Ceramic Design Guide

Medical Device Components

ADVANCED CERAMIC COMPONENTS FOR NEXT-GENERATION MEDICAL DEVICES

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

CERAMIC DESIGN GUIDE

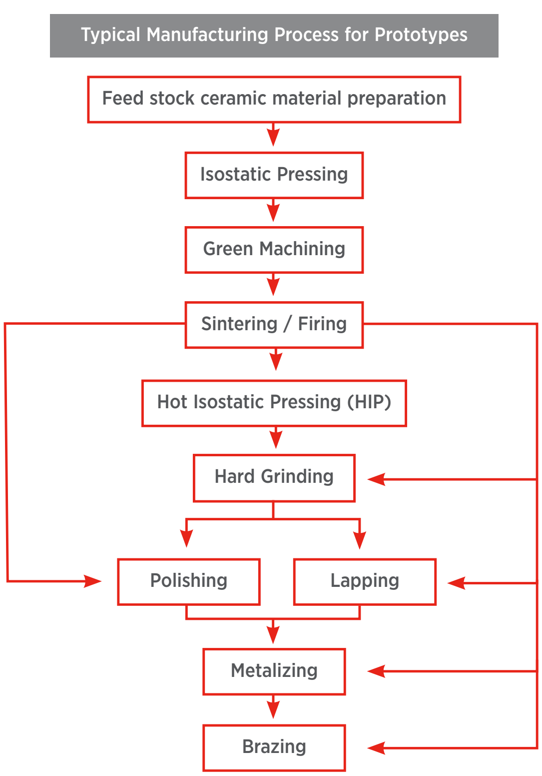
1. In the prototype phase, medical device design engineers are normally focused on the following criteria:
   - Compressed schedule and time to market
   - Design flexibility
   - Avoidance of costly tooling or engineering costs

   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.



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

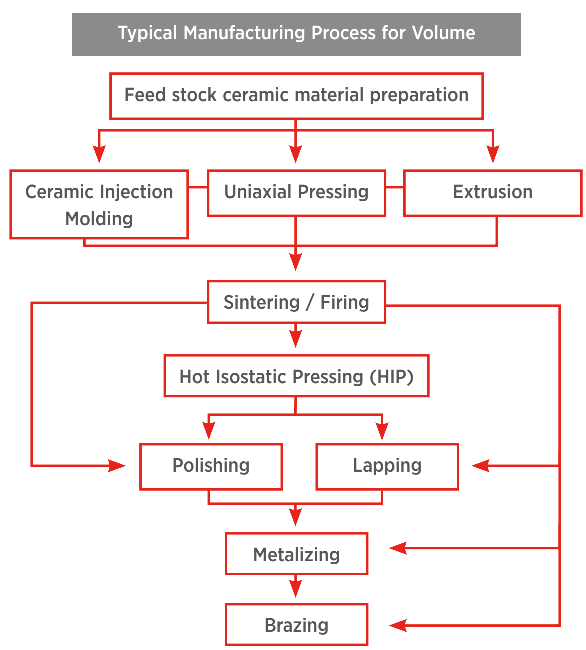
   Typical manufacturing methods used to support these criteria are:

   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.



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 (Al_2O_3)
   Typically used in high wear applications

   Zirconia (YTZP)
   Typically used in high mechanical strength applications

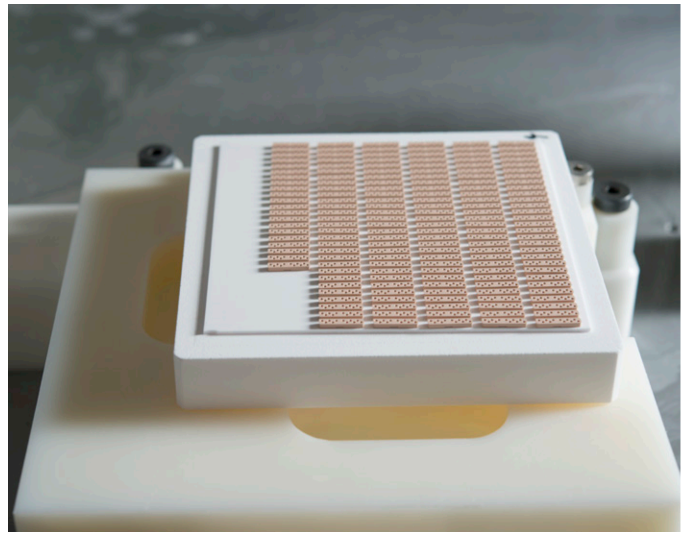
   Zirconia Toughened Alumina (ZTA) CeraSurf™
   Excellent combination of wear resistance and high strength

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

We Make The World Measurably Better

Global Presence

Whether your company is global or domestic, CoorsTek works to serve you locally — supporting your business with over 500,000 square meters of manufacturing space in over 50 locations worldwide. Our customer focus is the reason we have become the world's leading manufacturer of engineered ceramics and advanced materials, the partner of choice to more than 10,000 technology and manufacturing customers in 70 countries. With more than 6,000 dedicated employees, we're ready to help you with your next project.



CoorsTek Bioceramics

COORSTEK BIOCERAMICS

Americas
+1 303 271 7100
+1 855 929 7100 toll free in USA
www.coorstek.com
info@coorstek.com

Europe
+49 160 530 3768
infoeurope@coorstek.com

Japan
+1 81 3 5437 8411
japaninfo@coorstek.com

China
+86 21 6232 1125
info_shanghai@coorstek.com

Korea
+82 31 613 2946
koreainfo@coorstek.com