

# Press Release

Nantes, France. 30 August 2022

*Medtech – Autotransfusion or intraoperative blood recovery*

**Same™ by I-SEP medical device  
has obtained the CE mark and started marketing  
First autotransfusion device  
to obtain the CE marking certificate according to MDR 2017/745<sup>1</sup>**

i-SEP announces the CE marking and marketing of its autotransfusion medical device: same™ by i-SEP. For the past several months I-SEP has been preparing to market its highly innovative and unique autotransfusion system in the sector by intensifying its presence at scientific congresses such as NATA or ARCOTHOVA and presenting its unique autotransfusion system in European hospitals confirming the interest and support of the scientific community. Obtaining the CE mark represents a major step in the company's development and means this process can continue with the start of marketing the same™ blood recovery device to European hospitals and clinics.

- **Obtaining the CE mark according to the requirements of the new European regulation MDR 2017/745 for its unique and innovative intraoperative Blood Recovery Technology (RSPO) capable of recovering both red blood cells and platelets for the benefit of patients: same™ by I-SEP.**
- **This major step allows i-SEP to start marketing its patented technology in Europe; the first centres have already expressed their wish to acquire this device, which responds to the major public health issue of better blood management.**
- **i-SEP's goal: become the first company to market an autotransfusion system that can recover both red blood cells and platelets during bleeding surgical procedures, with ergonomic and intuitive equipment and with a treatment time compatible with surgical practice.**

**same™ by I-SEP is the 1<sup>st</sup> and only intraoperative autotransfusion technology capable of preserving platelets in addition to the patient's red blood cells.**

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<sup>1</sup> MDR: new regulation for medical devices.

**Rare, risky and expensive allogeneic blood products.** During bleeding surgery (several million procedures per year worldwide), the patient can benefit from either an allogeneic transfusion (blood products from blood banks) or an autotransfusion. Allogeneic products are expensive, rare and suffer from stock-outs; they must be preserved for emergencies and specific cases (oncology, etc.). Moreover, if they save lives, they are not risk-free and some patients cannot benefit from them. Current autotransfusion devices are insufficient because they do not preserve platelets, a figurative element of the blood whose main function is to participate in haemostasis, and therefore in stopping the bleeding. Their role is therefore essential during bleeding surgery.

**A solution to a major public health issue.** By allowing the bleeding patient to recover his own red blood cells and platelets, i-SEP provides a solution to a public health problem by providing significant patient benefits and savings for our healthcare system. In the context of blood product management under stress, it is an innovative solution that offers major progress in the field of transfusion strategy.

**Offer autologous platelets, a new alternative!** Thus i-SEP aims to:

- Propose a new blood strategy and help restore hospitals autonomy over their blood resources;
- Offer bleeding patients a new solution of autologous platelets with a functionality and patient benefit far superior to the only platelets currently available: allogeneic platelets (from a bank);
- Propose a solution developed and manufactured in France and contribute to France's sovereignty in the field of medical equipment.

*"The amazing strategy I see today with this new device is outstanding, and I'm pretty much sure developing around same™ new algorithms for many surgeries will make it a standard of care in a short time period."*  
**Professor Kai Zacharowski**, founder and leader of Patient blood Management in Europe, 2022 NATA Congress

**Strong interest and unprecedented commercial traction driven by the technology:** Healthcare professionals, heads of cardiac anaesthesia, resuscitation and surgery departments are showing strong interest in this innovation, which provides a unique benefit and a new approach to autotransfusion. The main French, Belgian and German hospitals are asking for the technology.

*"Our technology will revolutionise practices. It's a real challenge! Interest from hospitals in Europe is strong. This new equipment is easy for hospital practitioners to use and fits into the operating room, with easy and intuitive ergonomics for users, without the need for additional training."* **Sylvain Picot, President and co-founder of I-SEP.**

**A French innovation, developed over the past 6 years with well-controlled public and private resources:** Since its creation, i-SEP has successfully developed an industrialised device, carried out conclusive clinical studies in partnership with several major French hospitals, completed the regulatory process for CE marking and is now starting to market the product.

*"I am very pleased to announce that the notified body BSI has just issued us the CE mark, which opens up the European market for our intraoperative blood recovery solution. This is the culmination of six years of development conducted in partnership with hospitals, universities and opinion leaders in France, Europe and the United States. It is also proof that the i-SEP team is at the forefront of the latest regulatory and quality requirements. I am extremely proud of the team's dedication and meticulousness in achieving this goal, which allows us to launch our device now."* **Sylvain Picot, President and co-founder of I-SEP.**

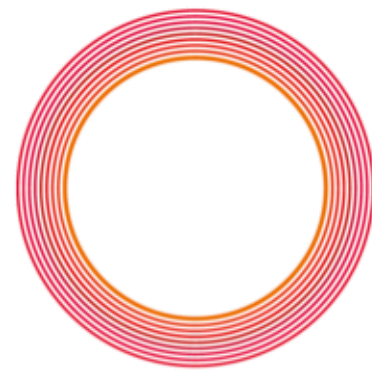
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### About i-SEP

i-SEP is a French Medtech, founded in 2015 in Nantes, specialised in intraoperative autotransfusion and Patient Blood Management. i-SEP has developed and patented an innovative technology for separating blood components. Its goal is to become the first laboratory to commercialise an autotransfusion system capable of recovering both red blood cells and platelets during bleeding surgery, with ergonomic and intuitive equipment. i-SEP works in close collaboration with leading anaesthetist-resuscitator teams with the mission of improving patient benefit, simplifying practitioners' work and helping to reduce healthcare costs. Our innovation brings significant added value compared to currently available solutions, especially in terms of blood quality. i-SEP was co-founded by three partners: Dr Francis Gadrat, an anaesthetist, Bertrand Chastenot, a former business executive and consultant in the pharmaceutical industry and advisor to the French Foreign Trade Office, and Sylvain Picot, an entrepreneur in the health sector. i-SEP is financed by GO CAPITAL, a venture capital management company, and private investors. It is supported by Atlanpole and a member of the Atlanpole Biotherapies innovation cluster.

For more information: [www.i-sep.com](http://www.i-sep.com)



**same™** by i-SEP

Smart autotransfusion  
for me

Figure 1: same™ by i-SEP machine