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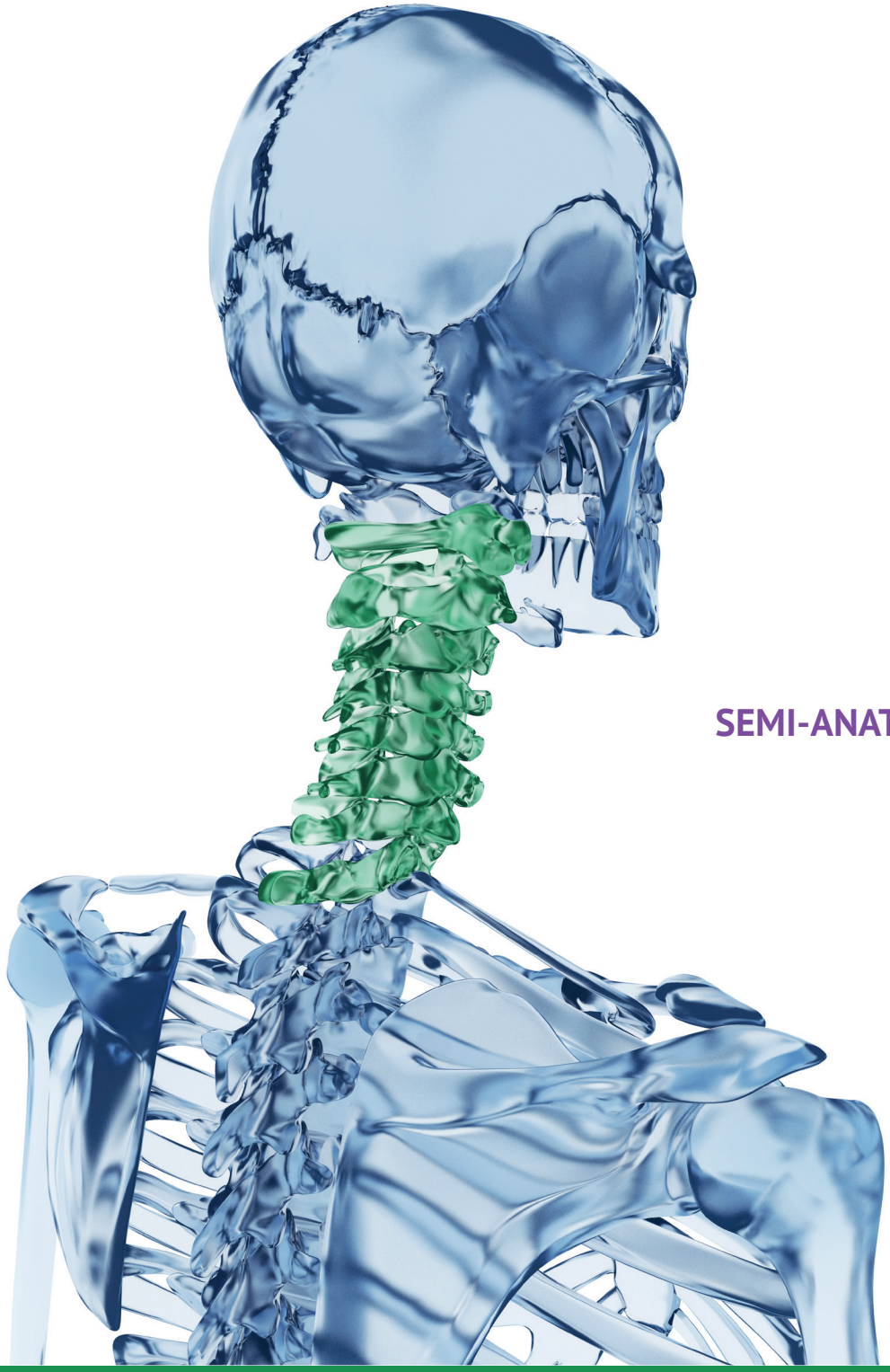
HI-TECH IMPLANTS • SOUTH AFRICA



CERAMIL®

SEMI-ANATOMIC CERVICAL CAGE

INTERVERTEBRAL CERVICAL SPINE IMPLANT

The **CERAMIL®** semi-anatomic 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).

CE 1014

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

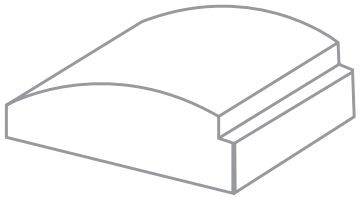
The anatomical design and range of sizes enables the surgeon to select a cage that matches the patient's unique anatomy.
The 16° anterior/posterior angulation has the following characteristics:

- restricts the implant from migrating backwards
- the lordotic design respects the anatomic lordosis
- ensures primary implant stability in the intervertebral space.

The anterior ledge prevents the implant from migrating forward.
The CERAMIL® cervical cage is available in 9 different sizes, please refer to the reference chart.

Reference	Dimensions (w x h x ant. h/post. h)
M 65 CC 1242 NP	12 x 14 x 4/2 mm
M 65 CC 1253 NP	12 x 14 x 5/3 mm
M 65 CC 1264 NP	12 x 14 x 6/4 mm
M 65 CC 1442 NP	14 x 14 x 4/2 mm
M 65 CC 1453 NP	14 x 14 x 5/3 mm
M 65 CC 1464 NP	14 x 14 x 6/4 mm
M 65 CC 1642 NP	16 x 16 x 4/2 mm
M 65 CC 1653 NP	16 x 16 x 5/3 mm
M 65 CC 1664 NP	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 µm.
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.

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Medical device: class IIb
CE 1014

Read the instructions that appear in the user manual and on the label carefully before using the device.