Designation: EASSI Standard Classification of Needles Used With Surgical Sutures

INTRODUCTION

The purpose of this standard is to provide a common classification for identifying and choosing a surgical needle. A suture device in its most common form comprises a thread attached to one or two needles. The needle is an essential component as it is the first part of the suture device to pass through the tissue and, to a certain extent, conditions the success of the suturing. The typical needle consists of a point, body, attachment section, length, wire size, and, if applicable, curvature.

Each of these features have to be carefully identified for choosing the most appropriate needle for the patient and surgical application.

1. Scope

1.1 This standard covers general classification for surgical needle wire diameter.

1.2 This standard provides an easy to recognize nomenclature for suture needle wire diameter but in no way mandates the use of this nomenclature on identifying packaging and product instruction for use (IFUs) since use of this nomenclature is not universally recognized today by the medical community.

2. Classification

This classification is used as a standard for defining the needle diameter.

For example, a Needle Classification 3 corresponds to a needle of 0.300-0.349mm in diameter.

Needle Classification	Needle Diameter in mm
0.4*	0.040-0.049
0.5*	0.050-0.069
0.7*	0.070-0.099
1*	0.100-0.149
1.5	0.150-0.199
2	0.200-0.249
2.5	0.250-0.299
3	0.300-0.349
3.5	0.350-0.399
4	0.400-0.499
5	0.500-0.599
6	0.600-0.699
7	0.700-0.799
8	0.800-0.899
9	0.900-0.999
10	1.000-1.099
11	1.100-1.199
12	1.200-1.299
13	1.300-1.399
14	1.400-1.499
15	1.500-1.599
16	1.600-1.699

(*) Micro-needles: Needle Classification 1 and below

3. Rationale

3.1 Because there is a clinical need for a variety of surgical suture needles for surgical procedures, they are manufactured in various configurations and from various materials. For practical purposes, these devices supplied by different manufacturers need a defined classification system.

3.2 The classification defined in this standard is most commonly used for surgical suture needles. However, the intent is not to prohibit technological innovation or to exclude surgical suture needles manufactured with other types of features. Therefore, there might be additional diameters. Moreover, units of measurement and classification vary considerable across the world and this standard is not meant to mandate additions or changes to packaging or IFUs. Such changes are left to the discretion of the suture manufacturer.