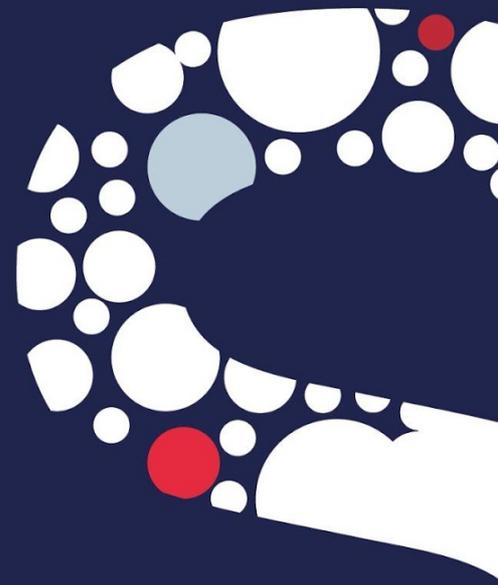


# PRESS RELEASE



Nantes, May 2021

## MedTech – IntraOperative Cell Recovery

**Innovative medical device same™ by i-SEP:  
Promising preclinical results for patients and physicians published in  
the prestigious journal *Anesthesiology*.**

The publication of the preclinical results obtained in recent months in collaboration with academic and hospital partners, including the University Hospital of Rennes and Bordeaux, the Georges Pompidou European Hospital (AP-HP, Paris) or the Bicêtre Hospital (AP-HP, Paris), in the journal *Anesthesiology* is recognition of the quality and scientific rigor of this preclinical study, but also of the prospects that the same™ by i-SEP technology will bring in the evolution of clinical practice and transfusion strategy.

- **The innovation of the same™ by i-SEP device lies in its ability to preserve platelets in addition to red blood cells, and their hemostatic competence: a significant platelet yield, superior to technologies currently available on the market<sup>2</sup>.**
- **i-SEP has developed and patented an innovative IntraOperative Cell Recovery device. Operating by tangential filtration, the technology is able of recovering both the patient's red blood cells and platelets during hemorrhagic surgeries.**

### Preserving platelets and their hemostatic competence

The unique tangential filtration process developed by i-SEP offers a red blood cell yield equivalent to competitive alternative centrifugation techniques, i.e. approximately **91% of preserved red blood cells<sup>1</sup>**.

The innovation lies in the ability of the i-SEP solution to deliver **platelet yields ranging from 26-43% per cycle<sup>1</sup>**. These figures are significant given the cost and risks associated with the transfusion of allogeneic platelet concentrates<sup>2</sup> (inflammatory reactions, alloimmunization, increased mortality in liver surgery and morbidity in cardiac surgery,

<sup>1</sup> Mansour A, Decouture B, Roussel M, Lefevre C, Skreko L, Picard V, Ouattara A, Bachelot-Loza C, Gaussem P, Nesseler N, Gouin-Thibault I. Combined Platelet and Erythrocyte Salvage: Evaluation of a New Filtration-based Autotransfusion Device. *Anesthesiology*. 2021 May 13. doi: 10.1097/ALN.0000000000003820.

<sup>2</sup> Bibliographic and experimental data

<sup>3</sup> Sources: Van Hout 2017, Tsigotis 2016, Kertai 2016, Glance 2014, Alfvieric 2011, Refaai 2011, Greinacher 2010, Pereboom 2009, Karkouti 2007, Vamvakas 2007, Spiess 2004, Dzik 2004

compatibility and contamination, etc.), and their quality (the platelets gradually become non-functional as they are stored until only 40% of them are functional on the 5th day<sup>4</sup>).

## **Ensure a concentration and washing of the blood at least equivalent to existing solutions**

Thanks to its tangential filtration process, the i-SEP solution achieves an average final hematocrit (red blood cell concentration) (treated blood product) **of 49% for the first cycle and 51% for the second cycle**<sup>1</sup>. This is equivalent to the performance of devices on the market. The **same™ by i-SEP device can remove heparin from the blood up to 99%**<sup>1</sup>.

The original research article, "Combined Platelet and Erythrocyte Salvage: Evaluation of a New Filtration-based Autotransfusion Device, is available on **the "[Anesthesiology](#)" website**. Mansour A, Decouture B, Roussel M, Lefevre C, Skreko L, Picard V, Ouattara A, Bachelot-Loza C, Gaussem P, Nesseler N, Gouin-Thibault I. Combined Platelet and Erythrocyte Salvage: Evaluation of a New Filtration-based Autotransfusion Device. *Anesthesiology*. 2021 May 13. doi: 10.1097/ALN.0000000000003820.

*"The same™ by i-SEP intraoperative cell recovery device was developed in partnership with leading French, European and American experts. We are very pleased with the publication of these preclinical results and to contribute to the emergence of a French cluster of expertise on blood processing, with an innovative technology allowing an unmatched quality on the blood product with the objective of a novel patient benefit. We would like to thank our academic and hospital partners, including the University Hospital of Rennes and Bordeaux, the Georges Pompidou European Hospital (AP-HP, Paris) and the Bicêtre Hospital (AP-HP, Paris) for their involvement in the realization of this study. Our ambition is to obtain our CE marking in the first half of 2022 to meet the expectations of centers to integrate the same™ by i-SEP device into their clinical practice. ", says Sylvain Picot, President and co-founder of i-SEP.*

*"The preclinical results are promising as evidenced by the very positive feedback from the scientific community following this first publication," says Alexandre Mansour, an anesthesiologist-intensive care physician at Rennes University Hospital and lead author of the publication.*

The same™ by i-SEP technology is currently undergoing clinical evaluation in a multi-center clinical study that aims to endorse the safety and performance of i-SEP's autotransfusion or Intraoperative Cell Salvage (IOCS) system, on the one hand in terms of blood processing (device safety), and on the other hand in terms of red blood cell and platelet recovery (performance). *"We are eagerly awaiting the results of the first clinical study that we have just completed in collaboration with teams in Rennes, Bordeaux, Paris (HEGP) and Nantes," say Alexandre Mansour and Nicolas Nesseler, anesthesiologists-intensive care physicians at the University Hospital of Rennes and investigators of the clinical study of the same™ by i-SEP intraoperative cell recovery device.*

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<sup>4</sup> Bontekoe IJ, Meer PF van der, Verhoeven AJ, Korte D de. Platelet storage properties are associated with donor age: in vitro quality of platelets from young donors and older donors with and without Type 2 diabetes. *Vox Sang*. 2018;114:129–36.  
Sperling S, Vinholt PJ, Sprogøe U, Yazer MH, Frederiksen H, Nielsen C. The effects of storage on platelet function in different blood products. *Hematology*. 2018;24:89–96.

### **About i-SEP**

i-SEP is a French medtech, founded in 2015 in Nantes, specialized in perioperative cell salvage and blood saving strategy (Patient Blood Management). i-SEP has developed and patented an innovative technology for the separation of blood components. Its ambition is to become the first laboratory to market an autotransfusion system capable of recovering both red blood cells and platelets during hemorrhagic surgeries, using equipment that is both ergonomic and intuitive. i-SEP works closely with reference teams of anesthesiologists-intensivists specialists with the aim of improving patient benefits, simplifying the work of physicians and helping to reduce healthcare costs. Our innovation brings significant added value compared to currently available solutions, particularly in terms of blood quality. i-SEP was co-founded by three partners: Dr Francis Gadrat, anesthesiologist-Intensivists from Bordeaux University Hospital, Bertrand Chastenet, former CEO and consultant in the pharmaceutical industry, French foreign trade advisor, and Sylvain Picot, Medtech entrepreneur. i-SEP is financed by GO CAPITAL, a venture capital management company, and private investors, and is supported by Atlanpole and a member of the Atlanpole Biotherapies competitiveness cluster.

More: [www.i-sep.com](http://www.i-sep.com)

### **About Anesthesiology**

ANESTHESIOLOGY is the highest-impact, peer-reviewed medical journal that publishes trusted evidence to transform the practice of medicine in the specialty.

Mission: Promoting scientific discovery and knowledge in perioperative, critical care, and pain medicine to advance patient care.

#1 ranked journal in the field and the highest score ever achieved by any anesthesia journal.

Founded in 1940, ANESTHESIOLOGY is the official journal of the American Society of Anesthesiologists but operates with complete editorial autonomy. With an independent and internationally recognized Editorial Board. The broad dissemination of the research published in the journal includes an active social media program and additional tools designed to engage readers with the content.