



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (Idt)
FOLDER: K000281 - 172 pages
COMPANY: BOSTON SCIENTIFIC CORP. (BOSTSCIE)
PRODUCT: STENT, COLONIC, METALIC, EXPANDABLE (MQR)
SUMMARY: Product: WALLSTENT INTERNAL PROSTHESIS

DATE REQUESTED: Oct 8, 2014

DATE PRINTED: Oct 8, 2014

Note: Printed



MAY 12 2000

K000281
1 of 2

SECTION 10
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

- DATE: January 28, 2000
 - COMMON/USUAL NAMES: Enteral Prosthesis
 - TRADE/PROPRIETARY NAME: Wallstent® Enteral Prostheseis
 - CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class III
- | Name | Number | 21 CFR Ref. |
|-----------------------|--------|-------------|
| Esophageal Prosthesis | 78 MQR | 878.3610 |
- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
Gastro-Renal (GRDB)
 - OWNER/OPERATOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
 - CONTACT PERSON: Lisa M. Quaglia, Regulatory Affairs Manager

DESCRIPTION OF DEVICE

The Wallstent® Enteral Endoprosthesis is comprised of two components: the implantable metallic stent and the Unistep™ Plus Delivery system (reference Figure A). The stent is composed of biomedical super alloy monofilament wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in. / 0,89 mm guide wire. The device may be inserted through the working channel of an endoscope (minimum channel diameter 3.7 mm).

INDICATIONS FOR USE

The Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery system is for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in malignant strictures. list indications

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Modified Enteral Wallstent® is substantially equivalent to the currently-marketed Enteral Wallstent®. The major components of the Modified Enteral Wallstent® are the stent and the delivery system. A thorough comparison of the descriptive characteristics between the Modified Enteral Wallstent® and the predicate device show equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on Modified Enteral Wallstent® to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Modified Enteral Wallstent® with satisfactory results.

CONCLUSION

Boston Scientific Corporation believes that Modified Enteral Wallstent® is substantially equivalent to the currently-marketed Enteral Wallstent®. A comparison of the descriptive characteristics of these products demonstrate the Modified Enteral Wallstent® is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Modified Enteral Wallstent® will meet the minimum requirements that are considered acceptable for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Microvvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Re: K000281
Modified Enteral Wallstent®
Dated: March 23, 2000
Received: March 24, 2000
Regulatory Class: II
21 CFR §878.3610/Procode: 78 MQR
21 CFR §878.3610/Procode: 78 MUM

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

SECTION 1
INDICATIONS FOR USE

510(k) Number: ~~To Be Determined~~ K000281/S⁰⁰¹

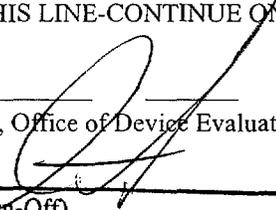
Device Name: Modified Enteral Wallstent®

Indication for Use:

The Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery system is indicated for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K000281

Prescription Use
(Per 21 CFR 801.1091)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Re: K000281
Modified Enteral Wallstent®
Dated: March 23, 2000
Received: March 24, 2000
Regulatory Class: II
21 CFR §878.3610/Procode: 78 MQR
21 CFR §878.3610/Procode: 78 MUM

Dear Ms. Quaglia:

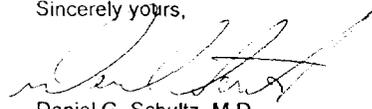
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

SECTION 1
INDICATIONS FOR USE

510(k) Number: ~~To Be Determined~~ K000281/S⁰⁰¹

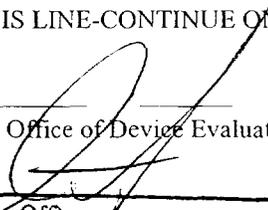
Device Name: Modified Enteral Wallstent®

Indication for Use:

The Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery system is indicated for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000281

Prescription Use (Per 21 CFR 801.1091)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Kathleen Chan

Subject: 510(k) Number K000281/S1

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

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

De Novo Classification Candidate? YES NO

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

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

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices N/A
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

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

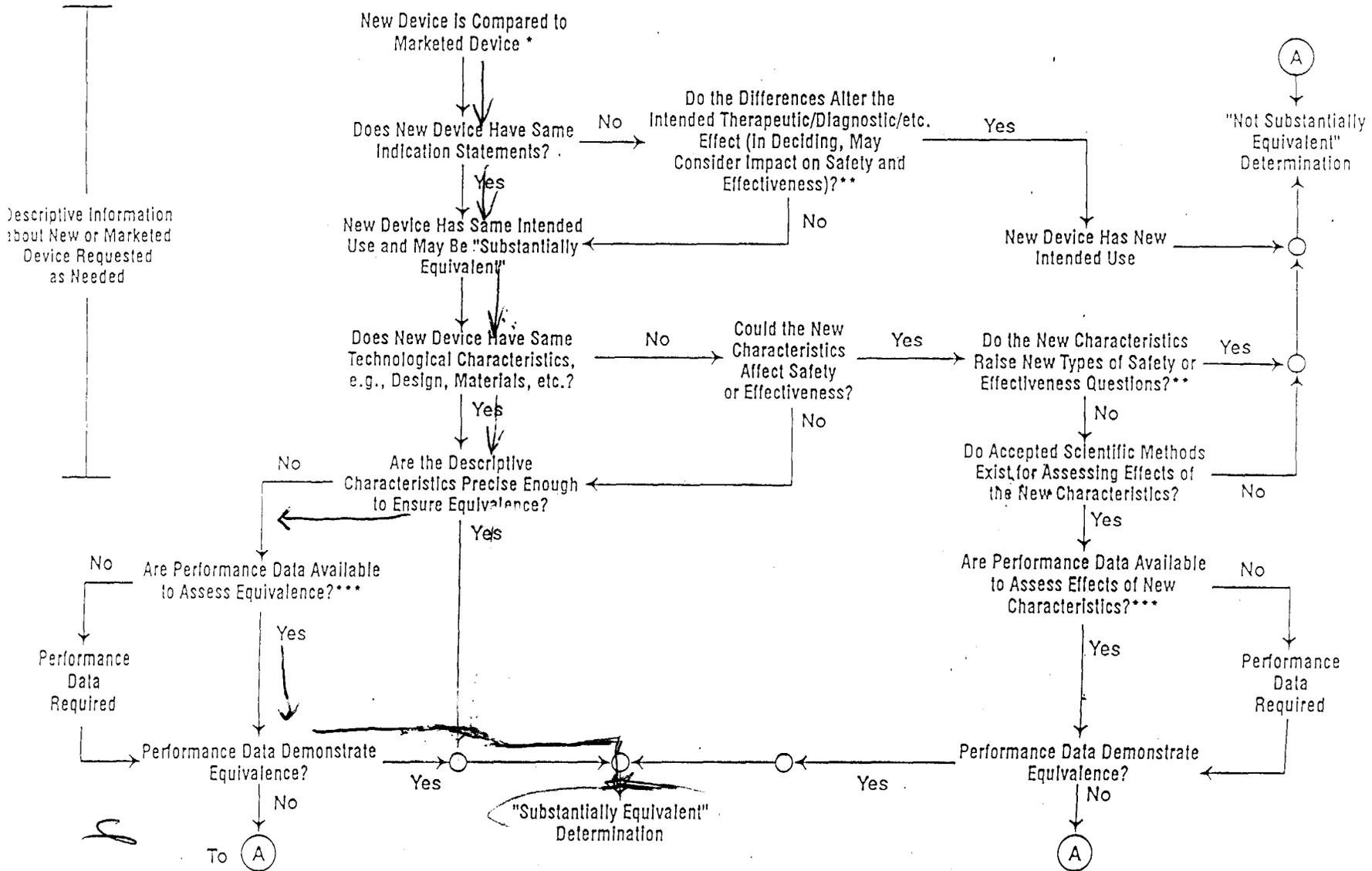
- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Class II 878.3610 mym, MAR Additional Product Code(s) with panel (optional): 3

Review: Carolyn Y. Heuland GRDB 5/11/00
 (Branch Chief) (Branch Code) (Date) (5/11/00)

Final Review: [Signature] 5/11/00
 (Division Director) (Date) (JMS)

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



* 510(k) Submission: Are New Devices to Marketed Devices Substantially Equivalent? Contact FDA/CDRH/OCE/DSD or CDRH, FD-1371, 301-796-6118. But Additional Information on the Relationship Between Marketed and "Predicate" Devices is Sometimes Required. ** Data May Be In the Public Domain. *** Data May Be In the Public Domain. The Agency May Require Additional Information.

K000281 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENT

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

TRADE NAME: Wallstent Enteral Endoprosthesis with Unistep Plus Delivery System
COMMON NAME: Metal Expandable Colorectal Stent, Metal Expandable Duodenal Stent
PRODUCT TO WHICH COMPARED: Wallstent Enteral Wallstent with Unistep Delivery System (510(k) NUMBER IF KNOWN) K954290, K980113, K991056

- | | YES | NO |
|---|--|--|
| 1. IS PRODUCT A DEVICE | <input checked="" type="checkbox"/> | <input type="checkbox"/> - IF NO STOP |
| 2. DEVICE SUBJECT TO 510(K)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> - IF NO STOP |
| 3. SAME INDICATION STATEMENT? | <input checked="" type="checkbox"/> | <input type="checkbox"/> - IF YES GO TO 5 |
| 4.* DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS? | <input type="checkbox"/> | <input type="checkbox"/> - IF YES STOP - NE |
| 5. SAME TECHNOLOGICAL CHARACTERISTICS? | <input checked="" type="checkbox"/> | <input type="checkbox"/> - IF YES GO TO 7 |
| 6.* COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS? | <input type="checkbox"/> | <input type="checkbox"/> - IF YES GO TO 8 |
| 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH? | <input type="checkbox"/> | <input checked="" type="checkbox"/> - IF NO GO TO 10
IF YES STOP - SE |
| 8.* NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS? | <input type="checkbox"/> | <input type="checkbox"/> - IF YES STOP - SE |
| 9. ACCEPTED SCIENTIFIC METHODS EXIST? | <input type="checkbox"/> | <input type="checkbox"/> - IF NO STOP - SE |
| 10. PERFORMANCE DATA AVAILABLE? | <input checked="" type="checkbox"/> | <input type="checkbox"/> - IF NO REQUEST DATA |
| 11.*DATA DEMONSTRATE EQUIVALENCE? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

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.

5

K000281, Boston Scientific Wallstent Enteral Prosthesis

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE:

The Wallstent Enteral Endoprosthesis with Unistep Delivery System is indicated for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

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 premarket notification for the Wallstent Enteral Prosthesis with the Unistep Plus Delivery system is for a modification to the delivery system. The self-expanding metal stent is identical to the predicate and is made from cobalt based superalloy wire braided in a tubular mesh configuration. The stent is pre-mounted on the delivery system.

The delivery system, which has been modified to allow reconstraint of the stent, is a 10French coaxial catheter used to deliver and deploy the metal stent to the desired location. The delivery system consists of the exterior tube, the interior tube, the stopcock and extension tube, stainless steel tube, and the valve body. The interior tube of the coaxial system, made of polyetheretherketone (PEEK), contains a central lumen that accommodates a 0.035" guidewire and serves as a core to mount the stent. The stent is premounted onto the delivery system and the exterior tube, constructed of PTFE, braid, and Pebax, holds the stent in place on the delivery system. As the exterior tube is retracted back, the stent is deployed. The delivery system allows for reconstraint in the event that the physician chooses to reposition the stent. This is accomplished by pulling the stainless steel tube toward the user while maintaining valve body position. The stopcock and extension tube are used for flushing. The 304 stainless steel tube is used for guiding the deployment and reconstraint force. A limit marker band is located on the delivery system to let the user know when the threshold has been met for reconstraint. Once the stent has been deployed beyond the threshold of the limit marker band, reconstraint will not be possible. Radiopaque markers are located on the delivery system to aid in placing the stent prior to deployment.

Modifications are being proposed to improve the ease of use and/or manufacture of the delivery system. The modifications are:

- The materials of the interior tube have been changed to increase pushability, reduce elongation, and allow for reconstraint.

6

K000281, Boston Scientific Wallstent Enteral Prosthesis

- The delivery system will be offered in a shorter, 135cm length for placement by interventional radiologists.

In addition, the delivery system can now be used to reconstrain the stent if the threshold deployment limit has not been reached.

	Enteral Wallstent K000281	Enteral Wallstent (K991056)
MATERIALS		
Inner tube catheter	PEEK	Pellethane
Inner jacket of catheter	Pellethane	N/A
Outer Tube (OT)	Composite of OT components	Pebax
OT liner	PTFE	N/A
OT Jacket	Pebax	N/A
OT Weld Sleeve	Pebax	N/A
OT Braid	Stainless steel wire	N/A
Marker bands (inner tube and outer tube)	Platinum/Iridium	Tantalum (no outer tube marker band present)
Stent cup	Nylon 60	N/A
Tip adhesive	Dymax 190M	N/A

The modified Enteral Wallstent will be available in several configurations:

Working Length	Stent Diameter	Stent Length	Working Length	Stent Diameter	Stent Length
230	18mm	60mm	135	18	60
230	18mm	90mm	135	18	90
230	20mm	60mm	135	20	60
230	20mm	90mm	135	20	90
230	22mm	60mm	135	22	60
230	22mm	90mm	135	22	90

After a stricture has been identified in the colon or duodenum, the delivery system is advanced over a guidewire to the site of the stricture through an endoscope with the aid of endoscopic and/or fluoroscopic visualization. Once in position, the outer sheath is retracted to begin release of the stent from the delivery system. If the stent requires repositioning, the stent may be repositioned if the threshold for reconstraint has not been reached. Placement of the stent may be confirmed fluoroscopically.

PERFORMANCE TESTING

Testing performed on the modified enteral Wallstent included: stent dimensional conformance test, deployment force, withdrawal, priming and trackability test, bond strengths, and delivery system dimensions.

Each product sample was sterilized. Only the longer stent length was tested (90mm) however,

K000281, Boston Scientific Wallstent Enteral Prosthesis

both lengths of the delivery catheter (230 and 135cm) were tested for all stent diameters (18, 20 and 22 mm). The longer length, 90mm, stent was chosen, as the longer stent will challenge the performance greater than the shorter, 60mm, stent.

Working Length	Stent Size	Number
230cm	18x90	15
230cm	20x90	15
230cm	22x90	15
135cm	18x90	15
135cm	20x90	15
135cm	22x90	15

Stent dimensional conformance test (delivery system dimensions) – this test was to confirm the dimensions of the stent post deployment with the Unistep Plus Delivery System. For each device tested, the working length, overall length, and marker band spacing was measured. A laser micrometer was used to measure the outside diameter at the exterior marker band, the clear section over the stent, the weld, and the blue working area. For each measurement, the minimum and maximum values were compared against the specification.

Priming and trackability test – this test was performed to verify adequate fluid flow and trackability in a simulated model. The same units tested for stent dimensions were used for this test. Each device was primed with a 10cc syringe and water prior to testing. The delivery system was then passed over a .035” guidewire and inserted into a simulated model for trackability testing.

Deploy and reconstrain test – this test was performed to verify acceptable deployment and reconstraint forces. The test units used for this test were then used for priming and tracking testing. From each lot, 5 stents were fully deployed (3rd deploy) in the model. The remaining stents were tested for withdrawal and stent dimensions. Each device was taken through two deploy and reconstrain cycles using a simulated model prior to full deployment or withdrawal. The maximum force for each deployment and reconstrain were measured.

Withdrawal test – the purpose of this test was to verify acceptable withdrawal when a stent is partially deployed. Five units from each lot of the 230cm length delivery system were tested (15 total). Each device was partially deployed and the stent should have remained attached to the delivery system as it is withdrawn from the model.

Stent dimensions test – this test was performed to verify the dimensions of the stent. The length and diameter for each device was measured. The acceptance criteria were met.

Bond strengths – the purpose of this test was to verify acceptable bond strengths to withstand normal use of the device. The same units used for deploy and reconstrain testing were used to verify bond tensile strength for a total of 78 units. Since the bonds are common to all models, the sponsor pooled the data. The bonds tested included; distal tip bond, interior tube bond to the

K000281, Boston Scientific Wallstent Enteral Prosthesis

stainless steel tube, valve body to the exterior tube bond, stainless steel tube to the hub bond, outer tube weld, holding sleeve to exterior tube marker band.

BIOCOMPATIBILITY

The materials used in the proposed Unistep Plus Delivery System are identical to materials currently used in other legally marketed Wallstents Unistep Delivery Systems.

Component	Material	Material also used in...
Hub, Valve Body, Cap	Lexan HPS1-803	Wallstent tracheobronchial stent with Unistep Plus Delivery System (K890163, K964121, K961507, K961296)
Hub adhesive	Sicoment 8400	Same as above
Stainless steel tube, outer tube braid	Stainless steel 304	Same as above
Inner tube	PEEK	Same as above
Inner Jacket, Tip, extension tube	Pellethane	Same as above
IM adhesive	Sicoment 40	Same as above
Stent cup	Nylon 60	Same as above
Marker bands	Platinum/iridium	Same as above
Holding sleeve	Tecothane	Same as above
Tip adhesive, VB adhesive	Dymax	Same as above
Stopcock	Polycarbonate	Same as above
O-ring	Silicone	Same as above
Outer tube liner	PTFE	Same as above
Outer tube jacket/weld sleeve*	Pebax	Same as above for the colorant Currently marketed Enteral Wallstent (Pebax) K991056, K980113, K954290
Coatings w/Heptane	Silicone	Currently marketed Enteral Wallstent
Stent	Elgiloy	Currently marketed Enteral Wallstent

* Pebax, available in either 72D or 63D (durometer). The tubes are either virgin or blended with a blue colorant. The 72D Pebax is identical to that used in the currently marketed 7.5Fr. Biliary Wallstent (K982005, K964119). The 63D Pebax is not used in a currently marketed device, however, biocompatibility testing was conducted in accordance with ISO 10993¹. The following tests were performed and all requirements were met: Cytotoxicity (MEM elution), indirect hemolysis, Ames mutagenicity, systemic injection, intracutaneous injection, rabbit pyrogen, skin sensitization, hemocompatibility assay, complement activation, prothrombin time. Toxicon conducted the testing. The blue colorant used in the outer jacket is identical to the colorant used on the 8-13.5Fr. Unistep Plus Delivery system provided with the Tracheobronchial Wallstent (K961296). The Pebax material is manufactured by AtoChem and is extruded by Boston Scientific.

K000281, Boston Scientific Wallstent Enteral Prosthesis

SUBSTANTIAL EQUIVALENCE

The Wallstent Enteral Endoprosthesis with Unistep Plus Delivery System is substantially equivalent to the currently marketed Enteral Wallstent K991056. There are actually three predicate stents, all Wallstents.

K954290 palliation of colonic strictures

K980113 palliation of duodenal strictures

K991056 use in malignant strictures prior to colectomy (bridge to surgery)¹

A table comparing the proposed device to the predicate is on page 8.

	Enteral Wallstent K000281	Enteral Wallstent (K991056)
USE		
Indication	Palliative treatment of colonic, duodenal (or gastric outlet obstruction) strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patient with malignant strictures	
Route of Administration	Endoscopic	
Stent sizes	18x90, 20x90, 22x90, 18x60, 20x60, 22x60	
DELIVERY SYSTEMS		
Catheter lengths	230cm, 135cm	230cm
Reconstrainable	Yes	No
MATERIALS		
Metal stent	Elgiloy	
Inner tube catheter	PEEK	Pellethane
Inner jacket of catheter	Pellethane	N/A
Outer Tube (OT)	Composite of OT components	Pebax
OT liner	PTFE	N/A
OT Jacket	Pebax	N/A
OT Weld Sleeve	Pebax	N/A
OT Braid	Stainless steel wire	N/A
Marker bands (inner tube and outer tube)	Platinum/Iridium	Tantalum (no outer tube marker band present)
Stent cup	Nylon 60	N/A
Tip adhesive	Dymax 190M	N/A

Unistep Plus Delivery Systems used to reconstrain stents have been used for other indications. The Unistep Plus Delivery System is almost identical to the delivery system used with the Tracheobronchial Wallstent. The differences are the clear distal exterior tube, length of the device, and use of silicone lubricant on the inner and outer assemblies. The clear distal exterior tube was incorporated to improve visualization during endoscopic placement. There are minor difference between the delivery system used with the biliary stent and the proposed delivery system. The biliary delivery systems utilize a tri-layer exterior tube. The inner jacket is not required due to the smaller diameter of the delivery system, and a different exterior tube material

10

K000281, Boston Scientific Wallstent Enteral Prosthesis

is utilized. The method used for deployment is the same. Reconstraint is slightly different in that the proposed delivery system holds the valve body stationary and pulling the inner assembly towards the user. The predicate Unistep Plus device reconstrains by holding the inner assembly stationary and pushing the valve body assembly away from the user.

STERILITY

The device will be sterilized using ethylene oxide by an outside contractor. Validation is accomplished by using a protocol consistent with the overkill method described in the AAMI 1988 guideline. The sterility assurance level is 10^{-6} the maximum residue levels are:

Ethylene oxide	250 ppm
Ethylene chlorohydrin	250 ppm
Ethylene glycol	5,000 ppm

Pyrogenicity – bacterial endotoxins will be monitored on a routine basis using LAL assay the modified enteral Wallstent will be released only if the endotoxin level is less than 0.5EU/m. The sensitivity of the pyrogen assay is 0.25EU/ml.

The modified enteral Wallstent will be packaged in a sterile double barrier seal, a PETG tray sealed with a Tyvek lid and a Tyvek/Mylar bag. This is the same method of packaging for the enteral Wallstent, K991056.

LABELING

The name of the device is the “Microvase Modified Enteral Wallstent”. The labeling contains a prescription statement, statements that the device is sterile, for single use only. The lot number, use before date and the company name and address are included. The sheath OD, the working length, minimum working channel, and stent size are also listed.

Instructions for Use

The user is told that the device is sterile, for single use only and not to reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and may also create a risk of contamination of the device.

The description of the device is that it is comprised of two components; the implantable metallic stent and the Unistep Plus Delivery System. Under Principles of Operation, the use of the device is described. A single operator can control deployment and implant the stent. The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. The stent deployment threshold is identified by the location of the limit marker band. Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the deployment process can be completed twice, allowing a total of three deployment attempts.

The Indications for Use reads “The Wallstent Enteral Endoprosthesis with Unistep Delivery System is indicated for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to

K000281, Boston Scientific Wallstent Enteral Prosthesis

colectomy in patients with malignant strictures.

The Contraindications are; enteral ischemia, suspected or impending perforation, and intra-abdominal abscess/perforation. [These are the same indication as in the labeling for the colonic and duodenal stents (K980113).]

Under Warnings – stents cannot be repositioned after the deployment threshold has been exceeded. [This warning has been modified from the labeling for K980113 which read “Stents cannot be repositioned after total deployment.”]

Under Precautions;

- The device is intended to be used by physicians who have received appropriate training.
- The system should not be resterilized.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspected to be compromised, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

[These precautions are identical to those in the labeling for K980113.]

Under Complication the user is told that the complications associated with the use of the device may include the usual complications reported for conventional stents and endoscopic procedures such as infection, stent misplacement, stent migration, intestinal perforation and stent obstructions secondary to tumor ingrowth through the stent, tumor overgrowth at the stent ends, or occlusion. [These complications are identical to those listed in the labeling for K980113. The Instructions for the proposed device continue with, post stent placement complications include: bleeding, perforation, pain, stent migration, tumor ingrowth through the stent, tumor overgrowth around ends of stent, foreign body sensation, bowel impaction, reflux, ulceration, fever, septicemia and death (other than that due to normal disease progression.)]

The section on “Preparation of the Instrument for Insertion” is almost identical to the labeling for K980113.

Under Procedure, the description of placement of the device under fluoroscopy or endoscopy (item 1, A and B; and 2) are almost identical to the labeling in the predicate K980113. There are some differences in the labeling for the description of deployment. In the predicate labeling the user is told that a stent that is partially deployed too far beyond the obstruction can be pulled back slightly or removed from the patient, providing no more than half the total stent length has been deployed. A stent once deployment begins, cannot be advanced. The labeling for the proposed device has instruction on how to reconstrain the stent once deployment has begun until the deployment threshold, identified by the location of the limit marker band, is reached. [The modifications to the delivery system are so that the stent can be reconstrained, this is why the labeling needed to be modified.] There is a Caution that reads “do not push forward on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible

12

K000281, Boston Scientific Wallstent Enteral Prosthesis

intestinal wall damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device.”

The instructions also contain a Caution that reads “do not reconstrain around tortuous anatomy as it may cause damage to the device.” The instructions for repositioning tell the user to first reconstrain the stent by holding the valve body stationary and gently pulling the stainless steel tube back. Under fluoroscopy, the stent will not be fully reconstrained until the leading marker band is even with the exterior tube marker band.

When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts. To remove a partially deployed stent, first reconstrain the stent. The entire delivery system can then be pulled into the endoscope. There is a caution that “A stent cannot be repositioned after the deployment threshold has been exceeded.”

After the stent is positioned and the delivery system removed, routine post implant radiographic procedures are performed to demonstrate location and patency of the stent.

The implanted stent length should allow for adequate overlapping into the non-obstructed anatomy to compensate for further tumor progression and stent shortening. If the stent does not adequately cover the obstruction, a second stent should be implanted providing adequate overlapping of the initially placed stent.

RECOMMENDATION

The Unistep Plus Delivery System for the Enteral Wallstent has been modified. The modifications are:

- The materials of the interior tube have been changed to increase pushability, reduce elongation, and allow for reconstraintment.
- The delivery system will be offered in a shorter, 135cm length for placement by interventional radiologists.

Sufficient information has been provided by the sponsor, Boston Scientific, Inc., for the modification to the Unistep Plus Delivery System allowing reconstraintment of the Wallstent Enteral Endoprosthesis. I am recommending that this device be found substantially equivalent.

Kathleen M. Olvey 5/19/00
Kathleen M. Olvey

C. Newland
5/11/00

K000281, Boston Scientific Wallstent Enteral Prosthesis

For the Unistep Plus Delivery System which has been modified:

- | | |
|---|-----|
| 1. Is the device life-supporting or life sustaining? | no |
| 2. Is the device implanted (short-term or long-term)? | no |
| 3. Is the device software-driven? | no |
| 4. Is the device sterile? | yes |
| 5. Is the device for single use? | yes |
| 6. Is the device for home use? | no |
| 7. Is the device for prescription use? | yes |
| 8. Does the device contain a drug or biological? | no |
| 9. Is this device a component of a kit? | no |

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:

14

K000281, Boston Scientific Wallstent Enteral Prosthesis

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

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:

Performance testing of the modified delivery system is needed to demonstrate that the new 1m step Delivery System is equivalent to the predicate currently marketed device

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:

Standard bench, in vitro, performance studies were performed. The device passed all tests and met the release specifications for the product. The data helps establish that the proposed device is substantially equivalent to the predicate device.

C. Neubund
5/11/00

15

Olvey, Kathleen M.

From: Shulman, Marjorie G.
Sent: Monday, April 10, 2000 1:49 PM
To: Olvey, Kathleen M.
Subject: FW: Class III Vs Class II

Kathy,

Heather's comments are below too. Thanks.

Marjorie Shulman
510(k) Staff
(301) 594-1190 x 144

-----Original Message-----

From: Rosecrans, Heather S.
Sent: Monday, April 10, 2000 1:23 PM
To: Shulman, Marjorie G.
Subject: RE: Class III Vs Class II

Marjie,
The only exception would be if they had pulled these out of the reclassification and kept them in class III. I only say this because I wasn't sure if it had happened or was about to happen.

Heather Rosecrans
510(k) Staff
(301) 594-1190 x143

-----Original Message-----

From: Shulman, Marjorie G.
Sent: Monday, April 10, 2000 10:15 AM
To: Olvey, Kathleen M.
Cc: Rosecrans, Heather S.
Subject: RE: Class III Vs Class II

Hi Kathy,

If we found the colonic stents SE to the expandable metal stents for esophageal indications using the same regulation number the colonic stents would be reclassified also. The reclassification applies to the regulation and anything we found SE to the regulation. Please let me know if you need anything else. Thanks.

Marjorie Shulman
510(k) Staff
(301) 594-1190 x 144

-----Original Message-----

From: Olvey, Kathleen M.
Sent: Sunday, April 09, 2000 12:25 PM
To: Shulman, Marjorie G.
Subject: Class III Vs Class II

Marjie,

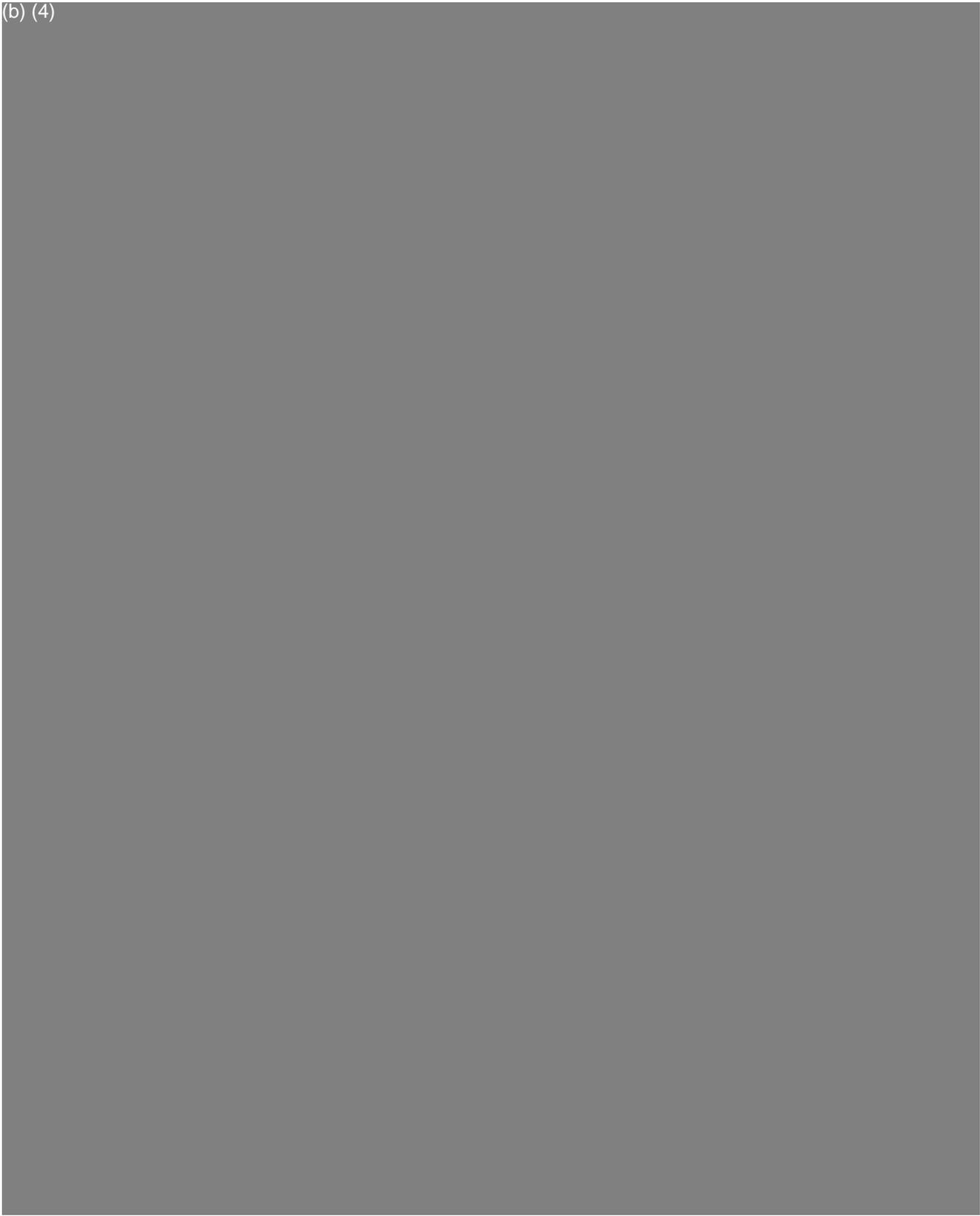
I heard that expandable metal stents for esophageal indications have been down classified from III to II. My question is what about colonic stents? They were Class III because for the first colonic stent, we stretched the predicate to the esophageal stents. So now that the colonic predicate is now Class II are my colonic stents Class II?

Thanks,
Kathy

PS I don't mind if they are now Class II.

16

(b) (4)



18

(b) (4)



19

RECOMMENDATION

The Unistep Plus Delivery System for the Enteral Wallstent has been modified. The modifications are:

(b) (4)



I believe that sufficient information has been provided for the modification to the Unistep Plus Delivery System allowing reconstraintment of the Wallstent Enteral Endoprosthesis. I am recommending that this device be found substantially equivalent.

Kathleen M. Olvey 5/9/00
Kathleen M. Olvey

C Newland
5/11/00

20

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

March 24, 2000

BOSTON SCIENTIFIC CORP.
ONE BOSTON SCIENTIFIC PL.
NATICK, MA 01760
ATTN: LISA M. QUAGLIA

510(k) Number: K000281
Product: WALLSTENT
INTERNAL
PROSTHESIS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

21

**DRAERD REVIEWER RECORD FOR ORIGINAL 510(K)S,
AND PMA AND IDE SUPPLEMENTS**

Document No. _____ Reviewer _____ Date Assigned _____

*CONSULTING REVIEWS DESIGNATED, AS APPROPRIATE, BY BRANCH CHIEF AND LEAD REVIEWER,
AT THE BEGINNING OF THE REVIEW:*

<u>SPECIALTY</u>	<u>REVIEW NEEDED?</u>		<u>REVIEWER</u>	<u>DATES</u>	
	YES	NO		SENT	RETURNED
CLINICAL	_____	_____	_____	_____	_____
ENGINEERING/ PHYSICS	_____	_____	_____	_____	_____
CHEMISTRY/ BIOMATERIALS	_____	_____	_____	_____	_____
SOFTWARE	_____	_____	_____	_____	_____
BIOLOGICAL/ STERILITY	_____	_____	_____	_____	_____
TOXICOLOGY/ BIOCOMPATIBILITY	_____	_____	_____	_____	_____
STATISTICS	_____	_____	_____	_____	_____
OTHER _____	_____	_____	_____	_____	_____

COMMENTS:

**REVISED 1/2/96 LMS
ON LAN AS REVREC.FRM**

28

QUALITY CONTROL OVERVIEW OF DOCUMENT

A. ASSOC. DIRECTOR QC OVERVIEW: MEDICAL QC OF SUBMISSION IS NECESSARY?

YES _____ NO _____ INITIALS/DATE _____

B. IF YES IS NOTED ABOVE, MEDICAL OFFICER QC OVERVIEW:

1. Examination of the specialty reviews indicate there are remaining clinical issues that should be addressed (See attached sheet for summary).

INITIALS/DATE _____

2. In my opinion, all pertinent clinical issues have been adequately addressed.

FINAL SIGNOFF: MEDICAL OFFICER/DATE _____

FINAL SIGNOFF: ASSOC. DIRECTOR/DATE _____

REVISED: 1/2/96 LMS
LOCATED ON LAN AS REVREC.FRM

23

K000281/S'

**Boston
Scientific**
MICROVASIVE

Microvative Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508.650.8000
www.bsci.com

March 23, 2000

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

SUBJECT: 510(k) K000281/A1 Modified Enteral Wallstent®

Dear Sir/Madam:

Boston Scientific Corporation is submitting this Amendment in response to FDA's March 6, 2000, request for additional information for 510(k) K000281, Modified Enteral Wallstent®. Each question below is in boldface italics and each response is in normal typeface. Please find below the questions and responses to FDA's questions.

RECEIVED
21 MAR 00 11 35
FDA/CDRH/OCE/DID

(b) (4)



24

4K
11

510(k) K000281/A1

Modified Enteral Wallstent

March 23, 2000

Page 2

(b) (4)



25

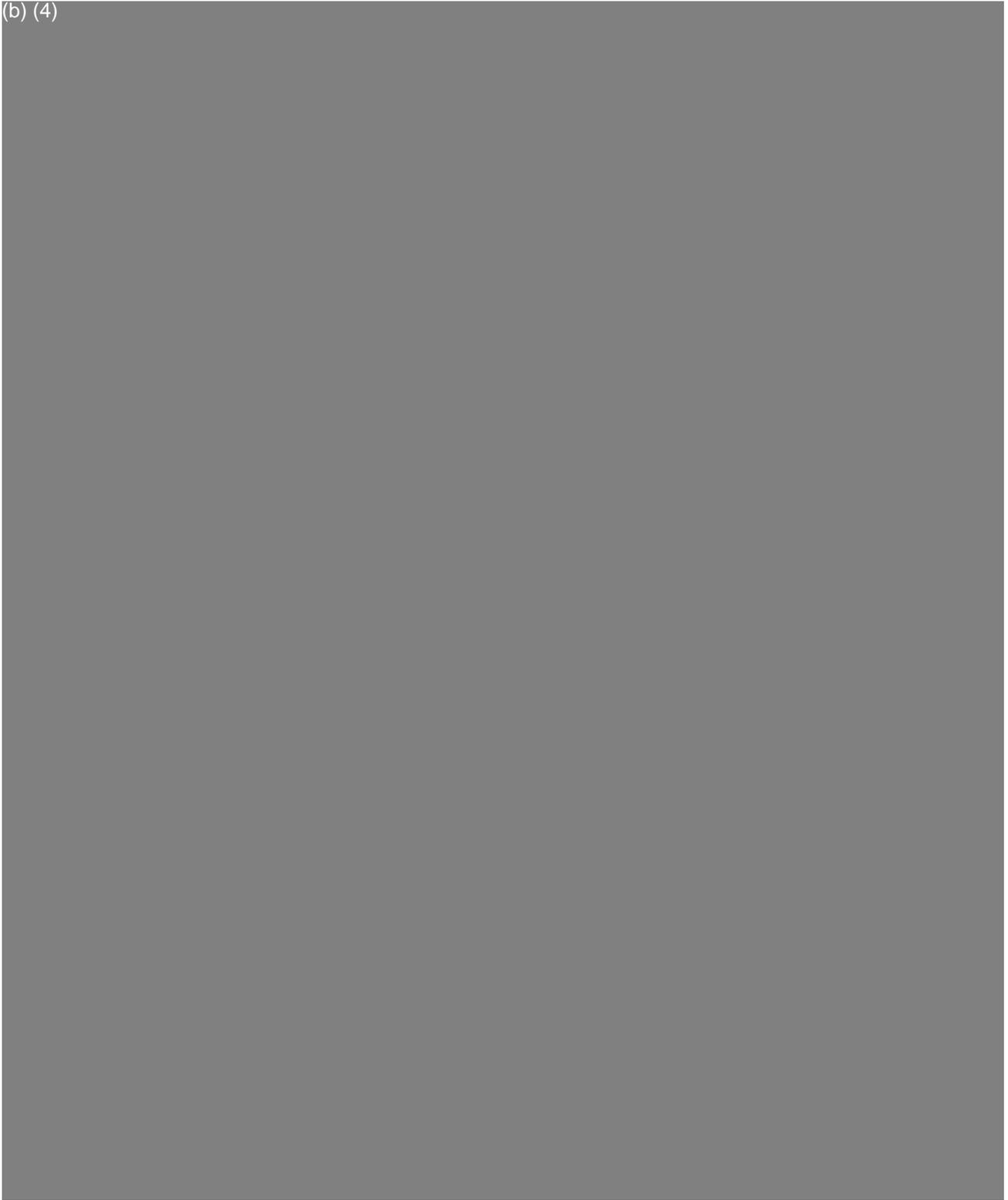
510(k) K000281/A1

Modified Enteral Wallstent

March 23, 2000

Page 3

(b) (4)



The following additional information is also being submitted:

24

510(k) K000281/A1

Modified Enteral Wallstent

March 23, 2000

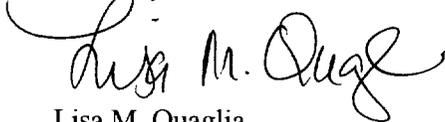
Page 4

- **Confidentiality:** Boston Scientific Corporation considers its intent to manufacture this device for distribution under its own label to be confidential commercial information, and therefore exempt from public disclosure. Boston Scientific Corporation understands that the data contained in this Amendment will be restricted from release under the Freedom of Information Act until FDA has issued a determination of substantial equivalence.
- **Post-Market Surveillance:** It is the understanding of Boston Scientific Corporation that FDA does not presently require the submission of postmarket surveillance plans for 510(k) devices and that manufacturers will be notified when such requirements become applicable.

Boston Scientific Corporation believes that the responses above will provide satisfactory information for the FDA to complete its review of this 510(k) submission and make a determination of substantial equivalence.

Per 21 CFR § 807.90(c), two copies of this Amendment are submitted. Please feel free to contact me at 508-650-8267 should you have any additional questions. Thank you.

Sincerely,



Lisa M. Quaglia
Regulatory Affairs Manager

27

Appendix A Declaration of Conformity for Biocompatibility

28

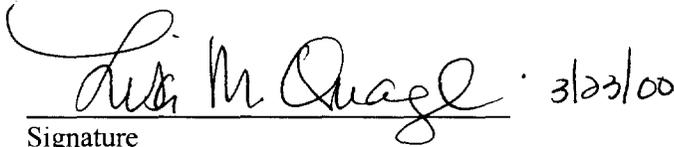
Declaration of Conformity to a Recognized Standard

As a responsible representative of Boston Scientific Corporation, I hereby certify that the material 63D Pebax, was tested in accordance with the International Standard ISO-10993, Biological evaluation of Medical Devices Part-1: Evaluation and Testing. Specifically, the following tests were performed and all requirements were met in accordance to the ISO-10993 standard:

Cytotoxicity Mem Elution
Indirect Hemolysis
AMES Mutagenicity
Systemic Injection
Intrautaneous Injection
Rabbit Pyrogen
Skin Sensitization, Kligman
Hemocompatibility Assay In Vitro
Complement Activation
Prothrombin Time

An outside laboratory performed these tests. This laboratory is Toxicon, 15 Wiggins Avenue, Bedford, MA 01730.

Signed by:

 3/23/00

Signature

Lisa M. Quaglia

Print Name

Regulatory Affairs Manager

Title

29

Appendix B Device Drawings

30

Records processed under FOIA Request 2014-6600; Released 10/16/14

Records processed under FOIA Request 2014-6600; Released 10/16/14

Records processed under FOIA Request 2014-6600; Released 10/16/14

Appendix C Revised Instructions for Use

35

DRAFT INSTRUCTIONS FOR USE

MICROVASIVE® Modified Enteral Wallstent®

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

MICROVASIVE®

Boston Scientific Corporation

480 Pleasant Street

Watertown, MA 02172

(617) 923-1720

Customer Service: (800) 225-3226

Rev. 0, 3/00

Sterile. For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DESCRIPTION

The Wallstent® Enteral Endoprosthesis is comprised of two components: the implantable metallic stent and the Unistep™ Plus Delivery system (reference Figure A). The stent is composed of biomedical super alloy monofilament wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in. / 0,89 mm guide wire. The device may be inserted through the working channel of an endoscope (minimum channel diameter 3.7 mm).

PRINCIPLE OF OPERATION

The exterior tube is easily retracted by immobilizing the stainless steel tube in one hand, grasping the valve body with the other hand, and gently sliding the valve body along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the stent from constraint. A single operator can thus control deployment and implant the stent.

The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. The stent deployment threshold, the point beyond which the stent cannot be reconstrained, is identified by the location of the limit marker band (Figure A.). Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the deployment process can be completed twice, allowing a total of three deployment attempts.

INDICATIONS FOR USE

The Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery system is indicated for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

CONTRAINDICATIONS

Contraindications associated with the use of the Wallstent® Enteral Endoprosthesis include:

- Enteral ischemia.
- Suspected or impending perforation.
- Intra-abdominal abscess / perforation.

WARNINGS

- Stents cannot be repositioned after the deployment threshold has been exceeded.

PRECAUTIONS

- The device is intended for use by physicians who have received appropriate training.
- The system should not be resterilized.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspected to be compromised, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

COMPLICATIONS

Complications associated with the use of the Wallstent® Enteral Endoprosthesis may include the usual complications reported for conventional stents and endoscopic procedures such as infection, stent misplacement, stent migration, intestinal perforation and stent obstruction secondary to tumor ingrowth through the stent, tumor overgrowth at the stent ends, or occlusion.

POST STENT PLACEMENT COMPLICATIONS

- Bleeding
- Perforation
- Pain
- Stent migration
- Tumor ingrowth through stent
- Tumor overgrowth around ends of stent
- Foreign body sensation
- Bowel impaction

37

- Reflux
- Ulceration
- Fever
- Septicemia
- Death (other than that due to normal disease progression)

PREPARATION OF THE INSTRUMENT FOR INSERTION

1. Recommended Material for Implant

Prepare the following material using sterile technique:

- 10 cc syringe filled with sterile saline.
- 0.035 in. / 0,89 mm guide wire of appropriate length.

2. Length Selection

Having calculated the obstruction length, allowing for possible further tumor development and post implant stent shortening (due to continued expansion), determine the number of stents necessary to cross the obstruction. Should multiple stents be required to cover the obstruction, place the leading stent first followed by the trailing stent(s), and allow for generous overlapping.

3. Initial preparation of instrument

- Carefully remove the delivery system from its protective packaging.
- Visually inspect the entire system for damage.
- Visually check that the leading end of the stent is covered by the exterior tube.
- Ensure that no stent wires have perforated the exterior tube.

4. Priming the delivery system

- Attach a 10 cc syringe filled with sterile saline to stopcock on extension tube.
- Holding the device horizontally, open the stopcock and flush until fluid is visible at the tip.
- After priming the delivery system, close the stopcock and remove the syringe.
- Reverify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved towards the trailing end, exposing the ends of the stent wires. Proper device function cannot be assured during implant, and such use may cause intestinal injury.

PROCEDURE

1. The Wallstent® Enteral Endoprosthesis can be placed with the aid of flouroscopy or under direct visualization with an endoscope or the combination of both.
 - A. Flouroscopy Procedure

Pass a 0.035 in. / 0,89 mm guide wire to the level of the obstruction. The guide wire is maneuvered until the wire transverses the obstructed area. The Wallstent® Enteral Endoprosthesis is threaded over the guide wire and guided to the level of the obstruction under fluoroscopy. Advance the stent across the obstruction until the leading marker band is at least 2 centimeters beyond the obstruction. The trailing marker band should be at least 2 centimeters beyond the trailing end of the obstruction. If there is not at least 2 centimeters on both sides of the obstruction, a longer stent may be required or a second overlapping stent may be used to adequately cross the obstruction.

B. Endoscopic Procedure

Pass an endoscope to the level of the obstruction. Under direct visualization, pass a 0.035 in. / 0,89 mm guide wire through the working channel of the scope and maneuver the guide wire across the obstruction. The guide wire can be used to estimate the length of the obstruction, and the trailing stent end is endoscopically visible by the transition from colored to clear exterior tube region. However, radiographic aids may be more accurate to estimate the obstruction length. A Wallstent® Enteral Endoprosthesis with an unconstrained length of 2-4 centimeters longer than the measured obstruction is threaded over the guide wire and passed to the level of the obstruction. The stent is passed through the obstruction with the leading marker band placed approximately 2 centimeters beyond the obstruction. (Radiographic aid may be required to accurately make this placement.)

2. The radiopaque marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. In order to assure precise placement, radiographic and endoscopic visualization of the stent itself is necessary.
3. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and *gently slide the valve body back along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached by the exterior marker band.*

CAUTION: Do not push forward on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible intestinal wall damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device. To remove the device, see step 6 below.

4. **CAUTION:** Do not reconstrain around tortuous anatomy as it may cause damage to the device.

Asses stent position and reposition if desired. To reposition, first reconstrain the stent by holding the valve body stationary and gently pulling the stainless steel tube back. Under fluoroscopy, the stent will not be fully reconstrained until the leading marker band is even with the exterior tube marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

As an alternative method for proximal repositioning (toward the user) only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

5. To complete stent deployment immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

CAUTION: A stent cannot be repositioned after the deployment threshold has been exceeded.

39

6. To remove a partially deployed stent, first reconstrain the stent (see step 4). The entire delivery system can be pulled into the endoscope. The delivery system and endoscope can then be removed, with the guide wire left in place.

As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

7. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.
8. Using standard operative procedures, perform routine post implant radiographic procedures to demonstrate location and patency of the stent.
9. The implanted stent length should allow for adequate overlapping into the non-obstructed anatomy to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the obstruction, a second stent should be implanted providing adequate overlapping of the initially placed stent.

HOW SUPPLIED

The *Modified Enteral Wallstent*® is supplied sterile by method of Ethylene Oxide. If the catheter package is opened or damaged, do not use or re-sterilize the device.

STORAGE

Store in a cool, dry place.

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

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Microvasive is a registered trademark of Boston Scientific Corporation.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

MAR , 6 2000

Re: K000281
Wallstent® Enteral Prosthesis
Dated: January 28, 2000
Received: January 31, 2000

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

(b) (4)



Page 2 – Ms. Lisa Quaglia

(b) (4)



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

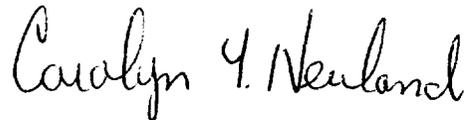
48

Page 3 – Ms. Lisa Quaglia

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

If you have any questions concerning the contents of this letter, please contact Ms. Kathleen Olvey at (301) 594-1220. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal
Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

43

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

General Program Memorandum - #G95-1

Date . MAY 1 1995

From Director, Office of Device Evaluation (ODE)

Subject Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"

To ODE Reviewing Staff

Purpose

The purpose of this memo is to replace, after July 1, 1995, the use of ODE General Program Memorandum G87-1, entitled "Tripartite Biocompatibility Guidance", dated April 24, 1987 with Part-1 of the ISO standard "Biological Evaluation of Medical Devices", which includes an FDA-modified matrix.

Background

Biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The device materials should not, either directly or through the release of their material constituents:

- (i) produce adverse local or systemic effects;
- (ii) be carcinogenic;
- or, (iii) produce adverse reproductive and developmental effects.

Therefore, evaluation of any new device intended for human use requires data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by device materials.

When selecting the appropriate tests for biological evaluation of a medical device, one must consider the chemical characteristics of device materials and the nature, degree, frequency and duration of its exposure to the body. In general, the tests include: acute, sub-chronic and chronic toxicity; irritation to skin, eyes and mucosal surfaces; sensitization; hemocompatibility; genotoxicity; carcinogenicity; and, effects on reproduction including developmental effects. However, depending on varying characteristics and intended uses of devices as well as the nature of contact, these general tests may not be sufficient to demonstrate the safety of some specialized devices. Additional tests for specific target organ toxicity, such as neurotoxicity and immunotoxicity may be necessary for some devices. For example, a neurological device with direct contact with brain parenchyma and cerebrospinal fluid (CSF) may require an animal implant test to evaluate its effects on the brain parenchyma, susceptibility to seizure, and effects on the functional mechanism of choroid plexus and arachnoid villi to secrete and absorb (CSF). The specific clinical application and the materials used in the manufacture of the new device determines which tests are appropriate.

44

General Program Memorandum - #095-1 - Page 2

Some devices are made of materials that have been well characterized chemically and physically in the published literature and have a long history of safe use. For the purposes of demonstrating the substantial equivalence of such devices to other marketed products, it may not be necessary to conduct all the tests suggested in the FDA matrix of this guidance. FDA reviewers are advised to use their scientific judgement in determining which tests are required for the demonstration of substantial equivalence under section 510(k). In such situations, the manufacturer must document the use of a particular material in a legally marketed predicate device or a legally marketed device with comparable patient exposure.

International Guidance and Standards

In 1986, FDA, Health and Welfare Canada, and Health and Social Services UK issued the Tripartite Biocompatibility Guidance for Medical Devices. This Guidance has been used by FDA reviewers, as well as by manufacturers of medical devices, in selecting appropriate tests to evaluate the adverse biological responses to medical devices. Since that time, the International Standards Organization (ISO), in an effort to harmonize biocompatibility testing, developed a standard for biological evaluation of medical devices (ISO 10993). The scope of this 12-part standard is to evaluate the effects of medical device materials on the body. The first part of this standard "Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing", provides guidance for selecting the tests to evaluate the biological response to medical devices. Most of the other parts of the ISO standard deal with appropriate methods to conduct the biological tests suggested in Part 1 of the standard.

ISO 10993, Part 1, and the FDA-modified Matrix

The ISO Standard, Part 1, uses an approach to test selection that is very similar to the currently-used Tripartite Guidance, including the same seven principles. It also uses a tabular format (matrix) for laying out the test requirements based on the various factors discussed above. The matrix consist of two tables. See Attachment A, Table 1 - Initial Evaluation Tests for Consideration, and Attachment B, Table 2 - Supplementary Evaluation Tests for Consideration. Attachment C is a biocompatibility flow chart for the selection of toxicity tests for 510(k)s. It may be applicable to some PMAs also but not all PMAs. In addition, FDA is in the process of preparing toxicology profiles for specific devices. These profiles will assist in determining appropriate toxicology tests for these devices.

To harmonize biological response testing with the requirements of other countries, FDA will apply the ISO standard, Part 1, in the review process in lieu of the Tripartite Biocompatibility Guidance.

FDA notes that the ISO standard acknowledges certain kinds of discrepancies. It states "due to diversity of medical devices, it is recognized that not all tests identified in a category will be necessary and practical for any given device. It is indispensable for testing that each device shall be considered on its own merits: additional tests not indicated in the table may be necessary." In keeping with this inherent flexibility of the ISO standard, FDA has made several modifications to the testing required by ISO 10993-Part 1. These modifications are required for the category of surface devices

45

General Program Memorandum - #G95-1 - Page 3

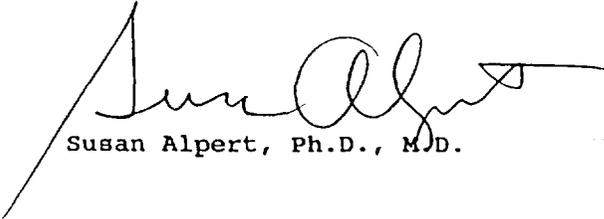
permanently contacting mucosal membranes (e.g., IUDs). The ISO standard would not require acute, sub-chronic, chronic toxicity and implantation tests. Also, for externally communicating devices, tissue/bone/dentin with prolonged and permanent contact (e.g., dental cements, filling materials etc.), the ISO standard does not require irritation, systemic toxicity, acute, sub-chronic and chronic toxicity tests. Therefore, FDA has included these types of tests in the matrix.

Although several tests were added to the matrix, reviewers should note that some tests are commonly requested while other tests are to be considered and only asked for on a case-by-case basis. Thus, the modified matrix is only a framework for the selection of tests and not a checklist of every required test. Reviewers should avoid proscriptive interpretation of the matrix. If a reviewer is uncertain about the applicability of a specific type of test for a specific device, the reviewer should consult toxicologists in ODE.

FDA expects that manufacturers will consider performing the additional tests for certain categories of devices suggested in the FDA-modified matrix. This does not mean that all the tests suggested in the modified matrix are essential and relevant for all devices. In addition, device manufacturers are advised to consider tests to detect chemical components of device materials which may be pyrogenic. We believe that ISO 10993, Part 1, and appropriate consideration of the additional tests suggested by knowledgeable individuals will generate adequate biological data to meet FDA's requirements. Reviewers in the Office of Device Evaluation will accept data developed according to the ISO-10993, Part 1, with the matrix as modified and presented in this memorandum (#G95-1).

Manufacturers are advised to initiate discussions with the appropriate review division in the Office of Device Evaluation, CDRH, prior to the initiation of expensive, long-term testing of any new device materials to ensure that the proper testing will be conducted. We also recognize that an ISO standard is a document that undergoes periodic review and is subject to revision. ODE will notify manufacturers of any future revisions to the ISO standard referenced here that affect this document's requirements and expectations.

Effective Date: This Guidance is effective for all submissions that will be received on or after July 1, 1995. The former guidance, G87-1 entitled "Tripartite Biocompatibility Guidance," may continue to be applied until a final decision is reached on each submission received prior to July 1, 1995. Sponsors may, however, choose to follow this new memorandum immediately. After this transition period for submissions covered by the Tripartite Biocompatibility Guidance, G87-1 will be recinded and replaced by this guidance.


Susan Alpert, Ph.D., M.D.

General Program Memorandum - #G95-1
Attachment A

Table 1 - Initial Evaluation Tests for Consideration.*

Device Categories			Biological Effect							
Body contact (see 4.1)	Contact duration (see 4.2)		Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Systemic toxicity (acute)	Sub-chronic toxicity (sub-acute toxicity)	Genotoxicity	Implantation	Haemocompatibility
Surface devices	Skin	A	X	X	X					
		B	X	X	X					
		C	X	X	X					
	Mucosal membrane	A	X	X	X					
		B	X	X	X	O	O		O	
		C	X	X	X	O	X	X	O	
	Breached or compromised surfaces	A	X	X	X	O				
		B	X	X	X	O	O		O	
		C	X	X	X	O	X	X	O	
External communicating devices	Blood path, indirect	A	X	X	X	X				X
		B	X	X	X	X	O			X
		C	X	X	O	X	X	X	O	X
	Tissue/bone/dentin communicating ¹	A	X	X	X	O				
		B	X	X	O	O	O	X	X	
		C	X	X	O	O	O	X	X	
	Circulating blood	A	X	X	X	X		O ²		X
		B	X	X	X	X	O	X	O	X
		C	X	X	X	X	X	X	O	X
Implant Devices	Tissue/bone	A	X	X	X	O				
		B	X	X	O	O	O	X	X	
		C	X	X	O	O	O	X	X	
	Blood	A	X	X	X	X			X	X
		B	X	X	X	X	O	X	X	X
		C	X	X	X	X	X	X	X	X

X = ISO Evaluation Tests for Consideration
 O = Additional Tests which may be applicable
 Note ¹ Tissue includes tissue fluids and subcutaneous spaces
 Note ² For all devices used in extracorporeal circuits

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

*See Table 2 for Supplementary Evaluation Tests

47

General Program Memorandum - #G95-1
Attachment B

Table 2 - Supplementary Evaluation Tests for Consideration. *

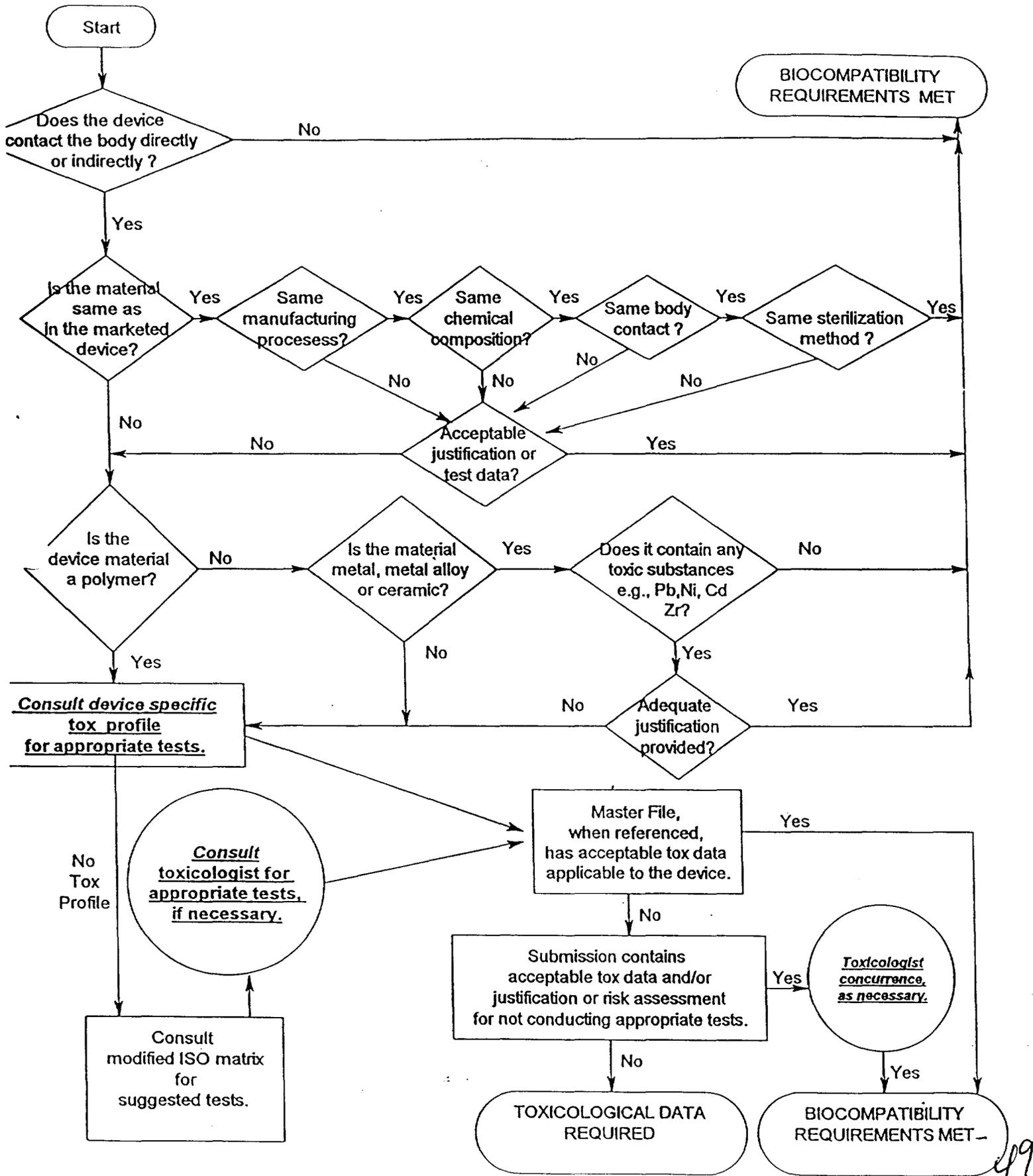
Device Categories			Biological Effect			
Body contact (see 4.1)	Contact duration (see 4.2)		Chronic toxicity	Carcinogenicity	Reproductive/Developmental	Biodegradation
Surface devices	Skin	A				
		B				
		C				
	Mucosal membrane	A				
		B				
		C	0			
	Breached or compromised surfaces	A				
		B				
		C	0			
External communicating devices	Blood path, indirect	A				
		B				
		C	X	X		
	Tissue/bone/dentin communicating	A				
		B				
		C	0	X		
	Circulating blood	A				
		B				
		C	X	X		
Implant Devices	Tissue/bone	A				
		B				
		C	X	X		
	Blood	A				
		B				
		C	X	X		

X = ISO Evaluation Tests for Consideration
0 = Additional Tests which may be applicable

*See Table 1 for Initial Evaluation Tests. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

48

Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s



49

MAR 6 2000

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K000281
Wallstent® Enteral Prosthesis
Dated: January 28, 2000
Received: January 31, 2000

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

(b) (4)



SD

Page 2 – Ms. Lisa Quaglia

(b) (4)



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

51

Page 3 – Ms. Lisa Quaglia

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

If you have any questions concerning the contents of this letter, please contact Ms. Kathleen Olvey at (301) 594-1220. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal
Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401
HFZ-404
HFZ-470
D.O.

KMO:lrn:3.1.2000

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z-470	Olvey-1	3/2/00						
HFZ-470	Neuland	3/3/00						

58

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Kathleen Olvey

Subject: 510(k) Number K000281

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

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

De Novo Classification Candidate? YES NO

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

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

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed (required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

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

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

Predicate Product Code with class:

878.3610

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

53

Class III 78 MAR, 78 MUM,

Review: Carilyn Y Newland
(Branch Chief)

GRDB
(Branch Code)

3/3/00
(Date)

3/6/00
JME

Final Review: _____
(Division Director)

(Date)

K000281, Boston Scientific Wallstent Enteral Prosthesis

Modifications are being proposed to improve the ease of use and/or manufacture of the delivery system. The modifications are:

- The materials of the interior tube have been changed to increase pushability, reduce elongation, and allow for reconstraintment.
- The delivery system will be offered in a shorter, 135cm length for placement by interventional radiologists.

In addition, the delivery system can now be used to reconstrain the stent if the threshold deployment limit has not been reached.

→I am not sure exactly what material has been changed. The interior tube durometer has been changed, but the sponsor has not identified the new material and has not provided the results of biocompatibility testing. In addition, it appears that the material used in the outer tube jacket/weld sleeve has been changed to the same material used in the currently marketed Wallstent and the colorant used in the tracheobronchial stent. This should be clarified. The diagram provided does not show the outer tube braid, the inner jacket, the stent cup, the holding sleeve, or the outer tube liner. I think that some of these components might be listed as something else in the diagram but I'm not sure. According to the table in the section on substantial equivalent the following changes have been made to the delivery system. I think that the components listed for the proposed device but identified by N/A in the predicate device are new components. This needs to be clarified.

	Enteral Wallstent K000281	Enteral Wallstent (K991056)
MATERIALS		
Inner tube catheter	PEEK	Pellethane
Inner jacket of catheter	Pellethane	N/A
Outer Tube (OT)	Composite of OT components	Pebax
OT liner	PTFE	N/A
OT Jacket	Pebax	N/A
OT Weld Sleeve	Pebax	N/A
OT Braid	Stainless steel wire	N/A
Marker bands (inner tube and outer tube)	Platinum/Iridium	Tantalum (no outer tube marker band present)
Stent cup	Nylon 60	N/A
Tip adhesive	Dymax 190M	N/A

56

K000281, Boston Scientific Wallstent Enteral Prosthesis

The modified Enteral Wallstent will be available in several configurations:

Working Length	Stent Diameter	Stent Length	Working Length	Stent Diameter	Stent Length
230	18mm	60mm	135	18	60
230	18mm	90mm	135	18	90
230	20mm	60mm	135	20	60
230	20mm	90mm	135	20	90
230	22mm	60mm	135	22	60
230	22mm	90mm	135	22	90

After a stricture has been identified in the colon or duodenum, the delivery system is advanced over a guidewire to the site of the stricture through an endoscope with the aid of endoscopic and/or fluoroscopic visualization. Once in position, the outer sheath is retracted to begin release of the stent from the delivery system. If the stent requires repositioning, the stent may be repositioned if the threshold for reconstraint has not been reached. Placement of the stent may be confirmed fluoroscopically.

PERFORMANCE TESTING (page 19)

Testing performed on the modified enteral Wallstent included:

- Stent dimensional conformance test
- Deployment force
- Withdrawal
- Priming and Trackability test
- Bond strengths
- Delivery system dimensions

Each product sample was sterilized. It should be noted that only the longer stent length was tested (90mm) however, both lengths of the delivery catheter (230 and 135cm) were tested for all stent diameters (18, 20 and 22 mm). According to the sponsor, the longer length, 90mm, stent was chosen, as the longer stent will challenge the performance greater than the shorter, 60mm, stent. The sponsor will validate all sizes prior to market release.

Working Length	Stent Size	Number
230cm	18x90	15
230cm	20x90	15
230cm	22x90	15
135cm	18x90	15
135cm	20x90	15
135cm	22x90	15

Stent dimensional conformance test (delivery system dimensions, page 20) – the purpose of

57

K000281, Boston Scientific Wallstent Enteral Prosthesis

this test was to confirm the dimensions of the stent post deployment with the Unistep Plus Delivery System. For each device tested, the working length, overall length, and marker band spacing was measured. A laser micrometer was used to measure the outside diameter at the exterior marker band, the clear section over the stent, the weld, and the blue working area. For each measurement, the minimum and maximum values were compared against the specification.

The acceptance criteria are listed in the following table.

Measurement	Size	Acceptance Criteria	Results
Overall length	230cm	255.0cm \pm 1.5cm	Passed
Overall length	135cm	160.0cm \pm 1.5cm	Passed
Working length	230cm	230cm \pm 1.5cm	Passed
Working length	135cm	135cm \pm 1.5cm	Passed
OD @ marker band	230 & 135	0.131" \pm 0.006	Passed
OD @ clear region	230 & 135	0.131" \pm 0.006	Passed
OD @ braid	230 & 135	0.131" \pm 0.006	Passed
OD @ weld	230 & 135	0.131" \pm 0.006	Passed
Marker band spacing	18x90	152mm \pm 1mm	Passed (151-153)
Marker band spacing	20x90	170mm \pm 1mm	Failed (165.5 – 168)
Marker band spacing	22x90	177mm \pm 1mm	Failed 174 - 176

According to the protocol, 90 samples were to be tested, 15 units for each size. However, the number of samples tested for the 135cm-length delivery system was only 14, 10, and 13 for the 18x90, 20x90, and 22x90 length stents. Some units were lost prior to testing so instead of 45 total samples there were only 37 samples.

The results of the testing are on pages 21-23. The sponsor's acceptance criteria were met for each of the tests except for marker band spacing. According to the sponsor, this setting is easy to control and does not raise serious concerns over the design of the delivery system. The template used to set the marker band settings was preliminary template. Prior to building production product, this template will be calibrated and validated. Product will not be released until complete validated models have been implemented. Comment: this explanation is acceptable.

In addition, testing of the outside diameter at the exterior marker band, over the stent in the clear braidless region and at the weld was done with the new durometer of the clear outer braidless region of the delivery system. The new durometer material was used because it was observed that during the reconstraint testing of the 135cm units, this region of the delivery system buckled. Additional testing was conducted on the 230cm and 135cm length delivery systems with 18x90 diameter stents. The samples passed the testing.

K000281, Boston Scientific Wallstent Enteral Prosthesis

Priming and trackability test (page 24) – the purpose of this test was to verify adequate fluid flow and trackability in a simulated model. The same units tested for stent dimensions were used for this test. Each device was primed with a 10cc syringe and water prior to testing. The delivery system was then passed over a .035” guidewire and inserted into a simulated model for trackability testing.

The acceptance criteria for priming were the presence of fluid exiting the distal end of the delivery system. The acceptance criteria for trackability was that each system shall track thorough the test model without incurring visible or functional damage. All samples passed the testing (page 24).

Deploy and reconstrain test (page 25) – the purpose of this test was to verify acceptable deployment and reconstraint forces. The test units used for this test were then used for priming and tracking testing. From each lot, 5 stents were fully deployed (3rd deploy) in the model. The remaining stents were tested for withdrawal and stent dimensions. Each device was taken through two deploy and reconstrain cycles using a simulated model prior to full deployment or withdrawal. The maximum force for each deployment and reconstrain were measured.

The acceptance criteria for deployment and reconstraint is $\geq .25$ lbs and ≤ 7.5 lbs. The results begin on page 26. All of the stents deployed with a force greater than .25 lbs. The averages ranged from 3.5 to 6.3 depending on the size. All of the samples tested met the acceptance criteria.

The sponsor noted that buckling of the clear outer braidless region of the delivery system was observed during the reconstraint testing of the 135 cm units. They made a modification to the durometer of the clear material encasing the PTFE and testing was conducted again. The results are in Table 6-11 on page 27. The samples tested met the acceptance criteria. The sponsor notes that for two samples the holding sleeve was either loose or slipped during reconstraint of the stent. The sponsor states that this failure mode was recreated and verified to be size related. They implemented a Go/NoGo gauge during manufacture of the product until validations are completed to ensure that this failure does not occur in the future. The sponsor has accepted the data with the corrective actions in place. The product will not be released until complete validated models have been implemented.

Withdrawal test (page 28) – the purpose of this test was to verify acceptable withdrawal when a stent is partially deployed. Five units from each lot of the 230cm length delivery system were tested (15 total). Each device was partially deployed and the stent should have remained attached to the delivery system as it is withdrawn from the model.

The acceptance criteria for withdraw is that the partially deployed stent shall remain attached to the delivery system after being withdrawn from the model. All samples passed this test.

K000281, Boston Scientific Wallstent Enteral Prosthesis

→ Why were the 135cm delivery systems not tested?

Stent dimensions test (page 29) – this test was done to verify the dimensions of the stent. Ten (10) units from each lot were tested. The length and diameter for each device was measured. The acceptance criteria for stent diameter is nominal $\pm 10\%$. Stent length is dependent upon diameter of the stent and set by marker band spacing on the delivery system. The stent length measured free standing is indicated for reference. The results are in the tables on page 29. The acceptance criteria have been met.

Bond strengths (page 30) – the purpose of this test was to verify acceptable bond strengths to withstand normal use of the device. The same units used for deploy and reconstrain testing were used to verify bond tensile strength for a total of 78 units. Since the bonds are common to all models, the sponsor pooled the data. The bonds to be tested and the inclusion criteria are:

BOND	ACCEPTANCE CRITERIA
Distal tip bond	≥ 4.5 lbs
Interior tube bond to the stainless steel tube	≥ 8.0 lbs
Valve body to the exterior tube bond	≥ 8.0 lbs
Stainless steel tube to the hub bond	≥ 8.0 lbs
Outer tube weld	≥ 8.0 lbs
Holding sleeve to exterior tube marker band	All holding sleeves must remain fully encapsulated post deployment

The results are in the table on page 31.

The average bond tensile strength results are:

Distal tip bond	11.85 lbs
Stainless steel tube to interior tube	18.78 lbs
Valve body to exterior tube bond	15.09 lbs
Stainless steel tube to hub	37.61 lbs
Outer tube weld*	9.89 lbs
Outer tube weld	11.39 lbs

*The minimum for the outer tube weld was 6.02 lbs. which is below the acceptance criteria. The sponsor states that although this weld did not meet the acceptance criteria, further evaluation conducted to review the actual force required to deploy the stent only. This data was measured between 3.16 and 3.49 lbs. The outer tube weld specification will be revised to be 6 lbs. minimum. The sponsor believes that this new acceptance criteria still leaves an acceptable safety margin in the difference between outer tube weld and peak force to deploy the stent. The second set of values for the outer tube weld was taken during the retest of the deploy/reconstrain with the change in durometer, as this change may have effected the outer tube weld.

The visualization of the holding sleeve/exterior tube marker band attachment showed that all samples passed this testing.

60

K000281, Boston Scientific Wallstent Enteral Prosthesis

BIOCOMPATIBILITY

The sponsor states that the materials in the proposed device are identical to materials currently used in other legally marketed Wallstents.

Component	Material	Material also used in...
Hub, Valve Body, Cap	Lexan HPS1-803	Wallstent tracheobronchial stent with Unistep Plus Delivery System (K890163, K964121, K961507, K961296)
Hub adhesive	Sicoment 8400	Same as above
Stainless steel tube, outer tube braid	Stainless steel 304	Same as above
Inner tube	PEEK	Same as above
Inner Jacket, Tip, extension tube	Pellethane	Same as above
IM adhesive	Sicoment 40	Same as above
Stent cup	Nylon 60	Same as above
Marker bands	Platinum/iridium	Same as above
Holding sleeve	Tecothane	Same as above
Tip adhesive, VB adhesive	Dymax	Same as above
Stopcock	Polycarbonate	Same as above
O-ring	Silicone	Same as above
Outer tube liner	PTFE	Same as above
Outer tube jacket/weld sleeve*	Pebax	Same as above for the colorant Currently marketed Enteral Wallstent (Pebax) K991056, K980113, K954290
Coatings w/Heptane	Silicone	Currently marketed Enteral Wallstent
Stent	Elgiloy	Currently marketed Enteral Wallstent

*Although the same base material is used, Pebax, a different durometer has been incorporated for the outer tube jacket from that used for the predicate device.

SUBSTANTIAL EQUIVALENCE

The sponsor states that the proposed device is substantially equivalent to the currently marketed Enteral Wallstent K991056. There are actually three predicate stents, all Wallstents.

K954290 palliation of colonic strictures
 K980113 palliation of duodenal strictures
 K991056 use in malignant strictures prior to colectomy (bridge to surgery)

K000281, Boston Scientific Wallstent Enteral Prosthesis

A table comparing the proposed device to the predicate is on page 8.

	Enteral Wallstent K000281	Enteral Wallstent (K991056)
USE		
Indication	Palliative treatment of colonic, duodenal (or gastric outlet obstruction) strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patient with malignant strictures	
Route of Administration	Endoscopic	
Stent sizes	18x90, 20x90, 22x90, 18x60,20x60, 22x60	
Delivery Systems		
Catheter lengths	230cm, 135cm	230cm
Reconstrainable	Yes	No
MATERIALS		
Metal stent	Elgiloy	
Inner tube catheter	PEEK	Pellethane
Inner jacket of catheter	Pellethane	N/A
Outer Tube (OT)	Composite of OT components	Pebax
OT liner	PTFE	N/A
OT Jacket	Pebax	N/A
OT Weld Sleeve	Pebax	N/A
OT Braid	Stainless steel wire	N/A
Marker bands (inner tube and outer tube)	Platinum/Iridium	Tantalum (no outer tube marker band present)
Stent cup	Nylon 60	N/A
Tip adhesive	Dymax 190M	N/A

Although the sponsor did not identify their biliary stent as a predicate, the same delivery system proposed for the enteral stent has already been cleared. In K982005, the sponsor received clearance for the use of the Unistep Plus Delivery System with the 12mm Wallstent biliary stent. This delivery system allows the biliary stent to be reconstrained. According to the submission for K982005, the delivery system was modified to incorporate four new elements: a stent holder, stent cup, limit marker band (located on the interior tube) and exterior marker band, and the inner member jacket. According to the review by Gema Gonzalez, during manufacturing, the constrained stent pattern is imprinted in the stent holder allowing the sleeve to hold the stent in place during partial deployment and reconstraint. The stent cup holds the proximal end to the stent allowing lower reconstraint forces. The marker bands aid the operator in determining the extent of stent deployment. The inner member jacket takes up transmission force for a "one-to-one" response during deployment and reconstraint. This member also minimizes "snaking" and kinking of the inner tube as it is pulled back during reconstraint. These changes in the delivery system were already implemented for the 5-10mm stent sizes

K000281, Boston Scientific Wallstent Enteral Prosthesis

(K964119). COMMENT: I am not sure if these same changes were made for the enteral Wallstent. The sponsor has not provided this information.

STERILITY (page 18)

The device will be sterilized using ethylene oxide by an outside contractor. Validation is accomplished by using a protocol consistent with the overkill method described in the AAMI 1988 guideline. The sterility assurance level is 10^{-6} the maximum residue levels are:

Ethylene oxide	250 ppm
Ethylene chlorohydrin	250 ppm
Ethylene glycol	5,000 ppm

Pyrogenicity – bacterial endotoxins will be monitored on a routine basis using LAL assay the modified enteral Wallstent will be released only if the endotoxin level is less than 0.5EU/m. The sensitivity of the pyrogen assay is 0.25EU/ml.

The modified enteral Wallstent will be packaged in a sterile double barrier seal, a PETG tray sealed with a Tyvek lid and a Tyvek/Mylar bag. This is the same method of packaging for the enteral Wallstent, K991056.

LABELING

The name of the device is the “Microvase Modified Enteral Wallstent”. The labeling contains a prescription statement, statements that the device is sterile, for single use only. The lot number, use before date and the company name and address are included. The sheath OD, the working length, minimum working channel, and stent size are also listed.

COMMENT: Schneider, the company that developed the Wallstent, was bought by Boston Scientific and it appears that the emphasis on the name of the device is now to call the device the “Microvase Modified Enteral Wallstent” instead of the Wallstent Enteral Endoprosthesis with Unistep Delivery System. Microvase is a name that is associated with Boston Scientific while Wallstent is the name used by Schneider.

Instructions for Use

The user is told that the device is sterile, for single use only and not to reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and may also create a risk of contamination of the device.

The description of the device is that it is comprised of two components; the implantable metallic stent and the Unistep Plus Delivery System. Under Principles of Operation, the use of the device is described. A single operator can control deployment and implant the stent. The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. The stent deployment threshold is identified by the location of the limit marker band. Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the

63

K000281, Boston Scientific Wallstent Enteral Prosthesis

deployment process can be completed twice, allowing a total of three deployment attempts.

The Indications for Use reads “The Wallstent Enteral Endoprosthesis with Unistep Delivery System is indicated for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

The Contraindications are; enteral ischemia, suspected or impending perforation, and intra-abdominal abscess/perforation. COMMENT: these are the same indication as in the labeling for the colonic and duodenal stents (K980113).

Under Warnings – stents cannot be repositioned after the deployment threshold has been exceeded. COMMENT: This warning has been modified from the labeling for K980113 which read “Stents cannot be repositioned after total deployment.”

Under Precautions;

- The device is intended to be used by physicians who have received appropriate training.
- The system should not be resterilized.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspected to be compromised, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

COMMENT: These precautions are identical to those in the labeling for K980113.

Under Complication the user is told that the complications associated with the use of the device may include the usual complications reported for conventional stents and endoscopic procedures such as infection, stent misplacement, stent migration, intestinal perforation and stent obstructions secondary to tumor ingrowth through the stent, tumor overgrowth at the stent ends, or occlusion. COMMENT: These complications are identical to those listed in the labeling for K980113. The Instructions for the proposed device continue with, post stent placement complications include: bleeding, perforation, pain, stent migration, tumor ingrowth through the stent, tumor overgrowth around ends of stent, foreign body sensation, bowel impaction, reflux, ulceration, fever, septicemia and death (other than that due to normal disease progression.)

The section on “Preparation of the Instrument for Insertion” is almost identical to the labeling for K980113.

Under Procedure, the description of placement of the device under fluoroscopy or endoscopy (item 1, A and B; and 2) are almost identical to the labeling in the predicate K980113. There are some differences in the labeling for the description of deployment. In the predicate labeling the user is told that a stent that is partially deployed too far beyond the obstruction can be pulled back slightly or removed from the patient, providing no more than half the total stent length has

64

K000281, Boston Scientific Wallstent Enteral Prosthesis

been deployed. A stent once deployment begins, cannot be advanced. The labeling for the proposed device has instruction on how to reconstrain the stent once deployment has begun until the deployment threshold, identified by the location of the limit marker band, is reached.

COMMENT: The modifications to the delivery system are so that the stent can be reconstrained, this is why the labeling needed to be modified. There is a Caution that reads "do not push forward on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible duct damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device." Comment: this is almost identical to the predicate labeling except that they use "possible intestinal wall damage" instead of "possible duct damage." Intestinal wall damage is more appropriate. I believe that some of the wording was taken from the Wallstent biliary endoprosthesis labeling. → Please modify this section.

The instructions also contain a Caution that reads "do not reconstrain around tortuous anatomy as it may cause damage to the device." The instructions for repositioning tell the user to first reconstrain the stent by holding the valve body stationary and gently pulling the stainless steel tube back. Under fluoroscopy, the stent will be reconstrained until the leading marker band is even with the exterior tube marker band. Ask LISA, Should this read "the stent will **not** be reconstrained until the leading ..."

When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repotoning can be completed twice, allowing a total of three deployment attempts. To remove a partially deployed stent, first reconstrain the stent. The entire delivery system can then be pulled into the endoscope. There is a caution that "A stent cannot be repositioned after the deployment threshold has been exceeded."

After the stent is positioned and the delivery system removed, routine post implant radiographic procedures are performed to demonstrate location and patency of the stent.

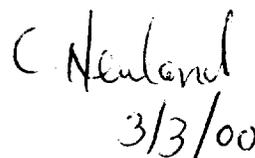
The implanted stent length should allow for adequate overlapping into the non-obstructed anatomy to compensate for further tumor progression and stent shortening. If the stent does not adequately cover the obstruction, a second stent should be implanted providing adequate overlapping of the initially placed stent.

RECOMMENDATION

This submission is not complete, the sponsor did not adequately address the changes that have been made to the Unistep Plus Delivery System. Although it is possible that the changes are the same made to the delivery system for the biliary stent (K982005), I am not sure. I am recommending that this submission be placed on hold until adequate information is received.


Kathleen M. Olvey

11


C. Newland
3/3/00



K000281, Boston Scientific Wallstent Enteral Prosthesis

(b) (4)



66

RRG/LLD 1/6/93
Rev. 2/6/96

DRAERD Premarket Notification 510(k)
Screening Checklist

510(k) Number & Device Name K000281, Enteral Wallstent with Unistep Plus Delivery System

Company Boston Scientific

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

67

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

February 01, 2000

BOSTON SCIENTIFIC CORP.
ONE BOSTON SCIENTIFIC PL.
NATICK, MA 01760
ATTN: LISA M. QUAGLIA

510(k) Number: K000281
Received: 31-JAN-2000
Product: WALLSTENT INTERNAL
PROSTHESIS

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

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

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

Sincerely yours,

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

69

K 000 281

**Boston Scientific Corporation
Premarket Notification**

Modified Enteral Wallstent®

January 28, 2000

Handwritten initials and markings, including "70" and a signature.

TABLE OF CONTENTS

Table of Contents	i
Table of Figures	i
RTA INDEX	ii
SECTION 1 Indications for Use	1
SECTION 2 DEVICE DESCRIPTION	2
SECTION 3 SUBSTANTIAL EQUIVALENCE	6
SECTION 4 DRAFT PRODUCT LABELING	10
DRAFT LABELS	11
DRAFT INSTRUCTIONS FOR USE	12
SECTION 5 PACKAGING, STERILIZATION, AND PYROGENICITY	18
SECTION 6 LABORATORY TESTING	19
STENT DIMENSIONAL CONFORMANCE TEST	20
PRIMING AND TRACKABILITY TEST	24
DEPLOY AND RECONSTRAIN TEST	25
WITHDRAWAL TEST	28
STENT DIMENSIONS TEST	29
BOND TEST	30
SECTION 7 BIOCOMPATIBILITY TESTING	32
SECTION 8 Class III Summary	33
SECTION 9 PREDICATE DEVICE LABELING	85
ENTERAL WALLSTENT® LABELING	86
SECTION 10 510(K) SUMMARY	91

TABLE OF FIGURES

Table 2-2 Modified Enteral Wallstent® Configurations	4
Figure 2-1 Device Drawing	5
Table 3-1 Similarities and Differences Between the Modified Enteral Wallstent® and the Currently Marketed Enteral Wallstent®	8
Figure 3-1 510(k) Decision Tree	9
Table 6-1 Modified Enteral Wallstent® Tested Product Codes	19
Table 7-1 Comparison of Materials of the Modified Enteral Wallstent® to Materials of	32

71

DEVICE TRADE NAME: Wallstent® Enteral Prostheseis
 REASON FOR 510(k): Modifications to Currently Marketed Predicate Devices
 DIVISION/BRANCH: DRAERD/Gastro-Renal (GRDB)

Note: Item Numbers in Left Column correspond to FDA's "Premarket Notification 510(k) Checklist"

INFORMATION REQUESTED LOCATION IN 510(k)

I.F. Information required under Sections 510(k), 513(f), and 513(i) of the Food, Drug, and Cosmetic Act and Part 807 of the Code of Federal Regulations

- 1. Device trade or proprietary name Cover Letter
- 2. Device common or usual name or classification name Cover Letter
- 3. Establishment registration number (only applies if establishment is registered) Cover Letter
- 4. Class into which the device is classified under 21 CFR Parts 862 to 892 Cover Letter
- 5. Classification Panel..... Cover Letter
- 6. Action taken to comply with Section 514 of the Act..... Cover Letter
- 7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo No. G91-1) Section 4
- 8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request Section 10
- 9. For Class III devices only, a Class III certification and a Class III Summary Section 8
- 10. Photographs of the device..... N/A
- 11. Engineering drawings for the device with dimensions and tolerances Figure 2-1
- 12. The marketed device(s) to which equivalence is claimed including labeling and description of device Sections 3 & 10
- 13. Statement of similarities and/or differences with marketed device(s)..... Section 3
- 14. Data to show consequences and effects of a modified device Sections 6 & 7
- 15. Truthful and Accurate Statement..... Cover Letter

II. Additional information that is necessary under 21 CFR 807.87(h):

- A. Submitter's name and address Cover Letter
- B. Contact person, telephone number and fax number Cover Letter
- C. Representative/Consultant if applicable Not Applicable
- D. Table of Contents with pagination Table of Contents
- E. Address of manufacturing facility/facilities and, if appropriate, sterilization sites..... Cover Letter

III. Additional information that may be necessary under 21 CFR 807.87(h):

- A. Comparison table of the new device to the marketed device(s) Table 3-1
- B. Action taken to comply with voluntary standards..... Not Applicable
- C. Performance data on:
 - marketed device(s)
 - bench testing N/A
 - animal testing N/A
 - clinical data N/A
 - new device
 - bench testing Section 6
 - animal testing Section 7
 - clinical data Section 8
- D. Sterilization information Section 5
- E. Software information N/A
- F. Hardware information N/A
- G. If this 510(k) is for a kit, has the kit certification statement been provided? N/A
- H. Is this device subject to issues that have been addressed in specific guidance documents? No

70



Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508.650.8000
www.bsci.com

January 28, 2000

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

31 JAN 12 01
FDA/CDRH/OCE/DMD

SUBJECT: 510(k) Premarket Notification for a Modified Enteral Wallstent®

Dear Sir/Madam:

Boston Scientific Corporation intends to introduce into interstate commercial distribution its Modified Enteral Wallstent®. This device can be used for palliative treatment of colonic and duodenal strictures caused by malignant neoplasms. The proposed modification to the currently marketed Enteral Wallstent® involves changes to the delivery system. A detailed description of the device can be found in Section 2.

Boston Scientific Corporation hereby submits a premarket notification for the Modified Enteral Wallstent® as required by Section 510(k) of the Federal Food, Drug and Cosmetic Act and 21 CFR 807(E). The following information is being submitted in conformance with 21 CFR 807.87:

Common/Usual Names: Enteral Prosthesis

Trade/Proprietary Name: Wallstent® Enteral Prostheseis

Classification Name & Device Classification: Based on the regulatory class of the predicate device and FDA's classification manual (HHS Publication FDA 95-4246), Boston Scientific Corporation believes that the Modified Enteral Wallstent® is best described as a Class III device with the following classification names:

Name	Number	21 CFR Ref.
Esophageal Prosthesis	78 MQR	878.3610

73 SK-16

Device Panel & Branch: Gastroenterology-Urology (GU)/ Gastro-Renal (GRDB)

Owner/Operator: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
Owner/Operator No. 9912058

Manufacturer: Boston Scientific Corporation
Plymouth Technology Center
5905 Nathan Lane
Plymouth, MN 55442
Establishment Registration No. 2183541

Sterilizer: (b) (4) 

Performance Standards: Boston Scientific Corporation is not aware that any formal performance standards applicable to this product have been established by the Food and Drug Administration under Section 514 of the Federal Food, Drug and Cosmetic Act.

Labeling: Draft labels and instructions for use for the Modified Enteral Wallstent® are included in Section 4.

Substantial Equivalence: Boston Scientific Corporation believes that the Modified Enteral Wallstent® is substantially equivalent to its currently marketed Enteral Wallstent® (510(k) No. K991056). For additional information, please refer to Section 3.

510(k) Summary: Please refer to Section 10.

Certification Statement: The "Truthful and Accurate" Statement required by 21 CFR 807.87(j) is at the end of this cover letter.

Submitter's Name, Address, and Contact: Lisa M. Quaglia (Contact Person)
Regulatory Affairs Manager
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
(508) 650-8267
(508) 650-8389 (FAX)

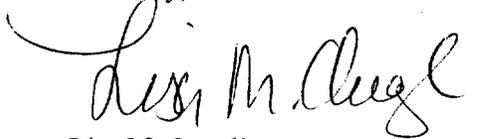
The following additional information is also being submitted:

79

- **Confidentiality:** Boston Scientific Corporation considers its intent to manufacture this device for distribution under its own label to be confidential commercial information, and therefore exempt from public disclosure. Boston Scientific Corporation understands that the data contained in this submission will be restricted from release under the Freedom of Information Act for at least 90 days or until FDA has issued a determination of substantial equivalence.
- **Post-Market Surveillance:** It is the understanding of Boston Scientific Corporation that FDA does not presently require the submission of postmarket surveillance plans for 510(k) devices and that manufacturers will be notified when such requirements become applicable.
- **FDA's "Refuse to Accept" Policy:** In order to assist the reviewer with FDA's "Premarket Notification (510(k)) Refuse to Accept Policy" (June 30, 1993 Draft), a Table of Contents, a Table of Figures, and an RTA Index were presented prior to this cover letter. The index references all of the information required in Sections I.F., II and III of FDA's "Premarket Notification (510(k)) Checklist for Acceptance Decision" (August 20, 1993, Revision). Boston Scientific Corporation hopes that this information will aid in the initial screening of the application.

Per 21 CFR § 807.90(c), two copies of this Premarket Notification are submitted, along with an additional copy of this cover letter. Please feel free to contact me at 508-650-8267 should you have any questions. Thank you.

Sincerely,

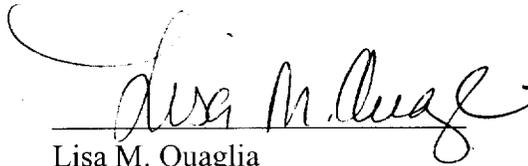


Lisa M. Quaglia
Regulatory Affairs Manager

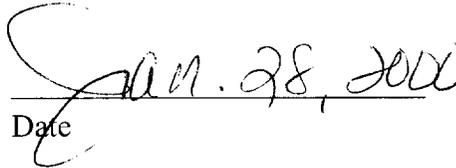
75

**Premarket Notification Truthful And Accurate Statement
(As Required by 21 CFR 807.87(j))**

I certify that, in my capacity as Senior Regulatory Affairs Specialist at Boston Scientific Corporation, I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



Lisa M. Quaglia
Regulatory Affairs Manager



Date

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

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

76

SECTION 1
INDICATIONS FOR USE

510(k) Number: To Be Determined

Device Name: Modified Enteral Wallstent®

Indication for Use:

The Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery system is indicated for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.1091)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

77

SECTION 2 DEVICE DESCRIPTION

The Modified Enteral Wallstent® is almost identical to the currently marketed Enteral Wallstent® (510(k) No. K991056). It is comprised of a metal stent and a delivery system. The metal stent is **identical** to the currently marketed Enteral Wallstent®. The only difference between the two devices is the delivery system. Several modifications to the delivery system have been made as are described below. The new delivery system will also be offered in 2 lengths. A 230cm length for endoscopic use and a 135cm length for interventional radiologists.

The Modified Enteral Wallstent® is a self-expanding metal stent supplied pre-mounted on a delivery system. It is a cobalt-based superalloy wire braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The purpose of the stent is to increase or maintain the inner lumen diameter of the colon or duodenum. Radiopaque markers are located on the delivery system to aid in placement under fluoroscopy.

The stent is placed by means of a delivery system. A variety of modifications are being proposed to the delivery system to improve the ease of use and/or manufacture of the product. These modifications are summarized in Section 3.

The delivery system is a coaxial tubing assembly that constrains the stent until it is released in a controlled manner. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen that will accommodate a 0.035" guidewire. The device may be inserted through the working channel of an endoscope with a minimum working channel of 3.7mm. The release of the stent is accomplished by retracting the outer sheath. The delivery system allows for reconstraint should the physician need to reposition the stent once deployment has begun.

The stent is packaged constrained on the delivery system ready for placement. The working length of the device is available in 230 cm or 135 cm. The system is sterile and intended for single use only. A detailed device drawing is provided in Figure 2-1.

The major components of this device are the stent and the delivery system. Each component is expanded upon below and presented in the attached device drawing (Figure 2-1). Table 3-1 (page 8) also outlines the characteristics of these components, while comparing the Modified Enteral Wallstent® to the currently-marketed Enteral Wallstent®. Laboratory results are presented in Section 6 to verify the safety and performance of the device. Biocompatibility information on the materials of the Modified Enteral Wallstent® are presented in Section 7 and Section 8 contains the Class III Summary of Adverse Safety and Effectiveness.

STENT

The metal stent is **identical** to the currently marketed Enteral Wallstent®. It is a self-expanding metal stent consisting of a cobalt-based superalloy wire braided in a tubular mesh configuration. The stent is supplied pre-mounted on the delivery system. The outward radial force along with the ends of the stent serves to stabilize the prosthesis after implantation.

DELIVERY SYSTEM

The delivery system is a 10 Fr. coaxial catheter used to deliver and deploy the metal stent to the desired location. The delivery system has been modified in that the materials of the interior tube have been changed to increase pushability, reduce elongation, and allow for reconstraintment. The delivery system will also be offered in a shorter, 135cm length for placement by Interventional Radiologists. The delivery system consists of the exterior tube, the interior tube, the stopcock and extension tube, stainless steel tube, and the valve body. The interior tube of the coaxial system, made of PEEK (polyetheretherkeytone), contains a central lumen that accommodates a 0.035" guidewire and serves as a core to mount the stent. The stent is pre-mounted onto the delivery system and the exterior tube, constructed of PTFE, braid, and Pebax, holds the stent in place on the delivery system. As the exterior tube is retracted back, the stent is deployed. The delivery system allows for reconstraintment in the event that the physician chooses to reposition the stent. This is accomplished by pulling the stainless steel tube towards the user while maintaining valve body position. The stopcock and extension tube are used for flushing. The 304 stainless steel tube is used for guiding the deployment and reconstraintment force. A limit marker band is located on the delivery system to let the user know when the threshold has been met for reconstraintment. Once the stent has been deployed beyond the threshold of the limit marker band, reconstraintment will not be possible. Radiopaque markers are located on the delivery system to aid in placing the stent prior to deployment.

The following technique would generally be used with the Modified Enteral Wallstent®. Once a stricture has been identified in the colon or duodenum, the delivery system, with the stent pre-mounted, would be advanced over a guidewire to the site of the stricture through an endoscope with the aid of endoscopic and/or fluoroscopic visualization. Once in position, the user would retract the outer sheath to begin release of the stent off of the delivery system. If the stent requires repositioning, the stent may be repositioned if the threshold for reconstraintment has not been reached. Placement of the stent may be confirmed fluoroscopically.

The Modified Enteral Wallstent® will be available in several configurations for use according to the patient's anatomy and the physician's preference:

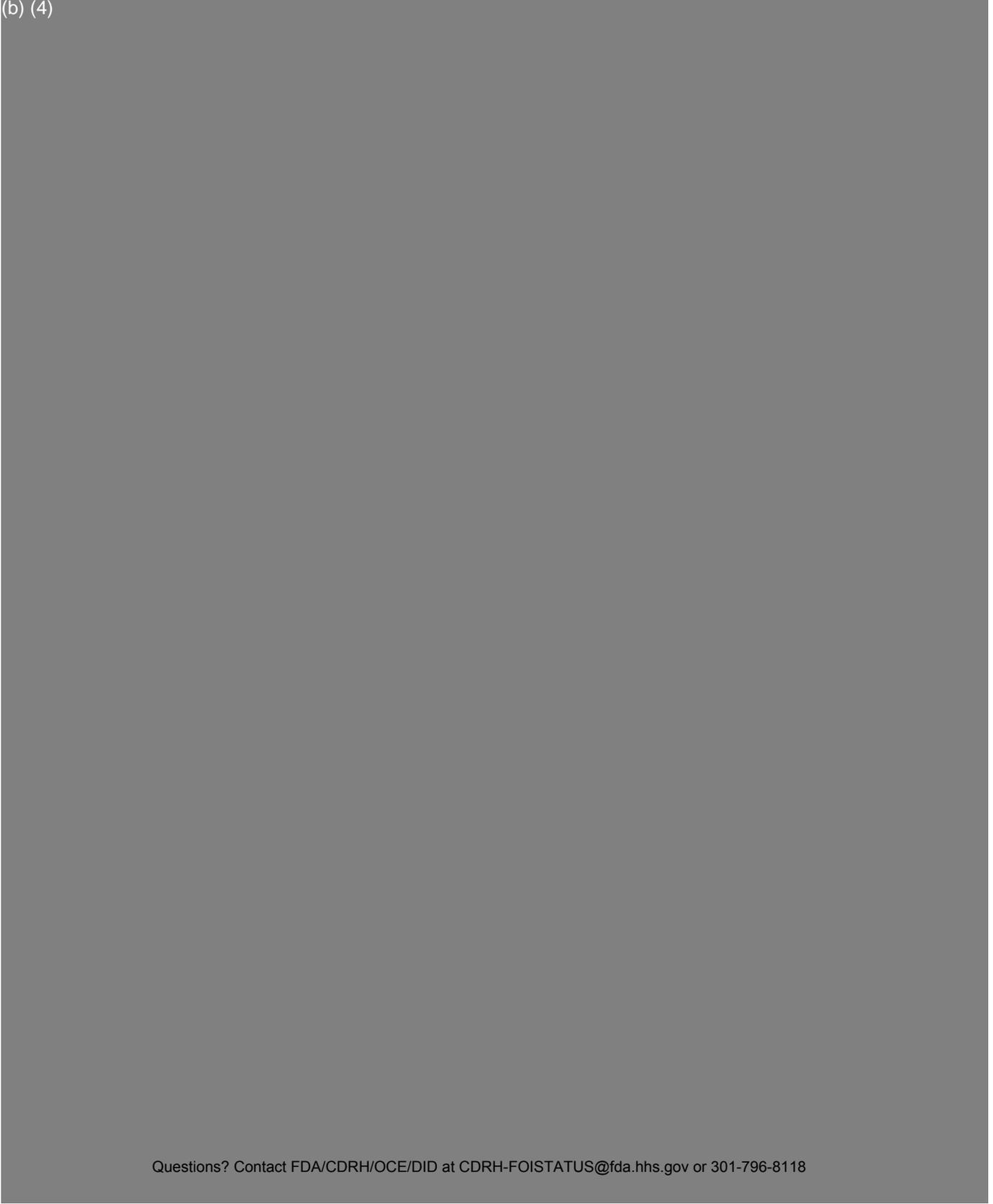
TABLE 2-2
 MODIFIED ENTERAL WALLSTENT® CONFIGURATIONS

<i>Cat. No.</i>	<i>Working Length</i>	<i>Stent Diameter</i>	<i>Stent Length</i>
M00565540	230	18 mm	60 mm
M00565550	230	18 mm	90 mm
M00565560	230	20 mm	60 mm
M00565570	230	20 mm	90 mm
M00565580	230	22 mm	60 mm
M00565590	230	22 mm	90 mm
M00565600	135	18 mm	60 mm
M00565610	135	18 mm	90 mm
M00565620	135	20 mm	60 mm
M00565630	135	20 mm	90 mm
M00565640	135	22 mm	60 mm
M00565650	135	22 mm	90 mm

80

**FIGURE 2-1
DEVICE DRAWING**

(b) (4)



SECTION 3
SUBSTANTIAL EQUIVALENCE

As stated in the device description, the Modified Enteral Wallstent® is almost identical to the currently marketed Enteral Wallstent® (K991056, 06/22/99).

Table 3-1 (page 8) compares the similarities and differences of the Modified Enteral Wallstent® to the currently marketed Enteral Wallstent® for substantial equivalence purposes.

The 510(k) Substantial Equivalence Decision-Making Process as outlined in ODE Guidance Document No. K86-3, "Guidance on the CDRH Premarket Notification Review Program," was used to determine substantial equivalence. Please refer to Figure 3-1 for the Decision Tree from that document. The answers to the following questions lead to a determination that the Modified Enteral Wallstent® is substantial equivalent to Enteral Wallstent®.

1) Does the new device have same indication statements?

Yes. As shown in Section 9, the currently marketed Enteral Wallstent® is used for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures. The Modified Enteral Wallstent® is used for the same indication. See draft product labeling in Section 4 (page 10).

2) Does the new device have same technological characteristics, e.g. design, materials, etc.?

No. The Modified Enteral Wallstent® is not identical to the predicate device; however, it is very similar in many of its design elements and materials, as can be seen Table 3-1 (page 8). The primary difference between the currently marketed Enteral Wallstent® and the proposed Modified Enteral Wallstent® is the delivery system. The new delivery system offers a shorter length for usage by the interventional radiologist and incorporated many features for ease of manufacturing and to improve the product for the physician. Specifically, the new delivery system offers reconstrainability and better visualization with the clear distal tip. These new features resulted in modification or addition of new materials. The metal stent is identical to the currently marketed Enteral Wallstent®.

3) Could the new characteristics affect safety or effectiveness?

Yes. It is possible that the design and material differences described above could affect safety or effectiveness. However, the materials chosen have a history of use within Boston Scientific and raise no new issues regarding safety or effectiveness.



4) Do the new characteristics raise new types of safety and effectiveness questions?

No. The changes described above do not raise any new types of safety and effectiveness questions. The laboratory testing data (Section 6) and the biocompatibility information (Section 7) provide further evidence that no new safety and effectiveness issues have been raised.

5) Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The data shown in Sections 6 and 7 was developed using accepted scientific methods. Although previous submissions focused on testing of the actual stent and do not specifically identify the tests described in this 510(k), adequate samples were tested with statistical rationale and scientific soundness. Information provided in Section 7 was also conducted using accepted scientific tests for studying biocompatibility.

6) Are performance data available to assess effects of new characteristics?

Yes. The laboratory testing results are provided in Section 6 and the biocompatibility information is provided in Section 7.

7) Do performance data demonstrate equivalence?

Yes. The performance data demonstrate that the Modified Enteral Wallstent® is equivalent to the currently-marketed Enteral Wallstent®.

In summary, based on the data presented in Section 6 and Section 7, Boston Scientific Corporation believes that Modified Enteral Wallstent® is substantially equivalent to the currently marketed Enteral Wallstent®.

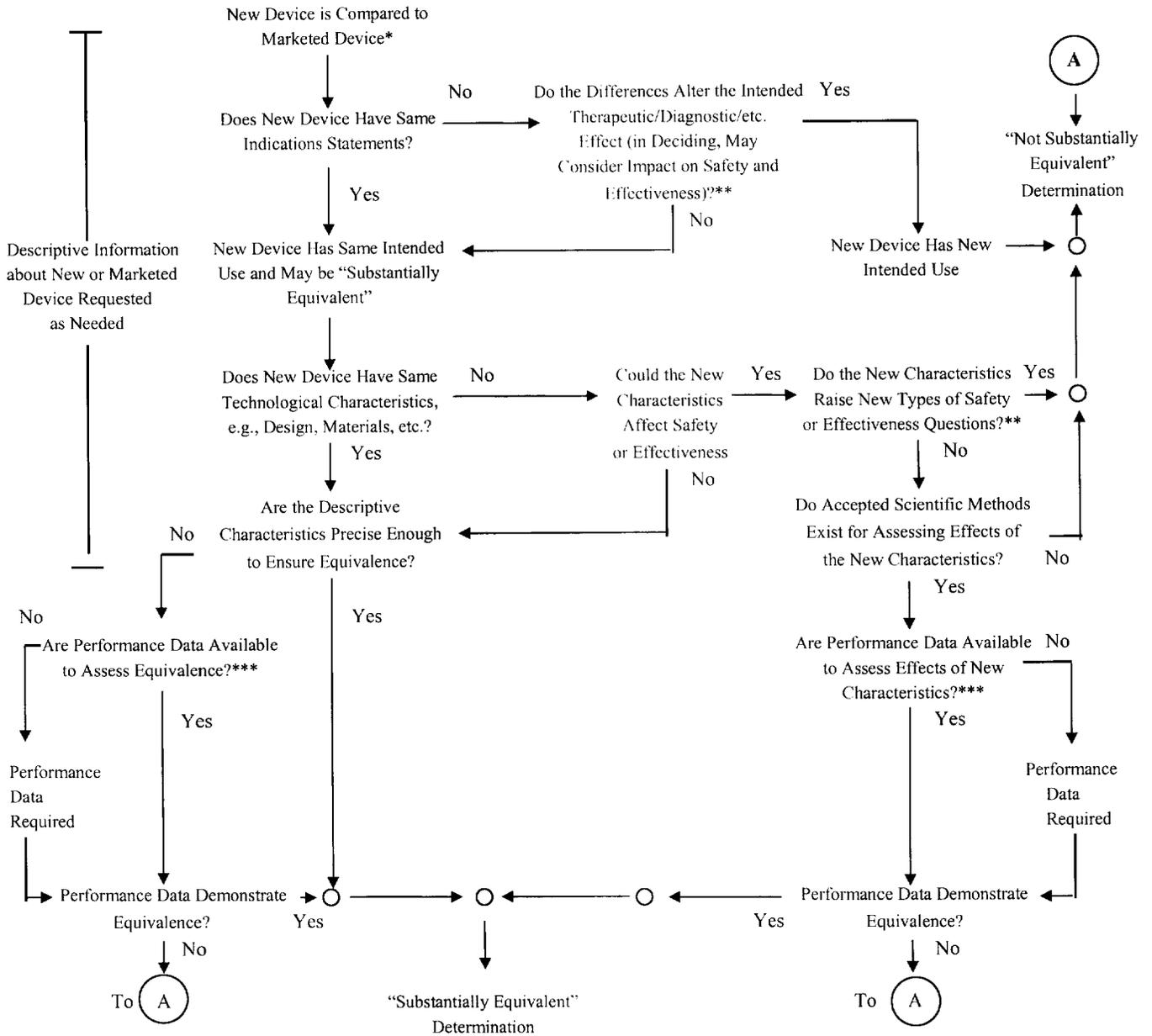
83

**TABLE 3-1
SIMILARITIES AND DIFFERENCES BETWEEN THE MODIFIED ENTERAL WALLSTENT® AND THE
CURRENTLY MARKETED ENTERAL WALLSTENT®**

	<i>Microvasive Modified Enteral Wallstent® (This 510(k))</i>	<i>Currently Marketed Enteral Wallstent®(K991056)</i>
USE		
<i>Indication</i>	Palliative treatment of colonic, duodenal (or gastric outlet obstruction) strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.	Same
<i>Route of Administration</i>	Endoscopic	Endoscopic
Stent		
<i>Stent Sizes (mm)</i>	18x90, 20x90, 22x90, 18x60, 20x60, 22x60	Same
Delivery System		
<i>Catheter Lengths</i>	230 cm, 135 cm	230 cm
<i>Catheter OD</i>	.131"	.131"
<i>Reconstrainable</i>	Yes	No
<i>Irrigation Capability</i>	Yes	Yes
<i>RO Marker Bands</i>	Yes	Yes
MATERIALS		
<i>Metal Stent</i>	Elgiloy	Same
<i>Inner Tube Catheter</i>	PEEK	Pellethane
<i>Inner Jacket of Catheter</i>	Pellethane	N/A
<i>Outer Tube (OT)</i>	Composite of OT components	Pebax
<i>OT Liner</i>	PTFE	N/A
<i>OT Jacket</i>	Pebax	N/A
<i>OT Weld Sleeve</i>	Pebax	N/A
<i>OT Braid</i>	Stainless Steel Wire	N/A
<i>Marker Bands (inner tube and outer tube)</i>	Platinum/Iridium	Tantalum (No outer tube Marker band present)
<i>Stent Cup</i>	Nylon 60	N/A
<i>Tip Adhesive</i>	Dymax 190M	N/A

84

**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.

FIGURE 3-1
510(K) DECISION TREE

SECTION 4
DRAFT PRODUCT LABELING

DRAFT LABELS
DRAFT INSTRUCTIONS FOR USE

Page 11
Page 12

86

DRAFT LABELS

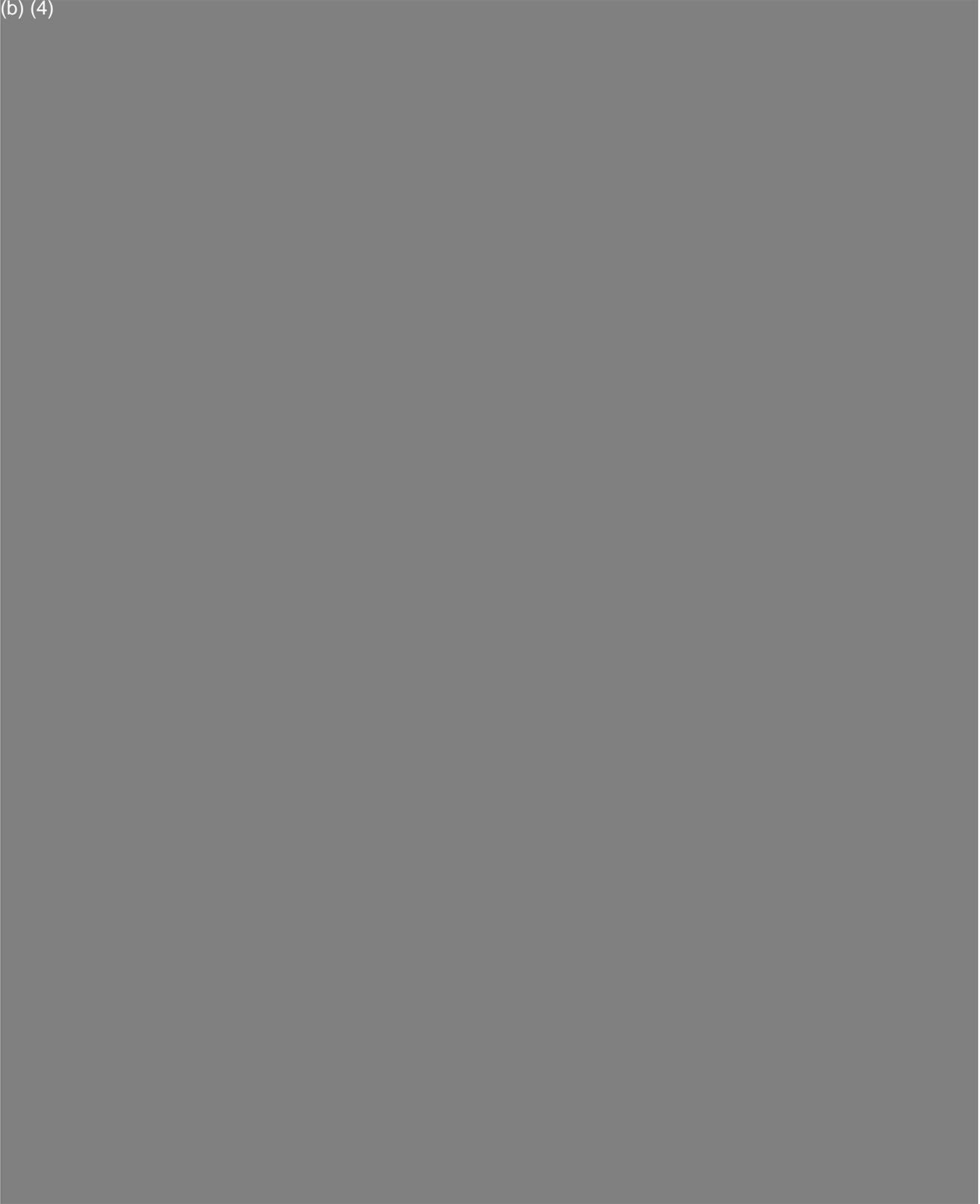
(b) (4)



87

DRAFT INSTRUCTIONS FOR USE

(b) (4)



88

(b) (4)



89

(b) (4)



90

(b) (4)



91

(b) (4)



92

(b) (4)



93

SECTION 5

PACKAGING, STERILIZATION, AND PYROGENICITY

The following information is provided in conformance with ODE Guidance Document No. K90-1, "510(k) Sterility Review Guidance."

PACKAGING

The Modified Enteral Wallstent® will be packaged in a sterile double barrier seal. The first barrier seal is a PETG tray sealed with a Tyvek lid. The second barrier seal is a Tyvek/Mylar bag. The device is then provided in a shelf carton. This is the same method of packaging for the the currently-cleared Enteral Wallstent® product (510(k) No. K991056).

STERILIZATION

Boston Scientific Corporation will utilize ETO gas to sterilize the Modified Enteral Wallstent®. ETO gas is used for the currently-marketed Enteral Wallstent® product (510(k) No. K991056). Sterilization is performed by outside firms per contractually-established guidelines. Sterilization validation is accomplished using a protocol consistent with the overkill approach described in the Association for the Advancement of Medical Instrumentation March 31, 1988, "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices." The sterility assurance level (SAL) for the Modified Enteral Wallstent® is 1×10^{-6} . To substantiate this SAL, Boston Scientific performs sterility testing on actual product, as well as on fractional-exposed products challenged with *Bacillus subtilis* var. niger. For routine sterilization, batches are released on sterility testing of systems challenged with 1×10^6 *Bacillus subtilis* var. niger. For release purposes, maximum residue levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol are at or below the levels for "devices contacting mucosa," as described in the proposed rule on ETO residuals (June 23, 1978 Federal Register):

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

PYROGENICITY

Bacterial endotoxins will be monitored for this product family on a routine basis using the Limulus Amebocyte Lysate (LAL) assay as described in the "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices," issued by the FDA in December 1987 and in USP, Chapter 85, "Bacterial Endotoxins Test." The Modified Enteral Wallstent® will be released for shipment only if the endotoxin level is less than 0.5 EU/ml (endotoxin units). The sensitivity of the pyrogen assay is 0.25 EU/ml.

94

SECTION 6
LABORATORY TESTING

Laboratory testing was performed on the Modified Enteral Wallstent® to verify its safety and performance. The following tests were performed on finished, ethylene oxide sterilized devices:

- Stent Dimensional Conformance Test
- Deployment Force
- Withdrawal
- Track Test
- Bond Strengths
- Delivery System Dimensions

Each test sample was sterilized using a validated cycle to establish that the sterilization process will not adversely affect the performance of the device. Table 6-1 below describes the product that was tested in this Section.

TABLE 6-1
MODIFIED ENTERAL WALLSTENT® TESTED PRODUCT CODES

<i>Catalog No.</i>	<i>Working Length</i>	<i>Stent Size</i>	<i>Number</i>
M00565550	230 cm	18x90	15
M00565570	230 cm	20x90	15
M00565590	230 cm	22x90	15
M00565610	135 cm	18x90	15
M00565630	135 cm	20x90	15
M00565650	135 cm	22x90	15

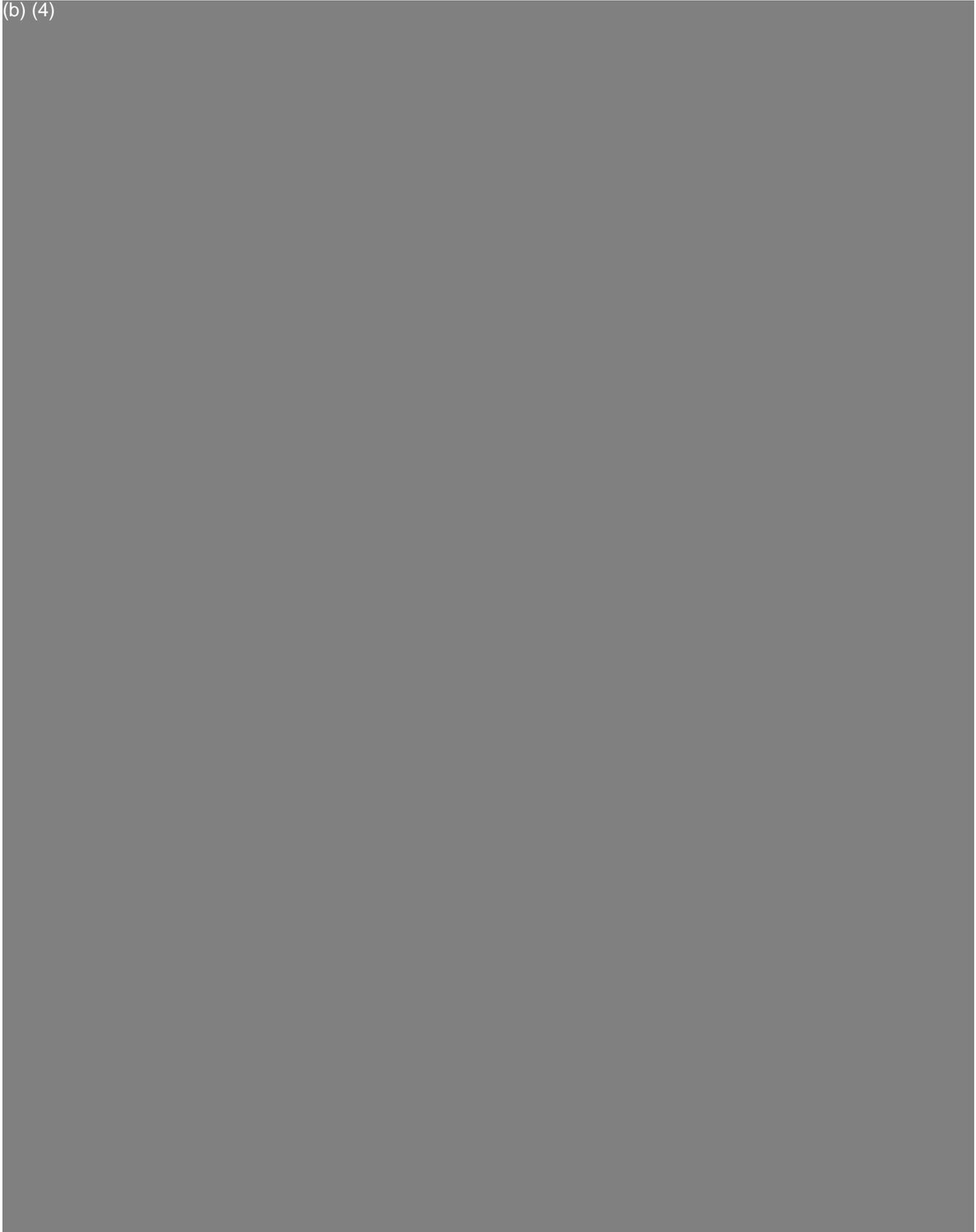
A sample size of 15 provides a confidence level of 90% with 85% reliability that all samples will meet specification. A sample size of 30, as is the case with 2 lots tested for a single attribute, provides a confidence level of 95% with 90% reliability that all samples will meet specification.

Samples from each diameter were chosen for each length offered for the delivery system. The longer, 90mm, stents were chosen as the longer stents will challenge the performance greater than the shorter, 60mm, stents. The data collected from the 90mm stents can be interpolated in short stent models. All sizes will be validated prior to market release.

95

Stent Dimensional Conformance Test

(b) (4)



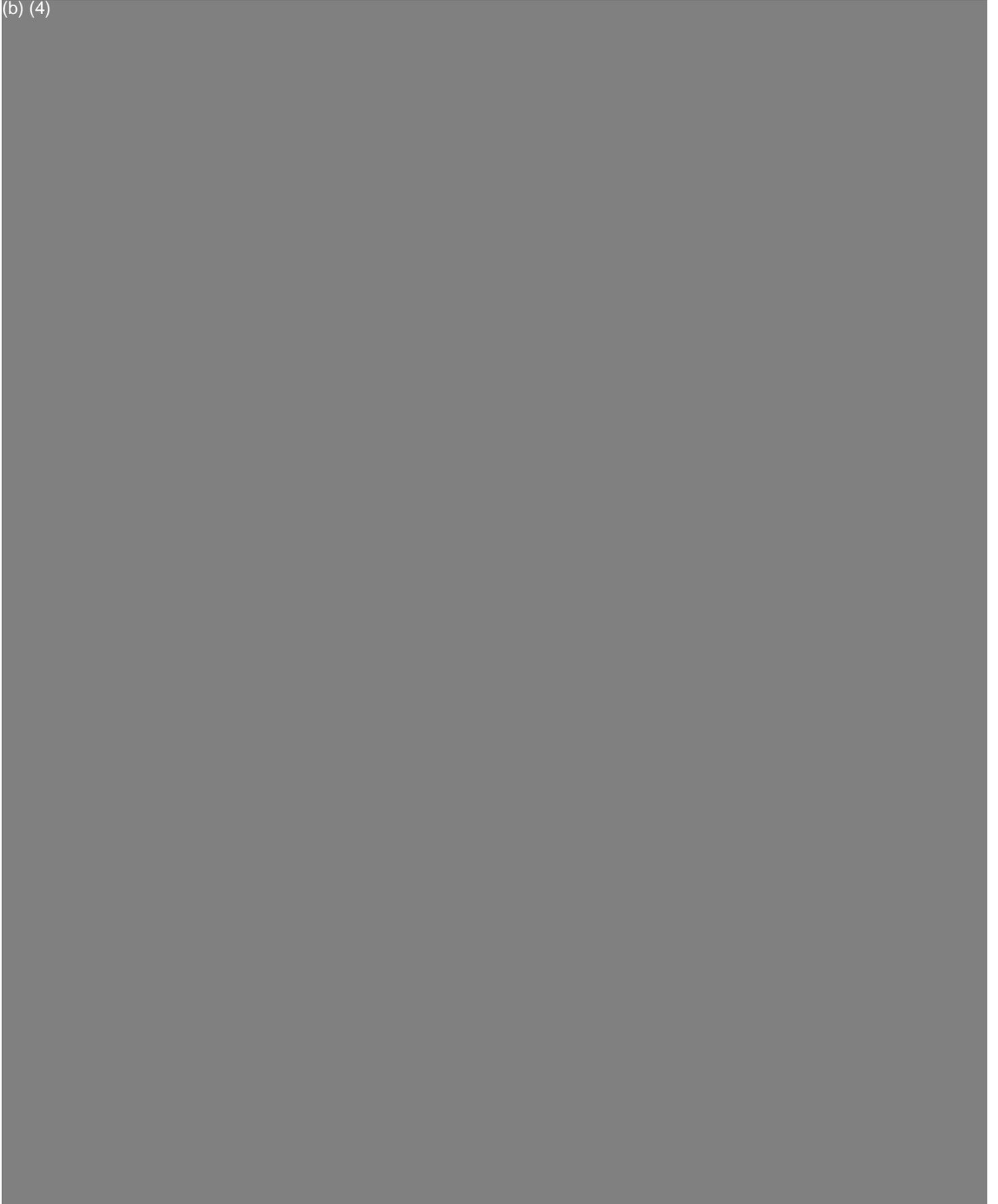
(b) (4)



(b) (4)

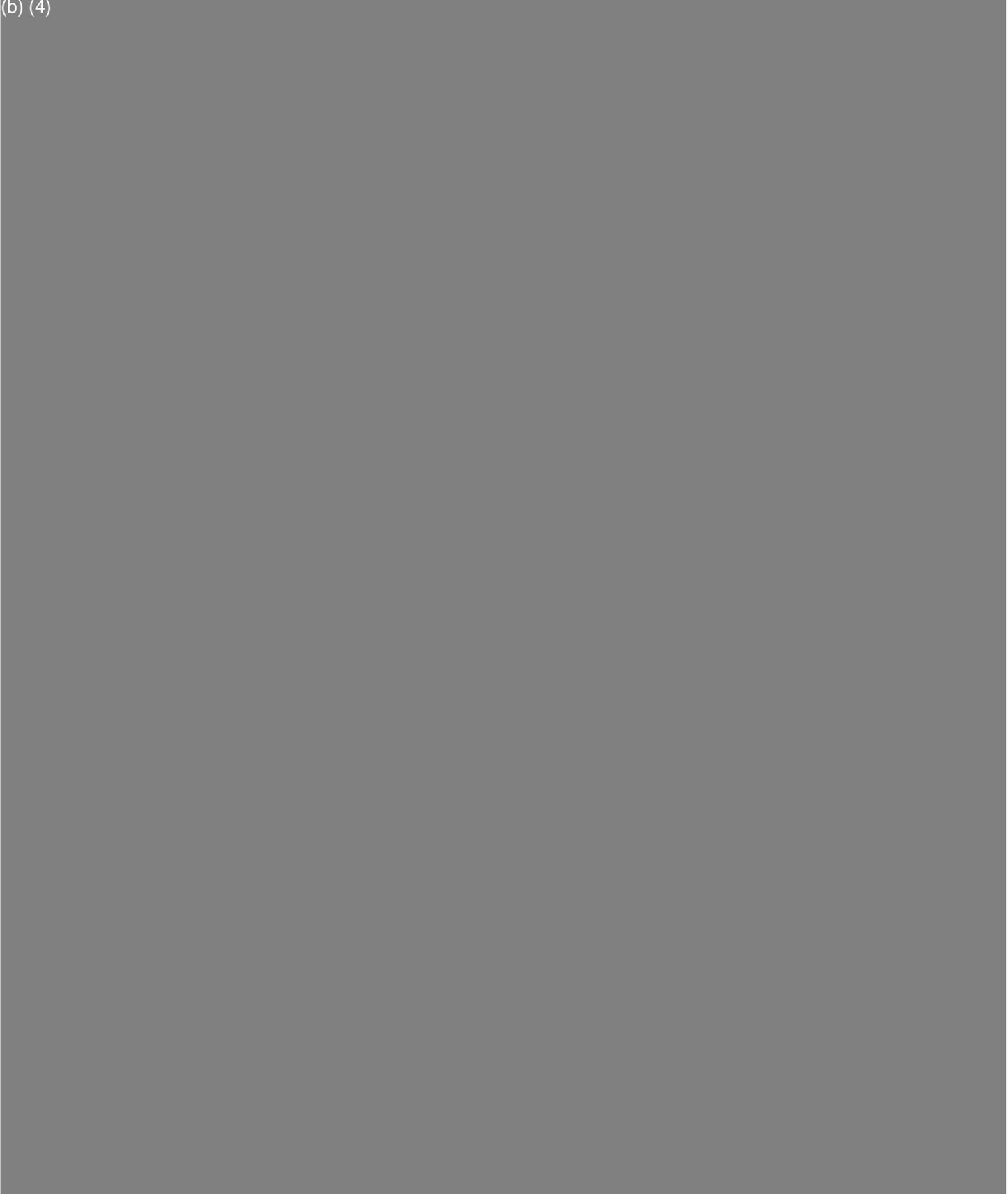


(b) (4)



Priming and Trackability Test

(b) (4)



Deploy and Reconstrain Test

(b) (4)



2025 475

(b) (4)

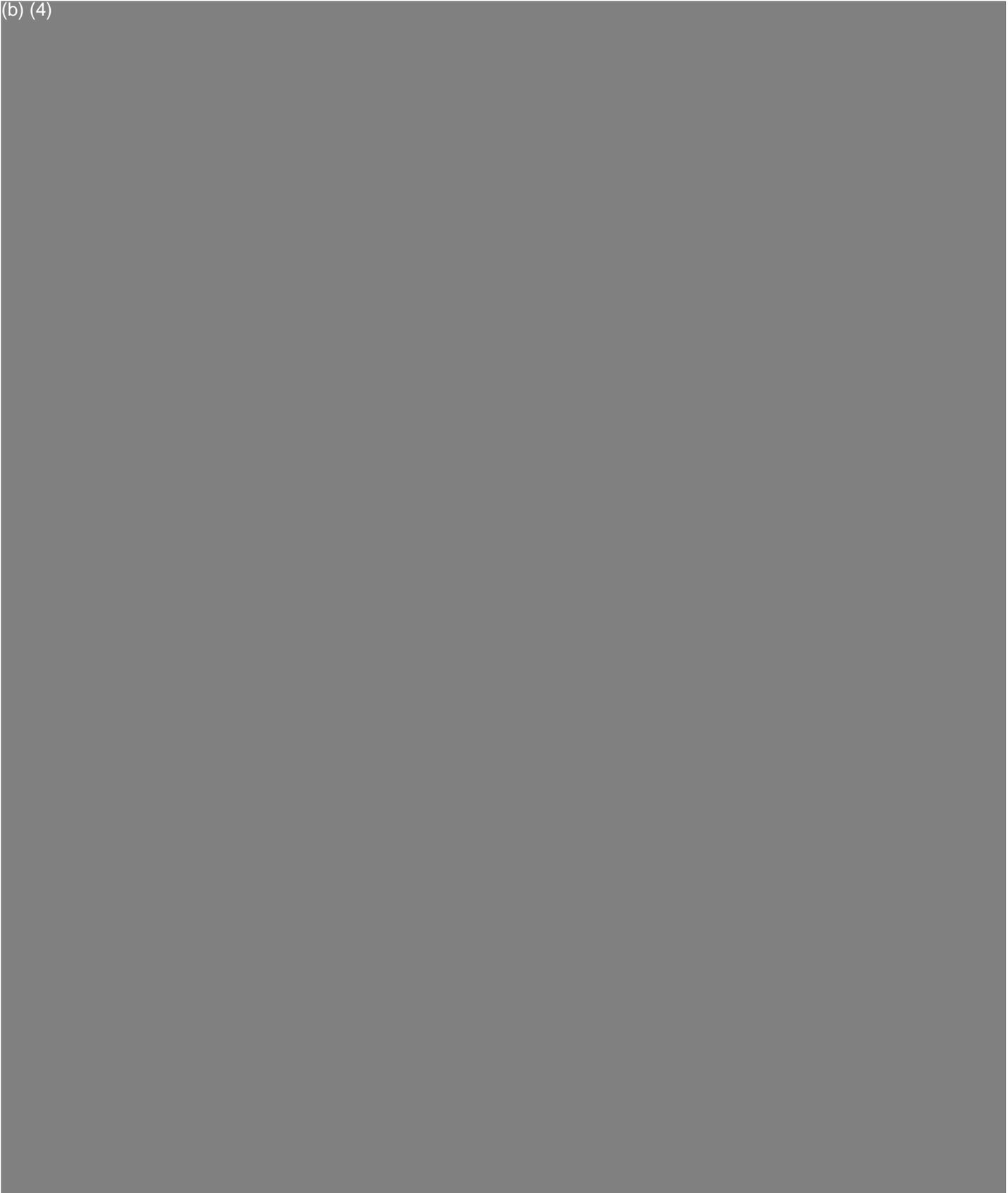


(b) (4)



Withdrawal Test

(b) (4)



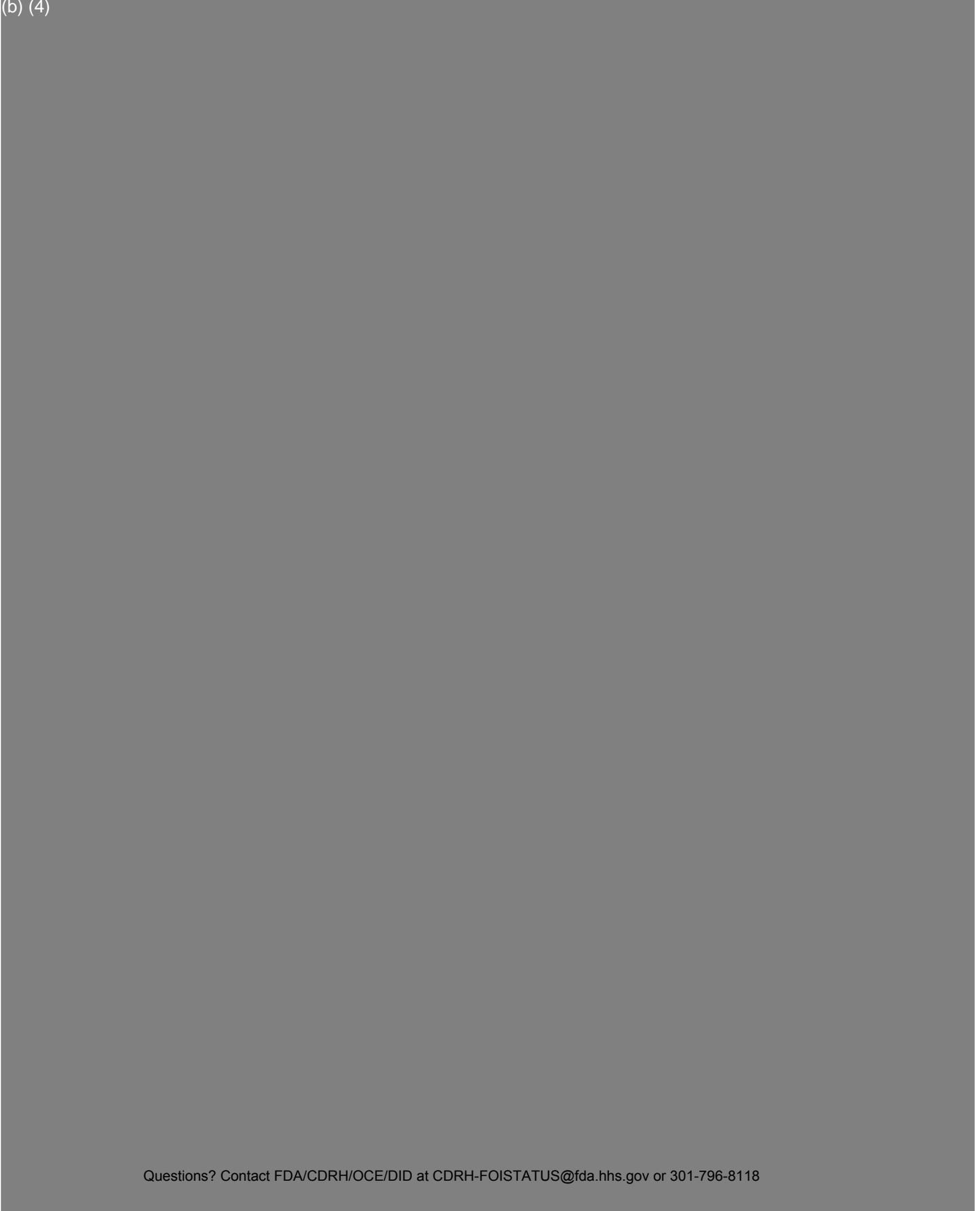
Stent Dimensions Test

(b) (4)



Bond Test

(b) (4)

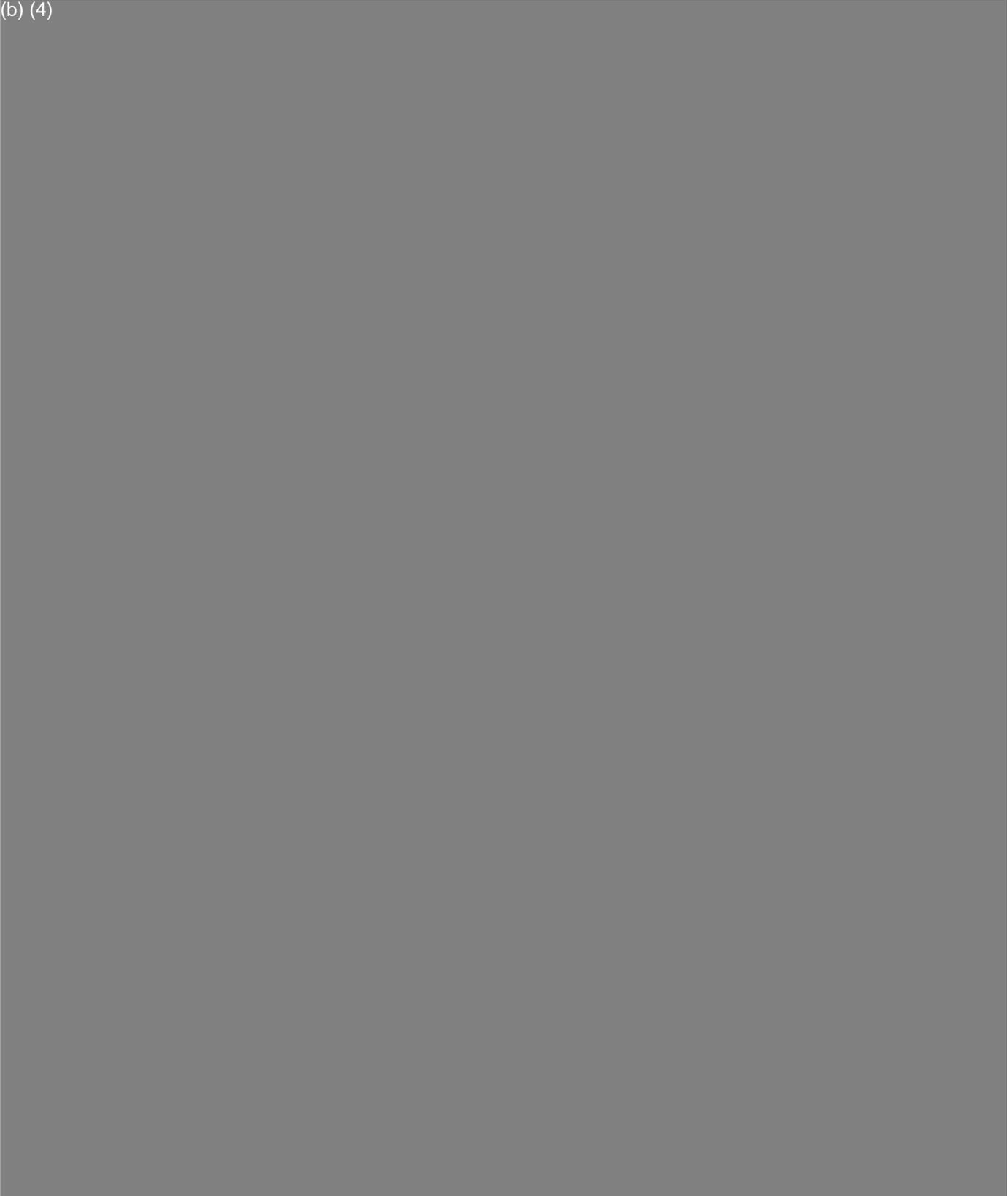


(b) (4)



SECTION 7
BIOCOMPATIBILITY TESTING

(b) (4)



Clinical Literature Review
Bibliography

1. Soetikno, Roy M., et.al: "Expandable Metal Stents for Gastric-Outlet, Duodenal, and Small-Intestinal Obstruction"; Gastrointestinal Endoscopy Clinics of North America, Vol. 9, No. 3, July, 1999, pp. 447-458.
2. Lo, Simon K.: "Metallic Stenting for Colorectal Obstruction"; Gastrointestinal Endoscopy Clinics of North America, Vol. 9, No. 3, July, 1999, pp. 459-477.
3. Carr-Locke, David L: "Role of endoscopic stenting in the duodenum",
4. Boorman, P, et.al: "Endoluminal stenting of obstructed colorectal tumours", Ann R Coll Surg Engl, 1999: 81, 251-254.
5. Wiggingshaus, B., et.al: "self-expandable metallic stents in malignant gastric outlet obstructions—an alternative approach using modified techniques", Z Gastroenterol, 1999, Nov; 37(11):1093-9.
6. Raijman, Issac, et.al: "Duodenal and Biliary Wallstent in the Palliation of Malignant Bilioduodenal Obstruction (MBDO)", DDW 1999, Abstract.
7. Kim, Jin Hong, et.al: "Endoscopic Placement of Nitinol "double Stents" (DS) for Palliation of Malignant Gastrointestinal (GI) Obstruction in Unusual Locations", DDW 1999, Abstract.
8. Raijman, Isaac, et.al: "Management of Malignant Colorectal Obstruction (MCO) with Expandable Stents: Experience in 34 Pts.", DDW 1999, Abstract.
9. Hatfield, Adrian, et.al: "Non-surgical Management of Malignant Gastric Outlet Obstruction in 20 Patients Treated with Self-Expanding Metal Wall Stents", DDW 1999, Abstract.

EXPANDABLE METAL STENTS FOR GASTRIC-OUTLET, DUODENAL, AND SMALL- INTESTINAL OBSTRUCTION

Roy M. Soetikno, MD, MS, and David L. Carr-Locke, MD, FRCP

Malignant gastric-outlet, duodenal, and small-intestinal obstructions are caused by occlusion to the lumen by intrinsic or extrinsic growth. Malignant obstruction may cause the presenting symptoms, or may develop during the course of both primary and metastatic cancers. Although the incidence of malignant gastrointestinal obstruction in the population is not known, several studies have reported this condition's significance in many clinical situations. Malignant gastrointestinal obstructions occur in up to 15% of patients who received palliative care.⁵ Malignant gastric-outlet obstructions develop in approximately 10% of patients during the course of pancreatic cancer.²⁵

The treatment of patients who have malignant gastrointestinal obstruction is difficult. The mortality and morbidity of surgery in these patients, who already have a short life expectancy, are significant.³⁵ Gastrojejunostomy, for example, is associated with up to a 10% mortality rate.³⁵ In addition to having advanced malignant disease, patients are often too debilitated to undergo palliative surgery. Therefore, it is not uncommon for patients to be treated with supportive therapy only. Unfortunately, supportive therapy neither relieves the severe nausea and vomiting associated with gastric-outlet, duodenal, or small-intestinal obstruction, nor allows adequate food intake.^{1,2} Treatment with antiemetics, chemotherapy, or radiation therapy is usually also unsuccessful. Endoscopic treatment with periodic dilation typically provides temporary relief and is associated with significant risks of perforation. Over the past few years, we and others have reported the safety and efficacy of self-expanding metal stents used to palliate malignant gastrointestinal obstruction in patients who were too ill to undergo surgery.^{2,3,6,7,9-31,33,34,36}

The stents vary in materials, designs, and sizes (Table 1). The first few used were the biliary Wallstent (Schneider Inc., Minneapolis, MN) and the esophageal

From the Department of Endoscopy, Division of Gastroenterology, VA Palo Alto Health Care System, Stanford University School of Medicine, Palo Alto, California (RMS); the Department of Endoscopy, Gastroenterology Division, Brigham and Women's Hospital; and the Department of Medicine, Harvard Medical School, Boston, Massachusetts (DLC-L)

GASTROINTESTINAL ENDOSCOPY CLINICS OF NORTH AMERICA

VOLUME 9 • NUMBER 3 • JULY 1999

447

Table 1. REPORTED CASES OF METAL STENTS TO PALLIATE MALIGNANT GASTRIC-OUTLET, DUODENAL, AND SMALL-INTESTINAL OBSTRUCTION

Authors	Year	Patients	Location	Stent			TTS		Outcomes		
				Type	Diameter (mm)	Length (mm)	Yes	No	Survival Mean (mo)	Diet	Patients with improvement (%)
Kozarek et al ¹⁴	1992	2	Afferent and efferent loops	Z-stent	15	40-60		X	2.5	NA	50
Topazian et al ³¹	1992	1	Gastrojejunostomy	B-Wallstent	10	68		X	0.4	Liquid	100
Truong et al ³²	1992	1	Pylorus	Wallstent	14	NA		X	3	Liquid	100
Song et al ²⁹	1993	1	Antrum	Song stent	18	80		X	3	Regular	100
Solt and Papp ²⁷	1993	1	Gastrojejunostomy	Strecker	19	40		X	6	NA	100
Keymling et al ¹³	1993	3	Duodenum	AV-Wallstent	16	100		X	4.2	Liquid (2); semisolid (1)	100
Maetani et al ¹⁸	1994	1	Duodenum	Z-stent	30	50		X	4	Regular	100
Strecker et al ³⁰	1995	1	Duodenum	Ultraflex	20	120		X	0.8	Liquid	100
Sommer and Bethge ²⁸	1995	1	Gastric body	AV-Wallstent	16	62		X	4.5	Regular	100
Freeman and Cass ⁸	1996	1	Afferent loop	B-Wallstent	10	90	X		4	NA	100
Binkert et al ³	1996	7	Stomach, gastroenterostomy, duodenum	AV-Wallstent	16	23-45	X	X	2.6	Soft	71
Maetani et al ¹⁷	1996	1	Antrum	Z-stent	30	NA		X	9	Regular	100
Feretic et al ⁷	1996	12	Gastroduodenostomy, duodenum, efferent loop	Wallstent	22	NA		X	>2	Semisolid	100
Kozarek et al ¹⁵	1997	5	Afferent and efferent loop	Ultraflex	16-20	NA		X	NA	NA	100
		1	Proximal jejunum								

119

Feretis et al ⁶	1997	10	Duodenum	Eso-Wallstent	22	90	X	NA 1 to 5	Regular (10)	100
de Baere et al ⁴	1997	10	Stomach, duodenum	Wallstent	16	56	X	3	Regular (8)	80
Pinto ²¹	1997	6	Antrum, duodenum	E-Wallstent (5)	20	70	X		Regular (1); liquids/soft (5)	100
Patton and Carter ²⁰	1997	1	Gastrojejunostomy	AV-Wallstent (1) E-Wallstent	16 21	45 70	X X	1.3	Soft	100
Langhorne et al ¹⁶	1997	1	Duodenum	Wallstent	12	90	X	0.8	Pureed	100
Soetikno et al ²⁶	1998	12	Antrum, duodenum	E-Wallstent	16-22	60, 90	X	3.3	Regular (6); pureed (3)	75
Yates et al ³⁶	1998	7 3 1	Antrum, duodenum, gastroduodenostomy, gastrojejunostomy, jejunum	B-Wallstent AV/TB-Wallstent Ultraflex	10 16-20 18		X ? X	2.8	Semisolid (8); liquid (2)	91*
Wayman et al ³⁴	1998	2	Jejunum	Ultraflex		120	X	3.5	Regular	100
Bethge et al ²	1998	6	Stomach, pylorus, duodenum, gastrojejunostomy	Wallstent	16	60, 90	X	0.8	NA	100
Zagnoon ³⁷	1998	1	Pylorus	E-Wallstent			X	2	Semisolid	100
Venu et al ³³	1998	1 7	Antrum, duodenum	B-Wallstent E-Wallstent	10 22	68 60-90	X X	4.1	Pureed	88

Based on articles published by December 1998.

B = biliary; AV = vascular; E = enteral; Eso = esophageal; TB = tracheobronchial.

* Half had continuing intermittent vomiting.

449

113

37

Gianturco-Rosch Z-stent (Wilson-Cook Inc., Winston-Salem, NC).^{14, 31} The biliary stent, which can be placed through the endoscope channel (TTS), has a small diameter (10 mm). The Z-stent has a larger diameter. Unfortunately, it has a large delivery system; it cannot be placed TTS. The vascular Wallstent has been used as well.¹³ It has a large diameter, but its delivery system is too short to allow placement TTS. Despite design and delivery system shortcomings, self-expandable metal stents were shown to be safe and feasible for palliation of malignant gastrointestinal obstruction.

TTS stent placement under fluoroscopy is easier and more precise than non-TTS routes. Once deployed TTS, the optimal stent must have a large diameter to prevent migration and to be clinically effective. The Wallstent Enteral stent was designed to meet some of these requirements. The Wallstent Enteral stents have been shown to be safe, to palliate obstructive symptoms, and to allow the patient to take in food orally.^{26, 33} In this article we focus on the use of self-expandable metal stents to treat malignant gastric-outlet, duodenal, and small-intestinal obstruction, with a particular emphasis on the use of Wallstent Enteral stent.

TECHNIQUE

The optimal placement of a self-expandable metal stent to treat malignant gastrointestinal obstruction requires combined use of endoscopy and fluoroscopy.^{26, 33} In addition, the majority of patients with unresectable gastric or small-intestinal obstruction have had abdominal CT scans and upper gastrointestinal and small bowel radiographic studies that can guide stenting by revealing the anatomy of the obstruction.

Endoscope Selection

The majority of malignant strictures of gastric-outlet and small-intestinal obstruction occur within reach of the upper endoscope. In these cases, the use of a therapeutic duodenoscope is particularly useful for deployment of the Wallstent Enteral,^{26, 33} even in patients who have malignant gastric stricture (Fig. 1). The elevator of the duodenoscope improves our ability to direct placement of the guidewire and provides the additional leverage necessary to push the stent through a tight stricture. The minimum channel diameter required for the deployment of Wallstent Enteral is 3.6 mm.

The choice of endoscope does not appear to be particularly important when non-TTS stent is to be deployed. Bethge et al² and Feretis et al,⁶ for example, used the forward-viewing pediatric endoscope (Olympus GIF-XP20 [Olympus America Inc., Long Beach, CA]) to pass through the malignant strictures and to place the guidewire.

Guidewire Selection

The authors use a standard 450-cm long, 0.035-in Glidewire or Zebra guidewire (Microvasive, Watertown, MA) through the stricture using a standard endoscopic retrograde cholangiopancreatography (ERCP) cannula.²⁶ Others have found that stiffer guidewires, such as the 0.038-in Savary guidewires (Wilson-Cook, Winston-Salem, NC),³⁶ preferable because these wires are less likely to form loops when the stent is advanced through a tight stricture.

114

Stent Selection

We determine the length of the stricture by observing fluoroscopically the distance that the catheter travels. Others use a forward-viewing pediatric endoscope and measure the length of the stenosis using markings on the endoscope shaft.² We recommend that the stent be at least 2 to 4 cm longer than the stricture.²⁶ Kozarek and colleagues used stents that were 1 to 3 cm longer than the neoplasm proximally and distally.¹⁹ The Wallstent Enteral stents are available in lengths of 60 and 90 mm and in diameters of 18, 20, and 22 mm. In general, we have found it safe to use the largest-diameter stent irrespective of the diameter of the stricture.

Deployment Technique

When we can pass an endoscope, we mark the distal end of the stricture by injecting iodinated contrast agent submucosally. Otherwise, we determine the distal end by infusing contrast agent through a standard ERCP cannula while observing fluoroscopically. In our experience, dilation of the stricture prior to stent deployment is usually unnecessary. We advance a 0.035-in guidewire coaxially through a standard ERCP cannula placed in the accessory channel until it traverses the stricture (see Fig. 1).

We prime the Wallstent Enteral stent assembly by injecting saline generously through the extension tube and activating the catheter's hydrophilic lining. We lubricate the external surface of the stent and examine it for perforated wire.

We then advance Wallstent Enteral stent over the guidewire such that its ends are equidistant from the ends of the stricture. We station the tip of the endoscope adjacent to the stricture to facilitate close observation and control of deployment. To deploy the stent, the assistant gently pulls its membrane covering. During deployment, we need to reposition the stent constantly, because it tends to move away from the endoscope. The stent delivery mechanism (Unistep) allows the stent to be repositioned to a more proximal location as long as it has not been fully deployed. Once deployed, however, these stents cannot be repositioned. Successful deployment of a stent is usually immediately evidenced by both endoscopic and fluoroscopic views. It is usually unnecessary to pass the endoscope through the stented stricture or to dilate the deployed stent. These stents may require 24 to 48 hours to deploy fully (see Fig. 1).

In cases where biliary obstruction occurs or is likely, we place a self-expandable biliary stent prior to deployment of a gastric or duodenal stent (Fig. 2).²⁶ Others have successfully placed biliary metal stents percutaneously⁴ or plastic stents TTS as needed when jaundice occurs.⁶

In cases where the stent is too short to cover the length of the stricture, it is safe to place multiple stents serially (Fig. 3). Additional stents are often also required in cases when the fully expanded stent does not cover the proximal or distal end of the stricture. The timing, potential etiology, and evaluation of patients who develop recurrent obstructive symptoms after stent placement are listed in Table 2.

After stenting, patients usually can be started on a clear liquid diet within a few hours, and can progress to a regular diet as tolerated, although we ask them to avoid uncooked vegetables.

OUTCOMES

Over the past 6 years, at least 25 articles have been published reporting the safety and efficacy of use of self-expanding metal stents in the treatment of more

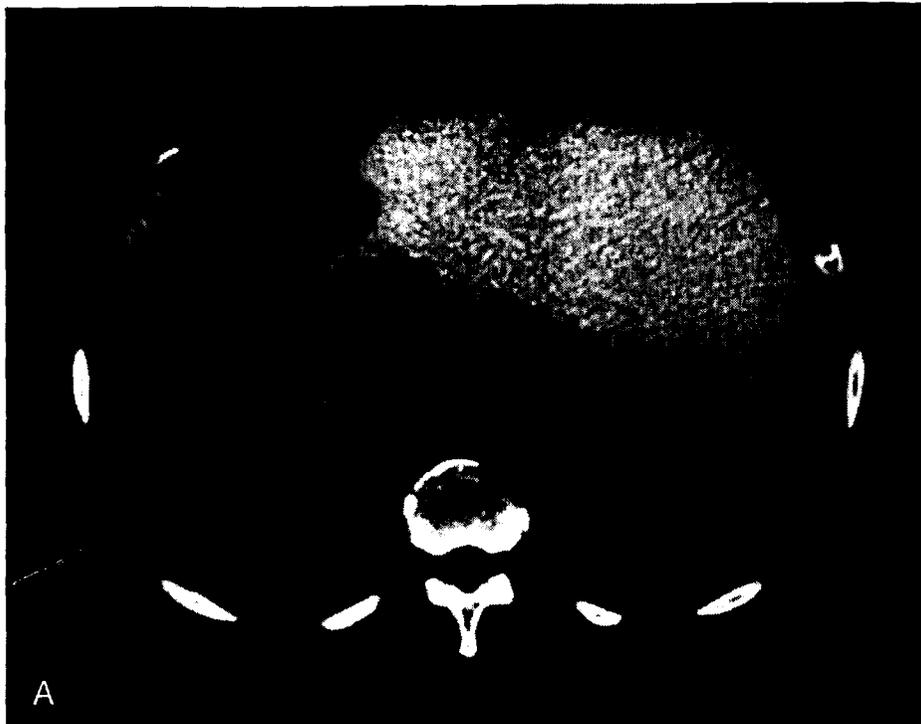


Figure 1. Palliation of gastric carcinoma with a Wallstent Enteral in 69-year-old man in whom gastric carcinoma had been diagnosed after complaints of early satiety and a 50-pound weight loss over 4 months. *A*, His CT scan showed a circumferential mass lesion in the antrum. The patient underwent stenting after an exploratory laparotomy showed that the tumor extended into the pancreas. He underwent venting gastrostomy and feeding jejunostomy surgery. Stent placement was however requested to allow peroral feeding. *B*, The stent (22 mm in diameter and 90 mm in length) was placed through the malignant stenosis over guidewire.

Illustration continued on opposite page

116

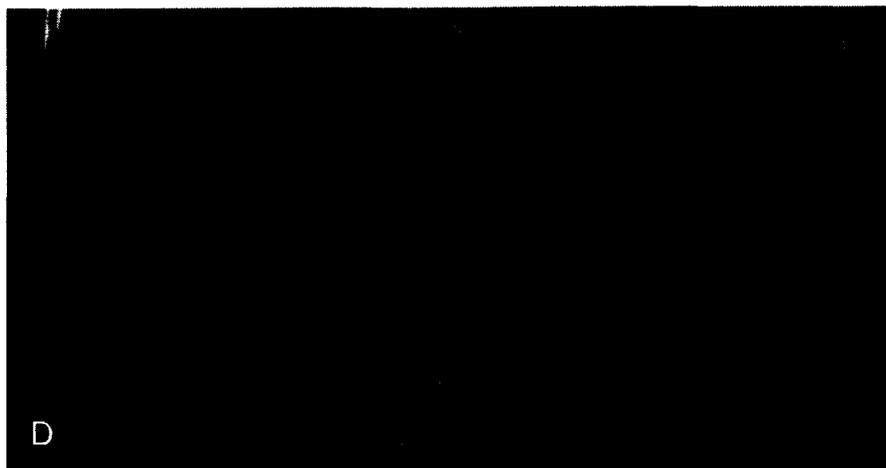


Figure 1 (Continued). C, Deployment of the stent. D, Fully expanded stent, 2 weeks after deployment.

than 100 patients with malignant gastric-outlet, duodenal, and small-intestinal obstructions (see Table 1). These studies indicate that self-expanding metal stents have had encouraging outcomes in treatment of malignant gastric-outlet, duodenal, and small-intestinal obstruction. Large-diameter stents provide significant lasting relief from obstructive symptoms and allow the majority of patients to eat a regular diet (see Table 1). In studies involving more than five patients, palliation of symptoms and ability to take adequate nutrition were achieved in more than 70% of patients (see Table 1).^{21, 26} In smaller studies, improved outcomes were usually attained in all subjects. When stents with a small diameter (e.g., biliary Wallstent) are used, recurrent vomiting and inability to take regular diet have been reported.³⁶ Most patients included in these studies would have received palliative care only and would have a very short life-expectancy. The use of stent placement appears to extend patients' life expectancy. The mean follow-up period, which in part represents patients' life expectancy, was reported to be approxi-

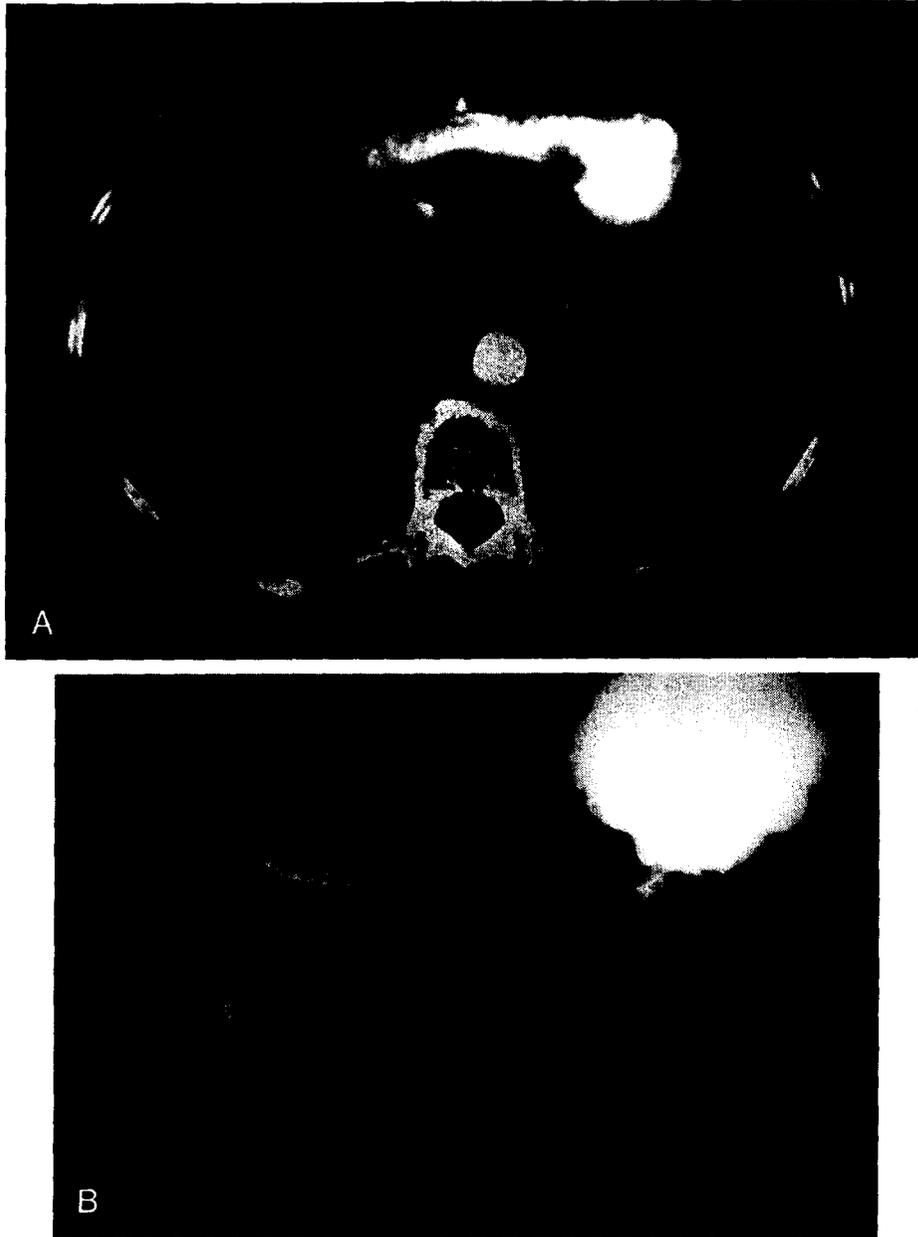


Figure 2. Concurrent palliation of gastric-outlet and biliary obstruction in 76-year-old woman in whom gallbladder carcinoma had been diagnosed 5 months earlier. *A*, The patient developed jaundice, nausea, and vomiting 1 week prior to her CT scan, which showed a large mass occupying most of the left liver lobe and encroaching the distal antrum and proximal duodenum. *B*, The patient underwent an ERCP, during which two self-expanding metallic Wallstent stents were placed: a biliary stent (diameter 10 mm) to alleviate stenosis of the common hepatic duct, and an enteral stent (diameter 20 mm and length 90 mm) to relieve stenosis of the antrum and duodenum. Her jaundice resolved and she went home able to eat a regular diet.



Figure 3. Tandem placement of Wallstent Enteral stents through the entire duodenum in a 64-year-old man in whom gastric outlet obstruction owing to an extensive neuroendocrine cancer of the pancreas had been diagnosed 1 month earlier. Obstruction of the second and third portions of the duodenum was confirmed by an UGI series. Two (22 mm in diameter and 90 mm in length) Wallstent Enteral stents were used to palliate his symptoms. The patient's obstructive symptoms were relieved and he was able to digest a liquid to regular diet at home.

mately 13 weeks in a number of studies.^{2,4,26,36} The cause of death in most patients was due to progression of their cancers rather than from complications of recurrent obstruction.

In the era of cost containment in medicine, we need to consider the cost-effectiveness of the self-expandable metal stent to treat malignant gastrointestinal obstruction, as compared with that of the standard therapy (surgical gastrojejunostomy). To date, the available data primarily reflect the safety, feasibility, and

Table 2. TIMING, ETIOLOGY, AND EVALUATION OF RECURRENT OBSTRUCTIVE SYMPTOMS AFTER STENT PLACEMENT

Timing	Etiology	Evaluation
Immediate (days)	Unrecognized multiple obstructions distal to stent placement Poor gastrointestinal motility due to medications or significant tumor infiltration to the submucosa and muscular layers, mesentery, or celiac plexus	Upper gastrointestinal series, CT
Intermediate (1-2 wk)	Fully developed stent is too short to bridge the stenosis	Endoscopy with possible repeat stent placement
Delayed (Weeks-months)	Tumor ingrowth or overgrowth	Endoscopy with possible repeat stent placement
Variable	Tumor metastasis to the central nervous system	CT of the brain

119
43

effectiveness of treatment with these stents, but they do suggest that self-expanding metal stents are potentially cost-effective. The overall cost of treatment with a stent probably is lower than that with surgery, because stenting does not require costly use of an operating room and a recovery stay in the hospital. We discharge patients after recovery in the endoscopy unit or after a 24-hour observation.²⁶ Other authors have reported similar brief hospitalization after stent placement.^{4,33} The effectiveness of stenting is measured by patients' quality and length of life. Patients who receive stents require less time to recuperate than do patients who have surgery. Bethge and colleagues² reported that patients' functional status, as measured by the Kanofsky score, increased after stenting. In comparison, surgery is associated with morbidity and mortality. Thus, the quality and length of life of patients who receive stents are likely to be higher and longer (on average) than those of patients who have palliative surgery (Table 3).

Complications

The use of self-expandable metal stents has been associated with minimal complications. The wire of the stent has been reported to cause ulceration with insignificant bleeding.⁶ Obstruction of the distal end of the stent has been reported; it was corrected by placement of an additional stent. There have been no reports of death attributed directly to stent placement.

The self-expandable metal stents used in the esophagus are usually covered to prevent tumor ingrowth. Unfortunately, the delivery system for covered stents is larger and more rigid than is that for noncovered stents, and it cannot be placed TTS. The Wallstent Enteral stent is not covered. Although it is theoretically plausible that tumor ingrowth limits the effectiveness of Wallstent Enteral stents, published experience suggests that tumor overgrowth is more common than ingrowth. Additional stent placement usually alleviates obstruction due to either tumor overgrowth or ingrowth.^{4,26}

FUTURE PROSPECTS

Various authors have now reported the safety and efficacy of self-expanding metallic stents used to palliate symptoms in patients who have malignant gastric-

Table 3. POTENTIAL COST-EFFECTIVENESS OF WALLSTENT ENTERAL TO TREAT MALIGNANT GASTROINTESTINAL STENOSES

	Surgery	Stent
Cost		
Treatment	More	Less
Posttreatment	+++	+
Overall	More	Less
Quality of life		
Relief of obstruction	Delayed due to postoperative care	Immediate
Remaining life expectancy	Similar	Similar
Overall	More	Less
Quantity of life		
Procedure mortality	Significant	Small
Overall		More cost-effective

120

outlet, duodenal, and small-intestinal obstruction. In this era of cost containment, however, application of new technologies in medical practice is scrutinized closely. Thus, future studies of metal stents used to treat malignant gastrointestinal obstruction need to assess cost-effectiveness. Stenting is so likely to be more cost-effective than surgery that its use probably will increase before it has been proved so. Self-expanding metal stents probably will be used in patients who are able to have surgery despite incurable malignancy, rather than being limited to patients who are too ill or are otherwise unsuitable candidates for surgical treatment. As we gain experience and gather long-term safety data, the use of expandable metal stents may be expanded to include patients who have benign strictures. Use of metal stents to treat benign gastric-outlet or small-intestinal obstruction has been reported for only a few cases.³ Binkert and colleagues³ used the vascular Wallstent (diameter 16 mm and length 45 mm) to treat two elderly patients who had pyloric stenoses. The patients were followed for 52 and 30 weeks. Both were able to eat solid foods and had no recurrent symptoms.

References

1. Baines MJ: The pathophysiology and management of malignant intestinal obstruction. In Doyle D, Hanke GWC, MacDonald N (eds): Oxford Textbook of Palliative Medicine, ed 2. Oxford, England, Oxford University Press, 1998, p 526
2. Bethge N, Breikreutz C, Vakil N: Metal stents for the palliation of inoperable upper gastrointestinal stenoses. *Am J Gastroenterol* 93:643, 1998
3. Binkert CA, Jost R, Steiner A, et al: Benign and malignant stenoses of the stomach and duodenum: Treatment with self-expanding metallic endoprosthesis. *Radiology* 199:335, 1996
4. de Baere T, Harry G, Ducreux M, et al: Self-expanding metallic stents as palliative treatment of malignant gastroduodenal stenosis. *AJR Am J Roentgenol* 169:1079, 1997
5. Faisinger RL, Spachynski K, Hanson J, et al: Symptom control in terminally ill patients with malignant bowel obstruction. *J Pain Symptom Manage* 9:12, 1994
6. Feretis C, Benakis P, Dimopoulos C, et al: Duodenal obstruction caused by pancreatic head carcinoma: Palliation with self-expandable endoprosthesis. *Gastrointest Endosc* 46:161, 1997
7. Feretis C, Benakis P, Dimopoulos C, et al: Palliation of malignant gastric outlet obstruction with self-expanding metal stents. *Endoscopy* 28:225, 1996
8. Freeman ML, Cass OW: Interlocking expandable metal stents for simultaneous treatment of malignant biliary and duodenal obstruction [letter]. *Gastrointest Endosc* 44:98, 1996
9. Ho SB, Silvis SE: Tandem wire mesh stents for palliation of obstructing gastroduodenal adenocarcinoma. *Gastrointest Endosc* 42:363, 1995
10. Holstege A, Gross V, Lock G, et al: Self-expanding metallic stent placement in the palliation of inoperable malignant gastric outlet obstruction. *Gastrointest Endosc* 41:A38, 1995
11. Howden CW, Woods BL: Self-expanding metal stents for palliative treatment of malignant biliary and duodenal stenoses. *Gastrointest Endosc* 42:104, 1995
12. Howell D, Bosco J, Muggia R, et al: Endoscopic double bypass: Duodenal metal expandable stenting in late stage malignancy. *Gastrointest Endosc* 140:A38, 1994
13. Keymling M, Wagner H, Vakil N, et al: Relief of malignant duodenal obstruction by percutaneous insertion of a metal stent. *Gastrointest Endosc* 39:439, 1993
14. Kozarek R, Ball T, Patterson D: Metallic self-expanding stent application in the upper gastrointestinal tract: Caveats and concerns. *Gastrointest Endosc* 38:1, 1992
15. Kozarek RA, Brandabur JJ, Raltz SL: Expandable stents: Unusual locations. *Am J Gastroenterol* 92:812, 1997
16. Langhorne NB, Asch MR, Jaffer N: Palliation of gastrointestinal obstruction with expandable metallic stents: 3 case reports. *Can Assoc Radiol J* 48:327, 1997

17. Maetani I, Inoue H, Sato M, et al: Peroral insertion techniques of self-expanding metal stents for malignant gastric outlet and duodenal stenoses. *Gastrointest Endosc* 44:468, 1996
18. Maetani I, Ogawa S, Hoshi H, et al: Self-expanding metal stents for palliative treatment of malignant biliary and duodenal stenoses. *Endoscopy* 26:701, 1994
19. Nevitt AW, Vida F, Kozarek RA, et al: Expandable metallic prostheses for malignant obstructions of gastric outlet and proximal small bowel. *Gastrointest Endosc* 47:271, 1998
20. Patton JT, Carter R: Endoscopic stenting for recurrent malignant gastric outlet obstruction. *Br J Surg* 84:865, 1997
21. Pinto IT: Malignant gastric and duodenal stenosis: Palliation by peroral implantation of a self-expanding metallic stent. *Cardiovasc Intervent Radiol* 20:431, 1997
22. Rajiman I, Roddey G: Treatment of malignant duodeno-biliary obstruction with double-endoscopic stenting. *Gastrointest Endosc* 41:A466, 1995
23. Scott-Mackie P, Morgan R, Farrugia M, et al: The role of metallic stents in malignant duodenal obstruction. *Br J Radiol* 70:252, 1997
24. Sebastian JJ, Zaragozano R, Vicente J, et al: Duodenal obstruction secondary to a metastasis from an adenocarcinoma of the cecum: A case report. *Am J Gastroenterol* 92:1051, 1997
25. Shepherd HA, Royle G, Ross APR, et al: Endoscopic biliary endoprosthesis in the palliation of malignant obstruction of the distal common bile duct: a randomized trial. *Br J Surg* 75:1166, 1988
26. Soetikno RM, Lichtenstein DR, Vandervoort J, et al: Palliation of malignant gastric outlet obstruction using an endoscopically placed Wallstent. *Gastrointest Endosc* 47:267, 1998
27. Solt J, Papp Z: Strecker stent implantation in malignant gastric outlet stenosis. *Gastrointest Endosc* 39:442, 1993
28. Sommer A, Bethge N: Relief of malignant external gastric obstruction by endoscopic implantation of a self-expanding metal stent. *Endoscopy* 27:210, 1995
29. Song HY, Yang DH, Kuh JH, et al: Obstructing cancer of the gastric antrum: Palliative treatment with covered metallic stents. *Radiology* 187:357, 1993
30. Strecker EP, Boos I, Husfeldt KJ: Malignant duodenal stenosis: Palliation with peroral implantation of a self-expanding nitinol stent. *Radiology* 196:349, 1995
31. Topazian M, Ring E, Grendell J: Palliation of obstructing gastric cancer with steel mesh, self-expanding prostheses. *Gastrointest Endosc* 38:58, 1992
32. Truong S, Bohndorf V, Geller H, et al: Self-expanding metal stents for palliation of malignant gastric outlet obstruction. *Endoscopy* 24:433, 1992
33. Venu RP, Pastika BJ, Kini M, et al: Self-expandable metal stents for malignant gastric outlet obstruction: A modified technique. *Endoscopy* 30:553, 1998
34. Wayman J, Bliss R, Richardson DL, et al: Self-expanding metal stents in the palliation of small bowel stenosis secondary to recurrent gastric cancer. *Gastrointest Endosc* 47:286, 1998
35. Weaver D, Winczek R, Bowman D, et al: Gastrojejunostomy: Is it helpful for patients with pancreatic cancer? *Surgery* 107:608, 1987
36. Yates MR 3rd, Morgan DE, Baron TH: Palliation of malignant gastric and small intestinal strictures with self-expandable metal stents. *Endoscopy* 30:266, 1998
37. Zagnoon A: Dr. Bethge et al.'s Case on Stent Use. *Am J Gastroenterol* 93:2311, 1998

Address reprint requests to

Roy M. Soetikno, MD, MS
VA Palo Alto Health Care System
Stanford University School of Medicine
3801 Miranda Ave, GI111
Palo Alto, CA 94304

e-mail: soetikno@alumni.stanford.edu

METALLIC STENTING FOR COLORECTAL OBSTRUCTION

Simon K. Lo, MD

Colorectal cancer is the third leading cause of cancer death in the United States, affecting men and women equally.²⁸ In 1998, there were an estimated 131,600 new cases of colon cancer in this country, making it the third most common cancer to be diagnosed. Worldwide, 150,000 patients die annually from this disease.¹⁵ Although most patients are unaware of its presence at the time of diagnosis, about 10% to 30% of colon cancer patients may experience obstructive symptoms during the course of their illness.^{15, 35}

COLONIC STRICTURES

Most colonic strictures are caused by cancer obstruction. Nearly half of the cases, however, may be due to benign diseases, especially when the site of obstruction is in the left colon.¹⁶ A vast majority of colonic emergencies (85%) are due to cancer obstruction.¹⁵ Other common causes of obstruction include diverticular disease, inflammatory bowel disease, extrinsic compression, postradiation stricture, and anastomosis scarring. Anastomotic strictures occur in 1% to 5% of patients following resection of colorectal cancer,⁶ although numbers as high as 25% to 40% have been quoted.⁵ Colonic cancer causing obstruction tends to be at a more advanced stage than in nonobstructed cases.¹⁵ A small study showed that all malignant rectal strictures were either stage III or stage IV cancer.³⁸ In another study, 40% of malignant colonic obstruction was due to Duke's D and 60% from Duke's C cancer.²⁰ Roughly 75% of obstructing colorectal cancers are discovered in the descending colon or rectosigmoid,^{29, 33, 35, 55} locations that are generally easily accessed by endoscopy.

Standard of Care

Whatever the cause of colonic obstruction, it appears that surgeons view the location differently and assign surgical treatment accordingly. Right colonic

From the Department of Medicine, University of California, Los Angeles, California; and the South Bay Gastroenterology Medical Group, Torrance, California

GASTROINTESTINAL ENDOSCOPY CLINICS OF NORTH AMERICA

VOLUME 9 • NUMBER 3 • JULY 1999

459

123
47

obstruction, for instance, is frequently treated with a one-stage procedure that includes resection and anastomosis without any colostomy.²⁹ A similar procedure, however, may become technically more difficult to perform on an acutely obstructing left colonic or rectal lesion. Malignant obstruction of colostomy poses a unique problem, because it is usually of a very advanced stage. Surgical bypass is usually recommended to avoid resection of the bulky tumor in a field scarred by previous operation.

More than half of emergently operated patients for colon cancer may require a stoma, with a 19% hospital mortality rate.⁴⁶ Colon cancer obstruction, particularly when it is located on the left side, predisposes to dehydration (50%) and abdominal distention (85%).²⁹ A colonic lumen filled with fecal contents, high cancer grades, older age, and debilitated states are all factors that demand caution when planning surgery in this setting.^{15, 16, 29} Even with recent surgical advances, only one quarter of all left-sided colonic obstructive cancer can be treated with a resective surgery without any need for a stoma.²⁹ When careful selection is made, a one-stage resection is as safe as each step of the conventional three-stage surgical procedures.¹⁵ Such selection criteria have not been worked out, however, and are usually not listed in the literature.^{15, 29} Whether it is for rehydration, feeding, or optimal colon preparation for surgery, an initial nonoperative procedure is highly desirable. Once the physical condition has improved, the patient can undergo a one-step operation for cancer resection. If metastatic disease is discovered at subsequent workup, a simple endoscopic treatment is the logical method of palliation.^{3, 5, 45}

In a literature pool of 2383 patients treated for colonic cancer obstruction between 1971 and 1991, a 22.4% surgical mortality rate was noted among the patients operated on emergently.⁴² A study that collected publications from 1985 to 1992 showed an improved 7.2% surgical mortality rate in 789 obstructed patients.¹⁵ Whether the surgery was performed in a one-stage operation, three-stage operation, or by diverting colostomy, the overall mortality rates were comparable. More recently, an impressive 2.8% mortality rate was reported among 143 patients who presented with the more difficult left-sided obstruction.¹⁶ These publications suggest a trend of improved surgical mortality over the last 30 years. The improved surgical survival today, however, may be influenced by better patient selection.¹⁵ For instance, the retrospective study of Deen et al¹⁶ reported on mostly subacute obstructive cases in which 83% of their patients could tolerate oral polyethylene glycol preparation.

Alternative Treatment Modalities

The key reason that surgery is preferred for colorectal obstruction is the ability to perform curative resection of the underlying cancer. Therefore, any alternative treatment modality must be viewed as a palliative or temporizing measure. It must compare well against surgery's 7% mortality rate and 15 to 20 day hospital stay.¹⁵

Several nonsurgical modalities have been applied for colonic strictures; almost all were transanal approaches for obvious reasons. These methods included bougienage,³⁶ scope dilator,³⁶ balloon dilator,^{4, 36} electrocautery,²¹ photodynamic therapy,³⁷ and laser ablation therapy.^{13, 34} Even cryotherapy and endoscopic injection of necrotizing agents have been tried.⁴⁹ Although effective, most endoscopic treatment of colonic strictures recurs and requires repeated sessions of therapy that invariably increase expenses and complications.^{6, 36, 49} In addition, the success rate for recanalization of colorectal strictures with these methods has only been reported to range from 56% to 72%.⁶ It becomes logical to assume that inserting a

tube device that traverses the obstruction is an appropriate technique for a more effective and lasting outcome. Indeed, this was an early version of colonic stenting successfully applied to convert an emergent surgery to an elective, single-stage surgical procedure.²³

COLONIC STENTING

Gastrointestinal stenting was first utilized for treatment of esophageal obstruction. Made of plastic material, these large and relatively inflexible tubes were hard to place orally and were not applicable in the typically tortuous colon. A small and more flexible 24F catheter thoracotomy tube has been used successfully to provide temporary relief of obstruction prior to a definitive surgical resection.²³ Nasogastric tubes have also been used and achieved similar, positive results.^{30, 40} These types of small-caliber tubes, however, can hardly result in any long-term or significant effect.¹ Securing these stents inside the colon could also pose serious technical problems. An ideal stent is one that is flexible, easy to insert transrectally, and can expand to approximate the caliber of the colon. These features are now being incorporated in the expandable metallic stents, which were first introduced to treat occlusive vascular diseases.⁴⁷ Contrary to the small vascular or biliary lumen, the colon is a large-caliber organ that makes it easier to design a collapsed stent delivery system without serious concern for its profile. But the large bowel also has its own unique features that make it more difficult for stent development. Sharp angulations and redundancy, typically worse in the most commonly obstructed distal colon, predispose to colonic folds draping over the two ends of the stent. The same factor also produces excessive tension at the points of contact, which may lead to reactive mucosal hyperplasia that threatens stent patency, or pressure necrosis that could result in chronic pain or perforation. Thus, it is difficult to design a stent that can maintain a large channel to handle fecal material but is sufficiently soft to conform to the shape of the large intestine. In the case of a proximal colonic lesion, the long distance and tortuosity pose even greater challenges to a radiologist or gastroenterologist in bringing the stent to the point of obstruction.

TYPES OF COLONIC ENDOPROSTHESES

Dohmoto was credited as the first to report on metallic stenting of the colon in 1991.¹ Today, there are four different types of metallic stents that have been used for this purpose; however, the only Food and Drug Administration-approved stent for malignant colonic obstruction is the enteral Wallstent (Microvasive Endoscopy, Boston Scientific Corporation, Natick, MA). The other metallic stents utilized are designed to treat esophageal or biliary tract obstruction. They are biliary Wallstent; esophageal Wallstent; Z-stent (Wilson-Cook, Winston-Salem, NC); EsophaCoil (Bard Interventional Products, Billerica, MA); and Ultraflex esophageal stent (Microvasive Endoscopy, Boston Scientific Corporation, Natick, MA) (Table 1). In Korea, a self-made Gianturco stent, with designs almost identical to that of the Z-stent, has been used extensively. Z-stent is the only fully covered stent, whereas the Ultraflex and esophageal Wallstent are partially covered.

Enteral Wallstent. This is the most popular colonic stent today, with approximately 125 placements reported in the literature (see Table 1).^{*} Clinical experience

* References 3, 5-7, 10, 12, 14, 18, 19, 22, 25, 26, 33, 39, 41, 43, 44, 48-53, and 55.

125
49

Table 1. COMPARISON OF THE DIFFERENT TYPES OF METALLIC STENTS

	Delivery Catheter Stiffness	Delivery Catheter Size	Radial Strength	Edge Design
Wallstent-enteral	+++	10F	+++	Sharp wires
Z-stent	+++	31F	+++	Coated
Ultraflex	++	16F	++	Soft wire loops
EsophaCoil	+++	32F	++++	Smooth coil
Wallstent-biliary	+	7.5F	+	Sharp wires
Wallstent-esophageal	++++	18F	+++	Sharp wires

	Assembling	Covered Option	Through-the-Scope Option	Cost (\$)
Wallstent-enteral	Minimal	No	Yes	1195-1825
Z-stent	Complicated	Complete	No	795-895
Ultraflex	None	Partial	No	1250-1350
EsophaCoil	None	No	No	1500
Wallstent-biliary	Minimal	No	Yes	1075-1505
Wallstent-esophageal	Minimal	Partial	No	1695-1895

suggests that this stent is sufficiently strong and yet flexible to conform to curvatures within the intestine.⁴⁹ Because of its through-the-scope delivery option, this is the only metallic stent that has been placed in the right and transverse colon.⁸ Experience in stenting proximal colonic obstruction, however, is still very limited. In spite of a thin external profile, the part of the delivery catheter that houses the stent is extremely stiff (see Table 1). Passage of this rather rigid device through an angulated endoscope channel or over a guidewire in the tortuous colon may not be possible. The free ends of its individual metallic filaments should be more effective in stabilizing a newly deployed stent relative to the other types of metallic stents. The uncovered, open mesh design raises concerns for early tumor ingrow and easy stent occlusion. There is little clinical evidence, however, to suggest that is the case.

Other Wallstents. Before the availability of the larger enteral Wallstents, the biliary Wallstent had been used for stenting of colonic obstruction. Being a truly through-the-scope device, this stent is very easy to place. Its small caliber predisposes to early migration, however, as shown in the limited literature and our own unpublished experience.⁵ The small internal diameter may pose additional problems, such as early stent occlusion and ineffective colonic decompression.⁴⁸ Nonetheless, the ease of stent placement may find this stent suitable for cases that are definitely going to be followed by surgical resection. Tracheobronchial Wallstents have also been used in this setting, with successful outcome.⁵⁵ With luminal diameters of 20 to 24 mm and lengths of 35 to 70 mm, these stents contain all the characteristics of the enteral Wallstents, but have a much shorter delivery catheter. They are more suitable for fluoroscopically directed stent placement. Another version of Wallstent, the covered esophageal Wallstent sold in the United States, is quite stiff and is probably not a good stent to use in the tortuous colon. Negotiating the sigmoid colon, with its rigid and bulky delivery catheter, is technically very challenging and potentially hazardous.

Esophageal Z-stent. Constructed of connecting 2-cm wire cages, this is a stent with good strength but lacking flexibility within each cage. The articulating design predisposes the stent to collapse at the flexible joints between the cages, if it is placed in an angulated colon. Being fully covered, it seldom allows tumor

ingrowth. This feature also renders it removable even months after its insertion. But the combination of a full coating and the minimal expansions on both ends is believed to be the cause of easy migration in the esophagus. The same problem may apply to the colon as well. Perhaps the biggest obstacle to placement of a Z-stent lies within the design of its delivery catheter. The catheter is quite rigid and it requires a relatively complicated loading process before fitting over a guidewire for stenting. In spite of its shortcomings, Z-stent is the second-most common stent used for treatment of colorectal obstruction (Table 2).

Ultraflex Esophageal Stent. This is a very flexible stent made of soft nitinol material. As opposed to the Wallstent, its two ends are constructed of tiny soft wire loops and are gentler to the colonic mucosa. This feature, however, reduces its ability to attach firmly to the colonic wall. The delivery catheter is reasonably soft and small to pass through a tortuous and tight colonic lumen, but still too large to insert through any endoscope. The end of the delivery device has the tendency to bow around the curvature of the colon instead of unraveling when the drawstring is pulled to release the stent. Using a proximal release device may overcome this problem. The externally located stent cover also predisposes to stent migration, which seems to occur more often than with the enteral Wallstent.

EsophaCoil Esophageal Stent. The experience of utilizing this esophageal stent for colonic obstruction is perhaps the most limited of all metallic stents (see Table 2). Similar to the other esophageal stents, the delivery catheter of the EsophaCoil stent is quite bulky and inflexible, making the passage through the distal colon a difficult task.⁵² Unlike the other metallic stents, the EsophaCoil stent is made of a strong coil that instantaneously reaches its natural caliber. This rapid expansion may lead to perforation before stricture tissue has an opportunity to accommodate to the stent. The strong, noncollapsible coils may also induce pressure necrosis by pushing excessively against the colon. In spite of these potential shortcomings the smooth ends, excellent bending properties, and tightly wound coil design could be advantageous to future stent development.⁶

UTILITY OF METALLIC STENTS

Palliation of Malignant Colonic Obstruction. Perhaps the best indication of colonic stenting is in the treatment of documented metastatic cancer with large bowel obstruction. In spite of a general impression of ease and safety, surgical management of obstructive colorectal cancer still results in significant operative mortality and morbidities. Regardless of the surgical option chosen, the best surgical mortality rate recorded in the most recent literature is still around 3%.^{11, 15, 16} For patients who are obviously terminal, a simple re-establishment of colonic patency with a stent is the most reasonable treatment modality. Of course,

Table 2. TECHNICAL SUCCESS IN METALLIC STENTING

Stent	Endoscopy + Fluoroscopy	Fluoroscopy Alone	Failed Placement	Failed Drainage
Wallstent	67	67	3	12
Z-stent	22	30	6	0
Ultraflex	22	1	3	0
EsophaCoil	12	0	0	2
TOTAL	123	98	12	14

this assumption is only appropriate if the mortality and morbidity rates of colonic stenting are superior or equivalent to that of surgery. Indeed, the early experience of colonic stenting with metal prostheses has been accompanied by death in 2% and perforation in 5% of the patients (Table 3). These figures are likely to improve as stenting devices improve and as endoscopists and radiologists gain more technical experience. There is no known contraindication to stenting except in the setting of a known bowel perforation.¹⁷

Temporary Treatment of Acute Colonic Obstruction. The surgical, radiologic, and endoscopic literature is filled with anecdotal reports of temporary stenting for acute colonic obstruction (Table 4).^{1, 5} These reports emphasize the advantage of converting an urgent surgery to an elective operation. Additional benefits are the ability to perform bowel cleansing, examination of the proximal colon to exclude coexisting lesions, and complete metastatic or diagnostic work-up prior to a surgical exploration. Perhaps the most compelling application of preoperative stenting is to optimize the patient's condition for a one-stage surgical resection of an obstructing lesion. In spite of these positive claims, there have been no scientific data to support the benefit of temporary stenting.

The potential of tumor dissemination as a result of stenting, no matter how unlikely, remains to be addressed.¹ Until this issue is fully addressed, aggressive stricture manipulations, other than guidewire passage and stent deployment, must be avoided. Another unresolved issue is the potential of stenting a benign disease. At the time of presentation, the etiology of an acute obstruction may not be readily diagnosed. The decision to perform stenting rests in the hands of the endoscopist or radiologist. The justifications of stenting these cases have not yet been defined.¹⁴ Fortunately, this type of lesion is neoplastic 85% of the time and palliation or resection is appropriate.¹⁵ In the cases of diverticular obstruction, surgical resection of the stented colonic segment is necessary anyway.⁷

Treatment of Benign Obstruction. Intentional stenting of benign disease is a potentially controversial area. Ten percent of all cases that involved the placement of a Wallstent were either known or subsequently proved benign strictures (see Table 4). Placement of these nonremovable stents as a permanent means of therapy must be viewed with great caution, because long-term consequences of leaving behind foreign bodies in the colon are unknown. Late colonic perforation, chronic abdominal discomfort, and late stent occlusion must be considered as realistic possibilities. Whether the immediate benefit of stenting is outweighed by its late sequelae is an uncertainty at this time. The cases reported in the literature offer reassurance because stenting seem justified, but it is difficult to guard against its indiscriminate use in these situations. If stenting is the logical choice based on overwhelming clinical reasons, it is best to consider placement of a metallic stent that can be removed subsequently. The completely covered Z-stent is ideal for this purpose, because late endoscopic retrieval is possible.³¹ There is also a short time window in which an Ultraflex stent can be removed before epithelium

Table 3. COMPLICATIONS OF METAL STENTING

Stent	Number	Distal Migration (%)	Proximal Migration (%)	Perforation (%)	Death (%)
Wallstent	135	14 (10.4)	1 (0.7)	8 (5.9)	5 (3.7)
Gianturco	52	5 (9.6)	1 (1.9)	3 (5.8)	0
Ultraflex	23	4 (17.4)	0	0	0
EsophaCoil	12	0	0	1 (8.3)	0
TOTAL	222	23 (10.4)	2 (0.9)	12 (5.4)	5 (2.3)

Table 4. INDICATIONS FOR METALLIC STENTING

Indication	No. Successfully Stented
Preoperative decompression	96
Stricture palliation	83
Benign obstruction	14
Obstructed stoma	1
Obstruction with fistula	1

grows over its exposed wire-mesh. Until the indications, circumstances, types of prostheses, and removal techniques are firmly established, performing stenting in known benign colonic strictures in a community setting should be discouraged.

Site of Obstruction. Theoretically, all levels of the colon can be stented. But the more proximal the stricture is located, the more difficult it is to insert a stent. Greater than 95% of all reported cases in the literature involved stenting of the descending colon or rectosigmoid. Obstructions located within a couple of centimeters from the dentate line may not be ideal for stenting, because perianal pain from stent irritation or stent migration may occur. Laser debulking of an unresectable tumor may be more desirable in this setting. Recurrent cancer that obstructs a colostomy poses a unique challenge to stenting, because this form of advanced disease has no distal shoulder to secure the stent. A Wallstent with a sharp distal end may create a management problem of punctured colostomy bags. Precise placement of an Ultraflex stent, with its distal end sutured to the stomal tissue, may be able to prevent another surgery for colonic bypass.

Cancer Treatment Following Colorectal Stenting. Planned chemotherapy or radiotherapy is generally considered a contraindication to esophageal stenting because of the risk of stent migration in the event of tumor shrinkage. There is only limited literature to address this issue in colonic stenting, but postoncotherapy stent migrations have been reported.^{3,5} As opposed to esophageal stent migration, colon stents usually migrate distally and may eventually be expelled spontaneously. Even in the event that a migrated stent is trapped within the distal colon, endoscopic retrieval is frequently successfully carried out. Therefore, it is uncertain if poststenting neoadjuvant chemoradiation should be prohibited.

Cost of Stenting. Metallic stenting is an expensive procedure. Just the stents alone cost \$795 to 1895 each (see Table 1). In spite of technical success reported with stenting, questions remain as to the cost-effectiveness of this new technology.⁴⁵ Even if the indications are appropriate, patient selection must be judicious to avoid unnecessary expenditures and potentially unwanted procedure-related morbidities and mortality. For instance, two out of seven patients in one report died within the same hospitalization because of known extensive disease.³ These cases illustrate that it is difficult to justify spending thousands of dollars on stenting without any realistic chance of impacting the course of illness or the quality of life. Moribund patients or those with a septic picture are probably best managed conservatively unless their conditions improve subsequently.

There is only one article that attempted to address the cost-effectiveness of colonic stenting.⁷ The total costs of 13 patients so treated were compared with 13 other patients who were treated solely with surgery. Ten stented patients underwent the procedure as a preoperative measure. Details for the surgical controls were not given. Nonetheless, the total cost was reduced with stenting by 19.7%. Interestingly, cost reduction was greater when the stents were placed prior to surgery. The cost savings were due to shorter hospitalization, fewer surgical procedures, and fewer days in the intensive care setting.

STENTING TECHNIQUE

Bowel Preparation. An attempt to clean up the colon is needed to facilitate endoscopic stenting; however, complete cleansing of the distal colon is not always possible. Oral bowel preparation should be avoided because of the risk of exacerbating the intestinal obstruction. In fact, many of these patients are treated with nasogastric suctioning at the time of procedure. Colonic enemas can be given in the majority of patients.⁵ It is too early to tell if there is a role for prophylactic antibiotics.⁴⁵ There is little mentioning of antibiotic usage for stenting in the literature. In our institution, it is not a routine component of management.

Radiographic Stent Placement. Stenting can be done fluoroscopically by a combination of endoscopy and fluoroscopy.⁴⁵ Performing colorectal stenting endoscopically without the benefit of radiograph is not advised. Interestingly, there are equal numbers of cases carried out with each method in the literature (see Table 2). The radiographic technique usually begins with placing the patient in the supine or prone position. The stenosed lumen is accessed with the use of a guidewire through a torque-controlled catheter.³³ A hydrophilic guidewire is frequently used for this purpose. When excessive tortuosity or redundancy is encountered, placement of a stiff guidewire alongside the probing catheter may help straighten out the bowel for cannulation. Once the wire has crossed the stricture, the latter is studied by injection of a water-soluble contrast through the catheter.⁵⁵ The characteristics and length of the structure are carefully documented. The two ends of the stricture are marked by placement of radiopaque skin markers under fluoroscopy. It is inadequate to study the stricture with a meglumine diatrizoate enema, because poor proximal luminal distention by retrograde contrast infusion tends to exaggerate the length of the stricture. If possible, infusion of contrast in the proximal colon is done to exclude synchronous lesions that may contribute to ineffective decompression.^{9,55} A stiff wire is then inserted through the catheter for stent placement. Either a super-stiff wire or a stainless steel wire used for passage of Savary dilators may be used to avoid acute-angle bending of the guidewire during passage of the stent delivery catheter. In order to avoid wire recoil or retraction back across the stricture, the guidewire is usually advanced as far proximally as possible.⁵³ Prebending the stiff delivery device may facilitate passage around the typically tortuous rectosigmoid.⁴⁸

Combined Endoscopic and Radiographic Stent Placement. With air insufflation kept to a minimum to avoid overfilling of the proximal colon, a therapeutic colonoscope or gastroscope is advanced until the distal end of the stricture is reached. A shorter scope is preferred if a distal colonic lesion is expected. Obstruction that arises from the sigmoid colon may be extremely difficult to traverse with the entire endoscope because of trouble in getting to visualize the obstructed lumen. If this is encountered, stricture probing under fluoroscopy, using techniques commonly employed to access biliary strictures, should result in identification of the proximal colonic lumen. After carefully studying the full length of the stricture, a superstiff guidewire is introduced as far across the stricture as possible. At this point, the options are either to remove the endoscope for radiographic placement or to pass the stent delivery catheter through the scope over the guidewire. If resistance on catheter passage is not an issue, through-the-scope stent deployment is always preferred. An enteral Wallstent with the length of 2 to 4 cm longer than the actual stricture may be chosen, allowing 1 to 2 cm of the stent to extend beyond both ends of the lesion (Fig. 1).

Stricture dilation before stenting is an unresolved issue. It is usually assumed that widening of the narrow channel facilitates stent insertion and expansion. Stricture dilation of the colon, however, may carry a higher risk of perforation

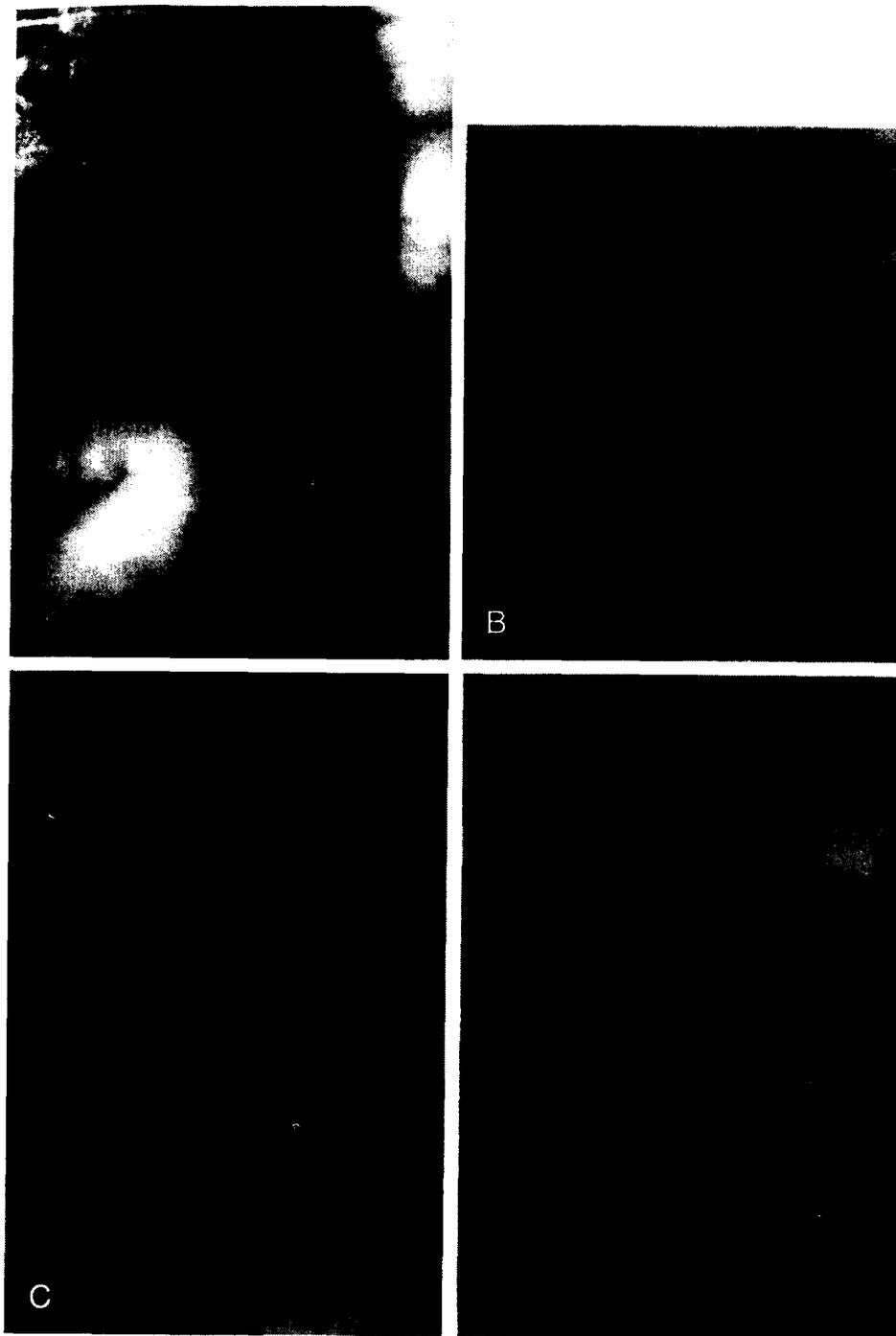


Figure 1. A, Extrinsic distal colonic stricture. B, Endoscopic-fluoroscopic placement of a Wallstent. C, Successful insertion of the Wallstent, with the hourglass appearance. D, Full expansion of the Wallstent 2 weeks later. Note the vascular stent in the background.

and bleeding than of the upper gastrointestinal tract.²⁴ In addition, there is no documentation that pre-stenting dilation is even necessary.⁵ Unless examination of the proximal aspect of the colon is absolutely necessary, scope passage across the stricture should be avoided to minimize the chance of perforation.⁷ Some authors used neodymium:yttrium-aluminum-garnet laser to ablate malignant

131

55

tissue to widen the tract for scope passage⁴¹; however, this practice is unlikely to add to stenting success or effectiveness. If the endoscope can easily traverse the obstruction, it is helpful to inject a water-soluble contrast intramucosally to mark the tumor margins for stent placement.⁵² Alternatively, radiopaque metallic clips can be used for margin identification.⁴³ If the obstructed lumen is not easily accessed endoscopically for local tumor marking, placement of external radiopaque reference markers can be done.

The Wallstent enteral endoprosthesis is designed to pass through an endoscope with a 3.6-mm or larger working channel.⁴⁸ Most therapeutic upper endoscopes or colonoscopes can be used for that purpose. In spite of a large scope channel, passage of the stent delivery device may still be difficult if it is situated in a highly angulated colon. Therefore, it is always desirable to lubricate the endoscope channel and keep the tip of the scope as straight as possible. Strictures located above the descending colon should always be assisted with an endoscope, because it may be impossible to negotiate the stent set over a guidewire around multiple turns.^{2, 27, 45} An additional advantage of the endoscopic method is that stent adjustment or removal can be carried out immediately.

POSTSTENTING CARE

Endoscopic colonic stenting can be carried out safely as an outpatient procedure, although many patients are hospitalized because of acute colonic obstruction. Immediate poststenting evaluations, however, should be done before the discharge of patients. If there is a question about adequate stenting of the entire stricture, injection of contrast into the stent lumen is needed to determine if an additional stent is needed to establish colonic patency. Likewise, the two ends of the stent should be examined to make certain that they are not covered by colonic folds. Otherwise, adjustment of the position of the stent is necessary. Some authors routinely perform contrast studies to exclude perforation following the procedure,^{22, 32} but that is rarely needed unless clinically indicated. After an initial observation of 12 to 24 hours, an assessment should be made to determine if it is safe to allow oral intake. When in doubt, an abdominal radiograph can be taken to document the degree of bowel distention and stent position.³² Patients frequently offer the history of effective flatus and fecal production following a successful procedure. Decompression of a distended abdomen may be quite obvious as well. In one study that involved 24 patients, 96% of the cases had demonstrable clinical and radiographic resolution of obstruction within 24 hours.¹⁷ If there is a question about the diagnosis or if surgery is being contemplated, bowel cleansing can begin within 24 hours. Either polyethyleneglycol or Fleet's phosphosoda is commonly prescribed for this purpose. We have originally had some concerns for stent dislodgment if bowel cleansing is begun before the stents have a chance to situate within the strictures; however, this has not been the observation in our patients. Some authors recommend that their patients adopt a low-residue diet and take daily mineral oil to prevent early stent blockage.^{1, 5} Whether they are essential recommendations remains to be seen.

CURRENT EXPERIENCE WITH METALLIC STENTING OF THE COLON

To the best of our knowledge, a total of 213 patients have been stented for colonic obstruction. Adding our nine unpublished patients, the total becomes 222

cases in which clinical experience can be tabulated (see Table 3). Ninety-four percent of stenting was for malignant obstruction. Sixty percent of cases were treated with the Wallstents, with Z-stents being the second most commonly used. Ultraflex and Z-stent seemed to have more failure with stent placement, whereas Wallstent seemed to have more unsatisfactory effects with drainage. Interestingly, 50% of all Wallstent cases were done as a preoperative procedure. There were five deaths, all related to Wallstents. All stents, except for EsophaCoil, seem to have similar rates of migration of 11% to 17%.

CAUSES OF FAILURE TO RELIEVE OBSTRUCTION

In spite of success in placement, 6% of stenting does not result in immediate decompression of the obstructed colon (see Table 2). In these cases, additional sites of intestinal obstruction must be sought.^{33, 48} Incomplete stenting of the entire length of stricture and early stent migration are other realistic possibilities. Other causes of early stent failure include underlying motility disorders, fecal impaction of the newly inserted stent, poor stent positioning, and incomplete expansion of the device as a result of bulky extrinsic compression (Fig. 2).^{7, 32, 33, 50} Baron et al⁵ described two cases of early EsophaCoil occlusion as the result of mucosal injury from tissue trapping by adjacent coils.

Late recurrence of obstruction raises the possibility of tumor ingrowth through the stent mesh or overgrowth at either end of the stents (Fig. 3). In one series where Ultraflex stents were used, all 11 stents were occluded at the average duration of 68 days.⁴¹ Tumor ingrowth was the reason in all cases. Late stent migration followed by restenosis of colonic lesions may also be another cause of delayed failure of stenting. Laser ablation or photodynamic therapy has been used effectively to re-establish stent patency,⁴¹ although there is the concern that stent disruption may occur.¹ As a result, argon plasma coagulation has been advocated for this purpose. Alternatively, additional stent insertion within the obstructed lumen may provide effective relief.¹

COMPLICATIONS

Stenting with the soft, flexible metallic endoprotheses is generally quite safe. The complication rates compare favorably with those of surgical therapy. Nonetheless, it is still a procedure with significant adverse consequences. Overall, five deaths were temporally related to the stenting procedure, giving it a 2.3% mortality rate (see Table 3). At least two of these deaths, however, were unrelated to the procedures. There was a total of 25 stent migrations, 12 perforations, and 3 cases of lasting and significant rectal pain, contributing to an 18% morbidity rate. The complication rate may be significantly higher if bleeding is taken into consideration, because some trivial degree of hemorrhage was described in a large number of patients. Saida et al,⁴³ for instance, reported that all 12 of their patients bled on the first day after their procedures with Z-stent insertion; however, there was no serious bleeding reported.

Perforation. Perhaps the most serious complication directly resulting from internal stenting is perforation, which may present in the peritoneum or retroperitoneum.⁹ Free peritoneal perforation is particularly lethal, because spillage of a large amount of fecal material may occur in the setting of colonic obstruction. Even if the perforation is small and does not result in infectious complications, the potential implication of inadvertent spillage of tumor cells should be a serious

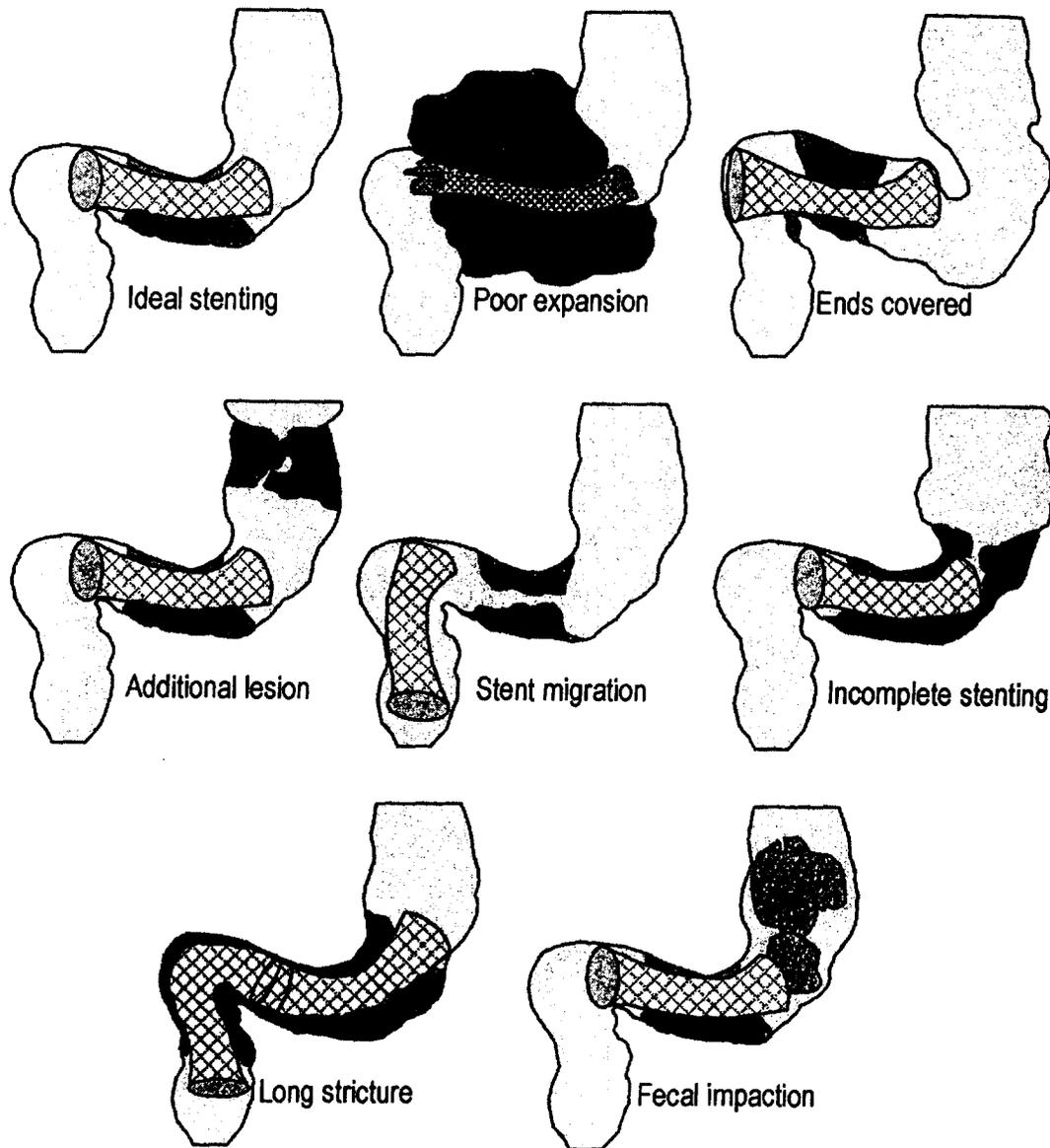


Figure 2. Possible causes of early failure after stenting.

concern. Five percent of stents are associated with colonic perforation, with most presenting within the first 3 days of procedure. We have, however, observed spontaneous perforation in the stented location at 2 months. In the literature, delayed perforation has even been reported to occur 3 months after stent deployment.⁴⁹ It is difficult to blame late perforations entirely on stenting, because spontaneous tumor perforations are known to occur. With increased experience and stent refinements, the relatively high early perforation rate is expected to fall.

Some authors have observed that the majority of serious perforations took place in the setting of balloon dilation and they regard dilation as the most important predisposing factor to stenting-related perforations.^{1,5,33} This is probably true in early perforations, but is unlikely to result in late-occurring problems. For instance, our two patients who developed late perforations had been treated with

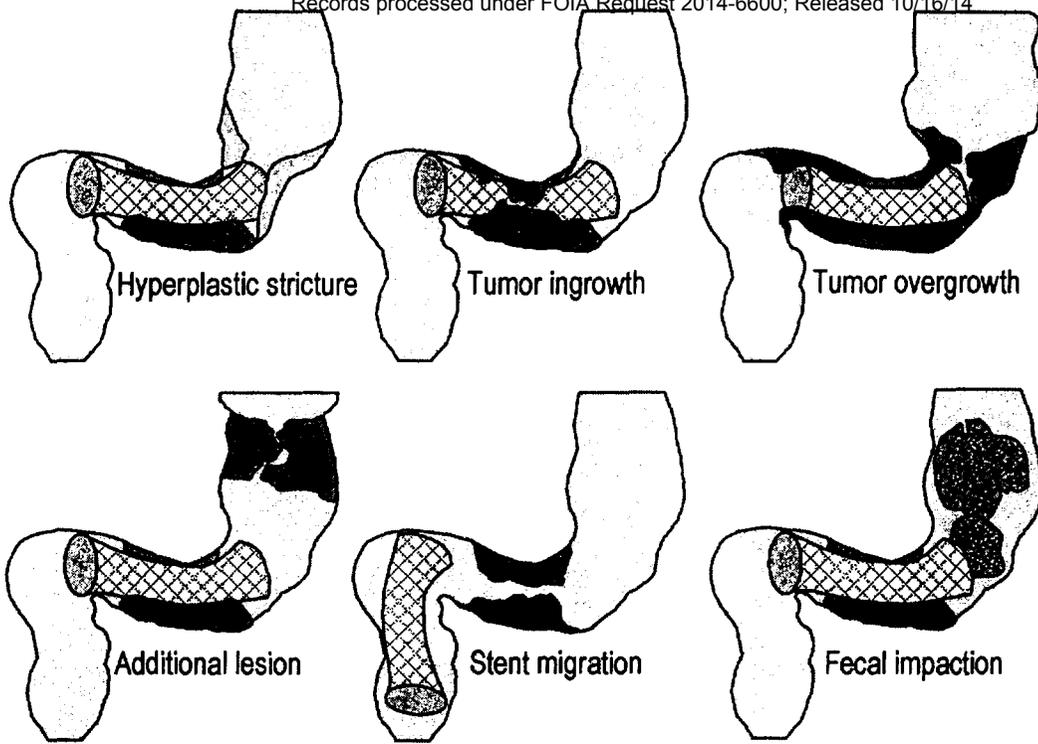


Figure 3. Late causes of recurrent obstruction following colonic stenting.

stricture dilations before. One of them had a stent placed in a highly angulated malignant stricture within a colostomy. Her perforation presented as a straight fistula, perhaps because of tissue necrosis from excessive pressure created by the sharp distal end of the Wallstent.

From a management standpoint, minor soft tissue perforations, induced by guidewire probing or stent catheter insertion, may be adequately managed with antibiotics alone.^{1,7,43} Any perforation associated with free peritoneal air, however, must be immediately treated with antibiotics, nasogastric suctioning, and exploratory laparotomy. Because stricture dilation is not essential in most cases of colonic stenting, avoidance of this maneuver should reduce the risk of full-thickness tear of the large bowel.

Bleeding. Once again, postprocedure hemorrhage is usually minor and should not be a major concern. Presumably, it is the result of tumor friability, superficial tissue tear, or mucosal irritation from the sharp end of a colonic prosthesis. Also, spontaneous stent migration may expose raw, denuded tissue that has the tendency to hemorrhage. Finally, stent-induced pressure necrosis may eventually lead to arterial erosion and potentially serious blood loss. Conservative management is generally all that is necessary for this situation. Blood transfusion, endoscopic inspection, and even surgical tumor resection are rarely needed.

Pain. Diffuse abdominal or localized discomfort is commonly seen in colonic obstruction at presentation. Therefore, it is not always easy to tell if poststenting symptoms are the result of the procedure. Nonetheless, transient and mild abdominal pain are considered common and may be felt for 3 to 5 days following the procedure.²² Another common symptom is perianal pain, which was reported in 20% of patients treated with the Z-stent.¹⁰ Oral analgesic therapy may be needed for up to 7 days. In approaching low-lying rectal lesions, care must be taken to

avoid stent-induced irritation of the nerve endings near the squamocolumnar junction, because severe protracted tenesmus has been reported.⁵¹ Excessive tension exerted by the stents on colonic tissue should be avoided, particularly with the Wallstents that produce sharp edges. One may also assume that some pain may be induced by stent expansion against tight strictures, but this cause may be very difficult to ascertain. In pain that is persistent and severe, long-term narcotic analgesic or surgical therapy may be necessary. There is probably very little one can do endoscopically in this situation.

Stent Migration. Spontaneous stent dislodgment and elimination without the patient's awareness are frequently reported.^{3, 9, 39, 48} Factors that are believed to predispose to stent migration include the following:

- Benign stricture
- Extrinsic lesion
- Prestenting laser debulking
- Stricture dilation
- Small stent caliber
- Stents with external cover
- Poststenting systemic chemotherapy
- Poststenting local radiation therapy

Perhaps half of the stent migrations are incidental findings on follow-up. Interestingly, the obstructive symptoms may not return even after stent disappearance from the colon.³⁹ Nonetheless, these patients commonly experience transient painful spasm.⁵⁴ Of course, the return of obstructive symptoms should always raise the suspicion for stent dislodgment. Migration can occur at any time, although it seems to take place either within the first 24 to 72 hours or many weeks later.^{10, 41, 54} As expected, it has been reported in patients with tumor shrinkage after neoadjuvant chemoradiation therapy or radiotherapy alone.^{3, 5} Some authors believe that stricture dilation predisposes to stent migration and advise against this practice unless absolutely necessary.^{5, 48} Likewise, preprocedure laser therapy may contribute to stent migration and should be discouraged.⁴¹ Other predisposing factors include colonic angulation, small-caliber stents, and covered stents.⁵ The issue of whether to prohibit systemic or local cancer therapy poststenting is still a matter of debate, because freely migrated stents are usually quite easy to remove. An assumption could be made that the sharp, free edges of Wallstents could serve as anchoring hooks and reduce the risk of migration; however, the literature has not supported this assumption (see Table 3). In total, 13% of all successfully placed colonic stents eventually migrate, mostly toward the distal direction.

Many dislodged stents are passed per rectum without the need to retrieve. Some stents, such as the Ultraflex and Z-stents, can be readily removed digitally. But care must be taken when reaching for a Wallstent, because trauma to the fingertip may result from the sharp endings of a Wallstent. A distally migrated stent can be removed in many ways. Wholey et al⁵⁴ described a method to remove a 22-mm-caliber Wallstent by looping a guidewire through the central lumen of the stent. The two ends of the guidewire were then pulled through a rectal speculum until the stent bent tightly against the upper end of the speculum, which was then gently retrieved. The same authors also reported using a fluoroscopically assisted method to remove an enteral Wallstent with a Kelly clamp transrectally. An anoscope speculum was not necessary, although they needed to assist the delivery with a finger in the rectum. Baron et al⁵ used biopsy forceps to remove these distally migrated stents endoscopically. We prefer to use the rat-tooth forceps for stent removal because of their strong grip. Care must be taken to avoid

pulling on the ends of a Wallstent, because the filaments may be unraveled into a disorganized meshwork of highly traumatic metal wires (Fig. 4). Instead, this type of stent is usually sufficiently flexible to fold up if the center is grasped and pulled downward. In this case, the free ends are facing upward during stent removal. The same technique can be applied for Ultraflex stents; however, it is actually simpler to pull on their distal ends and then gently drag them out of the rectum. The Z-stents can be snared in the center or grasped with rat-tooth forceps

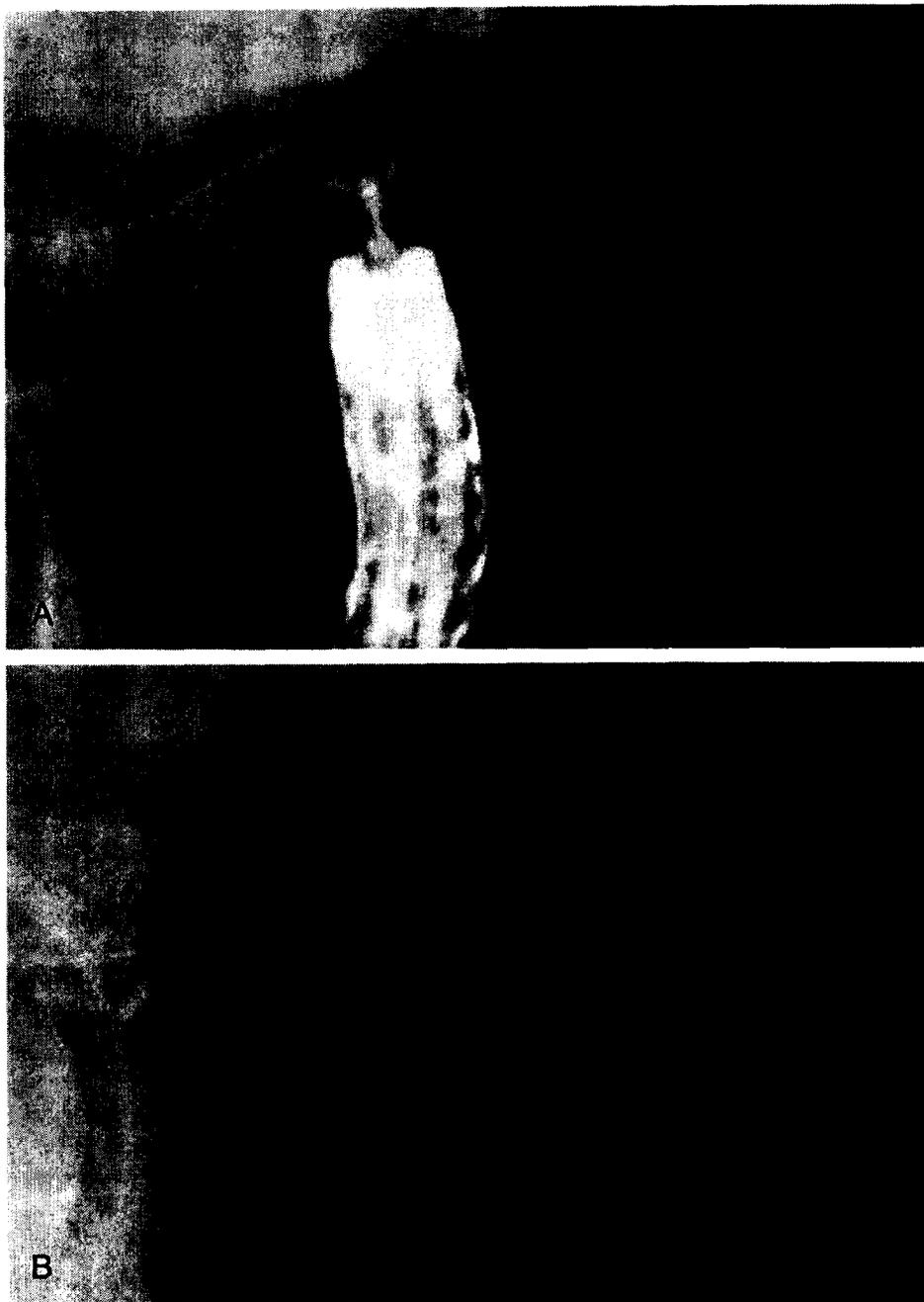


Figure 4. A, Endoscopic grasping of a Wallstent with forceps. B, The end of the Wallstent with separated wire filaments.

137 61

on their distal ends for retrieval. There is no report of EsophaCoil retrieval per rectum. We had successfully removed an esophageal stent by grasping an end with a rat-tooth forceps and pulling it through an endoscope overtube. The same can presumably be done for rectal stent removal. Proximally migrated stents are fortunately rare, because they may be quite difficult to retrieve endoscopically.

THE ULTIMATE STENT?

The current generation of metallic stents represents a major technical breakthrough in the management of colonic strictures; however, major improvements are still necessary to make them safer and easier to utilize. The length of the delivery catheter of enteral Wallstents should be shortened,⁴⁸ whereas that of Z-stents needs to be elongated. If possible, all delivery catheters should be sufficiently thin to be passed through endoscope channels. Excessive stiffness of these catheters is perhaps the single most important factor that contributes to technical difficulty in stent placement and needs to be corrected. Making stiffer and longer guidewires than those currently available will significantly improve the ease of stent placement. Addition of hooking mechanisms or enlargement of the ends may minimize stent migration. Graduated stiffness with soft ends may reduce the risks of stent-induced perforation and hyperplastic tissue reaction. Biodegradable or readily removable stents should improve long-term safety of these devices, especially if they must be placed in benign strictures.¹ Stents impregnated with pharmacologically active agents or made of radioactive wires may offer hope to contain malignancies or treat refractory benign strictures.^{1, 45}

SUMMARY

Intestinal obstruction is a major complication of colorectal cancer. Acute surgical decompression frequently requires subsequent operative interventions and is associated with mortality in more than 3% of the cases. Transanal metallic stenting is now possible to perform on an outpatient basis, thus providing quick symptom relief and the opportunity to cleanse the bowel for work-up or surgery. Early anecdotal reports suggest better patient acceptance, smoother transition to subsequent definitive surgery, and cheaper cost than the conventional surgical approaches. Stenting seems to be equally efficacious in providing temporary relief to facilitate subsequent management and permanent palliation of advanced malignant obstruction of the colon and rectum. Nearly half of all metallic stents have been inserted solely under the guidance of fluoroscopy, but the combined endoscopic-fluoroscopic method is always preferred. Although 95% are successfully placed in experienced hands, these stents can be rather difficult to insert. All four commercially available metallic stents have been used to relieve colonic obstruction, but only the enteral Wallstent is approved for treatment of this condition. Collectively, these stents are associated with 1% procedure-related mortality and 18% morbidity. Although there is every indication that metallic stenting is valuable in treating colorectal obstruction, randomized controlled trials are needed to put their utility in the proper place. Product refinements are necessary to improve on their safety profiles and to minimize the difficulty of stent insertion.

ACKNOWLEDGMENT

The author thanks Jan Daniels for her assistance in the preparation of the manuscript.

References

1. Akle CA: Endoprosthesis for colonic strictures. *Br J Surg* 85:310-314, 1998
2. Aquise M, Tejero E, Mainar A: A new option in the treatment of complete and acute obstruction due to colorectal cancer. *Endoscopy* 29:229, 1997
3. Arnell T, Stamos MJ, Takahashi P, et al: Colonic stents in colorectal obstruction. *Am Surg* 64:986-988, 1998
4. Aston NO, Owen WJ, Irving JD: Endoscopic balloon dilatation of colonic anastomotic strictures. *Br J Surg* 76:780-782, 1989
5. Baron TH, Deans PA, Yates MR, et al: Expandable metal stents for the treatment of colonic obstruction: Technique and outcomes. *Gastrointest Endosc* 47:277-286, 1998
6. Bashir RM, Fleischer DE, Stahl TJ, Benjamin SB: Self-expandable nitinol coil stent for management of colonic obstruction due to a malignant anastomotic stricture. *Gastrointest Endosc* 44:497-501, 1996
7. Binkert CA, Ledermann H, Jost R, et al: Acute colonic obstruction: Clinical aspects and cost-effectiveness of preoperative and palliative treatment with self-expanding metallic stents. *Radiology* 206:199-204, 1998
8. Campbell KL, Hussey JK, Eremin O: Expandable metallic stent application in obstructing carcinoma of the proximal colon. *Dis Colon Rectum* 40:1391-1393, 1997
9. Canon CL, Baron TH, Morgan DE, et al: Treatment of colonic obstruction with expandable metal stents. *AJR Am J Roentgenol* 168:199-205, 1997
10. Choo IW, Do YS, Suh SW, et al: Malignant colorectal obstruction: Treatment with a flexible covered stent. *Radiology* 206:415-421, 1998
11. Cugnenc PH, Berger A, Zinzindohoue F, et al: 2-stage surgery of neoplastic left colonic obstruction remains the safest procedure. *J Chir* 134:275-278, 1997
12. Cwikiel W, Andren-Sandberg A: Malignant stricture with colovesical fistula: Stent insertion in the colon. *Radiology* 186:563-564, 1993
13. Daneker GW, Carlson GW, Hohn DC, et al: Endoscopic laser recanalization is effective for prevention and treatment of obstruction in sigmoid and rectal cancer. *Arch Surg* 126:1348-1352, 1991
14. Davidson R, Sweeney WB: Endoluminal stenting for benign colonic obstruction. *Surg Endosc* 12:353-354, 1998
15. Deans GT, Krukowski ZH, Irwin ST: Malignant obstruction of the left colon. *Br J Surg* 81:1270-1276, 1994
16. Deen KI, Madoff RD, Goldberg SM, Rothenberger DA: Surgical management of left colon obstruction: The University of Minnesota experience. *J Am Coll Surg* 187:573-576, 1998
17. De Gregorio MA, Mainar A, Tejero E, et al: Acute colorectal obstruction: Stent placement for palliative treatment—results of a multicenter study. *Radiology* 209:117-120, 1998
18. Dohmoto M, Hunerbein M, Schlag PM: Application of rectal stents for palliation of obstructing rectosigmoid cancer. *Surg Endosc* 11:758-761, 1997
19. Feretis C, Benakis P, Dimopoulos C, et al: Palliation of large-bowel obstruction due to recurrent rectosigmoid tumor using self-expanding endoprosthesis. *Endoscopy* 28:319-322, 1996
20. Gandrup P, Lund L, Balslev I: Surgical treatment of acute malignant large bowel obstruction. *Eur J Surg* 158:427-430, 1992
21. Hoekstra HJ, Verschueren RCJ, Oldhoff J, van der Ploeg E: Palliative and curative electrocoagulation for rectal cancer: Experience and results. *Cancer* 55:210-213, 1985
22. Itabashi M, Hamano K, Kameoka S, Asahina K: Self-expanding stainless steel stent application in rectosigmoid stricture. *Dis Colon Rectum* 36:508-511, 1993
23. Keen RR, Orsay CP: Rectosigmoid stent for obstructing colonic neoplasms. *Dis Colon Rectum* 35:912-913, 1992
24. Kozarek RA: Hydrostatic balloon dilation of gastrointestinal stenoses: A national survey. *Gastrointest Endosc* 32:15-19, 1986

139
63

25. Kozarek RA, Brandabur JJ, Raltz SL: Expandable stents: Unusual locations. *Am J Gastroenterol* 92:812-815, 1997
26. Lamah M, Mathur P, Mckeown B, et al: The use of rectosigmoid stents in the management of acute large bowel obstruction. *J R Coll Surg Edinb* 43:318-321, 1998
27. Landi M, Tejero E, Mainar A: A new option in the treatment of complete and acute obstruction due to colorectal cancer. *Endoscopy* 29:229, 1997
28. Landis SH, Murray T, Bolden S, Wingo PA: Cancer Statistics 1998. *CA Cancer J Clin* 48:6-29, 1998
29. Leitman IM, Sullivan JD, Brams D, DeCosse J: Multivariate analysis of morbidity and mortality from the initial surgical management of obstructing carcinoma of the colon. *Surg Gynecol Obstet* 174:513-518, 1992
30. Lelcuk S, Ratan J, Klausner JM, et al: Endoscopic decompression of acute colonic obstruction: Avoiding staged surgery. *Ann Surg* 203:292-294, 1986
31. Lo SK: Temporary placement of metallic stents for benign gastrointestinal strictures and fistulae [abstract]. *Gastrointest Endosc* 47:AB33, 1998
32. Lopera JE, Ferral H, Wholey M, et al: Treatment of colonic obstructions with metallic stents: Indications, technique, and complications. *AJR Am J Roentgenol* 169:1285-1290, 1997
33. Mainar A, Tejero E, Maynar M, et al: Colorectal obstruction: Treatment with metallic stents. *Interventional Radiology* 198:761-764, 1996
34. Nagy AG: Palliative treatment of advanced colorectal carcinoma with the YAG laser. *Can J Surg* 33:261-264, 1990
35. Ohman U: Prognosis in patients with obstructing colorectal carcinoma. *Am J Surg* 143:742-747, 1982
36. Oz MC, Forde KA: Endoscopic alternatives in the management of colonic strictures. *Surgery* 108:513-519, 1990
37. Patrice T, Foultier MT, Yactayo S, et al: Endoscopic photodynamic therapy with hematoporphyrin derivative for primary treatment of gastrointestinal neoplasms in inoperable patients. *Dig Dis Sci* 35:545-552, 1990
38. Rajjman I, Catalano MF, Schwartz PJ, et al: Malignant rectal stricture is predictive of tumor stage [abstract]. *Am J Gastroenterol* 87:1330, 1992
39. Rajjman I, Siemens M, Marcon N: Use of an expandable Ultraflex stent in the treatment of malignant rectal stricture. *Endoscopy* 27:273-276, 1995
40. Rattan J, Klausner JM, Rozen P, et al: Acute left colonic obstruction: A new nonsurgical treatment. *J Clin Gastroenterol* 11:331-334, 1989
41. Rey JF, Romanczyk T, Greff M: Metal stents for palliation of rectal carcinoma: A preliminary report on 12 patients. *Endoscopy* 27:501-504, 1995
42. Runkel NS, Schlag P, Schwarz V, Herfarth C: Outcome after emergency surgery for cancer of the large intestine. *Br J Surg* 78:183-188, 1991
43. Saida Y, Sumiyama Y, Nagao J, Takase M: Stent endoprosthesis for obstructing colorectal cancers. *Dis Colon Rectum* 39:552-555, 1996
44. Salinas JC, Quintana J, De Gregorio MA, et al: Management of benign rectal stricture by implantation of a self-expanding prosthesis. *Br J Surg* 84:674, 1997
45. Saunders BP, Bartram C: Editorial: Self-expanding, metal stents for malignant colonic obstruction. *Clin Radiol* 53:237-238, 1998
46. Scott NA, Jeacock J, Kingston RD: Risk factors in patients presenting as an emergency with colorectal cancer. *Br J Surg* 82:321-323, 1995
47. Sigwart U, Puel J, Mirkovitch V, et al: Intravascular stents to prevent occlusion and restenosis after transluminal angioplasty. *N Engl J Med* 316:701-706, 1987
48. Soonawalla Z, Thakur K, Boorman P, et al: Use of self-expanding metallic stents in the management of obstruction of the sigmoid colon. *AJR Am J Roentgenol* 171:633-636, 1998
49. Spinelli P, Dal Fante M, Mancini A: Rectal metal stents for palliation of colorectal malignant stenosis. *Bildgebung* 60(suppl I):48-50, 1993
50. Tejero E, Fernández-Lobato R, Mainar A, et al: Initial results of a new procedure for treatment of malignant obstruction of the left colon. *Dis Colon Rectum* 40:432-436, 1997
51. Turégano-Fuentes F, Echenagusia-Belda A, Simó-Muerza G, et al: Transanal self-expanding metal stents as an alternative to palliative colostomy in selected patients with malignant obstruction of the left colon. *Br J Surg* 85:232-235, 1998

140

64

52. Vandervoort J, Weiss EJ, Somnay K, et al: Self-expanding metal stent for obstructing carcinoma of the sigmoid. *Gastrointest Endosc* 44:739-741, 1996
53. Wallis F, Campbell KL, Eremin O, Hussey JK: Self-expanding metal stents in the management of colorectal carcinoma: A preliminary report. *Clin Radiol* 53:251-254, 1998
54. Wholey MH, Ferral H, Reyes R, et al: Retrieval of migrated colonic stents from the rectum. *Cardiovasc Intervent Radiol* 20:477-480, 1997
55. Wholey MH, Levine EA, Ferral H, Castaneda-Zuniga W: Initial clinical experience with colonic stent placement. *Am J Surg* 175:194-197, 1998

Address reprint requests to

Simon K. Lo, MD
South Bay Gastroenterology Medical Group
23560 Madison Street, Suite 211
Torrance, CA 90505

e-mail: simonklo@pacbell.net

141

65

Self-expandable metallic stents in malignant gastric outlet obstructions – an alternative approach using modified techniques

WIGGINGHAUS, B., DORMANN, A. J., and GRÜNEWALD, Th.

Medizinische Klinik, Klinikum Minden (Leitender Chefarzt: Prof. Dr. H. Huchzermeyer)

Diese Arbeit ist Herrn Prof. Dr. H. Huchzermeyer zum 60. Geburtstag gewidmet.

Malignant gastric outlet obstructions are commonly present in an advanced tumor stage. Surgery and other therapy options are often accompanied with substantial problems and reduced quality of life. We therefore investigated the endoscopic palliation with self-expandable metallic stents. This report documents the clinical benefit of new stent systems.

During a period of eleven months we implanted eleven self-expandable metallic stents (one Ultraflex Esophageal Stent/five Ultraflex Duodenal Diamond Stents/five Enteral Wallstents) in eight patients with malignant gastric outlet stenoses (five female/three male, average age 66 years, range 42–85 years). The procedure was performed under analgosedation and in seven cases on an outpatient bases.

The stenosis could be dilated in all cases without complications, allowing semi-liquid oral feeding at the procedure day. Three patients needed a second stent in the follow-up. Stent dislocation appeared in one case after one month – the stent protruded per vias naturales. The stent struts broke in two patients after one and four months post stent implantation. A new stent could be inserted without complications in both cases.

The used products enabled a fast and precise positioning of the metallic stent in malignant gastric outlet stenosis. We experienced some problems with the Ultraflex Duodenal Diamond Stent. This didn't occur with the Enteral Wallstent. Additionally with the Enteral Wallstent we could solve the diamond stent complications. Due to the small diameter (10 French) the Enteral Wallstent system can be positioned wire guided in the stenosis through the working channel of the endoscope. Stent release is performed fluoroscopically and with the use of endoscopic guidance retaining the instrument in the stomach. In our point of view, this metallic stent is an optimal device for the palliative treatment of malignant gastric outlet obstructions.

Key words: Malignant gastric outlet obstructions – self-expanding metallic stent – Enteral Wallstent

Manuskript eingetroffen: 02.07.1999
In vorliegender Form angenommen: 23.08.1999

Address for correspondences: Dr. med. B. Wiggighaus,
Medizinische Klinik, Klinikum Minden, Friedrichstraße 17,
D-32427 Minden

(Selbstexpandierende Metallstents bei malignen Magenausgangsstenosen – eine Therapieoption durch neue Systeme)

In der primären palliativen Therapie maligner Magenausgangsstenosen sind die chirurgischen und anderen Therapieoptionen bei weit fortgeschrittenem Tumorstadium mit zum Teil erheblichen Problemen und einer eingeschränkten Lebensqualität behaftet. Aufgrund dieser Sachlage ist es erklärlich, daß zunehmend über Versuche einer endoskopischen Palliation mit selbstexpandierenden Metallstents berichtet wird. Eigene Erfahrungen bestätigen, unter Verwendung bisher verfügbarer Systeme, eine mögliche Therapieoption. Wir stellen hier die Ergebnisse unter Verwendung neuer Stentsysteme dar.

In einem Zeitraum von elf Monaten wurden bei acht Patienten (fünf Frauen/drei Männer, Durchschnittsalter 66 Jahre, Spannweite 42–85 Jahre) mit malignen Magenausgangsstenosen zehn selbstexpandierende Metallstents implantiert (ein Ultraflex Ösophagus Stent/fünf Ultraflex Duodenal Diamond Stents/fünf Enteral Wallstents). Die Implantation wurde in Analgosedierung durchgeführt, in sieben Fällen ambulant.

In jedem Fall ließ sich die Stenose komplikationslos überbrücken, mit sofortigem Kostenaufbau am Interventionstag. Bei drei Patienten mußte eine zweiter Stent gelegt werden. In einem Fall war nach einem Monat eine Stentdislokation aufgetreten (Stentabgang per vias naturales) und bei zwei Patienten kam es einen bzw. vier Monate nach Stentimplantation zu einem Stentbruch. Es erfolgte jeweils eine komplikationslose Neuanlage.

Die verwandten Kathetersysteme ließen eine schnelle exakte Positionierung der Metallstents in der malignen Magenausgangsstenose zu. Der Enteral Wallstent läßt sich aufgrund des geringen Durchmessers des Trägerkatheters von 10 French durch den Arbeitskanal eines Endoskops über den liegenden Führungsdraht in der Stenose positionieren. Die Stentfreisetzung erfolgt dann bei im Magen liegendem Endoskop unter radiologischer und endoskopischer Kontrolle. Dieser Metallstent stellt aus unserer Sicht zur Zeit die optimale Modifikation zur Überbrückung maligner Magenausgangsstenosen dar.

Schlüsselwörter: Maligne Magenausgangsstenosen – selbstexpandierende Metallstents – Enteral Wallstent

ORIGINALARBEIT

Table with 8 columns and 8 rows, containing clinical features of eight patients with malignant gastric outlet obstruction. The table content is mostly illegible due to heavy black redaction.

Tab. 1: Clinical features of eight patients with malignant gastric outlet obstruction

INTRODUCTION

Self-expandable metallic stents are used for the palliative treatment of malignant gastric outlet and duodenal stenoses since the early 90s (1, 2). There are only a few scientific publications with case reports and trials having a small number of patients. This is in contrast to the increasing amount of publications on the use of self-expandable metallic stents for the treatment of esophageal, biliary, colonic, urethral and vascular obstructions (3-11). Surgery is still the treatment of choice for the palliation of malignant gastric outlet and duodenal obstructions. Primary palliation with minimally invasive systems are mainly discussed for the advanced tumor stages. For such cases, balloon dilatation and laser treatment provides only limited efficacy (12-14). Surgery is often accompanied by increased morbidity and mortality (15-17). Recent publications and our own experience were the rationale for the increasing use of new metallic stents for the primary palliation of malignant gastric outlet obstructions (22-28). We also try to answer the question if this treatment is already a valid option.

MATERIAL AND METHODS

In a time period of eleven months (July 98 until May 99) primary palliation of malignant gastric outlet

stenoses was performed in our hospital in eight patients with the insertion of self-expandable metallic stents. The average age of the patients (five female/three male) was 66 years (range 42-85 years). Five patients suffered from a primary gastric cancer. One female patient presented with a pyloric stenosis due to recurrent hepatocellular carcinoma and two patients had a stenosis in the duodenum proximal the papilla because of a bile duct carcinoma. All patients had poor general conditions with an average Karnofsky-Index of 70% (range 60-90%) and suffered from nausea and vomiting. Surgery with resection or enteroanastomosis was not performed because of the advanced tumor stage, the risk profile of the patients (ASA-Score 3-4) or patient's refusal for this treatment option (tab. 1).

We implanted a total of eleven stents of three different types. The procedure was performed with ECG and SaO2 monitoring and intravenous analgo-sedation with Pethidin and Midazolam.

In five patients an Ultraflex Duodenal Diamond Stent (investigational prototypes for a clinical trial, Boston Scientific) with a diameter of 18 mm and the length of 70 or 120 mm was initially implanted. The delivery device has a maximum diameter of 12 mm at the tip and is 270 cm long. The guide wire (.038 inch) was introduced with endoscopic and fluoroscopic guidance, and the stent was implanted after withdrawal of

143 67

AKTUELLE ENDOSKOPIE

No.	Age	Sex	Diagnosis	Stent type	Stent length	Stent diameter	Stent position	Stent release	Stent migration	Stent obstruction	Stent fracture	Stent removal	Stent replacement	Stent revision	Stent follow-up
1	65	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
2	72	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
3	68	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
4	70	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
5	75	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
6	60	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
7	70	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
8	65	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
9	70	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
10	68	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
11	72	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
12	65	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
13	70	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
14	68	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
15	72	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
16	65	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
17	70	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
18	68	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
19	72	F	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year
20	65	M	Gastric cancer	Ultraflex	100 mm	18 mm	Distal stomach	Successful	No	No	No	No	No	No	1 year

Tab. 2: Treatment and follow-up of the patients

the endoscope. In order to pass the lesion with the stent delivery system, predilatation with a diameter 15 mm balloon was necessary in two cases.

An Enteral Wallstent (Boston Scientific, diameter 20 or 22 mm, 60 or 90 mm long) was implanted in five patients, either initially or due to complications of an other implanted stent. The delivery system of the Enteral Wallstent has a shaft size of 10 French. A guide wire (.035 or .038 inch) is endoscopically introduced. The Wallstent delivery system is introduced over the wire through the working channel of the endoscope

(min. 3.6 mm). With the endoscope proximal to the stenosis, the release of the stent can be monitored endoscopically and radiologically (fig. 1-4). Predilatation of the stenosis was necessary in neither case.

In one patient, we implanted an uncoated Ultraflex Esophageal Stent (diameter 18 mm, 100 mm long).

RESULTS

The malignant gastric outlet obstruction could be successfully palliated with a self-expandable metallic

144
608

ORIGINALARBEIT



Fig. 1: Guide wire placed in the duodenum passing the stenoses, endoscopically controlled and pushed through the working channel of the endoscop

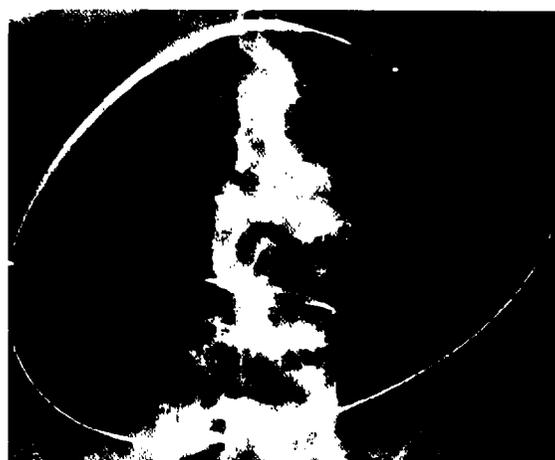


Fig. 2: Wallstent delivery system placed in the stenoses, x-ray markers showing the distal and proximal stent position on the shaft



Fig. 3: Stent after release with endoscope and guide wire still in position

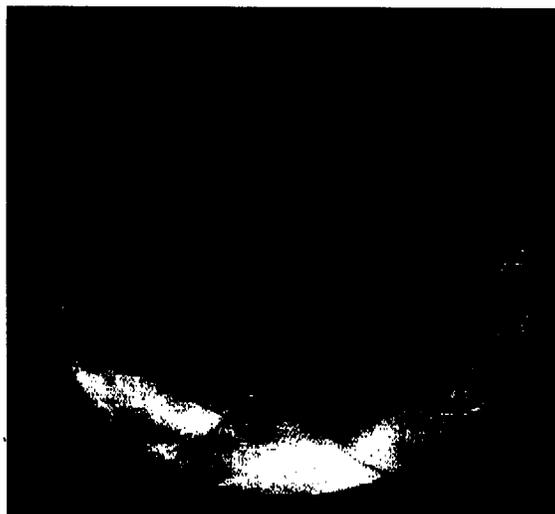


Fig. 4: Endoscopic view of Enteral Wallstent placed in the stenoses

stent in all eight patients without complications. No bleeding or perforation occurred during stent insertion and follow-up.

We experienced one stent dislocation (Duodenal Diamond Stent) with protrusion of the device per vias naturales and reoccurrence of vomiting. The stent might be placed too distally into the duodenum this could be the reason for migration. An Ultraflex Esophageal Stent was successfully inserted without complications and further problems.

The struts of two Duodenal Diamond Stents broke one month and four months after implantation. The reobstruction was succesfully treated in both cases with an Enteral Wallstent without procedural or follow-up complications. The median postinterventional survival time of all patients was four months.

Poststent oral feeding was possible in all patients except one lady who continuously suffered from vomiting. All other patients got a semiliquid regimen at the procedure day followed by increasingly solid food. Two patients couldn't progress more than the day-one-regimen (tab. 2).

DISCUSSION

Malignant gastric outlet obstructions and duodenal stenoses with continuous nausea and recurrent vomiting are mostly due to advanced tumor stages. Commonly used treatment like surgery or catheter jejunostomy show clear limits.

Therefore, several workers (18-28) investigated the use of self-expandable metallic stents (tab. 3). Promis-

145 69

ORIGINALARBEIT

delivery catheter is advanced through the working channel of the endoscope over a primarily positioned guide wire. The shaft size of the system is 10 French which usually allows lesion crossing without pre-dilation. The endoscope remains in the stomach close to the stenosis during stent release providing additional back-up of the system. These improvements resulted in an average stent implantation time of 20 min. In one case the Enteral Wallstent was combined with a self-expanding bile duct stent without problems (fig. 5). The procedure was performed under analgesedation, and in seven of eleven cases on an outpatient basis. This was acknowledged by the patients



Fig. 5: Double stenting with Enteral Wallstent in the duodenum and biliary Wallstent in the common bile duct (patient 7)

as well as the possibility to start oral feeding at the procedure day. We did not experience complications like bleeding or perforation. Expansion of the stent was not associated with pain nor did it increase existing pain.

Based on own former results (28) and on our experience of five investigational Ultraflex Duodenal Diamond Stents, one Ultraflex Esophageal stent and five Enteral Wallstents placed in the pylorus and the duodenum the Enteral Wallstents performed better overall. Much of the previous reported experience and one

case in our experience used a stent system which was designed and indicated for esophageal stricture placement. The improvements in the delivery systems designed for stent placement in the duodenum demonstrated the ability to easily and safely complete the stent implantation procedure. The safe and easy use with simultaneous endoscopic and radiological guidance of the Enteral Wallstent system make it an outstanding product available today. The Enteral Wallstent provides a clear alternative to traditional therapeutic options for the primary palliation of malignant gastric outlet obstruction.

REFERENCES

- 1 Song HY, Yang DH, Kuh JH, Choi KC. Obstructing cancer of gastric anatomy: Palliative treatment with covered metallic stents. *Radiology* 1993; 187: 357-8
- 2 Solt J, Papp Z. Strecker stent implantation in malignant gastric outlet stenosis. *Gastrointest Endosc* 1993; 39: 442-4
- 3 Knyrim K, Wagner HJ, Bethge N et al. A controlled trial of a expandible metal stent for palliation of esophageal obstruction due to inoperable cancer. *N Engl J Med* 1993; 329: 1302-7
- 4 Neuhaus H, Schumacher B. Einsatz von Metallstents in der Gastroenterologie. *Z Gastroenterol* 1998; 36: 121-34
- 5 Davis PHP, Groen AK, Rauws EAJ et al. Randomized trial of self-expanding metal stents versus polyethylene stents for distal biliary obstruction. *Lancet* 1992; 340: 1488-92
- 6 Höpfner N, Förster EC, Högemann B, Domschke W. Long-term experience in wallstent therapy for malignant choledochal stenosis. *Endoscopy* 1994; 26: 597-602
- 7 Feretis C, Benakis P, Kimopoulos C et al. Palliation of large bowel obstruction due to recurrent rectosigmoid tumor using self-expandable endoprotheses. *Endoscopy* 1996; 28: 319-22
- 8 Mainar A, Tejero E, Maynar M et al. Colorectal obstruction: Treatment with metallic stents. *Radiology* 1996; 196: 261-4
- 9 Baron TH, Dean PA, Yates RM, Canon C, Koehler RE. Expandable metal stents for the treatment of colonic obstruction: Techniques and outcomes. *Gastrointest Endosc* 1998; 47: 277-85
- 10 Van Sonnenberg E, D'Agostino HB, O'Laoide R et al. Malignant urethral obstruction: Treatment with metal stents - techniques, results and observation with percutaneous intraluminal ultrasound. *Radiology* 1994; 191: 765-8
- 11 Katzen BT, Becker GJ. Intravascular stents: Status of development and clinical applications. *Surg Clin North Am* 1992; 72: 941-57
- 12 Moses FM, Peura A, Wong RKH et al. Palliative dilation of esophageal carcinoma. *Gastrointest Endosc* 1985; 31: 61-3

AKTUELLE ENDOSKOPIE

- 13 Lambert M, Faintuch JS. Laser recanalization of pyloric stenosis: A guide wire-directed contact probe technique. *Lasers Surg Med* 1989; 9: 282-5
- 14 Suzuki H, Miho O, Watanabe Y et al. Endoscopic laser therapy in the curative and palliative treatment of upper gastrointestinal cancer. *World Surg* 1989; 13: 158-64
- 15 Weaver DW, Wienczek RG, Bouwman DL, Walt AJ. Gastrojejunostomy: Is it helpful for patients with pancreatic cancer? *Surgery* 1987; 107: 608-13
- 16 Sarr MG, Claden HE, Beart RW, Heerdan JA. Role of gastroenterostomy in patients with unresectable carcinoma of the pancreas. *Surg Gynecol Obstet* 1981; 152: 597-600
- 17 Potts JR, Brouham TA, Herrmann RE. Palliative operations for pancreatic cancer. *AM J Surg* 1990; 159: 72-8
- 18 Keymling M, Wagner H, Wakil N, Knyrim K. Relief of malignant duodenal obstruction by percutaneous insertion of a metal stent. *Gastrointest Endosc* 1993; 39: 439-41
- 19 Sommer A, Bethge N. Relief of malignant external gastric obstruction by endoscopic implantation of a self expanding metal stent. *Endoscopy* 1995; 27: 210-11
- 20 Feretis C, Benakis P, Dimopoulos C et al. Palliation of malignant gastric outlet obstruction with self-expanding metal stents. *Endoscopy* 1996; 28: 225-8
- 21 Maetani I, Inoue H, Sato M et al. Peroral insertion techniques of self expanding metalstents for malignant gastric outlet and duodenal stenoses. *Endoscopy* 1996; 44: 468-71
- 22 Howell DA, Bosco JJ, Muggia RA, Biber BP. Endoscopic double bypass: Duodenal metal expandable stenting late in malignancy. *Gastrointest Endosc* 1994; 40: 40A
- 23 Feretis C, Benakis P, Dimopoulos C et al. Self expanding endoprotheses for palliation of duodenal obstruction. *Gastrointest Endosc* 1997; 46: 161-5
- 24 Nevitt AW, Vida F, Kozarek RA, Traverso LW, Raltz SL. Expandable metallic protheses for malignant obstruction of gastric outlet and proximal small bowel. *Gastrointest Endosc* 1998; 47: 271-6
- 25 Seotikno RM, Lichtenstein DR, Vandervoort J et al. Palliation of malignant gastric outlet obstruction using an endoscopically placed wallstent. *Gastrointest Endosc* 1998; 47: 267-70
- 26 Yates MR, Morgan DE, Baron TH. Palliation of malignant gastric and small intestinal strictures with self-expandable metal stents. *Endoscopy* 1998; 30: 266-72
- 27 Venu RP, Pastika BJ, Kini M et al. Self-expandable metal stents for malignant gastric outlet obstruction: A modified technique. *Endoscopy* 1998; 30: 553-558
- 28 Wiggighaus B, Dormann AJ, Grünewald T, Huchzermeyer H. Primäre palliative Therapie maligner Magenausgangsstenosen mit selbstexpandierenden Metallstents. *Dtsch Med Wochenschr* 1999; 124: 109-13

148

72



The Royal College of Surgeons of England

Ann R Coll Surg Engl 1999; 81: 251-254

Endoluminal stenting of obstructed colorectal tumours

P. Boorman*, Z. Soonawalla*, N. Sathananthan†, P. MacFarlane‡, M.C. Parker*

Departments of *Colorectal Surgery, †Interventional Radiology and ‡Endoscopy, Joyce Green Hospital, Dartford, Kent, UK

A series of patients were selected to evaluate the clinical efficacy of a new self expanding metallic endoprosthesis in the management of left-sided colonic obstruction. The aim was to reduce the morbidity and mortality associated with the surgical management of patients with distal colonic obstruction.

Six patients with complete sigmoid colon obstruction were managed with the Wallstent Enteral Endoprosthesis [Schneider (USA) Inc.]. Four underwent subsequent elective colonic resection, while two were placed for palliation.

Stent placement was successful in all cases with resulting bowel decompression and there were no procedural complications. All four patients with resectable tumours avoided emergency surgery. Stenting allowed time for medical improvement and staging investigations in this group. Two patients with advanced metastatic colonic carcinoma were successfully palliated.

We found the Wallstent Enteral Endoprosthesis to be safe and effective in relieving obstruction in patients with resectable colonic tumours, permitting elective surgery and avoiding a temporary stoma. It can also be used to palliate those patients with advanced disease.

Key words: Colon – Stenosis or obstruction – Stents and prosthesis – Colon, interventional procedure

In Dartford, we see approximately 120 left-sided colonic tumours each year. Of these, 20–30% present with virtual or complete obstruction. Mortality rates for emergency surgery on obstructed cases has been

quoted as 15–40%. This compares with a 5% mortality in elective cases.¹⁻³

It is well known that patients undergoing emergency surgery for obstruction have a significantly increased

Correspondence to: Mr Michael C Parker, Consultant Surgeon, Department of Colorectal Surgery, Dartford & Gravesham NHS Trust, Joyce Green Hospital, Dartford DA1 5PL, Kent, UK. Tel: +44 (0)1322 227242 ext 3480; Fax: +44 (0)1322 283564.

149
73

BOORMAN

ENDOLUMINAL STENTING OF OBSTRUCTED COLORECTAL TUMOURS

risk of postoperative complications. They are twice as likely to develop a wound infection, 11 times as likely to suffer renal failure and respiratory complications are increased by a factor of 25-fold. These patients are at greater risk of intra-abdominal sepsis, the mortality of which is substantially higher in the obstructed group.⁴ It has also been documented that, even when patients with identical stage tumours are compared, survival is significantly reduced after emergency surgery.¹

History

A new technique of endoluminal stenting has recently been described. The first use of a steel stent for an inoperable malignant rectal stricture was reported by Dohmoto in 1991.⁵ In 1993, Itsabashi *et al.* stented two patients with inoperable rectosigmoid malignancies; both of these strictures required pre-stent dilatation.⁶ In 1995, Canon *et al.* stented 13 patients using a variety of stents designed for use elsewhere, such as oesophageal and biliary stents.⁷ More recently, Turegano-Fuentes *et al.* attempted stenting in 11 patients using oesophageal stents. They were successful in only seven cases, but employed fluoroscopy alone to position the stents.⁸

Method of stenting

We used the Wallstent Enteral Endoprosthesis [Schneider (USA) Inc.] which has recently been designed, produced and marketed specifically for use in the colon. It consists of two components, a metallic stent and a delivery system.

The stent is a monofilament, superalloy, tubular mesh available in 6 cm and 9 cm lengths, which expand to 22 mm diameter. Previously used oesophageal stents have a maximum diameter of 18 mm. The Wallstent is also more flexible (without deforming), allowing it to conform to the curve of the colon.

The delivery system consists of two coaxial tubes. The outer constrains the stent until deployment and the inner allows its passage over guidewires. The central lumen accommodates 0.89 mm or 0.97 mm wires. There are also proximal and distal markers on the delivery system to aid positioning.

Placement of the stent is by endoscopy, fluoroscopy or a combined procedure. In virtual obstruction, endoscopy is the method of choice. The whole system will pass through an endoscope of minimum channel diameter 3.6 mm. Completely obstructed cases where there is no visible lumen require fluoroscopy. Combined procedures allow the radiologist to view the tip of the naviguide wire from the endoscopic picture.



Figure 1 'Guiding' catheter, over wire, through the stricture.

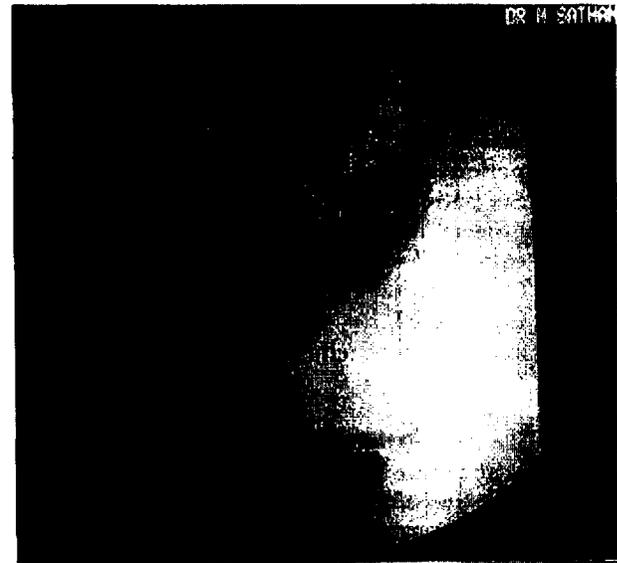


Figure 2 Delivery system/stent in position through stricture (safety wire also visible).

A guidewire is passed through the stricture and a 'guiding' catheter is then advanced over the wire (Fig. 1). This allows passage of a second 'safety' wire which is secured separately to the patient's leg. The 'safety' wire proves invaluable should the guidewire be displaced during stent placement. The catheter is then removed and the delivery system/stent is passed over the guidewire until the proximal marker is 2-3 cm

150

74

ENDOLUMINAL STENTING OF OBSTRUCTED COLORECTAL TUMOURS

BOORMAN

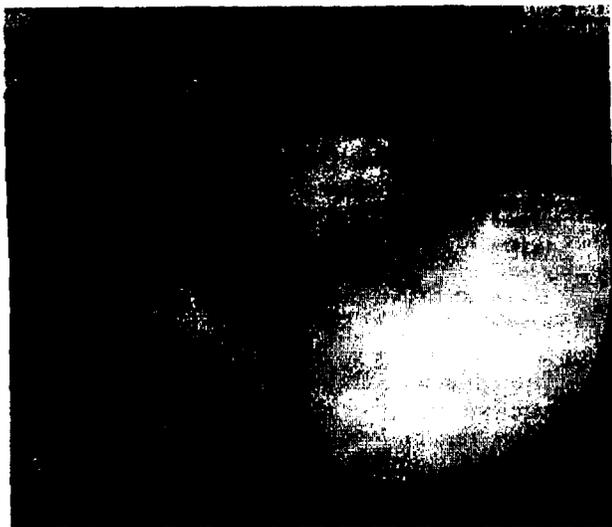


Figure 3 Stent being deployed.

beyond the stricture (Fig. 2). We found this easier with a stiffer guidewire and, on occasion, it was necessary to mould the system into a gentle curve to negotiate the bend of the recto-sigmoid colon. The stent is then deployed by withdrawing the outer (constraining) tube of the delivery system (Fig. 3). It is better to advance the deployment system more proximally beyond the stricture, as the stent can be withdrawn during deployment as long as it is not more than 50% expanded but it cannot be advanced further at this stage. The stent position is checked fluoroscopically (Fig. 4) and endoscopically (Fig. 5). The stent is self-expanding and no pre-dilatation of the stricture or stent dilatation is necessary.

Patients and Results

Between April and July 1997 we successfully stented six patients with malignant obstruction. All patients were admitted as emergencies with vomiting and absolute constipation. Radiographic and contrast enema confirmation of the diagnosis was made.

Four stents were placed pre-surgery and two were for palliation (Table 1). In all cases stent placement was successful (Table 2). There was no mortality.

Case 1 remained decompressed until her death from liver metastases 5 weeks later. Case 3 initially underwent emergency surgery but was found to have an inoperable tumour with bladder involvement and distant metastases. He was known to be virtually



Figure 4 Stent in position.



Figure 5 Endoscopic view of stent.

obstructed from pre-operative fluoroscopy and was, therefore stented and closed without stoma formation. He remains well 6 months later. Case 5 presented 19 days after stenting with abdominal pain and vomiting. A contrast enema confirmed stent patency and at semi-emergency surgery 2 days later he was found to have a loop of small bowel involved in the tumour which was resected *en bloc*. In Case 6, the stent was found to have displaced only on opening the specimen after surgery. She had remained decompressed for 3 weeks and had undergone standard pre-operative bowel preparation

157

75

BOORMAN

ENDOLUMINAL STENTING OF OBSTRUCTED COLORECTAL TUMOURS

Table 1 Patient details

Case	Age	Sex	Location	Length
1	81	F	20 cm	8 cm
2	59	F	22 cm	6 cm
3	66	M	15 cm	5 cm
4	75	F	18 cm	3 cm
5	60	M	25 cm	4 cm
6	77	F	25 cm	5 cm

Location of stricture is measured in centimetres from the anal verge at endoscopy.

Length of stricture is estimated from contrast radiographs after correction for magnification.

Table 2 Results

Case	Decom-pressed	Complications	Outcome
1	Yes		Palliation
2	Yes		Elective surgery
3	Yes		Palliation
4	Yes		Elective surgery
5	Yes	Small bowel obstruction	Emergency surgery
6	Yes	Stent migration	Elective surgery

without complication. It is possible that the stent may have migrated during bowel preparation.

Discussion

Endoluminal stenting provides a method for relief of obstruction, converting emergency surgery into elective, allowing bowel decompression and standard pre-operative bowel preparation. It gives time for both medical improvement of these often elderly frail patients and staging investigations. All our patients undergo pre-operative liver ultrasound scan, chest X-ray and serum tumour marker estimation. Those with a rectal tumour also have a pelvic CT scan. Stenting also allows visualisation of the entire colon to exclude any synchronous tumour.

The Wallstent avoids the need for either a temporary or permanent stoma with its associated morbidity and reduction in quality of life. In those patients with advanced metastatic disease, stenting has a valuable role in palliation avoiding surgery altogether.

Both in-patient and intensive care stay in patients undergoing emergency surgery for left-sided colonic obstruction has been shown to be significantly increased.⁴ The substantial cost of managing the common postoperative complications in this group, makes the Wallstent (£700) a cost effective alternative.

Enteral wallstents have proved useful in our small series in both operable and advanced colorectal tumours. They appear to be safe in our hands and relatively easy to deploy with a low incidence of complications.

If these stents can reduce the morbidity and mortality of surgery in the obstructed left colon to the same level as elective surgery it will be a significant breakthrough in the safety of colorectal cancer surgery. However, we recognise that in order to prove this, prospective randomised trials will be necessary and will probably require multicentre co-operation.

References

1. Runkel S, Schlag F, Schwarz V, Herfarth C. Outcome after emergency surgery for cancer of the large intestine. *Br J Surg* 1991; 78: 183-8
2. Gandrup P, Lund L, Balslev I. Surgical treatment of acute malignant large bowel obstruction. *Eur J Surg* 1992; 158: 427-30
3. McIntyre R, Reinbach D, Cuschieri A. Emergency abdominal surgery in the elderly. *J R Coll Surg Edinb* 1997; 42: 173-8
4. Scott-Conner C, Scher K. Implications of emergency operations on the colon. *Am J Surg* 1987; 153: 535-40
5. Dohmoto M. New method - endoscopic implantation of rectal stent in palliative treatment of malignant stenosis. *Endoscopia Digestiva* 1991; 3: 1507-12
6. Itsabashi M, Hamano K, Kameoka S, Asahina K. Self-expanding stainless steel stent application in rectosigmoid stricture. *Dis Colon Rectum* 1993; 36: 508-11
7. Canon C, Baron T, Morgan D, Dean P, Koehler R. Treatment of colonic obstruction with expandable metal stents: radiologic features. *Am J Roentgenol* 1997; 168: 199-205
8. Turegano-Fuentes F, Echenagusia-Belda A, Simo-Muerza G, Camunez F, Munoz-Jimenez F, Del Valle Hernandez F *et al.* Transanal self-expanding metal stents as an alternative to palliative colostomy in selected patients with malignant obstruction of the left colon. *Br J Surg* 1998; 85: 232-5

Original article

Role of endoscopic stenting in the duodenum

David L. Carr-Locke

Director of Endoscopy, Brigham and Women's Hospital, Associate Professor of Medicine, Harvard Medical School, Boston, Massachusetts, USA

Summary

Background: Gastric outlet obstruction may cause the presenting symptoms, or may develop during the course of pancreatic or biliary malignancy. Treatment options for malignant gastric outlet obstruction are limited. Surgical gastrojejunostomy is commonly performed, but carries significant morbidity and mortality.

Methods: Over the past two years, we conducted a prospective study to determine the safety, feasibility and outcomes of the newly-designed Wallstent Enteral® (Sneider, Minneapolis, MN) to treat a variety of malignant gastric outlet obstructions. We deployed stents 16 to 22 mm in diameter and 60 to 90 mm in length directly through the endoscope.

Results: Twelve patients (10 women and 2 men, mean age = 59.7 years) underwent the procedure. After stenting, six patients were

able to eat a regular diet, and three were able to eat a pureed diet. In three patients, the procedure was unsuccessful because of multiple obstructions that were not recognized prior to stenting in one and stents that were deployed either too proximally in one or too distally in another. Three patients were discharged within 24 hours after stenting and three had the procedure as an outpatient. **Conclusions:** Placement of the Wallstent Enteral through the endoscope is safe and effective palliation for a variety of malignant gastric outlet obstructions, and leads to significant improvement in many aspects of patients' quality of life.

Key words: duodenum, endoscopy, stenting

Introduction

Malignant gastric outlet and duodenal obstruction may cause the presenting symptoms, or may develop during the course of pancreatic or biliary malignancy. Approximately ten percent of patients with pancreatic cancer develop gastric outlet or duodenal obstruction during the course of their disease. Open surgical gastrojejunostomy is the standard treatment for malignant gastric outlet obstruction (GOO). Unfortunately, this intervention can be associated with significant morbidity and mortality [1]. Newer laparoscopic alternatives are still evolving. Self-expanding metallic stents designed for the biliary tract, such as the Gianturco-Rösch Z-stent (Wilson-Cook, Inc., Winston-Salem, NC) and the Wallstent (Schneider, Minneapolis, MN) have been reported to provide effective treatment alternatives with minimal morbidity [2-10] but small caliber lumens.

We have conducted a prospective study to determine the technical feasibility and clinical outcomes of using of an improved-design self-expanding metal stent (Wallstent Enteral®) to treat malignant GOO. These stents have the advantage of direct placement through the endoscope channel (TTS) and a large luminal diameter. Direct TTS stent placement is easier and more precise than non-TTS and the large stent diameter may allow patients to eat a regular diet.

Materials and methods

Over the past two years, we have used commercially available Wallstent Enteral stents or their prototypes to treat 12 patients who had malignant gastric or duodenal stenoses (see Table 1). All patients treated are included in this report. Several patients were treated before the stents were approved by the Food Drug Administration for marketing as a gastrointestinal device, but all were approved for compassionate use by the Brigham and Women's Research Committee. We obtained informed consent from all patients prior to treatment.

Subjects

The mean (± SD) age of the patients whom we treated (10 women and 2 men) was 59.7 ± 13.2 years. Eleven patients had nausea and vomiting and/or were unable to take adequate calories orally. One patient with pancreatic cancer and GOO had associated recurrent cholangitis because of episodes of food impaction into a biliary wallstent placed through a choledochoduodenostomy that had been created 20 years previously because of stone disease. The most common malignancy was pancreatic cancer (three patients). Nine patients had GOO due to a variety of primary duodenal (two) or metastatic cancer (two ovarian, one gallbladder, one cholangiocarcinoma, one colon, one breast, and one pseudomyxoma peritonei). Of the twelve patients, one with gallbladder cancer presented with both jaundice and GOO and four patients had had biliary Wallstent stents placed for treatment of malignant biliary stenoses. Most patients were too ill or were otherwise unsuitable for surgical treatment as assessed by their primary care physicians, gastroenterology consultants, and, in some cases, surgical consultants. Patients were followed for their symptoms by us or their primary care physicians.

Equipment

We used self-expanding metallic stents (Wallstent Enteral) 16 to 22 mm in diameter and 60, 83 or 90 mm in length. These stents are constructed from a woven stainless steel superalloy and have a larger diameter than the commonly used biliary Wallstent. Prior to deployment, these stents are constrained by a transparent plastic membrane (Unistep System) on a delivery system of outer diameter of 40 Fr (3.3 mm) and overall length of 230 cm. This slim and long delivery system allowed us to insert and deploy the stents through the biopsy channel of therapeutic upper endoscope for duodenoscopes (Fujinon, Inc, Wayne, NJ).

Technique

We placed all stents under endoscopic and fluoroscopic guidance. After identification of the stricture, we passed standard 0.035 inch Glidewire or Zebra guidewire (Microvasive, Watertown, MA) through it using a standard ERCP catheter (Figure 1). We determined the length of the stricture by the distance the catheter traveled over the guidewire while observing fluoroscopically. We used stents that were at least 2 cm longer than the stricture although early prototypes were not available in all sizes. We did not dilate any stricture prior to stent deployment. We advanced the Wallstent Enteral stent into the stricture such that the proximal and distal ends of the stent were equidistant from the ends of the stricture. In a few cases where an

153

Table 1. Technical feasibility and clinical outcomes of placement of Wallstent Enteral

Records processed under FOIA Request 2014-6600; Released 10/16/14

No	Age	Stricture	Etiology	Efficacy/ patency	Outcomes
	Gender	location			
1	57 M	Gastrojejunostomy	Pancreatic cancer	7 wk ^a	Pureed diet
2	45 M	Gastrojejunostomy	Pseudomyxoma peritonei	10 mo	Regular diet
3	65 W	Duodenal ^b	Pancreatic cancer	6 wk ^a	Pureed diet
4	51 W	Duodenal ^b	Colon cancer	4 of 7 wk ^a	Pureed diet
5	54 W	Duodenal ^b	Pancreatic cancer	15 wk ^a	Regular diet
6	66 W	Antrum/bulb	Ovarian cancer	2 wk ^a	Had multiple obstructions that were not recognized prior to stenting, had supportive therapy
7	71 W	Duodenal ^b	Duodenal cancer	2 wk ^a	Stent deployed too proximally, had supportive therapy
8	43 W	Duodenal	Ovarian cancer	7 wk	Stent deployed too distally, had gastrojejunostomy
9	85 W	Duodenal	Duodenal cancer	10 wk ^a	Regular diet
10	57 W	Antrum/bulb	Breast cancer	28 wk ^a	Regular diet
11	76 W	Antrum/bulb ^c	Gallbladder cancer	10 wk ^a	Regular diet
12	46 W	Antrum/bulb ^b	Biliary cancer	24 wk	Stent deployed too distally, had second stenting. Regular diet

^aExpired.

^bHad been treated with biliary Wallstent.

^cHad biliary and enteral Wallstents placed during one session.

endoscope could be passed through the stricture, we marked the distal end of the stricture by injecting Renografin contrast submucosally for additional guidance. During deployment, we repositioned stents frequently because there was a tendency for them to move away from the endoscope. We assessed the adequacy of stent placement at the conclusion of each procedure using endoscopy and fluoroscopy.

Results

The mean follow-up period for the group was thirteen weeks (range 2 to 40 weeks). One patient was lost to follow-up at 40 weeks, another patient who underwent gastrojejunostomy was lost to follow-up at seven weeks. Nine patients died after the procedure from progression of their cancer unrelated to the stent implantation.

Stent implantation

Fourteen Wallstent Enteral was implanted for the 12 patients. All stent deployments were technically successful. There were no major short or long-term complications, such as bleeding from the cancer, perforation, or stent migration. Placement of enteral stents in the second portion of the duodenum in patients who had biliary Wallstents did not cause obstruction of the biliary outflow. In at least three patients, the stent protruded approximately 1 to 2 cm into the normal antrum and did not cause any gastric obstruction or any new symptom.

Clinical outcomes

Six patients were able to eat a regular diet, and three others were able to eat a pureed diet within 24 hours of stent placement. Three patients developed recurrent symptoms of obstruction at two, four, and 21 weeks after stent placement. Of these three patients, one patient was found to have the stent deployed too distally and another patient was found to have tumor ingrowth into the stent. Both patients underwent successful restenting two and 21 weeks after the initial stent placement. The third patient had supportive therapy only. Stenting did not relieve the symptoms of three patients. One patient was found to have multiple distal small-bowel strictures that were not recognized prior to stent insertion and two patients had stents that were deployed suboptimally: one stent expanded too distally, and this patient subsequently underwent gastrojejunostomy, another stent was too proximal, and this patient was given supportive therapy only. Both technical failures occurred when one-size prototypes only were available. As we gained experience in stent placements, we were able to discharge patients earlier after stenting such that three patients were discharged within 24 hours after stent placement. Three patient had the procedure performed as an outpatient. Another patient had both biliary and enteral Wallstents placed during the same setting and was discharged two days later. Two other patients were also discharged within 48 hours after stenting. One patient was hospitalized for six days after stent placement to receive supportive care.

154

78

Discussion

The treatment of malignant gastroduodenal stenoses is difficult. Many patients have advanced malignant disease and are too ill to undergo surgical gastrojejunostomy, which is associated with significant morbidity and mortality [1]. It is not uncommon for patients to be treated with only supportive therapy, which, unfortunately, does not relieve nausea and vomiting or allow adequate food intake. Other treatment options have been tried. Treatment with chemotherapy or radiation therapy is typically unhelpful. A surgically-placed jejunostomy for feeding combined with percutaneous endoscopic gastrostomy has been used in patients with gastroduodenal stenoses [5], but this combined therapy is often unsatisfactory. Other endoscopic modalities to dilate or ablate the stenoses have been used infrequently, because they provide only a transient response and are associated with a significant risk of perforation .

Our prospective study found that endoluminal treatment of malignant GOO with the self-expanding metallic Wallstent Enteral is a safe and effective alternative to surgery. TTS deployment facilitates accurate and safe stent insertion. The slim and flexible delivery systems permit stent placements into the angulated lumen of the gastrointestinal tract without prior dilation of the stenoses. The large diameter of these stents allows patients to eat regular food and perhaps prevents early occlusion due to tumor ingrowth. With experience, we found that placements of Wallstent Enteral were associated with minimal morbidity, allowing us to discharge patients shortly after stenting.

The design of the stents that we used differed from those of the stents used in previous reports [2-10]. In 1992, Kozarek and colleagues, successfully placed Z-stents in the efferent limb of a patient who had had a Whipple resection for pancreatic carcinoma and in the efferent limb of a patient who had Bilroth II anastomosis for gastric carcinoma with good results [6]. Following this report, Maetani and associates, treated three patients who had malignant gastric and duodenal stenoses with Z-stents and reported similar results [7,8]. The delivery system of the Z-stent was large; thus, direct TTS placement was not possible. Keymling and colleagues used the endovascular Wallstent as palliative treatment for malignant duodenal stenoses [5], but as this stent had short delivery system, it was placed through a gastrostomy. The stents that we used had delivery system long enough to allow TTS placement (230 cm). Howell and others [4] used the biliary Wallstent as palliation for GOO. Although the biliary Wallstent allowed TTS placement, its diameter was small (10 mm) and thus limited patients' diets to clear liquids or soft foods. In comparison, the diameter of Wallstent Enteral is much larger (18, 20 or 22 mm), potentially allowing patients to eat a regular diet. Despite shortcomings in the design and delivery systems of the stents used previously, these reports indicate that self-expandable metal stents can be used safely to treat malignant gastric or duodenal obstruction.

In the era of cost containment, the cost effectiveness of the Wallstent Enteral to treat malignant gastrointestinal obstruction must be considered. Although our study evaluated only feasibility and outcomes, our experience suggests that use of the Wallstents would be cost effective (Table 2). The overall cost of treatment with the Wallstent is

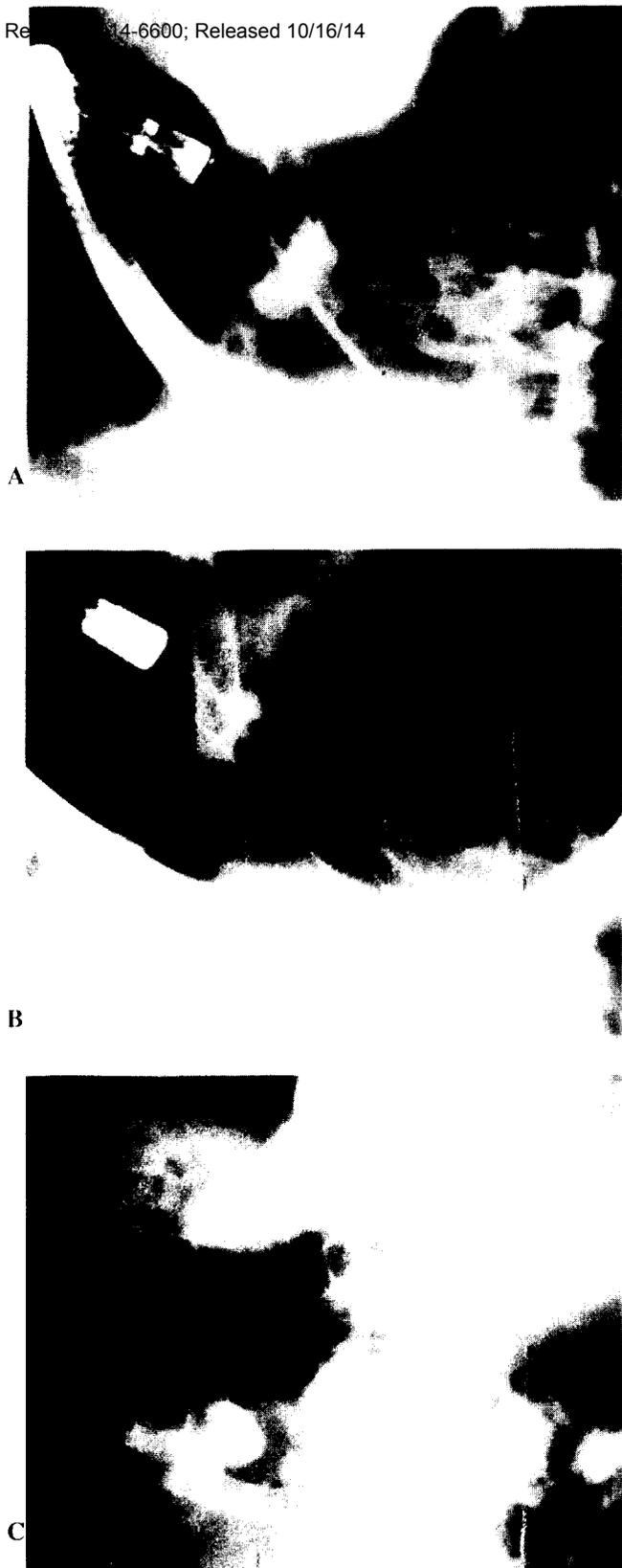


Fig.1: Wall-stent Enteral placement in patient with pancreatic cancer who had been previously treated with a biliary Wallstent and who developed duodenal obstruction. A: placement of the stent through the malignant stenosis over a guidewire B: partial deployment of the stent C: complete deployment of the stent.

156

likely to be lower than the overall cost of treatment with gastrojejunostomy, because stent placement does not require costly use of operating room and hospitalization for post-operative recuperation. In addition, stenting can be expected to provide more quality and quantity of life. Patients who receive stents require less time to recuperate than do patients who undergo surgery and stent placement is associated with minimal morbidity. In contrast, surgery is associated with significant mortality. In the future, we expect placement of the Wallstent to become the preferred treatment because it may improve quality and quantity of life and use fewer resources.

In conclusion, our initial experience with use of Wallstent Enteral to treat patients with malignant GOO is favorable. Stent deployment is technically feasible and in some patients allows effective palliation of obstructive symptoms and the ability to take food orally.

Correspondence to:
 Records processed under FOIA Request 2014-6600, Released 10/16/14 P
 Director of Endoscopy,
 Brigham and Women's Hospital,
 Associate Professor of Medicine,
 Harvard Medical School,
 Boston, Massachusetts, USA

Table 2. Potential Cost-effectiveness of Wallstent Enteral to treat malignant gastrointestinal stenoses.

	Surgery	Stent
Cost		
Treatment	+++	+
Post-treatment	+++	+
Overall	More	Less
Quality of life		
Post-op	Prolonged	Immediate
Remaining life expectancy	Similar	Similar
Overall	Less	More
Quantity of life		
Procedure mortality	Significant	Small
Overall	Less	More

References

1. Weaver D, Winczek R, Bowman D et al. Gastrojejunostomy: is it helpful for patients with pancreatic cancer? *Surgery* 1987;107:608-13.
2. Topazian M, Ring E, Grendell J. Palliation of obstructing gastric cancer with steel mesh, self-expanding prostheses. *Gastrointest Endosc* 1992;38(1):58-60.
3. Holstege A, Gross V, Lock G et al. Self-expanding metallic stent placement in the palliation of inoperable malignant gastric outlet obstruction (abstract). *Gastrointest Endosc* 1995;41(4):A38.
4. Howell D, Bosco J, Muggia R et al. Endoscopic double bypass: Duodenal metal expandable stenting in late stage malignancy (abstract). *Gastrointest Endosc* 1994;140:A38.
5. Keymling M, Wagner H, Vakil N et al. Relief of malignant duodenal obstruction by percutaneous insertion of a metal stent. *Gastrointest Endosc* 1993;39(3):439-41.
6. Kozarek R, Ball T, Patterson D. Metallic self-expanding stent application in the upper gastrointestinal tract: caveats and concerns. *Gastrointest Endosc* 1992;38:1-6.
7. Maetani I, Ogawa S, Hoshi H et al. Self-expanding metal stents for palliative treatment of malignant biliary and duodenal stenoses. *Endoscopy* 1994;26:701-4.
8. Maetani I, Inoue H, Sato M et al. Peroral insertion techniques of self-expanding metal stents for malignant gastric outlet and duodenal stenoses. *Gastrointest Endosc* 1996;44:468-71.
9. Rajjman I, Roddey G. Treatment of malignant duodeno-biliary obstruction with double-endoscopic stenting (abstract). *Gastrointest Endosc* 1995;41(4):A466.
10. Buto S, Tsang T, Crampton A et al. Nonsurgical bypass of malignant duodenal and biliary obstruction. *Gastrointest Endosc* 1990;36(5):518-20.

156
80

Duodenal And Biliary Wallstent In The Palliation Of Malignant Bilioduodenal Obstruction (MBDO).

Isaac Rajjman, Therapeutic and Diagnostic Gastroenterology Assoc, PA, Houston, TX; Shirley Pua, Vipul Amin, James Abbruzzese, Sandeep Lahoti, Stephen Curley, Yehuda patt, Peter Pisters, Jeff Lee, Douglas Evans, Jaffer Ajani, MD Anderson Cancer Ctr, Houston, TX

Pua S, Amin V, J Abbruzzese, Y Patt, S Curley, S Lahoti, J Ajani, P Pisters, J Lee, D Evans, I Rajjman. MD Anderson Cancer Ctr, Houston Introduction: Surgical bypass for palliation of MBDO is associated with increased morbidity and mortality. Endoscopic Rx may offer a reasonable alternative. We describe the clinical course and outcome of pts after combined biliary WS (bWS) and duodenal Wallstent (dWS)(Boston Scientific). Methods: 14 pts with combined dWS and bWS were studied There were 6 women, mean age 61yrs. The cancer was colon in 2, gastric in 2, leiomyosarcoma in 1, duodenal in 1 and pancreatic in 9. The mean follow-up was 280 days. All pts had resolution of jaundice after bWS . In 2 pts a plastic stent was left in place along with the WS. Enteral WS (11-22mm, and 3-10mm) were placed a median of 97.5 days after bWS for duodenal obstruction. All 14 pts had relief of symptoms within 24-48 hours. In 1 pt symptoms reoccurred due to a proximal jejunal tumor obstruction 4 days later. Complications included a duodenal perforation 7 days later in 1 (treated medically), transient cholangitis in 1 and acalculous cholecystitis in 1 (treated percutaneously). Two pts required endoscopically placed plastic stents into the biliary WS through the duodenal WS and 1 distal to for recurrent jaundice. Two pts had recurrent duodenal obstruction that responded to a 2nd dWS (1) or dilatation(1). In 5 pts advancement of the dWS through the scope was extremely difficult requiring out-of-the-scope placement in 3. Eleven pts died a mean of 2 months after dWS from tumor progression. Four pts are still alive a mean of 3 months after dWS Conclusion: Endoscopic bilio-duodenal stenting with the WS is a reasonable non-surgical alternative to MBDO. Survival after dWS is limited due to disease progression.

DDW[®]

Produced under
an unrestricted
educational grant from
Astra Pharmaceuticals

ASTRA[®]
Astra Pharmaceuticals

157

81

Endoscopic Placement of Nitinol 'Double Stents'(DS) for Palliation of Malignant Gastrointestinal(GI) Obstruction in Unusual Locations

Jin Hong Kim, Byung Moo You, Gyu Hyun Lee, Young Joon Kim, Kwang Jae Lee, Young Soo Lee, Ki Baek Baek Ham, Sung Won Won Cho, Ajou Univ Sch of Medicine, Suwon South Korea

Background: Through-the-scope(TTS) stent now provides a new option for palliation of malignant GI obstruction in unusual locations for stenting, such as gastric outlet, small bowel, and colon. However, reinterventions are frequently necessary to manage tumor ingrowth, a major disadvantage of the bare TTS stent alone. **Methods:** We prospectively studied a new method of placement of DS(Niti-s, Taewoong Inc., Seoul, Korea), consisting of a covered stent inside a bare stent, for the management or prevention of tumor ingrowth. After the nitinol bare stent(18 mm in diameter, 60 mm in length) had been initially inserted through 3.7 mm working channel of therapeutic upper GI endoscope(Olympus GIF-2T200), the nitinol covered stent(18 mm in diameter, 80 mm in length) was secondarily inserted into the bare stent through 5.5 mm working channel of therapeutic duodenoscope(Olympus TJF-M20). **Results:** All of 27 patients with malignant GI obstruction(20 in gastric antrum, 2 in duodenum, 3 in gastrojejunostomy stoma, 1 in jejunum, 1 in colon) were successfully managed with placement of DS without immediate major complications. After placement of DS, oral food intake and relief of obstructive symptoms were achieved in all the patients. During the follow-up, 12 patients died from stent-unrelated causes(14-68, mean 37.4 days) and 15 patients were still alive(35-116, mean 83.1 days). There were no tumor ingrowth or overgrowth. Late complications were delayed stent migration(2), bowel ulceration(2), and stent occlusion by food materials(1). **Conclusion:** Endoscopic placement of DS, consisting of a covered stent inside a bare stent, is a new effective non-surgical modality for palliation of malignant GI obstruction in unusual locations, resolving the disadvantage of the bare stent alone.

DDW[®]

Produced under
an unrestricted
educational grant from
Astra Pharmaceuticals

ASTRA[®]
Astra Pharmaceuticals

158

82

Management Of Malignant Colorectal Obstruction (MCO) With Expandable Stents: Experience In 34 Pts.

Isaac Raijman, Therapeutic and Diagnostic Gastroenterology Assoc, PA, Houston, TX; Jeffrey Linder, Vipul Amin, Patrick Lynch, Sandeep Lahoti, John Skibber, MD Anderson Cancer Ctr, Houston, TX; M F Catalano, St Lukes Med Ctr, Milwaukee, WI

J Linder, V Amin, P Lynch, S Lahoti, J Skibber, MF Catalano, I Raijman. MD Anderson Cancer Ctr, Houston, St Lukes Medical Ctr, Milwaukee Introduction: The use of expandable stents in the treatment of MCO is gaining popularity. We update our experience in 34 pts with MCO. Methods: There were 15 women, mean age of 59 yr. The cancer was colorectal in 29, cervical/ovarian in 3, gastric in 1 and transitional cell in 1. The site of MCO was rectosigmoid in 32 and transverse in 2. Previous Rx included laser in 6, surgery in 6, chemoXRT in 32. Twenty-two pts had a barium enema. The stent was placed under fluoroscopy in 12. The MCO was exophytic in 21, infiltrative in 9, and extrinsic in 4. The scope could be advanced beyond the MCO in 17. Dilatation was needed in 13 pts (12 mm). Enteral Wallstents (Boston Scientific) were placed in 27, non-enteral Wallstents in 6 (esophageal 5, biliary 1) and Ultraflex (Microvasive) in 1. Results: Stent placement was successful in 32/34 (94%), and all had clinical improvement. Stents could not be placed in 2 pts with cervical/ovarian cancers because of the tortuosity/angulation of the MCO. The mean follow up was 7.2 months. There were 5 complications (15%). One recto-vesical fistula after 2 weeks successfully treated with a Wallstent-I. One recto-vaginal fistula due to stent migration treated surgically. The pt who received a biliary Wallstent had distal stent migration. Two pts with an enteral Wallstent and a Wallstent-II had distal migration within 3 weeks causing proctalgia requiring surgical removal (transanal in 1). The mean survival was 6.2 months. Three pts are alive. There was no procedure-related mortality. Conclusions: Expandable metallic stents are safe, effective and provide a reasonable palliative option for unresectable MCO. Migration is a significant problem.

DDW[®]

Produced under
an unrestricted
educational grant from
Astra Pharmaceuticals

ASTRA[®]
Astra Pharmaceuticals

159

83

Non-Surgical Management Of Malignant Gastric Outlet Obstruction In 20 Patients Treated With Self-Expanding Metal Wall Stents

Adrian R Hatfield, Stephen Persson, The Middlesex Hosp, London United Kingdom

Background. Malignant gastric outlet obstruction often presents late and patients have previously needed a surgical gastroenterostomy at a time when they are frail and less able to cope with open surgery. The development of self-expanding, endoscopic, metal enteral stents provides a way of treating this without surgery. **Patients.** 20 such patients have been studied between May 1996 and November 1998, age range 42 - 82 (mean 74 years). The original tumour was stomach - 4, pancreas - 5, bile duct - 3, duodenum - 1, ampullary - 1 and other sites - 5. The site of obstruction was gastric antrum, pylorus and duodenal cap - 7 pts and 2nd / 3rd part of duodenum - 12 pts. **Technique.** Schneider Enteral metal stents were used, 22mm diam and 60 or 90 mm long when fully expanded. Stent placement was successful in 19/20 pts but failed in one due to a very tight, tortuous stricture. Insertion was endoscopic in 11 pts and finally radiological in 8. **Outcome.** There were no serious immediate complications. Late complications were seen in 6 pts, 3 with proximal stent migration from antrum into duodenal cap and 3 with distal tumour overgrowth. Further metal stent insertion for overlap was needed in 4 pts. A small asymptomatic duodenal perforation, caused by a stent, was seen in 1 pt at post mortem. All pts were taking liquids / sloppy diet within 48 hours. Only 4 / 18 pts needed to revert to pureed diet, the rest had a normal diet. 9 / 18 stented pts died during follow up with no further obstruction. **Conclusion.** The Enteral stent satisfactorily relieved malignant gastric outlet obstruction in 18 / 20 patients. Quality of life was excellent with good long term relief of obstruction, with no serious complications. Overlapping techniques for unsatisfactory positions or late tumour overgrowth were easy.

DDW®

Produced under
an unrestricted
educational grant from
Astra Pharmaceuticals

ASTRA®
Astra Pharmaceuticals

160

84

SECTION 9
PREDICATE DEVICE LABELING

LABELING	PAGE
Enteral Wallstent®	86

161

Enteral Wallstent® Labeling

WALLSTENT® ENTERAL

ENDOPROTHESIS WITH UNISTEP™ DELIVERY SYSTEM

ENTERALE ENDOPROTHESE MIT UNISTEP™ EINFÜHRSYSTEM

ENDOPROTHESE ENTERIQUE AVEC LE SYSTEME D'INSERTION UNISTEP™

ENDOPROTESI CON SISTEMA DI INTRODUZIONE UNISTEP™

ENDOPRÓTESIS ENTERAL CON EL DISPOSITIVO DE COLOCACIÓN UNISTEP™

ENDOPRÓTESE COM DISPOSITIVO DE APLICAÇÃO UNISTEP™

ENDOPROTHESE MET UNISTEP™ PLAATSINGSSYSTEMEEM

ENDOPROTES MED UNISTEP™ INFÖRINGSSYSTEM

ENDOPROTESE MED UNISTEP™ INDFØRINGSSYSTEM

ENDOPROTESE MED UNISTEP™ INNFØRINGSSYSTEM

ENDOPROTEESI JA UNISTEP™ -KOHDISTUSJÄRJESTELMÄ

ΕΝΔΟΠΡΟΘΕΣΗ ΜΕ ΣΥΣΤΗΜΑ ΠΑΡΟΧΗΣ UNISTEP™

体内プロテーゼ UNISTEP™ デリバリーシステム



162

GB Legend	E Leyenda	DK Tegnforklaring
D Zeichenklärung	P Legenda	N Tegnforklaring
F Légende	NL Legenda	SF Merkkieli selitykset
I Legenda	S Symbolförklaring	GR Υπόμνημα
		J 凡例

	GB Sterilized using ethylene oxide	E Esterilizado con óxido de etileno	DK Ethylenoxidsteriliseret
	D Sterilisiert durch Ethylenoxid	P Esterilizado usando óxido de etileno	N Sterilisert med Etylen-oksyd
	F Stérilisé à l'oxyde d'éthylène	NL Gesteriliseerd met Ethyleenoxide	SF Steriloitu etyyleenioksidilla
	I Sterilizzato con ossido di etilene	S Steriliserad med etylenoxidgas	GR Αποστειρωμένο με Οξείδιο Αιθυλενίου
			J エチレンオキシド滅菌済み

	GB Sterilized using gamma irradiation	P Esterilizado usando irradiación gamma	N Sterilisert med gamma-bestråling
	D Sterilisiert durch Gamma-Strahlung	NL Gesteriliseerd met gamma-straling	SF Steriloitu gammasäteilyllä
	F Stérilisé aux rayons gamma	S Steriliserad med gammastrålning	GR Αποστειρωμένο με ακτίνες γάμμα
	I Sterilizzato a raggi gamma	DK Gammastrålesteriliseret gamma	J ガンマ線滅菌済み

	GB Caution! Consult accompanying document	E ¡Atención! Consultar el documento adjunto	DK Advarsel! Se brugsanvisning
	D Vorsicht! Siehe Gebrauchsanweisung	P Atenção! Consultar as instruções de uso	N Advarsel! Råd før deg med vedlagt dokument
	F Attention! Consulter la documentation jointe	NL Opgelet! Raadpleeg de gebruiksaanwijzing	SF Varoitus! Tutustu ohjeisiin
	I Attenzione! Consultare le istruzioni per l'uso incluse	S OBS! Se bruksanvisning	GR Προσοχή, Συμβουλευτείτε το συνοδευτικό έγγραφο
			J 注意! 同封の書類参照

	GB Do not resterilize	P Não reesterilizar	SF Ei saa uudelleensteriloida
	D Nicht reesterilisieren	NL Niet opnieuw steriliseren	GR Μη επαναποστειρώνετε
	F Ne pas restériliser	S Får ej omsteriliseres	J 再滅菌禁止
	I Non risterilizzare	DK Må ikke gensteriliseres	
	E No reesterilizar	N Skal ikke reesteriliseres	

	GB Do not reuse	P Uso único	SF Kertakäyttöinen
	D Nur zum Einmalgebrauch	NL Eenmalig gebruik	GR Μίας χρήσεως
	F A usage unique	S Endast för engångsbruk	J 再使用禁止
	I Monouso	DK Kun til engangsbrug	
	E De un solo uso	N Engangsbruk	

	GB Non pyrogenic	P Não pirogênico	SF Ei-pyrogeeninen
	D Pyrogenfrei	NL Niet pyrogeen	GR Μη πυροτογόνο
	F Apyrogène	S Ej feberstrande	J 非発熱性
	I Apirogeno	DK Pyrogenfri	
	E Apirogéno	N Pyrogenfri	

	GB Store in a dry, cool place	E Almacenar en sitio fresco y seco	DK Opbevares tørt og køligt
	D Kühl und trocken aufbewahren	P Manter em local seco e fresco	N Lagres på tørt, kjølig sted
	F Conserver dans un endroit frais et sec	NL Bewaren op een droge koele plaats	SF Säilytä kuivassa, viileässä paikassa
	I Conservare in luogo fresco e asciutto	S Lagras torr och svalt	GR Αποθηκεύσατε σε στεγνό, δροσερό μέρος
			J 乾燥した涼しい場所に保管

	GB Recyclable material	P Material reciclável	SF Kierrätettävää materiaalia
	D Recyclebar	NL Recyclebaar materiaal	GR Ανακυκλώσιμο υλικό
	F Matériel recyclable	S Återvinningsbart material	J 再生資源
	I Materiale riciclabile	DK Kan genbruges	
	E Material reciclable	N Kan resirkuleres	

REF	GB Catalogue number	P Número de referência	SF Tilausnumero
	D Bestellnummer	NL Bestelnummer	GR Αριθμός παραγγελίας
	F N° de référence	S Artikelnummer	J 注文番号
	I Numero di codice	DK Varenummer	
	E Referencia	N Bestillings-nummer	

LOT	GB Batch code	P Número do lote	SF Eränumero
	D Lot-Nummer	NL Lotnummer	GR Αριθμός партиδας
	F N° de lot	S Batchnummer	J ロット番号
	I Numero di lotto	DK Lotnummer	
	E N° de lote	N Vareparti-nummer	

	GB Use by	E Utilizar antes de la fecha	N Brukes før
	D Vor Verfallsdatum verwenden	P Utilizar antes da data	SF Käytettävä ennen
	F Date de péremption	NL Houdbaarheidsdatum	GR Ημερομηνία λήξεως
	I Da usare entro il...	S Används före	J 有効期限
		DK Skal anvendes før	

	GB Content	P Conteúdo	SF Sisältö
	D Inhalt	NL Inhoud	GR Περιεχόμενο
	F Contenu	S innehåll	J 個数
	I Contenuto	DK Indhold	
	E Contenido	N Innhold	

	GB Guiding catheter	P Cateter guia	SF Ohjainkatetri
	D Führungskatheter	NL Geleide katheter	GR Οδηγός καθετήρα
	F Cathéter-guide	S Guidekateter	J ガイディングカテーテル
	I Catetere guida	DK Indføringskateter	
	E Catéter guía	N Førings-kateter	

	GB Recommended introducer	E Introducutor recomendado	N Anbefalt innføringshylse
	D Empfohlene Einführbesteck	P Introducutor recomendado	SF Suositeltu sisäänviejä
	F Introducuteur recommandé	NL Aanbevolen introducer	GR Συνιστώμενος εισαγωγέας
	I Introduttore consigliato	S Rekommenderad introducer	J 適正イントロデューサー
		DK Anbefalet introducer	

TABLE
ENGLI
DEUTS
FRAN
ITALIA
ESPAÑ
PORTI
NEDE
SVENS
DANSK
NORSK
SUOMI
ΕΛΛΗΝ
日本語

87
163

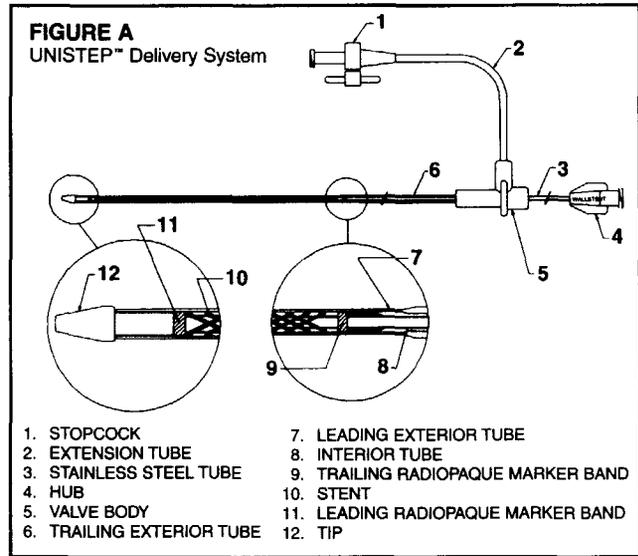
TABLE OF CONTENTS	
ENGLISH	2
DEUTSCH	5
FRANÇAIS	8
ITALIANO	10
ESPAÑOL	13
PORTUGUÊS	16
NEDERLANDS	18
SVENSKA	21
DANSK	23
NORSK	26
SUOMI	28
ΕΛΛΗΝΙΚΑ	31
日本語	34

ENGLISH

INSTRUCTIONS FOR USE

DESCRIPTION

The Schneider WALLSTENT® Enteral Endoprosthesis is comprised of two components: the implantable metallic stent and the Unistep™ delivery system (reference Figure A). The stent is composed of biomedical super alloy monofilament wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035" or 0.038" guidewire. The device may be inserted through the working channel of an endoscope (minimum channel diameter 3.6mm).



PRINCIPLE OF OPERATION

When sterile saline or contrast media is injected between the interior and exterior tube via the attached stopcock system, the delivery system becomes lubricated. Once lubricated, the exterior tube is easily retracted by moving the valve body towards the hub along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the stent from constraint. A single operator can thus control deployment and implant the stent.

INDICATIONS

The Schneider WALLSTENT® Enteral Endoprosthesis is indicated for palliative treatment of colonic and duodenal strictures caused by malignant neoplasms.

88
1604

CONTRAINDICATIONS

Contraindications associated with the use of the WALLSTENT® Enteral Endoprosthesis include:

- Enteral ischemia.
- Suspected or impending perforation.
- Intra-abdominal abscess/perforation.

WARNINGS

- Stents cannot be repositioned after total deployment.

PRECAUTIONS

- The device is intended for use by physicians who have received appropriate training.
- The system should not be resterilized.
- The sterile packaging and system should be inspected prior to use. If sterility or performance of the device is suspect to compromise, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed or partially deployed stents onto the delivery system.

COMPLICATIONS

Complications associated with the use of the WALLSTENT® Enteral Endoprosthesis may include the usual complications reported for conventional stents and endoscopic procedures such as infection, stent misplacement, stent migration, intestinal perforation and stent obstruction secondary to tumor ingrowth through the stent, tumor overgrowth at the stent ends, or occlusion.

PREPARATION OF THE INSTRUMENT FOR INSERTION

1. Recommended material for implant

Prepare the following material using sterile technique:

- 10cc syringe filled with sterile saline.
- 0.035" or 0.038" guidewire of appropriate length.

2. Length selection

Having calculated the obstruction length, allowing for possible further tumor development and post implant stent shortening (due to continued expansion), determine the number of stents necessary to cross the obstruction. Should multiple stents be required to cover the obstruction, place the leading stent first followed by the trailing stent(s), allowing for generous overlapping.

3. Initial preparation of instrument

- Carefully remove the delivery system from its protective packaging.
- Visually inspect the entire system for damage.
- Visually check that the leading end of the stent is covered by the exterior tube.
- Ensure that no stent wires have perforated the exterior tube.

4. Priming the delivery system

- Attach a 10cc syringe filled with sterile saline to stopcock on extension tube.
- Holding the device horizontally, open the stopcock and visually follow the advance of saline to the tip of the delivery system.
- After priming the delivery system, close the stopcock and remove the syringe.

- Reverify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved towards the trailing end, exposing the ends of the stent wires. Proper device function cannot be assured during implant, and such use may cause intestinal injury.

PROCEDURE

1. The WALLSTENT® Enteral Endoprosthesis can be placed with the aid of fluoroscopy or under direct visualization with an endoscope or the combination of both.

A. Fluoroscopy Procedure:

Pass a 0.035" or 0.038" guidewire to the level of the obstruction. The guidewire is maneuvered until the wire transverses the obstructed area. The WALLSTENT® Enteral Endoprosthesis is threaded over the guidewire and guided to the level of the obstruction under fluoroscopy. Advance the stent across the obstruction until the leading marker band is at least 2 centimeters beyond the obstruction. The trailing marker band should be at least 2 centimeters beyond the trailing end of the obstruction, if less than 2 centimeters a longer stent may be required or a second overlapping stent may be used to adequately cross the obstruction.

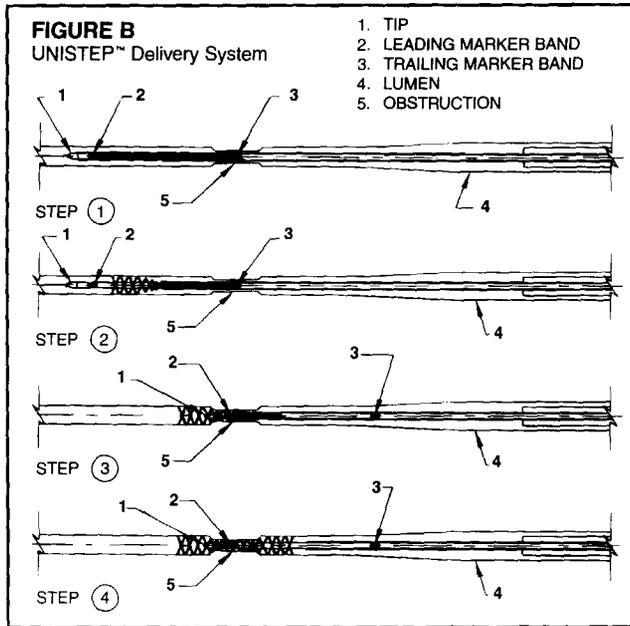
B. Endoscopic Procedure:

Pass an endoscope to the level of the obstruction. Under direct visualization, pass a 0.035" or 0.038" guidewire through the working channel of the scope and maneuver the guidewire across the obstruction. The guidewire can be used to estimate the length of the obstruction. However, radiographic aids may be more accurate to estimate the obstruction length. A WALLSTENT® Enteral Endoprosthesis with an unconstrained length of 2-4 centimeters longer than the measured obstruction is threaded over the guidewire and passed to the level of the obstruction. The stent is passed through the obstruction with the leading marker band placed approximately 2 centimeters beyond the obstruction. (Radiographic aid may be required to accurately make this placement).

2. The radiopaque marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. In order to assure precise stent placement, radiograph and endoscopic visualization of the stent itself is necessary.
3. Maintain the delivery system as straight as possible during deployment of the stent. **CAUTION: A stent that is partially deployed too far beyond the obstruction can be pulled back slightly or removed from the patient, provided no more than half the total stent length has been deployed (see Figure B, step 2). A stent, once deployment begins, cannot be advanced.**
4. Immobilize the stainless steel tube by holding the hub with one hand; grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube toward the hub, until the stent is approximately 50% deployed. **NOTE: Contrast medium may be injected through the valve body to ensure that 50% of the stent has been deployed. CAUTION: Do not push on the delivery system. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and**

68
165

possible intestinal wall damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see step 7 below.



5. In the event a stent is partially deployed too far beyond the obstruction site, the stent can be pulled back by first holding the valve body stationary and pulling back on the stainless steel tube. This action moves the tip and the radiopaque markers back and stops when the tip wedges in the unopened portion of the stent (see Figure B, step 3). Once the tip is locked in this position, the entire device can be pulled back aligning the center of the stent with the obstruction.
6. Immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube to complete stent deployment (see Figure B, step 4).
7. In the event that the leading end of the partially deployed stent is not positioned at least 2cm beyond the obstruction (stent cannot be advanced) and removal of the stent is desired, the stent may be removed by holding the valve body stationary and pulling back on the stainless steel tube. This action, as previously described in step 5, wedges the tip in the unopened portion of the stent. Once the tip is locked, the entire device can be pulled to the endoscope by pulling on the stainless steel tube. While holding the stainless steel tube and valve body in the locked position, the device and endoscope can be removed together. **CAUTION: Do not attempt to remove the delivery system by separately pulling on either the valve body or the exterior tube. This action could inadvertently misplace the stent.**

8. After the stent is correctly positioned and fully deployed, the delivery system may be removed.
9. Using standard operative procedures, perform routine post implant radiographic procedures to demonstrate location and patency of the stent.
10. The implanted stent length should allow for adequate overlapping into the non-obstructed anatomy to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the obstruction, a second stent should be implanted providing adequate overlapping of the initially placed stent.

Notes

The Schneider WALLSTENT® Enteral Endoprosthesis is returnable only with prior Schneider authorization, and only in unopened shelf packs with all seals intact. Schneider reserves the right to change or discontinue products without notice.

DISCLAIMER OF WARRANTIES

Schneider warrants that reasonable care has been used in the manufacture of this device. THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED, IMPLIED, WRITTEN OR ORAL, INCLUDING, BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact and since Schneider has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after the device leaves our possession, Schneider does not warrant either a good effect or against any ill effect following its use. Schneider shall not be liable for any incidental or consequential loss, damage, or expense arising directly or indirectly from the use of this device. Schneider will replace any device that it feels was defective at the time of shipment. Replacement of the device shall be the sole and exclusive remedy. No representative of Schneider may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

* WALLSTENT is a registered trademark of Schneider (USA) Inc and its affiliates.

** Unistep is a trademark of Schneider (USA) Inc and its affiliates.

Handwritten initials: 'db' and '1/16/14'.

SECTION 10
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

- DATE: January 28, 2000
 - COMMON/USUAL NAMES: Enteral Prosthesis
 - TRADE/PROPRIETARY NAME: Wallstent® Enteral Prostheseis
 - CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class III
- | Name | Number | 21 CFR Ref. |
|-----------------------|--------|-------------|
| Esophageal Prosthesis | 78 MQR | 878.3610 |
- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
Gastro-Renal (GRDB)
 - OWNER/OPERATOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
 - CONTACT PERSON: Lisa M. Quaglia, Regulatory Affairs Manager

DESCRIPTION OF DEVICE

The Wallstent® Enteral Endoprosthesis is comprised of two components: the implantable metallic stent and the Unistep™ Plus Delivery system (reference Figure A). The stent is composed of biomedical super alloy monofilament wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in. / 0,89 mm guide wire. The device may be inserted through the working channel of an endoscope (minimum channel diameter 3.7 mm).

167

INDICATIONS FOR USE

The Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery system is for palliative treatment of colonic or duodenal strictures or gastric outlet obstruction caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in malignant strictures. list indications

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Modified Enteral Wallstent® is substantially equivalent to the currently-marketed Enteral Wallstent®. The major components of the Modified Enteral Wallstent® are the stent and the delivery system. A thorough comparison of the descriptive characteristics between the Modified Enteral Wallstent® and the predicate device show equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on Modified Enteral Wallstent® to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Modified Enteral Wallstent® with satisfactory results.

CONCLUSION

Boston Scientific Corporation believes that Modified Enteral Wallstent® is substantially equivalent to the currently-marketed Enteral Wallstent®. A comparison of the descriptive characteristics of these products demonstrate the Modified Enteral Wallstent® is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Modified Enteral Wallstent® will meet the minimum requirements that are considered acceptable for its intended use.

168