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SMEs EXPORT

Argentine technology and innovation



HEALTH IMPLANTS



INSTITUTIONAL RELATIONS AND COMMUNICATIONS OPERATIONAL MANAGEMENT

Institutional Relations Deputy Management



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Editorial



The medical implant sector has experienced significant growth over the past 15 years, evolving from small machining shops into a robust and highly regulated industry, both nationally and internationally. This transformation began when many auto body shops started diversifying their operations to include the manufacture of medical products. At that time, the INTI Center of Mechanics set itself the challenge of supporting those companies in their transition to medical device production, a process that required extensive training and adaptation for all parties involved.

Today, Argentina's implant industry produces high value-added devices that meet quality standards comparable to international products, long regarded as the "gold standard." The challenges have evolved, and some time ago, INTI (National Institute of Industrial Technology) established the Health Technologies Working Group—an initiative aimed at leveraging our technological capabilities in health to assist the sector, including medical implants, in tackling the new challenge of comprehensive exportation.

Argentine companies that meet stringent quality requirements now have a unique opportunity in the region, as many countries lack local implant production. Additionally, the presence of renowned institutions such as ANMAT (National Administration of Drugs, Food and Medical Technology) and INTI helps enhance international recognition of Argentine products. Although the context is challenging, the industry is mature, meeting high quality standards and international certifications (such as ISO 13485). With the support of prestigious institutions, local manufacturers are well-positioned to expand their markets and continue to grow.

Belén Parodi

**Mechanical Product Performance Department
Coordination of the Health Technologies Department
National Institute of Industrial Technology**

AMERICAN IMPLANT S.A.



National leadership in spine implants



American Implant was founded 15 years ago by an Argentine metallurgist. Together with businessmen and professionals of the medical industry, he decided to start a very ambitious project, from which he obtained great results. Today, with the support of the National Institute of Industrial Technology (INTI), American Implant is a leader in the development of orthopedic systems for the spine.

The path of this company reflects the history of a deep transformation in the Argentine metallurgical industry. In its beginnings, it emerges with the vast experience in machining processes of one of its partners, who notices the possibility of applying his knowledge to the creation of medical implants. It was then that a medical professional suggested the manufacture of spinal implants, a field dominated by foreign suppliers.

Since its inception, the company has been producing prototypes that are constantly innovating. These are presented in a catalog that includes, among others, pedicle screws, facet screws and intersomatic boxes. All products are designed and manufactured with high quality materials certified under international standards for medical use, such as titanium and PEEK polymer (polyether ether ketone). These parts, which are essential for the treatment of different spinal pathologies, from degenerative diseases to complex vertebral deformities such as scoliosis, have been recognized not only for their quality, but also for the confidence they generate in health professionals.

One of the company's greatest achievements has been to offer solutions that compete as equals with imported products. As Lucas León Sánchez, the company's manager, points out: "Our products not only for their quality, but also for their safety they offer to surgeons during their placement and in the postoperative period of their patients".



In addition to traditional materials such as titanium and stainless-steel alloys, we are seeing an increase in the use of biomimetic materials and biodegradable polymers. These elements are designed to improve biocompatibility and reduce post-surgical complications.

Source: Allied Market Research.



The relationship with INTI was established ten years ago, when the company began conducting mechanical tests crucial for medical product registrations with the National Administration of Medicines, Food and Medical Technology (ANMAT).

But how important is it to have the support of INTI? This is where the story takes another turn. Belén Parodi, in charge of the INTI's Biomaterials laboratory, says the importance of this backing: "It is not only about manufacturing screws, but also about ensuring that each implant complies with the safety and efficacy standards required by regulatory bodies such as ANMAT". And he adds: "INTI has accompanied the company in the transition from manufacturing common screws to developing high quality and precision medical products, which today are a reference in the market".

Thanks to this support, the company has managed to obtain ISO 13485 certification, an international standard that guarantees the quality of its production processes. This has been fundamental in consolidating its reputation, both in the local market and abroad, emphasizes Sánchez.

Today, American Implant is not only the leading supplier of vertebral implants in Argentina, but is also taking its first steps towards internationalization, with customers in Bolivia and Brazil. Looking to the future, Sanchez is optimistic: "We know that there is unsatisfied demand in several Latin American countries, and we are ready to respond. The quality of our products, endorsed by INTI and ANMAT, is our best cover letter".



This company shows that success is built with vision, effort and, above all, with strategic alliances such as the one with INTI. With perspective, technical support and a commitment to quality, it is possible to compete globally.



Américan Implant S.A.
Ituzaingó, Buenos Aires

Development of orthopedic systems for spinal column.

Production plant: 1.061 m²

Annual production capacity: 50,000 pedicle screws, 2,000 facet screws and 10,000 intersomatic boxes.

• **HS CODE (NCM):**

-9021.10.10.200Y / Prosthesis-implants for the spine.





Highly Complex Solutions for Medicine



Certain moments mark a turning point in a company's history. For Lexel S.R.L., that moment was obtaining CE certification in 2005—a milestone that not only validated its products in Europe but also solidified a team committed to quality. Since then, this Argentinian SME has distinguished itself as one of only five companies worldwide capable of manufacturing highly complex medical devices, including the intragastric balloon and the titanium implantable portal.



Beyond its innovation and ability to stay competitive in a highly regulated market, Lexel stands out for the technical support it has received for over 20 years from the National Institute of Industrial Technology (INTI). According to Néstor Rava, the company's general manager, "INTI is an essential resource for our development; their solutions allow us to overcome technical barriers we encounter in international markets".

The implantable titanium portal, for example, not only meets demanding European standards, but has been subjected to rigorous strength and biocompatibility testing, largely thanks to the assistance of INTI. This device, used for drug administration, can withstand up to 1,000 punctures without losing its airtight seal, a technical feat certified by both Argentina's National Administration of Medicines, Food and Medical Technology (ANMAT) and international regulatory bodies.



The silicone intragastric balloon, another innovative product, can be implanted for up to 12 months to aid in weight reduction through a risk-free, endoscopic procedure. It is one of only three such devices in existence worldwide. Several of its features were developed in collaboration with INTI, following custom-designed studies to assess the product's effectiveness.



The global market for medical implants is projected to grow from \$111.33 billion in 2023 to \$157.62 billion by 2028, with a compound annual growth rate (CAGR) of 7.20% during this period (2023–2028).

Source: Mordor Intelligence



The INTI's impact on Lexel's growth is undeniable. From conducting resistance tests to designing custom studies, INTI's support has enabled Lexel to meet technical requirements and gain the trust of international auditors. According to Osiris Pato, a member of INTI's Primary Packaging and Packaging Systems Department, "Our collaboration with Lexel is mutual. We tailor our solutions to their needs, and our technical reports are accepted worldwide".

With a human team of excellence, this Argentinian SME has managed to export highly complex medical devices to countries such as Germany, Brazil, Bolivia, Chile, Colombia, Dubai, France, Kenya, Mexico, Nigeria, Peru, and South Africa. Looking to expand further, it aims to enter new markets in the Middle East, particularly Egypt, Jordan, and Saudi Arabia, to meet the growing demand for reliable and affordable medical products in regions with a high need for innovative solutions for chronic disease treatment and drug delivery. The goal is to continue delivering quality and innovation wherever demand exists.



According to a report by Allied Market Research, North America is the largest market, followed by Europe, with the Asia-Pacific region experiencing accelerated growth due to an aging population and improvements in healthcare systems.



As the Lexel team expands its reach, it remains dedicated to offering competitive prices that benefit both healthcare professionals and patients without compromising the quality that defines its products.

“The company aims to establish itself as a sector leader, positively impacting the lives of those who need access to high-quality, dependable medical equipment while improving health and wellness across communities globally”, Rava reflects.

Lexel’s career is a testament to perseverance, teamwork, and an unwavering pursuit of excellence. It exemplifies how an Argentinian SME can transform challenges into opportunities. In short, what really defines the success of a company in the health field is not only the products it develops, but the positive impact it generates on the lives of patients. Lexel exports technology and with it, hope and that is what truly makes the difference.



Lexel S.R.L.

Buenos Aires

Production, research, and development of health-related products

-Facility Size: 750 m²

• HS Code (NCM):

-9018.39.29: 90.18 / Instruments and apparatus for medical, surgical, dental, or veterinary purposes, including scintigraphic and other electromedical apparatus, as well as sight-testing apparatus.

-9018.39 / Other

-9018.39.29 / Other

-9021.90.19: 90.21 / Orthopedic appliances and articles (including medical or surgical girdles and bandages, crutches, splints, splints or other articles for fractures, prosthetic appliances, hearing aids, and other orthopedic items).

-9021.90 / Other

-9021.90.19 / Other



ML IMPLANT SYSTEM



Innovation and Quality in Dental Implants



ML Implant System, a trademark of Steeldec S.A., is rooted in the story of Miguel Libertini, an Italian immigrant who arrived in Argentina in 1949. From a young age, Miguel worked as a lathe operator until he established his own small company in Villa Adelina, a town in Buenos Aires Province. In the 1990s, a growing demand for dental components prompted him to start manufacturing parts for oral implantology, an emerging field at the time.

Founded in 2011, ML Implant System was created to provide high-quality solutions in a sector that demands precision and reliability. Since its inception, the company has faced numerous challenges, but its commitment to technological innovation and continuous improvement in production processes has enabled it to overcome these obstacles. Today, ML Implant System is an SME with a focus on innovation, quality, and international expansion.



According to a report by Market Data Forecast, orthopedic implants hold the largest market share due to their use in hip and knee replacements, while dental implants are expected to grow at an annual rate of 10.2%.

Specializing in the manufacture of biocompatible titanium dental implants, prosthetic attachments, and placement instruments, the company excels in producing a wide variety of compatible designs with precision machining. This ensures high quality and minimizes the risk of micro-movements.

A key pillar of the company's success has been its close collaboration with the National Institute of Industrial Technology (INTI). "The technical support provided in areas like surface characterization and cleaning validation of implants and drills has enabled ML Implant System to meet the rigorous international standards necessary for expansion", explains Belén Parodi, head of INTI's Biomaterials laboratory.

According to Luis Libertini, the company's general manager, "The guidance and testing provided by INTI allowed us to progress safely in product development, facilitating exports to Latin America and Europe".

Certified by Argentina's National Administration of Medicines, Food, and Medical Technology (ANMAT), ML Implant System also holds international certifications such as ISO 13485 and CE marking, which validate its product quality and compliance with international standards.

Currently, the company exports to several countries, including Saudi Arabia, Chile, Ecuador, Spain, Peru, and Uruguay. It is also seeking to expand further within Latin America, the Middle East, and Europe, since it finds in these markets an opportunity to satisfy demand with the quality that these markets demand destinations.

One of the company's core strengths lies in the technology applied throughout the product development and manufacturing process, from raw material intake to final packaging. Each stage is completed with the company's own resources, ensuring total quality control.



ML Implant System has also developed an extensive range of prosthetic solutions, both analog and digital, as well as the necessary tools for implant placement and adjustment. Additionally, it has incorporated components for bone regeneration, further expanding its comprehensive offerings within the dental sector.

What sets ML Implant System apart from other SMEs in the sector is not only the quality of its products but also its focus on continuous innovation and its ability to deliver customized solutions. “We pride ourselves on our flexibility in developing custom products and our technological integration at every stage of the process”, says Damián Errante, the company’s sales manager. This approach has allowed ML Implant System to anticipate market needs and quickly adapt to changing customer demands.



ML Implant System

Tortuguitas, Buenos Aires

Manufacture of biocompatible titanium dental implants, prosthetic attachments, and instruments for placement and rehabilitation.

-Facility size: 2.200 m²

-Annual production capacity: 800.000 units

• HS Code (NCM):

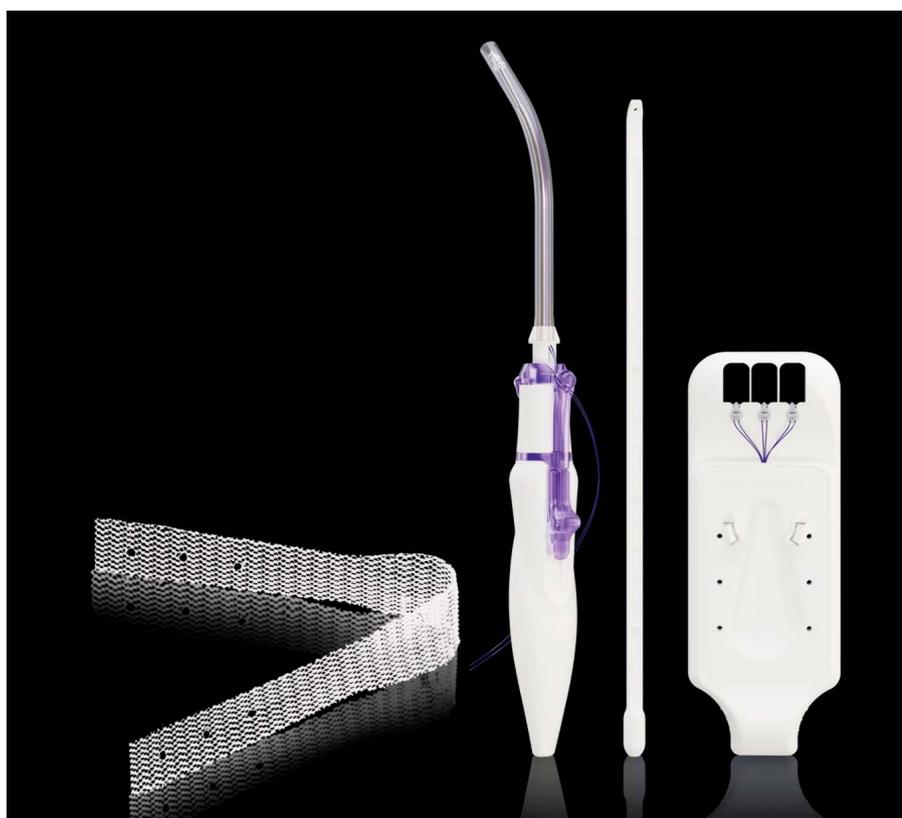
-9021.29.00.100E / Orthopedic articles and appliances, including medical-surgical girdles, bandages, crutches, splints, and other items for fractures; prosthetic devices; hearing aids and other appliances worn or implanted to compensate for a defect or disability.

-9018.49.99.100Y / Instruments and appliances used in medicine, surgery, dentistry, or veterinary medicine, including scintigraphic and other electromedical devices and sight-testing apparatus.





From Córdoba to the World: High-Complexity Implants for Urology



How do you build global reach from the roots of a local idea? In the advanced medical device sector, the answer lies in the delicate balance between the challenge of innovation and the precision of strategic support. When seeking to highlight a product in a demanding market, solid support is necessary that allows it to overcome regulatory obstacles and compete with the most rigorous standards. This is where collaboration between entrepreneurial vision and specialized technical assistance becomes essential for transforming a project into an international benchmark.

This is the story of Promedon, a company founded in Córdoba in 1985 by renowned urologist Raúl Olmedo, who sought to create local solutions for global challenges. Alongside his son Marcelo, an engineer with a keen business perspective, they established a company that today stands out in the fields of urology and traumatology. But they didn't do it alone. The National Institute of Industrial Technology (INTI) has been a key partner on their journey to internationalization.

In addition to technical support, INTI provided a strategic intelligence study that included intellectual property analysis and technological surveillance. This support allowed Promedon products, such as its implant for female urinary incontinence, to not only meet stringent regulatory standards but also to excel in demanding markets like Germany. “Protecting an idea is essential, but making it shine on the global stage is what truly makes the difference,” reflects Romina Gudiño, head of strategic intelligence for the Central region.

In the medical device market, quality is essential. Promedon is certified under ISO 13485:2016, issued by TÜV Rheinland, an international standard ensuring that medical devices meet regulatory requirements for quality and safety. This, together with the approvals of the markets in which they operate, such as the European Union, allows them to compete with the best in the world.



Companies face strict implant approval regulations, particularly in key markets like the United States and Europe. Regulatory bodies, such as the FDA in the U.S., have raised testing and safety standards.

Source: Allied Market Research

The company operates two distinct production lines, each targeting a specific healthcare segment:

- **Urological Implants and Endourology:** This line is the most developed and has the widest international reach. It includes innovative products for urological and urogynecological conditions, such as Victo, a treatment for male urinary incontinence with a unique advantage: it can be adjusted without requiring additional surgery, a feature that no competitor currently offers. Additionally, Promedon’s Calistar and Splentis meshes for minimally invasive pelvic organ prolapse treatment not only ensure effective correction but have shown a remarkably low complication rate—an example of how Promedon strives to enhance patients’ lives while reducing risks for physicians.



- **Sports Medicine:** Launched in 2021, this line focuses on implants for treating trauma injuries in the knee, shoulder, and other joints. These products offer advanced solutions for patients with sports-related injuries, utilizing state-of-the-art materials like polyurethane and titanium to ensure durability and biological compatibility.



PROMEDON S.A.

Córdoba, Province of Córdoba

Development of high-complexity implants for urology, urogynecology, and sports medicine.

-Production Plant: 3.000 m²

-Annual Production Capacity: 170.000 unidades

• **HS Code (NCM):**

-9021.39.80.900Q / KIT-CALISTAR

-9021.90.80.900T / KIT-VICTO

-9021.90.80.900T / KIT-ANC





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