



UNITRENTO

2016 1 MARCH - 25 MAY

* CRASH COURSE ON RESEARCH FUNDING, INTELLECTUAL PROPERTY AND START UP CREATION

Open series of seminars organized by Research and Technology Transfer Support Division
University of Trento - Polo Scientifico e Tecnologico Fabio Ferrari (Povo1), via Sommarive 9 - POVO

Managing innovative Biotech corporations and creating start ups

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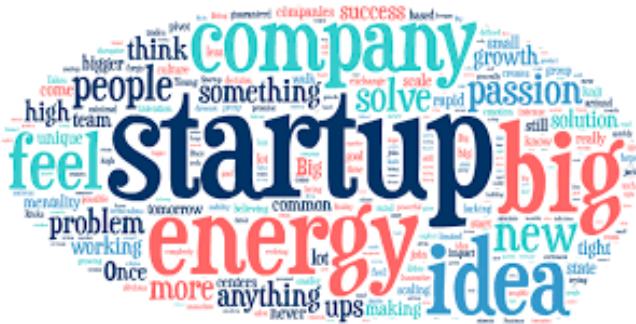
Agenda

Main topics of today

- 1. Desired Deliverables**
- 2. You have an idea!**
- 3. The business plan**
- 4. Considering support!**
- 5. Create the activity**
- 6. Ramp-up plan**
- 7. Managing risks**
- 8. Case Study**
- 9. Lessons learnt**

1. Deliverables

What do WE expect from this session of the Crash Course



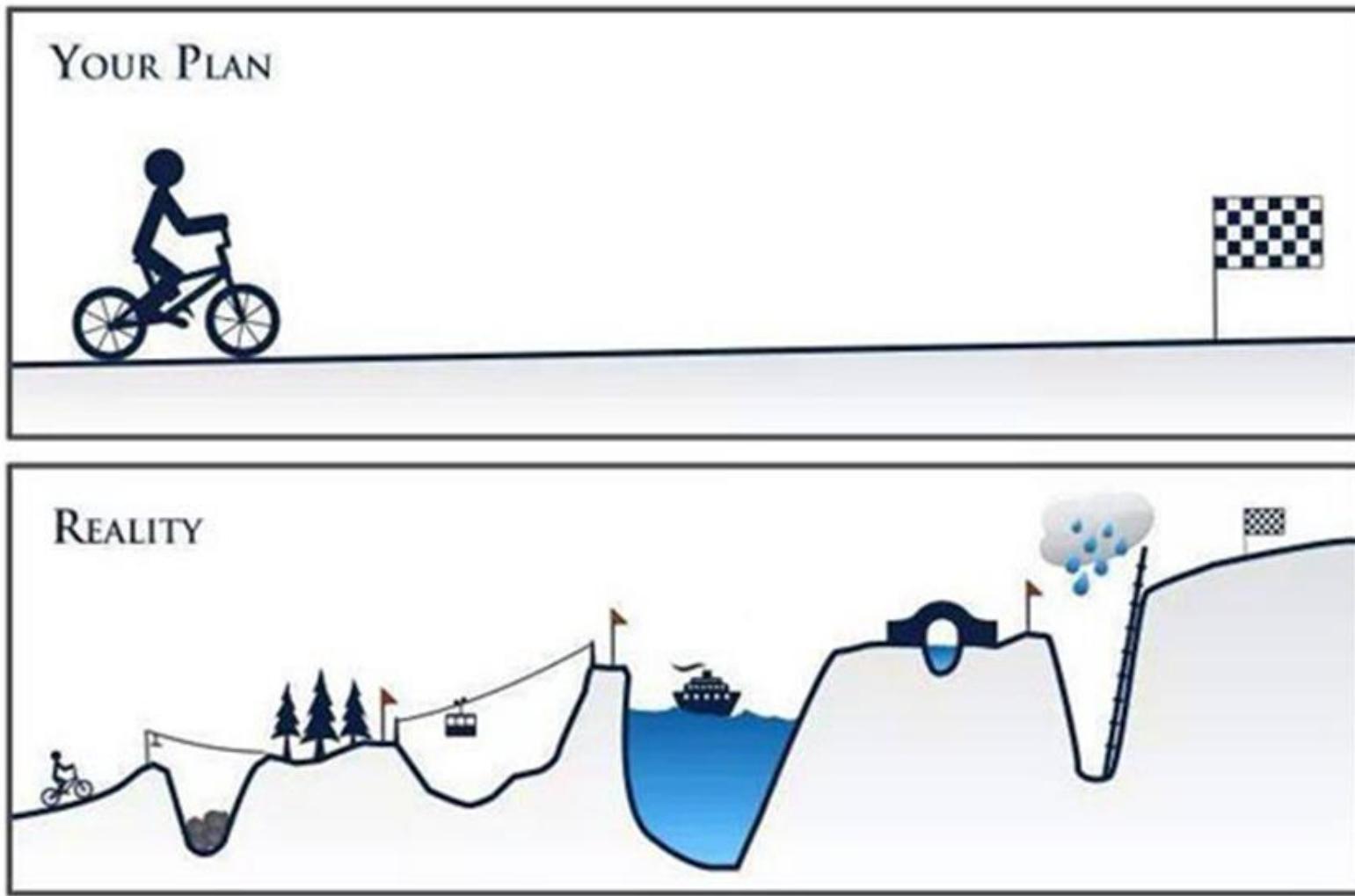
Why are you here today? (take a note)



No explanation of the tools
How to steer the process
Share experience
Indicate some traps
Encourage you to move
... and
convert you to MTB

1. Deliverables

What do WE expect from this session of the Crash Course



2. You have an idea!

Your idea and the environment

Articulate your vision/concept, write it down, think about who will benefit, how may it create sustainable value.

Keep it simple to get a first feeling

Attractiveness of Vision

Sanity check

Ability to Execute

Vision

Market Opportunity /25

Timeliness /25

Finance /25

Risk /25

Attractiveness of Vision /100

Execution

People /25

Marketing /25

Operations /25

Competitive Advantage /25

Ability to Execute /100

Business Case Scorecard
© simplicable.com

3. The business plan

How to proceed?

The «Plan»



**Challenge and get challenged!
Idea & Plan**



Get help !



3. The business plan

Why help is needed?

Your Dreamspace

Help small children with diabetes to live a good life



Your Idea & Concept:
Put a nano insulin pumping concept in a wearable RC - no tube Med Device



3. The business plan

Why help is needed?



Being a highly qualified engineer /specialist you are able to realize this concept technically

IP & Legal ?

Operations ?

Regulatory ?

Financing ?

Negotiation & Manageing ?

Communication ?

Plan for help early,

idealy as starting to develop the business plan

3. Make a proper business plan

Standard elements to consider for your business plan



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3. Make a proper business plan

Sanity check – again!

Attractiveness of Vision

Ability to Execute



**Balanced scorecards to evaluate
Mentor & Challenger**

Target group(s) for the plan

4. Considering support!

How to <sell> the business plan

Target audience

- Investors
(Seed/Angels/Banks/Shareholders/Funds/VC)
- Organizations / NGOs / etc
- Partners
- Customers

Personal presentation

Pitch the Business Plan



4. Considering support!

Selling the Idea - the first seconds to success

- 500 mio persons suffer from serious back pain
- The spine market is worth € 20 billion
- Med Tech Industry & HCP have not yet solved the problem



5. Considering support!

Selling the Idea - the first seconds to success

500 mio persons / market € 20 billion



x years to market

**y years to break even
€zz mio EBIT in year 5**

 **spontech**
spine intelligence

4. Considering support!

Selling the Idea - the first seconds to success

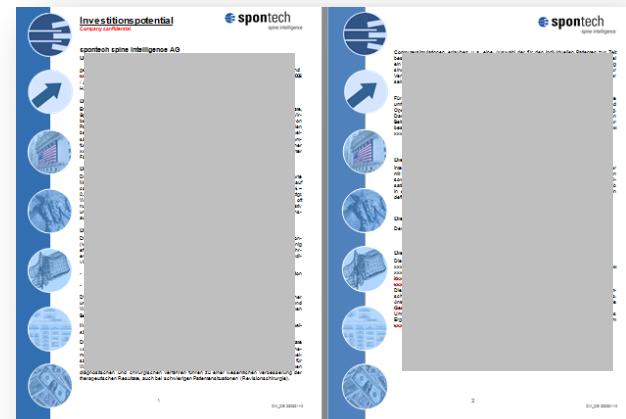
500 mio persons / market € 20 billion



Ready to market: x yrs / BE: y yrs / EBIT yr 5: €zz mio

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invites to share the success



4. Considering support!

Selling the Idea - the first seconds to success

Old but good ...



AIDA initially presented in 1898 by Elias St. Elmo Lewis
(same year as *<Quattro pezzi sacri>* from Giuseppe Verdi)

5. Create the activity!

What is the appropriate form to <materialize> the activity

Own legal entity

Organized start-up programmes /Tech parks

Co-operation (add / in)

... get help



6. Looking into details

The Ramp-Up plan

**Once the frame Business Plan is done, the detail preparation starts
This takes time and many modifications as going ahead
This tool is flexible – challenge it and get challenged**

7. Managing risks

Alternatives and fall-back position

- Accept that risks do exist or will appear
- Define the known risks
- Likelihood
- Severity of impact
- Outline CAPA
- Plan for reserves

7. Managing risks

Alternatives and fall-back position

Foresee CAPAs for the individual risk classes

Impact → Likelihood ↓	Low	Medium	High
High	Medium	High	High
Medium	Low	Medium	High
Low	Low	Low	Medium

7. Managing risks

Alternatives and fall-back position

Foresee CAPAs for the individual risk classes

- **Alternate strategy**
- **Product/concept modifications**
- **Revised timelines**
- **Revised financials**
- **Partnerships**
- **Revised IP strategy**
- **Exit strategy**

8. The case

«*Spontech Spine Intelligence AG*»



Focus on :

- 1. Selling the idea**
- 2. Strategic CAPA**

8. The case

The technical and the business model in a nutshell

Now the phase Incubation & Phase 1

vertaplan

Patientenname: Geburtsdatum: Geschlecht: Pat. ID: 252 Alter: 52 Größe: --- BMI: ---

Planung - Schritt 6 - Ergebnisse

Visualisierung: Simulation: PLIF Hypothetisch Range Of Motion: 0° 10° 20° 30° 40° L1 L1 v (mm) d (mm) PLIF-Länge s (mm) Fachwinkel α

Montage Kurzanleitung CSS Implantathalter (Inserter)

Teile des Implantathalters

- T-Griff
- Anschlusskappe
- Anschlagshülse
- Druckfeder
- Anzeigehölse
- Schathölse
- Gewindestange 8"
- Implantathalterschaft 8"

(weitere Größen ohne Abbildung: 10,12)

Entwurf noch nicht frei gegeben

spontech spine intelligence

1. Druckfeder auf die Anzeigehölse aufstecken bis sie einrastet.

2. Schathölse in die Anzeigehölse einführen und die Führungen der Schathölse in die dafür vorgesehenen Aussparungen der Anzeigehölse schieben.

3. Bitte Verbindung halten.

4. Anschlagshülse aufsetzen und bis zum Ende festschrauben.

5. Anschlusskappe auf die Anschlagshülse bis zum Anschlag festschrauben.

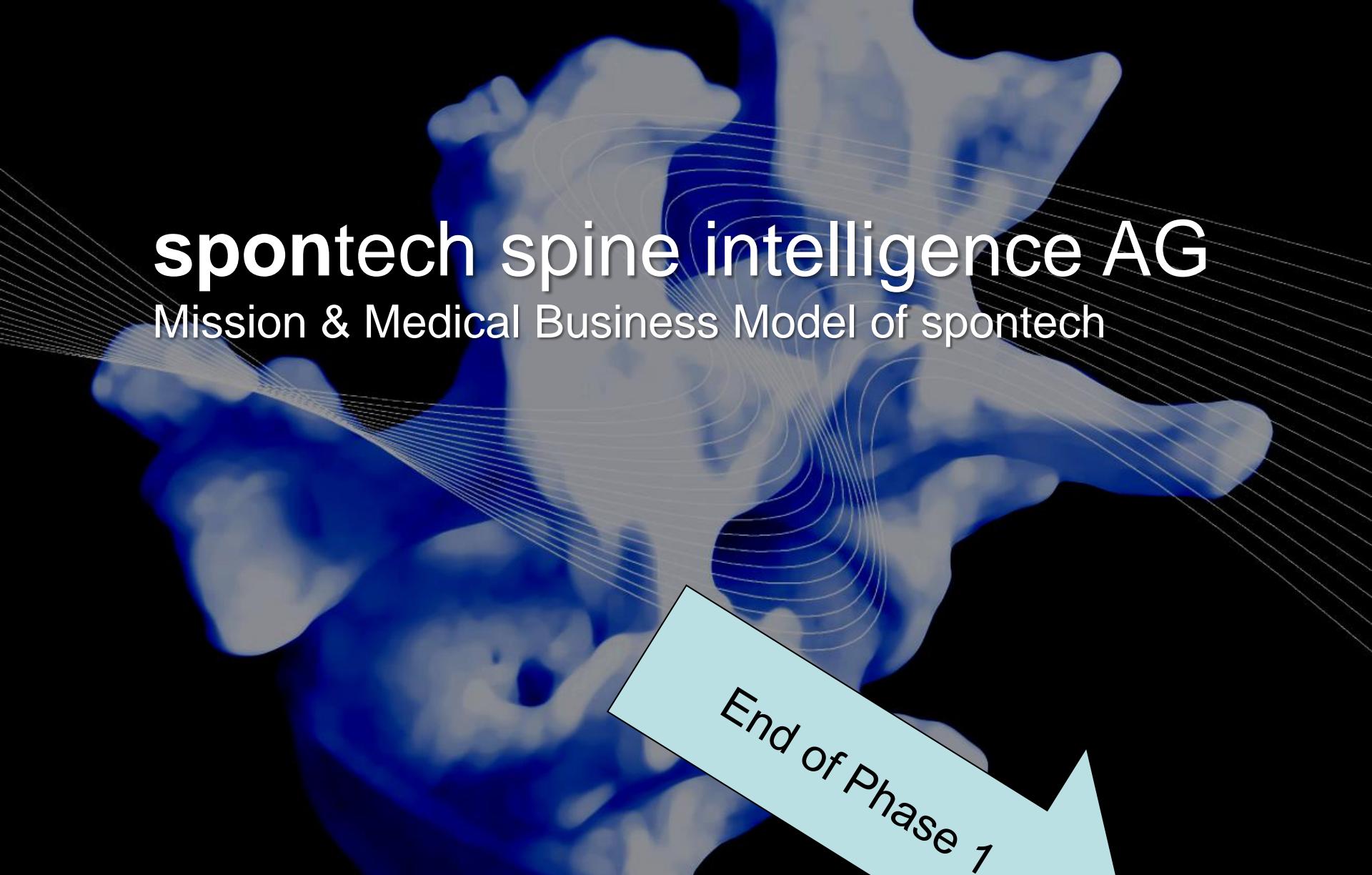
6. Durch den kompletten Anschlag den Implantathalterschaft einführen (bitte auf die Führung am Implantathalterschaft und die Aussparungen im Anschlag achten).

7. Jetzt wird in den Implantathalterschaft die Gewindestange, der gleichen Größe eingeführt.

8. Der T-Griff lässt sich nur dann sauber aufsetzen, wenn alle Komponenten zuvor richtig zusammengebaut wurden.

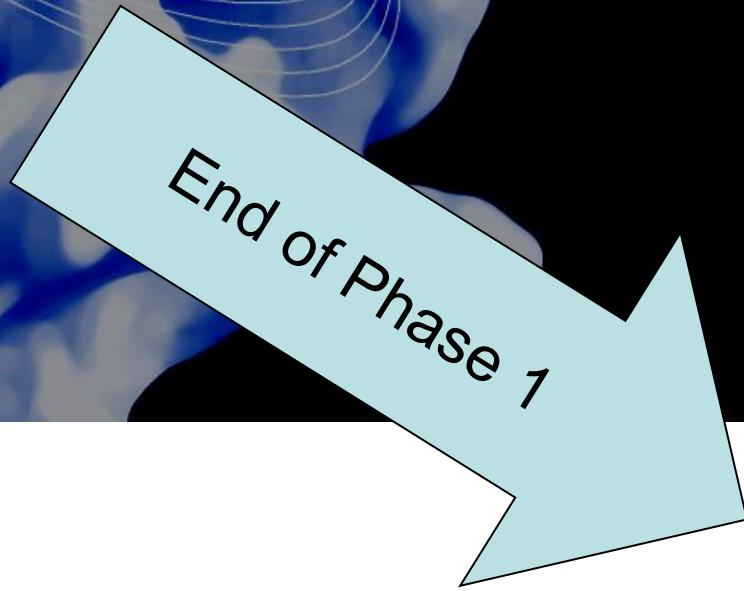
- die Öffnung des T-Griffs und die flache Seite des Implantathalterschafts nach oben richten.
- nun den T-Griff von unten auf den Implantathalterschaft aufsetzen
- die beiden Einkerbungen seitlich am Implantathalterschaft müssen rechts und links im T-Griff zu liegen kommen und hörbar einrasten

Um die Verbindung zu ameliorieren muss die Anschlusskappe nach oben in Richtung des T-Griff bis zum Anschlag geschraubt werden, damit eine Sicherung der Konstruktion zwischen Implantathalterschaft und T-Griff gewährleistet ist.



spontech spine intelligence AG

Mission & Medical Business Model of spontech



End of Phase 1

Mission and Medical Business Model

The Issue:

Each person has their own **personal motion profile** and his or her own individual coordination between head, shoulders and pelvis. The individual spine is formed by this unique motion profile



As the individual matures, **the human spine** is adapting exactly to these movement pattern and therefore it becomes **virtually unique to that single person**.

It is a multi functional very complex joint organ which needs to be understood as a **chain of joints** depending on each other.

Today's surgical spine therapies in Degenerative Disease do not or only marginally allow to individualize the required treatment.

Mission and Medical Business Model

The Challenge:

Spine surgery needs to use effectively a systematic approach ranging from advanced diagnostics over standardized planning and calculating using software modules, specialized instruments and a wide range of intelligent implants in order to **provide individualized solutions to spine problems.**

This is the **novel approach** to individualized surgical spine therapy

Therefore



was founded in 2008!



spontech spine intelligence AG has set itself the goal of enabling people suffering from spinal conditions and diseases

xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxx directly into the development of our products

Mission and Medical Business Model

The Innovation:

Closely cooperating with our near-by partner Galenus Clinic, **spontech AG** is translating their extensive accumulated diagnostic and clinic expertise into integrated and comprehensive **product- and process innovations**.

spontech: Innovation to revolution

With the revolutionary CSS system we have developed a new systemic approach for the best possible patient-specific treatment of the spine. The CSS comprises the diagnostic procedure, implants, special instrumentation and software for calculating to the exact degree and millimeter the precise adjustment of the spine geometry, software which to this date is **xxxxxxxxxx**.

All systems are developed and manufactured in **Germany** with highest quality standards.



Mission and Medical Business Model

The components of CSS (*Vertaplan*)

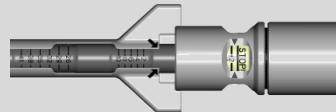
Advanced software



Modular implant system



Components of the CSS



Intra-surgery measurement tool



Specific support tools

The spontech CSS Surgery: Step 1: Software for Diagnose & Plan



Run CSS Software



Diagnose Images

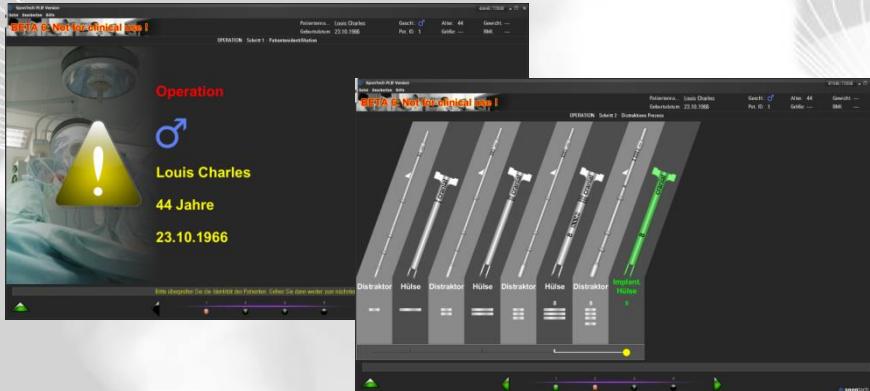


Plan Surgery

More ...

The spontech CSS Surgery:

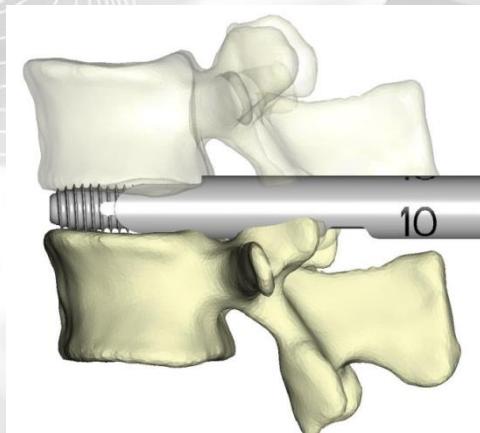
Step 2: Surgery



The Surgery Process is
Computer supported



The Implant has unique
features



More ...

Specific Tools allow for
unseen precision

The spontech CSS Surgery:

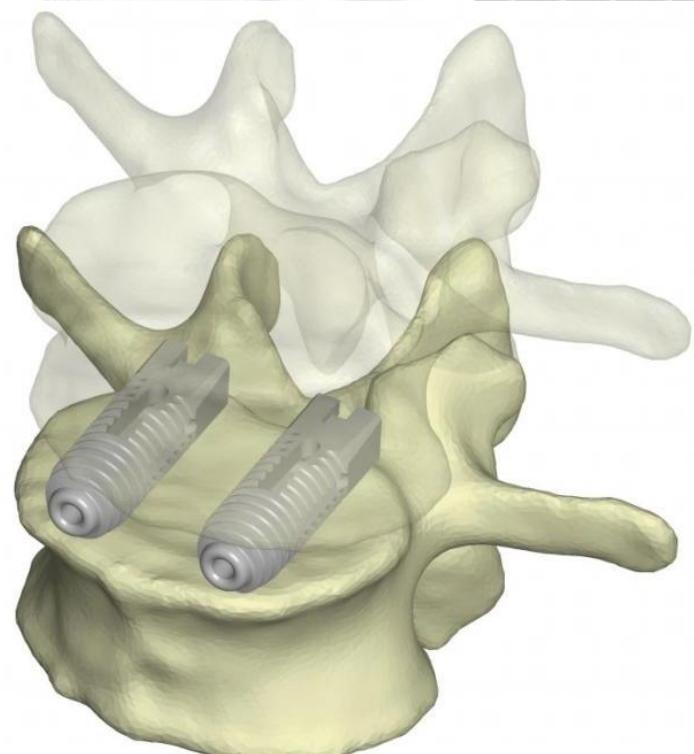
Step 3: Result

The CSS PLIF Implants are placed with perfect precision and rest exactly where they should:

On both sides of the cortical ring.

This helps to **avoid one of the historical problems of Lumbar Interbody Fusion:**

The sintering-in of the spacer/implant.



More ...



spontech spine intelligence

What makes **spontech** unique?

Patents and Innovations

Wide scale of patents and applications by numbers

- 18

Wide scale of patent applications

- Ca
- Ins
- No
- dia

Wide scale of patent rights

- Or
- pip

Wide scale of patent rights

- All
- to

Big Medtech firms are already infringing the patent rights

exploiting the patent
on.

ne technologies are
of charge.

More ...

Management and Board

Experienced Management Board with international background

- Thomas F, **CEO** (3M, Medtronic) DE, AT, CH
- Peter Georg Haag, **Fin & M&S** (Roche, Abbott) CH, RSA, CZ, SK, IT, LUX
- Dr. Thomas P, **R&D** (CeramTech) DE, FR, CH
- Dr. med. Roland S MD M.Sc., **QA/RA** (University of Hamburg) DE, CH

Highly reputed Medical Advisory Board

- Dr. Dr. med. Franz C
- Prof. Dr. med. Claus C
- Prof. Dr. med. Hans-Joachim W
- Prof. Dr. med. Kai S
- Pr. Doz. Dr. med. M. R

Experienced and connected Strategic Consultants

- Prof. Erich S: **R&D Software & Corp. Communications**
- Dipl.-Ing. Gerhard K: **Strategy** (HP, Fresenius, Medtronic)
- Dr. Gerhard P: **R&D Hardware** (Philips)
- Dr. R, **IP&Patents** (Fed. Patent Office)

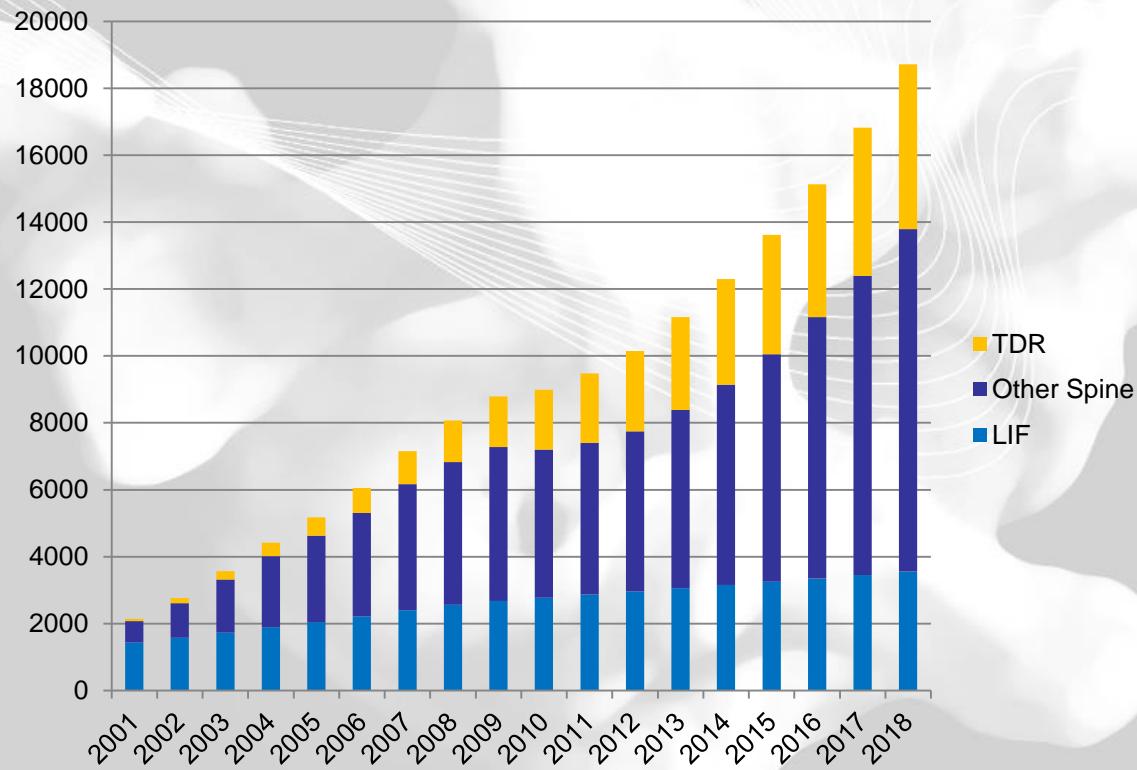


spontech spine intelligence

The Market Overview

The World Spine Market is attractive

Spine World Market by Segments



The global recession has slowed down the continuous growth of the spine market only for approx 2 years

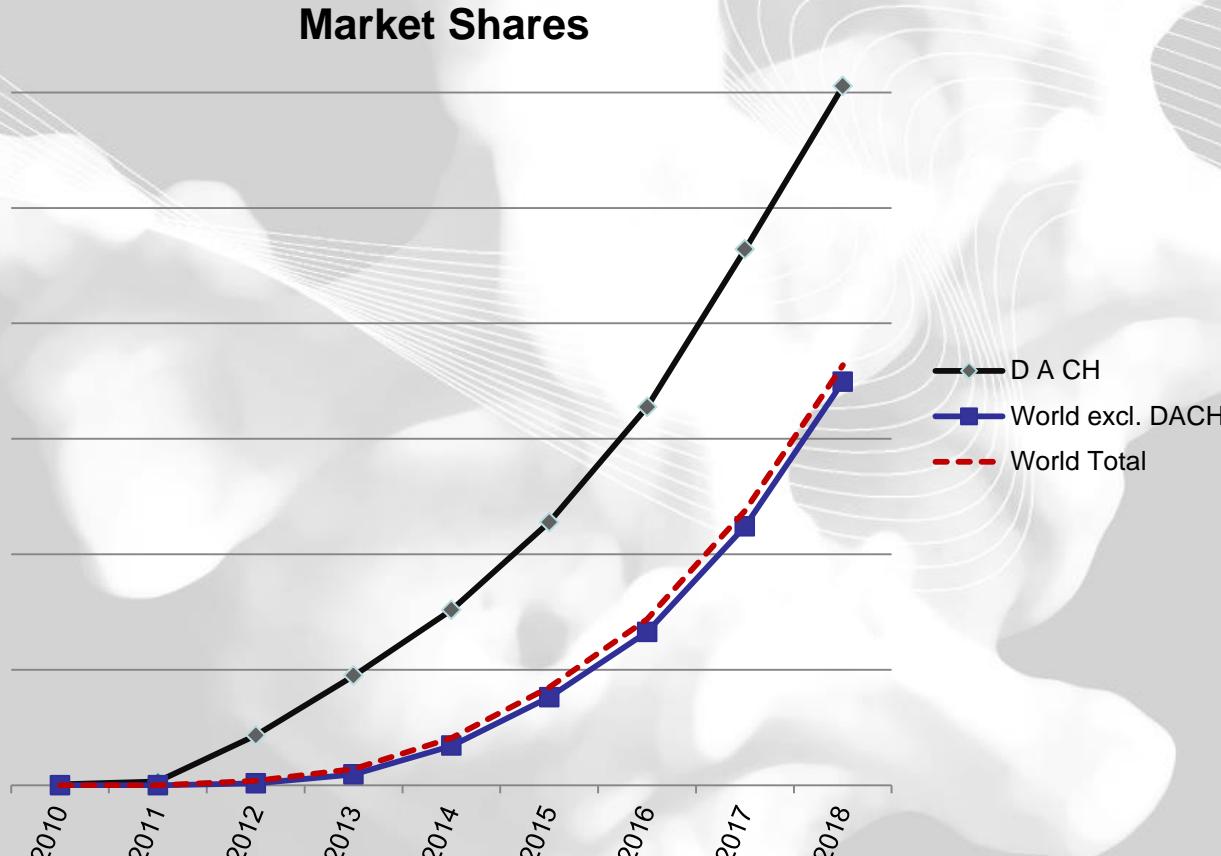
More ...



spontech spine intelligence

Financial and Business Case

Planned Market Shares (Fusion and Non-Fusion)



The Share is calculated ex Distributors + direct sales in the referenced markets Fusion and Non-Fusion Medical Devices

More ...

Imagine...

In 20xx, the current Business Plan goes for **% Market Share** in Non Fusion (artificial discs and other devices to keep mobility)

....that means **1 out of 27** patients with a Non-Fusion Spine Surgery will benefit from the CSS Spine System

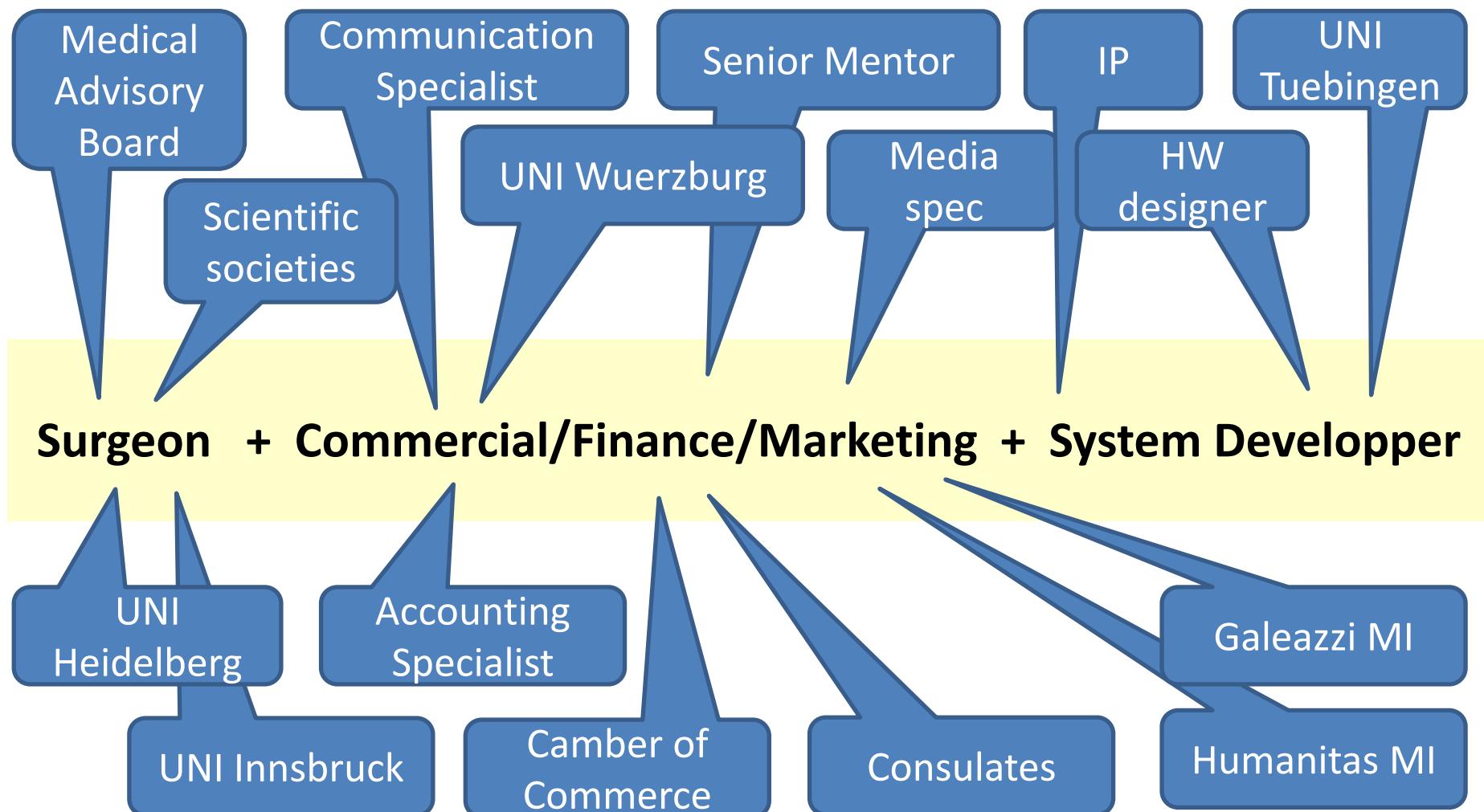


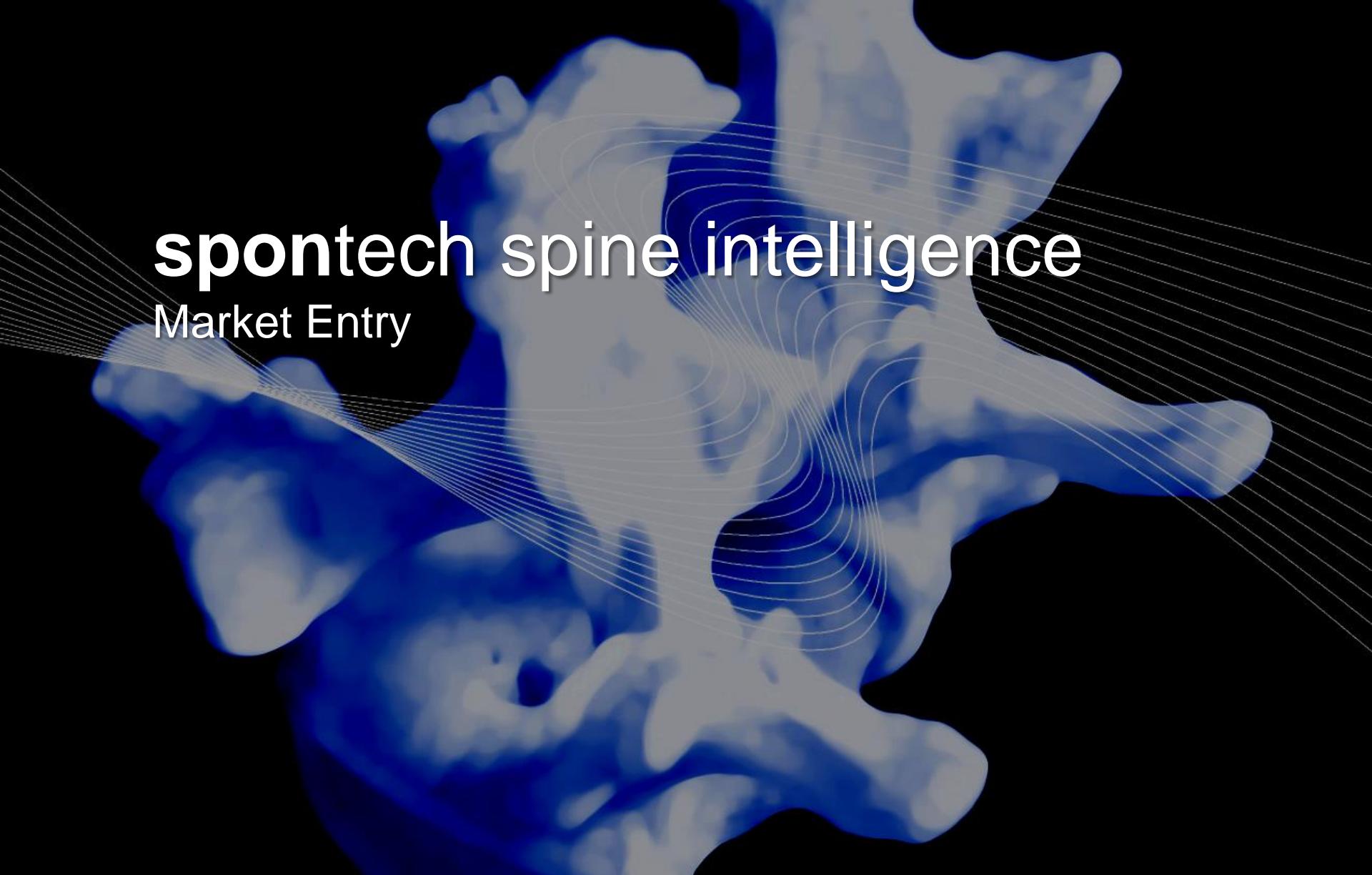
Imagine we convince 1 out of 10 patients



8. Case 1

Get help but keep control

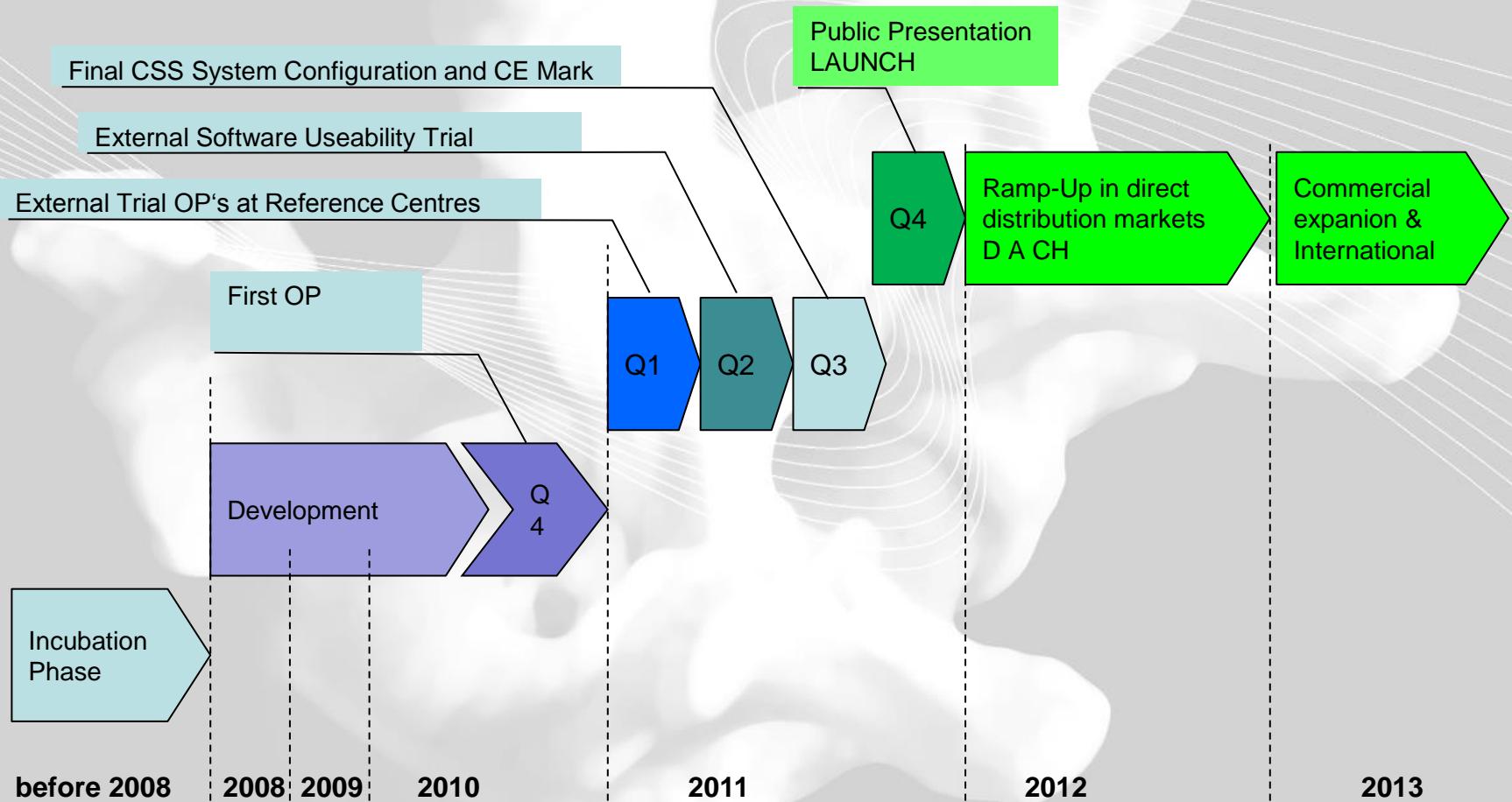




spontech spine intelligence

Market Entry

spontech Growth Phases



8. The case

«Spontech Spine Intelligence AG»

Vision > Sanity Check with professionals

Business Plan Abstract

Round 1 Seed Investment – Innovator+ Bank

Set-up founding Team

Business Plan + Ramp up plan started , 0 series

Selling Concept for Round 2 - Get professional help

Round 2 mid Investment – Regional funds + Angel Investors

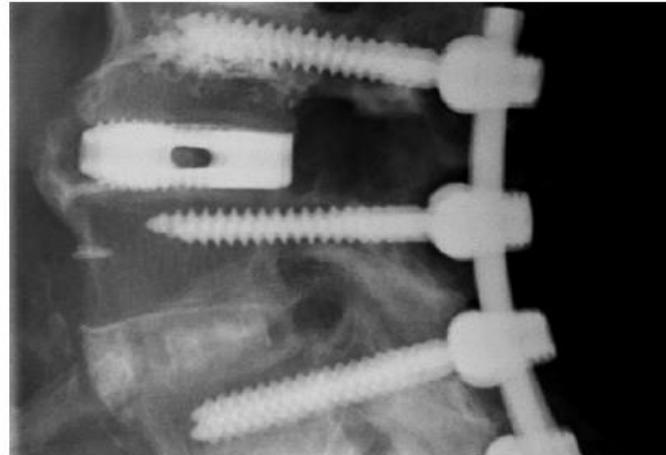
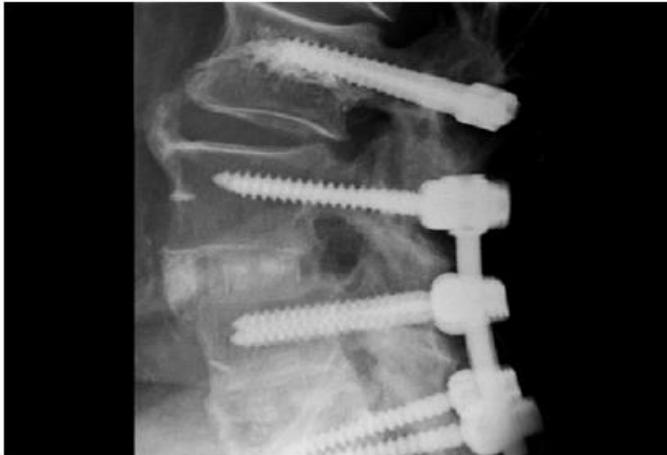


Registration of Vertaplan software – full portfolio + OP sets

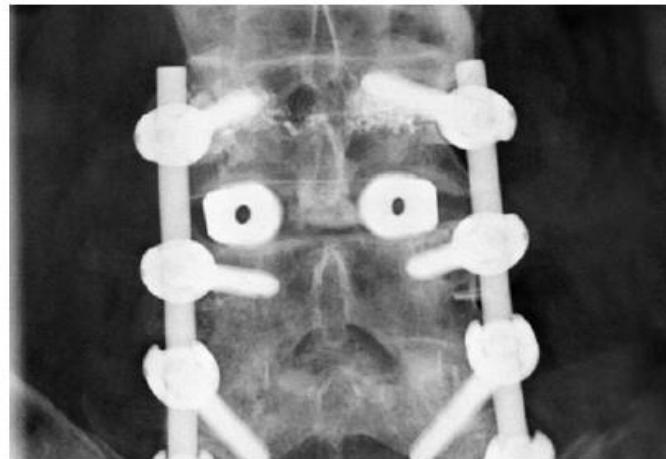
Create Awareness – leverage awareness

Round 3 big Investment – Private investors / selling equity

First 0 series successful surgery:



The implanted devices are perfectly positioned as previously planned



8. The case



Condurre un'operazione su un paziente, nel pieno del moto. È questa la risposta arriva con la schiena, con l'innovativo sistema impiantabile e

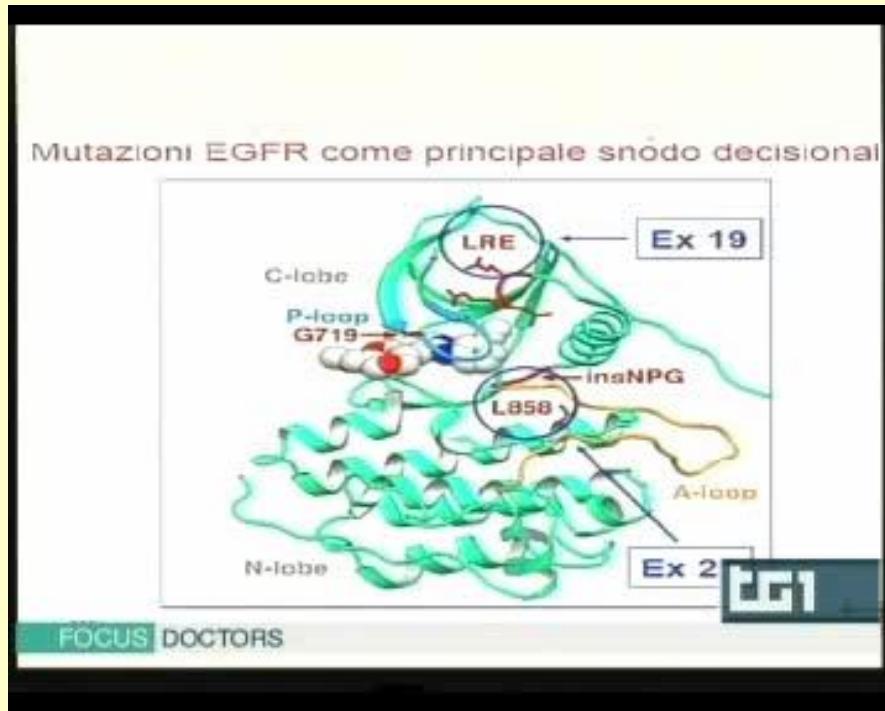
PUBLICATION	DATE	READERSHIP
News Agencies		
FIDEST. WORDPRESS.COM	October 19th 2011	Not available
IL VELINO	October 19th 2011	Not available
Newspapers		
LIBERO	October 25th 2011	500.000
IL TIRRENO	October 28th 2011	120.000
CORRIERE DELLA SERA - SALUTE	October 30th 2011	3.056.000
IL TEMPO	October 30th 2011	207.000
IL RESTO DEL CARLINO	October 31st 2011	1.207.000
IL GIORNO	October 31st 2011	349.000
LA NAZIONE	October 31st 2011	864.000
SALUTE E STAR BENE – LA STAMPA	December 15th 2011	1.908.000
IL GIORNALE	December 18th 2011	764.000
Medical press		
TECNICA OSPEDALIERA	December 1st 2011	4.349
ABOUT PHARMA	December 1st 2011	24.000
TV		
TG5 - CANALE 5	November 8th 2011	1.050.199
Websites		



8. The case

«Spontech Spine Intelligence AG»

Phase 3 : Become visible + Creating sound interest for the concept



8. The case

«*Spontech Spine Intelligence AG*»

.... unforeseen Issues comes to our attention:

Cash Burn Rate > CBR by far.

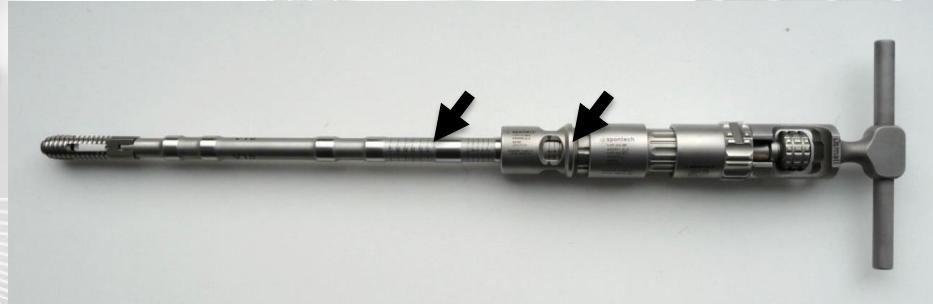
1. Fortunately we had proper accounting
2. Soon we found out it went into CAPEX, not into OR

Quarterly P&L worsent. Reason Increasing depreciation

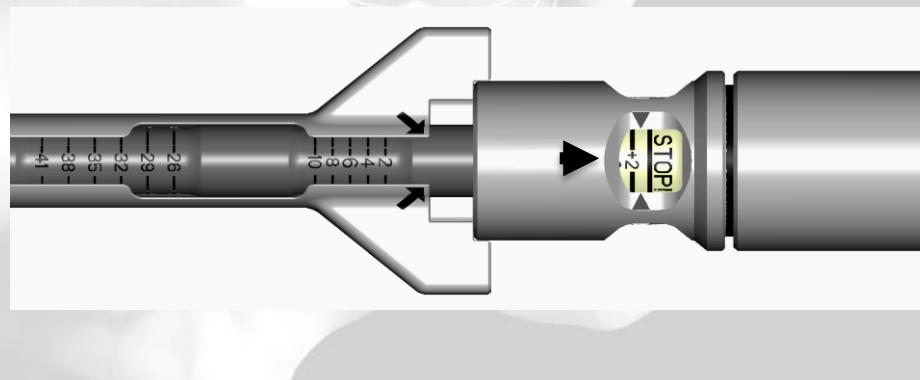
You remember the complex tools? (OPS-SETS)

Specific Instruments and Tools

Intelligent Inserter device

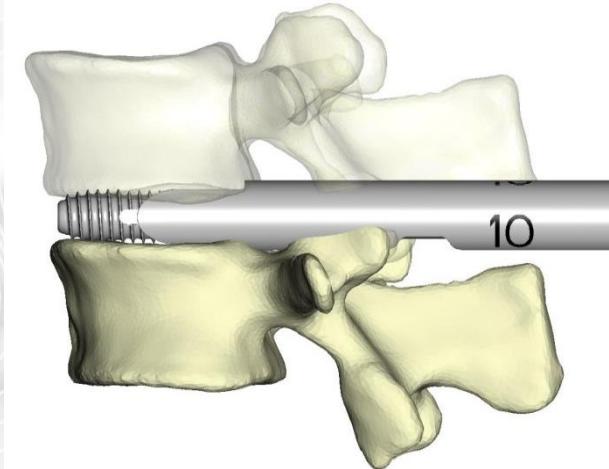
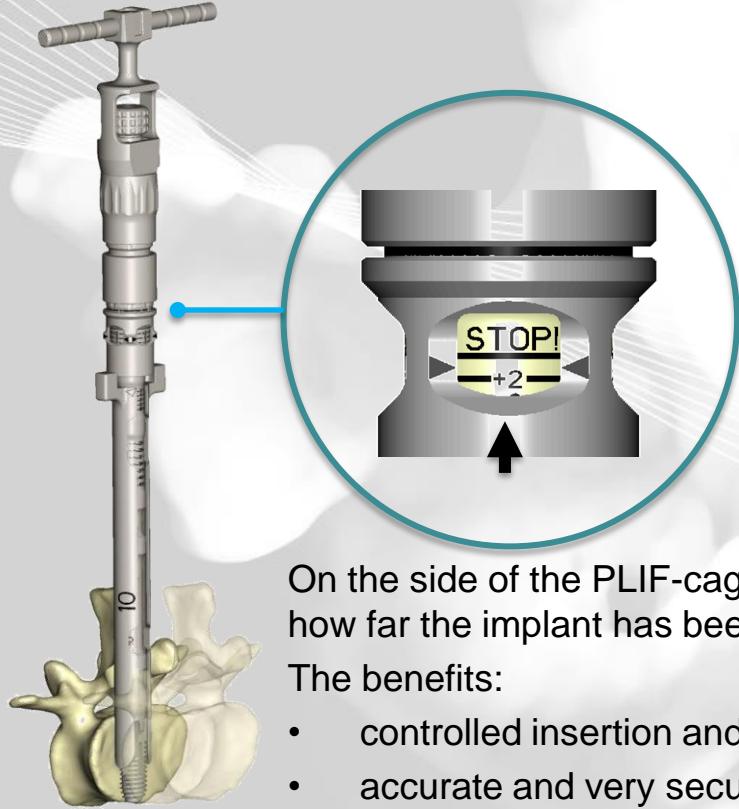


Controlled insertion of the cage. Measured against dorsal edge of the vertebrae
(equals 0 on the scale)



Specific Instruments and Tools

Intelligent Inserter for exact positioning



On the side of the PLIF-cage inserter there is a scale which is used to determine precisely how far the implant has been inserted into the disc space.

The benefits:

- controlled insertion and fixation of the implant
- accurate and very secure positioning for fine adjustment of the spine
- hence minimization of X-ray radiation exposure

Specific Instruments and Tools

Smooth distraction device



- Distractors
- Distractor shafts
- Implantation shaft
- Hammer
- Inserter
- Drill

8. Case 1

Symptoms of an issue

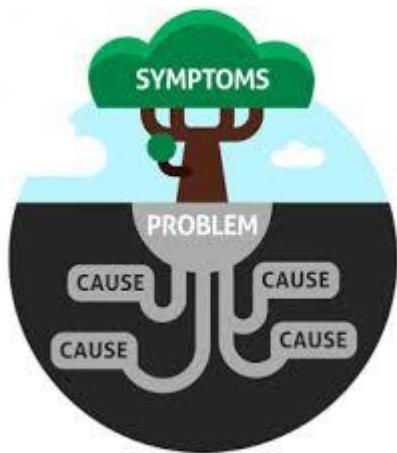


K€ 50-60 / OPS SET

8. Case 1

Addressing the issue

RCA



Syptom: **unplanned business critical increase in CAPEX**

Problem: **TAT**

Cause:

Assumption *1,5d = approx 18 Ops/month*

Actual *2 weeks = approx 2 Ops/month*

Consequence:

Fixed assets up – ROI down

Liquidity down

Investment attractiveness down

8. Case 1

Corrective Actions

TAT:

**Change from resident ops-set concept
to travelling ops-set concept**

Ops-Set:

Significant cost reduction

Products:



**Anticipate an innovative TLIF concept
Lower costs, Ops-Set more economic.
Higher volumes in the market.**

Legal form:

Change from SpA/AG to Srl/GmbH

Focus:

Key countries & key customers

8. The case

Where is the start-up now?

FACHKREISE PATIENTEN PRODUKTE UNTERNEHMEN AKTUELLES SERVICE & SUPPORT KONTAKT

Fachkreise **Patienten** **Produkte**

vertaplan gratis testen
Teste Sie jetzt die neue **vertaplan 2.0** Software **GRATIS!**

vertaplan Vernetzung
Zeit & Geld sparen mit effizientem Bilddatenmanagement via zentrale Datenbank und PACS Schnittstelle

Literatur
Aktuelle Veröffentlichungen über softwaregestützte Planung von Wirbelsäulenoperationen

OPS
Neuer **OPS Code 5-83w.2** für Computergestützte Planung von Wirbelsäulenoperationen

Hospitationsangebot
Nutzen Sie die praxisnahe Hospitatemöglichkeiten in unseren Referenzkliniken

Veranstaltungen

DWG Basiskurs
Freiburg
28. - 29. April 2016

DWG Basiskurs
Hamburg
24. - 26. August 2016

DWG Basiskurs
Aachen
01. - 02. September 2016

DWG Basiskurs
Dresden
18. - 19. November 2016

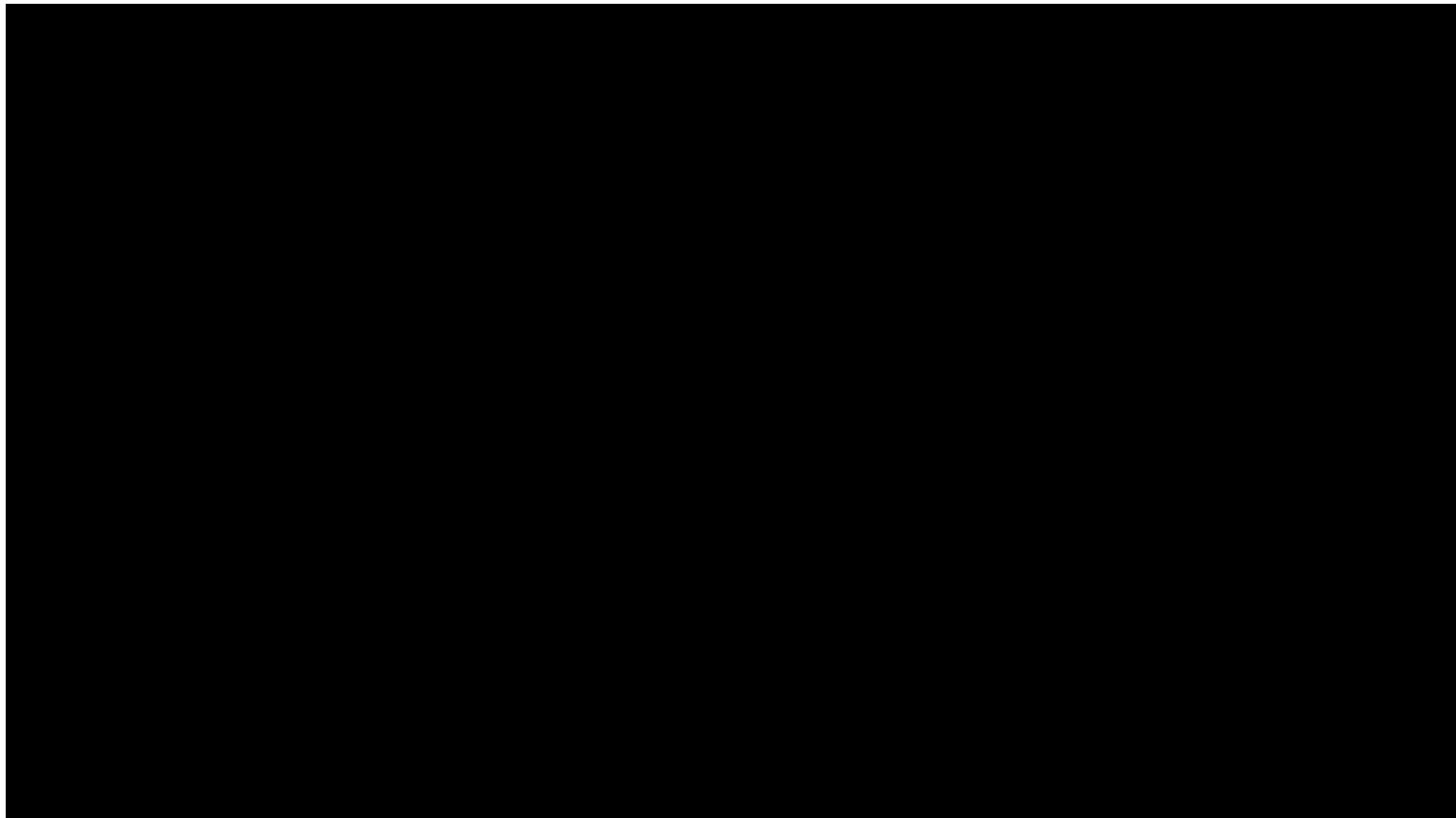
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Service **Newsletter**

► Service **vertaplan**
► Service **Implantate**
► **Made in Germany**
Sie möchten mehr erfahren oder benötigen Hilfe?
► Kontaktformular
Wir freuen uns auf das Gespräch mit Ihnen.

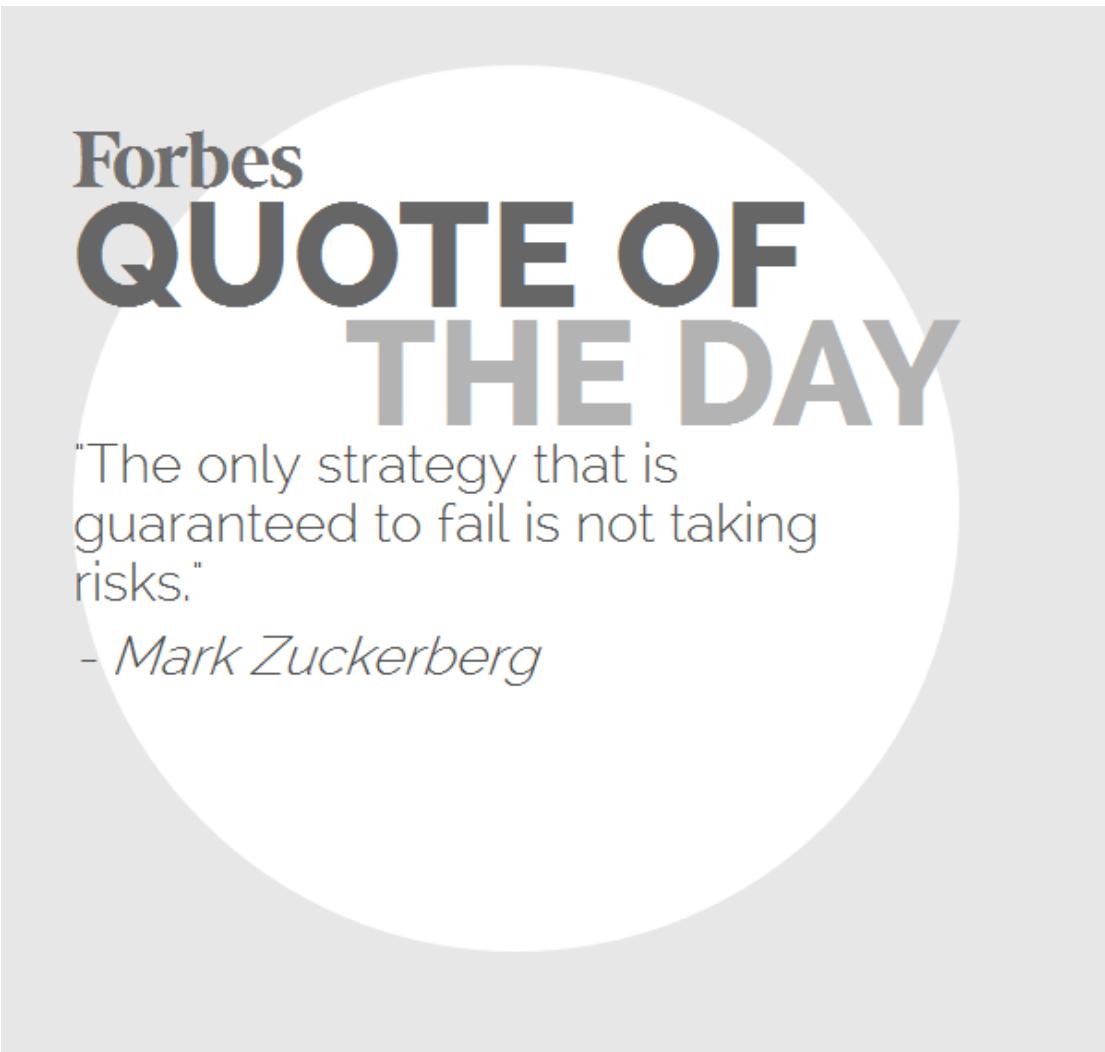
8. The case

Where is the start-up now?



9. Lessons learnt

Don't trust the shining stars



9. Lessons learnt

Genius and luck may be helpful,



9. Lessons learnt

Before starting

- Do your own SWOT on yourself related to your project

Starting

- Plan for help early
- Proper Planing (All aspects)
- Do not fall in love with your plan
- Stay critical but convinced
- Challenge everything, even the Challengers and Mentors
- Look deep into details as you start activity
- Document properly
- Accounting and Finance

Deliverables

Did this presentation give you some additional insight?

Further questions? Let me know. Thank you for the attention

