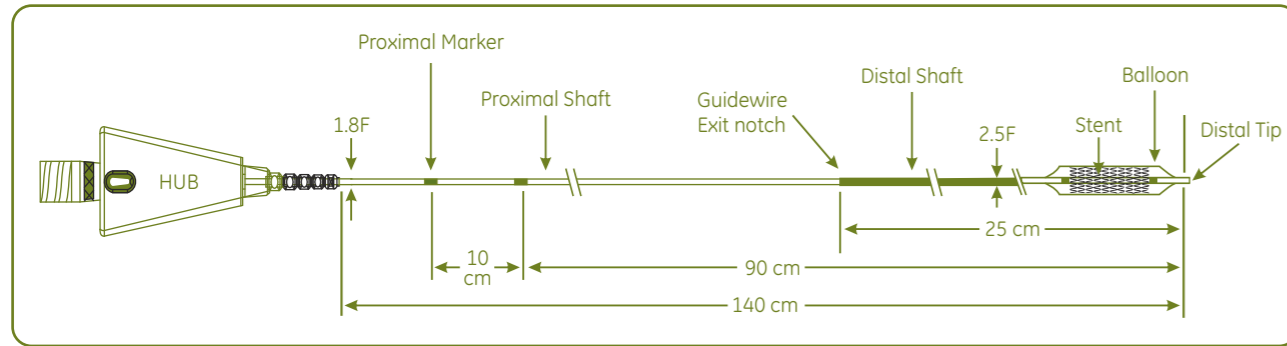




Abluminus drug eluting stent is a device for treatment of lesions in coronary arteries. The product is available as a system, mounted on a rapid exchange balloon catheter for delivery.



Technical Specifications

Drug	Sirolimus Drug
Drug Dose	0.98 micrograms per mm ²
Drug Carrier	Poly L Lactide Family of polymers
Stent Material	Cobalt Chromium alloy L605
Strut Thickness	73 microns (0.0029")
Strut Width	80 microns (hinge) - 120 microns (strut)
Average Recoil	less than 5%
Average Foreshortening	less than 1% (Zero foreshortening design)
Delivery System	Rapid exchange stent delivery system
Nominal Pressure	8 bar
Rated Burst Pressure	14 bar
Guiding Catheter Compatibility	5F (0.056" ID) for all sizes
Guidewire Compatibility	0.014" maximum recommended

Ordering Information

Dia / Length	8mm	12mm	16mm	20mm	24mm	28mm	32mm	36mm	40mm
2.25 mm	EAB22508	EAB22512	EAB22516	EAB22520	EAB22524	EAB22528	EAB22532	EAB22536	EAB22540
2.50 mm	EAB25008	EAB25012	EAB25016	EAB25020	EAB25024	EAB25028	EAB25032	EAB25036	EAB25040
2.75 mm	EAB27508	EAB27512	EAB27516	EAB27520	EAB27524	EAB27528	EAB27532	EAB27536	EAB27540
3.00 mm	EAB30008	EAB30012	EAB30016	EAB30020	EAB30024	EAB30028	EAB30032	EAB30036	EAB30040
3.50 mm	EAB35008	EAB35012	EAB35016	EAB35020	EAB35024	EAB35028	EAB35032	EAB35036	EAB35040
4.00 mm	EAB40008	EAB40012	EAB40016	EAB40020	EAB40024	EAB40028	EAB40032	EAB40036	EAB40040

DISCLAIMER:
For distribution in India and neighboring countries.
All cited trademarks are proprietary of Envision Scientific Pvt. Ltd. CAUTION: Law restricts these devices to sales by or on the order of Physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Image and graphics are representations of device and human anatomy and do not represent the actual anatomy or size of product.



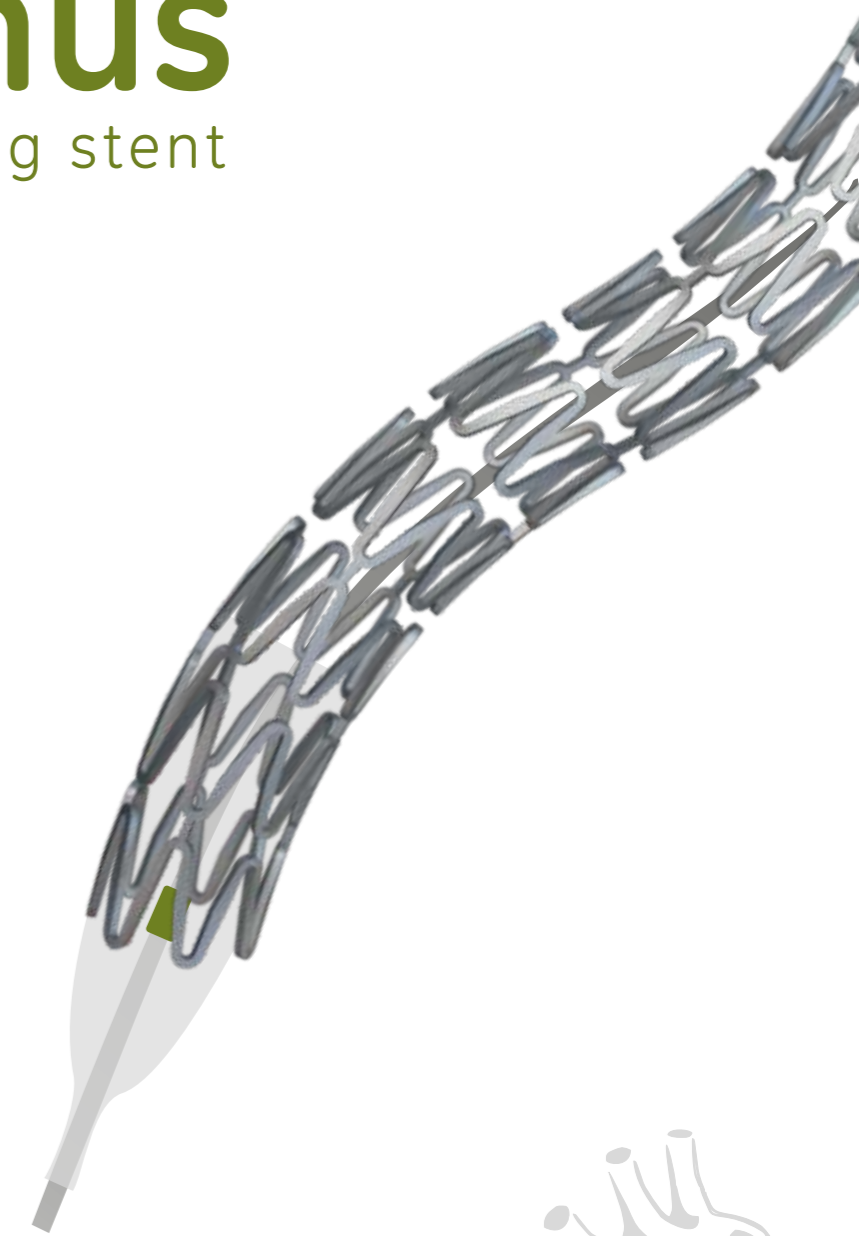
Manufactured by:
Envision Scientific Pvt. Ltd.
Factory: C1B-108, Bhatpore GIDC, Icchapore, Surat 395 001. GUJ-IN
Regd. Office: Office 1~3, Silver Palm II, Near Sneh Milan Garden, Kadampalli, Nanpura, Surat 394 510. GUJ-IN
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visioning for a happy and healthy world

AbluminusTM

Sirolimus drug eluting stent

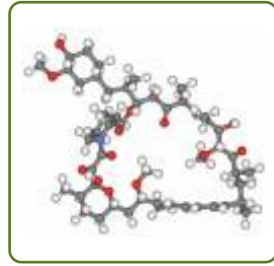


committed to a
**HAPPY &
HEALTHIER** world

A novel Sirolimus drug eluting stent system with bio-degradable polymer matrix.

The drug is eluted from a bio-degradable polymer based matrix. The platform is a thin strut Cobalt chromium stent with Open-close cell (hybrid) design. The stent combines well proven Sirolimus drug delivered in a controlled manner from the abluminal surface of stent and balloon. The device provides high level of safety with superior efficacy.

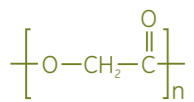
Proven Sirolimus drug, Highly safe and effective.



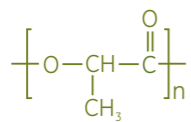
Sirolimus drug is an immunosuppressant drug molecule. The action of drug is to inhibit mTOR and block growth factor induce proliferation. The drug is cytostatic i.e. it blocks cell cycle in late G₁ phase.

Sirolimus has been one of the most widely used drug on stents. The nevel inhibition characteristics of cell proliferation and preventing tissue hyperplasia after vascular injury has led to its use as an agent for the prevention of restenosis.

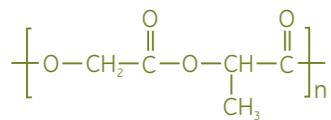
Poly (glycolic acid)



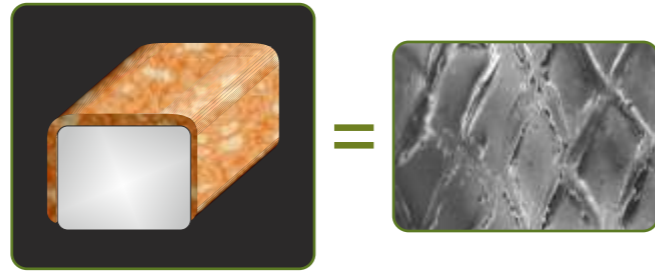
Poly (lactic acid)



Poly (D,L - Lactide-co-Glycolide) Copolymer



Abluminal Coating only,
On time healing performance.



Abluminus has a unique coating method - device is coated in crimped condition i.e. Balloon and Stent surface are only coated for drug delivery. This method ensures uniform drug delivery in the lesion and is more focused as only the outer surface has drug formulation.

The Inner surface is without any coating and with only abluminal biodegradable polymer coating achieves a greater level of endothelialization, like a BMS.

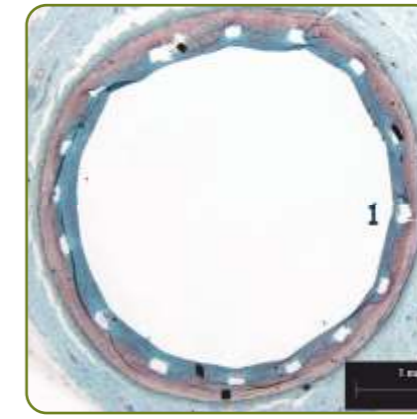
Bio-degradable polymer family achieving BMS healing profile.

The stent consists of Sirolimus drug released from a matrix of Poly-L Lactide family of co-polymers. The matrix degrades by hydrolysis to naturally occurring lactic acid. This is metabolized in the body to Carbon dioxide and water at approximately 6~8 months.

The non-toxic, low inflammatory Poly L-Lactide family of polymers are naturally occurring in human body with it presence in by-products of anerobic metabolism that degrades to CO₂ and water.

Pre-clinical Work: (Porcine Model)

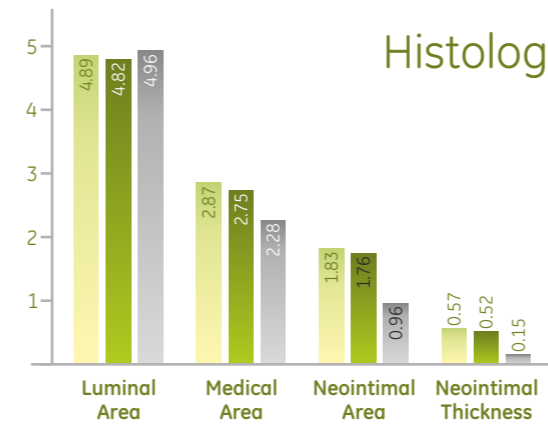
Study was performed using Abluminus drug eluting stent in porcine coronary artery model. Histologic and Morphometric analysis was performed at 7, 30, 90 and 180 day time points.



ENV 1.16 LCX @ 30 days

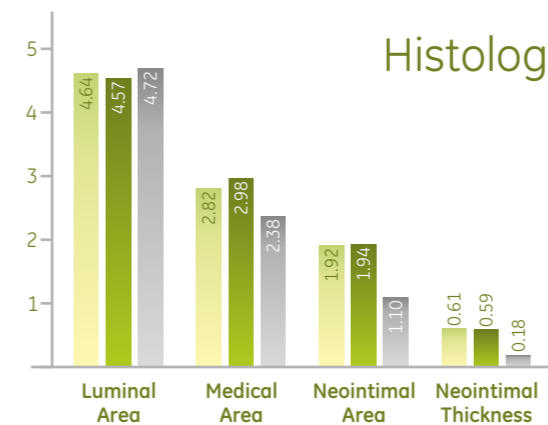


ENV 1.08 LCX @ 90 days



Histological data at 30 days

At 30 days, all the three stent groups were evaluated for neo-intimal growth, cellular matrix composition and vessel lumen patency. The measured neo-intimal thickness was found to be lower for Abluminus stent as compared with other groups.



Histological data at 90 days

At 90 days, evaluation of stent implants, the neo-intimal thickness showed minimal gain in Abluminus stent and was not found to be significant with inhibition of growth.

Time Points	Polymer thickness in mm
30 Days	0.01010 ± 0.06307
90 Days	0.00592 ± 0.00391
180 Days	0.00039 ± 0.00030

Measurements done with Hi-Power Optical Microscopy

Biodegradable polymer matrix degradation was evaluated at 30, 90 and 180 days in the model using Hi-Power Optical Microscopy. Systematic degradation was observed in line with degradation profile of polymer matrix and a minimal thickness of 0.39 microns was seen at 180 days confirming complete degradation.