Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K970864 - 593 pages
COMPANY:	ARROW INTL., INC. (ARROW)
PRODUCT:	CATHETER,INTRAVASCULAR,THERAPEUTIC,SHORT-TERM LESS THAN 30 DAYS (FOZ)
SUMMARY:	Product: ARROW-HOWES LARGE BORE MULTI-LUMEN CENTRAL VENOUS CATHETERS
DATE REQUESTED:	Jun 27, 2016
DATE PRINTED:	Jun 27, 2016

Note: Printed

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

K970864

OCT 17 1997

510(k) SUMMARY - K970864

Submitter:

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605

Contact Person: Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
610/478-3137

Date summary prepared - 10/16/97

Device:

Trade Name - Arrow-Howes™ Large Bore Multi-lumen central venous catheter

Common Name - Central venous catheter

Classification Name - Catheter, intravascular, 80FOZ, and 21 CFR 880.5200, Intravascular catheter

Legally marketed device to which the device is substantially equivalent:

Various Arrow central venous catheters; specifically K820648, K844080, K862056, and K895417

Description of device:

The device is a triple-lumen polyurethane catheter, 12 French in size, with three extension lines, luer hubs, and clamps. It is essentially the same in appearance and function to the Arrow multi-lumen predicate catheters except for the larger size to accommodate rapid fluid administration in emergency critical care situations in the hospital.

Intended use of the device:

The intended use and indications for use are comparable to the predicate devices, and appear below:

"Indications for use:
The large-bore multiple lumen catheter permits venous access to a central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, and femoral veins. The heparin coating on the catheter intended to decrease the incidence of thrombous formation associated with catheterization."

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Technological characteristics:

The device has the same exact technological characteristics as the predicates, with the only difference being the larger size and accompanying greater fluid flow rates.

The performance tests included in the submission include:

1. Flow rate
2. Tensile test
3. Pressure leak test
4. Positive pressure burst test
5. Biocompatibility tests
6. Flex (fatigue) test

No clinical testing was performed.

The results of the laboratory tests demonstrated that the device is safe, and as effective as the legally marketed predicate devices.

97095

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs and
Quality Assurance
Arrow International, Incorporated
3000 Bernville Road
Reading, Pennsylvania 19605

OCT 17 1997

Re: K970864
Trade Name: Arrow-Howes Large Bore Multi-Lumen Central Venous Catheters
Regulatory Class: II
Product Code: FOZ
Dated: July 21, 1997
Received: July 22, 1997

Dear Mr. Nickel:

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 (Premarket 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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

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not affect any obligation you might have under sections 531 through 542 of 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) 594-4618. 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

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

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P.O. Box 12888
Reading, PA 19612

ARROW
INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

K 970864: Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheters

Section 11 - Indications

The large bore multiple lumen catheter permits venous access to a central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, or femoral veins. The heparin coating on the catheter intended to decrease the incidence of thrombus formation associated with catheterization.

97021

X Prescription Use

Viola Hilliard for Catherine Cricenti
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970864

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

K970864/A

Certified Mail

P.O. Box 12888
Reading, PA 19612

DUPLICATE

ARROW INTERNATIONAL

2400 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

July 23, 1997

Center for Devices and Radiological Health
Document Mail Room HFZ-401
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RECEIVED
25 JUL 97 11 12
FDA/CDRH/OCE/DID

Re: 510(k) Premarket Notification K970864
Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheters
- Request for additional information of 7/2/97

Dear Mr. Burdick:

Pursuant to our phone discussion of July 2, 1997, we are providing the following additional information you requested.

Item 1

You voiced concerns about the potential for the inner lumen walls to crack during application of stress or pressure during use, which could go unnoticed by the user since the fracture could be invisible to observation of the exterior surface of the catheter. You were interested in how we could tell if the inner lumen fails prior to the external wall of the catheter.

Response

I discussed your concerns with the project engineer responsible for the 12 French 3-lumen central venous catheter product line, and his discussion is appended as Attachment 1.

In addition to his document, it should be noted that in practice we cannot recall ever having received a product complaint of an interlumen leak of a multi-lumen central venous catheter which was due to a defect in the lumen wall. We have had only rare reports of interlumen communication which, upon examination of the returned sample, have been found to be due to a juncture hub insert molding defect. We pressure test each multi-lumen catheter we manufacture for blocked lumens and interlumen leaks utilizing a calibrated automatic pressure decay tester. We have been making multi-lumen central venous catheters since 1982, which includes extrusion of the polyurethane catheter body and extension lines, and insert molding of the extension line hubs and juncture hub, and interlumen catheter failures for anything other than juncture hub molding defects have not been encountered.

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

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Item 2

You asked for information regarding interaction of drugs such as TPN, chemotherapy, and pain management with the Heparin coating in the lumen of the catheter.

Response

A discussion of this subject appears in Attachment 2.

Item 3

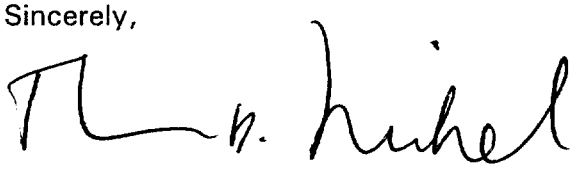
You asked that our indications statement be revised to remove the reference to femoral veins, or provide information why we want to retain it.

Response

While use of femoral veins was in disfavor at one time due to reported high infection rates associated with urine and fecal contamination, current critical care texts indicate it is considered relatively safe, and appropriate if other sites have failed, e.g. during resuscitation.

Extracts from two reference texts are appended as Attachment 3, with the appropriate discussions tabbed.

Sincerely,



Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

7050a

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ATTACHMENT 1

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

INTERNAL MEMO

ARROW
INTERNATIONAL, INC.

To: Tom Nickel

From: Paul Robertson P.R. 7/22/97

Date: July 22, 1997

Subject: 12 Fr. 3-L distal (central) lumen

I have completed the analysis of the central lumen of the 12 Fr. 3-lumen catheters and have concluded that your concern with the central lumen breaching, allowing inter-lumenal communication, is minimal. I base my conclusion on the following four points of discussion:

1. The central lumens of a ten catheter sample of two catheter types were tested at 50 psig for 60 seconds to verify that this lumen does not leak. Ten out of ten catheters of both catheter types passed as documented in *510(k) Premarket Notification K970864 - Request for additional information, Arrow-Howes Large Bore Multi-lumen Central Venous Catheters* dated May 1, 1997.
2. The central lumens of a ten catheter sample of two catheter types were tested for positive burst pressure. The central lumens of each catheter type did not fail, rather the extension lines failed at an average of 356 psig and 409 psig. This test is documented in *510(k) Premarket Notification K970864 - Request for additional information, Arrow-Howes Large Bore Multi-lumen Central Venous Catheters* dated May 1, 1997.
3. In addition to the static pressure tests (1. and 2.), I performed a dynamic fatigue test which documents the fatigue strength of the central lumen as compared to one of the larger outer lumens. The results indicate that the central lumen of both catheter versions endured more cycles than the outer lumens. These results are not surprising since flexural stresses are higher at the outer fibers (the outer edges) of a test specimen than the inner fibers. That is, the highest stress on the catheters in flexure occur furthest from the catheters' cross-sectional centers. This maximum stress is due to the higher strain (the stretching and compression) of these outer fibers. In theory, the stress at the very center of any specimen is zero and increases proportionally with the distance away from the center. The flexure formula for maximum stress is provided here for reference and is as follows:

(b) (4)

[redacted]

A more detailed test report is attached to this memo (pages 2-18) which includes the procedure, results, and raw data.

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

4. All lumens of all (100%) of the 12 French triple-lumen catheters are leaked tested at 15 psig as a routine manufacturing process. This detects and eliminates catheters that have manufacturing defects that cause inter-lumenal communication.

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Flex (Fatigue) Test—a Comparison of the Central and Outer Lumens of the 12 Fr. 3-Lumen Catheter
supplement to
510(k) Premarket Notification K970864
Arrow-Howes Large Bore Multi-lumen Central Venous Catheters

Scope

This test was performed to compare the flexural (fatigue) strength of the central (distal) lumen and the outer (medial or proximal) lumen of the 12 Fr. 3-L CVC. The medial lumen was used to represent the two outer lumens. This test is designed to record the number of flexures a lumen can endure before failure, where a failure is defined as a breach in the test lumen whereby fluids can cross-over to the other lumens (i.e. an internal, hidden breach) or fluids can leak to the atmosphere (i.e. an external breach).

Procedure

The procedure used was a modification to Arrow procedure AML-060, *Flex (Fatigue) Test*. AML-060 and *Modification to Protocol AML-060* is attached as pages 3-6.

To summarize, the flex test equipment was [redacted] (b) (4) [redacted]. The system was designed so that the motor that drives the flexing will stop when there is a sudden drop in pressure as detected by the pressure transducer. Any breach in the lumen is detected by way of a pressure drop from 15 psig to zero psig in the system which triggers the pressure transducer to stop the motor. The system counts the number of cycles by utilizing a digital counter and a proximity switch attached to the motor drive.

Results

The results of this flex test is summarized in the table below:

Specification	12 Fr., 3-L CVC, standard durometer, **central lumen**	12 Fr., 3-L CVC, standard durometer, **medial lumen**	12 Fr., 3-L CVC, firm durometer, **central lumen**	12 Fr., 3-L CVC, firm durometer, **medial lumen**	sample size
catheter lumen breach due to flexural fatigue	15,724 average cycles to failure	9,541 average cycles to failure	8,356 average cycles to failure	8,225 average cycles to failure	8

Raw data is attached as pages 7-19.

Conclusion

The results indicate that the central lumen of both catheter versions endured more cycles than the outer lumens. These results are not surprising since flexural stresses are higher at the outer fibers (the outer edges) of a test specimen than the inner fibers.

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

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ARROW INTERNATIONAL, INC.
FLEX (FATIGUE) TEST

UNCONTROLLED COPY IS

1. PURPOSE

To document the test method used to flex test catheters or extrusions.

2. SCOPE

This procedure applies to catheters or extrusions being flex (fatigue) tested.

3. RESPONSIBILITIES

(b) (4)

[redacted]

4. REQUIREMENTS DOCUMENTS

CP-4.4 "Design Control"
AMLF-027 "Flex (Fatigue) Test Results/Report"

5. PROCEDURE

5.1. (b)(4) Testing

5.2.

[redacted]

5.3.

5.4.

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(b)(4) Testing

[redacted]

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

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(b)(4) Testing

[redacted]

6. APPROVALS

Senior Materials Lab Technician Date

Senior Research Engineer Date

VP, RA/QA Date

PRINTED COPY UNCONTROLLED

7. REVISION HISTORY

Revision	Change	Approved by:
0 4/29/97	Original issue	T. Rarick, R. Citron, T. Nickel

8. HARD COPY DISTRIBUTION

J. Cadd - original

9. NOTIFICATION

R. Citron J. Guan	T. Rarick

I:/qsdocs/corp/cp404

page 5

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

8

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Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

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LAB REQUEST

Lab Request No.
7413

1. **Service Requested** (Only One Request Per Sheet):

   Flex (fatigue) test – medial lumen of 12 Fr. 3-L CVC

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: MC-12123-001B
   Lot Nos:
   Description: 12 Fr. 3-L CVC, standard durometer

4. **Target Date**: 7/18/97

5. **Additional Comments:**
   See attached modification to protocol AML-060. Test eight catheters to medial lumen failure.

Requestor: P. Robertson
Signature: P. Robertson 7/15/97
Date: 7/15/97

page 7

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

11

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-12123-001B
Lot No.:
Description: 12 FR x 16cm; 3-LUMEN CVC SOFT DUROMETER (MEDIAL LO
Lab Request No.: 7413
Included Angle:
Number of Cycles: Batch Setting:

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes No	Location of Failure
1	(b)(4) Testing [redacted]		
2			
3			
4			
5			
6			
7			
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: Approval:

Date: 7-21-97 Date: 7/22/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REQUEST

Lab Request No.
2414

1. **Service Requested** (Only One Request Per Sheet):

   Flex (fatigue) test – central lumen of 12 Fr. 3-L CVC

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos: _____
   Lot Nos: _____
   Description: _____

3. **Finished Product**

   Component Part Nos: MC-12123-001B
   Lot Nos: _____
   Description: 12 Fr. 3-L CVC, standard durometer

4. **Target Date**: 7/18/97

5. **Additional Comments:**
   See attached modification to protocol AML-060. Test eight catheters to central lumen failure.

Requestor: P. Robertson
Signature: P. Robertson 7/15/97
Date: 7/15/97

Questions? Contact CDRH/OCE/DISCDRH/OIS/ATIS@fda.hhs.gov or 301-796-8116

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-12123-001B
Lot No.:
Description: 12 fr x 16cm; 3-lumen CVC Soft Durometer (Dist/1)
Lab Request No.: 7414
Included Angle:
Number of Cycles: Batch Setting:

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
1	(b)(4) Testing [redacted]			
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4				
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7				
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: [signature] Approval: [signature]

Date: 7-21-97 Date: 7/22/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REQUEST

Lab Request No.
7416

1. **Service Requested** (Only One Request Per Sheet):

   Flex (fatigue) test – medial lumen of 12 Fr. 3-L CVC

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos: _____
   Lot Nos: _____
   Description: _____

3. **Finished Product**

   Component Part Nos: MC-35123-001A
   Lot Nos: _____
   Description: 12 Fr. 3-L CVC, firm durometer

4. **Target Date**: 7/18/97

5. **Additional Comments:**
   See attached modification to protocol AML-060. Test eight catheters to medial lumen failure.

Requestor: P. Robertson
Signature: P. Robertson 7/15/97
Date: 7/15/97

Questions? Contact FDA/CDRH/OCE/DIDSR at STATS@fda.hhs.gov or 301-796-5116

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Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-35123-001A
Lot No.:
Description: 12 FR, 3-Lumen CVC - Firm Durometer (MEDIAL LUMEN)
Lab Request No.: 7416
Included Angle:
Number of Cycles: Batch Setting:

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
1	(b)(4) Testing [redacted]			
2				
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4				
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: [signature] Approval: [signature]

Date: 7-21-97 Date: 7/22/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REQUEST

Lab Request No.
7415

1. **Service Requested** (Only One Request Per Sheet):

   Flex (fatigue) test – central lumen of 12 Fr. 3-L CVC

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: MC-35123-001A
   Lot Nos:
   Description: 12 Fr. 3-L CVC, firm durometer

4. **Target Date**: 7/18/97

5. **Additional Comments:**
   See attached modification to protocol AML-060. Test eight catheters to central lumen failure.

Requestor: P. Robertson
Signature: P. Robertson 7/15/97
Date: 7/15/97

Questions? Contact DAC/CDRH/OCE/DIDSP/CDRH4 GS TRACKS@fda.hhs.gov or 301-796-6116

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-35123-001A
Lot No.:
Description: 12 FR, 3-LUMEN CVC - FIRM DUROMETER (DISTAL LUMEN)
Lab Request No.: 7415
Included Angle:
Number of Cycles: **Batch Setting:**

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
1	(b)(4) Testing [redacted]			
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: [signature] **Approval:** [signature]

Date: 7-21-97 **Date:** 7/22/97

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

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ATTACHMENT 2

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

TO: Tom Nickel

FROM: Ronald Citron

DATE: July 18, 1997

SUBJECT: Response to FDA question on 510(K) **File #K-970864**

The FDA had a question concerning the interaction of a catheter inner lumen heparin coating with infused chemotherapeutic, TPN and pain management drugs.

The specific heparin coating that is applied to the Arrow catheters is the standard, FDA accepted heparin-benzalkonium chloride coating (referred to as HBAC). This particular coating has been used in the medical device industry for over 20 years. The second FDA accepted heparin coating is the tridodecylmethylammonium chloride-heparin coating (referred to as TDMAC). This latter coating has been applied to medical devices for over 30 years.

I have not been aware of any problems using either of these coatings. In addition, catheters have traditionally been coated on both the outer surface and inner lumens. In this way, blood that flashes back into the lumen and blood that is infused does not clot and block the lumen.

I did an extensive Internet search using the Excite, Infoseek, Yahoo and Alta Vista search engines. I employed the keywords of heparin, heparin coating, drug interaction, drug interactions, benzalkonium chloride. HBAC, drug incompatibility, TPN. I used these words in different combinations. I was unable to locate even one reference to drug complications relative to any type of heparin coating. I consider this lack of response as an indication that there have not been any reported or significant drug interactions with heparin coatings.

Furthermore, Arrow International, Inc., has not had any reported incidences of interactions or safety problems with any of the heparin-coated catheters sold since the process was first applied at Arrow 14 years ago.

When I developed the heparin coating process, I used only 25% of the active heparin level recommended by the manufacturer (b) (4) by using a dilution of the purchased heparin coating solution. During the original 510(K) process, I had contacted the FDA directly about the use of heparin for catheter coatings. I proceeded in accordance with the FDA recommendations. The FDA had informed me that using the heparin coating at the manufacturer's recommended level would be harmless to the patient, while affording the temporary surface thromboresistance characteristic of heparin. By proceeding with 25% of the manufacturer's recommendation, the system should be even safer for device applications. The coating process still employs the same heparin level discussed above.

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

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In light of the long history and broad-based usage of heparin coatings, the reduced level of heparin application used in the Arrow catheter, the absence of any reported field problems to Arrow, and the apparent lack of references relative to drug interactions and safety, Arrow International, Inc., continues to believe that the current heparin coating is completely safe.

Ronald Citron
Senior Research Scientist

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

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ATTACHMENT 3

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Critical Care

THIRD EDITION

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PUBLISHERS
Philadelphia • New York

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

24

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

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Compositor: Compset Inc.
Printer: Courier Book Company/Westford

Third Edition

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Library of Congress Cataloging-in-Publication Data

Critical care / [edited by] Joseph M. Civetta, Robert W. Taylor, Robert R. Kirby ; with 203 additional contributors.—3rd ed.
p. cm.
Includes bibliographical references and index.
ISBN 0-397-51527-8 (alk. paper)
1. Critical care medicine. I. Civetta, Joseph M. II. Taylor, Robert W. (Robert Wesley), 1949– . III. Kirby, Robert R.
[DNLM: 1. Critical Care. 2. Intensive Care Units. WX 218 C9334 1996]
RC86.7.C69 1996
616'.028—dc20
DNLM/DLC
for Library of Congress 96-15571
CIP

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The authors, editors, and publisher have exerted every effort to ensure that drug selection and dosage set forth in this text are in accordance with current recommendations and practice at the time of publication. However, in view of ongoing research, changes in government regulations, and the constant flow of information relating to drug therapy and drug reactions, the reader is urged to check the package insert for each drug for any change in indications and dosage and for added warnings and precautions. This is particularly important when the recommended agent is a new or infrequently employed drug.

Some drugs and medical devices presented in this publication have Food and Drug Administration (FDA) clearance for limited use in restricted research settings. It is the responsibility of the health care provider to ascertain the FDA status of each drug or device planned for use in their clinical practice.

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Contents

SECTION I 1

DECISION-MAKING

Chapter 1 3

How to Read a Medical Article and Understand Basic Statistics

Joseph M. Civetta
Theodore Colton

Critical Reading of the Medical Literature 4
Fundamentals of Biostatistics in Medical Research 9
Interpretation of Study Results 14
Coda 20

Chapter 2 21

Setting Objectives: Perspectives for Care

Orlando C. Kirton
Joseph M. Civetta

The Economic Issues: Is Economics King? 22
Selection of "Appropriate" Patients 22
Generic Goals of Intensive Care 23
Beneficence, Nonmaleficence, and Distributive Justice 24
Patient Autonomy 25
"Futility of Care" 25
The Family: Compassion and Avoiding Conflict 26
Immediate Objective: Examine Societal Values 27
Immediate Objective: Examine Bedside Care 29
Appendix 2-1: Advance Directive: Living Will 29
Appendix 2-2: Health Care Proxy Designation and Acceptance Form 31
Appendix 2-3: Durable Power of Attorney for Health Care and Health Care Surrogate Designation Form 32
Appendix 2-4: Affidavit 33

Chapter 3 35

Collaborative Care: Physician and Nursing Interactions

Danny Sleeman
Judith A. Hudson-Civetta
Joseph M. Civetta

The Surgeon Before the ICU 35
Members of the Team 35
Communications 36
Problems With Communication 37
Special Situations 37
Fellows' Function and Interrelationships 37
Functioning as a Team 39
Factors Contributing to Collaboration 40
Allocating Nursing Care 40
Nursing Care Functions 41
Allocation of Nursing Resources 41

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 4 — 49

Clinical Decision-Making

David V. Shatz
Joseph M. Civetta

Clinical Data as Scientific Variables 50
Cardiopulmonary Resuscitation and Do-Not-Resuscitate Orders 50
Elements of Clinical Care 52
The Influence of Time 55
First Vantage Point: Source of Admissions 55
Second Vantage Point: On ICU Admission 56
Third Vantage Point: Short-Term ICU Outcome 56
Fourth Vantage Point: Continued ICU Care 57
Fifth Vantage Point: Long-Term ICU Patients 58
Last Vantage Point: Discharge From Intensive Care 59

Chapter 5 — 63

Life and Death in the ICU: Ethical Considerations

Ernlé W. D. Young

Medical Ethics 63
The "Futility" Debate 73
Factors Compelling Treatment Even in the Likelihood of a Negative Outcome 74
Physician Aid-in-Dying 77

Chapter 6 — 81

Informed Consent and Refusal

Laurence B. McCullough

Key Considerations to Practice Informed Consent 81
When Patients Refuse Critical Care Intervention 84
Ethical Foundations of Informed Consent 85
Special Considerations 86

Chapter 7 — 89

Understanding Reactions of Patient and Family

George L. Wallace-Barnhill

Psychological Concepts 89
Staff Involvement With Families 91
The Patient in the ICU 92

Chapter 8 — 95

Iatrogenesis

Mark G. McKenney
Joseph M. Civetta

Type 1 Iatrogenesis: Incorrect Diagnosis 96
Type 2 Iatrogenesis: Therapy-Related 96
Type 3 Iatrogenesis: Procedure-Related 97
Type 4 Iatrogenesis: Laboratory Error 99
Type 5 Iatrogenesis: Decubitus Ulcer 100
Type 6 Iatrogenesis: Falls 101
Discussion and Legal Aspects 101

Chapter 9 — 105

Judicial Involvement in Treatment Decisions

Christopher Armstrong

The Beginnings of Court Involvement 106
A Consensus Emerges 107
Points on Which There Is No Consensus 114

Chapter 10 — 117

Important Legal Concepts in Critical Care

Baruch A. Brody

Informed Consent and the Refusal of Treatment 117
Levels of Care for Terminal Patients 119
Brain Death 122
Organ Transplantation 124

Chapter 11 — 127

Prediction and Definition of Outcome

Joseph M. Civetta

Cost Considerations 127
Definition of Outcome 128
Goals for Intensive Care 131
Descriptions of Quantitative Indices 134

Chapter 12 — 149

Resuscitation Outcomes

William H. Bickell
Matthew M. Rice

Immediate Concerns 149
Outcomes of Resuscitation 150

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

29

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Outcome After Out-of-Hospital Cardiac Arrest 150
Hospital Course of Patients Successfully Resuscitated From Out-of-Hospital Cardiac Arrest 154
Outcome After In-Hospital Cardiac Arrest 155
Neurologic Outcome After CPR 157
Termination of Resuscitation 157
On What Should the Decision to Terminate CPR Be Based? 158
Is Age a Factor to Be Considered in the Decision to Stop CPR? 159
Can the End-Tidal Carbon Dioxide Concentration or Coronary Perfusion Pressure Help Determine When to Stop CPR? 159
Should the Cost of Patient Care or the Postresuscitation Quality of Life Be Considered in the Decision to Stop CPR? 159
Who Should Decide to Terminate CPR? 159
Terminating Resuscitative Efforts Out-of-Hospital 160
Legal Implications of Terminating CPR 160
How Is It Possible to Determine Whether the Physician Is on Solid Legal Ground When Terminating CPR? 160
What Are the Considerations of Advance Directives and Family Interests in the Decision to Stop CPR? 161

Chapter 13 163

Quality Assessment and Improvement in the Adult Intensive Care Unit

Neil S. Yeston
Jamie Roche
Susan McCaffrey

Establishing a Program 164
A Quality Improvement Model for Surgical Critical Care 165
Risk Management 175
Critical Paths 175
The JCAHO Survey 176

SECTION II 187

ESSENTIAL PHYSIOLOGIC CONCERNS

Chapter 14 189

The Lungs and Their Function

Roger S. Mecca
Carlos A. Vaz Fragoso

Static Lung Volumes: Anatomic Considerations 189
Pulmonary Compliance 193
Airway Resistance 196
Gas Exchange 198
Ventilation-Perfusion Matching 199
Fluid and Protein Homeostasis 202
Central Control of Ventilation 204
Protective Functions 205
Metabolic Activity 205

Chapter 15 209

Respiratory Muscle Function and the Work of Breathing

Michael J. Banner

Immediate Concerns 209
Respiratory Muscles 210
Clinical Implications of Respiratory Muscle Loading 216
Decreasing Respiratory Muscle Afterload 219

Chapter 16 227

Cardiovascular System

Avner Sidi
Richard F. Davis

Cardiac Electrical Activity 227
Cardiac Contraction 231
Intrinsic Regulation of Cardiac Function 233
Characteristics of the Heart as a Pump 236
Ventricular Interaction 241
Ventricular Vascular Coupling 241
Neurogenic Control of the Cardiovascular System 242
Passive and Active Control of Systemic and Coronary Artery Size and Vasomotion 246
Metabolic Demand and Oxygen Supply of the Heart 247

Chapter 17 255

Acid–Base Chemistry and Physiology

Robert R. Kirby
Walter C. Bernards

Chemistry of Acids and Bases 255
Respiratory Derangements 257
Metabolic Derangements 257
Metabolic Compensation for Primary Respiratory Disturbances 258
Respiratory Compensation for Primary Metabolic Disturbances 259
Problem Solving 259
Metabolic Acidosis and Alkalosis 260
Respiratory Acidosis and Alkalosis 263

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 18 265

Coagulation

Robert I. Parker

Immediate Concerns 265
Physiology and Biochemistry of Primary Hemostasis 265
Physiology and Biochemistry of Secondary Hemostasis 267
Physiology and Biochemistry of Fibrinolysis 270
Coagulation as an Integrated System 272

Chapter 19 273

Central Nervous System Physiology

Christopher Veremakis
David H. Lindner

Immediate Concerns 273
Mechanisms of Brain Injury 274
Therapeutic Considerations During Brain Resuscitation 278
Specific Therapeutic Options in Brain Resuscitation 283

Chapter 20 291

The Host Response to Injury and Infection

Timothy H. Pohlman
Edward M. Boyle, Jr.

Reticuloendothelial System 292
Plasma Protein Defenses 296
Immunity 299

Chapter 21 303

Allergy and Immunology

R. Dwaine Rieves
Stewart J. Levine
James H. Shelhamer

Immediate Concerns 303
Overview 304
Antigen Recognition and Processing 304
Antigen Clearance 306
Antigen Clearance and Inflammation 308
Immune Defects and Critical Illness 308
Immunotherapy 311
Complications of Immunotherapy 313

Chapter 22 315

Pregnancy

Donald Caton

Pregnancy-Imposed Stress 315
Changes at Term 316
Coordination 318

SECTION III 323

MODULATING THE RESPONSE TO INJURY

Chapter 23 325

Metabolic Response to Injury and Critical Illness

Palmer Q. Bessey
Richard S. Downey
William W. Monafo

Immediate Concerns 325
General Features of the Response to Injury 326
Intermediary Metabolism in Critical Illness 327
Regulation of the Metabolic Responses to Critical Illness 331
Clinical Care and Metabolic Responses to Critical Illness 333

Chapter 24 337

Oxygen Delivery and Consumption in Critical Illness

Robert Schlichtig

Immediate Concerns 337

Chapter 25 343

Progression to Multiple Organ System Failure

George M. Matuschak

Immediate Concerns 343
Definitions 345
Epidemiology 346
Pathogenesis 347
Organ System Interactions 351

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

91

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Clinical Features 352
Prevention and Treatment 353

Chapter 26 359

Shock

Edgar J. Jimenez

Immediate Concerns 359
Overview 364
Definition 365
Classification and Clinical Recognition 365
Pathophysiologic Mechanisms of Shock 368
Management 373
Prognosis 381

Chapter 27 389

Cardiogenic Shock

John A. Farmer

Immediate Concerns 389
Classification 390
Etiology 390
Clinical Manifestations 395
Therapy 395

Chapter 28 405

Sepsis and Septic Shock

Janice L. Zimmerman
Robert W. Taylor

Immediate Concerns 405
Epidemiology and Etiology 406
Pathophysiology 407
Organ System Dysfunction in Sepsis 407
Clinical Manifestations 408
Diagnostic Considerations 409
Management of Sepsis 409

Chapter 29 413

Fluid and Electrolytes

Gary P. Zaloga
Robert R. Kirby
Walter C. Bernards
A. Joseph Layon

Immediate Concerns 413
Fluid Compartments 414
Electrolytes 415
Intraoperative and Postoperative Fluid Therapy 433
Hypoosmolar States 437

Chapter 30 443

Splanchnic Flow and Resuscitation

Orlando C. Kirton
Joseph M. Civetta

The Intestinal Microcirculation 443
Cellular Energy Metabolism 444
Intestinal Ischemia 445
Reperfusion Injury 445
Dysoxic Versus Normoxic State 446
Global Parameters of Delivery and Utilization: The Controversy 446
The Gastrointestinal Tract and Multiple Organ System Failure 447
Relevant Clinical Studies 448
The Monitoring Plan 450
Who Should Be Monitored? 451
Approach to Therapy 452
Future Investigations 452

Chapter 31 457

Enteral and Parenteral Nutrition

Patricia M. Byers
K. N. Jeejeebhoy

Immediate Concerns 457
Introduction 458
The Importance of a Nutritional Support Service 459
Nutritional Assessment and Patient Selection 459
Nutritional Requirements 460
Routes and Techniques of Administration 464
Nutritional Therapy of Patients with Organ System Dysfunction 468
Complications 468

Chapter 32 475

Pharmacologic Principles

Subhash K. Todi
Ronald A. Hartmann

Pharmacokinetics and Pharmacodynamics 475
Pharmacotherapy in Renal Diseases 478
Pharmacotherapy in Liver Disease 481
Adverse Drug Reactions 482

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

32

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

SECTION IV 489

TECHNIQUES, PROCEDURES, AND TREATMENT

Chapter 33 491

Fundamentals of Cardiopulmonary Resuscitation

Robert R. Kirby
Richard S. Melker

Immediate Concerns 491
Initial Considerations 492
Airway Patency 492
Breathing 495
Circulation 496
Defibrillation and Cardioversion 497
Pulseless Electrical Activity, Bradycardia, and Asystole 499
Pharmacologic Therapy 499

Chapter 34 507

Clean and Aseptic Technique at the Bedside

Judith A. Hudson-Civetta
Joseph M. Civetta

Questions Regarding Handwashing 507
Importance of Nosocomial Blood Stream Infection 510
Sources of Bacteria 510
Insertion Protocols 511
A Practical Bedside Approach 511
Preparation of Site and Dressing 511
Technique of Skin Preparation 512
Maintenance of Intravascular Catheters 514
Semiquantitative Culture Specimens Using Guidewire Exchange 515
Guidelines for the Use of Guidewires 517

Chapter 35 521

Vascular Cannulation

Bahman Venus
Paul Satish

Immediate Concerns 521
Venous Cannulation 522
Pulmonary Artery Cannulation 538
Peripheral Arterial Cannulation 539

Chapter 36 545

Temporary Cardiac Pacemakers

W. Ross Davis

Immediate Concerns 545
Indications for Temporary Pacing 545
Electrode Catheters and External Pacemaker Units 546
Procedures for Establishing Temporary Pacing 548

Chapter 37 553

Important Intensive Care Procedures

Neil S. Yeston
Richard L. Grotz
Laurie A. Loiacono

Thoracentesis 553
Tube Thoracostomy 556
Heimlich Catheter Insertion 560
Chest Tube Bottles 561
Paracentesis 562
Diagnostic Peritoneal Lavage 563
Intraabdominal Pressure Measurement 568
Venous Cutdown 569
Defibrillation 573
Cardioversion 575
Pericardiocentesis 577
Transtracheal Aspiration 580

Chapter 38 587

Interventional Radiology

Diego Nunez
Kimberly A. Lentz
Alejandro Zuluaga

Vascular Procedures 587
Nonvascular Procedures 590

Chapter 39 599

Feeding Tube Placement

Scott A. Shikora

Immediate Concerns 599
Overview 600
Determining the Most Appropriate Tube Type, Site, and Placement Technique 600
Tube Options 601
Placement Technique Options 602

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 40 609

Mechanical Cardiac Assist Devices

Thomas L. McKiernan
William H. Wehrmacher

Purpose 609
Synchronized Coronary Venous Retroperfusion 611
Ventricular Assist Devices 611

Chapter 41 613

Antithrombotic and Thrombolytic Therapy

Steven J. Trottier

Immediate Concerns 613
Antiplatelet Therapy 613
Antithrombotic Therapy 615
Thrombolytic Therapy 622

Chapter 42 631

Renal Replacement Therapies

Sudarshan Hebbar
Richard S. Muther

Immediate Concerns 631
Physiology 632
Extracorporeal Therapies 632
Peritoneal Dialysis 636
Choice of Therapy 636

Chapter 43 639

Transfusion Therapy

Richard C. Dennis
David Clas
Joan M. Niehoff
Neil S. Yeston

Immediate Concerns 639
Acute Massive Hemorrhage 640
Subacute Blood Volume Deficiency 643
Chronic Anemia 644
History of Blood Transfusion 644
Red Blood Cell Transfusion 645
Fresh Frozen Plasma 648
Cryoprecipitate 649
Platelets 649
DDAVP 651
Technical Aspects of Blood Product Administration 651
Transfusion Complications 652
Refusal of Transfusion 656

Chapter 44 661

Decreasing the Need for Homologous Blood Transfusion

Stephen F. Flaherty
Richard C. Dennis

Immediate Concerns 661
Optimization of Red Cell Production 663
Autotransfusion 663
Passive Blood Loss in the ICU 665
Blood Substitutes 666

Chapter 45 669

Extracorporeal Circulation for Respiratory or Cardiac Failure

Joseph B. Zwischenberger
Aravind B. Sankar
Robert H. Bartlett

Immediate Concerns 669
Background 670
Pathophysiology 671
Patient Selection 671
Techniques and Management 672
Venovenous ECMO 675
The ECMO Team 676
Complications 677
Results 678
Laboratory Investigation 679
Cardiac Support 679

Chapter 46 683

Fiberoptic Bronchoscopy

J. Steven Hata
David A. Schenk
R. Phillip Dellinger

Immediate Concerns 683
Complications 684
Fiberoptic Bronchoscopy in Airway Management 686

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 47 703

Oxygen Therapy

Robert A. Smith

Immediate Concerns 703
Therapeutic Considerations 704
Potential Complications 704

Chapter 48 711

Mechanical Ventilation

Michael J. Banner
Samsun Lampotang
Paul B. Blanch
Robert R. Kirby

Immediate Concerns 711
Peak Inflation Pressure 712
Ventilator Classification 712
Microprocessor-Controlled Ventilators 715
Conventional Mechanical Ventilatory Techniques 719
New or Experimental Techniques 727
Spontaneous Breathing 729
The Work of Breathing 734
Special Techniques 737
Transport Ventilation 738
Side Effects and Complications 739

Chapter 49 745

Ventilatory Support Modes

Orlando C. Kirton

Noninvasive Techniques 745
Truly Assisted Ventilation 747
Near-Total Ventilatory Support 750
Minimal Excursionary Ventilation 753
Spontaneous Augmented Low-Volume Ventilation 754

Chapter 50 757

Airway Management

Orlando G. Florete
Robert R. Kirby

Immediate Concerns 757
General Principles 758
Anatomic Considerations 759
Drugs 762
Esophageal, Pharyngeal, and Laryngeal Tubes 763
Tracheal Intubation 764
Tracheotomy 769
Cricothyroidotomy 770
Cuff Inflation 770

Chapter 51 777

Hyperbaric Medicine

Luis A. Matos

Immediate Concerns 777
Clinical Application 779
Indications 780
Care Before HBO Therapy 781

Chapter 52 787

Intrahospital Transport

Gregory M. Gullahorn

Immediate Concerns 787
Overview 788
Transport Scenarios 789
Planning: Preparatory Phase 792
On the Road Again: Transport Phase 794
Home at Last: Posttransport Stabilization 794
Individualizing Approaches 795

Chapter 53 803

Interhospital Transport of the Critically Ill

Robert E. Fromm

Immediate Concerns 803
Overview 803
Prehospital Practitioners 804
Air Medical Transport 805
Approach to the Transport of the Critically Ill 807

Chapter 54 809

Pain Control

David L. Brown
James F. Flynn

Immediate Concerns 809
Patient Selection 811
Analgesic Technique 811
Clinical Management 816
Problems and Related Complications 817
Special Considerations 819

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

35

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 55 821

Sedation and Paralysis

Antoni M. Nejman

Immediate Concerns 821
Sedation 822
Paralysis 828

SECTION V 837

MONITORING: PRACTICAL APPLICATIONS

Chapter 56 839

Invasive Pressure Monitoring

Reed M. Gardner

Equipment 839
Equipment Setup 841
Complications of Invasive Pressure Monitoring 844
Signal Amplification, Processing, and Display 844

Chapter 57 847

Arterial, Central Venous, and Pulmonary Artery Catheters

Albert J. Varon

Immediate Concerns 847
Introduction 848
Arterial Catheters 850
Central Venous Catheters 852
Pulmonary Artery Catheters 853
Derived Cardiopulmonary Parameters 861

Chapter 58 867

Assessment of Cardiopulmonary Function

Nikolaus Gravenstein
Michael L. Good
Tina E. Banner

Relative Attributes 867
Clinical Assessment of Cardiopulmonary Function 868
Noninvasive Blood Pressure Measurement 870
Electrocardiography 873
Pulse Oximetry 875
Capnometry 877
Noninvasive Assessment of Cardiac Output 883
Echocardiography 884
Invasive Cardiac Output Determinations 886

Chapter 59 899

Continuous ST Segment Monitoring

David V. Shatz
Valerie R. Wells

Prevalence of Silent Ischemia 899
Significance of Perioperative Ischemia 900
Pathophysiologic Basis of Electrocardiographic Changes 901
Advantages of ST Segment Monitoring 901
Limitations of ST Segment Monitoring 902
Indications for Monitoring 902
Lead Placement 902
Monitor Setup 903
Troubleshooting Alarm Conditions 905
Definition of Ischemic Events 906
Therapeutic Options 906

Chapter 60 909

Venous Saturation Monitoring and Usage

Joseph M. Civetta
Loren D. Nelson

Immediate Concerns 909
Physiology of Oxygen Transport 910
Assessment of Oxygen Transport Balance 911
Monitoring Oxygen Transport 912
Clinical Usefulness of Continuous $S\bar{v}O_2$ Monitoring 912
Combined Venous and Pulse Oximetry 916
Arterial Venous Oxygen Content Difference 916
Intrapulmonary Shunt 916
Applicability 917
Appendix 1: Normal Range, Units, and Derivation for Common Oxygen Transport Terms 917
Appendix 2: Clinical Examples 918

Chapter 61 921

Blood Gas Analysis

Barry A. Shapiro
William T. Peruzzi

Interpretive Guidelines 922
Arterial Oxygenation 923
Ventilation 924
Acute Respiratory Alkalosis 926
Metabolic Acid–Base Imbalances 926
Clinical Assessment of Oxygenation 928

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Hypoxemia and Oxygen Therapy 929
Tissue Oxygenation 930
Noninvasive Monitoring 931
Carbon Dioxide Stores 932
Carbon Monoxide Poisoning 933
Aberrant Intracellular Metabolism 934
Cardiopulmonary Resuscitation and Low Flow States 934
Temperature Correction 936
Point of Care Analyzers and Blood Gas Monitors 938

Chapter 62 941

Neurologic Monitoring

Thomas Grissom
Joyce Grissom
J. Christopher Farmer

Cerebral Function 941
Cerebral Perfusion 946
Cerebral Metabolism 951
Neurologic Imaging 952

Chapter 63 957

Radiographic Imaging

Carl E. Ravin

Plain Chest Radiograph 957
Evaluation of Life-Support and Monitoring Devices 965
Abdominal Radiography 969
Newer Imaging Technology 971
Magnetic Resonance Imaging 978

SECTION VI 985

THE SURGICAL PATIENT

Chapter 64 987

Perioperative Pulmonary Function Testing and Consultation

Philip G. Boysen
Robert R. Kirby

Immediate Concerns 987
General Considerations 988
Assessment for Lung Resection 989
Assessment for Abdominal Surgery 992
Specific Therapeutic Measures 994
Postoperative Care 995
Mechanical Ventilation and the Work of Breathing 996

Chapter 65 999

Preoperative Evaluation of High-Risk Surgical Patients

David L. Brown
Stephen O. Heard
Donald S. Stevens
Robert R. Kirby

Immediate Concerns 999
Overview 1000
Concurrent Disease 1001
Management 1004
Prevention of Complications 1006
Special Considerations 1007

Chapter 66 1013

Anesthesia: Physiology and Postanesthesia Problems

Eran Segal
A. Joseph Layon

Immediate Concerns 1013
Uptake and Distribution of Inhalational Agents 1015
Inhalation Agents and Organ System Function 1017
Intravenous Agents 1021
Preferred Anesthetic Techniques for Critically Ill Patients 1026
Postanesthetic Problems 1026

Chapter 67 1037

Initial Triage of the Trauma Patient

Larry C. Martin

Immediate Concerns 1037

Chapter 68 1045

Secondary Triage of the Trauma Patient

Marc D. Palter
Vicente Cortes

Immediate Concerns 1045
Obtaining the Patient's History and History of Injury 1047

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

37

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Reassessing the ABCs While Maintaining Vital Functions 1047
Persistent Shock 1050
Blunt Cardiac Injury 1052
Compartment Syndrome 1052
Intraabdominal Hypertension (Intraabdominal Compartment Syndrome) 1053
Delayed Diagnosis 1054
Pelvic Fractures 1058

Chapter 69 1065

Evaluation of Bleeding in the Surgical Patient

Timothy H. Pohlman
C. James Carrico

Immediate Concerns 1065
Evaluation of Bleeding 1067
Etiologies of Postoperative Bleeding 1067
Complex Postoperative Bleeding Problems 1071

Chapter 70 1075

Abdominal Trauma: Diagnostic Steps and Postoperative Considerations

Vicente Cortes
Marc D. Palter
Mark McKenney

Immediate Concerns 1075
General Considerations in Abdominal Injury 1077
Penetrating Injuries 1079
Blunt Injuries 1080
Mortality and Morbidity in Abdominal Trauma 1082
Specific Injuries 1083

Chapter 71 1099

Evaluating the Acute Abdomen

Jorge Luis Sosa
H. David Reines

Immediate Concerns 1099
Introduction 1100
Anatomy 1100
History 1101
Physical Examination 1102
Adjunctive Procedures 1102
Therapy 1103
Special Conditions 1104

Chapter 72 1109

The Complicated Postoperative Abdomen

Danny Sleeman
Scott Norwood

Immediate Concerns 1109
Evaluating the Elective Postoperative Patient 1110
Normal Postoperative Course 1111
Evaluating the Postoperative Abdomen for Sepsis 1112
Specific Surgical Problems 1113
Tube Technology 1116

Chapter 73 1121

Surgical Aspects of Hepatobiliary Disease

Alan S. Livingstone
Jorge Luis Sosa

Immediate Concerns 1121
Management of the Cirrhotic Patient 1122
Early Postshunt Complications 1123
Surgical Management of Ascites 1125
Major Hepatic Resections 1126
Budd-Chiari Syndrome 1127
Hemobilia 1127
Postoperative Cholecystitis 1127
Cholangitis 1128
Biliary Fistula After Cholecystectomy 1128

Chapter 74 1131

Thoracic Surgery

Eddy H. Carrillo
M. Jack Williams

Immediate Concerns 1131
Thoracic Surgery 1133
Preoperative Considerations 1133
Management of the Postthoracotomy Patient 1133
Thoracic Trauma 1137
Special Situations and Procedures 1143

Chapter 75 1147

Postoperative Management of the Adult Cardiac Surgical Patient

Daniel J. O'Brien
James A. Alexander

Immediate Concerns 1147
The First 8 Postcardiopulmonary Bypass Hours 1148

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

The Next 16 Post-CPB Hours 1148
The Second 24 Post-CPB Hours 1149
The Third 24 Post-CPB Hours 1149
Monitoring and Managing Cardiovascular Performance 1150
Special Concerns 1155

Chapter 76 1161

Postoperative Management of the Pediatric Cardiac Surgical Patient

Laurie K. Davies
Michael A. Greene

Immediate Concerns 1161
Hemodynamic Issues 1162
Respiratory Management 1169
Laboratory Values 1170
Cardiac Rhythm and Pacing 1170
Temperature 1171
Sedation and Paralysis 1171
Infections and Antibiotics 1171
Renal Failure and Diuretics 1172
Limb Ischemia 1172
Bleeding 1173
Later Concerns 1173
Transplantation 1175

Chapter 77 1177

Vascular Surgery and Trauma

Enrique Ginzburg
James M. Hurst
Richard J. Fowl

Immediate Concerns 1177
Principles of Intensive Care for the Vascular Patient 1178
Problems Common to All Vascular Reconstructions 1180
Management of Specific Reconstructions 1182
Vascular Trauma 1187
Management of Specific Vascular Injuries 1187
Thrombolytic Therapy 1189
Aortic Dissection 1191

Chapter 78 1195

Neurologic Injury: Prevention and Initial Care

Philip A. Villanueva
Bradley H. Ruben
Jonathan Greenberg

Immediate Concerns: Head Injury 1195
Immediate Concerns: Spinal Injury 1197
Head Injury 1198
Spinal Cord Injury 1208

Chapter 79 1219

Multiple Fractures

Gregory A. Zych

Immediate Concerns 1219
Diagnosis of Fractures and Dislocations 1220
Specific Treatment Methods 1221
Special Problems 1226
Complications 1227

Chapter 80 1231

Orthopedic Complications

Jill I. Freedman
F. Kayser Enneking

Immediate Concerns 1231
Spinal Surgery 1232
Joint Replacement 1234
Pathologic Processes Common to Orthopedic Patients 1235
Miscellaneous Problems 1245

Chapter 81 1253

Urologic Surgery and Trauma

Thomas E. Ahlering

Immediate Concerns 1253
Major Urologic Postoperative Management 1254
Urogenital Trauma 1256

Chapter 82 1265

Burn Injury

Michael D. Peck
C. Gillon Ward

Immediate Concerns 1265
Management of Respiratory Problems 1266
Management of Cardiovascular Problems 1267
Complications of Resuscitation 1268
Maintenance of Electrolyte Homeostasis and Acid–Base Balance 1269
Management of Renal Failure 1270
Management of Bleeding Disorders 1270
Provision of Nutritional Support 1271
Diagnosis and Treatment of Serious Infections 1272
Care of the Burn Wound 1273

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

The Importance of Physiotherapy 1274
The Psychosocial Needs of the Patient and Family 1274
The Team Approach to Burn Care 1274

Chapter 83 1277

The Obese Surgical Patient

Scott A. Shikora
Jay A. Johannigman

Immediate Concerns 1277
Overview 1278
Cardiovascular Disease 1278
Pulmonary Disease 1279
Thromboembolic Disease 1280
Soft Tissue Problems 1281
Sepsis 1281
Drug Dosing 1282
Nutritional Support 1282

SECTION VII 1287

ORGAN TRANSPLANTATION

Chapter 84 1289

Organ Transplantation: An Overview of Problems and Concerns

Ake Grenvik
Joseph M. Darby
Brian A. Broznick

Immediate Concerns 1289
Current Transplantation Activities 1290
Organ Need Versus Supply 1291
Evolution of the Brain Death Concept 1291
Procedural Considerations 1292
Organ Procurement, Recovery, and Preservation 1295
Transplantation Organizations and Allocation of Organs 1296

Chapter 85 1301

Renal Transplantation

Matthew E. Brunson
William W. Pfaff
George W. Burke, III
Gaetano Ciancio

Immediate Concerns 1301
Immunosuppressants and Their Complications 1303
Minimizing Infections in the Immunocompromised Host 1305
Other Problems 1305
"Stable" Allograft Recipients Readmitted to the ICU 1306
Other Conditions 1308

Chapter 86 1311

The Renal and Pancreatic Allograft Recipient

George W. Burke, III
Gaetano Ciancio

Immediate Concerns 1311
Overview 1312
Initial ICU Admission 1312
Immunosuppression 1314
Secondary ICU Admissions 1315

Chapter 87 1317

Heart-Lung, Double-Lung, and Single-Lung Transplantation

Cesar A. Keller

Indications 1317
Initial Management 1317
Postoperative Management 1320

Chapter 88 1333

Heart Transplantation

Leslie W. Miller

Indications 1333
Candidate Selection: Hemodynamic Assessment 1333
Initial Postoperative Management 1334
Immediate Concerns 1335

Chapter 89 1341

Orthotopic Liver Transplantation

Mathew E. Brunson
Richard J. Howard

Immediate Concerns 1341
Early Graft Function and Primary Nonfunction 1342
Coagulation Abnormalities 1343
Hemodynamic Function and Fluid Therapy 1343
Immunosuppression 1344
Hypertension 1345
Other Early Problems 1345
Assessing and Optimizing Graft Function 1346
Complications 1347
Late Readmissions to the ICU 1350
Consultation 1350

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 90 1353

Intestinal and Multivisceral Transplantation

Marc G. Webb
Andreas G. Tzakis

Immediate Concerns: Preoperative Care 1353
Immediate Concerns: Postoperative Care 1354
Overview 1354
Preoperative and Operative Care 1355
Postoperative Care 1360

Chapter 91 1367

Bone Marrow Transplantation

Richard K. Burt

Immediate Concerns (First 30 Days) 1367
Intermediate Concerns (Days 30 to 100) 1377
Late Concerns (Beyond Day 100) 1377

SECTION VIII 1387

THE OBSTETRIC PATIENT

Chapter 92 1389

Cardiac Disease and Hypertensive Disorders in Pregnancy

Christopher F. James

Immediate Concerns 1389
Hypertensive Disorders 1392
Cardiac Disease 1393
Cardiac Surgery During Pregnancy 1397
Pregnancy After Cardiac Surgery 1398
Cardiopulmonary Resuscitation 1398

Chapter 93 1401

Hemorrhagic Disorders

Connie E. Taylor

Immediate Concerns 1401
Cardiovascular Changes With Obstetric Drugs 1402
Coagulation Changes 1403
Hemorrhagic Complications 1403
Coagulopathies 1406

Chapter 94 1409

Pulmonary Abnormalities

Robert R. Kirby

Immediate Concerns 1409
Physiologic Considerations 1410
Ventilation and Perfusion 1411
Diagnosis and Treatment of Respiratory Failure 1412

Chapter 95 1419

Trauma and the Acute Abdomen

Sharon Salamat
Anthony Lai

Immediate Concerns 1419
Initial Assessment and Management 1420
Diagnostic Studies 1421
Specific Management 1423
Postoperative Period 1424
Delivery Concerns 1425
Maternal Brain Death 1425

Chapter 96 1429

Fetal Monitoring Concerns

Donald Caton

Immediate Concerns 1429
Special Considerations 1430
Fetal Oxygenation 1431
Monitoring 1432
Chronic Adaptations 1433
Acute Adaptations 1434

SECTION IX 1437

ENVIRONMENTAL HAZARDS

Chapter 97 1439

Protecting the Practitioner: Acquired Immunodeficiency Syndrome and Hepatitis

Salvatore Lopalo
A. Joseph Layon

Acquired Immunodeficiency Syndrome 1439
Health Care Workers and HIV Transmission 1440

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Testing of Health Care Workers After Possible Exposure 1441
Prevention 1442
The Hepatitides 1444
Protective and Therapeutic Measures 1447

Chapter 98 1451

Temperature-Related Injuries

J. Christopher Farmer

Immediate Concerns 1451
Hypothermia 1451
Hyperthermia 1454
Malignant Hyperthermia and the Neuroleptic Malignant Syndrome 1457

Chapter 99 1463

Toxicology: General Approach

Jeffrey A. Sadowsky

Immediate Concerns 1463
History 1464
Diagnosis and the General Approach to the Poisoned Patient 1467
Pregnancy 1475
Treatment Refusal: The Uncooperative Patient 1475
Appendix 99-1: Toxicology Information 1475

Chapter 100 1483

Toxicology: Specific Drugs and Poisons

Richard P. Ryskamp
Robert W. Taylor

Acetaminophen 1483
Salicylates 1486
Cyclic Antidepressants 1489
Lithium 1493
Antipsychotic Drugs 1494
Benzodiazepines 1495
Beta-Blockers 1496
Calcium Channel Blockers 1497
Digitalis 1498
Theophylline 1499
Alcohols 1501
Insecticides: Cholinergic Agents 1504

Chapter 101 1511

Substance Abuse and Withdrawal: Alcohol, Cocaine, and Opioids

Joan Shaffer

Immediate Concerns 1511
Ethanol 1512
Cocaine 1514
Opioids 1517

Chapter 102 1523

Envenomation

Charles L. Bryan
Charles A. Weber
Kenneth A. Perret

Immediate Concerns 1523
Venomous Snake Bites 1524
Black Widow Spider Bites 1528
Brown Recluse Spider Bites 1530
Scorpion Envenomation 1532
Marine Envenomations 1533

Chapter 103 1537

Electrical Injuries

Kenneth A. Perret
Charles A. Weber
Charles L. Bryan

Immediate Concerns 1537
Classification 1538
Basic Mechanisms in Electrical Injury 1538
Clinical Manifestations and Management 1539

Chapter 104 1543

Anaphylaxis

Stewart J. Levine
R. Dwaine Rieves
James H. Shelhamer

Immediate Concerns 1543
Clinical Manifestations 1544
Management 1546
Prevention 1549
Pathogenesis 1550
Implications and Outcome 1550

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

SECTION X 1553

INFECTIOUS DISEASE

Chapter 105 1555

An Approach to the Use of Antimicrobial Agents

George E. Crawford
Mimi Emig

Immediate Concerns 1555
Principles of Antibiotic Selection 1556
Antibiotic Therapy 1561
Prophylactic Antibiotics 1565
Antimicrobials Useful in the Critical Care Unit 1566

Chapter 106 1573

The Prevalence and Importance of Nosocomial Infections in the Intensive Care Unit

Mark G. McKenney
Scott Norwood

Immediate Concerns 1573
Risk Factors and Scope of Nosocomial Infections in Critical Illness 1575
Hospital-Acquired Respiratory Infections 1575
Catheter-Related Nosocomial Infections 1577
Surgical Wound Infections 1581
Hospital-Acquired Urinary Tract Infections 1582
Fungal Infections 1583
Sinusitis 1583
Antibiotic-Associated Pseudomembranous Colitis 1583
Hospital-Acquired Ventriculitis and Meningitis 1584

Chapter 107 1589

An Approach to the Febrile ICU Patient

David V. Shatz
Scott Norwood

Immediate Concerns 1589
Definition, Pathophysiology, and Purpose 1591
Common Causes of Fever 1592
Fever as a Predictor of Infection 1592
Recommended Approach to Fever Evaluation 1593

Chapter 108 1603

Infections in the Immunocompromised Host

Gregory P. Melcher
Douglas R. Leigh

Immediate Concerns 1603
Approach to the Immunocompromised Host 1604
The Granulocytopenic Patient 1605
The Corticosteroid-treated Patient 1606
The Renal Transplant Recipient 1609
Bone Marrow Transplant Recipient 1613

Chapter 109 1617

Human Immunodeficiency Virus in the Intensive Care Unit

Loretta M. O'Brien
Richard E. Winn

Immediate Concerns 1617
Pulmonary Manifestations of HIV 1618
Neurologic Manifestations of HIV Infection 1626
Sepsis and Bacteremia 1627
Gastrointestinal Manifestations of HIV 1629
Fever of Unknown Origin 1630
ICU Utilization in HIV Infection 1630
Control of HIV Infection in the ICU 1630

Chapter 110 1635

Neurologic Infections

David H. Gremillion

Immediate Concerns 1635
Clinical Presentation and Initial Diagnostic Measures 1635
Establishing the Diagnosis 1639
Management 1641
Prevention of Bacterial Meningitis 1642
Complications of Bacterial Meningitis 1643
Special Clinical Considerations 1644

Chapter 111 1649

Urinary Tract Infections

Mark E. Appleman
Richard E. Winn

Immediate Concerns 1649
Cystitis 1650

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Pyelonephritis 1650
Prostatitis 1654
Nosocomial Infections 1654
Fungal Infections 1655

Chapter 112 1657

Bacterial Infections

Judith R. Anderson
Ferric C. Fang

Staphylococcus aureus 1657
Coagulase-Negative Staphylococci (Including *Staphylococcus epidermidis*) 1661
Streptococcal and Enterococcal Infections 1663
Streptotoccus pyogenes (Group A Streptococcus) 1663
Streptococcus agalactiae (Group B Streptococcus) 1664
Streptococcus pneumoniae 1664
Viridans Streptococci 1665
Streptococcus milleri/intermedius Group 1665
Enterococci 1666
Moraxella (Branhamella) catarrhalis 1666
Neisseria meningitidis 1666
Neisseria gonorrhoeae 1667
Bacillus Infections 1668
Corynebacteria (Diphtheroids) 1668
Listeria monocytogenes 1668
Nocardia 1668
Acinetobacter 1669
Campylobacter and *Helicobacter* 1669
Enterobacteriaceae 1669
Enterobacter 1669
Escherichia 1670
Klebsiella 1670
Proteus 1670
Salmonella 1670
Serratia 1671
Shigella 1671
Yersinia 1671
Other Enterobacteriaceae 1672
Flavobacterium 1672
Francisella 1672
Haemophilus influenzae 1672
Other HACEK Organisms 1673
Legionella 1673
Pasteurella 1673
Pseudomonas aeruginosa 1673
Pseudomonas (burkholderia) cepacia 1674
Stenotrophomonas (xanthomonas) maltophilia 1675
Vibrios and Related Organisms 1675
Anaerobic Cocci 1675
Actinomycosis 1675
Clostridial Infections 1676
Propionibacterium acnes 1678
Anaerobic Gram-Negative Bacilli 1678
Bartonella (Rochalimaea) Infections 1679
Capnocytophaga 1679
Chlamydia 1680
Mycobacterium avium-intracellulare 1680
Mycobacterium kansasii 1680
Mycobacterium tuberculosis 1680
Mycoplasmal Infections 1681
Rickettsial Infections 1682
Borrelia 1682
Leptospirosis 1682
Syphylis 1682

Chapter 113 1685

Fungal and Viral Infections

Stephen B. Greenberg

Fungal Infections 1685
Viral Infections 1691

Chapter 114 1703

Unusual Infections

Richard E. Winn

Rickettsial Diseases 1703
Ehrlichia 1706
Brucellosis 1706
Tularemia 1707
Plague 1708
Borreliosis 1708
Hantavirus Pulmonary Syndrome 1709
Hemorrhagic Fever 1709
Head and Neck Infections 1710
Cerebral Malaria 1711

SECTION XI 1715

CARDIOVASCULAR DISEASE AND DYSFUNCTION

Chapter 115 1717

Evaluation of Chest Pain in the ICU

Stephen P. Taylor

Immediate Concerns 1717
Differentiation of Chest Pain Syndromes 1719
Differential Diagnosis of Life-Threatening Causes of Chest Pain 1720
Differential Diagnosis of Non–Life-Threatening Causes of Chest Pain 1724

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 116 1727

Acute Myocardial Infarction: Contemporary Management Strategies

Normand Racine

Immediate Concerns 1727
Role of Aspirin in Acute Myocardial Infarction 1727
Thrombolysis 1728
Percutaneous Transluminal Coronary Angioplasty 1733
Role of Heparin in Acute Myocardial Infarction 1733
Role of Intravenous β-Adrenergic Blocking Agents 1734
Role of Intravenous Nitroglycerin 1735
Role of Calcium Channel Blockers 1735
Lidocaine 1736
Angiotensine-Converting Enzyme Inhibitors (ACE-i) 1736
Heart Failure and Cardiogenic Shock 1737
Differentiation From Chronic Heart Failure 1737
Mechanical Complications 1737
Right Ventricular Infarction Diagnosis and Therapy 1738
Cardiogenic Shock 1738
Clinical Guidelines for Hemodynamic Monitoring 1738
Recommended Approach to Congestive Heart Failure 1739
Noninvasive Imaging Techniques 1740
Q Wave and Non-Q Wave Myocardial Infarctions 1742

Chapter 117 1749

Heart Failure

Mandeep R. Mehra
Hector O. Ventura

Immediate Concerns 1749
Introduction 1750
Epidemiology of Heart Failure 1751
Etiopathogenesis 1752
Neurohormonal Activation in Advanced Heart Failure 1752
Neurohormonal Activation: Adaptation or Maladaption? 1753
Prognostic Factors in Advanced Heart Failure 1753
Clinical Trials in the Medical Management of Heart Failure 1755
Pooled Studies of ACE Inhibitors 1756
Clinical Use of ACE Inhibitors 1756
Oral Inotropic Therapy–Hopeless or a Glimmer of Hope? 1756
A Summary of Clinical Trials in Advanced Heart Failure 1757
The Unique Management of Refractory Advanced Systolic Heart Failure 1758
Tailored Medical Therapy 1759
Practical Aspects of Intravenous Inotropic Therapy 1760
Fluid Removal in Refractory Heart Failure 1761
Non-pharmacological Cardiac Assistance 1762
Selection Criteria for Implantable Ventricular Assist Devices 1763
Emerging Pharmacologic Therapeutics in Heart Failure 1763
Diastolic Dysfunction: The Other Side of the Coin 1764

Chapter 118 1769

Valvular Heart Disease

W. Ross Davis

Immediate Concerns 1769
Critical Illness Caused by Valvular Heart Disease 1769
Complicating Cardiac Valvular Disease in Critically Ill Patients 1770
Considerations in Specific Valvular Abnormalities 1770

Chapter 119 1781

Cardiac Arrhythmias

W. Ross Davis

Immediate Concerns 1781
Diagnostic Maneuvers 1781
Supraventricular Arrhythmias 1783
Ventricular Arrhythmias 1783
Wide Complex Tachycardia 1784
Atrioventricular Block 1784
Management 1784

Chapter 120 1787

Infective Endocarditis

Stephen B. Greenberg

Immediate Concerns 1787
Overview 1787
Epidemiology 1788
Pathology and Pathogenesis 1788
Diagnostic Criteria 1789
Clinical Manifestations 1790
Laboratory Tests 1790
Microbiology 1791
Therapy 1793

Chapter 121 1803

The Pericardium

Thomas L. McKiernan

Acute Pericarditis 1803
Cardiac Tamponade 1805
Constrictive Pericarditis 1808
Postpericardiotomy Syndrome 1809

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45

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Chapter 122 1811

Hypertensive Emergencies and Urgencies

Patrick C. McKillion
R. Phillip Dellinger

Immediate Concerns 1811
Specific Considerations 1816
Hypertensive Urgencies 1819

SECTION XII 1823

PULMONARY DISEASE AND DYSFUNCTION

Chapter 123 1825

The Acute Respiratory Distress Syndrome

Barbara J. Foner
Scott H. Norwood
Robert W. Taylor

Immediate Concerns 1825
Overview 1826
Etiology 1826
Pathophysiology 1828
Clinical Presentation 1830
Treatment 1831
Novel Forms of Mechanical Ventilation 1835
Monitoring 1836
Complications 1836
Outcome 1836

Chapter 124 1841

Community Acquired Pneumonia

Dennis P. Lawlor
Mimi Emig

Immediate Concerns 1841
Characterization of Pneumonia 1842
Pathogens in Community Acquired Pneumonia 1842
New Pathogens 1843
Old Pathogens, New Problems 1843
Host Defense and Susceptibility 1844
Initial Diagnostic Evaluation 1846
Evaluation and Treatment of Pleural Effusions 1848
Lung Abscess 1849
Empiric Antibiotics 1850
Duration of Therapy 1852
Adjunctive Treatment 1852
Clinical Response to Therapy 1852
Invasive Testing 1852
Chronic Lung Infections 1854
Radiographic Resolution 1855
Prophylaxis 1855
Evaluation of Recurrence 1856
Future Directions 1856

Chapter 125 1861

Aspiration Syndromes

Salvatore R. Goodwin

Immediate Concerns 1861
Classification 1862
Further Diagnostic Concerns 1864
Subsequent Management 1865
Prevention 1868

Chapter 126 1875

Drowning and Near-Drowning

Eric T. Kunichika
Lawrence S. Berman

Immediate Concerns 1875
Presentation 1877
Pathophysiology 1877
Treatment 1878
Neurologic Sequelae 1880
Fluids and Electrolytes 1880
Renal Failure 1880
Hematologic Changes 1881
Sequelae 1881
Ice Water Submersion 1882
Prognosis and Outcome 1882
Other Concerns 1883

Chapter 127 1887

Venous Thrombosis and Pulmonary Embolism

Mandeep R. Mehra
Frederick R. Bode

Immediate Concerns 1887
Venous Thromboembolism: Ubiquitous Yet Undiagnosed 1888
The Medical ICU and Deep Venous Thrombosis: The Case for Routine Prophylaxis 1889
Natural History of Venous Thromboembolism 1891
Clinical Features and Diagnosis of Venous Thromboembolism 1891
Therapy of Venous Thromboembolism 1897
Future Directions 1901

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46

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Chapter 128 1905

Other Embolic Syndromes

Scott A. Deppe
Dan R. Thompson
Roger R. Barrette

Immediate Concerns 1905
Arterial Embolism of Gas, Cholesterol, or Fat 1905
Venous Air Embolism 1907
Fat Embolism Syndrome 1908
Amniotic Fluid Embolism 1910

Chapter 129 1917

Acute Respiratory Failure in Chronic Obstructive Lung Disease

Michael J. Cicale
Frederick L. Trent

Immediate Concerns 1917
Definitions 1918
Etiology 1919
Pathophysiology 1919
Management 1919
Complications 1927
Prognosis 1929

Chapter 130 1931

Life-Threatening Bronchospasm in the Asthmatic Patient

R. Phillip Dellinger

Immediate Concerns 1931
Pathophysiology and Pulmonary Function in Severe Asthma 1932
Diagnosis 1934
Admission Decisions 1936
Therapy 1936
Indications for Tracheal Intubation 1939
Summary of Treatment Priorities 1942
Nontraditional Therapy of Severe Bronchospasm 1943

Chapter 131 1947

Inhalation Injury

David A. Striker

Immediate Concerns 1947
Fire and Smoke 1948
Thermal Injury 1949
Pathogenesis 1950
Histopathology 1950
Clinical Presentation and Diagnosis 1950
Treatment 1951
Classification 1952

Chapter 132 1959

Pulmonary Barotrauma

David L. Brown
Robert R. Kirby

Immediate Concerns 1959
Pneumothorax 1960
Other Extra-Alveolar Air Conditions 1964
Prevention of Barotrauma and Related Complications 1965
Surveillance for Pulmonary Barotrauma 1966

SECTION XIII 1969

NEUROLOGIC DISEASE AND DYSFUNCTION

Chapter 133 1971

Altered Mental Status and Coma

Warren J. Strittmatter

Immediate Concerns 1971
Emergency Evaluation 1971
Bedside Evaluation of Coma 1972
Additional Studies 1975
Bilateral Hemispheric Lesions 1975
Brain Stem Lesions 1976
Metabolic–Toxic Etiologies 1977

Chapter 134 1981

Seizures and Status Epilepticus

Paul A. Rutecki

Immediate Concerns 1981
Definitions and Classification 1982
Etiology 1982
Pathophysiology 1983
Initial Therapy and Management 1983
Pharmacologic Therapy 1984
Laboratory Evaluation 1986
Prognosis 1986
Special Cases 1986

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47

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Chapter 135 1989

Cerebrovascular Disease

Ken P. Madden
Loren A. Rolak

Immediate Concerns 1989
Stroke 1990
Other Cerebrovascular Diseases 1999

Chapter 136 2005

Neuromuscular Disorders

Stephen Derdak

Immediate Concerns 2005
Guillain-Barré Syndrome (Acute Autoimmune Inflammatory Demyelinating Polyneuropathology) 2005
Myasthenia Gravis 2011

Chapter 137 2017

Behavioral Disturbances in the Intensive Care Unit

Michael G. Wise
Ned H. Cassem

Immediate Concerns 2017
Diagnosis and Clinical Features of a Delirium 2018
Behavioral Disorders Without Cognitive Dysfunction 2024

SECTION XIV 2031

GASTROINTESTINAL DISEASE AND DYSFUNCTION

Chapter 138 2033

Gastrointestinal Bleeding

Jack A. DiPalma

Immediate Concerns 2033
Overview 2033
Approach to Diagnosis and Management of Upper Gastrointestinal Bleeding 2034
Treatment for Gastrointestinal Bleeding 2035
Critical Assessment of Available Interventions 2037
Stress Ulceration 2037
Approach to Lower Gastrointestinal Bleeding 2040

Chapter 139 2045

Fulminant Hepatic Failure

Marc G. Webb
Andreas G. Tzakis

Immediate Concerns 2045
Etiology and Prognosis 2046
Complications and Treatment 2047

Chapter 140 2055

Pancreatic Disease

Danny Sleeman
Joe U. Levi

Immediate Concerns 2055
Overview 2056
Diagnosis of the Disease Process 2056
Classification 2057
Treatment of Acute Pancreatitis 2057
Surgical Management 2059

Chapter 141 2065

Inflammatory Bowel Disease

Charles E. Brady
Oscar A. Alvarez

Immediate Concerns 2065
Fulminant Colitis and Toxic Megacolon 2066
Colonic Perforation and Massive Hemorrhage 2069

Chapter 142 2071

Esophageal Disorders

Jack A. DiPalma

Immediate Concerns 2071
Esophageal Obstruction 2071
Foreign Bodies 2073
Corrosive Injury 2073
Esophageal Perforation 2075
Medication Injury 2076

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

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SECTION XV 2079

RENAL AND ENDOCRINE DISEASE AND DYSFUNCTION

Chapter 143 2081

Acute Renal Failure

Richard S. Muther

Immediate Concerns 2081
Differential Diagnosis of Acute Azotemia 2081
Differential Diagnosis of Acute Renal Failure 2084
Pathophysiology 2086
Prevention of ARF 2088
Treatment and Supportive Care 2088
Prognosis and Recovery 2090

Chapter 144 2093

Impact of Chronic Renal Failure

Gerald M. Reid
Richard S. Muther

Immediate Concerns 2093
Hypotension 2094
Chest Pain 2096
Cardiac Arrhythmias 2096
Respiratory Failure 2097
Disordered Consciousness 2098

Chapter 145 2101

Disordered Glucose Metabolism

Dan R. Thompson

Immediate Concerns 2101
Disordered Glucose Metabolism 2102
Diabetic Ketoacidosis 2102
Hyperosmolar Hyperglycemic Nonketotic Disease 2106
Decompensated Diabetes Mellitus in Patients With Coexistent Medical or Surgical Problems 2107

Chapter 146 2111

Hypothalamic and Pituitary Disease

Charles A. Reasner II
Gary L. Mueller

Immediate Concerns 2111
Overview 2112
Hypothalamic–Anterior Pituitary Unit 2112
Neurohypophysis 2116

Chapter 147 2121

Adrenal Disease

Robert B. Constant
Richard J. Barth

Immediate Concerns 2121
Physiology of the Adrenal Gland 2122
Adrenal Hormone Insufficiency 2123
Adrenal Hormone Excess (Cushing's Syndrome) 2125
Clinical Use of Glucocorticoid Medications 2125
Adrenal Function Tests 2126

Chapter 148 2129

Pheochromocytoma

Gary L. Mueller
Charles A. Reasner II

Immediate Concerns 2129
Presenting Symptoms and Signs 2130
Pathology 2130
Diagnosis 2131
Management 2133
Prevention of Complications 2133
Special Considerations 2133

Chapter 149 2137

Thyroid Disease

William L. Isley

Immediate Concerns 2137
Thyrotoxicosis 2137
Hypothyroidism 2142
Drugs, Thyroid Disease, and Thyroid Function 2146
Thyroid Function in Nonthyroidal Illness and Aging 2146
Airway Obstruction 2147

SECTION XVI 2151

SKIN AND MUSCLE DISEASE AND DYSFUNCTION

Chapter 150 2153

Critical Care of Rheumatic Disease

Jay B. Higgs
Ramon A. Arroyo
Kenneth F. Des Rosier
Matthew T. Carpenter

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Immediate Concerns 2153
Overview 2155
Principles and Pitfalls in the Critical Care of Rheumatic Disease 2155
Vasculitis 2159
Critical Care of Systemic Lupus Erythematosus 2164
Systemic Sclerosis 2171

Chapter 151 2175

Dermatologic Conditions

Richard L. Spielvogel

Immediate Concerns 2175
Erythema Multiforme 2175
Toxic Epidermal Necrolysis 2177
Staphylococcal Scalded Skin Syndrome 2178
Generalized Pustular Psoriasis (Von Zumbusch) 2179
Erythroderma and Exfoliative Dermatitis 2181
Pemphigus 2182
Bullous Pemphigoid 2183
Eczema Herpeticum (Kaposi's Varicelliform Eruption) 2184
Varicella-Zoster Infections 2185
Drug Eruptions 2186
Purpura 2188
Acquired Immunodeficiency Syndrome 2191
Contact Dermatitis 2191
Necrotizing Fasciitis 2192

Chapter 152 2195

Rhabdomyolysis

J. Christopher Farmer

Immediate Concerns 2195
Complications 2196
The Clinical Syndrome of Rhabdomyolysis 2198

Chapter 153 2203

Preventive Care

Deborah Weppler
Joseph M. Civetta

Skin and Subcutaneous Tissues 2203
Musculoskeletal System Considerations 2207
Subtle Infectious Processes 2209
Miscellaneous Conditions 2211
Types of ICU Beds 2212

SECTION XVII 2215

HEMATOLOGIC AND ONCOLOGIC DISEASE AND DYSFUNCTION

Chapter 154 2217

Coagulation Disorders

Robert I. Parker

Immediate Concerns 2217
Overview 2218
An Approach to the Patient With an Actual or Suspected Coagulation Disorder 2218
Conditions Associated With Serious Bleeding or a High Probability of Bleeding 2220
Thrombotic Syndromes 2229
Laboratory Abnormalities Not Associated With Bleeding 2229
Selected Disorders 2230

Chapter 155 2231

Hematologic Diseases

David A. Sears

Reduced Blood Counts 2231
Increased Blood Counts 2239
Altered Blood Rheology 2241

Chapter 156 2245

Oncologic Emergencies

Robert J. Downey
Jeffrey S. Groeger

Cancer Hypercalcemia 2245
Acute Tumor Lysis Syndrome 2247
Obstructive Syndromes 2248
Neurologic Syndromes 2249
Cardiac Tamponade 2250
Gastrointestinal Emergencies: Neutropenic Enterocolitis 2250
Toxicity of Chemotherapy 2251

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

50

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Appendix 2255

Critical Care Catalog

Stephen M. Koch

Appendix A: Prefixes and Conversions 2255
Appendix B: Dubois Body Surface Area Nomogram 2256
Appendix C: Fluids and Electrolytes 2257
Appendix D: Acid-Base 2259
Appendix E: Formulas 2261
Appendix F: Pharmacology 2266
Appendix G: Dermatomes 2273
Appendix H: Organ Injury Scaling 2273

Index 2283

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

51

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TABLE 35-2. General Guidelines for Central Vascular Cannulation

1. Avoid sites with previous surgery and trauma or obvious anatomic abnormalities.
2. An agitated patient may predispose to complications. Assure comfort and sedation.
3. Use ample local anesthetics without distorting landmarks or the vessel.
4. Assure optimum position for the patient. Avoid awkward or uncomfortable position for yourself.
5. Assure oxygenation, ventilation, and monitoring under drapes.*
6. Valsalva maneuver, inspiratory hold, volume challenge, and Trendelenburg position are additional techniques to deliver vein-distending forces.*
7. Gauge the depth and angle of insertion by first performing venipuncture with a small-gauge needle. The needle can temporarily be left in place unless it prohibits passage of the cannulating needle or needle/plastic cannula assembly.*
8. Puncture the skin and subcutaneous tissue generously or incise with a no. 11 scalpel blade to avoid skin plugs and to facilitate catheter or introducer passage.
9. If a stab incision is not used initially, inject a small amount of saline to express skin plugs.
10. When attempting to find the vein with a needle or while cannulating the vein, use a small syringe to apply slight negative pressure.*
11. When vascular puncture is accomplished, adjust the needle bevel and guidewire. Lower the needle slightly to move closely parallel to the vascular lumen and advance the needle 2–5 mm further to assure intravascular placement of the lumen.
12. Do not redirect the needle while it is partially inserted to avoid laceration of the vein. When advancement fails, withdraw slowly while observing for blood return. If blood return is not observed after full withdrawal, then vary the technique by slightly altering the needle angulation.
13. If resistance is felt, remove the catheter or guidewire. The location of the catheter or guidewire shape may give clues to the cause of the obstruction. If cannulation is unsuccessful, check the tip of your cannula. A sheared or occluded tip may be the problem.
14. Once in the vessel, never leave the needle or cannula unoccluded. Air embolism can occur through veins, and unacceptable blood loss can occur from arteries.
15. Estimate the safe length of guidewire that can be inserted before attempting the insertion. Always watch the monitor of the length of inserted guidewire to minimize potential arrhythmias.*
16. If resistance is met in advancing or withdrawing of a guidewire, never use force. Gently withdraw the guidewire and the catheter/needle together.
17. Allow yourself three to five attempts for each venous approach. Perhaps 5–10 passes can be reasonably attempted for arterial puncture with a 20-gauge needle. It is better to accept failure than cause a serious complication.
18. For placement of transcardiac or vena cava catheters, always order a stat follow-up radiograph to assure correct catheter tip placement. Right atrial electrocardiography is an acceptable alternative for correct placement of the catheter.

*Applies to venous cannulation only.

environment, and rotating the wrist or moving the arm at different angles from the body may help the catheter to advance. If these maneuvers fail, the catheter should not be forced in, because scarring of the vein or sclerosis may be the cause of obstruction, which dictates abandoning the procedure. A postprocedure radiograph of the chest is a must to confirm optimum positioning of the catheter.

Femoral Vein Cannulation

Femoral vein catheters fell into disfavor in the 1950s because of early references to high catheter infection rates.[11] The report by Shaldon and others[12] brought this site to favor during the 1960s, and currently it is regarded as relatively safe. The femoral vein is an easy site to cannulate, although

TABLE 35-3. Advantages and Disadvantages of Different Types of Central Venous Access

ADVANTAGES/DISADVANTAGES	CIVC	TSC	PICC
Complexity of placement	Moderate	High	Low
Time needed for insertion	Moderate	High	Low
Recommended dwell time	Days	Weeks to months	Weeks to months
Infection rate	High	Low	Low
Complexity of complications	High	High	Low
Complication rate	Moderate	Moderate	Low
Possibility for central pressure monitoring	Yes	No	No
Possibility of bolus injection & fluid resuscitation	Yes	Yes	No
Use in ambulatory/home care setting	No	Yes	Yes
Cost	Moderate	High	Low
Patient tolerance	Moderate	High	High

CIVC, centrally inserted venous catheters; TSC, tunneled silicone catheters; PICC, peripherally inserted central catheters.

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TABLE 35-4. Indications and Contraindications of PICC

INDICATIONS	CONTRAINDICATIONS
Difficult IV access	Skin lesion at or above the insertion site
Long-term (> 7 d) IV antibiotic therapy	Previous ipsilateral venous thrombosis
Hyperalimentation	High fluid volume infusion
Chemotherapy	Rapid bolus IV injection
Continuous narcotic infusion	Hemophoresis/hemodialysis
Hyperosmolar fluid infusion	Crutch walking*
Long-term rehydration	Mastectomy*
Long-term IV access in patients with coagulopathy	Presence of pacemaker wires*

PICC, peripherally inserted central catheters; IV, intravenous.
*Denotes relative contraindication.

it also has the disadvantage of requiring longer catheters to pass the diaphragm. Femoral venous cannulation during resuscitation should be reserved for instances in which attempts for cannulation of other sites have failed.[13]

Humans manifest congenital abnormalities of femoral vascular structures, although most patients possess the anatomic relationships represented in Figure 35-1. In patients with a palpable femoral arterial pulse, the vein can be located by probing just medial to the artery, one third of the way from the pubic tubercle toward the anterior superior iliac spine.

Basic equipment required for central venous cannulation should be assembled (see Table 35-1). The site is prepared by having the patient lie flat while slightly rotating the leg ernally. Use a 20-gauge, 5- or 7.5-cm (2- or 3-inch) needle directed toward the vein at an angle 45 degrees above the skin. Withdraw the syringe plunger continuously while advancing the needle. The distal tip should not traverse cephalad to the inguinal ligament to avoid retroperitoneal hematoma.

Once venous blood is obtained, repeat the procedure with a larger needle through which an appropriate J-tipped guidewire can be passed. An alternative method is to use an 18-gauge catheter over a 20-gauge needle, in which case the catheter is slid into the vein. If this option is used, after directing the needle toward a line more nearly parallel to the presumed axis of the vein, the needle should be advanced another 2 to 5 mm to ensure that the cannula tip is securely within the lumen.

The site should be appropriately dressed, and documentation should be completed in the chart. A radiograph is usually not taken because tip placement is reasonably assured to be correct if venous blood can be withdrawn easily. Inadvertent arterial puncture and local hematoma formation can be obviated by placing a 2- to 4.5-kg (5- to 10-lb) sandbag on the hematoma site for approximately 30 minutes.

Be sure to secure the dressing so that urine and fecal contamination does not occur. Transparent dressings are ideal for such purposes. Standard adhesive tape can be used to reinforce adherence of the transparent dressing to the skin, if necessary. The dressing should always be changed enever the percutaneous entry site appears to be moist contaminated. Complications are uncommon but can include infection, local or retroperitoneal hemorrhage, thrombosis, and arteriovenous fistula formation.[14]

Internal Jugular Vein Cannulation

Percutaneous cannulation of the internal jugular vein (IJV) has evolved over the last two decades.[15] Currently it is the urgent elective and emergency central venous approach preferred by most anesthesiologists and many intensivists (Table 35-5). The merits and disadvantages of IJV cannulation are always relative and must be weighed against the merits and disadvantages of other central vascular approaches (Table 35-6).

ANATOMY. A thorough knowledge of regional anatomy is essential before attempting to cannulate the vein. The IJV usually runs beneath the belly of the sternocleidomastoid muscle immediately lateral to the carotid artery. Patients manifest a surprising variety of anatomic variations. The vein may be absent or in an unusual anatomic location, on any one side, in approximately 10% of ICU patients. Nonetheless, most ICU patients have a patent IJV on at least one side.

CANNULATION APPROACHES. Cannulation can be attempted at relatively high sites (level of the cricoid cartilage) or at lower supraclavicular sites. Higher sites have slightly lower success rates than lower sites where the vein is larger and closer to the skin; however, the high sites have negligible risk of pneumothorax or hemothorax.

In general, high sites should be attempted first, followed by lower sites. We prefer to prepare the skin from the angle of the mandible to below the ipsilateral nipple. This approach gives the operator abundant options for cannulation of the IJV from anterior, central, posterior, and clavicular approaches.

TECHNIQUE. The IJV usually runs deep to the sternocleidomastoid muscle. It can be approached high or low from three directions: anterior to the sternocleidomastoid muscle, centrally between the bellies of the sternocleidomastoid, or posterior to the sternocleidomastoid (Fig. 35-2). These three approaches are illustrated at the level of the cricoid cartilage. Similar needle orientations are used for lower approaches near the clavicle.

The following steps are recommended:

1. Patient and equipment are prepared.
2. The patient should be flat or slightly hyperextended

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53

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American Heart Association℠
Fighting Heart Disease and Stroke

Textbook of Advanced Cardiac Life Support

Editor

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54

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Contents

1 Essentials of ACLS

Introduction 1-1
Core ACLS Concepts 1-2
The Primary-Secondary Survey Approach to Emergency Cardiac Care 1-4
The Universal Algorithm for Adult ECC 1-10
Ventricular Fibrillation/Pulseless Ventricular Tachycardia Algorithm 1-15
Pulseless Electrical Activity (PEA) Algorithm 1-21
Asystole Treatment Algorithm 1-23
Emergency Cardiac Care for Adults Not in Full Cardiac Arrest 1-27
Bradycardia Treatment Algorithm 1-28
Tachycardia Treatment Algorithms 1-32
Hypotension/Shock/Acute Pulmonary Edema 1-40
Acute Myocardial Infarction 1-47
Special Resuscitation Situations 1-58
Pediatric Advanced Life Support 1-60
ACLS Code Organization 1-69
CPR: The Human Dimension. The Psychological Aspects of CPR and Resuscitation 1-70
Ethical Aspects of Emergency Cardiac Care 1-71
Summary: Ten Commandments for ACLS 1-71

2 Adjuncts for Airway Control, Ventilation, and Oxygenation

Overview 2-1
Airway Control: Head and Jaw Position 2-1
Airway Adjuncts 2-2
Endotracheal Intubation 2-3
Administering Supplemental Oxygen 2-7
Techniques for Oxygenation and Ventilation 2-8

3 Arrhythmias

Causes of Cardiac Arrhythmias 3-1
The Electrocardiogram: Key to Interpreting Arrhythmias 3-1
Monitoring Systems 3-2
How to Identify Arrhythmias 3-3
ECG Analysis: Question 1 3-3
ECG Analysis: Question 2 3-10
ECG Analysis: Question 3 3-12
Summary of ECG Analysis 3-20
Appendix: Electrical Activity of the Heart 3-20

4 Defibrillation

Importance of Defibrillation 4-1
Overview of Defibrillators 4-3
Special Situations 4-7
Importance of Automated External Defibrillation 4-8
Overview of Automated External Defibrillators 4-8
Use of Automated External Defibrillators During Resuscitation Attempts 4-10
Postresuscitation Care 4-14
Maintaining Defibrillators in a State of Readiness 4-15
Training 4-19
Medical Control 4-19
Quality Assurance 4-20

5 Emergency Cardiac Pacing

Indications for Pacing 5-1
Contraindications to Cardiac Pacing 5-2
Transcutaneous Pacing 5-2
Transvenous Pacing 5-6
Other Pacing Techniques 5-7

6 Intravenous Techniques

Guidelines for Vascular Access: Choice of a Particular Approach 6-1
Intravenous Cannulas 6-2
General Principles of IV Therapy 6-3
Complications Common to All IV Techniques 6-3
Peripheral Veins 6-3
Femoral Veins 6-6
Internal Jugular and Subclavian Veins 6-7

7 Cardiovascular Pharmacology I

Overview: ACLS Pharmacology 7-1
Oxygen 7-1
Epinephrine 7-2
Atropine 7-4
Lidocaine 7-6
Procainamide 7-8
Bretylium 7-9
Verapamil and Diltiazem 7-11
Adenosine 7-13
Magnesium 7-14
Sodium Bicarbonate 7-14
Morphine 7-16
Calcium Chloride 7-16

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55

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8 Cardiovascular Pharmacology II

"Clinical" Pharmacology 8-1
Cardiovascular Adrenergic Receptors 8-1
Norepinephrine 8-2
Dopamine 8-3
Dobutamine 8-5
Isoproterenol 8-6
Amrinone 8-6
The Tapering of Vasoactive Drugs 8-7
Digitalis Glycosides 8-7
Sodium Nitroprusside 8-8
Nitroglycerin 8-9
β Blockers: Propranolol, Metoprolol, Atenolol, and Esmolol 8-11
Furosemide 8-12
Thrombolytic Agents 8-13

9 Myocardial Infarction

Clinical Presentation 9-1
General Management Approaches 9-2
Management of Arrhythmias and Heart Rate 9-3
Management of Abnormal Blood Pressure Responses in Myocardial Infarction 9-6
Management of Heart Failure in Acute Myocardial Infarction 9-6
Other Causes of Hemodynamic Collapse to Be Distinguished From Acute Infarction 9-8
Special Therapeutic Considerations 9-9
Thrombolytic Therapy 9-10

10 Special Resuscitation Situations

Stroke 10-1
Hypothermia 10-10
Near-Drowning 10-12
Cardiac Arrest Associated With Trauma 10-13
Electric Shock and Lightning Strike 10-15
Cardiac Arrest Associated With Pregnancy 10-17
Toxicologic Cardiac Emergencies 10-18

11 Adjuncts for Artificial Circulation

Alternative CPR Techniques 11-1
Mechanical Aids for CPR 11-2
Invasive CPR 11-3
Assessment of CPR 11-5

12 Invasive Monitoring Techniques

Introduction to Arterial Cannulation 12-1
Arterial Cannulation Sites, Techniques, and Complications 12-5
Bedside Pulmonary Artery Catheterization 12-13
Arterial Puncture 12-26

13 Invasive Therapeutic Techniques

Pericardiocentesis 13-1
Tension Pneumothorax 13-4

14 Cerebral Resuscitation: Treatment of the Brain After Cardiac Resuscitation

Pathophysiology 14-1
Brain-Oriented Treatment of the Patient After Resuscitation From Cardiac Arrest 14-2

15 Ethical Aspects of CPR and ECC

Ethical Principles and Guidelines 15-1
Initiating and Discontinuing Resuscitation in the Prehospital Setting 15-3
Resuscitation and Life Support in the Hospital 15-5
Role of Hospital Ethics Committees 15-7
Legal Considerations in CPR and ECC 15-7

16 Community Approach to ECC: Prevention and the Chain of Survival

Magnitude of the Problem 16-1
Prospects for the Future 16-2
The Responsibility to the Future 16-4
Ensuring Effectiveness of Communitywide Emergency Cardiac Care 16-4

Index I-1

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54

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Using Peripheral Veins for IV Therapy

Advantages

The technique is easy to master. Antecubital vein cannulation usually provides an effective route for the administration of drugs during cardiac arrest so that central cannulation or intracardiac injection may be unnecessary. If basic life support measures are under way, antecubital vein catheterization does not interfere with continuing ventilation and chest compression.

After administration of a drug during CPR, raise the arm and give at least a 20-mL bolus of IV fluid to facilitate delivery of the drug into the central circulation. Allow 1 to 2 minutes for agents to reach the central circulation.

Disadvantages

In circulatory collapse it may be difficult or impossible to establish access from a peripheral vein. Recent studies have demonstrated a significant delay in the arrival of a drug at the heart when peripheral IV sites are used for injection even during effective chest compression.[10,11] Compared with drugs given via a central vein, drugs administered via peripheral veins reach a lower peak concentration and take longer to reach the central circulation.[10,12] Hypertonic or irritating solutions should not be administered through a peripheral vein because pain and phlebitis will result. Even if isotonic solutions are used, the incidence of phlebitis is high if the long saphenous vein is used.

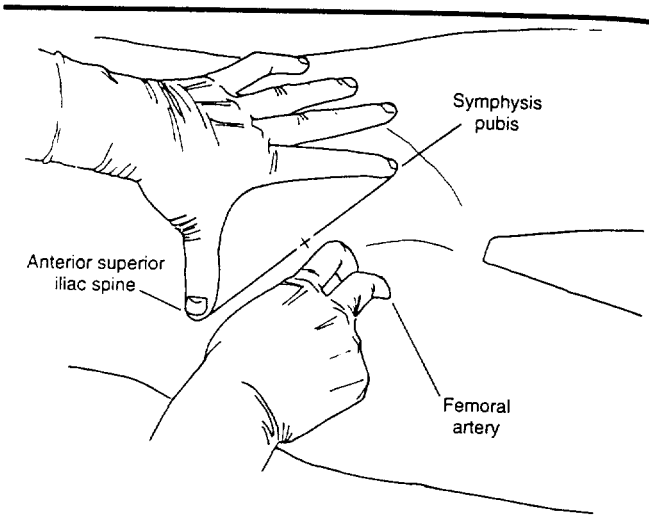

Fig 10. Femoral artery runs directly across the midpoint of line drawn between anterior superior iliac spine and symphysis pubis.

Femoral Veins[7,8]

The femoral vein lies in the femoral sheath, medial to the femoral artery immediately below the inguinal ligament. If a line is drawn between the anterior superior iliac spine and the symphysis pubis, the femoral artery runs directly across the midpoint; medial to that point is the femoral vein. If the femoral artery pulse is palpable, the artery can be located with a finger and the femoral vein will lie immediately medial to the pulsation (Fig 10). During CPR palpable pulsations may represent femoral venous pulsations. Hence, if the vein cannot be located medial to the pulsations, aspiration at the area of the pulsations should be attempted. (If a pulse cannot be felt with cardiac compression, the CPR team should be informed.)

The femoral vein is formed from both the deep and superficial (saphenous) veins of the legs. It extends above the inguinal ligament as the external iliac and becomes the common iliac after being joined by the internal iliac. Both common iliacs join to become the inferior vena cava (Fig 11).

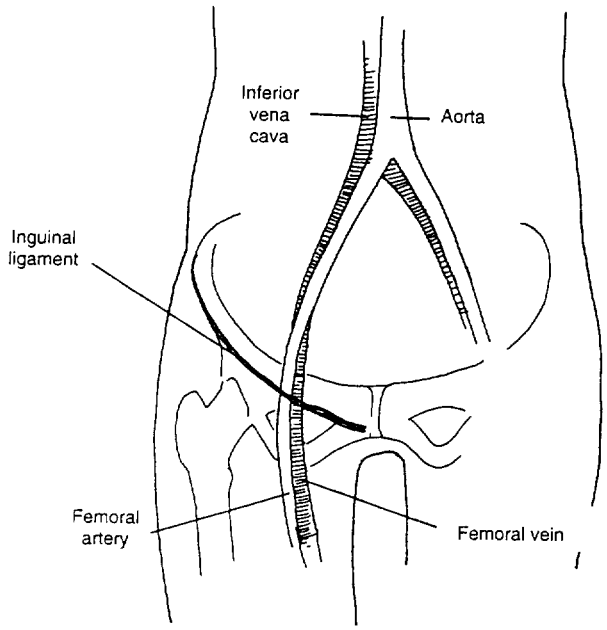

Fig 11. Anatomy of femoral vein. Femoral vein lies medial to femoral artery below inguinal ligament.

Technique

The steps for initiating IV therapy using the femoral vein follow. Although not described in this section, the Seldinger technique is commonly used in this approach.

1. Cleanse the overlying skin with povidone-iodine *when time permits.* When the procedure is elective, clip (do not shave) pubic hair and sterilely prep and drape the area.
2. Locate the femoral artery by its pulsation or Doppler flowmeter tones or by finding the midpoint of a line drawn between the anterior superior iliac spine and the symphysis pubis.
3. Infiltrate the skin with lidocaine if the patient is awake.
4. Make the puncture with the needle attached to a 5- or 10-mL syringe the breadth of two fingers below the inguinal ligament, medial to the artery, directing the needle cephalad at a 45° angle with the skin or

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57

frontal plane (some prefer to enter at a 90° angle) until the needle will go no farther (Fig 12).

5. Maintain suction on the syringe and pull the needle back slowly until blood appears in the syringe.
6. Lower the needle more parallel to the frontal plane and confirm placement and advance the catheter (if an over-the-needle device) or remove the syringe and insert the catheter (if a through-the-needle device).
7. The catheter is best secured with suture ligature.

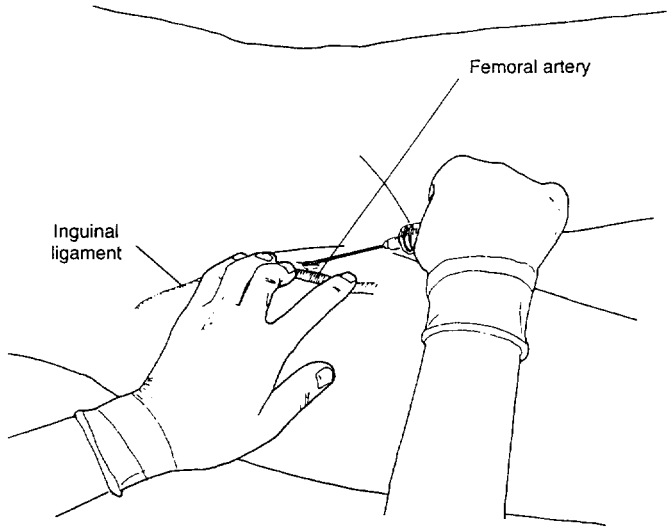

Fig 12. Femoral venipuncture.

Using the Femoral Vein for IV Therapy

Advantages

Interruption of basic life support is unnecessary for femoral cannulation. The femoral vein can be entered when more peripheral veins are collapsed. Once the femoral vein is cannulated, a long catheter can be passed above the diaphragm into the central circulation. Do not use the femoral vein for drug administration during cardiac arrest unless a long catheter that passes above the diaphragm is used.

Disadvantages

Easy location of the vein depends on the presence of the femoral artery pulse; in the absence of an arterial pulse, successful cannulation during CPR is difficult.[13,14] During CPR, venous backflow causes femoral vein pulsations; unsuccessful attempts to cannulate the vein medial to the pulsations should lead to a more lateral approach. Venous return from below the diaphragm is diminished during CPR, and drug delivery times to the central circulation are similar for femoral and peripheral routes.[12,15] For this reason long catheters advanced into the thoracic cavity and large quantities of flush solution are recommended if this technique is used during CPR.

Specific Complications

Hematoma may occur, either from the vein itself or from the adjacent femoral artery. Thrombosis and phlebitis may extend not only to the deep veins but also proximally to the iliac veins or the inferior vena cava. When this occurs, use of the femoral vein may preclude the later use of the saphenous vein.

Inadvertent cannulation of the femoral artery during cardiac arrest may not be recognized since femoral arterial pressure and oxygen tension may be so low that the aspirated blood resembles venous blood. Infusion of a potent vasopressor such as epinephrine into the femoral artery may cause ischemic injury to the involved limb.

Internal Jugular and Subclavian Veins

Anatomy: Internal Jugular Vein[7,8] (Fig 13)

The internal jugular vein emerges from the base of the skull, enters the carotid sheath posterior to the internal carotid artery, and runs posteriorly and laterally to the internal and common carotid artery. Finally, near its termination, the internal jugular vein is lateral and slightly anterior to the common carotid artery.

The internal jugular vein runs medial to the sternomastoid muscle in its upper part, posterior to it in the triangle between the two inferior heads of the sternomastoid in its middle part, and behind the anterior portion of the clavicular head of the muscle in its lower part, ending just above the medial end of the clavicle, where it joins the subclavian vein.

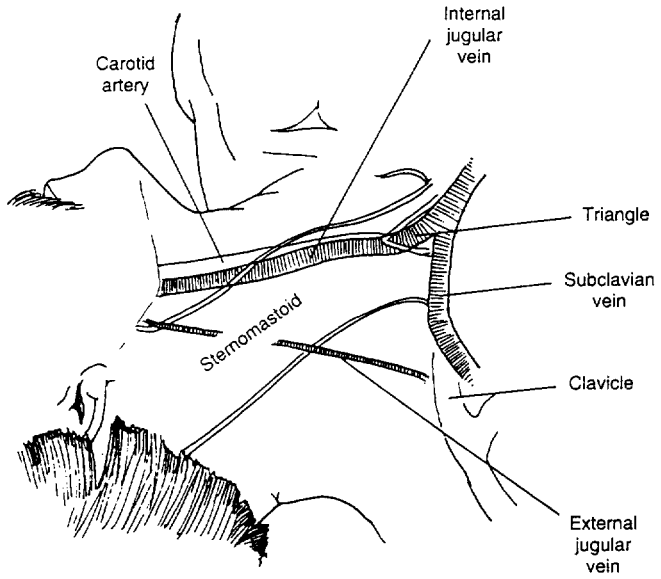

Fig 13. Anatomy of internal jugular vein.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs and
Quality Assurance
Arrow International, Incorporated
3000 Bernville Road
Reading, Pennsylvania 19605

OCT 17 1997

Re: K970864
Trade Name: Arrow-Howes Large Bore Multi-Lumen Central Venous Catheters
Regulatory Class: II
Product Code: FOZ
Dated: July 21, 1997
Received: July 22, 1997

Dear Mr. Nickel:

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 (Premarket 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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

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

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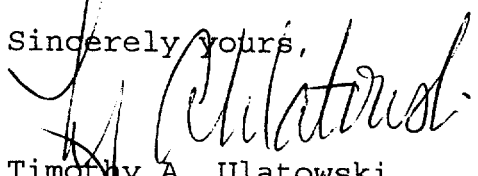
not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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

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

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P.O. Box 12888
Reading, PA 19612

ARROW
INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

K 970864: Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheters

Section 11 - Indications

The large bore multiple lumen catheter permits venous access to a central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, or femoral veins. The heparin coating on the catheter intended to decrease the incidence of thrombus formation associated with catheterization.

97021

X Prescription Use

Viola Hillard for Katherine Cicenti
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970864

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

3

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) William M. Burdick

Subject: 510(k) Number K970864/S2

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ 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

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 N/A

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

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

80 FOZ, Class II
880.5200 - Intravascular Catheter

Review: Yuk Hilmal for Pat Cheuvront GHDB 10/17/97
(Branch Chief) (Branch Code) (Date)

Final Review: 10/17/97
(Division Director) (Date)

Revised: 11-20-96

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

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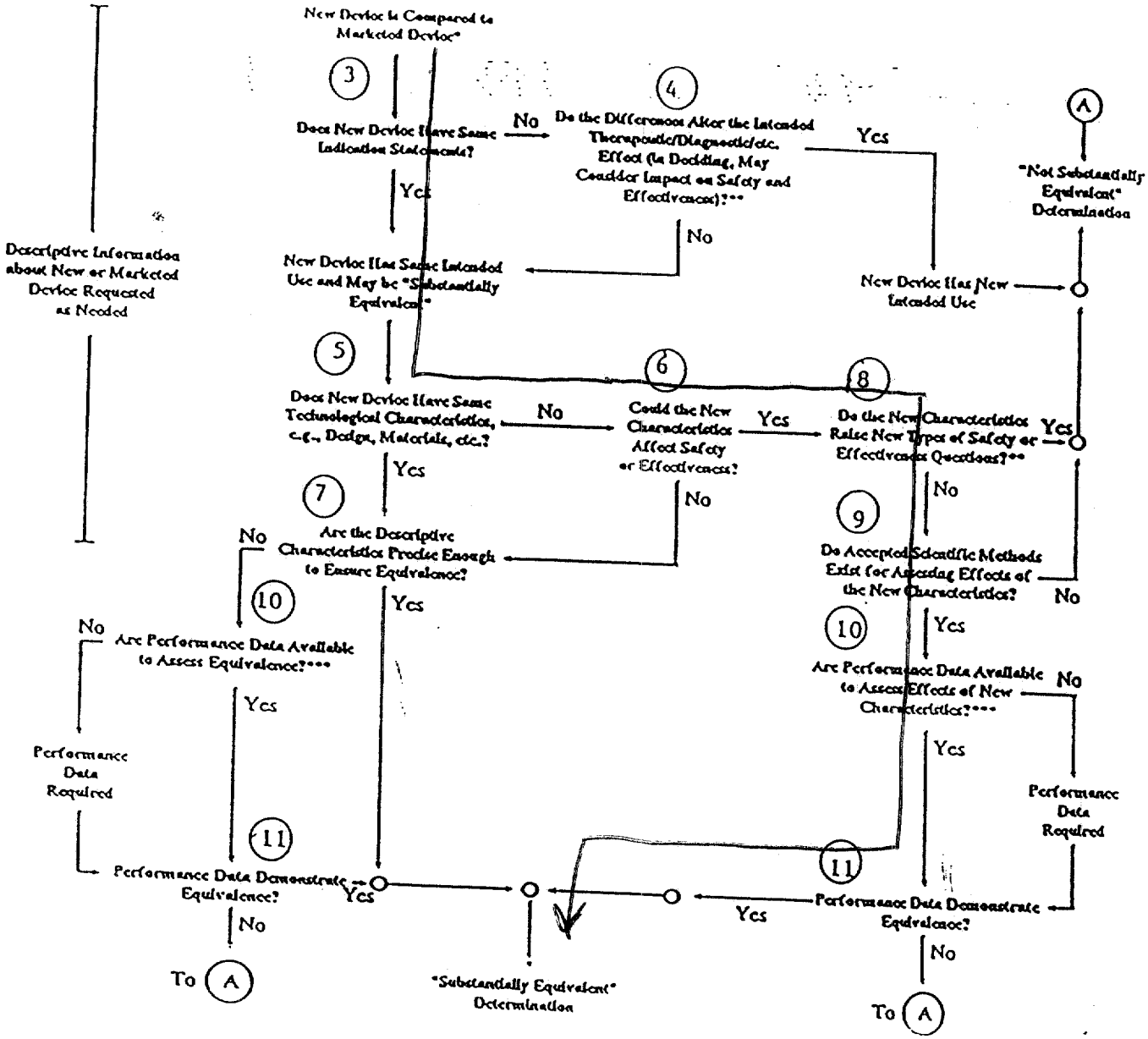
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** 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.

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

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K970864

Reviewer: William M. Burdick

Division/Branch: DDIGD/GHDB

Device Name: Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheter

Product To Which Compared (510(K) Number If Known): Please refer to 3L of attached "510(k) REVIEW".

	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?	X		If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?	Yes		If **NO** = Stop **NE**
10. Performance Data Available?	Yes		If **NO** = Request Data
11. Data Demonstrate Equivalence?	Yes		Final Decision: SE

(Continued on Next Page.)

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

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1. *Intended Use*: Please refer to #2 of attached "510(k) REVIEW".

2. *Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.*

Please refer to #1 of attached "510(k) REVIEW".

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. *Explain why not a device*: N/A

2. *Explain why not subject to 510(k)*: N/A

3. *How does the new indication differ from the predicate device's indication*: N/A

4. *Explain why there is or is not a new effect or safety or effectiveness issue*: N/A

5. *Describe the new technological characteristics*: Please refer to 3N of attached "510(k) REVIEW".

6. *Explain how new characteristics could or could not affect safety or effectiveness*: Please refer to 3N of attached "510(k) REVIEW".

7. *Explain how descriptive characteristics ar not precise enough*: N/A

8. *Explain new types of safety or effectiveness questions raised or why the questions are not new*: Please refer to 3N of attached "510(k) REVIEW".

9. *Explain why existing scientific methods can not be used*: N/A

10. *Explain what performance data is needed*: N/A

11. *Explain how the performance data demonstrates that the device is or is not substantially equivalent*: Please refer to 3N of attached "510(k) REVIEW".

ATTACH ADDITIONAL SUPPORTING INFORMATION

Please refer to the attached "510(k) REVIEW".

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

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MEMO TO THE RECORD

510(K) REVIEW

K970864

DATE: October 10, 1997
FROM: William M. Burdick DIVISION:DDIGD/GHDB

COMPANY NAME: Arrow International, Inc.
DEVICE NAME: Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheter

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The principal subject of this 510(k) is a short-term, nonpyrogenic, sterilized (EtO), single use, three lumen, polyurethane (P/U), central venous catheter. The catheter is to be sold as a single unit or in kit form, either with drugs or without. **All of the kit components are certified as being legally marketed medical devices.**

This device has a long and rather interesting history. In January 1991, Arrow decided that they would like to add a third lumen to their two lumen hemodialysis catheter (K895417) for the infusion of medications or the withdrawal of blood. They determined that the addition would neither be a safety nor effectiveness issue and wrote a letter to their master file to this effect. In December 1991, a field investigator from the Philadelphia district stated that the letter to the file was adequate. In 1994, counsel was sought from CDRH and the opposite conclusion was reached, forcing the company to submit a 510(k) to the hemodialysis group in ODE. Eventually, a reviewer with the hemodialysis group consulted with me regarding the requirements of an intravascular catheter. Their determination for the need of clinical results concerning infection rate influenced Arrow to seek substantial equivalence solely as an intravascular catheter.

The catheter has a unique design for a three lumen vessel. Unlike other three lumen intravascular catheters, one of the lumens is a cylindrical conduit inscribed between two conduits having D-shaped lumens; therefore, the walls of the inner lumen are not visible to the naked eye. This poses a testing problem. Fracture of the inner lumen can not be visibly detected, and Arrow has defined mechanical strength failure of the catheters to be fracture of the outer lumens. Given that the walls of the inner conduit are thinner than the walls of the external ones, this issue is a legitimate one. Arrow did not completely address this issue in their May 1, 1997, response to my November 28, 1996, request for additional information. On July 2, I called Mr. Nickel concerning this issue. His response was dated July 23, 1997. Mr. Nickel did provide results from burst and flexural fatigue testing which provided a reasonable assurance that the inner conduit would not fail prior to a detectable failure of the external catheter. What was left unanswered was whether a tensile failure would be detected. (b) (5) [redacted]

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

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(b) (5) [redacted]. I considered questioning Mr. Nickel on this but decided to check the MDRs and PRPs for Arrow's peritoneal and regular dialysis catheters (similar design), first. There were no reported problems with any of their dialysis catheters. Due to the lack of reported safety concerns as well as the acceptable results for the other mechanical strength tests, I decided to accept their results as reported.

The rest of the catheter description is as follows. Each catheter is a twelve french with two 12 gauge and one 16 gauge extensions for the outer and inner lumens, respectively. The extensions are fabricated from Pellethane P/U and are encircled with polycarbonate or acetyl pinch clamps. The manifold which connects the extensions to the central tube is fabricated from Tecoflex P/U, as well as the central tube and tip. The ink-marked, central tube is either 16 or 20 inches in length, with two holes staggered along its length and the third hole passing through the tip. Screw-on injection sites with latex septums "cap off" each extension hub (please refer to telephone memo dated 7/2/97).

As mentioned above, Arrow intends to market their product either as a kit, as a set (kit without drug components), or solely as a catheter. Please refer to the attached for a list of possible components, a description of the ten products to be offered in the three different forms, and the kit certification. Arrow also intends to market the catheter in both a coated and uncoated form. The coating is heparin, and Arrow cited some heparin-coated catheters which they have legally marketed; however, these heparin-coated catheters, which Arrow claims to be substantially equivalent to this three-lumen catheter, are not classified as intravascular catheters but as cardiovascular and hemodialysis catheters. Originally, [redacted] additional information presented by Arrow and FDA consults (please refer to the response from Mr. Nickel dated 7/23/97 and my memo the record dated 10/10/97) has reduced much concern over the potential for adverse reactions between heparin and other infusates.

Briefly mentioned in the first paragraph is that all products will be provided sterile and that sterilization will be by ethylene oxide. Validation of the sterilization cycle to a SAL of 10^{-6} will be according to ANSI/AAMI ST27-1988. Arrow assures that residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol will not exceed the FDA proposed limits of 25, 25, and 250 parts per million, respectively.

2. INTENDED USE:

This catheter is intended to permit venous access to the central venous circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, or femoral veins. The heparin coating on the catheter is intended to decrease the incidence of thrombus formation associated with catheterization.

3. DEVICE DESCRIPTION:

A. Life-supporting or life-sustaining: No
B. Implant (short-term or long-term): Yes
C. Is the device sterile? Yes
If yes, is sterility information provided? Yes

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D. Is the device for single use? Yes
E. Is the device for prescription use? Yes
If yes, is prescription labeling included? Yes

F. Is the device for home use or portable? yes

G. Does the device contain drug or biological product as a component? Yes

H. Is this device a kit? Yes (also offered as a single unit)
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent? Yes

I. Software-driven: No

J. Electrically Operated: No

K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): No

L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: **Infuse-a-Cath™ Triple Lumen Silicone Catheter Systems (K945956)** by Strato Medical Corporation.

M. Submission provides comparative specifications? No
comparative in vitro data? No
performance data? Yes
animal testing? No
clinical testing? No
biocompatibility testing? Yes

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The following is a comparison of the relative similarities and differences between the two devices:

CHARACTERISTIC	Strato	Arrow
INTENDED USE	Same	Same
# OF LUMENS	3	3
INFUSION SITES	Central Vein	Same
LENGTH OF INFUSION	Long-Term	Short-Term
RADIOPAQUE?	Yes	Yes
RADIOPAQUE MATERIAL	Barium Sulfate	Same
CATHETER TUBE MATERIAL	Silicone	Same
EXTENSION MATERIAL	Silicone	Polyurethane

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

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CATHETER LUMEN SIZES 11.5 Fr 12.0 Fr

No new issues of safety or effectiveness exist for this device.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

P. RECOMMENDATION:
I believe that this device is equivalent to: 80 FOZ

Classification should be based on:

880.5200 - Intravascular Catheter Class: II

William M. Burdick
Biomedical Engineer

- Attachments

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

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ARROW

International, Inc.
2400 Bernville Road
Reading, PA 19605 USA
610/478-3137
FAX: 610/478-3172

PLEASE DELIVER THE FOLLOWING PAGE(S) TO:

NAME: Viola Hibbard - CDRH - 301/594-2358

FROM: Thomas D. Nickel

RE: K970864 - Our phone discussion of 10/16/97

DATE: October 16, 1997

Total number of pages including cover letter 3

The revised 510(k) summary is attached.

Regards.

Tom Nickel

Tom Nickel

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

12

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510(k) SUMMARY - K970864

Submitter:

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605

Contact Person: Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
610/478-3137

Date summary prepared - 10/16/97

Device:

Trade Name - Arrow-Howes™ Large Bore Multi-lumen central venous catheter

Common Name - Central venous catheter

Classification Name - Catheter, intravascular, 80FOZ, and 21 CFR 880.5200, Intravascular catheter

Legally marketed device to which the device is substantially equivalent:

Various Arrow central venous catheters; specifically K820648, K844080, K862056, and K895417

Description of device:

The device is a triple-lumen polyurethane catheter, 12 French in size, with three extension lines, luer hubs, and clamps. It is essentially the same in appearance and function to the Arrow multi-lumen predicate catheters except for the larger size to accommodate rapid fluid administration in emergency critical care situations in the hospital.

Intended use of the device:

The intended use and indications for use are comparable to the predicate devices, and appear below:

"Indications for use:
The large-bore multiple lumen catheter permits venous access to a central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, and femoral veins. The heparin coating on the catheter intended to decrease the incidence of thrombous formation associated with catheterization."

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

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Technological characteristics:

The device has the same exact technological characteristics as the predicates, with the only difference being the larger size and accompanying greater fluid flow rates.

The performance tests included in the submission include:

1. Flow rate
2. Tensile test
3. Pressure leak test
4. Positive pressure burst test
5. Biocompatibility tests
6. Flex (fatigue) test

No clinical testing was performed.

The results of the laboratory tests demonstrated that the device is safe, and as effective as the legally marketed predicate devices.

97095

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

To: Thomas D. Nickel
Fax #: 610/478-3137
Re: K970864
Date: October 16, 1997
Pages: 5, including this cover sheet.

Please revise 510(k) Summary according to §807.92.

Thank you, Viola

From the desk of...

Viola S. Hibbard

Nurse Consultant
FDA/ODE/DDIGD/GHDB
9200 Corporate Blvd.
Rockville, MD 20850
Phone: (301) 594-1287
Fax: (301) 594-2358

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

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~~SECTION 9 - TRUTHFUL AND ACCURATE STATEMENT:~~

~~I certify that in my capacity as Vice President, Regulatory Affairs and Quality Assurance of Arrow International, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.~~

~~Thomas D. Nickel~~
March 6, 1997

Section 10 - Kit Component Listing and Certification

The "product" includes kit and set versions as listed in Attachment 1, and the General Hospital required component information is as follows.

Qty.	Component	Present In		Drug	Purchased bulk non-labeled, non-sterile	Arrow Mfg'd component	Purchased labeled, non-sterile
		Kits	Sets				
1	.035" dia spring wire guide	Y	Y			X	
1	vessel dilator	Y	Y			X	
1	25 ga. X 1" needle	Y			X		
1	22 ga. X 1" needle	Y				X	
1	18 ga. X 2 1/2" introducer needle	Y	Y			X	
1	18 ga. X 2 1/2" Radiopaque catheter over 20 ga. needle	Y	Y			X	
1	3 cc syringe	Y			X		
1	5 cc syringe	Y			X		
1	5 cc Arrow Raulerson syringe	Y	Y			X	
1	pressure transduction probe	Y	Y			X	
1	fenestrated drape	Y			X		
2	2" X 2" gauze pads	Y			X		
5	4" X 4" gauze pads	Y			X		
3	Povidone-Iodine swabsticks	Y		X			
1	Povidone-Iodine ointment 1gm	Y		X			
1	Lidocaine HCl, 5ml 1% ampule	Y		X			
1	Sharpsaway™ disposal cup	Y				X	
1	disposable scalpel (#11 blade)	Y			X		
1	suture: 3-O silk w/straight needle	Y					X
4	Usergard™ hubs	Y	Y			X	
4	Usergard™ injection caps	Y	Y			X	
1	catheter clamp w/fastener	Y	Y			X	
1	CSR wrap	Y			X		
4	extension line clamps	Y	Y			X	

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

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~~Certification~~ Kit Certification

I certify that all of the medical components of the subject kit or set, are either ① legally marketed preamendment devices, ② exempt from premarket notification (consistent with the exemption criteria described in the classification regulations and the limitations of exemptions from Section 510(k) of the Act (e.g., 21 CFR 862.9), or ③ have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is intended (i.e., not claiming or causing a new use for the component(s).

I further certify that we purchase all device components either in packaged and labeled form consistent with their preamendments, exemption, or premarket notification criteria and status, or as bulk non-labeled and non-sterile components, also consistent with their preamendments, exemption, or premarket notification criteria and status. The details per component appear in the chart above. In addition, all purchased drug components are also packaged and labeled consistent with their approval.

Both kit and set versions of the device utilize packaging which consists of a vacuum formed tray and Tyvek lid. All components are placed in the tray, it is sealed, packed in corrugated shipping cartons, and EtO sterilized. No components are "reprocessed" as a result of the sterilization. The drug components are either foil pouches impermeable to EtO, or glass ampules impermeable to EtO. Therefore, final processing of the kit has no effect whatsoever regarding the functionality (i.e., safety and effectiveness) of any kit components.

Note that the set labeling is identical to the kit labeling except the set lidstock lists fewer components.

(051a)

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

11

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Product Description

of the following products are 12 French multi-lumen (3-lumen) central venous catheters for n volume infusions. They exist as kits, sets, and single catheters in varying lengths, as lined below:

theter length	Kit	Set	Individual Catheter	Product Number
cm	X			AK-12123-H*
cm		X		CS-12123-E
cm		X		CS-12123-F
cm			X	MC-12123
cm	X			AK-12123-F
cm	X			AK-15123-H*
cm	X			AK-15123-F
cm		X		CS-15123-E
cm		X		CS-15123-F
cm			X	MC-15123

eparin coated

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

MEMORANDUM TO THE RECORD

DATE: October 10, 1997

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DDIGD/GHDB
HFZ-480
9200 Corporate Blvd.
Rockville, MD 20850

SUBJECT: 510K Number K970864 - Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheter

On July 2, 1997, I wrote a letter to Mr. Nickel requesting additional information. His response, dated July 23, 1997, answered the questions (briefly summarized below) as follows:

1. **Provide assurances that a mechanical strength failure of the inner circumscribed channel will be detected:** Mr. Nickel did provide results from burst and flexural fatigue testing which provided a reasonable assurance that the inner channel would not fail prior to a detectable external channel failure. What was left unanswered was whether a tensile failure would be detected. I do not know whether the fact that this question not being addressed was an oversight or a deliberate omission. I considered questioning Mr. Nickel on this but decided to check the MDRs and PRPs for Arrow's peritoneal and regular dialysis catheters (similar design), first. There were no reported problems with any of their dialysis catheters. Due to the lack of reported safety concerns as well as the acceptable results for the other mechanical strength tests, I decided to accept their results as reported.

2. **Provide assurances that the heparin coating is compatible with the substances (e.g., TPN, chemotherapeutics) normally infused through intravascular catheters.** Ronald Citron, a Senior Research Scientist, stated in a document to Mr. Nickel that he performed an extensive search through Internet medical and scientific data bases and did not identify any incidences of adverse drug or TPN interactions with heparin. He also stated that he had contacted FDA concerning heparin coatings and catheters and was informed that using the heparin coating at the manufacturer's recommended level would be harmless to the patient. Mr. Citron stated that Arrow's heparin coatings were actually at only 25% of the manufacturer's recommended concentration. Finally, I consulted with Ron Pytel, a FDA pharmacist. Mr. Pytel informed me, after looking through a

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

couple of standard texts of drug interactions , that although interactions are highly dependent on the composition of the TPN or chemotherapeutic, etc., his research did not uncover any safety issues (some did lower the thromboresistance of the coated substance) concerning heparin, TPN, or other pharmaceuticals.

3. Verify that intravascular catheters my be inserted through the femoral vein. Both Arrow personnel and individuals in the FDA with whom I discussed this issue have stated that the femoral vein is a potential site for intravascular catheters during emergency situations or when central or antecubital sites are not viable.

Sincerely,

William M. Burdick

William M. Burdick
Biomedical Engineer

cc. K970864
CHRON file

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/23/2018

K970864

Certified Mail

P.O. Box 12888
Reading, PA 19612

ARROW
INTERNATIONAL

2400 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

July 23, 1997

Center for Devices and Radiological Health
Document Mail Room HFZ-401
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RECEIVED
25 JUL 97 11 12
FDA/CDRH/ODE/DMC

Re: 510(k) Premarket Notification K970864
Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheters
- Request for additional information of 7/2/97

Dear Mr. Burdick:

Pursuant to our phone discussion of July 2, 1997, we are providing the following additional information you requested.

Item 1

You voiced concerns about the potential for the inner lumen walls to crack during application of stress or pressure during use, which could go unnoticed by the user since the fracture could be invisible to observation of the exterior surface of the catheter. You were interested in how we could tell if the inner lumen fails prior to the external wall of the catheter.

Response

I discussed your concerns with the project engineer responsible for the 12 French 3-lumen central venous catheter product line, and his discussion is appended as Attachment 1.

In addition to his document, it should be noted that in practice we cannot recall ever having received a product complaint of an interlumen leak of a multi-lumen central venous catheter which was due to a defect in the lumen wall. We have had only rare reports of interlumen communication which, upon examination of the returned sample, have been found to be due to a juncture hub insert molding defect. We pressure test each multi-lumen catheter we manufacture for blocked lumens and interlumen leaks utilizing a calibrated automatic pressure decay tester. We have been making multi-lumen central venous catheters since 1982, which includes extrusion of the polyurethane catheter body and extension lines, and insert molding of the extension line hubs and juncture hub, and interlumen catheter failures for anything other than juncture hub molding defects have not been encountered.

SK 43

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

21

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Item 2

You asked for information regarding interaction of drugs such as TPN, chemotherapy, and pain management with the Heparin coating in the lumen of the catheter.

Response

A discussion of this subject appears in Attachment 2.

Item 3

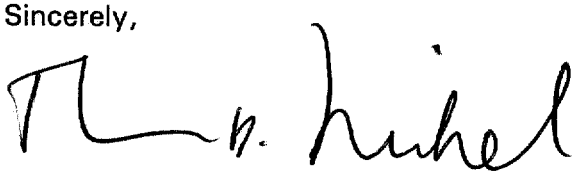
You asked that our indications statement be revised to remove the reference to femoral veins, or provide information why we want to retain it.

Response

While use of femoral veins was in disfavor at one time due to reported high infection rates associated with urine and fecal contamination, current critical care texts indicate it is considered relatively safe, and appropriate if other sites have failed, e.g. during resuscitation.

Extracts from two reference texts are appended as Attachment 3, with the appropriate discussions tabbed.

Sincerely,



Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

7050a

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ATTACHMENT 1

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

INTERNAL MEMO

ARROW
INTERNATIONAL, INC.

To: Tom Nickel

From: Paul Robertson P.R. 7/22/97

Date: July 22, 1997

Subject: 12 Fr. 3-L distal (central) lumen

I have completed the analysis of the central lumen of the 12 Fr. 3-lumen catheters and have concluded that your concern with the central lumen breaching, allowing inter-lumenal communication, is minimal. I base my conclusion on the following four points of discussion:

1. The central lumens of a ten catheter sample of two catheter types were tested at 50 psig for 60 seconds to verify that this lumen does not leak. Ten out of ten catheters of both catheter types passed as documented in *510(k) Premarket Notification K970864 - Request for additional information, Arrow-Howes Large Bore Multi-lumen Central Venous Catheters* dated May 1, 1997.
2. The central lumens of a ten catheter sample of two catheter types were tested for positive burst pressure. The central lumens of each catheter type did not fail, rather the extension lines failed at an average of 356 psig and 409 psig. This test is documented in *510(k) Premarket Notification K970864 - Request for additional information, Arrow-Howes Large Bore Multi-lumen Central Venous Catheters* dated May 1, 1997.
3. In addition to the static pressure tests (1. and 2.), I performed a dynamic fatigue test which documents the fatigue strength of the central lumen as compared to one of the larger outer lumens. The results indicate that the central lumen of both catheter versions endured more cycles than the outer lumens. These results are not surprising since flexural stresses are higher at the outer fibers (the outer edges) of a test specimen than the inner fibers. That is, the highest stress on the catheters in flexure occur furthest from the catheters' cross-sectional centers. This maximum stress is due to the higher strain (the stretching and compression) of these outer fibers. In theory, the stress at the very center of any specimen is zero and increases proportionally with the distance away from the center. The flexure formula for maximum stress is provided here for reference and is as follows:

(b) (4)

[redacted]

A more detailed test report is attached to this memo (pages 2-18) which includes the procedure, results, and raw data.

4. All lumens of all (100%) of the 12 French triple-lumen catheters are leaked tested at 15 psig as a routine manufacturing process. This detects and eliminates catheters that have manufacturing defects that cause inter-lumenal communication.

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

2h

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Flex (Fatigue) Test—a Comparison of the Central and Outer Lumens of the 12 Fr. 3-Lumen Catheter
supplement to
510(k) Premarket Notification K970864
Arrow-Howes Large Bore Multi-lumen Central Venous Catheters

Scope

This test was performed to compare the flexural (fatigue) strength of the central (distal) lumen and the outer (medial or proximal) lumen of the 12 Fr. 3-L CVC. The medial lumen was used to represent the two outer lumens. This test is designed to record the number of flexures a lumen can endure before failure, where a failure is defined as a breach in the test lumen whereby fluids can cross-over to the other lumens (i.e. an internal, hidden breach) or fluids can leak to the atmosphere (i.e. an external breach).

Procedure

The procedure used was a modification to Arrow procedure AML-060, *Flex (Fatigue) Test.* AML-060 and *Modification to Protocol AML-060* is attached as pages 3-6.

To summarize, the flex test equipment was [redacted] (b) (4) [redacted] The system was designed so that the motor that drives the flexing will stop when there is a sudden drop in pressure as detected by the pressure transducer. Any breach in the lumen is detected by way of a pressure drop from 15 psig to zero psig in the system which triggers the pressure transducer to stop the motor. The system counts the number of cycles by utilizing a digital counter and a proximity switch attached to the motor drive.

Results

The results of this flex test is summarized in the table below:

Specification	12 Fr., 3-L CVC, standard durometer, **central lumen**	12 Fr., 3-L CVC, standard durometer, **medial lumen**	12 Fr., 3-L CVC, firm durometer, **central lumen**	12 Fr., 3-L CVC, firm durometer, **medial lumen**	sample size
catheter lumen breach due to flexural fatigue	15,724 average cycles to failure	9,541 average cycles to failure	8,356 average cycles to failure	8,225 average cycles to failure	8

Raw data is attached as pages 7-19.

Conclusion

The results indicate that the central lumen of both catheter versions endured more cycles than the outer lumens. These results are not surprising since flexural stresses are higher at the outer fibers (the outer edges) of a test specimen than the inner fibers.

25

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ARROW INTERNATIONAL, INC.
FLEX (FATIGUE) TEST

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1. PURPOSE

To document the test method used to flex test catheters or extrusions.

2. SCOPE

This procedure applies to catheters or extrusions being flex (fatigue) tested.

3. RESPONSIBILITIES

(b) (4)

[redacted]

4. REQUIREMENTS DOCUMENTS

CP-4.4 "Design Control"
AMLF-027 "Flex (Fatigue) Test Results/Report"

5. PROCEDURE

(b)(4) Testing

[redacted]

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

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Copyright

[redacted]

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

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(b)(4) Testing

[redacted]

6. **APPROVALS**

Senior Materials Lab Technician Date

Senior Research Engineer Date

VP, RA/QA Date

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7. **REVISION HISTORY**

Revision	Change	Approved by:
0 4/29/97	Original issue	T. Rarick, R. Citron, T. Nickel

8. **HARD COPY DISTRIBUTION**

J. Cadd - original

9. **NOTIFICATION**

R. Citron J. Guan	T. Rarick

I:/qsdocs/corp/cp404

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REQUEST

Lab Request No.
7413

1. **Service Requested** (Only One Request Per Sheet):

   Flex (fatigue) test – medial lumen of 12 Fr. 3-L CVC

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: MC-12123-001B
   Lot Nos:
   Description: 12 Fr. 3-L CVC, standard durometer

4. **Target Date**: 7/18/97

5. **Additional Comments:**
   See attached modification to protocol AML-060. Test eight catheters to medial lumen failure.

Requestor: P. Robertson
Signature: P. Robertson 7/15/97
Date: 7/15/97

page 7

Questions? Contact FDA/CDRH/OCE/DMC/OSAS@fda.hhs.gov or 301-796-8040

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-12123-001B
Lot No.:
Description: 12 FR x 16 CM; 3-LUMEN CVC SOFT DUROMETER (MEDIAL LO
Lab Request No.: 7413
Included Angle:
Number of Cycles: Batch Setting:

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
1	(b) (4) [redacted]			
2				
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: [signature] Approval: [signature]

Date: 7-21-97 Date: 7/22/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REQUEST

Lab Request No.
2414

1. **Service Requested** (Only One Request Per Sheet):

   Flex (fatigue) test – central lumen of 12 Fr. 3-L CVC

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: MC-12123-001B
   Lot Nos:
   Description: 12 Fr. 3-L CVC, standard durometer

4. **Target Date**: 7/18/97

5. **Additional Comments:**
   See attached modification to protocol AML-060. Test eight catheters to central lumen failure.

Requestor: P. Robertson
Signature: P. Robertson 7/15/97
Date: 7/15/97

Questions? Contact FDA/CDRH/OCE/DSMICA/CDRHINFO@fda.hhs.gov or 301-796-8...

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-12123-001B
Lot No.:
Description: 12 Fr x 16cm ; 3-Lumen CVC Soft Durometer (D:5/41)
Lab Request No.: 7414
Included Angle:
Number of Cycles: Batch Setting:

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
1	(b) (4) [redacted]			
2				
3				
4				
5				
6				
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: [signature] Approval: [signature]

Date: 7-21-97 Date: 7/22/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REQUEST

Lab Request No.
7416

1. **Service Requested** (Only One Request Per Sheet):

   Flex (fatigue) test – medial lumen of 12 Fr. 3-L CVC

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: MC-35123-001A
   Lot Nos:
   Description: 12 Fr. 3-L CVC, firm durometer

4. **Target Date**: 7/18/97

5. **Additional Comments:**
   See attached modification to protocol AML-060. Test eight catheters to medial lumen failure.

Requestor: P. Robertson
Signature: P. Robertson 7/15/97
Date: 7/15/97

Questions? Contact FDA/CDRH/OCE/DMC at CDRHDMC@fda.hhs.gov or 301-796-8...

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

Records processed under FOIA Request #2015-8833 released to public on 12/8/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-35123-001A
Lot No.:
Description: 12 FR, 3-Lumen CVC - Firm Durometer (MEDIAL LUMEN)
Lab Request No.: 7416
Included Angle:
Number of Cycles: Batch Setting:

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes No	Location of Failure
1	(b)(4) Testing [redacted]		
2			
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5			
6			
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: [signature] Approval: [signature]

Date: 7-21-97 Date: 7/22/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REQUEST

Lab Request No.
7415

1. **Service Requested** (Only One Request Per Sheet):

   Flex (fatigue) test – central lumen of 12 Fr. 3-L CVC

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: MC-35123-001A
   Lot Nos:
   Description: 12 Fr. 3-L CVC, firm durometer

4. **Target Date**: 7/18/97

5. **Additional Comments:**
   See attached modification to protocol AML-060. Test eight catheters to central lumen failure.

Requestor: P. Robertson
Signature: P. Robertson 7/15/97
Date: 7/15/97

Questions? Contact FDA/CDRH/OCE/DID at ODRHFOIA@STATUS@fda.hhs.gov or 301-827-6567

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Modification to protocol AML-060

(b)(4) Protocol

[redacted]

P. Robertson, 7/15/97

7/15/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-35123-001A
Lot No.:
Description: 12 FR, 3-LUMEN CVC - FIRM DUROMETER (DISTAL LUMEN)
Lab Request No.: 7415
Included Angle:
Number of Cycles: **Batch Setting:**

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
1	(b)(4) Testing [redacted]			
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: [signature] **Approval:** [signature]

Date: 7-21-97 **Date:** 7/22/97

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

h1

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ATTACHMENT 2

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

TO: Tom Nickel

FROM: Ronald Citron

DATE: July 18, 1997

SUBJECT: Response to FDA question on 510(K) **File #K-970864**

The FDA had a question concerning the interaction of a catheter inner lumen heparin coating with infused chemotherapeutic, TPN and pain management drugs.

The specific heparin coating that is applied to the Arrow catheters is the standard, FDA accepted heparin-benzalkonium chloride coating (referred to as HBAC). This particular coating has been used in the medical device industry for over 20 years. The second FDA accepted heparin coating is the tridodecylmethylammonium chloride-heparin coating (referred to as TDMAC). This latter coating has been applied to medical devices for over 30 years.

I have not been aware of any problems using either of these coatings. In addition, catheters have traditionally been coated on both the outer surface and inner lumens. In this way, blood that flashes back into the lumen and blood that is infused does not clot and block the lumen.

I did an extensive Internet search using the Excite, Infoseek, Yahoo and Alta Vista search engines. I employed the keywords of heparin, heparin coating, drug interaction, drug interactions, benzalkonium chloride. HBAC, drug incompatibility, TPN. I used these words in different combinations. I was unable to locate even one reference to drug complications relative to any type of heparin coating. I consider this lack of response as an indication that there have not been any reported or significant drug interactions with heparin coatings.

Furthermore, Arrow International, Inc., has not had any reported incidences of interactions or safety problems with any of the heparin-coated catheters sold since the process was first applied at Arrow 14 years ago.

When I developed the heparin coating process, I used only 25% of the active heparin level recommended by the manufacturer ((b) (4) [redacted]) by using a dilution of the purchased heparin coating solution. During the original 510(K) process, I had contacted the FDA directly about the use of heparin for catheter coatings. I proceeded in accordance with the FDA recommendations. The FDA had informed me that using the heparin coating at the manufacturer's recommended level would be harmless to the patient, while affording the temporary surface thromboresistance characteristic of heparin. By proceeding with 25% of the manufacturer's recommendation, the system should be even safer for device applications. The coating process still employs the same heparin level discussed above.

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In light of the long history and broad-based usage of heparin coatings, the reduced level of heparin application used in the Arrow catheter, the absence of any reported field problems to Arrow, and the apparent lack of references relative to drug interactions and safety, Arrow International, Inc., continues to believe that the current heparin coating is completely safe.

Ronald Citron
Senior Research Scientist

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Critical Care

THIRD EDITION

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Lippincott - Raven
PUBLISHERS
Philadelphia • New York

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Acquisitions Editor: Lisa McAllister
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Indexer: Alexandra Nickerson
Compositor: Compset Inc.
Printer: Courier Book Company/Westford

Third Edition

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Library of Congress Cataloging-in-Publication Data

Critical care / [edited by] Joseph M. Civetta, Robert W. Taylor, Robert R. Kirby ; with 203 additional contributors.—3rd ed.
p. cm.
Includes bibliographical references and index.
ISBN 0-397-51527-8 (alk. paper)
1. Critical care medicine. I. Civetta, Joseph M. II. Taylor, Robert W. (Robert Wesley), 1949– . III. Kirby, Robert R.
[DNLM: 1. Critical Care. 2. Intensive Care Units. WX 218 C9334 1996]
RC86.7.C69 1996
616'.028—dc20
DNLM/DLC
for Library of Congress 96-15571
CIP

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Contents

SECTION I 1

DECISION-MAKING

Chapter 1 3

How to Read a Medical Article and Understand Basic Statistics

Joseph M. Civetta
Theodore Colton

Critical Reading of the Medical Literature 4
Fundamentals of Biostatistics in Medical Research 9
Interpretation of Study Results 14
Coda 20

Chapter 2 21

Setting Objectives: Perspectives for Care

Orlando C. Kirton
Joseph M. Civetta

The Economic Issues: Is Economics King? 22
Selection of "Appropriate" Patients 22
Generic Goals of Intensive Care 23
Beneficence, Nonmaleficence, and Distributive Justice 24
Patient Autonomy 25
"Futility of Care" 25
The Family: Compassion and Avoiding Conflict 26
Immediate Objective: Examine Societal Values 27
Immediate Objective: Examine Bedside Care 29
Appendix 2-1: Advance Directive: Living Will 29
Appendix 2-2: Health Care Proxy Designation and Acceptance Form 31
Appendix 2-3: Durable Power of Attorney for Health Care and Health Care Surrogate Designation Form 32
Appendix 2-4: Affidavit 33

Chapter 3 35

Collaborative Care: Physician and Nursing Interactions

Danny Sleeman
Judith A. Hudson-Civetta
Joseph M. Civetta

The Surgeon Before the ICU 35
Members of the Team 35
Communications 36
Problems With Communication 37
Special Situations 37
Fellows' Function and Interrelationships 37
Functioning as a Team 39
Factors Contributing to Collaboration 40
Allocating Nursing Care 40
Nursing Care Functions 41
Allocation of Nursing Resources 41

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 4 — 49

Clinical Decision-Making

David V. Shatz
Joseph M. Civetta

Clinical Data as Scientific Variables 50
Cardiopulmonary Resuscitation and Do-Not-Resuscitate Orders 50
Elements of Clinical Care 52
The Influence of Time 55
First Vantage Point: Source of Admissions 55
Second Vantage Point: On ICU Admission 56
Third Vantage Point: Short-Term ICU Outcome 56
Fourth Vantage Point: Continued ICU Care 57
Fifth Vantage Point: Long-Term ICU Patients 58
Last Vantage Point: Discharge From Intensive Care 59

Chapter 5 — 63

Life and Death in the ICU: Ethical Considerations

Ernlé W. D. Young

Medical Ethics 63
The "Futility" Debate 73
Factors Compelling Treatment Even in the Likelihood of a Negative Outcome 74
Physician Aid-in-Dying 77

Chapter 6 — 81

Informed Consent and Refusal

Laurence B. McCullough

Key Considerations to Practice Informed Consent 81
When Patients Refuse Critical Care Intervention 84
Ethical Foundations of Informed Consent 85
Special Considerations 86

Chapter 7 — 89

Understanding Reactions of Patient and Family

George L. Wallace-Barnhill

Psychological Concepts 89
Staff Involvement With Families 91
The Patient in the ICU 92

Chapter 8 — 95

Iatrogenesis

Mark G. McKenney
Joseph M. Civetta

Type 1 Iatrogenesis: Incorrect Diagnosis 96
Type 2 Iatrogenesis: Therapy-Related 96
Type 3 Iatrogenesis: Procedure-Related 97
Type 4 Iatrogenesis: Laboratory Error 99
Type 5 Iatrogenesis: Decubitus Ulcer 100
Type 6 Iatrogenesis: Falls 101
Discussion and Legal Aspects 101

Chapter 9 — 105

Judicial Involvement in Treatment Decisions

Christopher Armstrong

The Beginnings of Court Involvement 106
A Consensus Emerges 107
Points on Which There Is No Consensus 114

Chapter 10 — 117

Important Legal Concepts in Critical Care

Baruch A. Brody

Informed Consent and the Refusal of Treatment 117
Levels of Care for Terminal Patients 119
Brain Death 122
Organ Transplantation 124

Chapter 11 — 127

Prediction and Definition of Outcome

Joseph M. Civetta

Cost Considerations 127
Definition of Outcome 128
Goals for Intensive Care 131
Descriptions of Quantitative Indices 134

Chapter 12 — 149

Resuscitation Outcomes

William H. Bickell
Matthew M. Rice

Immediate Concerns 149
Outcomes of Resuscitation 150

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Outcome After Out-of-Hospital Cardiac Arrest 150
Hospital Course of Patients Successfully Resuscitated From Out-of-Hospital Cardiac Arrest 154
Outcome After In-Hospital Cardiac Arrest 155
Neurologic Outcome After CPR 157
Termination of Resuscitation 157
On What Should the Decision to Terminate CPR Be Based? 158
Is Age a Factor to Be Considered in the Decision to Stop CPR? 159
Can the End-Tidal Carbon Dioxide Concentration or Coronary Perfusion Pressure Help Determine When to Stop CPR? 159
Should the Cost of Patient Care or the Postresuscitation Quality of Life Be Considered in the Decision to Stop CPR? 159
Who Should Decide to Terminate CPR? 159
Terminating Resuscitative Efforts Out-of-Hospital 160
Legal Implications of Terminating CPR 160
How Is It Possible to Determine Whether the Physician Is on Solid Legal Ground When Terminating CPR? 160
What Are the Considerations of Advance Directives and Family Interests in the Decision to Stop CPR? 161

Chapter 13 163

Quality Assessment and Improvement in the Adult Intensive Care Unit

Neil S. Yeston
Jamie Roche
Susan McCaffrey

Establishing a Program 164
A Quality Improvement Model for Surgical Critical Care 165
Risk Management 175
Critical Paths 175
The JCAHO Survey 176

SECTION II 187

ESSENTIAL PHYSIOLOGIC CONCERNS

Chapter 14 189

The Lungs and Their Function

Roger S. Mecca
Carlos A. Vaz Fragoso

Static Lung Volumes: Anatomic Considerations 189
Pulmonary Compliance 193
Airway Resistance 196
Gas Exchange 198
Ventilation-Perfusion Matching 199
Fluid and Protein Homeostasis 202
Central Control of Ventilation 204
Protective Functions 205
Metabolic Activity 205

Chapter 15 209

Respiratory Muscle Function and the Work of Breathing

Michael J. Banner

Immediate Concerns 209
Respiratory Muscles 210
Clinical Implications of Respiratory Muscle Loading 216
Decreasing Respiratory Muscle Afterload 219

Chapter 16 227

Cardiovascular System

Avner Sidi
Richard F. Davis

Cardiac Electrical Activity 227
Cardiac Contraction 231
Intrinsic Regulation of Cardiac Function 233
Characteristics of the Heart as a Pump 236
Ventricular Interaction 241
Ventricular Vascular Coupling 241
Neurogenic Control of the Cardiovascular System 242
Passive and Active Control of Systemic and Coronary Artery Size and Vasomotion 246
Metabolic Demand and Oxygen Supply of the Heart 247

Chapter 17 255

Acid–Base Chemistry and Physiology

Robert R. Kirby
Walter C. Bernards

Chemistry of Acids and Bases 255
Respiratory Derangements 257
Metabolic Derangements 257
Metabolic Compensation for Primary Respiratory Disturbances 258
Respiratory Compensation for Primary Metabolic Disturbances 259
Problem Solving 259
Metabolic Acidosis and Alkalosis 260
Respiratory Acidosis and Alkalosis 263

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

50

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 18 265

Coagulation

Robert I. Parker

Immediate Concerns 265
Physiology and Biochemistry of Primary Hemostasis 265
Physiology and Biochemistry of Secondary Hemostasis 267
Physiology and Biochemistry of Fibrinolysis 270
Coagulation as an Integrated System 272

Chapter 19 273

Central Nervous System Physiology

Christopher Veremakis
David H. Lindner

Immediate Concerns 273
Mechanisms of Brain Injury 274
Therapeutic Considerations During Brain Resuscitation 278
Specific Therapeutic Options in Brain Resuscitation 283

Chapter 20 291

The Host Response to Injury and Infection

Timothy H. Pohlman
Edward M. Boyle, Jr.

Reticuloendothelial System 292
Plasma Protein Defenses 296
Immunity 299

Chapter 21 303

Allergy and Immunology

R. Dwaine Rieves
Stewart J. Levine
James H. Shelhamer

Immediate Concerns 303
Overview 304
Antigen Recognition and Processing 304
Antigen Clearance 306
Antigen Clearance and Inflammation 308
Immune Defects and Critical Illness 308
Immunotherapy 311
Complications of Immunotherapy 313

Chapter 22 315

Pregnancy

Donald Caton

Pregnancy-Imposed Stress 315
Changes at Term 316
Coordination 318

SECTION III 323

MODULATING THE RESPONSE TO INJURY

Chapter 23 325

Metabolic Response to Injury and Critical Illness

Palmer Q. Bessey
Richard S. Downey
William W. Monafo

Immediate Concerns 325
General Features of the Response to Injury 326
Intermediary Metabolism in Critical Illness 327
Regulation of the Metabolic Responses to Critical Illness 331
Clinical Care and Metabolic Responses to Critical Illness 333

Chapter 24 337

Oxygen Delivery and Consumption in Critical Illness

Robert Schlichtig

Immediate Concerns 337

Chapter 25 343

Progression to Multiple Organ System Failure

George M. Matuschak

Immediate Concerns 343
Definitions 345
Epidemiology 346
Pathogenesis 347
Organ System Interactions 351

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

51

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Clinical Features 352
Prevention and Treatment 353

Chapter 26 359

Shock

Edgar J. Jimenez

Immediate Concerns 359
Overview 364
Definition 365
Classification and Clinical Recognition 365
Pathophysiologic Mechanisms of Shock 368
Management 373
Prognosis 381

Chapter 27 389

Cardiogenic Shock

John A. Farmer

Immediate Concerns 389
Classification 390
Etiology 390
Clinical Manifestations 395
Therapy 395

Chapter 28 405

Sepsis and Septic Shock

Janice L. Zimmerman
Robert W. Taylor

Immediate Concerns 405
Epidemiology and Etiology 406
Pathophysiology 407
Organ System Dysfunction in Sepsis 407
Clinical Manifestations 408
Diagnostic Considerations 409
Management of Sepsis 409

Chapter 29 413

Fluid and Electrolytes

Gary P. Zaloga
Robert R. Kirby
Walter C. Bernards
A. Joseph Layon

Immediate Concerns 413
Fluid Compartments 414
Electrolytes 415
Intraoperative and Postoperative Fluid Therapy 433
Hypoosmolar States 437

Chapter 30 443

Splanchnic Flow and Resuscitation

Orlando C. Kirton
Joseph M. Civetta

The Intestinal Microcirculation 443
Cellular Energy Metabolism 444
Intestinal Ischemia 445
Reperfusion Injury 445
Dysoxic Versus Normoxic State 446
Global Parameters of Delivery and Utilization: The Controversy 446
The Gastrointestinal Tract and Multiple Organ System Failure 447
Relevant Clinical Studies 448
The Monitoring Plan 450
Who Should Be Monitored? 451
Approach to Therapy 452
Future Investigations 452

Chapter 31 457

Enteral and Parenteral Nutrition

Patricia M. Byers
K. N. Jeejeebhoy

Immediate Concerns 457
Introduction 458
The Importance of a Nutritional Support Service 459
Nutritional Assessment and Patient Selection 459
Nutritional Requirements 460
Routes and Techniques of Administration 464
Nutritional Therapy of Patients with Organ System Dysfunction 468
Complications 468

Chapter 32 475

Pharmacologic Principles

Subhash K. Todi
Ronald A. Hartmann

Pharmacokinetics and Pharmacodynamics 475
Pharmacotherapy in Renal Diseases 478
Pharmacotherapy in Liver Disease 481
Adverse Drug Reactions 482

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

52

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

SECTION IV 489

TECHNIQUES, PROCEDURES, AND TREATMENT

Chapter 33 491

Fundamentals of Cardiopulmonary Resuscitation

Robert R. Kirby
Richard S. Melker

Immediate Concerns 491
Initial Considerations 492
Airway Patency 492
Breathing 495
Circulation 496
Defibrillation and Cardioversion 497
Pulseless Electrical Activity, Bradycardia, and Asystole 499
Pharmacologic Therapy 499

Chapter 34 507

Clean and Aseptic Technique at the Bedside

Judith A. Hudson-Civetta
Joseph M. Civetta

Questions Regarding Handwashing 507
Importance of Nosocomial Blood Stream Infection 510
Sources of Bacteria 510
Insertion Protocols 511
A Practical Bedside Approach 511
Preparation of Site and Dressing 511
Technique of Skin Preparation 512
Maintenance of Intravascular Catheters 514
Semiquantitative Culture Specimens Using Guidewire Exchange 515
Guidelines for the Use of Guidewires 517

Chapter 35 521

Vascular Cannulation

Bahman Venus
Paul Satish

Immediate Concerns 521
Venous Cannulation 522
Pulmonary Artery Cannulation 538
Peripheral Arterial Cannulation 539

Chapter 36 545

Temporary Cardiac Pacemakers

W. Ross Davis

Immediate Concerns 545
Indications for Temporary Pacing 545
Electrode Catheters and External Pacemaker Units 546
Procedures for Establishing Temporary Pacing 548

Chapter 37 553

Important Intensive Care Procedures

Neil S. Yeston
Richard L. Grotz
Laurie A. Loiacono

Thoracentesis 553
Tube Thoracostomy 556
Heimlich Catheter Insertion 560
Chest Tube Bottles 561
Paracentesis 562
Diagnostic Peritoneal Lavage 563
Intraabdominal Pressure Measurement 568
Venous Cutdown 569
Defibrillation 573
Cardioversion 575
Pericardiocentesis 577
Transtracheal Aspiration 580

Chapter 38 587

Interventional Radiology

Diego Nunez
Kimberly A. Lentz
Alejandro Zuluaga

Vascular Procedures 587
Nonvascular Procedures 590

Chapter 39 599

Feeding Tube Placement

Scott A. Shikora

Immediate Concerns 599
Overview 600
Determining the Most Appropriate Tube Type, Site, and Placement Technique 600
Tube Options 601
Placement Technique Options 602

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

53

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 40 609

Mechanical Cardiac Assist Devices

Thomas L. McKiernan
William H. Wehrmacher

Purpose 609
Synchronized Coronary Venous Retroperfusion 611
Ventricular Assist Devices 611

Chapter 41 613

Antithrombotic and Thrombolytic Therapy

Steven J. Trottier

Immediate Concerns 613
Antiplatelet Therapy 613
Antithrombotic Therapy 615
Thrombolytic Therapy 622

Chapter 42 631

Renal Replacement Therapies

Sudarshan Hebbar
Richard S. Muther

Immediate Concerns 631
Physiology 632
Extracorporeal Therapies 632
Peritoneal Dialysis 636
Choice of Therapy 636

Chapter 43 639

Transfusion Therapy

Richard C. Dennis
David Clas
Joan M. Niehoff
Neil S. Yeston

Immediate Concerns 639
Acute Massive Hemorrhage 640
Subacute Blood Volume Deficiency 643
Chronic Anemia 644
History of Blood Transfusion 644
Red Blood Cell Transfusion 645
Fresh Frozen Plasma 648
Cryoprecipitate 649
Platelets 649
DDAVP 651
Technical Aspects of Blood Product Administration 651
Transfusion Complications 652
Refusal of Transfusion 656

Chapter 44 661

Decreasing the Need for Homologous Blood Transfusion

Stephen F. Flaherty
Richard C. Dennis

Immediate Concerns 661
Optimization of Red Cell Production 663
Autotransfusion 663
Passive Blood Loss in the ICU 665
Blood Substitutes 666

Chapter 45 669

Extracorporeal Circulation for Respiratory or Cardiac Failure

Joseph B. Zwischenberger
Aravind B. Sankar
Robert H. Bartlett

Immediate Concerns 669
Background 670
Pathophysiology 671
Patient Selection 671
Techniques and Management 672
Venovenous ECMO 675
The ECMO Team 676
Complications 677
Results 678
Laboratory Investigation 679
Cardiac Support 679

Chapter 46 683

Fiberoptic Bronchoscopy

J. Steven Hata
David A. Schenk
R. Phillip Dellinger

Immediate Concerns 683
Complications 684
Fiberoptic Bronchoscopy in Airway Management 686

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5h

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 47 703

Oxygen Therapy

Robert A. Smith

Immediate Concerns 703
Therapeutic Considerations 704
Potential Complications 704

Chapter 48 711

Mechanical Ventilation

Michael J. Banner
Samsun Lampotang
Paul B. Blanch
Robert R. Kirby

Immediate Concerns 711
Peak Inflation Pressure 712
Ventilator Classification 712
Microprocessor-Controlled Ventilators 715
Conventional Mechanical Ventilatory Techniques 719
New or Experimental Techniques 727
Spontaneous Breathing 729
The Work of Breathing 734
Special Techniques 737
Transport Ventilation 738
Side Effects and Complications 739

Chapter 49 745

Ventilatory Support Modes

Orlando C. Kirton

Noninvasive Techniques 745
Truly Assisted Ventilation 747
Near-Total Ventilatory Support 750
Minimal Excursionary Ventilation 753
Spontaneous Augmented Low-Volume Ventilation 754

Chapter 50 757

Airway Management

Orlando G. Florete
Robert R. Kirby

Immediate Concerns 757
General Principles 758
Anatomic Considerations 759
Drugs 762
Esophageal, Pharyngeal, and Laryngeal Tubes 763
Tracheal Intubation 764
Tracheotomy 769
Cricothyroidotomy 770
Cuff Inflation 770

Chapter 51 777

Hyperbaric Medicine

Luis A. Matos

Immediate Concerns 777
Clinical Application 779
Indications 780
Care Before HBO Therapy 781

Chapter 52 787

Intrahospital Transport

Gregory M. Gullahorn

Immediate Concerns 787
Overview 788
Transport Scenarios 789
Planning: Preparatory Phase 792
On the Road Again: Transport Phase 794
Home at Last: Posttransport Stabilization 794
Individualizing Approaches 795

Chapter 53 803

Interhospital Transport of the Critically Ill

Robert E. Fromm

Immediate Concerns 803
Overview 803
Prehospital Practitioners 804
Air Medical Transport 805
Approach to the Transport of the Critically Ill 807

Chapter 54 809

Pain Control

David L. Brown
James F. Flynn

Immediate Concerns 809
Patient Selection 811
Analgesic Technique 811
Clinical Management 816
Problems and Related Complications 817
Special Considerations 819

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Chapter 55 821

Sedation and Paralysis

Antoni M. Nejman

Immediate Concerns 821
Sedation 822
Paralysis 828

SECTION V 837

MONITORING: PRACTICAL APPLICATIONS

Chapter 56 839

Invasive Pressure Monitoring

Reed M. Gardner

Equipment 839
Equipment Setup 841
Complications of Invasive Pressure Monitoring 844
Signal Amplification, Processing, and Display 844

Chapter 57 847

Arterial, Central Venous, and Pulmonary Artery Catheters

Albert J. Varon

Immediate Concerns 847
Introduction 848
Arterial Catheters 850
Central Venous Catheters 852
Pulmonary Artery Catheters 853
Derived Cardiopulmonary Parameters 861

Chapter 58 867

Assessment of Cardiopulmonary Function

Nikolaus Gravenstein
Michael L. Good
Tina E. Banner

Relative Attributes 867
Clinical Assessment of Cardiopulmonary Function 868
Noninvasive Blood Pressure Measurement 870
Electrocardiography 873
Pulse Oximetry 875
Capnometry 877
Noninvasive Assessment of Cardiac Output 883
Echocardiography 884
Invasive Cardiac Output Determinations 886

Chapter 59 899

Continuous ST Segment Monitoring

David V. Shatz
Valerie R. Wells

Prevalence of Silent Ischemia 899
Significance of Perioperative Ischemia 900
Pathophysiologic Basis of Electrocardiographic Changes 901
Advantages of ST Segment Monitoring 901
Limitations of ST Segment Monitoring 902
Indications for Monitoring 902
Lead Placement 902
Monitor Setup 903
Troubleshooting Alarm Conditions 905
Definition of Ischemic Events 906
Therapeutic Options 906

Chapter 60 909

Venous Saturation Monitoring and Usage

Joseph M. Civetta
Loren D. Nelson

Immediate Concerns 909
Physiology of Oxygen Transport 910
Assessment of Oxygen Transport Balance 911
Monitoring Oxygen Transport 912
Clinical Usefulness of Continuous $S\bar{v}O_2$ Monitoring 912
Combined Venous and Pulse Oximetry 916
Arterial Venous Oxygen Content Difference 916
Intrapulmonary Shunt 916
Applicability 917
Appendix 1: Normal Range, Units, and Derivation for Common Oxygen Transport Terms 917
Appendix 2: Clinical Examples 918

Chapter 61 921

Blood Gas Analysis

Barry A. Shapiro
William T. Peruzzi

Interpretive Guidelines 922
Arterial Oxygenation 923
Ventilation 924
Acute Respiratory Alkalosis 926
Metabolic Acid–Base Imbalances 926
Clinical Assessment of Oxygenation 928

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

56

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Hypoxemia and Oxygen Therapy 929
Tissue Oxygenation 930
Noninvasive Monitoring 931
Carbon Dioxide Stores 932
Carbon Monoxide Poisoning 933
Aberrant Intracellular Metabolism 934
Cardiopulmonary Resuscitation and Low Flow States 934
Temperature Correction 936
Point of Care Analyzers and Blood Gas Monitors 938

Chapter 62 941

Neurologic Monitoring

Thomas Grissom
Joyce Grissom
J. Christopher Farmer

Cerebral Function 941
Cerebral Perfusion 946
Cerebral Metabolism 951
Neurologic Imaging 952

Chapter 63 957

Radiographic Imaging

Carl E. Ravin

Plain Chest Radiograph 957
Evaluation of Life-Support and Monitoring Devices 965
Abdominal Radiography 969
Newer Imaging Technology 971
Magnetic Resonance Imaging 978

SECTION VI 985

THE SURGICAL PATIENT

Chapter 64 987

Perioperative Pulmonary Function Testing and Consultation

Philip G. Boysen
Robert R. Kirby

Immediate Concerns 987
General Considerations 988
Assessment for Lung Resection 989
Assessment for Abdominal Surgery 992
Specific Therapeutic Measures 994
Postoperative Care 995
Mechanical Ventilation and the Work of Breathing 996

Chapter 65 999

Preoperative Evaluation of High-Risk Surgical Patients

David L. Brown
Stephen O. Heard
Donald S. Stevens
Robert R. Kirby

Immediate Concerns 999
Overview 1000
Concurrent Disease 1001
Management 1004
Prevention of Complications 1006
Special Considerations 1007

Chapter 66 1013

Anesthesia: Physiology and Postanesthesia Problems

Eran Segal
A. Joseph Layon

Immediate Concerns 1013
Uptake and Distribution of Inhalational Agents 1015
Inhalation Agents and Organ System Function 1017
Intravenous Agents 1021
Preferred Anesthetic Techniques for Critically Ill Patients 1026
Postanesthetic Problems 1026

Chapter 67 1037

Initial Triage of the Trauma Patient

Larry C. Martin

Immediate Concerns 1037

Chapter 68 1045

Secondary Triage of the Trauma Patient

Marc D. Palter
Vicente Cortes

Immediate Concerns 1045
Obtaining the Patient's History and History of Injury 1047

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57

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Reassessing the ABCs While Maintaining Vital Functions 1047
Persistent Shock 1050
Blunt Cardiac Injury 1052
Compartment Syndrome 1052
Intraabdominal Hypertension (Intraabdominal Compartment Syndrome) 1053
Delayed Diagnosis 1054
Pelvic Fractures 1058

Chapter 69 1065

Evaluation of Bleeding in the Surgical Patient

Timothy H. Pohlman
C. James Carrico

Immediate Concerns 1065
Evaluation of Bleeding 1067
Etiologies of Postoperative Bleeding 1067
Complex Postoperative Bleeding Problems 1071

Chapter 70 1075

Abdominal Trauma: Diagnostic Steps and Postoperative Considerations

Vicente Cortes
Marc D. Palter
Mark McKenney

Immediate Concerns 1075
General Considerations in Abdominal Injury 1077
Penetrating Injuries 1079
Blunt Injuries 1080
Mortality and Morbidity in Abdominal Trauma 1082
Specific Injuries 1083

Chapter 71 1099

Evaluating the Acute Abdomen

Jorge Luis Sosa
H. David Reines

Immediate Concerns 1099
Introduction 1100
Anatomy 1100
History 1101
Physical Examination 1102
Adjunctive Procedures 1102
Therapy 1103
Special Conditions 1104

Chapter 72 1109

The Complicated Postoperative Abdomen

Danny Sleeman
Scott Norwood

Immediate Concerns 1109
Evaluating the Elective Postoperative Patient 1110
Normal Postoperative Course 1111
Evaluating the Postoperative Abdomen for Sepsis 1112
Specific Surgical Problems 1113
Tube Technology 1116

Chapter 73 1121

Surgical Aspects of Hepatobiliary Disease

Alan S. Livingstone
Jorge Luis Sosa

Immediate Concerns 1121
Management of the Cirrhotic Patient 1122
Early Postshunt Complications 1123
Surgical Management of Ascites 1125
Major Hepatic Resections 1126
Budd-Chiari Syndrome 1127
Hemobilia 1127
Postoperative Cholecystitis 1127
Cholangitis 1128
Biliary Fistula After Cholecystectomy 1128

Chapter 74 1131

Thoracic Surgery

Eddy H. Carrillo
M. Jack Williams

Immediate Concerns 1131
Thoracic Surgery 1133
Preoperative Considerations 1133
Management of the Postthoracotomy Patient 1133
Thoracic Trauma 1137
Special Situations and Procedures 1143

Chapter 75 1147

Postoperative Management of the Adult Cardiac Surgical Patient

Daniel J. O'Brien
James A. Alexander

Immediate Concerns 1147
The First 8 Postcardiopulmonary Bypass Hours 1148

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58

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

The Next 16 Post-CPB Hours 1148
The Second 24 Post-CPB Hours 1149
The Third 24 Post-CPB Hours 1149
Monitoring and Managing Cardiovascular Performance 1150
Special Concerns 1155

Chapter 76 1161

Postoperative Management of the Pediatric Cardiac Surgical Patient

Laurie K. Davies
Michael A. Greene

Immediate Concerns 1161
Hemodynamic Issues 1162
Respiratory Management 1169
Laboratory Values 1170
Cardiac Rhythm and Pacing 1170
Temperature 1171
Sedation and Paralysis 1171
Infections and Antibiotics 1171
Renal Failure and Diuretics 1172
Limb Ischemia 1172
Bleeding 1173
Later Concerns 1173
Transplantation 1175

Chapter 77 1177

Vascular Surgery and Trauma

Enrique Ginzburg
James M. Hurst
Richard J. Fowl

Immediate Concerns 1177
Principles of Intensive Care for the Vascular Patient 1178
Problems Common to All Vascular Reconstructions 1180
Management of Specific Reconstructions 1182
Vascular Trauma 1187
Management of Specific Vascular Injuries 1187
Thrombolytic Therapy 1189
Aortic Dissection 1191

Chapter 78 1195

Neurologic Injury: Prevention and Initial Care

Philip A. Villanueva
Bradley H. Ruben
Jonathan Greenberg

Immediate Concerns: Head Injury 1195
Immediate Concerns: Spinal Injury 1197
Head Injury 1198
Spinal Cord Injury 1208

Chapter 79 1219

Multiple Fractures

Gregory A. Zych

Immediate Concerns 1219
Diagnosis of Fractures and Dislocations 1220
Specific Treatment Methods 1221
Special Problems 1226
Complications 1227

Chapter 80 1231

Orthopedic Complications

Jill I. Freedman
F. Kayser Enneking

Immediate Concerns 1231
Spinal Surgery 1232
Joint Replacement 1234
Pathologic Processes Common to Orthopedic Patients 1235
Miscellaneous Problems 1245

Chapter 81 1253

Urologic Surgery and Trauma

Thomas E. Ahlering

Immediate Concerns 1253
Major Urologic Postoperative Management 1254
Urogenital Trauma 1256

Chapter 82 1265

Burn Injury

Michael D. Peck
C. Gillon Ward

Immediate Concerns 1265
Management of Respiratory Problems 1266
Management of Cardiovascular Problems 1267
Complications of Resuscitation 1268
Maintenance of Electrolyte Homeostasis and Acid–Base Balance 1269
Management of Renal Failure 1270
Management of Bleeding Disorders 1270
Provision of Nutritional Support 1271
Diagnosis and Treatment of Serious Infections 1272
Care of the Burn Wound 1273

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

59

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

The Importance of Physiotherapy 1274
The Psychosocial Needs of the Patient and Family 1274
The Team Approach to Burn Care 1274

Chapter 83 1277

The Obese Surgical Patient

Scott A. Shikora
Jay A. Johannigman

Immediate Concerns 1277
Overview 1278
Cardiovascular Disease 1278
Pulmonary Disease 1279
Thromboembolic Disease 1280
Soft Tissue Problems 1281
Sepsis 1281
Drug Dosing 1282
Nutritional Support 1282

SECTION VII 1287

ORGAN TRANSPLANTATION

Chapter 84 1289

Organ Transplantation: An Overview of Problems and Concerns

Ake Grenvik
Joseph M. Darby
Brian A. Broznick

Immediate Concerns 1289
Current Transplantation Activities 1290
Organ Need Versus Supply 1291
Evolution of the Brain Death Concept 1291
Procedural Considerations 1292
Organ Procurement, Recovery, and Preservation 1295
Transplantation Organizations and Allocation of Organs 1296

Chapter 85 1301

Renal Transplantation

Matthew E. Brunson
William W. Pfaff
George W. Burke, III
Gaetano Ciancio

Immediate Concerns 1301
Immunosuppressants and Their Complications 1303
Minimizing Infections in the Immunocompromised Host 1305
Other Problems 1305
"Stable" Allograft Recipients Readmitted to the ICU 1306
Other Conditions 1308

Chapter 86 1311

The Renal and Pancreatic Allograft Recipient

George W. Burke, III
Gaetano Ciancio

Immediate Concerns 1311
Overview 1312
Initial ICU Admission 1312
Immunosuppression 1314
Secondary ICU Admissions 1315

Chapter 87 1317

Heart-Lung, Double-Lung, and Single-Lung Transplantation

Cesar A. Keller

Indications 1317
Initial Management 1317
Postoperative Management 1320

Chapter 88 1333

Heart Transplantation

Leslie W. Miller

Indications 1333
Candidate Selection: Hemodynamic Assessment 1333
Initial Postoperative Management 1334
Immediate Concerns 1335

Chapter 89 1341

Orthotopic Liver Transplantation

Mathew E. Brunson
Richard J. Howard

Immediate Concerns 1341
Early Graft Function and Primary Nonfunction 1342
Coagulation Abnormalities 1343
Hemodynamic Function and Fluid Therapy 1343
Immunosuppression 1344
Hypertension 1345
Other Early Problems 1345
Assessing and Optimizing Graft Function 1346
Complications 1347
Late Readmissions to the ICU 1350
Consultation 1350

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

60

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Chapter 90 1353

Intestinal and Multivisceral Transplantation

Marc G. Webb
Andreas G. Tzakis

Immediate Concerns: Preoperative Care 1353
Immediate Concerns: Postoperative Care 1354
Overview 1354
Preoperative and Operative Care 1355
Postoperative Care 1360

Chapter 91 1367

Bone Marrow Transplantation

Richard K. Burt

Immediate Concerns (First 30 Days) 1367
Intermediate Concerns (Days 30 to 100) 1377
Late Concerns (Beyond Day 100) 1377

SECTION VIII 1387

THE OBSTETRIC PATIENT

Chapter 92 1389

Cardiac Disease and Hypertensive Disorders in Pregnancy

Christopher F. James

Immediate Concerns 1389
Hypertensive Disorders 1392
Cardiac Disease 1393
Cardiac Surgery During Pregnancy 1397
Pregnancy After Cardiac Surgery 1398
Cardiopulmonary Resuscitation 1398

Chapter 93 1401

Hemorrhagic Disorders

Connie E. Taylor

Immediate Concerns 1401
Cardiovascular Changes With Obstetric Drugs 1402
Coagulation Changes 1403
Hemorrhagic Complications 1403
Coagulopathies 1406

Chapter 94 1409

Pulmonary Abnormalities

Robert R. Kirby

Immediate Concerns 1409
Physiologic Considerations 1410
Ventilation and Perfusion 1411
Diagnosis and Treatment of Respiratory Failure 1412

Chapter 95 1419

Trauma and the Acute Abdomen

Sharon Salamat
Anthony Lai

Immediate Concerns 1419
Initial Assessment and Management 1420
Diagnostic Studies 1421
Specific Management 1423
Postoperative Period 1424
Delivery Concerns 1425
Maternal Brain Death 1425

Chapter 96 1429

Fetal Monitoring Concerns

Donald Caton

Immediate Concerns 1429
Special Considerations 1430
Fetal Oxygenation 1431
Monitoring 1432
Chronic Adaptations 1433
Acute Adaptations 1434

SECTION IX 1437

ENVIRONMENTAL HAZARDS

Chapter 97 1439

Protecting the Practitioner: Acquired Immunodeficiency Syndrome and Hepatitis

Salvatore Lopalo
A. Joseph Layon

Acquired Immunodeficiency Syndrome 1439
Health Care Workers and HIV Transmission 1440

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

61

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Testing of Health Care Workers After Possible Exposure 1441
Prevention 1442
The Hepatitides 1444
Protective and Therapeutic Measures 1447

Chapter 98 1451

Temperature-Related Injuries

J. Christopher Farmer

Immediate Concerns 1451
Hypothermia 1451
Hyperthermia 1454
Malignant Hyperthermia and the Neuroleptic Malignant Syndrome 1457

Chapter 99 1463

Toxicology: General Approach

Jeffrey A. Sadowsky

Immediate Concerns 1463
History 1464
Diagnosis and the General Approach to the Poisoned Patient 1467
Pregnancy 1475
Treatment Refusal: The Uncooperative Patient 1475
Appendix 99-1: Toxicology Information 1475

Chapter 100 1483

Toxicology: Specific Drugs and Poisons

Richard P. Ryskamp
Robert W. Taylor

Acetaminophen 1483
Salicylates 1486
Cyclic Antidepressants 1489
Lithium 1493
Antipsychotic Drugs 1494
Benzodiazepines 1495
Beta-Blockers 1496
Calcium Channel Blockers 1497
Digitalis 1498
Theophylline 1499
Alcohols 1501
Insecticides: Cholinergic Agents 1504

Chapter 101 1511

Substance Abuse and Withdrawal: Alcohol, Cocaine, and Opioids

Joan Shaffer

Immediate Concerns 1511
Ethanol 1512
Cocaine 1514
Opioids 1517

Chapter 102 1523

Envenomation

Charles L. Bryan
Charles A. Weber
Kenneth A. Perret

Immediate Concerns 1523
Venomous Snake Bites 1524
Black Widow Spider Bites 1528
Brown Recluse Spider Bites 1530
Scorpion Envenomation 1532
Marine Envenomations 1533

Chapter 103 1537

Electrical Injuries

Kenneth A. Perret
Charles A. Weber
Charles L. Bryan

Immediate Concerns 1537
Classification 1538
Basic Mechanisms in Electrical Injury 1538
Clinical Manifestations and Management 1539

Chapter 104 1543

Anaphylaxis

Stewart J. Levine
R. Dwaine Rieves
James H. Shelhamer

Immediate Concerns 1543
Clinical Manifestations 1544
Management 1546
Prevention 1549
Pathogenesis 1550
Implications and Outcome 1550

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62

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SECTION X 1553

INFECTIOUS DISEASE

Chapter 105 1555

An Approach to the Use of Antimicrobial Agents

George E. Crawford
Mimi Emig

Immediate Concerns 1555
Principles of Antibiotic Selection 1556
Antibiotic Therapy 1561
Prophylactic Antibiotics 1565
Antimicrobials Useful in the Critical Care Unit 1566

Chapter 106 1573

The Prevalence and Importance of Nosocomial Infections in the Intensive Care Unit

Mark G. McKenney
Scott Norwood

Immediate Concerns 1573
Risk Factors and Scope of Nosocomial Infections in Critical Illness 1575
Hospital-Acquired Respiratory Infections 1575
Catheter-Related Nosocomial Infections 1577
Surgical Wound Infections 1581
Hospital-Acquired Urinary Tract Infections 1582
Fungal Infections 1583
Sinusitis 1583
Antibiotic-Associated Pseudomembranous Colitis 1583
Hospital-Acquired Ventriculitis and Meningitis 1584

Chapter 107 1589

An Approach to the Febrile ICU Patient

David V. Shatz
Scott Norwood

Immediate Concerns 1589
Definition, Pathophysiology, and Purpose 1591
Common Causes of Fever 1592
Fever as a Predictor of Infection 1592
Recommended Approach to Fever Evaluation 1593

Chapter 108 1603

Infections in the Immunocompromised Host

Gregory P. Melcher
Douglas R. Leigh

Immediate Concerns 1603
Approach to the Immunocompromised Host 1604
The Granulocytopenic Patient 1605
The Corticosteroid-treated Patient 1606
The Renal Transplant Recipient 1609
Bone Marrow Transplant Recipient 1613

Chapter 109 1617

Human Immunodeficiency Virus in the Intensive Care Unit

Loretta M. O'Brien
Richard E. Winn

Immediate Concerns 1617
Pulmonary Manifestations of HIV 1618
Neurologic Manifestations of HIV Infection 1626
Sepsis and Bacteremia 1627
Gastrointestinal Manifestations of HIV 1629
Fever of Unknown Origin 1630
ICU Utilization in HIV Infection 1630
Control of HIV Infection in the ICU 1630

Chapter 110 1635

Neurologic Infections

David H. Gremillion

Immediate Concerns 1635
Clinical Presentation and Initial Diagnostic Measures 1635
Establishing the Diagnosis 1639
Management 1641
Prevention of Bacterial Meningitis 1642
Complications of Bacterial Meningitis 1643
Special Clinical Considerations 1644

Chapter 111 1649

Urinary Tract Infections

Mark E. Appleman
Richard E. Winn

Immediate Concerns 1649
Cystitis 1650

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Pyelonephritis 1650
Prostatitis 1654
Nosocomial Infections 1654
Fungal Infections 1655

Chapter 112 1657

Bacterial Infections

Judith R. Anderson
Ferric C. Fang

Staphylococcus aureus 1657
Coagulase-Negative Staphylococci (Including *Staphylococcus epidermidis*) 1661
Streptococcal and Enterococcal Infections 1663
Streptotoccus pyogenes (Group A Streptococcus) 1663
Streptococcus agalactiae (Group B Streptococcus) 1664
Streptococcus pneumoniae 1664
Viridans Streptococci 1665
Streptococcus milleri/intermedius Group 1665
Enterococci 1666
Moraxella (Branhamella) catarrhalis 1666
Neisseria meningitidis 1666
Neisseria gonorrhoeae 1667
Bacillus Infections 1668
Corynebacteria (Diphtheroids) 1668
Listeria monocytogenes 1668
Nocardia 1668
Acinetobacter 1669
Campylobacter and *Helicobacter* 1669
Enterobacteriaceae 1669
Enterobacter 1669
Escherichia 1670
Klebsiella 1670
Proteus 1670
Salmonella 1670
Serratia 1671
Shigella 1671
Yersinia 1671
Other Enterobacteriaceae 1672
Flavobacterium 1672
Francisella 1672
Haemophilus influenzae 1672
Other HACEK Organisms 1673
Legionella 1673
Pasteurella 1673
Pseudomonas aeruginosa 1673
Pseudomonas (burkholderia) cepacia 1674
Stenotrophomonas (xanthomonas) maltophilia 1675
Vibrios and Related Organisms 1675
Anaerobic Cocci 1675
Actinomycosis 1675
Clostridial Infections 1676
Propionibacterium acnes 1678
Anaerobic Gram-Negative Bacilli 1678
Bartonella (Rochalimaea) Infections 1679
Capnocytophaga 1679
Chlamydia 1680
Mycobacterium avium-intracellulare 1680
Mycobacterium kansasii 1680
Mycobacterium tuberculosis 1680
Mycoplasmal Infections 1681
Rickettsial Infections 1682
Borrelia 1682
Leptospirosis 1682
Syphylis 1682

Chapter 113 1685

Fungal and Viral Infections

Stephen B. Greenberg

Fungal Infections 1685
Viral Infections 1691

Chapter 114 1703

Unusual Infections

Richard E. Winn

Rickettsial Diseases 1703
Ehrlichia 1706
Brucellosis 1706
Tularemia 1707
Plague 1708
Borreliosis 1708
Hantavirus Pulmonary Syndrome 1709
Hemorrhagic Fever 1709
Head and Neck Infections 1710
Cerebral Malaria 1711

SECTION XI 1715

CARDIOVASCULAR DISEASE AND DYSFUNCTION

Chapter 115 1717

Evaluation of Chest Pain in the ICU

Stephen P. Taylor

Immediate Concerns 1717
Differentiation of Chest Pain Syndromes 1719
Differential Diagnosis of Life-Threatening Causes of Chest Pain 1720
Differential Diagnosis of Non–Life-Threatening Causes of Chest Pain 1724

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6h

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Chapter 116 1727

Acute Myocardial Infarction: Contemporary Management Strategies

Normand Racine

Immediate Concerns 1727
Role of Aspirin in Acute Myocardial Infarction 1727
Thrombolysis 1728
Percutaneous Transluminal Coronary Angioplasty 1733
Role of Heparin in Acute Myocardial Infarction 1733
Role of Intravenous β-Adrenergic Blocking Agents 1734
Role of Intravenous Nitroglycerin 1735
Role of Calcium Channel Blockers 1735
Lidocaine 1736
Angiotensine-Converting Enzyme Inhibitors (ACE-i) 1736
Heart Failure and Cardiogenic Shock 1737
Differentiation From Chronic Heart Failure 1737
Mechanical Complications 1737
Right Ventricular Infarction Diagnosis and Therapy 1738
Cardiogenic Shock 1738
Clinical Guidelines for Hemodynamic Monitoring 1738
Recommended Approach to Congestive Heart Failure 1739
Noninvasive Imaging Techniques 1740
Q Wave and Non-Q Wave Myocardial Infarctions 1742

Chapter 117 1749

Heart Failure

Mandeep R. Mehra
Hector O. Ventura

Immediate Concerns 1749
Introduction 1750
Epidemiology of Heart Failure 1751
Etiopathogenesis 1752
Neurohormonal Activation in Advanced Heart Failure 1752
Neurohormonal Activation: Adaptation or Maladaption? 1753
Prognostic Factors in Advanced Heart Failure 1753
Clinical Trials in the Medical Management of Heart Failure 1755
Pooled Studies of ACE Inhibitors 1756
Clinical Use of ACE Inhibitors 1756
Oral Inotropic Therapy–Hopeless or a Glimmer of Hope? 1756
A Summary of Clinical Trials in Advanced Heart Failure 1757
The Unique Management of Refractory Advanced Systolic Heart Failure 1758
Tailored Medical Therapy 1759
Practical Aspects of Intravenous Inotropic Therapy 1760
Fluid Removal in Refractory Heart Failure 1761
Non-pharmacological Cardiac Assistance 1762
Selection Criteria for Implantable Ventricular Assist Devices 1763
Emerging Pharmacologic Therapeutics in Heart Failure 1763
Diastolic Dysfunction: The Other Side of the Coin 1764

Chapter 118 1769

Valvular Heart Disease

W. Ross Davis

Immediate Concerns 1769
Critical Illness Caused by Valvular Heart Disease 1769
Complicating Cardiac Valvular Disease in Critically Ill Patients 1770
Considerations in Specific Valvular Abnormalities 1770

Chapter 119 1781

Cardiac Arrhythmias

W. Ross Davis

Immediate Concerns 1781
Diagnostic Maneuvers 1781
Supraventricular Arrhythmias 1783
Ventricular Arrhythmias 1783
Wide Complex Tachycardia 1784
Atrioventricular Block 1784
Management 1784

Chapter 120 1787

Infective Endocarditis

Stephen B. Greenberg

Immediate Concerns 1787
Overview 1787
Epidemiology 1788
Pathology and Pathogenesis 1788
Diagnostic Criteria 1789
Clinical Manifestations 1790
Laboratory Tests 1790
Microbiology 1791
Therapy 1793

Chapter 121 1803

The Pericardium

Thomas L. McKiernan

Acute Pericarditis 1803
Cardiac Tamponade 1805
Constrictive Pericarditis 1808
Postpericardiotomy Syndrome 1809

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65

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Chapter 122 1811

Hypertensive Emergencies and Urgencies

Patrick C. McKillion
R. Phillip Dellinger

Immediate Concerns 1811
Specific Considerations 1816
Hypertensive Urgencies 1819

SECTION XII 1823

PULMONARY DISEASE AND DYSFUNCTION

Chapter 123 1825

The Acute Respiratory Distress Syndrome

Barbara J. Foner
Scott H. Norwood
Robert W. Taylor

Immediate Concerns 1825
Overview 1826
Etiology 1826
Pathophysiology 1828
Clinical Presentation 1830
Treatment 1831
Novel Forms of Mechanical Ventilation 1835
Monitoring 1836
Complications 1836
Outcome 1836

Chapter 124 1841

Community Acquired Pneumonia

Dennis P. Lawlor
Mimi Emig

Immediate Concerns 1841
Characterization of Pneumonia 1842
Pathogens in Community Acquired Pneumonia 1842
New Pathogens 1843
Old Pathogens, New Problems 1843
Host Defense and Susceptibility 1844
Initial Diagnostic Evaluation 1846
Evaluation and Treatment of Pleural Effusions 1848
Lung Abscess 1849
Empiric Antibiotics 1850
Duration of Therapy 1852
Adjunctive Treatment 1852
Clinical Response to Therapy 1852
Invasive Testing 1852
Chronic Lung Infections 1854
Radiographic Resolution 1855
Prophylaxis 1855
Evaluation of Recurrence 1856
Future Directions 1856

Chapter 125 1861

Aspiration Syndromes

Salvatore R. Goodwin

Immediate Concerns 1861
Classification 1862
Further Diagnostic Concerns 1864
Subsequent Management 1865
Prevention 1868

Chapter 126 1875

Drowning and Near-Drowning

Eric T. Kunichika
Lawrence S. Berman

Immediate Concerns 1875
Presentation 1877
Pathophysiology 1877
Treatment 1878
Neurologic Sequelae 1880
Fluids and Electrolytes 1880
Renal Failure 1880
Hematologic Changes 1881
Sequelae 1881
Ice Water Submersion 1882
Prognosis and Outcome 1882
Other Concerns 1883

Chapter 127 1887

Venous Thrombosis and Pulmonary Embolism

Mandeep R. Mehra
Frederick R. Bode

Immediate Concerns 1887
Venous Thromboembolism: Ubiquitous Yet Undiagnosed 1888
The Medical ICU and Deep Venous Thrombosis: The Case for Routine Prophylaxis 1889
Natural History of Venous Thromboembolism 1891
Clinical Features and Diagnosis of Venous Thromboembolism 1891
Therapy of Venous Thromboembolism 1897
Future Directions 1901

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66

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Chapter 128 1905

Other Embolic Syndromes

Scott A. Deppe
Dan R. Thompson
Roger R. Barrette

Immediate Concerns 1905
Arterial Embolism of Gas, Cholesterol, or Fat 1905
Venous Air Embolism 1907
Fat Embolism Syndrome 1908
Amniotic Fluid Embolism 1910

Chapter 129 1917

Acute Respiratory Failure in Chronic Obstructive Lung Disease

Michael J. Cicale
Frederick L. Trent

Immediate Concerns 1917
Definitions 1918
Etiology 1919
Pathophysiology 1919
Management 1919
Complications 1927
Prognosis 1929

Chapter 130 1931

Life-Threatening Bronchospasm in the Asthmatic Patient

R. Phillip Dellinger

Immediate Concerns 1931
Pathophysiology and Pulmonary Function in Severe Asthma 1932
Diagnosis 1934
Admission Decisions 1936
Therapy 1936
Indications for Tracheal Intubation 1939
Summary of Treatment Priorities 1942
Nontraditional Therapy of Severe Bronchospasm 1943

Chapter 131 1947

Inhalation Injury

David A. Striker

Immediate Concerns 1947
Fire and Smoke 1948
Thermal Injury 1949
Pathogenesis 1950
Histopathology 1950
Clinical Presentation and Diagnosis 1950
Treatment 1951
Classification 1952

Chapter 132 1959

Pulmonary Barotrauma

David L. Brown
Robert R. Kirby

Immediate Concerns 1959
Pneumothorax 1960
Other Extra-Alveolar Air Conditions 1964
Prevention of Barotrauma and Related Complications 1965
Surveillance for Pulmonary Barotrauma 1966

SECTION XIII 1969

NEUROLOGIC DISEASE AND DYSFUNCTION

Chapter 133 1971

Altered Mental Status and Coma

Warren J. Strittmatter

Immediate Concerns 1971
Emergency Evaluation 1971
Bedside Evaluation of Coma 1972
Additional Studies 1975
Bilateral Hemispheric Lesions 1975
Brain Stem Lesions 1976
Metabolic–Toxic Etiologies 1977

Chapter 134 1981

Seizures and Status Epilepticus

Paul A. Rutecki

Immediate Concerns 1981
Definitions and Classification 1982
Etiology 1982
Pathophysiology 1983
Initial Therapy and Management 1983
Pharmacologic Therapy 1984
Laboratory Evaluation 1986
Prognosis 1986
Special Cases 1986

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67

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Chapter 135 1989

Cerebrovascular Disease

Ken P. Madden
Loren A. Rolak

Immediate Concerns 1989
Stroke 1990
Other Cerebrovascular Diseases 1999

Chapter 136 2005

Neuromuscular Disorders

Stephen Derdak

Immediate Concerns 2005
Guillain-Barré Syndrome (Acute Autoimmune Inflammatory Demyelinating Polyneuropathology) 2005
Myasthenia Gravis 2011

Chapter 137 2017

Behavioral Disturbances in the Intensive Care Unit

Michael G. Wise
Ned H. Cassem

Immediate Concerns 2017
Diagnosis and Clinical Features of a Delirium 2018
Behavioral Disorders Without Cognitive Dysfunction 2024

SECTION XIV 2031

GASTROINTESTINAL DISEASE AND DYSFUNCTION

Chapter 138 2033

Gastrointestinal Bleeding

Jack A. DiPalma

Immediate Concerns 2033
Overview 2033
Approach to Diagnosis and Management of Upper Gastrointestinal Bleeding 2034
Treatment for Gastrointestinal Bleeding 2035
Critical Assessment of Available Interventions 2037
Stress Ulceration 2037
Approach to Lower Gastrointestinal Bleeding 2040

Chapter 139 2045

Fulminant Hepatic Failure

Marc G. Webb
Andreas G. Tzakis

Immediate Concerns 2045
Etiology and Prognosis 2046
Complications and Treatment 2047

Chapter 140 2055

Pancreatic Disease

Danny Sleeman
Joe U. Levi

Immediate Concerns 2055
Overview 2056
Diagnosis of the Disease Process 2056
Classification 2057
Treatment of Acute Pancreatitis 2057
Surgical Management 2059

Chapter 141 2065

Inflammatory Bowel Disease

Charles E. Brady
Oscar A. Alvarez

Immediate Concerns 2065
Fulminant Colitis and Toxic Megacolon 2066
Colonic Perforation and Massive Hemorrhage 2069

Chapter 142 2071

Esophageal Disorders

Jack A. DiPalma

Immediate Concerns 2071
Esophageal Obstruction 2071
Foreign Bodies 2073
Corrosive Injury 2073
Esophageal Perforation 2075
Medication Injury 2076

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SECTION XV 2079

RENAL AND ENDOCRINE DISEASE AND DYSFUNCTION

Chapter 143 2081

Acute Renal Failure

Richard S. Muther

Immediate Concerns 2081
Differential Diagnosis of Acute Azotemia 2081
Differential Diagnosis of Acute Renal Failure 2084
Pathophysiology 2086
Prevention of ARF 2088
Treatment and Supportive Care 2088
Prognosis and Recovery 2090

Chapter 144 2093

Impact of Chronic Renal Failure

Gerald M. Reid
Richard S. Muther

Immediate Concerns 2093
Hypotension 2094
Chest Pain 2096
Cardiac Arrhythmias 2096
Respiratory Failure 2097
Disordered Consciousness 2098

Chapter 145 2101

Disordered Glucose Metabolism

Dan R. Thompson

Immediate Concerns 2101
Disordered Glucose Metabolism 2102
Diabetic Ketoacidosis 2102
Hyperosmolar Hyperglycemic Nonketotic Disease 2106
Decompensated Diabetes Mellitus in Patients With Coexistent Medical or Surgical Problems 2107

Chapter 146 2111

Hypothalamic and Pituitary Disease

Charles A. Reasner II
Gary L. Mueller

Immediate Concerns 2111
Overview 2112
Hypothalamic–Anterior Pituitary Unit 2112
Neurohypophysis 2116

Chapter 147 2121

Adrenal Disease

Robert B. Constant
Richard J. Barth

Immediate Concerns 2121
Physiology of the Adrenal Gland 2122
Adrenal Hormone Insufficiency 2123
Adrenal Hormone Excess (Cushing's Syndrome) 2125
Clinical Use of Glucocorticoid Medications 2125
Adrenal Function Tests 2126

Chapter 148 2129

Pheochromocytoma

Gary L. Mueller
Charles A. Reasner II

Immediate Concerns 2129
Presenting Symptoms and Signs 2130
Pathology 2130
Diagnosis 2131
Management 2133
Prevention of Complications 2133
Special Considerations 2133

Chapter 149 2137

Thyroid Disease

William L. Isley

Immediate Concerns 2137
Thyrotoxicosis 2137
Hypothyroidism 2142
Drugs, Thyroid Disease, and Thyroid Function 2146
Thyroid Function in Nonthyroidal Illness and Aging 2146
Airway Obstruction 2147

SECTION XVI 2151

SKIN AND MUSCLE DISEASE AND DYSFUNCTION

Chapter 150 2153

Critical Care of Rheumatic Disease

Jay B. Higgs
Ramon A. Arroyo
Kenneth F. Des Rosier
Matthew T. Carpenter

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69

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Immediate Concerns 2153
Overview 2155
Principles and Pitfalls in the Critical Care of Rheumatic Disease 2155
Vasculitis 2159
Critical Care of Systemic Lupus Erythematosus 2164
Systemic Sclerosis 2171

Chapter 151 2175

Dermatologic Conditions

Richard L. Spielvogel

Immediate Concerns 2175
Erythema Multiforme 2175
Toxic Epidermal Necrolysis 2177
Staphylococcal Scalded Skin Syndrome 2178
Generalized Pustular Psoriasis (Von Zumbusch) 2179
Erythroderma and Exfoliative Dermatitis 2181
Pemphigus 2182
Bullous Pemphigoid 2183
Eczema Herpeticum (Kaposi's Varicelliform Eruption) 2184
Varicella-Zoster Infections 2185
Drug Eruptions 2186
Purpura 2188
Acquired Immunodeficiency Syndrome 2191
Contact Dermatitis 2191
Necrotizing Fasciitis 2192

Chapter 152 2195

Rhabdomyolysis

J. Christopher Farmer

Immediate Concerns 2195
Complications 2196
The Clinical Syndrome of Rhabdomyolysis 2198

Chapter 153 2203

Preventive Care

Deborah Weppler
Joseph M. Civetta

Skin and Subcutaneous Tissues 2203
Musculoskeletal System Considerations 2207
Subtle Infectious Processes 2209
Miscellaneous Conditions 2211
Types of ICU Beds 2212

SECTION XVII 2215

HEMATOLOGIC AND ONCOLOGIC DISEASE AND DYSFUNCTION

Chapter 154 2217

Coagulation Disorders

Robert I. Parker

Immediate Concerns 2217
Overview 2218
An Approach to the Patient With an Actual or Suspected Coagulation Disorder 2218
Conditions Associated With Serious Bleeding or a High Probability of Bleeding 2220
Thrombotic Syndromes 2229
Laboratory Abnormalities Not Associated With Bleeding 2229
Selected Disorders 2230

Chapter 155 2231

Hematologic Diseases

David A. Sears

Reduced Blood Counts 2231
Increased Blood Counts 2239
Altered Blood Rheology 2241

Chapter 156 2245

Oncologic Emergencies

Robert J. Downey
Jeffrey S. Groeger

Cancer Hypercalcemia 2245
Acute Tumor Lysis Syndrome 2247
Obstructive Syndromes 2248
Neurologic Syndromes 2249
Cardiac Tamponade 2250
Gastrointestinal Emergencies: Neutropenic Enterocolitis 2250
Toxicity of Chemotherapy 2251

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Appendix 2255

Critical Care Catalog

Stephen M. Koch

Appendix A: Prefixes and Conversions 2255
Appendix B: Dubois Body Surface Area Nomogram 2256
Appendix C: Fluids and Electrolytes 2257
Appendix D: Acid-Base 2259
Appendix E: Formulas 2261
Appendix F: Pharmacology 2266
Appendix G: Dermatomes 2273
Appendix H: Organ Injury Scaling 2273

Index 2283

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

71

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TABLE 35-2. General Guidelines for Central Vascular Cannulation

1. Avoid sites with previous surgery and trauma or obvious anatomic abnormalities.
2. An agitated patient may predispose to complications. Assure comfort and sedation.
3. Use ample local anesthetics without distorting landmarks or the vessel.
4. Assure optimum position for the patient. Avoid awkward or uncomfortable position for yourself.
5. Assure oxygenation, ventilation, and monitoring under drapes.*
6. Valsalva maneuver, inspiratory hold, volume challenge, and Trendelenburg position are additional techniques to deliver vein-distending forces.*
7. Gauge the depth and angle of insertion by first performing venipuncture with a small-gauge needle. The needle can temporarily be left in place unless it prohibits passage of the cannulating needle or needle/plastic cannula assembly.*
8. Puncture the skin and subcutaneous tissue generously or incise with a no. 11 scalpel blade to avoid skin plugs and to facilitate catheter or introducer passage.
9. If a stab incision is not used initially, inject a small amount of saline to express skin plugs.
10. When attempting to find the vein with a needle or while cannulating the vein, use a small syringe to apply slight negative pressure.*
11. When vascular puncture is accomplished, adjust the needle bevel and guidewire. Lower the needle slightly to move closely parallel to the vascular lumen and advance the needle 2–5 mm further to assure intravascular placement of the lumen.
12. Do not redirect the needle while it is partially inserted to avoid laceration of the vein. When advancement fails, withdraw slowly while observing for blood return. If blood return is not observed after full withdrawal, then vary the technique by slightly altering the needle angulation.
13. If resistance is felt, remove the catheter or guidewire. The location of the catheter or guidewire shape may give clues to the cause of the obstruction. If cannulation is unsuccessful, check the tip of your cannula. A sheared or occluded tip may be the problem.
14. Once in the vessel, never leave the needle or cannula unoccluded. Air embolism can occur through veins, and unacceptable blood loss can occur from arteries.
15. Estimate the safe length of guidewire that can be inserted before attempting the insertion. Always watch the monitor of the length of inserted guidewire to minimize potential arrhythmias.*
16. If resistance is met in advancing or withdrawing of a guidewire, never use force. Gently withdraw the guidewire and the catheter/needle together.
17. Allow yourself three to five attempts for each venous approach. Perhaps 5–10 passes can be reasonably attempted for arterial puncture with a 20-gauge needle. It is better to accept failure than cause a serious complication.
18. For placement of transcardiac or vena cava catheters, always order a stat follow-up radiograph to assure correct catheter tip placement. Right atrial electrocardiography is an acceptable alternative for correct placement of the catheter.

*Applies to venous cannulation only.

environment, and rotating the wrist or moving the arm at different angles from the body may help the catheter to advance. If these maneuvers fail, the catheter should not be forced in, because scarring of the vein or sclerosis may be the cause of obstruction, which dictates abandoning the procedure. A postprocedure radiograph of the chest is a must to confirm optimum positioning of the catheter.

Femoral Vein Cannulation

Femoral vein catheters fell into disfavor in the 1950s because of early references to high catheter infection rates.[11] The report by Shaldon and others[12] brought this site to favor during the 1960s, and currently it is regarded as relatively safe. The femoral vein is an easy site to cannulate, although

TABLE 35-3. Advantages and Disadvantages of Different Types of Central Venous Access

ADVANTAGES/DISADVANTAGES	CIVC	TSC	PICC
Complexity of placement	Moderate	High	Low
Time needed for insertion	Moderate	High	Low
Recommended dwell time	Days	Weeks to months	Weeks to months
Infection rate	High	Low	Low
Complexity of complications	High	High	Low
Complication rate	Moderate	Moderate	Low
Possibility for central pressure monitoring	Yes	No	No
Possibility of bolus injection & fluid resuscitation	Yes	Yes	No
Use in ambulatory/home care setting	No	Yes	Yes
Cost	Moderate	High	Low
Patient tolerance	Moderate	High	High

CIVC, centrally inserted venous catheters; TSC, tunneled silicone catheters; PICC, peripherally inserted central catheters.

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TABLE 35-4. Indications and Contraindications of PICC

INDICATIONS	CONTRAINDICATIONS
Difficult IV access	Skin lesion at or above the insertion site
Long-term (> 7 d) IV antibiotic therapy	Previous ipsilateral venous thrombosis
Hyperalimentation	High fluid volume infusion
Chemotherapy	Rapid bolus IV injection
Continuous narcotic infusion	Hemophoresis/hemodialysis
Hyperosmolar fluid infusion	Crutch walking*
Long-term rehydration	Mastectomy*
Long-term IV access in patients with coagulopathy	Presence of pacemaker wires*

PICC, peripherally inserted central catheters; IV, intravenous.
*Denotes relative contraindication.

it also has the disadvantage of requiring longer catheters to pass the diaphragm. Femoral venous cannulation during resuscitation should be reserved for instances in which attempts for cannulation of other sites have failed.[13]

Humans manifest congenital abnormalities of femoral vascular structures, although most patients possess the anatomic relationships represented in Figure 35-1. In patients with a palpable femoral arterial pulse, the vein can be located by probing just medial to the artery, one third of the way from the pubic tubercle toward the anterior superior iliac spine.

Basic equipment required for central venous cannulation should be assembled (see Table 35-1). The site is prepared by having the patient lie flat while slightly rotating the leg externally. Use a 20-gauge, 5- or 7.5-cm (2- or 3-inch) needle directed toward the vein at an angle 45 degrees above the skin. Withdraw the syringe plunger continuously while advancing the needle. The distal tip should not traverse cephalad to the inguinal ligament to avoid retroperitoneal hematoma.

Once venous blood is obtained, repeat the procedure with a larger needle through which an appropriate J-tipped guidewire can be passed. An alternative method is to use an 18-gauge catheter over a 20-gauge needle, in which case the catheter is slid into the vein. If this option is used, after directing the needle toward a line more nearly parallel to the presumed axis of the vein, the needle should be advanced another 2 to 5 mm to ensure that the cannula tip is securely within the lumen.

The site should be appropriately dressed, and documentation should be completed in the chart. A radiograph is usually not taken because tip placement is reasonably assured to be correct if venous blood can be withdrawn easily. Inadvertent arterial puncture and local hematoma formation can be obviated by placing a 2- to 4.5-kg (5- to 10-lb) sandbag on the hematoma site for approximately 30 minutes.

Be sure to secure the dressing so that urine and fecal contamination does not occur. Transparent dressings are ideal for such purposes. Standard adhesive tape can be used to reinforce adherence of the transparent dressing to the skin, if necessary. The dressing should always be changed whenever the percutaneous entry site appears to be moist or contaminated. Complications are uncommon but can include infection, local or retroperitoneal hemorrhage, thrombosis, and arteriovenous fistula formation.[14]

Internal Jugular Vein Cannulation

Percutaneous cannulation of the internal jugular vein (IJV) has evolved over the last two decades.[15] Currently it is the urgent elective and emergency central venous approach preferred by most anesthesiologists and many intensivists (Table 35-5). The merits and disadvantages of IJV cannulation are always relative and must be weighed against the merits and disadvantages of other central vascular approaches (Table 35-6).

ANATOMY. A thorough knowledge of regional anatomy is essential before attempting to cannulate the vein. The IJV usually runs beneath the belly of the sternocleidomastoid muscle immediately lateral to the carotid artery. Patients manifest a surprising variety of anatomic variations. The vein may be absent or in an unusual anatomic location, on any one side, in approximately 10% of ICU patients. Nonetheless, most ICU patients have a patent IJV on at least one side.

CANNULATION APPROACHES. Cannulation can be attempted at relatively high sites (level of the cricoid cartilage) or at lower supraclavicular sites. Higher sites have slightly lower success rates than lower sites where the vein is larger and closer to the skin; however, the high sites have negligible risk of pneumothorax or hemothorax.

In general, high sites should be attempted first, followed by lower sites. We prefer to prepare the skin from the angle of the mandible to below the ipsilateral nipple. This approach gives the operator abundant options for cannulation of the IJV from anterior, central, posterior, and clavicular approaches.

TECHNIQUE. The IJV usually runs deep to the sternocleidomastoid muscle. It can be approached high or low from three directions: anterior to the sternocleidomastoid muscle, centrally between the bellies of the sternocleidomastoid, or posterior to the sternocleidomastoid (Fig. 35-2). These three approaches are illustrated at the level of the cricoid cartilage. Similar needle orientations are used for lower approaches near the clavicle.

The following steps are recommended:

1. Patient and equipment are prepared.
2. The patient should be flat or slightly hyperextended

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73

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American Heart Association℠
Fighting Heart Disease and Stroke

Textbook of Advanced Cardiac Life Support

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ISBN 0-87493-626-8

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Contents

1 Essentials of ACLS

Introduction 1-1
Core ACLS Concepts 1-2
The Primary-Secondary Survey Approach to Emergency Cardiac Care 1-4
The Universal Algorithm for Adult ECC 1-10
Ventricular Fibrillation/Pulseless Ventricular Tachycardia Algorithm 1-15
Pulseless Electrical Activity (PEA) Algorithm 1-21
Asystole Treatment Algorithm 1-23
Emergency Cardiac Care for Adults Not in Full Cardiac Arrest 1-27
Bradycardia Treatment Algorithm 1-28
Tachycardia Treatment Algorithms 1-32
Hypotension/Shock/Acute Pulmonary Edema 1-40
Acute Myocardial Infarction 1-47
Special Resuscitation Situations 1-58
Pediatric Advanced Life Support 1-60
ACLS Code Organization 1-69
CPR: The Human Dimension. The Psychological Aspects of CPR and Resuscitation 1-70
Ethical Aspects of Emergency Cardiac Care 1-71
Summary: Ten Commandments for ACLS 1-71

2 Adjuncts for Airway Control, Ventilation, and Oxygenation

Overview 2-1
Airway Control: Head and Jaw Position 2-1
Airway Adjuncts 2-2
Endotracheal Intubation 2-3
Administering Supplemental Oxygen 2-7
Techniques for Oxygenation and Ventilation 2-8

3 Arrhythmias

Causes of Cardiac Arrhythmias 3-1
The Electrocardiogram: Key to Interpreting Arrhythmias 3-1
Monitoring Systems 3-2
How to Identify Arrhythmias 3-3
ECG Analysis: Question 1 3-3
ECG Analysis: Question 2 3-10
ECG Analysis: Question 3 3-12
Summary of ECG Analysis 3-20
Appendix: Electrical Activity of the Heart 3-20

4 Defibrillation

Importance of Defibrillation 4-1
Overview of Defibrillators 4-3
Special Situations 4-7
Importance of Automated External Defibrillation 4-8
Overview of Automated External Defibrillators 4-8
Use of Automated External Defibrillators During Resuscitation Attempts 4-10
Postresuscitation Care 4-14
Maintaining Defibrillators in a State of Readiness 4-15
Training 4-19
Medical Control 4-19
Quality Assurance 4-20

5 Emergency Cardiac Pacing

Indications for Pacing 5-1
Contraindications to Cardiac Pacing 5-2
Transcutaneous Pacing 5-2
Transvenous Pacing 5-6
Other Pacing Techniques 5-7

6 Intravenous Techniques

Guidelines for Vascular Access: Choice of a Particular Approach 6-1
Intravenous Cannulas 6-2
General Principles of IV Therapy 6-3
Complications Common to All IV Techniques 6-3
Peripheral Veins 6-3
Femoral Veins 6-6
Internal Jugular and Subclavian Veins 6-7

7 Cardiovascular Pharmacology I

Overview: ACLS Pharmacology 7-1
Oxygen 7-1
Epinephrine 7-2
Atropine 7-4
Lidocaine 7-6
Procainamide 7-8
Bretylium 7-9
Verapamil and Diltiazem 7-11
Adenosine 7-13
Magnesium 7-14
Sodium Bicarbonate 7-14
Morphine 7-16
Calcium Chloride 7-16

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

8 Cardiovascular Pharmacology II

"Clinical" Pharmacology 8-1
Cardiovascular Adrenergic Receptors 8-1
Norepinephrine 8-2
Dopamine 8-3
Dobutamine 8-5
Isoproterenol 8-6
Amrinone 8-6
The Tapering of Vasoactive Drugs 8-7
Digitalis Glycosides 8-7
Sodium Nitroprusside 8-8
Nitroglycerin 8-9
β Blockers: Propranolol, Metoprolol, Atenolol, and Esmolol 8-11
Furosemide 8-12
Thrombolytic Agents 8-13

9 Myocardial Infarction

Clinical Presentation 9-1
General Management Approaches 9-2
Management of Arrhythmias and Heart Rate 9-3
Management of Abnormal Blood Pressure Responses in Myocardial Infarction 9-6
Management of Heart Failure in Acute Myocardial Infarction 9-6
Other Causes of Hemodynamic Collapse to Be Distinguished From Acute Infarction 9-8
Special Therapeutic Considerations 9-9
Thrombolytic Therapy 9-10

10 Special Resuscitation Situations

Stroke 10-1
Hypothermia 10-10
Near-Drowning 10-12
Cardiac Arrest Associated With Trauma 10-13
Electric Shock and Lightning Strike 10-15
Cardiac Arrest Associated With Pregnancy 10-17
Toxicologic Cardiac Emergencies 10-18

11 Adjuncts for Artificial Circulation

Alternative CPR Techniques 11-1
Mechanical Aids for CPR 11-2
Invasive CPR 11-3
Assessment of CPR 11-5

12 Invasive Monitoring Techniques

Introduction to Arterial Cannulation 12-1
Arterial Cannulation Sites, Techniques, and Complications 12-5
Bedside Pulmonary Artery Catheterization 12-13
Arterial Puncture 12-26

13 Invasive Therapeutic Techniques

Pericardiocentesis 13-1
Tension Pneumothorax 13-4

14 Cerebral Resuscitation: Treatment of the Brain After Cardiac Resuscitation

Pathophysiology 14-1
Brain-Oriented Treatment of the Patient After Resuscitation From Cardiac Arrest 14-2

15 Ethical Aspects of CPR and ECC

Ethical Principles and Guidelines 15-1
Initiating and Discontinuing Resuscitation in the Prehospital Setting 15-3
Resuscitation and Life Support in the Hospital 15-5
Role of Hospital Ethics Committees 15-7
Legal Considerations in CPR and ECC 15-7

16 Community Approach to ECC: Prevention and the Chain of Survival

Magnitude of the Problem 16-1
Prospects for the Future 16-2
The Responsibility to the Future 16-4
Ensuring Effectiveness of Communitywide Emergency Cardiac Care 16-4

Index I-1

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76

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Using Peripheral Veins for IV Therapy

Advantages

The technique is easy to master. Antecubital vein cannulation usually provides an effective route for the administration of drugs during cardiac arrest so that central cannulation or intracardiac injection may be unnecessary. If basic life support measures are under way, antecubital vein catheterization does not interfere with continuing ventilation and chest compression.

After administration of a drug during CPR, raise the arm and give at least a 20-mL bolus of IV fluid to facilitate delivery of the drug into the central circulation. Allow 1 to 2 minutes for agents to reach the central circulation.

Disadvantages

In circulatory collapse it may be difficult or impossible to establish access from a peripheral vein. Recent studies have demonstrated a significant delay in the arrival of a drug at the heart when peripheral IV sites are used for injection even during effective chest compression.[10,11] Compared with drugs given via a central vein, drugs administered via peripheral veins reach a lower peak concentration and take longer to reach the central circulation.[10,12] Hypertonic or irritating solutions should not be administered through a peripheral vein because pain and phlebitis will result. Even if isotonic solutions are used, the incidence of phlebitis is high if the long saphenous vein is used.

Femoral Veins[7,8]

The femoral vein lies in the femoral sheath, medial to the femoral artery immediately below the inguinal ligament. If a line is drawn between the anterior superior iliac spine and the symphysis pubis, the femoral artery runs directly across the midpoint; medial to that point is the femoral vein. If the femoral artery pulse is palpable, the artery can be located with a finger and the femoral vein will lie immediately medial to the pulsation (Fig 10). During CPR palpable pulsations may represent femoral venous pulsations. Hence, if the vein cannot be located medial to the pulsations, aspiration at the area of the pulsations should be attempted. (If a pulse cannot be felt with cardiac compression, the CPR team should be informed.)

The femoral vein is formed from both the deep and superficial (saphenous) veins of the legs. It extends above the inguinal ligament as the external iliac and becomes the common iliac after being joined by the internal iliac. Both common iliacs join to become the inferior vena cava (Fig 11).

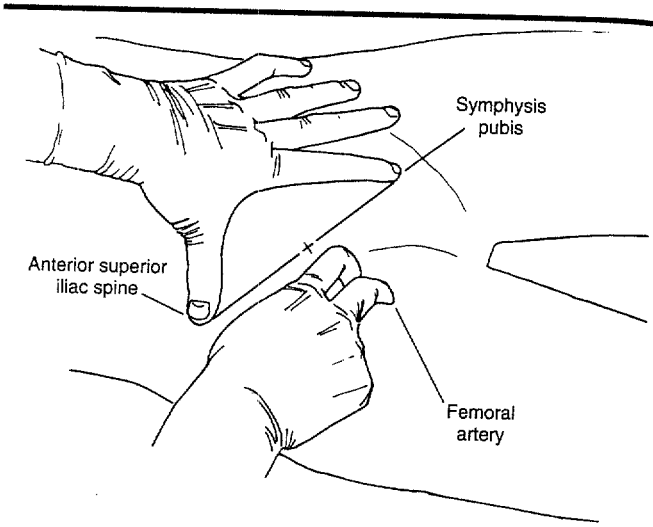

Fig 10. Femoral artery runs directly across the midpoint of line drawn between anterior superior iliac spine and symphysis pubis.

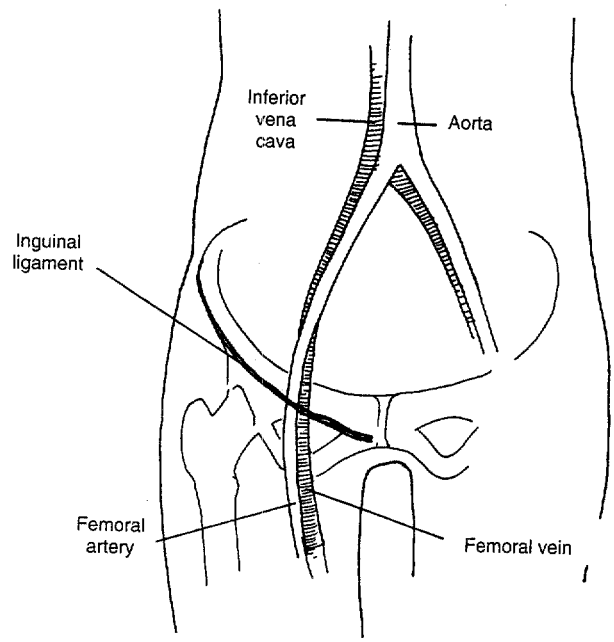

Fig 11. Anatomy of femoral vein. Femoral vein lies medial to femoral artery below inguinal ligament.

Technique

The steps for initiating IV therapy using the femoral vein follow. Although not described in this section, the Seldinger technique is commonly used in this approach.

1. Cleanse the overlying skin with povidone-iodine *when time permits.* When the procedure is elective, clip (do not shave) pubic hair and sterilely prep and drape the area.
2. Locate the femoral artery by its pulsation or Doppler flowmeter tones or by finding the midpoint of a line drawn between the anterior superior iliac spine and the symphysis pubis.
3. Infiltrate the skin with lidocaine if the patient is awake.
4. Make the puncture with the needle attached to a 5- or 10-mL syringe the breadth of two fingers below the inguinal ligament, medial to the artery, directing the needle cephalad at a 45° angle with the skin or

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frontal plane (some prefer to enter at a 90° angle) until the needle will go no farther (Fig 12).
5. Maintain suction on the syringe and pull the needle back slowly until blood appears in the syringe.
6. Lower the needle more parallel to the frontal plane and confirm placement and advance the catheter (if an over-the-needle device) or remove the syringe and insert the catheter (if a through-the-needle device).
7. The catheter is best secured with suture ligature.

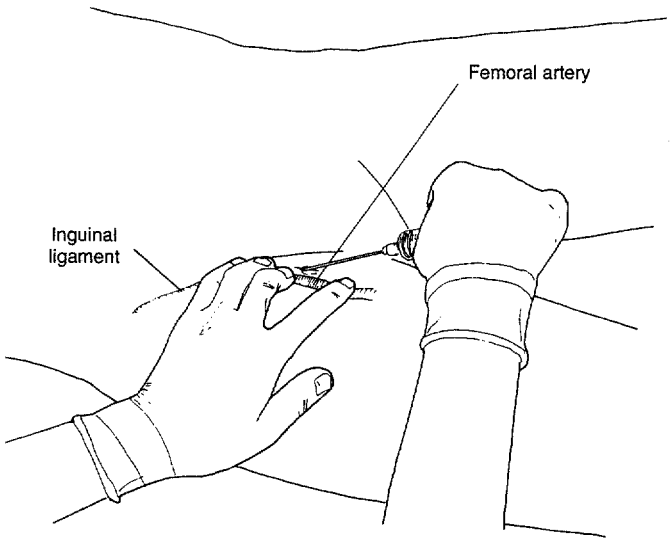

Fig 12. Femoral venipuncture.

Using the Femoral Vein for IV Therapy

Advantages

Interruption of basic life support is unnecessary for femoral cannulation. The femoral vein can be entered when more peripheral veins are collapsed. Once the femoral vein is cannulated, a long catheter can be passed above the diaphragm into the central circulation. Do not use the femoral vein for drug administration during cardiac arrest unless a long catheter that passes above the diaphragm is used.

Disadvantages

Easy location of the vein depends on the presence of the femoral artery pulse; in the absence of an arterial pulse, successful cannulation during CPR is difficult.[13,14] During CPR, venous backflow causes femoral vein pulsations; unsuccessful attempts to cannulate the vein medial to the pulsations should lead to a more lateral approach. Venous return from below the diaphragm is diminished during CPR, and drug delivery times to the central circulation are similar for femoral and peripheral routes.[12,15] For this reason long catheters advanced into the thoracic cavity and large quantities of flush solution are recommended if this technique is used during CPR.

Specific Complications

Hematoma may occur, either from the vein itself or from the adjacent femoral artery. Thrombosis and phlebitis may extend not only to the deep veins but also proximally to the iliac veins or the inferior vena cava. When this occurs, use of the femoral vein may preclude the later use of the saphenous vein.

Inadvertent cannulation of the femoral artery during cardiac arrest may not be recognized since femoral arterial pressure and oxygen tension may be so low that the aspirated blood resembles venous blood. Infusion of a potent vasopressor such as epinephrine into the femoral artery may cause ischemic injury to the involved limb.

Internal Jugular and Subclavian Veins

Anatomy: Internal Jugular Vein[7,8] (Fig 13)

The internal jugular vein emerges from the base of the skull, enters the carotid sheath posterior to the internal carotid artery, and runs posteriorly and laterally to the internal and common carotid artery. Finally, near its termination, the internal jugular vein is lateral and slightly anterior to the common carotid artery.

The internal jugular vein runs medial to the sternomastoid muscle in its upper part, posterior to it in the triangle between the two inferior heads of the sternomastoid in its middle part, and behind the anterior portion of the clavicular head of the muscle in its lower part, ending just above the medial end of the clavicle, where it joins the subclavian vein.

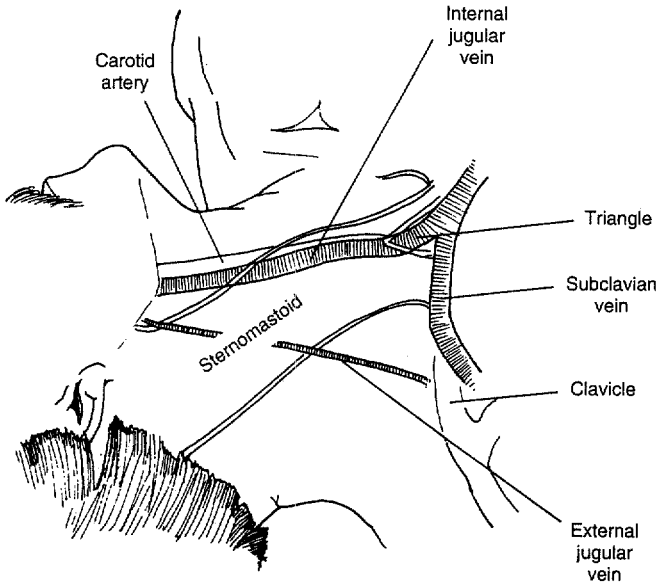

Fig 13. Anatomy of internal jugular vein.

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Rockville, Maryland 20850

July 22, 1997

ARROW INTL., INC.
3000 BERNVILLE ROAD
READING, PA 19605
ATTN: THOMAS D. NICKEL

510(k) Number: K970864
Product: ARROW-HOWES LARGE BORE MULTI-LUMEN CENTRAL VENOUS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

July 07, 1997

ARROW INTL., INC.
3000 BERNVILLE ROAD
READING, PA 19605
ATTN: THOMAS D. NICKEL

510(k) Number: K970864
Product: ARROW-HOWES LARGE BORE MULTI-LUMEN CENTRAL VENOUS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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80

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Memorandum

From: Reviewer(s) - Name(s) William M. Burdett

Subject: 510(k) Number K970864

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

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ 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
'as this 510(k) reviewed by a Third Party?	☐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 N/A

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

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

Review: Patricia Cucinotta (acting) (Branch Chief) ORDB (Branch Code) 7-2-97 (Date)

'al Review: _____ (Division Director) _____ (Date)

Revised 11-20-96

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

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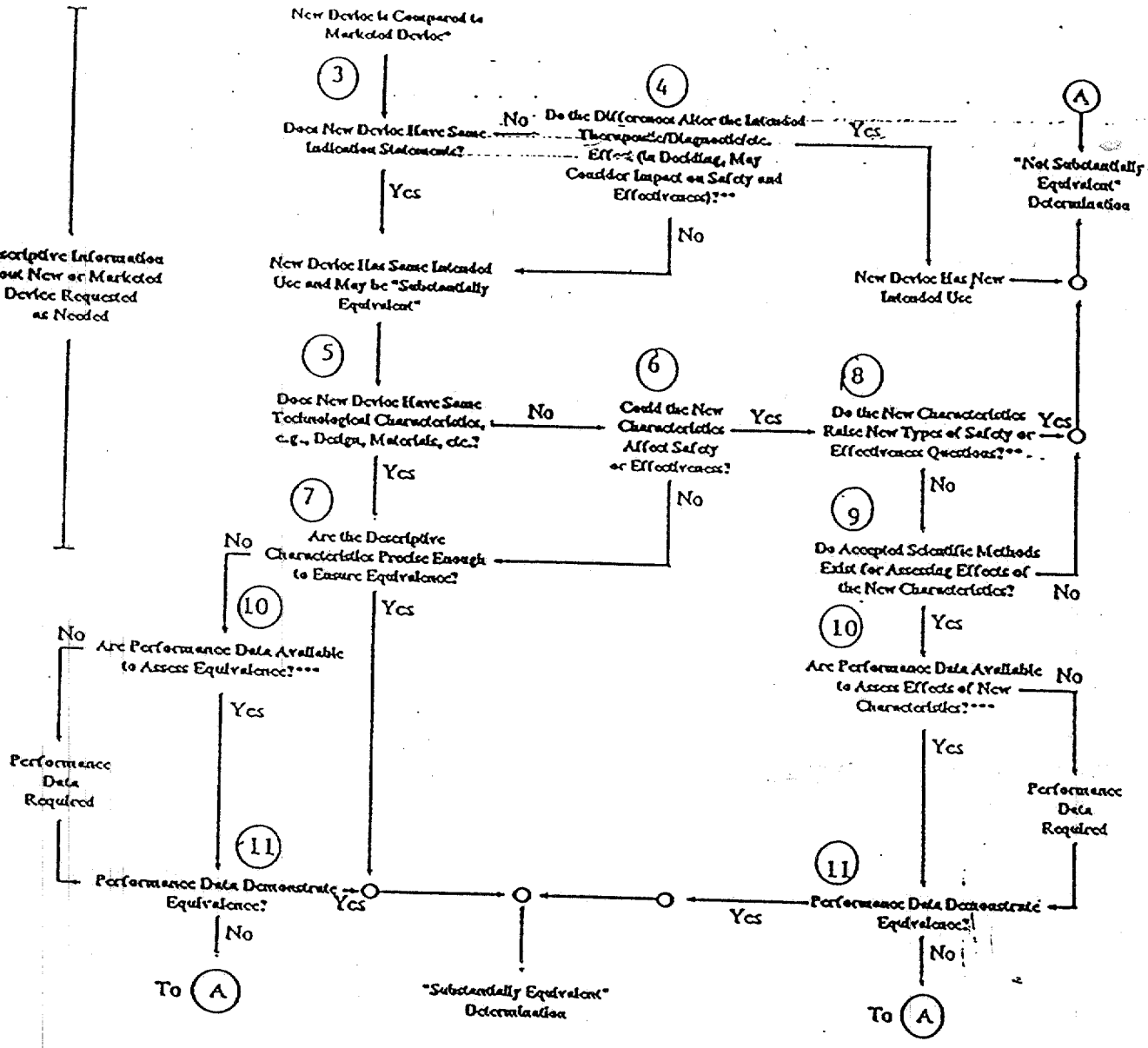
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** 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.

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

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MEMORANDUM OF TELEPHONE CONVERSATION

DATE: July 2, 1997

TO: Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance
Arrow International, Inc.
3000 Bernville Road
Reading, Pennsylvania 19605
(610)478-3137

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DDIGD/GHDB
HFZ-480
9200 Corporate Blvd.
Rockville, MD 20850
(301)594-1287

SUBJECT: 510K Number K970864 - Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheter

I called Mr. Nickel in order to obtain information which I needed to continue the premarket review of his device. A summary of the conversation follows:

1. During my administrative review of this submission, I noticed that one of the three lumens of this catheter is completely circumscribed by the other two lumens. I also noticed that the walls of this inner conduit are thinner than the exterior walls of the catheter. I was concerned that the typical, naked eye, visual examination of failure, fracture of the external catheter wall, may not detect a possible, prior fracture of the internal wall. I sent Mr. Nickel a fax (please refer to memo dated November 28, 1996 [actually, incorrectly dated November 28, 1997]) in which I requested the results of mechanical strength and burst testing which would assure that failure of the inner wall would be detected with the same precision as failure of an external conduit wall. In his response, Mr. Nickel provided a valid method for detecting inner wall fracture due to excessive hydrostatic pressure but failed to provide a valid method of detection of inner wall fracture during tensile or fatigue strength testing. I explained that visual detection of an external wall fracture will not detect an inner lumen failure. I suggested that evidence of inner wall failure may be detected through examination of the stress-strain curve (possibly, an atypical, extended elongation at a constant level of stress). I requested that Mr. Nickel have his technical experts examine the stress-strain curves for the previously tested specimens and submit the results of their assessment concerning the potential that inner wall failure was undetected.

2. In the original submission, Mr. Nickel stated that Arrow intends to market a heparin-coated model. I informed Mr. Nickel that the coated Arrow catheters cited in the submission are not intravascular catheters but cardiovascular and hemodialysis catheters and that I was unaware of any predicate heparin-coated intravascular catheters. I was concerned that heparin may not be compatible with the substances (e.g., TPN, chemotherapeutics) normally infused through intravascular catheters. I asked Mr. Nickel to either provide a predicate which is or was heparin-coated or provide assurances that

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drug compatibility would not be an issue. He replied that he would submit such data.

3. I told Mr. Nickel that the predicates cited in his submission were not classified as intravascular catheters but as cardiovascular and hemodialysis catheters. He stated that they are intravascular catheters. I tried to explain the difference to him, but he seemed unwilling to accept my explanation. I told him that I would compare his catheter to other intravascular catheter predicates of which I was aware.

4. The indications for use statement that was provided stated that their catheter may be inserted into the femoral vein. Since I was not aware of such an insertion site for an intravascular catheter, I asked Mr. Nickel for an explanation. He replied that it is an insertion site although not often used. He also stated that he would submit additional information attesting to this fact.

5. Injection sites at the end of the extensions were evident in the drawings of the catheter. I inquired as to whether they were screw-on models with a latex septum. He answered in the affirmative to both questions.

I concluded our conversation by informing Mr. Nickel that his submission would be placed on "HOLD" until the requested information was received by our office.

William M. Burdick
William M. Burdick
Biomedical Engineer

cc. K970864
CHRON file

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

87

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MEMORANDUM TO THE RECORD

DATE: June 25, 1997

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DDIGD/GHDB
HFZ-480
9200 Corporate Blvd.
Rockville, MD 20850

SUBJECT: 510K Number K970864 - Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheter

The principal subject of this 510(k) is a short-term, nonpyrogenic, sterilized (EtO), single use, three lumen, polyurethane (P/U), central venous catheter. The catheter is to be sold as a single unit or in kit form, either with drugs or without.

This device has a long and rather interesting history. In January 1991, Arrow decided that they would like to add a third lumen to their two lumen hemodialysis catheter (K895417) for the infusion of medications or the withdrawal of blood. They determined that the addition would neither be a safety nor effectiveness issue and wrote a letter to their master file to this effect. In December 1991, a field investigator from the Philadelphia district stated that the letter to the file was adequate. In 1994, council was sought from CDRH and the opposite conclusion was reached, forcing the company to submit a 510(k) to the hemodialysis group in ODE. Eventually, a reviewer with the hemodialysis group consulted with me regarding the requirements of an intravascular catheter. Their determination for the need of clinical results concerning infection rate influenced Arrow to seek substantial equivalence solely as an intravascular catheter.

The catheter has a unique design for a three lumen vessel. Unlike other three lumen intravascular catheters, one of the lumens is a cylindrical conduit inscribed between two conduits having D-shaped lumens; therefore, the walls of the inner lumen are not visible to the naked eye. This poses a testing problem. Fracture of the inner lumen can not be visibly detected, and Arrow has defined mechanical strength failure of the catheters to be fracture of the outer lumens. Given that the walls of the inner conduit are thinner than the walls of the external ones, this issue is a legitimate one. Arrow did not completely address this issue in their May 1, 1997, response to my November 28, 1996, request for additional information.

The rest of the catheter description is as follows. Each catheter is a twelve french with two 12 gauge and one 16 gauge extensions for the outer and inner lumens, respectively. The extensions are fabricated

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85

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from Pellethane P/U and are encircled with polycarbonate or acetyl pinch clamps. The manifold which connects the extensions to the central tube is fabricated from Tecoflex P/U, as well as the central tube and tip. The ink-marked, central tube is either 16 or 20 inches in length, with two holes staggered along its length and the third hole passing through the tip. Injection sites (latex? screw-on?) seem to "cap off" each extension hub.

As mentioned above, Arrow intends to market their product either as a kit, as a set (kit without drug components), or solely as a catheter. Please refer to the attached for a list of possible components, a description of the ten products to be offered in the three different forms, and the kit certification. Arrow also intends to market the catheter in both a coated and uncoated form. The coating is heparin, and Arrow cited some heparin-coated catheters which they have legally marketed; however, these heparin-coated catheters, which Arrow claims to be substantially equivalent to this three-lumen catheter, are not classified as intravascular catheters but as cardiovascular and hemodialysis catheters. Arrow and I had discussed this issue of a heparin-coated intravascular catheter on a previous occasion. At that time, I informed them that I was unaware of any intravascular catheters with a heparin coat. My concern then, as now, revolved around the possible incompatibility between heparin and the types of infusates typically passing through an intravascular catheter, provided the catheter is coated on the inside as well as outside. This concern still needs to be addressed.

Also mentioned briefly in the first paragraph is the fact that all products will be provided sterile. Sterilization will be by ethylene oxide. Validation of the sterilization cycle to a SAL of 10^{-6} will be according to ANSI/AAMI ST27-1988. Arrow assures that residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol will not exceed the FDA proposed limits of 25, 25, and 250 parts per million, respectively.

Sincerely,

William M. Burdick

William M. Burdick
Biomedical Engineer

- Attachments

cc. K970864
CHRON file

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

86

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~~SECTION 9 - TRUTHFUL AND ACCURATE STATEMENT:~~

~~I certify that in my capacity as Vice President, Regulatory Affairs and Quality Assurance of Arrow International, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.~~

~~Thomas D. Nickel~~
March 6, 1997

Section 10 - Kit Component Listing and Certification

The "product" includes kit and set versions as listed in Attachment 1, and the General Hospital required component information is as follows.

Qty.	Component	Present In		Drug	Purchased bulk non-labeled, non-sterile	Arrow Mfg'd component	Purchased labeled, non-sterile
		Kits	Sets				
1	.035" dia spring wire guide	Y	Y			X	
1	vessel dilator	Y	Y			X	
1	25 ga. X 1" needle	Y			X		
1	22 ga. X 1" needle	Y				X	
1	18 ga. X 2 1/2" introducer needle	Y	Y			X	
1	18 ga. X 2 1/2" Radiopaque catheter over 20 ga. needle	Y	Y			X	
1	3 cc syringe	Y			X		
1	5 cc syringe	Y			X		
1	5 cc Arrow Raulerson syringe	Y	Y			X	
1	pressure transduction probe	Y	Y			X	
1	fenestrated drape	Y			X		
2	2" X 2" gauze pads	Y			X		
5	4" X 4" gauze pads	Y			X		
3	Povidone-Iodine swabsticks	Y		X			
1	Povidone-Iodine ointment 1gm	Y		X			
1	Lidocaine HCl, 5ml 1% ampule	Y		X			
1	Sharpsaway™ disposal cup	Y				X	
1	disposable scalpel (#11 blade)	Y			X		
1	suture: 3-O silk w/straight needle	Y					X
4	Usergard™ hubs	Y	Y			X	
4	Usergard™ injection caps	Y	Y			X	
1	catheter clamp w/fastener	Y	Y			X	
1	CSR wrap	Y			X		
4	extension line clamps	Y	Y			X	

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

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Kit Certification

~~Certification~~

I certify that all of the medical components of the subject kit or set, are either ① legally marketed preamendment devices, ② exempt from premarket notification (consistent with the exemption criteria described in the classification regulations and the limitations of exemptions from Section 510(k) of the Act (e.g., 21 CFR 862.9), or ③ have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is intended (i.e., not claiming or causing a new use for the component(s).

I further certify that we purchase all device components either in packaged and labeled form consistent with their preamendments, exemption, or premarket notification criteria and status, or as bulk non-labeled and non-sterile components, also consistent with their preamendments, exemption, or premarket notification criteria and status. The details per component appear in the chart above. In addition, all purchased drug components are also packaged and labeled consistent with their approval.

Both kit and set versions of the device utilize packaging which consists of a vacuum formed tray and Tyvek lid. All components are placed in the tray, it is sealed, packed in corrugated shipping cartons, and EtO sterilized. No components are "reprocessed" as a result of the sterilization. The drug components are either foil pouches impermeable to EtO, or glass ampules impermeable to EtO. Therefore, final processing of the kit has no effect whatsoever regarding the functionality (i.e., safety and effectiveness) of any kit components.

Note that the set labeling is identical to the kit labeling except the set lidstock lists fewer components.

(51a)

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

88

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Product Description

f the following products are 12 French multi-lumen (3-lumen) central venous catheters for volume infusions. They exist as kits, sets, and single catheters in varying lengths, as ned below:

heter length	Kit	Set	Individual Catheter	Product Number
m	X			AK-12123-H*
m		X		CS-12123-E
m		X		CS-12123-F
m			X	MC-12123
m	X			AK-12123-F
m	X			AK-15123-H*
m	X			AK-15123-F
m		X		CS-15123-E
m		X		CS-15123-F
m			X	MC-15123

eparin coated

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

May 06, 1997

ARROW INTL., INC.
3000 BERNVILLE ROAD
READING, PA 19605
ATTN: THOMAS D. NICKEL

510(k) Number: K970864
Product: ARROW-HOWES LARGE BORE MULTI-LUMEN CENTRAL VENOUS

The additional information you have submitted has been received.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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K970864/S1

Certified Mail

P.O. Box 12888
Reading, PA 19612

ARROW
INTERNATIONAL

2400 Bernville Road
Reading, PA 19605
(610) 378-0131
FAX: (610) 374-5360

May 1, 1997

Center for Devices and Radiological Health
Document Mail Room HFZ-401
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RECEIVED
5 MAY 97 14 00
FDA/CDRH/ODE/DMS

Re: 510(k) Premarket Notification K970864 - Request for additional information
Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheters

Dear Mr. Burdick:

This letter is in response to your March 28, 1997 voicemail request for additional information.

Item 1

"Please provide the results from mechanical and performance testing as you have with past intravascular catheter submissions. In addition, please specify the manner in which you determine mechanical strength failure and fluid leakage of your central lumen. Since this lumen is totally enclosed within the catheter tubing, normal methods for determining failure and leakage would not apply."

Response

Test data on the two versions (firm and standard) of the 12 French triple lumen catheters are appended as Attachment 1. Included also are data on both the 7 French triple lumen and 12 French 2-lumen predicates. The attachment includes a matrix describing the test values, sample size, etc. for the various mechanical specifications, and the test protocols are appended as sub-attachments.

The burst pressure and leak testing of the central lumen is tested in the same manner as the larger lumens. As specified in attached protocols AML-038 and AML-055, the catheter end is clamped while one of the lumens is pressurized. In the leak test, the lumen is pressurized to 50 psi for one minute and any drop in pressure indicates a leak. Only one lumen of each sample catheter was tested, i.e., 30 catheters were tested, using 10 catheters for each lumen. The leak testing and burst pressure results of the central lumens are separated from the large lumens, refer to specifications 6c and 7c of Attachment 1.

In addition all lumens of all the 12 French triple-lumen catheters (as well as the predicates) are leak tested at 15 psi as a routine manufacturing process. This detects and eliminates catheters that have inter-lumenal communication.

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

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Item 2

"Please explain your reasons for coating your catheter with heparin. I have not been able to discover a legally marketed predicate intravascular catheter that was coated with heparin, and I am not clear as to why heparin would be used to coat such a catheter. If you are familiar with a heparin-coated predicate, please provide the name and 510(k) number, if possible."

Response

Some users feel a Heparin coating renders the catheter nonthrombogenic, and want this coating on the device. We consider this a customer preference issue, and make no claims whatsoever regarding the Heparin coating. The coating is also provided on a predicate 7 French 3-lumen device, premarket notification K840336, as stated on page 4 of this submission. We use the same Heparin coating solution and process as the predicate.

Item 3

"Please indicate whether the materials comprising your device are identical in composition and intended use to legally marketed predicate devices; otherwise, please specify all the materials comprising your device and provide the results from biocompatibility testing which considers patient blood pathways, tissue contact, and the duration of contact with your device according to the enclosed guidance document entitled "Use of International Standard ISO-10993", Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Your submission lacked this information which is required in order to assure that the materials comprising the device do not cause an allergic reaction or have a toxic effect on the patient."

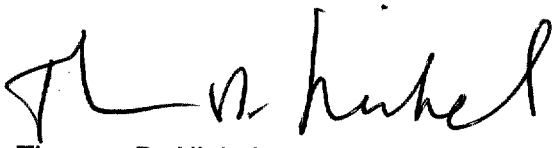
Response

The catheter tips, juncture hubs, and extension line hubs for both subject devices and predicates are identical. The extension lines and catheter shaft polyurethane material of the firm and standard 12 French triple lumen products are similar polyurethane but not identical to the 7 French predicate. The materials have passed all the same biocompatibility tests as the predicates, and the test result matrix, test protocols, and raw data are appended as Attachment 2.

If you have any questions, please call me at 610/478-3137.

Thank you.

Sincerely,



Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

7050b

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ATTACHMENT 1

Mechanical and performance testing, which includes the following, in order:

1. Test result matrix
2. Test protocols

    A. Tensile tester
    B. Pressure leak test
    C. Positive pressure burst test

3. Test data

    A. Specification 1 and 5 - lab request No. 6981
    B. Specification 2a - lab request No. 69979
    C. Specification 2b - lab request No. 6976
    D. Specification 2c - lab request No. 6975
    E. Specification 2d - lab request No. 6978
    F. Specification 2e - lab request No. 6977
    G. Specification 3 - lab request No. 7003
    H. Specification 4 - lab request No. 6980
    I. Specification 6 - lab request No. 6989
    J. Specification 7 - lab request No. 6990
    K. Specification 8 - lab request No. 6991

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

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Mechanical Specifications

Specification	7 Fr, 3-lumen CVC	sample size (7 Fr. testing)	12 Fr., 2-lumen hemo. cath., standard	12 Fr., 3-lumen CVC, standard	12 Fr., 2-lumen hemo. cath., firm	12 Fr., 3-lumen CVC, firm	sample size (12 Fr. 2-L and 3-L testing)
1. tensile strength of catheter body	[redacted]						(b)(4)
2. tensile strength of hub attachments a. cath. body to juncture hub b. juncture hub to extension lines c. juncture hub to extension line (12 Fr. 3-lumen distal) d. extension line to luer hub e. extension line to luer hub (12 Fr. 3-lumen distal)							
3. catheter stiffness (flexural modulus)							
4. catheter tip attachment strength							
5. catheter elongation							
6. leakage at hubs a. 7 Fr. b. 12 Fr. large lumens c. 12 Fr. 3-lumen small distal							
7. catheter burst pressure a. 7 Fr. b. 12 Fr. large lumens c. 12 Fr. 3-lumen small distal							
8. catheter flexural fatigue							

P. Ashton 4/28/97

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

CM 2

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ARROW INTERNATIONAL, INC.
OPERATION OF THE SINTECH UNIVERSAL TENSILE TESTER

1. PURPOSE

To Describe procedures used to operate the Sintech Universal Tensile Tester in the Bern Materials Testing Lab.

2. SCOPE

This procedure applies to all tensile and compression testing performed by the Bern Materials Testing Lab.

3. RESPONSIBILITIES

(b) (4)

[redacted]

4. REQUIREMENTS DOCUMENTS

ISO 9001/EN 46001, section 4.4 "Design Control"

5. REFERENCES

5.1. Technical Reference Manual for SINTECH Computer Integrated Testing Systems, June 1989

5.2. TestWorks™ Advanced Software for Materials Testing, Version 2.1, Latest Revision

5.3. TestWorks™ Manual

6. EQUIPMENT

6.1. SINTECH Universal Tensile Tester, Model 2W

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

7. SET UP

(b) (4)

[redacted]

9. REPORTING

9.1. Attach copies of the detailed report and appropriate graphs to the Lab Report Form.

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

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10. APPROVALS

Materials Lab Technician _____ Date _____

Senior Research Engineer _____ Date _____

Vice President, Research & Manufacturing _____ Date _____

Vice President, Regulatory Affairs/Quality Assurance _____ Date _____

11. REVISION HISTORY

Revision	Changes	Approved By
0 3/19/93	Original Issue	D. Ravel, R. Citron, P. Fleck, T. Nickel
1 5/22/96	Add Attachment 1	D. Ravel, R. Citron, P. Fleck, T. Nickel

12. DISTRIBUTION

J. Cadd
R. Citron
Device Master Records
Materials Test Lab

(4562)

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[1]

This standard is issued under the fixed designation D 790; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This test method has been approved for use by agencies of the Department of Defense to replace Method 1031 of Federal Test Method Standard 406. Consult the DoD Index of Specifications and Standards for the specific year of issue which has been adopted by the Department of Defense.

1. Scope

1.1 These test methods cover the determination of flexural properties of unreinforced and reinforced plastics, including high-modulus composites and electrical insulating materials in the form of rectangular bars molded directly or cut from sheets, plates, or molded shapes. These test methods are generally applicable to rigid and semirigid materials. However, flexural strength cannot be determined for those materials that do not break or that do not fail in the outer fibers. Two test methods are described as follows:

1.1.1 *Test Method I*—A three-point loading system utilizing center loading on a simply supported beam.

1.1.2 *Test Method II*—A four-point loading system utilizing two load points equally spaced from their adjacent support points, with a distance between load points of either one-third or one-half of the support span.

1.2 Either test method can be used with the two procedures that follow:

1.2.1 *Procedure A*, designed principally for materials that break at comparatively small deflections.

1.2.2 *Procedure B*, designed particularly for those materials that undergo large deflections during testing.

1.3 Comparative tests may be run according to either test method or procedure, provided that the test method or procedure is found satisfactory for the material being tested.

1.4 The values stated in SI units are to be regarded as the standard. The values provided in parentheses are for information only.

NOTE 1—A complete metric companion to Test Method D 790 has been developed—D 790M.

1.5 *This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 618 Practice for Conditioning Plastics and Electrical Insulating Materials for Testing[2]
D 638 Test Method for Tensile Properties of Plastics[2]
D 790M Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials [Metric][2]
D 883 Terminology Relating to Plastics[2]
D 4000 Classification System for Specifying Plastic Materials[3]
D 4066 Specification for Nylon Injection and Extrusion Materials[3]
E 4 Practices for Load Verification of Testing Machines[4]
E 691 Practice for Conducting an Interlaboratory Test Program to Determine the Precision of Test Methods[5]

3. Terminology

3.1 *Definitions*—Definitions of terms applying to these test methods appear in Terminology D 883 and Annex A1 of Test Method D 638.

4. Summary of Test Methods

4.1 A bar of rectangular cross section is tested in flexure as a beam as follows:

4.1.1 *Test Method I*—The bar rests on two supports and is loaded by means of a loading nose midway between the supports (see Fig. 1).

4.1.2 *Test Method II*—The bar rests on two supports and is loaded at two points (by means of two loading noses), each an equal distance from the adjacent support point. The distance between the loading noses (that is, the load span) is either one-third or one-half of the support span (see Fig. 2).

4.2 The specimen is deflected until rupture occurs in the outer fibers or until the maximum fiber strain (see 12.9) of 5 % is reached, whichever occurs first.

5. Significance and Use

5.1 Flexural properties determined by Test Method I are especially useful for quality control and specification purposes.

5.2 For many materials, there may be a specification that requires the use of these test methods, but with some procedural modifications that take precedence when ad-

[1] These test methods are under the jurisdiction of ASTM Committee D-20 on Plastics and are the direct responsibility of Subcommittee D20.10 on Mechanical Properties.

Current edition approved June 15, 1992. Published August 1992. Originally published as D 790 – 70. Last previous edition D 790 – 91.

[2] *Annual Book of ASTM Standards*, Vol 08.01.
[3] *Annual Book of ASTM Standards*, Vol 08.02.
[4] *Annual Book of ASTM Standards*, Vol 03.01.
[5] *Annual Book of ASTM Standards*, Vol 14.02.

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

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ARROW INTERNATIONAL, INC.
PRESSURE LEAK TEST

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1. PURPOSE

To describe procedures used to pressure test any luer fitted item for leaks.

2. SCOPE

This procedure applies to the pressure leak testing performed by the Materials Test Lab in the Arrow Bern township facility. This procedure generally applies to the pressure testing of corrugated sheaths but can be used with any device that is fitted with a luer connection.

3. RESPONSIBILITIES

(b) (4)

[redacted]

4. REQUIREMENTS DOCUMENTS

CP-4.4 "Design Control"
AML-F023 "Positive Pressure Leak Test"

5. SET UP

(b) (4)

[redacted]

6. PROCEDURE

(b) (4)

[redacted]

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

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(b) (4)

[redacted]

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7. APPROVALS:

Sr. Materials Lab Technician Date

Senior Research Engineer Date

VP, RA/QA Date

8. REVISION HISTORY:

Revision	Change	Approved By
0 4/26/93	Original issue	T. Rarick, R. Citron T. Nickel
1 3/31/97	reduce number of samples tested at a time to 1; add # to form	T. Rarick, R. Citron, T. Nickel

9. HARD COPY DISTRIBUTION:

Jody Cadd - original

10. NOTIFICATION

R. Citron
T. Rarick

m:/qsdocs/corp/cp404

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

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ARROW INTERNATIONAL, INC.
POSITIVE PRESSURE BURST TEST

UNCONTROLLED COPY IS

1. PURPOSE

To describe procedures used to pressure test any catheter or sheaths until failure occurs which is noted by ballooning of the material being tested or by the material bursting.

2. SCOPE

This procedure applies to the burst testing performed by the Materials Test Lab in the ARROW Bern Township facility.

3. RESPONSIBILITIES

(b) (4)

[redacted]

4. REQUIREMENTS DOCUMENTS

CP-4.4 "Design Control"
AML-F019 "Positive Pressure Burst Test"

5. SET UP

(b) (4)

[redacted]

6. PROCEDURE

(b) (4)

[redacted]

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b) (4)

[redacted]

7. APPROVALS

Senior Materials Lab Technician _____ Date _____

Senior Research Engineer _____ Date _____

VP, RA/QA _____ Date _____

8. REVISION HISTORY

Revision	Changes	Approved By
0 3/27/97	Original issue	T. Rarick, R. Citron, T. Nickel

9. HARD COPY DISTRIBUTION

J. Cadd - original

10. NOTIFICATION

R. Citron	T. Rarick

m:/qsdocs/corp/cp403

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(b) (4)

[redacted]

Paul Robertson 4/28/97

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

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ARROW INTERNATIONAL, INC.
FLEX (FATIGUE) TEST

PURPOSE
To document the test method used to flex test catheters or extrusions.

SCOPE
This procedure applies to catheters or extrusions being flex (fatigue) tested.

RESPONSIBILITIES
(b) (4)

[redacted]

PROCEDURE
(b) (4)

[redacted]

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

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Spec 1,5

LAB REQUEST

Lab Request No.
6981

1. **Service Requested** (Only One Request Per Sheet):

   tensile strength -- elongation of catheter body and ultimate tensile strength in pounds (peak load)

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 1: MC-12122-003B; 12 Fr 2-L std.
   group 2: MC-15123-002A; 12 Fr 3-L std.
   group 3: MC-32122-001C; 12 Fr 2-L firm
   group 4: MC-32123-001A; 12 Fr 3-L, firm

   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please pull 25 catheters from each test group; report results by catheter type. Report percent elongation and ultimate tensile strength (peak load).
   Report one representative graph from each group.

Requestor: P. Robertson
Signature: P. Robertson
Date: 4/14/97

REV: 04/27/95 (NEW)

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

113

25

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REPORT

Service Requested By: P. ROBERTSON

Service Requested: TENSILE TEST

Lab Request No. Assigned: 6981

Raw Material Part Number: N/A

Raw Material Lot Number: N/A

Description: N/A

Component Part Number: MC-12122-003B & MC-15123-002A & MC-32122-001C & MC-32123-001A

Component Lot Number: N/A

Description: 12FR 2-L STD & 12FR 3-L STD & 12FR 2-L FIRM & 12FR 3-L FIRM

Lab Procedure: AML-037

Data and/or Results: SEE ATTACHED

Comments:

Signed: [signature]

Date: 4.23.97

Approval: [signature]

Date: 4/23/97

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

11h 26

Report Date:Apr 22, 1997

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ARROW INTERNATIONAL
MATERIAL TEST LAB
TEST REPORT - Sintech 2W
LOAD VS. ELONGATION

Sample ID: 6-981:MC-12122-003B
Method: ARROW Pull & % Elong. @ Peak
Data path: C:\TW300

Test Date: Apr 22, 1997
Operator ID: KEVIN

	Peak Load Lb	Elong @ Pk Ld In	% Elong @ Pk Ld %
1	(b)(4) [redacted]		
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
Mean			
Min			
Max			
Stdv			

Specimen Comments:

Calculation Inputs:

Grip Separation 1.000 In

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

115 27

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Test Inputs:

Test Speed	20.000	In/Min

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(b) (4)

[redacted]

6-981:MC-12122-003B Spcm # 25

LOAD (Lb)

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

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Report Date: Apr 22, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
TEST REPORT
LOAD VS. ELONGATION

Property : "Peak Load" in (Lb)

(b)(4) (b) (4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

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Specimen Level Histogram

(b) (4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b) (4)

[redacted]

Specimen Trend

Specimen(s)

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

Report Date:Apr 22, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
TEST REPORT Sintech 2W
LOAD VS. ELONGATION

Sample ID: 6-981:MC-15123-002A
Method: ARROW Pull & % Elong. @ Peak
Data path: C:\TW300

Test Date: Apr 22, 1997
Operator ID: KEVIN

	Peak Load Lb	Elong @ Pk Ld In	% Elong @ Pk Ld %
1	(b)(4) [redacted]		
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
Mean			
Min			
Max			
Stdv			

Specimen Comments:

Calculation Inputs:
Grip Separation 1.000 In

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

D1

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Test Inputs:

Test Speed	20.000	In/Min

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Report Date: Apr 22, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
TEST REPORT
LOAD VS. ELONGATION

Property : "Peak Load" in (Lb)

(b)(4) (b) (4)

Cell

1
2
3
4
5
6
7
8
9
10

Grouped Mean
Grp. Std. Dev.
Skew
Kurtosis

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b) (4)

[redacted]

Freq

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

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Specimen Trend

(b) (4)

[redacted]

Peak Load (Lb)

Specimen(s)

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

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(b) (4)

[redacted]

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

Report Date:Apr 22, 1997 Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
TEST REPORT-Sintech 2w
LOAD VS. ELONGATION

Sample ID: 6-981:MC-32122-001C
Method: ARROW Pull & % Elong. @ Peak
Data path: C:\TW300

Test Date: Apr 22, 1997
Operator ID: KEVIN

	Peak Load Lb	Elong @ Pk Ld In	% Elong @ Pk Ld %
1	(b)(4) [redacted]		
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
Mean			
Min			
Max			
Stdv			

pecimen Comments:

Calculation Inputs:
Grip Separation 1.000 In

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

D7

Page 40 of 40 Freedom of Information Request #2015-5835; Released by CDRH on 7/28/2016

Test Inputs:

Test Speed	20.000	In/Min

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Report Date: Apr 22, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
TEST REPORT
LOAD VS. ELONGATION

Property : "Peak Load" in (Lb)

(b)(4) (b) (4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b) (4)

[redacted]

Fre

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

Peak Load (Lb)

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

131

Report Date:Apr 23, 1997 Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
TEST REPORT - Sintech 2w
LOAD VS. ELONGATION

Sample ID: 6-981:MC-32123-001A
Method: ARROW Pull & % Elong. @ Peak
Data path: C:\TW300

Test Date: Apr 22, 1997
Operator ID: KEVIN

	Peak Load Lb	Elong @ Pk Ld In	% Elong @ Pk Ld %
1	(b)(4) [redacted]		
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
Mean			
Min			
Max			
Stdv			

Specimen Comments:

Calculation Inputs:

Grip Separation 1.000 In

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Test Inputs:

Test Speed	20.000	In/Min

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(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 23, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
TEST REPORT
LOAD VS. ELONGATION

Property : "Peak Load" in (Lb)

(b)(4) [redacted]

(b)(4) [redacted]

Cell

1
2
3
4
5
6
7
8
9
10

Grouped Mean
Grp. Std. Dev.
Skew
Kurtosis

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

Freq

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

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(b)(4)

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

spec 2a

LAB REQUEST

Lab Request No.
6979

1. **Service Requested** (Only One Request Per Sheet):

   tensile strength -- catheter body to blue junction hub

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 1: MC-12122-003B; 12 Fr 2-L std.
   group 2: MC-15123-002A; 12 Fr 3-L std.
   group 3: MC-32122-001C; 12 Fr 2-L firm
   group 4: MC-32123-001A; 12 Fr 3-L, firm

   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please pull 25 catheters from each test group; report results by catheter type.

Requestor: P. Robertson
Signature: P. Robertson
Date: 4/14/97

REV: 04/27/95 (NEW)

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

138

51

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LAB REPORT

Service Requested By: P. ROBERTSON

Service Requested: TENSILE TEST

Lab Request No. Assigned: 6979

Raw Material Part Number: N/A

Raw Material Lot Number: N/A

Description: N/A

Component Part Number: MC-12122-003B & MC-15123-002A & MC-32122-001C & MC-32123-001A

Component Lot Number: N/A

Description: 12FR 2-L STD & 12FR 3-L STD & 12FR 2-L FIRM & 12FR 3-L FIRM

Lab Procedure: AML-037

Data and/or Results: SEE ATTACHED

Comments:

Signed: [signature]

Date: 4-21-97

Approval: [signature]

Date: 4/22/97

Report Date:Apr 21, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-979:MC-12122-003B
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 21, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
1 : catheter body broke
2 : catheter body broke flush with hub

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

1hD 53

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

3 : catheter body broke
4 : catheter body broke
5 : catheter body broke
6 : catheter body broke
7 : catheter body broke
8 : catheter body broke
9 : catheter body broke
10 : catheter body broke
11 : catheter body broke
12 : catheter body broke
13 : catheter body broke
14 : catheter body broke
15 : catheter body broke
16 : catheter body broke
17 : catheter body broke
18 : catheter body broke
19 : catheter body broke
20 : catheter body broke
21 : catheter body broke
22 : catheter body broke flush with hub
23 : catheter body broke
24 : catheter body broke
25 : catheter body broke

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 21, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) [redacted] (b)(4) [redacted]

Cell
1
2
3
4
5
6
7
8
9
10
Grouped Mea
Grp. Std. Dev
Skew
Kurtosis

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

Fre

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

1hh 57

Report Date:Apr 21, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-979:MC-15123-002A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 21, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
1 : catheter body broke
2 : catheter body broke

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

3 : catheter body broke
4 : catheter body broke
5 : catheter body broke
6 : catheter body broke
7 : catheter body broke
8 : catheter body broke
9 : catheter body broke
10 : catheter body broke
11 : catheter body broke
12 : catheter body broke
13 : catheter body broke
14 : catheter body broke
15 : catheter body broke
16 : catheter body broke
17 : catheter body broke
18 : catheter body broke
19 : catheter body broke
20 : catheter body broke
21 : catheter body broke
22 : catheter body broke
23 : catheter body broke
24 : catheter body broke
25 : catheter body broke

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 21, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

Fre

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Trend

(b)(4)

[redacted]

Pea
Loa
(Lb

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

Report Date:Apr 21, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-979:MC-32122-001C
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 21, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
1 : catheter body broke flush with hub
2 : catheter body broke flush with hub

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

VSD 63

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

3 : catheter body broke
4 : catheter body broke
5 : catheter body broke
6 : catheter body broke
7 : catheter body broke
8 : catheter body broke
9 : Catheter body broke inside hub
10 : Catheter body broke inside hub
11 : catheter body broke
12 : catheter body broke
13 : catheter body broke
14 : catheter body broke
15 : catheter body broke
16 : catheter body broke
17 : Catheter body broke inside hub
18 : Catheter body broke inside hub
19 : catheter body broke
20 : Catheter body broke inside hub
21 : Catheter body broke inside hub
22 : catheter body broke
23 : catheter body broke
24 : catheter body broke
25 : catheter body broke

Test Inputs:

Test Speed	20.00	In/Min

151 64

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 21, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) [redacted] (b)(4) [redacted]

Cell
1
2
3
4
5
6
7
8
9
10
Grouped Mean
Grp. Std. Dev.
Skew
Kurtosis

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

Ish 67

Report Date:Apr 21, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-979:MC-32123-001A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 21, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
1 : catheter pulled from hub
2 : catheter pulled from hub

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

3 : catheter pulled from hub
4 : catheter pulled from hub
5 : catheter pulled from hub
6 : catheter pulled from hub
7 : catheter pulled from hub
8 : catheter pulled from hub
9 : catheter pulled from hub
10 : catheter pulled from hub
11 : catheter pulled from hub
12 : catheter pulled from hub
13 : catheter pulled from hub
14 : catheter pulled from hub
15 : catheter pulled from hub
16 : catheter pulled from hub
17 : catheter pulled from hub
18 : catheter pulled from hub
19 : catheter pulled from hub
20 : catheter pulled from hub
21 : catheter pulled from hub
22 : catheter pulled from hub
23 : catheter pulled from hub
24 : catheter pulled from hub
25 : catheter pulled from hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 21, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

Cell	(b)(4)	(b)(4)
1	[redacted]	[redacted]
2	[redacted]	[redacted]
3	[redacted]	[redacted]
4	[redacted]	[redacted]
5	[redacted]	[redacted]
6	[redacted]	[redacted]
7	[redacted]	[redacted]
8	[redacted]	[redacted]
9	[redacted]	[redacted]
10	[redacted]	[redacted]
Grouped Mean	[redacted]	[redacted]
Grp. Std. Dev.	[redacted]	[redacted]
Skew	[redacted]	[redacted]
Kurtosis	[redacted]	[redacted]

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

157

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

spec 26

LAB REQUEST

Lab Request No.
6976

1. **Service Requested** (Only One Request Per Sheet):

   tensile strength -- blue junction hub to large extension lines

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 1: MC-12122-003B; 12 Fr 2-L std.
   group 2: MC-15123-002A; 12 Fr 3-L std.
   group 3: MC-32122-001C; 12 Fr 2-L firm
   group 4: MC-32123-001A; 12 Fr 3-L, firm
   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please pull 50 extension lines from 25 catheters from each test group, both extensions may be grouped together within each of the four catheter types.

Requestor: P. Robertson
Signature: D. Robertson
Date: 4/14/97

REV: 04/27/95 (NEW)

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

160 74

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REPORT

Service Requested By: P. ROBERTSON

Service Requested: TENSILE TEST

Lab Request No. Assigned: 6976

Raw Material Part Number: N/A

Raw Material Lot Number: N/A

Description: N/A

Component Part Number: MC-12122-003B & MC-15123-002A & MC-32122-001C & MC-32123-001A

Component Lot Number: N/A

Description: 12FR 2-L STD & 12FR 3-L STD & 12FR 2-L FIRM &12FR 3-L FRIM

Lab Procedure: AML-037

Data and/or Results: SEE ATTACHED

Comments:

Signed: [signature]

Date: 4/17/97

Approval: [signature]

Date: 4/18/97

Report Date:Apr 16, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-976:MC-12122-003B
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 16, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
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uestions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

162 76

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

39	(b)(4) [redacted]
40	
41	
42	
43	
44	
45	
46	
47	
48	
49	
50	

Mean	(b)(4) [redacted]
Min	
Max	
Stdv	

Specimen Comments:

1 : Extension line broke inside hub
2 : Extension line broke inside hub
3 : Extension line broke inside hub
4 : Extension line broke inside hub
5 : Extension line broke inside hub
6 : Extension line broke inside hub
7 : Extension line broke inside hub
8 : extension line pulled from hub
9 : Extension line broke inside hub
10 : Extension line broke inside hub
11 : Extension line broke inside hub
12 : extension line pulled from hub
13 : Extension line broke inside hub
14 : Extension line broke inside hub
15 : Extension line broke inside hub
16 : extension line pulled from hub
17 : Extension line broke inside hub
18 : Extension line broke inside hub
19 : Extension line broke inside hub
20 : Extension line broke inside hub
21 : Extension line broke inside hub
22 : Extension line broke inside hub
23 : Extension line broke inside hub
24 : Extension line broke inside hub
25 : Extension line broke inside hub
26 : extension line pulled from hub
27 : extension line pulled from hub
28 : extension line pulled from hub
29 : Extension line broke inside hub
30 : Extension line broke inside hub
31 : Extension line broke inside hub
32 : extension line pulled from hub
33 : extension line pulled from hub
34 : extension line pulled from hub
35 : Extension line broke inside hub

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

36 : extension line pulled from hub
37 : extension line pulled from hub
38 : extension line pulled from hub
39 : Extension line broke inside hub
40 : NO FAILURE
41 : extension line pulled from hub
42 : extension line pulled from hub
43 : Extension line broke inside hub
44 : extension line pulled from hub
45 : Extension line broke inside hub
46 : Extension line broke inside hub
47 : Extension line broke inside hub
48 : Extension line broke inside hub
49 : Extension line broke inside hub
50 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 16, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 17, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-976:MC-15123-002A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 17, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) (b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
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36	
37	
38	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

	(b)(4)	(b)(4)
39	[redacted]	[redacted]
40	[redacted]	[redacted]
41	[redacted]	[redacted]
42	[redacted]	[redacted]
43	[redacted]	[redacted]
44	[redacted]	[redacted]
45	[redacted]	[redacted]
46	[redacted]	[redacted]
47	[redacted]	[redacted]
48	[redacted]	[redacted]
49	[redacted]	[redacted]
50	[redacted]	[redacted]
Mean	[redacted]	[redacted]
Min	[redacted]	[redacted]
Max	[redacted]	[redacted]
Stdv	[redacted]	[redacted]

Specimen Comments:
1 : Extension line broke inside hub
2 : Extension line broke inside hub
3 : extension line pulled from hub
4 : Extension line broke inside hub
5 : Extension line broke inside hub
6 : extension line pulled from hub
7 : Extension line broke inside hub
8 : Extension line broke inside hub
9 : Extension line broke inside hub
10 : extension line pulled from hub
11 : Extension line broke inside hub
12 : Extension line broke inside hub
13 : Extension line broke inside hub
14 : extension line pulled from hub
15 : Extension line broke inside hub
16 : extension line pulled from hub
17 : Extension line broke inside hub
18 : extension line pulled from hub
19 : Extension line broke inside hub
20 : Extension line broke inside hub
21 : Extension line broke inside hub
22 : Extension line broke inside hub
23 : extension line pulled from hub
24 : extension line pulled from hub
25 : Extension line broke inside hub
26 : extension line pulled from hub
27 : Extension line broke inside hub
28 : extension line pulled from hub
29 : Extension line broke inside hub
30 : extension line pulled from hub
31 : Extension line broke inside hub
32 : extension line pulled from hub
33 : extension line pulled from hub
34 : Extension line broke inside hub
35 : Extension line broke inside hub

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

Records processed under FOIA Request #2015-5885; Released by CDRH on 7/28/2016

36 : Extension line broke inside hub
37 : Extension line broke inside hub
38 : Extension line broke inside hub
39 : Extension line broke inside hub
40 : Extension line broke inside hub
41 : Extension line broke inside hub
42 : extension line pulled from hub
43 : Extension line broke inside hub
44 : Extension line broke inside hub
45 : Extension line broke inside hub
46 : Extension line broke inside hub
47 : Extension line broke inside hub
48 : extension line pulled from hub
49 : Extension line broke inside hub
50 : extension line pulled from hub

Test Inputs:

Test Speed	20.00	In/Min

Report Date: Apr 17, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

171

85

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 17, 1997

Records processed under FOIA Request #2015-5835, Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-976:MC-32122-001C
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 17, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
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37	
38	

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

17M88

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

39	((b)(4)
40	(
41	[redacted]
42	
43	
44	
45	
46	
47	
48	
49	
50	
Mean	
Min	
Max	
Stdv	

Specimen Comments:

1 : Extension line broke inside hub
2 : Extension line broke inside hub
3 : Extension line broke inside hub
4 : Extension line broke inside hub
5 : Extension line broke inside hub
6 : Extension line broke inside hub
7 : NO FAILURE OCCURRED
8 : Extension line broke inside hub
9 : Extension line broke inside hub
10 : Extension line broke inside hub
11 : Extension line broke inside hub
12 : NO FAILURE OCCURRED
13 : Extension line broke inside hub
14 : Extension line broke inside hub
15 : Extension line broke inside hub
16 : Extension line broke inside hub
17 : Extension line broke inside hub
18 : Extension line broke inside hub
19 : Extension line broke inside hub
20 : Extension line broke inside hub
21 : Extension line broke inside hub
22 : Extension line broke inside hub
23 : extension line pulled from hub
24 : Extension line broke inside hub
25 : Extension line broke inside hub
26 : Extension line broke inside hub
27 : Extension line broke inside hub
28 : Extension line broke inside hub
29 : Extension line broke inside hub
30 : Extension line broke inside hub
31 : Extension line broke inside hub
32 : Extension line broke inside hub
33 : Extension line broke inside hub
34 : Extension line broke inside hub
35 : Extension line broke inside hub

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

36 : Extension line broke inside hub
37 : Extension line broke inside hub
38 : Extension line broke inside hub
39 : Extension line broke inside hub
0 : Extension line broke inside hub
41 : Extension line broke inside hub
42 : Extension line broke inside hub
43 : Extension line broke inside hub
44 : Extension line broke inside hub
45 : Extension line broke inside hub
46 : Extension line broke inside hub
47 : Extension line broke inside hub
48 : Extension line broke inside hub
49 : Extension line broke inside hub
50 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (L(b)(4)

(b)(4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 17, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-976:MC-32123-001A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 17, 1997
Operator ID: KEVIN

Sample Inputs:

Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
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stions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

39	[redacted]
40	
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Mean	
Min	
Max	
Stdv	

Specimen Comments:

1 : Extension line broke inside hub
2 : Extension line broke inside hub
3 : Extension line broke inside hub
4 : Extension line broke inside hub
5 : Extension line broke inside hub
6 : Extension line broke inside hub
7 : Extension line broke inside hub
8 : Extension line broke inside hub
9 : Extension line broke inside hub
10 : extension line pulled from hub
11 : Extension line broke inside hub
12 : Extension line broke inside hub
13 : Extension line broke inside hub
14 : Extension line broke inside hub
15 : Extension line broke inside hub
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34 : Extension line broke inside hub
35 : Extension line broke inside hub

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

36 : Extension line broke inside hub
37 : Extension line broke inside hub
38 : Extension line broke inside hub
39 : Extension line broke inside hub
40 : Extension line broke inside hub
41 : Extension line broke inside hub
42 : Extension line broke inside hub
43 : Extension line broke inside hub
44 : Extension line broke inside hub
45 : Extension line broke inside hub
46 : Extension line broke inside hub
47 : Extension line broke inside hub
48 : Extension line broke inside hub
49 : Extension line broke inside hub
50 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

Cell	(b)(4)	(b)(4)
1	[redacted]	[redacted]
2	[redacted]	[redacted]
3	[redacted]	[redacted]
4	[redacted]	[redacted]
5	[redacted]	[redacted]
6	[redacted]	[redacted]
7	[redacted]	[redacted]
8	[redacted]	[redacted]
9	[redacted]	[redacted]
10	[redacted]	[redacted]
Grouped Mean	[redacted]	[redacted]
Grp. Std. Dev.	[redacted]	[redacted]
Skew	[redacted]	[redacted]
Kurtosis	[redacted]	[redacted]

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

183 97

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

① 1

spec 2 c

LAB REQUEST

Lab Request No.
6975

1. **Service Requested** (Only One Request Per Sheet):

   tensile strength -- blue junction hub to small distal extension line

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 2: MC-15123-002A; 12 Fr 3-L std.
   group 4: MC-32123-001A; 12 Fr 3-L, firm
   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please pull 25 catheters from each test group; report results by catheter type.

Requestor: P. Robertson
Signature: P. Robertson
Date: 4/14/97

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

786 101

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REPORT

Service Requested By: P. ROBERTSON

Service Requested: TENSILE TEST

Lab Request No. Assigned: 6975

Raw Material Part Number: N/A

Raw Material Lot Number: N/A

Description: N/A

Component Part Number: MC-15123-002A & MC-32123-001A

Component Lot Number: N/A

Description: 12FR 3-L STD & FIRM

Lab Procedure: AML-037

Data and/or Results: SEE ATTACHED

Comments:

Signed: [signature]

Date: 4/16/97

Approval: [signature]

Date: 4/16/97

Report Date:Apr 16, 1997

Records processed under FOIA Request # 2015-5335, released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-975:MC-15123-002A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 16, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
0	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	(b)(4) [redacted]
Min	
Max	
Stdv	

Specimen Comments:
1 : Extension line broke inside hub
2 : Extension line broke inside hub

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

188

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

3 : Extension line broke inside hub
4 : Extension line broke inside hub
5 : Extension line broke inside hub
6 : Extension line broke inside hub
7 : Extension line broke inside hub
8 : Extension line broke inside hub
9 : Extension line broke inside hub
10 : Extension line broke inside hub
11 : Extension line broke inside hub
12 : Extension line broke inside hub
13 : Extension line broke inside hub
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15 : Extension line broke inside hub
16 : Extension line broke inside hub
17 : Extension line broke inside hub
18 : Extension line broke inside hub
19 : Extension line broke inside hub
20 : Extension line broke inside hub
21 : Extension line broke inside hub
22 : Extension line broke inside hub
23 : Extension line broke inside hub
24 : Extension line broke inside hub
25 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

Report Date: Apr 16, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

Cell	(b)(4)	(b)(4)	tive cy
1	[redacted]	[redacted]	
2			
3			
4			
5			
6			
7			
8			
9			
10			
Grouped Mean			
Grp. Std. Dev.			
Skew			
Kurtosis			

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

190,105

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 16, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-975:MC-32123-001A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 16, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
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22	
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25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
1 : Extension line broke inside hub
2 : Extension line broke inside hub

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

3 : Extension line broke inside hub
4 : Extension line broke inside hub
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7 : Extension line broke inside hub
8 : Extension line broke inside hub
9 : Extension line broke inside hub
10 : Extension line broke inside hub
11 : Extension line broke inside hub
12 : Extension line broke inside hub
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15 : Extension line broke inside hub
16 : Extension line broke inside hub
17 : Extension line broke inside hub
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19 : Extension line broke inside hub
20 : Extension line broke inside hub
21 : Extension line broke inside hub
22 : Extension line broke inside hub
23 : Extension line broke inside hub
24 : Extension line broke inside hub
25 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 16, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell

1
2
3
4
5
6
7
8
9
10

Grouped Mean
Grp. Std. Dev.
Skew
Kurtosis

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

spec 2d

LAB REQUEST

Lab Request No.
6978

1. **Service Requested** (Only One Request Per Sheet):

   Tensile strength -- large extension line luer hub bond

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 1: MC-12122-003B; 12 Fr 2-L std.
   group 2: MC-15123-002A; 12 Fr 3-L std.
   group 3: MC-32122-001C; 12 Fr 2-L firm
   group 4: MC-32123-001A; 12 Fr 3-L, firm

   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please pull 50 luer hubs from 25 catheters from each test group, both luer hubs may be grouped together within each of the four catheter types.

Requestor: P. Robertson
Signature: P. Robertson
Date: 4/14/97

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

198 114

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REPORT

Service Requested By: P. ROBERTSON

Service Requested: TENSILE TEST

Lab Request No. Assigned: 6978

Raw Material Part Number: N/A

Raw Material Lot Number: N/A

Description: N/A

Component Part Number: MC-15123-002A & MC-32123-001A & MC-12122-003B & MC-32122-001C

Component Lot Number: N/A

Description: 12FR 3-L STD & 12FR 3-L FIRM & 12FR 2-L STD & 12FR 2-L FIRM

Lab Procedure: AML-037

Data and/or Results: SEE ATTACHED

Comments:

Signed:

Date: 4-18-97

Approval:

Date:

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

Report Date:Apr 18, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-978:MC-12122-003B
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 18, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

39	(b)(4) [redacted]
40	
41	
42	
43	
44	

Mean	(b)(4) [redacted]
Min	
Max	
Stdv	

Specimen Comments:
1 : extension line pulled from hub
2 : Extension line broke inside hub
3 : Extension line broke inside hub
4 : extension line pulled from hub
5 : extension line pulled from hub
6 : Extension line broke inside hub
7 : Extension line broke inside hub
8 : extension line pulled from hub
9 : extension line pulled from hub
10 : Extension line broke inside hub
11 : Extension line broke inside hub
12 : extension line pulled from hub
13 : Extension line broke inside hub
14 : Extension line broke inside hub
15 : Extension line broke inside hub
16 : Extension line broke inside hub
17 : Extension line broke inside hub
18 : Extension line broke inside hub
19 : Extension line broke inside hub
20 : Extension line broke inside hub
21 : extension line pulled from hub
22 : extension line pulled from hub
23 : extension line pulled from hub
24 : Extension line broke inside hub
25 : Extension line broke inside hub
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27 : Extension line broke inside hub
28 : extension line pulled from hub
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33 : extension line pulled from hub
34 : Extension line broke inside hub
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36 : Extension line broke inside hub
37 : Extension line broke inside hub
38 : extension line pulled from hub
39 : extension line pulled from hub
40 : extension line pulled from hub
41 : extension line pulled from hub

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

42 : extension line pulled from hub
43 : Extension line broke inside hub
44 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 18, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
1	
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4	
5	
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7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 18, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-978:MC-15123-002A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 18, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
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stions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

39
40
41
42
43
44
45
46
47
48
49
50

Mean
Min
Max
Stdv

Specimen Comments:
1 : extension line pulled from hub
2 : Extension line broke inside hub
3 : Extension line broke inside hub
4 : Extension line broke inside hub
5 : Extension line broke inside hub
6 : Extension line broke inside hub
7 : Extension line broke inside hub
8 : Extension line broke inside hub
9 : Extension line broke inside hub
10 : Extension line broke inside hub
11 : extension line pulled from hub
12 : extension line pulled from hub
13 : Extension line broke inside hub
14 : extension line pulled from hub
15 : extension line pulled from hub
16 : extension line pulled from hub
17 : Extension line broke inside hub
18 : Extension line broke inside hub
19 : extension line pulled from hub
20 : extension line pulled from hub
21 : Extension line broke inside hub
22 : Extension line broke inside hub
23 : Extension line broke inside hub
24 : Extension line broke inside hub
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31 : Extension line broke inside hub
32 : Extension line broke inside hub
33 : Extension line broke inside hub
34 : Extension line broke inside hub
35 : Extension line broke inside hub

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

36 : extension line pulled from hub
37 : Extension line broke inside hub
38 : extension line pulled from hub
39 : extension line pulled from hub
40 : extension line pulled from hub
41 : Extension line broke inside hub
42 : extension line pulled from hub
43 : extension line pulled from hub
44 : Extension line broke inside hub
45 : Extension line broke inside hub
46 : Extension line broke inside hub
47 : extension line pulled from hub
48 : extension line pulled from hub
49 : extension line pulled from hub
50 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 18, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
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Grouped Mear	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/22/2016

(b)(4)

[redacted]

Specimen Level Histogram

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 18, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-978:MC-32122-001C
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 18, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
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estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

39	(b)(4)
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Mean	
Min	
Max	
Stdv	

Specimen Comments:

1 : Extension line broke inside hub
2 : Extension line broke inside hub
3 : Extension line broke inside hub
4 : Extension line broke inside hub
5 : extension line pulled from hub
6 : Extension line broke inside hub
7 : Extension line broke inside hub
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12 : Extension line broke inside hub
13 : Extension line broke inside hub
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19 : extension line pulled from hub
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22 : Extension line broke inside hub
23 : extension line pulled from hub
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25 : Extension line broke inside hub
26 : Extension line broke inside hub
27 : Extension line broke inside hub
28 : Extension line broke inside hub
29 : Extension line broke inside hub
30 : Extension line broke inside hub
31 : Extension line broke inside hub
32 : extension line pulled from hub
33 : Extension line broke inside hub
34 : Extension line broke inside hub
35 : Extension line broke inside hub

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

36 : Extension line broke inside hub
37 : Extension line broke inside hub
38 : Extension line broke inside hub
39 : Extension line broke inside hub
40 : Extension line broke inside hub
41 : Extension line broke inside hub
42 : Extension line broke inside hub
43 : Extension line broke inside hub
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46 : Extension line broke inside hub
47 : Extension line broke inside hub
48 : Extension line broke inside hub
49 : Extension line broke inside hub
50 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 18, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

Cell	(b)(4)	(b)(4)
1	[redacted]	[redacted]
2	[redacted]	[redacted]
3	[redacted]	[redacted]
4	[redacted]	[redacted]
5	[redacted]	[redacted]
6	[redacted]	[redacted]
7	[redacted]	[redacted]
8	[redacted]	[redacted]
9	[redacted]	[redacted]
10	[redacted]	[redacted]
Grouped Mean	[redacted]	[redacted]
Grp. Std. Dev.	[redacted]	[redacted]
Skew	[redacted]	[redacted]
Kurtosis	[redacted]	[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Level Histogram

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 18, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-978:MC-32123-001A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 18, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
	(b)((b)(4)
1	[redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
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33	
34	
35	
36	
37	
38	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

39	(b)(4) [redacted]
40	
41	
42	
43	
44	
45	
46	
47	
48	
49	
Mean	[redacted]
Min	
Max	
Stdv	

Specimen Comments:

1 : Extension line broke inside hub
2 : Extension line broke inside hub
3 : Extension line broke inside hub
4 : Extension line broke inside hub
5 : Extension line broke inside hub
6 : Extension line broke inside hub
7 : extension line pulled from hub
8 : Extension line broke inside hub
9 : Extension line broke inside hub
10 : Extension line broke inside hub
11 : Extension line broke inside hub
12 : Extension line broke inside hub
13 : extension line pulled from hub
14 : Extension line broke inside hub
15 : Extension line broke inside hub
16 : Extension line broke inside hub
17 : extension line pulled from hub
18 : Extension line broke inside hub
19 : Extension line broke inside hub
20 : Extension line broke inside hub
21 : Extension line broke inside hub
22 : Extension line broke inside hub
23 : Extension line broke inside hub
24 : Extension line broke inside hub
25 : Extension line broke inside hub
26 : Extension line broke inside hub
27 : Extension line broke inside hub
28 : Extension line broke inside hub
29 : Extension line broke inside hub
30 : Extension line broke inside hub
31 : Extension line broke inside hub
32 : Extension line broke inside hub
33 : Extension line broke inside hub
34 : Extension line broke inside hub
35 : Extension line broke inside hub
36 : Extension line broke inside hub

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

37 : Extension line broke inside hub
38 : Extension line broke inside hub
39 : Extension line broke inside hub
40 : extension line pulled from hub
41 : Extension line broke inside hub
42 : Extension line broke inside hub
43 : Extension line broke inside hub
44 : Extension line broke inside hub
45 : Extension line broke inside hub
46 : Extension line broke inside hub
47 : Extension line broke inside hub
48 : Extension line broke inside hub
49 : Extension line broke inside hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 18, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]	[redacted]
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
Grouped Mean		
Grp. Std. Dev.		
Skew		
Kurtosis		

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

(b)(4)

Specimen Trend

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Spec 2e

LAB REQUEST

Lab Request No.
6977

1. **Service Requested** (Only One Request Per Sheet):

   tensile strength -- small distal extension line luer hub bond

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 2: MC-15123-002A; 12 Fr 3-L std.
   group 4: MC-32123-001A; 12 Fr 3-L, firm
   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please pull 25 luer hubs from each test group; report results by catheter type.

Requestor: P. Robertson
Signature: P. Robertson
Date: 4/14/97

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

224 141

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REPORT

Service Requested By: P. ROBERTSON

Service Requested: TENSILE TEST

Lab Request No. Assigned: 6977

Raw Material Part Number: N/A

Raw Material Lot Number: N/A

Description: N/A

Component Part Number: MC-15123-002A & MC-32123-001A

Component Lot Number: N/A

Description: 12FR 3-L STD & 12FR 3-L FIRM

Lab Procedure: AML-037

Data and/or Results: SEE ATTACHED

Comments:

Signed: [illegible]

Date: 4-18-97

Approval: [illegible]

Date: 4/22/97

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

Report Date:Apr 18, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-977:MC-15123-002A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 18, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
1 : Extension line broke inside hub
2 : Extension line broke inside hub
3 : Extension line broke inside hub

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

226

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

4 : Extension line broke inside hub
5 : Extension line broke inside hub
6 : Extension line broke inside hub
7 : Extension line broke inside hub
8 : Extension line broke inside hub
9 : Extension line broke inside hub
10 : Extension line broke inside hub
11 : extension line pulled from hub
12 : extension line pulled from hub
13 : extension line pulled from hub
14 : extension line pulled from hub
15 : extension line pulled from hub
16 : extension line pulled from hub
17 : Extension line broke inside hub
18 : Extension line broke inside hub
19 : extension line pulled from hub
20 : extension line pulled from hub
21 : extension line pulled from hub
22 : Extension line broke inside hub
23 : extension line pulled from hub
24 : extension line pulled from hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 18, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell

1
2
3
4
5
6
7
8
9
10

Grouped Mean
Grp. Std. Dev.
Skew
Kurtosis

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Level Histogram

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 18, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-977:MC-32123-001A
Method: ARROW Cath/Hub Tensile Test
Data path: C:\TW300

Test Date: Apr 18, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. TENSILE TEST

	Peak Load Lb
	(b)(4) [redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
1 : Extension line broke inside hub
2 : Extension line broke inside hub
3 : extension line pulled from hub

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

4 : extension line pulled from hub
5 : extension line pulled from hub
6 : extension line pulled from hub
7 : extension line pulled from hub
8 : extension line pulled from hub
9 : Extension line broke inside hub
10 : Extension line broke inside hub
11 : Extension line broke inside hub
12 : Extension line broke inside hub
13 : extension line pulled from hub
14 : Extension line broke inside hub
15 : extension line pulled from hub
16 : Extension line broke inside hub
17 : Extension line broke inside hub
18 : Extension line broke inside hub
19 : Extension line broke inside hub
20 : Extension line broke inside hub
21 : extension line pulled from hub
22 : extension line pulled from hub
23 : extension line pulled from hub
24 : extension line pulled from hub

Test Inputs:

Test Speed	20.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 18, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

Cell	(b)(4)	(b)(4)
1	[redacted]	[redacted]
2	[redacted]	[redacted]
3	[redacted]	[redacted]
4	[redacted]	[redacted]
5	[redacted]	[redacted]
6	[redacted]	[redacted]
7	[redacted]	[redacted]
8	[redacted]	[redacted]
9	[redacted]	[redacted]
10	[redacted]	[redacted]
Grouped Mea	[redacted]	[redacted]
Grp. Std. Dev.	[redacted]	[redacted]
Skew	[redacted]	[redacted]
Kurtosis	[redacted]	[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

spec 3.

LAB REQUEST

Lab Request No.
7003

1. **Service Requested** (Only One Request Per Sheet):

   flex modulus -- per ASTM 790

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 1: EB-15122-001A; 12 Fr 2-L std.
   group 2: EB-15123-001; 12 Fr 3-L std.
   group 3: EB-35122-001B; 12 Fr 2-L firm
   group 4: EB-35123-001A; 12 Fr 3-L, firm

   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please test 10 catheter blanks from each test group; report results by catheter type. Orient the blanks so that the septums are in the horizontal plane.

Requestor: P. Robertson
Signature: P. Robertson
Date: 4/14/97

REV: 04/27/95 (NEW)

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REPORT

Service Requested By: P. ROBERTSON

Service Requested: FLEX MODULUS TEST

Lab Request No. Assigned: 7003

Raw Material Part Number: N/A

Raw Material Lot Number: N/A

Description: N/A

Component Part Number: EB-15122-001A & EB-15123-001 & EB-35122-001B & EB-35123-001A

Component Lot Number: N/A

Description: 12FR 2-L STD & 12FR 3-L STD & 12FR 2-L FIRM & 12FR 3-L FIRM

Lab Procedure: AML-037

Data and/or Results: SEE ATTACHED

Comments:

Signed: [signature]

Date: 4-25-97

Approval: [signature]

Date: 4/25/97

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

Report Date:Apr 25, 1997

Records processed under FOIA Request #2015-5833, Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 7-003:EB-15122-001A
Method: Arrow Flex Modulus
Data path: C:\TW300

Test Date: Apr 25, 1997
Operator ID: KEVIN

	Inner Diameter In	Outer Diameter In	Peak Load Lb	Flex Modulus PSI
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
8				
9				
10				
Mean				
Min				
Max				
Stdv				

Specimen Comments:

Calculation Inputs:

Support Span	1.000	In

Test Inputs:

Test Speed	1.00	In/Min
% Strain Limit	10.0	%

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

Report Date:Apr 25, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 7-003:EB-15123-001
Method: Arrow Flex Modulus
Data path: C:\TW300

Test Date: Apr 25, 1997
Operator ID: KEVIN

	Inner Diameter In	Outer Diameter In	Peak Load Lb	Flex Modulus PSI
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
8				
9				
10				
Mean				
Min				
Max				
Stdv				

Specimen Comments:

Calculation Inputs:

Support Span	1.000	In

Test Inputs:

Test Speed	1.00	In/Min
% Strain Limit	10.0	%

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

Report Date:Apr 25, 1997

Records processed under FOIA Request #2015-5895; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 7-003:EB-35122-001B
Method: Arrow Flex Modulus
Data path: C:\TW300

Test Date: Apr 25, 1997
Operator ID: KEVIN

	Inner Diameter In	Outer Diameter In	Peak Load Lb	Flex Modulus PSI
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
8				
9				
10				
Mean				
Min				
Max				
Stdv				

Specimen Comments:

Calculation Inputs:

Support Span	1.000	In

Test Inputs:

Test Speed	1.00	In/Min
% Strain Limit	10.0	%

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

Report Date:Apr 25, 1997

Records processed under FOIA Request #2015-5835, Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 7-003:EB-35123-001A
Method: Arrow Flex Modulus
Data path: C:\TW300

Test Date: Apr 25, 1997
Operator ID: KEVIN

	Inner Diameter In	Outer Diameter In	Peak Load Lb	Flex Modulus PSI
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
8				
9				
10				
Mean				
Min				
Max				
Stdv				

Specimen Comments:

Calculation Inputs:

Support Span	1.000	In

Test Inputs:

Test Speed	1.00	In/Min
% Strain Limit	10.0	%

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

spec 4

LAB REQUEST

Lab Request No.
6980

1. **Service Requested** (Only One Request Per Sheet):

   tensile strength -- blue tip bond strength

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 1: MC-12122-003B; 12 Fr 2-L std.
   group 2: MC-15123-002A; 12 Fr 3-L std.
   group 3: MC-32122-001C; 12 Fr 2-L firm
   group 4: MC-32123-001A; 12 Fr 3-L, firm
   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please pull 25 catheters from each test group; report results by catheter type.

Requestor: P. Robertson
Signature: P. Robertson
Date: 4/14/97

REV: 04/27/95 (NEW)

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

JM 161

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

LAB REPORT

Service Requested By: P. ROBERTSON

Service Requested: TENSILE TEST

Lab Request No. Assigned: 6980

Raw Material Part Number: N/A

Raw Material Lot Number: N/A

Description: N/A

Component Part Number: MC-12122-003B & MC-15123-002A & MC-32122-001C & MC-32123-001A

Component Lot Number: N/A

Description: 12FR 2-L STD & 12FR 3-L STD & 12FR 2-L FIRM & 12FR 3-L FIRM

Lab Procedure: AML-037

Data and/or Results: SEE ATTACHED

Comments:

Signed: Kim M Sa

Date: 4-21-97

Approval:

Date: 4/22/97

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

Report Date:Apr 21, 1997

Records processed under FOIA Request #2015-5603 Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-980:MC-12122-003B
Method: ARROW SOFT TIP TENSILE TEST
Data path: C:\TW300

Test Date: Apr 21, 1997
Operator ID: KEVIN

Sample Inputs:

Test Desc. Blue Tip Pull Test

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
0	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
1 : Tip break
2 : Tip break

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

2hh 163

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

18 : Tip break

Test Inputs:

Test Speed	5.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

Report Date:Apr 21, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-980:MC-15123-002A
Method: ARROW SOFT TIP TENSILE TEST
Data path: C:\TW300

Test Date: Apr 21, 1997
Operator ID: KEVIN

Sample Inputs:

Test Desc. Blue Tip Pull Test

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:

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

Sample ID: 6-980:MC-15123-002A (Test Inputs Continued...)

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Test Inputs:

Test Speed	5.00	In/Min

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 21, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Level Histogram

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 21, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-980:MC-32122-001C
Method: ARROW SOFT TIP TENSILE TEST
Data path: C:\TW300

Test Date: Apr 21, 1997
Operator ID: KEVIN

Sample Inputs:
Test Desc. Blue Tip Pull Test

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:
10 : Tip break

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Test Inputs:

Test Speed	5.00	In/Min

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Report Date: Apr 21, 1997

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

256 175

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Report Date:Apr 21, 1997

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Sample ID: 6-980:MC-32123-001A
Method: ARROW SOFT TIP TENSILE TEST
Data path: C:\TW300

Test Date: Apr 21, 1997
Operator ID: KEVIN

Sample Inputs:

Test Desc. Blue Tip Pull Test

	Peak Load Lb
1	(b)(4) [redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
Mean	
Min	
Max	
Stdv	

Specimen Comments:

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Test Inputs:

Test Speed	5.00	In/Min

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Process Capability Report

ARROW INTERNATIONAL
MATERIAL TEST LAB
SINTECH 2W
TEST REPORT

Property : "Peak Load" in (Lb)

(b)(4) (b)(4)

Cell	[redacted]
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Grouped Mean	
Grp. Std. Dev.	
Skew	
Kurtosis	

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Specimen Level Histogram

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

(b)(4)

[redacted]

Specimen Trend

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

spec 6

LAB REQUEST

Lab Request No.
6989

1. **Service Requested** (Only One Request Per Sheet):

leak pressure -- positive internal lumen pressure

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

Part Nos:
Lot Nos:
Description:

3. **Finished Product**

Component Part Nos: group 1: MC-15122-001B; 12 Fr 2-L std.
group 2: MC-12123-001B; 12 Fr 3-L std.
group 3: MC-35122-001C; 12 Fr 2-L firm
group 4: MC-35123-001A; 12 Fr 3-L, firm

Lot Nos:
Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**

Please test each lumen of 10 catheters from each test group; report results by catheter type and lumen, i.e. 2-L: prox. or distal; 3-L: prox., medial, or distal (small lumen). Report the pressure at which the lumen starts to leak at the hub. Testing parameters: 50 psi for 1 minute (AML-038)

Requestor: P. Robertson
Signature: P. Robertson 4/16/97

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

JGh 184

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-15122-001B

Lot No.: N/A

Description: 12 fr 2-L std.

Lab Request No.: 6989 (Distal)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
	(b)(4) [redacted]			
1				
2				
3				
4				
5				
6				
7				
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24				
25				

Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

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

185

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-15122-001B

Lot No.: N/A

Description: 12 fr 2-L - Std.

Lab Request No.: 6989 (~~Distal~~)(Proximal)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
2				
3				
4				
5				
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23				
24				
25				

Comments: [redacted]

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

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

266 186

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-12123-001B

Lot No.: N/A

Description: 12 F 3-L STD

Lab Request No.: 6989 (-Dista 1)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
2				
3				
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Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-12123-001B

Lot No.: N/A

Description: 12 fr 3-L Std.

Lab Request No.: 6989 (medin)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
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25				

Comments: [redacted]

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-12123-001B

Lot No.: N/A

Description: 12 Fr 3-L Std.

Lab Request No.: 6989 (Proximal)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
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Comments: _____

Technician: [signature] Approval: [signature]

Date: 4-24-97 Date: 4/25/97

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

169 189

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-35122-001C

Lot No.: N/A

Description: 12 fr 2-L firm

Lab Request No.: 6989 (Dist fr 1)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
2				
3				
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Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

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

270 190

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-35122-001C

Lot No.: N/A

Description: 12 fr 2-L Firm

Lab Request No.: 6989 (Proximal)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
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Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-35123-001A

Lot No.: N/A

Description: 12 fr 3-L Firm

Lab Request No.: 6989 (Distal)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
2				
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Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-35123-001A

Lot No.: N/A

Description: 12 Fr 3-L Firm

Lab Request No.: 6989 (medial)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
2				
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Comments:

Technician: [signature]

Date: 4-25-97

Approval: [signature]

Date: 4/25/97

AML-F023 **Rev. 0** **Issue date: 3/31/97** **SOP Ref.: AML-038**

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

POSITIVE PRESSURE LEAK TEST

Part or Sample No.: MC-35123-001A

Lot No.: N/A

Description: 12 fr 3-L Firm

Lab Request No.: 6989 (Proximal)

Specimen	Pressure Applied (psi)	Time Held at Specified Pressure (sec)	Pass Pressure Test	Fail Pressure Test
			check box that applies	
1	(b)(4) [redacted]			
2				
3				
4				
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Comments:

Technician: [signature]

Date: 4-25-97

Approval: [signature]

Date: 4/25/97

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

27M 194

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

spec 7

LAB REQUEST

Lab Request No.
6990

1. **Service Requested** (Only One Request Per Sheet):

   burst pressure -- positive internal lumen pressure

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 1: MC-15122-001B; 12 Fr 2-L std.
   group 2: MC-12123-001B; 12 Fr 3-L std.
   group 3: MC-35122-001C; 12 Fr 2-L firm
   group 4: MC-35123-001A; 12 Fr 3-L, firm
   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please test 10 lumens of each catheter test group, one lumen per catheter; report results by catheter type and lumen, i.e. 2-L: prox. or distal; 3-L: prox., medial, or distal (small lumen). Report the pressure at which the lumen bursts. Stop test of pressure reaches 400 psi. Protocol AML-055.

Requestor: P. Robertson
Signature: 4/16/97

REV: 04/27/95 (NEW)

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

275 196

Records processed under FOIA Request # 2015-6315, Released by CDRH on 5/23/2016

POSITIVE PRESSURE BURST TEST

Part or Sample No.: MC-15122-001B

Lot No.: N/A

Description: 12 fr 2-L STD

Test Request No.: 6990 C Distal 1)

Specimen	Failure Mode Balloons Bursts	Pressure Applied At Failure Units = psi	Location of Failure
1	(b)(4) [redacted]		
2			
3			
4			
5			
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24			
25			

Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/27/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

POSITIVE PRESSURE BURST TEST

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Part or Sample No.: MC-15122-001B

Lot No.: N/A

Description: 12 fr 2-L STD

Test Request No.: 6990 (Proximal)

Specimen	Failure Mode Balloons	Failure Mode Bursts	Pressure Applied At Failure Units =	Location of Failure
1	(b)(4) [redacted]			
2				
3				
4				
5				
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Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

POSITIVE PRESSURE BURST TEST

Records processed under FOIA Request #2015-5635; Released by CDRH on 7/28/2016

Part or Sample No.: MC- 12123-001B

Lot No.: N/A

Description: 12 Fr 3-L STD

Test Request No.: 6990 - (Dist 1)

Specimen	Failure Mode Balloons Bursts	Pressure Applied At Failure Units =	Location of Failure
1	(b)(4) [redacted]		
2			
3			
4			
5			
6			
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Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

POSITIVE PRESSURE BURST TEST

Records processed under FOIA Request # 2015-5835; Released by CDRH on 7/28/2016

Part or Sample No.: MC-12123-001B

Lot No.: N/A

Description: 12 Fr 3-L STD

Test Request No.: 6990 (media 1)

Specimen	Failure Mode Balloons Bursts	Pressure Applied At Failure Units = PSI	Location of Failure
1	(b)(4) [redacted]		
2			
3			
4			
5			
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25			

Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

229 200

POSITIVE PRESSURE BURST TEST

Records processed under FOIA Request #2015-6815; Released by CDRH on 7/28/2016

Part or Sample No.: MC- 12123-001B

Lot No.: N/A

Description: 12 fr 3-L STD

Test Request No.: 6990 (Proximal)

Specimen	Failure Mode Balloons Bursts	Pressure Applied At Failure Units = PSI	Location of Failure
1	(b)(4) [redacted]		
2			
3			
4			
5			
6			
7			
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24			
25			

Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

280 201

Records processed under FOIA Request # 1553835; Released by CDRH on 5/23/2016

POSITIVE PRESSURE BURST TEST

Part or Sample No.: MC-35122-001C

Lot No.: N/A

Description: 12 Fr 2-L Foley

Test Request No.: 6990 (Distal)

Specimen	Failure Mode Balloons Bursts	Pressure Applied At Failure Units = psi	Location of Failure
1	(b)(4) [redacted]		
2			
3			
4			
5			
6			
7			
8			
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10			
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12			
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24			
25			

Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

POSITIVE PRESSURE BURST TEST

Records processed under FOIA Request #2016-5835; Released by CDRH on 7/28/2016

Part or Sample No.: MC-35122-001C

Lot No.: N/A

Description: 12 Fr 2-L Firm (~~Distal~~) (Proximal)

Test Request No.: 6990

Specimen	Failure Mode Balloons	Bursts	Pressure Applied At Failure Units = PSI	Location of Failure
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
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23				
24				
25				

Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

POSITIVE PRESSURE BURST TEST

Records processed under FOIA Request #2015-6335; Released by CDRH on 7/28/2016

Part or Sample No.: MC-35123-001A

Lot No.: N/A

Description: 12 Fr 3-L Firm (Distal)

Test Request No.: 6990

Specimen	Failure Mode Balloons	Failure Mode Bursts	Pressure Applied At Failure Units = PSI	Location of Failure
1	(b)(4)	[redacted]	[redacted]	[redacted]
2	[redacted]	[redacted]	[redacted]	[redacted]
3	[redacted]	[redacted]	[redacted]	[redacted]
4	[redacted]	[redacted]	[redacted]	[redacted]
5	[redacted]	[redacted]	[redacted]	[redacted]
6	[redacted]	[redacted]	[redacted]	[redacted]
7	[redacted]	[redacted]	[redacted]	[redacted]
8	[redacted]	[redacted]	[redacted]	[redacted]
9	[redacted]	[redacted]	[redacted]	[redacted]
10	[redacted]	[redacted]	[redacted]	[redacted]
11	[redacted]	[redacted]	[redacted]	[redacted]
12	[redacted]	[redacted]	[redacted]	[redacted]
13	[redacted]	[redacted]	[redacted]	[redacted]
14	[redacted]	[redacted]	[redacted]	[redacted]
15	[redacted]	[redacted]	[redacted]	[redacted]
16	[redacted]	[redacted]	[redacted]	[redacted]
17	[redacted]	[redacted]	[redacted]	[redacted]
18	[redacted]	[redacted]	[redacted]	[redacted]
19	[redacted]	[redacted]	[redacted]	[redacted]
20	[redacted]	[redacted]	[redacted]	[redacted]
21	[redacted]	[redacted]	[redacted]	[redacted]
22	[redacted]	[redacted]	[redacted]	[redacted]
23	[redacted]	[redacted]	[redacted]	[redacted]
24	[redacted]	[redacted]	[redacted]	[redacted]
25	[redacted]	[redacted]	[redacted]	[redacted]

Comments:

Technician: [signature]

Date: 4-24-97

Approval: [signature]

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

POSITIVE PRESSURE BURST TEST

Records processed under FOIA Request #2015-5855; Released by CDRH on 7/28/2016

Part or Sample No.: MC-35123-001A

Lot No.: N/A

Description: 12 Fr 3-L Firm

Test Request No.: 6996 (Medal)

Specimen	Failure Mode Balloons Bursts	Pressure Applied At Failure Units = PSI	Location of Failure
1	(b)(4) [redacted]		
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
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16			
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24			
25			

Comments:

Technician: Kim M Sukas

Approval:

Date: 4-25-97

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

Records processed under FOIA Request # 2015-5635, Released by CDRH on 1/28/2016

POSITIVE PRESSURE BURST TEST

Part or Sample No.: MC-35123-001A

Lot No.: N/A

Description: 12 Fr 3-L Firm

Test Request No.: 6990 (Proximal)

Specimen	Failure Mode Balloons	Failure Mode Bursts	Pressure Applied At Failure Units = PSI	Location of Failure
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
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14				
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Comments:

Technician: [signature]

Date: 4-25-97

Approval: [signature]

Date: 4/25/97

AML-F019 Rev. 0 Issue date: 3/27/97 SOP Ref.: AML-055

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016 Tab 8

LAB REQUEST

Lab Request No.
6991

1. **Service Requested** (Only One Request Per Sheet):

   fatigue testing-- number of cycles to failure

MATERIALS OR PARTS MUST BE SUBMITTED WITH "LAB REQUEST FORM"

2. **Raw Material**

   Part Nos:
   Lot Nos:
   Description:

3. **Finished Product**

   Component Part Nos: group 1: MC-15122-001B; 12 Fr 2-L std.
   group 2: MC-15123-002A; 12 Fr 3-L std.
   group 3: MC-35122-001C; 12 Fr 2-L firm
   group 4: MC-35123-001A; 12 Fr 3-L, firm

   Lot Nos:
   Description:

4. **Target Date**: 4/18/97

5. **Additional Comments:**
   Please test 10 catheters from each test group; report results by catheter type. Use a 50 deg. included angle.

Requestor: P. Robertson
Signature:
Date: 4/14/97

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

Records processed under FOIA Request # 2015-5836 | Released/Closed | DRH | on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-15122-001B
Lot No.: N/A
Description: 12 FR, 2-LUMEN STANDARD CATHETER
Lab Request No.: 6991
Included Angle:
Number of Cycles: 50,000 Batch Setting: 0

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
~~8~~				
9				
~~10~~				
11				
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13				
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: [signature] Approval: [signature]

Date: 4/28/97 Date: 4/28/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-15123-002A
Lot No.: N/A
Description: 12FR, 3-LUMEN STANDARD CATHETER
Lab Request No.: 6991
Included Angle:
Number of Cycles: 50,000 Batch Setting: 0

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes No	Location of Failure
1	(b)(4) [redacted]		
2			
~~3~~			
4			
5			
6			
7			
8			
9			
~~10~~			
11			
12			
13			
14			
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*When flex testing [redacted] zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: Dan Dyanzia
Date: 4/28/97

Approval: [signature]
Date: 4/28/97

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

Records processed under FOIA Request # 2016-5836 Released to DPH on 12/23/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-35122-001C
Lot No.: N/A
Description: 12FR, 2-LUMEN FIRM CATHETER
Lab Request No.: 6991
Included Angle:
Number of Cycles: 50,000 Batch Setting: 0

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
1	(b)(4) [redacted]			
2				
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~~9~~				
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: Dan Dyanzio Approval:

Date: 4/28/97 Date: 4/28/97

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

Records Processed Under FOIA Request # 2016-5835 Released by CDRH on 12/23/2016

FLEX (FATIGUE) TEST RESULTS/REPORT

Sample No.: MC-35123-001A
Lot No.: N/A
Description: 12 FR, 3-LUMEN FIRM CATHETER
Lab Request No.: 6991
Included Angle:
Number of Cycles: 50,000 Batch Setting: 0

Specimen	Total Number of Cycles at End of Test*	Specimen Failure (check one) Yes	No	Location of Failure
~~1~~	(b)(4) [redacted]	(b)(4) [redacted]		
2				
3				
4				
5				
6				
~~7~~				
8				
9				
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*When flex testing the specimens to failure, remember to read the number of total batches run (this will be set to zero in set-up to run continuously regardless of the number of cycles) and multiply it by the set number of cycles. This value is then added to the number on the read-out after pressing "Display".

Signed: Dan Dyerzio Approval: [signature]

Date: 4/28/97 Date: 4/28/97

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ATTACHMENT 2

Biocompatibility Test Results

A. Test result matrix
B. Test protocols and raw data by material type as listed in the matrix, in order

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Document Name: Arrow-Howes Large Bore Multi-Lumen Central Venous Catheters [Testing in accordance with ISO 10993 Biological Evaluation of Medical Devices]	
Document Number: 510(k) submission K970864	Page 1 of 4
Senior Research Engineer	5/1/97 Issue Date

Component			Test Category		Material	Material Tested NOTE 2	Cyto-toxicity	Sensitiz-ation Assay	Irritation (Intracutan. Reactivity)	Acute Systemic Toxicity	Sub-chronic Toxicity	Geno-toxicity	Implant	Heamocom-patibility	U.S.P. Physico-Chemical Tests
No.	Part Name	Pre-dicate device	Type of Body Contact	Duration NOTE 1											
1	Catheter Tip	7 Fr., 12 Fr. Hemo-dialysis	Circulating Blood	B	(b)(4) [redacted]		Mildly Cytotoxic (Passed)	Non-Sensitizing	Passed	Passed		Both Saline & 95/5 Alcohol/ Water: Non-Mutagenic	Both 7-Day and 90-Day Implants: Non-Irritant	Non-Hemolytic; Complement of C3a 8% of Positive Control; Lee White Clot Time 11.3 Sec. (Test Expected: 6 -17 Sec.)	
2A	Catheter Blank	12 Fr. Hemo-dialysis	Circulating Blood	B			Agarose Overlay & MEM 72-Hour Tests: Non-Toxic	Non-Sensitizing	Passed	Passed		Both Saline & 95/5 Alcohol/ Water: Non-Mutagenic	7-Day Implant: Non-Irritant	Non-Hemolytic; Complement of C3a & C5a are essentially equivalent to Negative Control	
2B	Catheter Blank	12 Fr. Hemo-dialysis	Circulating Blood	B			Agarose Overlay & MEM 72-Hour Tests: Non-Toxic	Non-Sensitizing	Passed	Passed		Both Saline & 95/5 Alcohol/ Saline: Non-Mutagenic	7-Day Implant: Non-Irritant	Non-Hemolytic; Complement of C3a 8% of Positive Control	
3	Lumen Plug Extru-sion	None	Blood Path Indirect	B			See NOTE 5	See NOTE 5	See NOTE 5	See NOTE 5				See NOTE 5	
4A	Junction Hub	12 Fr. Hemo-dialysis	Blood Path Indirect	B			See NOTE 6	See NOTE 6	See NOTE 6	See NOTE 6				See NOTE 6	

Shaded blocks indicate tests not required according to ISO 10993 Biological Evaluation of Medical Devices.

292

314

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Component			Test Category		Material	Material Tested NOTE 3	Cyto-toxicity	Sensitiz-ation Assay	Irritation (Intracutan. Reactivity)	Acute Systemic Toxicity	Sub-chronic Toxicity	Geno-toxicity	Implant	Heamocom-patibility	U.S.P. Physico-Chemical Tests
No.	Part Name	Pre-dicate device	Type of Body Contact	Duration NOTE 1											
5A	Exten-sion Lines	7 Fr.	Blood Path Indirect	B	(b)(4) [redacted]		Agarose Overlay & MEM 72-Hour Tests: Non-Toxic	Non-Sensitizing	Passed	Passed	Non-Toxic	Non-Mutagenic	7-Day Implant: Slight Irritant (Score 3 out of 15)	Non-Hemolytic	
5B	Exten-sion Lines	12 Fr. Hemo-dialysis	Blood Path Indirect				Agarose Overlay & MEM 72-Hour Tests: Non-Toxic	Non-Sensitizing	Passed	Passed	Non-Toxic	Both Saline & 95/5 Alcohol/ Saline: Non-Mutagenic	7-Day Implant: Slight Irritant (Score 3 out of 15)	Non-Hemolytic Complement of C3a 6.6% of Positive Control; Lee White Clot Time 8.8 Sec. (Test Expected: 6 -17 Sec.)	
6A	Exten-sion Line Hubs	7 Fr. , 12 Fr. Hemo-dialysis	Blood Path Indirect	B			Agarose Overlay & MEM 72-Hour Tests: Non-Toxic	Non-Sensitizing	Passed	Passed	Non-Toxic	Non-Mutagenic	7-Day Implant: Slight Irritant (Score 4 out of 15)	Non-Hemolytic	
6B	Exten-sion Line Hubs	7 Fr.	Blood Path Indirect				Agarose Overlay & MEM 72-Hour Tests: Non-Toxic	Non-Sensitizing See NOTE 8	Passed See NOTE 8	Passed See NOTE 8		Non-Mutagenic (Saline) & 95/5 Alcohol/ Water: Non-Mutagenic See NOTE 8	7-Day Implant: Slight Irritant (Score 2 out of 15)	Non-Hemolytic Complement of C3a 8.4% of Positive Control; Lee White Clot Time 8.0 Sec. (Test Expected: 6 -17 Sec.). See NOTE 8	
7	Exten-sion Line Ink	7 Fr. , 12 Fr. Hemo-dialysis	Non-Contact	B	(b)(4) [redacted]		Mildly Cytotoxic (Passed)	Non-Sensitizing	Passed	Passed		Both Saline & 95/5 Alcohol/ Saline: Non-Mutagenic	7-Day Implant: Slight Irritant (Score 1 out of 15)	Non-Hemolytic Complement of C3a 9.3% of Positive Control; Lee White Clot Time 8.5 Sec. (Test Expected: 6 -17 Sec.).	

Shaded blocks indicate tests not required according to ISO 10993 Biological Evaluation of Medical Devices

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Component			Test Category		Material	Material Tested NOTE 3	Cyto-toxicity	Sensitiz-ation Assay	Irritation (Intracutan. Reactivity)	Acute Systemic Toxicity	Sub-chronic Toxicity	Geno-toxicity	Implant	Heamocom-patibility	U.S.P. Physico-Chemical Tests
No.	Part Name	Pre-dicate device	Type of Body Contact	Duratio n NOTE 1											
8	Centi-meter Mark	7 Fr. , 12 Fr. Hemo-dialysis	Circulating Blood	B	(b)(4) [redacted]		See NOTE 9	See NOTE 9	See NOTE 9	See NOTE 9		See NOTE 9	See NOTE 9	See NOTE 9	
9	Junction Ink	7 Fr. , 12 Fr. Hemo-dialysis	Non-Contact	B			Severe Cytotoxicity	Non-Sensitizing	Non-Irritating (Score = 0.00) See NOTE 7						
10	Extension Line clamp, distal	7 Fr. Catheter	Non-Contact	B	(b)(4)		Agarose Overlay & MEM 72-Hour Tests: Non-Toxic		Passed	Passed		Non-Mutagenic	Non-Irritant	Non-Hemolytic	
11	Extension Line clamp, commer-cial	12 Fr. Hemo-dialysis	Non-Contact	B											
[redacted]	Suture wing	12 Fr. Hemo-dialysis	skin	B			Agarose Overlay & MEM 72-Hour Tests: Non-Toxic	Non-Sensitizing	Passed	Passed				Non-Hemolytic	

Shaded blocks indicate tests not required according to ISO 10993 Biological Evaluation of Medical Devices.

NOTE 1: Duration is delineated as follows:
A: ≤ 24 hours
B: > 24 hours to 30 days
C: > 30 days

NOTE 2: All tests are performed on processed material, not resin pellets. All tests are run on sterilized product only.

NOTE 3: This particular material was not tested. The data is for the (b)(4) [redacted] bracketed (b)(4) [redacted] The data for the 80A blue Tecoflex is presented in Component 1. Tecoflex (b)(4) [redacted] is manufactured from three raw materials that are varied in different ratios to bring about the range of durometers. Since the (b)(4) [redacted] material is bracketed by the two materials presented herein, the data for these two materials is directly applicable to the (b)(4) [redacted]

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Component 1:

(b)(4)

[redacted]

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

 Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016.

STUDY TITLE:

CYTOTOXICITY STUDY

USING THE ISO ELUTION METHOD

IN THE L-929 MOUSE FIBROBLAST CELL LINE

TEST ARTICLE:

(b)(4) [redacted]

IDENTIFICATION NO.:

LOT: AR-10

SPONSOR:

RON CITRON
ARROW INTERNATIONAL INC
P O BOX 12888
READING, PA 19612-2888

(b)(4) [redacted]

TABLE OF CONTENTS

	Page Number
SUMMARY	3
INTRODUCTION	4
MATERIALS	4
METHODS	5
RESULTS	6
CONCLUSION	6
RECORD STORAGE	6

(b)(4)

[redacted]

 Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

SUMMARY

An in vitro biocompatibility study, based on the International Organization for Standardization (ISO 10993-5) guidelines, was conducted on the test article, TEC80, LOT: AR-10, in order to determine the potential for in vitro cytotoxicity. Triplicate extracts of the test article were prepared using minimum essential medium (MEM). Each test extract was placed onto separate confluent monolayers of L-929 Mouse Fibroblast cells. Separate triplicate flasks were prepared for a negative control, reagent control, and for a positive control. The monolayer in the test, negative, and reagent control flasks was examined microscopically at 48 hours to determine any change in cell morphology. The changes were graded on a 0-4 basis. The monolayer in the positive control flasks (end-point titration procedure) was examined at 24 hours and the result was compared to the (b)(4) historical value.

The MEM test extracts showed evidence of causing cell lysis or toxicity. The negative controls, reagent controls, and the positive controls performed as anticipated. Under the conditions of this study, the MEM test extracts were mildly cytotoxic and passed this ISO test.

Study and Supervisory Personnel:

Cherise M. McCoy, BS
Donald P. Barda, LAT
Tom A. Cline

Approved by: Heather M Whitmer for

Barry Phelps, BS
Section Manager, In-Vitro

1-20-97
Date Completed

/mm

(b)(4)

 Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

INTRODUCTION

The test article identified below was extracted, and the extracts were subjected to an in vitro cytotoxicity study for biocompatibility based on ISO 10993-5 guidelines. The test was performed in order to determine whether leachables extracted from the material would cause cytotoxicity. The test article was received on January 7, 1997. The cells were first exposed to the extract on January 14, 1997, and the observations were concluded on January 16, 1997.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	TEC80
Identification No.:	LOT: AR-10
Storage Conditions:	Room temperature
Extraction Vehicle:	Single Strength Minimum Essential Medium (MEM), supplemented with 5% calf serum and 2% antibiotics
Test Article Preparation:	Based on the USP ratio of 60 cm^2:20 ml, a 19.8 cm^2 portion of the test article was covered with 7 ml of MEM. Triplicate preparations were prepared and extracted at 37°C for 24-26 hours.
Negative Control:	The current (b)(4) [redacted] Negative Control Material, Low Density Polyethylene (Lot UP-1) was used as the negative control. Based on the USP ratio of 60 cm^2:20 ml, a 35.9 cm^2 portion of the control material was covered with 12 ml of MEM. Triplicate preparations were prepared and subjected to the same extraction conditions as described for the test article.
Reagent Control:	Triplicate aliquots of MEM without test material, subjected to the same extraction conditions as described for the test article.
Positive Control:	The (b)(4) [redacted] sitive control, Sodium Chloride Granules (SCG), was prepared in triplicate and used to determine a cytotoxic end-point. Three 1 g portions of SCG-14 were each covered with 5 ml of MEM and were subjected to the extraction conditions as described for the test article. The cytotoxic end-point was determined using a titration procedure.
Condition of Extracts:	Test: clear Negative Controls: clear Reagent Controls: clear Positive Controls: clear

(b)(4) [redacted]

 Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

METHODS

Test System Management:

(b)(4)

[redacted]

Experimental Procedure:

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4) Testing

 Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016.

STUDY TITLE:

DELAYED CONTACT SENSITIZATION STUDY IN THE GUINEA PIG

(Maximization Method, Saline Extract)

TEST ARTICLE:

(b)(4)

IDENTIFICATION NO.:

LOT: AR-10

SPONSOR:

RON CITRON
ARROW INTERNATIONAL INC
P O BOX 12888
READING, PA 19612-2888

(b)(4)

 Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

TABLE OF CONTENTS

	Page Number
SUMMARY	3
INTRODUCTION	4
MATERIALS	4
METHODS	5
DEVIATIONS	7
RESULTS	7
CONCLUSION	8
RECORD STORAGE	8
TABLE	
I - DERMAL REACTIONS - CHALLENGE	9

(b)(4)

[redacted]

(b)(4)Testing

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Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 1997

Mr. Thomas D. Nickel
Vice President Regulatory Affairs & Quality Assurance
Arrow International, Incorporated
3000 Bernville Road
Reading, Pennsylvania 19605

Re: K970864
Trade Name: Arrow-Howes Large Bore Multi-Lumen Central Venous Catheters
Dated: March 6, 1997
Received: March 10, 1997

Dear Mr. Nickel:

We have completed an administrative review of your section 510(k) Premarket Notification (510(k)) of intent to market the device referenced above. Our review indicates that your 510(k) is administratively incomplete and we are placing your 510(k) on hold for 30 days pending receipt of the additional information that was requested in a telephone conversation with the Office of Device Evaluation. We believe that this basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act).

The additional information should be submitted in duplicate, referencing the 510(k) number above to :

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

Please note that since your 510(K) submission has not been substantively reviewed, additional information may be required during the review process and the file may again be placed on hold. You may not market this device until you have provided adequate information as required by 21 CFR 807.87 and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however,

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

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distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations (21 CFR part 812).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Bill Burdick at (301) 594-1287. If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or its toll free number (800) 638-2041, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Patricia Cicero/for

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

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

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Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Screening Checklist for Premarket Notifications [510(k)s]
ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: Arrow - Howes Large Bore Multi-Lumen Central Venous Catheters K970864

Submitter Name: Arrow Intl., Inc.

General Content of a 510(k)	MISSING INFORMATION
1.* <u>General Information</u>: a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, I) applicant's name and address. COMMENT:	
2.* <u>Safe Medical Device Act of 1990 Requirements</u>: a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices). d) Indication for use statement COMMENT:	
3.* <u>Proposed Labeling</u>: a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device. COMMENT:	
4.* <u>Description of Device (or modification)</u>: diagrams, engineering drawings, or photographs. COMMENT:	

251

5.* Comparison Information: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness. COMMENT: Refer to telephone memo dated	d, e, f
6. Biocompatibility Data: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use. COMMENT: Refer to Telephone memo, dated	
7. Sterilization Information: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method. COMMENT:	
8. Software Validation & Verification: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification. COMMENT:	
9. Information Recommended in FDA Guidance: There is an FDA guidance document for this device that recommends additional data. COMMENT:	
10. Kit Information: see attachment if this device is a kit. COMMENT:	

HSV

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Memorandum

From: Reviewer(s) - Name(s) Tran / Burdick

Subject: 510(k) Number K970864

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

- ☑ Refused to accept. RTA (See Telephone Memo)
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ 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

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)

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

Review: Patricia Cucante (acting) (Branch Chief) HDB (Branch Code) 3/31/97 (Date)

Final Review: _____
(Division Director) (Date)

Revised:11-20-96

N53

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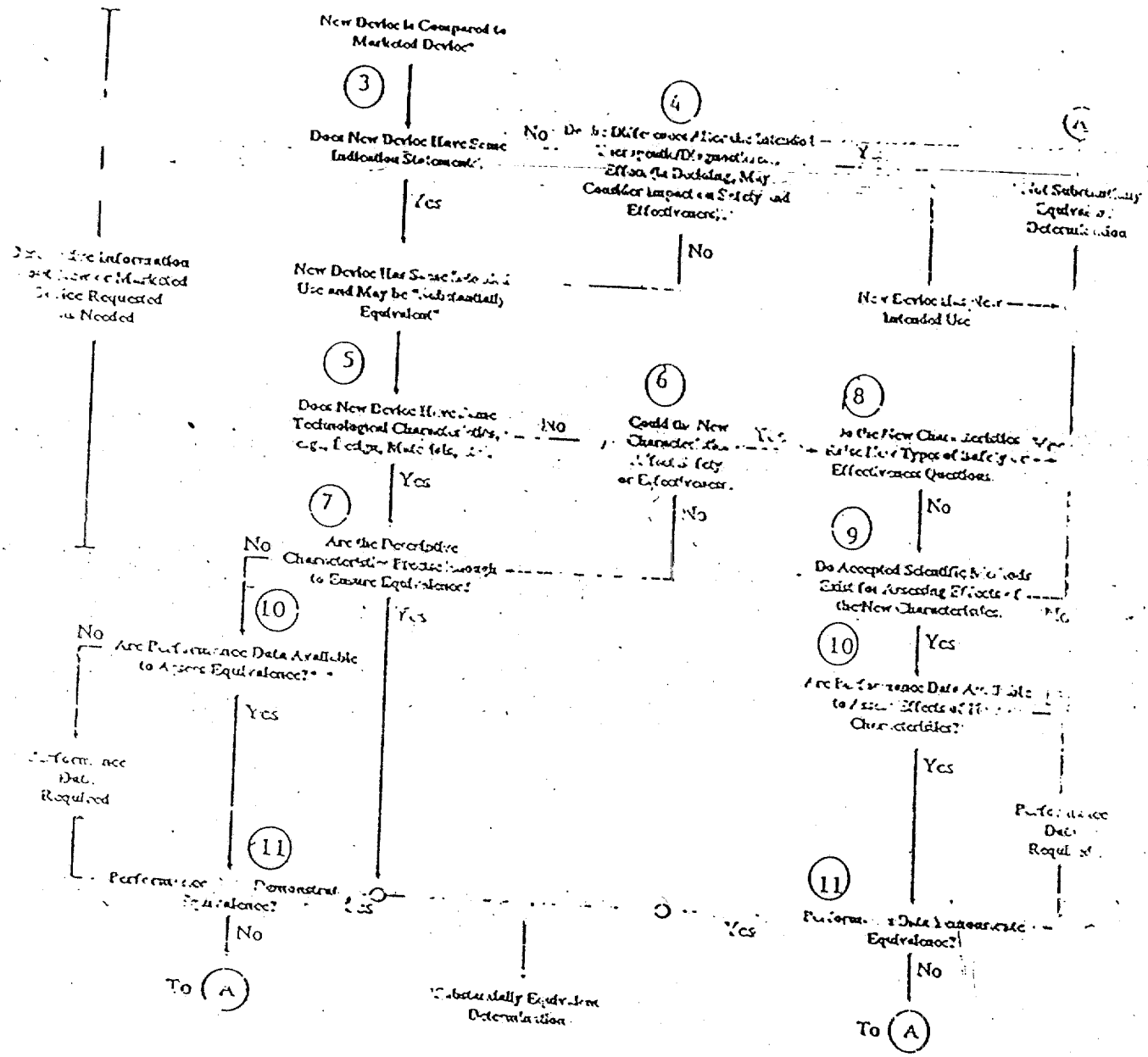
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** 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 classification files, or the literature.

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

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MEMORANDUM OF TELEPHONE CONVERSATION

DATE: November 28, 1997

TO: Thomas D. Nickel
Vice President
Regulatory Affairs &
Quality Assurance
3000 Bernville Road
Reading, PA 19605

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DDIGD/GHDB
HFZ-480
9200 Corporate Blvd.
Rockville, MD 20850
(301)594-1287

SUBJECT: 510K Number K970864 - Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheter

I called Mr. Nickel after completing my administrative review of this device. Mr. Nickel was not in, so I left a message on his voice mail informing him that the submission would be placed on administrative "HOLD" until he provided the information requested in the attached. I told him to call if he wished to discuss the issues further.

William M. Burdick
Biomedical Engineer

- Attachment

cc. K970864
CHRON file

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

NSS

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

REQUESTED INFORMATION CONCERNING K970864: Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheter

Date: March 28, 1997

To: Thomas D. Nickel
Vice President
Regulatory Affairs &
Quality Assurance
3000 Bernville Road
Reading, PA 19605
Ph: (610)378-0131
FAX: (610)374-5360

From: William M. Burdick
Biomedical Engineer
FDA/ODE/DDIGD
General Hospital Branch
9200 Corporate Blvd.
Rockville, MD 20877
Ph: (301)594-1287
FAX: (301)594-2358

Please address the following:

1. Please provide the results from mechanical and performance testing as you have with past intravascular catheter submissions. In addition, please specify the manner in which you determine mechanical strength failure and fluid leakage of your central lumen. Since this lumen is totally enclosed within the catheter tubing, normal methods for determining failure and leakage would not apply.

2. Please explain your reasons for coating your catheter with heparin. I have not been able to discover a legally marketed predicate intravascular catheter that was coated with heparin, and I am not clear as to why heparin would be used to coat such a catheter. If you are familiar with a heparin-coated predicate, please provide the name and 510(k) number, if possible.

3. Please indicate whether the materials comprising your device are <u>identical</u> in composition and intended use to legally marketed predicate devices; otherwise, please specify <u>all</u> the materials comprising your device and provide the results from biocompatibility testing which considers patient blood pathways, tissue contact, and the duration of contact with your device according to the enclosed guidance document entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Your submission lacked this information which is required in order to assure that the materials comprising the device do not cause an allergic reaction or have a toxic effect on the patient.

William M. Burdick
William M. Burdick

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

256

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)

Checklist for Premarket Notifications [510(k)s]

Device Trade Name: Arrow-Howes Large Bore Multi-Lumen Central Venous Catheters	K# 970864
Submitter Name: Arrow Intl., Inc.	
Date Received: ~~6/8/97~~ 3/13/97 90 Day Due Date: 6/8/97	
Review Tier : 1 (2) 3	

Question	Yes	No
A. Is the product a device?	✓	
B. Is the device exempt from 510(k)?		✓
C. Expedited Review Status: Requested by sponsor,		✓
or identified by PILOT Division		
Granted by Pilot Division?		
D. Has this device been the subject of a previous NSE decision?		✓
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		✓
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Decision: ACCEPT ~~✓~~ WDMB REFUSE TO ACCEPT ✓

Administrative Reviewer Signature: L. Fran Date: MAR 17 1997

Supervisory Signature: William M. Bunduk Date: March 28, 1997

457

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Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Screening Checklist for Premarket Notifications [510(k)s]
ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: Arrow - Howes Large Bore Multi-Lumen Central Venous Catheters K970864

Submitter Name: Arrow Intl., Inc.

General Content of a 510(k)	MISSING INFORMATION
1.* General Information: a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, I) applicant's name and address. COMMENT:	
2.* Safe Medical Device Act of 1990 Requirements: a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices). d) Indication for use statement COMMENT:	
3.* Proposed Labeling: a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device. COMMENT:	
4.* Description of Device (or modification): diagrams, engineering drawings, or photographs. COMMENT:	

5.*	Comparison Information: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness. COMMENT: Refer to telephone memo dated	d, e, f
6.	Biocompatibility Data: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use. COMMENT: Refer to Telephone memo, dated	
7.	Sterilization Information: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method. COMMENT:	
8.	Software Validation & Verification: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification. COMMENT:	
9.	Information Recommended in FDA Guidance: There is an FDA guidance document for this device that recommends additional data. COMMENT:	
10.	Kit Information: see attachment if this device is a kit. COMMENT:	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

March 12, 1997

ARROW INTL., INC.
3000 BERNVILLE ROAD
READING, PA 19605
ATTN: THOMAS D. NICKEL

510(k) Number: K970864
Received: 10-MAR-97
Product: ARROW-HOWES LARGE BORE MULTI-LUMEN CENTRAL VENOUS CATHETERS

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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. 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 Assistance (DSMA) 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 (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. 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 DSMA 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

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

460

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K970864

Certified Mail

RECEIVED
10 MAR 97 13 33
FDA/CDRH/ODE/DMC

P.O. Box 12888
Reading, PA 19612

ARROW INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

March 6, 1997

Center for Devices and Radiological Health
Document Mail Room HFZ-401
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Attached 510(k) Premarket Notification
Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheters

Dear Sir or Madam:

Enclosed are two copies of a 510(k) premarket notification for Arrow-Howes™ large bore multi-lumen central venous catheters. This submission is the concluding action of an interaction between Arrow and ODE which dates back to 1991, and is described in detail in Attachment 2 of the notification.

The reviewer who has been assigned the project of reviewing this 510(k) is William Burdick in DDIGD, with whom I have recently discussed the contents of the submission.

If you have any questions, please call me at 610/478-3137.

Thank you.

Sincerely,

Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

7050a

HO
Class II
761

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

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510(k) PREMARKET NOTIFICATION

ARROW-HOWES™ LARGE BORE MULTI-LUMEN CENTRAL VENOUS CATHETERS

Date: March 6, 1997

Submitted By: Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
Arrow International, Inc.
3000 Bernville Road
Reading, PA 19605

Direct Phone: (610) 478-3137
FAX: (610) 478-3172

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

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TABLE OF CONTENTS

	Page
Section 1 - General information	
a. Trade name and model number	3
b. Common or classification name	3
c. Establishment registration numbers	3
d. Manufacturing facilities and sterilization site	3
e. Classification	3
f. Reason for the premarket notification	3
g. Legally marketed device to which we claim substantial equivalence	4
h. Compliance with Sections 513(B) and 514	4
Section 2 - 510(k) Summary	5
Section 3 - Proposed labeling	
a. Sample of draft labeling and directions for use	6
Section 4 - Device description	6
Section 5 - Background and comparison to predicate	6
Section 6 - Sterilization Information	6
Section 7 - Software Validation and Verification	
a. Statement of non-applicability	7
Section 8 - Specific Standards and Guidance	
a. Discussion of compliance with applicable standards and guidance documents	7
Section 9 - Truthful and Accurate Statement	8
Section 10 - Kit components listing and certification	8
Section 11 - Indications	10
ATTACHMENTS	
Attachment 1 - Description of currently marketed 12 French multi-lumen central venous catheters	12
Attachment 2 - Background for the reason for this submission	15
Attachment 3 - Labeling - new device and predicates	28
Attachment 4 - Drawings - new device and predicates	56

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

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SECTION 1 - GENERAL INFORMATION

a. Trade name and model numbers

The device, for purposes of this submission is a line of ten (10) polyurethane 12 French large bore, triple-lumen central venous catheters for rapid fluid administration in critical care hospital settings. The catheters are provided in either 16cm or 20cm lengths, and are packaged in three basic formats:

1. Kits, with needles, vessel dilators, spring wire guides, syringes, scalpel, sutures, gauze pads, CSR wrap, fenestrated drape, etc., plus disinfectants such as povidone-iodine swabsticks, ointment, and/or solution, plus a Lidocaine HCl ampule.
2. Sets with only essential components, and no drugs.
3. Individual catheters

To date we have ten (10) catheters in the various sizes and styles noted above. A description of the various catheters currently being sold is appended as Attachment 1.

b. Common or classification name

The device was originally listed as "Catheter, intravascular, 80 FOZ, and was subsequently classified in Class II at 21 CFR 880.5200, Intravascular catheter.

Common names are central venous catheter and CVC.

c. Establishment registration numbers

The device is manufactured and sterilized at the following Arrow facility:

Arrow International, Inc.
312 Commerce Place
Asheboro, NC 27203
FDA Number 1036844

The owner/operator is:

Arrow International, Inc.
3000 Bernville Road
Reading, PA 19605
FDA Number 2518433

d. Manufacturing facilities and sterilization site

See c. above.

e. Classification

The device is classified in Class II at 21 CFR 880.5200, Intravascular catheter.

f. Reason for the premarket notification

Refer to Attachment 2 for a complete description of the reason for the submission.

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g. Legally marketed devices to which we claim equivalence

The device is substantially equivalent to the following Arrow central venous catheters:

1. 7 French, 3-lumen catheters in various lengths, the subject of 510(k) K820648, K844080, and K862056. The heparin coated version was the subject of K840336.
2. 12 French large bore two-lumen central venous catheters for hemodialysis and fluid infusion, the subject of K895417.

h. Compliance with sections 513(b) and 514

To the extent applicable at this time, we submit that we are in compliance with the requirements of Sections 513(b) and 514 as to this device.

K970867: Arrow-Howes™ Large Bore Multi-Lumen Central Venous Catheters

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

SECTION 2 - 510(k) SUMMARY

The device is essentially identical to the 7 French Arrow predicate device except it is 12 French rather than 7 French in diameter. The flow rates and priming volume are of course increased with the larger size.

The device is similar to the 12 French Arrow two-lumen predicate except it has a third lumen, in much the same configuration as the 7 French Arrow device.

The indications for use are comparable, and the specific indications for the device covered by this submission are as follows:

> "The large-bore multiple lumen catheter permits venous access to a central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, and femoral veins. The heparin coating on the catheter intended to decrease the incidence of thrombus formation associated with catheterization".

The submission includes comparisons of lumen cross sections, distal tip configuration, French size, priming volumes, and flow rates.

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SECTION 3 - PROPOSED LABELING

a. Samples of labeling and directions for use for a typical device are appended as Attachment 3. The labeling for the predicate devices also appears in this attachment.

SECTION 4 - DEVICE DESCRIPTION

Drawings of the device and predicates appear in Attachment 4. The drawings show the distal tip configuration, cross-sectional lumen configuration, and French size, as requested by Dr. Lillian Yin of ODE in her letter of September 9, 1996, included in Attachment 2.

SECTION 5 - BACKGROUND AND COMPARISON TO PREDICATES

The device is described in the drawings in Attachment 4, and compared to two Arrow predicate devices. All of the devices are polyurethane, the biocompatibility of which was established in the previous predicate 510(k) submissions listed in Section 1(g).

This device is clearly a mix-and-match with previously cleared Arrow 510(k) multi-lumen catheters, for the purpose of administration of fluids by means of central veins. The product has been successfully sold for this purpose since 1991.

SECTION 6 - STERILIZATION INFORMATION

a. The device is sterilized by (b)(4) ethylene oxide, utilizing the overkill approach.

ARROW INTERNATIONAL, INC.
PRODUCT STERILIZATION

STERILANT (b)(4) Ethylene Oxide

PRECONDITIONING - (b)(4)

STERILIZATION CYCLE

- (b)(4)

The entire cycle from entry to (b)(4)

AERATION A minimum of (b)

Post-Sterilization Forced Aeration

Minimum of (b)(4) in de-gassing room ma (b)(4)

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The cycle was originally validated and is re-validated annually using a 1/2 cycle microbial challenge procedure which meets the criteria described in ANSI/AAMI ST27-1988, Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices.

b. EtO Residuals Information
The maximum allowable residual levels are in accordance with AAMI guidelines, and are as follows:

Ethylene Oxide - <25 ppm
Ethylene Chlorohydrin - <25 ppm
Ethylene Glycol - <250 ppm

c. The sterility assurance level of the device will be 10^{-6}.

d. Expiration Date
The expiration dating applicable to the various versions of the device are as follows:
1. For kits with drugs - the shortest expiry drug determines the kit expiration date.
2. For sets with "E" suffix in the product number, the expiration date is 5 years, as required by some countries in Europe.

e. The product is labeled non-pyrogenic and is tested for pyrogenicity by either the Limulus Amebocyte Lysate (LAL) test or USP Pyrogen Test.

SECTION 7 - SOFTWARE VALIDATION AND VERIFICATION

Not applicable since this is not a computer controlled device.

SECTION 8 - SPECIFIC STANDARDS AND GUIDANCES

To the best of our knowledge, there are no industry or professional society standards applicable to this device. Our EtO Sterilization is in compliance with ANSI/AAMI ST27-1988, "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices".

This premarket certification was assembled and reviewed against requirements of the following CDRH guidance documents:

- CDRH Premarket Notification (510(k)) Refuse to Accept Policy - Final draft 6/30/93.
- DCRND screening checklist for Premarket Notification 510(k) - no date.
- Premarket Notification (510(k)) Check List for Acceptance Decisions 8/20/93.
- 510(k) "Substantial Equivalence" Decision-Making Process (Detailed) 11/18/91.
- Deciding When to Submit a 510(k) for Changes to an existing Device, January 10, 1997.
- Guidance on premarket notification 510(k) submission for short-term and long-term intravascular catheters - Draft, 7/94.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 168

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SECTION 9 - TRUTHFUL AND ACCURATE STATEMENT

I certify that in my capacity as Vice President, Regulatory Affairs and Quality Assurance of Arrow International, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Thomas D. Nickel
March 6, 1997

Section 10 - Kit Component Listing and Certification

The "product" includes kit and set versions as listed in Attachment 1, and the General Hospital required component information is as follows.

Qty.	Component	Present In		Drug	Purchased bulk non-labeled, non-sterile	Arrow Mfg'd component	Purchased labeled, non-sterile
		Kits	Sets				
1	.035" dia spring wire guide	Y	Y			X	
1	vessel dilator	Y	Y			X	
1	25 ga. X 1" needle	Y			X		
1	22 ga. X 1" needle	Y				X	
1	18 ga. X 2 1/2" introducer needle	Y	Y			X	
1	18 ga. X 2 1/2" Radiopaque catheter over 20 ga. needle	Y	Y			X	
1	3 cc syringe	Y			X		
1	5 cc syringe	Y			X		
1	5 cc Arrow Raulerson syringe	Y	Y			X	
1	pressure transduction probe	Y	Y			X	
1	fenestrated drape	Y			X		
2	2" X 2" gauze pads	Y			X		
5	4" X 4" gauze pads	Y			X		
3	Povidone-Iodine swabsticks	Y		X			
1	Povidone-Iodine ointment 1gm	Y		X			
1	Lidocaine HCl, 5ml 1% ampule	Y		X			
1	Sharpsaway™ disposal cup	Y				X	
1	disposable scalpel (#11 blade)	Y			X		
1	suture: 3-O silk w/straight needle	Y					X
4	Usergard™ hubs	Y	Y			X	
4	Usergard™ injection caps	Y	Y			X	
1	catheter clamp w/fastener	Y	Y			X	
1	CSR wrap	Y			X		
4	extension line clamps	Y	Y			X	

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Certification

I certify that all of the medical components of the subject kit or set, are either ① legally marketed preamendment devices, ② exempt from premarket notification (consistent with the exemption criteria described in the classification regulations and the limitations of exemptions from Section 510(k) of the Act (e.g., 21 CFR 862.9), or ③ have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is intended (i.e., not claiming or causing a new use for the component(s).

I further certify that we purchase all device components either in packaged and labeled form consistent with their preamendments, exemption, or premarket notification criteria and status, or as bulk non-labeled and non-sterile components, also consistent with their preamendments, exemption, or premarket notification criteria and status. The details per component appear in the chart above. In addition, all purchased drug components are also packaged and labeled consistent with their approval.

Both kit and set versions of the device utilize packaging which consists of a vacuum formed tray and Tyvek lid. All components are placed in the tray, it is sealed, packed in corrugated shipping cartons, and EtO sterilized. No components are "reprocessed" as a result of the sterilization. The drug components are either foil pouches impermeable to EtO, or glass ampules impermeable to EtO. Therefore, final processing of the kit has no effect whatsoever regarding the functionality (i.e., safety and effectiveness) of any kit components.

Note that the set labeling is identical to the kit labeling except the set lidstock lists fewer components.

(7051a)

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

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P.O. Box 12888
Reading, PA 19612

ARROW
INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

K 970864: Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheters

Section 11 - Indications

The large bore multiple lumen catheter permits venous access to a central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, or femoral veins. The heparin coating on the catheter intended to decrease the incidence of thrombus formation associated with catheterization.

97021

X Prescription Use

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

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ATTACHMENT 1

Description of currently marketed 12 French multi-lumen central venous catheters

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

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Product Description

All of the following products are 12 French multi-lumen (3-lumen) central venous catheters for high volume infusions. They exist as kits, sets, and single catheters in varying lengths, as outlined below:

Catheter length	Kit	Set	Individual Catheter	Product Number
16cm	X			(b)(4) [redacted]
16cm		X		
16cm		X		
16cm			X	
16cm	X			
20cm	X			
20cm	X			
20cm		X		
20cm		X		
20cm			X	

* Heparin coated

97022b

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

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ATTACHMENT 2

Background for the reason for this submission

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

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INTERNAL CORRESPONDENCE

ARROW
INTERNATIONAL INC.

DATE: January 31, 1997

TO: File

FROM: T. Nickel TN

SUBJECT: 12 French 3 lumen CVC - 510(k) issue

I received a voicemail message in response to my follow-up letter to Tim Ulatowski of 1/13/97 from CDRH-DDIGD reviewer Bill Burdick on 1/23/97, which I was not able to return immediately because I was in the Czech Republic. I have worked with him on two previous 510(k) submissions.

I returned the call the following week (i.e., w/o 1/27/97), and we agreed that I would submit the 510(k) and discussed the information he needs. I indicated I would get to it as soon as I could, and he said that was fine.

The submission will be made as soon as I can get all the necessary information from Engineering.

97019mem

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

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Certified Mail

P.O. Box 12888
Reading, PA 19612

ARROW
INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

January 13, 1997

Timothy Ulatowski
Director, Division of Dental, Infection Control, and
General Hospital Device Evaluation (HFZ-410)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: Attached correspondence to you -
October 21, 1996

Dear Mr. Ulatowski:

The attached letter was sent to you on October 21, 1996 and received in your division on October 28, 1996. Since I have heard nothing since, I would appreciate a phone call with the status - i.e., at least an acknowledgment that the request is under review, and an estimate as to when we can expect a response. My direct phone number is 610/478-3137.

Thank you.

Sincerely,

Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

c: Howard Holstein - Hogan & Hartson

97007ltr

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

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

Certified Mail

P.O. Box 12888
Reading, PA 19612

ARROW
INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

October 21, 1996

Timothy Ulatowski
Director, Division of Dental, Infection Control, and
General Hospital Device Evaluation (HFZ-410)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: Your phone discussion with Howard Holstein - 10/9/96

Dear Mr. Ulatowski:

This letter is in reference to your phone discussion on October 9, 1996 with our attorney, Howard Holstein, regarding whether a 510(k) Premarket Notification is necessary for our 12 French 3-lumen central venous catheters. Howard's letter to me of October 10, 1996 summarizing your discussion is appended as Attachment 1.

Unfortunately Howard's request comes at the tail end of a long and contorted scenario that dates back to January, 1991, the final chapter of which appears to be in your hands! The basic document is K945174, which was submitted to DRAERD in order to resolve a difference of opinion as to the necessity for submitting a 510(k) for the addition of a 3rd lumen to a 12 French 2-lumen central venous catheter indicated for use for both central venous catheterization and hemodialysis. A brief outline of the main events in the scenario is appended as Attachment 2.

Due to the time and expense involved with a DRAERD required IDE to compare the infection rates of the 3-lumen catheter to the 2-lumen predicate, we finally decided to eliminate the hemodialysis indication, leaving the product on the market for its primary intended use, large volume infusions of fluid for critical care settings. Our proposal for this to Bob Gatling of 4/15/96 is appended as Attachment 3.

We thought we had oral agreement on our proposal, but were surprised by the letter from Dr. Lillian Yin of 9/9/96 (Attachment 4), which indicated a 510(k) was necessary because of the third lumen, despite the fact that we are the leading manufacturer of 3-lumen central venous catheters, going back to 1982! Dr. Yin's letter indicated that Bob Gatling was the contact person for action, and when contacted he indicated you are now responsible.

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

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We would appreciate your looking into this, and would appreciate your thoughts on the following questions:

1. Do you agree that a 510(k) is necessary for the 12 French 3-lumen catheter for large volume infusion of fluids?
2. If so, what specific parameters would need to be addressed in the submission?

Thanks in advance for your help. If you need additional information, please call me direct at 610/478-3137.

Sincerely,

Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

c: Howard Holstein - Hogan & Hartson

9693ltr

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

N78/19

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ATTACHMENT 1

HOGAN & HARTSON
L.L.P.

HOWARD M. HOLSTEIN
PARTNER
DIRECT DIAL (202) 637-5813

October 10, 1996

COLUMBIA SQUARE
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
FAX (202) 637-5910

ATTORNEY/CLIENT PRIVILEGED

VIA - TELECOPY AND FIRST CLASS MAIL

Mr. Thomas D. Nickel
Vice President
Arrow International, Inc.
3000 Bernville Rd.
Reading, PA 19612

Dear Tom:

This letter will confirm my telephone conversation of October 9, 1996 with Tim Ulatowski at FDA. I called Mr. Ulatowski at the suggestion of Bob Gattling with regard to the September 9, 1996 letter that Arrow received from FDA regarding the Triple Lumen 12 French Catheters. As you recall, Mr. Gattling said that issues regarding the continued sale of the catheters for non-hemodialysis purposes were outside the purview of his group and suggested that I talk directly with Mr. Ulatowski. After discussing this with you, we agreed that I would call Mr. Ulatowski to determine whether he believed a 510(k) was necessary and to make clear the company's position that it can continue to sell these devices until either a decision is made that no 510(k) is necessary or a 510(k) is submitted and cleared.

I called Mr. Ulatowski and asked him if he was familiar with the September 9th letter and the overall situation involving these catheters. He said that he was not. I then provided him with a brief background of what has transpired over the past several years culminating in the September 9th letter. Mr. Ulatowski said that he was not in a position to make a 510(k) determination without additional information. He asked that we send such information to him.

I explained to Mr. Ulatowski FDA policy allows a company to continue to sell a product for which the Agency has determined a 510(k) is necessary so long as no safety issues exist, the company made a good faith determination that a 510(k) was not necessary, and the company agrees to submit a 510(k) in response to the FDA's demands. I told Mr. Ulatowski that I believed that these circumstances were satisfied here, and that Arrow is entitled to continue to sell this product under FDA policy. Mr. Ulatowski said that he would not raise this issue with Compliance

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

179/20

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and had no objection to continued sale. He said that once he reviewed the information sent to him he would be back in touch with either you or me to discuss whether he believes a 510(k) is necessary.

Please let me know if you have any questions about this information.

Sincerely,

Howard

Howard M. Holstein

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

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Attachment 2

Chronological Summary of Events

1. 1/14/91 - Arrow memo to file from T. Nickel - Large bore multi-lumen catheters for hemodialysis and high volume infusion. Original 12 Fr. 2-lumen catheter 510(k) K895417 did not focus on cross section details, so addition of 3rd lumen, considering clinical evaluation (appended) by J.D. Raulerson, MD, did not significantly affect safety or effectiveness.
2. FDA Philadelphia District Investigator Eldon Constant performed CDRH directed evaluation of 510(k) situation with 3-lumen device, agreed letter to file was adequate - 12/16/91.
3. 2-1/2 years later on 7/28/94, Philadelphia District Investigator James McElvoy arrived to repeat the above exercise, indicating CDRH did not agree with us. He collected the same information, and came to the same conclusion as Mr. Constant.
4. Warning letter from Philadelphia District of 8/17/94 - product mislabeled and adulterated - no 510(k).
5. Meeting with FDA at Philadelphia District office - T. Nickel with District Director and staff - 9/7/94. Agreed to submit 510(k), product to remain in commercial distribution.
6. 10/18/94 - 510(k) submission made - K945174.
7. CDRH deficiency letter 1/24/95.
8. Conference call with CDRH 3/31/96.
9. Response to CDRH 6/12/95.
10. CDRH deficiency letter 9/22/95.
11. Response to 9/22/95 deficiency letter sent 11/22/95.
12. CDRH deficiency letter 2/15/96.
13. Conference call with CDRH 4/16/96.
14. Letter from T. Nickel to B. Gatling requesting withdrawal of 510(k) - 4/15/96 (Attachment 3).
15. Letter from L. Yin to T. Nickel requiring 510(k) for CVC version of product - 9/9/96 (Attachment 4).
16. Howard Holstein discussion with Tim Ulatowski 10/9/96, acknowledgment letter to T. Nickel dated 10/10/96 (Attachment 1).

9695

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

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ATTACHMENT 3

Certified Mail

P.O. Box 12888
Reading, PA 19612

ARROW
INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

April 15, 1996

Robert Gatling, Associate Director
Division of Reproductive, Abdominal, ENT,
and Radiological Devices (HFZ-470)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) premarket Notification (b)(4) [redacted]
Arrow-Howes™ Multi-Lumen Hemodialysis
Catheterization Kits and Set - our phone
discussions of 3/20/96 and 4/11/96

Dear Mr. Gatling:

Pursuant to our phone discussions of March 26, 1996 and April 11, 1996, we propose the following actions to resolve the differences between Arrow and CDRH regarding the 12 Fr. 3-lumen device which is the subject of (b)(4) [redacted]:

1. We will cease labeling and promoting the device as a triple lumen hemodialysis catheter. The primary use and indication for the device is and always has been for large volume infusion of fluids. It is only secondarily indicated for hemodialysis. This primary central venous catheter focus is clearly stated in the labeling and directions for use included in pages 58 through 60 of the original submission of 10/18/94 and pages 100 through 117 of our 11/22/96 deficiency response letter.

   We will revise the labeling, directions for use, and any promotional material to indicate the device is a 12 Fr. triple lumen central venous catheter for large volume infusion of fluid only. THIS LABELING CHANGE WILL TAKE APPROXIMATELY 5 WEEKS TO EFFECT, SO WE CAN COMMIT TO PACKAGING PRODUCT WITH THE REVISED LABELING APPROXIMATELY 5 WEEKS AFTER WE RECEIVE YOUR APPROVAL TO PROCEED.

   Arrow is the market leader in central venous catheterization, and our multi-lumen central venous catheters are the world standard. Arrow CVC products have been the subject of numerous 510(k) submissions going back to 1978. Examples of multi-lumen 510(k) submissions are:

(b)(4) [redacted]

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

Page 2 of 2 K945174 Document released under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

2. We will withdraw K945174.

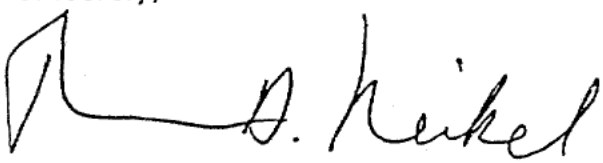
3. We have discussed the possibility of an IDE clinical trial with our biostatistician, whereby we would compare the 12 Fr. 3-lumen catheter to the 12 Fr. 2-lumen catheter regarding infection rate when used for hemodialysis. He indicated a total of 440 patients would be necessary.

   This is obviously a significant study for us in terms of time and resources, and it is not clear at this time whether customer demand for the 3-lumen hemodialysis indication is sufficient to justify proceeding with the IDE.

   If we do decide to proceed with this IDE, we will submit a pre-IDE written proposal to your group, probably to Elias Mallis, who is the reviewer for (b)(4) [redacted]

This proposal is intended to put this issue behind us both, and therefore we look forward to your response.

Sincerely,



Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

c: Howard Holstein - Hogan and Hartson

9631ltr

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

h83 24

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 1996

ATTACHMENT 4

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance
Arrow International
P.O. Box 12888
Reading, Pennsylvania 19612

Re: K945174
Arrow-Howes Triple-lumen 12 Fr Hemodialysis Catheterization Kits and Sets

Dear Mr. Nickel:

We have reviewed your April 15, 1996, letter in which you propose to withdraw the premarket notification (510(k)) for the device referenced above and to continue to market this 12 Fr triple lumen catheter for central venous infusion and not for hemodialysis.

We now consider this 510(k) withdrawn. We acknowledge that your cleared 510(k)s are for the large volume infusion of fluids. However, we do not agree that those 510(k)s for infusion cited in your letter are identical to the device referenced above, in terms of the device design (e.g., cross-sectional lumen, distal tip configuration, French size). Even though you proposed to change the intended use to large volume infusion of fluids, the 12 Fr triple lumen catheter requires a new 510(k), as described by 21 CFR 807.81(a)(3)(i). As a result, to commercially distribute your 12 Fr triple lumen catheter for infusion, you will need to submit a new 510(k) to FDA for review by the Division of Dental, Infection Control, and General Hospital Devices. Continued marketing of the 12 Fr triple-lumen catheter renders this device adulterated and misbranded in accordance with Sections 501(f)(1)(b) and 502(o) of the Federal Food, Drug, and Cosmetic Act (Act), respectively.

If you obtain investigational device exemption (IDE) approval for the 12 Fr triple lumen hemodialysis catheter, you may make this device available for investigational purposes to obtain clinical data to establish substantial equivalence. Clinical investigations of this significant risk device must be conducted in accordance with the IDE regulations.

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

25

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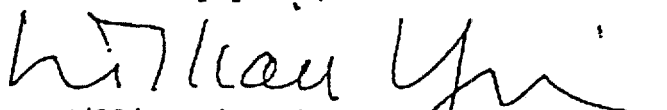
If you have any questions concerning the contents of this letter, please contact Robert Gatling at (301) 594-1220. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



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

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

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ATTACHMENT 3

Labeling, including lidstock and directions for use for a typical kit version of the device (i.e., the most components):

3A Arrow (b)(4) [redacted] the subject of this submission

3B Arrow (b)(4) [redacted] the 7 French 20cm currently marketed triple-lumen CVC comparable to the above device except for diameter

3C Arrow [redacted] (b) a two-lumen large bore 12 French, 16cm catheter used for both hemodialysis and rapid fluid administration

97022

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

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3A

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

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PMS #144

Product No. AK-15123-H

Arrow-Howes™ Large-Bore Multi-Lumen
Central Venous Catheterization Kit
For High Volume Infusions
with Heparin-Coated Catheter
HX-06-90380

ARROW

Contents:

One:..... 12 Fr. x 8" (20 cm) Radiopaque Polyurethane Heparin-Coated Multi-Lumen Indwelling Catheter with Blue FlexTip®
One:..... .035" (.89 mm) dia. x 26-13/16" (68 cm) Dual Purpose Marked Spring-Wire Guide (Straight Soft Tip on One End - "J" Tip on Other) with Arrow Advancer™
One:..... 18 Ga. x 2-1/2" (6.35 cm) Radiopaque Catheter over 20 Ga. Introducer Needle
One:..... 18 Ga. x 2-1/2" (6.35 cm) X.T.W. Needle
One:..... 22 Ga. x 1-1/2" (3.81 cm) Needle
One:..... 25 Ga. x 1" (2.54 cm) Needle
One:..... 3 cc Luer-Lock Syringe
One:..... 5 cc Luer-Slip Syringe
One:..... 5 cc Arrow Raulerson Spring-Wire Introduction Syringe*
One:..... Pressure Transduction Probe
One:..... SharpsAway® Disposal Cup
One:..... Disposable Scalpel, #11 Blade
One:..... Straight Silk Suture
Three:..... Povidone-Iodine Swabsticks, 10%
One:..... 5 ml Ampule Lidocaine HCl, 1%
One:..... Packette Povidone-Iodine Ointment, 10%
Two:..... 2" x 2" Gauze Pads
Five:..... 4" x 4" Gauze Pads
One:..... Vessel Dilator
Three:..... Extension Line Clamps
Three:..... Luer-Lock Injection Caps
One:..... Fenestrated Drape
One:..... CSR Wrap

*Licensed under U.S. Patent Nos. 4,813,938 and 5,045,065. Other U.S. and foreign patents pending.

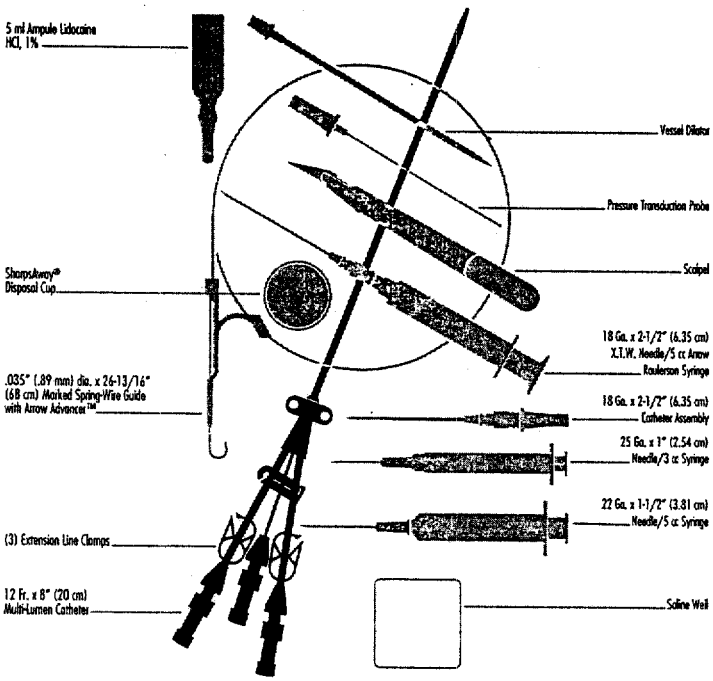
Caution: Do not wipe heparin-coated catheter before insertion.
Caution: U.S.A. Federal law restricts this device to sale by or on the order of a physician.
Warning: Prior to use read all package insert cautions and instructions.
Contraindications: Heparin-coated catheters are not for use in patients with a known sensitivity to heparin.

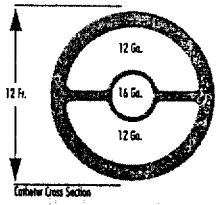
PMS #144

Sterile. Do not use if package has been previously opened or damaged. Fluid path components are non-pyrogenic. Contains medication. Single use — do not resterilize. Sterilized by ethylene oxide.

Licensed under U.S. Patent No. Re. 31873. Canadian Patent No. 1,112,533. Foreign patents pending and issued.

Manufactured by Arrow International, Inc.
3000 Bernville Road, Reading, PA 19605
Canadian Distributor:
Arrow Medical Products, Ltd.
Unit 20, 150 Britannia Road, East
Mississauga, Ontario L4Z 1S6





Lumen	Priming Volume[1] (cc)	Flow Rate[2] (cc/min)
Proximal (12 Ga.)	1.2	240
Medial (12 Ga.)	1.3	220
Distal (16 Ga.)	0.4	50

[1]Priming volumes are approximate and are done without the injection cap. Injection cap priming volume is 0.17 cc.

[2]Flow rates are done with normal saline, room temperature, 100 cm head height and represent approximate flow capabilities.

AK15123-100E

Product No. AK-15123-H — 12 Fr. — 3 Lumen — 20 cm catheter length — .035 inch dia. spring-wire guide

Arrow-Howes™ Large-Bore Multi-Lumen Central Venous Catheterization Kit with Heparin-Coated Catheter

PMS #144

Lot Control No. Expiration Date:

+H580AK15123H2(3)

PMS #144

Product No. AK-15123-H — 12 Fr. — 3 Lumen — 20 cm catheter length — .035 inch dia. spring-wire guide

ARROW INTERNATIONAL

Questions? Contact FDA/CDRH

Records processed under FOIA Request #2015-5835; Released by CDRH on 7/28/2016

ARROW

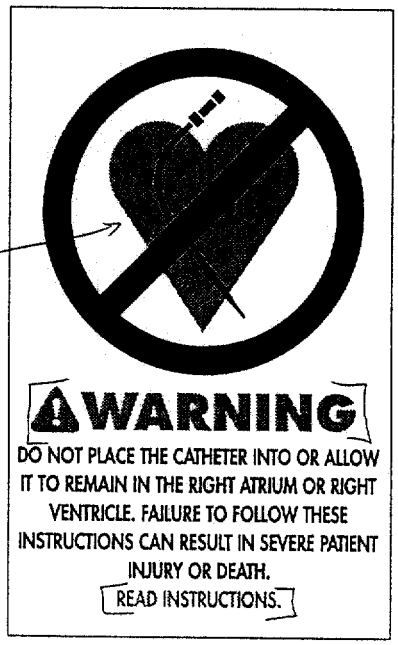
Large-Bore Multiple-Lumen Central Venous Catheterization Product with Heparin Coating and Arrow Raulerson Syringe

Safety and Efficacy Considerations:

The product is designed for single use only. Do not resterilize or reuse. Do not alter the catheter, spring-wire guide, or any other kit/set component during insertion, use, or removal.

Central venous catheterization must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.

Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Failure to follow these instructions can result in severe patient injury or death. Read instructions (refer to Fig. 1).



Heart Rad

Fig. 1

Cardiac Tamponade: It has been documented by many authors that placement of indwelling catheters in the right atrium is a dangerous practice[1,2,3,5,8,17,19] that may lead to cardiac perforation and tamponade[1,2,3,5,17,19]. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it[21]. Practitioners placing central venous catheters must be aware of this potentially fatal complication before advancing the catheter too far relative to patient size.

No particular route or catheter type is exempt from this potentially fatal complication[19]. The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion[1,2,5,17,19,22]. Central venous catheters should be placed in the superior vena cava[1,2,3,5,8,17,24] above its junction with the right atrium and parallel to the vessel wall[11,24] and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.

Central venous catheters should not be placed in the right atrium unless specifically required for special relatively short term procedures, such as aspiration of air emboli during neurosurgery. Such procedures are nevertheless risk prone and should be closely monitored and controlled.

Indications for Use:

The large-bore multiple-lumen catheter permits venous access to the central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, or femoral veins. The heparin coating on the catheter is intended to decrease the incidence of thrombus formation associated with catheterization[10,16].

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h89 31

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Contraindications:

Heparin-coated catheters are not for use in patients with a known sensitivity to heparin.

Central Venous Catheterization Warnings and Precautions:*

1. Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Central vein catheters should be positioned so that the distal tip of the catheter is in the superior vena cava (SVC) above the junction of the SVC and the right atrium and lies parallel to the vessel wall. For femoral vein approach the catheter should be advanced into the vessel so that the catheter tip lies parallel to the vessel wall and does not enter the right atrium.
2. Warning: Practitioners must be aware of complications associated with central vein catheters including cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma formation, hemorrhage, and dysrhythmias.
3. Warning: Do not apply excessive force in removing guide wire or catheters. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.
4. Warning: The practitioner must be aware of potential air embolism/hemorrhage problems associated with large-bore catheters. Do not leave open needles or catheters in central venous puncture sites. To lessen the risk of disconnects, only securely tightened Luer-Lock connections should be used with this device. It is recommended that the extension lines be kept clamped at all times when not in use because of the catheter's large lumens. Follow hospital protocol to guard against air embolism/ hemorrhage for all catheter maintenance.
5. Warning: Passage of the guide wire into the right heart can cause dysrhythmias, right bundle branch block[9], and vessel wall, atrial or ventricular perforation.
6. Warning: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients.
7. Warning: Falsely elevated levels of sodium and potassium have been reported in blood specimens collected through heparin-coated catheters and analyzed with ion-selective electrodes (ISE). This phenomenon is due to the presence of benzalkonium heparin to which some ISEs are sensitive. Samples exhibiting suspect sodium and/or potassium levels from instruments using ISEs should be assayed by flame photometry[7,13].
8. Precaution: Do not clamp the body of the large-bore catheter. Clamp only the extension lines and use only the clamps provided. Never use serrated forceps to clamp the extension lines.
9. Precaution: Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct catheter position and for secure Luer-Lock connection. Use centimeter markings to identify if the catheter position has changed.
10. Precaution: Only x-ray examination of the catheter placement can ensure that the catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If catheter position has changed, immediately perform chest x-ray examination to confirm catheter tip position.
11. Precaution: For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.
12. Precaution: Alcohol and acetone can weaken the structure of polyurethane material. Therefore, care should be taken when instilling drugs containing alcohol or when using high concentration of alcohol or acetone when performing routine catheter care and maintenance. Alcohol should not be utilized to declot polyurethane catheters.
13. Precaution: Use of a syringe smaller than 10 ml to irrigate or declot an occluded catheter may cause intraluminal leakage or catheter rupture[6].

Carefully read all warnings and precautions throughout procedure instructions.

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32

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Catheter Insertion Procedure:
Use sterile technique.

1. **Precaution: Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism. If femoral approach is used, place patient in supine position.**
2. Prep and drape puncture site as required.
3. Perform skin wheal with desired needle (25 Ga. or 22 Ga. needle). In kits where provided, a SharpsAway® disposal cup is used for the disposal of needles. Push needles into foam after use. Discard entire cup at completion of procedure. **Precaution: Do not reuse needles after they have been placed into the disposal cup. Particulate matter may adhere to needle tip.**
4. Prepare the catheter for insertion by flushing each lumen and clamping or attaching the injection caps to the appropriate pigtails. Leave the distal pigtail uncapped for guide wire passage. **Warning: Do not cut the catheter to alter length.**
5. Insert introducer needle with attached Arrow Raulerson Syringe into vein and aspirate. (If larger introducer needle is used, vessel may be pre-located with 22 Ga. locater needle and syringe). Remove locater needle.

Alternate Technique:

Catheter/needle may be used in the standard manner as alternative to introducer needle. If catheter/needle is used, Arrow Raulerson Syringe will function as a standard syringe, but will not pass spring-wire guide. If no free flow of venous blood is observed after needle is removed, attach syringe to the catheter and aspirate until good venous blood flow is established. **Precaution: The color of the blood aspirated is not always a reliable indicator of venous access[12]. Do not reinsert needle into introducer catheter.**

6. Because of the potential for inadvertent arterial placement, one of the following techniques should be utilized to verify venous access. Insert the fluid primed blunt tip transduction probe into the rear of the plunger and through the valves of the Raulerson Syringe. Observe for central venous placement via a wave form obtained by a calibrated pressure transducer. Remove transduction probe (refer to Fig. 2).

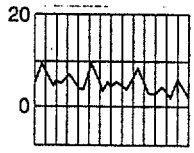

Fig. 2

Alternate Technique:

If hemodynamic monitoring equipment is not available to permit transducing a central venous wave form, check for pulsatile flow by either using the transduction probe to open the syringe valving system or by disconnecting the syringe from the needle. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

7. Using the two-piece Arrow Advancer™, advance spring-wire guide through syringe into vein. **Warning: Aspiration with spring-wire guide in place will cause introduction of air into syringe. Precaution: To avoid leakage of blood from syringe cap do not reinfuse blood with spring-wire guide in place.**

Arrow Two-Piece Advancer™ Instructions:

- Using your thumb, straighten the "J" by retracting the spring-wire guide into the Advancer™ (refer to Fig. 3). When the tip is straightened, the spring-wire guide is ready for insertion. Centimeter marks are referenced from "J" end. One band indicates 10 cm, two bands 20 cm, and three bands 30 cm.

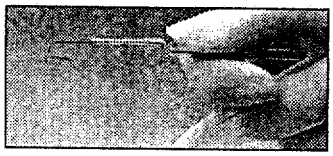

Fig. 3

Introducing the Spring-Wire Guide:

- Place the tip of the Advancer™ – with "J" retracted – into the hole in the rear of the Raulerson Syringe plunger (refer to Fig. 4).

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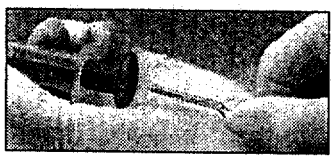

Fig. 4

- Advance spring-wire guide into the syringe approximately 10 cm until it passes through the valves.
- Lift your thumb and pull the Advancer™ approximately 4 cm to 8 cm away from the syringe. Lower thumb onto the Advancer™ and while maintaining a firm grip on the spring-wire guide, push the assembly into the syringe barrel to further advance the spring-wire guide. Continue until spring-wire guide reaches desired depth (refer to Fig. 5).

Fig. 5

Alternate Technique:

If a simple straightening tube is preferred, the straightening tube portion of the Advancer™ can be disconnected from the unit and used separately.

Separate the Advancer™ tip or straightening tube from the blue Advancer™ unit. If the "J" tip portion of the spring-wire guide is used, prepare for insertion by sliding the plastic tube over the "J" to straighten. The spring-wire guide should then be advanced in the routine fashion to the desired depth.

8. Advance guide wire until triple band mark reaches rear of syringe plunger. Advancement of "J" tip may require a gentle rotating motion. **Warning: Do not cut spring-wire guide to alter length. Do not withdraw spring-wire guide against needle bevel to avoid possible severing or damaging of spring-wire guide.**

9. Hold spring-wire guide in place and remove introducer needle and Raulerson Syringe (or catheter). **Precaution: Maintain firm grip on spring-wire guide at all times.** Use centimeter markings on spring-wire guide to adjust indwelling length according to desired depth of indwelling catheter placement.

10. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut guide wire.** Use vessel dilator to enlarge site as required. **Warning: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.**

11. Thread tip of multiple-lumen catheter over spring-wire guide. Sufficient guide wire length must remain exposed at hub end of catheter to maintain a firm grip on guide wire. Grasping near skin, advance catheter into vein with slight twisting motion.

12. Using cm marks on catheter as positioning reference points, advance catheter to final indwelling position.

13. Hold catheter at desired depth and remove spring-wire guide. The Arrow catheter included in this product has been designed to freely pass over the spring-wire guide. If resistance is encountered when attempting to remove the spring-wire guide after catheter placement, the spring-wire may be kinked about the tip of the catheter within the vessel (refer to Fig. 6).

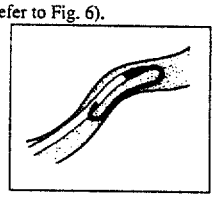

Fig. 6

In this circumstance, pulling back on the spring-wire guide may result in undue force being applied resulting in spring-wire guide breakage. If resistance is encountered, withdraw the catheter relative to the spring-wire guide about 2-3 cm and attempt to remove the spring-wire guide. If resistance is again encountered remove the spring-wire guide and catheter simultaneously. **Warning:**

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34

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Although the incidence of spring-wire guide failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire.

14. Verify that the entire spring-wire guide is intact upon removal.
15. Check lumen placement by attaching a syringe to each pigtail and aspirate until free flow of venous blood is observed. Connect all pigtails to appropriate Luer-Lock line(s) as required. Unused port(s) may be "locked" through injection cap(s) using standard hospital protocol. Pinch/slide clamps are provided on pigtails to occlude flow through each lumen during line and injection cap changes. **Precaution: To avoid damage to pigtails from excessive pressure, each clamp must be opened prior to infusing through that lumen.**
16. Secure and dress catheter temporarily.
17. Verify catheter tip position by chest x-ray immediately after placement. **Precaution: X-ray exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.** If catheter tip is malpositioned, reposition and re-verify.
18. Secure catheter to patient. Use triangular juncture hub with integral rotating suture wings as primary suture site. **Precaution: Do not suture directly to the outside diameter of the catheter to avoid cutting or damaging the catheter or impeding catheter flow.**
19. Dress puncture site per hospital protocol. **Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.**
20. Record on the patient's chart the indwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that the catheter has not moved.

Catheter Exchange Procedure:

1. Use sterile technique.
2. Proceed per hospital protocol. Cutting the catheter is not recommended due to the potential for catheter embolism.

Catheter Removal Procedure:

1. **Precaution: Place the patient in a supine position.**
2. Remove dressing. **Precaution: To avoid cutting of the catheter do not use scissors to remove the dressing.**
3. **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.** Remove suture(s) from primary suture site. Be careful not to cut the catheter. Remove catheter slowly, pulling it parallel to the skin. As catheter exits the site, apply pressure with a dressing impermeable to air, e.g. vaseline gauze. Because the residual catheter track remains an air entry point until completely sealed, the occlusive dressing should remain in place for at least 24-72 hours dependent upon the amount of time the catheter was indwelling[14,18,20,23].
4. Upon removal of the catheter, inspect it to make sure that the entire length has been withdrawn.
5. Verify that the catheter was intact upon removal. Document removal procedure.

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Arrow International, Inc. recommends that the user be acquainted with the reference literature.

*If you have any questions or would like additional reference information, please contact Arrow International, Inc.

ARROW
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3000 Bernville Road
Reading, PA 19605
1-800-523-8446
8 a.m. - 8 p.m. EST

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36

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Product No. AK-15703-H

<PMS#259

Arrow-Howes™ Multi-Lumen Central Venous Catheterization Kit

with Blue FlexTip® Heparin-Coated Catheter

ARROW

Contents:

One: 7 Fr. x 8" (20 cm) Radiopaque Polyurethane Heparin-Coated Multi-Lumen Indwelling Catheter with Blue FlexTip®
One: 25 Ga. x 1" (2.54 cm) Needle
One: 22 Ga. x 1-1/2" (3.81 cm) Needle
One: 18 Ga. x 2-1/2" (6.35 cm) Radiopaque Catheter over 20 Ga. Introducer Needle
One: 18 Ga. x 2-1/2" (6.35 cm) X.T.W. Needle
One: 3 cc Syringe
Two: 5 cc Syringes
One: .032" (.83 mm) dia. x 23-5/8" (60 cm) Dual Purpose Spring-Wire Guide (Straight Soft Tip on One End - "J" Tip on Other)
One: Disposable Scalpel (#11 Blade)
One: Straight Silk Suture
Three: Povidone-Iodine Swabsticks
One: 5 ml Ampule Lidocaine, HCl 1%
Two: 2" x 2" Gauze Pads
Five: 4" x 4" Gauze Pads
One: Vessel Dilator
Three: Extension Line Clamps
One: Catheter Clamp
Three: Luer-Lock Injection Caps
One: Packette Povidone-Iodine Ointment
One: SharpsAway® Disposal Cup
One: Fenestrated Drape
One: CSR Wrap

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

Warning: Prior to use read all package insert cautions and instructions.

Caution: Do not wipe heparin-coated catheter before use.

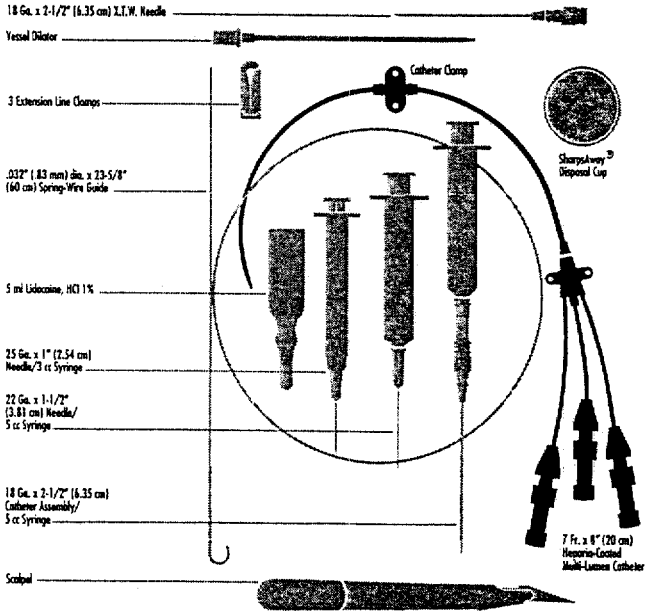
Caution: Contraindicated in patients with a known sensitivity to heparin.

PMS#259

Sterile. Do not use if package has been previously opened or damaged. Fluid path components are non-pyrogenic. Contains medication. Single use - do not resterilize. Sterilized by ethylene oxide.

Licensed under U.S. Patent No. Re. 31873. Canadian Patent No. 1,112,533. Foreign patents pending and issued.

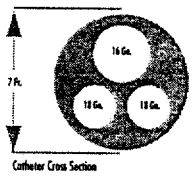
Manufactured by Arrow International, Inc.
3000 Bernville Road, Reading, PA 19605



Lumen	Priming Volume[1] (cc)	Flow Rate[2] (cc/hr)
Distal (16 Ga.)	0.44	3100
Medial (18 Ga.)	0.39	1500
Proximal (18 Ga.)	0.39	1600

[1] Priming volumes are approximate and are done without the injection cap. Injection cap priming volume is 0.17 cc.

[2] Flow rates are done with normal saline, room temperature, 100 cm head height and represent approximate flow capabilities.



Catheter Cross Section

IK15703-102H

Product No. AK-15703-H | 7 Fr. | 3 Lumen | 20 cm catheter length | .032 inch dia. spring-wire guide

Arrow-Howes™ Multi-Lumen Central Venous Catheterization Kit with Blue FlexTip®

<PMS#259

Lot Control No. Expiration Date:

+H580AK15703H2(7)

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Product No. AK-15703-H | 7 Fr. | 3 Lumen | 20 cm catheter length | .032 inch dia. spring-wire guide

Arrow-Howes™ Multi-Lumen Central Venous Catheterization Kit with Blue FlexTip®

<PMS#259

Peel to Open

Questions? Contact FDA/CDRH/OCE/DID at CDRH-PMS-ATTACS@fda.hhs.gov

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ARROW

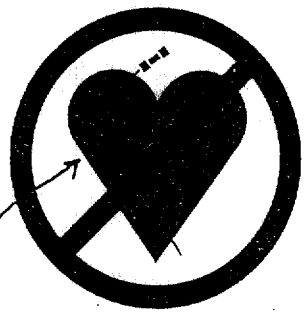
Multiple-Lumen Central Venous Catheterization Product with Heparin Coating

Safety and Efficacy Considerations:

The product is designed for single use only. Do not resterilize or reuse. Do not alter the catheter, spring-wire guide, or any other kit/set component during insertion, use, or removal.

Central venous catheterization must be performed by trained personnel, well versed in anatomical landmarks, safe technique and potential complications.

Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Failure to follow these instructions can result in severe patient injury or death. Read instructions (refer to Fig. 1).



WARNING

DO NOT PLACE THE CATHETER INTO OR ALLOW IT TO REMAIN IN THE RIGHT ATRIUM OR RIGHT VENTRICLE. FAILURE TO FOLLOW THESE INSTRUCTIONS CAN RESULT IN SEVERE PATIENT INJURY OR DEATH.

READ INSTRUCTIONS.

(Red Heart)

Fig. 1

Cardiac Tamponade: It has been documented by many authors that placement of indwelling catheters in the right atrium is a dangerous practice[1,2,3,5,8,17,19] that may lead to cardiac perforation and tamponade.[1,2,3,5,17,19] Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.[21] Practitioners placing central venous catheters must be aware of this potentially fatal complication before advancing the catheter too far relative to patient size. No particular route or catheter type is exempt from this potentially fatal complication.[19] The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion.[1,2,5,17,19,22] Central venous catheters should be placed in the superior vena cava[1,2,3,5,8,17,24] above its junction with the right atrium and parallel to the vessel wall[11,24] and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.

Central venous catheters should not be placed in the right atrium unless specifically required for special relatively short term procedures, such as aspiration of air emboli during neurosurgery. Such procedures are nevertheless risk prone and should be closely monitored and controlled.

Indications for Use:

The multiple-lumen catheter permits venous access to the central circulation.

The heparin coating on the catheter is intended to decrease the incidence of thrombus formation associated with catheterization.[10,16]

Contraindications:

Heparin-coated catheters are not for use in patients with a known sensitivity to heparin.

Central Venous Catheterization Warnings and Precautions:*

1. Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Central vein catheters should be positioned so that the distal tip of the catheter is in the superior vena cava (SVC) above the junction of the SVC and the right atrium and lies parallel to the vessel

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h97 39

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wall. For femoral vein approach the catheter should be advanced into the vessel so that the catheter tip lies parallel to the vessel wall and does not enter the right atrium.

2. Warning: Practitioners must be aware of complications associated with central vein catheters including cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma formation, hemorrhage, and dysrhythmias.

3. Warning: Do not apply excessive force in removing guide wire or catheters. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.

4. Warning: The practitioner must be aware of potential air embolism problems associated with leaving open needles or catheters in central venous puncture sites or as a consequence of inadvertent disconnects. To lessen the risk of disconnects, only securely tightened Luer-Lock connections should be used with this device. Follow hospital protocol to guard against air embolism for all catheter maintenance.

5. Warning: Passage of the guide wire into the right heart can cause dysrhythmias, right bundle branch block[9], and vessel wall, atrial or ventricular perforation.

6. Warning: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients.

7. Warning: Falsely elevated levels of sodium and potassium have been reported in blood specimens collected through heparin coated catheters and analyzed with ion-selective electrodes (ISE). This phenomenon is due to the presence of benzalkonium heparin to which some ISEs are sensitive. Samples exhibiting suspect sodium and/or potassium levels from instruments using ISEs should be assayed by flame photometry.[7,13]

8. Precaution: Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct catheter position and for secure Luer-Lock connection. Use centimeter markings to identify if the catheter position has changed.

9. Precaution: Only x-ray examination of the catheter placement can ensure that the catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If catheter position has changed, immediately perform chest x-ray examination to confirm catheter tip position.

10. Precaution: For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.

11. Precaution: Alcohol and acetone can weaken the structure of polyurethane material. Therefore, care should be taken when instilling drugs containing alcohol or when using high concentration of alcohol or acetone when performing routine catheter care and maintenance. Alcohol should not be utilized to declot polyurethane catheters.

12. Precaution: Use of a syringe smaller than 10 ml to irrigate or declot an occluded catheter may cause intraluminal leakage or catheter rupture.[5]

Carefully read all warnings and precautions throughout procedure instructions.

Catheter Insertion Procedure:
Use sterile technique.

1. Precaution: Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism. If femoral approach is used, place patient in supine position.
2. Prep and drape puncture site as required.
3. Perform skin wheal with desired needle (25 ga. or 22 ga. needle). In kits where provided, a SharpsAway® disposal cup is used for the disposal of needles. Push needles into foam after use. Discard entire cup at completion of procedure. Precaution: Do not re-use needles after they have been placed into the disposal cup. Particulate matter may adhere to needle tip.
4. Prepare the catheter for insertion by flushing each lumen and clamping or attaching the injection caps to the appropriate pigtails. Leave the distal pigtail uncapped for guide wire passage. Warning: Do not cut the catheter to alter length.

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h98 40

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5. Locate central vein with a 22 ga. needle and syringe.

6. Insert introducer catheter/needle with attached syringe into vein beside locater needle and aspirate. Remove locater needle. Withdraw needle from introducer catheter. If no free flow of venous blood is observed after needle is removed, attach syringe to the catheter and aspirate until good venous blood flow is established. **Precaution: The color of the blood aspirated is not always a reliable indicator of venous access.[12] Do not reinsert needle into introducer catheter.** Because of the potential for inadvertent arterial placement, verify venous access via a wave form obtained by a calibrated pressure transducer (refer to Fig. 2).

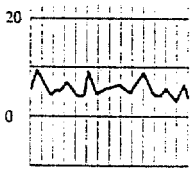

Fig. 2

If hemodynamic monitoring equipment is not available to permit transducing a central venous wave form, disconnect the syringe and check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

Alternate technique:

Introducer needle may be used in the standard manner as alternative to catheter/needle assembly.

7. Insert desired tip of spring-wire guide through the introducer needle or catheter into vein. If the "J"-tip portion of the spring-wire guide is used, prepare for insertion by sliding the plastic tube over the "J" to straighten. The spring-wire guide should then be advanced in the routine fashion to the desired depth. Advancement of "J"-tip may require a gentle rotating motion. **Warning: Do not cut spring-wire guide to alter length. Do not withdraw spring-wire guide against needle bevel to avoid possible severing or damaging of spring-wire guide.**

8. Hold spring-wire guide in place and remove introducer needle or catheter. **Precaution: Maintain firm grip on spring-wire guide at all times.**

9. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut guide wire.** Use vessel dilator to enlarge site as required. **Warning: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.**

10. Thread tip of multiple-lumen catheter over spring-wire guide. Sufficient guide wire length must remain exposed at hub end of catheter to maintain a firm grip on guide wire. Grasping near skin, advance catheter into vein with slight twisting motion. **Precaution: Catheter clamp and fastener must not be attached to catheter until spring-wire guide is removed.**

11. Using cm marks on catheter as positioning reference points, advance catheter to final indwelling position.

12. Hold catheter at desired depth and remove spring-wire guide. The Arrow catheter included in this product has been designed to freely pass over the spring-wire guide. If resistance is encountered when attempting to remove the spring-wire guide after catheter placement, the spring-wire may be kinked about the tip of the catheter within the vessel (refer to Fig. 3). In this circumstance, pulling back on the spring-wire guide may result in undue force being applied resulting in spring-wire guide breakage. If resistance is encountered, withdraw the catheter relative to the spring-wire guide about 2-3 cm and attempt to remove the spring-wire guide. If resistance is again encountered remove the spring-wire guide and catheter simultaneously. **Warning: Although the incidence of spring-wire guide failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire.**

Fig. 3

13. Verify that the entire spring-wire guide is intact upon removal.

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14. Check lumen placement by attaching a syringe to each pigtail and aspirate until free flow of venous blood is observed. Connect all pigtails to appropriate Luer-Lock line(s) as required. Unused port(s) may be "locked" through injection cap(s) using standard hospital protocol. Slide clamps are provided on pigtails to occlude flow through each lumen during line and injection cap changes. **Precaution: To avoid damage to pigtails from excessive pressure, each clamp must be opened prior to infusing through that lumen.**

15. Secure and dress catheter temporarily.

16. Verify catheter tip position by chest x-ray immediately after placement. **Precaution: X-ray exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.** If catheter tip is malpositioned, reposition and re-verify.

17. Secure catheter to patient. Use triangular juncture hub with integral suture ring and side wings as primary suture site. In kits where provided, the catheter clamp and fastener should be utilized as a secondary suture site as necessary. **Precaution: Do not suture directly to the outside diameter of the catheter to avoid cutting or damaging the catheter or impeding catheter flow.**

Catheter Clamp and Fastener Instructions:

- After spring-wire guide has been removed and the necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter as required to ensure proper tip location (refer to Fig. 4).

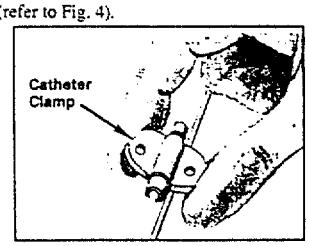

Fig. 4

- Snap rigid fastener onto catheter clamp (refer to Fig. 5).

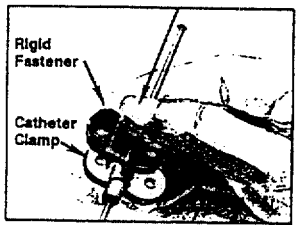

Fig. 5

- Secure catheter to patient by suturing the catheter clamp and fastener together to the skin, using side wings to prevent catheter migration (refer to Fig. 6).

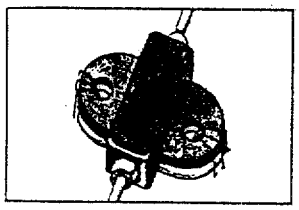

Fig. 6

18. Dress puncture site per hospital protocol. **Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.**

19. Record on the patient's chart the indwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that the catheter has not moved.

Catheter Exchange Procedure:

1. Use sterile technique.
2. **Precaution: Prior to attempting a catheter exchange procedure, remove the catheter clamp and fastener.**
3. Proceed per hospital protocol. Cutting the catheter is not recommended due to the potential for catheter embolism.

Catheter Removal Procedure:

1. **Precaution: Place the patient in a supine position.**
2. Remove dressing. **Precaution: To avoid cutting of the catheter do not use scissors to remove the dressing.**

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3. **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.** Remove suture(s) from catheter clamp and primary suture site. Be careful not to cut the catheter. Remove catheter slowly, pulling it parallel to the skin. As catheter exits the site, apply pressure with a dressing impermeable to air, e.g. vaseline gauze. Because the residual catheter track remains an air entry point until completely sealed, the occlusive dressing should remain in place for at least 24-72 hours dependent upon the amount of time the catheter was indwelling.[14,18,20,23]

4. Upon removal of the catheter, inspect it to make sure that the entire length has been withdrawn.

5. Verify that the catheter was intact upon removal. Document removal procedure.

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Arrow International, Inc. recommends that the user be acquainted with the reference literature.

*If you have any questions or would like additional reference information, please contact Arrow International, Inc.

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INTERNATIONAL
3000 Bernville Road
Reading, PA 19605
1-800-523-8446
8 a.m. - 8 p.m. EST

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Product No. AK-12122-H

Two-Lumen Hemodialysis Catheterization Kit

for High Volume Infusions
with Heparin-Coated Catheter
DIN 00899580

ARROW

Contents:

One: ..... 12 Fr. x 6" (16 cm) Radiopaque Polyurethane Heparin-Coated Two-Lumen Indwelling Catheter with Blue FlexTip®†
One: ..... .035" (.89 mm) dia. x 23-5/8" (60 cm) Dual Purpose Marked Spring-Wire Guide (Straight Soft Tip on One End – "J" Tip on Other) with Arrow Advance™
One: ..... 18 Ga. x 2-1/2" (6.35 cm) Radiopaque Catheter over 20 Ga. Introducer Needle
One: ..... 18 Ga. x 2-1/2" (6.35 cm) X.T.W. Needle
One: ..... 22 Ga. x 1-1/2" (3.81 cm) Needle
One: ..... 25 Ga. x 1" (2.54 cm) Needle
One: ..... 3 cc Luer-Lock Syringe
One: ..... 5 cc Luer-Slip Syringe
One: ..... 5 cc Arrow Raulerson Spring-Wire Introduction Syringe®
One: ..... Pressure Transduction Probe
One: ..... Disposable Scalpel (#11 Blade)
One: ..... Straight Silk Suture
Three: ..... Povidone-Iodine Swabsticks, 10%
One: ..... 5 ml Ampule Lidocaine HCl, 1%
One: ..... Packette Povidone-Iodine Ointment, 10%
Two: ..... 2" x 2" Gauze Pads
Five: ..... 4" x 4" Gauze Pads
One: ..... Vessel Dilator
Two: ..... Extension Line Clamps
Two: ..... Luer-Lock Injection Caps
One: ..... SharpsAway® Disposal Cup
One: ..... Fenestrated Drape
One: ..... CSR Wrap

†Licensed under U.S. Patent No. 4,813,938.
Other U.S. and foreign patents pending.

Caution: Do not wipe heparin-coated catheter before insertion.

Caution: Contraindicated in patients with a known sensitivity to heparin.

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

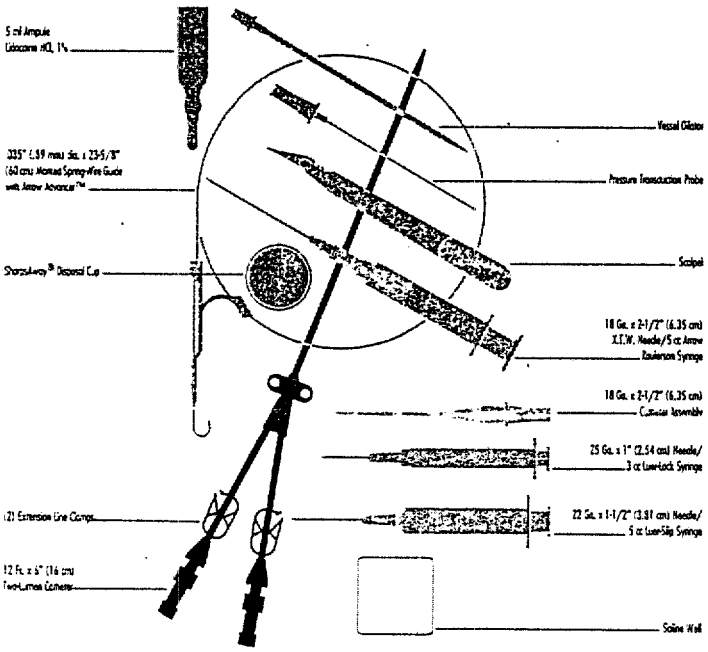
Warning: Prior to use read all package insert cautions and instructions.

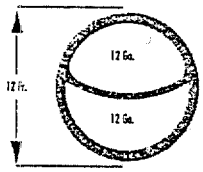
Sterile. Do not use if package has been previously opened or damaged. Fluid path components are non-pyrogenic. Contains medication. Single use – do not resterilize. Sterilized by ethylene oxide.

Contraindications: The Arrow large-bore two-lumen catheter is not designed for long-term hemodialysis or for use in patients with thrombosed vessels.

Manufactured by Arrow International, Inc.
3000 Berwick Road, Reading, PA 19605

Canadian Distributor:
Arrow Medical Products, Ltd.
Unit 20, 150 Britannia Road, East
Mississauga, Ontario L4Z 1S6





Catheter Cross Section

Lumen	Priming Volume[1] (cc)	Flow Rate[2] (cc/min)	Venous Pressure Setting (mm Hg)
Distal	1.3	220	100
		370	200
Proximal	1.2	220	100
		370	200

[1]Priming volumes are approximate and are done without the injection cap. Injection cap priming volume is 0.17 cc.
[2]Blood flow rates are approximate and were determined by varying the venous pressure setting from 100 to 200 mm Hg in an in vitro experiment using blood analog solution.

IK 12122-1000

Product No. AK-12122-H 12 Fr. 2 Lumen 16 cm catheter length .035 inch dia. spring-wire guide

Two-Lumen Hemodialysis Catheterization Kit with Heparin-Coated Catheter

Lot Control No. Expiration Date:

-H580AK12122H2(*)

SOH

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Product No. AK-12122-H 12 Fr. 2 Lumen 16 cm catheter length .035 inch dia. spring-wire guide

Two-Lumen Hemodialysis Catheterization Kit with Heparin-Coated Catheter

Questions? Contact FDA/CDRH

46

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[Red]

ARROW

Two-Lumen Hemodialysis Catheterization Product

with Heparin Coating and Arrow Raulerson Syringe

Safety and Efficacy Considerations:

The product is designed for single use only. Do not resterilize or reuse. Do not alter the catheter, spring-wire guide, or any other kit/set component during insertion, use, or removal.

Central venous catheterization must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.

[Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Failure to follow these instructions can result in severe patient injury or death. Read instructions (refer to Fig. 1).]

Fig. 1

Cardiac Tamponade: It has been documented by many authors that placement of indwelling catheters in the right atrium is a dangerous practice[1,2,3,5,8,18,20] that may lead to cardiac perforation and tamponade[1,2,3,8,18,20]. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it[22]. Practitioners placing central venous catheters must be aware of this potentially fatal complication before advancing the catheter too far relative to patient size.

No particular route or catheter type is exempt from this potentially fatal complication[20]. The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion[1,2,5,18,20,23]. Central venous catheters should be placed in the superior vena cava[1,2,3,5,8,18,25] above its junction with the right atrium and parallel to the vessel wall[11,25] and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.

Central venous catheters should not be placed in the right atrium unless specifically required for special relatively short term procedures, such as aspiration of air emboli during neurosurgery. Such procedures are nevertheless risk prone and should be closely monitored and controlled.

Indications for Use:

The large-bore two-lumen catheter permits venous access to the central circulation for rapid fluid administration, temporary or acute hemodialysis and apheresis. It may be inserted into the jugular, subclavian, or femoral veins. The heparin coating on the catheter is intended to decrease the incidence of thrombus formation associated with catheterization[10,17].

Contraindications:

The large-bore two-lumen catheter is not designed for long-term hemodialysis or for use in patients with

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thrombosed vessels. Heparin-coated catheters are not for use in patients with a known sensitivity to heparin.

Central Venous Catheterization Warnings and Precautions:*

1. **Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Central vein catheters should be positioned so that the distal tip of the catheter is in the superior vena cava (SVC) above the junction of the SVC and the right atrium and lies parallel to the vessel wall. For femoral vein approach the catheter should be advanced into the vessel so that the catheter tip lies parallel to the vessel wall and does not enter the right atrium.**

2. **Warning: Practitioners must be aware of complications associated with central vein catheters including cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma formation, hemorrhage, and dysrhythmias.**

3. **Warning: Do not apply excessive force in removing guide wire or catheters. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.**

4. **Warning: The practitioner must be aware of potential air embolism/hemorrhage problems associated with large-bore catheters. Do not leave open needles or catheters in central venous puncture sites. To lessen the risk of disconnects, only securely tightened Luer-Lock connections should be used with this device. It is recommended that the extension lines be kept clamped at all times when not in use because of the catheter's large lumens. Follow hospital protocol to guard against air embolism/ hemorrhage for all catheter maintenance.**

5. **Warning: Passage of the guide wire into the right heart can cause dysrhythmias, right bundle branch block[8], and vessel wall, atrial or ventricular perforation.**

6. **Warning: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients.**

7. **Warning: Faisely elevated levels of sodium and potassium have been reported in blood specimens collected through heparin coated catheters and analyzed with ion-selective electrodes (ISE). This phenomenon is due to the presence of benzalkonium heparin to which some ISEs are sensitive. Samples exhibiting suspect sodium and/or potassium levels from instruments using ISEs should be assayed by flame photometry[7,13].**

8. **Precaution: Do not clamp the body of the large-bore catheter. Clamp only the extension lines and use only the clamps provided. Never use serrated forceps to clamp the extension lines.**

9. **Precaution: Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct catheter position and for secure Luer-Lock connection. Use centimeter markings to identify if the catheter position has changed.**

10. **Precaution: Only x-ray examination of the catheter placement can ensure that the catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If catheter position has changed, immediately perform chest x-ray examination to confirm catheter tip position.**

11. **Precaution: For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.**

12. **Precaution: Alcohol and acetone can weaken the structure of polyurethane material. Therefore, care should be taken when instilling drugs containing alcohol or when using high concentration of alcohol or acetone when performing routine catheter care and maintenance. Alcohol should not be utilized to declot polyurethane catheters.**

13. **Precaution: Use of a syringe smaller than 10 ml to irrigate or declot an occluded catheter may cause intraluminal leakage or catheter rupture[6].**

Carefully read all warnings and precautions throughout procedure instructions.

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Catheter Insertion Procedure: Use sterile technique.

1. **Precaution: Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism. If femoral approach is used, place patient in supine position.**

2. Prep and drape puncture site as required.

3. Perform skin wheal with desired needle (25 Ga. or 22 Ga. needle). In kits where provided, a SharpsAway® disposal cup is used for the disposal of needles. Push needles into foam after use. Discard entire cup at completion of procedure. **Precaution: Do not reuse needles after they have been placed into the disposal cup. Particulate matter may adhere to needle tip.**

4. Prepare the catheter for insertion by flushing each lumen and clamping or attaching the injection caps to the appropriate pigtails. Leave the distal pigtail uncapped for guide wire passage. **Warning: Do not cut the catheter to alter length.**

5. Insert introducer needle with attached Arrow Raulerson Syringe into vein and aspirate. (If larger introducer needle is used, vessel may be pre-located with 22 Ga. locater needle and syringe). Remove locater needle.

   Alternate Technique:
   Catheter/needle may be used in the standard manner as alternative to introducer needle. If catheter/needle is used, Arrow Raulerson Syringe will function as a standard syringe, but will not pass spring-wire guide. If no free flow of venous blood is observed after needle is removed, attach syringe to the catheter and aspirate until good venous blood flow is established. **Precaution: The color of the blood aspirated is not always a reliable indicator of venous access[12]. Do not reinsert needle into introducer catheter.**

6. Because of the potential for inadvertent arterial placement, one of the following techniques should be utilized to verify venous access. Insert the fluid primed blunt tip transduction probe into the rear of the plunger and through the valves of the Raulerson Syringe. Observe for central venous placement via a wave form obtained by a calibrated pressure transducer. Remove transduction probe (refer to Fig. 2).

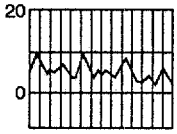

Fig. 2

Alternate Technique:

If hemodynamic monitoring equipment is not available to permit transducing a central venous wave form, check for pulsatile flow by either using the transduction probe to open the syringe valving system or by disconnecting the syringe from the needle. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

7. Using the two-piece Arrow Advancer™, advance spring-wire guide through syringe into vein. **Warning: Aspiration with spring-wire guide in place will cause introduction of air into syringe. Precaution: To avoid leakage of blood from syringe cap do not reinfuse blood with spring-wire guide in place.**

Arrow Two-Piece Advancer™ Instructions:

- Using your thumb, straighten the "J" by retracting the spring-wire guide into the Advancer™ (refer to Fig. 3). When the tip is straightened, the spring-wire guide is ready for insertion. Centimeter marks are referenced from "J" end. One band indicates 10 cm, two bands 20 cm, and three bands 30 cm.

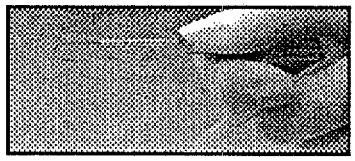

Fig. 3

Introducing the Spring-Wire Guide:

- Place the tip of the Advancer™—with "J" retracted—into the hole in the rear of the

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507 49

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Raulerson Syringe plunger (refer to Fig. 4).

Fig. 4

- Advance spring-wire guide into the syringe approximately 10 cm until it passes through the valves.
- Lift your thumb and pull the Advancer™ approximately 4 cm to 8 cm away from the syringe. Lower thumb onto the Advancer™ and while maintaining a firm grip on the spring-wire guide, push the assembly into the syringe barrel to further advance the spring-wire guide. Continue until spring-wire guide reaches desired depth (refer to Fig. 5).

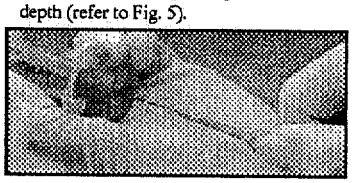

Fig. 5

Alternate Technique:

If a simple straightening tube is preferred, the straightening tube portion of the Advancer™ can be disconnected from the unit and used separately.

Separate the Advancer™ tip or straightening tube from the blue Advancer™ unit. If the "J" tip portion of the spring-wire guide is used, prepare for insertion by sliding the plastic tube over the "J" to straighten. The spring-wire guide should then be advanced in the routine fashion to the desired depth.

8. Advance guide wire until triple band mark reaches rear of syringe plunger. Advancement of "J" tip may require a gentle rotating motion. **Warning: Do not cut spring-wire guide to alter length. Do not withdraw spring-wire guide against needle bevel to avoid possible severing or damaging of spring-wire guide.**

9. Hold spring-wire guide in place and remove introducer needle and Raulerson Syringe (or catheter). **Precaution: Maintain firm grip on spring-wire guide at all times.** Use centimeter markings on spring-wire guide to adjust indwelling length according to desired depth of indwelling catheter placement.

10. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut guide wire.** Use vessel dilator to enlarge site as required. **Warning: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.**

11. Thread tip of two-lumen catheter over spring-wire guide. Sufficient guide wire length must remain exposed at hub end of catheter to maintain a firm grip on guide wire. Grasping near skin, advance catheter into vein with slight twisting motion.

12. Using cm marks on catheter as positioning reference points, advance catheter to final indwelling position. When using a subclavian approach, the catheter can be oriented with the outflow (arterial) sideholes toward the center of the vessel to reduce the possibility of contact between the outflow sideholes and the vessel wall.

13. Hold catheter at desired depth and remove spring-wire guide. The Arrow catheter included in this product has been designed to freely pass over the spring-wire guide. If resistance is encountered when attempting to remove the spring-wire guide after catheter placement, the spring-wire may be kinked about the tip of the catheter within the vessel (refer to Fig. 6).

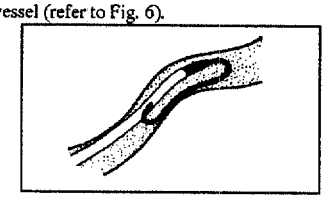

Fig. 6

In this circumstance, pulling back on the spring-wire guide may result in undue force being applied resulting in spring-wire guide breakage. If resistance is encountered, withdraw the catheter relative to the spring-wire guide about 2-3 cm and attempt to remove the spring-wire guide. If

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508 50

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resistance is again encountered remove the spring-wire guide and catheter simultaneously. **Warning: Although the incidence of spring-wire guide failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire.**

14. Verify that the entire spring-wire guide is intact upon removal.

15. Check lumen placement by attaching a syringe to each pigtail and aspirate until free flow of venous blood is observed. Connect both pigtails to appropriate Luer-Lock line(s) as required. Unused port(s) may be "locked" through injection cap(s) using standard hospital protocol. Pinch clamps are provided on pigtails to occlude flow through each lumen during line and injection cap changes. **Precaution: To avoid damage to pigtails from excessive pressure, each clamp must be opened prior to infusing through that lumen.**

16. Secure and dress catheter temporarily.

17. Verify catheter tip position by chest x-ray immediately after placement. **Precaution: X-ray exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.** If catheter tip is malpositioned, reposition and re-verify.

18. Secure catheter to patient. Use triangular juncture hub with integral rotating suture wings as primary suture site. **Precaution: Do not suture directly to the outside diameter of the catheter to avoid cutting or damaging the catheter or impeding catheter flow.**

19. Dress puncture site per hospital protocol. **Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.**

20. Record on the patient's chart the indwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that the catheter has not moved.

Catheter Exchange Procedure:

1. Use sterile technique.
2. Proceed per hospital protocol. Cutting the catheter is not recommended due to the potential for catheter embolism.

Catheter Removal Procedure:

1. **Precaution: Place the patient in a supine position.**
2. Remove dressing. **Precaution: To avoid cutting of the catheter do not use scissors to remove the dressing.**
3. **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.** Remove suture(s) from primary suture site. Be careful not to cut the catheter. Remove catheter slowly, pulling it parallel to the skin. As catheter exits the site, apply pressure with a dressing impermeable to air, e.g. vaseline gauze. Because the residual catheter track remains an air entry point until completely sealed, the occlusive dressing should remain in place for at least 24-72 hours dependent upon the amount of time the catheter was indwelling[14,19,21,24].
4. Upon removal of the catheter, inspect it to make sure that the entire length has been withdrawn.
5. Verify that the catheter was intact upon removal. Document removal procedure.

Heparinization (Hemodialysis):

1. A variety of "locking" solution concentrations are utilized to maintain the patency of the catheter. The amount of heparin used depends on physician preference, hospital protocol and patient condition[16].
2. The volume of heparin solution should be equal to or slightly more than the volume of the lumen that is being "locked".
3. **Warning: Prior to hemodialysis, the indwelling heparin must be aspirated from each lumen. After the heparin has been aspirated the lumens should be flushed with sterile normal saline solution.**

Poor Blood Flow:

1. If there is difficulty maintaining an adequate blood flow during the hemodialysis treatment, the following measures can be tried: lower patient's head, change patient's position, apply external

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509 51

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pressure to catheter exit site over sterile dressing, check for catheter kinks, rotate catheter if moveable within rotating suture wings, loosen tight dressing, reverse blood flow only if other attempts fail[16].

2. If the above measures fail and the flow problems are felt to be due to a clotted catheter, fibrinolytic agents can be used as prescribed.

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SID 52

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Arrow International, Inc. recommends that the user be acquainted with the reference literature.

*If you have any questions or would like additional reference information, please contact Arrow International, Inc.

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S11 53

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ATTACHMENT 4

Drawings of device and predicates, including cross-sectional area, distal tip configuration, and French size

4A Device

4B 7 French 3-lumen predicate

4C 12 French 2-lumen predicate

Also included is a comparison of priming volume and flow rates, included herein (b)(4)

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4A

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(b)(4) Schematic drawing

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4B

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(b)(4) Schematic drawing

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4C

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(b)(4) Schematic drawing

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FLOW RATE SUMMARY -- 12 FR. PRODUCTS

Two-Lumen Hemodialysis Catheters

Blood Flow Rates (blood analog)

	priming volumes (cc)	flow rates (cc/min.)	venous pressure setting (mmHg)
catheter length	25 cm N/A	(b)(4) [redacted]	
proximal lumen	-		
distal lumen	-		

High Volume Infusion (n-saline)

	priming volumes (cc)	flow rates (cc/min.)	high flow tubing, at 100 cm
catheter length	25 cm N/A	(b)(4) [redacted]	
proximal lumen	-		gravity (~80 mmHg)
distal lumen	-		gravity (~80 mmHg)

Multi-Lumen Large Bore CVCs

High Volume Infusion (n-saline)

	priming volumes (cc)	flow rates (cc/min.)	high flow tubing, at 100 cm
catheter length	(b)(4) [redacted]		
proximal lumen			gravity (~80 mmHg)
medial lumen			gravity (~80 mmHg)
distal lumen			gravity (~80 mmHg)

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