
***Ambulatory mamagement for PAD endovascular treatment***

# 5F Devices with 0.035”

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# Is there a need for low profile delivery systems?

- Historical trend toward smaller profile devices.
- Increasing operator's preference for radial, brachial, and antegrade femoral approach
- Increasing outpatient treatment – same day discharge
- Fewer complications
- Less time applying pressure
- Decreased need for closure
- Fewer sheath exchanges

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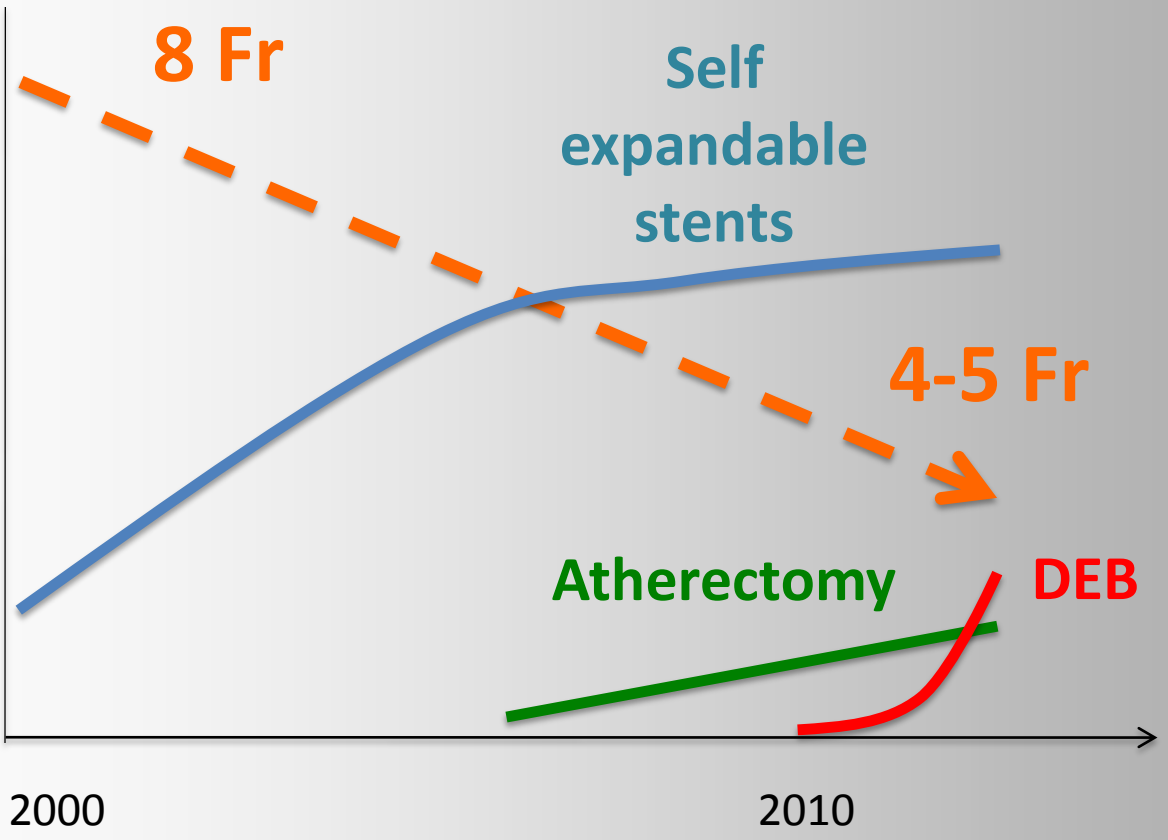
# Historical trends of technological innovations in lower limb revascularization



# Advantages of the 5-French approach

- Elective brachial approach (early mobilization)

- Mandatory brachial approach

- Less invasive 5-French femoral approach (both antegrade and cross over)

- Standard 6 F approach with possibility to inject contrast day during the entire procedure

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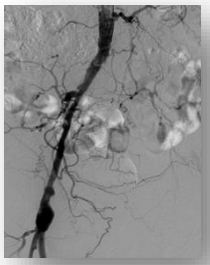
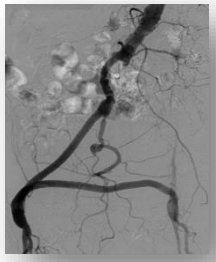
**- Previous surgery (aorto-bifemoral by-pass)**
**- Previous surgery (cross-over by-pass)**
**- Presence of aortic endoprothesis**
**- Iliac occlusion in the contralateral limb**
**- Iliac kissing stents**
**- Hostile groin**

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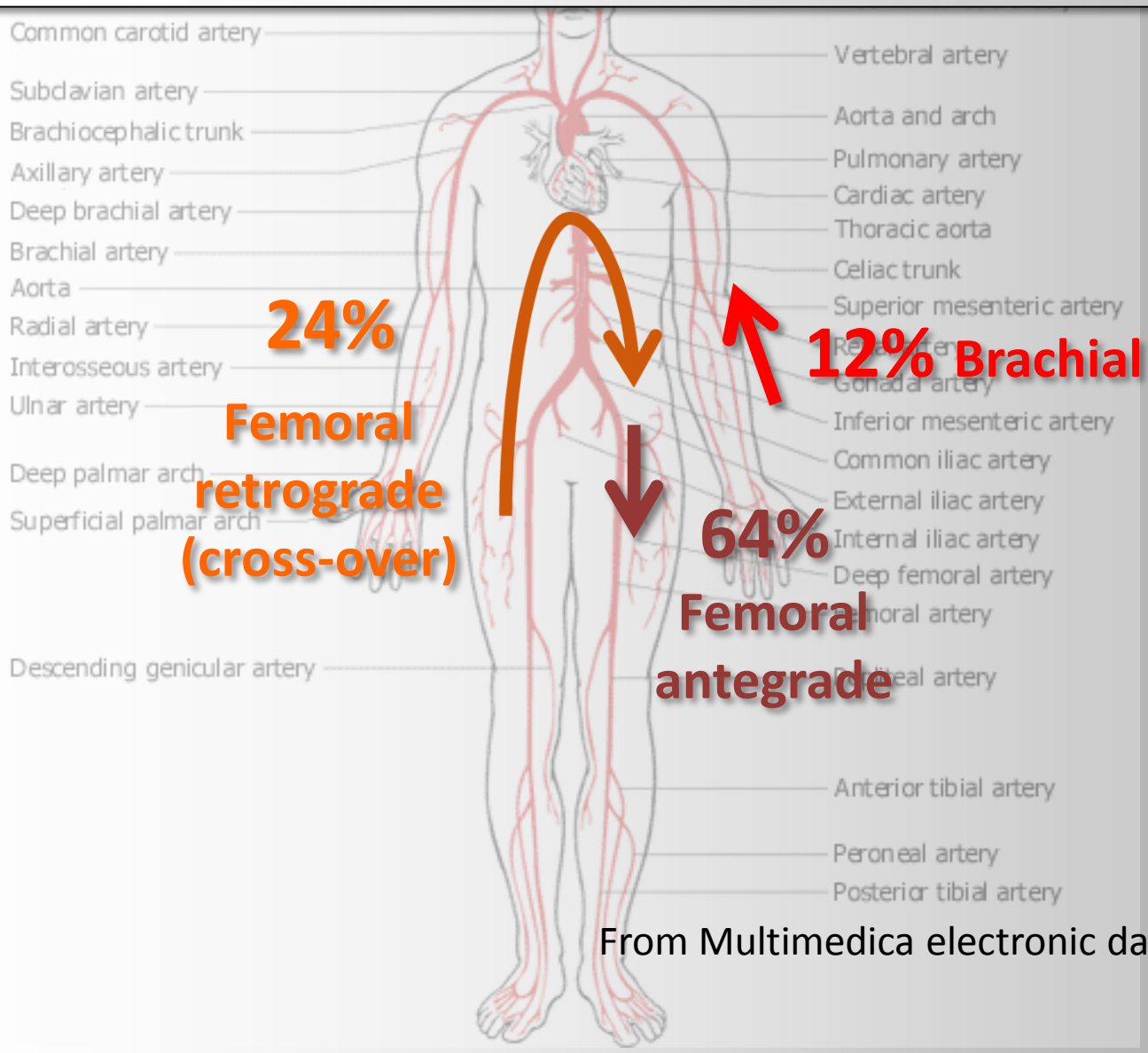
# Access route for endovascular lower limb revascularizations




From Multimedica electronic database, Milan - Italy

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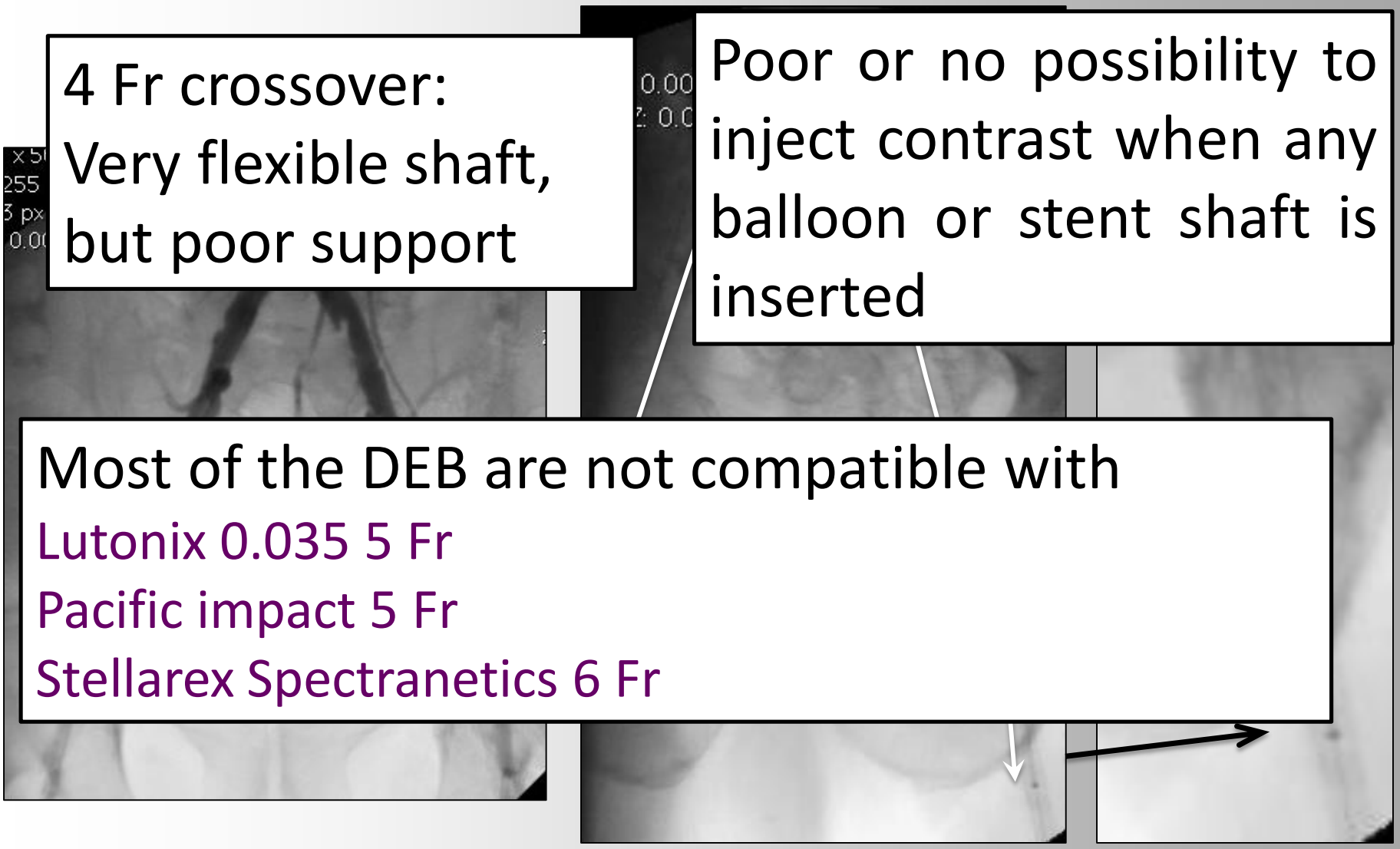
# PERCUTANEOUS TREATMENT OF CLI
## Minimal invasive 4 french cross-over approach



4 Fr crossover:
Very flexible shaft,
but poor support

Poor or no possibility to inject contrast when any balloon or stent shaft is inserted

Most of the DEB are not compatible with
Lutonix 0.035 5 Fr
Pacific impact 5 Fr
Stellarex Spectranetics 6 Fr

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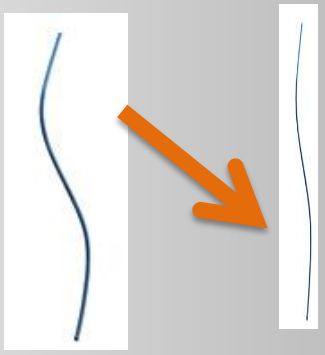
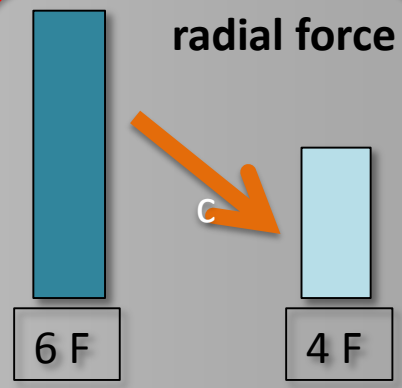
# Current Low Profile Systems Require Trade-offs

| | | | |
|---|---|---|---|
| **Current Products** | Most catheters are ≤135 cm | 0.018” or 0.014” guidewire compatible | Compromise radial force to achieve lower profile |
| **Need** | Longer catheter lengths for brachial access | Workhorse 0.035” guidewire on low profile systems | Low profile systems with comparable stent **radial force** |

**guidewires**

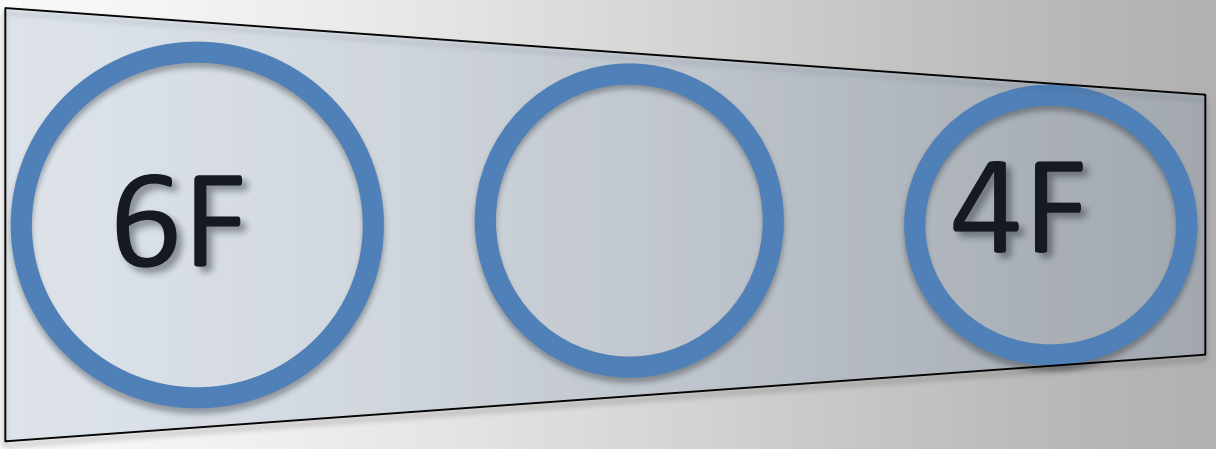


**radial force**




i-MEET NEXT GENERATION
Multidisciplinary European Endovascular Therapy

# Current attempt to downsize the nitinol stent systems



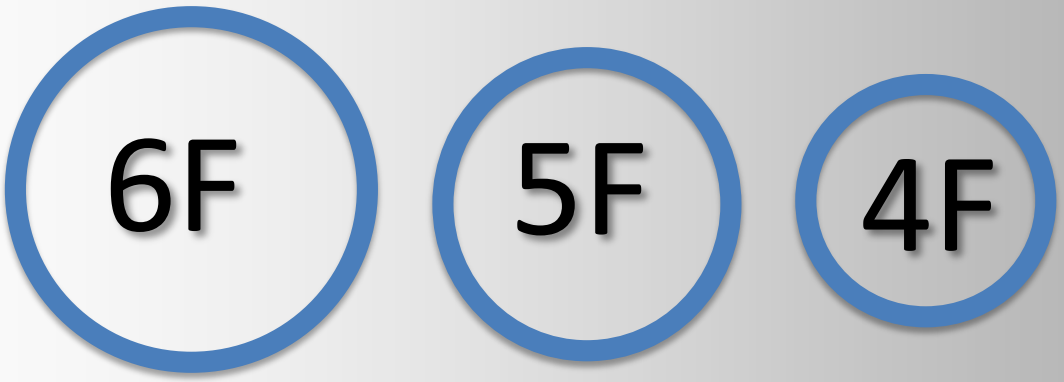

**PRO**

Improved trackability and flexibility

**CON**

Reduced radial force
Reduced longitudinal force
Reduced visibility
Need of 0.014” or 0.018” wires

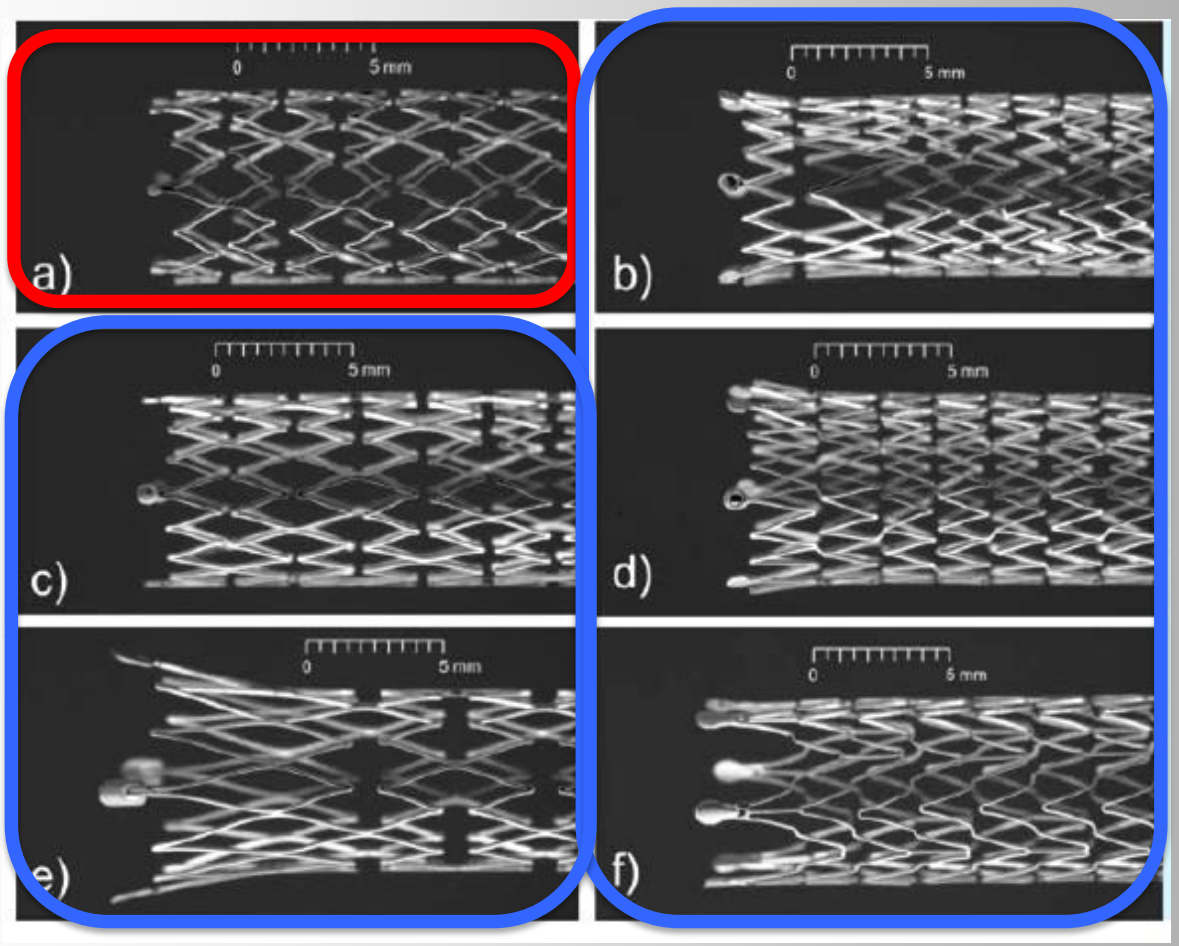
# Delivery system reduction from 6Fr to 5Fr




| | | | | |
|---|---|---|---|---|
| **Diameter** | 2.6 mm | 2.2 mm | 2.0 mm | 23% reduction |
| **Area** | 5.5 $mm^2$ | 3.8 $mm^2$ | 3.1 $mm^2$ | 43% reduction |

The 4F stents have thinner struts (160 μm) in comparison to 6F systems (200-230 μm)

**4 Fr**
(160 μm)



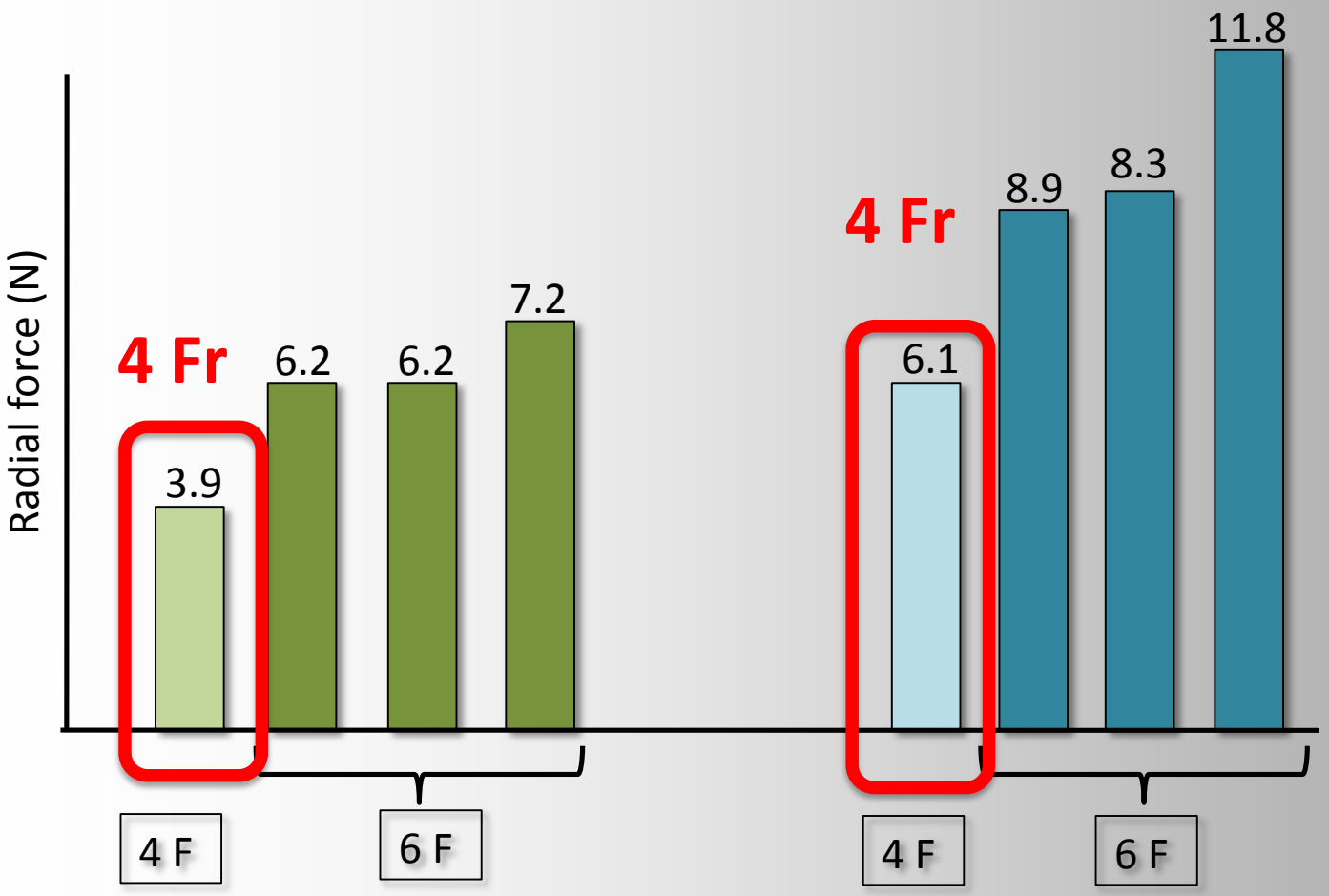

**6 Fr**
(200-230 μm)

*Schmitd W et al. Fortschr Rontgenstr 2011; 183:818-25*

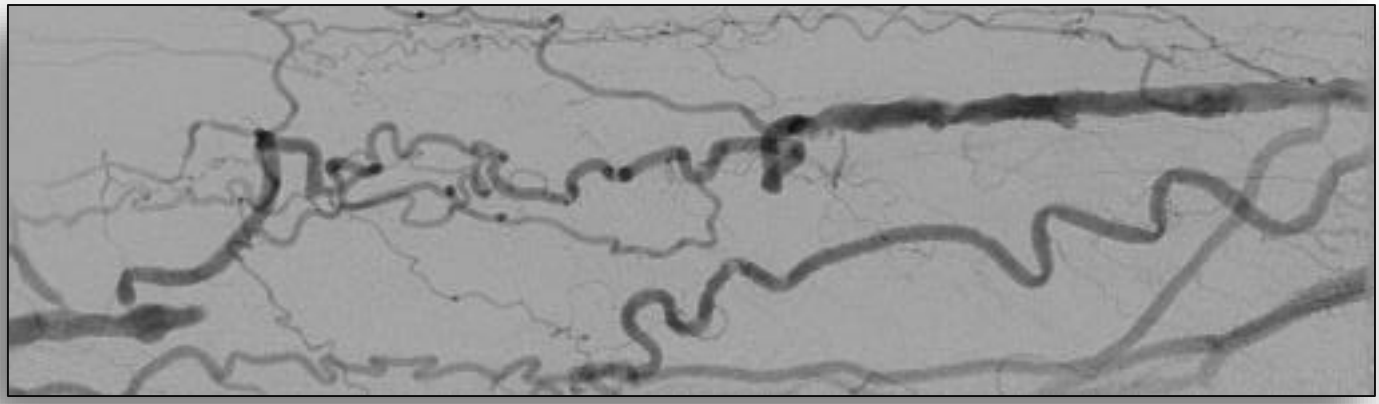
# Radial force of nitinol stents indicated for SFA

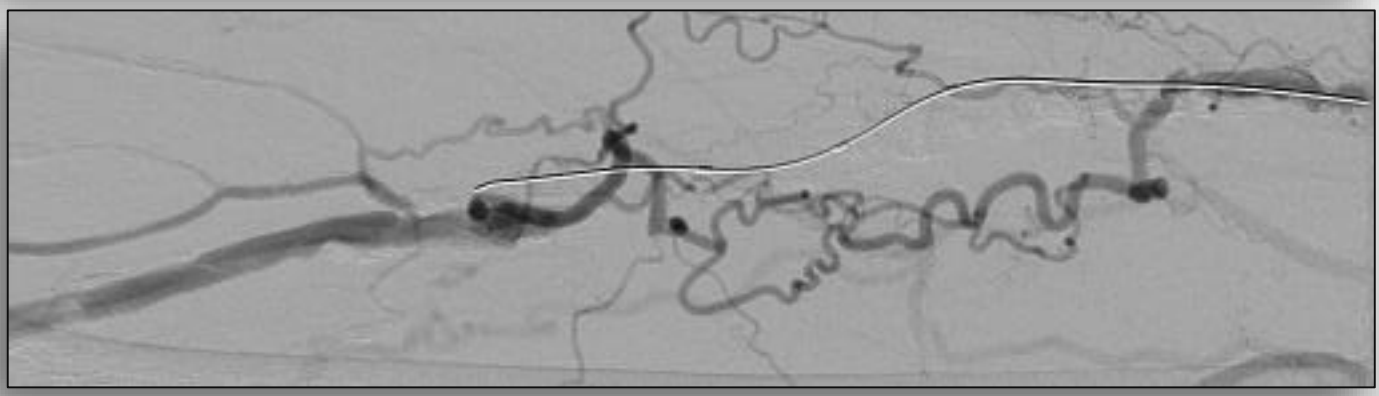
*7.0 x 80 mm nitinol stents expanded at **6 mm***

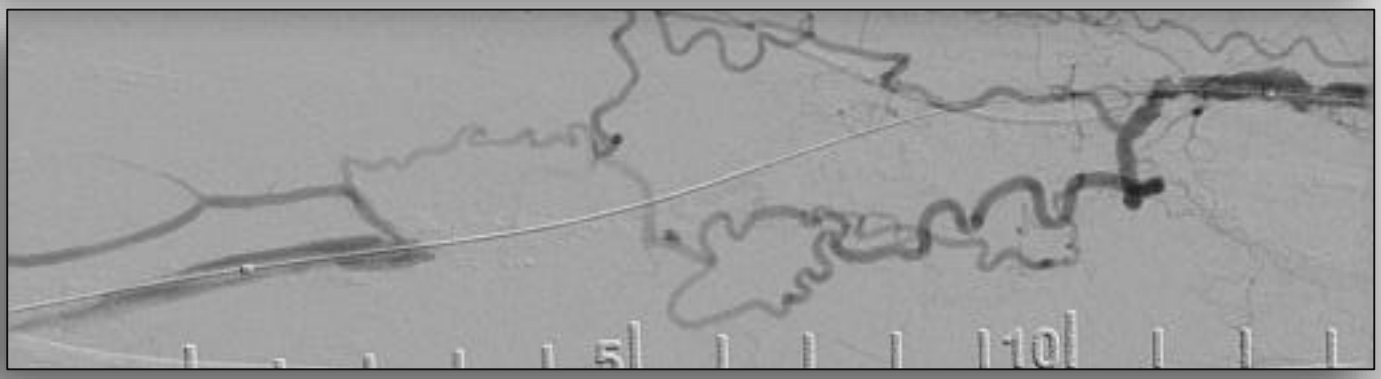
*7.0 x 80 mm nitinol stents expanded at **5 mm***




***Adapted from**:*
*Schmitd W et al. Fortschr Rontgenstr 2011; 183:818-25*



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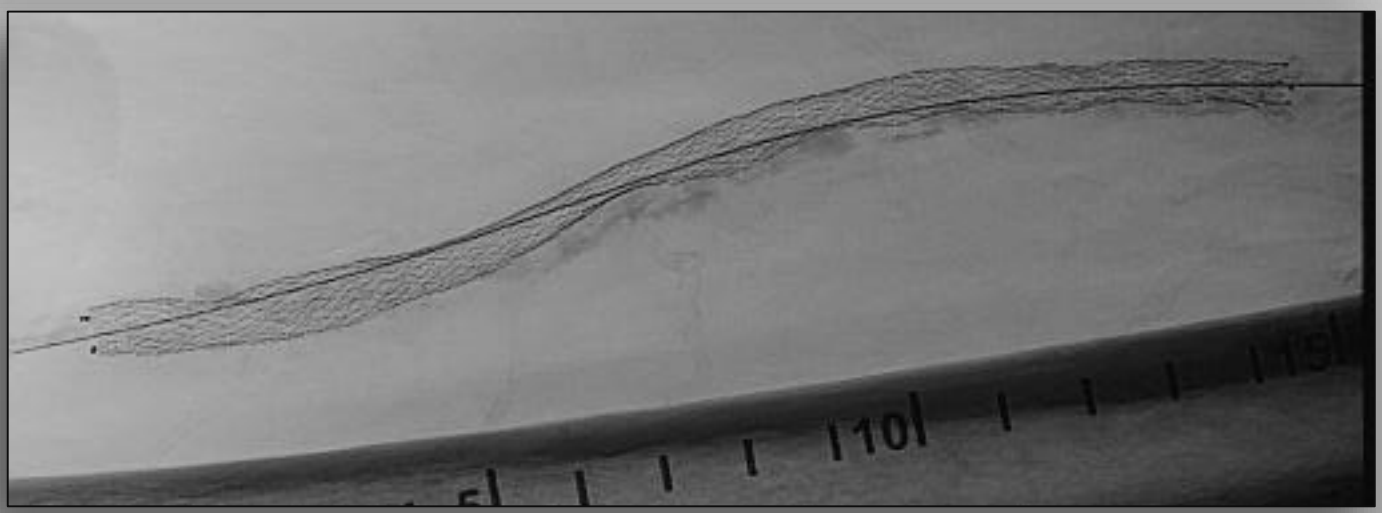
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# *The 0.035” 5-French systems*:

- MEDTRONIC COVIDIEN
- Everflex Entrust

  Diameters 5-8 mm lengths 20-150 mm

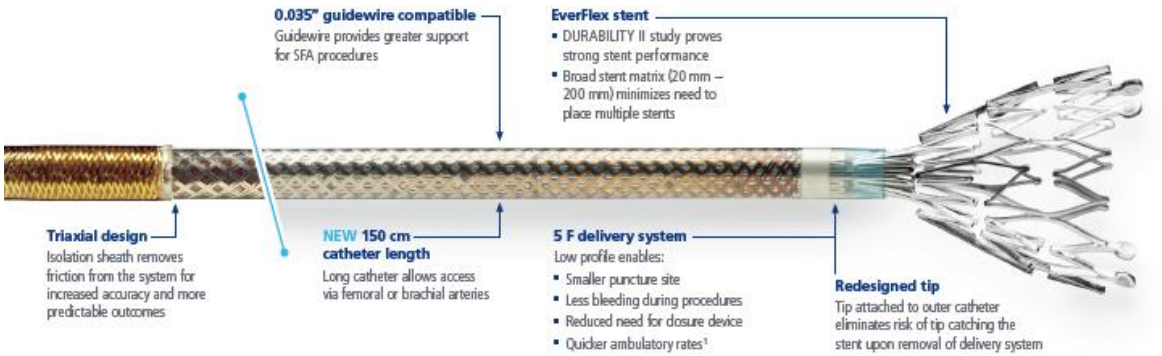
- OPTIMED

  Sinus Superflex 535

  Diameters 4-10 mm lengths 20-80 mm

# MEDTRONIC COVIDIEN Everflex Entrust system

Pin-pull delivery system




## Pin-Pull Delivery System

- Tip attached to inner catheter
- Tip and inner go through stent during retrieval

## Entrust Delivery System

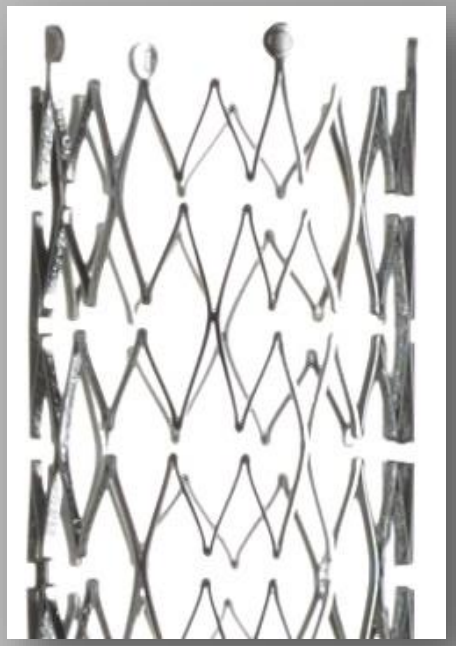
- Tip attached to retractable outer sheath
- Only the wire goes through the stent during retrieval

# The EverFlex™ Stent Clinically Proven Performance: DURABILITY II

A proven stent patency rate at one year by Kaplan-Meier analysis[1]:

- Freedom from loss of primary patency
- - 77.2%
  - 86.2% in lesion lengths ≤ 80 mm
  - 69.6% in lesion lengths > 80 mm

- A low one-year stent fracture rate of 0.4%



# Conclusions

***The 0.035" 5-French systems***:

- Are clinically proven stents on a downsized device without trades-off in stent performance (radial force, vessel scaffolding, visibility)
- Are compatible with all the guidewires (up to 0.035")
- Have multiple shaft lengths (80-120-150 cm) to allow SFA stenting from multiple access (femoral, brachial)

The routine 4 Fr approach is not compatible with most of the DEB and create difficulties in correct visualization during balloon expansion and stent delivery.

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