

MARGINUM

PIONEERS OF OPTICAL TISSUE MONITORING

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Why do we exist.

What's the challenge?



“During neurosurgical operation, distinguishing healthy brain tissue from malignant tumour is challenging with contemporary methods.”

- *Arto Immonen, Department Chief Physician of KUH Neurosurgery*

EASY
OBJECTIVE
PRECISE
SIMPLIFYING WORKFLOW



INCREASED DETECTION OF FLUORESCENCE

Founded in 2020, Marginum is a Finnish medical device manufacturer and market forerunner in **fluorescence-based aspirate tissue monitoring**.

Our technology analyses the fluorescence of resected surgical tissue from suction tube and **recognises fluorescence indicating malignant tissue**. When fluorescence is detected, surgeon will be immediately notified with objective and precise feedback.

The data-driven products improve **surgical performance and cost-effectiveness** integrating seamlessly with existing surgical workflows.



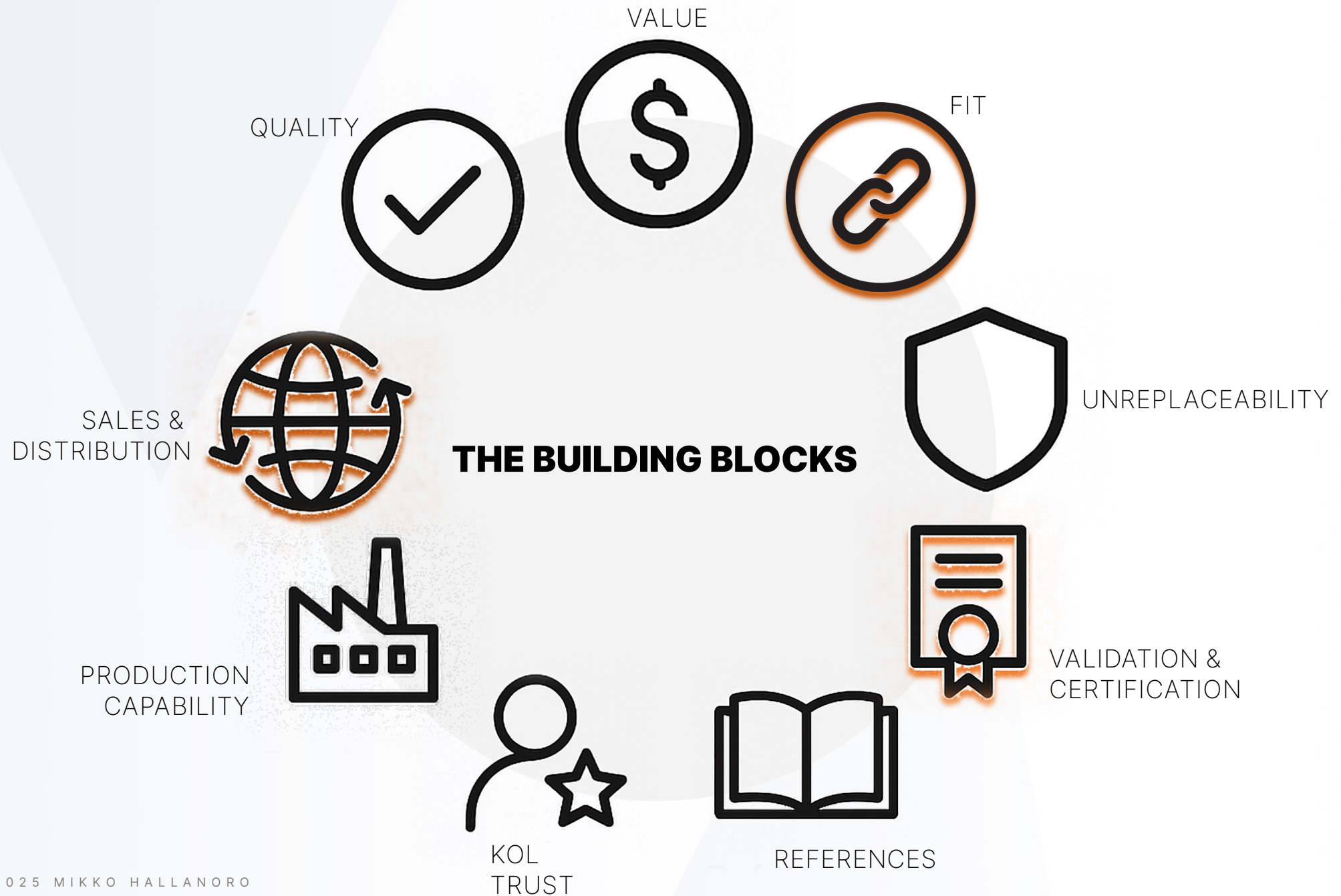
“Marginum’s pioneering solution challenges contemporary fluorescence-guided surgery and advances the state-of-the-art by enabling more versatile and precise surgery.”

– Professor Fady T. Charbel
Head of Department of Neurosurgery
Richard L. and Gertrude W. Fruin Professor
University of Illinois, Chicago



...of commercialising new
medtech

Mikko Hallanoro
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FIT

You must know your product's use environment extremely well. Not just what happens at the doctors appointment, but also in the background (for example IT environment and patient data flows).



- **Fit to use environment (ecosystem of users, work processes, environment, regulation, other equipment) is crucial**
- Care process, Other equipment, IT environment, Data protection, Workforce, public vs private
- The more the current processes and environment have to change, the more value is required
- Product customization (various setups, IT installations and environments) is expensive

VALIDATION

MDR

- QMS ISO13485
- Technical documentation (annex II and III)
- Clinical evaluation (Annex XIV)
- Risk management ISO 14971
- PMS

SW & Patient data

- IEC 62304; IEC 82304-1; IEC/TR 80002-1; IEC 62366-1;
- GDPR; ISO/IEC 27001; ISO/IEC 27701

Validation requirements have increased dramatically over the last 5-10 years – especially European Certification (MDR), Data Security and ESG requirements (Environmental, Social, Governance)



VALIDATION &
CERTIFICATION

SALES & DISTRIBUTION



Decisions on what you sell, to who you sell, and how you sell must be based on a thorough understanding of the operating and financial environment of the key purpose of the planned product / service

I have a new technical invention that will revolutionise healthcare function X...→

There is this huge problem how healthcare function X is performed...→



SALES & DISTRIBUTION

What

Component

Device

Software

Data handling

Hosting

Integrations

Service

How

Direct sales

Distribution

Licensing

To who

Hospital

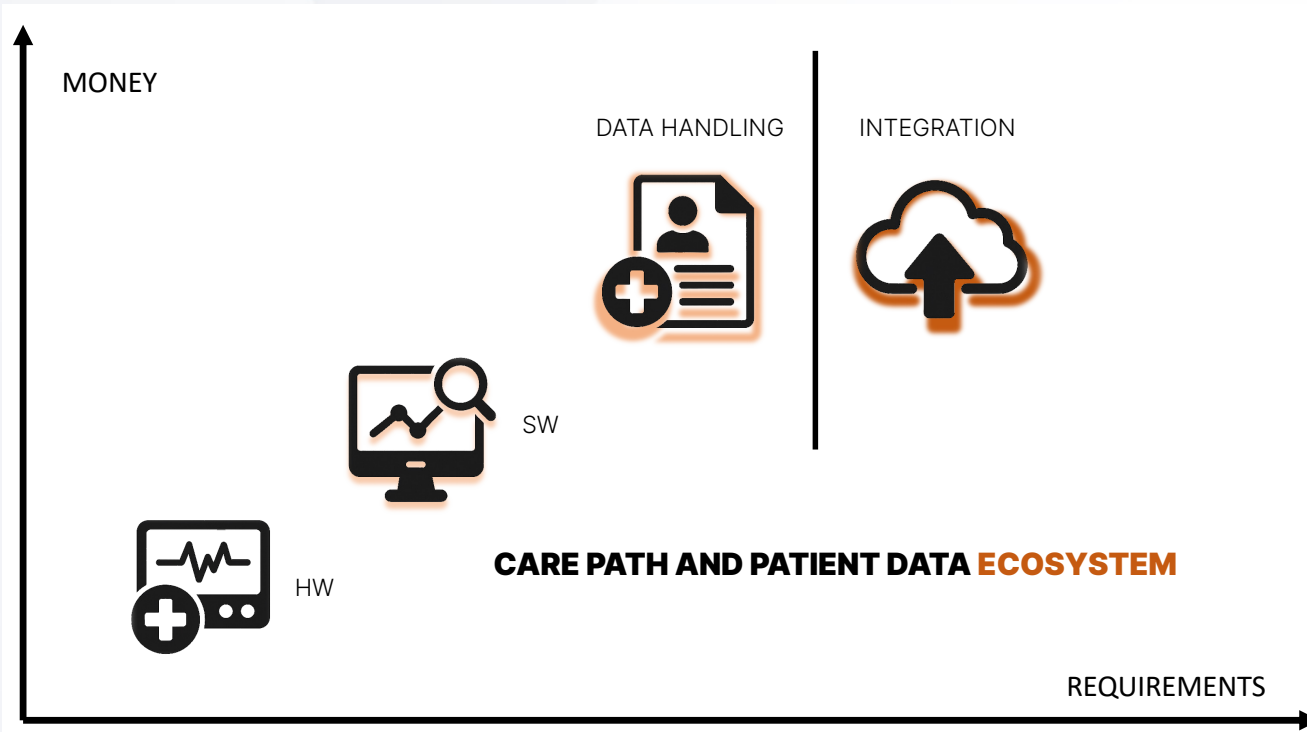
Clinic

Private service
provider

Manufacturer

Distributor

SALES & DISTRIBUTION



The more boxes you choose the more complicated, risky and costly it will be, but also with a bigger piece of the cake.

Choosing right boxes is key to success.

What part of the care path and patient data handling ecosystem is my system taking care of, and does it integrate seamlessly to technology and processes around it?



CROSSROAD DECISIONS

The key crossroads decisions can be defined as decisions which cannot be easily changed afterwards (or at least it is very costly or time consuming) and whose impact is critical.

TIPS & RECOMMENDATIONS

TECH AND CLINICAL KNOWLEDGE IS NOT ENOUGH → STUDY YOUR USE ENVIRONMENT

1

- Regulative requirements, other technologies present, working processes, reimbursements
- Ecosystem of patient data for the whole care path that your device is part of → know the dataflow diagram!

CONSIDER ALL BUILDING BLOCKS – THEY ARE ALL NEEDED BEFORE YOU CAN GROW

2

- Considering all of these helps you realize the size of the challenge
- Easier to recognize the key crossroad decisions, and to justify the need for investments

RECOGNIZE THE KEY CROSSROAD DECISIONS

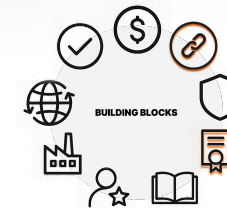
3

- Not too many start-ups have the possibility to walk the wrong way several times
- And if you do go wrong, you recognize it earlier, ready to correct the course

MATCH CAPITAL AND THE SIZE OF THE CHALLENGE

4

- Knowing all of the above, it is easier to estimate the skills, money and time required
- A tool for justifying the investment requirements



Thank you!

The Marginum team is happy to tell you more about our technology and products.

Contact us at any time at info@marginum.com

or by calling +358 44 237 0101

Our team of experts is at your service.



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