NICKEL

THE MAGAZINE DEVOTED TO NICKEL AND ITS APPLICATIONS

November 2010 Vol. 25, Nº 2

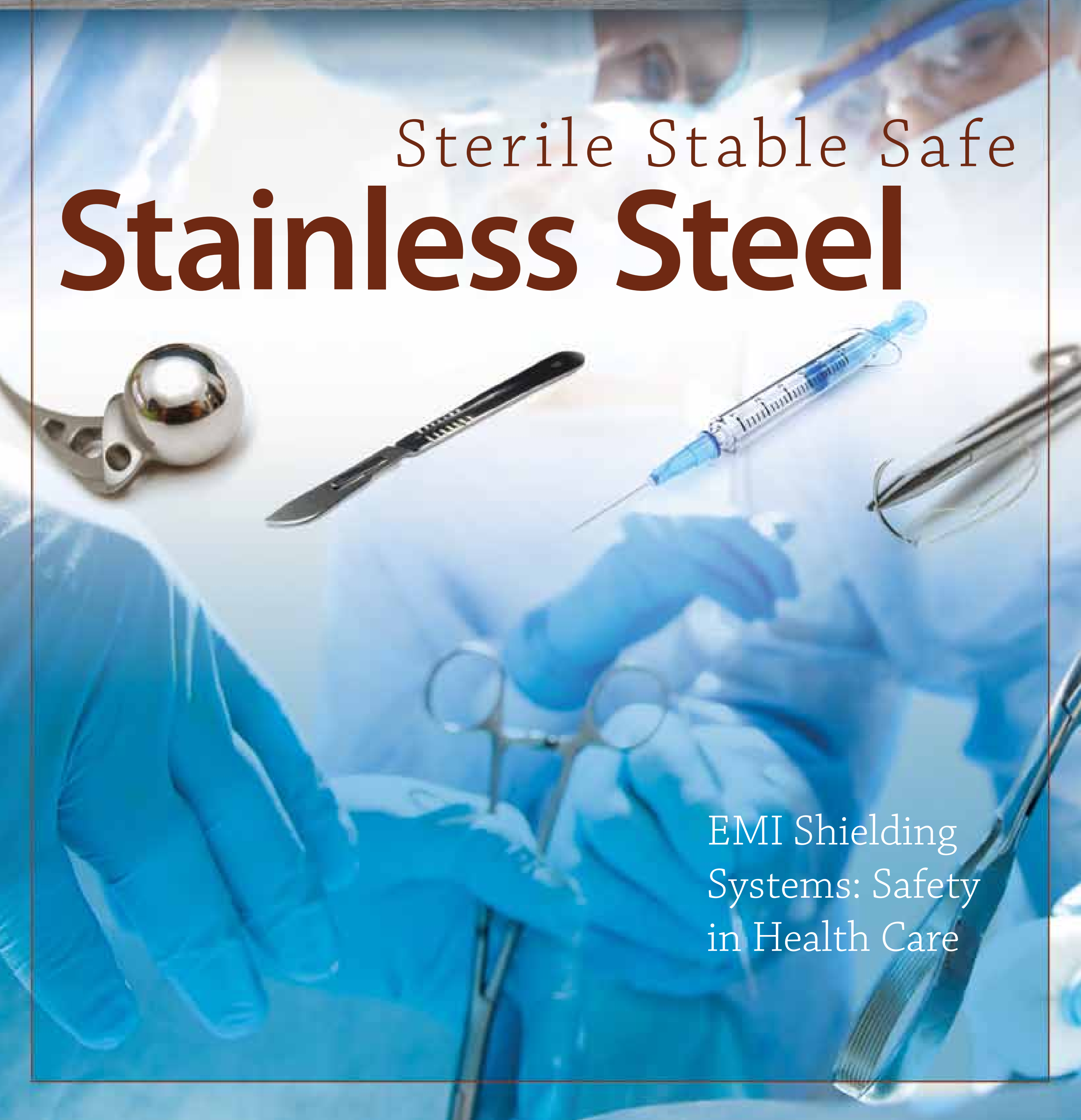
Rx: Stainless Medical and Surgical Tools

Clean and Efficient Drug Manufacturing

The Sharp End: Hypodermic Needles

Sterile Stable Safe

Stainless Steel



EMI Shielding Systems: Safety in Health Care

社会生活中的镍——持久的价值、创新的解决方案
EL NÍQUEL EN LA SOCIEDAD Valor duradero y soluciones innovadoras
NICKEL IN DER GESELLSCHAFT Dauerhafter Wert, innovative Lösungen
社会におけるニッケルの貢献 永続的な価値、革新的な問題解決
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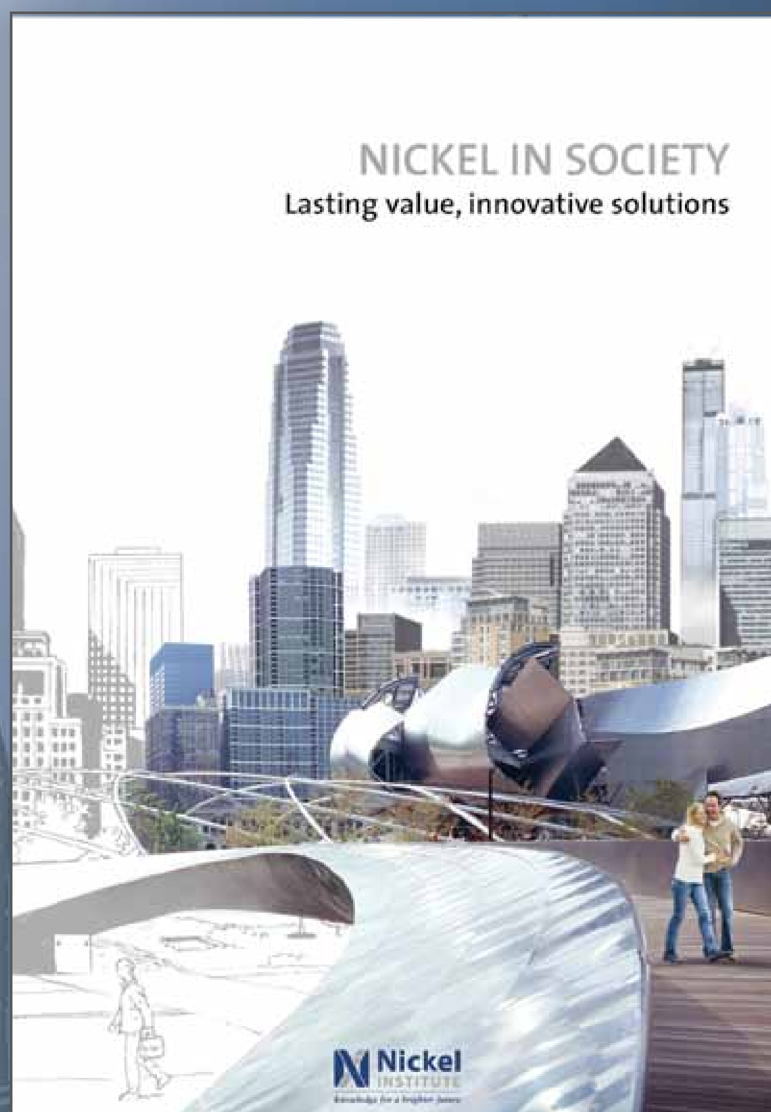

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Nickel INSTITUTE

NICKEL

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Nickel Magazine is published by
The Nickel Institute

Stephen Barnett, President
Stephanie Dunn, Editor
sdunn@nickelinstitute.org

Constructive Communications, Design

The Nickel Institute can be contacted at:
Eighth Floor
Avenue des Arts 13-14
Brussels 1210, Belgium
Tel. 32 2 290 3200
brussels@nickelinstitute.org

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UNSEEN AND UNNOTICED

The last thing anyone thinks about when they or someone close to them is in need of medical attention is the role nickel plays in protecting them or helping them back to health. But nickel is there, sometimes unseen and usually unnoticed.

This issue of *Nickel* explores how nickel-containing materials are used throughout the chain of health, from the manufacturing of pharmaceuticals, where the purity of the product is of paramount importance, all the way to the personal administration of emergency doses of adrenaline (epinephrine) in cases of acute allergic reactions.

One reason nickel tends to go unnoticed, is that in a health care situation, the attention is naturally on the patient and the procedure. Paradoxically, another reason is that nickel-containing materials are so very common in medical environments. An example can be seen in the resurgence of potent strains of influenza, of which the H1N1 variety is just the most recent, has sparked a dramatic increase in the number of vaccinations administered. Every year, billions of hollow needles are used to give flu shots or to deliver other drugs, as well as to remove blood for testing or donation and to provide transfusions. The needles invariably are made of nickel-containing stainless steel.

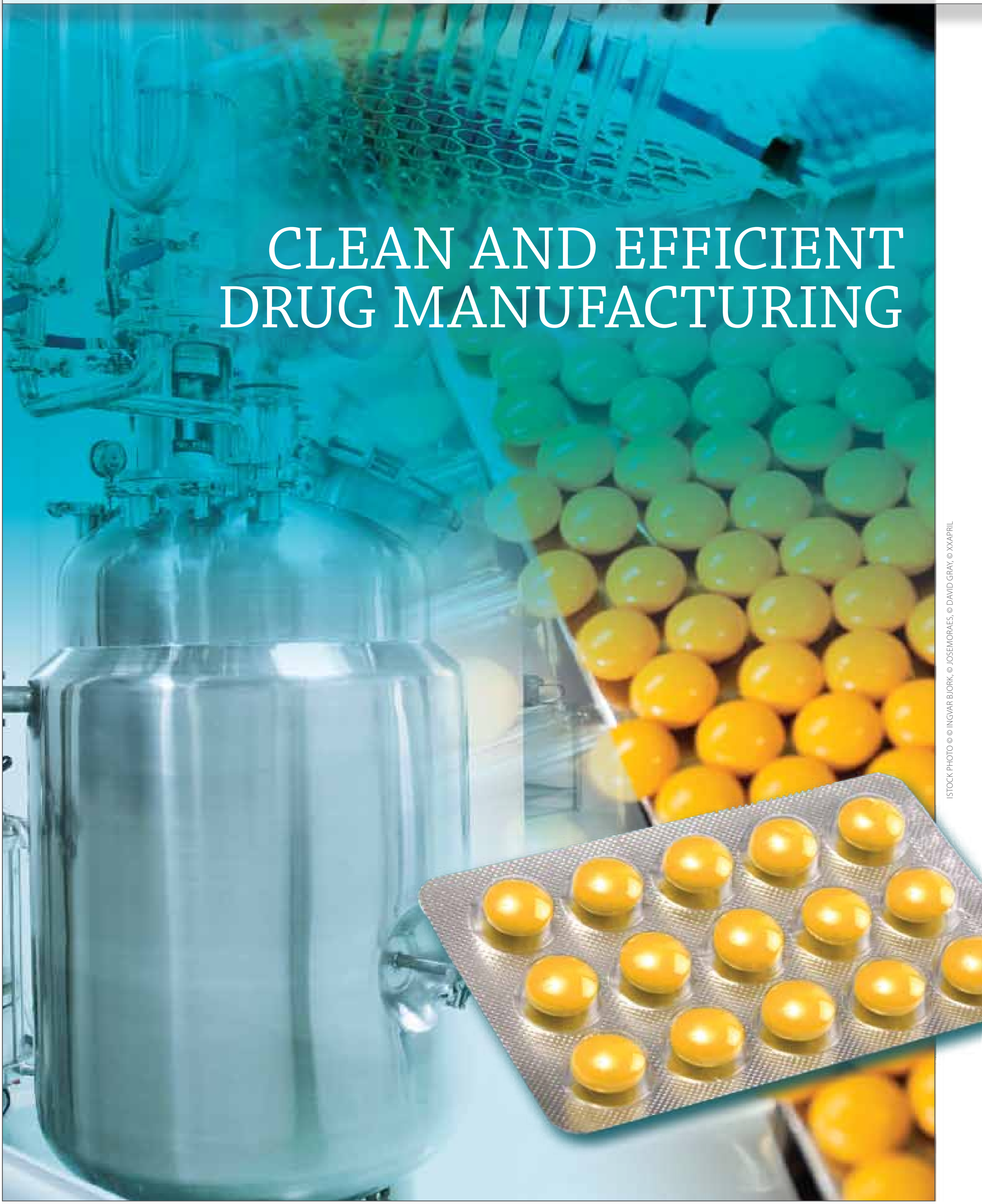
For the professional administering the sterile needle, the focus is on finding the right vein or muscle. For the patient watching the needle approach, the thought is on how much it's going to hurt. Both are grateful, however, that the needle is sharp and has the right combination of rigidity and strength, without being brittle – all qualities made possible by nickel-containing stainless steels.

One of nickel's invisible benefits is in the protection of sensitive imaging and other devices from electromagnetic radiation in health care environments. This protection has many applications, especially in communications. Our article on eletromagnetic interference explains its particular role in ensuring that medical equipment functions properly.

Other articles touch on other areas of the diverse world of nickel use where the pleasures in life are the focus; in dyes used to make colourful cotton clothing (Knowing Nickel: Nickel Sulphate) and in nickel-coated moulds that produce the special sound of vinyl records. No matter how you look at it, nickel plays a vital role in society today.

Stephanie Dunn
Editor, Nickel Magazine

CLEAN AND EFFICIENT DRUG MANUFACTURING



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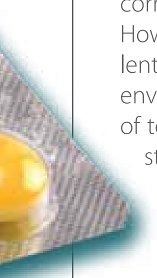
Nickel-containing alloys are the materials of choice for the bio-pharmaceutical industry

Stainless steel 316L (S31603) has traditionally been the workhorse for bio-pharmaceutical production equipment and is likely to remain the dominant alloy in this industry. However, changes in regulatory and performance requirements during the past 15 years have led to the increasing use of more corrosion-resistant nickel-containing alloys for process equipment.

The super-austenitic stainless steels, commonly referred to as the 6% molybdenum family (for example UNS N08367 or S31254) and the nickel base alloys of the nickel-chromium-molybdenum "C" family (e.g. UNS N10276 or N06022) are now the most common high-performance alloys used in the bio-pharmaceutical manufacturing industry.

One obvious incentive for using more corrosion resistant materials is to ensure compliance with U.S. federal regulations, such as Title CFR Parts 210 and 211. Subpart D-211.65 states: "Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements." This implies that corrosion of equipment or product contamination of any kind is not acceptable, and puts high demands on the material of construction.

These regulations have led bio-pharmaceutical companies to specify highly corrosion-resistant alloys. Many of the media used in the industry contain chlorides at acidic-to-neutral pH levels and at low-to-moderate temperatures. Stainless steel S31603 may have unsatisfactory performance in chloride-bearing environments, even at low temperatures, and so corrosion and therefore product contamination becomes a concern. In these conditions the 6% Mo stainless steel alloys generally have far superior corrosion resistance compared to the performance of S31603. However the nickel-chromium-molybdenum alloys have excellent corrosion resistance in a greater range of chloride-bearing environments, both acidic and alkaline, and in a greater range of temperatures thus providing greater versatility than stainless steels for process equipment.



As in any industry, choosing an alloy involves evaluating its cost-effectiveness. Capital expenditures in the sector total about U.S. $4.5 billion per year, including about half a billion dollars in corrosion-related costs. This figure does not include the indirect costs arising from unexpected downtime of critical production equipment and resulting production losses, or secondary effects on inventories and production scheduling. In the biotechnology sector the indirect costs can be 10-20X more than the direct costs. Consider a scenario where one batch of final product has to be discarded due to metal-catalyzed damage to the protein. For example, compare a 120 litre final product vessel constructed of stainless steel 316L (UNS S31603) costing $30,000 and one from a nickel-chromium-molybdenum alloy such as C-22 (UNS N06022) costing $60,000 holding bulk product worth $1,000,000. If one such batch has to be discarded due to some corrosion of 316L, not only the production cost is lost but the potential revenue and profit. Avoiding the loss of even one batch easily covers the extra capital cost of more corrosion resistant materials.

The metallurgical quality of alloys is important since it has a direct impact on corrosion resistance and ultimately on product contamination. The presence of discontinuities on surfaces resulting from the removal of inclusions which intersect the surface can release contaminants, and these in turn affect product quality and yields. Most equipment destined for bio-pharmaceutical applications needs to be of high quality, and it is essential to have a pit-free surface. The normal melting and processing method used to manufacture S31603 makes it difficult to produce a precipitation-free and segregation-free microstructure. The melting and processing of nickel-chromium-molybdenum alloys typically involve electroslag remelting (ESR) to achieve low-segregation characteristics. Therefore these alloys are expected to have a corrosion-resistant microstructure containing very few contaminants.

Corrosion of equipment or product contamination of any kind is not acceptable, and puts high demands on the material of construction.

S31603 is often electropolished and passivated to improve its corrosion resistance and cleanability. High-performance alloys are electropolished primarily to remove scratches, lapping and gouges with possible embedded abrasive compounds. Electropolishing removes these defects and imparts a surface that is microscopically featureless and clean. Electropolishing allows easier and better cleaning, sanitization, and sterilization, thereby lowering cleaning costs and keeping maintenance costs to a minimum.

The American Society of Mechanical Engineers (ASME) bioprocessing equipment (BPE) standard was first published in 1997 and is considered a good manufacturing practice document for equipment fabrication. For 10 years this standard was based solely on stainless steel type S31603. As a result *cont'd on page 15*

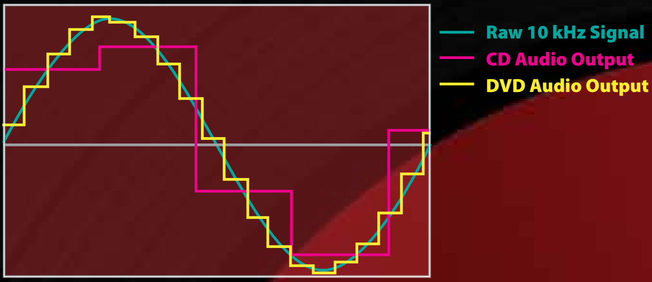
Vinyl

Nickel plays an essential role on both sides

For some, anything new, shiny and digital spells "quality". In the field of audio recording it can spell "compromise". There is, however, one thing that is a crucial part of every process that puts music into the hands and ears of listeners which is not a compromise: electroformed nickel. You may be surprised to learn that electroforming is used not only to produce CDs and DVDs but to make vinyl records as well.

Mainstream music wrote off vinyl 25 years ago. At the time, the future was digital and vinyl was for people who had more nostalgia than sense. But gradually and surprisingly, vinyl has managed to reclaim a place in music reproduction.

For one thing, the idea of "cutting" a record has captured the imaginations of recording artists. In the cutting process, a stylus is moved across the radius of a disc, cutting a precise spiral groove across a flat, lacquer-coated aluminum disc, spinning at an exact speed (33 1/3 r.p.m. for LPs). Although cutting, like digital, is an industrial process, it seems, to a good many artists, more "soulful" than the



way tens of millions of CDs and DVDs are cranked out or the way MP3 files are routinely downloaded.

Another reason for vinyl's staying power is that disc jockeys prefer vinyl because of its versatility and manageability in the making of mixes.

But the main reason vinyl won't go away is sound quality. The growing debate between analogue and digital sound recordings – between the quality of sound produced using vinyl compared with that produced using digital technology – is fierce and long-standing. Moreover, for people who care about such things, there is no neutral ground.

Analogue recording refers to a format of continuous vibrations which are analogous to original sound waves. Before digital took over, sound was cut or carved into vinyl records or written, as magnetic wave forms, to tape. Fact is, all sound is analogue thus all recordings begin that way. When turned into a digital format, the analogue wave is turned into a series of snapshots (i.e., bytes of information) which capture specific moments of the wave – but never the entire wave. Only with vinyl can the original analogue master be transferred in analogue format to the customer.

Whether this makes any noticeable difference to the auditory experience depends on the ear of the listener. Members of the analogue camp insist that the sound is "warmer" and has more "depth" and "character." Others might agree that there is a qualitative difference but that the convenience of digital cancels out vinyl as the medium of choice. Still others may not notice any difference at all.

▽ *Plating lacquer master*

▽ *Packing in sleeves*

Revival

of the ongoing analogue-digital debate

Nickel's role

Nickel plays no favourites. It provides two essential qualities regardless of the form in which the music is preserved: integrity and strength.

In the case of vinyl, polished aluminum or copper discs are coated with a nitro-cellulose lacquer similar to nail polish. It is this lacquer surface that receives the "cut": the analogue musical information is transferred into the grooves using a ruby, sapphire or diamond stylus. No detail is lost. The integrity of the sound is preserved on what is now called the "master."

The master, however, is not capable of surviving the stresses of pressing records. What is needed is something far more robust yet capable of faithfully reproducing the information in the grooves of the master. This is where nickel proves invaluable.

The master is first washed with soap and water and then sprayed with a mixture of tin chloride and liquid silver. The tin chloride is a sensitizer that helps the silver adhere. The result is a fragile master with a silver coating about 1 micrometre thick.

Typically, the lacquer/silver master is then moved to a nickel sulphamate electroplating bath. Metallic nickel is used as the anode and a coating of nickel about 200 micrometres thick is electroplated onto the face of the master.

When this electroplated nickel layer is removed, it carries with it the mirror image of the master and is called the "negative." The process is then repeated, using the negative and the result is called the "father." The father carries the exact same information as the original master; the only difference is that it is now reproduced in nickel instead of lacquer.

Using the same electroformed nickel process, typically two "mothers" (negatives of the father) are made, and from each mother a number of "stampers" are produced. As the name implies, the stampers are the workers of the family. From each stamper between 1,000 and 2,000 vinyl records can be made before deterioration sets in.

So chose your format, but understand that the debate between analogue and digital is not going away . . . and that nickel makes both of them possible. Ni

PHOTOS: ISTOCKPHOTO © KRYSTIAN KACZMARSKI

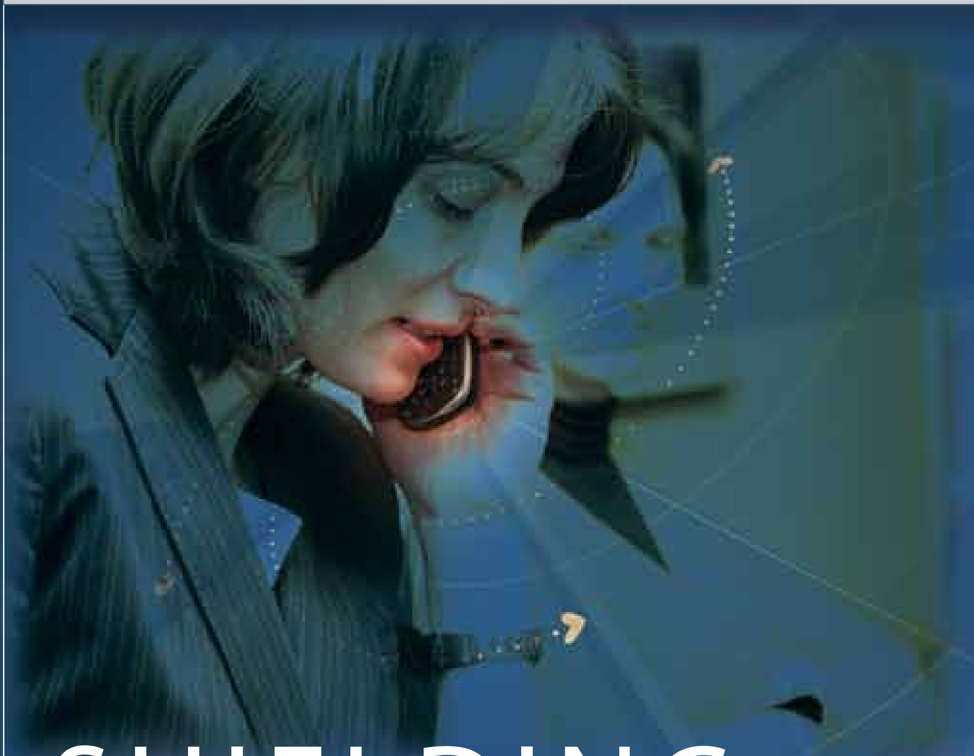
Nickel Plays No Favourites

When CD and, later, DVD formats were developed and perfected, the physical technology for transferring the musical or video information in digital form onto a physical product already existed – the same nickel-dependent process that made the vinyl technology possible.

There are differences of course. The usual master material is optical-quality glass, not aluminum or copper. Whereas the vinyl master usually has a thin silver layer to receive the final electro-deposited nickel coating, this first layer on glass masters for digital discs is more often vacuum-evaporated nickel-vanadium. The final layer in all cases is electro-deposited nickel although typically slightly thicker (~300 micrometres) for glass masters.

For short runs, this first nickel-coated product from the glass master can be used as a stamper. For longer runs, however, the same sequence for vinyl production of master – father – mother – stamper is used.

So whatever the format, nickel makes it happen. Ni



SHIELDING FOR SAFETY

Nickel is the conductive material of choice in the design of electromagnetic shielding systems in the health care industry.

In hospitals, clinics and private homes, shielding electronic medical devices from electromagnetic waves can be literally a matter of life and death. Equipment has been known to malfunction or fail as a result of electromagnetic interference (or EMI, including radio frequency interference or RFI) from cell phones and other electronic devices. EMI causes currents or voltages in one circuit to produce currents or voltages in another circuit. Shielding is applied both to protect pieces of equipment from signals emitted from nearby devices and to prevent electrical signals getting out of the equipment and interfering with other devices.

But as electronics proliferate and become more compact and portable, designing foolproof shielding solutions for the health care sector is becoming more of a challenge. Meanwhile regulatory bodies are developing increasingly comprehensive standards to prevent medical devices from interfering with one another and be affected by outside sources of EMI/RFI.

Two things make the design of EMI/RFI shielding for health care environments unique. First, medical devices are often used close to one another and to other electronic equipment, making them highly susceptible to interference. Second, the shielding mechanisms must be able to resist chemicals that are used to clean and sterilize such devices.

Nickel is playing an integral role in this growing field of design. Although just about any conductive metal can offset EMI/RFI to some degree, nickel has a high magnetic permeability and corrosion resistance and is available in small flakes that can be applied in a polymer coating or able to be plated on other materials.

For example MG Chemicals, a Canadian manufacturer of chemical products for the electronics industry, makes a simple nickel coating which is widely used in consumer electronics to prevent EMI/RFI and which has potential applications in health care.

> "...the nickel coating is by far the most popular as it's highly effective at most frequencies. It's also less expensive than the alternatives and capable of blocking both magnetic and electric waves."

The acrylic coating, containing about 40-70% nickel flake by weight, can be sprayed inside the plastic enclosure to provide homogenous protection of the electronic device within as well as EMI from escaping. Since the coating is applied to the inner surface of the enclosure, there is no chance of user contact with the nickel.

Although the company also produces silver coatings and silver-coated copper coatings, President Howard Clark says the nickel coating is by far the most popular as it's highly effective at most frequencies. It's also less expensive than the alternatives and capable of blocking both magnetic and electric waves.

"At certain frequencies, such as in military applications, silver outperforms nickel, but nickel will do the job for most of our customers," Clark says.

Shielding becomes more complicated when there are seams or other openings in the electronic enclosures, as is often the case with medical equipment that requires cables, switches, and monitors. Electromagnetic radiation can leak through even the tiniest crack.

In this case, conductive gaskets can be used for both EMI/RFI shielding and sealing against environmental contaminants such as dust. There is a wide variety of gasket designs, depending on the properties and requirements of the enclosure and the frequency of the radiation, and nickel is often an important component.

For example, the foam gaskets produced by the Chomerics division of Cleveland, Ohio-based Parker Hannifin Corporation provide effective shielding and excellent compression-deflection. They consist of a fine knitted wire mesh commonly made of MONEL® (a nickel-copper alloy) fitted over a soft urethane foam core. The gaskets are especially useful in enclosures with tight space constraints or in ones that require low closure force.

The latest products to enter the market allow EMI shielding to be integrated into the plastic moulding of the enclosure, eliminating the expense of designing a separate shield. An example is Chomerics Premier: an injection-moulded thermoplastic resin which is impregnated with conductive nickel-plated carbon fibres. The moulded sections can be as thin as 2 mm yet have high mechanical strength and are stable at temperatures of up to 180° Celsius.

Shielding the electronic components of a medical device still leaves its monitor(s) unprotected. Chromerics also produces lightweight glass and plastic windows that provide EMI shielding with good optical clarity and image resolution. The shielding is provided by knitted or woven wire mesh – sometimes made of stainless steel – which is laminated between the glass or plastic substrates.

Compliance requirements for medical devices are stringent. International standards require manufacturers to specify that the electromagnetic compatibility (EMC) of their medical devices is acceptable. (EMC is the ability

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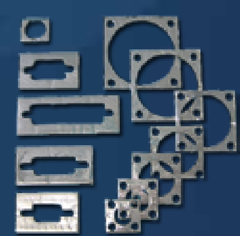
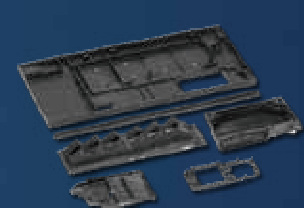
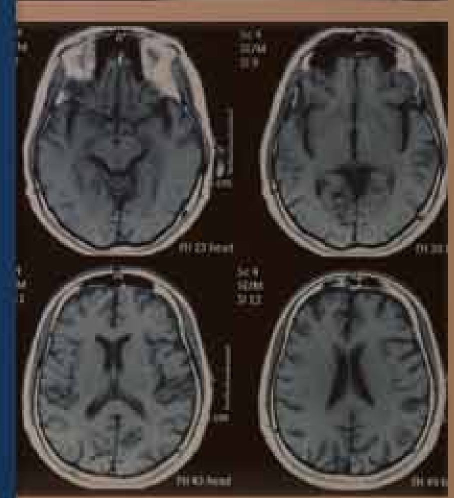
△ UPPER: MONEL mesh material for flexible gaskets.
▽ LOWER: Gaskets, again using MONEL, for small openings required for electrical supply





△ Chomerics Premier injection-moulded thermoplastic resin impregnated with conductive nickel-plated carbon fibres

△ Lightweight glass and plastic windows provide EMI shielding with good optical clarity and image resolution



ISTOCKPHOTO © YUMIYUM, © SCOTT HIRKO, © MARK KOSTICH © YARINCA, © KARL DOLENC SHIELDING PRODUCTS COURTESY OF CHOMERICS, HOLLAND SHIELDING SYSTEMS

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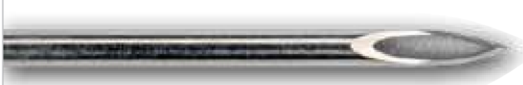
Nickel-containing stainless steels make the hypodermic needle a life-saver

THE SHARP END



VITA NEEDLE COMPANY

Practically everyone has been on the receiving end of a hypodermic needle. It's a workhorse in the medical world, delivering drugs and inoculations, drawing blood samples, and generally saving lives. The hypodermic needle is a simple device – a thin, hollow metal needle attached to a plastic plunger – but it's an essential part of today's medical toolkits.

The hypodermic (Greek for "under the skin") was developed in the mid-nineteenth century. The needle itself, known as the "cannula" (Latin for "little reed"), must be strong, sharp-tipped and sterile. The alloys of choice are grades 304 (UNS S30400) and 316 (S31600) stainless steel, which have "excellent corrosion resistance and strength capabilities, making them ideal for medical applications," says Frederick Hartman II, director of marketing and engineering for Vita Needle Company Inc. of Needham, Massachusetts, U.S.A. The company produces fully assembled syringes and sharpened cannula for customers in North America, Europe, Asia and the Middle East.

Vita Needle has been using 300-series stainless in its manufacturing process since the company was founded in 1932. Hartman estimates the company transforms five tons of stainless into needles every year.

◁ *Cutting stainless steel tubing in preparation for grinding needle tips*

"The material is versatile, cost-effective and has predictable properties," says Hartman. "It's also popular in a variety of applications, which means tubing is easy to source at a reasonable cost. And since there's a lot of material available, it's easy to find sizes that correspond with customers' needs."

The exceptional workability of the material enables the needles to be made to precise tolerances. Stock tubing is cut electrochemically and the needle tip can be formed electrochemically or by using abrasives.

The needles are in a hard-tempered condition with a high tensile strength. "You want the needle tip to be as sharp as possible, wide enough to draw or inject material efficiently, thin–walled, and strong," Hartman explains. In addition, the corrosion resistance of 304 and 316 means the needles can be stored in a variety of conditions or, for re-usable needles, aggressively sterilized, without fear of corrosion.

In order to be used in health care, the material must be easily sterilized and must not be harmful to human health, which are chief properties of the 300 series of stainless steels. Most syringes used in hospitals and doctors' offices are intended for one-time use, yet 300-series stainless steel is durable and well-suited for specialized needles that are cleaned and reused. Ni

NICKEL(II) SULPHATE

$NiSO_4$ - a mainstay of the nickel plating industry

This is the second in a series of articles spotlighting nickel chemicals (see Volume 25, No. 1 for information on nickel hydroxide).

While the majority of nickel is used for the production of nickel-containing alloys, approximately 15% of all nickel goes into the making of nickel chemicals, of which nickel sulphate is one of the most widely used in its salt form but can also be marketed in small amounts in solution.

Nickel sulphate – or Nickel(II) sulphate – is a highly soluble salt which is yellow in colour in its anhydrous form but has shades of green to blue-green in the more commonly produced hydrated forms. Industrial electroplating of nickel is its most prominent end-use.

About 10,000 tonnes of nickel sulphate are produced each year with an average nickel content of around 22% in the hexahydrate crystal form. Various levels of purity are also available depending on the application.

Nickel sulphate is used directly and indirectly in the production of certain pigments and dyes, batteries and catalysts. It is also used as an intermediate in the production of other nickel chemicals. For instance, nickel carbonate, which is also used in certain catalysts and for pigments, is produced by reacting nickel sulphate with sodium carbonate. Nickel sulphate is used to improve colour fastness of dyes, especially in cotton textiles. It can also be used to produce certain decorative finishes such as "blackened bronze".

PHOTO: AMERICAN STANDARD JASMINE WIDESPREAD LAVATORY FAUCET

◁ *Blackened bronze achieved using $NiSO_4$.*

However, its most important use is as the key constituent of solutions in nickel plating baths.

Plating

There are many reasons for plating a surface with nickel and several ways to achieve the desirable end-results, including low-friction, high hardness and high corrosion resistance. Plating can also provide a base for the adherence of a decorative finish coat such as gold, chromium or iridium. On circuit boards, a flash coat of nickel is usually applied prior to the deposition of copper, which provides the electrical pathway.

Not all nickel plating processes require the use of nickel sulphate, but its presence is key in the most common of them all, the "Watts electrolyte," in which nickel sulphate is supplemented at a ratio of about 1:8 with nickel chloride. Using other additions, metallic surfaces ranging from brilliant to satin can be achieved.

Sulphate-chloride solutions having equal amounts of both salts allow faster and thicker deposition of nickel than is possible in a Watts bath. Nickel sulphate solutions without nickel chloride are mainly used to allow plating in the slightly "hidden" areas of tubes and small fittings. Where high-tensile strength and hardness are required, ammonium chloride is added to the nickel sulphate bath at a ratio of 1:7. Nickel sulphate is also commonly used in electroless nickel processes.

For more information on nickel plating, see NI publication No. 10088 Nickel Plating and Electroforming, downloadable from our website. http://www.nickelinstitute.org/index.cfm/ci_id/3307/la_id/1/document/1/re_id/0 Ni

Common name variants:
Nickel(II) sulphate $NiSO_4$
Nickelous Sulphate

CAS numbers:
Anhydrous form: yellow solid
CAS number: 7786-81-4

Hexahydrate form: emerald green crystals
CAS number: 10101-97-0

Heptahydrate: green crystals
CAS number: 10101-98-1

EINECS number:
232-104-9

Properties (hexahydrate)

Molar mass:
262.84 g/mol

Density:
2.07 g/cm³

Crystal structure:
tetragonal

Specific gravity:
2.07

Melting point:
53° C

PHOTO © MASHADI TRADING CO. LLC

PHOTO COURTESY OF BENJAH-BMM27

Rx: STAINLESS

Nickel-containing stainless steels are a vital component for medical excellence

Mention "sterile material" and "stainless steel" in the same sentence and many people will immediately think of a hospital environment. Although stainless is not *inherently* sterile, it has many medical uses as a sterile material. That's because it can be treated repeatedly with aggressive disinfecting chemicals without suffering deterioration. This is particularly important in hospitals and medical offices where harmful organisms from outside could easily spread. Two medical applications where sterility is especially important are implants and tools.

Orthopedic implants such as knee, hip and other joint replacements, and the associated screws, plates and wires are typically made from stainless steels. Other metals used include alloys based on cobalt (which often contain nickel) and on titanium. The stainless implants typically rub against a hard plastic called polyethylene as the joint moves. Some other designs use ceramic implants. The number of joint replacement surgeries is increasing at a rapid rate worldwide.

Materials for implants need to be compatible not only with the human body but with post-treatment diagnostic techniques such as X-ray and magnetic resonance imaging (MRI). To allow safe examination by MRI, implants must contain only non-ferromagnetic materials. To ensure the absence of the ferro-magnetic ferrite phase, additional amounts of austenite forming elements such as nickel, nitrogen and manganese are used in these austenitic stainless steels.

Photos: © thiebaut, iStockphoto © mediaphotos

Industry specifications for four commonly used stainless implant materials are ASTM F138 (S31673), F1314 (S20910), F1586 (S31675) and F2229 (S29108). Because these standards require the alloy to be very "clean", i.e. to have low concentrations of non-metallic impurities such as sulphides, silicates and oxides, they are generally made using electro-slag remelting (ESR). ESR is an extra refining step that give stainless steels outstanding micro-cleanliness levels to meet these specifications. It can also meet the other special requirements of these ASTM specifications for implant materials, such as having a fine-grained microstructure.

> The market for medical tools and instruments is about US$30 billion worldwide, and stainless steel is a big part of it.

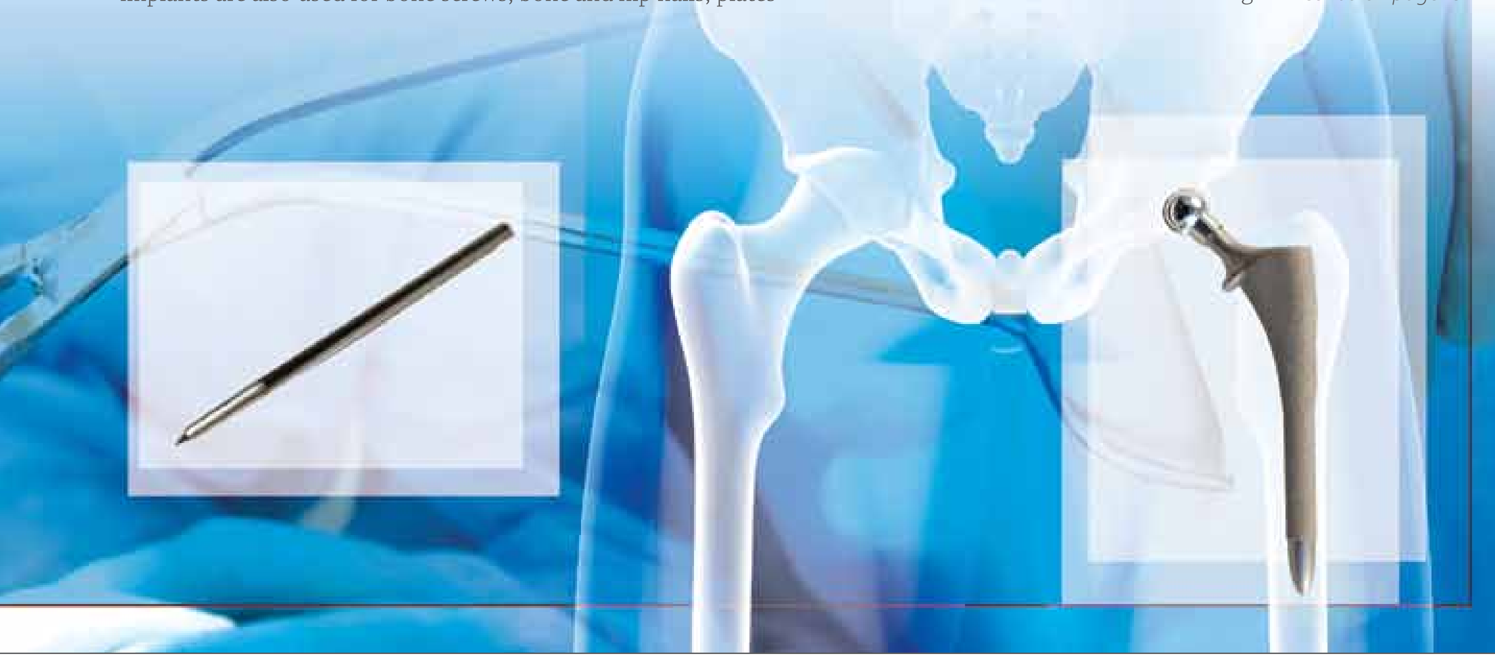
Long-term clinical experience with S31673 stainless steel implants made to ASTM F138 confirms that it has acceptable bio-compatibility with the human body. This stainless steel is one of several control materials against which new materials are compared for bio-compatibility. The F138 standard notes that no surgical implant material can be guaranteed to avoid adverse reactions such as inflammation in the body. A very low nickel implant grade (S29108) can be used by patients who are especially sensitive to the metal.

Some of the same grades of stainless that are used in orthopedic implants are also used for bone screws, bone and hip nails, plates and wires. For screws that require exceptional mechanical strength, UNS S17400 (commonly known as 17-4PH or Type 630) stainless steel is used. This is a precipitation-hardenable grade that is heat treated to obtain the desired strength.

Medical tools and instruments represent another major application of stainless steels. The market for these items is about US$30 billion worldwide, and stainless steel has a large part of it. Nickel-containing stainless steels are used to manufacture retractors (for holding back underlying organs and tissue when surgery is performed), knives and other cutting and gouging instruments, forceps, tweezers, and scissors.

Recent medical developments have seen a rise in minimally invasive surgery, that is, surgery done with only a small incision or none at all. The benefits to patients include less body trauma, faster recovery times, shorter hospital stays, and lower health-care costs. Consequently, hospitals are requiring more instruments (small diameter but long) be designed for these procedures. On a global scale, the production of minimally invasive surgical devices is growing by nearly 8% each year.

Stainless steels used in medical tools and instruments must have specific mechanical properties and be able to withstand both body fluids and the chemicals used for cleaning *cont'd on page 15*



Nickel in Mobile Phones

The Nickel Institute is aware of recent media attention on possible allergic skin reactions from direct and prolonged contact with nickel-containing materials on the surfaces of some mobile (cell) phones. Such possible allergic reactions can be prevented and the Nickel Institute has been in discussion with major phone manufacturers about it since 2000.

Nickel release from the surface of a cell phone is the important factor, not the actual nickel content. This is recognised by countries which have placed nickel release limits on objects such as jewellery which are intended to be in close and prolonged contact with the skin: for example, the EU's 1994 Directive 94/27/EC as amended. In 2008, the EU clarified that the Directive does apply to the surfaces of mobile phones (see Nickel Vol 24, No 2, July 2009, http://www.nickelinstitute.org/index.cfm/ci_id/19074.htm).

"Prolonged" has been defined by the EU as 30 minutes or longer of close contact of a mobile phone with a user's face. Therefore if simple precautions are taken, such as using a hands-free kit, cover, loudspeaker or simply keeping calls short, possible nickel allergy should not be an issue.

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The Nickel Institute actively supports appropriate regulation and voluntary initiatives by manufacturers to prevent the possibility of allergic reaction from nickel-containing materials on the surfaces of phones. Thus the Nickel Institute welcomed recent research which provided a deeper understanding of the mechanism of nickel allergy (http://www.nickelinstitute.org/index.cfm/ci_id/19239/la_id/1.htm).

Nickel-containing materials continue to play an important role in many of the electronic and other internal components of mobile phones.

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Update: REACH Reached

On 28 September, more than a month in advance of the 30 November 2010 deadline, the Lead Registrants for the last 8 nickel dossiers managed by the Nickel REACH Consortia received confirmation from the European Chemicals Agency (ECHA) that registration of their dossiers was complete.

The registration process began in April 2010 with the registration of Nickel Metal and Nickel Sulphate by the Lead Registrants. Three additional substances were successfully registered in July 2010.

The registration of these 13 dossiers was challenging and necessitated the cooperation of

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UNS details

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

	C	Co	Cr	Cu	Fe	Mn	Mo	N	Nb	Ni	P	S	Si	V	W
N06022 p. 5	0.015 max	2.5 max	20.0-22.5		2.0-6.0	0.50 max	12.5-14.5			rem	0.02 max	0.02 max	0.08 max	0.35 max	2.5-3.5
N08367 p. 5	0.030 max		20.0-22.0		rem	2.00 max	6.00-7.00	0.18-0.25		23.50-25.50	0.040 max	0.030 max	1.00 max		
N10276 p. 5	0.02 max	2.5 max	14.5-16.5		4.0-7.0	1.0 max	15.0-17.0			rem	0.030 max	0.030 max	0.08 max	0.35 max	3.0-4.5
S17400 p. 13,15	0.07 max		15.0-17.5	3.00-5.00		1.00 max			0.15-0.45	3.00-5.00	0.040 max	0.030 max	1.00 max		
S20910 p. 13	0.06 max		20.50-23.50			4.00-6.00	1.50-3.00	0.20-0.40	0.10-0.30	11.50-13.50	0.040 max	0.030 max	1.00 max	0.10-0.30	
S29108 p. 13	0.08 max		19.00-23.00	0.25 max	rem	21.00-24.00	0.50-1.50	0.85-1.10		0.05 max	0.03 max	0.01 max	0.75 max		
S30400 p. 10,15,16	0.08 max		18.00-20.00			2.00 max				8.00-10.50	0.045 max.	0.030 max.	1.00 max		
S31254 p. 5	0.020 max		19.50-20.50	0.50-1.00		1.00 max	6.00-6.50	0.180-0.220		17.50-18.50	0.030 max	0.010 max	0.80 max		
S31600 p. 10	0.08 max		16.00-18.00			2.00 max	2.00-3.00			10.00-14.00	0.045 max	0.030 max	1.00 max		
S31603 p. 5,15	0.030 max		16.00-18.00			2.00 max	2.00-3.00			10.00-14.00	0.045 max	0.030 max	1.00 max		
S31673 p. 13	0.030 max		17.00-19.00	0.50 max		2.00 max	2.00-3.00	0.10 max		13.00-15.50	0.025 max	0.010 max	0.75 max		
S31675 p. 13	0.08 max		19.5-22.0	0.25 max		2.00-4.25	2.0-3.0	0.25-0.5	0.25-0.8	9.0-11.0	0.025 max	0.01 max	0.75 max		
S42020 p. 15	Over 0.15		12.00-14.00			1.25 max	0.60 max (optional)				0.060 max	0.15 min	1.00 max		
S43100 p. 15	0.20 max		15.00-17.00			1.00 max				1.25-2.50	0.040 max	0.030 max	1.00 max		
S44004 p. 15	0.95-1.20		16.00-18.00			1.00 max	0.75 max				0.040 max	0.030 max	1.00 max		

Clean and efficient drug manufacturing

cont'd from page 5

of the increased use of high-performance stainless steels and nickel base alloys, the latest (2009) edition includes both the 6% molybdenum stainless steels and the nickel-chromium-molybdenum nickel base alloys.

One thing is abundantly clear: the high performance nickel base alloys play a vital role in the manufacture of high-quality drugs. Ni

Shielding for Safety

cont'd from page 9

of a device to be used in its intended environment without causing or receiving degradation due to unintentional electromagnetic interference.) Manufacturers must also comply with standards set by the Center for Devices and Radiological Health (a division of the American Food and Drug Administration), the Association for the Advancement of Medical Instrumentation (also based in the U.S.), and the European Union's Medical Device Directive.

As applications for EMI/RFI shielding in the medical field proliferate, nickel is proving invaluable as a conductive material in the design of shielding systems for many devices. Ni

Rx Stainless

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and sterilizing. They must also comply with industry specifications. ISO 7153/1 contains a survey and a selection of stainless steels available for use in the manufacture of surgical, dental and orthopedic instruments and ASTM F899 is a standard specification for wrought stainless steels for use in surgical instruments.

Stainless surgical instruments are often made from hardenable martensitic stainless steels. Common grades include 431 (S43100), 420F (S42020), 440C (S44004) and 17-4PH (S17400). Some of these grades contain up to 4% nickel.

The familiar austenitic stainless steel grades Type 304 (S30400) and Type 316L (S31603) are used to make instruments that do not require high strength and hardness. They have much greater corrosion resistance than the 400-series hardenable martensitic stainless steels.

It's worth noting that the term "surgical stainless steel," often used by advertisers to describe jewelry, watch bands, and even cookware, normally refers to one of the 300-series grades; however, the term is not precise and does not specify any particular alloy specification.

Advances in health care are ever developing, and it's good to know that stainless steels, especially the nickel-containing grades, are helping to make those advances possible. Ni

Mobile Phones

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Information and guidance on how to avoid the possibility of allergy in common situations, including the use of mobile phones, is available on the Nickel Institute's website (http://www.nickelinstitute.org/1/1/2/index1.shtml) Ni

REACH

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many participants in the Nickel industry value chain including importers and producers as well as downstream users such as the stainless steel, alloy, plating, batteries and catalyst industries. The success was been made possible by the excellent work of the Lead Registrants who made a considerable effort to achieve registration well before the deadline.

Dr. Kevin Bradley, speaking on behalf of the Nickel Institute that managed the process for the Nickel Consortia, said: "This achievement sets the stage for everything that comes after. The important thing now is for companies that have not been active contributors and have yet to complete their REACH registration to do so as soon as possible."

Additional information on the responsibilities of producers, importers and users of nickel and nickel chemicals can be found at http://www.nickelconsortia.org/ and more generally on the site of the European Chemicals Agency: http://echa.europa.eu Ni

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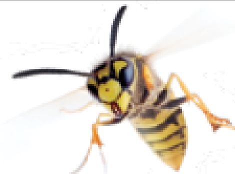
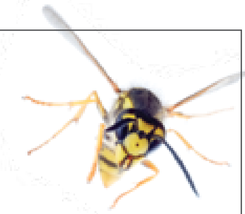
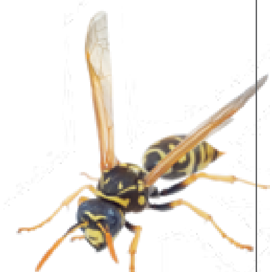
www.youtube.com/user/NickelInstitute





Life Saver

Corrosion-resistant stainless steel needles in epinephrine injection pens remain sterile until needed



The emergency injection of a drug to counter severe allergic reactions provides one example of a life-saving application of hypodermic needles. The EpiPen®, invented in the mid-1970s, uses a sterile needle made of nickel-containing stainless steel.

The EpiPen is a handheld, automatic injection device which contains epinephrine (adrenaline) for allergic emergencies. The epinephrine is crucial in the treating anaphylaxis, which is triggered by allergic reactions to certain foods (peanuts or eggs, for example), bee or wasp stings and other allergens. Those susceptible to anaphylaxis can die literally within minutes: swelling shuts off air passages and the victim's blood pressure plummets, causing convulsions. Unless the epinephrine is administered at once, the victim will often die or they are likely to suffer severe long term effects.

Invented by Sheldon Kaplan (1939-2009), an American engineer, the EpiPen auto-injector is a form of first-aid which is delivered immediately into the muscle of the thigh, through clothing if necessary.

Many scientists believe that the number of people with food allergies is on the rise, and not coincidentally, so is the number of foods to which they are allergic. Children in particular are increasingly having allergic reactions to certain foods. "It is generally believed that the limited data currently available represent an under-reporting of food allergy-related reactions and deaths," the Food Allergy & Anaphylaxis Network in the U.S. reports. Indeed, for every case reported, there are perhaps two or three that don't get reported.

> "It's reliable, safe and ready-to-use over its entire lifetime, and that's partly because of the durable, hygienic and corrosion-resistant needle."

All of which makes the epinephrine injection device – and by extension, nickel – indispensible in the saving of lives.

Type 304 (UNS S30400) stainless steel needles are the industry standard for medical applications, and the EpiPen is no exception. "Stainless steel needles can be sterilized without degradation," says Ava Armstrong, marketing director for King Pharmaceuticals Canada, which manufactures the EpiPen in Canada. "Our patients rely on this product to treat severe allergic emergencies. It's reliable, safe and ready-to-use over its entire lifetime, and that's partly because of the durable, hygienic and corrosion-resistant needle."

Epinephrine auto-injectors have been used now for some 25 years. The needle, which is similar to that used in a typical syringe, has a protection feature which prevents exposure to its point before and after use. After it is used, the cover automatically extends beyond the needle. As a result, the needle is not exposed before, during or after injection.

"The prompt and correct administration of epinephrine during a severe allergic reaction can help save lives," confirms Dr. Susan Waserman, an allergist and immunologist at McMaster University in Hamilton, Canada. "Ease of use and simplicity in a crisis can make a significant difference for users during a health emergency." Ni

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