Instructions for Use

Danis Procedure Pack - BASIC

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Danis Procedure Pack contents: Medical devices and accessories

Medical devices:
- 1 piece of SX-ELLA Stent Danis (model 08S) compressed inside the delivery system, trade name Danis Stent (CE 1014)

<table>
<thead>
<tr>
<th>Model</th>
<th>Nominal (relaxed) diameter of the stent body [mm]</th>
<th>Nominal (relaxed) diameter of both throats [mm]</th>
<th>Nominal (relaxed) length of the stent [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>08S</td>
<td>25</td>
<td>30</td>
<td>135</td>
</tr>
</tbody>
</table>

Material Composition of the Stent

*Nitinol* – wire the stent is made of
*Special medical grade alloy* – retrieval loops tying up the stent throats
*Au* – one tube (marker) placed on both retrieval loops
*Pt/Ir* – one Pt/Ir marker placed in the middle of the stent
*Silicone* – the foil covering the stent body

- 1 piece of the delivery system with preloaded SX-ELLA Stent Danis (model 08S)

Sheath (delivery system) dimensions:

<table>
<thead>
<tr>
<th>Sheath</th>
<th>Outer diameter [mm] ([F])</th>
<th>Active length [cm]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9.4 mm / 6.6 mm (28 F) / (20 F)</td>
<td>60</td>
</tr>
</tbody>
</table>

Balloon catheter dimensions:

<table>
<thead>
<tr>
<th>Balloon</th>
<th>Nominal diameter of inflated balloon [cm]</th>
<th>Nominal length of inflated balloon [mm]</th>
<th>Nominal volume of the air to be inflated [ml]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloon</td>
<td>6.0 – 7.0 (max.)</td>
<td>50</td>
<td>Maximum 180</td>
</tr>
</tbody>
</table>

The wire lumen of the delivery system fits the 0.89-mm (0.035”) guide wire.

- 1 piece of plastic syringe 50 ml, CE 0434

Accessories:
- 1 piece of guide wire, Ultra Stiff with soft tip, length 260 cm, diameter 0.89-mm (0.035”)
- 1 piece of Instructions for Use
- 1 piece of unfixed product (delivery system with compressed stent) label (to be inserted into the patient’s medical record)
- 1 piece of patient’s card

Storage:
The whole Danis Procedure Pack shall be stored in a dust-free, dry and dark place at room temperature.

Precautions:
The whole Danis Procedure Pack is intended for single use only. The stent in the delivery system, the guide wire, and plastic syringe are supplied sterile. Do not re-sterilize them. Use only an undamaged and unopened package.
Do not use a device that is suspected to be damaged. The device must be used before the expiry date printed on the product label.

Warnings:
• The physician implanting the stent shall be skilled and trained appropriately.
• SX-ELLA Stent Danis must be withdrawn within seven days from the date of implantation due to the risk of in-growth of esophageal mucosa into the stent mesh and formation of decubital necrosis followed by fistula (esophagorespiratory or esophagoaortic).
• If the stent does not stop the bleeding, re-evaluate the conditions and remove stent at least after 48 hours. Therapy of the bleeding shall continue.
• After TIPS implantation SX – ELLA Stent Danis should be removed in one-step procedure.
• Treatment of the bleeding and its consequences shall continue after the stent implantation (e.g. monitoring of the patient, search for another source of bleeding, administration of vasoactive medicaments, fluids and blood substitution etc.).
• Protect yourself from infection transmitted by blood, especially viruses of hepatitis B, C as well as HIV by wearing the gloves.
• Used, contaminated parts of the set produce a biological hazard. They must be eliminated in accordance with approved practice and legal regulations.
• The stent shall be introduced by using exclusively an ultra stiff guide wire with soft tip (wire added in the Danis Procedure Pack).
• The guide wire shall not be introduced without either skiascopic or endoscopic control.
• After its full expansion to the nominal (relaxed) diameter, the stent shortens (see Table No. 1).
• If the indication balloon starts to get inflated during the fixing (gastric) balloon inflation, immediately stop inflating.
• If the distal part of the delivery system is wrongly positioned, the indication balloon gets inflated. Carefully remove the delivery system by the manner recommended in Instructions for Use. It is not possible to use the delivery system again because of partially released aboral part of the stent from the sheath. It is not possible to compress the partially deployed part of the stent into the sheath without the whole system’s loss of proper function. A new delivery system has to be used.
• Should the patient need to be ventilated, after the implantation of the esophageal stent, (e.g. during surgery or due to the hepatic failure or prolonged hemorrhagic shock), it is necessary to check the position of the tracheal tubus in relation to the stent immediately after the trachea intubation, by means of Chest X-ray or computer tomography (CT-scan). In case of level collision of the tracheal tubus or its cuff with the esophageal stent, the position of the tubus has to be adjusted. The distal end of the tracheal tubus must not overlap the proximal end of the esophageal stent in order to avoid creation of the decubitus ulcer of both organs or fistula between esophagus and trachea and/or into the mediastinum. The stent is seldom to be extracted prematurely.
• It is recommended to perform chest x-ray examination within 2 hours and endoscopic examination within 48 hours.
• Perform endoscopic check up of correct stent position in the esophagus.
• Do not use for person younger than 16 year and/or weight less than 45 kg. The height of the patient should be 140 - 210 cm.

Indications:
SX-ELLA Stent Danis (see scheme No. 1) is intended for stopping the acute bleeding from esophageal varices. The stent implantation may be an option in refractory esophageal variceal bleeding as an alternative method to the early TIPS or the balloon tamponade.

Contraindications:
Diagnosed malignancy or stricture affecting the esophagus, case history of irradiation therapy of the chest or the esophagus. Malignancy of the throat or larynx, bronchial cancer or fistula. Stomach malignancy. Suspicion of bleeding due to foreign body injuring the upper GIT.

Recommended implantation procedure:
Perform a standard gastroscopic examination.
Instructions for Use

I. Preparation of the delivery system (see scheme No. 2)
- Open the carton box up and remove the delivery system packed in see-through, heat sealed, package sleeve. Check the integrity of the sleeve. The damage of the sleeve might violate the sterility of the delivery system and the stent. Do not use the device in such a case. Use another product set or method of stopping the variceal bleeding. Only if there is no other option, use non-sterile product in order to avoid the acute danger of exsanguination.
- Check the delivery system through the transparent package sleeve for a mechanical damage.

II. Positioning of the patient
Recommended position of the patient is stabilized left side position. Sitting position is an alternative.

III. Introduce the delivery system (see figure No. 1)
Introduce an ultra stiff guide wire into stomach under endoscopic control. Open the sleeve containing the delivery system with compressed stent and remove it. Apply a lubricant-anesthetic gel on the ball-tip and distal part of the sheath. The lubricant-anesthetic gel is not provided with the product set.
Tilt the patient’s head forward (chin to chest) and insert the delivery system through the plastic mouthpiece into the mouth, throat and further into the stomach until the protecting plate touches the mouthpiece. The protecting plate should be locked and touching the blue handle of the sheath. The sheath of the delivery system is provided with scale markers (see the scheme No. 2) that facilitate checking of the position of the inserted delivery system.

IV. Fixing the delivery system in the stomach (see figure No. 2a and No. 2b)
Remove the blue lock. Push the balloon out of the sheath by pushing the Y-connector handle towards the sheath handle until the white lock reaches the sheath handle.
Remove the 50-ml syringe out of the product package and screw it on the balloon port of the Y-connector (slanting arm of the Y-connector). Inflate maximum 180 ml of the air into the balloon (inflation performed three times). This volume should ensure dilation of the balloon to the nominal diameter of 6.0 – 7.0 cm. Such a diameter should prevent an unintended movement of the delivery system out of the stomach. The automatic closing valve prevents deflation of the balloon. In case the indication balloon starts to get inflated, stop immediately the inflation, deflate the air from fixation gastric balloon and check the position of the delivery system.

Pull back the whole delivery system until you feel a resistance which means that the balloon docked the cardia, distal outlet of the esophagus. Unlock (Scheme No. 2) and move the yellow protecting plate along the sheath until it touches the mouthpiece. Stabilize an appropriate position of the balloon and, consequently the whole delivery system, by contacting the protecting plate with the mouthpiece ring, and lock it again there (Scheme No. 2).

V. Stent deployment (see figure No. 3)
Remove white lock from the delivery system. Keep the Y-connector (handle of the pusher) in a stable towards the patient fixed position. Pull back the sheath handle with one your hand until it touches the Y-connector which means that the stent is fully deployed. Contemporary, the position of the pusher must be stabilized by the other hand keeping the pusher gently in its position. The fixation (gastric) balloon should touch the cardia during deployment of the stent. After stent releasing wait for about one minute until the stent completely expands.

VI. Remove the delivery system (see figure No. 4a and No. 4b)
Unscrew the balloon valve and remove it from the balloon port of the Y-connector. Wait until the balloon gets empty (about 30 seconds). Carefully remove the delivery system by pulling it back.

If you feel a resistance, suck the rest of the air from the fixation (gastric) balloon which is described below and shown in scheme no. 3.
- Unscrew the syringe from the balloon port of the delivery system
- Unscrew the balloon valve
- Insert the syringe with its piston into a balloon port’s lower position (without using a balloon valve) and suck the rest of air from the fixation (gastric) balloon

Then continue gentle removing of the delivery system.
Remove the guide wire.
VII. Monitoring and treatment of the patient
Resuscitation and intensive therapy has to be performed during the transport of the patient to an emergency care unit. Monitoring of the circulation, substitution of circulating volume and blood (saline, plasma expanders), application of vasoactive medicaments (somatostatin and vasopressin derivates) and, if needed, blood products should follow.

VIII. Stent removal
The stent shall be removed within the period of 7 days after the implantation. The stent has to be removed - using the special stent extractor which is delivered by ELLA – CS Company and appropriate endoscopic equipment (gastroscope, etc.). Grasp and pull the pursing string at the proximal end of the stent. Pull the stent gently during its removal. See also instruction for use of the ELLA Extractor.

Complications:
- **Persistent bleeding**
  Symptoms: Hematemesis, circulatory shock.
  Diagnostic procedures: Endoscopy, search for another source of bleeding than burst esophageal varices.
  Treatment: Stopping of the other sources of bleeding by using endoscopic or surgical methods.
- **Perforation of the pharynx, the esophagus and/or the stomach**
  Prevention: All maneuvers (pushing, pulling) should be conducted slowly and gently.
  Symptoms: Chest or stomach pain, signs of peritonitis, subcutaneous emphysema.
  Diagnostic procedures: CT by using water soluble contrast.
  Therapy: Endoscopic intervention or surgery.
- **Stent dislocation / migration into the stomach**
  Symptoms: Persisting or repeated acute bleeding
  Treatment: Gastroscopy and stent reposition into the esophagus by catching the pursing string and gentle pulling the stent into the esophagus.
- **Balloon malfunction**
  a) **Balloon can not be inflated sufficiently** (burst of the positioning balloon, burst of the indicating balloon, their disconnection from inflation lumen etc.)
  Signs: No matter that you follow the instruction as described under the point IV (pulling the sheath back until feeling the resistance which means that the balloon reached the cardia), you do not feel any resistance. By continuing the pulling, you remove the delivery system easily.
  Treatment: Use another set.
  b) **Deflation of the balloon is impossible** (e.g. occluded balloon lumen)
  Signs: After the stent is deployed, the set cannot be removed. Persistent resistance when trying to remove the delivery system.
  Treatment: Transport of the patient to the emergency unit with the inserted delivery system. The balloon may be punctured by means of the endoscopic needle during gastroscopy.
Scheme No. 1: Design of SX-ELLA Stent Danis
Scheme No. 2: Design of the delivery system of SX-ELLA Stent Danis
Instructions for Use

Scheme No. 3: Releasing the air out of the balloons

Table No. 1: Shortening chart of SX-ELLA Stent Danis (model 08S)

<table>
<thead>
<tr>
<th>Stent diameter [mm]</th>
<th>Stent length [mm]</th>
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<td>25</td>
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<td>24</td>
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