IC 11.040.99

PROFESSIONAL STANDARD
OF THE PEOPLE’S REPUBLIC OF CHINA

YY/T 0127.4-2009

Biological evaluation of medical
devices used in dentistry
Part 2: Test method
Bone implant test

口腔医疗器械生物学评价
第 2 单元: 试验方法
骨埋植试验

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Issued by: The State Food and Drug Administration
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**Foreword**

This Standard is one of the series standards of “Dental Medical device Biology Assessment”.

The 1st unit, YY/T 0268:2008 “Dentistry. Biological evaluation of medical devices used in dentistry. Part 1: Evaluation and test” of Dental Medical device Biology Assessment series standards, is an option for dental medical device biology assessment and test items; it is a guideline standard.

The 2nd unit of the series standards is “Dental medical devices specific biological test methods”. It is divided into the following sections:

1. YY/T 0127.1-93 Dental materials biological test methods Hemolysis test
3. YY/T 0127.3-1998 Biological evaluation of dental materials - Unit 2: Biological evaluation method of dental materials - Endodontic usage test
4. YY/T 0127.4-2009 Biological evaluation of medical devices used in dentistry. Part 2: Test method Bone implant test
5. YY/T 0127.5-1999 Biological evaluation of dental materials - Unit 2: Biological test methods of dental materials - Inhalation toxicity test
6. YY/T 0127.6-1998 Biological evaluation of dental materials - Unit 2: Biological test methods of dental materials - Dominant lethal test


This Standard is Part 4 of YY/T 0127 series standards.

This Standard is the revised version of YY/T 0127.4-1998 “Biological evaluation of medical devices used in dentistry. Part 2: Test method Bone implant test”. During the drafting process, it references to the ISO 10993.6-2007 “Biological evaluation of medical devices - Part 6: Tests for local effects after implantation”. Test principles of ISO 10993.6-2007 are applicable to this Standard.

Compared with the standard YY/T 0127.4-1998, the main changes are as follows:

- Standard name is renamed as: “Biological evaluation of medical devices used in dentistry. Part 2: Test method Bone implant test”.

- 3.1 Sample preparation adds samples with different types of materials. The sample quantity number of each test cycle is changed to at least 10.

- 3.2, 4, 5, 6 add a variety of options.
- 7 During surgical procedure, "25g/L iodine and 75% ethanol" are changed to "5g/L iodine".

- 10 Biological evaluation is modified.

- ADD Appendix A.

Appendix A is an informative appendix.

From the date of implementation, this Standard will replace the obsolete Y/T 0217.4-1998 “Biological evaluation of medical devices used in dentistry. Part 2: Test method - Bone implant test”.

This Standard was proposed by the State Food and Drug Administration.

This Standard is administered by the National Dental Materials and Appliances Equipment Standardization Technical Committee (SAC/TC 99).

This Standard was responsibly drafted by Dental Medical Device Inspection Center, School of Stomatology of Peking University.

The main drafters of this Standard: Lin Hong, Li Shenglin, and Hao Peng.

This Standard was first-published in 1998, it is first-revised in 2009. The previous edition which is substituted by this Standard is:

- YY/T 0127.4-1998
Biological evaluation of medical devices
used in dentistry
Part 2: Test method
Bone implant test

1 Scope

This Standard specifies the test method of bone implantation of dental medical devices.
This Standard shall be used to evaluate the biological reactions of bone tissue of which the
dental bone issue is planned to contact with dental medical devices in long-term.

2 Normative References

The articles contained in the following documents have become part of this Standard when
they are quoted herein. For the dated documents so quoted, all the modifications
(excluding corrections) or revisions made thereafter shall not be applicable to this
Standard. For the undated documents so quoted, the latest edition shall be applicable to
this Standard.
GB/T 13810 Wrought titanium and titanium alloy for surgical implants
GB/T 16886.6 Biological evaluation of medical devices - Part 6: Tests for local effects after
implantation (GB/T 16886.6-1997, ISO 10993-6:1994, IDDT)
GB/T 16886.12 Biological evaluation of medical devices - Part 12: Sample preparation and

3 Sample Preparation

3.1 CONDUCT preparation, processing, cleaning, and disinfection for the implanted
materials according to the same method used for final product. At least 10 samples shall
be used for each test cycle.
3.1.1 Solid sample: sample shall be made in cylinder with diameter of 2 mm, height of 6
When conducting research to the implant / tissue interface, it is recommended to use a hard plastic to embed the implant together with its surrounding integral tissue; USE appropriate slicing or grinding technology to prepare histological slice. The fact shows that the use of plastic embedding techniques will not cause significant changes to the interface tissue.

Recommended steps are as follows:
CUT the tissue blocks which contains the implant and the surrounding bone tissue; FIX them in formaldehyde solution. USE suitable decalcifying agent (such as 5% nitric acid) to decalcify; USE conventional series ethanol to dehydrate; USE paraffin for embedding. CONDUCT slicing in parallel to the long axis of the implant; TAKE tablets in interval; and H-E coloring.

10.3 Microscopic (microscope observation) evaluation
When using quantitative scoring system (e.g. expressed in μm) or semi-quantitative scoring system to evaluate histological, it shall consider the extent of affected area.

The biological reaction indicators which need to be evaluated and recorded include:
   a) Fibrosis / fibrous cysts (thickness expressed in μm) and inflammation degree;
   b) Determined denaturation caused by changes of histomorphology;
   c) The types of material / tissue interface inflammatory cells, i.e. the number and distribution of neutrophils, lymphocytes, plasma cells, eosinophils, macrophages and other multicore cells;
   d) Occurrence, range and type of necrosis;
   e) Other tissue changes such as neovascular, fatty infiltration, granuloma, and bone forming;
   f) Material parameters, such as fragments and/or debris, the status and location of residues of biodegradable material;
   g) For porous and biodegradable materials, qualitatively and quantitatively MEASURE the tissue which grows into the material.

For biodegradable materials and absorbent materials, when the degradation is half or nearly completely, it shall exist residue of degradable implant degraded in the evaluated tissue specimens. In addition, when evaluating the repair of normal tissue structure, it shall observe the representative implanting position of implantation, such as marks or template tags.

For bone tissue, it shall primarily observe the interface between tissue and materials; it shall evaluate the contact area between the implant and the bone AND number of
### Table A3 Semi-quantitative scoring system

**Test material:**  

<table>
<thead>
<tr>
<th>Neovascularization</th>
<th>0</th>
<th>Small amount of new blood capillaries, 1-3 buds</th>
<th>4-7 group of new capillaries with fibroblasts structural support</th>
<th>wide belt of new capillaries with fibroblasts structural support</th>
<th>large area of new capillaries with fibroblasts structural support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibrosis</td>
<td>0</td>
<td>Narrowband</td>
<td>Medium thick belt</td>
<td>Thick belt</td>
<td>large area belt</td>
</tr>
<tr>
<td>Fatty infiltration</td>
<td>0</td>
<td>Small amount fat associated with fibrosis</td>
<td>Several layers of fat and fibrosis</td>
<td>Large accumulation of fat cells in the implant position and extends</td>
<td>Fat completely covers the large area around the implant</td>
</tr>
</tbody>
</table>

| Inflammation                |  |                                                |                                                               |                                                               |                                                               |
|-----------------------------|---|-------------------------------------------------|                                                               |                                                               |                                                               |
| Polymorphonuclear leukocytes|  |                                                |                                                               |                                                               |                                                               |
| Lymphocytes                 |  |                                                |                                                               |                                                               |                                                               |
| Plasma cells                |  |                                                |                                                               |                                                               |                                                               |
| Macrophages                 |  |                                                |                                                               |                                                               |                                                               |
| Cytomegalo                  |  |                                                |                                                               |                                                               |                                                               |
| Necrosis                    |  |                                                |                                                               |                                                               |                                                               |
| Subtotal 1 (X2)             |  |                                                |                                                               |                                                               |                                                               |

**Test Sample**

<table>
<thead>
<tr>
<th>Animal quantity: 1 2 3 4 5 6 7 8 9 10</th>
<th>1 2 3 4 5 6 7 8 9 10</th>
</tr>
</thead>
</table>

**Comparison Sample**

<table>
<thead>
<tr>
<th>Animal quantity: 1 2 3 4 5 6 7 8 9 10</th>
<th>1 2 3 4 5 6 7 8 9 10</th>
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</tr>
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</table>

| Subtotal 1 (X2)             |  |                                                |                                                               |                                                               |                                                               |

| Total = (Subtotal 1 + Subtotal 2) |  |                                                |                                                               |                                                               |                                                               |

| 1 Group Total               |  |                                                |                                                               |                                                               |                                                               |
| 2 Group average             |  |                                                |                                                               |                                                               |                                                               |

$^3$ Stimulation index = average value of test groups – average value of comparison groups
References

[1] GB/T 3620.1-2007 iron and alloy grades and chemical composition
Translation References and Original Chinese Documents
