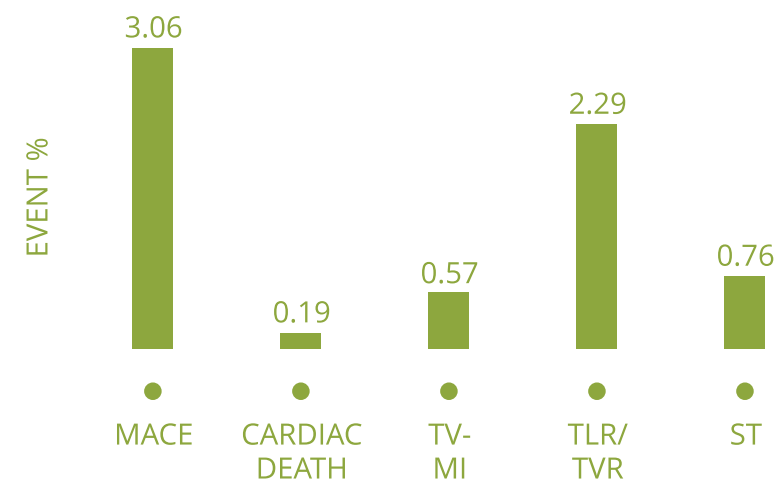


ABLUMINUS® DES+

CLINICAL PERFORMANCE IN DIABETIC PATIENTS

Diabetic Patients from en-ABL e-registry



DIABETIC PATIENTS (N=669)

BASELINE CHARACTERISTICS

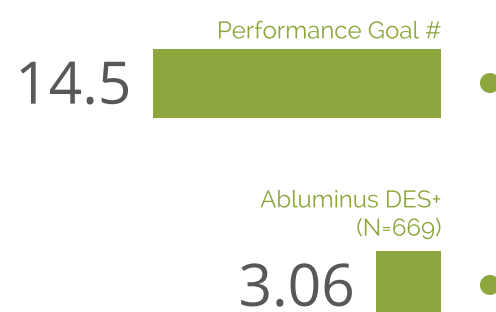
Age, Year	57.73 ± 9.61
Men, (%)	77.58
History of smoking, (%)	7.92
History of hypertension, (%)	60.69
Prior MI, (%)	14.65
Prior PCI, (%)	06.73
Prior CABG, (%)	02.24
ACS clinical presentation, (%)	57.85

LESION CHARACTERISTICS

No. of lesions=800, No. of Devices=891

Long Lesions (≥ 28mm)	51.87
Small Vessels (RVD ≤ 2.75mm)	57.87
Reference vessel diameter (mm)	02.84±0.4
Lesion length (mm)	29.22±13.04
Number of device per patient, (%)	013

Abluminus® DES+ Diabetes group was compared against pre-specified performance goal based on DES+ Meta-analysis



1 year MACE rate is concluded to be less than the performance goal (14.5%)

#Performance goal based on DES trials meta-analysis: DIABETES, RAVEL DM, SIRIUS DM, TAXUS IV, SCORPIUS, ENDEAVOR Pooled DM
Major Adverse Cardiac Events (MACE) is defined as Cardiac Death, Target Vessel Myocardial Infarction (TV-MI), and Target Lesion/Vessel Revascularization (TLR/TVR) which is similar to Target Lesion Failure (TLF)

TECHNICAL SPECIFICATIONS

Drug / Polymer

Drug	- Sirolimus
Drug Dose	- 0.70 µg/mm ²
Drug Carrier	- Lactide and glycolide family of biodegradable polymer

Stent

Stent Material	- Cobalt Chromium Alloy L605
Strut Thickness	- 73 µm
Strut Width	- 80 µ (hinge) - 120 µ (strut)
Average Recoil	- Less than 5%
Average Foreshortening	- Less than 1% (zero foreshortening design)

Delivery System

Delivery System	- Rapid exchange (Rx) stent delivery system
Nominal Pressure	- 6 bar
Rated Burst Pressure	- 16 bar

ORDERING INFORMATION

Dia/Length	08 mm	12 mm	16 mm	20 mm	24 mm	28 mm	32 mm	36 mm	40 mm
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

The law permits devices to be sold by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. **envisiolution and Abluminus are registered trademarks or trademarks of Envision Scientific Pvt. Ltd. in India, USA and other countries.**

The product and its technology is protected by anyone of US8801662B2, US8778013B2, US8178379B2, US8529983, US8585642, South Africa 2011/09416, South Africa 2011/09415, WO2012056473, US20140107615, WO2011089620, WO2011089618



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Redefining Boundaries

ABLUMINUS® DES+

DESIGNED TO TREAT

DIABETIC PATIENTS

D RUG
E LUTING
S TENT+BALLOON

DIABETES

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces.

DIABETES-COMPLEXITY

- Both DM and MVD are associated with increased major cardiac events in patients with IHD
- Advanced glycosylation promotes inflammatory cell recruitment and smooth muscle cell proliferation.
- Outcomes like coronary thrombosis and restenosis are characterized in diabetic patient

KEY FACTS OF DIABETES

- About 347 million people worldwide have diabetes
- In 2014 the global prevalence of diabetes was estimated to be 9% among adults aged 18+ years
- In 2012, an estimated 1.5 million deaths were directly caused by diabetes
- Diabetes is predicted to become the 7th leading cause of death in the world by the year 2030
- Cardiovascular disease (CVD) is responsible for between 50-80% of deaths in people with diabetes
- Diabetes has become one of the major causes of death in most countries, mainly through the increased risk of cardiovascular disease (CVD)

http://applications.emro.who.int/dsaf/EMROPUB_2016_EN_1817.pdf?ua=1
<http://www.who.int/mediacentre/factsheets/fs312/en/>

envisöolution™ TECHNOLOGY

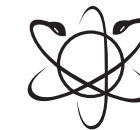
envisöolution™ is a highly effective drug delivery technology with a target specific coating abluminal configuration on stent and parts of balloon. It also uses biodegradable polymer to achieve longer drug release.



COATED ON BOTH STENT AND PARTS OF BALLOON

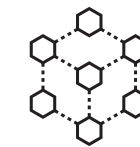
ABLUMINAL SURFACE COATING

Abluminal surface coating on balloon & stent system for faster re-endothelialization



HIGH PERFORMANCE DELIVERY SYSTEM

Unique coating of system allows for better drug distribution in the vessel wall



DIRECTION DRUG RELEASE



Lesser Systemic Dose

BIODEGRADABLE POLYMER MATRIX



Highly biocompatible matrix of bio-degradable polymers for sustained drug release

ENDOTHELIAL DYSFUNCTION

ABLUMINAL SURFACE COATING

- The diabetic patients have slower rate of revascularization.
- The abluminal coating of Abluminus helps in faster re-endothelialization.
- Less systemic exposure.
- Enhances drug delivery to address disease area.

ABLUMINUS SURFACE



STENT STRUT

DIFFUSED DISEASE

BIODEGRADABLE FILM

- The formation of Film when DES+ is inflated.
- Formation of film is due to the coating of both the parts of the stent and the balloon.
- A thin film gets apposed to the vessel wall which can range from seconds to minutes.
- The film which is elastic in nature addresses the diffuse disease in diabetic patients.

