Highest requirements for new surgical instruments

The concept of the entire BONEBANK project is mainly predicated upon the availability of a specific surgical instrument, which can be used by surgeons during the course of fracture treatment to remove an adequate quantity of biologically vital, high-quality stem cells.
As a globally recognised manufacturer of medical products, the company STRYKER has the expertise, capacity and internal structure to purposefully and efficiently succeed in providing provision of, and approval for such an instrument in Europe.
As part of the development work, relevant property rights and regulatory constraints are also being processed, which have increased in importance since the introduction of new regulations for medicinal devices in April 2017.

Intuitive handling in Surgery

Through an internally certified development steering process, STRYKER has created a list of requirements for the prospective medical device. These include the necessary clinical- and specific handling-requirements, as well as geometric and material specifications.
Furthermore, the medical device manufacturer has also determined additional functional requirements, through biomechanical tests on both human and animal samples.
The high viscosity (high fat content) and the adhesion are the main problems of the to-be-collected materials. Therefore, the transport and the need to maintain a secure hold on said materials are the central tasks to be solved. As the apparatus must be inserted deep into the long bones of the patients, the most important requirements of the apparatus are its safety and intuitive handling in the operating theatre. Risks to the patient must be minimised.
In the context of recent development work various mechanical, manual and electrically-driven processes were evaluated. Special attention was paid to certified materials, making the realisation and implementation of robust designs quicker.

Contact: Roman Nassutt, Stryker Trauma GmbH, Roman.Nassutt@stryker.com