Medical devices



Newclip Technics

Test protocols tailored to each implant

Though some orthopaedic implants are covered by standards, it is often necessary to go beyond them in dealing with complex products. Newclip Technics called on Cetim to develop specific test protocols for all implant types.



OUR CUSTOMER

Corporate name Newclip Technics

Workforce

240 employees

Business activity

Formed in 2002 and based close to Nantes, the company designs, manufactures and sells various ranges of osteosynthetic implants for planned and emergency surgery. The company markets its implants in 40 countries (Europe, the US, Japan, etc.).

nome fractures can't be treated using plaster casts, in which case pins, plates and screws are required to reposition and consolidate the bone. In France, Newclip Technics designs and manufactures just such anatomical orthopaedic implants and plates for the upper and lower limbs. For almost 20 years the company has been developing new innovative products designed to solve a range of problems. However, in the field of medicine, inventiveness is not always enough. The implants have to meet strict standards if they are to be approved for market release. For example, when it comes to their mechanical characteristics, a range of values has to be measured and compared with those specified in the relevant standards.

Standards that are difficult to apply

Some standards, such as those relating to fatigue and wear testing, are particularly difficult to apply. They simply set out in schematic terms the tests to be carried out and give the tester complete licence as to how this is done. "That's why we ask Cetim to carry out these tests. As well as having a Cofrac-accredited biomechanics laboratory, they have the right testing facilities and the expertise required to devise and implement the test protocols necessary to ensure our products meet the requirements set out in the standards. Their engineers can also develop the protocols we need to achieve our target

performances for complex implants. And their knowhow is equally valuable when it comes to deciding on a test procedure for an assembly (plate and screws) for which there are no established standards.", explains Renaud Rougé, Head of R&D at Newclip Technics. As a result, the protocols are devised according to the specific needs set out by the company in order to reproduce the in vivo conditions of the implant on our static and fatigue test benches while applying any necessary constraints in a reproducible manner.

Cetim's asset



Cetim's biomechanics laboratory is Cofracaccredited (accreditation no. 1.1006, scope available on Cofrac.fr) and equipped with 15 static and fatigue test benches for orthopaedic implants and 12 wear test benches for cervical and lumbar spine surgery implants. It helps manufacturers

make the right testing procedure and parameter selections, performs the necessary tests using the appropriate procedures and analyses the results.

