


Title:	Workmanship Standard	
Document Number:	SOP-9001008	
Revision:	J	
Document Level:	II	
Effective Date:	2/10/2017	Page 1 of 4

1.0 Purpose

- 1.1 To communicate basic requirements to our suppliers/sub-contractors regarding the manufacturing, visual, functional and shipping expectations for devices created for NuVasive.
- 1.2 This document shall not supersede any part of the released drawings, purchasing specifications or other referenced technical guidance. Where actual conflict exists, the provisions of the contract or applicable drawing or specification shall take precedence over the requirements herein.

2.0 Scope

- 2.1 This procedure applies to all fabricated and assembled products produced by or for NuVasive.

3.0 Responsibilities

- 3.1 Development
 - 3.1.1 Development has primary responsibility for and must approve all changes to this document.
- 3.2 Supply Chain
 - 3.2.1 Supply Chain will be responsible for assuring that copies of this document are provided to all approved suppliers/sub-contractors that manufacture or assemble NuVasive products
- 3.3 It is recommended that the following departments be conferred with, when making changes to this document: *Development; Supply Chain; Quality Assurance; Quality Engineering; Regulatory.*

4.0 References


- 4.1 [ANSI Y14.5](#) – Dimensioning and Tolerancing
- 4.2 [ASTM A967](#) – Standard Specification for Chemical Passivation Treatments of Stainless Steel Parts
- 4.3 [ASTM F86](#) – Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants
- 4.4 [AWS-A2.4](#) – Standard Symbols for Welding, Brazing and Non-destructive Examination
- 4.5 [SOP-9004632](#) Visual and Cosmetic Standards for Manufacturing

5.0 Abbreviations

- 5.1 Refer to NuVasive [SOP-9001635](#) for all abbreviations and definitions.

6.0 General

- 6.1 This document is to be used adjunctively with other released documents as a baseline for procedures and processes utilized when manufacturing, packaging and shipping devices for NuVasive. This document establishes minimum requirements and expectations where not explicitly defined by other released documents that accompany purchase orders.

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7.0 Procedure

7.1 Drawings:

7.1.1 Drawing preparation and interpretation shall be per ANSI Y14.5. The part number and revision letter shall be the contractual identifier between NuVasive and the manufacturing suppliers.

7.2 Surface Finish:

7.2.1 Unless otherwise specified, a maximum surface roughness of 32 R_a is required for instruments and 16 R_a for implants. Best efforts to remove machining marks should be implemented where possible while maintaining dimensional integrity.

7.3 Deburring / Edge Breaks / Fillets:

7.3.1 All parts shall be free from burrs.

7.3.2 All sharp edges shall have a .005" maximum edge break unless otherwise specified.

7.3.3 All sharp corners shall have a .005" maximum fillet unless otherwise specified.


7.4 Welding:

7.4.1 Interpret welding symbols per AWS-A2.4. All welds shall be free of harmful defects such as cracks, porosity, undercuts, voids, and gaps. There shall be no burn-through when welding cannulated parts or tubing. Fillets shall be buffed or machined uniform and smooth. Angular or thickness misalignment, warping, or dimensional change due to heat from the operation shall be within permitted tolerances specified on the drawing. There shall be no damage to adjacent parts resulting from welding.

7.5 Injection Molding:

7.5.1 Material certification is required by NuVasive for all materials, including base material, pigmentation, release agent and printing materials. Material to be processed (dried and molded) per supplier recommendations. All material to be virgin, no recycled (regrind) material is allowed. All molded parts shall be free of readily visible particulate matter, parent or foreign, surface or embedded. Parts shall be completely packed out, with no short shots. Mold release agents shall not be used without NuVasive's written approval prior to usage.

7.5.2 NuVasive's Development Department shall approve all knock out pin locations, gates and parting lines that are not specified on the engineering drawing. Flow and knit lines as well as ejector pin marks shall be evaluated for acceptability by NuVasive. Gate vestige, flash, parting line mismatch and sinks shall be within specified tolerances.

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7.5.3 Part identification is to be placed on surface as noted on the engineering drawing(s). Optional methods must be approved by NuVasive.

7.5.4 Cavity I.D. to be indicated per engineering drawing where applicable.

7.6 Hexalobe Standard:

7.6.1 The manufacturing of all NuVasive® instruments and implants that require a hexalobe feature, both male and female, shall meet the dimensional requirements that are called out by the following NuVasive Engineering Standards:

7.6.1.1 EST 9890044 NuVasive Hexalobe Female Recess

7.6.1.2 EST 9890045 NuVasive Hexalobe Male Driver

7.6.1.3 EST 9890046 NuVasive Tapered Male Driver

7.7 Chrome Finishes:

7.7.1 Final surface appearance of parts called out for chrome finish on the drawing shall be in accordance with the NuVasive supplied Chrome Reference Gauge, P/N 9800641. The *suggested* surface treatment methods to obtain the finishes are as follows:

7.7.1.1 For Chrome Finish A: Fiber wheel with an 8 S medium wheel

7.7.1.2 For Chrome Finish B: Fiber wheel with an 8 S medium wheel, then glassbead with #8 - #10 bead at 50 - 80 psi

7.7.1.3 For Chrome Finish C: Fiber wheel with an 8 S medium wheel, then Sisal Buff with SST compound, then cotton buff with white rouge

7.7.1.4 For Chrome Finish D: Fiber wheel with an 8 S medium wheel, then grit blast with 16-grit AL at 40 - 50 psi


7.8 Cleaning:

7.8.1 After fabrication, parts and assembled devices shall be cleaned of all smudges, finger prints, grit, metal chips, machining oils, mold release agents, finishing compound, blasting media or any other foreign material. This cleaning shall take place before the parts are assembled into the equipment. The nature of the contaminant must be determined to the extent that a suitable cleaning solvent can be selected for removal. Cleaning processes shall have no deleterious effect on the components, raw materials, or parts, and shall themselves leave no residues.

7.9 Passivation:

7.9.1 After fabrication and cleaning, all stainless steel components shall be passivated per ASTM A967.

7.9.2 After fabrication and cleaning, all non-anodized, titanium implant components shall be passivated per ASTM F86.

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7.10 Packaging:

7.10.1 Items shall be packaged and protected against functional and cosmetic damage and contamination during shipment and receipt.

7.10.2 Implants and devices that are going to be terminally sterilized shall be double-bagged prior to packaging for shipment.

7.11 General visual and cosmetic standards

7.11.1 Refer to NuVasive SOP-9004632 Visual and Cosmetic Standards for Manufacturing

8.0 Records and Reports

N/A

9.0 Attachments

N/A

10.0 Revision History

Revision History:				
Level	Rev	Description of Change	Sections	CN Number
III	A.0	Initial Release	All	CN040700-004
III	B.0	Revised	2,4,5,10,12	CN102400-002
III	C.0	Added redlines not incorporated from previous release	All	CN022001-001
III	D.0	Revised SOP to current standards, Update SOP to current department roles, removed revision references.	All	CN 122706-003
III	E.0	Add Internal Hexalobe Standard	5, 10	033007-002
III	F	Updated material and document part numbering SOP's	References	CN 091410-001
III	G	Complete re-write; Added Chrome Finish	All	CN 053013-002
III	H	Add reference to SOP-9004632	3, 6	CN 110113-001
III	J	Added Hyperlinks to References Replaced FRM-0105 with ESTs Added corner fillet note	4.0 7.6.1 7.3.3	CN-972

Printed documents may not be the revision currently in effect.
Current revision may be verified or obtained through Document Control.

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