FOR AORTA

FROZENIX

manufactured in Japan

JL Japan Lifeline
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.
Features of FROZENIX

Advanced Delivery System

**Guide Wire Lumen**
Guide wire lumen added for safer and 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

**Tip with increased flexibility**
Easily conforms to shape of aorta because of the increased flexibility of tip

**Marker**
Marker on non-stented [graft] section, scaled at every 1 cm for more precise stent positioning

**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
Case Example

Acute Type A Dissection

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

\textsuperscript{1} Naoichi Uehida, Department of Cardiovascular Surgery, Akane-foundation Tsukuiya 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)

- Cover
- Grip length 135mm
- Total length 570mm

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.

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

Note: Catalogue numbers are subject to countries.