CALIQX Synopsis

CAlcified Coronary Lesions Identification & Quantification with X-rays

Version 1.6 – 23 October 2025
ID-CRB Number: 2024-A02724-43

SUMMARY

Sponsor :
RCF@ICPS
5 rue du Théâtre
91300 Massy, France

STUDY SUMMARY

Study title and name
CAlcified Coronary Lesions Identification & Quantification with X-rays
(Identification and Quantification of Calcified Coronary Lesions using X-rays)

Protocol version and date
Version 1.6 dated 23/10/2025

Study description
Medical device clinical investigation – Category 4.3

Study objective
To compare the 3DStent tool with the currently available reference method (intravascular ultrasound imaging – IVUS) for the assessment and quantification of native coronary calcifications.

Investigational device
Allia IGS 5 (including 3DStent)

Number of patients
30 patients

Participating centers
- Hôpital Privé d'Antony, 92160 Antony, France

- Hôpital Privé Claude Galien, 91480 Quincy-sous-Sénart, France
- Hôpital Privé Jacques Cartier, 91300 Massy, France

Study duration
1 month for each patient

Follow-up procedures
Patients will be contacted by telephone to assess their clinical status, complications and events, and any examinations and procedures that occurred after the procedure.

INCLUSION CRITERIA

To be included, patients must meet all of the following criteria:

- Male or female aged 18 years or older
- Patient presenting with a coronary lesion
- Angiographically calcified culprit lesion (Mintz classification)
    - **Moderate:** lesion with radiopacities visible only during the cardiac cycle before contrast injection
    - **Severe:** lesion with radiopacities visible without cardiac motion before contrast injection and visible on both sides of the arterial lumen
- Ability to cross the culprit lesion with an IVUS catheter
- Having been informed by an investigator about the research and having provided free, explicit, and informed consent
- Affiliation to a social security system (beneficiary or entitled person)

NON-INCLUSION CRITERIA

Patients presenting with one or more of the following criteria must not be included:

- Acute coronary syndrome with ST-segment elevation myocardial infarction
- Ongoing cardiogenic shock
- Culprit lesion not crossable with an IVUS catheter
- Pregnant, parturient or breastfeeding women and other categories of vulnerable persons: protected adults, adults unable to express consent and not subject to a protection measure, persons deprived of liberty
- Body mass index (BMI) > 35 kg/m^2

OBJECTIVE

To compare the assessment of native coronary calcifications using the 3DStent tool with IVUS assessment.

PRIMARY ENDPOINT

The primary endpoint of the study is the maximum radial extent of calcification (expressed in quadrants and degrees) before stent implantation, measured by 3DStent and IVUS.

SECONDARY ENDPOINTS

- Longitudinal extent of calcification before stent implantation, measured by 3DStent (a posteriori) and IVUS, expressed in millimeters
- Maximum thickness of calcification, measured by 3DStent (a posteriori), expressed in micrometers (µm)
- Minimal luminal area before stent implantation, measured by IVUS, expressed in mm^2
- Minimal in-stent area after implantation, measured by 3DStent and IVUS, expressed in mm^2
- Radiation dose and mean contrast volume during the procedure, expressed in mGy and ml respectively
- Procedure duration, expressed in minutes
- Major adverse cardiovascular events (cardiovascular death + stent thrombosis + myocardial infarction + need for target vessel revascularization) during the in-hospital period and at Day 30 post-angioplasty

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BENEFITS / RISKS

The benefits of participating in the study include improvement in the quality of angioplasty through the systematic use of IVUS (which is not always used during stent implantation) and improved evaluation of native coronary calcifications by IVUS, allowing better adaptation of the procedure, as well as the potential reduction of short- and long-term risks inherent to angioplasty (thrombosis, restenosis, etc.).

The risks induced by the protocol are considered low. Patient management remains identical to standard care, with all potential contraindications assessed during the planning of the angioplasty procedure.

There is a foreseeable increase in X-ray dosimetry received by the subject related to the rotational angiography performed for 3DStent. This increase remains modest: each acquisition represents less than 10% of the maximum total dose tolerated for a radiological examination.

CLINICAL INVESTIGATION TIMELINE

- Total planned duration of the clinical investigation: 15 months
- Start of inclusions: 01/11/2025
- Inclusion period duration: 9 months
- Planned end of inclusions: 01/08/2026
- End of follow-up: 01/09/2026
- End of data collection: 01/02/2027

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CLINICAL INVESTIGATION FLOW CHART

Evaluations / Procedures	Inclusion Day 0	Follow-up Day 30
Patient informed consent	X	
Review of inclusion/exclusion criteria (1)	X	
Physical examination*	X	
Medical history*	X	
Concomitant treatments*	X	X
Adverse events (2)	X	X

* Procedures performed according to standard care

(1) Inclusion and exclusion criteria must be verified before obtaining patient consent

(2) Adverse events are recorded from the Day 0 consent visit until the end of the last follow-up at 1 month