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REVIEW ARTICLE

A Comprehensive Overview of Coronary Stents in India

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ABSTRACT

Coronary artery diseases (CAD), a non-communicable disease, pose a formidable healthcare challenge globally, particularly in India. Therefore, the demand for advanced medical interventions continues to rise. Coronary stents (CS) play a pivotal role in managing CAD. Coronary stents CS are generally available as bare-metal and drug-eluting varieties. This research delves into the landscape of coronary stents approved in India, leveraging data from the official website of the Central Drugs Standard Control Organization (CDSCO), which is the national Regulatory Authority for Medical Devices in India. This study provides critical insights for stakeholders, informing strategies for future research, development, and policy formulation in coronary stent technology in India.

Keywords: Coronary artery disease, Coronary stents, Drug-eluting stents, Bare-metal stents, Atherosclerosis, Plaque formation, manufacturers, Regulatory landscape, Market dynamics, Drug types, Domestic manufacturing, Interventional cardiology, Cardiovascular care, Medical devices.

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INTRODUCTION

Coronary artery disease is caused by plaque buildup in the wall of the arteries that supply blood to the heart (called coronary arteries). Plaque is made up of cholesterol deposits. Plaque buildup causes the inside of the arteries to narrow over time. This process is called atherosclerosis.[1] Atherosclerotic events are increasing in India. Due to the sedentary lifestyle consumption of junk food, plaque formation in coronary arteries is very common nowadays. Coronary artery diseases (CAD) continue to pose a significant health challenge worldwide, and in the context of India, the demand for advanced medical interventions is ever-growing. Among the pivotal advancements in cardiac care [1], coronary stents play a crucial role in alleviating the impact of CAD. This research delves into the landscape of coronary stents in India, presenting a comprehensive analysis of manufacturers, types, and materials approved by the Central Drugs Standard Control Organization (CDSCO).[2]

METHODOLOGY

CDSCO, the National Regulatory Authority for "DRUGS" under the Ministry of Health and Family Welfare, Govt. of India, runs their official website www.cdsco online. Medical devices data was collected from the CDSCO.gov.in portal (Table 1). The details consist of names of manufacturers & importers, description, indication, dimension, date of approval, license number (Table 2).

Regulatory Landscape

Medical Device Rule- 2017 (MDR-17) was enacted by the Ministry of Health & Family Welfare, Govt. of India since 1st January 2018 under the enabling clauses of the existing Drugs Act-1940. CDSCO is responsible for the issuance of Import Registration of all Risk classes of medical devices, while the manufacturing Licenses for risk class A & B are issued by the respective state drugs control

Department, where the factory is situated, under these provisions made in MDR-17 & Drugs Act. The manufacturing Licenses for risk class C & D are granted by the office of DCG(I) after a satisfactory inspection report is received from the Inspectorate Team deputed by the CDSCO to visit the respective factories. The manufacturing premises for all class B devices and class -A (measurable & sterile) devices are audited by the Notified Bodies (NBs), duly registered by CDSCO-HQ and such audit reports are submitted to the State Drugs Control

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Dept, for the issuance of manufacturing licenses.

The entire regulatory documentation and approval of the License are maintained on the www.cdsco online portal.

Evolution of Coronary Stents

In the early 1990s, Bare metal stents were used to treat plaque formation in cardiovascular arteries. In India, alloy metal stents with polymers coated with various immunosuppressive drugs are in use. The evolution of DES from early bare-metal iterations reflects the dynamic nature of cardiovascular disease intervention. Over time, these advancements have enhanced efficacy and raised questions regarding optimal choices in the diverse patient population of India.[3]

Manufacturers and Importers

A multitude of companies are actively engaged in the manufacturing and importation of coronary stents in India. The robust market features a spectrum of players, each contributing to the availability and accessibility of these life-saving devices. A detailed exploration of these companies unveils the intricate dynamics shaping the industry.

Diversity in Stent Types

The spectrum of stent types available in India spans from traditional bare-metal stents to highly specialized drug-eluting variants incorporating sirolimus and everolimus. Additionally, balloon-expandable stents and other innovative designs cater to the diverse needs of patients and healthcare practitioners[4].

Materials in Focus

Stainless steel (ss), cobalt-chromium (co-cr), and other materials form the backbone of these devices, influencing their mechanical properties and biocompatibility. A closer examination of these materials sheds light on the engineering considerations behind coronary stent development.[5]

Efficacy and Safety: Drug-eluting stents (DES) reduce restenosis and target lesion revascularization more effectively than bare metal stents (BMS). However, optimal patient selection should consider factors such as lesion complexity, patient comorbidities, and bleeding risk to ensure the most appropriate stent choice for each individual case.

OBJECTIVE OF THE RESEARCH

This review aims to synthesize the wealth of data available through the CDSCO Portal and other reputable sources, offering valuable insights into the state of coronary stents in India. This article seeks to contribute to the ongoing discourse surrounding cardiovascular care in India by amalgamating regulatory perspectives, industry dynamics, and technological nuances.

TYPES OF STENTS AND THEIR APPLICATIONS

Types of stents and their applications are as follows.

DRUG-ELUTING CARDIAC STENT

One essential tool in the treatment of coronary artery disease (CAD) is the drug-eluting cardiac stent. Compared to conventional bare-metal stents, these novel devices give better results and patient care, which is a major improvement in interventional cardiology.[6]

Advancement in the stent

The distinction between DES and BMS

Since bare metal stents (BMS) don't have any medication coatings, they are a good option for individuals who can't tolerate long-term dual antiplatelet treatment (DAPT). On the other hand, drug-eluting stents (DES) have drug coatings designed to lower restenosis rates; these coatings are especially helpful in treating complex lesions. Additionally, the efficacy and safety profiles of more recent versions of DES are improved by addressing problems such as delayed endothelialization.

Types of Drug-Eluting Cardiac Stent

Everolimus eluting stent

Everolimus, a different advanced generation medication, is used in the creation of DES via scaffold metal-alloy construction, much as sirolimus, to help overcome the drawbacks of bare-metal stents and previous DES generations. Typically, a small layer of polymer containing the immunosuppressive medication everolimus is applied to the cobalt-chromium or platinum-chromium metal scaffolds. A kinase inhibitor called everolimus is authorized for use in organ transplant patients in order to stop organ rejection. This falls under the category of inhibitors of mammalian rapamycin (mTOR) targets and has strong inhibitory effects on the proliferation of smooth muscle cells, which is a crucial step in restenosis after stent implantation [7].

- *Material Construction*

Platinum Chromium

- *Size in diameter*

Diameter- < 2 mm length- 8 to 12 mm

- *Indication for use*

Used to Improve luminal diameter in native coronary arteries with discrete, *de novo* stenosis in patients with symptomatic ischemic heart disease

Used for patients with symptomatic ischemic heart disease due to discrete *de novo* native coronary artery lesions

- *Advantages*

Better patient outcomes, longer clinical durability, reduced rates of thrombosis in stents, quicker endothelial healing, biocompatible polymer coating, optimized drug delivery, versatility in lesion treatment, and superior efficacy

- *Disadvantages*

Risk of neoatherosclerosis, complicated lesion navigation, limited long-term data, possible polymer-related problems, and delayed endothelialization.

Sirolimus eluting stent

The use of sirolimus-eluting stents (SES) in interventional cardiology has advanced significantly. Sirolimus, a strong immunosuppressive and antiproliferative medication, is coated

Table 1: Import of Stents

S. No	*Type of drug*	*Type of material*	*Company*	*Size in diameter X length*	*Indication*
1.	Everolimus _DES (Drug Eluting Stent)	1. Platinum Chromium	Boston Scientific India PVT, Ltd.	Diameter- < 2 mm Length- 8 mm	Used to increase luminal diameter for patients having symptomatic ischemic heart disease who have distinct, de novo stenosis in their native coronary arteries
			Abbott Healthcare	Diameter- < 2 mm Length-12 mm	Used to increase luminal diameter for patients having symptomatic ischemic heart disease who have distinct, de novo stenosis in their native coronary arteries
		NA	Abbott Healthcare Private Limited	stent length (8 mm, 12 mm, 15 mm, 18 mm,) diameter of ≥ 2.25 mm and ≤ 4.25 mm	The following patients will benefit from increasing coronary artery luminal diameter: • Individuals with ischemic heart disease who have distinct de novo native coronary artery lesions that cause symptoms. • To restore coronary flow in individuals who appear within 12 hours of the beginning of symptoms and are suffering from an acute myocardial infarction.
2.	Sirolimus eluting Stent	Coronary Stent Balloon expandable (metal / polymer)	Bio India Interventional Technologies Pvt Ltd	Length: <40 mm; Diam: 2.5 mm -4.0 mm	Patients with Symptomatic Ischaemic heart disease and to improve the coronary Luminal Diameter by implantation
		Cob-Cr	Vascular Concepts	Length : <40 mm; Diam: 2.5 mm	Used to increase luminal diameter for patients having symptomatic ischemic heart disease who have distinct, de novo stenosis in their native coronary arteries
		NA	M/s. Terumo India Pvt. Ltd	Length : <40 mm; Diam: 2.5 mm	Patients with Symptomatic Ischaemic heart disease and to improve the coronary Luminal Diameter by implantation
		Cob-Cr (lactide/ Glycolide polymer)	Veena Cardio System	Diameters from 2–4.5 mm.	used to increase an artery's internal diameter in the scenarios that follow in an effort to improve blood flow: - Individuals experiencing ischemic heart disease symptoms as a result of "de novo" stenotic and restenotic lesions in their arteries
		Cobalt Chromium	M/s. Translumina Therapeutics LLP	diameter ranging from 2.0–4.0 mm	Coronary stents are used to keep narrowed coronary arteries bypass grafts open after acute blockages. They're also for restenosis after PTCA. Patients considered for stent placement should also be eligible for coronary balloon angioplasty.
		CoCr Stent	M/s. Lepu Care (India) Vascular Solutions Pvt. Ltd	lesions (length~32 mm) with reference vessel diameters ranging from 2.25–4.5 mm	i] Improving coronary luminal diameter in the following: • Patients with symptomatic ischemic heart disease due to de novo native coronary artery ii] Patients eligible for balloon angioplasty with symptomatic ischemic heart disease due to discrete de novo and/or restenotic native coronary artery lesions with reference vessel diameters ranging from 2.5 mm to 4.0 mm
		CoCr Stent and permanent polymer.	1. M/s. Tapadiya Interventional Technologies & Health Care LLP	diameters from 2–4.5mm.	Use in the following situations to increase an artery's internal diameter and improve blood flow: • Individuals experiencing ischemic heart disease symptoms as a result of "de novo" stenotic and restenotic lesions in arteries
		NA	Raymed Trading Group Private Limited	diameters from 2–4.5 mm.	Utilized to expand an artery's internal diameter in these circumstances in an effort to improve blood flow: • Individuals experiencing ischemic heart disease symptoms as a result of "de novo" stenotic and restenotic lesions in arteries
		NA	M/s. Sai Health Innovation	Length : <40 mm; Diam: 2.5 mm	In the following situations, it is used to increase an artery's internal diameter in an effort to improve blood flow: • Individuals experiencing ischemic heart disease symptoms as a result of "de novo" stenotic and restenotic lesions in their arteries

	Cobalt Chromium with 85/15 DL-Lactide/ Glycolide Polymer) -	M/s Vascular Concepts Ltd.	(length <40 mm) with a reference vessel diameter ranging from 2.5–4.0mm	In the following situations, it is used to increase an artery's internal diameter in an effort to improve blood flow: • Individuals experiencing ischemic heart disease symptoms as a result of "de novo" stenotic and restenotic lesions in their arteries
	Cobalt Chromium with Poly sulfone Polymer	M/s Vascular Concepts Ltd.	(length <40 mm) with a reference vessel diameter ranging from 2.0–4.0mm (maximum stent diameter 4.5 mm	Use in patients with symptomatic ischemic heart disease due to discrete de novo coronary artery lesions
	Cobalt Chromium Degradable Matrix	M/s Vascular Concepts Ltd.	length <40 mm) with a reference vessel diameter ranging from 2.5–4.0 mm	used to increase coronary luminal diameter in individuals with ischemic heart disease symptoms brought on by isolated de novo coronary artery lesions. It is still uncertain what will happen to this permanent implant in the long run.
	Cobalt Chromium	M/S. L2mtech India Private Limited	diameter of 2.25–4.00 mm	use in PTCA-eligible patients with the goal of maintaining vessel patency and expanding the coronary artery lumen
	CoCr Stent and permanent polymer (iVascular angiolite)-	M/s. B.V Enterprise	diameters from 2–4.5mm	Used for increasing the internal diameter of an artery with the aim of improving blood flow in the following cases: • Patients with symptomatic ischemic heart disease due to "de novo" stenotic and restenotic lesions located in arteries.
	CoCr Stent and permanent polymer	M/s. JMD Surgical	Diameters from 2–4.5 mm	In the following situations, the device is approved for enlarging an artery's internal diameter in an effort to improve blood flow: • Individuals experiencing ischemic heart disease symptoms as a result of "de novo" stenotic and restenotic lesions in arteries
	CoCr Stent and permanent polymer (iVascular enviros)-	M/s. B.V Enterprise	Diameters from 2–4.5 mm	Used to increase an artery's internal diameter in the following situations in an effort to improve blood flow: • Individuals experiencing ischemic heart disease symptoms as a result of "de novo" stenotic and restenotic lesions in their arteries
	CoCr Stent and permanent polymer	M/s. Heart Rhythm Therapeutic Private Limited	Diameters from 2–4.5 mm.	Used to increase an artery's internal diameter in the following situations in an effort to improve blood flow: • Individuals experiencing ischemic heart disease symptoms as a result of "de novo" stenotic and restenotic lesions in their arteries
	Stainless Steel with Polysulfone Polymer	M/s Vascular Concepts Ltd.	NA	Patients with distinct de novo coronary artery lesions that cause symptomatic ischemic heart disease are eligible to use the Pronova SS Coronary Stent System. As of right now, the permanent implant's long-term results are uncertain.
	Sirolimus Eluting Coronary Stent SysteM	M/s. Terumo India Pvt. Ltd	NA	Sirolimus-eluting coronary stent system is a sterile, single-use implantable device containing sirolimus drug. It's mounted on a semi-compliant balloon delivery catheter and is designed to enhance blood flow in the heart muscle for patients with narrowed or blocked coronary arteries.
	Orsiro	M/s. Biotronik Medical Devices India Pvt Ltd.	diameter of 2.25–4.0 mm and length ≤ 40 mm*)	Improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions
3	Stainless Steel	M/s Vascular Concepts Ltd.	length <40 mm) with a reference vessel diameter ranging from 2.5–4.0 mm (maximum stent diameter 4.5 mm,	Use in individuals with distinct de novo coronary artery lesions causing ischemic heart disease symptoms

4.	Rapamycin Stent		M/s.Micro Port Scientific India Pvt. Ltd.		When paired with reference vessel sizes of 2.25 to 4.0 mm, this treatment is used to increase coronary luminal diameter in individuals who have symptomatic heart disease as a result of de novo native coronary artery lesions length < 60 mm.
5.	NA Drug Eluting Coronary Stent System (BioMatrix Alpha)-	NA	M/s. Cardiologix	with a reference diameter ranging between 2.25 and 4.0 mm.	When treating de novo lesions in native coronary arteries, the BioMatrix Alpha stent is recommended for increasing coronary luminal diameter.
6.	NA Drug Eluting Coronary Stent System (BioMatrix Alpha)-	NA	M/s. Pious Medi Solutions	Diameter ranging between 2.25 and 4.0 mm.	When treating de novo lesions in native coronary arteries, the BioMatrix Alpha stent is recommended for increasing coronary luminal diameter as a point of reference.
7.	Onyx TruCor Zotarolimus	Material is not given	M/s. India Medtronic Private Limited	Diameter- 2.25–4.0 mm Length is not given	Use in patients eligible for (PTCA) with a reference vessel diameter of 2.25 mm to 4.0 mm.
8.	BioMatrix NeoFlex	NA	M/S. Eurasia Healthcare Llp	Diameter - 2.25 and 4.0 mm Length- 33 mm	When treating de novo lesion in native artery walls, use to increase coronary luminal diameter.
9.	Coroflex ISAR Neo	NA	M/S. B Braun Medical India Private Limited	Diameter - 2.0–4.0 mm length -38 mm	Its goals are to increase the intraluminal diameter of coronary arteries and lower the risk of restenosis.
10.	Cobalt Chromium Coronary Stent	Cobalt Chromium	M/s. Envision Scientific Pvt. Ltd	diameters of 2.25–5.00 mm	use in the management of individuals exhibiting clinical signs of myocardial ischemia associated with the disease state of multiple coronary arteries.
11.	Stainless Steel Coronary Stent	Stainless Steel	M/s. Translumina Therapeutics LLP	NA	usage in individuals who qualify for PTCA, or percutaneous transluminal coronary angioplasty. Its goal is to increase the coronary luminal diameter in individuals who have distinct de novo lesions in their native coronary arteries, resulting in symptomatic ischemia illness.
12.	Self Expandable Nitinol Stent	Nitinol	M/s. Vascular Concepts Limited	NA	It is recommended for the treatment of vena-cava syndrome as well as dissections, stenoses, and other particular pathologies of the abdominal and thoracic descending aortas.
13.	Cobalt Chromium Coronary Stent	Cobalt Chromium	M/s. Envision Scientific Pvt. Ltd	Inner vessel diameters of 2.25–5.00 mm.	usage in the management of individuals experiencing myocardial ischemia symptoms that are connected to the diseased states of multiple coronary vessels. Intracoronary stents are now approved for use in treating de novo or restenotic lesions in native coronary arteries as well as de novo lesions in saphenous vein grafts.
14.	Rapamycin	Rapamycin Target Eluting Coronary Stent	M/s. Reinvent Medical Pvt. Ltd	lesions length ≤ 60 mm with reference vessel diameters of ≥ 2.25–≤ 4.0 mm.	Use for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery.
15.	Rapamycin	Target Eluting Coronary Stent	M/s. Purple Micro Port Cardiovascular Private Limited	length ≤ 60 mm with reference vessel diameters of ≥ 2.25–≤ 4.0 mm.	Applied to individuals with symptomatic cardiac disease as a result of de novo native coronary artery lesions in order to increase coronary luminal diameter
16.	Drug Coated Coronary Stent System	NA	M/s. Curis Healthcare	diameter ranging from 2.25–4.0 mm. Stents with lengths of 33, 36 mm,	recommended for treating de-novo lesions in native coronary arteries by increasing coronary luminal diameter.
17.	Bio Matrix Neo Flex	Not available in CDSCO portal	M/s. Curis Healthcare	diameter ranging between 2.25 and 4.0 mm	Recommended for treating de novo lesions in native coronary arteries by increasing coronary luminal diameter.

18.	NA (Drug CoatedCoronary Stent System(Bio Freedom)	Not available in CDSCO portal	M/s. T. A. Technologies And Healthcare	diameter ranging from 2.25–4.0 mm.	increasing the width of the coronary lumen to treat de novo lesions in native coronary arteries
19.	Drug Coated Coronary Stent System(BioF reedom Ultra)-	Not available in CDSCO portal	M/s. Biosensors Medical India Pvt. Ltd	Diameter ranging from 2.25–4.0 mm. Stents with lengths of 33 and 36 mm	Improves coronary luminal diameter in native coronary arteries to treat de novo lesions.
20.	Drug Coated Coronary Stent System (BioFreedom)	Not available in CDSCO portal	M/s. Pious Medi Solutions	Diameter ranging from 2.25–4.0 mm Lengths of 33 and 36 mm	Improves coronary luminal diameter in native coronary arteries to treat de novo lesions.
21.	Drug Coated Coronary Stent System(HT Supreme)-	NA	M/s. Innovant Scientific Pvt. Ltd.	Length ≤ 35 mm) with reference vessel diameters of 2.25–4.00 mm.	Improves coronary luminal diameter in native coronary arteries to treat de novo lesions.
22.	Balloon Expandable Coronary Stent System	Sirolimus Eluting Stent) (euca Limus - Balloon Expandable Coronary Stent System	M/s. Vascular Concepts Limited	diameter of 2.25–4.00mm (maximum stent diameter after placement is 0.5 mm above the nominal value) and is intended to expand the lumen of the coronary arteries	for use in individuals with symptomatic ischemic coronary heart disease brought on by newly formed coronary artery lesions or coronary artery restenosis lesions. In patients who did not react well to an interventional therapy after balloon dilatation, stent systems can also be used to treat acute or suspected occlusions.
23.	Balloon Expandable Coronary Stent	Cobalt Chromium	M/s. Vascular Concepts Limited	diameter ranging from 2.0–4.0 mm (maximum stent diameter 4.5 mm,	Improves coronary luminal diameter in native coronary arteries to treat de novo lesions.
24.	Balloon Expandable Coronary Stent System (Sirolimus Eluting Stent)	Sirolimus	M/s Vascular Concepts Ltd.	-	In patients who did not react well to an interventional therapy after balloon dilatation, stent systems can also be used to treat acute or suspected occlusions.
25.	Stainless Steel Balloon Expandable	Stainless Steel	M/s Vascular Concepts Ltd.	diameter ranging from 2.0–4.5 mm (maximum stent diameter 4.5 mm,	Use in individuals with distinct coronary de novo arterial lesions with a reference vessel who have symptomatic ischemic heart disease

on these stents to prevent smooth muscle cell proliferation, which is a factor in restenosis or the re-narrowing of arteries following angioplasty.[8]

Individuals with symptomatic ischemic heart disease and those seeking to increase the coronary luminal diameter by sirolimus-eluting stent implantation:- To repair PTCA ballooning-induced tears, aneurysms, ruptured arteries, and perforated arteries

- Helps patients with stenotic coronary artery lesions by increasing blood flow to the heart.
- Employed to expand an artery's internal diameter in the following situations in an effort to improve blood flow: - Individuals experiencing ischemic heart disease symptoms as a result of "*de novo*" stenotic and restenotic lesions in arteries
- Managing coronary artery bypass surgery and stenotic lesions in order to preserve vascular patency.

Rapamycin Stent

Sirolimus-eluting stents (SES), also referred to as rapamycin-eluting stents (RES), have advanced interventional cardiology significantly. These stents are coated with rapamycin, a strong immunosuppressive and antiproliferative medication that lessens the chance of restenosis, or the re-narrowing of arteries after angioplasty, by preventing smooth muscle cell growth [9].

- *Advantages*

reduced restenosis rates, lower need for repeat revascularization, improved long-term clinical outcomes, enhanced vascular healing, customized drug delivery, versatility in lesion management, proven clinical efficacy

- *Disadvantages*

Decreased rates of restenosis, decreased need for repeat revascularization, enhanced vascular healing, customized drug delivery, versatility in lesion management, and demonstrated clinical efficacy

Bare metal stent

The development of interventional cardiology and the treatment of coronary artery disease (CAD) have been greatly aided by bare metal stents (BMS). These devices, made of a metal scaffold, improve blood flow to the heart muscle by acting as a mechanical support to keep coronary arteries open during angioplasty.[4]

Table 2: Stents manufactured In India

S.No	*Type of DES*	*Type of Material*	*Company*	*Size in Diameter X Length*	*Indication*
r1.	Everolimus-DES (Drug Eluting Stent)	Not available in CDSCO portal	M/S. Purple Microport Cardiovascular	Not available in CDSCO portal	PTCA-eligible individuals with symptomatic ischemic heart disease can improve their coronary luminal diameter in native coronary arteries with a de novo coronary artery lesion.
		Not available in CDSCO portal	M/S. Kamal Encon Industries Limited	length ≤ 48 mm in native coronary arteries with a reference vessel diameter of 2.00–4.50 mm	When used in PTCA-eligible patients, this treatment improves coronary luminal diameter in individuals with symptomatic ischemia disease brought on by distinct de novo lesions.
		Not available in CDSCO portal	M/s. Kamal Encon Industries Limited	length ≤ 40 mm in native coronary arteries with a reference vessel diameter of 2.00–4.50 mm.	Use in patients who meet the criteria for PTCA in order to improve coronary luminal diameter (CLD) in individuals who have distinct de novo lesions-related symptomatic ischemic illness.
		Co-Cr	M/s.Sahajanand Laser Technology Limited	Not available in CDSCO portal	for enhancing coronary luminal diameter in individuals suffering from distinct de novo or restenotic lesions that are the cause of symptomatic ischemic heart disease.
		Co-Cr	M/s. Relisys Medical Devices Limited	Length 08 to 44mm) diameters ≥2.25 or ≤ 5.00mm.	for the treatment of "de novo" lesions in native coronary arteries, in order to increase luminal diameter and lower restenosis. In patients who have not responded to interventional therapy, it is also recommended for the treatment of abrupt or threatening closure.
		Biodegradable polymer based Everolimus Eluting Coronary Stent	M/S. Multimedics	NA	A coronary stent is a tube-shaped medical device used to treat coronary heart disease by keeping the coronary arteries, which supply blood to the heart.
		Not available in CDSCO portal	M/s. Veritas Bioventions Pvt. Ltd	Diameter ranging from 2.00–4.50 mm	The Enovo Everolimus eluting coronary stent system is used to treat blockages in coronary arteries and improve their diameter. It's designed to prevent repeated blockages and is recommended for patients with symptomatic heart disease due to specific artery issues.
		Not Available in CDSCO Portal	M/s. Meril Life Sciences Pvt. Ltd.	Length ≤ 44 mm) diameter of 2.00–4.50 mm	in patients eligible for PTCA and Stenting procedures, with the goal of improving coronary luminal diameter in patients with symptomatic ischemic heart disease caused by de novo and in-stent restenotic lesions
2.	Sirolimus-DES (Drug Eluting Stent)	Biodegradable Polymer based-DES	M/s. PURPLE MICROPORT	diameter of 2.00–4.50 mm	for increasing coronary luminal diameter in individuals who meet the criteria for PTCA and who have symptomatic ischemic heart disease in native coronary arteries with a de novo coronary artery lesion.
		Polymer free Hydroxyapatite SES	M/S. Purple Microport	lesions length ≤60 mm with reference vessel diameters of ≥2.25–4.0 mm	with the goal of increasing coronary luminal diameter in PTCA-eligible patients with symptomatic ischemic heart disease in de novo coronary artery lesions in native coronary arteries.
		SS (Nickel free)	M/s. S3V Vascular Technologies Pvt, Ltd.	Not Available in CDSCO Portal	Designed to increase coronary luminal diameter in individuals with symptomatic ischemia disease resulting from distinct native coronary artery restenotic lesions, including de novo and in-stent,
		Not Available in CDSCO Portal	M/s. S3V Vascular Technologies Pvt, Ltd.	Not Available in CDSCO Portal	Designed to increase coronary luminal diameter in individuals with symptomatic ischemia disease resulting from distinct native coronary artery restenotic lesions, including de novo and in-stent,

		Not Available in CDSCO Portal	M/s. KAMAL ENCON INDUSTRIES LIMITED	lesions of length 40 mm & diameter of 2.00–4.50 mm.,	Use in patients who meet the requirements for PTCA. The purpose of the Sirolimus Eluting Coronary Stent System is to increase coronary luminal diameter in individuals who have distinct de novo lesions and symptomatic ischemia disease.
		Not Available in CDSCO Portal	M/s. Relisys Medical Devices Limited	stent length (10–40 mm) with reference vessel diameters ≥ 2.25 or ≤ 4.00 mm.	increasing luminal diameter and decreasing restenosis in native coronary arteries to treat "de novo" lesions. In patients who have not responded to interventional therapy, it is also recommended for the treatment of abrupt or threatening closure.
		Biodegradable polymer based SES	M/s. Multimedics	NA	A cardiac stent is a tube-shaped medical device used to treat coronary heart disease by keeping the coronary arteries, which supply blood to the heart
		Not Available in CDSCO Portal	M/s. Relisys Medical Devices Vasc Limited	Not Available in CDSCO Portal	increasing luminal diameter and decreasing restenosis in native coronary arteries to treat de novo lesions. In patients who have not responded to interventional therapy, the Sirolimus Eluting Coronary Stent System is suggested for the treatment of abrupt or threatening closure.
		Not Available in CDSCO Portal	M/s. Manufacturing Veritas Bioventions Pvt. Ltd	Diameter ranging from 2.00–4.50 mm and is intended to improve coronary luminal diameter	The Enovo Everolimus eluting coronary stent system is used to treat blockages in coronary arteries and improve their diameter. It's designed to prevent repeated blockages and is recommended for patients with symptomatic heart disease due to specific artery issues.
		Not Available in CDSCO Portal	M/s. Envision Scientific Pvt. Ltd	Lesions of length 52 mm in native coronary arteries with a reference diameter from 2.25–5.00 mm.	The Enovo Everolimus eluting coronary stent system is used to treat blockages in coronary arteries and improve their diameter. It's designed to prevent repeated blockages and is recommended for patients with symptomatic heart disease due to specific artery issues.
		Sirolimus Based Bifurcation Stent System	M/s. Envision Scientific Pvt. Ltd.	Length 18 mm Diameter of 2.50–3.50 mm and with a side branch reference vessel diameter of 2.00–3.00 mm	It is indicated for improving coronary artery luminal diameter, while simultaneously maintaining side branch access in patients with symptomatic ischemic disease due to discrete de novo lesions
		Not Available in CDSCO Portal	M/s. Invent Biomed Private Limited	NA	The stent is intended for use as an adjunct to coronary interventions
		Biodegradable polymer based SES	M/s. Meril Life Sciences Pvt. Ltd.	lesions with a side branch < 2 mm in diameter	Enhancing coronary luminal diameter in the subsequent instances:Individuals suffering from distinct native coronary artery lesions that have resulted in ischemic heart disease symptoms. for reestablishing coronary flow in individuals who appear within 12 hours of the beginning of symptoms and are suffering from an acute myocardial infarction.
		Not Available in CDSCO Portal	M/s. RELISYS MEDICAL DEVICES LIMITED	stent length (08 to 44 mm) with reference vessel diameter more than 2.25 or less than 5.00 mm.	The treatment of "de novo" lesions in native coronary arteries can benefit from this stent's increased luminal diameter and less restenosis. It is recommended for individuals who have not responded well to interventional therapy to treat sudden or threatening closure.
3.	Rapamycin DES (Drug Eluting Stent)	Not Available in CDSCO Portal	M/s. S3V Vascular Technologies Pvt, Ltd.	Not Available in CDSCO Portal	increasing the coronary luminal diameter in individuals whose native coronary arteries have distinct de novo and in-stent restenotic lesions causing symptomatic ischemia illness,

		SS	M/s. Sahajanand Laser Technology Limited	Not Available in CDSCO Portal	increasing the coronary luminal diameter in individuals whose native coronary arteries have distinct de novo and in-stent restenotic lesions causing symptomatic ischemia illness,
		Co-Cr SES	M/s. Sahajanand Laser Technology Limited	Not Available in CDSCO Portal	increasing the coronary luminal diameter in individuals whose native coronary arteries have distinct de novo and in-stent restenotic lesions causing symptomatic ischemia illness,
4.	Paclitaxel -DES (Drug Eluting Stent)	Not Available in CDSCO Portal	M/s. Veritas Bioventions Pvt. Ltd	Dia-2-4.5 mm	The Enovo Everolimus eluting coronary stent system is utilized to address blockages in coronary arteries, enhancing their diameter and preventing recurrent issues. It's prescribed for individuals experiencing symptomatic heart disease as a result of particular artery conditions.
	BMS (Bare Metal Stent) NA	SS	M/s. PURPLE MICROPORT	Not Available in CDSCO Portal	When a patient qualifies for PTCA, the product is suggested for increasing coronary luminal diameter in patients with symptomatic ischemic heart disease in de novo coronary artery lesions in native coronary arteries.
	BMS NA	Stainless Steel (Nickel free) Coronary stent	M/s. S3V Vascular Technologies Pvt, Ltd.	Not Available in CDSCO Portal	increasing the coronary luminal diameter in individuals whose native coronary arteries have distinct de novo and in-stent restenotic lesions causing symptomatic ischemia illness,
	BMS	SS			For improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo or restenotic lesions,
	BMS	SS	M/s. MULTIMEDICS	Not Available in CDSCO Portal	A coronary stent is a tube-shaped medical device used to treat coronary heart disease by keeping the coronary arteries, which feed blood to the heart, open.
	BMS	SS	M/s. Veritas Bioventions Pvt. Ltd	NA	designed to be utilized as an implantable device that is placed into the central circulatory system by a physically intrusive process.
	BMS	Stainless Steel Coronary Stent System	M/s. Meril Life Sciences Pvt. Ltd.	with reference vessel diameter of 2.50–4.50 mm	It is recommended for de novo coronary artery lesions in native coronary arteries for (PTCA) & stenting procedures in order to improve coronary luminal diameter in patients with symptomatic ischemic heart disease.
	BMS	Covered Bare Metal Aortic Stent (Little Angels)-	M/s. Meril Life Sciences Pvt. Ltd.		Patients with the following clinical conditions are eligible for device implantation in the native and/or recurrent coarctation of the aorta: • Aortic stenosis resulting in hemodynamic changes, such as a systolic pressure gradient, systemic hypertension, or altered left ventricular function; • Aortic stenosis resulting in significant anatomic narrowing as assessed by angiography or non-invasive imaging, such as echocardiography, magnetic resonance imaging (MRI), or CT scan;
	BMS	Cobalt Chromium Coronary	M/s. Meril Life Sciences Pvt. Ltd.	Diameter of 2.5–4.5 mm and lesion length ≤ 36 mm in patients eligible for Percutaneous Transluminal Coronary Angioplasty	It is indicated for improving coronary luminal diameter in patient with symptomatic ischemic heart disease in de novo coronary artery lesion in native coronary arteries
	BMS NA	Cobalt Chromium	M/S. Purple Microport	NA	increasing the coronary luminal diameter in individuals whose native coronary arteries have distinct de novo and in-stent restenotic lesions causing symptomatic ischemia illness,

BMS NA	Cobalt Chromium	M/S. S3v Vascular Technologies Pvt, Ltd.	NA	increasing the coronary luminal diameter in individuals whose native coronary arteries have distinct de novo and in-stent restenotic lesions causing symptomatic ischemia illness,
BMS NA	Co-Cr Stent Delivery System	M/S. Kamal Encon Industries Limited	NA	Use in patients eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA)
BMS NA	Chromium Cobalt	M/S. Multimedics	NA	A coronary stent is a tube-shaped medical device used to treat coronary heart disease by keeping the coronary arteries, which feed blood to the heart, open.
BMS	Cobalt Chromium	M/S. Veritas Bioventions Pvt. Ltd	Diameter 2.00–4.50 mm	indicated for use in patients with symptomatic ischemic heart disease due to discrete de novo coronary artery lesions with a reference vessel. Intended to improve coronary luminal diameter
BMS NA	Co-Cr Stent Delivery System	M/S. Invent Biomed Private Limited	NA	is intended for use in patients eligible for PTCA
Coated coronary stent	Hydroxyapatite Cobalt Chromium	M/S. Purple Microport Cardiovascular Private Limited	NA	The product is recommended for increasing coronary luminal diameter in symptomatic ischemic heart disease patients who are qualified for PTCA and have a de novo coronary artery lesion in their native coronary arteries.
	Cobalt Chromium	M/S. Sahajanand Laser Technology Limited	NA	Product is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease in de novo coronary artery lesion in native coronary arteries in patients eligible for PTCA
Target eluting stent Rapamycin		M/S. Purple Microport Cardiovascular Private Limited	length ≤60 mm with reference vessel diameters of ≥2.25 to ≤4.0 mm	increasing the coronary luminal diameter in individuals whose native coronary arteries have distinct de novo and in-stent restenotic lesions causing symptomatic ischemia illness,

Different types of bare metal stents

- *Stainless Steel Coronary Stent*

Used in the patient eligible for percutaneous transluminal coronary angioplasty (PTCA). It is intended to improve coronary luminal diameter in patients with symptomatic ischemic disease due to discrete *de novo* lesions in native coronary arteries.[11]

- *Self-Expandable Nitinol Stent*

It is indicated for the treatment of dissections, stenoses and other specific lesions of the thoracic descending aorta the abdominal aorta as well as for the treatment of vena-cava syndrome[12].

- *Cobalt-chromium coronary stent*

Used in the treatment of patients with clinical symptoms of myocardial ischemia related to the pathological conditions of one or more coronary arteries. Recognized use of intracoronary stents currently includes but is not limited to the treatment of *de novo* or restenotic lesions in native coronary arteries and in *de novo* lesions of saphenous vein grafts [13].

Target Eluting Coronary Stent

In order to prevent neointimal hyperplasia and encourage vascular healing after stent implantation, target-eluting coronary stents offer a novel strategy to medication delivery [14]. This allows for the exact and targeted administration of therapeutic medicines.

TYPES OF TARGET ELUTING CORONARY STENT

Types of target eluting coronary stent are as follows.

Rapamycin Target Eluting Coronary Atent

Use for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery

Rapamycin target eluting coronary stent system (Firehawk Liberty)-The Firehawk LibertyTM [15].

Drug Coated Coronary Stent System

Bio matrix neo flex

For the treatment of *de novo* lesions in native coronary arteries with a reference diameter range between 2.25 and 4.0 mm, the BioMatrix NeoFlex DES is recommended for increasing coronary luminal diameter [16, 17].

Balloon expandable coronary stent

Balloon Expandable Coronary Stent System: intended for

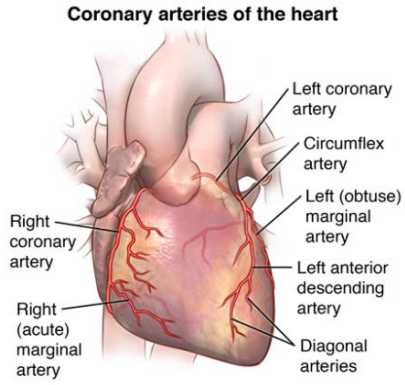


Figure 1: Coronary arteries of heart

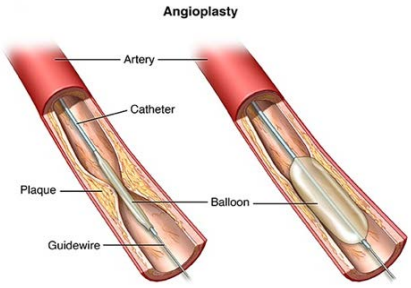
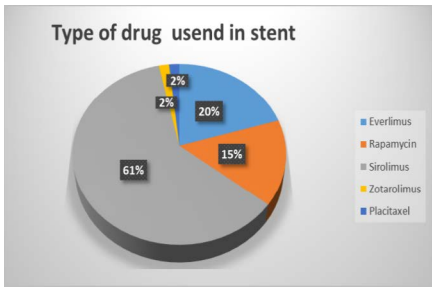
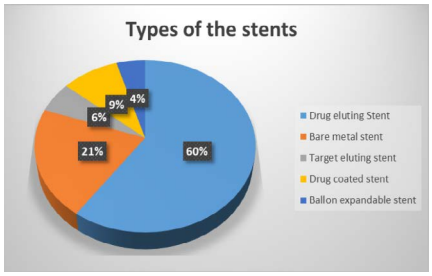


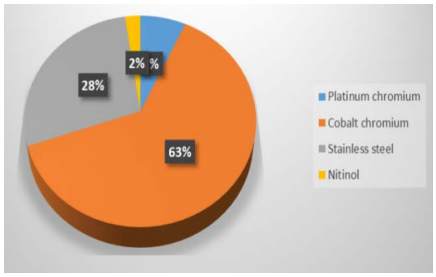
Figure 2: Balloon expandable coronary stent



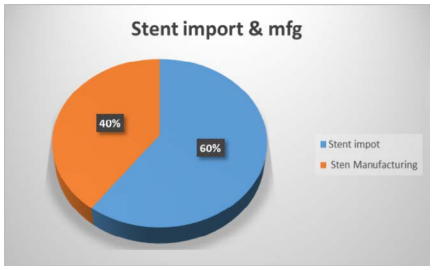
Graph 1: Type of drugs used in stent



Graph 2: Types of Stents



Graph 3: Types of metals used in stent



Graph 4: Stent import & manufacturing

use in individuals with symptomatic ischemic heart disease resulting from coronary artery restenosis or *de novo* lesions. In patients who did not respond well to interventional therapy after balloon dilatation, stent systems are also recommended for the treatment of acute or suspected occlusions [18].

Individuals with symptomatic ischemic coronary heart disease who have *de novo* or restenosis lesions in their coronary arteries should use the balloon expandable coronary stent system (Sirolimus Eluting Stent).

The use of stent systems is also recommended for the management of acute or suspected occlusions in patients who did not improve with interventional therapy after balloon dilatation [19].

Stainless steel balloon expandable

used in patients with distinct coronary artery lesions with a reference vessel who have ischemic heart disease symptoms [20].

Figures 1 and 2 show that coronary arteries are blood vessels that supply oxygen-rich blood to the heart muscle. Coronary stents are small mesh-like tubes inserted into these arteries to keep them open, often used to treat blockages and improve blood flow to the heart.

RESULTS

This Analysis encompasses manufacturers & Importers, materials of construction, and regulatory frameworks, shedding light on market dynamics. The overall findings reveal that 40% of stents are indigenously manufactured, while 60% are imported. Predominantly, Sirolimus-based stents lead the market at 61%, followed by zotarolimus (25%), everolimus (20%), rapamycin (15%), and paclitaxel (2%). Material-wise, cobalt chromium dominates at 63%, followed by stainless steel (28%), platinum chromium (2%), and nitinol (2%). Also the bare metal Stents (BMS) capture the list at (21%) and DES at (60%).

However, in the list of approved medical devices, there are certain limitations of availability of harmonized data in terms of dimensions, material of construction, indications etc.

Technologies of Coronary Stent

Despite being well-established, coronary stents have undergone continuous advancements to improve patient outcomes. Recent innovations encompass bioabsorbable stents, enhancements in drug-eluting stent (DES) technologies, next-generation stent

designs, and the development of drug-free coatings. These innovations aim to promote endothelial healing and mitigate long-term complications associated with stent implantation.

Types of the stents based on the used drugs. = 12 Everolimus DES, 9 Rapamycin-stents, 36 Sirolimus –DES, 1 Zotarolimus DES, 1 Placitaxel –DES Shows in Graph 1

Types of stents; 52 are Drug eluting stents, 18 Bare metal stents, 5 Target eluting stents, 8 Drug coated stents, 4 Balloon expandable stents shows in Graph 2

Types of metal used in stents. Platinum chromium =3 Stents, Cobalt chromium =27 Stents, Stainless steel =12 stents and Nitinol (Nickel + titanium) = 1 Stent shows in Graph 3

Graph 4 shows that 51 of stents are imported in India while only 44 of stents are manufactured in India.

CONCLUSION

This research offers a comprehensive analysis of the coronary stent landscape in India, elucidating their vital role in CAD management. The diversity of stent types and materials underscores the need for tailored solutions to address the heterogeneous patient population. The prominence of sirolimus-based stents suggests ongoing interest and investment in drug-eluting technologies. Additionally, the significant reliance on imported stents highlights opportunities for domestic manufacturing to enhance self-sufficiency and address market demands. Regulatory oversight by CDSCO ensures adherence to rigorous standards, safeguarding patient welfare and treatment efficacy. As a review article, this study contributes foundational knowledge for further investigations, guiding future innovations and policy interventions aimed at optimizing cardiovascular care in India.

However, harmonized data/reports in terms of construction material, dimensions, polymer coating, and drugs are not presented on CDSCO's official portal. Therefore, the exact percentages of various parameters may not be corroborating with the factual scenario of cardiac stents in India. Also, the Indication Statements need to be attended and written carefully so as to eliminate variations.

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