osteobionix

Patient-specific solutions
Chest wall reconstruction

Francesco La Palombara

Who we are

osteobionix is a company, focused on **patient-specific solutions for bone and joint reconstruction and regeneration**, founded in 2018 as a spin-off of the Canary Islands Institute of Technology (**ITC** – Instituto Tecnológico de Canarias).

The **ITC Department of Biomedical Engineering** has worked on innovative solutions for bone and cartilage deficiencies since 2006. The first custom porous metal implant designed and manufactured by ITC was implanted in 2011.

itc INSTITUTO TECNOLÓGICO DE CANARIAS

Gobierno de Canarias

osteobionix

Our mission

osteobionix is a company dedicated to advancing the standards of care for people suffering from cartilage or bone loss. Cartilage and bone loss may result from a variety of causes including osteoarthritis, trauma and tumor and can severely affect a person's lifestyle.

osteobionix wants to provide people suffering from cartilage or bone loss with innovative, high-quality, proven, customized solutions, which can help them regain the lifestyle they deserve.

osteobionix collaborates with surgeons in designing and manufacturing reliable, cost-effective solutions, which take into account the uniqueness and complexity of each single surgical case.

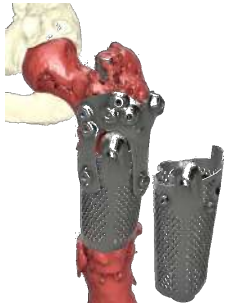
osteobionix strives to be an industry leader in the progressive paradigm shift from replacement to regeneration in cartilage and bone surgery.

osteobionix

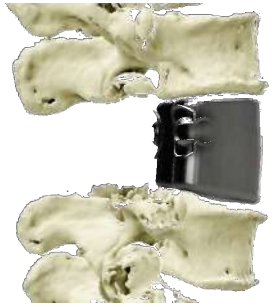
What we do

osteobionix – **patient-specific** solutions for bone and joint reconstruction and regeneration in **human** surgery

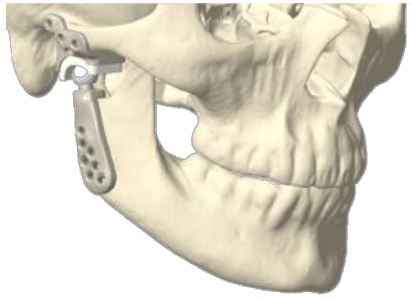
thoracic surgery
85+ implants to date



orthopedic & trauma surgery
140+ implants to date



spine surgery
30+ implants to date



CMF surgery
200+ implants to date

(data June 2023)

osteobionix

Thoracic

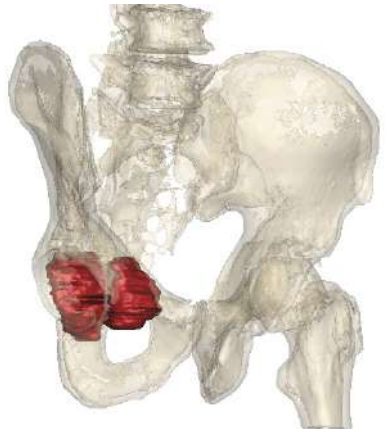
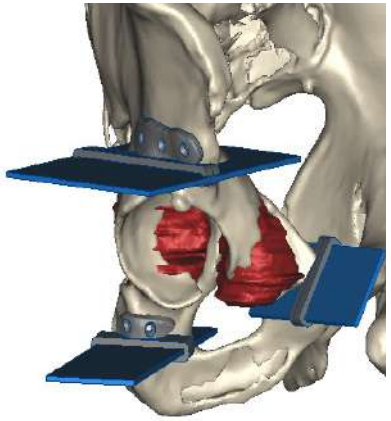
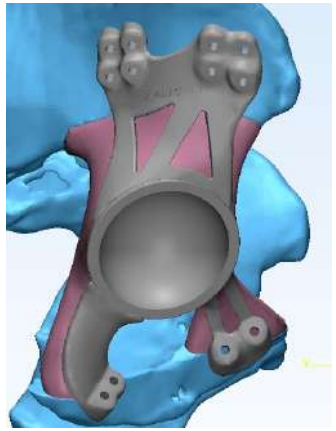
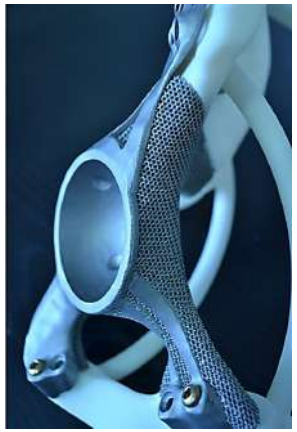



large rib cage reconstruction (ribs and part of the sternum)

85+ thoracic cases (Spain, Italy, Germany, Austria, UK, The Netherlands, USA)

osteobionix

Orthopedic – Hip

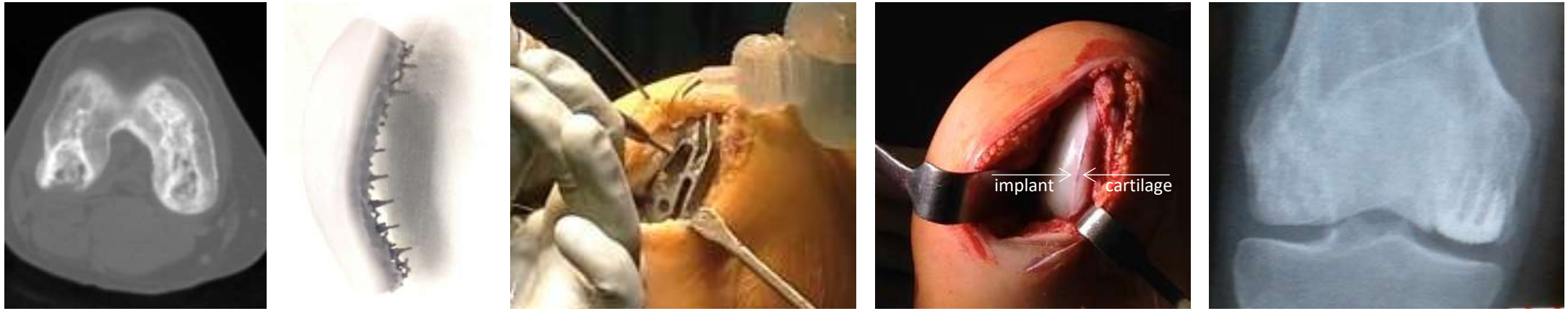





large hip reconstruction

40+ hip cases (Argentina -with Raomed-, Italy, Spain, UK)

osteobionix

Orthopedic – Knee

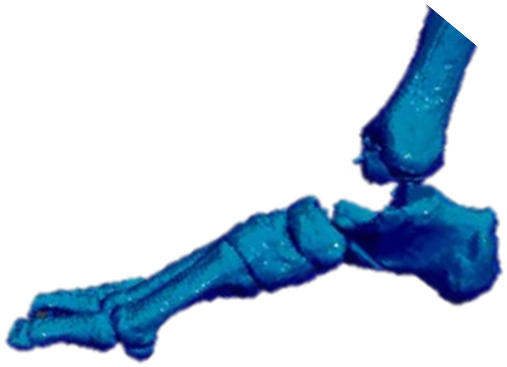


focal defect repair (milling guide + porous titanium & polycaprolactone

6 knee focal defect cases (Italy)

osteobionix

Orthopedic – Ankle



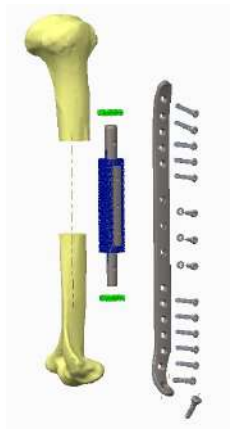


talus reconstruction (positioning & reaming/cutting guides + porous/smooth implant)

30+ ankle cases (Italy)

osteobionix

Orthopedic – Segmental

humerus segmental reconstruction (porous segment + plate)

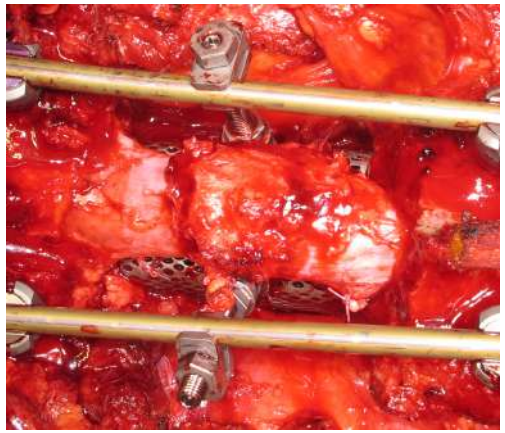
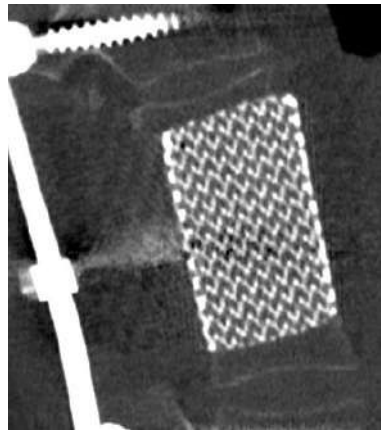
35+ segmental cases (different bones, Italy, Spain, Syria and Argentina -with Raomed-)

osteobionix

Spine





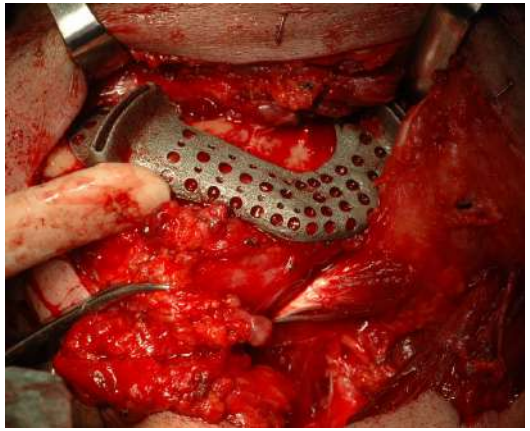
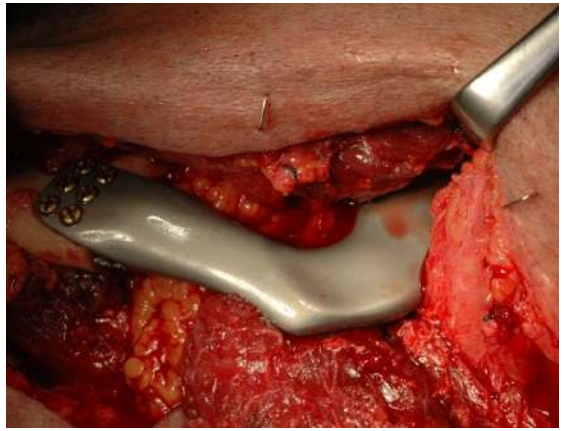
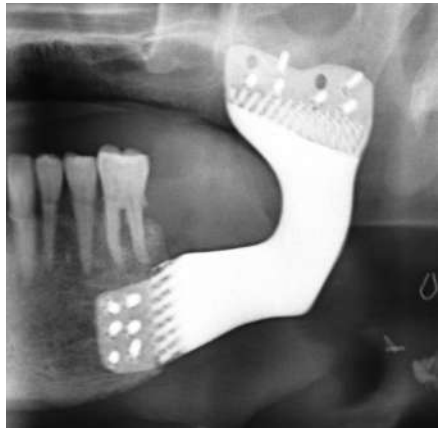



T12 reconstruction case (porous titanium implant – 90% air)

30+ vertebral reconstruction cases (Italy)

osteobionix

CMF - Jaw

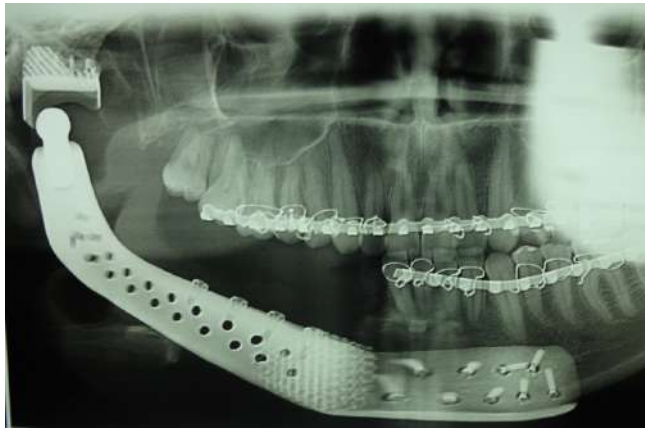
mandible reconstruction (cutting guide + porous/smooth implant)

25+ mandible/maxilla reconstruction cases (Spain and Italy)

osteobionix

CMF - TMJ



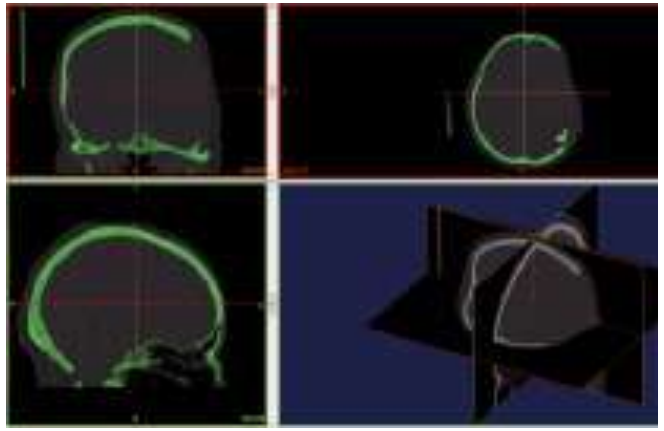
TMJ and mandible reconstruction

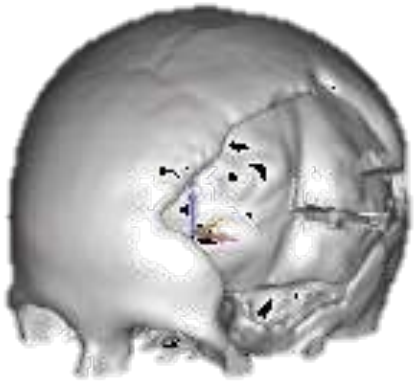
Unique, patented, minimally invasive TMJ design to be launched in 2023

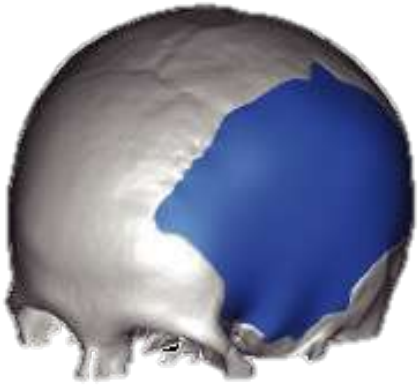
100+ TMJ cases (Spain, Italy and Argentina -with Raomed-)

osteobionix

CMF - Skull







cranial plates in PMMA or titanium

60+ cranial cases (Spain and Italy)

osteobionix

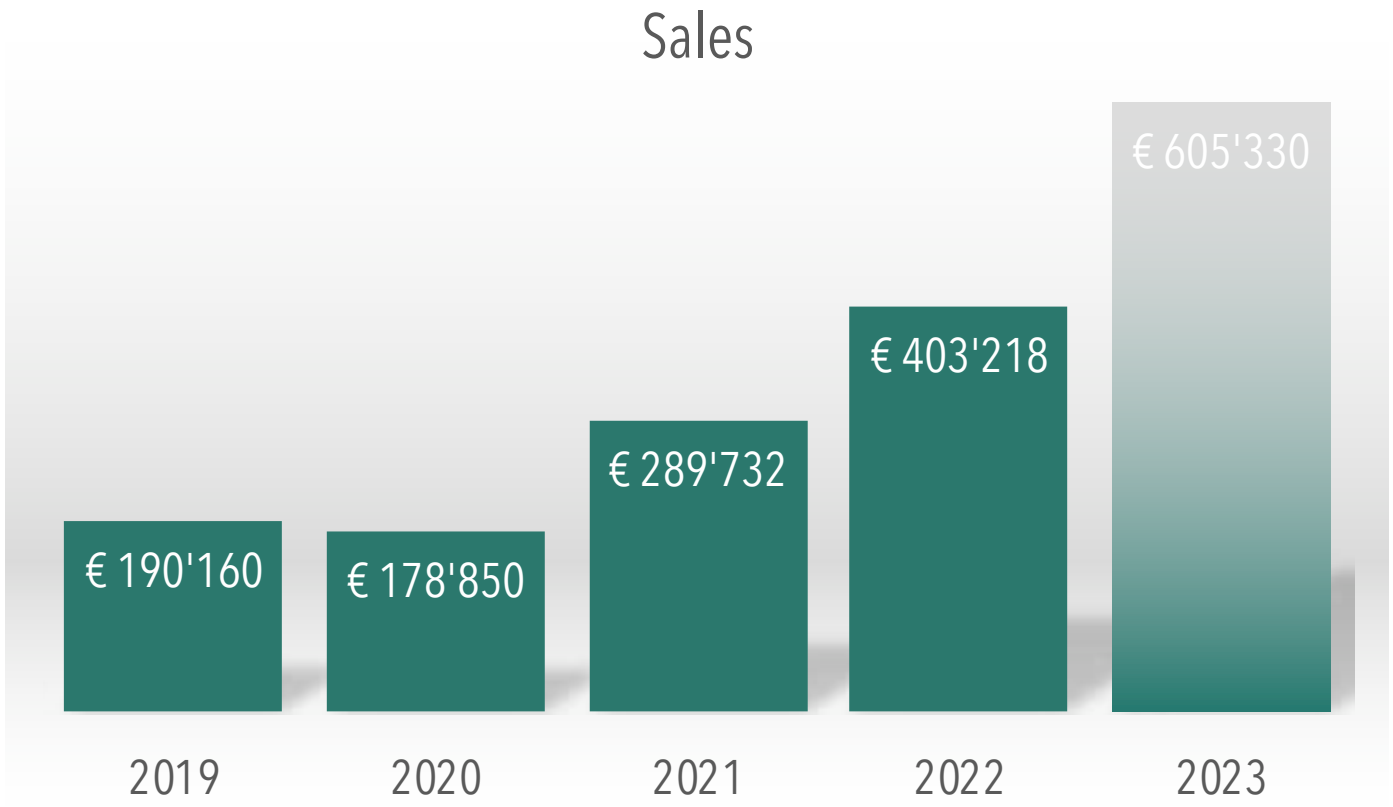
Other reconstructive surgery

osteobionix has also designed and manufactured solutions for:

- elbow
- maxillary bone and sinuses
- orbital wall

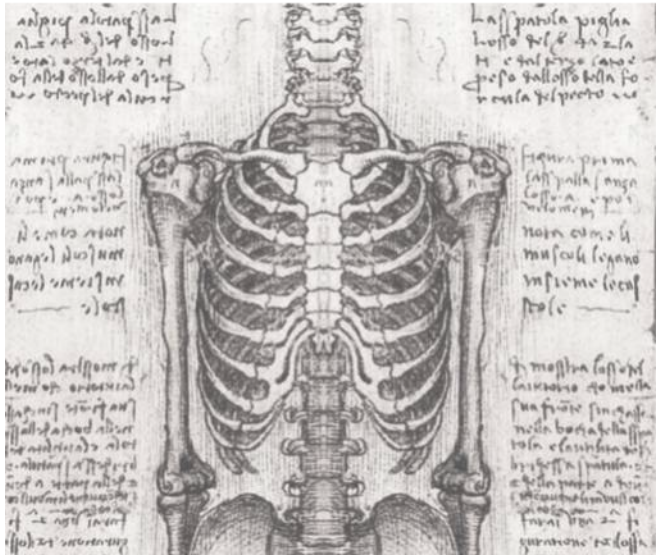
To date 450 **osteobionix** custom solutions have been implanted.

Growth



osteobionix

Chest wall reconstruction



Demolition, reconstruction and stabilization of the thoracic cage can become necessary due to a variety of medical conditions including

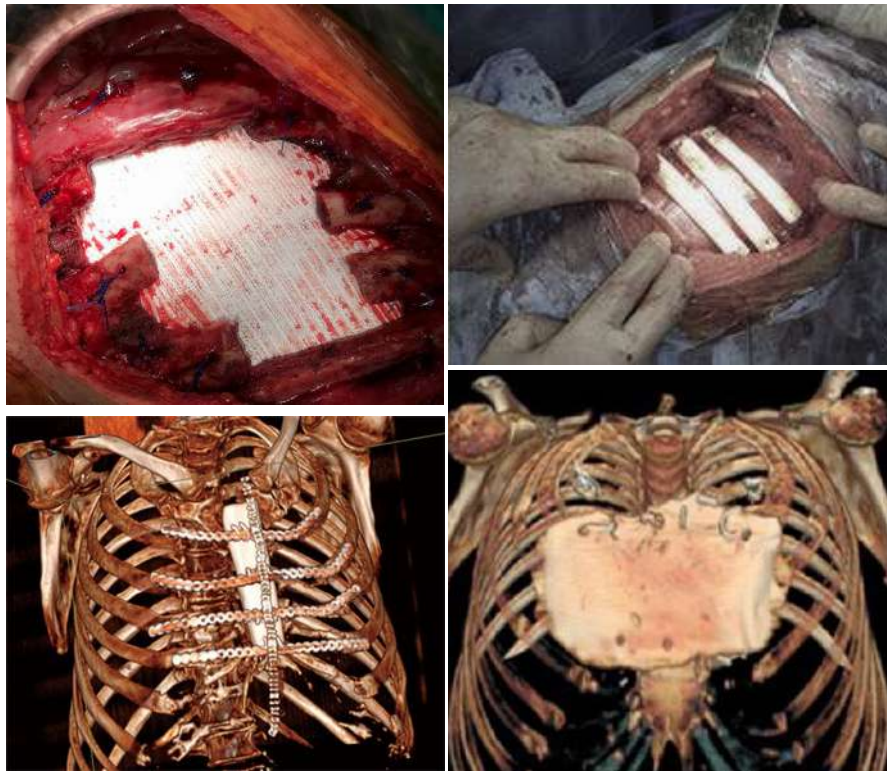
- ✓ neoplasms
- ✓ trauma
- ✓ malformations

In all cases targets of a successful reconstruction are

- ✓ **structural stability** – protect internal organs
- ✓ **elasticity** – preserve respiratory mechanics
- ✓ **deformity minimization** – function and cosmetics

osteobionix

Conventional implant options



The procedural complexity of thorax reconstruction has led to a variety of solutions, none of which has, however, proven to be optimal

- ✓ synthetic (PTFE and other polymers), biomaterial and titanium meshes
- ✓ mesh + PMMA sandwich
- ✓ mesh + other material (carbon fiber, silicone…) composites
- ✓ (allografts +) titanium plates

osteobionix

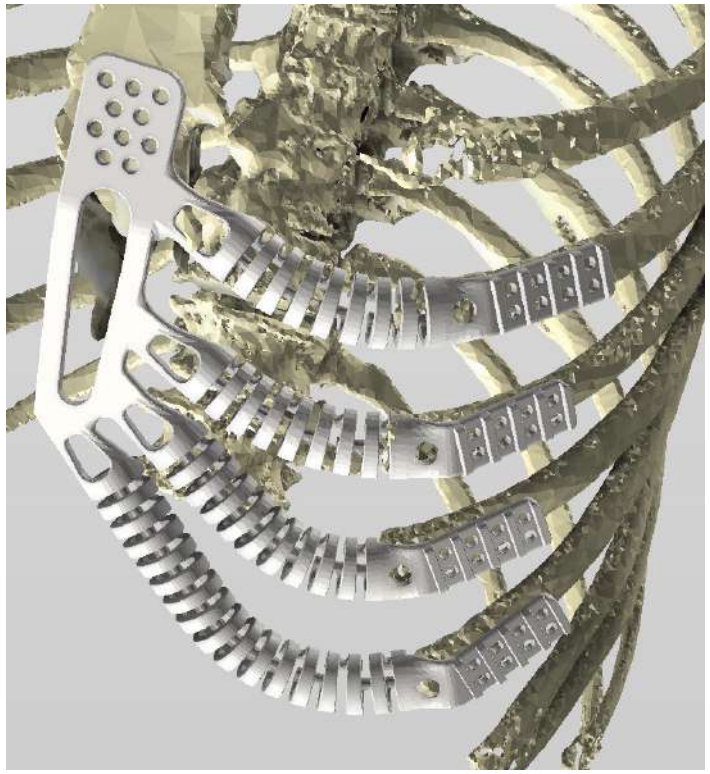
Conventional implant drawbacks

All conventional solutions have weaknesses, which, to different extents, make their advantages less attractive. Common implant drawbacks include

- ✓ **incomplete protection** (lack of rigidity/stability)
- ✓ **paradoxical breathing** (lack of rigidity/stability)
- ✓ **respiratory distress** (excessive rigidity)
- ✓ **post-operative pain** (rigidity, insufficient permeability)
- ✓ **implant breakage** (inadequate mechanical resistance)
- ✓ **infection** (impermeability, no tissue ingrowth, no vascularization)

osteobionix

Our solution



Our solution is an industry-first **customized implant**, designed with the surgeon, based on a patient's CT scan.

- ✓ implant is made of 3D printed titanium alloy
- ✓ size can range from a single rib to sternum with multiple ribs
- ✓ structure is **solid and stable** to avoid paradoxical chest motion and protect internal organs
- ✓ **ribs are flexible and extensible** to allow for normal respiratory mechanics
- ✓ shape mimics sound rib cage to **minimize deformity**
- ✓ implant options can include **detachable sternum-rib connections**
- ✓ implant can be fixed to resected ribs with screws, claw-type fixation or cerclage

osteobionix

Publications

- ✓ Aragón J, Pérez Méndez I (2016) **Dynamic 3D printed titanium copy prosthesis: a novel design for large chest wall resection and reconstruction**. J Thorac Dis 8(6):e385-389
- ✓ Simal I, García-Casillas MA, Cerdá JA, Riquelme O, Lorca-García C, Pérez-Egido L, Fernández-Bautista B, de la Torre M, de Agustín JC (2016) **Three-dimensional custom-made titanium ribs for reconstruction of a large chest wall defect**. Eur J Pediatr Surg Rep 4:26–30
- ✓ Moradiellos J, Amor S, Córdoba M, Rocco G, Vidal M, Varela A (2017) **Functional chest wall reconstruction with a biomechanical three-dimensionally printed implant**. Ann Thorac Surg 103:e389–91
- ✓ Cano JR, Hernández Escobar F, Pérez Alonso D, López Rivero L (2018) **Reconstruction of the anterior chest wall with a 3-dimensionally printed biodynamic prosthesis**. J Thorac Cardiovasc Surg 155:e59-60
- ✓ Vannucci J, Scarnecchia E, Potenza R, Ceccarelli S, Monopoli D, Puma F (2020) **Dynamic titanium prosthesis based on 3D-printed replica for chest wall resection and reconstruction**. Transl Lung Cancer Res

osteobionix

Intellectual property

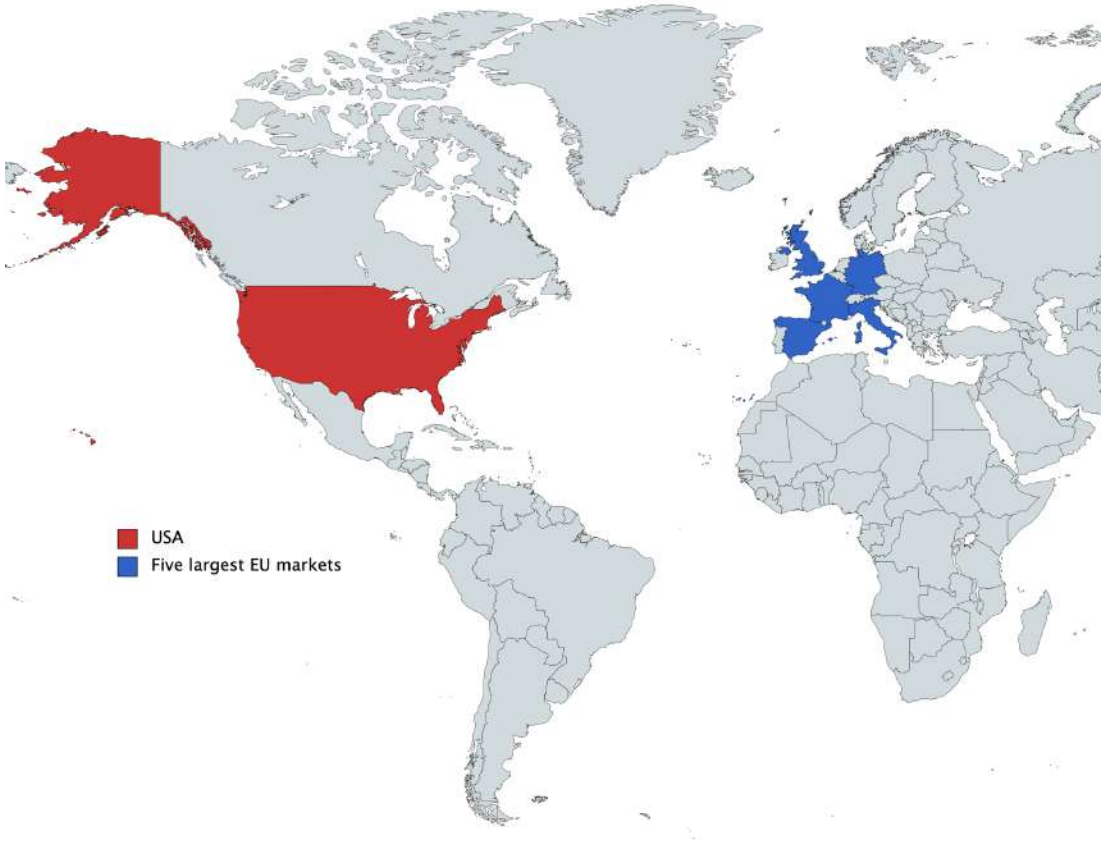
Osteobionix S.L. is currently pursuing intellectual property protection for two inventions.

Polyaxial screw mechanism for osteosynthesis
Ownership: Osteobionix S.L.
Authority: German Patent Office – territorial extension planned
Status: Submitted, waiting for feedback

Flexible geometry for surgical implants (chest wall and potentially other applications)
Ownership: ITC. Osteobionix S.L. would be exclusive licensee
Authority: German Patent Office – territorial extension planned
Status: Submitted, waiting for feedback

osteobionix

Market opportunity



Market opportunity, calculated by adding the *high-complexity* and 50% of the *medium-complexity* tumoral chest wall reconstructions and the *high-complexity* non-tumoral chest wall reconstructions, is 1.63 cases per million people per year.

First commercial targets: **five largest European markets** and **USA**

Five largest European markets (DE, UK, FR, IT, ES)

322 million people
525 cases/year (potential sales volume)
6.3 million €/year (6.8 million US$/year, potential sales revenue)

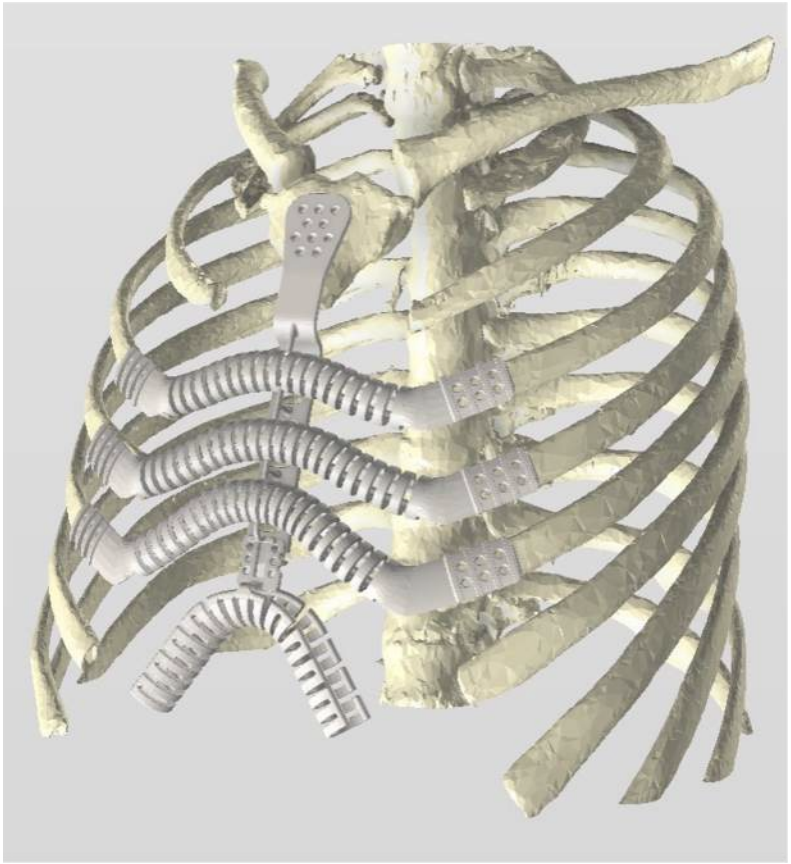
USA

328 million people
535 cases/year (potential sales volume)
8.6 million US$/year (potential sales revenue)

osteobionix

Reference centers and surgeons

- James D. Geiger – C.S. Mott Children's Hospital, University of Michigan, Ann Arbor, MI, USA
- José Ramón Cano – University Hospital Las Palmas, Spain
- Javier Aragón – Central University Hospital of Asturias, Oviedo, Spain
- Nicolás Moreno – Ramón y Cajal University Hospital, Madrid, Spain
- Francisco Javier Moradiellos – Quirónsalud University Hospital, Madrid, Spain
- Unai Jiménez – Cruces University Hospital, Bilbao, Spain
- Juan Carlos Trujillo-Reyes – University Hospital de la Santa Creu i Sant Pau, Barcelona, Spain
- Ana Blanco – Virgen del Rocío University Hospital, Seville, Spain
- José Ramón Matilla – AKH Universiy Hospital, Vienna, Austria
- Pieter Jan van Huijstee – HagaZiekenhuis, The Hague, The Netherlands
- Enrico Ruffini – Molinette University Hospital, Turin, Italy
- Michele Rocca – Rizzoli Orthopedic Institute, Bologna, Italy
- Michele Torre – Gaslini Children's Hospital, Genoa, Italy
- Jacopo Vannucci – Umberto I University Hospital, Rome, Italy



osteobionix

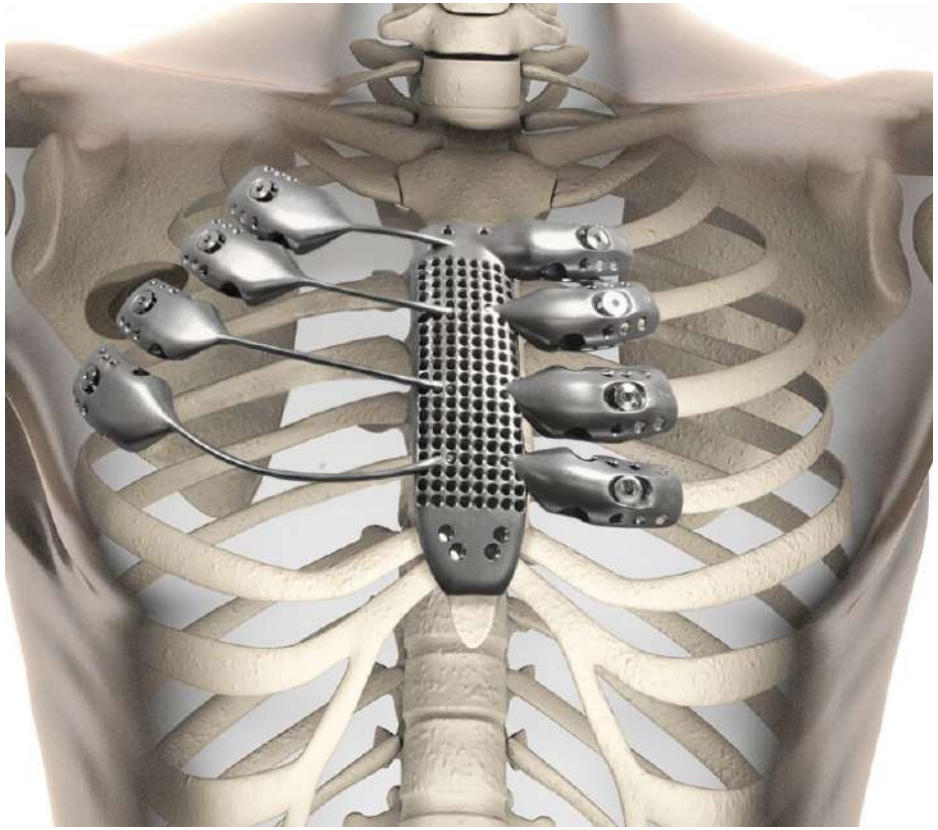
Competitive landscape

Anatomics, Australian company, implanted world first 3D-printed custom thoracic prosthesis – Salamanca, Spain, **2014**

- Aranda JL et al., (2015) Tridimensional titanium-printed custom-made prosthesis for sternocostal reconstruction. Eur J Cardio-Thor Surg 48(4):e92-94

ITC (osteobionix' parent institution) implanted their first custom thoracic prosthesis –developed through **independent research**– in Oviedo, Spain in **2015**

- Aragón J et al., (2016) Dynamic 3D printed titanium copy prosthesis: a novel design for large chest wall resection and reconstruction. J Thorac Dis 8(6):e385-389



osteobionix

Competitive landscape

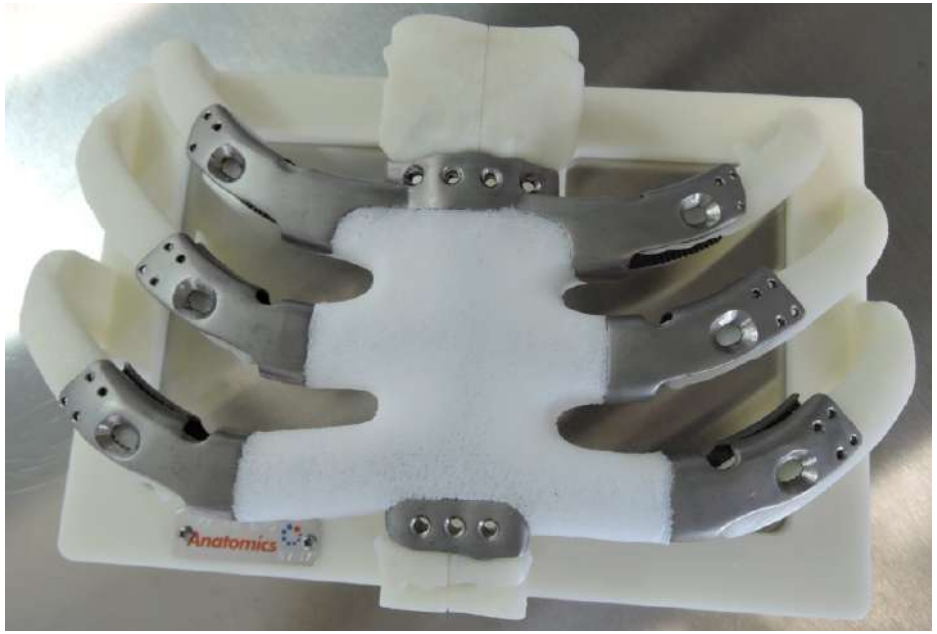
Anatomics' first chest wall reconstruction surgery in the US in **2017**

- Dr Jeffrey L. Port, New York-Presbyterian/Weill Cornell Medical Center
- 20 yo patient suffering from Chondrosarcoma
- Combined titanium and **porous polyethylene** (**StarPore**) implant
- **FDA** clearance through **Expanded Access** (**Compassionate Use**)

Anatomics is now producing custom chest wall implants made of StarPore only (no metal).

Anatomics implants

- **lack extensibility** (extensible structure patented by ITC/osteobionix)
- no info available on implants including sternoclavicular joint, fixed to spine, accommodating patient's growth etc. (**lack versatility**)

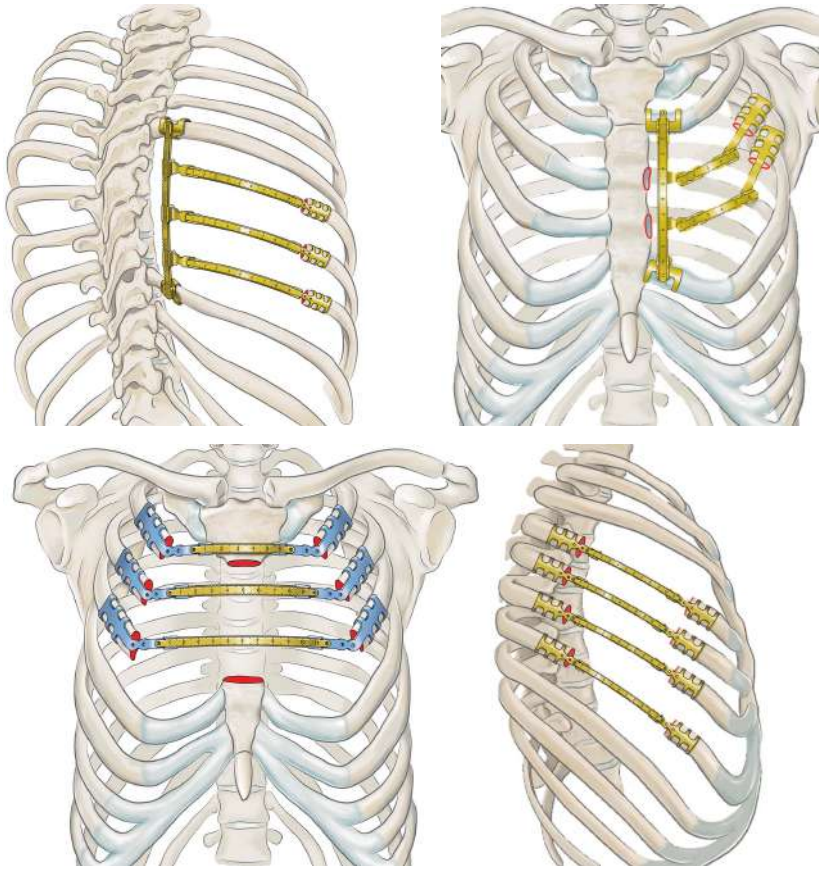


osteobionix

Competitive landscape

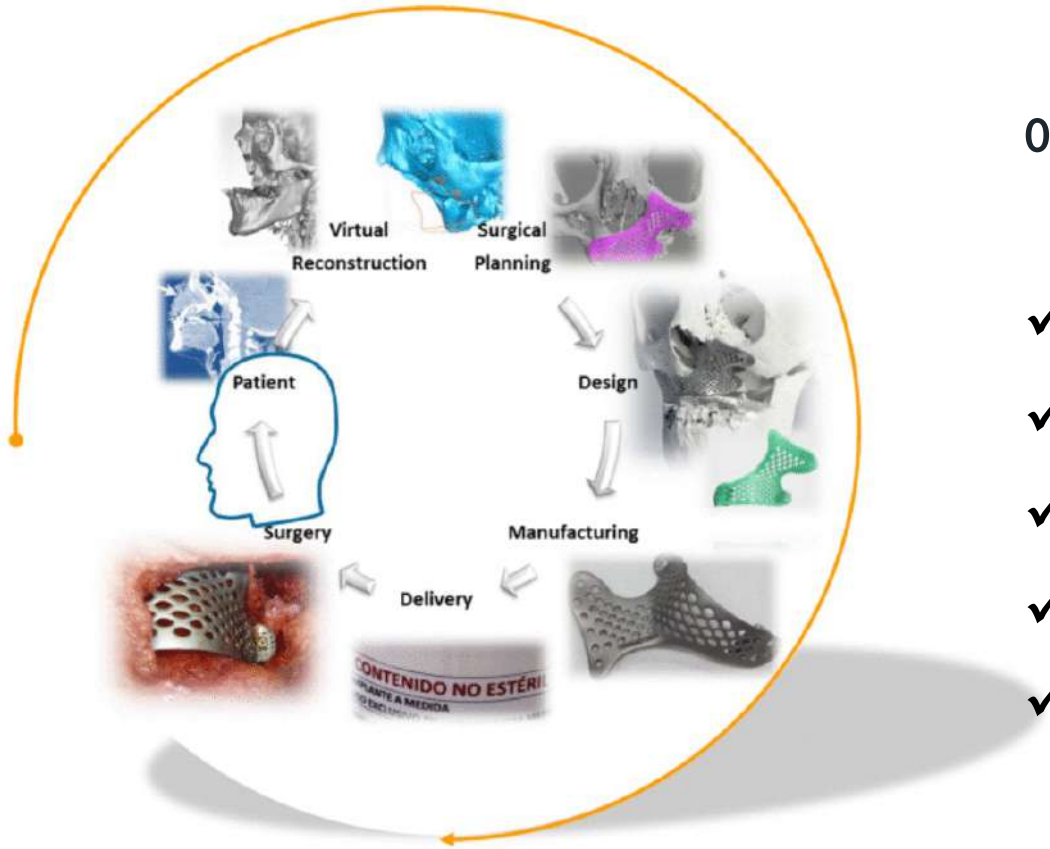
The closest off-the-shelf implant is possibly **Stratos** by **MedXpert**

- Received 510(k) – Class II – Regulation number 21CFR888.3030: Single/multiple component metallic bone fixation appliances and accessories
- Non-anatomic – requires longer pre-op and intra-op time for planning, bar bending and assembly
- Rigid
- Multiple failure reported
  - Sharma PK et al. (2017) Implant Failure: STRATOS System for Pectus Repair. Ann Thor Surg 103(5):1536-43
  - Muthialu N. et al. (2019) Disturbingly high fracture rate of STRATOS bars in pectus corrections. Eur J Cardio-Thor Surg 55:300–3



osteobionix

How we work



osteobionix offers

- ✓ long-term experience in complex cases
- ✓ close collaboration with the surgeon
- ✓ fast and easy information exchange
- ✓ accurate planning, design and manufacturing
- ✓ implant delivery in three weeks from design freeze

osteobionix

How we work


surgical simulation on plastic model

osteobionix receives the patient's CT scan and a signed request for a patient-specific implant. Images are segmented and a virtual 3D model of the patient's anatomy is created and shared with the surgeon. The 3D model is used for pre-op planning.

Starting from an initial proposal from **osteobionix** and through a frequent and fast information exchange between surgeon and engineers, patient-specific implant and instruments are designed.

Once the design phase is completed, a design report is submitted to the surgeon for final approval.

Implant and instruments are then manufactured and shipped non-sterile, along with a polymer anatomical model, to the hospital. The surgeon also receive a user manual. Prior to surgery surgeons can receive remote pre-op surgical training if they wish.

Surgeon evaluates implant and instruments by simulating the surgical procedure on the anatomical model.

osteobionix

How we sell

- ✓ product not ideal for standard distribution:
  - ✓ no inventory
  - ✓ no stock
  - ✓ no warehousing
  - ✓ parent company very involved throughout the sales process
- ✓ distributor's main requirements:
  - ✓ extensive network of relevant surgeons
  - ✓ familiarity with complex bone and joint reconstruction procedures
  - ✓ competence to act as surgeons' advisor

osteobionix

How we sell

- ✓ distributor's main tasks:
  - ✓ prospect identification (mainly centers/surgeons specialized in oncology and/or complex reconstructions)
  - ✓ initial presentation of company and products/services
  - ✓ hospital administration process management
  - ✓ follow-up visits
- ✓ price to hospital depends on implant complexity.
- ✓ distributor's compensation: discount on final selling price (e.g. price to customer € 15,000, price to distributor € 12,000)

osteobionix