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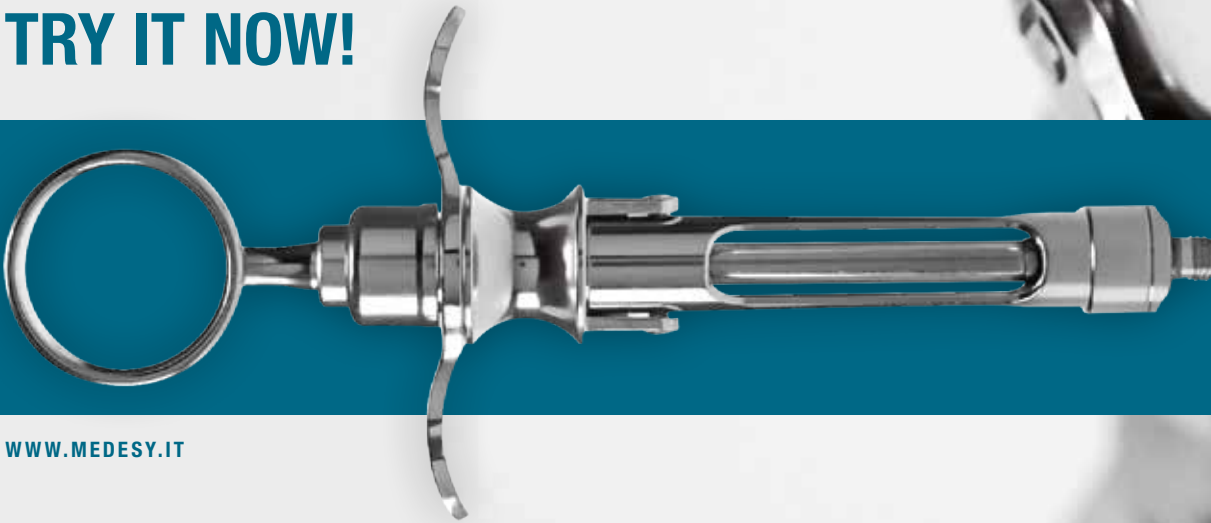


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Don't miss our brand new Distributors' Wall
pp. 76-84

Edited by



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Why Infodent International?

WHY INFODENT INTERNATIONAL?



It might sound like I am doing some marketing, and I might well be, but my intent this time is to remind you what INFODENT INTERNATIONAL is all about. Our contents focus on news, regulations and novelties in the international dental market; we make deep research, using many different sources, to give you thorough outlooks on the different markets for the import and export of your products

around the world; previews and post-show reports on international exhibitions as well as latest products highlights; company profiles of dental companies and more... We help manufacturers export around the world and we do our best to give our readers the most reliable information on the markets of export. We are, for this, a B2B magazine especially designed for the dental trade and industry, mailed to over 20,500 addresses of manufacturers, distributors, importers and suppliers, covering 165 countries around the world. We are specialized in a dental database of the industry and, on this regard, we might have the biggest one on the market as we have been operating in this sector for over 20 years. Thanks to its wide circulation, Infodent International can give manufacturers and distributors worldwide visibility. Manufacturers looking for distributors and importers around the world choose Infodent International to expand their distribution network and enter new markets; distributors and importers use our magazine to find new products to distribute and new partners. To help our readers even further, we have been focusing our attention on what we have called the **“DISTRIBUTORS’ WALL”, a service of commercial announcements made by distributors, importers, manufacturers and suppliers where each one is looking for new contacts to start or increase business.**

You will find, in each issue of our magazines, a section full of announcements sent to us by manufacturers, distributors, importers and suppliers that are searching for one another... You can let the market know of a product you are searching for or selling, second-hand products, new initiatives, markets you are looking at, exhibitions you are attending and more. I invite you all to send us commercial announcements of any kind to publish in our magazine...believe it or not, this is one of the mostly read sections by our readers!

Lastly, we have expanded the distributors’ wall service in some of the international exhibitions we are attending with our own booths around the world! How? Some of our booths have a dedicated wall to attach your announcements and you can read all the others; with announcements of any kind, of distributors and manufacturers looking for new business and contacts. You can use the wall at our booths to copy or give us contacts throughout the exhibition, creating an Infodent meeting point! But Infodent International is not just a magazine. It is made up of a group of hard working people and consultants with a long-standing expertise capable of giving you information and tips on world markets, including tailored made services such as newsletters, mailings, consulting services to help you find partners worldwide. We work in close collaboration with the most important international trade exhibitions and offer you services within the exhibitions... Let us know what you are looking for, we can surely be of help!

Infodent International Magazine is published and mailed around the world four times a year... with its targeted circulation and its wide range of B2B and online marketing services we can help you grow and create a network of business relationships!

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Contents

We are excited to develop an innovation in our Infodent magazine. Starting from the upcoming issue our focuses are changing, nevertheless remaining loyal to our articles on the economic and medical markets as well as worldwide industry news.



FOCUS ON SPAIN

The Spanish economy is the fifth-largest in Europe behind Germany, United Kingdom, Italy and France and the 14th largest in the world.

Highlights

6-45 Learn more about our Advertiser's Products...

Focus

46-55 Focus on Spain

Hot Topic

56-58 New EU Rules on Medical Devices to Enhance Patient Safety and Modernise Public Health

Marketing

60-63 The Perfect Newsletter

Market Overview

64-65 The Italian dental market: current prospect and evolutionary trends

66-70 Post Show

Non-Profit

72-74 Henry Schein Supports Volunteer Endodontists Expanding Oral Health Care In Jamaica

76-84 The Distributors Wall

86-87 Calendar

Cover page

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3DISC Europe.....	p. 10
AdDent, Inc.....	p. 32
AEEDC 2018.....	p. 73
Apixia Corp.....	p. 5
AXELMED S.r.l.....	p. 1
B.M.S. Dental Srl.....	p. 31
B&L Biotech USA Inc.....	p. 25
Beyes Dental Canada Inc.....	p. 3
Biotech Dental.....	p. 33
CEDE 2017.....	p. 71
Deflex Global S.L.....	p. 19
Dentag Srl.....	p. 17
Dental Medrano S.A.....	p. 36

Dental Salon 2017.....	p. 75
Dental South China International.....	p. 85
DenTech China 2017.....	p. 57
Dentmate Technology Co., Ltd.....	p. 34
Diadent Group International.....	p. 7
DMP SA.....	p. 30
Dr. Wild & Co. AG.....	p. 21
FLEXAFIL SACI- SABILEX S.R.L.....	p. 37
GNYDM 2017 Greater New York Dental Meeting.....	II Cover
Idea 2017 - Promunidi Srl.....	p. 88
Lord Corporation.....	p. 29
Mariotti & Co. Srl.....	p. 14
MDT Micro Diamond Technologies Ltd.....	p. 65
Medical Precision Implants, S.A.....	p. 18
Medirel S.A.....	p. 35
Mid-Continental Dental Supply Co. Ltd.....	p. 86
Miromed s.r.l.....	p. 11
Mocom Srl.....	p. 15

Nanning Baolai Medical Instrument Co., Ltd.....	p. 26
New Life Radiology Srl.....	p. 13
Ningbo Ican Machines Co., Ltd.....	p. 42
Ningbo Runyes Medical Instrument Co., Ltd.....	p. 41
Novobrush GmbH.....	p. 69
Oralplant Suisse SA.....	III Cover
Owandy Radiology Sas.....	p. 43
Silfradent srl.....	pp. 44-45
Sisma Spa.....	p. 27
Suni Medical.....	IV Cover
Talleres Mestraitua S.L.....	p. 39
Techim Group Srl.....	p. 23
TeKne Dental Srl - TKD.....	p. 12
Thermoplastic Comfort Systems Inc.....	p. 29
Top Nova.....	p. 81
Tribest Dental Products Co. Ltd.....	p. 22
Troll Dental.....	p. 38
Ziacom Medical, S.L.....	p. 83



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HIGHLIGHTS

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HIGHLIGHTS

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• **QUARK®CAL - Compact contra-angle handpiece**



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HIGHLIGHTS

Our Advertisers' Products

• Tethys H10 Plus, the world of disinfection is no longer the same.



Mocom has revolutionised the disinfection world with its new Tethys H10 Plus, the device that decontaminates, washes, thermally disinfects and dries instruments with hot air, all in a single process, automatically preparing them for subsequent packaging and sterilization. Thanks to this innovative, compact device, the reconditioning process is as simple as it is effective; it also frees personnel from tasks that were time-consuming and at risk. Tethys H10 Plus is a medical device that complies with the EN ISO 15883-1/2 standard: it allows attainment of extremely high thermal disinfection levels, the A0 value being settable from 600 to 6000. Decontamination, ultrasound washing, thermal disinfection and hot air drying are completed in a single stage lasting just 35 minutes. Tethys H10 Plus is a table top unit that comes complete with everything. It offers the same performance and features as traditional thermal disinfectors - water softener, detergent reservoir, filling pump, discharge pump and aqua stop - all in a compact unit suitable for any surgery.

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HIGHLIGHTS

Our Advertisers' Products

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The possibility of injury is during use, handling or passing the instrument between Assistant-Dentist-Assistant while performing the procedures on the patient. Directive 2010/32/EU - prevention from sharp injuries in the hospital and healthcare sector, also it states that it's necessary to prevent workers' injuries caused by all medical sharps and pointed devices. Instruments with a handle 100, 105 mm are too short and the tips, even if they are turned contrary than working one, very often touch on the back of his hand.

Instead, what it can do as an additional preventive action is to choose, when buying or replacing, one instrument with a long handle. The longer instruments can be wrapped exactly like the other and, in the event that the dentist use cassettes or trays for sterilization of small size, it will be sufficient to put the instruments in the direction of the longer side

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HIGHLIGHTS

Our Advertisers' Products

• MPI



MPI will be present at the FDI Congress which will take place in Madrid from August 29th until September 1st, 2017. We will welcome all doctors on our booth 7E13 in hall 7. MPI has incorporated into its product range the

new conical implant MPI Excellence®, so that each clinician can find the exact and most comfortable implant for whatever clinical case may present itself, enabling him to cover all his requirements.

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www.mpimplants.com // info@mpimplants.com Visit us at: FDI 2017; Hall 7, Booth 7E13



The advertisement banner features the MPI logo on the left. The main text reads: "MPI Implant Systems designed by professionals for professionals." Below this, it states "WE ARE SEARCHING FOR DISTRIBUTORS" and lists five bullet points: "State of the art technology", "Cero defect policy", "R & D", "Clinical training", and "Exclusive know-how". A handwritten-style quote says: "The commitment in excellence which we all are searching for." To the right of the quote are three different MPI implant models. At the bottom left is the website "www.mpimplants.com" and at the bottom right is contact information for Regina Bosch: "Tif. +34 91 684 60 63" and "r.bosch@mpimplants.com".

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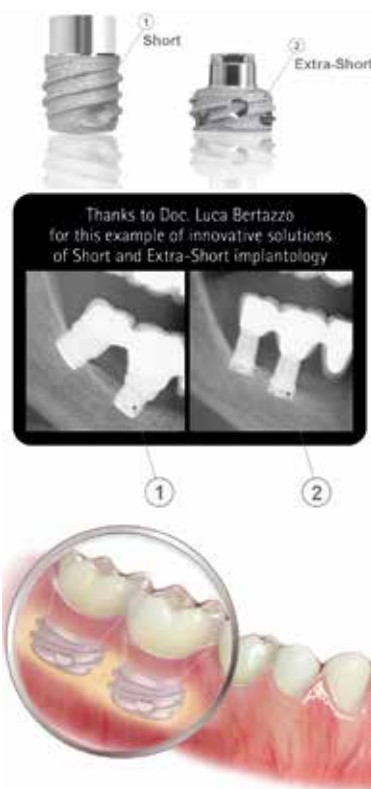


Oralplant Suisse is the company that holds the research, development and manufacturing rights of this formidable Extra-Short Implant called Tuber-Plant SC

Oralplant implantology is based on the extensive osteointegration capacity of the TPSS (Titanium Pull Spray Superficial) surface treatment which for 25 years has confirmed the excellent reactions for maintenance of osteointegration on Oralplant medical devices; the conviction of professionals and researchers working with it on a daily basis is to be in the presence of an implant surface, that can be applied to other solutions in osteointegrated implantology in the future. Oralplant, osteointegrated implantology of excellence since 1991, is constantly searching for techniques addressed to implant insertion in the most extreme bone conditions. From the beginning it designed and manufactured Tuber-Plant, osteointegrated medical device with 7mm lengths and various diameters, reaping significant success. Case studies over the years showed that it was still possible to reduce the length, in fact, 6, 5 (ref. Figure 1), 4.5 and, more recently, 3.5 and 2.5 mm (ref. Figure 2) unique in the world implants were invented.

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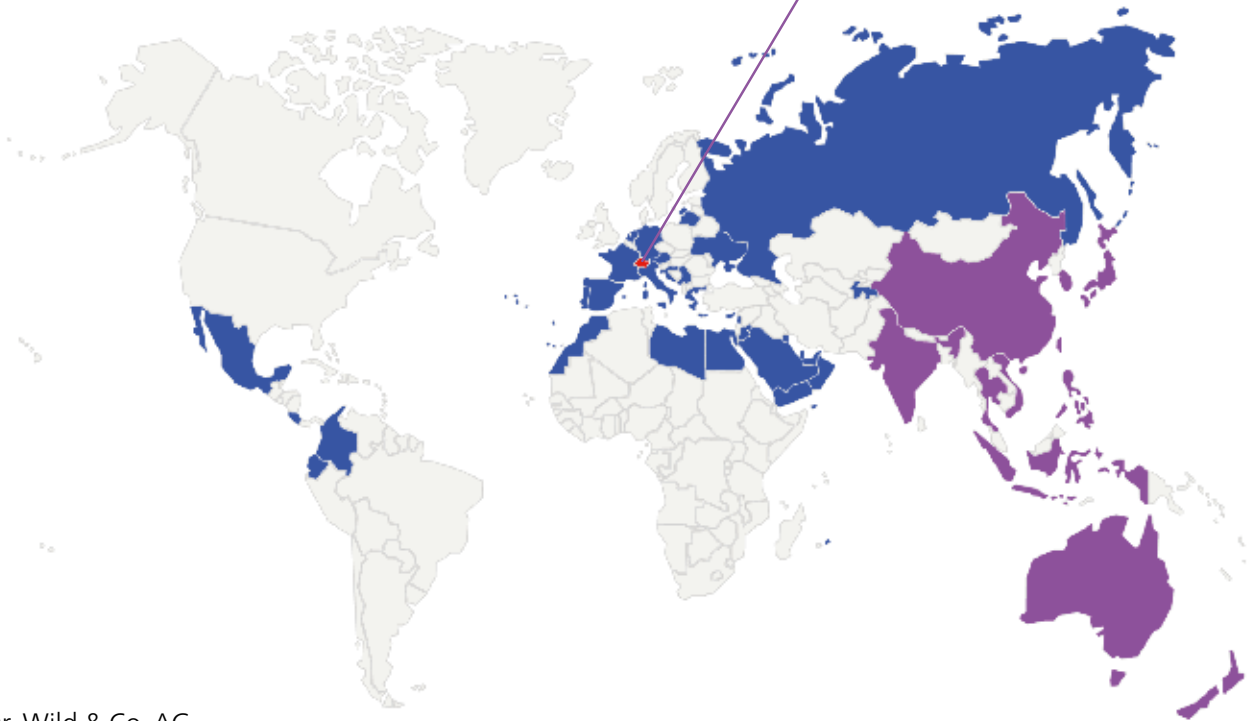
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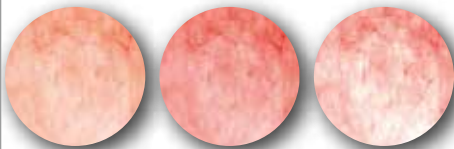
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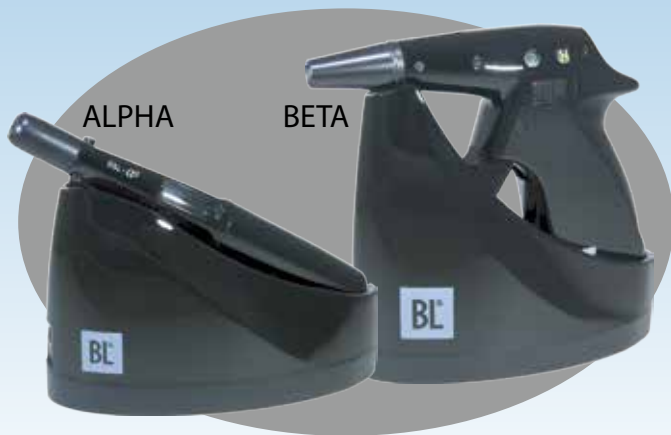


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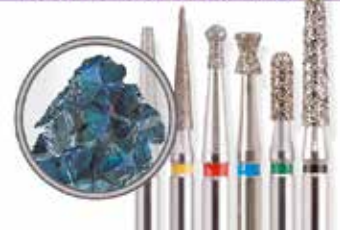
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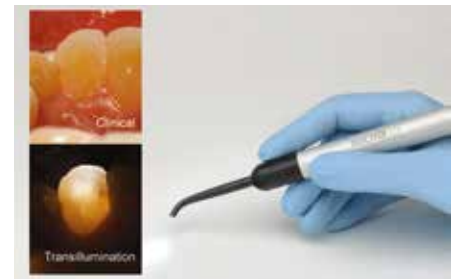
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• Novobrush MicroTips

NOVOBRUSH

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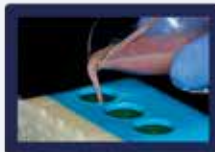
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• Axelmed presents Paradigma



Axelmed presents **Paradigma**. It is the result of a 4-year research project, whose aim was to develop a quality medical device, simple to use and with clinical features that are the results of the synthesis of the current state of art in implantology.

SIMPLICITY

- A. **One prosthetic connection** for 5 implant diameters (internal hexagon connection with conical marginal seal) compatible with major brands;
- B. **5 Design of the implants** to ensure control during insertion and optimal primary stability in most situations;
- C. **SAP the Axelmed Surface Treatment**: micro roughness, high purity and minimal ratio of pollution assure fast and safe osteo-integration;
- D. **A complete and intuitive surgical kit** with high quality instruments, drills with DLC coating made in Italy, to deal with all clinical situations;



RATIONAL OF THE IMPLANT DESIGN AND INNOVATIVE TECHNICAL FEATURES

1. **Implant surface**: the Axelmed Paradigma **Hybrid Surface SAP** (Sandblasted, Acid Etching, Plasma Treatment) is a minimally-rough surface, with a high degree of decontamination, obtained through a blasting process using pure AL₂O₃, a triple acidification process with strong acids and a double treatment in the Argon Plasma reactor. The result is the creation of a surface able to reduce the osseointegration phase. At the same time, at the implant neck level,



the presence of a **machined surface**, in combination with microthreads, allows to reduce the risk of developing peri-implantitis without compromising the stability of the marginal bone levels.

2. **Implant geometry**: Axelmed Paradigma is a crestal or subcrestal implant, with **5 diameters, each one with a specific thread design**, based on dynamic screwing in different types of bone. This feature is unique in the implant field and it was developed in order to guarantee good primary stability even in critical surgical conditions.

Another important aspect is the **implant neck**, which includes different features:

- a back tapered design, useful to increase the space for peri-implant bone and eliminate compression at the cortical bone level in order to minimize peri-implant bone resorption;
- platform switching, that contributes to reduce peri-implant bone resorption;
- microthread, that reduces stress and promotes new bone formation.

• ALL-in-ONE Axelmed: a way to solve 80% of cases by ordering just 1 code

ALL-in-ONE is an innovative and rational product, manufactured by the implant company Axelmed. It has been developed with the aim to simplify the clinical daily routine in implant dentistry. Inside the box there are 3 different vials:

- A. The main vial contains the Axelmed Paradigma implant, its cover screw and healing cap.
- B. The vial with the blue cap contains the laboratory components (laboratory fixing screw, implant analog, castable abutment).
- C. The vial with the white cap contains the components to perform the prosthetic phase in the dental office (aesthetic abutment, single use plastic transfer for closed tray impression technique, definitive fixing screw).

This kind of packaging allows to achieve different benefits:

- **simplification**: at the end of the surgery, the dentist sends to the dental technician the vial with the blue cap. Inside he can find everything he needs to create the prosthesis;
- **time saving**: the possibility to order 9 components, using only 1 code, allows to simplify the dental office organization and save time to order the implant materials;
- **money saving**: the price for the ALL-in-ONE kit is 20% lower than the price calculated by the sum of each component.
- In case some components are not used in the procedure, they can be used with single implants in next cases.



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HIGHLIGHTS

Our Advertisers' Products

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- * for Veterinarian autoclaves ranging in size application.
- * for laboratory autoclaves ranging in size and application

Technical Directives: Medical Device Directive 93/42/EEC

Technical Standards include:

- * EN 13060 (small steam sterilizer)
- * EN 61010-1 (Safety regulations for electrical Measuring, controlling and laboratory Devices-Part 1)
- * EN 61010-2-040 (Safety regulations for electrical Measuring, controlling and laboratory Devices-Part 2)
- * EN 61326

Certificates: CE0197, ISO9001:2008, ISO13485:2003+AC:2009

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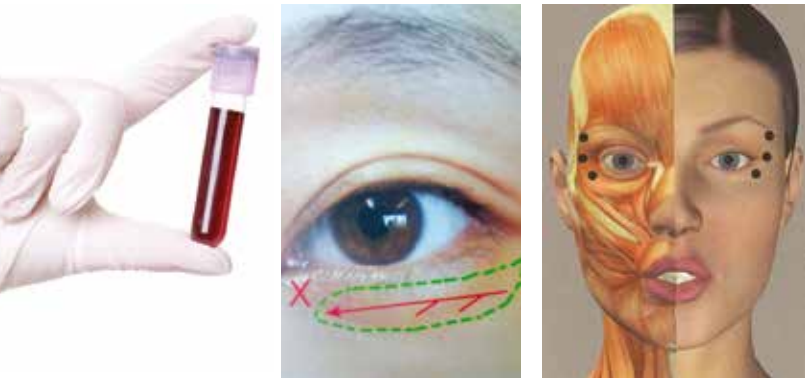
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Blood therapy, a new trend in skin ageing regeneration

CGF, your blood is re-injected into affected areas.
CGF vs. aging skin is a popular among many People
CGF Fraction, Platelet Rich Plasma (PRP) is a concentrated growth factors therapy without exogenous chemical material.

A trend for rejuvenating skin that has emerged in the past few years requires the use of one's own blood to be re-injected into skin. By using Concentrated Growth Factors (CGF) from platelets, your blood is used to heal regenerate tissues and build collagen. This treatment modality harnesses the healing power of platelets – components in the blood that initiate and regulate tissue repair – and release biphasic growth factors from blood to stimulate a stem cell response. Then stem cells help you to grow new collagen and blood vessels, repair and regenerate damaged skin, and help slow the signs of aging. CGF started its in orthopedic medicine, dentistry, sport medicine, gynecology, dermatology and reconstructive surgery. Now, Doctors have discovered its healing and regeneration properties can also be used in cosmetic to stimulate skin rejuvenation.



The Ageing Face

As we age, we experience a loss of volume and skin laxity that results in common complaints, which include:

- Volume loss in the cheeks
- Dehydrated skin
- Crow's feet
- Lip and frown lines
- Acne scarring
- Deep depressions around the nose and mouth
- Filling of missing tissue
- Voluminizing effect Gel
- Scarring around the jaw line
- Overall loss of healthy, youthful skin texture and tone
- Rosacea

The face becomes triangle – shaped as the skin and fat begins to flatten with gravity. A poor diet, smoking and exposure all cause oxidative stress, a key component of the ageing process, that appears as fine lines, hyperpigmentation, unevenness of skin tone, sagging skin and advanced wrinkling. CGF/ PRP addresses these problems – it is a skin regeneration therapy that uses the patient's own blood to boost the natural healing power and repair the cells. The Concentrated growth factors,

when released, induce the production of collagen and generation of new capillaries to rejuvenate the skin. It has the advantage of a longer duration of efficacy compared with injections of Hyaluronic acid, Botox and collagen that are absorbed into the body. A unique technologies developed by Silfradent®, can generate low release matrix from human albumin (APAG device, from Silfradent®). Combination of CFG plus APAG, is considered the thirds generation of PRP. Filler effect and collagen stimulation can be reached with this method. Autologous CGF/PRP/ APAG procedure is a quick 30 minute treatment. It involves removing a vial of the patient's own blood and spinning it in a special device (Medifuge, Silfradent®), to separate out the red blood cells, plasma, platelets and stem cells CD34+ without exogenous chemicals components. This plasma (the clear, liquid part of blood) now contains from 3-5 fold the basal levels of platelets. This PRP fraction is injected into the affected areas around the skin in tiny needles or cannula. Now, Doctors are applying the technique to other problem, including helping with hair loss by using PRP to stimulate hair follicles.

CGF in Skin regeneration

CGF is a completely natural treatment, there's no risk of allergy, infection or rejection, it can be done at all ages, on all skin types. The treatment is ideal for individuals looking for gradual, but noticeable improvement in skin texture, tone and color with minimal downtime. It gives you a fresher and healthier appearance without looking frozen or over – plumped, without aggressive surgery, chemicals or toxins. The treatment also rejuvenates saggy skin, reduces fine lines, eye bags and neck wrinkles, and helps with any acne-scarring. CGF is effective particularly for crinkling skin under the eyes that are difficult to treat by conventional rejuvenation therapy. Like all cosmetic treatments, it requires a few treatments for best results – with most Doctors recommending three treatments, once a month. Top- up treatment can be done once or twice every year: Noticeable results will be seen around the three – months mark and will continue as new collagen production. Results are variable from person to person, but in general, could last from 12 – 18 months. CGF uses the patient's natural biology to address skin defects and volume loss, triggering production of new cells and collagen formation. Thus, CGF (PRP) therapy is very promising in facial restoration. Results are optimal when patients receive a combination of PRP with microdermabrasion, chemical peels, laser therapy and Gel A.P.A.G to accelerate and sustain the benefits of CGF (PRP).

Disclaims:

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The concentrated growth factor (CGF) The advanced breakthrough in regenerative medicine

What makes the innovative CGF (Concentrated Growth Factors) technique different and more advanced than the conventional regenerative techniques (PRP, PRGF, PRF, etc.)? - A question that is frequently asked by fellow clinicians and patients that favour the natural, personalised approach in medicine.

Regenerative medicine is one of the most dominant objectives of today's rehabilitation therapies. The ability to reconstruct lost or damaged tissues has been intensively researched as an important aspect of modern medicine. In dentistry, the research of growth factors applicable to bone regeneration techniques has been significant and a large number of studies recognise that the best tissue regenerative stimulus are present amongst the autologous growth factors (GFs), which have clinically proven to induce regeneration and tissue healing. Therefore many techniques were developed for this purpose (e.g. Tissucol, PRP, PRGF, PRF, etc.) aiming to achieve the appropriate biostimulation, which demonstrated degrees of success in many clinical scenarios.

Research and clinical studies concluded that in addition to stem cells or the premature cells that can differentiate into osteo- or fibroblasts, there are several factors involved in tissue regeneration (Growth Factors GFs), such as Bone Morphogenetic Proteins (BMP), Platelet Derived Growth Factor (PDGF), Insulin-like Growth Factors (IGFs: IGF-I and IGF-II), Osteoprotegerin (OPG), Transforming Growth Factors (TGF), Fibroblast Growth Factors (FGFs), and other cytokines particularly type IL1 and TNF- powerful stimulants for bone reabsorption.

As it is recognised that many of these factors are naturally circulating in our blood and bearing in mind the ultimate regenerative characteristic of those factors, The CGF technique was developed to achieve the optimal phase separation and concentrate the factors for maximum recruitment and biostimulation of those cells (Concentrated Growth Factors 2006, IAIO).

The process starts with collecting patients' venous blood, and then applying the centrifuging process, in which the temperature and speed are specifically controlled for every stage ensuring the separation of each protein. This controlled process, with alternated and controlled speed and gravitational acceleration of approximately RCF770 (always below RCF1.000), results in the optimal separation with significantly high concentration of growth factors, thus making the CGF advanced and more specific.

The CGF is characterized by the existence of four phases:

1. SERUM: Upper phase; the lightest and most liquid part of the blood (fibrinogen-free with only few cells). It represents a fundamental element of the CGF protocol that amalgamates grafts and supplies many biochemical components and activators. The serum is used to wash the cavity, to cover and protect all the regenerated portions

2. FIBRIN Buffy Coat: Interim phase represented by large and dense polymerized fibrin block, which is obtained by comprising three-dimensional polymer networks with interwoven fibres that develop during centrifuging, allowing a volume growth of these fibres in all directions, in a single phase in the form of gel.

This development ensures control of many components, determining numerous therapeutic actions, such as:

- Plasma and platelet cytokines: repair; anti-inflammatory and painkilling effect during repair (TNF- α);
- Platelets: transmission of the signals and release of the GFs. The most important are the PDGF-BB, TGF β 1 and IGF-1

Furthermore the fibrin gel blocks with excellent resistance can be used as:

- Cavity fillers
- Membrane supports
- Autologous membranes
- Biological particles to be mixed with another filling material.



This translates into simplified work, superior regenerative induction and greater versatility of use of the fibrin block, ranging from the use of the whole block to the particles or membrane.

3. Liquid phase containing GFs: It is demonstrated that the liquid phase contains not only GFs, but also white cells and stem cells able to differentiate into specialized cell types.

4. Lower red phase: a dense, dark, reddish, gel-like coagulation consisting of concentrated red and white blood cells and clotting factors, that can be added to an autologous or heterologous bone when filling very large cavities.

We can therefore contemplate that the application of CGF in regenerative medicine should be conceived as a multifactor stimulation system. In fact, all the phases and components are used according to specific requirements. This versatility and multipurpose application makes it stand out among other techniques.

In addition to its significant applications in oral surgery, periodontology and tissue augmentation, the CGF system has shown noteworthy outcomes when used in facial aesthetics procedures. The CGF therapy is an advanced, powerful anti-ageing treatment for the ultimate natural approach to facial rejuvenation; it is toxin and animal product free and simply uses the patient's own blood.

The treatment is evidently effective in all aspects of facial aesthetics such as Mesotherapy (the liquid-phase LPCGF), the newly developed protocol for collagen induction (ICF), as well as non-surgical facial augmentation, lips enhancement and lip line couture, treating smile lines, the forehead, cheeks, neck, décolletage, hands, knees and elbows and other unwanted folds and wrinkles on the face in a similar fashion to dermal fillers, however achieving natural results, and more importantly not involving the injection of foreign chemical substances into the skin. As a result, the rare but potentially serious allergic reactions and inflammation seen with these products do not occur following the injection of CGF, not forgetting the cost effectiveness of using the autologous system to replace traditional fillers and homologues products. The autologous CGF is a relatively new biotechnology auto-graft, that evidently demonstrates significant stimulation and acceleration of soft-tissue and bone, healing and formation. The efficacy of this therapy lies in the local delivery of a wide range and high concentration of growth factors and proteins, mimicking and supporting physiologic wound healing, reparative tissue process and local infiltration therapy, taking the practice of regenerative techniques to a sophisticated higher level.

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Total Population
(2016)

46.5
million

Urban
Population

79.1%

GDP
per capita

26,528
USD

GDP

1,232.6
Billion USD

*Nulla inerdum
hendre it erat,
a ornare sem
consectetur id.
Maure id eget
dignae ac quam
molestie congue
et et velit.*

Focus on Spain

Author: Silvia Borriello

- Employment rate (1st quarter 2017): 60.4% of working age population
- Internet access (2015): 78.7% of all households
- Official Language: Castilian is the official State language. Other Spanish languages also have official status in their respective Autonomous Communities, in accordance with their Charters of Autonomy (Article 3 of the Constitution)
- Territory: Spain covers 505,955 km², third largest surface area in western Europe
- Political structure of State: Parliamentary Monarchy
- Head of State: H.M. the King Felipe VI
- Prime Minister: Mariano Rajoy Brey, since October 2016
- Party in power: Popular Party (PP)
- Political organization: the Spanish state is made up of the central state and 17 highly decentralized regions (Comunidades Autónomas, that is, autonomous communities) with their respective governments and parliaments

Spain's Economic Recovery

The Spanish economy is the fifth-largest in Europe behind Germany, United Kingdom, Italy and France and the 14th largest in the world. Following the financial crisis of 2007–2008, the Spanish economy plunged into recession, entering a cycle of negative macroeconomic performance. Compared to the EU's and US average however, the Spanish economy entered recession later (the economy was still growing by 2008), but stayed there for longer. **The economic boom of the 2000s was reversed, leaving over a quarter of Spain's workforce unemployed by 2012. In aggregated terms, the Spanish GDP contracted by almost 9% during the 2009-2013 period.**

The economic situation started improving by 2013-2014 and after three years of impressive economic growth, Spain's economy is experiencing a notable rebound facilitated by structural reforms and is now on the verge of exceeding its pre-crisis level of gross domestic product. Nine years after Spain slid into a long and bitter recession, the country is back where it was in 2008.

The recovery of the eurozone's fourth-largest economy shows that the unpopular policies pushed through at the height of the crisis worked. Despite causing initial pain, Spain's efforts have focused on reducing the inefficient and oversized government sector and reforming the labour market. Top income tax rates on individuals and corporations have been lowered as well. Furthermore, the decision to overhaul the banking system and cut the deficit paved the way for a return to growth.

Spain is now growing again and it is creating jobs and the outlines of a new economic model for Spain are beginning to move into view. But its ongoing economic recovery remains highly vulnerable to challenges related to ensuring fiscal stability and restoring the financial sector's competitiveness. **Despite relatively sound economic institutions and transparent regulatory and judicial systems, the indebted public sector is still a drag on overall economic dynamism.** A lack of progress in fiscal consolidation has resulted in a high level of public debt that is close to the size of the economy.

In fact, critics argue that the country's recovery is not just incomplete but that the price of austerity and reform was too high. The unemployment rate may have fallen sharply, but at 18.6% it remains far above the pre-crisis level and almost double the eurozone average. **Inequality has increased dramatically and public finances continue to bear the scars of the crisis: Spanish government debt is 100% of GDP, up from 40% before the crisis.** There is also concern about the low productivity of Spain's private sector and the poor state of the country's education system. But a deeper look at the origins and causes

of the post-2007 downturn suggests that Spain has tackled some of the country's old weaknesses. The once decrepit banking system is on a sound footing, companies have become more competitive and the over-reliance on construction is gone. In 2007, Spain accounted for more housing starts than Germany, France, Britain and Italy combined and 2.7m Spanish workers were active in the construction sector — equivalent to 13% of the national workforce.

Today, growth rates are nearly back to levels during the boom years. The Spanish economy expanded by more than 3% in both 2015 and 2016, far ahead of its European peers. That is expected to continue this year, with GDP forecast to rise at least 2.5%.

The composition of Spanish output is however the most important aspect. In the years before the crisis, the volatile construction sector accounted for more than 10% of GDP. Today, that share has fallen to 5%. At the same time, Spanish exports of goods and services have risen from 25% of GDP to 33%. The country's exports are also more diversified, with more companies in more sectors selling to more markets. The export boom reflects, among other things, the country's recent competitiveness gains. Spanish unit labour costs have fallen 14% since 2010, in response to long years of wage restraint as well as the new flexibility granted to companies by the 2012 labour market reform.

Possibly the most important break with the past has come in banking. **Messy and costly as it seemed at the time, Spain's 2012 banking bailout and recapitalisation package turned out to be vital for the country's recovery.** But it also meant that markets regained trust in the broader banking system relatively quickly and, most importantly, credit started flowing to the private sector and to households once again.

Overview of the Spanish Healthcare System

The Spanish healthcare system is considered among the best in the world, in 7th position in the ranking calculated by the World Health Organization.

Its National Healthcare System (SNS) or "Instituto Nacional de la Salud", is founded on Spain's General Healthcare Act of 1986 and guarantees universal coverage and free healthcare access to all Spanish nationals, regardless of economic situation or participation in the social security network. Non-nationals who participate in the social security system — and their family members — are also covered by public healthcare.

As the system is based on universal healthcare, non-residents and tourists (and even people living in the country illegally) are never denied treatment.

Population coverage is almost universal (99.5%) and guarantees quite a comprehensive benefits package to all citizens. Only 0.5% of the population falls outside this welfare network; this group consists

Spain is now growing again and it is creating jobs and the outlines of a new economic model for Spain are beginning to move into view.

of high-income non-salaried individuals who are not obliged to join the social security system as per the 1088/89 Royal Decree.

Organization of the Health System

The Spanish National Health System (SNS) is almost fully funded from taxes and predominantly operates within the public sector. **Provision is free of charge at the point of delivery except for pharmaceuticals prescribed to people aged under 65, which entail a 40% co-payment with some exceptions.**

Health competences were totally devolved to the regional level (Autonomous Communities) as from the end of 2002; this devolution resulted in 17 regional health ministries with primary jurisdiction over the organization and delivery of health services within their territory. **The Autonomous Communities' financing scheme promotes regional autonomy both in expenditure and in revenue raising (especially after the 2009 revision).** The reforms, which regionalised the system, were implemented to provide greater and equal access to the population, thus avoiding the concentration of health services in urban areas. This has also improved response time and increased the participation of the target community in the development and management of the national healthcare system at regional and local levels. On the local level, the "areas de salud" are the fundamental structures of the national healthcare system and are responsible for the unitary management of the health services offered at the level of the Autonomous Community. To increase operability and efficiency, the "areas de salud" are subdivided into smaller units called "zonas basicas de salud".

The national Ministry of Health, Social Services and Inequalities (MSSSI) is therefore vested with only a limited extent of power. It holds authority over certain strategic areas, such as pharmaceuticals' legislation and as guarantor of the equitable functioning of health services across the country, including the definition of the basic benefits basket, the setting of minimum thresholds for services regarding expenditure and quality. **While the Inter-Territorial Council of the National Health System (CISNS) is the highest body for the National Health System coordination, responsible for the cooperation and liaison among the central and autonomous region public health administrations.** The board is chaired by the National Ministry of Health and the members are the 17 Regional Ministers. It approves the national catalogue of services that must be provided by all regional health services (cartera de servicios comunes). **Decisions in the CISNS must be adopted by consensus and, as they affect matters that have been transferred, they can only take the form of recommendations.**

The Spanish National Health System under citizens' scrutiny

The Spanish Ministry of Health has recently released the 2016 Health Care Barometer. This annual survey since 1993, is designed to capture the degree of satisfaction of Spanish citizens with the public health system as well as their assessment of the health care services as users.

According to these latest figures, the general satisfaction with the public national health system has remained constant since 2010, scoring around 6.5 out of 10 in 2016. Further, a 69.6% of citizens believe that services are provided regardless of the socioeconomic status of the individuals, similar to the 70.9% declared in 2010. However, the perception of regional inequalities in the provision of health services has increased over time, with the percentage of citizens who declare that health services are offered equally among regions decreasing since 2010, from a 43.8% to a 37.7% in 2016. It is also relevant to highlight the steady increase in citizens who think that waiting lists are worsening, from 11.7% in 2010 to 28% in 2016.

The Health Care Barometer results are available (in Spanish) at the following link:

https://www.msssi.gob.es/estadEstudios/estadisticas/BarometroSanitario/home_BS.htm

Source: <http://hspm.org/countries/spain25062012/livinghit.aspx?Section=2.5%20Planning&Type=Chapter>

As in most European countries, the numbers in all categories of health professionals per 100 000 persons have increased over time; **it is worth noting the expansion in Spain of certain profiles, such as nurses, dentists or pharmacists (which have multiplied several times over their availability in the context of a growing population), compared to the relative stability of physicians.** This phenomenon reflects well how those professionals' role has grown within the range of services offered.

Primary Healthcare Services - The primary care network is entirely public and most of the providers are salaried professionals within the public sector with a few exceptions. Primary Healthcare services are available within a 15-minute radius from any place of residence. The main facilities are the healthcare centres, staffed by multidisciplinary teams comprising of general practitioners (family doctors), paediatricians, nurses, administrative staff and social workers, as well as, in some cases, midwives, physiotherapists and dentists' surgeries and are linked to some basic laboratory and image diagnosis resources, either in the same premises or centralized and serving several centres in the vicinity. There is a total of 13,121 primary health care centres that serve 35,233 citizens each on average.

Secondary Healthcare Services - Specialist care is



provided in specialist care centres and hospitals in the form of outpatient and inpatient care. **Access to specialist care requires referral from the GP, who acts as a gatekeeper.**

Around 40% of hospitals belong to the SNS; the remainder are privately owned, though many are included in the networks of public utilization or within a substitute concession by which their activity is publicly funded (around 40% of private hospitals' discharges in Spain are funded out of the SNS budget). The total number of hospital beds amounts to 160,981 or 3.43 beds per 1000 inhabitants. Overall, some 40% of total bed capacity is concentrated in big tertiary/quaternary hospitals with over 500 beds (mainly public); every Autonomous Community has at least one of these centres, with variations subject to access considerations such as levels of population dispersion and volume. **71.2% of the available beds are functionally dependent on the public sector.**

Health Expenditure

Based on 2015 OECD statistics and compared to health expenditure in other WHO European Region countries, Spain invests a percentage of GDP (9.3%) slightly below the average (10.4% in Belgium, 10.6% in Denmark, 11% in France, 11.1% in Germany and 9.8% in the U.K). **Most of the health expenditure, 71% relies on the public sector and is sourced mainly from taxation.**

The total expenditure of the Spanish Health System (both public and private), increased to 99,974 million Euros in 2015 (71,036 million coming from the public sectors and 28,937 million from the private). During the period 2011-2015 the annual average growth of total health expenditure was 0.2%. While public health expenditure decreased by 0.8%, private expenditure increased on average 2.8% per year.

The share of private health expenditure has increased over the years. The most recent international figures for Spain yield a 28.9% share of private sources in total health expenditure in 2015; this private expenditure unfolds into 22.4% funded out of pocket by households (mainly co-payment for drug prescriptions for under-65s, over-the-counter drugs, dental care and optical items such as lenses and glasses), 5.5% corresponding to private insurance and the remaining 0.9% spent by private non-profit-making organizations serving families.

The preference for paid, private healthcare is not caused by a lack in quality of the public system but mainly due to the long waiting periods patients are often faced with to see specialist doctors in the public healthcare system that can often be of weeks or months (excluding emergency care, which is immediate) or to access services such as adult dental care, which are limited within the benefits package.

Private voluntary insurance schemes still play a relatively minor, though increasingly relevant, role within the Spanish health system. In 2016, there were about 9.7 million private insurance policyholders in Spain (around 20% of the population), representing a 4.9% increase with respect to 2015.

Furthermore, the public system has traditionally contracted out some 15–20% of specialized care provision to private (mostly non-profit-making) hospital providers. This contracting out typically buys some high-resolution diagnostic services or outpatient surgical procedures as part of the management of waiting lists.

As far as per capita expenditure, total public health expenditure increased from 2,125 euros per inhabitant in 2011 to 2,152 euros per inhabitant in 2015, representing an average annual increase of 0.3% in the five-year period.

Total expenditure of the Spanish Health System (2011-2015), public and private (Million Euros)

	2011	2012	2013	2014	2015
Total Health Expenditure	99,191	95,742	93,662	95,382	99,974
Public Health Expenditure	73,261	69,152	66,552	66,799	71,036
Private Health Expenditure	25,930	26,590	27,110	28,583	28,937

Total health expenditure, public and private. Percentage of gross domestic product

	2011	2012	2013	2014	2015
Total Health Expenditure	9.3	9.2	9.1	9.2	9.3
Public Health Expenditure	6.8	6.7	6.5	6.4	6.6
Private Health Expenditure	2.4	2.6	2.6	2.8	2.7

Source: Spanish Ministry of Health, Social Services and Equality <http://www.msssi.gob.es/estadEstudios/estadisticas/sisInfSanSNS/pdf/SCSPincipalesResultados.pdf>

Spain has among the world's healthiest people with an average life expectancy of 81, one of the highest in the EU.

Health Market Trend

Spanish public healthcare institutions are the main purchasers of medical equipment and supplies and while they previously accounted for 80-85% of the market, austerity measures over the past several years have generated a decline in size and scope. This reduction in coverage has been offset to a certain extent by an ongoing growth in the private healthcare sector during the same period, which accounts for approximately 20% of the market and is still on the rise. The market for medical equipment and devices is estimated at approximately USD 8 billion. The regions of Madrid and Catalonia account for over 80% of medical equipment sales.

The sector relies heavily on imports. Imports in 2016 increased to approximately Euros 5.7 billion. Germany accounts for approximately 50% of the imports, while the U.S. has approximately 25 – 30% of the market share.

While a minority, large companies represent only 8% of the market, they account for approximately 60% of the sales. Because of each region being responsible for administering its corresponding healthcare budget, the rest of the market is made up of small and medium sized companies.

Except for companies in Madrid, Barcelona and the Basque Country, the vast majority operate mainly in their own region. However, these small and medium sized companies represent the 90% of the market and account for more than 40% of the sales.

Because of the difficult economic situation over the past few years cost-efficiency continues to be a deciding factor when it comes to procure-

ment. As part of the economic measures adopted by the Government, adjustments were made to the Value Added Tax (VAT). As of 2015, many healthcare products, medical equipment, sanitary instruments and other sanitary products that formerly paid 10% are now subject to the 21% rate. To reduce expenditures, more and more items, particularly single use items, are being imported from Asia. However, when it comes to more complex and sophisticated items, quality continues to be an important factor in the purchasing decision.

Non-EU companies need to have either a Spanish distributor or their own branch in Spain to participate in official tenders and to avail of other market opportunities, as also to provide the after-care service required by law.

Spanish manufacturers are compensating for the drop in domestic activity by stepping up their international activities. Medical device exports from Spain have increased over 20% since 2008. The figure for 2016 exceeded USD 2.7 billion, a 2.3% increase over 2015. Europe continues to be the principal destination for exports in this sector, with 70% of exports going to Germany, Portugal, Belgium, France and Italy.

Healthcare Assessment

Spain has among the world's healthiest people with an average life expectancy of 81, one of the highest in the EU. It is the 1st country in the world in organ transplants, the incidence of heart disease in Spain is among the lowest in the world, however, skin cancer is one of the highest.

Measured by international standards, the SNS ranks, in general, in a fairly good position yielding sustained good results in different dimensions of performance such as:

- population health status parameters
- coverage, access and financial equity parameters
- health care amenable outcomes, health care quality and safety
- users' satisfaction and system legitimacy according to the population (except for patient-oriented information and waiting list management).

These achievements have been attained with a relatively low level of expenditure (below the European average). The conclusion would then be that overall Spaniards are obtaining quite good value for money. Although international comparison offers important insights, in the case of a quasi-federal country like Spain assessment across the country becomes crucial. In fact, from the perspective of geographical differences in utilization and outcomes there is evidence suggesting large unwarranted variability in access, quality, safety and efficiency, not only across regions but mainly among health care areas and hospitals.

FACTS AND FIGURES ON THE DENTAL MARKET

Active dentists (estimated)	33,286
Active dental offices (2016)	21,500
Population to (active) dentist ratio	1,394
Number of new graduate dentists (2015-2016)	Between 1,500-1,800
Number of dentist training institutions	21 (public and private)
Membership of the Dental Association (Consejo General de Colegios Oficiales de odontólogos y estomatólogos de España)	100%
Dental technicians (2016)	Between 13,000 -14,000
Dental labs (dentists' & commercial labs)	4,200
No. of Dental Dealers	350

* All figures are approximate, varying year by year, taken and/or compared from different sources (see "among main sources" below).



- Share of dental expenditure on total health expenditure (2011) - 5%
- % of Oral Health expenditure private - 85%

The Spanish population has the right to all primary healthcare but dental, psychiatric and cosmetic services are excluded and almost all oral healthcare in Spain is provided by private practitioners with patients paying the total cost. A limited dental coverage is offered in each region through small Public Dental Services available to all sections of the population delivering free emergency treatments, for example extractions and prescription of antibiotics, although patients may be referred to an oral surgeon if necessary. Patients attending the public dental service pay nothing for their care. Less than 5% of registered dentists work in the service.

A few regions have introduced a capitation scheme, but only for children up to 14–18 years (depending on the region), except for braces. Framed within the SNS National Plan for Dental Health, the Ministry of Health has funded a broad set of dental health prevention and care measures in the years; the interventions include annual check-ups of teeth and oral cavity and dental treatment (fillings, endodontics, extractions and cleaning), in an attempt to homogenize basic dental care benefits for children across the regions.

There has been a positive evolution over the decades of the basic indicator “decayed, missing and filled teeth” (DMFT) at age 12 years, as shown below:

DMFT at age 12 years (mean value)

Year	1984	1994	2000	2015
DMFT index	4.2	2.3	1.12	0.7

Source: WHO Regional Office for Europe 2009 and Organizacion Collegial de Dentistas de Espana

DMFT in Spain 2015

Age	DMFT
5-6 (*)	1.1
12	0.7
15	1.3
35-44	8.4
65-74	16.3

(*) dft / Source: Organizacion Collegial de Dentistas de Espana

Spain has an excess of supply of dentists over need as it had a tradition of accepting dentists trained in “third world” countries, usually South America but, as entry examinations have become progressively more difficult, the numbers entering Spain have reduced.

92% of dentists in active practice are working in private (general) practices, largely in single-handed practice, most are self-employed and earn their living through charging fees for treatments. **Generally private practitioners accept only private fee-paying patients. There is no prescribed fee scale and the laws controlling free competition restrict the possibility of set fees.** However, prices for visiting dentists in Spain tend to be more affordable than in some neighbouring countries. Apart from the special compulsory insurance scheme for government employees with limited dental care covering only examinations, extractions and prophylaxis, there are several private health insurance plans which include these items and X-ray diagnosis. Several companies offer more comprehensive dental care for an additional premium. **However, just over 19% of the Spanish population uses private complementary insurances for their private dental care.**

Specialist care is very limited and no specialties are formally recognized (no specialist training in Spain). There are an increasing number of practitioners who are limiting their practice to a given specialty, mainly orthodontics, periodontics, endodontics and oral surgery. Clinical auxiliaries are limited to hygienists.

Patients in Spain do not attend for dental care on a regular basis, but tend to go when they have dental problems, only around 43% of Spaniards visit a dentist within a year. The dental association indicated in 2013 that there was a mean 2.2 years between visits to dentists by the population. Uptake of oral health-care services is therefore rather low in comparison with many other EU countries.

According to the Spanish Dental Council, there has been an evolution of treatment in the years. **In 2015 basic treatments have increased while more complex treatments such as implants and cosmetic dentistry have suffered a decline in demand up to 22%. 1 in 4 dentists has suffered important reduction in revenues.** In 2015 Spanish dentists worked 120 hours by month attending an average of 190 patients. A decrease in the number of hours worked is appreciated as well as the average number of patients in the second half of 2015. Spanish dentists devote 76% of their time to clinical activities, mainly curative care. The most commonly demanded treatments are restorative care, endodontics, prosthodontics and periodontics care.

QUICK FACTS, 2015

DENTAL CARIES

- 1.8 million Spanish children less than 12 years have dental caries in primary teeth (31.2%)
- 33 million Spaniards 12 years or more have dental caries in permanent teeth (86.5%)
- 803,000 Spaniards 64 years or more are fully edentulous (13.8%)

PERIODONTAL DISEASES IN SPAIN

- 8 millions of Spaniards have periodontal disease (30.7%), 1 in 3 adults
- 2 millions of Spaniards have severe periodontal disease, 1 in 13 adults

ORAL CANCER IN SPAIN

- Approximately 5,000 new cases of oral cancer were diagnosed in Spain in 2016, 1,200 Spaniard will die due to oral cancer: 85% of cases of oral cancer are diagnosed in Spain in late stage, early detection would reduce mortality by half.

USE OF DENTAL SERVICES

Adult population:

- only 5 out of 10 Spaniards have been to the dentist in the last year
- 8/10 chose a private dentist

- 1/10 chose a franchised clinic
- 1/10 chose a clinic insurance company

Which are the reasons for not going to the dentist in the last year?

- 56% don't have dental problems
- 21% for economic reasons
- 15% for fear of the dentist

Child population:

How often do your children brush teeth?

- 70% two or more/day
- 30% less

How often do you take your child to the dentist?

Age	Never been	Every 6 months	Every Year
2-6	54%		46%
7-10	11%	71%	18%
11-13		30%	70%

Which of the following treatments has your child received?

- 37% has received a dental restoration
- 17% has received a tooth cleaning
- 15% has received an orthodontic treatment

Source: Organizacion Collegial de Dentistas de Espana (2015)

Dental market - According to latest figures by the Association of Dental Dealers in Europe (ADDE) **total sales value of dental products in Spain reached 680.5 million Euros in 2016, ranking fourth after Germany (2,500 Mio. Euro), Italy (1,170 Mio. Euro) and France (1,123 Mio. Euro).**

Among the approximately 350 dental dealers in Spain, 80 are full service dental dealers providing also technical services, 15 are mail order dealers and 60 are specialized dealers concentrated on particular segments such as laboratory or orthodontics.

Considering the total dental business (dentists and laboratories), 43% of dental supply is delivered by solely full service dealers, 17% through mail orders, tele-sales and catalogue houses, 15% by specialized dealers, 13% directly by manufacturers. Only 3% of dental and laboratory consumables and equipment are supplied from outside Spain directly to dentists and technicians, bypassing the local dealer net.

As the Spanish market is fragmented in different regional markets joined by two hubs of Madrid and Barcelona, most of the dental companies wishing to appoint their representative in Spain focus on these two areas as the majority of agents, distributors, foreign subsidiaries and government-controlled entities that make up the economic power bloc of the country operate in these two hubs.

Sales channels to consumers have developed significantly in the last few years. While the traditional method of wholesalers selling directly to dentists continues, online sales are growing rapidly throughout the country.

Total Sales Values by Sector (2016)

Metal implants	215 MILLION EURO
Sundries	283 MILLION EURO
Teeth delivered to dentists and laboratories	11 MILLION EURO
After-sales technical service incl. spare parts	9.5 MILLION EURO

Source: ADDE, Association of Dental Dealers in Europe

Among main sources:

- Extracts from the "EU Manual of Dental Practice", commissioned by the Council of European Dentists. For full and detailed report: <http://www.cedentists.eu/library/eu-manual.html>
- ADDE, Association of Dental Dealers in Europe "2017 Survey of the European Dental Trade" for full report: www.adde.info
- Extracts from "Oral health in Spain: an update 2015" by the Spanish Dental Council, Consejo Dentistas (Organizacion Collegial de Dentistas de Espana)
- The U.S. Department of Commerce's International Trade Administration: <https://www.export.gov/article?id=Spain-Healthcare>
- http://ec.europa.eu/eurostat/statistics-explained/images/0/0b/Practising_dentists%2C_pharmacists_and_physiotherapists%2C_2014.png
- <http://data.worldbank.org/country/spain>
- Extracts from The Financial Times: <https://www.ft.com/content/254bb8a8-1940-11e7-a53d-df09f373be87?mhq5j=e3>
- <https://data.oecd.org/spain.htm>
- ICEX – Spain Trade & Investment, The Spanish institute for foreign trade <http://www.investinspain.org/invest/en/-invest-in-spain/spain-profile/spain-in-numbers/index.html>
- Extracts from "Health systems in transition" (WHO, on behalf of the European Observatory on Health Systems and Policies): <http://hspm.org/countries/spain25062012/livinghit.aspx?Section=2.5%20Planning&Type=Chapter>
- Ministry of Health, Social Services and Inequalities (MSSSI)

New EU Rules on Medical Devices to Enhance Patient Safety and Modernise Public Health

Brussels 5 April, 2017 - The European Commission welcomes the adoption of its proposal for two Regulations on medical devices which establish a modernised and more robust EU legislative framework to ensure better protection of public health and patient safety.

These replace the existing Directives.

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

The new Regulations on medical and in-vitro diagnostic medical devices proposed by the Commission in 2012 will help to ensure that all medical devices - from heart valves to sticking plasters to artificial hips - are safe and perform well. To address this, the new rules will improve market surveillance and traceability as well as make sure that all medical and in vitro diagnostic devices are designed to reflect the latest scientific and technological state-of-the art. The rules will also provide more transparency and legal certainty for producers, manufacturers and importers and help to strengthen international competitiveness and innovation in this strategic sector.

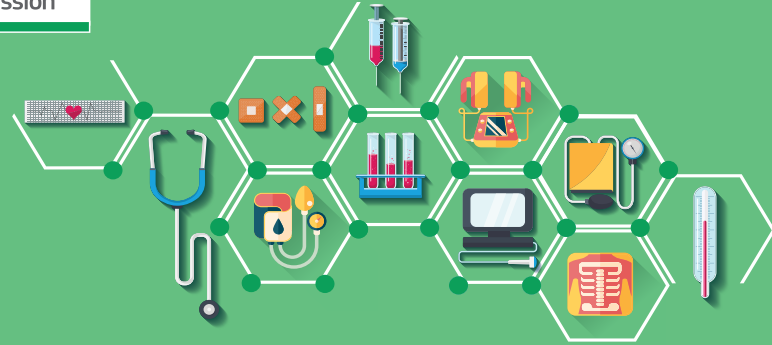
Elżbieta Bieńkowska, Commissioner for Internal Market, Industry, Entrepreneurship and SMEs, said: *"I'm extremely happy that our push for stricter controls of medical devices on the EU market will now become a reality. Whether for medical devices, cars or other products, we must ensure stronger supervision in the interest of our citizens. We should not wait for another scandal instead we should start a discussion how to strengthen European oversight over Member States' market surveillance activities."*

The two new Regulations bring a number of improvements for medical and in-vitro devices:

- **Improve the quality, safety and reliability of medical devices:** The new rules will impose tighter controls on high-risk devices such as implants, requiring a pool of experts at the EU level to be consulted before placing the device on the market. Controls will also be tightened on clinical trials as well as on the bodies that can approve the marketing of medical devices. The new rules will also cover certain, previously unregulated aesthetic products (e.g. coloured contact lenses that do not correct vision). In addition, a new system for risk classification in line with international guidelines will apply to in vitro diagnostic medical devices.



New EU rules to ensure safety of medical devices



EXISTING RULES

Outdated rules – rules on medical devices date back to the 1990s and don't reflect the technological progress made since then

Control of high-risk devices such as implants relies **on national Notified Bodies** – separate bodies risk inconsistency

Clinical trials taking place in more than one Member State are subject to **multiple national assessments**

Most aesthetic products, such as coloured contact lenses, are **regulated as general products**

Only one in five *in vitro* diagnostic medical devices is checked by a Notified Body before they are placed on the market

European database contains **limited** information on medical devices that is not publicly accessible

Varying and often limited information on implanted devices available to patients

In case of harm resulting from medical devices, compensation is **not guaranteed** if, for example, manufacturer goes bankrupt

Multiple registration procedures might be required for medical devices in different EU countries

NEW RULES

Up-to-date rules – new rules take into account technological progress and drive innovation

Control of high-risk devices such as implants involve also **panels of independent experts** at EU level

Clinical trials taking place in more than one Member State will be subject to **a single coordinated assessment**

Many aesthetic products are **regulated as medical devices and subject to stricter controls**

Four out of five *in vitro* diagnostic medical devices are checked by a Notified Body before they are placed on the market

European database contains **extensive** information on medical devices, most of which is publicly available

An **"implant card"** for implanted devices gives patients more information

A financial mechanism **ensures patients are compensated** in case defective medical devices harm them

Simplified procedure allows manufacturers to register their device only once at the EU level



- **Strengthen transparency of information for consumers:** The new regulations will make sure that vital information is easy to find. For instance, patients will receive an implant card with all the essential information, and a unique device identifier will be mandatory for every product so that it can be found in the new European database of medical devices (EUDAMED).
- **Enhance vigilance and market surveillance:** Once devices are available for use on the market, manufacturers will be obliged to collect data about their performance and EU countries will coordinate more closely in the field of market surveillance.

Background

There are over 500,000 types of medical devices and in-vitro diagnostic medical devices on the EU market. Examples of medical devices are contact lenses, x-ray machines, pacemakers, breast implants and hip replacements and sticking plasters. In vitro diagnostic medical devices, which are used to perform tests on samples, include HIV blood tests, pregnancy tests and blood sugar monitoring systems for diabetics.

The existing regulatory framework dates back to the 1990s and consists of three Directives. However, problems with divergences in the interpretation and application of the rules, technological progress as well as incidents involving malfunctions of medi-

cal devices—i.e. the PIP breast implant scandal—highlighted the need for revision of current legislation. The Commission is also currently working on more structural and horizontal solutions for better market surveillance within the broader frame of a goods package reform.

To address this, the European Commission presented two legislative proposals on medical and in-vitro diagnostic on 26 September 2012. This was followed by extensive expert consultations that resulted in an agreement on the general approach to the medical devices package among Member States' health ministers on 5 October 2015. The adoption of the package by Parliament, following today's vote in plenary, fully reflects the position of the Council reached in its first reading and in turn the agreement of the co-legislators from June 2016, therefore allowing to conclude the legislative process.

To allow manufacturers and authorities to adapt, the new rules will only apply after a transitional period. Namely, 3 years after entry into force for the Regulation on medical devices (spring 2020) and 5 years after entry into force (spring 2022) for the Regulation on in vitro diagnostic medical devices.

Source: European Commission Press Release, for more details: http://europa.eu/rapid/press-release_IP-17-847_en.htm

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Shanghai Stomatological Hospital, Fudan University



Shanghai World Expo Exhibition and
Convention Center, Shanghai, China
October 25~28, 2017



ShowStar

The Perfect Newsletter

Do you think the e-mail is dead?

The e-mail is the oldest web protocol, but it doesn't mean it has retired. Do you really think you can do without a fruitful strategy just because it's not the most recent one on the market? You fool!

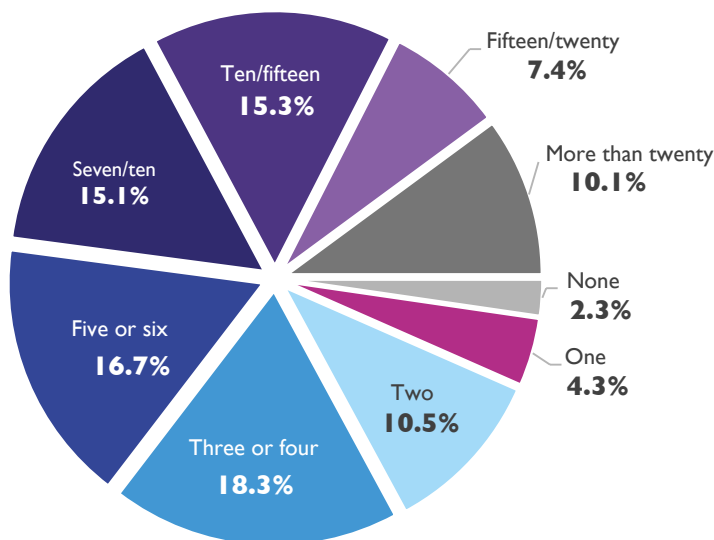
The e-mail is a tool with no rivals in customer care but it is also a media that can help you get in touch with your target and, most of all, it can be used to "nourish" potential customers and eventually turn them into customers.

MagNews has interviewed 1,000 Italian users by asking them what they wished to find in the e-mails, newsletters or DEMs they receive from other companies each day. The outcome will give you hints and advice on when you will need to plan your own content strategy.

Is it difficult to meet public expectations? Maybe. But not doing so means giving up a unique opportunity for your business: *human to human* communication.



How many Newsletters/DEMs do you receive each day?



Why subscribing to a newsletter?

Why do you subscribe to a newsletter? We've asked a thousand users. No one said they wished to receive daily newsletters full of fake discounts and institutional news of little interest.

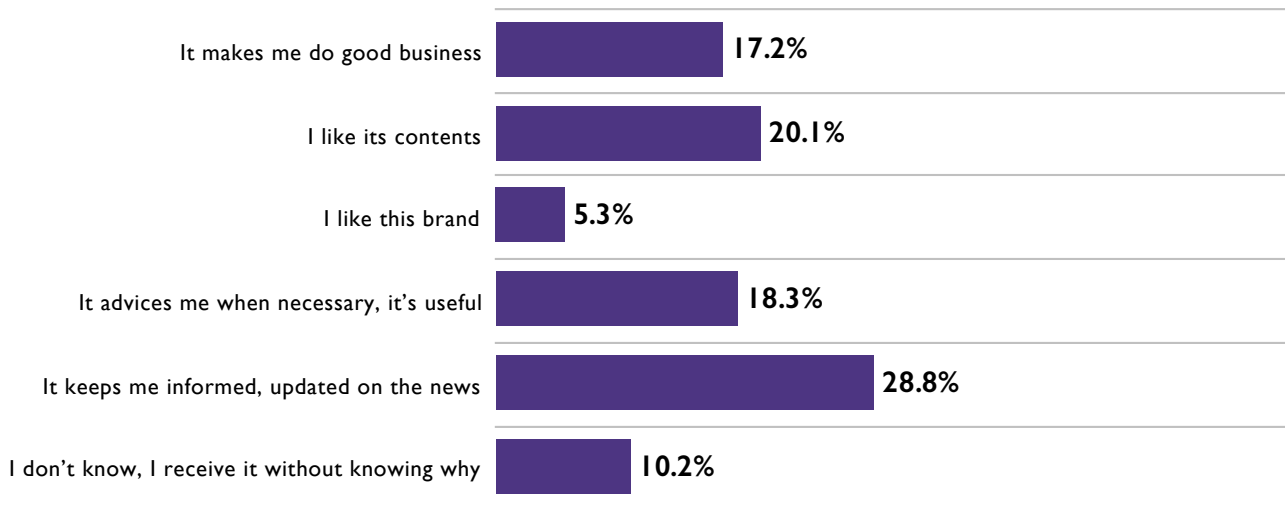
When you are writing to your mailing list you are writing to people that are trusting you (and given you their e-mail address), because you have promised them something. You should not disturb them with non-inherent information.

The main reasons of subscription to a newsletter are "It keeps me informed and updated" (28.8%); "I like its contents" (20.1%); "it advises me when necessary" (18.3%); "It makes me do good business" (17.2%).

Only 5% subscribe to a newsletter no matter of the contents, only because they are "fond" of a trade mark. Most likely, many are the brands believing to be favorite brands and believing that their news is important. But for the user this is not necessarily so.

Lastly, about 10% of users receive newsletters without knowing the reason. It's not nice. Those senders will give some work to the anti-spam filters.

Which are the reasons you have subscribed to this newsletter?



What do your favorite newsletters talk about?

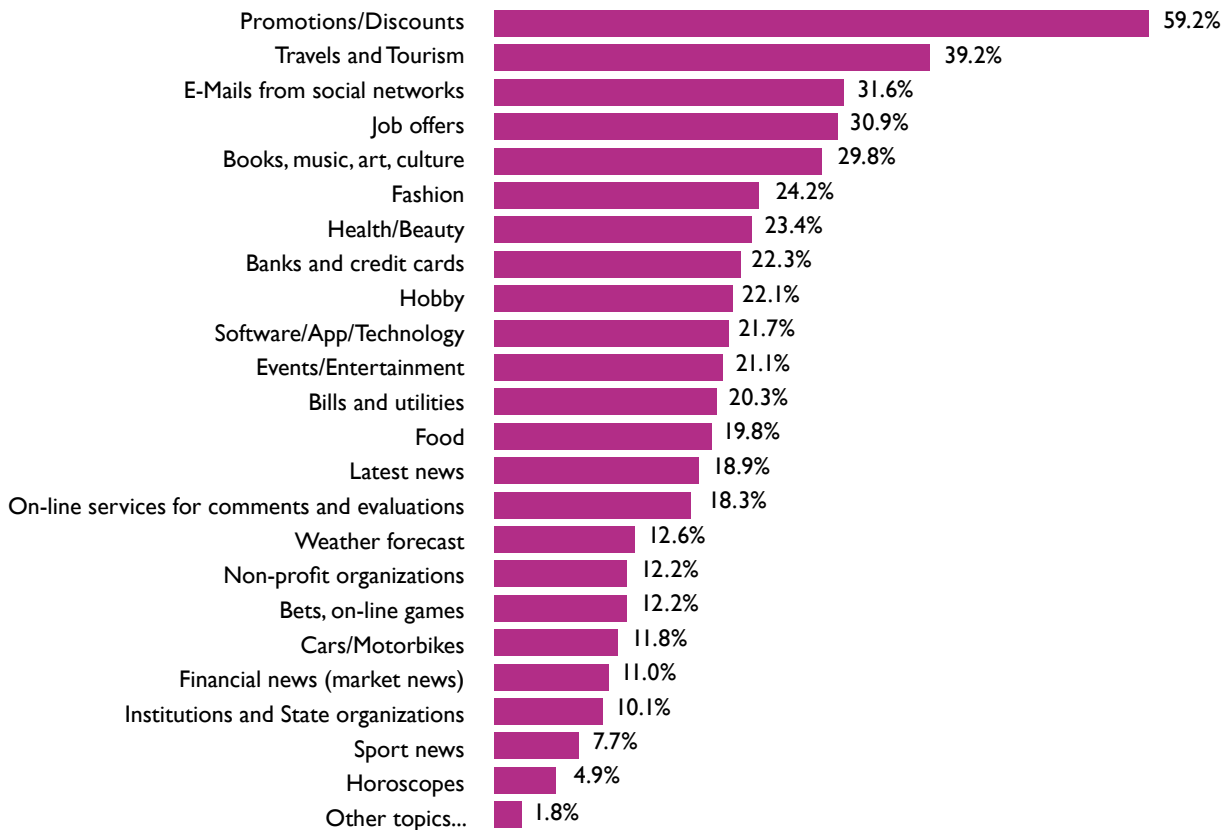
One subscribes to a newsletter because interested in specific topics. Creating a newsletter also means "to remain focused": you are not TV commentators.

Almost 60% of people subscribe to newsletters on "discounts/promotions". The second topic is "Travels/tourism": almost 40% of people interviewed subscribe to these newsletters. This data is not surprising, considering the exponential growth of on-line shopping for tourism services.

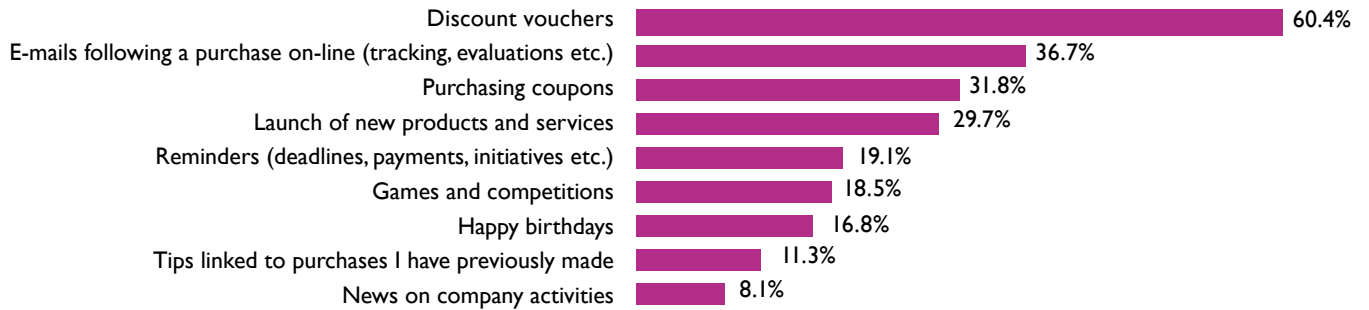
"Job offers" are also a strong topic; "Books, music, art and culture", "Fashion"; "Health/Beauty". Next are "Banks and credit cards"; "Technology"; "Events"; "Bills"; "Food".

Favorite topics are discounts and coupons (60.4% and 31.8% respectively). But also, service e-mails, those that follow an on-line purchase (order confirmation, parcel tracking...), "reminders" (deadlines, events...) are significant and receive their "like" from users.

Which are the topics of the newsletters you have subscribed to?



And which are the contents you most like?

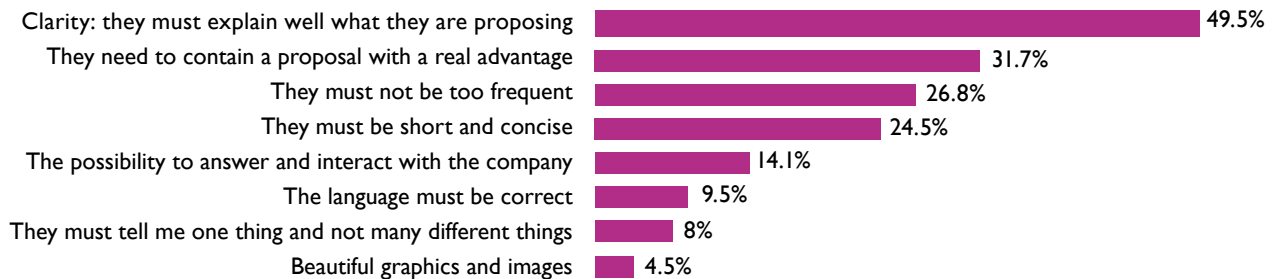


Newsletter: How would you like it?

Clarity (and not simply conciseness) is considered the most important characteristic in a newsletter from 49.5% of people interviewed. 31.7% wishes to receive discounts and proposals with a real profitability and 26.5% doesn't want to receive too many updates.

Only 4.5% of interviewers gives much importance to the graphics of the communications they receive from companies. Linguistic correctness gains a good 9.5% of preferences.

Which are the most important characteristics in the newsletters you receive?



Diennea-MagNews is a company specialized in digital marketing solutions since 1996. A complete partner to aid businesses in designing their digital strategy, from technology to consultancy.

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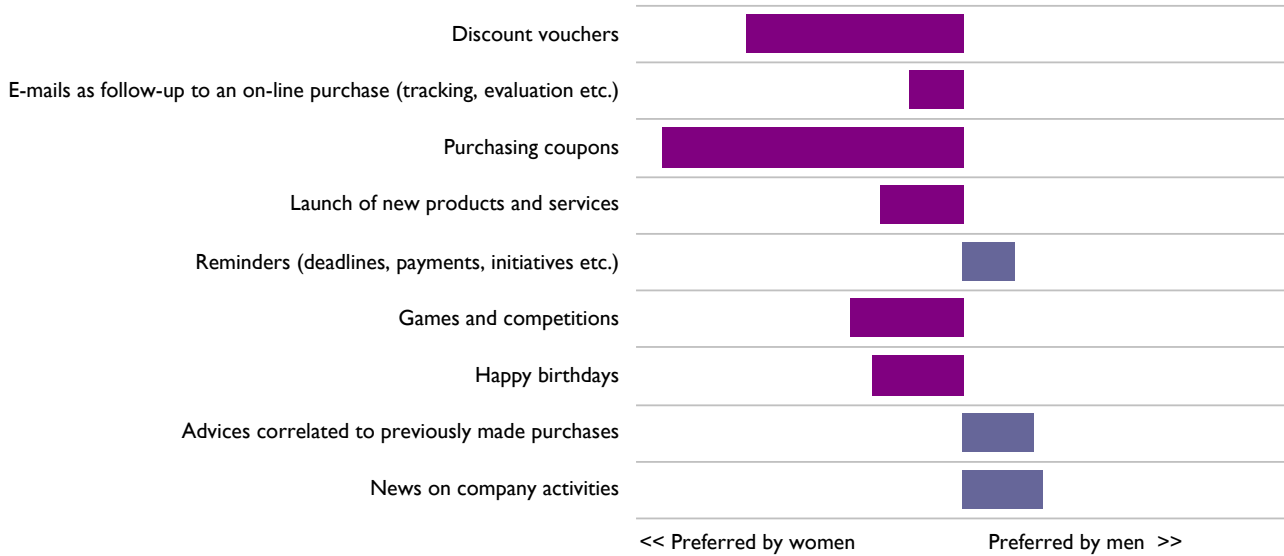
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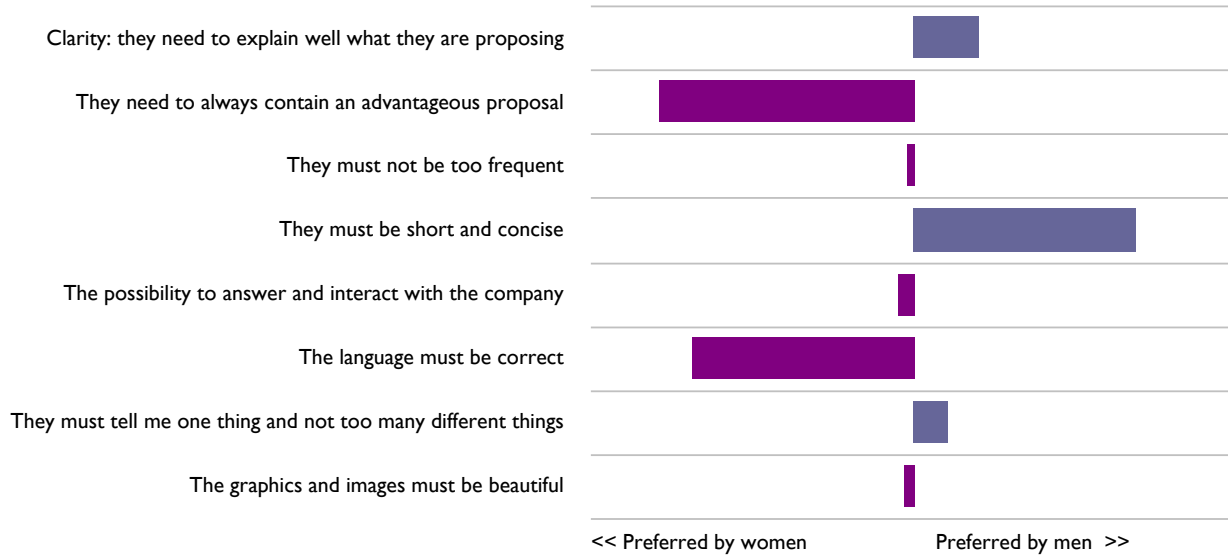


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Which is your favorite characteristic in the newsletter you receive?



Which are the contents you most like?



Men and Women

Lastly, we finish with some curiosities on the different preferences between men and women. Who prefers to receive happy birthdays from companies? Women! And advice on products correlated to previously made purchases? Men. And if men seem to appreciate clarity and conciseness more than women, the latter seem to place more attention on grammar and spelling.

The research sample

1001 internet users of at least 15 years of age were interviewed. The sample represents a collectivity of 30.5 million individuals and weighed per gender, age, geographic area of residence, device usually utilized to access internet (desktop, smartphone, tablet). The research took place in January 2015 in collaboration with the Human Highway Research Institute.

Let's give some numbers!

940 million e-mails received every day in Italy

+30 per user

59% subscribers to newsletters offering discounts

220 million e-mails from companies

+7 per user

39% subscribers to travels/tourism newsletters

Source: <http://www.magnews.it/newsletter-perfetta/>
MagNews is a very powerful software for the creation and sending of newsletters and for the management of your mailing list! But it is also made up of a team of consultants ready to plan with you incredible e-mail campaigns!

The Italian dental market: current prospect and evolutionary trends



Roberto Rosso
CEO at Key-Stone
www.key-stone.it

After the structural crisis that hit the industry in 2012, the operators' trust in the future is perceived as comforting.

To analyse the dental industry, we should consider simultaneously two different sectors, connected but not necessarily dependent one to the other: the "national market" and the "Italian production".

The first one concerns consumptions and investments in our Country of both dental practises and dental laboratories, while the second takes into account the production of devices by Italian manufacturers, intended to satisfy the domestic demand and partially aimed to the export.

The Italian dental market

Nowadays, the total market value almost reaches 1.2 billion euros, getting closer for the first time to the all-time record set in 2011. This value is determined by "retail" prices, that is the purchase of devices by dentists and dental technicians.

Just like the Country in general, also this industry is living a positive period confirmed by the economic trend of the first trimester 2016, showing a slow recovery in consumption and a substantial increase of investments towards dental equipment.

As shown in the graphic, the trends in consumption (red line) are rather uniform and structural, while the equipment sector (blue line) is characterized by sudden turns due to the higher cyclical nature of the professionals' investments.

Regarding the equipment sector, after a stagnant and negative development in the 2014-2015 two-year period, we can notice, since the second half of last year and the first months of 2016, a surge in sales closing at +10% until the end of March.

As said before, way more homogeneous are the consumption trends closing at +3.2%: these are directly linked to the workload (number of patients and treatments) unlike the investments in technologies, strictly subordinated to the operators' trust and sense of confidence in the future.

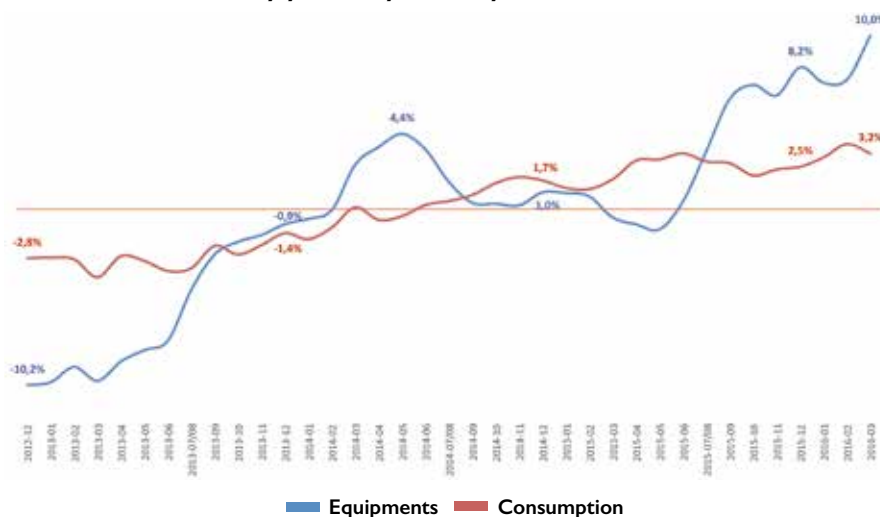
Following the positive trend of this first trimester, 2016 could become the awakening year for this sector, hoping that the sales recovery comes together with an increase in the number of provided care and patients.

The positive signals derived from the equipment sales for dental practices and dental technicians come without any doubts from the digital development and from some other influencing factors: such as a renewed positive "sentiment", the tax benefits and the new dentistry models.

After the structural crisis that hit the industry in 2012, the operators' trust in the future is perceived as comforting. Now the operators start to make major purchases again, innovating their business. Especially involved in this renewal are dental laboratories, considering the ongoing digital revolution of the production methods necessary to survive the competition. Key-Stone research shows that 60% of Italian dental laboratories offer dentists the possibility to realize devices digitally.

The tax benefits established by the 2016 stability law, allow to put into effect this

Monthly year-on-year analysis of economic trends



The Italian dental market: current prospect and evolutionary trends

renovation cycle: for instance, the tax bonus is an excellent help for the purchase of capital goods and an opportunity for professionals to equip themselves as well under the digital aspect. All of this, dumping the costs in the following years.

The third driver is the booming in recent years of group dental practises belonging to "franchising": since 2012 the number doubled, counting today more than 600 group dental practices. In the biennial period 2012/2013 we saw a much faster development of these realities, recovered again in 2015 despite numerous closures. The year 2016, even though is experiencing a growth slowdown, should be monitored due to the declared upcoming opening of such dental practices.

The Italian production

The Italian dental production has always been known as the crown-jewel of our manufacturing industry. With a strong presence in almost every country in the World, its trend is constantly overseen by the studies that Key-Stone, on behalf of UNIDI, has been carrying out for the past 10 years.

Taking a closer look to the manufacturing sector, we should remember that Italy represents one of the most important hubs for the production of medical and dental devices, presenting almost always a virtuous trend: without counting the 2009 sudden crisis (-3,5%) and after an incredibly positive two-year period in 2010/2011 followed by a growth slowdown, the year 2015 proved to be the year of the dental awakening with a reassuring 4.1% growth, consolidating the Italian dental sector to 802 million euros.

These Italian dental industry positive data owe its performance mostly to the export market which in 2015 reached approximately 490 million, with a 40% increase from 2009 until now (average trend on the period 5.8%). This shows the worldwide confirmation of appreciation and importance for the Made in Italy in the dental sector.

Source: Il mercato dentale italiano: attuali prospettive e trend evolutivi. R. Rosso - Doctor Os - 2016; XXVII (6): 473-474

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EXPODENTAL MEETING 2017

With a 20% increase over 2016 and 18,000 total visitors, Expodental Meeting proves to be a reflection of a more than ever vital sector

Expodental Meeting 2017 confirmed and exceeded the success of the first edition in 2016: **281 exhibiting Companies and more than 18,000 visitors with an overall 20% increase compared to the 2016 statistics.** The exhibition and the comprehensive cultural and scientific program - more than 35 clinical and non-clinical events and workshops - has attracted a huge number of dental professionals and buyers, which resulted more business opportunities and returns for the Exhibitors.

Expodental Meeting is the showcase of the Italian dental industry, which has confirmed its position in the forefront of international markets on the strength of products that are appreciated throughout the world for the reliability of their components, their avant-garde technological solutions and pleasing design.

Expodental Meeting is growing together with the Italian dental sector, which has proved to be as vi-

tal as ever, with growing investments by Italian dental practices and dental technicians' laboratories.

Expodental Meeting represents the most important hub for the Italian dental world, even from a more political point of view: in fact, thanks to UNIDI, the Italian Dental Industries Association, the fair hosted a Conference organized and promoted by the Italian Ministry of Health, concerning sustainability and access to oral health prevention and treatment, especially during childhood.

What really made the difference at this year's edition was the new pavilion called **EXPO3D: an entire area totally dedicated to the digital workflow from dental practice to dental lab.** Besides the display of materials, equipment and technologies used within the digital workflow, a comprehensive scientific program entirely focused on digital technologies took place, including events by dental associations and scientific lectures by academic experts.

Infodent International long-standing marketing partnership with the most international trade exhibitions around the world



Infodent International marketing team at Expodental Rimini with the Greater New York Dental Meeting team, Dr. R. Edwab, Executive Director (first left) and Dr. Marc B. Gainor, General Chairman (last right)



The Infodent International marketing team at Expodental Rimini with Dr. Matios Tcholakian, Senior Business Development Manager for the AEEDC Show in Dubai (third from left)



Expodental Meeting is becoming more and more international, thanks to the intense cooperation with ICE/ITA (Italian Trade Agency): more than 80 foreign delegates from 26 Countries met the Italian Companies in 1,250 b2b meetings.

For further Inquiries on the show:
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Stomatology St. Petersburg 2017



On 16–18 May 2017 the 20th International exhibition of equipment, instruments, materials and services for dentistry Stomatology St. Petersburg was held in St. Petersburg, Russia.

Stomatology St. Petersburg is the largest by the number of exhibitors and visitors spring dental exhibition in the Northwest Russia. 86 leading local and foreign suppliers of tools and materials took part in the exhibition and presented equipment, instruments, materials and services for dentistry: dental technology and lab equipment, dental units, disinfectants, orthodontic and composite materials, surgical instruments, impression compounds, cements, teeth whitening systems, tools and others.

Among the participants there were DIF/Dental Implants, GlaxoSmithKline, Johnson & Johnson, DRC Group, SPLAT, VLADMIVA, JVMTranzit, Dentex, CORAL, MEGASTOM, N.Sella, Olimp-Dental, RAUDENTALL, North Carolina, Techno-Dent Group, EURMED Neva, UNIDENT and many others companies.

Brands regularly represented at Dental-Expo St. Petersburg: 3M ESPE, ADIN, AVERON, CROSSTEX, DENTSPLY, ELEXXION, FEDESA, FGM, DENTSCARE, GENDEX, GERMIPHENE, IDS, INIBSA, ITENA, IVOCLAR VIVADENT, JUN AIR, KAVO, KERR, KEYSTONE, MEDICA, MELAG, MYRAY, PLANMECA, RENFERT, SS WHITE, STERN WEBER, VOCO, WATERPIK, ZHERMACK and many other brands.

Within three days **3924 people visited the exhibition.** Among them:

- 3414 visitors make or influence purchasing decisions in the company
- 2550 visitors do not attend other exhibitions on similar subject
- 98% exhibitors consider the exhibition to be important for their business

Within the framework of the exhibition business programme the following conferences took place:

- All-Russian scientific-practical conference '**Dentistry topical issues**'
- XXII International conference of maxillofacial surgeons and stomatologists '**New technology in dentistry**'
- All-Russian scientific and practical conference of the Periodontal Association 'RPA' with international participation '**Periodontology and implantology selected issues**'
- XIII All-Russian scientific and practical conference '**Pediatric dentistry and dental diseases prevention**'

The conferences were organised with support of Russian Dental Association, Dental Association of St. Petersburg, Pavlov First St. Petersburg State medical University, North-Western State Medical University n.a. I. I. Mechnikov, St. Petersburg Institute of Dentistry Postgraduate Education.

The exhibition organisers are PRIMEXPO / ITE St. Petersburg and DENTALEXPO companies. Among the organisers joint projects there is the International exhibition Dental-Expo St. Petersburg that will be held in St. Petersburg in EXPOFORUM on 24–26 October 2017.

Find out more at:

stomatology-expo.ru
dental-expo.com/stomatology



STOMATOLOGY
ST.PETERSBURG

Dental Salon 2017

41st Moscow International Dental forum and exhibition "Dental Salon 2017" was successfully completed on the 20th of April in Crocus Expo. The result of the forum and exhibition revealed some trends of the industry and speciality. There is a growth in buying activity of the visitors, a trend in complete solution based on digital technologies as well as in the field of diagnostic and prophylaxis of stomatopathy. Russian dentists' interest towards the scientific program of the forum is very indicative. Practically all conference halls and presentation zones on booths were occupied, taking into account that Moscow forums DentalExpo offer a very large program that consists of more than 500 educational events.

The exhibition lived up to the exhibitors' and visitors' expectations and even surpassed them.

The main events of the Forum are: within

the framework of the Russian Dental Association events were held 13 simposia, from which the most interesting were "Club of periodontists of Russia", "Topical issues in the orthodontics", "Children's dentistry", "Strategy and tactics of dental rehabilitation", "Endodontics", "Problems in organising radiographical examination". International congress ENDOPOINT attracted a record number of participants. More than 450 doctors from all over the country as well as from abroad came to the Congress in order to listen to foreign and Russian opinion-leaders. A new simposium ORTHOPERIO had a very successful start and attracted 190 participants. The preparations for Dental Expo 2017 in September are already started. Forum and exhibition are going to be even more interesting and widespread. Don't miss the event!

www.dental-expo.com/dental-salon



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CEDE 2017

#CEDE2017: exhibition and education - the perfect combination



26
**Central European
 Dental Exhibition**



1
**Polish Union
 Dentistry
 Congress**

**Poznań, Poland
 14-16.09.2017**

The 26th edition of Central European Dental Exhibition (Poland, Poznań, 14-16 September 2017) is the announcement of change - to make it better than ever. For a quarter of a century Central European Dental Exhibition was not only the scene of fantastic progress in Polish dentistry, but often its initiator. In Łódź and Poznań, those who met decided on the direction of development, at first technological, and with time also scientific. Exhibitors in the 26th edition of CEDE have, by the end of March, booked nearly 5 000 m²

in exhibition pavilions. All those interested will be able to visit the exhibition free of charge upon registration. Nowadays, organisers believe that the best exhibitions cannot function without a good educational part. Five sessions, satellite seminars, renowned experts from Poland and the world and a rich blend of science and practice for representatives from all fields of dentistry - this will be the premiere edition of the Polish Union Dentistry Congress, which from this year will be an important part of CEDE.

The formula of the Congress will be modelled on the standards of organisational and substantive events such as the Association Dentaire Française Congress in Paris or the annual FDI World Dental Congress. – The FDI 2016 Poznań Congress proved that Polish dentistry, both in terms of content and organization, has nothing to be ashamed of. It gave us the answer to the question of: which topics are popular and which speakers from home and abroad are able to talk about them interestingly. We want to continue to educate representatives from all fields of dentistry - ensures prof. Marzena Dominiak,

The Chairperson of the Scientific Council of the Union of Polish of Dentistry, prominent surgeon and implantologist, President of the Scientific Committee of FDI 2016 Poznań.



Participation in the Congress has already been confirmed by, among others, the prominent implantologist Itzhak Binderman, the excellent endodontists: Renato de Toledo Leonardo, Hugo Sousa Dias, Vittorio Franco and Antonio Cerutti and renowned experts in the field of paediatric dentistry - Jacobo Limeres Posse and Mindra Badea. Poznań will also be attended by Frank Liebaug, CBCT specialist.

CEDE 2017 mobile application

CEDE 2017 mobile app is a useful and convenient tool that provides all necessary information to the Congress participants and exhibition visitors. The app is available for IOS, Android and Windows systems, free for all smartphone users.



26

Central European
Dental Exhibition

1

Polish Union
Dentistry Congress

Poznań, Poland 14–16. 09. 2017



- **Polish Union Dentistry Congress:**
world level of education and organization, innovative idea of scientific integration, learning opportunities for all dental professionals
- **CEDE 2017:**
the most important dental exhibition in Central and Eastern Europe, leading producers and distributors of equipment, tools and dental materials, polish and international products premiere.



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Henry Schein Supports Volunteer Endodontists Expanding Oral Health Care In Jamaica

Company Donates Health Care Products and Funds to Support Foundation for Endodontics' Outreach Trips to Jamaica's Treasure Beach Community



MELVILLE, N.Y., July 5, 2017 -- Henry Schein, Inc. (Nasdaq: HSIC) announced today its commitment to donate \$100,000 in health care products and cash over the next five years to the Foundation for Endodontics in support of the organization's upcoming outreach trips to treat the endodontic needs of people living in the underserved Jamaican community of Treasure Beach and surrounding areas. The donation is an initiative of Henry Schein Cares, the company's global corporate social responsibility program, and Henry Schein Dental.

As part of the donation, Henry Schein will donate \$8,000 in health care products—including endodontic motors, files, and filling materials—and Henry Schein Dental will contribute \$12,000 in cash each year through 2021 in support of the Foundation's outreach trips to the Helping Hands Clinic in Treasure Beach. In three previous outreach trips to the area, volunteer endodontists, endodontic residents, and dental students treated more than 1,200 patients and performed over 100 root canals. Henry

Schein's support will allow the Foundation, which is the philanthropic arm of the American Association of Endodontists (AAE), to conduct four outreach trips annually.

"We are grateful to have the support of Henry Schein, which understands the impact that the Foundation for Endodontics can have on the oral health and overall health of people who lack access to quality endodontic care," said Dr. Peter Morgan, President, Foundation for Endodontics. "Thanks to this generous donation, our volunteers are able to deliver treatment to a greater number of Treasure Beach residents, thus enhancing their quality of life while improving public health."

Dr. Morgan recently sat down for a conversation with John Ferone, Senior Director, Global Endodontic Category Management, Henry Schein Dental, to discuss the power of volunteerism in the endodontic community as part of #ScheinChats, the company's Facebook Live interview series. The chat took place at the recent AAE annual meeting in New Orleans.

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National Pavilions



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9
Exhibition
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“Henry Schein is pleased to support the Foundation for Endodontics, whose commitment to enhancing the oral health of people in need so closely mirrors our own,” said Stanley M. Bergman, Chairman of the Board and Chief Executive Officer of Henry Schein. “This agreement will provide the Foundation with the resources it needs to conduct its outreach work, while also increasing the number of patients who will receive the high-quality endodontic care its volunteers so ably provide.”

About the Foundation for Endodontics

The mission of the Foundation for Endodontics is to support endodontics by providing resources and funding for research, education, public awareness and access to care. The Foundation for Endodontics supports saving natural teeth for all through the efforts of endodontic specialists. For information about the Foundation for Endodontics, please visit www.aae.org/foundation.

About Henry Schein Cares:

Henry Schein Cares stands on four pillars: engaging Team Schein Members to reach their potential, ensuring accountability by extending ethical business practices to all levels within Henry Schein, promoting environmental sustainability, and expanding access to health care for underserved and at-risk communities around the world. Health care activities supported by Henry Schein Cares focus on three main areas: Advancing wellness, building capacity in the delivery of health care services and assisting in emergency preparedness and relief.

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About Henry Schein, Inc.

Henry Schein, Inc. (Nasdaq: HSI) is the world’s largest provider of health care products and services to office-based dental, animal health and medical practitioners. The company also serves dental laboratories, government and institutional health care clinics, and other alternate care sites. A Fortune 500® Company and a member of the S&P 500® and the Nasdaq 100® indexes, Henry Schein employs more than 21,000 Team Schein Members and serves more than 1 million customers.

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Headquartered in Melville, N.Y., Henry Schein has operations or affiliates in 32 countries. The company’s sales reached a record \$11.6 billion in 2016, and have grown at a compound annual rate of approximately 15 percent since Henry Schein became a public company in 1995.

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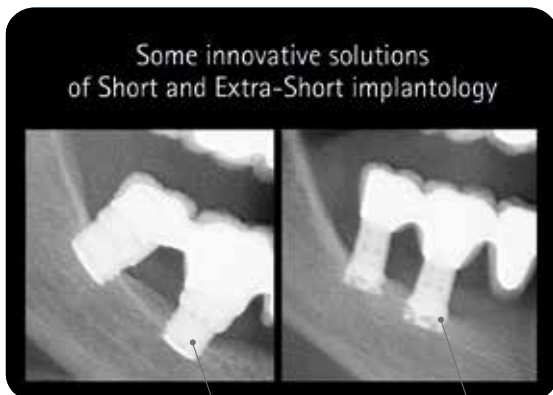


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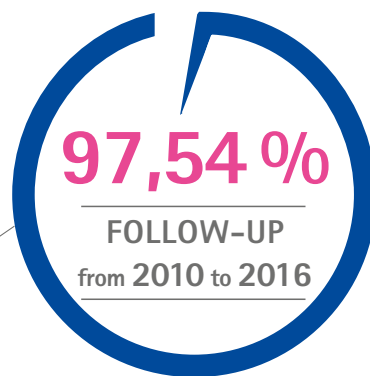
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