Autologous fibrin sealant CryoSeal FS system: Performance and efficacy evaluation for use in surgical procedures.

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Abstract:

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 plasma. When the cryoprecipitate and the thrombin produced by the CryoSeal FS System are mixed together, a Fibrin Sealant is obtained from a single unit of plasma. Furthermore, the CryoSealSystem's ability to also produce human Thrombin eliminates the need to use bovine thrombin present in other fibrin sealants and other adjuncts to hemostasis. The primary objective of this study was to investigate the efficacy and performance of the Fibrin Sealant prepared by the CryoSeal FS System as an adjunct, in terminating bleeding of liver resection, heart valve replacement, aortocoronary shunts and thoraco-abdominal aorta replacement procedures. Materials and methods: The study was designed to use the Fibrin Sealant produced by the CryoSeal System as an adjunct to hemostasis. The product evaluation trial reported here was a clinical study involving total 11 patients for 4 different surgical procedures: liver resections (2), heart valve replacements (3), aortocoronary shunts (4) and thoraco-abdominal aorta (2) replacement procedures. Results: The CryoSeal FS system produced an average 11 mL of fibrin sealant with an average fibrinogen concentration (31 mg/mL) and thrombin activity (50 U/mL). The primary efficacy endpoint for this study was complete hemostasis. In all procedures the CryoSeal FS System derived fibrin Sealant provided complete hemostasis in the peri-operative region. Conclusions: The results of this trial show that the Fibrin Sealant produced by the CryoSeal FS System conforms to its stated

characteristics, provides good hemostatic properties and is comparable to the pharmaceutical fibrin adhesive in terms of biocompatibility and adhesiveness.