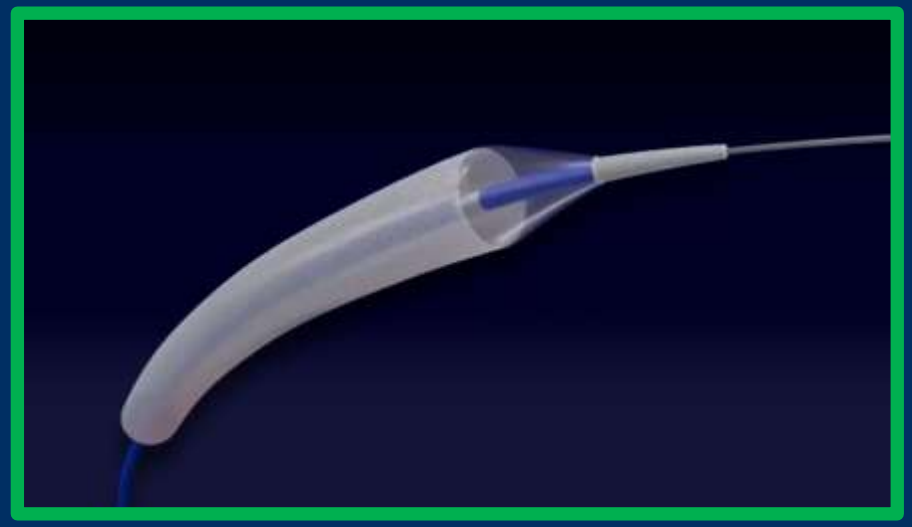
SELUTION SLR™ sirolimus eluting balloon: World's first experience treating TASC C & D tibial occlusive disease – 12 months results



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LINC

Disclosures

Investigator –initiated grants and honoraria from:

- M.A. MedAlliance SA

Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.

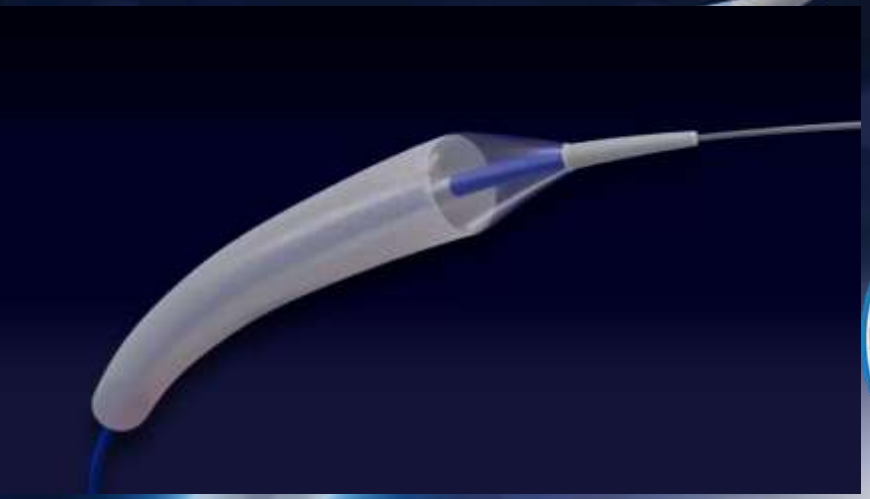
PRESTIGE Trial

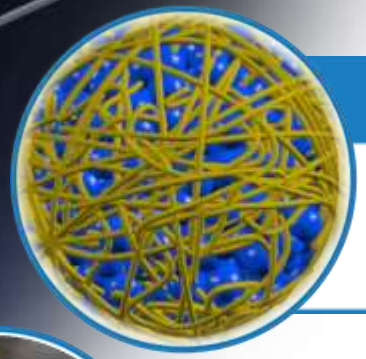
Physician initiated, prospective, non-Randomized single-center trial, investigating the safety and Efficacy of the Treatment with the Selution Sirolimus Coated Balloon in TASC C and D Tibial occlusive disease In patients with critical limb Ischemia from SinGaporE

NCT04071782

Sirolimus-Eluting Balloon with Sustained Release

SelutionSLR™
SUSTAINED LIMUS RELEASE





Proprietary MicroReservoir Technology

- Creation of MicroReservoirs combining sirolimus & biodegradable polymer
- Sirolimus - a proven safe & effective cytostatic drug
- Offering a wider therapeutic range

MicroReservoirs: Miniature Drug-Delivery Systems

- Optimal size MicroReservoirs to achieve pharmaco- kinetic release profile comparable to best in class DES
- Consistent and predictable drug release
- Sustained therapeutic effect for up to 90 days [1].

Cell Adherent Technology (CAT™)

Proprietary amphipathic lipid technology which binds MicroReservoirs to the balloon surface

- Contains and protects micro-reservoirs during insertion and inflation
- Enhances drug retention and bioavailability, allowing for a lower drug dose concentration on the balloon surface (1 µg/mm²).
- Optimizes transfer of MicroReservoirs to the tissue and maximizes the cellular uptake of sirolimus.

MedAlliance

1. Drug concentration evident in MicroReservoirs and tissue - Data on file at M.A. Med Alliance SA

PRESTIGE Endpoints

- **Freedom from device- or procedure-related mortality** through 30 days
- **Freedom from Target Lesion Revascularization (TLR)** at 6 months and 12 months
  - Defined as any re-intervention performed for ≥50% diameter stenosis of the target lesion
- **Freedom from major target limb amputation**
- **Primary Patency rate** at 6 and 12 months post-study procedure (Duplex defined)
- **Technical success** (i.e. able to cross and dilate lesion to achieve <30% residual stenosis)
- **Clinical success** (i.e. improvement of Rutherford classification at follow-up)
- **Wound healing** (i.e. complete closure of wound / >70% healed)

Inclusion Criteria

1. De novo and post-PTA restenotic lesions located in tibial arteries
2. Target lesion is >100mm, TASC C or D lesion
3. Target lesion has angiographic evidence of stenosis >50% or occlusion
4. Lesion traversed with standard guidewire and predilated to <30% residual stenosis
5. Target vessel diameter > 1.5 mm and < 4.5mm below knee (visual estimate)
6. Any tibial vessel intervened on must have distal reconstitution above ankle
7. Inflow iliac, SFA and popliteal lesions treated first prior to treating BTK lesions (<30% residual stenosis and no evidence of embolization)
8. Angiographic evidence of at least one vessel runoff through ankle and into foot

Post-op Follow Up

1 month POST-SURGERY

- Clinical follow-up (telephone or office visit)
- Data collected:
  - Walking impairment questionnaire
  - EQ-5D

3 months POST-SURGERY

- Clinical follow-up (telephone or office visit)

6 months POST-SURGERY

- Clinical follow-up (office visit)
- Data collected:
  - Walking impairment questionnaire
  - EQ-5D
  - Ankle Brachial Index Test
  - Duplex Ultrasound

12 months POST-SURGERY

- Clinical follow-up (office visit)
- Data collected:
  - Walking impairment questionnaire
  - EQ-5D
  - Ankle Brachial Index Test
  - Duplex Ultrasound

Patient Demographics

Characteristics	Total patients = 25, n (%)
Age, mean ± sd	63.72 ± 9.73
BMI, mean ± sd	24.40 ± 4.88
Male gender	17 (68.0)
Ethnic Group	
Chinese	18 (72.0)
Malay	4 (16.0)
Indian	3 (12.0)
Co-Morbidities	
Diabetes	22 (88.0)
Hypercholesterolemia	19 (76.0)
Hypertension	22 (88.0)
CVA in the past 12 months	1 (4.0)
Myocardial Infarction	3 (12.0)
Angina	2 (8.0)
Congestive Heart Failure	4 (16.0)
End Stage Renal Failure (ESRF)	11 (44.0)
Rutherford Score 5	25 (100.0)
Mean WIFi Score	3.72 ± 1.14
Clinical Stages (Risk of Amputation)	
1 (Very Low Risk)	2 (8.0)
2 (Low Risk)	9 (36.0)
3 (Moderate Risk)	9 (36.0)
4 (High Risk)	5 (20.0)
Toe Pressure (mmHg), median (range)	37.5 (0 – 100)

88% had DM

44% w/ ESRF

100% subjects are Rutherford 5

56.0% at moderate to high risk for amputations based on WIFi

Characteristics	n (%)
Operative Details	
Leg Treated (n = 25)	
Left	11 (44.0)
Right	14 (56.0)
Number of vessel runoff post-angioplasty	
1	9 (36.0)
2	13 (52.0)
3	3 (12.0)
Concomitant treatment of SFA/Popliteal	15 (60.0)
Concomitant treatment of infra-malleolar disease	10 (40.0)
Bailout tibial stenting	0 (0.0)
SAFARI	1 (4.0)
Minor Amputation	11 (44.0)
Lesion-specific details (n = 33)	
Location of Treated Vessel (n = 33)	
Anterior Tibial Artery (ATA)	17 (51.5)
Posterior Tibial Artery (PTA)	10 (30.3)
Common Plantar Artery	3 (9.1)
Dorsalis Pedis Artery (DPA)	3 (9.1)
De novo	21 (63.6)
Re-stenotic	12 (36.4)
TASC Classification	
C	18 (54.5)
D	15 (45.5)
Lesion Length (mm), mean ± sd	190.61 ± 111.30
Diameter Stenosis (%), mean ± sd	88.88 ± 12.43
Calcification Classification	
2 (focal)	6 (18.2)
3 (mild)	6 (18.2)
4 (moderate)	11 (33.3)
5 (severe)	10 (30.3)

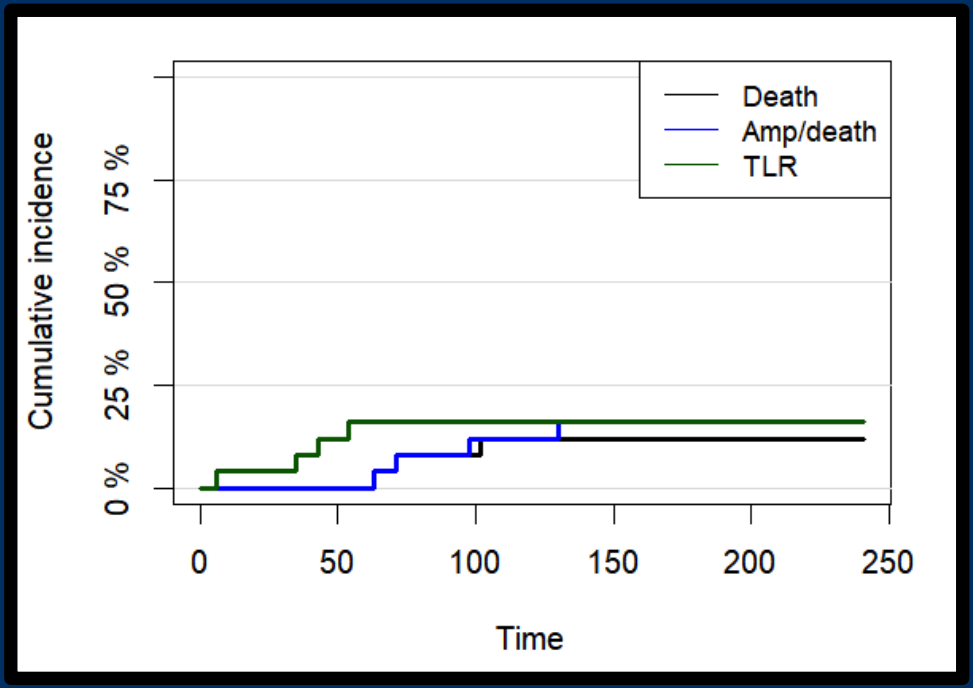
0 bailout stenting performed

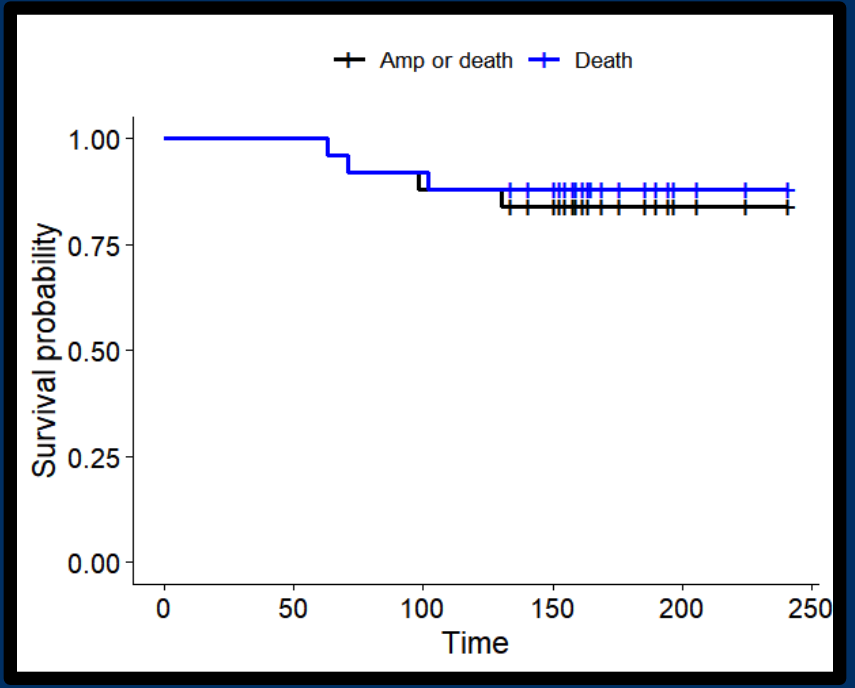
ATA is the most treated vessel

63.6% of lesions had moderate to severe calcification

At 6 months...

- Technical success : **100.0%**
- Freedom from device- or procedure-related mortality through 30 days : **100.0%**
- Freedom from Target Lesion Revascularization (TLR) : **92.6% (25/27)**
- Amputation Free Survival (AFS): **84.0% (21/25); 3 deaths and 1 BKA**
- Primary Patency rate : **81.5% (22/27)**
- Wound healing : **81.8% (18/22)**

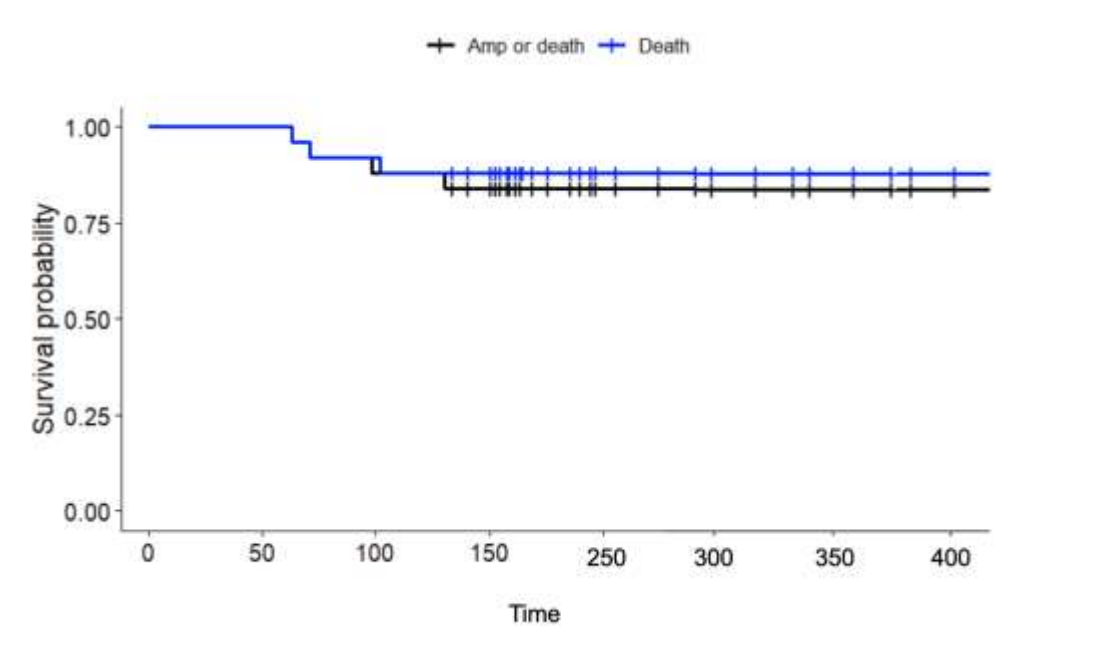


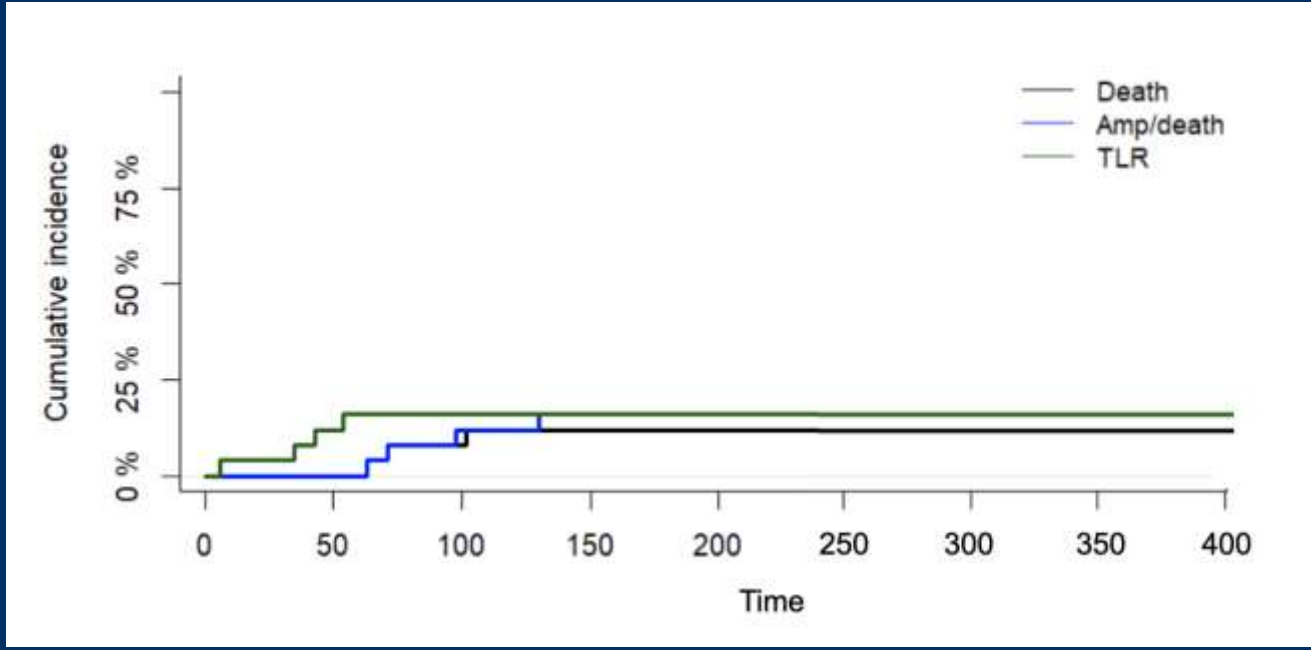


At 12 months…

- Freedom from Target Lesion Revascularization (TLR) : 92.6% (25/27)
- Amputation Free Survival (AFS) : 84.0% (21/25): 3 deaths and 1 BKA
- Primary Patency rate : 77.8% (21/27)
- Wound healing : 81.8 (18/22)

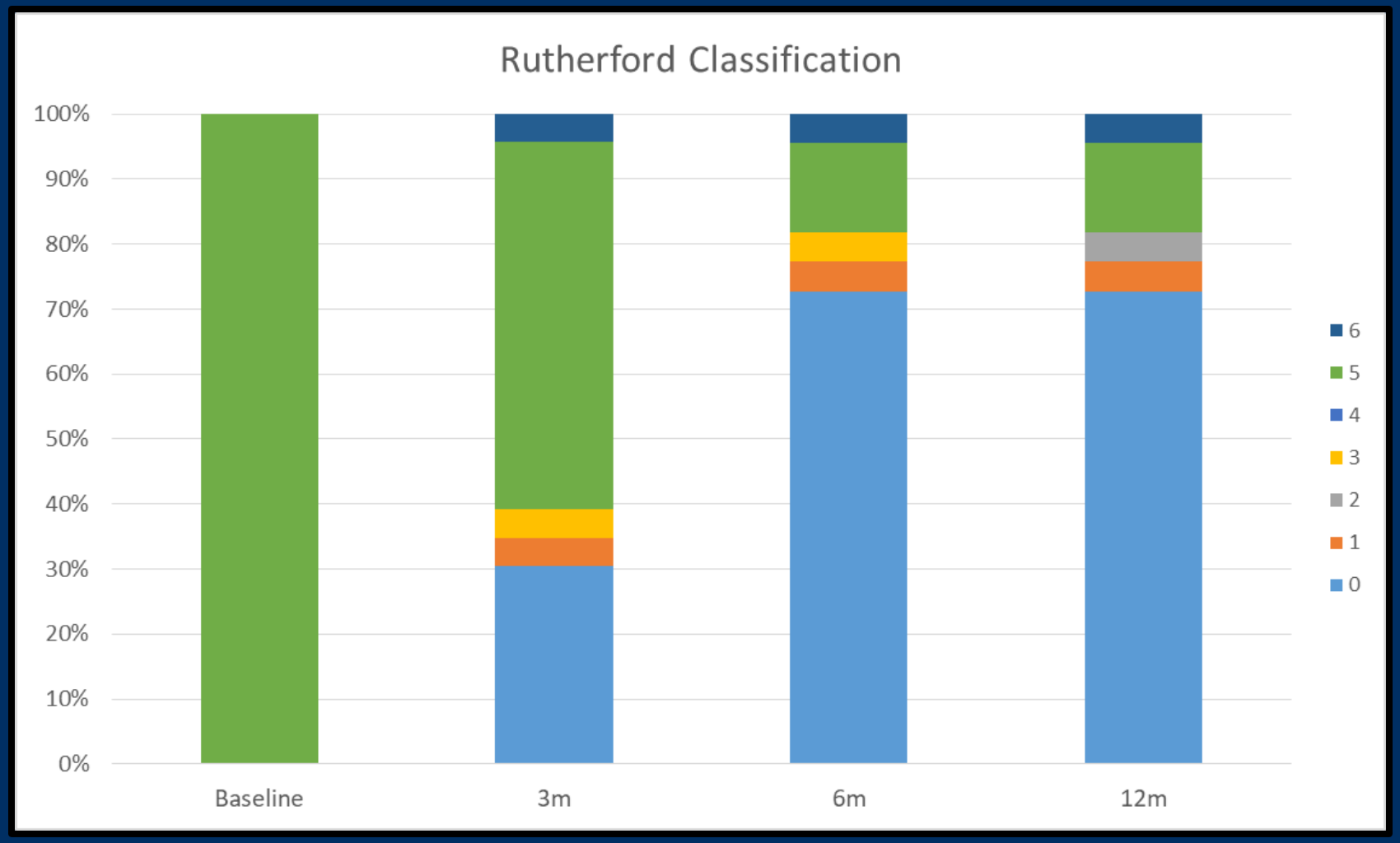
Sustained from 6 M





Clinical Success

(i.e. improvement of ≥1 category)



- Mean Rutherford score improved from
- 5.00 at baseline

→ 3.26 ± 2.40 at 3 months

→ 1.14 ± 2.10 at 6 months

→ 1.09 ± 2.07 at 12 months

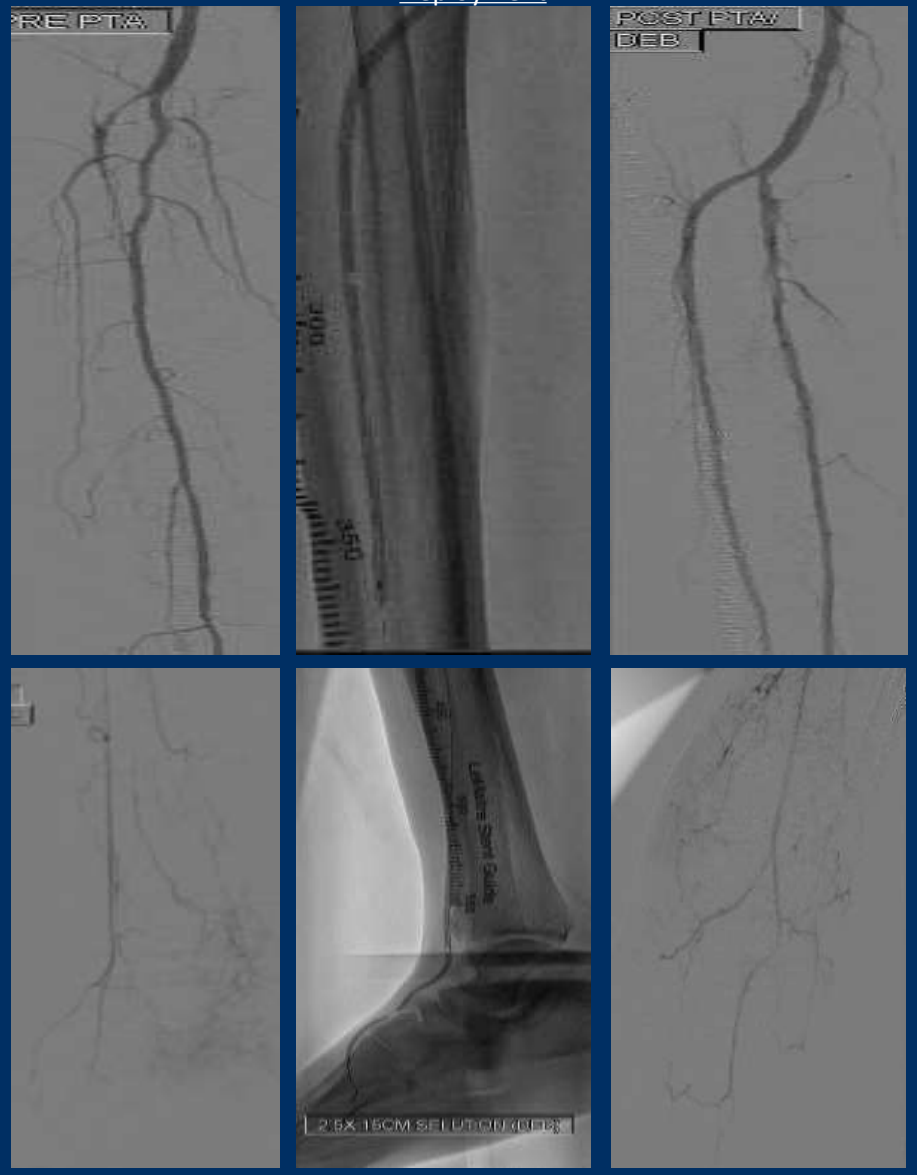
- **18/22 (81.8%)** patients showed improvement by at least 1 Rutherford category by 6 months and this is sustained at 12 months

(A)

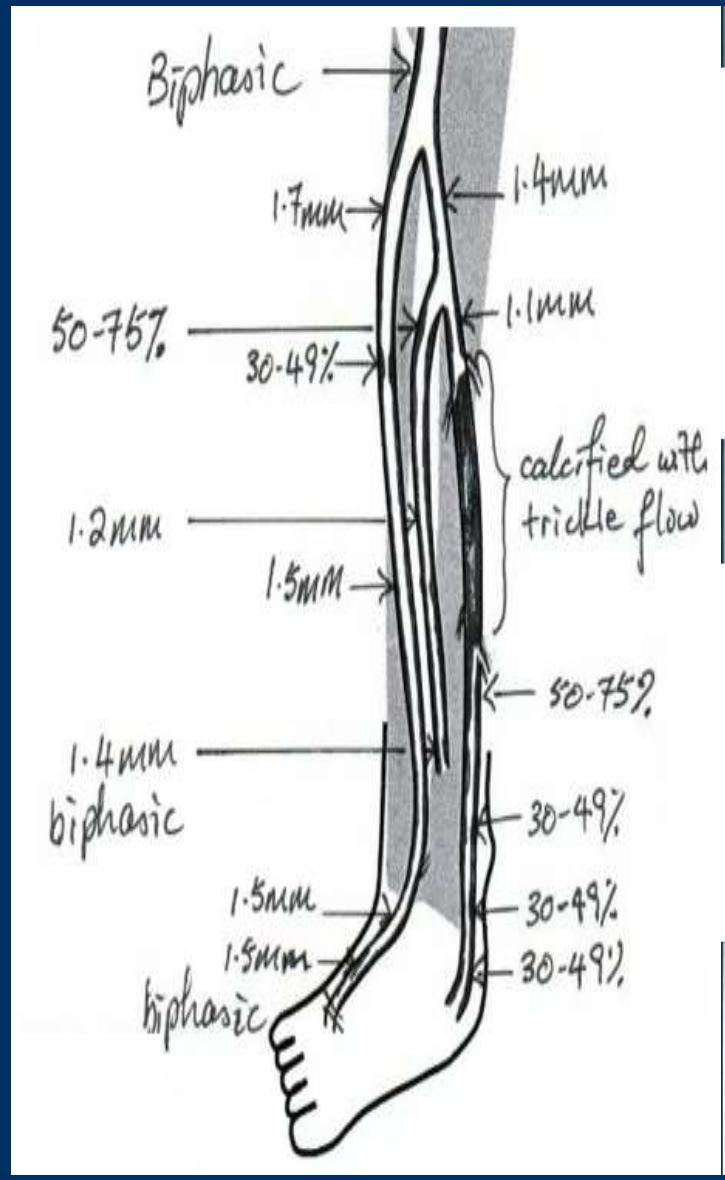
Pre-PTA

SELUTION SLR™ Deployment

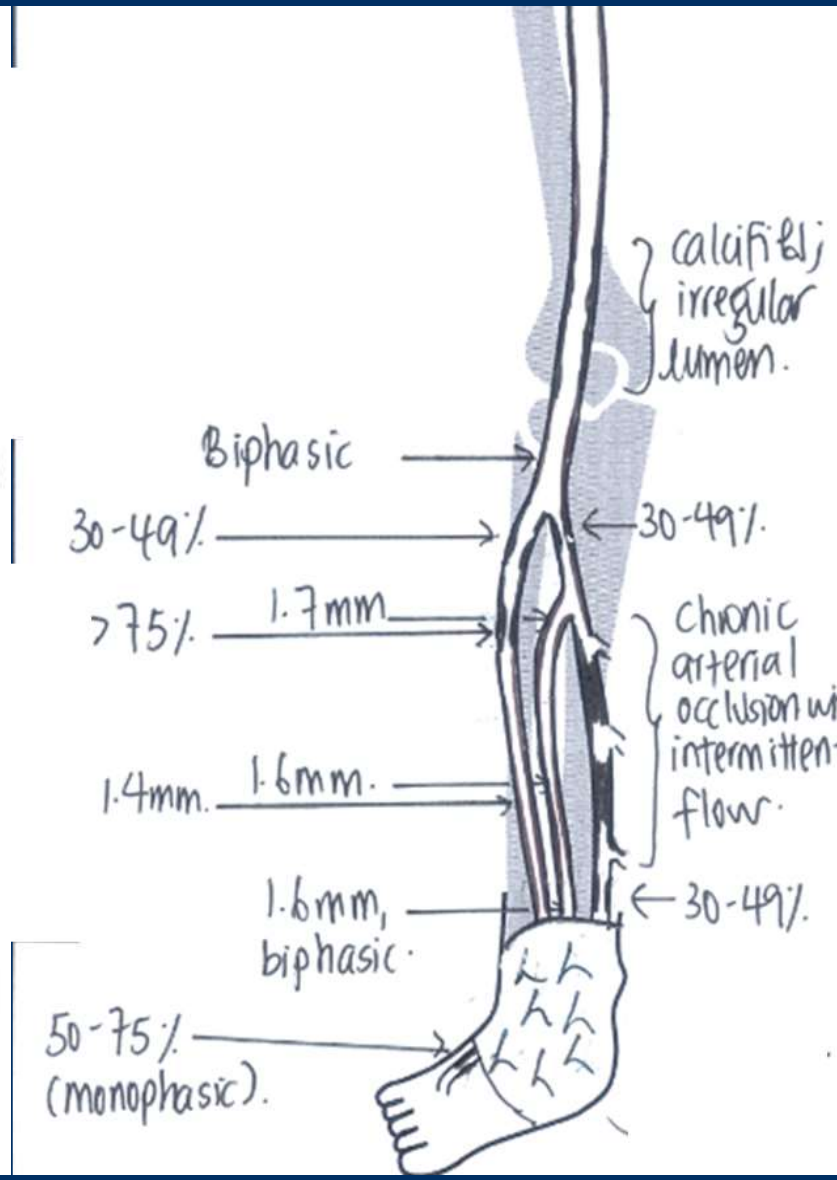
Post-PTA



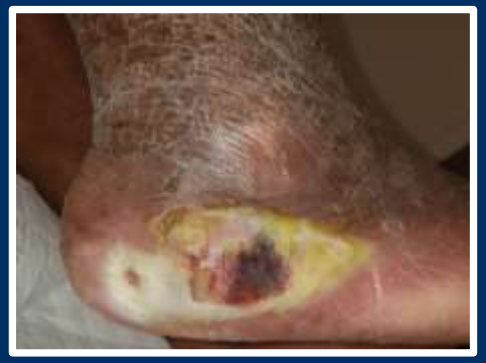
6m post-op



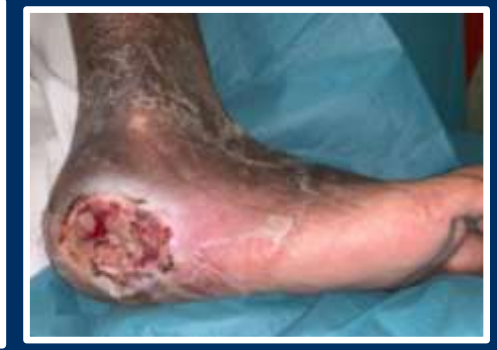
12m post-op



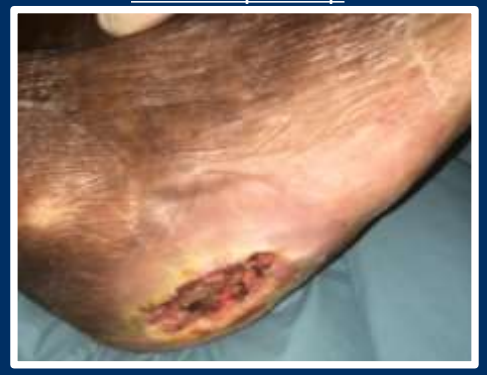
Pre-operation



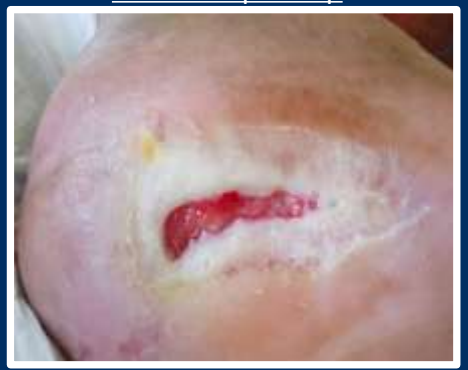
Post-operation



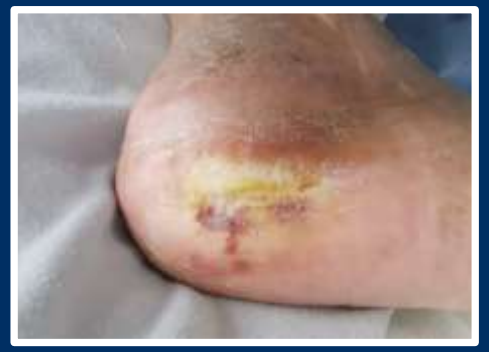
3 weeks post-op



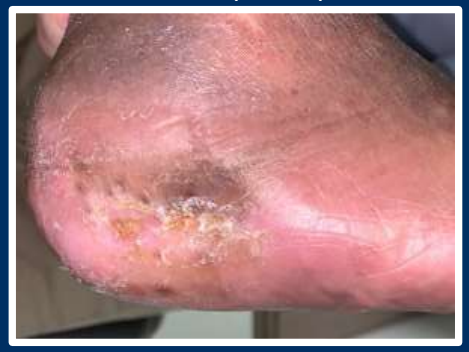
3 months post-op



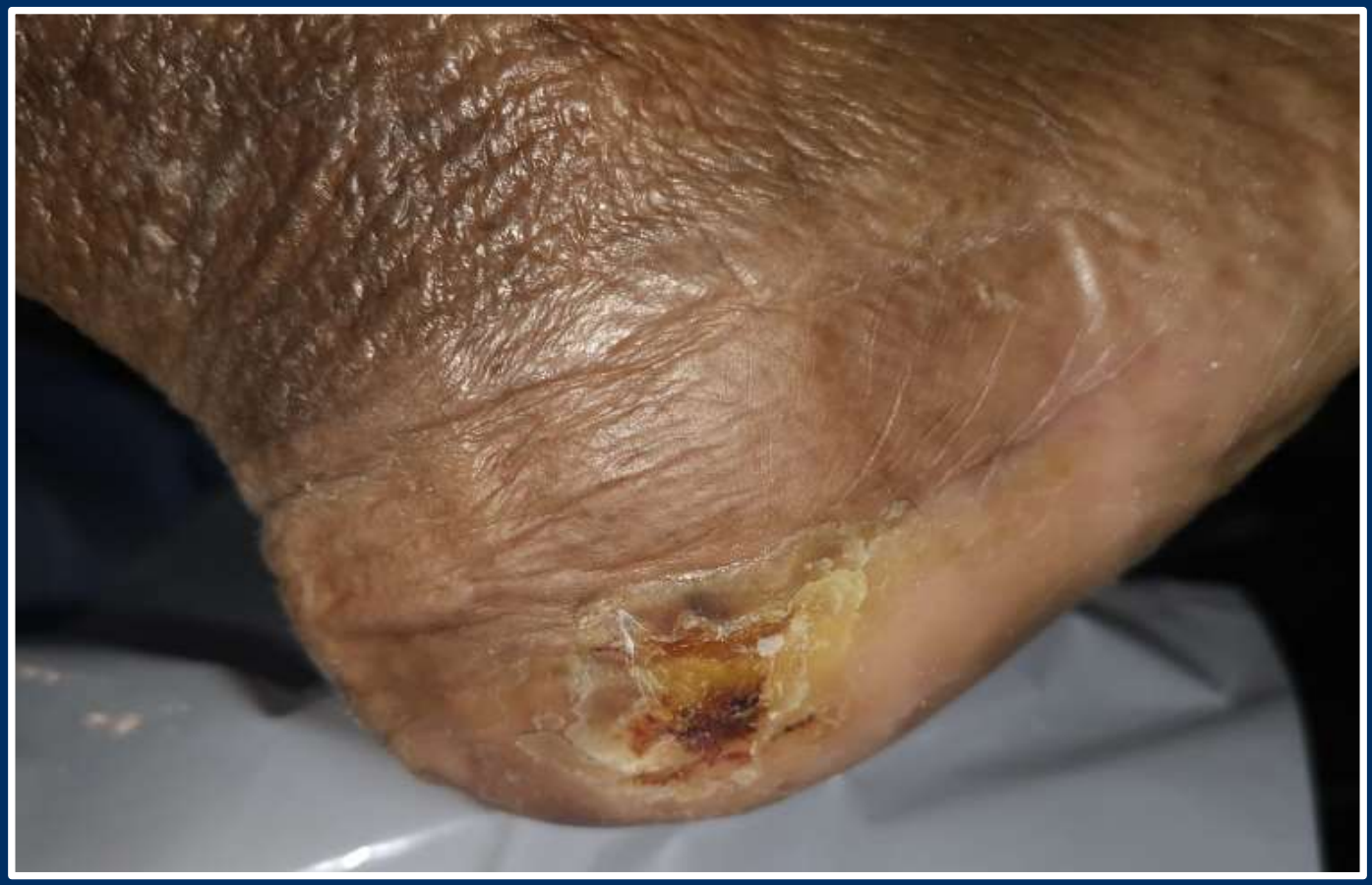
5 months post-op



6 months post-op



12 month post-op



Conclusions: SELUTION SLR™ Balloon SGH Experience

- Positive Initial SCB Experience
- No issue to follow a 1:1 POBA-DCB sizing when using a DCB 0.5mm bigger
- Good trackability on a 0.018”platform & Short Deflation time
- Good visible markers to place the balloon accurately
- Safe device - No serious adverse events using the SELUTION SLR balloon
- Minimal slow flow phenomenon after treating **infra-malleolar lesions**
  - **Primary Patency rate: 78%**
  - **Amputation free survival: 84%**
  - **Freedom from TLR: 83%**
  - **Wound healing rate: 81%**
- Encouraging 6 month outcomes have been maintained out to 12 month

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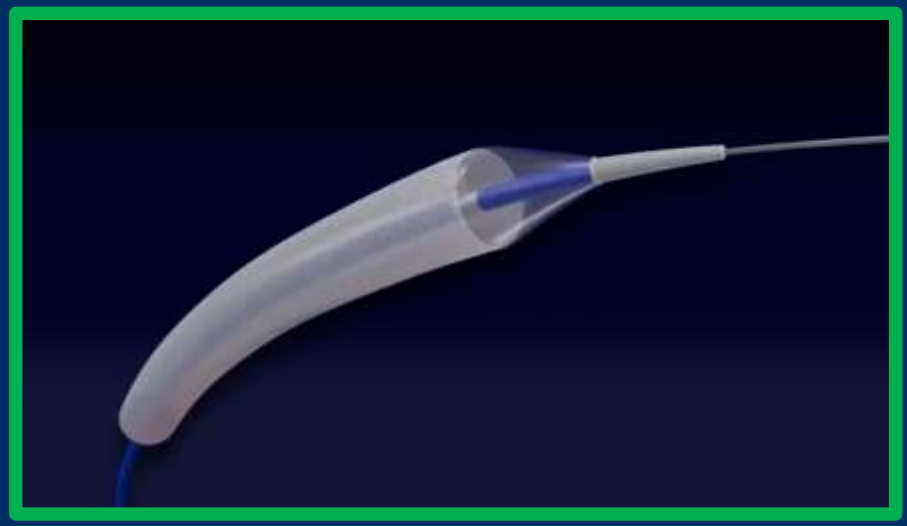

Thank you!

Singapore General Hospital
SingHealth