

Novastep

Implants that comply with US standards

Novastep enlisted the assistance of field experts in order to meet the new requirements of US medical equipment certification bodies and understand the purpose of the required tests.



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Corporate name
Novastep

Activity
Created in 2013, Novastep manufactures medical implants and devices for foot and ankle surgery. Since its incorporation, the company has expended its presence in Europe, the United States, Australia and South Africa.

Turnover
6.1 million euros

Workforce
30 people

Novastep, a company located in the municipality of Saint-Grégoire (Ille-et-Vilaine, France), manufactures implants and medical devices for foot and ankle surgery. Since its creation in 2013, the company's goal has been international market expansion. Further to obtaining ISO 13485 certification followed by CE marking and the first 510(k) clearances (approval on the American market) in 2014; the French manufacturer opened Novastep Inc. in Orangeburg, United States in 2015. On account of this international expansion, it has to demonstrate the utmost vigilance in relation

to the quality of its products as well as compliance with applicable regulations and standards.

Nitrogen tests

In order to meet new requirements from the Food and Drug Administration (FDA), the company called on Cetim's experts to characterise the corrosion susceptibility of the superelastic compression foot staple system (Arcad range) in accordance with standard ASTM F2129. The aim of this standard is to determine the corrosion susceptibility of small implant devices using nitrogen. "We would like to certify these memory compression staples used during osteotomy or arthrodesis so that they can comply with ASTM F2129, which is increasingly being required by the FDA", explained Loïc Girod, R&D Manager.

Joint work

Naturally, Novastep could have used the services of American laboratories, however "I was familiar with Cetim because I had attended a training course on damage analysis there, and we wanted to be able to monitor the tests from start to finish, while working with the experts of the centre to understand both the results

obtained and the methods of improving our products, where necessary, added Loïc Girod. This approach of working in conjunction with an analysis laboratory is more complicated in the United States."

This open and joint effort specific to Cetim was successful as the staples of the Arcad range were immediately approved by the American services.

Cetim's asset

Cetim's experts possess the expertise and the tools to characterise parts and materials as well as their resistance to corrosion in keeping with applicable international standards.

