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Gathering real-world data on LumiGuide: understanding its clinical use and benefits through the Xperience registry

Submission date
04/09/2024

Recruitment status
Recruiting

Registration date
29/10/2024

Overall study status
Ongoing

Last Edited
12/11/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
When one or more blood vessels are dilated or blood flow is impaired they may require surgical repair. Nowadays most of these surgeries are done via the blood vessels, called “endovascular surgery”. During such surgery often a stent is placed within the weakened vessel wall. To get the stent in the correct position, a thin wire (guidewire) and a thin tube (catheter) are used. Typically, Xray radiation and contrast fluid are used to view navigation of the guidewire and catheter within the human body. Using Xray and contrast fluid can be harmful to the human body. A new kind of guidewire enabled with Fiber Optic RealShape (FORS) technology, called LumiGuide will be used during surgery in this registry. Inside this guidewire is a thin glass fiber. This allows the doctor to continuously see where the guidewire and catheter are inside the body in full shape (in color) and 3D, without needing Xray or contrast fluid. The rationale for conducting the LumiGuide Xperience Registry is to continue building ‘real-world’ evidence on how this recently introduced innovative technology is used in clinical practice, and on the potential benefits of using LumiGuide. The expected main benefits of using LumiGuide compared to using X-ray guidance include a reduction in radiation exposure to the subject, the operator, and supporting staff as well as procedure time reduction due to improved visualization during navigation. The fact that there is a high variety in types of endovascular procedures and high variation in radiation exposure (minutes to hours of fluoroscopy time) and procedure time (tens of minutes to many hours), a large data set is required to gain sufficient information per procedure type where LumiGuide is used. This data serves as input for hypothesis generation and study designs for future studies.

Who can participate?
Adult patients aged 18 years old and over who are indicated for endovascular repair procedures in the peripheral, aortic and aortic side branch vasculature

What does the study involve?
All subjects in the registry will undergo endovascular procedures as per the standard of care. During the endovascular procedure, LumiGuide will be used in every subject enrolled for navigation to the target vessels in the endovascular repair procedure. There are no study-related

procedures for this study other than collecting patient and procedure-related data on top of normal clinical practice. There are no additional devices or medications required for the study other than the standard of care for treatment using FORS.

What are the possible benefits and risks of participating?
Participants may not experience any medical benefits. Use of LumiGuide may lead to a reduction of radiation exposure to the subject (and to the operator). Participation in the registry will provide no additional risk other than risks that are part of the endovascular repair.

Where is the study run from?
The registry will be performed by approximately 25 hospitals across Europe and USA

When is the study starting and how long is it expected to run for?
January 2024 until December 2026

Who is funding the study?
Philips Medical Systems Nederland BV

Who is the main contact?
Bart Wessels, Clinical Scientist, FORS venture
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Contact information

Type(s)
Public, Scientific

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Integrated Research Application System (IRAS)
329453

Protocol serial number
IGT-200010

Study information

Scientific Title
LumiGuide Xperience registry

Study objectives
A new kind of guidewire enabled with Fiber Optic RealShape FORS technology, called LumiGuide, has been developed for 3D visualisation during endovascular surgery. The rationale for conducting the LumiGuide Xperience Registry is to continue building 'real-world' evidence on how this recently introduced innovative technology is used in clinical practice, and on the potential benefits of using LumiGuide. Therefore the main purpose of the LumiGuide Xperience Registry is to characterize procedural characteristics obtained using LumiGuide.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/02/2024, London Bridge REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; 0207 104 8229; londonbridge.rec@hra.nhs.uk), ref: 23/LO/0906

Study design
Prospective observational (real-world) multicenter study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subject indicated for primary endovascular repair procedures in the peripheral, aortic and aortic side branch vasculature

Interventions
There are no study-related procedures for this study other than collecting patient and procedure-related data on top of normal clinical practice. Data that will be collected includes, but is not limited to,
• Verification of the inclusion/exclusion criteria.
• Medical history (relevant recent surgery, comorbidities, eGFR, etc.) and physical assessment of the subject
• Demographic information (gender, age, BMI, Body Weight, aneurysm size – if applicable)

• Radiation exposure-related parameters
• Procedure time-related parameters

Procedure time will be measured to assess whether there is an effect of LumiGuide on time during the procedure. Radiation exposure will be measured to assess whether there is an effect of LumiGuide on fluoroscopy time/dose, DAP, and/or AK during the procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Procedure time, defined as duration (min), measured using data collected in procedure records at one timepoint
2. Radiation exposure, defined as fluoroscopy time (min) and dose (Gy*cm2), digital subtraction angiography dose (DSA) (DAP, Gy*cm2), dose area product dose (DAP, Gy*cm2), air kerma (AK, mGy) and contrast agent volume (mL), measured using data collected in procedure records at one timepoint

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Subject indicated for any of the following primary endovascular repair procedures in the peripheral, aortic and aortic side branch vasculature including,
1.1. Complex EVAR (B/FEVAR and PMEG)
1.2. Standard EVAR, including IBD
1.3. Lower extremity PTA & stenting
1.4. Lower extremity venous obstruction repair
2. Subject can give informed consent and is 18 years of age or older, or of legal age to give informed consent per state or national law

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Subject participates in a potentially confounding drug or device trial during the study. Co-enrollment in concurrent trials may be allowed provided that pre-approval is obtained from Philips
2. Subject treated for re-intervention (e.g. endoleak, rebleeding) or staged procedure post-primary repair procedure
3. Subjects indicated for endovascular repair procedure not listed in the inclusion criteria (e.g. TEVAR, Chimney/snorkel, CERAB) unless pre-approval is obtained from Philips
4. All vulnerable subjects such as immuno-compromised subjects, subjects lacking the capacity to provide consent, subjects in emergencies, pregnant or breastfeeding women, or any other subject who meets exclusion criteria, according to applicable national laws, if any
5. Subject unwilling or unable to comply with the protocol and unable to understand verbal and /or written informed consent

Date of first enrolment
07/01/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Austria

Belgium

Denmark

France

Germany

Netherlands

Sweden

United States of America

Study participating centre
Guys & St. Thomas
Great Maze Pond
London
England
SE1 9RT

Study participating centre
UMCU University Medical Centre Utrecht
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Utrecht
Netherlands
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Study participating centre
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Maastricht
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55 Lake Ave North
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United States of America
1655

Study participating centre
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375 Longwood Avenue
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Study participating centre
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Birmingham Alabama
United States of America
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Study participating centre
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6020

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Visionsgatan 4

Solna, Stockholm
Sweden
17164

Study participating centre
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161 Fort Washington Avenue
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4716 Alliance Blvd
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United States of America
75093

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HonorHealth
8125 North Hayden Road
Scottsdale, Arizona
United States of America
85258

Study participating centre
Northwestern Medicine
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Chicago, Illinois
United States of America
60611

Study participating centre
Emory University Hospital
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Atlanta Georgia
United States of America
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Study participating centre
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Sponsor information

Organisation
Philips Medical Systems Nederland B.V.

Funder(s)

Funder type
Industry

Funder Name
Philips Medical Systems Nederland B.V.

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 (Philips Data Catalog)
A dataset entry can be added in data catalog by all Philips employees. Once the dataset is added, the person adding will become data custodian for that particular dataset. Philips employee may contact the data set custodian to learn more details about the data set. Datasets can be re-used or shared only after passing through the privacy compliance process.
Dataset metadata for the study have been made available, retention time is 15 years after end of study.

IPD sharing plan summary

Stored in non-publicly available repository