Astra Tech Implant System®

Evolution through science – Astra Tech Implant System® EV

Dentsply Sirona Implants

Astra Tech Implant System
BioManagement Complex™

A successful implant system cannot be determined by one single feature alone. Just as in nature, there are several interdependent features working together. The following combination of key features is unique to the Astra Tech Implant System:

OsseoSpeed® — more bone more rapidly
MicroThread® — biomechanical bone stimulation
Conical Seal Design™ — a strong and stable fit
Connective Contour™ — increased soft tissue contact zone and volume

Evolution through science – Astra Tech Implant System® EV

For all dental professionals working with implants, we are pleased to introduce the next step in the continuous evolution of the Astra Tech Implant System. The foundation of this evolutionary step is the unique Astra Tech Implant System BioManagement Complex, well documented for its long-term marginal bone maintenance and esthetic results.

Design philosophy

When designing an implant system, several parameters need to be considered:

- Long-term biological and clinical performance
- Ease of use and tactility
- Versatility and indication coverage
- Mechanical integrity and robustness

In addition, the design philosophy of the Astra Tech Implant System EV is based on the natural dentition utilizing a site-specific, crown-down approach.
By using the natural dentition as a guide, implants, abutments and abutment screws – including cylinders and bridge screws – are designed to meet the requirements for mechanical integrity, bone quantity, load carrying capacity and biological response.

The result of this design philosophy is a product assortment that provides versatility for meeting the needs of each individual clinical situation.

One of the prerequisites for the development of the implant system was to maintain the key features of the Astra Tech Implant System BioManagement Complex: the OsseoSpeed[1–3] surface; the MicroThread[4, 5] design; the Conical Seal Design[6, 7] connection; and the Connective Contour[8, 9] feature.

By maintaining all the unique features of the Astra Tech Implant System BioManagement Complex, a reliable, predictable and esthetic result, both in the short and long term, is ensured.

During the design and development process, the Astra Tech Implant System EV was extensively tested using several different methods. The results of these tests led to the further optimization of the mechanical integrity of all components.

This leaflet highlights the key results from some of the testings and presents an ongoing clinical study of the Astra Tech Implant System EV.

Verification of design philosophy

Material selection and design considerations

The selection of appropriate materials for a dental implant and its associated components is critical for achieving long-term clinical success and robust mechanical integrity.

In conjunction with material selection, design and geometry have a major impact on the total mechanical integrity of the implant-abutment pillar.

OsseoSpeed EV implants are produced from commercially pure titanium (Grade 4) according to requirements for dental implants (ISO ASTM 67) for ensuring biocompatibility. Additionally, the material is cold worked and selected according to our specifications to ensure increased strength characteristics.

	Product	**Tensile strength (MPa)**
Ti Grade 4 (ASTM 67 selected batch)	Implants	820
Ti-6AL-4V ELI (ASTM F 136)	Stock abutments	860
Ti-6AL-4V ELI (ASTM F 136 selected batch)	Abutment screws	1095
Ti Grade 4 (ASTM 67 standard batch)	Generic implant	550

Material specification and tensile strengths for the Astra Tech Implant System EV and a generic implant.

Methods for mechanical integrity testing

The standard method for measuring mechanical integrity used for implant designs is ISO 14801:2007. This fatigue-testing method consists of applying a 30° off-axis load to an implant-abutment pillar. According to the standard, simulating long-term use, the endurance strength is determined by the load where three consecutive samples of each implant diameter survives five million load cycles. This 30° standard method primarily evaluates the strength of the implant itself and not the entire implant-abutment pillar of an implant with an internal conical connection.

To be able to specifically test the fatigue of the implant-abutment and abutment-cylinder interface, DENTSPLY Implants developed a fatigue-testing method which uses a 90° off-axis load application. The strength index is based on the survival load at 100,000 cycles using a Wöhler diagram.
The strength of the internal conical connection is better evaluated by the 90° model.

During the design and development process, both the ISO 30° and the Dentsply Sirona 90° off-axis load methods were used to evaluate mechanical integrity. This was done in order to gain a larger perspective of the endurance properties of the new implant system design.

30° off-axis load method (ISO 14801:2007) and Dentsply Sirona 90° off-axis load method.

The OsseoSpeed® EV 4.2 S implant is 17% stronger than its predecessor[10].

Implant testing

OsseoSpeed EV implants were connected to their corresponding TiDesign EV abutments. The test outcome was compared to the predecessor, an OsseoSpeed TX 4.0 implant connected to a TiDesign abutment. The fatigue limit was defined according to the ISO 14801:2007 30° off-axis load method.

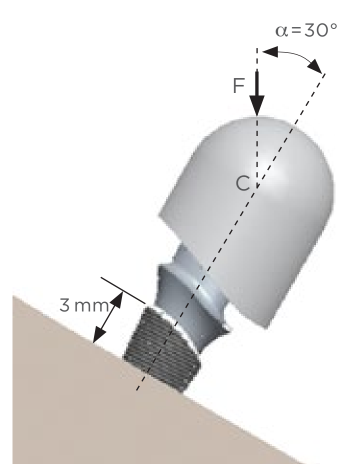
OsseoSpeed EV/ TiDesign EV	Implant* strength index
3.0 S	0.50
3.6 S	0.75
4.2 S	1.17
4.2 C	0.83
4.8 S	1.92
4.8 C	1.33
5.4 S	2.58
OsseoSpeed TX 4.0 / TiDesign	1.00

Endurance strength for OsseoSpeed EV implants (*when testing implant-abutment pillars) presented as an index proportional to the strength of an OsseoSpeed TX 4.0 implant.

OsseoSpeed Profile EV implants were tested in the 30° off-axis load method according to ISO 14801:2007 with the buccal profile facing downwards (presenting the most demanding load case), connected to their corresponding TiDesign abutments. The outcome was compared to an OsseoSpeed TX Profile 4.5 with a corresponding TiDesign abutment.

OsseoSpeed Profile EV/ TiDesign Profile EV	Implant* strength index
4.2 C	1.05
4.2 S	1.16
4.8 C	1.42
4.8 S	1.52
OsseoSpeed TX Profile 4.5 / TiDesign	1.00

Endurance strength for OsseoSpeed Profile EV implants (*when testing implant-abutment pillars) presented as an index proportional to the strength of an OsseoSpeed TX 4.5 Profile (conical) implant.



Test setup per ISO 14801:2007. The OsseoSpeed Profile EV implant – abutment assemblies were tested at a 30° angle with the implant embedded to a level 3 mm below the implant shoulder (i.e., nominal bone level). A hemispherical test cap (C) was placed on top of the abutment to ensure proper load (F) distribution.

Abutment testing

Both the one-piece abutment with an integrated abutment screw and the two-piece abutment with a separate abutment screw were tested according to the 90° off-axis load method.

The test outcome was compared to the predecessors, TiDesign and Direct Abutment, respectively, connected to an OsseoSpeed TX 4.0 implant or to an OsseoSpeed TX Profile 4.5 implant.

The OsseoSpeed Profile EV abutments were mounted in the 90° off-axis load method with the buccal profile facing downwards, presenting the most demanding load case.

OsseoSpeed EV abutment pillar

	Strength index
Implant	**TiDesign EV separate screw**
3.0 S	0.74
3.6 S	1.37
4.2 S	1.47
4.2 C	1.47
4.8 S	2.11
4.8 C	2.05
5.4 S	2.74
OsseoSpeed TX 4.0	1.00

	Strength index
Implant	**Direct Abutment EV integrated screw**
3.0 S	0.73
3.6 S	0.95
4.2 S	1.50
4.2 C	1.36
4.8 S	1.82
4.8 C	1.77
5.4 S	2.00
OsseoSpeed TX 4.0	1.00

Endurance strength for TiDesign EV and Direct Abutment EV – presented as an index proportional to the strength of corresponding abutments (TiDesign with a separate screw and Direct Abutment with an integrated screw, respectively) connected to a OsseoSpeed TX 4.0 implant. (data on file)

OsseoSpeed Profile EV abutment pillar

	Strength index
Implant	**TiDesign EV separate screw**
4.2 C	0.91
4.2 S	1.04
4.8 C	1.17
4.8 S	1.22
OsseoSpeed TX Profile 4.5	1.00

	Strength index
Implant	**Direct Abutment EV integrated screw**
4.2 C	0.88
4.2 S	1.16
4.8 C	1.12
4.8 S	1.44
OsseoSpeed TX Profile 4.5	1.00

Endurance strength for TiDesign Profile EV and Direct Abutment Profile EV – presented as an index proportional to the strength of corresponding abutments (TiDesign with a separate screw and Direct Abutment with an integrated screw, respectively) connected to a OsseoSpeed TX Profile 4.5 (conical) implant. (data on file)

The OsseoSpeed® EV 4.2 S abutment is 47% stronger than its predecessor.

Each individual abutment screw delivers controlled preload and reduced torsion at the recommended installation torque[12].

Uni Abutment EV top cone testing

Uni Abutment EV is specially designed with a 33° tapered cone top and can compensate for up to 66° of convergence or divergence between two implants. This design delivers generous surgical and restorative versatility and strong mechanical integrity.

The mechanical integrity of the Uni Abutment EV pillar, including the cylinder and bridge screw, was tested according to the DENTSPLY Implants 90° off-axis method.

The test outcome was compared to the predecessor, a UniAbutment 20° mounted with a corresponding cylinder and bridge screw.

Abutment	Strength Index
Uni Abutment EV 33°	1.40
UniAbutment 20°	1.00

Endurance strength for the Uni Abutment EV top cone reported as an index proportional to the strength of a UniAbutment.

Uni Abutment EV is 40% stronger than its predecessor[11].

Screw mechanics

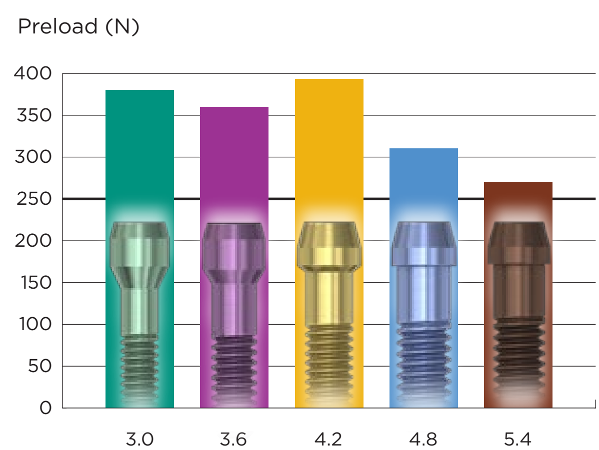
When an abutment screw is tightened, preload (axial force) is created, which securely seats the abutment in the implant. Achieving the proper preload is a key factor for maintaining integrity of the implant-abutment connection. The correct preload leads to a reduction of screw loosening, an endurance to high bite forces and an absence of leakage at the interface. The preload depends on multiple factors such as:

- abutment screw size
- abutment surface characteristics
- abutment design
- implant design and surface characteristics

For Astra Tech Implant System a preload of at least 250 N is preferred.

Upon tightening, torsion stresses are also induced in the abutment screw. High torsion stresses should be avoided as they may lead to screw loosening and abutment screw fractures. The optimal screw achieves a sufficient preload while at the same time minimizing the amount of torsion in the screw.

Abutment screws for Astra Tech Implant System EV are uniquely designed with tapered screw heads and anodized-treated surfaces for color coding, which ensures a controlled preload and reduces torsion stresses while using the uniform tightening torque of 25 Ncm.



All abutment screws for Astra Tech Implant System EV exceeded the preload of at least 250 N at the tightening torque of 25 Ncm.

Leakage testing of Conical Seal Design™

Leakage of microbial content through the implant-abutment junction has been discussed as a factor contributing to inflammatory reactions in the adjacent tissue. When further updating and improving the implant-abutment connection, the assurance of a tight seal of this interface is an important aspect for the clinical outcome.

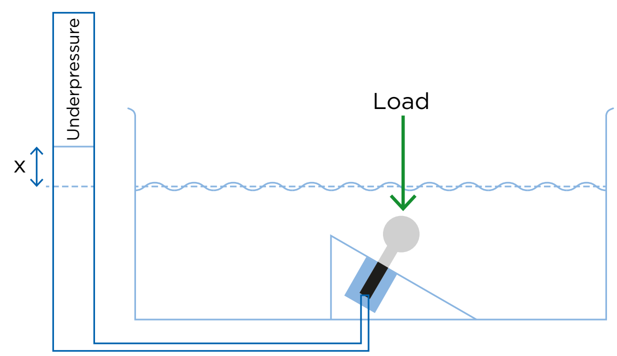
Dentsply Sirona Implants has developed a test method to verify the integrity of the Conical Seal Design connection. The purpose of the test method is to verify that the sealing of the implant-abutment connection remains intact under simulated loading conditions.

First, the entire assembly is submerged in a sodium chloride (NaCl) solution. Then, an “underpressure” is created within the cone of the implant-abutment assembly and the assembly is subjected to cyclic loading at a 30° angle per ISO 14801:2007.

With an intact seal, the underpressure remains and no leakage can be detected. Should the seal break, the underpressure would allow the solution to pass through the conical connection, thus producing a measurable increase of the liquid level in the underpressure column.

For this test, OsseoSpeed EV implants and corresponding TiDesign EV abutments were mounted and loaded using a 30° off-axis cyclic load of 275 N for ten minutes. No fluid leakage was detected for any of the tested assemblies[13].

The Conical Seal Design™ connection showed no micro-leakage[13].



A schematic illustration of the Dentsply Sirona Implants leak test method. The implant and abutment are mounted according to the 30° off-axis method. The underpressure is created through a drilled hole at the bottom of the implant. Fluid leakage can be detected through a rise of the fluid column, which is schematically illustrated as “x”.

Drilling procedure and insertion torque testing

Implant site preparation for the Astra Tech Implant System EV is carried out with a drilling procedure that delivers a preferred degree of primary implant stability. The streamlined protocol developed describes a procedure for preparing an osteotomy with two options to address the cortical bone thickness: thin cortical bone <2 mm and thick cortical bone ≥2mm. The drilling protocol provides the same relationship between cortical bone preparation and implant diameter as the drilling protocols for OsseoSpeed TX. The protocol also includes the flexibility of a wider osteotomy preparation apically or along the osteotomy as needed.

In artificial bone, the implant sites for OsseoSpeed EV 4.2 S and OsseoSpeed TX 4.0 S of 11 mm length respectively were prepared. For the OsseoSpeed EV implant, a preparation addressing a thin cortical bone was applied, and for OsseoSpeed TX a soft bone protocol was used. Implants were inserted using the drilling unit, and insertion torque values were recorded.

The results indicate the possibility of achieving a higher primary stability measured as insertion torque in soft bone. This comparison does not reflect the flexibility offered by the optional wider osteotomy preparation.

Implant	Drilling protocol	Insertion torque index
OsseoSpeed EV	Thin cortical bone	1.4*
OsseoSpeed TX	Soft bone protocol	1.0

Insertion torque for OsseoSpeed EV presented as an index proportional to the insertion torque of OsseoSpeed TX.
*Optional drills for OsseoSpeed EV providing a possibility for a wider osteotomy have not been used. (data on file)

The flexible drilling protocol delivers preferred primary stability.

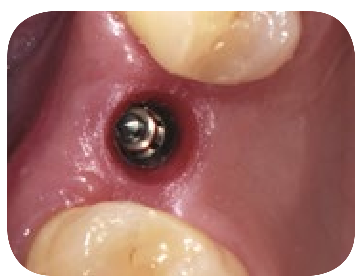
Clinical evidence

Clinical experience

The Astra Tech Implant System EV is a result of a collaborative input and insights from dental professionals throughout the global dental community. A group of international peers continuously participated in all development phases, sharing their perspectives and acknowledging the objectives of the new assortment. This group was gradually expanded, involving 47 multinational participants. In total, more than 700 implant treatments in 14 countries were performed with surgical, prosthetic and clinical outcome results recorded prior to official product release. The feedback received during this collaboration helped us refine the Astra Tech Implant System EV, including the OsseoSpeed Profile EV assortment. Some of these experiences have also been summarized in a scientific publication[14].

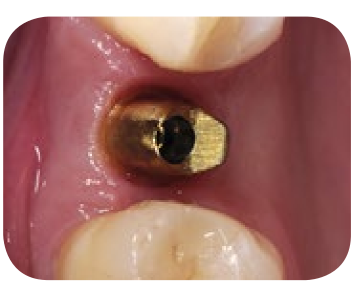
Below is a patient case from the international collaboration program.

A female patient in need of a single tooth restoration due to a root fracture, position 15. Area healed for 12 weeks.



OsseoSpeed EV 4.2 S left to heal with a transmucosal healing abutment for 8 weeks. Soft tissue contour at removal of the healing abutment.

The soft tissue contour has been anatomically sculptured after 4 weeks of provisionalization with Temporary Abutment EV and a temporary cemented crown.



Final Atlantis Abutment in gold-shaded titanium connected.

Clinical view of the full ceramic monolithic crown being in function for 18 months.

Radiographic control at 18 months of follow-up.

Courtesy of Dr. Marcus Dagnelid, Dagnelidkliniken, Gothenburg, Sweden

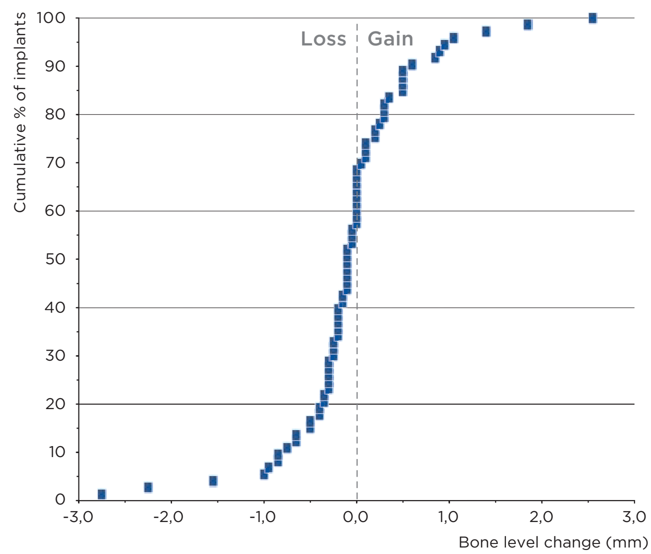
Ongoing clinical study

In an ongoing prospective, randomized, controlled multi-center study, investigators from five clinics (4 university based and 1 private) will follow 120 patients for 5 years.

To date, a group of 59 patients has received 79 OsseoSpeed EV implants while the control group of 61 patients has been treated with 87 OsseoSpeed TX implants in all positions in the mouth.

Preliminary results demonstrate that the marginal bone surrounding all implants remains stable from implant placement to the 1-year follow-up with no statistical difference between the groups[15, 16].

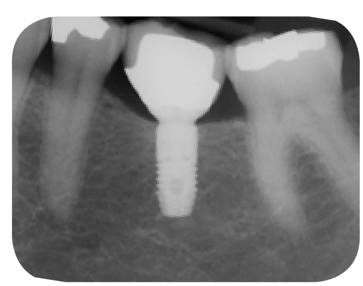
When asked for the clinical perception of implant stability achieved during installation, more than two-thirds of the clinicians stated that OsseoSpeed EV delivered better primary stability compared to OsseoSpeed TX. This qualitative feedback supports one of the goals of the drilling protocol developed.



Frequency distribution of bone level changes measured from radiographs from time of implant placement to 1-year follow-up; 44% of OsseoSpeed EV implants lost no marginal bone or even had a gain.

A 50-year-old female patient rehabilitated with a single implant restored with a metal ceramic crown at position 36; x-ray at implant placement.

No mesial or distal marginal bone loss was observed at the 6 months follow-up.



No mesial or distal marginal bone loss was observed at the 2-year control.

Courtesy of Dr. Nurit Bittner and Dr. James Fine. Columbia University, College of Dental Medicine, New York, NY, USA.

A continuous evolution

The groundbreaking innovations are the result of knowledge and understanding of the biological and clinical processes involved in dental implant therapy.

2007

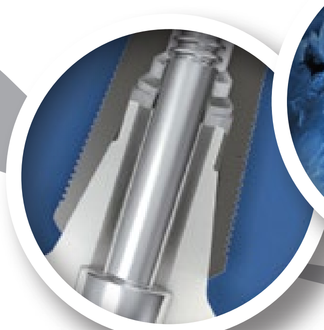
Atlantis patient-specific, CAD/CAM abutments introduced for the Astra Tech Implant System.

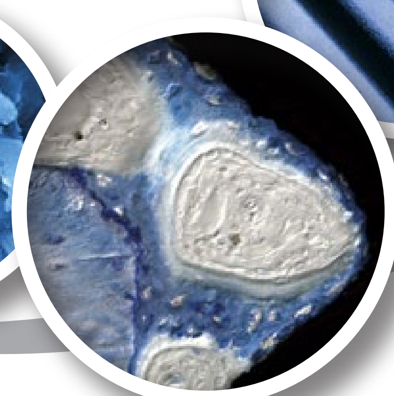
1989

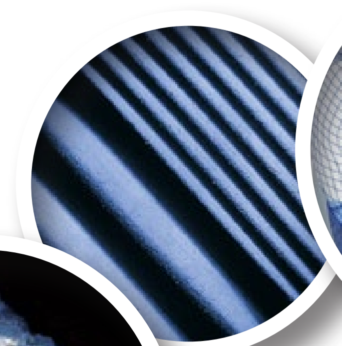
The idea of blasting the implant surface with titanium dioxide particles to increase bone growth and osseo-integration is presented and the TiOblast surface is born.

1985

Clinical use of the first generation of implants with Conical Seal Design and Connective Contour is initiated in a study at the Karolinska University Hospital in Stockholm, Sweden.







1991

The idea of minute threads on the implant neck to ensure positive biomechanical bone stimulation and maintained marginal bone level is born – MicroThread. After comparing 840 threads of different shapes and sizes, the optimal profile for positive stress distribution is identified.

1990

The concept of a a fluoride modified implant surface to help speed up the osseointegration process is conceived by a team at the University of Oslo, Norway. As a result, the first experimental pre-clinical studies on OsseoSpeed are initiated in 1993. In 2000, the first patient receives an OsseoSpeed implant at the University of Oslo.
The first and only chemically modified implant surface – OsseoSpeed – is launched in 2004 at EAO in Paris.

2010

OsseoSpeed TX is launched. TX stands for tapered apex and it is introduced on the complete implant assortment.

2011

OsseoSpeed TX Profile, the unique, patented implant that is anatomically designed for sloped ridges, is introduced.

2014

Introduction of the Astra Tech Implant System EV. The design philosophy of the implant system is based on the natural dentition utilizing a site-specific, crown-down approach.

Featuring a unique interface* with one-position-only placement for Atlantis patient-specific, CAD/CAM abutments.

*Patent pending

Summary and conclusion

Material selection and thorough testing have demonstrated that the Astra Tech Implant System EV surpasses its predecessor in strength and reliability while maintaining the benefits and principles of the Astra Tech Implant System BioManagement Complex.

Additionally, ongoing clinical documentation demonstrates that the Astra Tech Implant System EV provides increased surgical and prosthetic flexibility while simultaneously delivering good clinical results and maintaining marginal bone levels.

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About Dentsply Sirona Implants

Dentsply Sirona Implants offers comprehensive solutions for all phases of implant therapy, including Ankylos®, Astra Tech Implant System® and Xive® implant lines, digital technologies, such as Atlantis® patient-specific CAD/CAM solutions and Simplant® guided surgery, Symbios® regenerative solutions, and professional and business development programs, such as STEPPS™. Dentsply Sirona Implants creates value for dental professionals and allows for predictable and lasting implant treatment outcomes, resulting in enhanced quality of life for patients.

About Dentsply Sirona

Dentsply Sirona is the world's largest manufacturer of professional dental products and technologies, with a 130-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets a comprehensive solutions offering including dental and oral health products as well as other consumable medical devices under a strong portfolio of world class brands. As The Dental Solutions Company™, Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. Dentsply Sirona's global headquarters is located in York, Pennsylvania, and the international headquarters is based in Salzburg, Austria. The company's shares are listed in the United States on NASDAQ under the symbol XRAY.

Visit www.dentsplysirona.com for more information about Dentsply Sirona and its products.

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