No Difference in Hemostasis Performance: ECHELON FLEX™ Powered Vascular Stapler with tissue specific 2-row design compared to conventional 3-row staplers

Hemostasis testing: 3-point approach

The tissue specific 2-row design of the ECHELON FLEX™ Powered Vascular Stapler (PVS) has been rigorously tested to demonstrate no difference in hemostasis performance compared to 3-row staplers. ECHELON FLEX™ PVS has been tested and fired 1000s of times on vessels and pedicles of varying thicknesses and widths in multiple models and anatomy. This evidence summary is a subset of the PVS testing including (1) a reliable laboratory analog for evaluating hemostasis, (2) animal models that were used for FDA 510(k) clearance and (3) validation testing with surgical specialists to confirm that 2-rows have no difference in hemostasis performance compared to 3-rows.

1 Hemostasis analog

Benchtop "leak onset" versus 3-row Endo GIA™

Benchtop studies using porcine carotids that determined the pressure for the initial onset of fluid leakage in a controlled laboratory environment. N=19 for each device • 1mm mean thickness • 78mm mean flattened width

CONCLUSION: No statistically significant difference in leak onset pressure performance compared to the 3-row Endo GIA™ Gray Curved Tip (p=0.406).1

2 Animal models

Hemostasis on range of vessels versus ENDOPATH ETS

Preclinical porcine models were used to evaluate the ECHELON FLEX™ PVS with Ethicon’s predicate device, the ENDOPATH ETS Articulating Linear Cutter (ATW 35mm, 3-row).

CONCLUSION: Equivalent hemostasis to 3-row ENDOPATH ETS Articulating Linear Cutter.2

3 Validation testing

Hemostasis evaluation by thoracic and urology specialists

Preclinical porcine surgical labs with thoracic and urology surgeons from domestic and international markets to evaluate hemostasis in lobectomy and nephrectomy procedures. Firing: Side-by-side in same animal • Specialists: 27 Thoracic; 16 Urology.

CONCLUSION: No clinically significant difference in hemostasis between ECHELON FLEX™ PVS 2-row stapler and the 3-row ENDO GIA™ Tan or Gray stapler.3