i-SEP

Innovative solutions
& efficiency for the patient

Press release

Nantes, June, 2020 - MedTech - INTRAOPERATIVE CELL SALVAGE

i-SEP authorized by ANSM[1] and FAMHP[2] to launch its clinical trial in France and Belgium

I-SEP, a French Medtech company based in Nantes, specialized in blood treatment and Patient Blood Management[3], has developed and patented an innovative technology for the separation of blood components. Operating by tangential filtration, the technology is able of recovering both the patient's red blood cells and platelets during hemorrhagic surgery.

After obtaining ISO 13485:2016 certification in January 2020, i-SEP has just received authorization from ANSM[1] and FAMHP[2] to launch its European clinical trial in France and Belgium. This study will confirm the very promising preclinical results obtained in vitro and in vivo. Faced with situations where stocks of labile blood products (LBP) can be insufficient, particularly as regards platelets, the i-SEP solution promises to be a major innovation for patients and physicians.

This European multi-center clinical trial aims to confirm the performance and safety of the i-SEP perioperative blood salvage solution, both in terms of blood washing and salvaging of red blood cells and platelets. The challenge is therefore to confirm the very promising preclinical results and evaluate whether they are associated with a reduction in allogeneic transfusions and even patient bleeding. The trial will be carried out on 50 patients in four hospitals in France (Bordeaux University Hospital, Rennes University and Private Hospitals, HEGP (APHP) hospital in Paris) and two hospitals in Belgium (Charleroi University Hospital, Liege University Hospital), with the aim of obtaining CE marking in the first half of 2022.

Autotransfusion has been recommended by health authorities since 2010.

The World Health Organization and Patient Blood Management have been promoting the use of autotransfusion since 2010[3], both in the interest of the patient and to reduce healthcare costs.

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[1] French health products competent authority

[2] Belgian health products competent authority

[3] WHA63.12 - Sixty-third World Health Assembly: Patient Blood Management (PBM) optimizes the management of patients undergoing surgery at risk of bleeding through the implementation of a coordinated, multimodal and multidisciplinary strategy aimed at maintaining acceptable hemoglobin levels, optimizing hemostasis, minimizing blood loss and limiting allogeneic transfusions (donor blood).

In France, more than 500,000 patients are transfused each year. Although a life-saving and necessary act, an allogeneic blood transfusion[4] must nevertheless be justified. Far from being a harmless intervention, it carries risks of incompatibility, contamination and complications, and can be the cause of undesirable effects, mainly respiratory. Nearly 60%[5] of allogeneic transfusions are considered inappropriate, leading to multiple increased risks. Autotransfusion reduces these risks and may also help to preserve banked blood supplies for patients with no alternative. In particular, it helps relieve pressure on the allogeneic platelets supply, which is increasingly needed in hematology/oncology. The only autotransfusion technology currently available on the market works by centrifugation and allows only red blood cells to be saved, but no other blood components such as platelets.

"The i-SEP technology is extremely innovative because it changes the concept of autologous transfusion in a meaningful way. As Head of my department, fully involved in anesthesia-resuscitation for cardiovascular, thoracic and heavy digestive surgeries including organ transplantation, the results of the preclinical trials seem very promising to me, and I am looking forward to the results of the clinical trial that is about to begin", explains Professor Alexandre Ouattara, Head of the Anesthesia-Resuscitation Department at Bordeaux 3 University Hospital.

Promising preclinical results for patients and physicians

On the eve of its clinical trial launch, i-SEP already relies on its preclinical results obtained in recent months in collaboration with its academic and hospital partners, including the Bordeaux and Rennes University Hospitals and the ONIRIS Veterinary School of Nantes. For physicians, the i-SEP solution differs first by the quality of the final product (with platelets) and also by its ergonomics and intuitiveness. The equipment is designed to allow immediate use and installation in less than 2 minutes (compared to up to 5 to 10 minutes for existing solutions). The blood treatment speed is also an important feature, which limits the risk of hemorrhagic shock for the patient. i-SEP offers a faster treatment than the average of competitive alternative techniques (6 minutes[6]), with 500 mL treated in only 4 minutes[7].

From the perspective of the patient, the stakes are twofold:

- **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.
- The innovation lies in the ability of the i-SEP solution to deliver **platelet yields ranging from 53-81% per cycle**[7], compared to only 5-11% for currently commercially available devices. These figures are significant given the cost and risks associated with the transfusion of

[4] In an allogeneic transfusion, the patient receives blood or blood cells from a donor or from blood banks.
[5] Aryeh Shander et al. Transfusion Med Rev Volume 25, Issue 3, July 2011, Pages 232-246.e53
[6] Bibliographic and experimental data
[7] i-SEP, internal data

allogeneic platelet concentrates[8] (inflammatory reactions, alloimmunization, increased mortality in liver surgery and morbidity in cardiac surgery, etc.).

- **Ensure a concentration and washing of the blood at least equivalent to existing solutions, in particular according to two essential criteria:**

- Concentration of red blood cells (hematocrit) in the treated blood product: the i-SEP solution using tangential filtration technology achieves an output hematocrit of 49.6%[9], which is equivalent to already commercialized devices.
- The i-SEP solution can remove heparin from the blood up to 99.7%[9].

"*Our clinical trial, which will begin in the second half of 2020, aims to demonstrate the performance and safety of our autotransfusion device before it is launched on the market: this is a key step on the regulatory pathway towards the CE marking planned in 2022*," said 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 surgery, using equipment that is both ergonomic and intuitive. i-SEP works closely with teams of reference anesthetists and resuscitation 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-Resuscitator from Bordeaux University hospital, Bertrand Chastenet, former company director and consultant in the pharmaceutical industry, French foreign trade advisor, and Sylvain Picot, Medtech entrepreneur, founder of Biom'Up. 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

[8] Sources: Van Hout 2017, Tsirigotis 2016, Kertai 2016, Glance 2014, Alfiveric 2011, Refaai 2011, Greinacher 2010, Pereboom 2009, Karkouti 2007, Vamvakas 2007, Spiess 2004, Dzik 2004
[9] i-SEP, internal data