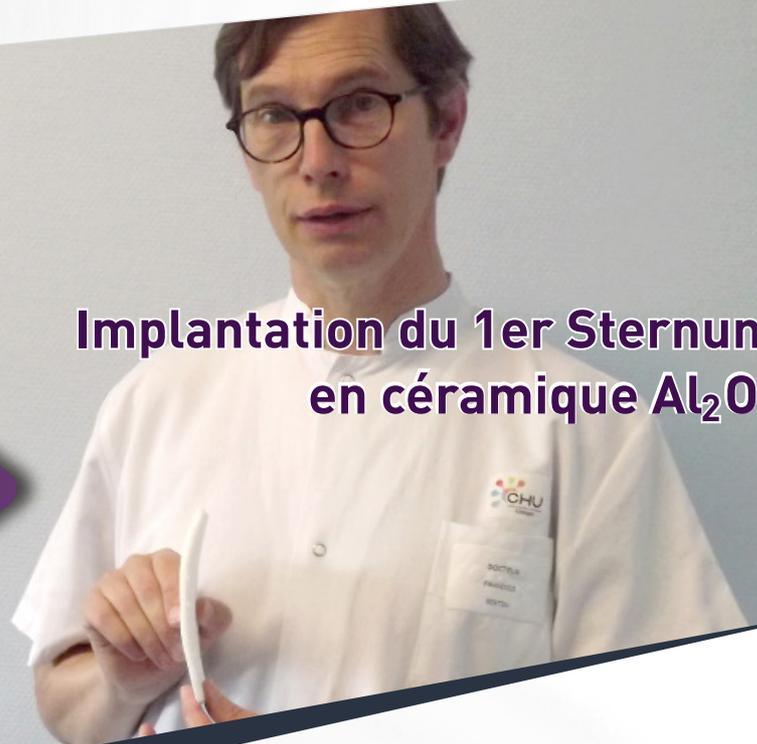


WORLD'S 1st  
ceramic sternum  $Al_2O_3$

AT THE LIMOGES  
UNIVERSITY HOSPITAL  
(CHU LIMOGES)  
FRANCE

Implantation du 1er Sternum  
en céramique  $Al_2O_3$



## A Global Innovation

The 19th of March 2015, Dr. François Bertin, a thoracic surgeon together with Professor Marc Laskar, the director of the cardio-vascular and angiology department at the University Hospital of Limoges performed the world's first implantation of a ceramic sternum. This procedure marks a turning point in surgeries pertaining to bone infections and bone metastases as it comprises a technology that is 100% biocompatible and rehabilitable:

*A complete porous ceramic sternum.*

The patient, 55 years of age, had undergone nine years of treatment for breast cancer. Following this treatment, she developed a radiation induced cancer of the sternum. The treatment of radiation induced bone cancer does not permit the use of chemotherapy or radiation therapy as a treatment but requires invasive surgery with the partial or total removal of the sternum. The removed infected sternum was normally replaced by cement filling or reconstructed by means of a metal structure with fixations. I.CERAM has used its competence and unique expertise of bioceramics to develop a biocompatible ceramic sternum.

After 3 months of clinical evaluations the operation was classified as a success with the patient benefiting from a new healthy sternum with continually improving respiratory capacity. Dr François Bertin, who was involved in the design of the device, added the following, *"the operation's results are very positive and the patient is recovering gradually. The sternum ceramic has fully met my expectations during the operation and we should see respiratory improvements in the patient during the coming months. From a surgical point of view, this is an important evolution in the reduction of operating time. Furthermore, the biocompatibility combined with the strength of the material allows us to return to the essence of surgery by providing a more natural operation, limiting the risk of infection and rejection. It is this characteristic of ceramic that has provided me with the opportunity to collaborate with I.CERAM in developing this innovative implant"*.

It is this combination of the surgical expertise of Dr. François Bertin and the conception and manufacturing expertise of the Ceramil ceramics of I.CERAM that has enabled the realization of this medical innovation. Initial pilot studies at the Limoges University Hospital with future multi-centered studies at other hospitals throughout France has validated the importance that ceramic has to offer as a solution in the treatment of bone infections and bone metastases.



**André KERISIT**  
President and CEO of I.CERAM

#### What is your reaction following this first implant ?

*I am very happy for the patient and very proud of the whole team who worked on this project for the past 18 months. The original idea was born several years ago, through persistence we made sure that we had the technical expertise, clinical expertise and financial resources in place to succeed with this project. This milestone is also directly related to our listing to the Alternext Paris stock exchange last December: We would like to thank all our investors whose support enabled us to achieve our daily objectives. We have to date the necessary means for the first phase of our implant development in bone infections and bone metastases.*

#### Why did you wait 3 months before announcing this achievement ?

*Dr. François Bertin and the medical team of the Limoges University Hospital wanted to have a sufficient period to determine if any possible post-operative complications might develop and also have concrete evidence regarding patient recovery. We agreed that caution was necessary and we decided to not communicate until after the usual clinical tests at 3 months. The clinical results are in line with what was expected and today we can congratulate everyone that has contributed towards the success of the ceramic sternum implant.*

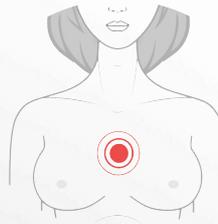
#### What significant importance does the ceramic sternum have for I.CERAM ?

*This is a step in our strategy that has been validated ! With this operation, we show our ability to manufacture significant parts of the skeletal system in various dimensions. Our Ceramil technology (porous alumina implants) allows us to pioneer the use of ceramics for bone metastases surgery. The opportunities are very important as demonstrated by two figures: 14 million cancer cases are diagnosed each year in the world ... and 70% of people with cancer develop bone metastases! Furthermore, the implant approximates I.CERAM in the field of cardiovascular surgery that has shown significant increases in recent years.*

#### What is the next step ?

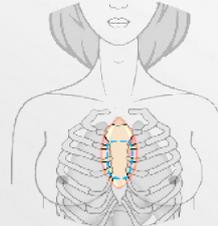
*We will continue our research and development at a sustained pace. The objective is to provide within 18 months a sternum loaded with active molecules in order to treat indications of sternal infections. Bone infection is a very important market, to illustrate: 2 to 4% of prostheses become infected, and there are more than a million hip replacements per year worldwide. As for heart surgery (bypass surgery, heart transplants ...), an estimated 4% of sternums become infected from a total of 40,000 operations per year in France alone! This market is very important and to date there are no infected sternum treatment solutions. So we have good prospects and promising projects to make I.CERAM a world leader in the treatment of bone infections and bone metastases!*

## The operation technique simplified



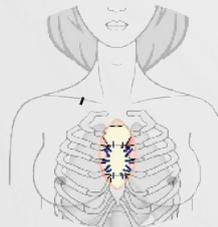
### Identification of metastases

The surgeon localises the bone metastases following examinations.



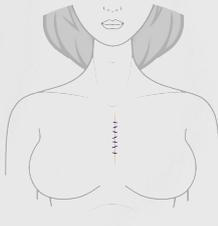
### Removal of the tumor

After carrying out the anatomical markings, the surgeon makes an incision following the path and the entry point of the biopsy, severing the ribs and removes the tumor in one-piece.



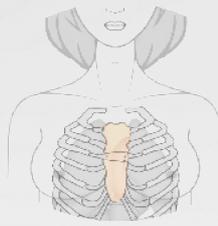
### Positioning of the implant

The surgeon positions the implant and secures it with the necessary sutures, the ceramic implant is then covered with a portion or flap of the pectoralis major.



### A global innovation

Finally, the surgeon performs a drainage and sutures the deep tissues to the skin. The healing of the wound is generally in the region of 7 days and the staples can be removed after 10 days.



### A perennial bone incorporation

12 months after implantation, the sternal implant will be completely integrated.



Explanatory video in French :  
<https://youtu.be/op1HoHvm7C8>

## A significant therapeutic improvement

The radiation-induced cancer presents complex and limited treatment options. Until today, two alternatives were available to cardiovascular surgeons, either replacing the sternum with a titanium prosthesis (but recent studies showed a high risk of infection), or building during operation a customized structure from bone cement with the addition of metal fixators. Both solutions multiply the risk of infection.

I.CERAM Ceramic Sternum	Avantages	Reduced operating time Total biocompatibility Complete bone integration within 12 months Very low risk of infection Reduced psychological impact for the patient Compatible with radiology therapy and x-rays
	Disadvantages	Limited clinical results
Titanium Sternum	Avantages	Reduced operating time Made to measure
	Disadvantages	High risk of infection High psychological impact Results in distortion with x-rays
Construction of a bone cement based sternum	Avantages	Made to measure at the time of the operation
	Disadvantages	Operating time greatly increased Difficulty in fixation High risk of infection Heat is emitted with a risk of burning

The I.CERAM ceramic sternum provides total biocompatibility for sustainable osseointegration. The fact that no metals are implanted in this procedure enables the surgeon to capture high quality radiographic imagery that has an important part to play in the clinical follow ups. The I.CERAM sternal implant reduces the operating time that in turn reduces the risk of infection (studies indicate that by increasing the operating time by one hour the risk of infection will be doubled).

The overall impact to the patient is decreased. The integration of the "natural" implant reduces the psychological effects of such an operation and facilitates the acceptance of the implant by the patient with regained plasticity of the thorax.

The ceramic sternum also ensures reproducibility of the operation and corresponds to modern surgical standards. It offers surgeons an additional convenience through holes that allows a simplified anchoring of the implant.

## The cardio thoracique potential

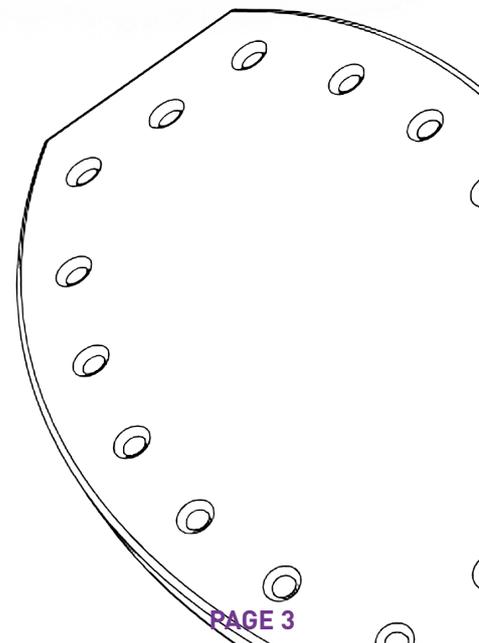
Radiation-induced cancer of the sternum and metastases of the sternum amounts to approximately 200 cases per year in France (about 3% of bone metastases). These indications may benefit from the technology developed by I.CERAM.

Primary sternal cancers or metastatic sternal cancers are not the only diseases that can benefit from the alumina sternal implant. Today in France more than a 100 heart operations are performed each day. Of the 42 000 patients that have undergone heart operations (cardio-vascular, bypass, transplant), about 4% of these have developed post operative complications of the sternum: postoperative mediastinitis (DSWI). In France alone over 1,300 people are affected by this disease every year.

To date, bone infections are very difficult to treat orally or by injections, because of this the effectiveness rate of conventional treatments on bone infections is very low. Furthermore, it is unthinkable to insert a metal implant into an infectious area, that could be immediately rejected by the body and lead to a superinfection.

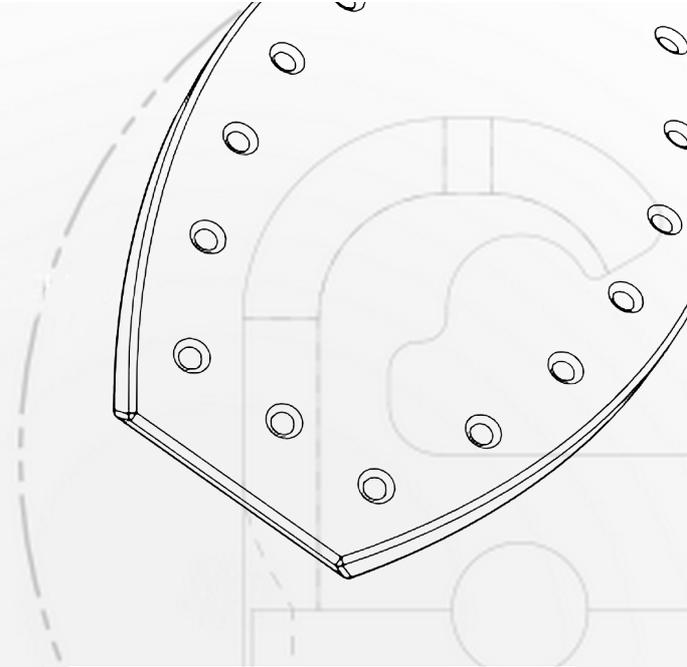
The sternum ceramic, through its biocompatibility, inertness and ability to be loaded with active molecules (antibiotics) has a very promising future for these pathologies. The economic potential of this innovation is estimated to be in the region of several millions of euros in France.

DETAIL  
SCALE 3





I.CERAM  
Sternal implant



## I.CERAM, the creator of innovant implants

2005 saw the creation of a French Medtech company at the epicentre of the European Centre of Ceramics dedicated to the manufacture of orthopaedic and bioceramic implants (11 patents), offering a unique biocompatibility. The wealth of knowledge and expertise from over 30 years of experience as well as dialogue with surgeons has enabled I.CERAM to accelerate its bioceramic development.

This conviction, backed by a clinical history of over 15 years, is that the alumina ceramics allows the conception and development of breakthrough treatments in the field of bone infections and bone metastases. To date, the solutions that exist, have very important psychological and functional costs to patients that can amount to tens of thousands of euros in most cases. It is the I.CERAM belief that porous ceramics have the intrinsic qualities needed to create an innovative breakthrough in the treatment of bone infections and metastasis, the company is currently developing ceramic implants that leaches out active molecules to the infected areas of the human skeleton. The ambition of the company is to become the world leader in the treatment of bone infections and bone metastases.

I.CERAM is labeled as an "innovative company", ISO 9001, ISO 13485 certified and CE certified. With 40 employees and a production tool at the forefront of technology, I.CERAM continues to show a very high potential to continuously develop. On the 19th of December I.CERAM was listed on the Alternext (Euronext Paris) stock exchange.

## The CHU Limoges

The CHU Limoges, headed by Mr. Hamid Siahmed, was established in 1974 and has three public service missions: patient care, teaching, research and innovation. The CHU Limoges is composed of numerous institutions, (Hospital Dupuytren, Hospital Jean Rebeyrol, Hospital Cluzeau, the Mother and Child Hospital and the Hospital Dr. Chastaingt) as well as a Biology and Health Research Centre. The training institutes and the faculties of medicine and pharmaceuticals provides a professional environment for the caregivers and the doctors of tomorrow.

The teams labelled INSERM and the various and numerous projects recognized at national and European level illustrate the excellence of the University Hospital's commitment to the development of its research activities. Doctors Laskar, Azorin and Bertin in 2004 performed at the CHU Limoges, the first trachea transplant by using a sample of the aorta. In 2006, Dr. Joel Brie, the head of maxillofacial surgery department performed the the first cranium implant.



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