Bridging from off- to on-label

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Disclosures

- William Cook Europe/Cook Inc.
  - Consultant & Research Grants
- Getinge
  - Consultant
- Bentley
  - Part of “Early Launch” Group of the BeGraft PLUS
  - Consultant

Lay-Out

- Why Bentley
- Why BeGraft and BeGraft PLUS?

- Approval Study in Germany

Timelines BeGraft Peripheral

BeGraft peripheral

BeGraft peripheral

BeGraft+ peripheral

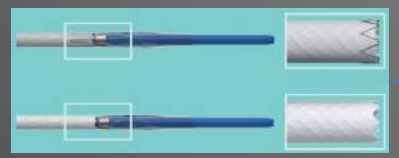
2013 — Launch BeGraft peripheral

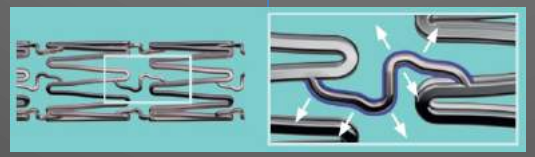
2014

2015 — Launch BeGraft peripheral - modified design -

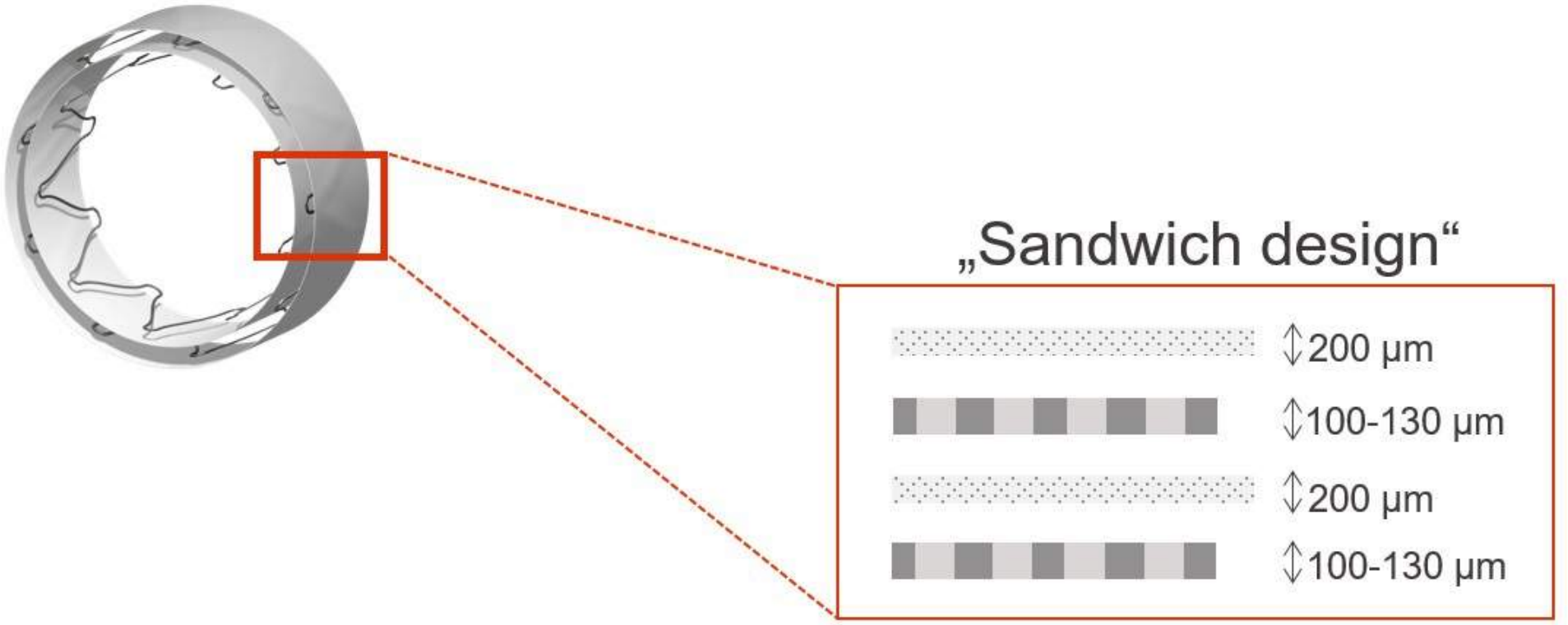
2016

2017 — Launch BeGraft peripheral PLUS





BeGraft PLUS



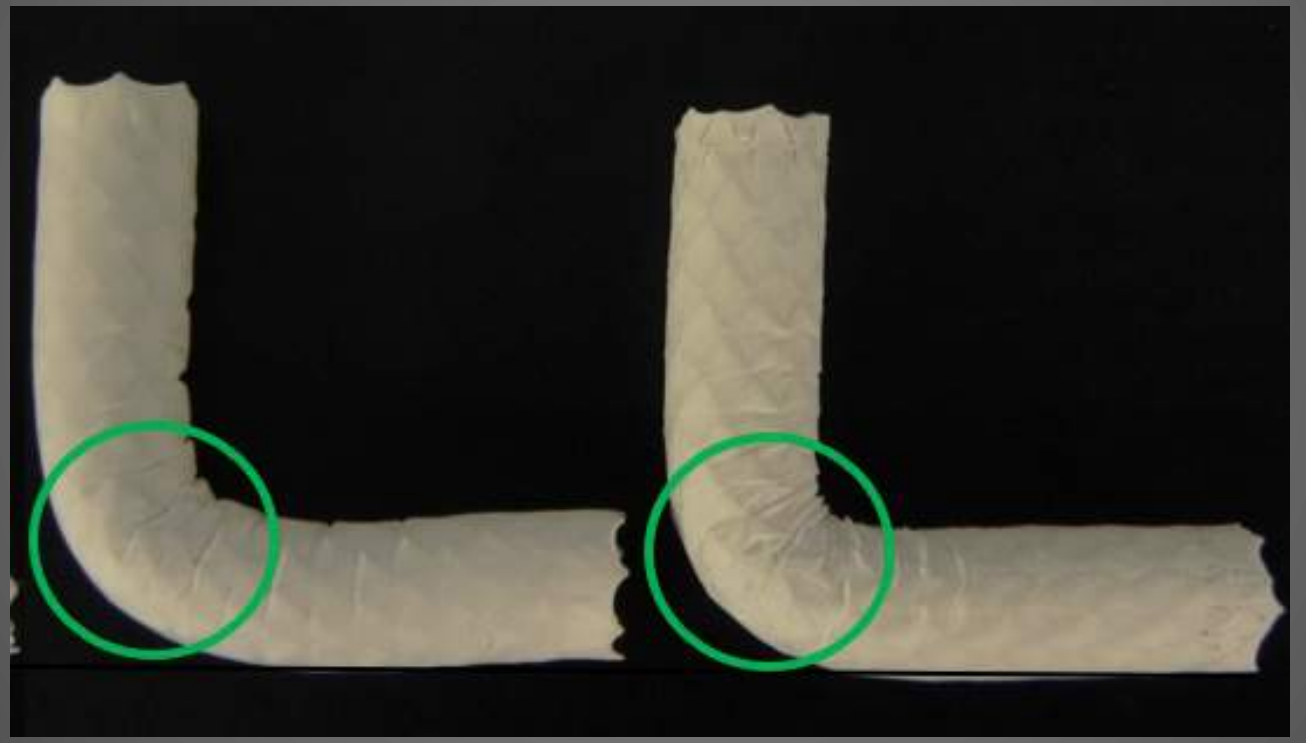
Why Bentley?

- Clear interest in development of dedicated covered stents for Fenestrations and Branches
- Factory in Germany
- Reliable Logistics

Lay-Out
Why BeGraft and BeGraft PLUS?

- First Impression (tactile)
- Testing by the Company
- First Clinical Experience
- Logistics

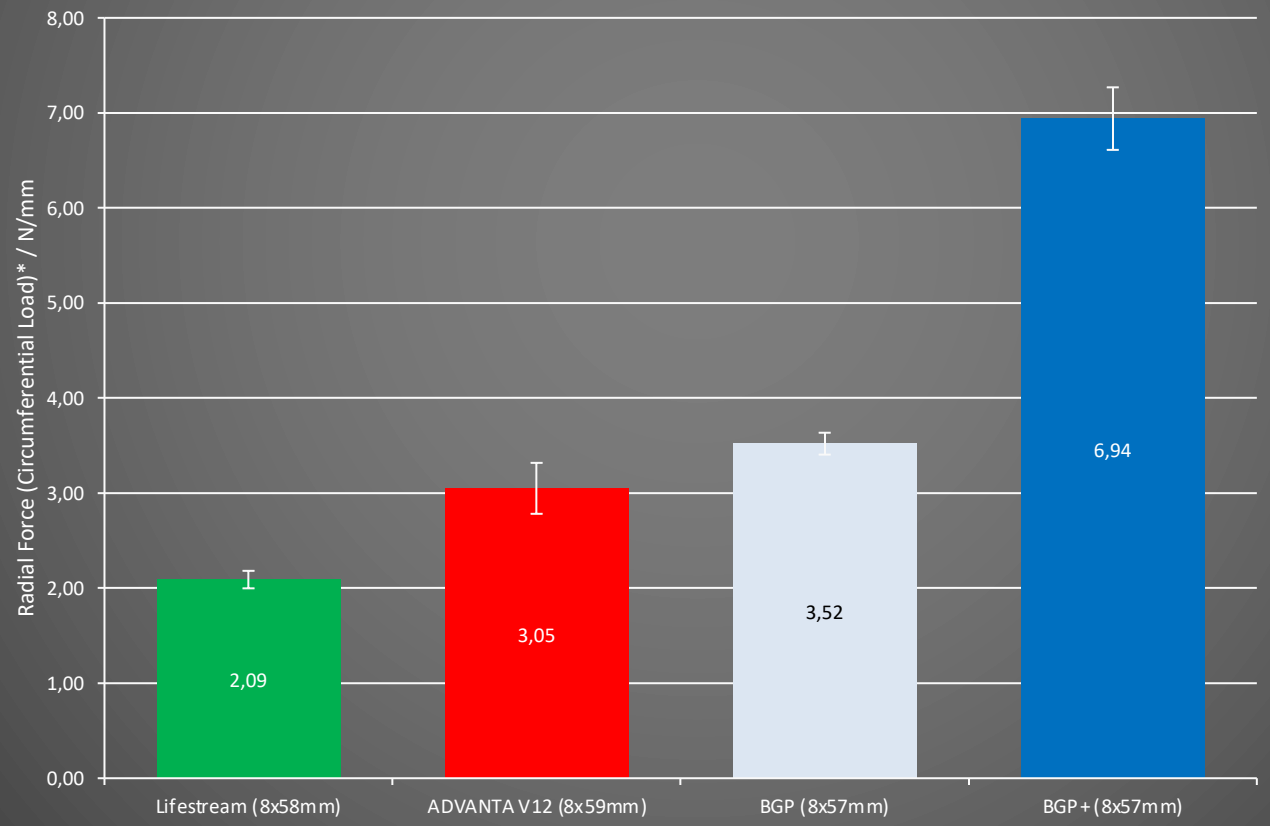
Performance: Kink Resistance



BeGraft
(8x57mm)

BeGraft PLUS
(8x57mm)

Performance: Radial Force
(Circumferential Load)



First Experience

- BeGraft in Fenestrations
  - Visibility and Handling ++
  - Available in all diameters and lengths
    - Lengths: 22/23, 27/28, 37, 57
  - 6F compatible
- BeGraft+ in Branches
  - High radial force, kink-resistant and flexible
  - Visibility and handling ++
  - 7F compatible

Nürnberg Experience with Be-Graft
(initially mainly length 27-28mm)

- Patients: N=232 (BeGraft: N=524)
  - All fenestrations
- Outcome
  - Technical issues: N=6
    - N=5: Stent migration due to reinsertion sheath
    - N=1: Too short in Fenestration SMA (need to add a 8x27 into a 7x37)
  - Occlusions: N=2 (0.5%)
  - Endoleaks: N=1

Nürnberg Experience with BeGraft+
(initially tested in „difficult anatomy“)

- Patients: N=132 (BeGraft+: N=275)
  - Branches in TAAA patients: N=230
  - IBD branches: N=45
- Related Complications and Outcome
  - Disconnection due to advancement of sheath: N=1
  - Occlusion: N=3 (1.4%) (due to Transition Problem, N=2)
  - Difficult insertion in steerable sheath: N=5

Problem

- All Bridging Stentgrafts in FEVAR/BEVAR are OFF-LABEL

Study

- Purpose: provide an on-label indication for use of the BeGraft in Fenestrations

- Physician-Initiated Trial Investigating the BeGraft Stent Graft System as bridging stent in FEVAR for complex aortic aneurysms

Trial Design

- Prospective, single arm, multi-center, clinical study
- 9 Clinical Centres in Germany

  Nürnberg (Verhoeven) / Münster (Austermann) / Munich (Tsilimparis) / Regensburg (Pfister) / Aachen (Kotelis) / Stuttgart (Geisbüsch) / Gießen (Kalder) / Freiburg (Czerny) / Hamburg (Kölbel)
- 100 Patients (expected: about 250 BeGrafts)

Objective

- To evaluate the safety and performance of the BeGraft balloon expandable covered stent Graft System (Bentley Innomed, Hechingen, Germany) implanted as bridging stent in FEVAR (fenestrated endovascular aortic repair) for complex aortic aneurysms

Primary Endpoints

- Efficacy endpoint
  a. Technical success, defined as successful introduction and deployment of the BeGraft
  b. Bridging stent patency at 12 months, defined as absence of restenosis (≥50% stenosis) or sole target vessel occlusion based on CT Angio at 12 months
- Safety endpoint
  – Absence of procedure related complications and bridging stent related endoleaks at 12 months.

Secundary Endpoints

1. Bridging stent patency post-op and at 6-months
2. Freedom from bridging stent related endoleaks post-op and at 6 months
3. Freedom from bridging stent related secondary intervention
4. Freedom from type I & III endoleaks post procedure and at 6 and 12 months
5. 30-day mortality
6. Freedom from stent graft migration, freedom of fracture or dislocation of bridging stent.
7. Freedom from AAA diameter increase at 6 and 12 months as compared to post-op implantation
8. Freedom from aneurysm related secondary endovascular procedures
9. Freedom from conversion to open surgical repair post procedure and at 6 and 12 months
10. Freedom from aneurysm related mortality post procedure and at 6 and 12 months
11. Freedom from aneurysm rupture within 12 months post-implantation
12. Freedom from any major adverse events post procedural and at 6 and 12 months
13. Health Related Quality of Life scores at 12 months post implantation

Conclusions

- Bentley is the first Medical Company to support a physician-initiated trial to finally achieve on-label indication for a covered stent in FEVAR

- Studies:
  - Begraft Study in FEVAR: inclusion almost complete
    - First report on 1-month outcome expected soon
  - *BeGraft PLUS Study in BEVAR is also running!*