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AUSTRIAN CENTER FOR MEDICAL INNOVATION AND TECHNOLOGY

Design and Implementation of a Medical Robot System

Gernot Kronreif

European Surgical Robotics Demonstration Day

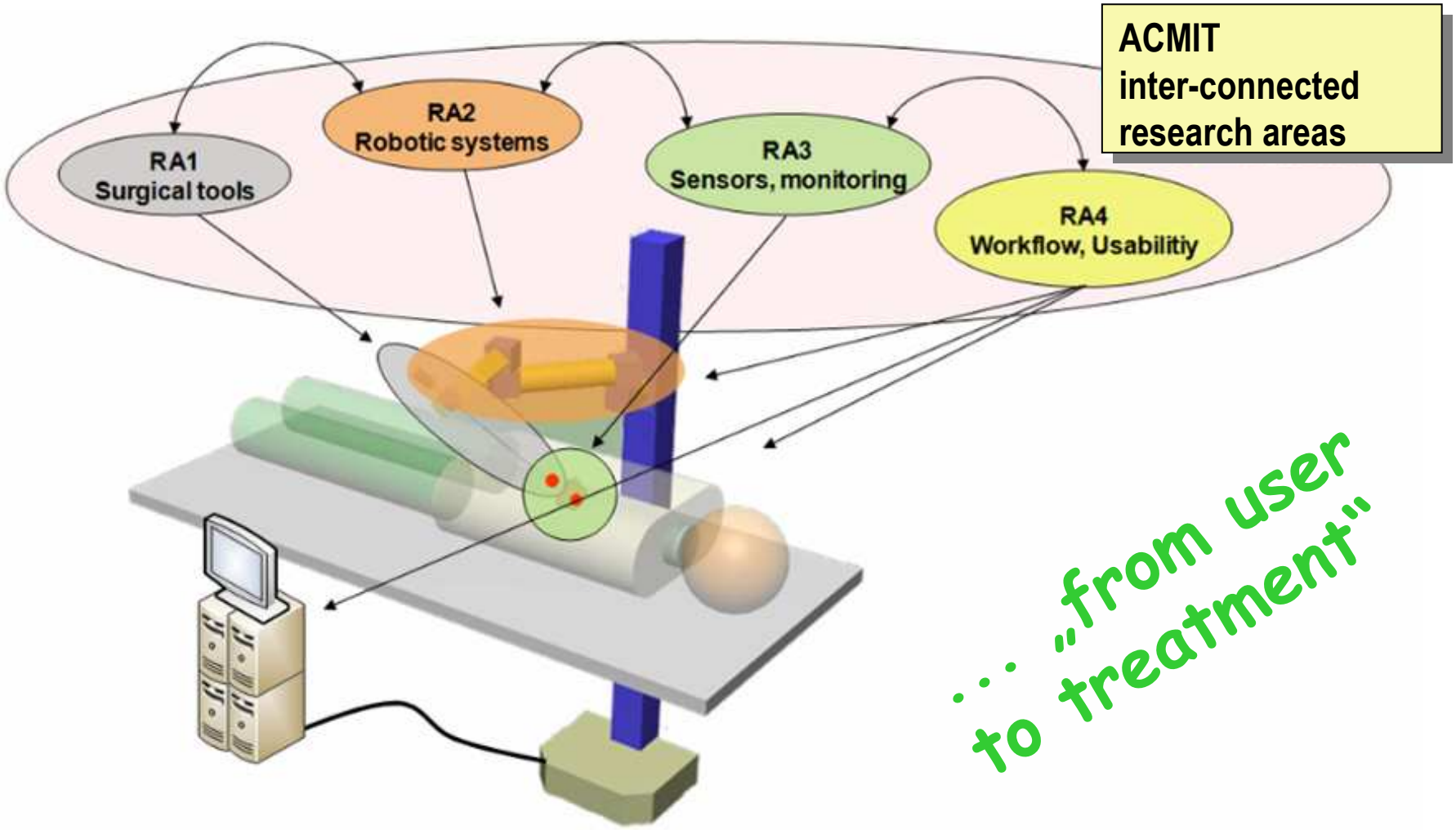
27/03/2014

Leuven

ACMIT

- **Development of new technology approaches for „Minimally Invasive Procedures“ and modern therapies in an integrative way**
- **Research and innovation center for collaborative and translational research between science and industry**
- **Key data:**
  - 1st funding period (2010-2014): overall budget of 18MEUR
  - 2nd funding period (2014-2017): overall budget 13MEUR
  - International network:
    25 industry partners
    27 research partners (technical + clinical)
  - Match funding

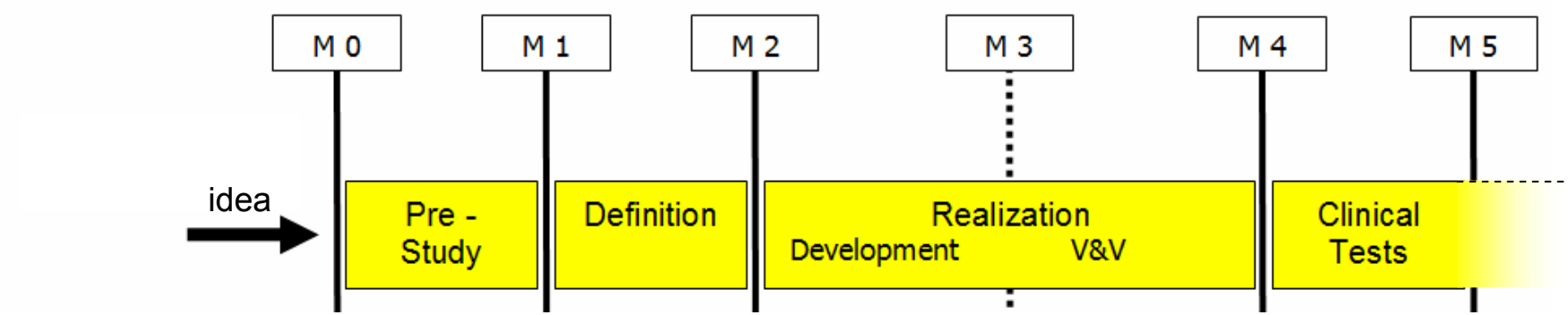
ACMIT – Integrative View



ACMIT – Integrative View

- **Applied R&D → Translational R&D**
  - Work-flow assessment and specification
  - Inter-disciplinary work
    - Technical development
    - Regulatory issues
    - Clinical issues
    - Market requirements
- Baseline: technology with **clinical relevance**

„from idea to clinical use" ...



Disclosure

+ **Integrated Microsystems Austria GmbH:**
  - Producer of iSYS1 robot system on behalf of iSYS Medizintechnik GmbH, Kitzbühel, Austria

+ **Gernot Kronreif:**
  - Manufacturing Manager for iSYS1 production

Set-up for CT-guided Biopsies

B-Rob I - Tests CT-guided Biopsies

Review: First Prototype „B-Rob I“

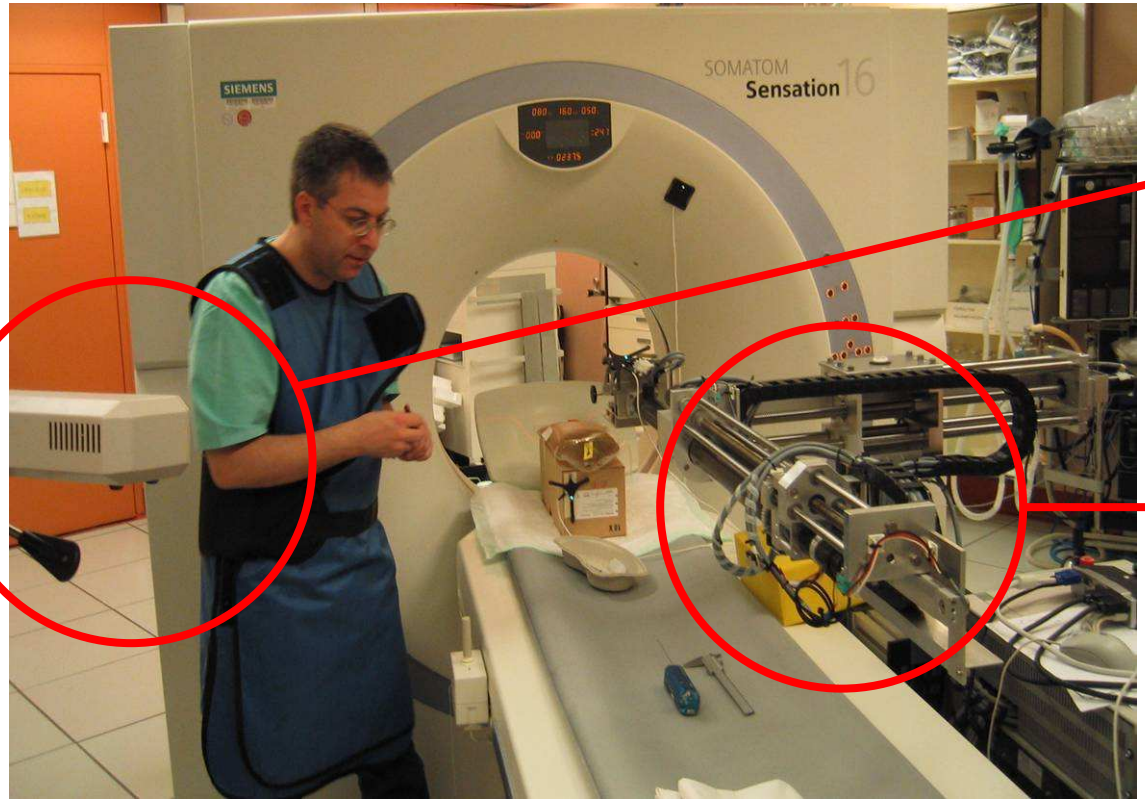
Accuracy sufficient ✓

Workflow ✓

Data acquisition ✓

Kronreif G. et al., “Evaluation of a robotic targeting device for interventional radiology”, Proceedings der 18th International Conference on “Computer Assisted Radiology and Surgery CARS2004”, Elsevier Science B.V.

Review: First Prototype „B-Rob I“



Optical tracker – main source of problems (accuracy, latency, working area, line of sight)

„Stand-alone“ setup: Synchronization table – robot, (dynamic) stability

Kettenbach J., Kronreif G., Figl M., Fürst M., Birkfellner W., Hanel R., Ptacek W., Bergmann H., „Robot-assisted biopsy using CT-guidance: initial results from in vitro tests”, Journal Investigative Radiology, Vol 40(4), Lippincott Williams & Wilkins

Review: First Prototype „B-Rob I“

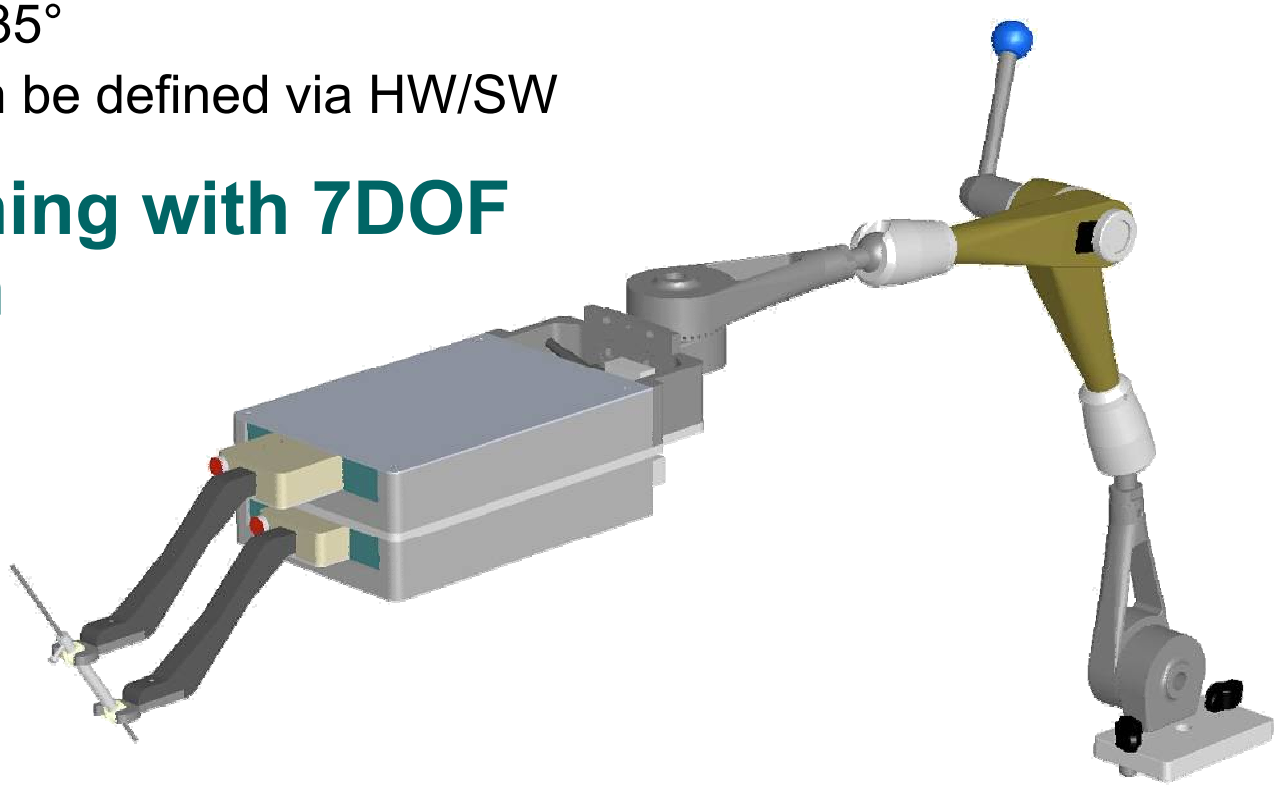
NPU based on parallelogram ✓

Registration / Calibration for both CT and US ✓

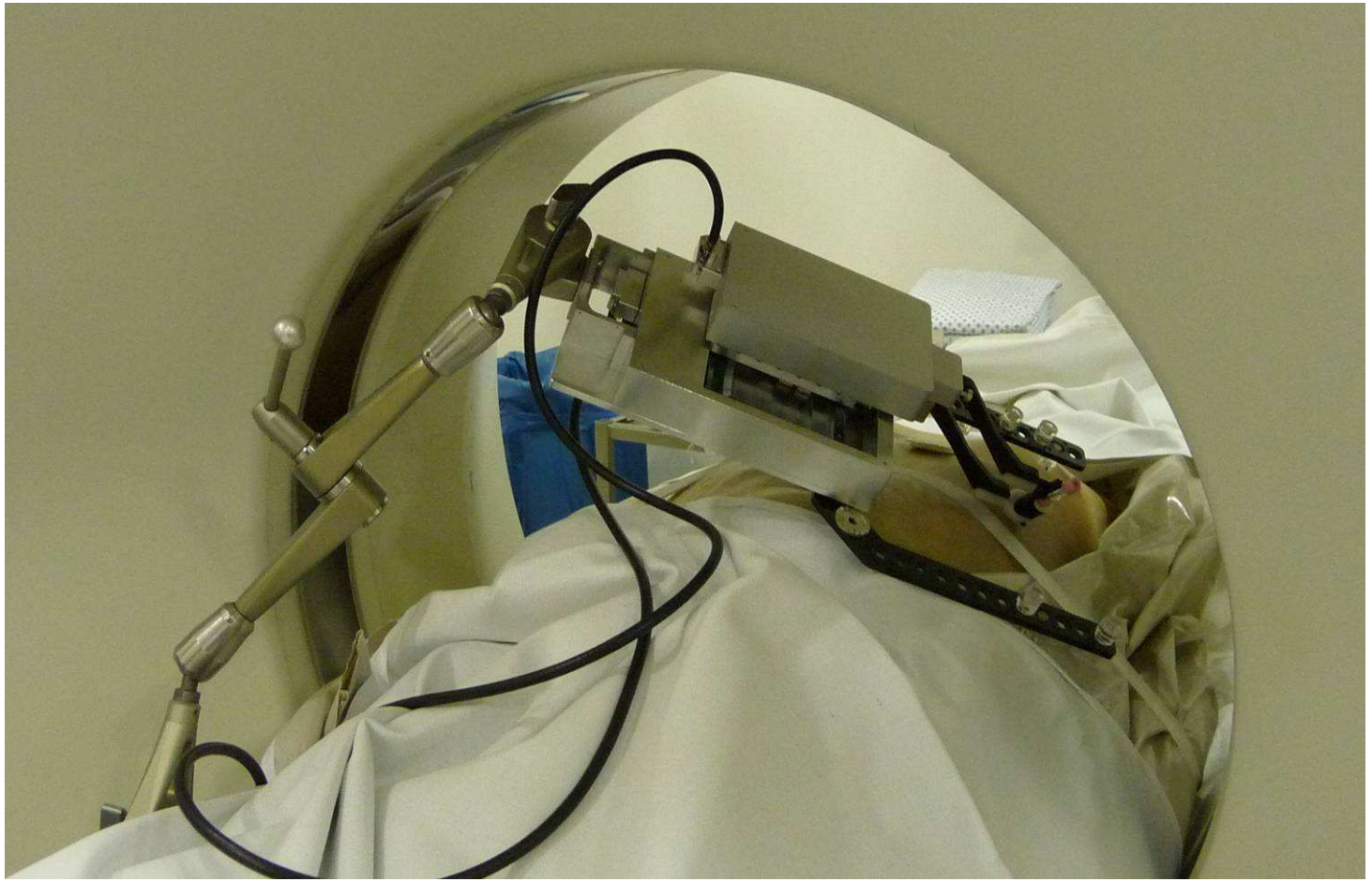
Kronreif G. et al., "Robotic Guidance for Percutaneous Interventions", Advanced Robotics, Vol. 17, No. 6, VSP and Robotics Society of Japan

Prototype "B-Rob II"

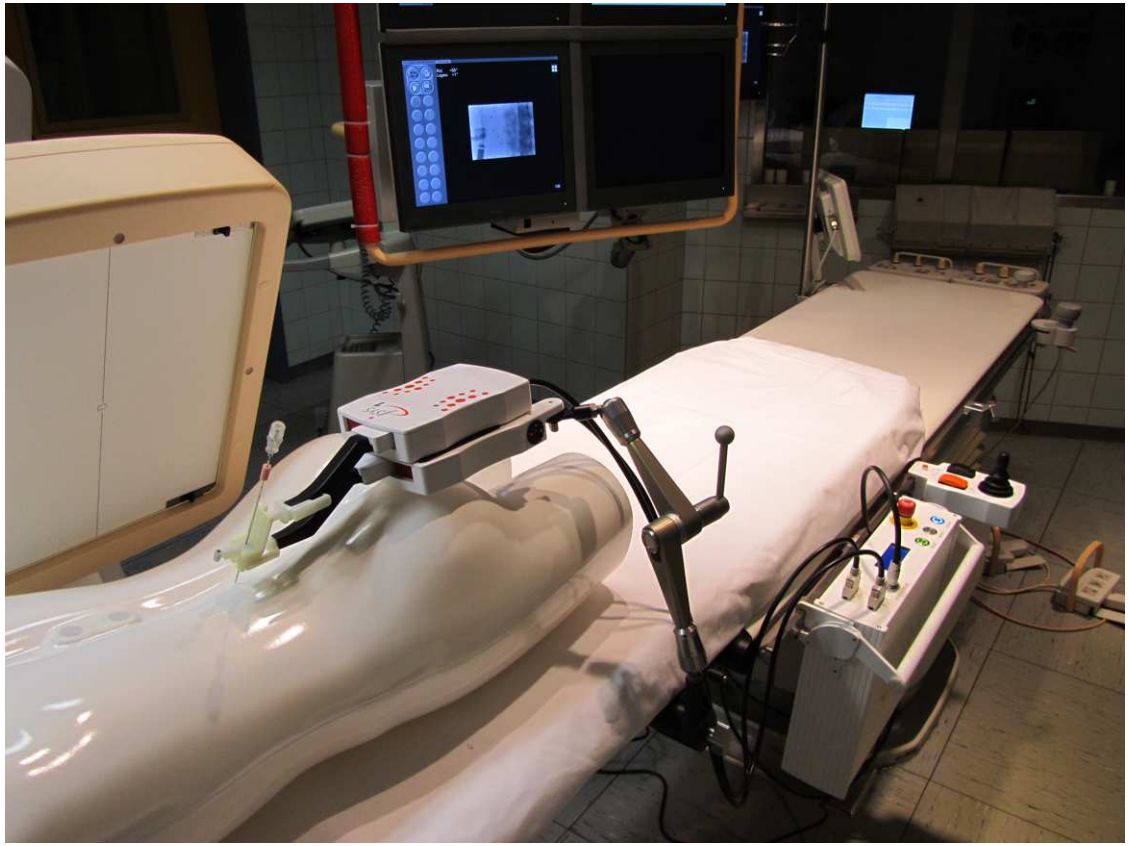
+ **2 x 2DOF-Modules with tool holder**
  - Positioning: ± 20 mm
  - Angulation: ± 35°
  - Pivot point can be defined via HW/SW
+ **Pre-positioning with 7DOF passive arm**

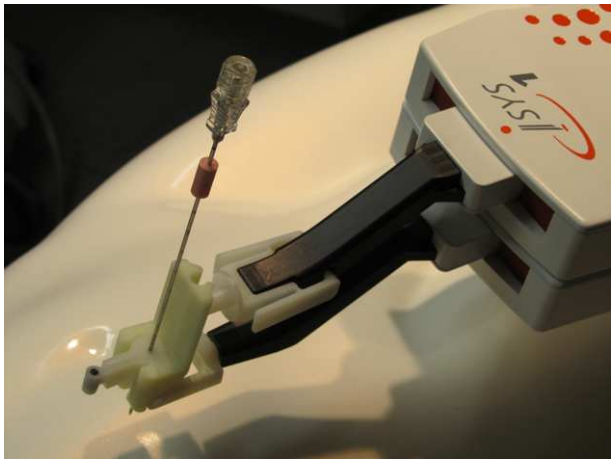


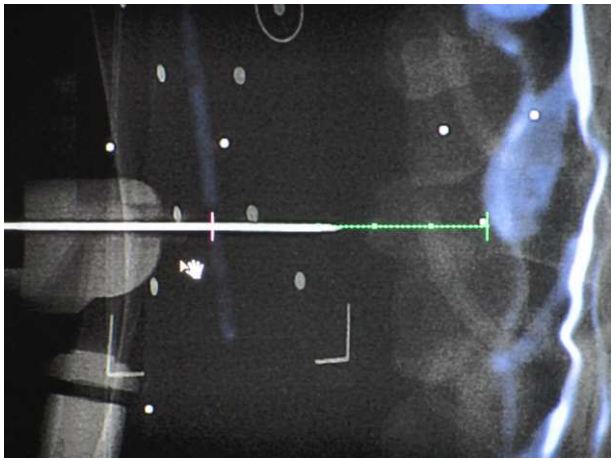
CT-guided Biopsy – Cadaver Study



Transfer to CE-marked system „iSYS 1“

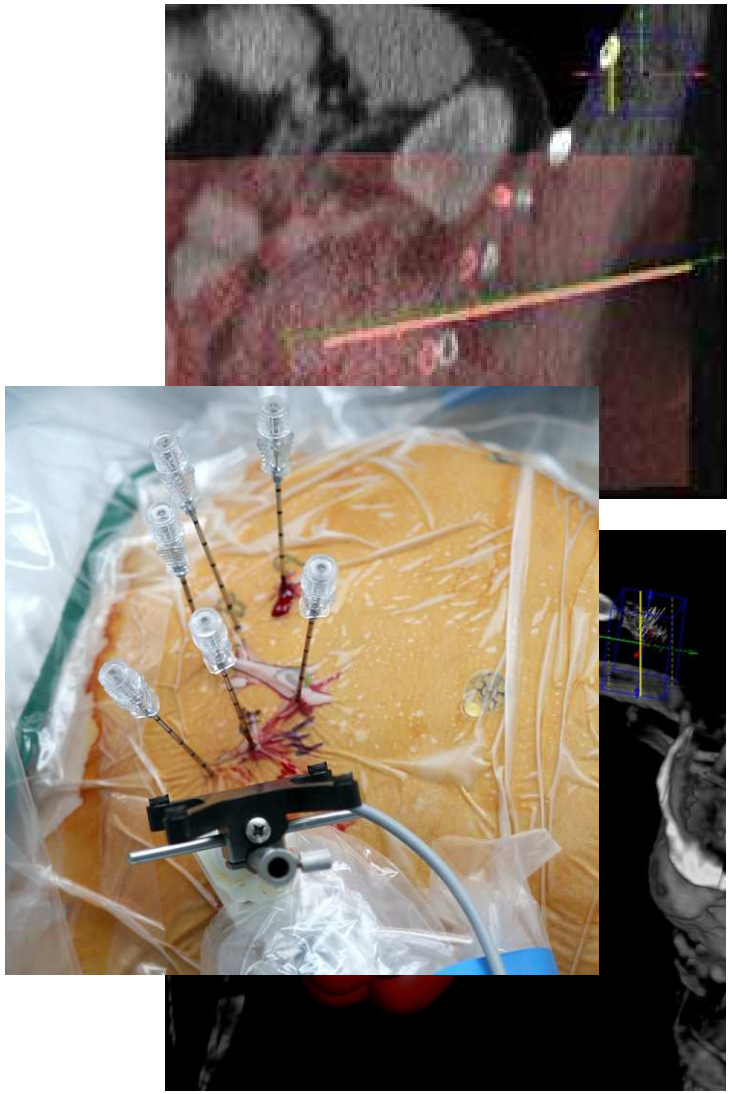






Clinical Use

- **Multi-centric study**
- **Applications:**
  - RFA Trigeminus, renal
  - Biopsy spine, liver, lung
  - Multi-needle tumor ablation
  - Pain treatment L1, L3, L4 (left, right)
- **Results:**
  - Avg. positioning error 1.21 mm at needle tip and 0,78 mm at entry point (n=21)
  - Application with robot support rated as „simpler“ (n=15) or „no effect“ (n=3)



What you should know ...

+ **What are the real needs of the user?**
  → Assistance for daily use!

+ **Clinical relevance?**

+ **Cost vs (clinical) benefit?**
  → Refunding option?

+ **Right partners?**
  → Interest of the partner(s)

It is more than just „functioning“!

+ **Demonstration of clinical benefit**
  - Demonstration in clinical evaluation ↔ device already product
  - Task specific design or universal device?

+ **What else?**
  - Human factors
    - Impact of new technology to existing structures and processes
    - Usability, Intuitiveness
  - Interfaces to existing setup and procedures
  - “Life cycle” of the device
  - Economic constraints
    - New technology resulting in higher cost?
    - Is it possible to have any additional cost refunded?
    - Is the device yet profitable for manufacturers?

What makes a medical technology successful?

+ **Successful setup depends on four criteria:**
  - Device must provide quantifiable, functional benefits to the patient.
  - Device should improve the efficiency of physician's current practice.
  - Device should be affordable for clinics yet profitable for manufacturers.
  - Device should not increase the cost of health care.

Some of the „Lessons Lerned", Ctd

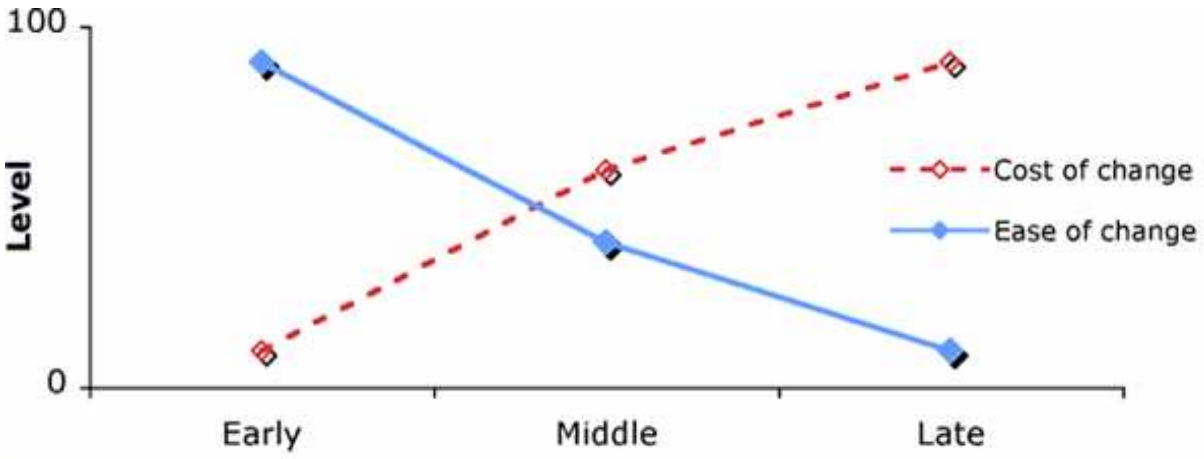
- **Look for applications and procedures that benefit from a new (robotic) solution!**
- **How to demonstrate clinical benefit and cost reduction?**
- **Integration**
  - into existing hardware
  - into existing workflow
- **Complete setup rather than „component"**
- **Time of intervention (also including setup time!) must not be increased!**

Some of the „Lessons Lerned", Ctd

+ **„KISS" -- Keep it simple, stupid**
  - The more functions the system have the more can go wrong
  - Complexity doesn't help during certification
  - Ease of interaction is key!
  - Complexity of setup must be considered!

Some of the „Lessons Lerned“

+ **The later you change your design, the more expensive it will be**
  - Careful selection of external components and suppliers
  - Extensive evaluation is key!
  - Evaluate system under real clinical requirements ASAP!
  - Clear separation between research and production phase



Some of the „Lessons Lerned“

+ **Set up the right team and infrastructure**
  - Good researchers are not (necessarily) good product developers!
  - Don‘t underestimate the problems of (mass) production
  - Additional competences required (quality manager, regulatory affairs manager, product manager)

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Thank you!

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