

Frankenman stapler report synopsis

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Frankenman curved circular staplers (28 mm diameter) were compared against 29 mm Ethicon equivalents, and 45 mm linear non-cutting Frankenman staplers were compared against 30 mm Ethicon linear staplers. In each case the green cartridges, i.e. those intended for a stapling thickness of 2.0 mm, were employed.

The Frankenman staplers are internally and externally similar to the Ethicon counterparts and appear to be manufactured and assembled to a similar standard. The Frankenman products are provided in secure sterile packaging, complete with clear and simple instructions in thirteen languages.

The force required to close the handles of five specimens of each device was measured whilst stapling neoprene. This test was conducted twice with two different thicknesses of neoprene. In the case of the linear staplers a fixed width of neoprene was used to circumvent the penalty the Frankenman device might otherwise have incurred due to its greater jaw size (45 mm *cf* 30). It was found that circular Frankenman staplers and linear Ethicon staplers are easier to fire than their counterparts. The resulting staple patterns in the neoprene were then analysed to compare the separation of the two staple lines and the overlap between staples in each row or circle. No statistical difference was found between the Frankenman and Ethicon devices.

All staples from the neoprene test material were then carefully cut free and the dimensions of the staples noted. The Frankenman instruments produce more tightly formed staples than the Ethicon product. It was noted that the Frankenman staples are made of thicker wire ($\varnothing 0.30$ *cf* $\varnothing 0.27$ mm).

Finally, these staples were secured in a tensometer and the legs distended to determine the force required to straighten the staple. When comparing the staples from the linear staplers, the Ethicon staples were approximately 50% stronger. The comparison of staples from the circular devices did not produce a clear difference.

To test leakage from the staple lines five examples of each stapler were used to create anastomoses in porcine bowel: the linear staplers were each used to occlude a single sample while the circular staplers were used to create side-to-side anastomoses. The leakage flow from each sample under a test pressure of 50mmHg was then measured. In the case of the linear devices the wide variation in results prevented any statistically significant comparison while in the case of the circular staplers the Frankenman device permitted significantly less leakage.

Tear-down tests of two samples of each stapler identified only minor differences.

The design, construction and performance of the staplers from these two manufacturers is substantially the same.