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Inside:



- Focus on: **East Asia**



- Outlook on: **Brazil**



- Hot Topic: **Determinants of oral healthcare in developing countries**



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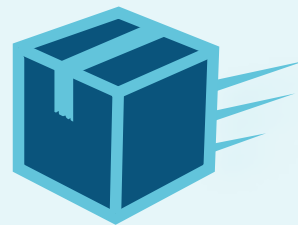
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Prof. A.Scarano, Department of Oral Sciences, Nano and Biotechnology University "G.D'Annunzio" Chieti.



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On this issue



FOCUS ON JAPAN, KOREA, MALAYSIA AND THAILAND

“This article will focus on two distinct areas of East Asia. divided historically by a tormented relationship made of reciprocal domination and cultural influence, but also of long-established trade link...”



OUTLOOK ON BRAZIL

“According to the Brazilian Association of Dental, Medical and Hospital Equipment Manufacturer - ABIMO’s 2014-2015 report, in just two years (2011 to 2013), the Ministry of Health increased seven fold the budget invested in health researches...”



REGULATORY UPDATES IN ASIA-PACIFIC

“China: The substantial regulatory reform that recently took place in China has introduced major updates to both pre- and post-market compliance requirements for medical devices and in vitro diagnostic reagents...”



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DETERMINANTS OF ORAL HEALTHCARE IN DEVELOPING COUNTRIES

“In the developing world, essential oral health care should be a main focus of primary health programmes according to the specific health needs of the population...”



SOCIAL MEDIA MARKETING: USERS' EXPECTATIONS

“Communications have changed and companies are responding to this evolving interactive scenario by redefining some very important concepts. In this article you will find different suggestions on what we should expect in the next months...”

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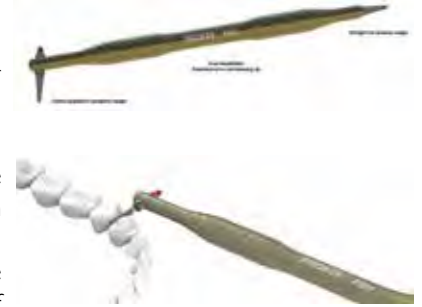


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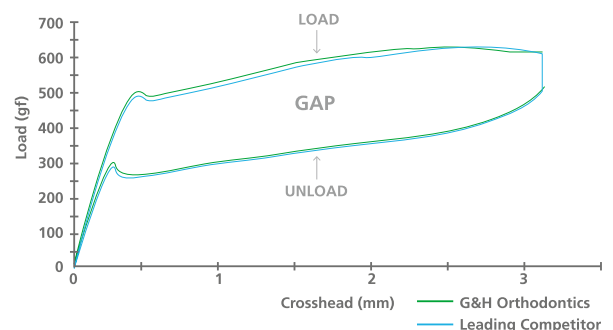
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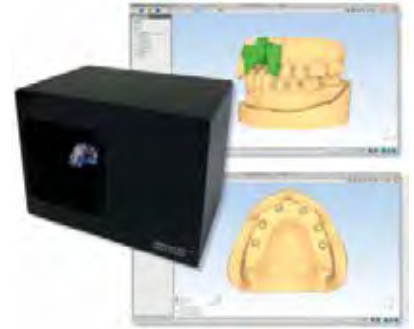
Maestro 3D is the scanner for dental applications. The system simplifies and automates the process of planning and production of personalized dental prostheses. Maestro 3D dental scanner allows the user to get in a simple and intuitive way, with a precision of 10 microns, the open STL files that will leave the user the free choice of the center of production. **Maestro 3D Easy Dental Scan** is the scan control software of the dental scanner.

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• X-LINEAR DC



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• Leonardo - The Innovative Rapid Palatal Expander



Rapid palatal expander Leonardo has several innovative features thought to simplify the work of technicians and doctors, and to be easy to use for the patient. The main features are:

Stability. The two telescopic components of Leonardo's body are always overlapped for the maximal longitudinal and torsional rigidity and high stability, at its maximum opening. The inbuilt housing of the arms and their laser welding grant an highest resistance and a perfect oral hygiene.

Compact dimensions: its body design minimize encumbrance into the mouth, and increase patient's comfort.

Easy-to-use:

- chamfered hole to simplify the insertion of the opening tool;
- lateral screw for fast opening/closing in laboratory;
- graduate scale for an immediate reading of the opening level achieved

Safety:

- mechanical stop to prevent disassembling at the maximum open;
- mechanical anti-unscrewing system to avoid unwished opening into the mouth.

Leonardo is protected by international patents.



www.siaorthodontics.com // info@siaorthodontics.com

• TRIBEST, focus on infection control Items



Tribest is one of the major manufacturers and exporters of dental disposable consumables in China. The company was founded in 2006, and most of the products are CE, ISO 13485, FDA Certificate approved.

Our main products are face masks, cotton roll, dental bib, dental syringes, dental kits, saliva ejector, microbrush, impression trays, denture

box, sterilization pouches, bur block, disinfection box, oral health products, orthodontic products etc.

Tribest focuses on infection control, and gives you the complete infection control scheme with full set of series products, which enables you to know infection control concept easily, and enjoy one-stop products and services.

Infection control is TRIBEST responsibility, and also is your responsibility!



www.tribestdental.com // kevin@tribest.cn Visit us at 2015 CEDE Poland Exhibition Sep 10-12th, Pavillion 7, Booth 3B.3

• The dental plaque detector for clinic & home care



Dental plaque is the sticky film that forms on teeth. If it is not removed on a frequent basis, it can lead to tooth decay and gum disease. You or your child may be brushing regularly, but plaque is nearly the same color as teeth, so it can be difficult for you to see where it is accumulating. The **FINDEX dental plaque detector** uses a plaque filter window, it is easy to check dental plaque which transfer to red

fluorescence via a violet light exposure. Just one second can get the result, you will see dental plaque clearly via plaque filter window. The traditional way to detect dental plaque is using chemical dye, it will leave a few residue of chemical dyes; FINDEX is not using the chemical inspection way, it can avoid residue of chemical dyes in your mouth.



www.dentmate.com.tw // info@dentmate.com.tw

Visit us at DenTech China 2015, Hall 2, Booth U59

• IRIS-100: Navigating the Future of Dental Implants!



EPED is a leading company of design and manufacture dental navigation system around the world. Our new product, The Implant Real-time Imaging System (IRIS-100), features the utilization of optical tracking systems to instantly visualize the implant handpiece and drill together with a CBCT 3D image. With the aid of this real-time

imaging system, users can see the position of the drill and also data such as bone quality, nerve and sinus location and more. Similar to a car navigation system, the system is set up to visualize the destination and helps to guide the pre-planned placement of implants, avoiding dangerous areas, reducing risk and increasing the likelihood of successful implant surgery. This system has been widely used worldwide.

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www.eped.com.tw // eped-sales@eped.com.tw

Visit us at China Dental Show - CDS 2015, Hall 8.2, Booth G091



• STH High-speed Dental Bearings



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- 120 models bearings with stainless steel balls, or ceramic balls
- including Radial ball bearings & Angular Contact ball bearings

Specifications of our products:

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- Tolerance grade super-high precision ABEC 7 (P4) & ABEC 9 (P2)
- High quality, Continuous improvement
- Quick delivery & Sincere service

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• iVAC and iVAC-TWIN

QUATRO's newest iVAC™ and iVAC-TWIN™ dust collectors are specifically designed for use with die-stone, gypsum, plaster, sand, aluminum oxide, glass beads, fine Zirconium dust and CAD/CAM milling. A built-in slide and glide "COLLECTOR" accumulates and stores up to 26 litres in the iVAC and 38 litres in the iVAC-TWIN (twin motor high volume model).

Both the iVAC and iVAC-TWIN feature high capacity (FCS) filter cleaning systems which provide 100% self-activating fully automatic hands-free filter cleaning. Both model iVAC's are in-stock and available for delivery.

For additional information contact WORLDENT:

E-mail: worldent1@aol.com



• EndoUltra – Cordless Ultrasonic Activator



Now available in Europe!

Science has shown that irrigants are more effective when they are electro-mechanically activated. Acoustic streaming and cavitation of endodontic solutions has been shown to significantly enhance cleansing of difficult anatomy. Studies have shown that low frequency (Sonic) oscillation (160-190Hz) was not sufficient in creating acoustic streaming or cavitation within the canal space. **EndoUltra™** is the only cordless, compact, battery operated piezo ultrasonic (40kHz) activation device. Only EndoUltra™ is capable of producing acoustic streaming and cavitation in small canal spaces, resulting in significantly improved debridement, disruption of biofilm, improved penetration of irrigants into dentinal tubules, and the removal of vapor lock. Resulting in improved outcomes. EndoUltra™ features unique 15/02 Activator Tips, which resonate along the entire length of the tip and do not engage tooth structure. Activator tips feature depth markers at 18, 19, and 20 mm.



www.EndoUltra.com - www.Vista-dental.com

• OMS



OMS and its traditional experience in the production of dental unit, introduces to the market LINEA ESSE PLUS .

LINEA ESSE PLUS is the evolution of the classical long lasting and reliable Linea Esse. It maintains the same features of Linea Esse as to the instrument table but the advantages and the evolution are represented by the column water group with adjustable spittoon and ergonomic suction arm with articulated and pantograph movement included. OMS Excellence has today one more choice.



www.omsstaff.com

• New protection for sharp tips and edges



With the new products “**TipCover**” and “**QuadroPack TipLine**”, rose plastic medical packaging GmbH in Hergensweiler/Germany has developed two packaging solutions which offer optimum protection for delicate tips and edges of surgical instruments and applications. The application of “**TipCover**” is self-explanatory and intuitive. The elliptical internal geometry enables sharp tips or edges of medical instruments to be easily inserted. “**TipCover**” is patented and can be used both as primary and secondary packaging. With its telescopic length adjustment, “**QuadroPack TipLine**” offers the ideal protection for long surgical instruments and applications. The tapered ends prevents the content from breaking through. “**QuadroPack TipLine**” is re-sealable and re-usable. “**TipCover**” as well as “**QuadroPack TipLine**” meet the requirement of biocompatibility and are validated up to 50 Kilogray (kGy). Both of them are suitable for gas sterilization, TipCover also for steam sterilization. Both can be produced according to EN ISO 13485 standard with medical grade.



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precision

Comfort,
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dispensing

PROVEN:
Save between
20% and 40%
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7.5 kg
700 mm
430 mm
350 mm

R-080592

Steam Cleaning Cabin

Altamira
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- Designed to operate with a steam cleaning machine
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- Manufactured from high quality plastic.



570 mm
490 mm
520 mm
24 kg

R-080600

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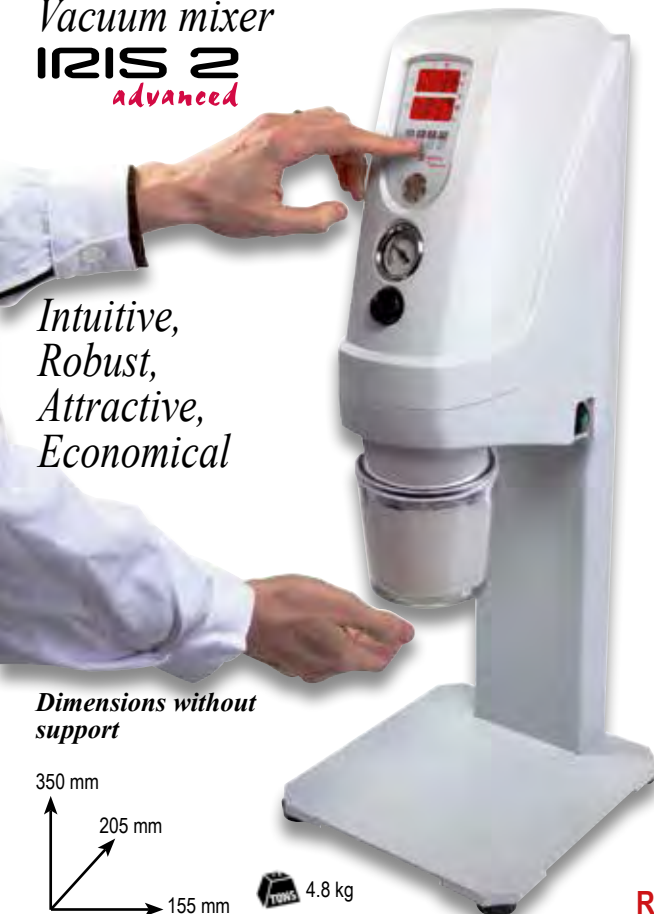
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Dimensions without support

350 mm
205 mm
155 mm
4.8 kg

R-080518

Model Trimmer **Mulhacen**
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Powerful, reliable, secure and cutting edge

- Easily removable cover (wide-opening hinge). Easy to clean and easy access to the disc.
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- Corrosion free.
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- Built-in brake (the disc stops in less than a turn).
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420 mm
345 mm
14.5 kg

R-080093

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SPIRO dental distributes dental replacement parts for handpiece and unit repair. Our products are suitable for a wide range of the world's best known brands. We are one of the most reliable and trustworthy suppliers with the focus on our clients needs and requirements. We supply our clients all over the world in the fastest possible time.

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• Xcem Elite: a submerged fixture from Xcem Implants



Xcem Implants (Xcem Limited) has been manufacturing and trading Dental Implants & accessories for many years in the UK and worldwide. Xcem Limited also manufactures dental products and wear. Our Implants have a novel design which reduces risk of Abutments losing due to fatigue and rotational forces.

The submerged fixture **Xcem Elite (XE)** has a Micro Thread on top and a Main Thread with Dual Thread and Cutting Edge. The micro thread increases thread contact with bone thereby improving the initial fixation effect. When the fixture is inserted into the implant bed, the conical shape and lower deep thread of the fixture increase stability and make immediate loading possible. As pitch of dual thread type, the surgery time is reduced. Surface areas are increased through blasting by highly biocompatible Calcium-Phosphate Media. When placing the implants, the cutting edge of the Twist Type increases Self Tapping ability and minimizes Bone resistance.

www.xcemimplants.com // sales@xcem.co.uk



• TCS Flexible Partial



TCS, an ISO 13485:2003 Certified Company was established in 2000 in USA and is now one of the leading manufacturers of flexible partial material and equipment.

tcs® Unbreakable (nylon) and iFlex (polyolefin) are extremely resilient high-performance materials used for the fabrication of RPDs, they both offer uncompromising aesthetics and functionality.

These materials are lightweight, durable, and can be repaired and rebased. tcs® Unbreakable is guaranteed unbreakable, has very low water absorption and has a proven history of success. iFlex is clinically unbreakable, stain-free, has virtually no water absorption, is easy to finish and polish, and is slightly more translucent than tcs® Unbreakable.

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monitor arms, tray arms, instruments hoses, tubings, vacuum tubings, pneumatic valves, infection control devices, foot control, syringes, pressure regulators, control blocks, electro-pneumatic boards and many others.

G.comm will also design and create your custom product under your specific request to help you find the best and finest solution to your dental unit.

Currently working with over 25 different countries, G.Comm is now determined to grow larger and experience new markets all around the world.



• Iris View

IRIS View is a Surgery Light with integrated Full-HD Videocamera system up to 30 times Optical Zoom. The patented color mixing technology may allow the surgeon to adjust the color temperature (from 4200°K to 6000°K) to the optimal contrast when operating on soft tissue areas or change it to a natural daylight for color teeth matching.

IRIS View is equipped with a keypad that has 3 preset programmes: Anti-Polymerisation Mode (to prevent hardness of composite in a very short time); Surgical Treatment Mode (to better distinguish the shades of the gums, blood and periodontium); Color Capture (facilitating the dentist's choices during tooth replacement operations).

Moreover, IRIS View can be controlled via Wi-fi with the combination of an i-Pad through a Software (my-light) to be downloaded (Free Of Charge) from the App Store.



www.gcomm-online.com // info@gcomm-online.com

• Baolai Medical aims to make the best ultrasonic scaler in China



Baolai Medical professionally designs and manufactures the piezo ultrasonic scaler. We're the first one launching 'No cracking' aluminum alloy detachable handpiece and 'No consumables' auto-water supply scaler in the world. All products have obtained CE, FDA, TGA certificate and 24 national patents. We offer OEM/ODM service for world famous brands.

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- Functions: scaling and endo
- Water supply system without consumables
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• SONOSURGERY® AIR POWER



Manufactured from high-quality and robust materials, the new SONOSURGERY® AIR POWER pneumatic handpiece has been especially designed to use them with surgery inserts. This improved handpiece, which can be used on any dental unit instead of a turbine without requiring any additional air pressure adjustment, can be employed for all prophylaxis or bone surgery procedures with the aid of the special Komet® surgery inserts. Vibration power level can be adjusted by means of a larger rotating nut, making the procedure more flexible and accurate.

The handpiece can be used together with any MULTIflex®-compatible rapid coupling or, optionally, with the new SONOSURGERY® STERIL rapid coupling which allows external inlet of medical sterile liquids. Both handpiece and the supplied dynamometric wrench are fully thermodisinfectable and sterilizable.

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• Medesy new periodontal micro-tweezers



The new tweezers have been conceived and realized through a cooperation with our Key Opinion Leaders, a joined study on micro surgery specific requirements aimed at developing a product which could offer excellent performance as well as easy handling. The result a very practical instrument with remarkable features such as:

- Optimal balance between weight and sizes
- Rounded and anatomical handle allowing easy circular finger control
- First-quality surgical stainless steel selected for its elevated corrosion resistance

Range of 5 different micro-surgical tweezers

Main technical features:

- Tungsten carbide inserts;
- Diamond dusted tips:
- 0,7 mm hole
- 1x2 teeth
- Standard serration

The ultra-thin tips ensure a precise and firm grip of the tissue fragments and also a wider visual field

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• High Quality Dynamic Mixer



High quality Dynamic mixing tips are for use with automatic impression material mixing machines.

• Accurate ratio base and catalyst are checked by a special blender built in the tips which helps to achieve the perfect 5:1 ratio from the very beginning.

- The base and catalyst are dispensed at the same time with constant speed.
- Dynamic mixer minimizes any waste of the impression material while dispensing occurs.

Watch as it precisely mixes and dispenses the perfect ratio of impression material!

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• TRAUS SUS10 - Ultrasonic + Implant Dual Engine



Saeshin, as professional manufacturer and exporter for dental handpiece and high precision medical device with 40-year-experience, launches **TRAUS SUS10** equipped Ultrasonic piezo surgery and implant motor engine in one unit. The Piezo surgery engine provides big power with stable frequency for work efficiency and for minimizing pain. Furthermore, it has safety system which operates on touching the hard tissue only, and it brings longer span life of the tips as well as safety for patient avoiding damage to soft tissue. The implant engine with handpiece provides maximum torque and LED for efficient and safe surgery. The LCD and panel provide easy set up and controlling of operation and handpieces and motor are autoclavable. The pedal is included and unit is qualified by international certifications.



<http://www.saeshin.com> // sales@saeshin.com

• New tray trolley



MESTRA launches its **new trolley R-100048** for model trays. Its low weight and the rotating wheels, makes it highly maneuverable when driving around different spaces in the lab. Moreover, its dimensions allow it to pass without problems through doors or narrow passages. Since it is built in tubular steel, it is extremely robust. It is fully compatible with the MESTRA R-10005X and R-10006X system tray, allowing accommodate up to 60 small or 40 large units. It is supplied as a kit to be assembled by the customer. It is very simple to assemble (instructions included).

Height: 135 cm / Width: 85 cm / Depth: 85 cm / Weight: 13,5 kg

R-100048 Trolley

R-100048-50 Trolley + 30 small + 20 large trays

R-100048-60 Trolley + 60 small trays



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• HDR System



HDR system is professionally designed & manufactured by Handy team. Thanks to Handy's advanced CMOS technology and skilled production process, every HDR sensor is guaranteed to bring high definition images to simplify our clients' daily dental practice. In a very short time, the digital radiographs will be shown on the PC for instant diagnoses with more detailed and accurate information. HDR system helps dental professionals work more efficiently and facilitate communication with patients by showing those sufficient "evidences". Now, the clients may use HDR system software APP in movable devices and show the images freely.

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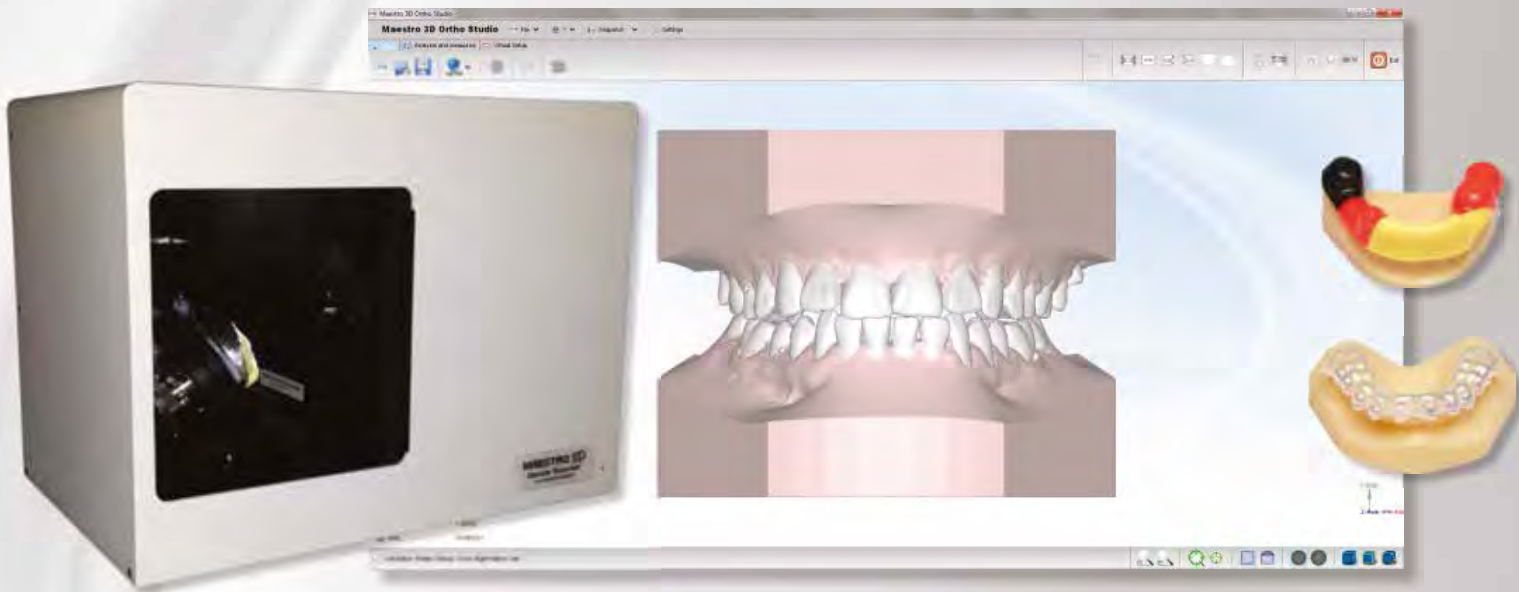
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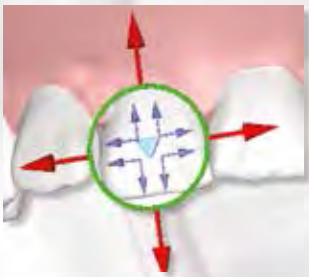
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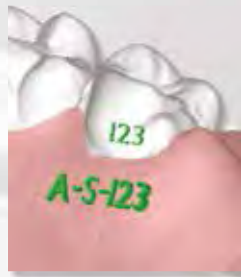


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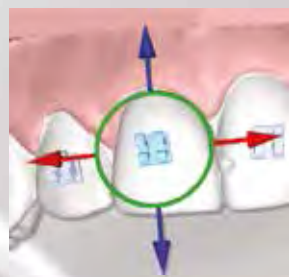
Attachment designer



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Brackets module



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Interproximal reduction



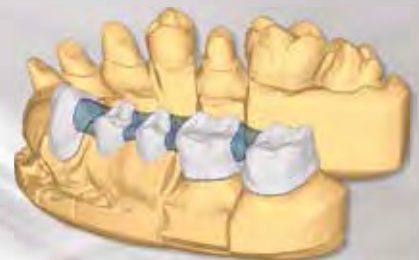
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• Runyes Medical



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- + Maximum cutting power : 21 watts
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- + Extreme bur concentricity means better work precision
- + Available in Medium and Mini head

Wolf Light Black Label (LED+ Plasma)

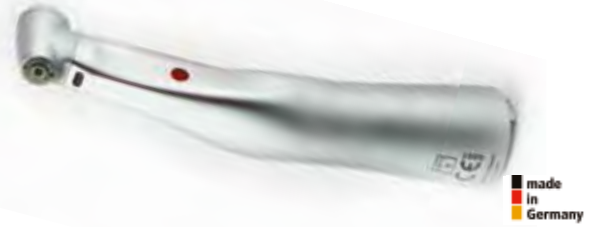


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Wolf Electric Handpiece



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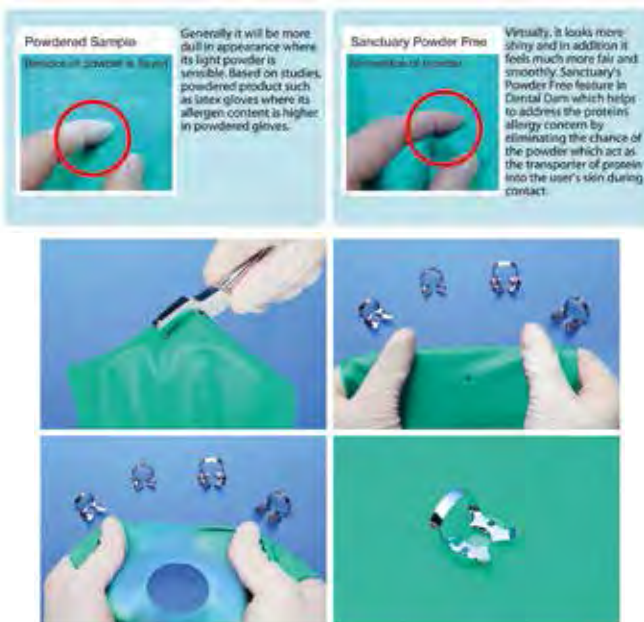
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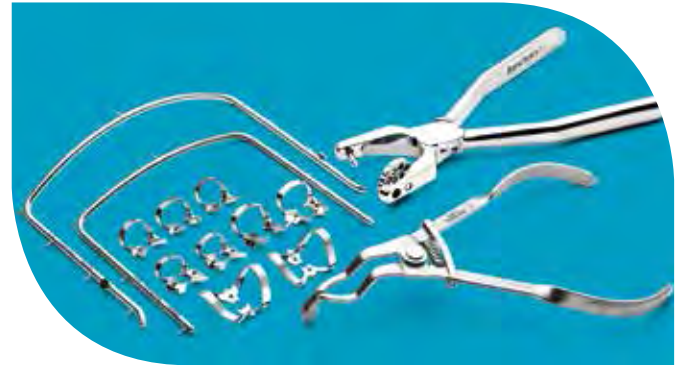
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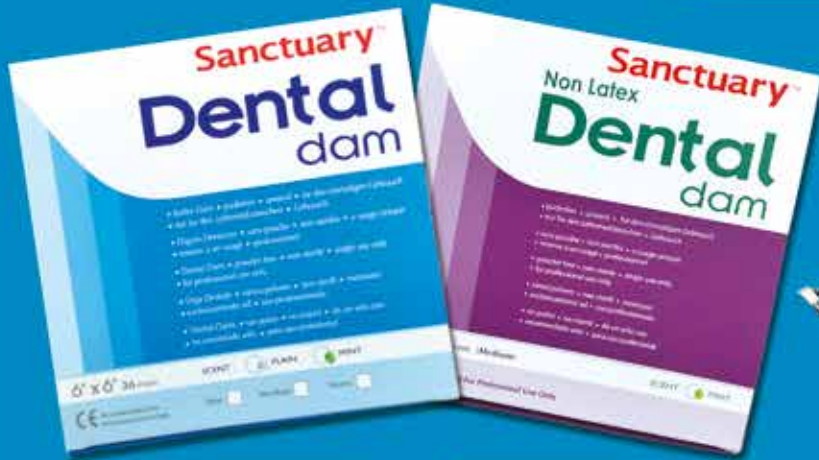
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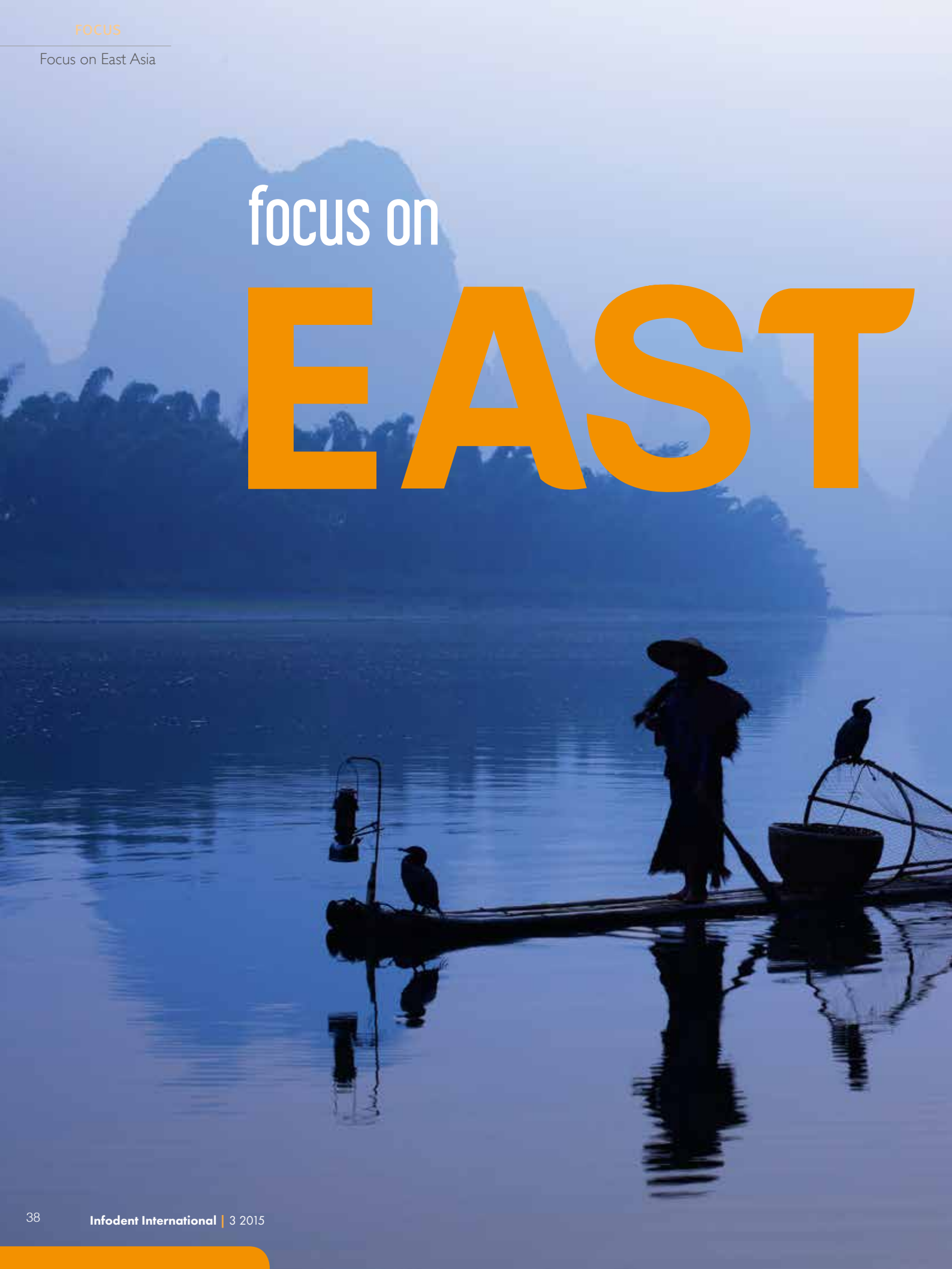


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EAST





ASIA

This article will focus on two distinct areas of East Asia.

*Japan and Korea, lying at the Eastern tip of the Asian continent, are divided geographically by the Korean Strait.
Malaysia and Thailand, covering together a large part of the Indochinese peninsula.*

Author: Michela Adinolfi

Japan and Korea, lying at the Eastern tip of the Asian continent, are divided geographically by the Korean Strait, and historically by a tormented relationship made of reciprocal domination and cultural influence, but also of long-established trade links. They are both advanced economies and major industrial powers with a sophisticated technological infrastructure, a highly urbanised landscape as well as similar demographic trends.

Malaysia and Thailand, covering together a large part of the Indochinese peninsula, share the same border and experienced a parallel economic development “boom” in the last decades of the 20th century, that brought both countries to reach the upper-middle income status.

However, while Thailand's population is roughly twice the size of Malaysia's, the latter's per capita GDP is 1.6 times higher. The two countries, together with Indonesia, have recently been criticised for their refusal to provide relief to prosecute migrants held off their coasts, adding to the persisting issue of insufficient human rights law enforcement in Southeast Asia.

Japan

Economy outlook

According to the IMF, Japan's GDP should reach 1% growth in 2015, after a prolonged contraction that has affected its economy in 2014. Strong exports, boosted by a weak yen, were accountable for a large share of the growth, while consumer spending and business investment remain low, expressing the concerns of household and investors. With a budget deficit of 7%, and an ageing population, the Japanese government needs to keep a tight control over public finances and in 2014 it imposed a tax increase that eventually brought a recession. Moreover, stagnating wages and very low inflation contributed to the difficulty in regaining a confident market sentiment.

However, in a recent outlook published by Deloitte, some positive signals were highlighted, including the falling unemployment rates, although less full time and more part time or contract workers are hired and the recovering of the industrial production after five years of sharp decline.

When it comes to the economic fundamentals, Japan is quite solid with low bond yields, but low labour productivity and high corporate income tax have so far influenced business investment negatively.

Healthcare system

Japan has a universal health insurance system in place that helped the country achieving one of the world's highest life expectancy rates, ensuring a high level of health standards. Any insured citizen is entitled to receive free examinations for a list of diseases and for prenatal care, both from locally administered or state-level facilities.

The health insurance is divided into two main schemes, employment-based or community based, named the Employees' Health Insurance and the National Health Insurance. It is mandatory to enter one of the two schemes, both requiring salary-based monthly premiums.

Under the Employees' Health Insurance scheme, people who are working in private schools, in the national and the local government and in medium or large companies, receive insurance certificates from their employers.

All those who are not covered by Employees' Health Insurance, including visiting people who remain in Japan for more than one year, must subscribe to the National Health Insurance.

Despite the wide coverage provided by the universal insurance system, there is still a small percentage of medical expenses (around 14%) that is paid through co-payments.

The healthcare sector is influenced by a marked declining birth rate and population ageing trend, which impact on medical costs and poses a significant challenge for the welfare system.

Demographic issues:

The rapid pace of Japan's population ageing is evident in the statistics made available by the National Institute of Population and Social Security Research, who released the following figures for the period 2010-2030:

- The population will decrease from 128.05 million to 116.62 million;
- The ratio of people aged 65 and older is expected to rise from 23% to 31.6%
- The ratio of the productive-age population comprising people aged 15 to 64 is expected to fall from 63.8% to 58%.

Consequently, by 2030 there will be two workers supporting each elderly person, and by 2060 there will be just 1.2 workers supporting each elderly person. This problem will strike more in rural communities and is likely to accelerate the excessive urbanisation. With this in mind, the government is under pressure to strengthen home-based medical services and nursing care, while reforming the tax system to restore the financial sustainability.

Dental market highlights:

- Market profile: Japan is a high-end market, dominated by major local dental equipment manufacturers.
- Utilisation of dental services: A recent study reported that dental care in Japan has traditionally been treatment-oriented, with low use of preventive care especially among working-age adults. Only 29.4% of people in their twenties had dental check-ups, while the percentage climbed to 32.2% of those in their thirties or forties and to 41.4% of those in their sixties. Despite an improvement in preventive behaviors, there are consistent inequalities across the different socioeconomic groups, which prompted experts advocating for public insurance coverage for preventive care in order to narrow the gap.

Japan and Korea are two advanced economies and major industrial powers with a sophisticated technological infrastructure, a highly urbanised landscape as well as similar demographic trends.

FOCUS ON East Asia

Cover Photo

Fisherman on Li River

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- **Implants:** According to a recent report by Technavio, the implant market in Japan was valued at US\$460 million in 2014, expected to reach US\$814 million by 2019 (CAGR 12%). However, the market is relatively saturated and premium brands enjoy a well established predominant position.

Japan's dental figures

- In fiscal year 2011, dental care expenditure accounted for about 7% of the total spending on medical care.
- Total dental expenses in 2011 were 2.6 billion yen - of these, 426 million were paid for elderly dental care.
- In 2010 there were 68,384 dental clinics in Japan

Source: Ministry of Health, Labour and Welfare

Korea

Economy outlook

Korea is Asia's fourth largest economy, and it represents a key trade partner in the region for Europe and USA. According to the OECD and the World Bank, economic growth in Korea was quite moderate in 2014, in a context of low domestic and external demand where only fixed investment posted a positive trend. GDP is expected to grow about 3.5% in 2015, provided that the low and stable inflation and a current account surplus continue. The improved trade conditions and low global oil prices, as the country's energy sector is almost entirely dependent on imports, should impact positively on this estimate. Partly as a confirmation, in a recent article the BBC reported that during the first three months of 2015 the Korean economy expanded 2.5% compared with a year earlier, a tiny but encouraging 0.1% point over Bank of Korea's own estimate for the period. Construction investment and manufacturing as well as a rebound in private consumption contributed to the increase.

Healthcare system and demographic trends

Total healthcare spending in South Korea is quite low compared to other advanced economies, at an estimated 6.9% of GDP. Healthcare services are based on a three-tier system consisting of clinics, small hospitals up to 100 beds and general hospitals up to 700 beds at the second level and universities or general hospitals with more than 700 beds at the third. All South Koreans may access these facilities, but a referral system is in place to receive care in a third-tier centre.

A universal healthcare insurance is in place, based on a mixed financing from taxation and premiums and is divided into three branches: the National Health Insurance Program (NHIP), the Medical Aid Program, covering those who are not able to pay for their own insurance; and the Long-term Care Insurance Program specially targeting the elderly.

From a demographic perspective, the ageing trend is becoming an issue in Korea: according to a study, the shrinking workforce due to a low birth rate and rapidly aging population, pictures a situation that is quite similar to that in Japan: the workforce aged between 15 to 64 should at 37 million in 2016 before declining to 33 million in 2030, 29 million in 2040, 25 million in 2050 and 22 million in 2060. Parallel expectations show that the total population should decline from 52 million in 2030 to 51 million in 2040, 48 million in 2050 and 44 million in 2060.

Dental market highlights

It is worth mentioning that dental equipment or supplies rank among the top ten medical items produced in 2013, according to official figures released by the Korea Medical Devices Industry Association (KMDIA). Specifically, dental implants registered the highest production value, totaling 556 billion won from 52 manufacturing companies.

Dental precious metal alloys were the third most produced item with 136.4 billion won and 45 companies involved in the production. Implantology was also present, further down in the list, with instruments for dental implanting ranking 11th; the total production value for the segment was 73.1 billion won with 48 manufacturing companies.

At the 19th place, the value of dental units and chairs produced in 2013 reached 41 billion won, split among the 9th manufacturers in this segment. As regards exports, the top performers in the same year were by far dental implants, with exports worth 112.5 billion won, which helped this segment gain the 3rd place in the top 20 exported items in 2013. Instruments for dental implanting managed to get the 20th position with 20.2 billion won of export value.

It is interesting to note that dental products and equipment disappeared from the 2013 ranking of the top 20 imported items. This finding shows that, despite the increase in medical imports as a general category, dental products do not account for a significant share.

Highlights

- In 2013 there were 2,607 medical manufacturers in Korea, a 14.5% increase from the previous year. Their number grew at an average 8.7% per year between 2008 and 2013.
- 750, or roughly one third of them, were also exporters and recorded an average annual growth rate of 9.6% in the same period.
- The number of medical importers grew from 1,456 in 2008 to 2,009 in 2013, recording average annual growth rate of 6.7% during this period.

Malaysia

Economy outlook

In the last decades of the 20th century, the rapid growth of the Malaysian economy has gained the name of "Asian Dragon". Malaysia's GDP growth peaked at 6% in 2014 thanks to strong private consumption and exports, despite contracted fixed investment and government spending. Private consumption, in particular, contributed more than half of GDP growth from the demand side, with robust 7% growth, driven by job creation, low unemployment, and higher wages, as well as the support of cash transfers from the government. On the other hand, the government balanced the expenses by reducing public consumption to 4.4%.

From the supply side, services grew by 6.3% to generate most of the GDP growth. The sector's growth was led by communications, wholesale and retail trade, and real estate and business services. Tourism was another important factor boosting growth in accommodation and restaurants.

Economic growth is projected to slow to around 4.7% in 2015 and 5% in 2016 as demand weakens while prices of oil and other commodities remain

low. However, the manufacturing sector, accounting for about one quarter of the economy and services such as tourism are expected to keep their favourable momentum due to low fuel costs, currency depreciation and improved outlook for the main trading partners. Since services and manufacturing now account for 80% of GDP, their healthy status means positive spillover effects on the entire economy.

Healthcare system and market highlights

Healthcare in Malaysia has changed radically from traditional remedies of the pre-colonial era to the more modern and westernized medical practices now widespread in the country. The health system is divided into two sectors, public and private, where doctors may shift to private practice after having completed three years of service in public hospitals. Malaysia also encourages foreign doctors to practice in its health sector.

Despite the theoretical commitment to a universal access to high-quality healthcare, remote areas suffer from a low distribution of facilities and specialists, an issue that is being targeted through the so-called "Tele-primary Care", allowing doctors in remote areas to discuss problem cases through Tele-consultations with specialists and doctors in other hospitals.

Malaysia and Thailand experienced a parallel economic development "boom" in the last decades of the 20th century; however, while Thailand's population is roughly twice the size of Malaysia's, the latter's per capita GDP is 1.6 times higher.



Photo

Mt Fuji and
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Thailand

Economy outlook

According to the Asian Development Bank, after the military takeover of the government that occurred in May 2014, following a series of political unrests that disrupted economic activity in the first half of the year, growth prospects should improve for 2015, rising to 3.6% in 2015 and slightly over 4% in 2016.

These estimates are based on the assumption of the persistence of a relatively calmer political environment, that is supposed to revitalise public fixed investment, especially in the transportation and infrastructure sectors. The government is undertaking a large-scale investment project that will allocate \$95 billion over 8 years starting from 2016.

As Thailand's main export destinations (China, Japan, Europe) are still in a fragile position, the only partner with a stronger outlook is the USA but it is insufficient to compensate the weak exports to other traditional destinations. On the other hand, a growing tourist sector and the low price of energy are fueling the economy and an easier monetary policy should help the highly indebted households (especially in the agricultural sector) and boost consumption, provided that a smooth transition to a civilian government takes place in the near future.

Another unsolved issue, common to many Asian countries, is the habit of over-prescribing drugs to artificially boost doctors' own incomes.

As a popular destination for health tourism, Malaysia offers many high-end services in the fields of cardiology, dentistry, gastroenterology, screenings, general surgery, orthopaedics, ophthalmology, and plastic surgery.

The medical devices industry is dominated by the production and export of catheters and surgical and examination gloves, two product segments where Malaysia is a global market leader supplying 80% of the world market for catheters and 60% for medical gloves, including specialty gloves such as low protein, powder-free medical gloves and safety gloves. However, this industry is also beginning to diversify the production towards higher value medical devices. Most of the about 180 medical manufacturers are small- to medium-sized companies with some multinationals. The medical industry employs over 20,400 people, most of whom are in the managerial, professional, supervisory and technical staff levels. Currently, there are more than 180 medical devices manufacturers in the country.

As regards oral healthcare, today it is provided in both the public and private sectors with the Oral Health Division, MOH that has assumed the role of lead agency for the profession. The private sector gives a significant contribution although mainly in the well-populated urban areas.

The market appears very mature and oral hygiene is by far the largest category driving growth.

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Healthcare system and market highlights

According to the World Health Organization, the rapid economic expansion occurred in Thailand over the last two decades has caused a decrease in the mortality rate and an improvement of general health indicators. In 2002, universal healthcare was introduced, based on the primary health services network and a focus on prevention measures such as alcohol and tobacco tax to finance health promotion activities.

Under the 11th National Development Plan (2012-2016), there was a marked progression towards the health-related Millennium Development Goals. However, there are great disparities across the different regions of the country, where poverty rates are 4 to 8 times higher than in Bangkok. The government has started a nonconditional cash transfer program for all Thais aged over 60 years and a parallel program for 0-6 year old low-income children.

Another issue is represented by the estimated 2.4 million migrants, most of whom work informally, and therefore cannot count in the 99% citizens that result covered by the Thai health protection schemes. Although the government has proposed a particular scheme to cover this group, it is still at an early stage and the outcome cannot yet be assessed. Some other challenges include the ageing population, the incidence of non communicable and communicable diseases and administrative inefficiencies.

As regards the medical device sector, Thailand depends on imports for almost all of the higher-end equipment and products, since the over 300 local manufacturers are mainly producing basic items such as bandages, sutures, syringes, blood transfusion sets, disposable gowns, examination gloves, condoms, HIV and AIDS kits, and wheelchairs. In particular, imports must satisfy almost entirely the demand for advanced products such as ocular prostheses, heart valves, electrocardiographs, ultrasound equipment, X-ray equipment, dental drill engines and artificial teeth, which are especially sought in the over 250 private hospitals across the country.

The Thai Medical Device Technology Industry Association estimated the dental market to be worth US\$65 million in 2014.

Photo

Malaysia

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The Trans-Pacific Partnership:

a controversial agreement to liberalise trade in Asia-Pacific

Eleven countries in the Asia-Pacific region, namely Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States and Vietnam, are participating to negotiations aimed at establishing the "Trans-Pacific Partnership". This trade agreement should, in the view of the negotiating countries, "open markets, set high-standard trade rules and address 21st-century issues in the global economy."

However, this agreement has been strongly opposed by global health professionals, internet freedom activists, environmentalists, organised labour and advocacy groups, as well as elected officials. The main issues with the TPP are the secrecy of negotiations, conducted without any parliamentary vote or commitment, and also outside the framework of the World Trade Organisation, as well as the controversial nature of many of the provisions about product safety requirements, copyright protection and environmental standards.

The fear expressed by relevant international experts is that such an agreement would be of little benefit to workers and households, and mainly serve to the interest of large multinationals to bypass national regulations entitled to protect workers, consumers and the environment. Another problem arises from the participation of countries where human rights are severely violated. From the economic point of view, the interest of some Asian countries to join in the TPP, such as Thailand and Indonesia, contrasts with their protectionist policy that is incompatible with the liberalisation measures imposed by the treaty.



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Outlook on BRAZIL

Author: Michela Adinolfi

Brazil increases investments in health researches and establishes key international partnerships

According to the Brazilian Association of Dental, Medical and Hospital Equipment Manufacturer - ABIMO's 2014-2015 report, in just two years (2011 to 2013), the Ministry of Health increased seven fold the budget invested in health researches, from R\$35.6 to R\$248.7 million. The aim of the government is to develop innovative solutions for the country's healthcare system, organised under the Sistema Unico de Saude (SUS) and to improve the use of health services. Of the overall budget, slightly less than R\$60 million were allocated for the direct hiring of research institutions. In particular, these researches focused on the areas of maternal health, prevalent diseases and impact of strategic public policies.

The increase in R&D budget is part of a comprehensive effort to make Brazil's public healthcare sector more competitive. ABIMO reports that the research investment level in Brazil is now comparable to that in the biggest countries around the world. Recently, a partnership agreement was signed with the National Institute for Clinical Excellence (NICE), an independent agency of the British Health Ministry that is supposed to cooperate with its Brazilian counterpart in a program aimed at exchanging knowledge and competences to bring key health technologies to the public health system.

The new research projects financed by the Brazilian MOH for a total investment of R\$47.1 million, include, among the others:

- Construction of the National Network of Research on Health Policies
- Strengthening of the Brazilian Network of Health Technologies Assessment
- Development of new therapies
- Improving the treatment of endocrine and metabolic disorders.

Photo

Rio de Janeiro, Brazil, Christ The Redeemer, Corcovado

Kseniya Ragozina / shutterstock



Another important international partnership has been established with Germany, under the theme "Where ideas connect" which includes several areas of cooperation such as economy, education, sciences and sustainable development. Within the framework of the Quantitative Imaging in Oncology research network, the German Cancer Research Center (DKFZ) based in Heidelberg, is working with the São-Paulo Oncology Center and the Sírio-Libanês Hospital on a tumor screening software.

The dental industry production has reached R\$760 million in 2012, with a surplus worth more than US\$12 million.

The medical devices industry

According to a consultant from the Getúlio Vargas Foundation (FGV), that together with ABIMO conducted a joint analysis of the Brazilian medical and dental industry, national policies conducted to reduce poverty allowed an increase in the number of lower income Brazilian households, that were able to get a healthcare plan in the past few years and receive periodical medical examination.

The positive impact on the medical device sector is mirrored in several indicators of the recent industry's performance:

- Production: In the first quarter of 2014, physical production of medical, hospital and dental equipment has accelerated 5.8%, with an estimated invoicing growth of 7% for the year.
- Employment: Between 2012 and 2013, almost 1,500 new jobs have been created but even if many jobs were added in the first six months of 2014, that contributed to an acceleration of the trend anyway.
- Export: In the first half of 2014, exports increased by almost 5% during the same period of 2013, while imports fell by 1.2%.
- Trade partners: The USA are the main business partner of Brazil, accounting for 32% of Brazilian medical imports and 24% of export. Argentina is the second importer.

However, there is still a gap between imported and exported medical products, as domestic production does not meet the growing demand for high quality equipment.

As the largest South-American market, Brazil represents an important export destination for medical and dental manufacturers, despite barriers on imports add difficulties to the market penetration.

A closer look on the dental sector

Brazil has about one thousand Centres of Dental Specialties or CEOs, supplied by the "Brasil Sorridente" (Smiling Brazil), a Program run by the Ministry of Health since 10 years and which is a part of the National Oral Health Policy. These centres provide completely free oral healthcare, including endodontic treatment, surgeries, gum treatment and oral cancer detection.

In some cases they also support patients needing implantology and orthodontic treatments.

The program currently benefits 79.6 million citizens, employing 23,150 Oral Health Teams that operate across almost 5,000 cities, which represents approximately 90% coverage.

In particular, the CEOs cover more than 800 cities. Until November 2013, the program had received R\$803 million in resources, both for the Oral Health Teams and CEOs, which make it the major public oral health program worldwide.

Just to give some figures, after the implementation of the program started in 2004, the number of prostheses performed every year jumped from previous 100 thousand to 405,000 in 2012 and 415,000 in 2013.

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DIC 15	• GNYDM •										
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JAN 16											
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								• IDEM •			
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2015

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12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
		• ICOI Symposium •													• CAE •				
							• BIHE •						• CDS •				• Dental Expo •		
									• Dentech China •										
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The oral hygiene market

According to a research carried out by the BBC in 2014, the Brazilian oral hygiene sector is the core of the country's dental market. Mentioning an estimate by Euromonitor International, Brazil has the highest number of dentists in the world, around 240,000 or 15% of the total and the third-largest market after USA and China. Interestingly, an average Brazilian household spends as much as a US household in oral care. Brazil is a very competitive market and the economy is now growing slower than in the past decade, but well-known American and European brands have maintained their sales potential quite unshaken.

The implant market

The Brazilian market for implants kept a growing pace in the last five years, with a 10% increase in the period 2012 – 2013, according to a market research carried out in 2013 by VMCom. Unlike the other product segments, the implantology sector is largely dominated by domestic manufacturers, and the five industry-leading companies are all Brazilians. As regards the consumers preferences, a survey among professionals attending implantology events showed that cone-morse connections and cemented prostheses were the preferred cases for single implants, while for multiple prostheses it showed a prevalence for external hex system with screwed prosthesis.

As for the market of biomaterials and tissue regeneration, about 80% of oral surgery professionals use membranes and the 86% bones substitutes.

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- <http://www.segs.com.br/saude/11657-abimo-mapeia-perfil-de-atuacao-e-consumo-de-dentistas-do-pais.html>



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Accessing the Brazilian market

Despite the high demand of sophisticated medical equipment, 80% of which is met by imports, that makes the Brazilian market very attractive to foreign manufacturers, its strongly protectionist regulations also make it difficult to access. This is especially the case for small and medium companies with limited (or minimal) investment capacity and international infrastructure.

The Brazilian Health Surveillance Agency, or Anvisa, is the regulatory body for all the health-related devices and products. Under the Anvisa categorisation, medical devices are divided into four categories depending on their risk level, which may be summarised as follows:

Category I: Non-invasive equipment that present minimal risk to humans (such as heart rate monitors, bandages, trolleys etc.)

Category II: Non-invasive equipment that present a considerable risk to humans (ultrasound, endoscopes, resins for dental surgery etc.)

Category III: Invasive products that present a high risk for humans

Category IV: Invasive products with maximum risk for humans

On general terms, products included in categories III and IV, and even products in lower categories that may present a risk to humans are required to be registered with Anvisa and become subject to the Health Surveillance Regime. As most of category I and II products pose minor risks to humans, they only need to be listed on the Anvisa database. In both cases, Anvisa issues an 11-digit number to each product that is required for the marketing and sales in Brazil.

The two different registrations are known as "Cadastro", for the lower-risk products and "Registro" for the higher risk. The "Cadastro" registration is quite simple and fast, taking about 6 to 10 months, while the "Registro" procedure can last up to 24-36 months.

It is important to note that foreign manufacturers cannot directly apply for the ANVISA registration. If the company does not wish to use an intermediary, the only way to enter the market is to establish a local branch (either through a merger, acquisition, joint venture or establishing a subsidiary) and register the products. Otherwise, the company must appoint a local distributor or a third party recognised by ANVISA as the Brazilian Registration Holder (BRH). The BRH holds the market and import licence and registrations, the responsible entity for adverse events report before the Brazilian government as well as the holder of ANVISA's permit to keep a deposit of the registered products.

Registering with ANVISA

In order to obtain the registration, the applicant must start the process through Anvisa's website and then file the application directly to ANVISA's headquarter either in person or via e-mail. The company must then provide ANVISA with all the necessary documents in Portuguese, which include:

For all categories

- Autorização de Funcionamento da Empresa, by which Anvisa authorises the company's activity related to medical products, including manufacturing, distribution and importing;
- Licença or Alvará de Funcionamento, allowing the company to operate in Brazilian territory issued by municipal or state Health Surveillance institutions;
- Boas Práticas de Fabricação e Controle (aka Good Manufacturing Practice) certifying the compliance to good manufacturing standards as listed in the RDC-59/2000 resolution. The certificate is issued after inspection by the Health Surveillance institutions or Anvisa itself depending on the company's location, which can be repeated once every two years.

For products in category I and II

- Detailed product description, user manual, tag and label models both displaying the product characteristics, risks for usage and storage conditions;
- Proof of payment of Health Surveillance service tax;
- Certificate of conformity, if required

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- Copy of proof of registry or Free Trade certificate from the country of origin and letter of consent to the commercialization of the equipment in Brazil (required for imported class II products only);
- Copy of Anvisa's Boas Práticas de Fabricação e Controle (Good Manufacturing Practice) Certificate;
- Equipment based on new technologies are required a specific technical dossier.

The registration becomes valid once reported in the Brazilian Official Journal (Diário Oficial da União) and the registration number is granted. It lasts for 5 years, after then must be revalidated.

For products in category III and IV

- Special form for identification of the product, manufacturer or importer;
- Proof of payment of Health Surveillance service tax;
- Copy of the company's Autorização de Funcionamento da Empresa;
- Product label, user manual and technical report (to be submitted in additional CD format);
- Proof of compliance to Anvisa's Technical regulation
- Copy of Anvisa's Boas Práticas de Fabricação e Controle Certificate
- Copy of proof of registry or Free Trade certificate from the country of origin and letter of consent to the commercialization of the equipment in Brazil.

This registration too expires after five years and needs revalidation.

Depending on the products, further documentation may be needed, such as:

- Relatório de Informações Econômicas, an economic report of the medical equipment including information about the price established outside of Brazil, the potential targeted patients, the intended price for Brazil including taxes, manufacturing costs and replacement products available in Brazil. This applies to particular products such as pacemakers, surgical prosthesis and hearing aids.

- Certificado de Conformidade INMETRO, a certificate issued by the National Institute of Metrology, Quality and Technology after laboratory tests have proved compliance to electrical equipment safety regulations. Brazil now applies the third edition of the IEC 60601-1 regulation for the INMETRO certification. This certificate relates only to active medical equipment or devices involving electricity such as electroencephalography devices and lung ventilators.

- A risk analysis is mandatory for all implantable medical devices, intrauterine devices and blood bags. It is useful to remind that Brazil applies the technical standard ISO 14971 for risk management.

Revalidation and additional regulation

The revalidation of an existing registration as well as the change in the products specifications, such as:

- addition of new models in the registered device family
- addition of further manufacturers or change of manufacturer's information (address, company name etc.)

can be filed by the manufacturer or its BRH and it requires an ex-novo submission of the documents already submitted for the first registration, including those certifying the company's compliance to ANVISA's regulations. On this purpose, the manufacturer (or the BRH) should always keep a copy of the technical dossier submitted to ANVISA for each product. Moreover, the marketing content related to registered products must adhere to the specifications submitted to ANVISA.

Important note: the renewal of the registration must be completed at least one year and half before the expiry date of the current registration.

Recent regulatory updates

The law 13,097/2015 introduced some changes in the existing ANVISA regulatory process, as summarised by the global regulatory consultant Emergo in a recent post:

- Increase of validity period up to 10 years for some devices;
- Possibility for ANVISA to accept quality management system inspection reports issued by inspection organisations outside

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of Brazil, and to expand certifications of laboratories allowed to conduct health surveillance inspection and post-market surveillance.

- Updated requirements for registration transfers and operating permit renewal exemptions

Further indications are awaited from AN-VISA as for the implementation of these regulatory updates.

Moreover, with law RDC 15/2014 the Brazilian government has simplified the registration process for some low-risk and IVD devices. One of the most relevant updates is related to the category I and II devices, included class II IVD devices, which are registered with ANVISA and included in the exemption list "IN 2/2011". These devices do not require any more GMP certification and registration tax payment.

Sources:

ANVISA Brazil Product Registration - Mandala International

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Brazilian Regulation for Health Technology - <http://techinbrazil.com/brazilian-regulation-for-health-technology>

Emergo Group - <http://www.emergogroup.com/blog/2015/01/anvisa-granted-more-leverage-prioritize-medical-device-related-health-risks#sthash.leG4oVdK.dpuf>

CGF: concentrate growth factor from tissue regeneration

The ability to regenerate tissues and organs is a topic of great scientific, social and ethical interest.

Tissue engineering and regenerative medicine have made and continue to make great progress identifying new strategies in the field of tissue regeneration, such as the use of "platelet concentrate" which constitutes a relevant and innovative clinical approach.

From years Silfradent deals with the study of platelet concentrates and, in particular, with CGF (Concentrated Growth Factors) that represents a new generation of platelet concentrates able to hold inside a higher concentration of autologous growth factors. CGF, like other platelet concentrates, is isolated from blood samples through a simple and standardized separation protocol, which is performed by a specific centrifuge device (Medifuge MF200, Silfradent srl, Forlì, Italy) without the addition of exogenous substances.

A study made in the "Laboratory of Organ and Tissue Regeneration", headed by Professor Luigi F. Rodella of the Section of Human Anatomy, Department of Biomedical Sciences and Biotechnologies of the University of Brescia and published in the international journal "Microscopy Research and Technique" has highlighted some of its main features: the CGF consists of an organic matrix rich in fibrin that is able to "trap" a greater amount of growth factors (TGF- β 1 and VEGF); moreover, it contains CD34 positive stem cells, which are known to be recruited from blood to injured tissue and play a role in vascular maintenance, neovascularisation and angiogenesis.¹ In addition, another study underlined the need to establish a standardized protocol for preparing CGF (also said PRF-Platelet Rich Fibrin) membranes for clinical use.²



Form a clinical point of view, some recent studies about the use of CGF in maxillofacial surgery showed the efficacy of CGF in guided bone regeneration before dental implant placement.³⁻⁵ In particular, there are satisfying results about the use of CGF as alternative to bone substitutes for sinus augmentation.^{4,5}

However, its features make it suitable for its use, alone or with other biomaterials, in other fields where tissue regeneration and remodelling is required. To date, the research continue and is addressed to evaluate "in vitro" the ability of CGF of stimulate cellular proliferation and to test the efficacy of CGF in different clinical applications ranging from oral surgery, dermatology and cosmetic surgery.



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Regulatory updates in Asia-Pacific

Extract from: Medical Devices News, September 2014, SGS Group and Asia-Pacific New Regulations Updates, US Export)





China

Cover Photo

The kimono is a Japanese traditional garment. The word "kimono", which literally means a "thing to wear" (ki "wear" and mono "thing"), has come to denote these full-length robes.

Stock photo © Rich Legg

The substantial regulatory reform that recently took place in China has introduced major updates to both pre- and post-market compliance requirements for medical devices and in vitro diagnostic reagents.

These reforms came into effect on 1 October 2014 and were aimed at implementing a system that significantly raised the standard on clinical safety requirements for high-risk medical devices in China. The revised legislation has now established a default position that requires mandatory in-China clinical trials for all imported Class II and III medical devices (unless specifically exempted). Manufacturers must, in addition, supply the Clinical Evaluation Report used to support the medical device approval in the country of origin. This article, which is written by Lucy Xiao, Davey Dehui Han and Arthur Brandwood, outlines the new in-China clinical trial requirements for imported medical devices, how clinical trials are conducted in China, and the key challenges facing non-Chinese manufacturers during this time of regulatory transition

Chinese Regulatory Environment For Medical Devices Approval from the China Food and Drug Administration (CFDA) is required to introduce medical devices into the Chinese market.

The most relevant laws and regulations for medical devices are:

The Council Statute Order No.650: 'Regulations for the Supervision and Administration of Medical Devices' (1 June 2014)

CFDA Order No.4: Administrative Measures for Medical Device Registration (will go into effect on 1 October 2014)

CFDA Order No.5: Administrative Measures for the Registration of In Vitro Diagnostic Reagents (1 October 2014)

CFDA Order No.6:Administrative Rules for Instructions and Labels of Medical Devices (1 October 2014)

CFDA Order No.7: Administrative Measures for the Supervision of Medical Device Manufacturing (1 October 2014)

CFDA Order No. 8: Administrative Measures for the Supervision of distribution of Medical Devices (1 October 2014)

Harmonised GB National Standards and YY&YY/T standard (e.g. GB 9706.1:2007 – identical to IEC 60601-1 Ed.2 – and GB 16866 series – identical to ISO 10993 series)



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Medical Device Classification And Testing

The CFDA has a similar classification for medical devices as the FDA: Class I devices are carried through routine administration, but Class II and III have stricter controls, accordingly. Provisions for classification are given in CFDA's Order 15 here.

(NB: To support new regulations, the updated provisions for classification are in draft format.)

For Class II and III equipment testing, the manufacturer should draft the technical requirements. These requirements are similar to the Essential Requirements Checklist and should:

- Be in compliance with adopted standards (GB National standards and YY&YY/T industrial standards)
- Include performance specification and testing method

For active Class II and Class III devices, the CB test reports do not exempt them from testing, but they can be helpful. Devices will be tested according to the technical requirements in a Chinese testing laboratory that is supervised by the CFDA. The applicable national standards are:

- For General Safety: GB 9706.1:2007 (identical to IEC 60601-1 Ed.2) is mandatory
- For Class II Devices: EMC testing YY0505:2012 (identical to IEC 60601-1-2:2004) is mandatory from 2015
- For Class III Devices: EMC testing YY0505:2012 (identical to IEC 60601-1-2:2004) is mandatory from 2014

Clinical Requirements

For Class I, the supplied clinical evaluation report will be accepted.

For Class II and Class III device:

- If the device falls under 'clinical trial exemption database' the supplied clinical evaluation report will be accepted
- If the device does not fall under 'clinical trial exemption database' clinical trial in China is mandatory

(NB: The 'clinical trial exemption database' is still in draft format.)

CFDA Application And Registration

The CFDA application and the required documents need to be provided in Chinese and in English. For the application and contacts, a Chinese Registration Agency is required – the manufacturer signs the English versions of documents and the agency in China signs Chinese versions.

In addition to the application, several other documents are required:

- Qualification for Manufacture: a certificate issued by the authorities (or Notified Body) of the Country of Origin (CoO) that authorizes the manufacturer to produce and distribute medical devices, for example in the EU this is an EN/ISO 13485 certificate.
- Approval for the device in the CoO: for example in the EU this is the CE Certificate and Declaration of Conformity.

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Shape No.	835	S835	835	836
Size (1/10 mm)	009	010	012	012
Length (mm)	3.0	4.0	4.0	5.0
Order No.	541	S835-010	835-012	515.5
Grit	C	M, C	C	C, SC

Occlusal Reduction / Finishing

Shape No.	368	368	811	811	909	S858	6055	834
Size (1/10 mm)	018	023	033	037	043	008	018	021
Length (mm)	5.0	5.0	4.2	7.0	1.3	3.0	8.0	6.0
Order No.	280.5	285.5	230	234	863	S1390	ST8	834 021
Grit	F, C, SC	XF, F, C, SC	C, SC	C, SC	C, SC	XF	C, SC	M

Round End Taper

Shape No.	850	855	856	850	855	S855	856	850	855	856	847	847	847	847	848
Size (1/10 mm)	012	012	014	014	016	016	016	018	018	018	012	014	016	018	023
Length (mm)	11/0.5	7/0.7	8/0.9	10/0.8	7/1.0	7/1.0	8/1.1	10/1.1	7/1.4	9/1.4	9/0.6	9/0.7	9/1.1	8/1.1	10/1.4
Order No.	770.11	771.7	771.8	771.10	772.7	S772.7	772.8	772.10	773.7	773.9	700.9	701.9	702.9	703.8	703.10
Grit	XF, F, M, C	C	M, C	F, M, C	M, C, SC	M, C, SC	F, C, SC	F, M, C, SC	F, M, C, SC	F, M, C, SC	F, C	M, C	M, C, SC	M, C, SC	M, C, SC

Flat End Taper

Turbo FG

Shape No.	368T	856T	837KRT	850KRT
Size (1/10 mm)	023	018	012	018
Length (mm)	5.0	9.0	8.0	9.0
Order No.	285.5T	773.9T	837KRT012	850KRT018

Flame

Shape No.	862	863	862	863	878K	879K	878	879	878	801	801	801
Size (1/10 mm)	012	014	016	018	012	012	012	012	014	014	018	023
Length (mm)	8.0	8.0	8.0	9.0	8.0	10.0	8.0	10.0	8.0	1.4	1.6	2.3
Order No.	260.8	265.8	267.8	270.9	1712.8	1712.10	250.8	250.10	251.8	120	125	135
Grit	XF, M, C	F, C, SC	XF, F, M, C	M, C	M, C	M, C	F, M, C, SC	M, C	M, C	XF, M, C	M, C	F, C

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Round

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- Qualification of Registration Agency: comprises the License of the Agency and an Authorisation Letter from the manufacturer.
- Technical Requirements: typically drafted together with the manufacturer and the registration agency, is based on the user manuals, test reports and technical specifications.
- Test Report for Class II and Class III devices: issued by the testing laboratory that is authorised by CFDA, based on the technical requirements.
- User Manual and Labelling in Chinese.
- Clinical Evaluation Report: (see clinical requirements).
- Product Quality Guarantee Letter: with this letter the manufacturer guarantees that the quality of the product which has to be registered for sale in China, is exactly the same in CoO and that the quality management system is continuously supervised.
- Letter of Authorisation and Letter of Promise for the Responsible Agency in China: the agency will need a business license, will undertake the relevant legal responsibility of product quality, report possible incidents to the CFDA, take care of product recalls and contact the CFDA and manufacturer when necessary.
- Letter of Authorisation and Letter of Promise for the After-sales Agency: the agency will need a business license and will have responsibility of all neces-

sary technical documents, training, spare parts, consumables, and after-sales of the device.

- Self-declaration for Documents Submitted: provided by the manufacturer and includes a promise from the manufacturer to undertake legal responsibility (NB: To support new regulations the document list above will be updated – no official notice of changes to date).

In principle, the CFDA technical review and administrative review need 90 working days if there are no on-hold comments. In practice, the expected lead-time for a Class II device is typically 9-16 months (e.g. documents preparation, testing, CFDA review).

China Decree 650 framework

- Key changes in registration requirements
- Clinical trial impact on product registration timeline in China

1. In-China clinical trials: required for Class II and III imported medical devices
2. In-China clinical trial can only be conducted after successful completion of type testing
3. On-site Quality System audit: moved to during product registration, risk based and manufacturers outside of China may be audited
4. More technical documents are required

New regulation results in 9 - 12 months longer time-line for registration due to clinical trial requirement



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5. Potential overseas Auditing
6. Longer evaluation time for class III Devices:
 - 90 working days for class III devices. Change evaluation time from 60WD to 90WD assuming no supplement requirement
 - 60 working days for class II devices. No change to evaluation time for class II devices assuming No supplement requirement

Removing barriers in registration

1. Filing only. Registration approval for Class I MD and IVD is not required.
2. Registration license is valid for 5 years. Extended from 4 years to 5 years.
3. Registration Certificate is reformed, the initial registration number will be kept with device in life time
4. Extended days for submitting supplementary documentation from 60 to 365 days
5. Country of Origin (COO) Requirement: COO from Legal Manufacturer OR Manufacturing Site
6. Exemption from the clinical trials requirements is feasible for products listed in the Catalogue of Clinical criteria for clinical exemptions.

India

India-specific labels are required for both regulated and unregulated products imported to India by September 27, 2014.

Specifically the following information is mandatory:

- **manufacturing date and expiry date**
- **MRP or “Not intended for retail sale”**
- **import license #**
- **customer care phone**
- **number in India**
- **registered address in India**
- **warehouse address in India**
- **legal**
- **manufacturer name and address**
- **manufacturing site**

• Key Challenges:

1. Products must be India label compliant BEFORE they are imported. Labeling operation cannot be done in India.
2. Small packages cannot accommodate the additional information.
3. Short transition period (6 months).

• Advocacy Success:

1. Additional Labelling can be added to products after imports in India.
2. Small label exemption: India specific labelling can be provided on Shelf Carton only.
3. Products for use by Hospital/Diagnostic labs (not supplied to customers directly) are exempted for India Specific Labelling on unit pack.

Japan

Pharmaceuticals Affairs Laws (PAL) is revised to be PMD (Pharmaceuticals and Medical Devices) Act. The PMD Act comprises both the PAL and some Medical Device specific requirements. Main characteristics of the new PMD Act are:

- More medical specific requirements are added.
- Creation of new MAH license category that is specific to IVD reagent.
- Standalone software will be regulated as MD (currently non-PAL).
- Regenerative medical products will be defined and covered by PMD Act.
- Expanded 3rd party review to higher class MD
- FMA (Foreign Manufacturer Accreditation) is relaxed from “accreditation” to “registration”.
- QMS (for manufacturer) and GQP (for MAH) requirements will be merged into one.
- MAH in Japan will have more supervisory responsibility for product life cycle management.

The effective implementation time was November 25, 2014

Malaysia

By 2015, mandatory enforcement will take place for medical device registration.

The class of medical device is based on the Classification Rules (1st Schedule of MD Regulation) according to 4 main classes:

- Class A: Low risk
- Class B: Low moderate risk
- Class C: High moderate risk
- Class D: High risk

Classification of Medical Device

CLASS A

RISK LEVEL

Low Individual Risk and Low Public Health Risk

DIVICE EXAMPLES

Clinical Chemistry Analyzer, Prepared Selective Culture Media

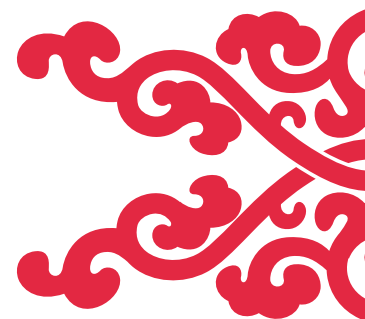
CLASS B

RISK LEVEL

Moderate Individual Risk and/or Low Public Health Risk

DIVICE EXAMPLES

Vitamin B12, Pregnancy SelfTesting, Anti-Nuclear Antibody, Urine Test Strips



CLASS C**RISK LEVEL**

High Individual Risk and/or
Moderate Public Health Risk

DIVICE EXAMPLES

Blood Glucose Self-Testing, HLA
Typing, PSA Screening, Rubella

CLASS D

High Individual Risk and High
RISK LEVEL

Public Health Risk

DIVICE EXAMPLES

HIV Blood Donor Screening, HIV
Blood Diagnostic

Moreover, Medical Devices will be categorised according to the Rules of Grouping (Regulation 3(1)(b) of MD Regulation), into 6 groups:

1. Single
2. System
3. Family
4. Set
5. IVD Test Kit
6. IVD Cluster

Source:

Medical Devices News, September 2014, SGS Group - <http://www.sgsgroup.com.cn/~media/Global/Documents/Technical%20Documents/Newsletters/SGS%20SSC%20Medical%20Devices%20Newsletter%20issue%20LR%2011%20A4%20EN%2014%2009.pdf>

Asia-Pacific New Regulations Updates, US Export - http://export.gov/minnesota/build/groups/public/@eg_us_mn/documents/webcontent/eg_us_mn_080825.pdf

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Determinants of oral health-care in developing countries

In the developing world, essential oral health care should be a main focus of primary health programmes according to the specific health needs of the population.

Author: Michela Adinolfi

The burden of oral health diseases in developing countries

In developed countries, there are a series of trends that show the improvement of oral healthcare, such as the decline in the incidence of dental caries among children, the higher number of adults that retain their natural teeth and a general increase in oral health awareness and behaviours that favour oral hygiene. However, lifestyle and dietary habits of the population in these countries often pose their own challenge to the oral health conditions of the population, increasing the incidence of diseases related to the use (or the abuse) of tobacco and alcohol, soft drinks and excessive sugar intake. On the other hand, even in developed countries there are groups or communities, such as lower income or migrant people, that have restricted access to oral healthcare and show higher prevalence of dental diseases. In general terms, however, dental services are available to the average citizen thanks to a variable mixture of public and private provision, with the public service focusing on children, elderly and other vulnerable groups such as pregnant women; while more sophisticated procedures such as implantology are mainly covered by private expenditure, either through direct out-of-pocket payment or contributed by a form of health insurance.

The picture for the developing countries is quite different. According to the WHO, in these countries the health budget allocated for oral healthcare is low and it is mainly used to provide emergency care and pain relief in regional or central hospitals of urban centres.

This type of care tends to be the only option available, either because of the excessive costs of dental treatments compared to the average income, or due to the shortage of dental professionals and facilities (like in Africa, where there is a dentist every 150,000 people), or for both reasons. Moreover, preventive and restorative dental care have very limited priority and proper oral health promotion programmes are often lacking or poorly implemented.

As a result, most of the population only seeks treatment when the disease has progressed too much and an emergency intervention is necessary. For instance, many developing countries present a low rate of dental caries. This is not as positive as it may seem, since the reason is generally the lack of timely treatment, so when the patient goes to see the dentist, the only option left is tooth extraction. In fact, the use of fluoride is very limited in developing countries, in a context where water and sanitation conditions are far from being ideal and do not help to radicate proper oral hygiene habits. Combined with the poor access to primary dental care and simple prevention measures, even a simply treatable disease eventually goes too far to prevent radical interventions. Furthermore, the dietary habits are shifting to more westernised models and the use of tobacco is continuously spreading.

Some figures account for the global size of the problem: for instance, the WHO estimated that in the South-East Asia Region about 45% of people aged 35–44 years suffer from severe or advanced periodontal disease. In the poorest and most disadvantaged countries, poverty and malnutrition create the sub-

stratum for the plague of Noma (CancrumOris, a gangrenous necrosis of oro-facial tissues), that is an extremely painful and devastating condition affecting a large number of children, currently estimated in 100-140 thousand (with 80-90% mortality rate for untreated cases). In many African countries where this disease is particularly widespread, the HIV/AIDS pandemic worsens the situation.

How do these trends affect the developing countries?

In these countries, out-of-pocket payments are the primary source of health care financing. When households have to reduce expenditure on basic needs in order to face healthcare expenses, these are defined as catastrophic health expenditure or CHE. It has been estimated that roughly 3% of households in low income countries, 1.8% of households in middle income countries and 0.6% of households in high income countries face some CHE. Generally speaking, the proportion is higher in lower income countries, especially with greater income inequality, but the income level, urban/rural location, household composition and availability of health insurance are associated with higher incidence of CHE.

Oral diseases are the 4th most expensive disease to treat. Their treatment cost is often excessive for average households even in high income countries with 5-10% of public health spending used for oral health. In most low income countries, they are usually beyond the available resources for the provision of an essential public health care package, therefore people can seldom rely on a functioning public oral healthcare service to satisfy their essential oral health needs and private dental care is usually unaffordable for large segments of the population. The high direct out-of-pocket expenditure, added to the indirect loss of income caused by the necessary time to visit the dentist or get the treatment, are enough to discourage many households who cannot afford to lose a large proportion of their available income or take on their shoulders long-term debts.

When these costs reach such a level, they are estimated as catastrophic dental health expenditure or CDHE, with the same parameters used to calculate the CHE. Interestingly, the incidence of CDHE in low and middle income countries is reported at similar rates as for the CHE. This evidence suggests that

out-of-pocket dental payments may play a significant role in the overall CHE, especially in a context of low financial protection against this type of expenses. In low and middle income countries, even more than in the developed ones, the use of dental services is not much related to the actual needs of the population, but rather to the household's ability to pay for treatment.

Unfortunately, in these countries there are generally few, if any, financing schemes for dental care, resulting in an exaggerate prevalence of out-of-pocket payments that exposes the population to a higher probability of incurring CDHE. Several studies have highlighted that the implementation of social protection policies based on prepayment and risk-pooling mechanisms result in a more equitable access to dental care and provide better protection from large health shocks. Combined with increased resources allocated for oral health awareness campaign and prevention programmes, this integrated approach can significantly reduce the burden of oral healthcare costs on households' disposable income. The successful application of these policies of course requires that policymakers and officials within the different healthcare systems in developing countries increase their own awareness of the matter and include dental care in the process towards a universal health coverage, which is theoretically in the agenda of many of these countries.

What is the role of dental insurance in this context?

In several studies, dental insurance has been identified as one of the key factors affecting the use of dental services. In general terms, by reducing the out-of-pocket expenditure, dental insurance can be an important determinant for a patient's decision to seek dental care. Insured people, for instance, have been shown to use preventive and restorative services more than those without insurance.

The extent of coverage is also crucial, since the use of dental services increases significantly as the proportion of co-payment required declines. Insurance has a relevant impact particularly on the use of more expensive dental care. Even the World Health Organisation has included the reorientation of oral health services towards prevention among its priority action areas. In the developing countries, it is particularly important that insurance schemes support the focus on preventive care.

Cover Photo

Isfahan Iran

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Evidence from country-focused studies

The impact of national health insurance schemes on oral health-care and out-of-pocket payments.

Iran (2011 study): In Iran there are two dental insurance systems, public and commercial, subsidising treatment costs. In public insurance, both the employer and employee pay a compulsory premium, deducted from the employee's wage or income, while the commercial insurance requires the employer to pay the premium as fringe benefit. Public insurance covers examination, dental X-ray, teeth extractions, scaling, amalgam and composite fillings and removable denture. Treatment is fully subsidised at public clinics and it is subsidised by 70% at clinics contracted with the public system; the commercial insurance, instead, covers all dental treatments with a subsidy of 70%.

In Tehran there were approximately 4,500 practicing dentists serving 8 million inhabitants. 71% of the people surveyed in the study had dental insurance, 65% public, 6% commercial, while 29% had no insurance at all. Among the relevant findings of the study, there was the higher incidence of teeth extractions among the non-insured respondents, which was reported almost twice as frequently as for the insured ones. Moreover, half of the non-insured people with a low household income reported tooth extraction as their most recent treatment. Other determinants for the highest rate of extractions were low level of education, infrequent visits to the dentist (more than 12 months ago) and poor oral health hygiene (less than daily tooth brushing).

However, the insurance status didn't seem to make any relevant difference in the higher frequency of restorative treatments compared to preventive care; according to the authors, these findings show that although insurance is an effective determinant of better access to essential dental care, there is still an insufficient focus on prevention, both in the insurance schemes and in the general oral healthcare system.

Ghana (2013 study): Ghana's National Health Insurance Scheme allows three different kinds of insurance plans: District Mutual Health Insurance Schemes, or DMHIS; private mutual insurance schemes and private commercial insurance schemes. The most popular plan is the DMHIS, which operates in every district in Ghana. The other insurance plans cover less than 1% of the insured population. By the end of 2011, around 15.5 million people (66% of the population) were covered by the insurance scheme, with 5,000 accredited health facilities. With the introduction of the health insurance, outpatient utilization of healthcare services increased more than 40-fold, from 0.6 million in 2005 to 25.5 million in 2011, while inpatient use increased more than 30-fold from 28,906 in 2005 to 1.4 million in 2011. In the same period, private out-of-pocket expenditure has fallen from 80% to 66% of total private health spending and public health expenditure as a share of total health expenditure increased by 19%.

The range of premiums varies according to the person's income, but many DMHIS apply a standard premium.

The NHIS covers oral health treatments including pain relief (tooth extraction, temporary incision and drainage) and dental restoration (simple amalgam filling, temporary dressing). It doesn't cover dentures and cosmetic procedures.

A study by Nguyen et al. found evidence of the financial protection effect of the NHIS in significantly lower payments for care and uncovered drugs and tests compared to the uninsured and especially for the poorest. However, out-of-pocket payments were not eliminated. Another study by Witter and Garshong confirmed that 70-75% of total NHIS funding comes from taxation and there is a substantial exempted group at about 30%.

Factors influencing oral healthcare in developing countries

Economic and demographic trends:

globalised economy urbanisation population ageing



Social, behavioural and environmental factors:

poor living conditions, unhealthy lifestyles (dietary shift to more sugar-rich food and drinks, malnutrition, increased use of tobacco alcohol, poor oral hygiene) low availability and accessibility of oral health services.

influence

Risk factors:

dental caries, gum disease, trauma of teeth and jaws dental erosion, developmental enamel defects, oral mucosal lesions oral cancer / Noma HIV/AIDS related oral disease Problems related to non-communicable chronic diseases (diabetes, obesity, cancer, cardiovascular disease)

create

An unmet demand for dental care and prevention programmes

- Availability of dental services (distribution and operativity of equipped facilities and skilled workforce)
- access to financing means (insurance, low-income benefit packages, etc.)

Political environment AND degree of awareness among officials

influence

budget allocations and inclusion of oral health into national health insurance schemes

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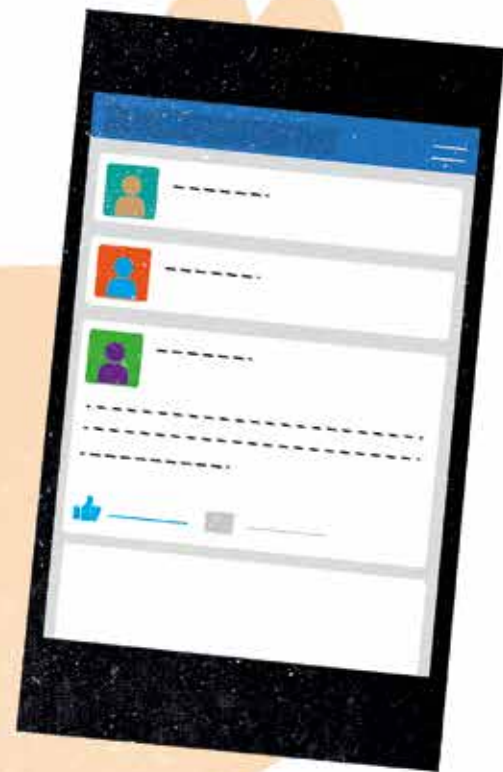
users' expectations

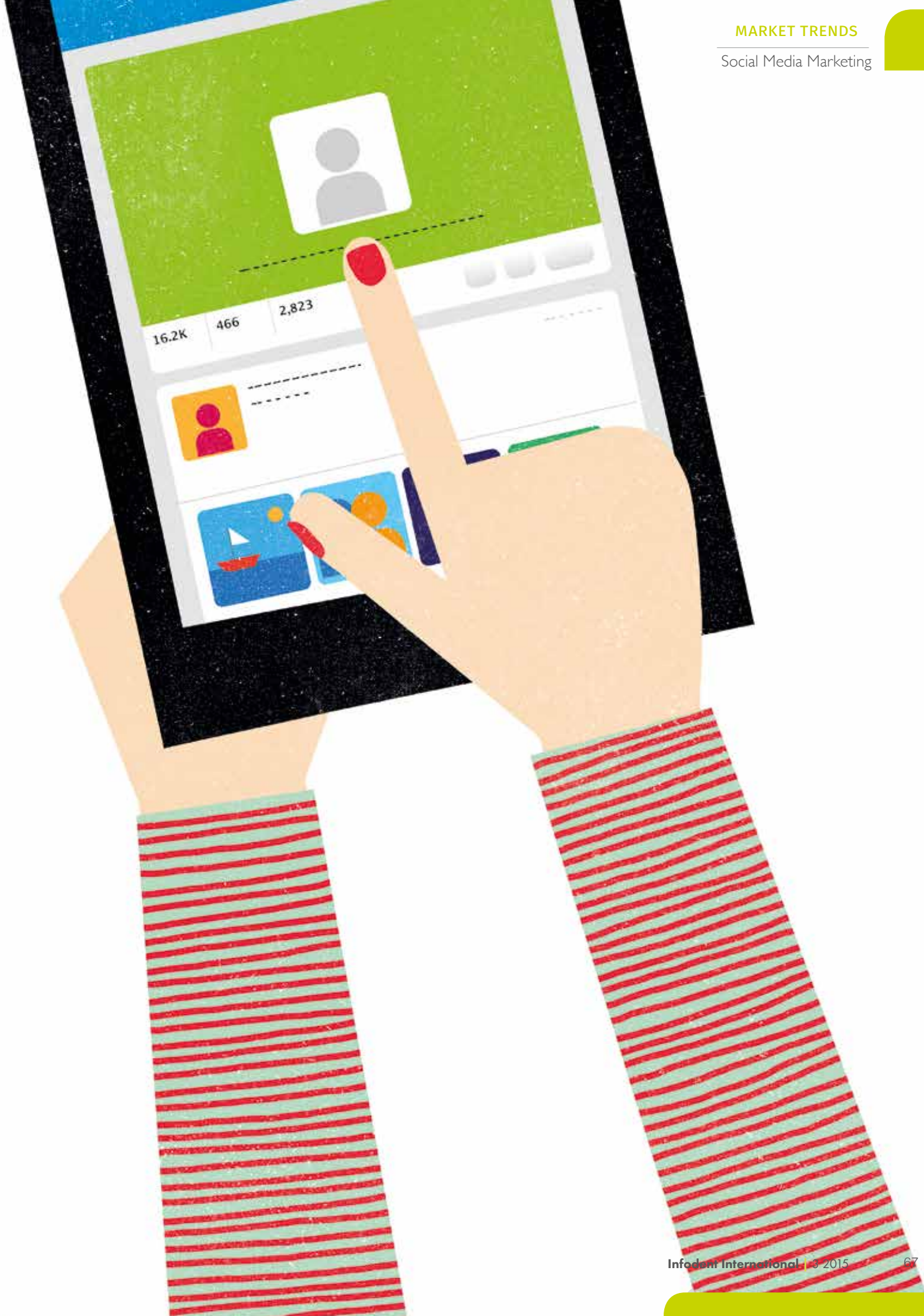
Communications have changed and companies are responding to this evolving interactive scenario by redefining some very important concepts. In this article you will find different suggestions on what we should expect in the next months.

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Cover Image

Illustration made by
Silvia Piscopiello







In 2014 you should consider that most of the brands have social media platforms. These changes are reflecting the importance of the customers' voice. As regards the opinions born on the Internet, especially on Facebook or Twitter; we have to admit that they require a fast reply.

Everybody needs fast answers, mostly during start-ups periods, when your brand isn't consolidated enough. If you think that customers using social media expect a response from you within an hour to enjoy a service... This is another reason to go towards customer service direction.

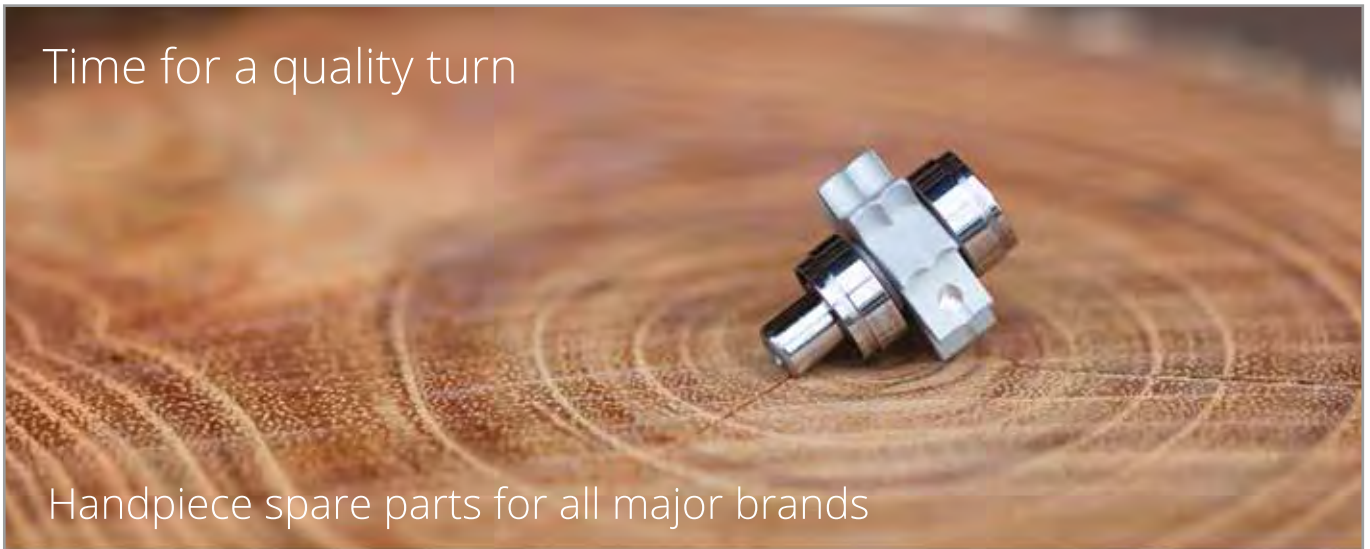
Apparently, during your company's start-up, your brand is still not so famous to support a lot of answers, but you have to consider that about 1/4 of users can wait the rest of the day to receive your replies. This is the reason why start-ups must monitor online conversations providing fast answers to users. 2014 has been a very prosperous year regarding the growing use of social channels, both in terms of volume and ways of interaction between people.

In this topic I will try to give different suggestions on what we should expect in the next months. The global population has increased from 7 to 7.2 billion of people and the number of active Internet users has exceeded 3 billion users -12 months ago were 2.5 billion- (with a penetration that has reached 42% of the world population). Active accounts on social media are

now more than 2 billion (29% penetration), this means that compared to 12 months ago the percentage has grown by 12%. If we take a look to data regarding mobiles, it is interesting to note that compared to an increase of 5% of mobile users, the number of people who actively use social media from their smartphone has grown of 23% (more than 313 million of people). The growth of these indicators truly represents a global phenomenon.

What happens in Italy? If a level of penetration data is higher than the average (60% vs 42% of the world average), observing the time spent online, we consider that the percentage of people who enters the internet from a desktop is lower than people who browse the net from mobile (2.2 hours per day, compared with an average of 2.7 hours). So, it seems that Italians prefer many sessions of a shorter duration compared to what happens in other countries: globally, the number of pages visited by desktop has decreased by 13% but has increased of 39% by smartphone (and 17% by tablet).

The analysis on the active use of social channels, highlights how year after year is important to let people interact and find the information they are seeking. Today there are more than 2 billion active accounts on social platforms (with a penetration of 29% of the total population): in Italy the penetration is 46% (the highest value is the one registered in Singapore - 66% - while in France, for example, is 45%, and in Germany 35%). Between all the platforms, the most used is still Facebook (1.36 billion ac-



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tive users), but it is interesting to notice the continuous growth trend of instant messaging services (as WhatsApp, that has exceeded 600 million users, compared to 400 million 12 months ago, Facebook Messenger that is used today by more than 500 million people and Wechat which has almost doubled its user-base, now reaching 468 million users). The big new entry in this ranking is Instagram, which is now used by more than 300 million people.

Italian people spend 6.7 hours a day on the internet (including mobile and personal computers: 2.5 hours are dedicated to the use of social channels against a world average of 2.4 hours (2 hours in France and 1.9 in Spain - to provide the terms of comparison). The 60% of Italians regularly browse the internet and the active accounts on social channels are now 28 million (22 million of logins are made from mobile devices).

Data regarding the access to social channels from mobile have seen the greatest increase in the last 12 months (11%), demonstrating a particular inclination to interact in mobility and actively with content that can be accessed online. We have noticed how WhatsApp and instant messaging platforms are more and more used worldwide, in particular in Italy: considering the total population, the most used service during a month is actually WhatsApp (even more than Facebook).

So, even in Italy, the mobile represents the mean by which people mostly access to platforms relationships and conversations online.

Therefore, Italians use their smartphones to complete various tasks, once delegated to larger screens: the use of video content is growing as well as the use of applications related to social platforms. It is also interesting to observe how the percentages of people seeking information about products to buy and who then actually buy from desktop are identical (39%), while there is a small deviation between those seeking from smartphones and those who complete a purchase by the same device (20% vs 19%). This happens probably because people prefer using personal computers to conclude transactions.

So, despite not being a lover of annual reports, it is interesting to take a look on how important has been 2014 for social medias, in order to understand what is the starting point of this 2015.

Let's start from some aggregated data.

Today nearly 3 out of 10 people are active users of at least one social platform. Social media have effectively reached a penetration of 28% on the total population, exceeding the 2 billion active users:

- Facebook has 1.3 billion users
- Google 343 millions
- 300 millions LinkedIn
- Instagram 300 millions
- Twitter 280 millions
- Tumblr 230 millions



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These are people who frequently enter these platforms, to which they dedicate more time. The 28% of the time spent on-line regards social channels (in particular children aged between 15 and 19 spend, on average, three hours a day interacting on social networks and those aged between 20 to 29, on average, two hours a day).

Companies are replying to the evolution of this scenario where they have to interact with people and they are doing it by redefining some important concepts. Five of these are the result of a rationalisation that I want to examine here below:

1. Real-time ≠ Right-time

"Real-time marketing" was one of the terms used (and often abused) in recent months, but the focus is shifting now on finding a right-time, rather than the real-time. Even if 2014 has been characterized by the importance of thinking about how to deliver the right audience and the best content when they could create a real value of people.

2. Media and content are not two separate worlds

2014 has been also the year that changed the dynamics of content distribution: the quality of content now requires a dedicated media strategy that applies more leverage on a "copy-paste-do-it-yourself", but planned, anyway.

Each day grows the number of individual content products which are shared not only by users, but also by brands. Therefore is really important to develop together both strategy media

and strategy contents in order to ensure visibility in important moments, especially for contents addressed to a specific audience.

Focusing on the brand is a decisive element, as customers identify their interest in products and services through this public spec of the company. Therefore, they become "Leads" in generating conversations that increase positive opinions and valorise the company on the market. The promotion carried out by the brand positioning, outlines the target of the real and the potential consumer. In this way, it is possible to make promotional campaigns more effective through a physiological segmentation of targets by attracting the specific and customized interest of the customer: that motivates the consumer to buy.

The promotion of content makes possible to segment more precisely and effectively the audience and to ensure that you can reach interesting and interested people at specific times, with content tailored to their needs.

3. The editorial approach is becoming more and more important

Brands are aware of the importance to create quality content which will give birth to a world that can excite and engage people. The 59% of companies expect to increase the budget dedicated to create content during the next 12 months.

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4. The word Video doesn't mean only YouTube

Last months of 2014, were characterized by an historic overtake: for the first time Facebook collected more videos visualization than YouTube . This fact is important not only for the data in itself, but even because it represents the growing tendency to enjoy video contents from different platforms: YouTube is not the first media anymore, but right now new tools have appeared besides Facebook, such as Vine and Instagram.

It is important to understand what is the audience section that you want to reach and the project of the content you want to accomplish.

For example, YouTube is the only platform that has got a very high penetration. But nowadays, there are several factors that we have to consider, as the different methods of access to content from people. And not only are the views to make Facebook an increasingly important channel for the creation of video, but also shares.

As regards Facebook, it has become an important channel for the creation of video not only for the high percentage of views but even for the high level of content sharing.

5. Time to answer.

Apparently, during your company's start-up, your brand isn't famous enough to support a lot of answers, but you have to consider that about a quarter of users can wait the rest of the day to receive your answers. This is the reason why start-ups must monitor online conversations and answer to users faster.

It's time to answer! Why?

Firstly because your potential customers need to receive immediately the information they need and, secondly because there are many information that can be easily reached and you have to reach them before your competitors.



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Dental Implants and Prosthetics Market Worth \$10,427.7 Million by 2020



DALLAS, June 23, 2015 /PRNewswire/ – According to a new market research report "Dental Implants and Prosthetics Market by Material (Titanium, Zirconium, PFM, All Ceramics), by Stage (Two Stage, Single Stage), by Connectors (External hexagonal), by Product Type (Crowns, Bridges, Dentures, Abutments) - Global Forecast to 2020", published by MarketsandMarkets, the global Dental Implants & Prosthetics Market is expected to reach \$10,427.7 Millions in 2020 and is poised to grow at a CAGR of 7.2% during the forecast period of 2015 to 2020.

The global Dental Implants & Prosthetics Market has witnessed major growth over the past few years. With the rising incidence of tooth caries and other periodontal conditions, there is an overall increase in edentulism globally. The baby boomer population is also aging, which is further contributing to the rising incidences of tooth loss. This has resulted in the rise for the demand of tooth restorative techniques and products like dental implants and prosthetics. The increasing focus on quality dental care and rising dental awareness among patients are further expected to propel the growth of this market. However, limited dental insurance coverage and reimbursement could hinder the growth of this market to a certain extent.



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The global Dental Implants & Prosthetics Market is segmented by products, product material, and geography. This report also covers main market drivers, restraints, opportunities and challenges for the Dental Implants & Prosthetics Market.

In 2014, the titanium implants segment accounted for the largest share of the dental implants market, by material. The extensive use of titanium is mainly attributed to its biocompatibility with the human body and its lower cost than zirconium. Dental bridges segment accounted for the largest share of the dental prosthetics market, by type, in 2014, mainly due to the technological developments in this field. Improvements in the materials used, such as high-performance ceramics and translucent resin nanoceramics, help to decrease the work time and provide higher standards of aesthetics and function. Moreover, the introduction of the CAD/CAM technology helps to increase the accuracy and saves designing and manufacturing times.

Europe was the largest market for the global Dental Implants & Prosthetics Market in 2014, with a share of 39.8%. It was followed by North America, Asia-Pacific (APAC), and the Rest of the World (RoW). APAC and Latin America are expected to show the strongest growth rate during the forecast period.

This is mainly attributed to the rising dental tourism due to the low prices of dental implants there. The increase in the number of trained dentists and better medical infrastructure will also drive the growth of this market.

The global Dental Implants & Prosthetics Market is a consolidated market. Some prominent players in this market include STRAUMANN (Switzerland), DENTSPLY International (U.S.), Zimmer Holdings (U.S.), Biomet 3i (U.S.), 3M ESPE (U.S.), Danaher Corporation (U.S.), Avinent Implant System (Spain), and OSSTEM IMPLANT Co. Ltd. (South Korea).

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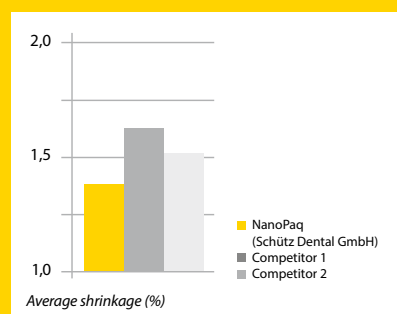
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POST SHOW REPORT. DENTAL SALON-2015

The 37th Moscow international dental forum and exhibition "Dental Salon 2015" - the main event of the first half in dentistry of Russia - finished successfully on April 23 at the IEC "Crocus Expo". Organizer - exhibition company DENTALEXPO - says the undoubted success of the event. In two exhibition halls gathered more than 390 companies from 21 countries of Europe, Asia and America. The exhibition occupied the area of 21000 sq. m.

Numerous presentations of new products of 2014-2015 were held at Dental Salon 2015. Among the novelties there were solutions for CAD / CAM system, hybrid ceramic similar to dentine, composites, dental equipment of economy class, tips and their motors, sets for implant dentistry and anesthesia, scanners and devices for dental photography, cutting technology, tools, portable X-rays, dental paste and brushes, bleaching systems.

Traditionally top managers and consultants of world leading manufacturers attended the exhibition. For the Russian market still keeps its importance and perspectives for the global dental industry despite the difficult political situation in the world.

As always, there were a lot of activities at stands. In addition to the presentation part of the exposition industry leaders increasingly offer visitors training courses at the exhibition floor of both theoretical and practical direction that invariably increases interest of dentists. The exhibition demonstrated a high activity. In the first two days of the show exhibitors felt the serious pressure. The total number of visitors exceeded the figures of April 2014.

The program of the forum was as always various and rich. More than three hundred events of different level and content were presented to the participants of the Forum.

The main events of the Forum scientific program were following:

- traditional Russian Dental Association conference "Actual problems of dentistry";
- the first endodontic congress ENDOPOINT with presentations of TOP speakers from Italy attracted the most strong attention;
- Dental LAB held a conference for dental technicians and prosthodontists for the fifth time.

All fields of dentistry were affected during the Forum, with particular focus on periodontology, dental innovations, implants, dental surgery, hygiene, dental laboratory, endodontics, digital dentistry.

The most strong attention attracted the first endodontic congress ENDOPOINT, held within the program of the Forum. More than 400 participants enjoyed presentations of TOP speakers from Italy.

Those dentists who couldn't attend could participate at the event online. The option was provided by the general scientific information partner of the event - Dental Tribune Russia. ENDOPOINT received a very positive feedback and was launched as a continued project in endodontic education.



DYNAMIC
Exhibitions Schedule

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Congress International of Orthodontics & Stomatology

IDS 2015

Dental South China

Dental South China International

SINO-DENTAL

DenTech China 2015

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Stomatology 2015



POST SHOW REPORT. STOMATOLOGY St. PETERSBURG -2015

On 3-5 June, 2015 the 18th International exhibition Stomatology St. Petersburg, the largest exhibition of equipment, instruments, materials and services for dentistry in the Northwest of Russia was held at Expoforum, St. Petersburg.

Within three days 3 298 people visited the exhibition.

A saturated business program is an integral part of the Stomatology St. Petersburg exhibition. This year program attracted over 1000 listeners. Within three exhibition days the following events were held:

- Symposium 'Current trends, technologies and innovations in dental practice': Therapy Day and Implantology and Orthopaedics Day;
- XX International Conference of Maxillofacial Surgeons and Stomatologists 'Modern technology in dentistry';
- International Scientific and Practical Conference 'Current issues of pediatric dentistry and prevention of dental diseases';

- International Scientific and Practical Conference 'Integrated rehabilitation of patients with diseases of dental system and the TMJ using dental implantation and 3D technology';
- Round Table 'Examination and treatment for dental patients with ENT diseases';
- Seminar 'Today aspects of functional orthodontic care';
- Dr. Goncharov's seminar 'Diagnostic system of integral planning in dentistry. Clear occlusion: physiologically grounded practical approach according to the Dr. John Koid system';
- Master class of N.M. Batyukov, PhD in medicine 'Modern possibilities of endodontic treatment'.

Exhibitors including leading Russian and foreign experts held their presentations on the demonstration site.

The exhibition was held with the official support of the Committee on public health services for St. Petersburg and the Committee on public health services for the Leningrad region.

The exhibition organizers are PRIMEXPO, part of the ITE Group, and DENTALEXPO. The joint projects include not only the Spring edition "Stomatology St.-Petersburg", but also 'Dental-Expo St. Petersburg' which will be held on 27-29 October, 2015 in EXPOFORUM.



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Don't miss out on the UK's largest dental show

BDIA Dental Showcase is the UK's biggest and best attended dental trade show, with over 12,000 attendees from the dental industry. It's the perfect opportunity to find out about the latest products and innovations, attend free CPD lectures and network with colleagues and associations.

This year's event is on 22-24 October at the NEC in Birmingham and brings together the biggest names in the world of dentistry. By attending BDIA Dental Showcase you will have the opportunity to meet over three hundred exhibitors and to get hands-on experience of the most comprehensive range of dental equipment, materials and services available in the UK.

You can also visit the new Dietary Zone, supported by The Dairy Council, which looks at the latest thinking in the link between diet and oral health, and how you can help patients by providing appropriate advice. And with so many of your colleagues attending, BDIA Dental Showcase is a great place to network, seek careers advice from recruitment agencies, and meet other members of professional associations.

Fiona Ellwood, President, from the British Association of Dental Nurses said about the BDIA Dental Showcase, "It is one of the highlights of the year for many of our members. Not only is there a chance to see the latest products, the BDIA provides practical advice and experiences that positively impact on skillsets and careers alike."

Make sure BDIA Dental Showcase is on your year planner. You can register for tickets and find out more by visiting www.dentalshowcase.com



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The 39th Moscow International Dental Forum

Moscow 2016

The 39th Moscow International Dental Forum



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GNYDM 2015

Greater New York Dental Meeting NEW YORK, USA
Visitors: 54,629 Exhibiting companies: 600

The Greater New York Dental Meeting (GNYDM) is the largest Dental and Healthcare Congress and Exhibition in the United States. The previous GNYDM in 2013 registered 54,629 attendees from all 50 states of USA and 131 countries out of which 19724 were dentists, 4078 were hygienists, 5323 were dental assistants and about 1000 were dental technicians. The total area of the show was 38,000 square meters with 16,000 square meters dedicated to the floor exhibition area. There were 600 exhibiting companies in over 1,600 booths. In 2015, the GNYDM will be held from November 27 - December 2, 2015.



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Sino-Dental 2015 NEW PRODUCTS AND TECHNOLOGY PROMOTION

The 20th China International Dental Exhibition & Scientific Conference 2015 (SINO-DENTAL 2015), jointly organized by International Health Exchange and Cooperation Centre, Ministry of Health, P.R. China (IHECC) and Chinese Stomatological Association (CSA), was staged at China National Convention Center (CNCC) from June 9 to June 12, 2015. SINO-DENTAL is no doubt the most authoritative and professional dental conference in China.

In 2015, the total exhibition area was 36000 sq meters and more than 700 exhibitors from over 24 countries and regions presented their products and service in SINO-DENTAL.

For years, Sino-Dental has been striving to serve as the most ideal platform for new dental products and technology launching in China. Many of the exhibitors now regard Sino-Dental as their first choice in China for new products launching.

This year, Sino-Dental published a Handbook for New Products and Technology to distribute to all visitors. A full display of the new products and technology was also be available on LED screen and panel board at the main entrance. Special Edition of newsletters were pushed to visitors phones as warm-up promotion.

Sino-Dental Organization Committee



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25th CEDE Exhibition will be held in Poznań (Poland) September 10-12, 2015.

Conveniently located in the center of the vibrant city of Poznań on the Poznań Fair Grounds just opposite the main railway station and 6 kms from Ławica airport.

CEDE is not only an exhibition, but also a scientific-training “gathering” for dentists, technicians, dental assistants and students keen to keep track of the latest developments in their field. CEDE hosts the CLINICAL DENTISTRY - Conference of Polish Dental Society, hands on courses organized by young dentists of Be Active Dentist Foundation, LASER SHOW by Dental Tribune International, TOUCH & TRY ZONE, numerous lectures, courses and demonstrations organised by exhibitors and professional organisations, all of which ensure participants access to the latest, already proven advances in science that can be applied in dental practice.

The CEDE mobile application is gaining in popularity. It is easy to use, intuitive and very helpful in constructing your own visit and lecture programme. Also this year visitors will use mobile app to vote for one of the products nominated for the Grand Prix CEDE2015. It's very simple: each participating product will be tagged with unique QR voting code. The only thing visitor will be asked to do is to scan a product's QR code with the app! The results will be displayed live on the screens next to Fair Office. One person will be able to vote for one product only.

Attending CEDE is a must to visit event for many reasons, to mention just a few: a convenient platform for exhibitors, comfortable conditions for visitors, professionally organised events, computer facilities, digitalisation, road access, parking facilities, a large number of excellent exhibitors, many leading manufacturers, high-standard conference facilities, countless excellent lectures, courses, demonstrations – a warm, friendly atmosphere and social events... You simply cannot miss CEDE 2015

For more information visit: www.cede.pl



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China Has Offers Matching All Budgets

In an exclusive interview with Prof. Wang Xing, President of China Stomatological Association (CSA), he tells us why China Dental Show (CDS) 2015 is the only place that brings together latest technology offerings and key knowledge exchange programs, all under one roof.

What is the idea behind this year's theme Digital Dentistry? What can visitors expect on this topic from the high-profile seminars and conferences organized by CSA?

Digital technology has made a huge presence in today's lifestyle. Hence, it is no surprise that Digital Dentistry is the logical evolution of the stomatological industry also. The challenge before us is to keep pace with these rapid changes in dental technology. Innovations are emerging from China and overseas almost every month, owing to the latest technology registration policies. We are delighted to see that our selected theme has been received very well, evinced by the quick registrations for more than 400 technical sessions at CDS 2015.

What makes CDS different from other dental trade shows in the world? How does it reflect on the Chinese dental industry?

CDS is unique for these three reasons:

- 1) It reflects our association's principle that education and information exchange comes before business. China is a huge market with varying demands, needs and budgets. Hence, our members need to be well updated and trained before they select the right products. Thus, every three years we select a new theme developed by the CSA Committee Board.
- 2) CDS 2015 plays host to the CSA Annual Meeting which is a must-attend event for all our members. It is the only opportunity for members from across China to meet socially and professionally.
- 3) The new venue at National Exhibition & Convention Center in Shanghai is more user-friendly with buyers and exhibitors meeting on the same level without spending much time travelling across the fairgrounds. Hence, CDS 2015 is sure to be an invigorating experience for all visitors and participants.

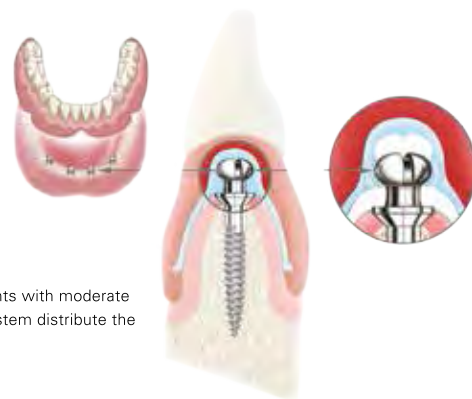
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“Oral diseases continue to be a major public health problem in the African region. They are a source of considerable pain, suffering, and disability for many, especially the poor and deprived”

Thorpe, S. (2006). 'Oral Health Issues in the African Region: Current Situation and Future Perspectives'

Bridge2Aid – the dental charity



For those of us who work in the dental industry we often focus on the need to innovate and discover new techniques and technologies – so sometimes it’s a shock to remember that 70% of the world still has no access to even the most basic dentistry. One charity is working to solve the consequences of using an innovative and sustainable approach which harnesses the good will of the dental profession to bring about positive change.

What we do:

Bridge2Aid works to address the causes of poverty in some of the poorest communities in the world. We do this by strengthening local healthcare systems – by training local healthcare workers to carry out emergency dental treatment.

There is a desperate need to tackle oral disease, infection and chronic pain in communities throughout the developing world and to enable people to work,

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attend school and care for their families. We want to see skills taught in these communities that mean local people are able to function free from pain, and avoid the risk of preventable infections and diseases. Crucially our sustainable training model pass these skills into local communities to provide long-term lasting change. All of these skills are taught by dentists, dental nurses, hygienists and therapists from Europe who voluntarily deliver one of our fortnight long intensive training courses.

Initially we have developed our working model in rural Tanzania, but our long term aim is to roll this training model out to any country where necessary.

Our East African programme:

Bridge2Aid training programmes teach emergency dental skills to Tanzanian health workers in remote rural areas. Armed with these skills they can provide help to people who have been in constant pain for months or years.

In 2004, we began our programme by training four Tanzanian health workers in emergency dental care. This was the first ever Bridge2Aid volunteer programme. Now we have forged ahead and our amazing UK volunteers are helping us to train fifty health workers every year.

Daniel Masesa from a health centre in the heart of Geita district is one of those we have taught to vital emergency dental skills. When asked about the training he has received from Bridge2Aid David said:

"Bridge2Aid volunteers pass on knowledge that stays long after they've gone home."

"This knowledge trains health workers in lifesaving dental skills. I am now confident in carrying out emergency dental care, extractions, effective oral examinations, diagnosis, infiltration and inferior dental nerve block injections. I understand causes of oral disease, the results of cross infection, sterilisation techniques, and I can communicate oral health messages throughout my village."

"Once finished my training, I received a steriliser (pressure cooker) and basic instrument kit, allowing me to take my new skills back to my rural dispensary where I can treat my own patients - no longer having to refer them to the district hospital".

"In one year I can expect to free 200 people of dental pain, who otherwise faced the option of enduring the pain or risk visiting unskilled practitioners."

Dental pain in rural Tanzania doesn't just hurt – it's destructive. It is a threat to lives and livelihoods. Experiencing pain, problems with communicating, eating and smiling due to dental decay leave people ostracised from their communities, unable to work or attend school.

Bridge2Aid-trained health workers can expect to carry out extractions on 84% of patients, immediately taking them out of pain, give a prescription of antibiotics/analgesics to 14% and to refer just 2%.

A sustainable training model:

We strive to ensure that our work is all about training, so skills are passed into the hands of local communities – and remain there. It is vital that the long-term work can continue without our input. In this way we strengthen the basic health infrastructure of a country which is among the poorest on the planet.

Each Health Worker that Bridge2Aid trains serves a rural community of around 10,000 people. This means that we have now provided over 3 million people access to emergency dental care in rural Tanzania

Photo

Bridge2Aid

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Benzian & Helderma (2006). *International Dental Journal*

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<http://www.dentaid.org/wp-content/uploads/2015/04/Golf-Day-Registration-Form-2015.pdf>

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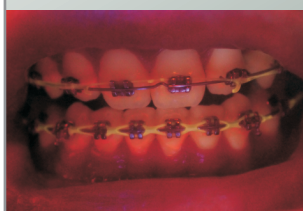
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(Poznan - Poland)

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Finger Textured	XL	BM 49489-N-PF

Our Avocado Green Nitrile Gloves has been rated an 88% (++++) by The Dental Advisor. For more details, please visit the following website:

<http://www.dentaladvisor.com/blossom-brand-avocado-green-nitrile-examination-gloves>

In addition, Dr. Molinari has nominated our Avocado Green Nitrile Gloves as a 2013 "Clinical Problem Solver" due to their durability and tear resistance when donning.

For more details, please visit the following website:

<http://www.dentaladvisor.com/clinical-evaluations/product-awards/2013-clinical-problem-solvers.shtml>



POWDER FREE NITRILE EXAMINATION GLOVES WITH COATS™

DESCRIPTION	SIZE	ITEM NO.
Ambidextrous/Beaded Cuff	XS	BM 44895-C-NIT-PF
Non-Sterile / Disposable	S	BM 44896-C-NIT-PF
XS-L 200 Gloves Per Box	M	BM 44897-C-NIT-PF
XL 180 Gloves Per Box	L	BM 44898-C-NIT-PF
10 Boxes Per Case	XL	BM 44899-C-NIT-PF
Finger Textured		

See your Blossom® distributor or call 1(800) 838 8299 (USA & Canada Toll Free) Website: www.blossom-disposables.com Email: blossomglo@aol.com blossomeurope@aol.com tim@mexpo-glove.com

Tel: +1(510) 489-6800 Fax: +1(510) 489-3111 (U.S.A.) Product of: Mexpo International, Inc. 2828 Faber Street Union City, CA 94587-1204 U.S.A.

EC REP M.I.B.P. F-14170 Boissey Blossom Europe, S.L. Paseo de Recoletos 37-41 28004 Madrid, SPAIN

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WARNING :
 EN Warning: Do not use this product if you have a known allergy to chemical additives. If you experience a reaction to this product, discontinue use and seek medical advice.
 FR Attention: N'utilisez pas ce produit si vous avez une allergie connue aux additifs chimiques. Si vous rencontrez une réaction à ce produit, cessez l'utilisation et demandez conseil à votre médecin.
 ES Advertencia: No utilizar este producto si tienes una alergia sabida a los aditivos químicos. Si experimentas una reacción a este producto, descontinúa el uso y buscar el consejo médico.
 DE Warnung: Verwenden Sie dieses Produkt nicht bei einer bekannten Allergie gegen Vulkanisationsbeschleuniger. Wenn Sie eine unvorhergesehene Reaktion beim Gebrauch dieses Produktes feststellen, stellen Sie die Benutzung ein und suchen Sie einen Arzt auf.

RU Внимание! Не используйте эти перчатки в случае подтвержденной аллергии на химические компоненты. Обязательно проконсультируйтесь со специалистом перед применением.
 PL Ostrzeżenie: Nie używać rękawiczek jeśli macie Państwo rozpoznaną alergię na substancje chemiczne. Jeśli zaobserwujecie objawy uczulenia na ten produkt, należy zaprzestać używania rękawiczek i skonsultować się z lekarzem.
 IT Avvertenza: Non utilizzare questo prodotto se si è a conoscenza di allergie agli additivi chimici. Se si verifica una reazione a questo prodotto, è necessario sospendere l'utilizzo e consultare un medico.

All products above are not made with natural rubber latex



Patent no.		
6,953,582	6,274,154	7,740,622
6,630,152	7,691,436	8,075,965
6,423,328	7,718,240	8,458,818

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