Press Release

Finceramica's CustomizedBone Service obtains FDA approval

For the Faenza-based company, which is part of the Tampieri Group, 2016 closed with its flagship product achieving such a remarkable target

Whoever tried it learned the hard way that obtaining FDA approval is not easy. For the uninitiated, this is the product marketing authorization issued by the influential Food and Drug Administration, the US equivalent of a Ministry for Health, regarded as the "strictest and most scrupulous" regulatory body in the world. Such a recognition is of crucial importance in terms of product quality, safety, and effectiveness across all global markets. CustomizedBone Service, which is how the well-known CustomBone Service is trademarked in the US, obtained this approval at the end of a process which lasted about three-years.

This ground-breaking technology is developed by Finceramica, an Italian company operating worldwide. It deals with an implant or, to be more accurate, a custom-made regeneration support (hence its name CustomBone) which integrates seamlessly with the patient's skull. The bioceramic material employed can be colonized by vascularized areas, thus making for natural bone regeneration and complete implant reabsorption. Implant design starts on-line via a dedicated portal. Finceramica technicians analyse the patient's CT or MRI scan and through an ad-hoc software design and create a 3D model of the implant which is then submitted to the surgeon for approval. The device is produced in a sterile environment through a number of processing stages, the first of which closely resemble those of a standard ceramic process. The biomaterial contains calcium just like the human bones, which makes it more compatible or "familiar" with the patient's body; this is what the cells expect to receive. The risks of rejection or infection are minimized. In most cases, it takes just one surgery for the patient to resume his normal life. This is the great benefit offered by such technology if compared with others: the need of just one surgery significantly reduces the risks of rejection and infection, while increasing the surgery success rate. These results are relevant in economic terms too, due to the reduction of medium- to long-term health care costs, so much so that several health systems, such as the French health system, have adopted the technology as their reference resource for cranial surgeries.

The US health care market is the most lucrative in the world, with much higher prices than in Europe, 320 million users and an almost entirely private health care system. FDA approval means that CustomizedBone Service can now be marketed in that country. It also means that the partnership between Finceramica and Johnson&Johnson, the largest pharmaceutical-biomedical company in the world with its $70 billion annual turnover, has finally become truly global.

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Finceramica stands for Italian excellence. Established in 1992 in Faenza (Italy) as a spin-off of the Institute for Science and Technology for Ceramics (ISTEC-CNR), it was later taken over by the Tampieri Group, which, though active in completely different sectors, understood its great added value and invested heavily to boost its growth. Finceramica combines the tradition of ceramic processes with the innovation of the biomedical field. It designs and manufactures medical solutions from organic material for the repair and regeneration of bone and cartilage tissues. The biomaterial colonizes the human cells and merges with them. This contributes to a speedier recovery. Concerning cancer care, CustomBone implants make it possible to perform cancer extirpation and cranial cavity reconstruction during the same surgery, thus optimizing resources. Finceramica boasts a wealth of international experience, focusing on niches of excellence worldwide.