

URGENT MEDICAL DEVICE INFORMATION

Thomas Medical Products, Inc.
65 Great Valley Parkway
Malvern, PA 19355
1.610.296.3000

September 16th, 2008

Subject: Product Advisory – This is to advise you of potential difficulty associated with inserting the guidewire through the 18 gage XTW introducer needle of the SafeSheath Hemostatic Tear-away Introducer Kits.

Dear Doctor,

This letter provides important patient management information regarding the SafeSheath Hemostatic Tear-away Introducer Kits.

Description of Issue

Thomas Medical Products has recently identified an issue with potential difficulty inserting the guidewire through the 18 gage XTW introducer needle. The affected needles exhibit a defect whereby the lead-in feature of the needle hub does not guide the guidewire into the needle. The clinical effect of this defect ranges from none to an extended time required to introduce the guidewire and ultimately to the user discarding the needle and using another. The latter effect would require a second stick. All subclavian punctures risk a pneumothorax (<1%). The necessity of a second stick doubles the normal risk.

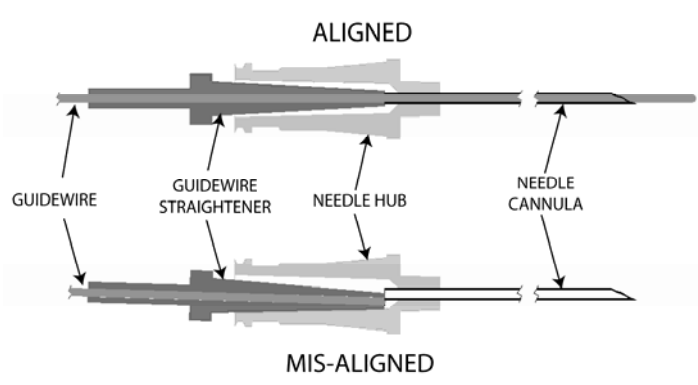
Rate of Occurrence

Based on testing it has been estimated that 30% of the units with the defect will work as intended. Clinical input indicates that <1% of subclavian sticks results in a pneumothorax.

Recommendations

For specific lot numbers identified, the following procedures are recommended:

1. Discard 18 gage XTW introducer needle supplied with the SafeSheath Kit and utilize an alternate sterile 18 gage XTW introducer needle



Devices Affected

The affected product is confined to a subset of devices within the SafeSheath[®] family. Below is a list of affected lot numbers.

S25589	S25948	S25997	S26039	S26088	S26183
S25590	S25949	S25998	S26040	S26089	S26198
S25756	S25950	S26001	S26044	S26092	S26203
S25769	S25951	S26002	S26045	S26095	S26214
S25787	S25972	S26003	S26058	S26102	S26217
S25909	S25973	S26009	S26059	S26146	S26218
S25910X1	S25974	S26010	S26060	S26177	S26230
S25911	S25975	S26011	S26063	S26178	S26345
S25924	S25996	S26012	S26064	S26182	

Further Information

Thomas Medical Products recognizes the impact of this communication on you and your accounts and wants to reassure you that patient safety remains our primary concern. If you have any questions regarding this communication, please contact your Thomas Medical Customer Service or Quality Assurance representative at (610) 296-3000.

Sincerely,

Tim Stoudt
Manager, Quality Assurance and Regulatory Affairs
Thomas Medical Products, Inc.