICAL

Padeda Jums gauti kokybiškesnius ir patikimesnius branduolio mėginius.

Kiekvienas **Bard biopsijos instrumentas** ir kiekviena **adata** yra specialiai sukurti padėti Jums pasiekti vieną iš svarbiausių tikslų: aukšta kokybė ir patikimi branduolio mėginiai. Visos adatos yra sukurtos išskirtiniam našumui pasiekti naudojant ypač aštrius antgalius ir poliruotą paviršių švelniai antgalio įvesčiai ir išvesčiai. Platus biopsijos sistemų ir adatos dydžių pasirinkimas užtikrina idealią atitikti procedūrinėms adatoms ir asmeniniams poreikiams.

Bard® Magnum® instrumento adatos

- Ypač aštrus adatos troakaras, skirtas surinkti pastoviai aukštesnės kokybės branduolio mėginius su minimaliu sutraiškymu.
- Įsiskverbimo gylių pasirinkimas prieigai prie sėklidžių ir sėklinių pūslių biopsijai atlikti.
- Išgraviruotas adatos galius geresnei adatos padėties vizualizacijai naudojant ultragarso orientyrą.
- Spalviniai kodai ant centrų lengvesnei identifikacijai atlikti.

Bard® Magnum® instrumentas

- Galinga dviejų spyruoklių sistema pastoviems aukštos kokybės branduolio mėginiams gauti bei greitam šovimo veiksmui gauti.
- Mažo dydžio, lengvo svorio instrumentas skirtas naudoti vienam vartotojui.
- Vienos rankos aktyvavimas suteikia lengvą prieigą prie audinio mėginio.
- Dvigubas įsiskverbimo gylis lankstumui ir patikimumui (22 mm arba 15 mm).

Bard® Max●Core® instrumentas

- Galima naudoti tik su viena ranka greitesniam, lengvesniam panaudojimui suteikiant daugiau kontrolės mūvint pirštinę.
- Dvigubas gaidukas suteikia lankstumo; gydytojas gali naudoti skirtingas biopsijos technikas.
- Aštrus nuožulnus troakaras mėginio surinkimui su mažiausiu sutraiškymo artefaktu.
- Pakreipta, gili mėginio anga dideliam aukštos kokybės branduolio mėginio surinkimui.

Bard® Monopoty® instrumentas

- Sukama rankena lengvam branduolio mėginio išėmimui; greitas ir lengvas naudoti.
- Mažo svorio ergonomiška rankena didesnei kontrolei mūvint pirštinę.
- Aštrus nuožulnus troakaras mėginio surinkimui su mažiausiu sutraiškymo artefaktu.
- Pakreipta, gili mėginio anga dideliam aukštos kokybės branduolio mėginio surinkimui.

Užsakymų informacija:				
Magnum® adatų užsakymo numeris	**Dydis x ilgis (om)**	**TruGuide™ adatos ilgis (om)**	**TruGuide™ adatos užsakymo numeris**	**Standartinės adatos užsakymo numeris**
MN2010	20 X10	7.0	C2010B	--
MN2013	20 X 13	10.0	C2013B	--
MN2016	20 X 16	13.0	C2016B	--
MN2020	20 X 20	17.0	C2020B	--
MN1810	18 X 10	7.0	C1810B	--
MN1813	18 X 13	10.0	C1813B	--
MN1816	18 X 16	13.0	C1816B	--
MN1820	18 X 20	17.0	C1820B	--
MN1825	18 X 25	--	--	--
MN1830	18 X 30	--	--	--
MN1610	16 X 10	7.0	C1610B	--
MN1613	16 X 13	10.0	C1613B	--
MN1616	16 X 16	13.0	C1616B	--
MN1620	16 X 20	17.0	C1620B	--
MN1410	14 X 10	7.0	C1410B	AX1410
MN1413	14 X 13	10.0	C1413B	AX1413
MN1416	14 X 16	13.0	C1416B	AX1416
MN1420	14 X 20	--	--	--
MN1210	12 X 10	7.0	C1210B	--
MN1213	12 X 13	10.0	C1213B	--
MN1216	12 X 16	13.0	C1216B	--
MN1220	12 X 20	--	--	--
Max●Core™ instrumento užsakymo numeris	**Dydis x ilgis (om)**	**TruGuide™ adatos ilgis (om)**	**TruGuide™ adatos užsakymo numeris**	**Standartinės adatos užsakymo numeris**
MC2010	20 X10	7.8	C2010A	--
MC2016	20 X 16	13.8	C2016A	--
MC2020	20 X 20	17.8	C2020A	--
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	--	--	--
MC1610	16 X 10	7.8	C1610A	--
MC1616	16 X 16	13.8	C1616A	--
MC1410	14 X 10	7.8	C1410A	--
MC1416	14 X 16	13.8	C1416A	--
Monopty® instrumento užsakymo numeris	**Dydis x ilgis (om)**	**TruGuide™ adatos ilgis (om)**	**TruGuide™ adatos užsakymo numeris**	**Standartinės adatos užsakymo numeris**
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	--
122016	20 X 16	13.8	C2016A	--
122020	20 X 20	17.8	C2020A	--

27.1 p.d.

Papildomai informacijai gauti susisiekite su savo vietiniu Bard atstovu arba skambinkite 1-888-367-2273. Užsakymą galite siųsti ir faksu 1-888-383-3839.

BARD | MEDICAL

C.R. Bard, Inc. Covington, GA 30014
www.bardmedical.com

Indikacijos, kontraindikacijos, perspėjimai, pavojai, įspėjimai ir naudojimo instrukcijos pateikiami produkto įdėtiniuose lapuose ir etiketėse.

Atspausdinta JAV. 1207-49 R06/13 THP P07/13 1M

Raising the level of
core needle biopsy since 1987

Proven. Powerful. Precise.

BD

BARD
has joined BD

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

Specialty needles		Available gauge sizes	Available needle lengths
Coaxial biopsy needle	 TRUGUIDE® Disposable Coaxial Biopsy Needle	11 g 13 g 15 g 17 g 19 g	7.8 cm 13.8 cm 17.8 cm 7 cm 10 cm 13 cm 17 cm
Fine needle aspiration biopsy	 VACU-CUT® Disposable Aspiration Biopsy Needle	18 g 19.5 g 21 g 22 g	10 cm 15 cm 20 cm
Bone biopsy	 OSTYCUT® Disposable Bone Biopsy Needle	14 g 15 g 16 g 17 g	5 cm 7.5 cm 10 cm 12.5 cm 15 cm

Core Capabilities: Innovations inspired by your procedural challenges

Automatic and Semi-Automatic

BARD® MARQUEE®

Disposable Core Biopsy Instrument

A comprehensive core needle that provides unparalleled procedural versatility

Performance

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

Versatility

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

Adjustable Penetration Depth

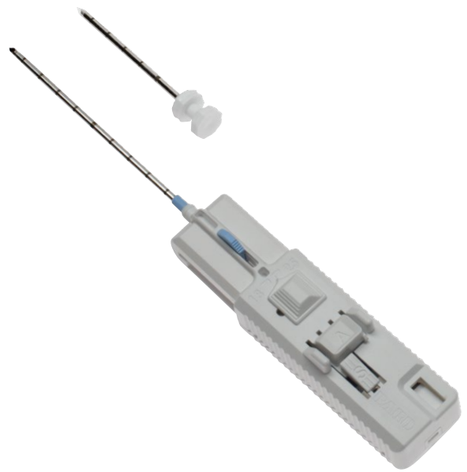
Automatic and Semi-Automatic

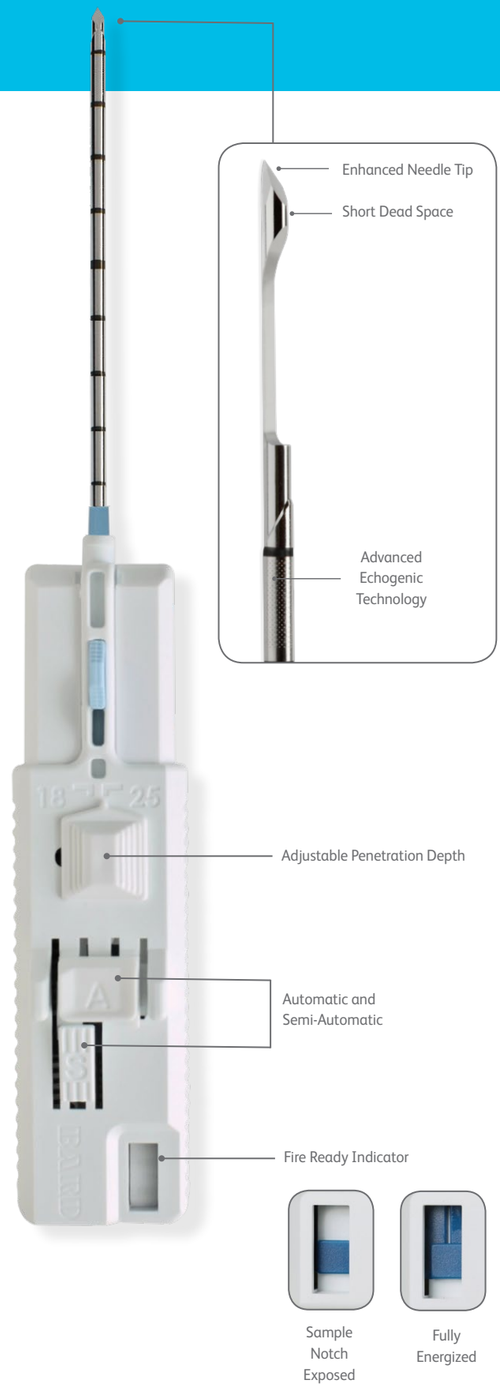
Security

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

Convenience

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





BARD® MARQUEE® Disposable Core Biopsy Instrument

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

* Instrument only.
† Kit includes instrument and compatible coaxial biopsy needle.
5 instruments per case.

Semi-Automatic

BARD® MISSION®

Disposable Core Biopsy Instrument

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

Simplicity

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

Security

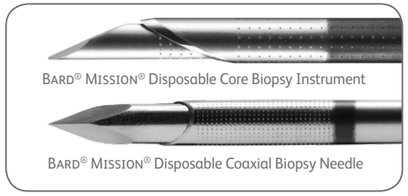
- Penetration depth indicator displays the primed penetration depth
- Visual Fire Ready Indicator confirms the sample notch is fully advanced
- Optional Coaxial Blunt Tip Stylet helps reduce the risk of damage to vasculature or other organs
- 10 mm Adapter attaches to coaxial cannula for accurate biopsy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

Coaxial Blunt Tip Stylet

10 mm Adapter

Speed

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

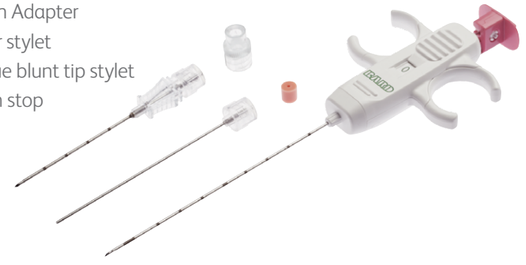


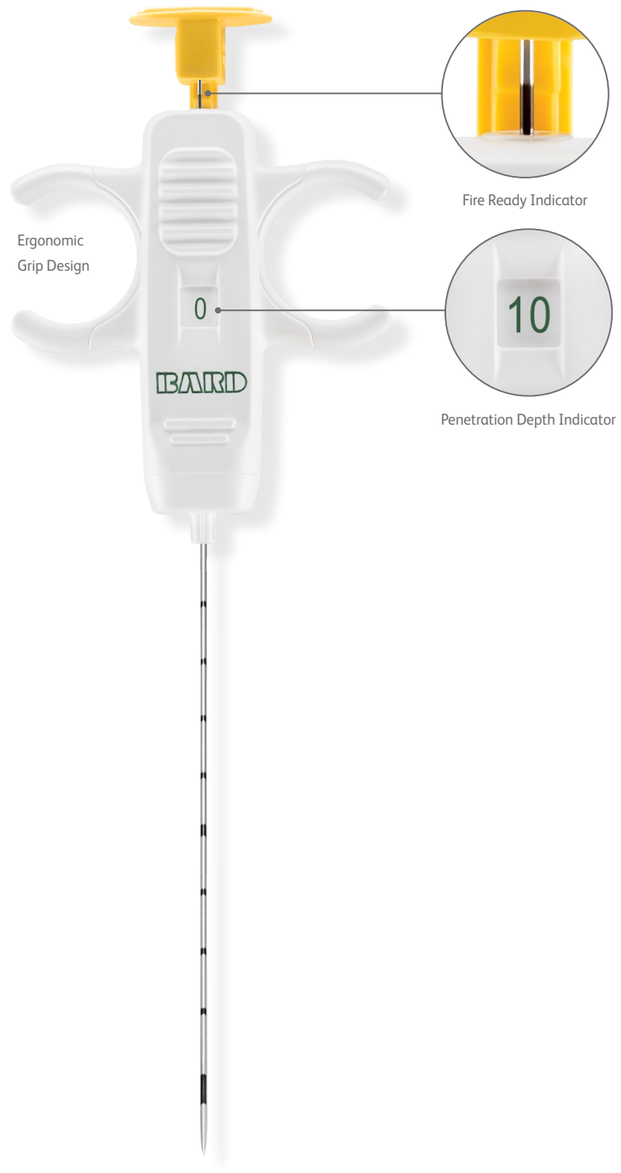
BARD® MISSION® Disposable Core Biopsy Instrument

BARD® MISSION® Disposable Coaxial Biopsy Needle

Complete

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





BARD® MISSION® Disposable Core Biopsy Instrument

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

5 instruments per case.

BARD® MISSION® Disposable Core Biopsy Instrument Kit

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

5 instruments per case.

Automatic

BARD® MAX-CORE®

Disposable Core Biopsy Instrument

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

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

BARD® MAX-CORE® Disposable Core Biopsy Instrument

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

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

Automatic

BARD® MONOPTY®

Disposable Core Biopsy Instrument

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

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

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

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

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

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

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

Biopsy Systems

BARD® MAGNUM®

Reusable Core Biopsy Instrument

High power instrument with one-handed cocking

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

BARD® MAGNUM® Reusable Core Biopsy Instrument
Order number MG1552

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

BARD® MAGNUM® Disposable Core Biopsy Needle

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

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

Coaxial

BARD® TRUGUIDE®

Disposable Coaxial Biopsy Needle

Innovative and lightweight

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

BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle
For use with BARD® MAX-CORE®, BARD® MONOPTY®, or BARD® MISSION® Biopsy Instruments

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

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

BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle
For use with BARD® MAGNUM®, or BARD® BIOPTY® Biopsy Instruments

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

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

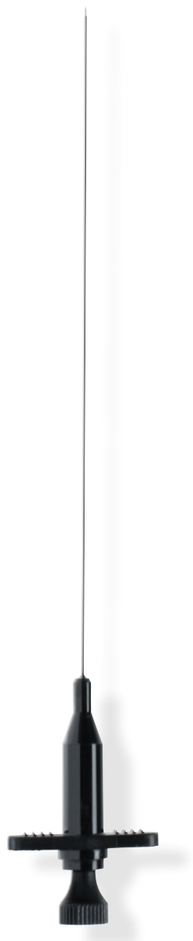
Specialty

VACU-CUT®

Disposable Aspiration Biopsy Needle

Self-aspirating for effective and simple fine needle aspiration

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



VACU-CUT® Disposable Aspiration Biopsy Needle

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

10 needles per case.

Specialty

OSTYCUT®

Disposable Bone Biopsy Needle

Performance, control and a wide range of sizes

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

OSTYCUT® Disposable Bone Biopsy Needle

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

1 needle per case.

Marquee® Disposable Core Biopsy Instrument

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

Mission® Disposable Core Biopsy Instrument

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

Max-Core® Disposable Core Biopsy Instrument

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

Monopty® Disposable Core Biopsy Instrument

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

Magnum® Core Biopsy System

27.1 p.d.

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

Ostycut® Disposable Bone Biopsy Needle

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

Vacu-Cut® Disposable Aspiration Biopsy Needle

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

TruGuide® Disposable Coaxial Biopsy Needle

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

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

Contact information

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UAE	C.R. Bard GmbH, Sheikh Zayed Road PO Box 413043, Dubai, United Arab Emirates Tel: 00-971-4-314-0900 Fax: 00-971-4-359-8980
UK	Bard Limited, Forest House, Tilgate Forest Business Park, Brighton Road, Crawley, West Sussex RH11 9BP, UK Tel: +44 1293 527888 Fax: +44 1293 552428

1.800.323.9088

crbard.com/biopsy

BD

BARD
has joined BD

Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA
Tel: 1-480-894-9515
1-800-321-4254
bd.com

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Bard Peripheral Vascular, Inc
Manufacturer address and contact details	1625 W. 3rd Street Tempe, AZ 85281, USA EUDAMEDenquiries@bd.com +1 (480) 894-9515
Single Registration Number (SRN) (if available)	US-MF-000017556

Authorised Representative name (if applicable)	Becton Dickinson Ireland Limited
Authorised Representative address and contact details	Donore Road, A92 YW26 Drogheda, Ireland EUDAMEDenquiries@bd.com +32 53 720 211
Single Registration Number (SRN) (if available)	IE-AR-000007610

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☒ Expired *before* 20 March 2023:

  ☒ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

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☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Bard Peripheral Vascular, Inc.
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Tempe, AZ 85281
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Signed for and on behalf of the manufacturer:

Full Company Name: Bard Peripheral Vascular, Inc.

Location & Date: 1625 West 3rd Street, Tempe, Arizona 85281 USA
03-Apr-2024

Signature:

DocuSigned by:

Jennifer Logvin

Signer Name: Jennifer Logvin
Signing Reason: I approve this document
Signing Time: 03-Apr-2024 | 11:42:07 AM EDT
9E5E6FBBA3774C2D8019B2488D5D71C2

Print Name: Jennifer Logvin

Title: Vice President Regulatory Affairs, Peripheral Intervention

Contact Details (at least email): Jennifer.Logvin@bd.com

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Catalogue Number	**Identification of the device(s)**[3]	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
007018	Bard® PTFE Felt (Thick)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007019	Bard® PTFE Felt (Thick)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007021	Bard® Low Porosity PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007828	Bard® Sauvage® Filamentous Fabric	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007829	Bard® Sauvage®	FQA: CE	FQA: 26	BSI, NB#	BSI, NB# 2797	31 December	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

	Filamentous Fabric	01467 DE: CE 87585	May 2024 DE: 26 May 2024	2797		2027	
007836	Bard® PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007837	Bard® PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007838	Bard® Low Porosity PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007839	Bard® Low Porosity PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007913	Bard® PTFE Braided Tape	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007914	Bard® PTFE Braided Tape	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007917	Bard® PTFE Braided Tape	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007918	Bard® PTFE Braided Tape	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007940	Bard® Sauvage® Filamentous Fabric	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007942	Bard® Sauvage®	FQA: CE	FQA: 26	BSI, NB#	BSI, NB# 2797	31 December	N/A

	Filamentous Fabric	01467 DE: CE 87585	May 2024 DE: 26 May 2024	2797		2027	
007943	Bard® Sauvage® Filamentous Fabric	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007944	Bard® Sauvage® Filamentous Fabric	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007958	Bard® PTFE Felt (Thick)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007959	Bard® PTFE Felt (Thick)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007963	Bard® PTFE Felt Pledget (Rectangle)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007965	Bard® PTFE Felt Pledget (Square)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007968	Bard® PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007969	Bard® PTFE Felt Pledget (Oval)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007970	Bard® PTFE Felt Pledget (Rectangle)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007971	Bard® PTFE Felt	FQA: CE	FQA: 26	BSI, NB#	BSI, NB# 2797	31 December	N/A

	Pledget, Thick (Round)	01467 DE: CE 87585	May 2024 DE: 26 May 2024	2797		2027	
007972	Bard® PTFE Felt Pledget (Square)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007973	Bard® PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007974	Bard® PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007975	Bard® PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007976	Bard® PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007977	Bard® PTFE Felt	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
007984	Bard® PTFE Felt Pledget (Round)	FQA: CE 01467 DE: CE 87585	FQA: 26 May 2024 DE: 26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2027	N/A
CQF50410	Conquest 40 PTA Dilatation Catheter	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
CQF5042	Conquest 40 PTA Dilatation Catheter	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
CQF5044	Conquest 40 PTA Dilatation Catheter	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
CQF5048	Conquest 40 PTA Dilatation Catheter	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
CQF50510	Conquest 40 PTA	CE 01467	26 May	BSI, NB#	BSI, NB# 2797	31 December	N/A

	Catheters						
U480520RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U480525RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U48052RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U480530RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U48054RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U48056RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U48058RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U48064RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U48066RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U48074RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
U48076RX	Ultraverse® RX PTA Balloon Dilatation Catheters	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	N/A
47020	Ghiatas™ Beaded Breast Localization Wire	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	Ghiatas Bead Breast Localization Wire and Dualok Breast Localization Wire
47320	Ghiatas™ Beaded Breast Localization	CE 01467	26 May 2024	BSI, NB# 2797	BSI, NB# 2797	31 December 2028	Ghiatas Bead Breast Localization Wire and