TRYTON
Medical

Urgent Field Safety Notice

Tryton Side Branch Stent
Tryton FSCA # 0002
Field Safety Corrective Action - Return of Product to the Supplier

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Date: 4 December 2008

Attention [customer]:
[institution]

As described to you previously, Tryton Medical has received three reports of Tryton Side Branch Stent dislodgement. Although no patient has been harmed, this failure mode could lead to serious health consequences for the patient if the stent were to come off the catheter prematurely in the patient. Tryton Medical has determined that a field safety corrective action is appropriate and has decided to withdraw the Tryton Side Branch Stents from the market. Product will be returned to Tryton to facilitate further investigation and to prevent potential patient harm.

Tryton Medical has already communicated that you need to:

- Immediately discontinue use of the Tryton Side Branch Stent
- Quarantine all Tryton Side Branch Stent product

At this time, Tryton Medical is communicating its plan to withdraw product from the market. To facilitate this, a representative of Tryton Medical or your local distributor will arrange for retrieval of product from your site.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. We appreciate your assistance with this matter. Tryton Medical will strive to replace your affected product with product of superior quality as quickly as possible.

Should you have any questions or concerns regarding this notice, please contact:

[redacted]
Tryton Medical, Inc.
Mobile: [redacted]

Or

[redacted]
Office: +44 560 2768263
Mobile: [redacted]

The undersigned confirms that Tryton Medical will notify the appropriate Regulatory Agency regarding this action.

Regards,

[redacted]
Chief Technical Officer