



Article 52 : « France Faces Similar Challenges as the U.S. »

**VOICE OF THE INDUSTRY**

## France Faces Similar Challenges as the U.S.



**An Interview with Claire Daculsi**  
*Biomatlante*

France's medical device market ranks among the top five largest in the world, with the consumption of equipment and supplies valued at \$133 billion in 2012, according to a recent Espicom business intelligence report.

According to the same report, the medical device import market grew 0.8% to \$11.2 billion in 2011. The market as a whole is only expected to see moderate growth in the next five years as the country's healthcare system undergoes a series of reforms structured to cut costs and improve efficiency.

**BONEZONE** asked Claire Daculsi, Marketing Manager for Biomatlante, a manufacturer of synthetic bone graft, to shed light on France's orthopaedic industry.

**BONEZONE:** *In your experience, what unique challenges are faced by companies that do business in France's orthopaedic market? What are the unique advantages?*

**Claire Daculsi:** The challenges for French companies are a high level of competition, fixed prices due to health policies, low prices due to public deficits, as well as the right choice of notified body to obtain the CE Mark—reputation, price, different reactivity, evolution of the European directives with the evaluation of the notified bodies by European health authorities.

The advantages are that European requirements make the registration a bit easier than FDA's, even if we are turning toward similar rules. We also have a recognized quality of health services and professionals, resulting in high surgical techniques and innovation, supported by a strong culture and a long history of excellence in orthopaedic technologies. Surgeon support, industry networks and a mix of public and private investments also make the environment favorable.

**BONEZONE:** *Current headwinds affecting U.S. orthopaedic market performance include longer (and more intense) regulatory clearance processes, growing price pressure from hospitals, lower procedure rates, etc. How does the U.S. market situation impact France? How has it affected your business?*

**Daculsi:** For French companies like us (medical devices class III) operating in France, there is not much influence. Tougher rules, processes and transparency requirements have been implemented here for a long time. These are still getting stronger due to recent events and the will for more common standards in Europe.

Also, as for FDA registration, CE Mark usually requires complementary studies.

**BONEZONE:** *What resources have you found to be reliable for France-specific orthopaedic market data, hospital/patient data, implant pricing or any other information that you require to plan for business development?*

**Daculsi:** The most reliable sources in France are the reimbursement rates (LPPR), domestic scientific societies and, of course, industry and health system networks.

**BONEZONE:** *In what other countries do you presently do business? What countries do you seek to enter?*

**Daculsi:** We do business worldwide—almost 75% of our revenue is outside France. BRIC countries represent the biggest growth lever, but they require full attention and should not make us neglect our historical partnerships.