

BUSINESS PLAN

CEN/TC 285

NON-ACTIVE SURGICAL IMPLANTS

EXECUTIVE SUMMARY

Business Environment

The task of CEN/TC 285 is to standardize non-active surgical implants, including implant material. Not included in the scope are dental and ophthalmic implants. The standardization work is done to satisfy at least the essential requirements of the European Directive on Medical Devices 93/42/EEC.

This work is done in close cooperation with the corresponding ISO Technical Committee on Implants for Surgery - ISO/TC 150 - as well as other Technical Committees of CEN, CENELEC, ISO and IEC.

The parties involved are

- Industry of non-active surgical implants
- Users of non-active surgical implants
- Public authorities
- Notified bodies
- Testing laboratories for non-active surgical implants

CEN/TC 285 standards address the safety, quality and performance as well as interchangeability and compatibility of non-active surgical implants in order to satisfy three needs: The safety and comfort of patients, the surgeons' confidence in the product quality and the facilitation of European and global trade and regulation. Its work is therefore of importance to industry, government regulators, purchasers, users (surgeons) and of course the most important end-user, the patient.

Benefits

European Standards created by CEN/TC 285 provide a means to demonstrate compliance with the essential requirements of the European Directive on Medical Devices 93/42/EEC and build a framework for a harmonized regulatory process, i. e. testing and certification for non-active surgical implants.

Close cooperation with ISO/TC 150 "Implants for surgery" has led to EN ISO standards, improving accessibility of the worldwide market for non-active surgical implants. These EN ISO standards cover the fields general requirements, endoprostheses, neurosurgical implants, instrumentation, vascular implants, mammary implants and minimum data sets.

In cooperation with ISO/TC 157 "Mechanical contraceptives", EN ISO 7439 "Copper-bearing intra-uterine contraceptive devices – Requirements, tests contraceptive devices" has been published.

In the field of injectable implants, one CEN Technical Specification has been published.

Priorities

The priority of this Technical Committee is to ensure the safety of non-active surgical implants for the patient. The main objective is to improve the availability of safe surgical implants on the European Market and, in close cooperation with ISO/TC 150, also on the International Market.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC. They may significantly influence the conduct of the development process of the relevant standards and the content of the resulting standards:

CEN/TC 285 (in close cooperation with ISO/TC 150) sets standards for non-active medical devices for implantation in the body either permanently or temporarily for therapeutic or diagnostic purposes. These implants are dedicated to replacement, repair or stimulation of defective, worn-out or damaged parts of the body. The range of products comprises a range from highly sophisticated complete systems (such as an artificial knee joint) to semi-finished products (such as a bone screw) and components.

1.2 Quantitative Indicators of the Business Environment

The market for non-active surgical implants is a considerable part of the largest healthcare market and is fast growing. Future growth is driven by technical changes (active implants, spinal implants, combination products (combination of an implant with for example medicinal products or tissue engineered products)) and the social and economic changes in the developing countries. This growth in large parts is also due to the change in the age structure (ageing Baby Boomers and people reaching higher age) in the industrialized countries. The most promising markets are the continuously growing market for hip and knee replacements, sports medicine (mainly arthroscopic surgery), ortho/osteobiologics (meniscal/cartilage repair/bone substitutes), spinal implants, trauma fixation and cardiovascular stents.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

CEN/TC 285 expects to satisfy three needs: The safety and comfort of patients, the confidence of surgeons in the product, and the facilitation of European and global trade and market access.

International Standards serve as the preferred basis of agreements and contracts in bi- or multi-lateral business relationships throughout the world and are therefore of particular importance for an expanding global market. The publication of Standards developed under the Vienna Agreement in close cooperation between the ISO and CEN committee improve the compatibility between the requirements of different market places even further.

The expected benefits from CEN/TC 285 standards include helping manufacturers to demonstrate conformity with relevant legal requirements, by reducing the time needed for regulatory review, by specifying the types of information needed to evaluate the safety and/or effectiveness of these devices, and by global harmonization of regulatory requirements for these devices. They are used by many regulatory bodies in many areas:

- as a means of validation of test methods,
- in the evaluation of performance,
- in the determination of conformity with existing specifications,
- in the development of guidance documents for review or industry submission, and
- in marketing application clearance or approval of marketing applications.

The standards are also used in litigation cases to establish or refute liability for defendants and plaintiffs.

In addition, the standards on minimum requirements and test methods for product characteristics are very helpful for quality management purposes. They support the establishment of quality management systems.

Interface standards support a modular and flexible design of implant systems and help also to deal with the associated instrumentation properly.

The groups who profit from CEN/TC 285 standards are therefore: patients, surgeons, health service providers, manufacturers, scientists, engineers and regulatory bodies.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

The priority of this Technical Committee is to ensure the safety of non-active surgical implants for the patient. The main objective is to improve the availability of safe surgical implants on the European Market and, in close cooperation with ISO/TC 150 and its Sub Committees, also on the International Market.

The scope of CEN/TC 285 is as follows:

To standardize non-active surgical implants, including implant materials but not including dental implants and ophthalmic implants and, where appropriate, associated instrumentation to satisfy at least the essential requirements of the European Directive on Medical Devices, taking into account the work of CEN, CENELEC and ISO Technical Committees.

CEN/TC 285 standards address the safety, quality and performance as well as interchangeability and compatibility of non-active surgical implants in order to satisfy three needs: The safety and comfort of patients, surgeons' confidence in the product quality and the facilitation of European and global trade and regulation. Its work is therefore of the utmost importance to industry, government regulators, purchasers, users (surgeons) and of course the most important end-user, the patient, (who could be any of us).

4.2 Identified strategies to achieve the CEN/TC's defined objectives.

Work done on the ISO level shall not be duplicated at the CEN level. Therefore, the strategy is to develop the standards in the closest possible cooperation with the ISO mirror committee.

This work is done applying the rules of the Vienna Agreement on the cooperation between CEN and ISO.

CEN/TC 285 has the following liaisons:

CEN/TC 206	Biological evaluation of medical devices
CEN/TC 258	Clinical investigation of medical devices
CEN/TC 316	Medical devices utilizing tissues
CEN/TC 403	Project Committee – Aesthetic surgery services

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4.3 Environmental aspects

Every product has an impact on the environment during all stages of its life cycle, e.g. acquisition of raw materials, production, distribution, application/use, up till the product's final disposal. These impacts range from slight to significant; they can be short-term or long-term; and they occur at global, regional or local level.

Standards writers should consider the need to reduce risks to the environment taking into account the consequences and the likelihood of incidents and accidents. They should as much as possible take into account environmental aspects all along the design, execution, operation and dismantling, and study the assessment of the environmental impact during these different stages.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

A number of factors that do have and could put constraints on the completion and the work programme include the following:

- 1) competing standards developing bodies working in the same technical area;
- 2) being too ambitious in taking on new work items without sufficient number of volunteers for task group leaders and members;
- 3) mergers and acquisitions of manufacturers causing delays for task group chairs and members;
- 4) initiation of new work items not fully developed by a national standards body beforehand; and
- 5) having a backlog of standards in need of periodic review without having sufficient number of volunteers for task group chairs and members.

Like most of the standards committees, CEN/TC 285 has limited resources of experts and the corporate management of the experts involved is requesting minimization of meeting time and travel.

There is often too little input from clinicians due to financial and time problems. Ever-growing waiting lists of patients needing surgery make it harder for surgeons to attend meetings, and the unpaid nature of standards work means that there is financial loss to surgeon or employer if time is spent working on or discussing standards. Those who most obviously benefit from standards work are often remote from those who actually work on the standards.