



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (latoye.lewis)
FOLDER: K935094 - 124 pages
COMPANY: WILSON-COOK MEDICAL, INC. (WILSCOOKMEDI)
PRODUCT: DILATOR, ESOPHAGEAL (KNQ)
SUMMARY: Product: BALLOON DILATION CATHETER

DATE REQUESTED: Oct 27, 2014

DATE PRINTED: Oct 27, 2014

Note: Printed





JAN 24 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Paula A. Joyce
Regulatory Affairs Specialist
Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Re: K935094
Quantum T.T.C. Balloon
Dilatation Catheter
Dated: October 20, 1993
Received: October 22, 1993
Regulatory class: II
21 CFR §876.5365/Procode: 78 KNQ

Dear Ms. Joyce:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their 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

510(K) ROUTE SLIP

510(k) NUMBER K935094 PANEL GU DIVISION DRAER BRANCH ORD B

TRADE NAME BALLOON DILATION CATHETER

COMMON NAME BALLOON DILATION CATHETER

PRODUCT CODE _____

APPLICANT WILSON-COOK MEDICAL, INC.

SHORT NAME WILSCOOKMEDI

CONTACT PAULA A JOYCE

DIVISION _____

ADDRESS 4900 BETHANIA STATION ROAD

WINSTON-SALEM, NC 27105

PHONE NO. (919) 744-0157

FAX NO. (919) 744-1147

MANUFACTURER WILSON-COOK MEDICAL, INC.

REGISTRATION NO. 1037905

DATE ON SUBMISSION 20-OCT-93

DATE DUE TO 510(K) STAFF 05-JAN-94

DATE RECEIVED IN ODE 22-OCT-93

DATE DECISION DUE 20-JAN-94

DECISION _____

DECISION DATE JAN 24 1995

emo

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Memorandum

Date

From

REVIEWER(S) - NAME(S)

Kathleen OLUF

Subject

510(k) NOTIFICATION

K935094

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes No

This 510(k) contains: (check appropriate box(es))

- A 510(k) summary of safety and effectiveness, or
- A 510(k) statement that safety and effectiveness information will be made available
- The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

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

Predicate Product Code w/panel and class:

class II 78 KNQ 876 5365

Additional Product Code(s) w/Panel (optional):

REVIEW: EC Derrin
(BRANCH CHIEF)

GROB 01/23/95
[BRANCH CODE] (DATE)

FINAL REVIEW: R. Patton / LYon
(DIVISION DIRECTOR)

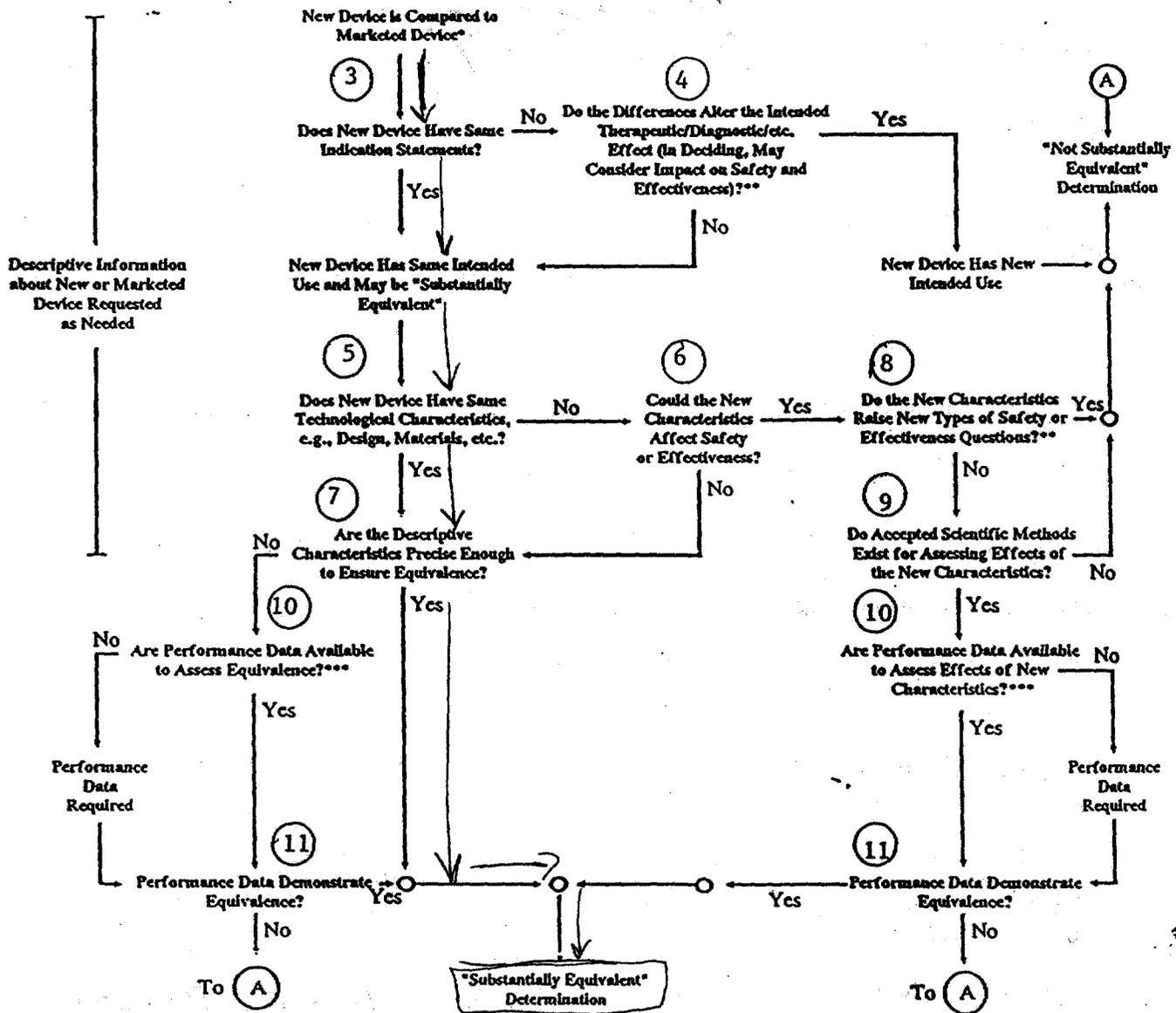
1/24/95
(DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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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.

K935094 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENT

REVIEWER: Kathleen M. Olvey DIVISION/BRANCH: DRAERD/GRDB

TRADE NAME: Quantum T.T.C. Balloon Dilation Catheter COMMON NAME: Esophageal/Biliary Dilator

PRODUCT TO WHICH COMPARED: Microvasive Rigiflex TTS Dilators, Microvasive Achiever System, Bard disposable biliary balloon dilators
 (510(k) NUMBER IF KNOWN) K910931, K910931, K863437

- | | YES | NO | |
|---|----------|-----|--------------------------------------|
| 1. IS PRODUCT A DEVICE | <u>X</u> | ___ | - IF NO STOP |
| 2. DEVICE SUBJECT TO 510(K)? | <u>X</u> | ___ | - IF NO STOP |
| 3. SAME INDICATION STATEMENT? | <u>X</u> | ___ | - 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? | <u>X</u> | ___ | - IF YES GO TO 7 |
| 6.* COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS? | ___ | ___ | - IF YES GO TO 8 |
| 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH? | <u>X</u> | ___ | - IF NO GO TO 10
IF YES STOP - SE |
| 8.* NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS? | ___ | ___ | - IF YES STOP - SE |
| 9. ACCEPTED SCIENTIFIC METHODS EXIST? | ___ | ___ | - IF NO STOP - SE |
| 10. PERFORMANCE DATA AVAILABLE? | ___ | ___ | - IF NO REQUEST DATA |
| 11.*DATA DEMONSTRATE EQUIVALENCE? | ___ | ___ | |

NOTE: IN ADDITION TO COMPLETING PAGE 2, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY NO RESPONSE REQUIRES AN EXPLANATION ON PAGE 3 AND/OR 4.

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NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE:

The Wilson-Cook Medical, Inc. Quantum T.T.C. Disposable Balloon Dilation Catheter (K935094), is to be used to dilate strictures of the gastrointestinal tract including strictures of the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.

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. The following should be considered when preparing the summary of 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 products as components? Is this device a kit? Provide a summary about the device's design, materials, physical properties and toxicology profile if important.

SUMMARY:

The Wilson-Cook Quantum TTC Balloon Dilator is a sterile, disposable balloon dilator consisting of a high pressure dilating balloon, mounted on a kink resistant catheter system. It is intended for use to dilate strictures of the gastrointestinal tract, including but not limited to, strictures of the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tract, and colon.

Four dilation devices for use in different areas of the gastrointestinal tract will be available.

Quantum TTC Esophageal Balloon Dilator - 6mm X 8cm Balloon, 180 cm length
Esophageal Balloon Dilator (All Sizes)

Inflated Diameter (mm)	O.D. (FR)	Balloon Length (cm)	Minimum Channel Size (mm)	Catheter Size (mm)	Size (FR)	Length (cm)
6	18	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
8	24	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
10	30	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
12	36	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
14	42	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
16	48	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
18	54	8	2.8	1.7, 2, or 2.3	5, 6, 7	180

When compared to the Microvasive Achiever, the sizes are very similar. Microvasive has and O.D. (Fr) of 18, 24, 30, 36, 45, 54 while the Wilson-Cook Device has 18, 24, 30, 36, 42, 48 and 54. The Microvasive literature does not include the French size of the catheter.

Quantum TTC Biliary Balloon Dilator - 6mm X 3cm Balloon, 180 cm length, accepts .035 Wire Guide

Biliary Balloon Dilator (All Sizes)

Inflated Diameter (mm)	O.D. (FR)	Balloon Length (cm)	Minimum Channel Size (mm)	Catheter Size (mm)	Size (FR)	Length (cm)
4	12	3	2.8	1.7, 2, or 2.3	5, 6, 7	180
6	18	3	2.8	1.7, 2, or 2.3	5, 6, 7	180
8	24	3	2.8	1.7, 2, or 2.3	5, 6, 7	180

The Rigidflex TTS Balloon Dilatation Catheters are available in the same sizes as the Wilson-Cook Device. However, it is only available in a catheter size of 1.7mm (5 French). The Bard Biliary Balloon Dilators are available in similar sizes (although the balloon length is slightly shorter 2 vs 3 cm).

Quantum TTC Pyloric Balloon Dilator - 8mm X 3cm, 180 cm length

Pyloric Balloon Dilator (All Sizes)

Inflated Diameter (mm)	O.D. (FR)	Balloon Length (cm)	Minimum Channel Size (mm)	Catheter Size (mm)	Size (FR)	Length (cm)
6	18	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
8	24	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
10	30	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
12	36	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
14	42	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
16	48	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
18	54	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180

When compared to the Microvasive Achiever, the sizes are very similar. Microvasive has an O.D. (Fr) of 18, 24, 30, 36, 45, 54 while the Wilson-Cook Device has 18, 24, 30, 36, 42, 48 and 54. The Microvasive literature does not include the French size of the catheter and the balloon length is only 5.5 cm not 3-5.5cm.

Quantum TTC Colonic Balloon Dilator - 8mm X 3cm, 240 cm length
Colonic Balloon Dilator (All Sizes)

Inflated Diameter (mm)	O.D. (FR)	Balloon Length (cm)	Minimum Channel Size (mm)	Catheter Size (mm)	Size (FR)	Length (cm)
6	18	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
8	24	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
10	30	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
12	36	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
14	42	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
16	48	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
18	54	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240

When compared to the Microvasive Achiever, the sizes are very similar. Microvasive has an O.D. (Fr) of 18, 24, 30, 36, 45, 54 while the Wilson-Cook Device has 18, 24, 30, 36, 42, 48 and 54. The Microvasive literature does not include the French size of the catheter and the balloon length is only 5.5 cm not 3-5.5cm.

DEVICE COMPONENTS

The only real description of the materials used in this device is in the section for biocompatibility testing. The Wilson-Cook device is described as "Polyurethane (Pellethane) Catheter w/Polyethylene (PET) Balloon w/light green ink (Type-B-NT). Balloon affixed to catheter w/Loctite 18013. In the engineering drawings there is a catheter with the balloon affixed toward the distal end (.79cm from the tip) and a luer taper hub at the proximal end. The company should provide a written description for their device and include the specific name and manufacturer of all materials. They should also clarify if the luer hub and the balloon are both affixed to the catheter with Loctite.

BIOCOMPATIBILITY

Wilson-Cook has provided biocompatibility data for its device. The testing was done by NAMSA (Northwood, Ohio) on the product described as "Polyurethane (Pellethane) Catheter w/Polyethylene (PET) Balloon w/light green ink (Type-B-NT). Balloon affixed to catheter w/Loctite 18013. The tests conducted include; intracutaneous toxicity, acute systemic toxicity, hemolysis, pyrogen test T10, cytotoxicity (MEM elution), 7 day implantation, and mutagenicity (Ames Test). All results were negative except that the microscopic examination of the implanted samples showed the device to be a slight irritant. The extracts of the device were done in sodium chloride and cottonseed oil only. The company did not use extracts of the device in ethanol or propylene glycol, however, by using extracts of the device in sodium chloride and cottonseed oil both polar and nonpolar interactions were examined.

SUBSTANTIAL EQUIVALENCE

The Wilson-Cook Balloon Dilators are substantially equivalent to the Microvasive Rigiflex TTS Dilators (K910931) and the Microvasive Achiever System (K910931). Wilson-Cook claims that all three products share the same

intended use as well as size ranges for each indicated use. The Microvasive Achiever Disposable Balloon Dilator (K910931) has indications for use to dilate strictures of varied etiology found in the gastrointestinal tract including the esophagus pylorus, duodenum and colon. The Achiever is not intended for use in the Sphincter of Oddi or the biliary tract. However the Microvasive Rigiflex TTS Dilators (K910931) is indicated for use in the sphincter of Oddi and the biliary tree as well as the esophagus, pylorus, duodenum, and colon. The Microvasive Rigiflex uses a guidewire to aid in placement as does the Wilson-Cook Biliary Dilator. The Microvasive Rigiflex is not a disposable product and can be reused. Bard also has a disposable Biliary balloon dilators (K863437) that is similar to the Wilson-Cook device.

STERILITY

The device will be sterilized using ethylene oxide to a sterility assurance level of 10⁻⁶. Validation will be by the Overkill Method as described in the AAMI "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices." The allowable ethylene oxide residues will be:

Ethylene Oxide	250 ppm
Ethylene Chlorohydrin	250 ppm
Ethylene Glycol	5000 ppm

Each disposable balloon dilator will be sealed in a mylar and Tyvek pouch.

LABELING

Wilson-Cook has submitted draft labeling for each of the intended uses: Esophageal Balloon Dilator; Biliary Balloon Dilator; Pyloric Balloon Dilator; and Colonic Balloon Dilator.

The labeling includes a prescription statement, that the device is sterile (however, this is in very small print), that the device is disposable/one time use, the company name and address, the lot number, and expiration date,

	<u>YES</u>	<u>NO</u>
1. Is the device life-supporting or life sustaining?	—	<u>X</u>
2. Is the device implanted (short-term or long-term)?	<u>X</u>	—
3. Is the device software-driven?	—	<u>X</u>
4. Is the device sterile?	<u>X</u>	—
5. Is the device for single use?	<u>X</u>	—
6. Is the device for home use?	—	<u>X</u>
7. Is the device for prescription use?	<u>X</u>	—
8. Does the device contain a drug or biological?	—	<u>X</u>

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

1. EXPLAIN WHY NOT A DEVICE:

2. EXPLAIN WHY NOT SUBJECT TO A 510(K):

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

DATE: January 19, 1995

FROM: Kathleen Olvey, Biologist
Gastrointestinal and Renal Devices Branch, DRAERD

SUBJECT: Wilson-Cook Medical, Inc.
Esophageal/Biliary Dilator, K935094

TO: The Record

CONTACT: Paula Joyce, Regulatory Affairs Specialist, 1-800-245-4717.

When trying to locate the predicate devices in the image system, K910931 is not the submission for the either the Microvasive Achiever or the Microvasive Rigiflex TTS Dilators. I called Joe Curtis of Boston Scientific (508-650-8171) and asked him about the Achiever and the Rigiflex dilators. He informed me that these dilators were approved under K781772. He said that in 1978, the Bureau of Medical Devices approved devices in a broad category, such as dilators (both urological and gastrointestinal) and then the company would subdivide the dilators and marketed them under different names.

The reason I was looking for this predicate was because of the language in the indication statement used by Wilson-Cook that was also present in the Microvasive Rigiflex dilators. The indication statements of both devices includes the phrase "To dilate strictures of the gastrointestinal tract, including but not limited to. . .". Using the phrase but not limited to is not acceptable. When I spoke with Paula Joyce she indicated that they included this statement because the predicate had used it and Joe Curtis stated that in 1978 when there device was approved, FDA requested that they use it. I then asked Paula Joyce to remove the phrase "but not limited to" from their indications for use statement.

Kathleen M. Olvey 1/20/95
Kathleen M. Olvey

*ecp
1/23/95*

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WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

WILSON-COOK® MEDICAL INC.

FAX TRANSMISSION

TO: Kathy Olvey, - FDA, Office of Device Evaluation

FROM: Paula Joyce

DATE: January 19, 1995

**RE: REQUESTED CHANGE TO INTENDED USE FOR WILSON-COOK
BALLOON DILATOR, K935094**

Total Number of Pages (including cover): 1

Dear Kathy:

As per our recent phone conversation, the indications for use statement (instructions for use)/intended use will be amended as follows:

INDICATIONS FOR USE:

To dilate strictures of the gastrointestinal tract, including strictures of the esophagus, pylorus, duodenum, Sphincter of Oddi, biliary tree and colon.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Paula Joyce
Regulatory Affairs Specialist

4900 Bethania Station Road

Winston-Salem, NC 27105

(910) 744-0157

Customer Service: (800) 245-4717

Office: (800) 245-4707

Fax: (910) 744-1147

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

DATE: January 13, 1995

FROM: Kathleen Olvey, Biologist
Gastrointestinal and Renal Devices Branch, DRAERD

SUBJECT: Wilson-Cook Medical, Inc.
Esophageal/Biliary Dilator, K935094

TO: The Record

CONTACT: Paula Joyce, Regulatory Affairs Specialist, 1-800-245-4717.

A response to my request for additional information was received by fax on January 12, 1995.

(b) (4)



(b) (4)



(b) (4)



Kathleen M. O'Leary 1/14/95

WILSON COOK

FAX NO. 310-744-1147



**WILSON-COOK®
MEDICAL INC.**
A COOK GROUP COMPANY

WILSON-COOK® MEDICAL INC.

CONFIDENTIAL

FAX TRANSMISSION

TO: Kathy Olvey - FDA, Office of Device Evaluation

FROM: Paula Joyce

DATE: January 12, 1995

**RE: REQUESTED ADDITIONAL INFORMATION FOR WILSON-COOK BALLOON
DILATOR, K935094**

Total Number of Pages (including cover): 6

Dear Kathy:

As per our recent phone conversation, I am writing to supply you with the requested additional information. I have restated your concerns and responded as follows:

(b) (4)



4900 Bethania Station Road

Winston-Salem, NC 27105

(910) 744-0157

Customer Service: (800) 245-4717

Office: (800) 245-4707

Fax: (910) 744-1147

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

Page 2 of 6

TO: Kathy Olvey - FDA, Office of Device Evaluation

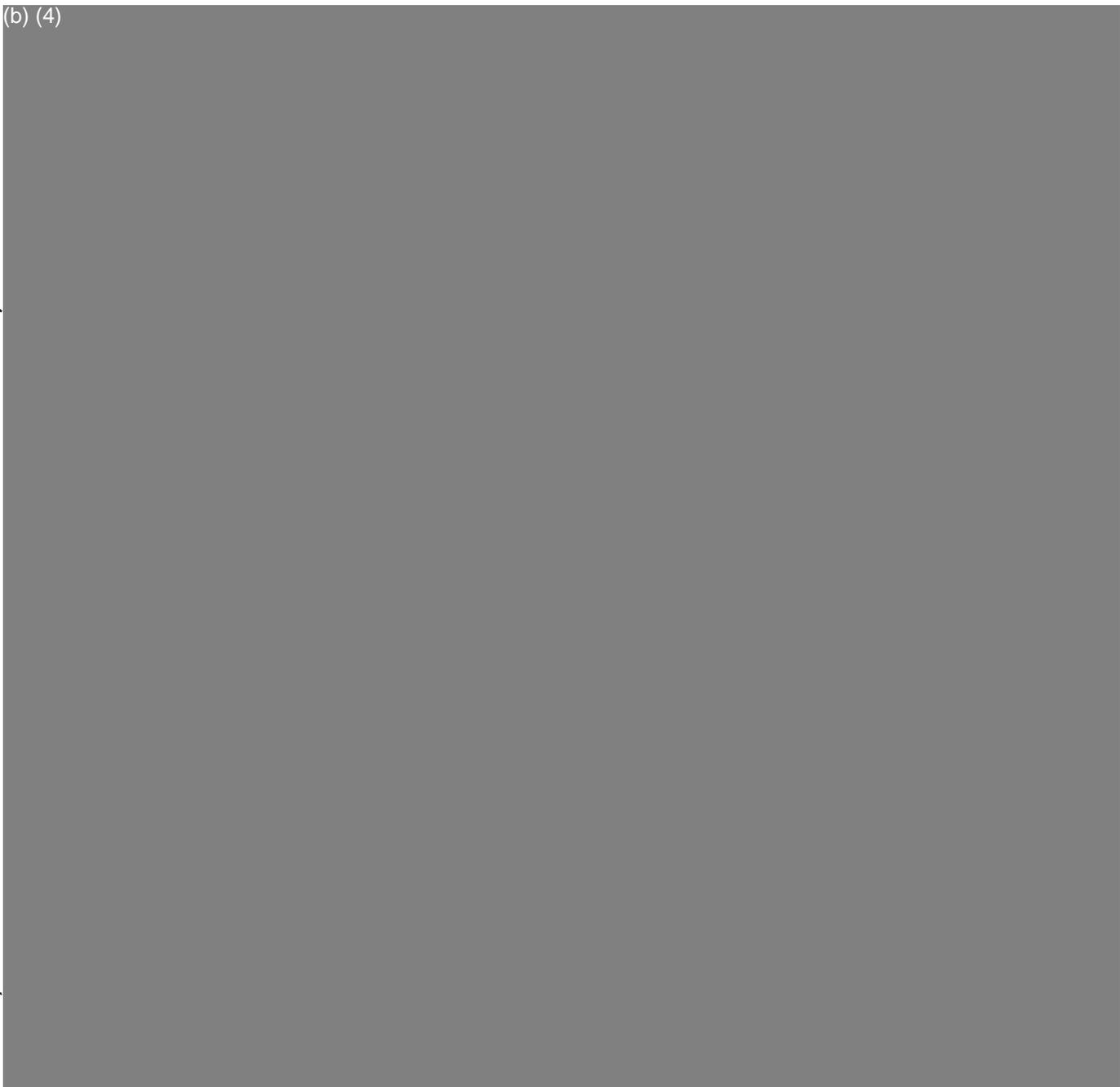
CONFIDENTIAL

FROM: Paula Joyce

DATE: January 12, 1995

**RE: REQUESTED ADDITIONAL INFORMATION FOR WILSON-COOK BALLOON
DILATOR, K935094**

(b) (4)



Page 3 of 6

TO: Kathy Olvey - FDA, Office of Device Evaluation

FROM: Paula Joyce

DATE: January 12, 1995

**RE: REQUESTED ADDITIONAL INFORMATION FOR WILSON-COOK BALLOON
DILATOR, K935094**

(b) (4)



Page 4 of 6

TO: Kathy Olvey - FDA, Office of Device Evaluation

FROM: Paula Joyce

DATE: January 12, 1995

CONFIDENTIAL

**RE: REQUESTED ADDITIONAL INFORMATION FOR WILSON-COOK BALLOON
DILATOR, K935094**

(b) (4)



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Page 5 of 6

TO: Kathy Olvey - FDA, Office of Device Evaluation

FROM: Paula Joyce

DATE: January 12, 1995

RE: REQUESTED ADDITIONAL INFORMATION FOR WILSON-COOK BALLOON DILATOR, K935094

CONFIDENTIAL

(b) (4)



I hope that this information is sufficient. Should you have any questions, please do not hesitate to contact me.

Sincerely,
WILSON-COOK® MEDICAL INC.

Paula Joyce
Regulatory Affairs Specialist

DATE: January 11, 1995

FROM: Kathleen Olvey, Biologist
Gastrointestinal and Renal Devices Branch, DRAERD

SUBJECT: Wilson-Cook Medical, Inc.
Esophageal/Biliary Dilator, K935094

TO: The Record

CONTACT: Paula Joyce, Regulatory Affairs Specialist, 1-800-245-4717.

Wilson-Cook will make available a Summary of safety and effectiveness to any interested persons.

INTENDED USE

This device is to be used to dilate strictures of the gastrointestinal tract including, but not limited to, strictures of the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.

DESCRIPTION OF DEVICE

The Wilson-Cook Quantum TTC Balloon Dilator is a sterile, disposable balloon dilator consisting of a high pressure dilating balloon, mounted on a kink resistant catheter system. It is intended for use to dilate strictures of the gastrointestinal tract, including but not limited to, strictures of the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tract, and colon.

INSTRUCTIONS FOR USE

The Wilson-Cook Quantum T.T.C. Balloon Dilator consists of a high pressure dilating balloon, mounted on a kink resistant catheter system. Disposable, intended for one time use. It is intended to dilate strictures of the gastrointestinal tract, including but not limited to, strictures of the esophagus, pylorus, duodenum, Sphincter of Oddi, biliary tract, and colon.

The contraindications are:

1. acute corrosive injury of less than one week duration;
2. uncooperative patient;
3. asymptomatic rings, webs, or strictures;
4. failure to advance guidewire/balloon through strictured area; and
5. known or suspected esophageal perforation.

Under warnings:

Do not exceed recommended balloon inflation pressure.

Do not advance the balloon dilator or guidewire if resistance is encountered. Assess the cause of resistance to determine if dilation should be re-attempted.

Under precautions:

- . The endoscope insertion tube should remain as straight as possible when inserting the balloon dilator.
- . Angulation of the endoscope tip bending section should be less than a 45° angle.

- . The entire dilation balloon should extend beyond the tip of the endoscope and be completely visualized before inflation.
- . Wilson-Cook Balloon Dilators are to be used in conjunction with the Wilson-Cook inflation system or a manometer gauge and fluid filled syringe. Do not use air or gaseous substances to inflate balloon. Doing so will result in sub-maximal balloon radial force.
- . During withdrawal of balloon dilator from endoscope, negative pressure is mandatory.

Inspection/Preparation:

1. Prior to use, examine each dilator for visible kinks, cracks, breaks, or bends. Do not use if defective.
2. Pre-inflate the balloon with the Wilson-Cook inflation system or other inflation system with gauge. Purge air and completely deflate balloon so that negative pressure is maintained to ensure easy insertion into the scope.

Insertion of dilator into endoscope accessory channel:

- A. Apply a water soluble lubricant to the balloon.
- B. Using the Wilson-Cook inflation system or a syringe manometer system, apply and maintain a negative pressure to the balloon. This negative pressure is maintained throughout the insertion procedure.
- C. Insert the balloon dilator into the endoscope accessory channel using short, quick movements until balloon dilator is endoscopically visualized.
- D. Before inflation, ensure balloon fully exits the endoscope channel.

Balloon inflation:

- A. Position the balloon within the targeted stricture.
- B. Inflate the balloon to the specified pressure using the Wilson-Cook inflation system or by using a syringe with stopcock and manometer.

IF USING THE WILSON-COOK INFLATION SYSTEM METHOD

- . Fill the system with 30cc of fluid, i.e., sterile water or sterile water/contrast solution mixture.
- . Inflate to specified pressure for individual balloon by rotating handle clockwise (to the right).

Balloon deflation:

- A. Extend balloon completely beyond the tip of the endoscope. Ensure that the balloon is not in the endoscope channel.
- B. Apply negative pressure with a 60cc syringe, thoroughly deflating and removing fluid from the balloon.

IF USING THE WILSON-COOK INFLATION SYSTEM DEFLATION METHOD

- . Depress the deflate lever and pull the knob back toward you.
- . Turn the handle counterclockwise (to the left) to deflate. Continue turning counterclockwise until zero or negative pressure is obtained.
- . Release the deflate lever - this will lock in negative pressure of balloon. Maintain this pressure for a minimum of one minute

Under CAUTION:

The balloon must be thoroughly deflated and fluid removed before withdrawal.

Balloon Withdrawal:

- A. Straighten the endoscope tip and apply continuous pressure and twisting motion to withdraw balloon catheter from the endoscope channel.

NOTE: The Wilson-Cook Balloon Dilatation catheter is intended for one-time use. If any package is opened or damaged, do not use or resterilize the device. Any use of this device, other than those indicated in these instructions, is not recommended.

Wilson-Cook has included Instructions for Use for the Microvasive Achiever Disposable Balloon Dilator (K910931). The indications for use are to dilate strictures of varied etiology found in the gastrointestinal tract including the esophagus pylorus, duodenum and colon. The Achiever does not include indications for use in the Sphincter of Oddi or the biliary tract. The Instructions for Use of the two device is very similar.

Although the Achiever does not include indications for use in the sphincter of Oddi or the biliary tract, Wilson-Cook has include the Instructions for Use for the Microvasive Rigiflex TTS Dilators (K910931). They are indicated for use to dilate strictures of varied etiology found in the gastrointestinal tract included, but not limited to, the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon. This device uses a guidewire to aid in placement and is a reusable device. There is literature from Bard for their disposable Biliary balloon dilators (K863437). They are available in similar sizes as the Wilson-Cook Biliary Dilators.

The labeling provided is for four separate devices. This labeling is for one version of each dilation catheter.

**Quantum TTC Esophageal Balloon Dilator - 6mm X 8cm Balloon, 180 cm length
Esophageal Balloon Dilator (All Sizes)**

Inflated Diameter (mm)	O.D. (FR)	Balloon Length (cm)	Minimum Channel Size (mm)	Catheter Size (mm)	Size (FR)	Length (cm)
6	18	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
8	24	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
10	30	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
12	36	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
14	42	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
16	48	8	2.8	1.7, 2, or 2.3	5, 6, 7	180
18	54	8	2.8	1.7, 2, or 2.3	5, 6, 7	180

When compared to the Microvasive Achiever, the sizes are very similar. Microvasive has an O.D. (Fr) of 18, 24, 30, 36, 45, 54 while the Wilson-Cook Device has 18, 24, 30, 36, 42, 48 and 54. The Microvasive literature does not include the French size of the catheter.

Quantum TTC Biliary Balloon Dilator - 6mm X 3cm Balloon, 180 cm length, accepts .035 Wire Guide

Biliary Balloon Dilator (All Sizes)

Inflated Diameter (mm)	O.D. (FR)	Balloon Length (cm)	Minimum Channel Size (mm)	Catheter Size (mm)	Size (FR)	Length (cm)
4	12	3	2.8	1.7, 2, or 2.3	5, 6, 7	180
6	18	3	2.8	1.7, 2, or 2.3	5, 6, 7	180
8	24	3	2.8	1.7, 2, or 2.3	5, 6, 7	180

The Rigiflex TTS Balloon Dilatation Catheters are available in the same sizes as the Wilson-Cook Device. However, it is only available in a catheter size of 1.7mm (5 French). The Bard Biliary Balloon Dilators are available in similar sizes (although the balloon length is slightly shorter 2 vs 3 cm).

Quantum TTC Pyloric Balloon Dilator - 8mm X 3cm, 180 cm length

Pyloric Balloon Dilator (All Sizes)

Inflated Diameter (mm)	O.D. (FR)	Balloon Length (cm)	Minimum Channel Size (mm)	Catheter Size (mm)	Size (FR)	Length (cm)
6	18	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
8	24	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
10	30	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
12	36	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
14	42	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
16	48	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180
18	54	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	180

When compared to the Microvasive Achiever, the sizes are very similar. Microvasive has an O.D. (Fr) of 18, 24, 30, 36, 45, 54 while the Wilson-Cook Device has 18, 24, 30, 36, 42, 48 and 54. The Microvasive literature does not include the French size of the catheter and the balloon length is only 5.5 cm not 3-5.5cm.

Quantum TTC Colonic Balloon Dilator - 8mm X 3cm, 240 cm length
Colonic Balloon Dilator (All Sizes)

Inflated Diameter (mm)	O.D. (FR)	Balloon Length (cm)	Minimum Channel Size (mm)	Catheter Size (mm)	Size (FR)	Length (cm)
6	18	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
8	24	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
10	30	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
12	36	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
14	42	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
16	48	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240
18	54	3-5.5	2.8	1.7, 2, or 2.3	5, 6, 7	240

When compared to the Microvasive Achiever, the sizes are very similar. Microvasive has an O.D. (Fr) of 18, 24, 30, 36, 45, 54 while the Wilson-Cook Device has 18, 24, 30, 36, 42, 48 and 54. The Microvasive literature does not include the French size of the catheter and the balloon length is only 5.5 cm not 3-5.5cm.

DEVICE COMPONENTS

The only real description of the materials used in this device is in the section for biocompatibility testing. The Wilson-Cook device is described as "Polyurethane (Pellethane) Catheter w/Polyethylene (PET) Balloon w/light green ink (Type-B-NT). Balloon affixed to catheter w/Loctite 18013. In the engineering drawings there is a catheter with the balloon affixed toward the distal end (.79cm from the tip) and a luer taper hub at the proximal end. The company should provide a written description for their device and include the specific name and manufacturer of all materials. They should also clarify if the luer hub and the balloon are both affixed to the catheter with Loctite.

BENCH TESTING

Balloon Integrity Testing

Tests were performed on twenty samples for each size of balloon.

Balloon Size	Recommended Pressure	High (psi)	Low (psi)	Average Burst Pressure (psi)	Standard Deviation
6mmx8cm	120 psi	266.64	223.96	246.01	10.77
8mmx8cm	120 psi	209.54	188.09	202.58	6.04
10mmx8cm	90 psi	196.27	181.03	187.57	4.92
12mmx8cm	90 psi	161.86	139.85	153.37	8.54
14mmx8cm	60 psi	154.64	124.64	145.09	6.91
16mmx8cm	60 psi	119.93	101.55	109.58	9.28
18mmx8cm	50 psi	102.68	93.82	99.33	2.32

All samples tested (20 in each group) exceed the recommended pressure by at least 55% (55-108% psi over the recommended pressure).

BIOCOMPATIBILITY

Wilson-Cook has provided biocompatibility data for its device. The testing was done by NAmSA (Northwood, Ohio) on the product described as "Polyurethane (Pellethane) Catheter w/Polyethylene (PET) Balloon w/light green ink (Type-B-NT). Balloon affixed to catheter w/Loctite 18013. The tests conducted include; intracutaneous toxicity, acute systemic toxicity, hemolysis, pyrogen test T10, cytotoxicity (MEM elution), 7 day implantation, and mutagenicity (Ames Test). All results were negative except that the microscopic examination of the implanted samples showed the device to be a slight irritant. The extracts of the device were done in sodium chloride and cottonseed oil only. The company did not use extracts of the device in ethanol or propylene glycol, however, by using extracts of the device in sodium chloride and cottonseed oil both polar and nonpolar interactions were examined.

SUBSTANTIAL EQUIVALENCE

The Wilson-Cook Balloon Dilators are substantially equivalent to the Microvasive Rigiflex TTS Dilators (K910931) and the Microvasive Achiever System (K910931). Wilson-Cook claims that all three products share the same intended use as well as size ranges for each indicated use. The Microvasive Achiever Disposable Balloon Dilator (K910931) has indications for use to dilate strictures of varied etiology found in the gastrointestinal tract including the esophagus pylorus, duodenum and colon. The Achiever is not intended for use in the Sphincter of Oddi or the biliary tract. However the Microvasive Rigiflex TTS Dilators (K910931) is indicated for use in the sphincter of Oddi and the biliary tree as well as the esophagus, pylorus, duodenum, and colon. The Microvasive Rigiflex uses a guidewire to aid in placement as does the Wilson-Cook Biliary Dilator. The Microvasive Rigiflex is not a disposable product and can be reused. Bard also has a disposable Biliary balloon dilators (K863437) that is similar to the Wilson-Cook device.

STERILITY

The device will be sterilized using ethylene oxide to a sterility assurance level of 10^{-6} . Validation will be by the Overkill Method as described in the AAMI "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices." The allowable ethylene oxide residues will be:

Ethylene Oxide	250 ppm
Ethylene Chlorohydrin	250 ppm
Ethylene Glycol	5000 ppm

Each disposable balloon dilator will be sealed in a mylar and Tyvek pouch.

LABELING

Wilson-Cook has submitted draft labeling for each of the intended uses: Esophageal Balloon Dilator; Biliary Balloon Dilator; Pyloric Balloon Dilator; and Colonic Balloon Dilator.

The labeling includes a prescription statement, that the device is sterile (however, this is in very small print), that the device is disposable/one time use, the company name and address, the lot number, and expiration date,

FURTHER INFORMATION

There are several items that need to be clarified before this device can be found to be substantially equivalent to other legally marketed devices. I spoke with Paula Joyce by phone on Thursday, January 12, 1995. She will be responding to these questions as soon as possible.

1. Please provide a written description for your device and include the specific name and manufacturer of all materials. Please clarify whether the luer hub and the balloon are both affixed to the catheter with Loctite.
2. Please clarify whether there is the potential of overextension of the balloon with increased pressure.
3. Please explain what is meant in your intended use statement "including but not limited to".

Kathleen M. Olvey 1/12/95
Kathleen M. Olvey

RRG/LLD 1/6/93

Rev. 9/24/93

DRAERD Premarket Notification 510(k)

Reviewer's Screening Checklist

510(k) Number &

Device Name

K 935094 Wilson-Cook Balloon Dilator

Company

Wilson-Cook Medical

ITEM	PRESENT		NEEDED (Y/N/?)
	Yes	No	
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reason for 510(k) - new device or modification	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Identification of legally marketed equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	no
2. Proposed Labeling, Labels, Advertisements	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of new device/modification	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intended use statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diagrams, Engineering Drawings, Photographs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Comparison of similarities/differences to named legally marketed equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Equivalent Device Labeling, Labels, Advertising	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intended use of equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. List of all patient contacting materials in new device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comparison of materials to equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Biocompatibility information/data for patient contacting materials, OR, Certification - identical material/formulation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Performance data: Bench data	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Animal data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Sterilization information	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Software validation & verification	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>NO</u>
9. 510(k) summary or statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. If Class III, Class III Certification & Summary	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>NO</u>
11. If kit, kit certification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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FOR REVIEWER'S USE ONLY

RRG 9/24/93

**DRAERD Premarket Notification 510(k)
SUPPLEMENTAL
Reviewer's Screening Checklist**

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: 935094 TIER (Circle) I / II / III

Expedited Review Requested: Y/N Granted: Y/N OR, FDA Identified Expedited: Y/N

ITEM	<u>Yes</u>	<u>No</u>
1. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is the device exempt from 510(k) by regulation or policy?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Are you aware that this device has been the subject of a previous NSE decision? If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Is there a specific guidance document for this device or device issue(s)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

In addition, the following item is new to the 510(k) review process. It will not be counted as a screening deficiency since it is new and "unknown" to the industry. It should be identified as a deficiency and requested as part of the technical review. The Explanation of the DRAERD Screening Checklist has been modified to include this information.

6. Address of manufacturing facility/facilities, and if applicable, sterilization site(s). _ _

Administrative Reviewer Signature: Kathleen M. Cluey Date: 11/29/93

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)
 1390 Piccard Drive
 Rockville, Maryland 20850

November 05, 1993

WILSON-COOK MEDICAL, INC.
 4900 BETHANIA STATION ROAD
 WINSTON-SALEM, NC 27105
 ATTN: PAULA A. JOYCE

510(k) Number: K935094
 Received: 22-OCT-93
 Product: BALLOON DILATION
 CATHETER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), 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. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- o Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
 - 510(k) Status Coordinator
 - Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
 - Center for Devices and Radiological Health, FDA
 - 5600 Fishers Lane
 - Rockville, Maryland 20857 USA

Because of staff limitations, we cannot answer telephone status requests.

- o 510(k) status requests should include:
 - (1) submitter's name and mailing address;
 - (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

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- (3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- o Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
 - (1) the branch to which the 510(k) has been assigned;
 - (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
 - (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0006.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or 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

K935094



WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

RECEIVED
22 Oct 93 13 50
FDA/CDRH/OCE/DIC

October 20, 1993

Food and Drug Administration
Office of Device Evaluation
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 510(k) Notification

Attention: Document Control Clerk

This letter serves as notification to the Food and Drug Administration of the intent by Wilson-Cook Medical Inc. to manufacture and market the device summarized below:

- **Common/Usual Name** - Esophageal/Biliary Dilator
- **Classification Name** - Dilator, Esophageal 78 KNQ
- **Classification** - FDA has classified similar devices as Class II. This device falls within the purview of the Gastroenterology and Urology Device Panel, Section 876.5365. To our knowledge no performance standards exist.
- **Intended Use** - Disposable device used to dilate strictures of the gastrointestinal tract including, but not limited to, strictures of the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.
- **Configuration** - One sterile, disposable balloon dilator sealed in a mylar and tyvek pouch. Each pouch affixed with sterility indicator label and disposable label, examples included as Attachment III.
- **Sterilization** - Sterilized by ethylene oxide to a SAL of 1×10^{-6} . The sterilization validation follows the concept of the "Overkill Method" also known as the Half Cycle Technique, as described in the AAMI "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices".

4900 Bethania Station Road
Winston-Salem, NC 27105
(919) 744-0157
Customer Service: (800) 245-4717
Office: (800) 245-4707
Fax: (919) 744-1147

Page 2

Food and Drug Administration
October 20, 1993

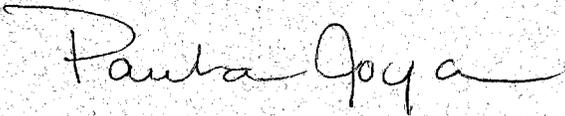
RE: 510(k) Notification

- **Residuals** - Evaluated annually, the residuals will not exceed 250 ppm EO, 250 ppm ECH, 5000 ppm EGLY as per the guidance for "Devices Contacting Mucosa".
- **Facility Registration Number** - 1037905
- **Safety and Effectiveness Statement** - Wilson-Cook will make available a summary of safety and effectiveness upon request from any party.

A complete product discussion is enclosed as well as multiple attachments. We believe this information should be sufficient for FDA to determine substantial equivalence of the device. Should any questions arise concerning this submission, please do not hesitate to contact me.

Sincerely,

WILSON-COOK® MEDICAL INC.



Paula A Joyce
Regulatory Affairs Specialist

Attachments

NOTE: This notification is considered by Wilson-Cook Medical Inc. to be confidential commercial information and we ask that the FDA regard it as such.

Product Discussion and Substantial Equivalence

The Wilson-Cook line of Balloon Dilators are intended to be used to dilate strictures of the gastrointestinal tract including, but not limited to, the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.

The Wilson-Cook line of Balloon Dilators are substantially equivalent to the *Microvasive Rigiflex® TTS™ Dilators and the *Microvasive Achiever™ System currently in commercial distribution.

The Wilson-Cook Dilation Balloons and the comparison products by Microvasive share the same intended use as well as size ranges for each indicated use. The following comparison table is used to illustrate the substantial equivalence of the Wilson-Cook device to the referenced predicate devices.

Product Comparison Table

	Wilson-Cook Disposable Balloon Dilator	Microvasive Rigiflex® TTS™ Dilator (K910931) Reusable	Microvasive Disposable Achiever™ Balloon Dilation Catheters (K910931)
Intended Use	Dilate strictures in the gastrointestinal tract including, but not limited to, the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.	Dilate strictures in the gastrointestinal tract including, but not limited to, the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.	Dilate strictures in the gastrointestinal tract including, but not limited to, the esophagus, pylorus, duodenum, sphincter of Oddi, biliary tree and colon.

* Note: A search of all 510(k) numbers for Microvasive/Boston Scientific leads us to believe that the referenced predicate devices were cleared via K910931.

Product Discussion and Substantial Equivalence

Product Comparison Table

	Wilson-Cook Disposable Balloon Dilator	Microvasive Rigiflex® TTS™ Dilator (K910931) Reusable	Microvasive Disposable Achiever™ Balloon Dilation Catheters (K910931)
Balloon Material	polyethylene	proprietary polymer Polytuff 310™	proprietary polymer Polytuff 310™
Esophageal Inflated Balloon Diameter (mm)	6, 8, 10, 12, 14, 16, & 18	6, 8, 10, 12, 15, & 18	6, 8, 10, 12, 15, & 18
Biliary Inflated Balloon Diameter (mm)	4, 6, & 8	4, 6, & 8	Not applicable
Pyloric Inflated Balloon Diameter (mm)	6, 8, 10, 12, 14, 16, & 18	8, 10, 12, & 15, & 18	6, 8, 10, 12, 15, & 18
Colonic Inflated Balloon Diameter (mm)	6, 8, 10, 12, 14, 16, & 18	6, 10, 12, 15, & 18	6, 8, 10, 12, 15, & 18
Esophageal Balloon Length (cm)	8 cm	8 cm	8 cm
Biliary Balloon Length (cm)	3 cm	2 cm, 3 cm	Not applicable
Pyloric Balloon Length (cm)	3 cm - 5.5 cm	3 cm, 5.5 cm	5.5 cm
Colonic Balloon Length (cm)	3 cm - 5.5 cm	3 cm, 5.5 cm	5.5 cm

Page 5

**Product Discussion and Substantial Equivalence
Product Comparison Table**

	Wilson-Cook Disposable Balloon Dilator	Microvasive Rigiflex® TTS™ Dilator (K910931) Reusable	Microvasive Disposable Achiever™ Balloon Dilation Catheters (K910931)
Minimum Required Channel	2.8 mm	2.8mm for all sizes except 8mm Biliary Balloon which is 3.7 mm.	2.8 mm
Esophageal, Biliary & Pyloric Catheter Length	180 cm	180 cm	Not Applicable
Colonic Catheter Length	240 cm	240 cm	240 cm

As illustrated by the above product comparison table, the Wilson-Cook Balloon Dilators are virtually identical to the predicate devices. The only difference lies in the availability of sizes for each indication and the balloon material.

As successful balloon dilation is dependant upon the radial force exerted along the entire length of a stricture, the Wilson-Cook Dilation Balloons are available in a wide variety of sizes, consistent with the size ranges available for the predicate devices.

The Wilson-Cook Balloons are constructed from polyethylene. The chosen material has been proven to be both safe and effective through in-house burst testing and biocompatibility data which are included in **Attachments I and II**, respectively.

The Wilson-Cook Balloon Dilators are also substantially equivalent to the **Bard Balloon Dilation System (K863437)**. The Bard devices are constructed of a polyethylene balloon and are also available in a variety of sizes.

We feel that the comparison of similarities and the device labeling included as **Attachment III** should render the Wilson-Cook device substantially equivalent to the predicate devices.

Wilson-Cook Balloon Dilator

510(k) Submission

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Attachments

Attachment I - Balloon Integrity Data & Discussion

Attachment II - Biocompatibility Data

Attachment III - Device Labeling for Wilson-Cook Balloon Dilator and Referenced Predicate Devices

Copy of SE decision for Bard Balloon Dilation System (K863437)

Attachment IV - Engineering Drawing and Photograph



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Attachment I
Balloon Integrity Testing



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Attachment II

Biocompatibility Data

Wilson-Cook Balloon Dilation Catheters

Part I - USP Intracutaneous Toxicity Test

Part II - USP Systemic Toxicity

Part III - Hemolysis Test, In-Vitro

Part IV - Pyrogen Test

Part V - Cytotoxicity Test

Part VI - USP Muscle Implantation Test w/ Histopathology

Part VII - Mutagenicity, Ames Test

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Part I

USP Intracutaneous Toxicity Test



Part II

USP Systemic Toxicity

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Part III

Hemolysis Test, In-Vitro



Part IV

Pyrogen Test



Part V

Cytotoxicity Test



Part VI

USP Implantation Test w/ Histopathology



Part VII

Mutagenicity, Ames Test



211.

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Attachment III

Wilson-Cook Medical Balloon Dilation Catheters

Instructions for Use

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QUANTUM T.T.C.

(BALLOON DILATION CATHETER)

DESCRIPTION:

The Wilson-Cook® Quantum T.T.C.™ Balloon Dilator consists of a high pressure dilating balloon, mounted on a kink resistant catheter system. Disposable, intended for one time use.

INDICATIONS FOR USE:

To dilate strictures of the gastrointestinal tract, including but not limited to, strictures of the esophagus, pylorus, duodenum, Sphincter of Oddi, biliary tract, and colon.

CONTRAINDICATIONS:

1. Acute corrosive injury of less than one week duration.
2. Uncooperative patient.
3. Asymptomatic rings, webs, or strictures.
4. Failure to advance guidewire/balloon through strictured area.
5. Known or suspected esophageal perforation.

WARNINGS:

Do not exceed recommended balloon inflation pressure. Do not advance the balloon dilator or guidewire if resistance is encountered. Assess the cause of resistance to determine if dilation should be re-attempted.

PRECAUTIONS:

- The endoscope insertion tube should remain as straight as possible when inserting the balloon dilator.
- Angulation of the endoscope tip bending section should be less than a 45° angle.
- The entire dilation balloon should extend beyond the tip of the endoscope and be completely visualized before inflation.
- Wilson-Cook Balloon Dilators are to be used in conjunction with the Wilson-Cook inflation system or a manometer gauge and fluid filled syringe. Do not use air or gaseous substances to inflate balloon. Doing so will result in sub-maximal balloon radial force.
- During withdrawal of balloon dilator from endoscope, negative pressure is mandatory.

INSPECTION/PREPARATION:

1. Prior to use, examine each dilator for visible kinks, cracks, breaks, or bends. Do not use if defective.

INSTRUCTIONS FOR USE:

Insertion of dilator into endoscope accessory channel:

- A. Apply a water soluble lubricant to the balloon. This will allow for easier passage through the endoscope channel.
- B. Using the Wilson-Cook inflation system or a syringe manometer system, apply and maintain a negative pressure to the balloon. This negative pressure is maintained throughout the insertion procedure.
- C. Insert the balloon dilator into the endoscope accessory channel using short, quick movements until balloon dilator is endoscopically visualized.
- D. Before inflation, ensure balloon fully exits the endoscope channel.

Balloon inflation:

- A. Position the balloon within the targeted stricture.
- B. Inflate the balloon to the specified pressure using the Wilson-Cook inflation system or by using a syringe with stopcock and manometer.

*** * * * * WILSON-COOK INFLATION SYSTEM METHOD * * * * ***

- Fill the system with 30cc of fluid, i.e., sterile water or sterile water/contrast solution mixture.
- Inflate to specified pressure for individual balloon by rotating handle clockwise (to the right).

Balloon deflation:

- A. Extend balloon completely beyond the tip of the endoscope. Ensure that the balloon is not in the endoscope channel.
- B. Apply negative pressure with a 60cc syringe, thoroughly deflating and removing fluid from the balloon.

*** * * * * WILSON-COOK INFLATION SYSTEM DEFLATION METHOD * * * * ***

- Depress the deflate lever and pull the knob back toward you.
- Turn the handle counterclockwise (to the left) to deflate. Continue turning counterclockwise until zero or negative pressure is obtained.
- Release the deflate lever - this will lock in negative pressure of balloon. Maintain this pressure for a minimum of one minute.



2. Pre-inflate the balloon with the Wilson-Cook inflation system or other inflation system with gauge. Purge air and completely deflate balloon so that negative pressure is maintained to ensure easy insertion into the scope.

INSTRUCTIONS FOR USE:

Insertion of dilator into endoscope accessory channel:

- A. Apply a water soluble lubricant to the balloon. This will allow for easier passage through the endoscope channel.
- B. Using the Wilson-Cook inflation system or a syringe manometer system, apply and maintain a negative pressure to the balloon. This negative pressure is maintained throughout the insertion procedure.
- C. Insert the balloon dilator into the endoscope accessory channel using short, quick movements until balloon dilator is endoscopically visualized.
- D. Before inflation, ensure balloon fully exits the endoscope channel.

Balloon inflation:

- A. Position the balloon within the targeted stricture.
- B. Inflate the balloon to the specified pressure using the Wilson-Cook inflation system or by using a syringe with stopcock and manometer.

*** * * * * WILSON-COOK INFLATION SYSTEM METHOD * * * * ***

- Fill the system with 30cc of fluid, i.e., sterile water or sterile water/contrast solution mixture.
- Inflate to specified pressure for individual balloon by rotating handle clockwise (to the right).

Balloon deflation:

- A. Extend balloon completely beyond the tip of the endoscope. Ensure that the balloon is not in the endoscope channel.
- B. Apply negative pressure with a 60cc syringe, thoroughly deflating and removing fluid from the balloon.



* * * * * WILSON-COOK INFLATION SYSTEM DEFLATION METHOD * * * * *

- Depress the deflate lever and pull the knob back toward you.
- Turn the handle counterclockwise (to the left) to deflate. Continue turning counterclockwise until zero or negative pressure is obtained.
- Release the deflate lever - this will lock in negative pressure of balloon. Maintain this pressure for a minimum of one minute.

CAUTION:

The balloon must be thoroughly deflated and fluid removed before withdrawal.

Balloon withdrawal:

- A. Straighten the endoscope tip and apply continuous pressure and twisting motion to withdraw balloon catheter from the endoscope channel.

NOTE: The Wilson-Cook Balloon Dilation catheter is intended for one-time use. If any package is opened or damaged, do not use or resterilize the device.

Any use of this device, other than those indicated in these instructions, is not recommended.



Wilson-Cook Medical

Balloon Dilation Catheters

Each mylar and tyvek pouch will be affixed with a sterility indicator product label and a Disposable label. Examples for one version of each dilation catheter is included along with the disposable label.

THIS DOT BECOMES YELLOW WHEN EXPOSED TO ETHYLENE OXIDE. CE POINT DEVIENT JAUNE QUAND IL EST EXPOSE A L'OXYDE D'ETHYLENE. BEI KONTAKT MIT ETHYLENOXYD WIRD DISSER PUNKT GELB. ESTE PUNTO SE PONE AMARILLO AL EXPOSERSE A OXIDO DE ETILENO.	STERILIZATION DATE DATE DE STERILISATION DATUM DER STERILISIERUNG FECHA DE ESTERILIZACION	EXPIRY DATE DATE D'EXPIRATION VERFAUSSDATUM FECHA DE EXPIRACION	BATCH NUMBER NUMERO DU GROUPE GRUPOENUMMER NUMERO DE LOTE
	XXXXXX	XXXXXX	XXXXXX
	<p>Quantum TTC Esophageal Balloon Dilator 6mm X 8cm Balloon, 180 cm length</p>		
WILSON-COOK MEDICAL INC. A COOK GROUP COMPANY 4900 Bethania Station Road, Winston-Salem, NC 27105 U.S.A.		9064/031991	
CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. STERILE IF PACKAGE IS UNOPENED OR UNDAMAGED. MADE IN U.S.A.			

THIS DOT BECOMES YELLOW WHEN EXPOSED TO ETHYLENE OXIDE. CE POINT DEVIENT JAUNE QUAND IL EST EXPOSE A L'OXYDE D'ETHYLENE. BEI KONTAKT MIT ETHYLENOXYD WIRD DISSER PUNKT GELB. ESTE PUNTO SE PONE AMARILLO AL EXPOSERSE A OXIDO DE ETILENO.	STERILIZATION DATE DATE DE STERILISATION DATUM DER STERILISIERUNG FECHA DE ESTERILIZACION	EXPIRY DATE DATE D'EXPIRATION VERFAUSSDATUM FECHA DE EXPIRACION	BATCH NUMBER NUMERO DU GROUPE GRUPOENUMMER NUMERO DE LOTE
	XXXXXX	XXXXXX	XXXXXX
	<p>Quantum TTC Biliary Balloon Dilator 6mm X 3cm Balloon, 180 cm length Accepts .035 Wire Guide</p>		
WILSON-COOK MEDICAL INC. A COOK GROUP COMPANY 4900 Bethania Station Road, Winston-Salem, NC 27105 U.S.A.		9064/031991	
CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. STERILE IF PACKAGE IS UNOPENED OR UNDAMAGED. MADE IN U.S.A.			

DISPOSABLE
 INTENDED FOR ONE-TIME USE
 9002/100491

90

Wilson-Cook Medical

Balloon Dilation Catheters

Each mylar and tyvek pouch will be affixed with a sterility indicator product label and a Disposable label. Examples for one version of each dilation catheter is included along with the disposable label.

STERILIZATION DATE DATE DE STÉRILISATION DATUM DER STERILISIERUNG FECHA DE ESTERILIZACIÓN	EXPIRY DATE DATE D'EXPIRATION VERFAUSDATUM FECHA DE EXPIRACIÓN	BATCH NUMBER NUMERO DU GROUPE GRUPPENNUMMER NUMERO DE LOTE
XXXXXX	XXXXXX	XXXXXX

THIS DOT BECOMES YELLOW WHEN EXPOSED TO ETHYLENE OXIDE
CE POINT DEVIENT JAUNE QUAND IL EST EXPOSÉ À L'OXIDE D'ETHYLENE
BEI KONTAKT MIT ÄTHYLEN-OXID WIRD DIESES PUNKT GELB
ESTE PUNTO SE PONE AMARILLO AL EXPONERSE A OXIDO DE ETILENO

Quantum TTC
Pyloric Balloon Dilator
8mm X 3cm, 180 cm length

 **WILSON-COOK MEDICAL INC.**
A COOK GROUP COMPANY
4900 Bethania Station Road, Winston-Salem, NC 27105, U.S.A. 9064/031991

CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. STERILE IF PACKAGE IS UNOPENED OR UNDAMAGED. MADE IN U.S.A.

STERILIZATION DATE DATE DE STÉRILISATION DATUM DER STERILISIERUNG FECHA DE ESTERILIZACIÓN	EXPIRY DATE DATE D'EXPIRATION VERFAUSDATUM FECHA DE EXPIRACIÓN	BATCH NUMBER NUMERO DU GROUPE GRUPPENNUMMER NUMERO DE LOTE
XXXXXX	XXXXXX	XXXXXX

THIS DOT BECOMES YELLOW WHEN EXPOSED TO ETHYLENE OXIDE
CE POINT DEVIENT JAUNE QUAND IL EST EXPOSÉ À L'OXIDE D'ETHYLENE
BEI KONTAKT MIT ÄTHYLEN-OXID WIRD DIESES PUNKT GELB
ESTE PUNTO SE PONE AMARILLO AL EXPONERSE A OXIDO DE ETILENO

Quantum TTC
Colonic Balloon Dilator
8mm X 3cm, 240 cm length

 **WILSON-COOK MEDICAL INC.**
A COOK GROUP COMPANY
4900 Bethania Station Road, Winston-Salem, NC 27105, U.S.A. 9064/031991

CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. STERILE IF PACKAGE IS UNOPENED OR UNDAMAGED. MADE IN U.S.A.

DISPOSABLE
INTENDED FOR ONE-TIME USE
9002/100491

Wilson-Cook Medical
Balloon Dilation Catheters
Specifications Sheet



**Wilson-Cook Balloon Dilation Catheters
Specification Sheets**

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**Wilson-Cook Balloon Dilation Catheters
Specifications Sheets**

(b) (4)



**Wilson-Cook Balloon Dilation Catheters
Specifications Sheets**

(b) (4)



Microvasive Achiever™ Instructions for Use

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Achiever™

Disposable Balloon Dilator

DIRECTIONS FOR USE



Inspection

Inspect each dilator before use. Do not use if tip is frayed, shaft is kinked, or balloon material is damaged. The Achiever™ is designed for single patient use to insure reliability, safety and convenience.

Preparation

The Achiever™ Balloon should only be inflated with water or contrast solution. The fluids create maximum radial pressure for more effective dilatation of strictures.

Remove the colored protective sheath covering the balloon material.

Apply silicone spray (Microvasive Order No. 0081) to balloon material and rub over entire balloon surface to improve passage through the endoscope. Do not use petroleum-based lubricants.

Attach balloon hub to Digiflator™ 60cc inflation device (Microvasive Order No. 5050) or other inflation system with gauge. Pre-inflate balloon, purge air, then fully deflate balloon to create negative pressure for easier scope insertion. Turn the stopcock appropriately to seal the balloon and maintain a vacuum.

Balloon Insertion

Insert balloon into the working channel of your endoscope. Short, 2cm movements are recommended. The dilator should move out of the tip of scope and into stricture. Once centered, the balloon should be inflated to pressure sufficient to properly

dilate stricture, but not to exceed balloon's maximum rated working pressure found on the hub label.

When more than one balloon is to be used during a single procedure, close the stopcock before detaching a balloon from the inflation device. Any excess air can then be purged by opening the stopcock and advancing water or fluid to the end of inflation tubing.

Balloon Withdrawal

When dilatation has been completed, deflate the balloon using negative pressure created by Digiflator™ or inflation device. **CAUTION: THE BALLOON MUST BE THOROUGHLY DEFLATED AND ALL FLUID REMOVED PRIOR TO WITHDRAWAL.** Suction applied and held during withdrawal decreases the deflated profile of the balloon and aids in removal.

Balloon should be disposed of in accordance with accepted hospital protocol.

Warning

- Do not exceed the recommended maximum balloon pressure
- Do not use air as balloon inflation medium
- Do not store balloons near flame or temperatures in excess of 60°C
- Do not reuse

CAUTION: Federal law (USA) restricts this device to sale, distribution, and use by or on the order of a physician.

SINGLE-USE ONLY. Non-sterile.

Achiever and Digiflator are trademarks of Boston Scientific Corporation.

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480 Pleasant Street Watertown, MA 02172
(617) 923-1720

Customer Service (800) 225-3226

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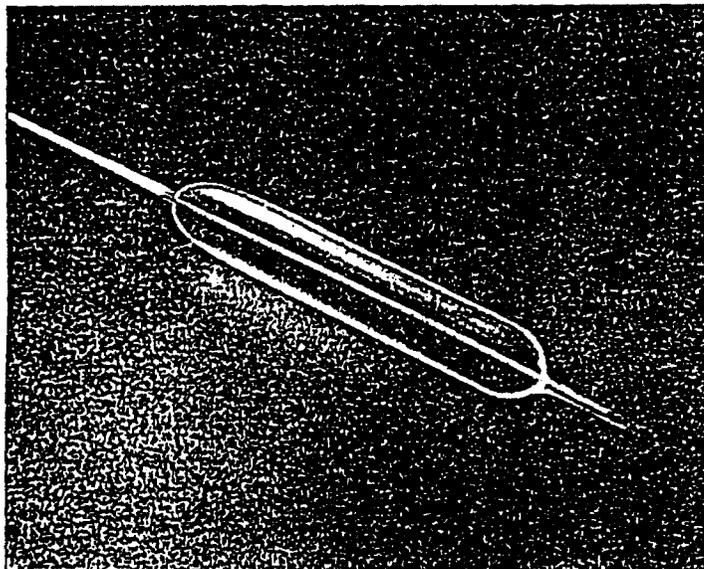
Microvasive Achiever™ Literature



Achiever™

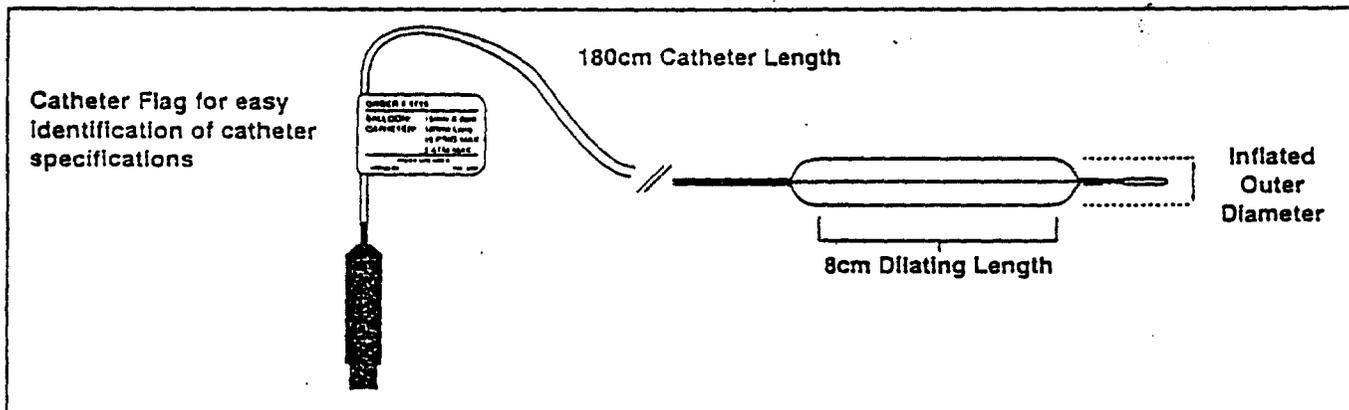
Achiever™ Esophageal Balloon Dilatation Catheters and Kit

Designed for single-use, this through-the-scope balloon dilator provides radial force for dilatation of esophageal strictures



- 8cm balloon dilating length produces dependable, controlled-force radial dilatation
- Through-the-scope access provides the control of direct vision
- Single-use design ensures convenience and the reliability of first-use performance for every procedure
- Proprietary balloon material maintains low profile to ease passage through working channels as small as 2.8mm
- Flexible catheter tip allows less traumatic advancement through tortuous strictures

Dilatator



- Kink-resistant, firm catheter shaft material facilitates rapid passage through the scope
- Wide variety of balloon diameters allows accurate match to procedural requirements
- Catheter flag clearly identifies catheter specifications
- Unique hub design ensures proper inflation device attachment

Microvasive.
Boston Scientific Corporation

800-225-3226

Achiever™ Esophageal Balloon Dilatation Catheters and Kit

Ordering Information

Catheters

Order Number	Balloon O.D. (Fr) (mm)	Balloon Length (cm)	Catheter Length (cm)	Minimum Required Biopsy Channel (mm)	Quantity Supplied
5706	18 6	8	180	2.8	1 ea
5708	24 8	8	180	2.8	1 ea
5710	30 10	8	180	2.8	1 ea
5712	36 12	8	180	2.8	1 ea
5715	45 15	8	180	2.8	1 ea
5718	54 18	8	180	2.8	1 ea
5715-05	45 15	8	180	2.8	Box 5
5718-05	54 18	8	180	2.8	Box 5

Kit

Order Number	Balloon O.D. (Fr) (mm)	Balloon Length (cm)	Catheter Length (cm)	Minimum Required Biopsy Channel (mm)	Quantity Supplied
5732	Assorted	8	180	2.8	1 Kit

Each Kit Includes: 6 Achiever Esophageal Balloon Dilatation Catheters, one each of the following: #5706, 6mm; #5708, 8mm; #5710, 10mm; #5712, 12mm; #5715, 15mm; #5718, 18mm

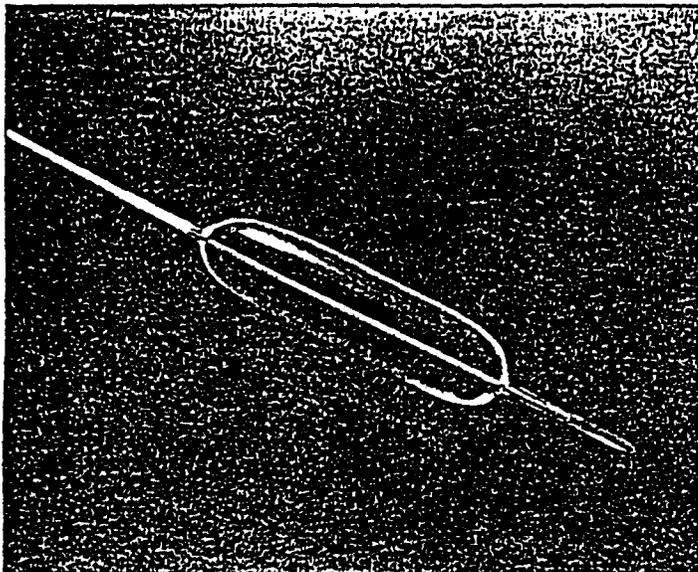
 **Microvasive.**
Boston Scientific Corporation

800-225-3226

Achiever™

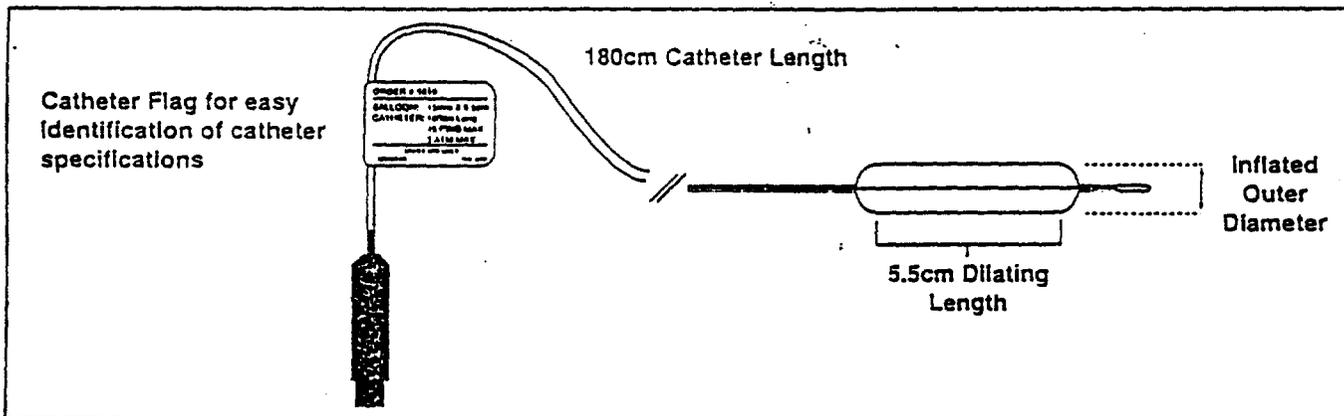
Achiever™ Pyloric Balloon Dilatation Catheters and Kit

Designed for single-use, this through-the-scope balloon dilator is ideally matched for pyloric stricture dilatation



- 5.5cm balloon dilating length produces dependable, controlled-force radial dilatation
- Through-the-scope access provides the control of direct vision
- Single-use design ensures convenience and the reliability of first-use performance for every procedure
- Proprietary balloon material maintains low profile to ease passage through working channels as small as 2.8mm
- Flexible catheter tip allows less traumatic advancement through tortuous strictures

Dilatation



- Kink-resistant, firm catheter shaft material facilitates rapid passage through the scope
- Wide variety of balloon diameters allows accurate match to procedural requirements
- Catheter flag clearly identifies catheter specifications
- Unique hub design ensures proper inflation device attachment

Microvasive.
Boston Scientific Corporation

800-225-3226

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Achiever™ Pyloric Balloon Dilatation Catheters and Kit

Ordering Information

Catheters

Order Number	Balloon O.D. (Fr) (mm)	Balloon Length (cm)	Catheter Length (cm)	Minimum Required Biopsy Channel (mm)	Quantity Supplied
5806	18 6	5.5	180	2.8	1 ea
5808	24 8	5.5	180	2.8	1 ea
5810	30 10	5.5	180	2.8	1 ea
5812	36 12	5.5	180	2.8	1 ea
5815	45 15	5.5	180	2.8	1 ea
5818	54 18	5.5	180	2.8	1 ea

Kit

Order Number	Balloon O.D. (Fr) (mm)	Balloon Length (cm)	Catheter Length (cm)	Minimum Required Biopsy Channel (mm)	Quantity Supplied
5832	Assorted	5.5	180	2.8	1 Kit

Each Kit Includes: 6 Achiever Pyloric Balloon Dilatation Catheters: #5806, 6mm; #5808, 8mm; #5810, 10mm; #5812, 12mm; #5815, 15mm; #5818, 18mm



800-225-3226

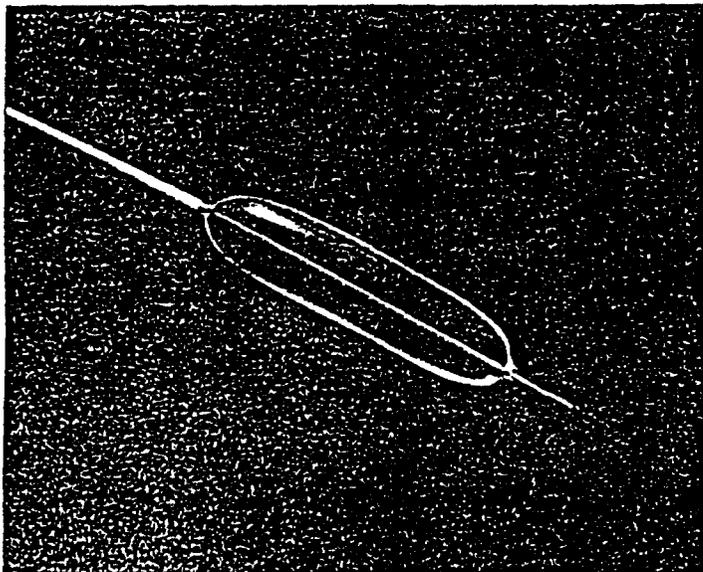
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Achiever™

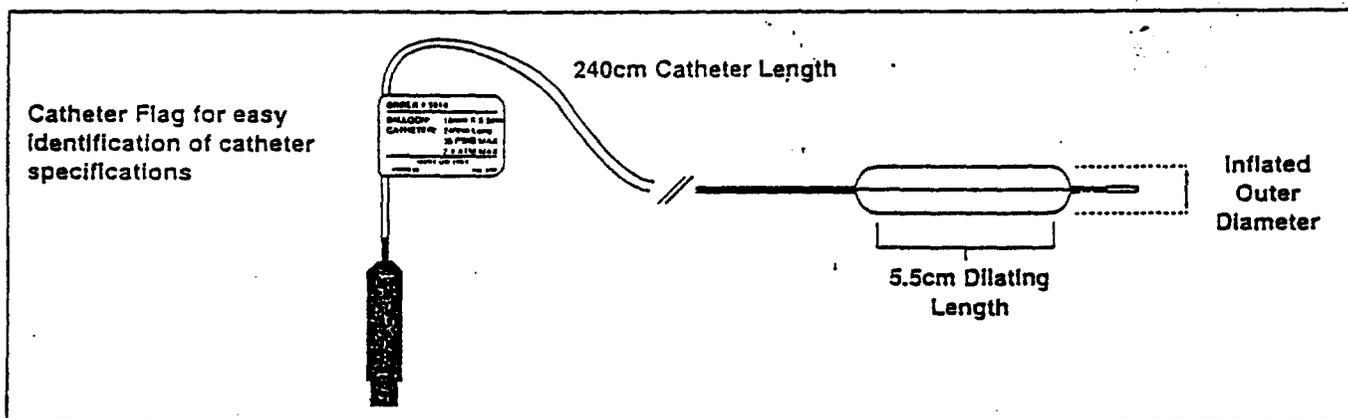
Achiever™ Colonic Balloon Dilatation Catheters and Kit

Designed for single-use, this through-the-scope balloon dilator provides the 240cm catheter length ideal for colonic applications



- 240cm catheter length ensures access for colonic stricture dilatation
- 5.5cm balloon dilating length produces dependable, controlled-force radial dilatation
- Through-the-scope access provides the control of direct vision
- Single-use design ensures convenience and the reliability of first-use performance for every procedure
- Proprietary balloon material maintains low profile to ease passage through working channels as small as 2.8mm
- Flexible catheter tip allows less traumatic advancement through tortuous strictures

Dilatator



- Kink-resistant, firm catheter shaft material facilitates rapid passage through the scope
- Wide variety of balloon diameters allows accurate match to procedural requirements

- Catheter flag clearly identifies catheter specifications
- Unique hub design ensures proper inflation device attachment

Microvasive.
Boston Scientific Corporation

800-225-3226

WB

Achiever™ Colonic Balloon Dilatation Catheters and Kit

Ordering Information

Catheters

Order Number	Balloon O.D. (Fr) (mm)	Balloon Length (cm)	Catheter Length (cm)	Minimum Required Biopsy Channel (mm)	Quantity Supplied
5906	18 6	5.5	240	2.8	1 ea
5908	24 8	5.5	240	2.8	1 ea
5910	30 10	5.5	240	2.8	1 ea
5912	36 12	5.5	240	2.8	1 ea
5915	45 15	5.5	240	2.8	1 ea
5918	54 18	5.5	240	2.8	1 ea

Kit

Order Number	Balloon O.D. (Fr) (mm)	Balloon Length (cm)	Catheter Length (cm)	Minimum Required Biopsy Channel (mm)	Quantity Supplied
5932	Assorted	5.5	240	2.8	1 Kit

Each Kit Includes: 6 Achiever Colonic Balloon Dilatation Catheters: #5906, 6mm; #5908, 8mm; #5910, 10mm; #5912, 12mm; #5915, 15mm; #5918, 18mm

 **Microvasive.**
Boston Scientific Corporation

800-225-3226

Microvase Rigiflex[®] TTS[™] Instructions for Use

10/29/14

Microvasive. RIGIFLEX®
Boston Scientific Corporation **TTS™ DILATORS**

Instructions for Use
Read Carefully Before Using

CONCEPT:

The MICROVASIVE RigiFlex® TTS™ Balloon Dilator is a special inelastic balloon made of Polytuff 310™ (a proprietary polymer) which is filled with water to exert radial force on a narrow segment.

The Dilator has the following important safety features:

1. The balloon is non-distending. Excess pressure does not cause greater expansion as with latex balloons.
2. Radial pressure is generated by the inflated balloon therefore maximizing patient safety. Conventional dilators, such as bougies and olives, require axial force which can cause trauma or push occluding material to a different site.
3. Balloon dilatation is performed under direct vision maximizing physician control over the procedure.

INDICATIONS FOR USE:



CATHETER CONSTRUCTION:

Radiopaque Guidewire

The catheter has a built-in radiopaque guidewire. This guidewire provides adequate stiffness for advancement of the catheter through the endoscope channel and stricture, and helps prevent kinking.

Balloon

The Balloon portion of the RigiFlex® Dilator is made of Polytuff 310™. Polytuff 310™ is a specially compounded polymer whose molecular structure has been altered to increase strength greatly and minimize stretching. Polytuff 310™ can withstand temperatures up to 140°F (60 degrees C).

NOTE: Suction applied and held during withdrawal decreases the deflated profile of the balloon. A decreased balloon profile lessens resistance during catheter withdrawal and thereby prolongs balloon life. For maximum suction a 60cc syringe is recommended.

TTS EASE OF USE EQUIPMENT/INSTRUCTION REVIEW

Supplies Needed

- | | |
|---|------------------------------|
| - Pressure Monitor | - 20-30cc Inflation Syringe* |
| - Dome Hub | - 60cc Deflation Syringe* |
| - O-Ring | - 1, 2-way stopcock |
| - 2 Extension Tubes
- (1 Male, 1 Female) | - Silicone, Spray or Liquid |
| - 4x4 Gauze | - TTS Balloons |

* Optional Supplies

- "RIGIFLATOR" Inflation - Deflation Gun
- LeVeen[®] Inflation Syringe

1. Seat the O-Ring in the dome kit.
2. Screw the dome kit to the pressure monitor until "finger tight".
3. Attach extension tubes to the dome hub (see figure #1).
4. Attach the 2-way stopcock to the extension tube off the side port of the dome hub (see figure #1).
5. Attach a 20cc or 30cc syringe filled with water to the stopcock (see figure #1).
6. Turn the monitor upside down and prime the dome hub and extension tubes with water. After purging, disconnect your 20cc or 30cc syringe - reload it with water and reattach to the stopcock. (NOTE: By turning the monitor upside down all the air will be purged from the dome hub insuring proper inflation).
7. Attach a 60cc syringe to the balloon hub and apply suction - purging the balloon of any residual air. Detach the 60cc syringe.

8. Attach balloon to the male adapter extension tube. (NOTE: The balloon extension tube should be attached to the vertical port of the dome kit, (see figure #1).
9. Liberally lubricate the balloon with silicone spray or liquid. Do not lubricate the balloon catheter. Do not use water or petroleum based lubricants.
10. Insert the balloon into the endoscope and advance using short, 2-3cm strokes. Using a 4x4 gauze may facilitate the catheter advancement, (see catheter insertion and balloon inflation).

sterilizing bag in a coil not less than eight inches in diameter. The gas sterilizer must be operated on the cold cycle (less than 60°C). Temperatures greater than 60°C will damage the dilator permanently. After sterilization, the dilator should be allowed to aerate for 24 hours at room temperature.

NOTE: It is recommended that proper sterility verification procedures (i.e., the use of biological test indicators) as well as pyrogen testing be employed on any resterilized product. Ample time should be allowed for the residual gas to dissipate. Seven days is the recommended time unless an aeration device is used.

DO NOT EXCEED 140°F (60°C)

DO NOT AUTOCLAVE

CLEANING:

Immediately after use, the dilator should be submerged in cool water. Flush the balloon lumen and balloon with clean water several times if contrast has been used to fill the balloon. The RIGIFLEX® TTS™ dilator may be immersed in and wiped with a cleaning solution such as Detergicide®.

STORAGE:

Store RIGIFLEX® TTS™ dilators in a cool, dry area away from sunlight. Before storage, catheters should be allowed to drip dry.

STERILIZATION:

RIGIFLEX dilators may be cold sterilized or gas sterilized. For cold sterilization, a solution such as Cidex® or Detergicide® should be used. The dilators may be completely immersed in the solution and flushed repeatedly without damage.

HOW SUPPLIED:

MICROVASIVE's RIGIFLEX® TTS™ Dilators are supplied non-sterile.

For gas sterilization (12/88 ETO), the dilator should be packaged in a

480 Pleasant Street, Watertown, MA 02172 (800) 225-3226

100265-01

REV. 9/89

Catheter Shaft

The shaft of the Rigiflex[®]TTS[™] Dilator is made of Polyethylene. This material offers good torque control.

CARE:

RIGIFLEX[®]TTS[™] dilators are made of materials that are abrasion resistant and impervious to most chemical solvents. Rigiflex[®]TTS[™] dilators can be reused. The actual number of uses will depend upon the care taken by the users.

The most common cause of failure is balloon rupture caused by over-inflation or incomplete evacuation. This situation may be avoided by using the pressure monitor (cat. # 5150) in conjunction with the MICROVASIVE "Rigiflator" inflation-deflation gun (cat. # 0105). If inflating the balloon with a syringe, the user should be aware that the smaller the size of the syringe used to inflate the dilator, the greater the pressure that can be generated. The dilator, Luer Lok hub, strain relief and balloon cover are similarly color coded to indicate the balloon type (i.e. esophageal, pyloric, etc.) Additionally, the Luer Lok hub stickers indicate balloon inflated outer diameter in both millimeters and French as well as balloon maximum inflation pressure and balloon length. This information has also been included on the package labels. The balloon lot and catalog number are indicated on the Luer Lok hub.

When advancing the TTS balloon through the 2.8mm working channel application of negative pressure with a 60cc syringe may be applied to the Luer Lok hub. This action will facilitate balloon passage, i.e. reducing balloon-wall friction and therefore potentially increasing balloon longevity. Upon termination of dilatation, the water must

be completely removed from the balloon. **CAUTION: FAILURE TO EVACUATE THE BALLOON COMPLETELY MAY RESULT IN TEARING OF THE BALLOON WHEN CATHETER WITHDRAWAL IS ATTEMPTED.**

Other causes of balloon breakage are penetration by sharp objects and exposure to excessive heat during storage. Dilators should be stored away from sharp objects and heat (e.g., in automobiles or in direct sunlight).

Other causes of failure include kinking of the catheter due to forceful manipulation of the dilator and fraying at the tip caused by abrasion against tissue. Additionally, should contrast be used to fill the balloon for fluoroscopic visualization, balloons should be flushed immediately after removal from the patient. This will avoid crystallization of the contrast within the catheter rendering the balloon inoperable.

INSPECTION:

Inspect each dilator before every use for the following:

1. Fraying of the Tip - abrasion against tissue may cause fraying at the tip.
2. Kinking - sharp bends can weaken the catheter and/or guidewire and create surface roughness that makes insertion through the endoscope difficult.
3. Twisting - twisting may also weaken the tubing and/or guidewire.
4. Overheating or Solvent Damage - heat over 60°C (140°F) may cause the balloon to become distorted and/or the surface to roughen. Likewise, the use of solvents other than alcohol or specifi

cally approved solutions, or leaving the dilator for long periods of time immersed in sterilizing solution can cause surface irregularities which weaken the balloon and catheter.

- 5. **Balloon Leakage** - rough handling, storage near sharp objects, exposure to heat and sunlight and over-inflation may cause balloon rupture.

In either case, the air in the balloon must be displaced to ensure that only fluid fills the balloon.

NOTE: The balloon catheter should be fully deflated before introduction into the endoscope channel. Creation of a vacuum in the balloon with the 60cc syringe and stopcock facilitates insertion and minimizes wear.

USE:

CAUTION: REMOVE PROTECTIVE SHEATH FROM RIGIFLEX TTS CATHETER BEFORE USING. SLIDE THE SHEATH PROXIMAL OR TOWARD THE HUB. THE SHEATH CAN BE EASILY SLID BACK OVER THE BALLOON AFTER CLEANING. THE SHEATH IS COLOR CODED TO CORRESPOND WITH THE BALLOON TYPE.

RIGIFLEX® TTS™ balloons must be inflated with water. The water creates maximum radial pressure in the balloon for more effective dilatation of strictures. Depending on technique, the balloon may be filled with a dilute radiopaque fluid (Renographin 15%, water 85%). CAUTION: THE USE OF CONTRAST MATERIAL IS NOT GENERALLY RECOMMENDED, AND COULD LIMIT THE BALLOON'S LIFE EXPECTANCY.

CATHETER INSERTION:

1. Removal of the rubber valve covering the endoscope biopsy channel to facilitate insertion of the balloon is not necessary.
2. Apply a lubricant, silicone liquid or spray (preferably spray), to entire endoscope channel with a cleaning brush or cytology brush (MICRO-VASIVE cat. no. 1612). This procedure applies a thin layer of silicone to the inside wall of the channel and facilitates balloon passage.

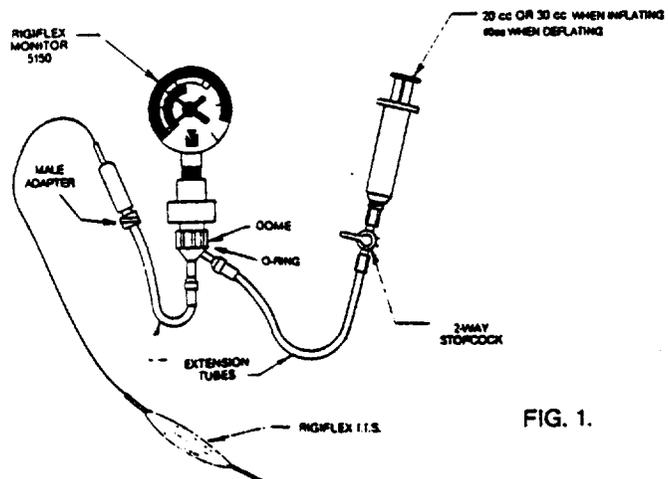


FIG. 1.

**RIGIFLEX T.T.S. DILATORS
SET-UP DIAGRAM**

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3. Apply silicone lubricant (preferably spray) to the balloon and rub over the balloon surface to ensure uniform coating. Lubricants other than silicone are not recommended. CAUTION; DO NOT USE WATER OR PETROLEUM BASED JELLIES.

4. Deflate the balloon with a 60cc syringe or larger and hold negative pressure while inserting the balloon into the biopsy channel. Assemble the dilator, pressure monitor, syringes, and stopcock as shown in figure #1 and as discussed in the next section, "Balloon Inflation".

5. As with other instruments that are placed down the endoscope channel, short, quick 2cm movements are recommended. Users should be aware that two sections of the endoscope form angles during use. Resistance will be felt immediately upon entering the endoscope channel and 3 to 4 inches from the tip. Again, short, firm pushes are recommended.

#0105) or LeVein[®] Syringe (Cat.#0102), while monitoring the pressure in the balloon with the Rigiflex Dilatation Monitor (Cat.#5150). The use of a pressure monitor is strongly recommended. Please refer to monitor instructions for a detailed description of its use.

To inflate the balloon, turn the stopcock handle so that the butterfly tabs are parallel to the syringe barrel. Then, inflate the balloon using the inflation syringe, RIGIFLATOR or LeVein[®] syringe. The balloon should be completely inflated as the maximum rated pressure is achieved. When the balloon is completely inflated, the stopcock handle should be turned so that the butterfly tabs are perpendicular to the syringe barrel. Balloon pressure will thereby be maintained.

Maximum ratings refer to steady state pressure achieved when inflation is complete. Maximum use pressure is indicated on the balloon hub.

CATHETER WITHDRAWAL:

To deflate the balloon, insure that the stopcock finger tabs are perpendicular to the syringe barrel. Then detach the 20cc or 30cc syringe. Attach the 60cc syringe to the stopcock. Turn the finger tabs parallel to the syringe barrel. Apply suction to the balloon lumen.

CAUTION: THE BALLOON MUST BE THOROUGHLY DEFLATED AND ALL FLUID REMOVED BEFORE WITHDRAWAL.

To be deflated properly, the entire balloon must be extended beyond the distal opening of the endoscope. No part of the balloon should be in the endoscope channel while it is being deflated. The balloon can be removed after complete deflation.

BALLOON INFLATION:

In most cases, the dilator (in deflated state) will move out of the endoscope and easily into the stricture. However, in other cases (perhaps when a 10mm or larger balloon is used) only a small portion of the dilator may enter the stricture. Here the balloon should be inflated to open the stricture longitudinally as much as possible. Once partially opened, the dilator can be deflated and advance into the stricture and the process repeated.

Once the balloon is centered within the stricture, it should be inflated to the recommended maximum use pressure indicated on the balloon hub with a hand held syringe, Rigiflator (Cat.

**Microvasive Price List
(Includes Rigiflex® TTS™ Specifications)**

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DILATATION

RIGIFLEX TTS® (THROUGH THE SCOPE) BALLOON DILATATION CATHETERS

■ ESOPHAGEAL BALLOON CATHETERS

Order Number	Inflated O.D. (mm) (Fr)		Balloon Length (cm)	Required Working Channel (mm)	Catheter Size (mm) (Fr)		Usable Length (cm)	Price
5500	6	18	8	2.8	1.7	5	180	\$175 ea
5501	8	24	8	2.8	1.7	5	180	\$175 ea
5502	10	30	8	2.8	1.7	5	180	\$175 ea
5503	12	36	8	2.8	1.7	5	180	\$175 ea
5504	15	45	8	2.8	1.7	5	180	\$175 ea
5505	18	54	8	2.8	1.7	5	180	\$175 ea

■ PYLORIC BALLOON CATHETERS

Order Number	Inflated O.D. (mm) (Fr)		Balloon Length (cm)	Required Working Channel (mm)	Catheter Size (mm) (Fr)		Usable Length (cm)	Price
5506	8	24	3	2.8	1.7	5	180	\$215 ea
5507	10	30	3	2.8	1.7	5	180	\$215 ea
5508	12	36	3	2.8	1.7	5	180	\$215 ea
5509	15	45	3	2.8	1.7	5	180	\$215 ea
5523	8	24	5.5	2.8	1.7	5	180	\$215 ea
5519	10	30	5.5	2.8	1.7	5	180	\$215 ea
5524	12	36	5.5	2.8	1.7	5	180	\$215 ea
5520	15	45	5.5	2.8	1.7	5	180	\$215 ea

■ COLONIC BALLOON CATHETERS

Order Number	Inflated O.D. (mm) (Fr)		Balloon Length (cm)	Required Working Channel (mm)	Catheter Size (mm) (Fr)		Usable Length (cm)	Price
5511	6	18	3	2.8	1.7	5	240	\$215 ea
5512	10	30	3	2.8	1.7	5	240	\$215 ea
5513	12	36	3	2.8	1.7	5	240	\$215 ea
5514	15	45	3	2.8	1.7	5	240	\$215 ea
5515	18	54	3	2.8	1.7	5	240	\$215 ea
5528	6	18	5.5	2.8	1.7	5	240	\$215 ea
5529	10	30	5.5	2.8	1.7	5	240	\$215 ea
5530	12	36	5.5	2.8	1.7	5	240	\$215 ea
5521	15	45	5.5	2.8	1.7	5	240	\$215 ea
5522	18	54	5.5	2.8	1.7	5	240	\$215 ea

■ BILIARY BALLOON CATHETERS*

Order Number	Inflated O.D. (mm) (Fr)		Balloon Length (cm)	Required Working Channel (mm)	Catheter Size (mm) (Fr)		Usable Length (cm)	Price
5516	4	12	2	2.8	1.7	5	180	\$230 ea
5517	6	18	2	2.8	1.7	5	180	\$230 ea
5518	8	24	3	3.7	1.7	5	180	\$230 ea

*Recommended Guidewire .025", Order #5173

TO PLACE AN ORDER, CALL MICROVASIVE CUSTOMER SERVICE 1-800-225-3226

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

DILATATION

RIGIFLEX TTS® (THROUGH THE SCOPE) BALLOON DILATATION CATHETERS

ANASTOMOTIC BALLOON CATHETERS

Order Number	Inflated O.D. (mm) (Fr)	Balloon Length (cm)	Required Working Channel (mm)	Catheter Size (mm) (Fr)	Usable Length (cm)	Price
5525	20 60	8	3.7	2.3 7	180	\$230 ea
5526	25 75	8	3.7	2.3 7	180	\$230 ea
5531	20 60	8	3.7	2.3 7	210	\$230 ea
5532	25 75	8	3.7	2.3 7	210	\$230 ea

RIGIFLEX TTS® (THROUGH THE SCOPE) KITS

■ ESOPHAGEAL DILATATION KIT*

Order Number	Description	Price
5680	Kit Includes: 1 5500 6mm Dilator 1 5501 8mm Dilator 1 5502 10mm Dilator 1 5503 12mm Dilator 1 5504 15mm Dilator 1 5505 18mm Dilator 1 0105 Rigiflator 1 5150 Pressure Monitor 1 0081 Silicone Spray	\$1,780 ea

■ BILIARY DILATATION KIT*

Order Number	Description	Price
5682	Kit Includes: 1 5516 4mm Dilator 1 5517 6mm Dilator 1 5518 8mm Dilator 1 0105 Rigiflator 1 5150 Pressure Monitor 1 0081 Silicone Spray	\$1,400 ea

■ PYLORIC DILATATION KIT*

Order Number	Description	Price
5681	Kit Includes: 1 5523 8mm Dilator 1 5519 10mm Dilator 1 5524 12mm Dilator 1 5520 15mm Dilator 1 0105 Rigiflator 1 5150 Pressure Monitor 1 0081 Silicone Spray	\$1,555 ea

■ COLONIC DILATATION KIT*

Order Number	Description	Price
5683	Kit Includes: 1 5528 6mm Dilator 1 5529 10mm Dilator 1 5530 12mm Dilator 1 5521 15mm Dilator 1 5522 18mm Dilator 1 0105 Rigiflator 1 5150 Pressure Monitor 1 0081 Silicone Spray	\$1,660 ea

* Other dilator sizes may be substituted. Please contact Microvasive Endoscopy customer service for information.

MAX FORCE™ BILIARY BALLOON DILATATION CATHETERS

■ DISPOSABLE BILIARY BALLOON CATHETERS

Order Number	Inflated O.D. (mm) (Fr)	Balloon Length (cm)	Required Working Channel (mm)	Catheter Size (mm) (Fr)	Usable Length (cm)	Price 1-5	Price 6-10	Price 11+
6733	4 12	2	2.8	1.7 5	180	\$195 ea	\$180 ea	\$155 ea
6734	4 12	4	2.8	1.7 5	180	\$195 ea	\$180 ea	\$155 ea
37	6 18	2	2.8	1.7 5	180	\$195 ea	\$180 ea	\$155 ea
38	6 18	4	2.8	1.7 5	180	\$195 ea	\$180 ea	\$155 ea
6741	8 24	2	2.8	1.7 5	180	\$195 ea	\$180 ea	\$155 ea
6742	8 24	3	2.8	1.7 5	180	\$195 ea	\$180 ea	\$155 ea

TO PLACE AN ORDER, CALL MICROVASIVE CUSTOMER SERVICE 1-800-225-3226

DILATATION

RIGIFLEX TTS® (THROUGH THE SCOPE) BALLOON DILATATION CATHETERS

■ ANASTOMOTIC BALLOON CATHETERS

Order Number	Inflated O.D. (mm) (Fr)		Balloon Length (cm)	Required Working Channel (mm)	Catheter Size (mm) (Fr)		Usable Length (cm)	Price
5525	20	60	8	3.7	2.3	7	180	\$230 ea
5526	25	75	8	3.7	2.3	7	180	\$230 ea
5531	20	60	8	3.7	2.3	7	210	\$230 ea
5532	25	75	8	3.7	2.3	7	210	\$230 ea

RIGIFLEX TTS® (THROUGH THE SCOPE) KITS

■ ESOPHAGEAL DILATATION KIT*

Order Number	Description	Price
5680	Kit Includes: 1 5500 6mm Dilator 1 5501 8mm Dilator 1 5502 10mm Dilator 1 5503 12mm Dilator 1 5504 15mm Dilator 1 5505 18mm Dilator 1 0105 Rigiflator 1 5150 Pressure Monitor 1 0081 Silicone Spray	\$1,780 ea

■ BILIARY DILATATION KIT*

Order Number	Description	Price
5682	Kit Includes: 1 5516 4mm Dilator 1 5517 6mm Dilator 1 5518 8mm Dilator 1 0105 Rigiflator 1 5150 Pressure Monitor 1 0081 Silicone Spray	\$1,400 ea

■ PYLORIC DILATATION KIT*

Order Number	Description	Price
5681	Kit Includes: 1 5523 8mm Dilator 1 5519 10mm Dilator 1 5524 12mm Dilator 1 5520 15mm Dilator 1 0105 Rigiflator 1 5150 Pressure Monitor 1 0081 Silicone Spray	\$1,555 ea

■ COLONIC DILATATION KIT*

Order Number	Description	Price
5683	Kit Includes: 1 5528 6mm Dilator 1 5529 10mm Dilator 1 5530 12mm Dilator 1 5521 15mm Dilator 1 5522 18mm Dilator 1 0105 Rigiflator 1 5150 Pressure Monitor 1 0081 Silicone Spray	\$1,660 ea

* Other dilator sizes may be substituted. Please contact Microvasive Endoscopy customer service for information.

MAX FORCE™ BILIARY BALLOON DILATATION CATHETERS

■ DISPOSABLE BILIARY BALLOON CATHETERS

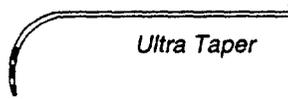
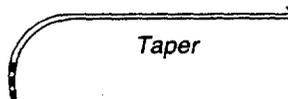
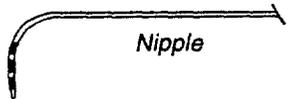
Order Number	Inflated O.D. (mm) (Fr)		Balloon Length (cm)	Required Working Channel (mm)	Catheter Size (mm) (Fr)		Usable Length (cm)	Price 1-5	Price 6-10	Price 11+
6733	4	12	2	2.8	1.7	5	180	\$195 ea	\$180 ea	\$155 ea
6734	4	12	4	2.8	1.7	5	180	\$195 ea	\$180 ea	\$155 ea
6737	6	18	2	2.8	1.7	5	180	\$195 ea	\$180 ea	\$155 ea
6738	6	18	4	2.8	1.7	5	180	\$195 ea	\$180 ea	\$155 ea
6741	8	24	2	2.8	1.7	5	180	\$195 ea	\$180 ea	\$155 ea
6742	8	24	3	2.8	1.7	5	180	\$195 ea	\$180 ea	\$155 ea

**Bard Esophageal & Biliary Dilators
Specifications Literature**



Biliary Endoscopic Accessories

ERCP Cannulas



Catalog Number	Description	O.D. (mm)	Length (cm)	Unit	Price Each		
					2	4-10	12+
000155	Nipple Tip ERCP cannula and stylet	1.8	200	2/box	\$40	\$38	\$34
000156	Taper Tip ERCP cannula and stylet	1.8	200	2/box	40	38	34
000159*	Standard Tip ERCP cannula and stylet	1.8	200	2/box	40	38	34
000183	Ultra Taper Tip ERCP cannula and stylet	1.8	200	2/box	40	38	34

*Accepts .038 in. and .035 in. guide wire

Guide Wires

Catalog Number	Description	O.D. (in.)	Length (cm)	Unit	Price Each
200018	J Guide Wire - 12mm "J" Moveable Core (use with #000159 ERCP cannula)	.038	400	1/box	\$55
00173W	Straight Guide Wire - Standard Taper Moveable Core (use with #000159 ERCP cannula)	.035	400	1/box	55
000150	Marked Spring Tip Guide Wire (use with American Dilators)		210	2/box	115

Disposable Biliary Balloon Dilators



Catalog Number	Description	Balloon Diameter (mm)	Balloon Length (cm)	Catheter Length (cm)	Biopsy Channel Minimum (mm)	Catheter O.D. (mm)	Unit	Price Each		
								1-4	5-9	10+
000347	Biliary Balloon Dilator	4	2	180	2.8	1.9	1/box	\$200	\$180	\$160
000348	Biliary Balloon Dilator	6	2	180	2.8	1.9	1/box	200	180	160
000349	Biliary Balloon Dilator	8	3	180	2.8	1.9	1/box	200	180	160

Esophageal Dilators and Other Therapeutic Devices

ELIMINATOR™ P.E.T. Balloon Dilators

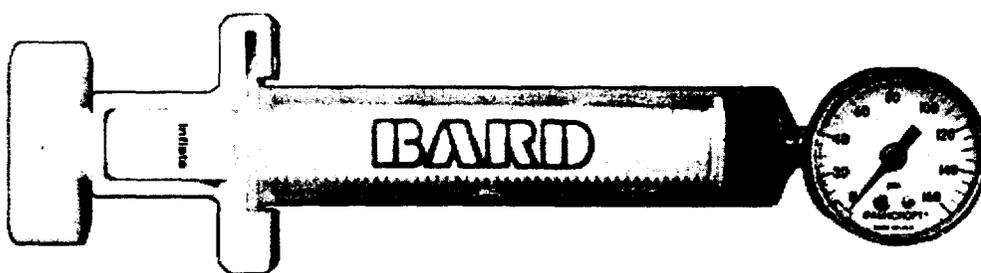


Catalog Number	Description	Balloon Diameter (mm)	Balloon Length (cm)	Catheter Length (cm)	Biopsy Channel Minimum(mm)	Unit	Price Each		
							1-4	5-9	10+
000340	Esophageal Balloon Dilator	6	8	180	2.8	1/box	\$160	\$140	\$120
000341	Esophageal Balloon Dilator	8	8	180	2.8	1/box	160	140	120
000342	Esophageal Balloon Dilator	10	8	180	2.8	1/box	160	140	120
000343	Esophageal Balloon Dilator	12	8	180	2.8	1/box	160	140	120
000344	Esophageal Balloon Dilator	15	8	180	2.8	1/box	160	140	120
000345	Esophageal Balloon Dilator	18	8	180	2.8	1/box	160	140	120
000735	Advantage Pack	15	8	180	2.8	5/box	575		
000736	Advantage Pack	18	8	180	2.8	5/box	575		
000346	Esophageal Balloon Dilator Kit (1 Each of Cat. No's 000340 – 000345)					1/box	720		

Bard Balloon Inflation System

Each System includes:*

- 1 Ea. Inflator
- 1 Ea. Inflation Manometer



Catalog Number	Description	Unit	Price Each
000390*	Bard Balloon Inflation System	1/box	\$200
000391	Inflation Manometer	5/box	30

Customer Service: 1-800-826-2273

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



Bard SE Decision Letter (K863437)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 29 1986

Ms. Catherine V. Beath
C. R. Bard, Inc.
731 Central Avenue
Murray Hill, New Jersey 07974

Re: K863437
Bard Balloon Dilatation System
Dated: September 2, 1986
Received: September 5, 1986
Regulatory Class: II

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Dear Ms. Beath:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This device has been placed into the regulatory class shown above, by a final regulation published in the Federal Register. All classes of devices are regulated by the general controls provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices must also meet present or future performance standards; class III devices will be required to undergo premarket approval at some time in the future. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Section 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire and be notified of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Fernando Villarroel, Ph.D.
Director
Division of Gastroenterology-Urology
and General Use Devices (HFZ-420)
Office of Device Evaluation
Center for Devices and Radiological Health

BEST AVAILABLE COPY

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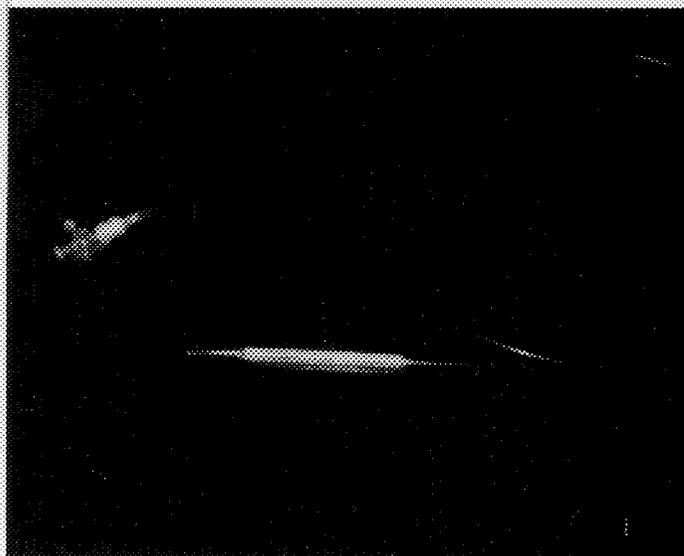
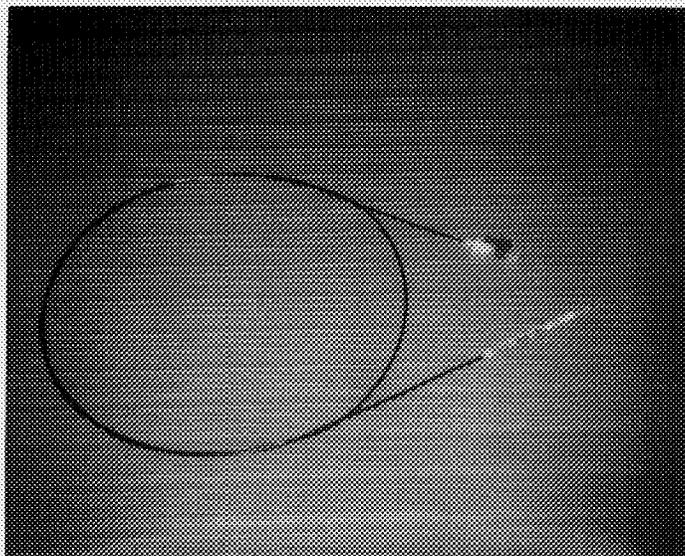
Attachment IV
Engineering Drawing



Attachment IV

Wilson-Cook Balloon Dilator Device Photograph

The device photographs are included for the Esophageal Balloon Dilator, 6mm x 8cm version.



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