

Metal Allergy Information for Patients

This document was prepared to summarize information about metal allergies for patients undergoing treatment at Minimally Invasive Procedure Specialists (MIPS). If you have any remaining questions or concerns after reviewing this information, please speak with your provider.

What are the different types of stents?

Several types of stents exist and can vary in any of the following characteristics:

- Where they are placed in the body (e.g., in the brain, artery, or vein)
- What materials they are made of/contain (e.g., nitinol, elgiloy, or stainless steel)
- How they are deployed (e.g., self-expanding or balloon-expanding)
- The sizes they come in (diameters ranging from 2mm to 26mm and lengths ranging from 20mm to 150mm)¹
- Many other characteristics like flexibility, radial force, or crush resistance

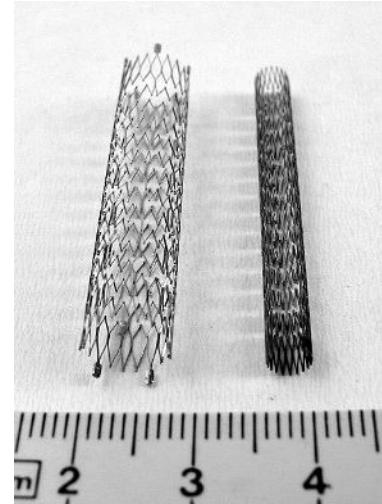


Image 1. Examples of what a stent may look like. (Image sourced from Frank C. Müller; no changes were made to this image. Distributed under the following license: <https://creativecommons.org/licenses/by-sa/2.5/deed.en>.)

Choosing the correct stent depends on where the stent will be deployed. For example, a stent that is going to be placed in an artery is typically smaller in diameter when compared to a stent that is being placed in a vein.

At MIPS, two types of stents are typically used: the Medtronic Abre self-expanding stent (made of nitinol) and the Boston Scientific Wallstent (made of elgiloy). Nitinol is an alloy (or combination of metals) made of approximately half nickel and half titanium. Elgiloy is an alloy that contains approximately 14-16% nickel, in addition to 39-41% cobalt, 19-21% chromium, 6-8% molybdenum, 1.5-2.5% manganese, and the remainder is made of iron. Elgiloy may also contain small amounts of carbon, silicon, phosphorus, sulfur, or beryllium.³ Some other stents use stainless steel or other metals and materials, but these stents are often not as flexible and would not be suitable for veins.

What is nickel allergy?

The term allergy is a broad category that refers to your body's immune system responding to a substance in the environment and triggering a reaction. A few common symptoms of a systemic (or widespread) allergic reaction include rash, hives, nausea, difficulty breathing, and swelling of the lips, tongue, or airway. The mechanism (or process by which something occurs) behind an allergy often depends on the trigger.⁴ Allergies can be triggered by a variety of factors, including environmental triggers, food, medication, and even other substances, such as metals.

Metal allergies differ from systemic allergies since they generally only cause localized T-cell-mediated reactions. This means that the local inflammatory cells in the skin react and cause symptoms at a specific site, rather than a reaction occurring across the entire body, as seen in systemic allergies. It is rare for metal allergies to cause a systemic or widespread reaction. One common type of metal allergy is a nickel allergy. An allergy to nickel is present when direct contact with nickel causes a localized reaction. Commonly, a nickel allergy can result in reactions to everyday items, such as earrings, bracelets, and watches.⁵

An allergic reaction to nickel happens when the nickel comes into contact with the skin, and a hapten—or small molecule that can cause an immune response, in this case a metal ion—binds to a skin protein carrier, which is a protein that helps transport substances through the skin. Once passing across the skin barrier, the hapten and protein carrier complex interacts with T cells—a type of white blood cell that helps to fight infection—and may cause the T cells to become increasingly responsive to the substance. This process of the T cells becoming increasingly reactive to a specific substance is called sensitization. When sensitized T cells encounter nickel haptens in the future, the T cells trigger the release of cytokines, which are proteins that signal the immune system to fight an infection.^{5,6} In summary, when nickel comes into contact with the skin, a chain reaction of events can begin, culminating in T cells triggering the release of cytokines, which leads to a localized allergic reaction.

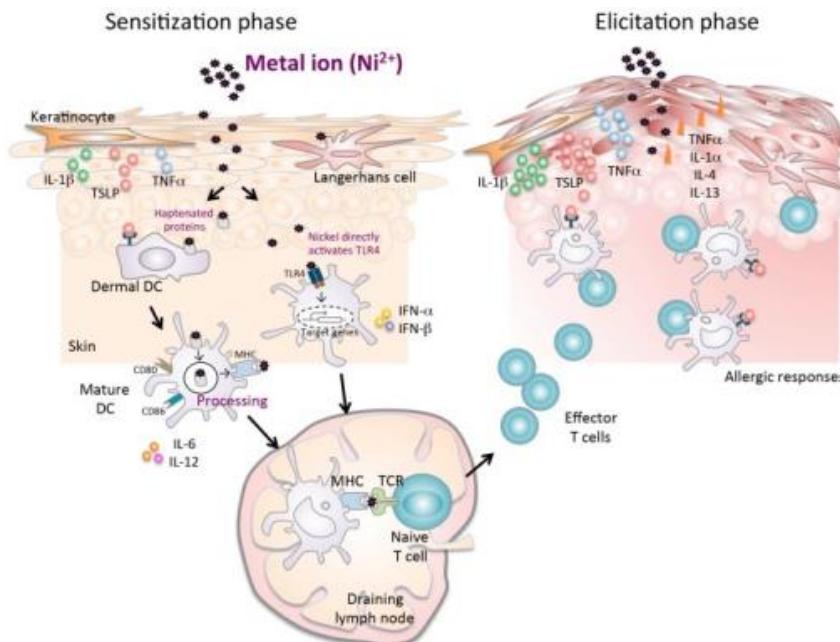


Image 2. This image shows the complex mechanism behind a metal allergy. The left side shows the metal ion crossing the skin and being transported to a lymph node. The bottom part of the image shows the metal ion interacting with a T cell within the lymph node. The last step (on the right) shows T cells initiating a localized allergic response to a metal ion. (Image originally published in Saito et al. article and distributed under the following license: <https://creativecommons.org/licenses/by/4.0/>)⁷

How do I find out if I have a Nickel allergy?

It is estimated that 17% of women and 3% of men have nickel allergies.⁸ If you have a history of allergic-type reactions to jewelry, your provider may recommend completing a metal allergy test. This often involves visiting an allergist who will place small patches of potential allergens on your skin. The allergist will then have you return to their office after a few days so that they can assess for reactions that may have occurred. A positive reaction typically consists of red skin, raised skin, or itchiness.⁹

Patches of the stents do not exist to test against; however, MIPS has worked with the stent manufacturing companies to create a special patch of the stent materials for testing as part of clinical investigation. These special stent patches are not available at any other practices.

MIPS does this since patients may not react to the device material itself, even if they react to the metals the device contains. This is because nitinol stents are often treated

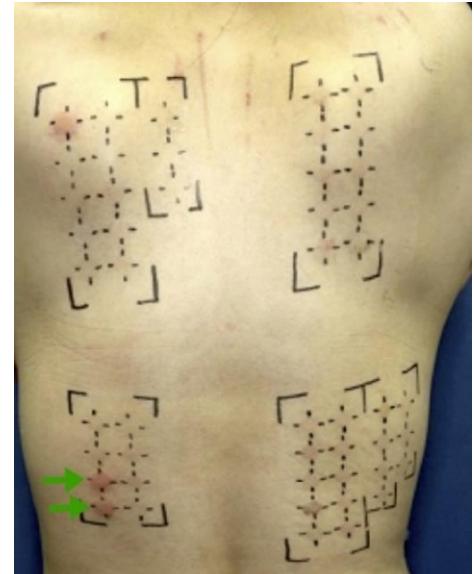


Image 3. This image shows an example of allergy patch testing. The green arrows in the bottom left-hand corner show what a positive reaction may look like. (Image originally published in Shikino et al. article and distributed under the following license: <https://creativecommons.org/licenses/by-nc-nd/4.0/>)²

with electro-polishing or passivation, and a protective titanium oxide layer forms on the surface of the nitinol to serve as an effective barrier that prevents corrosion and the release of nickel ions.¹⁰⁻¹² Because of this polishing, it is felt that the nitinol stents, despite containing 50% nickel, would release nickel to a lesser degree when compared to the 15% nickel-containing elgiloy stent (a stainless steel).

Today's nitinol vascular self-expanding metallic stents, designed and FDA approved for use in veins, show no evidence of clinically relevant corrosion or nickel release, and outcomes in patients with or without nickel allergies are often indistinguishable. Despite this, the FDA advises the stent companies to use the following language on their labels:

Warning: This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

The Abre nitinol stent used at MIPS has the following language on its labeling:

Contraindications: Do not use the Abre system with patients with known hypersensitivity to nickel titanium (nitinol).

The Boston Scientific elgiloy stent used at MIPS has the following language on its labeling:

Warnings: The device contains nickel, which may cause allergic reaction in individuals with nickel sensitivity

The current state of the research

A common question—and one that is still being researched—is whether it is safe for patients with nickel allergies to undergo a stenting procedure and receive a nickel-containing stent. There is currently no definitive answer to this question, but the following sections will summarize the current state of research on this topic. The summaries of research studies have been split into the following sections: (1) research on stenting done within the venous system, (2) research on stenting done in the arterial system, (3) research that was not performed in humans, and (4) research on other implants (e.g., orthopedic implants). These distinctions are made because veins have different properties compared to arteries or other parts of the body, meaning that the results of interventions using nickel-containing products may differ depending on the location of the intervention and the product used. Additionally, it is important to note that prior research studies may not use the same stents used at MIPS, and that stent technology has advanced over the past several decades.

Research on venous stenting in patients with metal allergies

To our knowledge, there has only been one published study about venous stenting in patients with nickel allergies. A retrospective, multicenter study by McGrath et al., published in 2024, showed that there were no allergic reactions or complications in nickel-allergic patients after receiving a nickel-containing venous stent. Of the nine patients included in the analysis, seven patients received a nitinol stent, and two patients were stented with stents made of other alloys that contained nickel. The study reviewed follow-up notes for the nine nickel-allergic patients who received an intracranial venous stent that contained nickel. None of the patients reported allergic reaction symptoms or other complications. The authors of this study concluded that, although their patient population was small, it is likely that the risk of stenting patients with a documented allergy is quite low.¹³

Research on arterial stenting in patients with metal allergies – this data may not translate to venous stents since veins have different properties than arteries, and therefore, results may differ. However, the research is summarized here to provide further background information.

In a study published in 2011, Thyssen et al. reviewed records of 149 patients who had undergone metal allergy testing (both positive and negative) and also received a metal stent (the metal composition was not specified by the authors). In this group, only two of the seventeen patients with positive metal allergy tests had restenosis (recurrent narrowing of the stent). Because of this, the authors reported that there is no association between being metal-allergic and an increased rate of in-stent restenosis.¹⁴

A study by Slodownik et al., published in 2018, explored the relationship between metal allergy and in-stent restenosis in ninety-nine patients who received a 316 L stainless steel stent (which contains iron, nickel, chromium, and molybdenum) in an artery. The researchers grouped patients into two cohorts: one of patients with restenosis of the stent, and another of patients without restenosis (called the control group). When comparing the restenosis group to the control group, there was no significant difference in the presence of metal allergy. The authors concluded that their data did not support the theory of metal contact allergy playing a role in the pathogenesis of in-stent restenosis.¹⁵

In 2023, Baranoski et al. published an article showing that the use of nickel-containing devices in metal-allergic patients for the treatment of arterial aneurysms and dissections in the brain was safe and effective. This group reviewed charts of seven patients who had vascular lesions treated with nickel-containing devices. After treatment, there was no

evidence of allergic reactions or in-stent stenosis. None of the patients had evidence of an adverse outcome that could have been attributed to nickel or metal allergy reactions. The authors concluded that the use of nickel-containing devices in metal-allergic patients was safe and effective.¹⁶

In 2020, Guntani et al. published a case report about a woman who had an allergic reaction to an iliac artery stent made from 316L stainless steel. A woman presented with pruritus (itchiness) and rash after receiving a metallic stent 4 years prior. She was diagnosed with contact dermatitis due to nickel contained in the stent, and her symptoms did not improve with steroid treatment. The stent was ultimately removed, and her symptoms resolved.¹⁷

Jetty et al. published a case report in 2013 about a man who had an allergic reaction to a nitinol stent. The patient had a nitinol stent placed in the superficial femoral artery. Two weeks after the stenting procedure, he had onset of pruritus and rash. Eventually, the patient had the stent removed, and their symptoms resolved. In this patient, there was evidence of stent fracture. The authors hypothesize that this may have contributed to the allergic reaction seen in this patient.¹⁸

A 2012 publication by Romero-Brufau et al. discusses coronary stenting in patients with metal allergies. This study looked at records for twenty-nine stent patients with confirmed metal allergies (including nickel, chromium, and molybdenum allergy) and compared them to a control group of over 13,000 stent patients without a metal allergy and a second control group of 250 non-allergic matched controls. Patients received stents made of 316L stainless steel, L605 cobalt chromium, and MP35N cobalt chromium. There was no evidence of a statistically significant difference in stenting outcomes that could be attributed to metal allergy, and there was no evidence of allergic reactions.¹⁹

Relevant research on metal allergies that were not conducted in humans – this data may not translate to venous stents since many of these studies were performed in various environments. However, the research is summarized here to provide further background information.

In 2022, Vanent et al. published their findings after investigating whether intracranial stents release nickel ions. This research group tested seven stents from different manufacturers. Of these stents, five were made of nitinol and two were made of other alloys that contained nickel. The stents were incubated in human plasma-like media (HPLM) for 30 days. HPLM mimics the environment inside the human body and allows researchers to investigate how things will react within the human body. After the incubation period, researchers used highly precise spectroscopy equipment to measure the amount of nickel released into the

HPLM. They found that none of the stents incubated in HPLM released detectable amounts of nickel. Since the release of nickel is needed for an immune reaction to occur, the data from this study suggest that stent placement in patients with nickel allergy is unlikely to cause an allergic reaction.²⁰

In 2003, Carroll et al. published an article after performing galvanic tests, surface analysis, and corrosion tests on several nitinol wire samples. The samples varied in diameter, oxide layer, and manufacturer. The authors found varying corrosion resistance based on the oxide layer of the wire, and they concluded that surface treatments are necessary to improve corrosion resistance when used in chloride environments. Testing also found that oxide thickening occurs after heat treatments, which is important to note since stents are typically heated to establish shape memory for when the stent is deployed.²¹ After performing similar experiments, Clarke et al. published findings in 2006 stating that surface treatment is needed to ensure optimal bio-performance of nitinol. They observed that there was no release of nickel from surface-treated wire samples.¹⁰

In 2010, Hu et al. performed research on the corrosion behaviors of nitinol in environments that mimic the high Cl⁻ environment of the human body. Research in this study found that mechanically polished nitinol alloy samples can be subject to corrosion in solutions that replicate fluids of the human body. However, they found that when nickel ions are released during corrosion, the titanium reacts with oxygen to re-form a titanium oxide layer. This titanium oxide layer helps to impede further corrosion.²²

In 2009, Pérez et al. investigated the effect of different surface treatments on the properties of nitinol. This group found that different surface treatments can result in different thicknesses of the titanium oxide layer. Therefore, surface treatments can help improve the corrosion resistance of nitinol, and specific surface treatments can help ensure there is virtually no nickel on the external surface.¹²

In 2015, Sullivan et al. published results after researching nickel release seen in five nitinol cardiovascular stents that differed in material surface condition and processing steps. After performing pitting corrosion testing, immersion testing, and nickel ion quantification, the authors concluded that surface processing has a significant impact on the release of nickel ions. Results showed that nitinol stents with a thin oxide layer and a final surface treatment of polishing had high corrosion resistance.²³

Nagaraja et al. published a study in 2018 after studying the effects of stent implantation in healthy mini pigs after 180 days. They concluded that the varying surface finishes of nitinol stents that they used did not increase system nickel concentrations and did not negatively impact the kidney or liver.¹¹

Es-Souni et al. published a report in 2002 after studying the corrosion behavior and biocompatibility of elgiloy when used in orthodontics. Researchers compared two elgiloy wire samples to control samples of Neo Sentalloy™ (a subtype of nitinol) and the β -III-Ti alloy TMA®. The wire samples underwent tests to study corrosion behaviors, surface morphology, chemical composition, and in vitro biocompatibility. Results showed that Neo Sentalloy™ released negligible amounts of nickel, while the elgiloy samples released high amounts of nickel and cobalt. The authors concluded that elgiloy had a lower corrosion resistance and worse biocompatibility when compared to Neo Sentalloy™ and the β -III-Ti alloy TMA®.²⁴

Research on other types of implants in patients with metal allergies – *This data may not translate to venous stents considering that the following research is on other implants/devices that may be larger in size or may be more prone to wear and tear. However, the research is summarized here to provide further background information.*

A case report from 2005 by Lai et al. described a possible reaction to a nitinol device used to occlude (or plug) a patent foramen ovale (PFO), which is a small hole between two chambers of the heart. The patient received a nitinol PFO occluder device and later had symptoms resembling an allergic reaction. The patient was prescribed prednisone (a steroid used to treat allergic reactions), and their symptoms improved. The authors clarified that the symptoms seen in this patient are consistent with an allergic reaction to nickel, but could only be proven with a biopsy, which was not performed. The authors of this case report acknowledged that there were no other reports of allergic reactions to the nitinol device used in this patient.²⁵

In their article published in 2018, Pacheco et al. reviewed articles that discussed allergic responses to surgical implants/devices made of a range of materials, including nitinol. This review discusses the possibility of allergic reaction symptoms after having orthopedic surgery, such as a hip replacement or knee replacement. It also included a few cases of reactions to nitinol stents placed in arteries; however, there was no discussion of reactions in nitinol venous stents. The authors of this review stressed the importance of patch testing and working with the physician and allergist if there is concern for potential metal sensitivity.²⁶

In 2017, Esparaz and Ahmed published a case report after a woman had an allergic reaction to a nickel-based metallic biliary (liver bile duct) stent. The patient received a metal biliary stent and one year later reported that she had been experiencing nausea, itching, hives, and asthma attacks. A procedure was performed to partially remove the biliary stent. Afterwards, the patient had complete resolution of her symptoms. The

authors hypothesized that the biliary stent was not fully epithelialized (or not fully covered in tissue). Therefore, an exposed portion of the stent was in contact with bile fluids, causing corrosion, which led to the allergic reaction that was observed in this patient. This hypothesis is supported by the fact that the removal of only the non-epithelialized portion of the stent resulted in the resolution of symptoms.²⁷

Overall takeaway

Implanting metal stents in patients with confirmed metal sensitivities is still being researched, and there is currently no consensus on the safety or efficacy of venous stenting in metal-allergic patients. At the time of creation of this document in September 2025, there were no documented allergic reactions to nitinol venous stents. To summarize the above research, the majority of the literature on stenting in metal-allergic patients is arterial; however, one study on venous stenting showed that it may be safe and effective. Several of the in vitro studies discussed in this document have shown that there is negligible release of nickel ions from nitinol stents due to specialized surface finishing processes. In conclusion, orthopedic implants and arterial stents have the potential to cause allergic-type reactions; however, there has been no evidence to support that this happens in venous stenting as well. Additionally, the available in vitro studies show that the quantity of nickel ions that are released by nitinol stents may be less than the threshold needed to trigger a reaction.

It is often mentioned on social media pages for pelvic pain and May-Thurner that patients had allergic reactions to their stents after placement, as evidenced by terrible post-stenting pain. However, there is no data to support these claims, and many of these patients likely have increased pain due to oversized or misplaced stents as opposed to a true allergic reaction. In the absence of evaluating each case individually, it is also important to determine that there is no other source of the patient's pain before concluding the symptoms are due to an allergic response. For example, occult tethered cord is often missed and presents similarly to iliac vein compression, with symptoms including back and lower extremity pain.

Alternative treatment options

There has been research into alternative treatment options to stenting for patients with iliac vein compression. A few of these options include extravascular sheaths/shields (available in the US), 3D printed extravascular stents (used in China and Germany in experimental studies only to date) that do not contain nickel, or other surgical options.

Extravascular stenting involves placing a tube made from expanded polytetrafluoroethylene (ePTFE) on the outside of the vein instead of within the vein. There is limited experience with this technique in treating renal vein compression. This alternative typically uses shorter stents, which may not fully resolve the compression that is seen in the iliac vein. Unlike typical stents, these external stents can only be placed via open, laparoscopic, or robotically-assisted surgery. Currently, there is no published literature on the use of extravascular stents to treat iliac vein compression. However, there are a few papers that discuss using extravascular stents to treat other venous compression disorders (such as nutcracker syndrome) and that show extravascular stenting is a potentially safe and effective treatment option.²⁸⁻³²

One paper by He et al. published in 2020 discusses using 3D-printed polyetheretherketone (PEEK) extravascular stents to treat nutcracker syndrome (or compression of the left renal vein). The authors concluded that extravascular stenting with a 3D printed stent is a potentially safe and effective treatment option for nutcracker syndrome.²⁹ Although these results are promising, similar research to see if this is a viable treatment option for iliac vein compression has not been performed.

Another surgical option to relieve iliac vein compression is anteriorization of the left common iliac vein. This procedure involves surgically moving the left common iliac vein to be in front of the crossing right common iliac artery. By moving the vein to the front, the compression can be alleviated. A study by Nagarsheth et al. published in 2024 showed that anteriorization of the left common iliac vein can improve venous outflow.³³ It is important to note that surgical anteriorization of the left common iliac vein would require a large surgery. The vein may still be narrowed by draping over the aorta and we have had to stent some of these veins in the past even after this surgery.

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