MEDTECHBUSINESSREVIEW.COM **NGDTECHBUSINESSREVIEW.COM BUSSINESSREVIEW.COM BUSSINESSREVIEW.COM**

Simon Gsell, VP and Co-Owner

René Gsell, President and Founder

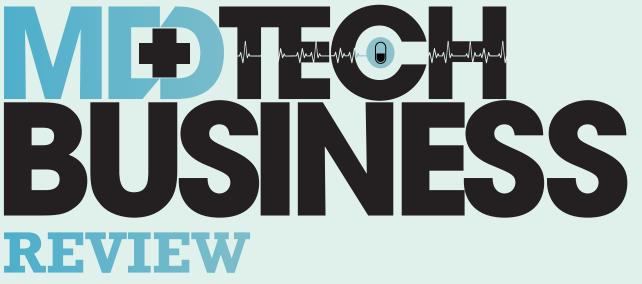
ISSN 2837-3421

EUROPE SPECIAL

SETTING THE STANDARD FOR EXCELLENCE IN MEDICAL DEVICE MANUFACTURING



ISSN 2837-3421





•

-••

MEDTECHBUSINESSREVIEW.COM EUROPE SPECIAL







. . .

COVER STORY

SETTING THE STANDARD FOR EXCELLENCE IN MEDICAL DEVICE MANUFACTURING

he twin pillars of quality and reliability are a brand's most valuable attributes. Gsell doesn't just uphold these virtues-it builds on them

with the distinct Swiss precision and excellence that are part of The Gsell Way.

What is The Gsell Way?

It is the company's approach of bringing unmatched standards of manufacturing and co-engineering to polymer processing, embodying a pursuit of perfection across every facet of its operations. Leveraging advanced technical capabilities, including CNC machining, injection molding, compression molding, thermoforming and 3D printing, Gsell delivers solutions that exceed the demands of the healthcare industry.

Since its inception in 1984, the family-owned enterprise ensures each product demonstrates Swiss-quality craftsmanship. Marking 40 years of outstanding achievement, it remains committed to advancing and enhancing the impact.

"Innovation is at the heart of our operations," says René Gsell, president and founder. "By continually investing in digitalization and automation, we ensure seamless compliance with MDR and FDA regulations and unparalleled product quality."

66

We always listen to our customers and adapt to their requirements. Whether we invest in new equipment, expand our facilities or develop novel materials and processes, we are committed to being a flexible and responsive partner

of Healthcare Providers Gsell is anchored in the motto 'We'll find a solution.' established by the company's founder. This attitude is applied to creating innovative solutions that meet every customer's unique needs.

Simon Gsell. VP and Co-Owner

> René Gsell, **President and Founder**

Patrick Fässler, Member of the Management

TOP 10 COMPANIES IN BUSINESS ENGINEERING PLASTICS - IN FUROPF 2024





This makes Gsell the go-to partner for providing toptier medical manufacturing solutions, offering reliability and quality that healthcare professionals trust.

How Gsell Meets the Dynamic Needs

"We always listen to our customers and adapt to their requirements. Whether we invest in new equipment, expand our facilities or develop novel materials and processes, we are committed to being a flexible and responsive partner," explains René Gsell.

Customer focus is evident in the way Gsell's experienced engineers and project managers collaborate with clients at every step, from initial design and prototyping to full-scale production and quality assurance. Leveraging its expertise in design for manufacturability, Gsell helps customers optimize their products for cost-effectiveness, reliability and regulatory compliance.

Financial independence allows it to swiftly and effectively support customer needs. The company's proactive investment strategy—funding projects it believes in for the future rather than waiting for orders—allows for quick decision-making and rapid scaling of production capabilities.

For instance, when a customer faced challenges with implant injection molding. Gsell rapidly adapted its operations. procuring the necessary equipment and expertise to resolve the issue.

This agility and responsiveness have not only solved immediate customer problems but also secured Gsell a place on approved supplier lists for major healthcare companies, which usually takes years to achieve.

"We understand that speed is critical, especially in prototyping," says Patrick Fässler, member of the management. "Our quality system includes processes that allow us to follow standard procedures and deliver hardware guickly, often within a few weeks."

Material Mastery, Trendsetting Innovation

Gsell possesses in-depth material expertise and an innate ability to blend emerging trends with established methods. It continuously invests in new, forward-looking materials and technologies to overcome the challenges of tomorrow.

A prime example of Gsell's capabilities is using carbon fiberreinforced polymers (CFRP) to create lightweight, radiolucent medical instruments and implants. This material transforms trauma surgery and implant technology, offering a superior alternative to traditional metal components. CFRP's advantage lies in its radiolucency, which allows X-rays to pass through without interference, enabling surgeons to monitor bone alignment with clarity during and bone healing after surgery.

These advanced CFRP implants balance strength and flexibility, closely mimicking the mechanical properties of bone while rivalling the durability of metal. Gsell is also producing specialized, non-metallic implants for cancer patients undergoing tumor removal, addressing the need for materials that don't interfere with subsequent cancer therapies.

CFRP's radiolucent nature supports minimally invasive surgical techniques. Guided by unobstructed imaging, surgeons can now perform complex operations, like repairing femur fractures, through small incisions. This advancement significantly reduces trauma and accelerates recovery times.

To complement these innovations, Gsell developed proprietary materials to create durable, reusable CFRP instruments such as retractors manufactured by the means of compression molding tailored for a wide range of other applications than for Trauma such as for Spine and Joint Replacement surgeries. These instruments combine the strength needed for orthopedic procedures with the radiolucency required for precise intraoperative imaging, setting a new precedent in surgical instrumentation.



"We like to push the boundaries of what's possible in medical device manufacturing. Our goal is to equip healthcare providers with the tools they need to deliver the best possible patient outcomes," says Fässler.

CFRP instruments gain an edge through 3D printing with Gsell's proprietary 3D Forming technology. This 3D Forming process enables the continuous printing of carbon fiber and high-performance medical polymers, optimizing fiber alignment to maximize strength and stiffness while reducing waste and production time. Already employed in the creation of radiolucent medical instruments, this innovative approach holds promising potential for applications beyond healthcare, positioning Gsell at the forefront of advanced manufacturing.

Interactive Implants and Breakthrough Materials

Gsell is at the leading edge, spearheading trends in medical technology, such as smart implants and polyethylene implant inlays.

Smart implants represent one part of next-generation medical devices, providing real-time feedback on a patient's healing progress and activity level. Valuable information is communicated to surgeons and post-operative monitoring is supported through Al-driven data analysis, enabling personalized treatment plans.

To illustrate. Gsell is co-developing and producing a smart implant that incorporates sensors to measure bone growth and assist in healing through targeted electrical impulses. It is tackling the challenge of integrating these electronics into its injection molding process with polyetheretherketone (PEEK), furthering the boundaries of implant technology.

In addition to smart implants, Gsell actively enhances traditional materials. It closely follows and contributes to the evolution of polyethene used in joint replacement implants. Recent developments include enhanced polyethylene materials with vitamin E and cross-linking via X-rays to increase wear resistance. This signals a shift towards more sophisticated and customized materials replacing standard polymers.

These advancements in polyethylene are particularly significant for joint replacement implants. They offer improved durability and potentially longer-lasting outcomes for patients. The enhanced wear resistance reduces the need for revision surgeries and improves the quality of life for those with joint replacements.



Examples of Smart, PEEK and PE implants for Spine and Orthopedic Applications

3D printing continues to play a crucial role in these

advancements. While already utilized in titanium spine

applications, Gsell is actively exploring ways to expand the

use of 3D-printed implants more broadly, including in the

production of PEEK and carbon fiber-reinforced PEEK implants.

PEEK Mastery

techniques.

Immersed in Peek processing, Gsell produces complex PEEK components and assemblies such as for cancer therapy in oncology. These assemblies combine specially developed injection and thermoforming processes with specific assembly

Its PEEK portfolio exceeds standard components, incorporating machined parts, traditional injection-molded components and specially developed thermoformed applications. A notable example is the thermoforming of a tip into a tube that can be inserted through patient tissue, demonstrating the company's ability to create tailored solutions for specific medical needs.

"While the MedTech sector remains our primary focus, accounting for 80 percent of our work," explains Fässler, "we

see potential in leveraging our manufacturing expertise for PEEK solutions that includes 3D printing and continuous carbon fiber PEEK printing for various industrial applications."

This culmination is due to the synergy between Gsell Medical Plastics and Gsell Engineering Plastics, operating under one roof, which facilitates knowledge transfer and techniques between medical and industrial applications.

Gsell Engineering Plastics has long focused on special polymer solutions for various industrial uses. For motorsports, trials have explored replacing metal components with special PEEK applications, leveraging the material's high temperature and chemical resistance. For aerospace, samples have been produced using thermoformed solutions.

Single Use Instruments

Gsell's development of custom single-use instruments aligns perfectly with the evolving U.S. healthcare landscape. As simpler procedures shift from traditional hospitals to ambulatory surgery centers, the demand for efficient, highquality disposable instruments is rising.

Its single-use instruments range from targeting tools made of high-glass fiber-filled polymers with in-molded stainlesssteel components to various extruded tube-based instruments for cardiology and oncology. They meet the needs of the U.S. healthcare system's growing emphasis on efficiency in ambulatory settings, reduced risk of cross-contamination, consistent quality across procedures and cost-effectiveness in instrument management.

> Examples of custom single-use instruments for Minimal Invasive Surgeries (MIS)

Swiss Quality without Premium Pricing

Gsell shatters the long-held notion that Swiss-made products are expensive by demonstrating that superior products are achievable at globally competitive prices. This is enabled through the strategic use of advanced technologies like automated production lines and AI-powered quality control, which enhance efficiency and reduce costs without compromising the high standards set by the ISO 13485 and 21 CFR 820 certification.

The recently expanded facility in Muri, Switzerland, consists of three buildings that provide about 120,000 square feet of production area, of which about 60 percent is currently used. These include six manufacturing processes, three post-processing processes (cleaning, assembling and packaging), two modern office areas and two clean rooms.

It employs a team of highly skilled quality engineers who work closely with customers to design comprehensive inspection and testing programs. These programs are supported by state-of-theart metrology equipment and data analytics tools, allowing Gsell to identify and address potential issues early in manufacturing.

Its cleaning validation process, for example, is designed to handle even the most demanding products, ensuring flawless quality for every new product. Its specialists, leveraging their extensive project experience, can develop coordinate measuring machine (CMM) programs in just a few hours. These programs comply with good manufacturing practices (GMP) and include a detailed change process with comprehensive checklists to prevent oversights during product updates or modifications.



A view into one of the machining facilities of Gsell

One notable case of Gsell's commitment to quality and customer satisfaction involved a client who needed to streamline their purchasing process. They sought to buy cleaned, packaged and labelled products for immediate distribution. Gsell adapted its operations to meet these requirements by leveraging a previously established cleanroom. It expanded its services to include final packaging within the cleanroom, incorporating additional cleaning equipment and adopting the same printers and software used by the customer for swift validation. This customer-specific investment allowed the client to purchase a single, ready-to-use item shipped directly to their distribution center.

"More customers are requesting finished products – machined, produced, packaged, cleaned, labelled and ready to be shipped directly to surgeons. We eliminate the need for extensive cleaning infrastructure and allow for quick turnarounds, as there's no need for additional re-inspection and re-packaging at the customer," says Simon Gsell, VP and co-owner.

Driven by Commitment

Machines and processes are crucial, but the employees, from the leaders to the operators, truly drive excellence. Under the leadership of René and Simon Gsell, it cultivates a family atmosphere that extends throughout the organization, promoting passion and enthusiasm among its workforces.

66

We like to push the boundaries of what's possible in medical device manufacturing. Our goal is to equip healthcare providers with the tools they need to deliver the best possible patient outcomes

"We strive to meet individual needs and create win-win situations, considering personal, health and family circumstances, as well as work-life balance. We share part of the company's profit with employees, offer flexible working hours and support continuing professional education and training, especially for top talents," says Simon Gsell.

This distinctive culture fosters a strong internal community and attracts top talent from across Switzerland, enhancing Gsell's capability in various specialized fields, from machining to engineering.

It benefits enormously from Switzerland's robust educational system, which embraces a dual education system. The system equips individuals with practical skills in diverse roles, such as machinists, technicians and quality assurance professionals. This educational framework supports Gsell in building a versatile and highly skilled workforce capable of driving innovation and maintaining the company's competitive edge.

Looking to the future, Gsell is committed to staying ahead of industry trends and continuously adapting to the evolving technological landscape. The management team prioritizes constant communication and customer engagement to understand emerging trends and future challenges. Active participation in trade shows helps it keep pace with market demands and anticipate future needs, creating new business opportunities. Underlining its customer-centric approach and supporting further growth in the US market, Gsell founded a subsidiary in the USA last year, Gsell Inc., establishing US Sales and Engineering offices.

Gsell supports its adaptability and sustainable growth by fostering thoughtful dialogue in varied settings. Unlike many competitors, it is driven not by investor pressures but by a pledge to provide high-quality jobs and develop innovative products that meet tomorrow's needs. MBP www.gsell.ch