THE CHANNEL

A COOK NEWS PUBLICATION

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INSIDE THIS ISSUE

FUSION
FROM THE GROUND UP

Wilson-Cook pioneered the tradition of partnering with physicians to develop new products. Instead of a "you will use what we make" philosophy, Wilson-Cook, often in spite of market pressures, listened to physicians and is well known for its "we will make what you need" philosophy.

Perhaps there is no better example of just how powerful a force that partnership between physicians and device manufacturers is than with the development of Wilson-Cook's new Fusion line of ERCP products.

Fusion launch at DDW 2004

Over the years, new technologies appeared that attempted to streamline procedures by giving the physician more control of the wire guide throughout an ERCP procedure. Wilson-Cook's aim was to streamline procedures even more.

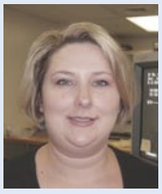
A major breakthrough occurred in the spring of 2003, when several Wilson-Cook employees met with Dr. Stephen Deal (Carolina Medical Center, Charlotte, North Carolina). The team was investigating possible ways to streamline ERCP devices and procedures. During one of the work sessions, Dr. Deal asked the prophetic question: "What if, instead of exchanging catheters on the outside of the body in the procedure room, we do it inside the body within the ductal system?"

FUSION *Continued on page 5*

COOK® Wilson-Cook Medical
GI Endoscopy

CHOLEDOCOLITHIASIS DURING PREGNANCY: A FUSION CASE

By Melissa H. Clark, RN, BSN



Shortly after Fusion was released, Carolina's Medical Center would present its first challenge for the new Wilson-Cook Medical biliary equipment. A female patient presented to the hospital with complaints of nausea, vomiting, and left upper quadrant pain. To further complicate the case, the patient was pregnant. Dr. Scott Brotze, a physician with Charlotte Gastroenterology and Hepatology, was assigned to the case through the hospital staff services. For Dr. Brotze, this would be his first Endoscopic Retrograde

FUSION CASE *Continued on page 6*

WILSON-COOK ENGINEER WINS DESIGN AWARD

Vihar Surti, a Senior Research Engineer at Wilson-Cook Medical, recently received an Excellence in Design Award from Design News magazine for his work on Wilson-Cook's TriClip Endoscopic Clipping Device.

"In developing the TriClip," Surti says, "we researched the market. All previous endoscopic clipping devices utilized two-pronged clips, and there had been no significant improvements in clipping devices in about ten years."

Surti and team members developed three-pronged clips with the goal of giving the clinician more flexibility in positioning and attaching the clip. But that was only half the battle, says Surti. "The development of an easy-to-use handle presented the biggest design challenge."

Because Wilson-Cook manufactures many devices that require plastic handles, Surti attempted to adapt one of those for use with the TriClip. "Those first prototypes went through a complete series of tests, but they weren't ideal for our purposes," he says.

Surti then created a new design, a 3D "virtual" model, which he

DESIGN AWARD *Continued on page 3*

Welcome TO THE CHANNEL

By Bill Gibbons, President, Wilson-Cook Medical Inc.

We live in an exciting time of innovation and creativity. It is more important than ever to keep up with – and stay ahead of – fast developing trends and technologies.

Unfortunately, the fast pace of technology is often mirrored by the fast pace you experience every day in your practice, making it more and more difficult to find time to keep up with the latest developments in the growing field of gastroenterology.

We at Wilson-Cook Medical understand this and that's why we have created The Channel. The Channel was designed with you – the busy clinician – in mind. Our goal is to accommodate your hectic schedule by providing you with relevant, reliable, and accessible information on the latest trends in GI technology and procedures. In The Channel, you will find the latest news on Wilson-Cook products, everything from innovative developments to the latest clinical procedures that are rapidly changing our field.

Since our company's founding, we've maintained an active commitment to education; The Channel is a natural extension of that commitment. Whether we're introducing you to a new device or to a new procedure, the information contained in The Channel is designed to be clear, concise, dependable, and usable.

And, since the best ideas result from an exchange of ideas, I would personally like to take this opportunity to invite you to become an active participant in the ongoing development of The Channel. I invite you to share interesting and challenging cases, to examine the many stimulating issues that impact our field, and share your experiences with your fellow professionals in our regular clinical column.

In this, the premier issue of The Channel, we are focusing on a new line of biliary accessories that combine the proven results of traditional long-wire ERCP techniques with the powerful new Intra Ductal Exchange (IDE) technology. It's called Fusion™ and it may just redefine the future of endoscopic procedures.

We welcome you to The Channel.

FUSION
A NEW KIND OF ERCP SYSTEM

By Prof. Jacques Deviére, Prof. Guido Costamagna, Prof. Horst Neuhaus

A new system called Fusion (Wilson-Cook Medical Inc., Winston-Salem, NC, USA) for therapeutic endoscopic retrograde cholangiopancreatography (ERCP) was launched at DDW in May 2004. The Fusion system features the revolutionary Intra Ductal Exchange (IDE) technology which can potentially speed wire guide exchange during manipulations in the bile ducts or pancreatic ducts, possibly reducing the duration of the procedure and, thereby, fluoroscopic exposure for patients, nurses, and practitioners.

Prof. Jacques Deviére

Prof. Guido Costamagna

Prof. Horst Neuhaus

The most unique feature of the system is a side port 6 cm from the distal tip of the device catheters. (The only exception is the stent introducer system, which has a side port 2.5 cm from the distal tip.) This design allows more efficient device exchange over the wire guide as well as a disengagement of the wire guide from the device that occurs within the ductal system – an Intra Ductal exchange).

The Wilson Cook 185 cm Ultra Short Wire Guide remains locked in place with the Wilson-Cook Wire Guide Locking Device which clips onto the accessory port of the scope. The short wire (which could potentially limit the risk of contamination) and the locking device combine to provide excellent wire guide control by the physician.

The variety of Fusion devices already available allow the performance of most therapeutic procedures and are designed to be similar to what clinicians have come to expect with the traditional devices. In addition, at any time during a procedure, the Fusion system offers the clinician the option to move from the "short wire" technique (in which the wire is manipulated by the physician) to the "long wire" or "classic" technique (in which the wire is manipulated of a GI assistant).

While the Fusion system seems to offer all the advantages of tradition-

NEW ERCP SYSTEM *Continued on page 7*

DESIGN AWARD

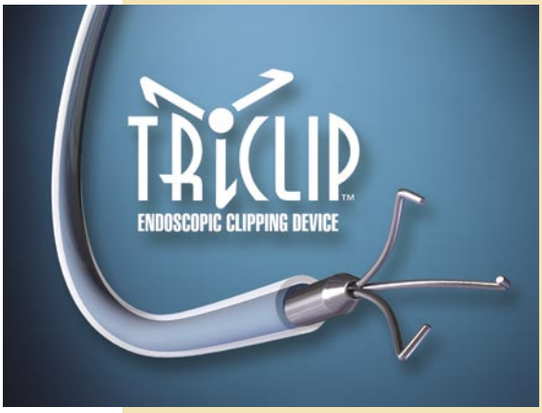
Continued from page 2

examined and "tested" to the extent possible using CAD software. His aim was to make operation of the handle as efficient as possible, enabling the clinician to place a TriClip properly, snap it into position, and then release it from its cable.

Using a rapid-prototyping system, Surti built a model that allowed him examine how things operated and fit together. The refinement of that prototype eventually led to the final TriClip handle design, which was thoroughly tested by clinicians.

The TriClip was successfully launched at DDW 2003 and is rapidly becoming utilized in the field as an innovative solution for hemostasis and endoscopic marking.

Vihar Surti joined Wilson-Cook Medical in 2000, shortly after graduation from North Carolina State University.



INTERESTED IN OUR

NEW

PRODUCTS

Ask your sales rep for CD's, Quick Reference Cards and /or Clinical Clips on products such as Fusion and Triclip. These marketing materials are informative and available upon request!

GI CENTER GETS CONNECTED

WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER

In November 2004, distinguished guest speaker Gregory B. Haber, MD, Director, Division of Gastroenterology, Lenox Hill Hospital, NY, delivered the inaugural Grand Rounds presentation in the new Digestive Health Conference Room at the Wake Forest University Baptist Medical Center (WFUBMC) in Winston-Salem, NC. This new conference room represents the medical center's dedicated emphasis on state-of-the-art clinical education and training. Through contributions from the medical center, its faculty and Wilson-Cook Medical, this conference room was designed to provide direct connection to three procedure rooms (General GI, EUS and ERCP) for training and education. The conference room features live video feed (room view, endoscopic view, EUS view, fluoroscopic view) and clinicians will have the ability to communicate with the conference room in real time as well as to transmit conferences to and from Duke University, the University of North Carolina at Chapel Hill, and the University of North Carolina at Charlotte. This conference room also provides a permanent home for Grand Rounds presentations, such as the one presented by Dr. Haber. Attending this inaugural presentation were Wilson-Cook personnel and WFUBMC physicians/nurses, including Kenneth L. Koch, MD, Gastroenterology Director, Digestive Health Center, who was instrumental in making this initiative a reality.

Dr. Gregory B. Haber

Dr. Kenneth Koch

The New Digestive Health Conference Room at the Wake Forest University Baptist Medical Center (WFUBMC) in Winston-Salem, NC, USA.

FUSION *Continued from page 1*

At that moment the concept of Intra Ductal Exchange was born and the team began experimenting with putting a wire guide port as close as possible to the distal end of device catheters to facilitate wire guide exchanges within the ductal system.

From the beginning, Wilson-Cook was determined merge the traditional long wire option into the products, making them completely compatible with all existing devices and accessories. The company set out to build the Fusion system, giving it three distinct device-exchange options: 1) Stay over the wire (traditional long-wire method), 2) slide up and down the wire and "zip" exchange at the working channel port, or 3) separate the device from the wire guide within the ductal system and simply pull the catheter out (Intra Ductal Exchange).

Dr. Stephen Deal

That mission was made more daunting by the company's goal to produce an entire line of Intra Ductal Exchange devices by the 2004 DDW exposition. That effort entailed the challenges of testing logistics, regulatory filings, and having production up and running smoothly – all in less than one year.

"What if, instead of exchanging catheters on the outside of the body in the procedure room, we do it inside the body within the ductal system?"

Teams were formed throughout the entire company and experts in the field were brought on board. After months of experimentation and testing, the system was refined and it was time for the ultimate test: using the Intra Ductal Exchange devices in human cases.

On the same day on two separate continents, two procedure teams began the first Intra Ductal Exchange cases in history. Project leaders waited by the phones in Winston-Salem, monitoring what was happening in two different time zones: in Belgium and Costa Rica. Reports came in first from the team headed by Professor Jacques Devieré (Hôpital Erasme, Brussels, Belgium). The news was good: the new devices performed as predicted. It was an exhilarating success.

Next, attention turned to Costa Rica and the team of Dr. Herbert Burgos (Gastro Clinica, San Jose, Costa Rica), Dr. Deal, and Melissa Clark, RN, BSN (Carolina Medical Center, Charlotte, North Carolina). As the wire guide descended to the Intra Ductal Exchange port, it slipped out of the catheter and remained in the duct and the catheter was easily removed from the endoscope – the success experienced in Belgium was duplicated and confirmed.

The world of endoscopy changed on that day. Fusing traditional long-wire ERCP techniques with the revolutionary Intra Ductal Exchange (IDE) technology has given clinicians everywhere new and exciting procedural options, and may well redefine the future of all endoscopic procedures.

Educational PROGRAMS

Wilson-Cook Medical has long understood that optimal patient care is your focus, and it continues to be our focus as well. That's why for more than twenty years we have assisted healthcare professionals in learning the latest in endoscopic GI technology and related disease information.

That tradition continues in the first quarter of 2005. Wilson-Cook, in partnership with HealthStream (an accredited provider of continuing nursing education), will offer three new courses: "Endoscopic Polypectomy," "Malignant Biliary Disease," and "Options for Enteral Feeding."

The courses are offered free of charge when presented by your Wilson-Cook Sales Representative, and each course has a value of one contact hour. Please check with your state licensing board or agency regarding specific renewal requirements in the U.S.

Additional courses will be made available later in the year including "Endoscopic Ultrasound," "PSC or Primary Sclerosing Cholangitis," "Biliary Stone Management," "Hemostasis," and "Esophageal Cancer."

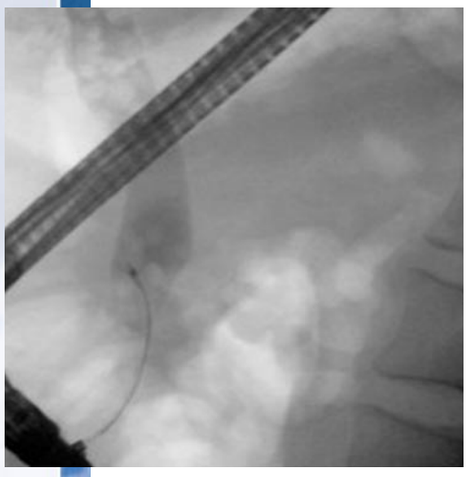
Please check with your sales representative for course availability and to discuss future presentation opportunities.

Courses are available worldwide, only CEU will be issued in the US.

FUSION CASE *Continued from page 1*

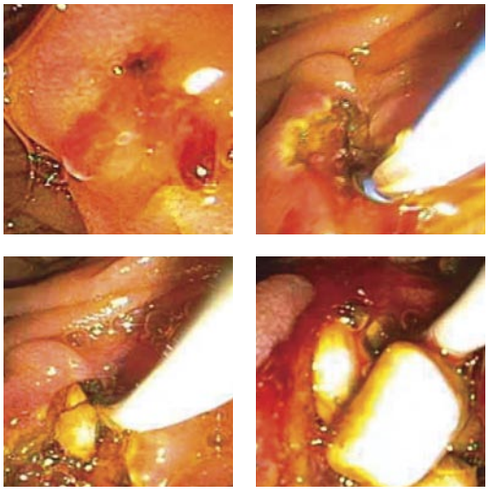
Cholangiopancreatography (ERCP) with Fusion. Three elements to ensure a successful ERCP included Dr. Brotze receiving an in-service on Fusion, implementation of appropriate Radiology guidelines, and completion of therapeutic intervention.

First, Dr. Brotze received an in-service about Fusion explaining the use and benefits of the new product. One of the many key benefits of Fusion is the ability to reduce the amount of fluoroscopy used during a procedure. By utilizing the external markers on the equipment to perform an Intra Ductal Exchange (IDE), the physician can significantly reduce the amount of radiation exposure to the patient and healthcare workers.



Next, lead barriers were placed appropriately according to Radiology guidelines prior to the initiation of the procedure. Pulsed fluoroscopy format would be used. The risks and benefits of the procedure were explained to the patient with verbalization of understanding. The decision was made to use moderate sedation during the procedure to maintain comfort and tolerance.

Finally, the procedure was initiated. Dr. Brotze began the procedure using an Olympus TJF 160-F Duodenoscope advancing to the second portion of the duodenum to reveal the major papilla. The major papilla appeared enlarged and inflamed. A Fusion sphincterotome and a Fusion .035 ultra short wire guide preloaded into the IDE port were used for initial cannulation. The physician gained access to the common bile duct (CBD) and wire guide placement was achieved. A cholangiogram was performed by injecting half-strength contrast into the biliary system. The cholangiogram revealed a dilated duct to 12 millimeters with multiple CBD stones. A sphincterotomy was made for a total cut length of 12 millimeters. The first IDE using only external markers would be performed to switch over to a multi-sized 8.5-15 millimeter stone extraction balloon. The use of external markers during the IDE was successful. The stone extraction balloon was advanced to the bifurca-



tion of the common hepatic duct. The first balloon sweep removed several 5-7 millimeter stones. Due to the irregularity of the stones, the balloon would have to be replaced three times. All Intra Ductal Exchanges were performed by using the external markers. At the conclusion of the case, there would be an estimated 12-15 stones removed from the CBD. The total amount of fluoroscopy used during the procedure would be an astonishing 1.3 minutes.

As a result, Dr Brotze, a first time user of Fusion, proved that utilizing the external markers during IDE may reduce the amount of fluoroscopy needed during an ERCP. Performing an ERCP is difficult under normal circumstances despite the added risk of pregnancy. This new technology brings added benefits to provide a more safe and efficient procedure for the patient and healthcare workers. With these new advances, Fusion will become the standard for ERCP.

NEW ERCP SYSTEM *Continued from page 3*

al ERCP systems, its unique Intra Ductal exchange capability holds the promise of some major technical advantages over traditional ERCP systems. Pre-market studies of Fusion performed in three endoscopy centers (Rome, Düsseldorf and Brussels) confirmed the feasibility of Intra Ductal exchanges with some particularly interesting indications, such as: the repositioning and/or removability of plastic stents, the placement of multiple stents, and the use of multiple wire guides.

The Wilson-Cook Fusion Team

Randomized studies are being done to investigate these potential advantages as well as the system's potential ability to shorten the duration of procedure (and concomitant fluoroscopic exposure). Based on my current experience with this new ERCP system – and if further investigation corroborates the benefits of the system – it my feeling that the Fusion system could be a valuable addition to any endoscopic suite.

THE CHANNEL

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If you would like to submit material for The Channel, please email us at thechannel@wilsoncook.com. We welcome your comments and suggestions.

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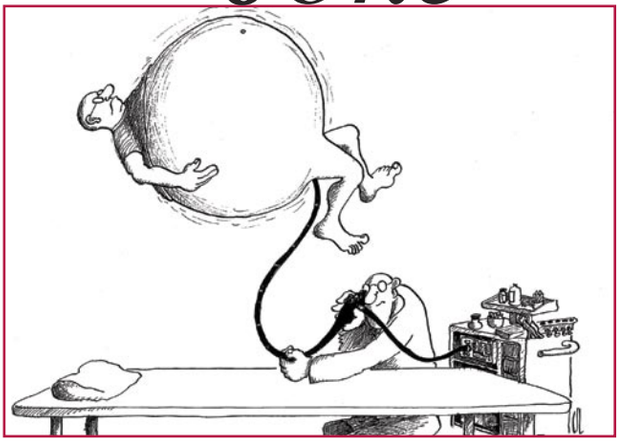
UPCOMING 2005 EVENTS

Pancreatic and Biliary Endoscopy *Simon Lo, MD*	*Los Angeles, CA*	***January 21 - 23***
National Israelian Congress of Gastroenterology and Digestive Endoscopy	*Dead Sea, Israel*	***January***
Diagnostic and Therapeutic Endoscopy *Joseph Geenen, MD*	*San Antonio, TX*	***February 18 - 20***
7th International Symposium: Diagnostic & Therapeutic Endoscopy *Prof. Horst Neuhaus*	*Dusseldorf, Germany*	***February 18 - 19***
Endoscopic Ultrasonography and Advanced Therapeutic Endoscopy *Dr. Chan-Sup Shim, Dr. Nib Soehendra, Dr. Greg Haber, Dr. Masatsugu Nakajima*	*Seoul, Korea*	***March 4 - 6***
"Innovation in Endoscopy" Looking into the Future	*Palm Springs, CA*	***March 10 - 11***
BSG	*Birmingham, U.K.*	***March 15-17***
National Dutch Meeting	*Eindhoven, The Netherlands*	***March 18-19***
Annual Conference of the Society of Gastrointestinal Endoscopy of India	*Calcutta, India*	***March 27 - 29***
Endoscopy 2005 *Prof. Khean - Lee Goh*	*Kuala Lumpur, Malaysia*	***April 1 - 3***
Francophony Meeting	*Paris, France*	***April 2 - 6***
ACG Therapeutic Endoscopy *Joseph Leung, MD*	*Sacramento, CA*	***April 8 - 9***
DDW	*Chicago, IL*	***May 15 - 18***
SGNA	*Minneapolis, MN*	***May 15 - 17***
Advanced Endoscopy Update *Dr. Peter Cotton, Medical University of South Carolina*	*Isle of Palms, SC*	***May 20 - 22***

INSIDE *Joke*



COOK® Wilson-Cook Medical GI Endoscopy