PHILIPS

Endovascular Procedures using Fiber Optic 3D Guidance

LumiGuide

March 2024 ICD-10 Coordination and Maintenance Committee Meeting

innovation + you

Disclaimer: The following presentation includes discussion of devices that have not been cleared by the FDA and are not yet available for commercial sale in the United States.

LumiGuide Overview

LumiGuide enables groundbreaking real-time and 3D device guidance of the full shape of a guidewire and catheter inside the body, without the need for X-ray

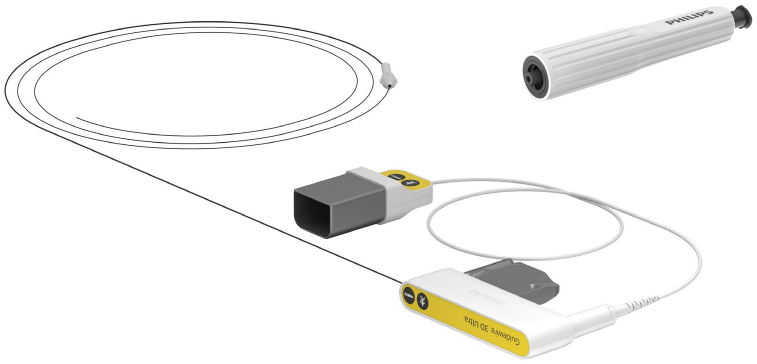
LumiGuide is comprised of a single-use angiographic guidewire with 3D visualization and a single-use 3D Hub

Guidewire
The guidewire* is intended to assist physicians direct a catheter in endovascular procedures of the peripheral, aortic and aortic side branch vasculature

3D Hub
The 3D Hub* is intended to visualize a catheter, when used in combination with a LumiGuide guidewire

LumiGuide Guidewire

3D Hub



* LumiGuide guidewire and LumiGuide 3D Hub are anticipated to attain FDA clearance by Q1 2024.

Comprehensive Navigation Necessary for Patients with Aortic Disease

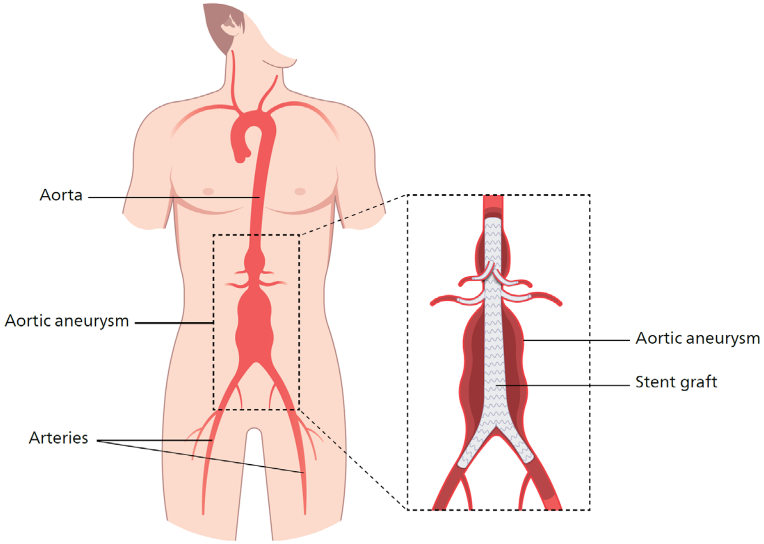
LumiGuide's anticipated intended use is to treat patients endovascularly in the peripheral, aortic and aortic side branch vasculature, particularly patients with thoracic, abdominal or thoracoabdominal aneurysms

An aortic aneurysm is a dilation of the vessel wall that is treated with an endovascular stent graft to prevent rupture

- Rupture associated with high mortality rates of 80-90%[1]
- Over 42,000 patients (U.S.) receive an endovascular stent graft yearly[2]

However, endovascular aneurysm repair is a complex procedure, typically requiring comprehensive navigation and positioning of multiple stents

Endovascular aneurysm repair



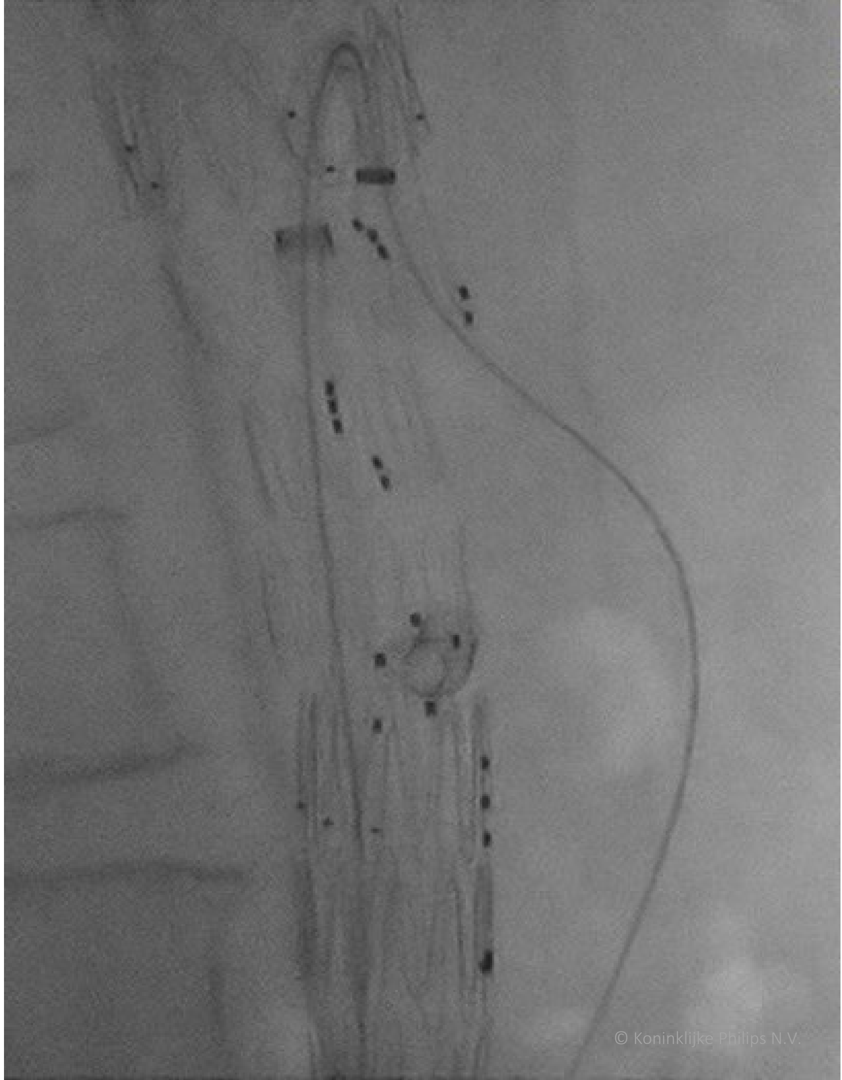
Conventional Approach for Endovascular Aortic Repair

Patients with aortic disease that are suitable for endovascular repair have complex anatomy requiring comprehensive navigation steps

Conventional navigation techniques include fluoroscopy, whereby the physician uses devices in a 2D X-ray image.

The physician needs to navigate to a difficult to reach target location, with limited visualization, resulting in:

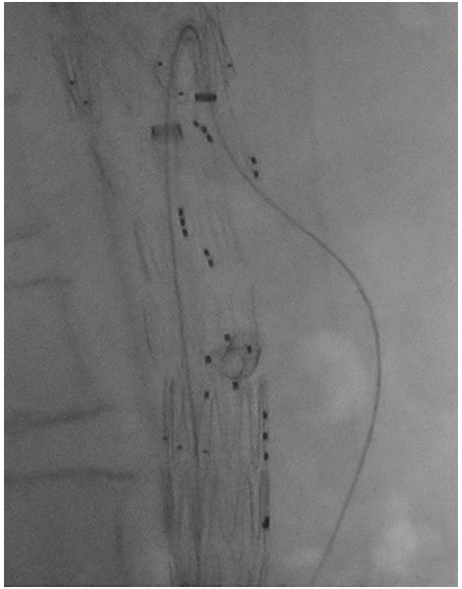
- Long procedure times[3]
- Procedure time associated complication rates[4,5]
- High radiation dose for both the patient and staff[6]



LumiGuide as New Device Guidance Option

LumiGuide enables more purposeful and easier navigation of devices and reduces radiation exposure[7]

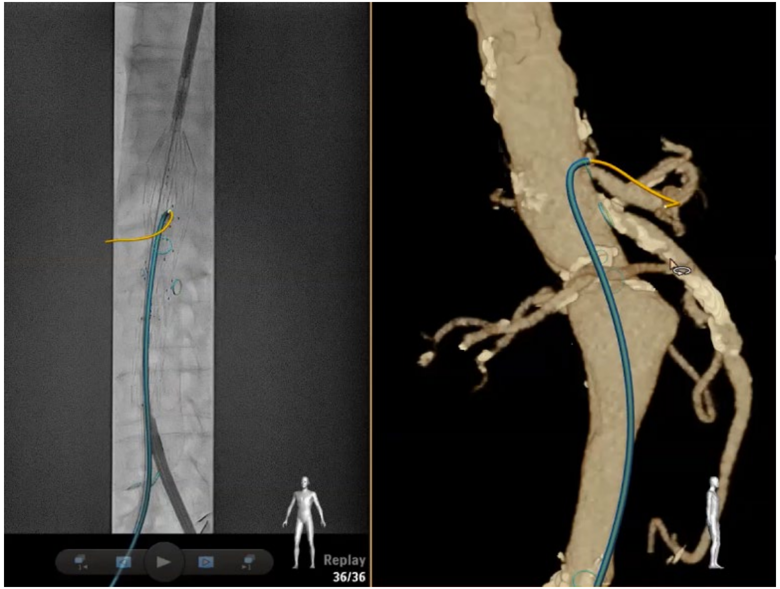
Conventional approach (X-ray)



LumiGuide* is solving the clinical need with **fiber optic real-time 3D device guidance**, and

- Limits the need for X-ray
- Enables complex navigation in multiple views
- Enables device visualization in color and in context of patient's anatomy
- Allows for unrestricted viewing angles
- Potentially reduces procedure time[7]
- Potentially reduces procedure time associated complication rates[4,5]

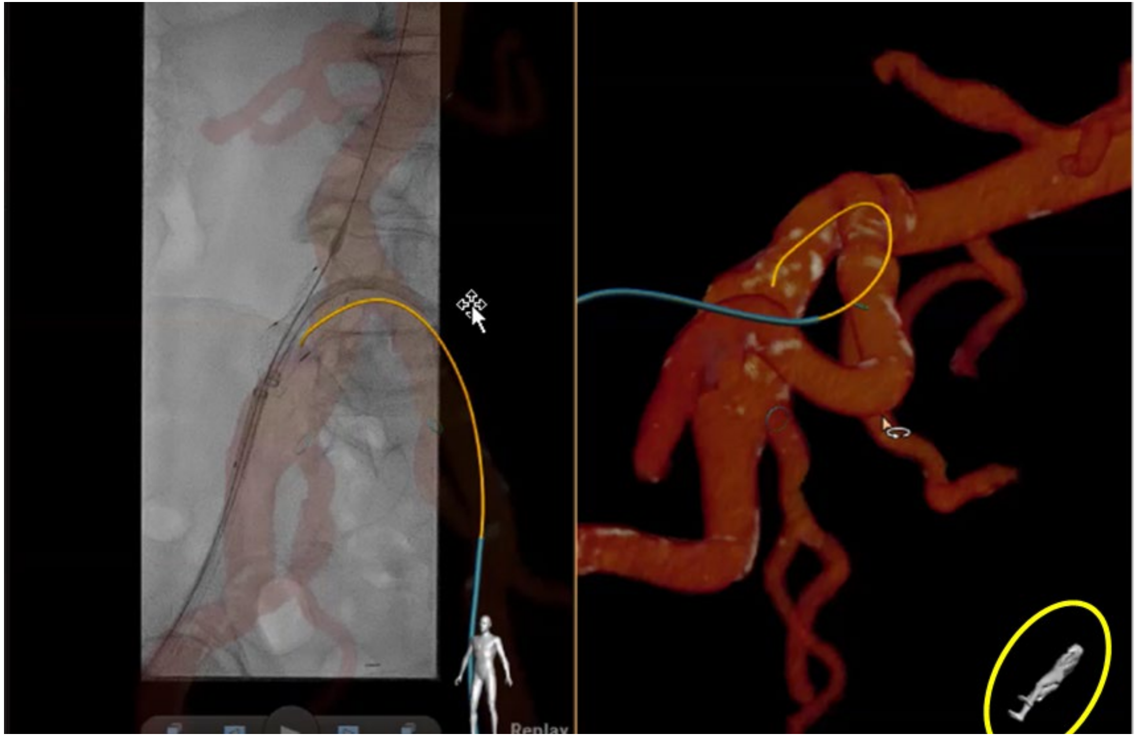
LumiGuide



* As with all endovascular procedures, complications may be encountered with the use of LumiGuide. The major risks may include, but are not limited to access site complications, dissection, perforation, embolization, and spasm

LumiGuide Allows for Unrestricted Viewing Angles

LumiGuide allows for device guidance from unrestricted viewing angles using multiple views to allow the physician to search for the best angle to support the task

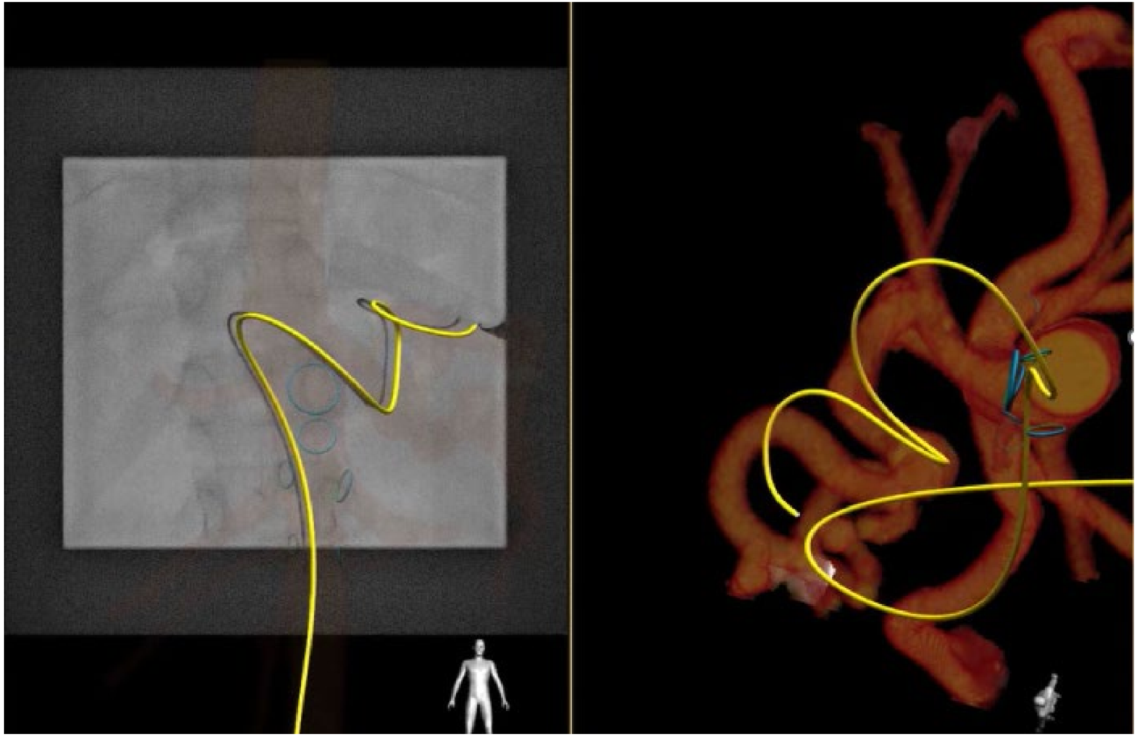


Enables Complex Navigation in Multiple Views

LumiGuide enables complex navigation in multiple views, as evidenced by caudo-cranial projections used by manually setting the 3D overlay

- Device safely navigated through tortuosity of splenic artery

- View not achievable by X-ray



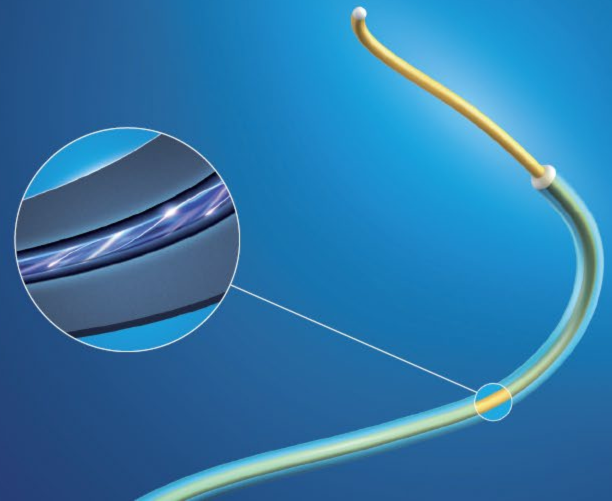
LumiGuide Mechanism of Action

LumiGuide provides real-time 3D visualization by measuring light reflection differences caused by strain in optical fibers

Step A
Light is sent through the optical sensor integrated in the guidewire

Step B
The reflected light is measured from the sensor

Step C
The difference between the reference light and the reflection is calculated, and the full shape of the guidewire is measured



LumiGuide Procedural Steps

The main steps involved in the LumiGuide procedure include:

Step 1:
Vessel access

Vessel access is obtained via a percutaneous puncture, usually through femoral arterial access*

Introducer sheath is placed at entry point for device introduction

Step 2:
Percutaneous insertion of LumiGuide

LumiGuide is set-up by connecting the guidewire to the equipment and the 3D Hub to the desired catheter

The guidewire and catheter combination is percutaneously inserted at access point

Step 3:
Navigate LumiGuide to the target vessel

LumiGuide and the 3D CT roadmap are registered to the x-ray system

The operator can use LumiGuide without additional fluoroscopy

The operator navigates to the target vessel using 3D device guidance in a 3D roadmap

Step 4:
Removal of LumiGuide from the body

After completion of the LumiGuide procedural steps, it can be put aside

Treatment delivery can now be done (e.g., stenting of target vessels)

After procedure completion LumiGuide can be disposed of per hospital protocols

*Different access points can be used (i.e., brachial or axillary artery), albeit rare.

Medical Record Documentation / Regulatory Status

LumiGuide guidewire and 3D Hub are anticipated to attain FDA clearance by Q1 2024

Documentation of LumiGuide will be included in the operative report and may be referred to as:

- LumiGuide
- LumiGuide Wire and 3D Hub
- LumiGuide powered by Fiber Optic RealShape (FORS) technology

Summary

– LumiGuide enables groundbreaking real-time and 3D device guidance by visualizing the full shape of a guidewire and catheter inside the body, without the need for X-ray

– LumiGuide is intended for use in the aortic, aortic side branch and peripheral vasculature

– LumiGuide provides real-time 3D visualization by measuring light reflection differences caused by strain in optical fibers

– The main steps in the LumiGuide procedure include: (1) Vessel access; (2) Percutaneous insertion of LumiGuide; (3) Navigating LumiGuide to the target vessel; and (4) Removal of LumiGuide from the body

Citations

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