MicroNET-Covered Self-EXpandable STent In High-Risk Vascular Lesions Beyond The CArotid Bifurcation: The EXTRA-GUARD Multi-center Multi-specialty Study


Addressing unmet endo-vascular needs...

Symptomatic, Thrombotic High-risk iliac
Symptomatic, v. large plaque burden Subclavian
V. Highly-Symptomatic (NSTEMI) Large-Diameter Thrombotic Saphenous Vein Graft
V. Highly-Calcific Large-Diameter Thrombotic Saphenous Vein Graft
TIAS -> Retinal Stroke ostial CCA

...beyond the carotid bifurcation

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**Background**

Thrombotic (T), Highly-Calcific (HC) and High-plaque burden (HPB), symptomatic arterial lesions pose a significant clinical and procedural challenge in vascular medicine because of the risk of embolism (on the one side of the complication/risk spectrum) and perforation (on the other); the endovascular procedures in T, HC and HPB are often hard - or impossible - to optimize using conventional stents.

**The Device**

**CGuard™ Embolic Prevention Stent System**

<table>
<thead>
<tr>
<th>System specifications</th>
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</thead>
<tbody>
<tr>
<td>Stent type</td>
<td>Nitinol – self expanding</td>
</tr>
<tr>
<td>Micronet aperture size</td>
<td>150-180 μm</td>
</tr>
<tr>
<td>Guidewire</td>
<td>0.014”</td>
</tr>
<tr>
<td>Sizes</td>
<td></td>
</tr>
<tr>
<td>- Diameter</td>
<td>6-10mm</td>
</tr>
<tr>
<td>- Length</td>
<td>20-60mm</td>
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</tbody>
</table>

This stent design performs very well in high-risk (such as thrombotic & highly calcific) carotid lesions.

Nitinol frame open-cell area ≈ 21 mm²

MicroNet closed-cell area ≈ 0.3mm²

LARGEST

SMALLEST
Aim

- To evaluate feasibility/efficacy of the CGuard™ Embolic Prevention Stent System use to address unmet needs in consecutive high-risk angioplasty (symptomatic T, HC, HPB) in vascular beds beyond the carotid bifurcation.

Methods

- Multi-center, multi-specialty study in high-risk (T, HC and HPB) endovascular revascularization

- Currently 25 consecutive patients recruited (9 women); 31 arteries treated

- Mandatory clinical and CT angiographic follow-up at 6-12mo

Already completed in 17 (in-the-window) out of the presently total 25 subjects

References

Thrombus-containing / ruptured lesions

Safe & Effective endovascular reconstruction in absence of restenosis
Thrombus-containing / ruptured lesions

Safe & Effective endovascular reconstruction in absence of restenosis
EXTRA-GUARD Study

Thrombus-containing / ruptured lesions

Safe & Effective endovascular reconstruction in absence of restenosis
Highly-calcific lesions

Safe & Effective endovascular reconstruction in absence of restenosis
High-risk Ostial Lesions
(note adequate radial force and placement precision)

OPTIMAL angiographic + clinical + duplex result @ 12mo
(and LECA patent)

Safe & Effective endovascular reconstruction in absence of restenosis
MicroNET-Covered Self-**EX**pandable **ST**ent In High-**R**isk Vascular Lesions Beyond The **CA**rotid Bifurcation: The **EXTRA**-GUARD Multi-center Multi-specialty Study

**Conclusions**

- The MicroNET-Covered self-expandable stent system is well-suited to address unmet needs in high-risk PTA beyond the carotid bifurcation due to its unique mechanical properties (very high conformability and optimal radial force combined with plaque sequestration).

- The lesion spectrum extends from high-thrombus burden to high-calcium burden, through complex ostial lesions where this stent specific behavior (including lack of foreshortening/elongation) enables high placement precision.

- Sealing properties of the MicroNET enable gradual, large-balloon, high-pressure optimization of the angiographic effect – and absence of residual stenosis.

- EXTRA-GUARD study procedures showed no procedural complications, no device-related issues, and optimal clinical and (per-protocol mandatory) CT angio result at 6-12months.

- The study demonstrates full, optimal, endovascular reconstruction in absence of restenosis in vascular beds beyond the carotid bifurcation, consistent with **ENDOVASCULAR RECONSTRUCTION of normal anatomy**

***Combined properties of self-expandable and balloon-expandable stent PLUS plaque sequestration***

Supported by a research grant from the Jagiellonian University Medical College (ZDS/007819)
**STUDY UPDATE**

**PARADIGM – Extend**

402 patients / 436 arteries (f/u ≥30d; 31 Aug 2019)

- **Peri-procedural outcome**
  - 0 death/major stroke – 0%
  - 1 minor stroke – 0.25%
  - 1 MI (type2) – 0.25%

- **By 30 days**
  - 1 haemorrhagic transformation of prior ischaemic cerebral infarct leading to death – 0.25%
  - 1 bleeding-related death – 0.25%

1 haemorrhagic transformation of prior ischaemic cerebral infarct leading to death – 0.25%

**NB. ALL-Comer, Unselected Population** (eg. AFib 8.9%)

<table>
<thead>
<tr>
<th></th>
<th>1-12 mo</th>
<th>13-24 mo</th>
<th>25-36 mo</th>
<th>37-48 mo</th>
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<tbody>
<tr>
<td><strong>ipsilateral stroke</strong></td>
<td>0</td>
<td>0</td>
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<tr>
<td><strong>any stroke</strong></td>
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<td>2</td>
<td>1</td>
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<td><strong>stroke-related death</strong></td>
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<td>1</td>
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<tr>
<td><strong>MI or other non-cerebral VA</strong></td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
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<tr>
<td><strong>any death</strong></td>
<td>13</td>
<td>10</td>
<td>6</td>
<td>4</td>
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<tr>
<td><strong>in-stent velocities</strong></td>
<td>PSV 0.79±0.41 m/s</td>
<td>PSV 0.75±0.36 m/s</td>
<td>PSV 0.75±0.36 m/s</td>
<td>PSV 0.74±0.28 m/s</td>
</tr>
<tr>
<td></td>
<td>EDV 0.21±0.11 m/s</td>
<td>EDV 0.19±0.09 m/s</td>
<td>EDV 0.20±0.09 m/s</td>
<td>EDV 0.20±0.07 m/s</td>
</tr>
</tbody>
</table>

**Total**

30-day death/MI/any stroke – 0.995% (4/402)

**no post-proc. ischaemic stroke by 30 days** – 0.0% (0/402)

Normal in-stent velocities; Low ISR rate: n=1 by 12mo, total of n=4; effective DEB-PTA