Background

- Numerous randomized trials of drug-coated balloons (DCBs) have shown improved outcomes of DCB over percutaneous transluminal angioplasty (PTA) over the past 10 years.

- Published results of the IN.PACT SFA Trial have demonstrated superiority of the IN.PACT DCB over PTA.

- Numerous randomized trials with drug-coated balloons (DCBs) have shown improved outcomes of DCB over percutaneous transluminal angioplasty (PTA). This includes the IN.PACT SFA I and IN.PACT SFA II trials.

IN.PACT SFA I

- 331 patients enrolled: Prospective, multicenter EU and US, randomized (2:1), single-blinded trial.
- Subjects followed up to 5 years.
- External monitoring with 100% source data verification.
- Independent Safety Monitoring Board.
- Committee.

IN.PACT SFA II

- 181 subjects enrolled at 44 US sites.
- Apr 2012 to Jan 2013.
- Not assessed after 3 years.

CD-TLR

- Clinically-driven TLR: CD-TLR was adjudicated by an independent Clinical Event Committee.

Restenosis is assessed by the blinded Duplex and Angiographic Core Labs through the 3-year follow-up visits. Clinically-driven TLR: CD-TLR was adjudicated by an independent Clinical Event Committee.

5 Year Follow-up Assessment

- Clinically-driven TLR: CD-TLR was adjudicated by an independent Clinical Event Committee.

5 Year Results from the IN.PACT SFA Randomized Trial

John R. Laird, MD
Adventist Heart and Vascular Institute
St. Helena, CA

IN.PACT SFA Trial

Blinded, Independently Assessed Outcomes

5 Year Follow-up Assessment

- Clinically-driven TLR: CD-TLR was adjudicated by an independent Clinical Event Committee.

Disclosure Statement of Financial Interest

John R. Laird

- Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

- Scientific Advisory Board/Stock Options: Reflow Medical, Endoluminal Sciences, Syntervention, PQ Bypass, Eximo Medical, Shockwave Medical, Navien.


- Affiliation/Financial Relationship: Company

IN.PACT SFA Trial*: Overview

2. Schneider P. et al. Circ-CI 2018;11:15
3. Rosenfield K et al. NEJM 2015;373:145-53
4. LEVANT 2 2-Year Results. Presented by Laurich C, SVS Chicago 2015
5. Medtronic IFU M052624T0001_rev1H
### IN.PACT SFA Trial: Baseline Characteristics

|                   | IN.PACT (N=220) | PTA (N=111) | P-value
|------------------|-----------------|-------------|---------
| Age, Y ± SD      | 67.5 ± 9.5      | 68.0 ± 8.2  | 0.612   |
| Male, % (n)      | 62.0% (143/220) | 67.6% (75/111)| 0.713   |
| Diabetes, % (n)  | 40.5% (89/220)  | 48.6% (54/111)| 0.161   |
| Current smoker, % (n) | 35.8% (80/220) | 36.0% (40/111)| 0.719   |
| Rutherford class | 2   | 3           | 4   | 5   | 6   |
| 2%               | 37.7% (83/220)  | 37.8% (42/111)| 0.906   |
| 3%               | 57.2% (128/220)| 55.6% (62/111)| 5.4% (9/111)| 3.3% (7/111)| 0.898   |
| Lesion length (cm ± SD) | 8.94 ± 4.89 | 8.81 ± 5.12 | 0.315   |
| Total occlusions, % (n) | 25.5% (57/221) | 19.5% (22/113)| 0.222   |
| Calcification, % (n) | 39.3% (131/221) | 36.1% (66/113)| 0.907   |
| Severe calcification, % (n) | 10.5% (23/221) | 9.0% (10/113)| 0.602   |
| Provisional stenting, % (n) | 7.3% (16/220) | 12.6% (14/111)| 0.116   |

### IN.PACT SFA Trial: Freedom from CD-TLR through 5 Years

#### Time to First CD-TLR within 1800 days (Min, Max)

|                   | IN.PACT (N=220) | PTA (N=111) | P-value
|------------------|-----------------|-------------|---------
| CD-TLR           | 25.5% (47/184)  | 35.6% (37/104)| 0.080   |
| Any TLR          | 26.6% (49/184)  | 37.5% (39/104)| 0.063   |
| Time to First CD-TLR within 1800 days (Min, Max) | 877.5 ± 439.9 (1, 1701) | 474.0 ± 464.3 (1, 1705) | < 0.001 |

### IN.PACT SFA Trial: Safety Outcomes through 5 Years

#### Primary Safety Composite

|                   | IN.PACT (N=220) | PTA (N=111) | P-value
|------------------|-----------------|-------------|---------
| Primary Safety Composite | 70.7% (130/184) | 59.6% (62/104)| 0.068   |
| Major Adverse Events | 42.9% (79/184)  | 48.1% (50/104)| 0.459   |
| All-cause Death    | 15.8% (29/184)  | 9.6% (10/104)| 0.156   |
| Device or Procedure related death through 5 years | 0 (0/184) | 0 (0/104) | -- |
| CD-TVR             | 29.3% (54/184)  | 40.4% (42/104)| 0.068   |
| Major Target Limb Amputation | 0.5% (1/184) | 0.0% (0/104)| 1.000   |
| Thrombosis         | 2.2% (4/184)    | 4.8% (5/104)| 0.292   |

#### CD-TLR Rates

|                   | IN.PACT (N=220) | PTA (N=111) | P-value
|------------------|-----------------|-------------|---------
| 1-year           | 18.2% (39/215)  | 19.1% (21/111)| 0.761   |
| 2-year           | 20.5% (43/208)  | 21.4% (23/109)| 0.719   |
| 3-year           | 26.3% (54/202)  | 28.1% (29/103)| 0.651   |
| 4-year           | 31.1% (62/198)  | 33.4% (34/102)| 0.694   |
| 5-year           | 33.8% (66/196)  | 36.4% (37/102)| 0.692   |

### IN.PACT SFA Trial Through the Years

1. Medtronic IFU M052624T001_Rev1H
5. Schneider P. VIVA 2017
Summary

• First independently adjudicated, blinded, randomized trial to demonstrate superior effectiveness of a drug-coated balloon (DCB) through five years.

• This final report of the IN.PACT SFA Trial demonstrates long-term safety of the IN.PACT Admiral™ DCB through 5 years
  • No device-, procedure- or paclitaxel-related deaths through 5 years
  • Low Thrombosis rates through 5 years

• The IN.PACT SFA Trial demonstrates durable effectiveness of the IN.PACT Admiral DCB

• Results support DCB as a first line strategy for the treatment of femoropopliteal disease

The Better Mode of Drug Delivery!