

## CPS and Healthcare

Leonard Radtke

March 12, 2012

## Outline

- Short overview on Medtronic, and the Medical space we operate in.
- Examples of CPS in Mainstream Product
- A Progression of CPS in Medical Devices
  - Hardware
  - Implanted
  - Beyond the body
- The Future
  - Opportunity & Challenges

## Improving Healthcare

"Across the world, we are in a continuous quest to improve healthcare. People everywhere want better outcomes, fewer errors, quicker recoveries, and fewer side effects. We're developing medical technology solutions that not only improve healthcare, but do so while delivering better economic value."

**OMAR ISHRAK,** Chief Executive Officer

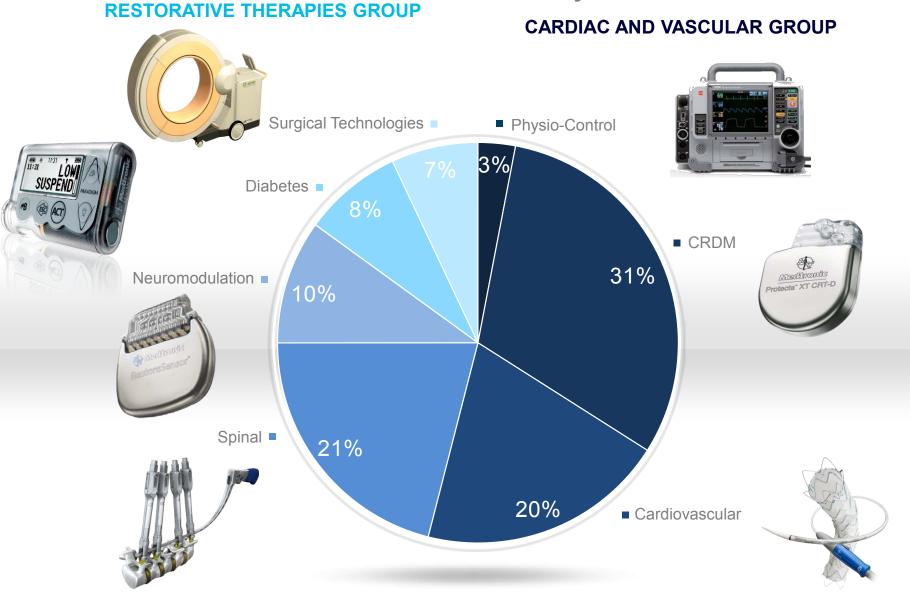


## Serving the World's Major Geographies



Our business is on track to served > 800K patients this year

## Diverse Businesses to Treat Many Conditions





Based on FY2011 revenues of \$15.9 billion

## A Broad Platform of Core Technologies

Targeted Drug Delivery
Raw Materials
Power Sources
Miniaturization
Electrical Stimulation
Closed Loop Systems
Sensors
Connected Care
Imaging Navigation



## Therapies to Address Many Chronic Conditions

Hydrocephalus
Sinus Diseases
Sinus Augmentation
Sleep Disordered Breathing
Cervical Degenerative Disc Disease
Thyroid Conditions

Parkinson's Disease E

Epilepsy\*

**Essential Tremor** 

**Cranial Trauma** 

Dystonia\*\*

**Brain Tumors** 

Obsessive-Compulsive Disorder\*\*



Atrial Fibrillation Heart Failure Congenital Heart Disease <u>Hear</u>t Rhythm Disorders

Angina\*

Coronary Artery Disease Heart Valve Disease

Scoliosis
Spinal Fracture
Lumbar Spinal Stenosis
Degenerative Disc Disease

Pelvic Trauma

Peripheral Vascular Disease\*

Otologic Disorders
Meniere's Disease

**Aortic Disease** 

Severe Spasticity associated with Multiple Sclerosis, Cerebral Palsy, Stroke and Spinal Cord and Brain Injuries

Chronic Pain

Nausea and Vomiting associated with Gastroparesis\*\*

Diabetes

Overactive Bladder and Urinary Retention

**Fecal Incontinence** 

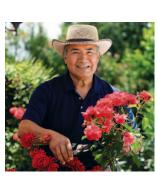
**Tibial Fractures** 

<sup>\*\*</sup> Humanitarian Device in the United States – the effectiveness for this use has not been demonstrated



<sup>\*</sup> Not approved for commercial distribution in the United States

# Improving Another Life Every 4 Seconds













Some common examples of CPS in Medical Devices.

## Cardiac Rhythm Disease Management

Implanted CPS, communicating to outside clinician







Atrial fibrillation diagnostics | Insertable heart monitor

Monitoring | Insertable heart monitor

Heart arrhythmia monitoring | Insertable heart monitor

Tachycardia (fast heart rate) | Implantable cardioverter defibrillator (ICD)

Heart failure | Cardiac resynchronization therapy (CRT-D, CRT-P)

Bradycardia (slow heart rate) | Pacemaker

Paroxysmal atrial fibrillation | Cryoballoon cardiac ablation catheter system

Remote heart device monitoring | Internet-based information technology system



## Physio-Control

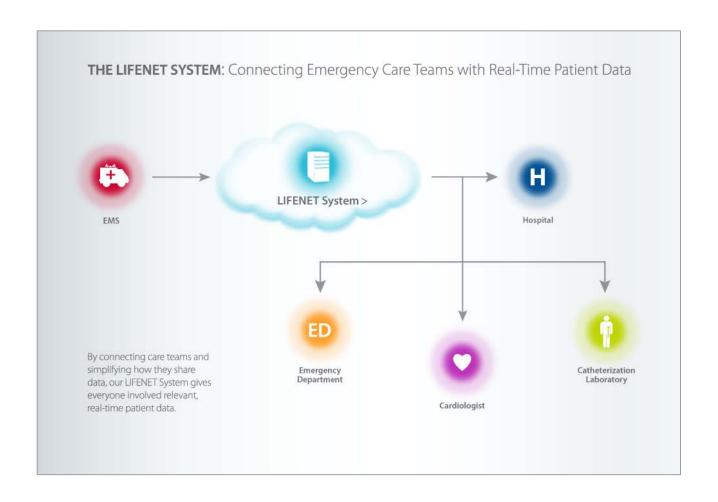
Non-implanted CPS, communicating real time to clinician and Hospital



Sudden cardiac arrest and other cardiorespiratory emergencies

Automated external defibrillators (AEDs)
Information management system linking emergency medical services (EMS) and hospitals
CPR assist device

## Speeding and improving Emergency Response



## Neuromodulation







Movement disorders

Implantable deep brain stimulation systems, drug-infusion systems

Obsessive-compulsive disorder\*

Implantable deep brain stimulation systems

Chronic pain

Implantable neurostimulation systems, drug-infusion systems

#### Implanted CPS

<sup>\*</sup> Humanitarian Device in the United States - the effectiveness for this use has not been demonstrated

### Neuromodulation







Overactive bladder/urinary retention/chronic fecal incontinence

Nausea and vomiting associated with gastroparesis

Implantable sacral neuromodulation systems

Implantable gastric stimulation systems\*

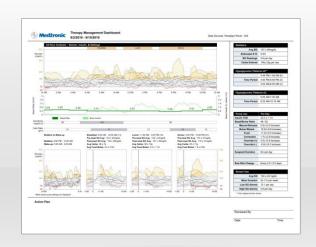
Implanted CPS, using patient real time as part of feedback loop



<sup>\*</sup> Humanitarian Device in the United States - the effectiveness for this use has not been demonstrated

### **Diabetes**





Insulin delivery

External insulin pumps

Glucose monitoring

Personal and professional continuous glucose monitoring systems

Therapy management software

Online tool that simplifies diabetes management by providing clear insights into personal glucose patterns

Non-implanted CPS, using patient real time as part of feedback loop, communicating to clinician



## CRDM progression of CPS

- •1st generation systems were hardware-centric. Matured from "execute a set routine, to prescription based routine, to fully closed loop response systems."
- •2nd generation evolved to implanted CPS. Wide variety of complexity to manage diversity of physiological conditions. Still primarily a closed loop, in-vivo, system.
- •Current generation. Implanted CPS, communicates to a specific nonimplanted CPS, which connects to several information networks and in some cases, CPS systems.

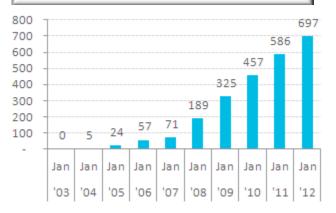
## CareLink— Connecting Our Implanted CPS to the World



- 1. Clinic staff can preschedule up to 6 automatic device checks for each patient
- 2. The Medtronic CareLink
  Monitor is set up within 10 feet
  of where the patient sleeps.
  The device automatically
  "wakes up" at the scheduled
  time and communicates with
  the Medtronic CareLink
  Monitor. Data are transferred
  automatically as the patient
  sleeps.
- 3. Data are transferred to a secure server via the patient's standard phone line.
- 4. The clinician reviews the patient's device data on the secure website

## CareLink Network – FY12'Q3 Serving Over 6,400 Clinics and 697,000 Patients in 32 Countries

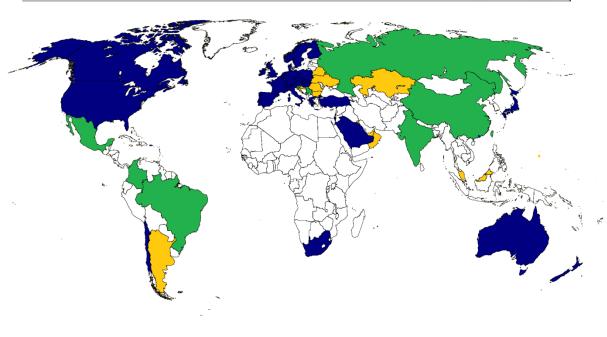
## Global CareLink Patients (thousands)



## Global CareLink Patients (yoy growth)



#### **CareLink Global Presence**



**Current Country** 

In-progress/planned

## The Future

Opportunity & Challenges

# In 2005 35 million people died from noncommunicable diseases worldwide







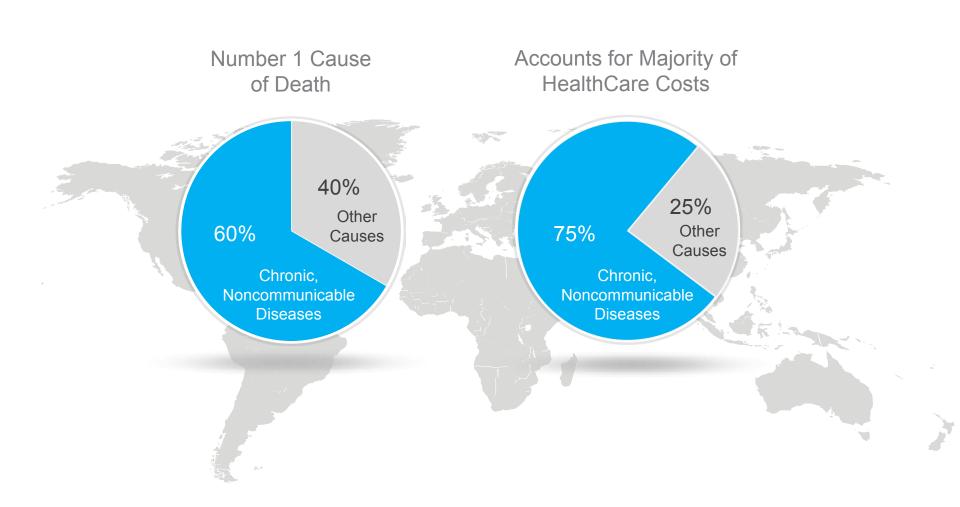






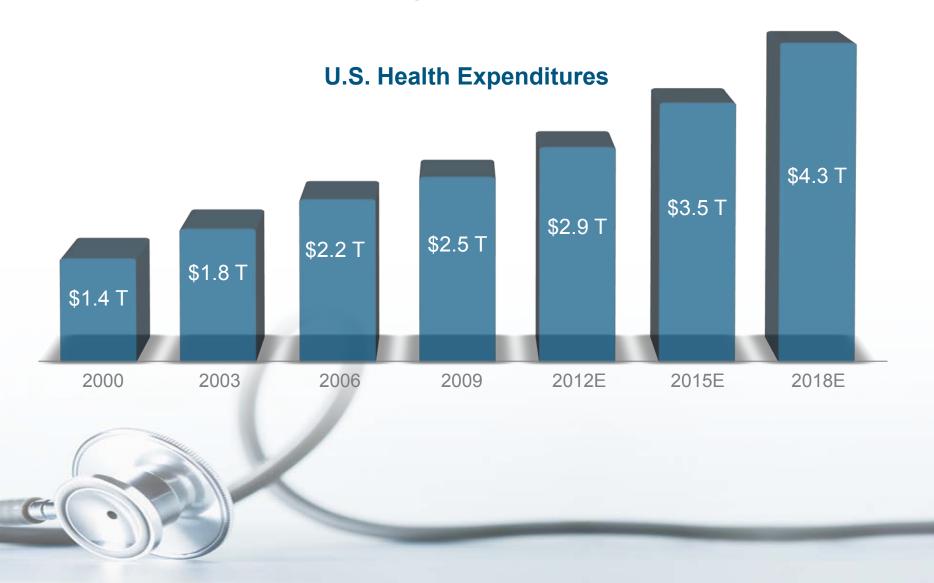


## Chronic Disease Becoming a Global Epidemic



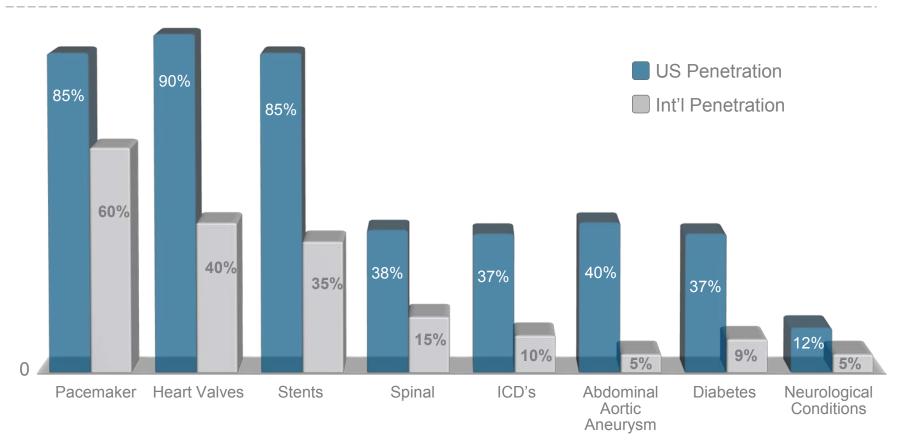
Source: U.S. Census Bureau, International Data Base (IDB), June 2011

## The Need to Curb Rising Healthcare Costs



## Many Populations Still Underserved

100%



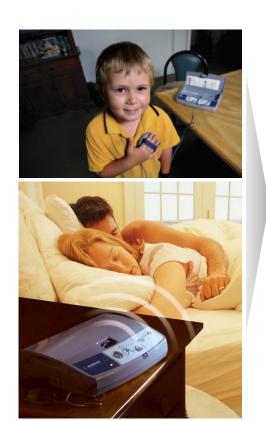


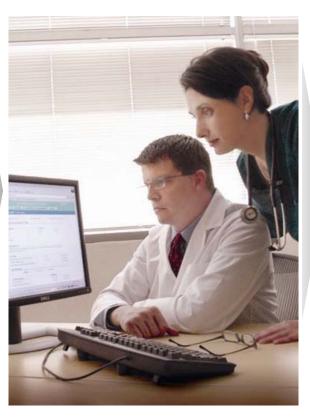


## Opportunity

- Healthcare and Medical Devices are a big part of the world wide Economy
- Need to make Healthcare more affordable
- •Possibility to improve national and world wide health at the same time we reduce Healthcare costs.
- •Prevention and proactive management are far more economical and effective that reactional medicine.
- "Onboard diagnostics" for personal heath.
- •CPS enables safety features such as fault tolerance, therapy modification, and patient and product management in the event of performance issues (environmental or reliability)

## Information Technology to Monitor Patients







## Providing Therapies Across More of the Care Continuum

CPS is moving from playing an integral role in treatment of an existing condition – to being the center the whole care continuum.

## Targeted Diagnostics

Better selection of patients who need therapies

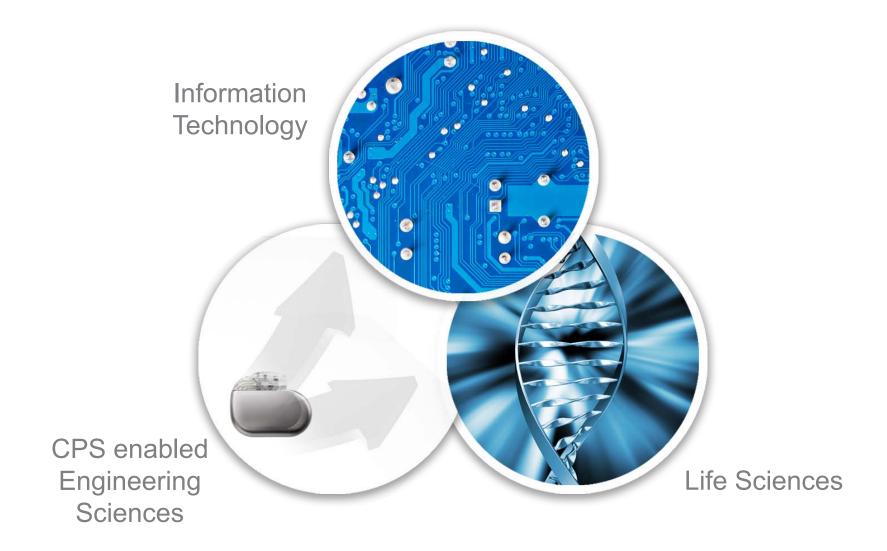
#### **Treatment**

Earlier intervention and individual treatment plans

#### Chronic Disease Management

Better long-term management to improve lives and control costs

## Combining Core Technologies for Greater Impact



## Challenges

- Healthcare IT infrastructure is heterogeneous
- No overall integration strategy Industry currently develops application specific infrastructure – costly
- •As system complexity increases, more issues are seen in the field regulatory and media reaction results in more caution towards innovation.
- Security.
  - Systems connect directly to the human physiological system.
  - Systems are connected to IT infrastructure in the Healthcare industry.
- Technology
  - Low power
  - Biocompatible or biocompatible encapsulation
  - Communication

## Challenges

- •Regulations and the industry focus is on a proving that a specific treatment of a medical condition is safe and effective. CPS use and complexity is accelerating, and current practice isn't well suited to driving the right assessment of product in development or for market use.
  - the benefits of fault tolerant design added to a system currently result in additional regulatory effort over and above basic therapy.
  - We need a safe, standardized way to manage Risk/Benefit when incorporating CPS in a treatment strategy that may enable multiple operational profiles, and not constrain itself to standard reliability and safety limitations. "Onboard diagnostics" for personal heath.
  - No easy balance for healthcare economics relative to leveraging CPS
    - Revenue via insurance comes from treating the sick, not preventing sickness, or managing patients.
    - Hospitals can become more economically efficient and effective in treating patients if we can enable them to manage to the continuum