Designation: EASSI Standard Test Method for Visual Aspect Control of Needles Used With Surgical Sutures

INTRODUCTION

The purpose of this test method is to provide a common method for controlling the visual appearance of a surgical needle.

1. Scope

1.1 This test method describes a method for inspecting the physical shape and appearance of a surgical needle. It also describes test procedures and equipment.

1.2 This test method does not intend to address the accepted quality level with respect to actual conditions of use.

2. Tip control

2.1 Control aim:

The aim is to check the quality of the needle tip for damage that would decrease the penetration performance.

2.2 Equipment:

Appropriate magnification used for inspection should be at least similar to that utilized in surgery, which is most often unaided (0x magnification) but typically does not exceed 5X on cardio procedures, and does not exceed 10x for needles used in micro-vascular anastomosis, nerve surgery, or ophthalmic surgery. The manufacturer should define magnification according to needle wire diameter and/or intended specialty (i.e. Cardiovascular, Ophthalmic, Microsurgery). Magnifications of 5x and 10x are proposed as a minimum guideline and binocular examination in excess of 5x and 10x is permitted.

2.3 Procedure:

Three different general methods may be used to inspect needle tips:

- binocular microscope examination (when magnification is required as defined under section 2.2),
- comparator microscope examination used to compare a needle tip profile against a defined profile, and
- automated computer assisted vision system inspection.

If inspection is conducted via binocular microscope examination, needle defects and point or cutting edge dulling may be detected. If inspection is conducted via comparator microscope or automated vision system, a defined needle point profile with tolerances may be effectively assessed. A combination of binocular examination of a representative sample set on a per lot basis with comparator microscope or automated vision system used in line during manufacturing is the preferred method to prevent needle defects (such as burrs, pits, dull cutting edges) while providing adherence to the needle point shape as defined in the manufacturer's needle specification.

2.4 Results:

- The tips observed have to be appropriately sharp (no unintended rounded tip or tip with flat extremity visible under the right magnification). The edges of the cutting tip needles have to be sharp (no defect on edge, no rounded edges obvious under specified magnification).
  - This provision does not apply to blunt point needles used for soft tissues or used to prevent the transmission of infectious diseases to healthcare workers.
- The tips observed shall not show any damage due to shock, such as a damaged tip or hooked tip visible under binocular microscope examination, automated vision system examination, or comparator microscope examination with the minimum magnification defined under section 2.2, and shall meet specifications, as applicable, and, as defined by the manufacturer's specified needle geometry.

3. General appearance control

3.1 Control aim:

The aim is to evaluate the visual appearance of the needles following different criteria.

3.2 Equipment:

Appropriate magnification used for inspection should be at the least similar to that utilized in surgery, which is most often unaided (0x magnification) but typically does not exceed 5X on cardio procedures, and does not exceed 10x for needles used in micro-vascular anastomosis, nerve

surgery, or ophthalmic surgery. The manufacturer should define magnification according to needle wire diameter and/or intended specialty (i.e. Cardiovascular, Ophthalmic, Microsurgery). Magnifications of 5x and 10x are proposed as a minimum guideline and binocular examination in excess of 5x and 10x is permitted.

3.3 Procedure:

Examine the set of samples per needle lot in a well-lit environment or under a well-lit binocular microscope where magnification is appropriate per section 3.2.

3.4 Results:

- Variation in surface appearance and reflectivity due to electrochemical processing or due to metal forming process that do not compromise the shape of the needle or lead to burrs, defects outside of the defined outline of the needle, or pitting are acceptable as long as penetration performance is not compromised as a consequence.
- Discolorations, stains, pits, or marks on the surface that are obvious to the unaided eye or under the defined magnification constitute a needle defect.
- Particulates on the surface visible to the unaided eye or under the specified magnification constitute a defect.

4. Sampling

4.1 Acceptable Quality Level (AQL): sampling plans should be developed based upon the product performance needs, process capability, and risk management.

5. Report

5.1 All data should be reported, including the following information:

4.1.1 Sample identification, test conditions, and apparatus;

4.1.2 Test date and test technician.

6. Precision

Precision - The precision of the results of this test method is dependent on the equipment selected.

7. Keywords

Surgical needle tip; needle defect; visual aspect control; visual inspection.