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Helena Sparf, Dental Hygienist, Finland

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Focus on the US
Dental Industry



ISO Quality
Management Principles



New Standards in
Tooth Whitening



Growth in the
Dental Industry

No Pre-Registration

2011

87th Annual Session

Greater New York Dental Meeting[®]

Scientific Meeting:
Friday, November 25 -
Wednesday, November 30



Exhibits:
Sunday, November 27 -
Wednesday, November 30

For Additional Information Visit www.gnydm.com

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T-BLACK

LESS ABRASION AND WEAR-OUT

MORE EFFECTIVE CUT AND LOWER HEATING OF THE TISSUE

ANTI-REFLECTIVE SURFACE



SURGYSONIC® MOTO

SURGYSONIC MOTO is a brand new approach to hard tissues surgery. Thanks to the combination into a single device of the high speed brushless micromotor and the "Ultrasound" technologies, it widens its applications from the dental field to general surgery and ultrasonic debridement.

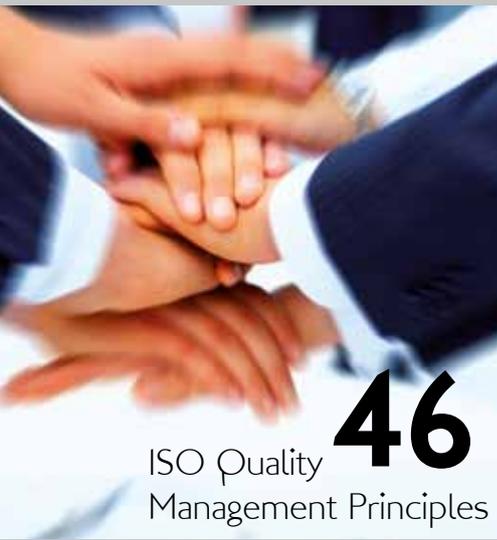


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AGE Solutions is an Italian company located in Pontedera (PISA) that produces 3D Dental Scanner, and CAD applications.

AGE Solutions is specialized in the elaboration, visualization, comparison and processing of tridimensional data coming from 3D acquisition systems.

Thanks to a technology result of years of research in 3D and to a development team highly qualified that works with passion and competence, AGE Solutions S.r.l. offers hardware and software solutions of quality, flexible and highly innovative, at very



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B&L Biotech, Inc. was established in January 2000 by two Korean Endontists who shared a common goal of providing and improving the quality of treatment delivery and patient care with unprecedented innovation, excellence, quality, service and product development.



B&L is now servicing over 32 countries worldwide and employ about 45 people in our main office in Seoul, Korea. In May, 2010 B&L has opened their first facility in the USA outside of Philadelphia to better serve the global dental community.

B&L is one of the fastest rising companies in the global dental community. B&L has partnered with a leading dental company to introduce the first cordless gutta-percha delivery system and heated plugger system known respectively as the Hot Shot and Hot Tip. Along with a patented micro-projection ultrasonic tip technology, these are just a few of B&L's innovative products, with many more to come.

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 URL: www.bnlbio.com

Our company established in 1983 and expanded its import program very rapidly and successfully according to the trends and needs of the Turkish Dental market . While we have been one of the leading Dental Equipment importer-distributor company at Turkey, we started manufacturing and exporting HILUX Halogen Dental Curing Lights and exporting worldwide to 50 countries.



One universal model designed to cover all world market and able to provide the needs of most demanding dental applications like bracket bonding, multiple veneer bonding, inlay onlay cementation, Daylight shade selection or Photo dynamic disinfection with its most ergonomyc anatomic design.

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All world markets are open for distribution. Please ask a possible distribution or private labeling of a Curing Light you are searching for.

BENLIOGLU DENTAL Inc.
 Mrs. Zula Benlioglu /Export Manager
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VICTOR V200
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China's quality brand, Suzhou Victor Medical Equipment, has more than a little Italian design and technology in its range of modern dental units. Over 30 years experience based in China's most up-to-date industrial region combined with the know-how of Europe's leading multi-brand dental equipment manufacturer make the Victor range a winning choice in terms of reliability, design and value for money.



which ensure maximum quality and minimum waste, the dentist benefits from equipment which is conceived exclusively around their real professional needs. Select materials and ergonomic design features are the result of decades of research conducted by the Italian design laboratory throughout the world.

The V200 is an Italian design concept incorporating modern day technology and components. Built according to strict manufacturing principles

Contact details:
 E-mail: roberto.capucci@victordentalequipment.com
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Bio Micron Transilvania was founded in 2004, in Cluj-Napoca (Romania) as a result of a higher demand of dental implants on the global market, at the initiative of Bio Micron Italy, company founded in 1972 by association of engineers and researchers having experience in aerospace technology and bio-medical engineering.



We address mainly to the medical domain as we process the titanium, but we may as well execute parts of small size and high accuracy for the following:

- cars manufacturing industry
- electronics
- aerospace
- munition
- automotive
- chemical industries

Due to the fact that the know-how of Bio Micron Italy has been transferred to our company by consultancy concerning the purchase of control and technological equipment, respectively by training the operating personnel, we are proud that today we are able to achieve the same performance as the traditional manufacturers. Our purpose is to find high quality processing solutions and it is focused on the following principles:

- High accuracy
- Reliability
- Productivity
- Innovation

BMT produces according to the requirements and needs of their clients, fulfilling strictly all their conditions.

BMT's aims are to:

- Support the clients in all their needs
- Help them develop new products
- Be more flexible towards clients demands

Contact details:

Phone: +40 264 599 608

E-mail: europa@biomicron.eu- Website: www.biomicron.eu

DiaDent is one of the leading Endodontic Supply Companies in the dental industry since 1985. DiaDent has grown to become one of the world's leading dental companies, specializing in Endodontic devices and materials as like Gutta Percha Points, Paper Points, Endodontic Files, Composite Resin Items and Obturation devices.



Always striving to be better, DiaDent puts in our utmost effort to improve our Endodontic lines, furthermore we have expanded our product lines adding innovative items to fulfill and satisfy our customer's needs and demands. DiaDent will continue to see every challenge as an opportunity and we will do the best to be perfectly positioned as one of the world's recognized leaders in the dental industry.

DiaDent's innovative and top quality items and processes are recognized as the world's brand, today DiaDent has been exporting them to over 950 dealers in 112 countries all around the globe.

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For 30 years, Your ergonomic requirements are the challenges to our creativity of work methods.

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Diagram activity also focuses on the implementation of new techniques permitting the optimisation of both equipment and working methods.

for finishing and aesthetic characterizations. The material acquires excellent adaptation to the cavity under treatment.

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MARIOTTI & C was founded in Forlì – Italy - in 1973, as a company specialised in designing and manufacturing precision mechanical equipments. Our first machinery line entered the market of the dental sector in 1978, as we started to produce micro-motors for dental laboratories.

Over a few years, and as a result of constant research and experimentation, our company reached a well-deserved success, thanks to the production of specialised machinery which can satisfy all technical needs, can guarantee users' satisfaction and comply with requirements of modularity, simplicity, ease of use, strength and reliability.

Today, our experience is the result of a merge of different skills in the mechanical sector: our company production is based on equipments such as laboratory MICROMOTORS, including the last brushless generation, on PARALLELOMETERS/MILLING-MACHINES and on the new systems



of ENDODONTIC and IMPLANTOLOGY micromotors, able to meet the specific requirements of professionals and trainees. The high quality and technology of our products offer countless possibilities of programming with the best ease of use and can guarantee extreme reliability and high performance under all working conditions.

MARIOTTI & C. SRL
Forlì ITALY

Via Seganti 73 – 47100

Tel: +39 0543 474105- Fax: +39 0543 781811

E-mail: info@mariotti-italy.com - Website: www.mariotti-italy.com

FTC – Friedheim Tool Co. is the manufacturer and distributor of the small JOFRE® Table Top Steam Cleaners that are in use by all kinds of industries for all kinds of different cleaning applications. (www.ftcsteamers.com)

THE LAB MODEL STEAM CLEANER can be used for cleaning instruments and equipment prior sterilization with super heated steam vapor.

FDA Registration #3005033500

FULL 195 PSI of Steam Power will do the following: clean models, impressions, articulators, remove oil, grease, polishing compounds, grime and other contaminants in seconds. Perfect for consecutive porcelain bakes. HANDS-FREE NOZZLE INCLUDED



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Innovative prophylactic and therapeutic R.O.C.S. oral care products are available for ordering worldwide!

DRC research and production group of companies – manufacturer and distributor of R.O.C.S. in Europe, CIS, Asia is inviting everyone interested in additional information or in ordering R.O.C.S. products or samples to visit official company portal <http://www.rocsinfo.com> and e-shop <http://shop.rocs.eu>.

DRC company is one of the leaders in oral care premium segment. Since 2006 DRC, including manufacturing department, is ISO-9001- (2000) 2008 certified. Manufactured products formulas are protected by European patents, toothpastes passed product safety control in EU, received product dossiers and conformity certificates.



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1 // SCHWERT Composite Instruments



This new set of SCHWERT composite instruments is distinguished because of their new smoother, harder and more scratch resistant coated instrument tip. Because of that and the black anti-glare surface, the modeling gets even easier for the dentist.

In this inexpensive set the 4 most popular modeling instruments are combined in a wash tray. It consists of a small and delicate spatula for smallest cavities. The bigger spatula for bigger cavities. The pear-shaped burnisher and the modeling instrument for fissures, in a combination of contra-angle and double-angle, complete this set for everyday use. Of course all the instruments are available separately as well. The exchangeable working tips are mounted in a premium plastic handle, so it is possible to replace just them instead of the complete instrument. Their ergonomic and lightweight handle allows a tactile and non tiring handling.

For further information please contact:
A. Schweickhardt GmbH u. Co KG – SCHWERT Instruments
 78606 Seitingen-Oberflacht, Germany
 contact@schwert.com- www.schwert.com

2 // The Aloe Vera Powder Free Latex Examination Gloves- A patented glove

Formulated with Aloe Vera Gel to moisturize the skin, Blossom brand textured powder free latex examination gloves are low in water soluble protein and chemical allergens.

The Aloe Vera used in this product has been certified by the International Aloe Science Council, Inc and rated by The Dental Advisor at 96% and also been awarded Gold Medal by The Poznan International Fair (Dentistry Fair - Saldent 2007). These gloves are available in Sizes X-Small, Small, Medium and Large and are packaged 100 gloves per box, 10 boxes per case.



For more information, please visit our website www.blossom-disposables.com or fax your inquiry to +1 (510) 293-9056 in USA

E-mail: blossomglo@aol.com

3 // Fimet dental units - Known for their ergonomics

Placing Fimet units is easy thanks to their compact sizes. The movement ranges of the units are extensive and versatile. The dentist's working area is optimized to ensure comfortable and ergonomic working positions. Instruments, trays, suction head, and cuspidor are all easy to reach. They are adjustable according to the needs of the dentist, the patient and the requirements of the current treatment.

The wide selection of available options allows a huge amount of different configurations to serve every dentist's needs and preferences. Turning and detachable arm rests and a large selection of head rests are among the many options available.

Fimet units have an easy-to-use wireless foot switch for controlling both the chair and the unit. The wireless control improves hygiene by making cleaning easier and is convenient to use.

Fimet Oy
 Teollisuustie 6
 FI-07230 Monninkylä, Finland
 Tel: +358 19 521 6600
 Fax: +358 19 521 6666
 fimet@fimet.fi- www.fimet.fi



4 // DR. DETOX The Ionic Sponge Oven Cleaner!

Dr. Detox eliminates ion contaminants that can cause problems with metal work and ceramics. An oven cleaned with Dr. Detox eliminates greening, discoloration, and bubbling in porcelain restorations. Extends the muffle and the thermocouple life because there is no longer a need to take the muffle to high temperatures when cleaning the oven as with old-fashioned carbon products. Maintains the thermocouple accuracy by removing the ions of various metals that stick to the thermocouple and distort temperatures.

Formula 1: Removes Ag, Pd, Cu and Co.
Formula 2: Removes Li, Sr, Fe, K, Cd, Cs, Ca, Al, Hg, Zn, Cr, C, Rb, Na, Ba, Mg, and Be.

Gold is not a problem alloy. Other alloys that are in the gold that are the problem.

Dr. Detox Kit Includes:
 ½ lb. of Formula 1
 ½ lb. of Formula 2
 1 Ceramic Crucible
Price: \$49.95 US per kit

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 For free samples and information visit www.wonderfill.com.
 1.254.772.4661 or in EU, call 0.808.120.2372.



5 // The New Tecnomed Italia's Communication Kit

Tecnomed Italia pays always attention to customer requirements and it has launched into the market a new communication and diagnostics kit consisting of a digital X-ray DC, Tecnoray RVG sensor, USB intra-oral camera and touch screen PC monitor. The intra-oral camera and RVG sensor are managed by a single multimedia software that facilitates, simplifies and optimizes the work of the dentist.



The Tecnomed Italia multimedia kit has all the modern technology in dentistry. On the touch screen PC monitor, the program has a virtual assistant that, when called by a button on the desktop, grants the installation of updates and resolve any problems.

**Tecnomed Italia s.r.l. Via Salvador Allende n.2, 61040
Castelvecchio di Monte Porzio (PU) Italy
Phone +39 0721 95 65 14 Phone +39 0721 95 51 46
Fax +39 0721 95 52 29**

6 // FGM offers the best in worldwide aesthetic dentistry



FGM, the dental bleaching leader in Latin America offers what's the best in worldwide aesthetic dentistry. In addition to its 80% Brazilian market share, the company faces the competitive international market being present in more than 40 countries.

Whiteness, the FGM bleaching product line sets design trends in terms of packages, as a synonym of:

- Safety and efficiency for the procedures
- Practicability and trust for dentists
- Comfort and the best results for patients

Learn more about Opallis and Ambar to reach excellence in restorations.

Opallis is a microhybrid composite resin with nanoparticles, developed under strict quality control and high technology, privileging the right viscosity and brightness.

Ambar is a light curing conventional two-step adhesive with nanoparticles and ethanol-based solvent, that allows high bond strength and clinical longevity.

The company holds important technologies to make professionals' daily life easier and successfully with more than 160 items.

FGM, you're worth it.

Please visit www.fgm.ind.br for more information

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Export sales manager (Latin America, Spain, Portugal, Germany): Alexandre Hashimoto | alexandre.hashimoto@dentscare.ind.br | +55 47 3441 5421

7 // DIA-PLUS G7 – Single Component Self-Etching Light Cured Bonding Agent



Dia-Plus G7, the innovative 7th Generation bonding agent offers superior and consistent bonding results on dentin and enamel with one bottle, one coat self-etching bonding system.

- Has Etch, Desensitize, Prime and Bond all with One-Bottle, One-Coat bonding system and no separate etching
- Fast 3 Steps (less than 35 seconds) reduces the risk of contamination
- Offer a tight and long-lasting bond between light-cured composite and both enamel and dentin by a highly advanced formulation whether wet or dry on dentin and enamel
- Strong and tight bond to dentin and enamel is offered by 4-MET monomer for adhesive to dentin and phosphoric acid ester monomer for superior bonding strength to enamel
- Consistent and a long term bond strength with the unique Nano-Filler
- Provide a very low risk of post-operative sensitivity
- Remarkable thin bonding layer less than 10µm offers a frosty surface for much easier application of the first composite layer



**DiaDent Group
International- Rep. of Korea
www.diadent.co.kr
diadent@diadent.co.kr**

8 // R.O.C.S. offers all major oral care products



R.O.C.S. products range is developed taking into consideration all individual differences and preferences of various consumer groups to provide most effective care of your smile!

R.O.C.S. offers all major oral care products – toothpastes, toothbrushes, sprays, mouthwashes, interdental and dentures care products – more than 50 products in common. Professional range - R.O.C.S. Medical helps dental professionals to solve important treatment and aesthetic problems of patients, in particular to restore dental enamel mineralization in cases caused by increased sensitiveness of teeth, erosions or enamel spots of different etiologies.

R.O.C.S. is actively developing new ideas for the industry – for example manufacturing of eco-products with high level of clinical efficiency or manufacturing of oral care products for various age groups (toothpastes range for children consists of three main groups – 0-3 y.o, 4-7 y.o. and 8-18 y.o)

More information about R.O.C.S. oral care products can be found on official company portal <http://www.rocsinfo.com> and e-shop <http://shop.rocs.eu>.

9 // Surgysonic Moto and T-Black: Moving Forward

Esacrom, is leader in the design and production of electronic and medical devices and is continuously working on the evolution in the field of hard tissue surgery. The skilled experiences of Esacrom staff in terms of electronics and mechanics, together with the national and international expertise of our scientific board, have set the basis for the realisation of a new device, which represents a turning point in hard tissues surgery.



SURGYSONIC MOTO, is a combination between the technologies of "Piezo" and "micromotor". It confirms the brand Esacrom in the dental field and widens its application to the General Microsurgeries: Neurosurgery, ETL, Maxillo-facial and Orthopedics. ESACROM regularly invests time and resources in the development of new products and new finishing.

To this purposes we would like to introduce the new line of T-Black.

A brand new finishing is applied on our standard tips resulting in a more effective cut and lower heating of the tissue. At the same time thanks to the higher hardening we can grant a less abrasion and wear out and the anti reflective surface grant a better visibility of the operating fields.

The whole range of our "tips" are made by our own production facility and represents the largest number of models present in the market.

Esacrom pays very much attention to details. In fact the new concept is the result of a long and continuous research of Esacrom, translated in its current design by Sardi Innovation – leader in the Innovation business. Surgysonic moto will be available in different colours to satisfy different aesthetic needs and the very compact configuration has been designed to allow an easy handling and need a minimum of space in the clinic.

Other innovative solutions are still in-progress and soon will become true, thanks to the skills and energy of Esacrom's team and the investments in research and development. Esacrom's evolution does not stop, but will continue for more and more to transform new ideas of today into the reality of tomorrow, finding new solutions again.



ESACROM SRL - Italy
www.esacrom.com - Esacrom@esacrom.com

10 // Nova Instruments

Nova dental instruments offer excellent quality at competitive prices, backed with outstanding service. From explorers, probes, excavators and carvers, to scalers, forceps, mirrors and syringes, every instrument is manufactured by highly skilled craftsmen at Dentafix – the international experts in precision engineering who have been producing dental and surgical instruments for almost 30 years, and now craft more than 30,000 each month.

Nova insists on using the highest quality 440C and T303/440A grade stainless steel, with enhanced heat treatment for increased strength, resistance to wear, and long life. Nova has just launched a new range of ergonomic mirror handles in four distinctive colours. Other recent innovations include Titanium Nitride tip composite instruments, silicone handle periodontal instruments plus a lightweight resin handle range. And it's not just about great products – Nova provides excellent dealer network support, including quality photography, catalogues, advertisements, exhibition artwork plus a detailed website.



For more information visit www.nova-instruments.com.

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II // Implant-bridge comparison model set (Tooth Model 3000)

Quickly compare and contrast restorative implant treatment versus a three-unit bridge with the Implant-Bridge Comparison Model Set (Tooth model 3000). Enlarged 6X life-size, each two-model set includes:

- One model with as simulated implant fixture and abutment with removable crown
- One model with a adjacent teeth prepped for the removable three-unit bridge

Both have removable teeth with anatomical roots. Durable, stable plastic bases.

For more information please visit www.hanildent.com



12 // Presentación kit de Osteosíntesis MACO

Introducción:

La implantología actual ha experimentado un indudable auge, hoy prácticamente no existe consultorio dental donde no se empleen los implantes dentales como método predecible para la restitución dentaria.

Sin embargo, las exigencias de los pacientes son cada vez mayores, y hoy en día no se puede aceptar un tratamiento que no alcance unos niveles de éxito, estéticos y funcionales, muy elevados.

Para dicho fin el manejo de técnicas mucogingivales y de regeneración ósea son unas herramientas fundamentales.

El propósito del presente artículo es el de mostrar, al colectivo de profesionales de la salud dental, un kit de fijación de tornillos desarrollado por la compañía Maco y diseñado por quien firma éstas líneas.

Que resulta de enorme utilidad tanto para el manejo de injertos de tejidos blandos, como de injertos óseos (autógenos o alógenos) y para técnicas de Regeneración Ósea Guiada.

Descripción del producto:

Se trata de set compacto y de enorme versatilidad, con una serie de peculiaridades en su diseño que lo hacen enormemente atractivo para su uso clínico.

- Dimensiones del cuerpo del tornillo: tres diámetros de fijaciones de 1'2 mm, 1'6 mm y 2'0 mm con cabeza en cruz. Para los siguientes fines: los tornillos de 1,2 se emplean para la fijación de membranas y corticales óseas estrechas (menores de 1 mm), los de 1,6 mm para la fijación de los injertos corticales anchos (mayores de 1 mm de espesor) o los injertos corticoesponjosos, y por último los tornillos de 2 mm de diámetro para la fijación de grandes injertos óseos o para rescate de los tornillos de 1,6 mm (por falta de sujeción de los mismos).

- Diseño autoperforante del tornillo: se trata de un tornillo que presenta una parte apical con gran capacidad de corte, una espira incremental en cuanto a tamaño, lo que permite por una parte la penetración sencilla del mismo en el lecho receptor y por otra la correcta estabilidad del tornillo.

- Todos los diámetros de los tornillos son insertados con un mismo acoplamiento para el destornillador, que puede ser accionado manualmente o mediante micromotor reductor.

- Base de la cabeza del tornillo: Semiesférica. Lo cual permite la colocación de los tornillos de forma disparelela, asegurando una máxima estabilidad del injerto, y evitando la invasión de tejidos blandos en el interior del lecho.

- Kit de fresas perfectamente estandarizado, lo que garantiza el correcto asentamiento del tornillo, sin necesidad de emplear las fresas repetidas veces en un mismo área.

Conclusiones:

El desarrollo, por parte de la industria, de materiales altamente evolucionados, donde se han optimizado cada uno de los aspectos y se han superado los más exigentes controles, permiten al usuario disponer de una herramienta de trabajo que le ayudará a la consecución de tratamientos de la más alta calidad.

Es por ello que me enorgullece presentar el Kit de Osteosíntesis de Maco, con la certeza de que les será de enorme ayuda en su práctica diaria.



Fdo. Dr. Juan Alberto Fernández Ruiz.

www.macointernational.com

13 // “Bravo” new milling-machine for the best precision

The design staff at Mariotti is proud to present the new milling-machines line “Bravo”.

This represents a real evolution in precision and lightness at the same time. Thanks to the cooperation with the milling expert dental technicians, Bravo allows optimum working conditions for the best milling technique with the greatest precision system. Another very useful device is also the new internal light to work well without any shade.

Vertical and micrometric with 360° freedom of movement, the milling-machine arm can be used for: milling, vertical movement, parallelometer, attachment placing. The set includes: 1000/30000 rpm micromotor with internal light, power supply with rpm and reverse display, 90° tilting and electro-magnetic holding model-table. Approximate size: cm 25x25xh40.



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14 // HI-TEC IMPLANTS LTD

HI-TEC IMPLANTS LTD is an innovative dental implant manufacturer established in 1991. The production facility - located in Herzlia, Israel - includes all production processes under one roof:

- State-of-the-art CNC machines
- Surface processing
- Clean room assembly
- Clinical testing



HI-TEC IMPLANTS LTD complies with the highest international standards, approvals and directives in the field of medical devices: FDA approval since 1994, CE mark – Medical Devices Directive 93/42/EEC, ISO 13485:2003, ISO 9001:2000.

HI-TEC IMPLANTS LTD specializes in producing unique as well as compatible implants and are the inventors of mini/monoblock implants.

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- Vision root shape implant compatible with Nobel Replace
- Logic Bone condensing implant compatible with Nobel Active.

Monoblock Implants:

- TRI- mini implants for cement or ball attachment.
- TRX- for screw retained prosthesis.
- TRX-OP monoblock implants for cemented restorations
- TRX-BA & TRX-TP monoblock implants with ball attachment

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15 // Keystone Industries

Pro-form manufactures the only pre-made laminated mouth guard material in the industry.

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16 // Mectron Piezosurgery® touch

Mectron launched the very first generation of PIEZOSURGERY® in 2001, in a time where talking about piezoelectric bone surgery was revolutionary and pioneering at the same time!

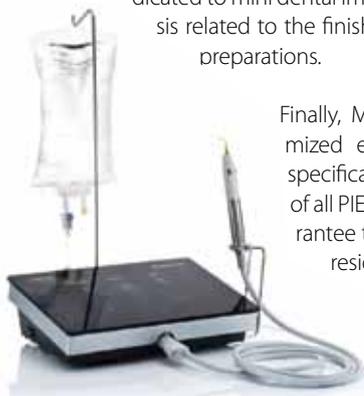
In the last 10 years, this new surgical technique has become a standard in many clinical indications, from sinus lift techniques to split crest, from periodontal surgery to implant site preparation. Many universities and famous surgeons have contributed in validating Mectron Piezosurgery® worldwide: today, more than 100 international publications makes it the only evidence based technology for piezoelectric bone surgery.

Mectron is presenting the last generation of PIEZOSURGERY®, with the main aim to consolidate his philosophy of "clinician orientated" unit. Highest attention has been paid to the user interface, in order to make the controls even more intuitive: an exclusive black glass touch screen allows to select in no time the correct bone quality and the irrigation flow rate – and here you go!

Not only the touch screen, but also the complete device can rely on a new hi-tech design, which guarantees optimum ergonomics and easy to clean surfaces.

Furthermore, the new Mectron PIEZOSURGERY® touch is characterized by a new handpiece with LED which enables the user to switch the light on or off directly from the keyboard, or to select the "auto" mode to activate automatically the LED when the foot pedal is pressed.

New inserts will be available for Mectron PIEZOSURGERY®: from tips dedicated to mini dental implants to new applications in prosthesis related to the finishing of the cervical margin in crown preparations.



Finally, Mectron is introducing a new customized enzymatic solution (Enzymec – 1L) specifically dedicated to the "clean" function of all PIEZOSURGERY® devices, in order to guarantee the maxim result in removing organic residuals from device tubings, handpiece, inserts and dynamometric wrench. Enzymec represents also a valid detergent to clean all the hand surgical instruments by soaking. Scientific tests have shown its cleaning efficiency distinctly superior as compared to standard enzymatic solutions.

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17 // T-CRYSTAL

Perflex Ltd, develops continuously new formulas of high performance materials and tools to simplify the working processes in dental laboratories, we are proud to introduce the new innovation! a premium thermoplastic material: T-CRYSTAL which CAN BE RELINED WITH CONVENTIONAL ACRYLICS, suitable for ALL TYPES of removable dentures specially for IMPLANT-RETAINED OVER DENTURES, FULL DENTURES, PARTIALS, MINI DENTURES, NIGHT GUARDS without the need of a metal construction for reinforcement.

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18 // WEINGART pliers

Otto Leibinger GmbH has recently enlarged its orthodontic program by some variety of the universally used WEINGART pliers. All of them are designed with an ergonomic handle that provides comfortable use. Their special surface grip ensures an easy use. Additionally the program has been completed by some combination instruments as there are two different ligature instruments with strong tips and different angles as well as an universal Explorer / Ligature Instrument for placing bands and to remove cement straps.



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19 // Sabilex Injection System Flexible Partial



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* Multicentric prospective study published on the Official Journal of The Spanish Oral and Maxillofacial Surgery Association, Vol. 35 Num. 5. September-October 2009.

21 // Right solution for impression – A Patented New Mixing tip

With high technology, Seilglobal Co., Ltd developed new version of mixing tip. It is used for impression, resin and core materials. Unlike general mixing tips, it can be easily combined with material cartridge by two-way rotation system. Any kinds of impression cartridges are compatible with new mixing tips which means you don't need to find out the exclusive cartridge at all. Material leak in the bottom of mixing tip cylinder has been protected by two inner protrusions.



Along with the technological advancement, manufacturing process is simplified and it has effect on products' cost. Therefore patented new mixing tips can be on hands of dentists with cost-effective price. In Korea, Japan, China, Seilglobal Co., Ltd has a patent on new mixing tip as well as patent pending in EU, U.S.A. Brazil, India, and Taiwan. In addition, new mixing tip has been applied for Patent Cooperation Treaty.

Seilglobal CO., Ltd, Korea

Address: #715-1 Choryang 3-dong Dong-Ku, Busan, Korea

Tel: 82 51 465 5456 Fax: 82 51 465 5459

Email: world@seilglobal.co.kr

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22 // Esthetic Dental Prosthetics

prிடidenta® is offering esthetic dental prosthetics with the highest quality standard, manufactured in a new highly innovative and efficient production process. The prிடidenta® GmbH, Leinfelden-Echterdingen, emerged from prிடidenta® b.v., Netherland. prிடidenta® b.v. is an internationally leading provider for denture teeth made of acrylic and ceramic.

The business foundation of prிடidenta® GmbH is grounded in a completely digitalised production process of dental prosthetics using CAD/CAM technology.

Achieving aesthetic dental care more reliably, rapidly and economically than ever before is what the new prிடi®process is all about. It integrates well-known CAD/CAM systems, providing an additional, new imaging technology, and it enables the deployment of pre-produced ceramic glass crowns, the prிடi®crowns.

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23 // NewTom: the first Company to Apply the "Cone Beam" Technology in Dental Field

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24 // Innovation - Technology - Rapidity - Simplicity - Reliability

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27 // Laboratorios Inibsa - Dental Anaesthetics

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28 // Injection Molding Technology

TAVDental is a Division of TAV Medical Ltd with over 40 years of experience in product design. The company's main area of specialization is production, using injection molding technology, which enables the manufacturing of an impressive variety of quality products for the dental market and the rising demand for implantology and metal-free products.

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29 // Tribest Dental Products Co.,Ltd.



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30 // Providing Dental Professionals with Innovative Solutions

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Focus on: The US Dental Industry

Basic facts

| | |
|---------------------------------------|--|
| Area: | 9,826,675 km ² |
| Population: | 312,4 million |
| Capital: | Washington, D.C. |
| Government: | Federal presidential republic with 50 States |
| GDP, 2010, current prices: | US\$ 14.526,5 billion |
| GDP per capita, 2010, current prices: | US\$46,860 |
| Main export destinations: | Canada, Mexico, China |
| Main import sources: | China, Canada, Mexico |

The US economy has been facing a very difficult year, due to several internal and external factors including the downgrade of its debt rating, rising inflation, weak job growth, high oil and energy prices and tensions in the EU area resulting in persistent market volatility that impacted significantly on household and business confidence.

**For the period 2011 - 2012,
the International Monetary
Fund forecasts a moderate
1.5 to 1.7% GDP growth**



The US Department of Commerce estimated 1.3% annual increase for real GDP in the second quarter of 2011, after weak 0.4% growth in the previous quarter, a slight increase that is mainly due to a deceleration of imports and rising federal government expenditure that counterbalanced the lower consumer spending. Exports of goods slowed in 2011 but were partly compensated by a pickup in exports of services. However, both State and local government spending decreased and personal income also slowed down in consequence of higher social contributions.

For the period 2011 - 2012, the International Monetary Fund forecasts a moderate 1.5 to 1.7% GDP growth, which is likely to remain modest through 2012 and 2013 in comparison to the pre-crisis era.

Issues in Medical Coverage

The main indicator of the ability of US citizens to afford adequate healthcare services is the profile of health insurance coverage. About half Americans under 65 obtain health coverage as an employer benefit. The federal social assistance programs, Medicare and Medicaid, are responsible for coverage of elderly, children and lower income groups, together with other state-subsidized insurance programs. However, the picture is not very comforting at the moment, as the reform of the healthcare system that aims to

expand coverage to the majority of the American population has to deal with the necessity of tighter fiscal policies and budget cuts, while the number of uninsured increases due to the struggling economy and the high unemployment rate. In the last decade, the decline in employer-sponsored health coverage caused a growing number of uninsured; currently, the percentage of people covered by this type of health insurance is about 55.8%.

According to the "National Health Interview Survey, January - March 2011", approximately 46.5 million people, or 15% of US population, lack health insurance, and further 25 million are underinsured because their insurance does not provide sufficient financial protection. More than three-quarters of the uninsured come from working families, and four in ten are individuals and families with incomes below the federal poverty level of \$22,050 for a family of four. Most of them are adults, who have limited eligibility for Medicaid compared to children, but cannot afford private insurance or benefit from coverage provided by an employer. Lack of coverage for medical bills exacerbates the financial burdens of the unemployed and leads lower income people to delay even urgent treatments to satisfy other essential needs, and in worse cases, the impact of medical expenses especially when an emergency intervention or a chronic disease occurs can easily force a household into poverty.



On general terms, there are important economic, employment and health disparities across states and communities. Patients living in poor inner-city and rural areas are the less favoured, and many in the lower income groups seek treatment in community health centers (CHCs), free clinics and public or nonprofit hospitals that treat low-income patients. Some of them are located in such underserved, depressed rural and inner-city communities, and they also take care of providing patient outreach, case management, health education and referrals. However, the current economic conditions have caused a rising demand while funds and other forms of institutional support are often declining.

On the other hand, according to the Association “AmeriCares”, the safety net of Medicaid and the Children’s Health Insurance Program (CHIP) has played an important role in preventing a larger increase in the uninsured and, in particular, in safeguarding children from fully paying the consequences of the economic turmoil. June 2010 Medicaid enrolment nationwide exceeded 50 million.

Oral healthcare delivery

As reported by the National Association of Dental Plans, virtually all Americans with a dental policy obtain it through an employer, union or public program. About 85% of employees pay all or part of the cost of their dental coverage, while only 1% of dental policies are purchased by individuals.

Employers usually provide three types of policies: for employee, for employee with a dependent (spouse or child), or for employee and family. With the exception of the federal Children’s Health Insurance Program (CHIP) program, child-only policies are rarely offered in the private market.

Dental policies are a separate product, distinct from medical coverage. About 98% of Americans with private dental coverage have it separated from their

medical policy, and also provided by a different carrier, due to the peculiar characteristics of dentistry and dental services as compared to general health care delivery.

Access to oral health services highly depends from an individual’s ability to get and keep dental insurance. In the report “Americas dental insurance crisis” CBS News gives an impressive figure stating that 100 million people, that means one-third of the country, is without dental insurance. Limited dental coverage is provided to children up to 21 years of age through the Children’s Health Insurance Program (CHIP) and Medicaid, the latter alone covering about 28 million children, but only nine States provide Medicaid dental coverage for adults and in many cases, the report claims, dentists don’t accept it.

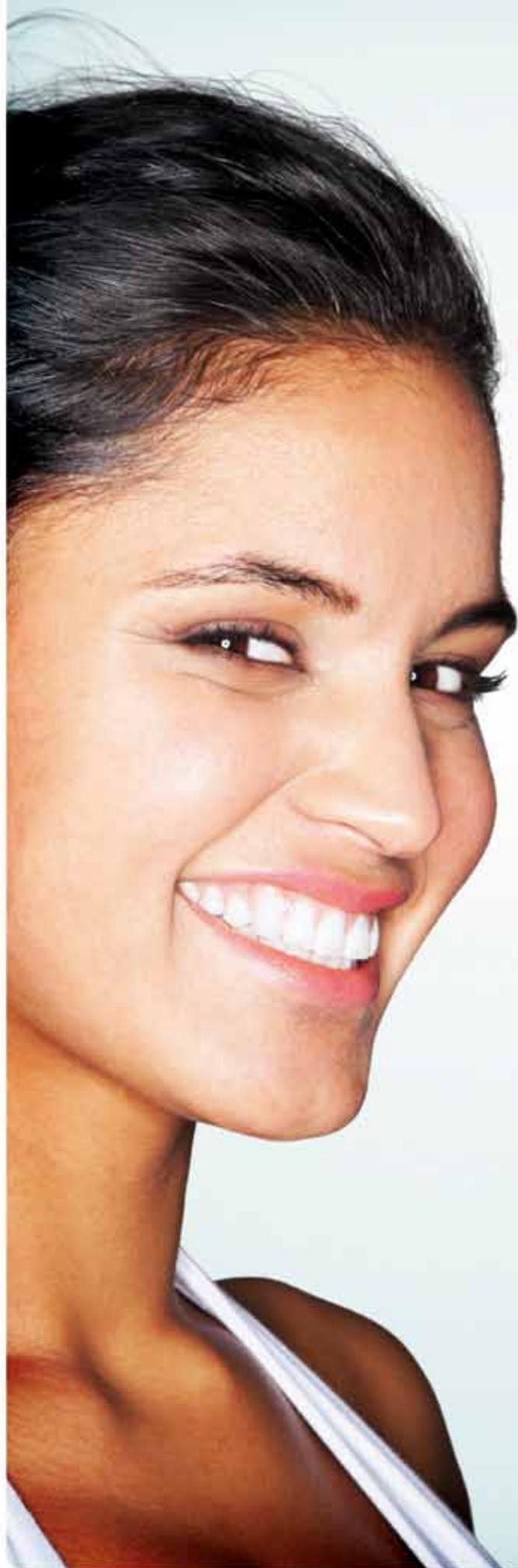
More specifically, all individuals under 21 are covered to an extent that varies according to the different state policies: for instance, Alaska, Arizona, Hawaii, Maine, Michigan, Nevada, New Hampshire, Oklahoma, South Carolina, Tennessee, Virginia, Wisconsin, and Wyoming provide care primarily in emergency situations, or cover basic critical care. The other states grant more extended dental services but each state poses limits on the number of visits in a year or co-payments. However, preventative care is generally available with dental exams and cleanings.

The Patient Protection and Affordable Care Act (ACA), signed in 2010 by President Obama, is expected to improve access to oral health by expanding the Medicaid program and providing premium subsidies to make private insurance more affordable for households below specific thresholds in federal poverty levels. With the upcoming expansion of Medicaid eligibility, the number of people covered by this public program is expected to rise by almost 16 million by 2019. Over 5 million children are expected to get first-time access to dental coverage as a result of ACA, with most of them being added to public programs.

Overview of the Dental Market

According to the American Dental Association, there are nine recognized dental specialties in the U.S.: orthodontics, oral and maxillofacial surgery, pediatric dentistry, periodontics, prosthodontics, endodontics, dental public health, oral pathology, and oral and maxillofacial radiology.

Dental policies are a separate product, distinct from medical coverage. About 98% of Americans with private dental coverage have it separated from their medical policy, and also provided by a different carrier, due to the peculiar characteristics of dentistry and dental services as compared to general health care delivery.



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Approximately 85% of dental care is provided by general dentists in an office setting, usually by a solo practitioner. About 81% of dentists are general practitioners. As reported in ADA surveys for 2008, among private practitioners, solo dentists were 59.8%, while 22.0% worked with one other dentist, and 18.2% with two or more dentists.

Number of dentists

| | |
|-------------------------------------|---|
| Professionally active dentists | 186,084 |
| of which private practitioners | 170,694 (this figure is included in the former) |
| Orthodontists | 7,700 |
| Oral and maxillofacial surgeons | 6,700 |
| Prosthodontists | 500 |
| Dentists, all other specialists | 6,900 |
| Number of accredited dental schools | 62 |

Source: ADA, US Department of Labor

According to a market analysis released by Brocair Partners, there are 120,000 office-based dental practices in the USA, which are supplied by dental distributors. The biggest dental distributors in the U.S. are Henry Schein, Inc. and Patterson Companies, Inc., holding about 40% and 32% of the market share respectively. The manufacturing industry is described as more fragmented, with ten companies accounting for approximately 50% of the market.

Several industry reports estimate a total volume of the US dental market ranging from US\$9 to 11 billion. The largest segment is restorative and preventive dentistry, considering that the groups requiring the greatest share of these services, children and elderly, are backed to a certain extent by the Medicaid or CHIP programs. Dental consumables, including sundries and small equipment such as sealants, anesthetics, bone grafting materials, handpieces, ultrasonic scalers and polishers, are valued at roughly \$4 billion, while the market for dental equipment, including high-tech products such as CAD/CAM systems, digital radiography, 3D imaging systems, and lasers, was estimated at \$1.8 billion in 2009. Moreover, although they represent a small proportion of dental expenditures at the moment, cosmetic dental services, such

as bleaching, are gaining popularity due to the increasing consciousness of a consumer base that is for the greatest part already largely educated. New technologies are making these procedures faster, less invasive and cheaper, bringing them to the reach of larger groups of the population.

The effects of recession and tighter spending on dental services continue to affect the various segments of the market, as well as the behaviours of dental practices, as it happens for dental implant procedures. Many patients opt for less expensive alternatives, such as crowns and bridges, so the volume of dental implant products purchased has declined in the latest years. However, the demand for dental services is expected to be supported in the long term from the expansion of medical coverage envisaged by the health reform. Furthermore, US population is growing and the elderly segment is one of the fastest growing groups. According to the US Department of Labor, these demographic trends will increase the demand for dental care since many members of the baby-boom generation are going to be in need of treatment in the coming years, and elderly people are more likely to retain their teeth and require dental care.

According to a report by Millennium Research Group, although the modest economic growth expected for the next few years, the dental market could benefit from technological innovations and improved training for practitioners for minimally invasive procedures that offer improved aesthetic results with shorter treatment lengths. Moreover, automated and digital technologies that increase laboratory production capabilities and digital dental imaging are gaining importance as a good number of practices chooses to shift to digital and to upgrade or replace dental softwares.



Selected dental trade figures, 2010

| Commodity Group | Import value, US\$ million | Export value, US\$ million |
|--|-------------------------------|-------------------------------|
| Preparations for oral hygiene | 84,4 | 203,9 |
| Dental floss | 81 | 27,9 |
| Dental drill engines | 71,4 | 37 |
| Dental instruments/apparatuses, excl. drills | 573,7 | 421,3 |
| Artificial teeth | 95,9 | 137,1 |
| Dental fittings excl. teeth | 261,6 | 396 |
| X-ray apparatuses for dental uses | 157,9 | 98 |

Source: United Nations Commodity Trade Statistics Database

Regulations affecting the Dental Market

FDA is responsible for the registration of any dental device or product to be sold in the USA territory, and it does not recognize any other certification. The marketing process of a medical device depends on its classification: FDA can either "clear" a medical device after reviewing a Premarket Notification known as 510(k), or "approve" it after reviewing a premarket approval (PMA) application. Classification of medical devices is based on three risk levels: Class I, Class II and Class III, the highest risk class.

A small number of Class I devices and almost all Class II medical (or dental) devices requiring clearance for US market entry must follow a pre-market notification procedure known as 510(k), from the number of the related section of the Federal Food, Drug and Cosmetic Act. A 510(k) submission is based on comparison of the new device with devices already legally marketed in the USA. Medical device manufacturers are required to submit a 510(k) if they intend either to introduce a device for commercial distribution in the USA for the first time, or to reintroduce a device that has been substantially modified. Class I devices and some Class II devices that do not require FDA review are considered "510(k) exempt", but they are still subject to general controls on suitability for intended use, packaging and labeling, establishment registration and device listing forms and manufacturing quality system, except for a few class I devices that are subject only to complaint files and general recordkeeping requirements.

Class III medical devices need instead a Pre-Market Approval, that requires the submission of clinical data in support of the application. For high risk devices introduced after 1990 manufacturers are required to have procedures for post-market surveillance, Quality Systems (QS), also known as Good Manufacturing Practices (GMPs) and Medical Device Reporting (MDR) for adverse events in place.

Besides marketing clearance, basic Pre-market Requirements are labeling in accordance with FDA regulation, establishment registration with the FDA and medical device listing in the FDA Unified Registration and Listing System (FURLS).

FDA is responsible for the registration of any dental device or product to be sold in the USA territory, and it does not recognize any other certification.

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In particular, foreign manufacturers that export electronic products that emit radiation to the USA are subject to the requirements of the FD&C Act, Subchapter C - Electronic Product Radiation Control, including performance standards, labeling, and submission of radiation safety product reports. Importers may submit these reports on behalf of manufacturers.

All medical devices that are imported into the U.S. must meet Bureau of Customs and Border Protection (CBP) requirements.

All medical devices that are imported into the U.S. must meet Bureau of Customs and Border Protection (CBP) requirements. The importer submits entry information to the local CBP district office, or asks "filers", domestic customhouse brokers, to fill these forms electronically on its behalf. Filers have access to the Operational and Administrative Systems for Import Support (OASIS), the FDA computerized import system serving as interface between FDA and the CBPs Automated Commercial System (ACS). When an entry is filed with CBP, a copy is also provided to the local FDA district office which determines if the product complies with FDA requirements. FDA may detain a product that appears to be out of compliance with the FD&C Act, and the FDA office will issue a "Notice of FDA Action" specifying the nature of the violation to the owner or consignee, who is then entitled to an informal hearing to submit evidence that the product is in compliance. If he fails submitting such evidence, FDA will issue another "Notice of FDA Action" refusing admission to the product, that has to be exported or destroyed within 90 days, under penalty of an assessment for liquidated damages for up to 3 times its value.

Entering the US market

Some important factors may help to correctly approach the US market.

1. Market Analysis: it is essential to understand that US market requires simple, safe, efficient, cost-effective solutions. This is particularly true for the medical and dental domain. A clear understanding of US pricing structure is part of this analysis.
2. Pre-market Approval: obtaining FDA clearance can be a relatively complicated process, companies entering the market for the first time are advised to get support from a third party that can help dealing with the legal requirements.
3. Building up the distribution/sales network: accurate research and selection of dealers is essential, but not enough. Post-sales assistance and the provision of adequate promotional material and training are equally important. The US market requires an in-country representation and a well structured logistic management, as the territory is too wide for just one or two distributors.

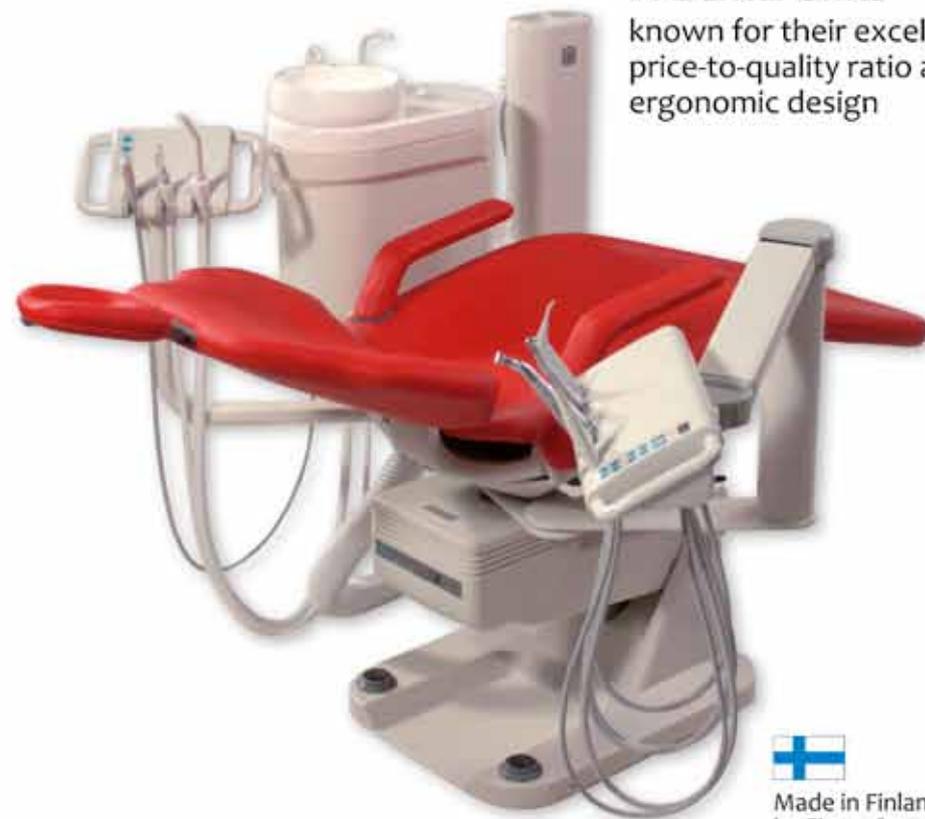
Sources:

International Monetary Fund - www.imf.org
 US Department of Commerce, Bureau of Economic Analysis - www.bea.gov
 AmeriCares - www.AmeriCares.org
 Kaiser Family Foundation - www.kff.org
 Centers for Disease Control and Prevention - www.cdc.gov
 US Department of Health and Human Services - www.hhs.gov
 American Dental Association - www.ada.org
 National Association of Dental Plans - www.nadp.org
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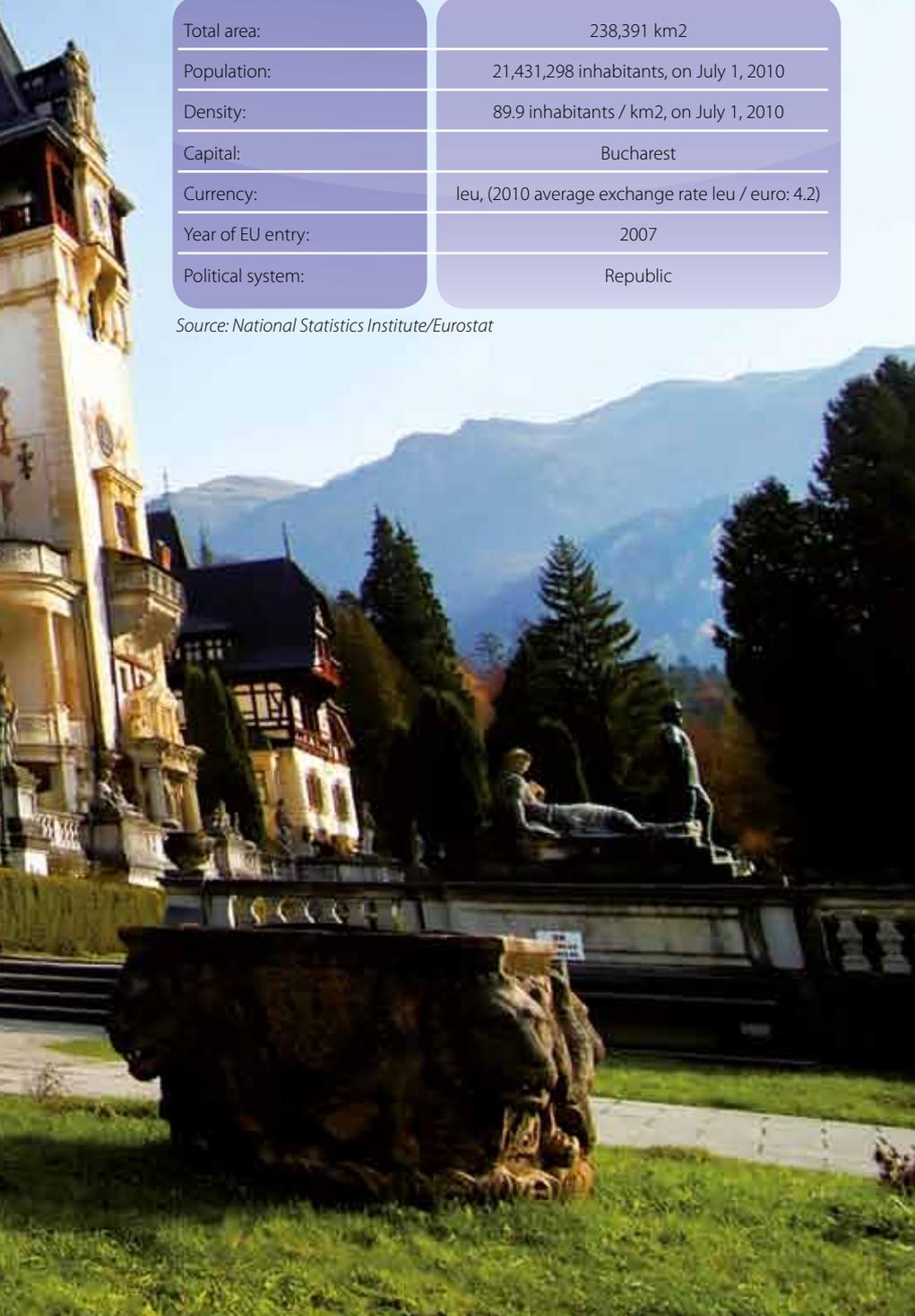


An outlook on: Romania

Basic Facts

| | |
|-------------------|--|
| Total area: | 238,391 km ² |
| Population: | 21,431,298 inhabitants, on July 1, 2010 |
| Density: | 89.9 inhabitants / km ² , on July 1, 2010 |
| Capital: | Bucharest |
| Currency: | leu, (2010 average exchange rate leu / euro: 4.2) |
| Year of EU entry: | 2007 |
| Political system: | Republic |

Source: National Statistics Institute/Eurostat




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Romania is located in the south-eastern part of Central Europe, on the Danube lower course. The geographic position of the country is highly favourable, at the crossroads of important trade routes including the Danube River and the port of Constanta, one of the largest ports on the Black Sea, which is linked to the North Sea by a new navigation route through the Rhine-Main-Danube Canal. In 2010, 11.8 million persons were living in the urban area, more than half of the country's population, while about 45% were living in rural areas. Bucharest is the capital city, with a population of 2 million. Other large cities include Iasi, Cluj-Napoca, Timisoara, Constanta, Craiova, Galati and Brasov.

Romania became a free market economy in early 90s, and in the first decade the government has attempted to limit the extensive state presence in the industrial sector by progressive liberalization. The process has not been easy due to old-structured bureaucracy and finance, a legacy of the centralized communist regime, and reducing budget deficit still remains one of the main challenges.

The world financial crisis impacted on Romanian economy causing a recession in the period 2008-2010 which resulted in a GDP contraction by estimated 2% in 2010, against average 6.8% growth registered in years 2006-2008. The unemployment rate also rose to 8% from 5.6 in 2009. The downturn hit foreign investments in the country as well, their rate in capital formation decreased from 29.2% in 2009 to 25.6% in 2010. The European Union and the International Monetary Fund imposed a series of measures to the Romanian government in order to reduce the budget deficit to 3% of GDP by 2012. This is a hard goal to reach considering the current economic uncertainty dominating the whole EU area, that represents the main trade partner for Romania.

Romania became a free market economy in early 90s, and in the first decade the government has attempted to limit the extensive state presence in the industrial sector by progressive liberalization.

The economy is dominated by the services sector, which contributed to 47.5% of GDP in 2010, while industry accounted for 26.4%, construction by 8.9%, and agriculture, hunting, forestry and fish breeding only 6%. Romania is rich on natural resources including oil, natural gas, salt, coal, iron ore, copper. Under the National Infrastructure Development Programme, several projects were implemented or envisaged for the upgrade and expansion of the country's transportation network, for a total of 845 km of new highways by 2020 and 9,016 km of roads repaired.

As regards international trade in goods, 2010 FOB exports amounted to €37.3 million (increasing by 28.2% against 2009) and CIF imports amounted to €46.8 million (20% increase on 2009), recording negative trade balance of €-9.5 million. EU Member States are the main export destination, accounting for roughly 72% of both total exports and imports in 2010.

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- Dental laboratories: 2,208
- Dentists working in urban areas: 10,427
- Dentists working in rural areas: 1,474
- Dentists working in the public sector: 4,067
- Dentists working in the private sector: 7,834
- Density per 10,000 inhabitants: 6.1

Source: National Institute of Statistics, 2008

Dental market profile

According to the consulting firm FRD Center, the Romanian dental market is expected to grow by 17% annually by 2012, boosted by the rising dental tourism that is favoured by lower treatment costs and the improvement in quality standards of Romanian dental practices. Part of the growth is also due to the increasing awareness of Romanians towards their oral health. However, many citizens still cannot afford private dental care. Especially children, teenagers and retirees lack adequate public coverage for dental treatments.

The National Sole Social Health Insurance Fund (FNUASS) requires a mandatory social health insurance contribution to all citizens residing in Romania but, as reported by the Romanian Dental Association of Private Practitioners (RDAPP), the funds set for public dental health assistance are less than 0.5% of the overall health funds, causing long waiting times and incorrect practices in public oral healthcare delivery. Moreover, pressed by the need to reduce costs, the Romanian government is cutting welfare expenditure, affecting the oral health status of the population.

At present, the Romanian market of dental practices is very fragmented, consisting of over 12,400 individual practices throughout the country. According to the National Institute of Statistics, there were 3,584 public dental centres and 8,071 private dental centres in Romania in 2008 and the private dental practices represented some 70% of the total. Although only part

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of the population can afford private dental care, public and private sectors are following opposite trends, with public practices decreasing while private dental offices recorded 10% average annual growth during the period 2003 – 2009 and are expected to continue the ascending trend. Several factors are influencing this trend:

- corporations include dental insurance in their employee packages
- individual clients prefer private services rather than public
- the purchasing power of the middle class increased considerably in the last decade

and high technology assistance from the dental centres of international standards, the number of the dental tourists in Romania is expected to rise in the next future.

Some of the main dental clinics in Romania are: Dent Estet, Trident Dental, Velvet Dental, City Dent, NeoClinique, HappyDental, DentaTourism, Dent Expert, Smilemed, Sensident Med, Bote-San Clinique. The prices for dental implants in these clinics, for instance, vary between 350 EUR and 950 EUR.

In particular, the private sector of cosmetic dentistry treatments recorded a significant development in recent years, accounting for about 10% of all dental procedures. The most popular treatments offered by private dental clinics include tooth whitening, porcelain veneers, bonding, gum re-contouring and dental jewels. The growth of the cosmetic segment is supported by the rising interest for more sophisticated dental treatments among the higher income groups.

The demand of the dental instruments and equipment in Romania increased along with the rapid development of the private sector and with the privatisation of the state sector, requiring the replacement of the worn-out equipment. The main factors that influence the potential buyers of the dental equipment are price, local availability of service and spare parts and short delivery terms.

The dental equipment in Romania is imported mainly from Germany, Italy, the Czech Republic, Hungary, Ukraine. Among the main importers of dental equipment on the domestic market there are Dentotal Protect and Dentex Trading, headquartered in Bucharest, and Medica M3 Comexim, headquartered in Cluj Napoca.



Some private centres that provide general medical care services in Romania are active also in the dental services segment. Private dental clinics are increasing at a sustained pace along with the flow of dental tourists from all European Union and recently also from the USA, due to the rise in the number of uninsured population who seeks cheaper dental treatments abroad. Given the relatively low cost of treatments

• Source:



FRD Center Market Entry Services, "The Dental Services and Equipment Market in Romania – April 2010"

FRD Center offers tailor-made market access consulting services to foreign companies interested to enter the Romanian and other emerging markets in Europe as exporters, consultants, investors or joint-ventures, to

relocate their operations, or to source in CE and SE Europe.

Contact: Jackie Bojor, Director (europa@frdcenter.ro)

• Other Sources:

Romanian National Institute of Statistics, "Romania in Figures 2011" - www.insse.ro

Ernst & Young, "Romania Business Passport, 2011 edition" / Ministry of Economy - www.minind.ro



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The system has been created even for those who doesn't love technology: in fact it can work independently. The user can be helped by a virtual technical assistant that, once retrieved from the desktop, may solve doubts, erroneous commands sent to the software and install any updates to be innovative at any time.



CEDE

Central European Dental Exhibition is the biggest and the most important dental event in Poland. CEDE 2011 was held on 22-24 of September at Poznań International Fair Grounds and was visited by 14,494 dentists, dental technicians, assistants and professionals connected with the dental industry. Visitors not only from Poland, but also from Ukraine, Belarus, Estonia, Lithuania, Latvia, Russia, Germany, Norway, the Netherlands,



Czech Republic, Slovakia, Greece, Great Britain, Italy, France, Sweden, Croatia, Montenegro, Switzerland, Taiwan and China visited 4 large pavilions with a total area of 18,500 sq m. CEDE exhibition pavilions were clearly divided to: dental equipment (pav. 6A), dental materials (pav. 7A), technical equipment and materials (pav. 8) and hygiene, prophylaxis and sterilization (pav.7).

At the area of 8 thousand sq m 251 exhibitors representing 418 companies from around the world presented their offer.

The novelty at CEDE 2011 was the CEDE ARENA. An idea of creating a place where doctors sitting comfortably would be able to watch live demonstrations of various dental procedures, was transformed into sports stadium shaped ARENA with tiered seating for spectators.



Thanks to the cooperation with the exhibitors was created a dentist office with live demonstrations attracting great interest of visitors. Within three days of the exhibition the shows at the CEDE ARENA were watched by nearly 1,000 people.

Traditionally, the exhibition was accompanied by the Congress of Dental Teams. Nine Congress sessions was attended by 1,211 doctors and dental technicians.

A great interest aroused the sessions of: Endodontic, restorative dentistry; The wellbeing of the Polish dentist. Health and business psychology; Esthetic dentistry; Marketing, management, finance in dental office. Also an interesting scientific program for dental technicians attracted hundreds of them. Simultaneously, in numerous conference rooms were held lectures, courses and workshops organized by the exhibitors.

By tradition, during the CEDE exhibition were awarded the CEDE GRAND PRIX statuettes. The awards were presented during the official part of GALA CEDE, which took place in the beautiful Concert Hall of Adam Mickiewicz University.

This year, for the first time, the participants of the Congress, as well as the exhibitors, could travel free of charge around Poznań by public transport – on the basis of the CEDE ID. It was a really nice gesture of the city authorities towards CEDE visitors, and we do hope it will be repeated next year.

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FDM 2011 has fulfilled the expectations: 10,000 visitors

Forum Dental Mediterráneo (FDM) closed its latest edition feeling that it has well done its homework. In spite of the current economic difficulties, the organizers have reached their goal by registering a total of 10,000 visitors during the three days of the Forum, once again an excellent platform for dental professionals.

FDM 2011 hosted a wide industry exhibition, discussions, congresses and high-level scientific meetings with the essential cooperation of the Association of Catalan Dentists (COEC), the Catalan Association of Dental Prosthetics (COPDEC), the Association of Catalan Hygienists and Dental Assistants (AHIADEC) and the Catalan Association of Speech Therapists, as well as dental suppliers and other institutions and companies in the dental sector.

Puntex has been promoting and organizing the FDM since 1999 and truly appreciates the years of close collaboration with suppliers, cooperating institutions, visitors, professionals and all those who took part to the 7 editions (biennial) held in Barcelona to date.

Starting from next edition, FIRA DE BARCELONA will be the organizer of FDM. We are convinced that thanks to its national and international experience it will achieve those objectives that the dental sector needs and deserves.

PUNTEX will be ready and eager to cooperate with FIRA in organizing the next edition of FDM in 2013.



Opening ceremony of FDM 2011 was held by Dr Francesc Sancho, Secretary of Strategy and Coordination of the Department of Health, in representation of Hon. Artur Mas, President of the Generalitat de Catalunya and Hon. Boi Ruiz, Counsellor of Health, accompanied by Dr Josep Lluí Navarro, President of the Official Association of Catalan Dentists; Dr Josep M Clemente, President of the Mediterranean Dental Association (Asociación Dental del Mediterráneo); Josep M. Fonollosa, President of the Catalan Association of Dental Prosthetics, and Ramon Martín, President of Puntex.

Contact information:

Ms Susana Lopez

PUNTEX-Publicaciones Nacionales Técnicas y Extranjeras, S.A.

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SIDEX 2011 Results

1. Total enrollment by year

| | 2010 | 2010 Show | Year on Year |
|-------|-------|-----------|--------------|
| DAY 1 | 1,022 | 2,799 | 173.9% |
| DAY 2 | 3,882 | 4,995 | 28.7% |
| DAY 3 | 4,103 | 4,727 | 15.2% |
| Total | 9,007 | 12,521 | 39.0% |

2. Total enrollment by detail

| Classification | | The number of people | Ratio |
|---------------------|----------------------|----------------------|-------|
| Exhibition | pre-registration | 2,129 | 17.0% |
| | on-site registration | 1,090 | 8.7% |
| | Students | 1,514 | 12.1% |
| Scientific Congress | pre-registration | 6,557 | 52.4% |
| | on-site registration | 898 | 7.2% |
| Reporter | | 55 | 0.4% |
| Foreigner | | 278 | 2.2% |
| Total | | 12,521 | 100% |

3. Classification of Exhibitors' Origin

| No. | Nation | The Number of Exhibitors | No. | Nation | The Number of Exhibitors |
|-----|-----------|--------------------------|-----|-------------|--------------------------|
| 1 | CHINA | 3 | 10 | PAKISTAN | 1 |
| 2 | FINLAND | 1 | 11 | PHILIPPINES | 1 |
| 3 | FRANCE | 1 | 12 | POLAND | 1 |
| 4 | GERMANY | 11 | 13 | SINGAPORE | 2 |
| 5 | HONG KONG | 1 | 14 | SWITZERLAND | 2 |
| 6 | INDIA | 1 | 15 | TAIWAN | 3 |
| 7 | ITALY | 2 | 16 | UAE | 1 |
| 8 | JAPAN | 6 | 17 | USA | 10 |
| 9 | KOREA | 221 | | | |

TOTAL : 17 Nations / 268 Companies / 831 Booths

4. Various Conferences and Scientific Congress

Scientific Congress was entitled 'To the World, To the Future'. It is made up of 50 lectures and was held in the Grand ball Room, conference rooms and auditorium at the Seoul Convention and Exhibition Center(COEX).

5. 221 Korean companies and 47 Foreign companies

SIDEX 2011 was held at COEX Exhibition Hall C, D(17,649m²) with the most advanced dental equipment and took on a more international aspect since internationally renowned companies participated.

6. Expanding Conveniences

During SIDEX 2011, the Organizing Committee prepared a kids play zone, stockroom booth, business lounge, internet lounge and meeting point etc. for the participants.

In addition, the Organizing Committee installed a 'Free Interpretation Service Center' at each entrance of the exhibition hall for foreigners and installed a 'Service Center' in order to react quickly for any inconvenience in the exhibition hall.

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IDEM Singapore 2012 bridges Asian dental players to innovations across the globe

With nine national pavilions and more than 380 exhibitors, IDEM Singapore 2012 is set to be the biggest showcase for the region's dental players

In recent years, modern dentistry has introduced numerous advances that has radically changed dental treatments today. Globally and across Asia, digital imagery and laser treatments have made dental procedures faster and safer, while the burgeoning field of cosmetic dentistry is fast gaining traction alongside the region's rising wealth.

According to a report by market research firm Global Industry Analyst, Inc1, the international dental supplies market is expected to cross US\$16 billion by 2015, with Asian markets expected to witness the highest growth rate. In fact, Global Industry Analyst predicts that by the year 2013, the dental implants market in Asia Pacific will exceed US\$670 million.

Riding on the rising opportunities in Asia's advanced dental care, the biennial International Dental Exhibition and Meeting (IDEM) returns for its seventh edition this year, showcasing the latest advances across major disciplines of dentistry. IDEM Singapore 2012 will be held from 20 to 22 April 2012 at the Suntec International Convention and Exhibition Centre, Singapore, with a post-congress session taking place on 23 April 2012.

Innovations from key markets

Organized by Koelnmesse and the Singapore Dental Association, the seventh edition of the event will feature a total of nine national pavilions.

For the first time this year, Italy will host over 15 exhibitors in their national pavilion, supported by the Unione Nazionale Industrie Dentarie Italiane (UNIDI). Leading names such as Faro, Mectron, and Tekne Dental will feature within the pavilion, which will also see the debut of other household Italian brands such as, Cominox, Dyamach and Pastelli.

"We see synergy in coming together as a pavilion this year, to showcase the vibrancy of the industry in Italy and underline our commitment to grow our presence in the regional dentistry market. Besides, by participating as a pavilion, both experienced and first time exhibitors will be able to gain greater visibility on the exhibition floor," said Mr. Gianfranco Berrutti, Director, UNIDI.

Other national pavilions include Australia, France, Germany, Korea, Singapore, Switzerland, the United Kingdom and the US. Together, the pavilions will provide visitors with a comprehensive view of the dental value-chain across the globe.

"IDEM Singapore is the perfect platform for us to reach out to key business contacts in Asia," said Dr. Markus Heibach, Managing Director, VDDI, Association of German Dental Manufacturers. "Germany is known for our leading-edge research and development in dental technology and international business remains a stable anchor of growth for the German dental industry. Being at IDEM Singapore is a strategic part of furthering business for Germany's leading players," he added.

Leading brands from across the globe

In all, over 380 leading companies from over 30 countries in dentistry will be part of the trade fair at IDEM Singapore 2012. These companies will be showcasing the latest innovations in clinical dentistry, dental technology and patient care across every segment of the dental market, covering restorative and preventive treatments, surgical procedures and equipment, orthodontics, endodontics, periodontics and laboratory tools.

"Being a global meeting point for the dental community in Asia, IDEM Singapore 2012 is the ideal platform for Invisalign to introduce our broad range of orthodontic solutions to potential partners in the region. The large number of international visitors expected at IDEM Singapore is definitely a key consideration, as we seek to increase awareness of our revolutionary solutions across the globe," said Mr. Mark van Weelde, Managing Director, Invisalign Singapore.

Other first time exhibitors at IDEM Singapore 2012 include Japan's dental milling machine maker Roland DG; Finland's Salli, producer of ergonomic clinical furnishing; dental ceramics manufacturer Jyoti from India; and Israel's dental implant systems manufacturer Implay.

The latest advances in dentistry discussed

Reflecting the rising sophistication and emergence of complexities in dental technologies and treatments in recent years, the IDEM Scientific Conference for 2012 is aptly themed Advances and Controversies. Presented by world-renowned dental practitioners and professionals, the conference aims to help participants keep up-to-date with the latest techniques and devices in dental solutions such as New Technologies in Tooth Cutting and Digital Dentistry, as well as gain insights into related topics in dental practice such as Risk Management in Orthodontics. Seventeen experts from Australia, France, Italy, the United Kingdom and the United States will present the latest treatments, procedures and trends in various dental fields.

IDEM Singapore 2010 attracted over 6,000 trade visitors and conference delegates from 55 countries.

Online registration for IDEM Singapore 2012 conference is now open. For more information visit www.idem-singapore.com

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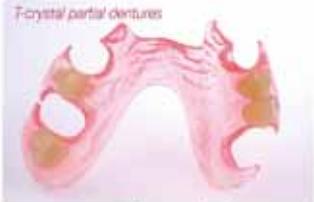
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Dental-Expo breaks new records:

462 exhibiting companies from 25 countries and more than 30,000 dental professionals have met at the anniversary forum in Moscow

The 30th Moscow International Dental Forum and Exhibition Dental-Expo 2011 were held in Moscow's Crocus Expo fairgrounds from 26 to 29 of September, 2011.

Undoubtedly, the 30th Forum is a record breaking event in terms of the total area, number of exhibiting companies and attendees. Also it was marked by an increase in the overall interest and buying attitude of the attendees.

The organizers and exhibitors have also noted increasing interest of the foreign manufacturers to the Russian market showing up in the growing percentage of the foreign exhibitors at Dental-Expo. Most of the foreign companies being for the first time at the Moscow exhibition, were, to say the least, pleasantly surprised by the activity of attendees' at Dental-Expo 2011.

| | |
|------------------------------------|--------|
| Total Attendees | 30,968 |
| Exhibition visitors: | 25,919 |
| RDA Delegates and VIP: | 704 |
| Exhibitors' staff: | 4,057 |
| Organizing committee staff: | 176 |
| Dental Press: | 112 |
| Total area, sqm: | 19,425 |
| Exhibitors: | 462 |



Intensive participation of the foreign companies has become one of the specific features of Dental-Expo 2011. It is not only the result of many years of work on the part of Dental-Expo in the international relationships, but also an indicator of the overall tendency towards the Russian market in the foreign industry. Exhibition halls of Russia, Germany, Korea, China, Slovenia, Italy and USA, representing 86 manufacturers, were presented at Dental-Expo 2011. More than 100 foreign manufacturers have taken part in the exhibition with their own stands. This is also a record in itself.

The scientific program of the forum splendidly complemented the exhibit offering a wide choice of educational programs in all areas of dental industry to the visitors. Many presentations were held by the manufacturers' representatives. Taking into account the scope of the programs brought virtually from all over the world, this was a unique opportunity to obtain first-hand information on the newest developments in the world dentistry.

As it seems, the construction of the subway station at the Crocus City and the traffic interchange at the Moscow Outer Ring Road has made the Crocus Expo fairgrounds easily accessible not only for guests to the Russian capital, but for Moscow residents as well. At the same time, the unique facilities of the Crocus Expo, such as the huge parking lot capable of accommodating 26,000 cars, the vast exhibition area suitable for hosting events of any scale and level, and the wide choice of conference halls, seem to have exhausted their resources – the exhibition halls were overcrowded in the first two days of the exhibition, such was the attendance.

This fact confirmed the timeliness of the innovations introduced by the Organizational Committee and the fairground: simplified e-registration, web-based events scheduler, mobile navigation system for the exhibition and the scientific program, an upgraded food court with a new menu and new pricing policy.

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The 2011 FDI Annual World Dental Congress in figures

With entry free-of-charge, just under 5,300 square metres of exhibition space, some 27,000 visitors, 200 exhibitors and nearly 1,000 exhibition staff, 2011 proved to be the largest FDI World Dental Exhibition in recent years. Jointly organized by FDI and the Mexican Dental Industry (AMIC), it was held alongside the 2011 FDI Annual World Dental Congress at the Centro Banamex Convention Centre, Mexico City, from 14-17 September 2011.

Over 5000 individuals, principally dental practitioners, but also hygienists and students, participated in the sessions and meetings scheduled in and around the event. The four-day Scientific Programme, held under the theme 'New horizons in oral health care', featured 112 scientific sessions facilitated by more than 128 speakers from 29 different countries.

Sessions covered a wide range of issues, from oral health and non-communicable diseases to caries management, from patient safety to salivary diagnostics and from oral and maxillofacial surgery to orthodontics – in fact full coverage of the today's key areas of interest and discussion in dental art, science and practice.

In addition, 121 scientific posters were on display and 59 free communications were presented. The three winners of the 2011 FDI Poster Award Competition were announced during the VIP reception on 14 September. They are Assoc. Prof. Josimeri Hebling from Brazil, Assoc. Prof. Aziza Eldarrat from the United Arab Emirates and Prof. Hyun-Duck KIM from South Korea.



A total of 157 delegates from around the world attended the FDI General Assembly proceedings, which saw the election of the President-Elect, Dr Tin Chun Wong, as well as 8 members to the FDI Council and 8 to FDI Committees.

In all, 98 nationalities were represented at the 2011 FDI Annual World Dental Congress.

And FDI AWDC 2012?

With a successful Congress in 2011, what plans are underway for 2012? FDI recently held an industry site visit and briefing in Hong Kong for an audience comprising members of the dental industry, representatives from the Hong Kong Dental Association, and key providers. The aim was to detail the numerous opportunities at the 2012 Annual World Dental Congress as well as respond to questions.

"We outlined our plans for new sessions and products envisaged for the 2012 Congress and feedback was very positive," said FDI Executive Director Jean-Luc Eiselé, "I really picked up on an interest and willingness to invest in the event."

"Success, as they say, is measured by attention to detail and understanding needs and expectations," added Dr. Eiselé, "and that is exactly the approach FDI plans to adopt for the AWDC 2012."

Meanwhile, the Congress website will soon be open, with a preliminary programme online by the end of November.



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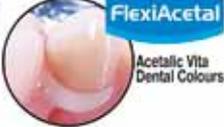
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An Overview of ISO Quality management principles

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The advertisement features a purple background. On the left, there is contact information for Blossom gloves. In the center, there is a graphic of a hand holding an aloe vera plant, with the words 'Feel' and 'The Silky Touch' written in a stylized font. On the right, there are three circular images showing different packages of Blossom gloves. At the bottom, there is a slogan 'A Partnership That Grows' and 'Aloe Vera Glove + Vitamin E'.

The quality management principles underlying the ISO 9000:2000 series form a basis for performance improvement and organizational excellence. The eight quality management principles are defined in ISO 9000:2005, Quality management systems Fundamentals and vocabulary, and in ISO 9004:2000, Quality management systems Guidelines for performance improvements.

Principle 1: Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Key benefits:

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organization's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business.

Applying the principle of customer focus typically leads to:

- Researching and understanding customer needs and expectations.
- Ensuring that the objectives of the organization are linked to customer needs and expectations.
- Communicating customer needs and expectations throughout the organization.
- Measuring customer satisfaction and acting on the results.
- Systematically managing customer relationships.
- Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers, local communities and society as a whole).

Principle 2: Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Key benefits:

- People will understand and be motivated towards the organization's goals and objectives.
- Activities are evaluated, aligned and implemented in a unified way.
- Miscommunication between levels of an organization will be minimized.

Applying the principle of leadership typically leads to:

- Considering the needs of all interested parties including customers, owners, employees, suppliers, financiers, local communities and society as a whole.
- Establishing a clear vision of the organization's future.
- Setting challenging goals and targets.
- Creating and sustaining shared values, fairness and ethical role models at all levels of the organization.
- Establishing trust and eliminating fear.
- Providing people with the required resources, training and freedom to act with responsibility and accountability.
- Inspiring, encouraging and recognizing people's contributions.

Principle 3: Involvement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Key benefits:

- Motivated, committed and involved people within the organization.
- Innovation and creativity in furthering the organization's objectives.
- People being accountable for their own performance.
- People eager to participate in and contribute to continual improvement.

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Applying the principle of involvement of people typically leads to:

- People understanding the importance of their contribution and role in the organization.
- People identifying constraints to their performance.
- People accepting ownership of problems and their responsibility for solving them.
- People evaluating their performance against their personal goals and objectives.
- People actively seeking opportunities to enhance their competence, knowledge and experience.
- People freely sharing knowledge and experience.
- People openly discussing problems and issues.

Principle 4: Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

Key benefits:

- Lower costs and shorter cycle times through effective use of resources.
- Improved, consistent and predictable results.
- Focused and prioritized improvement opportunities.

Applying the principle of process approach typically leads to:

- Systematically defining the activities necessary to obtain a desired result.
- Establishing clear responsibility and accountability for managing key activities.



VGi

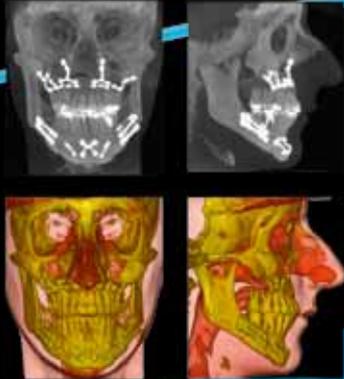
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- Analysing and measuring of the capability of key activities.
- Identifying the interfaces of key activities within and between the functions of the organization.
- Focusing on the factors such as resources, methods, and materials that will improve key activities of the organization.
- Evaluating risks, consequences and impacts of activities on customers, suppliers and other interested parties.

Principle 5: System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

Key benefits:

- Integration and alignment of the processes that will best achieve the desired results.
- Ability to focus effort on the key processes.
- Providing confidence to interested parties as to the consistency, effectiveness and efficiency of the organization.

Applying the principle of system approach to management typically leads to:

- Structuring a system to achieve the organization's objectives in the most effective and efficient way.
- Understanding the interdependencies between the processes of the system.
- Structured approaches that harmonize and integrate processes.
- Providing a better understanding of the roles and responsibilities necessary for achieving common objectives and thereby reducing cross-functional barriers.
- Understanding organizational capabilities and establishing resource constraints prior to action.
- Targeting and defining how specific activities within a system should operate.
- Continually improving the system through measurement and evaluation.

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Principle 6: Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

Key benefits:

- Performance advantage through improved organizational capabilities.
- Alignment of improvement activities at all levels to an organization's strategic intent.
- Flexibility to react quickly to opportunities.

Applying the principle of continual improvement typically leads to:

- Employing a consistent organization-wide approach to continual improvement of the organization's performance.
- Providing people with training in the methods and tools of continual improvement.
- Making continual improvement of products, processes and systems an objective for every individual in the organization.
- Establishing goals to guide, and measures to track, continual improvement.
- Recognizing and acknowledging improvements.

Principle 7: Factual approach to decision making

Effective decisions are based on the analysis of data and information

Key benefits:

- Informed decisions.
- An increased ability to demonstrate the effectiveness of past decisions through reference to factual records.
- Increased ability to review, challenge and change opinions and decisions.

Applying the principle of factual approach to decision making typically leads to:

- Ensuring that data and information are sufficiently accurate and reliable.
- Making data accessible to those who need it.
- Analysing data and information using valid methods.
- Making decisions and taking action based on factual analysis, balanced with experience and intuition.

Principle 8: Mutually beneficial supplier relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value

Key benefits:

- Increased ability to create value for both parties.
- Flexibility and speed of joint responses to changing market or customer needs and expectations.
- Optimization of costs and resources.

Applying the principles of mutually beneficial supplier relationships typically leads to:

- Establishing relationships that balance short-term gains with long-term considerations.
- Pooling of expertise and resources with partners.
- Identifying and selecting key suppliers.
- Clear and open communication.
- Sharing information and future plans.
- Establishing joint development and improvement activities.
- Inspiring, encouraging and recognizing improvements and achievements by suppliers.

There are many different ways of applying these quality management principles. The nature of the organization and the specific challenges it faces will determine how to implement them. Many organizations will find it beneficial to set up quality management systems based on these principles.

Source:

International Organization for Standardization - www.iso.org
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The Dental Certification System in Kenya

The below reported information is an extract from the "GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES" issued by the Kenya Pharmacy and Poisons Board, which do not apply to Medicinal products, Cosmetic products and Active implantable devices.

The regulation of Medical Devices in Kenya is supervised by Kenya Pharmacy and Poisons Board (PPB). Regulatory benchmarks taken into account from the PPB are mainly:

1. The Pharmacy and Poisons Act Chapter 244 of 2002
2. Global Harmonization Task Force (GHTF) for Medical Device EU Medical Device Directives 93/42/EEC
3. EU In Vitro Diagnostic Device Directive (IVDD) 98/79/EC and EU Active Implantable Medical Device Directive (AIMDD) 90/385/EEC
4. US FDA (United States Food & Drug Administration)
5. Australia TGA (Therapeutics Goods Act)

Registration procedure

All manufacturers based outside Kenya must appoint a local authorized representative (LAR), which will be addressed by PPB in Kenya on their behalf for legal obligations and responsibilities. The manufacturer or its LAR should apply for the Medical device registration at the PPB to get a valid Registration certificate that allows a Medical Device to be placed in the Kenyan market. The PPB reviews the Medical Device and decides if further evaluations or documents from the manufacturer are necessary. The whole registration process, including acceptance and evaluation of the application, request for additional data/samples and further clarifications, nominally takes about 90 calendar days.

Medical Devices are divided into four risk-based classes: I, IIa, IIb and III. According to the class, there are different application and evaluation fees due to the PPB to complete the registration procedure. When submitting an application, a Screening Fee of US\$ 25 is charged for Class I Medical Devices that are not exempt and of US\$ 50 for Class IIa, IIb and III Medical Devices. Once an application has been accepted for evaluation, it is subject to an Evaluation Fee that varies according to the risk class. Moreover, an Annual Retention fee has to be paid for each registered device family, before the end of January for each year that the device family is maintained on the medical device register. The registration number of the device must be quoted at the time of payment. These fees are also proportioned to the risk class.

Medical Devices Registration Fees

| Risk Class | Screening Fee, | Evaluation | Annual Retention |
|------------|----------------|------------|------------------|
| | US\$ | Fee, US\$ | Fee, US\$ |
| Class I | 25 | 200 | 25 |
| Class IIa | 50 | 500 | 40 |
| Class IIb | | 750 | 60 |
| Class III | | 1000 | 100 |

Source: Kenya Pharmacy and Poisons Board

Once the Medical Device gets approval from PPB, it is granted a Registration certificate entitling the applicant to import and freely sell the registered medical device. The certificate has 5 years validity unless significant changes are made to the approved application data. However, the PPB may suspend or revoke the registration of a device, or amend the conditions of its registration within a reasonable time, by giving written notice to the registrant. Reasons for cancellation of the registration certificate are applicant request, non-compliance with the manufacturer's obligations, any harm caused to health by the product, lowered product quality compared to the time of the application, alteration from the approved label or violation of intellectual property rights.



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A registrant may also terminate the registration of a device by giving 60 days written notice and reasons to the PPB. Furthermore, the applicant must notify to the PPB any significant change made to the Medical Device, that could affect the safety or effectiveness of a medical device, including the manufacturing process, facility, equipment, quality control procedures, the design of the device and its intended use of the device. All these changes must receive PPB approval before implementation, while other changes, although requiring immediate notification, do not need prior approval. All applications for variation to a registered device entail a variation fee.

As regards registration maintenance, the application should be made at least 90 days before the expiry date of registration of the device. All information related to changes that were made to the registered device should be submitted together with the application form.

Post-Market Requirements

In order to meet post-market requirements, manufacturers and local authorized representatives must maintain records of the device distribution channels in Kenya, including medical device exports from Kenya. They are required to notify the PPB of any adverse events that resulted in the death or a serious harm to the health of a patient, users or other person, or could potentially lead to such consequences due to its recurrence. Manufacturers and LAR must have Complaint Handling, Adverse Incident reporting and Recall procedures in place and keep the related records.

Documents for these procedures are required at the initial application stage in order to place the medical device on the Kenyan market. If post-market procedures were already submitted in one product application, subsequent applications do not require further submissions, as long as documents submitted in the earlier application are available.

Registration Dossier

The administrative information to be included in the application is:

- Details of the manufacturer
- Product Information: description of the device, intended use and instructions of use
- Proprietary name of the product
- GMDN Code specific to the product
- Device Description including functions, basic scientific concepts, component materials and accessories used in its operation as well as packaging. A complete description of each functional component, material or ingredient of the device should be provided.
- Sterilization requirements
- If devices contain biological materials, the devices and manufacturing processes must include validated methods of elimination or viral inactivation.
- Intended Use and indication, general description of the disease or condition that the device will diagnose, treat, prevent cure, or mitigate.
- Potential Adverse Effects
- Contraindications, Warnings and Precautions
- List of components
- Instruction of Use
- Shelf life/ Storage Conditions

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- Details of the Local Authorized Representative
- Quality Systems Standard and Quality Management System
- Details of conformity assessment: whether product is marketed in the country of origin, when the device was originally introduced in the market and the registration number.
- Certification/approval held for the product indicating the agency(s) and year of approval.
- Mode of dispensing and classification of the medical device in the country of origin

Support information to be provided includes copies of all manufacturer certificates related to ISO 9001 standards and GMP certificate issued by the relevant health authorities at country of origin.

Medical devices that already obtained approvals or clearance from recognized regulatory authorities such as FDA (Usa), CE (EU), TGA (Australia), TPP (Canada), MLHW (Japan), SFDA(China), ANVISA (Brazil) and CDSCO (India) can provide evidence of that by presenting certification and/or relevant documents in order to speed up the and evaluation process for market clearance in Kenya.

Evidence of established procedures and systems for Distribution Records, complaint Handling, Adverse Incident Reporting and Recall should also be submitted.

A Declaration by the applicant should be submitted, including the following statements:

- a) all submitted documents are true
- b) the applicant will be fully responsible for the product and post market plan submitted for complain handling or recall
- c) the applicant will fully comply with the requirements of the PPB after placing the product in the market.

All documents, including certificates, should be in English or Swahili.

• **Source:**

Ministry of Medical Services, Pharmacy and Poisons Board Kenya
 "GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES", First Edition, September 2011
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New standards at last for safe tooth whitening

The use of hydrogen peroxide in tooth whitening products will continue to be legally authorised in the EU but will be subject to strict conditions set out in European legislation.

On 20 September, the Council of the EU adopted the directive amending Directive 76/768 on cosmetic products, in order to authorise the continued use of hydrogen peroxide in maximum concentrations of 0.1% in dental products, including whitening or bleaching products.

The use of whitening products that contain the substance in concentrations of between 0.1% and 6% will require a clinical examination and an initial treatment by a practising dentist. Consumers will then be able to continue the treatment themselves.



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The text should be published in the Official Journal by the end of October and will give one year to Member States to implement these new provisions. In the meantime, a 'direct effect' is likely to be attached to provisions relating (1) to the prohibition of circulating products in EU with a higher concentration of 6% and (2) to the authorization of circulating directly to the EU consumer products with a lower concentration of 0.1%.

These new provisions adapt annex III of the Cosmetic Products Directive to technical progress based on the 2007 opinion from the EU's scientific committee on consumer products (CSC).

This committee in effect confirmed that a maximum concentration of 0.1% of hydrogen peroxide present in dental products or released by other substances or mixtures contained in these products does not present a risk.

The CSC also considered that in order to be sure, the use of such products containing hydrogen peroxide in concentrations of between 0.1 and 6% would require an appropriate clinical examination to guarantee the absence of risk factors or any kind of oral pathology that could be a cause for concern.

The committee also considered that tooth whitening and bleaching products containing more than 0.1% of this substance should be correctly labelled in an effort to guarantee appropriate use".

Source:
 FEDCAR - Federation of European Dental Competent Authorities and Regulators
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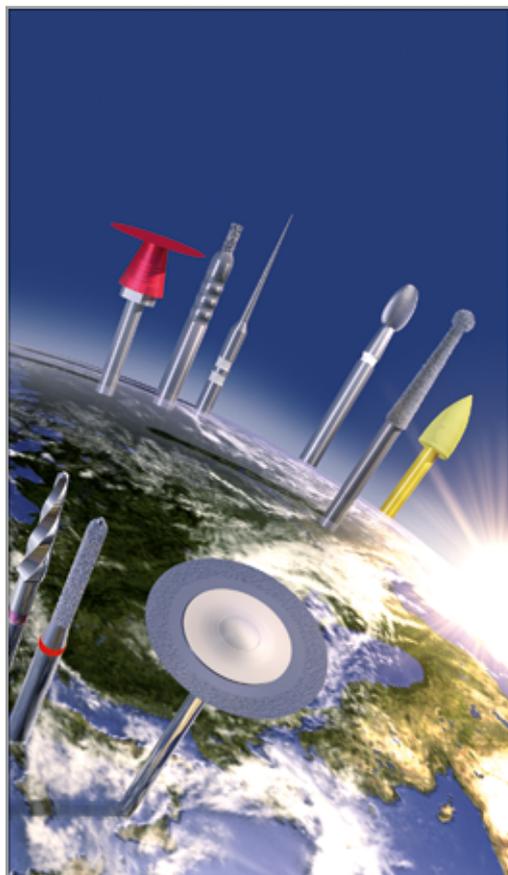
Growth in the Dental Industry continues

The global dental equipment and consumables market is estimated to be \$26 billion by 2014, growing at a compound annual growth rate (CAGR) of 6.8%. The market is expected to grow because of the tremendous demand for dental biomaterial and dental implants

It is expected that the market for dental implants and dental biomaterials will grow at an overall CAGR of 12.2% and 10.5% respectively to 2014. The main non-geographical driving element for global dental equipment market is the advancement in technologies that are available to dentists' for treating their patients.

However, the largest element of growth is the expansion of the market in countries like China and India. For example, by the year 2017 the forecasted market volume of both countries for dental implants is to exceed US\$400 million. Strong double-digit growth rates are also predicted for Brazil, another potent global Emerging Market.

The rapid growth of dental implants will also drive the market for dental biomaterials and bone-craft substitutes. The number of procedures using these materials is expected to reach almost 400,000 in both countries by 2017, with growth also expected in the ASEAN region. The de-regulation of dental care services in China and India has fueled growth of private dental clinics in major urban centres. In addition, the low cost of labor has kept implant procedural costs relatively low, promoting dental tourism from countries such as Japan, South Korea and Australia.



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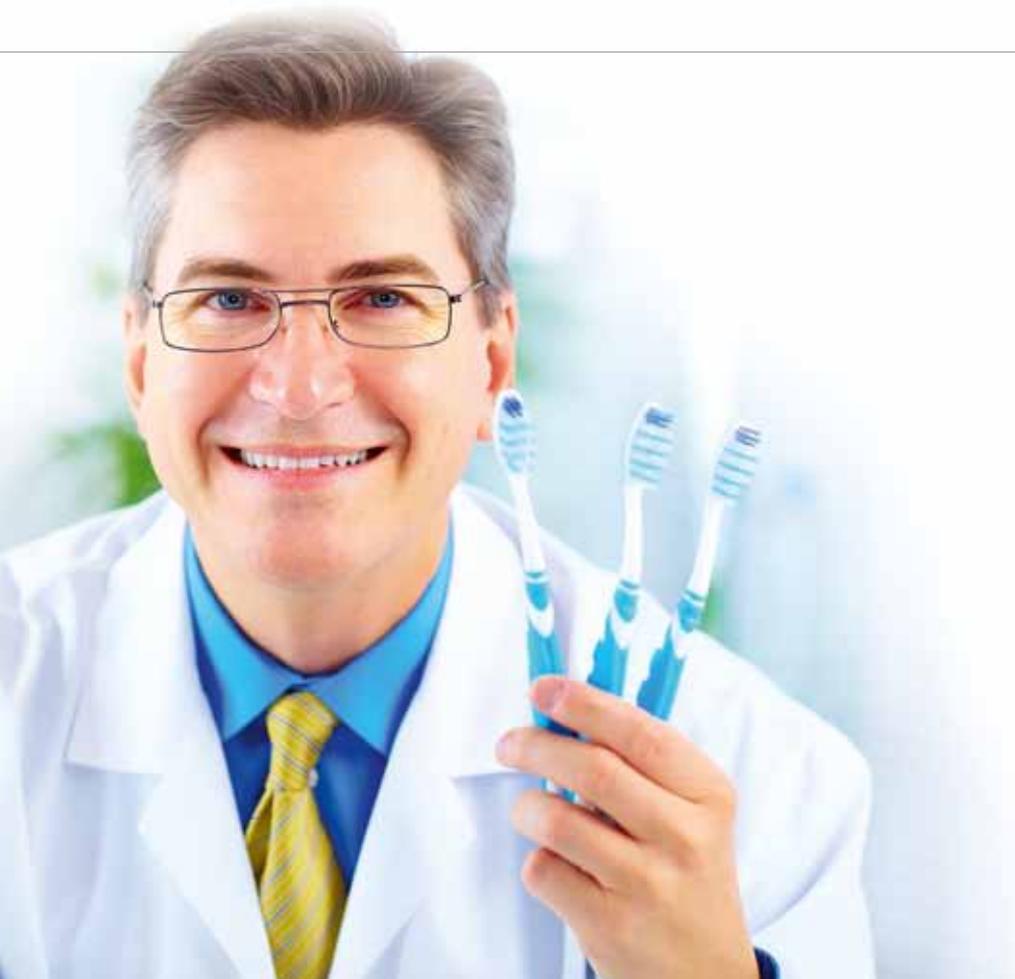
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Markets in China and India are currently dominated by a few foreign manufacturers such as Dentsply-Friadent, Nobel Biocare or Straumann. The Swiss-based company particularly has increased its market share in China and South Eastern Asia with the introduction of innovative products including the Bone Level Implant and SLActive dental implant surface technology.

Global business consultant Frost & Sullivan recently awarded the company with its 2010 Asia Pacific Dental Implant Company of the Year Award for superior performance in different areas such as strategic product development.

However, Europe still holds the largest share of the US\$3.2 billion worth global dental implant market followed by the US, Korea and Japan. The market itself is projected to growth by more than 20 percent over the next five years.

One way to gain exposure to these high growth markets, would be to sponsor and exhibit at the 2012 Commonwealth Dental Association/ Malaysian Dental Association/FDI International Scientific Convention and Trade Exhibition being held in conjunction with the 69th MDA AGM, an event attracting up to 3000 dental practitioners from throughout the world and providing access to the high growth ASEAN +2 (China and India) market.

For more details contact Todd Soulas at tsoulas@industrygrowth.net

Source:
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Occidental S.R.L. Company is an importer of products and dental equipment, with over 30 years in the dental market in Argentina. The company markets its products through dealers houses around the country. We are looking for exclusive representation of dental manufacturers interested to enter to the Argentinian Dental Market. The dental manufacturers interested send commercial proposal to: consultores@planeta-dental.com.ar Att. Dr. Carlos Tobio. For more information go to: www.planeta-dental.com.ar



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The company, well-known on the dental market of Ukraine, with advanced dealer network, offers cooperation on exclusive distribution to manufacturers of dental equipment, materials and instruments. The basic request - payment of obligatory registration of own production in Ministry of Health of Ukraine. Our Contact Details: Service-Centre Ltd.

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New research is focusing on the use of blood-derived growth factors that are useful to increase tissue healing.

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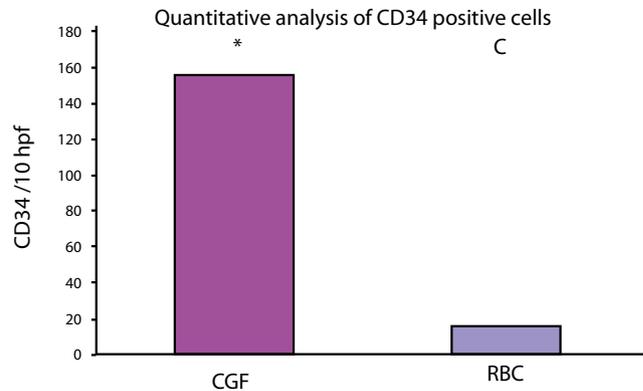
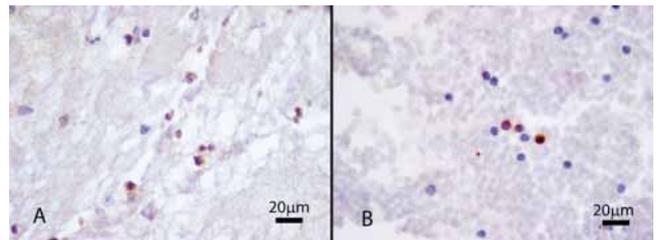
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The CGF's process is simple and automated and permits to obtain an optimal product regardless of the patient hematocrit or the operator's experience.

CGF is produced by fast centrifugation of small blood venous samples with a special centrifuge machine (Medifuge MF200, Silfradent srl, Forlì, Italy) without the addition of any chemical or additives, such as bovine thrombin or anticoagulant factors, so it is free from risk of viral transmission disease. Because anticoagulants are not used, the blood sample is centrifuged immediately with a computer programmed centrifugation speed that permits the isolation of a much larger, denser and richer in growth factors fibrin matrix with a better regenerative capacity and higher versatility.

Some experimental observations underlie that CGF is a rich and dense fibrin matrix in which multiple platelet cell elements are "trapped" and growth factors, such as TGF- β 1 and VEGF, are present. In addition, several CD34 positive cells, which are known to be recruited from blood to injured tissue and play a role in vascular maintenance, neovascularisation and angiogenesis, are present.

Surgeons can use CGF as barrier membrane to accelerate soft tissue healing or mixed with bone graft or other biomaterials to accelerate hard tissue formation and remodeling. Evidences suggest the possible use of CGF alone without bone substitutes for sinus augmentation; however, CGF can be applied for guided bone regeneration, soft tissue healing, periodontal surgery and any other oral surgery associated with bone defects in order to reduce healing time and cost of the biomaterials and barrier membranes. Nevertheless, the CGF's properties could make it functional for different clinical applications in the field of tissue regeneration: Orthopedic Surgery, Maxillofacial Surgery, Dental Surgery, Ophthalmology, Cosmetic Surgery, Sport Medicine, Dermatology, Gynecology and Neurosurgery.



Immunohistochemical staining of CD34 in CGF (A) and RBC (B) layers. The graphs showed the number of CD34 positive cells in 10 hpf for ten sections in CGF and in RBC layers (C). (Available on line www.wileyonlinelibrary.com)



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| Voltage: | 230 V, 50/60 Hz |
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| Iris 2 Evolution speed: | 100/400 rpm |
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Claudio Mongardini

*Professor of Periodontology
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Climb Kilimanjaro – ‘The Roof of Africa’

Described by Hemmingway as “wide as all the world, great, high, and unbelievably white in the sun”, and televised most recently by Gary Barlow, Cheryl Cole and Chris Moyles’ Comic Relief trip back in 2009, you now have the chance to climb Mount Kilimanjaro, while raising money to restore smiles and change lives in Africa. Last month saw the 2011 Kili team, including Mark Topley, B2A’s CEO and renowned speaker Chris Barrow from The Dental Business Coach, climb Mount Kilimanjaro, and now it’s your opportunity to sign up for the 2012 challenge. Mark Topley comments:

“Climbing Kili is by far the most challenging, rewarding and emotional achievements of my life, I am still reeling from it now! I couldn’t recommend it more highly to anyone looking for something that will challenge you physically, emotionally and mentally while making a lasting difference to the lives of people in Tanzania. DO IT!”

The highest mountain on the African continent, and located in the north-east of Tanzania, climbing Kilimanjaro is the challenge of a lifetime. At 5895m (19,341ft) high, more or less 24 miles wide and 49 miles long it dominates the savannah of East Africa. Consisting of three snow-capped peaks: Shira, Mawenzi, and Kibo, the group will spend 11 days in Tanzania climbing Mount Kibo peak. Experience a challenge unlike no other and help support B2A in their quest to free the world from dental pain, dates for 2012 are August 18-28, 2012. To find out more contact Kerry Dutton, fundraising coordinator on 07881 912060 or email her at fundraising@bridge2aid.org. Alternatively visit www.bridge2aid.org to download an application form.



Editors Notes

Bridge2Aid (B2A) is a dental and community development charity working in the Mwanza region of North West Tanzania. We started full scale operations in 2004 and work closely with the Tanzanian Government to deliver aspects of their dental strategy. We operate a not-for-profit dental clinic in the city of Mwanza (Hope Dental Centre), and have a community development programme for the disabled community based at Bukumbi Care Centre. Our focus is sustainability – empowering local people to improve their own lives over the long-term. We have Trustees and administration in the UK and we are a UK registered charity no. 1092481. Bridge2Aid is a registered Non-Governmental Organisation (NGO) in Tanzania with additional Tanzania-based Advisors.

The four key aspects of Bridge2Aid’s vision are:

- To provide primary dental care and oral health education to communities in Tanzania
- To equip and further train local health personnel to provide emergency dentistry to rural communities
- To care for and empower the poor and marginalised in Tanzanian society
- To provide opportunities for UK dental professionals and others to use their skills to serve Tanzania, as locums or participants on the Dental Volunteer Programme (DVP).

Further information/pictures/comment available from:
 Brian Strotton, B2A UK Administrator, brian@bridge2aid.org
 Or contact Mark Topley, B2A Chief Exec 0845 0047559, mark@bridge2aid.org



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•• **16-19/11/2011 DENTA 2011 - 26th Edition Autumn (Bucharest – Romania)**
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E-mail: denta@romexpo.ro
Exhibition Venue: Romexpo Exhibition Center
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•• **17-19/11/2011 SWEDENTAL 2011 (Stockholm – Sweden)**
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E-post: info@stofair.se
Webiste: www.stockholmsmassan.se
Event Manager: Mr. Kim Lindhe
E-mail: kim.lindhe@stofair.se
Direct Phone +46 8 749 43 96
Venue: Stockholm International Fairs
Mässvägen 1, S-125 80 Stockholm

•• **23-26/11/2011 ADF 2011 Conference and Trade Exhibition (Paris – France)**
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7 rue Mariotte
75017 PARIS - FRANCE
Tel: +33 1 58 22 17 10
Fax: +33 1 58 22 17 40
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Exhibits Coordinator: Ms. Carla M. Borg
E-mail: info@gnydm.com
Exhibition Venue: Jacob K. Javits Convention Center
Infodent booth no. 516

December '11

•• **07-10/12/2011 MEDVIN DentalExpo 2011 - The 55th international special Exhibition (Kiev – Ukraine)**
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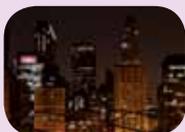
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- **28-31/01/2012 30th CIOSP - Sao Paulo International Dental Meeting (Sao Paulo - Brazil)**
APCD- Sao Paulo State Dental Association
Rua Voluntarios da Patria, 547
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Brazil
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E-mail: ciosp@apcd.org.br
Website: www.ciosp.com.br
Exhibition Venue: Expo Center Norte, Sao Paulo-SP



- **31/01-02/02/2012 AEEDC Dubai 2012 (Dubai - United Arab Emirates)**
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Website: www.aeedc.com // www.index.ae
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February '12



- **22/02/2012 DTA Chicago Midwinter Preview Show 2012 (Chicago - USA)**
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E-Mail: info@dentaltradealliance.org
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Venue: Hyatt Regency McCormick Place, Chicago



- **23-25/02/2012 147th Chicago Midwinter Meeting 2012 (Chicago - USA)**
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E-mail: mwm@cds.org
Contact Person: Ms. Lisa Girardi
E-mail: lgirardi@cds.org
Website: www.cds.org
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- **23-25/02/2012 Expodental 2012 (Madrid - Spain)**
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•• **07-10/03/2012 17th Dental South China International Expo 2012 (Guangzhou - China)**

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•• **14-16/03/2012 Dental Salon Krasnoyarsk 2012 (Krasnoyarsk - Russia)**

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