Benatav
ADVANCED WINDING TECHNOLOGIES

White Paper:

Ultra-Fine Wire Technologies in Medical Devices

Introduction

One of the major challenges facing the mechanical designer of invasive medical devices is to fit the physical size of the device within the constraints imposed by the body region for which it is intended. Ever more invasive devices inserted into the body – via catheters, minimally invasive procedures, and permanent or temporary implants – are undergoing a continuous process of miniaturization. Miniaturization serves several purposes: reaching otherwise inaccessible regions in the body, minimizing disruption of regular body functioning, minimizing energy consumption, and increasing the lifetime of implanted components. The designer is thus faced with multiple challenges, both in the realm of manufacturing miniature components and in connecting these components to each other and to their operating systems. The first part of this paper presents the modern technologies available for working with ultra-fine wires and how these technologies are used to manufacture miniature coils, connect between various miniature components, and connect miniature components to the "outside world". The second part discusses the options these innovative technologies open for the designer, and also discusses several use cases and applications where ultra-fine wire solutions assist in resolving design challenges that were previously unsolvable.

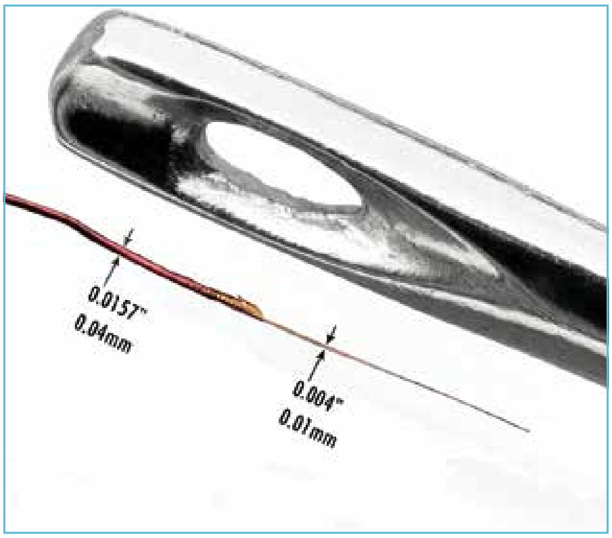
The Technology

Using ultra-fine wires to manufacture inductive components and provide connectivity within miniature medical devices requires the interplay of several innovative technologies. These technologies are predicated on an array of methods for handling copper and other metal wires at any diameter, down to the finest serially manufactured size of 59 AWG (9 microns, 0.00035”). Handling wires which can be 5-10 times thinner than a human hair is a non-trivial challenge, especially if the expected final shape of the wound coil is constrained by a long list of physical and environmental factors, and must meet very strict tolerance requirements. The machinery used for winding such coils, which controls and monitors the wire’s position and tension at any given time during the winding process, is in most cases custom-built by the coil manufacturer, and requires state-of-the-art micro-motion and control systems. As a result, only a handful of manufacturers in the world claim to have the technical capability to serially manufacture coils that small.

The complexities inherent in using micro-coils in medical applications are not limited to their manufacturing challenges: since micro-coils always serve as only one component in a larger system, their electrical connection to these systems poses additional challenges, because traditional, soldering-based connections were proven over time to be inadequate for the task. In particular, heat-based soldering of ultra-fine wires creates multiple undesired side effects, such as: oxidization of the connection and its vicinity - resulting in inferior conductivity and low durability; excess strain - resulting in degraded durability; and heat damage to the area - resulting in degraded connection reliability and durability.

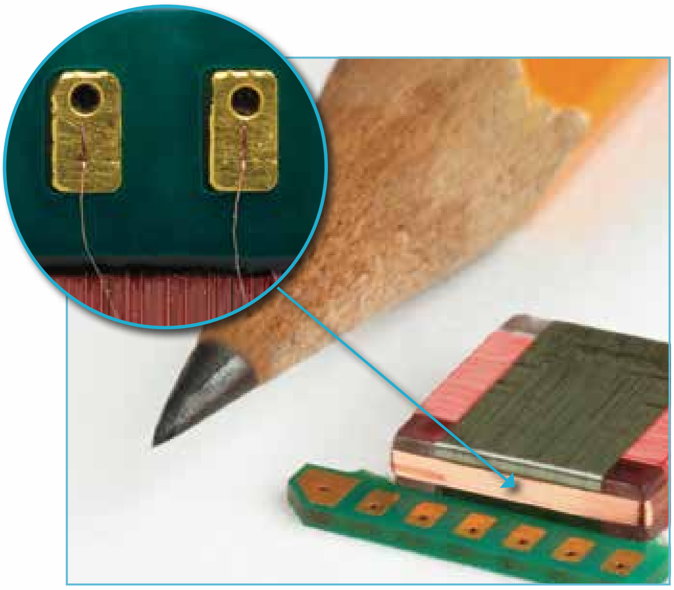
A serially-manufactured micro-coil with 2300 windings of a 9 micron (59 AWG) wire and overall size smaller than a pin-head. Coil placed near a standard sewing needle for reference purposes. Manufactured by Benatav.

The ultimate answer to all these connectivity challenges was found in the form of an innovative thermo-pressure bonding technology recently developed by Benatav. This technology enables connecting ultra-fine wires at any serially manufactured diameter to other ultra-fine wires similar in diameter or to wires up to 12 times as thick. In those cases where design requirements dictate the use of a terminal-based connection, the same technology is implemented in a slightly different manner, by connecting the wire’s end to a gold-plated terminal.



A serially-manufactured soldering-free connection of a 9 micron (59 AWG) wire to a 40 Micron (46 AWG) wire. Manufactured by Benatav.

The molecular connections formed by this thermo-pressure bonding technology provide highly reliable, corrosion-free, and strain-free connectivity without any soldering, thus simplifying and lowering manufacturing costs. Thorough testing of the technology in a wide variety of customer environments, coupled with its implementation in several production processes, have proven its readiness for integration into mass serial production processes, while meeting the standards required by medical applications, both of disposable products and of life-long ones (e.g. permanent implants). Given the criticality of the various components that utilize this technology, its implementation requires a careful design process prior to mass production. The design process entails meticulous formulation of design specs based on the component's specific requirements, followed by the design and manufacturing of dedicated machinery that meets these specs while adhering to stringent standards of quality and reliability.



Connecting a 9 micron (59 AWG) wire to a gold plated terminal, using Thermo-Pressure Bonding technologies. Manufactured by Benatav

Typical Use-Cases

The technologies for handling ultra-fine wires open a vast array of possibilities to medical device designers. Miniature coils, for example, can be used to provide capabilities such as:

- Transferring control, monitoring, and logging data to/from miniature implants
- Transferring energy to implants requiring battery charging or electrical charge input to activate and operate their systems
- Radiating energy for RF treatments, heat treatments, or electromagnetic radiation-based treatments
- In-vivo magnetic navigation, employing a local or external magnetic field

A serially-manufactured micro-coil with 700 windings, made with a 10 micron (58 AWG) wire. Elliptical shape and dimensions customized per customer's specifications. Manufactured by Benatav

Thermo pressure bonding can be used to connect ultra-fine wires to other ultra-fine wires, to terminals or to PCBs. For example:

- Miniature thermocouple based on a copper to constantan ultra-fine wires' connection
- Copper to copper connection of micro-coils to PCBs, using a mediating thicker wire
- Connecting micro-coils to a support system using a gold-plated terminal

Applications

The applications that can benefit from miniature coils technologies and ultra-fine wire connectivity technologies, include:

A flat multi-layer micro-coil, made with a 10 micron (58 AWG) wire. Shape and dimensions customized per customer's specifications. Manufactured by Benatav

- Diagnostic applications: wireless communications with miniature implants serving as sensors, whether physiological (blood pressure, heartbeat), glycemic, or flow (blood, respiratory)
- Active implants applications: monitoring/ controlling of miniature implanted pace-makers, or deep brain stimulation components in pain management implanted devices
- Therapeutic applications: end devices in electrophysiology treatments (cardiac, neural, brain) or electricity-based ablations (microwave and RF)
- Navigation and orientation applications: targeted drug delivery, targeted radiation catheters, stents positioning, highly-accurate ablations, implanted markers, inter-body tagging, as well as endoscopic, gastroscopic, colonoscopic, laproscopic, and other similar procedures
- Temperature measuring applications: chromel-constantan miniature thermocouple (type E), based on thermo-pressure molecular bonding technology
- Hearing aids: connecting micro-coils to their operating system on a PCB, using a mediating thicker wire, which can withstand soldering

The Future of Ultra-Fine Wire Technologies

The use of innovative ultra-fine wire technologies opens a limitless range of new possibilities to designers of miniaturization based medical equipment. The growing need to access very dense body regions, while minimizing interference with the body's regular functioning, reducing energy consumption and lengthening implanted components' lifetimes, underscores the importance of miniaturization in medical devices. Thus, for example, a miniature coil manufactured by Benatav serves as the navigation component in a cardio-vascular catheter performing cardiac ablation. This component, serving as a key element in a disposable catheter, is a typical example of the technological ability to mass-produce a miniature component having a high and predictable quality at a reasonable cost. We foresee that as designers become more aware of these advanced technologies and the variety of applications that can utilize them, their usage will become increasingly widespread.

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16 Zvi - Bergman street
Petach-Tikva, 4927973 Israel
Tel: 972-3-9345951 | Fax: 972-3-9345952
info@benatav.com | **www.benatav.com**