erties and performance of the resultant homemade fibrin sealant.

Vivostat is the first fully automated, microprocessor controlled medical device for the preparation of a reproducible autologous fibrin sealant from 120 ml of the patient's blood, produced within 30 minutes of being in the operating room and may be easily prepared by a nurse or perfusionist. The spraypen delivery system allows the surgeon to spray the solution evenly over the target tissue in a controlled fashion. Intermittent application at various rates of delivery is possible - thus small amounts of sealant can be very precisely delivered. The Vivostat delivery system represents a major advance over the commonly used two syringe techniques of fibrin sealant delivery, and allows optimal utilization of the entire volume of sealant produced. The sealant polymerizes immediately upon application and crosslinks over several minutes. There is no risk of transmission to the patient of bloodborne viruses or potential risks from exogenous thrombin since the Vivostat system utilizes only endogenous thrombin for polymerization of the final sealant. The first study in man using the Vivostat system prototype has been successfully conducted in cardiac surgery patients with no adverse reactions. A detailed report of that clinical study will be the subject of another paper.

The Vivostat system is not yet commercially available. Multicenter pivotal studies in several countries are planned to support applications for regulatory approval.

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