



SURFACE VEHICLE RECOMMENDED PRACTICE

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Medical Device Shot Peening

RATIONALE

The intent of this document is to establish an industry standard for the shot peening of a medical device. The focus of this standard is to address the undefined requirements needed for shot peening in the medical device industry that are not included in current shot peening standards used by other industries.

1. SCOPE

This SAE Standard and its supplementary detail specifications cover the engineering requirements for the controlled shot peening of a medical device where shot peening is required for enhancement of a material's mechanical properties through the intentional creation of compressive residual stress.

1.1 Purpose

This SAE Standard covers the engineering requirements for peening of medical device surfaces by impingement of stainless steel, glass beads, or ceramic media.

2. REFERENCES

2.1 Applicable Documents

The following publications form a part of this specification to the extent specified herein. Unless otherwise indicated, the latest issue of SAE publications shall apply.

2.1.1 SAE Publications

Available from SAE International, 400 Commonwealth Drive, Warrendale, PA 15096-0001, Tel: 877-606-7323 (inside USA and Canada) or 724-776-4970 (outside USA), www.sae.org.

AMS 2431	Peening Media General Requirements
AMS 2431/4	Peening Media, Conditioned Stainless Steel Cut Wire Shot
AMS 2431/6	Peening Media, Glass Shot
AMS 2431/7	Peening Media, Ceramic Shot
SAE J442	Test Strip, Holder, and Gage for Shot Peening
SAE J443	Procedures for Using Standard Shot Peening Almen Strip
SAE J2277	Shot Peening Coverage Determination

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Documents

Document Sharing Hub

SAE J2597 Computer Generated Shot Peening Curves

AMS 2430 Shot Peening, Automatic

2.1.2 ASTM Publications

Available from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959, Tel: 610-832-9585, www.astm.org.

ASTM E 18 Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials

ASTM E 11 Standard Specification for Wire Cloth and Sieves for Testing Purposes

3. DEFINITIONS

3.1 MEDICAL DEVICE

A medical device is a product which is used for medical purposes in patients, in diagnosis, therapy or surgery.

3.2 SHOT PEENING

Shot peening is a cold working process used to produce a compressive residual stress layer and modify mechanical properties of metals. It entails impacting a surface with shot (round metallic, glass, or ceramic particles) with force sufficient to create plastic deformation.

3.3 COGNIZANT ENGINEERING ORGANIZATION

Cognizant Engineering Organization is a term applied to the engineering organization responsible for the design of the part or a designee of that organization.

4. GENERAL REQUIREMENTS

4.1 Peening Area Designation

- 4.1.1 All surfaces designated by the engineering drawing to be peened shall be peened and exhibit full coverage unless otherwise specified.
- 4.1.2 Areas designated not to be peened, shall be masked or otherwise protected from the peening stream to prevent overspray into prohibited areas. Masking shall be removed after the peening operation and parts shall be free of peening overspray and damage due to the masking method.
- 4.1.3 Sections under 1mm (.040 inch.) in nominal thickness shall not be peened unless specifically required on the engineering drawing.
- 4.1.4 Areas where peening is designated as optional, may remain unpeened, peened with full coverage, partially peened, or exhibit peening overspray that does not achieve full coverage.
- 4.1.5 Peening is optional in areas where peening is neither specified nor prohibited.

In areas of optional peening, coverage verification is not required. When the masking tolerance is not indicated on the drawing, and a peening required zone is adjacent to a peening prohibited zone, the area of peening tolerance shall encroach into the peening required areas to a maximum of 3.2mm, while the peening prohibited area shall remain free from peening indentations and overspray. If the peening required zone is adjacent to a peening optional zone no tolerance is required and the peening required zone shall receive required coverage with no allotment for peening tolerance permitted.

4.2 Intensity Verification

- 4.2.1 Intensity verification locations shall be as indicated on the drawing; when not specified on the drawing, locations shall be established by the cognizant engineering organization and shall represent locations of critical importance.
- 4.2.2 Verification locations shall be positioned to embody shot peen standoff distance and angle of impingement that correlates to the conditions that are to be practiced in the peening process of the part.
- 4.2.3 In areas of optional peening, intensity verification is not required.
- 4.2.4 Intensity and coverage shall be specified on the engineering drawing.

4.3 Media

4.4 As Received Shot Peen Media

- 4.4.1 Conditioned Cut Wire, Glass Bead, and Ceramic as received media shall conform to AMS 2431.
- 4.4.2 Use of carbon Steel peening media is prohibited.

4.5 Media in Machine

- 4.5.1 In machine media size uniformity shall be in accordance with AMS 2430.
- 4.5.2 Media size uniformity shall be determined using the sampling and sieving procedures defined in 7.3.7.4.
- 4.5.3 Glass bead and ceramic media shall be sampled, in accordance with Table 2, and inspected to ensure that not more than 10 percent (by number) of the beads or shot are broken.

4.6 Measuring Instruments

- 4.6.1 Almen gages, scales, air pressure gages, tachometers, and other applicable instruments, used for controlling shot peening, shall be calibrated against instruments whose calibration is traceable to National Institute of Standards and Technology (NIST) or other national accredited standards organization acceptable to the cognizant engineering organization.
- 4.6.2 Almen strips shall conform to SAE J442, except thickness and pre-bow tolerances shall be $\pm 0.013\text{mm}$ (± 0.0005 inch). Compensation for pre-bow of the Almen strip shall be performed in accordance with 4.10.5. Mechanically deforming strips to meet the pre-bow requirements is not permitted. Hardness of strip shall be 73.0 to 74.5 HRA for N strips and 45 to 48 HRC, or equivalent, for all other strips.
- 4.6.3 Gages for determining pre-bow and arc height of Almen strips shall conform to the requirements of SAE J442 with end stops, except that the gages shall have digital readouts and have a minimum resolution of 0.001mm (0.00005 inch). Almen gages shall be zeroed before each period of use, and at a minimum, once every 8 hours. Zeroing of the Almen gage shall be performed using a block that is flat within 0.005mm (0.0002 inch).

4.7 Almen Strip Holding Fixture

- 4.7.1 A representative non-adjustable fixture used to hold Almen strips shall be used to hold strips for the purpose of establishing or verifying a specified peening intensity. Almen strip holding fixtures shall conform to SAE J442 and shall be oriented to the peening shot stream and rotated or translated in the same manner and equipment as for peening the part. The design of the Almen strip fixturing shall be approved by the cognizant engineering organization and shall be recorded in process documentation and used for all subsequent Almen intensity verifications.

4.8 Shaded Strips or Sub-size Strips

- 4.8.1 In locations where standard Almen strips cannot be placed to accurately reflect the peening intensity, shaded or sub-size strips (as defined in SAE J442) shall be used. The relationship between the peening intensity on the shaded or sub-size strip and that on the standard strip shall be established. The intensity thus established for the shaded or sub-size strip shall be used for control of the peening intensity.

4.9 Process Monitoring

- 4.9.1 Peening machines shall provide means for continuously monitoring and recording the parameters shown in Table 1 within the tolerance indicated. Monitoring and recording of process parameters shall be performed with the use of computerized controls or any other system that is approved by cognizant engineering organization.

TABLE 1 - PROCESS MONITORING PARAMETERS

Parameter	Units	Process Tolerance Shutdown Limits Plus or Minus
Media Flow (each nozzle)	pounds / minute	10% of full scale
Air Pressure (each nozzle)	Psi	> 20 psi 10%, ≤ 20 psi 20%
Wheel Speed (each wheel)	Rpm	> 2000 rpm 1% ≤ 2000rpm 20 rpm
Translation Speed	mm/minute (Inches/minute)	10%
Deflector Speed	mm/minute (Inches/minute)	10%
Rotary Speed	Rpm	10%
Part Speed	rpm mm/minute (inch/minute)	10%
Conveyor Speed	mm/minute (Inches/minute)	10%
Peening Cycle Time	Seconds	1
Nozzle/Wheel Position	mm/degree (Inch/degree)	1.57mm (0.062 inch) /5 degrees
Table/Part Indexing	mm/degree (Inch/degree)	1.57mm (0.062 inch) /5 degrees

* Calibration of measuring devices used in the peening system shall be performed in accordance with ISO-10012-1.

- 4.9.2 The peening system shall be capable of interrupting the cycle within one second, when excursions outside set tolerances are detected for media flow, air pressure, wheel speed, nozzle or wheel translation speed, turntable speed, part speed, or conveyor speed. Excursions outside the limits in Table 1 shall cause an aborted cycle and the computer system shall record the time and abort details for the parameters listed in Table 1. Notation of root cause and corrective action shall be documented. After the out-of-tolerance condition has been corrected, the peening system shall be able to resume operation to complete the balance of the process cycle from the position of shut-down, or restart program from the beginning. Restarting of the machine shall only be done by authorized personnel. Parts processed during an aborted cycle shall be so identified on the peening certification of conformance, computer print-out, or both. Reprocessing of parts processed during a cycle abort is only permitted at the discretion of the cognizant engineering organization.

4.10 Process Intensity

- 4.10.1 Conditioned Stainless Steel Cut Wire peening media may be used for peening to intensities requiring use of "N", "A", and "C" Almen strips.
- 4.10.2 Glass bead peening media may be used for peening to intensities requiring use of the "N" Almen strip.
- 4.10.3 Ceramic peening media may be used for peening to intensities requiring either "A" and "N" Almen strips.