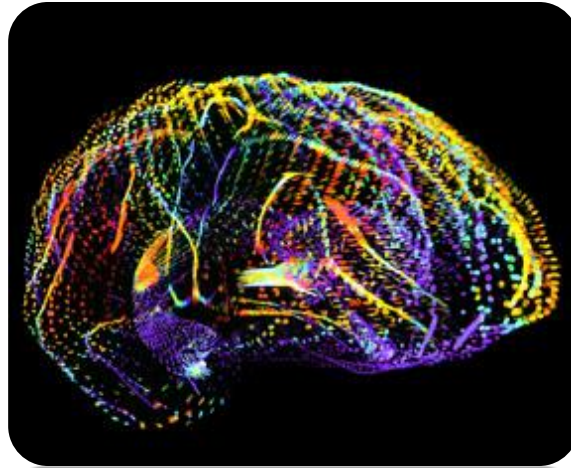


# Medical Robots for Surgery



Tamás Haidegger, PhD



# Rising surgical robots

2

- Google + Johnson & Johnson



# Virtual Incision

3

## University of Nebraska spin-off

D. Oleynikov et al.

Since 2008

Received over \$80 m investment



# ALF-X Telelap

4

- Advanced Laparoscopy through Force-RefleCT(X)ion
- **Sofar S.a.P.** (Milan, IT)
- NES Academy, EU grant support
- 2006–
- Acquired by **TransEnterix** for \$100m





# EurEyeCase – eye surgery robot

6

- **Tech. University of Eindhoven (NL)** and
  - K. U. Leuven
- Tremor filtering, 1:10 motion scaling
- Haptic feedback
- RCM mechanism
- Tools of a diameter of 0.5 millimeter (forceps, scissors and drains)
- Fast instrument changing



Credit: Tech. University of Eindhoven



## IMRIS (2010–)

Developed by Univ. Calgary and MD Robotics

- With experience gained at the Space Station SPDM
- 1 systems, MR compatibly up to 3 T
- First brain tumor patient: 2008
- Few dozen human surgeries
- Looking for FDA clearance in 2012
  - Treating up to 120 patients

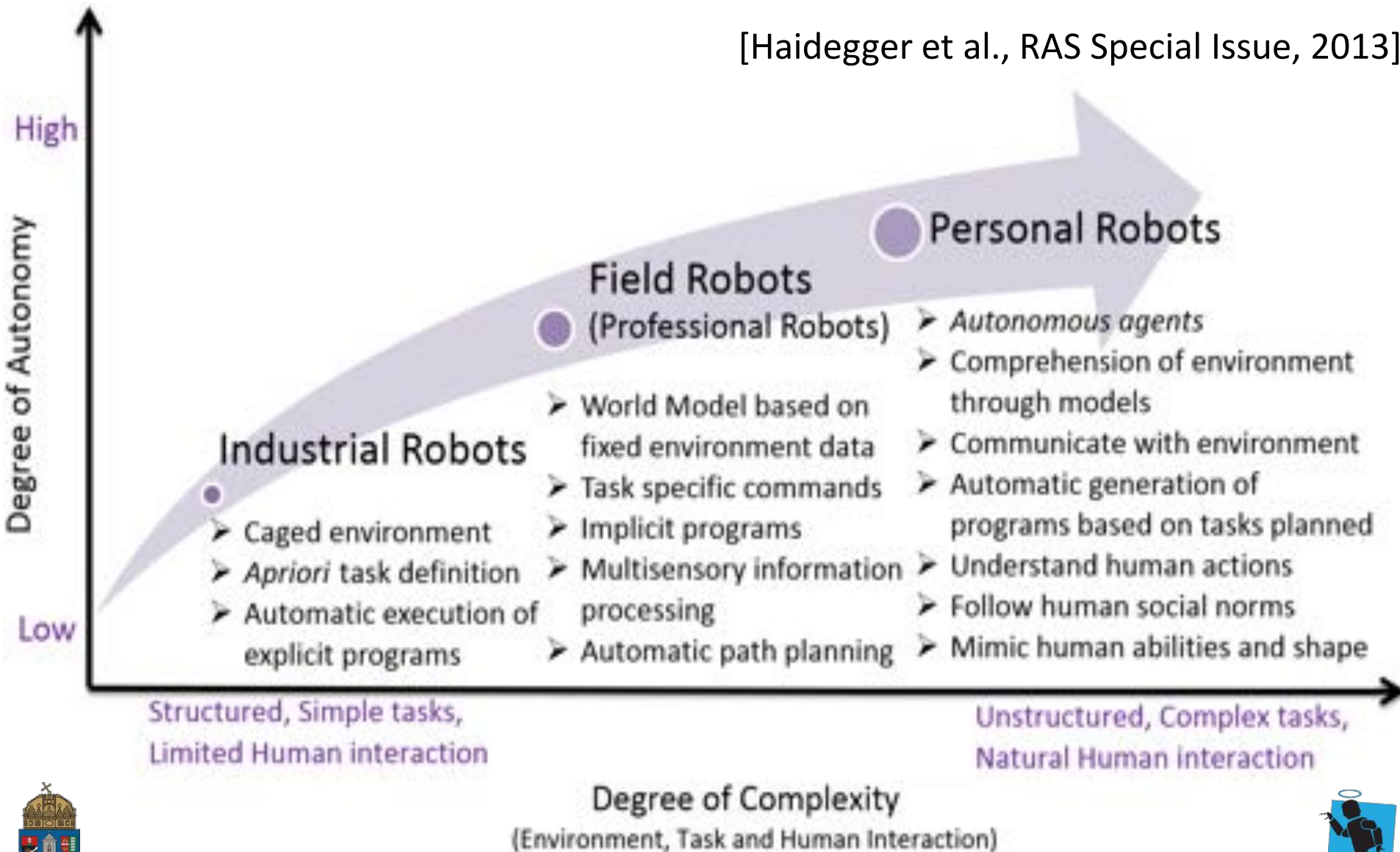
Credit: Univ. of Calgary,  
[www.neuroarm.org](http://www.neuroarm.org)

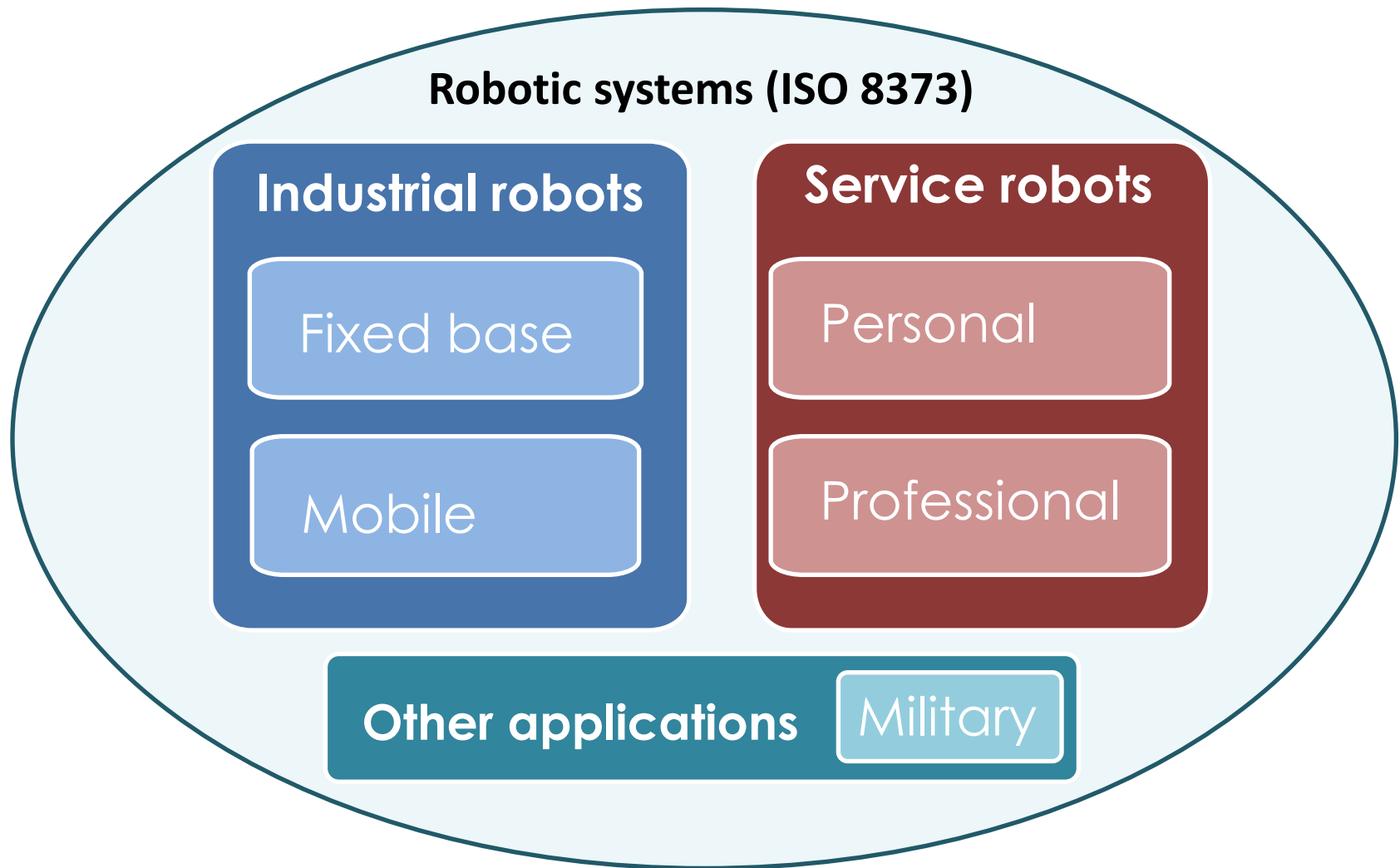


# Robots are everywhere

8

[Haidegger et al., RAS Special Issue, 2013]







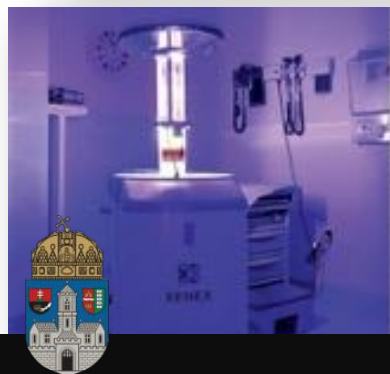
# Medical robots

10

- Visiting robots (FDA approval or RP-2/iRobot)
- Patient/goods carriers (widespread application)
- Medical delivery (GE's new radiotherapy deliv.)



iRobot



# Rehabilitation robots

11

- Rehabilitation devices
- Assistive robots
- Exoskeletons
- Prosthetics
- Physiology therapy



Credit: CYBERDYNE  
Hybrid Assistive Limb



Credit: REHAROB cons.



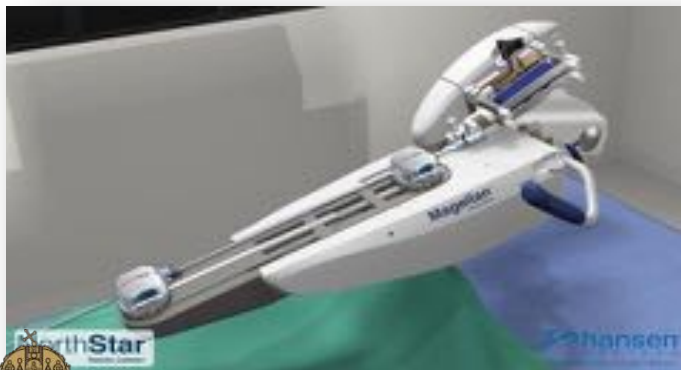
# Surgical robots

12

\$20 B estimated market for **IGS** and medical imaging

\$20 B estimated market for **MIS** in 2015

\$15 B estimated for **robotic surgery**



Credit: Hansen Medical, ARAKNES, Vector, WPI





# Surgical robot sales

13

- NeuroMate: ~30 sold (16 by ISS)
- Zeus: 50 (2002, discontinued 2003)
- ROBODOC: ~50 (37 before 2000)
- CASPAR: ~93 (discontinued in 2003)
- MAKO RIO: ~250 systems sold (2015)
- SpineAssist: 3 in the USA (07.2010)
- Renaissance: 70+ (03.2014.)
- CyberKnife: 240 (2013)
- Hansen Sensei: 130 (Q3 2012)
- ATRAS: 100+ (2014Q4)
- EndoAssist: ~100 (-2005)
- PathFinder: ~10
- Niobe: ~100?
- ROSA 55+ (2015)
- Zeego: 500+ (2014)
- **da Vinci: 3500+ robots (Q1 2016)**





# Medical robots

## Non-robotic standards

### Professional service robots

Rehabilitation robots

Neuro-rehabilitation robots

Assistive/day-care robots

Nursing/rounding robots

## Medical robots

### Invasive/surgical robots

Through a natural orifice

Invasive endoscopy

Through the skin

Biopsy robots

### Diagnostic robots

### Non-medical service robots

### Out of scope devices

Image-guided radiotherapy (IGRT) devices

Dental medical devices

Laser medical devices

High intensity therapeutic ultrasound (HIFU)

Brachytherapy devices

Ultra Sound holder devices

X-ray holder devices

Microscopes

Hand-held robots

Nano robots

Capsule robots

## “Robots for medical intended use”

### EC Machinery Directive:

- Non-medical personal care robots -> machines for performing “aiding actions, and actions contributing directly towards improvement in the quality of life of humans, except medical application”

### EC Medical Device Directive:

- Medical robots are classified and will be regulated as *medical electrical equipment and systems* which are to be used to diagnose, treat or rehabilitate patients from medical conditions



# Regulatory approaches



17

## European Economic Community (EU)

- CE mark (Conformité Européenne) managed by independent Notified Bodies
- ISO 9000 Quality Standards family (ISO 9001:2000) – possibility of self-certification
- New: 2007/47/EC extension to 1993/42/EEC Medical Device Directive
  - more clinical data required



## Food and Drug Administration (USA)

- Pre-Market Approval (PMA): long, thorough, expensive
- Premarket notification, 510(k): doctrine of “substantial equivalency”
- FDA Quality System Regulations (QSR)
- All surgical robots went down 510(k)

Device Type	Regulatory Class	Bench Testing	Animal Testing	Software Validation	Clinical Data
Preoperative planning	II			X	
Stereotactic frames	II	X			
Computer-assisted or navigation device	II	X		X	X
Computer-assisted intraoperative planning and surgical guidance					
Robotic operating assistants	II or III	X		X	X
Computer-assisted intraoperative planning and surgical guidance or action					
Fly-by-wire	II or III	X		X	X
Robots	Unclassified	X	X	X	X



## IEC 60601-1 updates

- supportive medical data as evidence for the safety and performance
- risk assessment and analysis even for OEMs
- Improved field monitoring (e.g., FDA MAUDE)

## 510(k) is under fire

- 510(k) Working Group
- Task Force on the Utilization of Science in Regulatory Decision Making

## Joint ISO–IEC workgroup on Medical Robot standards

- ISO/TC 299 (Robots and Robotic Devices)
- IEC/SC 62A (Common Aspects of Electrical Eq. used in Medical Practice)
- **JWG 9: Joint Work Group on Standard for Medical Robot Safety**
- **JWG 35: Medical robots for surgery**
- **JWG 36: Medical robots for rehabilitation, compensation or alleviation of disease, injury or disability**





## IEC 80601-2-77

### MEDICAL ELECTRICAL EQUIPMENT – Part 2-77:

Particular requirements for basic safety and essential performance of  
MEDICAL ROBOT FOR SURGERY

### Basic issues:

- Definitions (aligning with major standards and organizations)
- Criteria for inclusion/exclusion
  - 120+ advanced surgical robot projects identified
- Matching with other robotics standards

### Next meeting:

- 13-16 May 2016, Gävle, Sweden



# Inclusion issues

Source: Kiyoyuki CHINZEI  
Note: Subject to change

## Surgically invasive



## Not surgically invasive



## Hand-held



## No penetration




## Radiosurgery



(SC62C)

- Invasive diagnosis (bx)
- Physical navigation
- Dental use





**Thank you for your attention!**

**Follow the progress on: [www.surgrob.blogspot.com](http://www.surgrob.blogspot.com)**

**Andrea Bertolini, Scuola Superiore Sant'Anna**

**Jan Veneman, Tecnalia**

**Tamás Haidegger, Óbuda University**





**Would you accept a tele-surgery tool delivered to your home?**



**Would you accept an automated surgery?**



**Would you accept robotic nurses handling you?**



**Are you afraid of robot apocalypse?**

