



FOR AORTA

FROZENIX

manufactured in Japan



The preferred choice for Frozen Elephant Trunk reconstruction

Open Stented Grafting originated in Japan is recognized as the Frozen Elephant Trunk Technique across the world.

The case number in Japan is increasing year by year since FROZENIX was launched in July, 2014.

The device also advances along with the accumulated experience in clinical practice.

FROZENIX

As a supplementary device in Total Arch Replacement, we hope FROZENIX will continue to provide a better option for treatment of Aortic Aneurysm.



Advanced Delivery System



Tip with increased flexibility

Easily conforms to shape of aorta because of the increased flexibility of tip


Guide Wire Lumen

Guide wire lumen added for safer and more precise stent positioning


Marker

Marker on non-stented (graft) section, scaled at every 1cm for more precise stent positioning

Unique stent design




Hand-knitted unique stent design that yields flexibility



Supple yet strong enough to conform to the aortic arch


FROZENIX can be deployed in 3 easy steps.

STEP 1 Uncase




Unpack the whole package from the sterilization pouch and uncase FROZENIX to right above.

STEP 2 Tip adjustment




Adjust the curve of the tip to facilitate insertion of the device.

STEP 3 Deployment



Pull the sleeve whilst holding on to the grip.

NEW Insertion of guide wire



If required, the guide wire is inserted here.
* recommended diameter of guide wire: 0.035 inch

Guide Wire Lumen Entry Port



Grip

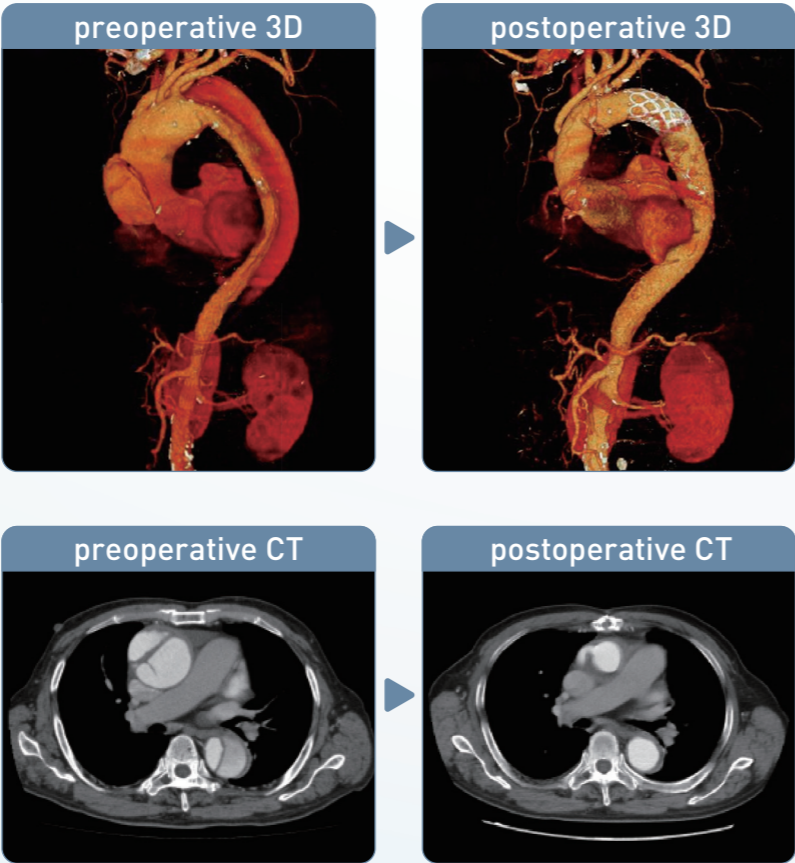
New design with better handling and slip resistance



Acute Type A Dissection

It is reported that FROZENIX can produce an excellent remodeling of the thoracic aorta.¹⁾

Here is a case example of total arch replacement with FROZENIX for treatment of the acute type A dissection. The false lumen of the descending thoracic aorta became thrombosed after the operation and an excellent remodeling of the thoracic aorta was confirmed by CT after 6 months.



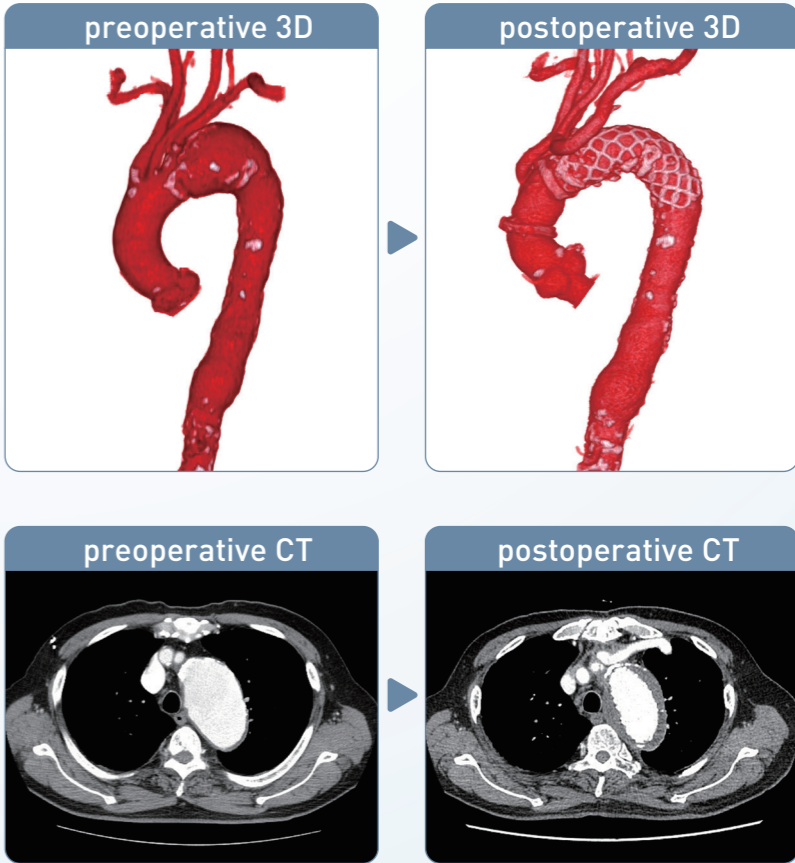
Aneurysm

Anastomosis at the distal end of the distal arch aneurysm can be simplified and can treat at one time by median sternotomy.

Here is a case example of total arch replacement with FROZENIX for treatment of the distal arch aneurysm.

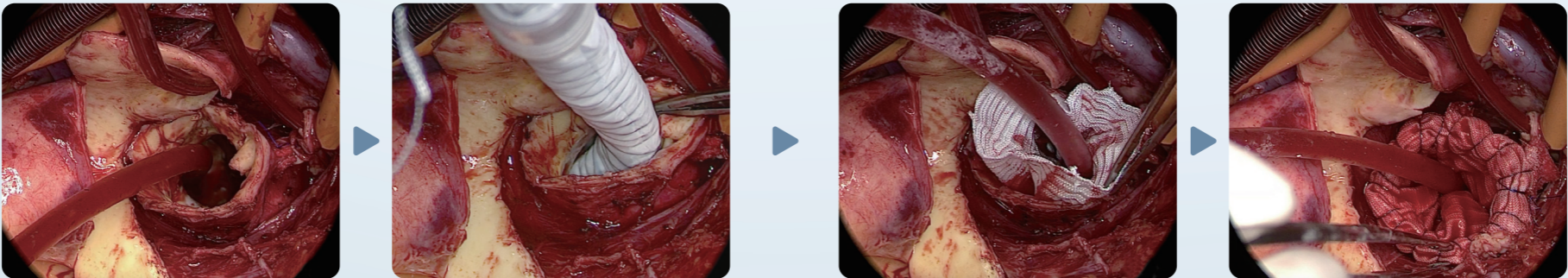
It is reported that the risk of respiratory complications such as hoarseness and dysphagia can be reduced as damage to a recurrent laryngeal nerve is limited by minimum exfoliation of the aortic arch.

Also, it helps graft anastomosing at the proximal end under good vision and makes the bleeding control easy.



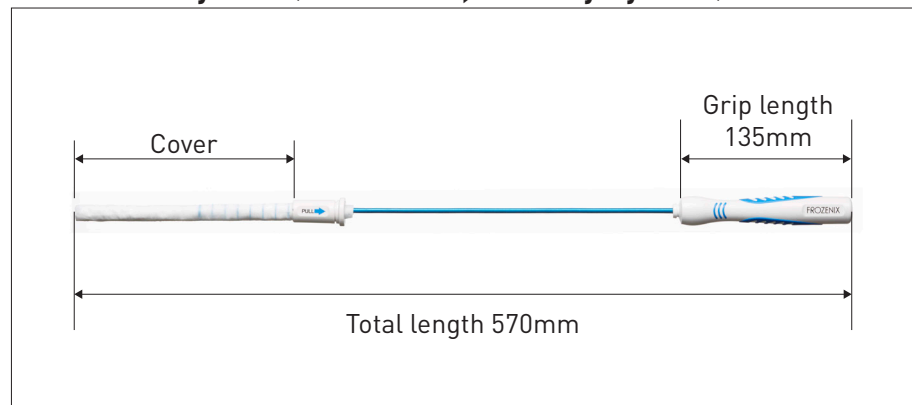
Stump Formation

It is necessary to make stump formation at the proximal end after the deployment of stent in order to control the bleeding as FROZENIX uses a non-coated graft (porosity: 150cc)



1) Naomichi Uchida, Department of Cardiovascular Surgery, Akane-foundation Tsuchiya General Hospital, et al. A new device as an open stent graft for extended aortic repair: a multicentre early experience in Japan. Eur J Cardiothorac Surg (2016) 49 (4): 1270-127

Stent Graft System (Stent Graft, Delivery System)

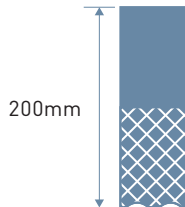


Stent Graft



- Graft Material : Polyester
- Stent Material : Nickel-titanium alloy

Stent Material	Nickel-titanium alloy
Graft Material	Uncoated Polyester
MR Safety	MR Conditional FROZENIX can be scanned safely under static magnetic field of 3.0 Tesla or less.
Durability	After 380 million cycles (equivalent to 10 years) of pulsatile test, no breakage, damage, or deformation was observed (according to JIS T 0401:2013).
Rod	The graft is loaded between a bendable rod and a cover; therefore, the curve of the tip is adjustable.

Total length	Stent length		60mm	90mm	120mm	150mm
	Outer diameter					
	21mm	FRZX-_21060	FRZX-_21090	FRZX-_21120	—	
	23mm	FRZX-_23060	FRZX-_23090	FRZX-_23120	FRZX-_23150	
	25mm	FRZX-_25060	FRZX-_25090	FRZX-_25120	FRZX-_25150	
	27mm	FRZX-_27060	FRZX-_27090	FRZX-_27120	FRZX-_27150	
	29mm	FRZX-_29060	FRZX-_29090	FRZX-_29120	FRZX-_29150	
	31mm	FRZX-_31060	FRZX-_31090	FRZX-_31120	FRZX-_31150	
	33mm	FRZX-_33060	FRZX-_33090	FRZX-_33120	FRZX-_33150	
	35mm	FRZX-_35060	FRZX-_35090	FRZX-_35120	FRZX-_35150	
	37mm	FRZX-_37060	FRZX-_37090	FRZX-_37120	FRZX-_37150	
	39mm	FRZX-_39060	FRZX-_39090	FRZX-_39120	FRZX-_39150	

Note: Catalogue numbers are subject to countries.

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