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Field Safety Notice

Field Safety Corrective Action

26/5/2014

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 announced a 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.

The root cause of the dislodgements was investigated and it was determined that there were two (2) main reasons:

1. Pre procedure dislodgment –the sleeve stent was stuck in the protective cap or slipped from the balloon.

   Root cause – The device was prepared for a procedure out of the lesion and not according to the IFU instruction (paragraph 7.2). In these situations, device dislodgment can occur outside the body only.

   Risk- There is no patient risk when dislodgment happens out of the body. In this situation, physicians will identify that there is a missing stent prior stent insertion.

2. Stent dislodgment following attempt to cross the lesion and pullback the system back into the guiding catheter.

   Root cause - At pullback, the stent was caught in the guiding catheter tip, further pulling out the balloon catheter caused the stent to slip out of the balloon. Device pullback into the guiding catheter is not allowed per IFU paragraph 7.

   Risk – In the event of stent dislodgment during pullback the physicians should deploy the stent at its location (proximally to the lesion) and introduce a new device to treat the lesion. At this type of events, patient will get second stent to successfully finalize the procedure. All the events of stent dislodgment during pullback were with no harm to the patient.

There is no risk for Patient that the stent was already implanted.

All MGuard Prime devices are being called back to InspireMD and upon approval from the European notify body, InspireMD intends to perform a manufacturing enhancement to all unexpired units of the MGuard Prime EPS system. This enhancement should improve stent retention.

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

The 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:

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

[redacted]

CTO & Sr. VP R&D