



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms: Lynne Aronson
Regulatory Affairs Manager
Global Therapeutics, Inc.
2150 West 6th Avenue
Broomfield, CO 80020

OCT 5 1998

Re: P960014
Magellan-C PTCA Catheter
Filed: May 10, 1996
Amended: June 24 and September 25, 1996, March 20 and
September 22, 1997, February 24, May 4, July 27 and
September 9, 1998

Dear Ms. Aronson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Magellan-C PTCA Catheter. This device is indicated for balloon dilatation of the stenotic portion of a coronary or bypass graft stenosis for the purpose of improving myocardial perfusion. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for this device has been established and approved at eighteen (18) months.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that

this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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

If you have any questions concerning this approval order, please contact Shang W. Hwang, Ph. D. at (301) 443-8243.

Sincerely yours,



for Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effectuated" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effectuated" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effectuated." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

- (1) May have caused or contributed to a death or serious injury; or
- (2) Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW

Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

MAGELLAN-C PTCA Catheter

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MAGELLAN-C PTCA Catheter

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1. INFORMATION

Device generic name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter
Device trade name:	MAGELLAN-C PTCA Catheter
Applicant:	Global Therapeutics, Inc. 2150 West 6th Avenue Broomfield, CO 80020
PMA Number:	P960014
Date of Panel Recommendation:	none
Date of Notice of Approval to the Applicant:	OCT - 5 1998

2. INDICATIONS

The MAGELLAN-C PTCA Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

3. CONTRAINDICATIONS

The MAGELLAN-C PTCA Catheter is contraindicated in patients with:

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of a significant stenosis

4. WARNINGS AND PRECAUTIONS

4.1 Warnings

- This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

- Balloon pressure should not exceed the rated burst. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9 percent of the balloons, (with 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate balloon.
- Use the catheter prior to the "Use Before" date specified on the package.
- This catheter is not intended for the delivery or expansion of stents.

4.2 Precautions

- Prior to PTCA, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained in the performance of PTCA.
- Before insertion of the dilatation catheter administer appropriate anticoagulant and coronary vasodilator therapy.
- Caution should be taken not to over-tighten a Thouhy-Borst type hemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

5. DEVICE DESCRIPTION

The MAGELLAN-C PTCA Catheter is a double lumen coaxial catheter with a balloon near the distal tip. The catheter is constructed from two coaxially aligned high density polyethylene (HDPE) tubings. The HPDE balloon is designed to expand to a controlled diameter and length at a specific pressure. A single gold marker band is located at the center of the balloon. The outer lumen is used for inflation of the balloon, while the inner provides a through lumen for guide wire movement. The MAGELLAN-C PTCA Catheter does not provide for distal dye injection or pressure measurement.

As with other removable guide wire systems, a side-arm adapter attached to the proximal end of the catheter provides access to the lumens. The side-arm port provides access to the outer balloon inflation lumen by means of a luer-lock fitting. Balloon inflation and deflation are accomplished by connecting the side-arm port with an inflation device. The straight-arm port is continuous with the inner lumen of the catheter and provides access for the guide wire. The catheter is available in four dilatation balloon sizes: nominally 2.0, 2.5, 3.0 and 3.5 mm. The MAGELLAN-C PTCA Catheter can be used with any off-the-shelf 0.014 PTCA guide wire.

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6. ALTERNATIVE PRACTICES AND PROCEDURES

Other methods for treatment of coronary artery disease include (1) medical treatment, (2) use of other market approved PTCA catheters, (3) other catheter-based interventions, including laser, atherectomy, and stenting, and (4) coronary artery bypass graft (CABG) surgery.

7. MARKETING HISTORY

The MAGELLAN-C PTCA Catheter has not been marketed in the United States. A similar device incorporating all the components and processes of the device has been marketed in Asia and Europe since 1994. Of the over 11,000 catheters marketed overseas, there have been no countries from which the device has been withdrawn from marketing for any reason related to safety or effectiveness of the device.

8. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

8.1 Observed Adverse Events

Table 1 lists the adverse events that occurred during hospitalization. Table 7 lists all adverse events, both in-hospital and post discharge.

Table 1. In-Hospital Adverse Events (N = 206)

Event	n	%
Myocardial Infarction	2	1.0
CABG	5	2.4
Dissection (Total)	34	16.5
complicated	10	4.9
Total Occlusion (in lab)	4	1.9
Reocclusion	4	1.9
Repeat PTCA-same lesion	3	1.5
PTCA-new lesion	2	1.0
Chest Pain	11	5.4
Arrythmia	1	0.5
Thrombosis	1	0.5
Hematoma (requiring surgery)	3	1.5
Aneurysm	1	0.5
Stroke	1	0.5
Spasm	2	1.0
GI bleed	1	0.5
Embolectomy	1	0.5
Hypotension	1	0.5
Bradycardia	1	0.5
Groin Bleed	1	0.5
Arterial Recoil	1	0.5
Total # of Events	80	

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8.2 Potential Adverse Events

Possible adverse events (in alphabetical order) associated with PTCA include, but are not limited to, the following:

- acute myocardial infarction
- arrhythmias, including ventricular fibrillation
- arteriovenous fistula
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury
- death
- drug reactions, allergic reaction to contrast medium
- embolism
- hemorrhage or hematoma
- hypo/hypertension
- infection
- restenosis of the dilated vessel
- total occlusion of the coronary artery or bypass graft
- unstable angina pectoris

9. SUMMARY OF PRECLINICAL STUDIES

9.1 *In Vitro* (Laboratory) Studies

Bench testing was conducted on finished devices or sub-assemblies in accordance with the draft "Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices," May 1994. For each recommended test, the results were provided, or a justification for omitting the test. Table 2 at the end of this section provides a summary of the results of the finished device testing. All results met device specifications.

9.1.1 BIOCOMPATABILITY AND TOXICOLOGICAL TESTING

Biological assay testing indicated that the tissue-contacting materials of the MAGELLAN-C PTCA Catheter were biocompatible and non-toxic. The biological assays were conducted in accordance with the International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing." All testing was performed according to GLP guidelines on component materials or finished products sterilized by ETO gas.

Biological assays conducted include hemolysis, cytotoxicity, intracutaneous toxicity, acute systemic toxicity, thromboresistance, sensitization, 7-day muscle implantation, mutagenicity, subchronic toxicity, and pyrogenicity (LAL). All testing had passing results.

9.1.2 STERILIZATION, PACKAGING AND SHELF-LIFE TESTING

The sterilization cycle for the MAGELLAN-C PTCA Catheter was validated by the Overkill Method in accordance with the ANSI/AAMI ST27 (3/88) "Guideline for Industrial Ethylene Oxide Sterilization for Medical Devices: Process Design, Validation, Routine Sterilization, and Contract Sterilization." Results of testing validated the sterilization cycle at a sterility assurance level (SAL) of 10^{-6} . Samples of the MAGELLAN-C PTCA Catheter were tested after aeration to determine if ethylene oxide, ethylene chlorohydrin or ethylene glycol were present. All residual levels were below the maximum residual limits for devices contacting blood as specified in the Federal Register 43, June 23, 1978.

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Shelf-life testing was conducted to show that performance did not degrade following a minimum of 18 months of aging. All samples were aged real-time. Package integrity testing verified sterility after 24 months. Tyvek peel strength, tip pull strength, balloon compliance (distensibility), and balloon minimum burst strength were evaluated for the catheters. A comparison of the aged and non-aged data indicates that there was no degradation in performance. Results of the testing indicate that an 18 month shelf-life is acceptable

9.1.3 BALLOON MINIMUM BURST STRENGTH

Sixty catheters from each model were tested to determine the inflation pressure at which failure of the catheter occurs. The catheters were tested in 37°C water, inflating the balloon with water to 4 atmospheres (ATM) and increasing pressure by 1 ATM increments for 60 seconds each until balloon failure occurred. Mode of failure and burst pressure were recorded. All catheters demonstrated longitudinal balloon failure. The results demonstrated that with 95% confidence, 99.9% of the balloons will not burst at or below the rated burst pressure.

9.1.4 BALLOON COMPLIANCE (DISTENSIBILITY) TEST

Sixty catheters from each model were tested to determine the change in balloon diameter with increased pressure and the inflation pressure at which the balloon attains its nominal (labeled) diameter. The catheters were tested in 37°C water, inflating the balloon with water to 4 ATM and increasing pressure by 1 ATM increments for 60 seconds, recording balloon diameter at each increment until balloon failure. Typical balloon compliance is presented below.

ATM	Balloon Diameter (mm)			
	2.0	2.5	3.0	3.5
5	2.0	2.5	2.8	3.5
6	2.1	2.5	2.9	3.6
7	2.1	2.6	3.0	3.7
8	2.2	2.7	3.1	3.8
9	2.2	2.8	3.2	3.9
10	2.3	2.9	3.3	4.0
11	2.3	3.0	3.4	4.1
12	2.3	3.0	3.4	4.2

Nominal Pressure
Rated Burst Pressure

9.1.5 BALLOON INFLATION/DEFLATION PERFORMANCE

Five catheters from each model were tested to determine the balloon inflation and deflation times for each balloon model at nominal pressure. The catheters were tested in room temperature air, inflating the balloon with 50% contrast media in saline in a simulated aortic arch, recording time in seconds for balloon inflation. The balloon was deflated after 30 seconds, recording time in seconds for balloon to deflate.

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9.1.6 BALLOON FATIGUE (REPEATED BALLOON INFLATION)

Thirty catheters from each model were tested to determine the durability of the balloon when subjected to multiple inflation cycles to the rated burst pressure. The catheters were tested in 37°C water, inflating the balloon through 40 cycles to rated burst pressure with water, maintaining inflation and deflation time for 30 seconds. Mode and number of cycles to failure were recorded.

9.1.7 BOND STRENGTH

Thirty catheters (or sub-assemblies) were tested for adhesive bond testing, and 20 catheters for proximal bond testing, to determine the strength of the adhesive and thermal bonds when subjected to a constant pull. The samples were tested in room temperature air with a calibrated force gauge attached to the wire luer and a vise grip held below each bond being evaluated. The pull force in pounds up to 10 pounds and mode of failure were recorded.

9.1.8 CATHETER DIAMETER, BALLOON AND TIP PROFILE

Five catheters of each model were tested to determine the distal and proximal catheter shaft diameter and to determine the largest balloon profile measurement while the balloon is under vacuum. Using a calibrated micrometer, catheter shaft diameter was measured 30 cm, 60 cm, 90 cm, 120 cm and 130 cm distal to the proximal shrink tubing attached to the coaxial Luer. Measurements were made on the distal half of the balloon using a profile gauge. Measurements of the balloon tip were made with a calibrated micrometer.

9.1.9 TIP PULL TEST

Ten catheters were tested to determine the strength of the catheter when subjected to a horizontal pull force from luer hub to catheter tip. The catheters were tested in room temperature air with a calibrated force gauge attached to the wire luer and catheter tip secured in a vise grip. The pull rate was at a slow and constant speed. The pull force in pounds at failure and mode of failure were recorded.

9.1.10 OVER THE ARCH TORQUE STRENGTH TEST

Twelve catheters were tested to determine the number of revolutions the catheter can be torqued in a simulated aortic arch when the tip is not free to rotate. The catheters were tested in room temperature air in a simulated aortic arch. With the tip of the catheter secured, the catheter was rotated clockwise at the luer for a maximum of 200 revolutions or until failure occurred. The number of revolutions and mode of failure were recorded.

9.1.11 OVER THE ARCH TORQUE RESPONSE TEST

Eight catheters were tested to determine the degree of distal rotation with respect to rotation of the proximal end of the catheter. The catheters were tested in room temperature air in a simulated aortic arch. With the tip of the catheter allowed to rotate freely, the catheter was rotated clockwise at the luer for a maximum of 100 revolutions. The number of distal tip revolutions was counted.

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9.1.12 TYVEK PEEL STRENGTH

Twelve hundred forty Tyvek sealed tray units were tested to determine the strength of the heat sealed adhesive bond when subjected to a constant pull. The units were tested in room temperature air with a calibrated force gauge attached to one end of the Tyvek and slowly pulled horizontally across the tray within a defined area. The maximum pull force in pounds was recorded and calculated to lb./in. based on the sealed area tested. The average was 3.58 pounds per inch. No failure occurred below the minimum acceptable strength of 1.5 pounds per inch.

Table 2. Summary of Device Testing

TEST	SAMPLES	METHOD	RESULTS		
			Size	Mean	RBP
Balloon Minimum Burst Strength	N = 60/size	Catheters tested in 37° water bath; inflated with water to 4 ATM; increased pressure by 1 ATM for 60 seconds until burst	2.0-mm 2.5 mm 3.0 mm 3.5 mm	15.7 ± 1.4 17.9 ± 1.3 15.7 ± 1.3 13.1 ± 1.1	10 ATM 10 ATM 10 ATM 9 ATM
Balloon Compliance (Distensibility)	N = 60/size	Catheters tested in 37° water bath; inflated with water to 4 ATM; increased pressure by 1 ATM for 60 seconds until burst	The nominal diameter inflation pressure (NIDP) is 5 ATM. A balloon compliance chart is included in the Instruction for Use.		
Balloon Inflation/deflation Performance	N = 20 (5/size)	Catheters tested in air; inflated with 50% contrast in simulated aortic arch; recorded time for inflation; inflated for 30 seconds; recorded time for deflation	All catheters inflated in < 5 seconds and deflated in < 10 seconds.		
Balloon Fatigue (repeated balloon inflation)	N = 30/size	Catheters tested in 37° water bath; inflated with water to recommended burst pressure (RBP) for 40 cycles, maintaining inflation and deflation for 30 seconds	All catheters survived the 40 cycles. There is a 95% confidence that 90% of the catheters will not burst when cycled 40 times to the RBP.		
Bond Strength	N = 50	All bonds were pulled to failure In addition, all catheters subjected to burst testing were tested for pull strength.	<i>Wire Luer-to-shrink tubing</i> n = 10, F = 3.45 ± 0.19 lb <i>Coaxial Luer-to-shrink tubing</i> n = 10, F = 9.03 ± 0.35 lb <i>Coaxial Luer-to-wire Luer</i> n = 10, F > 10 lb <i>Proximal bond</i> n = 20, F = 2.52 ± 0.60 lb All bonds withstood the minimum specification of 1.0 lb pull force. Pull strength was similar to the above results for all other catheters tested.		
Catheter Diameter, Balloon and Tip Profile	N = 5/size	The catheter shaft was measured at 30, 60, 90 and 120 cm distal to the shrink tubing with a calibrated micrometer; the distal half of the balloon was measured with a profile gauge; the tip was measured with a calibrated micrometer	Proximal shaft diameters for all models was 0.045 inches. Depending on balloon diameter, the distal shaft was 0.034 - 0.036 inches, balloon profile was 0.036 - 0.039 inches, and balloon tip was 0.025 - 0.027 inches. All dimensions met specifications.		
Tip Pull Test	N = 10	At room temperature, catheters were pulled from the proximal end to the tip; catheters were pulled from a simulated left anterior descending artery model	The average force to failure was 3.16 ± 0.65 lb, with failure at the proximal bond. No failures occurred during the simulated use testing, with an average force of withdrawal of 0.43 ± 0.05 lb.		
Over the Arch Torque Strength Test	N = 12	Catheters were tested in a simulated aortic arch at room temperature; the catheter tip was secured, and the proximal end was rotated until failure or 200 revolutions	The average revolutions to failure were 174.7 ± 24.11. No failures occurred below 100 revolutions. All failures occurred at the proximal bond.		
Over the Arch Torque Response Test	N = 8	Catheters were tested in a simulated aortic arch at room temperature; the catheter was rotated from the proximal end for 100 revolutions; rotations of the distal tip were counted	An average of 87 distal rotations were noted for 100 proximal rotations.		

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9.2 Animal Studies

The MAGELLAN-C PTCA Catheter was evaluated *in vivo* to demonstrate that the catheter system would function safely and effectively in actual use in the coronary anatomy. Animal studies were conducted on four dogs who had coronary arteries similar in diameter to those of human coronary arteries with no stenosis. Balloon sizes used were 2.0 X 20 and 3.5 X 20 (diameter X length, mm) on each animal.

In summary, the balloon catheters performed well and were:

- easily purged of all air.
- easily loaded with the recommended size market approved coronary guide wires and easily steered through the balloon catheters to any area of the coronary arteries.
- easily passed through the guide catheter, with no resistance while advancing through the guide catheter regardless of curves or bends.
- advanced without resistance through the coronary arteries both with and without acute bends. All balloon catheters were advanced through the proximal and distal portion of the coronary arteries and no resistance was met.
- easily advanced over the guide wire to the target area to be dilated in the coronary artery.
- easily inflated to nominal size and deflated with no problem.
- easily withdrawn from the coronary arteries with no resistance, and once removed were found to have no kinks or bends in the balloon catheter or the guide wire.
- easily positioned with use of the acceptable radiopaqueness of the gold band.

In no case did the guide catheter disengage from the coronary ostium when removing the balloon catheter from the coronary artery. No adverse effects were noted.

10. SUMMARY OF CLINICAL STUDIES

A multi-center non-randomized single-arm prospective clinical trial was conducted to evaluate the safety and effectiveness of the MAGELLAN-C PTCA Catheter during percutaneous transluminal coronary angioplasty (PTCA). Data were collected from 206 patients enrolled at 11 investigational sites between September 16, 1992 and June 2, 1995.

10.1 Objectives

The primary objective of the study was to establish the effectiveness of the catheter by measuring percent stenosis pre- and post-PTCA. Major adverse cardiac events were recorded, and at two months post-procedure vessel lumen diameter was measured to determine vessel patency in those patients who exhibited angina. Patients without angina were subjected to an exercise, or pharmacologic thallium, exam. Results obtained were analyzed in terms of frequency and degree of initial success, incidence of adverse events, and long-term follow-up of symptoms.

10.2 Patient Selection

Patients eligible for this study had symptomatic cardiovascular disease and were candidates for PTCA. Following a baseline angiogram, all eligible patients were offered a chance to participate in the study. Prior to PTCA, the target lesion(s) was angiographically characterized as to anatomic location, length, percent stenosis, and descriptive characteristics.

10.3 Inclusion Criteria

Patients had to be clinically stable, but had experienced unstable angina or recent myocardial infarction (MI) (within one month), and be acceptable candidates for coronary artery bypass graft (CABG) surgery, with significant stenosis of 50% or greater reduction in coronary vessel diameter. The lesions considered for this study were described as:

- discrete (≤ 10 mm length with little or no calcification)
- concentric (less than totally occluded)
- readily accessible (non-ostial in location)
- non-angulated segment $< 45^\circ$ (no major branch involvement)
- smooth contour (absence of thrombus)

10.4 Exclusion Criteria

Excluded were hemodynamically unstable patients, patients with left main coronary artery lesions, totally occluded arteries, and those experiencing coronary artery spasm with no fixed stenosis.

10.5 Study Population

The following four tables present the characteristics of the patients enrolled in the study, the types of coronary vessels treated, and the nature of the lesions as assessed by the 11 investigational sites and by a core angiographic laboratory. The overall age of the patients was 63.2 ± 10.7 years. Of the 206 patients entered into the study, 153 (74.3%) were males and 53 (26.7%) were female. Prior to hospitalization for PTCA, these patients were being treated with medications relating to their cardiovascular and other underlying disease state(s). Medications relevant to cardiovascular disease that had been administered within 72 hours of admission to the study are grouped by therapeutic class and listed in Table 3.

Table 3. Concomitant Medications at Entry

(N = 206 patients)

	Number of Patients	% of Patients
Antithrombotic Agents	185	89.8
Calcium Channel Blockers	121	58.7
Nitrates	120	58.3
Beta Blockers	62	30.1
Lipid Lowering Agents	48	23.3
Anticoagulants	42	20.4
Insulin	31	15.0
ACE Inhibitors	30	14.6
Diuretics (other)	26	12.6
Oral Hypoglycemics	24	11.7
Digitalis	23	11.2
Antiarrhythmics	5	2.5
Antihypertensives (other)	4	1.9
Patients with no data	3	1.5

Table 4. Demographic and Clinical Characteristics

	N		%	
Number of patients	206			
Mean age (years)	63.2±10.7			
range	(32.8 - 86.1)			
Gender (male)	153/206		74.3	
Previous myocardial infarction	99/206		48.1	
recent (≤ 6 weeks)		50/206		24.3
old (> 6 weeks)		49/206		23.8
Previous PTCA	61/206		29.6	
Previous thrombolytic therapy	31/206		15.0	
Previous CABG	30/206		14.6	
Dyspnea	63/206		30.6	
NYHA				
I		9/203*		4.4
II		30/203		14.8
III		17/203		8.4
IV		4/203		2.0
Angina	182/206		88.3	
CCS Class				
I		5/202*		2.5
II		43/202		21.3
III		110/202		54.5
IV		20/202		9.9
*missing classification data				

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10.6 Lesion Characteristics

Table 5. Angiographic Review by Investigational Site

	n	%	Range
Number of lesions	226		
Lesion length (mm)	9.4 \pm 4.7		1.0 - 20
Percent diameter stenosis (%)	84.7 \pm 9.4		49 - 100
Target vessel			
RCA	74/226	32.7	
LAD	74/226	32.7	
LCX	76/226	33.6	
Graft	2/226	1.0	
Discrete	226/226	100.0	
Concentric	154/224*	68.8	
Noncalcific	185/226	81.9	
ACC/AHA lesion Type A	226/226	100.0	
* missing data			

Table 6. Angiographic Review by Core Laboratory

	n	%	Range
Number of lesions	184		
Lesion length (mm)	9.3 \pm 4.5		1 - 20
Percent diameter stenosis (%)	83.6 \pm 13.5		35 - 100
Target vessel			
RCA	66/184	35.9	
LAD	59/184	32.1	
LCX	57/184	31.0	
Graft	2/184	1.1	
Concentric	126/183*	71.0	
ACC/AHA lesion Type A	184/184	100.0	
* missing data			

10.7 Safety Data

10.7.1 ADVERSE EVENTS

During the investigation, adverse events were noted while patients were in the hospital and after discharge. Table 7 describes these for the entire patient population

Table 7. Adverse Events .

Event	In Hospital (N = 206)			Post Discharge (N = 192)		
	n	%	95%C.I.	n	%	95%C.I.
Death	0			2	1.0	0.0 - 2.4
Myocardial Infarction	2	1.0	0.0 - 2.4	2	1.0	0.0 - 2.4
CABG	5	2.4	0.3 - 4.5	3	1.6	0.0 - 3.4
Dissection (Total)	34	16.5	11.4 - 21.6			
complicated	10	4.9	2.0 - 7.8			
Total Occlusion (in lab)	4	1.9	0.0 - 3.8			
Reocclusion	4	1.9	0.0 - 3.8	13	6.8	3.2 - 10.4
Repeat PTCA-same lesion	3	1.5	0.0 - 3.2	11	5.7	2.4 - 9.0
PTCA-new lesion	2	1.0	0.0 - 2.4	8	4.2	1.4 - 7.0
Chest Pain	11	5.4	2.3 - 8.5	44	22.9	17.0 - 28.8
Angina (positive stress test)	0			20	10.4	6.2 - 14.6
Arrythmia	1	0.5	0.0 - 1.4	0		
Thrombosis	1	0.5	0.0 - 1.4	0		
Hematoma (require surg)	3	1.5	0.0 - 3.2	0		
Aneurysm	1	0.5	0.0 - 1.4	0		
Stroke	1	0.5	0.0 - 1.4	0		
Spasm	2	1.0	0.0 - 2.4	1	0.5	0.0 - 1.5
GI bleed	1	0.5	0.0 - 1.4	0		
Embolectomy	1	0.5	0.0 - 1.4	0		
Hypotension	1	0.5	0.0 - 1.4	0		
Bradycardia	1	0.5	0.0 - 1.4	0		
Groin Bleed	1	0.5	0.0 - 1.4	0		
Arterial Recoil	1	0.5	0.0 - 1.4	0		
TOTAL no. of events	80			104		
TOTAL no. of patients w/events	46	22.3	16.6 - 28.0	58	30.2	23.7 - 36.7

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10.7.2 MAJOR ADVERSE CARDIAC EVENTS

The clinical data were evaluated in-hospital and at two months for a major adverse cardiac event (MACE). MACE is defined as a composite of death, MI (Q- and non-Q-wave), and CABG or PTCA to the target vessel. Table 8 describes the principal safety results for the study.

Table 8. Principal Safety Results

Safety Measures* (n = 206)	
	MAGELLAN-C Patients, (%)
MACE in hospital	6/202, (2.9)
MACE at 2 months	7/192, (3.6)
Repeat PTCA in hospital - same lesion	3/206, (1.5)
Repeat PTCA at 2 months - same lesion	11/192, (5.7)
Dissection - total	34/206, (16.5)
- complicated	10/206, (4.9)
Chest pain - in-hospital	11/206, (5.4)
-post-discharge	44/192, (22.9)
Angina (positive stress test)	20/192, (10.4)
Number of patients with any event - in-hospital	46/206, (22.3)
- post-discharge	58/192, (30.2)

* Patients with multiple MACEs are counted once per time period.

10.7.3 DEATHS

There were no procedural or in-hospital deaths in this 206 patient study group. Two patients died during the two-month follow-up period. Summaries of these two cases follow:

- The patient had two lesions that were successfully treated with MAGELLAN-C PTCA Catheters. No complications arose from the procedure. Three months after discharge the patient died at home with no witnesses. No autopsy was performed. The death was judged not related to the procedure.
- During the PTCA procedure, a 2.75 legally marketed PTCA catheter followed a 2.5 MAGELLAN-C PTCA Catheter. A dissection occurred following the legally marketed catheter. Several months following hospital release, the patient returned in cardiogenic shock and was sent to emergency surgery, where the patient died.

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10.7.4 TECHNICAL PROBLEMS

There were 244 MAGELLAN-C PTCA Catheters used in treating 235 lesions in 206 patients. A list of technical problems follow:

N = 244	# of Catheters	%	95% C.I.
Balloon rupture	6	2.4	0.5, 4.3
Leaking luer	1	0.4	0.0, 1.2
Leaking hub	1	0.4	0.0, 1.2
TOTAL	8	3.3	1.1, 5.5

Of the six balloon ruptures, in three cases the stenosis was reduced in spite of the rupture, in one case a second MAGELLAN-C PTCA Catheter was used successfully, in one case the catheter also failed to cross lesion but a legally marketed catheter was used successfully completing the procedure, and in the last case a legally marketed catheter was used successfully completing the procedure.

Other technical problems related to the failure of the MAGELLAN-C PTCA Catheter to cross the lesion are listed below:

N = 244	# of Catheters	%	95% C.I.
Failure to cross lesion	9	3.7	1.3, 6.1%
Legally Marketed catheter successful	7	2.7	0.7, 4.7%
Legally Marketed catheter unsuccessful	2	0.8	0.0, 1.9%

In eight of the nine cases, the lesion was attempted with the MAGELLAN-C PTCA Catheter first. In the one remaining case, a legally marketed catheter was first, which also failed to cross the lesion. Of the two lesions that were unsuccessfully treated by a legally marketed catheter, one patient required CABG.

10.8 Effectiveness Data

10.8.1 DEFINITIONS

Technical success. All of the following must occur:

- Lesion crossed with a MAGELLAN-C PTCA Catheter
- No mechanical failure
- No other device used

Clinical success. All of the following must occur:

- Reduction in % stenosis of $\geq 20\%$
- Residual stenosis of $\leq 50\%$
- No acute complications, no in-hospital reclosure, emergent reintervention, myocardial infarction, or death

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MAGELLAN-C Only Population. All patients treated exclusively with the MAGELLAN-C PTCA Catheter for all lesions. In calculating the success rates, the denominator is all patients in which all lesions were treated with the MAGELLAN-C PTCA Catheter first.

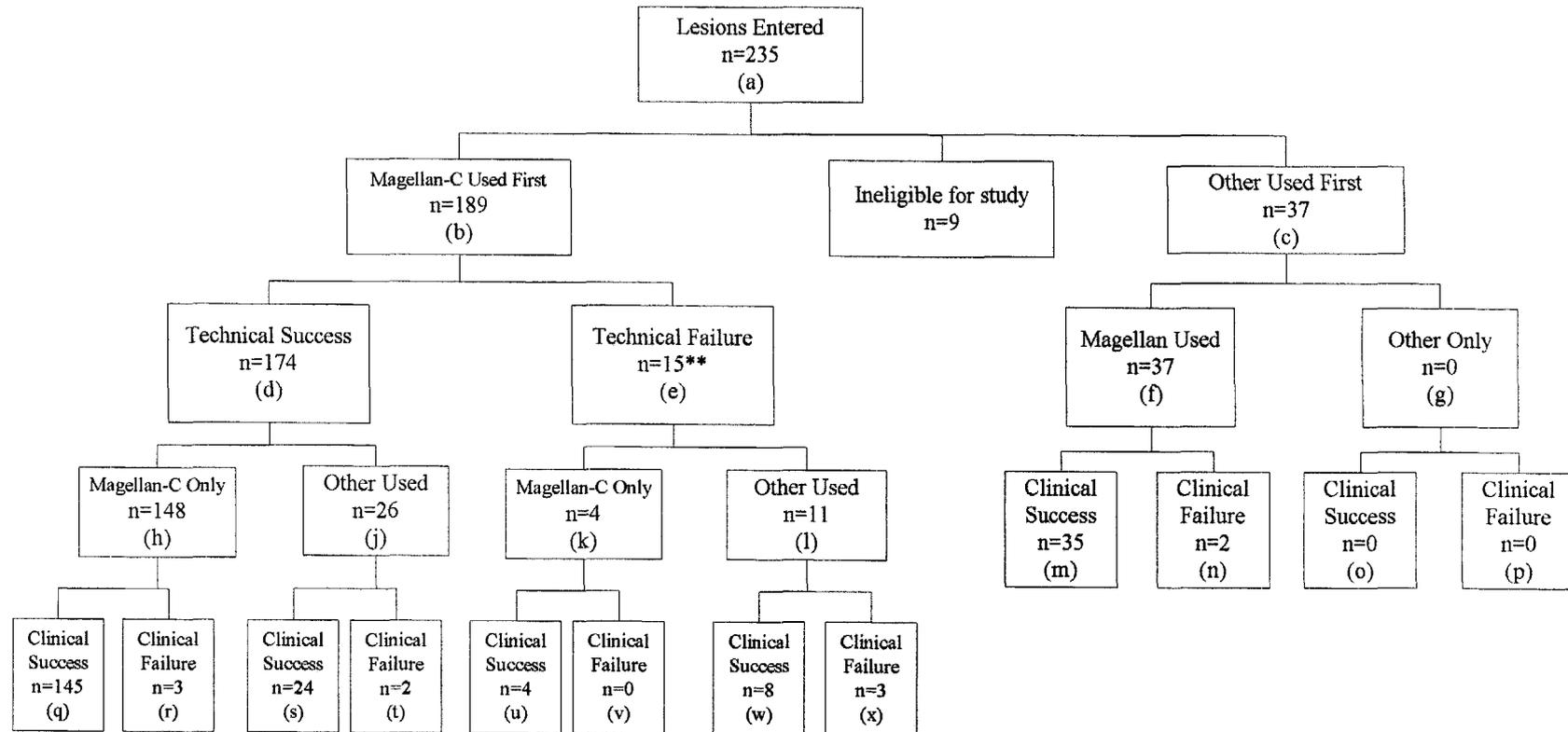
MAGELLAN-C First Population. All patients in which all lesions were treated with the MAGELLAN-C PTCA Catheter first.

Patient/Procedure Success. All lesions successfully dilated to <50% maximum residual stenosis and an increase in luminal diameter of $\geq 20\%$ with no major in-hospital ischemic complications (death, MI, or CABG).

10.8.2 PATIENTS NOT MEETING ELIGIBILITY REQUIREMENTS

Nine lesions in eight patients did not meet eligibility requirements and are thus excluded from the lesion effectiveness analysis. Of these nine lesions, three were excluded due to left main lesions, two were excluded for total occlusion, two were excluded due to presence of thrombus, and two were excluded because the procedural data and results were missing from the case report form.

Figure 1. Lesion Results Flow Chart



** One lesion experienced two technical failures with the Magellan-C catheter used first

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10.8.3 CLINICAL SUCCESS RATE

Table 9 presents the clinical success rate using the data in figure 1.

Table 9. Clinical Success Rates for MAGELLAN-C PTCA Catheter

	N	%	95% C.I.
Lesions treated with MAGELLAN-C first [(q+s+u+w)/b]	181/189	95.8	92.9, 98.7%
Lesions treated successfully with MAGELLAN-C first [(q+s)/b]	169/189	89.4	85.0, 93.8%
Acute technical & clinical success for lesions treated with MAGELLAN-C only (q/b)	145/189	76.7	70.6, 82.8%

10.8.4 DETAILS OF LESION RESULTS

Tables 10 and 11 describe the number of lesions treated with devices other than the MAGELLAN-C PTCA Catheter where the other device was used first or following the MAGELLAN-C PTCA Catheter. Tables 12 and 13 describe the reasons for technical and clinical failures. The data are obtained from Figure 1.

Table 10. Other devices used first (c)

Type of Catheter	# of Lesions
PTCA Catheter, Legally Marketed	28
Directional Coronary Atherectomy	9
TOTAL	37

Table 11. Other devices used following MAGELLAN-C (j and l)

Type of Device	# of Lesions
PTCA Catheter, Legally Marketed	29
Stents	6
Directional Coronary Atherectomy	2
TOTAL	37

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Table 12. Reasons for MAGELLAN-C PTCA Catheter Technical Failures (e)

Type of Failure	# of Lesions
Balloon Rupture	5
Balloon Rupture/Failure to Cross Lesion*	1
Luer Leak	1
Hub Leak	1
Failure to Cross Lesion*	7
TOTAL	15

*A legally marketed catheter was successful in 6 of the 8 cases in which the MAGELLAN-C catheter failed to cross the lesion. Of the two cases not successful with the legally marketed catheter, one patient went to CABG and one received no further treatment.

Table 13. Reasons for MAGELLAN-C PTCA Catheter clinical failure (r)

Reason	# of Lesions
Occlusion/Reocclusion with MI	1
Occlusion/Reocclusion without MI	2
TOTAL	3

10.8.5 PATIENT ACCOUNTABILITY

There were 137 patients in whom one or more lesions were attempted with the MAGELLAN-C PTCA Catheter only. In 134 patients, at least one of the attempted lesions was successfully treated. In 124 patients, all attempted lesions were treated successfully.

Table 14. Patient Accountability

	N	%	95% C.I.
One or more MAGELLAN-C only lesions	137		
One or more lesions successful	134	97.8	96.4, 99.2%
All lesions MAGELLAN-C only	127		
All lesions successful	124	97.6	94.9, 100.0%

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10.8.6 EVALUATION OF GENDER BIAS

The patient population enrolled in this clinical study was 74.3% male which is typical for patients presenting with coronary artery disease. Acute procedure success rates for all patients and for patients with eligible lesions did not differ significantly by patient gender nor did MACE rates. Tables 15, 16 and 17 describe the analyses for the total population and two subsets.

Table 15. Total Population:

Procedure Success: All Patients (N=206)			
	N	%	95% C.I.
Males (N = 153)	147	96.8	94.0, 99.6%
Females (N = 53)	52	98.1	94.4, 100.0%
	p= 0.48		
CABG/QMI/Death (In Hospital)			
Males	5	3.3	0.5, 6.1%
Females	1	1.9	0.0, 5.6%
	p= 0.61		
Procedure Success: Patients w/ Eligible Lesion (N=200)			
	N	%	95% C.I.
Males (N = 148)	142	95.9	92.8, 99.0%
Females (N = 52)	51	98.1	94.4, 100.0%
	p= 0.47		
CABG/QMI/Death (In Hospital)			
Males	5	3.3	0.5, 6.3%
Females	1	1.9	0.0, 5.6%
	p= 0.60		

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Table 16. MAGELLAN-C Catheter First Population:

Procedure Success: All Patients (N=166)			
	N	%	95% C.I.
Males (N = 121)	116	95.9	92.4, 99.4%
Females (N = 45)	44	97.8	93.4, 100.0%
	p= 0.56		
CABG/QMI/Death (In Hospital)			
Males	4	3.3	0.1, 5.5%
Females	1	2.2	0.0, 7.9%
	p= 0.72		
Procedure Success: Patients with Eligible Lesion (N=163)			
	N	%	95% C.I.
Males (N = 119)	114	95.8	92.2, 99.4%
Females (N = 44)	43	97.7	93.3, 100.0%
	p= 0.56		
CABG/QMI/Death (In Hospital)			
Males	4	3.3	0.1, 6.7%
Females	1	2.2	0.0, 6.7%
	p= 0.72		

Table 17. MAGELLAN-C Only Population

Procedure Success: All Patients (N=130)			
	N	%	95% C.I.
Males (N = 96)	94	97.9	95.0, 100.0%
Females (N = 34)	34	100.0	n/a
	p= 0.40		
CABG/QMI/Death (In Hospital)			
Males	2	2.1	0.0, 4.8%
Females	0	0.0	n/a
	p= 0.40		
Procedure Success: Patients with Eligible Lesion (N=127)			
	N	%	95% C.I.
Males (N = 94)	92	97.9	95.0, 100.0%
Females (N = 33)	33	100.0	n/a
	p= 0.40		
CABG/QMI/Death (In Hospital)			
Males	2	2.1	0.0, 4.8%
Females	0	0.0	n/a
	p= 0.40		

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10.8.7 ANGIOGRAPHIC RESULTS

The angiographic data for lesions treated in this investigation are summarized below. Both investigational site data and core laboratory data for the total population and the MAGELLAN-C Only population are presented.

Table 18. Angiographic Results

Investigational Site Angiographic data: Total Population			
Angiographic percent stenosis			
N = 226 lesions	Mean	SD	Range
Pre-PTCA	84.7	9.38	49 - 100
Post PTCA	17.8	13.32	0 - 100
<hr/>			
Investigational Site Angiographic data: MAGELLAN-C Only			
Angiographic percent stenosis			
N = 152 lesions	Mean	SD	Range
Pre-PTCA	84.8	8.93	50 - 99
Post PTCA	17.1	9.37	0 - 40
<hr/>			
Core Laboratory Angiographic data: Total Population			
Angiographic percent stenosis			
N = 184 lesions	Mean	SD	Range
Pre-PTCA	83.6	13.47	35 - 100
Post PTCA	25.6	12.81	0 - 80
<hr/>			
Core Laboratory Angiographic data: MAGELLAN-C Only			
Angiographic percent stenosis			
N = 118 lesions	Mean	SD	Range
Pre-PTCA	83.4	13.29	35 - 99
Post PTCA	24.9	11.19	0 - 60

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10.8.8 TWO MONTH FOLLOW-UP

Angiographic assessments were to be performed on all patients who had documented ischemia post dilatation. All patients in the clinically successful population were to have a stress test for noninvasive evaluation of vessel patency. Table 19 presents the two month follow-up data for those patients with angiographic follow-up.

Table 19. Two-Month Angiographic Follow-up

	N	%	95% C.I.
Number of patients enrolled	206		
Lost to follow-up	14		
<hr/>			
Number of patients with follow-up	192		
Clinical evidence of Restenosis (chest pain or positive ETT)	53	25.7	18.5, 31.9%
by chest pain	44	22.9	17.0, 28.8%
by positive ETT	20	10.4	6.2, 14.6%
<hr/>			
Angiography (indicated by symptoms)	21	11.0	6.6, 15.4%
Angiographic evidence of restenosis	13	6.8	3.2, 10.4%
<hr/>			
Other Clinical Complications			
Death	2	1.1	0.0, 2.4%
QMI	2	1.1	0.0, 2.4%
non QMI			
CABG	3	1.6	0.0, 3.4%
Repeat PTCA - same lesion	11	5.7	2.4, 9.0%
Repeat PTCA - new lesion	8	4.2	1.4, 7.0%
Spasm	1	0.5	0.0, 1.5%
None (patients complication-free)	134	69.8	63.3, 76.3%

10.8.9 SUMMARY OF RESULTS OF CLINICAL STUDY

Table 20. Summary of the Study

Clinical Success: All Patients	n/N	%	95% C.I.
Acute Clinical Success (Lesions treated with MAGELLAN-C first)	181/189	95.8	92.9, 98.7%
Acute Technical & Clinical Success (Lesions Treated with MAGELLAN-C First)	169/189	89.4	85.0, 93.8%
Acute Technical & Clinical Success (Lesions Treated with MAGELLAN-C Only)	145/189	76.7	70.6, 82.8%
Procedure Success: All Patients	n/N	%	95% C.I.
Total Population	199/206	96.6	94.1, 99.15%
MAGELLAN-C First Population	160/166	96.4	93.6, 99.2%
MAGELLAN-C Only	128/166	77.1	70.7, 83.5%
Procedure Success: Patients with Eligible Lesions	n/N	%	95% C.I.
Total Population	193/200	96.5	94.0, 99.15%
MAGELLAN-C First Population	157/163	96.3	93.4, 99.2%
MAGELLAN-C Only	126/163	76.7	70.2, 83.2%
% Diameter Stenosis - Investigational Site Data		%	SD
Total Population - Pre		84.7	9.38
- Post		17.8	13.32
MAGELLAN-C Only - Pre		84.8	8.93
- Post		17.1	9.37
% Diameter Stenosis - Core Laboratory Data		%	SD
Total Population - Pre		83.6	13.47
- Post		25.6	12.81
MAGELLAN -C Only - Pre		83.4	13.29
- Post		24.9	11.19
Acute Adverse Events (MACE)	n/N	%	95% C.I.
Major Cardiac Events			
Death	0/206		n/a
MI	2/206	1.0	0.0, 2.4%
CABG	5/206	2.4	0.3, 4.5%
Repeat PTCA - same lesion	3/206	1.5	0.0, 3.2%
Follow-up Adverse Events (MACE)	n/N	%	95% C.I.
Major Cardiac Events			
Death	2/192	1.0	0.0, 2.4%
MI	2/192	1.0	0.0, 2.4%
CABG	3/192	1.6	0.0, 3.4%
Repeat PTCA- same lesion	11/192	5.7	2.4, 9.0%

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11. CONCLUSIONS DRAWN FROM STUDIES

The results of laboratory and animal studies demonstrate that there are no biocompatibility issues and that the MAGELLAN-C PTCA Catheter has the appropriate physical and performance characteristics for its intended use. The MAGELLAN-C PTCA Catheter was evaluated *in vivo* and successfully demonstrate that the catheter system would function safely and effectively in actual use in the coronary anatomy.

The results of the clinical study indicate that the MAGELLAN-C PTCA Catheter is safe and effective for the treatment of patients with coronary artery disease.

Therefore, it is reasonable to conclude that the benefits of use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use.

12. PANEL RECOMMENDATIONS

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

13. FDA DECISION

FDA issued an approval order on OCT - 5 1998. FDA performed an inspection and found the applicant in compliance with the Good Manufacturing Practices (GMP) regulation (21 CFR, Part 820).

14. APPROVAL SPECIFICATIONS

- Directions for use: See the labeling.
- Hazards To Health From Use Of The Device: See Indications, Contraindications, Warnings, Precautions And Adverse Events in the labeling.
- Post Approval Requirements and Restrictions: See approval order.
- The Approval Order, Summary of Safety and Effectiveness Data, and labeling can be found on the Internet at <http://www.fda.gov/cdrh/pmapage.html>.

MAGELLAN-C

PTCA Catheter

INSTRUCTIONS FOR USE

GLOBAL
THERAPEUTICS®

DEVICE NAME

Global Therapeutics® MAGELLAN-C PTCA Catheter. The generic name of the device is Percutaneous Transluminal Coronary Angioplasty Catheter.

DESCRIPTION

The MAGELLAN-C PTCA Catheter is a double lumen coaxial catheter with a balloon near the distal tip. The catheter is constructed from two coaxially aligned high density polyethylene (HDPE) tubings. The HDPE balloon is designed to expand to a controlled diameter and length at a specific pressure. A single gold marker band is located at the center of the balloon. The outer lumen is used for inflation of the balloon, while the inner provides a through lumen for guide wire movement. The MAGELLAN-C Catheter does not provide for distal dye injection or pressure measurement.

As with other removable guide wire systems, a side-arm adapter attached to the proximal end of the catheter provides access to the lumens. The angled-arm port provides access to the outer balloon inflation lumen by means of a luer-lock fitting. Balloon inflation and deflation are accomplished by connecting the angled-arm port with an inflation device. The straight-arm port is continuous with the inner lumen of the catheter and provides access for the guide wire. The catheter is available in four dilatation balloon sizes: nominally 2.0, 2.5, 3.0, and 3.5 mm. The MAGELLAN-C Catheter can be used with any off-the-shelf 0.014 inch PTCA guide wire.

INDICATIONS

The MAGELLAN-C is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of a significant stenosis

WARNINGS

1. This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
2. To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
3. PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

4. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
5. Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
6. PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
7. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
8. Use the catheter prior to the "Use Before" date specified on the package.
9. This catheter is not intended for the delivery or expansion of stents.

PRECAUTIONS

1. Prior to PTCA, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
2. The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
3. Before insertion of the dilatation catheter administer appropriate anticoagulant and coronary vasodilator therapy.
4. Caution should be taken not to over-lighten a Touhy-Borst type hemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

INSTRUCTIONS FOR USE

Materials Required for PTCA with the MAGELLAN-C PTCA System

- Guide wire(s) of appropriate size for advancement of guide catheter
- Appropriate arterial sheath and dilator set (for femoral approach only)
- Femoral or brachial guiding catheters in the appropriate size and configuration to select the coronary artery
- Vial of contrast medium
- Inflation device with manometer
- MAGELLAN-C PTCA catheter(s)
- 0.014 in. x 175 cm guide wire(s)
- 0.014 in. x 300 cm guide wire
- 20 cc luer-lock syringe
- Hemostatic adapter

Prior to PTCA, carefully examine all equipment to be used during the procedure, including the dilatation catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended. Also, inflate the dilatation catheter to the appropriate Rated Burst Pressure (Table 1) and deflate to verify proper function.

Inflation Device Preparation

1. Prepare the inflation device according to the manufacturer's instructions.
2. Purge the system of air.

Dilatation Catheter Selection

The inflation diameter of the balloon must not exceed the diameter of the coronary artery proximal and distal to the stenosis. If the stenosis cannot be crossed with the desired dilatation catheter, use a smaller diameter catheter to predilate the lesion to facilitate passage of a more appropriate-sized dilatation catheter.

Dilatation Catheter Preparation

1. Carefully remove the catheter from the protective tray.
2. Remove the balloon protector by grasping the balloon catheter just proximal to the balloon (at the proximal balloon bond site), and with the other hand, gently grasp the proximal section of the balloon protector and slide distally.
3. Prepare the balloon dilatation catheter for purging. Fill a 20 cc luer-lock syringe with 3 cc of contrast medium. Use only the appropriate balloon inflation medium (e.g., the equivalent of a 50:50 mixture of Renografin 76 and sterile normal saline). Do not use air or any gaseous medium to inflate the balloon.
4. Connect the syringe to the angled-arm port fitting on the dilatation catheter.
5. Hold the syringe with the nozzle pointing downward and aspirate for 15 seconds. Slowly release the plunger.
6. Remove the syringe and evacuate all air from the barrel.

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7. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. Release the plunger and set aside until step 2 of Inflation Device Connection.

Inflation Device Connection to Catheter

1. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 cc of contrast medium.
2. By applying positive pressure to the balloon before disconnecting the syringe used in preparation, a meniscus will appear in the angled-arm port when the syringe is removed. Verify that a meniscus of contrast medium is evident in both the dilatation catheter angled-arm port and the inflation device connection. This will avoid the possible introduction of air. Securely couple the inflation device to the angled-arm port of the balloon dilatation catheter.

Dilatation Catheter Testing Prior to Use

1. When all connections are completed, test the connections under 5 atm (75 psi) of pressure for possible fluid leaks. Loss of pressure indicates the presence of a fluid leak in the system.
2. Test the dilatation catheter by inflating the balloon to the rated burst pressure for 5 seconds. (see Table 1) Retract the plunger to fully deflate the balloon. Verify that the inflation and deflation times are satisfactory. Maintain the balloon in a fully deflated state.

Table 1 Rated Burst Pressure

Inflated Balloon Diameter (mm)	Rated Burst Pressure (atm)
2.0	10
2.5	10
3.0	10
3.5	9

Insertion Technique

1. Insert sheath introducer and guiding catheter using standard techniques. The choice of guiding catheters depends upon anatomy and lesion location. Before insertion of the dilatation catheter, administer appropriate anticoagulant and coronary vasodilator therapy.
2. Prepare the dilatation catheter and guide wire(s) as follows:
 - Flush the dilatation catheter lumen.
 - Introduce the guide wire, flexible end first, into the straight-arm (back) port of the manifold. To avoid kinking, advance the guide wire slowly, in small increments.
 - Advance the guide wire to the end of the dilatation catheter. Leave the distal end of the guide wire inside the catheter lumen for protection.
 - Place the guiding catheter hemostatic adapter (with swivel) over the balloon dilatation catheter and advance the adapter proximally (up) the catheter shaft approximately 30 cm. Advance the catheter slowly, while the balloon is fully deflated. If resistance is encountered, do not advance the dilatation catheter through the adapter. Caution should be taken not to over-tighten a Touhy-Borst type hemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.
3. Thoroughly aspirate and flush the guiding catheter in preparation for introduction of the dilatation catheter.

4. Connect the side port of the guiding catheter hemostatic adapter to the proximal pressure recording/infusion line or manifold assembly, which permits proximal pressure recording or infusion through the guiding catheter. Flush thoroughly.
5. With the balloon fully deflated, carefully insert the dilatation catheter into the luer fitting of the guiding catheter. Advance the dilatation catheter approximately 30 cm.
6. Connect the guiding catheter hemostatic adapter. While holding the adapter at an upward angle, vigorously flush forward to remove air from the adapter and to allow back bleeding through the guiding catheter. This will permit a fluid connection to be made as the swivel is tightened to the dilatation catheter.
7. Advance the guide wire through the dilatation catheter. The guide wire should extend approximately 1 cm beyond the tip of the dilatation catheter.
8. Using test injection of contrast medium to confirm guide catheter tip location, position the guiding catheter in the orifice of the appropriate coronary artery.
9. Rotate the guide wire in the direction necessary to negotiate the coronary vasculature, or to avoid entering coronary branches. Slowly rotate the guide wire while advancing through the coronary artery, until the desired branch is selected and the stenosis crossed. Confirm crossing of the stenosis by angiographic assessment.
10. To alter the distal tip of the guide wire, withdraw and gently form it into the desired shape. Reinsert the guide wire as described in step 2 immediately above.
11. Position the balloon relative to the lesion to be dilated and inflate the balloon to the appropriate pressure (Table 2). Balloon pressure must not exceed the RATED BURST PRESSURE (Table 1).

NOTE: Technique variables, such as positioning of the guiding catheter or balloon dilatation catheter and duration of the balloon inflation cycle, depend largely on individual anatomy and the nature of the lesion to be dilated. (see REFERENCES below)

12. After PTCA is completed, deflate the dilatation balloon and withdraw the balloon catheter until it is clear of the lesion. Maintain the guide wire across the dilated stenosis.
13. Immediately after PTCA, perform angiography using the guiding catheter as an angiographic catheter to confirm dilatation.
14. Maintain the guide wire across the dilated stenosis for approximately 10 minutes after PTCA. After angiography has confirmed that the lumen of the dilated artery has not acutely occluded, slowly withdraw the guide wire and the deflated balloon from the guiding catheter and through the adapter.
15. After completion of angiography, withdraw the tip of the guiding catheter from the coronary ostium and remove the guiding catheter through the sheath introducer.
16. Leave the introducer sheath in situ until hemodynamic profile becomes normal. Close the skin in routine fashion.

STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Use prior to the "Use Before" date. Store in a dry, dark, cool place.

Table 2
Typical MAGELLAN-C Balloon Compliance
(all dimensions are nominal)

ATM	Balloon Diameter (mm)			
	2.0	2.5	3.0	3.5
5	2.0	2.5	2.8	3.5
6	2.1	2.5	2.9	3.6
7	2.1	2.6	3.0	3.7
8	2.2	2.7	3.1	3.8
9	2.2	2.8	3.2	3.9
10	2.3	2.9	3.3	4.0
11	2.3	3.0	3.4	4.1
12	2.3	3.0	3.4	4.2

Nominal Pressure

Rated Burst Pressure

REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

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PK0016-09 [USA]
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