

MANAGEMENT COMMENTARY



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Straumann Group in brief

Our business and vision

WHO WE ARE, WHAT WE DO AND WHERE WE ARE HEADED

Headquartered in Basel, Switzerland, the Straumann Group is a global leader in esthetic dentistry. It unites global and international brands that stand for excellence, innovation and quality in replacement, corrective, preventive and digital dentistry, including Anthogyr, ClearCorrect, Dental Wings, Medentika, Neodent, and Straumann, as well as other fully or partly-owned companies and partners.

The Group develops, manufactures and supplies dental implant systems, biomaterials, CAD/CAM prosthetics, digital equipment, software, clear aligner systems and various materials for dental applications. Its principal production sites are in Brazil, France, Germany, Switzerland and the US.

As a total solution provider for esthetic dentistry, the Group takes a holistic approach, including training, support and a wide range of services to dental practitioners, clinics and laboratories all over the world. It is recognized as a leading innovator and works together with universities, clinics, research institutes, networks and communities to enhance the standard of patient care. Through unique collaborations with academic networks like the International Team for Implantology (ITI) and the Latin American Institute of Dental Research and Education (Instituto Latino Americano de Pesquisa e Ensino Odontológico ILAPEO), the Group supports research and offers training and education to dental professionals.

With a team of approximately 7600 people, the Group is present in more than 100 countries around the world through a broad network of subsidiaries and distribution partners.

Straumann's heritage stretches back to the early 1950s, although the company in its present form with an exclusive focus on dentistry was established 30 years ago. Over the years, it has enabled millions of people to smile and laugh without the stigma of ugly or missing teeth. By restoring the ability to eat and enjoy food, it has helped to restore health, self-esteem, well-being and confidence – literally changing lives.



Straumann Group is a global leader in esthetic dentistry. Beyond creating smiles, our aim is to restore confidence in patients around the world.

Our vision: More than creating smiles, restoring confidence – we want to be the partner of choice in esthetic dentistry.

OUR VISION

Confidence relates to all our activities; it is built on trust, integrity, respect, communication, transparency, collaboration and delivering what we promise. To our customers, confidence means peace of mind, because our solutions are predictable and durable. To our employees, it means secure, rewarding jobs. To our shareholders, it means sustainable returns from a highly ethical business. For the communities in which we operate, confidence means that we care for the world around us as a responsible corporate citizen. For all our stakeholders it means that the Straumann Group is a reliable partner.

We want to be the first place that people come to do business, to find genuine solutions, to turn ideas into reality, to learn, master and succeed and to improve lives. This is what being the partner of choice means for us.

A PLAYER-LEARNER MINDSET, LED BY EXAMPLE

The Group's unique culture is a key to its success. It pivots on the mindset of players and learners, who inspire trust, are energized and embrace change, listen, find out, share, collaborate, take risks, find solutions, learn by doing, encourage and celebrate.

To help our employees achieve their best, we strive for a culture that builds trust and collaboration, fosters diversity and inclusion, promotes learning and engagement, and encourages people to take responsibility and ownership. To support this, we have a set of core behaviors that apply for everyone in the Straumann Group and which are listed in our Code of Conduct.

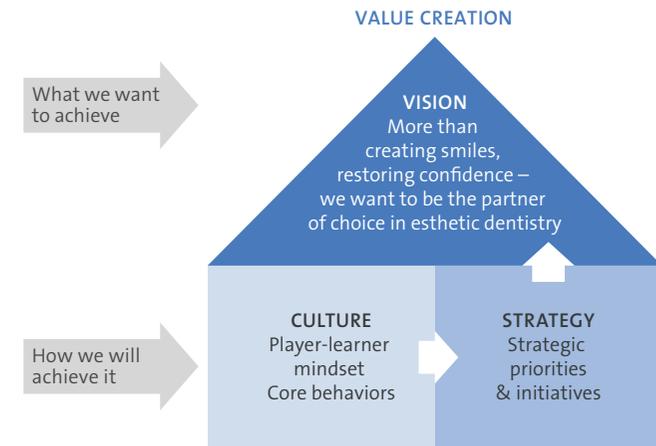
OUR BRAND

STRAUMANN GROUP – UNITING GLOBAL EXCELLENCE IN DENTISTRY

Our journey into new segments, geographies and technologies has turned Straumann into a global group of national and international brands, companies and partners. The Group's umbrella brand provides a common identity that generates value for the individual brands, companies and partners.

Straumann is the leading premium brand in implant dentistry, renowned for innovation, quality, clinically proven long-term success, support, expertise, education and peace of mind. At the same time, the Group is a global leader in the non-premium segment, making high quality implant and prosthetic solutions more affordable to a broader population through our Anthogyr, Equinox, Medentika, Neodent, T-Plus, Warantec and Zinedent brands.

Our company home



Making vision a reality

The way to a sustainable future is mapped out in our three 'strategic priorities' (see p. 18 ff.), which form the backbone of our strategy. Making it happen is a matter of culture and behavior. Thus, vision, strategy and behavior form the figurative building of our company home.



We strive for a culture that builds trust and collaboration, fosters diversity and inclusion.

In these and its other businesses, including biomaterials, digital dentistry and orthodontic clear aligners, the Group is committed to being the partner of choice.

UMBRELLA BRAND



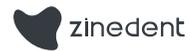
GLOBAL BRANDS








LOCAL BRANDS






The Straumann Group unites various global and local or regional product brands with a number of fully or partially owned companies, as well as independent partners, which provide technology and manufacturing expertise.

Strategy in action

Esthetic dentistry: beyond tooth replacement

With our focus continuing on esthetic dentistry, our three strategic priorities remained unchanged in 2019. They translate into a number of clearly defined initiatives and deliverables, which are continuously tracked and adjusted as necessary. They are reflected in the investments, launches, pipeline, partnerships, achievements and other activities featured in this report (see following examples). The Group's continuing strong growth and outperformance confirm that our strategy is appropriate.

We continue to drive a high performance culture, to embrace change, raise bars and focus on execution. The leadership succession plans that we worked on in 2019 were designed both to ensure continuity and yet also to drive change. By filling the CEO and two other EMB positions with talented internal candidates we have achieved a smooth transition and continuity in our strategy and culture. At the same time, we have brought in experience from other industries to challenge and broaden our thinking.

STRATEGIC PRIORITIES UNCHANGED

DRIVE OUR HIGH PERFORMANCE STRAUMANN GROUP CULTURE AND ORGANIZATION

Culture is at the heart of execution; it drives results and creates value, which is why it has remained our key priority.

Examples of this strategic priority in action in 2019

Culture	<ul style="list-style-type: none"> Continued high investment in Cultural Journey program (see p. 66) Cultural Journey 2.0 initiated to help leaders reach full potential, inspire high performance, and drive organizational culture through others (see p. 67) Good progress confirmed in annual staff survey (see p. 66 ff.)
People	<ul style="list-style-type: none"> Global team expanded to support business growth (see pp. 66 ff.) CEO, EMB & Board succession planning: smooth transition and continuity (see p. 108) Increased investment in People Management & Development (see p. 66 ff.)
Operational excellence	<ul style="list-style-type: none"> Investments in production expansion (see p. 74) Ensuring readiness for European Medical Device Regulation (MDR) (see p. 58 ff.) Operational excellence program Program / initiatives to optimize sales channel approach



Our strategy addresses the increase in society's desire for esthetics.

We continue to drive a high performance culture, to embrace change, raise bars and focus on execution.

TARGET UNEXPLOITED GROWTH MARKETS AND SEGMENTS

Our efforts to target unexploited growth markets and segments were intense and fruitful. In addition to opening new subsidiaries, we made further inroads into the non-premium implant segment.

Examples of this strategic priority in action in 2019

Geographic reach	<ul style="list-style-type: none"> • Distributor buyouts; new subsidiaries in Taiwan and Croatia (Adriatic regional hub) • Joint venture to serve the dental communities in Hong Kong and Macau
Non-premium	<ul style="list-style-type: none"> • Investment in Warantec; increased ownership of Anthogyr, Medentika, Zinedent • International roll-out of Neodent, Anthogyr and Medentika • Expansion of multiplatform prosthetics for third-party implants • Development of nuvo, a completely new brand targeting the lower value segment
Corporate dentistry	<ul style="list-style-type: none"> • Partnerships with the top implant-focused DSO chains in the US and Europe • Initial steps into DSO business in China

BECOME THE TOTAL SOLUTION PROVIDER FOR ESTHETIC DENTISTRY

The increase in society's desire for dental esthetics and in customer preferences for a single supplier are reflected in our strategy to providing complete solutions that cover replacement and corrective dentistry. Our strength in innovation and our ability to create partnerships enabled us to expand our offering in 2019.

Examples of this strategic priority in action in 2019

Differentiating solutions	<ul style="list-style-type: none"> • BLX implant system & immediacy suite launched • Two-piece fully-ceramic implant launched • First products made by ceramic injection moulding launched (see p. 35)
Digital and orthodontic dentistry	<ul style="list-style-type: none"> • Clear aligner business launched in Brazil, Europe and China • Further agreements to cobrand and distribute third-party scanners • Agreements to link/integrate DWOS as preferred software in third party scanners • Entry into thermoplastics and 3D-printing materials businesses • Acquisition of clear aligner design/planning company
Biomaterials	<ul style="list-style-type: none"> • Continued roll-out of botiss and Nibec products
Preventive dentistry	<ul style="list-style-type: none"> • Pilots to assess implant health and other products in selected GP markets



3D-printing – an exciting technology that is driving change in the dental industry.

Our strength in innovation and our ability to create partnerships enabled us to expand our offering in 2019.

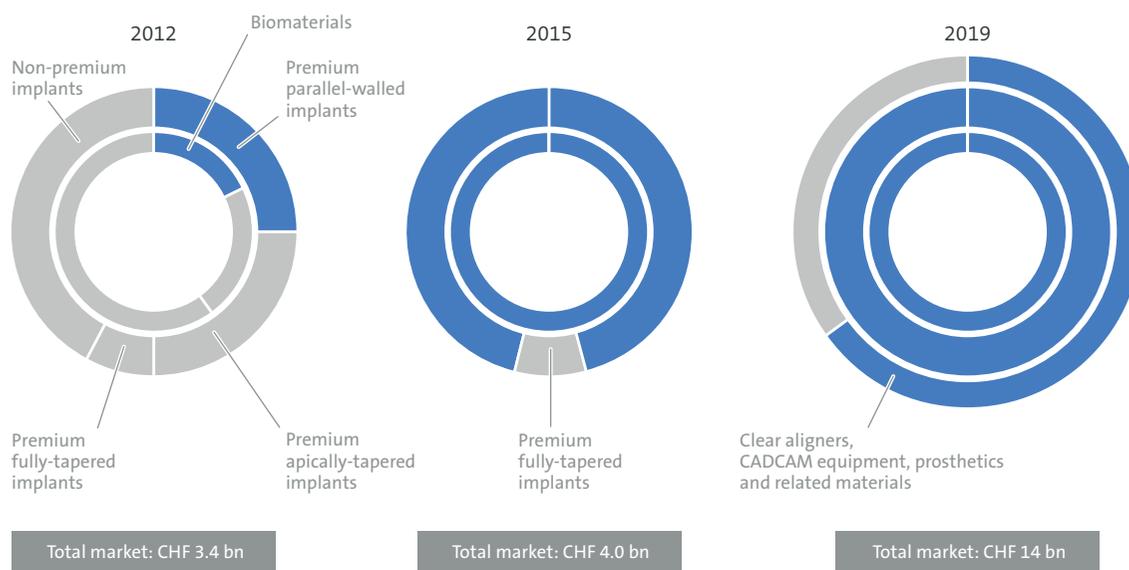
STRATEGY DELIVERS SUSTAINABLE GROWTH

Through internal development, acquisitions, investments and partnerships, we have significantly expanded our addressable market, which has more than trebled over the past three years (see below) and still offers considerable growth potential (see p. 27 ff.). We have set the stage for sustainable future growth and will continue to create opportunities that are aligned with our strategic priorities, constantly vigilant and agile to adapt to a fast-changing environment.

We have set the stage for sustainable future growth and will continue to create opportunities.

Straumann Group's expanding addressable market

Milestone launches/events:	Variobase abutment	BLT implant	Neodent consolidation	Lab and chairside CAD/CAM systems	Clear aligners	BLX implant
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Prior to the acquisition of Neodent in mid-2012, we focused on a market worth CHF 3.4 billion, of which we were able to address segments worth a total of just CHF 1 billion because our portfolio focused on premium parallel-walled implants, standard CAD/CAM prosthetics and a limited range of biomaterials. In seven years we have expanded in the non-premium segment, and have entered the large tapered implant segments. Through partnerships we have assembled a complete portfolio of biomaterials and we have added lab- and chairside-milling solutions, 3D-printing and a range of digital scanners. In 2019, our addressable market had increased to CHF 14 billion.

Products, solutions and services

Some of our brands have been innovating, developing, testing and refining products for decades that address patient needs and contribute to their quality of life. Our product range includes dental implant systems, prosthetics, digital equipment and solutions, orthodontics, biomaterials, implant health and caries treatments as well as materials for 3D-printing and clear aligner production. As a Group, we strive to provide total solutions across segments, enhancing convenience, raising efficiency, and adding value, comfort and security for customers and patients.

To complement the Group's products and solutions, we offer a broad spectrum of services under the Straumann Group brands, such as:

- Modular surgical planning, prosthetic design and centralized manufacturing services covering a wide range of indications
- Comprehensive service packages tailored to the specific needs of future dentists or those who have recently started their careers, with professional practice-oriented and individual support
- Information concepts to address trends in patient information behavior, in order to support dentists in reaching patients who wish to learn more about treatment
- Exclusive access to a great variety of practice-oriented training materials related to the treatment of straightforward implant cases
- Blended learning opportunities, that combine online modules and hands-on tuition.

To provide services of this kind, our staff requires a comprehensive understanding of the dental business and our products. Extensive staff training is therefore an important aspect of our service offering.

MEETING CUSTOMER NEEDS

In line with the Group's strategic priorities to offer total solutions and to penetrate unexploited markets / segments, we introduced numerous new items and solutions at various trade shows in 2019. We began rolling them out on a country by country basis following regulatory approvals.

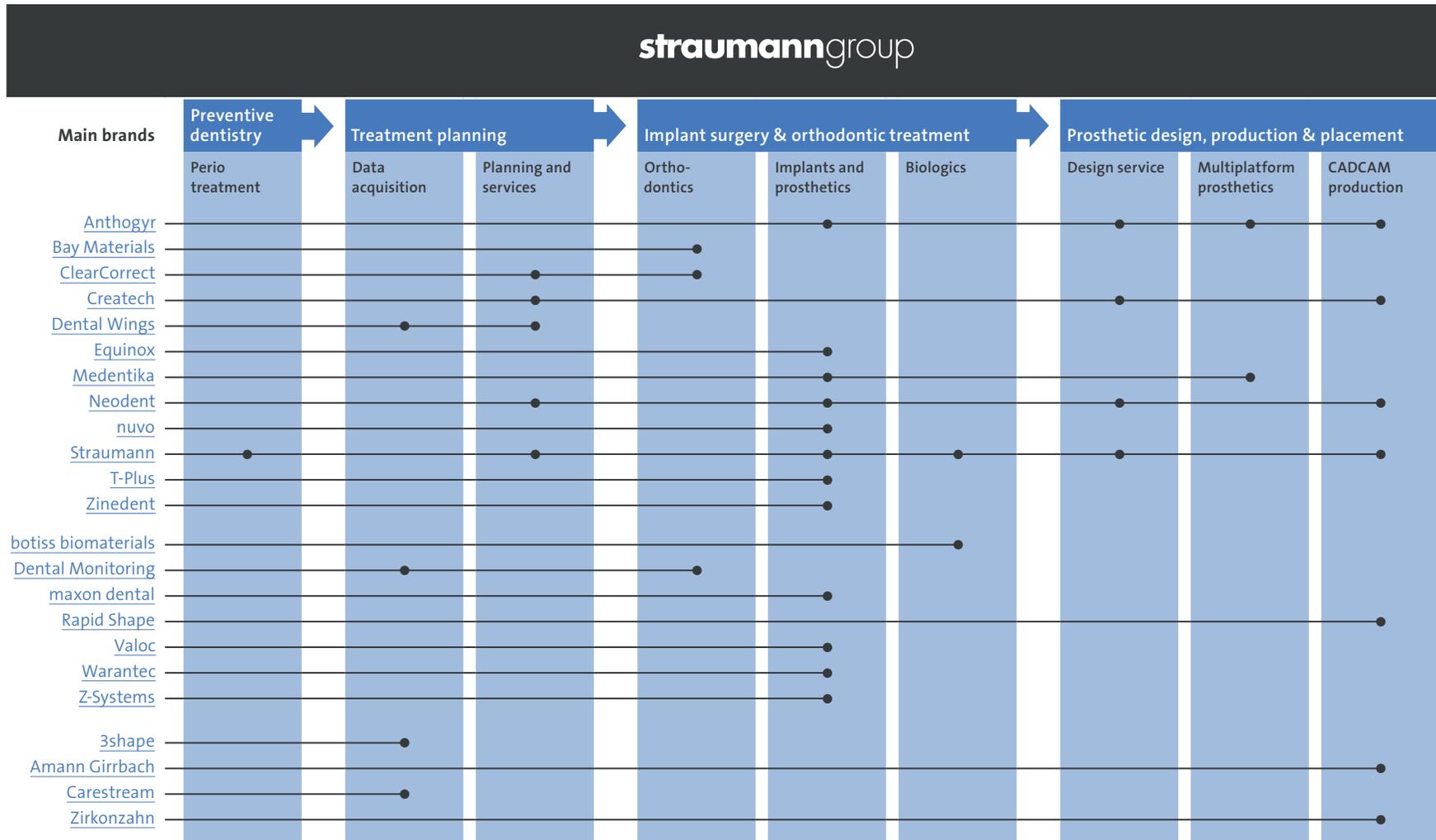
[Click here for more product information](#) 



Launched in 2019, Straumann BLX is much more than an innovative implant design; it's a complete system of implants, prosthetics, heat-reducing drills and more.



Trios 4, a best-in-class intraoral scanner sold under the Straumann brand through our partnership with 3Shape.



This chart shows the Group's main brands, the degree of ownership and how they each support the dental treatment cycle from prevention and correction to replacement and restoration.

The Group's new offerings include implant systems and components (both titanium and ceramic), guided and non-guided surgical instruments, fully integrated digital workflows, additional edentulous solutions, more efficient prosthetics, as well as new digital and orthodontic solutions (see table below).

2019 main product launches	Benefit and added value for customers and their patients
Surgical	
Straumann BLX implant (Brazil, Europe and North America)	<ul style="list-style-type: none"> • New fully tapered implant for all bone types and indications, especially for immediacy • Excellent osseointegration and bone maintenance properties; designed to shorten treatment duration
Straumann VeloDrill	<ul style="list-style-type: none"> • Innovative drill concept • Reduced heat generation, high stability and time saving
Straumann SNOW	<ul style="list-style-type: none"> • First completely metal- and plastic-free, two-piece, screw-retained dental implant for prosthetic flexibility and highly esthetic results
Straumann Modular Cassette	<ul style="list-style-type: none"> • Customizable surgical cassette for all workflows; increased efficiency
Restorative	
Straumann Ceramic Healing Abutments	<ul style="list-style-type: none"> • Ensures favorable conditions for soft-tissue attachment, supporting a healthy peri-implant environment
Straumann screw-retained abutments (SRAs) – new range	<ul style="list-style-type: none"> • Unique slim and edge-free design for better soft-tissue health • SRAs are the most popular abutments for immediate fixed full-arch rehabilitations
Digital	
3Shape TRIOS 4 intraoral scanning solutions	<ul style="list-style-type: none"> • High-end intraoral scanner with fluorescent technology to identify surface caries; zero radiation, infrared scanning detects interproximal caries
Straumann Virtuo Vivo	<ul style="list-style-type: none"> • High-speed intraoral scanner, powder-free, color scanning, highly attractive price, compact • Very small light hand piece for easy handling and enhanced patient comfort
Orthodontics	
ClearCorrect	<ul style="list-style-type: none"> • High-quality, easy-to-use clear aligner solutions; transparent, removable, comfortable, attractively priced • Typically used to treat minor-to-medium malocclusions
DenToGo	<ul style="list-style-type: none"> • Suite of software solutions using artificial intelligence and smartphone / tablet technology to remotely assess patient's oral situation prior to and during treatment • Produces photo simulations of patient's smile after treatment
Biomaterials and prevention	
Emdogain Flapless	<ul style="list-style-type: none"> • Regeneration and elimination of periodontal pockets up to 9mm deep as part of periodontal procedures without surgical flap
GP portfolio (pilot)	<ul style="list-style-type: none"> • Various products to prevent tooth and implant loss and to support esthetic treatments
Integrated solutions	
Straumann Smile in a Box	<ul style="list-style-type: none"> • Digital, modular, integrated treatment planning and manufacturing service to cover surgical and prosthetic indications • Everything needed for treatment conveniently supplied in one box

Our strategy to become a leader in all price segments

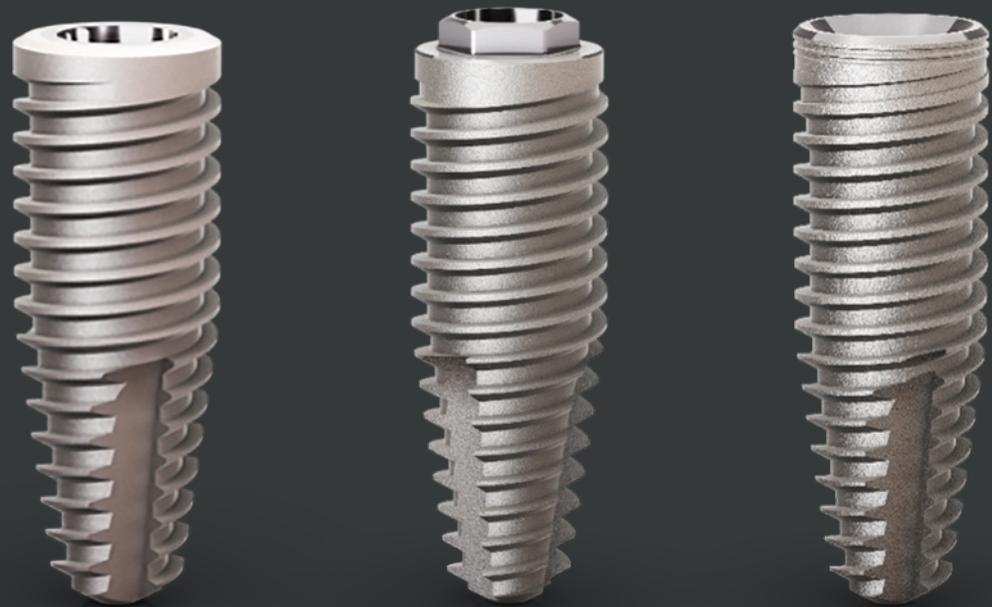
BEYOND THE FEAR OF CANNIBALIZATION

Our strategy to become a leader in all price segments

The economic recession of 2008–2010, the surge in low price competitors and the opportunities in emerging markets made it clear that we could not continue in the long term as an exclusively premium company. In 2012, we took our first step into the upper value segment by investing in Neodent in Brazil. Overcoming the concern of cannibalization, we extended Neodent to new markets and fuelled growth in our Swiss premium brand through innovation and a new pricing strategy. With the two businesses thriving, we intensified our efforts to penetrate the upper value segment by joining forces with Medentika in Germany and Anthogyr in France.

The logical progression was to create opportunities in the lower value segment – especially in emerging markets. We therefore invested in T-Plus in Taiwan, equinox in India and Zinedent in Turkey. In 2019, we had a unique opportunity to invest in Warantec, an established implant brand in Korea, who granted us distribution rights for their products outside Korea. Furthermore, we took over T-Plus and Zinedent.

Beyond this, we developed nuvo, a new brand of attractively priced implants made in Brazil. These are ready for launch pending regulatory approvals. These initiatives broaden our path into the lower value segment and enable us to offer high quality solutions for patients who have not been able to afford implant treatment.

Innovation

Turning ideas into innovations

Straumann has been a leading innovator in the field since the pioneering days of implant dentistry. As in previous years, we continued to invest in research and development in 2019 to fuel our pipeline and to bring significant benefits to patients and customers. As changemakers, we promote innovation in all our activities – for example the use of artificial intelligence in treatment planning. In the past 24 months, we have revised our core competences and technologies to gain competitive advantages and to ensure that our innovation pipeline is focused on customers and patients.

DRIVING INNOVATION ACROSS THE GROUP

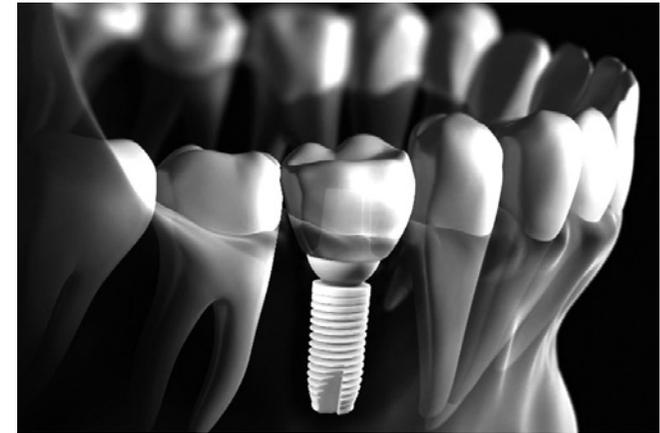
Innovative products, processes and solutions are the key drivers of our global success. Their seed ideas come from various sources. An important characteristic of the Group's culture of innovation is the 'freedom to flourish' – the ability to provide space and resources for innovation across businesses, brands, locations and functions – within a centralized organized framework that coordinates, shares and prioritizes.

The Straumann Group is in a unique position to identify and bring in technologies and expertise from outside and to blend them into total solutions that span the dental ecosystem. Often the innovation is not in the individual elements but in combining and commercializing them.

The addition of companies and partners with their own innovation capabilities – like Anthogyr, Bay Materials, or Yllor Biomaterials and Z-Systems – has increased our access to customers, helping the Group to identify current and future customer needs, generate ideas, create opportunities, develop products and solutions, and successfully commercialise them.

BRINGING INNOVATIONS TO CUSTOMERS AND PATIENTS

The following table highlights the development pipeline projects that we worked on in 2019 with a view to launches starting in 2020.



Developed by our partner Z-Systems and launched in 2019, Straumann SNOW is the first metal- and plastic-free screw-retained two-piece ceramic implant.



The DenToGo remote monitoring system uses smart phone technology and artificial intelligence. [Watch the DenToGo video here.](#) ►

Examples of development projects scheduled for introduction or rollout starting in 2020

Project	Key benefit target	Premium	Value
Surgical			
New implant designs	Less invasive and shorter procedures (immediacy), additional indications	✓	✓
Ceramic portfolio extension	Highly esthetic, metal-free advanced implant design and novel production technology	✓	✓
Prosthetics			
Angulated solutions	Enhanced screw-retained prosthetic solutions for tilted implants, focus on CAD/CAM	✓	✓
Ti-base portfolio	Extends multi-implant offering, including angulated solutions for conventional and CAD/CAM workflows		✓
Edentulous			
Edentulous solution offerings	Patient-centric approach with a broad choice of fixed and removable options, mini implants, focus on immediate procedures	✓	
MPS portfolio	Portfolio extension covering additional competitive brands, attractively priced alternatives to in-market competitor products		✓
Ortho			
Software	Automatic assessment of patient's oral health, aligner treatment acceptance tool, software upgrades to simplify and manage treatment setups	✓	
Integrated planning and design service	Add-on central service for finalized tooth or implant-borne restorations	✓	
Improved clear aligner material	Patient comfort, esthetics	✓	
Digital dentistry			
CAD/CAM materials	Full range of materials for labs and dentists, additional material options in centralized milling service	✓	
3D-printer resins	Portfolio extension	✓	✓
Planning software	New feature releases of CoDiagnostiX	✓	
Biomaterials			
Periodontal pocket treatment	Minimally invasive, easy to perform	✓	
Novel regeneration system	Controlled degradation time, reduced invasiveness and reduced chair time	✓	
Implant health			
Treatments for peri-implantitis	Innovative portfolio aimed at long-term success in peri-implant conditions	✓	

Markets

Further market share gains – new segments tapped

THE GLOBAL DENTAL SUPPLY AND EQUIPMENT MARKET

The dental supply and equipment market is an attractive subsector of the medical device sector and ranges from instruments, adhesives and filling materials to imaging hardware and practice equipment. It also includes specialty segments like implant dentistry, endodontics, biomaterials, CAD/CAM equipment, prosthetics, and orthodontics. The total dentistry market was valued at CHF 27–29 billion in 2019 (see chart on the right) and is growing rapidly, driven by the aging and growing population, increasing prosperity, awareness of oral health, and innovation.

IMPLANT DENTISTRY

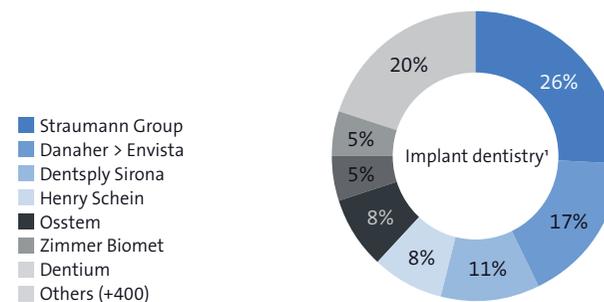
The Straumann Group’s main market is implant dentistry¹, which is estimated to be worth approximately CHF 4 billion globally² (or CHF 4.6 billion including healing screws, temporary abutments and copings). Based on initial reports, we estimate that it grew in the mid-single digit percentage range in 2019, driven almost entirely by volume growth. Having continually outperformed for several years and with the addition of Anthogyr, Createch, Medentika and T-Plus complementing our organic growth, we now lead the implant market with a share of 26%. Three quarters of the market are controlled by the leading six companies, while the rest is divided among several hundred manufacturers, most of whom operate on a regional or local basis and compete in the non-premium segment. The latter has been growing faster than premium, due to the increase in manufacturers, the lack of reimbursement schemes, and stronger growth in emerging markets where procedure prices and disposable income are lower. The non-premium brands collectively account for approximately half of the worldwide implant market in value terms.

Having focused exclusively on premium implants, Straumann entered the non-premium segment in 2012 and, by acquiring various brands, now offers a broad range of solutions in both the upper and lower value price segments. Since then, the Group has gained a leading position in the non-premium segment, although our market share is still only about 10% and therefore offers an attractive growth potential in the coming years.

Having outperformed again, we lead the implant market with a share of 26%.

Dental market overview

	Total dentistry	Implant dentistry ¹
Market	CHF ≈27–29 bn	CHF 4.6 bn
Straumann share	6%	26%
Straumann position	#6	#1



¹ The Implant dentistry market segment includes implant fixtures, abutments, temporary abutments, healing screws, copings and related instruments; information based on Decision Resources Group and Straumann data.

THE TAPERED IMPLANT SEGMENT

Dental implants can be distinguished by their shape. Tapered implants offer high primary stability and are the preferred choice of many clinicians in extraction-socket indications and immediacy protocols or when patients have a soft bone morphology. Almost 80% of dental implants sold in 2018 had a tapered design. Parallel-walled implants, on the other hand, are valued for their periodontal performance (soft-tissue attachment properties) and have been documented for more than 30 years. The Straumann brand dominates the latter category, while our Neodent and other value brands focus on tapered implants.

In 2014, Straumann entered the premium tapered segment with its apically-tapered BLT implant, which has spurred growth and enabled us to outpace the market. A major highlight in 2019 was the launch of Straumann BLX in Brazil, EMEA and North America. This next-generation implant, together with BLT, Neodent Helix and Drive GM, Anthogyr Axiom PX and Medentika Quattrocone, provides us with a formidable portfolio of fully and apically tapered implants. This broad range will enable the Group to win further market share in the fastest growing implant segment and to become the leading provider of immediacy solutions – which was hardly imaginable a few years ago, when our fully-tapered offering comprised a single non-premium design.

Unparalleled range of immediacy solutions



Straumann
BLT



Straumann
BLX



Neodent
Helix GM



Neodent
Drive GM



Anthogyr
Axiom PX



Medentika
Quattrocone

We have a broad range to penetrate the fastest-growing implant segment.



Full-arch replacements on four implants are a popular choice for immediacy protocols.

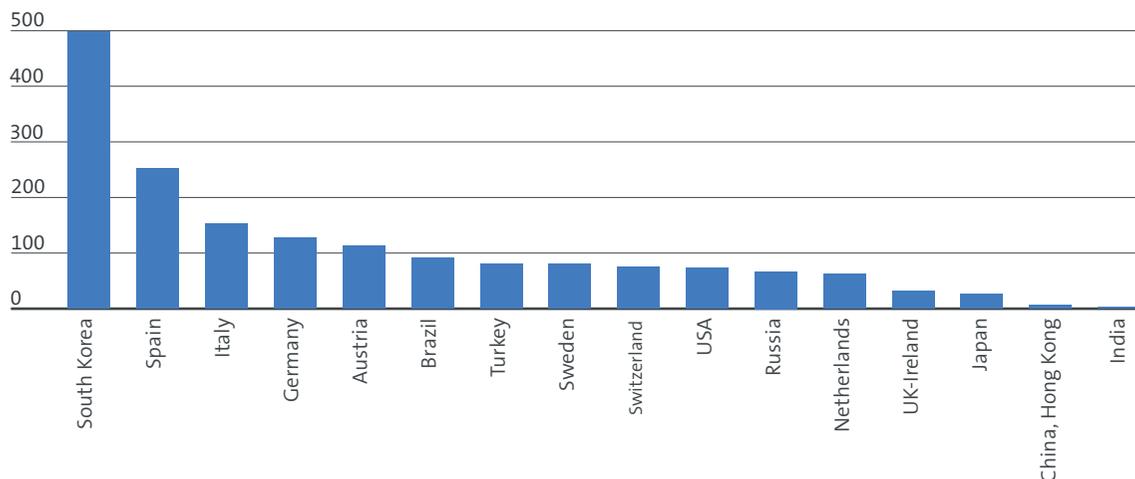
CONSIDERABLE POTENTIAL

Independent researchers expect implant dentistry to continue outpacing the overall dental market. In the world’s largest dental market, the US, more than 120 million people are missing at least one tooth, yet just one and a half million are treated each year (corresponding to 2.7 million implants). This is low in absolute terms and in comparison with other countries. Our analysis shows that only one in four medically eligible US residents who seek treatment for tooth loss actually receive implants. In Germany, the penetration level is approximately 30%, while in Switzerland, it is close to 40%³. The tooth replacement market therefore offers considerable potential and its principal growth drivers are:

- demographics – in an ageing population, more elderly people need tooth replacement
- affordability – the middle class is growing in developing countries
- treatment provision – rising number of trained dentists who are confident placing implants
- awareness – patients are better informed about the negative effects of poor oral health
- esthetics – the trend in people choosing cosmetic treatments and dental implants is growing and consumer expectations are rising.

As the chart below shows, the number of patients treated per 10 000 adult population in the US is only half that of Italy and only a third that of Spain, the largest European market. This illustrates the considerable growth potential there. Penetration in other highly populated countries like the UK, India, China and Japan is also clearly below average, offering strong upside potential in the coming years.

Implant penetration: Patients treated annually (per 10 000 adult population)



In an ageing population, more elderly people need tooth replacement.

◀ With very few exceptions, tooth replacement is an out-of-pocket expense. In South Korea, reimbursement was gradually introduced for senior citizens in 2014. This, together with the fact that more than 70% of the dentists in the country place implants, explains the high penetration rate. By contrast, large economies like China and India remain heavily under-penetrated due to a lack of qualified dental professionals.

BIOMATERIALS

The Straumann Group is also active in the global market for oral biomaterials, which include bone-augmentation materials, membranes, fleeces, sponges and soft-tissue regenerative products. As biomaterials are used in a large proportion of dental implant procedures, market growth is linked to that of implant and bone ridge preservation treatments (although biomaterials are used less with mini and short implants and in immediacy protocols).

In 2018, the worldwide market for oral biomaterials was estimated to be worth more than CHF 600 million⁷. In recent years, the Group has significantly expanded its biomaterials franchise through partnerships (botiss, Genoss, and Nibec) and today is a top-5 global player in this market.

CADCAM EQUIPMENT

The development of digital hardware makes it possible to design and mill abutments, crowns, bars, and bridges (commonly referred to as prosthetics) using computers, saving time and increasing accuracy. Digital implant workflows are becoming increasingly important for clinicians, dental technicians and patients. We estimate that the global market for CAD/CAM dental equipment, which comprises optical scanners as well as milling and 3D-printing equipment, is worth CHF 1.6 billion, including new installations, upgrades and replacements.

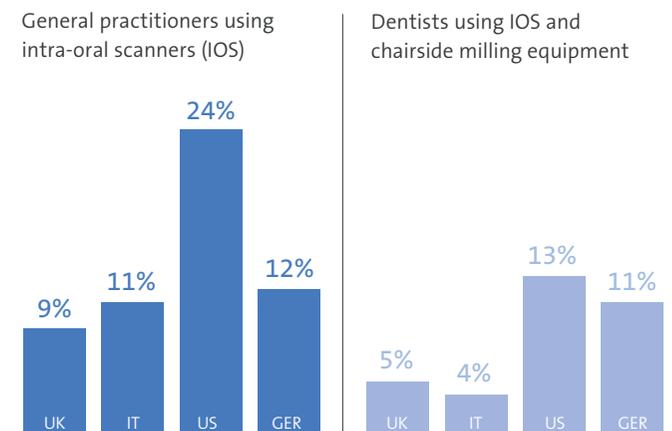
Dental CAD/CAM systems fall into three categories:

- Chairside systems, where scanning, design and milling are all performed in the dental practice
- In-lab systems for scanning, design, and manufacture on medium-sized milling machines
- Central milling, in which lab scanners connect to an external milling center that uses sophisticated, heavy milling machines.

Straumann has been an established player in the centralized milling segment for more than a decade and entered the lab and chairside milling segments in 2016. Penetration of the latter is still modest in spite of the speed, convenience and patient acceptance of intraoral scanning. Even in advanced markets like the US and Germany, fewer than one in four dental practices use intra-oral scanners and few have invested in chairside milling systems (see chart on the right), which indicates the large potential for growth in this segment. By contrast, many dental labs have gone digital and have invested in digital production equipment and systems⁸.

Today, the Group is a top-5 global player in the biomaterials market.

Large potential for growth in digital equipment



Source: Straumann proprietary GP survey in US, DE, IT, and UK; sample size >200 dentists.

We are convinced that the future of dentistry lies in digital workflows. Technology and software are evolving rapidly and there are clear signs that digital transformation is already underway. Intra-oral scanners are becoming increasingly intuitive and versatile and will become the gateway to the digital dental universe. Multiple studies have shown that digital impressions are more accurate⁹, faster¹⁰ and more comfortable than taking physical impressions. In the US, 50% of dental labs use CAD/CAM and nearly all larger labs accept digital scans from their referring dentists. More than 80% of larger labs have a complete CAD/CAM system including scanner, milling system, and sintering furnace because they have the financial resources and a high throughput¹¹. This is why we are constantly developing our current range and offer an integrated, open architecture portfolio, with leading chairside and in-lab scanning and milling technology, 3D in-lab printing and central milling. All are supported by cutting-edge software and validated workflows that cover the tooth-replacement and orthodontic spectrum. With regard to central milling services, we expanded our options and reach through the acquisitions of Createch, Sameda (Anthogy) and Fischler Dental AG (etkon Switzerland).

PROSTHETICS

The CAD/CAM prosthetics market is estimated at almost CHF 4 billion¹² and comprises crowns, inlays, onlays, bars, and bridges designed on a computer and manufactured with a milling machine or an additive process. Tooth-borne restorations, such as single crowns, inlays and small bridges, account for the largest part. While CAD/CAM production is growing strongly, most crowns and bridges are still porcelain-fused-to-metal or press ceramics made in a time-consuming manual process. Market research¹³ indicates that general dentists usually obtain CAD/CAM crowns and bridges from local labs, and most use models or impressions to order the restorations.

This segment is expanding due to the increase in local laboratories offering CAD/CAM services and the growing popularity of individualized prosthetics, which have esthetic and clinical advantages over traditional pre-fabricated abutments and custom castings. Another driver is the popularity of cost-effective titanium-base implant abutments, like Straumann's Variobase, which allow customers to produce their own prosthetics through an open software platform while still ensuring an original interface between the implant and the abutment brand.

The future of dentistry lies in digital workflows, seamless connectivity and reach.



The Straumann / Dental Wings Virtuo Vivo intraoral scanner connects seamlessly to our C-Series chairside mill (left).

Internal and independent surveys show that patients are increasingly willing to invest in treatments that not only restore function, but also improve appearance. CAD/CAM makes it possible to use strong, highly esthetic translucent glass ceramics or hybrid materials and Straumann competes in the materials market with its innovative proprietary glass ceramic, nIce.

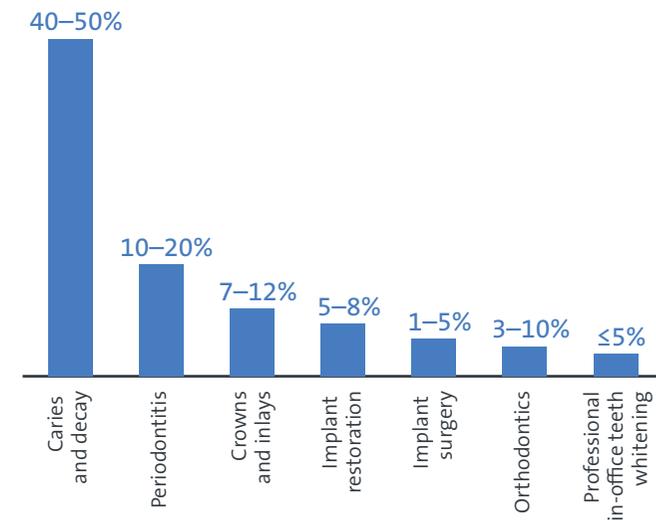
DYNAMIC CLEAR ALIGNER MARKET

Approximately two in five children in North America have misaligned teeth and 10% have severe malocclusion. More than 60% of teenagers have severe tooth displacement and approx. 17% have either lingual or buccal crossbite.¹⁴ Of the three million orthodontic cases actually treated in North America in 2018, the majority received conventional wires and brackets, while approximately one third received modern clear aligner solutions (see chart on the right). Conservative estimates state that 50–60% of all patients with misaligned teeth could theoretically be treated with clear aligner solutions. Outside North America, penetration rates are considerably lower. Internationally, fewer than 5% of dentists offer clear aligners.¹⁵ The global market for clear aligners is estimated to be worth approximately CHF 3.2 billion and is growing at around 20%, representing one of the most attractive areas in dentistry. The dynamic growth is due to the significant advantages of clear aligners offer over conventional wires and brackets, including esthetics, patient compliance, cleaning, teeth stains and convenience. In addition, research shows a strong preference for clear aligners among adult orthodontic patients. Growing awareness of these advantages among dentists and patients as well as broader availability of the solutions (through general dentists and direct-to-consumer offerings) will lead to higher penetration rates in the future.

We entered this attractive field in 2017 by acquiring ClearCorrect. In 2018, we invested in, and partnered with Dental Monitoring, a pioneer of remote monitoring systems and in 2019, we formed a partnership with ZhengLi Technology to enter the Chinese clear aligner market. Between 2006 and 2016, the percentage of adults with malocclusion and misaligned teeth who received orthodontic treatments rose from 10–20% to 30% and even 50% in more developed regions. According to market intelligence and industry data, the clear aligner market is growing faster in China than anywhere else and it is expected to grow by more than 50% in the next five years¹⁶. With ZhengLi Technology, we plan to cater for moderate and complex cases, which are particularly prevalent.

Conservative estimates state that 50–60% of all patients with misaligned teeth could theoretically be treated with clear aligner solutions.

Percentage of patients treated by general dentists by indication



Source: Straumann proprietary GP survey in US, DE, IT, and UK; sample size >200 dentists.

MATERIALS

We also took initial steps into the market for clear aligner and 3D-printing materials markets in 2019 through the acquisitions of Bay Materials in the US and Yller Biomaterials in Brazil. In addition to securing supplies for our own business, our strategic intention is to continue providing these materials to third party manufacturers. The collective addressable dental market for these materials is estimated to be approximately CHF 500 million.

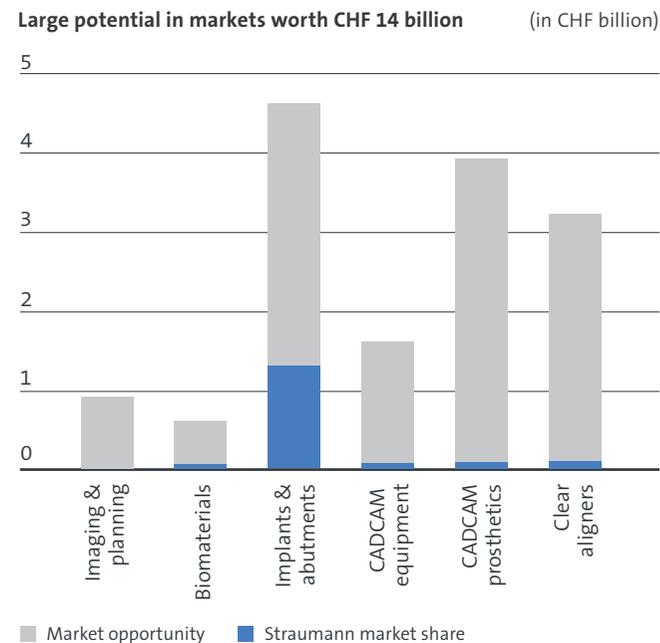
PREVENTIVE DENTISTRY

Dental caries is a significant global health problem that affects 60–90% of schoolchildren and the vast majority of adults¹⁶. The increasing world population and life expectancy will drive the need for treatment. Although oral care, the use of fluoride and regular check-ups have helped to reduce the prevalence and severity in developed countries¹⁸, periodontal disease is the sixth-most prevalent disease worldwide¹⁸ and a majority of adults are affected by mild to moderate periodontitis²⁰. In Germany, one in two adults aged 35 to 44 suffers from periodontal disease, 43% of whom have moderate disease, while 10% are severe cases²¹. In the US, the total prevalence of periodontitis in adults aged 30 years and older was 47% in 2012, and the prevalence of moderate and severe disease was 39%²².

The significant medical need and opportunity in fields related to our existing businesses provided the rationale for exploring the preventive dentistry market. The need for improved treatment concepts is further underpinned by our field research²³ that outlines the most frequent treatment forms in a general dentist practice (see chart on the previous page). General dentists on average treat 4–5 times more patients for decay than with implants. Periodontal treatments are twice as frequent. In the course of 2019, we piloted a number of innovative products for treating diseases that lead to decay, tooth loss or implant failure. The portfolio addresses the needs of general practitioners.

ADDRESSING MARKETS COLLECTIVELY WORTH CHF 14 BILLION

Having concentrated on premium parallel-walled implants for many years, we have significantly broadened our scope through internal development, acquisitions, investments and partnerships, with the goal of offering complete solutions in both replacement and esthetic dentistry. As a result, our addressable market has expanded significantly, more than tripling in the past three years to approximately CHF 14 billion (see chart on the right).



Notes and references

- 1 Including implant fixtures, abutments and instruments.
- 2 Decision Resources Group 2017–18, iData 2017 and Straumann bottom-up estimates in 70 countries.
- 3 Straumann proprietary survey.
- 4 Population Reference Bureau (www.prb.org).
- 5 American College of Prosthodontists, 2018 (www.gotoapro.org/facts-figures).
- 6 iData 2017.
- 7 Decision Resources Group 2017–18, iData 2017 and Straumann bottom-up estimates in 70 countries.
- 8 Research by KeyGroup 2018, Frost & Sullivan 2017.
- 9 Fawaz Alqahtani 2017, Boeddinghaus 2015, Zarauz 2014.
- 10 Yuzbasioglu et al., BMC oral health, 2014.
- 11 The Key Group Inc. 2017.
- 12 Decision Resources Group 2017–18, iData 2017 and Straumann estimates.
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- 14 National Center for Health Statistics. An assessment of the occlusion of the teeth of children 6–11 years. Vital and health statistics, 1973.
- 15 Global Industry Analyst Inc. 2016, company reports and Straumann estimates.
- 16 Commercial Opportunities in the Dental Care Market in China; KPMG China, 2016.
- 17 Petersen, 2008; WHO, 2016.
- 18 Poul Erik Petersen and Hiroshi Ogawa, Community Dental Health, 2016.
- 19 Kassebaum et al., Global burden of severe periodontitis in 1990–2010: A systematic review and metaregression, Journal of Dental Research, 2014.
- 20 Dye, 2012; Petersen and Ogawa, 2012.
- 21 The fifth German oral health study, 2016.
- 22 Eke et al., Prevalence of periodontitis in adults in the United States, 2012.
- 23 Exevia, 2018, based on market research data in Germany, Italy, Spain and the US.

BEYOND CONTINUITY IN INNOVATION

Ceramic technology to improve healing

Major projects, like our Straumann BLX and SNOW implant systems, can easily eclipse other innovations that are no less relevant or meaningful. The ceramic healing abutments we launched in 2019 are a truly differentiating innovation that exemplify this. Fitted to an implant after placement, they are designed to prepare and shape the gum around the implant during the healing period before prosthetic restoration. By comparison with titanium, ceramic (zirconia) is more favourable to soft tissue attachment and less prone to plaque formation¹⁻⁹. The new abutments thus support soft-tissue healing, although the most innovative thing about them is the fast, cost-effective production technique, which uses ceramic injection moulding instead of conventional milling. The technique was developed by Maxon Dental, the joint venture between Straumann and maxon motor.



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- 1 Kajiwaru N et al. *Implant Dent* 24(1):37-41.
- 2 Degidi M et al. *J. Clin. Periodontol.* 2006 Jan;77(1):73-80.
- 3 Liñares A et al. *J. Clin. Periodontol.* 2016 Jun;43(6):538-46.
- 4 Erbshäuser M *Implantologie Journal* 2015;11:32-36.
- 5 Welander M et al. *Clin Oral Implants Res.* 2008 Jul;19(7):635-41.
- 6 Tetè S et al. *Int J. Oral Maxillofac Implants.* 2009 Jan-Feb;24(1):52-8.
- 7 De Medeiros RA et al. *J Contemp Dent Pract.* 14(3):567-572.
- 8 S. Roehling, M et al. *Clin. Oral Impl. Res.* 26 (Suppl. 12), 2015.
- 9 Scarano A et al. *J. Clin. Periodontol.* 2004 Feb;75(2):292-6.

Business performance

Group

ANOTHER STRONG PERFORMANCE ALL ROUND

In 2019, the Straumann Group posted another strong all-round performance, as revenue grew 17% both organically and in Swiss-franc terms to CHF 1.6 billion, fuelled by double-digit increases across all businesses and regions, in spite of the challenging baseline and difficult environment in Latin America. Along with this impressive growth, we achieved further improvements in profitability, despite significant investments in people, culture, innovative technologies, marketing, sales, regulatory support and infrastructure.

By business, more than half of our growth came from implants and restoratives, driven by robust demand for premium solutions and the international expansion of our value brands, especially Neodent. Straumann's innovative BLX implant attracted customers from competitors and sold more than 100 000 units in its first year on the market, adding to the solid growth contribution of our BLT range. Biomaterials continued to thrive, driven by robust sales of bone-graft and membrane products, the roll-out of botiss and Nibec products in certain markets, and Emdogain's return to the US market in mid-2018. Our combined digital and orthodontics business also reported strong growth driven by dynamic sales in clear aligners, which compensated for softer digital equipment sales.

ACQUISITIONS TO EXPAND REACH, INCREASE AFFORDABILITY AND SECURE TECHNOLOGY AND SERVICES

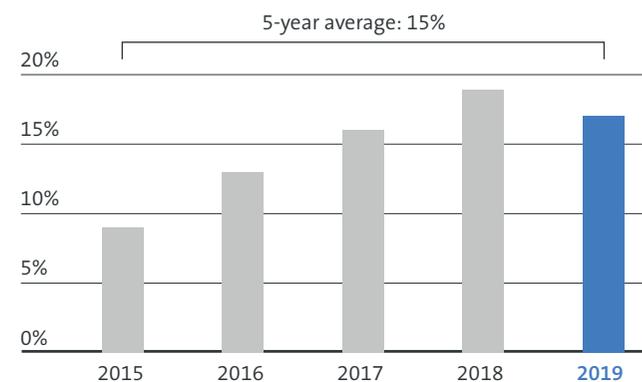
During 2019, the Group completed ten business combinations (see Note 2.1 on p. 153 ff.): In May, we increased our stake in Anthogyr from 30% to full ownership. Based in France, Anthogyr develops, manufactures and sells high quality, innovative implant and CAD/CAM solutions. In October, we fully acquired Bay Materials, a US company specializing in the design, development and supply of high-performance thermoplastics for orthodontic applications. We completed eight other business combinations: Abutment Direct in Canada, the Chilean distributor of Alpha-Bio Tec, Digital Planning Service in Pakistan, etkon (formerly Fischler Dental) in Switzerland, Medikadent in Croatia, Valoc in Switzerland, Yller Biomaterials in Brazil and Zinedent in Turkey. Collectively, these combinations contributed 2.5 percentage points to topline growth.

Key performance figures

	2019	2018
	Core ¹	Core ¹
Revenue (CHF m)	1 596	1 364
Gross profit margin (%)	75.6	75.4
EBITDA margin (%)	31.6	29.6
EBIT margin (%)	27.1	26.9
Net profit margin (%)	21.2	21.5

1 In accordance with the new directive of the Swiss Stock Exchange, the Group has started to implement the reporting of alternative performance measures (APM), which facilitates the assessment of the underlying business performance but may differ from IFRS reported figures. The 'core' figures used in this document exclude one-time M&A effects, exceptional pension-plan items, restructuring expenses, amortization and impairment of goodwill and acquisition-related intangible assets. 'Before-exceptional results', which were used historically, excluded the same non-recurring items but not acquisition-related asset amortizations. A reconciliation table of the reported and core income statement with additional descriptions is provided on p. 137 f. of the Financial Report.

Organic revenue growth



OPERATIONS AND FINANCES

We started to implement alternative performance measure (APM) reporting in our first-half report, in accordance with a new directive from the Swiss Stock Exchange and international practice in the sector. In addition to providing the figures as reported according to IFRS, we also present the income statement on a 'core' basis. Core figures exclude exceptional items as well as acquisition-related asset amortizations.

In 2019, the following effects were defined as non-core items:

- the Align Technology patent dispute settlement charge of CHF 26 million or CHF 22 million after tax deduction (administrative expense)
- fire damage at Dental Wings of CHF 4 million (COGS) and CHF 3 million (administrative expense); the insurance coverage to date amounts to CHF 7 million (other income)
- amortization of acquisition-related intangible assets of CHF 19 million (EBIT level)
- consolidation gains of CHF 6 million related to the acquisition / consolidation of former associates (below EBIT).

A reconciliation table is shown on page 139 of the Financial Report.

The adoption of the new lease standard IFRS 16 led to changes in the EBITDA, EBIT and net profit margins of +175 base points (CHF 28 million), +25 base points (CHF 4 million), and -15 base points (CHF 2 million), respectively.

DOUBLE-DIGIT VOLUME EXPANSION LIFTS CORE GROSS PROFIT

Strong implant volume expansion in both premium and value implants lifted gross profit 17% (CHF 179 million) to CHF 1.2 billion. The respective margin expanded 20 base points to 75.6%, despite the fact that we had to absorb currency headwind of 40 base points. The aforementioned fire damage in 2019 and an exceptional inventory-revaluation expense of CHF 9 million following the acquisition of Batigroup in the prior year were excluded from the core results.

CORE EBITDA MARGIN CLOSE TO 32%

Operational gearing and the effects of the new lease accounting standard resulted in an increase of 200 base points in core earnings before interest, tax, depreciation, and amortization (EBITDA) margin.

We started to implement alternative performance measure (APM) reporting in accordance with a new SIX directive.

Strong implant volume expansion lifted gross profit 17% to CHF 1.2 billion.

Core distribution expenses, which comprise sales-force salaries, commissions and logistics costs, rose CHF 40 million to CHF 321 million, as we entered new businesses and invested further in our distribution network. Despite these important investments, distribution costs decreased by 50 base points relative to sales, contributing to the operating profit margin improvement.

Core administrative expenses, which include research and development (R&D) as well as marketing, sales and general overhead costs, increased by CHF 77 million to CHF 460 million, mainly due to new product launches, brand rollouts, the integration of acquisitions and additional expenses related to the new Medical Device Regulation (MDR) in Europe. As a percentage of sales, administrative expenses increased 70 base points.

Investments in our innovation pipeline and clinical programs for new products, e.g. BLX, led to an increase in R&D investments in absolute terms, although this remained stable relative to sales. Taking these items into account, core EBITDA increased 25% to CHF 505 million, lifting the core margin to 31.6%.

We have invested significantly in production sites and capacity in recent years and continue to do so in order to meet increasing demand. As a consequence, depreciation expenses increased by CHF 9 million. Amortization expenses rose by CHF 4 million, mainly for customer and technology-related intangible assets connected to recently-acquired businesses. After depreciation and amortization charges of CHF 73 million, core EBIT rose to CHF 432 million and the core margin edged above 27%.

CORE NET PROFIT RISES 15%

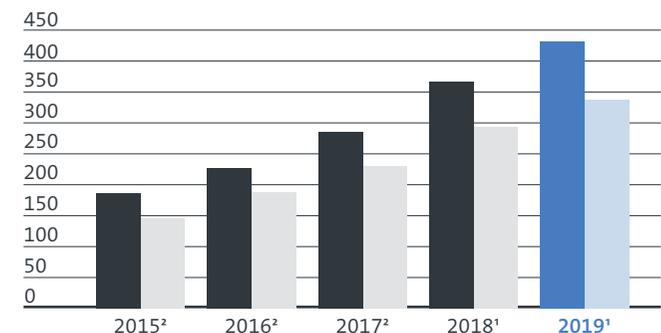
Core net financial expenses increased from CHF 17 million to CHF 25 million, reflecting higher interest costs of CHF 7 million due to IFRS 16, higher hedging costs and foreign-exchange losses mainly in emerging markets.

The rise in profits led to an income-tax increase of CHF 9 million, translating into a corporate tax rate of 15.7%. The core tax rate amounted to slightly above 16%, which is broadly in line with the Group's long-term guidance.

As a result of the above items, core net profit increased 15% to CHF 338 million, with the corresponding margin reaching 21.2%. Reported net profit rose 11% to CHF 308 million with the corresponding margin reaching 19.3%. Basic core earnings per share climbed almost 17% to CHF 21.21.

Core net profit rose 15% to CHF 338 million.

Operating and net profit (in CHF million)



■ Operating profit (EBIT)
■ Net profit

1 Core.
2 Excluding exceptionals.

FREE CASH FLOW REACHES CHF 230 MILLION

The improved operating result and the impact of IFRS 16 lifted cash flow from operating activities by 37% to CHF 378 million. Strong volume growth, a higher share of sales in emerging markets and a significant increase in stock keeping units including acquisitions collectively increased working capital by CHF 33 million to CHF 266 million. Days of sales outstanding increased by one to 57, and days of supplies increased to 175. Net interest expenses including interest on lease liabilities and tax payments collectively increased by CHF 2 million.

The Group's investments in production expansion include additional machinery and buildings in Villeret (CH), Round Rock (USA), Curitiba (BR) and Markkleeberg (D). As a result, capital expenditure increased by CHF 40 million to CHF 150 million, including CHF 15 million for the purchase of intangible assets and CHF 15 million related to the acquisition of Anthogyr. Combining the above effects with the proceeds of CHF 1 million from the sale of non-current assets, free cash flow amounted to CHF 230 million.

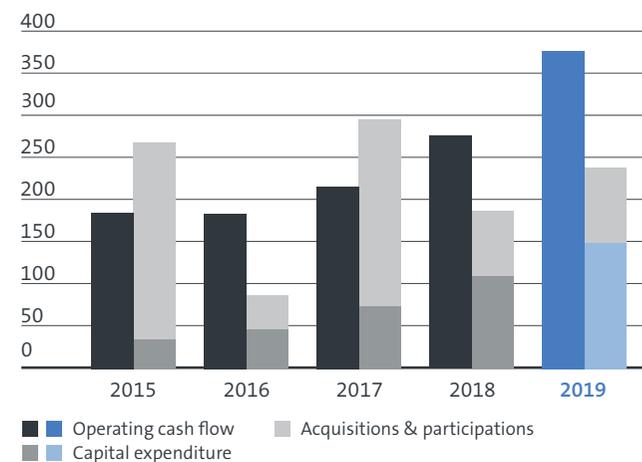
The cash position at year-end remained solid at CHF 260 million, which exceeds our interest-bearing liabilities by CHF 20 million (2018: CHF 19 million).

FURTHER DIVIDEND INCREASE PROPOSED

Based on the excellent results in 2019, the Board of Directors proposes a further dividend increase of CHF 0.50 to CHF 5.75 per share, payable on 15 April 2020, and intends to continue increasing the dividend in the future, subject to further good performance.

Free cash flow reached CHF 230 million despite investments.

Cash flow and investments (in CHF million)



SUMMARY OF MAIN INVESTMENTS

INVESTMENTS TO EXTEND OUR GEOGRAPHICAL REACH

To increase our direct presence and boost our business in regional markets, we acquired our distributor in Croatia and gained control of Medentika's distributor in Canada. We significantly increased our customer base in Chile by acquiring the local distribution activities of Alpha-Bio Tec. In Switzerland, we acquired etkon Schweiz AG (formerly Fischler Dental AG), a specialist CAD/CAM milling center. Collectively, these investments amounted to approximately CHF 16 million.

INVESTMENTS IN THE VALUE IMPLANT SEGMENT

In the non-premium implant segment, we increased our respective stakes in Anthogyr in France and Zinedent in Turkey from 30% and 50% to full ownership. We also raised our stake in Medentika in Germany from 51% to 91%. At the same time, we obtained a 33% stake in the Korean implant manufacturer Warantec together with exclusive international distribution rights in return for a capital injection. Collectively, these investments amounted to CHF 102 million.

INVESTMENTS IN TECHNOLOGY PARTNERS

We obtained control of Valoc, our Swiss partner in implant prosthetic fixtures, by increasing our stake from 44% to 55%. To support our orthodontics business, we acquired Digital Planning Service Ltd. in Pakistan, which provides digital planning for clear aligner treatment. We also acquired Bay Materials LLC, a US company specializing in orthodontic thermoplastics, and Yller biomaterials, a Brazilian producer of resins for 3D-printing. Collectively, these investments amounted to CHF 42 million.

INVESTMENTS IN INFRASTRUCTURE

To meet the strong increase in demand, we invested approximately CHF 116 million in land, buildings and machinery, mainly to increase production capacity in Switzerland, Brazil and the US. Together with investments in IT hard/software and in fixed assets, capital expenditures reached an all-time high of CHF 150 million.

OTHER INVESTMENTS

Information on investments in distribution (including selling activities, research and development) as well as tangible and intangible assets, are presented in the financial report. Investments in people are covered in the sections on Employees and Compensation.

Business investments in 2019

Entity	Location	Stake	Rationale
Abutment Direct Inc.	Canada	45.5%	Take over distribution of Medentika in Canada
Alpha-Bio Tec. Ltd.	Chile	100%	Penetrate upper-value implant segment
Anthogyr SAS	France	30 → 100%	Strengthen position in upper-value implant segment
Bay Materials LLC	USA	100%	Secure access to orthodontic thermoplastics
Digital Planning Service Ltd.	Pakistan	100%	Secure digital planning for clear aligner treatment
etkon Schweiz AG (formerly Fischler Dental AG)	Switzerland	70%	Provide central CAD/CAM milling service in Switzerland
Medentika GmbH	Germany	51 → 91%	Penetrate value implant segment
Medikadent d.o.o.	Croatia	100%	Take over distribution of Medentika in Croatia
Valoc AG	Switzerland	44 → 55%	Innovative implant prosthetic fixtures
Warantec Co Ltd.	Korea	33.5%	Strengthen position in lower-value implant segment
Yller Biomaterials S.A.	Brazil	100%	Entry into 3D-printing materials
Zinedent Implant Üretim AS	Turkey	50 → 100%	Strengthen position in lower-value implant segment

Business performance

Regions

Throughout 2019, we continued to outperform the market and gain share in all regions. Once again, Asia / Pacific led the performance with organic revenue growth of more than 20% for a third consecutive year. The other regions all achieved solid double-digit increases, despite the high prior-year baselines.

Due to its size, EMEA continued to be the largest contributor, delivering a third consecutive year of double-digit growth, driven by solid European performances boosted by emerging and distributor markets.

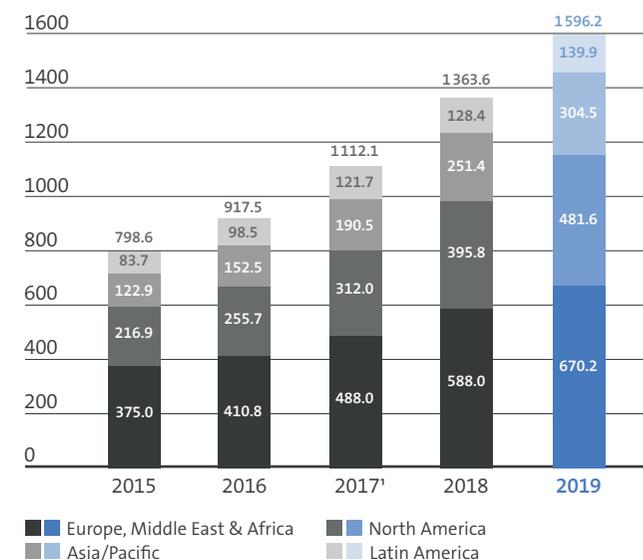
Regional sales performance by quarter

	(in CHF million)					
	Q1	Q2	Q3	Q4	Total 2019	Total 2018
Europe, Middle East & Africa	160.7	174.2	142.6	192.7	670.2	588.0
Change in CHF %	9.3	11.0	16.8	19.0	14.0	20.5
Change (organic ¹) in %	14.4	12.7	13.1	13.4	13.4	14.6
North America	110.2	120.2	117.1	134.2	481.6	395.8
Change in CHF %	22.1	20.4	25.5	19.3	21.7	26.9
Change (organic ¹) in %	17.4	18.8	23.5	19.4	19.8	20.0
Asia / Pacific	71.8	75.4	76.2	81.1	304.5	251.4
Change in CHF %	22.1	14.1	24.4	24.3	21.1	32.0
Change (organic ¹) in %	22.1	16.0	23.4	24.5	21.5	27.8
Latin America	29.5	38.0	35.2	37.2	139.9	128.4
Change in CHF %	5.3	10.2	14.0	6.3	9.0	5.5
Change (organic ¹) in %	19.7	17.6	17.3	13.4	16.8	20.2
TOTAL	372.3	407.8	371.1	445.1	1596.2	1363.6
Change in CHF %	14.9	14.1	20.7	18.8	17.1	22.6
Change (local currencies) in %	17.2	17.1	22.4	21.8	19.6	23.1
Change (organic ¹) in %	17.1	15.5	18.7	17.1	17.1	18.9

1 Excluding the effects of currencies and acquisitions (mainly Anthogyr).

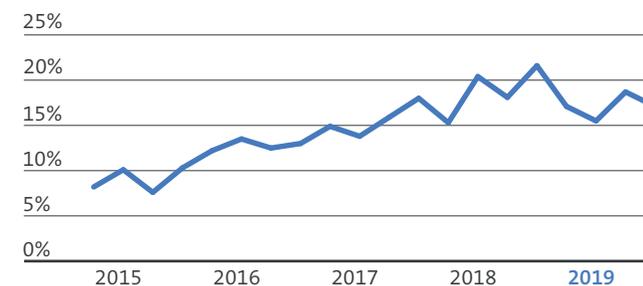
Regional sales performance by year

(in CHF million)



1 Restated.

Five-year quarterly revenue growth (organic)



Europe, Middle East & Africa

Third year of double-digit growth

Our largest region achieved double-digit organic growth for a third consecutive year, which is remarkable in view of the high baseline and the fact that the region includes the most mature markets. While Germany – the region’s largest market – continued to deliver a solid performance, the strongest growth was achieved in Austria, France, Iberia, Russia, South Africa and Turkey.

The strong overall performance was driven by the continuing success of Straumann BLT implants and the launch of Straumann BLX in most countries. The roll out of our Neodent and Zinedent implants, as well as Medentika’s multiplatform prosthetics and botiss biomaterials, also contributed to growth. Following the introduction of Clear Correct at the International Dental Show, we began to roll out the clear aligner business in Europe.

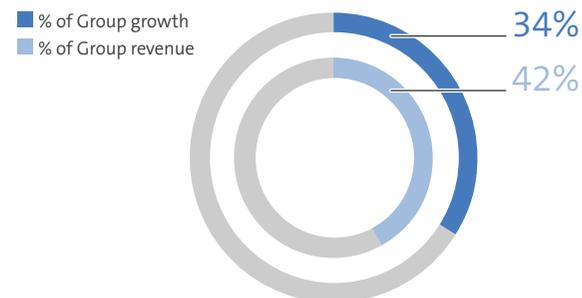
Additional revenues came through the full acquisitions of Anthogyr in France – where we now lead the implant market, Zinedent in Turkey and our former distributor in Croatia, which has become a hub for the Balkan region. In addition to winning new customers with BLX and our value brands, we built important supply partnerships with some of Europe’s largest dental chains.

All of the aforementioned activities reflect our strategy to penetrate unexploited markets and segments. Apart from product launches and business expansion, we continued to invest in preparing for the new European Medical Devices Regulation and successfully completed audits at key European production sites.

EMEA REGION



EMEA CONTRIBUTION TO GROUP



LARGEST REGIONAL MARKETS

1. Germany
2. Spain
3. France

ORGANIC GROWTH

+13%

CHANGE IN CHF

+14%

REVENUE

CHF 670m

North America

Further customer gains

North America almost equalled its prior year growth rate – the highest in 14 years. Canada and the US both delivered double-digit organic increases, driven by robust demand for premium implants and strong growth in the value segment. Sales of Straumann BLT continued to rise, complemented by BLX, which was launched in July. Together with Neodent GM, these tapered implants continue to win customers from our key competitors. The same is true for our Medentika prosthetic solutions, which added to the fast-growing value business in the US and Canada. Biomaterials benefitted from the launch of Jason Membrane and cross-selling activities, as the Neodent team began to target its customers with the Group’s biomaterials portfolio.

ClearCorrect continued to grow dynamically and expanded production to cater for growing demand. To support this business, we acquired Bay Materials LLC in California, which specializes in the design, development and supply of high-performance thermoplastics for orthodontic applications.

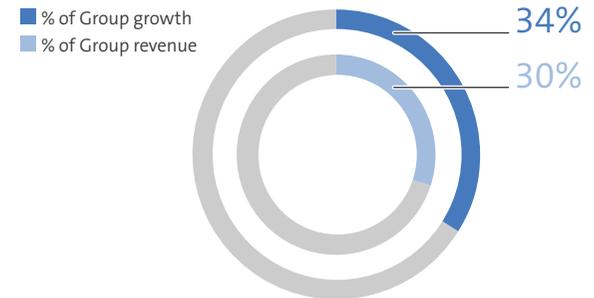
We made further gains in the DSO segment, which accounts for 10% of regional sales. In addition to renewing our preferred supplier agreement with ClearChoice Dental Implant Centers for five years, we won a supply contract with another of North America’s leading implant clinic networks.

The only set back to the region’s progress in 2019 was the fire at Dental Wings in Montreal in May. This caused severe damage and disrupted our scanner business. In the meantime, Dental Wings was able to relocate and resume activities quickly.

NAM REGION



NAM CONTRIBUTION TO GROUP



LARGEST REGIONAL MARKETS

1. USA
2. Canada

ORGANIC GROWTH

+20%

CHANGE IN CHF

+22%

REVENUE

CHF 482m

Asia/Pacific

Still our fastest-growing region

China maintained its dynamism as the region’s growth powerhouse as we gained share in the premium implant segment, reflecting our investments in sales-force expansion, training and education. We also benefitted from digital equipment sales and an acceleration in the DSO business.

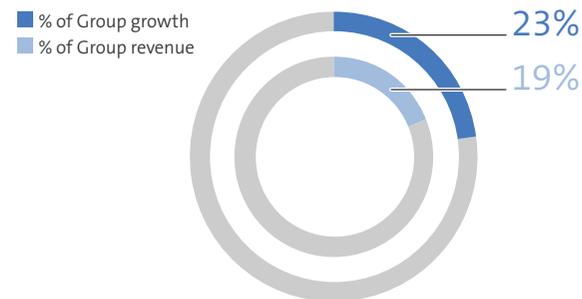
At the same time, we took steps to increase our presence in the non-premium segment: we continued the rollout of Anthogyr and T-Plus in China and Taiwan and we introduced Neodent in Australia, Indonesia and Thailand. Furthermore, we acquired a 34% stake in the South Korean implant company Warantec, broadening our access to the lower value implant segment in markets where Korean manufacturers are increasingly successful.

Other strategic initiatives in the region included a new subsidiary in Taiwan and a joint venture with Modern Dental to serve customers in Hong Kong and Macau. In China, we entered an exclusive distribution agreement with ZhenLi to provide affordable state-of-the-art clear aligner solutions and we entered a distribution agreement with Carestream to sell a co-branded version of their CS3600 intraoral scanner. This enables us to grasp opportunities in the rapidly emerging intraoral scanner market while we wait for regulatory approval of our Dental Wings scanner. Furthermore, we obtained distribution rights for cobranded in-lab scanners made by Medit in Korea. This and other agreements promote the integration of our DWOS® platform as a preferred software. Finally, we acquired Digital Planning Service PL in Pakistan, bringing the case planning service for ClearCorrect in house.

APAC REGION



APAC CONTRIBUTION TO GROUP



ORGANIC GROWTH

+22%

CHANGE IN CHF

+21%

REVENUE

CHF 305m

LARGEST REGIONAL MARKETS

1. China
2. Japan
3. Korea

Latin America

Mastering instability

Roughly 80% of the region’s sales are generated in Brazil, which is the world’s second largest market for implant dentistry. Despite the improvement in socio-political stability towards mid-year, the market remained weak in 2019 and, as the year drew to a close, main competitors resorted to heavy discounting. In spite of this, the Group continued to outperform significantly, with Brazil posting high single-digit organic growth for the full year. Straumann and Neodent drove the performance, which was boosted by BLX and biomaterials. ClearCorrect was launched in Brazil early in the year, bringing us a step closer to our goal of becoming a total solution provider for esthetic dentistry in the region.

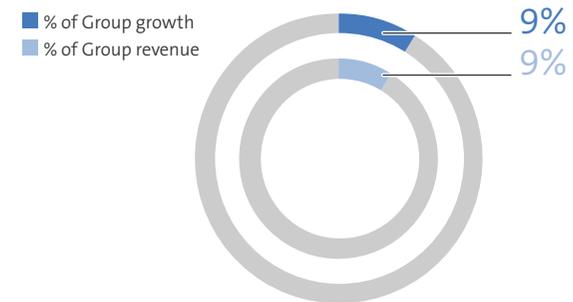
Elsewhere, our prompt reaction to the severe economic and political challenges in the second half of the year enabled us to gain market share in Argentina, Chile, Colombia and Mexico, all of which delivered strong organic growth throughout. The performance was particularly outstanding in the latter two, where Neodent and Straumann achieved double-digit increases in a flat market. We also strengthened our position in Chile by acquiring the local distribution business of Alpha Bio Tec.

To complement our growing 3D printer business and to generate recurring revenues with consumables, Neodent acquired Yller Biomateriais S.A., a Brazilian company specialized in developing and manufacturing high-tech materials for 3D-printing. Apart from this, we invested significantly in a large new production facility in Curitiba to meet demand for clear aligners and value implants (see pp. 46, 74ff.).

LATAM REGION



LATAM CONTRIBUTION TO GROUP



LARGEST REGIONAL MARKETS

1. Brazil
2. Mexico
3. Colombia

ORGANIC GROWTH

+17%

CHANGE IN CHF

+9%

REVENUE

CHF 140m

Expanding sustainably



In 2019, we significantly expanded clear aligner production in the US and began setting up aligner production units in Germany and Brazil. Our new factory in Curitiba (BR) produces implants and clear aligners.



BEYOND CONTINUITY IN PRODUCTION

Expanding sustainably

A company like ours cannot exist without continuity in production. Maintaining quality, ensuring availability, keeping in line with regulatory changes, and staying competitive are all areas where continuity is the expected norm. Beyond this, for 5 years we have experienced continued double-digit volume growth and have built capabilities to make and supply new products and solutions. To illustrate how challenging this is, when we launched our new BLX system in 2019, it comprised more than 500 components (SKUs) and by year-end we had sold more than 100 000 implants alone. On top of this, the Straumann Group introduced more than a hundred other new items during the year. Beyond continuity indeed!

To make this increase sustainable, we have seven major expansion projects, which are all on track (see p. 74 ff.). In Villeret (CH), the shell of our large new implant production building was completed in 2019 and interior construction began. In nearby Corgé, we created a permanent rather than temporary unit because we need more space in Villeret than expected. In Andover (USA), we rented an additional 3000 m² of space. In Curitiba (BR), we constructed a new factory in less than a year, which will produce our new implant brand nuvo. In Round Rock (USA), we expanded clear aligner production significantly. We also began setting up aligner production units in Germany and Brazil. Collectively, these projects will add 51 250 m² of production space.

Business performance

Financials

Five-year overview – operating performance

(in CHF million)	2015	2016	2017	2 018	2019
Net revenue	798.6	917.5	1 112.1	1 363.6	1 596.2
Growth in %	12.4	14.9	21.2	22.6	17.1
Gross profit	614.9	718.5	840.5	1 019.2	1 200.5
Margin in %	77.0	78.3	75.6	74.7	75.2
Operating result before depreciation and amortization (EBITDA)	207.6	259.2	323.5	395.0	480.6
Margin in %	26.0	28.3	29.1	29.0	30.1
Growth in %	17.8	24.9	24.8	22.1	21.7
Operating result before amortization (EBITA)	182.0	236.3	298.6	365.0	414.2
Margin in %	22.8	25.8	26.9	26.8	25.9
Growth in %	18.9	29.8	26.3	22.3	13.5
Operating profit (EBIT)	172.6	227.2	283.3	342.6	387.1
Margin in %	21.6	24.8	25.5	25.1	24.3
Growth in %	16.4	31.6	24.7	21.0	13.0
Net profit	71.5	229.6	282.2	277.8	308.0
Margin in %	9.0	25.0	25.4	20.4	19.3
Growth in %	(54.7)	221.1	22.9	(1.6)	10.9
Basic earnings per share (in CHF)	4.52	14.68	18.04	17.24	19.33
Value added / economic profit ¹	27.1	182.2	214.5	189.6	208.6
Change in value added	(86.6)	155.1	32.3	(24.8)	18.9
Change in value added in %	(76.2)	572.5	17.7	(11.6)	10.0
as a % of net revenue	3.4	19.9	19.3	13.9	13.1
Number of employees (year-end)	3 471	3 797	4 881	5 954	7 590
Number of employees (average)	3 232	3 615	4 305	5 580	6 837
Sales per employee (average) in CHF 1 000	247	254	258	244	233

1 Figures as reported in the financial reports.

**Impressive profitability:
24.3% average EBIT margin
over five years.**

Five-year overview – financial performance

(in CHF million)	2015	2016	2017	2018 (restated)	2019
Cash and cash equivalents	318.3	164.0	281.8	278.7	260.2
Net Cash (Net Debt)	117.2	(36.9)	23.2	16.8	20.2
Net working capital (net of cash)	63.3	123.9	187.7	233.0	265.6
as a % of revenue	7.9	13.5	16.9	17.3	16.6
Inventories	76.1	102.0	152.1	182.1	234.6
Days of supplies	155	171	174	165	175
Trade receivables	125.2	148.9	191.9	231.3	281.2
Days of sales outstanding	53	55	56	56	57
Balance sheet total	1 046.3	1 089.9	1 697.0	1 864.6	2 390.0
Return on assets in % (ROA)	6.8	21.5	20.3	15.6	13.6
Equity	605.0	633.7	1 077.0	1 204.3	1 367.2
Equity ratio in %	57.8	58.1	63.5	64.6	57.2
Return on equity in % (ROE)	11.8	37.1	33.0	24.4	24.0
Capital employed	341.8	476.2	908.0	1 011.6	1 455.0
Return on capital employed in % (ROCE)	50.5	55.5	40.9	35.7	28.4
Cash generated from operating activities	185.6	184.7	217.3	277.1	378.5
as a % of revenue	23.2	20.1	19.5	20.3	23.7
Investments	(44.5)	(87.9)	(296.5)	(188.2)	(239.3)
as a % of revenue	5.6	9.6	26.7	13.8	15.0
thereof capital expenditures	(35.2)	(46.7)	(74.4)	(109.7)	(149.9)
thereof business combinations related	4.9	(25.5)	(178.8)	(22.2)	(77.1)
thereof investments in associates	(14.2)	(15.7)	(43.3)	(56.3)	(12.3)
Free cash flow	151.1	138.7	144.7	169.4	229.6
as a % of revenue	18.9	15.1	13.0	12.4	14.4
Dividend	63.2	65.1	75.1	83.1	91.2 ¹
Dividend per share (in CHF)	4.00	4.25	4.75	5.25	5.75 ¹
Pay-out ratio in % (core results)	43.4	35.6	32.4	28.9	27.1

1 To be proposed to the shareholder's AGM in 2020.

Cash generated from operating activities was doubled in 5 years.

Share performance

Continued outperformance

After a significant drop in the last quarter of 2018, the world's leading indices recovered quickly in 2019 and the generally positive mood in the stock market proved to be fairly resilient. Market volatilities remained relatively low, despite continuing uncertainty surrounding the trade tariff disputes between the US and China, the Brexit negotiations and the political instability in various countries. The ambiguous outlook in some of the world's leading economies pushed central banks such as the ECB towards more expansive policies. Having raised interest rates in the prior year, the US Federal Reserve initiated a cycle of cuts in 2019.

The Straumann Group delivered strong results throughout the year, raising its full-year guidance twice and exceeding the expectations of numerous research institutes. Its anticipation of future prosperity was underpinned by further strategic acquisitions, joint ventures, partnerships, innovations, key hirings and leadership succession planning. These factors, the strong business performance and the continuing growth of its markets were all reflected in the Group's share price and market capitalization, which rose to a record high of more than CHF 15 billion.

By year end, the share price had climbed to more than CHF 950 and closed 53.8% up from the prior year, while the SMI and SMIM indices closed the year up 26.0% and 31.7%, respectively. Straumann was the fourth-best performing share in the SMIM universe in 2019 and the best performer over the past four years.

With the gross dividend increasing 10.5% to CHF 5.25 in 2019, pre-tax shareholder return amounted to a gain of 54.8% or CHF 337.65. After peaking at 27% in February, the one-year stock volatility dropped to slightly below 22% in December, in line with the general market trend. The average trading volumes in 2019 decreased from 45 600 to 41 400 shares per day, while the overall trading turnover rose by almost 10%, reflecting the increase in the share price.

Stock exchange information

Listing	SIX Swiss Exchange (STMN)
Bloomberg	STMN SW
Reuters	STMN.S
Investdata	STMN
Ex date	9 April 2020
Payment date	15 April 2020
Security ID	001 228 007
ISIN	CH 0012 280 076

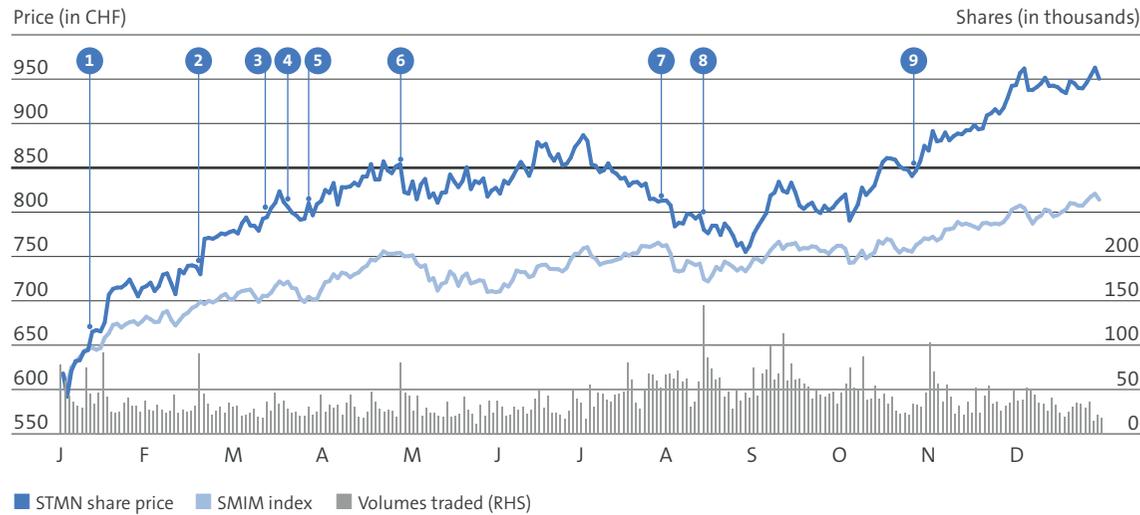
Share price data

	(in CHF)			
	2019		2018	
	Value	Date	Value	Date
First trading day	592.00	3 Jan	697.50	3 Jan
Lowest ¹	587.00	3 Jan	584.50	26 Mar
Highest ¹	963.00	27 Dec	809.50	15 Aug
Last trading day (tax value)	950.40	30 Dec	618.00	28 Dec
Average	821.60		687.58	
Total shareholder return, gross of tax	54.8%		(9.5%)	
Share price performance	53.8%		(10.2%)	
Market capitalization at year end (CHF million) ²	15 091		9 785	

¹ Value reflects daily closing price.

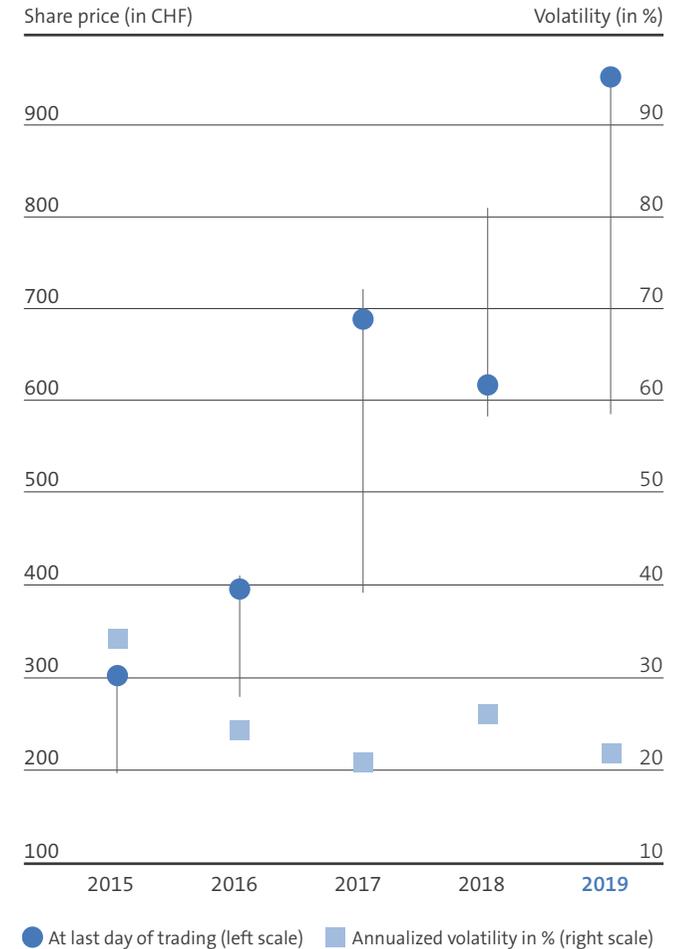
² Treasury shares are excluded from calculation.

Share price development



- 1 15 Jan Group announces CEO succession in 2020
- 2 19 Feb 2018 results: organic growth of 19%, underlying EBITDA of 30%
- 3 12 Mar Full acquisition of Anthogyr announced
- 4 19 Mar Mirabaud Securities raises price target to CHF 1 011
- 5 28 Mar Patent dispute between ClearCorrect and Align Technology settled
- 6 30 Apr Q1 results: organic revenue rises 17%
- 7 30 Jul Straumann invests in and partners with Warantec in Korea
- 8 14 Aug Strong Q2; Group raises guidance for full-year revenue growth
- 9 29 Oct Q3 results: organic revenue growth reaches 19%; full-year guidance raised

Trading information



Risk management

Integrated control framework for sustainability

We are committed to implementing appropriate controls, processes and strategies to identify, assess and manage risks associated with our activities in order to prevent or minimize the impact of unexpected events on our business and our ability to create value.

RESPONSIBILITIES AND ORGANIZATION

The Straumann Group applies a globally standardized process for identifying and managing possible developments within and outside the Group that could jeopardize its sustained growth, profitability and objectives. Risk monitoring and control are management objectives. The Group’s Chief Financial Officer (CFO) is also the Chief Risk Officer (CRO) and is responsible for risk management.

Our risk assessment and management is embedded in a comprehensive internal control framework, which we address through a holistic, disciplined and deliberate approach. It matches that of the COSO (Committee of Sponsoring Organizations of the Treadway Commission), which is one of the most widely used.

For identified risks that arise from accounting and financial reporting, relevant control measures are defined throughout our Internal Control System (ICS) framework, which we revised and adapted in 2019. Various tools and aids are used to assess and manage risks. For instance, foreign exchange risks are managed with an SAP Treasury tool, while external consultants are used on a regular basis to assess insurance coverage risks.

RISK REPORTING

We produce a comprehensive corporate risk assessment report annually (or ad hoc if necessary), which serves as a working document for the coming year and includes key risks that are critical for the Group’s business. A specific scenario is developed for each risk topic, including existing and new measures and controls. The risks are ranked and prioritized. Action plans are defined and the implementation of measures to reduce risk is monitored. The significance of a risk scenario is estimated in terms of EBIT cumulated over three years. Certain risks are assessed according to qualitative criteria,

Risk management approach

Straumann’s risk assessment takes into account:

- Operational risks
- Strategic risks
- Compliance-related risks
- Financial market risks
- Other internal risk factors
- Other external risk factors

Corporate risk assessment report

The report covers the following topics:

- Risk description
- Assessment of possible damage
- Occurrence probability
- Risk monitoring and counteracting measures

Risk assessment report process

Step	Execution
Preparation	Chief Risk Officer
Discussion	Executive Management Board
Risk assessment and discussion based on report	Audit & Risk Committee with Chief Risk Officer and Senior Management
Key findings presented to Board	Chief Risk Officer

e.g. risks to the Group’s reputation. The reporting of key risks is based on fixed value limits. Pressing risks that emerge very rapidly are discussed by the Board on short notice.

INTERNAL AUDIT

The tasks of Internal Audit are:

- to provide independent assurance to the Board of Directors that key risks of the organization are under control
- to support Management in ensuring compliance, operational efficiency and control effectiveness across the Group.

In a consulting role, its main tasks are:

- to assess internal processes and controls
- to propose recommendations and improvements.

The objective is to safeguard the Group’s tangible and intangible assets and to evaluate the effectiveness of its risk management and governance processes.

Since 2017, KPMG has been mandated with the Straumann Group’s Internal Audit function (see p. 100), reporting to the Board of Directors with the CFO/CRO as the administrative contact person.

RISK ASSESSMENT

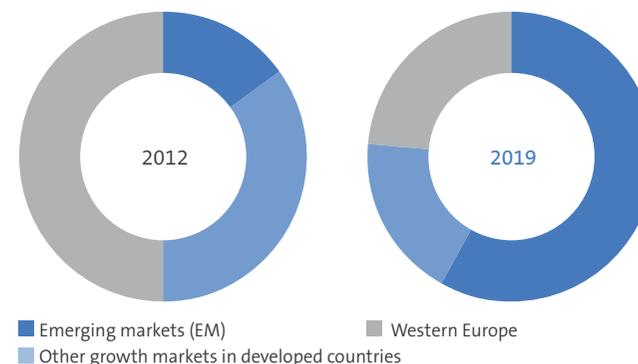
STRATEGIC RISK

MARKET ENVIRONMENT

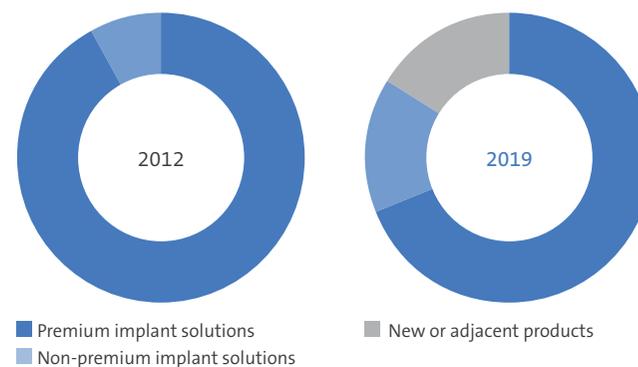
The Straumann Group is active in specialty segments of the dental industry. Based on the aging population, the rising number of professionals trained, and increasing awareness, there are no discernible reasons why these segments should not continue to offer attractive growth prospects in the long term (see p. 27 ff.). However, economic uncertainties and political developments seen in recent years might continue for some time and affect the prospects of market growth.

Our future revenues depend on market reach and expansion as well as on our ability to defend and increase our business with existing customers, to enlarge our customer base, to develop innovative solutions that meet customers’ needs and bring them to market in a timely manner.

Share of implant volumes



Product portfolio break-down (in value)



New market entrants and price pressure from discounters pose a potential threat to established brands (see charts on the previous page). We conduct analyses of competitors based on our own and external market intelligence to counteract such risks and to evaluate our opportunities. Examples of managing and addressing this risk in 2019 are:

- the rollout of our BLX implant system
- the continued penetration of the non-premium segment with our existing brands and further acquisitions (Anthogyr, Medentika, Warentec)
- the continued expansion into orthodontics (e.g. through our acquisition of Digital Planning Service in Pakistan and our partnership with ZhengLi Technology in China)
- investments in the materials supply chain (e.g. our acquisition of Bay Materials and Yller)
- investments in production centers on three continents (see p. 74 ff.).

OPERATIONAL RISK

LEGAL RISKS

We operate in a competitive market, in which legal compliance, agreements and intellectual property rights are of significant importance. The Group continues to be involved in a dispute against CapNet Securities regarding the recognition of converting warrants into shares from ClearCorrect. The Group also continues to enforce its IP rights and has initiated an IP litigation against a California based company selling copies of patented Straumann products.

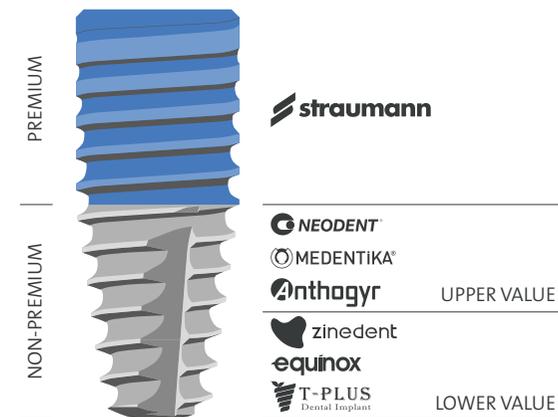
CYBER SECURITY RISK

Reliable, correct and safe handling of information is essential to our business. Risk and security management are therefore an integral part of the Group's IT strategy. The main objectives are:

- to achieve business goals while reducing IT risks through security measures, controls and by the creation of security awareness among employees and management
- to safeguard data and to protect and guarantee the integrity of the Group's digital assets and infrastructure around the world
- to ensure the availability of IT services (applications and systems) as required by business processes and stakeholders.

The Group's IT risk and security management framework is derived from widely used industry standards, such as the ISO/IEC 27000 series, GMP and COBIT, to manage cyber and IT security risks, threats and controls. Ethical, legal, economic and social principles are taken into consideration.

Illustration of the Straumann Group implant brand map, which covers all price levels



Reliable, correct and safe handling of information is essential to our business.

The Group's IT Risk and Security Management Committee approves and adopts the information security strategy as well as essential business-critical implementations. The Committee meets regularly and includes the CFO/CRO, the Head of Corporate IT Business Applications (ITBA), the Head of Corporate Information and Communication Technologies (ICT), the Data Protection Officer (Corporate Legal Services) as well as the Head of IT Risk & Security Management, who is responsible for:

- assessing IT security threats and their business value
- mitigating IT risks (including data loss and corruption)
- evaluating IT service continuity plans
- verifying the effectiveness and efficiency of IT security controls and hardening IT assets security
- improving IT security awareness for all employees
- maintaining security policies, procedures and supporting standards in alignment with (core) business processes
- establishing IT security key performance indicators and reporting structures.

MANUFACTURING AND SUPPLIER RISK

The Group has spread its manufacturing risk by establishing production centers for key products at different locations around the globe. The ongoing expansion of Straumann's and Neodent's production facilities as well as the establishment of additional CAD/CAM milling and printing centers help to mitigate this risk. Recent acquisitions of implant companies provide the Group with implant manufacturing facilities in Asia and the EU.

With regard to suppliers, we pursue a second source strategy which offers a high degree of independence from single suppliers. Straumann and Neodent production facilities keep about a year's stock of titanium, the key material for the Group's implant systems, to avoid any bottleneck in the chain of supply and demand.

ETHICAL SUPPLY CHAIN

Our Code of Conduct for Suppliers refers to working conditions, human rights protection, business ethics, legal compliance, and environmental protection in the supply chain. A signed copy of the Code is requested in instances where a potential conflict has been identified, e.g. for raw material suppliers in countries where child labor might be an issue.

Recent acquisitions and expansion provide the Group with implant and clear aligner manufacturing facilities on four continents.

We pursue a second source strategy which offers a high degree of independence.

PRODUCT RISK AND TREATMENT OUTCOME

We seek to minimize product risks by using state-of-the-art techniques for product risk management, and we conduct long-term product surveillance. These processes are frequently reviewed by regulatory agencies to confirm that internationally recognized standards are met. Furthermore, we conduct pre-clinical and clinical trials, followed by controlled, selective introductions where appropriate. We also offer a comprehensive range of educational courses, at all levels and in all countries where our products are sold.

FINANCIAL RISK (see also Financial Report)

EXCHANGE RATE RISK

As the major part of our business is international and since we prepare our financial statements in Swiss francs, fluctuations in exchange rates affect both the Group's operating results and the reported values of the assets and liabilities. The Group is primarily exposed to the euro, the US dollar, the Brazilian real and the Chinese renminbi.

Given the Group's structure, the transactional foreign currency exposure is naturally concentrated centrally and subsequently managed by Group Treasury applying a selective hedging approach. Speculative trading is forbidden. The Group CEO reviews and approves the policy for managing these risks, and the Audit and Risk Committee is informed about all changes.

The Group's gross transactional booked exposure at year-end is presented in the table on the right.

CREDIT RISK

Credit risk refers to the ability of our customers to settle their obligations as agreed. There are no significant concentrations of credit risk within the Group.

COUNTERPARTY RISK

Counterparty risk encompasses issuer risk on marketable securities, settlement risk on derivative and money-market contracts, as well as credit risk on cash and time deposits. Exposure to these is closely monitored and kept within predetermined parameters.

Further information on financial risk management is provided in 9.2 (see p. 178 ff. of the consolidated financial statements).

Group currency breakdown & gross transactional booked exposure (TBE at year-end)

	Sales	Cost	TBE
CHF	6%	17%	n/a
EUR	27%	27%	13%
USD/CAD/AUD	32%	32%	23%
BRL	7%	8%	1%
CNY	10%	5%	12%
Others	18%	11%	51%

Currency chart (USD, EUR, CNY, BRL)



INSURANCE POLICIES

The Group covers its inherent key business risks in the same way that it covers product or employer liability risks and property loss through corresponding insurance policies held with reputable companies.

PENSION LIABILITY RISKS

The Group offers its staff competitive pensions. The pension funds are managed locally and invested by independent financial institutions. The investment strategy of the Swiss pension fund, which represents the largest pension plan of the Group, is determined by the Group's Pension Fund Commission and is executed by its Investment Committee and financial institution. The pension funds publish regular reports for all members.

COMPLIANCE RISK

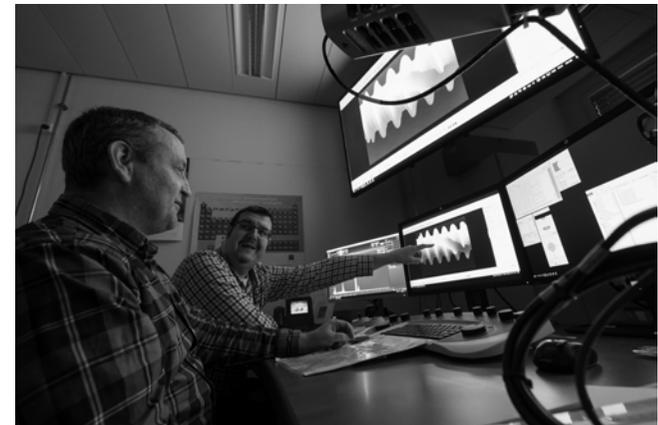
It is essential for the Group to ensure that the company in general, as well as its employees, conduct business in a legal, ethical and responsible manner. Following the revised Code of Conduct, Straumann has improved its compliance hotline in 2019, by contracting with a third party provider, ensuring that all employees in all subsidiaries can report Code of Conduct violations anonymously in their local language. Infringements of the Code are tracked, and appropriate measures are taken against cases of non-compliance.

LEGAL COMPLIANCE

We manage and ensure compliance with laws and regulations by implementing internal policies, processes and trainings, and by monitoring legal and regulatory developments throughout the Group worldwide. Our compliance management in particular covers areas such as anti-corruption, data protection and privacy, anti-trust and insider trading as well as finance legislation. Our management system is set up to be fully compliant with Sunshine legislations, which have been enacted in several countries.

REGULATORY AND QUALITY COMPLIANCE

Medical device companies face growing scrutiny from regulators around the world as well as increasing requirements for documented evidence in order to demonstrate compliance. To avoid the risks associated with regulatory compliance for medical devices, we have a qualified team of experts in regulatory and quality assurance.



Quality assured: for decades, Straumann has been using the latest technology to analyze material composition, surface structure and performance.

Focused quality objectives and key performance indicators together with comprehensive audit programs – both internal and for suppliers – are used to assure compliance and to identify opportunities for improvement. The Group also runs a continuing education program to streamline processes.

In 2019, Straumann Group subsidiaries in France, Norway and the United Kingdom were inspected by local authorities for proper storage of products derived from human tissue. Facilities in Spain were inspected for other criteria. No major observations were identified. We passed all Notified Body audits at our manufacturing and design /development sites, which are required to maintain the certification status of the quality and environmental management systems. The Group's global regulatory team coordinates and supports all our brands in the area of international quality compliance and regulatory affairs.

Some of our design and manufacturing sites use the Medical Device Single Audit Program (MDSAP), a global approach to auditing and monitoring the manufacture of medical devices, which could improve compliance internationally. The MDSAP allows a recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program:

- Therapeutic Goods Administration of Australia
- Brazil's Agência Nacional de Vigilância Sanitária
- Health Canada
- Japan's Ministry of Health, Labour and Welfare & the Japanese Pharmaceuticals and Medical Devices Agency
- U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health CDRH (accepting MDSAP audit reports as a substitute for routine Agency inspections).

We continue to challenge our quality by mock FDA inspections at the FDA-registered establishments. To ensure the readiness of our people and processes at our certified sites, we have also conducted unannounced internal audits and dedicated audits of our technical files.

Several regulatory authorities continue to inspect manufacturers in foreign countries. We are prepared for this and have experienced teams of regulatory and compliance experts in Basel, the US, China, Japan, Korea and Brazil. As a consequence, recent successful registrations were achieved through excellent collaboration between our experts in Basel and our colleagues in the regions.



Implants are rigorously tested for stability during development.

The new Medical Device Regulation (MDR) issued in Europe means greater surveillance, higher need for more and better clinical data, more involvement of competent authorities for higher risk products, longer approval times and active post market surveillance. Notified Bodies have declined in number and their control has increased. Stricter requirements and regulations are also expected in smaller markets, which will increase the need for enhanced compliance and safe and efficient products. In order to ensure access to European markets under MDR, planning for remediation is essential. Across the Straumann Group, projects to comply with the new European Regulation for Medical Devices are well underway. We successfully completed our first MDR certification audit in December with excellent results.

REPUTATION RISK

Like other leading manufacturers, the Group is exposed to the risk of damaged public perception of its products and solutions by third parties. This might be the result of poor implant placement, competitors' inferior quality implants and other solutions, or unethical business practices. Various Straumann Group country organizations belong to associations of manufacturers of medical and /or dental products, such as FASMED in Switzerland, Comident in France and ABIMO in Brazil. These associations are dedicated to the advancement of medical technology and its safe and effective use.

Projects to comply with the new European Regulation for Medical Devices are well underway across the Straumann Group.
