

Field Safety Notice
Relay and Relay NBS Thoracic Stent-Graft Systems
(References 28M3#####X and 28N2#####X)
All lots manufactured prior to August 2014
08-2014-001-C

August 8, 2014

Dear Valued Relay / Relay NBS Customer:

This notification is intended to provide you with information to avoid a possible difficulty with the advancement and deployment of Relay and Relay NBS stent-grafts.

Issue Description and Impact

The advancement instructions of the Relay and Relay NBS systems indicate the following:

“verify that the gray Deployment Grip has reached or passed the black line on the main handle body. This will ensure that the Inner Secondary Sheath has completely exited the Outer Primary Sheath. Also, the distal stent marker bands will be seen approximately 2 cm out of the Outer Primary Sheath.”

It has been observed in a small number of cases that the Inner Secondary Sheath may not fully exit the Outer Primary Sheath upon reaching the black line. In this situation, the distal end of the stent-graft will also remain within the Outer Primary Sheath. Failure to recognize this condition prior to deployment can lead to deployment difficulty or deployment failure. There is no impact on devices already implanted.

Additional Verification Steps and Troubleshooting

Because of this possible scenario, Bolton Medical is recommending the following additional verification steps prior to proceeding to the final stent-graft positioning and deployment.

1. Upon reaching the intended proximal landing zone, visually confirm that the distal stent marker bands can be seen approximately 2cm outside of the Outer Primary Sheath.
2. If the distal stent marker bands do not appear to have exited the Outer Primary Sheath, while in Position 1, hold the gray Deployment Grip stationary while pulling back on the black Stationary Grip until the distal stent marker bands have exited the Outer Primary Sheath by approximately 2cm.

Please contact your local representative with any questions. Bolton Medical appreciates your prompt implementation of these additional instructions.