## Ongoing clinical study with OmniTaper EV Implant

An open, prospective, multicenter study to evaluate clinical outcome of the OmniTaper EV Implant in extraction sockets and healed ridges.

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#### Introduction

The OmniTaper EV Implant is a further development of the well documented Xive implant, with the addition of the scientifically proven OsseoSpeed surface and the established internal conical EV implant/abutment connection, making it compatible with the full Astra Tech Implant System EV prosthetic assortment. Pre-clinical data for OmniTaper EV is proving the safety and performance in accordance with applicable standards. This post-market clinical follow-up study was initiated to confirm the safety and performance of the implant. The aim of this clinical investigation is to evaluate the short- and long-term survival and success rates as well as safety of OmniTaper EV when used for single tooth replacements.

#### Methods and materials

This company initiated study is an open, prospective, multicenter, international clinical investigation with a 5-year follow-up period. Subjects in need of one implant in the maxilla or mandible are included until 137 subjects are reached. The implant can be placed in extraction sockets or healed ridges, with a one- or two-stage surgical protocol. Loading protocol can be chosen as per investigator's preference; immediate, early or delayed. The primary objective is to evaluate implant survival 1 year after Permanent Restoration.

Screening	Implant placement	Post-op	Impression	Permanent restoration	6 months Follow-up	1 year Follow-up	2 year Follow-up	3 year Follow-up	4 year Follow-up	5 year Follow-up
1-2 weeks Max 6 months			Baseline							
	X-ray ISQ ITV			X-ray ISQ		X-ray		X-ray		X-ray
	Perception			BoP, PPD and PI						
	Implant survival, Implant success and Safety Events									

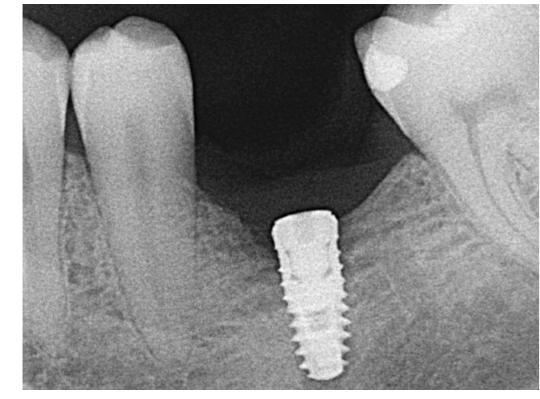
Figure 1. Flowchart of patient visits and measures taken

#### Status

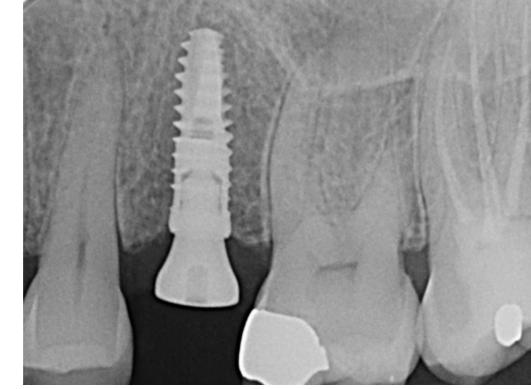
88 subjects are included, and two subjects have had the permanent restoration placed. No implant losses are reported to date. Recruitment is planned to be completed in June 2023.



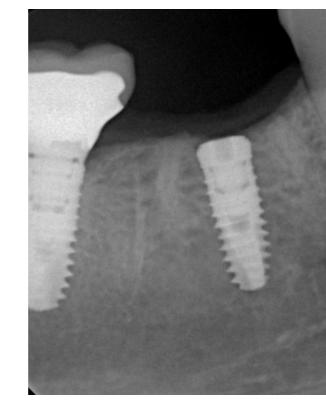
21 Extraction socket, bone quality and quantity 4A.



36 Healed site, bone quality and quantity 2B.



25 Healed site, bone quality and quantity 3A.



45 Healed site, bone quality and quantity 2A.

Clinical cases: Radiographs from placement of OmniTaper EV Implants Courtesy of Dr. Dr. Gehrke, Dr. Dietrich and Dr. Ponte.



### Our global Investigator Initiated Study program



THE IIS PROCESS

**SUBMISSION** 

**GLOBAL IIS REVIEW** 

**DECISION** 

YES

**SUPPORT** 

**FOLLOW-UP** 

**PUBLICATION** 

We make your research happen

Let us support your study

The Investigator Initiated Study program (IIS) is an important part of Dentsply Sirona's global research program. If you have a study proposal and want to investigate any of our products, we can support.

#### Will your proposal be the next one to qualify?

As a company and manufacturer of premium dental implant solutions, Dentsply Sirona is committed to extensive research and scientific documentation of our products. The results from your study help to increase the knowledge of our products. Each year several articles are published in scientific journals and presented at congresses around the world as a result of our IIS program. We highly appreciate your contribution, and so do millions of satisfied patients all over the world.

#### Research support

The objective of the study is determined by your own research interest. Todays ongoing studies cover a variety of research topics and are conducted as clinical studies, case series, *in-vitro* and mechanical studies.

Dentsply Sirona can offer either products and/or financial support up to a maximum of 49% of your total study cost. We handle your proposal and the study details confidentially.

For clinical studies, an ethics committee approval is required before the support can be provided, and off-label use of our products is not approved within the IIS program.

#### **Study Proposals**

Between 2003 and 2022 a total of 1,084 proposals from 44 countries were received from all over the world.

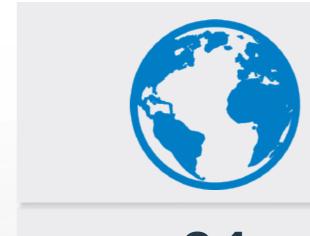
#### More information

The application form is found at dentsplysirona.com. You can also contact us at iis.dental@dentsplysirona.com.



# Other 35 Australia 29 Austria 20 USA 227 China 34 Gerece 9 Hong Kong 5 India 7 Spain 45 Spain 45 Purcia 6 Regium 56 Czech Republic 5 Denmark 23 Finland 6 France 14 Gerece 9 Hong Kong 5 India 7

#### Current ongoing studies within the IIS program



24 Countries



**84**Clinics



112 Investigators



**141** Studies



**5,264** Patients