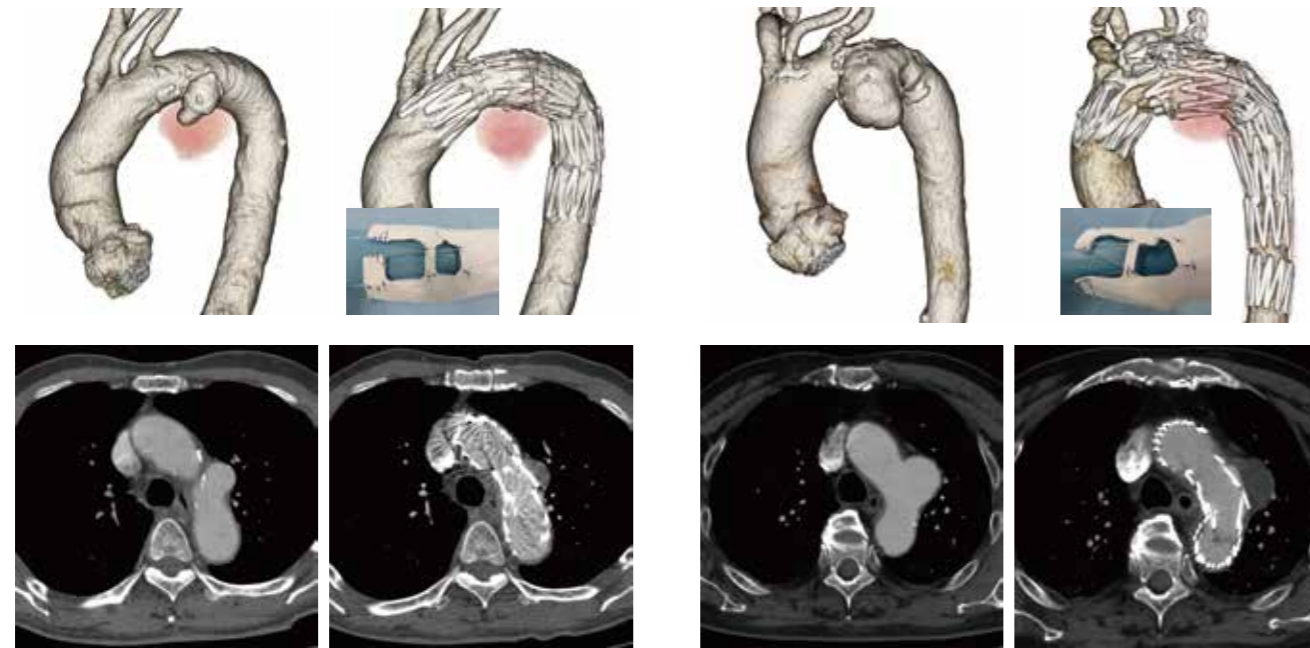


[Table 2. Najuta TEVAR experience at Kurume University hospital]

Patient characteristics	n	Mid-term outcome	n (%) , n = 29
Period	2007 - 2016	Follow-up period	53.9 (2-103) months
Patients	29	All-cause mortality	5 (17)
Sex (M / F)	27 / 2	Aneurysm-related mortality	0 (0)
Age	74 (61 - 85) yr	Open conversion	1 (3)
Etiology		Re intervention	1 (3)
Degenerative	22 (Saccular 19)	Type I / III EL	1 / 1 (7)
Dissection	6 (Double barrel 3)	Aneurysm expansion	2 (7)
Pseudo	1	Migration	0 (0)
Type Ia EL p/o TEVAR	5 (Homemade)	Obstruction of Arch vessel	1 (3) ; LSA

Cases

TEVAR of the distal arch saccular aneurysm using Najuta fenestrated Stent Graft.



Note: Data as shown below tables was including some cases of outside IFU and this does not recommend to use, refer to IFU booklet supplied with device.



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- 1994 MD, Kurume University, School of Medical Department
- 2005 PhD, Kurume University, School of Medical Department
- 2006 Board Certified Surgeon in Cardiovascular Surgery
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INTRODUCTION

Najuta Thoracic Stent Graft System (Kawasumi Laboratories, Inc, Tokyo, Japan) is a fenestrated endograft developed to treat thoracic aneurysm of the distal arch. It is the only commercially available fenestrated device indicated for thoracic endovascular aneurysm repair (TEVAR), that obtained Japanese regulatory approval in 2013 and CE mark in 2017.



Device

Semi-order made system

Total 1,590 types of device specification are available dependent on skeleton frame patterns, graft size and fenestration patterns, according to patient's anatomy.



► Skeleton frame (Stainless steel):

64 types of 3D dimensional frame.

► Graft (PTFE):

Diameter ranges from 24 mm to 42 mm, for 20 mm to 38 mm aorta. Straight type and Tapered type (4mm or 6mm) are available.

► Fenestration:

One to three fenestrated designed depending on patient's anatomy and aneurysm location.

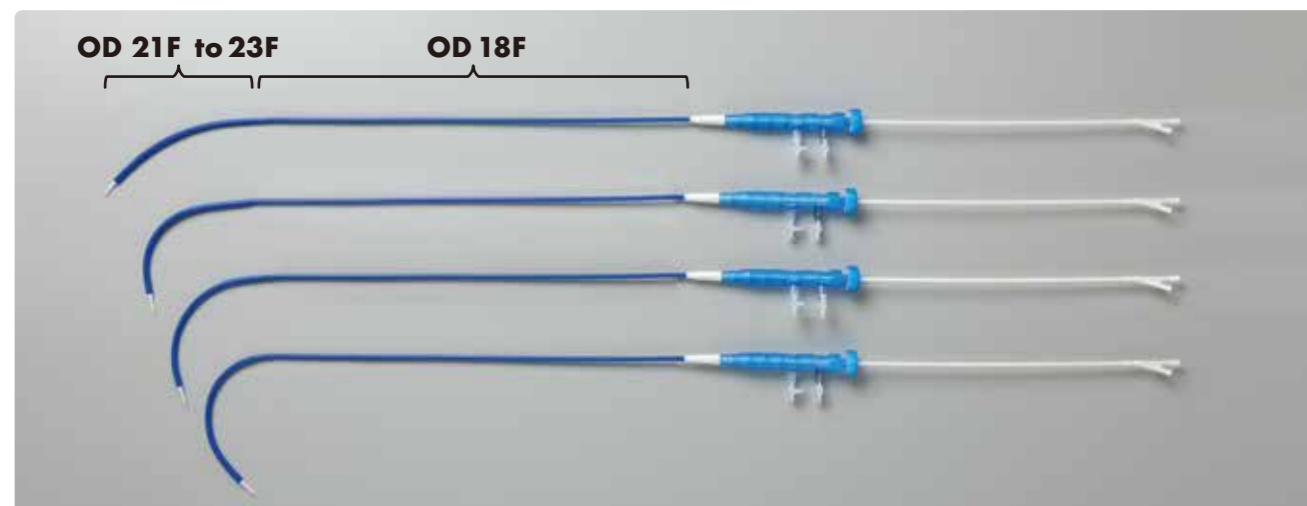
Simulation test

An endograft is assembled and deployed into 3D-printed vessel model prior to production of actual device. Device configuration and fenestration positions are adjusted dependent on the result.



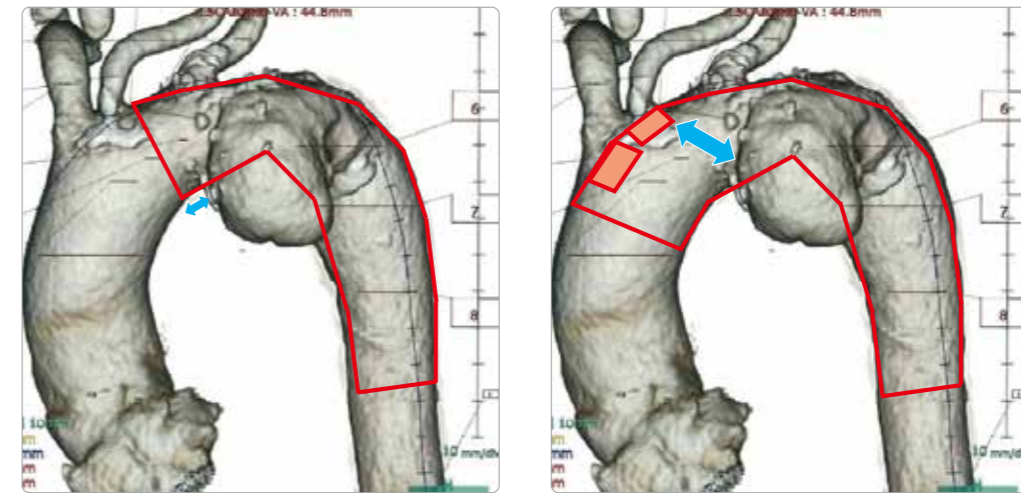
Low-profile sheath

Diameter of delivery sheath is 21F to 23F at proximal part where device is loaded, distal part is 18F.



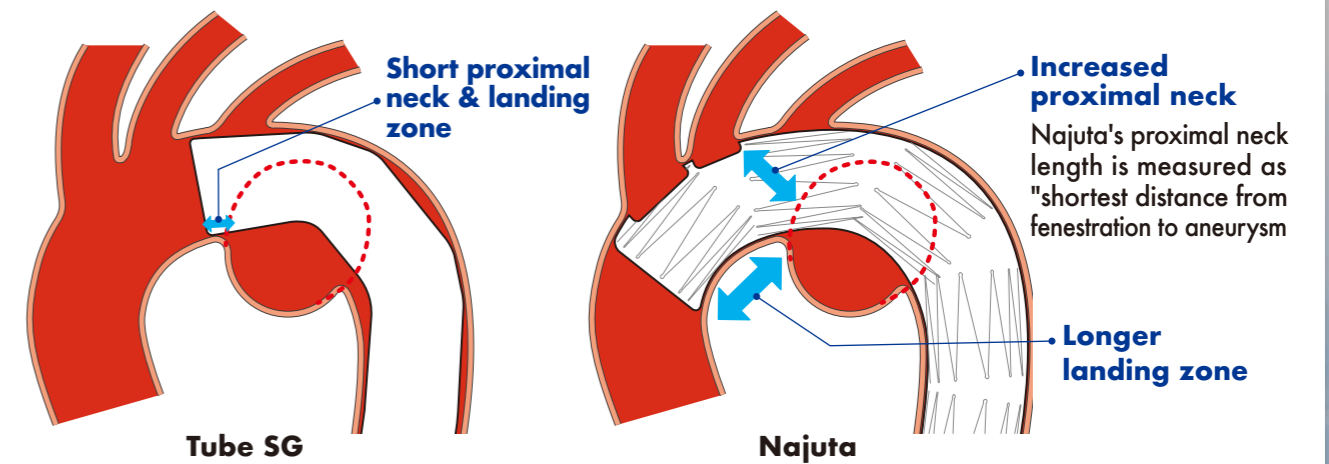
Advantage of Najuta Stent Graft

Najuta is effective for the lesion at lesser curvature of aortic arch where TEVAR is occasionally not able to be performed with general tube-type stent graft due to short proximal neck. On the other hands, such aneurysm is able to be treated with Najuta due to longer landing zone and increased proximal neck length thanks to fenestration.



Tube SG

Fenestrated SG



Tube SG

Najuta

Clinical experience

The proximal neck length of the past twenty-nine arch TEVAR cases performed with Najuta at Kurume University hospital were retrospectively reviewed. If common thoracic stent graft had been used for these cases, the average of proximal neck length would be calculated to be 16.8 ± 6.5 mm. However, for Najuta Stent Graft it is actually 24.9 ± 6.7 mm. These data show that Najuta is able to significantly increase proximal sealing neck length compared to other devices.

[Table 1. Comparison of proximal neck length]

	Tube SG	Najuta	P
Length (mm)	16.8 ± 6.5	24.9 ± 6.7	<.0001
(range)	(5.9 - 31.5)	(14.3 - 43.7)	
> 20 mm Cases, N(%)	10 (37%)	20 (83%)	0.0006
< 15 mm Cases, N(%)	13 (48%)	1 (4%)	0.0002