AR SPECTRA

Aligning
novel medical innovations
with
technology precedents

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Solving a bottleneck of modern medical imaging

Specialists need to focus on patient & wound instead of medical displays

Assistance & Training

Data Visualization

Navigation

Complex Performances

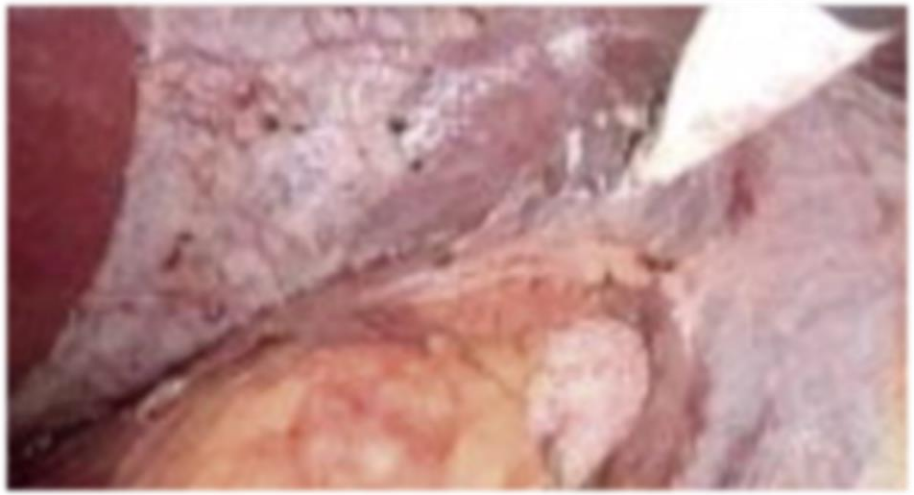
Risk on Patient Outcomes

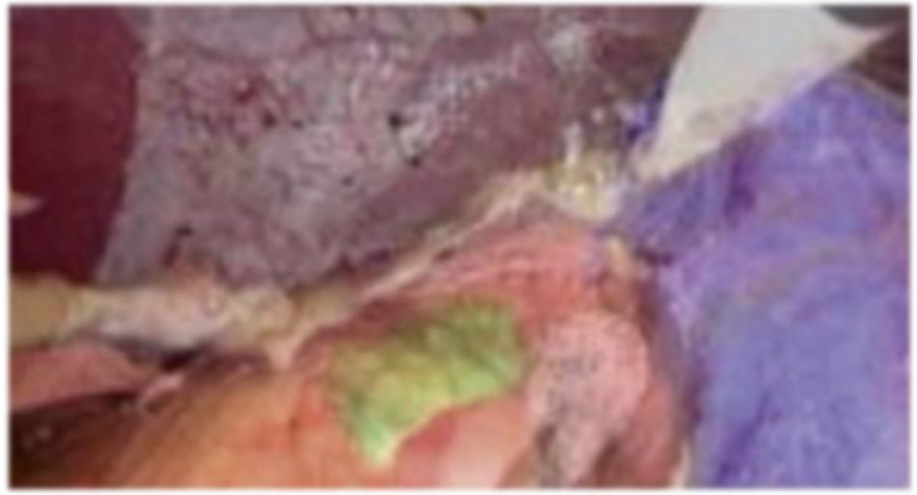
Time-Consuming

High Costs

Arspectra offers operational focus & novel performance

Augmented Reality: a new technology adding value to digital visualization





Assistance & Training

Data Visualization

Navigation

Natural Accuracy

Completeness

Time-Efficiency

Cost-Efficiency

Safety

Application Range

Successful R&D to effective medical solutions

Designed & delivered by experience & key partnerships


Combined 12 y + Medical AR hardware
& software design & development

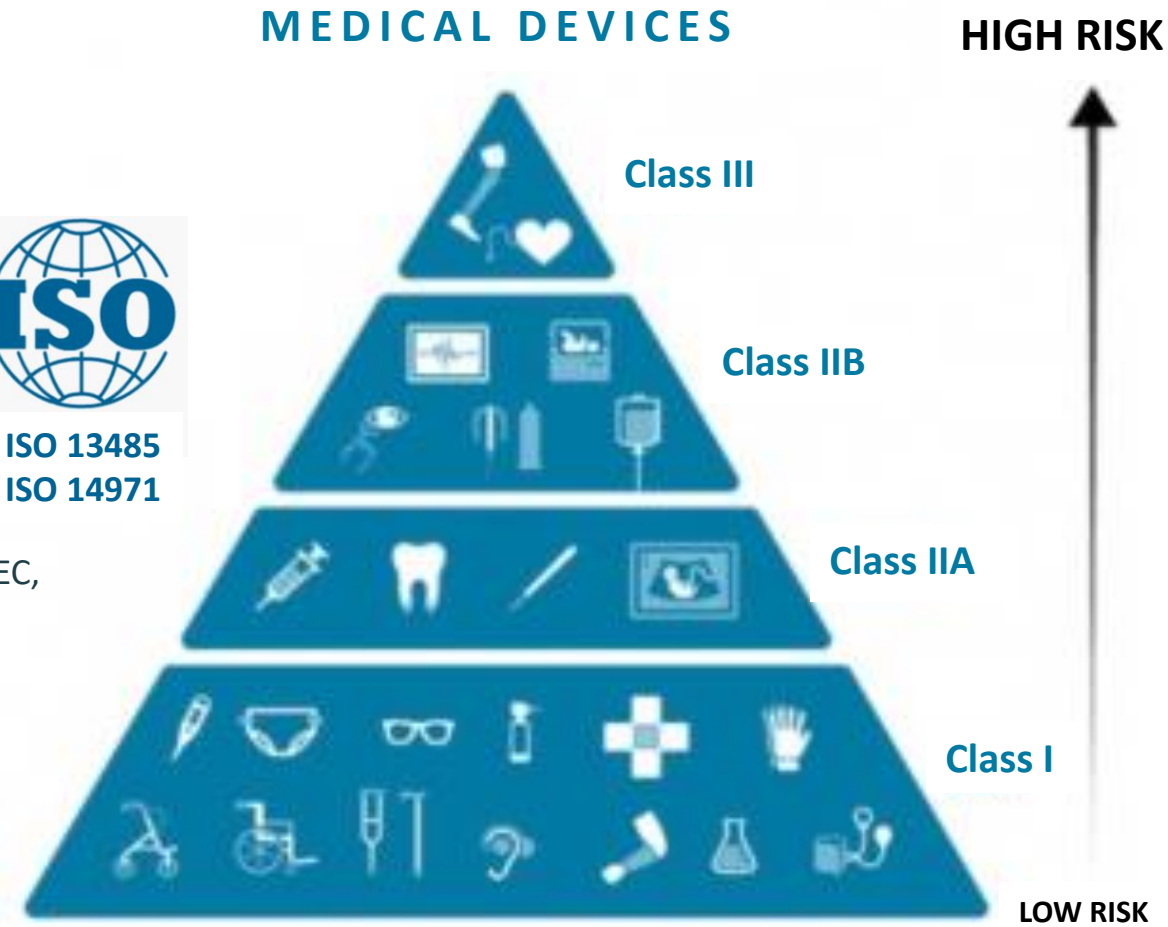
10 y + in Med Tech Business Development
& Clinical Research and Validation

4 y + Experience Medical
Marketing & Best Practices

LUXINNOVATION
TRUSTED PARTNER FOR BUSINESS
Fraunhofer
HORIZON 2020
FIT4 START
LUXEMBOURG INSTITUTE OF HEALTH
RESEARCH DEDICATED TO LIFE
TÜV
CHL
Centre Hospitalier de Luxembourg
UZ LEUVEN
UZ GENT

Impact of regulations on innovation

Risk assessment based on the intend of use



2020: Medical Devices Directive 93/42/EEC, replaced by Medical Devices Regulation 2017/745

ISO 13485
ISO 14971

Complexity and degree of risk to patients
- 510(k) Clearance
- Class II labeling & higher PMS standards
- PMA evaluation in accordance with GCP

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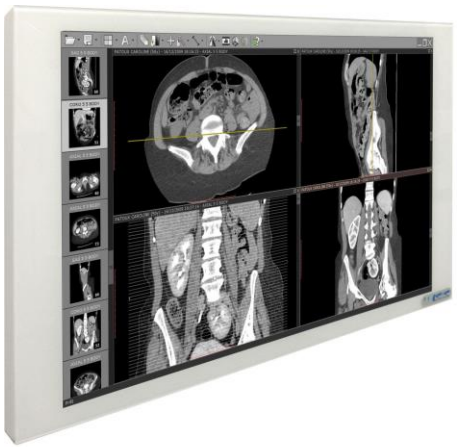

CLASS IIA
> € 100 k
> 6 months

In-sight Display

VISUALIZATION

CE
NON-MEDICAL
€ 5 k
2 months

NAVIGATION

CLASS I
€ 30 k
2-3 months

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In-sight Display

VISUALIZATION

Remote Teleassistance

NAVIGATION

Smart Training & Maintenance

Impact of regulations on innovation

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In-sight Display

Minimally Invasive Surgery

Remote Teleassistance

VISUALIZATION

NAVIGATION

Open Surgery

Smart Training & Maintenance

*broad current estimation

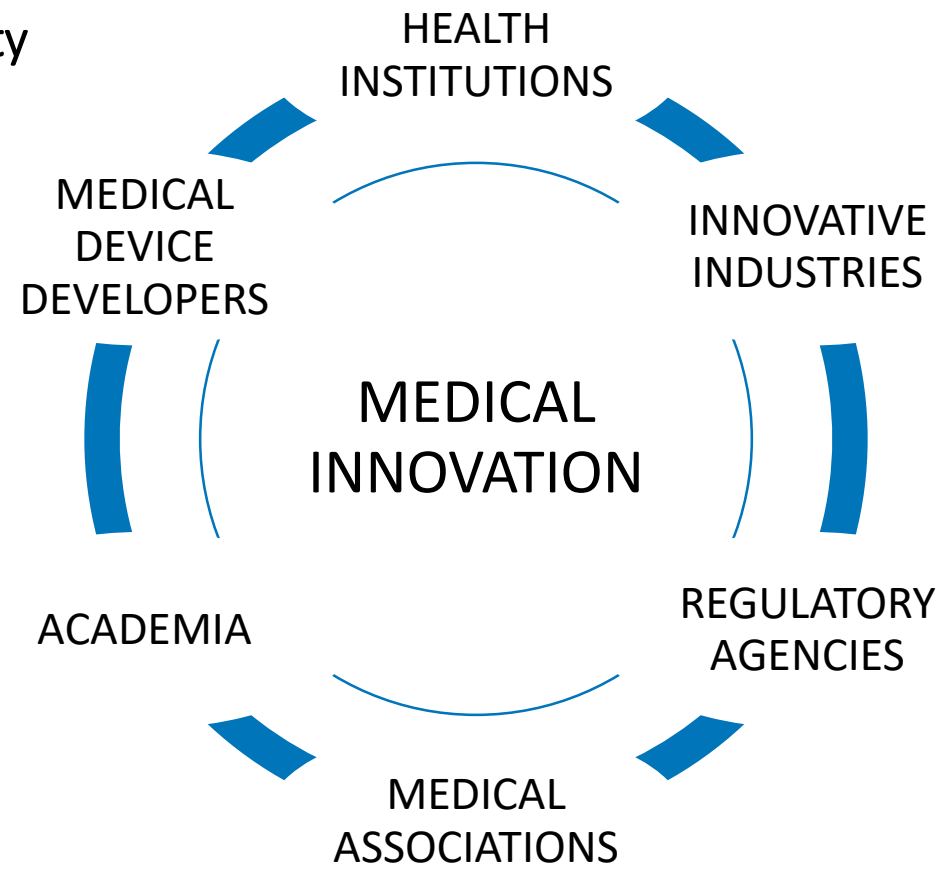
Impact of regulations on innovation

Importance of coordinated efforts among multiple critical stakeholders

Goal of protecting patients & society from unsafe technology

Clinical evidence and evaluation in proportion to the class of risk

Responsibility of assuring safety and effectiveness of devices falls on every stakeholder



Open innovation models and early collaboration to facilitate innovation processes

Harmonization reduces regulatory load and promotes industry compliance

Streamlined regulatory procedures to encourage innovation and expedite novel innovative devices

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Empowering

Healthcare Professionals

& Medical Partners

with Augmented Reality Solutions

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