

How collaboration between Physicians and Engineers prepares the future of Medicine

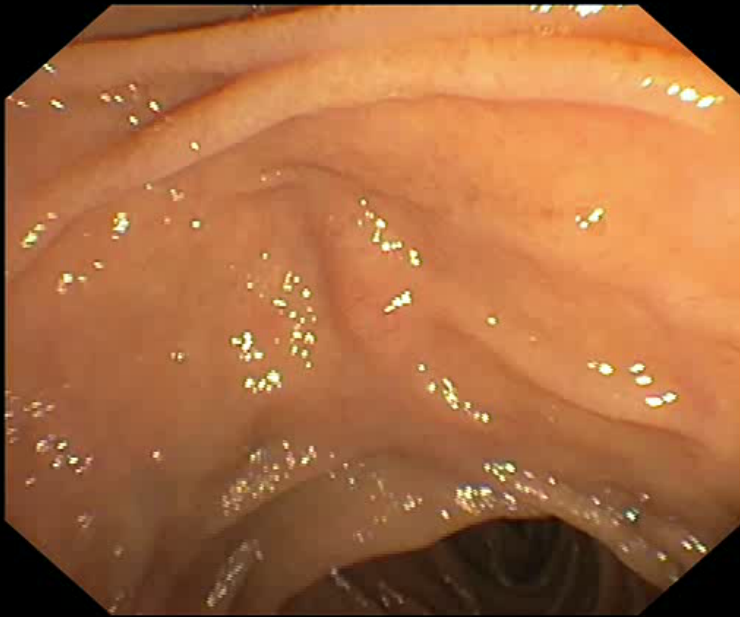
Alain Delchambre and Jacques Devière

Flexible endoscopy is an area where physicians and engineers are working in tandem since 60 years

- Collaboration focused historically with industry (devices/endoscopes makers)
- Start-up private companies possibly acquired by big players
- Real developments focused on single devices
- Role of physicians in expressing their needs
- Role of clinical research in assessing efficacy and outcomes impact
- Few examples of academic cooperation
- Fast track access and fast track regulatory clinical processes
- New indications

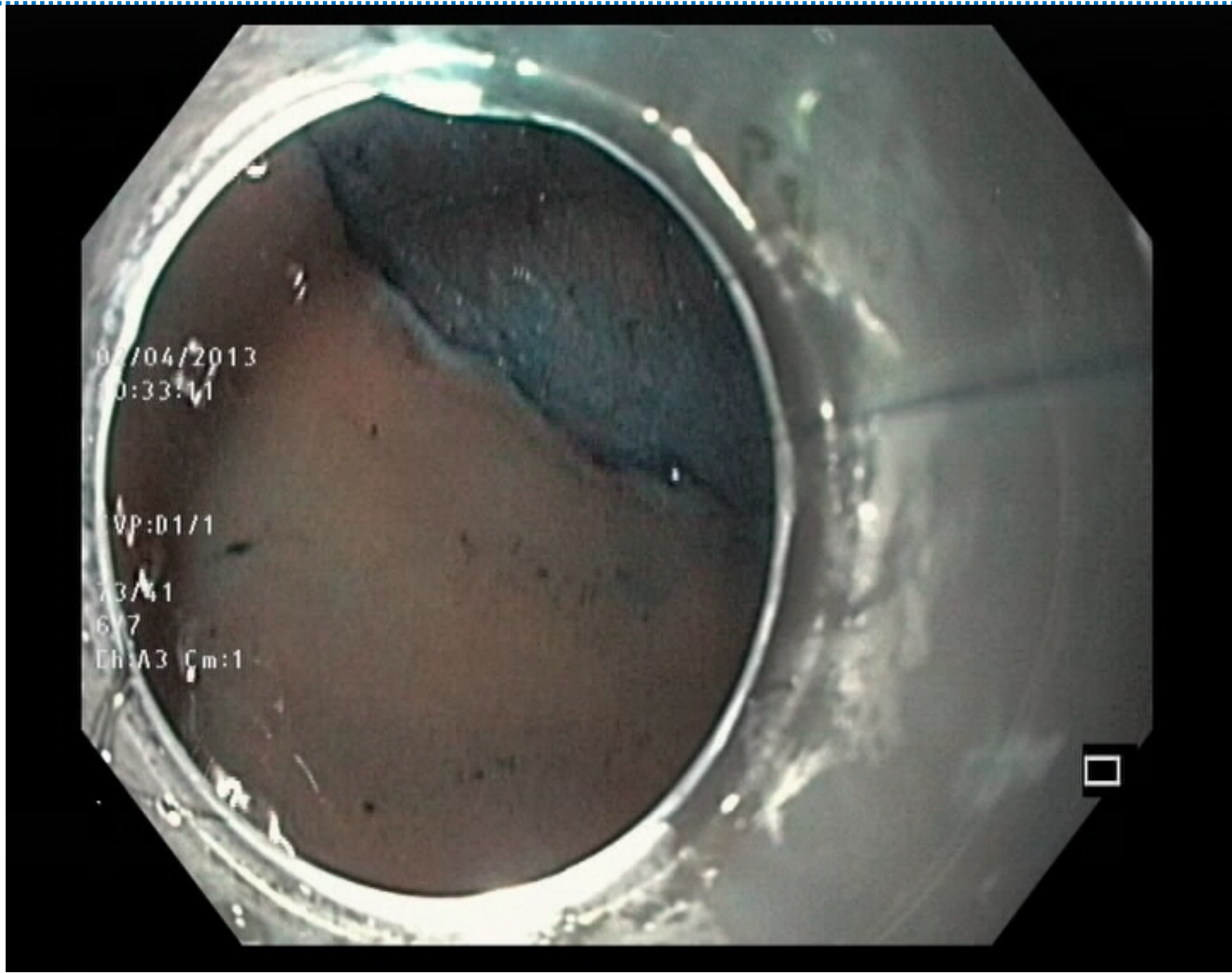


From flexible endoscopy to transoral surgery



New indications: Tumor resection, Obesity, diabetes, GERD

- Most of the superficial tumors of the GI tract have become amenable to endoscopic curative resection
- Obesity is the pandemic of the 21st century and both restrictive and malabsorptive surgery might be performed by transoral route
- Metabolic syndrome (obesity, diabetes, NAFLD/NASH) is associated with insulin resistance, a feature which is mediated through the endocrine system of the gut and may be modified by endoscopic interventions
- Flexible interventions have already replaced surgical approach for all « plumbing » palliative or curative procedures in the GI tract and the bilio-pancreatic system



07/04/2013
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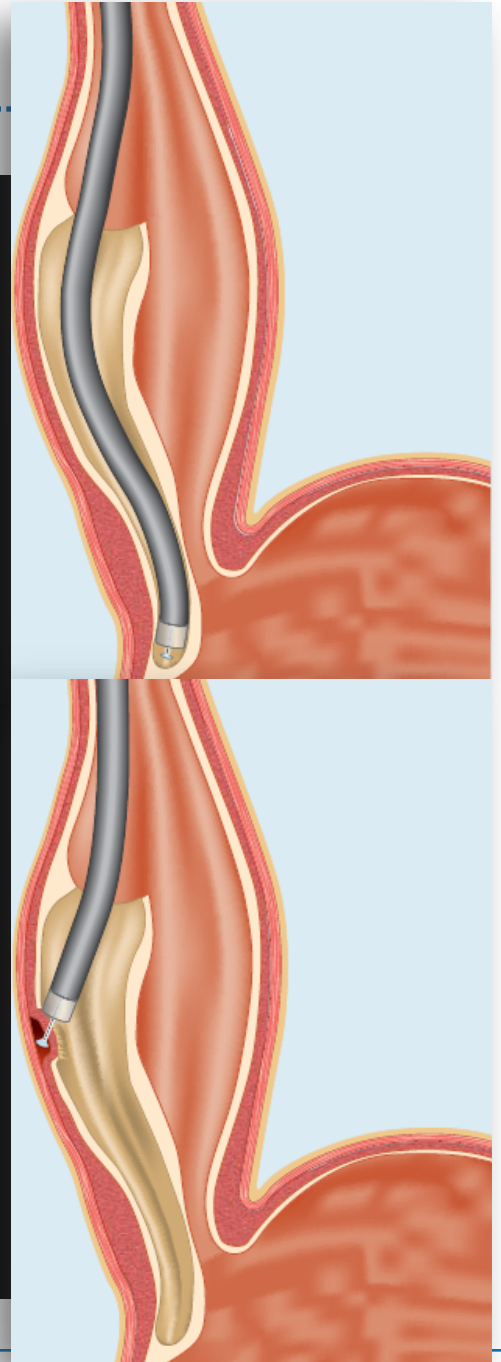
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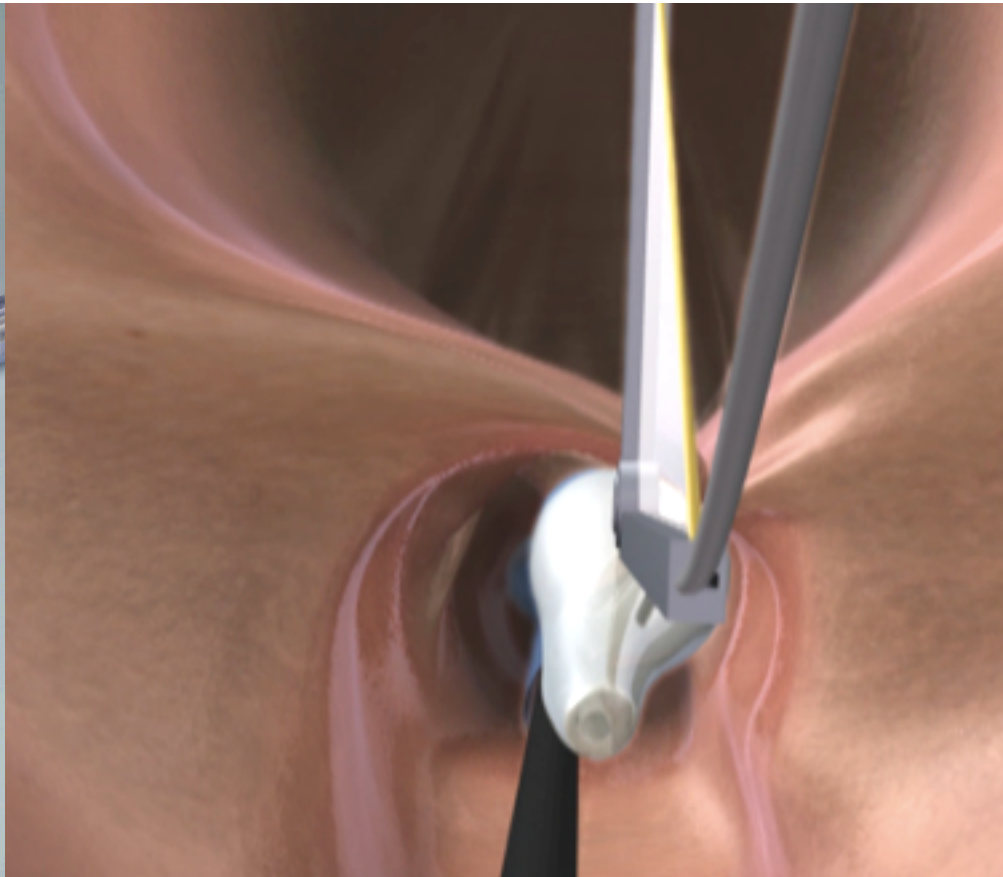
CH:A3 Cm:1





Still major hurdles: Endoscopist is a single hand surgeon !

Lifting, suturing, stapling require triangulation



In search for a simple system to become a « real » surgeon

Endoscopic Treatment for obesity: Why?

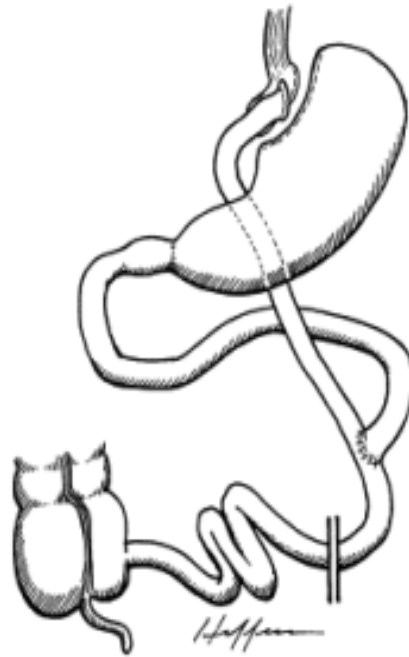
- Obesity and diabetes are the pandemy of the 21st Century
- Exponential increase in incidence in North America , Europe, Middle East, South America, India, China
- Surgery is offered to < 10 % morbid obeses and resources will be overwhelmed
- Obesity is a chronic disease requiring lifelong therapy, and sometimes multiple treatments
- Metabolic syndroom includes obesity, diabetes, NAFLD....

Lessons from bariatric surgery: remission of Diabetes



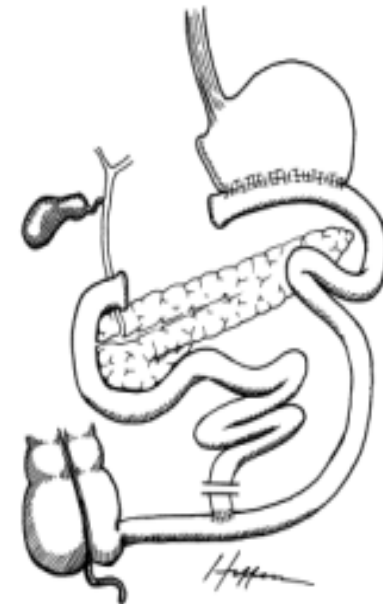
**Adjustable
Gastric Banding**

38%



**Roux-en-Y
Gastric Bypass**

84%

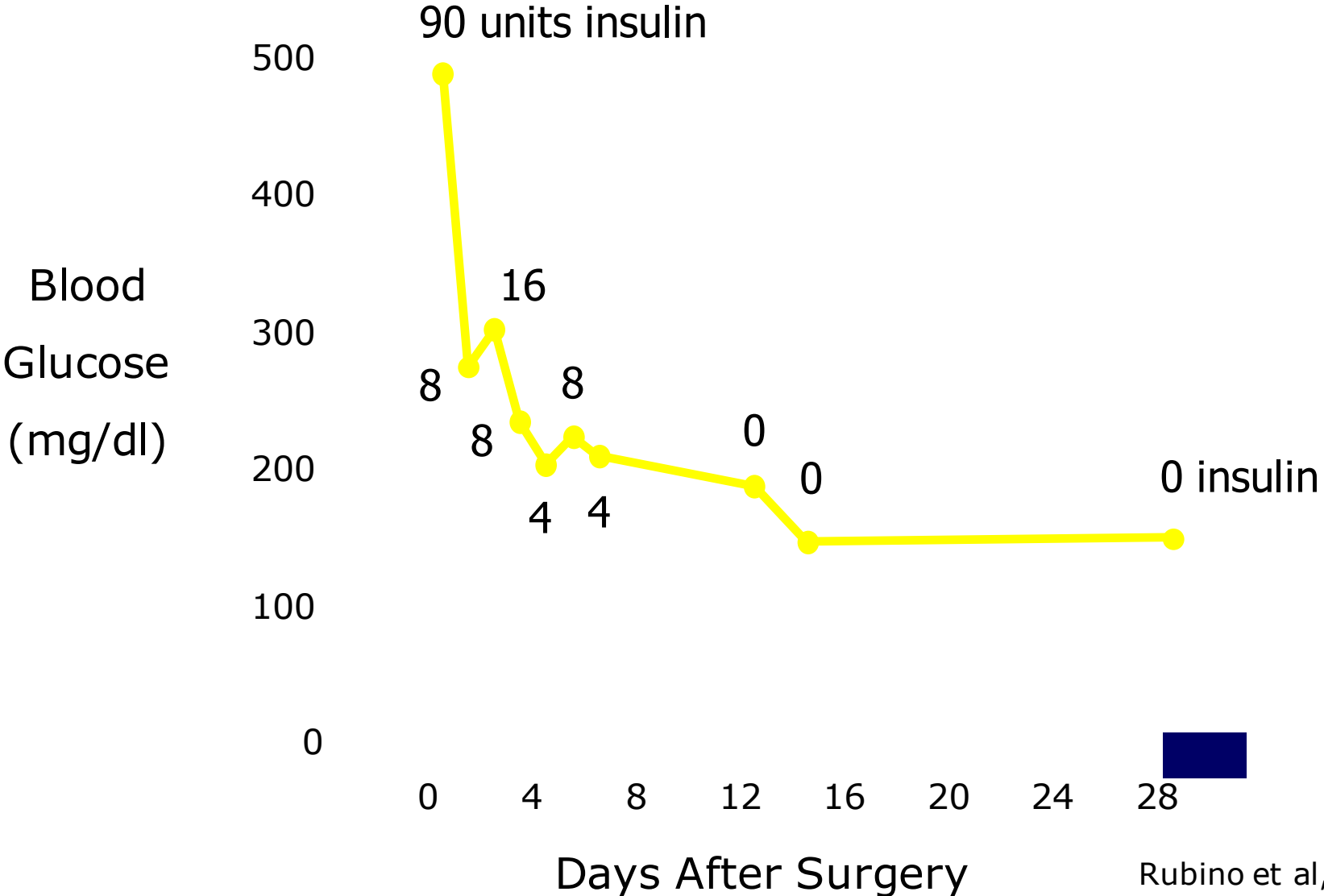


**Biliopancreatic
Diversion**

98%

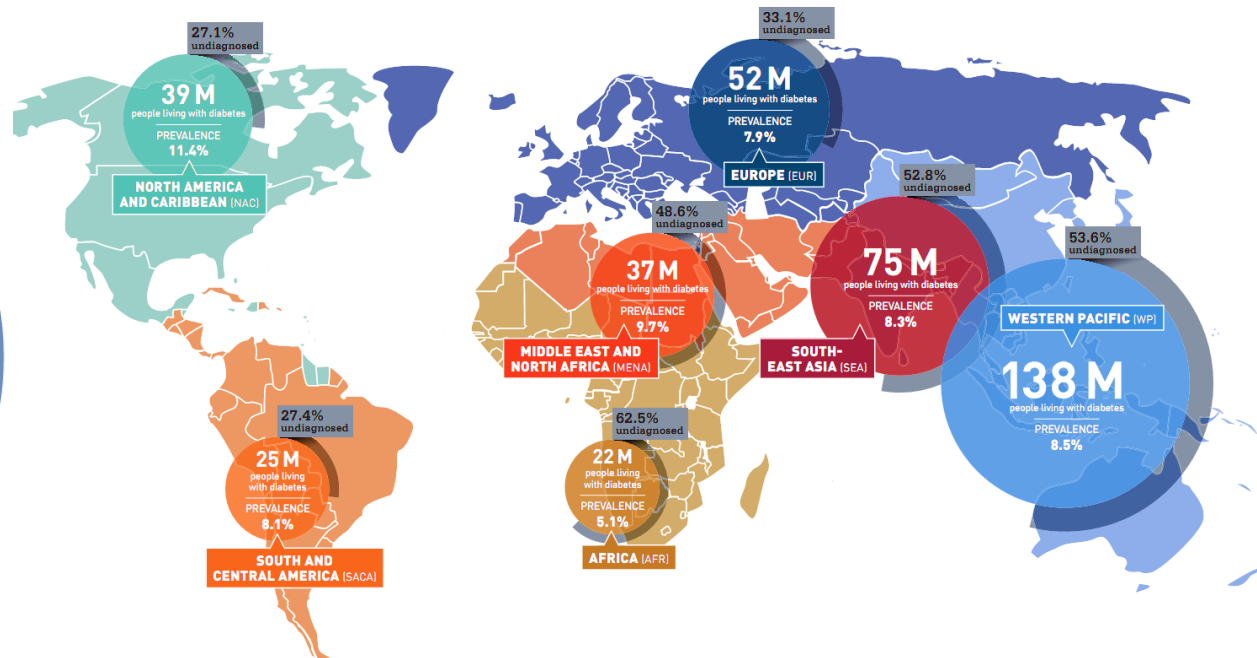
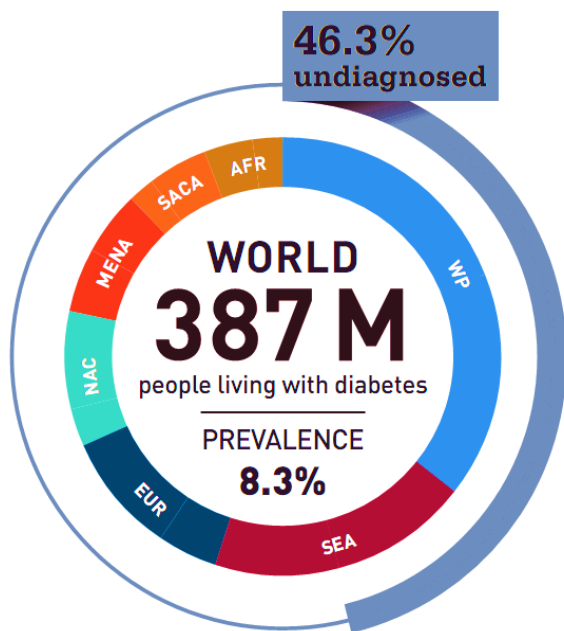
Buchwald H., JAMA 2004

Rapid Improvement of Diabetes After RYGB



Rubino et al, 2006

Type 2 Diabetes: The Challenge



Battling the epidemic



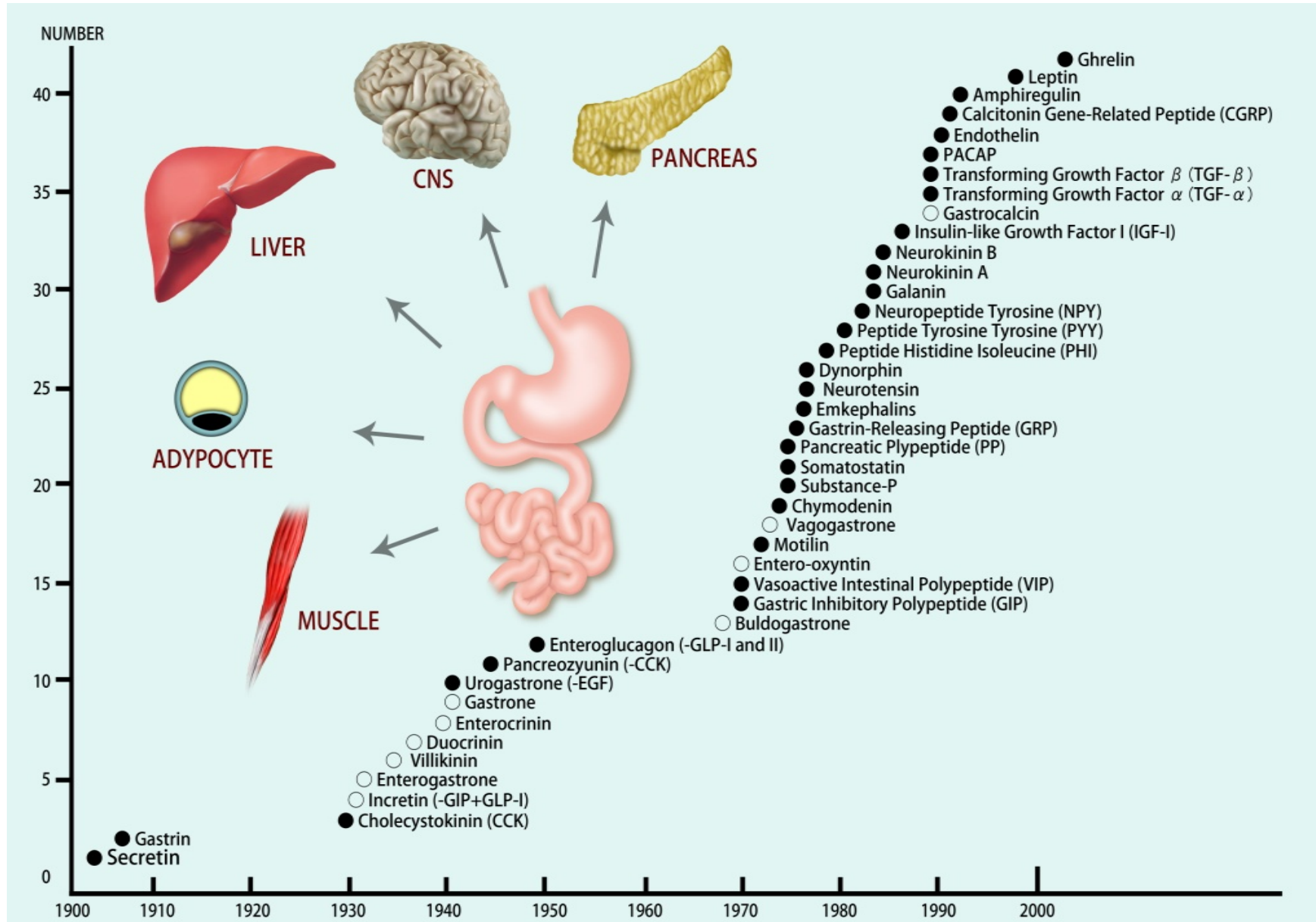
Treatment shortcomings recognized



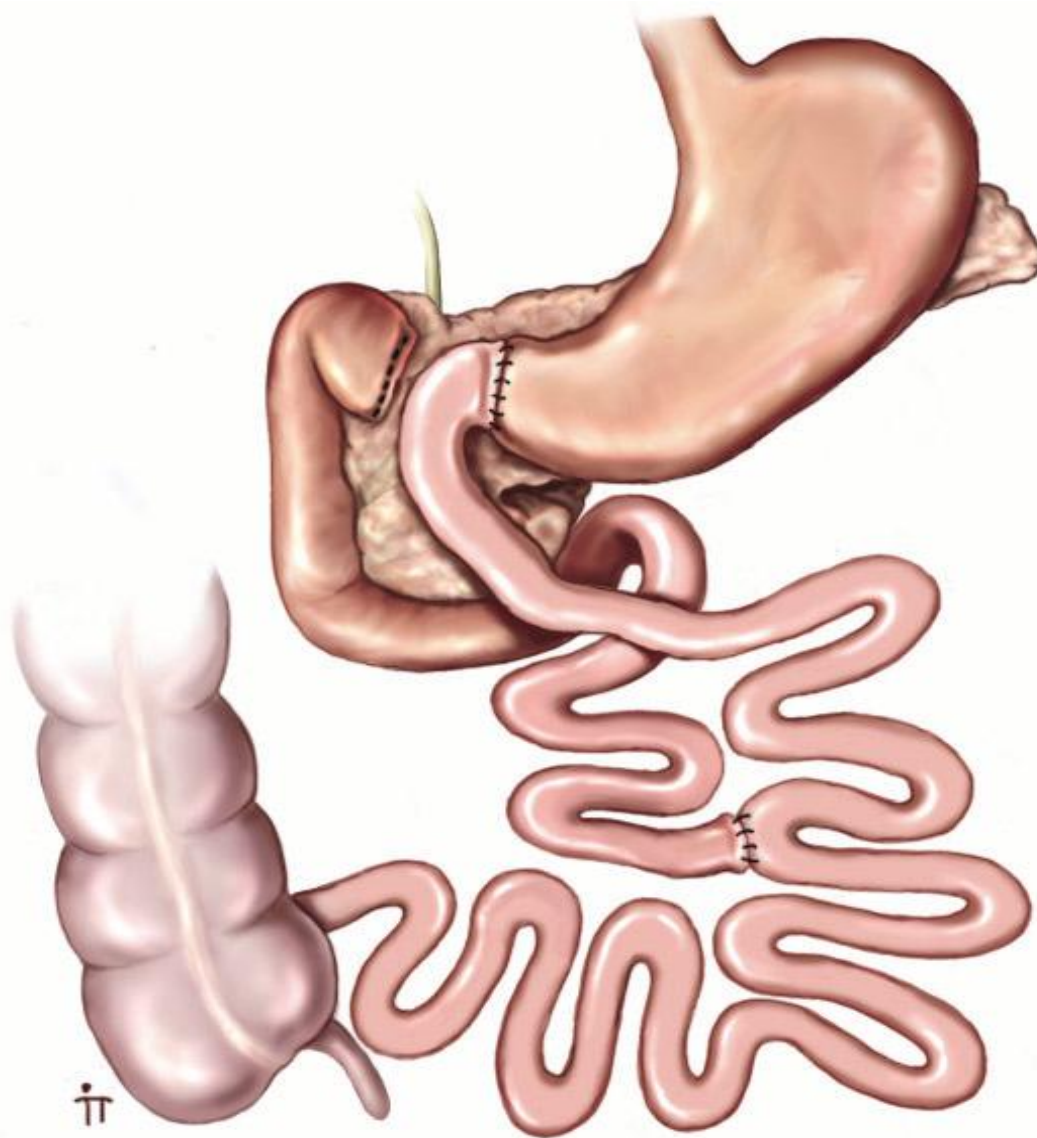
New solutions necessary

Images from IDF Diabetes Atlas 2014

The Gut is major endocrine organ



Duodenal-jejunal Bypass (DJB)



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Medical Applications

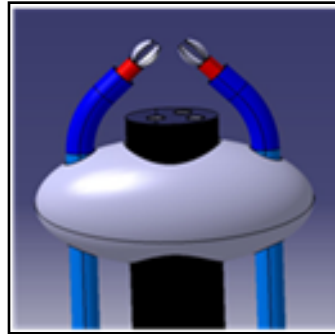
NOTES

Gastro-enterologic Treatment of Obesity

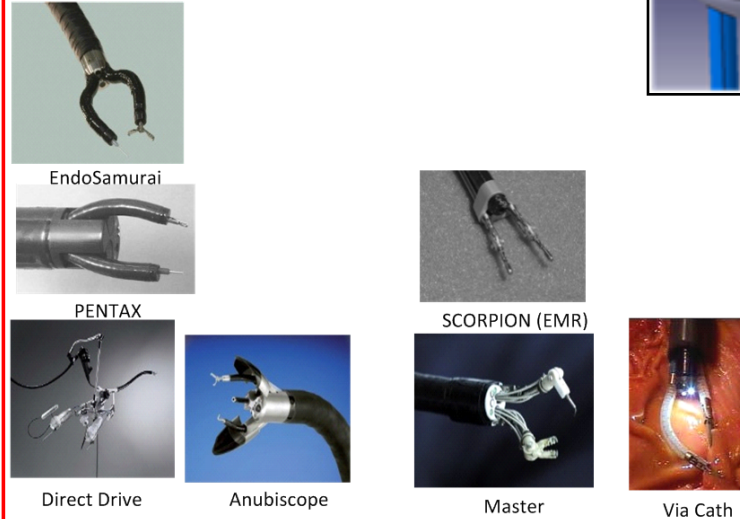
EFTR

ESD/EMR

GI Tumors treatments



Additional Features are:
 (1) Visual Tracking
 (2) Force Feedback
 (3) Augmented Reality
 (4) Stereovision



Non Motorized Triangulation System

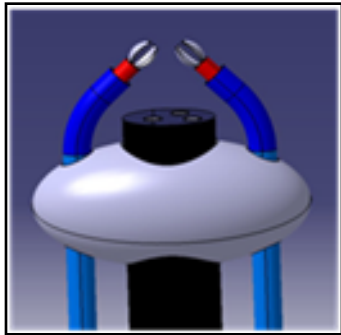
Motorized Triangulation System

Motorized Triangulation System With 1 additional features

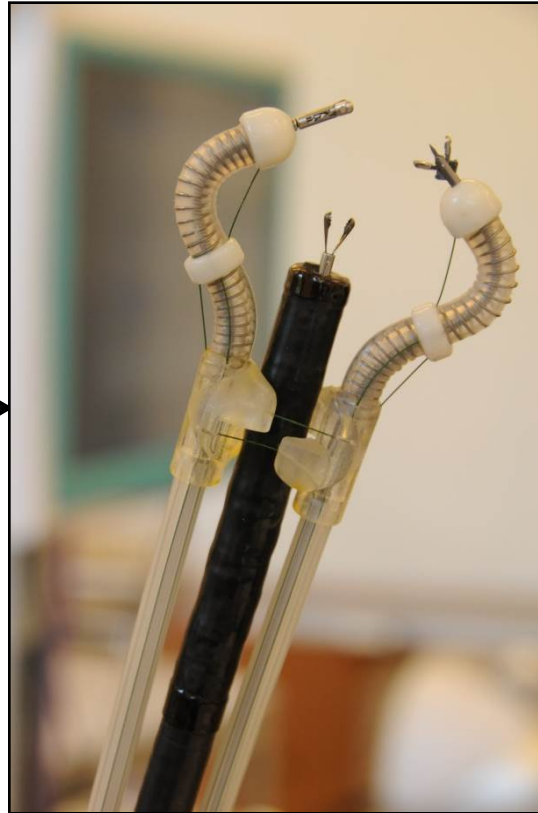
Motorized Triangulation System With 2 additional features

Engineering Features

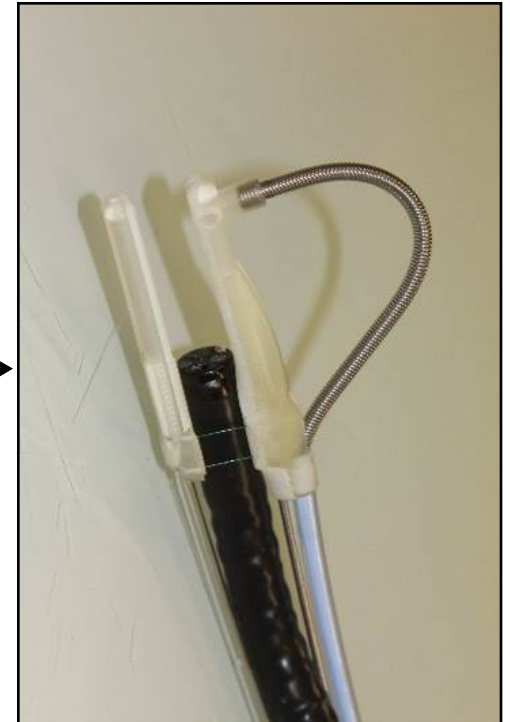
From the Endomina project to the spin-off EndoTools Therapeutics



Physician idea



Research Platform



Specialization : Obesity

Endomina: the universal triangulation system for gastro-enterology

- Robotized and flexible system
- Universal: can be used with any endoscope and with any therapeutic tool up to 9 French
- In situ assembly system to an endoscope
- 2 guiding catheters enabled to bend with 3 degrees of freedom
 - S-Shape
 - Up and down

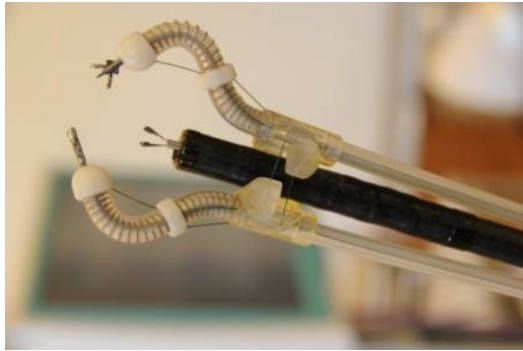


Endomina: the universal triangulation system for gastro-enterology

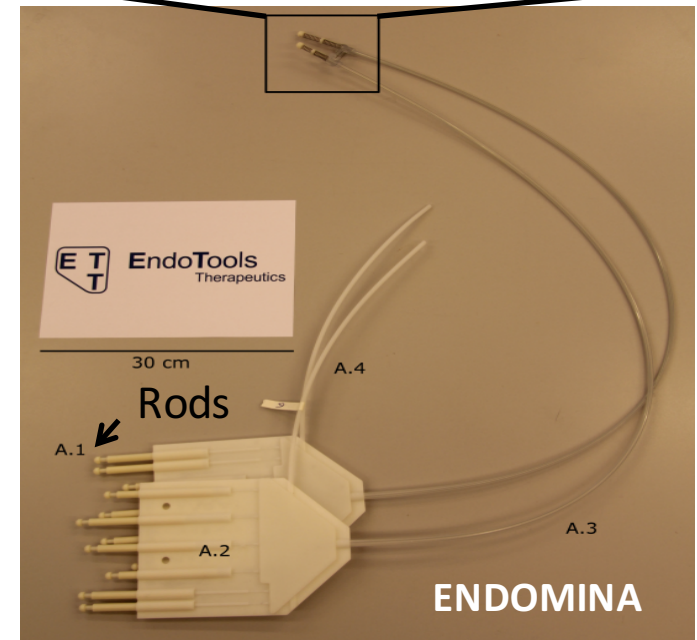
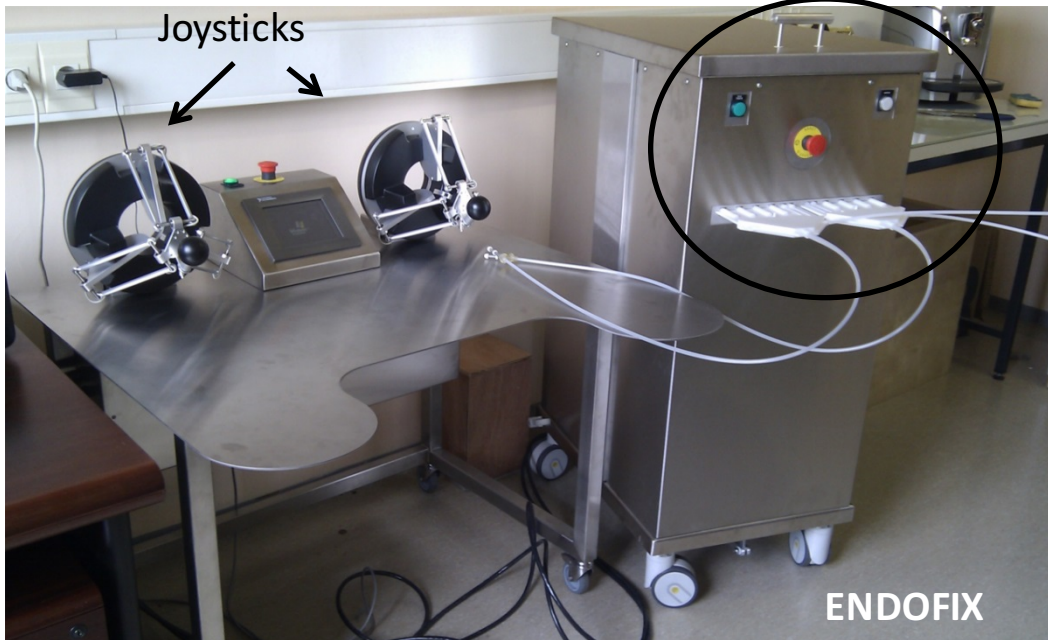
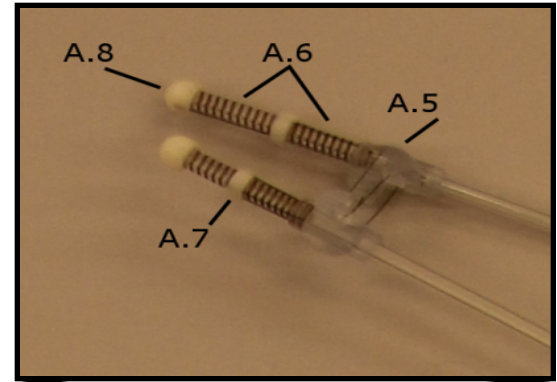
- To perform real endoluminal surgery
- Mimics 2 hands in the GI tract to
 - Lift & Cut the tissue
 - Suture the tissue
- Potential applications
 - Morbid obesity treatment
 - Gastro-esophageal reflux treatment
 - Endoscopic full thickness resection
 - Single Port Access procedure



Medical device: general view



Plug & Play

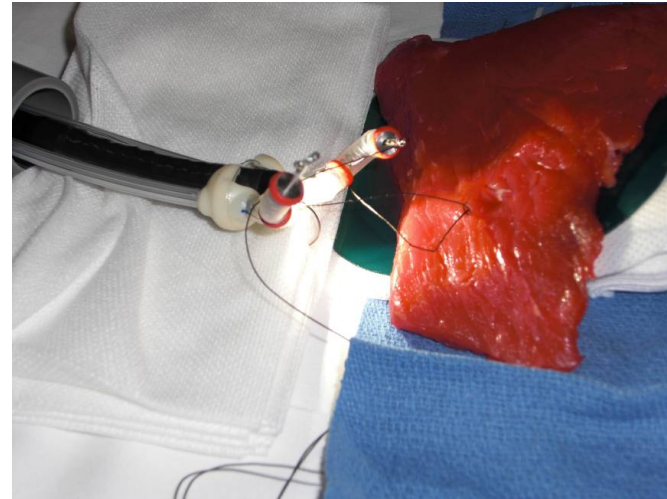


CE marked in 2011 (incl. Electro-medical device Endofix)

Preliminary tests



Lift & Cut



Suturing

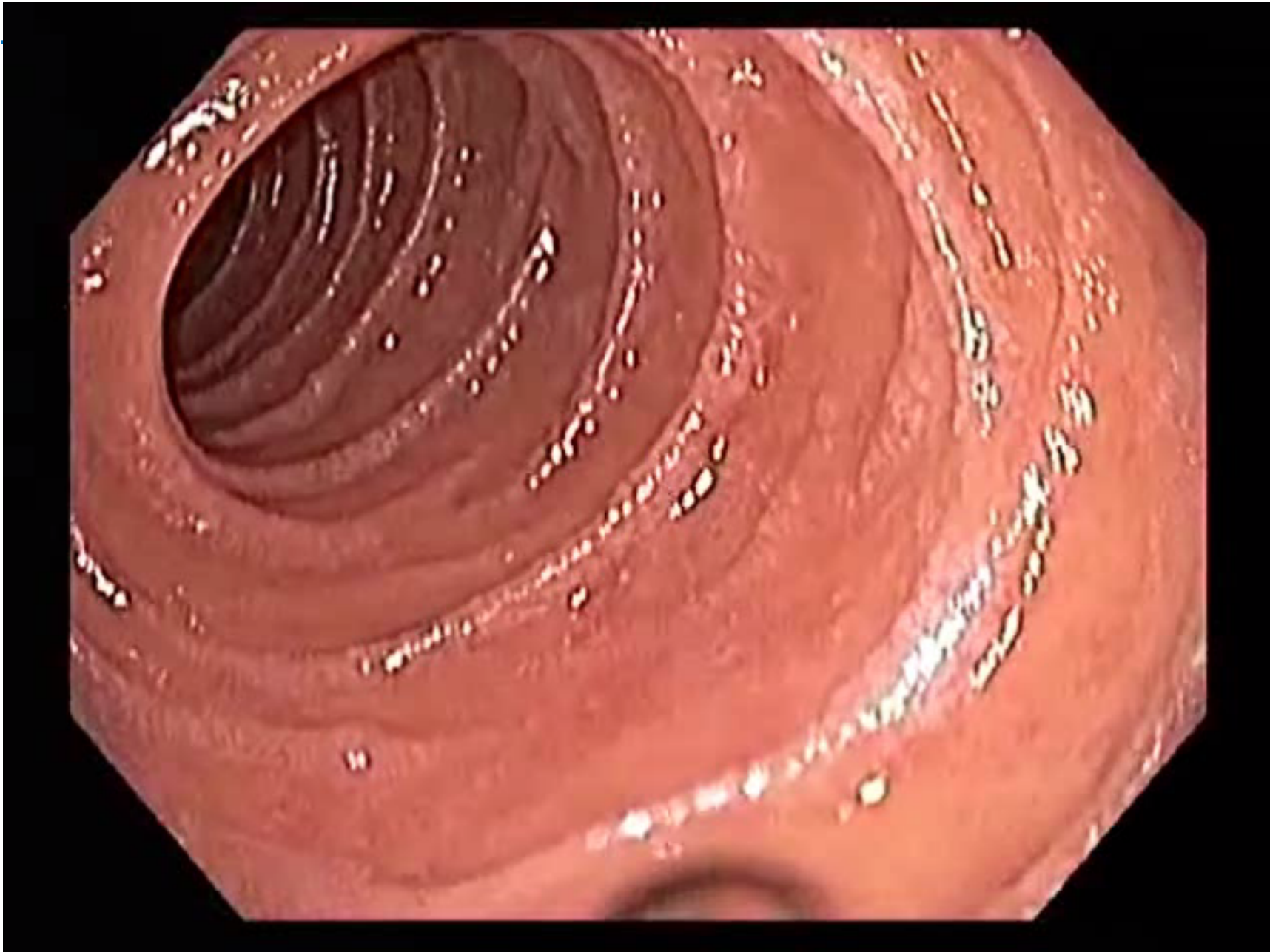


Gastroscope

Clinical trial

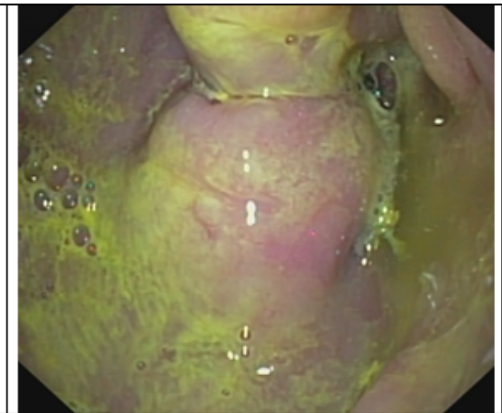
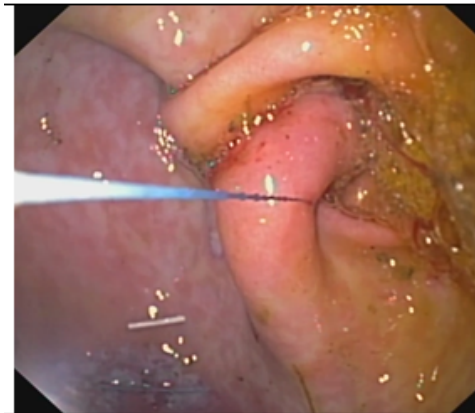
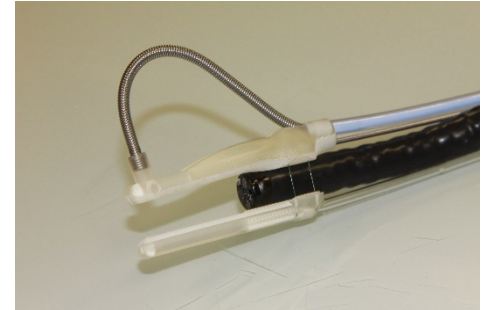
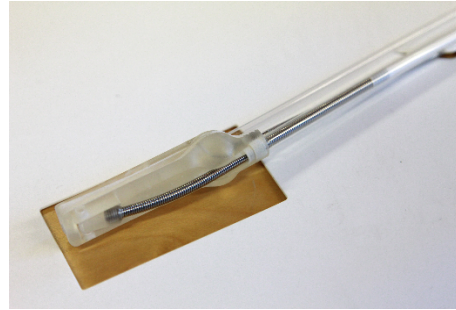


Treatment of morbid obesity

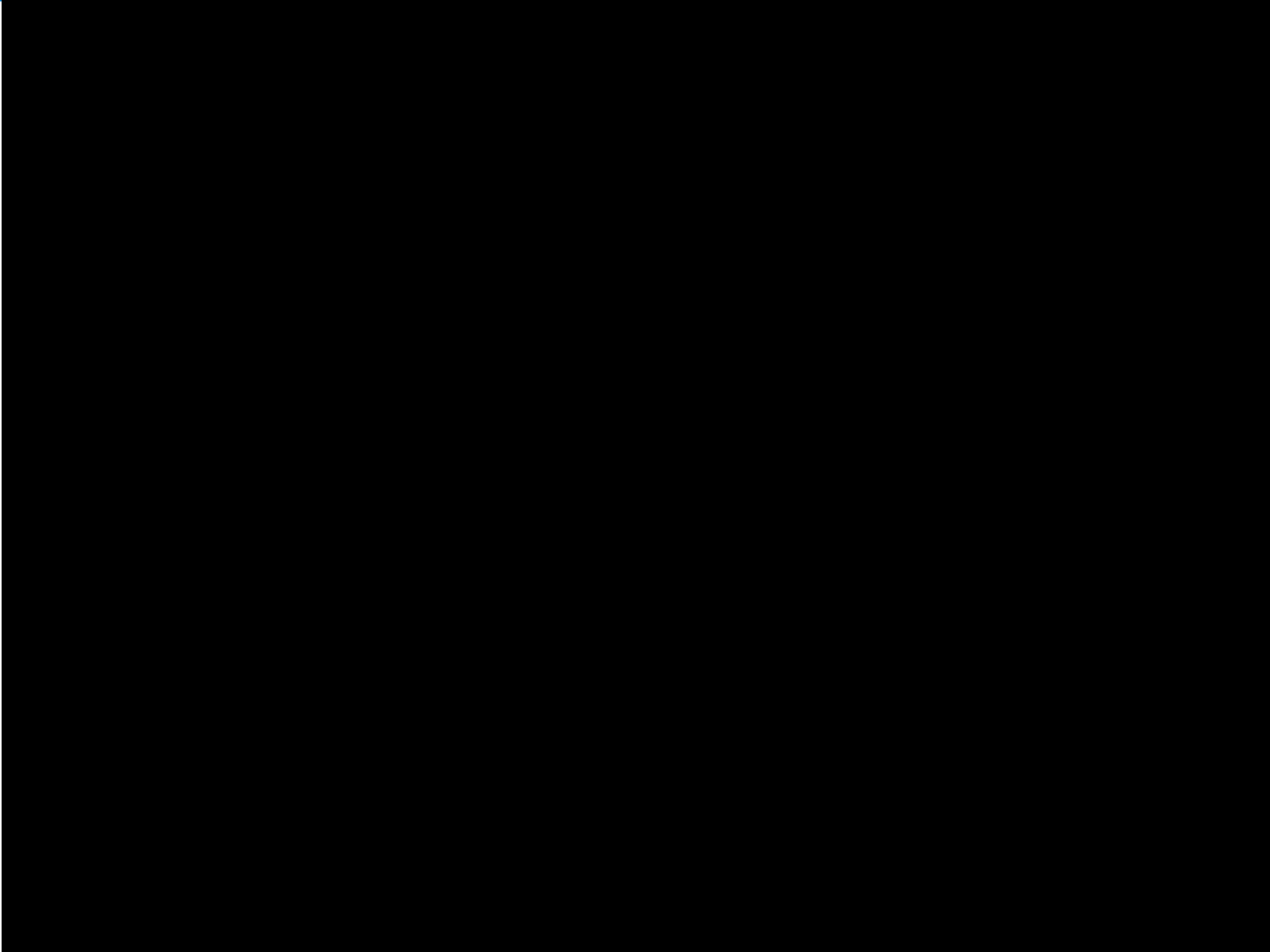


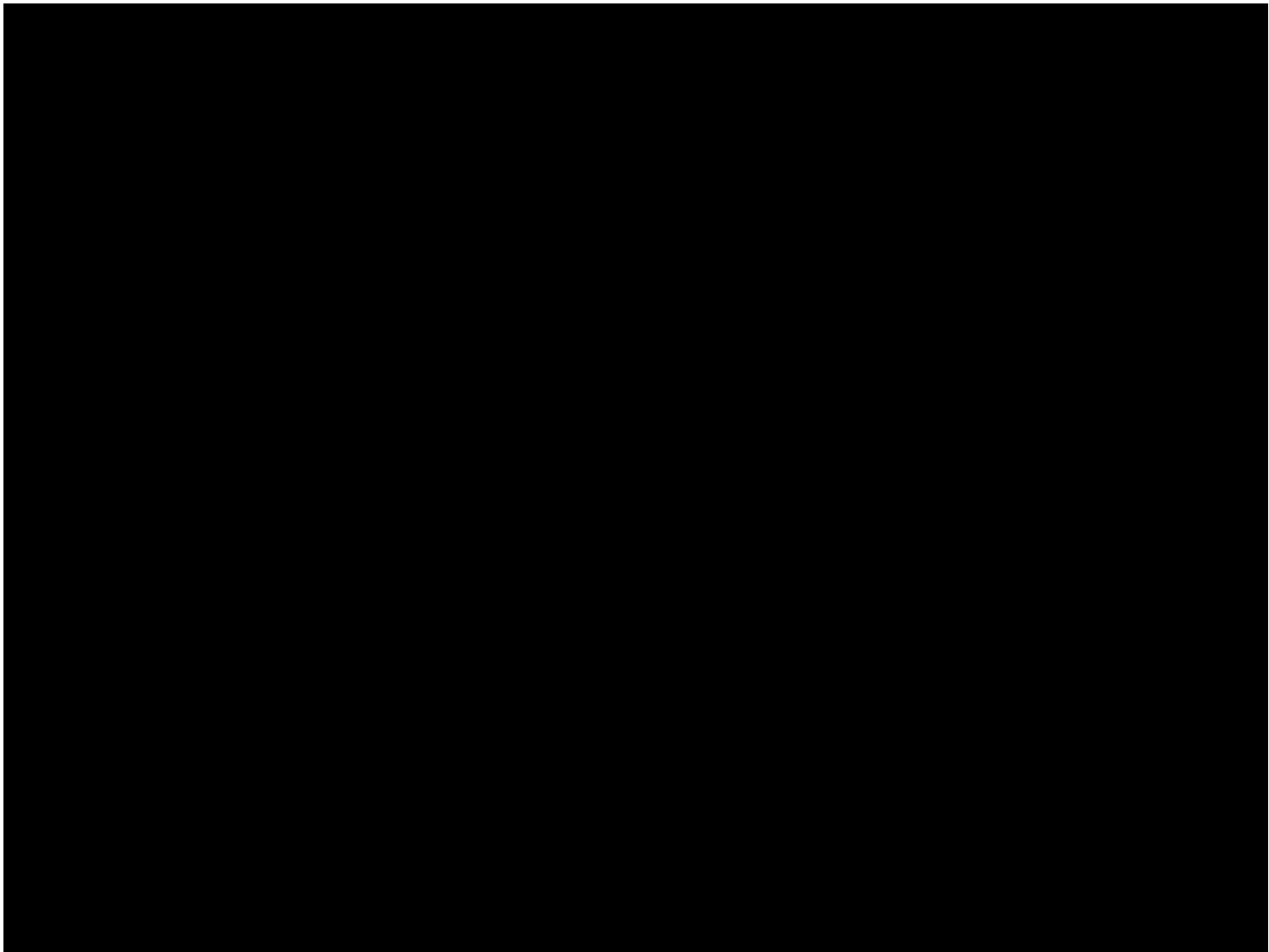
Endomina v2 is 100% compatible with most endoscopes and surgical tools

- Single use
- Single flexible arm compared to v1
- Overcomes current limitations of interventional gastroenterology by adding triangulation
- Universal (i.e. can be used with any endoscope and endoscopy tools), limiting costs for hospital and social security systems



Video





Activity

Development and commercialisation of tools for gastroscopic surgery

Ambition

To become leader on the world market for morbid obesity treatment by natural orifices

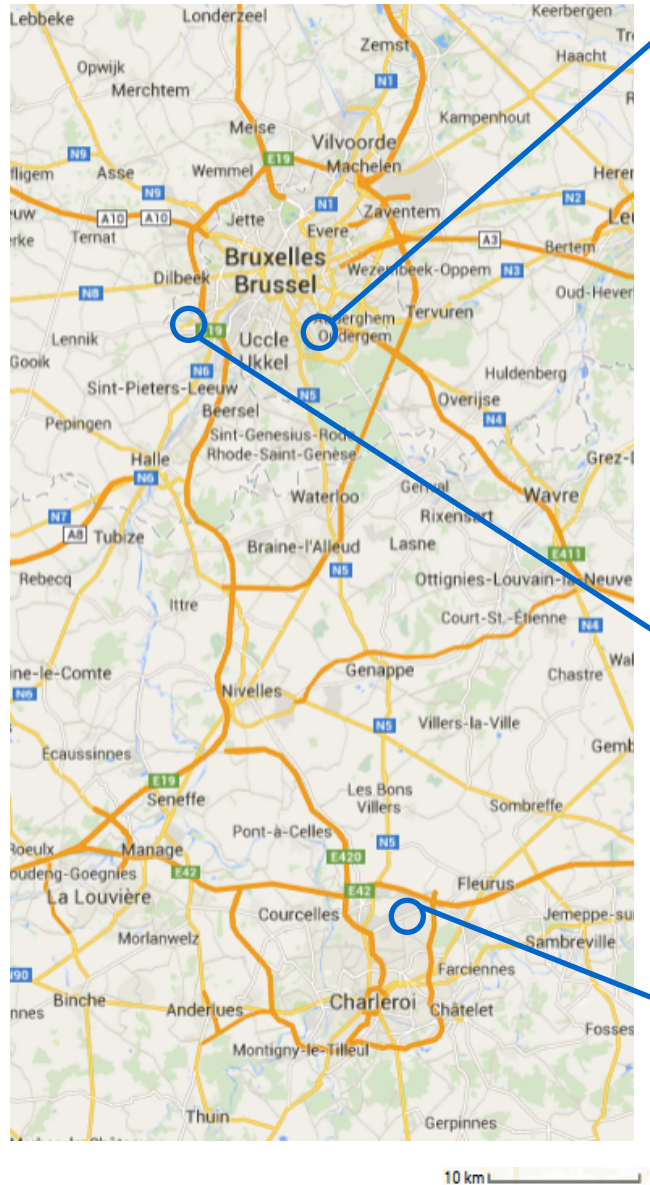
Major operational elements

- First capitalization of the SA in 2009
- In July 2011, CE marking obtained for the Endomina product
- First clinical trials on 6 patients (V1)

- In 2013, 2,5 MEUR fund raising to finance future developments, on the basis of a company value of 4,8 MEUR

- 2015, pilot clinical trial completed (14 patients), safety and feasibility, 40% EWL at 4 months
- 11/2015, multicenter trial started (efficacy)

The facilities



- BEAMS – Bio, electro and mechanical systems department (Solbosch + Erasme) : **Engineers**



- LGE – Gastro-enterology department (Erasme) : **Physicians**



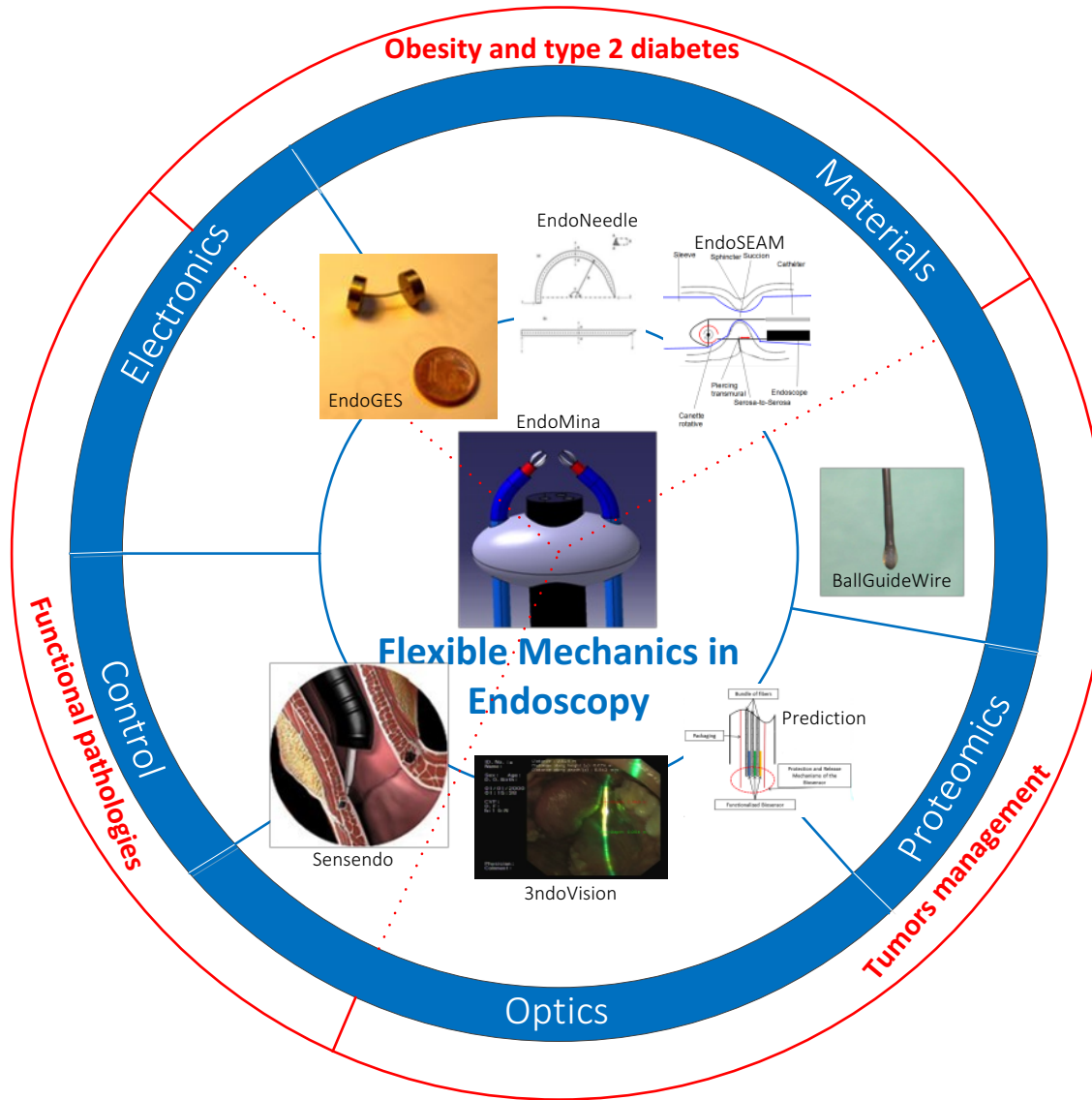
- ETT (Charleroi) : **Spin-off**

Development process

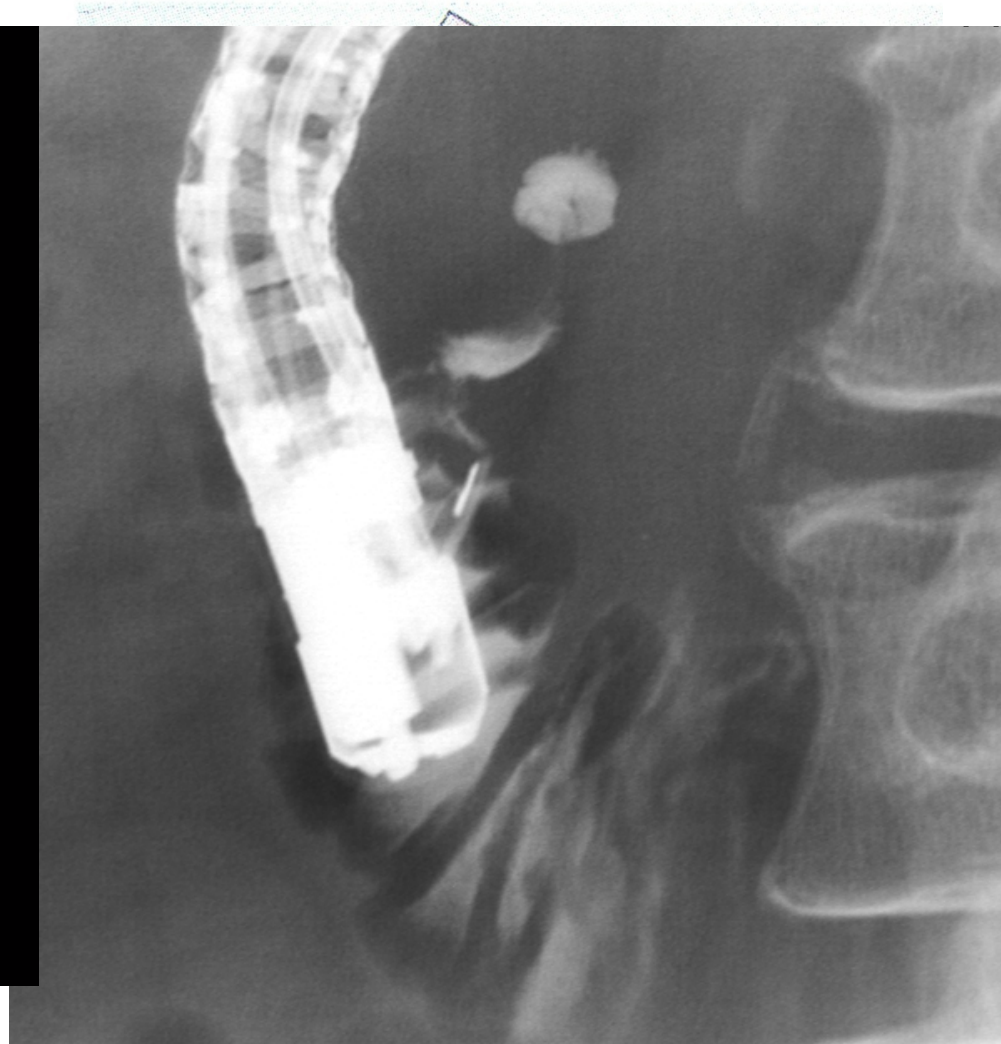
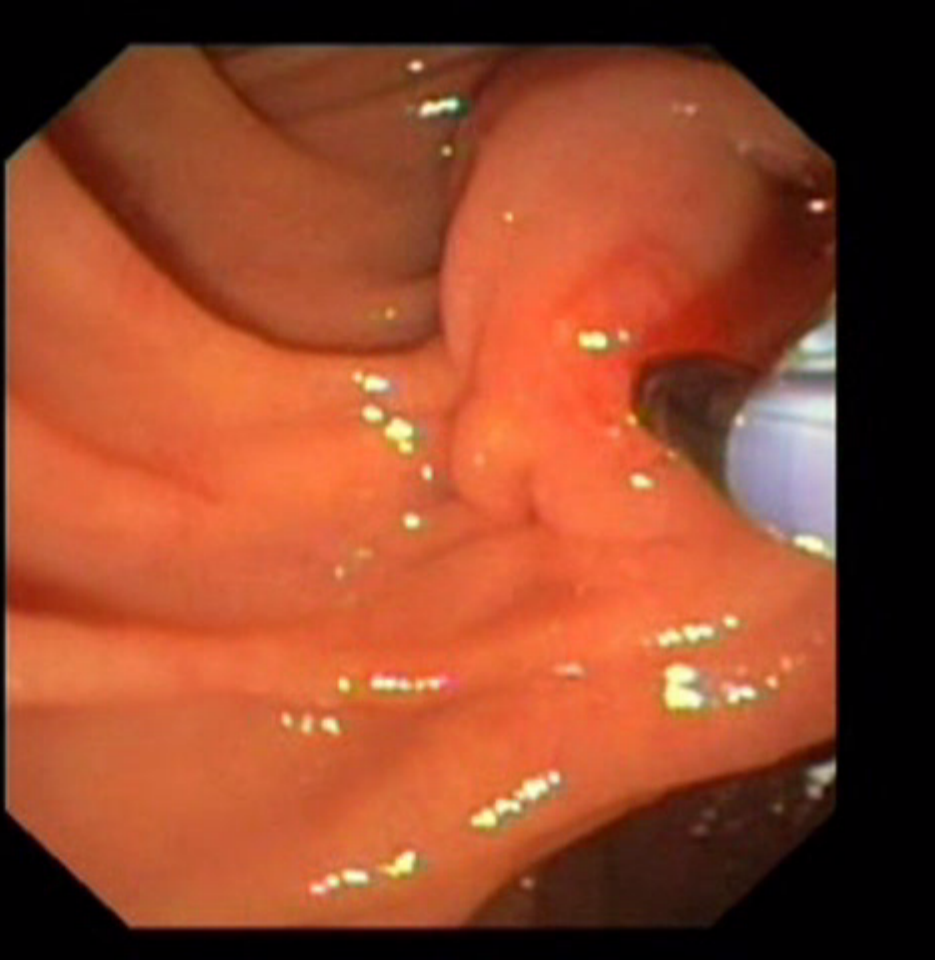


- Rich flow of ideas based on daily medical practice by Jacques Devière and his team
- 10 engineers developing and testing prototypes in close relation with physicians
- Animal investigation in veterinary school in Liège (100km)
- Limited volume industrialization with sub-contractors
- CE marking and ISO standards (mechanical, electrical electronics, software)
- Clinical investigation in Erasme
- Spin-off for Endomina
- Currently no distribution network

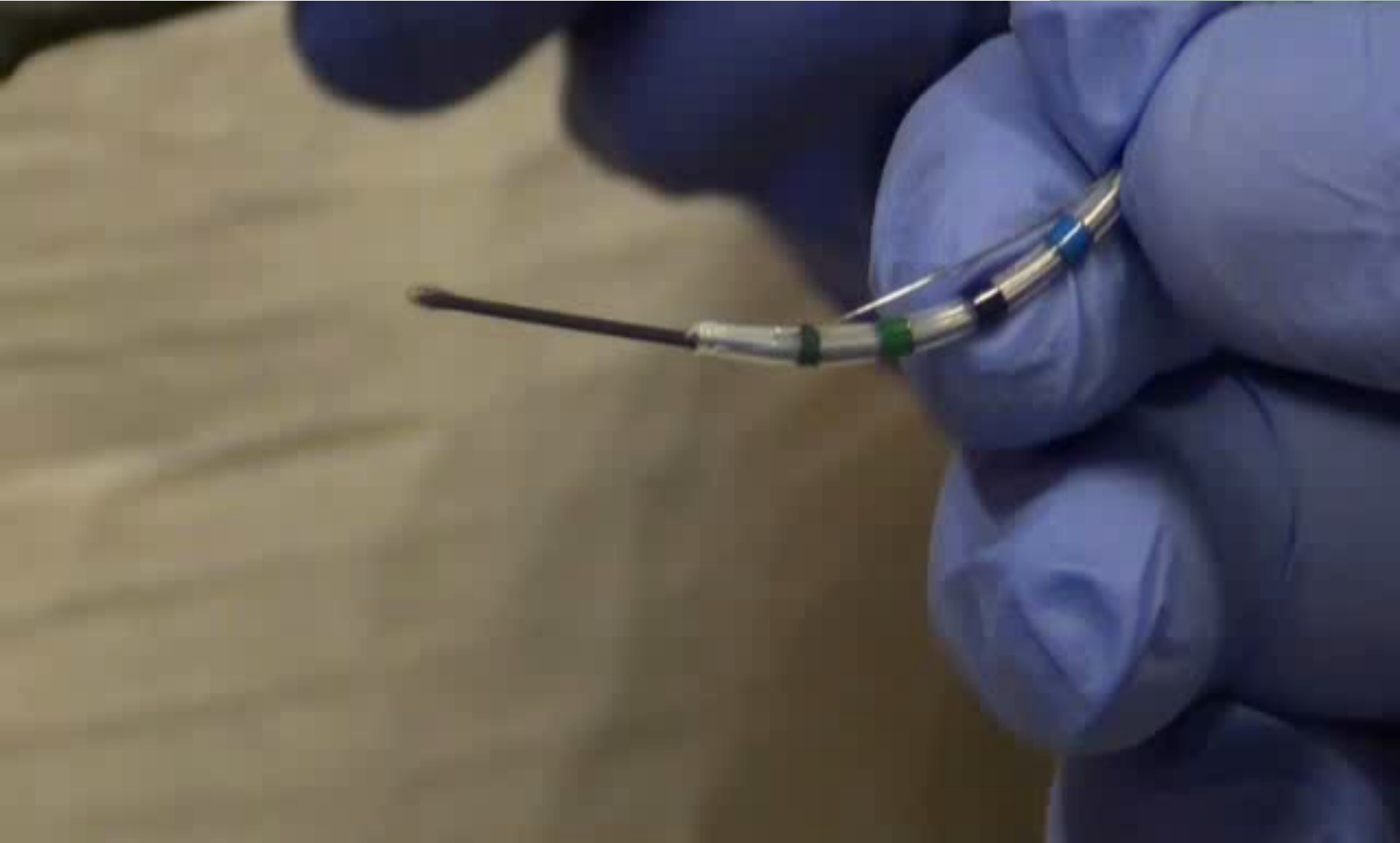
Research themes



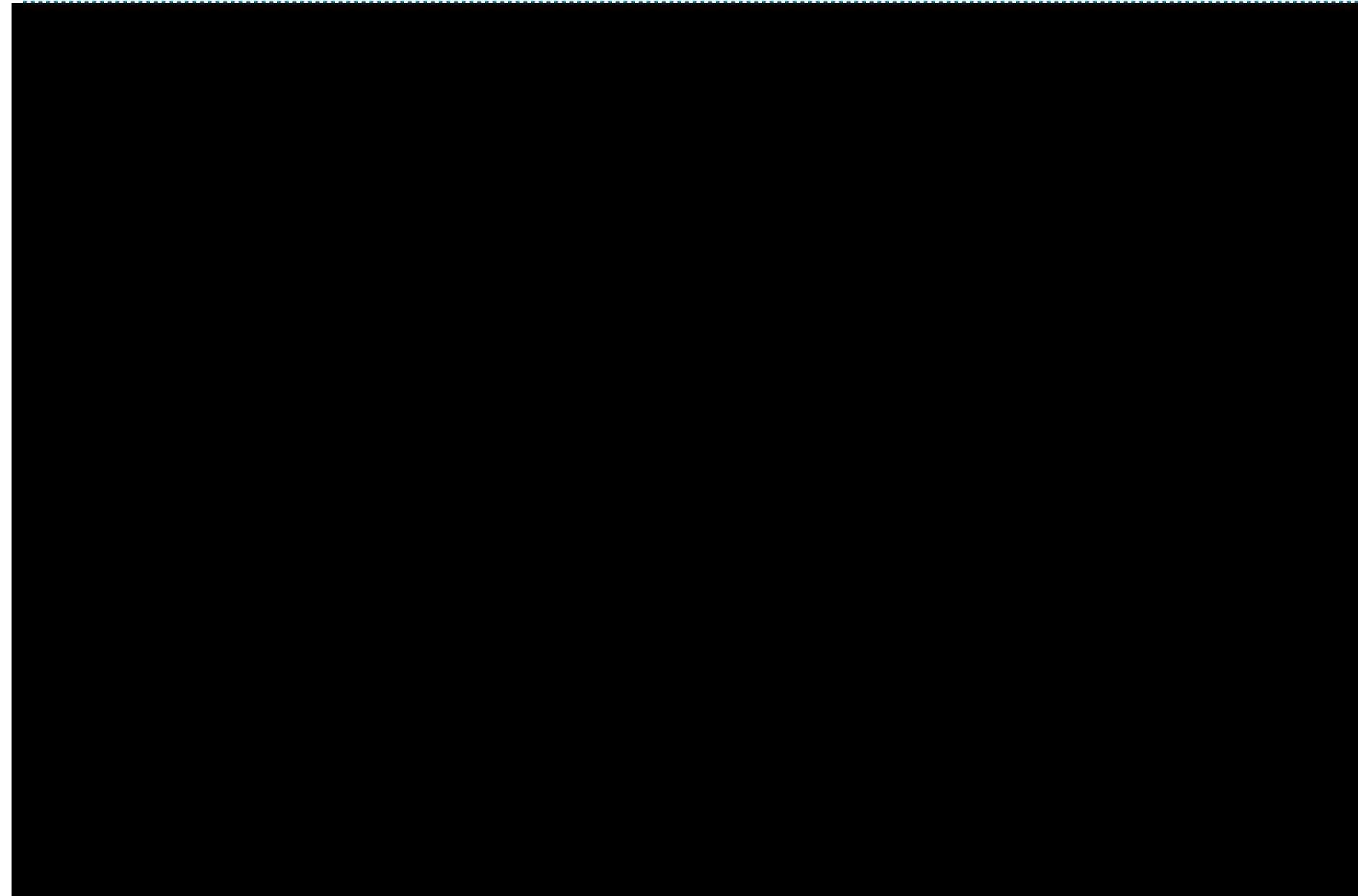
Access: Selective cannulation is one of the most challenging steps of ERCP



Some examples: Detachable Ball tip wire

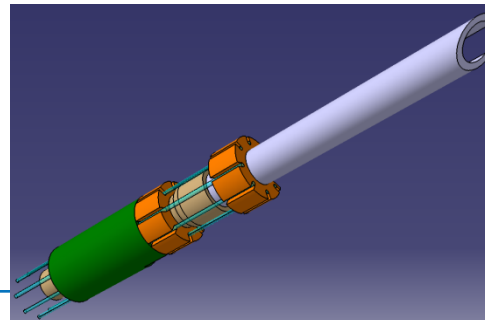


Some examples: Magnetic anastomoses

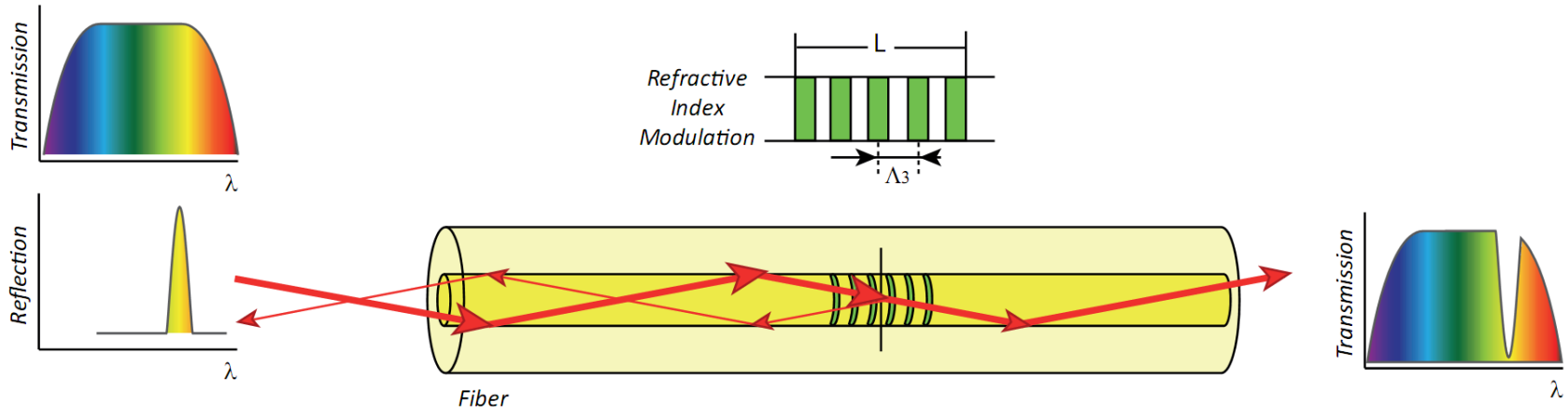


Sensendo: to overcome the absence of tactile feedback

- In situ force measurement
- Force feedback system
- GERD treatment by polymer injection
- Tumor recognition (hardness)
- Layers dissection
- Team:
 - SGE (Gastroenterology)
 - BEAMS (Electro-mécanics)
 - SET (optic)
 - SAAS (automatic)



Bragg's fibers captor

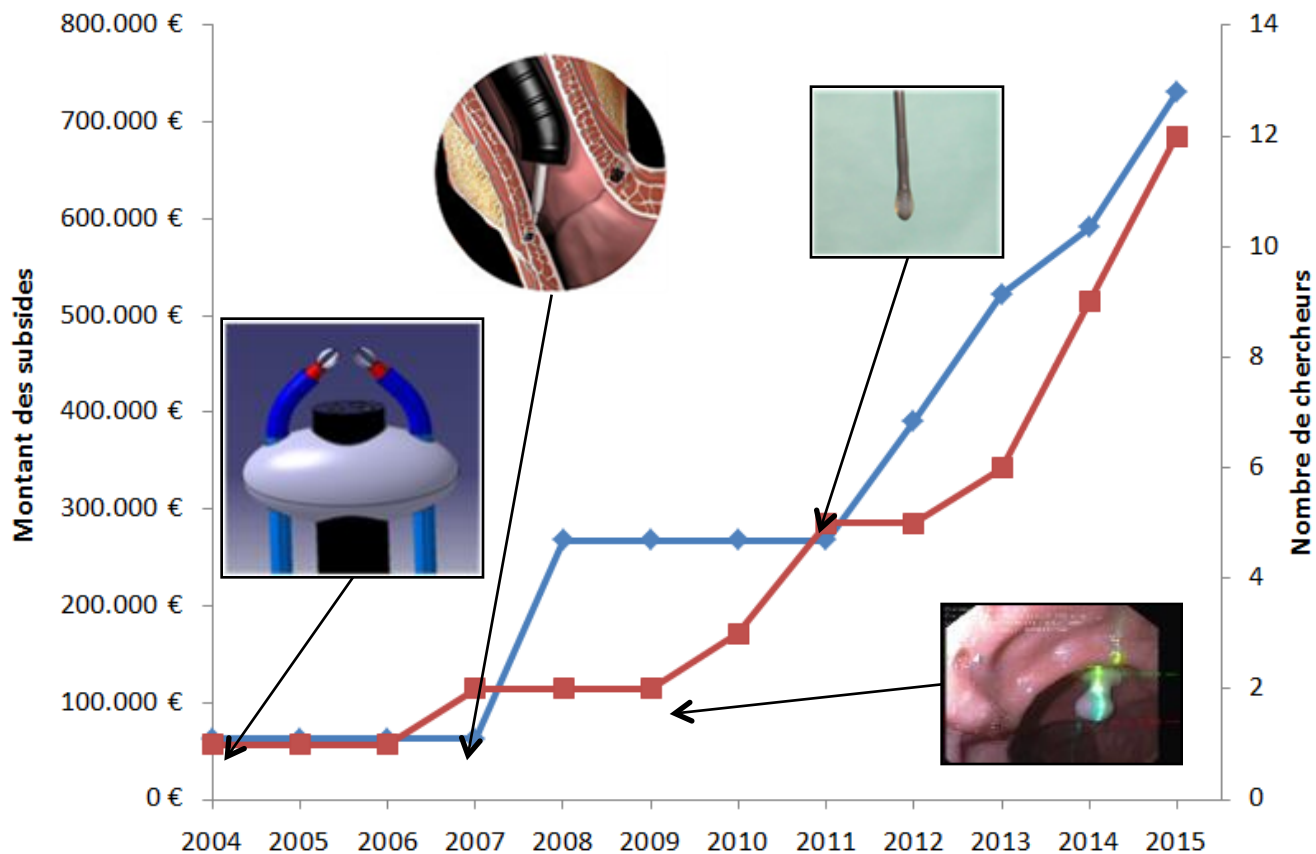


$$\lambda_B = 2n_{eff}\Lambda$$

- Compression modifies the wavelength of transmission
- Young module and geometry correlate force and shortening
- Electronical amplification is possible: Augmented reality !!

Gastro-Ir research projects

◆ Subsidies reçus pour l'ingénierie en endoscopie digestive / an
 ■ Nombre de chercheurs temps plein lié à cette collaboration



3 Professors (EP)
 8 PhD-engineers;
 2 Post-Doc -
 engineers,
 2 PhD-physicians

4,5 M€ public funding

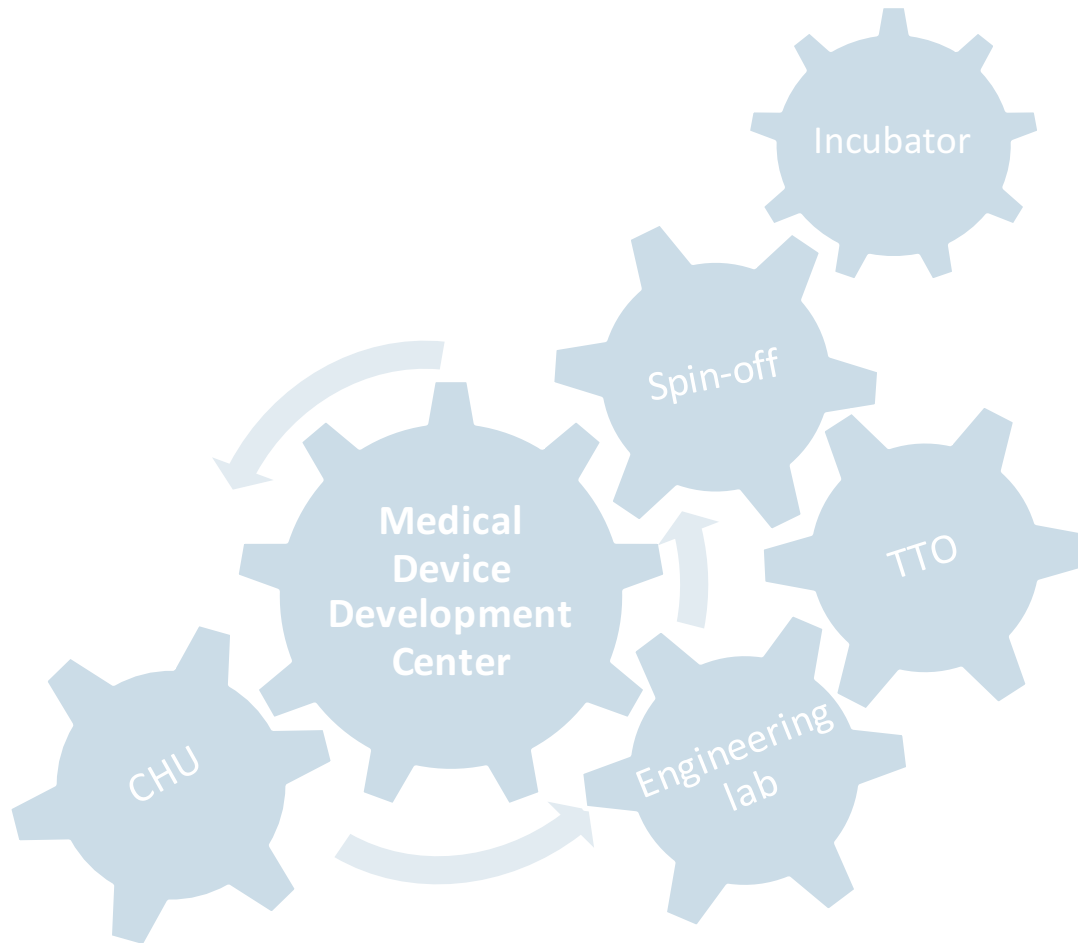
7 ongoing projects

Possible collaborations with other medical units

Expertise developed in engineering department

Medical Units	Triangulation	Flexible mechanics	Force sensor	Length Measurement
Neurosurgery	✓			✓
Interventional Radiology		✓	✓	
Orthopedics			✓	✓
Surgery	✓	✓	✓	✓
Radiotherapy			✓	
Gynecology		✓	✓	✓
Ophthalmology			✓	✓
Pulmonary et urology		✓		✓

Future structure: Platform of innovations



Surgery

- As they did for many years for most of surgical improvements
- Even more with the new challenges of flexible endoscopy
- The need for platforms of innovation will most probably further increase with the challenge of new indications
- The potential impact on patients outcomes is fabulous
 - All “plumbing” curative and palliative interventions
 - Superficial tumors GI, pulmonary, uro-genital
 - Obesity (pandemy, disease with no pharmalogical treatment)
 - Transoral treatment is an ideal first line approach which does not compromise further surgery
 - Endoscopy might cure Diabetes

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