WARANTEC

TrueFit Pro 5 Instructions for Use

[Product Composition]

The product consists of a dental implant scan body, screws, and a screwdriver. None of the components are manufactured using additive manufacturing processes. The product is provided non-sterile and must be sterilized by the healthcare facility according to the instructions for use before each procedure.

The dental implant scan body is manufactured from titanium alloy and medical-grade polymer materials via CNC machining.

The screws are made from titanium alloy using CNC machining.

The screwdriver is produced from 420-grade stainless steel through CNC machining.

[Intended Use] For use in dental implant procedures.

[Specification] TrueFit Pro 5

Component Name	Model	Catalogue number	Technical Specifications
Scan Body	C526	04TF54048S	S
	C527	04TF54048M	M
	C528	04TF54048L	L
	C529	04TF54048X	X
	C530	04TF56648S2	S
	C531	04TF56648M2	M
	C532	04TF56648L2	L
	C533	04TF56648X2	X
	C534	04TF55648G	Ø4.8
	C535	TPCT	/
Screw	S237	04TF5M142	M1.4×0.3
	S238	04TF5M162	M1.6×0.2
	S248	04TF5M182	M1.8×0.35
	S249	04TF5M202	M2.0×0.4
	S250	04TF5M14B2	M1.4×0.25
	S251	04TF5M14G	M1.4×0.3
	S252	04TF5M16G	M1.6×0.2
	S253	04TF5M18G	M1.8×0.35
	S254	04TF5M20G	M2.0×0.4
	S255	04TF5M14BG	M1.4×0.25
Screwdriver	SD23	04TF5CA48	ϕ4.8
	SD35	HD1210S	Hex 1.2

[Storage Conditions] Store at room temperature, protected from light and moisture.

[Shelf Life] 5 years

[Date of Manufacture] See label

[Instructions Before Use]

1.Read the instructions carefully before use;

2.This product must be cleaned, disinfected, and sterilized prior to use. Otherwise, its use is prohibited;

3.This tool kit is used for intraoral scanning to obtain precise positional information of dental implants or abutments;

4.Before clinically using this product, the dentist or technician must be fully familiar with the product and obtain the patient's fully informed consent by discussing the advantages and limitations of the implant. Regarding the patient, they must clearly understand the functional and aesthetic limitations of the implant;

5.If any defects or problems arise from the use of non-TrueFit Pro 5 products, we are not obligated to replace our products or provide refunds, nor liable for any resulting consequences;

6.A thorough oral examination must be performed prior to selecting a medical device for a patient, and a restoration plan should be developed based on comprehensive analysis;

7.Once the product is used on a patient, measures should be taken to prevent the patient from inhaling or ingesting the product;

8.This product can only be used with compatible database files installed in the design software;

9.This product is to be used and handled only by dental professionals;

10.Instruments that have reached the specified service life or number of uses should be disposed of as medical waste.

[Method of Use]

1.Using the screwdriver and screw, install and secure scan body C534 onto the MUA abutment;

2.Use an intraoral scanner to capture the patient's soft tissue morphology;

3.After capturing the soft tissue contour, loosen the screw with the screwdriver and remove scan body C534;

4.Using the screwdriver and screw, connect and secure the scan body (models C526-C533) to the MUA abutment. If the abutment exhibits significant differences in gingival emergence profile (height and angle), install the connector C535 into the corresponding mounting hole of the primary scan body. Adjust it to an appropriate angle to establish a connection between the scan bodies, thereby facilitating the scanning process;

5.Use an intraoral scanner to capture data by scanning the top pentagonal area (scanning region);

6.Upon completion of scanning, remove the scan body using the screwdriver.

[Cleaning and Sterilization by the End User]

Components of this kit should not be reprocessed more than 50 times. As they are provided non-sterile, they must be cleaned and sterilized before each use.

(1)Cleaning: Whether using mechanical or manual cleaning, it is essential to ensure thorough removal of residues and cleaning agents from the product;

(2)Sterilization: Pressure steam sterilization

Equipment Type	Sterilization Temperature	Minimum Sterilization Time	Pressure Range
Gravity Displacement Type	121 ℃	20 min	102.8 kPa ~ 122.9 kPa

[Main Performance Index]

1.Appearance

a.The product surface shall be free of macroscopic processing defects such as scratches, cracks, sharp edges, burrs, thread curling, tool marks, and gaps, and shall have no foreign attachments;

b.The surface-treated parts of the product shall have a uniform color with no obvious holes or inclusions.

2. Surface Roughness

The roughness Ra of the non-surface-treated parts of the product shall be ⩽ 1.6μm.

[Caution]

The following conditions are associated with higher risks in implant surgery. The dentist or technician must conduct a thorough assessment of the patient's health status and develop a corresponding treatment plan accordingly:

1.Metabolic disorders, such as diabetes;

2.Endocrine disorders, such as hypothyroidism, hyperthyroidism, and adrenal dysfunction;

3.Circulatory system diseases, such as angina pectoris, myocardial infarction, congestive heart failure, chronic valvular heart disease, and hypertension/hypotension;

4.Respiratory diseases, such as asthma;

5.Kidney and blood-related diseases;

6.Bone diseases, such as osteoporosis, osteomalacia, and Behcet's disease;

7.Collagen diseases.

[Contraindication]

1.Severe intraoral infection;

2.Impacted teeth, cysts, tumors, or related conditions;

3.Unclear or incomplete medical history;

4.Insufficient alveolar bone volume;

5.Poor alveolar bone quality (e.g., osteoporosis, osteomalacia, or Behcet's disease);

6.Inadequate interarch space;

7.Unhealthy adjacent teeth;

8.Do not use these components in patients with a known allergy to titanium or titanium alloys.

[Explanation of Symbol]

MD	Medical Device		Caution
	Consult instructions for use	NON STERILE	Non-sterile
	Manufacturer		Date of manufacture
UDI	Unique device identifier	LOT	Batch code
	Do not use if package is damaged		Use-by date
EU REP	Authorized representative	CE	CE Mark

[Basic Information]

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