

K021094

JUL 3 2002

7.0 510(k) Summary

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2280

Contact: Patricia D. Wilson, Regulatory Affairs Specialist

DEVICE NAME: Introcan[®] Safety[™] IV Catheter

COMMON OR USUAL NAME: Safety Intravascular Catheter / Safety Introducer Catheter

DEVICE CLASSIFICATION: Class II, 21 CFR § 880.5200: Intravascular Catheter and 21 CFR § 870.1340: Catheter Introducer

PREDICATE DEVICE: B. Braun Medical Inc. Introcan Safety IV Catheter (K982805)
B. Braun Medical Inc. Introducer Catheter (Kit component of K810460 / K810461)
Becton Dickinson Infusion Therapy Systems Inc., BD Introsyte[™] Autoguard[™] Shielded Introducer (K013304)

DESCRIPTION: The Introcan Safety IV Catheter consists of an over-the-needle catheter with a safety clip feature. Upon removal of the needle from the catheter, the safety clip is automatically secured over the needle tip as it exits the catheter hub. The Introcan Safety IV Catheter is available in sizes ranging from 14 Gauge through 24 Gauge.

INTENDED USE: The Introcan Safety IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

SUBSTANTIAL EQUIVALENCE: The Introcan Safety IV Catheter includes the same materials, construction, design, and safety clip feature as the Introcan Safety IV Catheter previously cleared under the B. Braun Medical Inc. Premarket Notification, K982805. The Introcan Safety IV Catheter is also similar in materials and design, with the exception of the safety clip feature, as the introducer catheter previously cleared as a kit component under the B. Braun Medical Inc. Premarket

B Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

Notifications, Burrion Percutaneous Introducer Set (K810460) and Burrion Central Vein Catherization Kit (K810461). The new indication for the Introcan Safety IV Catheter, for use as an introducer catheter, is the same indication previously cleared for Becton Dickinson Infusion Therapy Systems Inc.'s Premarket Notification, BD Introsyte™ Precision Introducer, BD Introsyte™ Autoguard™ Shielded Introducer, K013304.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

B. Braun Medical, Inc
c/o Ms. Patricia D. Wilson
Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, PA 18109-9341

JUL 3 2002

Re: K021094
Introcan® Safety™ IV Catheter
Regulation Number: 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: April 3, 2002
Received: April 4, 2002

Dear Ms. Wilson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 - Ms. Patricia D. Wilson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman". The signature is fluid and cursive, with the first name being more prominent.

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

Page 1 of 1

510(k) Number (if known): K021094

Device Name: Introcan® Safety™ IV Catheter

Indications For Use:

The Introcan® Safety™ IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR Over-The-Counter Use

[Signature]
(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K021094

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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B | BRAUN

Angela J. Caravella
Regulatory Affairs Specialist
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109
Telephone: 610-266-0500 x 2966
Fax: 610-266-4962

August 15, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
AUG 17 2011
Received
K2B

RE: Add-to-File for 510(k) K021094, Introcan® Safety™ IV Catheter

Dear Sir/Madam,

During the course of review for the 510(k) K111236, B. Braun Medical Inc. received a request from Ms. Mary E. Brooks to submit an Add-to-File for K021094. Ms. Brooks acknowledged that the CFR reference for K021094 was incorrect and requested that B. Braun submit a revised 510(k) summary. The specific question from Ms. Brooks is restated below:

(b)(4)



We appreciate your assistance in processing this Add-to-File request. Please contact me if you have any questions.

Sincerely,



Angela J. Caravella
Regulatory Affairs Specialist
B. BRAUN MEDICAL, INC.
encl.



Angela J. Caravella
Regulatory Affairs Specialist

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109

Telephone: 610-266-0500 x 2966
Fax: 610-266-4962

August 15, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Add-to-File for 510(k) K021094, Introcan® Safety™ IV Catheter

Dear Sir/Madam,

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(b)(4)

A large black rectangular redaction box covers the majority of the page's content. The text '(b)(4)' is written in red at the top left corner of this redacted area.

We appreciate your assistance in processing this Add-to-File request. Please contact me if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads 'Angela J. Caravella'.

Angela J. Caravella
Regulatory Affairs Specialist
B. BRAUN MEDICAL, INC.
encl.

5.0 510(k) Summary

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500

Contact: Angela Caravella, Regulatory Affairs Specialist

DEVICE NAME: Introcan® Safety™ IV Catheter

COMMON OR USUAL NAME: Safety Intravascular Catheter / Safety Introducer Catheter

DEVICE CLASSIFICATION: Class II, 21 CFR § 880.5200: Intravascular Catheter

PREDICATE DEVICE: B. Braun Medical Inc. Introcan Safety IV Catheter (K982805)
B. Braun Medical Inc. Introducer Catheter (Kit component of K810460 / K810461)
Becton Dickinson Infusion Therapy Systems Inc., BD Introsyte™ Autoguard™ Shielded Introducer (K013304)

DESCRIPTION: The Introcan Safety IV Catheter consists of an over-the-needle catheter with a safety clip feature. Upon removal of the needle from the catheter, the safety clip is automatically secured over the needle tip as it exits the catheter hub. The Introcan Safety IV Catheter is available in sizes ranging from 14 Gauge through 24 Gauge.

INTENDED USE: The Introcan Safety IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

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The new indication for the Introcan Safety IV Catheter, for use as an introducer catheter, is the same indication previously cleared for Becton Dickinson Infusion Therapy Systems Inc.'s Premarket Notification, BD Introsyte™ Precision Introducer, BD Introsyte™ Autoguard™ Shielded Introducer, K013304.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

B. Braun Medical, Inc
c/o Ms. Patricia D. Wilson
Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, PA 18109-9341

JUL 3 2002

Re: K021094
Introcan® Safety™ IV Catheter
Regulation Number: 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: April 3, 2002
Received: April 4, 2002

Dear Ms. Wilson:

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.

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Page 2 - Ms. Patricia D. Wilson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

Page 1 of 1

510(k) Number (if known): K021094

Device Name: Introcan® Safety™ IV Catheter

Indications For Use:

The Introcan® Safety™ IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use

[Signature]
(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K021094

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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

April 05, 2002

B. BRAUN MEDICAL, INC.
901 MARCON BLVD.
ALLENTOWN, PA 18109
ATTN: PATRICIA D. WILSON

510(k) Number: K021094
Received: 04-APR-2002
Product: INTROCAN SAFETY IV
CATHETER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh.ode/A02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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Patricia D. Wilson
Regulatory Affairs Specialist

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109

Telephone: 610-266-0500 x2375
Fax: 610-266-4962

April 3, 2002

Food and Drug Administration
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

RECEIVED
APR 4 2 53 PM '02
FDA/CDRH/OCE/DID

Re: 510(k) Notification: Introcan® Safety™ IV Catheter

Dear Sir/Madam:

In accordance with 21 CFR §807.81, B. Braun Medical Inc. is submitting to the Agency a Premarket Notification [510(k) Notification]. This application contains information regarding B. Braun Medical Inc.'s Introcan® Safety™ IV Catheter. It is B. Braun Medical Inc.'s intent to market this device for the indications listed within this submission.

The Introcan Safety IV Catheter is currently marketed under B. Braun Medical Inc.'s premarket notification K982805 as a passive anti-needle stick device to be placed in a peripheral vein for the infusion of fluids, drugs, and/or blood components. This submission expands the indications to include use as an introducer catheter to facilitate the placement of Vascular Access devices, and expands the available sizes to include a length of up to 2-1/2 in. (64 mm).

The following documentation is presented in accordance with 21 CFR §807.87 and §807.90.

Device Name and Classification:

Proprietary / Trade Name: Introcan® Safety™ IV Catheter
Common Name: Safety Intravascular Catheter / Safety Introducer Catheter
Classification: Class II, 21 CFR § 880.5200: Intravascular Catheter (Product Code FOZ) and 21 CFR § 870.1340: Catheter Introducer (Product Code DYB)

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This application is being submitted by the following B. Braun establishment:

B. Braun Medical Inc. Establishment Registration #2523676
901 Marcon Boulevard
Allentown, PA 18109
USA

The Introcan Safety IV Catheter will be manufactured, packaged, and sterilized at the following establishment:

B. Braun Medical Industries SDN. BHD. Establishment Registration #9612086
Bayan Lepas Free Trade Zone
Penang, Malaysia

To assist the Agency in review of this application, a sample of the Introcan Safety IV Catheter is included with this submission. B. Braun Medical Inc. is not aware of any performance standards promulgated for this device.

We consider our intent to market this device to be confidential commercial information. B. Braun Medical Inc. has not disclosed the intent to market this device to others who are not collaborators and consultants. We have taken caution to protect the confidentiality of our intent.

If you have any questions concerning this submission, please contact me by phone at (610) 266-0500 ext. 2280, by fax at (610) 266-4962, or by e-mail at patricia.wilson@bbmus.com.

Sincerely,



Patricia D. Wilson
Regulatory Affairs Specialist
B. Braun Medical Inc.

/enc.



Patricia D. Wilson
Regulatory Affairs Specialist

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109
Telephone: 610-266-0500 x2375
Fax: 610-266-4962

April 3, 2002

Food and Drug Administration
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: 510(k) Notification: Introcan[®] Safety[™] IV Catheter

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Device Name and Classification:

Proprietary / Trade Name: Introcan[®] Safety[™] IV Catheter
Common Name: Safety Intravascular Catheter / Safety Introducer Catheter
Classification: Class II, 21 CFR § 880.5200: Intravascular Catheter
(Product Code FOZ) and 21 CFR § 870.1340: Catheter
Introducer (Product Code DYB)

A handwritten signature in black ink, appearing to be 'P. Wilson', is located in the bottom right corner of the page.

This application is being submitted by the following B. Braun establishment:

B. Braun Medical Inc. Establishment Registration #2523676
901 Marcon Boulevard
Allentown, PA 18109
USA

The Introcan Safety IV Catheter will be manufactured, packaged, and sterilized at the following establishment:

B. Braun Medical Industries SDN. BHD. Establishment Registration #9612086
Bayan Lepas Free Trade Zone
Penang, Malaysia

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If you have any questions concerning this submission, please contact me by phone at (610) 266-0500 ext. 2280, by fax at (610) 266-4962, or by e-mail at patricia.wilson@bbmus.com.

Sincerely,



Patricia D. Wilson
Regulatory Affairs Specialist
B. Braun Medical Inc.

/enc.

13

B. Braun Medical Inc. Premarket Notification

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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The term "predicate device(s)" as used throughout this entire premarket notification (cover letter, body, attachments, and summary), and the supporting information pertaining to equivalence, are intended to demonstrate equivalence to the predicate device(s) for the purposes of obtaining clearance of the subject device(s) under the Federal Food, Drug and Cosmetic Act. Any references to equivalence in this submission are in no way related to any form of equivalence under patent laws.

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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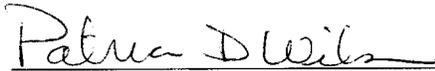
1.0 Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*

[As Required By 21 CFR 807.87(j)]

I certify that, in my capacity as Regulatory Affairs Specialist of B. Braun Medical 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.



Patricia D. Wilson

April 3, 2002

K _____ B. Braun Medical Inc. Introcan[®] Safety[™] IV Catheter

*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

2.0 Indications for Use Statement

Page 1 of 1

510(k) Number (if known): _____

Device Name: Introcan[®] Safety[™] IV Catheter

Indications For Use:

The Introcan[®] Safety[™] IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

000005

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3.0 Description of the Device

The Introcan[®] Safety[™] IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Introcan Safety IV Catheter is currently marketed under the B. Braun Medical Inc. premarket notification K982805 as a passive anti-needle stick device to be placed in a peripheral vein for the infusion of fluids, drugs, and/or blood components. This submission expands the indications, to include use as an introducer catheter to facilitate the placement of Vascular Access devices. Refer to Attachment I for a copy of draft labeling for the Introcan Safety IV Catheter with the expanded indications for use. Advertising or promotional materials have not been prepared at this time.

The Introcan Safety IV Catheter consists of an over-the-needle catheter with a safety clip feature. Upon removal of the needle from the catheter, the safety clip is automatically secured over the needle tip as it exits the catheter hub. The Introcan Safety IV Catheter is currently available in sizes ranging from 14 Gauge through 24 Gauge with an exposed (useable) length of 25 mm to 45 mm. This submission expands the available sizes to include a length of up to 2-1/2 in. (64 mm). For a more detailed description of this device, please refer to Attachment II for a copy of the engineering drawing.

The Introcan Safety IV Catheter has the same materials, design, and method of construction as the currently marketed Introcan Safety IV Catheter cleared under the B. Braun Medical Inc. premarket notification K982805. A detailed list of materials is provided in Table I following this section, as a reference for Agency review. Additional details are also provided in Table II (Substantial Equivalence Comparison). Since there are no new materials, biocompatibility information has not been included in this submission.

As the Introcan Safety IV Catheter is a passive anti-needle stick device, a risk analysis was completed. This 510(k) expands the indications for this device to include use as an introducer catheter to facilitate placement of Vascular Access devices. The safety feature for this device reduces the risk of inadvertent needle sticks. Please refer to Attachment III for a copy of the risk analysis.

The risk analysis and draft labeling include information on the use of the Introcan Safety IV Catheter with a power injector. This indication is currently pending Agency clearance under the B. Braun Medical Inc. premarket notification K020785 (submitted March 8, 2002), and is noted in the current submission as a reference for Agency review.

Table I: Material List for Introcan[®] Safety[™] IV Catheter

Part	Material	Grade/Trade name	Manufacturer
Protective Cap	(b)(4)		
Catheter Tube			
Capillary Transparent Area			
Opaque Stripes			
Housing			
Metal Bush (b)(4) for Capillary			
Cannula Assembly Cannula			
Hub			
Glue			
Oil for Cannula			
Filter Assembly Bloodstopper Housing			
Filter (5.0 µm)			
Filter (1.2 µm)			
Safety Clip			

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

000007

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4.0 Substantial Equivalence Comparison to Predicate Devices

The Introcan[®] Safety[™] IV Catheter includes the same materials, construction, design, and safety clip feature as the Introcan Safety IV Catheter previously cleared under the following B. Braun Medical Inc. Premarket Notification:

K982805 Introcan Safety IV Catheter

The Introcan Safety IV Catheter is similar in materials and design, with the exception of the safety clip feature, as the introducer catheter previously cleared as a kit component under the following B. Braun Medical Inc. Premarket Notifications:

K810460 Burrton Percutaneous Introducer Set
K810461 Burrton Central Vein Catherization Kit

The new indication for the Introcan Safety IV Catheter, for use as an introducer catheter, is the same indication previously cleared for BD Introsyte[™] Autoguard[™] Shielded Introducer under the following Becton Dickinson Infusion Therapy Systems Inc. Premarket Notification:

K013304 BD Introsyte[™] Precision Introducer, BD Introsyte[™] Autoguard[™] Shielded Introducer

Please refer to Table II for a comparison of the Introcan Safety IV Catheter to predicate devices. A copy of predicate device labeling is also included in Attachment IV.

Table II: Substantial Equivalence Comparison

<p>Introcan® Safety™ IV Catheter</p> <p>Indications: Passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.</p> <p>Materials: Catheter Tube: Catheter Hub: Needle Needle Hub: Safety Clip:</p>	<p>Prediccate: K982805 Introcan® Safety™ IV Catheter</p> <p>Passive anti-needle stick device to be placed in a peripheral vein for the infusion of fluids, drugs, and/or blood components.</p>	<p>Prediccate: K810460/K810461 Introducer Catheter (as CVC and PCI Kit Component)</p> <p>The catheter over the needle is a kit component. As indicated in the labeling, this component is for insertion of guidewire during the Percutaneous Catheter Introducer or Central Venous Catheterization procedure.</p>	<p>Prediccate: K013304 BD Introstyle™ Autoguard™ Shielded Introducer</p> <p>To facilitate the placement of devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.</p>
<p>(b)(4)</p>	<p>(b)(4)</p>	<p>(b)(4)</p>	<p>(b)(4)</p>

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B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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Table II (Continued): Substantial Equivalence Comparison

Introcath[®] Safety[™] IV Catheter	Predicate: K982805 Introcath[®] Safety[™] IV Catheter	Predicate: K810460/K810461 Introducer Catheter (as CVC or PCI Kit Component)	Predicate: K013304 BD Introsyte[™] Autoguard[™] Shielded Introducer
Dimensions:			
Gauge	14 G - 24 G	18 G	14 G - 24 G
Length	25 mm - 64 mm	64 mm	Unknown - current products include 33 mm length
Catheter I.D.	0.064" (1.626 mm) - 0.018" (0.457 mm)	0.039" (1 mm)	Unknown - current products include I.D. of 1.1 mm, 1.5 mm and 1.8 mm
Catheter O.D.	0.083" (2.108 mm) - 0.026" (0.66 mm)	0.052" (1.3 mm)	Unknown - current products include O.D. of 1.5 mm, 1.9 mm and 2.3 mm
Configuration	Single Lumen, Tapered Tip	Single Lumen, Tapered Tip	Unknown - current products include single lumen, tapered tip, splittable sheath
Performance: Must allow passage of the appropriate sized guidewire or catheter – see Section 5.0	Not Applicable	Must allow passage of the appropriate sized guidewire.	Unknown
Manufacturing:			
Catheter Construction:	(b)(4)		
Sterilization:	(b)(4)		

000010 33

5.0 Performance /Functionality

The Introcan[®] Safety[™] IV Catheter will be capable of the passage of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Testing was completed (b)(4)

(b)(4)

Testing was also completed (b)(4)

(b)(4)

For a more detailed summary of performance testing, please refer to Attachment VI.

6.0 Manufacturing, Sterilization and Packaging Processes

The Introcan Safety IV Catheter that is the subject of this premarket notification has the same manufacturing, sterilization, and packaging methods as the Introcan Safety IV Catheter cleared under the B. Braun Medical Inc. premarket notification K982805.

The Introcan Safety IV Catheter is sold sterile in individual blister packages. This device may also be provided bulk/nonsterile for use in B. Braun convenience kits (and sterilized as part of the final packaged kit).

Detailed sterilization information for the individually packaged Introcan Safety IV Catheter is presented below, as a reference for Agency review:

Site: The Introcan Safety IV Catheter will be sterilized at the B. Braun Medical Industries SDN. BHD. facility in Penang, Malaysia.

Validation

Method:

(b)(4)

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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Sterilization information (Continued):

Assurance Level: The sterility assurance level (SAL) will be 10^{(b)(4)}

Pyrogen Test: The device will be pyrogen free. The clinical laboratory standard test procedure for determination of pyrogenicity, (b)(4) will be used for validation.

(b)(4)

(b)(4)

(b)(4)

7.0 510(k) Summary

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2280

Contact: Patricia D. Wilson, Regulatory Affairs Specialist

DEVICE NAME: Introcan® Safety™ IV Catheter

COMMON OR USUAL NAME: Safety Intravascular Catheter / Safety Introducer Catheter

DEVICE CLASSIFICATION: Class II, 21 CFR § 880.5200: Intravascular Catheter and 21 CFR § 870.1340: Catheter Introducer

PREDICATE DEVICE: B. Braun Medical Inc. Introcan Safety IV Catheter (K982805)
B. Braun Medical Inc. Introducer Catheter (Kit component of K810460 / K810461)
Becton Dickinson Infusion Therapy Systems Inc., BD Introsyte™ Autoguard™ Shielded Introducer (K013304)

DESCRIPTION: The Introcan Safety IV Catheter consists of an over-the-needle catheter with a safety clip feature. Upon removal of the needle from the catheter, the safety clip is automatically secured over the needle tip as it exits the catheter hub. The Introcan Safety IV Catheter is available in sizes ranging from 14 Gauge through 24 Gauge.

INTENDED USE: The Introcan Safety IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

SUBSTANTIAL EQUIVALENCE: The Introcan Safety IV Catheter includes the same materials, construction, design, and safety clip feature as the Introcan Safety IV Catheter previously cleared under the B. Braun Medical Inc. Premarket Notification, K982805. The Introcan Safety IV Catheter is also similar in materials and design, with the exception of the safety clip feature, as the introducer catheter previously cleared as a kit component under the B. Braun Medical Inc. Premarket

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

Notifications, Burrion Percutaneous Introducer Set (K810460) and Burrion Central Vein Catherization Kit (K810461). The new indication for the Introcan Safety IV Catheter, for use as an introducer catheter, is the same indication previously cleared for Becton Dickinson Infusion Therapy Systems Inc.'s Premarket Notification, BD Introsyte™ Precision Introducer, BD Introsyte™ Autoguard™ Shielded Introducer, K013304.

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

000014

8.0 Attachments

Attachment I:	Proposed Device Labeling
Attachment II:	Device Drawings
Attachment III:	Risk Analysis
Attachment IV:	Predicate Device Labeling
Attachment V:	Performance Test Data

Attachment I
Proposed Device Labeling

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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Draft Labeling

Introcan[®] Safety[™] IV Catheter
(Teflon)

Includes:

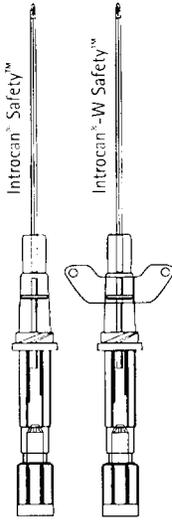
Proposed IFU (One IFU to be used for all sizes/Teflon)
Proposed Label (One size provided as an example)

I.V. catheter designed to minimize inadvertent needlesticks, made of EP, radioopaque, with or without fixation wings. For single use only.

Introcan® Safety™ Introcan® -W Safety™

B | BRAUN

Manufactured for:
B. Braun Medical Inc.
Bethlehem, PA 18018



REV. 3/02

Instructions for use

Materials used

FEP, PP, ABS, chrome-nickel steel

Indications

Creation of a secure peripheral or central venous or arterial access with a passive anti-needlestick device. Blood transfusions or infusion of I.V. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration.

Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures. Intermittent blood sampling, especially from arterial sites.

Invasive (intra-arterial) measurement of arterial blood pressure.

14 - 22 Ga. catheters may be used with power injectors for which the maximum pressure setting is $\leq 300\text{ psi}$.

Facilitate the placement of Vascular Access Devices such as guidewires, indwelling central

venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Contraindications

Introcan® Safety™ should not be used in patients with known hypersensitivity to any of the materials employed.

Risks

This I. V. catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to avoid needlesticks. Universal precautions must be adhered to in accordance with Centers for Disease Control and Prevention / Occupational Safety and Health Administration (CDC/OSHA) standards for bloodborne pathogens, when starting or maintaining any I. V. catheter, to avoid the risk of exposure to contaminated blood. Depending on how long the cannula is left in situ, on the type and amount of infusions or injections administered, and on

individual predisposition, thrombophlebitis may occur in the accessed vein. In arterial puncture, the artery may occlude in rare cases due to thrombotic or embolic complications, resulting in ischaemia.

Duration of use

Change according to CDC Guidelines and / or Hospital or Institutional protocols. The puncture site should be checked at regular intervals. Introcan® Safety™ should be removed in the event of local or systemic signs of infection.

Warning

- After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.
- Always clearly mark arterial lines to avoid inadvertent injection. Verify adequate collateral circulation prior to arterial puncture.
- Use only if packaging is intact.

• Prior to use with power injectors, ensure that a secure connection exists between the catheter and power injector.

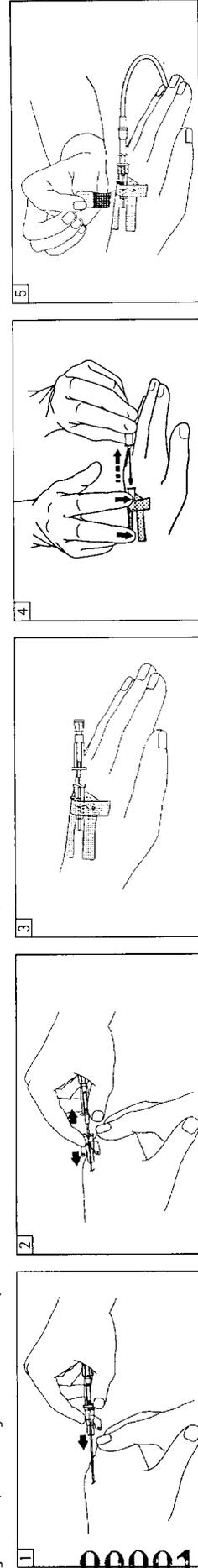
Storage
Store at room temperature. Protect from extreme heat and freezing.

Application

- 1 After disinfection of the puncture site and removal of the protective cap, puncture a suitable vein. If venipuncture was successful, blood will immediately be visible inside the transparent grip part.
- 2 Advance the catheter further into the vein, while slightly withdrawing the steel needle.
- 3 For peripheral access, use adhesive tape to secure catheter to the skin. The steel needle still in situ minimizes spillage of blood.
- 4 Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle

straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub. Dispose of needle immediately into sharps container.
5 If used as an indwelling IV catheter connect to infusion line and cover puncture site with a sterile dressing. If used to facilitate the placement of a Vascular Access Device follow manufacturer's instructions for use of the specific device being placed.

Rx only



000018

⊗ For single use only. Do not resterilize.

△ See instruction leaflet

LOT Lot number

STERILE Sterile

Exp.: Expiration date

41

Introcan® - W Safety™

IV Catheter designed to minimize inadvertent needlesticks, with fixation wings.

For single use only. Do not resterilize.

Rx only

CAUTION: Read instructions for use.

U.S. Patent No. 6,117,108

**Introcan®
Safety™**



B | BRAUN

Manufactured for:

B. Braun Medical Inc.
Bethlehem, PA 18018

Components made in U.S.A., Malaysia and Japan.

22 G x 1 in.
0.9 x 25 mm
35 mL/min



FEP



STERILE EO
NONPYROGENIC

in unopened undamaged package.

4252519

RFF

LOT



000019

42

Draft Labeling

Introcan[®] Safety[™] IV Catheter
(Polyurethane)

Includes:

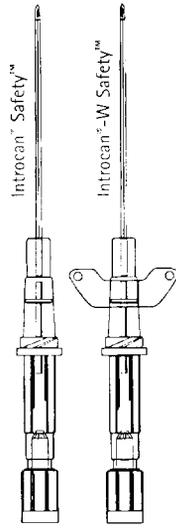
Proposed IFU (One IFU to be used for all sizes/Polyurethane)
Proposed Label (One size provided as an example)

I.V. catheter designed to minimize inadvertent needlesticks, made of Polyurethane, radiopaque, with or without fixation wings. For single use only.

Introcan® Safety™ Introcan® -W Safety™

B | BRAUN

Manufactured for:
B. Braun Medical Inc.
Bethlehem, PA 18018



REV. 3/02

Instructions for use

Materials used
Polyurethane, PP, ABS, chrome-nickel steel

Indications
Creation of a secure peripheral or central venous access with a passive anti-needlestick device. Blood transfusions or infusion of I.V. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration.
Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures.
14 - 22 Ga. catheters may be used with power injectors for which the maximum pressure setting is 300 psi.
Facilitate the placement of Vascular Access Devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Contraindications
Introcan® Safety™ should not be used in patients with known hypersensitivity to any of the materials employed.

Risks
This I. V. catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to avoid needlesticks. Universal precautions must be adhered to in accordance with Centers for Disease Control and Prevention / Occupational Safety and Health Administration (CDC/OSHA) standards for bloodborne pathogens, when starting or maintaining any I.V. catheter, to avoid the risk of exposure to contaminated blood. Depending on how long the cannula is left in situ, on the type and amount of infusions or injections administered, and on individual predisposition, thrombophlebitis may occur in the accessed vein.

Duration of use
Change according to CDC Guidelines and / or Hospital or Institutional protocols. The puncture site should be checked at regular intervals. Introcan® Safety™ should be removed in the event of local or systemic signs of infection.

Warning

- After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.
- Use only if packaging is intact.
- Prior to use with power injectors, ensure that a secure connection exists between the catheter and power injector.

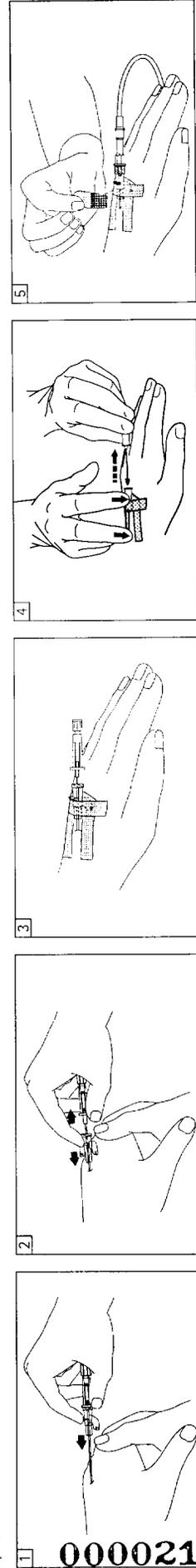
Storage
Store at room temperature. Protect from extreme heat and freezing.

Application

- 1 After disinfection of the puncture site and removal of the protective cap, puncture a suitable vein. If venipuncture was successful, blood will immediately be visible inside the transparent grip part.
- 2 Advance the catheter further into the vein, while slightly withdrawing the steel needle.
- 3 For peripheral access use adhesive tape to secure catheter to the skin. The steel needle still in situ minimizes spillage of blood.
- 4 Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to catheter hub. Dispose of needle immediately into sharps container.
- 5 If used as an indwelling IV catheter connect to infusion line and cover puncture site

with a sterile dressing. If used to facilitate the placement of a Vascular Access Device follow manufacturer's instructions for use of the specific device being placed.

Rx only



000021

⊗ For single use only. Do not sterilize.

△ See instruction leaflet

LOT Lot number

STERILE Sterile

Exp.: Expiration date

44

Introcan®-W Safety™

IV Catheter designed to minimize inadvertent needlesticks, with fixation wings.

For single use only. Do not resterilize.

Rx only

CAUTION: Read instructions for use.

U.S. Patent No. 6,117,108

Introcan®
Safety™



B | BRAUN

Manufactured for:

B. Braun Medical Inc.
Bethlehem, PA 18018

Components made in U.S.A., Malaysia and Japan.

22 G x 1 in.
0.9 x 25 mm
35 mL/min



PUR



STERILE EO
NONPYROGENIC

in unopened undamaged package.

4252519

REF

LOT



000022

4/5

Attachment II

Device Drawing

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

000023 46

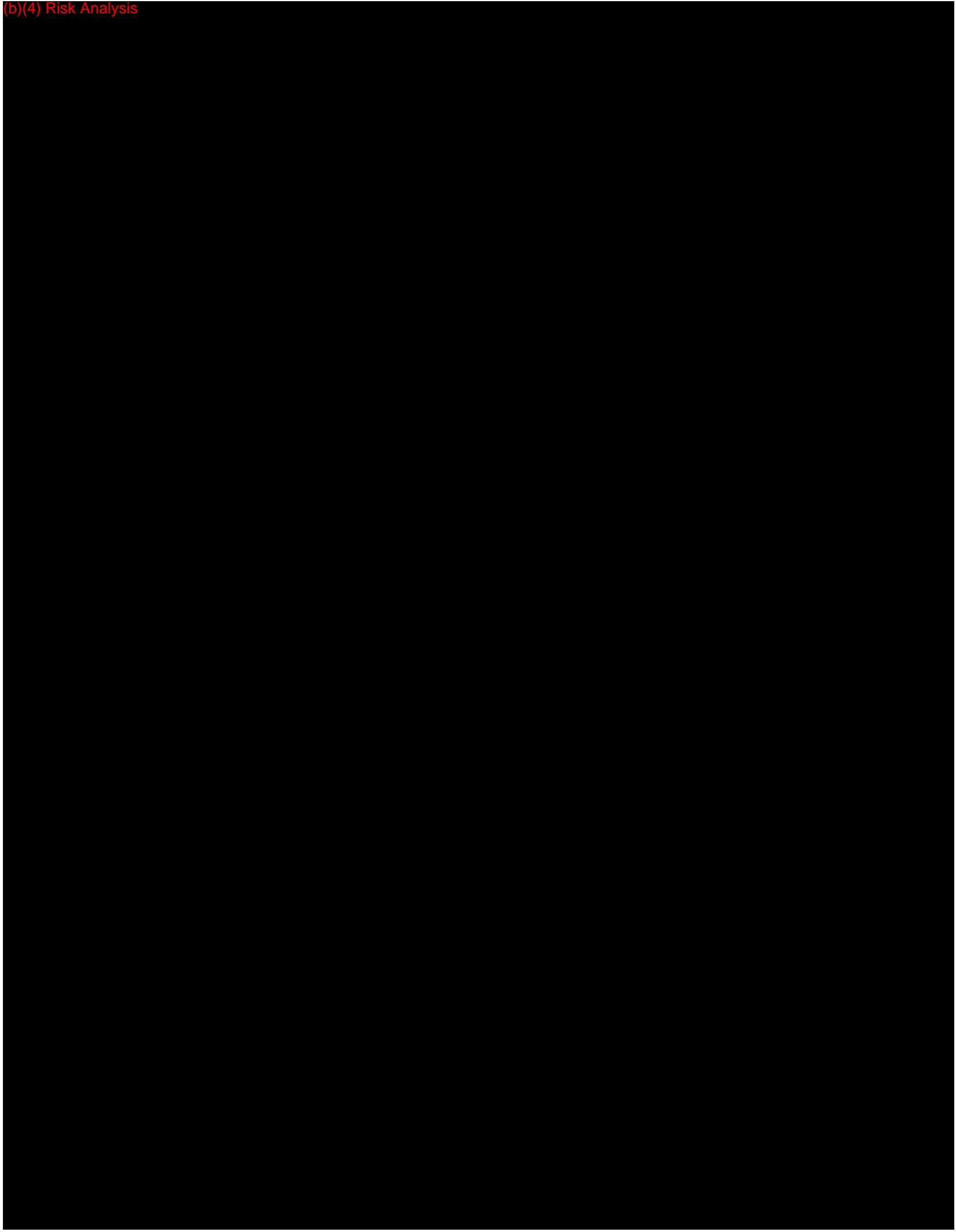
Attachment III

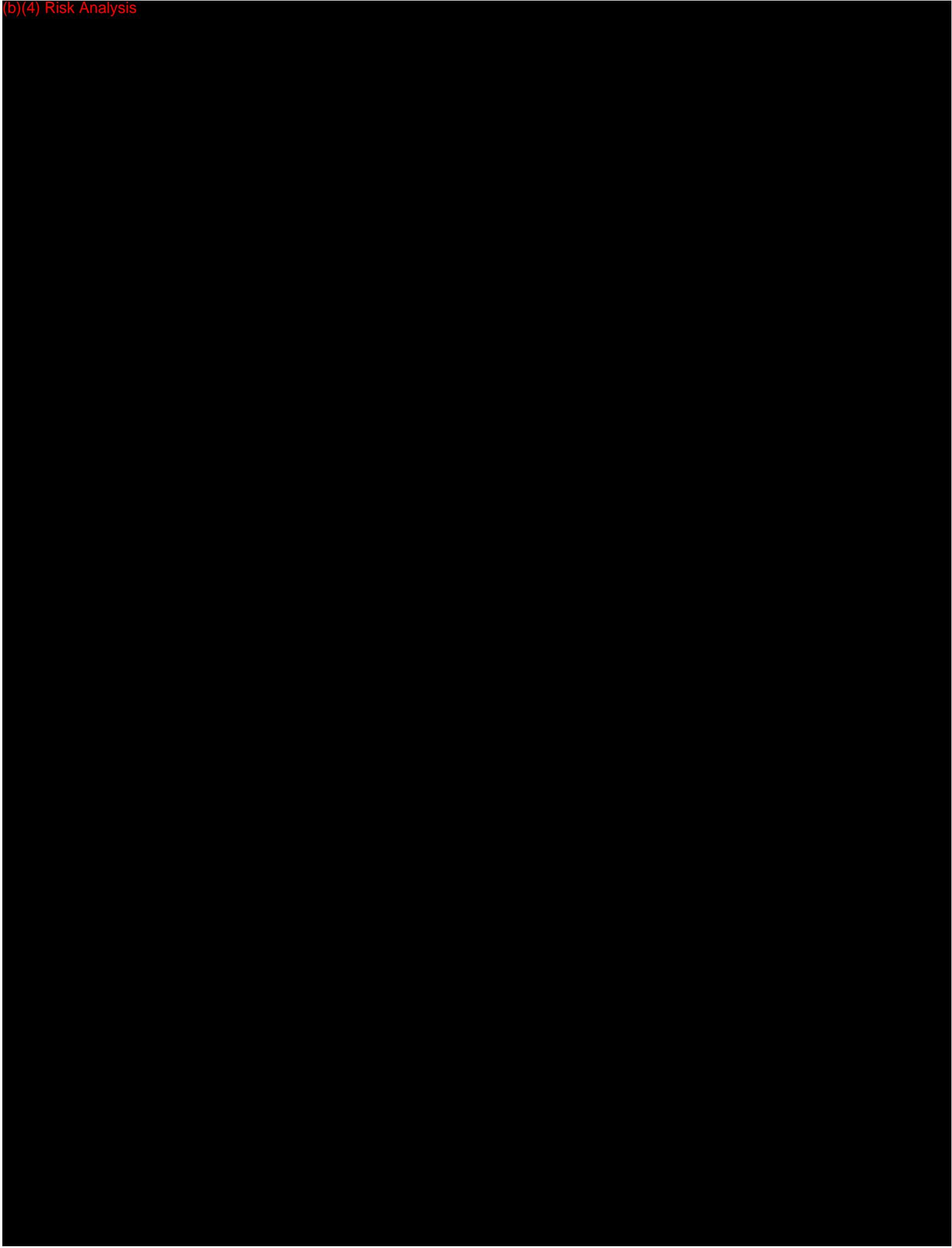
Risk Analysis

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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Attachment IV

Predicate Device Labeling

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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Predicate Labeling & 510(k) Information

Introcan[®] Safety[™] IV Catheter
(K982805)

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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000030

An actual IFU for the Introcan[®] Safety[™] IV Catheter (Teflon) is attached below; a photocopy is included on the next page.

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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000031

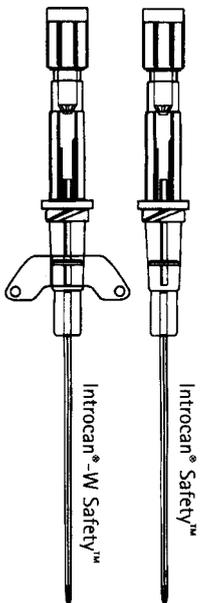
Introcan® Safety™ Introcan®-W Safety™

BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018

Rohstoff-Nr.: 1242 7004 09.99

I. V. catheter designed to minimize inadvertent needlesticks, made of FEP, radiopaque, with or without fixation wings. For single use only.



Instructions for use

Materials used
FEP, PP, ABS, chrome-nickel steel

Indications
Creation of a secure peripheral venous or arterial access with a passive anti-needlestick device.

Good transfusions or infusion of I. V. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration.
Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration in particular prior to diagnostic or therapeutic procedures.
Intermittent blood sampling, especially from arterial sites.
Invasive (intra-arterial) measurement of arterial blood pressure.

Contraindications
Introcan® should not be used in patients with known hypersensitivity to any of the materials employed.

Risks
The I. V. catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to avoid needlesticks. Universal precautions

must be adhered to in accordance with Centers for Disease Control and Prevention / Occupational Safety and Health Administration (CDC/OSHA) standards for bloodborne pathogens, when starting or maintaining any I. V. catheter, to avoid the risk of exposure to contaminated blood.

Depending on how long the cannula is left in situ, on the type and amount of infusions or injections administered, and on individual predisposition, thrombophlebitis may occur in the accessed vein.
In arterial puncture, the artery may occlude in rare cases due to thrombotic or embolic complications, resulting in ischaemia.

Duration of use
Change according to CDC Guidelines and / or Hospital or Institutional protocols. The puncture site should be checked at regular intervals. Introcan® should be removed in the event of local or systemic signs of infection.

Warning
After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.

Always clearly mark arterial lines to avoid inadvertent injection. Verify adequate collateral circulation prior to arterial puncture.
Use only if packaging is intact.

Storage
Until needed, the product should be stored in its original packaging at temperatures between 10 °C and 25 °C and at 50 % to 60 % humidity. Protect from direct light exposure.
If stored properly, the product may be used up to the expiration date (see packaging).

Application
After disinfection of the puncture site and removal of the protective cap, puncture a suitable vein. If venipuncture was successful, blood will immediately be visible inside the transparent grip part.
Advance the catheter further into the vein, while slightly withdrawing the steel needle.

Using adhesive tape, fix catheter to the skin. The steel needle still in situ minimizes spillage of blood.

Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub.
Dispose of needle immediately into sharps container.
Connect to infusion line and cover puncture site with a sterile dressing.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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For single use only

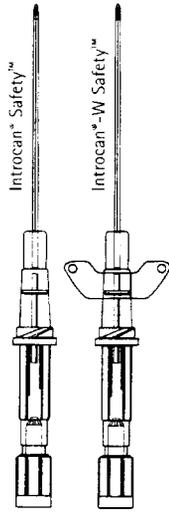
See instruction leaflet

lot number

STERILE Sterile

Exp.: Expiration date

I.V. catheter designed to minimize inadvertent needlesticks, made of FEP, radiopaque, with or without fixation wings. For single use only.



Introcan® Safety™ Introcan®-W Safety™

B | BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018

Rohstoff-Nr.: 1242 7004 09.99

Instructions for use

Materials used

FEP, PP, ABS, chrome-nickel steel

Indications

Creation of a secure peripheral venous or arterial access with a passive anti-needlestick device.

Blood transfusions or infusion of I.V. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration. Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures. Intermittent blood sampling, especially from arterial sites.

Invasive (intra-arterial) measurement of arterial blood pressure.

Contraindications

Introcan® should not be used in patients with known hypersensitivity to any of the materials employed.

Risks

This I.V. catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to avoid needlesticks. Universal precautions

must be adhered to in accordance with Centers for Disease Control and Prevention / Occupational Safety and Health Administration (CDC/OSHA) standards for bloodborne pathogens, when starting or maintaining any I.V. catheter, to avoid the risk of exposure to contaminated blood.

Depending on how long the cannula is left in situ, on the type and amount of infusions or injections administered, and on individual predisposition, thrombophlebitis may occur in the accessed vein. In arterial puncture, the artery may occlude in rare cases due to thrombotic or embolic complications, resulting in ischaemia.

Duration of use

Change according to CDC Guidelines and / or Hospital or Institutional protocols. The puncture site should be checked at regular intervals. Introcan® should be removed in the event of local or systemic signs of infection.

Warning

After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.

Always clearly mark arterial lines to avoid inadvertent injection. Verify adequate collateral circulation prior to arterial puncture. Use only if packaging is intact.

Storage

Until needed, the product should be stored in its original packaging at temperatures between 10 °C and 25 °C and at 50 % to 60 % humidity. Protect from direct light exposure. If stored properly, the product may be used up to the expiration date (see packaging).

Application

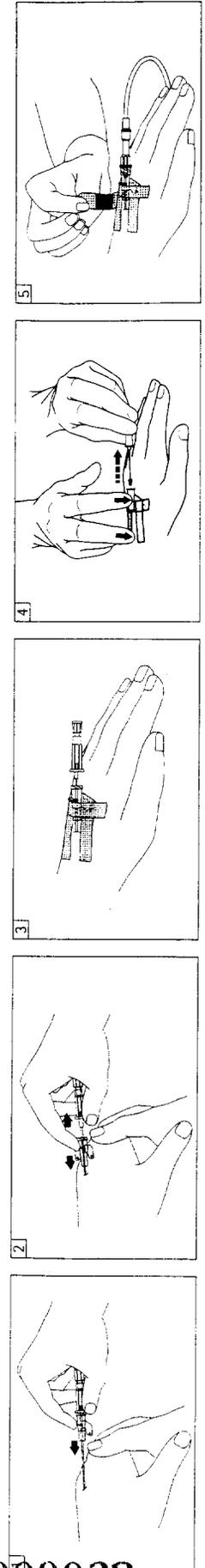
After disinfection of the puncture site and removal of the protective cap, puncture a suitable vein. If venipuncture was successful, blood will immediately be visible inside the transparent grip part.

Advance the catheter further into the vein, while slightly withdrawing the steel needle.

Using adhesive tape, fix catheter to the skin. The steel needle still in situ minimizes spillage of blood.

Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub. Dispose of needle immediately into sharps container.

Connect to infusion line and cover puncture site with a sterile dressing.



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Introcan®-W Safety™

IV Catheter designed to minimize inadvertent needlesticks, with fixation wings. For single use only. CAUTION: HANDLE WITH CARE -- Read Instructions for Use.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Patent pending.

Introcan®
Safety™ 

B BRAUN

B. Braun Medical Inc.
Billerica, MA 01818

19
1099
1532 7124



B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

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000033

An actual IFU for the Introcan[®] Safety[™] IV Catheter (Polyurethane) is attached below; a photocopy is included on the next page.

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B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

000034

I.V. catheter designed to minimize inadvertent needlesticks, made of Polyurethane, radiopaque, with or without fixation wings. For single use only.

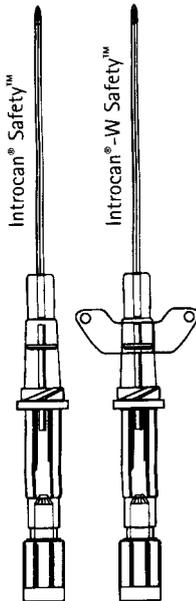
Introcan® Safety™ Introcan®-W Safety™

Questions? Contact FDA/CDRH/OCE/DIV 101

1-800-796-8118

B. Braun Medical Inc.
Bethlehem, PA 18018

BRAUN



Instructions for use

Materials used
Polyurethane, PP, ABS, chrome-nickel steel

Indications
Creation of a secure peripheral venous access with a passive anti-needlestick device for transfusions or infusion of I.V. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration.

Contraindications
Introcan® should not be used in patients with known hypersensitivity to any of the materials employed.

Risks
This I.V. catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to avoid needlesticks. Universal precautions must be adhered to in accordance with Centers for Disease Control and Prevention Occupational Safety and Health Administration (CDC/OSHA) standards

for bloodborne pathogens, when starting or maintaining any I.V. catheter, to avoid the risk of exposure to contaminated blood.

Depending on how long the cannula is left in situ, on the type and amount of infusions or injections administered, and on individual predisposition, thrombophlebitis may occur in the accessed vein.

Duration of use

Change according to CDC Guidelines and /or Hospital or Institutional protocols. The puncture site should be checked at regular intervals. Introcan® should be removed in the event of local or systemic signs of infection.

Warning

After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.
Use only if packaging is intact.

Storage

Until needed, the product should be stored in its original packaging at temperatures between 10 °C and 25 °C and at 50 % to 60 % humidity. Protect from direct light exposure.

If stored properly, the product may be used up to the expiration date (see packaging).

Application

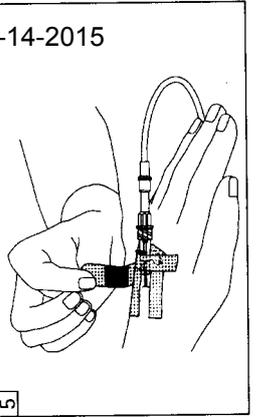
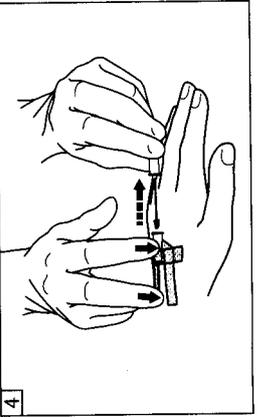
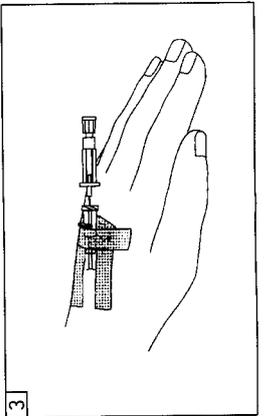
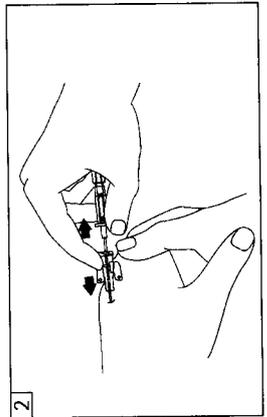
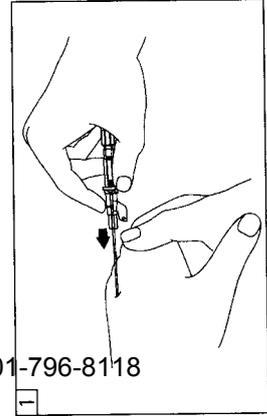
1 After disinfection of the puncture site and removal of the protective cap, puncture a suitable vein. If venipuncture was successful, blood will immediately be visible inside the transparent grip part.

2 Advance the catheter further into the vein, while slightly withdrawing the steel needle.

3 Using adhesive tape, fix catheter to the skin. The steel needle still in situ minimizes spillage of blood.

4 Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub.
Dispose of needle immediately into sharps container.

5 Connect to infusion line and cover puncture site with a sterile dressing.



⊗ For single use only

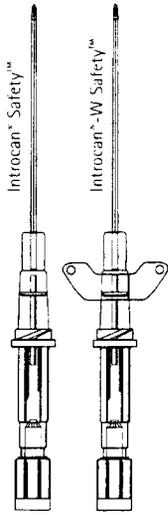
△ See instruction leaflet

LOT Lot number

STERILE Sterile

Exp.: Expiration date

I.V. catheter designed to minimize inadvertent needlesticks, made of Polyurethane, radiopaque, with or without fixation wings. For single use only.



Introcan[®] Safety[™] Introcan[®] -W Safety[™]

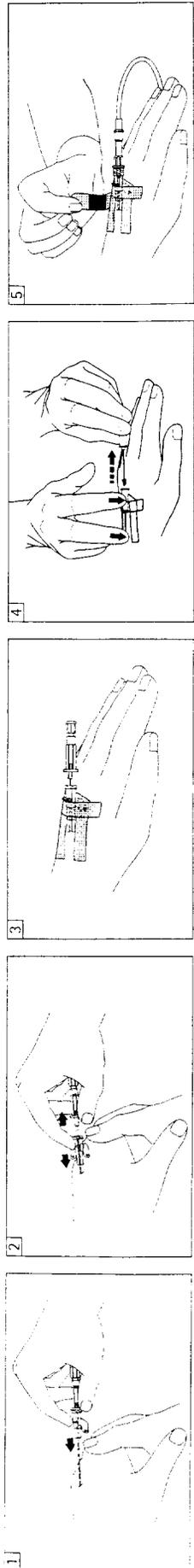
B | BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018

Rohstoff-Nr.: 1242 7012 09.99

Instructions for use

<p>Materials used Polyurethane, PP, ABS, chrome-nickel steel</p> <p>Indications Creation of a secure peripheral venous access with a passive anti-needlestick device</p> <p>Blood transfusions or infusion of I.V. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration.</p> <p>Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures.</p>	<p>for bloodborne pathogens, when starting or maintaining any I.V. catheter, to avoid the risk of exposure to contaminated blood.</p> <p>Depending on how long the cannula is left in situ, on the type and amount of infusions or injections administered, and on individual predisposition, thrombophlebitis may occur in the accessed vein.</p> <p>Duration of use Change according to CDC Guidelines and / or Hospital or Institutional protocols. The puncture site should be checked at regular intervals. Introcan[®] should be removed in the event of local or systemic signs of infection.</p> <p>Warning After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism. Use only if packaging is intact.</p> <p>Storage If/when needed, the product should be stored in its original packaging at temperatures between 10 °C and 25 °C and at 50 % to 60 % humidity. Protect from direct light exposure.</p>	<p>If stored properly, the product may be used up to the expiration date (see packaging).</p> <p>Application 1 After disinfection of the puncture site and removal of the protective cap, puncture a suitable vein. If venipuncture was successful, blood will immediately be visible inside the transparent grip part.</p> <p>2 Advance the catheter further into the vein, while slightly withdrawing the steel needle.</p> <p>3 Using adhesive tape, fix catheter to the skin. The steel needle still in situ minimizes spillage of blood.</p> <p>4 Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub.</p> <p>5 Dispose of needle immediately into sharps container.</p> <p>6 Connect to infusion line and cover puncture site with a sterile dressing.</p>		
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For single use only
See instruction leaflet
LOT Lot number
STERILE
Sterile
Exp. Expiration date

000035

Introcan Safety

IV Catheter designed to minimize inadvertent needlesticks. For single use only.
CAUTION: HANDLE WITH CARE -
Read instructions for Use.

B BRAUN

Introcan
Safety 

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.
U.S. patent no. 6117108

B. Braun Medical Inc.
Bethlehem, PA 18018

09/00
15327116

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

000036

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 1999

Mr. Mark S. Alsberge
Regulatory Affairs Director
B. Braun Medical, Incorporated
824 12th Avenue
Bethlehem, Pennsylvania 18018-0027

Re: K982805
Trade Name: Introcan Safety I.V. Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 9, 1998
Received: November 12, 1998

Dear Mr. Alsberge:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

62

000037

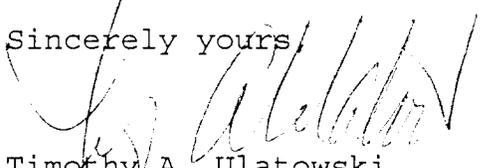
Page 2 - Mr. Alsberge

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

63

000038

510(k) Number (if known): _____

Device Name: Intracan Safety I.V. Catheter

Indications For Use:

A passive anti-needle stick device to be placed in to a peripheral vein for the infusion of fluids, drugs, and/or blood components

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Encarnate

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K982805

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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000039

Predicate Labeling & 510(k) Information

Catheter Introducer
Kit Component in
B. Braun PCI and CVC Kits
(K810460 / K810461)

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

65

000040

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

MAR 11 1991

Mr. Thomas R. Ronca
Director, Quality Assurance &
Regulatory Affairs
Burron Medical Inc.
824 Twelfth Avenue
Bethlehem, PA 18018

Ref: K810460 Burron Percutaneous Inducer
Set

Dear Mr. Ronca:

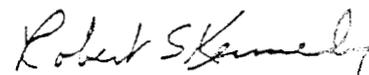
We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 3757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,



Robert S. Kennedy, Ph.D.
Associate Director
for Device Evaluation
Bureau of Medical Devices

66

000041

BURRON PERCUTANEOUS INTRODUCER SET

Draft Copy

CONTENTS:

- ONE 25 Ga. x 1" (2.54cm) Skin Wheel Needle
- ONE 22 Ga. x 1 1/4" (3.81cm) Vessel Locating Needle
- ONE 18 Ga. x 2 1/4" (6.35cm) T.W. Needle
- ONE 18 Ga. x 2 1/4" (6.35cm) Teflon* Radiopaque Catheter over 20 Ga. Introducer Needle
- ONE 3cc Syringe
- TWO 5cc Syringes
- ONE .035" (.89mm) dia. x 17 3/4" (45cm) Dual Purpose Spring Wire Guide (Straight Soft Tip on one end - "J" Tip on other)
- ONE Disposable Scalpel (#11 Blade)
- ONE Straight Silk Suture
- TWO Prep Sponge Swabs
- TWO 2" x 2" Gauze Pads
- FIVE 4" x 4" Gauze Pads
- ONE Teflon* Radiopaque Sheath-Dilator Assembly - 8 FR.
- ONE Catheter/Sheath Adapter with Side Port (for 7 FR. Catheters)
- ONE Removable Prep Tray
- ONE CSR Wrap
- ONE Fenestrated Drape

CONTENTS OF UNOPENED
UNDAMAGED KIT ARE
STERILE. CONTAINS NO
MEDICATION.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a Physician.

DISPOSABLE
DO NOT RESTERILIZE

A SUGGESTED PROCEDURE - USE STERILE TECHNIQUE

1. Peel open package and remove CSR Wrapped Tray.
2. Open CSR Wrap to create sterile field and expose components for use. Remove prep tray.
3. Prep skin in area of anticipated veni-puncture. Place fenestrated drape over field.
4. Use 18 Ga. needle to aspirate anesthetic solution into 5cc syringe. Perform skin wheel using 25 Ga. needle.
5. If flow directed catheter is used, inflate and deflate balloon with 3cc syringe to insure integrity. CAUTION: DO NOT EXCEED BALLOON CATHETER MANUFACTURER'S RECOMMENDED VOLUME. Place catheter and adapter on sterile field awaiting final sheath placement.
6. 22 Ga. needle and 5cc syringe may be used to locate vessel.
7. Attach 5cc syringe to 18 Ga. T.W. Catheter Introducer. Insert into vessel along side of 22 Ga. Locater needle. Remove 22 Ga. needle.
8. Remove Introducer Needle. If no free flow of venous blood is observed, attach syringe to catheter and aspirate until good venous blood flow is established. CAUTION: DO NOT REINSERT NEEDLE INTO CATHETER.
9. Insert desired tip of spring wire guide through 18 Ga. x 2 1/4" (6.35cm) catheter into vein. If "J" tip is used, prepare for insertion by sliding plastic tube over "J" to straighten it. Advance spring wire guide to required depth. NOTE: Advancement of "J" tip may require a gentle rotating motion.
10. Hold spring wire guide in place and remove Introducer Catheter.
11. Enlarge cutaneous puncture site with scalpel.
12. Thread tapered tip of dilator over spring wire guide. Grasping near skin, advance dilator into vessel with slight twisting motion.
13. Advance sheath over dilator into vessel, again grasping tip near skin and using slight twisting motion.
14. Hold sheath in place, remove spring wire guide and dilator, and insert balloon catheter.
15. Advance catheter to desired position and turn knob on adapter until snug.
16. Use suture to secure sheath and/or purse-string insertion site if necessary.

NOTE: 18 Ga. x 2 1/4" (6.35cm) T.W. Needle will pierce .035" (.89mm) dia. spring wire guide if desired.

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000042

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

MAR 11 1981

Mr. Thomas R. Ronca
Director, Quality Assurance &
Regulatory Affairs
Burrton Medical Inc.
824 Twelfth Avenue
Bethlehem, PA 18018

Ref: K810461 - Burrton Central Vein
Catherization Kit

Dear Mr. Ronca:

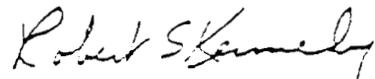
We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,



Robert S. Kennedy, Ph.D.
Associate Director
for Device Evaluation
Bureau of Medical Devices

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000043

BURRON CENTRAL VEIN CATHETERIZATION KIT

Draft Copy

CONTENTS:

- ONE 25 Ga. x 1" (2.54cm) Skin Wheel Needle
- ONE 22 Ga. x 1½" (3.81cm) Vessel Locating Needle
- ONE 18 Ga. x 2½" (6.35cm) T.W. Needle
- ONE 16 Ga. x 2½" (6.35cm) Heavy Wall Teflon* Radiopaque Catheter over 20 Ga. Introducer Needle
- TWO 5cc Syringes
- ONE .035" (.89mm) dia. x 17 3/4" (45cm) Dual Purpose Spring Wire Guide (Straight Soft Tip on One End - "J" Tip on Other)
- ONE Disposable Scalpel (#11 Blade)
- ONE Straight Silk Suture
- TWO Prep Sponge Swabs
- THREE 2" x 2" Gauze Pads
- FOUR 4" x 4" Gauze Pads
- ONE 16 Ga. x 8" Polyurethane Radiopaque Indwelling Catheter
- ONE Fenestrated Drape
- ONE Removable Prep Tray
- ONE CSR Wrap
- ONE Povidone - Iodine Ointment
- *DuPont Trademark

CONTENTS OF UNOPENED,
UNDAMAGED KIT ARE
STERILE.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a Physician.

DISPOSABLE

DO NOT RESTERILIZE

A SUGGESTED PROCEDURE - USE STERILE TECHNIQUE:

1. Peel open package and remove CSR wrapped tray.
2. Open CSR wrap to create sterile field and expose components for use. Remove prep tray.
3. Prep skin in area of anticipated venipuncture. Place fenestrated drape over field.
4. Use 18 Ga. needle to aspirate anesthetic solution into 5cc syringe. Perform skin wheel using 25 Ga. needle.
5. 22 Ga. needle and 5cc syringe may be used to locate central vein.
6. Attach 5cc syringe to 16 Ga. x 2½" (6.35cm) Catheter Introducer. Insert into vein along side of 22 Ga. locator needle. Remove 22 Ga. needle.
7. Remove introducer needle. If no free flow of venous blood is observed, attach syringe to catheter and aspirate until good venous blood flow is established. CAUTION: DO NOT REINSERT NEEDLE INTO CATHETER.
8. Insert desired tip of spring wire guide through 16 Ga. x 2½" (6.35cm) catheter into vein. If "J" tip is used, prepare for insertion by sliding plastic tube over "J" to straighten it. Advance spring wire guide to required depth. Note: Advancement of the "J" tip may require a gentle rotating motion.
9. Hold spring wire in place and remove introducer catheter.
10. Enlarge cutaneous puncture site with scalpel.
11. Thread tip of indwelling catheter over spring wire guide. (Be certain that sufficient wire guide length remains exposed at hub end of catheter to maintain firm grip on wire guide.) Grasping near skin, advance catheter into vein with slight twisting motion.
12. Advance catheter to required position.
13. Hold catheter at depth desired and remove spring wire guide. Attach syringe and aspirate until free flow of venous blood is observed.
14. Connect catheter to intravenous line or manometer.
15. Use suture to secure catheter and/or purse-string insertion site if necessary. Povidone-Iodine ointment can be used to cover puncture site.

NOTE: 18 Ga. x 2½" (6.35cm) T.W. Needle will pass .035" (.89mm) Dia. Spring Wire Guide if desired.

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000044

Predicate Labeling & 510(k) Information

BD Introsyte™ Autoguard™ Shielded Introducer
(K013304)

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

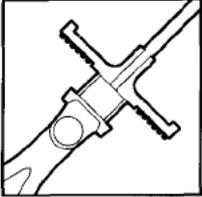
70
000045

An actual IFU for the BD Introsyte™ Autoguard™ Shielded Introducer is attached below; a photocopy is included on the next page.

71

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

000046



**BD Introsyte™
Autoguard™**
Shielded Introducer

INSTRUCTIONS FOR USE

The following suggestions are given to aid in the use of the INTROSYTE AUTOGUARD Shielded Introducer.

STERILE EO   Rx ONLY

D13729 (11-00)

GENERAL GUIDELINES:

- The INTROSYTE AUTOGUARD Shielded Introducer has been designed for use with BD PICC and midline products.
- For proper use, clinicians must be familiar with and trained in the use of these products. Use of these devices should be preceded by an established institutional protocol and performed by persons trained in the procedure and knowledgeable of the inherent risks. BD provides a comprehensive clinical education program to instruct clinicians on recommended practices for catheter insertion and maintenance.
- **REPORT NEEDLESTICKS IMMEDIATELY AND FOLLOW ESTABLISHED PROTOCOL.** Percutaneous puncture with a contaminated needle may lead to serious illness such as hepatitis, HIV (AIDS) or other infectious diseases. Resheathing needles is hazardous.
- Refer to appropriate institutional or governmental guidelines for handling and discarding needles and other sharps as well as proper disposal of all potentially contaminated items.
- **DO NOT** reuse introducer after a failed attempt.
- **NEVER** pull the catheter backthrough the needle as this could cut or sever the catheter.

Remove the INTROSYTE AUTOGUARD Shielded Introducer from the package and begin with step 1.

72

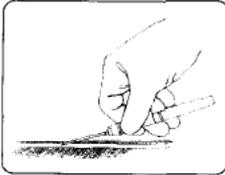
Becton Dickinson Infusion Therapy Systems Inc.,
Sandy, Utah 84070

① **Remove Cover**

- Remove the protective cover in a straight outward motion.

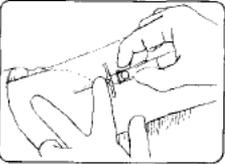
② **Venipuncture**

- Perform the venipuncture and thread the introducer at least ¼" off the needle. **NOTE:** In 26 and 22 gauge, look for initial flash along the catheter. **CAUTION:** Never reinsert the needle into the introducer as this could shear or sever the introducer.



③ **Retract Needle**

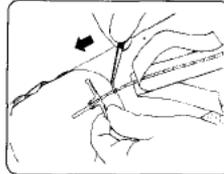
- Release the tourniquet. Support the introducer to avoid displacement. Apply digital pressure on the vessel, above the introducer tip, to minimize blood flow.
- Retract the needle from the introducer by



depressing the white button. **CAUTION:** Do not withdraw needle from introducer without depressing the white button. (If needle retraction does not occur, depress the button again. Dispose of any unshielded needles immediately.

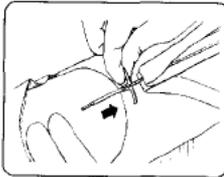
④ **Insert the Catheter**

- Grasp the catheter close to the tip and advance approximately 10cm. **CAUTION:** Do not grasp the catheter tightly with forceps.



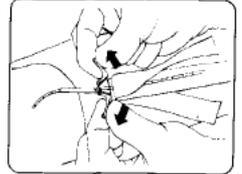
⑤ **Withdraw the Introducer**

- Maintain the catheter position by applying digital pressure to the vein above the introducer. Withdraw the introducer from the vein and away from the site.

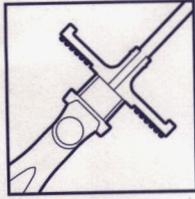


⑥ **Split and Peel the Introducer**

- Grasp the wings, bend them up and down and peel the introducer apart. Use care to maintain catheter position.



73



REF 384091

**BD Introsyte™
Autoguard™**
Shielded Introducer

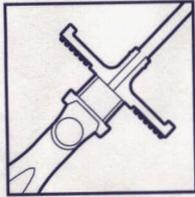
Radiopaque, Nonpyrogenic
Becton Dickinson Infusion Therapy Systems Inc.
Sandy, Utah 84070
Made in USA. D13412A (5-00)

3 Fr.

Sheath:
OD. 1.5 mm
ID. 1.1 mm
Length 3.2 cm

STERILE EO
Ⓢ ⚠

2004-07
107281
Ⓢ **LOT**



REF 384092

**BD Introsyte™
Autoguard™**
Shielded Introducer

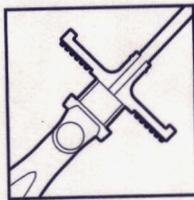
Radiopaque, Nonpyrogenic
Becton Dickinson Infusion Therapy Systems Inc.
Sandy, Utah 84070
Made in USA. D13413A (5-00)

4 Fr.

Sheath:
OD. 1.9 mm
ID. 1.5 mm
Length 3.2 cm

STERILE EO
Ⓢ ⚠

2004-06
107282
Ⓢ **LOT**



REF 384093

**BD Introsyte™
Autoguard™**
Shielded Introducer

Radiopaque, Nonpyrogenic
Becton Dickinson Infusion Therapy Systems Inc.
Sandy, Utah 84070
Made in USA. D13414A (5-00)

5 Fr.

Sheath:
OD. 2.3 mm
ID. 1.8 mm
Length 3.2 cm

STERILE EO
Ⓢ ⚠

2004-07
107283
Ⓢ **LOT**

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

75

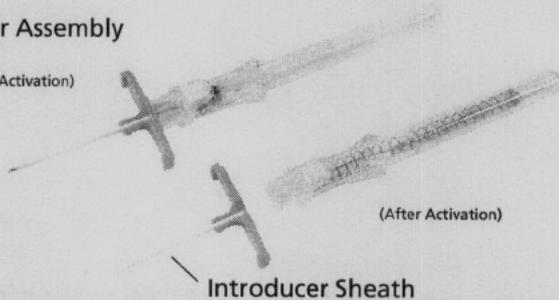
000048

BD Introsyte™ Autoguard™

Shielded Introducer for PICC and Midline Catheters

Introducer Assembly

(Before Activation)



(After Activation)

Introducer Sheath

POINTS TO PRACTICE

1 PREPARATION

- Holding onto the wings, remove cover in a straight manner

2 VENIPUNCTURE

- Perform venipuncture using a low angle
- Observe flashback behind activation button
- Lower insertion angle and proceed slightly to ensure both the needle and cannula are in the vessel
- Thread introducer sheath at least 1/8 inch off the needle into the vessel

3 RETRACT NEEDLE FROM INTRODUCER SHEATH

- Release tourniquet
- Support introducer to avoid displacement
- Apply digital pressure above the introducer to minimize blood flow
- Press the white activation button and the needle will retract into the shielded barrel
- Dispose of the shielded needle in an appropriate sharps container

4 INSERT CATHETER

- Grasp the catheter close to the distal tip and begin advancing through the opening in the introducer sheath

5 WITHDRAW INTRODUCER SHEATH

- Withdraw the introducer sheath after the catheter has been inserted at least 10 cms
- Stabilize the catheter by applying digital pressure above the introducer sheath
- Withdraw the introducer sheath from the vein and away from the site

6 SPLIT INTRODUCER SHEATH AND PEEL-AWAY

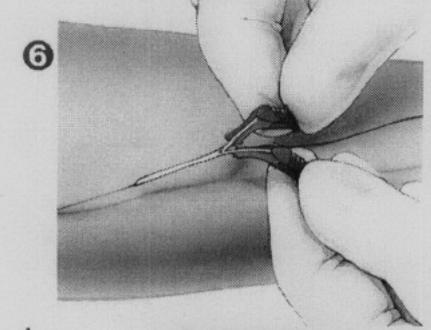
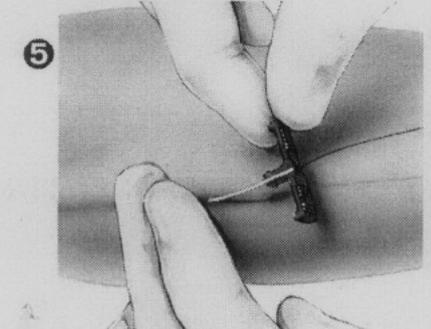
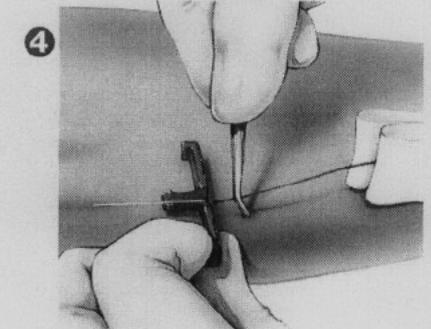
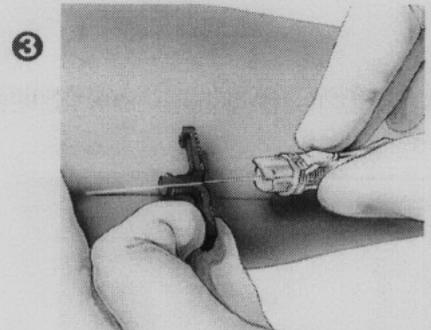
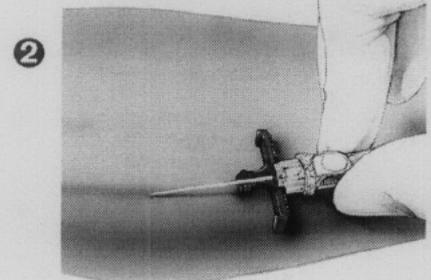
- Rock introducer sheath wings back and forth and split
- Peel introducer sheath away from catheter using care to maintain catheter position

TIPS FOR SUCCESS

- KEEP FINGERS AWAY FROM ACTIVATION BUTTON
- Low insertion angle
- Make sure introducer sheath is at least 1/8 inch off the needle prior to button activation
- Digital pressure above introducer sheath tip
- Observe for flashback behind activation button
- Have catheter ready for insertion prior to button activation

CAUTION REMINDERS

- Do not recannulate
- Do not place excessive pressure on introducer sheath
- Always retract needle prior to withdrawal from the introducer sheath
- Always handle all sharps with caution. Place all shielded and unshielded needles in appropriate sharps container
- Report all needle stick injuries and follow established protocols



BD Medical Systems, Sandy, Utah 84070
1.888.237.2762, www.bd.com/infusion

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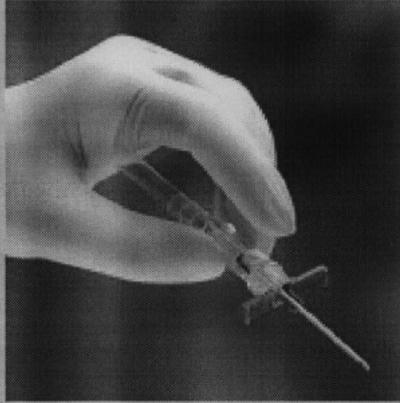
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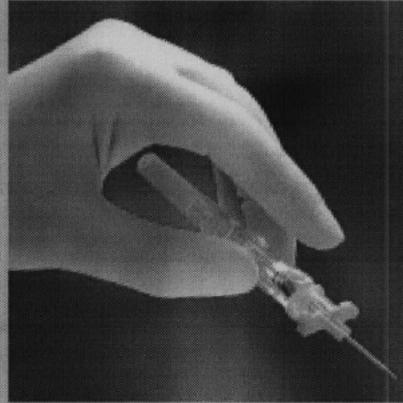


Finding REAL Solutions

Infusion Therapy



**BD Introsyte™
Autoguard™ Shielded
Introducer for PICCs and
Midlines**



**BD Introsyte-N™
Autoguard™ Shielded
Introducer for
Neonatal PICCs**

BD Safety Products Ordering Information

BD Introsyte Autoguard Shielded Introducer

Cat. #	Description	Packaging
384091	20G (3 FR x 3.2 cm), Teal	10/Case
384092	18G (4 FR x 3.2 cm), Magenta	10/Case
384093	16G (5 FR x 3.2 cm), Violet	10/Case

BD Introsyte-N Autoguard Shielded Introducer

Cat. #	Description	Packaging
384090	24G (1.9 FR x 1.9 cm), Yellow	10/Case



77

1 Becton Drive
Franklin Lakes, NJ 07417

For more information, call 1.888.237.2762, press Prompt #1 or visit our website at www.bd.com

000050



Indispensable to
human health

BD Introsyte™ Autoguard™ BD Introsyte™-N Autoguard™

Shielded Introducers for PICC and Midline Catheters

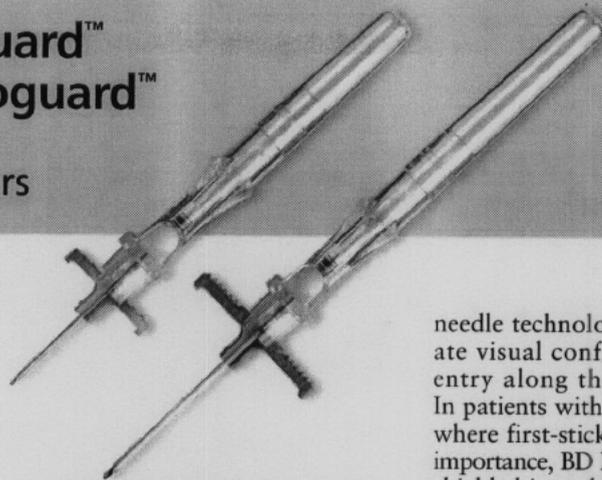
● Familiar by design

78

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BD Introsyte™ Autoguard™ BD Introsyte™-N Autoguard™

Shielded Introducers for PICC and Midline Catheters



Clinically proven to effectively reduce needlestick injuries.

The proven effectiveness of BD Autoguard shielding technology is now available in BD Introsyte™ Autoguard™ shielded introducers for PICC and Midline insertions.

BD Introsyte Autoguard shielded introducers mean greater safety for you. The patented BD Autoguard shielding technology is proven to safeguard healthcare workers from accidental needlestick injuries.

"...the safety IV catheter (Insyte Autoguard) resulted in a marked and significant reduction in IV stylet-related injuries..." *

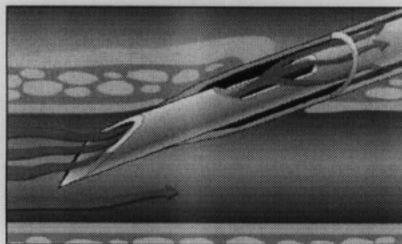
Superior insertion characteristics.

Through leveraging proprietary BD technologies, including plastic canula tipping, needle fabrication and lubrication systems, the BD Introsyte Autoguard family of introducers have shown insertion characteristics

similar to that of the popular BD Insyte™ IV catheter, and substantially better than the other market-leading splitable sheath introducer.**

Designed specifically for neonates.

BD Introsyte™-N Autoguard™ shielded introducers are designed especially for neonates. The unique BD notched-



needle technology assures immediate visual confirmation of vessel entry along the catheter shaft. In patients with compromised veins where first-stick success is of special importance, BD Introsyte-N Autoguard shielded introducers provide added confidence in vascular access.

Familiar by design.

BD Introsyte Autoguard shielded introducers combine the proven shielding technology of the BD Autoguard family of peripheral IV catheters with the name you trust in conventional introducers, BD Introsyte precision introducers.

BD Introsyte Autoguard shielded introducers. One more choice of effective safety-engineered devices from BD, designed with your safety in mind.

Ordering Information

BD Introsyte Autoguard shielded introducers

Catalog #	Description	Needle	Sheath	Product Compatibility
384091	20 ga (3 FR) x 3.2 cm	19 ga	17 ga	20 ga (2.6-3.0 FR) PICC and midline catheters
384092	18 ga (4 FR) x 3.2 cm	17 ga	15 ga	18 ga (3.5-4.0 FR) PICC and midline catheters
384093	16 ga (5 FR) x 3.2 cm	15 ga	14 ga	16 ga (5 FR) PICC and midline catheters

BD Introsyte-N Autoguard shielded introducers

Catalog #	Description	Needle	Sheath	Product Compatibility
384090	24 ga. (1.9 FR) x 1.9 cm	21 ga	19 ga	24 ga (1.9-2.0 FR) PICC catheters

Shipping case contains 10 introducers



* Mendelson MH, Chen LBY, Finkelstein LE, Bailey E, Kogan G, Mt Sinai Medical Center, New York, NY. "Preliminary Evaluation of a Safety IV Catheter (Insyte Autoguard, Becton Dickinson) Using the Centers for Disease Control and Prevention (CDC) National Surveillance System for Hospital Healthcare Workers Database. Abstr. Centers for Disease Control and Prevention - 4th Decennial International Conference on Nosocomial and Healthcare-Associated Infections. March 2000.

**Laboratory testing on file at BD.

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Sandy, Utah 84070
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www.bd.com/infusion

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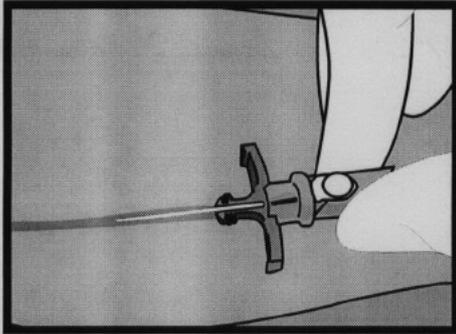


Indispensable to human health

BD Introsyte™ Autoguard™ and BD Introsyte™-N Autoguard™ Shielded Introducers

QUICK REFERENCE CARD

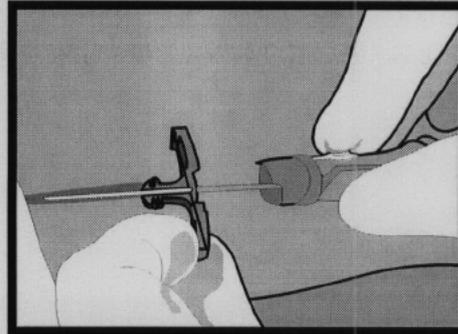
1



Venipuncture

- Perform venipuncture using a low angle
- Observe flashback behind activation button
- Lower insertion angle and proceed slightly to ensure both the needle and sheath are in the vessel
- Thread introducer sheath at least 1/8 inch off the needle into the vessel

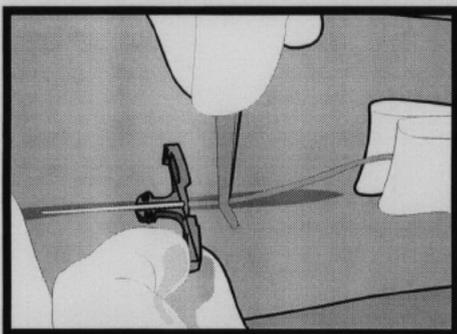
2



Retract Needle

- Release tourniquet
- Support Introducer to avoid displacement
- Apply digital pressure above the introducer to minimize blood flow
- Press the white activation button and the needle will retract into the shielded barrel
- Dispose of the shielded needle in an appropriate sharps container

3



Insert Catheter

- Grasp the catheter close to the distal tip and begin advancing it through the opening in the introducer sheath

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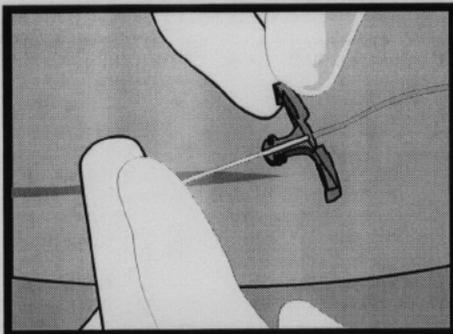
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BD Introsyte™ Autoguard™ and BD Introsyte™-N Autoguard™ Shielded Introducers

QUICK REFERENCE CARD

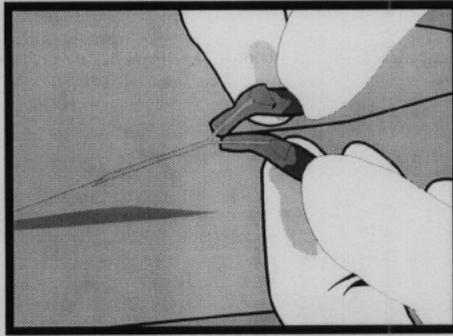
4



Withdraw Introducer

- Withdraw the introducer sheath after the catheter has been inserted at least 10cms
- Stabilize the catheter by applying digital pressure above the introducer sheath
- Withdraw the introducer sheath from the vein and away from the site

5



Split Introducer Sheath and Peel Away

- Rock introducer sheath wings back and forth and split
- Peel introducer sheath away from catheter using care to maintain catheter position

Things to Remember:

- KEEP FINGERS AWAY FROM ACTIVATION BUTTON
- Low insertion angle
- Make sure introducer sheath is at least 1/8 inch off the needle prior to button activation
- Digital pressure above introducer sheath tip
- Observe for flashback behind activation button
- Have catheter ready for insertion prior to button activation
- Do not recannulate
- Do not place excessive pressure on introducer sheath.
- Always retract needle prior to withdrawal from the introducer sheath
- Always handle all sharps with caution. Place all shielded and unshielded needles in appropriate sharps container
- Report all needlestick injuries and follow established protocols

81

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K013304

BD Medical Systems
9450 South State Street
Sandy, Utah 84070
tel: 801.565.2300
fax: 801.565.2740
www.bd.com

JAN 02 2002



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human health

**Premarket Notification [510(k)] Summary of Safety and Effectiveness for
BD Introsyte™ Precision Introducer and BD Introsyte™ Autoguard™
Shielded Introducer**

Submitter: Becton Dickinson Infusion Therapy Systems Inc.
Address: 9450 South State Street
Sandy, UT 84070
Contact Person: Leslie Wood, Manager, Regulatory Affairs
Telephone Number: (801) 565-2504
FAX Number: (801) 565-2749
Date Summary Prepared: September 27, 2001
Trade Names: BD Introsyte™ Precision Introducer
BD Introsyte™ Autoguard™ Shielded Introducer
Common Name: Introducer Catheter
Classification Name: Introducer Catheter
Predicate Devices: Same as trade names listed above.

Product Descriptions:

The products identified in this 510(k) notification are splittable, polyethylene introducer catheters. The BD Introsyte™ Autoguard™ Shielded Introducer includes a needle-shielding feature that the BD Introsyte™ Precision Introducer does not include. Autoguard products incorporate spring-activated needle-shielding technology. The Autoguard component incorporates a cylindrical needle-shielding barrel, a spring, a needle hub with flash chamber and hydrophobic flow control plug, and a needle. The user-activated Autoguard™ product has a button, which the user pushes to initiate the needle's retraction into the needle-shielding barrel.

The Introsyte introducers are available in sizes ranging from 14 to 24 gauge.

82

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Intended Use:

An introducer catheter is used to facilitate the placement of devices such as guide wires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Technological Characteristics Comparison:

The catheter design and technological characteristics have not changed. The lubrication systems used have been modified to make the manufacturing process 'ozone friendly.'

Nonclinical Tests Support Substantial Equivalence:

Side-by-side testing of modified and unmodified devices was conducted to compare product attributes.

Conclusions from Nonclinical Tests:

Data have been provided to demonstrate that product performance and biocompatibility are substantially equivalent between the modified and unmodified devices.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 02 2002

Ms. Leslie Wood
Manager, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070

Re: K013304
BD Introsyte™ Precision Introducer, BD Introsyte™ Autoguard™ Shielded Introducer
Regulation Number: 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: Class II
Product Code: DBY
Dated: October 3, 2001
Received: October 4, 2001

Dear Ms. Wood:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

24

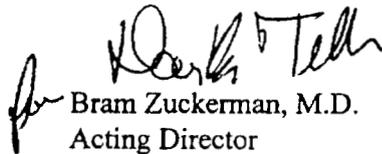
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Page 2 - Ms. Leslie Wood

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

75
000058

Becton Dickinson Infusion Therapy Systems Inc.
Sandy, UT 84070

INDICATIONS FOR USE

Device Name: BD Introsyte™ Precision Introducer
BD Introsyte™ Autoguard™ Shielded Introducer

To facilitate the placement of devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The Counter Use:
(per 21 CFR 801.109)


Division of Cardiovascular & Respiratory Devices
510(k) Number B013304

510(k) Lubrication System
Indications for Use 8/1/01

86
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Attachment V:
Performance Test Data

B. Braun Medical Inc.
510(k) Premarket Notification
Introcan Safety IV Catheter

87

000060

MEMO

DATE : 6-26-02

FROM : Shang W. Hwang, Ph.D., Pharmacologist, ICDG/DCRD, HFZ-450

SUBJECT : Document Number: K021094
Company Name: B. Braun Medical Inc
Contact: Patricia D. Wilson
Device Name: The Introcan® Safety™ IV Catheter

TO : THE RECORD

This 510K application was originally locked in to DDIGD, and the document was transferred to DCRD from DDIGD (memo attached).

Introcan Safety IV Catheter is currently marketed under the B. Braun Medical Inc. premarket notification K982805 as a passive anti-needle stick device to be placed in a peripheral vein for the infusion of fluids, drugs, and/or blood components. This submission expands the indications, to include use as an introducer catheter to facilitate the placement of Vascular Access devices.

The Introcan Safety IV Catheter consists of an over-the-needle catheter with a safety clip feature. Upon removal of the needle from the catheter, the safety clip is automatically secured over the needle tip as it exits the catheter hub. The Introcan Safety IV Catheter is currently available in sizes ranging from 14 Gauge through 24 Gauge with an exposed (useable) length of 25 mm to 45 mm. This submission expands the available sizes to include a length of up to 2-1/2 in. (64 mm). The Introcan Safety IV Catheter has the same materials, design, and method of construction as the currently marketed Introcan Safety IV Catheter cleared under the B. Braun Medical Inc. premarket notification K982805.

Testing was completed (b)(4)

(b)(4)

(b)(4)

Testing was also completed (b)(4)

(b)(4)

The indication for the Introcan Safety IV Catheter, for use as an introducer catheter, is the same indication previously cleared for the following two devices:

1. BD Introsyte™ Autoguard™ Shielded Introducer under the following Becton Dickinson Infusion Therapy Systems Inc. Premarket Notification: K013304.
2. Burrion Percutaneous Introducer Set and Burrion Central Vein Catheterization Kit under the following B. Braun Medical Inc. Premarket Notifications: K810460 and K810461.

Recommendation for Response:

x SE


Shang W. Hwang



PS.

ICDB Branch Chief, Ashley Boam re-checked the labeling of the device labeling and found that the labeling included the following statement:

(b)(4)



Shang W Hwang
Shang W. Hwang
June 26, 2002

*ABB
7/2/02*





Fax

To
Dr. Shang Hwang
FDA / CDRH

From
Patricia Wilson, Regulatory Affairs Specialist
B. Braun Medical Inc.

E-mail: patricia.wilson@bbmus.com

To Fax Number
(301) 480-4204

Fax
610-266-4962

Pages (Including cover)
3

Tel
610-266-0500 ext. 2280

Date
June 26, 2002

Dear Dr. Hwang,

A copy of revised labeling is attached. As you requested during our telephone conversation today,

(b)(4)

If you have any questions, or need any other information, please contact me at (610) 266-0500 x2280.

Sincerely,

Patricia Wilson
Regulatory Affairs Specialist
B. Braun Medical Inc.

This communication is CONFIDENTIAL information that is intended only for the use of the addressee named above. If the reader of this message is not the intended recipient or the employee/agent responsible for delivering the message to the intended recipient, please note that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please immediately notify us by telephone/fax and destroy the facsimile.

(b)(4)

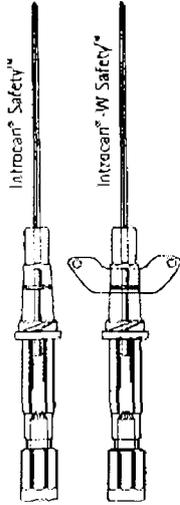
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

I.V. catheter designed to minimize inadvertent needlesticks, made of ETFE, radiopaque, with or without fixation wings, for single use only.

Introcan® Safety™ Introcan® -W Safety™

B | BRAUN

Manufactured for:
B. Braun Medical Inc.
Bethlehem, PA 18078



REV. 3/02

Instructions for use

Materials used
FEP, PP, ABS, chrome-nickel steel

Indications
Creation of a secure peripheral or central venous or arterial access with a passive anti-needlestick device. Blood transfusions or infusion of I.V. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration.

Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures. Intermittent blood sampling, especially from arterial sites.
Invasive (intra-arterial) measurement of arterial blood pressure.
Facilitate the placement of Vascular Access Devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Contraindications
Introcan® Safety™ should not be used in patients with known hypersensitivity to any of the materials employed.

Risks

This I. V. catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to avoid needlesticks. Universal precautions must be adhered to in accordance with Centers for Disease Control and Prevention / Occupational Safety and Health Administration (CDC/OSHA) standards for bloodborne pathogens, when starting or maintaining any I. V. catheter, to avoid the risk of exposure to contaminated blood. Depending on how long the cannula is left in situ, on the type and amount of infusions or injections administered, and on individual predisposition, thrombophlebitis may occur in the accessed vein; in arterial puncture, the artery may occlude in rare cases due to thrombotic or

embolic complications, resulting in ischaemia.

Duration of use

Change according to CDC Guidelines and / or Hospital or Institutional protocols. The puncture site should be checked at regular intervals. Introcan® Safety™ should be removed in the event of local or systemic signs of infection.

Warning

- After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.
- Always clearly mark arterial lines to avoid inadvertent injection. Verify adequate collateral circulation prior to arterial puncture.
- Use only if packaging is intact.

Storage

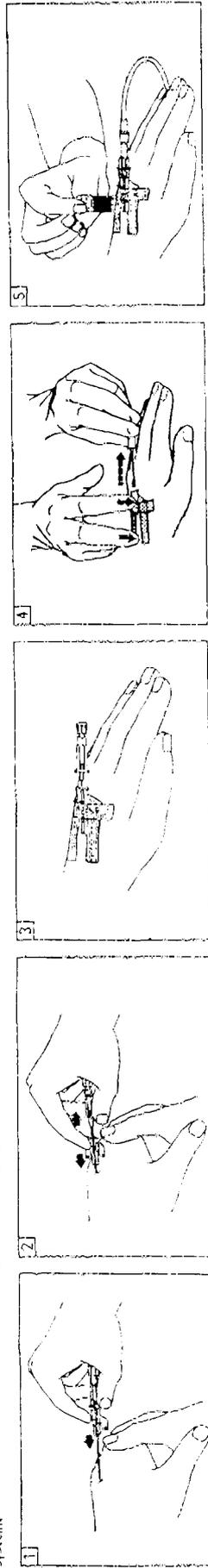
Store at room temperature. Protect from extreme heat and freezing.

Application

- 1 After disinfection of the puncture site, and removal of the protective cap, puncture a suitable vein. If venipuncture was successful, blood will immediately be visible inside the transparent grip part.
- 2 Advance the catheter further into the vein. While slightly withdrawing the steel needle, use adhesive tape to secure catheter to the skin. The steel needle still in situ minimizes spillage of blood.
- 3 Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub. Dispose of needle immediately into sharps container.
- 4 If used as an indwelling IV catheter connect to infusion line and cover puncture site

Rx only

with a sterile dressing, if used to facilitate the placement of a Vascular Access Device follow manufacturer's instructions for use of the specific device being placed.



For a complete only Do not re-use

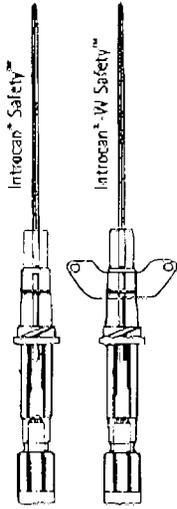
See instructions leaflet

For lot number

STERILE

Exp. Expiration date

I.V. catheter designed to minimize inadvertent needlesticks, made of Polyurethane, radiopaque, with or without fixation wings. For single use only.



REV. 3/02

Introcan® Safety™ Introcan®-W Safety™

B | BRAUN

Manufactured for:
B. Braun Medical Inc.
Bethlehem, PA 18018

Instructions for use

Materials used
Polyurethane, PP, ABS, chrome-nickel steel

Indications
Creation of a secure, peripheral or central venous access with a passive anti-needlestick device. Blood transfusions or infusion of I.V. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration.
Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures.
Facilitate the placement of Vascular Access Devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Contraindications
Introcan® Safety™ should not be used in patients with known hypersensitivity to any of the materials employed.

Risks
This I.V. catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to avoid needlesticks. Universal precautions must be adhered to in accordance with Centers for Disease Control and Prevention / Occupational Safety and Health Administration (CDC/OSHA) standards for bloodborne pathogens, when starting or maintaining any I.V. catheter, to avoid the risk of exposure to contaminated blood. Depending on how long the cannula is left in situ, on the type and amount of infusions or injections administered, and on individual predisposition, thrombophlebitis may occur in the accessed vein.

Duration of use
Change according to CDC Guidelines and / or Hospital or Institutional protocols. The puncture site should be checked at regular intervals. Introcan® Safety™ should be removed in the event of local or systemic signs of infection.

Warning

- After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.
- Use only if packaging is intact.

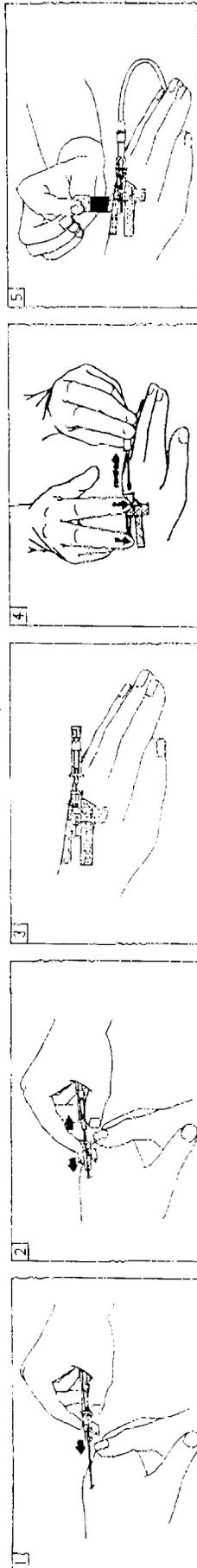
Storage
Store at room temperature. Protect from extreme heat and freezing.

Application

- After disinfection of the puncture site and removal of the protective cap, puncture a suitable vein. If venipuncture was successful, blood will immediately be visible inside the transparent grip part.

- If used as an indwelling IV catheter connect to infusion line and cover puncture site with a sterile dressing. If used to facilitate the placement of a Vascular Access Device follow manufacturer's instructions for use of the specific device being placed.
- Advance the catheter further into the vein, while slightly withdrawing the steel needle. For peripheral access use adhesive tape to secure catheter to the skin. The steel needle still in situ minimizes spillage of blood.
- Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub. Dispose of needle immediately into sharps container.

Rx Only



For single use only. Do not reuse. See instruction leaflet. Exp. - Expiration date.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 021094

REVIEWER: SWH DIVISION/BRANCH: DCRD/ICDG

TRADE NAME: The Introcan® Safety™ IV Catheter

PRODUCT TO WHICH COMPARED (510(k) NUMBER IF KNOWN):
 The currently marketed Introcan® Safety™ IV Catheter (K982805)

YES NO			
1.	Is Product A Device	x	If NO = Stop
2.	Is Device Subject To 510(k)?	x	If NO = Stop
3.	Same Indication Statement?	x	If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NE
5.	Same Technological Characteristics?	x	If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?	x	If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?		If YES = Stop NE
9.	Accepted Scientific Methods Exist?		If NO = Stop NE
10.	Performance Data Available?		If NO = Request Data
11.	Data Demonstrate Equivalence?		Final Decision:

INTEROFFICE MEMORANDUM

TO: THE RECORD
FROM: BRENDA J. BOLDEN, BIOLOGIST
SUBJECT: B.BRAUN INTROCAN® SAFETY IV CATHETER, K021094
DATE: APRIL 8, 2002

In the MOU regarding the lead division for reviewing introducers, embolization devices and delivery catheters, it was determined that DCRD will take the lead for introducers, for both general and specific cardiovascular indications. DDIGD will take the lead for catheters with general indications.

The current B.Braun device has an expanded indication beyond the previous 510(k), K982905 (a passive anti-needle stick device to be placed in a peripheral vein for the infusion of fluids, drugs, and/or blood components (see enclosure). The revised indication expands the above indication to include use as an introducer catheter. The expanded indication includes a statement "or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system. Also, the available sizes were increased to include a length of up to 2-1/2inches.

* B.Braun indicated in a statement that the materials, construction, design, and safety clip feature are the same as in the K982805 original device. If it's determined that changes were made to the safety feature, we will review any changes in a consult review. *

B.Braun indicated that the expanded indications are the same as in a BD device, K013304 reviewed under procode DBY as a catheter introducer (see enclosure). We believe with the expanded indication that DCRD should take the lead on the review. If needed, we will be happy to do a consult review.

Brenda Bolden
Brenda Bolden

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Chief G.H.D.B.

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K021094

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

- * - May not be applicable for Special 510(k)s.
- ** - Required for Class III devices, only.
- *** - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
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.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that 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. This statement is signed by the individual responsible for those particular activities.		

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Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: _____

Concurrence by Review Branch: Ashley Boam for CDB 6/26/02

Date: APR 8

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		
5. Is the product a device?	✓	✓
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?	✓	-
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓ ✓

Memorandum

m: Reviewer(s) - Name(s) Shang W Huang

Subject: 510(k) Number K0210914

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
 (required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

04B II 870.1340

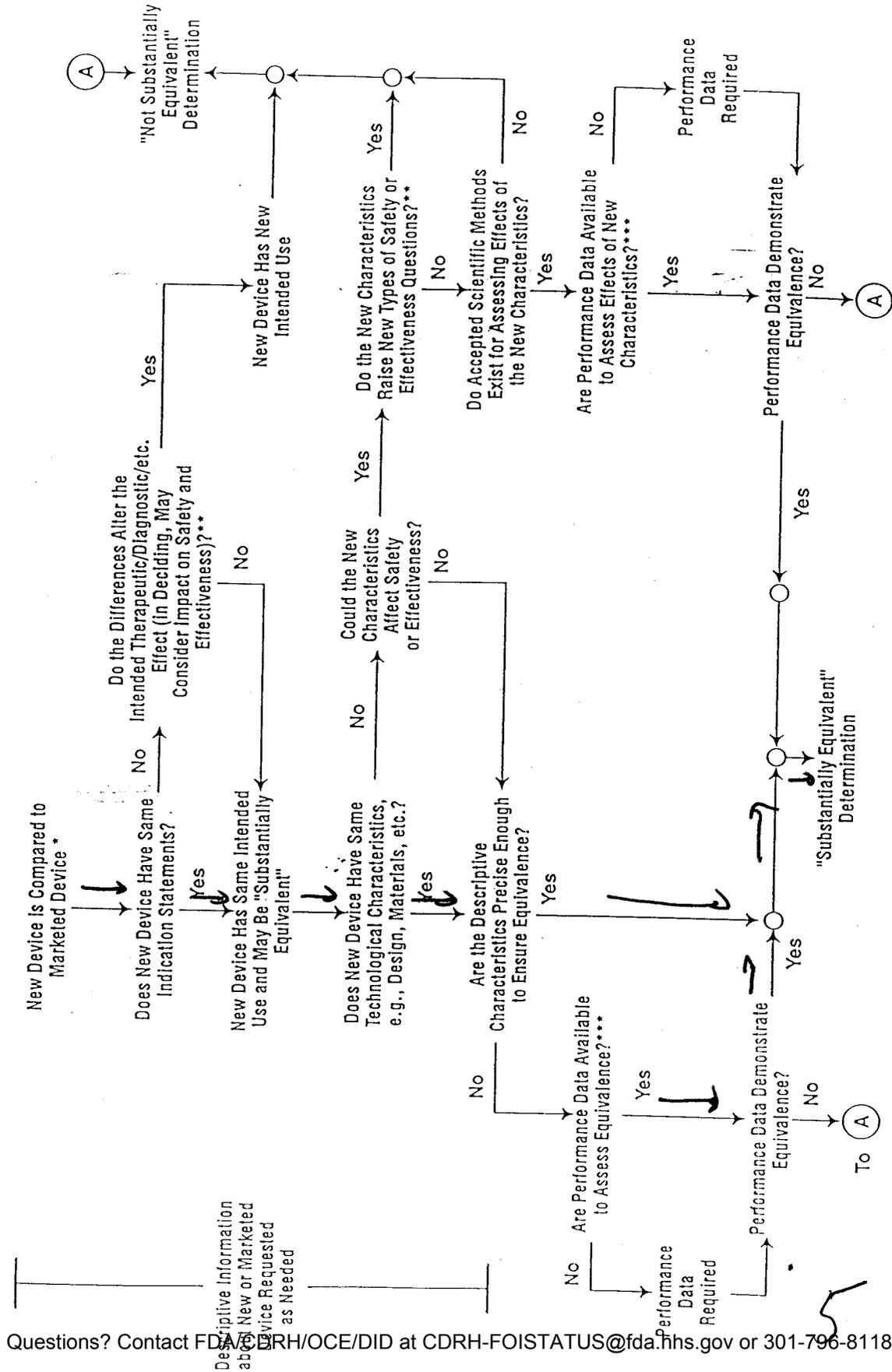
Review: Asheley B. Brown ICDB 7/2/02
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] [Signature] 7/3/02
 (Division Director) (Date)

Revised: 8/17/99

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510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.
 *** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.