



<b>Document Title:</b>	<b>Visual and Cosmetic Standards for Manufacturing</b>	
<b>Document Number:</b>	<b>9004632</b>	
<b>Document Revision:</b>	<b>A</b>	
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## 1.0 **Purpose**

The purpose of this document is to define the standardization of cosmetic and visual acceptance criteria for NuVasive products upon receipt from the manufacturer.

## 2.0 **Scope**

The information in this document applies to NuVasive finished products except tissue/biologics and IOS products. The goal of this document is to provide a “visual standard” for NuVasive and its suppliers to verify when products go through incoming and outbound inspection. Where a conflict exists, drawings, product specifications, and QIRs take precedence over this standard. Cosmetic defects are not limited to what is defined in this document. NuVasive quality inspectors and distribution coordinators maintain responsibility for identifying and documenting obvious cosmetic defects when they arise.

## 3.0 **Responsibilities**

### 3.1 NuVasive Suppliers

Suppliers are responsible for producing an end product that meets the visual acceptance criteria and packaging them in a manner that maintains that quality in accordance with NuVasive SOP 9001008, *Workmanship Standard*.

### 3.2 Development

Development, in conjunction with Quality Engineering, is responsible for establishing the appropriate cosmetic specifications for products that fall under the scope of this document.

### 3.3 Quality Engineering

Quality Engineering is responsible for the enforcement and documentation of adherence to this standard per NuVasive SOP 9001410, *Non-Conforming Material or Product Program*.

### 3.4 Quality Control

Quality Control is responsible for assuring the defined criteria are met when products are received from NuVasive suppliers in accordance with NuVasive SOP 9001037, *Inspection and Acceptance Criteria*.

### 3.5 Operations

Operations is responsible for ensuring that the handling, transport, and outbound packaging maintain the quality specified in this standard in accordance with NuVasive SOP 9001557, *Distribution Control System*.

## 4.0 **References**

4.1 NuVasive SOP 9001008, Workmanship Standard

4.2 NuVasive SOP 9001410, Non-Conforming Material or Product Program


4.3 NuVasive SOP 9001037, Inspection and Acceptance Criteria

4.4 NuVasive SOP 9001557, Distribution Control System

4.5 NuVasive SOP 9001635, Acronyms and Definitions

4.6 9800679 NuVasive Cosmetic and Blemish Size Overlay Chart

4.7 NuVasive Color Block (9800807 for Titanium parts and 9800808 for Aluminum)

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## 5.0 Abbreviations

5.1 See SOP 9001635 for Acronymns

5.2 QIR = Quality Inspection Report

## 6.0 Definitions

6.1 See SOP 9001635 for Definitions

6.2 “Visual Standard” for the purpose of this document pertains to defects that can be detected by the “unaided eye” (**vision corrected to 20/20**) **at a distance of 12-18” within 3-5 seconds under standard lighting conditions**. Magnification is only used for clarification.

6.3 Cosmetic Defect: any defect detected visually that detracts from the component’s aesthetic appearance.

6.4 Lay: the direction of the predominant surface pattern ordinarily determined by the production method used. For example, a verification of uniform lay includes ensuring the laser marking and surface finish appear consistent across the product.

## 7.0 Materials and Methods

7.1 9800679 NuVasive Cosmetic and Blemish Size Overlay Chart

7.2 NuVasive Color Block (9800807 for Titanium parts and 9800808 for Aluminum)

## 8.0 Procedure

8.1 NuVasive Quality Control will perform cosmetic inspection on an incoming product lot in accordance with the applicable QIR.

8.2 When cosmetic defects are found to exceed the limits specified in 2.1.1, material is handled in accordance with SOP 9001410, Non-Conforming Material or Product Program.

## 9.0 Machined Parts

### 9.1 General

Scope: All visible machined product surfaces.


Examples: Polyaxial screws, Plates, Screw drivers, Inserters,

Requirement:

- Surface finished as specified in SOP 9001008, Workmanship Standard.
- Uniform lay
- Uniform color

Note: The following photos demonstrate examples of acceptable lay, surface finish, and color:



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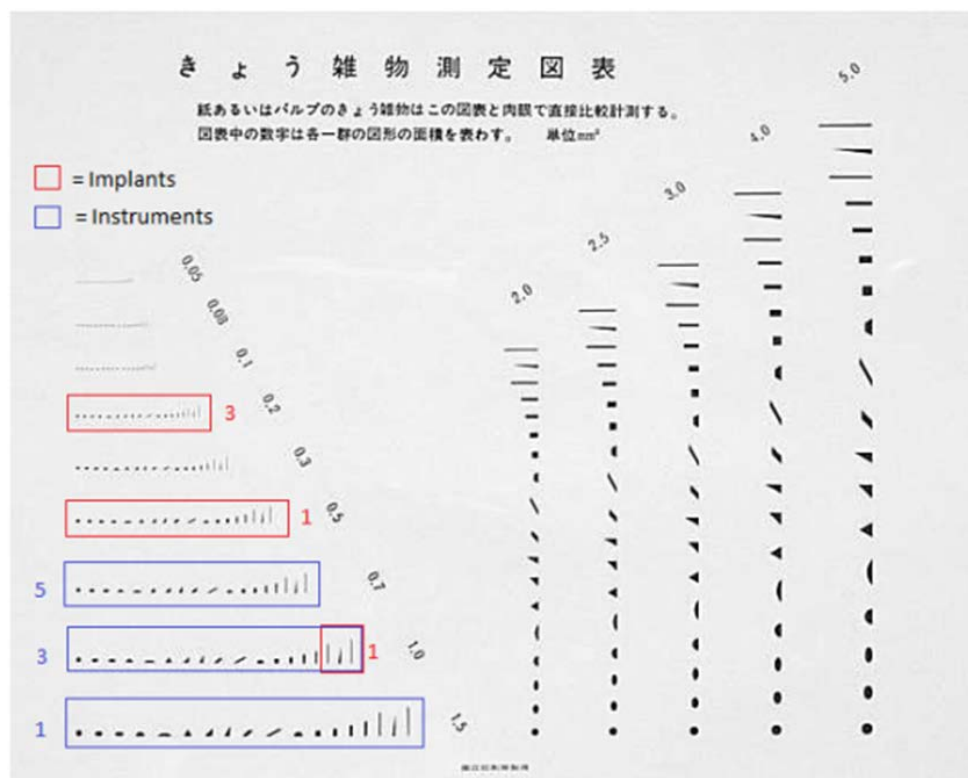
## 9.2 Acceptable Cosmetic Defects

Minor scratches, tool marks, dents, or pits must meet the following criteria using the NuVasive Cosmetic and Blemish Size Overlay Chart (9800679):


Implants: No more than 1 defect > 1.0mm<sup>2</sup> (only the 3 thinnest on chart)  
No more than 1 defect > 0.5mm<sup>2</sup>  
No more than 3 defects > 0.2mm<sup>2</sup>

Instruments: No more than 1 defect > 1.5mm<sup>2</sup>  
No more than 3 defects > 1.0mm<sup>2</sup>  
No more than 5 defects > 0.7mm<sup>2</sup>

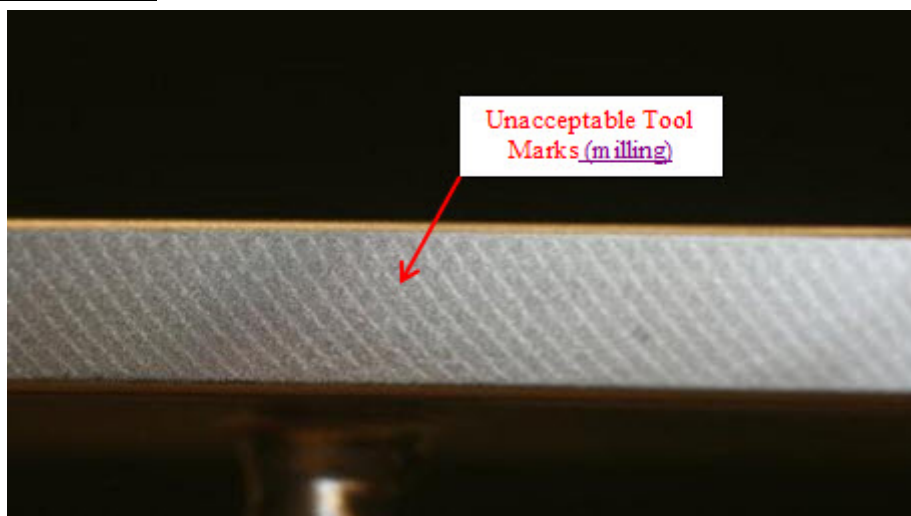
See figure below for visual representation of acceptable defects on the NuVasive Cosmetic and Blemish Size Overlay Chart (9800679).




Quality Engineering may reject acceptable cosmetic defects (such as deep cracks or dents) if the defect could compromise the functional integrity of the product.

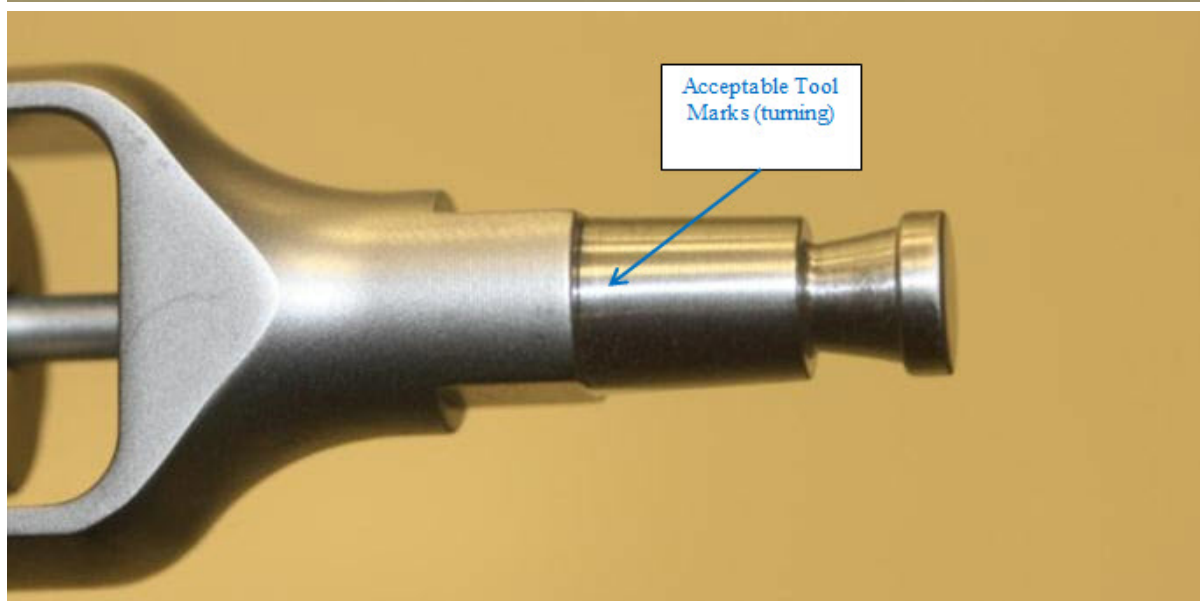
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### 9.3 Tool Marks



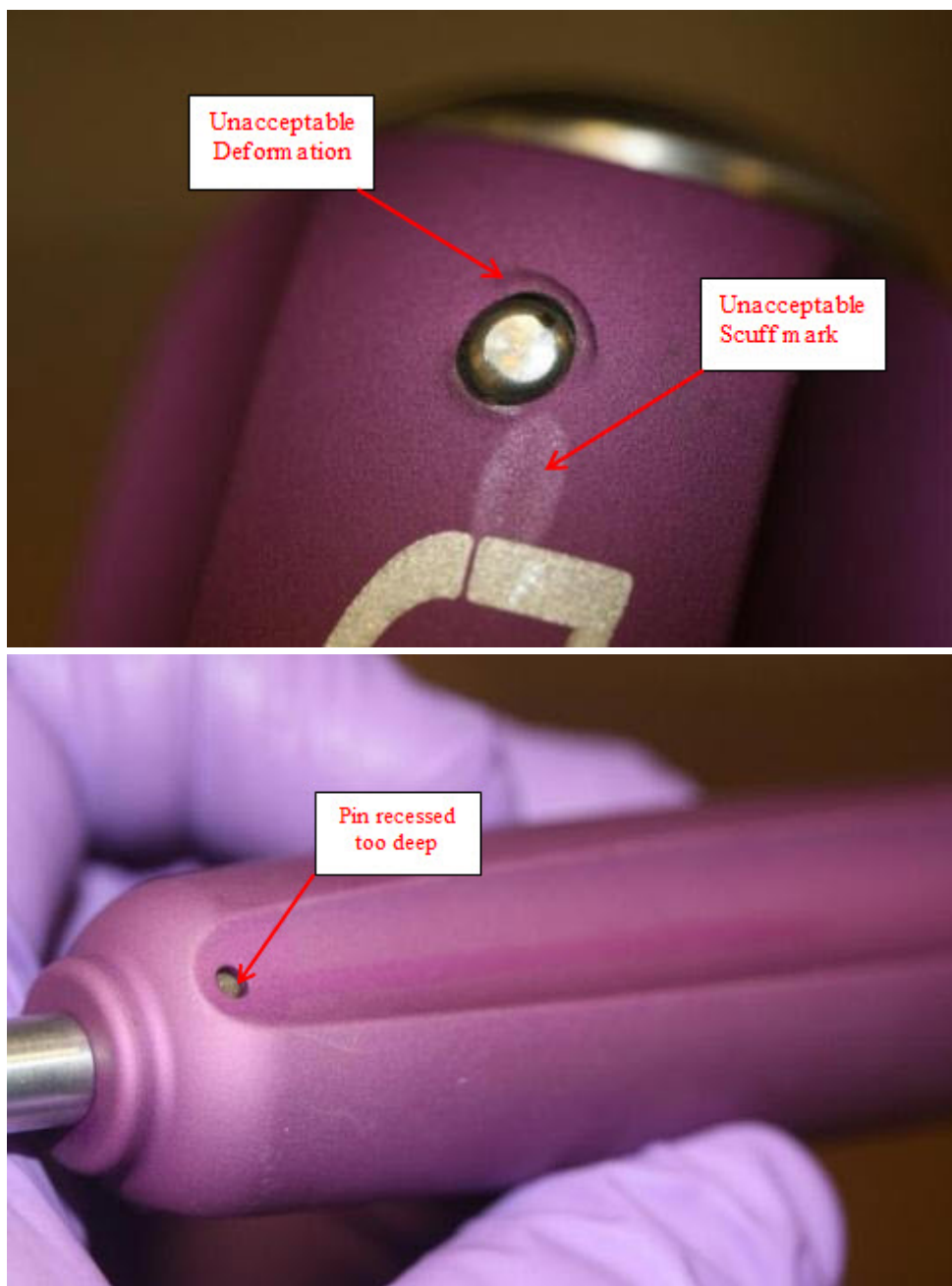



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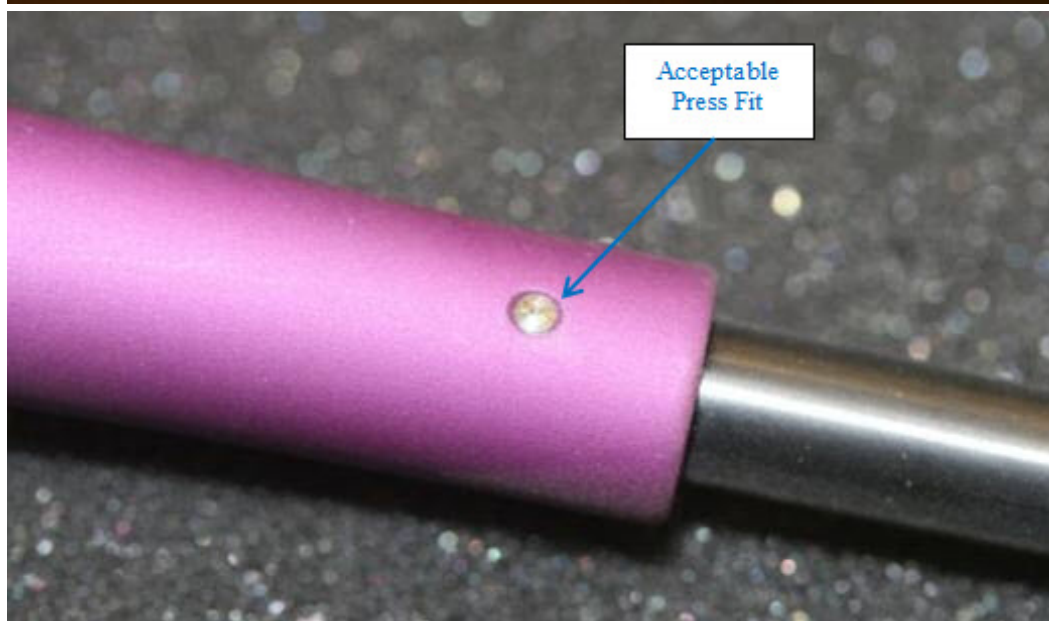
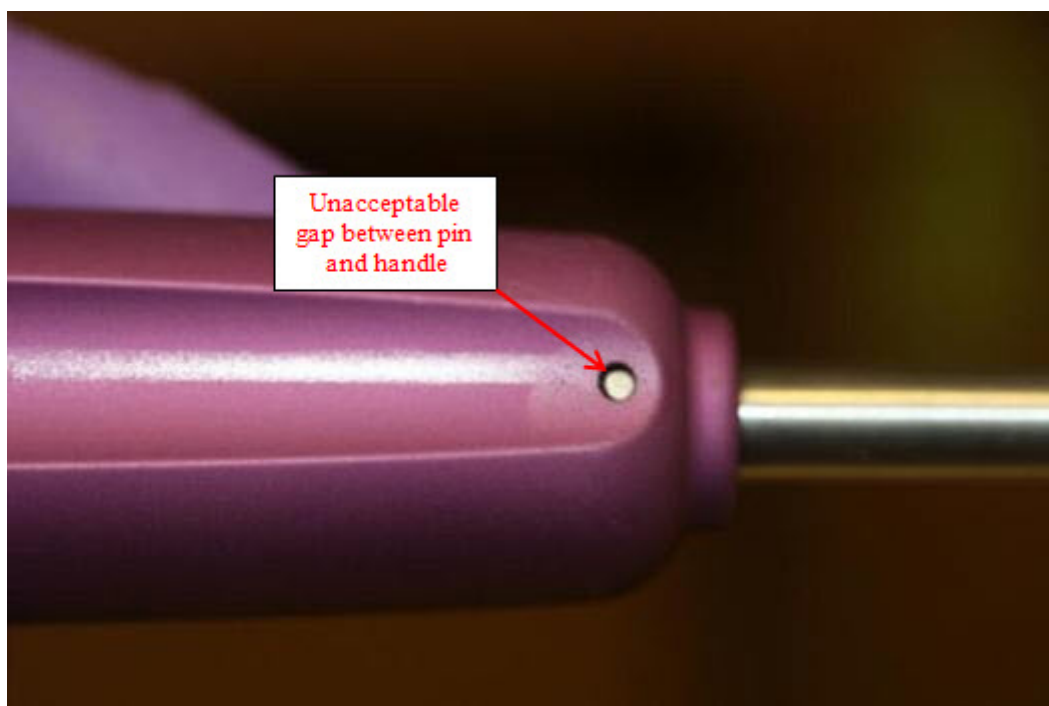


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**9.4 Press Fits** (please note that some pins can be recessed or protrude due to tolerance stack ups, please verify component dimensions before rejecting for poor workmanship).



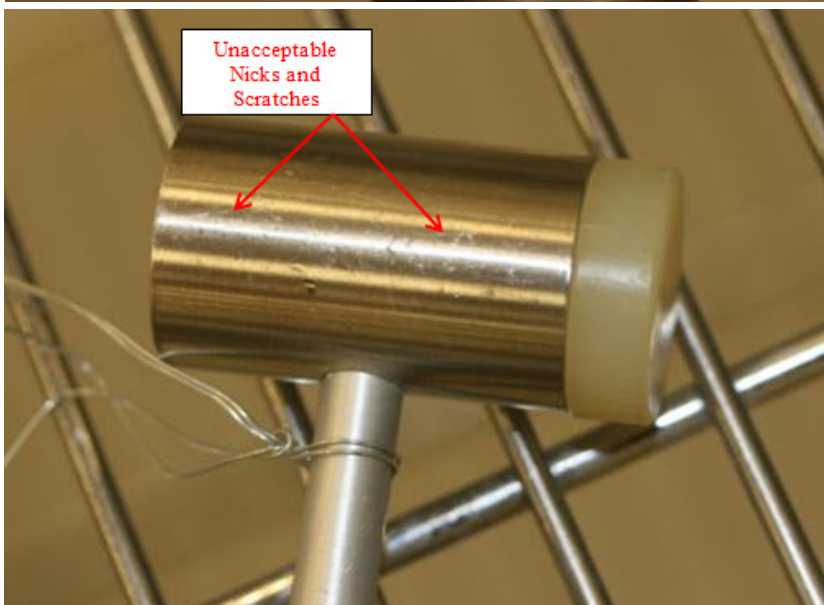
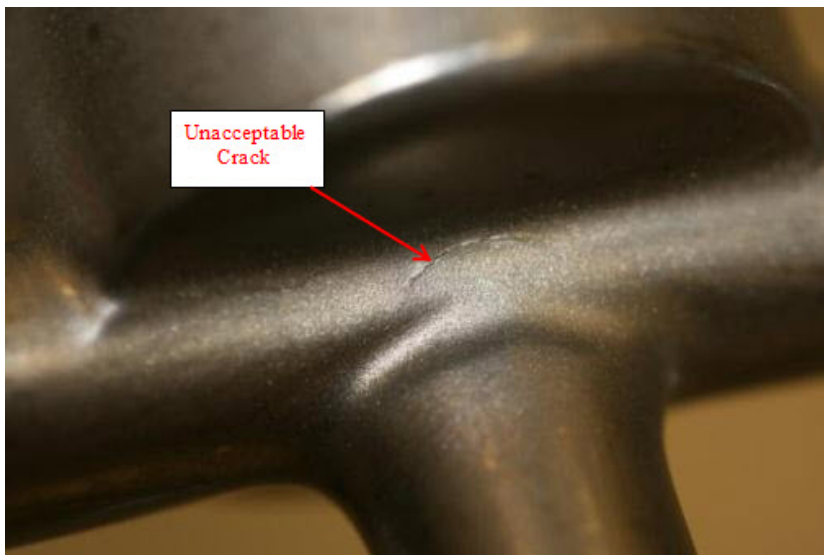
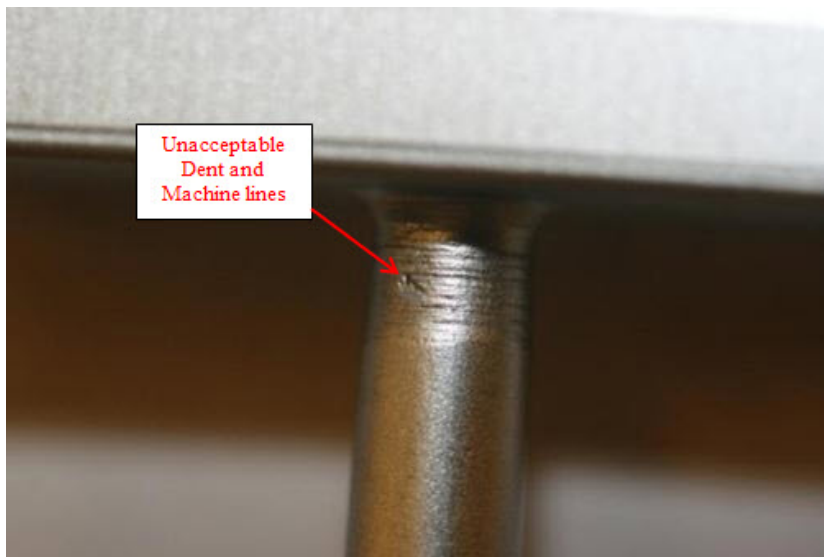
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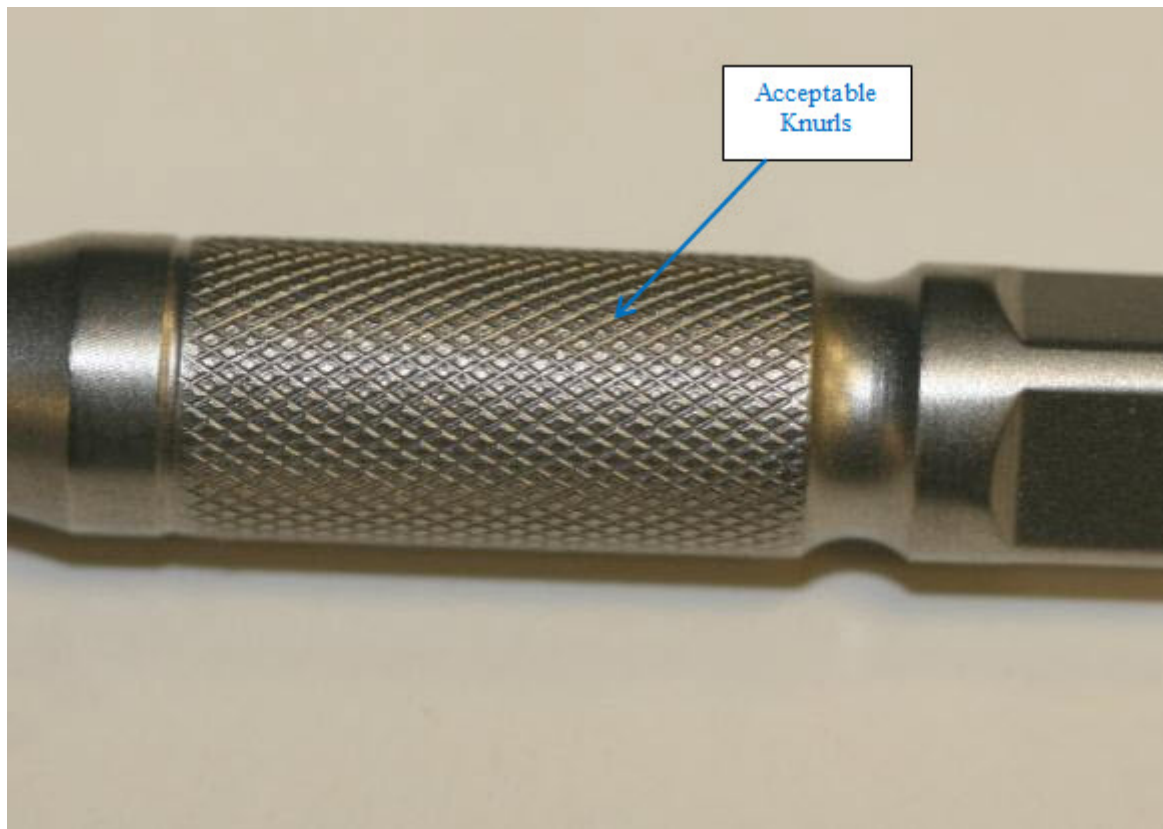
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## 9.5 Cracks, Nicks, and Dents




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## 9.6 Knurls



The following table provides guidance for teeth per inch (TPI) for each knurl type:

Type of knurl	Teeth Per Inch "TPI"
Coarse	12-14
Medium	21-25
Fine	30-33

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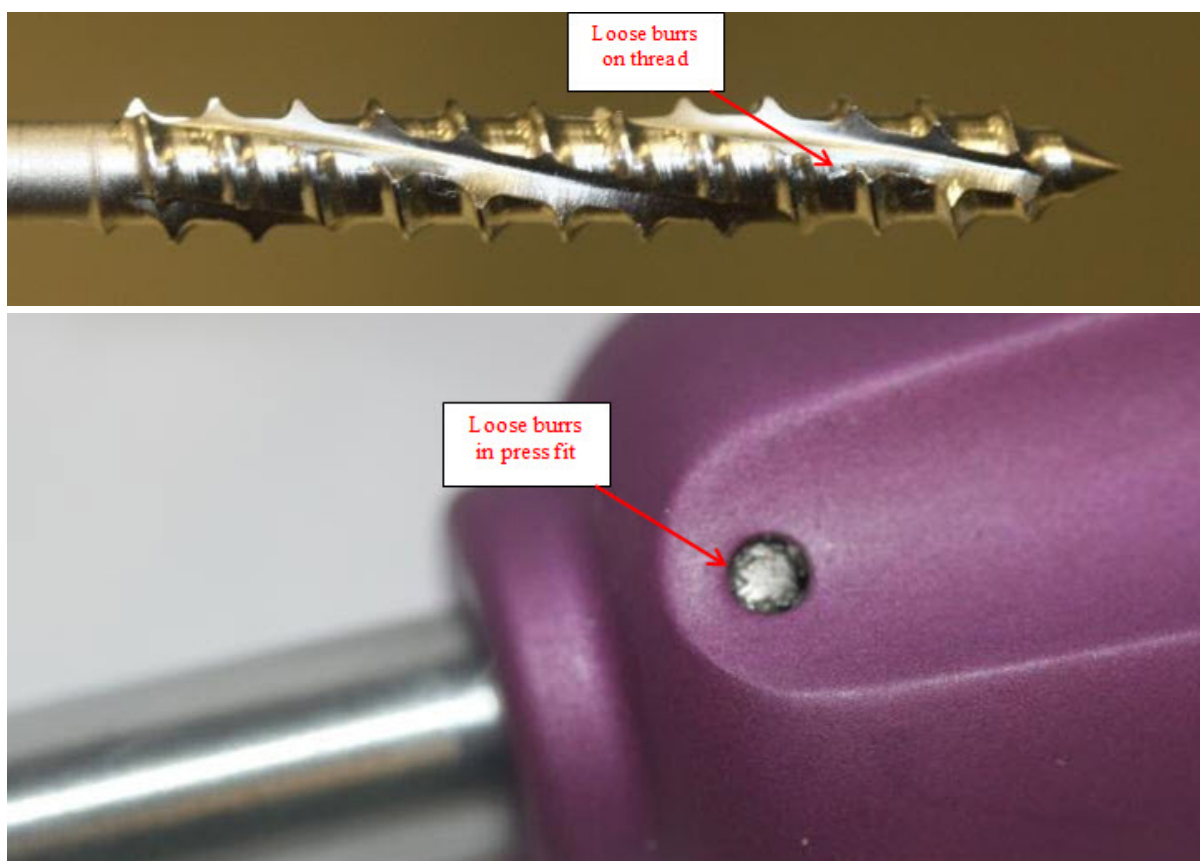
## 9.7 Burrs


Scope: All visible machined product surfaces.

Examples: Screw drivers, reduction towers, and retractor blades

Requirement:

- Parts should be free of burrs
- Acceptable Cosmetic Defects:
- Minor deformed first or last thread that is not loose



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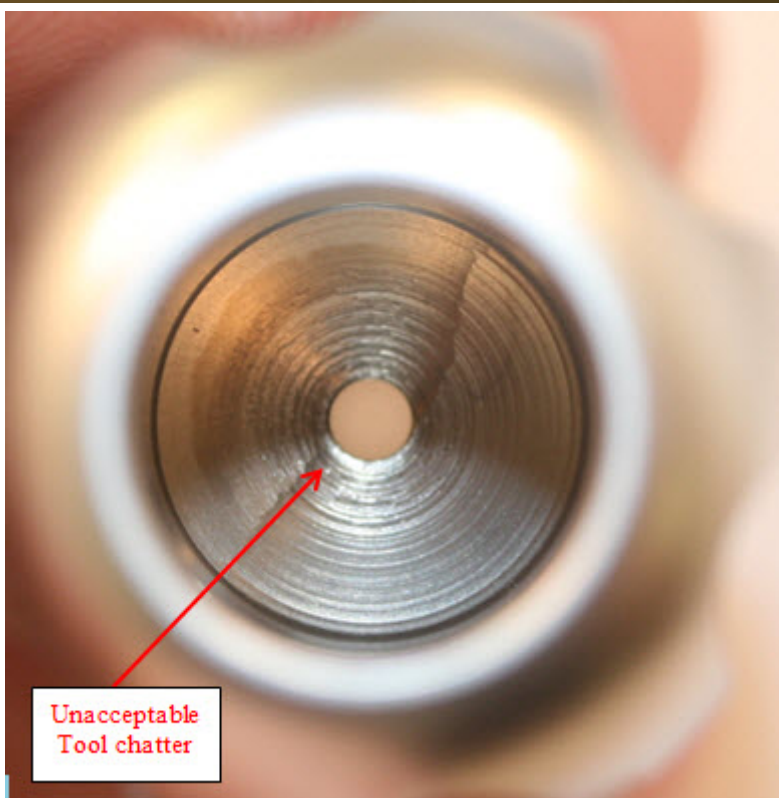
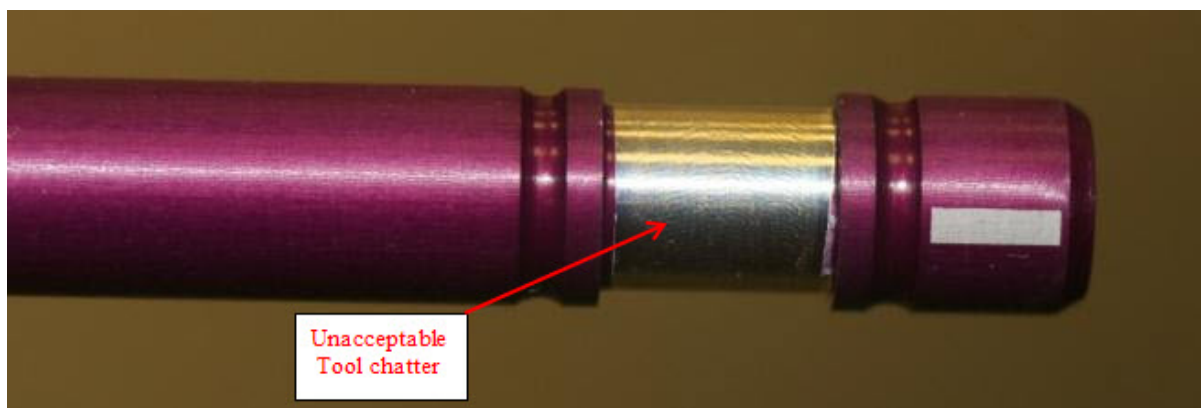
## 9.8 Tool Chatter


Scope: All finished product surfaces.

Examples: Screw threads

Requirement:

- No visible tool chatter



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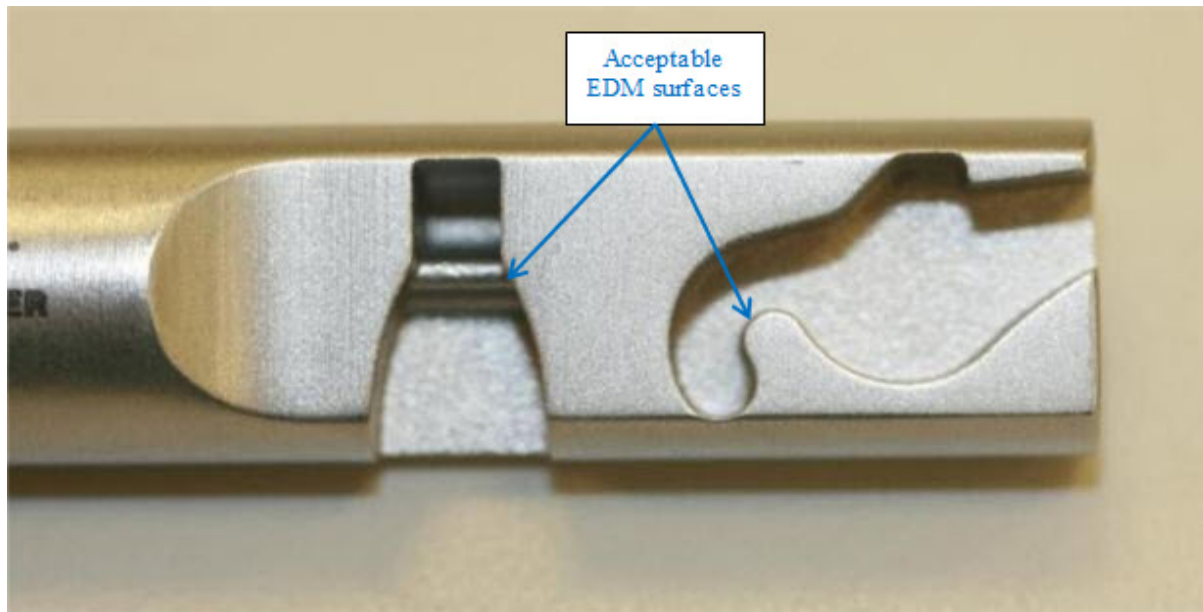
### 9.9 Electrical Discharge Machining

Scope: All finished product surfaces.

Examples: Components machined by EDM

Requirement:

- Smooth transitions with surface free of pits or cracks
- Recast layer removed



### 10.0 Finish


Scope: All finished surfaces.

Examples: probe shafts, retractor blades, implants, screws, handles

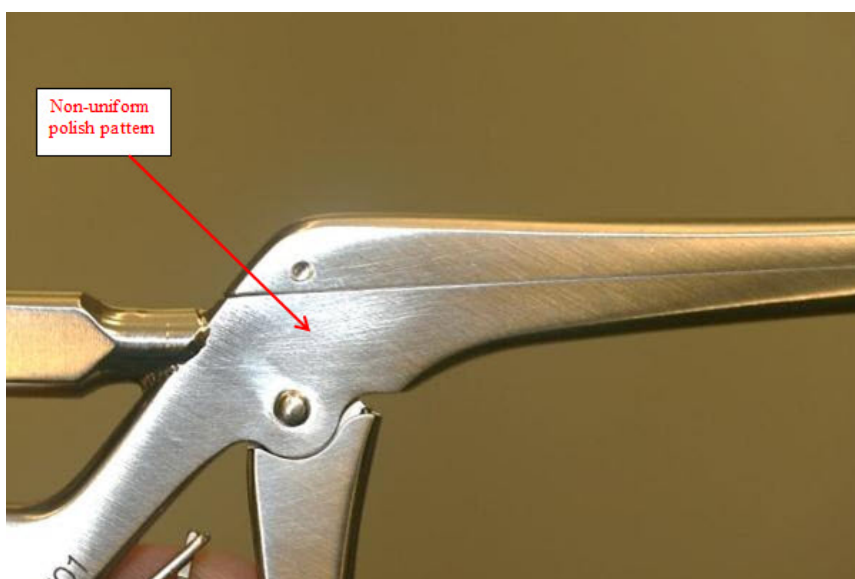
Requirement:


- Uniform lay
- Uniform color
- Uniform pattern and coverage
- No flaking/peeling
- No transition lines
- No fingerprints (handle anodized surfaces with gloves)



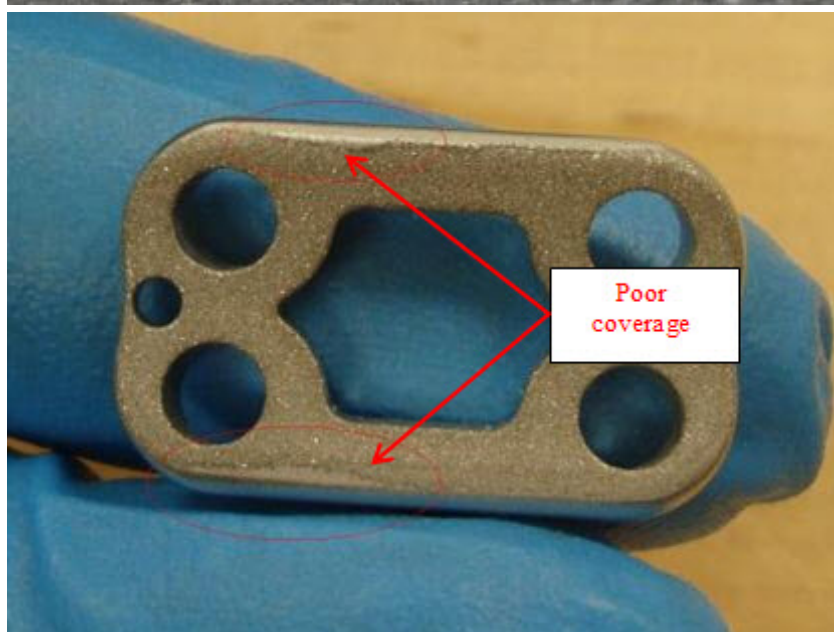
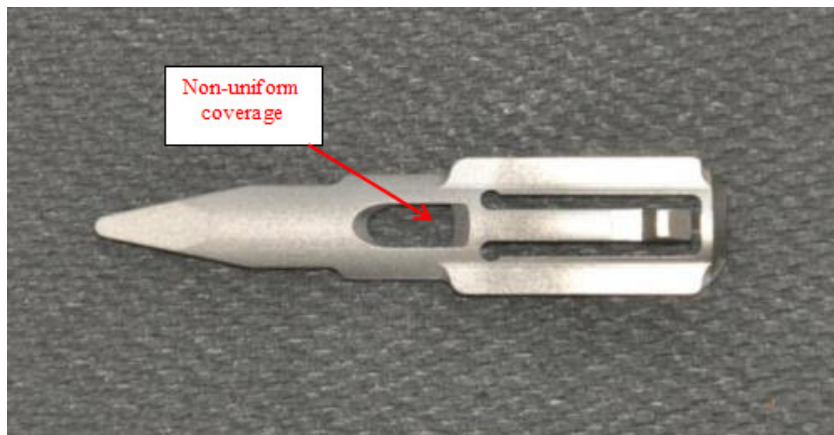
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## 10.1 Polishing



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## 10.2 Blasting



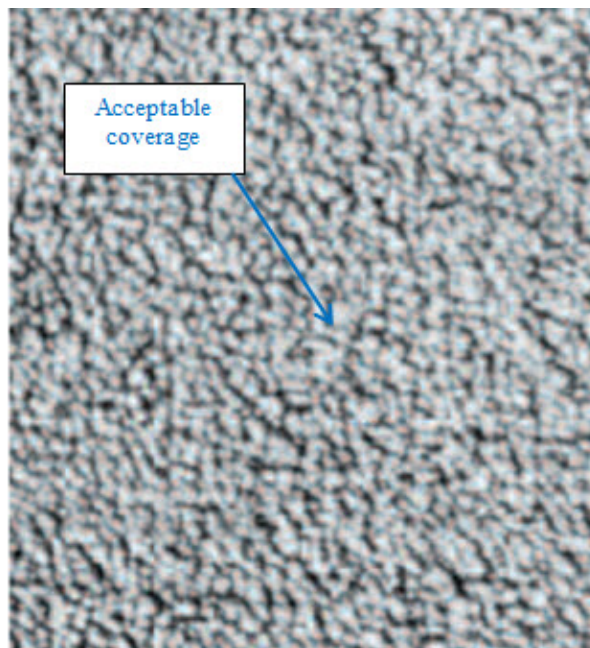
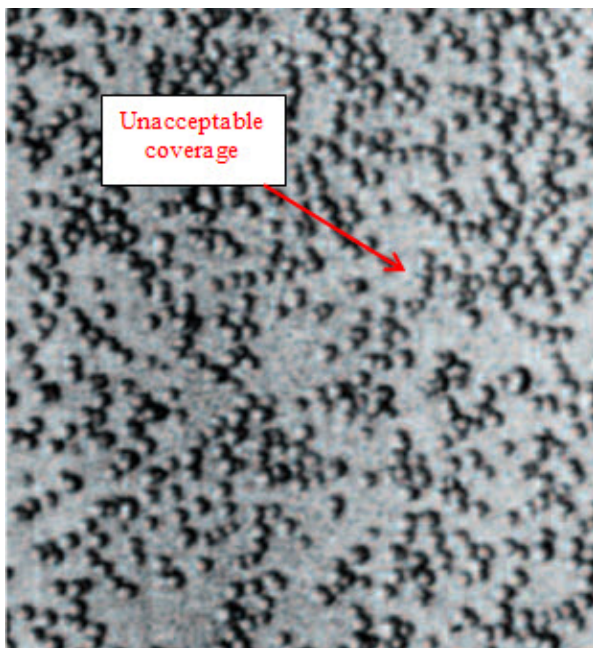
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### 10.3 Vibratory Finish




### 10.4 Shot Peen

- Shot peen coverage must be uniform and have no gaps visible to the naked eye.

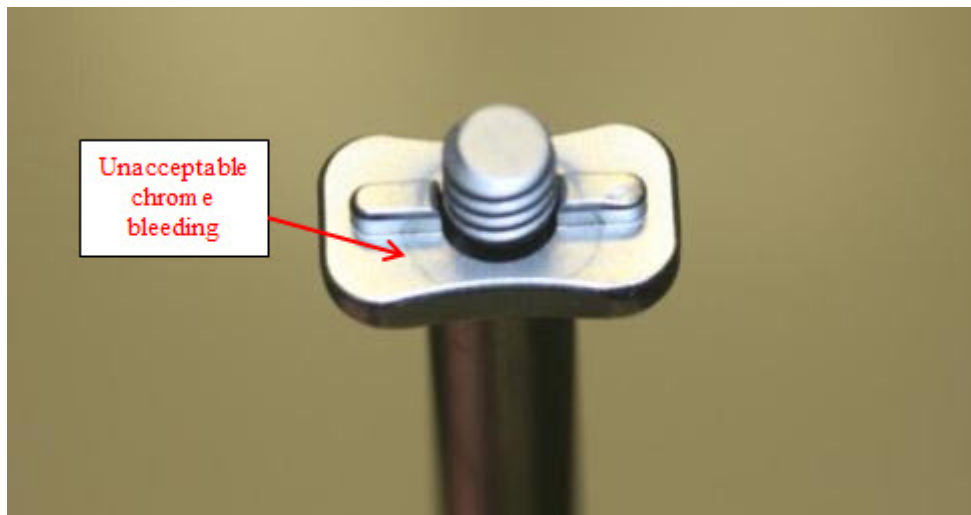




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### 10.5 Coating

- Chrome coat must closely match NuVasive Chrome Reference Gauge 9800641 if specified on product drawing or purchasing spec.



- Other coatings – (e.g., parylene, tin coat, DLC, TiAlN) no flaking, peeling, bleeding, etc. Must have a consistent finish.
- Electropolishing – consistent finish, no bleeding


### 10.6 Anodize

Care should be taken when handling parts prior to anodizing to ensure fingerprints or other foreign contaminants do not prevent proper coverage. Do not handle parts with bare fingers.

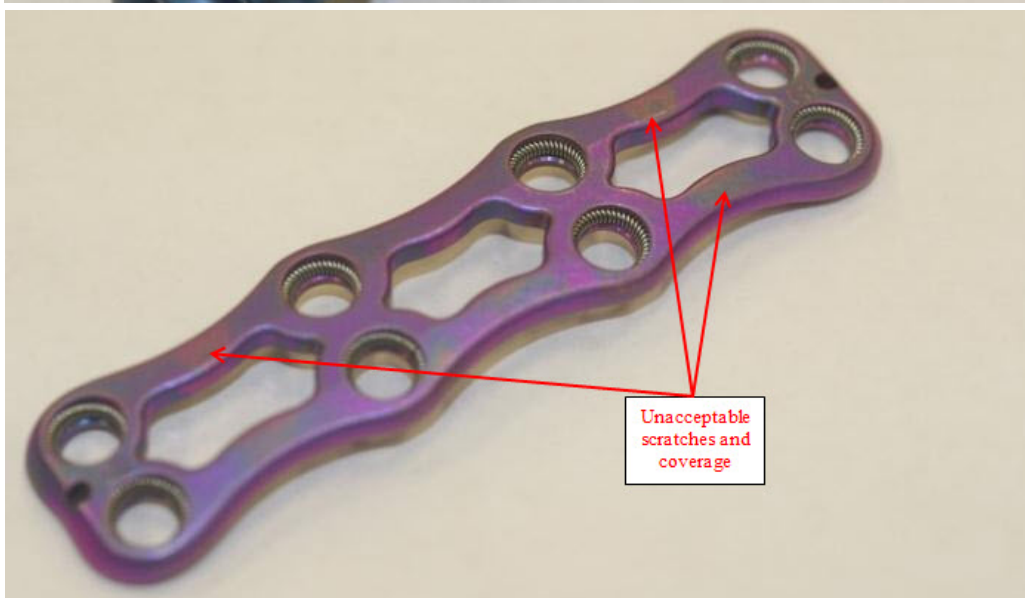
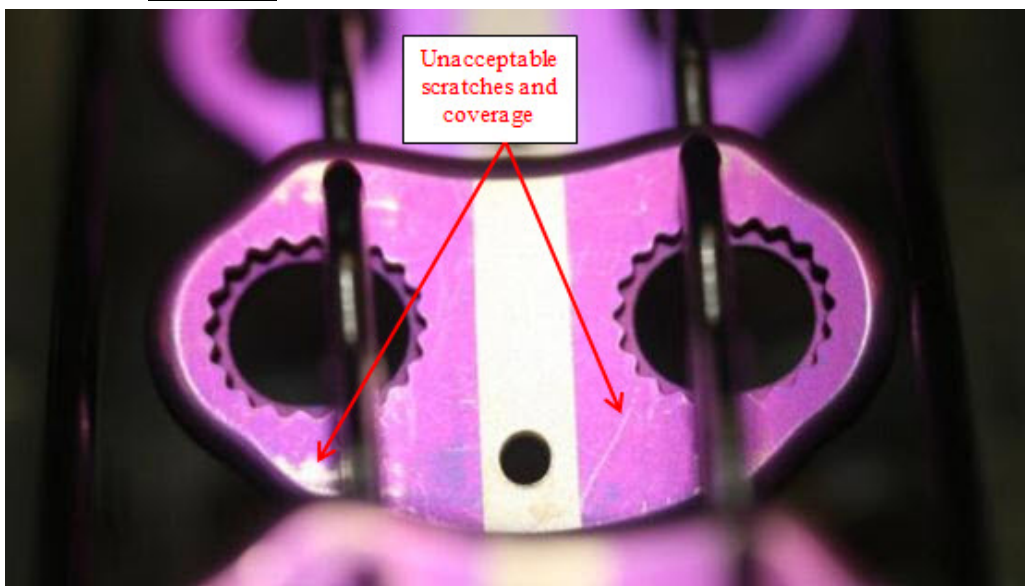
Acceptable unprocessed sections determined by the same criteria as outlined in 2.1.1. Anodization color defects should be determined using NuVasive Color Block 9800807 for Titanium parts and 9800808 for Aluminium.

- **Aluminum**




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- **Titanium**





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## 11.0 Welds

Scope: All welded product surfaces.

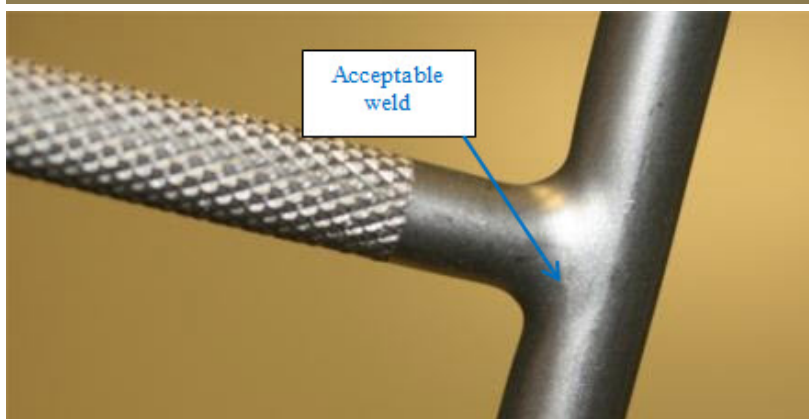
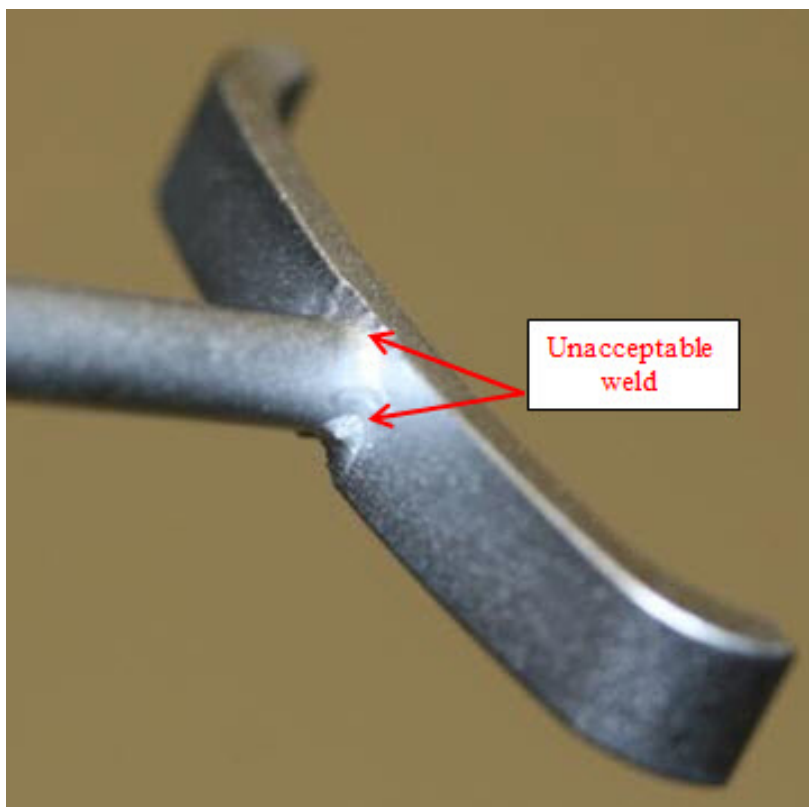
Examples: T-Handles, welded pins, and implant trials


Requirement:

- Refer to SOP 9001008, Workmanship Standard for weld criteria.

Acceptable Cosmetic Defects

- A smooth joint may not be possible for certain parts. Acceptable deviations from this requirement will be determined by Memphis Quality Engineering.



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## 12.0 Marking

Scope: All laser marked and silk screened product surfaces.

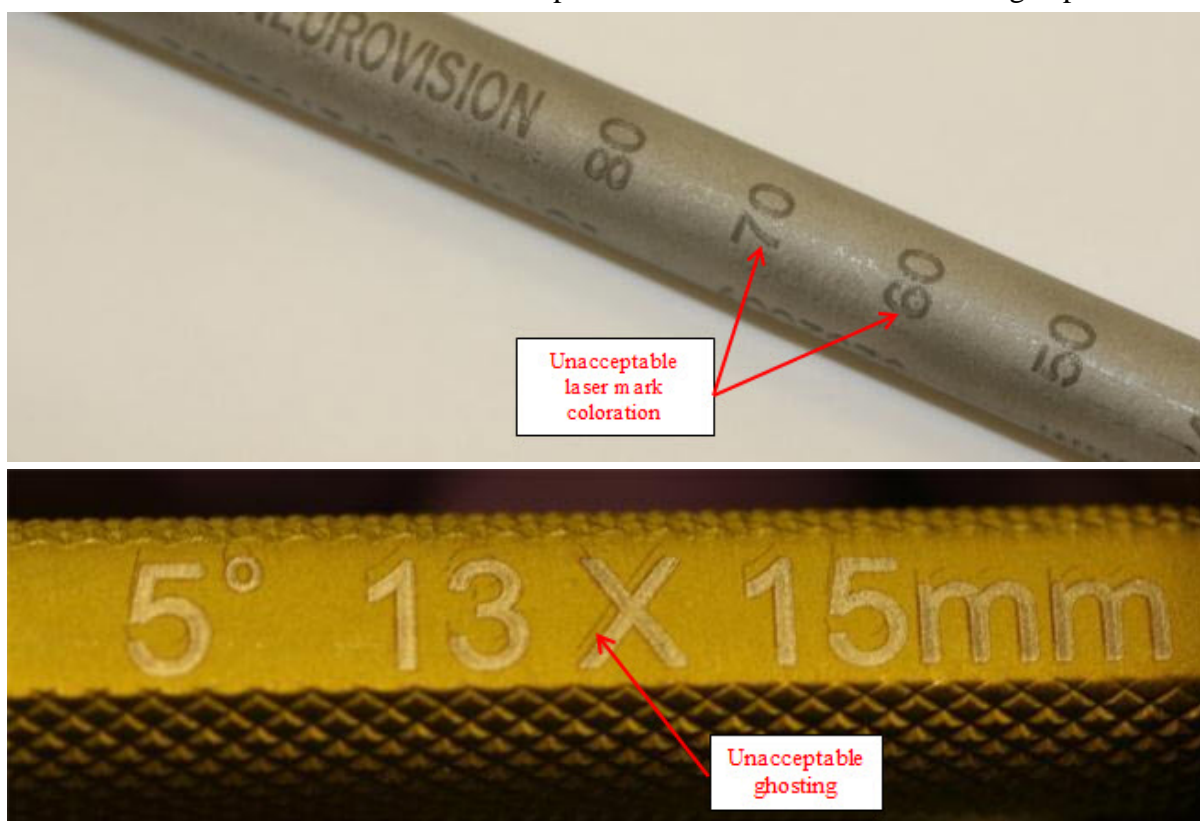
Examples: part numbers, lot numbers, part descriptions, and depth markings on instruments and implants


Requirement:

- All markings are clear and legible to the naked eye (magnification may be required for small parts)
- Marking size, font, and location match product specification/drawing
- No double etching or ghosting
- Marking must not have burnt appearance


Acceptable Cosmetic Defects

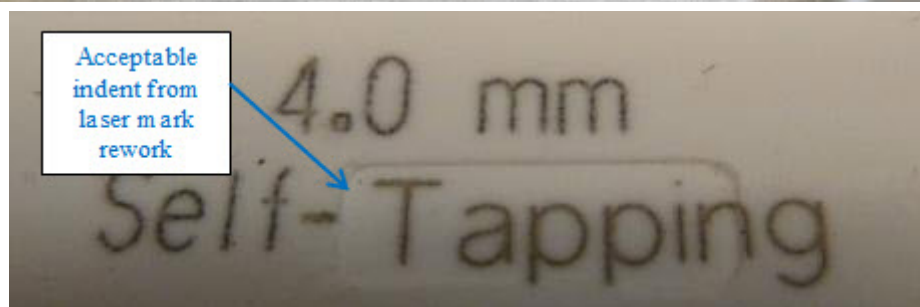
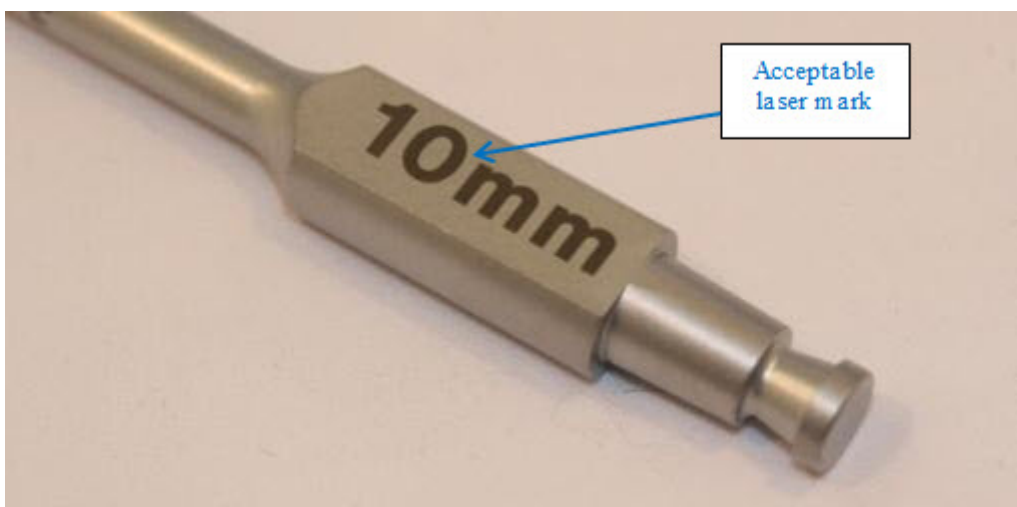
- Product surface indents are acceptable when rework of laser marking is performed.




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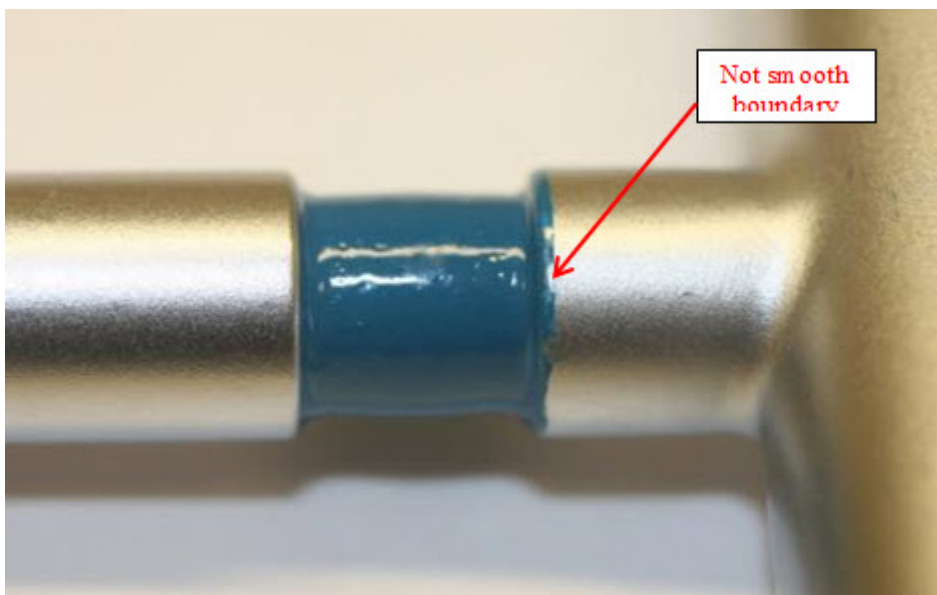
### 13.0 Uniglaze Paint

Scope: All unglazed painted product surfaces.


Examples: part numbers, size indicators, and depth markings on instruments and instruments

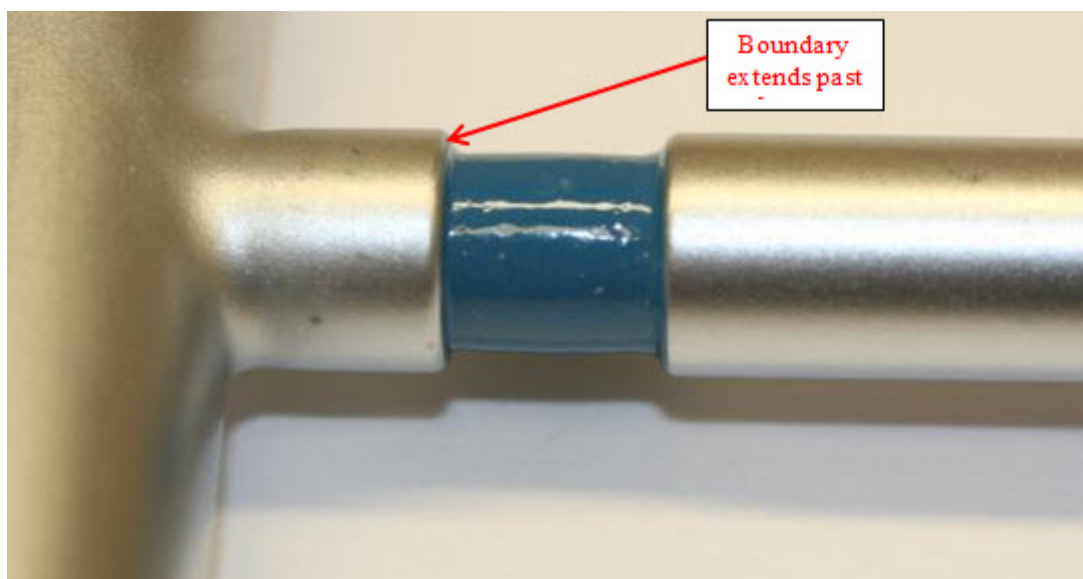
Requirement:


- Color must match print callout.
- Uniform color
- Uniform lay
- Uniform surface finish
- Smooth boundaries





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#### 14.0 Molded Components

Scope: All molded product features.

Examples: Shims and silicone over molded handles

Requirement:

- Material Color must match print callout.
- Uniform color
- Uniform lay
- Uniform surface finish
- No flash, chips, cracks, blisters, or pits
- No excessive flow marks, or splay
- No foreign particulates
- No delamination
- Refer to SOP 9001008, Workmanship Standard for additional Injection Molding requirements.




#### 15.0 Adhesives

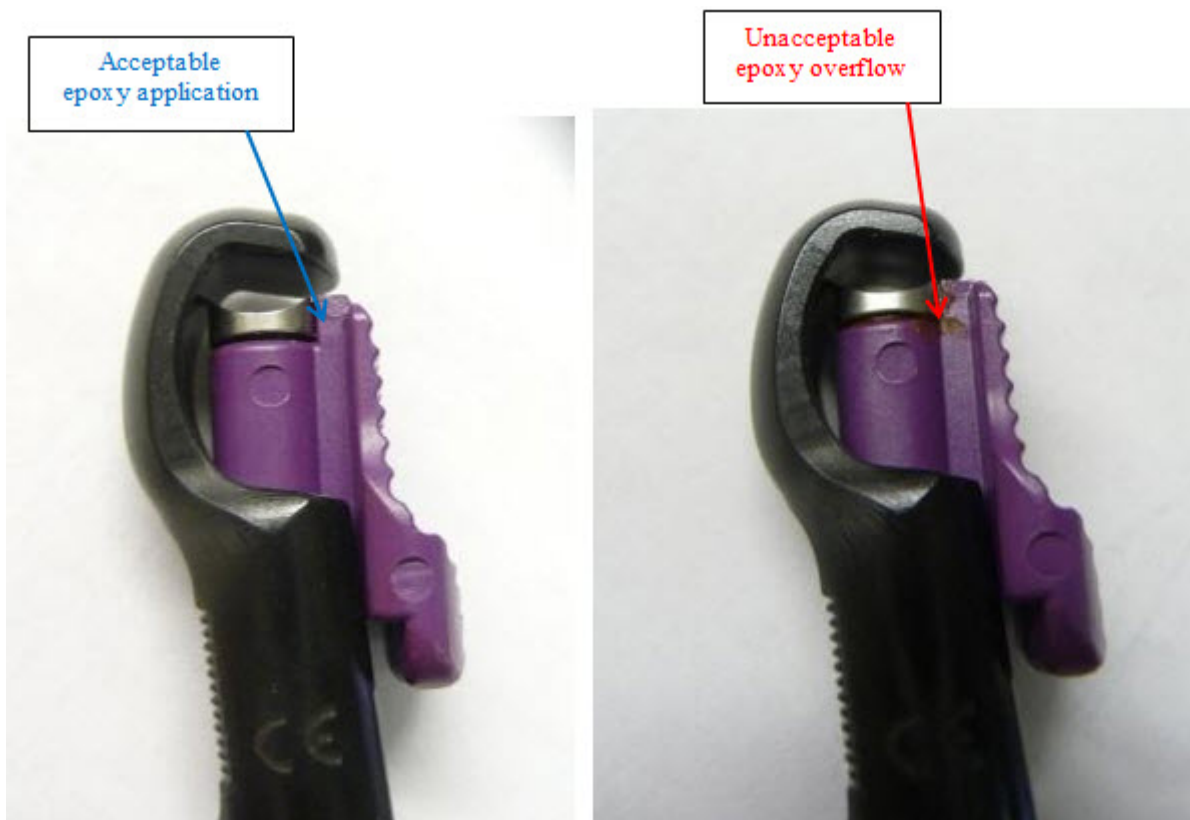
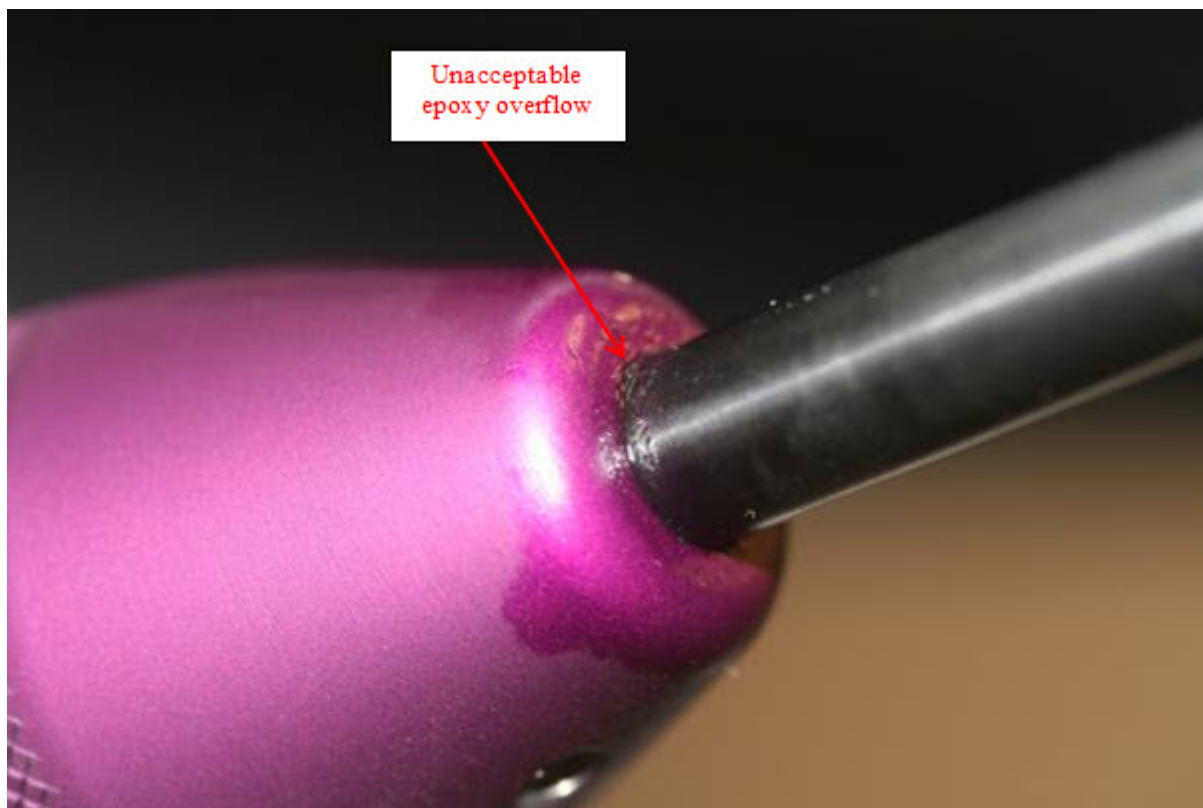
Scope: All products using adhesives.


Examples: Threads and pins sealed with medical grade Loctite or epoxy resin

Requirement:

- Minimal overflow at mating surfaces.
- No excess adhesive from improper wiping or application

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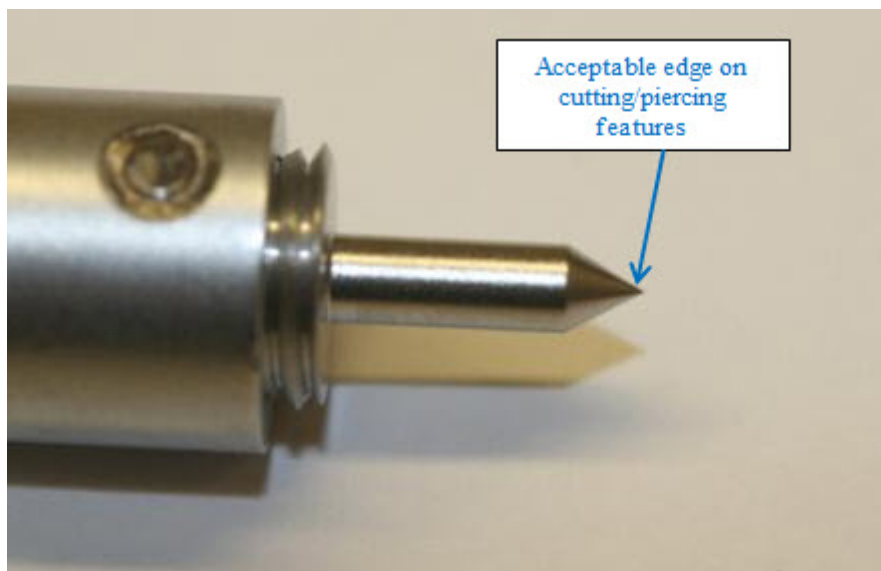
## 16.0 Cutting Edges

Scope: All instrument features designed to cut, pierce, or remove bone or tissue.

Examples: Drills, taps, reamers, broaches

Requirement:

- No excessively flat, dull, or rounded edges that would prevent proper instrument function. Must meet applicable callout on print.



## 17.0 Revision History

Revision History:				
Level	Rev	Description of Change	Sections	CN Number
III	A	Initial Release	All	CN 110113-001