Keystone Heart

New Options May Lower Your Stroke Risk and Brain Injury During a Heart Procedure

Introducing

TriGuard HDH

Cerebral Embolic Protective Device

The TriGuard HDH device is investigational and not yet approved for sale in the US. It is already CE marked in Europe.

Protecting the Brain: While Treating the Heart

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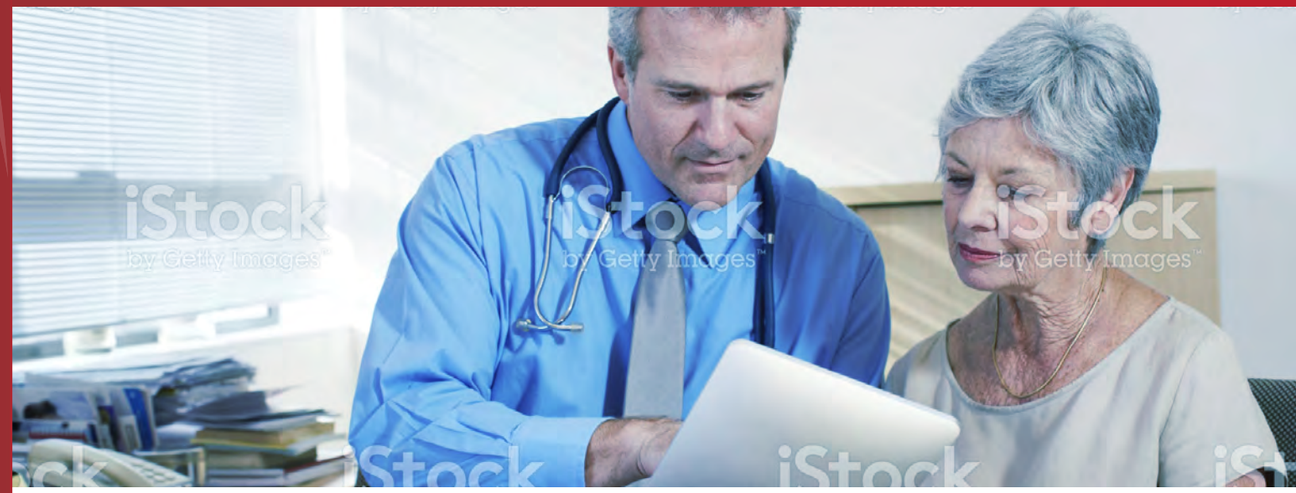
Thinking about a heart procedure?



If your physician has recommended that you consider **aortic valve replacement** or **implantation** (known as transcatheter aortic valve implantation or TAVI), then you may be a candidate for participation in a study evaluating a new stroke/brain injury protection device called **TriGuard HDH**.

Interventional Cardiologists agree

A device like the TriGuard HDH was foreseen in the early 2000's:

"We're going to be using something - a filter or filter-deflector - in every single patient to prevent the abnormal brain hits that are seen with all of these procedures. The need for brain protection is not going away."

Dr. David Holmes, Mayo Clinic

"TriGuard helps deliver a better patient outcome."

Dr. Rajesh Makkar, Director, Interventional Cardiology, Cardiac Catheterization Lab at Cedars Sinai Medical Center

"I Will use TriGuard by default in all TAVR cases in order to provide optimal care to my patients"

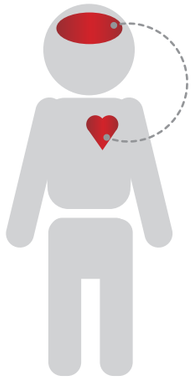
DR. P.R. Stella, Head of the Interventional Cathlab and Clinical Research & Development at the University Medical Centre of Utrecht (UMCU), the Netherlands

The TriGuard HDH device is experimental and not yet approved for sale in the US. It is already CE marked in Europe.

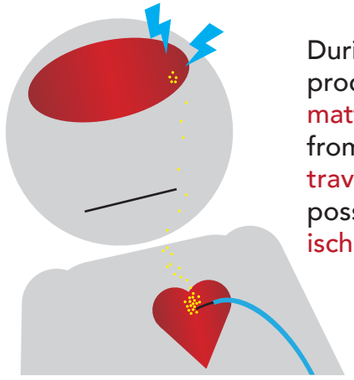
Minimizing Stroke and Brain Injury Risk

It may seem odd to discuss stroke, a neurological event (or something that happens to the brain) while in a cardiologist's office. But the two are connected.

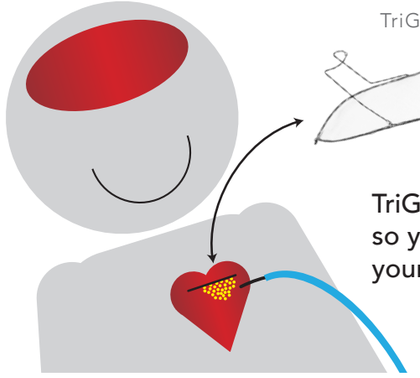
Stroke and other ischemic events remain a **significant side effect** to many interventional cardiac procedures. That risk was often taken because the potential good outweighed the possibility of stroke and other brain injuries. A brain injury may be obvious, like a stroke, or "silent" like diminished problem-solving capacity or impaired memory recall.



There is a direct connection between your heart and your brain - always - but especially when having a heart procedure



During a heart procedure particulate matter can be released from your heart and travel up to your brain possibly causing an ischemic event

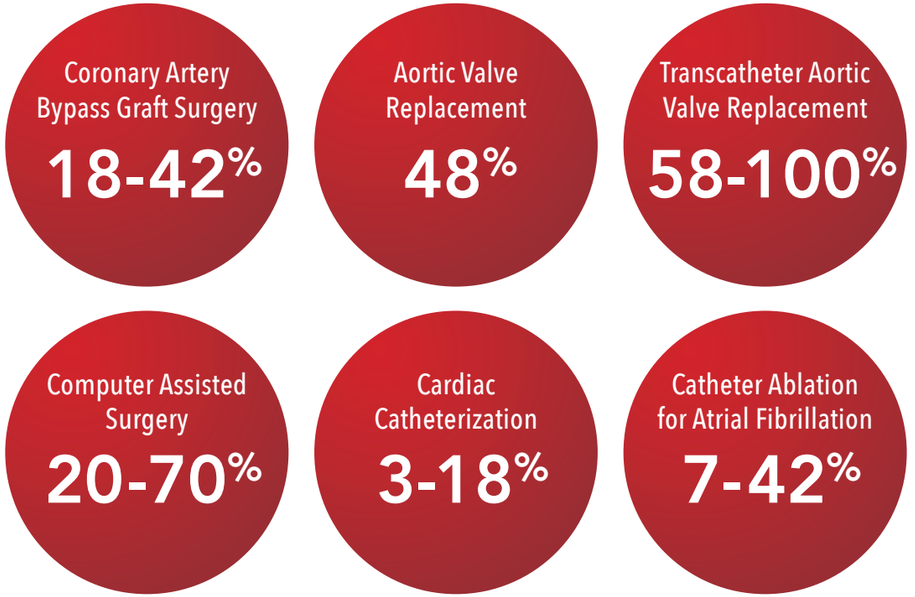


TriGuard HDH blocks the particulates so your brain stays safe while your heart is being taken care of.

Is a device like this necessary?

Brain injury as a result of interventional cardiac procedures is not new. What changed is how **these events are measured** and defined. With more sophisticated metrics and research using **MRI** (magnetic resonance imaging); **CT** (computerized tomography) scans and neurological evaluations, it was discovered that **brain injury after a heart procedure was much more frequent** than originally understood.

This discovery motivated the need for brain protection devices like TriGuard HDH.

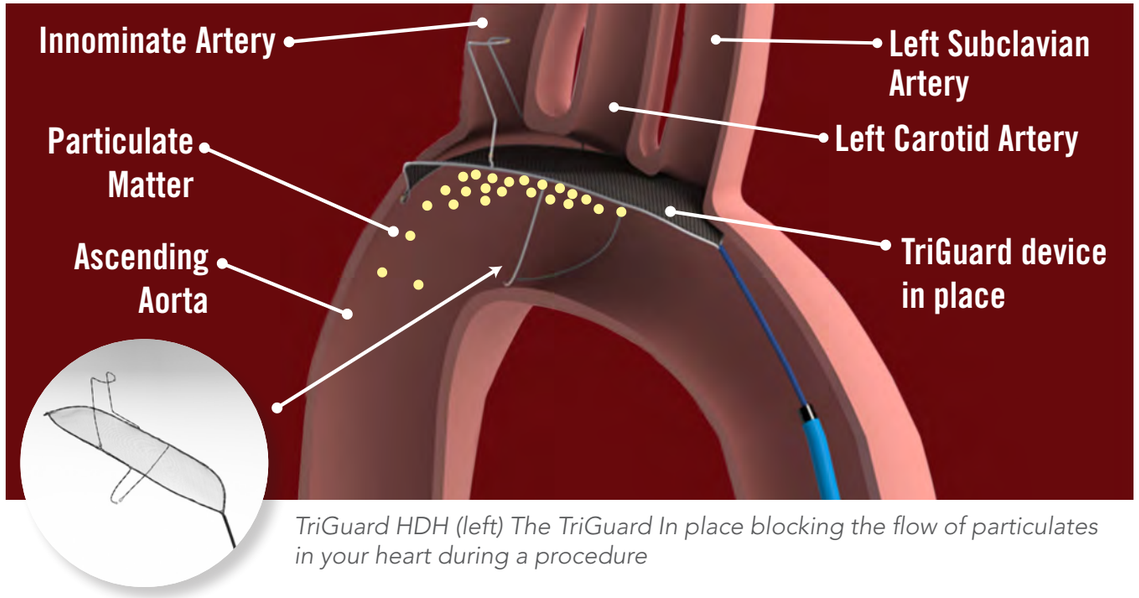


New Ischemic Lesions are present in a substantial number of patients undergoing cardiovascular interventations with DWI MRIs

Gress D, J Am Coll Cardiol. 2012 Oct 23;60(17):1614-6

How the TriGuard HDH Works

The **TriGuard HDH** device is a small flexible wire mesh filter that allows blood or other fluid to flow through it while **deflecting or preventing the passage of particulate matter**. During the TAVI procedure, it is positioned to **act as a shield** covering or protecting the blood vessels leading **to the brain**. While allowing blood to flow to the brain, the TriGuard HDH reduces particles from entering those blood vessels. Once the procedure is completed the TriGuard device is removed.



TriGuard HDH (left) The TriGuard In place blocking the flow of particulates in your heart during a procedure

Heart-Brain/Stroke-TAVI connection

New evidence demonstrates that **stroke** and other **ischemic events** post-TAVI procedure are **under-reported.**

The risk of stroke and other brain injury has long plagued Interventional Cardiology. Until now, there were little in the way of tools to mitigate that risk. The TriGuard device, currently being studied, acts as a screen to deflect plaque or cast off from a TAVI procedure that could have posed a risk for brain injury or even stroke.

This "cast off" (known as emboli) can lead to stroke, death or more subtle signs of brain injury like memory or recall impairment or trouble processing information. This study of the TriGuard HDH device, already available for use in Europe, is designed to determine its effectiveness in deflecting or preventing some or all of this cast off.

A better patient outcome

"TriGuard helps deliver a better patient outcome," Dr. Rajesh Makkar, Director, Interventional Cardiology, Cardiac Catheterization lab at Cedars Sinai Medical Center

The TriGuard HDH device was created to protect the brain during an interventional cardiac procedure. New evidence demonstrates the need for a device to do just that.

Ultimately the TriGuard device was designed to deliver a better patient outcome – for you.

Heart Procedure and Then Brain Tests

After your successful TAVI procedure, to ensure the TriGuard's efficacy, you will be asked to participate in follow up examinations.

After 30 Days + After 90 Days

At these follow-up appointments, you will have some routine tests and procedures that are not experimental but are done for the purposes of the study. These tests include:

A physical exam

Routine blood tests

An electrocardiogram

The same neurological exam you had before the TAVI procedure

An MRI

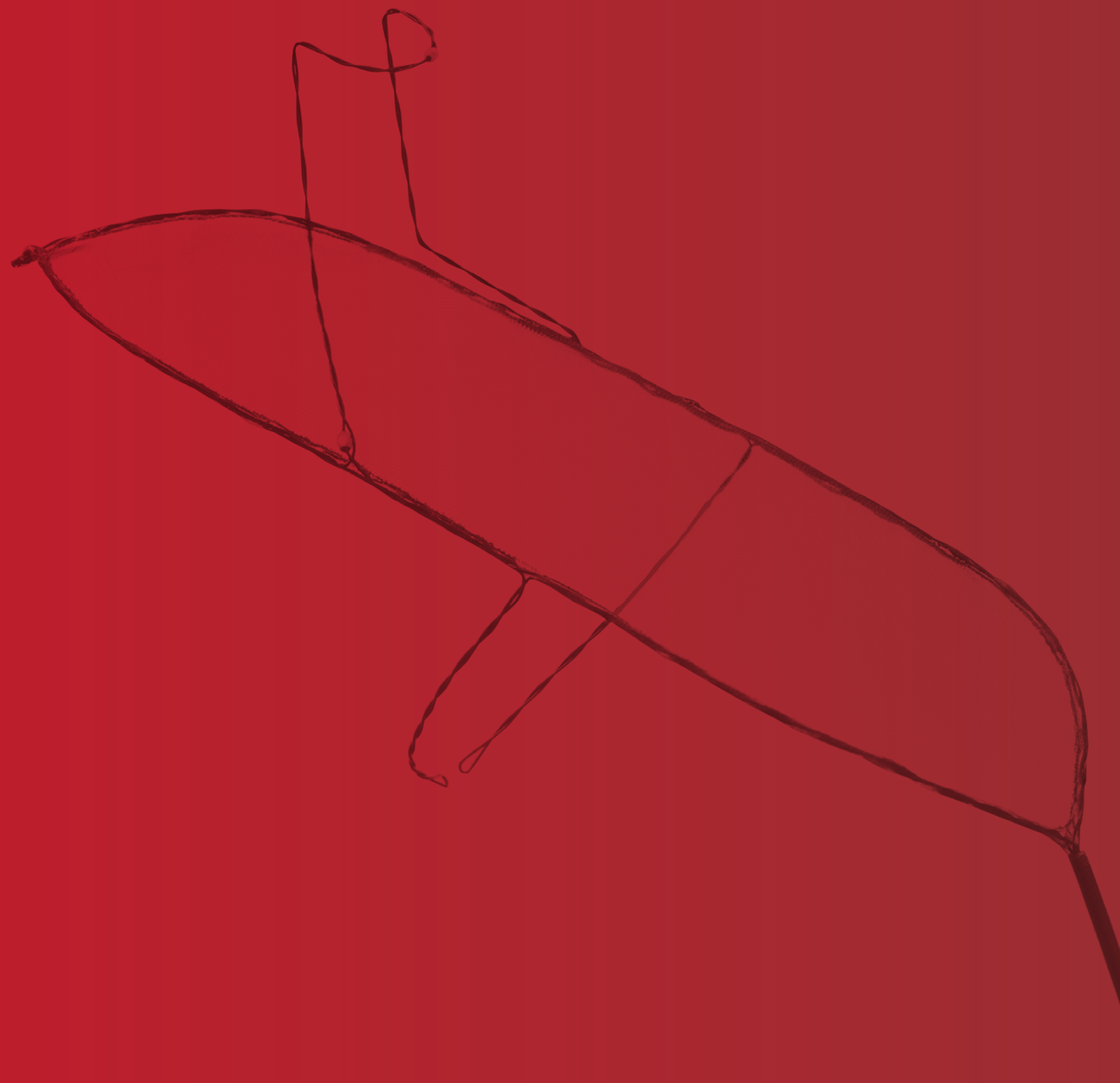
Risks and Inconveniences

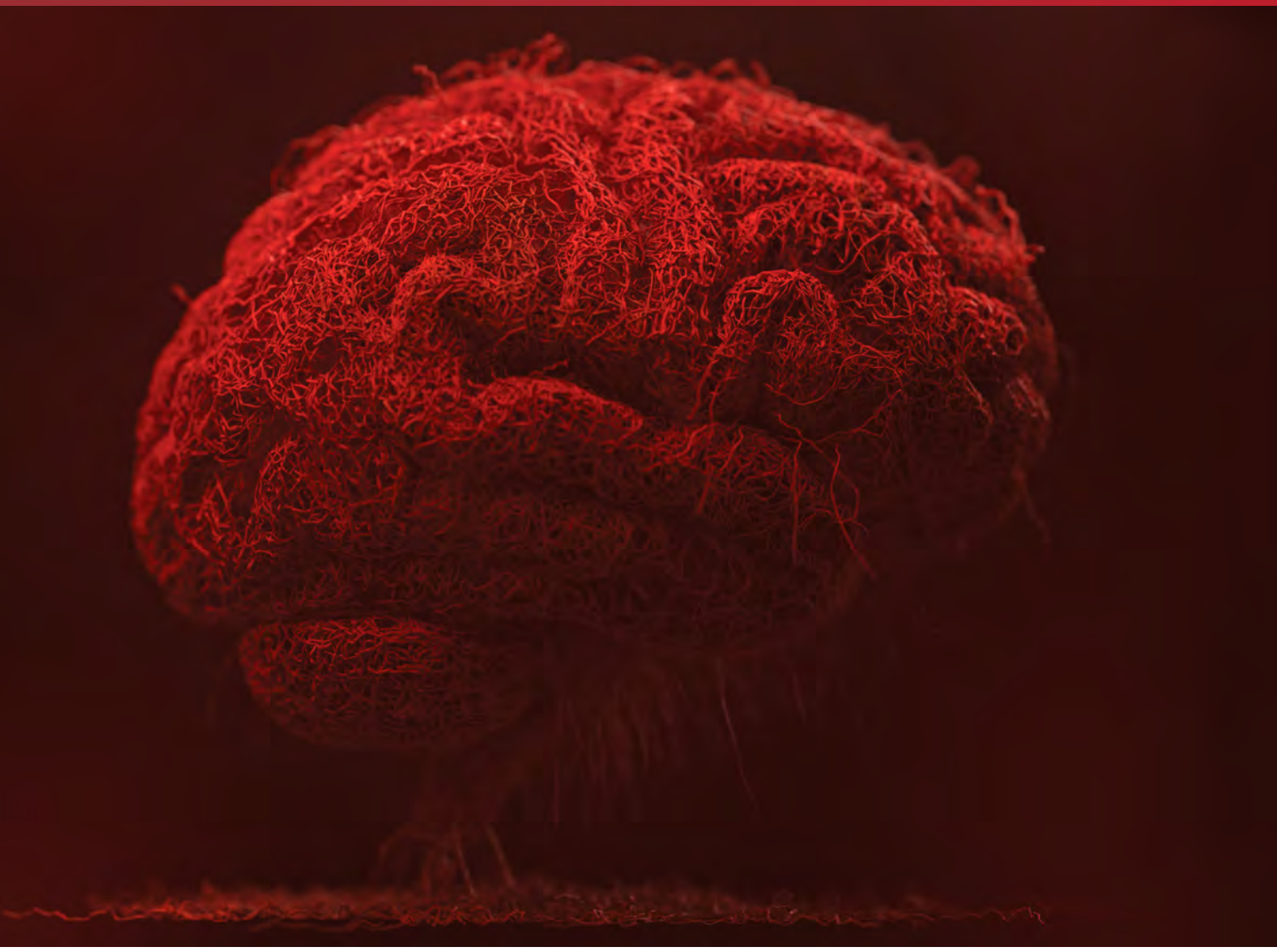
Like any medical procedure and experimental device, both TAVI and the TriGuard HDH device carry some measure of risk. Most risks of participation in this trial are not materially different than those encountered by undergoing TAVI in general. However, the use of the TriGuard HDH embolic deflection device may involve additional risks that are unknown at present.

The TriGuard clinical investigation plan is specifically designed to manage and minimize risks through careful subject selection, thorough training of investigators, adherence to pre-determined time points to assess subject clinical status, and regular clinical monitoring visits. Your safety and well-being are our main concern.

Talk to your physician to understand and acknowledge all the risks before you decide if TriGuard is right for you.

Notes





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