

Nitinol and the SCOUT Reflector

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Nitinol is a metallic alloy of nickel and titanium that was first considered for medical use in the early 1980s. Nitinol has unique properties that are useful in surgical applications because it can be deformed and reformed several times more than conventional metal alloys (like stainless steel) without losing strength or rigidity. This elasticity and shape memory effect make the material an excellent candidate for use in many different medical applications. Orthodontic wires for tooth alignment, vena cava filters, vascular stents, biopsy markers, and various orthopedic implants are just a few of the devices manufactured using nitinol and currently approved for their intended use in patients. Self-expandable nitinol stents have also been introduced in gastroenterology, radiology, and numerous cardiovascular applications.

While the specific test results for the reflector and the broad body of information regarding the safety of Nitinol devices indicate an extremely low toxicological risk¹, the FDA provides guidance that ALL devices that contain Nitinol must have a precautionary statement in their labeling regarding the potential for an allergic reaction for those patients with a KNOWN Nitinol allergy.

SCOUT Nitinol Evaluation

The materials used in the SCOUT Reflector have been evaluated using multiple standardized test procedures that have been reviewed and recognized by the FDA². One of these tests specifically addresses the amount of nickel that can leach from a device under extreme extraction conditions.

Using the highest values (worst case observed), a total of approximately 0.0075 ug of nickel was released, from each device, over a 30-day period³. This translates to about 0.00025 µg per day released per reflector

Perspective – *Nickel potentially released from the reflector is less than 0.0004% of nickel absorbed by adults during the normal course of each day.*

Exposure to nickel from the everyday world occurs predominantly from food⁴. A typical adult consumes between about 69 and 162 µg of nickel per day. Infants typically ingest about 9 µg of nickel per day. Up to about 40% of ingested nickel (through water and/or food) is bio absorbed.

This would mean that for a typical adult, about 65 µg of nickel is absorbed through ingestion per day (=162 µg x 0.40), as an upper limit.

¹ Tsuji, J, Heinz, K, Rosenbloom, S, Bogen, K, Yost, L, “Health Risk of Internal Nickel Exposure from Medical Devices”, presented at the Annual Meeting of the Society of Toxicology, Salt Lake City, UT, March 7-11, 2010

² Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems. Guidance for Industry and Food and Drug Administration Staff Document issued on: August 18, 2015.

³ Results on file at Cianna Medical, Inc.

⁴ U.S. Department of Health and Human Services, Public Health Service, ATSDR (Agency for Toxic Substances & Disease Registry), “Toxicological Profile for Nickel”, published August 2005, as viewed at: <http://www.atsdr.cdc.gov/toxprofiles/tp15.pdf>