



## Quality mark affirms implant cleanliness

**R**esidues on sterile-packaged implants, in particular organic particles from the production or packaging process, are highly suspected of being responsible for an incomplete osseointegration of dental implants or even a loss of bone in the early healing period. Studies from recent years have shown that neither the CE mark (designating European Conformity) nor FDA clearance can provide a reliable indication of the cleanliness of dental implants. In March 2017, a new initiative was presented at the IDS in Cologne, which is focusing on this topic for the protection of both the users and the patients.

In three consecutive studies using scanning electron microscopes, scientists with the University of Cologne and the Charité-University Berlin analyzed more than 200 sterile-packaged implants since 2007. Results from the most recent study and comparisons with previous years showed a noteworthy increase in implants with conspicuous residues. With growing numbers of practitioners raising concerns about a biologic answer to these impurities, questions also arise about possible legal implications.

Because of the variety of implant systems, it has become difficult for the individual dentist to identify which implants are not affected by these impurities.

In response, the CleanImplant Foundation has set itself the goal of providing such information worldwide. The independent nonprofit organization is supported by a scientific advisory board that is chaired by scientists and practitioners, including Prof. Tomas Albrektsson (University of Gothenburg, Sweden), Prof. Ann Wennerberg (Malmö University, Sweden), Prof. Florian Beuer (Charité-University Medicine Berlin, Germany), Prof. Jaafar Mouhyi (University of Agadir, Morocco), Luigi Canullo (Rome, Italy) and Michael Norton (London, U.K.), who is president of the U.S. Academy of Osseointegration.

In September 2017, this group of scientists released a consensus paper providing objective evaluation criteria for enabling a “clean implant” to carry the “Trusted Quality” award for a two-year period. The 20-pages document is available for download on the project website.

This new global quality mark is designed to enable clinicians to see at a glance whether the appropriate type of implant meets a minimum of cleanliness. Through a five-step approach, the Trusted Quality award can be earned by implants demonstrating in a comprehensive neutral analysis that they are free of significant organic impurities (Fig. 1) and free of particles containing copper, chromium, nickel, iron, tin, zinc, bronze, stainless

steel or particles of antimony on the implant surface.

Technically, it is possible to produce residue-free implants, as many of the implants demonstrated in the recent quality assessment studies. However, if quality control steps are reduced for production or economic reasons, medical devices of inferior quality can result — despite CE certification and/or FDA clearance.

For the Quality Mark awarding process, five implants per type are examined, with at least two of those bought through blind purchase from practices. The analytical reports are screened and released by the CleanImplant scientific advisory board in a peer-review process.

“Through these procedures we want to make absolutely sure that there is no connection between the financial support of the project and the analysis result,” said Dirk Duddeck, DDS, managing director of the CleanImplant Foundation. “The biggest difference to all previous attempts to develop such a quality mark is that we not only re-evaluate the results with new implants of the same type every two years, but also regularly tighten the criteria for this quality mark. Thus, the existing analytics will be substantially expanded in the coming years.”

Results will be published on the project’s website, [www.cleanimplant.com](http://www.cleanimplant.com), to

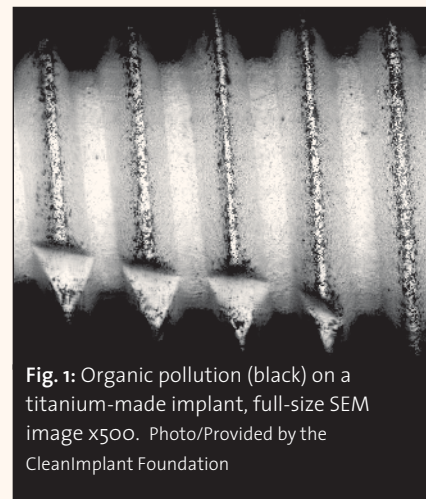


Fig. 1: Organic pollution (black) on a titanium-made implant, full-size SEM image x500. Photo/Provided by the CleanImplant Foundation

provide implantologists with comprehensive information about possible implant pollution as well as analysis results of contaminated and clean implants. The project is open to all dentists and manufacturers concerned about the protection of patients from potentially inferior medical devices.

At the European Association for Osseointegration congress in Madrid in October 2017, two implants (UniCA from BTI and the T6 implant made by NucleOSS)

► See CLEANLINESS, page B4

## Disposable system mixes two components

The time-saving Unit Dose 0.5 ml from Sulzer Mixpac is a single-use hygienic application system for two-component dental materials such as cements and bleaching materials. MIXPAC™ T-Mixer mixing technology produces high-quality, reliable mixing results, according to the company.

The ergonomic and easy-to-use system has a range of safe-

ty features including transport protection and a safety fastener. Clear visual indicators ensure that the user can see at a glance whether the system has been activated and is ready to use.



(Source: Sulzer Mixpac)

The Unit Dose 0.5 ml from Sulzer Mixpac has clear visual indicators to ensure that the user can see at a glance whether the system has been activated and is ready to use. Photo/Provided by Sulzer Mixpac

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# Functional and esthetic overdentures



By Marco Montanari, DDS

The removable denture may seem an outdated rehabilitation. However, it is the foundation on which all prosthetic procedures are based; therefore, it is imperative to know it and to follow its constructive steps when restoring the patient's oral cavity to obtain an esthetic result not only of the smile but of the whole face.

The possibility to anchor a denture to teeth/roots or implants enables the benefits of a removable prosthesis in terms of soft-tissues support, oral hygiene and the greater stability associated with the use of retentive attachments.

Preserving roots for the anchoring of a denture provides several strategic ad-

vantages, including the maintaining of the alveolar bone (for preserving the periodontal ligament), proprioception and physiological masticatory dynamics (Scotti R. *et al.*, 2003).

After an endodontic treatment, different types of post attachments can be applied into the roots. These attachments can be identified as spherical attachments and low profile attachments.

Spherical attachments (Pivot Block Normo and Micro and Pivot Flex, Rhein83, Italy, [www.rhein83.com](http://www.rhein83.com)) are good anchoring devices because of their self-aligning capacity, small dimensions (in particular for the Micro sphere) and ability to compensate severe divergences between the roots (Flex). Today's spherical attachments have further evolved into the low-profile

Pivot OT Equator (Rhein83). This new attachment maintains the same diameter and retentive capacity as the Pivot Block Normo sphere but has a substantially smaller vertical size (only 2.2 mm, including the retentive cap and the housing).

These attachments are recommended when there is the need of a good anchorage for denture but the available prosthetic space is reduced. The Pivot OT Equator, thanks to its sandblasted pin, ensures greater retention inside the root canal, and the nitride surface improves the resistance of the attachment and reduces the wearing process over time.

The morphology of the OT Equator attachment has been validated for more than 10 years by clinical procedures and scientific studies performed on implant-denture rehabilitations (Montanari *et al.*, 2015-2016).

For all these reasons, I believe that the Pivot OT Equator is the most effective and reliable overdenture retentive post currently on the market.

## Contact Rhein83

For more information, contact American Recovery-Rhein83 USA Attachments at (914) 633-6363 or [www.rhein83usa.com](http://www.rhein83usa.com).

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## CLEANLINESS, page B1

received the first "Trusted Quality 2017-2018" certificates. One week later the CleanImplant Foundation presented the third award in Tokyo at the 13th Annual MegaGen International Symposium to Dr. Kwam Bum Park, active implantologist and CEO of the Korean implant manufacturer. Implants of many more manufacturers are already in the process of comprehensive analyses and will be published soon, according to the foundation.

According to Albrektsson, the industry should abide to his fundamental guiding principle written in an article a decade ago to not only believe — but know — that the implants being used do not harm patients.

Because patients trust practitioners' decisions regarding dental implant systems, dentists can benefit from access to an independent guide covering which implant systems meet the expectation of a high-quality medical device.

The CleanImplant Foundation reports that it will support future research on the clinical impact of impurities and extend the periodic analyses of dental implants across the globe to provide dentists with independent research results. Additionally, it will evaluate improvements in the manufacturing process of previously analyzed implants. Details and a newsletter are available at [www.cleanimplant.com](http://www.cleanimplant.com).

(Source: CleanImplant Foundation)

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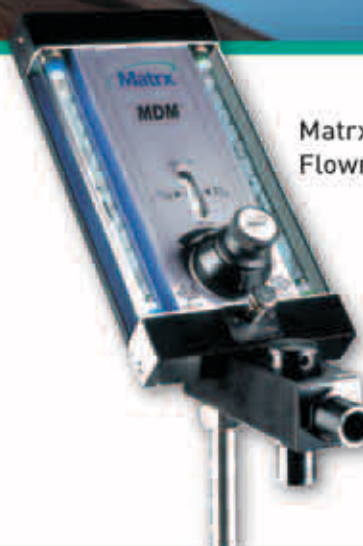
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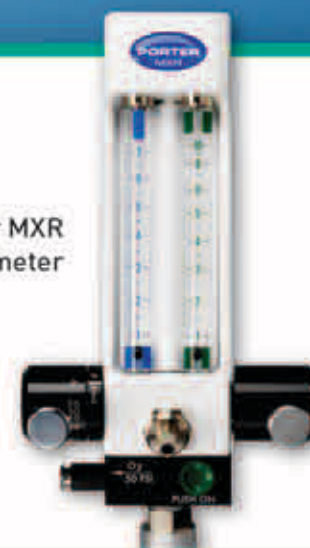
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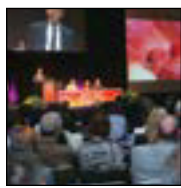


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**Implant news**  
Botox may be able to relieve jaw pain, according to JOMS study  
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**Future events**  
'Inspiring Imagination and Enhancing Health' with the AO  
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**Dental Tribune**  
Quality mark designed to affirm implants' cleanliness threshold  
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The International Congress of Oral Implantologists will host its Winter Implant Symposium in Orlando this January.  
  
Photo/www.freeimages.com



## ICOI to host its annual Winter Implant Symposium in Orlando

By ICOI Staff

Orlando and the surrounding Central Florida region is a favorite destination among travelers from around the globe. Join us there on Jan. 11-13 for the ICOI Winter Implant Symposium for a spectacular program designed by ICOI President Dr. Michael Pikos. Serving as our host hotel, the Orlando World Center Marriott offers amazing on-site amenities as well as a shuttle service to nearby amusement parks.

The theme for this meeting will be

"Maxillary Arch Reconstruction: Single Tooth to Full Arch." Scientific Program Chair Pikos, from Trinity, Fla., has assembled a talented group of experienced and enthusiastic, private practice and academic-based clinicians who will share their respective wealth of knowledge in a friendly and scientific environment.

The first day will feature a full afternoon podium devoted to our "Young Implantologists." Quickly becoming a highlight of the ICOI meetings, this afternoon session on Thursday, Jan. 11, will showcase the fresh ideas and talents from our

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## Conference focuses on implants



Chicago will be the site of the 25th AAOMS Dental Implant Conference from Nov. 30 to Dec. 2. Photo/www.freeimages.com

## 25th AAOMS Dental Implant Conference to continue its educational tradition

By AAOMS Staff

The American Association of Oral and Maxillofacial Surgeons (AAOMS) will host its 25th Dental Implant Conference — a premier dental implant educational event featuring an internationally renowned faculty of experts — from Nov. 30 to Dec. 2 in Chicago, Ill.

More than 1,000 oral and maxillofacial surgeons, their staff and restorative dentists will gather to enhance their knowledge of dental implants,

which offer patients a long-term solution to missing teeth. The event caters to the entire dental implant team.

By attending the three days of innovative research and procedural courses, participants can elevate their implant practice. Session topics — taught by more than 30 speakers — range from replacing congenital missing teeth to effectively applying digital technology in a practice.

Highlights of the preconference sessions and the intensive educational

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# JOMS study: Botox can relieve jaw muscle pain

By JOMS Staff

**B**otox therapy can provide significant relief with only a mild risk for negative effects to patients with stubborn pain in the muscles involved in chewing, according to a new retrospective study.

Chemically known as botulinum toxin A, Botox is a protein made from bacteria that, when injected, stops nerve signals that command muscles to contract – resulting in a months-long decrease in muscle activity. It has been used to treat conditions such as muscle spasms, facial wrinkles, migraines and excessive sweating.

According to the study published in the November issue of the *Journal of Oral and Maxillofacial Surgery* — the official journal of the American Association of Oral and Maxillofacial Surgeons (AAOMS) — botulinum toxin A injections also may have pain-relieving properties.

To determine the therapy's safety and effectiveness in treating stubborn jaw muscle pain, researchers conducted a retrospective review of 116 patients. The patients underwent at least two Botox injection cycles for refractory masticatory myalgia — pain in the muscles used for chewing — that had not responded to other therapies.

The patients at the Department of Oral and Maxillofacial Surgery at Massachusetts General Hospital also had coexisting chronic pain disorders and were receiving other therapies and/or taking medications.

Nearly one-third of participants (30.6 percent) reported significant pain relief — defined as 75 percent or greater — for an average of 10.1 weeks.

"This is an important outcome for this particular cohort of participants, considering that 72.9 percent of the participants had been in pain for at least five years, with 60 percent or more receiving two or more concurrent therapies," researchers



According to a study published in the November issue of the *Journal of Oral and Maxillofacial Surgery*, botulinum toxin A injections also may have pain-relieving properties.

Photo/  
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wrote.

In addition, 39.8 percent of participants had moderate relief for 8.7 weeks on average, and 29.6 percent had no or minimal relief for 1.3 weeks on average.

Among the participants, 16.4 percent reported at least one negative effect during the two injection cycles. Those who had significant pain relief had the largest number of adverse effects at 30.3 percent.

The most common side effect was a decrease in the size of the masticatory muscle, possibly due to blocked release of a chemical that activates muscles, the study states. However, all of the negative effects were minor and brief, and full recovery occurred within 16 weeks.

Simultaneous use of opioid pain relievers was a predictor of no or minimal relief. Of the participants, 36 percent were using a long-term opioid therapy. Long-term opioid use can result in opioid-induced hyperalgesia — a painful response to the medications — and having chronic pain disorders can lead to diminished effect of pain relievers, researchers wrote. "Together, these factors may result in poor outcome and response to therapy," they said.

The authors of "Effectiveness, Safety, and Predictors of Response to Botulinum Toxin Type A in Refractory Masti-

catory Myalgia: A Retrospective Study" are all from the Department of Oral and Maxillofacial Surgery at Massachusetts General Hospital: David A. Keith, DMD, BDS, professor at Harvard School of Dental Medicine; Steven J. Scrivani, DDS, DMedSc, chief, Division of Oral and Maxillofacial Pain; Nicole Holland, DDS, MS; and Shehryar N. Khawaja, BDS, MS, post-graduate Fellow at Harvard School of Dental Medicine.

The full article can be accessed at [www.joms.org/article/S0278-2391\(17\)30116-7/fulltext](http://www.joms.org/article/S0278-2391(17)30116-7/fulltext).

## About JOMS

The *Journal of Oral and Maxillofacial Surgery* is published by the American Association of Oral and Maxillofacial Surgeons to present to the dental and medical communities comprehensive coverage of new techniques, important developments and innovative ideas in oral and maxillofacial surgery. Practice-applicable articles help develop the methods used to handle dentoalveolar surgery, facial injuries and deformities, TMJ disorders, oral and head and neck cancer, jaw reconstruction, anesthesia and analgesia. The journal also includes specifics on new instruments and diagnostic equipment, and modern therapeutic drugs and devices.

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programs include:

- Didactic sessions and hands-on workshops on topics such as implant restorations and case-based dental implant techniques.
- Point/counterpoint discussions exploring clinically common topics, such as implant options when treating the lower jaw.
- Question-and-answer sessions with the session speakers.
- Faculty reflecting on the history of AAOMS and the specialty while assessing the future of oral and maxillofacial surgery, as the association gets ready to celebrate its centennial in 2018.
- New this year, a live simulcast option for participants to watch general sessions

from wherever they are.

"As AAOMS offers its 25th Dental Implant Conference, oral and maxillofacial surgeons, their staff and referring dentists can participate in a range of preconference sessions and educational programs geared toward the dental implant practice," said AAOMS President Brett L. Ferguson, DDS, FACS. "After three days of focused courses and exhibits, doctors and their staff can enhance their practices with renewed knowledge. We look forward to collectively learning the innovations and groundbreaking research in the field of dental implants."

More than 100 companies will showcase the most technologically advanced products and services in the specialty in

the exhibit hall at the Sheraton Grand Chicago. The exhibit hall also will feature the AAOMS Product Resource Center, where attendees can receive educational, regulatory compliance, practice management and marketing materials for their practice.

Dental anesthesia and surgical assistants also can renew their anesthesia knowledge and skills through assistant-focused courses, including a hands-on, four-hour workshop and a two-day review course on such topics as methods of anesthesia administration, monitoring and emergency preparedness.

Registration is open to AAOMS members, students, non-members and the media. View [AAOMS.org/DIC](http://AAOMS.org/DIC) for additional information.

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Torsten Oemus [t.oemus@dental-tribune.com](mailto:t.oemus@dental-tribune.com)

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### MANAGING EDITOR IMPLANT TRIBUNE

Sierra Rendon [s.rendon@dental-tribune.com](mailto:s.rendon@dental-tribune.com)

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Fred Michmershuizen  
[f.michmershuizen@dental-tribune.com](mailto:f.michmershuizen@dental-tribune.com)

### MANAGING EDITOR

Robert Selleck, [r.selleck@dental-tribune.com](mailto:r.selleck@dental-tribune.com)

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Humberto Estrada  
[h.estrada@dental-tribune.com](mailto:h.estrada@dental-tribune.com)

### PRODUCT/ACCOUNT MANAGER

Jordan McCumbee  
[j.mccumbee@dental-tribune.com](mailto:j.mccumbee@dental-tribune.com)

### PRODUCT/ACCOUNT MANAGER

Maria Kaiser  
[m.kaiser@dental-tribune.com](mailto:m.kaiser@dental-tribune.com)

### EDUCATION DIRECTOR

Christiane Ferret [c.ferret@dtstudyclub.com](mailto:c.ferret@dtstudyclub.com)

### CLIENT RELATIONS COORDINATOR

Leerol Colquhoun  
[l.colquhoun@dental-tribune.com](mailto:l.colquhoun@dental-tribune.com)

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## Human Biopsy

Reference: Myron Nevins, DDS, et. al., "Clinical and Histologic Evaluations of SLA Dental Implants"  
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