

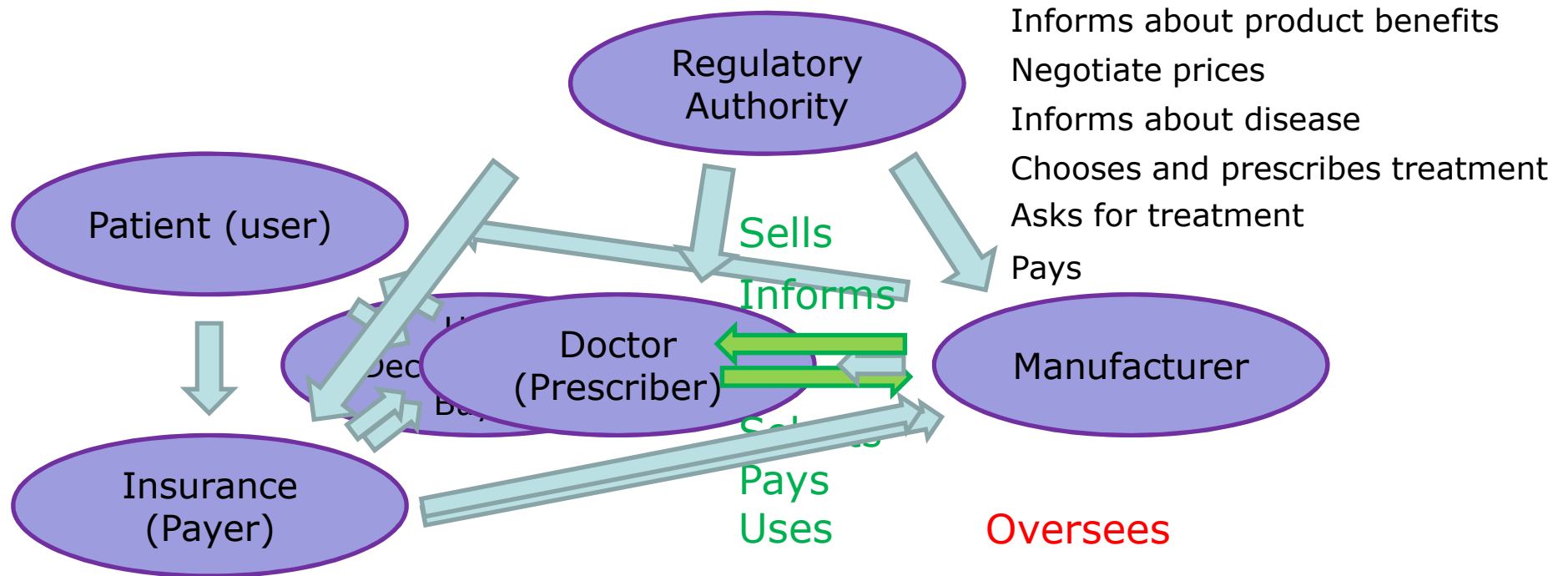
# **AO in Switzerland: a model for the future ?**

**Laurent-Dominique Piveteau**

## ***Chapter 9***

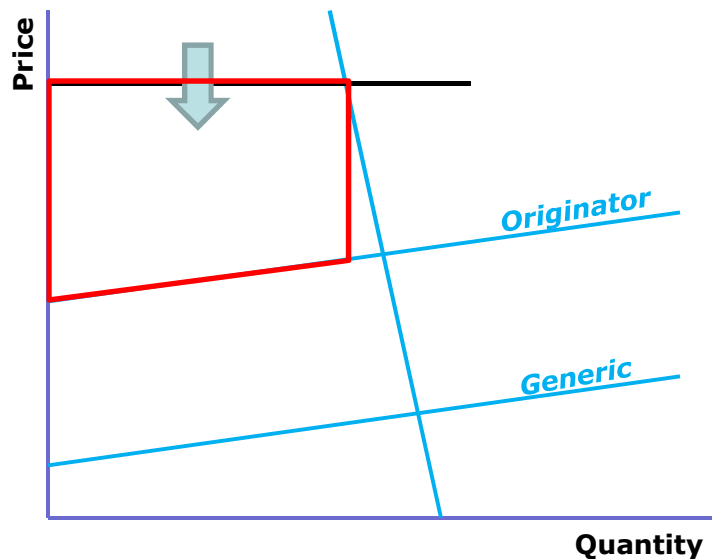
**The economics of innovation in the bio-medical industry - MGT 403  
Spring 2019**

# The medical market



# Innovation at the center

Pressure to reduce cost over time



Price fixed by negotiation

Surplus used to cover:

- R&D costs
- Failed developments
- Investments for the future

As soon as patents lapse  
prices drop rapidly

## From Suzanne Berger: *Making in America*

- *Studies of industry have often observed that innovation in CH/German manufacturing leads to incremental improvements in existing processes and products rather than the creation of radically new products and businesses, where the US appears to do better. Apple iPods, Facebook, and early generation of drugs personalized for an individual genome are not the kind of products likely to emerge first in CH or Germany while new generations of high end capital equipment and production machinery, microtechniques and instruments are more likely to come out of German/Swiss factories than out of US plants.*
- *These differences have to do with different industrial specializations and different human capital formation. They also reflect differences in business models, with the German/Swiss firms' access to finance that is less demanding of immediate returns thus making it possible for management to invest in longer-term projects*

# Incremental vs. Radical

- Incremental
  - No fundamental change of therapy
  - No fundamental change of the product
  - Short development cycle
  - Low regulatory risk
  - Easy acceptance by the market

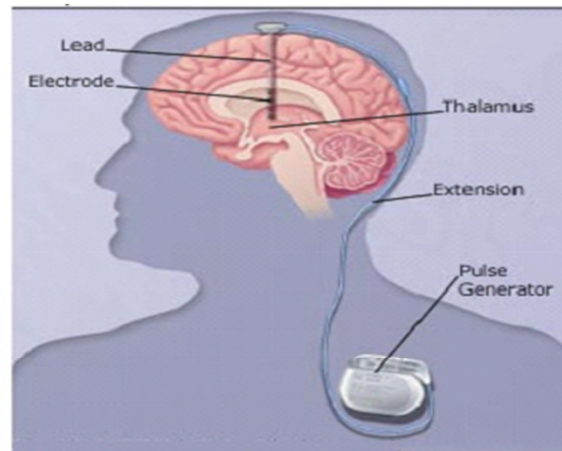
# Incremental



# Incremental vs. Radical

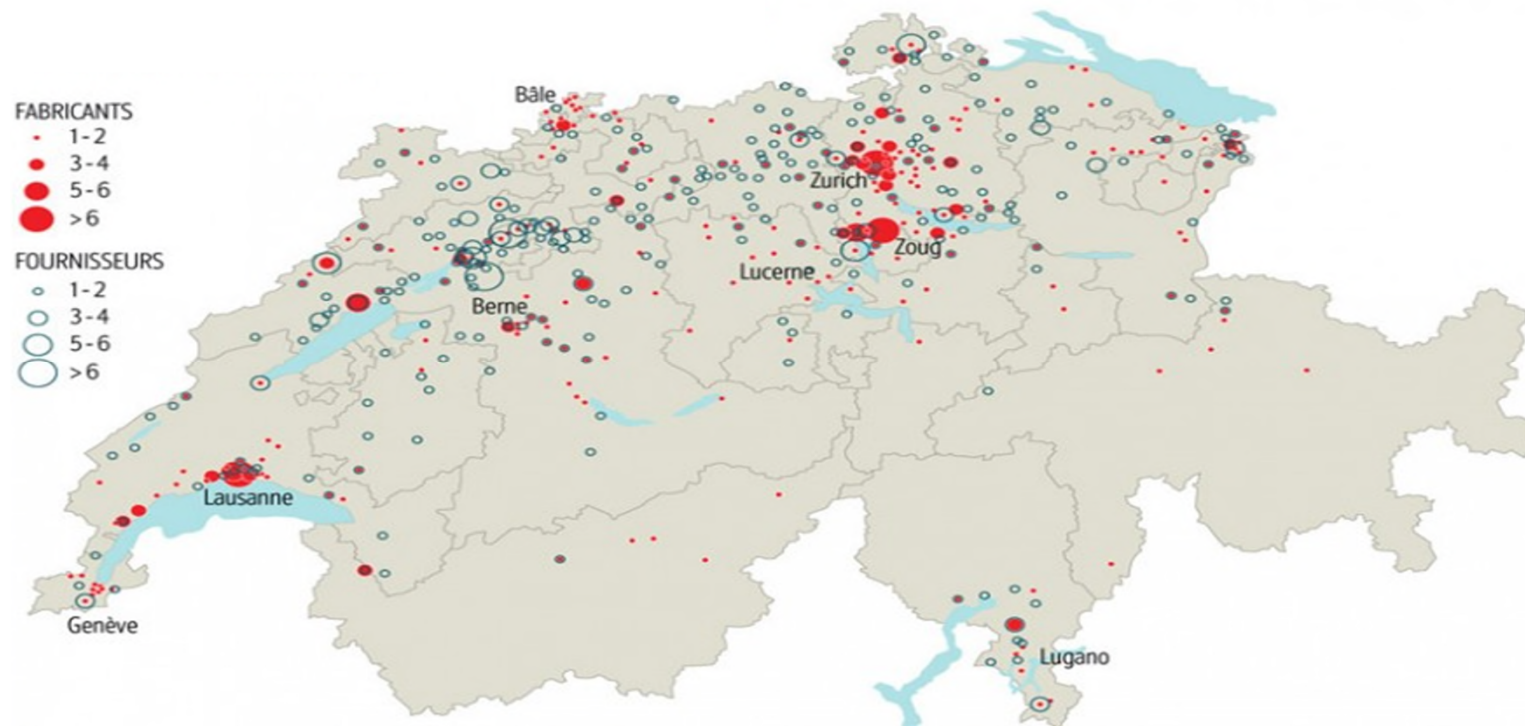
- Incremental
  - No fundamental change of therapy
  - No fundamental change of the product
  - Short development cycle
  - Low regulatory risk
  - Easy acceptance by the market
- Radical
  - Change of therapy paradigm
  - Fundamentally new product
  - Long development cycle
  - Regulatory pathway unknown; high risk
  - Potential rejection from the market

# Radical





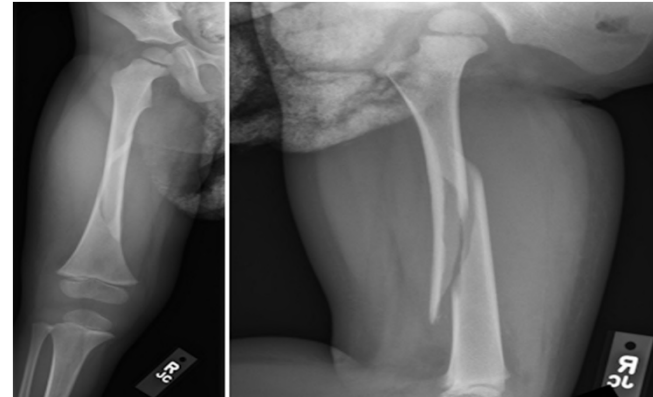
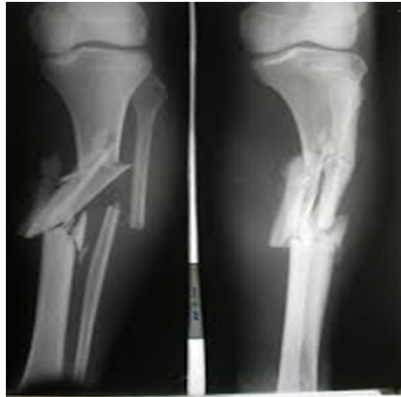
# Today





Arbeitsgemeinschaft für  
Osteosynthesis

# ***Bone fractures***



# How to treat bone fracture?

- Conservative approach
  - Bones are realigned by extension
  - ~~Distraction osteotomy~~
  - Muscle resorption due to long immobilization
  - Requires extensive re-education following recovery

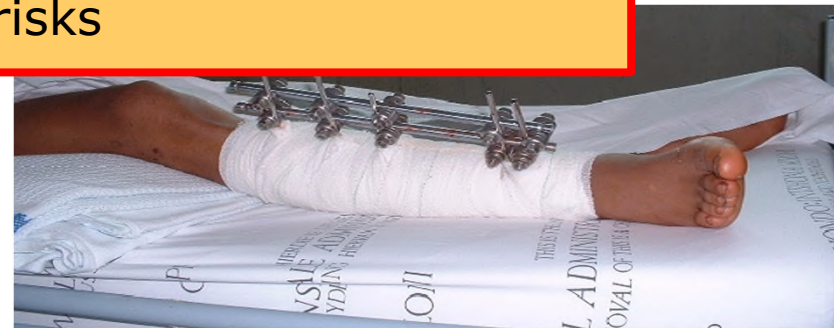
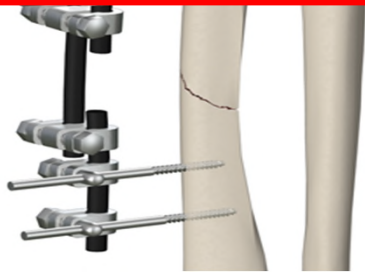


# How to treat bone fracture?

- External Fixation
  - Bones are realigned and immobilized using

Inconvenient procedure

Aseptic risks

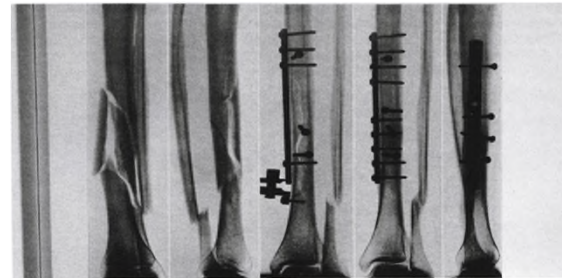
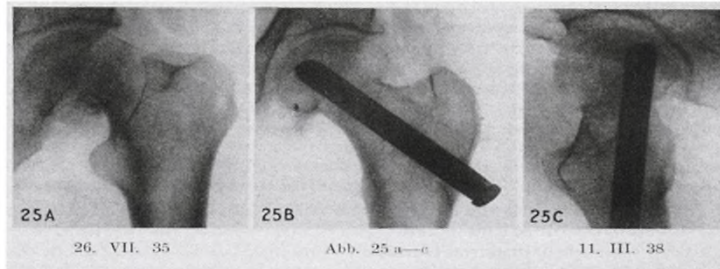


# How to treat bone fracture?

- Surgical approach: osteosynthesis
  - Create a strong link between the bone and an external element

Difficult medical procedure

– Success linked to the performing surgeon



# Need for osteosynthesis

- Number of cases is growing
  - War injuries / traffic accidents
  - Bone fracture becomes natural
- Fractures are more complex
  - Multiple fractures

# Risks linked to osteosynthesis

- Understand the need of as well as control the asepsis during intervention
- Control the materials used to avoid long term complications
- Control the good positioning of the elements to avoid wrong- or non-healing of the bone
- Understand the importance of medical gesture during the procedure



# Medical environment

- Traditional, hierarchical milieu
- In favor of conservative treatment approaches
  - Accompany the body in its own healing process
  - Limiting medical intervention to its minimum extent

# **A short history of the Arbeitsgemeinschaft für Osteosynthese**



# Early time: Adoption and rejection

- “Internal fixation will never become the method of choice because the method is too difficult, the requirements for asepsis too strict and the risks too high” Fritz Steinmann, German surgeon, 1927
- “It is questionable if open bone surgery should ever be done except by highly trained men, with highly trained assistants, in highly trained hospitals; otherwise disaster is likely to result”. Expert opinion based on 34'753 cases of the Aetna Life Insurance Company, USA, 1927

# 1944-1950: Inspiration



Gerhard Küntscher, military surgeon  
Kiel, Germany (1900–1972)

Femoral nailing



Cornelis Pieter van Nes  
Leiden, Netherlands (1897–1972)

Fellowship in Holland  
Advise Müller to visit Robert Danis in  
Bruxelles



Maurice Müller  
Bern, Switzerland (1918–2009)

# 1950: The precursor

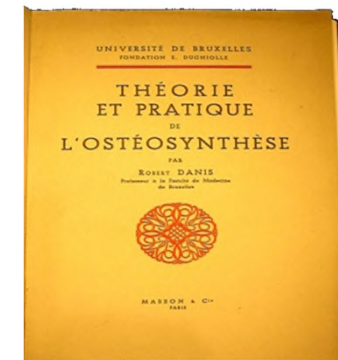
Robert Danis  
Bruxelles, Belgium (1880–1962)

Defines the concept of compression plating

Uses his coaptateur plate for rigid fixation



Compression for “per primam” healing  
Absence of callus “soudure autogène”



# 1958: AO Foundation

November 6, 1958, Hotel Elite  
Biel (Bienne), Switzerland



# 1958: The founding fathers



Maurice Müller

Zürich

1918–2009



Martin Allgöwer

Chur

1917–2007



Walter Bandi

Interlaken

1912–1997



Robert Schneider

Grosshöchstetten

1912–1990

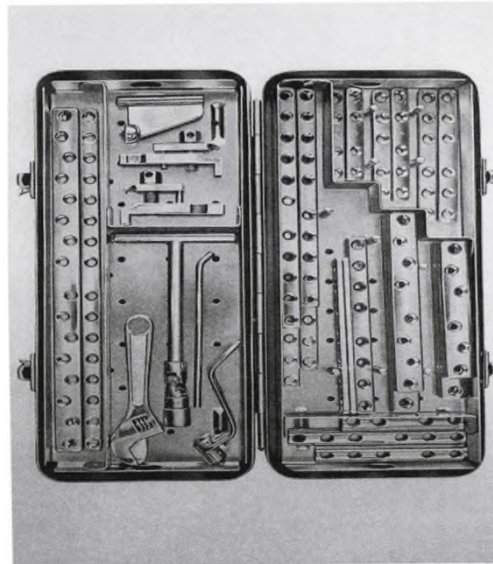
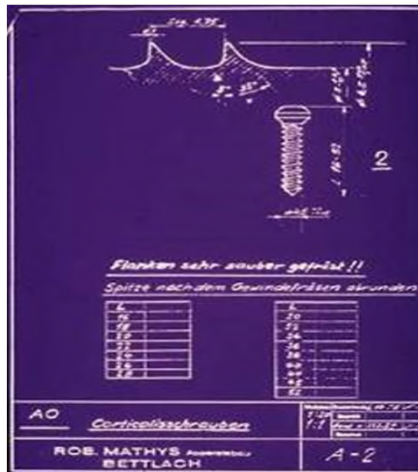


Hans Willenegger

Liestal

1910–1998

# 1958: Partnership with industry



Robert Mathys  
Bettlach, Switzerland (1921–2000)



# 1959: The principles of AO

## The Four Pillars

- Development of implants and instruments
- Research on fracture healing and tissue cultures
- Documenting cases of all patients
- Teaching of osteosynthesis techniques



# 1959: Initiating research

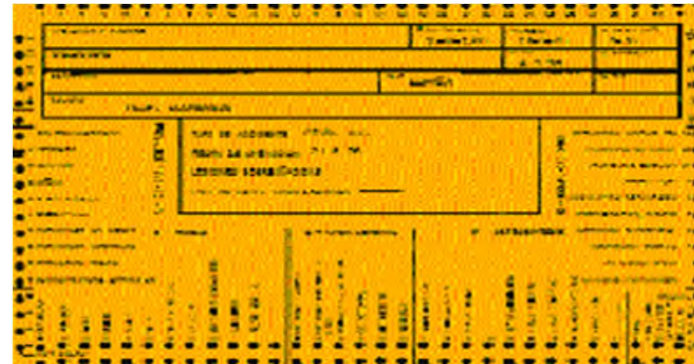
## Understanding the underlying biology of osteosynthesis

*"If the biological foundation of a technique is flawed, no technical improvement whatsoever could make it viable"* (John Charnley)



AO Laboratory  
for Experimental  
Surgery  
Forschungsinstitut  
Obere Strasse

# 1959: Documenting cases



- Follow long term healing to demonstrate superiority
- Learn from failure
- Feed educational programs

# 1960: 1st AO Course in Davos

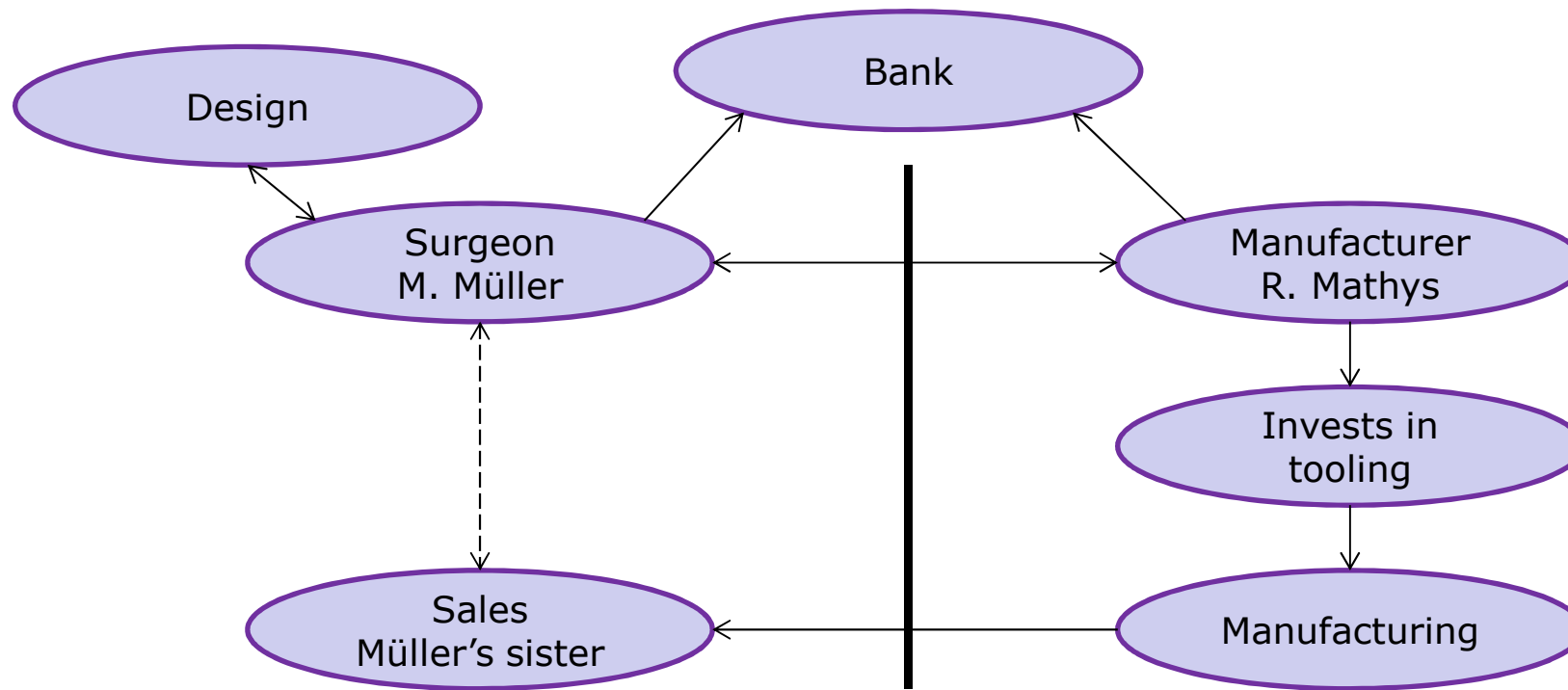
Participants:

- 56 
- 7 
- 2 
- 3 
- 1 



Maurice Müller teaches femoral nailing in the AO Lab.

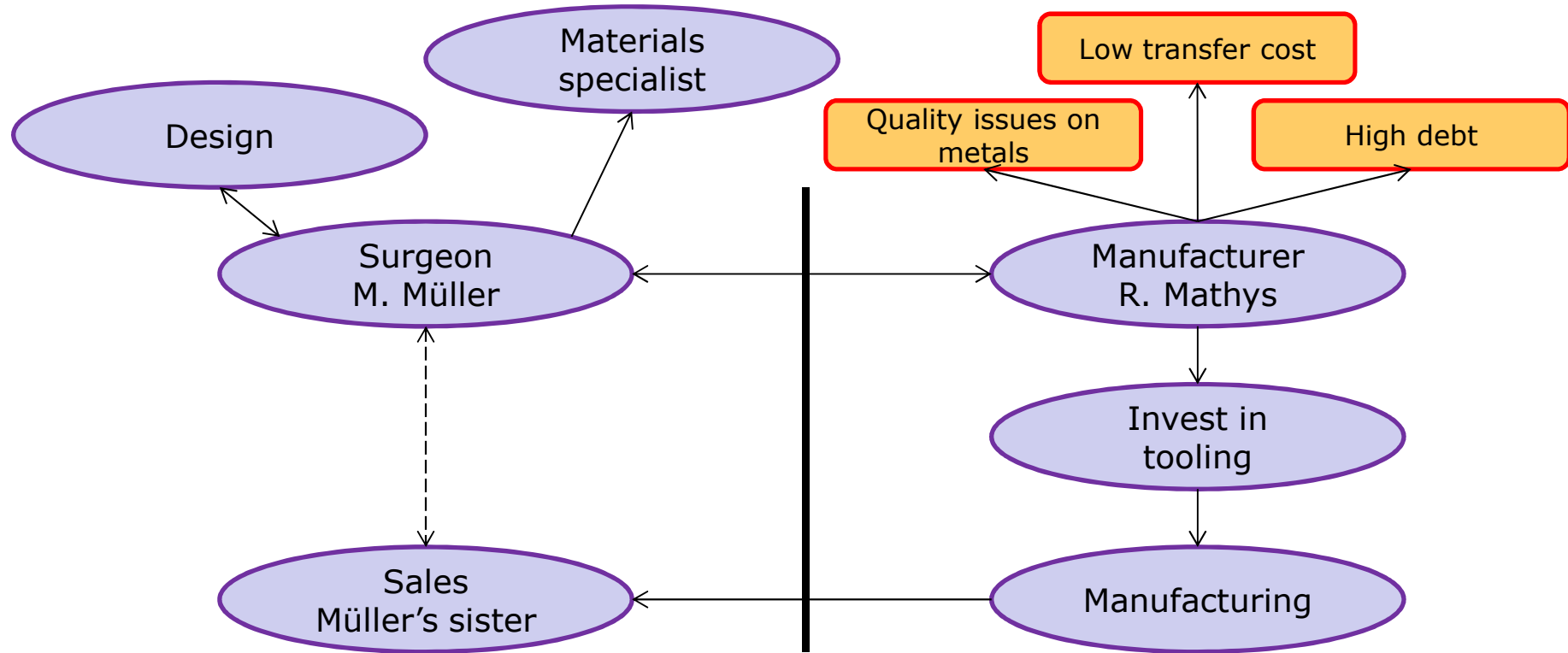
# 1958-1961: Business structure



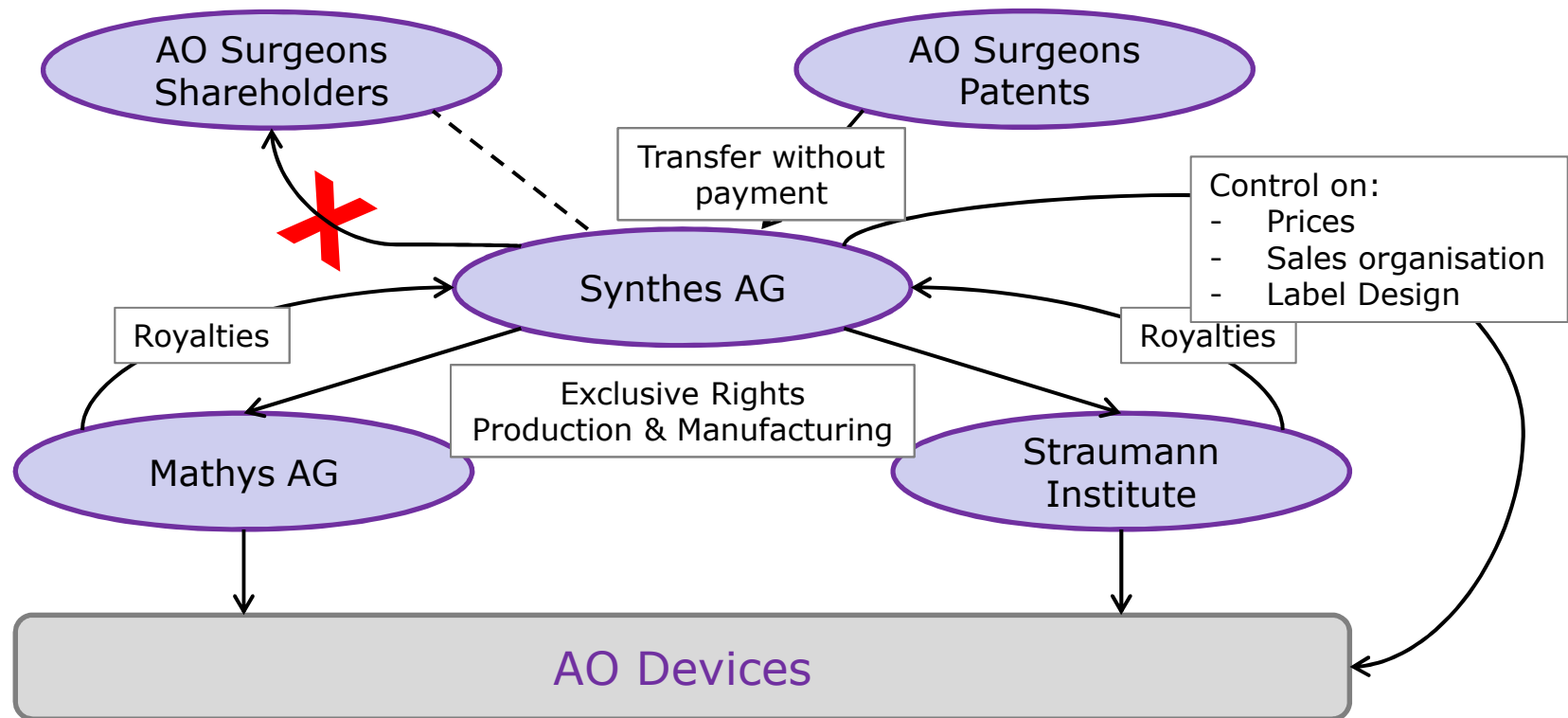
# Entrepreneurial phase

- Product
  - Creation of a first offer
- Informal collaboration
  - Based on personal network
    - Family and military
  - Central role of trust
- Risk
  - Entrepreneurial behavior of the different parties (financial and reputation)

# 1958-1961: Business structure



# 1958-1961: Business structure

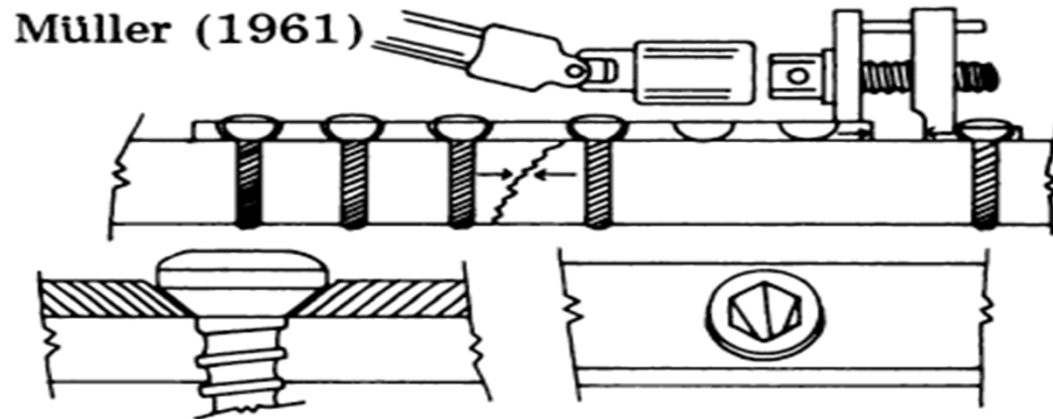
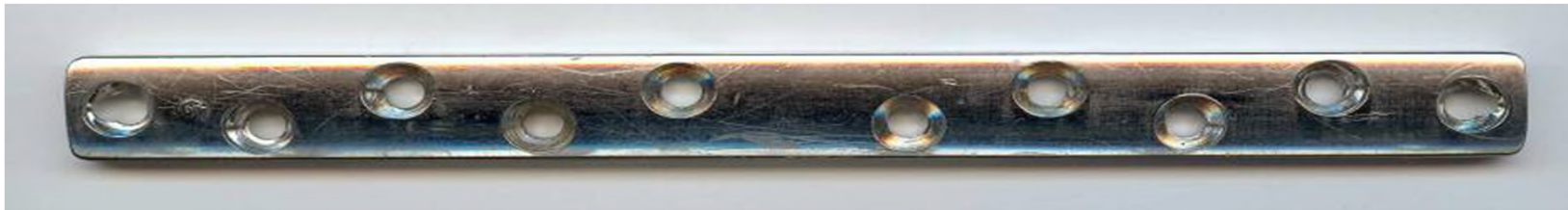




# Maturation phase

- Product
  - Completing / improving the portfolio
  - Alternative approaches
- More actors involved
- Higher financial investments at stake
  - Need to create stable, clear and predictable financial streams
- Need for more organization
  - Establishment of rules between the commercial and/or non-commercial actors

# 1961: Round plate & compression device



# 1961: Creation of the TK

*(Technische Kommission)*

- Becomes the place where the interests of the different parties are negotiated
- Led by Maurice Müller
- Comprising the main AO founders, Mathys and Straumann
- Informal organization
- Decision taken at majority
- Binding for all members



# 1963: Comprehensive Instrument boxes

- Offering a complete set of implants and accessories for successful intervention
- Attendance at an official AO Course was mandatory for purchasing any of the six official AO Instrument boxes.

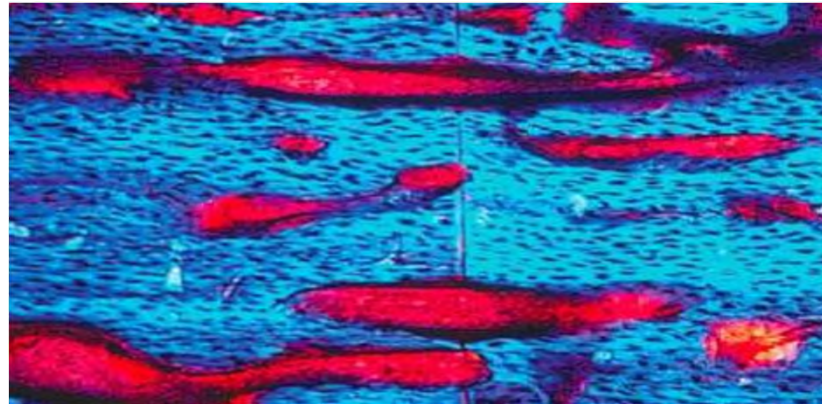
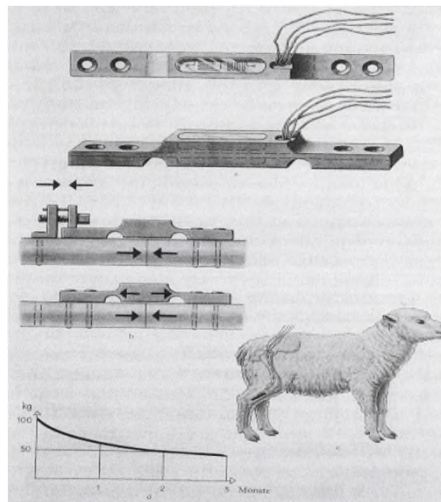


# 1963: Teaching nurses

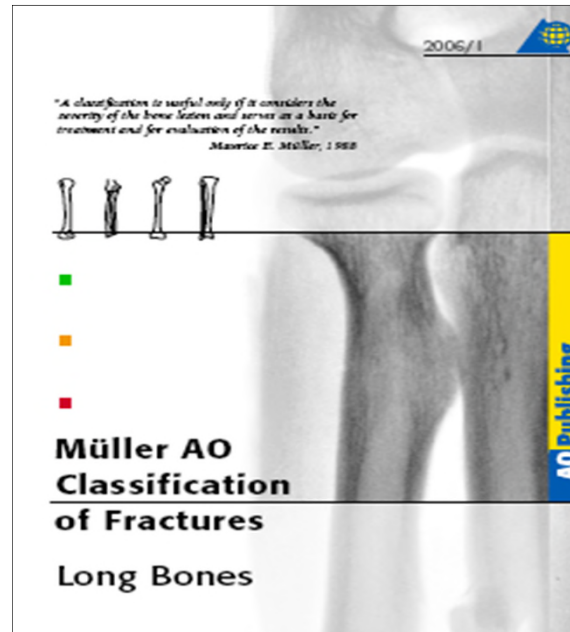
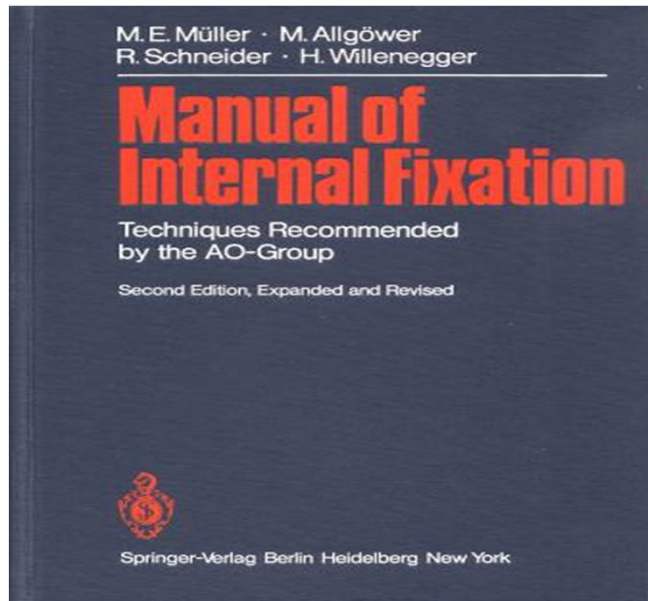






# 1963: Primary bone healing

- Fundamental principle underlying the concept of osteosynthesis



# 1963 → 2000: Textbooks



1963		
1965		(Partial)
1969		
1969		
1970		
1970		
1975		
1981		
1983		
1996		

110k books in 2000

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**EPFL**

# Continuous innovation

- **1963:** AO Tubular plates
- **1965:** AO Nailing
- **1968:** High-energy fractures
- **1969:** Dynamic compression
- **1981:** Mimax System
- **1988:** Plastic bones
- **1995:** LISS (Less Invasive Stabilization System)
- **1997:** Mini-Incisions



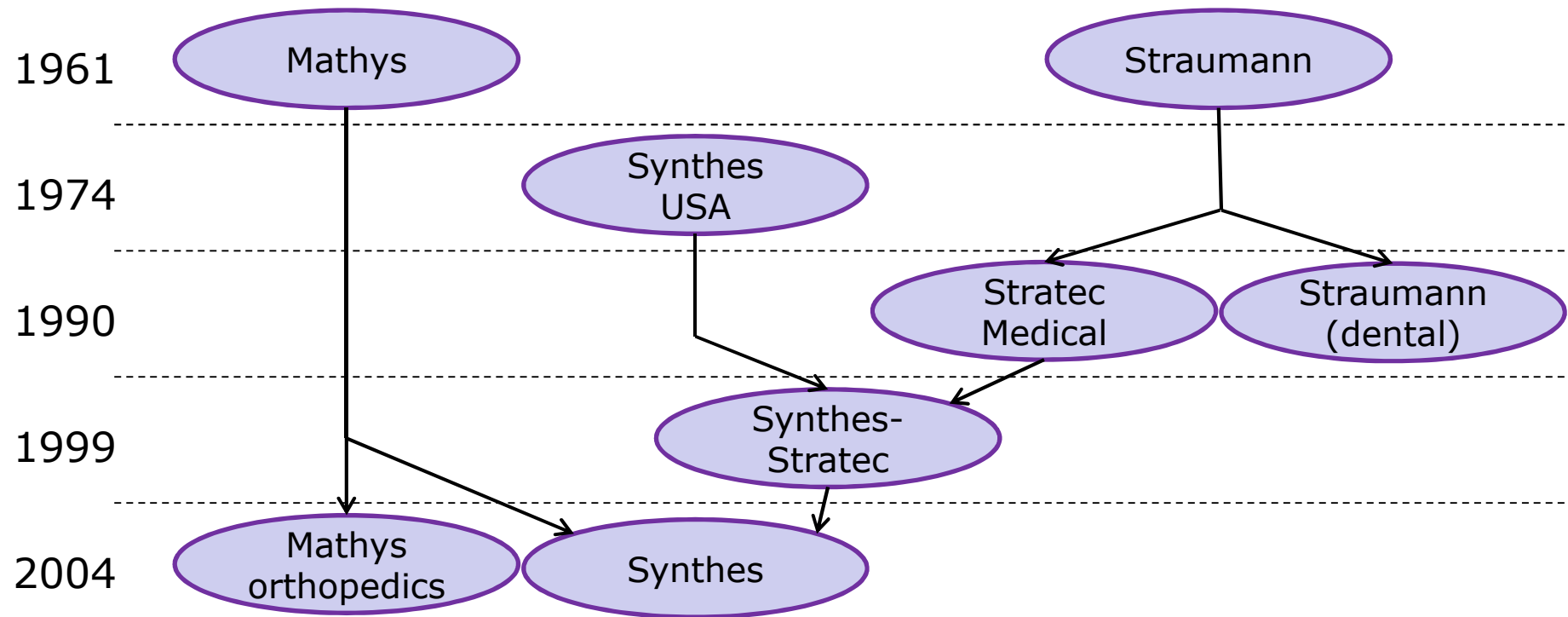


# 1989 AO Alumni Association

56 local chapters in 6 AO Regions in 2008



# 1961-2004: Growing the business



# 2004-2011 the end of the story

2004: Merger of Synthes-Stratec with Mathys activities in Osteosynthesis



2006 Synthes acquires Synthes tradename, trademarks and intellectual property from the commercial subsidiary of the AO Foundation

2011 Merger of DePuy (Johnson & Johnson) and Synthes



# To summarize

- Education
  - New medical technique, requiring high skills to be successful
  - Central role of education
    - Surgeons and nurses
    - Not only targeting the elite
- Science
  - Visionary on developing evidence based medicine
    - Collection of medical cases to demonstrate efficacy
    - Learn from errors
    - Development of a large corpus knowledge to bring scientific proof for the method

# To summarize

- Product
  - Product as a complete solution
  - Continuous product improvement
  - Development in close collaboration with the users

# Why is this story interesting?

- It shows the importance of **managing the adoption** of an innovation
- It shows the need to **adapt the structure** and business model to the development stage of an innovation
- It shows the importance of the **ecosystem** in the emergence and growth of innovation
- It shows that if technology is important, it is not the only element leading to success
  - **Culture and values** play an essential role
  - Importance of finding the **right equilibrium** between the different parties in the game

# Managing Adoption

# Adopting innovation

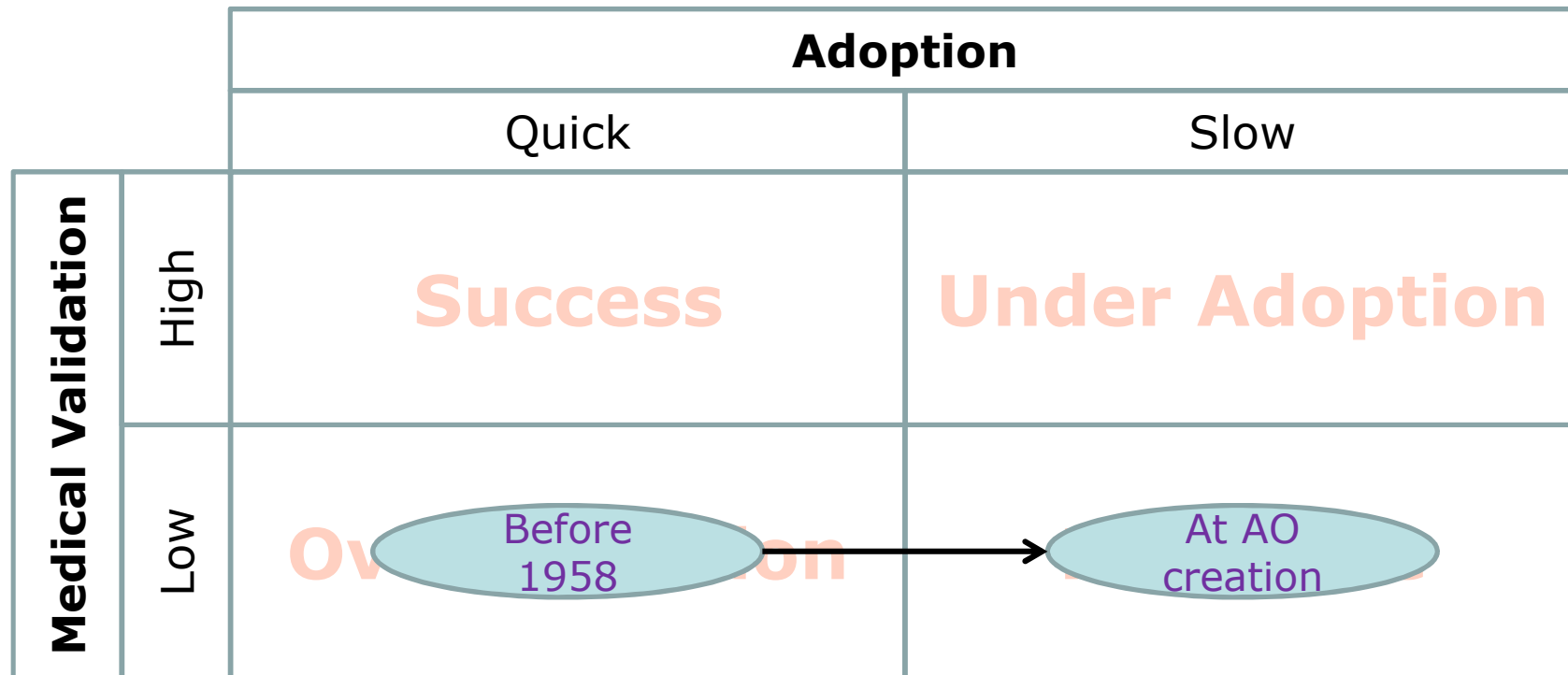
		Adoption	
		Quick	Slow
Medical Validation	High	<b>Success</b>	<b>Under Adoption</b>
	Low	<b>Over Adoption</b>	<b>Prudence</b>



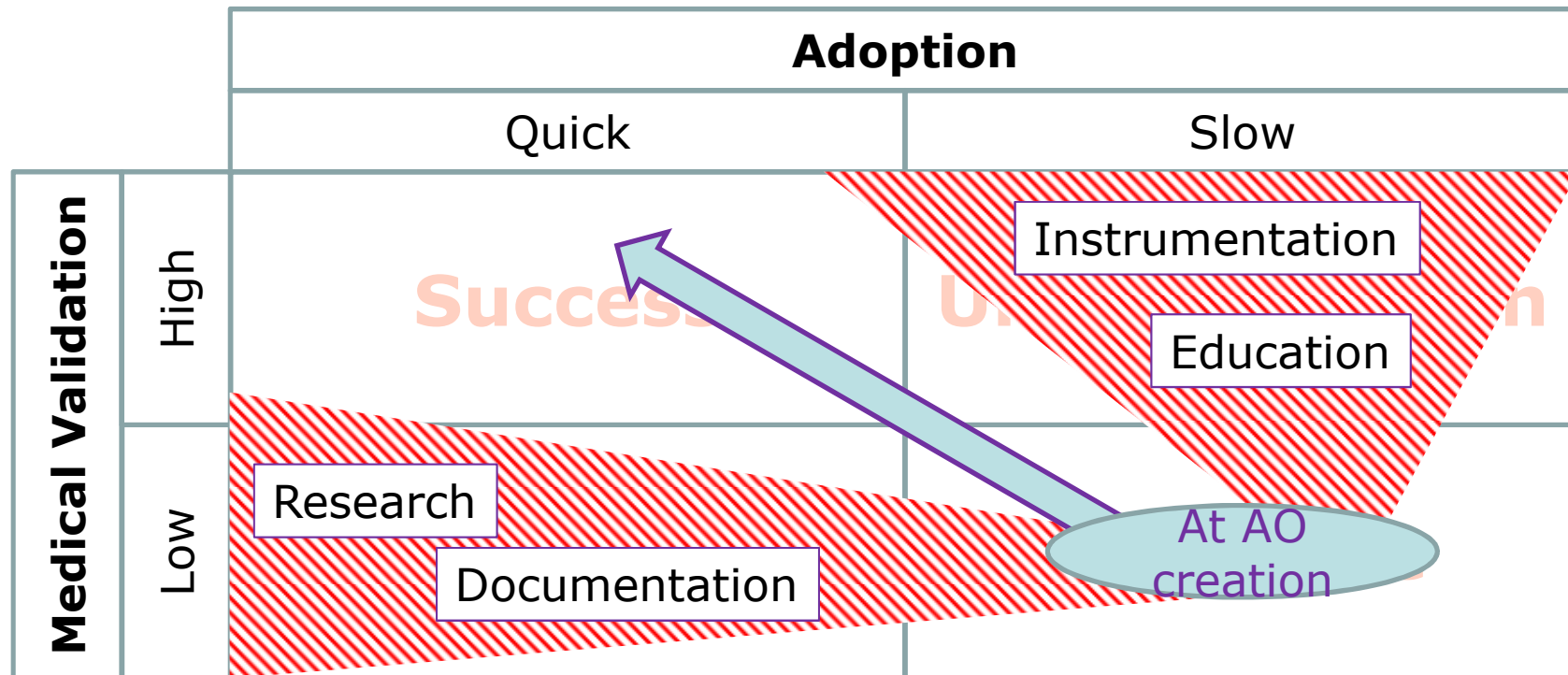
# Adopting innovation

		Adoption	
		Quick	Slow
Medical Validation	High	The Goal	Financial interests of certain actors Traditional environment
	Low	Absence of treatment Need to differentiate from existing actors	Often the Starting Point

# Adopting innovation



# Adopting innovation



# Adapting structure



MATHYS

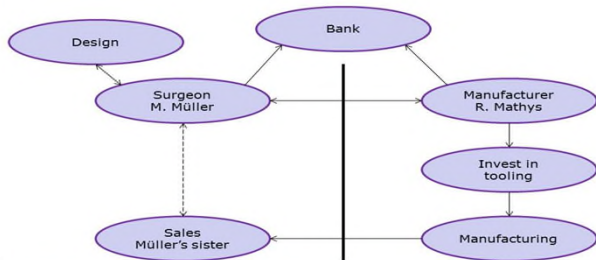


DePuy Synthes

COMPANIES OF *Johnson & Johnson*

# Adapting structure: Staged history

1958-1961: Business structure

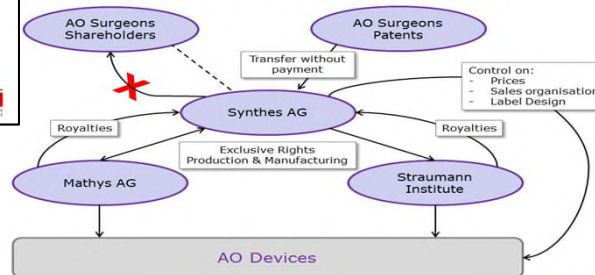


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Light and flexible  
Rapid adaptation  
Trust is central

1958-1961: Business structure



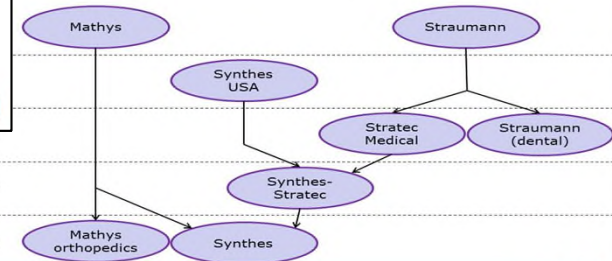
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Setting rules  
Protect various interests  
Fair negotiations

Creating world leader  
*Simplification, integration*  
Exit

1961-2004 Divestures and M&A



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# Ecosystem

# Building on an ecosystem

- Close ties of surgeons with industry and finance
- Local network of potential developers and suppliers
  - Precision machining
  - Quality products
- Strong human capital and skills
  - Engineering / Materials Science

# Private structure

- Surgeons rely on a private structure (Synthes / AO Foundation) to provide club (education, data) and public (research results) goods
  - Assistance to SMEs in their development
  - Not provided by public bodies / no governmental involvement
- Mechanisms to maximize knowledge sharing while rewarding innovators
  - Encourage further innovation
  - Develop the market
  - Maintain alignment of interests



# Club / Public / Private goods

	Excludable	Non-Excludable
Rivalrous		
Non-rivalrous		

# Private structure

- Surgeons rely on a private structure (Synthes / AO Foundation) to provide club (education, data) and public (research results) goods
  - Assistance to SMEs in their development
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# Values and culture

# Anti-elitist structure

- Open exchange between surgeons to learn from mistakes
  - Swiss culture of student fraternities and local associations
  - Group of surgeons coming from smaller hospitals (outside of major research centers)
- Anti-elitist communities facilitates building of social relationships in order to solve collectively innovation problems (easier than in an elitist society)

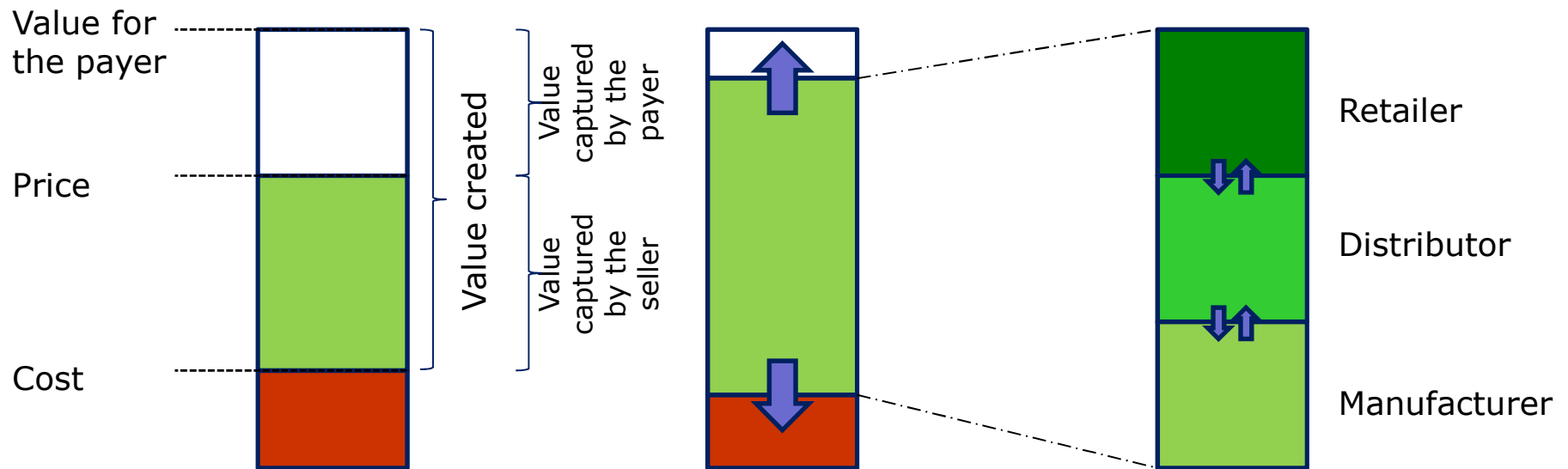
# Ethics

- Surgeons shall not have a direct financial interest into the venture
  - Reinforce their role as key opinion leader towards their colleagues by maintaining their independence
    - Patents transferred free of charge to Synthes
    - Defense of patents by manufacturers
    - All money received by Synthes invested in research. No distribution to shareholders
- Indirect revenues through the success of the procedures
- Clear separation in communication activities
  - Education by surgeons
  - Marketing and advertisement by the manufacturers

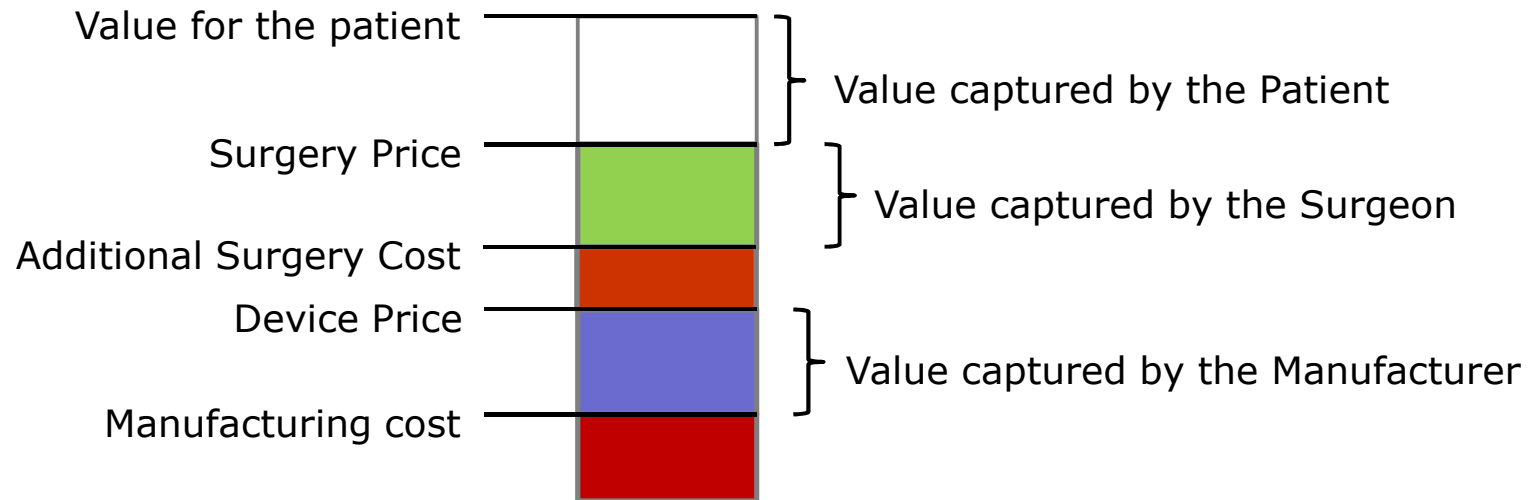
## Voka case

- Competitor incorporated by two former employees of Mathys and Straumann (Vogt and Karpf)
  - Left with insider knowledge of product
  - No R&D costs
  - Copies of the products at a lower cost
- Incentive for surgeons to capture more value

# Creating and capturing value

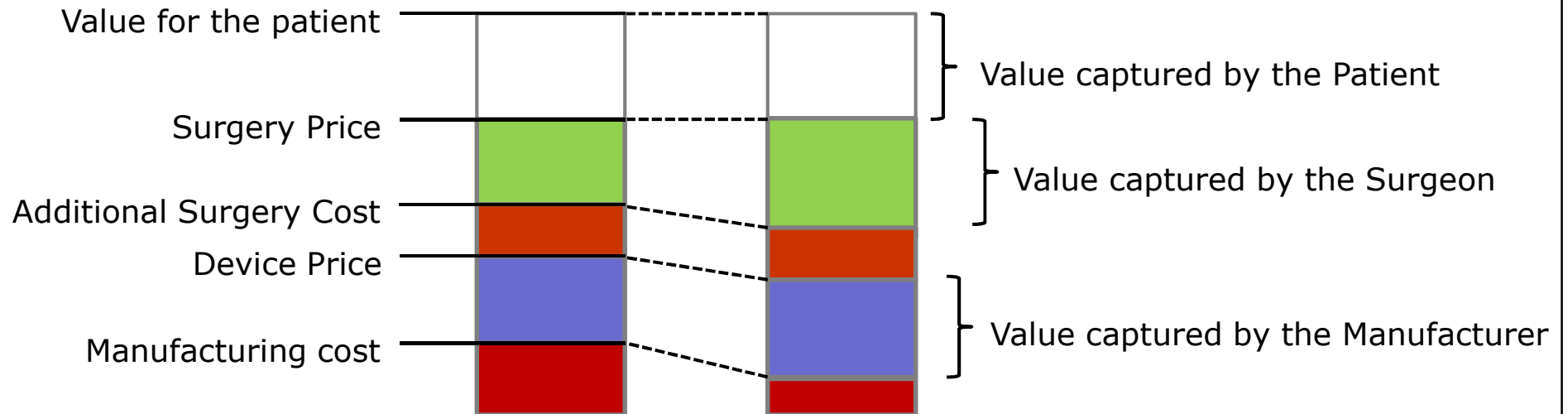


# Creating and capturing value





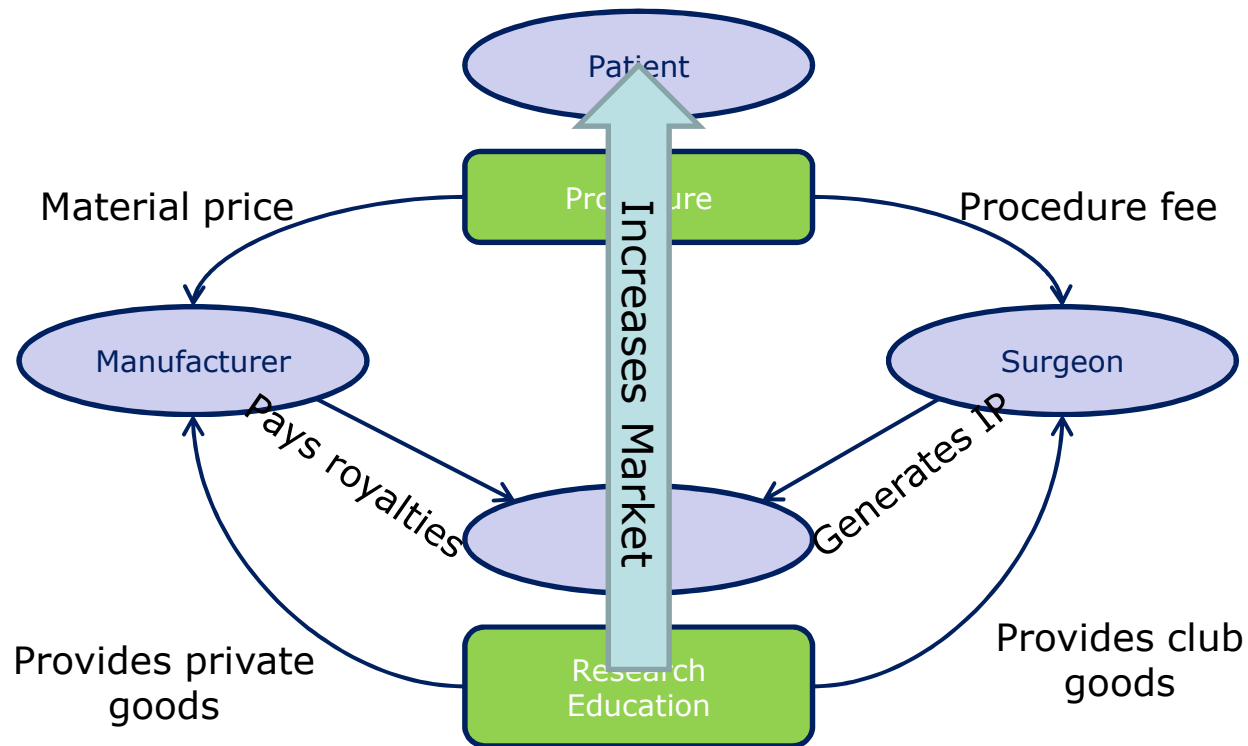
# Creating and capturing: Voka case



# Voka case

- Dilemma for AO surgeons
  - Active role
    - Participate in patent violation hearings
    - Send warning letters to their colleagues
  - Passive role
    - Leave manufacturers conduct information campaign
    - Maintain leadership in research and innovation
- Maintain the independent image of AO

# Long term view



# Practical & bottom-up culture

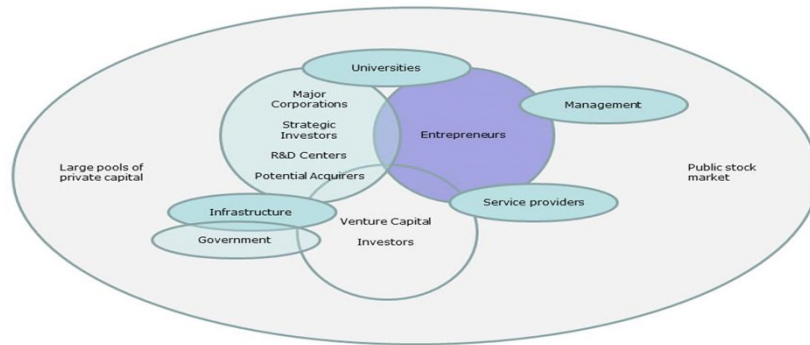
- Practical knowledge highly valued in the Swiss society
  - e.g. ETHZ aimed from the start at strong collaboration with industry and put practices and pragmatisms very high in the academic agenda
- A bottom-up – anti-authoritarian culture : the surgeons don't rely on the State to provide the public and club goods but they create a private entity: Synthes

# Practical & bottom-up culture

- Contrast with the authoritarian style in France or Germany where people are much more prepared to subject themselves to authority and rely on the Government to solve collective action problems
- Ability to create private institutions (and not to rely on government)
- Reflects a more general feature of Switzerland as compared with other countries (most countries having an authoritarian tradition)

# Two models of innovation

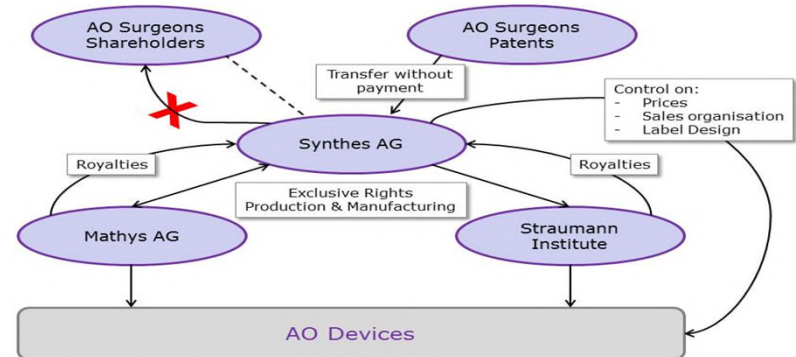
Clusters of Innovation



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1958-1961: Business structure



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# Two models of innovation

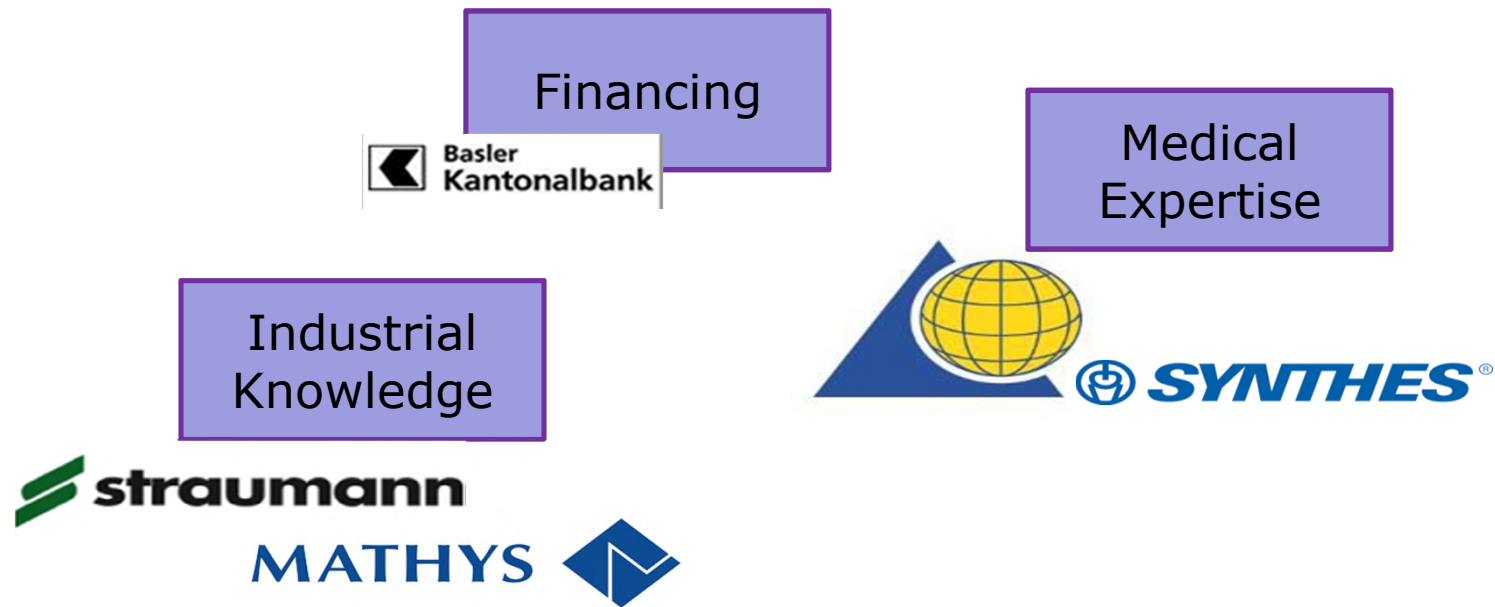
- Entrepreneurial discovery & progressive innovation
  - Strong symbiotic relationships between the surgeons and the manufacturers
  - Centrality of SME's innovativeness (human capital, skills, incentives)
  - A specific eco-system designed to provide the complementary resources that are needed
  - Rather traditional finance to fund R&D
- Start-Up and Open Innovation
  - « just-off campus biotech firms » and VC

# Discussion

- Can this model be reproduced today or is the model underlying the COI the only possible way for future innovation?
- What has changed in the general environment? Are the conditions today the same than fifty years ago?
- Do we need additional actors? Who would they be? What would be their role?



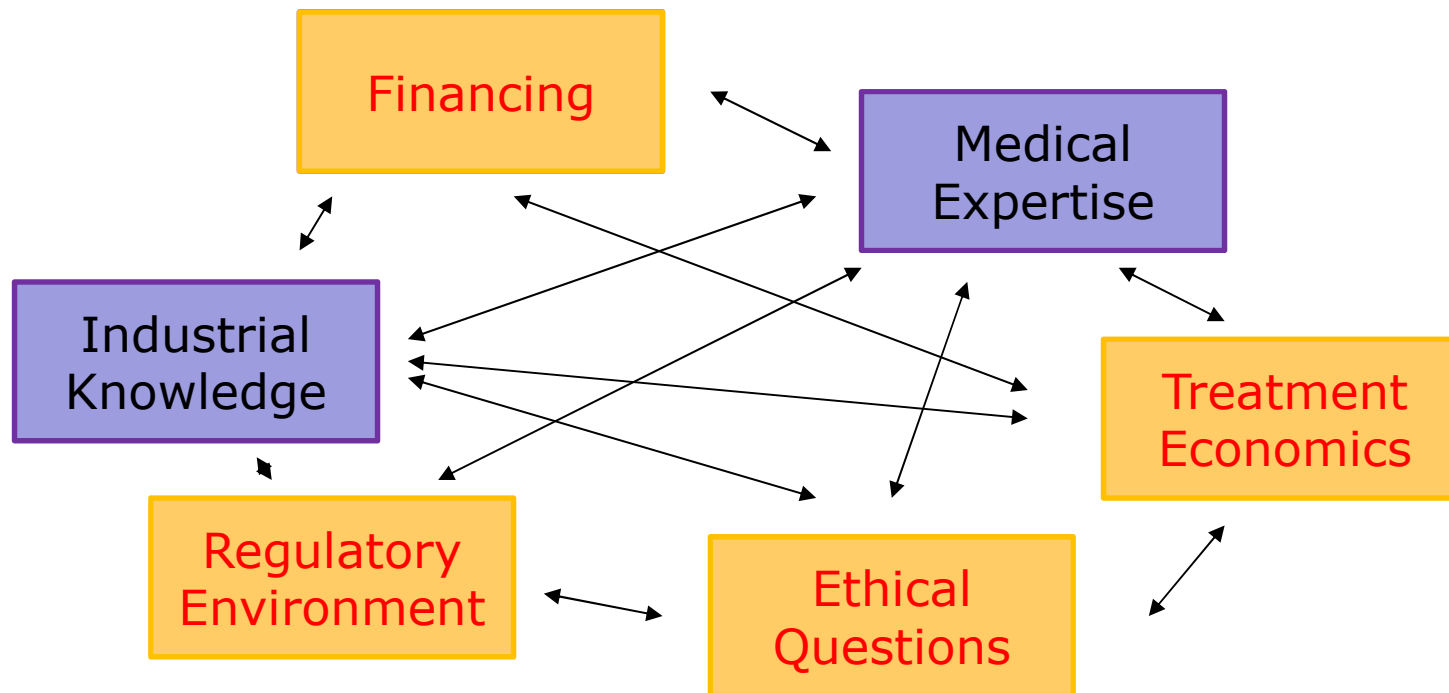
# The environment then:



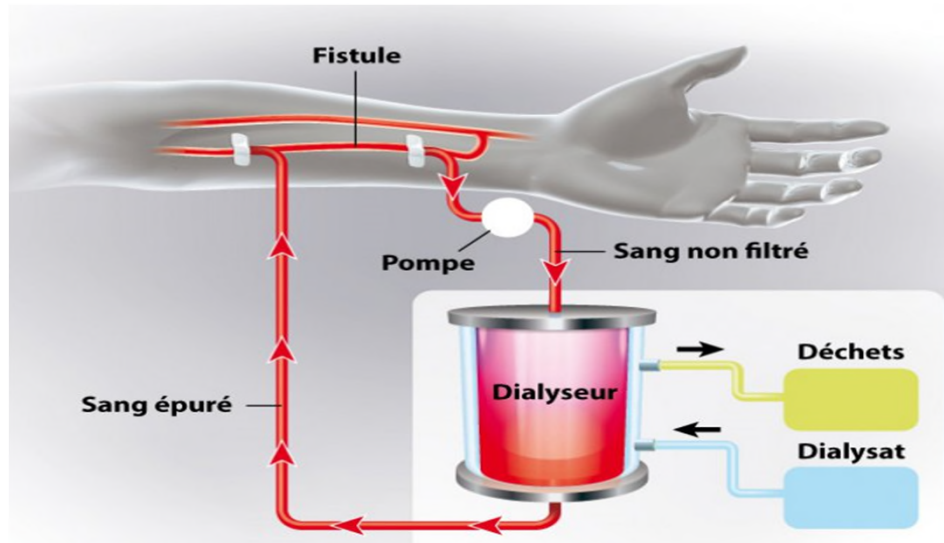
# What is different today?

- Global risk of the market has increased
  - Sulzer settlement of 1 billion USD on defective hip implants in 2002 e.g.
- Safety expectation have increased
  - Need to demonstrate safety and efficacy early in the development
- Development costs have exploded
  - Quality control and clinical trials
- Higher cost sensitivity
  - Solution shall present from day 1 a more favorable benefit/cost than existing approaches
- Many innovative solutions include living organisms
  - Unknown regulatory pathway / opens new ethical issues

## What is needed?



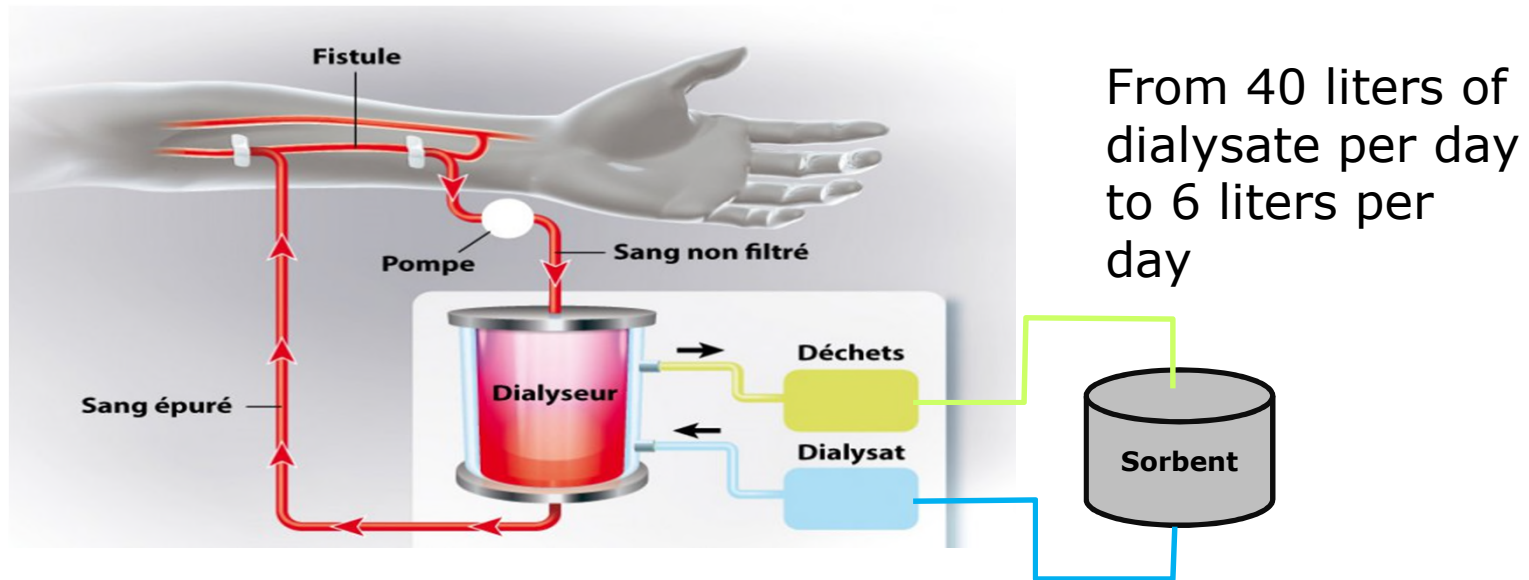
# From classical to sorbent HD



Purify blood from accumulated waste products

Remove excess amount of water accumulated in the body

# From classical to sorbent HD

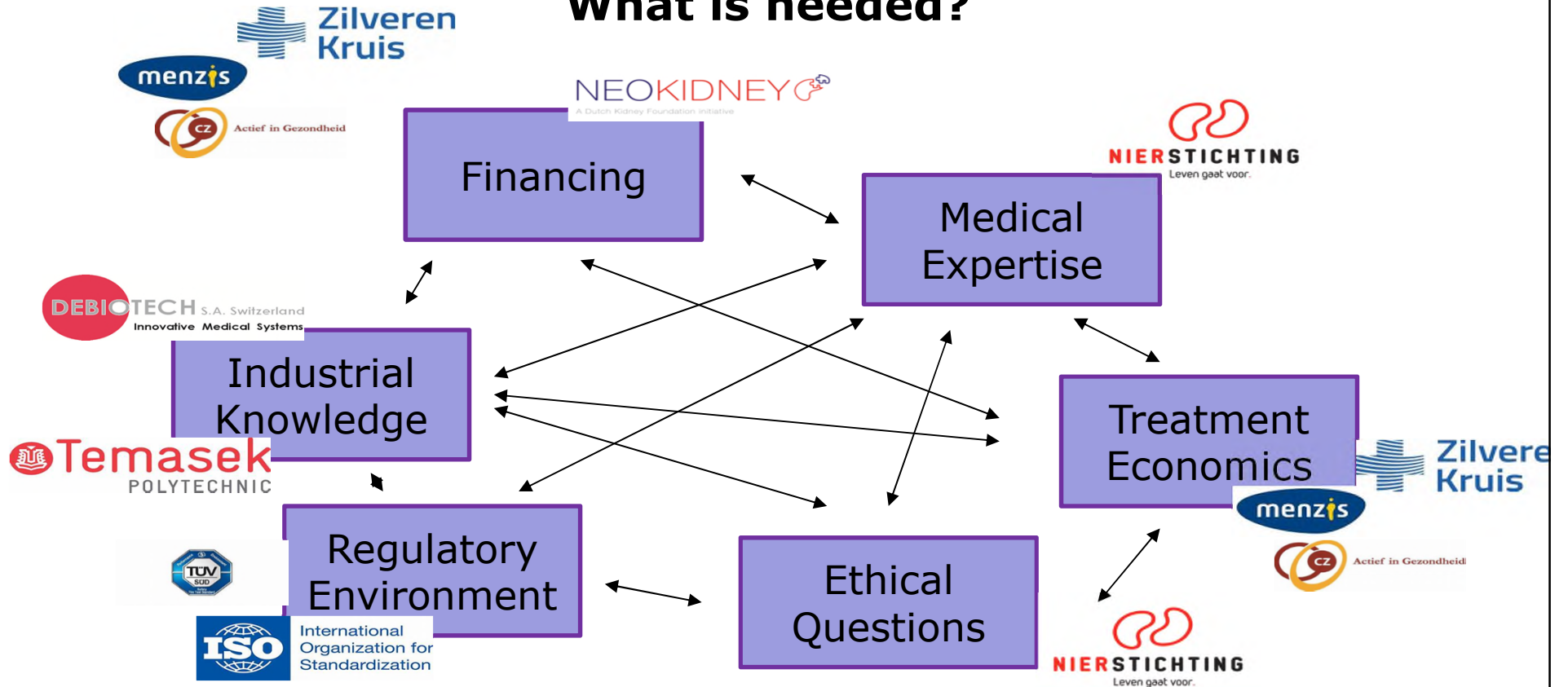


# 2018: an example in HHD



Combination of radical and  
incremental innovations  
For a known therapy

# What is needed?



# 2018: an example in HHD

- Radical and Incremental
- Combining knowledge and innovations from the different partners
- Not purely Swiss
- Complementarity of capabilities
  - Foundation centered on research
  - Its private body to drive innovation
  - Private partners
  - Innovative implication from insurance companies
  - Close exchanges with regulatory
- Flat, non authoritarian structure



# Take home messages

- Open innovation may not be the only way to solve the innovation crisis that the healthcare industry is facing today
- The Swiss mentality with its («anti-elitist») culture, its values and its ability to find the right equilibrium between the stakeholders can create a favorable environment for radical innovation