



Absorb GT1 Bioresorbable Vascular Scaffold System Post-marketing Surveillance Protocol

16-310

Version 1.0

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Result of this post-marketing surveillance shall be reported to the Ministry of Health, Labour and Welfare as a condition to marketing approval of the Absorb GT1 Bioresorbable Vascular Scaffold System.

Your cooperation in this surveillance would be highly appreciated.

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| Surveillance Device Approval Number | 2800BZX00406000 |
| Surveillance Device Approval Date | Nov 2, 2016. |
| Generic Name of the Surveillance Device | Absorbable Coronary Stent |
| Brand Name of the Surveillance Device | Absorb GT1 Bioresorbable Vascular Scaffold System |
| Surveillance Period (Registration Period) | From Nov, 2016 to Oct, 2023. (From Dec 1, 2016 to May 31, 2018) |
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LIST OF ACRONYMS AND ABBREVIATIONS

| Acronym/ Abbreviation | Description |
|----------------------------------|--|
| %DS | Percent Diameter Stenosis |
| ACC | American College of Cardiology |
| ACE | Angiotensin-converting Enzyme |
| ACS | Acute Coronary Syndrome |
| AHA | American Heart Association |
| ARB | Angiotensin Receptor Blocker |
| BVS | Bioresorbable Vascular Scaffold |
| CABG | Coronary Artery Bypass Graft |
| CAG | Coronary Angiography |
| CEC | Clinical Event Committee |
| CFR | Coronary Flow Reserve |
| CK | Creatine Kinase |
| CK-MB | Creatine Kinase Myocardial Band Isoenzymes |
| CRP | C-reactive Protein |
| CT | Computer Tomography |
| CTO | Chronic Total Occlusion |
| CVA | Cerebrovascular Accident |
| CVIT | Japanese Association of Cardiovascular Intervention and Therapeutics |
| DCA | Directional Coronary Atherectomy |
| ECG | Electrocardiogram |
| eGFR | Estimated Glomerular Filtration Rate |
| FFR | Fractional Flow Reserve |
| GPSP | Good Post-marketing Study Practice |
| HDL | High Density Lipoprotein |
| IFU | Instruction for Use |
| IVUS | Intravascular Ultrasound |
| LAD | Left Anterior Descending Artery |
| LCX | Left Circumflex Artery |

| Acronym/ Abbreviation | Description |
|----------------------------------|--|
| LDL | Low Density Lipoprotein |
| LMCA | Left Main Coronary Artery |
| LMT | Left Main Trunk |
| LVEF | Left Ventricular Ejection Fraction |
| MACE | Major Adverse Cardiac Event |
| MI | Myocardial Infarction |
| MLA | Minimal Lumen Area |
| MLD | Minimum Luminal Diameter |
| MSCT | Multiple Slice Computer Tomography |
| MRA | Magnetic Resonance Angiography |
| NQMI | Non Q-wave Myocardial Infarction |
| NSTEMI | Non-ST elevation Myocardial Infarction |
| OCT | Optical Coherence Tomography |
| PCI | Percutaneous Coronary Intervention |
| PMS | Post-marketing surveillance |
| PRU | P2Y12 Reaction Unit |
| QCA | Quantitative Coronary Angiography |
| QMI | Q-wave Myocardial Infarction |
| RCA | Right Coronary Artery |
| RVD | Reference Vessel Diameter |
| ST | Scaffold/Stent Thrombosis |
| STEMI | ST-elevation Myocardial Infarction |
| SVG | Great Saphenous Vein Graft |
| TIA | Transient Ischemia Attack |
| TIMI | Thrombolysis in Myocardial Infarction |
| TLR | Target Lesion Revascularization |
| TVF | Target Vessel Failure |
| TVR | Target Vessel Revascularization |

1. PURPOSE

This is a post-marketing use result surveillance (hereinafter referred to as “Surveillance”) conducted per the standards required by the Minister of Health, Labour and Welfare provided in the standards for post-marketing surveillances and studies [except for those defined in the Ministerial Ordinance on Good Clinical Practice for Medical Devices (MHLW Ordinance No. 36, 2005)] based on Paragraph 4, Article 23-2-9 (including application *mutatis mutandis* per Article 23-2-19 of Revised PAL) of the Law on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices, etc. (Law No. 145, 1960, hereinafter referred to as “Revised PAL”) by the Marketing Authorization Holder or accredited foreign manufacturer of a medical device defined in Paragraph 1, Article 23-2-5 of Revised PAL. The purpose of the Surveillance is to know the frequency and status of adverse device effects and adverse events in order to assure the safety of the new medical device, and to collect efficacy and safety information for evaluating clinical use results.

2. SURVEILLANCE METHOD

2.1 Subjects

Based on the Ministerial Ordinance on Good Post-marketing Study Practice for Medical Device, the Surveillance will **continuously register** patients with ischemic heart disease potentially indicated for treatment with the Absorb GT1 Bioresorbable Vascular Scaffold System (Marketing Approval No. 2800BZX00406000, Nov 2, 2016, hereinafter referred to as “Absorb GT1”).

Only on-label use of the Absorb GT1 will occur in this Surveillance until otherwise allowed by the Sponsor although this is a post-marketing use result surveillance. Detailed patient enrolment eligibility will be determined separately in guidelines.

2.2 Registration Method

- The Surveillance may be conducted per site-specific requirements for patient registration to post-marketing surveillance such as provision of information to patients and signed informed consent by patients, if applicable.
- Patient registration will continuously occur when treatment with Absorb GT1 is attempted.
 - Lesions for which treatment with Absorb GT1 was attempted will be target lesions.
 - If an attempt of Absorb GT1 implantation was failed and the treatment was done with other stent/device instead, the background information and procedure information on the Absorb GT1 will be recorded. Follow-up is not required unless any adverse event occurred in relation to the attempted Absorb GT1 implantation.
 - Lesions treated with other stent during the index procedure will be non-target lesions.

- If planning staged implantation (treatment is divided into several times in stages) is performed, the patient registration will occur at the time when treatment with Absorb GT1 is first attempted.
 - If treatment with Absorb GT1 is attempted for initial procedure, it will be the study procedure.
 - If treatment with Absorb GT1 is attempted for additional procedure in addition to the initial procedure, only additional treatment form will be entered.
 - Follow-up is also required for lesions treated with additional procedure. If any adverse events occur, the information will be recorded.
 - If treatment with Absorb GT1 is not attempted for initial procedure but attempted for additional procedure, the additional procedure will be the study procedure. The initial procedure is treated as history.
- De novo lesions observed during follow-up can be treated with Absorb GT1. Such case will not be considered as a new registration.
 - Before starting commercial sale (if ST rate at 3 months is $\leq 0.9\%$, commercial sale will be started), if Absorb GT1 is attempted as the additional procedure during follow-up, only the additional treatment form will be entered.
 - Result of use of Absorb GT1 for treatment of in-scaffold restenosis of Absorb GT1 or stent restenosis of other stent is currently unknown. Do not use Absorb GT1 for restenosis treatment until the Sponsor provides updated information.
 - Follow-up is required for lesions treated with additional procedure. If any adverse events occur, the information will be recorded.
- Quantitative measurement of RVD is strongly recommended for treatment with Absorb GT1
 - If IVUS/OCT is used for RVD measurement, RVD may be measured after pre-dilatation (if difficulty in lesion crossing is predicted)
- Post-procedure IVUS/OCT is strongly recommended until operators became familiar with use of Absorb GT1. **If incomplete scaffold expansion or apposition was observed, consider additional post-dilatation** within the maximum balloon pressure of the device.
- It is not recommended that patients registered in the Surveillance participate in any other therapeutic clinical study. Non-surveillance information/data obtained by the standard procedures of Surveillance Sites (eg, intravascular imaging) can separately be analyzed.
- Scheduled imaging follow-up is not required in the Surveillance. However;
 - When a follow-up imaging is conducted as a scheduled or diagnostic test, the Sponsor may request Surveillance Sites for images and related materials. Surveillance sites will cooperate in providing to the Sponsor, if requested.
 - Absorb GT1 loses strength along with progression of bioresorption. Therefore, after proceeding of bioresorption, intravascular imaging is in principle limited for a diagnostic purpose.

- Absorb GT1 is not visible under X-RAY. Therefore, MSCT or MRA can be used as an initial stenotic diagnosis.

2.3 Planned Sample Size

Target sample size of the Surveillance is approximately 2,000 patients. Commercial sale of Absorb GT1 beyond the purpose of the Surveillance will be started if the scaffold thrombosis (ST) rate in the 2,000 patients at 3 month is 0.9% or lower (ST rates for patients with Absorb GT1).

In the ABSORB III clinical trial, 19 events of definite/probable ST reported through 1 year, and 18 of them except 1 occurred within 3 months (maximum of 78 days) post-procedure. Therefore, it is appropriate to perform interim analysis for the safety using ST rate through 3 months. The event occurred after 3 months was reported 362 days after the procedure, and the patient stopped treatment with thienopyridine antiplatelet agent on Day 356.

Both in the AVJ-301 and the ABSORB III clinical trials, ST rate through 1 year was 1.5%. In the ABSORB III clinical trial, ST rate in target lesion with RVD \geq 2.25 mm was 0.9%. As explained above, ST rates at 3 months and 1 year are almost similar. The half widths of the 95% confidence intervals (CI) to different sample sizes are presented in the table 2.3-1. The half width of 95% CI decreases from 0.6% to 0.4% when a sample size is increased from 1,000 to 2,000. However, further increase in the sample size does not result in significant decrease in the half width of 95% CI. Therefore, the sample size of the Surveillance was established as 2,000 patients.

Table 2.3-1: Relationship between Sample Size and Half Width of 95% Confidence Interval assuming Scaffold Thrombosis Rate of 0.9%

| | N=1000 | N=1500 | N=2000 | N=2500 | N=3000 |
|-------------|--------|--------|--------|--------|--------|
| ST Rate | 0.9% | 0.9% | 0.9% | 0.9% | 0.9% |
| ½ of 95% CI | 0.6% | 0.5% | 0.4% | 0.4% | 0.4% |

2.4 Method

The surveillance consists of two phases as detailed below. All- patients will be continuously registered in each phases. This means that Absorb GT1 must not be used outside of the Surveillance, except in the case of revascularization to the registered patients.

Phase 1 (All- patients):

- 250 patients (approximately 45 sites)
 - Surveillance Sites:

AVJ-301 investigational sites or medical institutions which have a physician with experience of implantation of Absorb GT1 (or previous types of the device) in or outside of Japan (considering possible move of AVJ-301 investigators to another site)

- Main Purpose: To confirm the efficacy of physician training and to establish optimal training for increasing medical institutions participating in post-marketing evaluation. Procedural results will be evaluated sequentially for early feedback to the sites. Therefore, there will be no quantitative goal established to move to Phase 2. However, recommended procedure may be updated as required in order to achieve optimal acute result.
- Lesions to be treated: Per product IFU
- All cases will be treated by imaging-guided implantation technique using IVUS/OCT
 - At least first 150 cases will be analyzed by the core lab.
- Primary Endpoint 1: Exclusion of very small vessels
 - In the ABSORB III trial, very small vessel with RVD < 2.25 mm per core lab QCA was a risk factor of scaffold thrombosis.
 - In the AVJ-301 and the ABSORB III trials, lesions with RVD < 2.25 mm consisted of 14.4% (59/411) and less than 20% of all the lesions registered respectively. Therefore, goal of the training is to exclude these very small vessels.
 - Angiograms and IVUS/OCT images taken during procedure will be sent immediately to the core lab, which will analyze the images and give feedback to the site. Additional training or revision of registration criteria may occur as required in order to exclude almost all lesions with RVD < 2.5 mm from registration by the last half of Phase 1.
- Primary Endpoint 2: Scaffold apposition and complete expansion evaluated by IVUS/OCT (analyzed by the core lab)
 - Descriptive analysis only

Numerical goal will not be set because there is currently no imaging-guided BVS implantation technique established.

However, implantation guidelines will be established upon agreement by Sponsor's medical adviser and the core lab based on results of the clinical studies with this device and imaging-guided metallic stent implantation technique.

IVUS/OCT images taken during procedure will be sent immediately to the core lab, which will analyze the images and give feedback to the site as required. Images of ST, if occurred, will also be sent to the core lab.
 - All core labs will be those located in Japan in order to fulfill the goals mentioned above.

Phase 2 (All- patients):

- Until 2000 patients are registered (up to 200 sites)
 - Surveillance sites:
 - Phase 1 sites
 - Sites which have a physician accredited by CVIT, and experience of ≥ 100 PCI cases per year.

- Main Purpose: To confirm safety
- Lesions to be treated: Per product IFU unless otherwise instructed
- To be treated by site standard procedure (imaging-guided implantation technique using IVUS/OCT recommended per product IFU)
- Primary Endpoint: ST through 3 months
 - Criteria: ST rate (in 2,000 patients: sum of Phase 1 and Phase 2)
 - ≤ 18 patients (0.9%): To start commercial sale
 - ≥ 19 patients: To investigate the cause and take appropriate actions
- All images of ST, if occurred, will be sent to the core lab.
- At Phase 2, IVUS/OCT images post procedure may be analyzed in the core lab as well. Surveillance sites will cooperate to the Sponsor, if requested.

3. SURVEILLANCE PERIOD

Information will be collected for up to 5 years post procedure. The target registration period will be from the date that patient registration is allowed upon execution of study agreement with each site to May 31, 2018.

- Registration Period: 1.5 years
- Follow-up Period: 5 years
- Analysis for final report: 0.5 year
- Total: 7.0 years

Annual reports will be submitted to the regulatory authority after marketing approval. Data will be collected until all patients complete 5-year follow-up, and application for use result evaluation will then be submitted.

Separately from the annual reports, frequency of ST will be reported as required.

Data will be collected at the following time points:

- Baseline (pre-procedure)
- Procedure
- Post-procedure to discharge
- 3 months (by visit preferred; by telephone is allowed) (Day 90 ± 14 days)
- 1 year (by visit preferred; by telephone is allowed) (Day 365 ± 28 days)
- 2 years (by visit or telephone) (Day 730 ± 28 days)
- 3 years (by visit or telephone) (Day 1095 ± 28 days)
- 4 years (by visit or telephone) (Day 1460 ± 28 days)
- 5 years (by visit or telephone) (Day 1825 ± 28 days)

Scheduled imaging follow-up is not required for this surveillance. If any imaging is performed as site standard practice, the imaging modality and results should be recorded in case report forms. In addition, if any imaging is performed for diagnosis, these should also be recorded in case report forms.

4. TREATMENT OF PATIENTS

Absorb GT1 will be implanted per optimal technique recommended by Abbott Vascular Japan Co., Ltd. Physicians should refer to the warnings, contraindications, and precautions in the most current version of product IFU for optimal treatment of each patient.

Physician will make final decision on antiplatelet therapy. However, product IFU of the Absorb GT1 BVS recommends dual antiplatelet therapy (DAPT) for at least 12 months. However, severe adverse device effect of very late stent thrombosis for more than one year after implantation was reported. Therefore, scheduled follow-up should be performed depending on the patient's condition and necessity of extending antiplatelet therapy should be considered with paying attention to the risk of adverse reactions such as bleeding, patient's background information, and anatomic features of the lesions. In addition to that, physician should also pay full attention to the increasing risk of bleeding due to the combination with anticoagulants. Physician should refer to the most current version of ADP antagonist IFU before treatment of each patient. Laboratory tests and clinical observation required for evaluating adverse reactions to ADP antagonists should be performed per the product IFU.

5. INFORMATION TO BE COLLECTED FOR THE SURVEILLANCE

Details are shown in the surveillance items of Attachment 1.

5.1 Patient Baseline Information

- 1) Rave System Information
- 2) Registration Information
- 3) Demography
- 4) Ischemic Status and Other Cardiac Complications
- 5) Risk Factors and Comorbidities
- 6) Pre-procedural Laboratory Tests (If done, cardiac enzyme to be captured in cardiac enzyme form)
- 7) Pre-procedural Antiplatelet Medications

5.2 Procedural Information

- 1) Basic Procedural Information
- 2) Treated Lesion Information (Per lesion, stenting procedure only. Bifurcation lesion should be regarded as two lesions if both stented)
- 3) Pre-dilatation/Preparation (to be generated per dilatation/preparation)
- 4) Stenting Information (Including attempted but not implanted, to be generated per stent)
- 5) Post-dilatation (to be generated per dilatation)
- 6) Final Results

5.3 Pre- and Post-procedural Cardiac Enzymes

5.4 Procedural Complications

5.5 Antiplatelet Medications after the Procedure

5.6 Other Medications (Pre/Post-procedure)

5.7 Clinical Follow-up

5.8 Imaging Follow-up (target lesion only)

- 1) Primary imaging modality
- 2) If MSCT/MRA, Restenosis assessment
- 3) CAG
- 4) Intravascular imaging

5.9 Device Malfunction/Deficiency

5.10 Scaffold/Stent Thrombosis

5.11 Adverse Event Other Than ST (to be reported)

- Coronary Adverse events
 - Ischemia (Angina or ischemic test)
 - Diagnostic Catheter
 - Revascularization
- Bleeding
- Other serious adverse events (including adverse events related to antiplatelet medications)*
- Any adverse events related to Absorb GT1, or their causal relationship is "unknown"

*a serious adverse event: led to death, resulted in a life-threatening illness or injury, requires inpatient hospitalization or prolongation of existing hospitalization for treatment, impairment (e.g. resulted in a permanent impairment of a body structure or a body function) or threatened to impairment, led to a congenital abnormality or birth defect, an important medical event that may not result above but may be considered serious based upon the investigator's appropriate judgment.

For the adverse events described above, the causal relationship with the device or the procedure, adverse events related to antiplatelet medications, and outcomes of every adverse event should be recorded. For serious adverse events, reasons for the judgment of seriousness should be recorded as well.

5.12 Additional Treatment (If done with Absorb GT1)

If Absorb GT1 is used for treatment in the registered patients before starting commercial use (i.e., before ST rate through 3 months is available for all the registered patients, as primary endpoint), the information should be recorded.

- 1) Type
- 2) Basic Procedural Information
- 3) Treated Lesion Information (Per lesion, stenting procedure only. Bifurcation lesion should be regarded as two lesions if both stented)
- 4) Pre-dilatation/Preparation (to be generated per dilatation/preparation)
- 5) Stenting Information (Including attempted but not implanted, to be generated per stent)
- 6) Post-dilatation (to be generated per dilatation)
- 7) Final Results

6. ENDPOINTS

6.1 Primary Endpoints

- Scaffold thrombosis (Phase-1 + Phase 2 all patients with Absorb GT1):
 - If ST rate at 3 months is $\leq 0.9\%$, commercial sale will be started.
 - If ST rate at 2 years is $\geq 1.5\%$, investigation will be implemented to identify the cause.
- Exclusion of very small vessels
 - For Phase-1 patients only
- Scaffold apposition assessed by intravascular imaging:
 - For Phase-1 patients only
- Device deficiency at procedure of implantation (all patients)

6.2 Other Endpoints

To be evaluated per typical DES clinical studies.

6.2.1 Clinical Endpoints

- Component endpoints
 - Death (Cardiac/Vascular/Non-Cardiovascular)
 - Myocardial Infarction (TV-MI/NTV-MI)
 - Target Lesion Revascularization (ID-TLR/NID-TLR)
 - Target Vessel Revascularization (ID-TVR/NID-TVR)
 - All coronary revascularization
- Composite endpoints
 - DMR (All death/All MI/All revascularization)
 - TVF (Cardiac death/All MI/ID-TVR)
 - MACE (Cardiac death/All MI/ID-TLR)
 - TLF (Cardiac death/TV-MI/ID-TLR)
 - Cardiac death/All MI

6.2.2 Angiographic Endpoints (core lab analysis)

Include the following:

- Pre-procedure
 - Morphology
 - TIMI blood flow
 - Lesion length
 - Proximal RVD
 - Distal RVD
 - MLD
 - %DS
- Post-procedure
 - TIMI blood flow
 - Proximal RVD
 - Distal RVD
 - MLD (in-stent/in-segment)
 - %DS (in-stent/in-segment)
 - Acute gain (in-stent/in-segment)

6.2.3 IVUS/OCT Endpoints (core lab analysis)

Include the following:

- Pre-procedure (or after pre-dilatation)
 - Lumen diameter or Lumen area (proximal/distal)
- Post-procedure
 - Lumen diameter or Lumen area (proximal/distal)
 - MLA
 - Incomplete apposition of the Absorb BVS strut
 - Fracture of the Absorb BVS strut

7. ANALYSIS AND REPORTING

7.1 Adverse Event Reporting

When the Surveillance Site obtains the information on occurrence of the following events, capture the information to the case recording form in principle within 48 hours.

- ST or events possibly considered as scaffold or stent thrombosis
- adverse events to be reported, described in Section 5.11
- device malfunction or deficiency

Adjudication of deaths, MIs, and STs is performed by clinical events committee or scaffold thrombosis image-review committee. Surveillance sites will cooperate in providing images and relevant materials for adjudication to the Sponsor.

7.2 Angiographic Core Laboratory

For Phase-1 patients, QCA assessments of baseline and post-procedure angiograms and lesion morphology will be performed also by the angiographic core lab as well as by Surveillance Sites.

In case of ST, angiograms at baseline, procedure and the event will be analyzed by the angiographic core lab.

The Sponsor may request Surveillance Sites for angiograms for any purpose other than the above. Surveillance sites will cooperate in providing the angiograms to the Sponsor, if requested.

7.3 Intravascular Imaging

For Phase-1 patients, intravascular (IVUS/OCT) assessments will be performed by the respective core lab.

In case of ST, IVUS/OCT images at baseline, procedure and the event will be analyzed by the respective core lab.

The Sponsor may request Surveillance Sites for IVUS/OCT images for any purpose other than the above. Surveillance sites will cooperate in providing the IVUS/OCT images to the Sponsor, if requested.

7.4 Scaffold Thrombosis Image-Review Committee

Scaffold thrombosis events occurred during the Surveillance will be adjudicated by a scaffold thrombosis image-review committee. The committee will evaluate events reported by Surveillance Sites as scaffold thrombosis as outlined below:

- **Purpose**

To minimize risk of scaffold thrombosis by informing Surveillance Sites of result of investigation of scaffold thrombosis events occurred during the Surveillance based on all images, patient background information, and other relevant information concerning the events used to assess relationship to Absorb GT1 and complexity of lesions and to identify cause of scaffold thrombosis. Therefore, Surveillance sites will provide the information to the Sponsor as requested.

- **Member Selection**

In cooperation with CVIT, five (5) physicians who are well experienced with Absorb GT1 implantation or intravascular imaging will be selected in advance. Review committee meetings will require attendance of at least three (3) members. One (1) representative of Abbott Vascular may (not mandatory) attend the meetings or may present their opinion in advance. Physicians from relevant core labs may attend meetings or present their opinion depending on individual cases.

- **Review Method**

By teleconference or physical meeting.

7.5 Clinical Observation - Clinical Events Committee (CEC)

Clinical events committee (CEC) will evaluate all deaths and suspicion of MIs for 3 years maximally. Surveillance sites will cooperate in providing materials needed to adjudication (e.g., death report, discharged summary) to the Sponsor, if a patient is dead or is suspected to MI.

7.6 Analysis of Surveillance Results

Analysis and reporting used for annual reports and application for use result evaluation will be performed per the *Yakushokukisanhatsu* Notification No. 1121-44 (November 21, 2014), “Handling of Use Result Evaluation Concerning Marketing Approval of Medical Devices and In-vitro Diagnostic Drugs”. Subgroup analysis may be performed as required for demonstrating the safety and efficacy, and the results will be included in the surveillance result overview of the application for use result evaluation. Adverse events other than death/MI/scaffold thrombosis will be adjudicated by Surveillance Sites.

The following populations will be used for clinical evaluation:

- Intent-to-Treat (all registered patients including patients with failure of Absorb GT1 procedure): only for evaluation of acute success
- Full Analysis Set (all patients with Absorb GT1)
- Absorb Only Population (patients who complete treatments only by Absorb)

Sub-group analysis includes the following but not limited to:

- Sex
- Diabetes
- Stent diameter

8. PUBLICATION POLICY

The Sponsor shall have the right to access and use all data and results generated during the Surveillance. The publication and/or presentation of results from a single Surveillance Site are not allowed until publication and/or presentation of the multi-center results. The Sponsor acknowledges that the Surveillance’s Principal Investigator intends to publish a multi-center publication regarding the Surveillance results. The Sponsor must receive any proposed publication and/or presentation materials at least 60 days prior to the proposed date of the presentation or the initial submission of the proposed publication in order for the materials to be reviewed by the Sponsor in compliance with the Sponsor’s publication policy. Prior approval from the Principal Investigator and the Sponsor is required for a live use or case reporting at Sites.

Among the data obtained in the Surveillance, the data that are included in the JPCI Registry will periodically be transferred to the JPCI Registry Database. Therefore, use of these data only will be an exception to the policy above.

9. DEFINITIONS

Definitions in the Surveillance are shown in Attachment 2.

ATTACHMENT 1: INFORMATION TO BE COLLECTED FOR THE SURVEILLANCE

Patient Baseline Information

1) Rave System Information

- Registration Date
- Initial JPCI Registration Date
- UMIN Patient ID
- JPCI Site ID
- Birthdate or Age at Procedure (JPCI 6, JPCI 7, NCDR A-1)
- Screening ID (auto generation)
- PMS Patient ID (auto generation)

2) Registration Information

- Date of Informed Consent Obtained
- Absorb GT1 treatment or attempt of treatment
- Study Procedure involve Staged PCI
 - Yes
 - Absorb GT1 attempted only at the initial procedure
 - Absorb GT1 attempted only at the 2nd (or 3rd/later) procedure (JPCI 12)
 - Absorb GT1 attempted both at the initial and 2nd (or 3rd/later) procedure (JPCI 12)
 - No

3) Demography

- Gender (JPCI 5, NCDR A-1)
- Height (NCDR A-2)
- Weight (NCDR A-2)
- BMI (Auto calc.)

4) Ischemic Status and Other Cardiac Complications

Ischemic Status (if staged procedure done, please record for the first procedure)

- Symptomatic (JPCI 11, NCDR B-1)
 - Stable Angina
 - Unstable Angina
 - Acute MI

- NSTEMI
- STEMI
 - Door to balloon time (JPCI 19-1, NCDR C-2)
- Unknown
- Related to Stent Thrombosis?
- Asymptomatic (JPCI 12, NCDR B-1)
 - Old MI (no evidence of ischemia but with evidence of infarct [eg. wall motion abnormality] from non-invasive studies)
 - Silent Ischemia (evidence of ischemia from non-invasive studies)
 - Others (no evidence of ischemia or infarct by non-invasive studies)

If stable angina or asymptomatic,

- Ischemic evaluation done within 3M (JPCI 13-1, NCDR B-1)
 - Yes (JPCI 13-2)
 - Stress ECG
 - Stress Scintigram (SPECT)
 - Stress Echo
 - Stress MRA
 - Cardiac CT
 - FFR
 - No (JPCI 13-2)

Cardiac Information at the Procedure (if staged procedure done, please record for the first procedure)

- Cardiac Arrest within 24 hours (JPCI 118, NCDR B-1)
- Cardiogenic Shock within 24 hours (JPCI 119, NCDR B-1)
- Acute HF within 24 hours (JPCI 120, NCDR B-1)

5) Risk Factors and Comorbidities

Risk Factors

- Hypertension (JPCI 13, NCDR A-2) → Medication captured separately
- Dyslipidemia (JPCI 13, NCDR A-2) → Medication captured separately
- DM (JPCI 13, NCDR A-2) → Medication captured separately
- Renal Failure (JPCI 13)
 - On-dialysis (JPCI 13, NCDR A-2)
- Current Smoker (NCDR A-2)
- Arteriosclerosis Obliterans (ASO) or Abdominal Aortic Aneurysm (AAA) (Prior and/or planned procedure) (JPCI 13)

- Prior CVA/TIA (NCDR A-2)
- Chronic Lung Disease (COPD), (JPCI 13, NCDR A-2)
- Family History of CAD (NCDR A-2)
- Hepatic Cirrhosis
- Prior Severe Bleeding Complications within 2Y
- Unresolved Cancer (NCDR A-2)

Cardiovascular Comorbidities

- Prior MI (JPCI 10, NCDR A-2)
- Prior PCI (if staged procedure done before index procedure) (JPCI 8, NCDR A-2)
 - LMT
 - Proximal LAD
 - Non-proximal LAD
 - LCX
 - RCA
 - Graft
- Prior CABG (JPCI 9, NCDR A-2)
- Prior Valve Surgery/Procedure
- Chronic Heart Failure(JPCI 117, NCDR A-2)
- Atrial fibrillation (NCDR A-2)
 - Within 24 hours

6) Pre-Procedural Laboratory Tests (If done, Cardiac Enzyme to be captured in Cardiac Enzyme Form)

- Creatinine (NCDR E-1)
 - eGFR (automatic calculation)
- HbA1c
- CRP (NCDR E-1)
- Hemoglobin (NCDR E-1)
- Total Cholesterol (NCDR E-1)
- TG (NCDR E-1)
- HDL-C (NCDR E-1)
- LDL-C (NCDR E-1)
- PRU

7) Pre-procedural Antiplatelet Medications

- Aspirin (JPCI 13-4, NCDR C-2)
- ADP antagonist
 - Prasugrel (JPCI 13-4, NCDR C-2)

- Clopidogrel (JPCI 13-4, NCDR C-2)
- Ticagrelor (JPCI 13-4, NCDR C-2)
- Ticlopidine (JPCI 13-4, NCDR C-2)
- Cilostazol (JPCI 13-4, NCDR C-2)

Procedural Information

1) Basic Procedural Information

- Date of the Index Procedure (1st procedure with BVS attempted), (JPCI 16, NCDR C-2)
- Admission date
- Discharge/In-hospital Death Date
- First Operator (JPCI 17, NCDR C-2)
- Second Operator (Supervising Operator), (JPCI 18, NCDR C-2)
- Procedure Start Time (Guide catheter insertion)
- Procedure End Time (Guide catheter removal)
- Fluoroscopy Time (JPCI 20, NCDR B-2)
- Volume of Contrast Media (NCDR B-2)
- Type of PCI (JPCI 19, NCDR C-2)
 - Elective
 - Non-elective
- Access Site (JPCI 121, NCDR B-2)
 - Femoral
 - Radial
 - Brachial
- Diseased Vessels (%DS > 75% visually, or $\geq 50\%$ by quantitative) (JPCI 14, NCDR B-2)
 - LMCA
 - LAD - Proximal
 - LAD - Non-proximal
 - LCX
 - RCA
- Number of Lesion Treated with Stent in this Procedure (to generate treated lesion form)
 - X lesions in Y vessels (NCDR C-2)

2) Treated Lesion Information (Per lesion, stenting procedure only. Bifurcation lesion should be regarded as two lesions if both stented)

- Lesion Number (Automatic)
- This lesion was intended to treat with
 - BVS (target lesion)
 - Other stent (non-target lesion)

- ACC/AHA Lesion Segment + SVG and AG (JPCI 23 to be modified, NCDR C-2)
 - If LMCA, protected or not
 - If main branch, Lesion involved bifurcation ≥ 2.0 mm in visual
 - Yes
 - No
 - If side branch,
 - Stenting both to MB and SB
 - Stenting to SB only
- Lesion Type (JPCI 25)
 - De novo
 - Restenosis – In-stent
 - Restenosis - Other
 - Unknown
- Quantitative Vessel Size Assessment
 - Yes
 - OCT
 - IVUS (NCDR C-2)
 - On-line QCA
 - No
- Proximal RVD (can be measured after successful post-dilatation)
 - Value
- Distal RVD (can be measured after successful post-dilatation)
 - Value
- Lesion Length (can be measured after successful post-dilatation)
 - Value
- %DS (NCDR C-2)
 - Value
- FFR (NCDR C-2)
 - Yes (Value)
 - No
- ACC/AHA Lesion Classification (physician assessment) (NCDR C-2)
 - A, B1, B2, C
- Lesion Complexity (physicians visual assessment)
 - Culprit Lesion of STEMI
 - Ostium Lesion
 - CTO (NCDR C-2)
 - Severe Calcification
 - Presence of Thrombus
 - Extremely angulated ($>90^\circ$)
 - Extreme Tortuosity
 - Myocardial bridge

- Hinge motion segment
- Thrombosuction before stenting (JPCI 27, NCDR C-2)
- Use of distal protection device (JPCI 27, NCDR C-2)

3) Pre-Dilatation/Preparation (to be generated per dilatation/preparation)

- Pre-dilatation/preparation
 - Yes
 - No, direct Stent
- Number of pre-dilatation/preparations
- To be entered per pre-dilatation
 - Pre-dilatation/preparation sequence # (automatic)
 - Pre-dilatation/preparation device Information (per dilatation)
 - Type of Device (JPCI 27, NCDR C-2)
 - Standard Balloon
 - Non-Compliant Balloon
 - Scoring Balloon
 - Cutting Balloon
 - Rotablator
 - DCA
 - Other Atherectomy Device
 - If balloon used
 - Balloon length
 - Nominal Balloon Diameter
 - Number of Dilatation for the Same Balloon
 - Dilatation Pressure (per dilatation)

4) Stenting Information (Including attempted but not implanted, to be generated per stent)

- Number of stents attempted to treat this lesion
- To be entered per stent attempted
 - Stent Sequence # (automatic)
 - Stent Name (JPCI 27)
 - Absorb GT1
 - Other (select from list)
 - Intention of this stent
 - Planned Single
 - Planned Overlap
 - Bailout to Proximal
 - Bailout to Distal

- TAP (T-Stenting and Small Protrusion)
- Stent diameter (NCDR C-2)
- Stent length (NCDR C-2)
- Successful deployment at intended location
- The use of additional approach (planned)
 - Parallel wire (Buddy wire)
 - Guideliner
 - Ko-catheter
- Device deficiencies
 - Cannot deliver to intended location
 - Difficulty in delivery (finally delivered)
 - How managed?
 - Buddy wire
 - Ko-catheter
 - Guideliner
 - Additional dilatation
 - Cannot re-cross implanted stent (in the case of planned overlap or bailout to distal)
 - Difficulty in re-crossing implanted stent (finally succeeded to re-cross)
 - How managed?
 - Buddy wire
 - Wiggle wire
 - Ko-catheter
 - Guideliner
 - Others

5) Post-Dilatation (to be generated per dilatation)

- Post-dilatation Done
- Number of post-dilatations
- To be entered per pre-dilatation
 - Post-dilatation sequence number (Automatic)
 - Post-dilatation balloon Information (per dilatation)
 - Type of Balloon
 - Delivery Balloon
 - Standard Balloon
 - Non-Compliant Balloon
 - Balloon Size
 - Nominal Balloon Diameter
 - Balloon Length
 - Number of Dilatation for the Same Balloon
 - Dilatation Pressure (per dilatation)

- Is this post-dilatation done after IVUS/OCT assessment to achieve better result?
- Device deficiencies
 - Cannot re-cross implanted stent (in the case of planned overlap or bailout to distal)
 - Difficulty in re-crossing implanted stent (finally succeeded to re-cross)
 - How managed?
 - Buddy wire
 - Wiggle wire
 - Ko-catheter
 - Guideliner
 - Change to another balloon (smaller balloon, semi-compliant balloon)
 - Others

6) Final Results

- TIMI Flow
- Post Procedural Intravascular Imaging done
 - IVUS
 - OCT
 - None
- Lumen Patency
 - %DS by
 - On-line QCA
 - Visual
 - MLA
- Strut malapposition observed by IVUS or OCT (NCDR C-2)
 - No
 - Yes, $\leq 150 \mu\text{m}$ (visual estimation)
 - Proximal edge
 - In-stent
 - Distal edge
 - Yes, $> 150 \mu\text{m}$ (visual estimation)
 - Proximal edge
 - In-stent
 - Distal edge
- Any difficulties to re-cross the implanted stent by IVUS/OCT
 - Cannot recross
 - Difficult to recross
 - How managed?
 - Buddy wire
 - Wiggle wire
 - Ko-catheter

- Guideliner
- Strut Fracture observed by IVUS/OCT
- Success of this lesion treatment (successful implantation, $\leq 25\%$ residual stenosis visually, and TIMI 3 flow) (JPCI 30)

Pre and Post Procedural Cardiac Enzymes

- Date (if multiple, record peak value date)
- CK (Value and Site standard) (NCDR E-1)
- CK-MB (Value and Site standard) (NCDR E-1)
- Troponin I (Value and Site standard, or Positive/Negative) (NCDR E-1)
- Troponin T (Value and Site standard, or Positive/Negative) (NCDR E-1)

Procedural Complications

- Successful PCI (lesion success + No in-hospital MACE)
- In-hospital Death (JPCI 21, NCDR E-1)
- Peri-procedural MI (JPCI 21, NCDR D-1)
 - Target Vessel related
 - QMI, NQMI
- Stent/Scaffold Thrombosis (in-hospital) (JPCI 21)
- Cardiac tamponade (JPCI 21, NCDR D-1)
- Cardiogenic shock (JPCI 21, NCDR D-1)
- Acute HF (JPCI 21, NCDR D-1)
- Severe Dissection (NCDR D-1)
- Perforation (NCDR D-1)
- Stroke (NCDR D-1)
- Bleeding complications within 72 hours, that required blood transfusion or Hb drop $> 3\text{g/dL}$
 - Access Site (JPCI 21)
 - Access site bleeding (NCDR D-1)
 - Hematoma (Femoral: $\geq 10\text{cm}$, Radial: $\geq 2\text{ cm}$, Brachial: $\geq 5\text{ cm}$) (NCDR D-1)
 - Non-access Site (JPCI 21)
 - Intracranial Bleeding (NCDR D-1)
 - Retroperitoneal bleeding (NCDR D-1)
 - Digestive organ bleeding (NCDR D-1)
 - Urinary bleeding (NCDR D-1)
 - Other bleeding (NCDR D-1)
- Other

Antiplatelet Medication after the Procedure

- Aspirin
 - Dose
 - Start Date
 - Stop Date
- ADP antagonist
 - Prasugrel, Clopidogrel, Ticagrelor
 - Dose
 - Start Date
 - Stop Date
- Cilostazol
 - Yes
 - Dose
 - Start Date
 - Stop Date
 - No

Other Medications (Pre/Post-Procedure)

- Oral Anticoagulant (JPCI 13-5)
 - Warfarin (JPCI 13-6)
 - Dabigatran (JPCI 13-6)
 - Rivaroxaban (JPCI 13-6)
 - Edoxaban (JPCI 13-6)
- RAA Inhibitor
 - ACE Inhibitor
 - ARB
 - Aldosterone antagonist (including spironolactone)
 - Renin antagonist
- Beta Blocker
- Alpha Blocker
- Ca channel blocker
- Nicorandil
- Dyslipidemia Agent
 - Statin
 - Other hypertension medication
- Diuretic
- Antiarrhythmic agent
- DM Agent
 - Insulin
 - Other hypoglycemic agent
- Ulcer Agent

- Histamine H2-receptor antagonist
- Proton pump inhibitor

Clinical Follow-up

- Follow-up Method (site visit, telephone)
- Follow-up date
- Follow-up reason
 - PMS Requirement
 - Site-standard
 - Unscheduled (New or worsened Adverse events)
- Change in Antiplatelet Medications
- Device malfunction/deficiencies
- Imaging Done?
 - Target Vessel – Fill Imaging FU form
 - Non target vessel
- PRU value (if measured)

Imaging Follow-up (target lesion only)

1) Primary Imaging Modality

- Date of Primary Imaging
- Method
 - MSCT
 - MRA
 - CAG

2) If MSCT/MRA, Restenosis Assessment

- No stenosis
- Inconclusive, Diagnostic Angiogram done
- Significant Stenosis, Elective PCI done

3) CAG

- Date of CAG (done by secondary diagnosis)
- No significant stenosis
- Inconclusive, FFR done
 - Negative
 - Positive, PCI done

- Significant stenosis, PCI done
- Other

4) Intravascular Imaging

- OCT
 - Strut malapposition
 - Uncovered strut
 - Strut fracture
- IVUS
 - Strut malapposition
 - Uncovered strut
 - Strut fracture

Device Malfunction/Deficiency

- Date
- Type of device malfunction/deficiencies
- Any AE related to this malfunctions
- Comments
- Product information (e.g., Lot number, Serial number)

Scaffold/Stent Thrombosis

For Absorb GT1, information for the additional procedure is captured as well as the index procedure. For other stents, information for the index procedure is only captured.

- Date
- Device (Absorb GT1 or other stents)
- Definite, Probable Possible
- Associated with
 - QMI
 - NQMI
 - STEMI
 - NSTEMI
 - Unstable angina
- Source document and images provided to the sponsor

Adverse Event Other than ST (to be reported)

- Adverse Event Below to be reported
 - Coronary AEs
 - Death
 - Cardiovascular Death
 - Unwitnessed Death <24hr
 - Unwitnessed Death 1-7 days
 - Other cause
 - ACS Admission
 - STEMI Admission
 - UA/NSTEMI Admission
 - Stable Coronary Disease
 - Symptomatic
 - Asymptomatic
 - Positive non-invasive testing (TYPE)
 - Positive invasive testing (TYPE)
 - Revascularization Procedure
 - Stent Thrombosis Confirmed or Suspected
 - Ischemia (Angina or ischemic test)
 - Diagnostic Catheter
 - Revascularization
 - Bleeding
 - Other Serious Adverse Events (including adverse events related to antiplatelet medications)*
 - Any adverse events related to Absorb GT1, or their causal relationship is "unknown"

*a serious adverse event: led to death, resulted in a life-threatening illness or injury, requires inpatient hospitalization or prolongation of existing hospitalization for treatment, impairment (e.g. resulted in a permanent impairment of a body structure or a body function) or threatened to impairment, led to a congenital abnormality or birth defect, an important medical event that may not result above but may be considered serious based upon the investigator's appropriate judgment.

For the adverse events described above, the causality relationship with the device or the procedure, adverse events related to antiplatelet medications, and outcomes of every adverse event should be recorded. For serious adverse events, reasons for the judgment of seriousness should be recorded as well.

Additional Treatment (If done with ABSORB GT1)

1) Type

- Additional Procedure of Planned Staged Procedure (not AE)
- Unplanned Procedure (AE)

Other information is the same with the "Procedural Information"

- 2) **Basic Procedural Information**
- 3) **Treated Lesion Information (Per lesion, stenting procedure only. Bifurcation lesion should be regarded as two lesions if both stented)**
- 4) **Pre-Dilatation/Preparation (to be generated per dilatation/preparation)**
- 5) **Stenting Information (Including attempted but not implanted, to be generated per stent)**
- 6) **Post-Dilatation (to be generated per dilatation)**
- 7) **Final Results**

ATTACHMENT 2: DEFINITION IN THE SURVEILLANCE

Scaffold/Stent Thrombosis

The definition of ARC will be used. The scaffold thrombosis image-review committee will adjudicate scaffold/stent thrombosis reported from the Surveillance Site based on this definition.

Scaffold/Stent thrombosis should be reported as a cumulative value at the different time points and with the different separate time points. Time 0 is defined as the time point after the guiding catheter has been removed and the subject left the catheterization lab.

- **Timing:**

- Acute scaffold/stent thrombosis*: 0 - 24 hours post stent implantation
- Subacute scaffold/stent thrombosis*: >24 hours - 30 days post stent implantation
- Late scaffold/stent thrombosis†: 30 days - 1 year post stent implantation
- Very late scaffold/stent thrombosis†: >1 year post stent implantation

*Acute/subacute can also be replaced by early scaffold/stent thrombosis. Early scaffold/stent thrombosis (0 - 30 days) - this definition is currently used in the community.

†Including “primary” as well as “secondary” late scaffold/stent thrombosis; “secondary” late scaffold/stent thrombosis is a scaffold/stent thrombosis after a target segment revascularization.

- **Categories:**

- Definite
- Probable

Definitions of each category are as follows.

- **Definite scaffold/stent thrombosis**

Definite scaffold/stent thrombosis is considered to have occurred by either angiographic or pathologic confirmation.

Angiographic confirmation of scaffold/stent thrombosis*

The presence of a thrombus† that originates in the scaffold/stent or in the segment 5 mm proximal or distal to the scaffold/stent and presence of at least one of the following criteria within a 48-hour time window:

- Acute onset of ischemic symptoms at rest
- New ischemic ECG changes that suggest acute ischemia
- Typical elevation or depression in cardiac biomarkers (refer to definition of spontaneous MI)

- Nonocclusive thrombosis
 - Intracoronary thrombus is defined as a (spheric, ovoid, or irregular) noncalcified filling defect or lucency surrounded by contrast material (on 3 sides or within a coronary stenosis) seen in multiple projections, or persistence of contrast material within the lumen, or a visible embolization of intraluminal material downstream.
- Occlusive thrombus
 - TIMI 0 or TIMI 1 in- scaffold/stent or proximal to a scaffold/stent up to the most adjacent proximal side branch or main branch (if originates from the side branch).

*The incidental angiographic documentation of stent occlusion in the absence of clinical signs or symptoms is not considered a confirmed stent thrombosis.

†Intracoronary thrombus.

Pathological confirmation

Evidence of recent thrombus within the scaffold/stent determined at autopsy or via examination of tissue retrieved following thrombectomy.

- **Probable scaffold/stent thrombosis**

Either of the following occurred after scaffold/stent implantation will be considered a probable scaffold/stent thrombosis:

- Any unexplained death within the first 30 days‡
- Irrespective of the time after the index procedure, any MI that is related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause

‡For studies with ST-elevation MI population, one may consider the exclusion of unexplained death within 30 days as evidence of probable stent thrombosis.

For the Surveillance, the principal definition of scaffold/stent thrombosis will be ARC definite or probable scaffold/stent thrombosis.

Death (Per ARC Circulation 2007; 115: 2344-2351)

CEC will adjudicate deaths based on ARC definition.

The deaths in the Surveillance will be adjudicated per the ARC definition. All deaths are considered cardiac unless an unequivocal non-cardiac cause can be established. Specifically, any unexpected death even in

patients with coexisting potentially fatal non-cardiac disease (e.g. cancer, infection) should be classified as cardiac.

- **Cardiac death:**
Any death due to proximate cardiac cause (e.g. MI, low-output failure, fatal arrhythmia), unwitnessed death and death of unknown cause, all study procedure related deaths including those related to concomitant treatment.

- **Vascular death:**
Death due to non-coronary vascular causes such as cerebrovascular disease, pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular cause.

- **Non-cardiovascular death:**
Any death not covered by the above definitions such as death caused by infection, malignancy, sepsis, pulmonary causes, accident, suicide, or trauma.

Myocardial Infarction

CEC will adjudicate myocardial infarction.

ECG assessment

- **Q wave MI (Q-MI)**
Development of new, pathological Q wave on the ECG in ≥ 2 contiguous leads.

- **Non-Q wave MI (NQ-MI)**
Not categorized as Q-MI but increasing biomarkers.

Biomarker assessment

If CK-MB is measured by Site-standards, the definition used in Absorb Japan clinical trial will be used. For other cases, use the Modified WHO definition.

Definition used in the Absorb Japan clinical trial

Classification and criteria of NQMI

| Classification | Biomarker Criteria | Additional Criteria |
|---|---|---|
| Periprocedural PCI (≤48h post-PCI) | CK-MB >5 x URL | Baseline value* < URL |
| Periprocedural CABG (≤48h post-CABG) | CK-MB >10 x URL | Baseline value < URL, and any of the following: New pathologic Q waves** or LBBB; new native or graft vessel occlusion; imaging evidence of loss of viable myocardium |
| Spontaneous All late events that are not associated with a revascularization procedure will be considered simply as spontaneous. | CK-MB > URL, or Troponin*** > URL | One or more of the following must <u>also</u> be present: (a) symptoms of ischemia; (b) development of pathological Q waves** (c) ECG changes indicative of new ischemia - (new ST-T changes or new LBBB), (d) or imaging evidence of a new loss of viable myocardium or a new regional wall motion abnormality |
| Reinfarction (not related to procedure) | If the CK and CK-MB values are stable or decreasing on 2 samples, a 25% or greater increase 3 to 12 hours after second sample is required to diagnose recurrent MI. | If biomarkers are increasing or peak not reached then insufficient data to diagnose recurrent MI. |
| URL=Upper Reference Limit LBBB=Left Bundle-branch Block * Baseline biomarker value is required before study procedure and presumes a typical rise and fall post ** If abnormal Q-wave is observed, then adjudicated as Q-MI *** If both values are obtained, then CK-MB must be used for adjudication | | |

Modified WHO definition

Elevation of CK > 2 x URL and CK-MB > URL without abnormal Q-wave.

Myocardial infarction - Relation to the Target Vessel

All infarcts that cannot be clearly attributed to a vessel other than the target vessel will be considered related to the target vessel.

Revascularization

The revascularizations in the Surveillance will be adjudicated by Sites per the ARC definition.

- **Location of Revascularization:**
 - **Target Lesion Revascularization (TLR)**

TLR is defined as any repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion. All TLR should be classified prospectively as clinically indicated or not clinically indicated by the investigator prior to repeat angiography. An independent angiographic core laboratory should verify that the severity of percent diameter stenosis meets requirements for clinical indication and will overrule in cases where investigator reports are not in agreement. The target lesion is defined as the treated segment from 5 mm proximal to the stent and to 5 mm distal to the scaffold/stent.
 - **Target Vessel Revascularization (TVR)**

TVR is defined as any repeat percutaneous intervention or surgical bypass of any segment of the target vessel. The target vessel is defined as the entire major coronary vessel proximal and distal to the target lesion which includes upstream and downstream branches and the target lesion itself.
 - **Non Target Lesion Revascularization (Non-TLR)**

Any revascularization in the target vessel for a lesion other than the target lesion is considered a non-TLR.
 - **Non Target Vessel Revascularization (Non-TVR)**

Revascularization of the vessel identified and treated as the non-target vessel at the time of the index procedure.
 - **Non Treated Vessel Revascularization**

Revascularization of the vessel that is not treated at the time of the index procedure.

Note: TLR and TVR will be adjudicated by the angiographic core laboratory.

- **Ischemia-driven Revascularization (ID-TLR/TVR)**
 - A revascularization is considered ischemia-driven if associated with any of the following:
 - Positive functional ischemia study including positive FFR
 - Ischemic symptoms and angiographic diameter stenosis $\geq 50\%$ by core laboratory QCA
 - Angiographic diameter stenosis $\geq 70\%$ by core laboratory QCA without angina or positive functional study

Other definitions

Other definitions are based on the latest J-PCI definition.