



Success Story Endostim Inc.

Key milestones on our way to securing market access in Germany

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Agenda

- Clinical issue and the EndoStim solution
- Reimbursement milestones in Germany
- Success Factors
- Summary

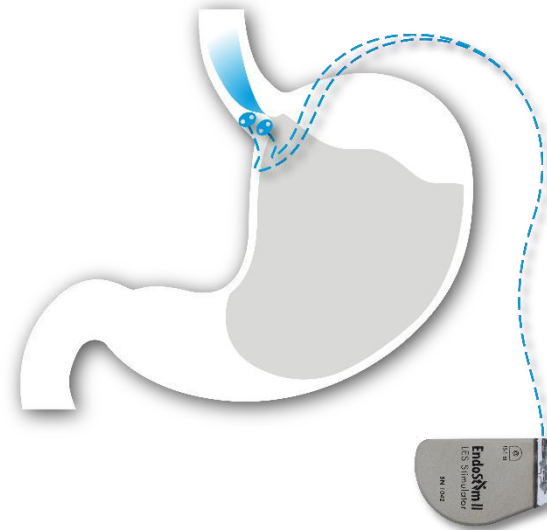
EndoStim Therapy

Neurostimulation to normalize esophageal function

Gentle procedure – leaves anatomy intact, minimizes side effects of traditional anti-reflux surgery

Smart therapy – can be personalized in the clinic with a wireless programmer

Safe and effective – excellent outcomes in clinical trials and in standard clinical practice



EndoStim

Targeting the GERD Therapy Gap

GERD: gastro-esophageal reflux disease

- Caused by a weak lower esophageal sphincter (LES) that allows stomach contents to reflux into the esophagus
- Normally treated by long-term PPI medications that block stomach acid production but do not address the weak sphincter

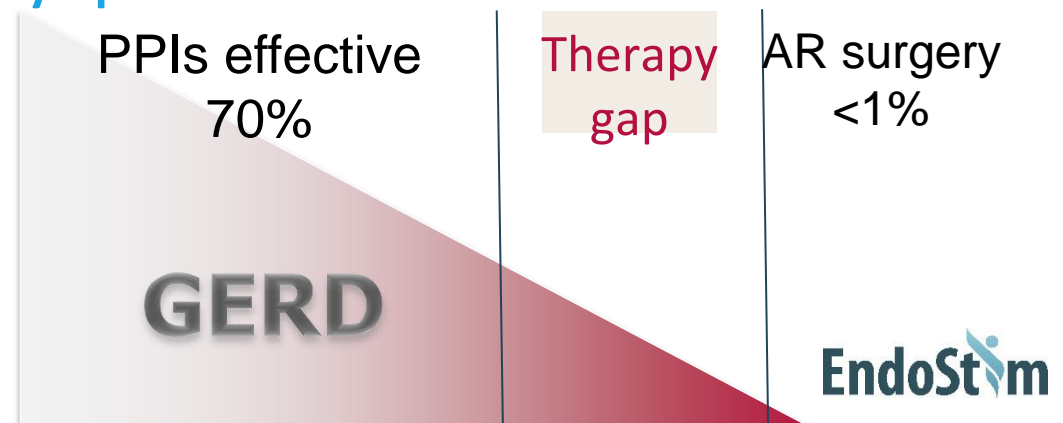


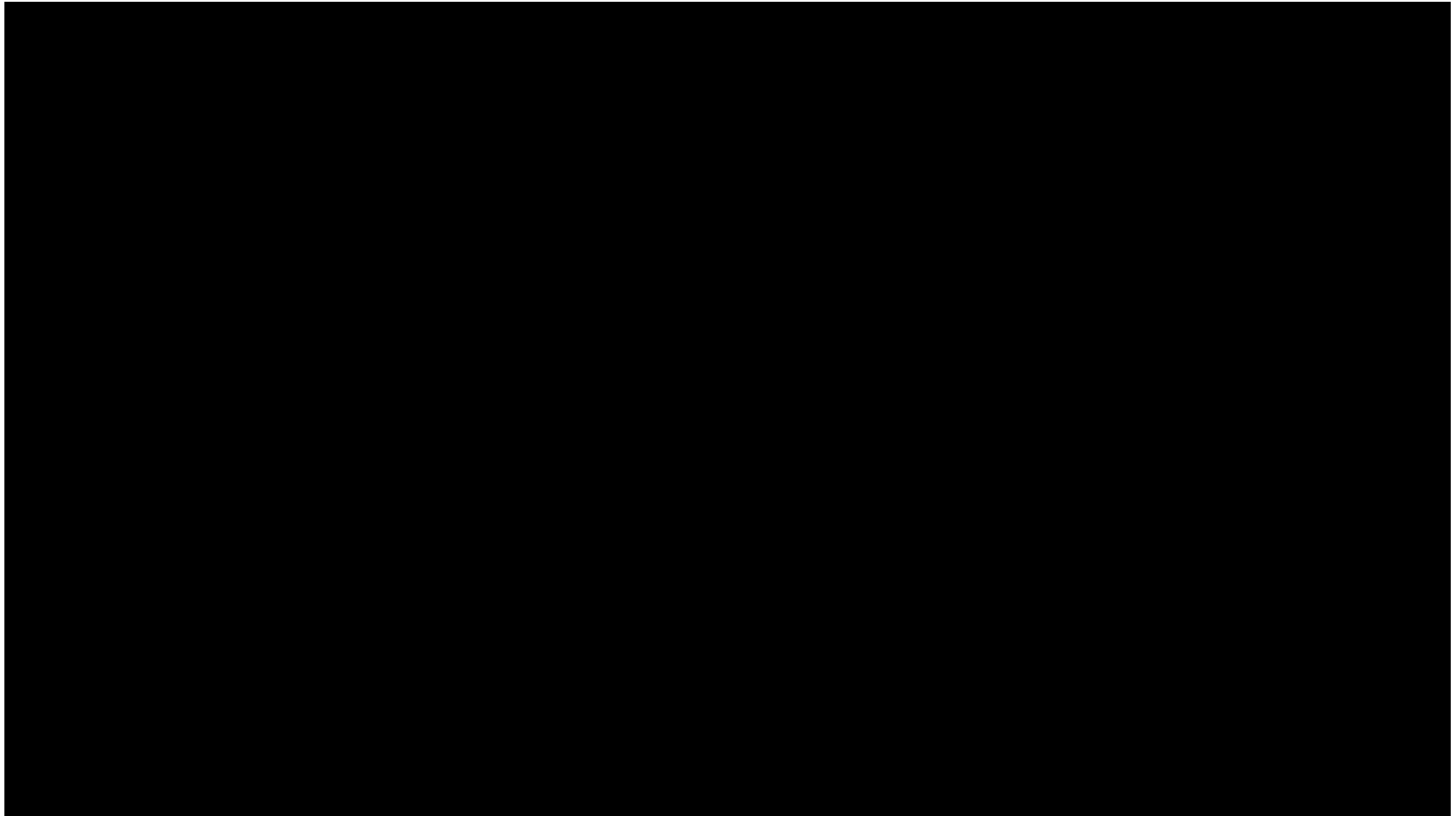
A weak LES allows stomach contents to flow back into the esophagus

A healthy LES closes completely after the passage of food

30% of GERD patients still have symptoms despite medication

- Sleep disruption
- Ongoing regurgitation
- Ongoing heartburn
- Reflux-related pain
- Vocal impairment
- Respiratory complications

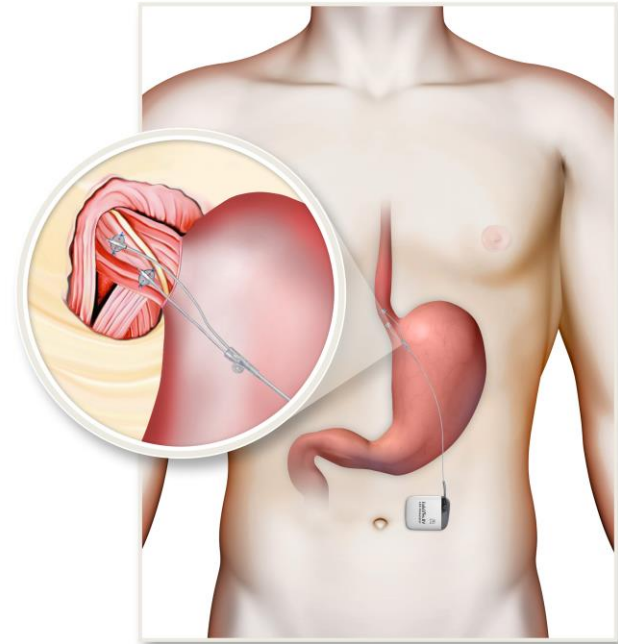




EndoStim's Solution for the "Lost Patient"

Long-term option for GERD patients unsatisfied on PPI

- ✓ Effective long-term barrier to acid
- ✓ Relieves regurgitation and nighttime reflux
- ✓ Typically eliminates need for long-term daily PPI use
- ✓ Minimal impact on gastro-esophageal junction (GEJ) minimizes GI side effects
- ✓ Technically simple, minimizes operator variability
- ✓ Personalized therapy – Treatment can be wirelessly customized



First technology that restores the normal LES function to treat GERD

EndoStim

Excellent Clinical Outcomes

Published clinical trials show that most patients experience:

- ✓ Resolution of regurgitation and heartburn
- ✓ Significant improvement in sleep issues related to reflux
- ✓ Elimination of dependency on PPI medication
- ✓ Long-term normalization of acid exposure and esophageal function

Recent publications:

Soffer E, et al. World J Gastrointest Pharmacol Ther. 2016;7(1): 145-155.

Kim SE, et al. Clin Exp Gastroenterol. 2016; 9:11-19.

Rodriguez L, et al. Surg Endosc. 2015; DOI 10.1007/s00464-015-4539-5.

Kappelle W, et al. Aliment Pharmacol Ther. 2015 Sep;42(5):614-25.

Rodriguez L, et al. Surgery. 2015; 157(3):556-567.



Siersema PD, et al. Gastroenterology. 2016; 150(4):S216.

Rinsma NF, et al. Gastroenterology. 2016; 150(4):S478.

Rodriguez L, et al. Gastroenterology. 2016; 150(4):S476.

Labenz J, et al. Gastroenterology. 2016; 150(4):S478.



Nieponice A, et al. Surg Endosc. 2016; 30:S263.

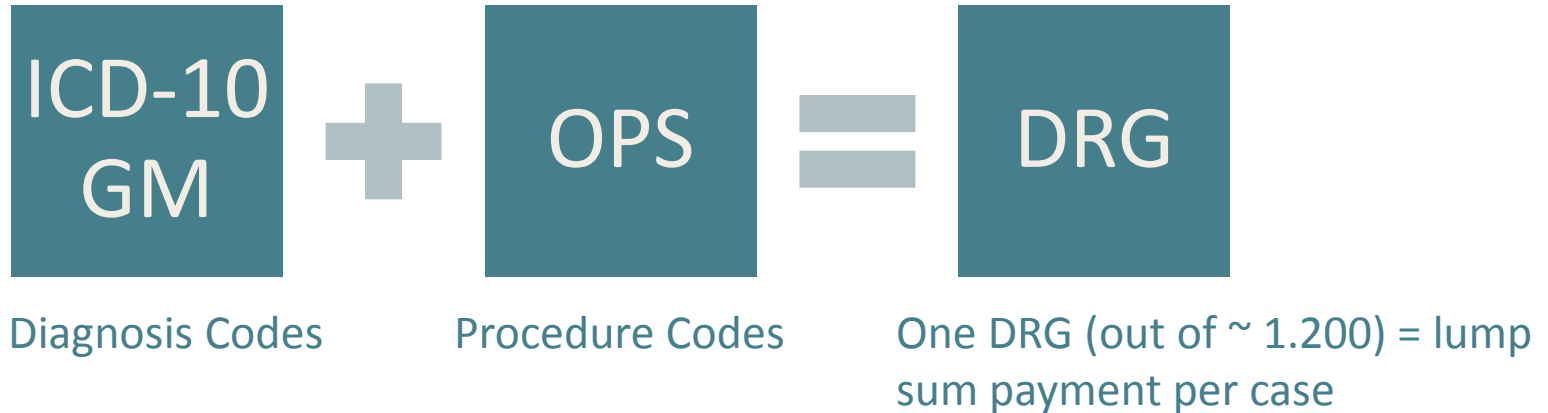


Attwood SE, et al. UEG Journal. 2015; 3(5S):A295.

Schulz HG, et al. UEG Journal. 2015; 3(5S):A294-295.



Reimbursement Germany - Running costs per case



Apart from DRGs:

Innovation payments NUB:

NUB Status 1 - 2 - 3 - 4

1=NUB granted, 2=not granted, 3 = not enough data to assess the method, 4 = implausible information

Extra rates (**ZE** - Zusatzentgelt)

Timeline: Milestones EndoStim in Germany



EndoStim
receives
CE Mark

EndoStim
receives
NUB Status 1

Implementation
of a
**new, specific
OPS code +
initial DRG
assignment**

**NUB Status 1
renewed**

**DRG
application**

**NUB Status 1
renewed**

**New DRG
assignment**

**NUB Status 1
renewed**

Success Factors: Intelligence

Need

Market

Users

Partners

- Business Case
- Distribution channel
- Reimbursement Strategy

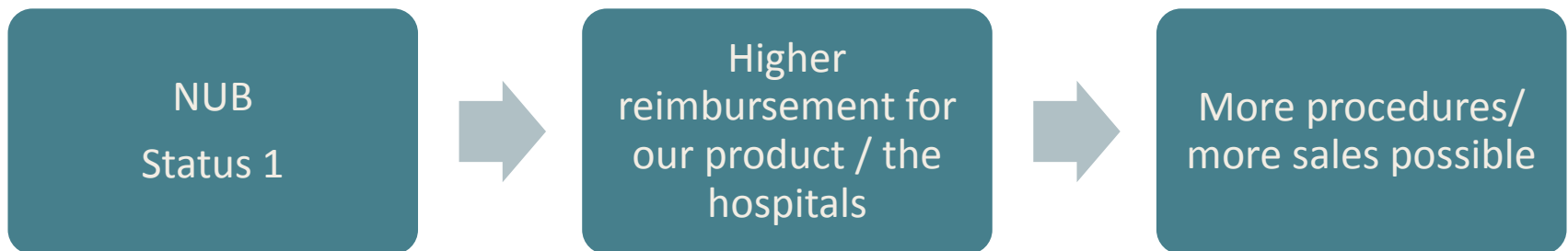
Action plan

Success Factors: NUB

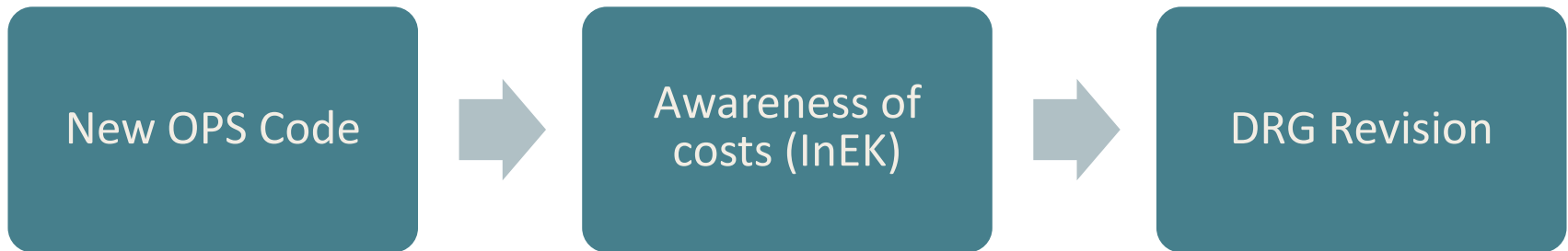
2013	2014	2015	2016
Status 1	Status 1	Status 1	Status 1
9 Hospitals	40 Hospitals	65 Hospitals	89 Hospitals
„Elektrostimulationssystem zur Behandlung der gastroösophagealen Refluxkrankheit ² “			
No. 58	No. 55	No. 62	No. 71

NUB Status:

1=NUB granted, 2=not granted, 3 = not enough data to assess the method, 4 = implausible information



Success Factors: OPS Codes



5-429.r Implantation of an antireflux stimulation system

5-429.s (Partial) exchange of antireflux stimulation system

5-429.s0 Complete exchange

5-429.s1 Probe exchange

5-429.s2 Unit exchange

5-429.t Removing an antireflux stimulation system

Success Factors: DRG Shift

Initial DRG assignment:

G19C/G19B

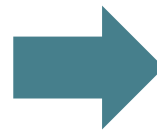


New DRG assignment:

G04A

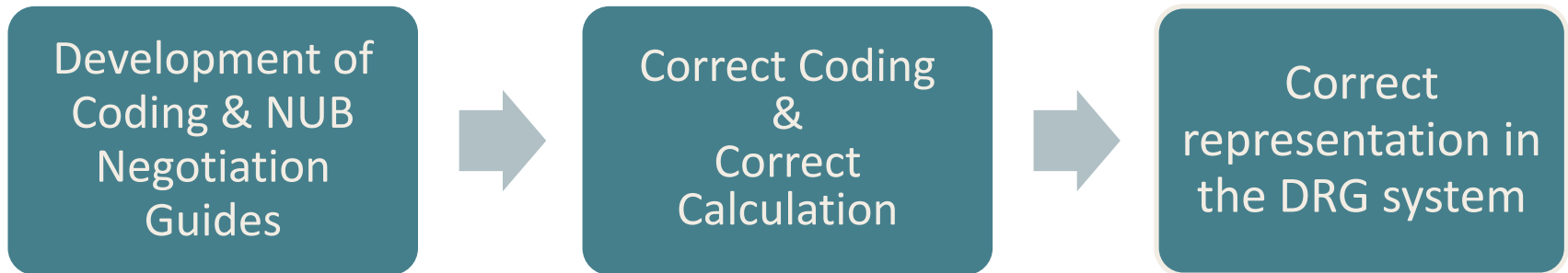
- Essential supporting factors:
 - Well-prepared argumentation lines in the application
 - Cost data in the DRG system
 - Support by Medical Association

G19C: 5.017,65 €* /
G19B: 8286,57 €*



G04A: 10.750,69 €

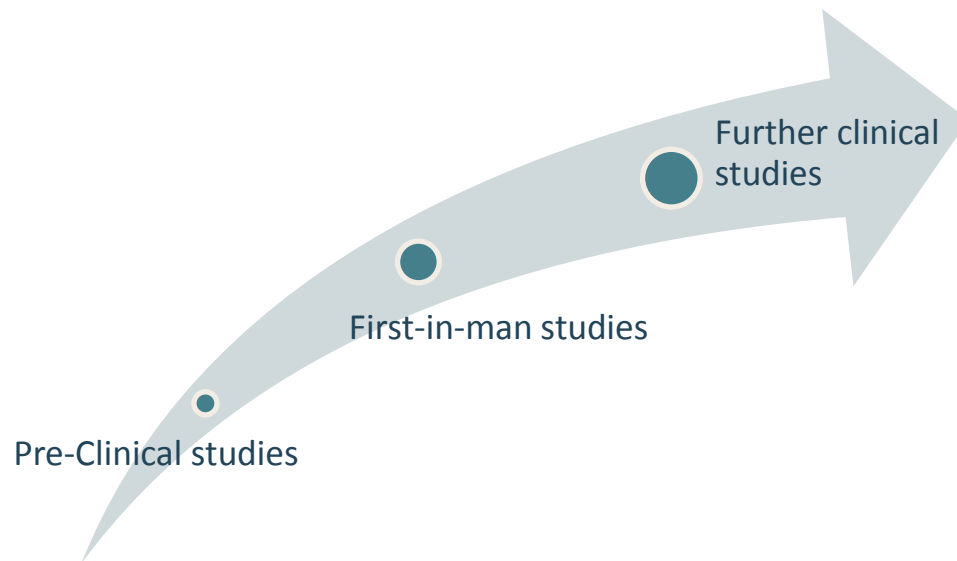
Success Factors: Coding & Negotiation Guides



- Coding guides help to ensure the correct coding of the procedure and the correct DRG assignment
- NUB negotiation guides help the customer centers to correctly calculate and successfully negotiate innovation payments
- Together, they help to show the correct costing data inside the DRG system and to ensure an adequate DRG representation

Success Factors: Growing Evidence Basis

- Clinical work: Safety, Efficacy, Quality of Life & Economic Efficiency
- Supporting reimbursement activities
- Supporting uptake of the procedure, awareness & podium time
- Local data & registry = Enhancement of Customer-Relationship



Success Factors: KOL management

Training

Supply

Reimbursement Support

Help in case of queries
(clinical questions, coding,
payer evaluations)

Success Factors: The Team

➤ Essential: People on site, in Germany with corresponding language skills

- Training
- Supply
- Support

... for our customers

➤ Growing team

➤ Optimal mixture of team members

Summary

Key factors for success:

- Clinical need
- Intelligent solution for the need
- Market intelligence & strategy
- Good partners to work on the reimbursement challenges
- A trained team being on site in Germany

Thank you for your attention!

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