

Ceramic Packaging in Medical Applications

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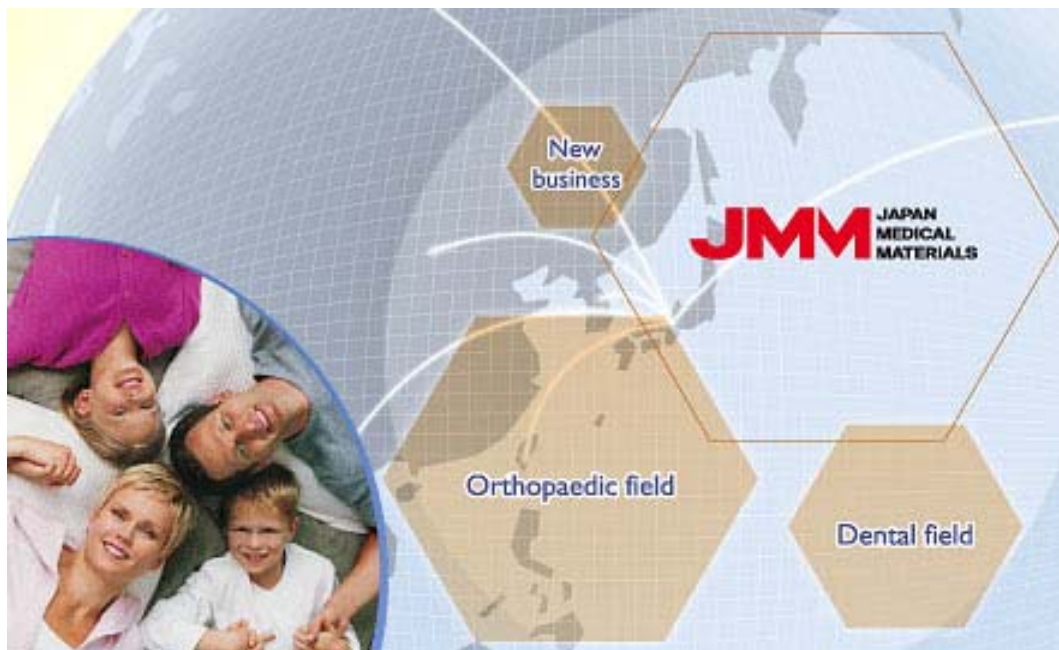
Agenda

- 1. Introduction**
- 2. Implanted Ceramics – Pacemakers and Defibrillators**
- 3. Implanted Ceramics: Fabrication considerations**
 - Microstructure
 - Machining
 - Mechanical properties
 - Biocompatibility
 - (Biostability)
- 4. Other Applications**
- 5. Equipment: Image sensors**
- 6. Conclusions**

Why use ceramics?

- Strong
- Chemically and biologically inert
- Electrically – active or inert
- Reliable attachment (brazing) to metals and other ceramics
- May be fabricated with 3-D structures

Kyocera's Presence in the Medical Market: Japan Medical Materials (JMM)



- Formed in 2004
- Joint venture:
Kyocera (Ceramics)
Kobe Steel (Metals)

JMM continues to supply excellent products to the medical field.

Dental implant

Dental field



Alumina ceramics cranial plate



Centrifugal blood pump

Cardiovascular field



Artificial hip joint

Orthopaedic field



Internal fixation material /Spinal fixation material

Orthopaedic field



Limb salvage system

Orthopaedic field

Artificial knee joint

Orthopaedic field



Varieties of artificial joints

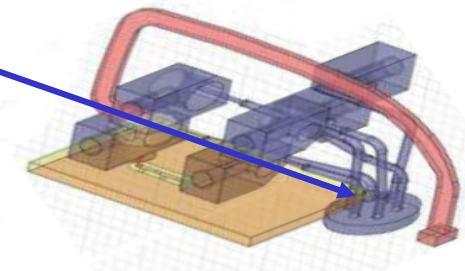
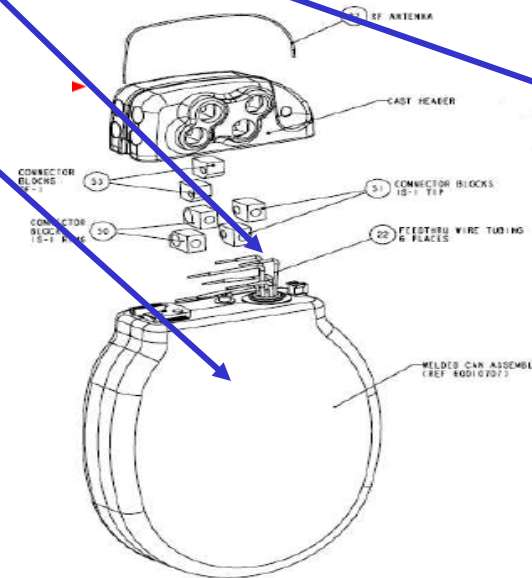
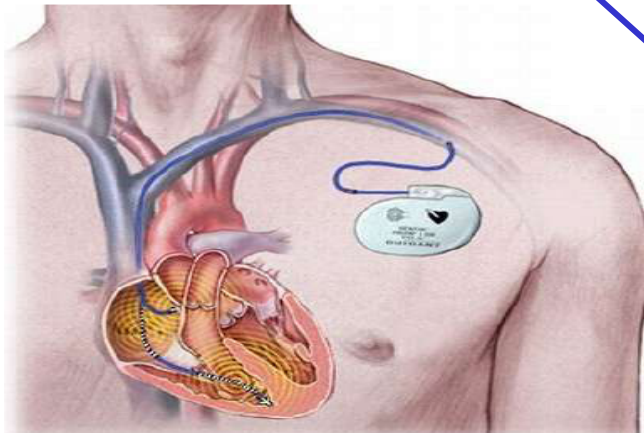
Orthopaedic field



One of the most interesting markets for packaging...

Defibrillators and Pacemakers

- Opportunities in:
 - Telemetry (external)
 - Feedthroughs
 - Control substrates



Filtered Feedthrough



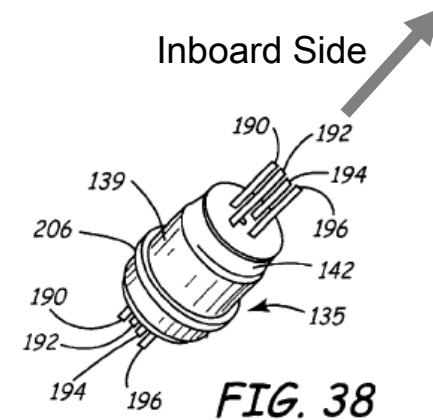
Unfiltered
Feedthrough

+



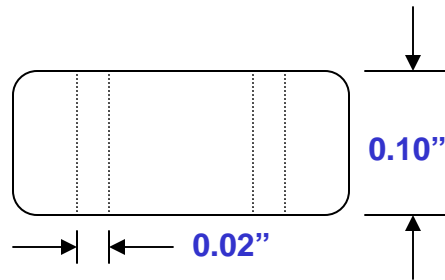
EMI Filter

=

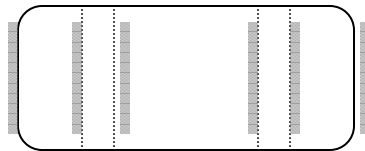


Filtered Feedthrough
Assembly

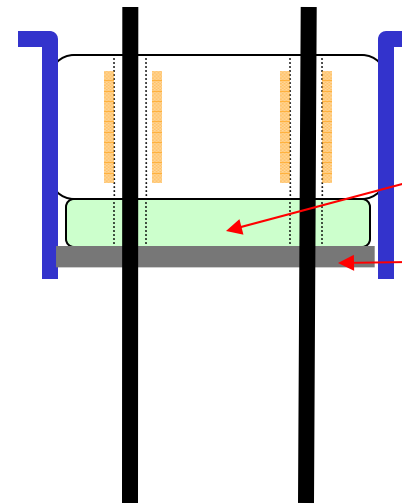
Feedthrough – Typical Process



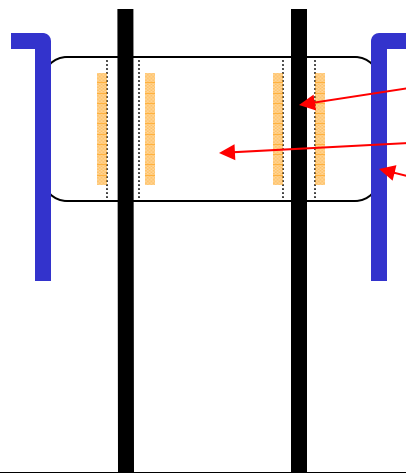
Fabrication: 99% Al_2O_3



Sputter / Vacuum
Deposition Ti - Mo

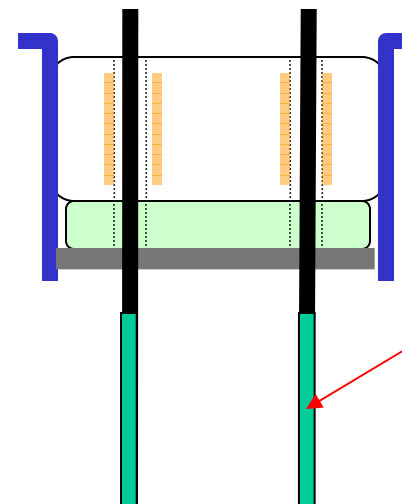


Attach:
Filter capacitor
Polyimide



Au braze @ 1064°C:

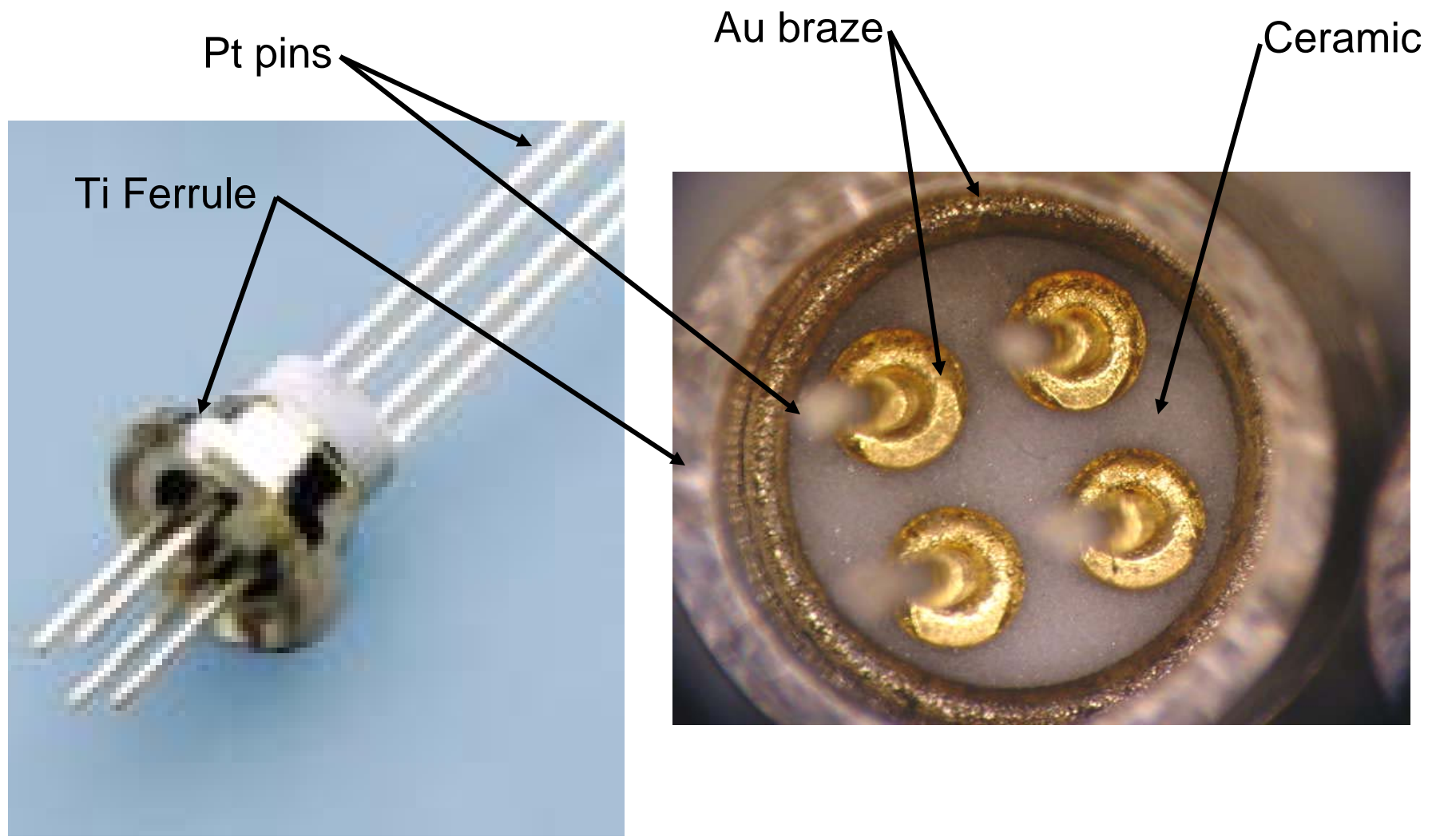
Pt Pins
Ceramic
Ti Ferrule



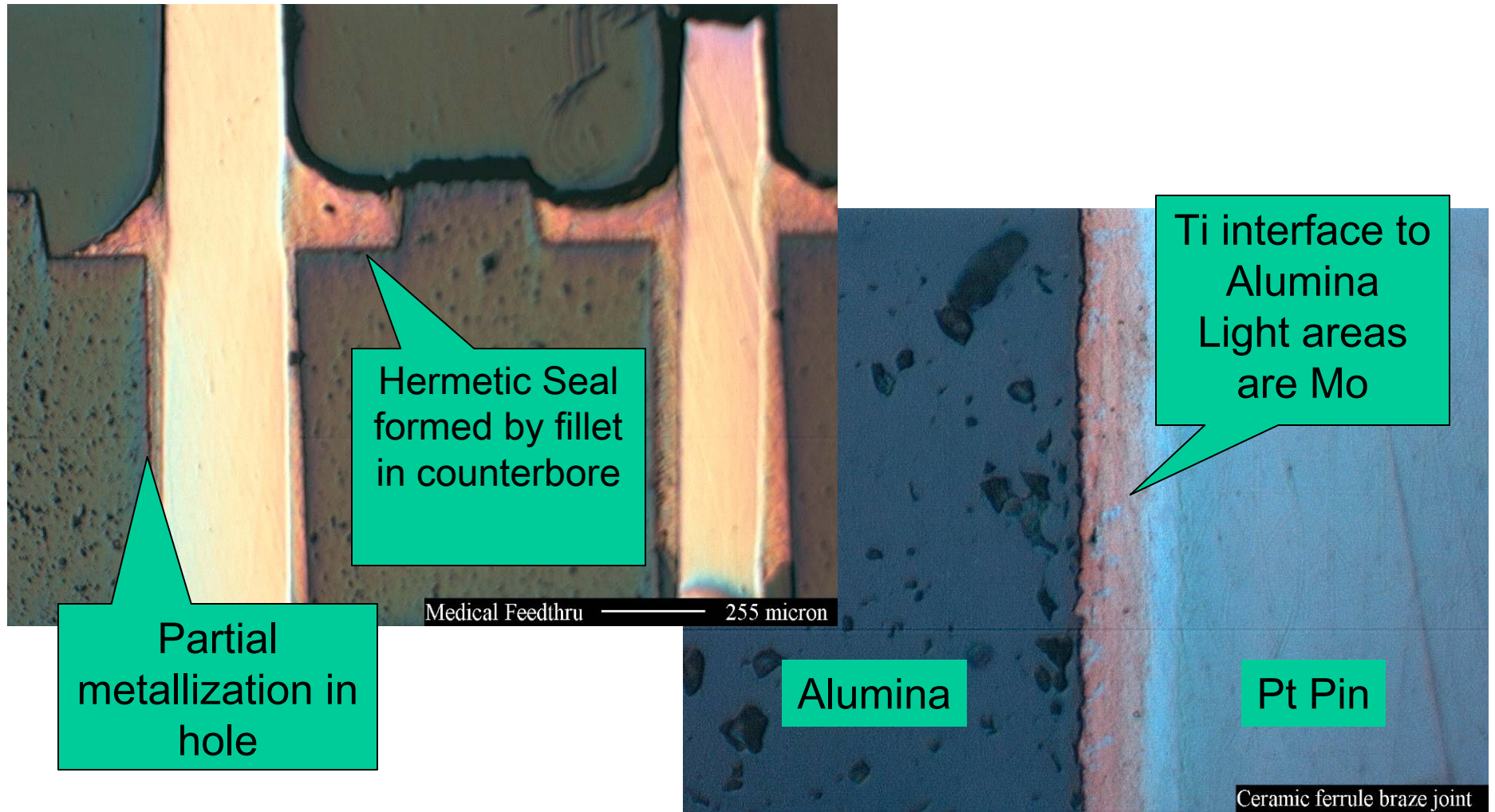
Pre-tin Leads

Biocompatible Metals Used in FT Construction

Material	Density (g/cm ³)	Elongation (%)	Tensile strength(MPa)	Yield strength (MPa)	Elastic modulus(GPa)
cp Ti(Grade I)	4.51	24	240	170(0.2%)	100
cp Ti(Grade II)	4.51	20	340	280(0.2%)	100
cp Ti(Grade III)	4.51	18	450	380(0.2%)	100
cp Ti(Grade IV)	4.51	15	550	480(0.2%)	100
TiAl6V4	4.43	10	900	890(0.1%)	113.8
TiAl6Nb7		10	900	800(0.2%)	100
Au alloys	18.3-19.3	10-18	840	~420(0.1%)	108.2(type IV)
Mo	10.3	5	686-980		324
Pt	21.5		240		168



Feedthrough Construction



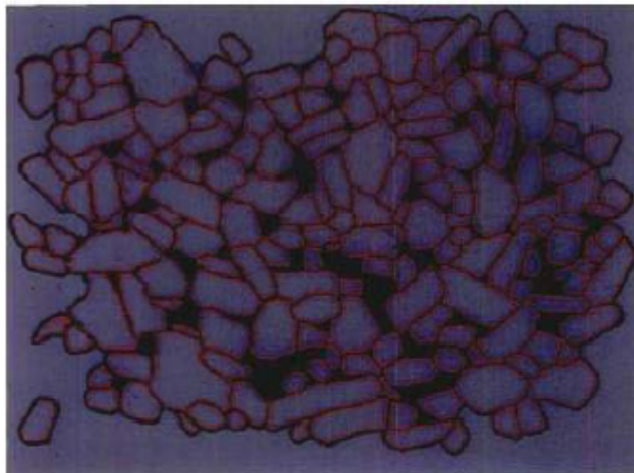
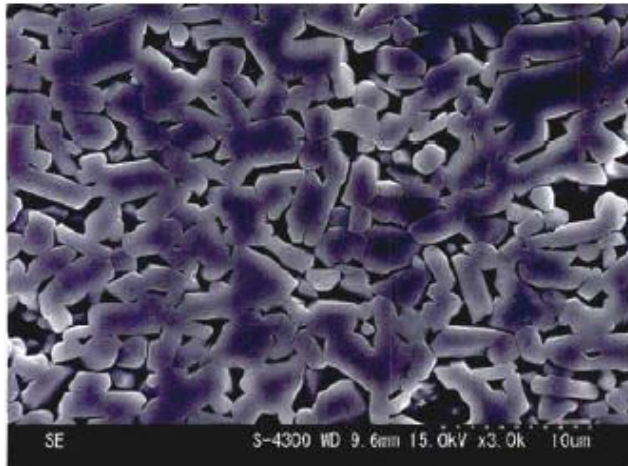
What Factors are Important in Implanted Ceramics?

- Microstructure
- Dimensions
- Surface properties
- Mechanical properties
- Chemistry

Microstructure vs. Firing Conditions

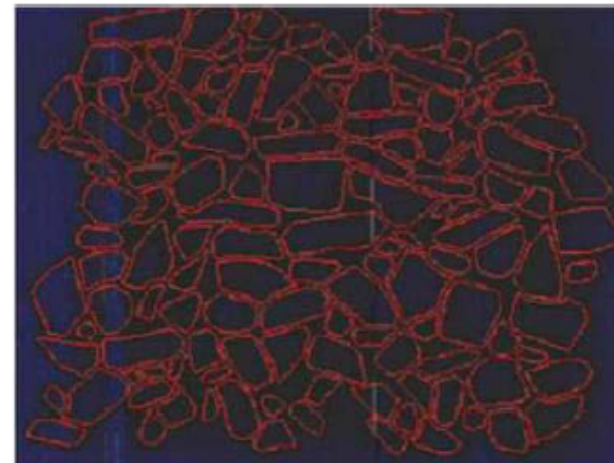
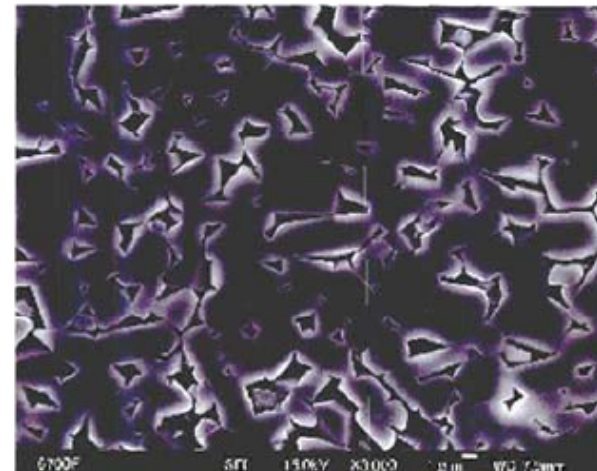
Firing Condition 1

Alumina grain size: 2.10um



Firing Condition 2

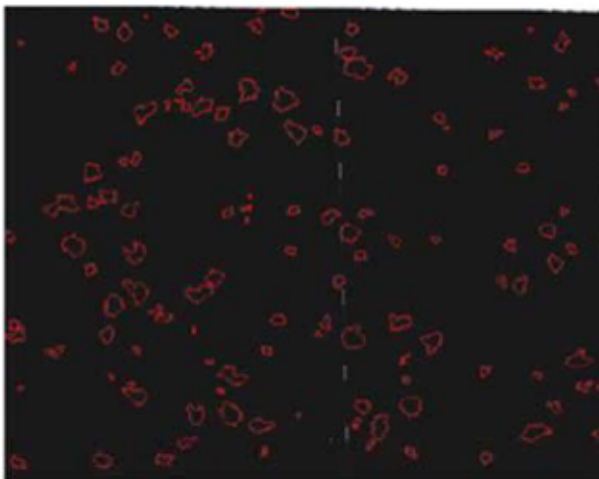
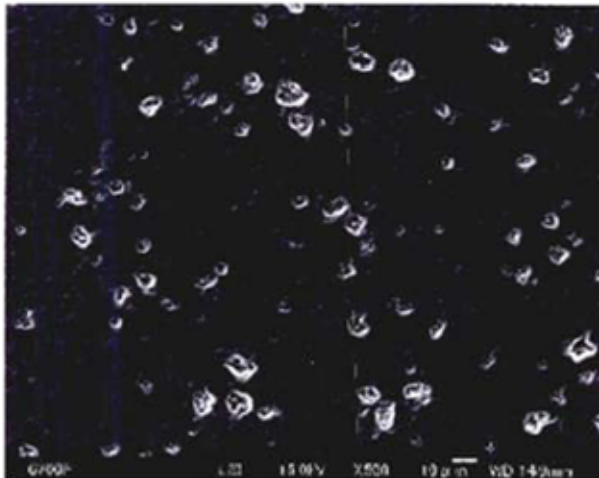
Alumina grain size: 2.46um



Microstructure vs. Firing Conditions

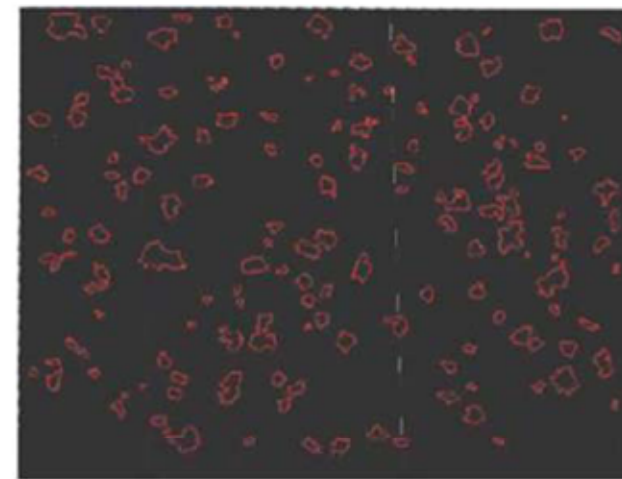
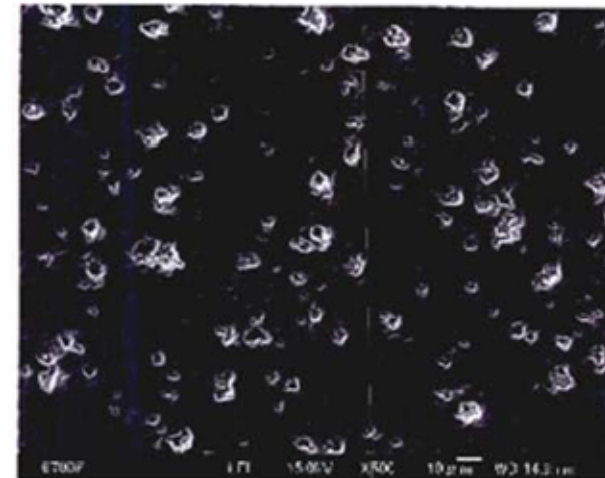
Firing Condition 1

Void rate: 3.7%

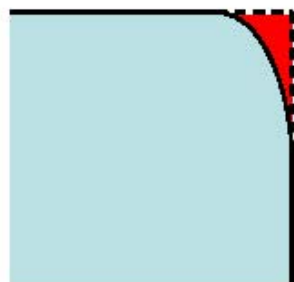
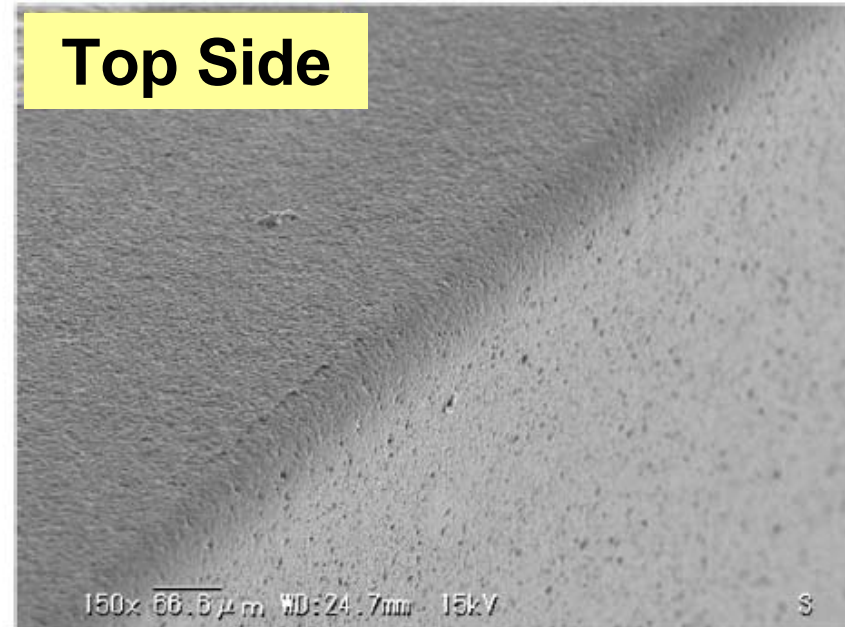


Firing Condition 2

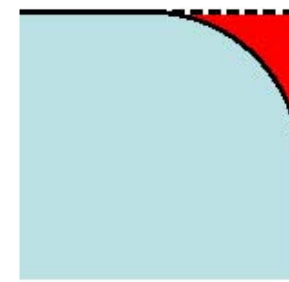
Void rate: 6.8%



Surface Structure and Machining



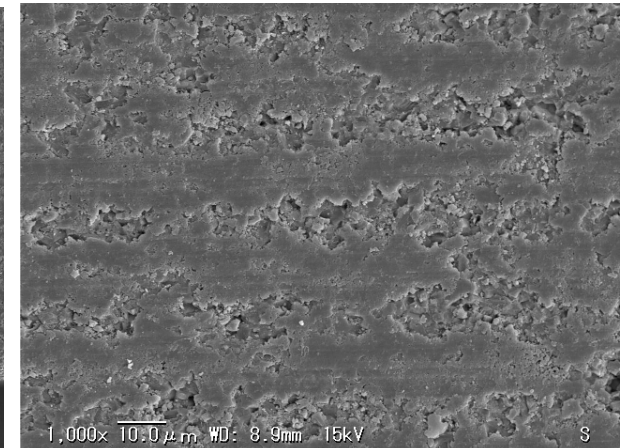
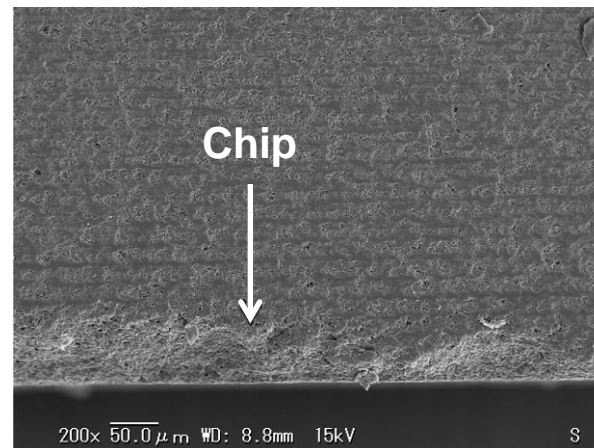
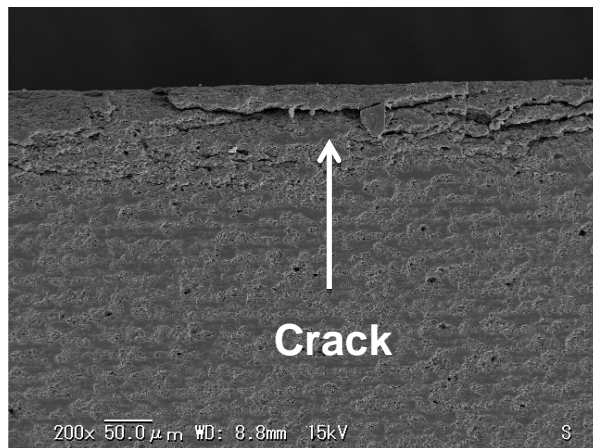
Cross section image



Cross section image

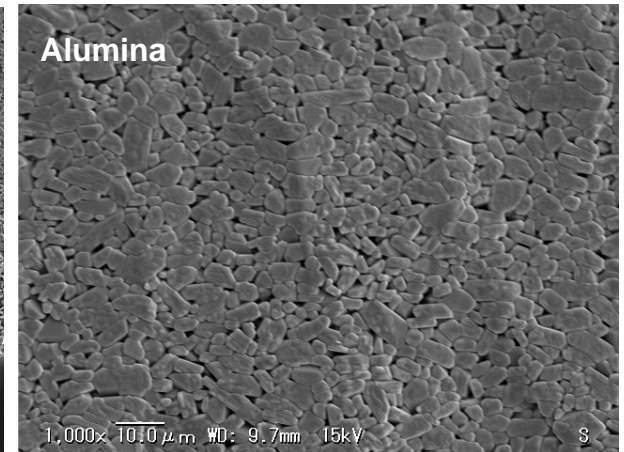
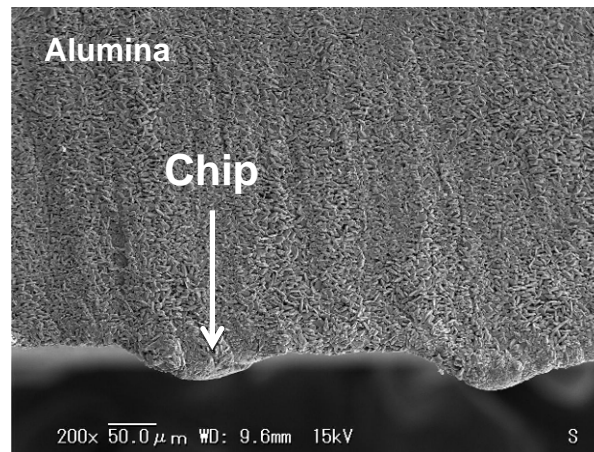
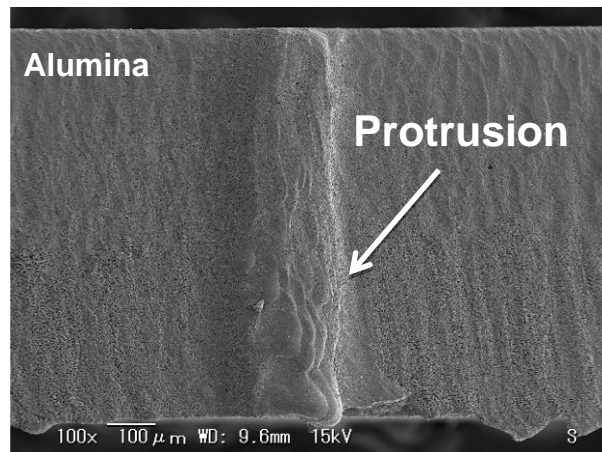
Traditional Grinding

- Well established
- Accurate
- Expensive (slow)
- Prone to introducing defects



Laser Machining

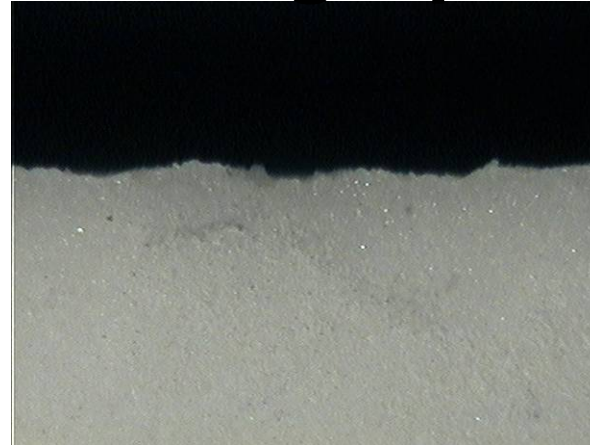
- Convenient means of producing curved surfaces
- Inexpensive
- Prone to rough surfaces and defects



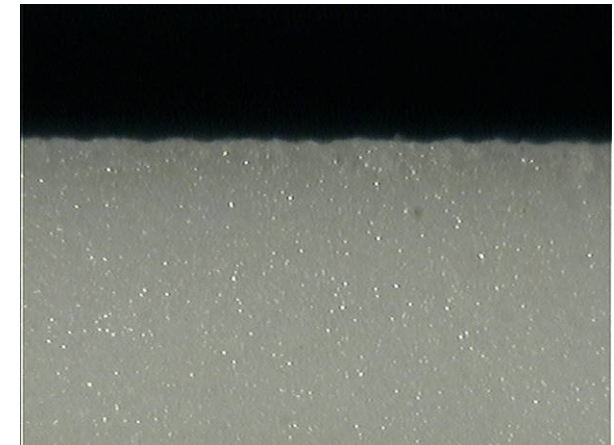
Machining Options



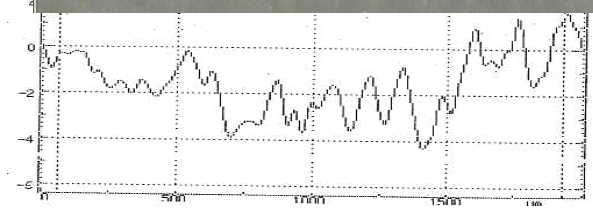
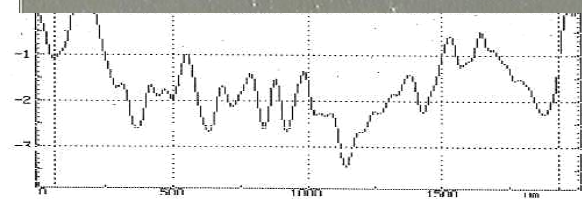
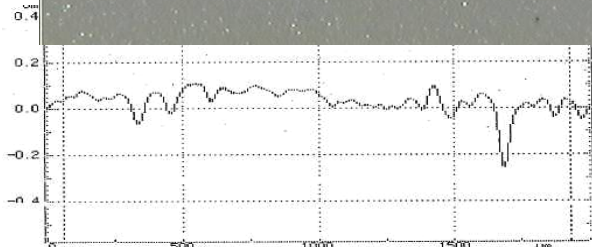
Diced, Ra~0.05um



Green cut, Ra~0.6um

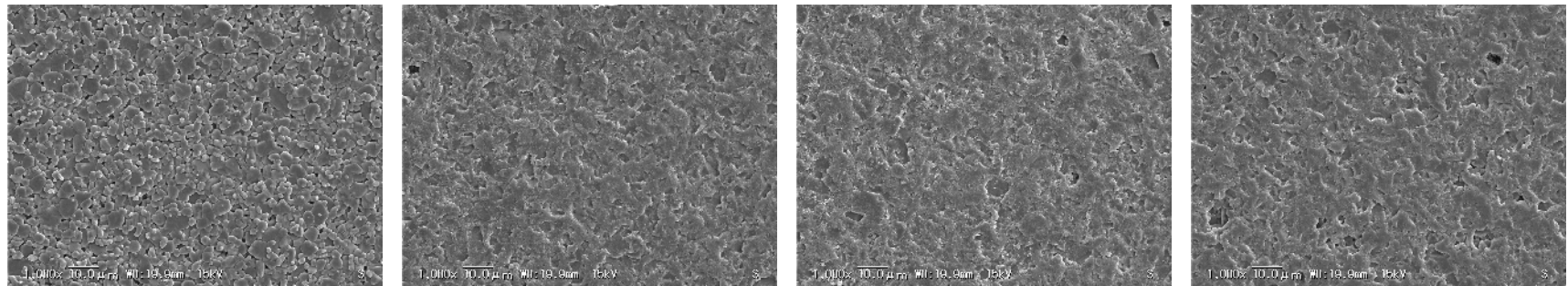


Laser, Ra~1um



Surface Finish – 92% and 96% Al₂O₃

92%



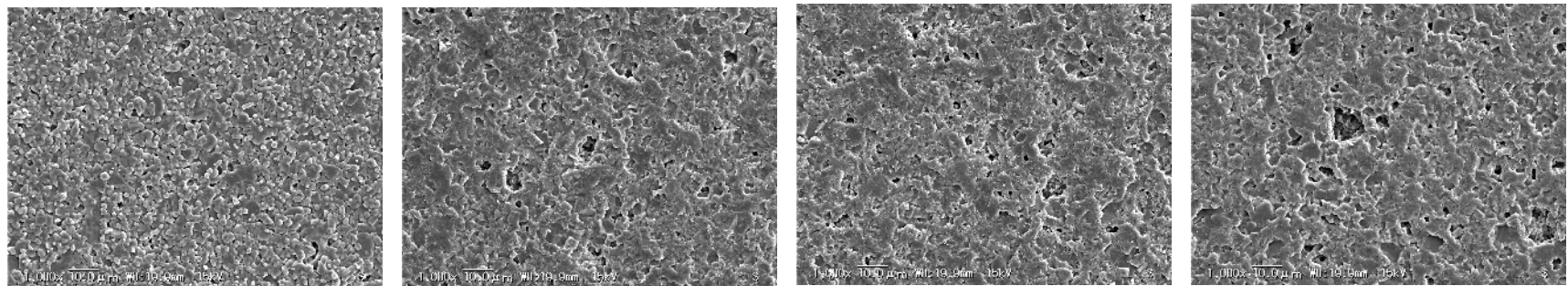
Firing

Forming

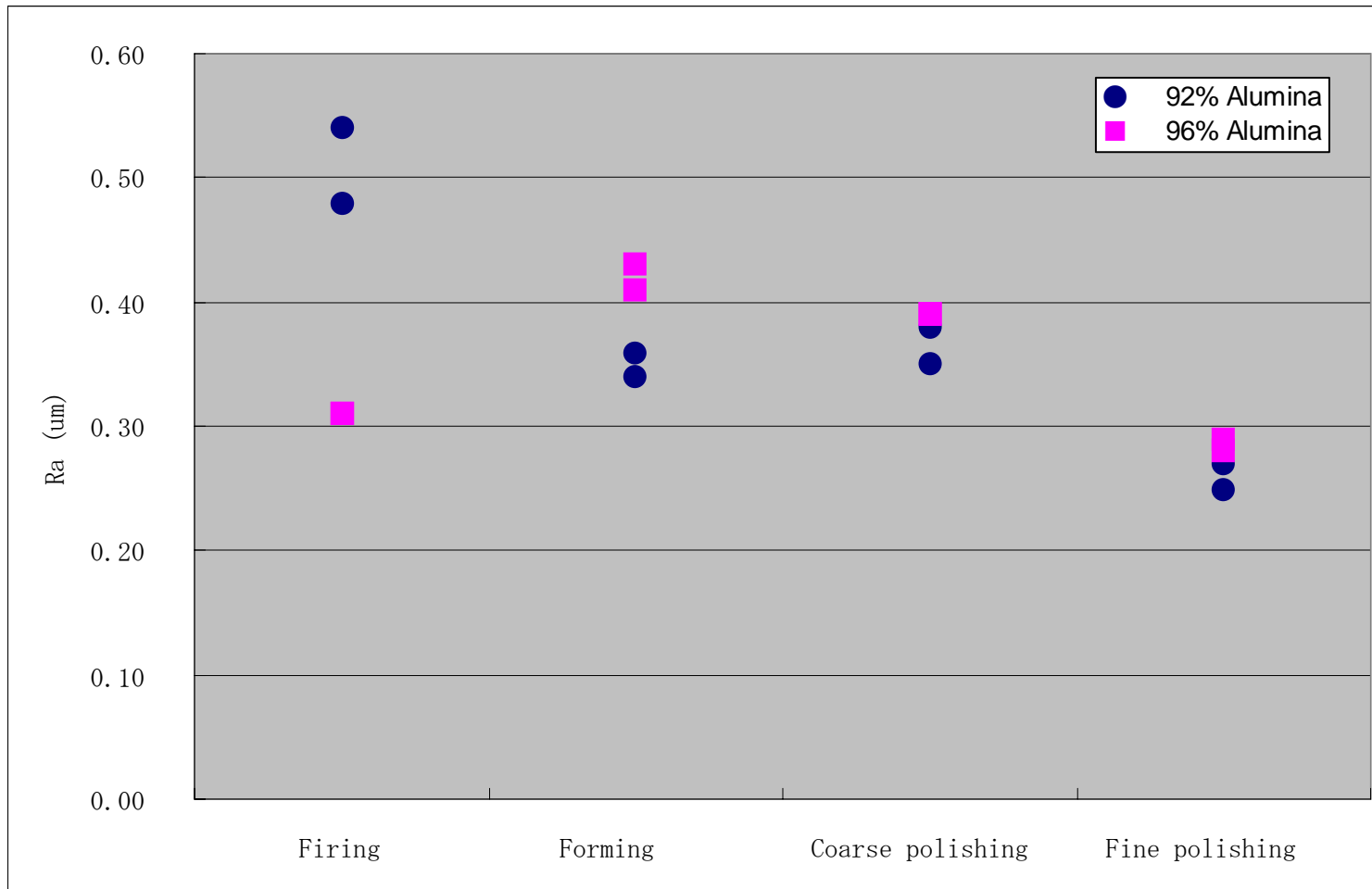
Coarse Polish

Fine Polish

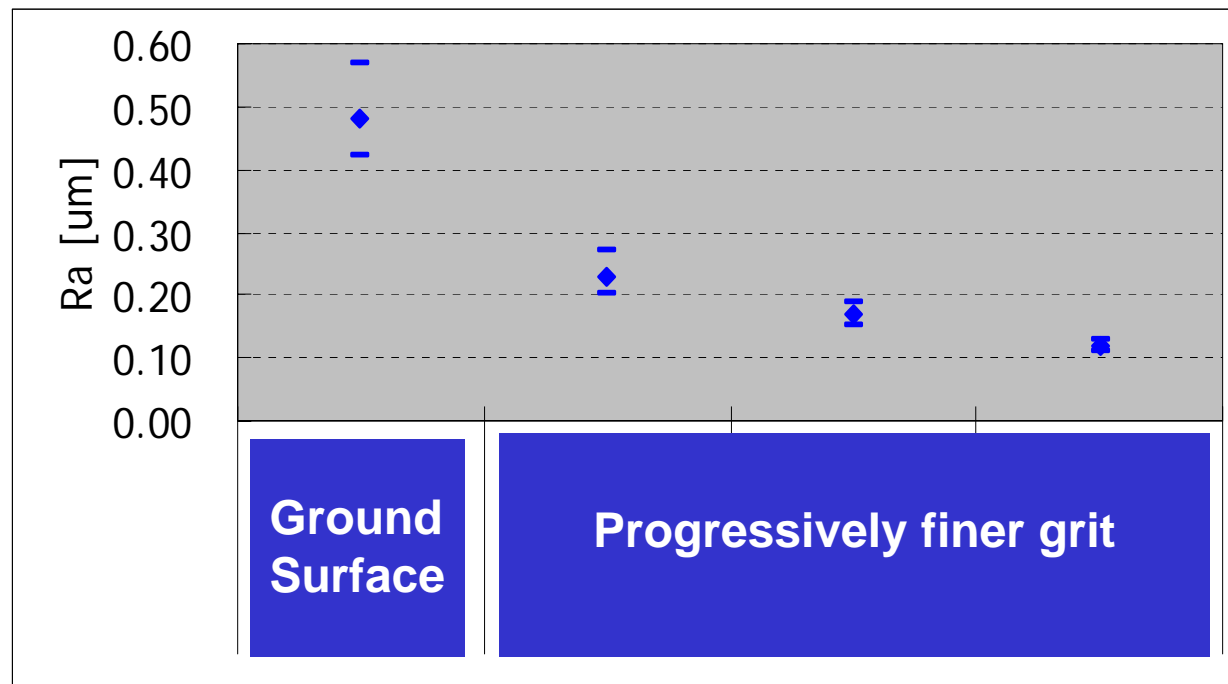
96%



Numerical Data – 92% and 96% Al₂O₃

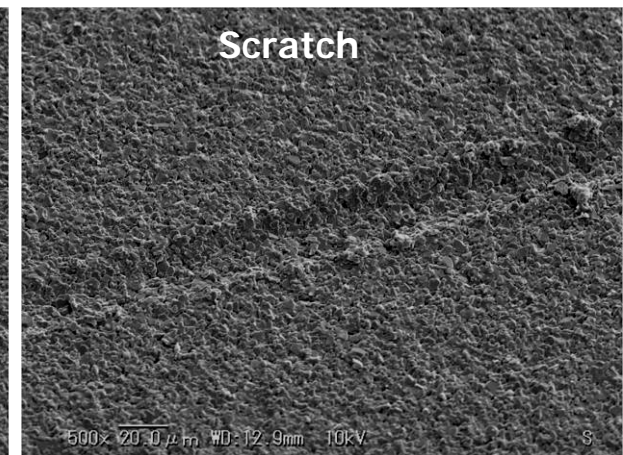
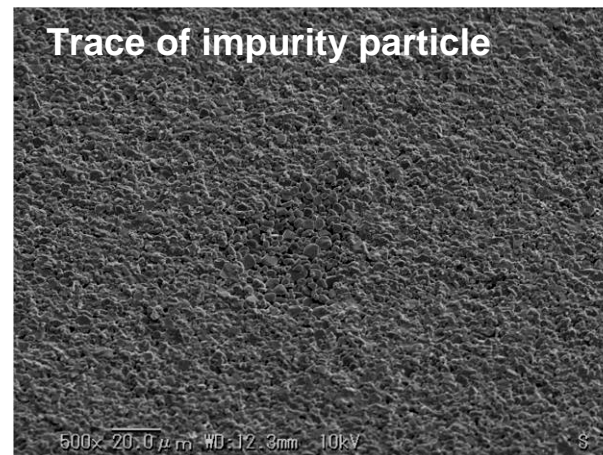


Surface Roughness – Extensive Polishing



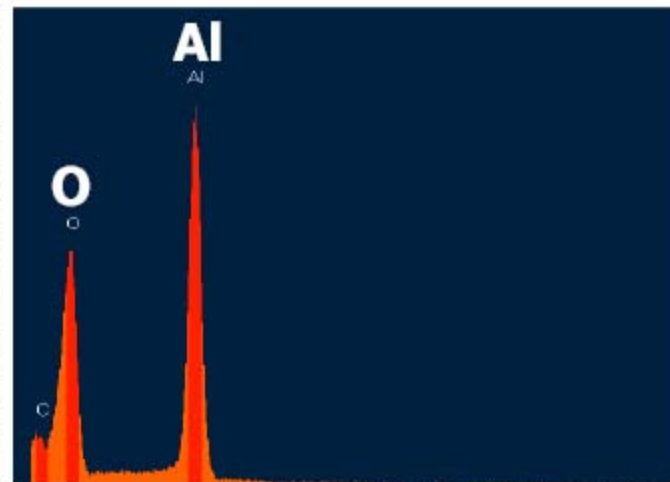
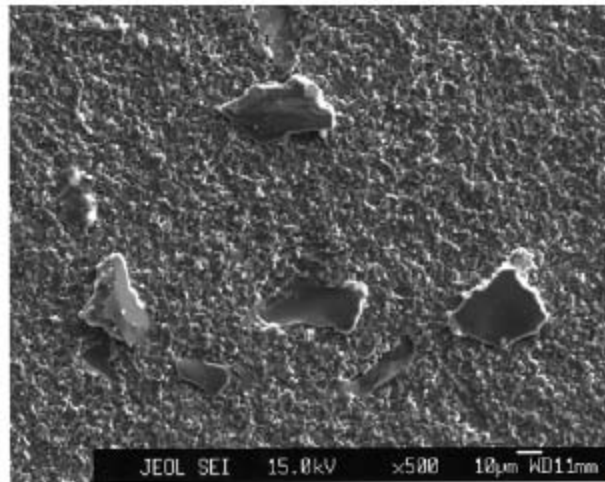
Firing Defects

- May result from ceramic, binders, handling, firing, atmosphere, etc.
- May or may not be removable

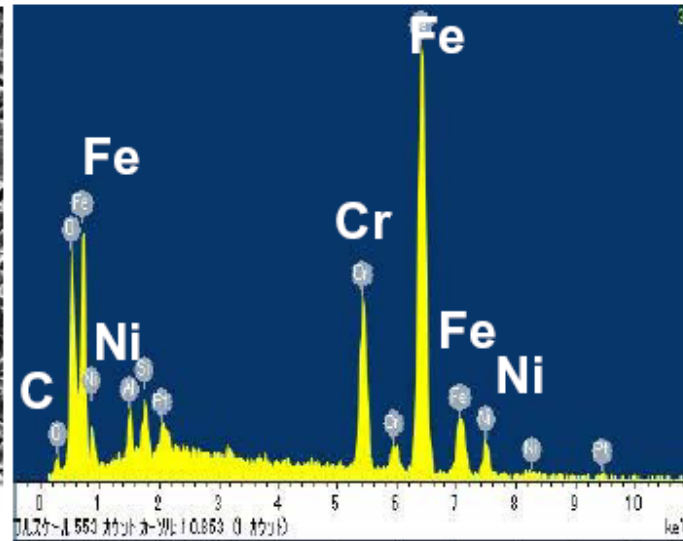
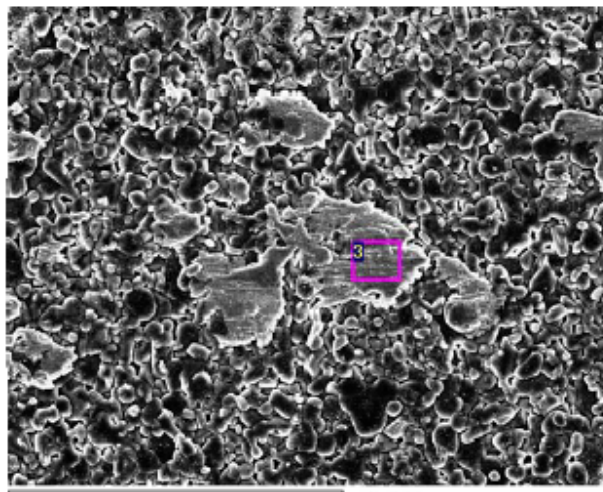


Foreign Materials

Firing

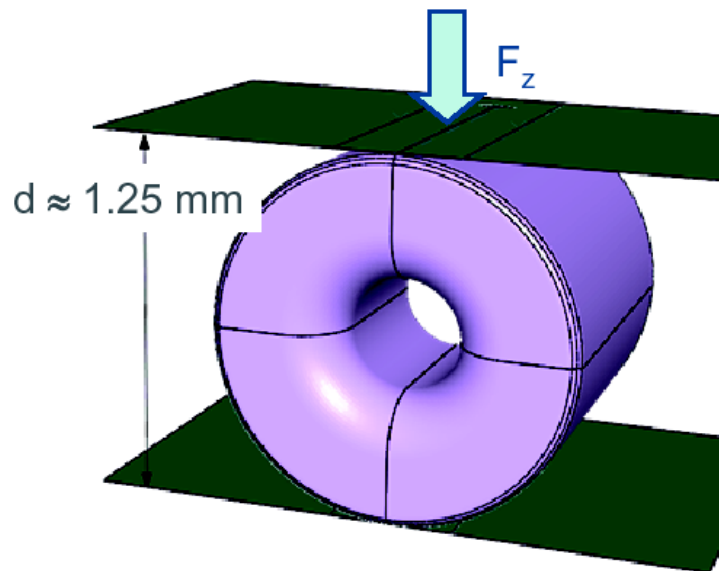


Machining



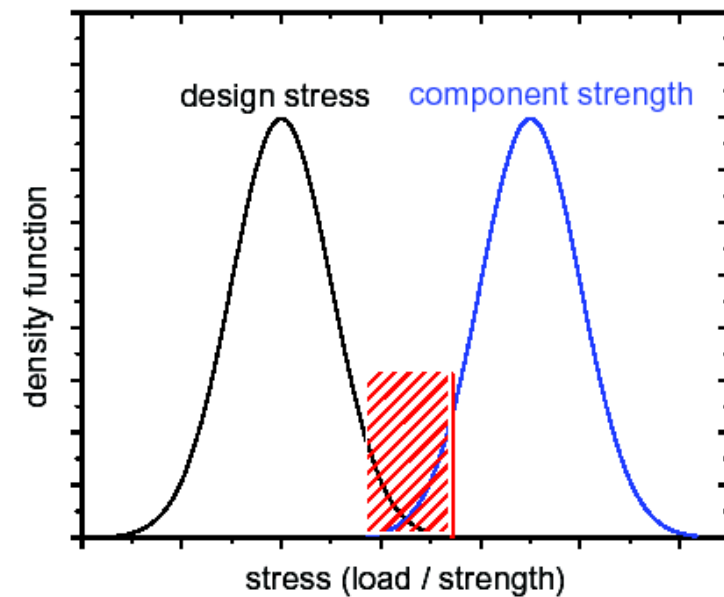
SEM Image

Mechanical Evaluation of Medical Ceramics*



Small cylindrical part with hole in “diametral compression test”

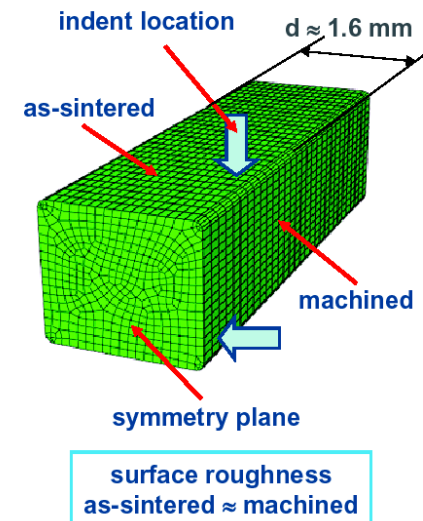
- Sample prep challenging
- Meaningful samples?
- Difficult to characterize



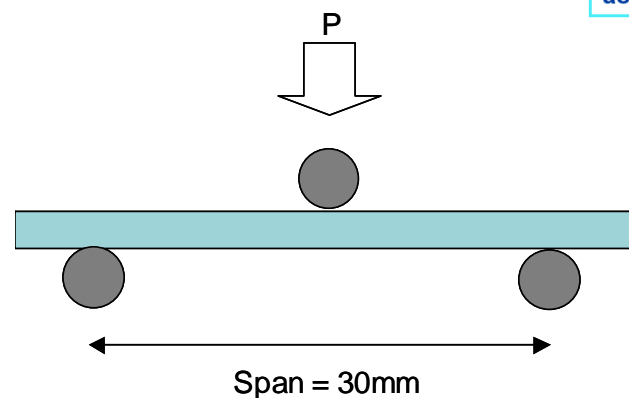
- Avoid overlap
- Acceleration factors?
- Incorporate data and modeling

There are Many Measurement Methods

- **Indentation / Thermal Shock**
 - Allows measurement of “real” parts



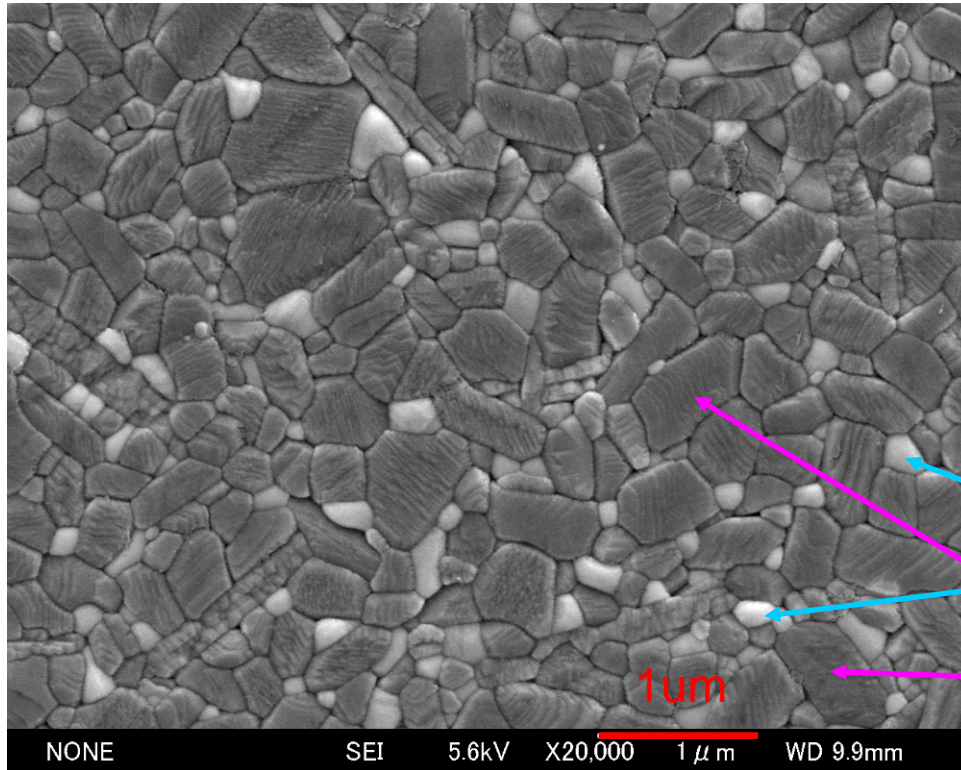
- **3- / 4-point bending**
 - Traditional methodology
 - Machined samples



BIOCERAM® **AZ209**



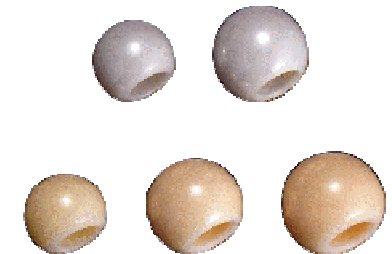
Microstructure of **BIOCERAM® AZ209**



	Al ₂ O ₃	ZrO ₂
Average grain size (μm)	0.28	0.18
Areal fraction (%)	86	14

Zirconia

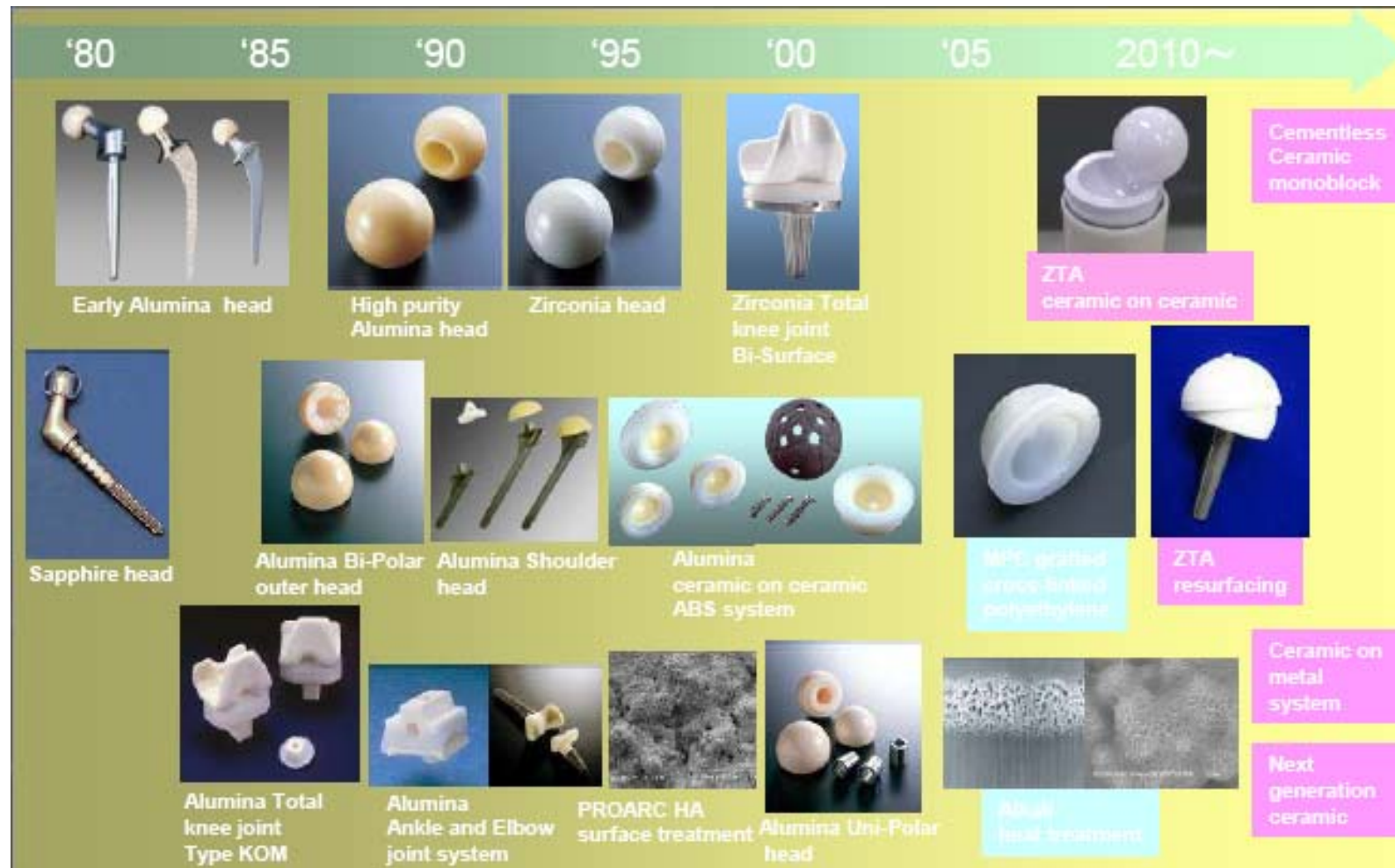
Alumina



Optimized microstructure contributes excellent properties
 ↑ **selected by best alumina / zirconia ratio**

- **Very fine grains (Alumina, Zirconia <1μm)**
- **Homogeneous dispersion of fine zirconia grains in alumina matrix**
- **No voids or agglomeration**

Kyocera's Bioceramic Development

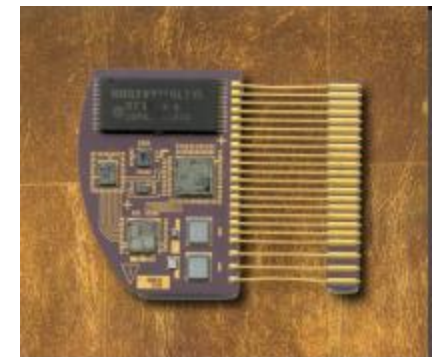
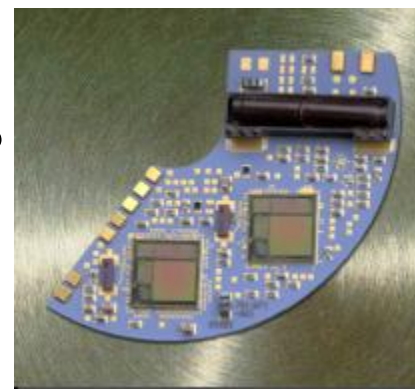


Implanted Cofired Substrates

- Control substrates
- Direct body exposure?
- Drug delivery

Control Substrates

- Not directly exposed to body fluids
 - Biocompatibility not required
- Thick Film hybrid
- HTCC
- Migrating to Organics (cost-driven)



Biocompatibility Assessment – Direct Body Exposure

Surface Devices

External communication

Implant

<1 day

1 – 30 days

>30 days

Biocompatibility: ISO-10993 (Based on intended use)

- **Materials characterization: 10993-14**
 - TGA, STA, DSC
 - Chemistry
 - Extraction
 - Chemical composition
 - Trace element composition
- **Cytotoxicity: 10993-5**
 - Incubation (mouse cells)
- **Intramuscular implantation (rabbit): 10993-6**
 - Short and long term

Chemical Composition – Multilayer Materials

- Typical formulations:
 - 99%: Metallized, thin film
 - 96%
 - Monolithic
 - Cofired
 - 92% - Cofired
 - 90% - Cofired

Cofired Alumina Ceramics – Impurities/Additives

<u>Grade</u>	<u>Color</u>	<u>Additives</u>	<u>Impurities</u>
96%	White	MgO, SiO ₂ , CaO	Cr, Sc, Y, Mn, Cd, Pb, Hg <5ppm
92%	White	MgO, SiO ₂ , CaO, ZrO ₂	Cr, Sc, Y, Mn, Cd, Pb, Hg <5ppm
92%	Black	MgO, SiO ₂ , CaO, Na, Mo, W, Cr	Sc, Y, Mn, Cd, Pb, Hg <5ppm
90%	Black	MgO, CaO, Ti, Cr	Si, Sc, Y, Mn, Cd, Pb, Hg <5ppm

Metallization Chemistry

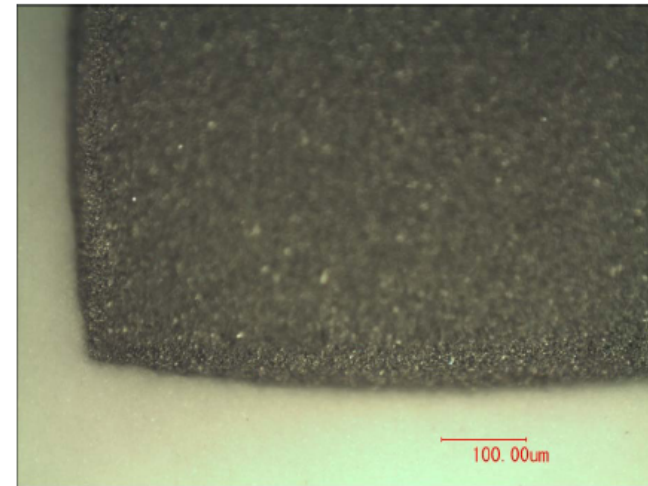
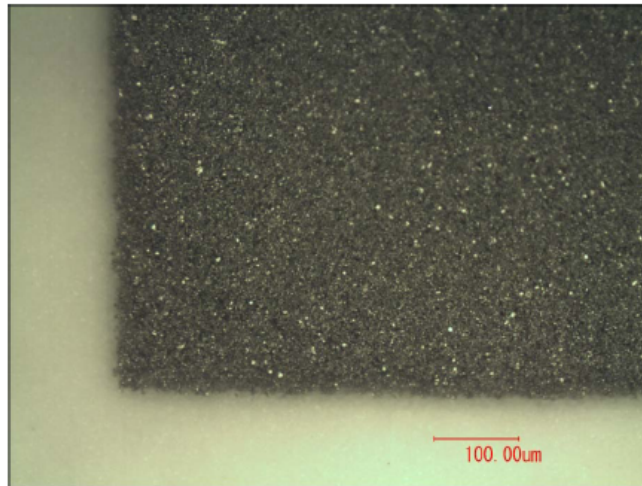
- Standard cofired metallization:
 - W/Mo with Ni/Au plating
- Precious metal conductors
 - Ag
 - Au
 - Pt
 - Cu
- Thin film
 - Too numerous to mention

Surface Metallization Quality

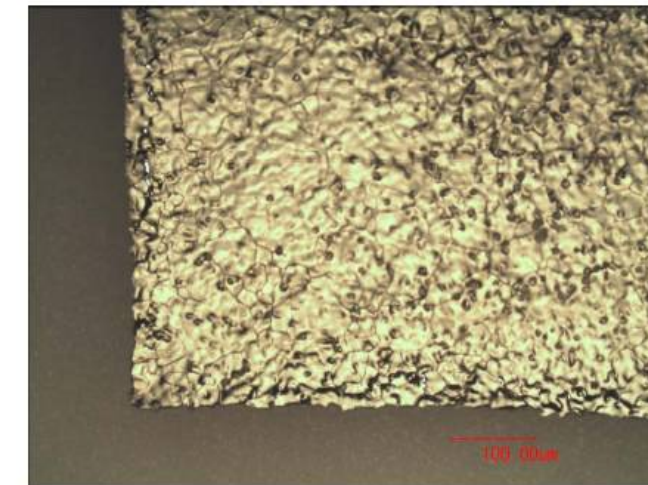
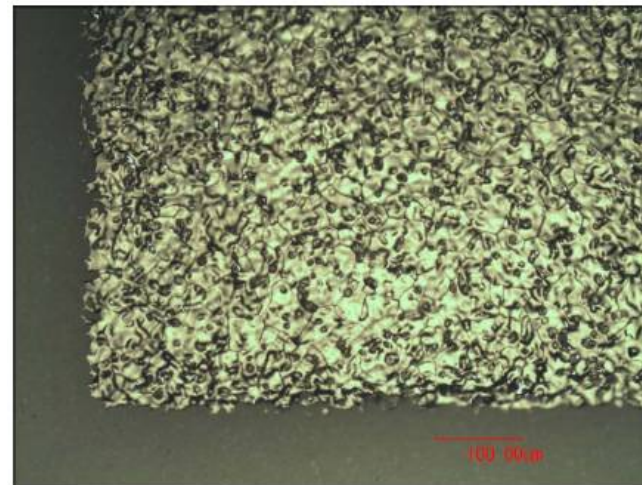
Condition A

Condition B

Printing



Firing



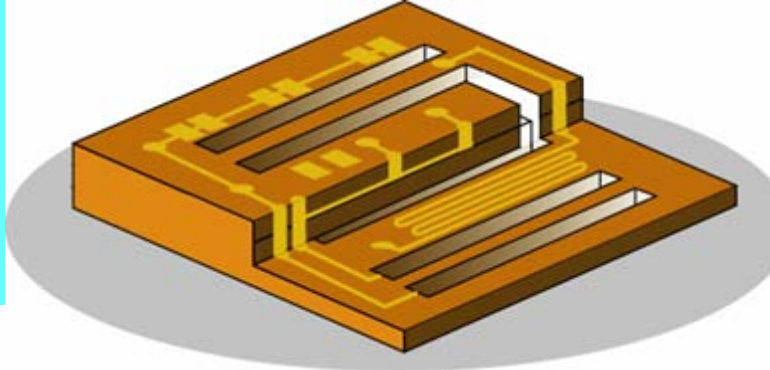
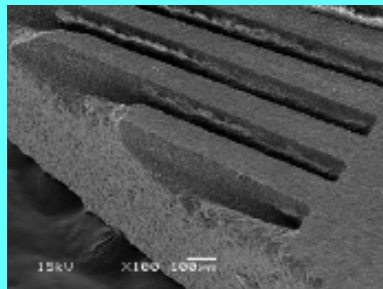
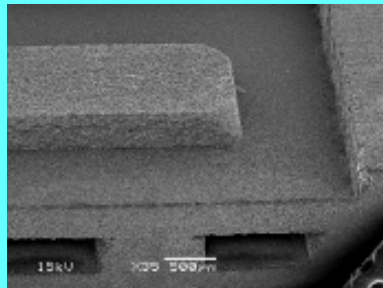
Via Integrity



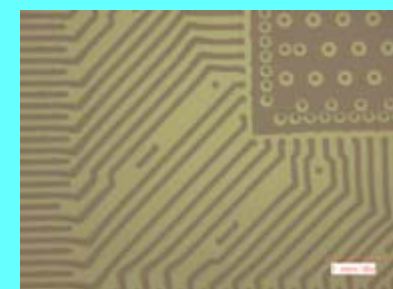
Microfluidics for Drug Delivery, Pumps, Sensors, etc.

Combination of “plumbing” and “electrical” functions

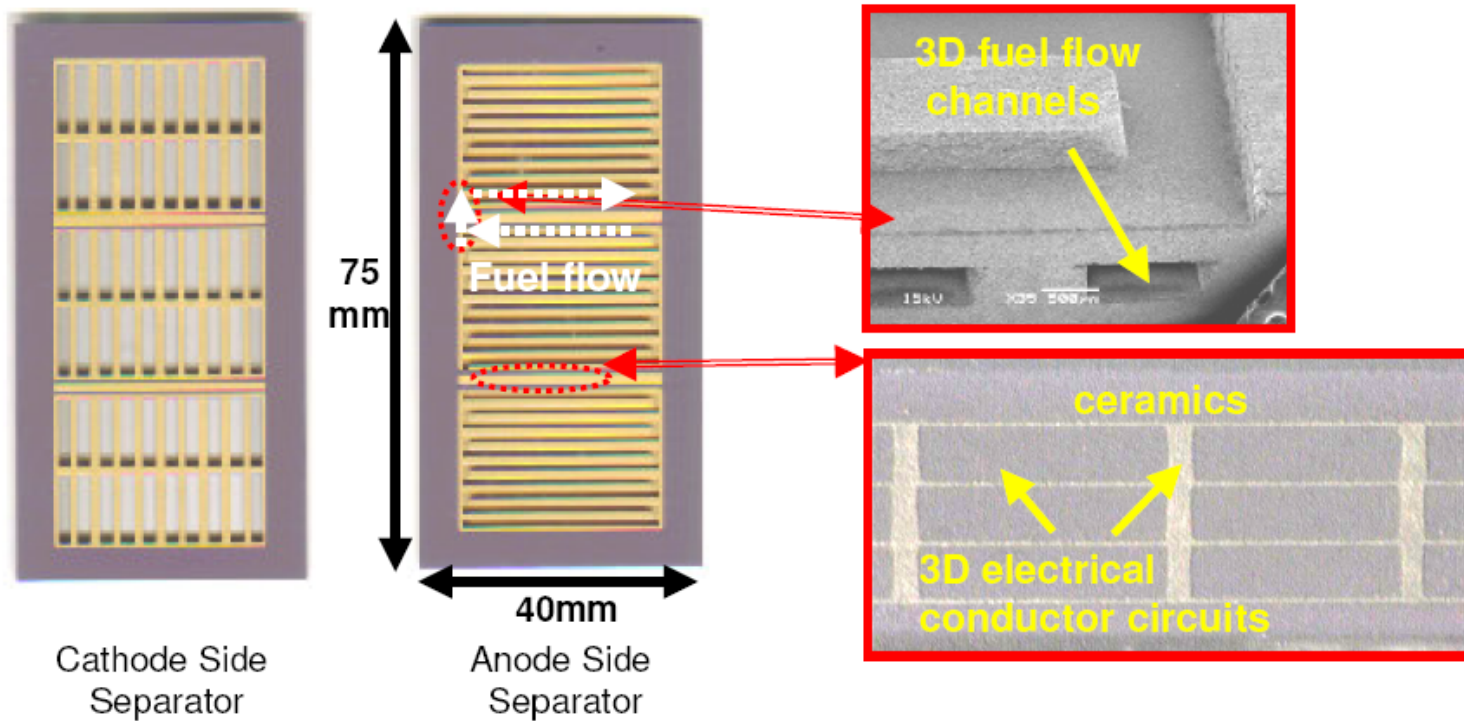
Fluid Channels



Electrical Circuits

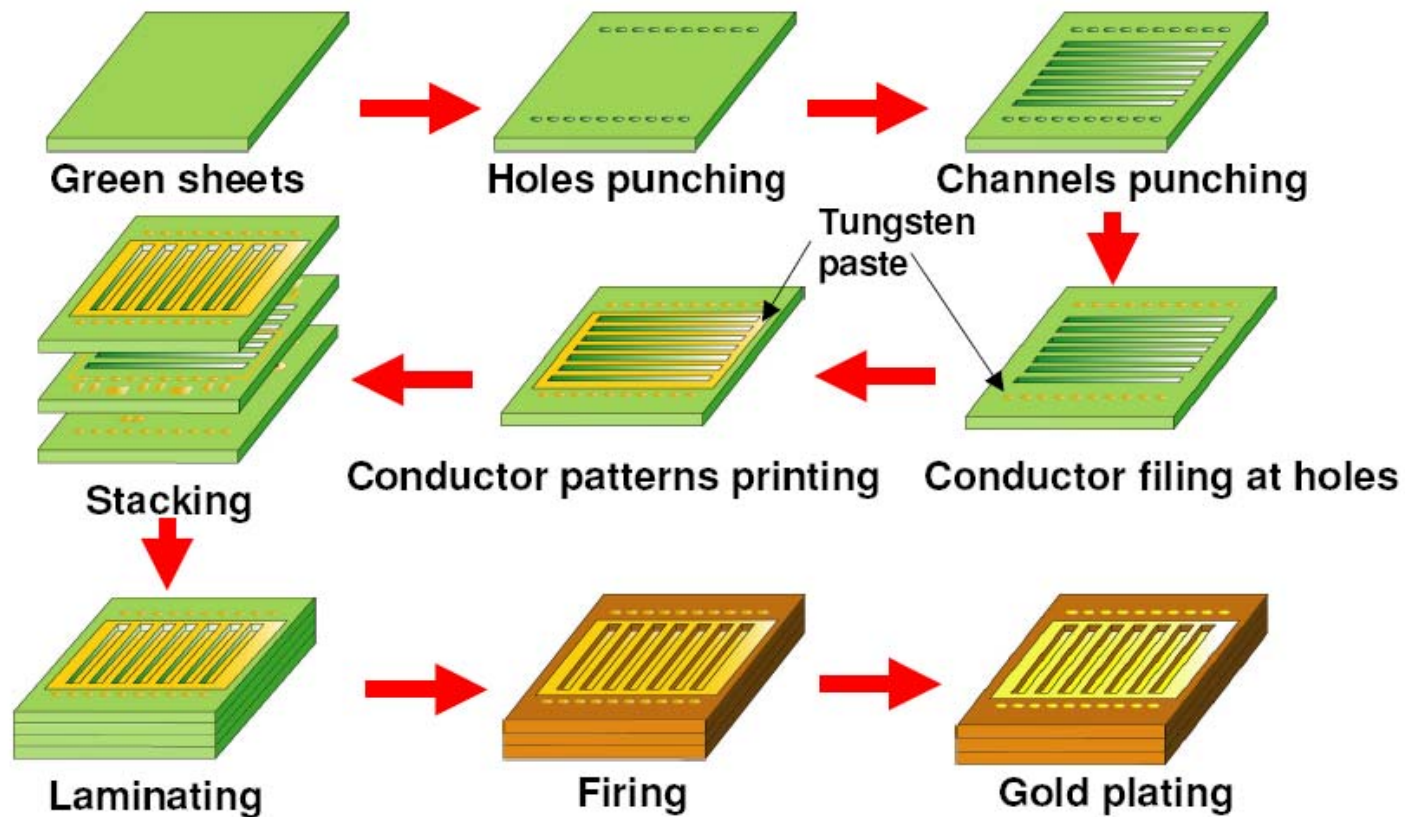


For example – Fuel Cell Substrate

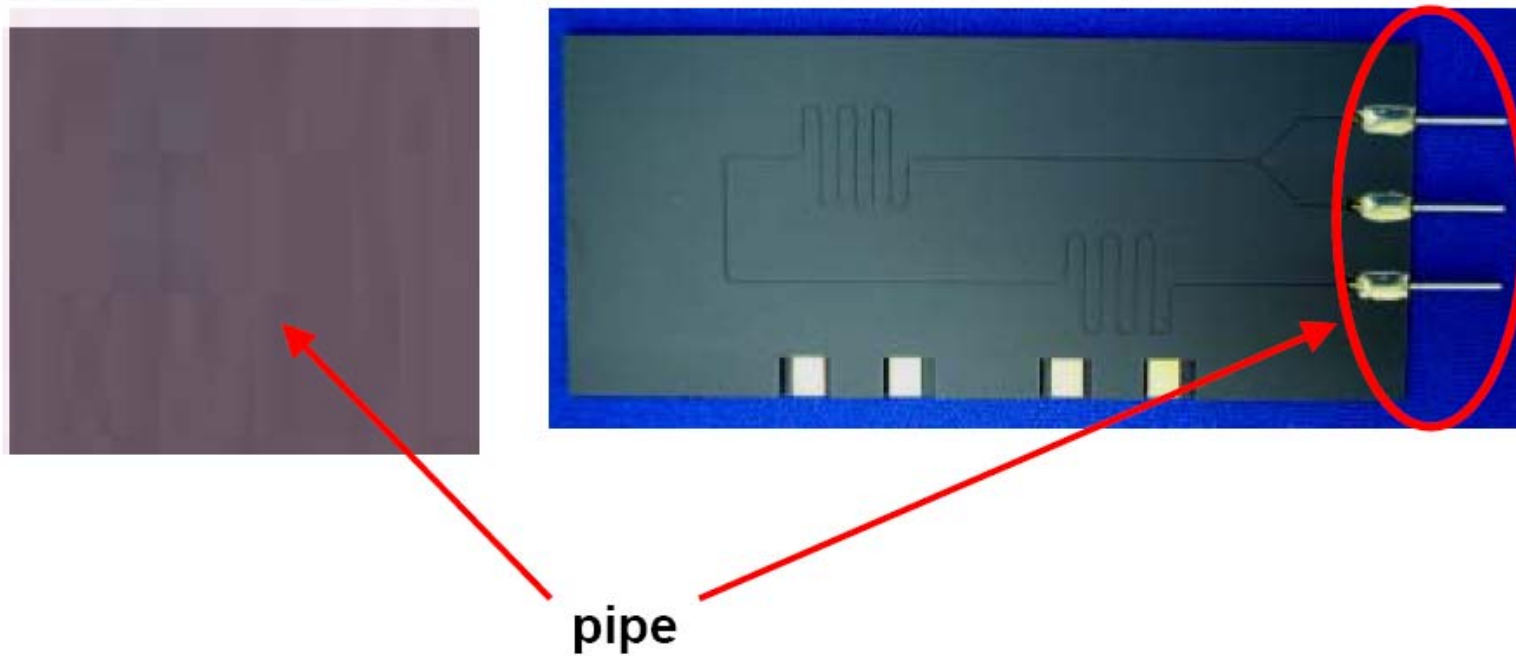


Fuel flow channels
Electrical conductor circuits } *Flexibly designed*

Typical Process Flow



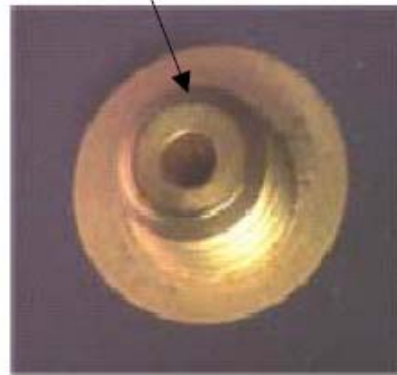
Built-In Pipes



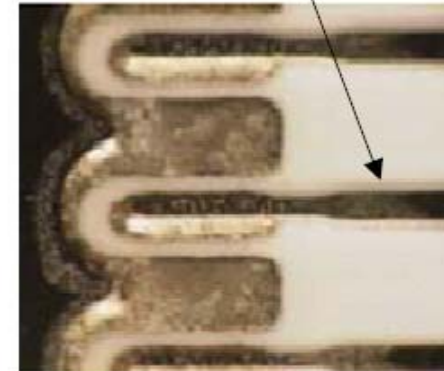
Additional Functionality - Heaters

**Metal Terminal
Pipe Connection**

Metal Pipe

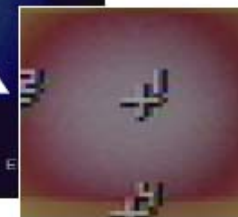
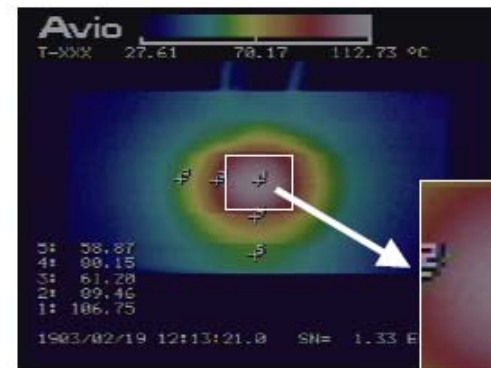
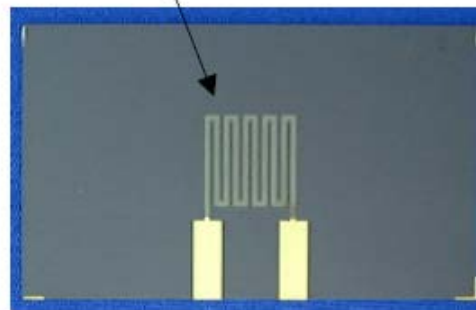


Metal Lead



Built-in Heater

Heater Pattern

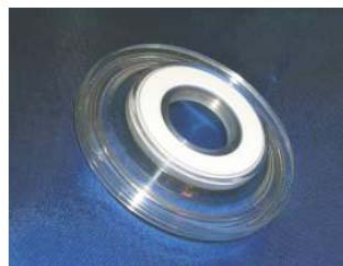
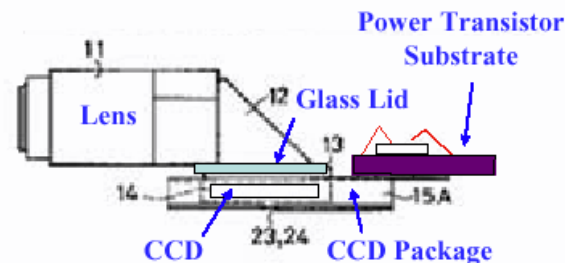
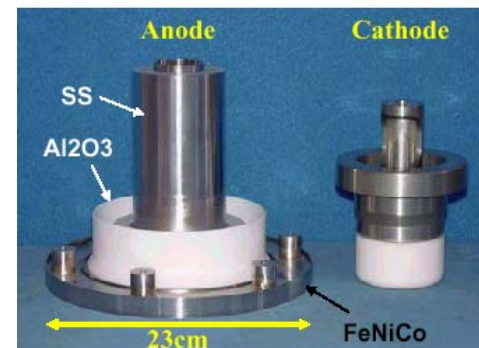


Other Medical Products

- Standard electronic substrates
- Specialized components
 - CT scanners
 - LINEAC
 - X-Ray tubes
 - Photodiode arrays
 - Endoscopy
 - Haemonetics



LightSpeed VCT



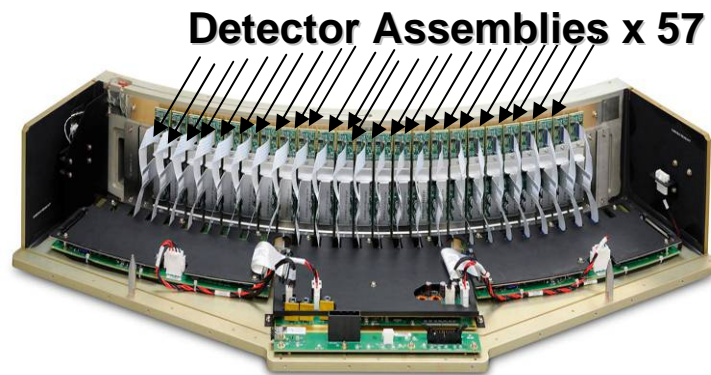


Photodiode Assembly

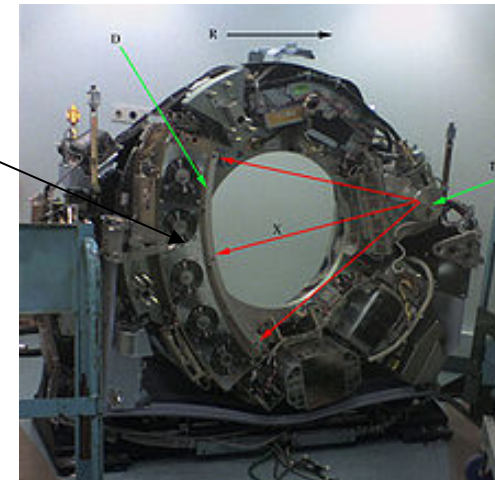
- Assy
- Flex
- Photodiode
- Ceramic

Detector

Gantry

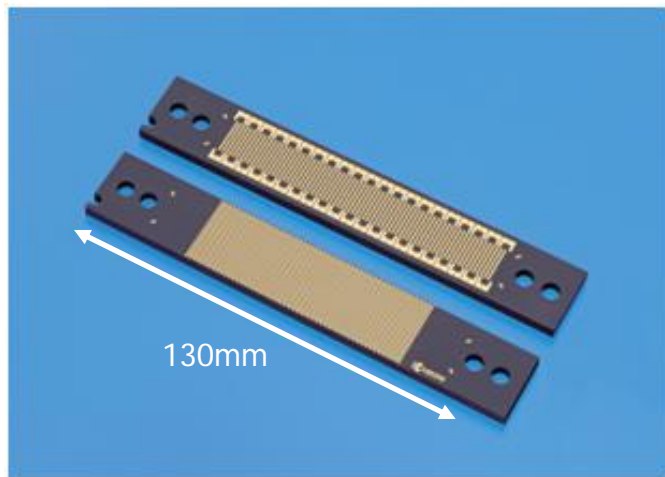
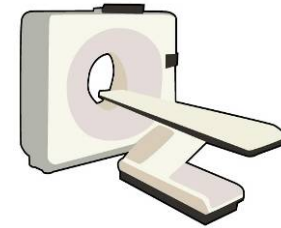


Detector



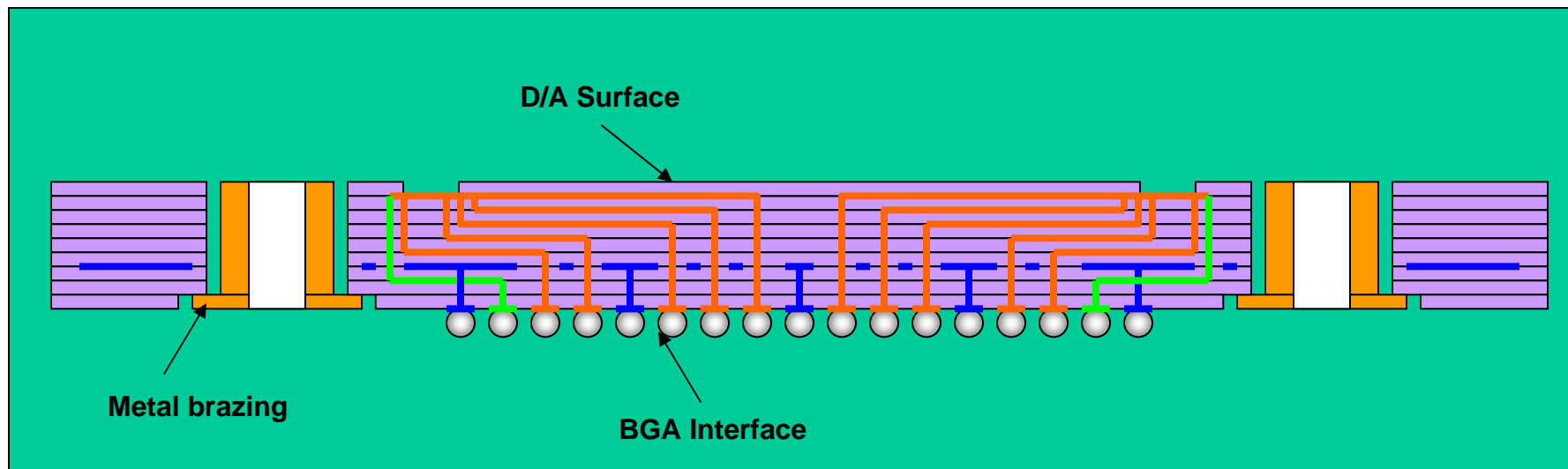
<http://www.analogic.com/products-medical-computer-tomography-integrated-gantries.htm>

X-Ray Sensor Substrate

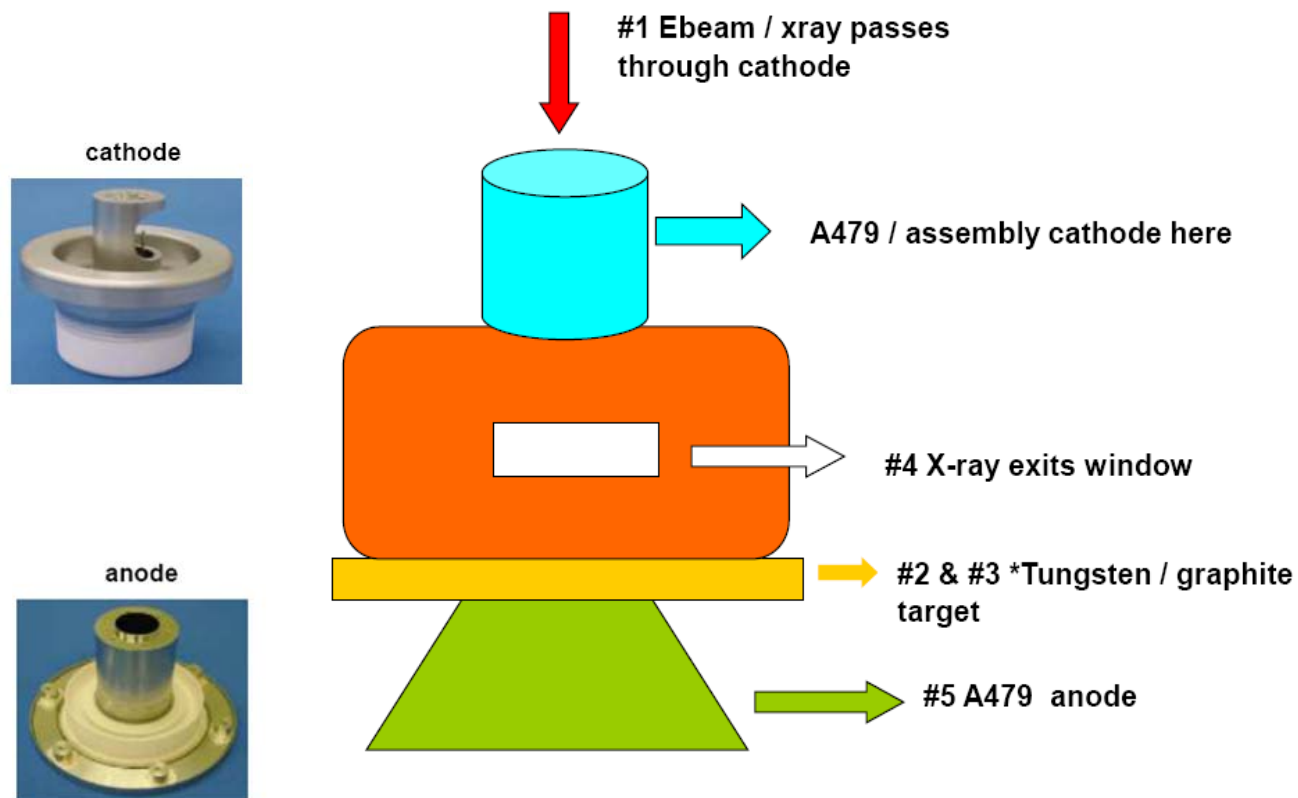


Features:

- High Mechanical Strength
- Good Flatness with surface grinding.
- Good Pattern Accuracy
- High Thermal Dissipation (Alumina 14W/mK, AlN 150W/mK)
- Large-scale PD can be Mounted (CTE Matching to PD)



X-Ray Tube



Rough X-Ray “Flow”

- #1 xray / ebeam pass through cathode.
- #2 ebeam hits target.
- #3 X-ray generated from target.
- #4 X-ray exits window.
- #5 anode holds target – spins @ 6k rpm.

Why ceramic?

- Target focal spot temp is 2,200 C.
- Anode temp is 1,200 C.
- Cathode temp is 500 C.
- Gantry pulls ~ 14 G's had to move away from glass.

In the future...

- Nanostructures:
 - Targeted delivery
 - Drug therapy
- Integrated antennae
- Improved composites

Conclusions

- Ceramics offer many advantages in medical applications
- Packaging remains critical for high reliability and performance
- Fabrication can be a “deal-breaker”
 - Specifications
 - Process
 - Cost