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HOT TOPIC
Bilateral Regulatory
Harmonization Protocol



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Well-Root ST
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Well-Root ST

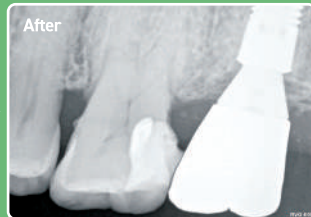
Premixed Bioceramic Sealer
2g syringe type



Using MTA

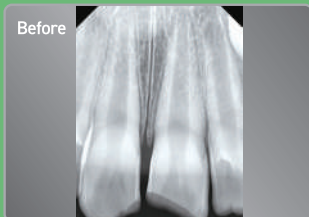
Case1 : Pulp Capping

*Dr. Sung Baik Choi



Case2 : Pulpotomy

*Dr. Mina Moheb_Egypt

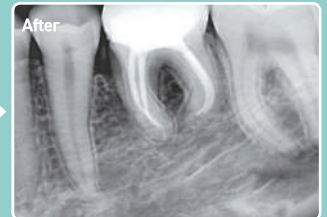


INDICATIONS

- Pulp capping
- Root-end filling
- Repair of perforation
- Apexification

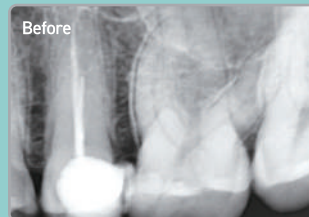
Case 1 : Management of Periapical Radiolucency

*Dr. Mina Moheb_Egypt



Case 2 : Severely Curved Canals

*Dr. Mina Moheb_Egypt



INDICATIONS

- Permanent obturation of the root canal



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C

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From Efficiency to Resilience: The Economic Lesson of the Iran Crisis

The conflict involving Iran may be moving into a more uncertain diplomatic phase, but its economic consequences continue to reverberate far beyond the Middle East. While shipping has gradually resumed through the Strait of Hormuz, the disruption exposed a deeper weakness in the global economy: the heavy dependence of international trade on a small number of strategic transport corridors and concentrated supply networks.

For decades, globalization has been built around efficiency. Countries specialized in specific industries, supply chains stretched across continents, and goods moved through a limited number of maritime routes connecting producers and consumers at the lowest possible cost. This model delivered significant productivity gains and helped contain costs for businesses worldwide. However, recent events have highlighted the risks of relying on systems optimized primarily for efficiency rather than resilience.

The Strait of Hormuz remains the clearest example. Although traffic has resumed, shipping activity continues to face higher insurance costs, security concerns, and logistical delays. The disruption demonstrated how quickly problems in a single corridor can spread throughout the global economy. For manufacturers, the consequences extend beyond oil prices, affecting transportation costs, delivery schedules, inventory planning, and supplier reliability.

The lesson extends beyond the Gulf region. In recent years, drought has restricted traffic through the Panama Canal, while security concerns in the Red Sea have disrupted routes through the Bab el-Mandeb Strait. Together, these events reveal a common challenge: global commerce increasingly depends on a handful of geographic bottlenecks. When one of these routes becomes unstable, the effects are rapidly transmitted across manufacturing supply chains and international trade flows.

For importers and exporters, the Iran crisis reinforced the importance of supply-chain visibility and diversification. Higher freight rates, longer transit times, and rising insur-

ance premiums can ripple through production schedules and customer deliveries, even when suppliers remain operational. The impact is particularly significant for manufacturers relying on complex international sourcing networks, where components and raw materials often cross multiple borders before final assembly. When trade routes become uncertain, businesses face difficult choices between absorbing higher costs, increasing inventories, or seeking alternative suppliers.

The crisis also accelerated a strategic shift that began during the pandemic. Many companies are moving away from supply-chain models designed exclusively around cost efficiency and are placing greater emphasis on resilience. Supplier diversification, regional sourcing, larger safety stocks, and greater supply-chain transparency are becoming central elements of risk management.

This does not mean globalization is ending. International trade remains essential to modern manufacturing, but the balance between efficiency and security is changing. Businesses are increasingly willing to accept slightly higher operating costs if doing so reduces their exposure to disruptions that could halt production or delay deliveries. Governments are pursuing similar objectives by strengthening energy security, diversifying strategic imports, and reducing dependence on vulnerable trade routes.

The most important lesson from the Iran crisis is not only about the conflict itself, but about the structure of global trade. Even temporary disruptions in critical transport corridors can generate consequences far beyond the affected region. For manufacturers, importers, and exporters, resilience is no longer a secondary consideration but a core competitive advantage. As geopolitical uncertainty continues to shape international markets, companies that invest in flexible sourcing strategies, diversified supplier networks, and adaptable supply chains will be best positioned for long-term success.



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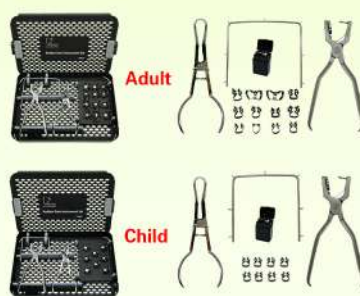
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[Dental endodontic suction tube]

Chinese Story

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Steam cleaning units of the new generation: an evolution in reliability

© RENFERT

Renfert launches the technically optimized next generation of its steam cleaning units. With upgrades to key components, both POWER steamer units are engineered for uninterrupted, longterm operation — ideal for the heavy-duty demands of daily laboratory routines. In the dental laboratory, steam cleaning units are among the most continuously used devices. High temperatures and constant pressure place significant strain on both materials and components. With the first-generation POWER steamer, Renfert had already established a robust and dependable system, backed by a threeyear warranty for added peace of mind. The POWER steamer 1 and 2 build on this foundation with redesigned elements where reliability, durability, and easy maintenance are essential.

Optimization in detail

At the core of the redesign is a newly engineered solenoid valve. Featuring a larger diameter for improved steam flow, it is built to withstand intensive continuous load. Additionally, the solenoid valve can now be replaced directly by the user when needed, reducing downtime and simplifying maintenance. Visually, the new units present a subtle facelift while retaining their proven ergonomic design. As in the first generation, Renfert continues to rely on established performance characteristics:

- Consistent power: a working pressure of 4.5 bar (65.3 psi) ensures effective cleaning.
- Reliable heating system: the heating element cast inside the boiler base is protected against corrosion.
- Easy maintenance: a real-time calcification indicator and an extra-large service opening ensure efficient, safe, and user-friendly maintenance.

The POWER steamer is available in two versions: POWER steamer 1 with manual filling, or POWER steamer 2 with automatic filling via mains water connection and integrated pump, ensuring continuous steam availability.

Beyond steam cleaning: a smart, integrated system

“We recommend using distilled water or our specialized POWER steamer water softener,” explains Product Manager Jens Erich. The filtration system monitors water flow via a flow sensor and provides proactive protection against limescale damage. As an optional accessory, the STEAM tube offers a cleverly designed steam cleaning station. Renfert also demonstrates innovation in service and digital support. With the “Product Virtualizer”, users can explore the POWER steamer 2 interactively — including 3D function animations and augmented reality for virtual placement in the laboratory.



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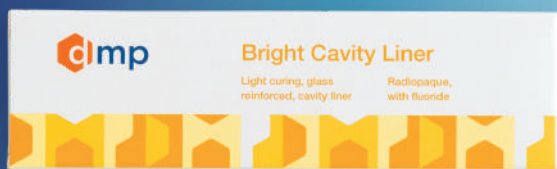


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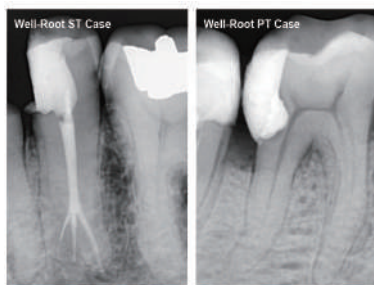


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*Source : Dr. Mina Moheb



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Drive Air Launches New Catalogue: Over 600 Hoses for Dental Units

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The Evolution of Ugin Dentaire

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Evolution is driven by experience, innovation, and the ability to understand the needs of today and anticipate those of tomorrow. In 2026, Ugin Dentaire marks a new step forward in its journey with the launch of three new high-quality solutions: e.ON Sinter Fast Neo, U Former, and U Glaze. Together, they expand the company's product portfolio and reflect its ongoing commitment to innovation, quality, and performance.

Developed from years of expertise and a deep understanding of the dental market, this new generation of equipment is designed to deliver greater efficiency, reliability, and ease of use in both dental practices and laboratories. By combining advanced technology with intuitive operation, these new machines help streamline workflows and support the evolving demands of modern dentistry.

More than just the introduction of three new products, this launch also represents the continued and renewed commitment of Ugin Dentaire to its decades-long mission: standing alongside dental professionals with solutions that effectively answer their needs, transforming innovation into practical, everyday value.

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Clinical Versatility and Configurations

The device offers a wide range of fields of view (FOV) to suit different specialisations:

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- Superior configuration: extended to maxillofacial, ENT and gnathological applications (FOV up to 17x18 cm).
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Technology and Artificial Intelligence

The system features a Direct Conversion Detector, which translates the radiological signal directly into digital data. The result is sharp, high-resolution 2D images with a low radiation dose, which can also be obtained using the ECO Dose rapid scanning mode, ensuring excellent exam quality.

The integration of Neowise software uses Artificial Intelligence to automate complex tasks such as anatomical segmentation,

alveolar nerve identification and cephalometric analysis, significantly speeding up the workflow.

Efficient workflow

For a smooth and repeatable workflow, Newtom GiANO HR FullView has technological features that allow images to be acquired with maximum ergonomics and efficiency.

- Perfect positioning using the 10" full touch control panel on the machine, which allows servo-assisted centring using the Scout View and Real Vision Multimedia Pack systems.
- 3DPic generates three-dimensional images of the face and dentofacial structures, which can be superimposed on X-ray scans.
- Enhanced cooling system maintains high performance even during continuous use.

Patient Safety

Safety is guaranteed by SafeBeam™ technology, which automatically adapts the dose to the patient's anatomy.

In conclusion

GiANO HR Full View is a comprehensive diagnostic tool that reduces operating times, improves communication with the patient thanks to real-time 3D rendering and ensures excellent clinical results in every situation.

► www.newtom.it/en/dispositivi-radiologici-odontoiatrici/giano-hr_fullview

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SPIROdental a quality turn for dental repair companies

● SPIRO

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HIGHLIGHTS

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Zirconia prosthetics have become the trend, and more customers have to buy a porcelain furnace just for glazing.

The **GLAZING AIR** is furnace only for zirconia glazing, which boldly excludes vacuum functions not used for glazing, and is an affordable product that leaves only fast and precise temperature control technology, compact size and economic cost.



REF. 100252

ADVANTAGES



AFFORDABLE FURNACE ONLY FOR GLAZING

Furnace only for zirconia glazing that excludes functions such as vacuum, and leaved absolutely necessary functions.



PRECISE TEMPERATURE CONTROL

Precise temperature control provides the perfect outcome for any brand.



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- Improves user convenience by including an auxiliary pedestal in the design (to place the result).



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It reaches 1000 °C in less than 10 (average 5 minutes) minutes using a Kanthal® heater with good thermal conductivity.

Specification

Dimensions: Width 246 mm x Depth 319 mm x Height 434 mm
Weight: 13 kg • Rating power: Max. 1,3 kW • Fuse: 10 A
Input power source: AC 220~240V 50/60Hz
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The anodizing unit for titanium is a simple device that allows you to process titanium dental elements quickly, easily and economically. The results are comparable to products belonging to a much higher category.

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- ✓ Wear resistance.
- ✓ Better adhesion and surface finish.
- ✓ Less release of metal ions.
- ✓ It works with a solution of water and sodium bicarbonate.

Specifications

Dimension: 207 x 245 x 160 mm • Weight: 2,73 kg
Voltage: 10~65 V • Power supply: AC220~240 V, 50/60 Hz
Power: 100 W • Anodizing time: 5 seconds

Appearance:

The anodic layer can be colored with different shades, giving the titanium a more attractive appearance than the original taupe.



Solution of water (600 ml) and sodium bicarbonate (20 g)



REF. 100295

Video explanation



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One Stop Shop

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Ideal for new and experienced clinicians, Aseptico Inc., a global leader in electric dental motor technology, recently launched the AEU-27DTCR.

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The compact console features a stylish design, plus an intuitive control panel and bright display.

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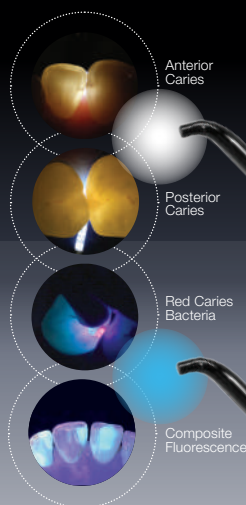
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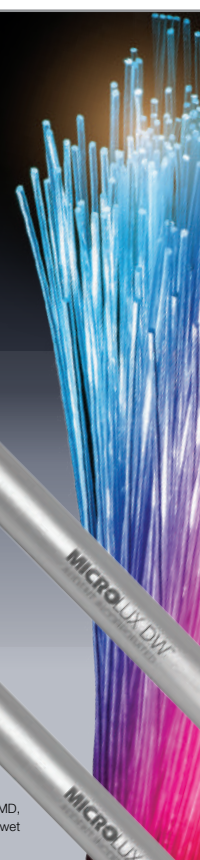


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Cold Case: Problems with Attachments for Implant-Supported Overdentures

An article by Prof. Dr. Matthias Karl and Eva Jakovleski

IMPLANT PROSTHODONTICS /// The implant-prosthetic restoration of edentulous jaws with removable dentures is regarded as simple and predictable, with a marked improvement in patients' quality of life. In clinical practice, however, prefabricated attachments such as ball and Locator attachments often prove problematic.



Fig. 1: Classic situation of an edentulous mandible with two freehand-placed implants lacking axial parallelism, and Locator-type abutments for anchoring an overdenture.

Fig. 2: To optimize the use of prefabricated attachments (here: Novaloc, Straumann), the industry offers matrices with an extended angulation range and uses different polymers as retention inserts. The attachments shown are additionally coated (ADLC coating – amorphous diamond-like carbon) to prevent wear of the polymer matrices. In this particular case, fracture of the abutment occurred under occlusal contact with a telescopic crown in the mandible; massive plaque accumulation is also evident.

The placement of two dental implants to anchor a removable overdenture is a cost-effective treatment that improves masticatory function and produces high patient satisfaction, which is why this restoration is regarded as the “standard of care” in several countries.^{1,6,14} The attachments used for this purpose, which removably connect the denture to the implants, are decisive for denture retention, patient satisfaction and clinical success.¹⁴ Bars, ball attachments and Locators are frequently used and lead to an improvement in oral health-related quality of life.^{4-6,14} The double-crown (telescopic) systems widely used in Germany run counter to the underlying idea of a cost-effective baseline restoration because of their high fabrication costs.^{10,15,8}

Loss of retention and attachment systems

Widely scattered retention forces are reported for the individual attachments, with loss of retention being the dominant clinical problem¹⁵ and leading to repeated interventions.^{12,13} This occurs in particular with nonparallel implants, which is why the industry offers so-called “extended range” attachments intended to compensate for non-parallelism. According to a retrospective study with a three-year observation period, however, this is not achieved.⁹ A further contributing factor appears to be transfer errors when reproducing the patient situation on a laboratory cast for fabrication of the restoration.⁷

Wear and complications

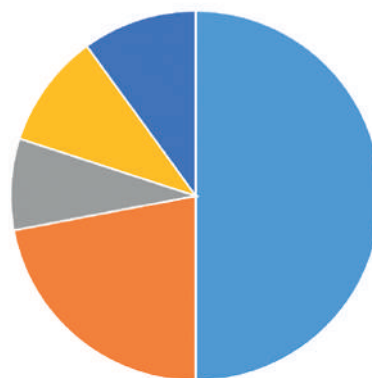
A randomized clinical trial on implant-supported mandibular overdentures described wear of the attachments as the most frequent complication.¹ Similar results are reported from a randomized clinical trial in 18 patients over a nine-year observation period, with 136 prosthetic complications.¹¹



Fig. 3 a-e: Edentulous maxilla with two pre-existing implants at sites 15 and 16 (a), used via Locator-type attachments (here: Novaloc, Straumann) for additional retention of a maxillary complete denture (b) (c). The two implants show marked non-parallelism (d) which, although it allows insertion of the denture, led to noticeable wear of the patrices (d) as well as deformation with loss of retention of the matrices (e) after only a few months of wear.

What are the most common problems with attachments for implant-supported overdentures?

Results of a general survey among 13 dental and dental-technician colleagues on attachment systems for implant-supported overdentures, conducted at IDS 2025.



- Loss of retention / replacement of retention inserts
- Need for special instruments
- High costs
- Poor design
- Retention force difficult to adjust

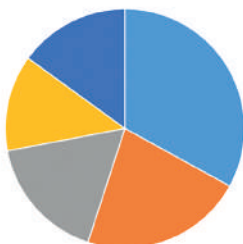
This is also supported by a retrospective study of ball attachments and Locators, which describes the need for treatment due to wear of the attachment as the most frequent complication.² A high proportion of the necessary interventions appears to occur as early as the initial phase, up to one year, which is likely associated with finding a retention force adequate for the individual patient.^{3,15}

Survey results and possible solutions

A total of 13 dental and dental-technician colleagues responded to a general survey on attachment systems

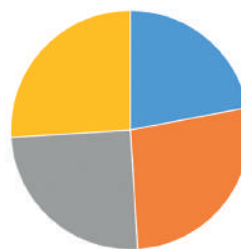
for implant-supported overdentures conducted during IDS 2025, in which multiple answers were permitted. Loss of retention was described as the most frequent problem, followed by the need for special, system-specific instruments. This is consistent with the literature, which names loss of retention as the principal complication. The service life of plastic retention inserts was reported with wide scatter, ranging from under three up to 24 months. This range can be explained by varying degrees of parallelism of the supporting implants.

What would be desirable in a real-world attachment system?

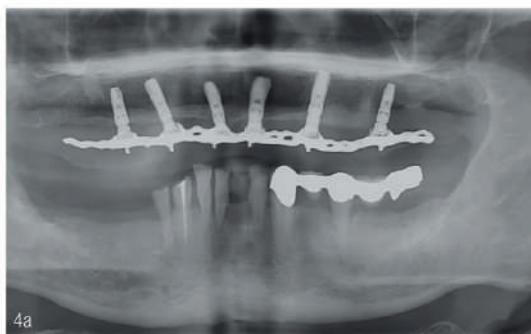


- Compensate for implant divergences
- Less wear of the retention inserts
- Lower costs
- Easier cleaning and maintenance
- Patient comfort

What is the service life of plastic retention inserts?



- < 3 months
- < 6 months
- < 6–12 months
- < 12–24 months



Consequently, the ability to compensate for non-parallel implants and a longer service life of the retention inserts were named as desirable properties for attachment systems

Optimization and conclusion

Abutment divergences and transfer errors currently prevent high success rates from being achieved with prefabricated attachments, despite the good survival rates of implant-supported removable overdentures. Likewise, setting predictable retention values represents a clinical problem, since with multiple and non-parallel implants this can only be arrived at by trial and error. Because of their lower profile and their rotational symmetry, ball attachments are more advantageous and, through further development to compensate for implant divergences, could solve the problems described.

Fig. 4 a-c: Panoramic radiograph of a patient with six pre-existing implants retaining a removable maxillary complete denture via Locator attachments (a). Marked discrepancies in the implant axes are evident. The patient reported that he had not removed the denture for several years after the most posterior implant in the upper left had loosened and become lodged within the denture. Radiographically there is consequently massive osseous destruction, and after removal the denture was correspondingly covered with hard and soft deposits (b). After removal the implant showed no bony attachment whatsoever (c), supporting the patient's report of a spontaneous explantation that had occurred.

INFORMATION ///

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PROBLEM

SOLUTION

Retention Loss Over Time

Prefabricated systems gradually lose retention, requiring frequent replacements

Misalignment Issues

Transfer inaccuracies cause uneven load distribution and accelerated wear

Increased Maintenance

Wear leads to frequent visits and costly repairs

Misfit & Failures

Stress on rigid attachments increases the risk of component failure

Higher Long-Term Costs

Maintenance can equal or exceed initial treatment cost after 5 years



HADER REFLEX

Self-Adjusting

Compensates for implant misalignment, ensuring a passive and secure fit



Minimizes Wear

Optimizes load distribution, reducing material fatigue

Predictable Retention

Reliable performance regardless of implant angulation

Fewer Patient Visits

Extended longevity reduces maintenance needs



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Take the Survey !

Global Digital Dentistry Community Unites at Insights 2026

Global experts gathered for education, innovation, and collaboration at exocad's flagship event

exocad, an Align Technology, Inc. company and a leading dental CAD/CAM software provider, successfully concluded Insights 2026, the fifth edition of its global digital dentistry event, held April 30–May 1, 2026, in Palma de Mallorca, Spain. The two-day meeting brought together dental professionals from across the laboratory and clinical spectrum under the inspiring motto “Calling all heroes.”

Insights 2026 welcomed an international audience, offering a highvalue educational experience focused on multidisciplinary exchange, practical learning and connection.



What's new and what's next? The audience welcomed Tillmann Steinbrecher, CEO of exocad, and Niloofar Sotouhi, Senior Marketing Manager at exocad, with enthusiastic applause. They kicked off with exciting insights into the future of digital dentistry.



“Calling All Heroes”—under this motto, around 850 dental technicians and dentists from over 44 countries came together to attend the 5th edition of exocad Insights, held on April 30 and May 1, 2026, in Palma de Mallorca, Spain.



New developments from exocad in the world of digital dentistry were presented by Tillmann Steinbrecher, CEO at exocad, Maik Gerth, CTO at exocad and Novica Savic, CCO at exocad (from left to right).



Christine McClymont, Global Head of Marketing and Communications at exocad and host of the two-day event, welcomed attendees to the Palau de Congressos de Palma.

“Insights 2026 once again demonstrated the power of bringing the global digital dentistry community together in person,” said Novica Savic, CCO at exocad. “The curiosity and collaborative spirit we experienced at Insights reflect exactly what ‘Calling all heroes’ stands for: learning from one another and sharing ideas to help shape the future of digital dentistry.”

International speakers across the digital dentistry spectrum

Insights 2026 featured a high caliber lineup of internationally renowned speakers from across the laboratory and clinical spectrum. Experts from around the globe shared practical, futurefocused perspectives on interdisciplinary workflows, esthetics,

communication driven treatment concepts, and the evolving digital patient. The program included contributions from Dr. Alexis Ioannidis (Switzerland), Caroline Kirkpatrick (Scotland), Dr. Zhiqiang Luo (China/USA), Seth Potter (Canada), Prof. Dr. Marco Tallarico (Italy), Lukas Wichnalek (Germany/Mexico), and Michaela Sehnert (Germany), highlighting collaborative approaches across lab and clinical environments.

Exclusive Diamond partner sessions further enriched the agenda, featuring Dr. Christian Coachman (Brazil) and his presentation on the 7 steps towards modern dentistry. A dedicated session about ART (Advanced Restorative Treatment) with experts from IDI Evolution (Italy) emphasized how digital innovation and multidisciplinary collaboration can drive predictable outcomes and how exocad ART can help to enhance patient treatment.

The program also featured exocad-led sessions with exocad management, including a “What’s new,

what’s next” session with exocad CEO Tillmann Steinbrecher, CTO Maik Gerth, CCO Novica Savic, and Senior Product Marketing Manager Nilou Sotouhi, alongside in-depth lab sessions led by exocad application specialists, offering attendees practical insights into workflows, innovation, and the future of digital dentistry.

Innovation expo and partner engagement

A central highlight of Insights 2026 was the innovation expo, where leading industry partners showcased the latest materials, equipment, and CAD/CAM solutions. Diamond, Platinum, and Gold partners also hosted dedicated sessions to share clinical cases, product updates, and integrated workflows. Complementing the main stage program, 60 targeted breakout sessions allowed dental technicians and clinicians to dive deeper into work-flow optimization, practical applications, and realworld use cases with exocad software solutions.

Community and global exchange

Beyond the educational program, Insights 2026 emphasized connection and exchange. Attendees networked with peers, partners, and exocad experts throughout the event, including the “exoGlam night” celebration, the “Women in dentistry” lunch, and other special event activities. exocad also supported a charitable initiative during the event with special exocad T-shirts and merchandise sold to benefit a dental nonprofit organization and introduced its new spotlight country concept. The initiative debuted with China, reflecting exocad’s commitment to global connection, knowledge exchange and cross-border collaboration in digital dentistry.



On Thursday afternoon, dentists moved into the practice-focused clinical stream. Three renowned guest speakers shared inspiring insights into their digital workflows.

Additional information is available at <https://exocad.com/insights2026>



“Smile + stack + split = predictable and accurate fit” was the title of the two-hour lab stream, which was specifically designed for dental technicians. exocad application specialists Clemens Schwerin, Pina Maginot, Friedemann Stang and Joh Härich (from left to right) shared practical tips and tricks for working with exocad software and showcased the latest features.



During the breaks, attendees visited the large innovation exhibition hosted by industry partners. Numerous strategic partner companies of exocad showcased their digital innovations as well as their latest machines and materials.

exocad and Beyond: Juan Carlos Palma's Vision for Digital Dentistry

Juan Carlos Palma - DentalCAD Academy CEO & Founder



During exocad Insights 2026 in Palma de Mallorca, the editorial team of Infodent International had the opportunity to speak with Juan Carlos Palma, CEO & Founder of DentalCAD Academy and an internationally recognized exocad trainer.

In this exclusive interview, Juan Carlos shares his perspectives on the evolution of digital dentistry, the growing importance of education and workflow integration, and the latest innovations shaping the future of exocad. Drawing on his extensive international teaching experience, he offers valuable insights into how clinicians and dental technicians can adapt, grow, and thrive in an increasingly digital world.

What are your key takeaways from exocad Insights? What did you learn?

exocad Insights is not just an event... it's a snapshot of the future. What I take away most is that digital dentistry is no longer "coming" — it's already here, and evolving at an incredible speed.

But there's one key thing that becomes clearer every year: exocad never stands still. It constantly surprises us with new features, new workflows, and especially new ways of communication between the lab and the clinic.

What I've learned is that digital workflows are no longer just about designing better, but about thinking better: integration, automation, and real connection between professionals.

If I had to sum it up in one sentence: if you don't understand the full workflow, you're out of the game.

As an independent certified exocad trainer, what is it about exocad that still inspires you as an educator, and how is it changing the way digital dentistry is taught?

What still inspires me about exocad is that it's a living software. It's not a closed tool — it's an ecosystem that grows with you.

As an educator, that's incredibly powerful. Because you're not just teaching "buttons", you're teaching digital criteria.

exocad is changing education because it forces us to move away from passive learning. Now students need to experiment, make mistakes, iterate... just like in real life.

That's the difference: training professionals who think, not just repeat.

How does your own day-to-day use of exocad influence the way you train clinicians and technicians to work digitally?

I use exocad every single day, and that changes everything.

I don't teach from theory — I teach from real-world experience. I know exactly where people struggle, where they lose time, and where they get stuck.

My training is designed to prevent that: less frustration, more efficiency, and real results from day one.

Your social media blends education with personality—how do platforms like Instagram or LinkedIn support your mission in digital dentistry?

In my case, everything revolves much more around Instagram. That's where I truly combine my personal and more humorous side with my technical knowledge.

I've been active on social media for over 10 years, and I was the first to create the concept of "exotips": small, practical tips that reach directly to my followers' mobile devices, which they then share with colleagues, generating hundreds of thousands of views. This format has been key to democratizing knowledge — fast, useful, and immediately applicable content.

That's why on my account @juancarlospalma, I post exotips every Wednesday, without exception. It's a consistent way to provide value and stay connected with the community.

How have your international teaching experiences shaped your approach to education, and why does exocad translate so well across different markets?

I love traveling around the world, sharing my protocols and tricks in exocad, exoplan, and artificial intelligence. It's one of the most rewarding parts of what I do.

When you teach in different countries, you realize there is a huge amount of talent

everywhere. And that's exactly why one of the things I enjoy the most is helping my students grow and take their skills to the next level.

There's also something I strongly believe in: I don't like "selling courses" — I like delivering experiences. I always say that great training is 50% fun and 50% learning. Because when people enjoy the process, they learn twice as fast. This mindset has shaped the way I teach: clearer, more practical, and focused on real results. exocad works so well globally because it speaks a universal language: digital workflow, logic, and freedom. No matter where you are, the concept is the same.

Which is your favorite feature or improvement in the latest releases? Why?

I would highlight the evolution in automation and workflow customization.

exocad is increasingly removing repetitive tasks and allowing you to focus on what really matters: design and clinical decision-making.

That completely changes your role — you go from being an operator to becoming a strategist.

Your online courses are open to anyone around the world, can you tell us about them?

We have a very clear and flexible approach to education.

On one hand, we offer in-person training in many parts of the world, as well as at our academy, DentalCAD Academy, where students can experience a complete and immersive learning environment.

On the other hand, we provide online courses designed for all types of professionals — from beginners to advanced users looking to specialize or refine their workflows.

Our goal is simple: to train professionals who are fully prepared for the real demands of digital dentistry.



<https://juancarlospalma.com/>

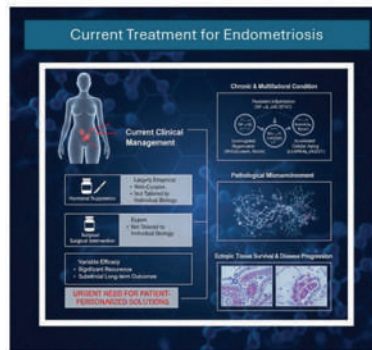


ORGANOIDS HUB: THE FUTURE OF PERSONALIZED REGENERATIVE MEDICINE

Fauget Health Solution

TRUSTED SOLUTIONS ENABLING THE FUTURE OF PERSONALIZED REGENERATIVE MEDICINE.

Discover cutting-edge
technologies powering the future
of personalized regenerative
medicine.

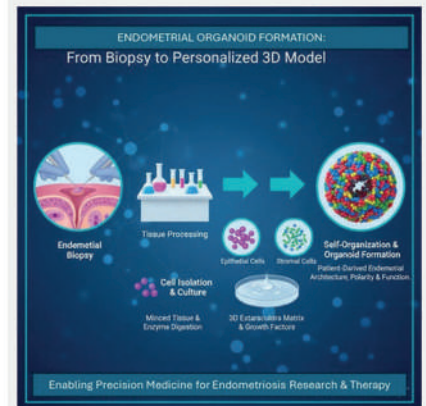


AI-DRIVEN ORGANOIDS FOR PERSONALIZED REGENERATIVE MEDICINE

- Modern medicine is transitioning toward personalized, predictive, and regenerative care.
- LifetAlme operates at the intersection of academia, biotechnology, and AI-driven innovation.
- The Organoids Hub reproduces patient-specific tissue biology in vitro.
- Organoids capture disease heterogeneity with superior predictive power.
- Endometriosis exemplifies the need for personalized, biology-driven therapeutic strategies.

DECODING ENDOMETRIOSIS: MECHANISMS AND PERSONALIZED TRANSLATIONAL MODELS

- Inflammation:** NF- κ B and JAK/STAT drive lesion survival.
- Regeneration:** Wnt/ β -catenin, Notch fuel abnormal growth.
- Senescence:** Senescent cells fibrosis, pain, infertility.
- Organoids:** Patient cells form 3D models mimicking real tissue.
- Translation:** Organoids enable personalized therapy testing.
- Targeted Integration:** PI3K/Akt/mTOR, TGF- β /Smad, disease-specific microRNAs, and epigenetic modifiers are explored for precision therapies and non-invasive diagnostics.



AI AND ORGANOIDS: SHAPING THE FUTURE OF PERSONALIZED REGENERATIVE MEDICINE

The Organoids Hub embodies LifetAlme's commitment to shaping the future of regenerative medicine through science-driven innovation and strategic vision. By transforming patient biology into predictive and actionable intelligence, LifetAlme is redefining the standards of care for complex diseases and laying the foundation for a new era of personalized healthcare.

Authors: Prof. Mario De Felice – CEO, LifetAlme | Dr. Vincenzo Di Donna – Managing Medical Director, LifetAlme

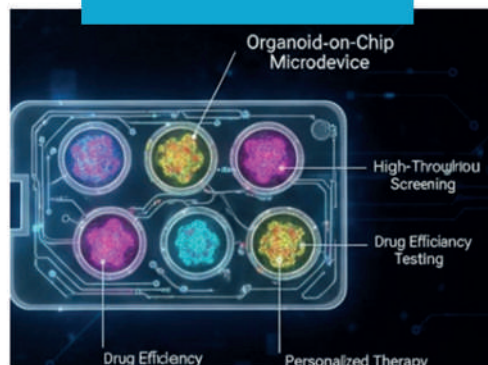


DRIVING VALUE ACROSS THE HEALTHCARE ECOSYSTEM

- Clinical Partners: Greater predictability and personalized care.
- Industrial Stakeholders: Lower development risk, faster validation.
- Healthcare Systems: More effective and sustainable therapies.

"LifetAlme turns 3D tissue engineering, bioinformatics, and regenerative medicine into global, deployable solutions."

Medical Device



Contact Us
+39 3386342807



Our Website
www.lifetaime.com



Our E-mail
info@lifetaime.com

Your Health, Our Priority

- Government, **Presidential Republic**
- Currency, **United States Dollar (USD)**
- GDP per capita at current prices, 2025 - **US\$ 5,764**
- Population 2025 - **6.4**
- Total export volume, **€ 6.5 billion**
- Total import volume, **€15.8 billion**
- The country hosts, **17 Free Trade Zones**

Association Agreement between Central America and the European Union

High expectations have surrounded this agreement, particularly regarding European investment in the Central American region. The agreement aims to lay the foundations for sustainable development while fostering the adoption of new technologies. As the European Union is Latin America's second-largest trading partner, it also represents an important source of development cooperation and technical support.

VAT 13%

Import taxation is calculated on the CIF value (Cost, Insurance and Freight) stated on the invoice, increased by the applicable tariff rate and then subject to a 13% Value Added Tax (VAT).

Free Trade Agreements

The implementation of free trade agreements with Mexico, Chile, and the Dominican Republic in 2001, followed by the entry into force of the Central America–United States Free Trade Agreement (CAFTA) in 2006, further opened the country to international markets. Nevertheless, significant efforts are still required to provide businesses with a truly open and competitive trading environment.

President Nayib Bukele

In office since 2019, President Nayib Bukele continues to enjoy exceptionally high public approval ratings, exceeding 80%. This popularity is largely attributed to his administration's management of the COVID-19 pandemic and its extensive military and police operations against the country's criminal gangs (maras).

El Salvador The Small Central American Nation Rewriting Its Image

🕒 6'
Reading time

For many years, El Salvador was associated almost exclusively with crime, instability, and migration. Today, however, the smallest country in Central America is undergoing a profound transformation that is reshaping its international image, attracting new investment, tourism, and economic interest.

With a population of approximately 6.4 million people and a territory covering just over 20,000 square kilometers, El Salvador represents a relatively small market in terms of size, yet one that is strategically positioned within the Central American region. The economy maintains strong ties with the United States, not only for commercial reasons but also because of the large Salvadoran community living abroad. Remittances sent by emigrants continue to be one of the main pillars of the national economy.

The country uses the U.S. dollar as its official currency and has progressively strengthened its openness to international markets over the past decades.

Free trade agreements with Mexico, Chile, and the Dominican Republic, together with participation in the CAFTA agreement between the United States and Central America, have helped expand business opportunities and attract foreign investment. These initiatives are complemented by the Association Agreement between Central America and the European Union and by the presence of 17 free trade zones across the country, all of which have supported the development of manufacturing activities and exports.

A New Face for the Country

One of the aspects that has attracted the greatest international attention in recent years is undoubtedly the security policy promoted by President Nayib Bukele, who has been in office since 2019. Through an extensive crackdown on criminal gangs, El Salvador has experienced a dramatic reduction in homicide rates and organized crime, significantly improving perceptions of safety among both citizens and foreign investors.

Public support for the government remains remarkably high, exceeding 80% according to several surveys. This popularity is largely linked to the administration's handling of the pandemic and its security policies. Nevertheless, criticism has emerged from international organizations and observers who have raised concerns about the concentration of power and the protection of civil liberties.

Beyond the political debate, it is undeniable that the country is experiencing a level of stability that would have seemed difficult to imagine just a few years ago.

This transformation is helping reshape El Salvador's international reputation and making it increasingly attractive to businesses and investors.

Economy: Moderate but Stable Growth

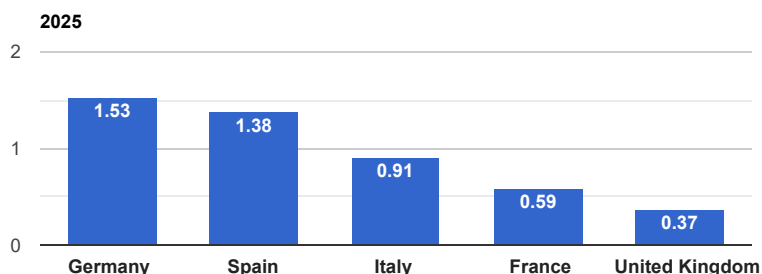
Following the severe impact of the pandemic, the Salvadoran economy has demonstrated a significant capacity for recovery. According to recent estimates, GDP stands at approximately €33 billion, while growth of close to 3% is forecast for 2026. GDP per capita has surpassed USD 5,700, and inflation remains relatively contained.

However, some structural challenges persist. Public debt continues to be one of the government's main concerns, while the country remains heavily dependent on imports. Import volumes significantly exceed exports, resulting in a traditionally negative trade balance.

Despite these challenges, prospects for foreign investment remain positive. Increased domestic stability, a strategic geographic location, and a broad network of international trade agreements are helping strengthen investor confidence.

Foreign direct investment inflows are expected to exceed USD 800 million in 2026, reflecting growing international interest in the Salvadoran market.

European Export Market Shares in El Salvador (% data)



Sources: www.infomercatiesteri.it – Italian Ministry of Foreign Affairs and International Cooperation

The Bitcoin Case

El Salvador made economic history in 2021 by becoming the first country in the world to adopt Bitcoin as legal tender alongside the U.S. dollar. The decision attracted global media attention and sparked intense debate among supporters and critics alike.

While the initiative helped reinforce the country's image as an innovative nation and attracted interest from the technology sector, major international financial institutions, including the International Monetary Fund and the World Bank, expressed concerns regarding potential macroeconomic and financial risks.

In everyday life, however, the U.S. dollar continues to be the primary currency used for most transactions, while Bitcoin remains largely symbolic and strategic in terms of the country's international positioning.

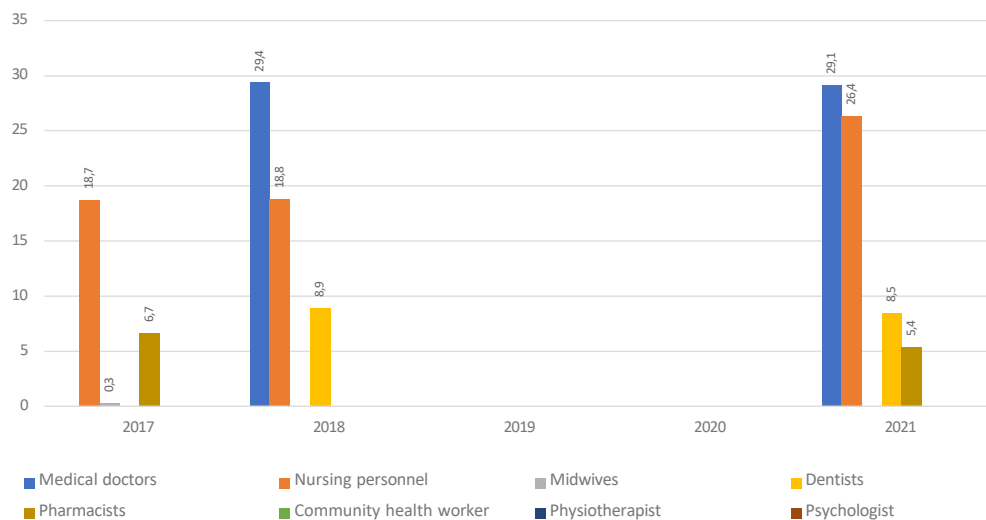
A Healthcare System Reflecting the Country's Transformation

The changes taking place in El Salvador are not limited to the economy and public security. The healthcare sector has also undergone significant development in recent years, reflecting the country's broader transformation.

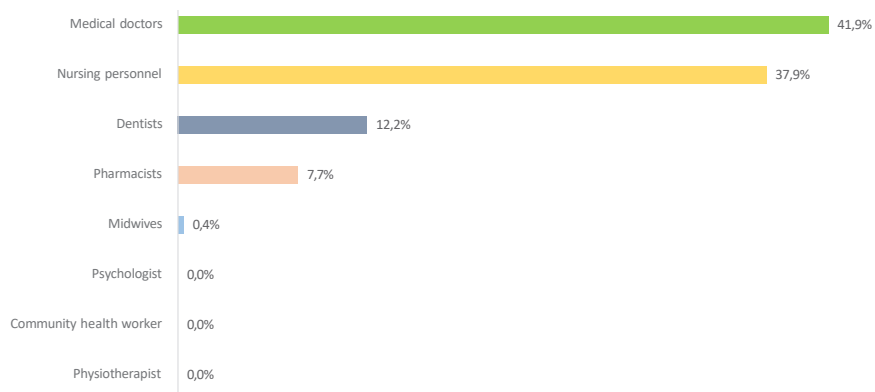
Health indicators present a generally positive picture. Life expectancy has surpassed 72 years, infant mortality has declined substantially compared with previous generations, and universal health coverage has reached encouraging levels.

According to the World Health Organization, the country's essential health services coverage index stands at 79 out of 100.

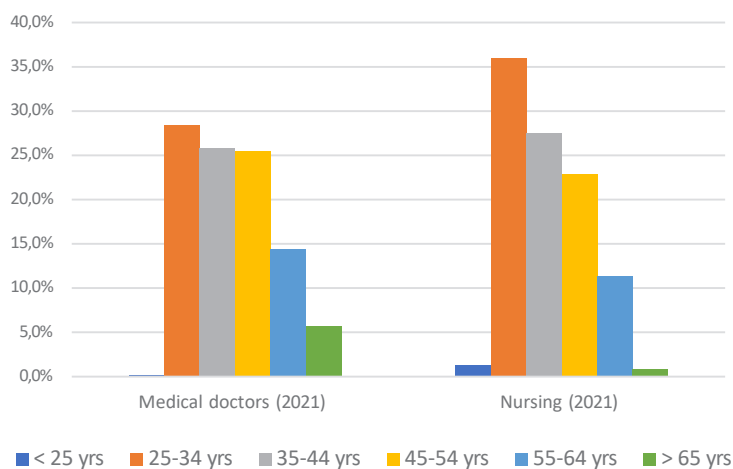
Density Per 10,000 Population



Share of professional health workforce (latest data)



Health Workforce Distribution By Age Group



Sources: Pan American Health Organization. Human Resources for Health: Country Profile – Republic of El Salvador. Washington, DC: PAHO/WHO. Available from the PAHO Human Resources for Health Country Profiles series.

The public healthcare system, primarily managed by the Ministry of Health (MINSAL) and the Salvadoran Social Security Institute (ISSS), provides broad coverage and offers free or heavily subsidized services. Alongside it, a modern and dynamic private sector has emerged, particularly in major cities such as San Salvador, Santa Ana, and San Miguel, where many facilities offer standards comparable to those found in the region's most advanced healthcare systems.

Nevertheless, challenges remain, particularly regarding available resources, workforce distribution, and access to care in more remote areas. In recent years, the government has invested in digitalization and infrastructure improvements with the aim of enhancing the overall efficiency of the healthcare system.

The Role of Oral Health

Within this context, oral health represents one of the areas where significant progress coexists with substantial unmet needs.

Although dentistry has been incorporated into national health strategies and preventive and basic dental services are available through the public system, oral diseases remain widespread.

According to WHO data, approximately 41% of children aged 1 to 9 suffer from untreated caries in their primary dentition, while more than 30% of the population over the age of five lives with untreated caries in permanent teeth. Severe periodontal disease also remains highly prevalent, affecting around 22% of adults.

These figures highlight broader issues related to access to prevention, oral health education, and the availability of timely treatment. As in many countries throughout the region, improving oral health remains one of the most important challenges facing the national healthcare system.

The Economic Burden of Oral Diseases

Oral diseases affect not only patients' quality of life but also generate tangible economic and social consequences. Tooth loss continues to be a widespread issue throughout the country.

Recent studies conducted among the Salvadoran population have shown that edentulism and the loss of anterior teeth are associated with a significant decline in quality of life, affecting not only chewing function but also social interaction, employment opportunities, and psychological well-being.

For this reason, oral health is becoming an increasingly important component of public health strategies, particularly as El Salvador seeks to consolidate the progress achieved in improving overall health indicators.

A Well-Represented Profession and an Evolving Sector

From a professional standpoint, El Salvador has a relatively large dental workforce by regional standards. According to the WHO country profile, more than 5,500 dentists are currently practicing in the country, equivalent to approximately 8.7 professionals per 10,000 inhabitants.

The distribution of these professionals, however, mirrors patterns seen across other healthcare sectors. Urban areas, particularly San Salvador and the country's main economic centers, concentrate the majority of dental facilities and advanced technologies, while more peripheral regions continue to rely heavily on basic public services.

This situation has created a dual market: on one side, demand for preventive and essential treatments; on the other, growing demand for specialized, aesthetic, and rehabilitative dental services among the urban population.

Alongside domestic demand, another increasingly important phenomenon has emerged in recent years: dental tourism.

Thanks to treatment costs that are significantly lower than those found in the United States and Canada, a growing number of international patients are choosing El Salvador for complex procedures such as implantology, prosthetic rehabilitation, and cosmetic dentistry.

In many cases, the cost of a dental implant can be more than 70% lower than in the U.S. market, while ceramic crowns and veneers are offered at highly competitive prices. This economic advantage, combined with geographic proximity to North America and the presence of bilingual professionals, is contributing to the growth of one of the most dynamic segments of the country's private healthcare sector.

Opportunities and Prospects for the Dental Industry

For international dental companies, El Salvador represents a relatively small but attractive market.

The country lacks a significant domestic manufacturing base for dental equipment, devices, and technologies, and therefore remains heavily dependent on imports. This creates opportunities for foreign suppliers, particularly as private clinics continue to invest in upgrading their facilities.

The most promising segments include restorative materials, digital dentistry solutions, CAD/CAM systems, diagnostic imaging technologies, sterilization equipment, and products designed to improve clinical efficiency while maintaining affordability. Implantology and cosmetic dentistry also offer strong potential thanks to the growth of dental tourism and increasing demand from urban consumers.

The country's openness to international trade, supported by free trade agreements and free trade zones, further facilitates the introduction of imported products and technologies. Looking ahead, the expansion of the urban middle class, improving healthcare indicators, and growing awareness of preventive care are likely to support the continued development of the Salvadoran dental market.

Looking Ahead

Although it remains a relatively small market, El Salvador is undergoing a transformation that makes it one of the most interesting cases in Central America. The combination of improved security, moderate economic growth, openness to investment, and the expansion of private healthcare is helping redefine the country's role within the region.

For companies operating in the dental and medical sectors, closely monitoring this evolution may prove to be a strategic decision.

Challenges undoubtedly remain, but the path El Salvador has embarked upon suggests that this small Central American nation could play an increasingly important role in the region's future economic and healthcare landscape.

Per capita current health expenditure in PPP (2019)	int\$ 657
Total expenditure on dental healthcare	US\$ 63 million
Per capita expenditure on dental healthcare	US\$ 9.4
Total productivity losses due to 5 oral diseases	US\$ 90 million

Source: WHO-World Health Organization, Oral Health Country Profile. WHO/UCN/NCD/MND/SLV/2022.1 – © WHO 2022

Prevalence of Oral Diseases

Prevalence of untreated caries of deciduous teeth in children 1-9 years	41%
Prevalence of untreated caries of permanent teeth in people 5+ years	30.6%
Prevalence of severe periodontal disease in people 15+ years	21.8%
Prevalence of edentulism in people 20+ years	8.5%

Source: WHO-World Health Organization, Oral Health Country Profile. WHO/UCN/NCD/MND/SLV/2022.1 – © WHO 2022

Oral Health Workers

	Total No.	Per 10,000 pop.
Dental Assistants and therapists, 2016	1011	1.6
Dentists, 2018	5,586	8.7

Source: WHO-World Health Organization, Oral Health Country Profile. WHO/UCN/NCD/MND/SLV/2022.1 – © WHO 2022

Policies, Measures and Resources

Implementation of tax on sugar-sweetened beverages (SSB)	yes
Existence of a national oral health policy/strategy/action plan (operational/drafting stage)	yes
Presence of dedicated staff for oral health working on NCDs at the MoH	yes

Source: WHO-World Health Organization, Oral Health Country Profile. WHO/UCN/NCD/MND/SLV/2022.1 – © WHO 2022

Availability of Procedures for Detecting, Managing and Treating Oral Diseases in the Primary Care Facilities in the Public Health Sector

Oral Health screening for early detection of oral diseases	available
Urgent treatment for providing emergency oral care & pain relief	available
Basic restorative dental procedures to treat existing dental decay	available

Source: WHO-World Health Organization, Oral Health Country Profile. WHO/UCN/NCD/MND/SLV/2022.1 – © WHO 2022

Inclusion of Oral health Interventions As Part of Health Benefit Packages

Coverage of the largest government health financing scheme	100 % of the population
Routine and preventive oral health care	yes
Essential curative oral health care	yes
Advanced curative oral health care	yes
Rehabilitation oral health care	yes

Source: WHO-World Health Organization, Oral Health Country Profile. WHO/UCN/NCD/MND/SLV/2022.1 – © WHO 2022

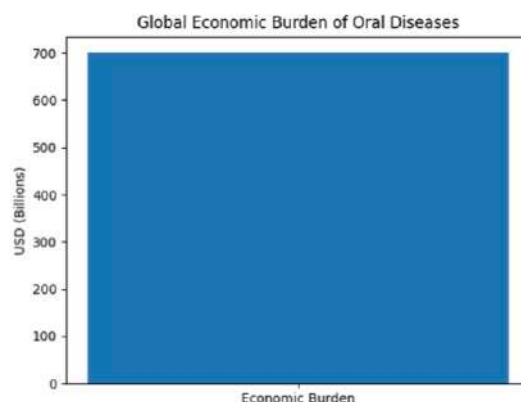
Reframing Oral Health: From Clinical Discipline to Global Policy Priority

Adjunct Professor Dato^o Dr How Kim Chuan
President, World Stomatological Organization (WSO)



cern. It must be recognised as a major public health, economic, and policy priority.

For too long, the global oral healthcare model has remained largely treatment-driven, reactive, and urban-cen-



Oral diseases remain among the most widespread yet underestimated global health challenges of our time. Despite affecting billions of people worldwide, oral health continues to be structurally underprioritised in many healthcare systems, often treated as secondary rather than fundamental to overall health and wellbeing.

This is no longer sustainable.

According to the World Health Organization, nearly 3.5 billion people worldwide are affected by oral diseases, with untreated dental caries remaining the most common health condition globally. Severe periodontal disease alone affects more than one billion people. At the same time, the FDI World Dental Federation has estimated that the global economic burden of oral diseases exceeds USD 700 billion annually, with substantial productivity losses linked to preventable oral health conditions.

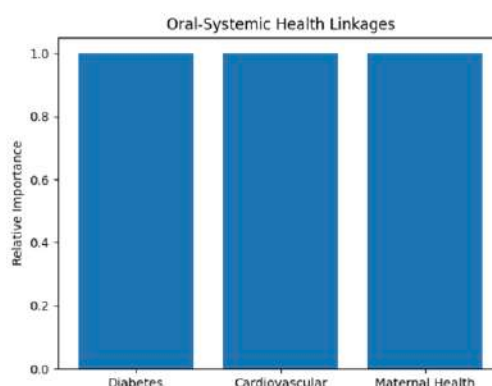
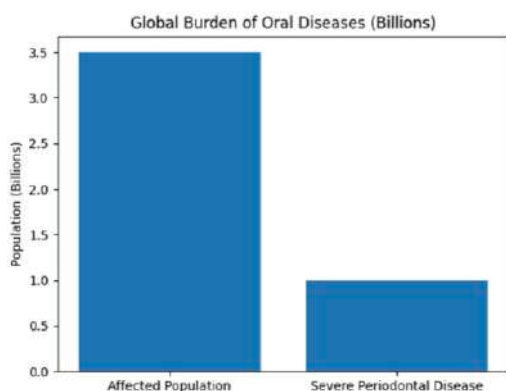
These figures make one reality unmistakably clear: oral health can no longer be viewed as a narrow clinical con-

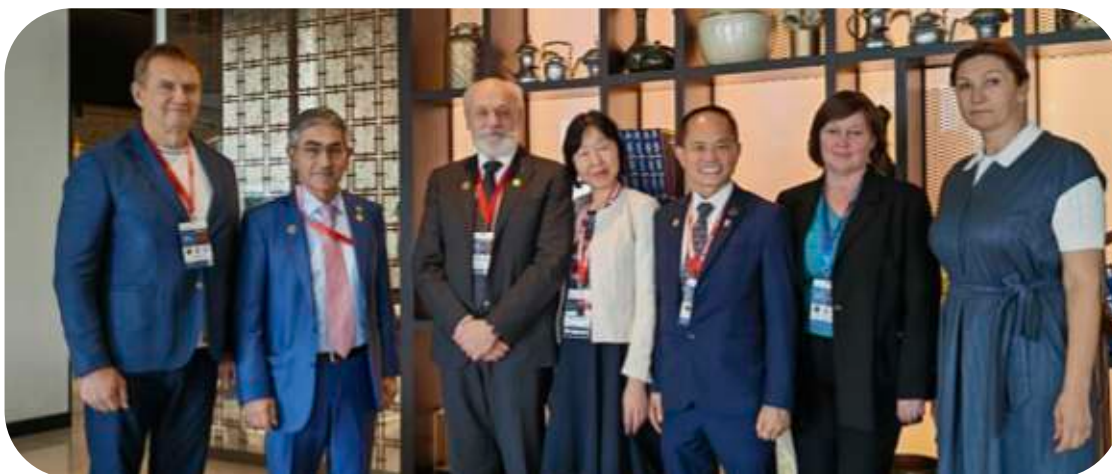
cern. Across many systems, care is still organised around intervention rather than prevention, with access often concentrated in developed urban settings while underserved communities continue to face major barriers. This model is now under growing pressure from ageing populations, rising treatment costs, limited accessibility, and weak integration between oral health services and broader healthcare systems.

What is required now is a fundamental shift in perspective, from procedure-based care to preventive, policy-driven, and system-integrated oral healthcare.

This shift is especially important because oral health does not exist in isolation. It is closely linked to wider health outcomes, including diabetes, cardiovascular disease, maternal and child health, and healthy ageing. The implications extend well beyond the mouth. Poor oral health affects quality of life, nutrition, employability, social confidence, and long-term systemic wellbeing.

Recognising this, the WHO Global Oral Health Action Plan 2023–2030 has called for stronger integration of oral





health into Universal Health Coverage, with greater emphasis on prevention, early intervention, workforce strengthening, and healthcare system reform. This is a significant and timely development. It affirms that oral health must now be understood not only as a clinical discipline, but as a core pillar of public health policy and economic sustainability.

The advancement of this agenda, however, depends not only on international policy frameworks, but also on strong leadership and regional collaboration.

In Central Asia, the strong support and leadership of **Professor Jasur Rizaev**, Rector of Samarkand Medical University and WSO Fellow, has significantly advanced WSO's engagement in Uzbekistan and across the wider CIS region. His commitment to academic collaboration, institutional partnership, and regional development reflects the growing alignment between WSO and key educational institutions in Central Asia.

In Africa, Dr Nawal Rabii, WSO Councilor, plays an important role in advancing preventive oral health initiatives



Under the strategic guidance of our Co-President, **Professor Dr Gerhard Konrad Seeberger**, Past President of the FDI World Dental Federation, the World Stomatological Organization (WSO) continues to align closely with global policy thinking and international professional standards. At the same time, our Vice President, **Professor Bedros Yavru Sakuk**, plays an important role in expanding WSO's engagement across Europe, Central Asia, and the CIS region, strengthening academic exchange and institutional partnership across diverse geographies.

In Russia and the CIS, the contribution of Professor Elena Ivanova, WSO Councilor, has been instrumental in fostering academic collaboration and professional engagement.

and strengthening regional engagement, particularly in addressing challenges of accessibility and public health integration.

Together, these efforts reflect a multi-speed but increasingly coordinated landscape of transformation.

In **Europe**, oral health systems continue to provide important examples of preventive care, policy integration, and sustainable delivery models. In the **Middle East**, platforms such as **AEEDC Dubai** are helping position the region as a hub for innovation, investment, and international collaboration. In **Africa**, the opportunity for impact is especially significant, particularly through community-based prevention, primary healthcare integration, and digital



health solutions. Across **Russia and the CIS**, academic strength, cross-border collaboration, and expanding institutional partnerships continue to demonstrate the region's potential, with Uzbekistan emerging as an increasingly important academic hub.

This evolving landscape shows that progress will not come from isolated effort. It requires alignment between governments, academia, industry, and professional bodies.

That is why international platforms matter. WSO's collaboration with **AEEDC Dubai / INDEX, Infodent Interna-**

not merely as a service category, but as part of a wider national investment in human capital and social wellbeing.

Education will remain central to this transformation.

The **World Stomatological Academy (WSA)**, as the educational pillar of WSO, plays a key role in advancing postgraduate education, clinical training and certification, and leadership development. Through WSA, we are helping to shape a new generation of oral health professionals who are not only clinically competent, but also prevention-focused, policy-aware, and globally connected.



tional, and **Dental Asia** reflects the importance of global connectors that can bridge innovation, education, and policy dialogue. These partnerships are not simply promotional in nature. They are part of a broader effort to create meaningful international pathways through which knowledge, strategy, and opportunity can move across borders.

At the same time, the conversation must also expand beyond healthcare alone and into health economics.

Poor oral health carries consequences that are not only clinical, but economic. It contributes to reduced workforce productivity, increased healthcare expenditure, and a greater long-term burden of systemic disease. By contrast, investment in prevention offers measurable long-term value. It supports more sustainable healthcare systems, reduces avoidable downstream costs, and improves population-level outcomes. In this sense, oral health should be understood

This is essential, because the future of oral health will require more than technical excellence alone. It will require professionals who can think across systems, engage across disciplines, and contribute meaningfully to broader public health agendas.

We are now at a pivotal moment.

The science is clear. The economic case is compelling. The global need is undeniable.

What is required next is stronger alignment, between clinical practice and policy, between innovation and accessibility, and between regional progress and global frameworks.

The World Stomatological Organization is committed to advancing this transformation not merely as an institution, but as a growing global movement for oral health.

One World · One Oral Health · One Smile

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The author recommends the following immediate actions:

- Establishment of a U.S.-based LLC in Miami, Florida, as the operational headquarters for the protocol's development and implementation, leveraging the city's unique institutional proximity to PAHO/AMRO, SOUTHCOM, and the Latin American medical device industry.
- Formal engagement with AdvaMed (Advanced Medical Technology Association) and the Regulatory Affairs Professionals Society (RAPS) to establish industry partnerships and dissemination channels for the Regulatory Divergence Atlas.
- Initiation of dialogue with PAHO/AMRO regarding the protocol's potential integration into the Pan American Network on Drug Regulatory Harmonization (PANDRH) framework.
- Presentation of the protocol's preliminary findings at the World Health Expo (Miami), MD&M West (Anaheim), RSNA (Chicago), and HIMSS Global Health Conference.

Bilateral Regulatory Harmonization Protocol: *Bridging the FDA and Latin American Regulatory Frameworks for Medical Device Market Access*

🕒 4'
Reading time

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Vallejo**

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The regulatory fragmentation between the U.S. Food and Drug Administration (FDA) and the five principal Latin American health regulatory authorities — INVIMA (Colombia), ANVISA (Brazil), ARCSA (Ecuador), ANMAT (Argentina), and COFEPRIS (Mexico) — constitutes a critical structural barrier to the timely flow of medical technology across the Americas. This paper proposes a bilateral regulatory harmonization protocol designed to reduce approval timelines, eliminate duplicative certification requirements, and establish a convergence framework anchored in FDA standards. Drawing on over 13 years of direct operational experience in medical device import/export and a landmark 2014 regulatory precedent before INVIMA — in which FDA-aligned international nomenclature standards were successfully invoked to establish a novel device classification category in Colombia — the author presents a structured methodology applicable to all five jurisdictions. The protocol addresses a documented \$2.1 billion annual loss to the U.S. medical device industry attributable to regulatory fragmentation, while simultaneously improving access to life-saving diagnostic and therapeutic technologies across a Latin American market projected to grow from \$45.37 billion in 2024 to \$75.30 billion in 2033.

1. INTRODUCTION

The global medical device industry operates within a complex and heterogeneous regulatory landscape. While the United States Food and Drug Administration (FDA) has established one of the world's most rigorous and widely recognized regulatory frameworks for medical devices, the five principal Latin American regulatory authorities — INVIMA (Colombia), ANVISA (Brazil), ARCSA (Ecuador), ANMAT (Argentina), and COFEPRIS (Mexico) — each maintain independent, structurally divergent approval pathways that create substantial barriers to cross-border market access.

The consequences of this fragmentation are measurable and severe. U.S. manufacturers face average approval timelines of 18 to 36 months per Latin American market, redundant technical dossier requirements, duplicative safety testing, and inconsistent device classification standards. The cumulative economic impact on the U.S. medical device sector has been estimated at \$2.1 billion in annual losses attributable to re-certification costs and market entry delays (SelectUSA, 2024). Simultaneously, Latin American healthcare systems bear the cost of delayed access to medical innovations that could improve diagnostic accuracy, reduce surgical morbidity, and address the growing burden of non-communicable diseases — including cardiovascular disease, cancer, and diabetes, which are projected to cause 81% of deaths in Latin America by 2030 (Population Reference Bureau, 2023).

This white paper proposes a structured Bilateral Regulatory Harmonization Protocol (BRHP) that takes FDA approval as the primary reference standard and establishes a convergence methodology applicable to the five identified Latin American jurisdictions. The protocol is grounded in direct regulatory practice, including a documented precedent before INVIMA in 2014 in which the author successfully applied FDA-aligned international standards to establish a new device classification category in Colombia — a case that serves as the methodological foundation for the broader framework proposed herein.

2. BACKGROUND AND PROBLEM STATEMENT

2.1 The Latin American Medical Device Market

Latin America represents one of the most significant growth opportunities for U.S. medical device exporters. The regional market was valued at \$45.37 billion in 2024 and is projected to reach \$75.30 billion by 2033, representing a compound annual growth rate (CAGR) of 5.79% (www.marketdataforecast.com, 2024). Brazil alone constitutes the largest medical device import market in the region, with total imports reaching \$9.33 billion in 2024 — an 18% year-over-year increase — and the United States maintaining its position as the single largest supplier with a 20.64% market share and \$1.93 billion in exports (UN Comtrade, 2025; www.pureglobal.com, 2025).

In 2023, the United States was the world's largest exporter of medical instruments, with \$34.8 billion in total exports (www.towardshealthcare.com, 2025). Despite this dominant position, regulatory fragmentation across Latin American jurisdictions significantly constrains the U.S. sector's ability to capitalize on regional demand growth.

2.2 Regulatory Fragmentation as a Structural Barrier

Each of the five principal Latin American regulatory authorities operates under a distinct legal framework, device classification system, technical dossier structure, and approval timeline:

- INVIMA (Colombia): Governed by Decree 4725/2005. Devices classified in four risk categories (I, IIA, IIB, III). Approval timelines for Class IIB devices historically range from 18 to 36 months. Requires Spanish-language technical documentation, independent risk analysis per ISO 14971, and clinical evidence of safety and efficacy.

- ANVISA (Brazil): Governed by RDC 185/2001 and subsequent resolutions. Maintains an independent classification system with four risk classes. Brazil requires localized labeling, Portuguese-language documentation, and mandatory registration renewal every five years. Total approval timeline averages 24 months for Class III devices.
- ARCSA (Ecuador): Governed by Agreement No. 00004521. Classification system partially aligned with PAHO/WHO recommendations but diverges significantly from FDA risk classification criteria, creating uncertainty for U.S. exporters.
- ANMAT (Argentina): Governed by Decree 9763/64 and subsequent resolutions. Requires a local technical director, Spanish-language labeling, and Argentine-specific clinical validation data for high-risk devices.
- COFEPRIS (Mexico): Governed by NOM standards and the General Health Law. Mexico benefits from partial supply chain integration with U.S. manufacturers through maquiladora operations, but maintains an independent approval pathway for market authorization that does not recognize FDA clearance as sufficient for domestic commercialization.

The cumulative effect of these divergent frameworks is a system in which a device approved by the FDA — arguably the world's most stringent regulatory authority — must nonetheless undergo independent, duplicative evaluation in each Latin American jurisdiction before it can be legally commercialized. This structural inefficiency imposes disproportionate costs on small and medium-sized U.S. manufacturers and delays patient access to innovative technologies by years.

2.3 The COVID-19 Precedent

The COVID-19 pandemic provided the most dramatic and consequential demonstration of the human cost of regulatory fragmentation in the Americas. As demand for respiratory support equipment, diagnostic imaging systems, and personal protective equipment surged globally in early 2020, Latin American health authorities faced the impossible task of rapidly approving devices that had already received FDA Emergency Use Authorization — but whose domestic registration processes remained subject to standard multi-year timelines. The resulting delays in the availability of ventilators, portable X-ray units, and critical care supplies contributed directly to preventable mortality across the region. This experience establishes an irrefutable public health rationale for the harmonization protocol proposed in this paper.

3. FOUNDATIONAL CASE STUDY: INVIMA 2014 REGULATORY PRECEDENT

The methodological foundation of the proposed harmonization protocol is grounded in a regulatory precedent established in Colombia in 2014. In November 2013, the author initiated, on behalf of TRADE AND S.A.S. — as legal representative Claudio Molinari — a petition before INVIMA for a Marketing Authorization (Permiso de Comercialización) for X-ray tube assemblies and protective housings manufactured by IAE Industria Applicazioni Elettroniche S.p.A. (Italy), classified as Class IIB Controlled Technology Biomedical Equipment.

INVIMA's initial technical review (Auto No. 2014002047, March 14, 2014) concluded that X-ray tubes and housings, when considered independently of the complete radiological system, did not meet the definition of a medical device under Article 2 of Decree 4725/2005, and therefore could not be granted independent marketing authorization. This position reflected a structural gap between the Colombian regulatory framework and the internationally accepted classification of these components as autonomous biomedical devices.

To contest this determination, the author invoked the classification authority of the ECRI Institute (Emergency Care Research Institute, USA) — the not-for-profit organization responsible for developing and maintaining the Universal Medical Device Nomenclature System (UMDNS), an internationally standardized device nomenclature adopted by regulatory agencies, healthcare systems, and government bodies worldwide, including the U.S. Department of Defense. The ECRI UMDNS assigns code 16604 to X-ray tubes, formally classifying them as independent biomedical equipment. Additionally, the technical submission demonstrated that the X-ray tube, by converting high-voltage electrical energy into ionizing radiation, constitutes an Active Medical Device under Article 2 of Decree 4725/2005 — independent of any associated radiological system.

INVIMA accepted the argument in its entirety. Resolution No. 2014027135 (August 22, 2014) granted Marketing Authorization No. INVIMA 2014EBC-0011808, valid for ten years, classifying Carcasas y Tubos de Rayos X — IAE as Class IIB Biomedical Support Equipment for diagnostic imaging. TRADE AND S.A.S. became the only company in the Colombian market to hold marketing authorization for X-ray tube assemblies as independent medical devices — establishing a regulatory category that did not previously exist in Colombian law.

This precedent demonstrates the core methodology of the proposed harmonization protocol: the systematic application of FDA-aligned international nomenclature standards (ECRI UMDNS, ISO 14971, IEC 60601 series) as a regulatory convergence bridge between the FDA framework and Latin American approval authorities. What was achieved individually for one product category in one jurisdiction in 2014 can be systematized, scaled, and applied across five jurisdictions and multiple device categories through a structured bilateral protocol.

4. PROPOSED BILATERAL REGULATORY HARMONIZATION PROTOCOL (BRHP)

4.1 Conceptual Framework

The Bilateral Regulatory Harmonization Protocol (BRHP) is structured around three operational pillars: (1) Comparative Regulatory Mapping, (2) Convergence Methodology, and (3) Digital Interoperability Infrastructure. Together, these pillars create a systematic pathway through which FDA device clearance can serve as the evidentiary foundation for accelerated market authorization across INVIMA, ANVISA, ARCSA, ANMAT, and COFEPRIS.

4.2 Pillar I — Comparative Regulatory Mapping

The first operational pillar involves the systematic mapping of divergences between the FDA's device classification system (21 CFR Parts 860-892) and the classification frameworks of the five Latin American authorities. This mapping exercise, to be conducted using Natural Language Processing (NLP) algorithms applied to the regulatory corpora of each jurisdiction, will identify:

- Device categories for which FDA classification directly corresponds to Latin American risk categories — enabling immediate equivalence recognition.
- Device categories where partial correspondence exists — enabling streamlined supplementary documentation requirements.
- Device categories where structural divergence requires targeted harmonization — representing the highest-complexity cases for the protocol.

The output of this mapping exercise will be a publicly available Regulatory Divergence Atlas — a comprehensive reference document for U.S. manufacturers seeking Latin American market access — updated annually to reflect regulatory changes in all six jurisdictions.

4.3 Pillar II — Convergence Methodology

The second pillar establishes a standardized technical

dossier structure that satisfies the core documentation requirements of all five Latin American authorities simultaneously, while anchoring evidentiary standards to FDA-cleared submissions. The convergence dossier will include:

- FDA 510(k) clearance or PMA approval as the primary safety and efficacy evidence base.
- ECRI UMDNS classification as the international device nomenclature reference.
- ISO 14971 risk analysis as the harmonized risk management standard.
- IEC 60601 series compliance as the harmonized electrical safety standard.
- Multilingual technical translation (English, Spanish, Portuguese) of all core documentation.
- Jurisdiction-specific supplementary modules addressing labeling, clinical validation, and local representative requirements.

4.4 Pillar III — Digital Interoperability Infrastructure

The third pillar involves the development of a regional digital platform for regulatory data exchange, built on FHIR (Fast Healthcare Interoperability Resources) and HL7 standards, with blockchain-based traceability to ensure the integrity and provenance of all shared regulatory documentation. This infrastructure will enable real-time exchange of approval status, safety alerts, and technical updates between the FDA and Latin American authorities — reducing approval timelines and eliminating redundant document submission requirements.

5. PROJECTED IMPACT

5.1 Economic Impact on the United States

The U.S. medical device industry employs over 420,000 Americans and generated \$34.8 billion in medical instrument exports in 2023 (SelectUSA, 2024; www.towardshealthcare.com, 2025). The elimination of duplicative certification requirements across five Latin American jurisdictions is projected to recover a significant portion of the estimated \$2.1 billion in annual losses currently attributable to regulatory fragmentation, while accelerating U.S. manufacturers' access to a market growing at 5.79% annually.

5.2 Public Health Impact in Latin America

Over 50 million people in Latin America live with diabetes as of 2023, and non-communicable diseases are projected to account for 81% of regional mortality by 2030 (PAHO, 2023). Accelerated access to FDA-approved diagnostic and therapeutic devices — including imaging systems, cardiac monitors, surgical robotics, and in vitro diagnostics — will directly improve clinical outcomes for millions of patients who currently experience multi-year delays between device innovation and clinical availability.

5.3 Strategic Positioning of the United States

The implementation of the BRHP from U.S. territory, anchored in FDA standards, positions the United States as the global reference center for medical device regulatory governance in the Western Hemisphere. This strategic positioning strengthens bilateral health diplomacy, reinforces U.S. influence within multilateral health forums including the Pan American Health Organization (PAHO/AMRO), and creates a replicable model for regulatory harmonization applicable to other high-growth markets in Africa, Southeast Asia, and the Middle East.

6. CONCLUSIONS AND RECOMMENDATIONS

The regulatory fragmentation between FDA standards and Latin American medical device approval frameworks represents a structural inefficiency with documented costs to U.S. economic competitiveness, Latin American public health outcomes, and the broader mission of equitable access to medical technology. The Bilateral Regulatory Harmonization Protocol proposed in this paper offers a systematic, evidence-based solution grounded in direct regulatory practice and validated by a landmark 2014 precedent before INVIMA.

The Number Every Dental Practice Should Know



Luca Gentili
Dental Office Manager

Why the Break-Even Point Is More Than an Accounting Metric

Most dental practices know how much they produce, many also know how much they collect, yet far fewer can say with precision how much they must collect every month simply to support the organization they have built. This difference is more important than it may initially appear, because a full schedule, high production figures and intense clinical activity can create the impression that the practice is performing well, even when the financial results tell a very different story.

Activity, in fact, is not the same as profitability. A practice can be busy, deliver excellent dentistry and generate significant production while still failing to collect enough money to cover salaries, laboratory bills, rent, technology, supplies, financing and all the other costs required to keep the organization operating. For this reason, every dental practice should know one essential figure: its break-even point.

The Illusion of a Successful Month

Consider a practice that produces \$150,000 in treatment during a month. At first glance, the result appears positive: the schedule was full, the clinicians worked consistently and the team delivered a considerable amount of care. Production, however, is not the same as money received. After contractual adjustments, discounts, delayed payments, unpaid balances and other reductions, the practice may collect only \$110,000.

If the monthly break-even point is \$120,000, what appeared to be a successful month has actually created a financial shortfall. The problem is not necessarily the quality of the dentistry or the effort made by the team; the problem is that performance has been evaluated by looking at the wrong number.

Production represents the value assigned to the services delivered, while collections represent the money that has actually entered the practice. Both figures are useful and should be monitored, but they answer different questions. Production tells leadership how much treatment has been performed; collections indicate whether the organization has generated the financial resources necessary to sustain itself. When the distinction is ignored, a practice can appear productive while gradually losing financial stability.

What the Break-Even Point Really Represents

The break-even point is the minimum amount that a practice must collect during a specific period in order to cover its financial obligations. Below that threshold, the organization is losing ground; at that level, it is maintaining its existing structure; above it, the practice begins to create the resources required for profit, reserves, investments and future growth.

Although it is usually presented as an accounting concept, the break-even point is much more useful when treated as an operational management tool. Once leadership understands the number, the conversation changes. Instead of asking only whether the month was busy, the owner and the manager can evaluate whether collections supported the cost of the organization, whether available chair time was used effectively, whether cancellations had a meaningful financial impact and whether the current schedule is capable of supporting the existing staffing and cost structure.

The break-even point can also improve decisions concerning recruitment, technology and expansion. Before hiring another employee, purchasing a new piece of equipment or increasing opening hours, leadership should understand how that decision will affect the amount the practice must collect in the future. In this sense, the real value of the break-even point does not lie only in the number itself, but in the quality of the decisions that can be made once the number is known.

From the P&L to Decisions

Many owners and managers receive a Profit and Loss statement every month, review revenue, payroll, laboratory costs and supplies, notice that one category has increased or that the final result is lower than expected, and then return to daily activity without making any concrete change. That is financial observation, not financial management.

A P&L statement should not simply describe what has already happened; it should help determine what needs to happen next. Each significant number should generate a question: why did this expense increase, was the change temporary or structural, can the current revenue model support it and what action should be taken? Timing is equally important, because a report reviewed several months later may explain the past but arrives too late to influence the present.

Break-Even Is a Moving Target

The break-even point cannot be calculated once and considered permanent; it changes whenever the structure of the practice changes. Hiring a team member increases payroll, purchasing technology may introduce financing, maintenance, software and training expenses, while salary increases, higher laboratory fees, new locations and expanded hours can all raise the level of collections required to remain sustainable.

Even positive growth can increase financial exposure. A larger team or a more advanced facility may create new opportunities, but also new obligations. A growing practice is not automatically a more profitable one: if costs expand faster than collections, the organization may appear stronger from the outside while becoming more vulnerable internally.

For that reason, the break-even point should be recalculated whenever investments or structural changes are introduced. Every major decision should include one financial question: how will this change affect the amount the practice must collect each month?

Translating the Number into Daily Management

A monthly break-even point becomes useful when connected to everyday operations. Leadership should relate it to working days, available chair hours, clinician capacity, scheduled production, collection ratios, case acceptance, cancellations and payment timing.

This does not mean reducing dentistry to financial targets or turning each morning huddle into a discussion about money. Clinical judgment must remain independent, and financial objectives should never create pressure to recommend unnecessary treatment. The aim is to understand whether the schedule can support the structure that depends on it.

When a major appointment is cancelled, the consequence is not simply an empty space in the agenda. It may represent a measurable difference between the planned result of the day and the result the practice is now likely to achieve. If the team recognises the issue early, it can contact patients who are waiting or reorganise the schedule; if no one understands the impact, the problem may remain invisible until the end of the month.

The Role of the Team and the Manager

Not every team member needs access to the complete P&L or confidential financial details. Total secrecy, however, creates another problem: teams are often asked to reduce cancellations, collect outstanding balances or manage supplies more carefully without enough context to understand why these actions matter.

Team members should understand that cancellations affect capacity, unused clinical time cannot be recovered, delayed collections create cash-flow pressure and unnecessary waste increases the amount the practice must generate elsewhere. The purpose is not to make employees responsible for ownership's financial risk, but to help each person understand how their role contributes to the stability of the system.

The Dental Office Manager is central to this process because the role connects financial information with the daily life of the practice. The accountant prepares the reports; the manager sees how those numbers are created through scheduling, staffing, patient communication, case acceptance, collections and operational choices. Financial reports cannot improve performance on their own: someone must translate them into practical actions and connect financial consequences with operational decisions.

Final Insight

After more than fifteen years working inside real dental organizations, I have learned that financial instability rarely begins with one dramatic event. More often, it develops gradually through reports that are available but not fully understood, costs that increase without changing the targets, schedules that appear full without producing sufficient collections and financial conversations that take place only after the problem has become visible.

A dental practice can survive an occasional difficult month; what it cannot do sustainably is continue operating without knowing what a successful month must actually produce. The break-even point is not simply an accounting figure, but the line that separates activity from sustainability and intuition from informed management.

If you do not know the number that keeps your doors open, you are not managing profitability; you are hoping for it.



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13 - 15 / 10

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Dentsply Sirona and Smile Train Win Halo Award for Best Technology for Good Initiative, Advancing the Future of Cleft Care Worldwide

Using technology as a force to increase access to care and advance cleft care globally, Dentsply Sirona and Smile Train have been recognized for their global community engagement efforts as part of Dentsply Sirona's "BEYOND: Taking Action for a Brighter World" sustainability strategy. The partnership received a Gold Halo Award, while Dentsply Sirona also received Gold honors at the Brandon Hall Group Excellence in Action Awards, recognizing how it combines digital dentistry, clinical know-how, and employee engagement to expand access to oral care.

Dentsply Sirona, the world's largest diversified manufacturer of professional dental products and technologies, and Smile Train, the world's largest cleft-focused organization have been honored with a 2026 Gold Halo Award in the category Best Technology for Good Initiative.

Increasingly, digital dentistry solutions play an important role in amplifying impact by helping expand reach, improve treatment planning, and support more consistent, high-quality care delivery. The Halo Award recognizes how Dentsply Sirona and Smile Train leverage customer-centric digital dentistry solutions as well as personalized clinical education to help advance the future of cleft care globally.

Presented by Engage for Good, the Halo Awards honor standout collaborations between companies and nonprofits that leverage business strengths to create measurable, positive change for people and communities globally.

"At Smile Train, we see every day how access to timely, high-quality cleft care can change a life," said Susannah Schaefer, President and CEO of Smile Train. "Receiving a Halo Award together with Dentsply Sirona is a meaningful recognition of what strong partnerships can achieve. By combining digital dentistry solutions with training and local expertise, we are helping more clinicians reach more patients and expand access to safe, effective treatment around the world – even in settings where resources are limited."

Going BEYOND: Empowering Communities

In addition to the Halo Award, Dentsply Sirona was also recognized with Gold in the Corporate Social Responsibility (CSR) category at the 2025 Brandon Hall Group Excellence in Action Awards for its global community engagement efforts under the company's BEYOND sustainability strategy.

The Brandon Hall award highlights how the company mobilizes and engages employees worldwide through

long-term nonprofit partnerships to contribute to meaningful social impact. Through partnerships with organizations such as Smile Train, TeamSmile and Project 32, Dentsply Sirona combines monetary donations, in-kind donations of dental equipment and consumables, the exchange of know-how, clinical education and training, and active employee volunteering to create to help increase access to oral health care for communities in need.

By encouraging colleagues across regions and functions to actively contribute – whether through volunteering, supporting education efforts or helping implement programs on the ground – Dentsply Sirona embeds social responsibility into everyday work and fosters a strong sense of shared purpose and connection.

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