Ti-Link Instructions

Indication For Use

Solidex® Ti-Links and Screws is intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with Solidex® Ti-Links is to be sent to CREODENT HUDSON VALLEY validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

Device Description

Solidex® Ti-Links & Screws consists of a two-piece abutment, where the titanium base will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment. The system also includes a Solidex® Screw for fixation to the implant body. Solidex® Ti-Link are made of titanium alloy conforming to ASTM F136 standard specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications and are provided in various prosthetic platform diameters. Solidex® Screw is composed of titanium alloy per ASTM F136.

Solidex® Ti-Links & Screws is designed for fabrication of a patient-specific CAD/CAM zirconia superstructure on which a crown may be placed. There are two-piece abutments for which the second part (or top half) is the zirconia superstructure. They also may be used for support of a crown directly on the Ti-Link. CAD/CAM zirconia superstructure fabrication for Ti-Link is by prescription on the order of the clinician.

Solidex® Ti-Links & Screws all zirconia superstructures for use with the subject device Ti-Link will be manufactured using a digital dentistry workflow by using scan files from intra-oral and lab (desktop) scanners, CAD/CAM software, ceramic material, and associated tooling and accessories. The digital dentistry workflow uses scan files from intra-oral and lab (desktop) scanners, CAD/CAM software, ceramic material, and associated tooling and accessories. The digital workflow includes the following products (not subject devices of this submission):

- Ceramic material : Sagemax NexxZr T (K130991)
  This ceramic material has been validated with performance testing for use with the Solidex® Ti-Links and Screws.
- Cement : Panavia SA cement Universal (K183537)
  This cement has been validated with performance testing for use with the Solidex® Ti-Links and Screws.
- Desktop scanner : 3Shape E series Lab Scanner (510(k) exempt under 21 CFR 872.3661)
- Design software : 3Shape Abutment Designer Software (K151455)
- Milling machine : PrograMill PM7 (510(k) exempt under 21 CFR 872.3661)
- Milling software : PrograMill CAM (510(k) exempt under 21 CFR 872.3661)
- Digital Library / Templates (3 Shape) : The Solidex® Ti-Link CAD/CAM System shall only be used with the official "Solidex® Ti-Link Digital Library" and templates identified. The library is imported into the 3Shape software, and the design restriction parameters (minimum wall thickness, post height, maximum gingival height, etc.) are automatically applied.

The official "Solidex® Ti-Link Digital Library" can be obtained from CREODENT HUDSON VALLEY by contacting support email (inquiry@creodental.com) or from CREODENT HUDSON VALLEY web-site.

When imported into the 3Shape software, the design restriction parameters (minimum wall thickness, post height, maximum gingival height, etc.) and built-in protection features ("stops" and restriction shells) are automatically applied.

The design parameters for the CAD/CAM zirconia superstructure to be used Solidex® Ti-Links & Screws:

- Minimum wall thickness : 0.5 mm
- Minimum post height : 6.0 mm (Note : Feature maximum post height are based on patient anatomy and clinician discretion.)
- Minimum gingival height : 0.5 mm
- Maximum gingival height : 6.0 mm
- Minimum Angulation : 0°
- Maximum Angulation : 20°

Warning

Do not use the Solidex® Ti-Link System with dental cement, ceramic or other top-half components (and/or hybrid abutment-crown components), scanners, milling units and components, CAD/CAM software, templates, or tools other than those specifically identified in this labeling. Use of non-specified devices or materials may result in product failure, compromised performance, or patient harm. The zirconia superstructure must be cemented to the Solidex® Ti-Links using Panavia SA Cement Universal in a dental laboratory. Solidex® Ti-Links and Screws are provided non-sterile and must be sterilized after cementation of the zirconia superstructure. Solidex® Screws are designed to attach the abutment to the implant.

Prosthetic Procedures

3.1. CREODENT HUDSON VALLEY Validated milling center (†).

1. Using a digital workflow (desktop scanning)

- Obtain conventional impressions of a patient's teeth setup and create a working mode with an enclosed analog to represent the implant.
- Place a scan body in the analog to identify the position and orientation of the implant.
- Scan the working model by use of a dental desktop scanner such as the 3Shape Dental Lab Scanner

2. Designing a zirconia superstructure

The zirconia superstructure must be designed using 3Shape Abutment Designer Software (K151455) with Solidex® library installed. Refer to Section 'Applications' for design parameters.

- Import the digital file from the scanner into the design software.
- Select the relevant implant platform from the library.
- Design the zirconia superstructure in the design software.
- The digital file must be sent to the CREODENT HUDSON VALLEY validated milling center for manufacture.
- Solidex® Ti-Link and a zirconia superstructure will be sent to the dental lab with a Ti-Link screw.

3.2. Digital dentistry workflow

1. Using a digital workflow (desktop scanning)

- Obtain conventional impressions of a patient's teeth setup and create a working mode with an enclosed analog to represent the implant.
- Place a scan body in the analog to identify the position and orientation of the implant.
- Scan the working model by use of a dental desktop scanner such as the 3Shape Dental Lab Scanner

2. Designing a zirconia superstructure

The zirconia superstructure must be designed using 3Shape Abutment Designer Software (K151455) with Solidex® libraries installed. The Solidex® library can be downloaded via https://shop.creomc.com/apps/help-center. The Solidex® library has built-in design limitations and the user is not allowed to exceed the limitations. Refer to the section 'Applications' for design parameters.

3. Manufacturing the zirconia superstructure

- Import the digital files from the scanner into the design software.
- Import the library and select the relevant implant platform from the library.
- Design the zirconia superstructures in the design software.
- Send the zirconia superstructure files to the milling machine and fabricate them according to the equipment manufacturer's instructions.
- The zirconia superstructure must be created from Sagemax NexxZr T (K130991) and sintered according to the equipment manufacturer's instructions.

(†) Validated Milling Center (VMC): The subject device, including the zirconia superstructure as patient-specific abutment, is manufactured entirely in-house by CREODENT HUDSON VALLEY, including the CAD design and CAM milling process. Therefore, CREODENT HUDSON VALLEY serves as the Validated Milling Center (VMC) for the product.

Cementation

4.1. Preparing the dental restoration for cementing

Solidex® Ti-Links should be thoroughly cleaned to aid in cement adhesion before cementation. The ceramic surface of the superstructure in the cementing zone should be sandblasted and cleaned. The diameter and height of Solidex® Ti-Links should not be reduced for a secure grip. (e.g. by grinding).

4.1. Cementing the dental restoration

Solidex® Ti-Links and corresponding zirconia superstructures are provided to the clinician either with the superstructure cemented to the Ti-Link by the dental laboratory, or separately for the clinician to bond together chairside or intraorally using Panavia SA cement Universal (K183537) recommended in the labeling.

Reminder: Sterilization of the components (either bonded together or separately) shall be completed before placement in the mouth. If cementing the superstructure intraorally, be careful to maintain sterility while handling.

Applications

Solidex® Ti-Links and Screws are used for support of prosthetic restorations prepared by dental technicians in a dental laboratory using CAD/CAM technology. The Solidex® Ti-Links can be used to support a direct crown or a zirconia superstructure plus crown. The design parameters for the CAD/CAM zirconia superstructures (including direct crown and zirconia superstructure plus crown) are:

- Minimum wall thickness : 0.5 mm
- Minimum post height : 6.0 mm (Note : Feature maximum post height are based on patient anatomy and clinician discretion.)
- Minimum gingival height : 0.5 mm
- Maximum gingival height : 6.0 mm
- Minimum Angulation : 0°
- Maximum Angulation : 20°

5.1. Caution: Solidex® Ti-Links must never be changed or modified.

5.2. The Ti-Link screw is for fixing prosthetic restorations and auxiliary abutments onto implant or analog. Make sure to secure the parts with the corresponding screws and observe the specified torque values placed on the label. For best results, the following conditions must be meticulously met:

1) Position the patient to avoid aspiration in case the screw falls during screwing/unscrewing.

2) Check the compatibility of the screw with the implant model to which it will be connected.

3) Make sure the correct model of the screw is used for each case.

4) When transferring to the patient, do not use the same screw that was used in the laboratory.

5) Use the suitable model key and size for tightening and unscrewing. If in doubt, check that the next size key does not fit into the seat. The driver should be appropriately aligned with the screw head inside the screw channel of the prosthesis/implant assembly. A new screw must be used when assembling a prosthesis for the first time and every check thereafter.

6) For immediate load prostheses screw manually, avoiding excessive torque, and preventing the implant from turning while screwing.

7) Screws are provided with each Ti-Link for the corresponding implant systems. Also, screws are sold separately.

Sterilization

Prior to installation of the prosthetic restoration in the patient's mouth, it must be sterilized. The recommended sterilization cycle is a standard Pre-vacuum autoclave, exposure at 132 °C / 270 °F for 4 minutes with a drying time of 30 minutes, using a sterilization pouch or wrap that is FDA-cleared for the following indicated cycle.

Stage	Process	Parameter set-points
Set-up	Cycle profile	Pre-vacuum
Exposure (SteamInjection)	Sterilization temperature	132°C/270°F
	Sterilization time	4 minutes
Post-Exposure (exhaust/drying)	Drying time	30 minutes

Compatibility information

All Solidex components are available for a variety of connections, as listed in the section 'Indications for use'. For any questions concerning compatibility with dental implants and implant analogs, please contact CREODENT HUDSON VALLEY. Solidex® Ti-Link is provided with a Ti-Link screw corresponding to the compatible implant system.

Compatibility information

All materials used are biocompatible; however, some patients may present allergies or hypersensitivity to any of the materials and the components.

All Ti-Links are contraindicated for any angular correction to be fabricated into the ceramic component of the two-piece abutment.

Do not use the Ti-Links for restorations with a cantilever on a single implant, with patients who brux, with insufficient space, or with direct metal-to-interface casting.

Warnings

9.1. Solidex® Ti-Links must never be changed or modified.

9.2. Solidex® Ti-Links are for single use only.

9.3. Reuse of the products can result in loss of functionality and/or infections.

9.4. Solidex® Ti-Links must be attached to the implant using the compatible Ti-Link screw.

9.5. During any intraoral use and manipulation Solidex® Ti-Links and screws must be secured to prevent aspiration due to their small size and shape.

9.6. Place implant-borne restorations in occlusion only when the implant is fully osseointegrated.

9.7. This type of product must be used by dental specialists with experience in maxillofacial implantology and other specialties, such as dental diagnosis, planning, dental surgery, or prosthetic techniques.

9.8. The use of a different torque other than the one recommended by the manufacturer can damage the restorations and the implant.

9.9. The non-engaging connections are not intended for single-tooth dental restorations.

9.10. The use of any abutment device, dental cement, superstructure or other ceramic materials, scanners, milling units, CAD/CAM tools, and software other than those specifically identified as compatible with these instructions, may result in improper fit and/or damage to the dental restoration.

9.11. Small diameter implants and angled abutments are not recommended for the posterior region of the mouth.

9.12. This device is intended for use only by practitioners licensed by law to use dental implant systems.

Magnetic Resonance (MR) Safety Information

All Solidex® Ti-Links and Screws are labeled as MR Conditional with recommended scanning conditions listed below and in the instruction for use.

MR Conditional
Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30cm from the implant, or ensuring the implant is located outside the RF coil.
A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	Solidex® Ti-Links and Screws
Static Magnetic Field Strength (B_o)	≤ 3.0T
Maximum Spatial Field Gradient	20 T/M
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Precautions

Solidex® Ti-Links and screws must be dry-fitted before use to check the correct fitting. The clinician will be responsible for the correct application of those restorative products as planning and procedures are under his/her control. This is the reason why only dental specialists with the appropriate experience and training should work with these products.

Annual inspection of the prosthetic restoration by the dentist and the laboratory is recommended. This inspection must include a screw check. If the screws have suffered unusual wear, the complete integrity of the implant abutment should be checked. New screws must be used for any revision, correction, or replacement. Failure to follow this instruction puts the patient at risk and will void the warranty.

Potential adverse events

Potential adverse events associated with using Ti-Link products may include loss of integration and infection.

Validity

Upon publication of this instruction for use, all previous versions are superseded.

These instructions replace all previous editions.
For any information about Solidex products, please get in touch with CREODENT HUDSON VALLEY or your local Sales represenatives

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CreoDent Solidex® Torque Recommendation Sheet						
	System	Size	CreoDent Ref. #	TORQUE (Ncm)	Driver	Driver Head
A	AstraTech (OsseoSpeed TX)	3.0 mm	AS30	15	H05	Hex 1.27
		3.5/4.0 mm	AS40	20	H05	Hex 1.27
		4.5/5.0 mm	AS50	25	H05	Hex 1.27
	ANKYLOS	Pilar Regular	DPA	15	H10	Hex 1.00
	AstraTech (EV)	3.0 mm	EV30	25	H05	Hex 1.3
		3.6 mm	EV36	25	H05	Hex 1.3
		4.2 mm	EV42	25	H05	Hex 1.3
		4.8 mm	EV48	25	H05	Hex 1.3
		5.4 mm	EV54	25	H05	Hex 1.3
B	Biomet 3i (Certain)	3.4 mm	3i34	20	-	-
		4.1 mm	3i40	20	-	-
		5.0 mm	3i50	20	-	-
		6.0 mm	3i60	20	-	-
	Biomet 3i (External) Hex	NP (3.5 mm)	3IEM	20	H12	Hex 1.2
		WP (5.0 mm)	3IEW	20	H12	Hex 1.2
	Biohorizons (Internal)	3.0 mm	BI30	30	H12	Hex 1.25
		3.5 mm	BI35	30	H12	Hex 1.25
		4.5 mm	BI45	30	H12	Hex 1.25
		5.7 mm	BI57	30	H12	Hex 1.25
	Biohorizons (External)	3.5 mm	BE35	30	H12	Hex 1.25
		4.0 mm	BE40	30	H12	Hex 1.25
		5.0 mm	BE50	30	H12	Hex 1.25
		6.0 mm	BE60	30	H12	Hex 1.25
C	Camlog (Camlog)	3.3 mm	CL33	20	H05	Hex 1.27
		3.8 mm	CL38	20	H05	Hex 1.27
		4.3 mm	CL43	20	H05	Hex 1.27
		5.0 mm	CL50	20	H05	Hex 1.27
	Camlog (Conelog)	3.3 mm	CON33	20	H05	Hex 1.27
		3.8 mm	CON38	20	H05	Hex 1.27
		4.3 mm	CON43	20	H05	Hex 1.27
		5.0 mm	CON50	20	H05	Hex 1.27
D	Dentium (SuperLine)	Regular	DTR	30	H05	Hex 1.27
I	Implant Direct (InterActive)	NP (3.5 mm)	IA35	35	UNI	TORX
		RP (4.3 mm)	IA43	35	UNI	TORX
	ImplantDirect (Legacy)	3.0 mm	ID30	30	H05	Hex 1.27
	Implant Direct (Swish)	RN (4.8mm)	SS48	35	-	-
		WN (6.5mm)	SS65	35	-	-
	Implant Direct (TRI-LOBE)	NP (3.5 mm)	NB35	35	UNI	TORX
		RP (4.3 mm)	NB43	35	UNI	TORX
		WP (5.0 mm)	NB50	35	UNI	TORX
		6.0 mm	NB60	35	UNI	TORX
K	Keystone (PrimaConnex)	3.5 mm	KP35	30	-	-
		4.1 mm	KP41	30	-	-
		5.0 mm	KP50	30	-	-
M	MIS (SEVEN)	3.3 mm (NARROW)	MIS33	30	H05	Hex 1.27
		3.5 mm	Z37	30	H05	Hex 1.27
		4.7 mm	Z47	30	H05	Hex 1.27
		5.7 mm	Z57	30	H05	Hex 1.27
	MIS (Multi Unit)	ALL	MISM	15	-	-
	MIS (C1)	NARROW (3.3 mm)	C1NP	30	H05	Hex 1.27
		STANDARD (3.75 mm)	C1RP	30	H05	Hex 1.27

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	System	Size	CreoDent Ref. #	TORQUE (Ncm)	Driver	Driver Head
M	MIS (C1)	WIDE (4.2-5.0 mm)	C1WP	30	H05	Hex 1.27
	Megagen (EZ Plus)	Regular (4.0-4.5 mm)	MGR	35	H12	Hex 1.2
	Megagen (Anyridge)	Regular	MGAR	35	H12	Hex 1.2
	Megagen (AnyOne)	3.5-7.0 mm	MGAO	35	H12	Hex 1.2
N						
	Nobel Biocare (Replace)	NP (3.5 mm)	NB35	35	UNI	TORX
		RP (4.3 mm)	NB43	35	UNI	TORX
		WP (5.0 mm)	NB50	35	UNI	TORX
		6.0 mm	NB60	35	UNI	TORX
	Nobel BioCare (Active)	3.0 mm	ACT30	15	UNI	TORX
		NP (3.5 mm)	ACT35	35	UNI	TORX
		RP (4.3 mm)	ACT43	35	UNI	TORX
		WP (5.5 mm)	ACT55	35	UNI	TORX
	Nobel Biocare (Branemark)	NP (3.5mm)	B35	35	UNI	TORX
		RP (4.1 mm) & 3I External	B41	35	UNI	TORX
		WP (5.0 mm)	B50	35	UNI	TORX
	Nobel Biocare (Multi Unit)	ALL	NBM	15	UNI	TORX
	Neodent (GM)	(Universal)	NODG	20	-	-
	NEOSS (ProActive)	3.5-5.5 mm	NEOSS	30	SCS	TORX
O						
	Osstem (GS) Hiossen (SA)	Mini	OTM	20	H12	Hex 1.2
		Regular	OTR	30	H12	Hex 1.2
S						
	Straumann (Bone Level) [ITI]	NC (3.3 mm)	ST33	35	SCS	TORX
		RC (4.1 mm)	ST48	35	SCS	TORX
	Straumann (Tissue Level) [ITI] (Synocta)	RN (4.8mm)	SS48	35	-	-
		WN (6.5mm)	SS65	35	-	-
	SWEDEN & MARTINA (Premium Kohno, Shelta)	3.3 mm	SM33	20-25	H05	Hex 1.3
		3.8 mm	SM38	20-25	H05	Hex 1.3
		4.2 mm	SM42	20-25	H05	Hex 1.3
		5 mm	SM50	20-25	H05	Hex 1.3
T						
	Thommen (SPI)	3.5 mm	TM35	15	UNI	CROSS
		4.0 mm	TM40	25	UNI	CROSS
		4.5 mm	TM45	25	UNI	CROSS
		5.0 mm	TM50	25	UNI	CROSS
		6.0 mm	TM60	25	UNI	CROSS
Z						
	Zimmer (Screw-Vent)	3.5 mm	Z37	30	H05	Hex 1.27
		4.7 mm	Z47	30	H05	Hex 1.27
		5.7 mm	Z57	30	H05	Hex 1.27

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