Credence BtK TECHNICAL SPECIFICATIONS

SCAFFOLD BACKBONE

Scaffold Material	: BioResorbable PLLA (Poly L-lactide)
Scaffold Strut Thickness	: 100 μm
Scaffold Diameters	: 2.50, 3.00, 3.50 mm
Scaffold Lengths	: 32, 40 mm

SCAFFOLD RO MARKERS

Tri-axial RO Markers	: Platinum (Couplets of tri-axial RO markers on both ends, 120° apart from each other)

TOP COAT-DRUG+POLYMER

Drug	: Sirolimus
Equivalent Drug Dose	: 1.25 μg / mm2
Polymer	: Bioresorbable PDLLA (Poly D, L-lactide)

DELIVERY SYSTEM

Delivery System	: Rapid Exchange
Nominal Pressure (NP)	: 9 atm (Refer labels for more details)
Rated Burst Pressure (RBP)	: 16 atm (Refer labels for more details)
Balloon Overhang	: < 1 mm
Shaft Outer Diameter	: (Refer IFU for more details) Proximal: 2.13F, Distal: 2.7F for lineage delivery system
Radiopaque Markers	: 2 - Platinum / Iridium
Usable Catheter Length	: 142 cm (Refer IFU for more details)
Sheath Compatibility	: 6 F (Min. I D 0.070" / 1.8 mm)
Max. Guidewire Compatibility	: 0.014'' (0.36 mm)

Credence BtK ORDERING INFORMATION

Diameter / Lengths	32 mm	40 mm
2.50 mm	CBK25032	CBK25040
3.00 mm	CBK30032	CBK30040
3.50 mm	CBK32532	CBK32540

CBK/BROCHURE/001/20241019/GLOBAL

Meril

More to Life

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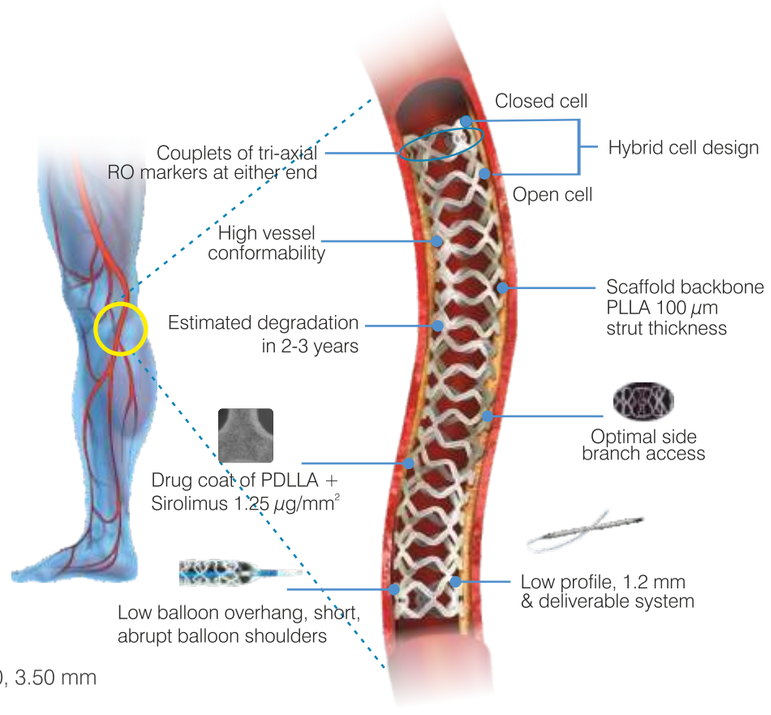
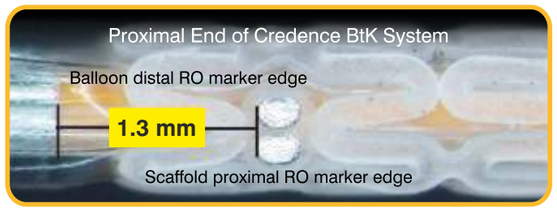


Size Matrix
Diameters: 2.50,3.00, 3.50 mm
Lengths: 32,40 mm

Credence BtK Enhanced Radiopacity



Distance from edge of Balloon RO marker (both proximal & distal) to edge of Scaffold RO = 1.3 mm

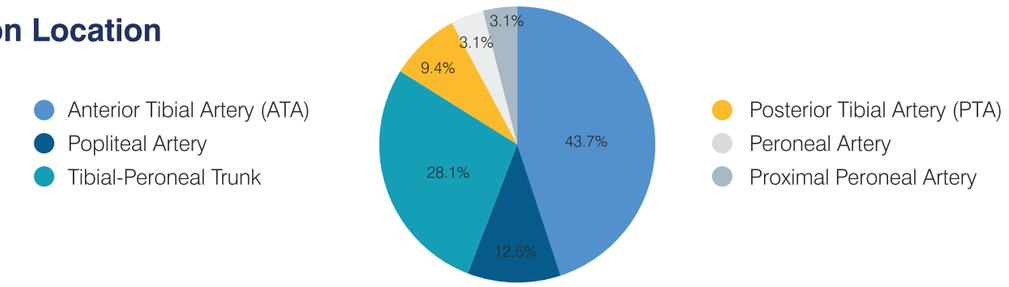
Credence BtK Implantation - Tibio-Peroneal Trunk Stenosis

Pre-Procedure | Peri-Procedure | Post-Procedure

Procedure and lesion characteristics

Variables	N = 32 lesions/ 30 Patients
Total number of lesions	61
Total number of lesions treatable with study device	32
Study device implanted	32
Lesion per patient	1.1
Technical success, n (%)	30 (100)

Lesion Location



CLINICAL OUTCOMES at 36 Months follow-up

Event description (n)	Post Procedure (n=30)	1 Month (n=29)	6 Months (n=29)	12 Months (n=27)	24 Months (n=23)	36 Months (n=23)
Death*	0	1	3	4	5	7
TLR	0	0	0	0	0	0
Major Amputation#	0	1	4	4	4	4
Limb Salvage	30	28	25	23	19	19

FU ongoing

*All deaths were not related to study device. Out of nine deaths, one patient died due to cardiac arrest at 1-month follow-up; one death was due to road traffic accident at 6-month follow-up; one death occurred due to accidental fall (caused head injury) at 6-month follow-up; one due to sudden bradycardia at 12 months follow-up; one death due to pineal region tumor at 24 months follow-up; one natural death and one death with unknown cause at 36 months follow-up;

#New lesions in great toe and heel were responsible for amputation in one patient, infected left foot with necrosis caused amputation in another patient, third patient amputation was due to non-healing wound on right foot and in fourth patient, there was debridement and below the knee amputation of left lower limb

ANGIOGRAPHIC ASSESSMENT of Target lesion

Parameters	Pre-procedure	Post-procedure	6 Months	p-value
In-Segment				
Percentage Stenosis	62.18±20.67	21.28±10.07	23.92±1217	0.504
MLD, (mm)	1.37±0.77	2.65±0.44	2.11±1.13	0.052
RVD, (mm)	3.21±0.70	3.41±0.66	3.07±0.96	0.182
Late Lumen Loss	-	-	0.47 ± 0.39	-
In Scaffold				
Percentage Stenosis	-	21.37±13.46	25.07±15.70	0.448
MLD, (mm)	-	2.74±0.49	2.22±0.69	0.010
RVD, (mm)	-	3.46±0.61	3.12±0.96	0.167
Late Lumen Loss	-	-	0.41± 0.35	-

Values are in Mean±SD, MLD: Minimal Lumen Diameter, RVD: Reference Vessel Diameter
Data are mean (SD) unless otherwise stated. *p values are between post- procedure and 6 month follow-up, and are given for exploratory analysis only.