

CreoDent Solidex™ Customized Dental Abutment and screw Version 1.6

Instructions for use

Indication for use:
The CreoDent Solidex® Customized Abutment and Screw is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely edentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant.

Warning
Implant surgery and restoration involve complex dental procedures. Appropriate and adequate training in proper technique is strongly recommended prior to implant use. Improper technique can result in implant failure and/or loss of supportive bone. Exposure to long-term use of bisphosphonate drugs may impact implant stability. Careful patient selection including consultant with the attending physician is strongly recommended prior to implant treatment. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site and allow site to heal as though it were an atraumatic extraction.

Warning: Small Diameter implants and angled abutments are not recommended for the posterior region.
Caution: Federal Law (USA) restricts the sales of this device to, or on the order of a licensed dentist or physician.

Product Description:
The CreoDent® Solidex Customized Abutment and screw is a patient specific dental implant abutment placed and mounted to the implant with an abutment screw provided with the abutment. The abutment screw shipped with the product is intended to secure the abutment to the implant.

Abutment and Abutment Screw
The CreoDent Solidex Customized Abutment and screw is made of Ti-6Al-4V Eli titanium alloy for surgical implants applications meets ASTM F-136 Standard. The abutment screw is intended to secure the abutment to the implant. The abutment screw meets the implant manufacturer's recommendation for torque. Tighten the abutment screw according to the recommended torque from the implant manufacturer. The Abutment Screw provided must be used. Do not replace with implant manufacturer's screw.

Magnetic Resonance (MR) safety information:
CreoDent Solidex Customized Abutment has not been evaluated for safety and compatibility with the MR environment. It has not been tested for heating, migration, or image artifact in the MR Environment. The safety of CreoDent Solidex Customized Abutment in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The CreoDent Solidex® Customized Abutment has not been evaluated for pyrogenicity. No claim is made related to pyrogenicity.

Contraindications
CreoDent Solidex® Customized Abutment and screw should not be placed if there is insufficient alveolar bone width and height to surround implant. Implants placed in the maxilla should not perforate the sinus. Insufficient availability of bone (minimum 1mm circumferential and 2mm apical), poor bone quality, poor patient oral hygiene, heavy smoking or use of chewing tobacco, and generalized diseases (diabetes, etc.) may contribute to lack of integration and subsequent implant failure. Severe bruxism, clenching, or overloading may cause failure of abutments and implants. Psychologically unstable patients may not represent good implant candidates. Clinicians should select patients whom they feel will be satisfied psychologically, as well as esthetically and functionally, with the restoration. Exposure to magnetic resonance imagining, radiation, and chemotherapy may impact health of the implant. Dental implant patients should be instructed to consult with their physician prior to such treatment options.

Side Effects
The following complications may occur: dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, and local and generalized allergic reaction.

Cleaning and Sterilization
Ultrasonic Cleaning:
•Place the components on a glass beaker
•Fill the beaker with instrument detergent concentrate and water (according to the detergent manufacturer's instructions)
•Run the beaker in the ultrasonic cleaning unit for 5 minutes
•Rinse the components thoroughly in water
•Let each item dry completely
Place the dry components into an appropriately sized sterilization pouch designated for use with your sterilizer according to manufacturer's instructions.

Sterilization instructions

CreoDent Solidex® Titanium Customized Abutment and Abutment Screw
The abutment and abutment screw must be cleaned and sterilized prior to use. See above ultrasonic cleaning instructions. The components should be steam sterilized to a Sterility Assurance Level (SAL) to 10⁻⁶ inside a pouch. FDA Cleared Sterilization Accessories are to be used for the recommended Sterilization parameters when wrapping the devices in a pouch.

Steam sterilizes the abutment and abutment screw at the following parameters validated under ANSI/AAMI ST: 79:2010.

Abutment Screws
The CreoDent Solidex abutment screw provided must be used.

Placement
Remove the cover screw or healing abutment (healing cap/healing cover) from the implant to expose the implant seating surface. Place the abutment on the implant. Do not force the abutment on to or into the implant surface. Connect the abutment to the implant, make sure the abutment is properly seated. Tighten the abutment screw with light finger force. An x-ray can be taken at the time to verify the abutment is fully seated. Tighten the abutment screw to the recommended torque. Follow implant manufacturer's directions for torque level.

Implant, Abutment Screw or Abutment Failure
In case of implant, abutment screw or abutment failure, please observe the following instructions for abutment removal. If the abutment fails, remove the abutment, preserving all damaged parts and return to CreoDent for investigation. If there is also screw failure and/or implant failure, follow the instructions below:

- If Abutment fails and the implant is intact:**
1. Remove crown (using standard crown removal protocols)
 2. Use screw removal tool to remove Abutment screw (standard tool-drill bit with reverse direction)
 3. Remove abutment

- If implant fails:**
1. Remove crown (using standard crown removal protocols)
 2. If Abutment Screw is intact, remove with appropriate driver
 3. If Abutment Screw is also broken, it will fall out with removal of crown
 4. Follow standard protocol for removal and replacement of failed implant

	Stage / Process	Parameter Set-Points
Set-up	Cycle Profile	Pre-vacuum
Pre-Exposure (Conditioning)	Chamber Purge	1 minute
Exposure (Steam Injection)	Sterilization Temperature	132°C / 270°F
	Sterilization Time	4 minutes
Post-Exposure (Exhaust / Dry)	Dry Time	30 minutes

CreoDent Solidex® Torque Recommendation Sheet

System		Size	CreoDent Ref. #	TORQUE (Ncm)	Driver	Driver Head	System		Size	CreoDent Ref. #	TORQUE (Ncm)	Driver	Driver Head	
A	AstraTech (OsseoSpeed TX)	3.0 mm	AS30	15	H05	Hex 1.27	M	MIS (SEVEN)	3.3 mm (NARROW)	MIS33	30	H05	Hex 1.27	
		3.5/4.0 mm	AS40	20	H05	Hex 1.27			3.5 mm	Z37	30	H05	Hex 1.27	
		4.5/5.0 mm	AS50	25	H05	Hex 1.27			4.7 mm	Z47	30	H05	Hex 1.27	
	ANKYLOS		Pilar Regular	DPA	15	H10			Hex 1.00	5.7 mm	Z57	30	H05	Hex 1.27
	AstraTech (EV)	3.0 mm	EV30	25	H05	Hex 1.3		MIS (Multi Unit)	ALL	MISM	15	-	-	-
		3.6 mm	EV36	25	H05	Hex 1.3		MIS (C1)	NARROW (3.3 mm)	C1NP	30	H05	Hex 1.27	
		4.2 mm	EV42	25	H05	Hex 1.3			STANDARD (3.75 mm)	C1RP	30	H05	Hex 1.27	
		4.8 mm	EV48	25	H05	Hex 1.3		MIS (C1)	WIDE (4.2-5.0 mm)	C1WP	30	H05	Hex 1.27	
		5.4 mm	EV54	25	H05	Hex 1.3		Megagen (EZ Plus)	Regular (4.0-4.5 mm)	MGR	35	H12	Hex 1.2	
	B	Biomet 3i (Certain)	3.4 mm	3i34	20	-		-	Megagen (Anyridge)	Regular	MGAR	35	H12	Hex 1.2
4.1 mm			3i40	20	-	-	Megagen (AnyOne)	3.5-7.0 mm	MGAO	35	H12	Hex 1.2		
5.0 mm			3i50	20	-	-	Nobel Biocare (Replace)	NP (3.5 mm)	NB35	35	UNI	TORX		
6.0 mm			3i60	20	-	-		RP (4.3 mm)	NB43	35	UNI	TORX		
Biomet 3i (External) Hex		NP (3.5 mm)	3iEM	20	H12	Hex 1.2		WP (6.0 mm)	NB50	35	UNI	TORX		
		WP (5.0 mm)	3iEW	20	H12	Hex 1.2		6.0 mm	NB60	35	UNI	TORX		
Biohorizons (Internal)		3.0 mm	BI30	30	H12	Hex 1.25		3.0 mm	ACT30	15	UNI	TORX		
		3.5 mm	BI35	30	H12	Hex 1.25		NP (3.5 mm)	ACT35	35	UNI	TORX		
		4.5 mm	BI45	30	H12	Hex 1.25	RP (4.3 mm)	ACT43	35	UNI	TORX			
		5.7 mm	BI57	30	H12	Hex 1.25	WP (5.5 mm)	ACT55	35	UNI	TORX			
Biohorizons (External)	3.5 mm	BE35	30	H12	Hex 1.25	Nobel Biocare (Branemark)	NP (3.5mm)	B35	35	UNI	TORX			
	4.0 mm	BE40	30	H12	Hex 1.25		RP (4.1 mm) & 3i External	B41	35	UNI	TORX			
	5.0 mm	BE50	30	H12	Hex 1.25	WP (5.0 mm)	B50	35	UNI	TORX				
	6.0 mm	BE60	30	H12	Hex 1.25	Nobel Biocare (Multi Unit)	ALL	NBM	15	UNI	TORX			
C	Camlog (Camlog)	3.3 mm	CL33	20	H05	Hex 1.27	Neodent (GM)	(Universal)	NODG	20	-	-		
		3.8 mm	CL38	20	H05	Hex 1.27	NEOSS (ProActive)	3.5-5.5 mm	NEOSS	30	SCS	TORX		
		4.3 mm	CL43	20	H05	Hex 1.27	Osstem (GS) Hiossen (SA)	Mini	OTM	20	H12	Hex 1.2		
		5.0 mm	CL50	20	H05	Hex 1.27		Regular	OTR	30	H12	Hex 1.2		
	Camlog (Conelog)	3.3 mm	CON33	20	H05	Hex 1.27	Straumann (Bone Level) [ITI]	NC (3.3 mm)	ST33	35	SCS	TORX		
		3.8 mm	CON38	20	H05	Hex 1.27		RC (4.1 mm)	ST48	35	SCS	TORX		
		4.3 mm	CON43	20	H05	Hex 1.27		RN (4.8mm)	SS48	35	-	-		
		5.0 mm	CON50	20	H05	Hex 1.27		WN (6.5mm)	SS65	35	-	-		
	D	Dentium (SuperLine)	Regular	DTR	30	H05	Hex 1.27	S	SWEDEN & MARTINA (Premium Kohno, Shelta)	3.3 mm	SM33	20-25	H05	Hex 1.3
	I	Implant Direct (InterActive)	NP (3.5 mm)	IA35	35	UNI	TORX			3.8 mm	SM38	20-25	H05	Hex 1.3
RP (4.3 mm)			IA43	35	UNI	TORX	4.2 mm			SM42	20-25	H05	Hex 1.3	
Implant Direct (Legacy)		3.0 mm	ID30	30	H05	Hex 1.27	5 mm			SM50	20-25	H05	Hex 1.3	
		Implant Direct (Swish)	RN (4.8mm)	SS48	35	-	-			T	Thommen (SPI)	3.5 mm	TM35	15
WN (6.5mm)			SS65	35	-	-	4.0 mm	TM40	25			UNI	CROSS	
NP (3.5 mm)	NB35		35	UNI	TORX	4.5 mm	TM45	25	UNI			CROSS		
Implant Direct (TRI-LOBE)	RP (4.3 mm)	NB43	35	UNI	TORX	5.0 mm	TM50	25	UNI			CROSS		
	WP (5.0 mm)	NB50	35	UNI	TORX	6.0 mm	TM60	25	UNI			CROSS		
K	Keystone (PrimaConnex)	3.5 mm	KP35	30	-	-	Z	Zimmer (Screw-Vent)	3.5 mm	Z37	30	H05	Hex 1.27	
		4.1 mm	KP41	30	-	-			4.7 mm	Z47	30	H05	Hex 1.27	
		5.0 mm	KP50	30	-	-			5.7 mm	Z57	30	H05	Hex 1.27	

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