STENT FOR SALIVARY DUCTS

Type 1 and Type 2

Contain: X-Ray View

The proximal part is funnel-shaped in order to prevent obstruction of the salivary ducts during the final stages of healing. Removal with almost no damage to the salivary ducts. Maximum comfort for the patient: The presence of the stent is barely felt. May be left in the salivary duct up to 28 days!!! Specially designed holes at the edge of the funnel for suturing. The blunt obturator is made of stainless steel and may be used as a dilator.

Instructions for use of Stent for Salivary Ducts

1. Open the package of the Stent for Salivary Ducts under sterile conditions.
2. Hold the Stent for Salivary Ducts with the introducer and put the entrance of the stent into the orifice of the salivary duct.
3. Hold the duct with a-traumatic forceps and pull the duct slowly over the stent.
4. Push the Stent for Salivary Ducts gently inside the duct up to the funnel.
5. Suture with 2/0 thread the Stent for Salivary Ducts in the 2 holes that are for this purpose. (The holes, small in size, surround the head of the funnel).

<table>
<thead>
<tr>
<th>Ref. number</th>
<th>Stent size</th>
<th>Stent length [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>DP4.5F40T1</td>
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<tr>
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<td>DP9F20T1</td>
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STENT FOR SALIVARY DUCTS
Type 1 and Type 2

WARNING: THE STENT FOR SALIVARY DUCTS IS TEMPORARY AND MUST BE TAKEN OUT WITHIN 28 DAYS.
Clinical experience shows average healing time is 2-3 weeks.

Removal of Device:

1. Remove the stitches
2. Pull of the stent anti clockwise with fine hemostat.

As the device is placed inside the duct and not inside the tissue, removal of the device is straight forward. The maximum period of the stent to be left is 28 days only. During this period some blood clotting or mucous plaque may surround the stent, but this does not cause problems when removing the stent. In case the device is lost inside the body, x-ray imaging is recommended as the device can be imaged by x-ray to locate the device in order to recover it. The flaps of the device are soft and do not cause damage to the surround tissue.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed physician or dentist
Stensen's duct (Parotid) lacerations occur most often during facial trauma especially from sharp instruments. The treatment of such lacerations of the duct involves identification of the distal and proximal parts. Following the identification there is a need for insertion of a miniature tube before suturing the duct.

In the past many types of catheter drains were used. The Stent for Salivary Ducts is a specially designed drain/tube/stent which fits to the diameter of the Parotid duct. It enables the user to insert the stent both from the laceration region and through the Stensen’s duct orifice. Due to the soft nature of this stent and its flexibility it is easy to use and the patient does not suffer from the rigidity of other types of drains/catheters.

Another advantage of the Stent for Salivary Ducts is the possibility to use it in minimal invasive procedures involving opening of the Parotid duct, especially for the removal of stones through the external insertion.

**Type 3**

<table>
<thead>
<tr>
<th>Ref. number</th>
<th>Stent size</th>
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</tr>
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</table>

**Manual instructions for use of Stent for Salivary Ducts**

1. Open the package of the Stent for Salivary Ducts under sterile conditions.
2. Important: The Stent for Salivary Ducts can be used both extra oral and intra oral. In the case that the duct is damaged or lacerated the Stent for Salivary Ducts can be extra oral and intra oral together.

**How to place the Stent for Salivary Ducts intra orally (via the mouth)**

A. Locate the orifice of the salivary duct.
B. Make a 2 mm dilatation of the duct.
C. Place and push the Stent for Salivary Ducts to a depth of 1 cm with a help of the introducer.
D. Pull the salivary duct with a-traumatic forceps and continue to push the Stent for Salivary Ducts to the required place.
E. Once you have placed the Stent for Salivary Ducts check both physically and with x-ray that the Stent for Salivary Ducts is stable. If there are kinks, simply pull from both sides until it is straight.
F. Cut off the rest of the Stent for Salivary Ducts that is not needed.

**How to place the Stent for Salivary Ducts extra orally (from the cheek)**

A. Locate the orifice of the salivary duct.
B. Make a 2 mm dilatation of the duct.
C. Push the Stent for Salivary Ducts with a help of the introducer to the required place.
D. Once you have placed the Stent for Salivary Ducts check both physically and with x-ray that the Stent for Salivary Ducts is stable. If there are kinks, simply pull from both sides until it is straight.
E. Cut off the rest of the Stent for Salivary Ducts that is not needed.
How to place the Stent for Salivary Ducts both extra orally and intra orally in the case of damaged/torn duct

A. Locate the ori/fice of the salivary duct.
B. Make a 2 mm dilatation of the duct from both sides and cut off the funnel.
C. Place and push the Stent for Salivary Ducts to a depth of 1 cm with a help of the introducer.
D. Start to introduce the Stent for Salivary Ducts on the other side.
E. Once you have placed the Stent for Salivary Ducts check both physically and with x-ray that the Stent for Salivary Ducts is stable. If there are kinks, simply pull from both sides until it is straight. Suture the duct were the damage/tear is.
F. Cut off the rest of the Stent for Salivary Ducts that is not needed.

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Clinical experience shows average healing time is 2-3 weeks.

Removal of Device:

1. Remove the stitches
2. Pull of the stent anti clockwise with fine hemostat.

As the device is placed inside the duct and not inside the tissue, removal of the device is straight forward. The maximum period of the stent to be left is 28 days only. During this period some blood clotting or mucous plaque may surround the stent, but this does not cause problems when removing the stent. In case the device is lost inside the body, x-ray imaging is recommended as the device can be imaged by x-ray to locate the device in order to recover it. The flaps of the device are soft and do not cause damage to the surround tissue.

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Manufactured by BALTON® exclusively for AD-TECH-MED Ltd.
DILATATION CATHETER FOR SALIVARY DUCTS
with High Pressure Balloon

Emphasis is on the balloon’s pushability, in contrast to the other balloons, where emphasis is on flexibility.

Available with high pressure up to 25 atm.

Available in six balloon lengths, 10 mm, 20 mm, 30 mm, 40 mm, 50 mm and 60 mm.

The balloon is inserted into the working channel.

**High Pressure Balloon**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Nominal balloon diameter (mm)</th>
<th>Nominal balloon length (mm)</th>
<th>Catheter length (mm)</th>
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<tbody>
<tr>
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<td>Sialo Dilatation Balloon - High Pressure 25 bar 10 mm Balloon, 25 cm</td>
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<td>Sialo Dilatation Balloon - High Pressure 25 bar 20 mm Balloon, 25 cm</td>
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<td>HPB4X3025</td>
<td>Sialo Dilatation Balloon - High Pressure 25 bar 30 mm Balloon, 25 cm</td>
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<tr>
<td>HPB4X4025</td>
<td>Sialo Dilatation Balloon - High Pressure 25 bar 40 mm Balloon, 25 cm</td>
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<td>HPB4X5025</td>
<td>Sialo Dilatation Balloon - High Pressure 25 bar 50 mm Balloon, 25 cm</td>
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<td>HPB4X6025</td>
<td>Sialo Dilatation Balloon - High Pressure 25 bar 60 mm Balloon, 25 cm</td>
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Instruction for use of High Pressure Balloon

1. Open the package of High Pressure Balloon under sterile conditions.
2. Insert the High Pressure Balloon through the working/biopsy channel of endoscope until you see the proximal end of the balloon.
3. Prepare a syringe with sterile water or saline with a capacity of 3 ml.
4. Start inflating the Balloon with the syringe and pull back the water and continue gradually.
5. Repeat the action until the blockage is cleared or the kinks are straight.
6. Pull back out the endoscope together with the Balloon.
7. Place the Stent for Salivary Ducts for a period of 28 days.

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