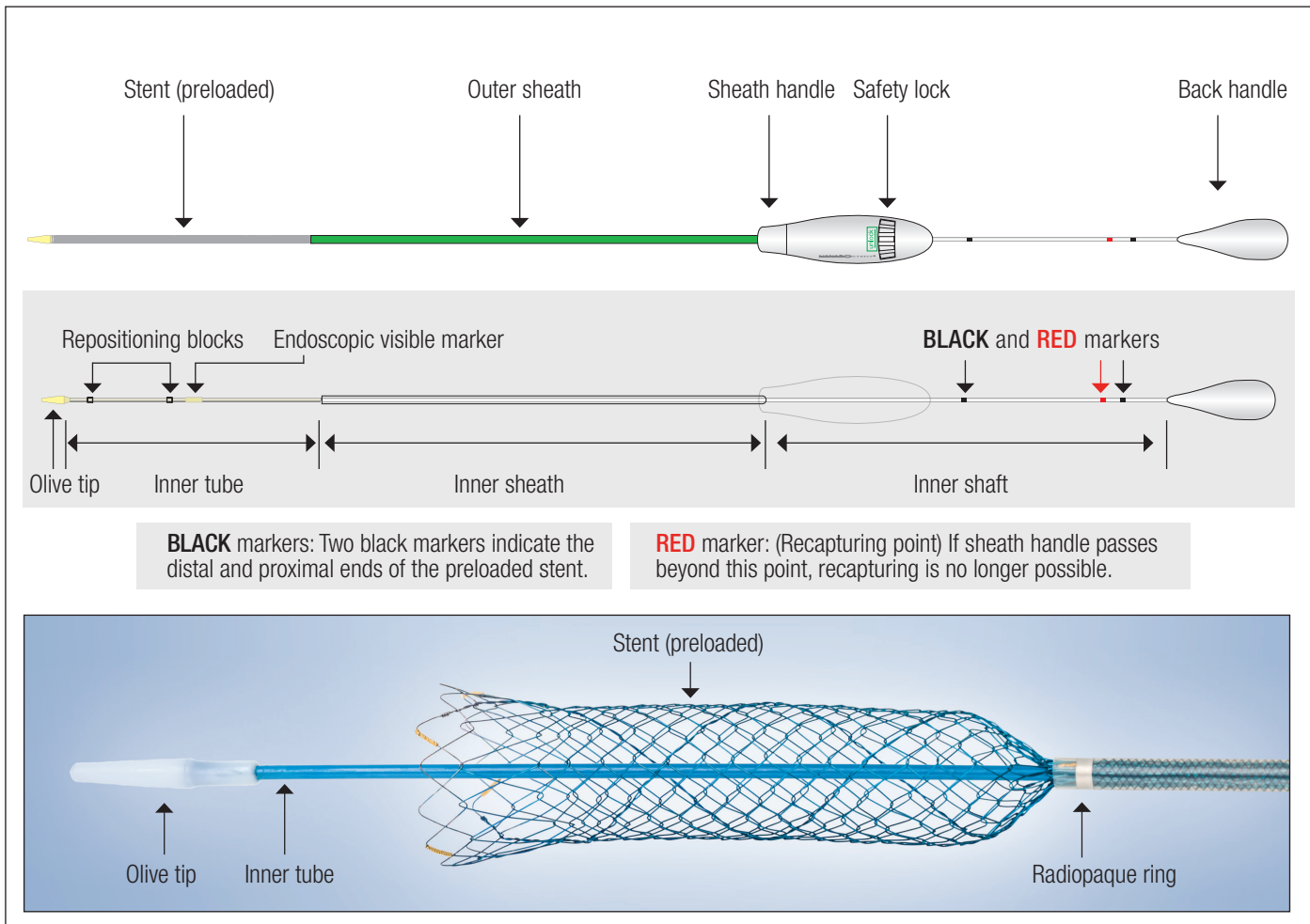


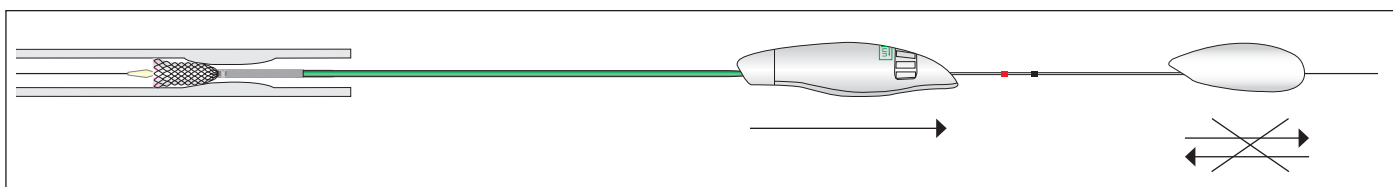
HANAROSTENT[®] Biliary (Uncovered Stent) Quick Reference Guide

CAUTION: This guide is only a summary of the instructions for use of the included device. Be sure to reference the instruction manual included with your product purchase.

Parts and Description



Delivery Overview



Stent releases from the distal end.
The amount stent released corresponds to the distance pulled.

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Stent Selection and Preparation

1. Choose the stent with an optimum diameter and length after measuring the length of the stricture using fluoroscope and/or an endoscope.
2. Choose the stent size which is at least 2cm longer in full length than the actual stricture. This will reduce the risk of tumor overgrowth and stent migration.
3. Make sure the safety lock is firmly locked.
4. Maintain the delivery device as straight as possible outside the body.
5. Prepare an 0.025" or 0.035" guidewire.

Procedure

Pre-Placement: Confirm the length and location of the narrowed area under endoscopy and/or fluoroscopy, and select a stent of suitable size which can cover the length of the stricture.



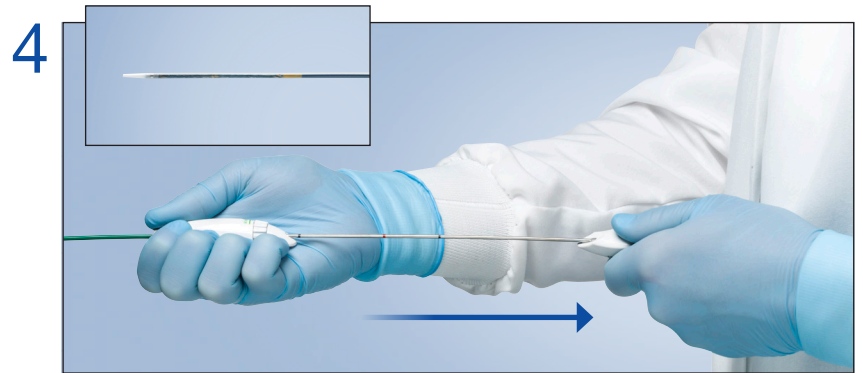
Carefully remove stent from package by the handle portion.



Load delivery device over 0.025" or 0.035" guidewire. For smooth insertion, it is recommended to pre-flush the catheter by utilizing the luer lock at the end of the delivery device.



Once the device is inserted and positioned across the target narrowed area, unlock the safety lock by twisting the knob counterclockwise.



Immobilize the inner shaft by firmly holding the back handle with one hand and then slowly pull the front handle (outer sheath) backwards until the stent is extruded.

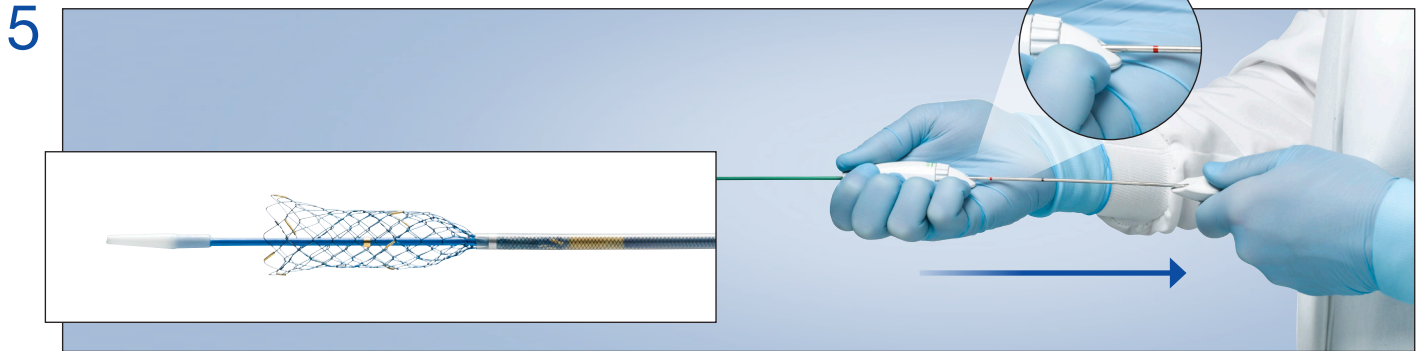


CAUTION: Do not push or pull the back handle while deploying the stent. This could cause misalignment of the stent and possible damage to the bile duct.

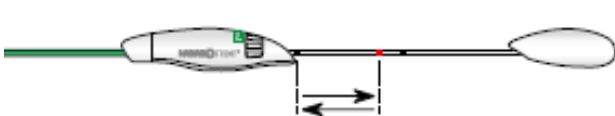
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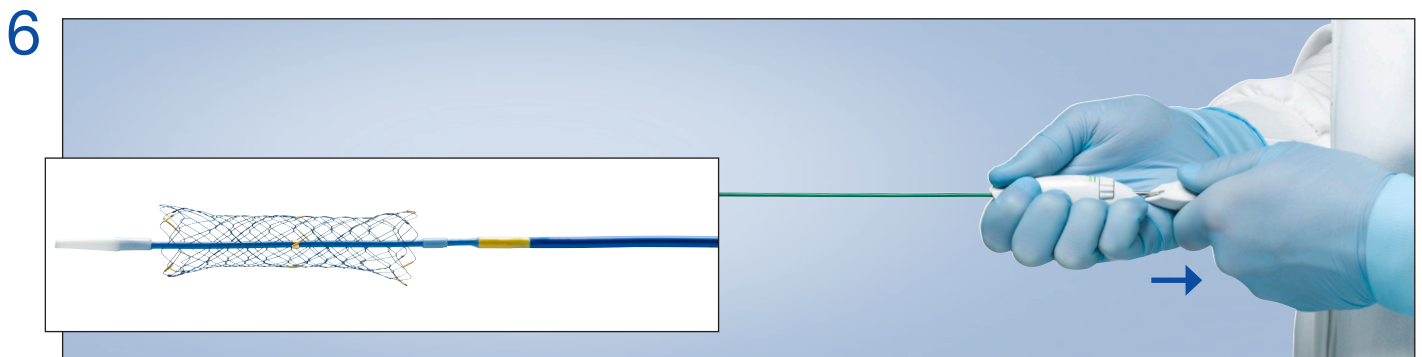
Procedure



Slowly deploy the stent to ensure desired positioning. If the physician has the need to recapture the stent, simply push the front handle forward (outer sheath).
NOTE: the stent cannot be recaptured once the handle is pulled beyond the **RED** marker on the inner shaft (the red marker indicates the point of no return).



CAUTION: Repetitive recapturing of the stent could cause unintended damage to the stent.



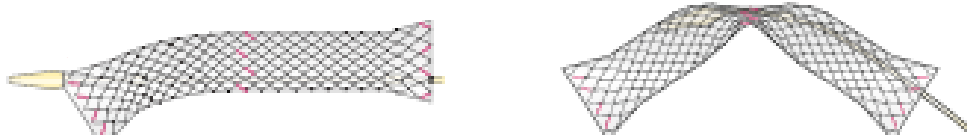
To fully deploy the stent, pull the front handle all the way back to where it meets the back handle.

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Procedure

- 7 Remove the delivery device after the stent is fully deployed.



CAUTION: If the olive tip gets caught in the distal part of the stent, or inside the stent lumen due to the tight stricture, wait until the stent expands more and/or gently manipulate the outer delivery catheter to rotate the olive tip and release it from the stent.

- 8 Optional: inject a contrast medium by using an ERCP catheter introduced through the endoscope channel, and ensure the correct placement of the stent through fluoroscopy.

NOTE: Post-deployment, the stent may require 24-48 hours to fully expand.

Post-procedure

1. Fluoroscopic or endoscopic examination is recommended immediately after the procedure or on the following day to check for patency of the lumen.
2. Periodic follow-ups are obtained in symptomatic patients, if necessary, to check for stent migration, perforation, or obstruction.
3. Post-deployment, the stent may require 24-48 hours to fully expand. If balloon dilation is necessary, please proceed with caution that dilating tumors may result in perforation, bleeding or stent migration.
4. Long-term patency of this device has not been established. Subsequent follow-up is required after the stent placement to make sure that the stent maintains the original position and shape. Periodic follow-up depends on the condition and the behavior of the patient, but it is recommended to be performed 1 week post-procedure, and in 3 month intervals following.
5. If stent rupture or migration is suspected or detected during follow-up, either fluoroscopic or endoscopic examination is required. Depending on the physician's decision, a new stent or stent-in-stent placement may be considered.
6. After stent placement, chemotherapy and radiation are not recommended, as this may increase risk of stent migration due to tumor shrinkage, and/or mucosal bleeding.

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