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Field Safety Notice

Field Safety Corrective Action – Voluntary Field Action

2/5/2014

Description: MGuard Prime Coronary Stent System Embolic Protective Stent (EPS)
Catalog number: All catalog number as describe in the letter below
Lot Number: All lot numbers

Dear Customer,

Following recent complaints of MGuard Prime EPS dislodgements, InspireMD has announced a Voluntary Field Safety Corrective Action.

These complaints have primarily occurred during the preparation of the MGuard Prime EPS, upon removal of the protective sleeve, or during withdrawal of the MGuard Prime EPS into the guide catheter. These complaints have not resulted in any patient injury.

Upon approval from the European regulatory agency, InspireMD intends to perform a manufacturing enhancement to all unexpired units of the MGuard Prime EPS systems. This upgrade in our manufacturing process will improve stent retention and product performance.

The complaints are only with our MGuard Prime product (Cobalt/Chromium): the MGuard product is not affected (stainless steel).

The Voluntary Field Safety Corrective Action includes all MGuard Prime products as describe in the table below:

	Stent length (mm)						
Diameter (mm)	8	13	18	23	28	33	38
2.5	MGP2508	MGP2513	MGP2518	MGP2523	MGP2528	MGP2533	MGP2538
2.75	MGP2708	MGP2713	MGP2718	MGP2723	MGP2728	MGP2733	MGP2738
3	MGP3008	MGP3013	MGP3018	MGP3023	MGP3028	MGP3033	MGP3038
3.25	MGP3208	MGP3213	MGP3218	MGP3223	MGP3228	MGP3233	MGP3238
3.5	MGP3508	MGP3513	MGP3518	MGP3523	MGP3528	MGP3533	MGP3538
4	MGP4008	MGP4013	MGP4018	MGP4023	MGP4028	MGP4033	MGP4038

We regret any inconvenience this action may cause you and thank you for your continued support of our MGuard products.

If you have any questions, please contact your local InspireMD sales representative or InspireMD customer service in e-mail customerservice@inspiremd.com, telephone and fax:

	France	Germany	Netherlands
InspireMD Customer Service Telephone	0800-940132	0800-3305097	+31-(0)13-5479308
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Regards,

Judith Antler

Director of Quality Assurance and Regulatory Affairs