The Hemafuse™ system is a portable, intraoperative autotransfusion device designed for the collection of whole blood shed during a surgical procedure during periods of significant hemorrhage for the purpose of reinfusion.

AUTOTRANSFUSION HISTORY

The process of recycling a person's own blood is known as autotransfusion. This medical process has been well documented in the clinical literature and understood since as early as the 1900's. The first documented case of intraoperative autotransfusion began in 1914, when a German obstetrician successfully returned blood lost from ruptured ectopic pregnancies through a gauze filter in three women [1]. A 1951 literature review showed that autotransfusion had been used in close to 500 patients with great success [2].

Early technical advances in autotransfusion centered on the development of cell-salvage systems, where the red blood cells were separated from the other blood components before transfusion. These systems require additional time and consumable resources to centrifuge the blood. Whole blood autotransfusion systems, that do not separate red blood cells from other constituents of blood, are simpler alternatives that provide equivalent clinical benefits.

Without question, since 1988 conventional whole blood autotransfusion represents hundreds of published clinical studies representing thousands of documented successful cases establishing safety and performance standards. See our bibliography section which highlights selected studies employing whole blood autotransfusion comparable to cell-salvage autotransfusion systems [3][4][5][6][7][8][9][10].

NONCLINICAL LABORATORY STUDIES

Hemafuse™ has completed nonclinical laboratory studies to meet established engineering standards. A blood study was conducted to examine the overall quality of human red blood cells collected and processed while using the Hemafuse™ and a comparative system. The study was performed using non-specific allogeneic donated human red blood cells obtained from American Red National Blood Services. The comparative system used has been an established medical device with the US-FDA, dating back to 1984. The Hemafuse™ device performance demonstrated no harm to blood cells during collection and processing through the filter components of the device along with the collection chamber.

The Hemafuse™ system also meets the industry standards for whole blood autotransfusion. The Hemafuse™ system has passed the ISO-10993 biocompatibility studies. It has also passed nonclinical laboratory studies including, microbiological, mechanical, shelf life tests as well as animal testing for material specific and device specific analyses. The pump has been validated to be reusable through manually cleaning and steam sterilization validation tests. Quality assurance documents are available upon request.

CLINICAL EVIDENCE

The Hemafuse™ was successfully used in a clinical study of 12 patients in Ethiopia. Reinfusion of blood was not conducted at time of the study but blood analysis retained from each case was examined for blood quality. Blood quality surrounding hemolysis determination was the primary focus. In each case, hemolysis levels were determined to be insignificant, at less than 1%. All patients have been followed up with, with no reported adverse effects.

HEMAFUSE PUBLICATIONS

Winget, Caitlin O., et al. "Blood salvage device for use during ruptured ectopic pregnancy in low-resource countries." International Journal of Gynecology & Obstetrics 128.1 (2015): 74-75.

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