Polymer Laminates for Microfluidic Life Science and IV Diagnostics Applications

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Founder, ALine, Inc.
About ALine

- Founded in 2003
- Revenue from Product Sales and Custom Services
  - Currently 6 employees
  - Sales through distribution (Ocean Optics)
- Manufacturing under FDA compliant quality system
Facilities

- Class 10k Clean room, Class 100 clean bench
- Microscopy, fluorescence and imaging capability
- Fluidic test platform for engineering development
- Surface modification capability
- Component bonding using medical grade UV curing
- Pressure and Thermal bonding
- CO$_2$ lasers with special focusing optics
- 3000 sq ft facility in Los Angeles County
Core Competencies

- Microfluidic, Lab-on-Chip Design & Fabrication
- Bioanalytical & Interfacial Science
- Materials and Membrane Science
- Instrumentation Development
- Manufacture under FDA Compliant Quality System
Polymer Laminate Technology

- Ideal for rapid prototyping, permits empirical testing hence lowers development costs, produces a better final product.
- Amenable to ‘mass customization”
- Robust, proven, inexpensive
- Incorporate different materials with little change in process.
- Create complexity without special tooling
- Simple interface to sensors or injection molded components “operational double sticky tape”
- Incorporation of functionality: valves, porous membranes, pumps
- Enclosed internal channels, high feature density
Laminate Construction: NASA Cell Culture Card

**Materials:**
- Optical Acrylic
- Pressure sensitive adhesive
- 0.45 micron nylon membrane
- Hose barb connector

**Layers:**
- Breathable membrane
- Capping layer
- Channel layer 1
- Well layer
- Channel layer 2
- Optical layer
ALine, Inc.
- Unique Functionality
- Standard Platforms
- High Quality
- Moderate to Low Cost
- Specialty Surfaces
- Automation Compatible

Laboratory Disposables
- Standard Platforms
- High Quality
- Low to Moderate Cost
- Specialty Surfaces
- Automation Compatible

BioMEMS
- Custom Instrumentation
- Unique Functionality
- Premium or No Disposable
- High Price
- Specialty Surfaces

ALine bridges the BioMEMS and Lab Disposables Industries
Customer Base

- Life Science Tools Developers
- Clinical Instrumentation
- Point of Care Diagnostics
- Environmental Test Labs
- Field Portable Instruments
- Life Science and Analytical Laboratories
- Government & Private Research Laboratories
How We Work with Clients

- Initial discussion of application and device requirements (may or may not require NDA).
- Client provides initial designs in pdf or dxf with part number and revision.
- ALine develops laminate fabrication process based on requirements, with design and documentation control.
- ALine sources materials and recommends bonding adhesive based on requirements.
- First set of prototypes fabricated on 6” x 12” footprint typical yield 6 to 12 devices.
- Typical turnaround time 3 to 7 days.
- Testing of parts for function possible if specified in project description.
General Design Rules

- No ceiling or floor of any channel is covered with adhesive.
- Kerf is dependant on material thickness, range approx. .002” (50 microns) to .005” (125 microns)
- Feature size minimum, 100 microns in x-y plane in thin material (75 microns or less)
- Shortest channel height possible is 25 microns.
- Feature density: require 0.5 mm spacing for 250 micron thick channels.
- Through holes or channel ends are oversized to accommodate alignment shift.
- Typical alignment 0.005”, 0.002” possible with additional fixturing.
- Connections: Tube stubs, o-rings, hose barb connections, tapped threaded connections
Applications

- Cell culture in space, fluidic card developed for NASA, successful deployment and data collection in Dec. 2006
  - Multiplexed bacterial analysis of patient sample
  - PCR, molecular diagnostics
  - Flowcells for a variety of biomolecular analyses
  - Re-circulating pumps
  - Integrated electrodes for cell sorting
  - Specialty cuvettes for spectroscopy
  - Pneumatic valves for multiplexed applications
CD-sized Centrifugal Cartridge

- Light weight polyethylene ester PET (Mylar) materials
- 75 wide x 50 micron tall channels
- No adhesive on the top or bottom of wells or channels
Fluidic Manifolds

- 0.5 mm up to 2 mm thick close tolerance acrylic stacks,
- Over 13 layers, 50 micron registration
- Inexpensive alternative to diffusion bonding
- Batch fabricate with stepped profile, does not need to be flat
- 500 micron to 1 mm wide channels
Cell for SAXS of protein solutions

- Adhesive on top and bottom to permit placement of mica or other window material
- Stack of three sheets of acrylic, 2.0 mm tall, 1.5 mm wide internal channel, 0.5” diameter
- Notches permit use of tweezers to guide cell into a custom holder,
- Cost about 1.50$ each
- Each batch produced several hundred parts
Cell Sorting – Example of Electrochemical Interface

Laser Etched ITO on Glass or Au on Plastic, 25 micron tall fluid channel, side channel is 0.8 mm wide, main channel 2.5 mm, electrode gap is around 50 microns.
Glucose Sensing Flowcell

- Pt electrode coated with GOX
- Ag/AgCl reference
- Electrodes threaded into the side of the card, glued in place with UV cure epoxy
On-Board Pneumatic Valves

- Multiplexed analysis, split sample 4, 8 or 16 ways
- Separate channels for independent reagent addition,
- Bonded to injection molded reservoirs, Bacteria capture on coated glass slide, integrated into laminate assembly
- Valves closed at 25 psi, for 5 psi fluid flow. Rule of thumb, closed at pneumatic pressure 5 x fluid pressure
- Initial fill, closed valve still lets air pass, fill each channel to stop; create even flow among eight independent channels
Products for Spectroscopy
Micro-volume Cuvettes: FluoroVette™

Flowcells or Pipette Interface
SpecVette™ - Absorbance

- Semi-micro to ultra-micro cuvette market
- Available in 1.0, 0.5, and 0.25 mm pathlengths.
- Cost effective alternative to expensive quartz cuvettes
- Works in standard Spectrometer
Meeting Customer Expectations

- Deliver Product with Superb Performance
- Provide Cost Effective Solution to Custom Analytical Need
- Permit Minimal Use of Precious & Costly Samples
- Minimal Time Constraints Setting Up and Performing Tests
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