Design Philosophy

There are two kinds of fixture in Chaorum implant, which is AT(SFBxxxxx) and PT(MSFxxxx implant). AT implant is good for initial stabilities in the area of small pitch thread, PT implant is good for easy insertion, which is effected by wide pitch of thread.

1. General details

-Manufacture : MEDIMECCA Co., Ltd.
-Product name: Dental Implant System
-Model : Chaorum Implant System

2 Overview

This product is a dental implant. It is a root-form bone fixture implanted into the alveolar bone to substitute for a missing tooth to regain the function. It is made of pure titanium and shaped into a screw. Internal hex (hexagonal structure) is used to combine with the upper structure.

3. Intended use

A. Application
Implant(Fixture, Abutment, Screw)
B. Purpose for use
1) Fixture : Fixture support the prosthetic parts under the patient bone.
2) Abutment : The abutment of the patient to insert the implant to support prosthesis such as an artificial tooth that is used for the masticatory movement recovery
3) Screw : Prevent debris during the fusion period.

4. Instruction for use

A. Preparation
1) Check the condition of patient and make a plan for operation.
2) Patient should be known the information below.
① results of diagnosis
② Goodness an Badness of operation
③ Contraindication (All the information on manual)
3) Before operation, check the information below.
① Over pressure causes the implant damaged or bone loss of patient.
② Patient should be operated with consideration of information below.
● Condition of bone ● Oral hygiene
● Patient who has Diseases which are associated with the blood or diabetes should be checked by Doctor.
4) According to the condition of patient, the radiography inspection should be done.
5) According to the condition of soft tissue, hard tissue and occlusion, Ct inspection should be done.
6) Check the condition of package, product, and the expiration date before using.
7) Check the condition bone of both maxilla and mandibles before using.

B. Instruction for use

1) The implantation procedure should be done under aseptic conditions using sterilized surgical instruments
2) Throughout the drilling procedure, a gentle up and down pumping motion should be continued and external irrigation system should be used to prevent bone heating. Product placement should be executed by specific drilling sequences with pumping up and down motion during the drilling procedure.(see user manual for instrument)
3) The insertion torque should be less than 55Ncm. Because too large insertion torque (over 55Ncm) may cause deformation of driver hex, thus attached driver cannot be removed. (Recommend Torque : 20N·㎝)
4) Continue to thread the implant into the site screwing it clockwise using torque wrench or implant surgical engine. After completing the insertion procedure, remove the implant and place the cover screw into the implant. Close and suture the tissue flap.
5) After enough recovery time(which is normally 6months for maxilla and 3months for mandibles), abutment and prosthetic parts will be placed on implant.

C. Single use sterilized medical device

This product is a disposable sterilized medical device.

5. Comparison to already marketed products.

1.Clinical equivalence

Company	Medimecca	Yesbiotech	CSM
Intended use	Used for oral edentulous state to make artificial dental root	Used for oral edentulous state to make artificial dental root	Used for oral edentulous state to make artificial dental root
applied part in human body	maxillary or mandibular alveolar bone	maxillary or mandibular alveolar bone	maxillary or mandibular alveolar bone
Shelf life	5 years	3 years	3 years
Similar population (age,contradication)	Recommend over 13 years old	Recommend over 13 years old	Recommend over 13 years old
	1.Hemophilia Patient 2.Patient experiencing difficulties related to bone and wound treatment 3.Patient with uncontrollable diabetes, tissue disease influencing bone or wound treatment 4.heavy smoker or alcoholic 5.Patient whose immunity system is inactivate due to chemical therapy and radiation therapy 6.patient with oral infection or inflammation 7.patient with untreatable occlusion / joint disorder, insufficient dental arch space 8.Patient with	1.Hemophilia Patient 2.Patient experiencing difficulties related to bone and wound treatment 3.Patient with uncontrollable diabetes, tissue disease influencing bone or wound treatment 4.heavy smoker or alcoholic 5.Patient whose immunity system is inactivate due to chemical therapy and radiation therapy 6.patient with oral infection or inflammation 7.patient with untreatable occlusion / joint disorder, insufficient dental arch space 8.Patient with	1.Hemophilia Patient 2.Patient experiencing difficulties related to bone and wound treatment 3.Patient with uncontrollable diabetes, tissue disease influencing bone or wound treatment 4.heavy smoker or alcoholic 5.Patient whose immunity system is inactivate due to chemical therapy and radiation therapy 6.patient with oral infection or inflammation 7.patient with untreatable occlusion / joint disorder, insufficient dental arch space 8.Patient with

	insufficient bone height or width	insufficient bone height or width	insufficient bone height or width

2. Technical equivalence

Company		Medimecca	Yesbiotech	CSM
Product name		Dental Implant system	Dental Implant	Dental Implants and related Surgical Instruments
Country /Manufacturer		Korea /Medimecca	Korea /Yesbiotech	Korea /CSM
Components		Fixture, Abutment Laboratory supplies, and Instrument	Fixture and Abutment	Fixture, Abutment and Surgery kit
Main technical equivalence	Dtaptation Accuracy test rotation angle	under 3°	under 3°	under 3°
	35' compressive loads test	over 500N	over 500N	over 500N
	Torsinal Breaking force test	over 24N/cm	over 24N/cm	over 24N/cm
	Removal Torgue Force test over	over 14N/cm	over 14N/cm	over 14N/cm
	Fatigue	Over 250N	Over 250N	Over 250N
CE certificate			13 0371 QS/NB	11 1111 QS/NB
NB no		CE 1023	CE 1023	CE 1023

3. Biological equivalence

Company	Medimecca	Yesbiotech	CSM
Biocompatibility test	Sterility Test (Direct Transfer Method) Cytotoxicity Test Acute Systemic Toxicity Test Intracutaneous Reactivity Test Pyrogen Test Local Lymph Node Assay, LLNA Test Bone Implantation Test	Biocompatability tests	Biocompatability tests
Sterilization method	Gamma sterilization	Gamma sterilization	Gamma sterilization
Raw material	Abutment : Titanium [ASTM F136, ASTM F67],	Abutment : Titanium [ASTM F136, ASTM F67],	Abutment : Titanium [ASTM F136, ASTM F67],
	Abutment : Titanium [ASTM F136, ASTM F67],	Abutment : Titanium [ASTM F136, ASTM F67],	Abutment : Titanium [ASTM F136, ASTM F67],
	Laboratory supplies : Titanium [ASTM F136, ASTM F67], Stainless steel, Aluminium, Polyacetal	N/A	Surgery kit : Stainless steel, Titanium [ASTM F136, ASTM F67]
	Instrument : Stainless steel, Titanium [ASTM F136, ASTM F67],	N/A	N/A
Used material in contact with human body	Fixture : Titanium [ASTM F136, ASTM F67]	Fixture : Titanium [ASTM F136, ASTM F67]	Fixture : Titanium [ASTM F136, ASTM F67]

As described in above chart, Dental Implant System has similar function and efficiencies when in compares to other or former devices. Therefore it cannot be recognized as a new device and, a clinical investigation is not needed in relation to MEDIMECCA Co., Ltd

6. Safety Test report

1) Physical Test Report

- Test Lab: Testing & Development for Dental Materials, Kyung Hee Univ.
- The tests was conducted according for the test method and requirement basis on KFDA Guideline for dental implant Technical file
- See the Physical and mechanical Test Report(CDM-12-0096-01(E) etc)

No	Test name	Test Result	Test Requirement	Test method	Test report
1	Visual Test	There were no crack, scratch, any disturbing points at use etc.	There were no crack, scratch, any disturbing points at use etc.	Visual	CDM-12-0096-01(E)
2	Packaging Test	Packaging was sealed completely and hasn't pollution of foreign body or impurity and penetrations	Packaging was sealed completely and hasn't pollution of foreign body or impurity and penetrations	Visual	CDM-12-0096-02(E)
3	Packaging Seal Efficacy Test	The integrity of packaging sealing for bacterial barrier of samples submitted by client is perfect.	Growth of microorganism : 0 test sample/5 test samples	ISO11607-1	CDM-12-0096 (E)
4	Dimension Test	Pass	Within 1% of value Stated by manufacturer	Measure using Image microscope system and Digital caliper	CDM-12-0096-03(E)

2) Surface treatment Test Report

- See the Surface treatment Test Report(PPT-13-0006-01(E)etc)

No	Test name	Test Result		Test method	Test report	
					No	Lab
1	Roughness Average Test	Ra: 1.91 ㎛ Rq: 2.43 ㎛		KFDA guideline for assessment procedure of surface characteristics for dental implant	PPT-13-0006-01(E)	Testing & Development for Dental Materials, Kyung Hee Univ.
2	Developed Surface Area Ration Test	Sdr: 53.67%			PPT-13-0006-02(E)	
3	Surface Characteristics Test (SEM)	The surface of product is confirmed the roughness shape and no any problems at use			PPT-13-0006-03R(E)	
4	Surface Composition Analysis Test (EDX)	Al	6.53%		PPT-13-0006-04R2(E)	
		P	0.62%			
		Ca	0.67%			
		Ti	89.31%			
		V	2.87%			

3) Mechanical Properties Test Report

- Test Lab: Testing & Development for Dental Materials, Kyung Hee Univ.
- The tests was conducted according for the test method and requirement basis on KFDA Guideline for dental implant Technical file
- See the Physical and mechanical Test Report(CDM-12-0096-01(E) etc)

No	Test name	Test Result	Test requirement	Test method	Test Report No.
1	Adaptation Accuracy Test (=Implant to abutment compatibility)	1.1° Below 10 ㎛	Within 3° Below 10 ㎛	Using Microscope, measure the interface gap between fixture and abutment by screw	CDM-12-0096-04(E)
2	35° Compressive Loads Test	871N	Over 500N	After connecting fixture and abutment with 20N·㎝(recommended torque), perform as per ISO14801: 2007(E) fatigue test method	CDM-12-0096-05(E)
3	Torsional Breaking Force Test	61.10 N·㎝	Over 24 N·㎝	After specimen setting, tighten until the specimen reached fracture at a speed of 2°/min on CW with torque testing equipment. Measure max torque force when specimen is broken.	CDM-12-0096-B01(E)
4	Removal Torque Force Test	24.32 N·㎝	Over 14 N·㎝	After specimen setting, tighten with 12% torque value(24N·㎝) of recommended torque value the manufacturer at a speed of 2°/min on CW with torque testing equipment. When tightened at a 120% torque value, loosen on CCW and measure the force indicated as removal maximum torque force.	CDM-12-0096-B02(E)
5	Fatigue Test	Fatigue limit: 250N	It shall be no crack, breakage,	ISO14801:2007(E) fatigue test method. - Cycles : 5 x106 - In air - 20±5℃	CDM-12-0096-06(E)

		There were no crack, breakage, deformation, loosening of screw and failure of adaptation accuracy when tested according to testing method.	deformation, loosening of screw and failure of adaptation accuracy when tested according to testing method.		

4) biological Test Report

On evaluation standard of ISO10993-1, we performed the following biocompatibility tests.

- Test Lab: Testing & Development for Dental Materials, Kyung Hee Univ.
- See the Biocompatibility Test Report (CDM-12-0096-01(E) etc)

No	Test name	Test method	Test Result	Test Report No.
1	Sterility Test (Direct Transfer Method)	KP 9nd, 9. Sterility Test USP24 NF19 Micro logical Test <71> Sterility Test	Pass (No Microbial growth)	CDM-12-0096-07(E)
2	Cytotoxicity Test	ISO10993-5:2009	Pass	CDM-12-0096-08(E)
3	Acute Systemic Toxicity Test	ISO10993-11:2006	Pass	CDM-12-0096-09(E)
4	Intracutaneous Reactivity Test	ISO10993-10:2010	Pass	CDM-12-0096-10(E)
5	Pyrogen Test	ISO10993-11:2006	Pass	CDM-12-0096-11(E)
6	Local Lymph Node Assay, LLNA Test	ISO10993-10:2010	Pass	CDM-12-0096-12(E)
7	Bone Implantation Test	ISO10993-6:2007	Pass	CDM-12-0096-13(E)

6. Results of appraisal

. Conclusion

We have manufactured Dental Implant System since 2012, and haven't received any complaint since 2012,in other word we have not been reported yet from customer. Clinical effects of these devices have been proved by users and they also have been proved that they have no clinical side effects and the other hazards.

Hazards verified in the hazard control document do not exist in the clinical data.

Results from search of adverse events also for other/competitive products, side effect or any complain from clients has not been occurred.