Materials are of central importance to new product development in the medical device industry. Designers must make best use of corporate knowledge about these materials, and they need access to the right data and tools to inform decisions on selection, substitution, qualification, regulation, and bio-compatibility, and for design calculations.

“Medical device designers can leverage existing knowledge to facilitate shorter and more cost-effective R&D programs.”

Dr Michael N. Helmus, Chairman of the ASM Medical Devices Database Committee

Granta helps you to manage and access your proprietary materials information as well as supplying valuable reference data tailored to medical applications. Our materials software helps all those involved in the design and manufacture of medical devices and surgical tools (including materials experts, product stewardship managers dealing with restricted substances or Critical Materials, and designers), to make the right decisions as they share, apply, and use information on, for example, metals, biomaterials, or medical grade polymers.

Managing data for medical device design and manufacture

The materials data that you generate in medical device development and regulatory approval is critical. You need the right data for design and decision-making, you need it up-to-date and accurate, and you need it deployed to designers and engineers in a secure, controlled, but easily usable manner. Quality processes such as ISO 13485 and Six Sigma demand that the quality of this data is fully understood, and that the data is “traceable”, so that any design decision can be audited. You also want to make sure that knowledge captured for one project is available for re-use in future projects. GRANTA MI™, the leading materials information management system for engineering enterprises, solves all of these problems.

Materials selection for medical devices and surgical tools

If you specify materials, you may face the following challenges: How do you ensure an audit trail for your material selection? How do you conduct an exhaustive search for suitable materials? How do you make that search reproducible? How do you navigate the wide choice of commercially available plastic and elastomer grades? Granta’s medical devices reference data and materials selection software provides the answers.

Support for in-depth research

How do you find and apply materials knowledge from authoritative sources? This knowledge is scattered over many different papers, publications, and databases. It becomes quickly outdated and it is fragmented—e.g., engineering properties, biocompatibility, and application information are rarely found in the same source. The Cardiovascular Materials, Orthopaedic Materials, and Human Biological Materials data modules (overleaf) provide data that solves these problems. Granta’s tools help you search and apply such crucial information across your organization, reducing development time, risk, and cost.

Example customers

- Covidien
- Cochlear
- DePuy
- Novo Nordisk
- Ethicon Surgical Care
- Others–confidential

Read our White Paper

The Business Case for Materials Information Management in Medical Device Design

www.grantadesign.com/medical
In-depth resources

The Orthopaedic Materials and Cardiovascular Materials data modules are comprehensive knowledge resources featuring engineering properties and biomedical response data. Information is fully traceable to its sources, including thousands of citations to published literature, FDA device approvals, manufacturers’ datasheets, and websites:

Orthopaedic Materials includes nearly 200 materials, coatings, and drugs for all types of orthopaedic device, including hips, knees, spinal, ankle, toe, elbow, finger, shoulder, wrist, and trauma, together with >10,000 FDA device approvals.
Cardiovascular Materials includes over 200 materials, coatings, and drugs relevant to artificial hearts, bypass devices, clips, defibrillators, filters, grafts, heart valves, hemostasis devices, pacemakers, patches, stents, and vascular embolization devices, together with >17,000 FDA device approvals.

The Human Biological Materials data module is a unique resource of mechanical property data for bones and human tissues, enabling fast access to data suitable as input to FEA calculations and for general reference. The latest release covers the humerus and radius, including age and direction dependence, as well as new strain rate dependency information and updates to primary load-bearing bones including femur, tibia, vertebrae, and acetabulum.

The data packaged with CES Medical Selector includes leading reference data such as M-Base & CAMPUS Plastics and IDES Plastics as well as the Medical MaterialUniverse data module. This extends Granta’s MaterialUniverse module, which provides engineering, economic, and environmental data for thousands of polymers, metals, composites, and ceramics. Key features of the Medical MaterialUniverse dataset are: sterilizability data (materials can be selected based on their durability to ethylene oxide, radiation, or steam autoclave processes); identification of materials available in medical or food contact approved grades; and comprehensive coverage of two very important sub-classes of material used in medical devices: transparent plastics and elastomers.

Granta services
Granta can help you to: audit materials data, organize data, research custom datasets, consolidate test and legacy data, and implement and configure materials information management systems. Granta also provides standard documentation that helps you to validate your information system for the requirements of FDA CFR 21 Part 11.

Relevant products and services

GRANTA MI for materials information management

GRANTA MI, the leading system for enterprise materials information management, helps you capture, control, analyze, and apply materials data—for example, proprietary data from testing, QA, and research. Materials experts use GRANTA MI to manage, analyze, and certify this data, publishing it in a secure, controlled manner. GRANTA MI can capture the vital relationships between data, ensuring traceability. And it can help to ensure that materials knowledge is retained and re-used once a project is completed. Appropriately-authorized engineers and designers can access the information in GRANTA MI via a web browser, or from within CAD, CAE, or FEA software. They can use the data in design, assured that it is relevant, traceable, and the best available.

As well as managing your proprietary data, GRANTA MI can provide efficient multi-user access to all of Granta’s medical reference data—the Medical MaterialUniverse selection data (described below) and medical materials information resources (left). You can browse and query materials properties via a simple web browser user interface and easily follow links to related data and information sources. GRANTA MI also provides tools to rank materials based on their performance for specific engineering applications.

Software and data for materials selection

CES Medical Selector provides advanced graphical tools for comparing materials properties and for systematic materials selection and substitution. It combines the powerful CES Selector™ software with specialist property data for medical applications, enabling materials decisions that are exhaustive, reproducible, and (critically for medical device designers) auditable. CES Medical Selector can be installed on any PC. Its in-depth analysis capabilities allow device designers and materials experts to understand and solve difficult selection problems—for example, finding a material with the optimal combination of performance, cost, and environmental properties, while meeting constraints such as sterilizability and durability to specific chemicals.

Granta’s selection software, CES Selector™, helps you with rational and auditable materials selection. The image is from a selection project choosing a plastic for use in medical forceps. Constraints have been applied on sterilizability, regulatory approval status, and mechanical properties, narrowing the choice to 48 materials. The plot allows the user to trade off cost against volume for these materials.

The data packaged with CES Medical Selector includes leading reference data such as M-Base & CAMPUS Plastics and IDES Plastics as well as the Medical MaterialUniverse data module. This extends Granta’s MaterialUniverse module, which provides engineering, economic, and environmental data for thousands of polymers, metals, composites, and ceramics. Key features of the Medical MaterialUniverse dataset are: sterilizability data (materials can be selected based on their durability to ethylene oxide, radiation, or steam autoclave processes); identification of materials available in medical or food contact approved grades; and comprehensive coverage of two very important sub-classes of material used in medical devices: transparent plastics and elastomers.

More: www.grantadesign.com/products/ces/medcase.htm