

INTERVERTEBRAL CERVICAL SPINE IMPLANT

The **CERAMIL®** inclinated cervical cage is a biocompatible intervertebral body fusion device. It is inert, non-resorbable and is indicated in cervical spine surgery for Anterior Cervical Discectomy and Fusion (ACDF).

INDICATIONS

The CERAMIL® cervical cage is indicated for the treatment of degenerative disc diseases (DDD), post-traumatic instability of the cervical spine and tumors. The technique of anterior cervical discectomy and fusion using the CERAMIL® cervical cage is similar to the standard Smith-Robinson technique.

MATERIAL

The CERAMIL® cervical cage is manufactured from porous cellular alumina ceramic (Al2O3).

This biocompatible, inert, non-resorbable implant has an open and interconnected porosity structure of 60% similar to that of cancellous bone.

The radiolucent characteristics of the implant enables the surgeon to radiographically monitor the positioning and consolidation of the implant.

DESIGN

The design and range of sizes enables the surgeon to select a cage that matches the patient's unique anatomy.

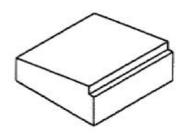
The 16° anterior/posterior angulation has the following characteristics:

- restricts the implant from migrating backwards
- ensures primary implant stability in the intervertebral space.
- The anterior ledge prevents the implant from migrating forward.

The CERAMIL® inclinated cervical cage is available in 9 different sizes, please refer to the reference chart.

Reference	Dimensions (w x h x ant. h/post. h)
RC04/3B/1242	12 x 14 x 4/2 mm
RC04/3B/1253	12 x 14 x 5/3 mm
RC04/3B/1264	12 x 14 x 6/4 mm
RC04/3B/1442	14 x 14 x 4/2 mm
RC04/3B/1453	14 x 14 x 5/3 mm
RC04/3B/1464	14 x 14 x 6/4 mm
RC04/3B/1642	16 x 16 x 4/2 mm
RC04/03/1653	16 x 16 x 5/3 mm
RC04/3B/1664	16 x 16 x 6/4 mm

Sterilization: 25kGy of Gamma radiation



BIOLOGICAL CHARACTERISTICS

The open and controlled interconnected porosity structure of the CERAMIL® cervical cage ranges from 200 to 600 $\mu m.$

This enables the implant to a serve as a scaffold with excellent osteoconductive properties contributing towards bone generation and ingrowth. Various clinical results have shown that secondary osseintegration occurs after 3 months with total consolidation taking place from 3 to 6 months.

MECHANICAL CHARACTERISTICS

The mechanical structure and angulation of the implant secures primary implant stability in the intervertebral space.

Compression tests have verified the mechanical resistance of the implant ranging from 25 to 60 MPa. It is important to note that the compression resistance of hydroxyapatite is < 10 MPa.

ADVANTAGES

- Eliminates the need for any internal screw fixations.
- Eliminates the need for supplemental cervical plating except in cases of cervical spine instability and post-traumatic instability.
- Eliminates the need for allogenous and autogenous bone grafts or any other bone graft alternatives.
- Favorable radiolucent qualities for intra-operative and post-operative imagery.

MANUFACTURER: I.CERAM S.A. Parc ESTER Technopole-1 rue Columbia

87068 LIMOGES, FRANCE Tel: +33(0)5 55 69 12 12 Fax: +33(0)5 55 35 06 50 www.iceram.fr Medical device: class IIb **C€ 1014**

