

... reduces transfusion requirements and improves patient outcome.

(Perfusion 2011; 26: 470-478)



ROCsafe®RX

Modular Perfusion Circuit

New clinical evidence

Minimized modular perfusion circuit ROCsafe®RX offers better patient outcome at lower cost

Optimizing Cardiac Surgery



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Published by Terumo Europe N.V.
CV155GB-1111FKFK-I(11.11)E

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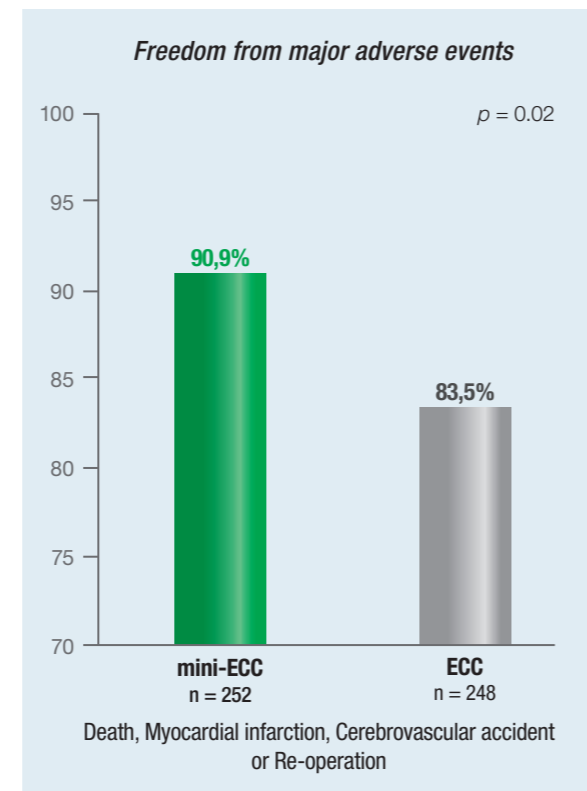
According to a recently published randomized multicenter study, the use of ROCsafe®RX, a minimized modular perfusion circuit for extracorporeal circulation (mini-ECC), reduces the amount of blood transfusions as well as the incidence of atrial fibrillation and other severe postoperative complications associated with cardiac surgery. In the study, the ROCsafe®RX circuit was compared to a conventional circuit for extracorporeal circulation (ECC). The results of this and other studies on minimized perfusion circuits have led to a change in international guidelines for reducing the amount of blood transfusions in cardiac surgery. The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists now strongly recommend the use of minimized perfusion circuits and have rated the use of minimized circuits for blood conservation in cardiac surgery with the highest level of clinical evidence Class I, Level A.

The prospective, randomized, multicenter study included 500 patients with a mean age of 65 years who underwent elective coronary bypass surgery and/or aortic valve replacement (1). 252 patients operated on using the ROCsafe®RX minimized extracorporeal perfusion circuit (mini-ECC) were compared to a control group of 248 patients who underwent surgery using a conventional heart-lung machine set up.

Transfusion requirements in the ROCsafe®RX group were 254mL lower compared to the control group, representing an average savings of one unit of blood per patient. Moreover, the incidence of atrial fibrillation and severe postoperative complications (death, myocardial infarction, cerebrovascular accident, and re-operation) occurred significantly less often when the ROCsafe®RX system was used. In particular, the rate of myocardial infarction was significantly lower in the ROCsafe®RX group as compared to the control group (1.6% vs. 5.2%). Patients in the ROCsafe®RX group also required fewer re-operations (3.6% vs. 10.1%). This indicates that ROCsafe®RX provides better myocardial protection during cardiac surgery as is demonstrated by significant differences in the postoperative rise in creatine kinase (CK) and CK-MB which favor mini-ECC. If optimal outcome is accessed in terms of the absence of postoperative complications and the need for blood transfusions, then better patient outcomes can be achieved using the ROCsafe®RX system, the authors of the study conclude. This is also reflected in a significantly shorter hospital stay among ROCsafe®RX patients. This group was discharged from the hospital an average of 1.5 days earlier.

“The ROCsafe®RX minimized perfusion circuit has the potential of improving the quality of patient care in cardiac surgery. This is evidenced by a reduction in transfusion requirements and postoperative complications, both of which bear a cost saving potential for hospitals. We are pleased to see that the other centers involved in the multicenter clinical trial have confirmed our positive findings and expect that the ROCsafe technology will be quickly adopted for routine clinical use”, concludes Principle Investigator Dr. Aschraf El-Essawi (Braunschweig).

Significantly less incidence of atrial fibrillation and severe postoperative complications



New guidelines recommend minimized perfusion circuits

The benefit of minimized perfusion circuits is confirmed by the fact that the Society of Thoracic Surgeons (STS) and the Society of Cardiovascular Anesthesiologists (SCA) recently revised their guidelines for reducing blood transfusion during cardiac surgery to include a strong recommendation for the use of minimized perfusion systems (2). Nine randomized clinical trials and a meta-analysis confirmed the efficacy of minimized perfusion systems in reducing hemodilution and consequently lowering transfusion requirements and the risk of postoperative bleeding. The new guidelines recommend the use of minimized perfusion circuits with the highest level of clinical evidence (Class I, Level A) because they show clear patient benefit.

SIRS no longer a concern

A serious complication of cardiac procedures is Systemic Inflammatory Response Syndrome (SIRS) which can occur when blood comes into contact with foreign surfaces during extracorporeal circulation. SIRS manifests itself clinically by increased bleeding, a higher need for blood transfusion and in severe cases, multi-organ failure. Blood transfusions in cardiac patients are, in turn, associated with serious adverse events and poor prognosis. Correlations have been shown between red blood cell transfusion and infection, ischemia and other postoperative complications as well as prolonged hospital stay, increased early and late mortality, and increased hospital costs (3).

To reduce these side effects, minimized ECC (mini-ECC) systems were developed which offer lower priming volume and a smaller foreign surface area compared

to conventional heart-lung machine set ups. The first generation mini-ECC systems in fact led to a reduction in blood loss and decreased the need for blood transfusion, but users were concerned by the absence of a venous/cardiotomy reservoir and potentially insufficient air-elimination. Therefore, the use of minimized perfusion was only recommended with Class II, Level B clinical evidence in the STS/SCA guidelines published in 2007 (4).

ROCsafe®RX offers superior air-elimination and excellent biocompatibility

These initial concerns were addressed with the development of ROCsafe®RX, a minimized closed perfusion system of the second generation with a modular concept. The latest version consists of three high-performance components with a lower priming volume and more efficient air-elimination. The system is treated with a biocompatible surface coating (X-Coating™) that minimizes platelet adhesion and activation. As a modular system, ROCsafe®RX can quickly and easily be adapted for use in a whole array of surgical procedures such as heart valve repair / replacement and combined procedures.

“In the current economic situation, innovation in medical device technology means improving the quality of patient care and at the same time reducing healthcare costs. With ROCsafe®RX we are proud to offer a perfusion system which meets both objectives” said Masao Hitotsuyanagi, President, Terumo Europe Surgical Products.

- Lower priming volume*
- More efficient air-elimination
- Biocompatible surface coating

* compared to ROCsafe

References:

1. El-Essawi A et al.: Are minimized perfusion circuits the better heart lung machines? Final results of a prospective randomized multicentre study. *Perfusion* 2011; 26: 470-478.
2. Ferraris VA et al.: 2011 Update to The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists Blood Conservation Clinical Practice Guidelines. *Ann Thorac Surg* 2011; 91: 944-982
3. Murphy GJ et al.: Increased mortality, postoperative morbidity, and cost after red blood cell transfusion in patients having cardiac surgery. *Circulation* 2007; 116: 2544-2552
4. Ferraris VA et al.: Perioperative Blood Transfusion and Blood Conservation in Cardiac Surgery: The Society of Thoracic Surgeons and The Society of Cardiovascular Anesthesiologists Clinical Practice Guideline. *Ann Thorac Surg* 2007; 83: S27-86