



Memorandum

Date . APR 30 1997

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Perclose, Inc.
Prostar® Percutaneous Vascular Surgical (PVS) System - ACTION

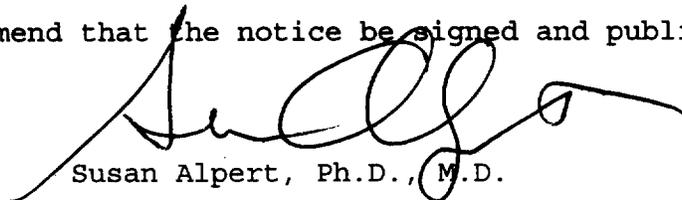
To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.



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

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Christopher M. Sloan, CDRH, HFZ-450, 3/27/97, 443-8243

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. _____]

Perclose, Inc.; PREMARKET APPROVAL OF Prostar® Percutaneous
Vascular Surgical (PVS) System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Perclose, Inc., Menlo Park, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Prostar® Percutaneous Vascular Surgical (PVS) System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 30, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Christopher M. Sloan,
Center for Devices and Radiological Health (HFZ-450),
Food and Drug Administration,
9200 Corporate Boulevard,
Rockville, Maryland 20850,
301-443-8243.

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SUPPLEMENTARY INFORMATION: On November 26, 1996, Perclose, Inc., Menlo Park, CA 94025, submitted to CDRH an application for premarket approval of the Prostar® Percutaneous Vascular Surgical (PVS) System. The Prostar® PVS System consists of the Prostar® PVS Device (9 and 11 French sizes) and the following accessories: a Prostar® Pre-Dilator (9 and 11 French sizes), a Perclose® Knot Pusher, a Prostar® Transition Guidewire, and a Perclose® Arterial Tamper. The Prostar® PVS System is a vascular hemostasis device and is indicated for the percutaneous delivery of sutures for closing the common femoral artery access site and reducing the time to hemostasis and ambulation (time-to-standing) of patients who have undergone interventional procedures using 8 to 11 French sheaths.

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 of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On April 30, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act, (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

APR 30 1997

Ms. Jane E. Beggs
Regulatory Affairs Manager
Perclose, Incorporated
199 Jefferson Drive
Menlo Park, California 94025

Re: P960043
Prostar® Percutaneous Vascular Surgical (PVS) System
Filed: November 26, 1996
Amended: December 5, 6, and 23, 1996; January 14, 27 and 31;
February 7, 10, 10, 11, 24 and 26; March 3 and 7,
and April 18, 1997

Dear Ms. Beggs:

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 Prostar® Percutaneous Vascular Surgical (PVS) System. The Prostar® PVS System consists of the Prostar® PVS Device (9 and 11 French sizes) and the following accessories: a Prostar® Pre-Dilator (9 and 11 French sizes), a Perclose® Knot Pusher, a Prostar® Transition Guidewire, and a Perclose® Arterial Tamper. The Prostar® PVS System is indicated for the percutaneous delivery of sutures for closing the common femoral artery access site and reducing the time to hemostasis and ambulation (time-to-standing) of patients who have undergone interventional procedures using 8 to 11 French sheaths. 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 that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating has been established and approved at six months for the Prostar® PVS System and at 18 months for the Perclose® Knot Pusher, Prostar® Transition Guidewire and the Perclose® Arterial Tamper accessory devices, which are packaged separately. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, 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.

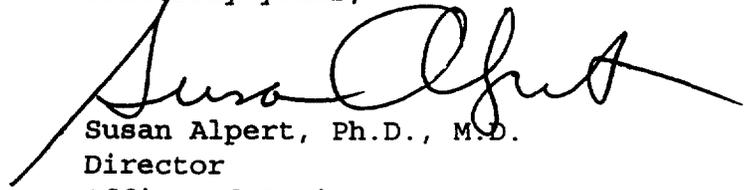
PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

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Page 3 - Ms. Jane E. Beggs

If you have questions concerning this approval order, please contact Christopher M. Sloan at (301) 443-8243.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Alpert". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

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

Enclosure

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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 Effected" 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.

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A "Special PMA Supplement - Changes Being Effected" 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 Effected." 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 mixup 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, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other 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 this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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Summary of Safety and Effectiveness Data

I. General Information

Device Generic Name: Vascular Hemostasis Device
Device Trade Name: Prostar® Percutaneous Vascular Surgical (PVS) System
Applicant: Perclose, Inc.
199 Jefferson Drive
Menlo Park, CA 94025
PMA Number: P960043
Date of Notice of Approval to the Applicant: APR 30 1997

II. Indications for Use

The Prostar® Percutaneous Vascular Surgical System is indicated for the percutaneous delivery of sutures for closing the common femoral artery access site and reducing time to hemostasis and ambulation (time-to-standing) of patients who have undergone interventional procedures using 8 to 11 French (Fr.) sheaths.

III. Device Description

The Prostar® PVS System consists of the Prostar® PVS Device (9 and 11 Fr. sizes) and the following accessories: a Prostar® Pre-Dilator (9 and 11 Fr. sizes), a Perclose® Knot Pusher, a Prostar® Transition Guidewire, and a Perclose® Arterial Tamper. The Prostar PVS Device and accessories are supplied sterile.

The Prostar PVS System is available in two sizes: 11 Fr. for the closure of punctures dilated by 10 and 11 Fr. introducer sheaths; and 9 Fr. for the closure of punctures dilated by 8 and 9 Fr. introducer sheaths.

The Prostar PVS System is provided with the following components:

One unit	Prostar PVS Device (9 Fr. or 11 Fr.)
One unit	Pre-Dilator (9 Fr. or 11 Fr.)
One unit	Knot Pusher
One unit	Transition Guidewire

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The Prostar PVS Device, Pre-Dilator, Knot Pusher and Transition Guidewire are required for the access site closure procedure. The Arterial Tamper may be used if, in the judgment of the physician, additional hemostatic control of the site is required. The system is designed to percutaneously deploy two pre-loaded sutures (from the Prostar PVS Device) to the femoral artery access site to achieve hemostasis. The sutures are Tevdek® II nonabsorbable, polytetrafluoroethylene-impregnated, polyester sutures. One white and one green suture are used in each Prostar PVS Device to aid the user in distinguishing the sutures during knot tying.

The Prostar PVS Device has a sheath which houses four sutured needles (i.e., a needle is attached to each end of the two sutures), a needle guide which controls the placement of needles around the puncture site and a barrel which receives deployed needles. The marker lumens are contained within the barrel of the device with the ports of the marker lumens positioned in the needle guide. The marker lumens, which exit proximally from the hub of the device, allow a pathway for back-bleeding from the femoral artery and ensure proper device positioning by communicating with the artery via ports proximal to the needle tips.

The Pre-Dilator, which can be front or back-loaded over the Transition Guidewire, is designed to prepare a subcutaneous track. The Pre-Dilator has a sheath and an independently rotating barrel which spins to assist in dilating the subcutaneous tissue. There are two marker intraluminal ports, one located 9 mm and one located 5 mm from the distal barrel edge. The marker ports are connected to marker lumens which exit from the hub of the Pre-Dilator and allow a pathway for back-bleeding to indicate appropriate Pre-Dilator advancement and positioning.

The Transition Guidewire is a 100 cm guidewire that transitions from 0.038" on the distal 55 cm to 0.014" on the proximal 45 cm. The distal tip has a standard "J" configuration to facilitate tracking. The Transition Guidewire is designed to allow the sheath to track over the 0.038" segment of the guidewire, while the 0.014" segment resides within the central lumen of the Prostar PVS Device.

The Knot Pusher is designed to advance the tied suture to the artery surface. The Arterial Tamper may be positioned over the access site to apply local pressure to the artery by securing placement with the tied sutures.

IV. Contraindications

None known

V. Warnings

Do not use the Prostar PVS Device or accessories if the package or sterile barrier has been previously opened or damaged, or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Prostar PVS Device and accessories are sterile devices intended for single use only.

VI. **Precautions**

The Prostar PVS System should only be used by physicians trained in the use of the Prostar PVS Device, e.g., participation in a Prostar PVS System physician training program or equivalent.

Observe sterile techniques at all times when using the Prostar PVS System. Employ appropriate groin management post procedure and post hospital discharge to prevent infection.

Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstances and the experience of the operator.

Use a single wall puncture technique. Do not puncture the posterior wall of the artery.

Do not rotate the indicator of the hub greater than 90 degrees in either direction from the 12 o'clock position while the Prostar PVS Device is in the artery.

If significant blood flow is returned through the barrel of the Prostar PVS Device, do not deploy needles. Remove the Prostar PVS Device over the Transition Guidewire and insert an appropriately sized introducer sheath.

Do not advance or withdraw the Prostar PVS Device against resistance until the cause of that resistance has been determined by fluoroscopy. If excessive resistance in advancing the Prostar PVS Device is encountered, withdraw the Prostar PVS Device over the Transition Guidewire and reinsert the introducer sheath. Excessive force used to advance or torque the Prostar PVS Device should be avoided as it may lead to significant arterial damage.

Use conventional compression methods in the event bleeding from the femoral access site persists after use of the Prostar PVS Device and Arterial Tamper.

Special Patient Populations

The safety and effectiveness of the Prostar PVS System has not been established in the following patient populations:

- Patients with puncture sites in the profunda femoris or superficial femoral artery or at the bifurcation of the arteries.
- Patients having a hematoma, pseudoaneurysm or arterio-venous fistula present prior to sheath removal.
- Patients requiring a repeat puncture at a site previously closed with the Prostar PVS System.
- Patients with common femoral artery calcium which is fluoroscopically visible.
- Patients with small femoral arteries (<5 mm in diameter).
- Patients with femoral artery stenosis greater than 50%.
- Patients with puncture sites in vascular grafts.
- Patients with antegrade punctures.

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- Patients who are pregnant or lactating.
- Patients with bleeding diathesis or coagulopathy.
- Patients younger than 18 years of age.

VII. Alternative Practices and Procedures

The alternative practices for achieving femoral artery puncture hemostasis post-catheterization include manual compression, mechanical compression, and collagen vascular hemostasis devices. Sandbags and pressure dressings are routinely used in combination with compression methods to control oozing.

VIII. Marketing History

The Prostar PVS Systems are commercially marketed in Canada, Japan, Germany, France, Spain, Italy, South Africa, the Netherlands and United Kingdom. The devices have not been subject to regulatory action in any of the above countries for any safety or effectiveness related issue.

IX. Adverse Effects of the Device on Health

The Prostar PVS System was evaluated in a randomized controlled clinical trial involving 501 patients. The trial compared the Prostar PVS System to conventional compression (i.e., manual or mechanical) methods. All patients enrolled in the trial underwent an interventional procedure prior to randomization to the Prostar PVS System or compression. In this trial, 248 patients were randomized to the Prostar PVS System (224 patients were treated with the 9 Fr. device and 24 patients were treated with the 11 Fr. device) and 253 were randomized to compression. The adverse events that were observed during the trial are reported in the table below:

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Table 1. Percentage of Patients Experiencing Adverse Events
(All patients enrolled in Prostar PVS Device Trial; n=501)

Study Arm	Prostar All Sizes (n=248)	Compression All Sizes (n=253)	Risk Ratio (95% CI)
Complications¹ [per event basis] n (percent)			
Device Malfunction**	23 (9.3%)	N/A	—
Device Failure	7 (2.8%)	N/A	—
Surgical Repair*	10 (4.0%)§	4 (1.6%)	2.6 (0.8, 8.0)
Ultrasound Guided Compression*	4 (1.6%)	5 (2.0%)	0.8 (0.2, 3.0)
Transfusion*	7 (2.8%)	4 (1.6%)	1.8 (0.5, 6.0)
Infection requiring IV antibiotics*	0 (0.0%)	0 (0.0%)	—
Hematoma >6 cm	6 (2.4%)	5 (2.0%)	1.2 (0.4, 4.0)
Arterio-venous Fistula	1 (0.4%)	2 (0.8%)	0.5 (0.0, 5.6)
Pseudoaneurysm	8 (3.2%)	6 (2.4%)	1.4 (0.5, 3.9)
Complications [per patient basis] n (percent)			
Any complication¶	23 (9.3%)	14 (5.5%)	1.7 (0.9, 3.2)
9Fr.	20(8.9%)	12 (5.3%)	
11Fr.	3(12.5%)	2 (8.0%)	
Major complication	15 (6.0%)	10 (4.0%)	1.5 (0.7, 3.3)
9Fr.	13 (5.8%)	9 (3.9%)	
11Fr.	2 (8.3%)	1 (4.0%)	
No major complication	233 (94.0%)	243 (96.0%)	
9Fr.	211 (94.2%)	219 (96.0%)	
11Fr.	22 (91.7%)	24 (96.0%)	

¹ patients with hematoma <6cm not included [n=43 (17.0%) Prostar arm, n=23 (9.0%) Compression arm]; these patients did not experience adverse reactions related to hematoma <6cm based on clinical and biological indicators (e.g., blood count, hematocrit)

** patients experiencing device malfunction proceeded to successful closure without clinical sequelae; malfunction included suture breaks, 17 (6.9%); failed suture deployment, 1(0.4%); failed marking 3 (1.2%); failed sheath deployment, 2 (0.8%)

* indicates a major complication

§ three (3) events attributable to protocol deviations

¶ patients with any complication, including 3 (1.2%) with infection requiring oral antibiotics

One in-hospital death occurred the day following the coronary intervention and was reported as a cardiac-related death, not associated to the arterial access closure.

Although not reported during the clinical trial, the following potential adverse reactions or conditions may be associated with the use of the Prostar PVS System: deep vein thrombosis, infection extending hospitalization, late bleeding, wound dehiscence, vessel

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laceration, local pulse deficits or ischemia, embolization, transitory local irritation, nerve injury and vascular spasm.

In addition, polyester surgical sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Polyester surgical sutures are not absorbed, nor is any significant change in tensile strength known to occur *in vivo*.

X. **Summary of Studies**

A. ***In Vitro (Laboratory) Studies***

1. **Biocompatibility Testing**

Biocompatibility testing of all body-contacting components of the Prostar PVS System was conducted in accordance with either the *Tripartite Biocompatibility Guidance for Medical Devices* or the FDA-modified matrix of International Standard ISO-10993, "*Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*." The battery of tests performed for a given material was dependent on the biocompatibility guidance that was in force during the time the device was being developed. The following tests were conducted: subchronic toxicity, pyrogenicity, dermal sensitization, cytotoxicity, systemic toxicity, hemolysis, Ames mutagenicity, thrombogenicity, 7-day implantation, and intracutaneous injection testing. Additional information supporting the biocompatibility of the Tevdek® II sutures as documented in N84366/S2 is incorporated by reference into this premarket approval (PMA) application for the Prostar PVS System. All device materials were demonstrated to be nonhemolytic, nonpyrogenic, nontoxic, nonthrombogenic, nonmutagenic, and biocompatible for their intended use.

2. **Device Functionality Testing**

Functionality testing was conducted at the bench to verify the designs of the Prostar 9 and 11 Fr. PVS Devices and accessories. The testing summarized below on the Prostar PVS System demonstrated that the functional performance and reliability of the Prostar Devices and accessories were acceptable and consistent with the intended uses of the system.

Suture

Both green and white sutures (n=10 of each color suture) were evaluated per USP requirements for a 4-0 size nonabsorbable suture after sterilization of finished Prostar PVS Devices. The white suture met the USP requirement for average diameter at the specified lengths, but the green suture slightly exceeded this specification. However, it was confirmed through additional testing that suture tensile strength, needle bond strength, and Prostar PVS Device compatibility were not affected by this minor deviation found with the green suture. Testing of the suture to needle bond was conducted to assure that needles reliably deliver sutures when extreme friction is placed on sutures during deployment. When tested to failure using USP methods, the average measured suture-to-needle bond strengths for the white and green suture samples were sufficient to

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overcome suture friction in the Prostar PVS Device and the path through the arterial tissue.

Prostar PVS Device

The Prostar 9 Fr. and 11 Fr. PVS Devices (n=10 of each size) and Transition Guidewires (n=20) were tested in an anatomical bench-top model that simulated a patient's vasculature at the access site in the femoral artery. After dilation by an introducer sheath, the Prostar PVS Device was introduced and evaluated for its ability to track over the Transition Guidewire. All devices passed the acceptance criteria for tracking. As the device was inserted to its deployment position, the marker lumens were verified for marking through both lumens. Marker lumen flow was obtained and aquastasis (control of water flow) was achieved at the catheter access site. During simulated use, each device successfully delivered sutures and needles to the access site and proximal barrel. The "back-down of needles" (the ability to retract deployed needles) was verified for all test devices.

Additional bench tests were performed on the Prostar PVS Device to evaluate the following: handle break-away force (9.9 lbf average for n=18 subassemblies), needle holder bond strength (14.4 lbf average for n=29 subassemblies), needle retention force (3.5 lbf average for 10 subassemblies), sheath crimp strength (20.8 lbf average for n=10 devices [9Fr. size] and 17.6 lbf average for n=10 devices [11Fr. size]), fixed funnel retention strength (19.7 lbf average for n=10 devices [9Fr. size] and 18.6 lbf average for n=10 devices [11Fr. size]), and hydrophilic coating adherence and integrity. All devices met design specifications and exhibited adequate functionality and reliability for their intended use.

Transition Guidewire

Transition Guidewires demonstrated acceptable tracking of the tortuous path in the anatomical model. Compatibility with the Prostar PVS Devices and Pre-Dilators was also shown. The results of pull force testing of the distal tip (n=15) and transition solder (n=15) joints demonstrated that the average strengths of these joints (7.3 lbf and 45.1 lbf, respectively) were adequate for the intended use of the device.

Pre-Dilator

Pre-Dilators (9 and 11 Fr.) demonstrated acceptable tracking over the Transition Guidewire, aquastasis (no water flow around the sheath), and sequence of flow from marker lumens in the anatomical model. The results of pull force testing confirmed that the strength of the sheath to the inner shaft joint was sufficient (35.6 lbf average for n=10 devices [9Fr. size] and 38 lbf average for n=10 devices [11Fr. size]). The functionality and adherence of the hydrophilic coating was demonstrated through simulated use testing.

Knot Pusher

The ability of the Knot Pusher to slide freely over the suture without causing damage to the suture was evaluated in the anatomical model. All Knot Pushers (n=10) met the

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design specification for free and atraumatic movement of the distal tip along sutures. The integrity of the Knot Pusher housing was evaluated by simulating a worst-case flexural load (2 lbf) during use. All Knot Pushers (n=10) met the acceptance criterion for maintaining a flexural load without deforming.

Arterial Tamper

All Arterial Tampers (n=5) exhibited acceptable suture loading and tamper aquastasis when evaluated in the anatomical model. The attachment strength of the tamper tip to the tamper body (19.8 lbf average for n=10 devices) was sufficient for the intended use of the Arterial Tamper.

3. Shelf Life Studies

Product stability testing performed for the Prostar PVS Systems demonstrated that functionality and sterility of the devices were maintained for a minimum of 6 months. Based on these results, a shelf life of 6 months for the Prostar PVS Systems has been established. Similar testing conducted for the Knot Pusher, Transition Guidewire, and Arterial Tamper supports a shelf life of 18 months for these accessories.

B. Animal (In-Vivo) Studies

Animal studies of the Prostar PVS System were conducted to evaluate its performance characteristics and to define its operating techniques. A total of five canines (one animal per study) met the size requirements of the *in vivo* protocol. For each animal, three to four surgical procedures were attempted at access sites on the left and right carotid arteries for a total of sixteen procedures. Each animal received 5000 U of heparin to achieve full anticoagulation.

The studies facilitated the evaluation of several device modifications as data regarding device performance were collected and sequential changes were implemented in the device design. The studies demonstrated that needle and suture components could be intraluminally delivered for suture hemostasis of the access site. In addition, the studies served to establish techniques for operating the device, managing sutures, optimal knot-tying, and the adjunctive use of the knot pusher and tamper. These findings supported the further evaluation of the Prostar PVS Device and accessories in human clinical feasibility studies.

The following performance characteristics of the Prostar PVS Device were evaluated in the animal studies:

Device Hemostasis

The ability of the Prostar PVS Device to occlude the access site or minimize peri-operative blood loss was assessed. Device hemostasis is assured by the sheath, the needle guide *in situ*, and the seal located in the inner lumen of the device. Inner lumen seals were modified after excessive blood loss (> 20 cc) was observed in two devices during the first animal study. Complete (< 6 cc blood loss) or acceptable hemostasis (< 20 cc blood loss) was achieved in all subsequent studies with devices with modified seals.

Device Insertion

Introduction of the Prostar PVS Device was difficult in the first study due to the abrupt shape of the tip of the sheath. The tip design was modified to include a softer material, a more gradual taper on the tip, and a nesting of the holder tube within the sheath, as in the final design. The design change was verified by the demonstration of easier introduction, less blood loss, and less creation of thrombus at the access site in the last four animal studies.

Function of Marker Lumen

It was shown that the device's marking permitted reliable intraluminal placement of the needles. Based on early observations in the animal model, the position of the marker port was changed after the third study to reduce ambiguity of marking. However, during the fourth study, even with the repositioned marker port, two of the access sites did not mark. These failures to mark were due to the constrictive effect of small canine arteries. In the fifth study, an animal with larger arteries (more indicative of small human femoral arteries) was used, and all devices used therein marked well.

Needle/Suture Deployment

Full deployment of needles and sutures was achieved in fourteen of the sixteen procedures. The two procedures with partial deployment of needles and sutures occurred in the fifth study when the resistance of tissue and needle friction inhibited movement. Engineering lab tests on needle deployment resistance using tough tissue models and tortuous vascular models which more closely represent the human femoral arteries verified successful design modifications prior to initiating the clinical studies.

Suture Management

During the second study, one of the sutures broke during knotting. As a result of this suture failure, all subsequent studies used the next larger suture, USP size 4-0. All sutures remained intact in subsequent studies demonstrating sufficient strength of the larger suture.

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Suture Hemostasis

Twelve of the sixteen procedures resulted in acceptable (< 20 cc blood loss) or complete (< 6 cc blood loss) suture hemostasis. In the second study, a suture broke resulting in unacceptable suture hemostasis. As noted above, devices incorporating a larger size suture (USP size 4-0) remained intact in subsequent studies. Suture hemostasis failed in the fourth study due to suboptimal tissue capture during a procedure where the needles and sutures were deployed without obtaining proper marking. This demonstrated the important relationship of proper marking and adequate tissue capture for suture hemostasis. The remaining two procedures in which suture hemostasis was not achieved occurred during the fifth study. Marking was immediate for these devices and signaled an optimally placed device. However, as noted under *Needle/Suture Deployment* above, needles and sutures could not be deployed due to prohibitively high frictional forces.

Tissue Capture

Effective tissue capture was characterized by an even and symmetric placement of the sutures. Constriction of the artery (diameter of artery at the suture site compared to the diameter adjacent to the suture site) was assessed in seven of sixteen post-mortem evaluations. Constriction of up to 40% was observed in the third study. Following improvements to the needle placement pattern, constriction was reduced to 24% in the fourth study. The relative effect of constriction due to suture placement in human femoral arteries (7-9 mm outer diameter) is expected to be less than that observed in canine carotid arteries (5-6 mm outer diameter) given the larger diameter of the human femoral arteries.

C. Clinical Studies

The Prostar PVS 9 Fr. and 11 Fr. Systems were evaluated clinically in the Prostar PVS Device Trial to determine the relative safety and effectiveness of femoral artery closure using the Prostar PVS Device versus conventional compression (i.e., mechanical or manual) methods following percutaneous coronary revascularization procedures. The Prostar PVS Device Trial was a multicenter, prospective, randomized, controlled trial. The study was conducted at six institutions from July of 1995 to March of 1996. Patients were randomly assigned with equal probability to percutaneous femoral artery closure with the Prostar PVS Device or compression.

The study was designed as an equivalency trial for the 30-day primary safety endpoint of the combined rate of major complications. Major complications included: surgery or ultrasound-guided compression for vascular repair, groin-related transfusion, and groin-related infection requiring intravenous antibiotics or prolonged hospitalization. The primary effectiveness endpoint was time to ambulation (patient stands at bedside).

The secondary endpoints included: time to hemostasis; procedure success; and device success. Time to hemostasis was defined as the time from the end of the interventional procedure to achievement of hemostasis. Procedure success was defined as the achievement of hemostasis at the femoral artery access site with freedom from major

complication using any closure method. Device success was defined as acute success using the Prostar PVS Device only or the Prostar PVS Device plus adjunctive (non-arterial) compression.

1. Subject Selection and Exclusion Criteria

Patients were enrolled in the study if they met the following criteria: the patient was at least 18 years of age; the patient was an acceptable candidate for an interventional coronary procedure performed percutaneously via the common femoral artery through an 7 - 11 French introducer sheath; the patient could not be pregnant (if female with child bearing potential); the patient was an acceptable candidate for emergent vascular surgery; the patient agreed to return for a 30-day (ranging from 3-6 weeks) follow-up physical examination and to a late telephone contact; the patient agreed to have an ultrasound of the femoral artery prior to discharge; the patient or guardian provided written informed consent.

Patients were excluded from the study if they met any of the following criteria: the patient had bilateral arterial access sites; the patient was ineligible for in-catheterization lab arterial sheath removal; the patient had a pre-existing hematoma, arterio-venous fistula, pseudoaneurysm, prior treatment with collagen vascular hemostasis devices, Dacron graft or patch, or fluoroscopically visible calcium at the femoral artery prior to sheath removal; the diameter of the target femoral artery was less than the diameter of the intended Prostar PVS Device; the patient had a femoral bruit, or claudication with angiographic demonstration of a common femoral artery stenosis > 50%; the posterior (back) wall of the intended artery was thought to have been punctured during the interventional procedure, or there was difficulty attaining arterial access resulting in multiple puncture attempts; the patient had a history of bleeding diathesis or coagulopathy; the patient's obesity precluded access with a standard single wall femoral access needle (e.g., Seldinger); the introducer sheath insertion prior to the interventional procedure was moderately difficult due to scarring or tortuosity; the patient was participating in another drug/device clinical trial or had previously participated in the Prostar PVS Device Trial.

2. Methodology

The following methodology was adhered to at each of the investigational sites:

- Informed consent and baseline medical histories were obtained prior to the coronary intervention;
- Following the coronary intervention, femoral angiography was performed to assess eligibility. Patients were then randomized to receive the Prostar PVS Device or conventional compression;
- Prostar PVS Device treated patients had immediate sheath removal in the catheterization laboratory. For patients in the compression arm of the study,

Activated Clotting Times (ACT) were assessed and sheaths were removed using standard conventional measures when the ACT measured 150 - 180 seconds.

- The times when hemostasis and ambulation occurred were recorded and the elapsed times to hemostasis and ambulation were calculated from the end of the interventional procedure (time at final angiogram).
- Femoral artery ultrasounds were performed in the first 200 (40%) consecutive patients for evidence of pseudoaneurysm or arterio-venous fistula and to compare ultrasound results to clinical observation.
- Patients were followed in the hospital and at 30 days (range; 3 to 6 weeks) following the procedure for major complications or evidence of other vascular complications.

3. Study Population

A total of 501 patients (78.6% male; mean age = 60.5 years) were enrolled in the Prostar PVS Device Trial, with 248 randomized to the Prostar PVS Device and 253 randomized to conventional compression. Patients had the following coronary interventional procedure(s) performed via the common femoral artery: PTCA (85.8%), stent (52.9%), atherectomy (19.8%). Arterial sheath sizes used [\leq 9 Fr. (90% of patients); $>$ 9 Fr. (10%)] were comparable between treatment arms. There were no significant differences between the two randomized groups with respect to sex, age, major comorbidities, angina severity, peri-procedural medications, body size, or blood pressure. Activated clotting times (ACT) at the time of sheath removal were significantly different between treatment arms [329.0 ± 121.5 seconds (Prostar) versus 162.8 ± 53.1 seconds (Compression); $p=0.0001$].

4. Gender Bias Analysis

The higher percentage of male patients enrolled in the study (78.6% male vs. 21.4 % female) reflects the gender referral pattern for patients undergoing coronary interventional procedures. All differences between the treatment groups with respect to time to ambulation, time to hemostasis and complication rate were consistent between the genders.

5. Safety Data

A summary of the adverse events (complications) experienced by patients enrolled in the PVS Device Trial is reported in Table 1 (see Section IX). Major complications were experienced by 15 (6.0%) of 248 patients randomized to the Prostar PVS Device compared to 10 (4.0%) of 253 patients randomized to compression ($p=0.28$). Although there was a higher surgical repair rate in the Prostar treatment arm (4.0%) versus the compression arm (1.6%), the difference was not statistically significant ($p=0.28$). All major complications observed for the Prostar treatment arm were in-hospital events. The only late events were 3 (1.2%) localized infections treated with oral antibiotics observed in the Prostar arm.

A higher frequency of small (<6 cm) hematomas was observed in the Prostar arm [17.0% (43/248)] versus the compression arm [9.0% (23/253)]. These events were not counted as complications because none of the patients with small hematomas required a groin-related transfusion or other intervention. In addition, in patients with hematoma <6cm, there were no statistically significant differences in either final hematocrit or the change in hematocrit between the Prostar and compression groups.

Failure to fully deploy the device occurred in 30 (12.1%) cases. Twenty three of these cases are considered "device malfunctions" as the patient proceeded to successful closure without clinical sequelae despite suture breakage (17 cases), failed suture deployment (1) failed marking (3) or failed sheath deployment (2). The remaining 7 cases in which complete device deployment was not achieved are termed "device failures" as each of these patients experienced a complication [5 (2%) were major complications].

No deaths related to the device or complications at the groin site were reported in the study. One in-hospital death occurred the day following the coronary intervention and was reported as a cardiac-related death, not associated with the arterial access closure.

6. Effectiveness Data

The effectiveness of the Prostar PVS System was assessed primarily by time to ambulation (i.e., time to standing). Time to hemostasis, procedure success, and device success were secondary effectiveness endpoints. Table 2 presents the results by study arm with all Prostar device sizes combined (i.e., 9 Fr. and 11 Fr.) while Table 3 includes results by study arm separated by sheath size.

Table 2. Principal Effectiveness Results for All Sizes
(All patients enrolled in Prostar PVS Device Trial; n=501)

Study Arm	Prostar	Compression	Δ (95% CI)
Effectiveness Measures* (in hours)			
Randomized Patients	n=248	n=253	—
Time to Hemostasis mean±S.D. median [quartiles]	n=232 1.2 ± 3.2 0.4 [0.2, 0.5]	n=248 8.1 ± 5.1 6.4 [5.2, 8.3]	-6.9# (-6.1, -7.6)
Time to Standing mean±S.D. median [quartiles]	n=235 13.5 ± 16.9 7.8 [5.7, 17.7]	n=237 25.6 ± 16.4 20.4 [11.6, 27.7]	-12.1# (-9.1, -15.1)
Device Success, n (%)	215 (86.7)	—	—

+ The number of patients listed under "Effectiveness Measures" is less than the total patients studied due to missing data for some patients

difference is statistically significant; p=0.0001

Device Success = acute success using the device only or the device + adjunctive (non-arterial) compression

Table 3. Principal Effectiveness Results by Sheath Size
(All patients enrolled in Prostar PVS Device Trial; n=501)

Study Arm by Sheath Size	Prostar 9 Fr.	Compression 9 Fr.	Prostar 11 Fr.	Compression 11 Fr.
Effectiveness Measures (in hours)				
Randomized Patients	n=224	n=228	n=24	n=25
Time to Hemostasis mean±S.D. median [quartiles]	n=209 1.2 ± 3.3 0.4 [0.2, 0.5]	n=224 8.0 ± 5.2 6.3 [5.2, 8.2]	n = 23 1.4 ± 2.9 0.4 [0.3, 0.6]	n = 24 8.3 ± 4.7 7.1 [5.7, 8.5]
Time to Standing mean±S.D. median [quartiles]	n=214 13.5 ± 17.2 7.7 [5.7, 17.8]	n=214 25.1 ± 16.1 20.0 [14.7, 26.8]	n = 21 13.0 ± 13.7 6.8 [4.4, 15.7]	n = 24 30.2 ± 18.4 23.7 [17.6, 44.6]
Device Success, n (%)	196 (87.5)	—	19 (79.2)	—

Time to Ambulation

Time to ambulation, the primary effectiveness endpoint, was measured from the time at the end of the interventional procedure to the time the patient stood at bedside. Upon obtaining hemostasis, the patient was allowed to ambulate (i.e., stand at bedside and take a few steps) if no or minimal subcutaneous oozing was observed. Mean time to ambulation for patients in the Prostar arm was significantly lower than that for patients in the compression arm (13.5 ± 16.9 hours versus 25.6 ± 16.4 hours, respectively; $p=0.0001$). At the median time to ambulation in the compression arm (20.4 hours), over 80% of the Prostar patients were standing. Conversely, at the median time to ambulation for the Prostar group (7.8 hours), there were no patients ambulated in the compression arm.

Time to Hemostasis

Time to hemostasis was measured from the time that the interventional procedure ended to the time hemostasis was achieved. For the Prostar treatment arm, the closure of the arterial access site took place immediately at the end of the intervention, independent of the anticoagulation level. For the compression treatment arm, time to hemostasis was delayed by the amount of time it took for the ACTs to reach appropriate levels conducive to safe sheath removal and clot formation. Mean time to hemostasis for patients in the Prostar arm was significantly lower than that for patients in the compression arm (1.2 ± 3.2 hours versus 8.1 ± 5.1 hours, respectively; $p=0.0001$).

Procedure and Device Success

Procedure success (successful hemostasis with freedom from major complication using any closure method) was achieved in 94.0% (233/248) of Prostar patients and 96.0% (243/253) of compression patients ($p=0.28$). Note that this measure of effectiveness for the Prostar PVS System includes the 18 patients who crossed over to conventional compression to achieve hemostasis without major complications. Device success (acute success using the Prostar device only or the Prostar device plus adjunctive [non-arterial] compression) was achieved in 86.7% (215/248) of patients enrolled in the Prostar arm of

the trial. Device success for the Prostar 9 Fr. and 11 Fr. PVS Devices was 87.5% (196/224) and 79.2% (19/24), respectively.

A review of failed deployments by device size showed no statistical difference in device malfunction between the 9 and 11 French size devices. Failure to deploy the device, whether or not associated with procedure success or complication, includes the following: inability to gain access with Prostar Pre-Dilator or Prostar PVS Device sheath, inability to obtain vascular "marking" with the Prostar Pre-Dilator or Prostar PVS Device, or inability to deliver or successfully secure both sutures. Successful hemostasis was achieved in 23 of 30 patients experiencing failed deployment without complication. Fourteen (14) of these failures were single-suture ruptures in which hemostasis was still achieved with the remaining suture. Successful hemostasis in the other nine cases (n=4, suture failure; n=3, failed marking; n=2, sheath not deployed) was achieved after crossing over to standard compression therapy. Thus, for this subset of failed deployments, hemostasis was obtained without further risk to the patient by the ability to return him or her to conventional compression.

XI. Conclusions Drawn from Studies

The results of *in vitro* (laboratory) testing, *in vivo* animal studies, and the clinical study together provide valid scientific evidence and reasonable assurance that the Prostar Percutaneous Vascular Surgical (PVS) System is safe and effective when used in accordance with its labeling.

The safety of the device has been demonstrated by the fact that the incidence of vascular complications in the clinical study was equivalent for both treatment arms (Prostar PVS procedure compared to conventional compression therapy). In addition, the study demonstrated that the Prostar PVS Device treatment had no statistically significant association with the incidence of vascular surgery or with the combined major complications endpoint. The effectiveness of the Prostar PVS Devices and accessories was demonstrated by a significant reduction in time to ambulation and time to hemostasis in patients assigned to Prostar treatment compared to those assigned to conventional compression.

XII. Panel Recommendation

Pursuant to section 515(f)(2) of the Federal Food, Drug, and Cosmetic 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 panel, for review and recommendation because the information in the PMA substantially duplicated information previously reviewed by this panel.

XIII. FDA Decision

This PMA received expedited review because FDA believed that the use of the Prostar PVS System offered a viable alternative to standard mechanical compression in some patients following interventional cardiology procedures. In anticoagulated patients with 9 to 11 French procedural sheaths, the device offered the potential for a safe and effective way to close the femoral access site. Because no legally marketed therapeutic device was available for closing 9 to 11 French femoral puncture sites in anticoagulated patients, FDA granted expedited review to the Prostar PVS System.

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An inspection was conducted and FDA found the manufacturing facility to be in compliance with the Good Manufacturing Practices regulation (21 CFR Part 820).

XIV. Approval Specifications

Instructions for Use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events sections of the labeling.

Postapproval Requirements and Restrictions: See approval order.

LABELING

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PROSTAR® PERCUTANEOUS VASCULAR SURGICAL SYSTEM INSTRUCTIONS FOR USE

TO ENSURE PROPER USE OF THIS DEVICE AND TO PREVENT INJURY TO PATIENTS, READ ALL INFORMATION CONTAINED IN THESE INSTRUCTIONS FOR USE.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Prostar Percutaneous Vascular Surgical (PVS) System consists of a Prostar PVS Device, a Prostar Pre-Dilator and Transition Guidewire (J-tipped, 100 cm transitioning from .038" on the distal 55 cm. to .014" on the proximal 45 cm) and a Perclose Knot Pusher and Arterial Tamper. The Prostar PVS Device is composed of a sheath which contains four sutured needles, and a needle guide and barrel which precisely control the needles during deployment. The Perclose Knot Pusher is used to advance surgical knots to the arteriotomy. Hemostasis is achieved by means of a percutaneous surgical closure of the arteriotomy following interventional catheterization procedures.

The 9 French (Fr.) Prostar Percutaneous Vascular Surgical (PVS) System is designed for use in 8 to 9 Fr. access sites. The 11 Fr. Prostar PVS System is designed for use in 10 to 11 Fr. access sites.

INDICATIONS

The Prostar Percutaneous Vascular Surgical System is indicated for the percutaneous delivery of sutures for closing the common femoral artery access site and reducing the time to hemostasis and ambulation (time-to-standing) of patients who have undergone interventional procedures using 8 to 11 Fr. sheaths.

CONTRAINDICATIONS

None known

WARNINGS

Do not use the Prostar PVS Device or accessories if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. Prostar PVS Devices and accessories are intended for single use only.

PRECAUTIONS

The Prostar PVS System should only be used by physicians trained in the use of the Prostar PVS Device, e.g., participation in a Prostar PVS System physician training program or equivalent.

Observe sterile technique at all times when using the Prostar PVS System. Employ appropriate groin management post procedure and post hospital discharge to prevent infection.

Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstances and the experience of the operator.

Use a single wall puncture technique. Do not puncture the posterior wall of the artery.

Do not rotate the indicator of the hub greater than 90 degrees in either direction from the 12 o'clock position while the Prostar PVS Device is in the artery.

If significant blood flow is returned through the barrel of the Prostar PVS Device, do not deploy needles. Remove the Prostar PVS Device over the Transition Guidewire and insert an appropriately sized introducer sheath.

Do not advance or withdraw the Prostar PVS Device against resistance until the cause of that resistance has been determined by fluoroscopy. If excessive resistance in advancing the Prostar PVS Device is encountered, withdraw the Prostar PVS Device over the Transition Guidewire and reinsert the introducer sheath. Excessive force used to advance or torque the Prostar PVS Device should be avoided as it may lead to significant arterial damage.

Use conventional compression methods in the event bleeding from the femoral access site persists after use of the Prostar PVS Device and Arterial Tamper.

Special Patient Populations

The safety and effectiveness of the Prostar PVS System has not been established in the following patient populations:

- Patients with puncture sites in the profunda femoris or superficial femoral artery or at the bifurcation of the arteries.
- Patients having a hematoma, pseudoaneurysm or arterio-venous fistula present prior to sheath removal.
- Patients requiring a repeat puncture at a site previously closed with the Prostar PVS System.
- Patients with common femoral artery calcium which is fluoroscopically visible.
- Patients with small femoral arteries (<5 mm in diameter).
- Patients with a femoral artery stenosis greater than 50%.
- Patients with puncture sites in vascular grafts.
- Patients with antegrade punctures.
- Patients who are pregnant or lactating.
- Patients with bleeding diathesis or coagulopathy.
- Patients younger than 18 years of age.

ADVERSE EVENTS

The Prostar PVS System was evaluated in a randomized controlled clinical trial involving 501 patients. The trial compared the Prostar PVS System to conventional compression (i.e., mechanical or manual) methods. All patients enrolled in the trial underwent an interventional procedure prior to randomization to the Prostar PVS System or compression. In this trial, 248 patients were randomized to the Prostar PVS System (224 patients were treated with the 9Fr. and 24 patients were treated with the 11 Fr.) and 253 were randomized to compression. The adverse events that were observed during the trial are reported in the table below:

Table 1. Percentage of Patients Experiencing Adverse Events
(all patients enrolled in Prostar PVS Device Trial; n=501)

Study Arm	Prostar All Sizes (n=248)	Compression All Sizes (n=253)	Risk Ratio (95% CI)
Complications † [per event] n (percent)			
Device Malfunction**	23 (9.3%)	N/A	—
Device Failure	7 (2.8%)	N/A	—
Surgical Repair*	10 (4.0%)§	4 (1.6%)	2.6 (0.8, 8.0)
Ultrasound Guided Compression*	4 (1.6%)	5 (2.0%)	0.8 (0.2, 3.0)
Transfusion*	7 (2.8%)	4 (1.6%)	1.8 (0.5, 6.0)
Infection requiring IV antibiotics*	0 (0.0%)	0 (0.0%)	—
Hematoma >6 cm	6 (2.4%)	5 (2.0%)	1.2 (0.4, 4.0)
Arterio-venous Fistula	1 (0.4%)	2 (0.8%)	0.5 (0.0, 5.6)
Pseudoaneurysm	8 (3.2%)	6 (2.4%)	1.4 (0.5, 3.9)
Complications [per patient] n (percent)			
Any complication¶	23 (9.3%)‡	14 (5.5%)	1.7 (0.9, 3.2)
9Fr.	20(8.9%)	12 (5.3%)	
11Fr.	3(12.5%)	2 (8.0%)	
Major complication	15 (6.0%)	10 (4.0%)	1.5 (0.7, 3.3)
9 Fr.	13 (5.8%)	9 (3.9%)	
11Fr.	2 (8.3%)	1 (4.0%)	
No major complication	233 (94.0%)	243 (96.0%)	
9Fr.	211 (94.2%)	219 (96.0%)	
11Fr.	22 (91.7%)	24 (96.0%)	

† patients with hematoma <6cm not included [n=43 (17.0%) Prostar arm, n=23 (9.0%) Compression arm]; these patients did not experience adverse reactions related to hematoma <6cm based on clinical and biological indicators (e.g., blood count, hematocrit)

** patients experiencing device malfunction proceeded to successful closure without clinical sequelae; malfunction included suture breaks, 17 (6.9%); failed suture deployment, 1(0.4%); failed marking 3 (1.2%); failed sheath deployment, 2 (0.8%)

* indicates a major complication

§ three (3) events attributable to protocol deviations

¶ patients with any complication, including 3 (1.2%) with infection requiring oral antibiotics

One in-hospital death occurred the day following the coronary intervention and was reported as a cardiac-related death, not associated to the arterial access closure.

Although not reported during the clinical trial, the following potential adverse reactions or conditions may be associated with the use of the Prostar PVS System: deep vein thrombosis, infection extending hospitalization, late bleeding, wound dehiscence, vessel laceration, local pulse deficits or ischemia, embolization, transitory local irritation, nerve injury and vascular spasm.

In addition, polyester surgical sutures elicit a limited acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Polyester surgical sutures are not absorbed, nor is any significant change in tensile strength known to occur *in vivo*.

CLINICAL TRIAL

The Prostar PVS 9 Fr. and 11 Fr. Systems were evaluated in a multicenter, prospective unblinded randomized trial involving 501 interventional patients (78.6% male) at six U.S. sites. Patients were randomly assigned with equal probability to percutaneous femoral artery closure with the Prostar PVS System (n=248) or to conventional compression (i.e., mechanical or manual) (n=253). The study was designed as an equivalency trial for the 30 day primary combined safety endpoint of freedom from major complications and a primary efficacy endpoint of time to ambulation (patient stands at bedside). The secondary endpoints were incidence of any complication, time to hemostasis, procedure success (achievement of hemostasis at the femoral artery access site and freedom from major complication using any closure method), and device success (acute success using the device only or the device plus adjunctive (non-arterial) compression).

Patients having a coronary interventional procedure (85.8% PTCA, 52.9% Stent, 19.8% atherectomy) performed via the common femoral artery through a 7-11 French introducer sheath were eligible. Exclusion criteria included patients with bilateral arterial access sites punctured within 48 hours, pre-existing vascular complication, small femoral arteries (<5 mm), femoral artery stenosis less than 50%, fluoroscopically visible calcium, posterior wall puncture, bleeding diathesis or coagulopathy, anatomy which made successful Prostar PVS Device placement unlikely and patients who were pregnant.

There were no significant differences between the two randomized groups with respect to sex, age, major comorbidities, angina severity, peri-procedural medications, body size, or blood pressure. The mean ACT at the time of arterial closure was 311.3±12.9 seconds for Prostar PVS Device patients versus 177.0± 81.9 seconds for patients in the compression arm. Arterial sheath sizes used (90.0% of patients, 9Fr. or smaller and 10.0% larger than 9 Fr.) were comparable between treatment arms.

In suitable patients following 8 to 11 Fr. interventional catheterization procedures, procedural success was achieved in 233 (94.0%) of 248 patients randomized to receive the Prostar PVS System compared to 243 (96.0%) of 253 patients randomized to compression (p=0.28). Device success was achieved in 215 (86.7%) patients. The Prostar PVS System resulted in significantly shorter times to hemostasis and ambulation compared to compression. Time-to-hemostasis for Prostar PVS Device patients was 1.2 ± 3.2 hours vs. 8.1 ± 5.1 hours for compression patients (p=0.0001); time-to-standing was 13.5 ± 16.9 hours vs. 25.6 ± 16.4 hours (p=0.0001). There was no statistically significant difference in the combined major complication rate between the Prostar PVS Device (6.0%) and compression (4.0%). Multivariable modeling demonstrated that the Prostar PVS treatment had no statistically significant association with the incidence of vascular surgery or with the combined major complications endpoint. In addition, this model showed that for all patients (Prostar and Compression) enrolled in the trial, time to ambulation was increased for those receiving abciximab (ReoPro), heparin, or a vascular stent.

Table 2. Principal Effectiveness Results for All Sizes
(All patients enrolled in Prostar PVS Device Trial; n=501)

Study Arm	Prostar	Compression	Δ (95% CI)
Effectiveness Measures[†] (in Hours)			
Randomized Patients	n=248	n=253	—
Time to Hemostasis	n=232	n=248	
mean±S.D.	1.2 ± 3.2	8.1 ± 5.1	-6.9 [‡]
median [quartiles]	0.4 [0.2, 0.5]	6.4 [5.2, 8.3]	(-6.1, -7.6)
Time to Standing	n=235	n=237	
mean±S.D.	13.5 ± 16.9	25.6 ± 16.4	-12.1 [‡]
median [quartiles]	7.8 [5.7, 17.7]	20.4 [11.6, 27.7]	(-9.1, -15.1)
Device Success, n (%)	215 (86.7)	—	—

[†] The number of patients listed under "Effectiveness Results" is less than the total patients studied due to missing data for some patients

[‡] difference is statistically significant; p=0.0001

Device Success = acute success using the device only or the device + adjunctive (non-arterial) compression

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Table 3. Principal Effectiveness Results by Sheath Size
(All patients enrolled in Prostar PVS Device Trial; n=501)

Study Arm by Sheath Size	Prostar 9 Fr.	Compression 9 Fr.	Prostar 11 Fr.	Compression 11 Fr.
Effectiveness Measures (in Hours)				
Randomized Patients	n=224	n=228	n=24	n=25
Time to Hemostasis	n=209	n=224	n = 23	n = 24
mean±S.D.	1.2±3.3	8.0±5.2	1.4±2.9	8.3±4.7
median [quartiles]	0.4 [0.2, 0.5]	6.3 [5.2, 8.2]	0.4 [0.3, 0.6]	7.1 [5.7, 8.5]
Time to Standing	n=214	n=214	n = 21	n = 24
mean±S.D.	13.5±17.2	25.1±16.1	13.0±13.7	30.2±18.4
median [quartiles]	7.7 [5.7, 17.8]	20.0 [14.7, 26.8]	6.8 [4.4, 15.7]	23.7 [17.6, 44.6]
Device Success, n (%)	196 (87.5)	—	19 (79.2%)	—

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of Prostar PVS System. The techniques and procedures described are not intended as a substitute for the physician's experience and judgment in treating any specific patients.

Examination and Selection of Products

1. After carefully inspecting the packaging of the Prostar PVS Device and accessories for damage to the sterile barrier remove the device from the package.
2. Select the appropriately sized Prostar PVS System. The Prostar 9Fr. PVS Device should be selected for closure of 8Fr. and 9Fr. introducer sheath access sites and the Prostar 11Fr. PVS Device should be selected for 10Fr. and 11Fr. sheath access sites.

Arterial Puncture Considerations

1. Puncture the anterior wall of the common femoral artery at an angle of approximately 45 degrees.
2. Avoid side or posterior wall punctures.

Preparation of the Subcutaneous Track

1. After completing the interventional procedure, use fluoroscopy and inject contrast through the introducer sheath to evaluate the femoral artery for size, calcium and tortuosity.
2. While the introducer sheath remains in place, use a scalpel to slightly extend the incision, and forceps to dilate subcutaneous tissue.
3. Flush the Pre-Dilator marker lumens with heparinized saline and verify marker port patency.
4. Place a Perclose Transition Guidewire through the introducer sheath. Remove the introducer sheath while applying pressure on the groin to maintain hemostasis.
5. Back-load and gently advance the Pre-Dilator over the guidewire until the .038" section is within the sheath tip. Continue advancing the Pre-Dilator at a steep angle (45°-60°) with the handle oriented vertically and pointing down. When the barrel enters the subcutaneous track, apply gentle forward pressure while continuously rotating the barrel 360 degrees. Change the direction of rotation and enlarge the skin incision as needed. Some resistance to barrel rotation will be felt depending on the amount of scar tissue present. A steady, continuous drip of blood exiting from the shorter (right-hand) marker lumen indicates near-complete advancement of the Pre-Dilator. Continue to gently advance the Pre-Dilator while rotating the barrel. Blood returned from the longer (left-hand) marker lumen indicates full advancement of the Pre-Dilator and complete preparation of the subcutaneous track.

6. If marking is not achieved from both lumens, replace the Pre-Dilator with an introducer sheath of equivalent size. Do not introduce the Prostar PVS Device.

Prostar PVS Device Placement

1. After preparing the subcutaneous tissue track, remove the tubing which locks the Prostar PVS Device handle in place, flush the marker lumens with heparinized saline and verify marker port patency. Carefully back-load the Prostar PVS Device over the guidewire with the indicator on the hub pointing upward (12 o'clock position). Introduce the device at a **60 degree angle** until the barrel enters the subcutaneous track. Using a slight twisting motion, advance the barrel at a 45 degree angle with the indicator on the hub rotating **no more** than 90 degrees in either direction.
2. A steady, continuous drip of blood should be obtained from both of the marker lumens when the Prostar PVS Device is fully seated and properly positioned. Marking from the lumens occurs either simultaneously from both lumens or from one lumen at a time. For example, when rotating the device clockwise so that the indicator is in the 2 o'clock position, marking will usually be in the lumen positioned on the downside. Likewise, when the indicator on the hub is in the 10 o'clock position, the other lumen, now positioned on the downside, will mark. **Never rotate the indicator on the hub from the upward (12 o'clock) position more than 90 degrees in either direction.** Marking must be achieved from both lumens either simultaneously or alternately to ensure needle tips are intraluminal prior to deployment. If luminal marking is still not achieved, remove the device, leaving the guidewire in place, replace the introducer sheath, and follow standard compression protocol.

Needle Deployment

1. Stabilize the device by holding the hub in position with the left hand in the position in which marking from one or both lumens is most prominent (Figure 1). **Do not hold the barrel during needle deployment.** Deploy the needles with the right hand by rotating the T-handle counter clockwise and pulling the handle straight back, away from the funnel-shaped hub. Continue to pull the handle until the needle tips emerge at the top of the barrel. **If significant resistance is encountered, if fewer than 4 needles are deployed, or if the handle detaches when deploying needles, terminate deployment and back the needles down into the sheath. Refer to Techniques for Needle Back-down.**

Technique For Needle Back-Down

The following describes a safety feature ("needle back-down") that permits the physician to return the needles into the sheath. This feature provides the option of exchanging the Prostar PVS Device for an introducer sheath so that the patient may be treated with conventional compression therapy.

Non-Deployment of Needles

- If significant resistance is encountered, if fewer than 4 needles are deployed, or if the handle detaches during needle deployment, terminate deployment and back the needles down into the sheath. Grasp the holder tube with forceps or a needle holder and gently feed the holder tube into the core. In order to transmit enough force to back-down the needles, grasp the holder tube one centimeter or less from the point that it exits the core. Prior to Prostar PVS Device removal, use fluoroscopy to verify the needles have been returned to the predeployment position within the needle guide. The needle tips should be as close as possible to the proximal edge of the radiopaque sheath ring before removal of the Prostar PVS Device.
- In the event fewer than four needles are deployed **DO NOT REMOVE ANY DEPLOYED NEEDLES.** Cut the sutures close to the needles prior to backing needles down into the sheath as described in step one of the Non-Deployment of Needles section.
- Do not attempt to redeploy the Prostar PVS Device after the needles have been backed-down following the initial deployment attempt. Replace the Prostar PVS Device with another Prostar PVS Device or an introducer sheath.

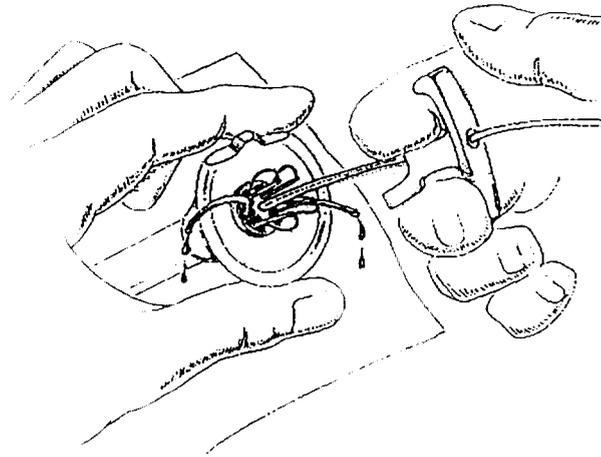


FIGURE 1

2. After needle deployment, verify that all needles and sutures have been deployed. White colored suture ends are attached to two needles and make up one suture loop; green colored suture ends are attached to two needles making up another suture loop. If needles and sutures are not fully deployed refer to the Techniques for Needle Back-down and Suture Breakage sections.
3. While holding the device in position, use a needle holder to remove the needles from the Prostar PVS Device. Remove the posterior needles followed by the anterior needles using the funnel-shaped hub as a fulcrum to facilitate needle removal (Figure 2). More force is required to remove the first needle than the remaining three needles.

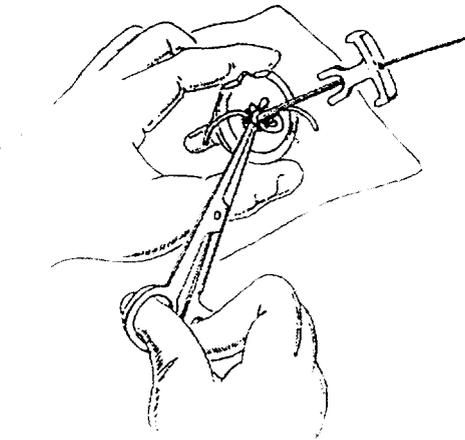


FIGURE 2

Suture Management

1. Position the sutures and needles in color-coded pairs (green/white) on each side of the device. Remove slack by gently pulling color-coded pairs until they are pulled completely out of the suture lumen. This is verified by an abrupt release of tension, followed by cessation of movement of the color-coded pair. Pull the white suture loop ends to an evenly matched length and cut the sutures close to the needles. Repeat the same steps with the green suture loop ends.

2. Withdraw the Prostar PVS Device until the fixed funnel located in the middle of the sheath is exposed (see Prostar PVS Device schematic). Maintain access to the sutures exiting the hub during this step. Create a "bow string" effect with the exposed sutures by bending the sheath upward and applying tension to the four suture ends exiting the hub. Grab the sutures below the sheath, one pair at a time, and pull the sutures through the distal end of the barrel (Figure 3).

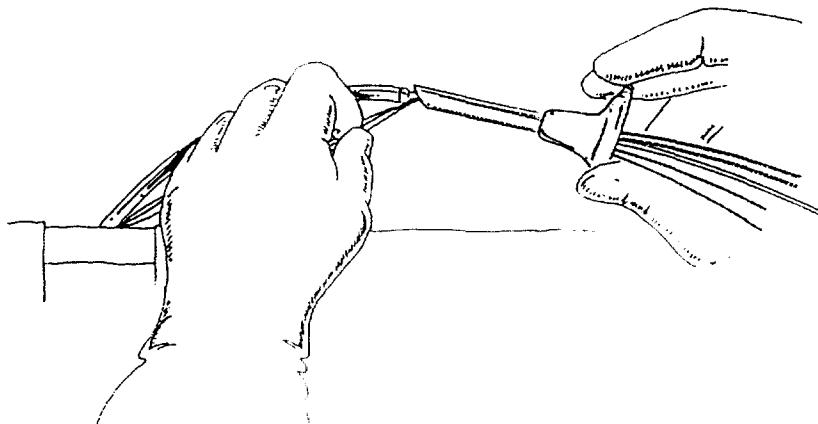


FIGURE 3

3. Collecting the sutures from below the sheath is important. This ensures sutures are not tied around the sheath and wire access can be maintained until hemostasis is verified.
4. Identify suture ends by color, then tension the ends using a gentle see-sawing motion.
5. Tie a square knot with the green pair of suture ends (Figure 4); place the tied green sutures on the field keeping it free from the white suture.

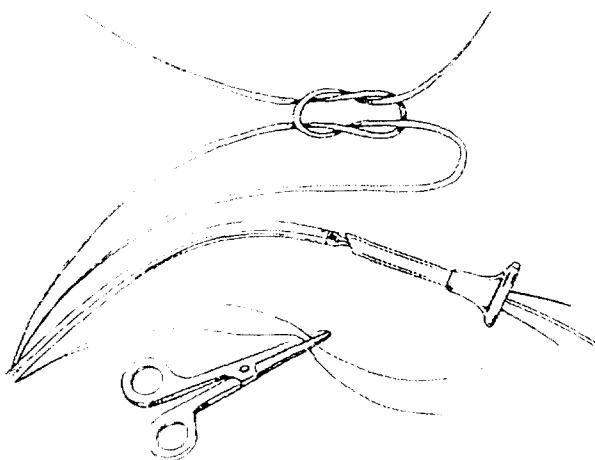


FIGURE 4

6. Tie a square knot with the white pair of suture ends. Place one suture end into the Knot Pusher by retracting the knob on the handle and positioning the suture across the window located at the distal end of the Knot Pusher. Release the knob to load the suture. The Knot Pusher should slide easily on the suture.

4/0

Advancing Knots

1. Prior to advancing knots, ensure that the 0.014" - 0.038" transition point of the Transition Guidewire is proximal to the vascular access site by withdrawing the guidewire until it stops.
2. Saturate the suture with saline. With the Knot Pusher positioned on one limb of the white suture, tension the suture limb with the fingers of one hand while applying forward pressure to the proximal end of the Knot Pusher with the thumb of the same hand. Leave the Transition Guidewire in place and gradually withdraw the Prostar PVS Device while simultaneously advancing the knot of the white suture to the guidewire with gentle forward pressure with the thumb on the Knot Pusher. Hold this position for 20 to 30 seconds to allow advancement of the knot around the Transition Guidewire. Pull the Knot Pusher back out of the subcutaneous track. Do not use the knob to release the suture from the Knot Pusher. Saturate the green suture with saline, position the Knot Pusher on the suture and advance the knot to the Transition Guidewire using the one-handed technique described above.
3. It is important to pull all of the slack out of the suture as the knot is advanced to avoid an "air knot" (tightening the knot around the suture loop without pulling the tissue in apposition). When advancing knots, use the suture as a rail for the Knot Pusher. To reduce resistance to knot advancement, hold the suture as vertical as possible while keeping the Knot Pusher coaxial to the suture.
4. Complete hemostasis of the access site is achieved when both knots are fully advanced to the arterial surface and the tissue is in complete apposition. If hemostasis is not complete, gently advance knots with the Knot Pusher with the one-handed technique while gently applying constant tension to the longer suture limb. Hold this position for 20 to 30 seconds or until hemostasis is obtained. Do not apply excessive pressure to the Knot Pusher or suture. If acceptable hemostasis is not achieved use the Arterial Tamper (refer to the Arterial Tamper section for instructions for use).
5. If hemostasis is achieved, remove the Transition Guidewire and further tighten both square knots. Secure square knots by advancing overhand knot throws with the Knot Pusher. Single overhand suture throws are advanced by holding the ends of the suture in the left hand and placing the Knot Pusher on the right-hand suture limb proximal to the throw. Advance the knot with the Knot Pusher held in the right hand while slightly tensioning the two suture ends held approximately 2 centimeters apart in the left hand. Advance two overhand suture throws on each suture pair.
6. Once hemostasis is achieved, trim the sutures below the skin.

Suture Breakage

1. If sutures are inadvertently tangled or removed prior to knot tying, discard the suture material and remove the Prostar PVS Device over the Transition Guidewire. Use another Prostar PVS Device to complete the procedure.
2. In the event suture breakage occurs prior to completing the initial square knot, discard the suture material and remove the device over the Transition Guidewire. Use another Prostar PVS Device to complete the procedure.
3. In the event suture breakage occurs after the initial square knot has been tied, and the remaining suture is secure in the artery, the Arterial Tamper may be used to augment hemostasis.

Arterial Tamper

1. If hemostasis is not adequate after attempts to fully advance the knots, use the Arterial Tamper or compression. To use the Arterial Tamper, thread the exposed suture ends through the snare. Unlock the snare handle by turning it counter-clockwise. Pull the snare through the Arterial Tamper with the snare handle. The snare will exit with the suture from the proximal end of the Arterial Tamper. Gently advance the Arterial Tamper over the tensioned suture until

it applies direct pressure to the access site. Keeping the stopcock lever facing to the patient's right ensures that the beveled tip is appropriately oriented to the arterial surface. The Arterial Tamper may be secured in place by tensioning the suture and rotating the stopcock lever 90 degrees in a counter-clockwise direction. When hemostasis has been achieved, rotate the stopcock lever clockwise until the suture moves freely. The Arterial Tamper can now be withdrawn.

2. Trim the sutures below the skin.

POST PROCEDURE PATIENT MANAGEMENT

1. Apply an appropriate dressing to the puncture site.
2. Assess the insertion site as per hospital protocol.

RECOMMENDATION FOR PATIENT AMBULATION

Patients may be ambulated post PVS procedures with normalized (150-180 seconds) activated clotting times (ACTs). In determining whether to ambulate an individual patient, it is important to consider all clinical factors including, but not limited to, anticoagulation, antiplatelet, and thrombolytic agents administered, oozing or bleeding from the access site, venous access site hemostasis, the general cardiovascular condition of the patient, anesthetic levels, and the overall clinical condition of the patient

Prostar Products

Prostar® 9Fr. Percutaneous Vascular Surgical System

Catalog Number
PVS-100-09

Includes:

- One (1) Prostar 9Fr. Percutaneous Vascular Surgical Device
- One (1) Perclose Knot Pusher
- One (1) Prostar 9Fr. Pre-Dilator
- One (1) Prostar Transition Guidewire

Prostar® 11Fr. Percutaneous Vascular Surgical System

PVS-100-11

Includes:

- One (1) Prostar 11Fr. Percutaneous Vascular Surgical Device
- One (1) Perclose Knot Pusher
- One (1) Prostar 11Fr. Pre-Dilator
- One (1) Prostar Transition Guidewire

Perclose® Arterial Tamper

PAT-301-03

Perclose® Knot Pusher

PSH-331-01

Prostar® Transition Guidewire

PTW-038-14

The Prostar PVS Device and accessories are provided sterile and nonpyrogenic in unopened, undamaged packages. Products are sterilized with ethylene oxide. Store in cool, dry place.

Product Information Disclosure

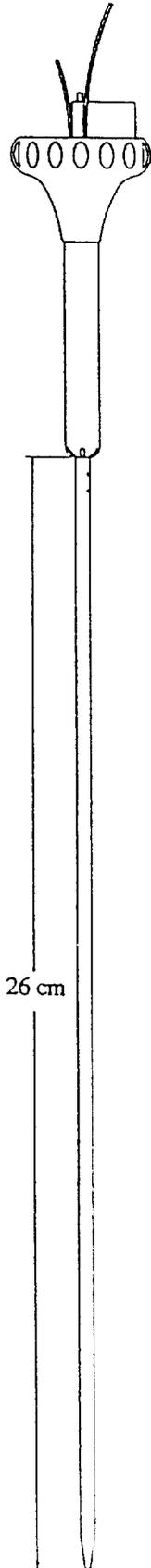
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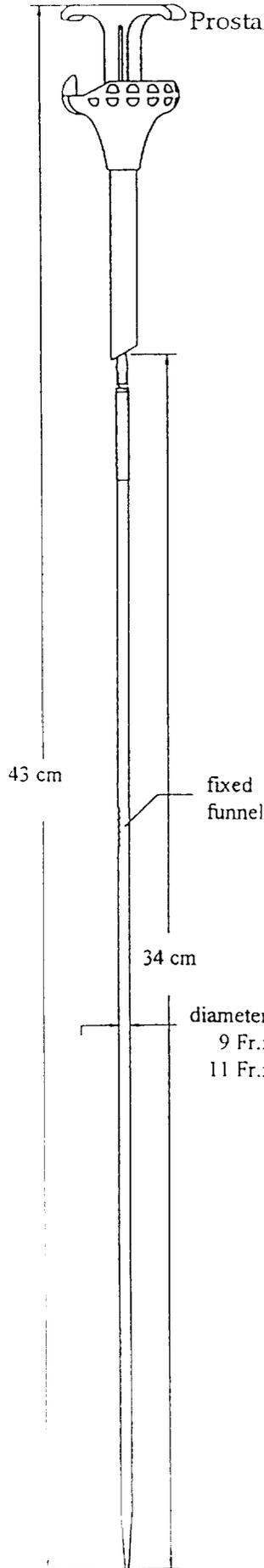
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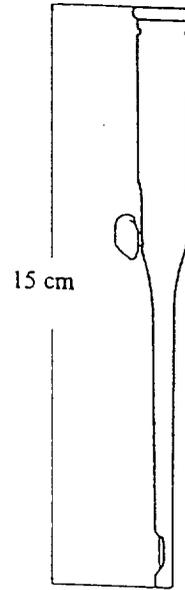
Predilator



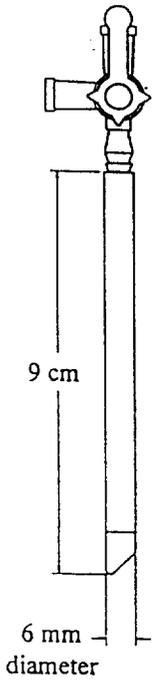
Prostar PVS Device



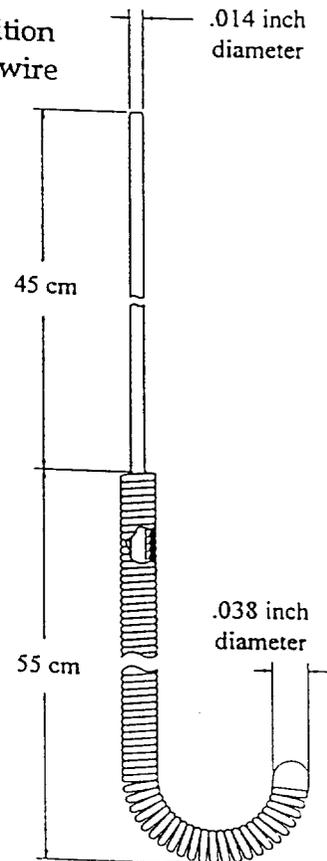
Knot Pusher



Arterial Tamper



Transition Guidewire



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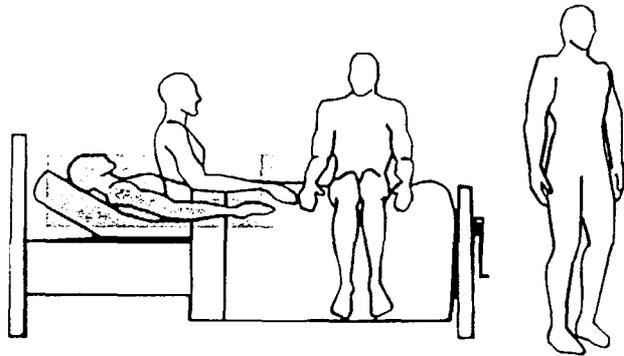
Understanding

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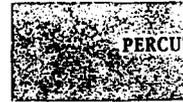
Percutaneous **V**ascular **S**urgery **S**

A Patient Guide

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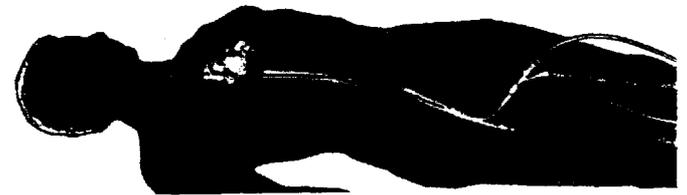
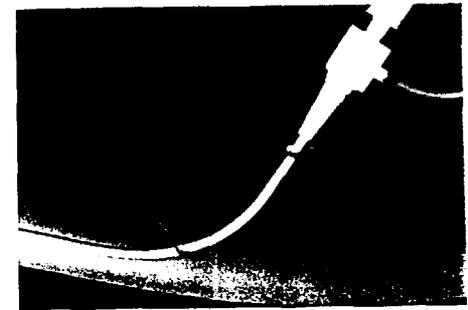
Perclose Percutaneous Vascular Surgery



PERCUTANEOUS VASCULAR SURGERY (PVS)

Percutaneous Vascular Surgery (PVS) is a new procedure which allows your doctor to close the femoral artery access site (opening in femoral artery) following your interventional procedure performed to open a blockage in your coronary artery.

Your doctor will perform the coronary interventional procedure through the skin (percutaneously) using vascular catheters (small flexible tubes) designed to open the blockage. The vascular catheters are introduced and advanced to the blockage in your coronary artery through a small access site in either your right or left femoral artery. At the end of the coronary interventional procedure your physician will use the PVS Device to perform another procedure which closes the small opening in the femoral artery with two stitches.



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HOW DOES PVS COMPARE WITH CONVENTIONAL TREATMENT?

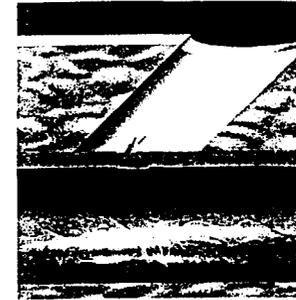
Before the PVS Device was available, the femoral artery was closed by applying direct pressure to the access site (compression) anywhere from fifteen minutes up to one hour. Applying direct pressure to the access site compressed the femoral artery allowing a blood clot to form in the opening of the femoral artery which closes the site. Any movement could dislodge the blood clot resulting in bleeding from the femoral artery, so it was necessary to remain immobile for 4 to 8 hours after compression was removed. Another method for closure of the access site involves plugging the site with collagen.

The PVS Device does not rely on blood clot formation to close the opening in the femoral artery. Instead, the stitches placed around the femoral artery close the access site. Since blood clot formation is not required to close the opening, patients who receive PVS may sit up in bed soon after the procedure rather than having to lie flat in bed for 4 to 8 hours. Depending on the results of the coronary interventional and the PVS procedure, patients usually may get out of bed sooner than when compression is used to close the femoral artery.

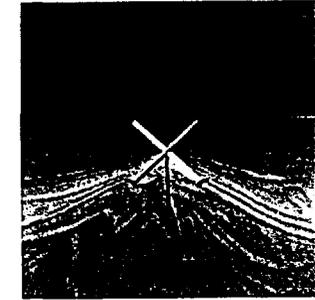
THE PVS PROCEDURE

The PVS procedure is performed by introducing the PVS Device through the opening in the femoral artery. The PVS Device allows the physician to put stitches in the femoral artery to close the opening.

The stitches delivered by the PVS Device are the same as those used over several years in blood vessels and other surgical procedures. Therefore the stitches are safe for both short and long term use.



Side view of stitches



Inside view of stitches

WHAT TO EXPECT DURING THE PVS PROCEDURE

The time of the PVS procedure may depend on the amount of scar tissue you may have from previous catheterization procedures. It may take longer to place the PVS Device if there is significant scar tissue from previous procedures.

Prior to the PVS procedure, your physician will administer a local pain medication to ensure that any discomfort is minimal. During the introduction of the PVS Device you will feel some pressure as your physician exchanges the introducer sheath used for your interventional procedure with the PVS Device. This pressure generally is not uncomfortable and lasts for just a few seconds. Most patients do not experience any discomfort during the PVS procedure. A few patients will feel some momentary discomfort when needles and stitches pass through the artery wall or when the surgical knots close the opening in the femoral artery.

saline (sterile water) is used to saturate the stitches prior to advancing them to the artery and you may feel the cold water on your leg when the saline is applied.

At the end of the PVS procedure, a small dressing will be applied to the opening in the skin.

4

AFTER THE PVS PROCEDURE

After the PVS procedure you will be moved to a post procedure care area or a standard hospital room depending on your coronary interventional procedure and whether you will be sent home later in the day or remain in the hospital overnight. Your heart rate, blood pressure and pulses will be monitored and the access site will be checked regularly for any bleeding.

In most cases you will be able to sit up in bed soon after the PVS procedure and your doctor may allow you to get up to use the bathroom. This will be dependent on the results of your interventional procedure, the use of a venous sheath (vascular catheter in the femoral vein), the medications administered during the procedures, and any oozing from the opening in the skin. Some oozing from tissue may occur if you have received blood thinners and other medications which prevent blood clotting. Light compression may be applied to control oozing.

GOING HOME

Your physician will tell you about any limitations in activities and how to take care of the groin access site. In general, you should limit any heavy lifting (greater than 10 lb.) for one week to allow for complete healing of the opening in the skin. Clean the access site by washing with soap and water to minimize any risk of infection.

Any bleeding from the groin should be reported to your physician immediately. Any increased oozing or oozing which persists should also be reported to your physician immediately.

GLOSSARY

Access site: the opening in the femoral artery used to introduce vascular catheters and closed by the Percutaneous Vascular Surgical Device

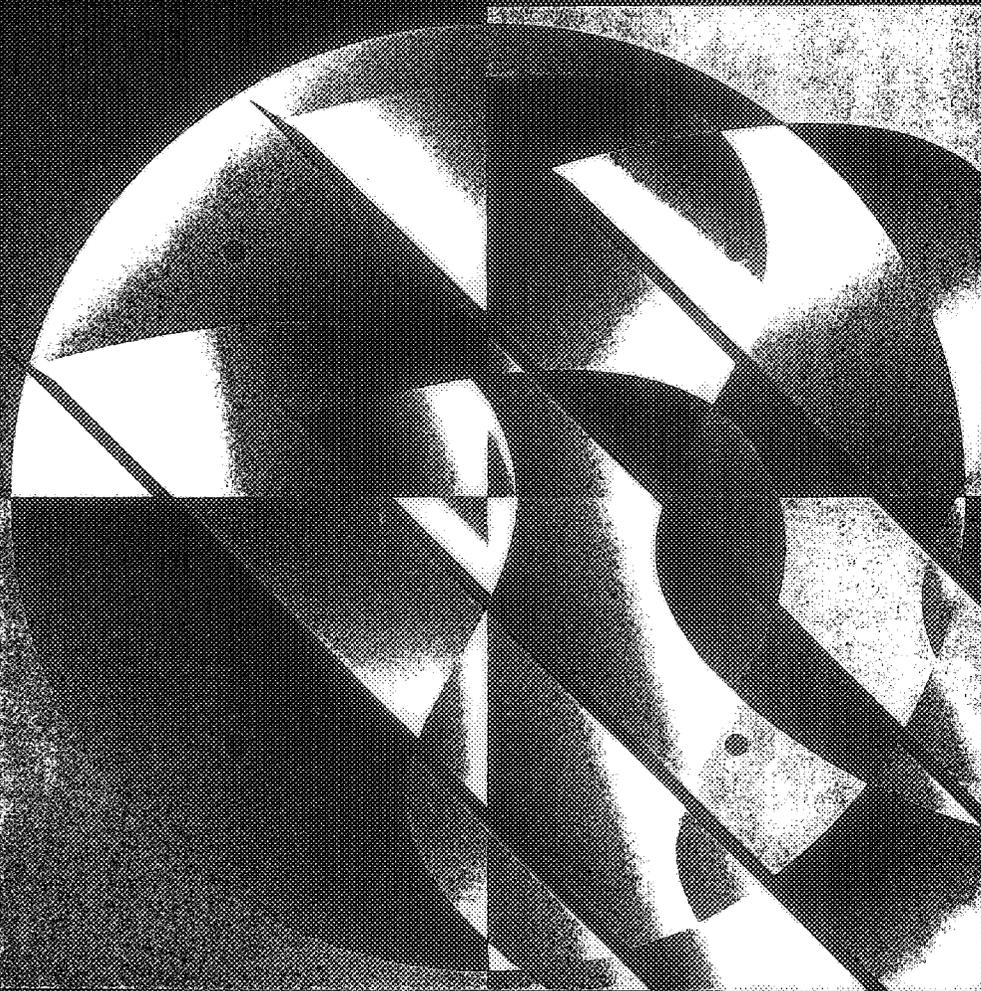
Compression: direct pressure applied to the femoral artery to permit blood clot formation at the opening of the access site.

Interventional procedure: therapeutic procedures to open blockages in coronary arteries (includes percutaneous transluminal coronary angioplasty (PTCA), stenting, and atherectomy)

Percutaneous: performed through the skin

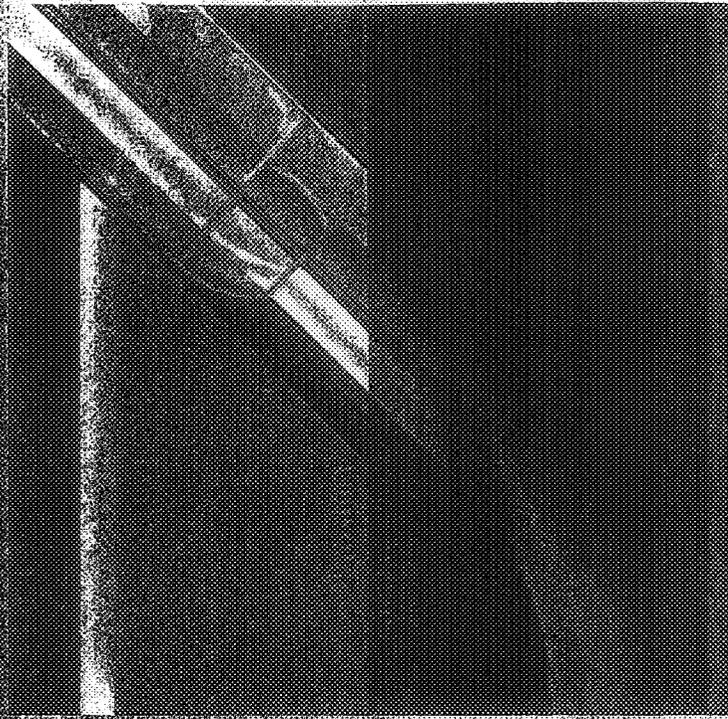
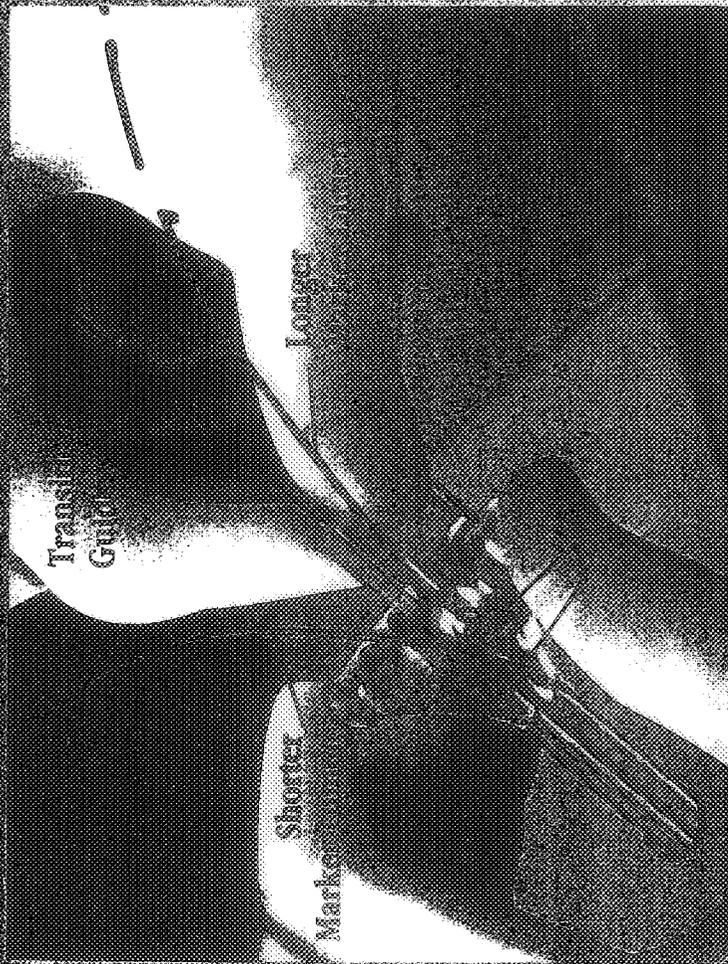
Vascular Catheter: a slender flexible tube used during interventional procedures designed to open blockages in arteries

DISCHARGE INSTRUCTIONS



CONSTRUCTIONS

PROSTAR

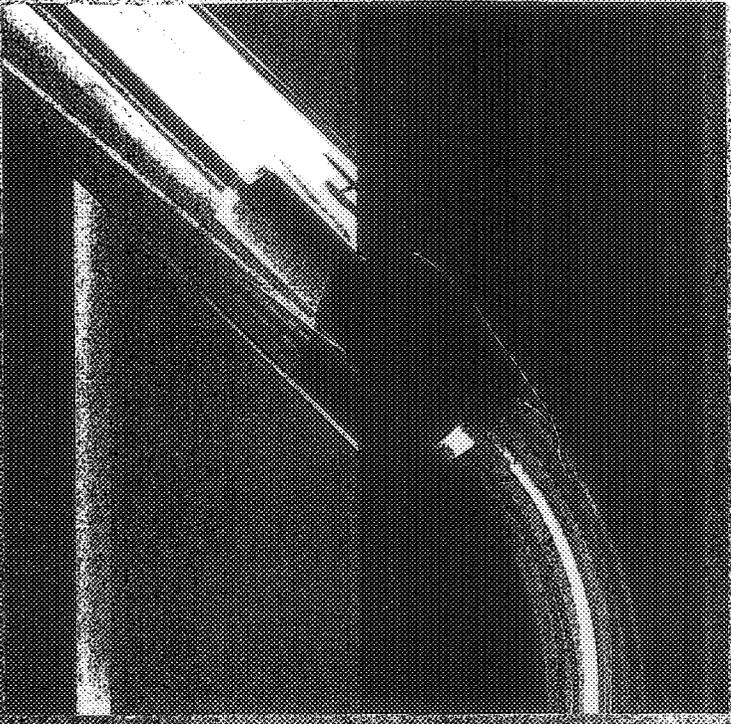
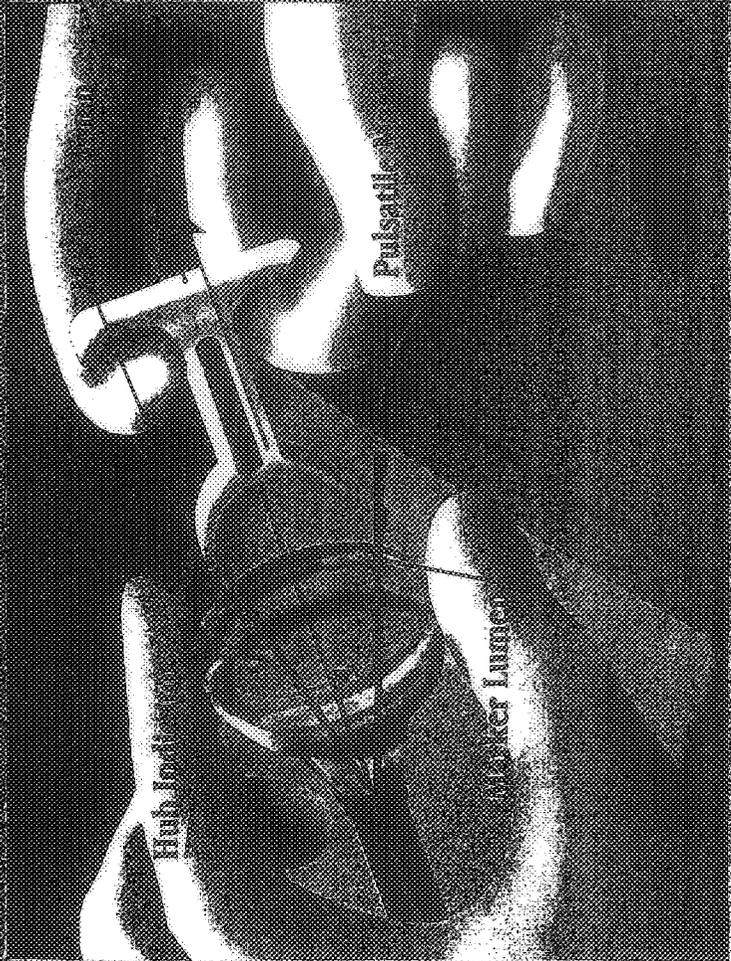


Use the Shorter Marker Lumen to communicate with the shorter, right-hand Marker Lumen.
Use the Longer Marker Lumen to communicate with the longer, left-hand Marker Lumen.
The Marking will occur first in the right-hand Marker Lumen, then in the left-hand
Marker Lumen.

Prostar

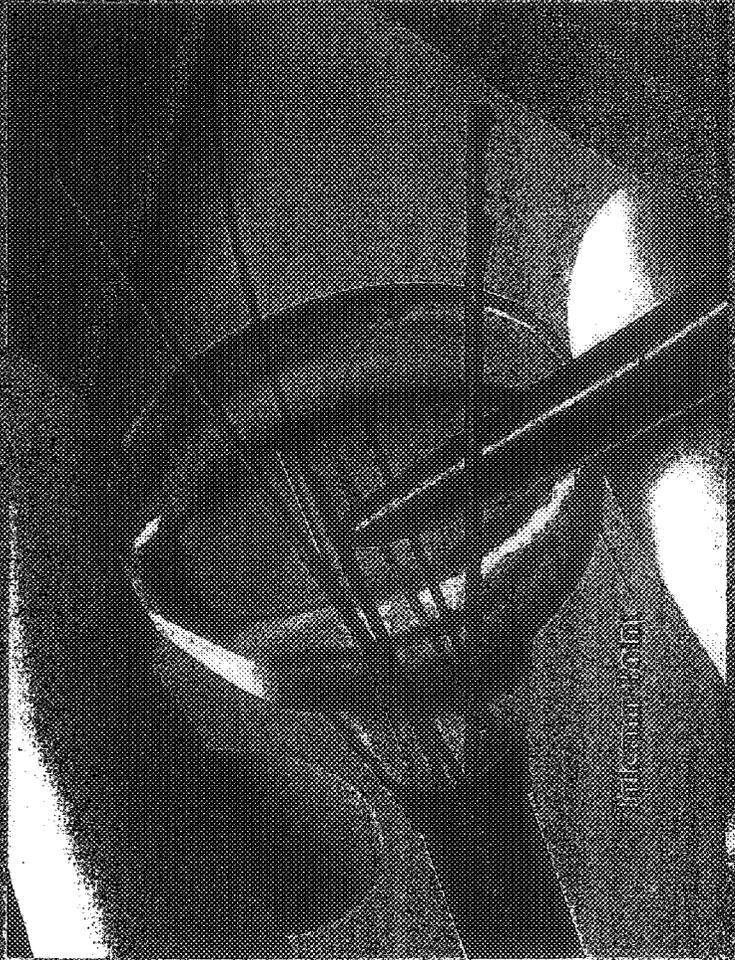
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NEEDLE DEPLOYMENT



- Do not rotate the arrow on the Hub Indicator from the upward position more than 90° in either direction.
- Pull the handle straight back away from the hub to deploy the needles.
- If needles are not easily deployed, back the needles down into the sheath prior to device removal.

INTELLIGENTE RUMICOMAVANT

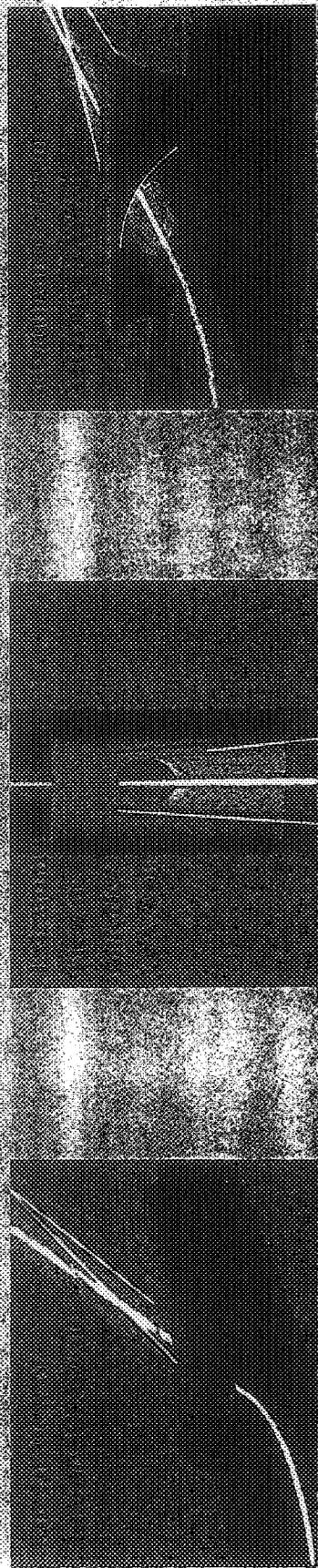
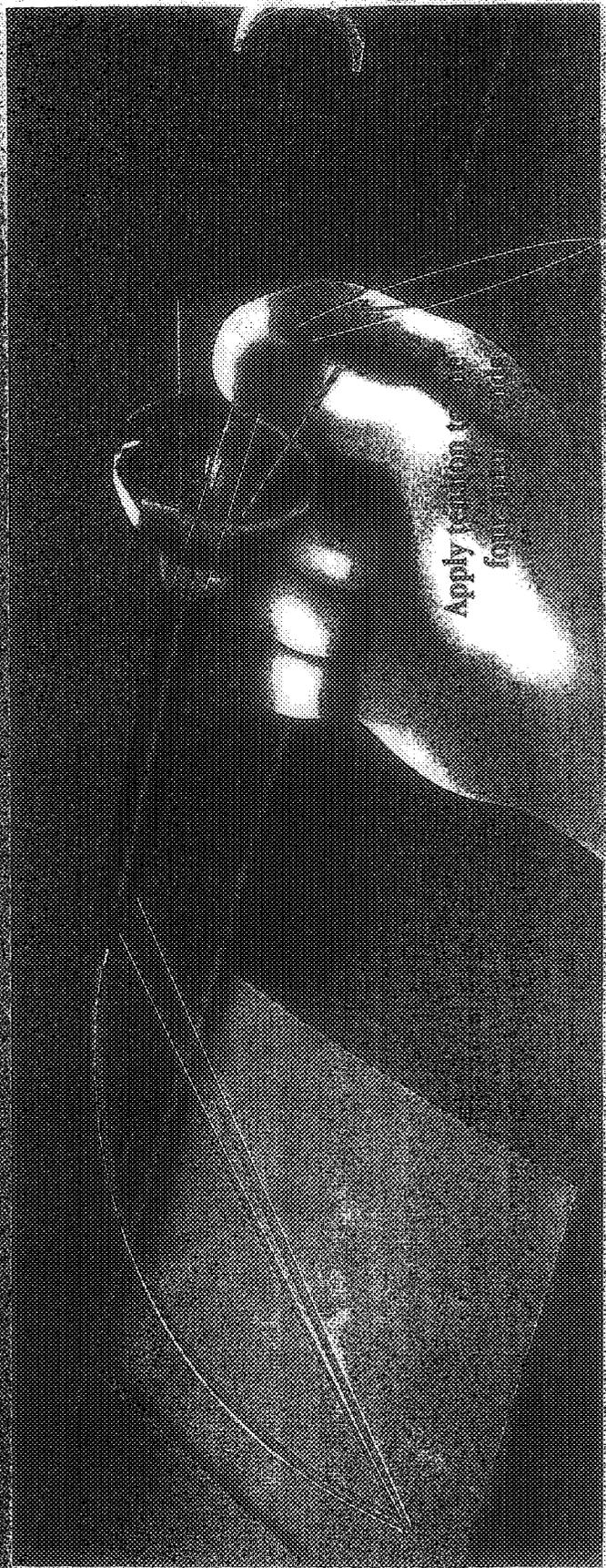


intelligent

• Verfügen Sie sich für mehr Informationen
• Remove the program from the website

TRISTAR

BOWSTRINGING



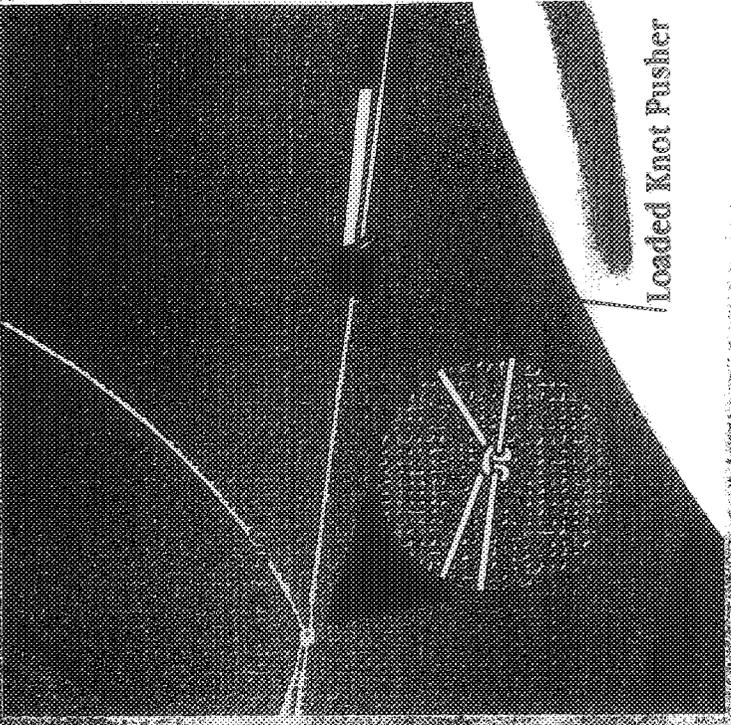
- Sheath should be bent upward between the lateral and medial sutures/pairs.
- Sutures should be isolated on each side of the sheath.
- Sutures should be positioned below the sheath and pulled from underneath the Prostar® PVS Device.

Prostar

Prostar® PVS Device

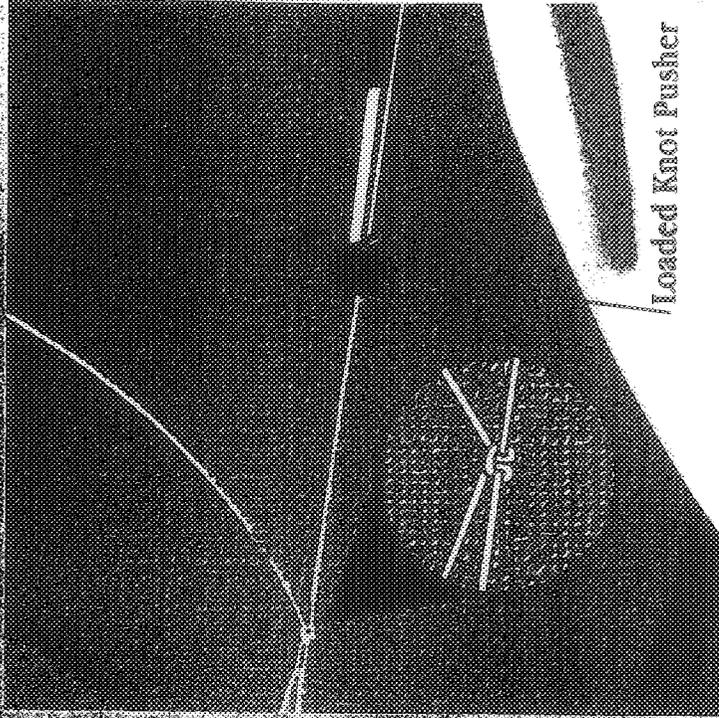
B

KNOT PUSHES THEIR MESSAGE



Prostar

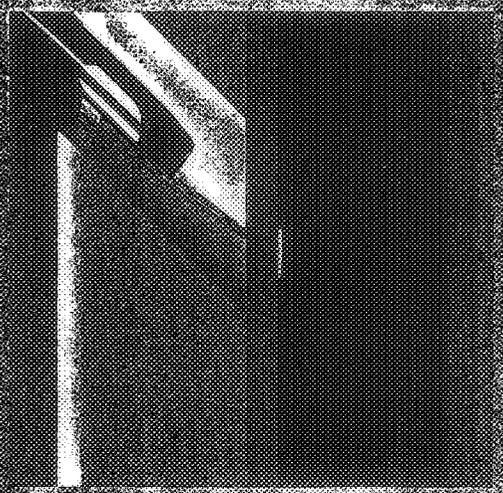
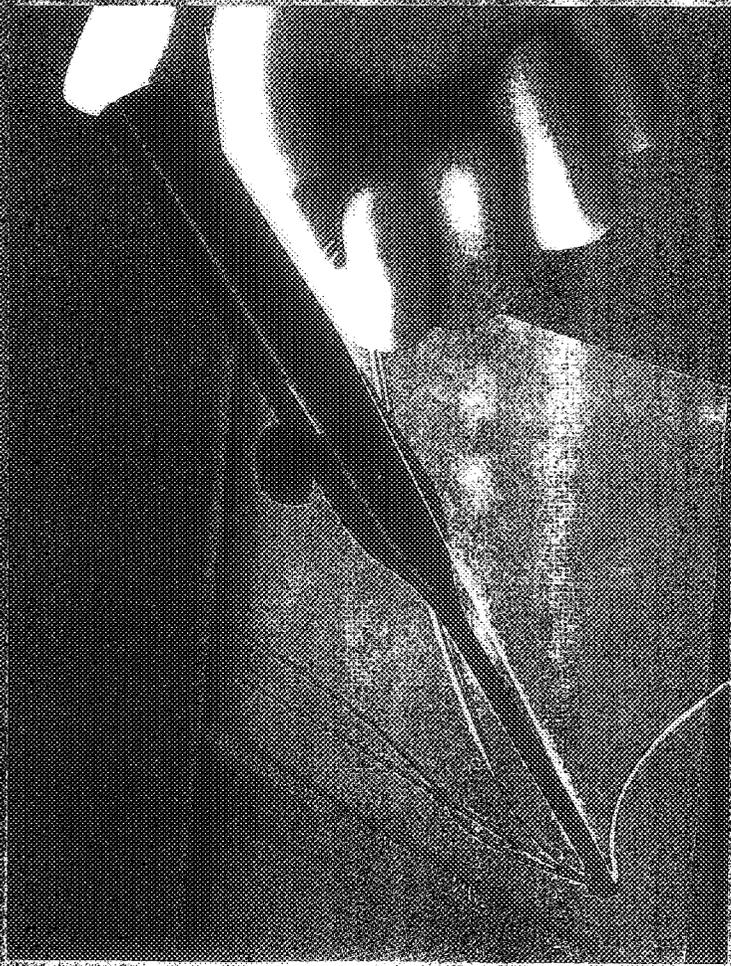
KNIGHT PUSHER (USA) GHE



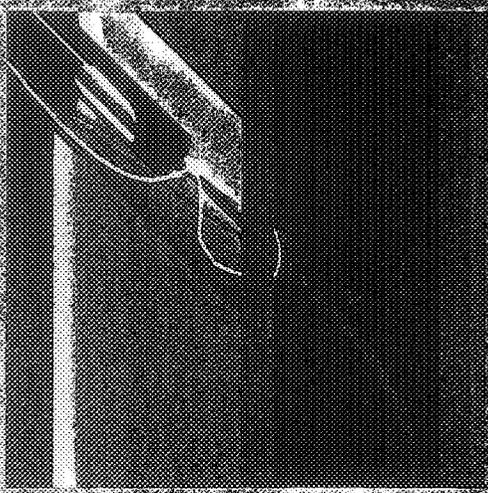
Prostar

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STING CURE THE HAND-KNOTTED ADVANCEMENT



Correct

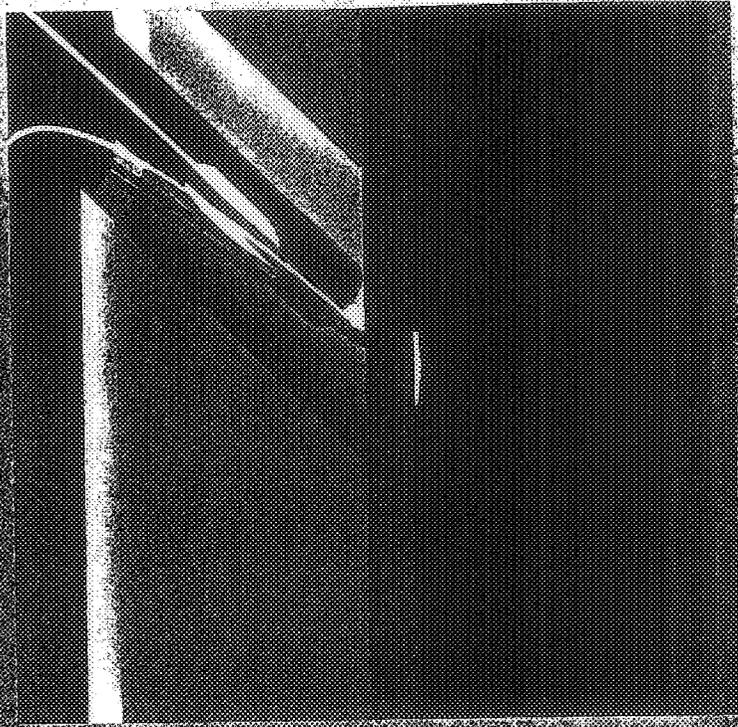
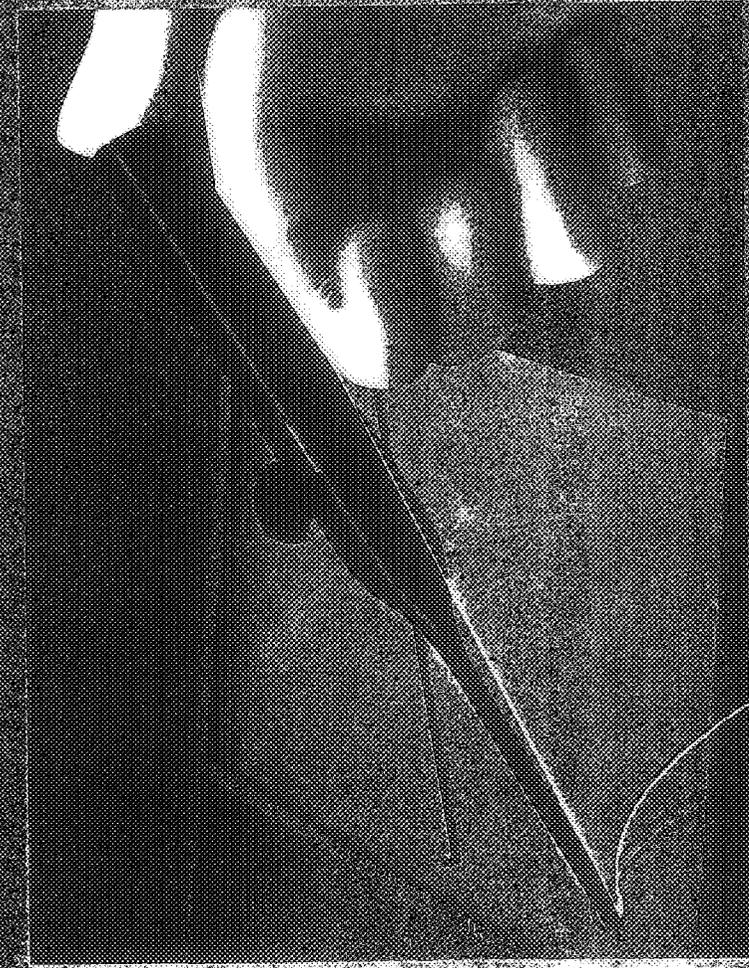


Incorrect (air knot)

- To avoid an "air knot" apply tension to the suture while advancing the knot.
- Tension must be applied to remove slack in the suture while advancing the knot.

Sting

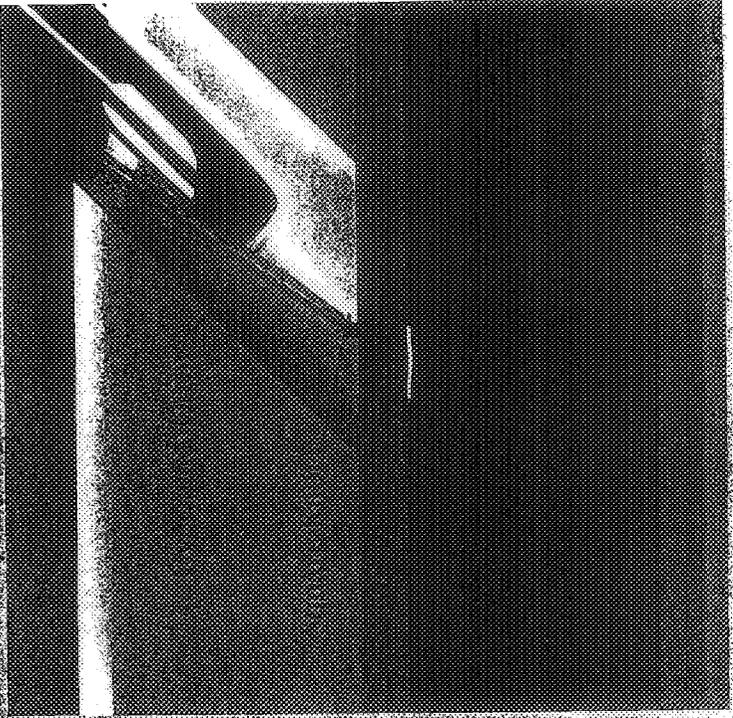
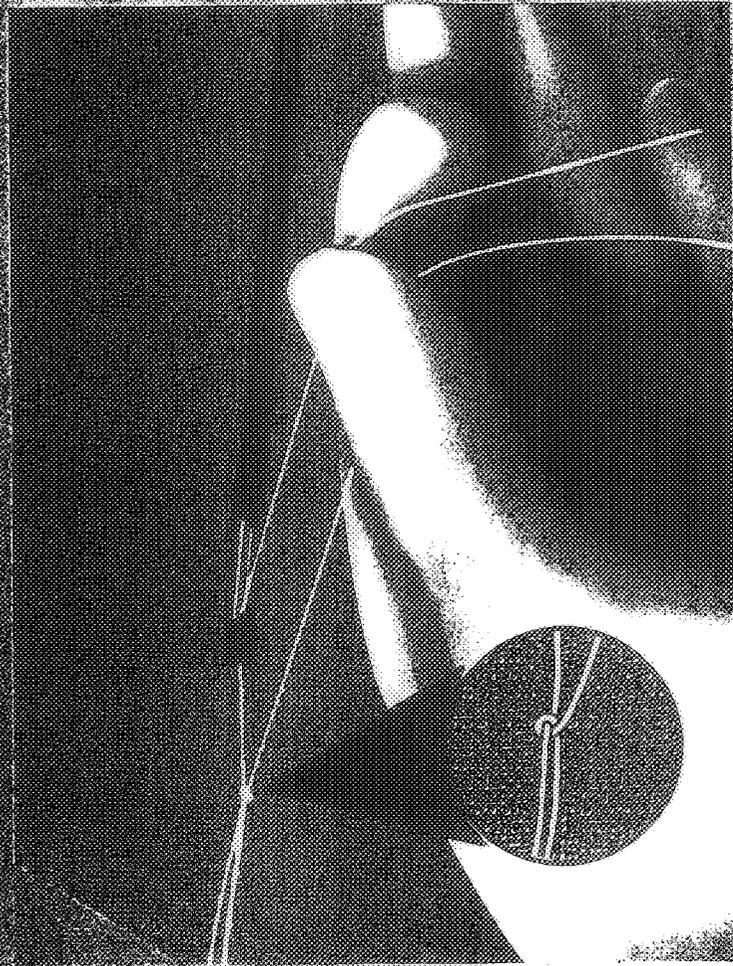
HEMIOSTASIS



- Apply constant gentle pressure to the surface with the kno. Push for 20-30 seconds until hemostasis is obtained.
- Alternate between the green and white surfaces to achieve hemostasis.

TRIPSTAR
SURGICAL

OVERHAND AND THROWS

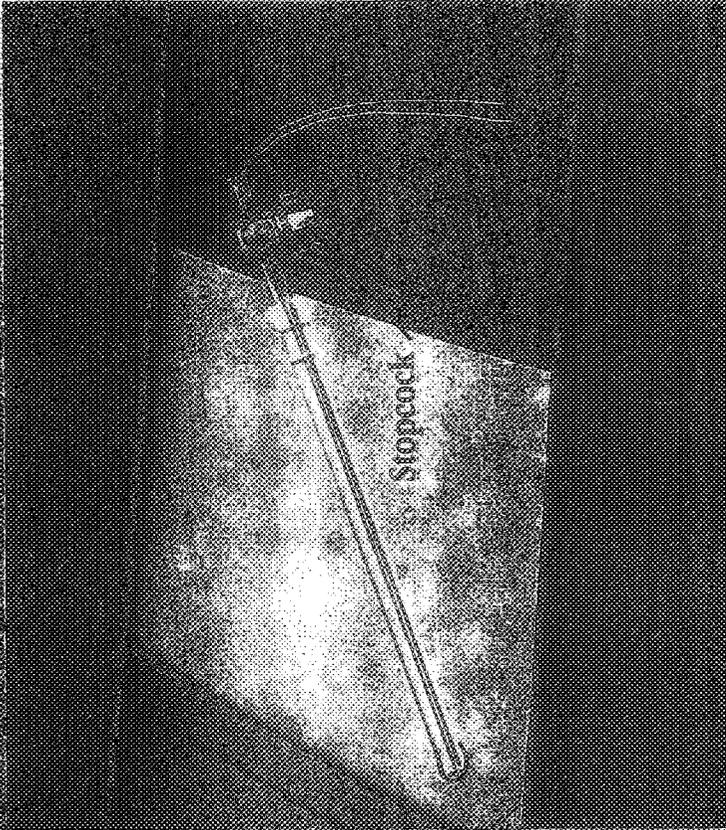


- To secure the square knots, advance two overhand throws on each suture pair.
- Maintain equal tension on both suture limbs.

ProStar

Perianeous Vascular Surgical Deyter

ARTERIAL TAMPER



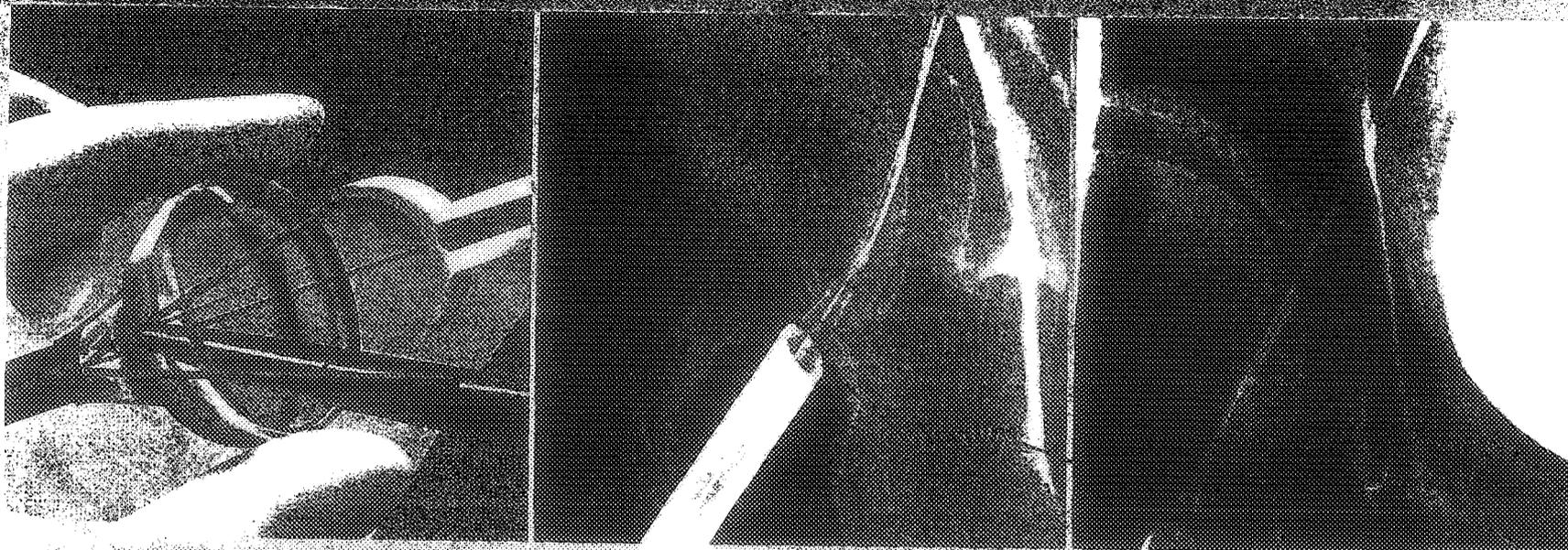
- The exposed suture ends, through the snare.
- Unlock snare handle by turning it counterclockwise.
- Pull the suture along with the snare through the Arterial Tamper.

- Gently advance over the tensioned suture.
- Keep stopcock lever facing the patient's right.
- Secure the Arterial Tamper by rotating the stopcock lever 90° counterclockwise.
- Remove Arterial Tamper after hemostasis is achieved.

Prostar
A Division of Prostar Surgical Device

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NEEDLE BACKDOWN



Radiopaque crimp ring

- If needles cannot easily be deployed, back the needles down into the sheath prior to device removal.
- Use cine to identify the position of the needle tips, prior to backing down the needles.
- Verify that the needle tips are within the needle guide (just proximal to the radiopaque crimp ring) prior to device removal.

PRO

®

Star

Percutaneous Vascular Surgical Device

Perceptics, Inc.
199 Jackson Drive
Menlo Park, CA 94025
U.S.A.

(415) 321-3100 • (415) 321-1000

Customer Service
(800) 731-7247 • (415) 321-1000

Perceptics Europe
The Manor
Harley Business Centre
Weybridge, Surrey
Middlesex, U.K.

Perceptics Japan
(03) 4333-7700 • (03) 4333-7700

Perceptics is a registered trademark of Perceptics, Inc. in the U.S.A. and other countries.

Prostar
Perceptics, Inc.

Label, Unit, Transition Guidewire

Prostar[®] Transition Guidewire Profil-Führungsdraht Prostar Fil de Guidage Transition Prostar Guida di Transizione Prostar Alambre Guia de Transición Prostar

Intended for use exclusively with
the Prostar Vascular Surgical
Device

Ausschließlich zum Gebrauch mit
dem Prostar Chirurgischen Vaskulären
Gerät

Destiné à être utilisé exclusivement
avec le Dispositif Chirurgical Vasculaire
Prostar

Destinato esclusivamente all'uso con il
Dispositivo Chirurgico Vascolare Prostar

Destinado exclusivamente al uso con el
Dispositivo Quirúrgico Vascular Prostar

STERILIZATION DATE
Sterilisationsdatum
Date de Stérilisation:
Data di sterilizzazione:
Fecha de esterilización:

Use before
Verw. bis
Ut. av.
Data di scadenza
Fecha de caducidad:

LOT / Ch. B.

Perclose Europe
Asmec Center
Eagle House
The Ring, Bracknell
Berkshire, RG12 1HB
United Kingdom
Phone: 44 344 382016
Fax: 44 344 303192

Perclose, Inc.
199 Jefferson Drive
Menlo Park, CA 94025
U.S.A.
Phone: 415 473-3100
Fax: 415 473-3110

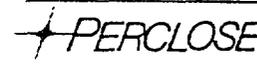
STERILE and NON-PYROGENIC in unopened,
undamaged package. Sterilized with ethylene
oxide. For SINGLE USE only. Do not
resterilize. Read Prostar Percutaneous
Vascular Surgical Device package insert prior
to use. Store in a cool, dry place.

Inhalt ist STERIL solange die Verpackung
ungeöffnet und unbeschädigt ist. Auf
PYROGENFREIHEIT geprüft. Sterilisiert mit
Äthylenoxid. Nur zur EINMALIGEN
VERWENDUNG bestimmt. Nicht
resterilisieren. Bitte vor jedem Einsatz die
Gebrauchsanweisung genau lesen. Kühl und
trocken aufbewahren.

STERILE et APYROGENE lorsque l'emballage
n'a pas été ouvert ou endommagé. A USAGE
UNIQUE. Ne pas restériliser. Détruire l'objet
après usage. Lire la notice d'instruction pour le
système de fermeture percutanée Prostar
avant toute utilisation. Conserver au frais et au
sec.

STERILE ed APIROGENO a confezione
integra. Sterilizzato con ossido di etilene.
MONCOSO. Da non risterilizzare. Prima dell'
uso leggere attentamente le istruzioni allegate
alla confezione del sistema di chiusura
percutaneo Prostar. Conservare in luogo
fresco ed asciutto.

El dispositivo es ESTERIL y APIROGENO si el
envase está cerrado y sin daño. Usar solo si el
envase unitario está intacto. Esterilizado con
óxido de etileno. Para UN SOLO USO. No
reesterilizar. Lea las instrucciones para Prostar
Surgical System antes de su uso. Conservar
en un lugar fresco y seco.

PERCLOSE

International Patents Pending

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

100-0093-A

U3

Contents/Inhalt/Contient/Contenuto/Contenido: 1 Unit/Stück/Pièce/Unità/Unidad

PAT-301-03

Perclose® Arterial Tamper Hämostasse Stössel Perclose Noeud de sûreté Perclose Nodo di sicurezza Perclose Nudo di seguridad Perclose

Intended for use exclusively with
the Prostar Vascular Surgical
Device

Ausschließlich zum Gebrauch mit
dem Prostar Chirurgischen Vaskulären
Gerät

Destiné à être utilisé exclusivement
avec le Dispositif Chirurgical Vasculaire
Prostar

Destinato esclusivamente all'uso con il
Dispositivo Chirurgico Vascolare Prostar

Destinado exclusivamente al uso con el
Dispositivo Quirúrgico Vascular Prostar

Sterilization Date:
Sterilisationsdatum:
Date de Stérilisation:
Data di sterilizzazione:
Fecha de esterilización:

Use before:
Verw. bis:
Ut. av.:
Data di scadenza:
Fecha de caducidad:

LOT / Ch.-B.:

Perclose Europe
Asmec Center
Eagle House
The Ring, Bracknell
Berkshire, RG12 1HB
United Kingdom
Phone: 44. 344. 382016
Fax: 44. 344. 303192

Perclose, Inc.
199 Jefferson Drive
Menlo Park, CA 94025
U.S.A.
Phone: (415) 473-3100
Fax: (415) 473-3110

STERILE and NON-PYROGENIC in unopened,
undamaged package. Sterilized with ethylene
oxide. For SINGLE USE only. Do not
resterilize. Read Prostar Percutaneous
Vascular Surgical Device package insert prior
to use. Store in a cool, dry place.

Inhalt ist STERIL solange die Verpackung
ungeöffnet und unbeschädigt ist. Auf
PYROGENFREIHEIT geprüft. Sterilisiert mit
Äthylenoxid. Nur zur EINMALIGEN
VERWENDUNG bestimmt. Nicht
resterilisieren. Bitte vor jedem Einsatz die
Gebrauchsanweisung genau lesen. Kühl und
trocken aufbewahren.

STERILE et APYROGENE lorsque l'emballage
n'a pas été ouvert ou endommagé. A USAGE
UNIQUE. Ne pas restériliser. Détruire l'objet
après usage. Lire la notice d'instruction pour le
système de fermeture percutanée Prostar
avant toute utilisation. Conserver au frais et
au sec.

STERILE ed APIROGENO a confezione
integrata. Sterilizzato con ossido di etilene.
MONOUSO. Da non risterrilizzare. Prima dell'
uso leggere attentamente le istruzioni allegate
alla confezione del sistema di chiusura
percutaneo Prostar. Conservare in luogo
fresco ed asciutto.

El dispositivo es ESTERIL y APIROGENO si el
envase está cerrado y sin daño. Usar solo si el
envase unitario está intacto. Esterilizado con
óxido de etileno. Para UN SOLO USO. No
reesterilizar. Lea las instrucciones para
Prostar Surgical System antes de su uso.
Conservar en un lugar fresco y seco.



International Patents Pending

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

100-0136-A

64

Contents/Inhalt/Contient/Contenuto/Contenido: 1 Unit/Stück/Pièce/Unita/Unidad

PSH-331-01

Perclose® Knot Pusher
Knotenführer Perclose
Système de positionnement du noeud de sûreté Perclose
Sistema per il posizionamento del nodo di sicurezza Perclose
Sistema de colocación del nudo de seguridad Perclose

Intended for use exclusively with
the Prostar Vascular Surgical
Device

Ausschließlich zum Gebrauch mit
dem Prostar Chirurgischen Vasculären
Gerät

Destiné à être utilisé exclusivement
avec le Dispositif Chirurgical Vasculaire
Prostar

Destinato esclusivamente all'uso con il
Dispositivo Chirurgico Vascolare Prostar

Destinado exclusivamente al uso con el
Dispositivo Quirúrgico Vascular Prostar

STERILE and NON-PYROGENIC in
unopened, undamaged package. Sterilized
with ethylene oxide. For SINGLE USE only.
Do not resterilize. Read Prostar Percutaneous
Vascular Surgical Device package insert prior
to use. Store in a cool, dry place.

Inhalt ist STERIL solange die Verpackung
ungeöffnet und unbeschädigt ist. Auf
PYROGENFREIHEIT geprüft. Sterilisiert mit
Äthylenoxid. Nur zur EINMALIGEN
VERWENDUNG bestimmt. Nicht
resterilisieren. Bitte vor jedem Einsatz die
Gebrauchsanweisung genau lesen. Kühl und
trocken aufbewahren.

STERILE et APYROGENE lorsque l'emballage
n'a pas été ouvert ou endommagé. A USAGE
UNIQUE. Ne pas restériliser. Détruire l'objet
après usage. Lire la notice d'instruction pour le
système de fermeture percutanée Prostar
avant toute utilisation. Conserver au frais et
au sec.

STERILE ed APIROGENO a confezione
integrata. Sterilizzato con ossido di etilene.
MONOUSO. Da non risterrizzare. Prima dell'
uso leggere attentamente le istruzioni allegate
alla confezione del sistema di chiusura
percutaneo Prostar. Conservare in luogo
fresco ed asciutto.

El dispositivo es ESTERIL y APIROGENO si el
envase está cerrado y sin daño. Usar solo si
el nevasse unitario está intacto. Esterilizado con
óxido de etileno. Para UN SOLO USO. No
reesterilizar. Lea las instrucciones para
Prostar Surgical System antes de su uso.
Conservar en un lugar fresco y seco.

Sterilization Date:
Sterilisationsdatum:
Date de Stérilisation:
Data di sterilizzazione:
Fecha de esterilización:

Use before:
Verw. bis:
Ut. av.:
Data di scadenza:
Fecha de caducidad:

LOT / Ch.-B.:

Perclose Europe
Asmec Center
Eagle House
The Ring, Bracknell
Berkshire, RG12 1HB
United Kingdom
Phone: 44. 344. 382016
Fax: 44. 344. 303192

Perclose, Inc.
199 Jefferson Drive
Menlo Park, CA 94025
U.S.A.
Phone: (415) 473-3100
Fax: (415) 473-3110

The logo for Perclose, featuring a stylized starburst or asterisk symbol to the left of the word "PERCLOSE" in a bold, sans-serif font.

International Patents Pending

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

100-0202-A

Handwritten signature or initials

Contents: One Unit

Prostar®

Percutaneous Vascular Surgical Device

9Fr.

Pre-Dilator PDL-301-09

Contains:

- One (1) 9Fr. Prostar® Pre-Dilator
- One (1) Prostar Transition Guidewire

STERILE and NON-PYROGENIC in unopened, undamaged package. For SINGLE use only. Do not resterilize. Read package insert prior to use. Store in cool, dry place.

Sterilization Date:

Lot Number:

Perclose Inc.
199 Jefferson Drive
Menlo Park, CA 94025
(415) 473-3100
(800) 256-7341

CE 0044

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PERCLOSE

0104

USE
BEFORE:

U.S. Pat No. 5,417,699

100-0169-C

100-0219-A

Contents: One Unit

Prostar[®]

Percutaneous Vascular Surgical Device

9Fr.

Prostar Device

PSD-201-09

Contains:

One (1) 9Fr. Prostar[®] Percutaneous Vascular Surgical Device

One (1) Perclose[®] Knot Pusher

STERILE and NON-PYROGENIC in unopened, undamaged package. For SINGLE use only. Do not resterilize. Read package insert prior to use. Store in cool, dry place.

Sterilization Date:

Lot Number:

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Menlo Park, CA 94025
(415) 473-3100
(800) 256-7341

CE 0044

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PERCLOSE

USE
BEFORE:

U.S. Pat. No. 5,417,699

100-0171-C

100-0219-A

M

Contents: One Unit

Prostar®

Percutaneous Vascular Surgical Device

11Fr.

Prostar Device

PSD-201-11

Contains:

One (1) 11Fr. Prostar® Percutaneous Vascular Surgical Device

One (1) Perclose® Knot Pusher

STERILE and NON-PYROGENIC in unopened, undamaged package. For SINGLE use only. Do not resterilize. Read package insert prior to use. Store in cool, dry place.

Sterilization Date:

Lot Number:

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Menlo Park, CA 94025
(415) 473-3100
(800) 256-7341

CE 0044

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 PERCLOSE

USE
BEFORE:

100-0219-A

U.S. Pat. No. 5,417,699

100-0172-C

0107



Contents: One Unit

Prostar®

Percutaneous Vascular Surgical Device

11Fr. Pre-Dilator PDL-301-11

Contains:

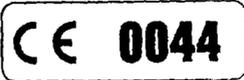
- One (1) 11Fr. Prostar® Pre-Dilator
- One (1) Prostar Transition Guidewire

STERILE and NON-PYROGENIC in unopened, undamaged package. For SINGLE use only. Do not resterilize. Read package insert prior to use. Store in cool, dry place.

Sterilization Date:

Lot Number:

Perclose Inc.
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Menlo Park, CA 94025
(415) 473-3100
(800) 256-7341



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BEFORE:

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U.S. Pat. No. 5,417,696

0105

100-0170-C