Fibrin sealant produced by the CryoSeal FS System: Product chemistry, material properties and possible preparation in the autologous preoperative setting.

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Abstract:

Background and Objectives: The CryoSeal FS has been introduced as an automated device for the production of fibrin sealant from small volumes of plasma. We tested this device and compared the product with commercially available fibrin sealants and with the requirements of the European Pharmacopoeia. Materials and Methods: The CP3 program and disposables required were used to manufacture fibrin sealant. The chemistry and mechanical properties of the product were investigated. Results: The cryoprecipitate generated with CryoSeal contains concentrated fibrinogen and critical clotting factors. The efficiency of the production process is poor, but the production procedure itself is simple and not time-consuming. The volume of plasma required allows application in the preoperative autologous setting. Conclusions: The CryoSeal FS is an automated device for cryoprecipitation and production of thrombin. It can be implemented easily in the clinical routine, although, owing to product specifications, the efficacy of the CryoSeal fibrin sealant requires further clinical trials.