

PRESS RELEASE



Nantes, October 21, 2021

MedTech - Autotransfusion or IntraOperative Cell Recovery

Innovative medical device same™ by i-SEP : promising clinical results **Recovery of platelets in addition to red blood cells, a world premiere**

Following the publication of preclinical results in May 2021, i-SEP's clinical results are now attracting the support of the scientific community. In the context of a pandemic the i-SEP teams managed to complete the First in Man study of the same™ by i-SEP autotransfusion device with results that surpassed expectations.

- **The 50 patients have been included in the university hospitals of Rennes (coordinating center), Bordeaux, Paris Georges Pompidou European Hospital and Nantes between September 2020 and April 2021.**
- **The clinical results confirm and surpass the preclinical data published in May 2021 in the journal "Anesthesiology", with notably a platelet yield higher than 50 % on average.**
- **This major milestone brings i-SEP one step closer to marketing its patented Intra Operative Cell Salvage (IOCS) technology capable of recovering both red blood cells and platelets for the benefit of patients.**

The abstract presenting the results of this study is selected for an oral communication in the "Masterclass Workshop transfusion & Hemostasis" session of the EACTAIC European Congress to be held from October 27 to 29. This is a recognition before the market launch of this innovative device.

same™ by i-SEP: the 1st and only intraoperative autotransfusion technology capable of preserving platelets in addition to the patient's red blood cells, evaluated for the first time in humans.

The French Blood Bank is alerting to an unprecedented tension on blood product stocks, particularly platelets. There is therefore a need for solutions that preserve blood resources to reserve them for patients who cannot do without them. For the past 15 years, British studies have shown that the application of Patient Blood Management guidelines results in strong patient benefits, preserves blood resources and significant savings on healthcare costs. Intraoperative Cell Salvage is one of the tools of PBM.

The study was conducted on 50 cardiothoracic surgery patients over an 8-month period (September 2020 - April 2021), at the Rennes University Hospital (coordinating center), the Bordeaux University Hospital, the Georges Pompidou European Hospital in Paris and the Nantes University Hospital. This multicenter clinical trial aimed to confirm the performance and safety of the same™ by i-SEP RSPO 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 restitution (performance).

The first use of the same™ by i-SEP device in humans was performed in September 2020 in the anesthesia-intensive care department of Professor Alexandre Ouattara at the Bordeaux University Hospital.

“As an anesthesiologist-resuscitator in cardiovascular, thoracic and heavy digestive surgery, I find i-SEP's technology truly innovative because it changes the concept of autologous transfusion in a relevant way. Its ergonomics and intuitiveness are remarkable: it takes no time at all to get used to it and installation takes less than two minutes”, explains Professor Alexandre Ouattara, Head of the GH Sud Anesthesia and Intensive Care Department at the Bordeaux 3 University Hospital.

According to Dr. Nicolas Nessler and Dr. Alexandre Mansour, Anesthesiologists at the University Hospital of Rennes, *“The inclusions went well, with very good feedback from the care teams, both surgeons and anesthetists. The device is fast and silent, which is really appreciated during complex procedures such as cardiac surgery. In addition, the device is really easy to use”.*

There have been no adverse events related to the device. All safety data were validated by the Data Safety Monitoring Board members Prof. Andrew Klein (Department of Anaesthesia & Intensive Care, Royal Papworth Hospital NHS Trust Cambridge, UK) and Prof. Patrick Meybohm (University Hospital Wuerzburg, Department of Anaesthesiology, Wuerzburg, Germany).

The results of the clinical study confirm and surpass the preclinical in-vitro results obtained in 2020 and published in May 2021 in the journal *Anesthesiology*, **with notably a platelet yield higher than 50 % on average.**

“This clinical study is a major milestone for i-SEP and for bringing our innovative same™ autotransfusion system to market. The level of involvement of the clinical centers and our investigators has been extremely strong in a context of pandemic and significant tensions for the teams in the operating room. We would therefore like to thank once again the entire medical profession for this mobilization around our project, which aims to improve the surgical management of the greatest number of patients who do not currently benefit from a satisfactory solution. We are very happy to be able to share the complete results with the European KOLs during the EACTAIC congress which will be held at the end of October in virtual. Our ambition is to obtain our CE mark in the first half of 2022 to meet the needs and requests of centers to integrate the same™ by i-SEP intra operative cell recovery device into their clinical practice”, says **Sylvain Picot, President and co-founder of i-SEP.**

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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 anesthetists-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 Chastenot, 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

About EACTAIC congress

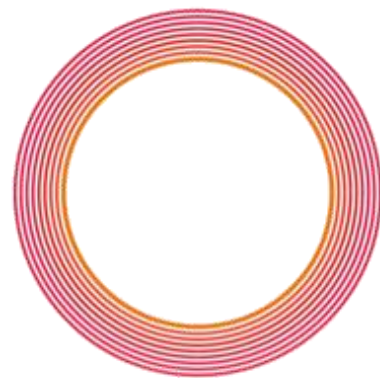
The EACTAIC Annual Congress is recognised as a leading international forum for the exchange of knowledge in the fields of cardiovascular and thoracic anaesthesia. The inaugural meeting took place in Cambridge in 1986. Subsequently, the meeting has been organised in a large number of cities around Europe. Most recently, the meetings have been held in Vienna (2011), Amsterdam (2012), Barcelona (2013), Florence (2014), Gothenburg (2015), Basel (2016), Berlin (2017), Manchester (2018), Ghent (2019), Grenoble (2020, Online edition due to COVID-19 pandemic). The 2021 **EACTAIC Annual Congress** will be a Joint congress with ICCVA and will be held virtually on **October 27-29, 2021**.

Each event attracts the region's key leaders in these fields. The Annual Meeting offers same™ a unique platform to connect with all the aspects of our sub-speciality of cardiothoracic and vascular anaesthesia and intensive care through educational symposia, round tables, lectures, networking and social activities. By doing so, the Annual Meeting is valuable to both professional colleagues and to our industry partners. We aim to provide the environment in which innovation and collaboration can take place, through the sharing of the latest knowledge, information, creative thinking and differing global perspectives.

En savoir plus : <https://www.eactaic.org/event/eactaic-iccva-joint-congress-2021/>



same™ by i-SEP autotransfusion system



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