Circulation (2004);110:515-21
Distal protection with a filter device during coronary stenting in patients with stable and unstable angina
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BACKGROUND: Filter protection after percutaneous coronary intervention (PCI) is now available to prevent distal embolization. The aims of this study were (1) to evaluate the microembolization phenomenon during procedures of stent implantation in native coronary arteries of patients with stable and unstable angina, (2) to assess the amount and characteristics of the debris captured by the Angioguard, and (3) to investigate the relation between clinical and angiographic variables and pathological data. METHODS AND RESULTS: Elective coronary stenting with the use of a protective filter was attempted in 39 consecutive coronary artery lesions with >60% stenosis (mean, 67.6+/-8.79%). Debris was present in 75.6% of the filters. Particle size ranged from 47.16 to 2503.48 microm (mean, 518.83+/-319.61 microm) in the major axis. Particles >300 microm were found in 24 of 28 filters with debris (85.7%), and particles >1000 microm were present in 10 of 28 filters (35.7%). Patients with unstable angina had greater particles (mean maximum longitudinal diameter, 1098.33+/-714.3 microm) than those with stable angina (412.91+/-453 microm; P<0.001). The presence of unstable angina (OR, 65; CI, 1.2 to 3420; P=0.03) and age >67 years (OR, 42; CI, 1 to 1698; P=0.04) were found to be the only independent predictors of embolic particle size. CONCLUSIONS: By limiting embolization, protective devices may prevent a number of potentially unfavorable events, thereby improving outcome. Our data support the use of these devices, especially in lesions with higher embolic potential, such as those occurring in older patients and in those with unstable angina.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15277328

Catheter Cardiovasc Interv (2004);61:360-3
Safety and feasibility of the use of a distal filter protection device in percutaneous revascularization of small coronary arteries
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The FilterWire EX is one of the filter protection devices developed as alternatives to balloon occlusion system for percutaneous coronary intervention. Its use has been recommended in vessels between 3.5 and 5.5 mm in diameter and no data are available on its use in smaller vessels. We evaluated the safety and feasibility of using FilterWire EX in native coronary arteries smaller than 3.5 mm. We successfully deployed and retrieved the FilterWire EX in 49 coronary arteries with a mean vessel diameter of 2.62 +/- 0.45 mm at device deployment. Reversible vasospasm was observed in 24 (50%) vessels, coronary flow was temporarily reduced in 22 (44.9%), and distal embolization was noted in 2 (4%). There was no vessel dissection induced by the device. These data suggest that it is safe and feasible to use the FilterWire EX in small coronary arteries.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14988896

J Am Coll Cardiol (2004);44:1801-8
Cost-effectiveness of distal embolic protection for patients undergoing percutaneous intervention of saphenous vein bypass grafts: results from the SAFER trial
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OBJECTIVES: The goal of this research was to determine the incremental cost and cost-effectiveness of embolic protection in patients undergoing percutaneous revascularization (PCI) of diseased saphenous vein bypass grafts (SVGs). BACKGROUND: Distal protection using the GuardWire balloon occlusion device has been shown to reduce major ischemic complications in patients undergoing SVG PCI, but the cost-effectiveness of this approach is unknown. METHODS: We prospectively measured medical resource utilization and cost for 801 patients undergoing SVG intervention who were randomized to distal protection using the GuardWire (n = 406) or conventional treatment (n = 395) in the Saphenous Vein Graft Angioplasty Free of Emboli Randomized (SAFER) trial. Long-term survival and cost-effectiveness were projected based on observed 30-day outcomes and a validated survival model for postcoronary artery bypass graft patients. RESULTS: Compared with conventional treatment, distal protection increased initial procedural costs by approximately $1,600 ($6,326 vs. $4,779, p < 0.001). However, by reducing ischemic complications, distal protection reduced mean length of stay by 0.4 days and other hospital costs by nearly $1,000 ($6,846 vs. $7,811, p = 0.018). As a result, overall initial hospital costs were only $582 per patient higher with distal protection. Based on the observed 30-day cost and outcome differences in the trial, the incremental cost-effectiveness ratio for distal protection was $3,718 per year of life saved and remained <$40,000 per year of life saved in 97.3% of bootstrap simulations (95% confidence interval, $0 to $43,079). CONCLUSIONS: For patients undergoing PCI of diseased SVGs, distal protection using the GuardWire system is an attractive use of limited health care resources.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15519010

Catheter Cardiovasc Interv (2005);64:67-74
Prevention of distal embolization and no-reflow in patients with acute myocardial infarction and total occlusion in the infarct-related vessel: A subgroup analysis of the cohort of acute revascularization in myocardial infarction with excimer laser-CARMEL multicenter study
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To overcome the adverse complications of percutaneous coronary interventions in thrombus laden lesions (i.e., distal embolization, platelet activation, no-reflow phenomenon), mechanical removal of the thrombus or distal embolization protection devices are frequently required. Pulsed-wave ultraviolet excimer laser light at 308 nm can vaporize thrombus, suppress platelet aggregation, and, unlike other thrombectomy devices, ablate the underlying plaque. The following multicenter registry was instituted to evaluate the safety and efficacy of laser ablation in patients presenting with acute myocardial infarction (AMI) complicated by persistent thrombotic occlusions. Patients

with AMI and complete thrombotic occlusion of the infarct-related vessel were included in eight participating centers. Patients with further compromising conditions (i.e., cardiogenic shock, thombolysis failures) were also included. Primary endpoint was procedural respective laser success; secondary combined endpoints were TIMI flow and % stenosis by quantitative coronary analysis and visual assessment at 1-month follow-up. Eighty-four percent of all patients enrolled (n = 56) had a very large thrombus burden (TIMI thrombus scale >/= 3), and 49% were compromised by complex clinical presentation, i.e., cardiogenic shock (21%), degenerated saphenous vein grafts (26%), or thrombolysis failures (5%). Laser success was achieved in 89%, angiographic success in 93%, and the overall procedural success rate was 86%. The angiographic prelaser total occlusion was reduced angiographically to 58% +/- 25% after laser treatment and to 4% +/- 13% final residual stenosis after adjunctive balloon angioplasty and/or stent placement. TIMI flow increased significantly from grade 0 to 2.7 +/- 0.5 following laser ablation (P < 0.001) and 3.0 +/- 0.2 upon completion of the angioplasty procedure (P > 0.001 vs. baseline). Distal embolizations occurred in 4%, no-reflow was observed in 2%, and perforations in 0.6% of cases. Laser-associated major dissections occurred in 4% of cases, and total MACE was 13%. The safety and efficacy of excimer laser for thrombus dissolution in a cohort of high-risk patients presenting with AMI and total thrombotic occlusion in the infarct-related vessel are encouraging and should lead to further investigation. Catheter Cardiovasc Interv 2005;64:67-74. (c) 2004 Wiley-Liss, Inc.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15619312

Am J Cardiol (2005);95:173-7
Determinants of 30-day adverse events following saphenous vein graft intervention with and without a distal occlusion embolic protection device
G. R. Giugliano*, et al.*
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Distal balloon occlusion was approved as a means of embolic protection during saphenous vein graft intervention based on its ability to decrease major adverse clinical events (MACEs) by 42% in the 801-patient Saphenous Vein Graft Angioplasty Free of Emboli Randomized (SAFER) trial. However, the cost and technical complexity of this device have limited its widespread use and prompted some to avoid its use in cases that appear at "low risk" for complications. If predictors of MACEs and their potential

grafts is increased in more diffusely diseased grafts and in bulkier lesions, but a significant benefit of the GuardWire was seen across all levels of MACE risk rather than just those perceived to be at highest risk.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15642547

Catheter Cardiovasc Interv (2004);61:293-305
Carotid angioplasty under cerebral protection with the PercuSurge GuardWire System
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The purpose of this study was to examine the possible beneficial effect of the PercuSurge GuardWire cerebral protection device based on balloon occlusion of the distal internal carotid artery and debris aspiration for patients undergoing carotid artery stenting (CAS). A total of 268 CAS procedures were attempted under cerebral protection using the PercuSurge GuardWire system in 242 patients (194 men; mean age, 71.2 +/- 9.4 years; range, 40-91). The lesions were mainly atherosclerotic; 64% were symptomatic. Technical success was 99.3%. All lesions were stented except three postangioplasty restenoses. Prophylactic occlusion during balloon dilatation and stenting was well tolerated in 255 patients (95.9%). Microscopic analysis of the aspirated blood showed different types of particles numbering between 7 and 145 per procedure, with a mean diameter of 250 microm (mean, 56-2,652 microm). The 30-day stroke and death rate was 2.3%, with four periprocedural complications at < 48 hr (one retinal embolism and three transient ischemic attacks), one intracerebral hemorrhage at 3 days, and one death of cardiac failure at 3 weeks. This technique appears safe and efficient with a low rate of periprocedural embolic events. Protection devices seem indispensable to perform CAS and expand the applicability of the procedure. Randomized studies (surgery vs. CAS with and without cerebral protection) are awaited.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14988883

Am J Cardiol (2004);94:1041-3
Comparison of temporary occlusion and aspiration system versus the conventional method during coronary stenting for acute myocardial infarction
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Department of Cardiology, Tsukazaki Memorial Hospital, Hyougo, Japan.
This study evaluated the effects of the temporary occlusion and aspiration device GuardWire on percutaneous coronary intervention for acute myocardial infarction. This device brought about a signi6nal t24i-7/tf((s gl1(Caraemt)-5.2(i)0.fs(indiT(8.1465 a)5.5iso)5.7l prot)-5.
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Percutaneous revascularization of diseased saphenous vein grafts is associated with increased risk of adverse events, although the use of distal protection mitigates this to a significant extent. However, anatomic characteristics may preclude the use of such devices in a proportion of vein grafts intended for percutaneous treatment. We reviewed our consecutive experience of saphenous vein graft interventions from 1 May 2001 through 30 April 2002 to determine suitability for distal protection. Relevant angiographic characteristics included lesion within 5 mm of the ostium; lesion < 20 mm from the distal anastomosis; planned distal landing site of the occlusion balloon < 3 mm or > 6 mm in diameter; total occlusion of the vein graft; or lesion in a sequential vein graft distal to the first anastomosis. One hundred twenty-seven patients (140 procedures, 147 vein grafts) were treated. One or more of the angiographic exclusion criteria for a balloon occlusion protection system existed in 57% of grafts, while 42% had exclusions for a filter device. A large number of patients with vein graft disease intended for percutaneous treatment have anatomic exclusions to available distal protection technology.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15390255

Circulation (2004);109:1735-40
Embolic protection with filtering or occlusion balloons during saphenous vein graft stenting retrieves identical volumes and sizes of particulate debris
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BACKGROUND: Distal embolization of plaque particulate liberated during stenting may cause periprocedural complications. The number, size, and volume of debris released during stenting, however, have not been quantified, rendering embolic protection approaches empiric. We used a novel method of microparticle size assessment to measure volume and characterize individual sizes of particles captured by the PercuSurge GuardWire balloon or a vascular filter during saphenous vein graft stenting. METHODS AND RESULTS: Braided nitinol filters (average distal pore size 100 microns) were used in 47 saphenous vein grafts in 44 patients. The PercuSurge GuardWire was used in 17 saphenous vein grafts in 16 patients. Particulate debris was subjected to microparticle size analysis

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15066954

Catheter Cardiovasc Interv (2004);63:1-6
Carotid stenting with a new system for distal embolic protection and stenting in high-risk patients: the carotid revascularization with ev3 arterial technology evolution (CREATE) feasibility trial
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The purpose of this study was to evaluate the feasibility of carotid artery revascularization using a new system for carotid stenting and distal embolic protection in 30 patients with severe carotid stenosis and high risk for carotid endarterectomy (Carotid Revascularization With ev3 Arterial Technology Evolution, or CREATE). Previous studies suggest that patients with carotid stenosis and serious comorbid cardiopulmonary and anatomic conditions are at high risk for carotid endarterectomy. All patients underwent percutaneous revascularization using the Protege GPS self-expanding nitinol stent (ev3, Plymouth, MN) and the Spider distal embolic protection system (ev3). In-hospital and 30-day outcomes were analyzed. High-risk features included age > 75 years (63%), left ventricular ejection fraction < 35% (20%), and restenosis after prior carotid endarterectomy (53%). Procedural success was 100%. In-hospital complications included severe vasovagal reactions in six patients (20%) and a popliteal embolus in one patient (3.3%), treated by successful embolectomy. During 30 days of follow-up, two patients (6.6%) experienced minor neurological deficits, including transient expressive aphasia that resolved without therapy in one patient and homonymous hemianopsia due to contralateral posterior circulation stroke in one patient. This study supports the feasibility of percutaneous carotid artery revascularization with the Protege GPS self-expanding stent and Spider distal embolic protection system, which will be evaluated in a large multicenter pivotal trial (CREATE Pivotal Trial).
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15343559

J Am Coll Cardiol (2004);44:1966-9
Effect of two different neuroprotection systems on microembolization during carotid artery stenting
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OBJECTIVES: This study sought to compare the efficacy of two different cerebral protection systems for the prevention of embolization during carotid artery stenting (CAS) using a transcranial Doppler (TCD) monitoring with the detection of microembolic signals (MES). BACKGROUND: Despite the introduction of cerebral protection systems, neurologic complications during CAS cannot completely be prevented. Transcranial Doppler and detection of MES may aid in assessing the efficacy of different neuroprotection systems. METHODS: A total of 42 patients with internal carotid artery stenoses were treated by CAS using either a filter (E.P.I. FilterWire, Boston Scientific

Corp., Santa Clara, California) (n = 21) or a proximal endovascular clamping device (MO.MA system, Invatec s.r.l., Roncadelle, Italy) (n = 21). Microembolic signal counts were compared during five phases: placement of the protection device, passage of the stenosis, stent deployment, balloon dilation, and retrieval of the protection device. RESULTS: There were no significant differences in clinical or angiographic outcomes between the two groups. Compared to the filter device, the MO.MA system significantly reduced MES counts during the procedural phases of wire passage of the stenosis, stent deployment, balloon dilation, and in total (MES counts for the filter device were 25 +/- 22, 73 +/- 49, 70 +/- 31, and 196 +/- 84 during the three phases and in total, MES counts for the MO.MA system were 1.8 +/- 3.2, 11 +/- 19, 12 +/- 21, and 57 +/- 41, respectively; p < 0.0001). CONCLUSIONS: In comparison to a filter device the MO.MA system led to significantly lower MES counts during CAS. The detection of MES by TCD may facilitate the evaluation and comparison of different neuroprotection systems.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15542277

Am J Cardiol (2004);94:1134-9
Effectiveness and safety of the Proxis system in demonstrating retrograde coronary blood flow during proximal occlusion and in capturing embolic material
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The Feasibility And Safety Trial for its embolic protection device during transluminal intervention in coronary vessels: a European Registry (FASTER) was designed to demonstrate that (1) the Proxis embolic protection system can control anterograde flow and reverse blood flow in native coronary arteries and saphenous vein grafts; and (2) this system can capture embolic debris. Percutaneous coronary intervention on stenotic coronary lesions revolutionized treatment of coronary disease, but is associated with the risk of major adverse cardiac events. This prospective, nonrandomized, multicenter clinical feasibility and safety study enrolled 40 patients with 51 lesions at 4 centers who who yroEand .8( )hw.ncb9.06esi.

Department of Cardiovascular and Interventional Radiology, University of Texas Health Science Center, San Antonio, Texas.
The objectives of this study were to reduce the risk of showering distal vessels with thromboemboli created during percutaneous interventions of the arteries in the lower extremities. Distal protection devices have been used in coronary and carotid interventions. Hence, using similar techniques, these filters and occlusion balloons were advanced past the targeted lesions and distally into femoral and popliteal arteries. Once opened, these devices allowed standard angioplasty and stent placement and captured the dislodged thromboemboli. Five cases were performed with the distal protection devices. One case used the distal occlusion balloon and four with the filter system. All five passed the lesion and were deployed. All five devices were retrieved without incident and were retrieved with substantial debris. There were no adverse events. The use of distal protection to treat high-risk or unstable lesions in the lower extremities shows great promise. Further case will be needed to evaluate the device for feasibility and safety. Catheter Cardiovasc Interv 2005;64:227-235. (c) 2005 Wiley-Liss, Inc.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15678460

Catheter Cardiovasc Interv (2005);64:35-42
Six-month angiographic results of primary angioplasty with adjunctive PercuSurge GuardWire device support: Evaluation of the restenotic rate of the target lesion and the fate of the distal balloon occlusion site
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Recently, the combination of primary percutaneous coronary intervention (PCI) and adjunctive PercuSurge device support has been reported to be superior to conventional primary PCI in terms of immediate angiographic results. However, there are no data regarding 6-month angiographic results for either the treatment site or the site of the distal protection balloon. The purpose of this study was to address these two issues. Between May and November 2002, a total of 74 patients who had experienced acute myocardial infarction (AMI) underwent either primary PCI (48 patients within 12 hr of AMI) or elective PCI (26 patients with AMI of > 12 hr and < 72 hr) using the PercuSurge device through a transradial approach. The final TIMI 3 flow and myocardial blush grade >/= 2 achieved were 94% and 93%, respectively. Of these patients, three died in the hospital, two died in the third month after discharge, and the remainder of the patients were followed up in our outpatient department for a mean of 13 +/- 2.9 months. Six-month angiographic follow-up was performed in 85.5% (59/69) of patients. The angiographic restenotic rate (defined as >/= 50% restenosis at the target lesion site) was 22.0% (13/59) of patients. However, only 11.9% (7/59) of patients required repeat target vessel revascularization. Moderate obstruction at the site of the distal protection balloon was found in 5.1% (n = 3) of patients during PCI. Six-month angiographic results demonstrated that all three patients had significant stenosis at the site of the distal protection balloon that required PCI. PercuSurge device utilization during PCI in the clinical setting of AMI yielded a substantially higher rate of immediate final TIMI 3 flow in epicardial vessels and increased the integrity of the microvasculature. Combined therapy of PCI with the PercuSurge device appeared to have favorable late angiographic results at the target site. Late significant stenosis occurred at the site of

the distal protection balloon if a preexisting moderate or more advanced atherosclerotic lesion was present there. Catheter Cardiovasc Interv 2005;64:35-42. (c) 2004 Wiley-Liss, Inc.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15619316

Am J Cardiol (2005);95:297-300
Symptomatic patients have similar outcomes compared with asymptomatic patients after carotid artery stenting with emboli protection
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In a single-center cohort of 174 consecutive patients, we sought to evaluate whether the use of emboli protection devices (EPDs) results in equivalent rates of adverse events in symptomatic and asymptomatic patients after carotid artery stenting (CAS) with EPDs. Death or stroke occurred in 3.3% in the symptomatic group and in 3.5% of the asymptomatic group at 30 days (p = NS). At 6 months, there was also no significant difference in the rate of stroke or death between the groups. Unlike surgical revascularization, symptomatic patients did not have a greater risk for stroke and death compared with asymptomatic patients after CAS with EPDs.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15642577

Catheter Cardiovasc Interv (2004);61:503-11
Transradial application of PercuSurge GuardWire device during primary percutaneous intervention of infarct-related artery with high-burden thrombus formation
H. K. Yip*, et al.*
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A large infarct-related artery (IRA), which mostly contains high-burden thrombus formation (HBTF) and lipid pool-like plaque contents, has been suggested to play a pivotal role in the no-reflow phenomenon during primary percutaneous coronary intervention (p-PCI). To reduce the thrombus burden of the IRA using the PercuSurge GuardWire device before intervention may be of crucial importance to preventing no-reflow. The purposes of this study were to test the transradial application (TRA) of this new mechanical device and to determine its impact on prevention of no-reflow during p-PCI. From May to September 2002, the PercuSurge GuardWire device was utilized in 42 consecutive patients with acute myocardial infarction and large IRA (vessel size >or= 3.5 mm with HBTF; group 1). From January to December 2000, p-PCI was performed in large IRA (vessel size >or= 3.5 mm) with HBTF using tranfemoral arterial approach in 101 consecutive patients (group 2). The angiographic and clinical outcomes of the two groups were compared in a chronologically consecutive manner. Successful reperfusion (final TIMI-3 flow) was significantly higher in group 1 than in group 2 patients (95.2% vs. 79.1%; P = 0.005). Moreover, the combined incidence of vascular complications, post-PCI thromboembolisms (defined as a distal embolism and a post-PCI residual thrombus score of >or= 3), and combined 30-day major adverse cardiac events were significantly lower in group 1 than in group 2 patients (all P values < 0.05). In group 1 patients, post-p-PCI myocardial blush (MB) of >or= 2 grades was

found to be more than 88.0%. Furthermore, when compared with preintervention, thrombus scores were significantly reduced after aspiration (P = 0.0001), whereas the minimal lumen diameter (P = 0.0001), TIMI flow grade (P = 0.0001), and MB grade (P = 0.0001) had all significantly increased after aspiration using Export Aspiration Catheter. There were no significant differences in corrected TIMI frame count (P = 0.42), TIMI flow grade (P > 0.5), or MB grade (all P values > 0.5) between postaspiration and post-PCI. The TRA of the PercuSurge GuardWire device during primary intervention of large IRA with HBTF was safe and feasible and provided benefits to patients. The initial successful reduction of the thrombus burden with this mechanical device before intervention can be translated into increased final TIMI-3 flow, a combined MB of >or= 2 grades, and fewer final thromboembolic events.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15065147

Am J Cardiol (2005);95:511-4
A novel, low-profile filter-wire (Interceptor) embolic protection device during saphenous vein graft stenting
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A novel, low-profile filter embolic protection device was deployed in 26 patients who underwent stent deployment for saphenous vein graft stenoses in a multicenter trial. Major adverse cardiovascular events were observed in only 2 patients (7.7%) and angiographic flow grades were improved.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15695142