Press release **Limoges, 2024 November 7th**

Professor Pascal Leprince, Head of the Cardiac Surgery Department at the Pitié-Salpêtrière Hospital in Paris, has agreed to set up a pilot clinical study to assess an antibiotic-loaded Porous Ceramic Sternal Stabilisation Implant.

I.CERAM, specialist in innovative biocompatible ceramic implants, has announced an agreement to set up an observational pilot clinical study in the department of Professor Pascal Leprince, Head of Cardiac Surgery at the Pitié-Salpêtrière Hospital in Paris, to assess the benefits of using an antibiotic-loaded Porous Ceramic Sternal Stabilisation Implant (ISS.C).

As part of its development work, I.Ceram has already initiated several technological breakthroughs, achieving two world firsts with the implantation of the first ceramic sternal implant and the first antibiotic-loaded sternal replacement implant.

The ***antibiotic-loaded Porous Ceramic Sternal Stabilisation*** Implant ***(ISS.C)*** has been designed to ensure optimal stability of the chest wall by insertion between the two parts of the native sternum that have already undergone sternotomy. This ISS.C implant was developed by I.Ceram as part of the S_2OP_2CI, project, winner of the I.nov 9th wave competition in January 2023. By integrating active antibiotic and antifungal molecules, this project aims to accelerate the osseointegration of implants in an infected environment.
Post-operative instability of the chest wall jeopardises bone healing of the sternum, encourages infection and makes post-operative management tricky. The expected objectives of using the antibiotic-loaded ISS.C sternal stabilisation implant are to avoid bacterial contamination of the implant in the implantation environment while stabilising the chest wall.

In the case of this pilot study, 10 implantations will be set up to assess the benefits of this system.

Professor Pascal Leprince's cardiac surgery department at the Pitié-Salpêtrière Hospital in Paris is a benchmark, both nationally and internationally, for all adult cardiac and aortic operations, from the simplest to the most complex. His active participation in this study is therefore a major asset in giving credibility to this new technological breakthrough.

Professor Pascal Leprince said: *"Cardiac surgery is now widely practised in many countries. The excellence and considerable progress made in their management have made them a benchmark procedure.*
However, postoperative mediastinitis, linked to risk factors such as obesity, diabetes and respiratory insufficiency, remains a potentially serious complication associated with a high mortality rate in all establishments.
I wanted to agree to this evaluation as part of a pilot study in view of the initial work already carried out by I.Ceram.
This pilot study will have three objectives: to measure the time taken to obtain negative bacteriological samples, their medical follow-up and the non-recurrence of chest wall instability'.

More than one million sternotomies are performed worldwide every year. Patients with multiple risk factors that can trigger infection of the sternal wound after sternotomy represent a risk for medical teams and health establishments, with an increase in the number of steps in patient management that could result in a less-than-optimal discharge in their care pathway. The associated management in the case of mediastinitis can lead to several repeat surgeries,

resulting in long weeks of hospitalization, sometimes in intensive care, with heavy demands on medical teams and exponential financial costs.

Despite the surgical excellence practiced in aorto-coronary bypass cases, according to scientific publications and their authors, the complication rate for mediastinitis varies from 0.3% to 2.5% or from 0.3 to 8%, depending on the populations involved, geographical areas and surgical practices. The risk of mortality associated with the occurrence of mediastinitis is between 5 and 20%, despite advances in its prevention, which remains an absolute priority.

For more information, please contact actionnaires@iceram.fr

About I.CERAM : Created in 2005 in Limoges, France, I.CERAM designs, manufactures and commercializes orthopedic implants and ceramic implants offering a unique biocompatibility (10 international patents). Based on its know-how and the experience of more than 30 years of its managers, the company has decided to strongly accelerate its development on bioceramics. I.CERAM is labelled «innovative company», certified ISO 13485, ISO 14001 and has the EC marking. With its breakthrough technology and state-of-the-art production facilities, I.CERAM has very strong growth potential. The company has been listed on Euronext Growth since 2014. ISIN: FR0014005IU4- ALICR

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