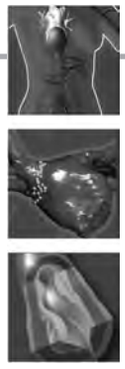

# Evidence for mesh-covered stent implantation in ST-segment elevation myocardial infarction

Primary percutaneous coronary intervention for acute myocardial infarction offers the highest effectiveness in achieving patency of the infarct-related artery. However, the presence of normal coronary flow in the infarct-related artery does not always translate into the restoration of myocardial perfusion through cardiac microcirculation. Several pharmacological agents, as well as mechanical devices (i.e., aspiration catheters, mechanical thrombectomy, distal protection devices) were introduced in recent years to reduce the risk of distal embolization during primary percutaneous coronary intervention and to improve myocardial reperfusion. Recently, a new device has been introduced in the market, aiming to protect microcirculation: the MGuard™ stent (InspireMD, Tel Aviv, Israel), a bare-metal stent covered by micron-level mesh, which prevents distal embolization by blocking the prolapse of thrombi through the stent struts during deployment. This article discusses data concerning safety and efficacy of mesh-covered stent implantation in an ST-segment elevation myocardial infarction setting.

**KEYWORDS: embolization ▪ mesh ▪ myocardial infarction ▪ primary angioplasty ▪ stent ▪ thrombus**

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Primary percutaneous coronary intervention (PCI) is the preferred method for reperfusion in ST-segment elevation myocardial infarction (STEMI) when logistically feasible [1]. Despite stent implantation during primary PCI being effective in epicardial vessel flow restoration, as mirrored by the high incidence of Thrombolysis In Myocardial Infarction (TIMI) grade 3 in the infarct-related artery, impaired myocardial perfusion still occurs, according to low final myocardial blush grade (MBG) and poor complete (>70%) ST-segment resolution achieved in two-thirds of patients undergoing urgent PCI [2,3]. Impaired myocardial reperfusion may be caused by distal embolization of thrombus or plaque debris [4,5]. Importantly, patients with impaired myocardial reperfusion are at higher risk of larger irreversible myocardial injury, higher incidence of adverse remodeling of the left ventricle leading to consequent heart failure, as well as at higher risk of death during short- and long-term follow-up [3,4].

## Overview of the market

Reduction of the risk of distal embolization during primary PCI for STEMI and improvement of myocardial reperfusion is an issue of special importance. The risk of distal embolization during primary PCI may be reduced by the use of thrombectomy/aspiration catheters and distal protection devices, especially in the setting of high-thrombus burden [6,7]. However, two large randomized trials (the EMERALD [8] and the ASPARAGUS [9] trials) with a distal occlusive device – PercuSurge GuardWire™ (Medtronic) – have failed to show any benefit of distal protection during primary PCI for STEMI. In the PROMISE trial the use of filters (FilterWire EZ™ [Boston Scientific]) was not associated with improvement in myocardial reperfusion and reduction of infarct size (as evaluated by cardiac magnetic resonance) in comparison to conventional PCI [10]. In the pooled analysis of seven trials with distal protection devices, despite benefits in terms of myocardial perfusion, no mortality reduction was observed [7]. The routine use of proximal (e.g., Proxis™ Embolic Protection System [St. Jude Medical]) and distal (e.g., PercuSurge GuardWire and FilterWire EZ) protection is not currently recommended during primary PCI for STEMI [11]. In contemporary clinical practice the usage rate of embolic protection devices during PCIs, even during saphenous vein graft interventions, is low (less than 25% of cases) [12].

On the other hand, in several studies, the use of simple, manual aspiration catheters before stenting during primary PCI was associated with improved myocardial reperfusion in comparison to standard balloon predilatation followed by stent implantation [6,13,14]. The TAPAS study [14,15], as well as meta-analyses from De Luca *et al.* [6] and Burzotta *et al.* [16] have shown clinical benefit including mortality reduction in

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**Table 1. Alternative devices.**

| Device examples | Advantages | Disadvantages | Recommendations |
|---|---|---|---|
| ***Distal protection systems*** | | | |
| GuardWire™ (Medtronic, Santa Rosa, CA, USA)<br>Spider™ (ev3, Plymouth, MN, USA)<br>FilterWire™ EZ Embolic Protection System (Boston Scientific, Mountain View, CA, USA) | Provides protection against distal embolization during each balloon inflation<br>Complete distal protection from all the particles and humoral mediators (for distal occlusion devices) | Distal embolization is possible from the mobilization of thrombi in the entire arterial segment when device crosses the target lesion<br>Distal landing zone is required<br>Has no ability to prevent distal embolization of side branches originating between site of occlusion and the device<br>Loss of small particles and humoral mediators (for filters)<br>Potential filter thrombosis (for filters)<br>No thrombus fragmentation<br>Training required<br>Cost<br>Lack of general acceptance for routine use | Distal embolic protection is recommended during PCI of saphenous vein graft disease to avoid distal embolization of debris and prevent myocardial infarction (I B, according to ESC/EACTS 2010 Guidelines on myocardial revascularization)<br>No recommendation for routine use in the STEMI setting |
| ***Proximal protection devices*** | | | |
| Proxis™ Embolic Protection System (St. Jude Medical, St. Paul, MN, USA) | Interruption of anterograde blood flow before crossing with guidewire may reduce the risk of distal embolization associated with passing with guidewire<br>Provides protection against distal embolization during each balloon inflation<br>Ability to use guidewire of choice | Proximal landing zone is required, may be unfeasible in the ostial and proximal localization of the target lesion<br>May be unfeasible in the small target vessels<br>Continuous visualization of the target lesion can be limited<br>Training required<br>No clinical benefits in comparison to standard primary PCI<br>Cost<br>Lack of general acceptance for routine use | Proximal embolic protection may be considered for preparation before PCI of saphenous vein graft disease (IIb B, according to ESC/EACTS 2010 Guidelines on myocardial revascularization).<br>No recommendation for routine use in the STEMI setting |
| ***Aspiration catheters/thrombectomy devices*** | | | |
| Export™ catheter (Medtronic, Santa Rosa, CA, USA)<br>Diver CE™ (Invatec, Roncadelle, Italy)<br>Eliminate™ (Terumo Europe NV, Leuven, Belgium)<br>Pronto™ catheter (Vascular Solution, Minneapolis, MN, USA)<br>Fetch™ catheter (Medrad Interventional/Possis, Warrendale, PA, USA)<br>RIO™ catheter (Boston Scientific, Natick, MA, USA)<br>Thrombuster™ III (Kaneka Corp., Osaka, Japan)<br>Angiojet™ (Possis Medical, Minneapolis, MN, USA)<br>X-Sizer™ (ev3, Plymouth, MN, USA)<br>Rescue catheter (Boston Scientific/Scimed, Maple Grove, MN, USA) | No landing zone required<br>Ability to perform angiography during the procedure<br>Ability to use guidewire of choice<br>Mortality benefit confirmed in patients with STEMI treated with simple, manual aspiration catheters | Does not prevent distal embolization from the material shed during stent implantation or following postdilatations<br>Large crossing profile, has limited ability to reach the distal segments in tortuous and/or highly calcified vessels<br>Potentially may cause mechanically induced distal embolization<br>No thrombus fragmentation (for simple, manual aspiration catheters)<br>Effectiveness may be reduced in large (>4 mm) vessels (for simple, manual aspiration catheters)<br>Training required (for active thrombectomy devices, i.e., AngioJet) | Manual catheter thrombus aspiration should be considered during PCI of the culprit lesion in STEMI (IIa A, according to ESC/EACTS 2010 Guidelines on myocardial revascularization) |

*EACTS: European Association for Cardio-Thoracic Surgery; ESC: European Society of Cardiology; PCI: Percutaneous coronary intervention; STEMI: ST-segment elevation myocardial infarction.*
*Data taken from* [6–11].

patients with STEMI treated with manual aspiration catheters. However, in patients treated with aspiration catheters before primary PCI with stenting, distal embolization occurs in more than 6% [17], suggesting that the use of such devices is unable to completely avoid the risk of debris protrusion or migration during stent implantation. In such clinical scenarios, the use of a mesh-covered stent – such as the MGuard stent (MGuard™ Coronary Stent System, InspireMD Ltd., Tel Aviv, Israel) [18–21] – seems a valuable option. Importantly, there is also possibility to use the MGuard stent with other devices, for example, after the use of aspiration catheters.

## Introduction to the device

The MGuard stent is a new device intended to prevent distal embolization by thrombus and plaque fragments released during stent implantation in thrombus-containing lesions. The MGuard stent is a bare-metal stent covered with an ultra-thin, micron-level, flexible mesh (Figure 1). The mesh, secured to the coronary stent, acts like a net and locks the potentially embolic particles or thrombus material rising during the interventional treatment behind the mesh against the vessel wall. Additionally, the sleeve may reduce the impact on the arterial wall and may reduce injury, thereby possibly lowering the restenosis rate. Also, mesh may facilitate re-endothelialization by serving as a scaffold. Optimal stent upsizing or post-dilatation with less concern of embolization is possible.

No special training is required for MGuard stent use, as the technique of implantation is the same as for conventional balloon-inflated coronary stents. Unlike distal protection devices (filters), no specific distal or proximal landing zone is required (Table 1). Deliverability and crossing profile remain virtually unchanged and deployment pressures are not affected. The MGuard stent is also available as MGuard Prime with cobalt–chromium design, and improved flexibility and deliverability. The sleeve patented mechanism prevents possible sliding, folding or dislodgement. However, small balloon predilatation using low pressures before stent implantation may facilitate deliverability of the stent. MGuard stent is not recommended in vessels with extreme tortuosity or heavy calcifications, as it may impede successful passage of the system. It is not recommended to use such a stent for treatment of the lesions located distally to previously implanted coronary stents. In addition, the MGuard stent system allows the perfusion of covered side branches. However, the data concerning the use of mesh-covered stent within bifurcation lesions, including accessibility of side branches originating at the site of stent implantation and possibility of post-dilatation with kissing balloons technique, are rather limited.

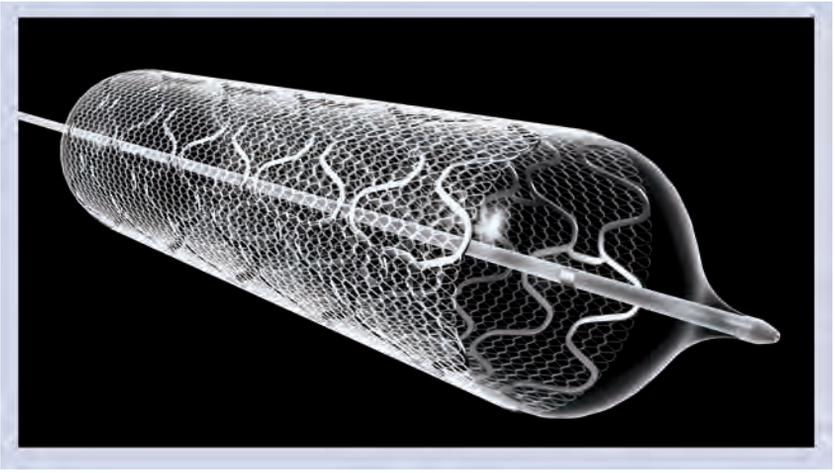

**Figure 1. MGuard™ stent is composed of a standard bare-metal stent, wrapped with a flexible micron net and mounted on a rapid exchange delivery system.**
Reproduced with permission from InspireMD, Tel Aviv, Israel.

## Clinical profile & postmarketing findings

MGuard stent was evaluated in a first-in-man trial in 29 patients with a mean age of 68.1 ± 12 years and acute coronary syndrome presentation in 72.4% [22]. Stents were implanted in both native coronary arteries (41.4%) and degenerated coronary vein grafts (58.6%). PCI with the MGuard stent was feasible and safe. The incidence of major adverse cardiac events was acceptable, and there were no incidents of PCI-related stent thrombosis, Q-wave myocardial infarction or cardiovascular death [22]. Observed rate of target vessel revascularization for the MGuard stent was 11.1%, with a mean late loss of 0.372 ± 0.23 mm and a mean percent diameter stenosis of 30.6% [18].

In the INSPIRE Study, a total of 30 patients with *de novo* lesions in saphenous vein graft or native vessels with angiographic evidence of instability with potential to provoke flow disturbances and/or distal embolization were included. Overall, 53.3% presented with acute coronary syndrome, and most lesions were located in the saphenous vein graft (53.3%). The MGuard stent was successfully implanted in all cases, and final TIMI grade 3 flow was achieved in all patients. There was no case of distal embolization during angioplasty [23]. At 6 months, routine control angiography was performed in all cases

and reported in-stent late loss and percentage of stent obstruction were 0.99 ± 0.70 mm and 31 ± 15.6%, respectively. During 1-year follow-up there were no cases of cardiac death, two (6.6%) cases of myocardial infarction and six (20%) cases of ischemia-driven target-vessel revascularization. Importantly, there was no stent thrombosis during the long-term follow-up period [24].

Data on 100 consecutive STEMI patients (16% of patients in shock) treated with primary (68 patients) or rescue (32 patients) PCI with MGuard stent implantation were reported by Piscione *et al.* [21]. In this multicenter study, the MGuard stent was implanted successfully in all patients and was able to achieve optimal myocardial reperfusion (MBG 3), as well as complete ST-segment resolution 60 min after PCI in 90% of patients. Thrombus aspiration was used in 10% of patients, and direct-stenting technique in 58% of patients. Observed in-hospital mortality was quite high (7%), mainly due to inclusion of shock patients. In two patients, subacute stent thrombosis occurred (one related to type B dissection at the distal edge of the stent, and the second probably occurred as a consequence of device undersizing). No additional major cardiovascular events have been reported during 1-month follow-up [21].

Safety and feasibility of MGuard implantation in STEMI patients were also confirmed by data from 60 patients enrolled in the MAGICAL Study [25]. In this study, the MGuard stent was successfully implanted within the target lesion in 98.3% of patients. Thrombus aspiration was used in 18.3% of patients, and direct-stenting technique in 38.3% of patients. The frequency of final TIMI grade 3 flow, MBG 3 and complete (>70%) ST-segment resolution 60–90 min after PCI assessed by an independent core laboratory was 90.0, 73.3 and 61.4%, respectively. The rate of distal embolization was 5%. There was no death, reinfarction related to target vessel or ischemic target-lesion revascularization during 6-month follow-up. By protocol definition, the total major adverse cardiac events rate at 6 months was 1.7% [25].

Similarly, 6-month clinical and angiographic outcomes for 100 STEMI patients were recently reported by Apro *et al.* In this single center, prospective, single-arm study predilatation was performed in 77% of cases and thrombus aspiration in 18%. Final TIMI grade 3 flow was observed in 96% of patients, and distal embolization in one (1%) patient. The in-hospital rate of major adverse cardiac events was 3%. Angiographic follow-up at 6 months demonstrated 19% of binary restenosis. There was no case of clinically driven target-vessel revascularization during the 6-month follow-up period [26].

In addition, the safety and efficacy of MGuard stent implantation during primary PCI for STEMI was confirmed by Weerackody *et al.* [27]. In this study, 51 patients were successfully treated with MGuard stent implantation. TIMI grade 3 flow was achieved in all cases, without procedural complications, and ST-segment elevation resolution >50% after PCI was reported for 96% of patients. There were two deaths (both in patients with cardiogenic shock) during hospital stay. Among

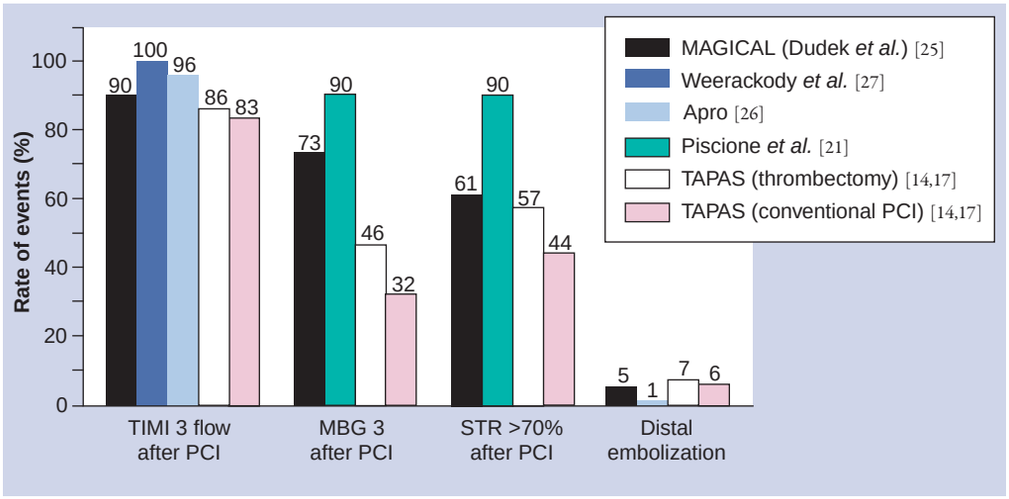


**Figure 2. Angiographic and electrocardiographic results of studies assessing the impact of MGuard™ stent implantation during primary angioplasty for ST-segment elevation myocardial infarction.** Data from the MAGICAL study represent independent core laboratory assessment. Results of the TAPAS study given as comparison.
MBG: Myocardial blush grade; PCI: Percutaneous coronary intervention; STR: ST-segment elevation resolution; TIMI: Thrombolysis In Myocardial Infarction.

nonshock patients, target-vessel revascularization rate at 1 year was 6%, without stent thrombosis occurrence [27]. Angiographic and electrocardiographic results of major studies assessing MGuard stent during primary PCI for STEMI are shown in Figure 2.

In the ongoing iMOS Registry more than 1000 patients will be enrolled and treated with MGuard stent in all approved indications. The interim analysis of 200 patients (77% with STEMI), presented by Danzi during EuroPCR 2010, revealed a 98% success rate, 96% rate of TIMI grade 3 flow after PCI and ST-segment elevation resolution >50% in 76% of patients [28]. Subanalysis of 157 STEMI patients from 211 patients enrolled revealed 1.9% rate of death, 1.3% rate of reinfarction and no need of repeated target vessel revascularization during 30-day follow-up. The total major adverse cardiac events rate was 2.5% [28].

The MASTER study, a large, randomized, multicentre study of 406 patients with STEMI treated with primary or rescue PCI is planned to compare MGuard stent implantation to standard bare-metal/drug-eluting stents (with or without prior thrombus aspiration). The primary end point of the study is the frequency of complete ST-segment resolution after PCI. Also, a second randomized study, called GUARDIAN [101], comparing MGuard versus thrombus aspiration with bare-metal stent implantation is ongoing.

## How does the technology fit into the field of medical devices?

According to current European Society of Cardiology/European Association for Cardio-Thoracic Surgery Guidelines on myocardial revascularization, the use of mesh-based protection may be considered for PCI of highly thrombotic or coronary vein graft lesions (IIb C) [11]. The MGuard stent is a bare-metal stent approved in the European community for use in native coronaries and saphenous vein grafts – CE mark registration number 51168-23-A0 was delivered on 13 November 2007. Based on the CE approval, MGuard stent also received approval in countries including: Australia, Brazil, Argentina, Mexico, Israel, South Africa, India, Pakistan, Thailand and Taiwan. MGuard Prime (not yet available for sale) received CE approval with a specific acute myocardial infarction indication. Both MGuard and MGuard Prime are not available in the USA and Japan.

## Executive summary

***Advantages of the MGuard™ stent***

- No special training is required.
- No specific distal or proximal landing zone is required.
- Deliverability and crossing profile remain virtually unchanged and deployment pressures are not affected.
- The sleeve may reduce the impact on the arterial wall and may reduce injury, thereby possibly lowering the restenosis rate.
- Mesh may facilitate re-endothelialization by serving as a scaffold.
- Optimal stent upsizing or postdilatation with less concern of embolization.

***Disadvantages of the MGuard stent***

- Not recommended in vessels with extreme tortuosity or heavy calcifications.
- Not recommended for lesions located distally to previously implanted coronary stents.
- Data concerning the use of mesh-covered stent within bifurcation lesions, including accessibility of side branches originating at the site of stent implantation and possibility of postdilatation with kissing balloons technique, are rather limited.

***Clinical efficacy in ST-segment elevation myocardial infarction***

- More than 600 ST-segment elevation myocardial infarction patients treated with MGuard stent have been reported.
- High procedural success rate.
- Final Thrombolysis In Myocardial Infarction grade 3 flow in 90–100% of patients.
- Final myocardial blush grade 3 in 73–90% of patients.
- Complete ST-segment elevation resolution >70% after percutaneous coronary intervention in 61–90% of patients.
- Distal embolization in 1–5% of patients.
- Low rates of major adverse cardiac events at 30 days and 6 months.
- Large 'real-world' registry is ongoing.
- Randomized clinical trials planned.

***Availability***

- CE marked.
- Not available in the USA and Japan.

***Recommendations***

- May be considered for percutaneous coronary intervention of highly thrombotic or coronary vein graft lesions (IIb C, according to European Society of Cardiology/European Association for Cardio-Thoracic Surgery 2010 Guidelines on myocardial revascularization).

## Conclusion

The use of MGuard stent during primary PCI for STEMI is an attractive option as the completed studies have shown that use of the stent is safe and effective. The MGuard stent and aspiration catheters could be used as complementary, rather than competitive devices during primary PCI in STEMI.

## Future perspective

The mesh can also potentially be used as a platform for drug delivery, especially for drug molecules with reduced diffusion capabilities. The mesh may provide more uniform coverage of arterial wall than a regular drug-eluting stent and thus may give better control of vessel healing and re-endothelialization. Case report data support the use of the MGuard stent in the case of coronary vessel perforation, however, the efficacy of such an approach was not tested in clinical studies [29]. The MGuard concept may also be used during stenting of carotid or peripheral arteries by applying the mesh onto a dedicated self-expanding stent.

## Information resources

- www.inspire-md.com/; InspireMD website with MGuard brochures, presentations and study results.
- http://cardio.pl/; educational website with lectures, scientific reports and case presentations.


### Financial & competing interests disclosure

*Dariusz Dudek, received a research grant as Principal Investigator for the MAGICAL study. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.*

*No writing assistance was utilized in the production of this manuscript.*


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101 MGuard Stent in ST-elevation Myocardial Infarction (GUARDIAN) http://clinicaltrials.gov/ct2/show/NCT01124942