

**Recall of TorFlex™ Transseptal Guiding Sheath
Lots S21244, S21903, S21940, S22739, S22739X1**

(Montreal, 16 March 2010) Baylis Medical is recalling the TorFlex™ Transseptal Guiding Sheath Lots S21244, S21903, S21940, S22739, S22739X1.

Baylis Medical has recently become aware from the supplier of the TorFlex™ Transseptal Guiding Sheath, of a potential danger that the radiopaque/soft tip of sheath in the TorFlex™ Guiding Sheath Kit (P/N) could fracture or detach during in vivo use. The potential impact is that the fragment could pass into systemic arterial circulation and lead to an embolic event, which could in turn lead to permanent injury.

Baylis Medical has not received any adverse complications from the fragmented/detached tips of the TorFlex™ Transseptal Guiding Sheath to date. This field safety action is to prevent complications that could result from this type of occurrence.

Baylis Medical has notified all the affected customers and distributors who could have received the lots of devices affected by the recall and is in communication with them to retrieve the recalled devices.

The FDA, Health Canada and applicable National Competent Authorities have been notified of this safety notice.

Any questions related to the recall can be referred to Baylis Medical Customer Service department at torflex@baylismedical.com