THE INTAGLIO™ WIRE TREATMENT

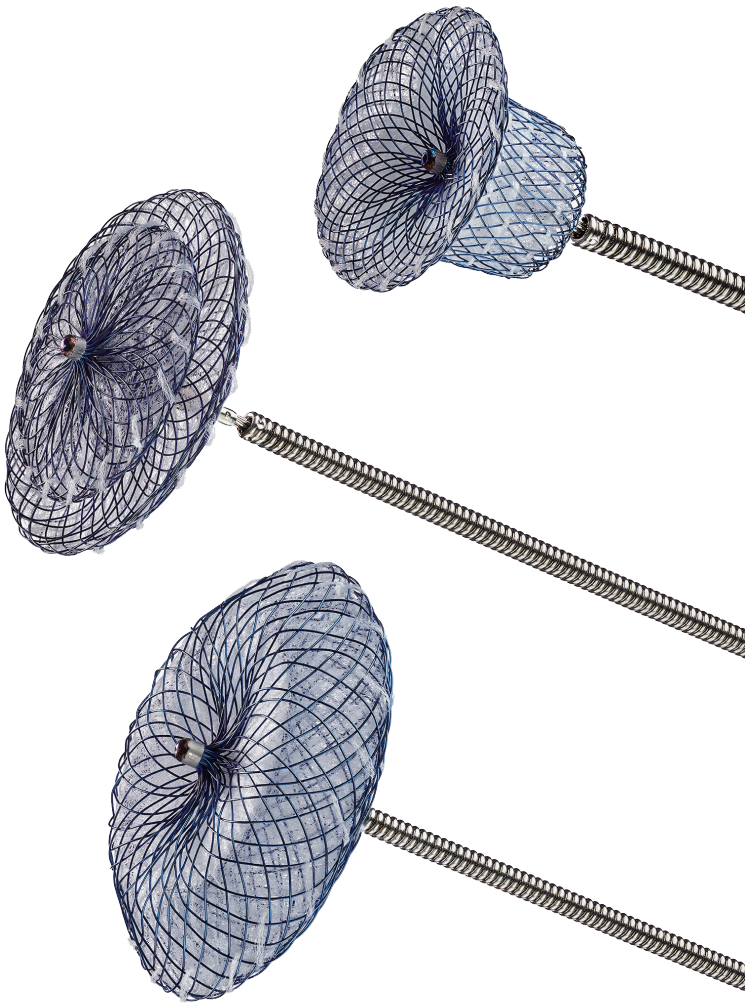
Amplatzer™ Structural Interventions

Abbott

Clinical Insights

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

The Amplatzer Occlusion Devices have historically been manufactured using Black Oxide Nitinol wire. In 2014, the Intaglio chemically etched finish was introduced to Amplatzer Occlusion devices.

SIGNIFICANCE OF INTAGLIO

Amplatzer products have been characterized utilizing a robust in-vitro chemical leaching study to assess the materials-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 mechanical performance of the device remains unchanged with the conversion to chemically etched wire.

INTAGLIO TREATMENT

The Intaglio treatment is a secondary step to the Nitinol material previously utilized in the production of Amplatzer products with a Black Oxide finish. The metal wire undergoes a chemical etch as a final process in the manufacturing of the product resulting 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. Devices treated with Intaglio have a slight blue or purple hue compared to previous devices with a Black Oxide finish.

CONCLUSIONS

Amplatzer Occluder Devices and the introduction of 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 in multiple devices more than 95% (varying depending on device model) further 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.

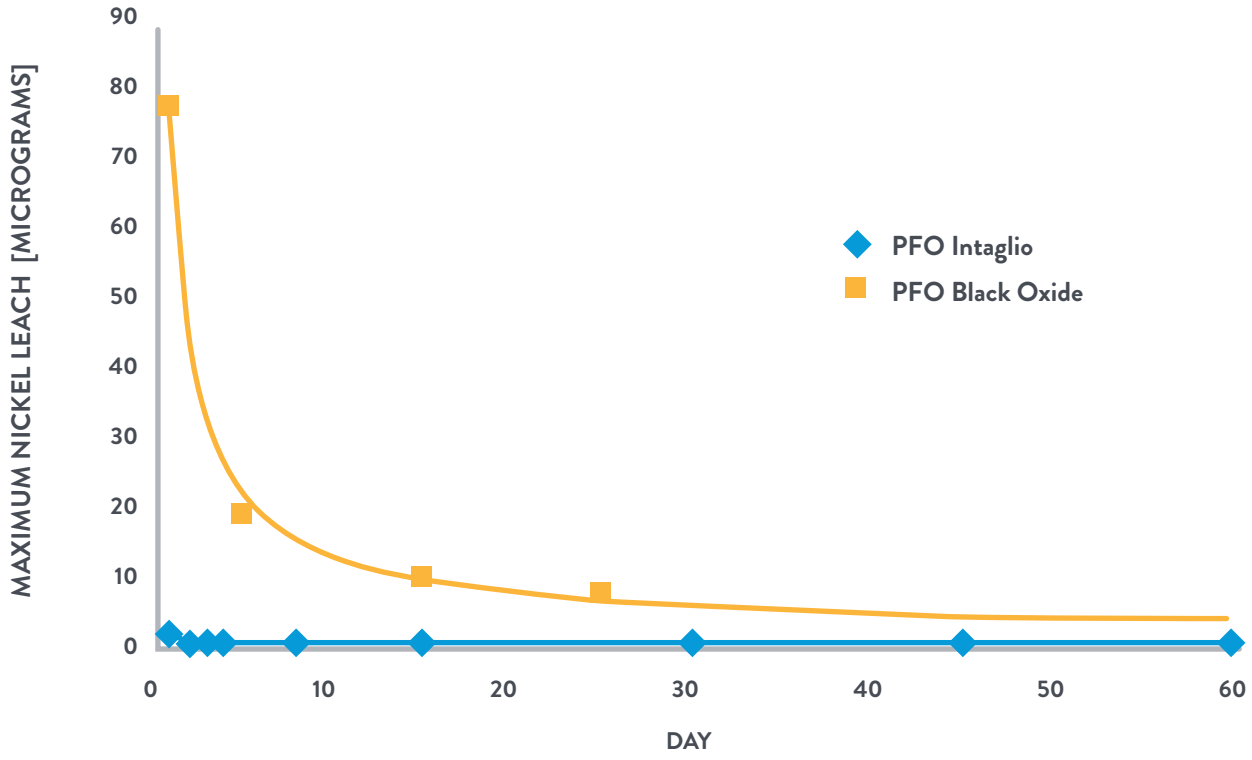
TABLE 1: NICKEL REDUCTION FROM INTAGLIO IN AMPLATZER OCCLUSION PRODUCTS*

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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