

**URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION**

**CONTRAINDICATION FOR THORACIC USE**

Duet TRS™ Loading Units

January 13<sup>th</sup>, 2012

**Attention:** *'Risk Management Director and O.R Materials Management'* **to be confirmed by local Sales and Mkt.**

**Please forward this communication to all surgeons / surgical personnel.**

Dear Customer,

Covidien (formerly United States Surgical, a division of Tyco Healthcare Group, L. P.) is conducting a FSCA of all production lots for the Duet TRS™ Universal Straight and Articulating Single Use Loading Units (SULU) **with respect to the use of this product family in the thoracic cavity.**

Serious injuries and deaths have occurred due to the failure mode associated with this FSCA. Covidien has received reports of 3 deaths and 13 serious injuries following the application of Duet TRS™ Loading Units in the thoracic cavity. We have concluded that Duet TRS™ has the potential to injure adjacent anatomical structures within the thorax which may result in life threatening post-operative complications.

**Users of Duet TRS™ Loading Units should not use the device in thoracic surgery in both adult and paediatric populations.**

**Users of Duet TRS™ may continue to use Duet TRS™ in other applications.**

Covidien will be revising the Instructions for Use for the Duet TRS™ to contraindicate the Duet TRS™ for use in thoracic procedures in adult and paediatric populations. In the interests of patient safety we are initiating this FSCA in advance of that change.

This FSCA only applies to the Duet TRS™ loading units and only for the use of this product in the thoracic cavity. Other Endo GIA™ families of SULUs are not affected.

**The affected product codes and descriptions are as follows:**

DUET4535	Duet TRS™ 45 3.5MM STRAIGHT SULU
DUET4535A	Duet TRS™ 45 3.5MM ARTICULATING SULU
DUET4548	Duet TRS™ 45 4.8MM STRAIGHT SULU
DUET4548A	Duet TRS™ 45 4.8MM ARTICULATING SULU
DUET6035	Duet TRS™ 60 3.5MM STRAIGHT SULU
DUET6035A	Duet TRS™ 60 3.5MM ARTICULATING SULU
DUET6048	Duet TRS™ 60 4.8MM STRAIGHT SULU
DUET6048A	Duet TRS™ 60 4.8MM ARTICULATING SULU

**REQUIRED ACTIONS:**

- 1 Immediately discontinue use of the device in thoracic surgery.
- 2 Immediately advise all surgeons / surgical personnel of this FSCA.
- 3 Complete form nr. 1 and return to the Covidien address listed.  
**Your response is vital to monitor the effectiveness of this FSCA.**
- 4 Product intended for thoracic use must be returned to Covidien by completing form nr. 2
- 5 If you are a Distributor please forward this communication to your customers immediately.

While we know you share our interest in the primacy of patient safety, we sincerely apologize for any inconvenience this may cause and thank you for your business and continued support.

This action is being taken with the knowledge of '*name of local C.A.*'.

If you have any questions or concerns, please do not hesitate to contact your Covidien Sales Representative.

Sincerely,



Michael Tarnoff, MD  
Corporate Chief Medical Officer  
Covidien