

**Title:**

**A Retrospective Multicenter Study Evaluating ATLANTIS™ Abutments on Implants from Four Manufacturers**

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## **A Retrospective Multicenter Study Evaluating ATLANTIS™ Abutments on Implants from Four Manufacturers.**

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### **Background and overall aim**

The ATLANTIS abutment is a CAD/CAM solution for patient-specific cement and screw retained implant restorations. The abutments are comprised of a unique combination of four key features, summarized under the term ATLANTIS BioDesign Matrix. Together the key features facilitate the soft tissue management for optimal functional and esthetic results. Using the ATLANTIS VAD (Virtual Abutment Design) software, the abutments are individually designed based on the desired final tooth shape for an esthetic result. Moreover, the software makes it possible to locate the margin in an optimal position, i.e. more coronally, in order to avoid cement-related complications. ATLANTIS abutments are available for all major implant systems.

These abutments were originally developed by a company that was founded 1996 (Atlantis Components, Inc.) and acquired by Astra Tech AB (now integrated in Dentsply Sirona Implants) in 2007.

ATLANTIS abutments are available for implant-abutment interfaces from many different implant manufacturers, while there are implant manufacturers proposing that only their own patient-specific abutments perform well on their implants. The rationale from their side is that other companies do not have access to in house engineering specifications and can therefore not optimally recreate the implant-abutment connection interface. However, the ATLANTIS abutment connection interfaces and abutment screws are specifically engineered and tested for each implant interface for optimal fit and stability, this in order to ensure good clinical results.

The rationale for this retrospective study is to provide scientific data on the clinical performance of titanium and gold-shaded titanium ATLANTIS abutments when connected to implants from four of the major implant manufacturers, whereof one being the ASTRA TECH Implant System (Dentsply Sirona Implants).

### **Study objectives**

#### *Primary objective*

The primary objective is to evaluate implant and abutment success.

Success is defined as study implant and abutment still in situ at time of the prospective study visits and no Adverse Device Effects related to the study implant, abutment or adjacent peri-implant tissues are reported during the study. Study start date is when the ATLANTIS abutment(s) was finally delivered / installed and included as part of the permanent prosthetic restoration, and the study ends when the subject leaves the prospective study visit.

#### *Secondary objectives*

The secondary objectives of the study are to evaluate :

- Implant and abutment survival
- Soft tissue response, by assessment of Papillae, Plaque, Probing Pocket Depth (PPD) and Bleeding on Probing (BoP)
- Bone tissue response, by measuring of marginal bone levels (MBL).
- Patient Reported Outcomes, by subject rating on chewing function, esthetics and satisfaction.
- Safety, by recording of adverse device effects (ADEs)

## Study design

This study is designed as a retrospective and multi-center study. The study population is US individuals previously restored with titanium and gold-shaded titanium ATLANTIS abutments on implants from four manufacturers: BIOMET 3i; Straumann; Nobel Biocare and Dentsply Sirona Implants (only ASTRA TECH Implant System). One hundred eighty individuals will be enrolled, 45 per implant manufacturer is planned. The study includes retrospective data collection from the medical records and data collection from one prospective study visit with a clinical examination.

The active study phase, at the study sites, is estimated to 6 months and includes: contacting, recalling and performing one study visit when the ICF will be signed and the clinical examination performed.

The study start date is when the ATLANTIS abutment(s) was finally delivered / installed and included as part of the permanent prosthetic restoration, and the study ends when the subject leaves the prospective study visit.

Success is chosen as primary objective to show that the ATLANTIS abutment has performed well during the study. This will be the case when the implant and abutment are in situ during study, and no ADEs related to implant, abutment or adjacent peri-implant tissues were reported during study. Thus, the study position is free of complications that could have been caused by the abutment. ADEs related to the prosthesis will only affect success when the investigator has actively judged that the event was caused by the abutment.

## Study population

The study population is individuals who received ATLANTIS abutments, between 2010 and 2013, connected to implants from BIOMET 3i, Straumann, Nobel Biocare or Dentsply Sirona Implants (only ASTRA TECH Implant System) replacing one or more teeth, in any position in the mouth, as part of a permanent prosthetic restoration. The partially dentate individuals have received either single-unit crowns or fixed partial or full dentures. The abutments need to be titanium or gold-shaded titanium.

### *Inclusion criteria*

For inclusion in the study subjects must fulfill all the following criteria:

1. Having received one or more ATLANTIS abutments included in one or more permanent prosthetic restoration(s)
  - during 2010, 2011, 2012 or 2013,
  - made of titanium or gold-shaded titanium (previously market as GoldHue),
  - connected to implants from: BIOMET 3i; Straumann; Nobel Biocare or Dentsply Sirona Implants (only ASTRA TECH Implant System), irrespective of implant-abutment interface.
2. Being at least 18 years at day of enrollment.
3. Having signed and dated the informed consent form.

### *Exclusion criteria*

Any of the following is regarded as a criterion for exclusion from the study:

1. Unable to come for study visit.
2. Not willing to participate in the study or not able to understand the content of the study.
3. Involvement in the planning and conduct of the study (applies to both DENTSPLY Implants staff and staff at the study site).
4. Simultaneous participation in another clinical study that may interfere with the present study.

### **Study products**

The investigational product (ATLANTIS abutment) in this study is already included in a restoration in the subject at enrollment, thus this study does not involve the installation of any investigational products.

### **Statistical methods**

If nothing else is stated, descriptive statistics will be given for each variable in the study. This means number of subjects or study positions (n), mean, median, standard deviation (SD), minimum (min) and maximum (max) values will be presented for continuous data and frequencies and percentages for categorical data.

The primary objective is to calculate the proportion of successful study positions. Each study position will be categorized as success (No/Yes). The proportion of successful study positions will be calculated by dividing the number of study positions with success=Yes, by the total number of study positions. This proportion will be presented together with a 95% confidence interval (using the exact Binomial approach) and an average follow-up time. Success will be calculated on a study position level although the sample size calculation provides the number of subjects needed; this approach is chosen since we do not in advance know the number of study positions per subject. Consequently, we assume that study positions within one subject are independent of each other if more than one.

### **Study timetable**

Estimated date of first subject enrolled: January 2015  
Estimated date of last subject completed: July 2015