

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

Submission date 04/09/2024	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/10/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/10/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

bart.wessels@philips.com

Contact information

Type(s)

Public, Scientific

Contact name

Mr Bart Wessels

Contact details

Philips Medical Systems Nederland BV, FORS Venture, Veenpluis 6

Best

Netherlands

5684PC

+31638295939

bart.wessels@philips.com

Type(s)

Principal Investigator

Contact name

Prof Bijan Modarai

Contact details

St Thomas Hospital, Kings College London, Westminster Bridge Road

London

United Kingdom

SE1 7EH

+44 (0)2071887188

bijan.modarai@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

329453

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IGT-200010, IRAS 329453

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

Secondary study design

Longitudinal study

Study setting(s)

Hospital, Medical and other records

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

07/01/2023

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

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

4000

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**

Austria

Belgium

Denmark

England

France

Germany

Netherlands

Sweden

United Kingdom

United States of America

Study participating centre

Guys & St. Thomas

Great Maze Pond

London

United Kingdom

SE1 9RT

Study participating centre

Universitäres Herzzentrum Hamburg GmbH

Martinistraße 52

Hamburg

Germany

D-20246

Study participating centre

UMCU University Medical Centre Utrecht

Heidelberglaan 100

Utrecht

Netherlands

3584 CX

Study participating centre

UMC Maastricht

P. Debyelaan 25

Maastricht

Netherlands

6202 AZ

Study participating centre

University of Massachusetts

55 Lake Ave North
Worcester Massachusetts
United States of America
1655

Study participating centre

Beth Israel Deaconess Medical Center

375 Longwood Avenue
Boston, Massachusetts
United States of America
02215

Study participating centre

University of Alabama

619 19th Street South
Birmingham Alabama
United States of America
35249

Study participating centre

University of Texas Southwestern Medical Center

5323 Harry Hines Blvd
Dallas Texas
United States of America
75390

Study participating centre

University of Pennsylvania

1 Convention Ave
Philadelphia Pennsylvania
United States of America
19104

Study participating centre

Hôpital Universitaire Pitié-Salpêtrière

47-83 Boulevard De L'hôpital
Paris
France
75013

Study participating centre

UZ Gent

C. Heymanslaan 10
Gent
Belgium
9000

Study participating centre

Tirol Kliniken Innsbruck

Anichstraße 35
Innsbruck
Austria
6020

Study participating centre

Karolinska University Hospital

Visionsgatan 4
Solna, Stockholm
Sweden
17164

Study participating centre

Rigshospitalet University Hospital

Blegdamsvej 9
Copenhagen
Denmark
2100

Study participating centre

New York Presbyterian

161 Fort Washington Avenue
New York
United States of America
10032

Study participating centre

BaylorScott&White

4716 Alliance Blvd
Plano, Texas

United States of America
75093

Study participating centre

HonorHealth

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

Study participating centre

Northwestern Medicine

676 North Saint Clair Street
Chicago, Illinois
United States of America
60611

Study participating centre

Emory University Hospital

1364 Clifton Rd NE
Atlanta Georgia
United States of America
30322

Study participating centre

Universitätsklinikum Leipzig

Liebigstraße 18
Leipzig
Germany
04103

Sponsor information

Organisation

Philips Medical Systems Nederland B.V.

Sponsor details

Image Guided Therapy – Fiber Optic RealShape (FORS) technology Venture Philips Medical Systems Nederland B.V., Building QG 144 Veenpluis 6

Best
Netherlands
5684PC
-
FORS_Quality@philips.com

Sponsor type
Industry

Website
<https://www.philips.com/>

Funder(s)

Funder type
Industry

Funder Name
Philips Medical Systems Nederland B.V.

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2027

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