

TEST REPORT

Report No. CWM-MT-17-N23
Date of Issue November 23, 2017

Manufacturing Tolerance Evaluation (Micro Measuring Method)

Manufacturing Tolerance Evaluation using Measuring Microscope

1. Specimen (Product): INNO SLA-SH ® Submerged Fixture (5pieces).

2. Classification: Dental Implant Fixture C 20030.01(3).

3. Model Number: ST4510S-16H3A870(# 1), ST4510S-16H3A871(# 2) ST4510S-16H3A872(# 3), ST4510S-16H3A873,(# 4) ST4510S-16H3A874(# 5)

4. Manufacturer: Cowellmedi Co., Ltd.

Address: 48, Hakgam-daero 221 beon-gil, Sasang-gu, Busan, 46986, Korea

Tel: +82 51 314 2028

Fax: +82 51 314 2026

5. Place of the Evaluation: REID (Research & Education in Implant Dentistry)

Address: #1404, ACE Twin Tower 1 Cha, 285, Digital-ro, Guro-gu, Seoul, 08381, Korea

Tel: +82 51 314 2028

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- 6. Date of the Evaluation: November 20, 2017.
- **7. Purpose:** To evaluate whether manufacturing tolerance of the Product is no more than ±0.001mm.
- **8. Criteria:** Each dimensional difference of 3 inner hexagonal sides should be no more than ±0.001mm from 2.500mm

9. Photos of the Specimens



10. Evaluation Equipment

- 1) Measuring Microscope Nikon, Japan / Model Number:

 MM-40 / Calibration completed day: November 20, 2017
- 2) Jig Cowellmedi, Korea / Model Number: N/A

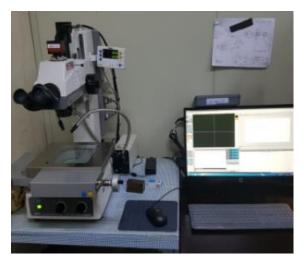


Fig 6. Measuring Microscope

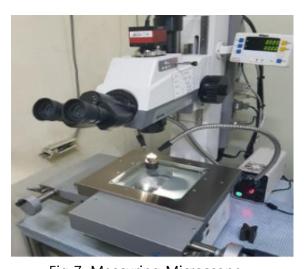
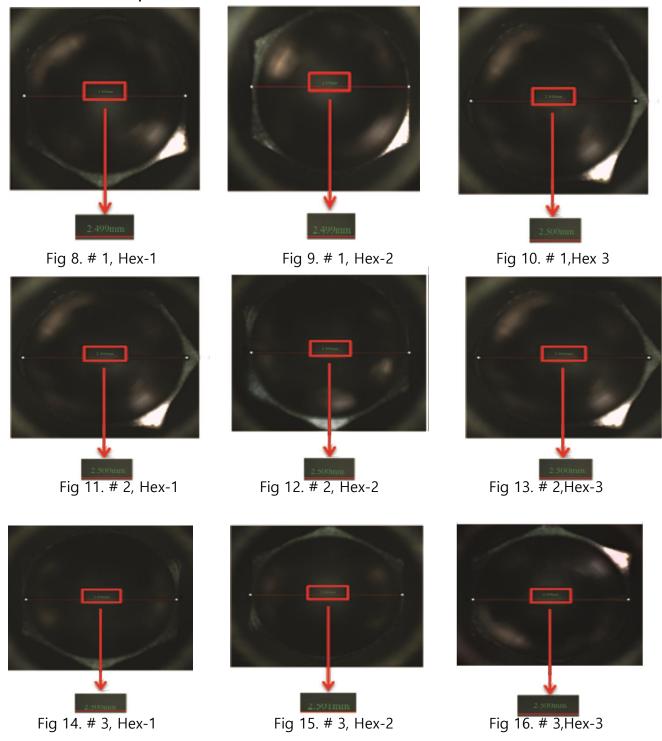
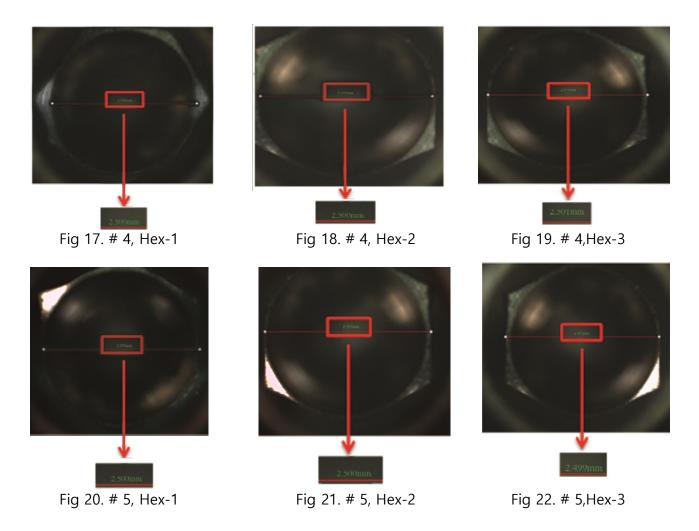


Fig 7. Measuring Microscope + Jig + Specimen

11. Method

- 1) The specimen was fixed in the Jig
- 2) Each dimensional difference of 3 inner hexagonal sides (Hex-1, Hex-2, Hex-3) of 5 specimens was measured using Measuring Microscope





12. Result

| Test Item | | Evaluation Criteria | Result (Pass/Fail) | | |
|-----------|----------------------------|---|---|--|--|
| 1 | Manufacturing Tolerance | Each dimensional difference of 3 inner hexagonal sides should be no more than ±0.001mm from 2.500mm | Pass No more than ±0.001mm Details are as below | | |

| 1. Test (Unit: mm) | | | | | | | |
|--------------------|-------|-------|-------|-------|-------|--|--|
| Classification | # 1 | # 2 | #3 | # 4 | # 5 | | |
| 1.1 Hex-1 | 2.499 | 2.500 | 2.500 | 2.500 | 2.500 | | |
| 1.2 Hex-2 | 2.500 | 2.500 | 2.501 | 2.500 | 2.500 | | |
| 1.3 Hex-3 | 2.500 | 2.500 | 2.500 | 2.501 | 2.499 | | |
| 1.4 Average | 2.500 | 2.500 | 2.500 | 2.500 | 2.500 | | |

| 1.5 Total Average | 2.500 | | |
|-------------------------|--|--|--|
| 1.6 Evaluation Criteria | Each dimensional difference of 3 inner hexagonal sides should be no more than ±0.001mm | | |
| | from 2.500mm | | |
| 2. Result (Pass/Fail) | Pass | | |
| 2.1 Manufacturing | No more than | | |
| Tolerance | ±0.001mm | | |