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Alloys

Attachments

Implants

Restorative Systems

Fatigue Testing Report for ERA Two Piece Angled Implant

Guidance Documents used:

**Class II Special Controls Guidance Document: Root-form
Endosseous Dental Implants and Endosseous Dental
Implants Abutments.**

*Resiment Standard used to cement abutment to rootform implant: 5 implants fatigue tested
5,000,000 times each with no failures. A total of 250,000,000 cycles.*

Test Description

Parts tested: 911291ERA Angle Implant
2.2mm thread diameter
10 mm thread length
3mm cuff height
411215 17° Female Insert

The 17° Female Insert part number 411215 was cemented to the Implant part number 911291 using Resiment RES –STD 2 and allowed to cure.

Five assembled units were delivered to a certified independent laboratory for fatigue testing.

Test description:

The implant was screwed into an aluminum block which had a 27° angle machined onto the face. This gives the sample being tested an extra 10° angulations. The implant was supported 3mm below the anticipated crestal bone level. The unit was then placed in the Instron tester and a cyclic load varying from 5 to 50 pounds and a frequency of 15 Hz was applied for duration of 5 million cycles. The test was done on all five samples individually.

A fixture was designed to accommodate this test. The fixture consisted of three parts (an implant block, a support cup and a loading platen), which were turned on a lathe in order to ensure that the axial alignment was correct. The implant block was machined from aluminum to a diameter of 1.25" and the face was milled to a 27° angle. The implant block was then drilled and counter bored in order so that the implant would be supported 3 mm below the anticipated crestal bone level when screwed into the block.

A support cup was machined from low carbon steel to an outside diameter of 1.78" and an inside diameter of 1.26" in order to attach the implant block to the actuator of the testing machine. The loading platen was machined from low carbon steel so that the contact face had a diameter 0.700 and attached to the load cell of the testing machine. The tests were performed on an Instron 8501 Low Frequency Fatigue Machine using an Instron 8500 servo-hydraulic control system and the Instron Fast Track Max testing software.

Sample Description

Five samples were tested using the above-described testing method per guidance document:

Class n Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments

Sample Information:

The test was performed using the angled abutments of the greatest angulations intended (i.e. the worst case scenario) of 17°.

	Implant	
Component P/N	Product No.	Product Description
911291 (Samples 1-5)	901291	10 x 3 mm Angled ERA Implant
	Angled Insert	
Component P/N	Product No.	Product Description
411215 (Samples 1-5)		ERA 17° Angled Implant

Sample Identification	Cycles	Passed / Failed
1	5,000,000	Passed
2	5,000,000	Passed
3	5,000,000	Passed
4	5,000,000	Passed
5	5,000,000	Passed

All of the samples successfully completed the testing without failure.

Sincerely

Lee Clermont