

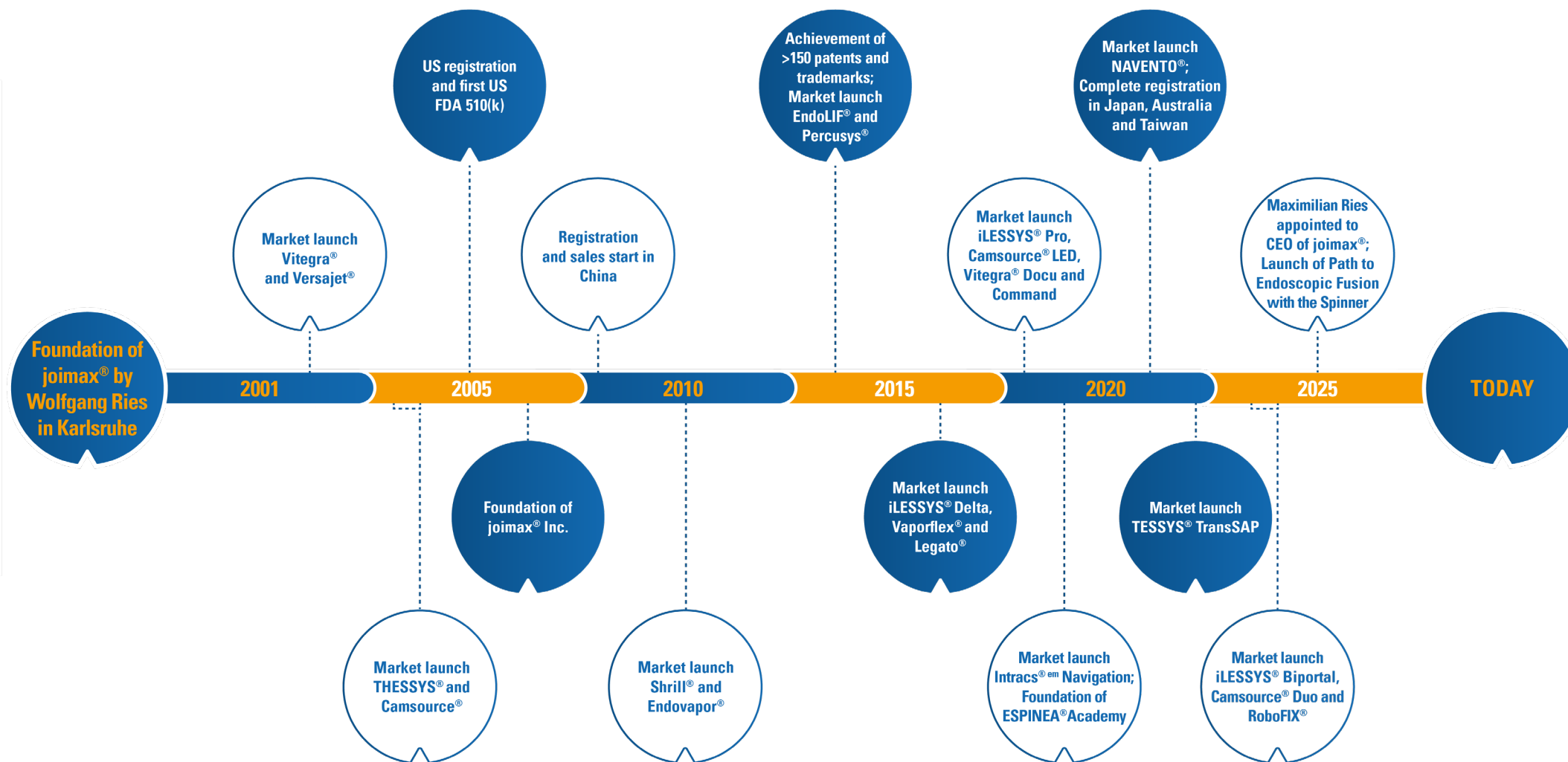
# Expert solutions for Endoscopic Spinal Therapy

Firma joimax® GmbH

Aya Makki

Senior Regulatory Affairs Manager

# Nearly 25 Years of Innovation



# GLOBAL PRESENCE. GLOBAL IMPACT.



Endoscopes

Enabling digital devices

Instrument systems

Implants

Disposables

Accessories

20+ years  
exclusively spine  
focused



>1,000,000  
Patients treated

In 65 countries  
worldwide



>3,000

Treatment centers  
worldwide



>7,000

Surgeons trained

>150 employees  
globally

>400

Patents and  
trademarks



>7,800  
publications  
on endoscopic  
spinal surgery

# Robust medical education Program



Step 1 | Visitation  
Step 2 | Workshops  
Step 3 | Supervised 1<sup>st</sup> Surgeries



## The curve of improving performance



## Trainers/Faculty

- All faculty are certified for their excellent qualifications and teaching abilities. They focus on the individual needs of the participants.

## Learning Environment

- Every training center is equipped with state-of-the art technology and equipment.
- ESPINEA Academy is accredited by **Royal College of Surgeons of Edinburgh** - RCSEd - standards.

# Comprehensive Product Portfolio

Customizable devices and systems  
for spine surgery worldwide, designed for  
surgeon confidence and control.

# Comprehensive Offering

Enables seamless minimally invasive endoscopic spinal surgery

## INTEGRATED DIGITAL DEVICES

### NAV ENTO®

Navigation Endoscopic Tower

### Vitegra®

Visual Integration System

### Camsource® Duo

Camera and Light Source System

### Intracis® em

Integrated Navigation Tracking and Control System

### Shrill®

Shaver Drill System

### Versicon®

Versatile Irrigation Control

### Endovapor® 2

Multi Radio Frequency System



## COMPLETE ENDOSCOPIC SURGERY SYSTEMS

### TESSYS®

Transforaminal Endoscopic Surgical System

### iLESSYS®

Interlaminar Endoscopic Surgical System

### CESSYS®

Cervical Endoscopic Surgical System

### MultiZYTE®

Endoscopic Facet and Sacroiliac Joint Treatment Set

### intENTS®

Interventional Endoscopic Nucleus Therapy Set



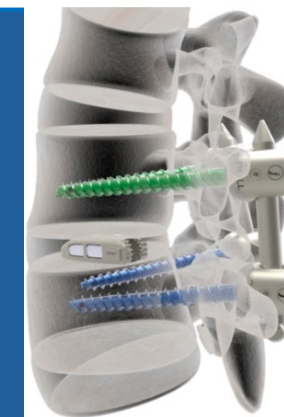
## INNOVATIVE IMPLANTS

### EndoLIF®

Endoscopic Lumbar Interbody Fusion

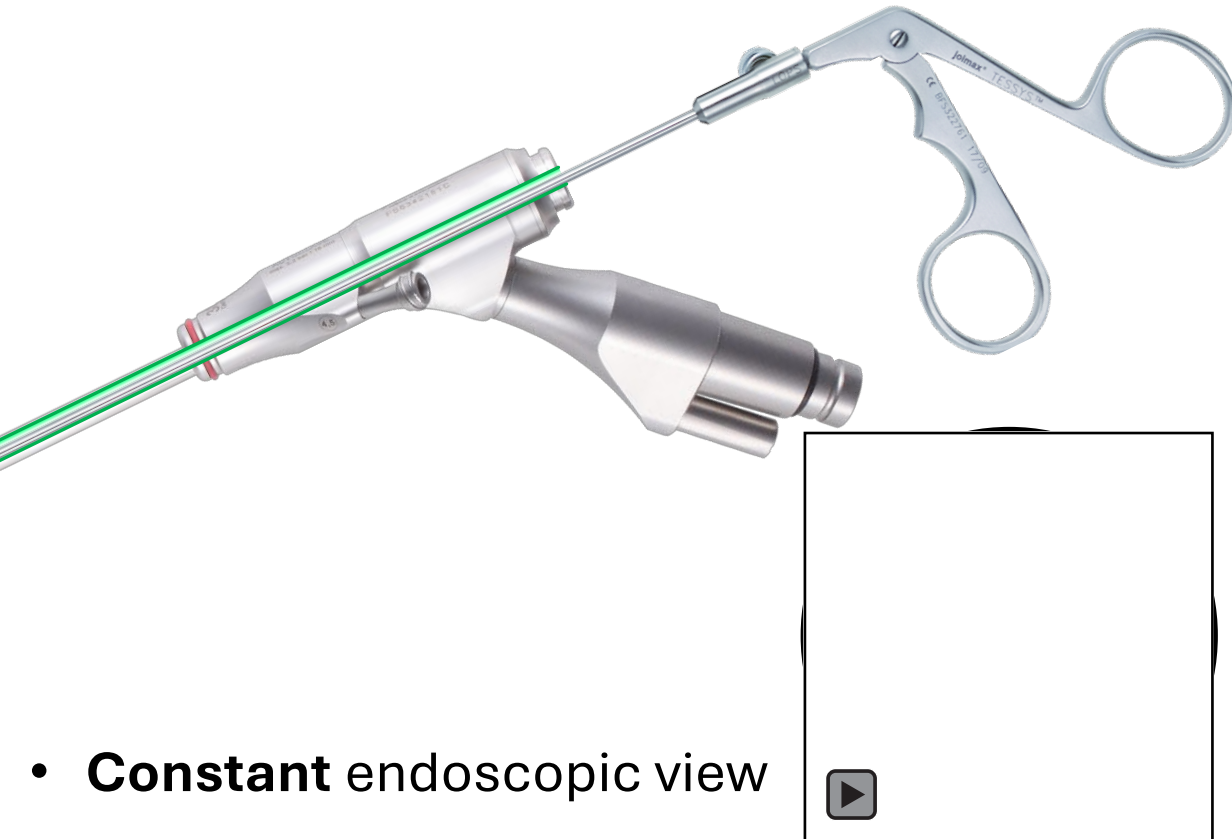
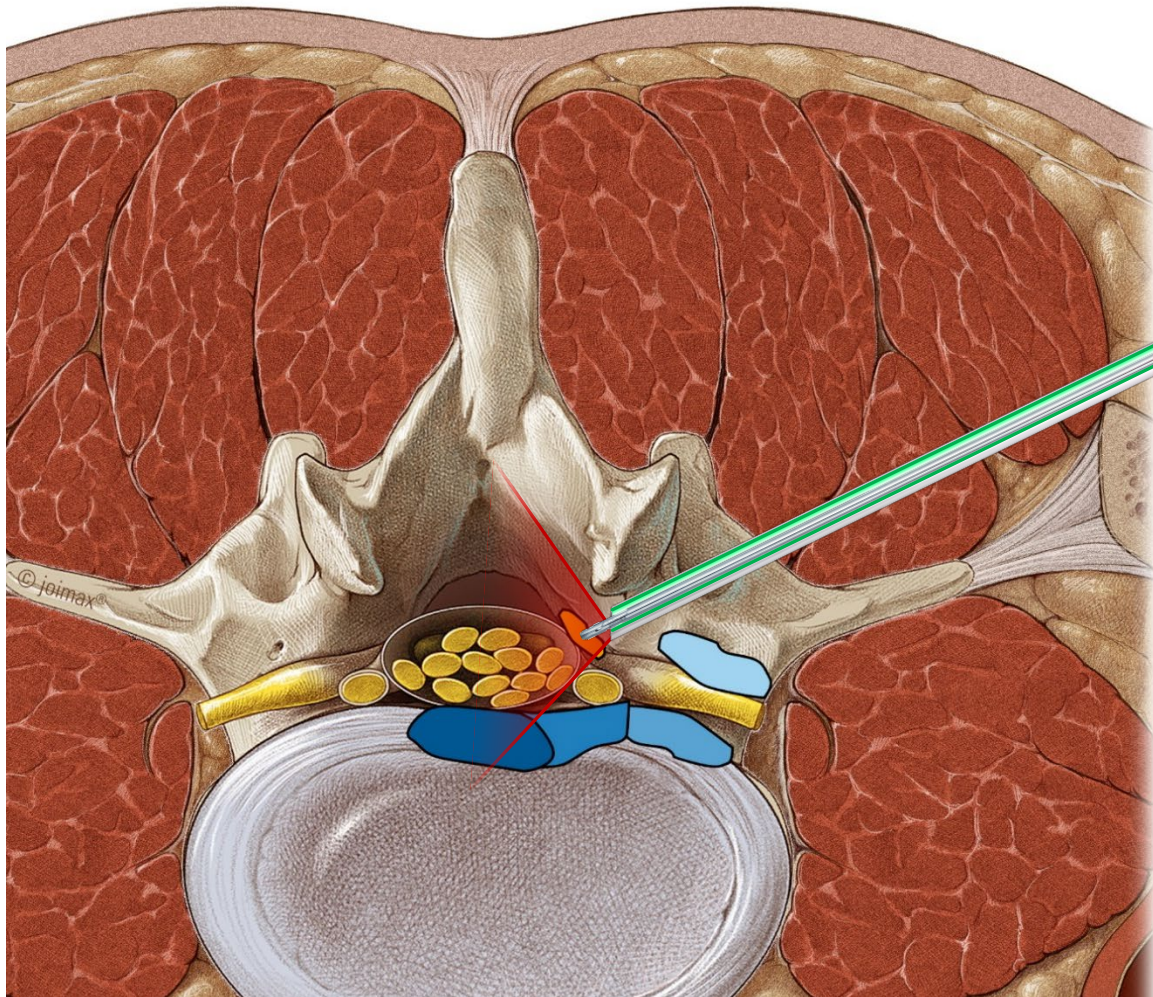
### Percusys® Plus

Percutaneous Screw Rod System



# Basics Principals of Spinal Endoscopy

## The Endoscope



- **Constant** endoscopic view
- **Channel/tunnel** to reach the inside of the Body
- ➔ **Working directly at the pathology under endoscopic visual control**

# EUDAMED

## Importance and implementation

# Timelines and Facts

**2017**

EUDAMED is  
established in the  
MDR as a central  
IT system



**2017-2025**

Transition from  
MDD to MDR

EUDAMED  
incorporation in  
our QM/RA  
Processes



**Deadlines:**

May 28th 2026  
UDI Module  
mandatory

All our devices  
should be  
registered

# Challenges 1- High number of Products and Changes

## A- High Number of products - New Products – initial Registration in EUDAMED

Over 1200 Product



More than 15 min per Product



over 300 hours

## B- Shift from MDD to MDR / Product Change

Over  $\frac{3}{4}$  of Registered  
Product



Additional 15 min per Product



over 225 hours

To Date: Theoretical time planned to be invested:  
**more than 525 Hours**

**Search for a more Time- Efficient Solution**

# Challenges 2- Restricted number of resources

## A- Resources in the Regulatory Affairs Department

Over 13 months of ONE full time employee  
ONLY for the UDI Module

What about other  
Modules?

## B- Synergy with other Databases?

Example: GUDID,  
Swissdamed, etc

Not established

Additional  
resources blocked  
for constant  
updates of ALL  
existing databases

Hiring a high number of resources for (almost) similar content/work  
**Leading to High Cost for MD companies**

# Challenges 3 - Software solution & availability

## A- EUDAMED Software Solution for Bulk upload

Very demanding and almost not manageable for Non-IT Regulatory employees



Search for Service Providers

## B- Service provider which covers multiple Databases

Goal: easier Data management in One Software



Limited availability

## C- Change of Service Provider

Possibility of managing previous Data in the Software of the new service provider

**Flexible and  
adaptable  
Service  
Provider**

# Ackomas Solution - 1

## 1- High number of Products/Product change/shift to MDR

- Easily handled in KOA software using 1 Excel files (previous Service Provider: 20 UDI per 1 Excel sheet)
- User friendly software for Non-IT employees (self explanatory)

## 2- Restricted number of Resources

- Many Team members can access the KOA platform – adapted to our need
- Ackomas has also solutions for other international Databases

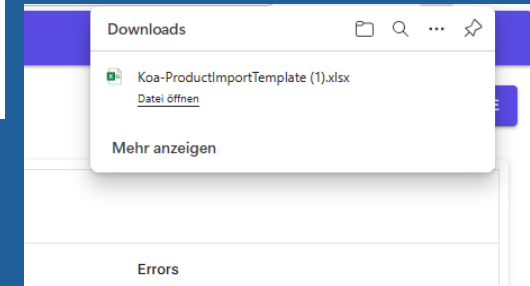
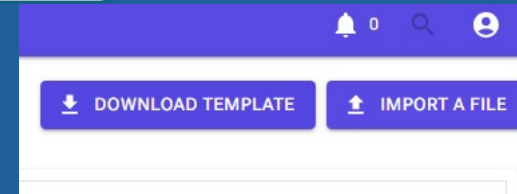
## 3- Change of Service Provider

- We are able to import previously registered Data in KOA and adjust them accordingly
- Ackomas Team always available for support

# Ackomas Solution - 2

## Automatic Software updates whenever EUDAMED releases new updates

In addition to optimising KOAs software ex: spreadsheets automatically updated in KOA




## Automatic transfer to EUDAMED

- With one-click all products in the excel spreadsheet are sent to EUDAMED (and are Error-free)

## Errors in Excel lists are automatically detected and explained!

- Errors in information in the excel list are detected in KOA and explained.

State	Date	File name	Total	Success (Created   Updated   Unchanged)	Errors
	2025-09-02 14:54:25	Koa-ProductImportTemplate.xlsx	8	0 0   0   0	8

Sheet Name	Line	Column name	Cell value	Error type	Message
Product_Eudamed_MDR	7	Actor SRN	DE-MF-000009201	Invalid value	Invalid Actor SRN
Product_Eudamed_MDR	7	Country Info	NL	Invalid value	Can't read UDI country info.
Product_Eudamed_MDR	7	Country Info	DK	Invalid value	Can't read UDI country info.
Product_Eudamed_MDR	7	Country Info	DE	Invalid value	Can't read UDI country info.
Product_Eudamed_MDR	7	Country Info	AT	Invalid value	Can't read UDI country info.
Product_Eudamed_MDR	7	Country Info	FR	Invalid value	Can't read UDI country info.
Product_Eudamed_MDR	7	Country Info	CZ	Invalid value	Can't read UDI country info.
Product_Eudamed_MDR	7	Country Info	ES	Invalid value	Can't read UDI country info.
Product_Eudamed_MDR	7	Country Info		Invalid value	There is none or more than one country marked as 'First placed on the EU market'

SUMMARY

ERROR

# Thank you