A Wafer-Based, 3-D Metal Micro-Manufacturing Technology for Ultraminiaturized Medical Devices

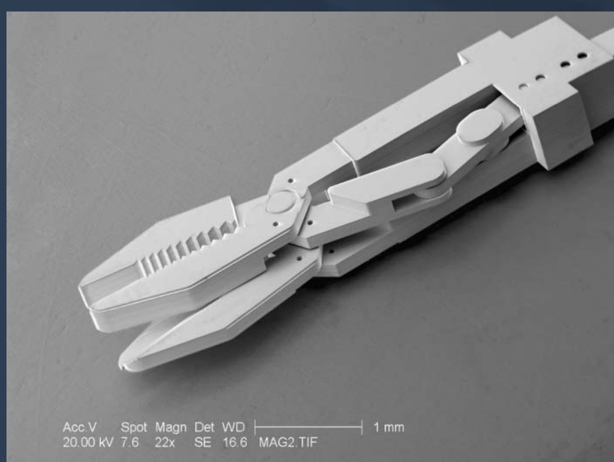
IEEE EMBS

October 2008

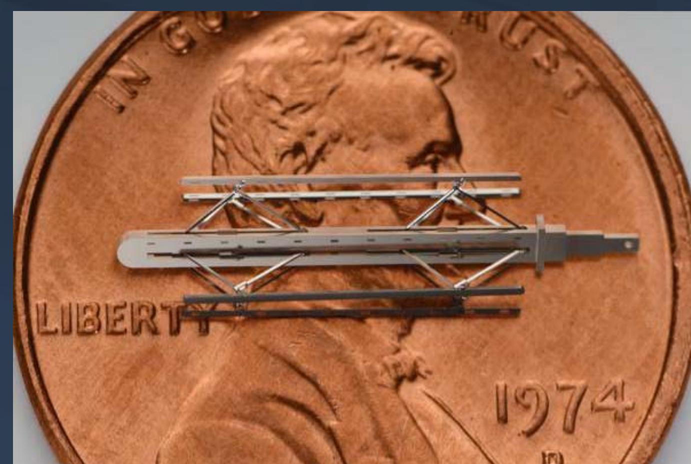
Microfabrica™

What is EFAB Technology?

- Unique, ultra-precision freeform metal manufacturing technology
- Multi-layer process builds unlimited variety of complex, micro to millimeter scale devices, subsystems, and components



Multi-function endoscopic tool



4-direction expander

Microfabrica™

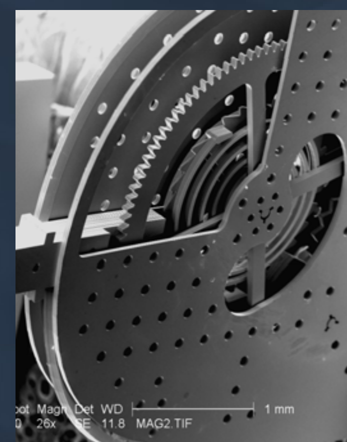
EFAB Technology

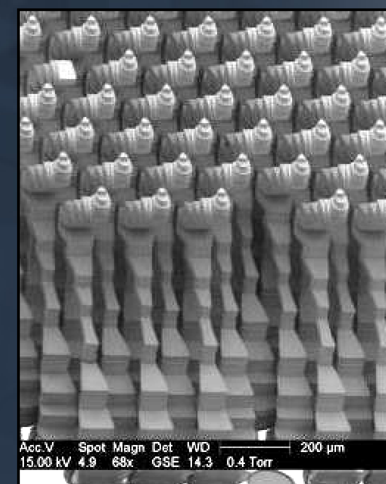
- Creates dynamic, intricate, 3-D metal devices with flexibility & robustness unheard of in the MEMS world – no assembly required

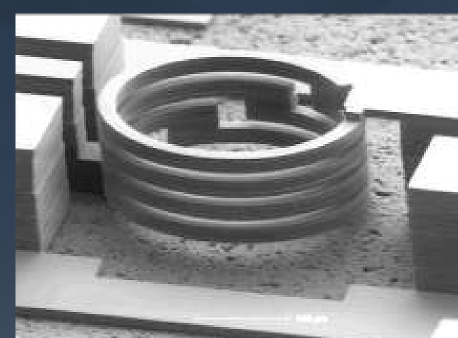
- Real-world, mm-to-cm scale devices with micron precision features

- Enables a large variety of miniaturized mechanical & electrical systems otherwise impossible or impractical to build

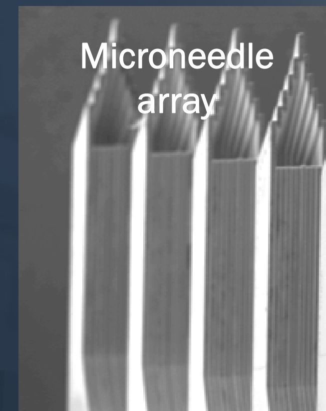
- One-of-a-kind, heavily patented process
  (>200 patents/applications)

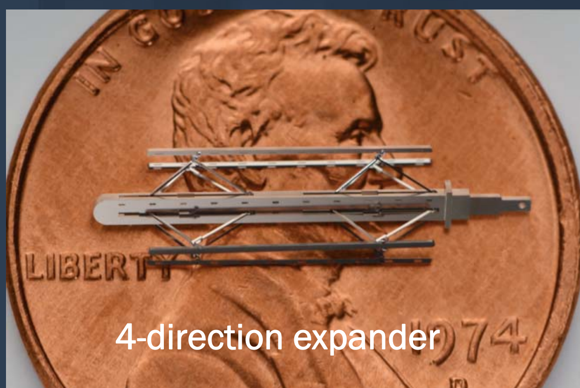


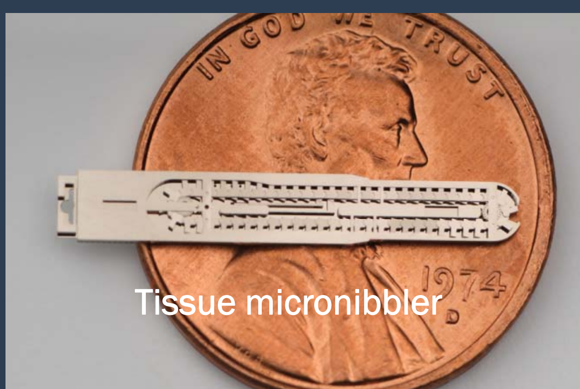


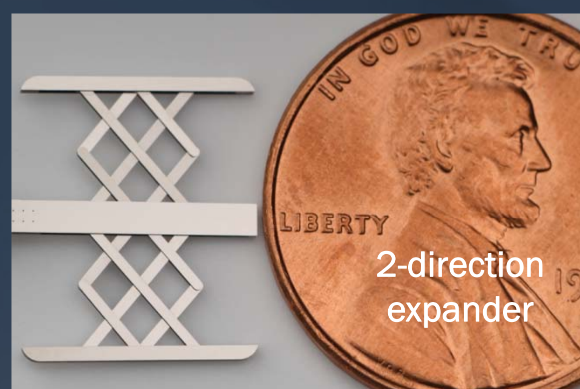


EFAB Devices



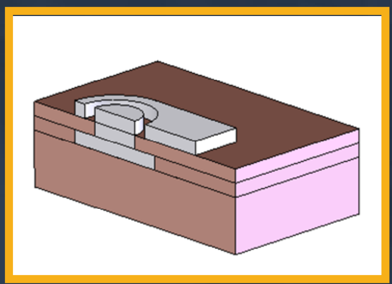




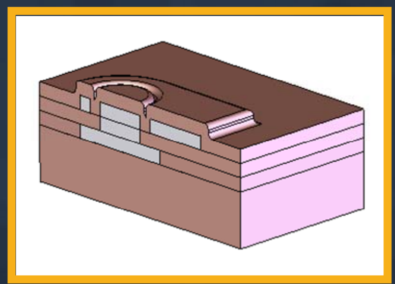


The EFAB Process

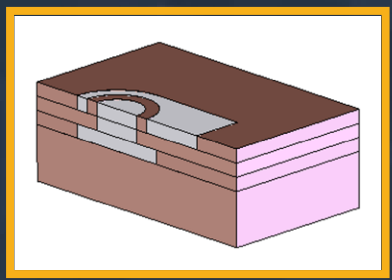
- EFAB is an additive/subtractive process performed in a cleanroom
- Devices are “grown” layer-by-layer on a wafer from at least two metals:
  - One is structural, one is sacrificial



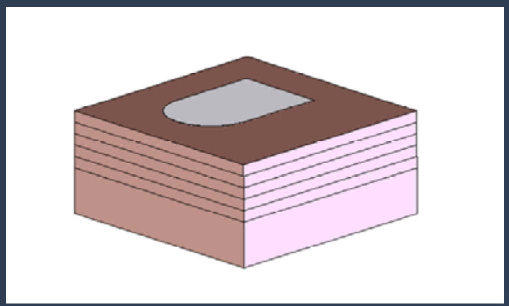
Step 1 – Pattern deposit structural metal



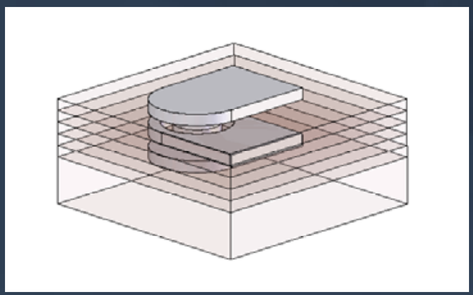
Step 2 - Blanket deposit sacrificial metal



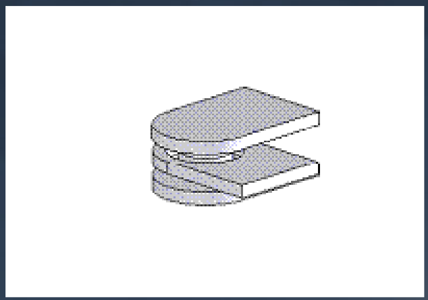
Step 3 -Planarize



Device before release



Device with sacrificial metal transparent



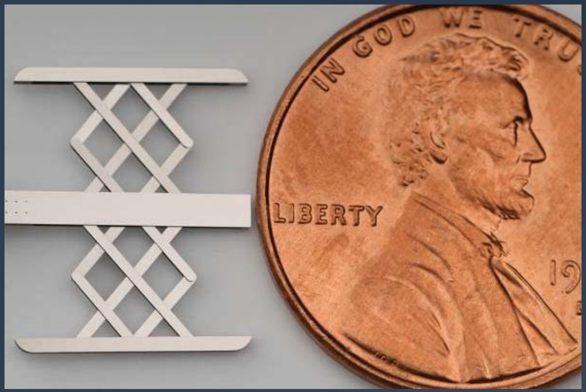
Finished device after etching away sacrificial metal

EFAB Process Flow

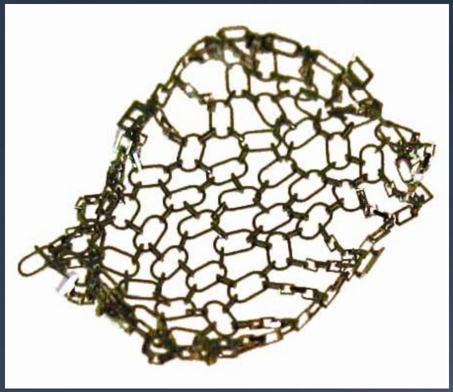
Microfabrica™

What's Really Unique About EFAB?

- Applies the paradigm of computer chip fabrication to metal part fabrication
- Can directly produce complex mechanisms with multiple moving parts without the need for assembly
- Complexity is nearly free
- Smaller is cheaper
- Large numbers of devices are produced simultaneously in a batch



2-direction expander



Chainmail basket

Additional EFAB Benefits

- Intricate free-form shapes, including internal features
- Features smaller than 0.0002”
- 0.0001” accuracy and repeatability
- Unlimited variety of products made by a single, well-characterized, well-controlled, proces
    - Individual layers are formed the same way no matter what is being made
- The same process is used for prototyping and volume production
- Net shape fabrication, without burrs or artifacts: ready to use
- Reduced time-to-market
    - Multiple design variations produced simultaneously
    - Scale from prototype to low-cost volume production in just weeks

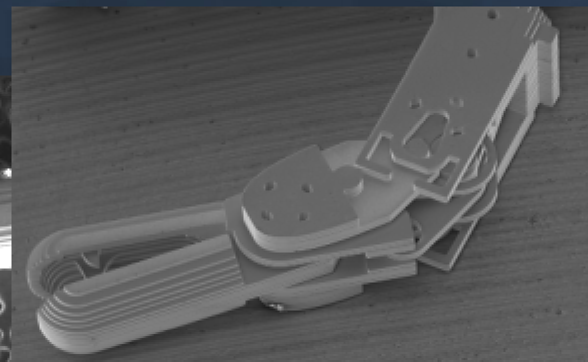
2-piece surgical clip with applier

2-French/22-23 gauge forceps

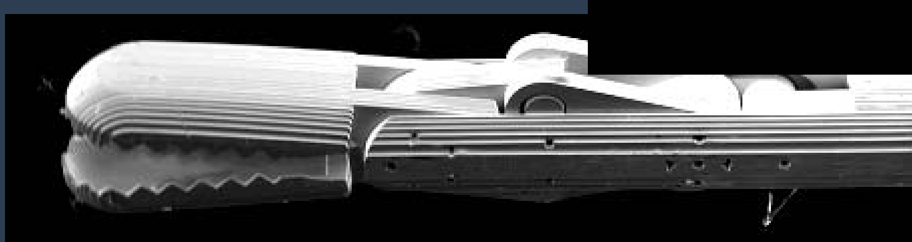
Microfabrica™

Medical device example

Biopsy Forceps, 2 & 3 French (0.7 & 1 mm)



EFAB-Produced
Biopsy Forceps
(~ 1 mm width)



Microfabrica™

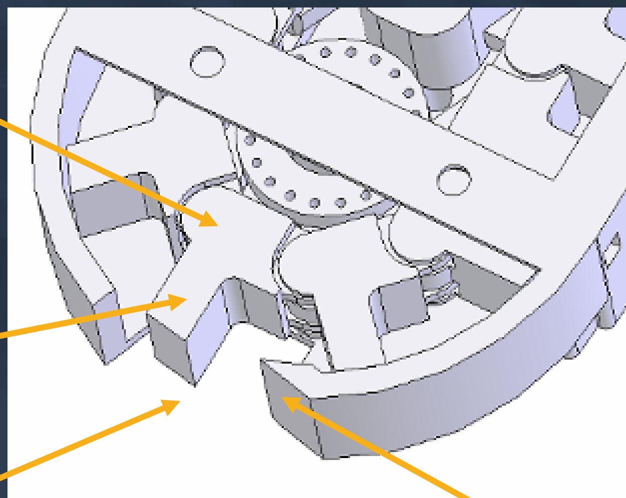
Medical device example

“MicroNibbler” Tissue Removal Device

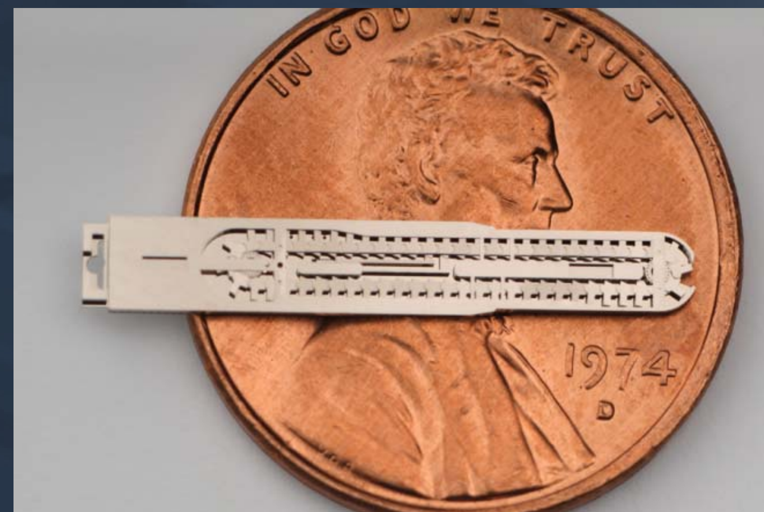
Chain link

Moving anvil

Inlet port



Fixed blade



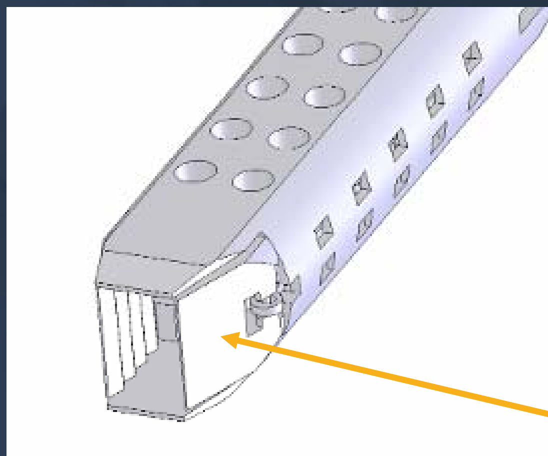
EFAB-Produced MicroNibbler (~ 3 mm width)

Cut/captured tissue

Microfabrica

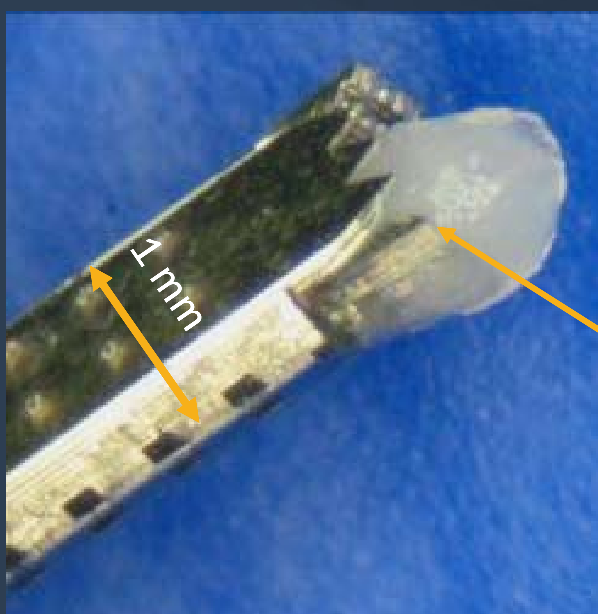
Medical device example

Internally-Barbed Biopsy Device

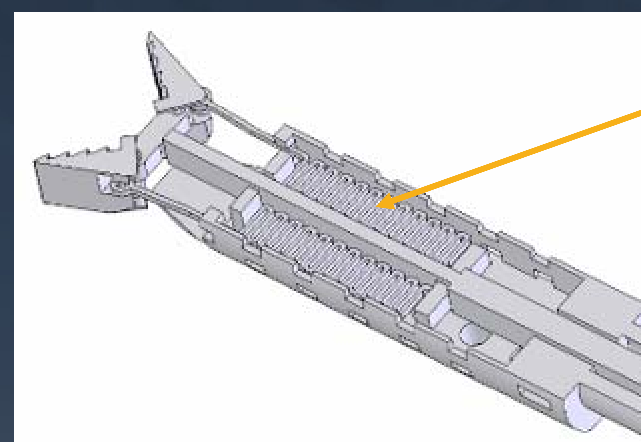


Internally-barbed jaw

Biopsy device (with ballpoint pen)



Captured tissue

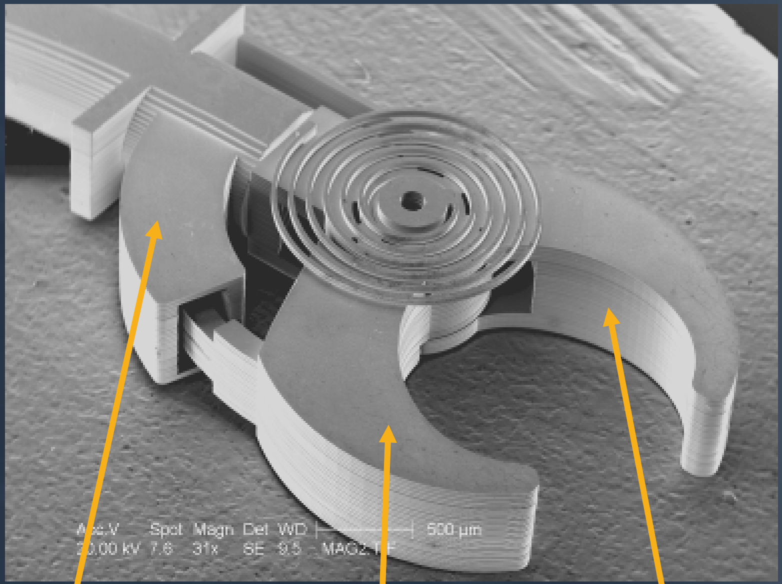


Internal spring

Medical device example

Hydraulic Forceps

- Saline-operated single-acting hydraulic forceps
- Hydraulic actuation
  - Allows use in tortuous anatomy
  - Offers precise force control and force feedback



Curved cylinder with internal piston

Moving jaw

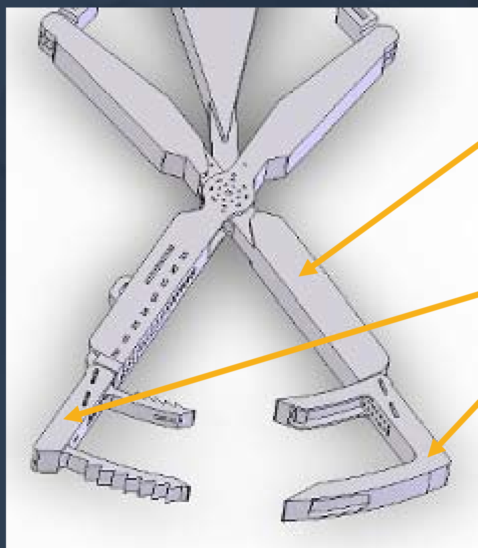
Fixed jaw

Hydraulic forceps (with ballpoint pen)

Microfabrica™

Medical device example

“SplitClip” Tissue Approximation Device



Clip applier

Detachable clip halves

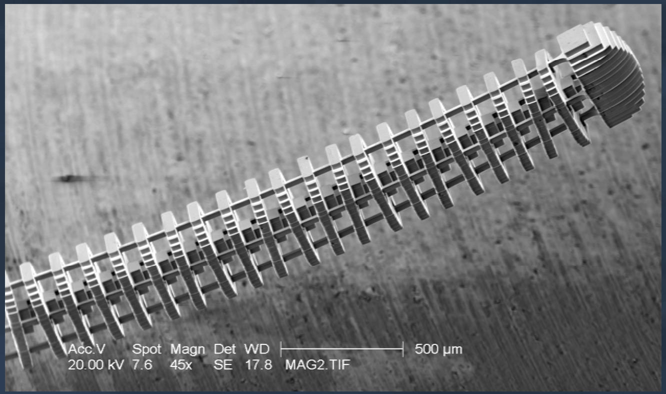
SplitClip (with applier and ballpoint pen)

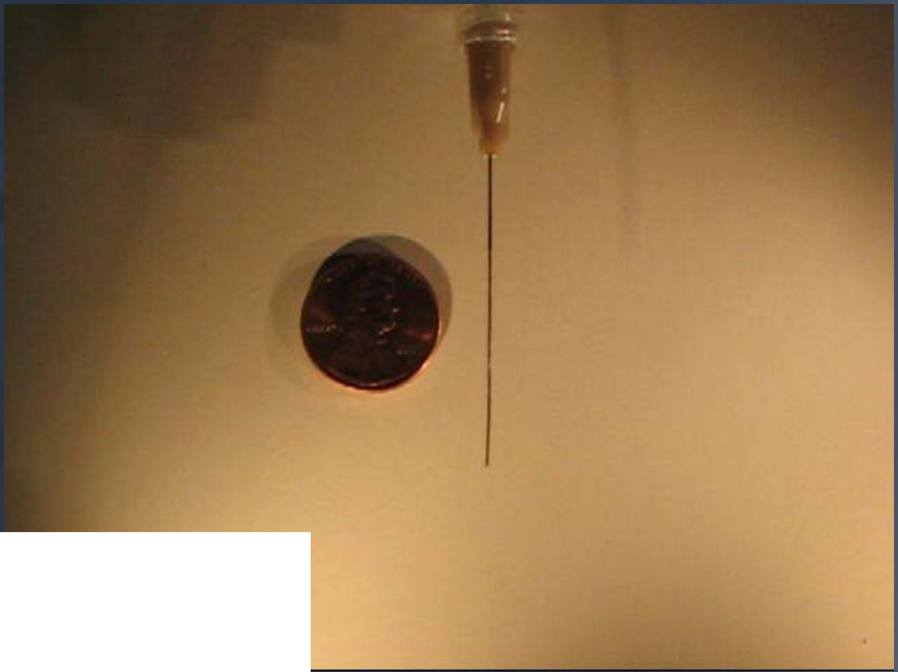
SplitClip delivered into tissue

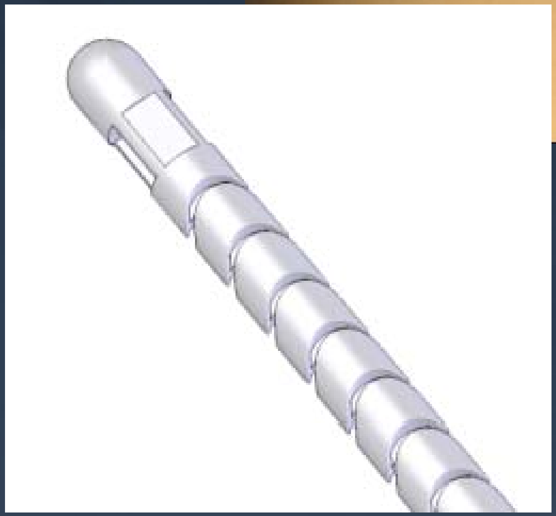
Microfabrica

Medical device example

Guidewire Distal Ends: Anchorable, Stiffenable, Steerable





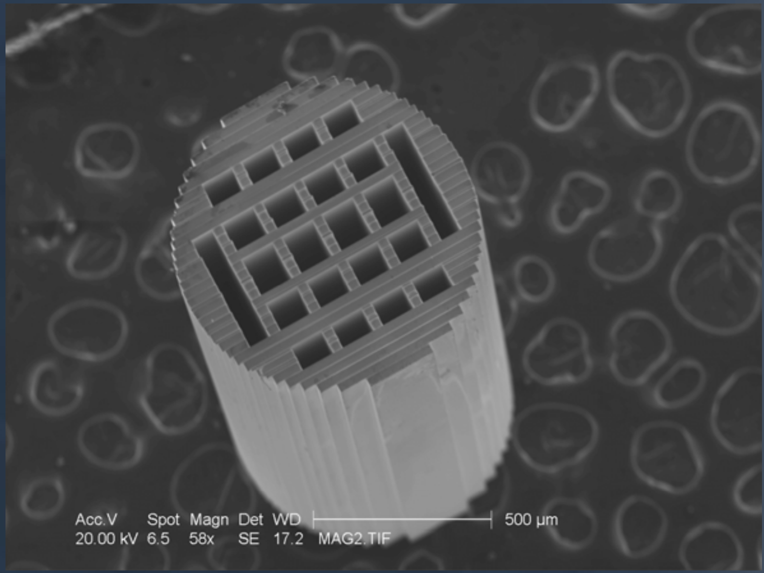


Microfabrica

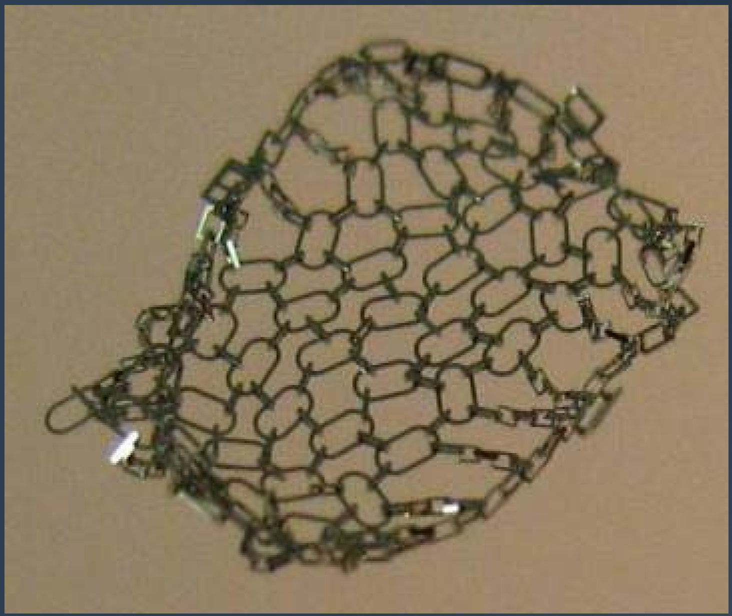
Medical device example

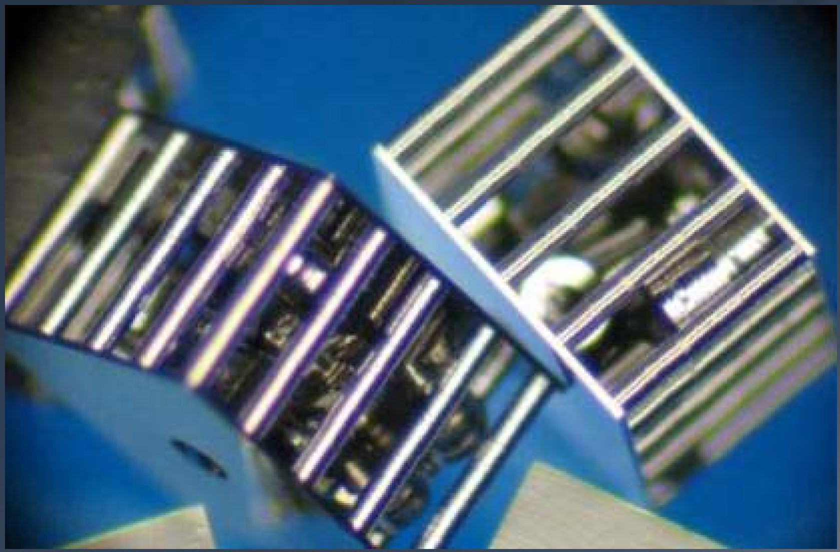
Precision Components

Examples of how EFAB can be used for “non-assembled” devices and components that require miniaturization and tight tolerances



- Multi-lumen metal structures
- Chain mail
- Micro “donuts” 254 µm in diameter and 200 µm tall built in a containment cage



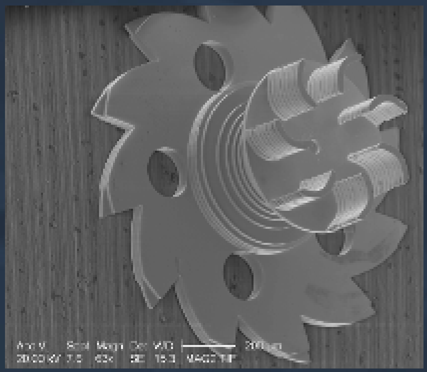


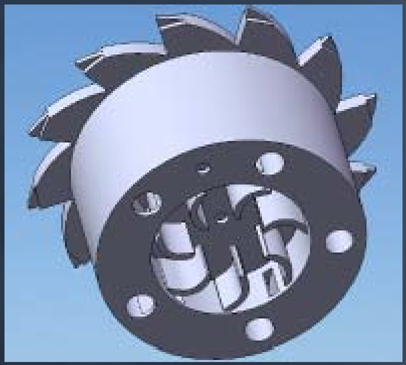
Microfabrica™

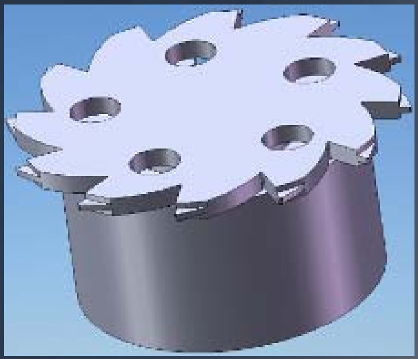
Example of capabilities

Hydraulic/Pneumatic Turbine

- Distal actuation for extremely small (0.9-1.2 mm diameter) and robust rotating devices
  - Cutting blade shown, other end-effectors may be used
- Not dependent on a stiff drive cable for rotation at high speeds
- Very hard metals (e.g., rhodium, a current EFAB material) can be used for wear resistance
- 1st prototypes built operated successfully: 120,000 RPM with flow rates ~ 10 ml/min



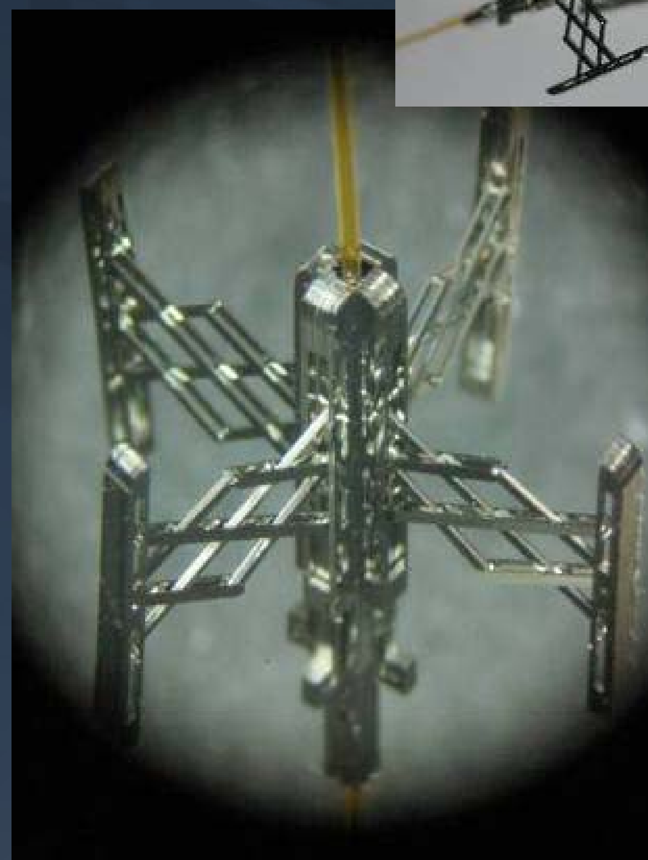


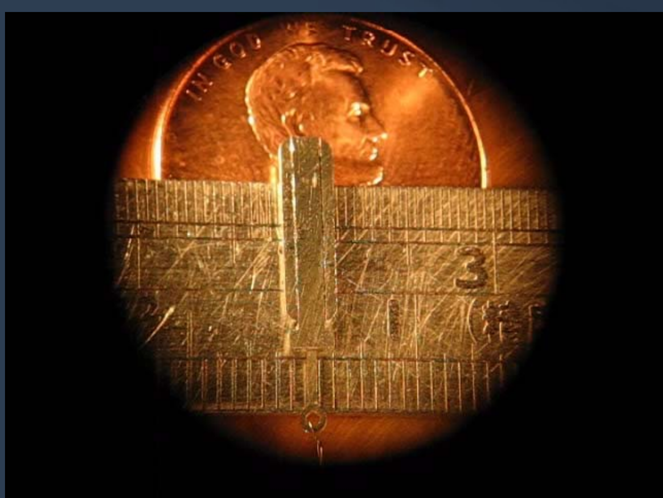


1.2-mm diameter turbine with blade

Example of capabilities
“Expander”

- Expands from ~3 to ~16 mm when actuated by cable
- 2 or 4-direction expansion

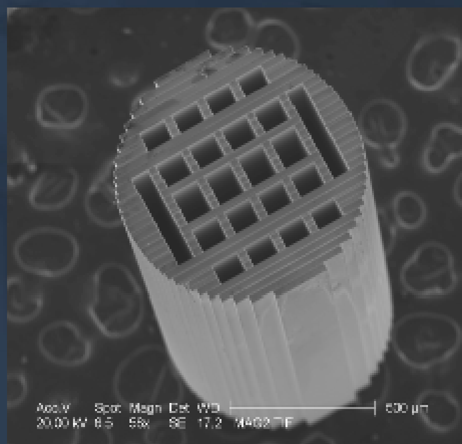





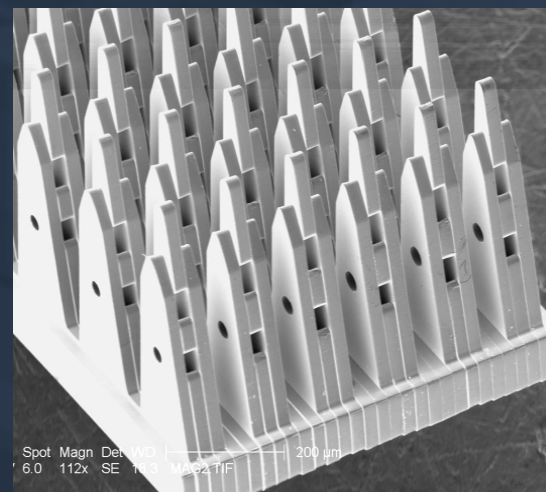
Microfabrica™

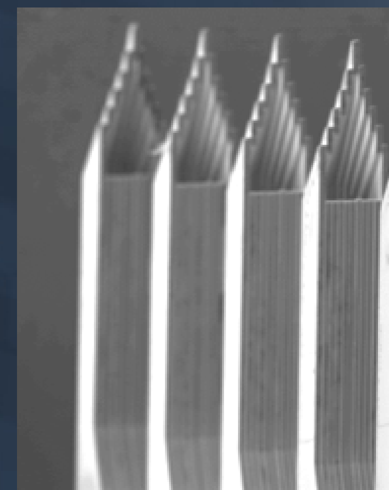
Example of capabilities

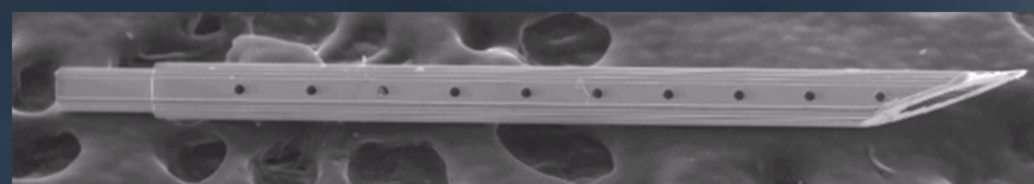
Miscellaneous



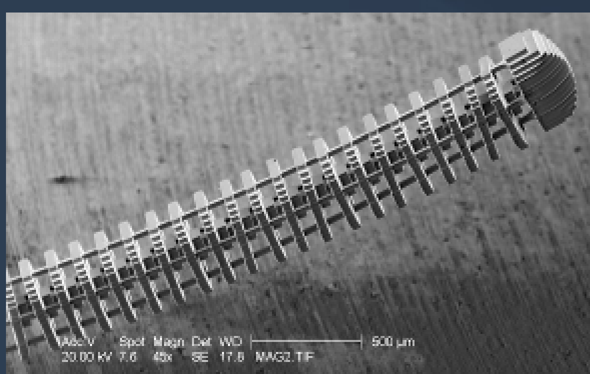
Multi-lumen metal tube







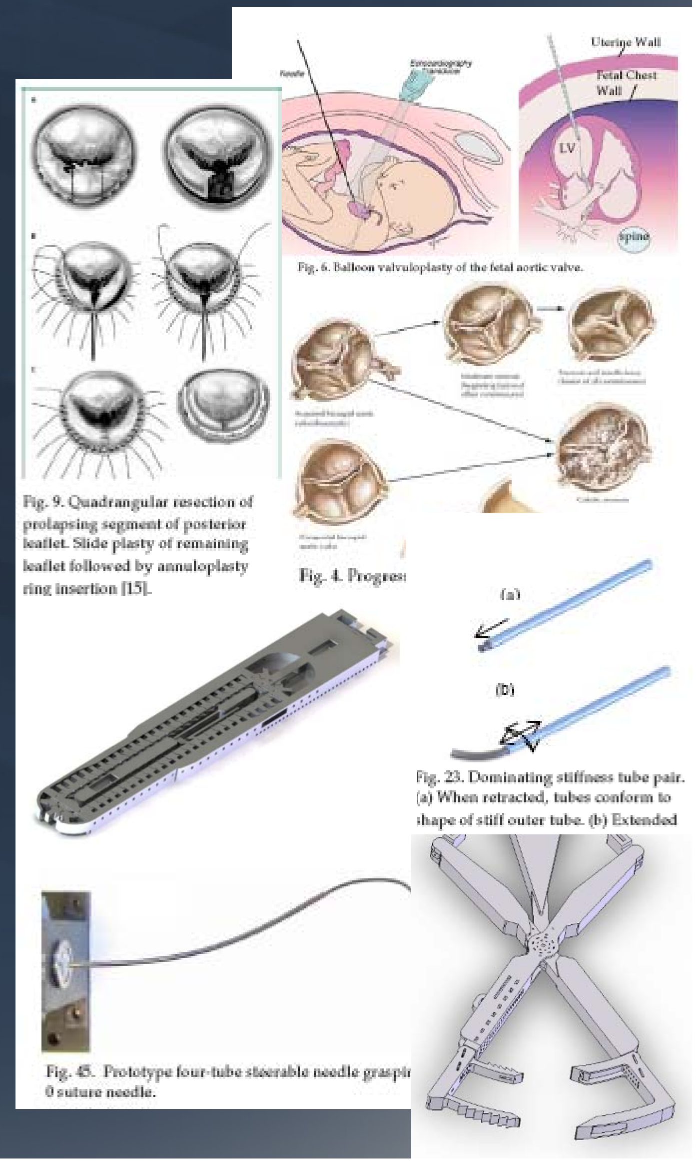
Microneedle array and 0.005” OD single microneedle



Omni-directional steerable guidewire (0.017” diameter)

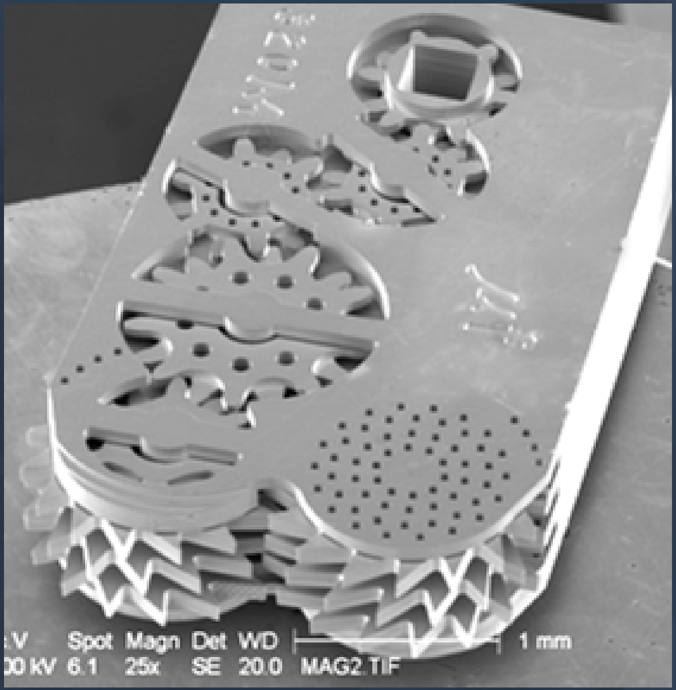
NIH BRP Project

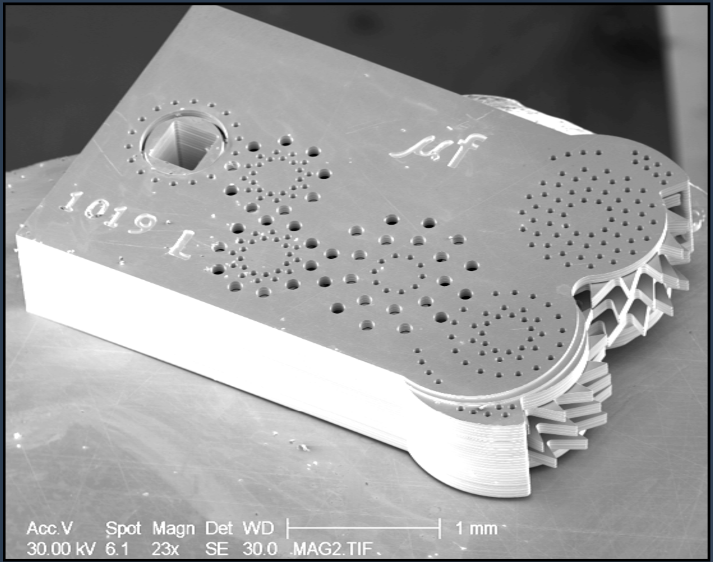
- $5.1M 'Bioengineering Research Partnership" (BRP) grant over 5 years
- Topic: "Steerable MEMS Instruments for Precise Intracardiac Surgery"
- Team
    - Boston University (P.I., steerable needle technology),
    - Microfabrica (MEMS instruments)
    - Harvard Medical School/Children's Hospital (cardiac and fetal surgery)
- Goal: develop instruments and techniques for minimally invasive heart surgery for patients ranging from adult through fetus.
- Conditions targeted are
    - PFOs
    - Mitral valve regurgitation
    - Hypoplastic left heart sydrome
    - Aortic valve thickening
    - Etc.

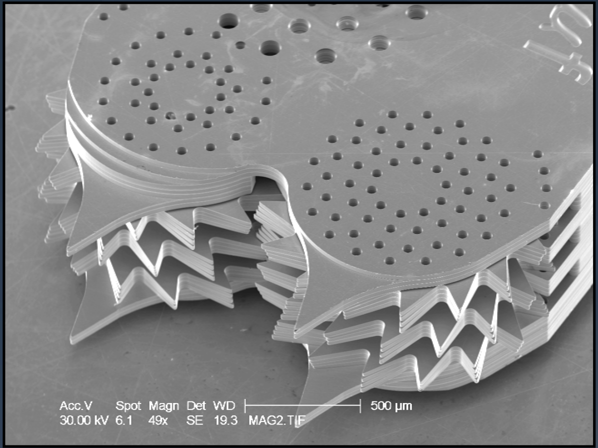


Tissue Removal
"Shredder"

- Targeted at removal of subpulmonary muscle in the treatment of Tetralogy of Fallot, etc.
- Needs to work on endocardium and myocardium
- Cuts, transports proximally without vacuum
- Applications in other surgical areas

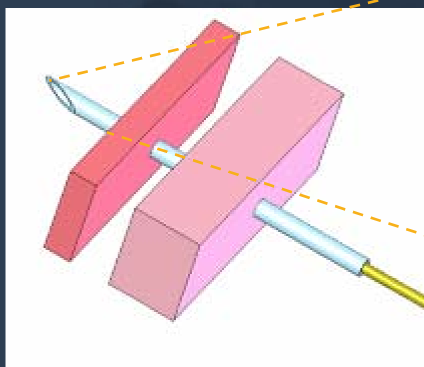


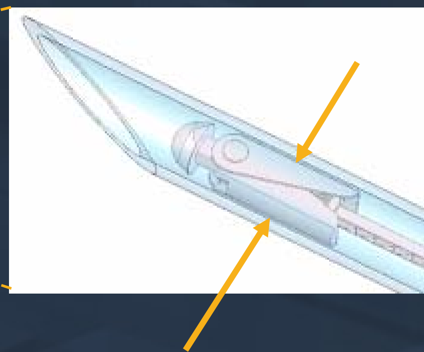




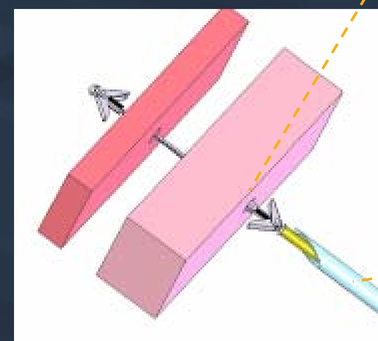
Microfabrica™

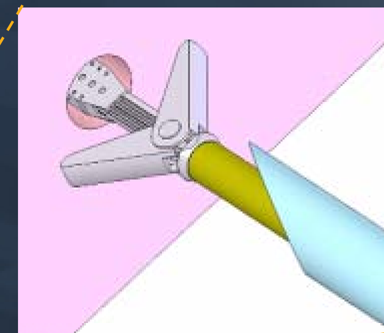
Tissue Approximation
“MicroToggle”



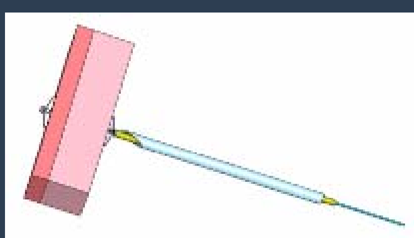


Step 1. Pierce tissue
with cannula

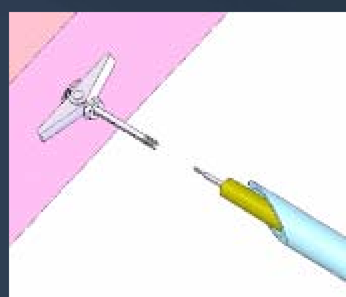




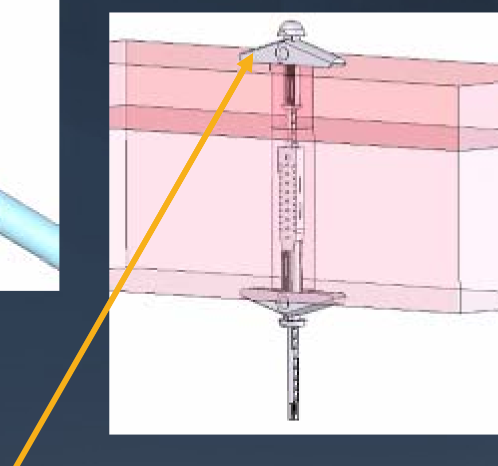
Step 2. Withdraw cannula



Step 3. Pull wire to
approximate tissue

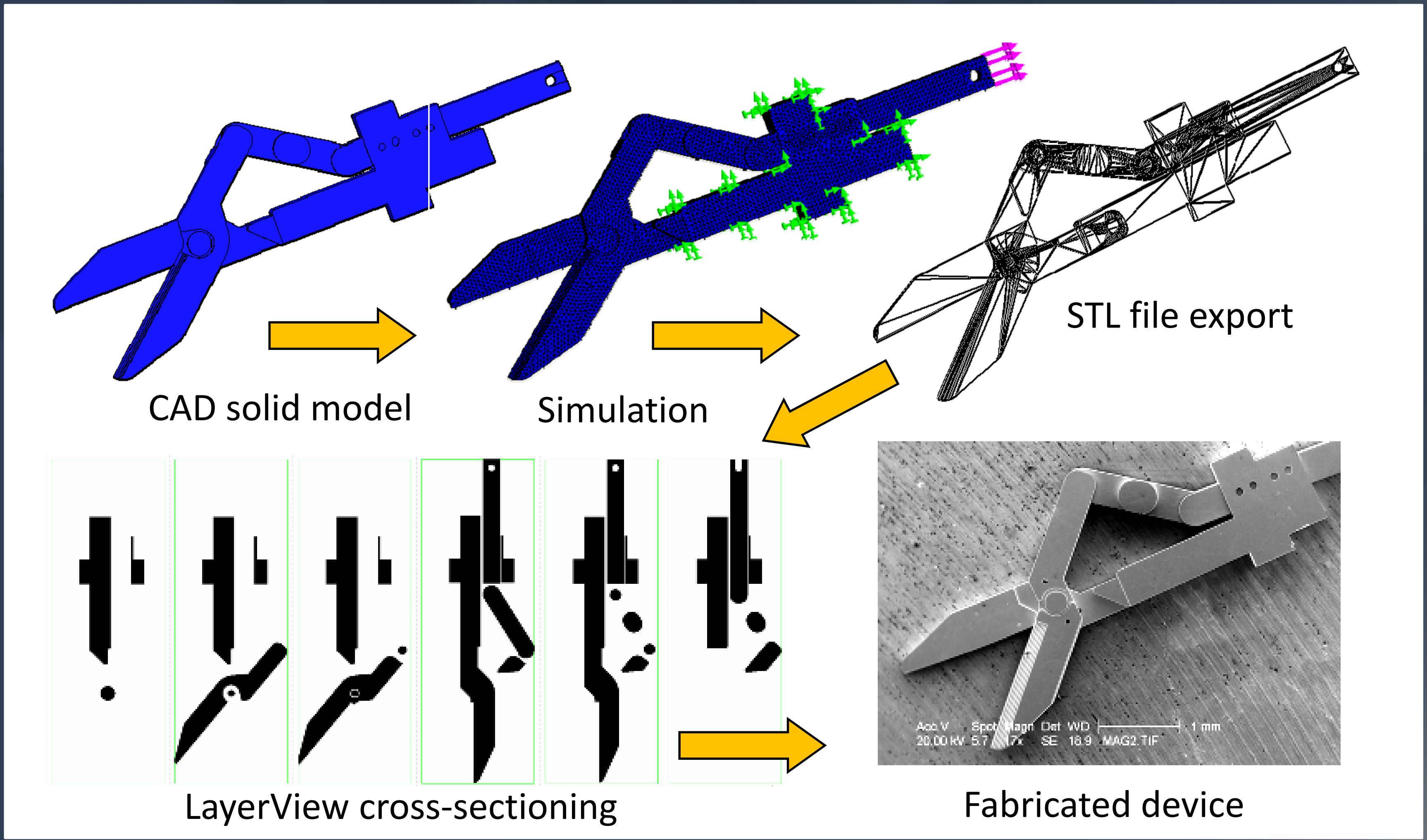


Step 4. Twist
wire to release



Final result

EFAB Design Flow



Microfabrica

Strength/Robustness

- Interlayer adhesion is very good (a large fraction of bulk strength)
- Examples
  - Multilayer boss broke without delamination
  - 1 mm diameter forceps survived >20 pounds tension
  - Milling cutter chucked in Mototool at ~6000 RPM easily milled acrylic

Microfabrica™

Typical EFAB Process Specs

Parameter	Value
Layer-to-layer registration	± 1.5 µm *
Layer thickness tolerance	± 2.0 µm
X/Y tolerance	~ +/- 1.0 µm
Maximum height	~3 mm (1 mm to date)
Maximum length and width	Limited only by wafer size
Minimum X/Y feature size	10-20 µm **
Layer thickness (can select for any layer)	4-30 µm***
Maximum number of layers	TBD (50 to date)
Substrate	High-purity alumina (if required)
Surface finish of layer top/bottom	0.15 µm Ra ****

* Expect 2-3X improvement with equipment upgrades

** At present comparable to layer thickness, but high-aspect ratio process being developed

*** 50 µm under development; 100-200 µm possible

**** Optical quality surfaces can be provided if needed

Microfabrica™

EFAB Materials

Metal	Status
Valloy™-120	Commercial: Ni-Co alloy, primary EFAB structural material
Edura™-180	Commercial: Rhodium (inert platinum group metal), used selectively where extreme hardness/wear resistance needed
Nickel	Commercial
Nickel-titanium	Feasibility demonstrated
Titanium, titanium alloy	Under investigation
Palladium, palladium-cobalt	Under investigation
Cobalt-chromium	Under investigation

Note: Coatings may be used to improve biocompatibility

Microfabrica™

Valloy-120

- Electroplated, fully-dense, nickel-cobalt alloy with excellent mechanical properties
- Laser weldable

Mechanical property	Value
Yield strength	900 MPa (130,534 psi) or greater
Ultimate tensile strength	~1.1 GPa (159,542 psi)
Modulus of elasticity	180 Gpa (26,106,793 psi)
Fatigue life	Infinite @ < 400 MPa (58,015 psi) stress
Interlayer adhesion	~ 600 MPa (87,023 psi)
Hardness	>400 HV (~40 Rc)

Microfabrica™

Biocompatibility of Valloy-120

- Passed all biocompatibility tests for <24 hr exposure to tissue and circulating blood
- Also passed mutagenicity and subacute toxicity tests

Test	Result
Cytotoxicity (ISO) ………………………………	Excellent: 0 cytotoxicity score
Systemic toxicity (USP, ISO) …………………	Excellent: No evidence or systemic toxicity
Intracutaneous irritation (ISO) ………………..	Excellent: Negligible primary irritation index
Sensitization (ISO maximization) …………….	Excellent: 0% sensitization response
Pyrogen (ISO) …………………………………	Excellent: Non-pyrogenic
Hemolysis (ASTM) …………………………….	Excellent: Hemolytic index 0.4% (non-hemolytic)
Partial thromboplastin time (ISO) …………….	Excellent: Non-activator of intrinsic coagulation pathway
Platelet and leukocyte counts (ISO) ………..	Excellent: Equivalent to HDPE
Ames mutagenicity (ISO) ……………………..	Excellent: Non-mutagenic
Subacute intraperitoneal toxicity (ISO) ………	Excellent: Negative for signs of systemic toxicity
Corrosion (ASTM) ……………………………..	Excellent: No signs of corrosion
Purity (glow discharge mass spectrometry)….	High

Microfabrica™

EFAB Materials and Some Medical Materials Compared

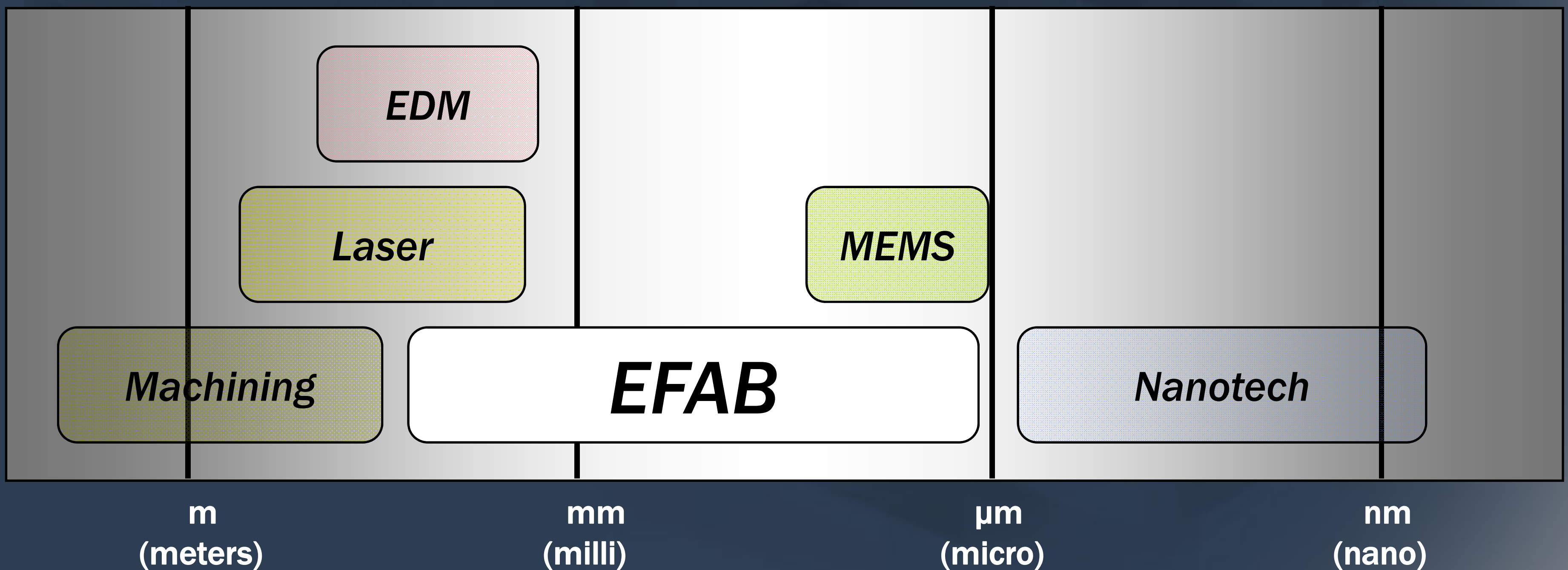
	Valloy-120	Edura-180	Ti6Al4V, wrought, F1472	410 stainless, 650° temper	BioDur 316LS stainless, 52% cold-worked	Superelastic Ni-Ti
Ultimate tensile strength (MPa)	1100	TBD	930	834	1034	1070
Yield strength (MPa)	900	TBD	860	721	848	814
Hardness (Rc)	40	>68*	32-36	25	36	~33

* 1000 Hv: nearly ceramic-like

Microfabrica™

EFAB vs. Other Manufacturing Technologies

EFAB bridges the gap, enabling unique mm-scale devices with micron-precision features



Microfabrica™

EFAB Compared with Conventional Metal Processes

- Compared with machining, metal injection molding, and electrical discharge machining, EFAB provides
  - Greater complexity
  - Mechanisms without assembly
  - Smaller features
  - Often, greater accuracy and lower cost
- Compared with laser or photochemical machining and stamping, EFAB provides
  - Far greater complexity
  - Mechanisms without assembly
  - Greater accuracy
  - Smaller features
  - Freedom from artifacts

EFAB Comparison Chart

	EFAB Technology	Milling, Turning, Grinding	Electrical Discharge Machining	Laser Machining	Metal Injection Molding	Photochemical Machining	Stamping, Fineblanking, Deep Drawing
Geometrical flexibility	Nearly arbitrary 3-D with internal and undercut features, curved channels, etc.	Limited 3-D (internal features difficult/impossible	Limited 3-D (e.g., no undercuts)	Typically flat or tubular 2.5-D (extruded-type features)	Complex 3-D; limited internal & undercut features limited	Typically flat 2.5-D (extruded-type features)	Punched and bent shapes from thin sheet metal
Overall device size (mm)	Max: >1 (current), 2-3 (probable limit). Min: ~ 0.01	Max: unlimited. Min: sub-mm (e.g., 0.2-0.5)	Max: unlimited. Min: sub-mm	Max: 0.4-1 sheet thickness. Min: 0.3	Max: unlimited. Min: 50 mg weight	Max: unlimited. Min: ~0.003 sheet thickness	Max: unlimited. Min: 0.05 sheet thickness, 0.2 OD (deep drawing)
Minimum feature size (μm)	10-20 (X/Y, current) 5 (X/Y, future), 4 (Z)	30 (holes), 38 (walls), 50 (wire)	5 (holes)	15-20	250	75, usually ~sheet thickness	Usually ~sheet thickness, 13 (deep drawing)
Accuracy (+/- μm)	1-2	10-25 typical, 1.3-5 possible (milling and turning), 0.6 (grinding)	10-100	3-5	Typically 0.3-0.4% of nominal	5-13 μm or at least 10-30% of sheet thickness	50 (stamping), 10 (fineblanking), 5 (deep drawing)
Surface finish (μm)	0.15 Ra typical on horizontal surfaces, optical quality available	0.1-0.8 on some surfaces; often have tool marks	10-30 nm Rmax (micro-EDM)	0.5 Ra	0.8 rms	Not available. Scalloping of sidewalls adds to roughness.	Limited by tool marks/dings/ scratches, 0.3 rms (deep drawing)
Assemblies with multiple components and materials	Yes	No	No	No	No	No	No
Net shape processing	Yes in most cases	May need deburring, hardening	Yes in most cases	May need electropolishing, etc.	May need machining of tight tolerances, deburring for mold flash	Yes in most cases	May need deburring
Choice of materials	Depositable metals and metal alloys	Nearly unlimited	Most metals	Most metals	Stainless steel primarily	Chemically-etchable metals such as stainless, Ti, Ni-Ti	Many, but difficult with harder metals due to springback
Cost and lead time	Largely independent of complexity. Low for production; protos requires tooling. Typically weeks.	Strongly dependent on complexity. May be high for production, low for protos. Days-weeks.	Strongly dependent on complexity. Often high for production since slow; fairly low for protos . Days-weeks.	Dependent on complexity. May be high for production; low for protos. Days-weeks.	Very low for production; high for protos. Tooling cost strongly dependent of complexity. Weeks.	Largely independent of complexity. Low for production; low for protos. Days-weeks.	Low for production; high for protos. Tooling cost strongly dependent on complexity. Weeks.

EFAB vs. Si MEMS Fabrication Processes

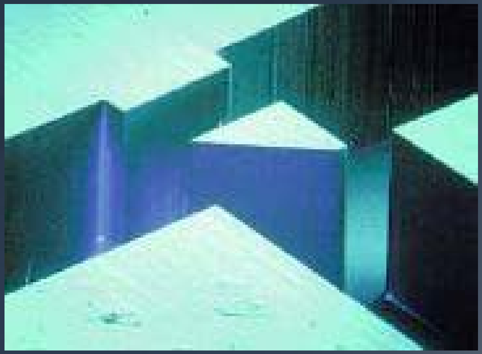
- Pros
  - Complex, true 3-D shapes with dozens of layers (vs. 3-5)
  - Larger, more robust structures
  - Variety of metals (vs. silicon)
    - Ductile (vs. brittle) behavior
    - Higher strength
    - Far greater electrical and thermal conductivity
    - Higher temperature tolerance
    - Superior optical, magnetic properties
  - Rapid, intuitive design in 3-D (vs. time-consuming 2-D design)
- Cons
  - Dielectrics more difficult to process
  - Polycrystalline material
    - Single crystal material properties (e.g., low damping capacity) not available

Si MEMS device

Microfabrica™

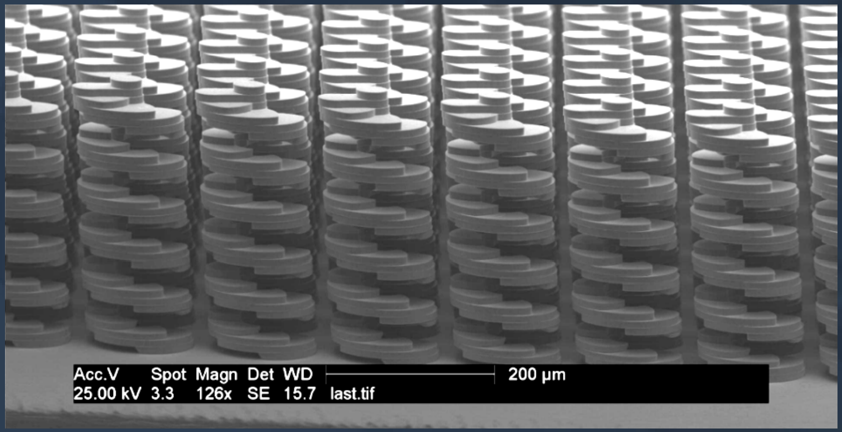
EFAB vs. LIGA

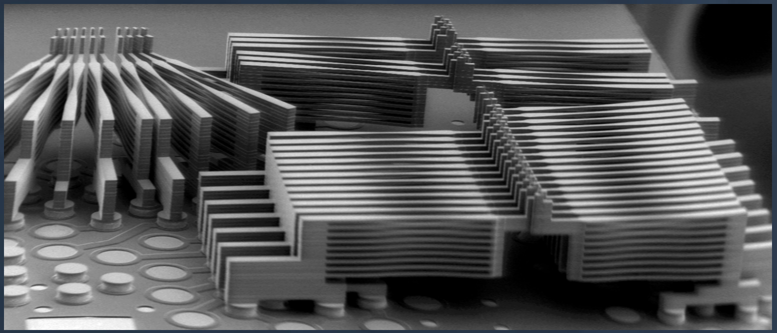
- Pros
  - Complex, true 3-D shapes (vs. 2-D extrusions)
  - Wider range of materials (vs. electroplated metals only)
  - Higher aspect ratio (height : minimum feature size), and without a synchrotron
  - More uniform alloy composition
- Cons
  - Rougher sidewalls
  - Somewhat lower strength along Z

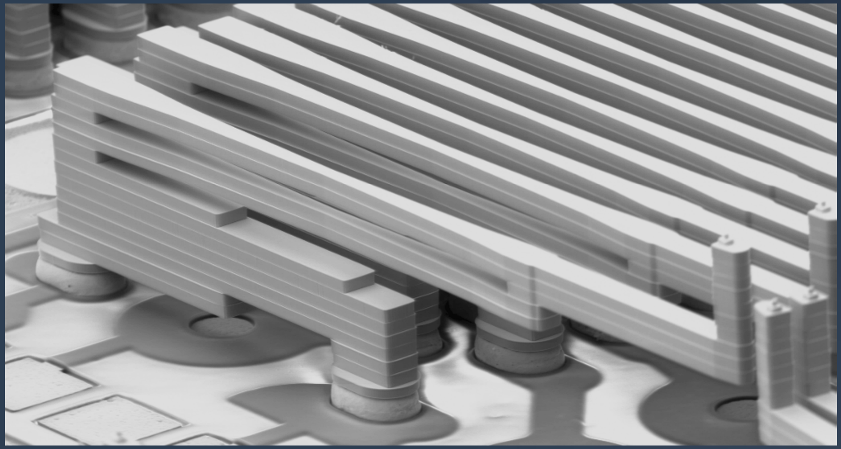


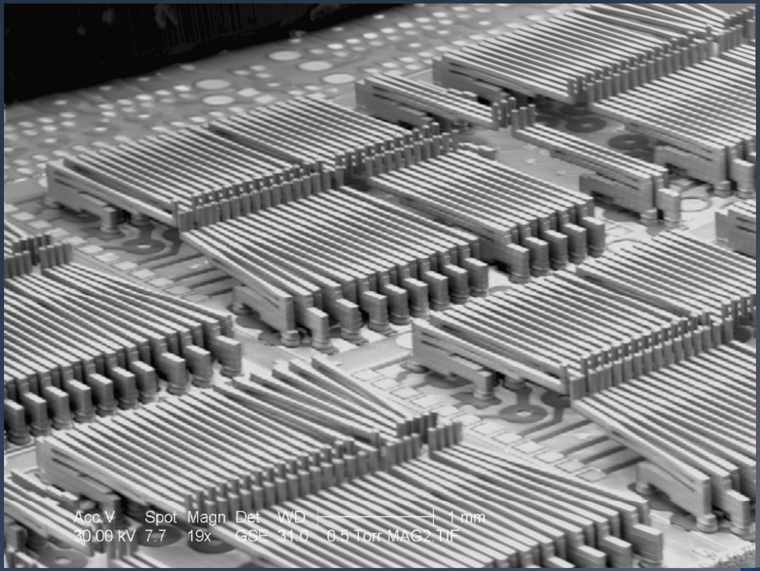
LIGA structure

Probing for Wafer Test





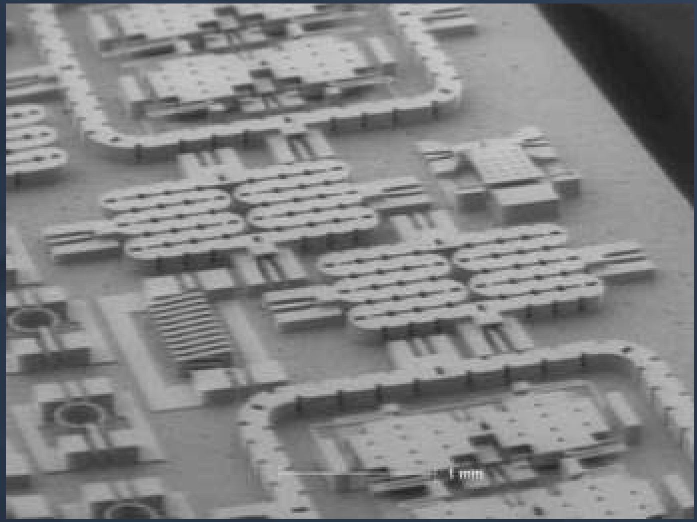


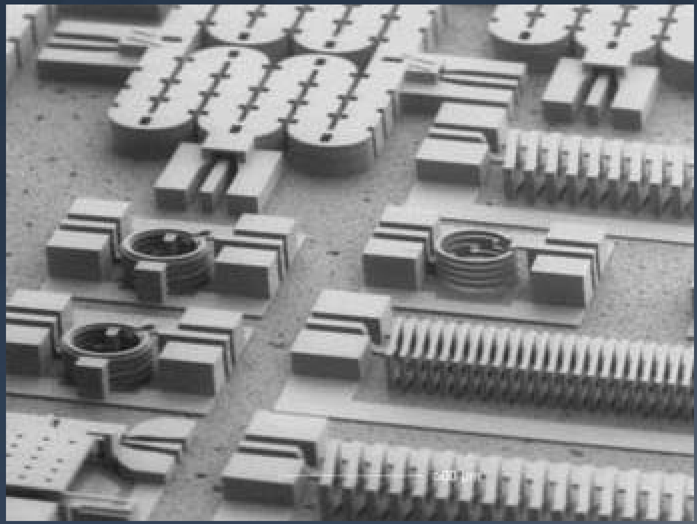


Microfabrica™

RF Devices Using EFAB

- Transmission Lines
- Antennas
    - Patch antennas
    - Phased array antenna
- RF Switches
- Filters
    - Fixed Filters
    - Tunable Filters
- Resonators
- Couplers
- Waveguides
- Duplexers
- Inductors
- Variable capacitors





Microfabrica™

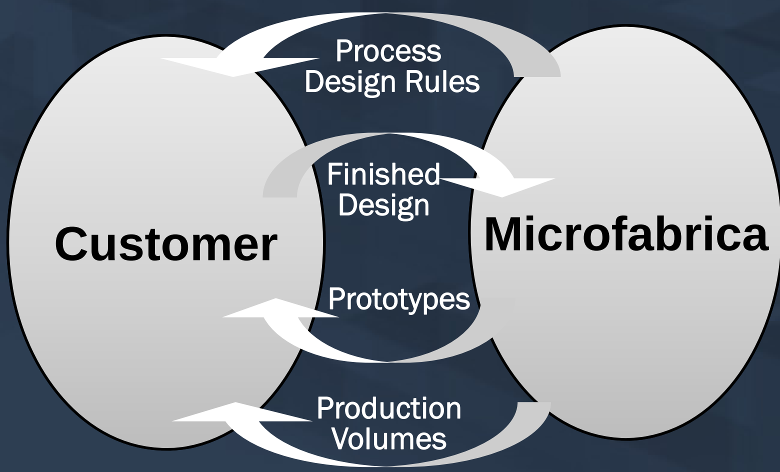
Microfabrica in a Nutshell

Business	Design, development, and manufacturing of custom miniaturized mechanical components and devices
Technology	EFAB®: unique production technology for manufacturing complex 3-D micro/mm-scale devices
Markets	- Medical - Semiconductor - Defense
Corporate	- Founded 1999 - Venture-funded: >$62M - 40,000 ft^2 facility in Van Nuys, CA (Los Angeles)

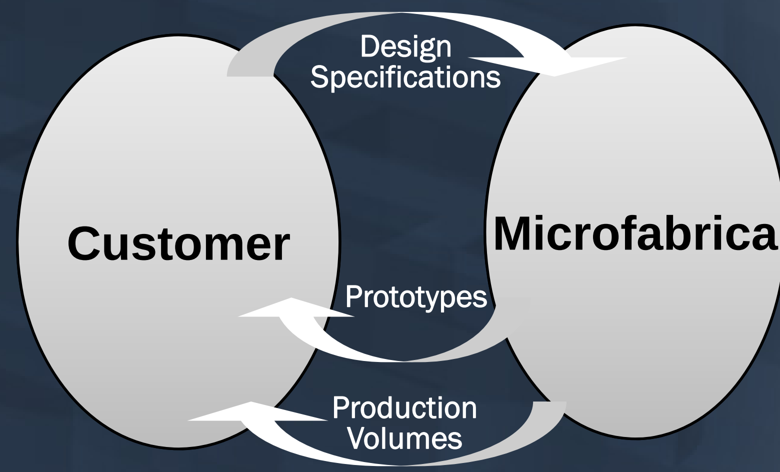
Microfabrica™

Microfabrica Design & Manufacturing Services

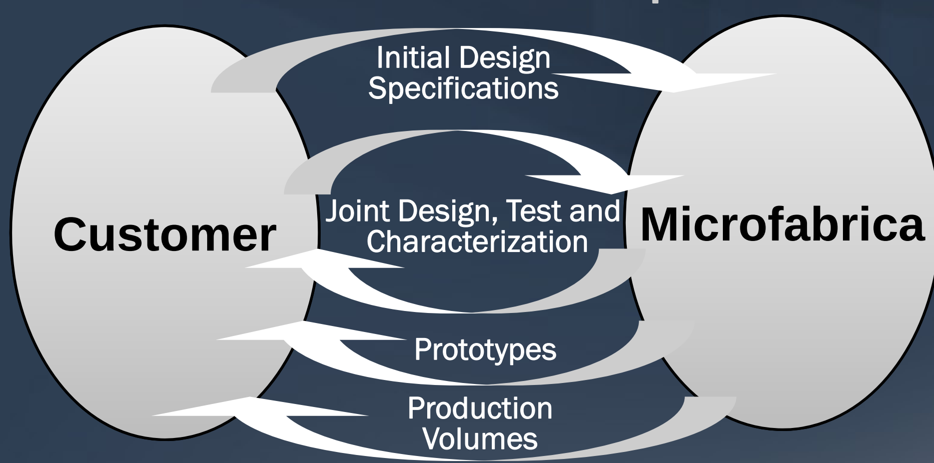
Customer–Designed Devices



Turnkey



Collaborative Development



Microfabrica™

For More Information

Microfabrica Inc.
7911 Haskell Ave.
Van Nuys, CA 91406
www.microfabrica.com

Microfabrica

EFAB® Technology:
Unlocking the Potential of Miniaturized Medical Devices

Adam L. Cohen
EVP, Technology and CTO, Microfabrica Inc.

Table of contents

Adam Cohen
EVP, Technology and CTO
818-786-3322

Microfabrica™