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
**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.

30% of GERD patients still have symptoms despite medication:
- Sleep disruption
- Ongoing regurgitation
- Ongoing heartburn
- Reflux-related pain
- Vocal impairment
- Respiratory complications

PPIs effective 70%  
Therapy gap
AR surgery <1%

A weak LES allows stomach contents to flow back into the esophagus.
A healthy LES closes completely after the passage of food.
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
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:
Reimbursement Germany - Running costs per case

ICD-10 + OPS = DRG

Diagnosis Codes + Procedure Codes = One DRG (out of ~ 1,200) = lump sum payment 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

- **2012**: EndoStim receives CE Mark
- **2013**: EndoStim receives NUB Status 1
- **2014**: Implementation of a new, specific OPS code + initial DRG assignment
- **2015**: DRG application
- **2016**: 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

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„Elektrostimulationssystem zur Behandlung der gastroösophagealen Refluxkrankheit“

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

NUB Status 1

- Higher reimbursement for our product / the hospitals
- More procedures / more sales possible
Success Factors: OPS Codes

New OPS Code: 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: 8,286,57 €*

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

Pre-Clinical studies
First-in-man studies
Further clinical studies
Success Factors: KOL management

- Training
- Reimbursement Support
- Supply
- 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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