# NICKEL

THE MAGAZINE DEVOTED TO NICKEL AND ITS APPLICATIONS

Trends in medical instruments

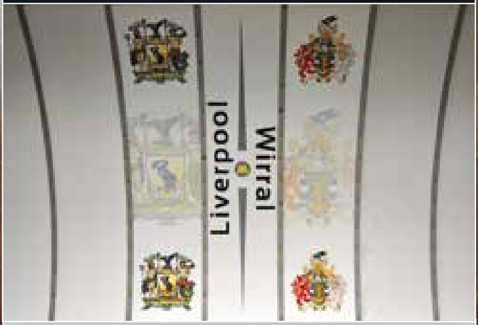
Nickel-containing medical material

Nitinol in endobronchial valves

VOLUME 32, NO. 3, 2017

Nickel in healthcare

# Improving lives




ANCON BUILDING PRODUCTS

△ *The cladding panels are supported by a lightweight modular nickel-containing stainless steel framework.*

*The frames were factory manufactured and assembled before transportation.* △

*Graphics by a local artist were screen printed onto some of the panels.* ▷

# CASE STUDY 11
# REFURBISHING AN UNDERWATER TUNNEL

The Queensway Tunnel is a road tunnel under the River Mersey, in the north west of England, between Liverpool and Birkenhead. When construction was completed in 1934, it was the longest underwater tunnel in the world at 3.24 kilometres.

In 2011, after 77 years of service, an 11-month refurbishment of the tunnel began.

The old plastic corrugated protective wall cladding was replaced with ceramic steel, chosen for its durability, strength and low maintenance. It's easy to clean as well as giving the tunnel a 21st century look.

The new cladding system also enhanced safety, improving light reflection and increasing brightness by 14%. This reduces energy consumption and extends the lightbulb life from seven to eight years, saving money, and reducing the carbon footprint.

The cladding panels are supported by a lightweight modular stainless steel framework of cold formed members, manufactured from 390 tonnes of stainless steel strip. Type 304 (UNS S30400) nickel-containing stainless steel was chosen for the framework because of the aggressive environment inside road tunnels.

A strict cleaning schedule was defined to prevent the accumulation of dirt and contaminants such as chlorides or sulfates which might lead to localised corrosion.

The stainless steel framework was designed to be as lightweight as possible, to both reduce material costs and facilitate quick installation, enabling the refurbishment to be completed with minimal disruption to the normal running of the tunnel. The framework system also needed to be easily demountable and panels replaceable in the event of any damage, for example by vehicle impact.

Designed on a modular basis, each sub-frame supports one cladding panel.

The innovative design concept of pre-fixing sturdy top and bottom rails to the tunnel wall and then fastening the stainless steel frames in position reduced installation time considerably. This process also minimised disruption to tunnel users. Ni

## The tunnel in numbers

- **Nearly 400 tonnes of stainless steel** were used for the framework supporting the new cladding system inside the Queensway Tunnel as part of a major refurbishment project
- **Constructed:** 1925-1934 at a cost of £8M (1934)
- **Length of Tunnel:** 3.24 km
- **Tunnel dimension:** 13.4 m in diameter, with four lanes of traffic, two in each direction, used by 35,000 vehicles each day
- **Cost of refurbishment:** £7M (2011)
- **Number of ceramic steel panels:** 6,000 covering a surface area of 36,000 $m^2$
- **Total weight of cladding system:** ~900 tonnes
- **Weight of stainless steel:** ~400 tonnes
- **Framework:** Type 304 (UNS S30400) austenitic stainless steel (approximately 8.3% nickel)
- **Anchors:** 48,000 anchors attach the framework to the tunnel wall made from grade A4 stainless steel (equivalent composition to Type 316 (UNS S31600))
- **Main support hook for each panel:** duplex stainless steel (UNS 32205) containing 5.5% nickel, was selected for its superior strength
- **Refurbishment took 11 months** and was completed in November 2011
- **Graphics created by a local artist** were screen printed onto some of the ceramic panels, making this the first tunnel in Europe to incorporate public art in the tunnel cladding
- In September 2009, **a scene from Harry Potter and the Deathly Hallows–Part 1** was filmed in the tunnel

The full case study can be downloaded from the Nickel Institute website: **www.nickelinstitute.org**

NICKEL, VOL. 32, NO. 3, 2017

# NICKEL

The Magazine Devoted to Nickel and its Applications

Nickel magazine is published by Nickel Institute
www.nickelinstitute.org

David Butler, President
Clare Richardson, Editor

Contributors:
Parul Chhabra, Gary Coates, Peter Kelly-Detwiler, Richard Matheson, Geir Moe, Kim Oakes, Kristina Osterman, Tony Newson, Lissel Port, Nigel Ward

Design: Constructive Communications

Nickel Institute can be contacted at:
Rue Belliard 12
Brussels 1040, Belgium
Tel. +32 2 290 3200
communications@nickelinstitute.org



ISSN 0829-8351

Printed in Canada on recycled paper by Hayes Print Group

Cover: Constructive Communications
Cover image: iStockPhoto.com © ERAXION

# TABLE OF CONTENTS

**Case Study**
Queensway Tunnel . . . . . . . . . . . . . . . . . . . 2

**In Focus**
Editorial . . . . . . . . . . . . . . . . . . . . . . . . . . . . . 3

**Feature**
Nickel sensitivity . . . . . . . . . . . . . . . . . . . . . 4
Nickel-containing medical material . . 5–7
Earfold® . . . . . . . . . . . . . . . . . . . . . . . . . . . . . 8
Nitinol . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . 8
Endobronchial valve . . . . . . . . . . . . . . . . . 9
Trends in medical instruments . . . 10–11
3D medical printing . . . . . . . . . . . . . . . . . 12
Neuron reading nanowires . . . . . . . . . . . 13
Pacemakers . . . . . . . . . . . . . . . . . . . . . . . . . 15
Disinfection in hospitals . . . . . . . . . . . . . 15

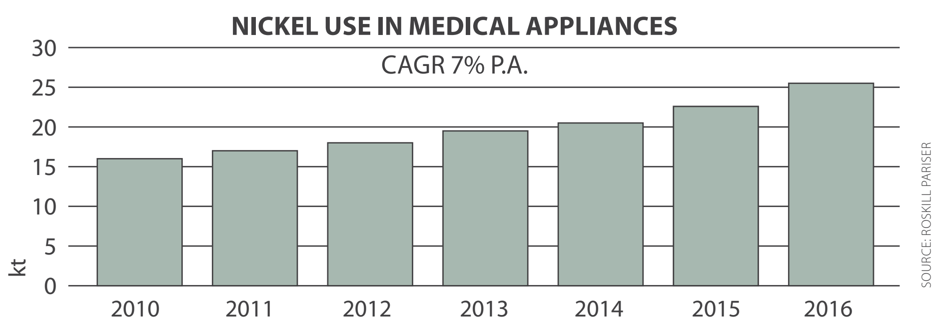
**In Use**
Light on the Land . . . . . . . . . . . . . . . . . . . 16

**In Brief**
UNS details . . . . . . . . . . . . . . . . . . . . . . . . . 14
Web links . . . . . . . . . . . . . . . . . . . . . . . . . . . 15

ISTOCK.COM/MONSTARRR_

# NICKEL IN HEALTHCARE

**Nickel-containing materials, including stainless steels, are recognised as safe, easy to clean and hygienic. Because of these properties they are widely employed in the medical sector, whether for instruments used in operations, implants, equipment in hospitals or further up the supply chain in pharmaceutical processing equipment that produces the life-saving drugs we rely on. And their effectiveness has a long history. Stainless steel has been used for scalpels, dental extraction forceps and implants since the 1920s.**




Hygiene is the number one priority of the health care industry and the universal use of stainless steel in hospitals for fixtures and fittings is testament to their ease of cleaning. As shown in a recent study by Manchester Metropolitan University and AgroParisTech, featured on page 15, stainless steel can withstand repeated sanitisation with harsh chemicals.

Nickel can also provide other properties that find their use in critical applications. For example, Nitinol (nickel-titanium) shape-memory alloys exhibit a combination of properties that make them particularly suited for self-expanding stents used to alleviate vascular conditions. Or in Magnetic Resonance Imaging (MRI), which provides unrivalled imaging of soft tissues e.g. brain, muscle, heart, tumours, without subjecting patients to ionising radiation. At the core of every MRI system is a powerful magnet (up to 300,000 times more powerful than the earth's magnetic field), which depends heavily on the nickel-containing stainless steel used in its construction.

But it's not just the corrosion resistance of nickel-containing austenitic stainless steel that makes it vital in a medical environment. Its ability to withstand ultra-low temperatures (-269°C) make it indispensable for containing liquid nitrogen used in cryosurgery for the removal of abnormal tissue. And its non-magnetic characteristics make it an ideal structural material for the fabrication of life-saving technology.

Nickel makes an unseen contribution to the medical sector. This edition of *Nickel* uncovers just some of the ways innovative nickel-containing materials are changing lives for the better.

Clare Richardson
Editor, Nickel magazine

Nickel INSTITUTE
knowledge for a brighter future

# NICKEL SENSITIVITY

## Assessing the risk

Stainless steel is one of the most commonly used materials for medical devices and hospital equipment. It's biocompatible, easy to clean and sterilise, strong and resistant to corrosion. There is a distinction between the stainless steel grades used for implant applications (e.g. Type 316LVM (UNS S31673) ) and the commercial grade stainless steels (e.g. Type 316L) (UNS S31603) used for other medical devices such as probes and retractors, which are used for transient (normally less than 60 minutes) and short term (normally not more than 30 days) continuous skin contact.

In recent years, Nitinol (UNS N01555) has emerged as another nickel-containing material for biomedical applications, valued for its shape memory properties in applications such as orthodontic appliances and stents.

Materials used in surgical implant procedures, such as artificial joint replacements, are usually well tolerated. Complaints associated with implants are mostly related to infection or mechanical problems, but in rare cases they may also be caused by allergic reactions. Typical allergens implicated are chromium, cobalt, constituents of bone cement and nickel.

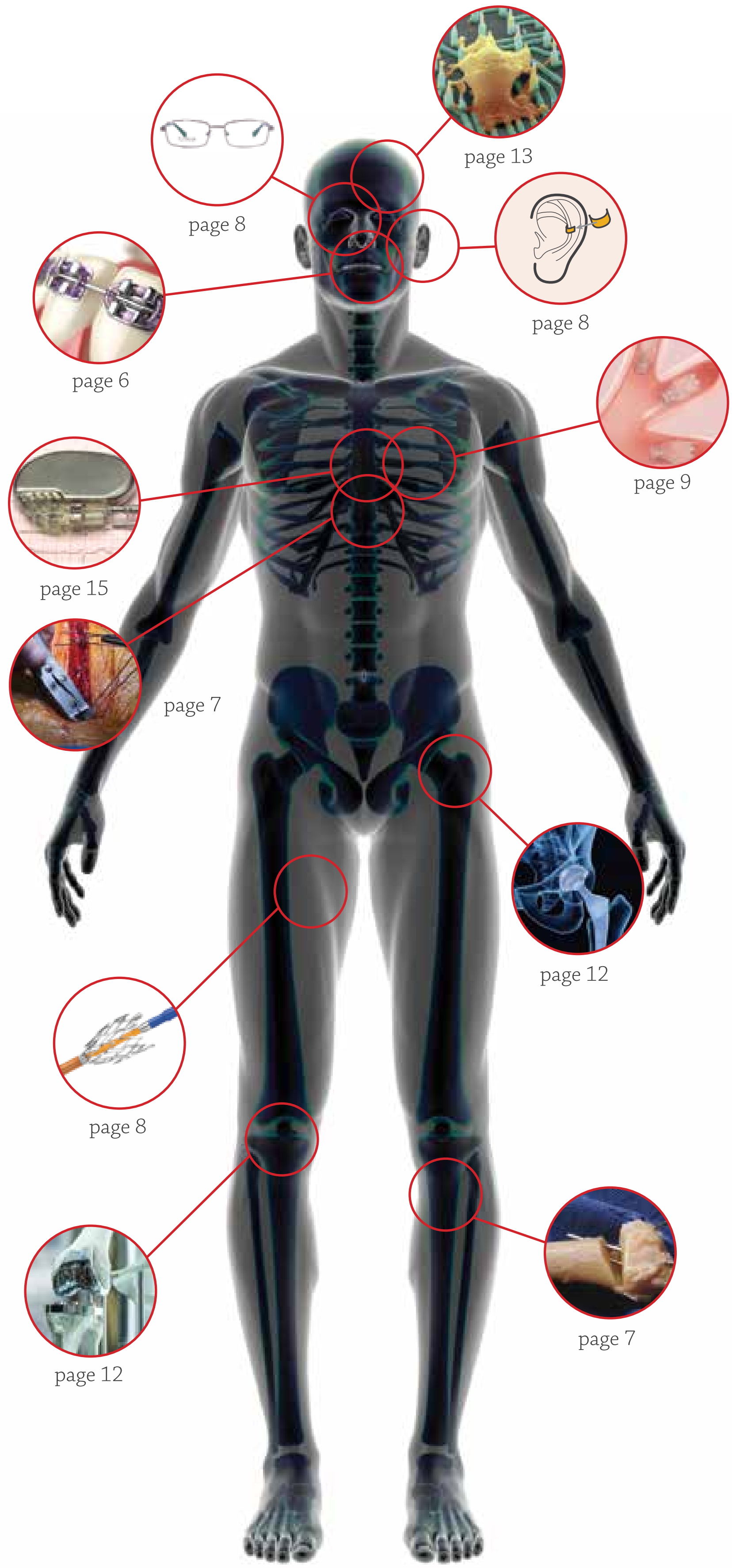
"In patch tests on patients already sensitised to nickel, the low and medium sulphur containing stainless steels, such as Type 316 'surgical grade', did not produce a statistically significant number of allergic reactions," comments Dr. Kate Heim, Senior Human Health Toxicologist at NiPERA. "It is generally agreed these stainless steels do not cause nickel dermatitis, although in hypersensitised individuals an allergic reaction may be elicited."

Current standards for implant materials ensure that metal release into body fluids and tissue surrounding implants is low. In addition, stainless steel-on-plastic prosthetic joints are designed to minimise frictional wear. This has resulted in a high success rate of hip prostheses even in patients with pre-existing allergies to metals.

"Patients who are already allergic to nickel or concerned about possible side-effects from the use of nickel-containing alloy implants should discuss this with their physician prior to surgery", advises Heim. Ni

△ *Dr. Kate Heim*
*Senior Human Health Toxicologist at NiPERA*

# WHERE NICKEL CAN BE FOUND




ISTOCK.COM/ANGELHELL

# Nickel-containing medical materials

ISTOCK.COM/CZGUR

# IMPROVING LIVES

Continued advancements in medical technologies are prolonging lives all over the world. The development of new uses of metals and alloys in internal and external medical applications has stimulated the progress being made. In 2016, more than 50 million surgical procedures were performed in the US alone. As that number grows each year, the demand for minimally invasive surgeries is also increasing as it offers many attractive benefits including shorter recovery times and reduced overall impact on the patient during the procedure.

Stainless steel is still the most commonly used material for medical instruments due to its versatility, biocompatibility and relatively low cost. Other materials, such as titanium and cobalt-chrome have also contributed to advancements. Nitinol (UNS N01555), a nickel-titanium shape memory alloy, is a star performer among medical metals and increasingly used in many medical applications.

**Nitinol guides the way**

Nitinol is an extraordinary material with super-elasticity and shape memory properties. It is 55% nickel-45% titanium and an attractive material for medical implants. Nitinol is biocompatible and because of the alloy's outstanding properties, many applications where stainless steel was previously used have been replaced with Nitinol over the past ten years.

The top three applications for Nitinol medical wire are vascular guidewire, diagnostic guidewire and dental arch wire. Every year, several hundred tonnes of nickel go into the manufacturing of Nitinol and stainless medical wire, which are used both in life-changing solutions and in life-saving situations. According to a 2014 research report published by Grand View Research, "Global guidewires market is expected to reach US $2.19 billion by 2020. Growing prevalence of target diseases coupled with growing geriatric population base is expected to drive guidewire demand over the next six years."

A guidewire is a thin, flexible, medical wire inserted into the body to guide a larger instrument, such as a catheter, central venous line, or feeding tube. While historically used in coronary procedures, the guidewire has become an integral part of a growing number of medical procedures with its use steadily increasing and expanding into more medical specialties.

"Nitinol wire has 16 times better super-elasticity and can withstand 8% strain compared to stainless wire, which can withstand around 0.5% strain before being deformed from its initial shape. For example, take a paper clip made of Nitinol. You could bend it to a 90 degree angle and it would spring back to its original shape", says David Plumely, Nitinol Product Manager at Fort Wayne Metals, a leading


ISTOCKPHOTO.COM \ MIRONOS

△ *Vascular guidewire*


ISTOCKPHOTO.COM / BET_NOIRE

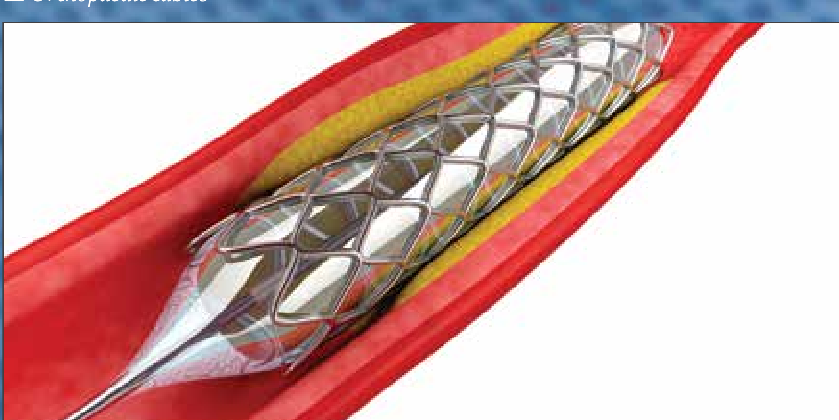
△ *Dental arch wire*


WIKIMEDIA COMMONS

△ *Nitinol shape memory*


FORT WAYNE METALS RESEARCH PRODUCTS CORP

△ *Orthopaedic cables*


ISTOCKPHOTO.COM / MILEA

△ *Vascular stent with guidewire*

supplier of Nitinol, stainless steel and specialty medical wires, based in Fort Wayne, Indiana, in the US. "Nitinol wire has great "push ability", good kink resistance and is able to maintain its straightness. The properties are very valuable to guidewire. We have seen beyond 10% annual growth in our production of Nitinol in the last ten years and we see continued growth opportunities for Nitinol in the future, both in medical and non-medical areas." Another important application for Nitinol is in reinforced catheter polymer tubes, where braided Nitinol acts as reinforcement between the inner and outer polymer layers.

**Stents that accommodate large strain**

Nitinol's extraordinary ability to accommodate large strain coupled with its physiological and chemical compatibility with the human body makes it an attractive material in medical device engineering and design. A key area of application for Nitinol is stents. Nitinol stents can be fabricated at one temperature, folded smaller at another temperature, then inserted into an artery where the body heats the material above its transformation temperature and it returns to its original size.

Nitinol vascular stents are made from a gun drilled bar. Once processed into exact dimensional requirements, they are laser cut into shapes. Vascular stent tubes used to treat aneurysms are typically 25.4 mm (1") in diameter and "crushed down" into only 6-7 mm (1/4") diameter, before being inserted into a delivery device tube and into the patient's aorta. The stent will expand on its own and take its original shape, enabling doctors to repair the aneurysm.

**High strength stainless steel applications**

"There are many applications for Types 302 (UNS S30200), 304 (UNS S30400) and 316L (UNS S31603) austenitic stainless medical wire", says Austin Lucas of Fort Wayne Metals. These fine medical wires have diameters ranging between 2.54 mm and 0.1016 mm, and can be drawn into even finer diameters. "Stainless alloys are attractive materials because of the high strengths (400-500+ ksi) that can be achieved in cold work condition, for example 0.127 mm wire with 450 ksi. This is important in the manufacturing of very small and thin parts, such as is typical in many medical applications". Uses will be found in a wide range of applications within vascular therapy, neuro-stimulation therapy, endoscopy, orthopaedic medicine, orthodontics and implant dentistry.

During open heart surgery the rib cage must be separated by breaking the sternum so the surgeon can reach the heart. Upon completion of the surgery, the ribs will be pulled back together and closed with the help of sternum closure wire. This is typically made from Type 316L stainless medical wire. Type 304 stainless medical wire is commonly used as guidewire for initial entry into veins and arteries in vascular procedures. Some stent designs use Type 304 stainless steel. Other common applications for Types 304 and 302 stainless steels are stylets, catheters, springs, needles and mandrels. In many surgical interventions, staples are commonly used for closing wounds. These are made from Types 316L and 304 stainless wires. The latter grade is also used in dental arch wire.

### Wires, pins and needles

Kirschners Wires (K-wires) and Steinmann Pins are made from implant grade 316L and used by orthopaedic surgeons as implantable devices for fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of another implant. They may also be implanted through the skin so that a pulling force may be applied to the skeletal system. Once the bone has healed four to six weeks later, the pins will be removed. Other uses for Type 316L stainless include orthopaedic cables.

Stainless medical wires used in medical implant applications are produced using Vacuum Arc Remelt (VAR), a secondary melting process for materials with elevated chemical and mechanical homogeneity for critical applications. Such controlled chemistry and high purity material is needed to ensure consistency in fatigue strength, which is of utmost importance in many medical applications.

Stainless medical wire is also used for the manufacturing of needles. Suture needles, for example must exhibit exceptionally high strength and ductility to resist bending and breaking, as well as provide stiffness and tissue penetration performance to enable good control in the hands of the surgeon. In order to meet these material requirements, suture needles are commonly made from high performance age-hardened martensitic stainless alloys such as Custom 455® (UNS S45500) and Custom 470®.

> Nitinol is a 55% nickel-45% titanium alloy and an attractive material for medical implants.

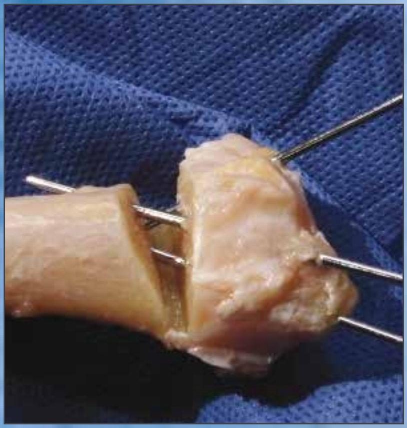
### The continued pursuit of innovative applications

Various other nickel-containing specialty wires also find medical uses, such as, FWM 1058®/Elgiloy®/Phynox®/Conichrome® (UNS R 30003), which is a cobalt-chrome-nickel-iron alloy. Applications include wire based stents, filters, pacemaker leads and orthopaedic implants. In addition, cobalt-nickel-chrome-molybdenum alloy 35NLT® (or other versions of the alloy (UNS R 30035)), with its high modulus of elasticity, finds uses in pacing leads, stylets, catheters and orthopaedic cables and permanent implantation applications.

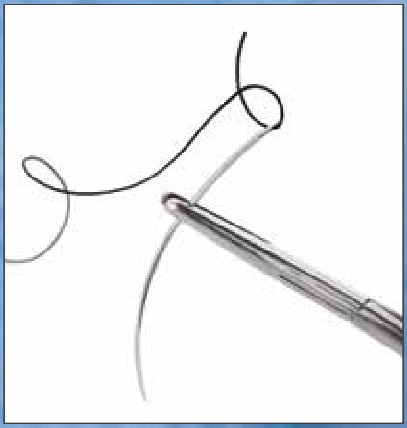
Medical technological advances go hand in hand with the availability of high performance materials with outstanding properties. Biocompatible materials such as Nitinol and nickel-containing alloys must not only match the present needs of medical device designers, but provide them with parameters for new ideas and possibilities. With the continued pursuit of new applications, these are certainly extraordinary and inspiring materials for future innovation. Ni


ISTOCKPHOTO.COM / MIRALEX

△ Sternum closure wire


ISTOCKPHOTO.COM / DEFUN

△ Kirschners Wires (K-wires)

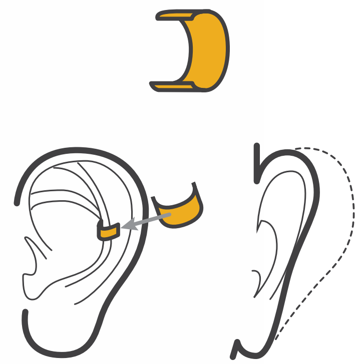

ISTOCKPHOTO.COM / CHAI2070

△ Suture needles

ISTOCKPHOTO.COM / BDSPN

△ Pacemaker leads

ISTOCKPHOTO.COM / LIZA5450



△ *The reshaping properties of Nitinol allows Earfold® to help correct prominent ears.*

WWW.EARFOLD.CO.UK

# Believe your ears

## How Nitinol is helping reshape prominent lobes

Everyone likes to hear good news. If you have ever been self-conscious about your ears "sticking out", you will be especially happy to learn that there is now an easier, less invasive way to reposition them, thanks to the unique properties of a lightweight metal alloy called Nitinol (UNS N01555), a super-elastic material made from nickel and titanium.

**A faster fix and shorter recovery**

Suitable for adults, teens and children over the age of seven, Earfold® is an alternative treatment to the traditional ear pinning and ear surgery (known as 'otoplasty'). It has been gaining popularity in recent years for its convenience, shorter recovery time and ability to preview the end result before the simple 20-minute procedure.

The Earfold® is a small implant with a pre-set, curved shape. On the day of the treatment, patients only need a local anaesthetic while it is inserted into the ear using a small handheld device that holds the implant flat. Once in position and released, the Earfold® takes up its curved shape again, repositioning the ear at the angle that was agreed upon before the operation. All because of the remarkable reshaping properties of Nitinol.

**Inspired by a coat hanger**

The inventor, Dr. Norbert Kang explains in a 2017 interview, "My intention was to offer patients and surgeons a treatment option that is quick, more predictable, has lower rates of recurrence, has low infection rates, offers patients some degree of control over the final outcome, and is reversible and correctable."

Dr. Kang had originally been using a technique to correct the ear prominence by bending and stitching the actual ear cartilage but then wondered if he could make something that would do the same job. The idea for the device started off in his garage, playing with a wire coat hanger.

Dr. Kang's ultimate goal was to avoid some of the problems inherent in standard surgical and non-surgical otoplasty techniques. Using Nitinol helped him achieve his goal.

"The alloy has a number of important properties including super-elasticity and shape memory. Therefore, when inserted into the front of the ear, Earfold® is able to fold and reshape the underlying cartilage according to the shape that has been pre-programmed into the implant."

**Natural results**

While Nitinol is the hero of this innovative medical implant, the results are pure gold. Literally, as the Nitinol is coated with 24-carat gold to reduce the visibility under the skin. Both substances are biocompatible (i.e. they should not react to your body) and widely used in many other healthcare products.

Earfold® has now been in use since 2011 and data continues to be collected to confirm that treatment with the implant produces durable and consistent correction of prominent ears. The ears look and move naturally and satisfaction rates for patients are high. Nitinol can literally 'bend your ear'. In a good way! Ni

# NITINOL

## the shape of things to come

As a metal alloy composed of nickel and titanium in approximately equal atomic percentages, Nitinol exhibits the unique properties of super-elasticity (SE) and shape memory effect (SME). These properties are due to a phase transformation (a change in crystal structure). Below the transformation temperature the microstructure is known as *martensite*, while above this temperature it is known as *austenite*.

Nitinol displays SE above its transformation temperature, due to martensite forming in areas that are stressed, even though the temperature is above where this normally occurs. When the stress is removed, this martensite returns to the undeformed austenitic state. While most metals can tolerate only a small fraction of a percent of strain without permanent deformation, Nitinol can take up to an eight percent strain and return to its original shape.

Similarly, SME enables Nitinol to revert to its original structure after deformation. When processed above its transformation temperature and given a specific shape, Nitinol's shape memory property enables it to revert to its original shape when deformed below its transformation temperature. Simply heating the Nitinol causes the martensite to transform back to the undeformed austenite.

Healthcare and medical device applications are increasingly making use of Nitinol's properties including ear implants, eyeglass frames and stents. A medical stent needs to be severely compressed so that it can be inserted into an artery, but when the compression is removed it springs out to support and hold open the artery. Ni

△ *U-Flex Stent: a self-expanding Nitinol stent*

WWW.ANDRAMED.COM/

△ *Eyeglass bridge made from Nitinol*

WWW.THINOPTICS.COM/FLEXIBLE-READING-GLASSES


△ *The valve is placed deep in the bronchioles allowing air to flow in one direction only.*

# Endobronchial valves working wonders

## Putting the squeeze on respiratory disease

Many patients around the world are breathing more comfortably with the help of a tiny nickel-containing valve implant that works much like those easy-squeeze ketchup bottle tops.

The Zephyr valve is made of a collapsible Nitinol (UNS N01555) wire outer 'basket'—not unlike a stent used in heart surgery—which surrounds the silicone inner valve. The flexible material is constructed in such a way as to form a one-way valve, that helps a patient exhale more efficiently.

It's led to a simpler, less damaging, minimally invasive procedure that helps ease the debilitating breathlessness that leaves those with chronic lung conditions unable to take a few steps without gasping for air.

**Controlled air flow and improved breathing**

Manufacturer PulmonX, describes the Zephyr Endobronchial Valve as an endoscopic lung volume reduction therapy that significantly improves lung function, exercise capacity and quality of life.

The valve, placed deep in the tiny branches within the lungs known as bronchioles, allows air to flow out, exhaling in one direction only. This is what makes it similar to the way rubber tops of ketchup bottles work.

In a 45 minute procedure, the surgeon uses a thin flexible tube called a bronchoscope to implant the valve, threading it into the lungs via the mouth and windpipe, while the patient is either under anaesthetic or sedation. Once in the correct position, the wire basket expands, holding the device in place.

This effectively cuts off the diseased areas of the lungs. Despite the volume of the lungs being smaller, the valve actually improves breathing because air flows through the healthy areas of the organ only. In essence, it ensures the remaining healthy regions function more efficiently.

**Improved quality of life**

PulmonX notes that the Zephyr Valve has the most clinical evidence of any endoscopic lung volume reduction therapy, supported by four published randomised controlled clinical trials, two more underway, and extensive scientific research into safety and efficacy. Multiple clinical trials have demonstrated its benefits and 12,000 patients have been treated worldwide.

Dr Samuel Kemp, consultant respiratory physician at the Royal Brompton & Harefield NHS Foundation Trust, in the UK, who led one recent study using the Zephyr, says: "After the procedure, patients can breathe more easily, walk further, dress themselves and generally have a better quality of life."

"Being breathless is miserable and people become afraid to exercise. But this gives them back their confidence and their quality of life without surgery, and may be suitable for many more patients with emphysema." Ni

# TRENDS IN MEDICAL INSTRUMENTS

## How stainless steel is meeting the surge for advancements in surgical instruments

It's a fast-growing sector fueling innovation and refinement of stainless steel alloy applications around the world. The global surgical instruments and equipment market is expected to double within the next decade. Valued at US $10.5 billion in 2016, according to Grand View Research Inc., it is projected to reach US $20.3 billion by 2025.

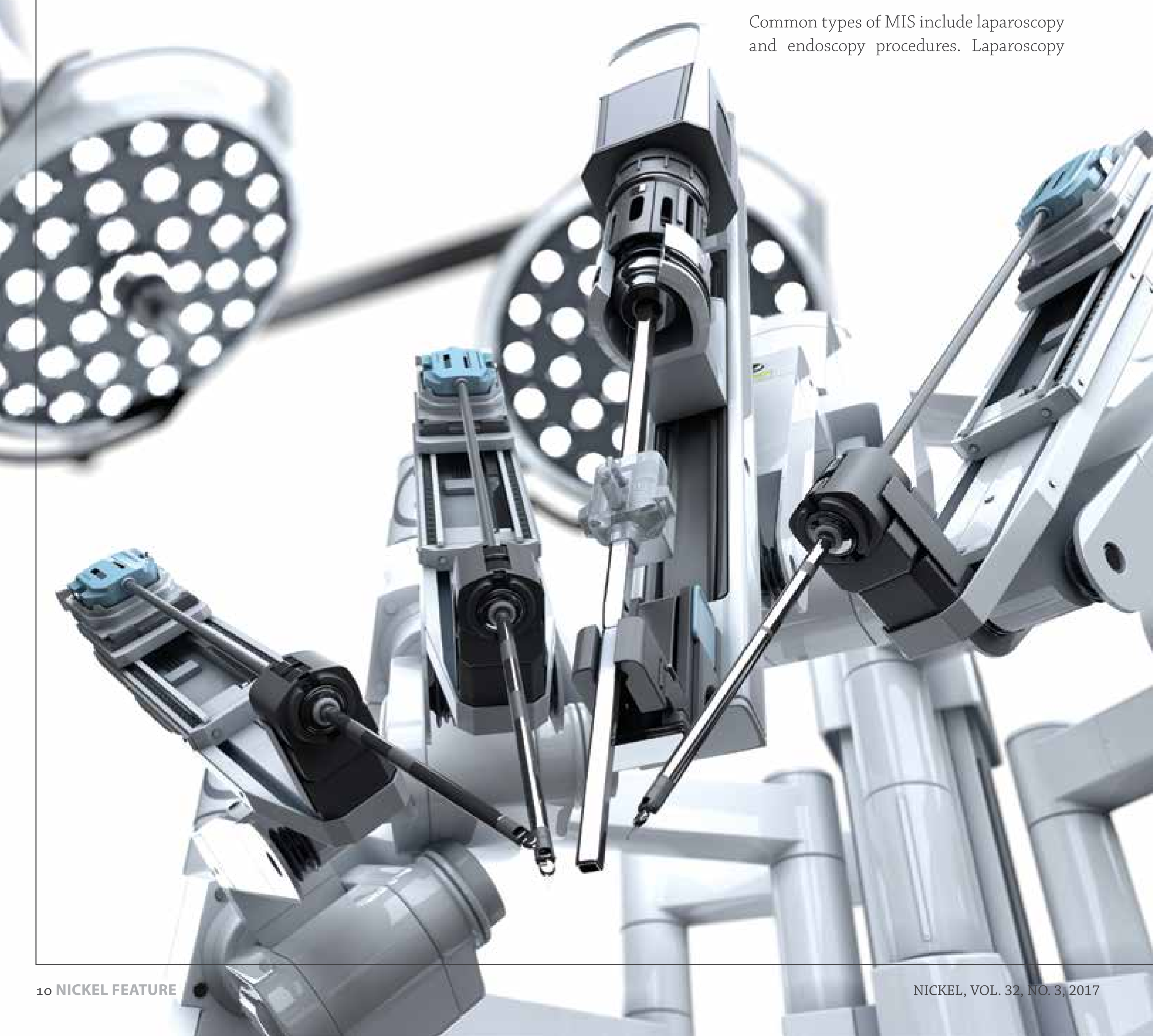
While handheld surgical devices, such as forceps, spatulas, retractors, and dilators represent a majority of the market, the electrosurgical devices and equipment market segment will witness steady growth, as a result of the trend towards Minimally Invasive Surgeries (MIS).

**MIS—Less is more**

Minimally Invasive Surgery is increasingly being opted for whenever possible. Why? Overall, it is safer for the patient and their recovery time is much faster. Other benefits include smaller incisions, considerably less tissue damage, less discomfort and decreased scarring.

Another significant advantage, is the higher accuracy rates, thanks to the use of video-assisted equipment. This gives the surgeon improved visualisation and magnification of internal organs.

Common types of MIS include laparoscopy and endoscopy procedures. Laparoscopy



ISTOCK.COM/JMIMAGES

involves surgery through small holes, while endoscopy encompasses diagnostic and therapeutic procedures performed through the body's organs and vessels, using specially designed, thin instruments.

### From skilled hands to robotics

Currently, the majority of MIS procedures involve hand manipulation. However, major advances are being made in robotic technologies that allow surgeons to perform finer and more delicate interventions, providing crucial benefits especially in neurological and spinal surgery. Surgical robots are expected to provide intuitive control, enhanced visualisation and higher dexterity. Consequently, surgical procedures have become more complex and confined.

### As techniques evolve, instruments also have to evolve

With more requirements placed on the surgical instruments, more is expected of the material they are made of. Using the most suitable alloys is critical for both performance and cost effectiveness. All surgical instruments are subjected to body fluids as well as pre- and post-surgical techniques. These involve disinfection solutions and autoclaves that use high pressure saturated steam to kill bacteria, spores and germs resistant to boiling water and powerful detergents.

Today's instruments must be "autoclavable" and able to withstand this process. The right alloys are selected based on their corrosion resistance, yield strength, toughness, fatigue strength, hardness or wear resistance. Many applications will require a combination of these properties.

### Tubular and non-cutting instruments

Austenitic stainless alloys Types 304/304L (UNS S30400/S30403) and 316/316L (UNS S31600/S31603) are commonly used in medical devices and non-cutting instruments where good corrosion resistance and moderate strength are needed. Enhanced strength Type 304 stainless steel is often the material of choice for the tubular components.

The outstanding formability of austenitic stainless steels is a key property for such applications that involve complex shapes. A smooth surface is necessary in order to facilitate easy cleaning of medical instruments.

These alloys are used to make surgical and dental instruments like pliers, clamps, and aspiration tubes, as well as trocars, not subjected to high stress or torsional loads.

### Load bearing and cutting edge

Martensitic stainless steels, Type 410 (UNS S4100), Type 416 (UNS S41600), Type 420 (UNS S42000), Type 431 (UNS S43100) and Type 440 (UNS S44002/3/4) are extensively used in medical and dental instruments that require hardness or increased toughness for load-bearing applications, such as in cutting instruments, bone curettes, dental chisels, orthodontic pliers and scalpels.

Precipitation hardening (PH) stainless steels, such as 17-4 PH (UNS S17400) are also used in surgical instruments, especially in long and narrow shafts and gripping mechanisms used in MIS.

### New solutions to autoclaving issues

With the popularity of autoclaving, martensitic stainless steels may not offer the required corrosion resistance, prematurely deteriorating some equipment. Manufacturers of dental and surgical instruments have experienced some problems with cutting edge retention, wear and galling, including prematurely dull edges, decreased performance, and the possibility of introducing metallic debris into the wound.

Innovative producers have responded to these issues to meet the exact material needs of the evolving surgical instruments industry. And nickel-containing materials are playing an important role.

ISTOCK.COM/3ALEXD

## Specialty Alloys

Carpenter Technologies, Reading, Pennsylvania, in the US has developed a number of nickel-containing specialty alloys to meet the growing demands of the medical industry including:

- **UNS S20161** (Cartech Gall-Tough®), a high-silicon, high-manganese, nitrogen strengthened austenitic stainless steel with 5.2% nickel.
- **Cartech Gall-Tough PLUS®** (UNS number is pending) with 8% nickel is a more corrosion resistant version.

These two grades offer similar corrosion resistance to Types 304 and 316, but superior yield strength, wear and galling resistance.

- **UNS 45000** with 6.5% nickel, a martensitic age-hardenable austenitic alloy offering reasonably good corrosion resistance as well as high strength, good ductility and toughness, by means of simple heat treatment.
- **UNS S45500** with 8.3% nickel, a martensitic age-hardenable austenitic alloy can develop multiple strength levels by simply using different heat treating schedules, without distortion issues. Excellent for very small instruments that grip at the working end of endoscopic instruments used in MIS.

Advanced surgical techniques require instruments that do not break, distort or otherwise fail during surgery.

- **UNS S46500 Custom 465®** is another martensitic age-hardenable stainless alloy, with 11% nickel content that offers a unique combination of toughness, fatigue strength, excellent notch tensile strength for parts with diameters less than 20 mm, as well as corrosion resistance. This facilitates the design of longer and smaller cross section instruments such as arthroscopic instruments and drivers for MIS and microsurgery, as well as cutting and shaping applications because of its edge retention and hardness.

CARPENTER TECHNOLOGIES

ISTOCK.COM / ALEX-MIT

# A BETTER FIT FOR IMPLANTS

## Nickel in the future of medical 3D printing

Those who are old enough to remember may recall the hit American TV show “The Six Million Dollar Man” that ran for five seasons in the mid-1970s. The show featured an astronaut—Colonel Steve Austin—who had been badly injured in a crash. Doctors decided to rebuild him “better...stronger...faster.” It was science fiction then, but now many of those original viewers share something with Colonel Austin: they also benefit from artificial body parts that improve quality of life, ease pain, and improve mobility.

### How additive manufacturing improves hip and joint fit

Artificial joints stand at the top of the list. Globally, millions of individuals have joint replacements. In fact, just in the US, more than a million hip and knee joints are replaced annually. These prosthetic joints are either made entirely of metal, or contain significant quantities of metal. Many metals are used, including stainless steel, nickel alloys, and titanium, in large part owing to their durability and ability to withstand corrosion in the human body.

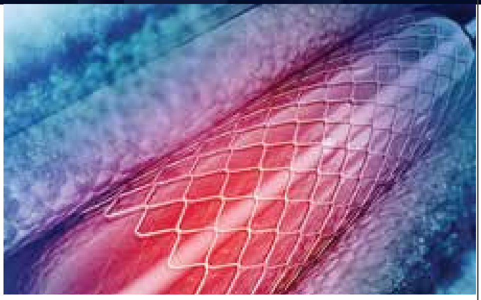
Until now, those parts have been off-the-shelf in standard sizes, but that may soon change. Additive manufacturing (AM—the process of designing finished products on computers and printing in 3D) holds the potential for each joint to be created so that it exactly fits each patient’s needs. A great deal of research is currently focused on this area, to improve the design, functionality, and cost-effectiveness of these implants.

The key single advantage in this new AM technology is the complexity involved in simulating bone. It is difficult to create a complex structure with a level of porosity and texture that allows the actual surrounding bone to embrace the foreign implant. Various techniques have been tried, but nothing comes close to the promise of additive manufacturing in achieving this goal.

### A bright future for 3D printed stents

At the same time, an entirely new potential field for nickel-based implants is about to take off: vascular medicine and the treatment of blood vessels. Global numbers are hard to come by, but in America alone, over 500,000 stents are implanted annually. These are small mesh tubes constructed of metal whose job is to keep coronary arteries open in order for blood to pass.

In this area, the 50-year old nickel-titanium alloy Nitinol (UNS N01555) has shown itself to be superior. Highly flexible and durable, with the ability to maintain a specific geometry (referred to as shape-memory), and a high strength-to-weight ratio, Nitinol has proved to be an ideal candidate for multiple vascular medical applications including stents, valves, and other devices. The shape memory property is particularly valuable, since



ISTOCK.COM / HYWARDS

Nitinol can self-expand and adapt to the shape of blood vessels.

Nitinol can be difficult to work with and few companies have been able to successfully meet the manufacturing challenge of making finished products with conventional manufacturing technologies. However, that all may be about to change, with the likely eventual application of additive manufacturing. Some companies and research institutions are focusing specifically on Nitinol in this regard.

Currently, some AM researchers have been able to develop personalized stents out of polymers. Compared with off-the-shelf medical stents, these are less likely to move in the blood vessel and cause resulting complications.

Some companies also use Nitinol stents cut with lasers, but to date, they have not yet been able to apply additive manufacturing technologies to the effort. Nonetheless, it will probably be just a matter of time before the industry routinely fabricates personalised stents from Nitinol. The Bionic Man would be jealous... Ni

# Neuron-reading nanowires

## Accelerating the development of drugs for neurological diseases

A breakthrough in nanowire technology is enabling researchers to dig deeper into the science of how the brain works, and help identify the most effective drugs for neurological diseases.

**New non-destructive technology**

The team, led by Shadi Dayeh, an electrical engineering professor at the UC San Diego Jacobs School of Engineering, has developed nanowires that can record the electrical activity of neurons in fine detail, allowing researchers to better understand how single cells communicate in large neuronal networks.

The key differentiator? The new nanowire technology is nondestructive and can simultaneously measure potential changes in multiple neurons—with the high sensitivity and resolution achieved by the current state of the art.

The new device consists of an array of silicon nanowires densely packed on a small chip patterned with nickel electrode leads that are coated with silica. The nanowires penetrate cells without damaging them and are sensitive enough to measure small potential changes that are a fraction of or a few millivolts in magnitude.

Researchers can uncover details about a neuron's health, activity and response to drugs by measuring ion channel currents and changes in its intracellular potential. These are due to the difference in ion concentration between the inside and outside of the cell.

This is in contrast to the existing high sensitivity measurement technique. It was ultimately destructive, breaking the cell membrane and eventually killing the cell. It was also limited to analysing only one cell at a time, making it impractical for studying large networks of neurons. And it was not scalable to 2D and 3D tissue-like structures cultured in vitro.

**Wafer bonding innovation**

Another innovative feature of this technology is it can isolate the electrical signal measured by each individual nanowire.

"This is unusual in existing nanowire technologies, where several wires are electrically shorted together and you cannot differentiate the signal from every single wire," Dayeh said.

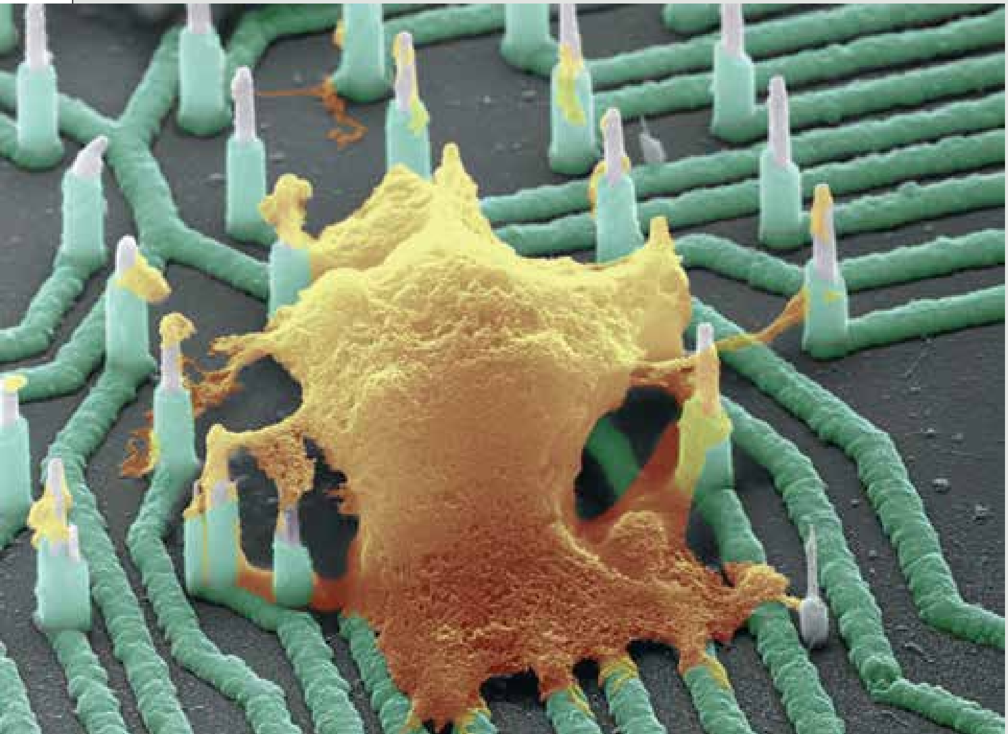
To overcome this hurdle, researchers invented a new wafer bonding approach to fuse the silicon nanowires to the nickel electrodes. They used a process called silicidation, which is a reaction that binds together two solids (silicon and another metal) without melting either material. This prevents the nickel electrodes from liquidising, spreading out and shorting adjacent electrode leads.

Researchers have used the new nanowire technology to record the electrical activity of neurons that were isolated from mice and derived from human induced pluripotent stem cells. These neurons survived and continued functioning for at least six weeks while interfaced with the nanowire array in vitro.

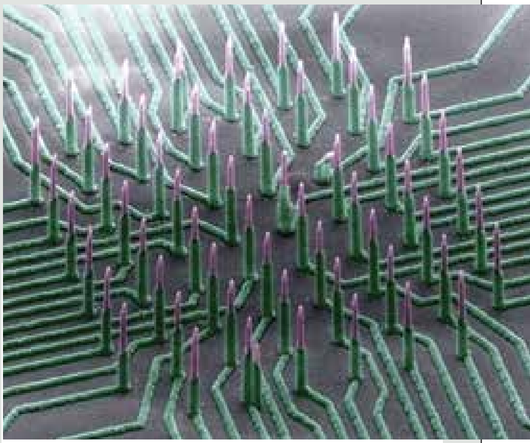
Dayeh noted that the technology needs further optimisation for brain-on-chip drug screening. "Our ultimate goal is to translate this technology to a device that can be implanted in the brain."

"We envision that this nanowire technology could be used on stem-cell-derived brain models to identify the most effective drugs for neurological diseases," said Anne Bang, director of cell biology at the Conrad Prebys Center for Chemical Genomics at the Sanford Burnham Medical Research Institute. Ni

▽ *Colourised SEM image of a neuron (orange) interfaced with the nanowire array.*



▽ *Colourised SEM image of the nanowire array.*



**Silicidation** is usually used to make contacts to transistors, but this is the first time it is being used for patterned wafer bonding. Since this process is used in semiconductor device fabrication, versions of these nanowires can be integrated with CMOS electronics. Dayeh's laboratory holds several pending patent applications for this technology.

INTEGRATED ELECTRONICS AND BIOINTERFACES LABORATORY, UC SAN DIEGO

## UNS details

Chemical compositions (in percent by weight) of the alloys and stainless steels mentioned in this issue of *Nickel.*

| UNS | C | Co | Cr | Cu | Fe | Mn | Mo | N | Nb | Ni | P | S | Si | Ti |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **S20161** p. 11 | 0.15 max | - | 15.0-18.0 | - | bal | 4.00-6.00 | - | 0.08-0.20 | - | 4.0-5.0 | 0.040 max | 0.040 max | 3.00-4.00 | - |
| **S30200** p. 6 | 0.15 max | - | 17.0-19.0 | - | bal | 2.00 max | - | 0.10 max | - | 8.0-10.0 | 0.045 max | 0.030 max | 0.75 max | - |
| **S30400** p. 2, 6, 11 | 0.08 max | - | 18.0-20.0 | - | bal | 2.00 max | - | 0.10 max | - | 8.0-10.0 | 0.045 max | 0.030 max | 0.75 max | - |
| **S30403** p. 11 | 0.03 max | - | 18.0-20.0 | - | bal | 2.00 max | - | 0.10 max | - | 8.0-12.0 | 0.045 max | 0.030 max | 0.75 max | - |
| **S31600** p. 2, 11 | 0.08 max | - | 16.0-18.0 | - | bal | 2.00 max. | | 0.10 max | - | 10.0-14.0 | 0.045 max | 0.030 max | 0.75 max | - |
| **S31603** p. 4, 6, 11, 16 | 0.03 max | - | 16.0-18.0 | - | bal | 2.00 max | 2.00-3.00 | 0.10 max | - | 10.0-14.0 | 0.045 max | 0.030 max | 0.75 max | - |
| **S31673** p. 4 | 0.03 max | | 17.0-19.0 | - | bal | 2.00 max | 2.50-3.20 | 0.10 max | - | 13.0-15.5 | 0.025 max | 0.010 max | 1.00 max | - |
| **S32205** p. 2 | 0.030 max | - | 22.0-23.0 | - | bal | 2.00 max | 3.00-3.50 | 0.14-0.20 | - | 4.50-6.50 | 0.030 max | 0.020 max. | 1.00 max | - |
| **S41000** p. 11 | 0.08-0.15 | - | 11.5-13.5 | - | bal | 1.00 max | - | - | - | 0.75 max | 0.040 max | 0.030 max | 1.00 max | - |
| **S41600** p. 11 | 0.15 max | - | 12.0-14.0 | | bal | 1.25 max | - | - | - | - | 0.06 max | 0.15 min | 1.00 max | - |
| **S42000** p. 11 | 0.15 min | - | 12.0-14.0 | - | bal | 1.00 max | - | - | - | - | 0.040 max | 0.030 max | 1.00 max | - |
| **S43100** p. 11 | 0.20 max | - | 15.0-17.0 | - | bal | 1.00 max | - | - | - | 1.25-2.50 | 0.040 max | 0.030 max | 1.00 max | - |
| **S44002** **S44003** **S44004** p. 11 | 0.60-0.75 0.75-0.95 0.95-1.20 | - | 16.0-18.0 | - | bal | 1.00 max | 0.75 max | - | - | - | 0.040 max | 0.030 max | 1.00 max | - |
| **S45000** p. 11 | 0.05 max | - | 14.00-16.00 | 1.25-1.75 | bal | 1.00 max | 0.50-1.00 | - | 8xC min | 5.00-7.00 | 0.030 max | 0.030 max | 1.00 max | - |
| **S45500** p. 7, 11 | 0.05 max | - | 11.00-12.50 | 1.50-2.50 | bal | 0.50 max | 0.50 max | - | Nb+Ta 0.10-0.50 | 7.50-9.50 | 0.040 max | 0.030 max | 0.50 max | 0.080-1.40 |
| **S46500** p. 11 | 0.02 max | - | 11.00-12.5 | - | bal | 0.25 max | 0.75-1.25 | - | - | 10.75-11.25 | 0.015 max | 0.010 max | 0.25 max | 1.5-1.8 |
| **S17400** p. 11 | 0.07 max | - | 15.00-17.50 | 3.00-5.00 | bal | 1.00 | - | - | - | 3.00-5.00 | 0.040 | 0.030 | 1.00 | - |
| **N01555** p. 4, 5, 8, 9, 12 | 0.005 max | 0.005 max | 0.005 max | 0.005 max | 0.005 max | - | - | 0.025 max | 0.005 max | 54-57 | - | - | - | bal |
| **R30003** p. 7 | 0.15 max | 39.0-41.0 | 19.0-21.0 | - | bal | 1.5-2.5 | 6.0-8.0 | - | - | 14.0-16.0 | 0.015 max | 0.015 max | 1.02 max | - |
| **R30035** p. 7, 15 | 0.02 max | bal. | 19.0-21.0 | - | 1.0 max | 0.15 max | 9.00-10.50 | - | - | 33.0-37.0 | 0.015 max | 0.01 max | 0.15 max | 1.00 max |

# Nickel alloys helping hearts beat stronger

With an aging population, demand is stronger than ever for pacemakers and defibrillators. With increased usage of Magnetic Resonance Imaging (MRI), it is important that permanent implants are made from non-magnetic materials, such as UNS R 30035.

ISTOCKPHOTO.COM / BDSPN

**UNS R 30035 Nickel alloys keeping pace**
UNS R 30035, a cobalt-nickel-chrome-molybdenum superalloy, with 33-37% nickel content, has been used successfully in pacemaker lead wires, conducting signals from the pacing module to the heart. Medical device designers require highly reliable materials because pacemakers are permanent implants, remaining in the body for years.

> with 33-37% nickel content, [UNS R 30035] has been used successfully in pacemaker lead wires

In the last several years, 35N LT® a proprietary version of UNS R 30035 (commonly known as MP35N®), has been developed by US-based Fort Wayne Metals specifically for demanding medical applications. The alloy is double melted, initially using Vacuum Induction Melting (VIM), followed by Vacuum Arc Remelting (VAR). This enables consistent controlled chemistries and exceptionally low inclusions levels, the cause of fatigue failure if it should occur.

"We have seen demand for 35N LT® grow considerably in the medical industry", says David Snyder, process engineer at Fort Wayne Metals. "It is increasingly used for pacing leads due to its excellent corrosion resistance, fatigue resistance and biocompatibility. It is also very cost-competitive in comparison to alternatives, such as platinum and tellurium."

**Supporting higher voltage defibrillators**
While pacemakers use batteries, which release the needed energy slowly, defibrillators require capacitors so high voltage electrical energy can be released quickly. The lead wires for defibrillators are therefore composite wires or drawn filled tubing (DFT) wire manufactured by Fort Wayne Metals. DFT wires consist of narrow tubes made from 35N LT® with a silver wire inside the tube.

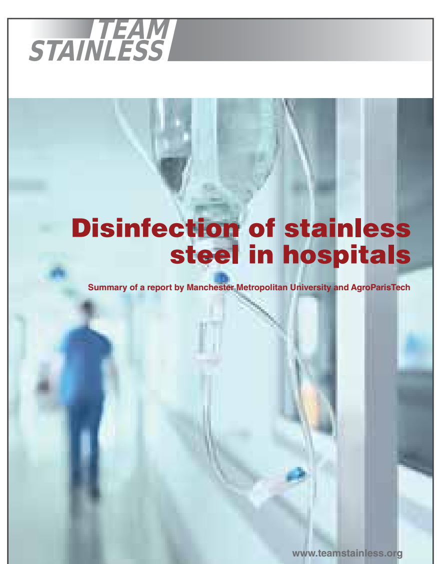
35N LT® is also used for stylets, catheters and orthopaedic cables, among other applications. The excellent features of this material will continue to inspire medical device designers into new possibilities and innovations.

*MP35N® is a registered trademark of SPS Technologies 35N LT® is a registered trade mark of Fort Wayne Metals.* Ni

# DISINFECTION OF STAINLESS STEEL IN HOSPITALS

## New study confirms continuing safety of stainless steel

The continuing safety of using stainless steel in hospital environments has been confirmed in a new study commissioned by Team Stainless. Researchers from Manchester Metropolitan University and AgroParisTech found that there was no discernible difference between the efficiency of disinfection across the range of grades and finishes, and whether or not the stainless steel was new or aged. This confirms the effectiveness of disinfecting stainless steel against bacteria connected with healthcare-associated infections and its ongoing suitability as a material for use in clinical environments.




A summary brochure, *Disinfection of stainless steel in hospitals* is available to download from the Team Stainless website www.teamstainless.org. Ni

# *LIGHT* ON THE LAND

The Taranaki region of New Zealand is ascending in the stainless steel world with the recent unveiling of a public sculpture, *Light on the Land*.

The dramatic stainless steel façade of the Len Lye Centre in New Plymouth made waves internationally in 2015. Now, just 450 metres away on the Taranaki coastline is an impressive work-of-art made from nickel-containing stainless steel.

Measuring 2.5 metres high, 6 metres long and 2.5 metres deep, *Light on the Land* is positioned on the New Plymouth city Coastal Walkway facing the Tasman Sea.

Fabricated by Rivet Engineering, the sculpture is made from Type 316L (UNS S31603), 1.5mm thick stainless steel sheet, and mirror polished to achieve the smooth and highly reflective surface finish. With the sculpture installed along the coastline with strong exposure to wind-borne sea salt, this grade and finish of stainless steel is an optimal specification for long life and aesthetic appearance.

Local artist Howard Tuffery designed the sculpture, which is his first stainless steel masterpiece after 40 plus years of traditionally working with wood and stone.

The Taranaki landscape inspired the sculpture's organic form, and the mirror finish complements this expression by reflecting the surrounding movement around the art work as well as nature.

According to the artist, *Light on the Land* was given its title to invite conversations on conservation and sustainability, while considering the commercial importance and reliance on our land for wealth.

Inspired by memorable artwork in the streets of European cities, the sculpture was commissioned by Nancy Mills, a local

resident, originally from the USA. The gift to New Plymouth was made in honour of her late parents.

Whilst the majestic Mount Taranaki and coastal views from the New Plymouth Coastal Walkway are stunning, this stainless steel sculpture is without doubt adding a touch of elegance to the seaside promenade. Ni

▷ Light on the Land *is positioned on the New Plymouth city Coastal Walkway facing the Tasman Sea.*

CLAY DRUMMOND PHOTOGRAPHY