



**ADVANCED CERAMIC COMPONENTS FOR
NEXT-GENERATION MEDICAL DEVICES**

An introduction to processes and materials used in implant components, subassemblies and devices.

CERAMIC DESIGN GUIDE

- In the prototype phase, medical device design engineers are normally focused on the following criteria:
 - Compressed schedule and time to market
 - Design flexibility
 - Avoidance of costly tooling or engineering costs

Typical manufacturing methods used to support these criteria are:

Isostatic pressing

Ceramic powder is poured into a flexible mold then inserted into a pressure vessel which uniformly compresses the mold and powder into a basic, non complex shape such as a cylinder. This produces a blank for secondary machining.

Pre sinter “Green” machining

In the unfired state, ceramic can be machined relatively easily taking into account shrinkage rates during the sinter or firing process.

Post sinter “Hard” grinding

Tight tolerances and critical surfaces can be ground after firing although minimizing the grinding and maximizing green machining will lower unit costs.

- In the production phase, the following criteria are normally more important:
 - Repeatability
 - Lower unit cost
 - Increased yields
 - High-volume production
 - Tighter tolerances

Typical manufacturing methods used to support these criteria are:

Uniaxial pressing

Ceramic powder is filled into the tool cavity and then compressed axially.

CIM (ceramic injection molding)

Ceramic feed stock is forced into a mold at high temperature similar to plastic injection molding although post mold sintering is still required

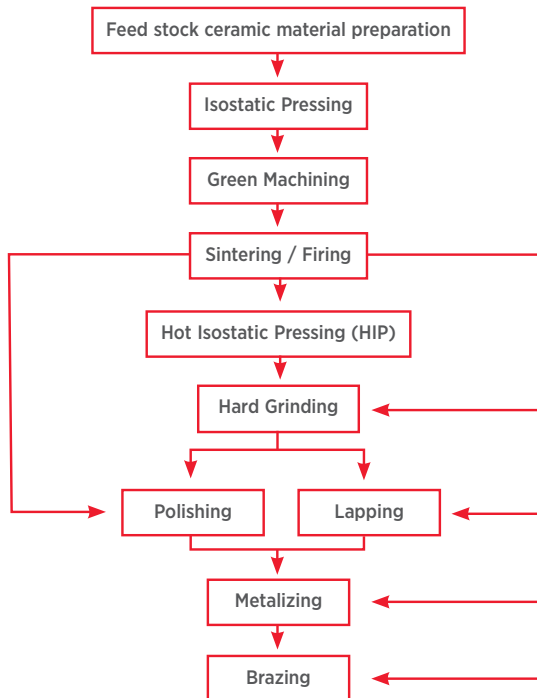
Extrusion

Ceramic material is forced through a die in various shapes and then cut to length before firing.

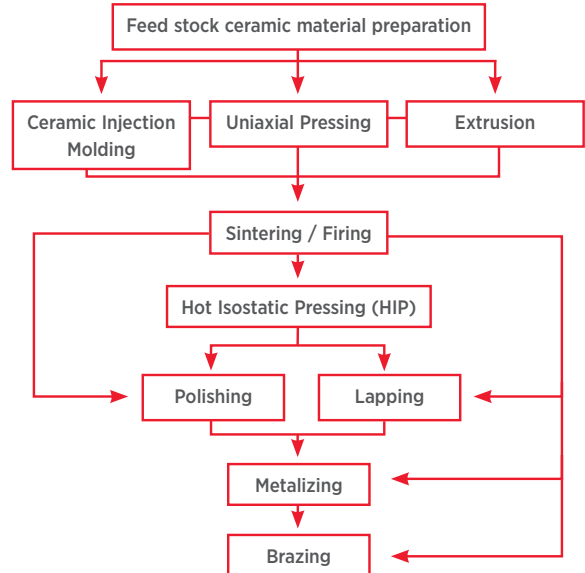
HIP

HIP (hot isostatic pressing) is used to increase the density and subsequently the mechanical properties of the fired ceramic material.

Typical Manufacturing Process for Prototypes



Typical Manufacturing Process for Volume





3. Other processing methods can be used on the ceramic:

Polishing / lapping

Used to generate a very flat, parallel or high mirrored surface finish.

Metalizing

Surface preparation for attaching ceramic to a metal component through brazing.

Brazing

Attaching ceramic to metal using a braze alloy by heating all three materials (ceramic, metal, braze alloy) to create an hermetic seal.

4. Typical applications where ceramic materials are used in medical devices:

Neurological stimulators / Cochlear implants / Retinal implants:

Feed through insulators
Electronic cases / packaging
RF window

CRM (cardio rhythm management)

Feed through insulators
Electronic cases / packaging
RF window

Orthopaedic

Hips

Femoral ball heads
Acetabular cups

Knees

Femoral knee components

Spinal

Total disc replacement (TDR)

Brachytherapy

Porous ceramic seeds

Dental

Crowns / pre sintered dental blanks
Abutments
Implants / jaw bone screws

5. In medical devices, the most commonly used ceramic materials are as follows:

Alumina (Al₂O₃)

Typically used in high wear applications

Zirconia (YTZP)

Typically used in high mechanical strength applications

Zirconia Toughened Alumina (ZTA) CeraSurf™

Excellent combination of wear resistance and high strength

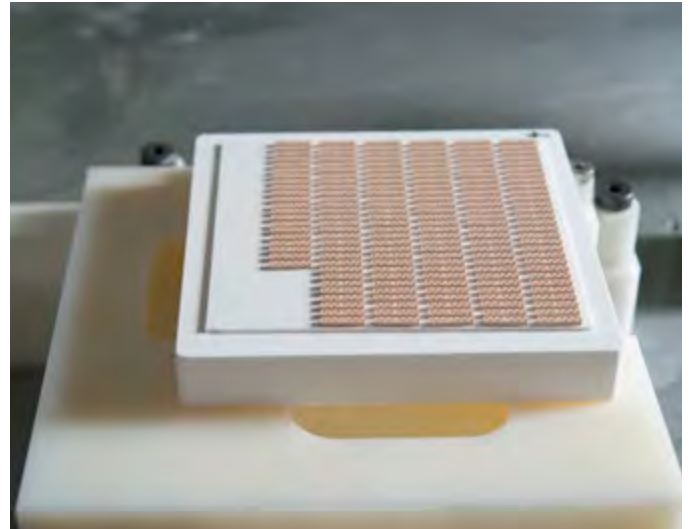
6. Ceramics may be considered for the following benefits (material dependent):

- Radio lucent / opaque
- Hermeticity / ability to be brazed
- High strength to weight ratio
- Electrical insulation
- High hardness and low wear
- Bio compatibility / Bio inert / non toxic
- Zero porosity (controlled porosity materials also available)
- Translucency / Aesthetics
- Thermally stable
- Chemical resistance

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