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International Standard 6474

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Implants for surgery — Ceramic materials based on alumina

Implants chirurgicaux — Produits céramiques à base d'alumine

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Foreword

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Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 6474 was developed by Technical Committee ISO/TC 150, *Implants for surgery*, and was circulated to the member bodies in October 1979.

It has been approved by the member bodies of the following countries :

Austria	India	Spain
Belgium	Mexico	Switzerland
Canada	New Zealand	USA
Egypt, Arab Rep. of	Philippines	USSR
France	Poland	
Germany, F. R.	South Africa, Rep. of	

The member body of the following country expressed disapproval of the document on technical grounds :

Australia

Printed in Switzerland

Implants for surgery — Ceramic materials based on alumina

1 Scope and field of application

This International Standard specifies the characteristics of, and corresponding test methods for, a body-compatible and body-stable ceramic bone substitute material based on alumina.

The field of application extends to all bone implants as joint substitutes and bone spacers.

2 References

ASTM C573, *Chemical analysis of fireclay and high-alumina refractories.*

ASTM C674, *Flexural properties of ceramic white ware materials.*

ASTM C773, *Compressive strength of fired white ware materials.*

ASTM D256, *Standard methods of test for impact resistance of plastics and electrical insulating materials*

ASTM E112, *Estimating the average grain size of metals.*

ASTM E384, *Microhardness of materials.*

BS 1902, *Methods of testing refractory materials.*

NOTE — The above references will be replaced by references to appropriate International Standards when the latter become available.

3 Physical and chemical properties

3.1 Density

$\geqslant 3{,}90$ g/cm^3

3.2 Chemical composition

Al_2O_3 $\geqslant 99{,}5$ %

SiO_2 and alkali metal oxides $\leqslant 0{,}1$ %

3.3 Microstructure

i.e. average grain size $\leqslant 7$ µm

3.4 Microhardness

(at room temperature) $\approx 2\,300$ HV

3.5 Compressive strength

(at room temperature) $\approx 4\,000$ MPa*

3.6 Flexural strength

(at room temperature) $\geqslant 400$ MPa*

3.7 Young's modulus

(at room temperature) $\approx 380\,000$ MPa*

* 1 MPa = 1 N/mm^2

3.8 Impact strength

(at room temperature) $\geqslant 4\,000\ J/m^2$

3.9 Wear resistance

After completion of the initial run as specified in 4.9, the average wear rate of the disc shall not exceed 0,01 mm^3/h.

3.10 Corrosion resistance

In the corrosive medium specified in clause 5, the corrosion shall be $\leqslant 0{,}1\ mg/m^2$ per day.

The mechanical properties shall not fall below the requirements listed above after an ageing period of 3 months in the corrosive medium.

4 Methods of test

4.1 Density

The determination of density shall be carried out in accordance with BS 1902.

4.2 Chemical composition

The determination of the chemical composition can be carried out in accordance with ASTM C573. Other methods may be chosen (the methods chosen shall be stated in the test report).

4.3 Microstructure

For the determination of the microstructure, in accordance with ASTM E112, the samples shall be polished and etched thermally :

etching temperature : 1 450 to 1 500 °C

etching time : 2 to 4 h

4.4 Microhardness

The determination of microhardness shall be carried out in accordance with ASTM E384. Because of the considerably higher hardness values of ceramic materials based on alumina

— the load shall be 2 N,

— the test samples shall be etched, and

— the diamond stylus shall be placed on the grain surface and not on the grain boundary.

4.5 Compressive strength

The determination of compressive strength shall be carried out in accordance with ASTM C773. Because of the considerably higher compressive strength of high alumina ceramics the dimensions of the test pieces have to be small and shall be as specified in 6.2.

NOTE — The supporting plates have to be made out of cemented carbide, i.e. tungsten carbide based alloy.

4.6 Flexural strength

The determination of flexural strength shall be carried out in accordance with ASTM C674.

For the dimensions of the test pieces, see 6.1.

The test conditions shall be adapted to alumina ceramic in accordance with the following :

length between supports : 25 mm

radius of supports : 1 to 2 mm

radius of loading bar : 2 to 5 mm

rate of application of load : 10 MPa/s*

NOTE — Both supports or one support and the loading bar should be movable.

4.7 Young's modulus

The determination of Young's modulus shall be carried out in accordance with ASTM C674.

For the dimensions of the test pieces see 6.1.

The test machine shall be rigid.

NOTE — In order to obtain a higher accuracy, the length of the test samples may be extended to 50 mm. In this case the relation between support length and sample cross-diameter should be approximately 10 : 1.

4.8 Impact strength

The determination of impact strength shall be carried out in accordance with ASTM D256.

For the dimensions of the test pieces see 6.1.

4.9 Wear resistance

The determination of wear resistance shall be carried out with a ring-on-disc device (see figure 1). The plane surfaces of the ring and the disc shall be in contact under a constant load and under oscillating sliding. The ring and the disc shall be made out of the same material. The wear rate shall be obtained by measuring the depth of the wear mark on the disc surface.

* 1 MPa/s = 1 $N/(mm^2.s)$

The test conditions shall be as follows :

deflection angle : ± 25°

ring, inner diameter : 14 mm

ring, outer diameter : 20 mm

surface pressure : 20 MPa*

frequency : 1 Hz

testing time : 96 h

surface : $R_a \leqslant 0{,}15$ µm

lubricant : corrosive medium complying with the requirements of clause 5.

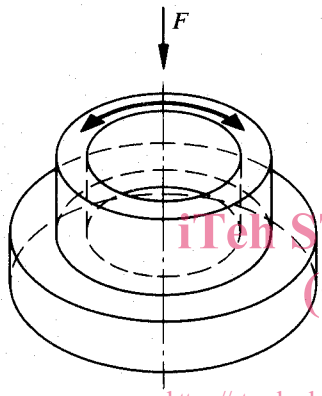

Figure 1

4.10 Corrosion resistance

For the determination of corrosion resistance, cubical or cylindrical samples shall be exposed to a corrosive medium as specified in clause 5. The evaluation of the corrosion resistance shall be carried out by weighing and reporting the measurement as a function of the surface area.

5 Corrosive medium

The corrosive medium shall be Ringer phosphate-bicarbonate solution (buffered to a pH of 7,0 to 7,4) and maintained at a temperature of 37 ± 2 °C. The Ringer phosphate-bicarbonate solution** shall have the following composition :

	Volumes
0,9 % sodium chloride solution :	94
1,15 % potassium chloride solution :	4
1,22 % calcium chloride solution :	3
2,11 % potassium dihydrogen phosphate solution :	1
3,82 % magnesium sulphate solution :	1
1,3 % sodium bicarbonate solution :	14
disodium hydrogen phosphate solution $c(Na_2HPO_4) = 1$ mol/l :	13

6 Test pieces

6.1 Test pieces for the determination of :

a) flexural strength (4.6);

b) Young's modulus (4.7), and

c) impact strength (4.8)

shall be in accordance with the following :

— cross-section : 4,5 ± 0,5 mm × 4,5 ± 0,5 mm (if necessary with a contraction of the diameter to 3 ± 0,1 mm, acting as a predetermined breaking point — see figure 2)

— length > 30 mm

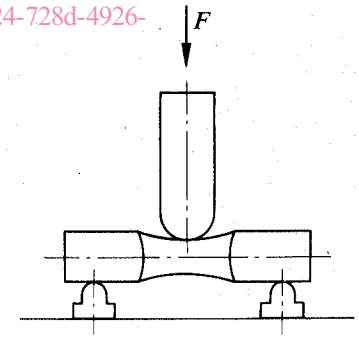

Figure 2

6.2 Test pieces for the determination of compressive strength (4.5) shall be in accordance with the following :

diameter of cylindrical test pieces : 10 mm;

length of cylindrical test pieces : 10 mm.

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* 1 MPa = 1 N/mm^2

** See *Biochemical Handbook* 1961.