

**Category**

Best Medical Technology

**Drug / Device Name**

Thoraflex Hybrid™

**Compound/ Tech Name**

Thoraflex Hybrid™

**Trade Name**

Thoraflex Hybrid™

**Date of Approval**

2022-04-19

**Indications**

Thoraflex Hybrid™ is the World's First Frozen Elephant Trunk Device with Aortic Arch Plexus indicated for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta with or without involvement of the ascending aorta in cases of aneurysm (bulge in the aorta) and/or dissection (tear in the aorta).

Thoraflex Hybrid™ is a single use medical device combining Terumo Aortic's proven Gelweave woven surgical polyester graft that reinforces a weakened section of the blood vessel, a connected stented section (nitinol wire frame on polyester graft material) that holds the artery open, and a delivery catheter that is used to place the device. The Gelweave woven surgical polyester graft and stented sections are coated with gelatin to seal the implant and prevent blood from leaking out.

Furthermore, this unique surgical hybrid device facilitates secondary interventions for distal extension and, solely in the United States, is designated for usage with Terumo Aortic's RelayPro NBS device. This unique labelling aspect provides surgeons with additional confidence should patients have continued aortic disease progression.

**Therapeutic Categories**

Thoracic and Thoracoabdominal

**Attached Files:**

- Prix Galien USA Award Terumo Aortic.docx

**Background information and need for drug/device**

Surgical treatment of thoracic arch disease has always presented significant challenges to surgeons. Terumo Aortic, in collaboration with eminent surgeons from the internationally respected Hannover Medical School in Germany, developed Thoraflex Hybrid™ by combining two of Terumo Aortic's core innovations – vascular grafts and stent technologies. Of great significance, this device enables surgeons to combine two major operations into one, thereby eliminating the need for a second major

invasive operation. This greatly improves patient outcomes by making the operation faster and more straightforward.

Our Research and Development team engaged with surgeons from multiple geographies over a period of three years to establish the ideal device configuration and trialed early designs in controlled studies. This resulted in the unique, lifesaving Thoraflex Hybrid™ device with more than 13,000 devices having been implanted around the world over more than a decade. Not only does this innovative device eliminate a second stage operation, it reduces the very high mortality and morbidity associated with the original two stage procedure.

In 2020, the Food and Drug Administration (FDA) granted this unique hybrid device Breakthrough Device Designation. The purpose of the FDA's Breakthrough Device Designation program is to fast-track the regulatory review process for certain medical technologies and device-led combination products that satisfy certain criteria; these include providing a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The aim of the program is to provide patients and healthcare professionals with timely access to important breakthrough medical devices by accelerating their development, assessment and review, while preserving the statutory standards for premarket approval and 510(k) clearance.

In 2022, Thoraflex Hybrid™ was subsequently granted FDA approval for commercial sale of this hybrid device in the United States.

### **History of the development of the drug/device**

Terumo Aortic is committed to developing devices to address and enhance new surgical techniques and procedures.

Over the years, surgeons have proposed many radical device solutions for surgical replacement or stenting of the aortic arch; the medical device industry has struggled to develop devices to bridge the two leading life-threatening diseases afflicting the aorta; aortic aneurysm and dissection.

In the eighties, an operation called the 'elephant trunk' was proposed, allowing replacement of the diseased aorta from the heart in an area of the chest which is very difficult to access; it involved two separate operations months apart.

An evolution of the procedure was developed, the "Frozen Elephant Trunk" technique eliminating the need for a second operation. This clinical innovation created a gap in the market for a product to allow the procedure to be fulfilled. Recognising this gap, Terumo Aortic collaborated with Hannover Medical School to develop a device with the ability to achieve complete blood flow, adapt to the patient's anatomy and meet the demands of the surgical techniques required.

It was important to establish a defined regime of maintaining bilateral perfusion of the head and neck via both carotid arteries. Cerebral spinal fluid was drained from the patient's spine to give a larger differential between the arterial blood pressure and the spine's internal pressure minimising the chance of paralysis. Also, the patient's entire body temperature was decreased to reduce oxygen uptake and metabolism to minimise brain damage.

This collaboration resulted in Thoraflex Hybrid™, the first of its kind device used in Frozen Elephant

Trunk (FET) repair globally. CE mark approval was granted in 2012; an Investigational Device Exemption (IDE) study was carried out in the United States, data from which was utilized to gain FDA (US) and Pharmaceuticals and Medical Devices Agency (PMDA Japan) approval of the device.

**Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition**

The innovation of Thoraflex Hybrid™ is a major milestone in the treatment of patients who require a total aortic arch replacement and have significant disease of the descending thoracic aorta. This unique device allows patients to be treated anytime with a single stage procedure rather than two major invasive operations (often with a gap of two months between each operation) which was previously the conventional pathway for this group of patients. This type of surgery is so traumatic that a high percentage of patients died before or refused to undergo the second operation. A single stage procedure has, in turn, led to lowering the risk of major adverse events over traditional treatments.

One key challenge was designing a delivery system to enable the device to be implanted in a rapid, accurate and non-traumatic manner into the aorta. The stented section of Thoraflex Hybrid™ is compacted within a low friction ePTFE sheath, designed for rapid positioning within the vessel wall and, importantly, reduces operating time.

Furthermore, it was critical to design an innovative device with the following criteria to provide vital support for both the surgeon and patient during complex surgery:

- intuitive;
- small enough to be manoeuvred in confined anatomical spaces;
- adaptable to all patient anatomies;
- easy to position;
- flexible;
- biocompatible;
- less blood leakage;
- durable to last the patient's lifetime.

The combination of two operations into one has a massive cost saving with fewer blood transfusions, reduced theatre time, reduced post-operative time spent by the patient in both intensive care and surgical wards, freeing up valuable space and hospital resources.

**Please provide appropriate references (ie Pubmed links)**

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