Interplex Medical

Tech Bulletin

Creating Smart-Catheters Requires Smart Design

This Tech Bulletin provides an overview of the rising trend toward deployment of "Smart-Catheter" technologies for a widening range of applications in the medical industry. Key topics include:

- What is a Smart-Catheter?
- Technology challenges in Smart-Catheter design
- Using an end-to-end smart design approach
- Importance of leveraging platform design techniques

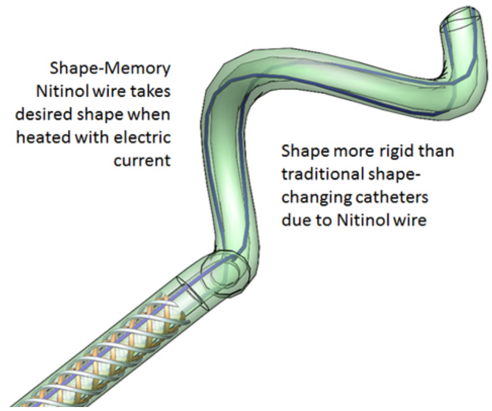
Subsequent Tech Bulletins in this Smart-Catheter series will provide detailed drill-down information on each of the key challenges and technology areas that will be critical for the successful implementation of next-generation Smart-Catheter designs.

What is a Smart-Catheter?

Catheter technologies have been steadily evolving over recent decades, with a widening variety of form factors, usage scenarios and distal-end configurations. Some in the industry have taken to loosely using the term "smart" for features like mechanically steerable catheters and distal-end mechanisms that trigger an action, such as ballooning, stent placement, etc.

However, the new generation of truly Smart-Catheters are now going well beyond these types of functionality. A more useful definition going forward would be as follows:

Smart-Catheters provide more than just a one-way conduit by incorporating two-way feedback and control mechanisms, such as sending and receiving signals between the proximal and distal ends, which enables applications to use the distal-end information to perform additional functions that are guided in real-time by the two-way feedback loops or the ability to provide energy at the distal tip for selected ablation.



For example, using closed-loop impedance-sensing to sense, control and adjust a distal-end ablation procedure in real-time would constitute a Smart-Catheter.

Another Smart-Catheter example would be the use of Nitinol Shape-Memory wire to enable precise control of unique distal-end shapes, using two-way signaling between the proximal and distal ends.

The following sections look at the over-arching challenges, emerging technology approaches and opportunities with new Smart-Catheter applications.

Technology Challenges in Smart-Catheter Design

The primary challenge across all Smart-Catheter applications is the need to implement two-way signaling, electrical current conductivity and feedback loops between the proximal and distal ends. To add a degree of extra difficulty, these advanced functions need to be implemented within the small form-factor constraints that are inherent to all catheter applications.

The most reliable approach to implementing these two-way communications and control functions is through specialized enhancements in the braiding process that's used in creation of most catheters. While the braiding process builds the "spine of the catheter" the use of advanced braiding techniques can also embed an intelligent nerve system directly into that spine.

Some examples of advanced braiding capabilities include:

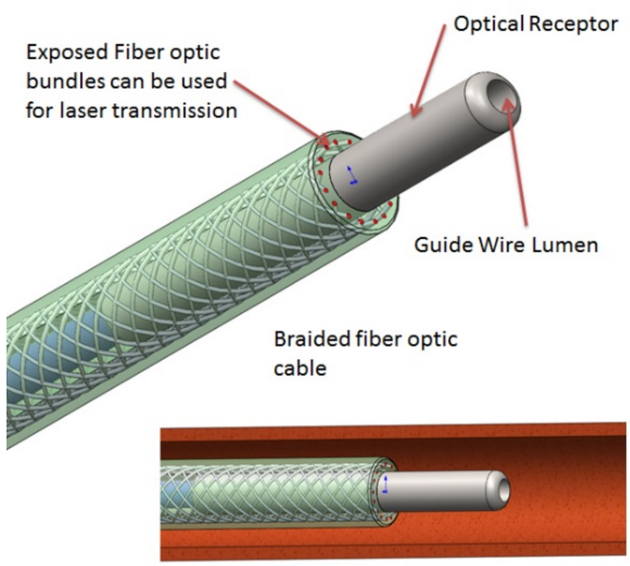
- Round or rectangular wire – down to .00075" diameter
- Embedded chaser wires – up to 8 power/signal wires
- Variable braid density PIC count (Per Inch Crosses)
- Tri-ax wires (up to 4 at 90º) longitudinal
- Embedded flex circuits
- Up to 16 wires in various configurations
  - Full braid (with or without chaser wires)
  - Diamond braid (with or without chaser wires)
  - Coiled
- Multiple materials can be braided simultaneously (including metallic and polymer)

Materials and coating options can include a mix of the following:

Braid/Coil Materials	Resins	Coatings/Additives
• SS 304V • Kevlar • Spectra • Vectra • Platinum • Be Cu • Phosphor Bronze • Nitinol • PEEK • Fiber optic	• Teflon/PTFE (liners) • PET • Polyethylene (LDPE/HDPE) • Pebax • Polyimide • Polyamide • PEEK	• Antimicrobial • Hydrophilic • Teflon/PFTE • Radio opaque

For example, a braided fiber optic cable could bring together combined functionality for guiding, lighting, focusing and controlling a distal-end optical receptor, from the proximal end.

This can now be implemented using embedded multi-functionality, with control and communication mechanisms that are integral elements of the catheter braid.



Using an End-to-End Smart-Design Approach

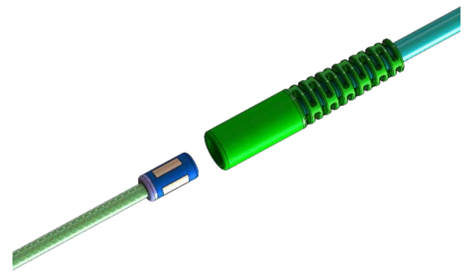
The key to success is addressing each Smart-Catheter design from a holistic viewpoint that begins with the overall objectives and then leverages the best-available technologies to achieve those design goals. This means using a "smart-design" approach that allows for blending and combining whichever technologies can get the job accomplished, rather than starting with subset of technology options and trying to make them fit the overall design goals.

It is also very important to view Smart-Catheter implementations from an end-to-end perspective as a complete system. This helps drive the best choices for technologies that perform distal-end functions, communications along the catheter spine, proximal-end control functions, and interfaces with backend systems and software. The end-to-end approach ensures that technology choices in any one area are compatible with the best choices available for other areas as well.

Importance of Leveraging Platform Design Techniques

One of the important advances that is helping lay the foundation for next-generation Smart-Catheter implementations is the rise of platform design techniques and sub-system modules that can be leveraged across a variety of design requirements.

For example, modular proximal connector technology can be used to support a variety of distal-end functionality through standardized interfacing to different back-end system and application requirements.



The ability to standardize on Smart-Catheter connectors also has the advantage of enhancing plug-and-play diversity of catheter types and functionality in conjunction with back-end systems. This can open the door for reduced deployment costs as well as improved patient outcomes.

Summary:

By leveraging a solid foundation of smart-design techniques along with a holistic design approach, engineers tasked with creating the next-generation of Smart-Catheters are expanding the range of patient care alternatives, while simultaneously fueling the acceleration of future innovations.

Upcoming Tech Bulletins in this series will drill down and focus on the details of implementing specific Smart-Catheter capabilities, including:

- Embedded Sensors (RFID, ultrasonic, etc.)
- Power Sources (batteries, capacitors, etc.)
- Embedded Shape-Memory Alloy (Nitinol) implementations
- Imaging, Lighting and 3D Mapping
- Embedded Circuitry and Flex Circuits
- Modular Connector technologies

More information regarding Interplex Medical technologies, service and products can also be found on the web by visiting http://interplexmedical.com or contacting Craig Berky at (513) 248-5120 extension 302.