

## New freedom from occlusion

### Double-stenting with the New Zilver<sup>®</sup> 635 Biliary Stent

A patient with cancer of the esophagus underwent chemotherapy in 2007. By January 2009, the patient exhibited jaundice, and a CT scan revealed a metastatic mass in the bile duct.

"The patient was generally in good condition," recalls Douglas A. Howell, M.D., FASGE, Director of the Pancreaticobiliary Center at the Maine Digestive Disease Center in Portland. "We performed an ERCP and found that the bifurcated duct had an obstruction with long strictures. We placed two 8-mm diameter self-expanding metal stents (SEMS). Fortunately, because we had available the new 6 French biliary introduction system called the Zilver<sup>®</sup> 635, we were able to align both stents precisely and successfully.

"Follow-up of the patient showed no complications and the patient was jaundice-free within a month."

#### Cutting-edge technology

Cutting-edge technology is the norm rather than the exception at the Maine Pancreaticobiliary Center. In an environment that fosters collaboration among gastroenterologists, surgeons,

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## NEW FREEDOM FROM OCCLUSION

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anesthesiologists, radiologists and pathologists, the Center has created a single infrastructure to coordinate services, improve access and optimize outcomes for patients. Physicians at the internationally recognized medical facility have vast experience treating patients with complex benign and malignant diseases of the pancreas and biliary tree.

Dr. Howell details how his endoscopy team used the Zilver 635 to treat the 56-year-old for metastatic cancer obstructing the bifurcation:

"When we had to negotiate difficult strictures through the ducts, we knew that the flexible 6 French catheter could press through without dilation."

### A double-barreled stent approach

The new Zilver 635 stent, Dr. Howell explains, opened up the possibility for an important new method of inserting two SEMS at the bifurcation of the biliary tree.

"In the past, some stent procedures were unsuccessful in draining both sides. The first stent often got in the way of the second stent. Using a 6 French introduction system, we can now introduce two SEMS at the same time. Once we position the first stent, we position the second stent and then deploy both simultaneously."

### A procedure summary

An anesthesiologist, a fourth year fellow, an endoscopy nurse and a technician joined Dr. Howell in the procedure room.

Work began with imaging to show the bifurcation of the bile duct as well as the tumor. With the patient under anesthesia, the team performed an ERCP and achieved cannulation with a wire guide. Then the wire and an extraction balloon were placed in the right hepatic duct. The balloon was taken to the level of bifurcation and was inflated filling the left duct. Then the team inserted a second wire guide, and manipulated it into the left hepatic duct.

The fluoroscopic view confirmed that the two wire guides were in place; two 6 French introducers were then positioned simultaneously in preparation for deployment." In some cases, each stent may be a different length to accommodate bifurcation strictures of varying lengths (for example, using one 60 mm and one 80 mm stent).

The next step was to align the bottom ends of the two stents precisely. Finally, once the stents were deployed, the team withdrew the introduction systems and wire guides and used fluoroscopy to confirm that the stents were in alignment.

### The global implications for the Zilver 6 FR system

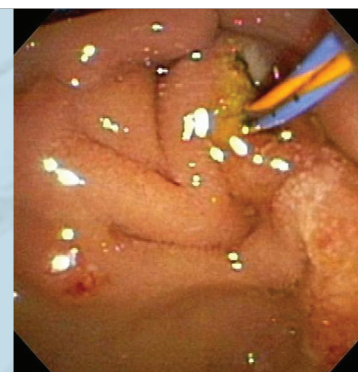
Obstruction by malignancy involving the bifurcation is the most common cause of obstructive jaundice world wide. Previous attempts at complete drainage have been complicated by failure resulting in cholangitis in many cases. This new introducing system insures success, results in improved drainage and should greatly reduce cholangitis. Finally, up to 40% of patients will require a follow-up ERCP for occlusion and this system insures future access better than all prior techniques and equipment.

### Looking to the future

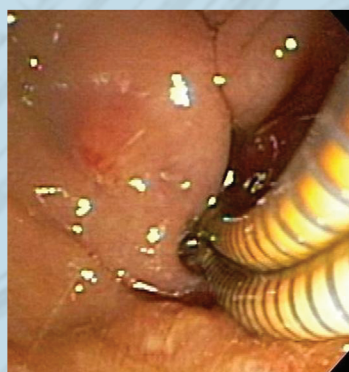
"Zilver is superior in all aspects of malignant stenting, especially for bifurcation malignancies," concludes Dr. Howell. "Because when we cannot treat jaundiced patients with chemotherapy, endoscopic stent placement using SEMS is the treatment of choice – possibly in all patients. The patency rate is twice that of a plastic stent."



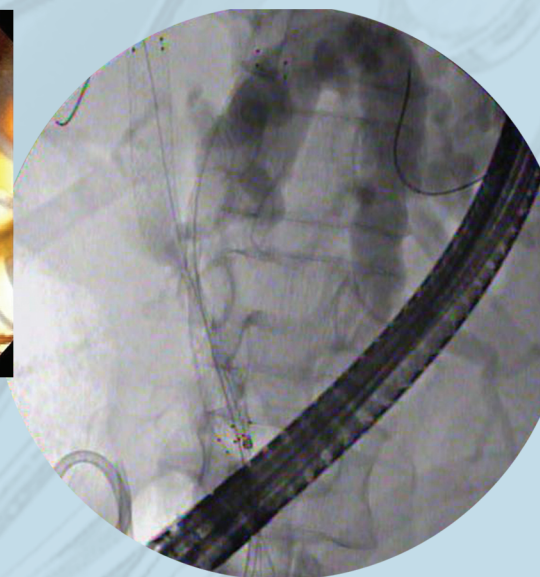
Wire guide has been placed through the bifurcation stricture into the left hepatic duct.



The second wire guide is now in position ready for the double stent placement.



Two 6 French introducers are now in simultaneous position in preparation for deployment.



The two 10 mm Zilver stents are in good position with their bottoms aligned for possible future access.

### Dr. Howell's observations about the Zilver 635 Biliary Self-Expanding Metal Stent

- Because of the gold markers at each end of the stent, it is highly visible under fluoroscopy.
- When placing stents in both ducts, outcomes to date have been superior to single stents.
- This is the first specialty device on the market that effectively addresses the problem of stenting two ducts simultaneously.
- The procedure will lead to a significant change worldwide in stenting bile ducts.
- Bifurcation stenting remains challenging and controversial.
- More controlled studies are needed.