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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Implants for surgery — Staples with parallel legs for orthopaedic use — General requirements

*Implants chirurgicaux — Agrafes à pattes parallèles à usage orthopédique — Spécifications
générales*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8827 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Implants for surgery — Staples with parallel legs for orthopaedic use — General requirements

1 Scope and field of application

This International Standard covers general requirements and the designation of dimensions and tolerances of staples with parallel legs intended for use in orthopaedic surgery.

NOTE — The annex gives guidance on the selection and use of staples and does not form an integral part of this International Standard.

2 References

ISO 5832, *Implants for surgery — Metallic materials —*

Part 1: Wrought stainless steel.

Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.

Part 4: Cobalt-chromium-molybdenum casting alloy.

Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.

ISO 6018, *Implants for surgery — General requirements for marking, packaging and labelling.*

ISO 6892, *Metallic materials — Tensile testing.*

3 Design

3.1 Radius of curvature

The internal radius of curvature of staples made from wire shall be not less than 2 mm or the diameter of the wire, whichever is the greater. The curve shall have a smooth contour.

3.2 Points

Points of staples shall be conical, trocar-shaped, spear-shaped or flattened (i.e tapered in one plane).

3.3 Legs

The legs shall be parallel.

NOTES

1 Examples of typical forms of staples used in orthopaedic surgery are illustrated in figure 1. Figure 1 shows the designation of dimensions and gives nomenclature; it does not purport to specify design requirements and does not otherwise form part of the requirements for staples as laid down in this International Standard.

2 Staples are commonly of circular, oval or modified rectangular cross-section, although other forms may be used. If staples are made from wire, wire 2,5 mm in diameter is commonly used. Greater strength may be achieved by using an oval cross-section, generally of the order of 4 mm x 2 mm, or by reinforcing the bend area with webs [see figure 1b)]. The legs may be plain, or have barbs or other surface features or treatments.