Coronary Stents

KIHT Technical Compendium

KIHT

विज्ञानेन जातानि जीवन्ति

CORONARY STENTS

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Version 1.0

Acknowledgment:

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LIST OF ABBREVIATIONS

Acronym	Definition
AIMD	Active Implantable Medical Device
AIMDD	Active Implantable Medical Device Directive
BES	Biolimus Eluting Stents
BMS	Bare metal stent
BP	Blood presure
BRS	Bioresorbable stent
BVS	Bioresorbable Vascular Scaffold
CA	Coronary artery
CABG	Coronary artery bypass graft surgery
CAD	Coronary artery disease
CAGR	Compound annual growth rate
CDRH	Center for Devices and Radiological Health
CE	Conformity European
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
CR	Crore
CT	Computed tomography
CTA	Computed tomography angiography
CVA	Cerebrovascular accident
CVD	Cardiovascular disease
CXR	Chest x-ray
DES	Drug-eluting stent
DTS	Dual Therapy Stent
EC	European Commission
ECG	Electrocardiogram
EEC	European Economic Community
EES	Everolimus Eluting Stents
EPC	Endothelial progenitor cell
EU	European Union
EXIM	Export-Import
FD	Federal food, drug
FDA	Food and Drug Administration
FEA	Finite element analysis

FFR	Fractional Flow Reserve
FIM	First in Man
GMP	Good Manufacturing Practice
GRII	Gianturco Roubin II
HGMS	High gradient magnetic separation
HIT	Heparin-Induced Thrombocytopenia
HITU	High-intensity therapeutic ultrasound
HS	Harmonized System
ICA	Invasive coronary angiography
IEC	International Electrotechnical Commission
IIT	Indian Institutes of Technology
IMPRINT	Impacting Research Innovation and Technology
INR	Indian rupee
ISO	International Organization for Standardization
ISR	In-stent restenosis
IV	Intravenous
IVDMDD	In Vitro Diagnostic medical devices directive
IVUS	Intravascular ultrasound
JIS	Japanese Industrial Standard
JMDN	Japanese Medical Device Nomenclature
KG	Kilogram
LV	Large vessel
LST	Late stent thrombosis
LTD	Limited
LVEF	Left ventricular ejection fraction
MACE	Major adverse cardiac event
MAH	Marketing Authorization Holder
MDCP	Magnetic drug carrier particle
MDD	Medical Device Directive
MDT	Magnetic drug targeting
ME	Medical Electrical
MHLW	Ministry of Health, Labor and Welfare
MI	Myocardial infarction
MIS	Magnetizable intravascular stents
MN	Million
MP	Multiphase

MPI	Myocardial perfusion imaging
MR	Magnetic resonance
MRI	Magnetic resonance imaging
MV	Medium vessel
NIC	National Interventional Council
NIRS	Near Infrared Spectroscopy
NMPA	National Medical Products Administration
NOAEL	No-observed-adverse-effect-level
NPPA	National Pharmaceutical Pricing Authority
OCT	Optical Coherence Tomography
PBMA	Poly(n-butyl methacrylate)
PC	Polycarbonate
PCI	Percutaneous coronary intervention
PCL	Poly-ε-caprolactone
PDLA	Poly-D- lactic acid
PDLGA	Poly-DL-lactide-co-glycolide
PDLLA	Poly (D,L-lactic acid)
PES	Paclitaxel-eluting stent
PEVA	Poly(ethylene-co-vinylacetate)
PGA	Polyglycolic acid
PLA	Polylactide Acid
PLGA	Poly(lactide-co-glycolide)
PLLA	Poly-L-lactic acid
PMA	Premarket approval
PMD	Pharmaceutical and Medical Device Act
PMDA	Pharmaceutical and Medical Device Agency
PMS	Post Market Surveillance
POLA	Poly-D- lactic acid
PTCA	Percutaneous transluminal coronary angioplasty
PTFE	Polytetrafluoroethylene
PTP	Pre-test probability
PU	Polyurethane
PVDFHFP	Poly (vinylidene fluoride)-hexafluoropropylene
RCB	Registered Certification Body
SAR	Specific absorption rate
SCAD	Stable coronary artery disease

SCS	Small cell-sized stent
SES	Sirolimus-Eluting Stents
SIBS	Poly(styrene-b-isobutylene-b-styrene)
SMC	Smooth muscle cell
SPECT	Single Photon Emission Computed Tomography
SS	Stainless steel
ST	Stent thrombosis
STEMI	ST elevated myocardial infarction
SV	Small vessel
TGA	Therapeutic Goods Administration
TIA	Transient ischemic attack
TVR	Target-vessel revascularization
UAE	United Arab Emirates
UK	United Kingdom
UPS	Uninterruptible Power Supply
US	United States
USA	United States of America
USD	United States Dollar
YAG	Yttrium Aluminum Garnet
ZES	Zotarolimus-Eluting Stent

EXECUTIVE SUMMARY

The Coronary artery disease (CAD) is a vascular disorder caused by stenosis of coronary arteries due to atheromatous plaque accumulation formed by calcium, fatty deposits, abnormal inflammatory cells within the artery walls, narrowing the lumen of the artery, causing partial or total obstruction and limiting the oxygen-carrying blood flow to the heart. CAD is currently the most common non-communicable disease resulting in serious circumstances frequently caused by partially blocked coronary arteries accounting for 35% fatality globally. In India, over 65 million people are affected by the year 2015. Cardiovascular diseases (CVD) account for nearly 25% of deaths between the ages of 25 and 70 years. Large prospective studies have shown age-standardized CVD mortality rates of up to 225-500 per 100,000 in men and 225-399 per 100,000 in women. These figures appear to be an underestimation given that a large number remain undetected. Along with the current conservative treatment strategies for CAD with medical therapies, invasive management with mechanical revascularization by percutaneous coronary intervention (PCI) followed by stent implantation is often employed to successfully restore the coronary blood flow. The number of interventional cardiologists in India is estimated to be 3 to 5 per million population, in contrast to 50 to 70 per million population in the USA. The number of cardiac catheterization laboratories in India was estimated to be around 960 in 2016. Keeping the burden of disease in mind, the facilities and infrastructure for invasive treatment modalities in India are inadequate. Despite these shortcomings, the number of PCIs performed is increasing steadily at an annual growth rate of 6%. The total number of PCI procedures carried out in 2016 was 495,000 with an estimated number of 594,000 stents used (1.20 per procedure). Of the stents implanted, 80% were DES.

The Global Drug Eluting Stents Market is poised to grow at a CAGR of around 3.8% over the next decade to reach approximately $9.45 billion by 2025.

The main objective of this product dossier is to cover the entire spectrum pertaining to coronary stents. This dossier explains the clinical need, requirements, working principle, detailed technical aspects to enlighten the criticality of the product at the component level and provide a glimpse on relevant standards and regulations to ensure the safety, integrity, and function. The report highlights the market figures and EXIM analysis information which will provide insight into the commercial aspects and demand of the product in the Indian scenario.

ABOUT:

Andhra Pradesh MedTech Zone (AMTZ) is an enterprise under the Government of Andhra Pradesh, a 270 Acre zone dedicated for medical device manufacturing with 200-250 manufacturing units. AMTZ provides the one-stop solution for all the manufacturers by providing, common scientific testing facilitates (EMI/EMC, Electrical Safety, Radiation, Biomaterials Testing, 3D printing facilities), commercial facilities such as expo halls and warehouse.

Kalam Institute of Health Technology (KIHT) in the premises of AMTZ facilitates focused research on critical components pertaining to medical devices, technology transfer of innovative technologies through e-auction, market innovation, and access. These end to end solutions help to reduce the cost of manufacturing up to 40% and make health care products more affordable and accessible.

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