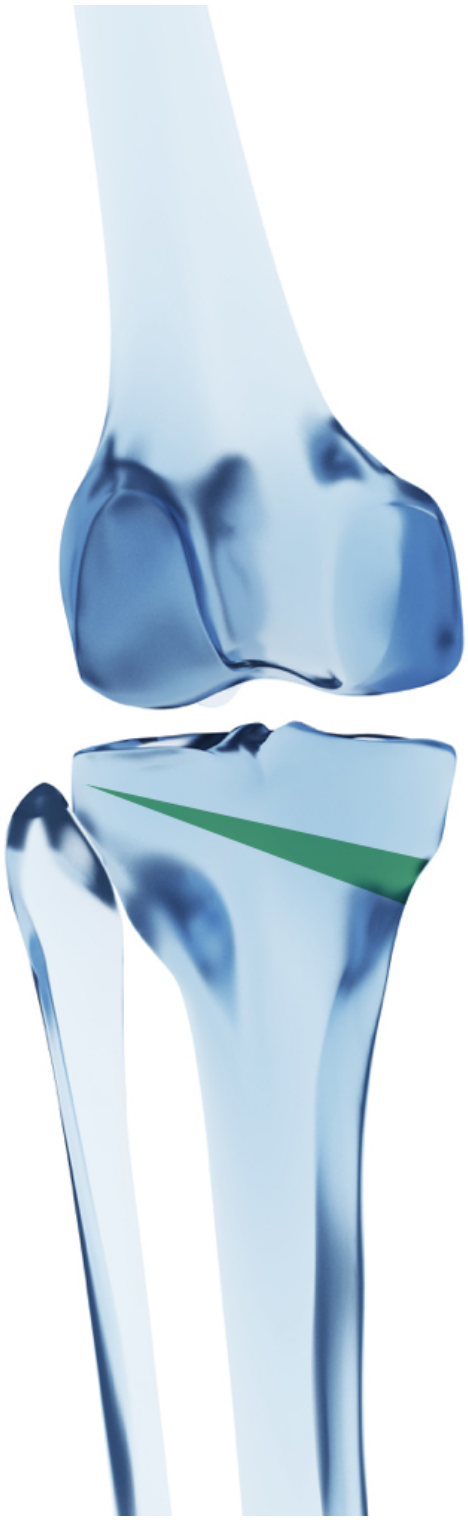
HI-TECH IMPLANTS • SOUTH AFRICA



CERAMIL®

HIGH TIBIAL OSTEOTOMY WEDGE

HIGH TIBIAL OSTEOTOMY WEDGE

The porous alumina ceramic HTO wedge is an inert, biocompatible, non-resorbable implantable device with a mechanical resistance superior to that of cancellous bone. This immediate weight-bearing device is available in a range of 13 varying dimensions to ensure the required correction.

CE 1014

INDICATIONS

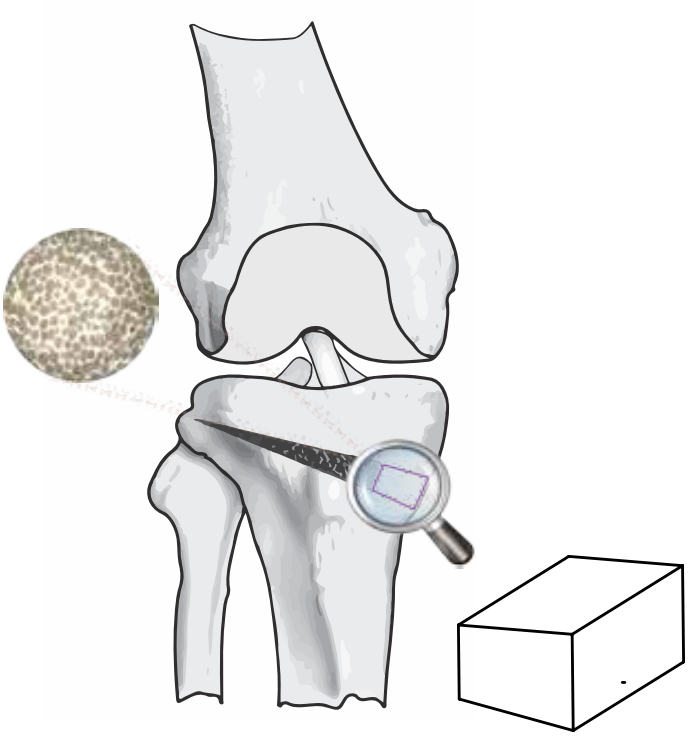
The CERAMIL® HTO wedge is an inert, non-resorbable, bio ceramic. This product is used in bone synthesis and is designed by its shape to restore heights from 5 mm to 17 mm in cases of opening wedge osteotomies.

MATERIAL

The CERAMIL® HTO wedge 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 an implant that corresponds to the patient's required correction.



MECHANICAL CHARACTERISTICS

Compression tests have verified the mechanical resistance of the implant ranging from 25 to 60 MPa that is 3 times that of cancvellous bone.
Supplemental osteosynthesis devices will be required to support primary fixation.

BIOLOGICAL CHARACTERISTICS

The open and controlled interconnected porosity structure of the CERAMIl® HTO wedges ranges from 100 to 900 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.

CERAMIL® HTO Porous ceramic wedge

Reference	*Dimentions*
M 69 CC 5	5,0 x 4,0 mm
M 69 CC 6	6,0 x 4,8 mm
M 69 CC 7	7,0 x 5,7 mm
M 69 CC 8	8,0 x 6,2 mm
M 69 CC 9	9,0 x 6,9 mm
M 69 CC 10	10,0 x 7,7 mm
M 69 CC 11	11,0 x 8,5 mm
M 69 CC 12	12,0 x 9,3 mm
M 69 CC 13	13,0 x 10,0 mm
M 69 CC 14	14,0 x 10,8 mm
M 69 CC 15	15,0 x 11,5 mm
M 69 CC 16	16,0 x 12,3 mm
M 69 CC 17	17,0 x 13,1 mm

ADVANTAGES

- Eliminates the need for any internal screw fixations.
- Eliminates the need for allogenous and autogenous bone grafts or any other bone graft alternatives.
- Excellent radiolucent qualities for pre and post-operative imagery.
- Minimal instrumentation

Sterilization: 25kGy of Gamma radiation

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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.