Life Without Limitations®

Grand Challenges

The medical device perspective

About the presenter

- Magnús Oddsson
- M.Sc. Mechanical and Industrial engineering 1999
- Worked as a software developer and analyst for four years before joining Össur
- Worked as a project manager in R&D
  - Did software development and maintenance of existing applications (few at the time)
- Established a R&D center in Shanghai 2006 with a focus on mechantronics
- Works as project manager for the Bionic product line since July 2009

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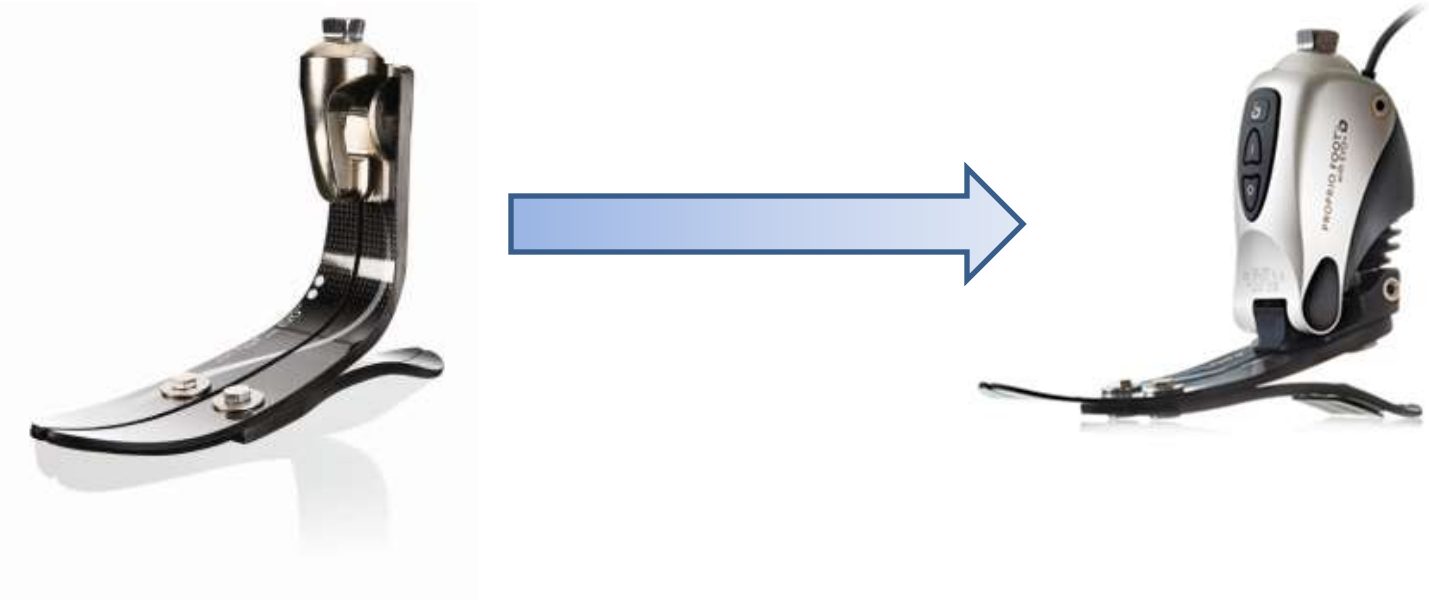
The company

Life Without Limitations®

- Founded in 1971 by prosthetist Össur Kristinsson
- Built around the innovative idea of using silicone to provide an interface between human skin and the prosthetic device
- Public listing in year 2000 on the Icelandic stock exchange
- Marketed the Bionic product line 2003



Video (if networked)

- http://www.youtube.com/watch?v=fVLiiFfZb_s&feature=player_detailpage

Challenges and Opportunities

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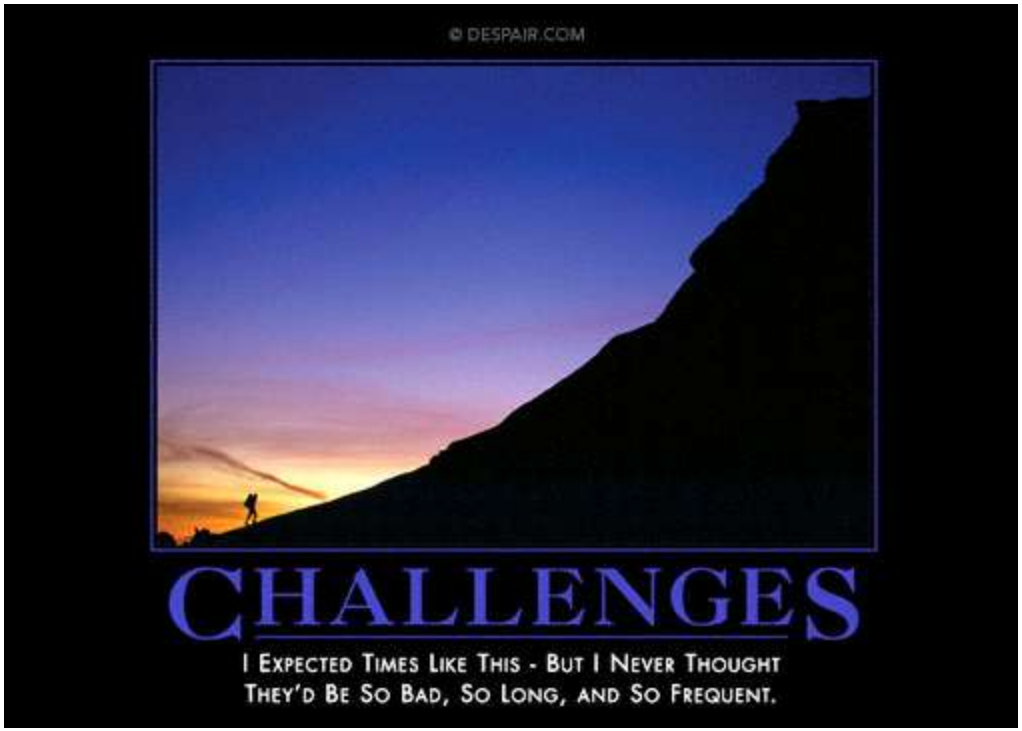
Challenges



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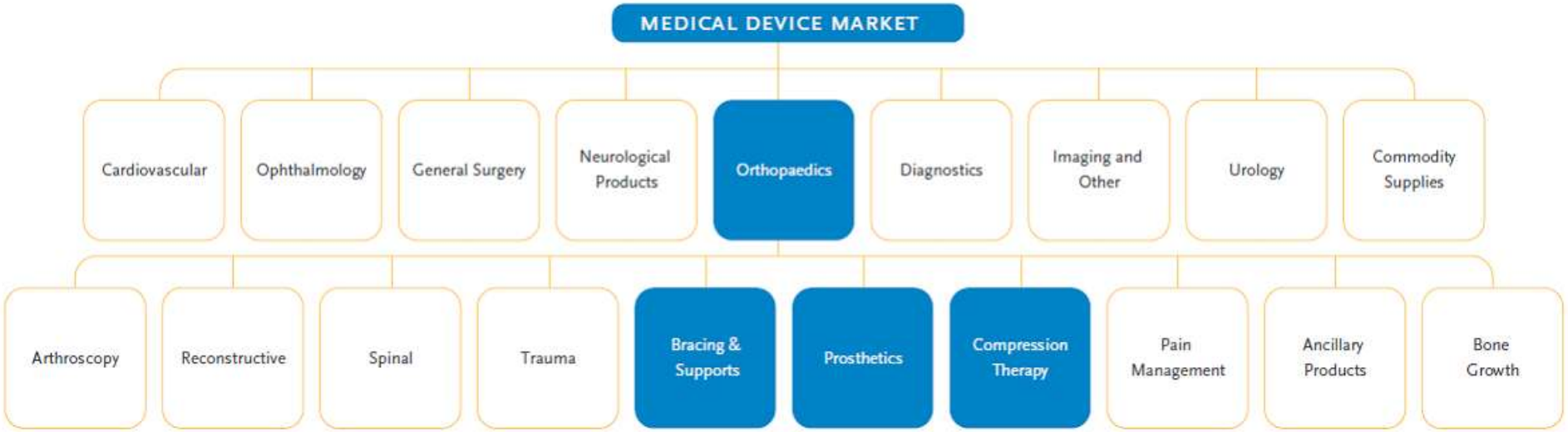
Opportunities

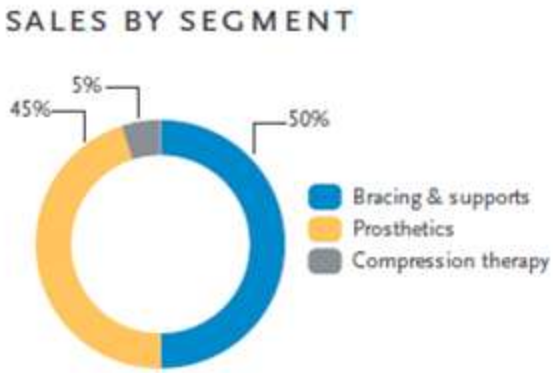
Hit number one from Google’s search with images

Challenges

- Knowing the (your) market
- Knowing the exact medical need
- Knowing the technology
- Fulfilling this medical need
- Verifying that the need has actually been fulfilled

The market


MEDICAL DEVICE MARKET
Cardiovascular
Ophthalmology
General Surgery
Neurological Products
Orthopaedics
Diagnostics
Imaging and Other
Urology
Commodity Supplies
Arthroscopy
Reconstructive
Spinal
Trauma
Bracing & Supports
Prosthetics
Compression Therapy
Pain Management
Ancillary Products
Bone Growth

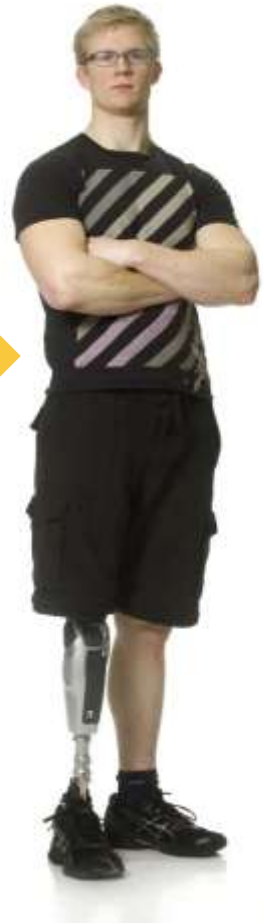

SALES BY SEGMENT
5%
45%
50%
Bracing & supports
Prosthetics
Compression therapy

Who pays the bill?

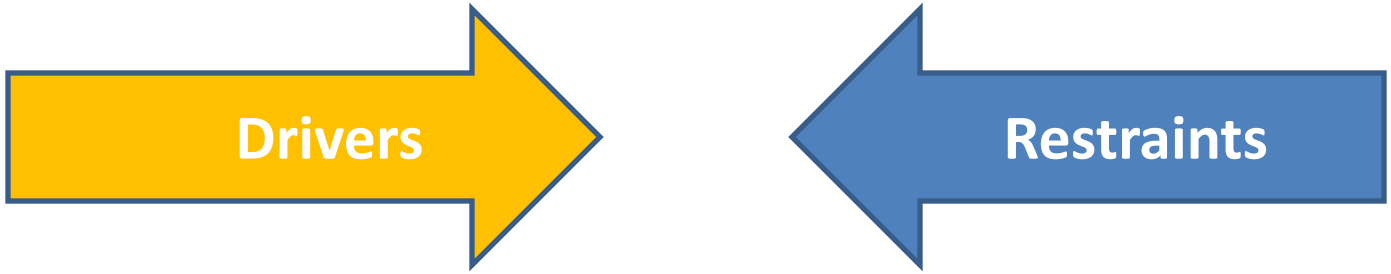
ÖSSUR PRODUCTS	SALES CHANNEL
PROSTHETICS 45 % OF SALES	O&P WORKSHOPS
BRACING AND SUPPORTS 50 % OF SALES	• CLINICS • HOSPITALS • PHARMACIES • DISTRIBUTORS • OTHERS
COMPRESSION THERAPY 5 % OF SALES	PHARMACIES

INFLUENCERS

- HEALTHCARE SYSTEMS
- INSURANCE COMPANIES
- MEDICAL ASSOCIATIONS
- PRIVATE PAYERS
- END USERS
- SCHOOLS
- FRIENDS
- FAMILIES



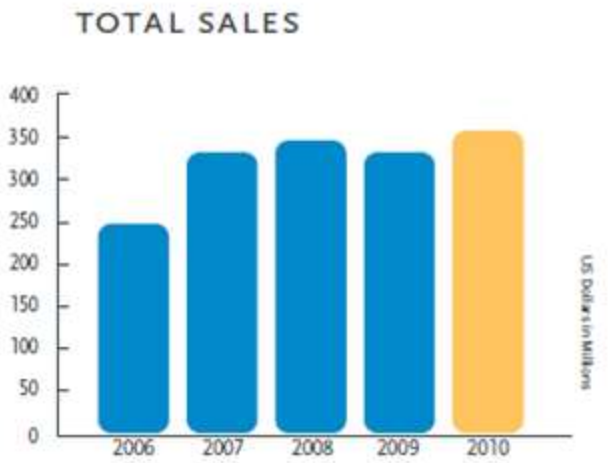
Market drivers and restraints

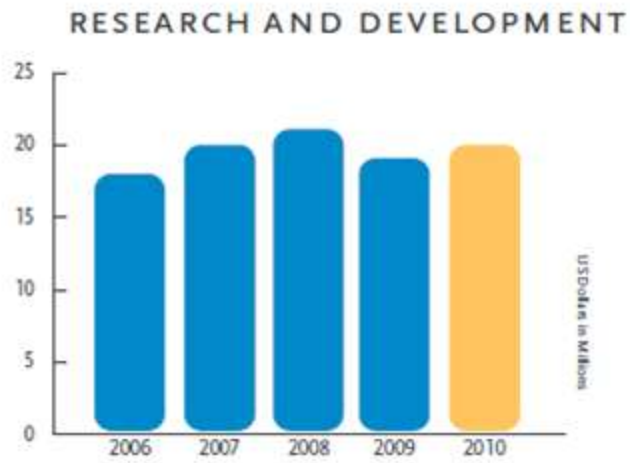


- Aging and more active population
- Better informed patients
- Diabetis, stroke, arthritis, OA emerging
- Demand for higher quality of life
- Increasing instances of obesity and vascular deseases

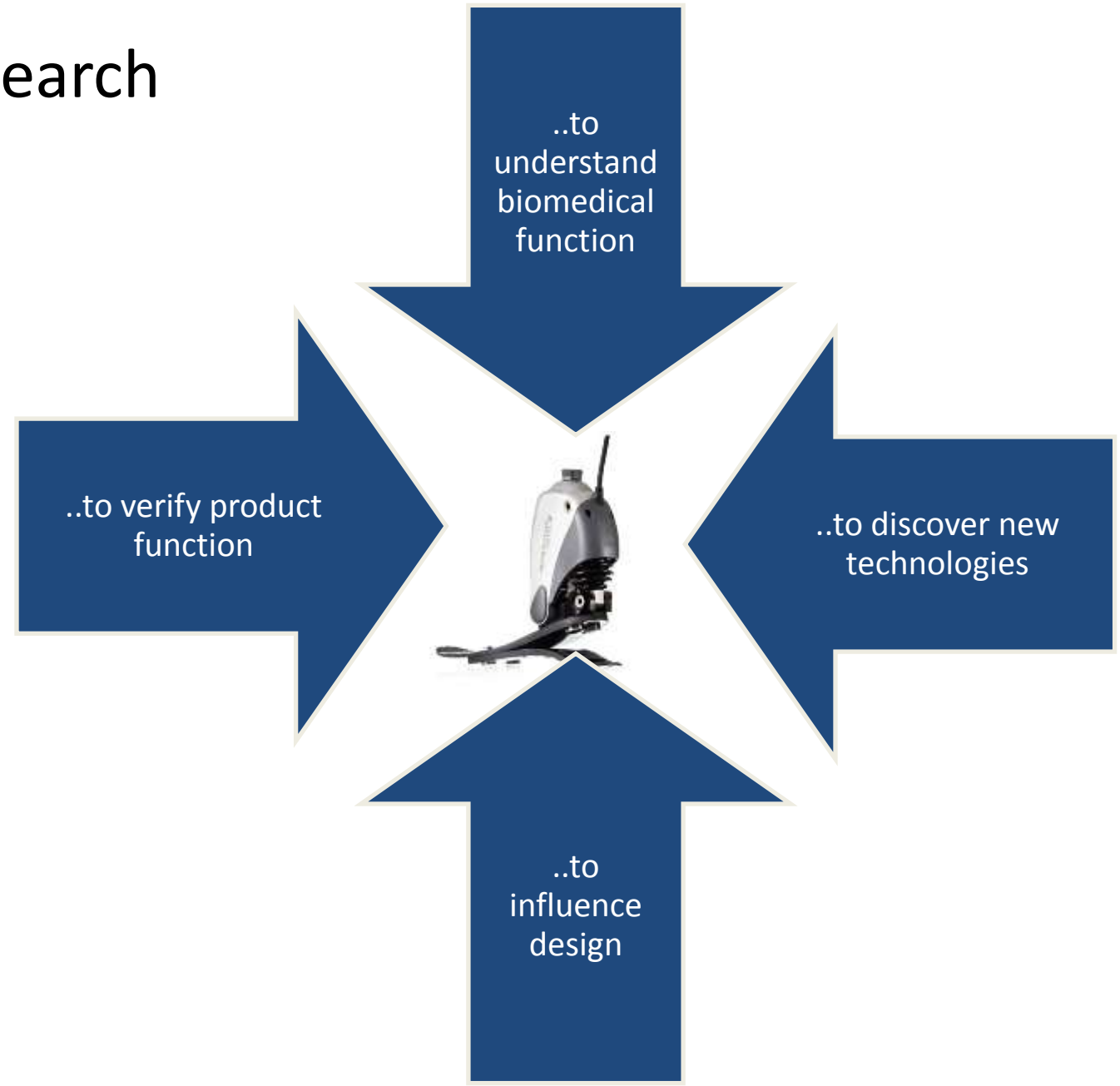
- Efforts to cut down healthcare expenditure
- Easy access to pain medication
- Changes in reimbursement structures
- People more health conscious
- Advances in vascular surgery

Investment in R&D





Research


..to understand biomedical function
..to verify product function
..to discover new technologies
..to influence design

The medical need

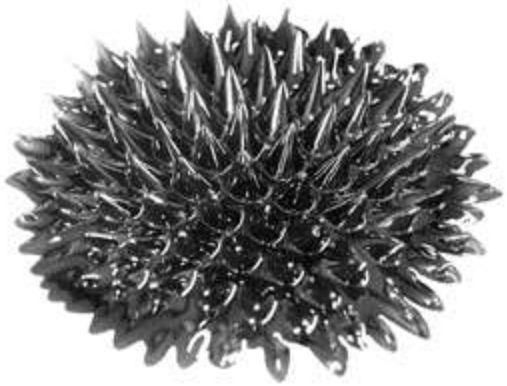
- Quite obvious in the field of prosthetics... or is it?

- Challenges:
  - Strict environment for clinical testing
    - the Medical Device Directives (Directive 2007/47/EC)
    - Motion capture for examble

- Opportunities:
  - Provide safe and efficient environment for for clinical testing
  - “Open source” clinical data and results

Discovery of technologies

- Usually does not involve patients directly
- International cooperation with universites
  - Magnetorheologic research
  - Reserch in artificial intelligence and signal processing
  - Material research



Challenges:

- The question of inventorship
- The “time value” of inventions

Opportunities:

- Train researcher to think in terms of patents – generate revenue stream for institutions
- Simplifies the handover of intellectual property

Technical platforms

- Knowledge is mapped onto several engineering platforms
  - Biomechanics
  - Composites
  - Injection moulding
  - Mechanics
  - Mechatronics
  - Silicone
  - Textile

Research/testing to support design

Research to support design

- Challenges:
  - Short iteration cycles of testing and adjusting
  - Non obvious how to properly fulfill all requirements of the MDD
- Opportunities:
  - Universities to train researchers in using the MDD
  - Provide MDD “certified” labs
  - Provide environment for rapid development – including user testing

Research to verify clinical outcome

- **Clinical Evaluation: The assessment and analysis of clinical data pertaining to a medical**
  - device to verify the clinical safety and performance of the device when used as intended by the manufacturer. *(This term is further explained in GHTF document SG5/N1R8:2007)*

Product development

Medical based marketing

Medical necessity
Condition, Indications, Procedures, Risks

We refer to this as:

Alpha testing and Beta testing as commonly used in the IT industry

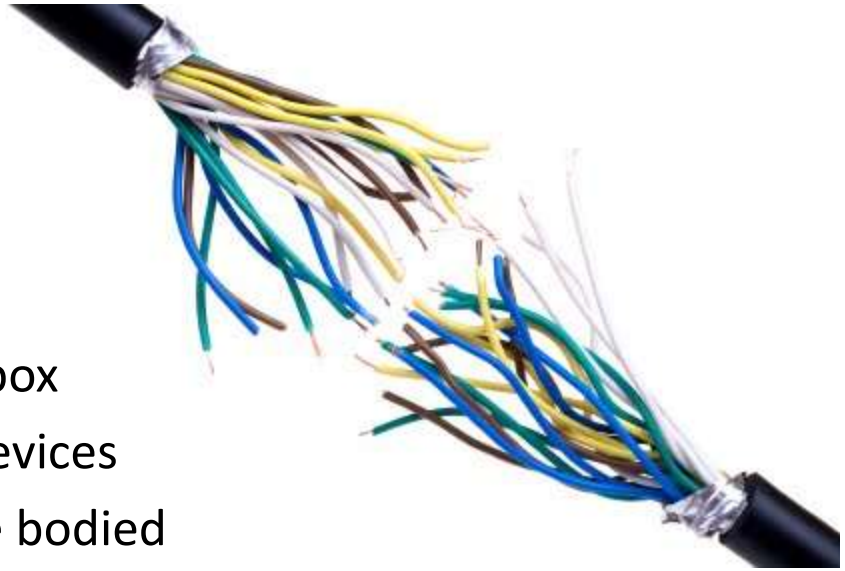
Medical necessity

- Provide support through peer reviewed studies

- Challenges:
  - The time factor.
- Opportunities
  - “Real time” universities.
  - Produce results before the product becomes obsolete
  - Provide better translation of technological features into clinical relevance

The greatest challenge of all

- Discover the mistery of neural signals to complete the neural pathway.
  - May require completely new methods in signal harvesting and processing



- Opportunities:
  - Remedy for spinal injuries in a box
  - Intuative contol of prosthetic devices
  - New interface methods for able bodied
  - Possible to monitor health through the nervous system directly

Thank you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