Quality control & quality assurance in metal additive manufacturing: the Medical Intramedullary Nail

The AM value chain. Quality during the production and design process of the Intramedullary nail is discussed according to the AM value chain.

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1. Introduction
We use a case of the Intramedullary Nail to discuss quality in metal additive manufacturing. On the ManSYS website, the AM value chain is used to describe AM quality aspects. We will use the value chain structure to discuss quality issues in this particular case.

2. Product description
Intramedullary (IM) Nails are Orthopaedic Trauma products that are surgically inserted and fixed into the medullary cavity of the long bones in order to provide support, and share loading with the bone after traumatic injury.

Metaphyseal fractures are typically associated with high energy injuries and as a consequence are often comminuted. These unstable fractures are difficult to treat given the tendency of the fragments to move around. The function of the IM nail, is to prevent bone fragments from translating, and help the fracture to heal in a more stable environment.

IM nails are commonly available in a range of sizes (lengths, increasing in 1 or 2 cm increments) and also in a small number alternative diameters.

Conventional products are currently produced by traditional reductive machining processes from solid Ti6Al4V bar stock using drilling, bending, milling and thread cutting steps to produce the raw part. Secondary manufacturing processes include anodisation, etching, cleaning, packaging and sterilisation.

3. Product requirements
Standards
The various ASTM Standards for Ti-6Al-4V are as follows:
1. ASTM F1472 – wrought/forged Ti-6Al-4V
2. ASTM F136 – wrought/forged Ti-6Al-4V ELI
3. ASTM F2924 – Additively Manufactured Ti-6Al-4V
4. ASTM F2885 – MIM’ed Ti-6Al-4V
5. ASTM F1108 – Cast and HIP’ed Ti-6Al-4V

Of the above, F2924 is the only one not specifically for medical devices (although medical devices are inferred in the text of the standard). The minimum mechanical properties are transcribed below in Table 1 (all other requirements can be found in the standards themselves):
Table 1 Minimum mechanical properties

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Tensile Strength</td>
<td>135 ksi</td>
<td>130 ksi</td>
<td>130 ksi</td>
<td>125 ksi</td>
<td>125 ksi</td>
</tr>
<tr>
<td>Yield Strength</td>
<td>125 ksi</td>
<td>120 ksi</td>
<td>120 ksi</td>
<td>115 ksi</td>
<td>110 ksi</td>
</tr>
<tr>
<td>Elongation</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>8%</td>
</tr>
<tr>
<td>Reduction of Area</td>
<td>2.5%</td>
<td>15%</td>
<td>15%</td>
<td>25%</td>
<td>14%</td>
</tr>
</tbody>
</table>

The Quality Management System standard that is most applicable to medical device OEM’s is ISO 13485 and is applicable to the manufacture of IM nails.

The finished part must also meet the tolerances described in the original device design that has received regulatory approval. The parts undergo a visual inspection and fit to an instrument jig. The surface finish, colour and any marking/etching of the part may also be scrutinised.

IM Nails are supplied clean and sterile. Parametric methods are used for testing of sterile finished product and batch release purposes. Packaging and sterilisation are completed using validated methodologies. Packaging, marking and labelling of the products must also conform to the standards described in ASTM F1264.

**Functional requirements**
The device is considered a temporary stabilising device and as such has a limited mechanical service life. The mechanical service lifetime is intended to exceed the time required for healing of hard and soft tissues required to regain the structural competency of the natural anatomy. These devices are not designed to support skeletal parts should they not heal. This function is distinct to prosthetic devices that are intended to replace the mechanical function of a skeletal or soft tissue part permanently and serve as the sole load bearing member.

As mentioned previously, the IM Nail is designed to prevent the translation of bone fragments. The device also allows compression of the fracture to aid healing.

**Usability requirements**
The product is used in conjunction with a set of tools and instruments that enable the correct implantation of the nail. The nail must remain compatible and be able to work in conjunction with this instrumentation. In addition the nail is supplied clean and sterile and sealed in packaging such that it is ready to use in the operating theatre and can be prepared for use easily by theatre staff. The finish of the AM part should be indistinguishable to that of the standard part.

**Technical requirements**
The Device is required to conform to ASTM F1264 (Standard specification and test methods for Intramedullary fixation devices).
ASTM F1264 provides characterisation of the design and mechanical function of the device specifies labelling and material requirements, provide test methods and performance criteria for the mechanical properties of the device.

4. Testing
The mechanical testing described in ASTM F1264 includes:

- Static four point bending (Bending strength and stiffness). The purpose of this test is to measure bending strength and bending stiffness intrinsic to the design and materials of intramedullary fixation devices
- Torsional Testing: the purpose of this test is to determine the torsional stiffness of intramedullary fixation devices. The central part of IMFD, with a straight and uniform cross-section and away from screw holes or other interlocking features, is tested in a static test.
- Cyclic Bending Fatigue: test procedure for performing cyclic bending fatigue testing of intramedullary fixation devices. The central part of the IMFD, with a straight and uniform cross section and away from screw holes or other interlocking features, is tested in cyclic four-point bending.