Tibion
BIONIC TECHNOLOGIES

Leveraging Consulting to Build a Bionic Technology Company

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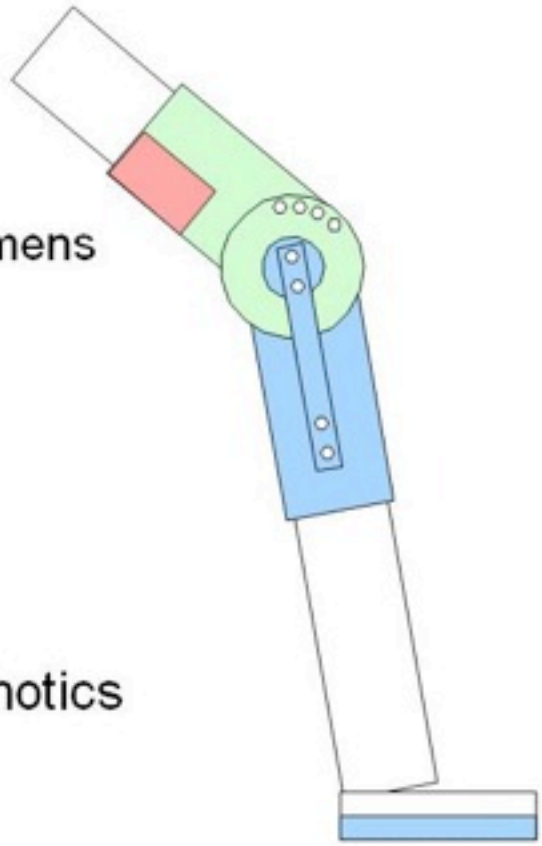
Outline

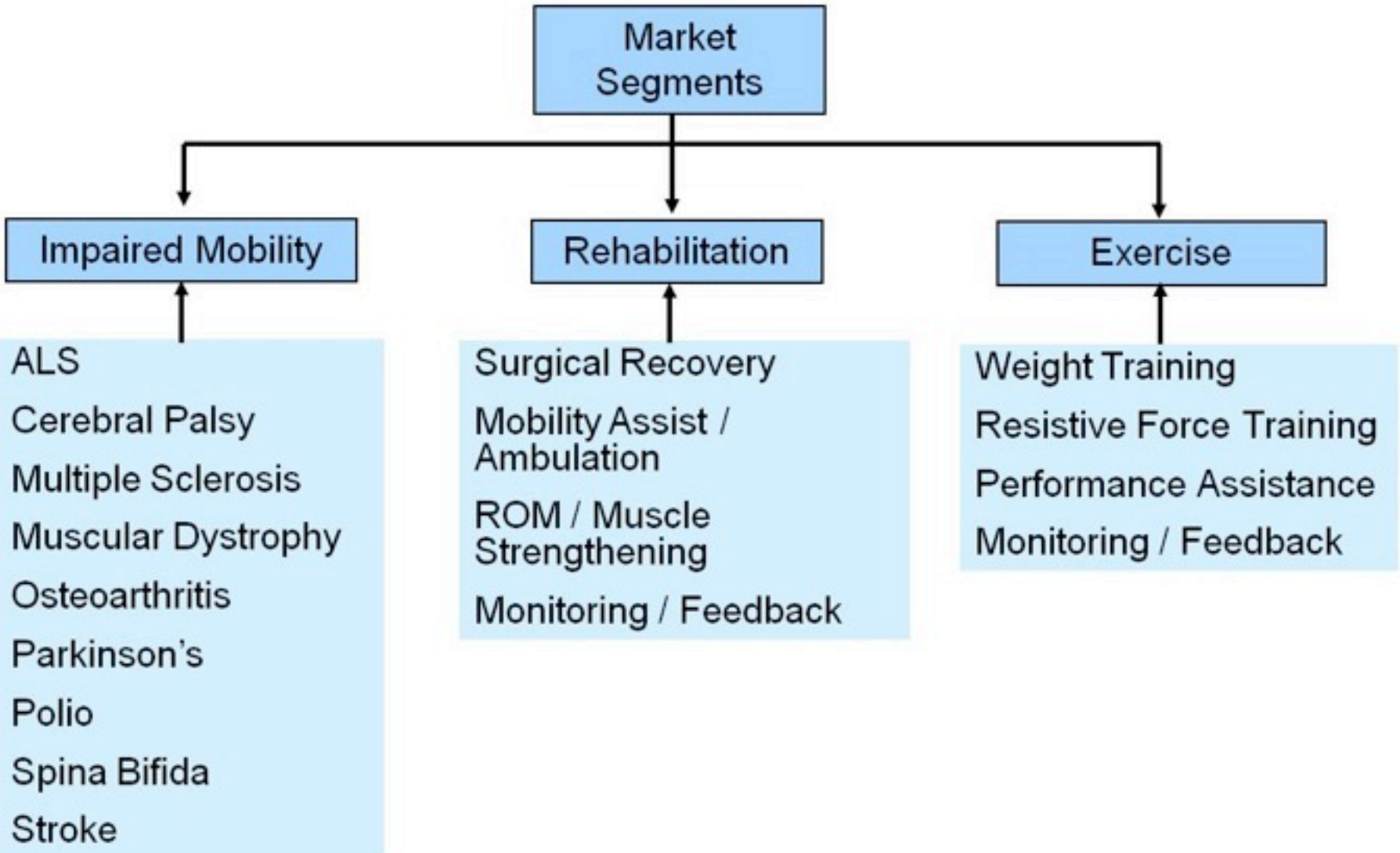
- Iterating to find and perfect the right technologies
- Building prototypes for early market feedback
- Addressing medical device challenges
  - **reimbursement**
  - **quality systems**
  - **FDA clearances**
- Meeting VC investment objectives
- Market focus and clinical validation
- Lessons learned

The Plan (in 2002)

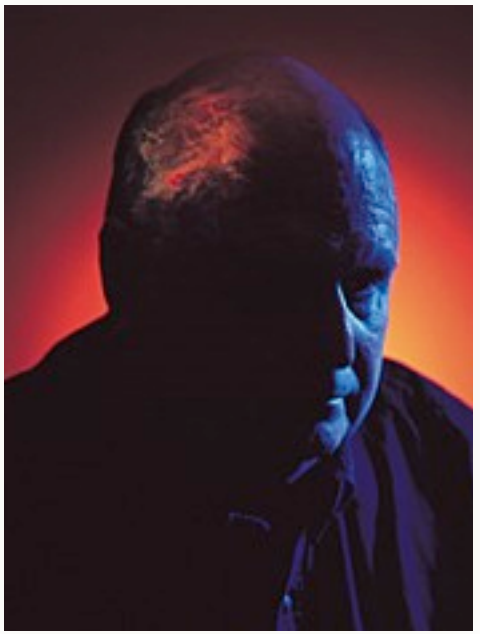
- Create active orthotic products to augment and rehabilitate muscle function
  - Enhance quality of life for the mobility impaired
  - Promote effective recovery and rehabilitation regimens
  - Address multiple musculo-skeletal pathologies
- Create revolutionary new technology
- Drive creation and ownership of a new active orthotics industry



Target Market Areas (2002)



Market



795,000 strokes per year

- Every 40 seconds, a stroke occurs

635,000

- Survive and require therapy
  (Conroy, Topics in Stroke Rehab)

400,000

- Enter rehab hospitals (IRF) or skilled nursing facilities (SNF) for therapy (Conroy, Topics in Stroke Rehab)

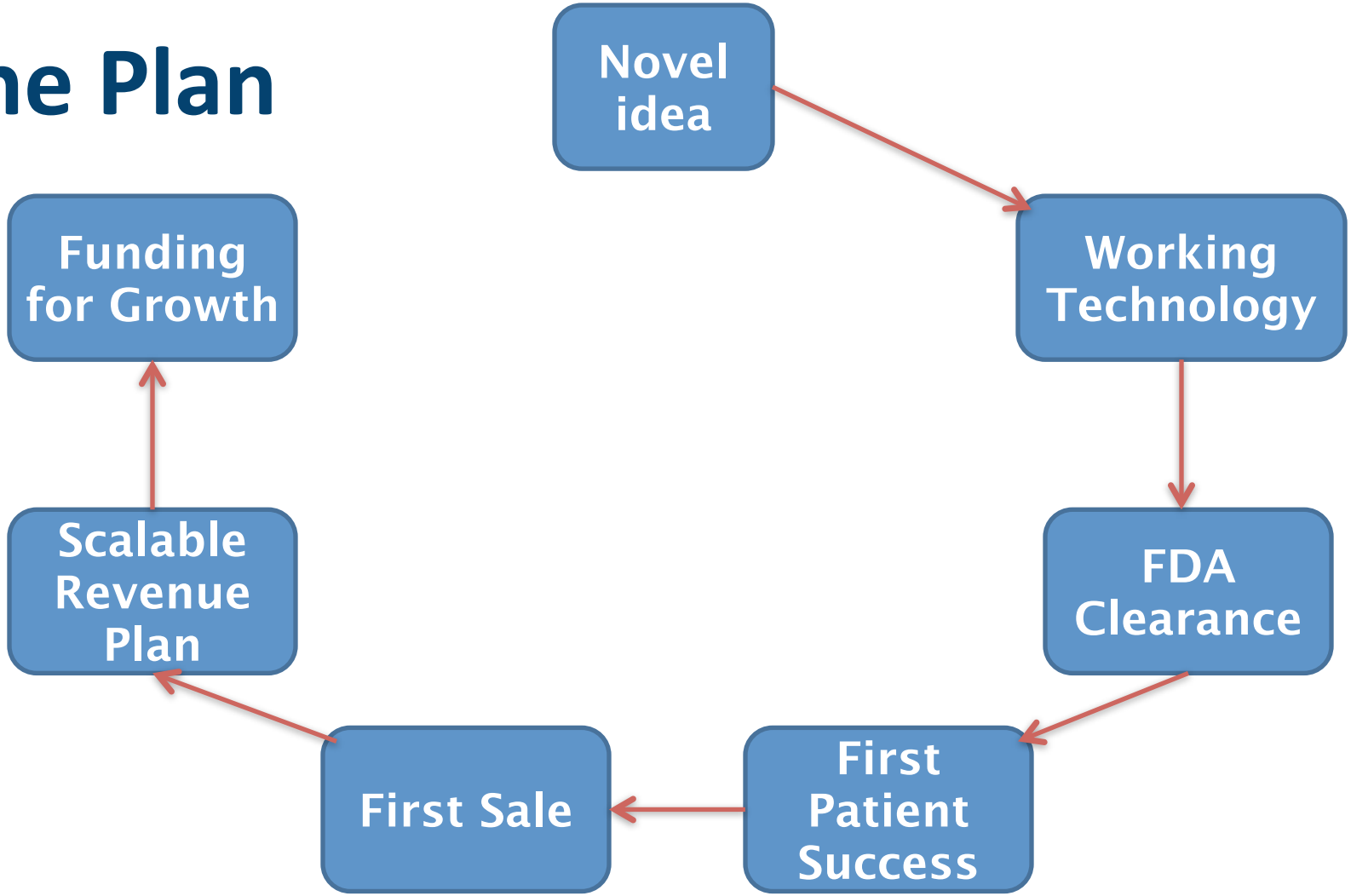
$7.6 billion/year on post-stroke rehab

- (Agency for Health Care Policy and Research)

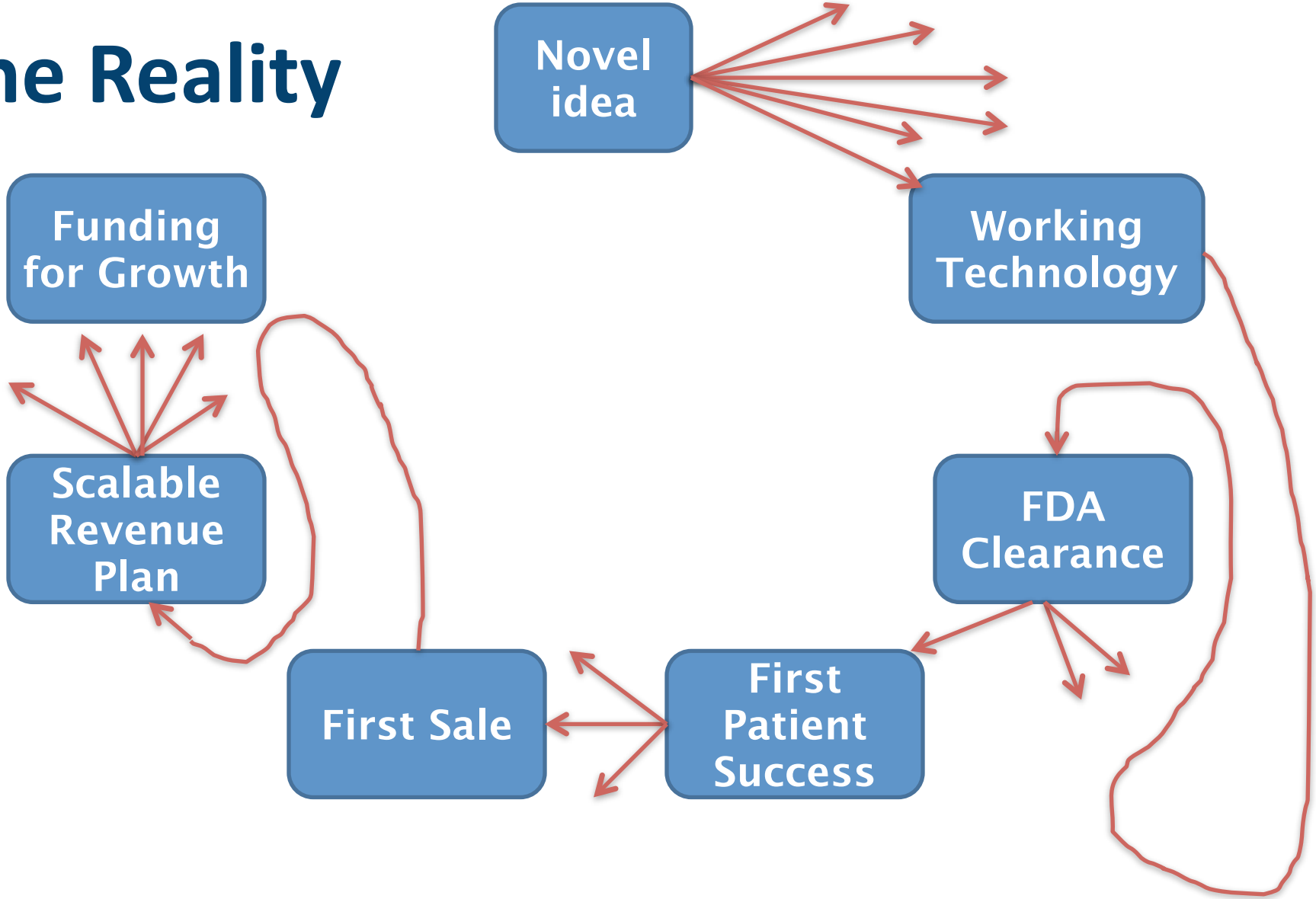
Stroke in the U.S. – Chronic

- **6.5 million people living with stroke** *(AHA)*
- **50% are stroke survivors that still have gait impairments** *(Visiten, Stroke Journal)*
- **3M+ chronic stroke survivors who would benefit from Bionic Leg Therapy**

The Plan


Novel idea
Working Technology
FDA Clearance
First Patient Success
First Sale
Scalable Revenue Plan
Funding for Growth

The Reality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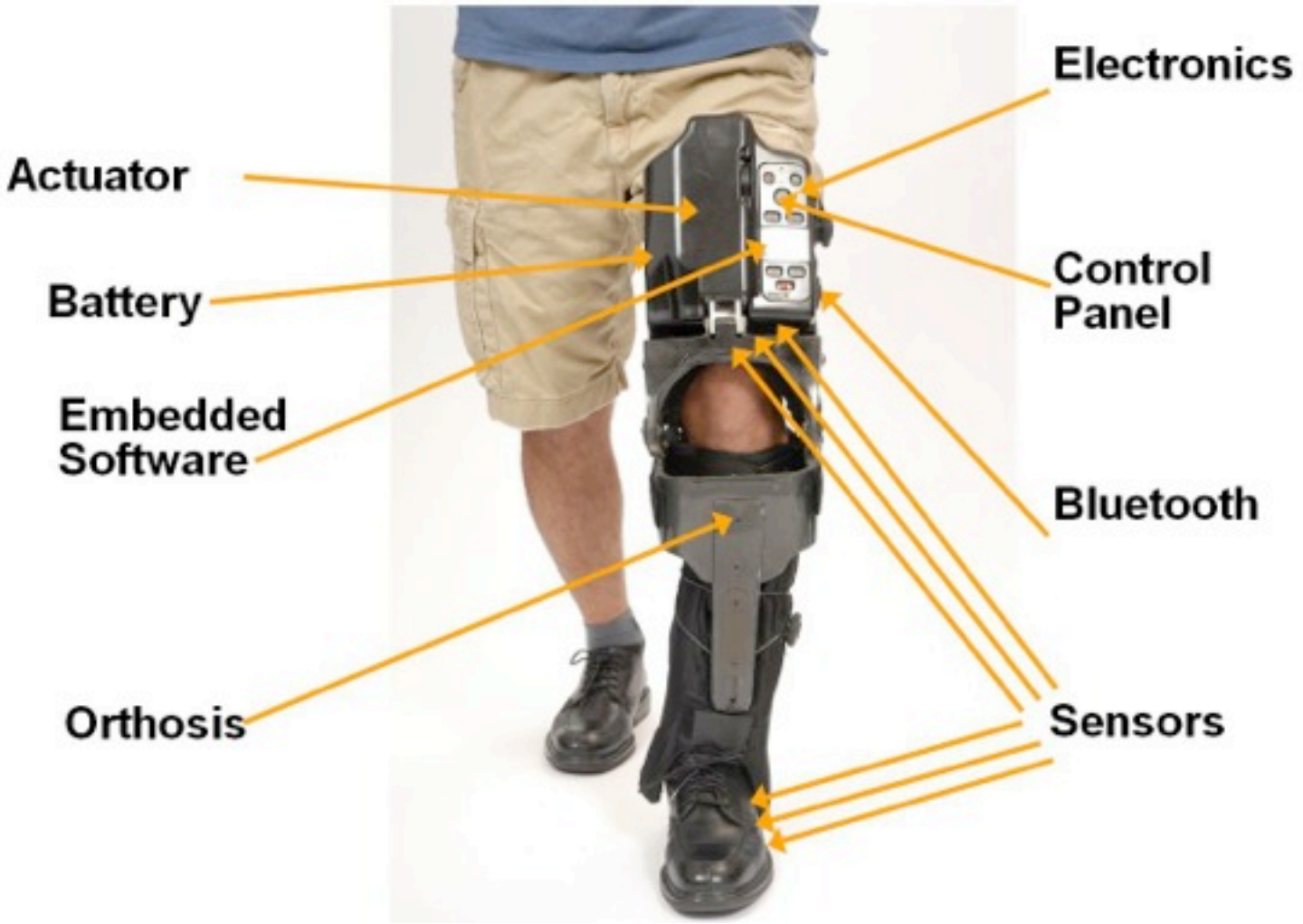
Key Technologies

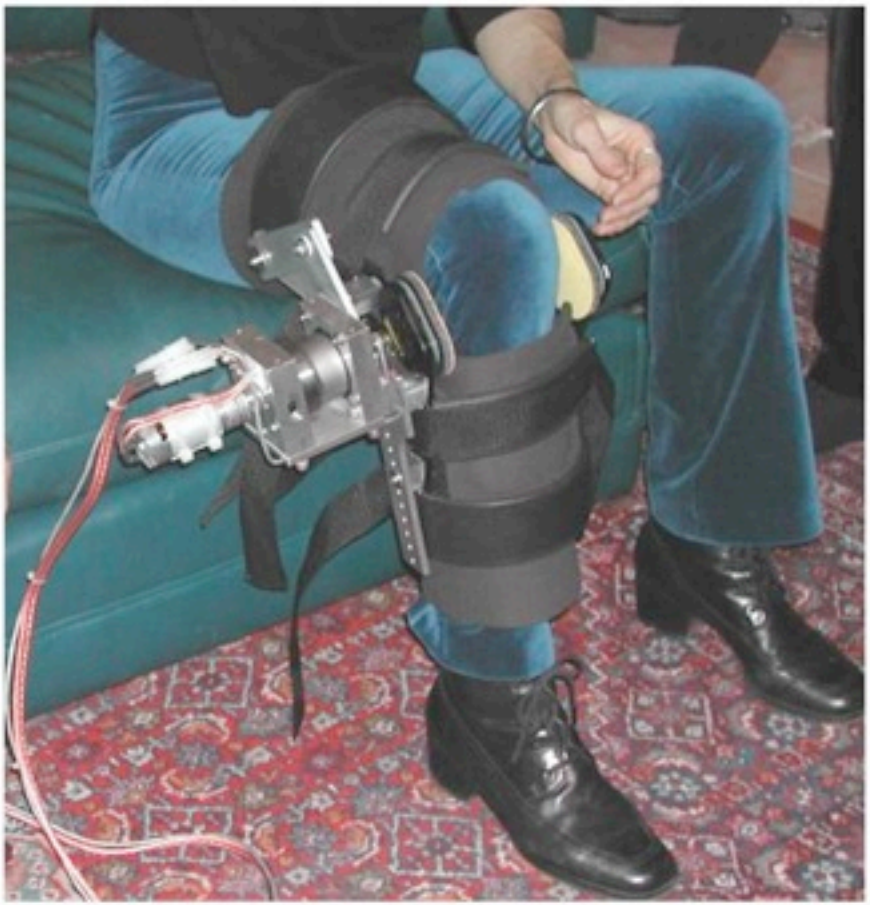


Tibion Technology Overview

- Efficient transfer of force to body
- Continuously variable transmission actuator
- Integrated electronics board with high current motor drivers that do not interfere with low voltage biomechanical sensors
- Charging and switching electronics for high-current Lithium Ion batteries
- Custom motor controller using a field programmable gate array to
- Real-time software system including sensor acquisition, motor control and user interfaces
- High-level software algorithms to address various patient needs
- Algorithms for transparent assistance
- Wireless data access

PowerKnee Mechanical Prototype

- Uses DC motor and 380:1 reduction gear to provide assistance
- Control electronics is embedded microprocessor plus motor controller
- Allows Tibion to:
  - Determine force requirements
  - Optimize control algorithms
  - Evaluate effectiveness of assistance
- Is much bulkier than final product
  - Motor/gearing is much heavier and larger than electrostatic motor
- Cannot replicate some uses of final product due to lack of free movement mode

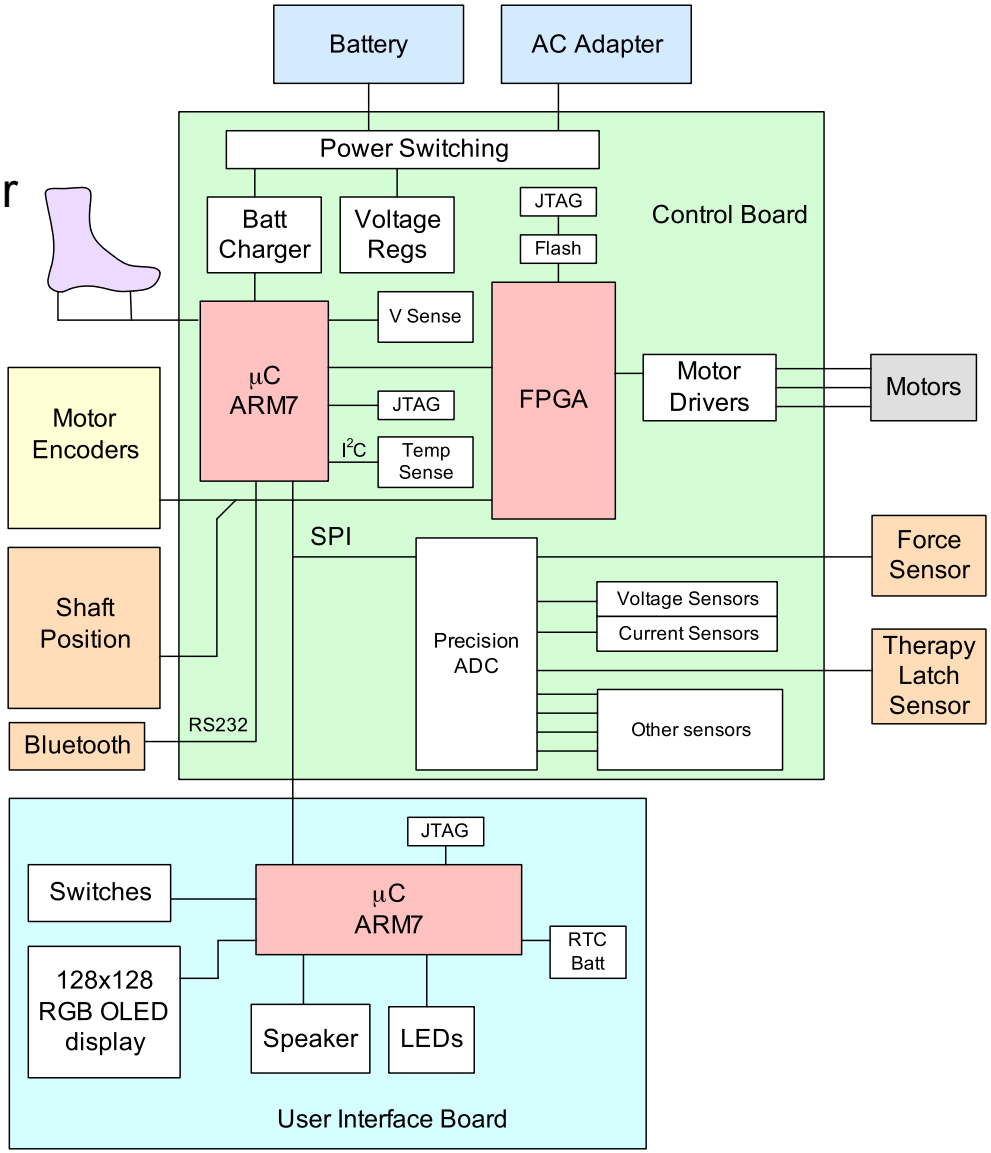


Actuator Development

- Much more difficult than we ever imagined
- Designed and/or prototyped 9 ideas before finding one that met all requirements
  1. **Linear Electrostatic**
  2. **Rotary Electrostatic**
  3. **Harmonic Rotary Electrostatic**
  4. **Hybrid Electrostatic/Magnetic A**
  5. **Hybrid Electrostatic/Magnetic B**
  6. **Hybrid Electrostatic/Magnetic C**
  7. **Single belted CVT (continuously variable transmission) A**
  8. **Single belted CVT B**
  9. **Dual belted CVT**
- Final approach
  - **Electronically variable CVT**

Electronics

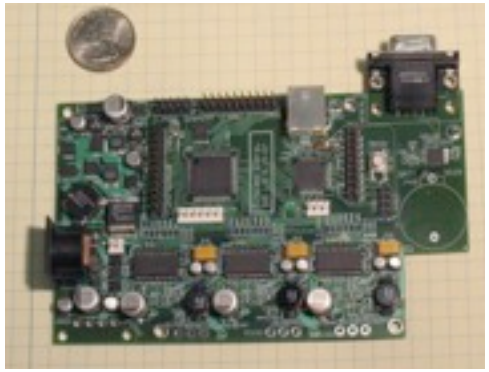
- Control Board
  - ARM7 Processor
  - Custom FPGA motor controller
  - Battery charger
  - Sensor Interfaces
    - Current/voltage/temperature
    - Force sensor
    - Position sensors
- User Interface Board
  - Display processor (ARM7)
  - 128 x 128 RGB Organic LED display
  - Speaker for audible alarms



Electronics Evolution

Off-the-shelf processor and motor controller boards

Custom motor controller prototype

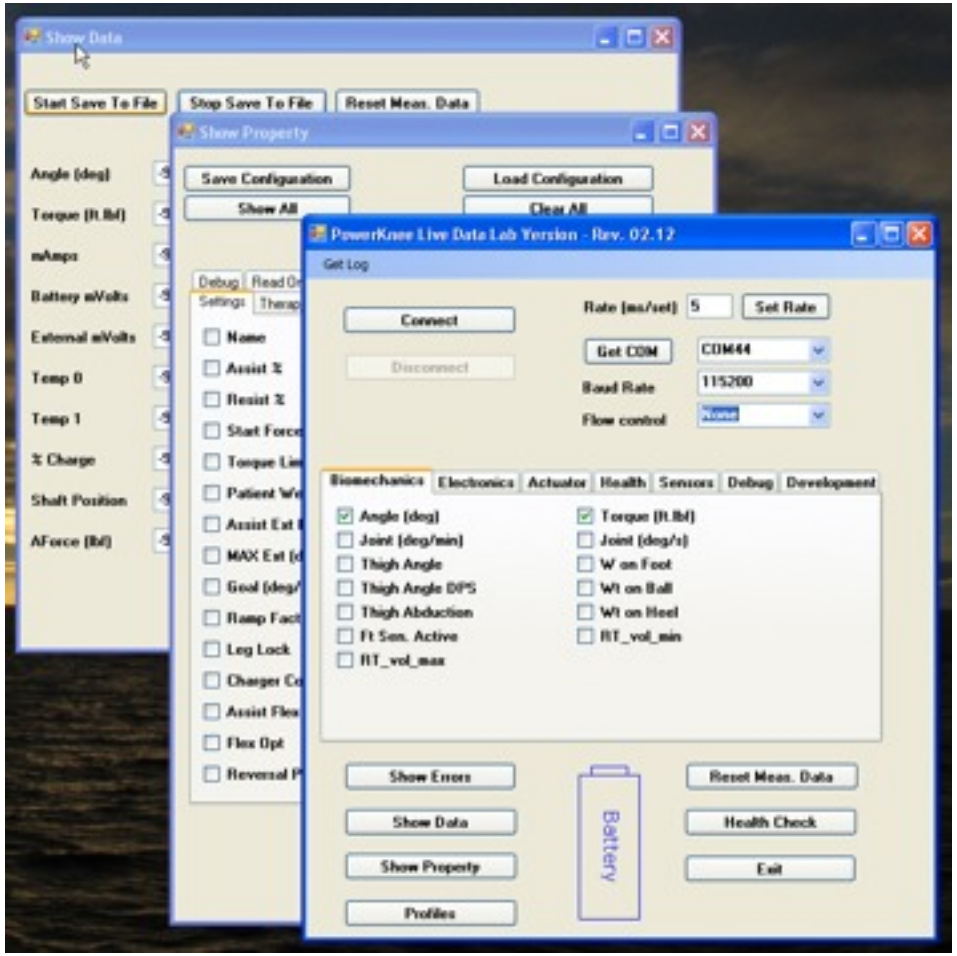


Integrated processor and motor controllers

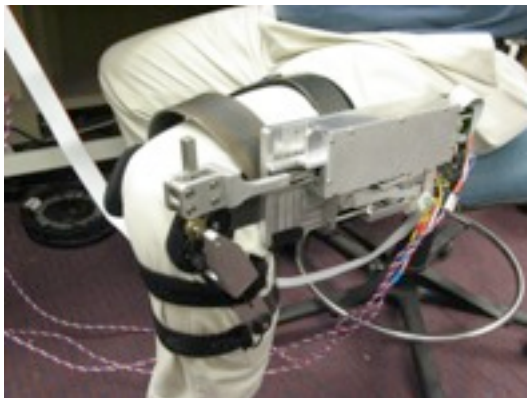
Reduced size with integrated processor, motor controllers and sensor interfaces

Live Data Utility

- PC application interfaced to PowerKnee via Serial Port or Bluetooth
- Observation of selected configuration information and live sensor data
- Setting of configuration parameters
- Recording min and max values of selected parameters
- Error logging
- Capture of traces for export to Excel graphs and later analysis



Tibion Bionic Leg Evolution



Stroke Rehabilitation Today

Related Products

Exoskeletons under development in US, Israel, Japan

- Not therapeutic, not for rehab
- Not intention based

Movement governed by:

- Position control and/or EMG feedback

Essentially,

"Vertical Wheelchairs"

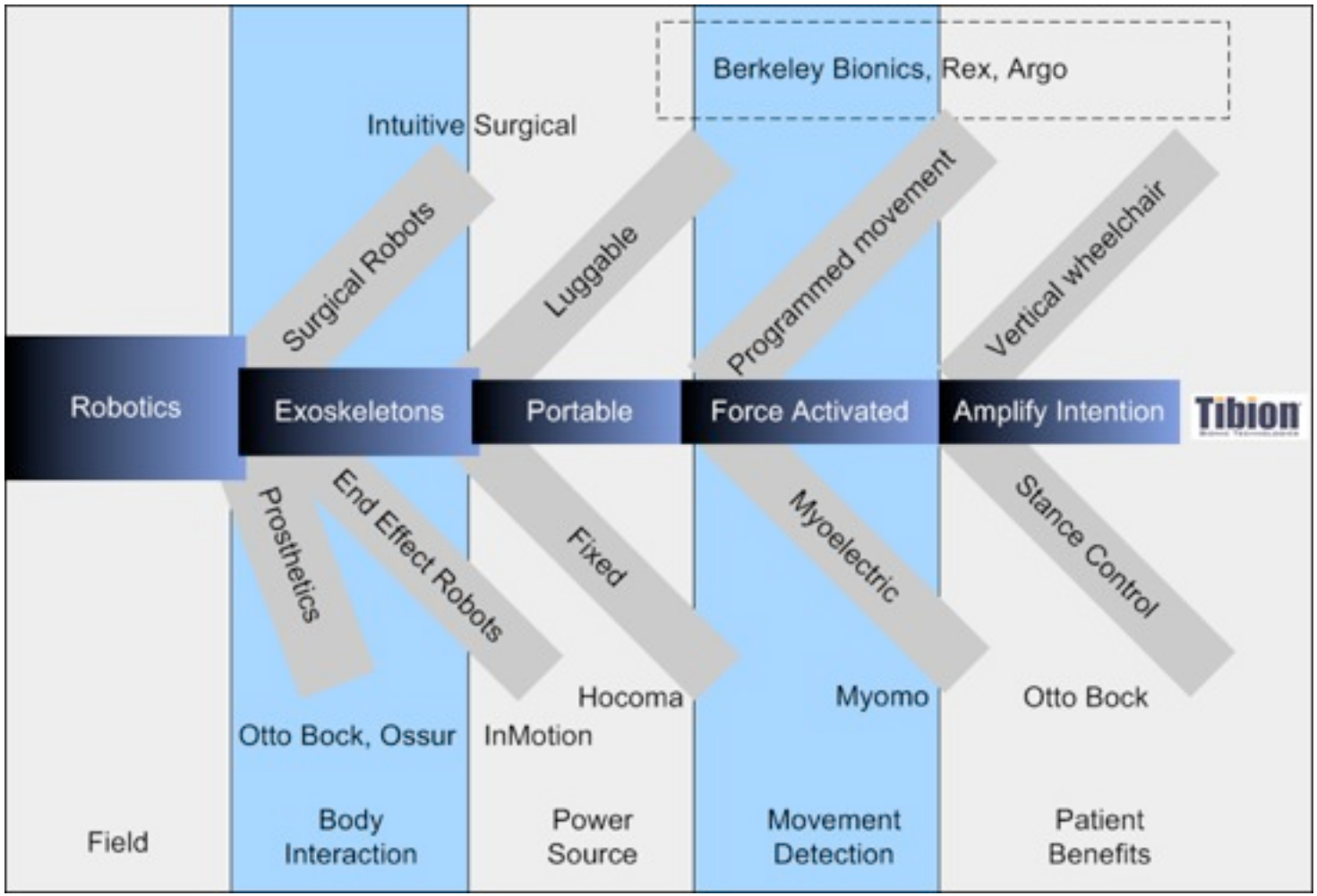
Cyberdyne

Berkeley Bionics

Honda Bodyweight Support Assist

Argo Robo-Walker

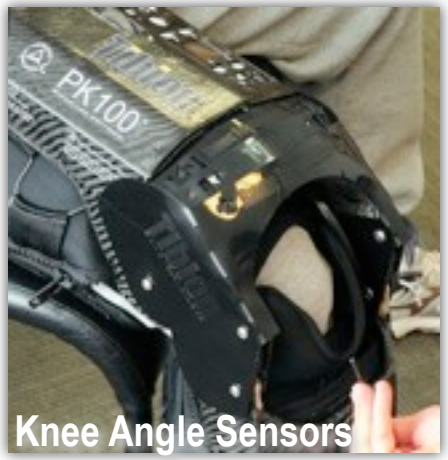
The Future of Medical Robotics



How Bionic Leg works

- Sensors in shoe detect weight distribution
- Sensors in knee orthosis
  - *Detect knee angle*
  - *Detect intended movement*
- Therapist programs Bionic Leg computer
  - *Patient weight*
  - *Start force*
  - *Assistance/resistance*
  - *Assist extension limit*


Shoe Sensors



Knee Angle Sensors


Bionic Leg computer

Bionic Leg: Transforms post-stroke gait recovery

- **Wearable robotic device** equalizes affected, unaffected legs

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Move... yourself.

Bionic Leg Therapy

- Progressive Functional Mobility Training
  - ***Sit to Stand, Transfers***
  - ***Pre-gait & Static Balance***
  - ***Progressive Gait and Stair Training Over-ground & Treadmill***
- Interactive Intervention
  - ***Therapist driven modulation***
  - ***Positive feedback: i.e. weight bearing thru limb leads to desired assistance***

Tibion Access Plan

Allows rapid implementation of latest rehabilitation technology

Avoid large capital investments

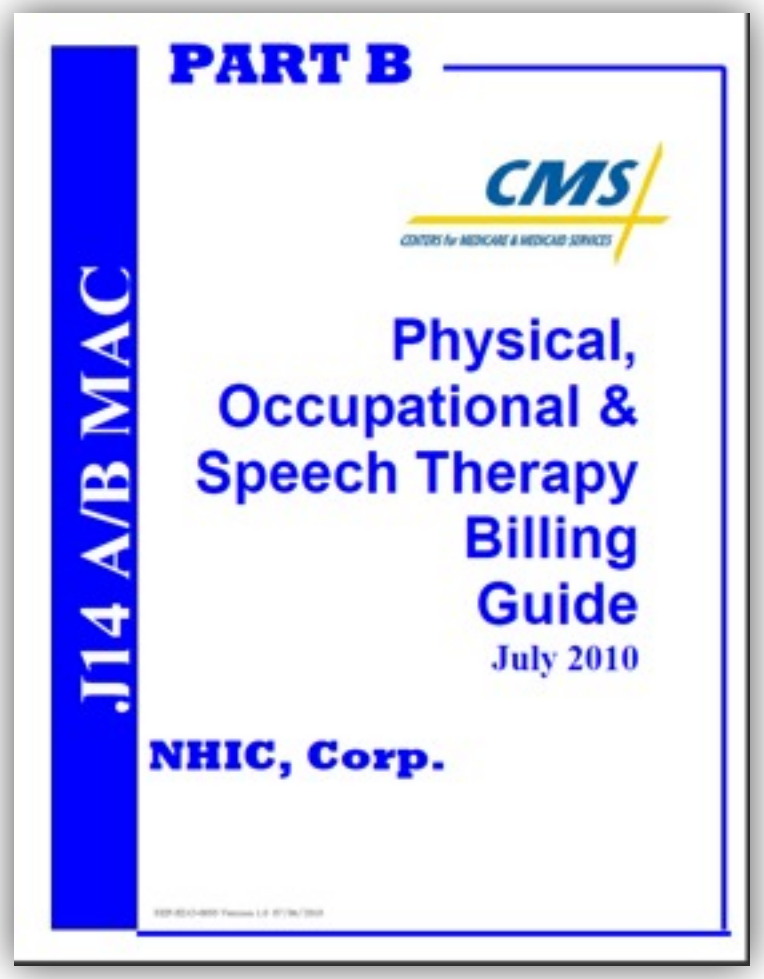
Always have cutting edge equipment through regular upgrades

Avoid obsolescence

Access Plan (12 month contract)		
TBL	**$999/Mo**	**Unlimited**
Training & Consumables	**$1,995**	**Starter Kit**

Compatible/compliant with CMS

- **Medicare Part A, Part B pay** for the therapy the Bionic Leg enables – no special codes, no extra paperwork
- **Bionic Leg persuades**
  - Patients to come back for more rehab sessions than conventional therapy
  - Private insurers to pick Bionic Leg providers, extend therapy past normal limits
  - SNF patients to pay for extra days



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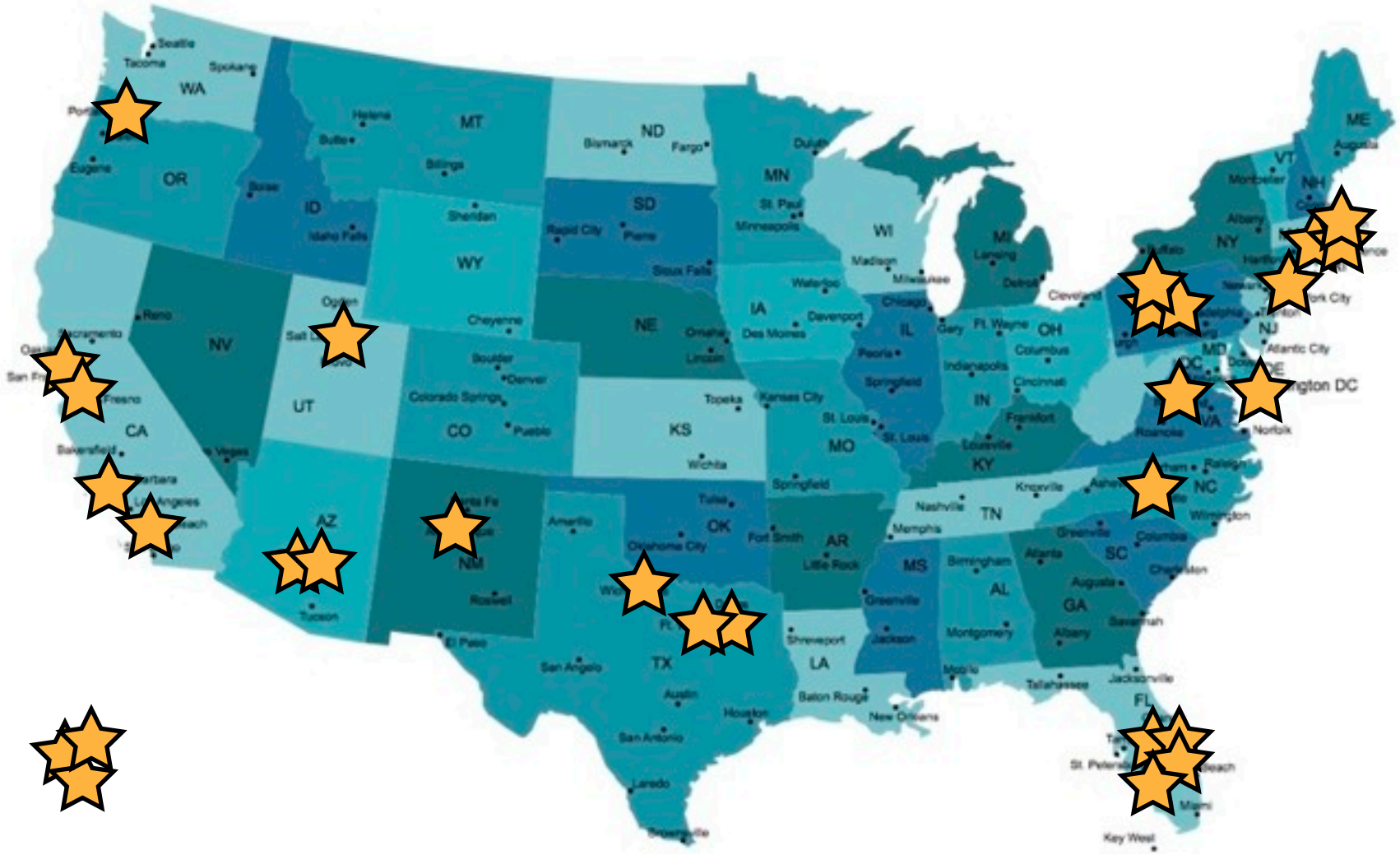
Bionic Leg Customers



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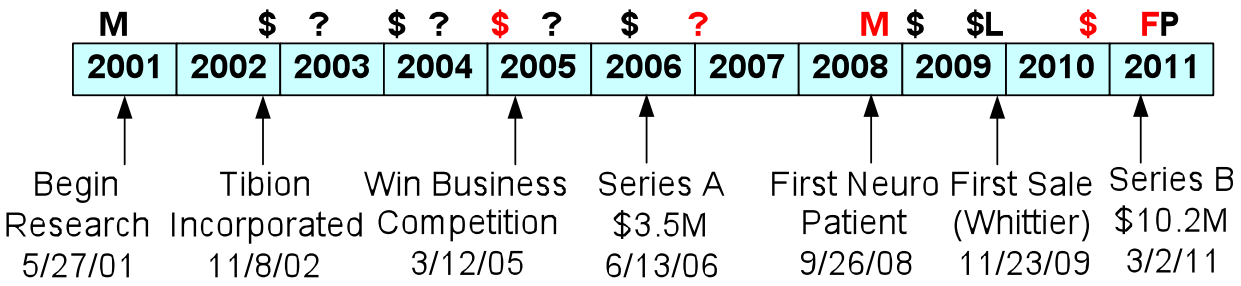
Move... yourself.

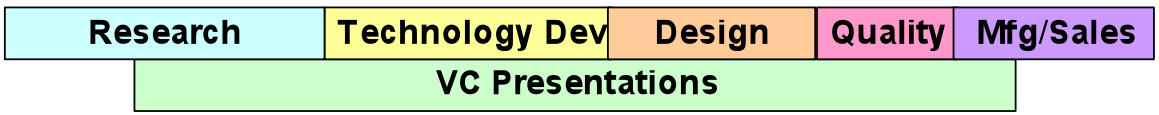
Timeline



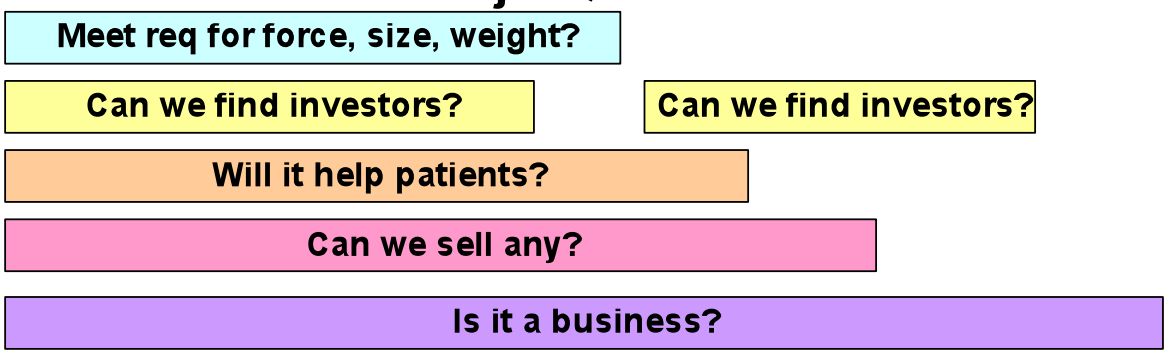
Key to Crisis

M - Financial Meltdown
$ - Out of money
? - New invention needed
L - Leadership change
F - FDA Audit
P - Production Problem

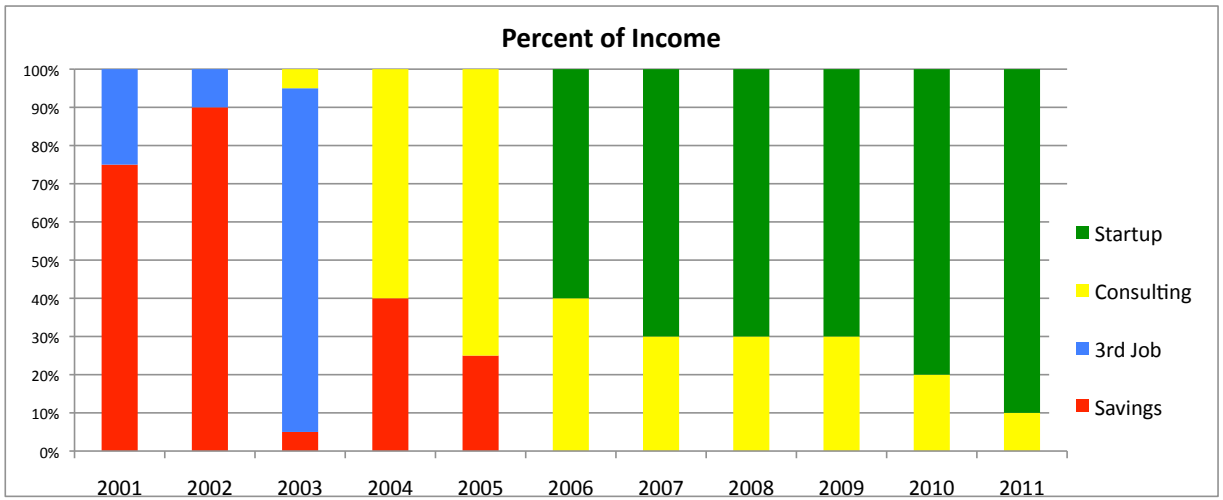
Major Activities

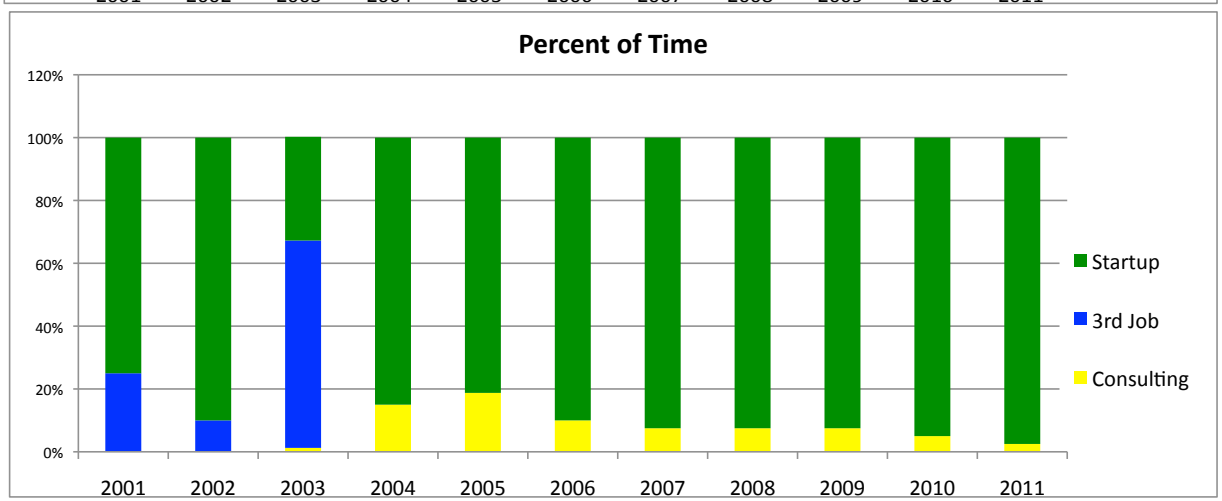


Major Questions



Consulting–Startup Transition





Lessons Learned

- Start a company for the right reasons
  - **To do exciting work**
  - **To make a contribution**
  - **Not to get rich (there are easier ways like the lottery)**
- Consulting as an alternative to seed funding
  - **Support yourself with consulting**
  - **Spend remaining waking hours at startup**
- Must be the right kind of startup
  - **Not for companies in competitive space (too slow)**
  - **Best for companies with unproven technology or market**
- Time management is difficult
  - **Initially hard to get enough consulting work to survive**
  - **Later hard to turn down work to build the startup.**