

Clinical Insights

TECHNICAL PRODUCT FEATURE ANALYSIS

AMPLATZER™ STRUCTURAL INTERVENTIONS

THE INTAGLIO™ WIRE TREATMENT

KEY MESSAGES

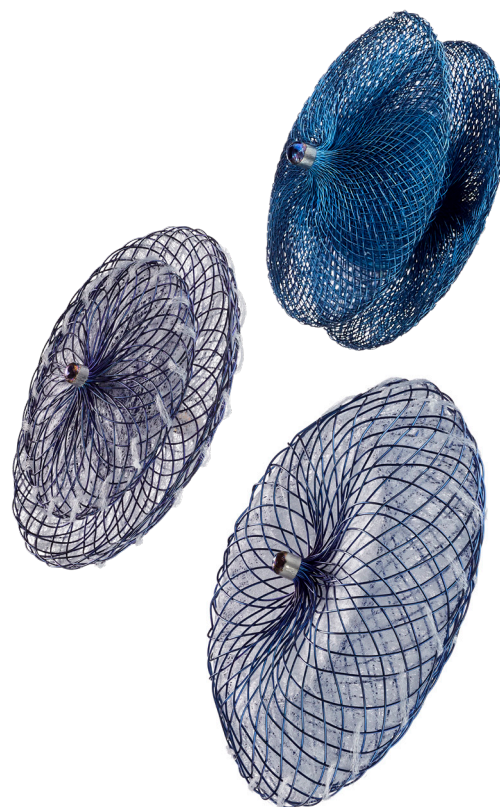
- Intaglio is a chemical etch treatment of Nitinol wire used in the manufacturing of Amplatzer Devices.
- Although Amplatzer products have always met the standards for nickel leaching, they were improved through the use of Intaglio wire treatment.
- The Intaglio wire treatment reduces the amount of nickel that may be leached from the device by more than 95% depending on the model. See next page for Nickel Reduction from Intaglio in Table 1 and PFO example in Graph 1.
- Intaglio is part of Abbott's commitment to increasing quality of all products.

INTRODUCTION

In 2014, a process for applying a chemically etched finish called Intaglio was introduced to the Amplatzer family of heart occluder devices. Prior to 2014, the Amplatzer occluder devices were manufactured using Black Oxide Nitinol wire. This process is part of continuing enhancements and improvements to Abbott's Amplatzer occluder and plug devices.

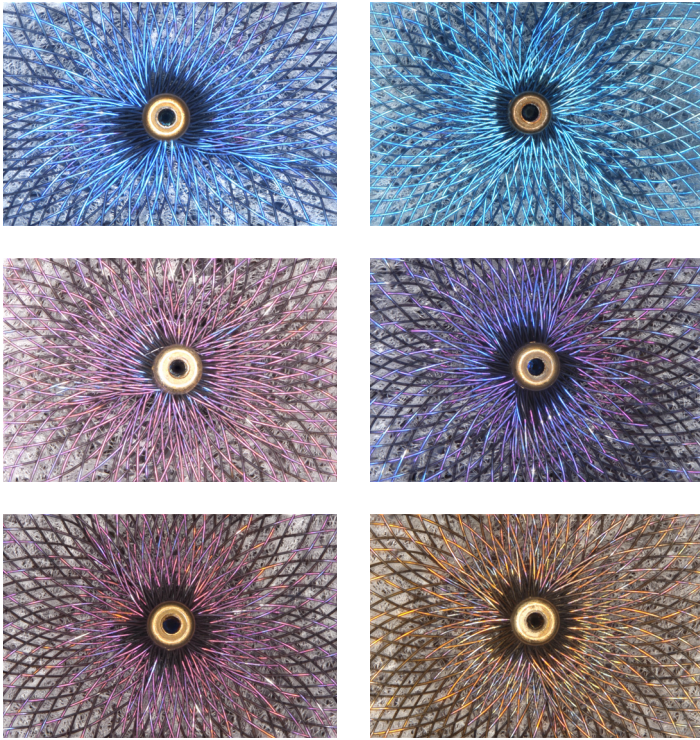
SIGNIFICANCE OF INTAGLIO

Amplatzer products have been evaluated using a robust in-vitro chemical leaching study to assess the material-related toxicity risks associated with nickel release after implantation. The conversion to the Intaglio chemical etching process has further reduced these toxicological risk factors with respect to nickel leaching. The Intaglio wire treatment reduces the amount of nickel that may be leached from the device by more than 95% depending on the model. Table 1 displays the outcome of this testing and shows that the amount of nickel leach from Amplatzer devices is well below recommended levels. The mechanical performance of the device remains unchanged with the conversion to chemically etched wire. Graph 1 shows the impact on nickel leaching over time as a result of the Intaglio process.



INTAGLIO TREATMENT

The Intaglio treatment is a secondary step applied to the Nitinol material utilized in the production of Amplatzer occluders. The metal wire undergoes a chemical etch as a process during manufacturing which results in a thinner, more consistent oxide layer on the device. The mechanical properties of the wire and finished device are not affected by this process so the proven clinical performance remains unaltered. Amplatzer devices with Intaglio have a slight coloration compared to previous devices with an untreated black oxide finish. This coloration is typically a blue or purple hue but can vary from nearly gold to dark purple as shown in the images below. This color variation can occur as a result of device size variation, wire size, and final device curing process. Color variation does not impact device performance characteristics.



CONCLUSIONS

Amplatzer™ Occluder devices and the Intaglio™ chemical etching are part of Abbott's commitment to continuous product improvement. Although Amplatzer products have an excellent safety profile and have always met the standards for nickel leaching, they were improved through the use of Intaglio wire treatment. Testing of Amplatzer Occluder devices with Intaglio chemical etching has demonstrated a significant reduction in nickel leaching compared to devices manufactured with a black oxide finish. Lower levels of nickel is intuitively better for patients and may reduce the potential for an adverse reaction to nickel.

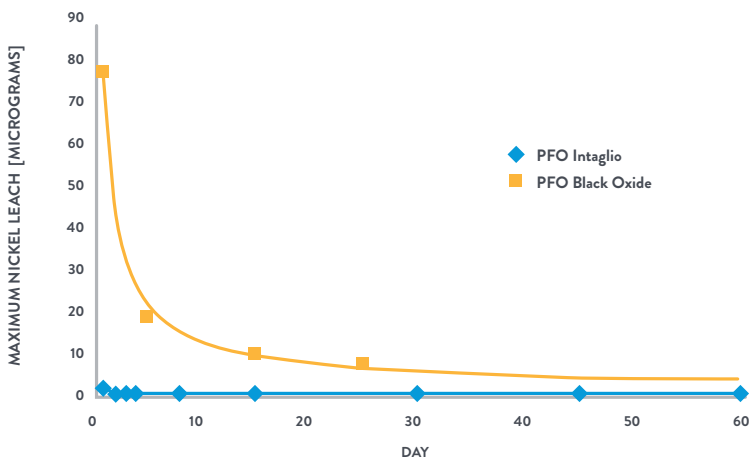
TABLE 1: NICKEL REDUCTION FROM INTAGLIO IN AMPLATZER OCCLUSION PRODUCTS*

Product	Black Oxide, Max Ni Leach 1st Day [µg]	Black Oxide, Max Ni Leach 10th Day [µg]	Intaglio, Max Ni Leach 1st Day [µg]	Intaglio, Max Ni Leach 10th Day [µg]	1st Day Reduction in Nickel Leach with Intaglio (%)	10th Day Reduction in Nickel Leach with Intaglio (%)
PFO	77.1	18.4	1.79	0.17	97.7%	99.1%
ADOII	45.2	7.0	0.74	0.08	98.4%	98.9%
ASD	78.1	21.8	3.36	1.05	95.7%	95.2%

- The Intaglio wire treatment reduces the amount of nickel that may be leached from the device by more than 95% depending on the model.
- Lower levels of nickel increase safety and may reduce the potential for an adverse reaction to nickel.

* Chemical Characterization Testing data on file at Abbott. For product specific Nickel precautions, please check the Instructions for Use.

GRAPH 1: NICKEL LEACH REDUCTION WITH INTAGLIO - PFO



CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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Always check the regulatory status of the device in your region.

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