Designation: EASSI Standard Test Method for Dimensional Measurement of Needles Used With Surgical Sutures

INTRODUCTION

The purpose of this test method is to provide a common method for measuring the dimensions of a surgical needle.

1. Scope

1.1 This test method describes a methodology for measuring needle dimensions: bore/hole size, bore/hole depth, wire size, curvature, length, and body geometry. It describes the test procedures, components, and equipment.

1.2 This test method applies to straight and curved surgical needles.

1.3 This test method does not intend to address the value of the test with respect to actual conditions of use.

1.4 In this test method, it is assumed that the needles used for this test have passed all applicable quality standards and have no physical malformation that would inappropriately influence the test results. Needles should be inspected prior to testing to verify there are no physical concerns that would interfere with the test or test results.

2. Hole size measurement (drilled needles)

2.1 Measurement aim:

Determine the bore/hole dimensions for suture attachment. (first main criteria for attaching process by suture manufacturers)

Components and equipment:

A range of pin gages or any other equipment, according to the range of bore/hole sizes requested. Optical vision or X-ray system measurement may be used.

2.2 Procedure:

Take a sample of needle and choose a pin gage or similar uniform cylindrical instrument which can be introduced into the bore/hole.

Select pin gages or pin gage set based upon the bore/hole that was drilled.

3. Hole depth measurement (drilled needles)

3.1 Measurement aim:

Determine the value of the bore/hole depth (second main criteria for attaching process by suture manufacturers)

3.2 Components and equipment (as example only):

The dimensional tolerance of the pin gage should exceed the specified dimensional tolerance of the bore/hole. Optical vision or X-ray system measurement may also used.

3.3 Procedure:

A series of pin gages spanning the tolerance range of the needle bore/hole should be used to check hole diameter and depth. Within the specified diameter tolerance range of the bore/hole, if the pin gage can be inserted to a depth in excess of the minimum specified bore/hole depth then the bore/hole depth is appropriate and acceptable. If pin gages of diameter greater than the maximum allowable diameter of the bore/hole can be inserted into the bore/hole, to the minimum allowable depth or beyond, then the needle should fail for oversized bore/hole. Otherwise the needle would pass since the bore/hole diameter would fall within the specified range, as verified by pin gage inspection. The pin gage can be physically inserted by an operator, or alternatively the pin gage can be stationary and the needle bore/hole can be made to fit over the pin gage. Automated insertion of the pin gage may also be used, in which case validated inspection equipment would be used in lieu of a human operator to assess the depth of the suture-receiving hole using the appropriate size and range of pin gages. If X- ray inspection is used, the minimum bore/hole diameter must be maintained for the minimum specified bore/hole depth as determined through analysis of the x-ray image. Similarly, the bore/hole diameter must be equal or less than the maximum bore/hole diameter allowable by the needle specification in at least one or more locations within the attachment area.

4. Wire diameter measurement

4.1 Measurement aim:

Determine the diameter of the wire.

4.2 Components and equipment:

- A micrometer with a rotating spindle* (as example only):
  - Min range: 2 mm
  - Max display resolution: 0,001 mm
  - Max accuracy: 0,01 mm
  - Heads: flat and Ø6,35 +/- 0,1 mm

or,

A dial or digital gage indicator with a chisel-point contacting head and counter-opposed flat platform

or,

A comparator microscope (also known as a profile projecting microscope) with appropriate templates and magnification for assessing wire diameter, or with functioning precision dial or digital caliper adjustments capable of taking measurement

or,

A machinist's microscope with functioning precision dial or digital caliper adjustments capable of taking measurement

or,

A laser micrometer or other similar direct-light based measurement instrument

(*) As a guideline.

These values should reflect the precision of the toolmaker quality instrument. Accuracy should be one decimal place more than required measurement.

4.3 Procedure:
Measure the wire in a section that is not distorted or formed. Measurement of the wire across orthogonally opposing directions is preferred. Alternatively, needle can be measured using a laser micrometer or any of the other instruments described under section 4.

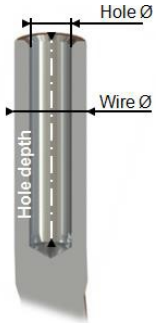


FIG. 1 Needle cross section – Drilling area

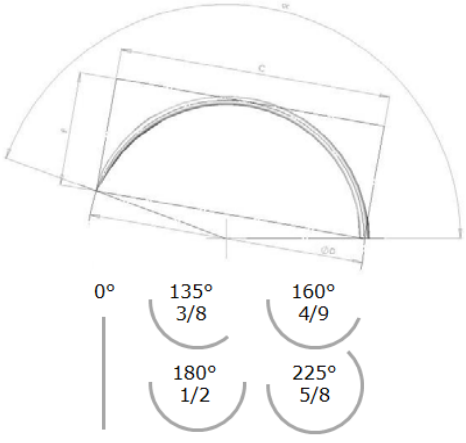
5. Curve angle and length measurement
5.1 Measurement aim:
Determine the degree of curvature and the overall needle length.
5.2 Components and equipment:

- A comparator microscope (also known as a profile projecting microscope) equipped with a 10x or greater zoom fitted with an XY measurement table.
- Templates (+/- 1° Min accuracy)*

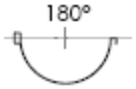
(*) As a guideline
Magnification should be at the discretion of the manufacturer and precision of the template should be treated in the same manner. Ultimately, the manufacturer needs to determine what is needed to meet their device and quality requirements.

5.3 Procedure:
Put the needle on the profile projector or template. With the measurement table, measure the chord (C) and the broach (F).
The curve angle and the length of the needle are calculated by using these equations:
C: Length of the chord (mm)
F: Broach of the arc (mm)
α: Angle of the arc (°)
L_{arc}: *Length of the arc (mm)*

$$D = \frac{C^2}{4F} + F \qquad Sin\alpha = \frac{C}{D} \qquad L_{arc} = \frac{\alpha \times \pi D}{360}$$



Or,
conforms to the template.



Optical vision system measurement or shadowgraph with overlay may also be used.
Angles may also be recorded in degrees. Curve convention is recommended as follows:

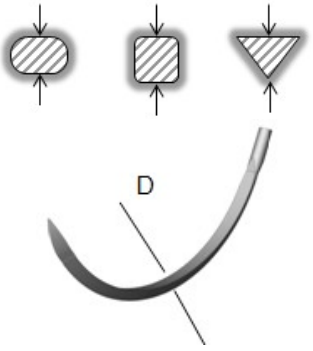
- 5/8 201-245°
- 4/8 (1/2) 156-200°
- 3/8 116-155°
- 2/8 (1/4) 70-115°
- 1/8 25-69°

Note: needles of unconventional curvature are also of use in the field of surgery and while they do not adhere to the scheme defined above, they are allowable and appropriate. Examples include but are not limited to: Fishhook, Ski, Reverse Ski and Compound curve needles. The curvature of these needles is most commonly assessed via comparator-template measurements

6. Geometry (for round flat, rectangular or square body) and triangle height measurement
6.1 Measurement aim:
Determine the value of the needle body thickness and/or triangle height.
6.2 Components and equipment:

- Dial or digital caliper
- Dial or digital indicator
- Comparator microscope (also known as a profile projecting microscope)
- Laser micrometer
- Dial or digital micrometer (by way of example only)
  - Min range: 2,5 mm
  - Max display resolution: 0,001 mm
  - Max accuracy: 0,01 mm / Min accuracy 5µm
  - Head 1: flat and Ø6,35 +/- 0,1 mm
  - Head 2: < Ø 2 mm, fixed and perpendicular to the Head 1

These values should reflect toolmaker quality instrument precision, and may be used as a guideline.
6.3 Procedure:
Put the needle between the two heads of the micrometer and measure the geometry in the middle of the needle body as shown on the picture below:



Blade micrometer, template, optical system, laser micrometer could also be used for measuring geometry as described above

7. Sampling

Acceptable Quality Level (AQL): sampling plans should be developed based upon the product performance needs, process capability, and risk management. For statistical purposes, a minimum of 30 needles is recommended.

8. Report

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

8.1.1 Sample identification, test conditions, and apparatus;

8.1.2 Test date and test technician.

9. Precision

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

10. Keywords

Surgical needle length; suture; bore/hole size; bore/ hole depth; curvature; body thickness; triangle height.