ELOS MEDTECH

BRING VALUE TO DENTAL RESTORATION

THE ELOS ACCURATE® PORTFOLIO

COMPATIBLE WITH MAJOR IMPLANT SYSTEMS

INTRODUCTION

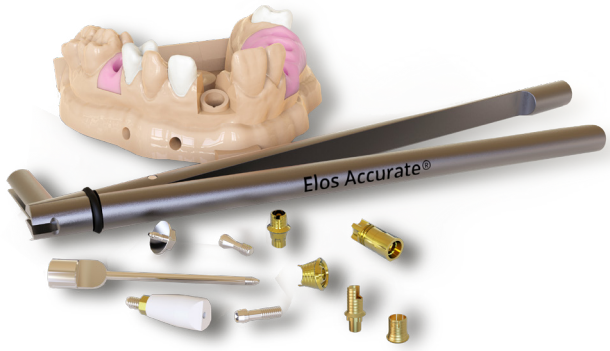
Oral health is one of the key indicators of well-being, overall health, and quality of life. Teeth play a significant role in the health system. However, oral diseases still affect 3.6 billion people worldwide.[1]

As a beaming white smile comes at a cost and as most people with tooth decay and tooth loss have no health insurance, the need to reduce costs is felt especially by restoring doctors and dental labs. In that context, speed and choice of implant systems are essential.

This document will focus on how the Elos Accurate® validated portfolio, a high quality prosthetic alternative to major implant systems, has been developed and tested to obtain its FDA clearance.

Through Elos Medtech's open digital workflow, you obtain the flexibility to work with most major implant systems and their platforms without compromising quality.

ELOS ACCURATE® — ORIGINAL ELOS MEDTECH QUALITY



Elos Accurate® Hybrid Base™ and Elos Accurate® Customized Abutments have received FDA 510(k) clearance for the U.S. dental implant market

Elos Medtech's open digital workflow and several portfolio solutions have obtained the US market's FDA clearance. The entire portfolio has, however, already been successfully deployed in Europe for several years. It offers compatibility with almost all the major, global implant systems and their platforms and covers several clinical indications. The product portfolio contains:

- Elos Accurate® Customized Abutments
- Elos Accurate® Analog for Printed Models
- Elos Accurate® Model Analog
- Elos Accurate® Hybrid Base™ Non-Engaging
- Elos Accurate® Hybrid Base™ Engaging
- Elos Accurate® Scan Body

This white paper documents that Elos Accurate products are safe to use and aims to give you the confidence to use them instead of major implant companies' solutions.

If you want to work with original parts, work with original Elos Accurate .

1 WHO "Oral Health" 2021, https://www.who.int/health-topics/oral-health#tab=tab_1

DEVELOPMENT - Preparation for the FDA clearance

Step 1: Measuring the implant interface connection

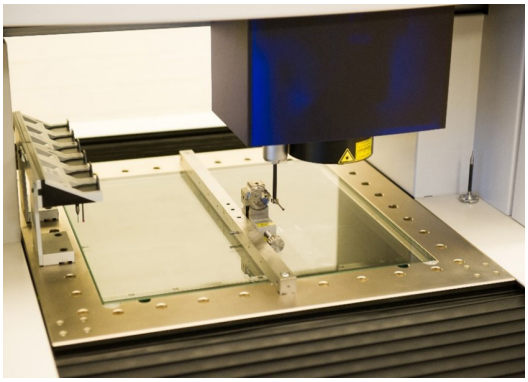
The most critical part of the design, which we cannot alter, is the *implant interface connection.*

All the major Implant companies put great effort into designing the best interface possible, securing a tight sealing, and the correct transfer and distribution of forces during use. Since the interfaces are not standardized, they will vary from one implant system to another.

Consequently, it is of the utmost importance to have complete compatibility with the relevant interfaces, **ensuring Elos Accurate constructions provide the equivalent strength and durability as offered by the implant company.**

We obrain this equivalent strength and durability through meticulous efforts.

Screws etc. are measured in order to obtain a complete specification



A Zeiss CMM

We base our development process on an engineering approach that starts with measuring the major implant manufacturers' components such as screws, implants and abutments.

Elos Medtech has developed and manufactured dental components for decades, so we have deep knowledge of and competence in what and how to measure, using industry-leading technology and state-of-the-art equipment including Zeiss CMM, vision-based systems, digital microscopy.

All equipment is calibrated according to international standards and used by experienced technicians.

Step 2: Determining the nominal value

Several components are measured to determine the nominal value. Tolerances are determined using general design criteria for placement of abutments on implants, with appropriate regard to required clearances and the avoidance of micro gaps.

The design alone cannot guarantee a proper strength in the construction, as the material itself also impacts performance. Most titanium-based prosthetic solutions are made from alloyed titanium, and the actual strength may vary. This will be verified during benchtop testing.

The design is verified by an initial computerized stress analysis (Finite Element Analysis) followed by fatigue testing of the re-designed abutment on implants from major implant manufacturers according to international standards (ISO 14801).

All of the above is in strict compliance with the requirements for obtaining a market approval. This is done by submitting a 510(k) premarket notification according to guidelines, which is then scrutinized and cleared by the FDA.[2]

Step 3: Setting tolerances

Elos Medtech has established general design criteria based on input from different dental laboratories and dentists experienced in implantology. These inputs have been combined into a set of design requirements. The results have then been evaluated by dental laboratories and dentists when performing the finished products' design validation (design output), which is especially crucial. The fit and "feel" of the products in an actual use situation is an integral part of the design validation.

The following general design criteria for placement accuracy of the abutment on implants is used as design inputs:

1. Maximum allowed misalignment in horizontal direction: 0.04mm
2. Maximum allowed rotational clearance: +/- 4 degrees
3.

All Elos Accurate prosthetic components are verified to be biocompatible
(ISO 10993)

2 Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments

TESTING

Bench testing – Fatigue testing

The components to be tested are selected to represent the Elos Accurate assembly's worst-case scenario for the individual implant system. The following parameters define the worst case scenario:

- Smallest implant diameter = Depends on the implant system
- Maximum angle of zirconia superstructure = 20° ***(See Figure 1)***
- Minimum wall thickness of zirconia superstructure = 0.5 mm ***(See Figure 1)***
- Maximum gingival height (from the top surface of the implant) = 5 mm ***(See Figure 1)***
- Worst case orientation of implant connection interface according to loading direction= Determined by FEM analysis. ***(See Figure 2)***

The dynamic fatigue test is performed in accordance with the standard ISO 14801 at 2 Hz in saline. The test set-up is shown in Figure 3.

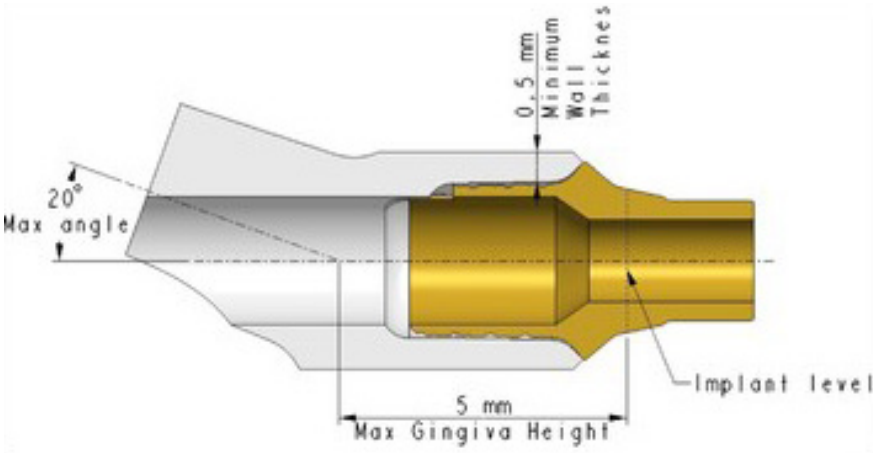


Figure 1: Worst case dimensions of zirconia superstructure

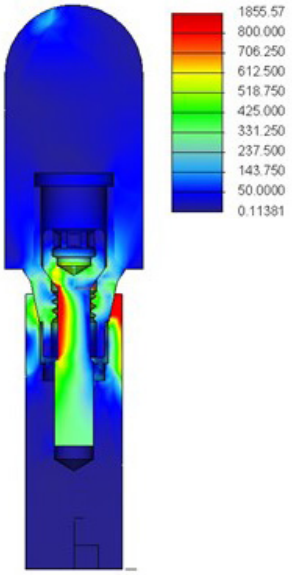


Figure 2: Example of FEM analysis

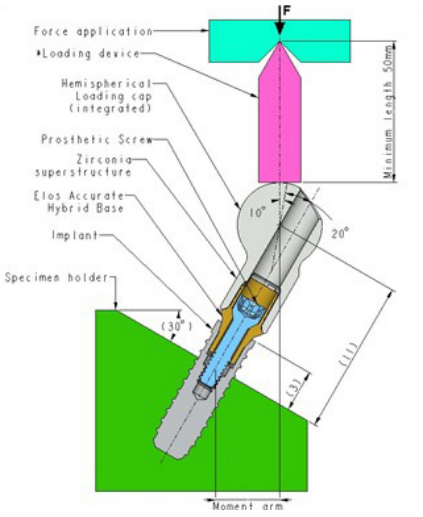


Figure 3: Test setup

The dynamic fatigue test result is a graph like the one seen in Figure 4 that will assess the implant abutment connection's strength.

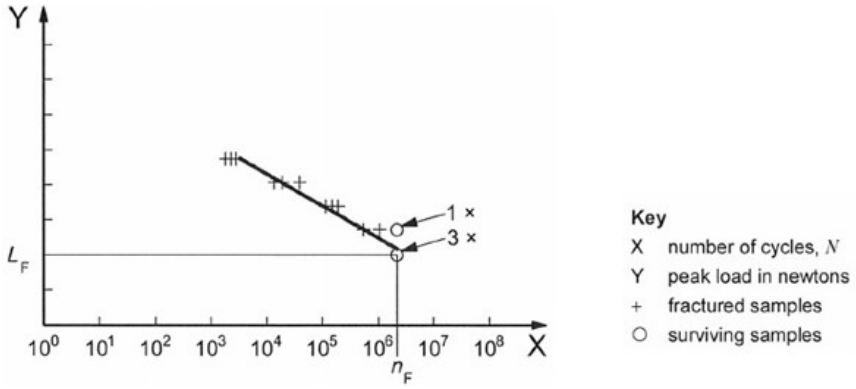


Figure 4: Example of a load-cycle diagram for tests run until 2x106

An example of a test set-up is shown below:

Figure 5: Embedded Nobel CC implant

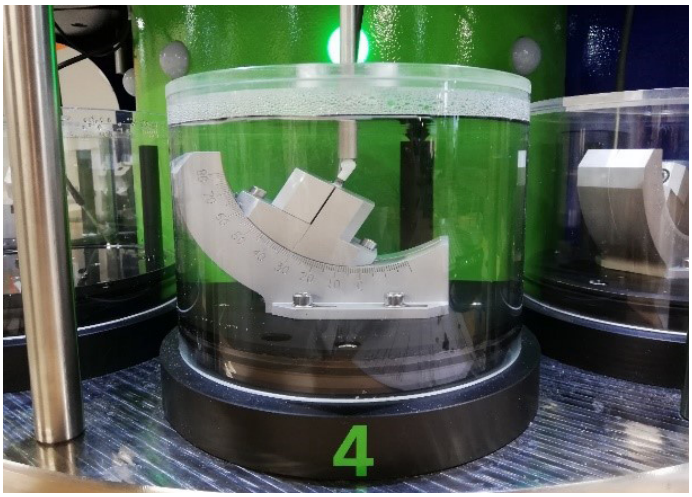


Figure 6: Dynamic test set-up

The dynamic fatigue test is conducted at 2Hz frequency in normal saline (NaCl 0.9%) using a DYNA-MESS – DYNA5dent 14801 testing machine.

A loading device, which allows free movement transversely to the loading direction, enables unconstrained loading of the implant system.

The sinusoidal loading cycle is performed at between 10% and 100% of the maximum load, resulting in a loading ratio of 1-10.

REGISTRATION

All Elos Accurate solutions offered in the US have been cleared by the FDA, thereby confirming the products' safety for use with implant systems and platforms of major implant manufacturers.

If you want to work with original parts, work with original Elos Accurate. We've been in the dental implant business for decades!

CERTIFICATIONS

21 CFR Part 820

MEDICAL DEVICES QUALITY MANAGEMENT ISO ISO 13485:2016

ISO 14001:2015

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

日健栄協認定製品 GMP

CMDCAS

ISO 14644

The Elos Medtech Story

Elos Medtech has been manufacturing dental implants and components for longer than most companies. Dentists learn that Prof. Brånemark first achieved successful osseointegration using titanium dental implants in Sweden during the 1950s and 60s. When Dr. Brånemark needed to manufacture his prototypes for the modern dental implants, he turned to Elos Medtech in Sweden.

Initially, Elos Medtech was solely a subcontractor for major dental implant companies, but since 2000 we began to identify ways to offer even more value to our customers. Having decades of know-how with dental implants and witnessing the beginning of the era of digital dentistry, we began to focus on developing products outside of our customers' core business and expertise.

In 2010, together with the digital dentistry market leader 3Shape, we developed and introduced the original PEEK scan body made with a titanium interface. This new design combined the scannability of PEEK and the durability of titanium. Today this design is the gold standard for scan bodies – copied all over the world. Additionally, Elos Medtech was the first company to introduce a high-precision scan body that allowed for the digitalization of implant restorations. Based on this innovative design we entered into partnerships with premium, global implant brands that today use the Elos Accurate Scan Body in their libraries and workflows.

Elos Medtech also developed pre-milled abutments (prefabricated blanks) for making customized abutments, and later analogs for printed models. Our philosophy has always been to develop best-in-class products using innovative ideas and designs, rather than copying what is already on the market.

This innovative spirit has led to our patented design for our Elos Accurate Analog for Printed models. With this new design we overcome many of the challenges that arise from the inaccuracies found in today's 3D-printers. These print model analogs have also become the trusted solution for global implant companies.

Additionally, Elos Accurate Hybrid Bases (Ti-bases) were designed from scratch taking human biology and material characteristics into account. Rather than having sharp angles or compromising the thickness of the zirconia crown, we carefully examined the implant with respect to soft tissue management and pioneered a new anatomical design. Our hybrid base has been adapted as the authentic solution for some of the leading implant companies.

In short, we have created a portfolio that has allowed us to partner with top implant companies around the world. We are a trusted partner because of the precision and quality of the parts we manufacture.

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