

SCS Systems Today: Unmet Needs

IPG	Leads	Patient Programmers & Rechargers	Clinician Programmers
<ul style="list-style-type: none"> Standardized configuration (2x8) Poor tri-pole capabilities Current steering Complete discharge recovery Limited parametric range Biphasic square waveform Inductive coupling Unidirectional recharge Restricted implant depth 	<p>Percutaneous Leads</p> <ul style="list-style-type: none"> Lead migration (13%)* Lead breakage (9%)* Limited coverage 1 - 2 spine levels Inability to capture target Need for splitters to achieve tri-pole stim <p>Paddle Leads</p> <ul style="list-style-type: none"> Excessive volume Blind positioning Lack of steering control 	<ul style="list-style-type: none"> Designed for in-home use Large and non-discrete Button sequences are confusing Small screens for feedback No color or touch screens Multiple devices for programmer/recharger Lack recharge feedback Inductive coupling required 	<ul style="list-style-type: none"> Time consuming Non-intuitive Dependent on sales team Lack patient feedback mechanism Awkward size devices Lack visual clarity Stylus required in handhelds Inductive coupling required

*SOURCE: Cameron et al., 2003 & updated with 2009 AAPM poster



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Product Strategy



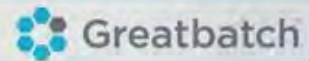
- Target unmet clinical needs
- Focus on product differentiation for all user groups
- Procedurally the same - but better
- Legacy free, proprietary system
- Design focused on safety
- Allows efficient regulatory approval
- Gen 1: Technology innovation drives market share
- Gen 2: Breakthrough technology enables market leadership

"A product designed by doctors for doctors"

Richard B. North, MD



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Algostim System

The image displays the Algostim System components, which are used for spinal cord stimulation. The components are arranged on a light-colored surface against a light blue background. The items include:

- Patient Feedback Tool (PFT):** A black, handheld device with a red sensor tip.
- Clinician Programmer (CP):** A large black tablet with a screen displaying the 'algostim' logo and a human figure.
- Patient Programmer Charger (PPC):** A black smartphone-like device with a screen showing various icons.
- Pocket Programmer (PoP):** A smaller black handheld device with a screen.
- Anchors:** Small metal surgical anchors.
- Extensions:** Thin, flexible wires.
- Implantable Pulse Generators (IPG):** Small, rectangular electronic devices.
- Perc Leads:** Long, thin leads with multiple electrodes.
- Paddle Leads:** Leads with a flat, paddle-shaped electrode array.
- External Pulse Generator (EPG):** A black rectangular device connected to a lead.
- Trial Cable:** A cable with a multi-colored connector.

At the bottom left, there is a navigation bar with five dots, the fourth of which is highlighted in blue, and the text "Commercialize Medical Device Innovation". At the bottom right, the "Greatbatch" logo is visible, consisting of a blue hexagonal icon and the company name. A small number "49" is located in the bottom right corner of the slide.

Algostim System Innovations

IPG



- 24 Channels
- Two Configurations
- Tri-Pole Capability
- Smallest Volume
- Thinnest Implant
- Largest Battery Capacity
- Broadest Parametric Ranges
- Bi-Directional Recharge
- MICS Wireless Telemetry
- Embedded Program Memory

Leads



Perc Leads

- 12 & 8 Contact Arrays
- Dual Coil Construction
- Body Compliant
- Lead ID System



Paddle Leads

- Thinnest >50%
- Smallest Volume >50%
- Body Compliant
- Multi-Midline Positioning
- Stylet Steering

Programmers/Software



- Color Touch Screen
- 3D Pain Mapping
- 3D Stim Mapping
- 3D Overlap Scoring
- CASP Algorithm
- CASP Feedback Device
- Camera / Barcode Reader
- Monitor Mirroring
- Combined Programmer / Charger
- Key Fob Programmer

Implantable Pulse Generator

Features

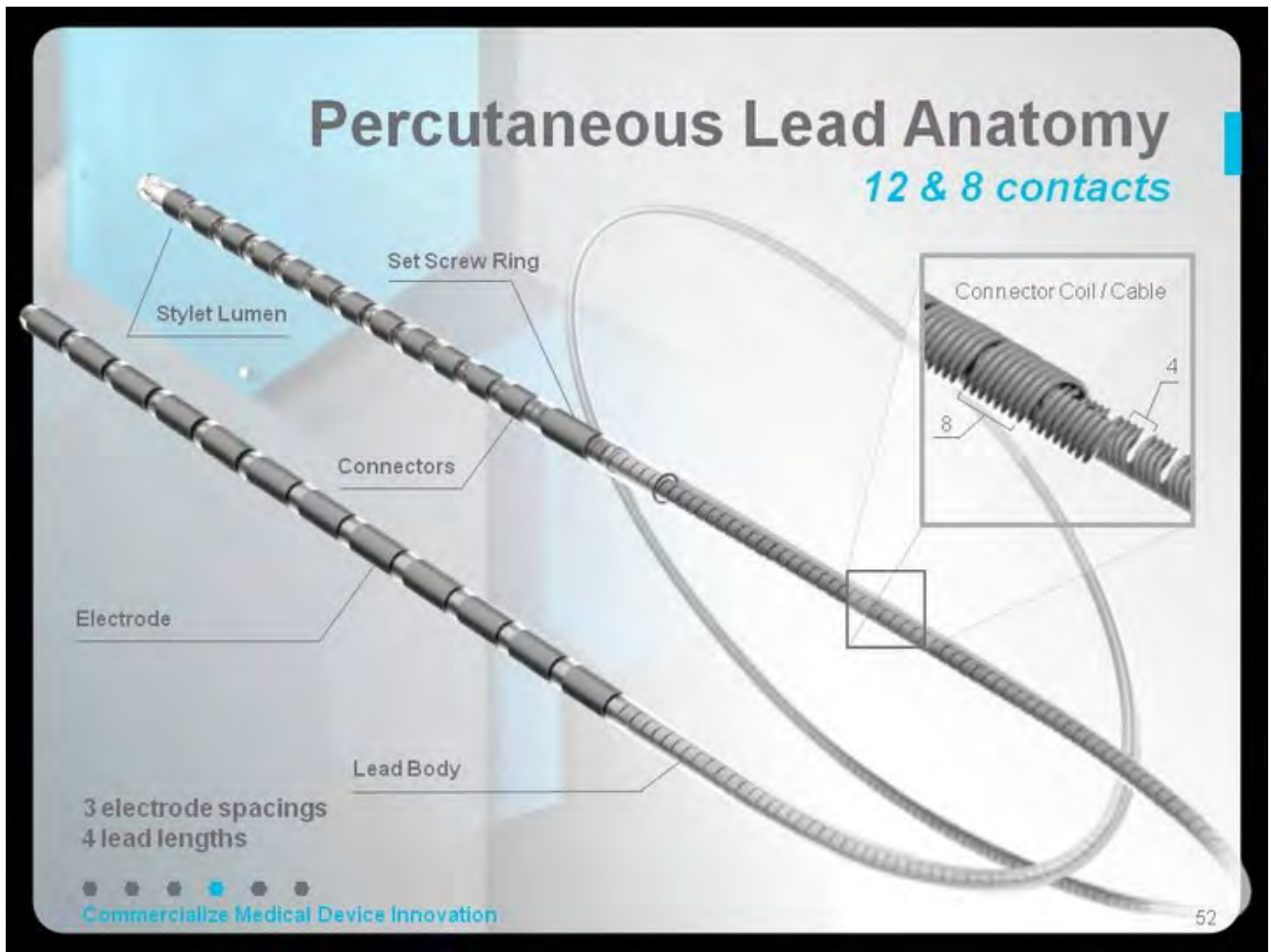
- 24 channels
- Two header configurations (2x12 & 3x8)
- Rechargeable battery
- Largest battery capacity
- Broadest parametric ranges
- Smallest & thinnest device
- Independent current sources
- Deep discharge recovery
- Constant current output
- MICS wireless telemetry
- Safety thermistor
- Bi-directional recharge
- Embedded memory



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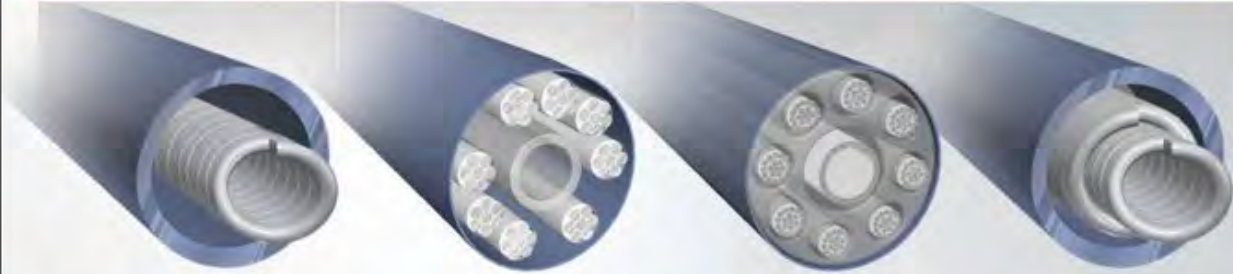


Lead Design Progression

Past

Present

Future



COIL DESIGN
COIL STRUCTURE
4-Electrode Leads

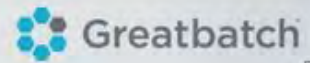
UNCONSTRAINED
STRAIGHT WIRE
8-Electrode Leads

INDEPENDENT
STRAIGHT WIRE
8 & 16-Electrode Leads

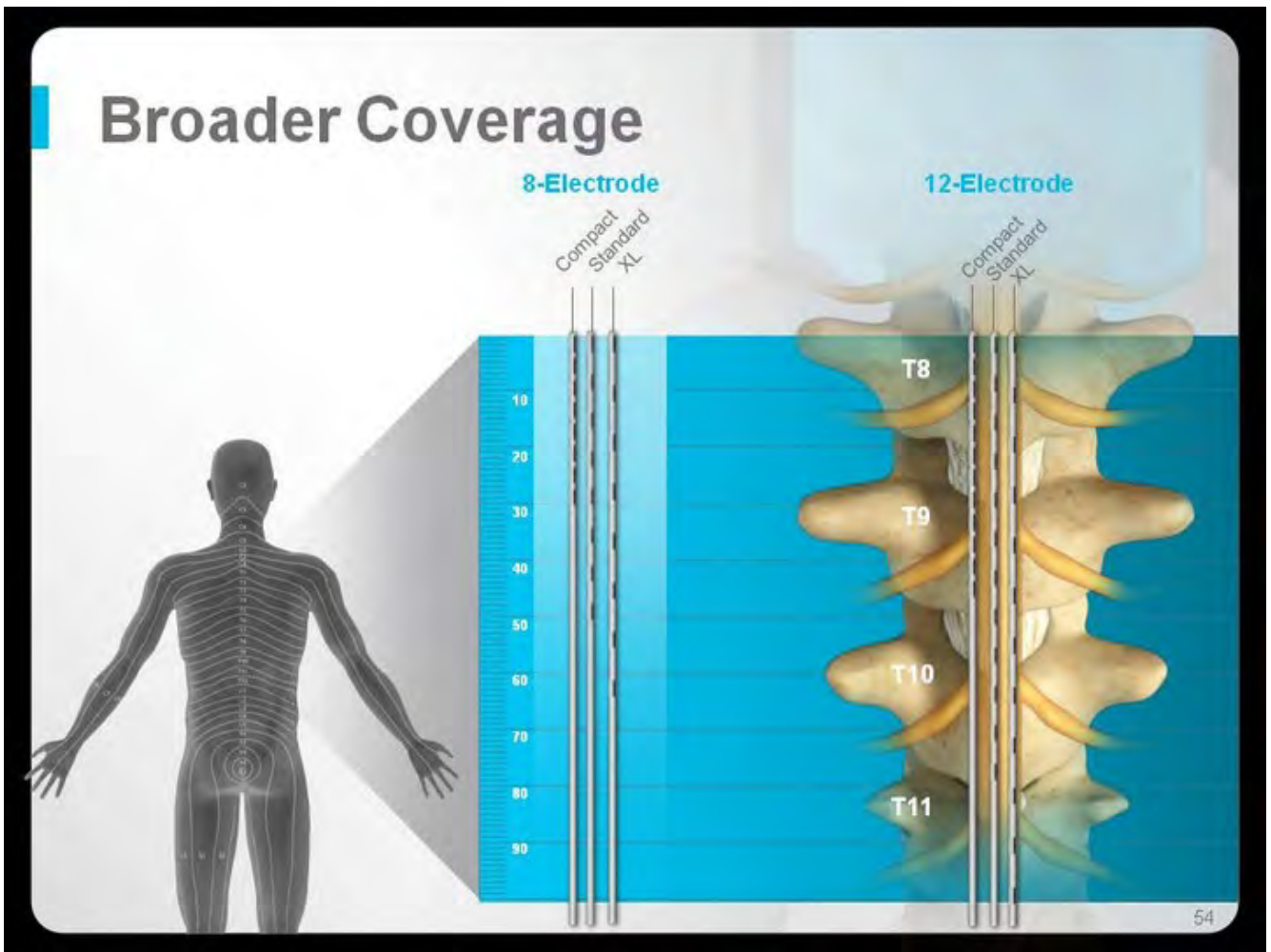
algotim
COIL IN COIL DESIGN
COIL STRUCTURE
8 & 12-Electrode Leads



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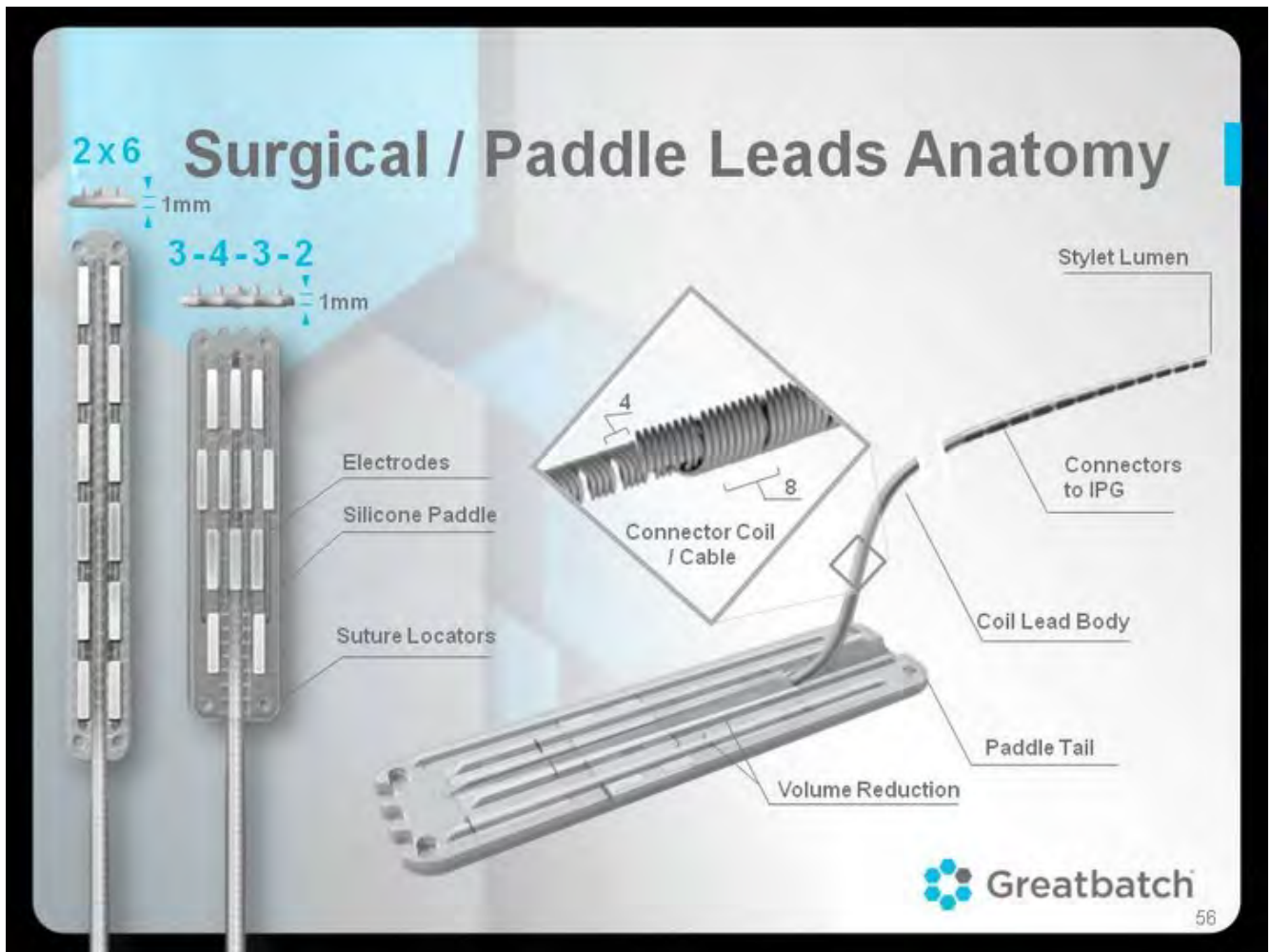


Paddle Lead Standards



Current product limitations

- Excessive volume
- Lack of steering control
- Blind positioning
- Have no / limited body compliance



Thin Profile Paddle Leads

Current Products



Programmer Family



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Patient Programmers



Pocket Programmer

- Discrete key fob design
- Daily control functions
- Rechargeable device
- MICS wireless telemetry
- Quick stim-off

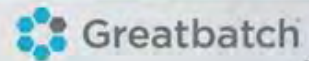


Programmer Charger

- Programming and recharging device
- Full control programming options
- Color touch screen interface
- MICS wireless telemetry
- Recharge location visual feedback
- Rechargeable device
- Quick stim-off



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Clinician Programmers



Clinician Programmer

- Resistive color touch screen
- External monitor connection
- Embedded camera
- Rechargeable device
- SD card storage
- Bluetooth communication
- MICS wireless implant telemetry
- Quick stim-off

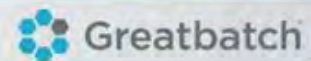
Patient Feedback Tool

'Computer Assisted Stimulation Programming'

- Automatic impedance check
- Stimulation threshold determination
- Patient identifies best stimulation coverage / optimal parasthesia patterns
- Bluetooth communication
- LED feedback
- Quick stim-off



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Clinician Programmer Software

Software Features

- 3D Virtual Environment
- 3D Pain Mapping
- 3D Stimulation Mapping
- 3D Overlap Scores
- Computer Assisted Stimulation Programming ('CASP')
- Presets for routine intra-operative trials
- Visual implant selector
- Patient programming history
- Secure log-ins
- Patient device emulator
- Auto report generation
- Bluetooth printer

Pain
Mapping

Product
Selection

CASP

Set
Program



Pulse Generators	Leads & Extensions	Programmings
 <p>IPG</p> <ul style="list-style-type: none"> • Thermistor • MICS Wireless Telemetry • Deep Discharge Recovery Battery • Bi-Directional Recharge • High Voltage Protection Circuitry • Independent Current Sources • Internal Self-Checks • Impedance Check • Quick Stim-Off by External Devices  <p>EPG</p> <ul style="list-style-type: none"> • Internal Self-Checks • Easy Trial Cable Connect/ Disconnect • Quick Stim-Off • Program Memory <p>Safety Features</p>	 <p>Perc & Paddle Leads, Extensions</p> <ul style="list-style-type: none"> • Minimize Size • Coil In Coil Design • Multiple Electrodes • Active Capture Set Screw (Extension) <p>Accessories</p>  <p>Stylets</p> <ul style="list-style-type: none"> • Multiple Tips <p>Introducer Needle</p> <ul style="list-style-type: none"> • Flared & Radius Tip <p>Tunneling Tool</p> <ul style="list-style-type: none"> • Malleable Rod & Tip • 2 Length Options • Accommodates 3 Leads 	 <p>All Programmings</p> <ul style="list-style-type: none"> • Battery Status of IPG • Paired to Single IPG / EPG • MICS Wireless Telemetry • Quick Stim-Off <p>Programmer Charger</p> <ul style="list-style-type: none"> • Rechargeable Device During IPG Recharge • Recharge Location Feedback • Recharge Temperature Sensing <p>Clinician Programmer</p> <ul style="list-style-type: none"> • Log-Ins for Different Users • Monitor Mirroring • Camera / Image Storage • Charge Density Limits • Model Based Implant Selection <p>Patient Feedback Tool</p> <ul style="list-style-type: none"> • 'CASP' (Computer Assisted Stimulation Programming)

Regulatory Plan

Proposed Indication

The Algostim Spinal Cord Stimulation (SCS) System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain.

History

Company (Product)	Original PMA	Supplements
Medtronic (Irel)	1984	233+
St. Jude (Genesis)	2001	65+
Boston Scientific (Precision)	2003	153+

Plan

- Pursue PMA approval (*literature based PMA*)
- Utilize pre-IDE / PMA process
- Obtain CE mark
- TÜV (*notified body*) utilizing modular review process



Next Generation

IPG Embedded Capabilities

- High Frequency Stimulation
- 3-axis accelerometer
- Novel waveforms & wave shaping

Lead Designs

- Thin-film perc lead designs
- 24+ electrode paddle leads

System Level

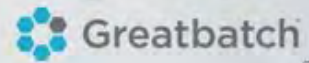
- MRI conditional system



Thin-Film Paddle: Planar Cylindrical
24+ Electrodes



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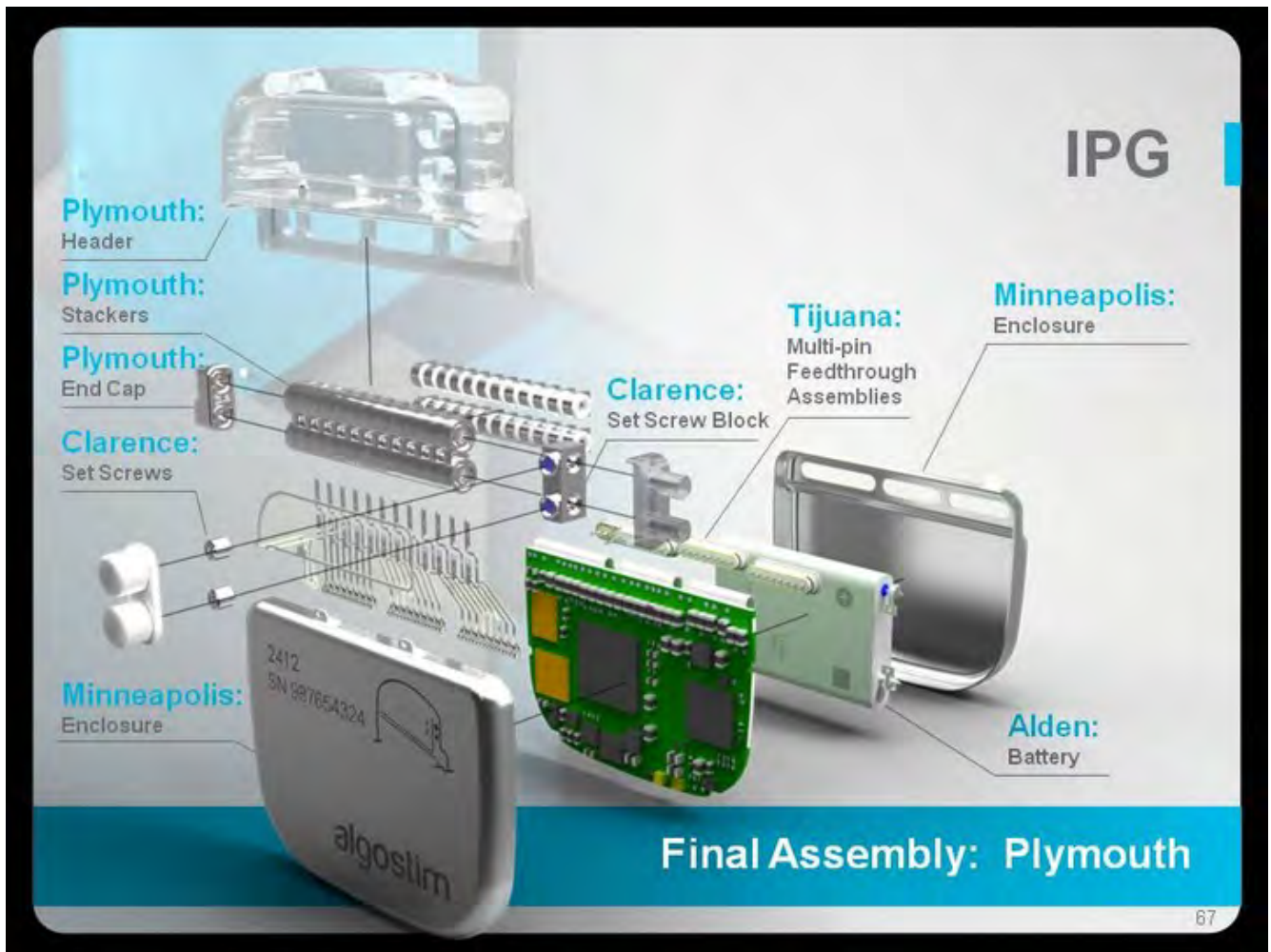


Intellectual Property

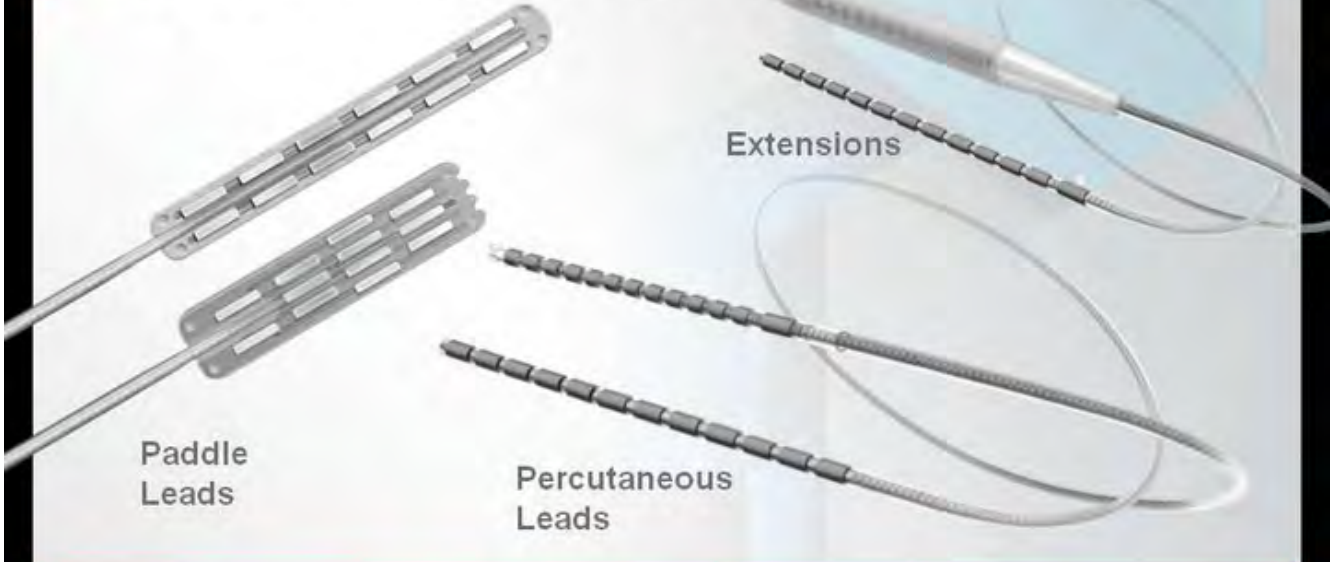
- Greatbatch IP portfolio > 1000
- Algostim invention disclosures 135
- Filed patent applications 86
- Patent applications in draft 18
- Patents licensed Dr. North & Barolat 11
- Patents issued to date 6
- Patent opinions 77

IP Product Distribution

	Leads	IPGs	Programmers & Software	Accessories	Total
Disclosures	26	44	51	14	135
Applications	19	23	36	8	86
Opinions	20	39	17	1	77



Leads & Extensions




Paddle Leads

Percutaneous Leads

Extensions

Manufacturing: Plymouth

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Programmers



Software

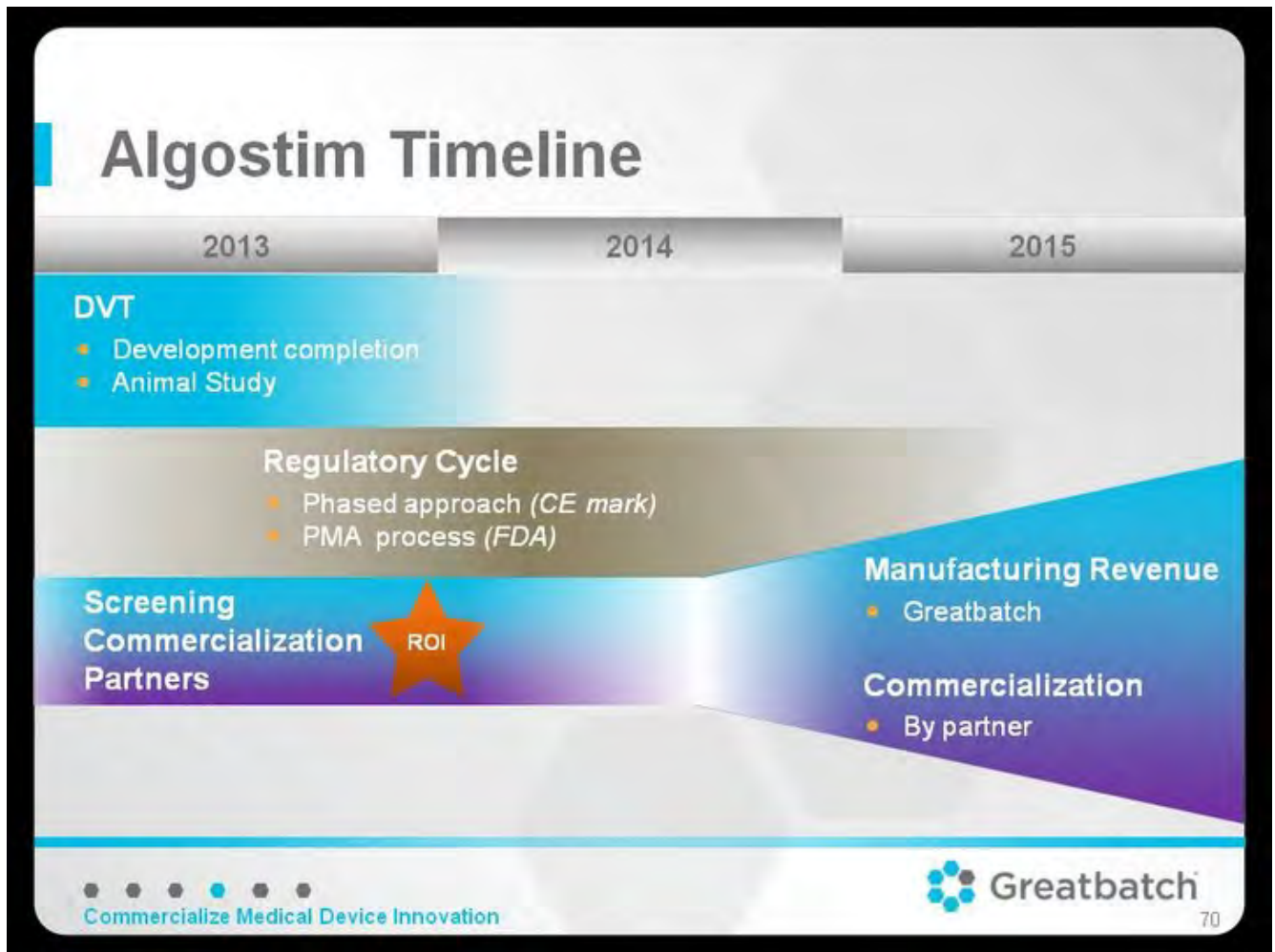


Batteries for Programmers



Software: Denver

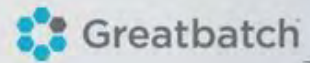
Portable Medical: Raynham



Strong Value Proposition



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Impact to Customer Groups



Physicians

- No change to implant procedures
- Improved body compliant lead design & steering control
- Broader stimulation coverage
- Multiple IPG options

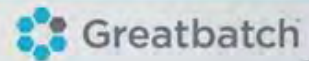
- Long list of Safety Features
- Highly visual & intuitive programmers
- Intraoperative visibility and engagement of surgical staff
- Patient interactive programming

Patients

- Portable & Discrete External Products
- Simple and familiar user interfaces
- Comfortable system for screening, recharge and daily transport
- Fits existing reimbursement standards



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Value Proposition



"A highly differentiated complete SCS system and platform with extensive offering of innovation, IP, advanced safety features, and future generation capabilities in the fast growing \$1.4B SCS market"

- 1% market share represents \$17M revenue to partner in 2015
- Highly under penetrated market (<10%)
- History of large market share shifts with technology innovation
- Strong SCS growth rate (7%+ CAGR)
- Extensive IP portfolio
- Gen 1: Technology innovation will drive market share
- Gen 2: Breakthrough technology can enable market leadership

Leverage Medical Device System Capabilities



Future NewCo's



- Deliver on complete system initiative
- Investment in capabilities
- Platform technology for additional opportunities

- Approved & emerging indications



- Entry into cardiac systems
- Implantable Loop Recorder
- Address unmet needs
 - › Remote monitoring
 - › High quality data

