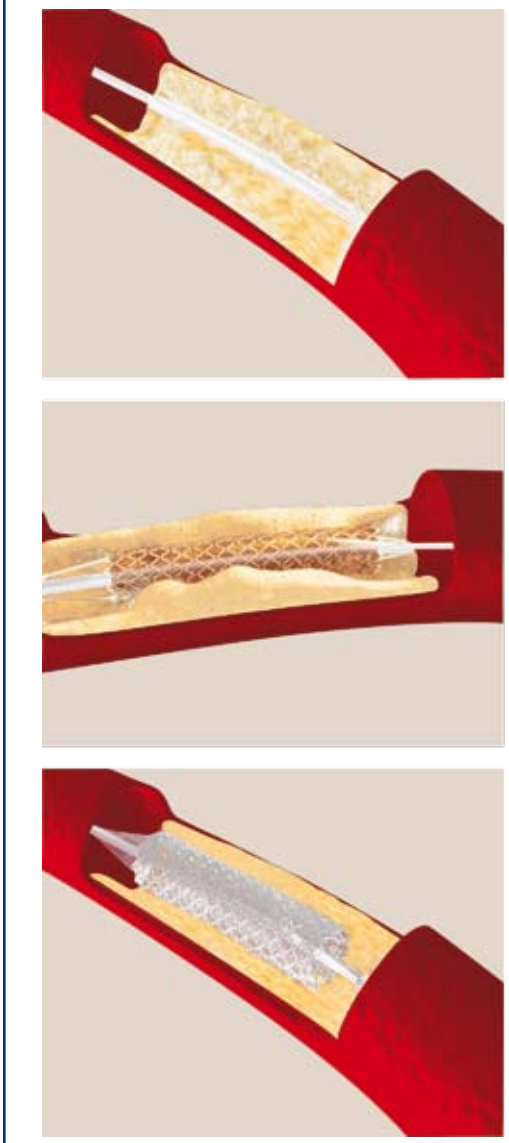

Net Protective Stent
MGUARD

MGuard™ Net Protective Stent

MGuard™ - A stent and embolic protection device merged into one

MGuard™ represents an innovative approach to the challenge of embolic showers. It provides a high degree of embolic protection during and post procedure, while maintaining the same deliverability as an ordinary stent.

MGuard™ is designed to address the key clinical issues of stenting: restenosis and thrombosis. MGuard™ also introduces a unique concept of merging a stent and an embolic protection into one device.
This breakthrough approach is designed to significantly reduce the risk of embolic dislodgment.



MGuard™ blocks debris from entering the bloodstream – during and post procedure

MGuard™ is based on our proprietary design of a stent wrapped with an ultra-thin mesh sleeve of an optimized aperture size. The sleeve blocks plaque from detaching thus providing protection during and post procedure. Our advanced technology presents a simpler and safer alternative.

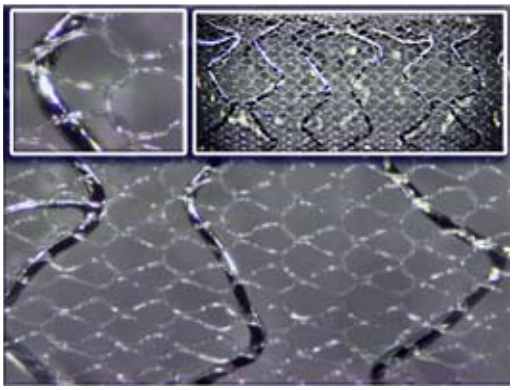
The protective sleeve is comprised of a micron level fiber knitted mesh, engineered in an optimal geometrical configuration designed for utmost flexibility while retaining the fiber's strength. Due to this design the sleeve seamlessly expands when the stent is deployed, without affecting the structural integrity of the stent.

MGuard™ is specifically designed to lower restenosis rate by reducing injury to the arterial wall

During stent expansion, the struts exert focal pressure on the arterial wall that causes injury. The injury, which correlates with the depth of the struts penetration into the arterial wall, leads to localized inflammatory and proliferative responses, resulting in neointimal proliferation and ultimately restenosis. The force exerted by a conventional stent is applied to the struts, a relatively small surface area, resulting in high focal pressure on the arterial wall and consequently increased injury. With MGuard™, the force is applied to the struts and to the sleeve combined, resulting in lower and diffused pressure. **The sleeve reduces the impact on the arterial wall and reduces injury, thereby may lower the restenosis rate.**

Can MGuard™ reduce thrombosis?

MGuard™ mesh sleeve provides the endothelial layer with a stable environment, safeguarded from thrombosis. The endothelial cells situated on the mesh sleeve are continuously connected to the basement membrane, as their width is larger than the mesh fiber. This connection is essential for adequate blood supply and waste removal and ensures a stable attachment of each cell to the endothelial layer. Conversely, in a conventional stent the endothelial cells situated on the struts are disconnected from the lumen wall, therefore they are prone to dislodgement rendering the uncovered strut surface thrombogenic. **The optimal healing environment provided by the MGuard™ sleeve significantly reduces the risk of cell detachment and thereby may reduce the risk of thrombosis.**



MGuard™ maintains simple deliverability

MGuard™ is deployed like a conventional balloon inflated stent. Deliverability and crossing profile remain virtually unchanged and deployment pressures are not affected. The sleeve patented mechanism prevents possible sliding, folding or dislodgement. This mechanism is seamlessly released upon stent full expansion.

Animal studies

Coronary porcine studies conducted at MIT-Harvard have established the safety profile of MGuard™. These trials demonstrated good feasibility and absence of safety issues like device thrombosis, animal morbidity or excessive inflammation and neointimal hyperplasia[1].

Histology and histomorphometric data from the MGuard™ stented segments suggest that MGuard™ yielded acceptable inflammatory response (0.8 ± 0.3 on a scale of 0-3), with the absence of medical necrosis, mineralization, neovascularization or granuloma response. Low Schwartz injury scores (0.15 ± 0.1), absence of fibrin score (0 on a scale of 0-3), and exceptionally good endothelization (4 ± 0) were noticed. The extent of intimal hyperplasia was very acceptable (average neointima thickness 260 micron ± 60)[2].

These studies concluded that MGuard™ can be safely delivered with conventional PCI equipment. Thrombosis, animal morbidity or mortality were not observed with the device. The extent of inflammation, endothelization, injury and intimal hyperplasia were similar or better than Bare Metal Stents.

---

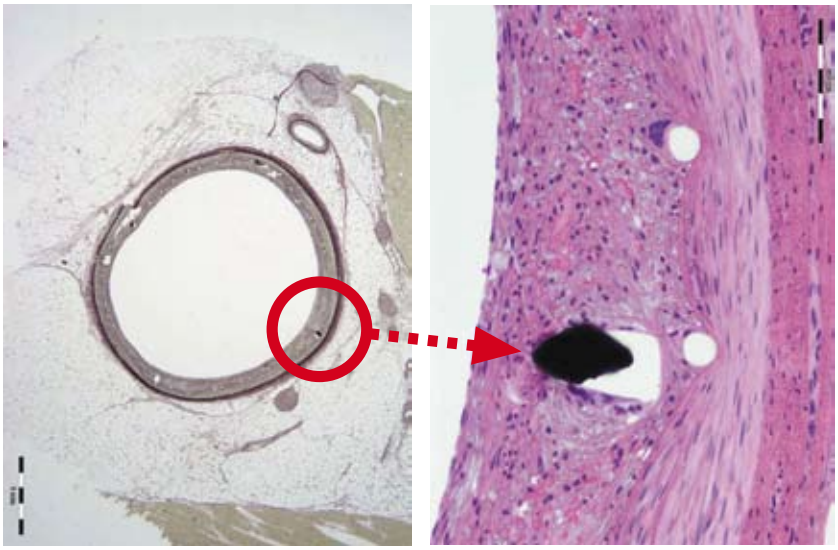
1. The procedure was identical to any standard coronary stenting procedure and used 7F delivery catheters. The MGuard™ stent results compared to BMS control group were tested after three and six months.
2. Kaluski E, Groothuis A, Klapholz M, Seifart P, Edelman E. Coronary stenting with MGuard: feasibility and safety porcine trial. J Invasive Cardiol. 2007;19(8):326-30.

Clinical Trials

An ongoing multi-center trial was initiated to evaluate MGuard™ deliverability and safety in a high risk PCI patients of native coronaries with acute coronary syndromes and degenerated Saphenous Vein Grafts (SVG).
Primary endpoints were 30 days post procedure MACE (Death, Q-wave or non-Q wave, MI, emergent coronary artery bypass surgery or target vessel revascularization).
Secondary endpoints were: device success, clinical procedure success, pre/post-procedural TIMI flow, and 6 month MACE and late loss.

Results

Half of the patients underwent PCI of native coronaries, whereas the other half underwent PCI of a vein graft (mean VG age was 11.8 years). Average patients' age was 70.2 years, majority of the patients were diabetic and presented with acute coronary syndromes. None were treated with Glycoprotein IIb/IIIA inhibitors, embolic protection devices or bivalirudin.



Interim results have shown a procedural success rate of 100% using conventional PCI equipment. There were no reports of any major adverse cardiac events. In follow-ups of 29-168 days no events of cardiovascular death, Q-wave myocardial infarction, stent thrombosis or device failure were reported.

These interim results of the use of MGuard™ in high-risk native coronaries and degenerated SVG are encouraging, especially in view of unfavorable patient and lesion characteristics.

"Based on the animal studies and the interim results in the clinical trial, we are confident that the MGuard™ stent is safe and effective"
Prof. Eberhard Grube, Chief of Department of Cardiology Angiology, Heart Center at Siegburg, Germany.

3. PCI performed with MGuard™ using heparin without glycoprotein IIb/IIIa inhibitors, or embolic protection devices.
4. Defined as successful delivery and deployment of the MGuard™ stent to the target site.
5. Defined as device success without in-hospital death or MACE events.

Specifications

STENT	
Stent Material	Stainless Steel 316
Stent Design	Low profile
Strut Thickness	Lower than 90 µm.

SLEEVE	
Sleeve Material	Poly Ethylene Terephthalate (PET) Fiber
Fiber Width	Less than 20 micron
Aperture Diameter at expanded mode	~200 micron

DELIVERY SYSTEM	
Guiding catheter size	6F
Nominal Pressure	6 atm.
Rated Burst Pressure	≤ 3.0 mm: 16 atm., ≥ 3.5 mm: 14 atm.
Radiopaque Markers	Proximal and Distal
Balloon Characteristic	Semi-compliant
Usable Catheter Length	1420 mm ± 20 mm

Table of sizes

		Stent Length / mm						
		12	15	19	24	29	34	39
Balloon Diameter /mm	2,00	X	X	X	X	X	X	X
	2,25	X	X	X	X	X	X	X
	2,50	X	X	X	X	X	X	X
	2,75	X	X	X	X	X	X	X
	3,00	X	X	X	X	X	X	X
	3,25	X	X	X	X	X	X	X
	3,50	X	X	X	X	X	X	X
	4,00	X	X	X	X	X	X	X
	4,50	X	X	X	X	X	X	X
	5,00	X	X	X	X	X	X	X

small medium large

About InspireMD

InspireMD is an innovative developer of next generation coronary and endovascular stents.

Our solutions are designed to benefit patients by providing physicians with effective and safe stenting procedures.

InspireMD
T: +972-3-691 7691 F: +972-3-691 7692
info@inspire-md.com www.inspire-md.com

MGUARD InspireMD