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Intervascular post-market clinical follow-up registry

Submission date 22/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/10/2025	**Overall study status** Ongoing	
Last Edited 22/10/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
This is a multi-center, retrospective review of participants who have received an Intervascular vascular graft or patch (Intergard Standard, Hemashield, Intergard Silver, Intergard Synergy) for bypass, repair or replacement of aortic, peripheral, or carotid arteries.
The purpose of the registry is to evaluate the long-term safety and performance of Intervascular Vascular Grafts and Patches (Intergard Standard, Hemashield, Intergard Silver, Intergard Synergy) for bypass, repair or replacement of aortic, peripheral, or carotid arteries. This registry is intended to further define the expected product lifetime of the devices and to collect data related to usefulness of the antimicrobial coatings.

Who can participate?
Patients who were at least 18 years of age at the time of the procedure who have undergone bypass, replacement or repair of the peripheral arteries, aorta, or carotid artery using the Intervascular Vascular Grafts and Patches (Intergard Standard, Hemashield, Intergard Silver, Intergard Synergy)

What does the study involve?
No registry-specific visits, interventions or assessments will be required by the protocol. Assessments conducted during participant visits will be according to local standard clinical practice and physician judgement. No intervention or follow-up assessments are stipulated.

What are the possible benefits and risks of participating?
There are no risks of physical harm associated with participation in the data registry. Participation in the registry does involve the potential risk of breach of confidentiality of medical information and associated privacy of the participants. The use of the information from the registry may provide future benefit to healthcare providers and patients who require bypass, replacement, or repair of peripheral, aortic, and carotid arteries by expanding knowledge regarding the use of the Intervascular Vascular Grafts and Patches (Intergard Standard, Hemashield, Intergard Silver, Intergard Synergy). The potential future benefits include assessing long-term safety and performance outcomes, and assisting sponsors in satisfying regulatory requirements. There is no expected direct benefit to the participant for participation in the registry itself.

Where is the study run from?
Intervascular SAS (France)

When is the study starting and how long is it expected to run for?
August 2025 to December 2026

Who is funding the study?
Intervascular SAS (France)

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
VV-TMF-00090

Study information

Scientific Title
Post-market clinical follow-up registry to evaluate the safety and performance of the intervascular vascular grafts and patches in patients undergoing bypass, replacement, or repair of aortic, peripheral, or carotid arteries

Study objectives
The purpose of the registry is to evaluate the long-term safety and performance of Intervascular Vascular Grafts and Patches (Intergard Standard, Hemashield, Intergard Silver, Intergard Synergy) for bypass, repair or replacement of aortic, peripheral, or carotid arteries. This registry is intended to further define the expected product lifetime of the devices and to collect data related to usefulness of the antimicrobial coatings.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/08/2025, Clinical Research Ethics Committee with Medicinal Products of the Chartered Community of Navarre (CEIM-NA) (Irunlarrea, 3, Pamplona, 31008, Spain; +34 (0)848 422 495; ceic@navarra.es), ref: PS_2025/13 EX

Study design
Multi-center retrospective review

Primary study design
Observational

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Peripheral arterial disease (PAD), aortic disease, carotid artery disease (CAD)

Interventions
No registry-specific visits, interventions or assessments will be required by the protocol. Assessments conducted during participant visits will be according to local standard clinical practice and physician judgement. No intervention or follow-up assessments are stipulated.

Duration of the long-term follow-up is a minimum of 3 years (36 months) and a maximum of 15 years (180 months). No specific timepoints are specified due to the nature of this post-market retrospective, data collection registry (i.e. collecting historical standard of care data as it was noted in the medical charts).

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Intergard Standard - Collagen Coated Vascular Grafts and Patches; Hemashield Collagen Coated Vascular Grafts and Patches; Intergard Silver - Antimicrobial Collagen Coated Vascular Grafts and Patches; Intergard Synergy – Antimicrobial Collagen Coated Vascular Grafts

Primary outcome(s)
1. PAD Cohort: Primary device patency, defined as freedom from device occlusion or reintervention [time frame: through long-term follow-up]
2. Aortic Disease Cohort: Primary device patency, defined as freedom from device occlusion or reintervention [time frame: through long-term follow-up]
3. Carotid Artery Disease Cohort: Freedom from occlusion or reintervention [time frame: through long-term follow-up]
4. PAD Cohort: Major Adverse Limb Events (MALE), defined as major amputation or major reintervention, including placement of a new bypass graft, interposition graft, thrombectomy, or thrombolysis [time frame: through long-term follow-up]
5. Aortic Disease Cohort: Major Adverse Event (MAE), defined as major bleeding or major reintervention [time frame: through long-term follow-up]
6. Carotid Artery Disease Cohort: Major Adverse Event (MAE), defined as major bleeding, or stroke [time frame: through long-term follow-up]
7. Devices with antimicrobial coating: freedom from infection [time frame: through long-term follow-up]

Duration of the long-term follow-up is a minimum of 3 years (36 months) and a maximum of 15 years (180 months). No specific timepoints are specified, due to the nature of this post-market retrospective, data collection registry (i.e. collecting historical standard of care data as it was noted in the medical charts).

Key secondary outcome(s))
1. PAD Cohort: Technical success; reported complications and events, primary-assisted device patency, secondary device patency, and any changes in Rutherford Category and ankle brachial index (ABI). Rutherford category and ABI measurements at follow-up will be compared with baseline, where available. Primary assisted device patency is defined as freedom from device occlusion irrespective of whether an intervention was performed; in other words, primary-assisted patency is not lost when a reintervention is performed to preserve device patency before occlusion occurs. Secondary device patency is defined as freedom from “permanent” loss of device patency determined through the last follow-up time point for each patient [time frame: through long-term follow-up]
2. Aortic Disease Cohort: Technical success; reported complications and events, primary- assisted device patency and secondary device patency [time frame: through long-term follow-up]
3. Carotid Artery Disease Cohort: Technical success; reported complications and events [time frame: through long-term follow-up]
4. For all cohorts: 30-day incidence of infection; complications and events include device infection, registry or device-related serious incident, or death [time frame: 30 days]

Duration of the long-term follow-up is a minimum of 3 years (36 months) and a maximum of 15 years (180 months). No specific timepoints are specified, due to the nature of this post-market retrospective, data collection registry (i.e. collecting historical standard of care data as it was noted in the medical charts).

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Willing and able to provide legally effective written informed consent (as required by IRB/EC)
2. Male and female participants that have undergone bypass, replacement or repair of the peripheral arteries, aorta, or carotid artery using the Intervascular Vascular Grafts and Patches (Intergard Standard, Hemashield, Intergard Silver, Intergard Synergy)
3. Were at least 18 years of age at the time of the procedure
4. Available records for data collection with a minimum of 3 years (36 months) of data/follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Active infection in the region of device placement at the time of implantation of the Intergard Standard and Hemashield Vascular Graft or Patch.

Date of first enrolment
01/12/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario de Navarra
C/ Irunlarrea 3

Pamplona
Spain
31008

Sponsor information

Organisation
Intervascular SAS

Funder(s)

Funder type
Industry

Funder Name
Intervascular SAS

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (iMedNet Electronic Data Capture system).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes