



# GreenBone Ortho

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## Leading innovation in bone regeneration

**With its innovative bone graft scaffold, GreenBone Ortho srl is well on its way to becoming a worldwide leader in bone regeneration.**

Patients with large bone defects caused by trauma, unhealed fractures, infection or cancer have limited treatment options. If the damaged area is greater than 2–3 cm, the only regenerative option is to transplant a replacement bone from another part of the body. If this is not possible, patients are faced with the prospect of artificial grafts that offer no possibility of bone regeneration; there is a high social and economic cost as patients often undergo multiple surgeries with long recovery times, and limb amputations are not uncommon. “What patients need is a large bone graft scaffold with a unique combination of chemical composition, porosity and mechanical strength that will provide a framework where new, living bone may grow and replace it,” said Lorenzo Pradella, CEO of GreenBone Ortho.

GreenBone Ortho, a startup based in Faenza, Italy, has developed an advanced biomimetic material that does just that. The company's product, also called ‘GreenBone’, is a highly innovative, bone-regenerating implant, suitable for the treatment of non-loaded and load-bearing large bone damage, including non-union fractures, trauma, bone loss induced by cancer and infection, and spinal fusion.

Using nature as a source of inspiration for better-performing biocompatible and regenerative solutions, GreenBone Ortho ingeniously uses wood as the starting material for its bone-regenerative implant. Engineered to reflect bone in its anatomy, morphology, physiology and composition, the GreenBone scaffold is a calcium phosphate biomimetic with a very high mechanical strength and high porosity, and has the unique capacity to regenerate large portions of bone. “GreenBone is able to repair large bone defects, enabling patients a faster return to normal life with their own bone completely regenerated,” said Pradella.

### Birth of the technology

The technology was originally conceived and developed by a research group at the prestigious ISTEC-CNR (Institute of Science and Technology for Ceramics), led by Anna Tampieri, in Faenza, Italy. A nature-inspired project to find new biocompatible materials able to sustain tissue regeneration in orthopedics prompted a screen for plants that have a similar internal structure to bone. The researchers identified rattan (a bamboo-like plant) as the best candidate, as it has a comparable load-bearing capacity and an internal 3D architecture that incorporates xylem-transporting channels, which mimic the way blood vessels run through bone. Cleverly applying their knowledge of ceramic processing to rattan, the researchers then developed a process that transforms the wood to hydroxyapatite (HA) and tricalcium phosphate (TCP) while—crucially—preserving its architecture.



**Fig. 1 | Lorenzo Pradella, CEO of GreenBone Ortho (top) and the GreenBone product (bottom).**

HA and TCP, major components of mammalian bone, are established and widely used ceramic biomaterials. Because they can support bone ingrowth and osteointegration, they are used extensively in orthopedics and dentistry as bone filler. Normally available as cement obtained from powder, however, they are suitable for filling only small cracks. In order for the powder to consolidate into a stable 3D shape

for bigger defects and injuries, the powder must be heated to a high temperature, which results in a complete loss of its biomimetic properties. “The body does not properly recognize this structure and bone very hardly regenerates,” explained Pradella. “What is unique about GreenBone is that our processing does not end with high temperatures and so the features of the biomimetic composition and structure are conserved for any size of bone damage.”

Critically, when transferred into a patient, GreenBone is recognized as real bone and replaced over time by new bone matrix made by osteoblasts. “GreenBone has unique properties to sustain massive bone regeneration” said Pradella. “It can be produced in large quantity with different shapes and sizes, and is easily sterilized and manipulated by surgeons to optimize the graft just before implantation in patients.”

New functional bone formation from GreenBone has been demonstrated in vitro and in vivo. In pre-clinical studies, computed tomography (CT) scans of sheep treated with GreenBone showed that after 6 months, the implanted GreenBone was completely replaced by new functional bone without any side effects. Devoid of risks in terms of morbidity and infections, GreenBone is a European class III and a US FDA 510(k) medical device with a short path to market. After the completion of two European clinical studies in patients with non-loaded and load-bearing long bone defects ( $\geq 3$  cm), GreenBone is expected to reach the market in 2020, with forecasted European and US peak sales of  $> \$500$  million.

### Partnering aspirations

Since its launch in 2014, GreenBone Ortho has attracted significant funding from Italian and international investors (€11.5 million in 2.5 years). After completing clinical development, the company is interested in establishing high-value deals for marketing and distribution with key market leaders in orthopedics; an initial public offering and mergers and acquisitions will also be considered.

“GreenBone is the strongest ever regenerative material with properties never before achieved in large scaffold,” said Pradella. “By improving bone healing, enhancing quality of life, preventing future amputations, and reducing healthcare and social costs, GreenBone is set to have tremendous impact on patients and society.”

contact

Lorenzo Pradella, CEO  
GreenBone Ortho srl  
Faenza, Italy  
Tel: +39 0546 46666  
Email: [lorenzo.pradella@greenbone.it](mailto:lorenzo.pradella@greenbone.it)