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CLINICAL EVALUATION OF FIBRIN SEALANT PRODUCED BY CRYOSEAL® FS SYSTEM IN PATIENTS UNDERGOING LIVER RESECTION: A MULTICENTER RANDOMIZED CLINICAL TRIAL

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Introduction: The CryoSeal® FS System consists of a medical device (the CS-1 instrument) and a proprietary plasma processing disposable that work in concert to rapidly (approximately 60 minutes) prepare both components of a Fibrin Sealant (FS), (cryoprecipitate and thrombin), from a single unit of autologous. When the cryoprecipitate and the thrombin produced by the CryoSeal® FS System are mixed with the supplied applicator, a Fibrin Sealant is obtained. Existing fibrin sealants are derived from pooled human plasma with bovine additives. Use of such sealants carries recognized risks of viral contamination, e.g. HBV and HIV, and of immunological reaction to bovine products. Alternatively, sealants generated from CryoSeal FS System using autologous blood do not carry the same concerns. The primary objective of this study was to investigate the safety and efficacy of the Fibrin Sealant prepared by the CryoSeal® FS System, in terminating bleeding of the raw liver resection margin following hepatectomy.

Materials and Methods: The study was designed to compare the use of Fibrin Sealant produced by the CryoSeal® System as an adjunct to hemostasis versus a currently approved adjunct to hemostasis, a collagen absorbable hemostat. The pivotal trial reported here was a randomized clinical study in 153 patients undergoing elective hepatectomy, and enrolled at 10 study sites. The primary study endpoint was time to hemostasis. The study compared the time to hemostasis for the study product, Fibrin Sealant prepared by the CryoSeal® System, to the standard care (a collagen absorbable hemostat, Instat, Ethicon, Inc.). Safety evaluation included a 30-day (3 days) follow-up post surgery.

Results: The primary efficacy endpoint for this study was the time to hemostasis (time between application of the study product and when hemostasis was obtained). The median time to reach hemostasis was 3.43 minutes in the FS group compared to 8.65 minutes in the control group. Percentage of patients that achieved hemostasis within 10 minutes was 94.0% for the FS group and 60.4% for the Control group. This difference was statistically significant ($p < 0.001$) and satisfied the non-inferiority criterion. The FS also satisfied the superiority criterion in a highly statistically significant manner ($p < 0.001$). The groups were not different in regards to operative blood loss, operative time, postoperative hospital stay or complications.

Conclusions: The results of this trial demonstrate that the Fibrin Sealant produced by the CryoSeal® FS System is safe, effective, well tolerated, and superior to the collagen absorbable standard of care in this patient population and indication.