COVIDIEN

IMPORTANT MEDICAL DEVICE INFORMATION
REGARDING DUET TRS™ RELOAD WITH TISSUE REINFORCEMENT
IN ABDOMINAL USE

March , 2012

Dear Customer,

In January 2012, Covidien voluntarily contraindicated the Duet TRS™ Reload with Tissue Reinforcement ("Duet TRS™ Reloads") for thoracic use by way of a recall letter sent to customers and a change in the Duet TRS™ Reload labeling. We decided to take this action after reviewing reports of serious injuries, including three patient deaths, when the Duet TRS™ Reload was used for the thoracic indication. Key Opinion Leader and customer feedback, peer reviewed literature and the documentation in our complaint history led us to conclude that the mechanism of injury in the thorax is abrasion of the reinforced staple line edge against the chest wall[(1)]. The reported events leading to our contraindication of the use of the Duet TRS™ Reloads in the thorax included soft tissue damage and bleeding that occurred within 21 days from the time of surgery. We have not received reports of such events beyond this timeframe.

Our action to contraindicate the Duet TRS™ Reloads for use in the thorax has not affected the other uses of the Duet TRS™ Reloads. The current Indication for Use for the Duet TRS™ Reload is for single use with Staple Line Reinforcement in abdominal, gynecologic and pediatric surgery for resection, transection, and creation of anastomoses. Duet TRS™ Reloads may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

We have received a number of inquiries from surgeons about the use of Duet TRS™ Reloads in the abdomen. To assure full transparency around our knowledge of this issue, we have reviewed the literature and drafted the following summary of the available data on the use of this product in the abdomen. In addition, we have conducted interviews with gastric surgeons who have extensive experience with Duet TRS™ Reload. Covidien is also committed to opening a post-market study/registry to follow the use of the Duet TRS™ Reloads in abdominal surgery. Results of the patient study/registry will be monitored closely on a rolling basis and shared with our customers.

Summary of Duet TRS™ Reloads Abdominal Use Analysis

Covidien estimates that Duet TRS™ Reloads have been used in approximately 70,000 abdominal procedures since the product launch in 2009. In these procedures, the device is most commonly used to reinforce the staple lines created along the stomach during Roux-en-y gastric bypass and sleeve gastrectomy. Our Medical Affairs and Quality Assurance departments recently completed a comprehensive review of the complaints received associated with the abdominal use of Duet TRS™ Reloads. Approximately 99% of these reports detail intra-operative incidents that represent common failure modes associated with any surgical stapler and are consistent with complaints received for our "legacy" non-buttressed (non-reinforced) surgical stapling products. These reports most commonly relate to use of staplers in thick tissue applications.

As of March 1, 2012, we have received five complaints alleging that the edge of Duet TRS™ Reload may have caused or contributed to staple line dehiscence in the stomach (n=1) and duodenum (n=4) after gastric surgery. The complaint history also contains three deaths associated with post-operative leak. Covidien has not received any complaints alleging that the Duet TRS™ Reload has injured the liver, spleen, abdominal or pelvic wall. As a stapler manufacturer, Covidien has long-standing experience in analyzing the relationship of staple formation and stapler performance in association with post-operative leak. Our analysis of these three specific cases, as well as other leak cases has led us to conclude that the pattern and nature of leak in association with Duet TRS™ Reload-reinforced staple lines is indistinguishable from the pattern associated with non-buttressed staplers.

We have conducted a literature search and found one study investigating the use of Duet TRS™ Reloads in the abdominal cavity [(2)]. This study did not report any incidence of Duet TRS™ Reload device-related injury. In addition, Covidien sponsored a post-market study in 2010 at Duke University evaluating the use of Duet TRS™ Reloads in gastric bypass surgery [(3)]. In this small prospective study (n=30), there was no incidence of device-related morbidity or mortality at 30 day follow-up. Lastly, a randomized blinded in-vivo pre-clinical study was conducted at the University of Texas Southwestern Medical Center [(4)]. This investigation compared the use of Duet TRS™ Reloads versus non-buttressed staple lines in laparoscopic sleeve gastrectomy in eight canines. This chronic (28 day planned survival) in-vivo study found no incidence of injury to the abdominal wall or abdominal viscera in association with use of Duet TRS™ Reloads or any other device-related adverse event.

As part of our investigation of the abdominal complaint history, Covidien Medical Affairs conducted interviews with three high-volume gastric surgeons with extensive experience with the Duet TRS™ Reload. We briefed these surgeons on the full complaint history of the Duet TRS™ Reload. Each surgeon confirmed that they believe that the Duet TRS™ Reload remains appropriate for use in the abdomen, informally corroborating Covidien's conclusion.

Finally, to further assess marketed use outcomes of the Duet TRS™ Reload in the abdomen, we plan to implement a post-market study or registry to follow the use of the Duet TRS™ Reload in abdominal surgery.

Conclusion

Based on the information currently available, we do not believe that there is a causal connection between the use of the Duet TRS™ Reloads in the abdomen and an increased risk of adverse events as compared to non-buttressed staplers. Accordingly, we believe that the product is appropriately indicated for use in the abdomen. In order to obtain additional data, Covidien will be conducting a post-market study/registry following the use of Duet TRS™ Reload in abdominal surgery. Covidien has been unable to substantiate any Duet TRS™ Reload use in the abdomen in either pediatric or gynecologic indications, but the post-market study/registry will capture this data to the extent possible. We will closely monitor this post-market study/registry on a rolling basis and share its information with our customers.

As with any medical device, we encourage you to report adverse events associated the Duet TRS™ Reload promptly to Covidien at [local phone number]

This letter is being sent by Covidien with the full knowledge of [local C.A.]

We appreciate your interest in the Duet TRS™ Reload and patient safety and we remain available to discuss any aspect of this information that you may have. *Please complete the attached acknowledgement form and return to Covidien at your earliest convenience. Your response is vital to our monitoring of the effectiveness of this notification.*

Thank you,

Michael Tarnoff, MD FACS
Corporate Chief Medical Officer
Mansfield, Massachusetts

Ross Segan, MD MBA FACS
Chief Medical Officer, Surgical Solutions
New Haven, Connecticut

REFERENCES

1. Kanai Y. et.al. Massive haemothorax after pulmonary endostapling preloaded with bioabsorbable tissue reinforcement material. Interactive Cardiovascular and thoracic surgery 0 (2011) 1-2.

2. Alley JB, et al. Integrated bioabsorbable tissue reinforcement in laparoscopic sleeve gastrectomy. Obesity Surgery 2011. 21(8): 1311-1315.

3. Pryor A, et al. Duet TRS™ Reload is a preloaded absorbable reinforcement material on an endoscopic stapler that is straightforward and effective for gastric pouch creation. Oral Presentation. IFSO 2010 Congress, Sept 3 -7 2010, Long Beach, CA.

4. Arsalla Islam MD, et al. Preloaded Reinforced Versus Non-Reinforced Linear Staple Lines: A Randomized, Blinded In-Vivo Comparison. Poster presentation at the 51st Digestive Disease Week, SSAT Annual Meeting, May 1-5, 2010, New Orleans, LA.

IMPORTANT MEDICAL DEVICE INFORMATION REGARDING THE DUET TRS™ RELOAD WITH TISSUE REINFORCEMENT IN ABDOMINAL USE

TO: COVIDIEN

SUBJECT: March 22, 2012 letter regarding Important Medical Device Information regarding the Duet TRS™ reload with tissue reinforcement in abdominal use.

_____ (please sign). I acknowledge receipt of the Important Medical Device Information regarding the Duet TRS™ reload with tissue reinforcement in abdominal use dated March 22, 2012. Please email this acknowledgement form to [enter email] OR FAX TO [enter fax number].

Date: _____

Name of Person Completing this form: _____ Title:_____

Direct Phone #:_____Email:_____

Account Name: _____Covidien Account Number:_____

Account Address:_____

City:_____State: _____Zip Code:_____