GHMAP

Full Country Intelligence

Imported Next-Generation Drug-Eluting Coronary Stent

Adult PCI | India

Project field	Definition
Sample manufacturer	Generic US/EU-based, revenue-generating, growth-stage MedTech manufacturer
Primary configuration	Balloon-expandable sirolimus-eluting cobalt-chromium DES with biodegradable polymer
Intended use	Adult PCI for eligible de novo lesions in native coronary arteries
India status	No Indian import licence or commercial sales assumed
Research cutoff	19 August 2026
Overall evidence confidence	MEDIUM
Decision conclusion	CONDITIONAL GO

1. Executive Decision Summary

Overall conclusion: CONDITIONAL GO

The locked Phase 5B evidence supports continued evaluation of India as a commercially meaningful market for the defined imported DES. Significant investment should proceed only after product-specific CDSCO classification/predicate confirmation, validation of confidential net acquisition economics, and confirmation of current national/priority-state PCI payment rules. Clinical demand is substantial, DES use is mature, and buyer/procurement pathways are identifiable. The principal constraints are regulated pricing, strong domestic and multinational competition, incomplete registry coverage, and reimbursement variation.

Confidence: MEDIUM - Critical commercial and regulatory inputs remain unresolved.

Decision dimension	Finding	Confidence
Market opportunity	Observed 2024 PCI base 726,715; scenario TAM 832,942-1,068,381 DES units.	MEDIUM
SAM	499,765-908,124 units; highly dependent on product-fit assumptions.	LOW
Pricing	NPPA 2026 DES ceiling ₹39,186.03 excluding GST; public patient/MRP observations ₹23,625 to ~₹41,145.	MEDIUM
Competition	15 products screened; five direct competitors profiled.	MEDIUM
Regulatory	Provisional Class D; MD-14 to MD-15 import route with Indian authorized agent.	MEDIUM
Reimbursement	PCI package funding relevant; Assam PM-JAY MC011A example ₹40,600.	MEDIUM
Buyers	Public institutes, state procurement bodies and private cardiac networks are	MEDIUM

Decision dimension	Finding	Confidence
	structurally important.	
Procurement	Public tenders/rate contracts plus private negotiated sourcing; consignment model evidenced.	MEDIUM

Top opportunity drivers

- Large observed PCI procedure base with 2024 registry volume 10.945% above 2023.
- Historical national evidence shows DES has become the dominant coronary-stent technology.
- Large public and private cardiac-care infrastructure provides multiple demand and procurement routes.

Top risks

- NPPA price control constrains premium pricing and may compress importer/distributor economics.
- Strong domestic value competitors coexist with established premium imported brands.
- Net acquisition prices, brand shares and private purchasing volumes are not publicly verifiable.

Three entry conditions

1. Obtain formal product-specific CDSCO classification/predicate confirmation and validate the exact evidence burden.
2. Validate confidential hospital acquisition and distributor economics before finalizing launch price and margin assumptions.
3. Confirm the current national PM-JAY PCI package and priority-state payment variations.

Sources: MKT-01; PRI-01; PRI-02; REG-01; REG-03; REI-01; REI-02; TEN-01

2. Integrated Country-Entry Assessment

India is a high-volume coronary-intervention market with a mature DES category, formal price regulation, a defined medical-device import pathway, and visible public/private procurement structures. For the hypothetical entrant, the central commercial question is not whether PCI demand exists; it is whether the product can differentiate inside the regulated price envelope while meeting CDSCO requirements and maintaining viable channel economics.

Evidence supporting continued entry work

- 726,715 observed PCI procedures in 2024.
- Base-case TAM 911,877 units and SAM 683,908 units under locked assumptions.
- Current hospital disclosures show lower-priced domestic DES and premium imported DES coexisting.
- CDSCO provides a defined import route and statutory review target.
- Recent public procurement evidence confirms coronary-stent rate contracts and consignment sourcing.

Evidence preventing an unconditional GO

- No verified current 2024 national DES share.
- No verified current national stents-per-PCI ratio.
- No verified confidential acquisition price or brand-level market share.
- No final product-specific CDSCO predicate/classification confirmation.
- No openly retrievable current national 2026 PM-JAY PCI rate table in the locked evidence.

Confidence: MEDIUM

3. Market Opportunity Intelligence

3.1 Product-market definition

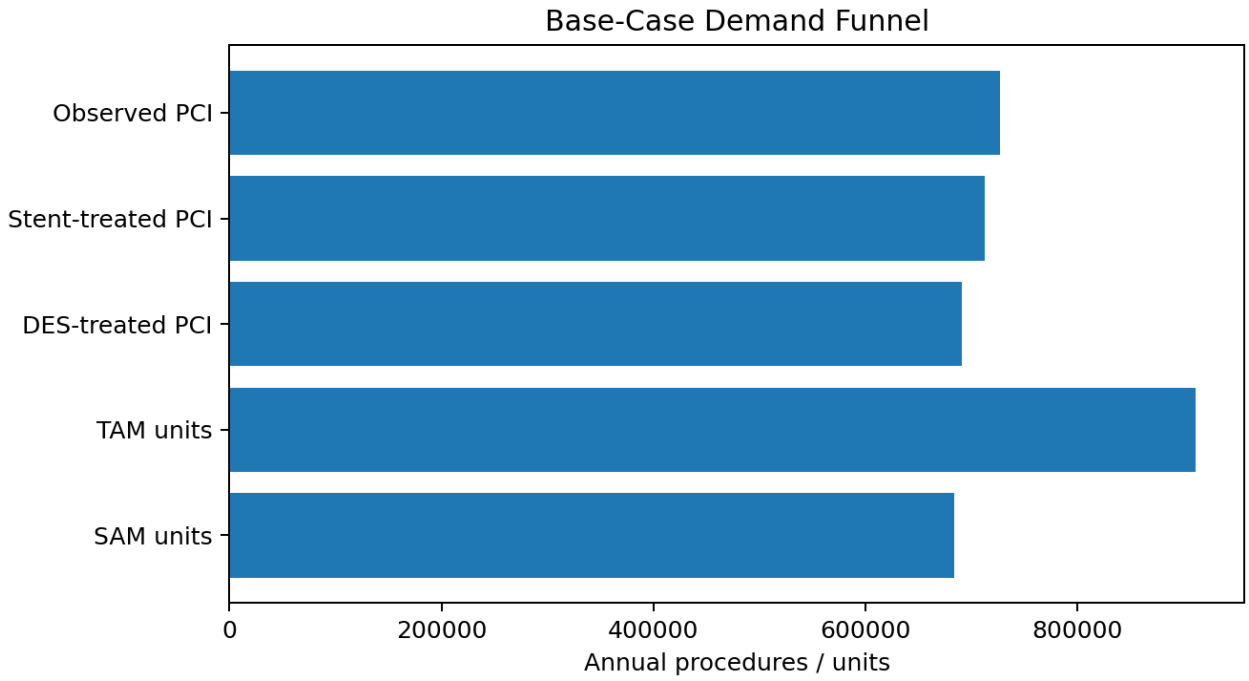
Element	Defined market
Product	Imported sirolimus-eluting cobalt-chromium coronary stent with biodegradable polymer
Use case	Adult PCI
Primary indication	Eligible de novo lesions in native coronary arteries
Care setting	Hospital cardiac catheterization laboratory
Clinical user	Interventional cardiologist
Demand denominator	Annual PCI procedures filtered for stent use, DES use and units per DES-treated PCI

3.2 National PCI base

The latest locked national registry evidence reports 726,715 PCI procedures in 2024 versus 655,023 in 2023. Approximately 2,200 cath labs were estimated to be operational; 1,448 centers contributed registry information and 1,096 reported complete PCI data. The report therefore treats 726,715 as an observed registry base rather than an exhaustive adjusted national total.

Metric	Evidence	Confidence	Use
2024 PCI procedures	726,715	HIGH	Current observed procedure base
2023 PCI procedures	655,023	HIGH	Historical comparator
2023-2024 growth	10.945%	HIGH	Directional growth
Operational cath labs	~2,200	MEDIUM	Structural capacity
Contributing centers	1,448	HIGH	Registry reach
Complete PCI-reporting centers	1,096	HIGH	Completeness limitation

Sources: MKT-01; MKT-02



Sources: GHMAP calculation from locked Phase 5B inputs.

3.3 Geographic concentration

State	Cath-lab share
Maharashtra	28.45%
Tamil Nadu	15.90%
Gujarat	12.22%
Uttar Pradesh	11.31%
Karnataka	11.18%
Top five	79.06%

This is capacity concentration, not procedure share or purchasing market share.

Sources: MKT-01

3.4 Funding mix

Funding source	Share	Commercial implication
Government schemes	48.8%	Public payment rules and state implementation are material.
Out-of-pocket	31.3%	Patient affordability and regulated stent pricing remain material.
Private insurance	19.9%	Private payer/provider arrangements matter; negotiated rates are not public.

Sources: MKT-01

3.5 DES adoption

Current national 2024 DES share is not publicly reported in the locked evidence. Historical national registry data show 81.1% DES share in 2011, 96.75% in 2017 and approximately 98% in 2018. A contemporary single-center signal exceeds 99%, but it is not nationally representative.

Confidence: MEDIUM - DES dominance is well supported; the exact current national share is not.

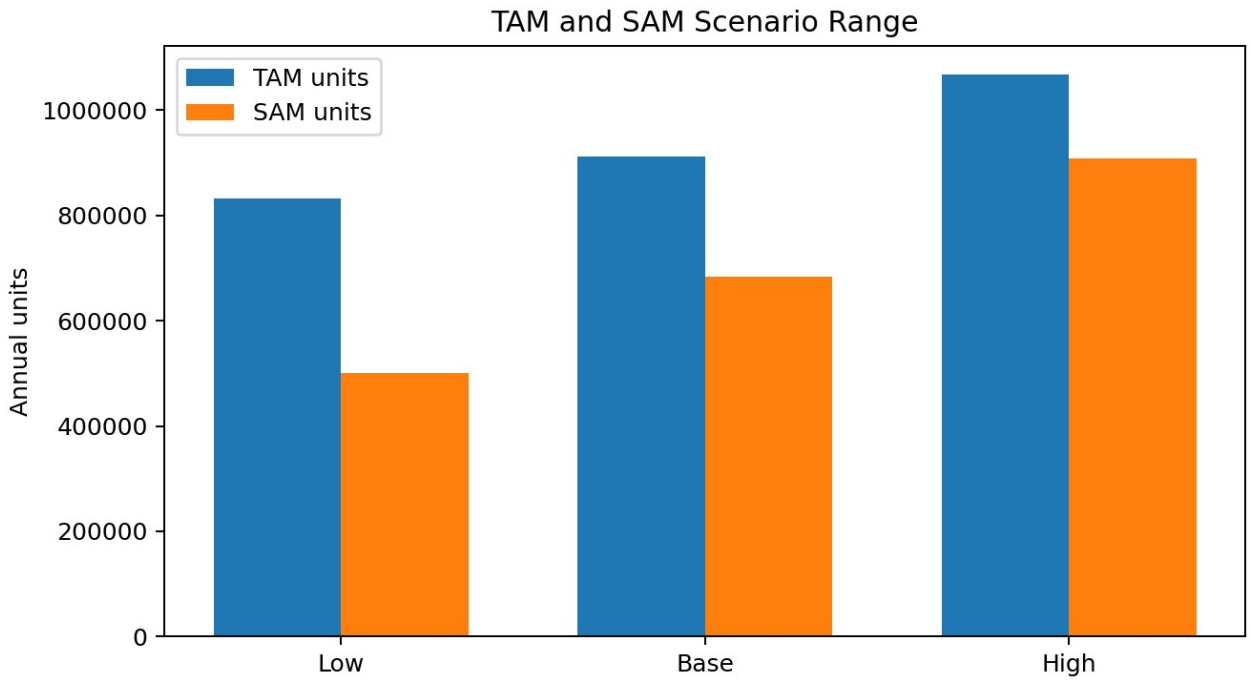
Sources: MKT-03; MKT-04; MKT-05; MKT-06

3.6 Demand model inputs

Input	Low	Base	High	Confidence
Annual PCI base	726,715	726,715	726,715	HIGH
Stent-use share	95%	98%	99%	MEDIUM
DES share	95%	97%	99%	MEDIUM
Stents per DES-treated PCI	1.27	1.32	1.50	MEDIUM
Product fit	60%	75%	85%	LOW
Observed patient-price basis	₹23,625	₹32,385.17	₹41,145.33	LOW

3.7 TAM and SAM

Metric	Low	Base	High
Stent-treated PCI	690,379	712,181	719,448
DES-treated PCI	655,860	690,816	712,254
TAM units	832,942	911,877	1,068,381
SAM units	499,765	683,908	908,124
Illustrative TAM value	₹1,967.8 crore	₹2,953.1 crore	₹4,395.9 crore
Illustrative SAM value	₹1,180.7 crore	₹2,214.8 crore	₹3,736.5 crore
NPPA ceiling-value reference - TAM	₹3,264.0 crore	₹3,573.3 crore	₹4,186.6 crore
NPPA ceiling-value reference - SAM	₹1,958.4 crore	₹2,680.0 crore	₹3,558.6 crore



Confidence: MEDIUM - TAM unit range is decision-useful; SAM and value ranges are more assumption-sensitive.

The illustrative value ranges use public patient/MRP observations and therefore do not represent audited market revenue, hospital acquisition economics or manufacturer net sales.

3.8 Market opportunity conclusion

The evidence supports a strong underlying clinical-demand opportunity. The observed PCI base is large and growing, and historical evidence indicates a DES-dominant treatment environment. The principal uncertainty is not category demand but the precision of current DES utilization, stents per PCI and the proportion of national demand fitting the sample product's intended use and configuration.

Dimension	Assessment
Procedure base	Strong
DES category maturity	Strong
Geographic concentration	Decision-useful for prioritization
Funding structure	Mixed public/private/self-pay
SAM precision	Low confidence
Module conclusion	Strong opportunity, conditional on commercial validation

Sources: MKT-01 to MKT-12; locked GHMAP calculations

4. Competitor & Pricing Intelligence

4.1 Competitive landscape

The locked evidence base screens 15 DES products with current India market-presence signals. The landscape includes domestic manufacturers competing on value and technology, alongside established imported brands. No brand-level market share is stated because no licensed sales or purchase-order dataset was used.

Manufacturer	Product	Origin	Drug	Polymer	Public price signal	Confidence
Sahajanand Medical Technologies	Tetriflex	India / Domestic	Sirolimus	Biodegradable	₹23,625 patient price observation	MEDIUM
Sahajanand Medical Technologies	Supralimus Core	India / Domestic	Sirolimus	Biodegradable	₹41,145.33 patient price observation	MEDIUM
Sahajanand Medical Technologies	Tetrilimus	India / Domestic	Everolimus	Biodegradable	₹41,145.33 patient price observation under hospital spelling variant	MEDIUM
Sahajanand Medical Technologies	Everoflex	India / Domestic	Everolimus	Not publicly verified in this phase	₹41,145.33 patient price observation	LOW
Vascular Concepts	Pronova XR	India / Domestic	Sirolimus	Biodegradable	₹41,145 MRP including 5% GST	MEDIUM
Translumina	Yukon Choice	India-linked / Marketed in India	Sirolimus	Biodegradable / polymer-based family	₹41,145.33 patient price observation	LOW
Envision Scientific	Abluminus	India / Domestic	Sirolimus	Abluminal drug delivery system	₹41,145.33 patient price observation	LOW
Nano Therapeutics	Encruso	India / Domestic listing	Not publicly verified	Not publicly verified	₹41,145.33 patient price observation	LOW
Biosensors International	BioMatrix NeoFlex	Imported	Biolimus A9	Biodegradable	₹41,145.33 patient price observation	LOW
Terumo	Ultimaster Nagomi	Imported	Sirolimus	Biodegradable poly(DL-lactide-co-caprolactone)	₹41,145.33 patient price observation	MEDIUM
Teleflex / Biotronik legacy branding	Orsiro Mission	Imported	Sirolimus	PLLA biodegradable polymer	₹41,143 patient price observation	MEDIUM
Abbott	Xience Skypoint	Imported	Everolimus	Durable fluorinated copolymer	₹41,145.33 patient price observation	HIGH
Boston Scientific	Synergy XD	Imported	Everolimus	Bioabsorbable polymer	₹41,145.33 patient price observation	MEDIUM
Medtronic	Onyx Frontier	Imported	Zotarolimus	Durable polymer	₹41,142.52 patient price observation	MEDIUM
B. Braun	Coroflex ISAR	Imported	Sirolimus	Polymer-free drug carrier technology	₹41,143.20 patient price observation	MEDIUM

Sources: CMP-01; CMP-02; CMP-03; CMP-04; CMP-05; CMP-06; PRI-04; PRI-05; PRI-06

4.2 Five direct competitor profiles

4.2.1 Tetriflex - Sahajanand Medical Technologies

Field	Finding
Selection rationale	Domestic low-price comparator with current product and hospital evidence.
India presence	Current manufacturer page and 2026 hospital patient-price listing.
Drug / polymer	Sirolimus; biodegradable polymer matrix.
Platform / dimensions	Metallic DES; complete normalized platform/size matrix not extracted.
Public price evidence	₹23,625 at Bombay Hospital Indore.
Positioning vs sample	Value-positioned domestic DES relative to a hypothetical imported next-generation device.
Evidence-based strengths	Domestic manufacturing position; materially lower observed patient price; biodegradable polymer.
Evidence-based limitations	No verified national share, confidential acquisition price or current

	licence record extracted.
Critical unknowns	Exact size matrix, strut thickness, licence number/status and procurement penetration.

Confidence: MEDIUM

Sources: CMP-01; PRI-05

4.2.2 Pronova XR - Vascular Concepts

Field	Finding
Selection rationale	Domestic sirolimus/biodegradable-polymer comparator close to sample technology.
India presence	Current manufacturer 2026 revised price page.
Drug / polymer	Sirolimus; biodegradable polymer.
Platform / dimensions	Cobalt-chromium DES; complete public dimensional matrix not extracted.
Public price evidence	₹41,145 MRP including 5% GST.
Positioning vs sample	Domestic technological analogue at the regulated upper patient-price level.
Evidence-based strengths	Technology closely matches sample assumptions and has current manufacturer price evidence.
Evidence-based limitations	MRP is not net transaction price; no current licence record extracted.
Critical unknowns	Exact size matrix, comparative clinical claims and procurement presence.

Confidence: MEDIUM

Sources: PRI-06

4.2.3 Ultimaster Nagomi - Terumo

Field	Finding
Selection rationale	Imported sirolimus/biodegradable-polymer benchmark with strong official technical documentation.
India presence	Official product page and 2026 Hinduja patient-price list.
Drug / polymer	Sirolimus; biodegradable poly(DL-lactide-co-caprolactone).
Platform / dimensions	CoCr L605; 80 µm; 2.0–4.5 mm; 9–50 mm; abluminal gradient coating.
Public price evidence	₹41,145.33 at Hinduja.
Positioning vs sample	Premium imported direct competitor with broad size range.
Evidence-based strengths	Strong official technical transparency; broad dimensions; comparable drug/polymer proposition.
Evidence-based limitations	Hospital patient price does not reveal acquisition economics or sales volume.
Critical unknowns	Current CDSCO licence number/status and actual India utilization.

Confidence: MEDIUM

Sources: CMP-03; PRI-04

4.2.4 Orsiro Mission - Teleflex / Biotronik legacy branding

Field	Finding
Selection rationale	Imported ultrathin-strut sirolimus/biodegradable-polymer comparator.
India presence	Current product page and 2026 Hinduja listing.
Drug / polymer	Sirolimus; PLLA biodegradable polymer.
Platform / dimensions	CoCr L605; 60/80 µm by diameter; 2.25–4.0 mm; 9–40 mm.
Public price evidence	₹41,143 at Hinduja.
Positioning vs sample	Premium imported competitor differentiated by thin-strut platform.
Evidence-based strengths	Strong technical comparability and current patient-price evidence.
Evidence-based limitations	Ownership/branding label differs across sources; acquisition price and market share unavailable.

Critical unknowns	Current Indian licence holder and procurement penetration.

Confidence: MEDIUM

Sources: CMP-04; PRI-04

4.2.5 Xience Skypoint - Abbott

Field	Finding
Selection rationale	Recently launched imported everolimus DES with broad diameter/length range.
India presence	Official India launch on 10 March 2026 and current Hinduja listing.
Drug / polymer	Everolimus; durable fluorinated copolymer.
Platform / dimensions	CoCr L605; approximately 81 µm; 2.25–5.0 mm; 8–48 mm.
Public price evidence	₹41,145.33 at Hinduja.
Positioning vs sample	Premium imported competitor with large-vessel and long-lesion configurations.
Evidence-based strengths	Clear India launch evidence; broad dimensions; strong official technical documentation.
Evidence-based limitations	Different drug/polymer strategy from the sample; no confidential net price or share data.
Critical unknowns	Current CDSCO licence record, hospital adoption and tender penetration.

Confidence: HIGH

Sources: CMP-05; CMP-06; PRI-04

4.3 Product comparison matrix

Attribute	Sample	Tetriflex	Pronova XR	Ultimaster Nagomi	Orsiro Mission	Xience Skypoint
Drug	Sirolimus	Sirolimus	Sirolimus	Sirolimus	Sirolimus	Everolimus
Polymer	Biodegradable	Biodegradable	Biodegradable	Biodegradable P(DL-LA-co-CL)	PLLA biodegradable	Durable fluorinated copolymer
Platform	Cobalt-chromium	Metallic; exact public alloy not extracted	Cobalt-chromium	CoCr L605	CoCr L605	CoCr L605
Strut thickness	Not yet specified	Not extracted	Not extracted	80 µm	60 µm (2.25–3.0 mm); 80 µm (3.5–4.0 mm)	Approximately 81 µm
Diameter range	Approximately 2.25–4.00 mm	Not normalized	Not normalized	2.0–4.5 mm	2.25–4.0 mm	2.25–5.0 mm
Length range	Approximately 8–48 mm	Not normalized	Not normalized	9–50 mm	9–40 mm	8–48 mm
India presence	Not yet registered or sold	Current manufacturer + hospital evidence	Current manufacturer price evidence	Current hospital evidence	Current hospital evidence	Official India launch + hospital evidence
Current public patient price	Not established	₹23,625	₹41,145 incl. 5% GST	₹41,145.33	₹41,143	₹41,145.33
Positioning signal	Hypothetical imported next-generation entrant	Value domestic	Domestic technology analogue	Premium imported biodegradable-polymer DES	Premium imported thin-strut biodegradable-polymer DES	Premium imported broad-size everolimus DES
Current CDSCO licence number	None assumed	Not extracted	Not extracted	Not extracted	Not extracted	Not extracted
Market share	Not applicable	Not publicly verifiable	Not publicly verifiable	Not publicly verifiable	Not publicly verifiable	Not publicly verifiable

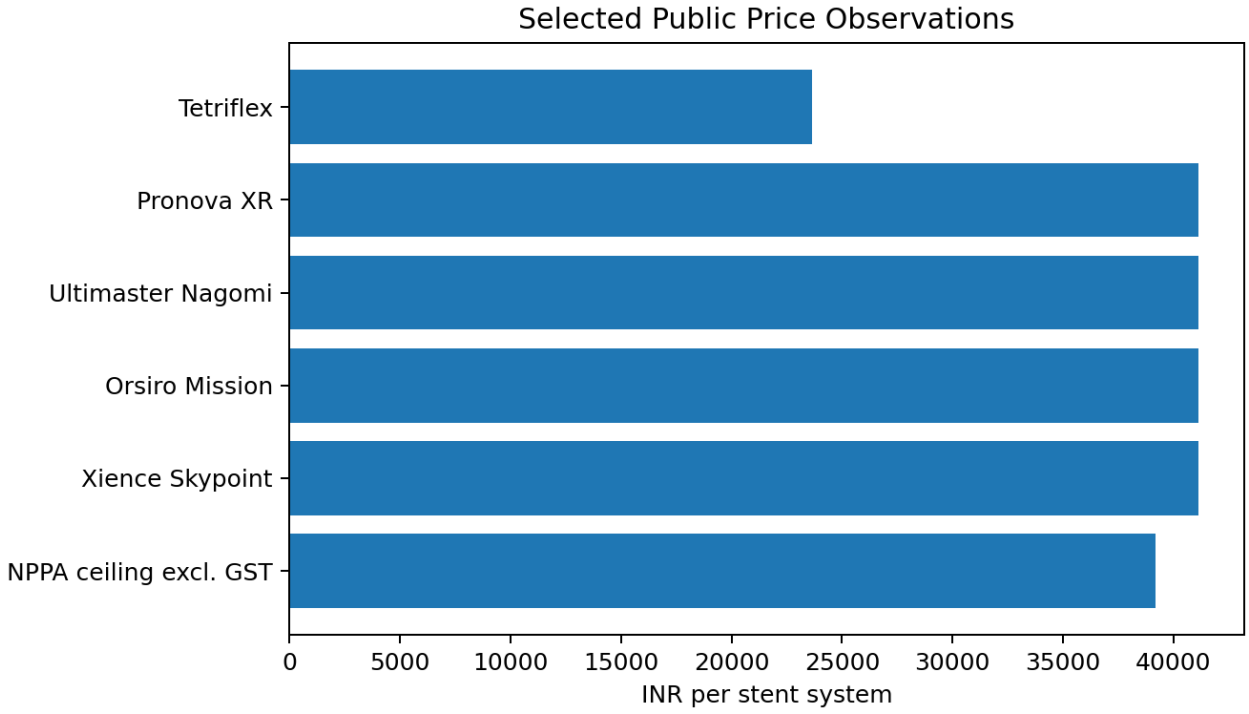
Sources: CMP-01; CMP-03; CMP-04; CMP-05; CMP-06; PRI-04; PRI-05; PRI-06; REG-07; REG-08

4.4 Pricing evidence

India requires strict separation of regulated ceiling price, patient/MRP observations, tender values, acquisition prices and reimbursement payments. The locked evidence does not support a single 'market price'.

Product / scope	Price type	Amount	Tax status	Buyer/channel	Confidence
DES category including metallic DES and BVS/biodegradable stents	NPPA REGULATED CEILING PRICE	39186.03	Excluding GST; GST only if actually paid/payable	India regulated market	HIGH
DES category	CEILING PLUS 5% GST	41145.33	Includes 5% GST	Hospital patient	HIGH

	REFERENCE			disclosure	
Tetriflex	HOSPITAL PATIENT PRICE OBSERVATION	23625	Tax treatment not explicitly stated on extracted page	Bombay Hospital Indore	MEDIUM
Seromount	HOSPITAL PATIENT PRICE OBSERVATION	23625	Tax treatment not explicitly stated	Bombay Hospital Indore	LOW
Synergy XD	HOSPITAL PATIENT PRICE OBSERVATION	41145.33	Appears to include 5% GST	P.D. Hinduja Hospital	MEDIUM
Ultimaster Nagomi	HOSPITAL PATIENT PRICE OBSERVATION	41145.33	Appears to include 5% GST	P.D. Hinduja Hospital	MEDIUM
Xience Skypoint	HOSPITAL PATIENT PRICE OBSERVATION	41145.33	Appears to include 5% GST	P.D. Hinduja Hospital	MEDIUM
Orsiro Mission	HOSPITAL PATIENT PRICE OBSERVATION	41143	Tax treatment inferred from proximity to regulated GST-inclusive ceiling	P.D. Hinduja Hospital	MEDIUM
Onyx Frontier	HOSPITAL PATIENT PRICE OBSERVATION	41142.52	Tax treatment inferred; not separately stated	P.D. Hinduja Hospital	MEDIUM
Pronova XR	MANUFACTURER MRP	41145	Includes 5% GST	Manufacturer public price page	HIGH
Bare-metal coronary stent category	NPPA REGULATED CEILING PRICE	10762.15	Excluding GST	India regulated market	HIGH
PTCA inclusive of diagnostic angiogram	REIMBURSEMENT / PROVIDER PACKAGE PAYMENT	40600	Package amount; tax treatment not applicable as product price	PM-JAY empanelled provider in Assam	HIGH
Hospital acquisition / net manufacturer price	HOSPITAL ACQUISITION PRICE	Not publicly verifiable	Unknown	Public and private hospitals	NOT PUBLICLY VERIFIABLE
Selected 2025 public tenders	TENDER UNIT RATE / AWARD PRICE	Not publicly verifiable	Varies by tender	Government buyers	NOT PUBLICLY VERIFIABLE



Interpretation rules: NPPA ceiling price is not a transaction price. Tender value is not a unit price. Reimbursement/package payment is not the product selling price. Patient/MRP disclosure is not hospital acquisition cost.

Confidence: MEDIUM - Current regulated and public patient-price evidence is strong; net acquisition economics are not publicly verifiable.

Sources: PRI-01 to PRI-06; REI-02; TEN-01 to TEN-05

4.5 Competitive conclusion

The sample product would enter a crowded, technology-mature DES market. Differentiation based only on being imported, sirolimus-eluting or biodegradable-polymer is unlikely to be sufficient because comparable propositions are already visible. A commercially credible entry case would require a defensible clinical/technical distinction plus viable channel economics under the NPPA ceiling.

Competitive issue	Evidence-based implication
Domestic value competition	Low public patient prices such as ₹23,625 demonstrate room below the regulated ceiling.
Premium imported competition	Multiple imported products are publicly listed near the GST-inclusive ceiling.
Market share	Not publicly verifiable; no ranking is claimed.
Net price	Not publicly verifiable; launch economics require separate validation.
Positioning	Technology and evidence differentiation matter because price headroom is constrained.

5. Regulatory Intelligence

5.1 Provisional classification and authority

The responsible national authority is CDSCO under the Medical Devices Rules. The working product-specific hypothesis is Class D because the sample is a high-risk implantable drug-eluting coronary stent. This classification is provisional and does not constitute a binding CDSCO determination.

Confidence: MEDIUM - Exact classification depends on the final intended use, claims, design and predicate position.

Sources: REG-01; REG-02; REG-06

5.2 Import pathway

Step	Locked finding	Implication
1. Indian authorized agent	MD-14 checklist requires an eligible Indian authorized agent and supporting power-of-attorney/undertaking documentation.	Agent must be appointed before filing.
2. MD-14 application	Import application is filed through SUGAM.	Product family/configuration and site evidence must be locked.
3. CDSCO review	Central Licensing Authority reviews the application and evidence.	Deficiencies, testing or clinical questions may extend elapsed time.
4. MD-15 licence	Successful review results in Form MD-15.	Commercial import/sale must follow licence conditions.
5. Post-market lifecycle	PMS, vigilance, PSUR and change-control obligations continue after approval.	India-specific compliance system is required.

Sources: REG-01; REG-03; REG-09

5.3 Reference approvals and predicate issue

The hypothetical product is assumed to hold EU MDR CE marking and US FDA premarket approval. Under the locked regulatory interpretation, reference-market approvals strengthen the import pathway and may reduce the likelihood of an Indian clinical investigation for an existing/predicate device. They do not automatically eliminate CDSCO evidence requests. A suitable Indian predicate for the exact drug, polymer, platform, intended use and size family remains unresolved.

Confidence: MEDIUM

Sources: REG-03; REG-05; REG-07; REG-08

5.4 Required evidence categories

Requirement	Evidence / obligation	Sample implication	Confidence
Application	Covering letter, Form MD-14 and fee challan.	Prepare a complete import application via SUGAM.	HIGH
Authorized agent	Power of attorney/undertaking; agent constitution; wholesale/manufacturing/MD-42 evidence as applicable.	Appoint an eligible Indian authorized agent.	HIGH
Reference approvals	Free Sale Certificate / marketing authorization from country of origin and reference markets.	Submit assumed EU and US approval evidence and current certificates.	HIGH
QMS	Quality-management-system evidence.	Provide current QMS certification and site information.	HIGH
Plant Master File	Plant Master File per Fourth Schedule/checklist.	Prepare site/manufacturing-system documentation.	HIGH
Device Master File	Device Master File with product description, design/manufacture,	Prepare a product-specific DMF for the DES system.	HIGH

	essential principles and technical evidence.		
Declaration of conformity	Declaration of Conformity and applicable standards.	Map applied standards and conformity evidence.	HIGH
Risk management	Risk analysis and conformity with essential principles.	Include implant, drug/polymer, delivery-system and sterilization risks.	HIGH
Verification / validation	Design verification, performance validation, stability and release evidence.	Provide complete bench and product performance package.	HIGH
Biocompatibility	Biocompatibility evidence.	Address all patient-contacting materials and implant duration.	HIGH
Medicinal substance	Data on incorporated medicinal substance.	Provide sirolimus identity, function, dose, release, safety and interaction evidence.	HIGH
Sterilization	Sterilization validation and sterile-packaging evidence.	Document method, SAL, residuals and package integrity.	HIGH
Clinical evidence	Clinical safety/performance data and substantial-equivalence evidence.	Submit reference-market clinical evidence and literature relevant to exact product.	MEDIUM
Three-batch evidence	Certificates of analysis/release for three batches.	Provide manufacturing release evidence for the marketed configuration.	HIGH
Labeling / IFU	Proposed labels and instructions for use under MDR.	Adapt label/IFU to Indian licence, importer/agent and statutory particulars.	MEDIUM
UDI	UDI rule exists under MDR as amended.	Confirm current implementation and code requirements before launch.	MEDIUM
Local testing / samples	Testing or samples may be requested depending on product and review.	Do not assume a universal waiver.	LOW
PMS / vigilance	Post-market surveillance and adverse-event reporting.	Maintain India-specific complaint, vigilance and field-action processes.	MEDIUM
PSUR	Periodic Safety Update Report requirements/circulars.	Confirm frequency applicable to the licence/permission.	MEDIUM
Post-approval changes	Material changes require controlled notification/approval under applicable MDR provisions.	Create change-control linkage between global and India product files.	MEDIUM

Sources: REG-03; REG-04; REG-09

5.5 Fees, timeline and licence validity

Item	Locked finding	Confidence
Class C/D overseas manufacturing-site fee	USD 3,000 per site	HIGH
Class C/D distinct-device fee	USD 1,500 per distinct device	HIGH
Baseline official filing-fee calculation	USD 4,500 for one site + one distinct device	HIGH
Possible overseas inspection fee	USD 6,000 plus applicable additional costs	MEDIUM
Official review target	Up to nine months for a complete application	HIGH
Licence validity	Valid in perpetuity subject to retention fees every five years and compliance	HIGH

These figures exclude authorized-agent, testing, clinical, translation, consulting and execution costs.

Sources: REG-05; REG-06; REG-06A

5.6 Regulatory uncertainties

- Final Class D confirmation for the exact product.
- Identification of an appropriate Indian predicate.
- Whether the full diameter/length range can be grouped under one application.
- Whether local clinical investigation, testing or samples will be requested.
- Current operational UDI and post-market details applicable at launch.

5.7 Regulatory conclusion

The pathway is identifiable and does not appear structurally prohibitive, but the product-specific evidence burden is not sufficiently certain for an unconditional entry decision. Formal classification/predicate confirmation is an entry condition.

Confidence: MEDIUM

6. Reimbursement Intelligence

6.1 Reimbursement relevance

Reimbursement and public payment are commercially relevant because a large share of PCI activity is reported as funded through government schemes, while private insurance and out-of-pocket payment also remain material. The product price and provider episode payment must be treated as separate financial flows.

Sources: MKT-01; REI-01; REI-02; PRI-01

6.2 Coverage, coding/package and payment

System / payer	Code / package	Payment	Device treatment	Confidence
PM-JAY — current national framework	Current HBP Manual Part 2 launched 20 Jan 2026.	Exact current national PTCA rate not openly retrievable in this research execution.	PCI is handled through a treatment package; product price must be analyzed separately.	MEDIUM
PM-JAY — Assam current package master	MC011 / procedure MC011A.	40600	Implants/high-end consumables: Yes; barcode of stents used required in claim documentation.	HIGH
Assam Atal Amrit Abhiyan variation	ASMC00025 / ASMC00026 mapped to MC011A.	47540	State package explicitly describes non-medicated stent episodes.	HIGH
Public hospital budget / procurement	Institutional procurement; no universal reimbursement code.	Procurement price varies and is not publicly complete.	Product acquired under hospital or authority contract.	MEDIUM
Private insurance	Policy/TPA-specific; no single national device code/rate.	Negotiated provider payment not publicly verifiable.	Stent cost may be embedded in hospital episode billing and remains subject to NPPA ceiling.	LOW
CGHS / other government schemes	Current PCI package/rate not conclusively verified.	Not publicly verifiable in this research execution.	Likely provider episode payment; product price remains separate.	NOT PUBLICLY VERIFIABLE
NPPA price control	S.O. 1587(E), effective 1 Apr 2026.	39186.03	Maximum DES price excluding GST; not coverage, coding or provider payment.	HIGH
HTA relevance	No product-specific mandatory code identified.	Not applicable / not established.	HTA may inform policy/procurement, but no mandatory DES-specific gate was verified.	NOT PUBLICLY VERIFIABLE

6.3 PM-JAY evidence

A current national Health Benefit Package Manual Part 2 was launched in January 2026. The exact current national PTCA rate table was not openly retrievable in the locked evidence. A current official Assam PM-JAY package provides a state-level example: MC011A, PTCA inclusive of diagnostic angiogram, provider payment ₹40,600, implants/high-end consumables flagged as included, and more than one implant permitted. Stent barcode documentation is required.

Confidence: MEDIUM - National framework is verified; the quoted ₹40,600 payment is Assam-specific.

Sources: REI-01; REI-02

6.4 Public/private payment distinction

Channel	Payment structure	Key limitation
PM-JAY / state scheme	Provider episode/package payment to empanelled hospital	Rates and implementation can vary by state.
Public hospital budget	Hospital or centralized body procures stents; clinical episode may be scheme-funded	Procurement price and provider payment are separate.
Private insurance	Policy/TPA-specific provider payment	Negotiated rates are confidential.

Out-of-pocket	Patient/hospital billing subject to applicable price regulation	Patient price does not reveal acquisition economics.
NPPA price control	Maximum DES selling-price ceiling	Not coverage, coding or reimbursement.

6.5 Reimbursement conclusion

The evidence supports reimbursement/payment relevance but not a single national device reimbursement amount. The commercial model must account for state package variation and the distinction between provider payment and stent procurement cost. Confirmation of the current national and priority-state PCI payment rules is an entry condition.

Confidence: MEDIUM

7. Buyer & Procurement Intelligence

7.1 Buyer ecosystem

Coronary-stent demand involves distinct stakeholder roles. The clinical user is the interventional cardiologist/cath-lab team; technical evaluation may involve cardiology committees, biomedical/quality functions and procurement; the economic buyer is the hospital, health system or public procurement authority; and the commercial seller for an imported device is the licensed Indian importer/distributor or other eligible supplier.

Stakeholder role	Typical function	Decision relevance
Clinical user / influencer	Interventional cardiologist and cath-lab leadership	Creates clinical demand and evaluates usability/clinical fit.
Technical evaluator	Cardiology committee, biomedical/quality/value function	Assesses technical compliance, evidence and operational fit.
Economic buyer	Hospital, chain, state procurement body or central institute	Controls budget or contract.
Procurement decision-maker	Purchase/stores/materials/tender function	Runs sourcing, rate contract or vendor process.
Funding authority	PM-JAY/SHA, insurer, government scheme or hospital budget	Determines provider payment/funding context.
Commercial seller	Licensed Indian importer/distributor/supplier	Contracts and supplies product; not necessarily the economic user.

7.2 Structurally important organizations

Organization	Status	Geography	Role	Confidence
AIIMS New Delhi	Public / Central	New Delhi	Clinical user, technical evaluator, institutional economic buyer and procurement authority.	HIGH
AIIMS Jodhpur	Public / Central	Rajasthan	Direct economic buyer/procurement authority; cath-lab clinical use implied by product-specific tender.	HIGH
PGIMER Chandigarh	Public / Central	Chandigarh	Clinical user, technical evaluator and institutional buyer.	MEDIUM
SCTIMST	Public / Central	Kerala	Clinical user, technical evaluator and institutional economic buyer.	HIGH
Sri Jayadeva Institute of Cardiovascular Sciences and Research	Public / State	Karnataka	High-capacity clinical user, evaluator and institutional buyer.	HIGH
Rajasthan Medical Services Corporation Ltd.	Public / State	Rajasthan	Economic buyer/procurement controller for state institutions where item is centrally procured.	HIGH
Kerala Medical Services Corporation Ltd.	Public / State	Kerala	Economic buyer/procurement controller where items are included in state tenders/running contracts.	HIGH
Apollo Hospitals	Private	Pan-India	Major clinical user; chain/facility economic buyer and procurement function.	HIGH
Fortis Healthcare	Private	Multi-state	Clinical user; facility/chain buyer and technical evaluator.	MEDIUM
Narayana Health	Private	Multi-state	Clinical user; facility/network buyer and technical evaluator.	MEDIUM

Manipal Hospitals	Private	Multi-state	Clinical user; facility/chain buyer and evaluator.	HIGH
Medanta	Private	North India / multi-city	Clinical user; facility/network buyer and evaluator.	MEDIUM
P.D. Hinduja Hospital	Private	Mumbai, Maharashtra	Clinical user and hospital economic buyer/procurement function.	HIGH
Bombay Hospital Indore	Private	Indore, Madhya Pradesh	Clinical user and hospital buyer/procurement function.	HIGH
Wockhardt Hospitals	Private	Maharashtra / multi-city	Clinical user and hospital/chain buyer.	HIGH

This organization set is structural intelligence, not a lead list. No organization is represented as interested in the hypothetical product.

Sources: BUY-01 to BUY-12; PRI-03; PRI-04; PRI-05

7.3 Public and private procurement pathways

Route	Economic buyer	Mechanism	Typical vendor requirements	Confidence
Central-government hospital rate contract	Hospital/institute purchase authority	Open e-tender/rate contract; may use consignment stock	CDSCO licence, technical compliance, bid security, past supply, samples/evaluation and NPPA compliance as specified	HIGH
GeM central/public procurement	Government purchasing organization / hospital	Two-packet bids, item-wise evaluation and sometimes reverse auction	OEM authorization, statutory licences, quality documents, delivery/shelf-life conditions and EMD as applicable	MEDIUM
State centralized procurement	State medical services corporation / state department	Competitive e-bidding, running/rate contracts and technical/financial evaluation	Registration/licence, technical standards, past performance, L1/quality criteria and performance security	HIGH
Public hospital direct purchase outside central contract	Hospital procurement/purchase committee	Hospital tender, quotation or rate-contract call under applicable rules	Product registration, NPPA compliance, technical specifications, prior supply and sample evaluation	MEDIUM
Private hospital or chain sourcing	Hospital or chain procurement function	Negotiated approved-vendor contracts, consignment and facility/chain formulary	CDSCO licence, supply continuity, clinician acceptance, price within NPPA ceiling, service and inventory terms	MEDIUM
Imported product commercial channel	Hospital or procurement authority remains economic buyer	Manufacturer → Indian authorized agent/licence holder → supplier/distributor → hospital	MD-15 import licence, compliant importer/seller, labeling, price control and tender/vendor qualification	HIGH

7.4 Recent tender evidence

Buyer	Tender / reference	Date	Product scope	Quantity	Award / unit value	Confidence
AIIMS Jodhpur	2025_AIIMS_879121_1 / PROC-2/RC/05/2025-AIIMS.JDH	Published 2025-09-25; opening 2025-11-10	Coronary stents	Not stated in portal index	Not publicly verified	HIGH
Director General Armed Forces Medical Services	GEM/2025/B/6826396	Published 2025-11-03	Multiple DES technologies including sirolimus, everolimus, zotarolimus and BVS categories	200	Estimated total ₹8,587,184 reported by mirror; not converted to unit price	MEDIUM
ESIC Medical College & Hospital, Chennai	GEM/2025/B/6607266	Posted 2025-09-13; close 2025-10-04	Drug-eluting stent 2.5 × 23 mm	10	Not publicly verified	MEDIUM
Government hospital procurement, Perambalur, Tamil Nadu	SRPHC153053	Deadline 2025-05-16	Zotarolimus DES with specified PtIr/CoCr platform and size/strut criteria	Not publicly visible	Not publicly verified	MEDIUM
South Central Railway	82250962	Posted 2025-07-12; close 2025-07-22	Platinum-chromium PVF everolimus-eluting coronary stent; 2.25–4.0 mm all	Not publicly visible	Not publicly verified	MEDIUM

			sizes			

The strongest primary example is the 2025 AIIMS Jodhpur rate contract for coronary stents on a consignment basis. Other selected examples provide useful technical and procedural evidence but rely on secondary tender mirrors. Award suppliers and defensible unit rates were not available for the selected tenders.

Sources: TEN-01 to TEN-05

7.5 Procurement barriers

- Indian regulatory licence and compliant local commercial entity are prerequisites for imported supply.
- Public tenders may require prior supply history, product-specific technical specifications, quality documents, bid security and sample/technical evaluation.
- NPPA price compliance constrains the commercial price envelope.
- Consignment or inventory obligations can shift working-capital and expiry risk to the supplier.
- Private-chain procurement terms, approved-vendor rules, volumes and acquisition prices are not public.

Confidence: MEDIUM

7.6 Buyer and procurement conclusion

The buying system is sufficiently visible to support a country-entry decision. Public procurement is formal and evidence-rich, while private procurement is commercially important but less transparent. The market requires both clinical acceptance and procurement qualification; legal sale through a local licensed channel does not replace hospital-level clinical and economic decision-making.

8. Critical Risks, Unknowns and Entry Conditions

ID	Type	Finding / unknown	Decision impact	Entry condition	Confidence
R-01	DATA GAP	Current 2024 national DES share is not published in the verified NIC 2024 paper.	Changes TAM unit estimate.	Yes	MEDIUM
R-02	DATA GAP	Current 2024 national average stents per PCI is not published.	Changes unit demand and value.	Yes	MEDIUM
R-03	DATA GAP	Complete national PCI registry coverage factor is not established.	Observed 726,715 PCI may understate total procedures.	No	HIGH
R-04	DATA GAP	Brand-level market share and sales volumes are unavailable.	Prevents verified share ranking.	No	NOT PUBLICLY VERIFIABLE
R-05	DATA GAP	Confidential hospital acquisition and distributor transfer prices are unavailable.	Commercial margin and true net-market value cannot be confirmed.	Yes	NOT PUBLICLY VERIFIABLE
R-06	REGULATORY UNCERTAINTY	Product-specific CDSCO predicate, active comparator licences and final Class D pathway require direct validation.	Could change evidence burden, grouping, clinical requirements and timing.	Yes	MEDIUM
R-07	PAYMENT GAP	Exact current national 2026 PM-JAY PTCA rate and additional-stent payment rule were not openly retrievable.	State economics and hospital incentives may differ.	Yes	MEDIUM
R-08	PROCUREMENT GAP	Award suppliers and defensible unit rates were not found for the selected recent tenders.	Limits price and competitor-win analysis.	No	NOT PUBLICLY VERIFIABLE
R-09	SAM UNCERTAINTY	National lesion, vessel-size and intended-use fit data are insufficient for a precise SAM filter.	SAM is highly assumption-dependent.	Yes	LOW
R-10	BUYER LIMITATION	Private hospital procurement policies, volumes and chain contracts are confidential.	Prevents account-level demand and concentration estimates.	No	MEDIUM
C-01	CONTRADICTION	NIC states participation is compulsory, but 2024 peer-reviewed reporting shows incomplete center data.	Risk of treating registry total as exhaustive national volume.	No	HIGH
C-02	CONTRADICTION	Hospital listing labels Orsiro under Biotronik while current product information is hosted by Teleflex.	Potential confusion in competitor attribution.	No	MEDIUM
C-03	CONTRADICTION	Bombay Hospital page appears to attribute BioMatrix NeoFlex to Sahajanand, while the product is associated with Biosensors.	Competitor-universe manufacturer field could be wrong.	No	LOW
C-04	CONTRADICTION	Current HBP Manual Part 2 exists, but the openly accessible current national PTCA table was not found; Assam shows ₹40,600.	Risk of assuming a state rate is national.	Yes	MEDIUM

8.1 Conditions that directly affect the conclusion

4. Formal product-specific CDSCO classification and predicate confirmation.
5. Confidential acquisition/distributor economics validation.
6. Current national and priority-state PCI payment-rule confirmation.

Other gaps - including brand-level market share, private purchasing volumes and tender award unit rates - reduce precision but do not prevent a country-entry intelligence conclusion.

Sources: R-01 to R-10; C-01 to C-04

9. Recommended Next Actions

Priority	Action	Evidence-based reason	Decision resolved	Suggested owner
1	Obtain formal CDSCO classification/predicate confirmation.	The locked pathway is provisional Class D and the exact predicate remains unresolved.	Confirms evidence burden, clinical requirements, grouping and timeline.	Regulatory Affairs
2	Validate confidential hospital acquisition and channel economics.	Public prices do not reveal net hospital acquisition or distributor transfer prices.	Confirms feasible launch price, margin and channel structure.	Commercial / Finance
3	Confirm current national PM-JAY and priority-state PCI package rules.	National HBP Manual Part 2 is current, but the national PTCA rate table was not openly retrievable.	Confirms provider economics and state reimbursement variation.	Market Access
4	Define a differentiated India value proposition against the five direct comparators.	Comparable sirolimus/biodegradable-polymer and premium imported products are already present.	Tests whether technical/clinical differentiation is commercially meaningful under the price ceiling.	Marketing / Medical Affairs
5	Build a procurement-readiness plan for public rate contracts and private hospital qualification.	Recent tenders show formal technical, regulatory and supply requirements; private terms remain non-public.	Determines launch readiness after regulatory and economic conditions are resolved.	Commercial Operations

These are recommended next actions only. Regulatory execution, pricing validation, distributor search, KOL validation, hospital outreach and tender execution are not included in this Full Country Intelligence product.

10. Methodology, Research Cutoff and Limitations

10.1 Methodology

This sample uses the locked GHMAP Full Country Intelligence research standard. Evidence was prioritized by source authority; source data, assumptions and GHMAP calculations were kept separate; confidence was assigned as HIGH, MEDIUM, LOW or NOT PUBLICLY VERIFIABLE; and material conflicts were preserved rather than silently resolved.

Evidence label	Meaning in this report
HIGH	Current, direct and authoritative evidence with no material unresolved conflict.
MEDIUM	Credible but incomplete, indirect, older or partly assumption-dependent evidence.
LOW	Sparse, materially conflicting or strongly assumption-dependent evidence.
NOT PUBLICLY VERIFIABLE	No reliable public evidence identified for the requested claim.

10.2 Research cutoff

All findings are current only through the locked research cutoff of 19 August 2026. No new research was added during Phase 5C.

10.3 Key limitations

- Regulatory classification and pathway are provisional and do not constitute legal advice or guarantee approval.
- Market estimates are transparent scenario ranges, not audited market values or sales forecasts.
- Current national DES utilization and stents-per-PCI inputs are not directly published for 2024 and therefore use evidence-anchored scenarios.
- Pricing observations do not represent confidential negotiated transaction prices unless explicitly labeled as such; no such confidential data were available.
- Reimbursement findings do not guarantee coverage, coding, payment or payment amount.
- Procurement evidence does not capture all private purchasing activity.
- Buyer organizations are included for structural analysis, not as sales leads or indications of purchasing interest.
- Brand-level market share is not estimated.

10.4 Minimum professional disclaimer

GHMAP Full Country Intelligence is a strategic decision-support product based on publicly available and customer-supplied evidence available through the stated research cutoff date. Findings apply only to the defined product, configuration, intended use and target country. Regulatory classifications and pathways are provisional and do not constitute legal advice or guarantee approval. Market estimates are transparent, assumption-based ranges rather than audited market values or sales forecasts. Reimbursement findings do not guarantee coverage, coding, payment or payment amount. Pricing observations may not reflect confidential negotiated transaction prices. Procurement evidence may not capture all private purchasing activity. Requirements, prices, policies and market conditions may change after the research cutoff date.

11. Source Appendix

The source IDs below correspond to the citations used throughout this report. The appendix reproduces only the locked Phase 5B source register.

ID	Module	Organization / publisher	Title / resource	Date	Confidence
MKT-01	Market	National Interventional Council / peer-reviewed journal	India PCI landscape and NIC Registry 2024 analysis	2026 publication; 2024 data	HIGH
MKT-02	Market	National Interventional Council	NIC Registry website	Current website	HIGH
MKT-03	Market	NIC / Indian Heart Journal	Percutaneous coronary intervention in India: 2011 report	2013 publication; 2011 data	MEDIUM
MKT-04	Market	NIC / Indian Heart Journal	India PCI registry 2017 report	2019 publication; 2017 data	MEDIUM
MKT-05	Market	NIC / Indian Heart Journal	India PCI registry 2018 report	2020 publication; 2018 data	MEDIUM
MKT-06	Market	Indian clinical investigators	PCI payment/insurance study	2022	LOW
MKT-07	Market	Indian clinical investigators	STEMI revascularization study	2024	LOW
MKT-08	Market	Indian clinical investigators	Supraflex registry	2021	MEDIUM
MKT-09	Market	CBHI / Ministry of Health and Family Welfare	National Health Profile	Latest listed NHP 2023	MEDIUM
MKT-10	Market	Ministry of Health and Family Welfare	National NCD Portal	Current portal	MEDIUM
MKT-11	Market	Indian clinical investigators	BioMatrix Indian registry	2013	LOW
MKT-12	Market	Indian clinical investigators	Contemporary PCI utilization study	2024	LOW
PRI-01	Pricing	National Pharmaceutical Pricing Authority	Notification listing for 2026 coronary-stent ceiling revision	2026-03-27 listing	HIGH
PRI-02	Pricing	Gazette of India / NPPA	S.O. 1587(E) coronary-stent ceiling order	2026-03-25; effective 2026-04-01	HIGH

ID	Module	Organization / publisher	Title / resource	Date	Confidence
PRI-03	Pricing / Buyer	Wockhardt Hospitals	2026 stent prices	2026	HIGH
PRI-04	Pricing / Competitor / Buyer	P.D. Hinduja Hospital	Coronary stent pricing	Current 2026 access	HIGH
PRI-05	Pricing / Competitor / Buyer	Bombay Hospital Indore	Stents pricing	Current 2026 access	MEDIUM
PRI-06	Pricing / Competitor	Vascular Concepts	Revised 2026 stent prices	2026	HIGH
CMP-01	Competitor	Sahajanand Medical Technologies	Tetriflex product page	Current access	MEDIUM
CMP-02	Competitor	Sahajanand Medical Technologies	Tetrilimus product page	Current access	MEDIUM
CMP-03	Competitor	Terumo	Ultimaster Nagomi product page	Current access	HIGH
CMP-04	Competitor	Teleflex	Orsiro Mission product page	Current access	HIGH
CMP-05	Competitor	Abbott India	Xience Skypoint India launch	2026-03-10	HIGH
CMP-06	Competitor	Abbott	Xience Skypoint ordering information	Current access	HIGH
REG-01	Regulatory	CDSCO	Medical Device & Diagnostics portal	Current access	HIGH
REG-02	Regulatory	CDSCO	Medical Devices Rules and amendments	Current access	HIGH
REG-03	Regulatory	CDSCO	Form MD-14 import application checklist	Current checklist access	HIGH
REG-04	Regulatory	CDSCO	Medical-device grouping guidance / FAQ	Current access	MEDIUM

ID	Module	Organization / publisher	Title / resource	Date	Confidence
REG-05	Regulatory	Government of India / Indian Kanoon	MDR Rule 36 — import licence decision and reliance	Rule text current to source	HIGH
REG-06	Regulatory	Government of India / Indian Kanoon	Medical Devices Rules 2017 full text / schedules	Rule text current to source	HIGH

REG-06A	Regulatory	Government of India / Indian Kanoon	MDR Rule 37 — import licence validity	Rule text current to source	HIGH
REG-07	Regulatory / Competitor	CDSCO	List of approved devices	Dynamic current database	MEDIUM
REG-08	Regulatory / Competitor	CDSCO	List of approved risk devices	Dynamic current database	MEDIUM
REG-09	Regulatory	CDSCO	Post-marketing / safety monitoring portal	Current access	MEDIUM
REI-01	Reimbursement	Press Information Bureau / National Health Authority	Launch of Health Benefit Package Manual Part 2	2026-01-20	HIGH
REI-02	Reimbursement	Government of Assam / PM-JAY	PM-JAY Package Master	Current page reviewed 2026	HIGH
REI-03	Reimbursement	Government of Assam	Atal Amrit Abhiyan Package Master	Current page reviewed 2026	HIGH
REI-04	Reimbursement	National Health Authority	NHA Data Privacy Policy / PM-JAY description	June 2023	HIGH
REI-05	Reimbursement	National Health Authority	CGHS transaction system	Current access	LOW
BUY-01	Buyer	AIIMS New Delhi	Department of Cardiology	Current access	HIGH
BUY-02	Buyer / Procurement	AIIMS Jodhpur / CPPP	Coronary-stent rate contract on consignment basis	2025-09-25	HIGH
BUY-03	Buyer	PGIMER Chandigarh	Department of Cardiology	Current access	MEDIUM

ID	Module	Organization / publisher	Title / resource	Date	Confidence
BUY-04	Buyer	SCTIMST	Cardiology Department	Current access	HIGH
BUY-05	Buyer	Sri Jayadeva Institute	Official institute website	Current access	HIGH
BUY-06	Buyer / Procurement	RMSCL	Introduction and equipment procurement	Current access	HIGH
BUY-07	Buyer / Procurement	KMSCL	About KMSCL / central procurement role	Current access	HIGH
BUY-08	Buyer	Apollo Hospitals	Apollo Heart Institutes	Current access	HIGH
BUY-09	Buyer	Fortis Healthcare	Cath-lab launch / interventional cardiology capability	2023-01-18 event	MEDIUM
BUY-10	Buyer	Narayana Health	Adult interventional cardiology capability	Current access	MEDIUM
BUY-11	Buyer	Manipal Hospitals	Coronary angiography / PCI services	Current access	HIGH
BUY-12	Buyer	Medanta	Interventional cardiology listing	Current access	MEDIUM
TEN-01	Procurement	AIIMS Jodhpur / CPPP	Rate contract for procurement of coronary stents on consignment basis	2025-09-25	HIGH
TEN-02	Procurement	DGAFMS / GeM mirror	GEM/2025/B/6826396 coronary-stent bid	2025-11-03	MEDIUM
TEN-03	Procurement	ESIC Chennai / GeM mirror	GEM/2025/B/6607266 DES 2.5 × 23	2025-09-13	MEDIUM
TEN-04	Procurement	Tamil Nadu public buyer mirror	SRPHC153053 zotarolimus DES	2025	MEDIUM
TEN-05	Procurement	South Central Railway mirror	Tender 82250962 everolimus DES	2025-07-12	MEDIUM

12. Final Decision Record

Decision item	Final sample finding
Overall country-entry conclusion	CONDITIONAL GO
Overall evidence confidence	MEDIUM
Market Opportunity	READY - large observed PCI base; TAM/SAM scenario model transparent.
Competitor & Pricing	READY - 15-product universe, five profiles, regulated/public pricing; net acquisition and share gaps disclosed.
Regulatory & Reimbursement	READY - pathway and state payment evidence sufficient for intelligence; formal classification and national rate confirmation remain entry conditions.
Buyer & Procurement	READY - 15 organizations, public/private pathways and five tender examples; private terms and award unit rates remain unavailable.
Report boundary	Strategic intelligence only; no execution services included.
Research cutoff	19 August 2026

Final QA

✓ All four approved modules are present.

✓ Locked Phase 5B calculations are unchanged.

✓ Locked competitor set and five detailed profiles are unchanged.

✓ Locked pricing evidence and price-type distinctions are unchanged.

✓ Locked regulatory and reimbursement findings are unchanged.

✓ Locked buyer set and tender evidence are unchanged.

✓ Confidence ratings and evidence gaps are preserved.

✓ No new research was conducted.

✓ No unsupported market share, confidential pricing or tender unit rate was introduced.

✓ Reimbursement payment is not represented as product selling price.

✓ NPPA ceiling price is not represented as transaction price.

✓ Conclusions follow the locked evidence and explicitly state the three entry conditions.

PHASE 5C STATUS: APPROVED FOR DESIGN