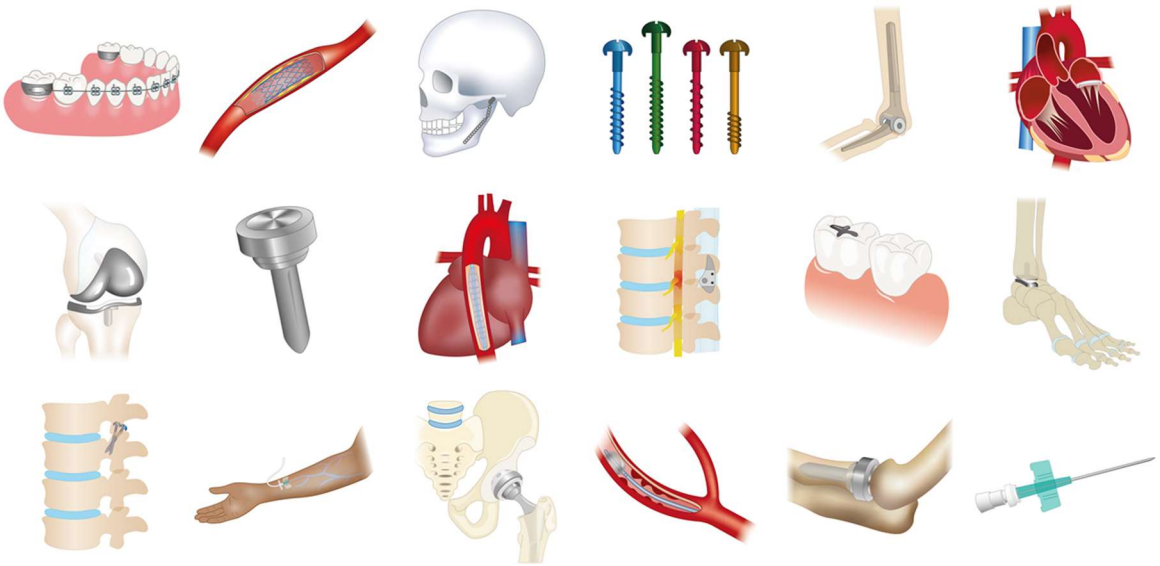
# Granta EduPack White Paper: Medical Devices Database



Harriet Parnell[1] and Mike Ashby[2]

[1]Ansys Granta, Cambridge, UK

[2] Department of Engineering, University of Cambridge

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# ABSTRACT

The Medical Devices database is a resource that supports the teaching of Biomedical Engineering (BME) at the High School, College and University levels. It fills a gap in a fast-evolving field that lacks teaching resources to support its emerging curricula. The database provides information about medical devices, provides background on the materials they contain and links them to current standards and legislation that impinge on them. It is accessed using Granta EduPack or Selector software platforms, already familiar to many engineering students, making the chart-making, selection and analysis functionalities of the System available for BME projects and studies. The package provides a visual, flexible learning platform accessible to interdisciplinary students at an introductory level but with functionality to engage with advanced classes as needed.

# Contents





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# 1. Introduction

Biomedical engineering (BME) is one of the fastest growing fields in applied science, combining the principles and problem-solving skills from unusually disparate disciplines. The Whitaker Foundation defines it in this way.

*"A discipline that advances knowledge in engineering, biology and medicine, and improves human health through cross-disciplinary activities that integrate the engineering sciences with the biomedical sciences and clinical practice. It includes:*

1. *The acquisition of new knowledge and understanding of living systems through the application of experimental and analytical techniques based on the engineering sciences.*
2. *The development of new devices, algorithms, processes and systems that advance biology and medicine and improve medical practice and health care delivery."*

Any student of BME will, at some point, encounter biomaterials.

When the Granta EduPack was initially developed, its primary focus was Materials Education at the College and University levels. Visual Material Property Charts (Figure 1) engage interest, reveal the relationship between material properties and performance, and provide a tool for materials selection in design projects. The underlying databases and tools, much expanded, now support the teaching of Mechanical engineering, Aerospace engineering, Product design, Materials science, Sustainability and Design for the Environment in over 1400 in Colleges and Universities worldwide.

This whitepaper introduces a new Medical Devices database, developed specifically to support the teaching of BME. Its structure is based on past and more recent surveys of BME teaching. They are a good place to start.

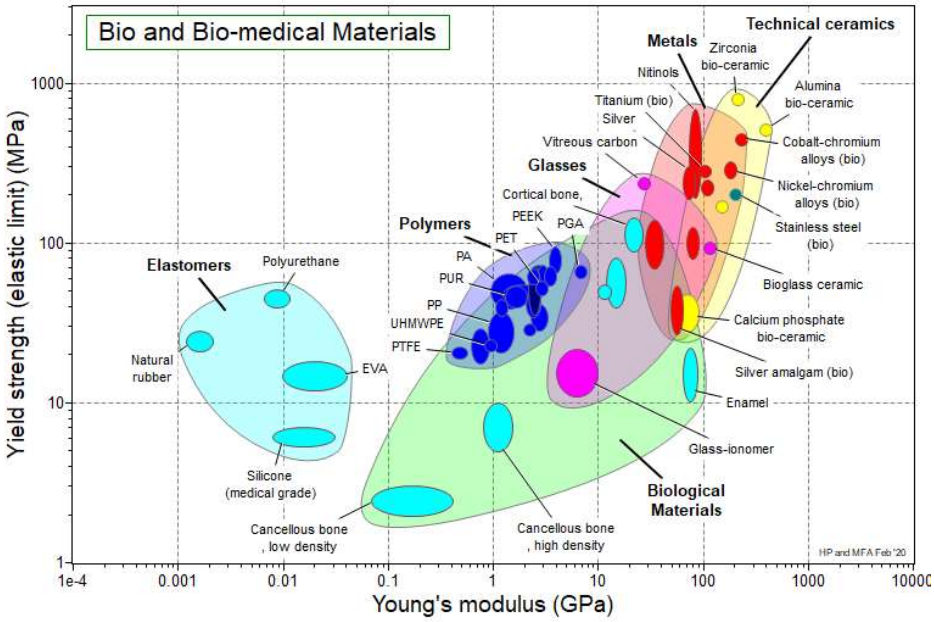


**Figure 1: An example of a material property chart plotted using MaterialsUniverse data in the Medical Device database.**



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# 2. Biomedical Engineering Education

'Bioengineering' and 'Biomedical Engineering' are terms that are often used interchangeably. For some, Bioengineering is an umbrella under which Biomedical Engineering sits. For others, the opposite is true, placing Bioengineering as a research activity supporting Biomedical Engineering. Either way, the two fields have a lot in common (Abu-Faraj, 2012). For the purposes of this whitepaper, 'Biomedical Engineering' has been used to conduct the curriculum review.

## 2.1. Early years

When Biomedical Engineering first entered educational programs in the 1950s, the curriculum largely reflected the academic's area of interest. As the profile of BME grew, so did its scope, highlighting the need for a curriculum that was more widely recognized.

A special issue of the *IEEE Transactions on Biomedical Engineering*, published in 1975, provides one of the earliest reviews of Biomedical Engineering Education (Harmon, 1975). Harmon concluded that *"… no single educational plan or establishment can readily encompass the great diversity of requirements in biomedical engineering training. We need specialists, generalists, multi-discipline hybrids, teams, researchers, practitioners, support technicians, teachers, and administrators- all in considerable sub-species variety"*.

That is a demanding assignment. And since then, the subject has broadened further, driven by developments such as the Human Genome Project, digitalization, instrumentation, advanced health-monitory, big data and the demands made on Health Services world-wide. Providing a balanced teaching in a field with such a span is a challenge.

## 2.2. Curriculum development

The state of Biomedical Engineering Education has periodically been reviewed, most notably in 1998 by the **VaNTH ERC** collaboration, a group was led by **Va**nderbilt University in collaboration with **N**orthwestern University, the University of **T**exas at Austin, and the **H**arvard/MIT Health Sciences and Technology Program. Together they formed an **E**ngineering **R**esearch **C**enter in Bioengineering Educational Technologies. Their vision was to transform biomedical engineering education to enable graduates to become 'adaptive experts' in their chosen specialty. To achieve this, the group identified key challenges, which included:

- How can undergraduates be properly trained in both biology and engineering, within the constraints of a four-year bachelor's degree?
- How can students be introduced to the practice of BME in business, industries and healthcare organizations?
- How can instructors cope with the limited amount of teaching material?
- How should the greater uncertainties in design that are inherent in technology aimed at living systems be treated?

The group identified five core areas of BME education:

- Biomechanics
- Bioinstrumentation
- Biosystems
- Cell/molecular engineering
- **Biomaterials**

We have carried out a survey of current *Biomaterials* courses, with the aim of identifying when they are introduced within the curriculum and what the learning objectives are. We found wide variation in the point



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at which BME topics first appeared, spread from the first year to the last. By contrast, there was much commonality in the learning objectives. These include the ability to:

- describe the use of biomaterials in medical devices;
- explain and apply regulatory/legislative matters that affect the selection and use of biomaterials;
- identify the nature of the most widely used biomaterials and their areas of application;
- identify materials currently approved for clinical applications, and describe their practical aspects;
- differentiate various biomedical devices based upon function, biomaterial composition, patient risk, and clinical application;
- understand the role of biomaterials in artificial organs, orthopedics and dentistry, and medicine

## Learning styles

The VaNTH ERC group recognized that the educational challenges posed by BME required inputs from Learning Science. The *Index of Learning Styles* (ILS), initially developed by Felder and Silverman (Felder, 1988), is an effective assessment tool with focus on cognitive processes for engineering students. Briefly, the tool assembles self-reported preferences for:

1. processing information in an **active** or **reflective** manner;
2. understanding information by **sequential** or **global** means;
3. interpreting information **visually** or **verbally**; and
4. recalling **sensory** or **intuitive** information.

Educators from Tulane University applied this tool to a range of classes, including those from biomedical engineering (Dee, 2002). Figure 2 shows their summary of Felder's cognitive preferences.

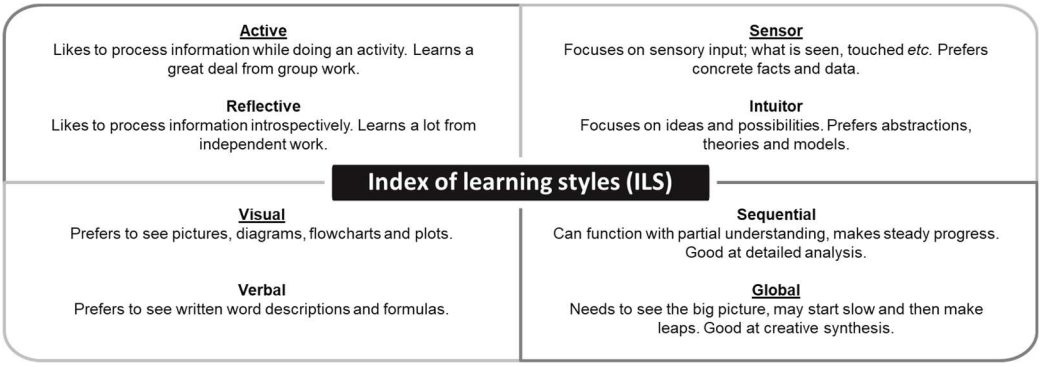


**Figure 2: Index of Learning Styles (ILS).**

Their study suggested that biomedical engineering students preferred active, global, visual and sensory learning styles. The most significant trend was an 88% preference for visual, rather than verbal, learning.

# 3. The Granta EduPack Medical Devices database

## 3.1. What is it?

The Medical Devices database is a resource that supports the teaching of Biomedical Engineering (BME) at the High School, College and University levels. It fills a gap in a fast-evolving field that, as the VaNTH ERC Report points out, lacks teaching resources to support its emerging curricula. The database provides information about medical materials, illustrates their application in devices, provides background on the materials they contain and links them to current standards and legislation that impinge on them. It is accessed using Granta



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EduPack, already familiar to many engineering students, making the chart-making, selection and analysis functionalities of the system available for BME projects and studies. The package provides a visual, flexible learning platform accessible to interdisciplinary students at an introductory level but with functionality to engage with advanced classes as needed.

## 3.2. Data sources

There were two main sources of information for this project. This first was the Bioengineering database which already exists in Granta EduPack, providing the materials foundations upon which to build the product-focused *Medical Devices* database. The second was the ASM Medical Materials database which contains reference data for over 63,000 FDA Approved medical devices; an example record is shown in Figure 3.

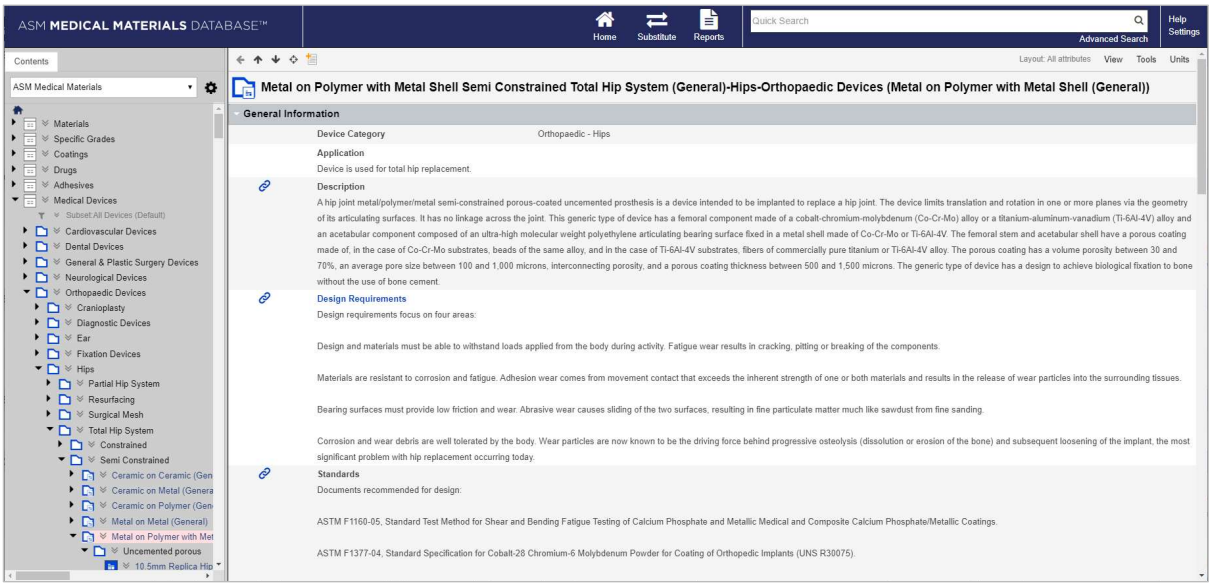


**Figure 3: Part of a Metal-on-polymer total hip replacement record from the ASM Medical Materials database.**

## 3.3. The structure of the database

The database contains a set of five linked data-tables shown in Figure 4. It has the following features.

- The ***Medical Devices data-table*** contains records for 50 generic cardiovascular, orthopedic and dental devices. Each record is linked to the materials of which it is made (not grade-specific) and two real-life FDA approved examples.
- The ***FDA approved examples data-table*** provides more specific data on approximately 100 FDA approved medical devices, including the regulation number and 510(k) Number or PMA Number. Each record is linked to its generic medical device and, if mentioned within the descriptions, relevant materials.
- The ***MaterialUniverse data-table*** combines engineering and biological materials, characterizing more than 250 of the most widely known alloys, polymers, elastomers, ceramics, glasses and biological materials. Each record is linked to relevant processes, medical devices, FDA approved examples and the elements from which it is made.
- The ***ProcessUniverse data-table*** contains processing methods for 116 shaping, joining and finishing processes. Records are illustrated with schematics and images of the process or products made using it and, in turn, are linked to the materials to which they can be applied.



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- The ***Elements data-table*** provides data for the elements of the Periodic Table at the nuclear and atomic levels, including electronic structure and electronegativity, crystal structure, physical, mechanical, thermal and electrical properties, environmental data and countries of origin.

The data-tables are linked in the ways shown as connecting lines in Figure 4. They connect records in one data-table with relevant records in another. More in this below.

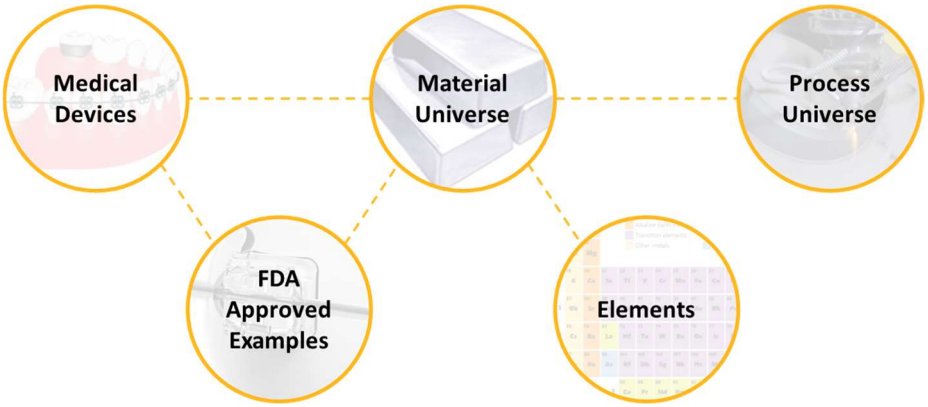


**Figure 4: Main data-tables in the Medical Devices database.**

# 4. Database contents

Two of the data-tables highlighted in Figure 4 are new to Granta EduPack and unique to this database. In this section, the *Medical Device* and *FDA approved examples* data-tables are explored in greater detail.

## 4.1. Medical Device data-table

The *Medical Device* data-table contains records for 50 generic medical devices from the cardiovascular, orthopedic and dental systems. Each record acts like a mini case study, providing a general overview of the product and an introduction to regulations it must meet. Figure 5 shows an example.



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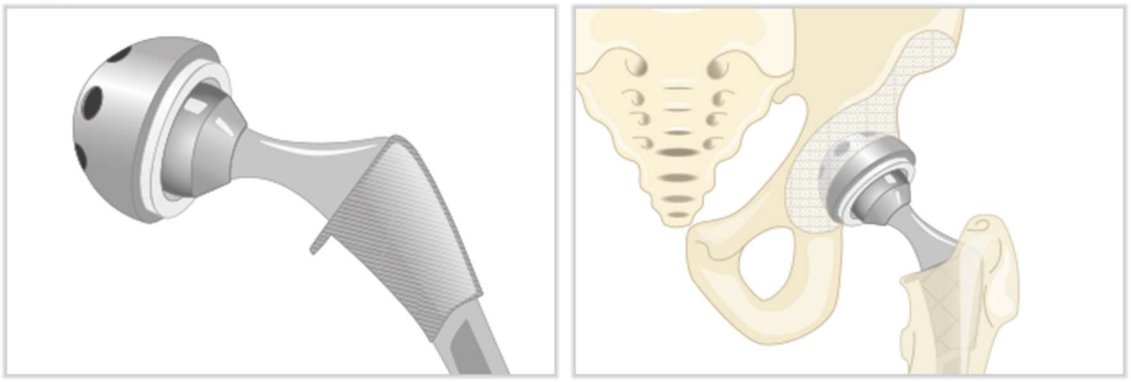
Orthopedic > Joint Replacements > Total Hip Replacement >

## General information

**Image**



**Caption**

1) Enlarge view of a metal on polymer hip implant; 2) Metal on polymer hip implant inserted into femur and articulating on the acetabulum

| | |
|---|---|
| Keywords | Orthopedic; Joint Replacement; Hips |
| Typical materials | Cobalt-chromium alloys, Titanium, Titanium alloys, Ultra-High Molecular Weight Polyethylene |

## Overview

**Application**

Total hip replacement (arthroplasty) is a common surgery used to replace a damaged hip joint.

**Description**

A semi-constrained hip replacement prosthesis limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. A metal-polymer device consists of a metal hip stem, a metal femoral head, a polymer acetabulum and a metal shell that is secured onto the acetabular cup.

| | |
|---|---|
| Duration of use | Permanent (> 30 days) |

## Classification

| | |
|---|---|
| FDA | Class II |
| CE mark | Class IIb |

## Design

**Design requirements**

Four key requirements: 1) Materials must withstand sufficient loads from body during activity; 2) Materials must resist corrosion and fatigue; 3) Bearing surfaces must provide low friction and wear; 4) Corrosion and wear debris are well tolerated by the body (i.e. to avoid osteolysis and subsequent loosening of the implant).

**Deployment method**

Under general anesthesia, a surgeon begins by removing the entire hip joint i.e. the upper part of the femur and the natural acetabulum socket in which the femoral head articulates. Once prepared, a metal prosthesis stem is inserted into the cavity of the femur with a smooth ball (head) attached. An acetabular cup is inserted into the pelvis. The new joint prosthesis is fitted together and incision is closed.

| | |
|---|---|
| Guidance documents | FDA Guidance Document |

## Links

| |
|---|
| FDA Approved Examples |
| MaterialUniverse |

ANSYS Granta provides no warranty for this data.

**Figure 5: Medical Device record. The metal on polymer total hip replacement is shown as an example.**



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As part of visual approach that we have adopted, each record opens with two images under the heading General Information. The first shows the device itself; the second, the device in-situ. The records include **keywords** and **typical materials**, which become useful when using the *Search* tool.

The Section headed '**Overview**' provides further information about the applications of the device. These attributes related to the '**Classification**' section that follows. A prescribed path of regulation must be followed to get a medical device to market. To do this, manufacturers must classify their devices based on two factors:

1. The intended use of the device (the application) and
2. Its physical characteristics (the description).

The class of a medical device generally increases with the risk associated with it. As examples, a polyurethane ligature, used in a fixed orthodontic brace, is a Class I medical device whereas, an intra-aortic balloon, used to support cardiovascular functioning during emergencies, is a Class III device.

The penultimate section focuses on '**Design**', meaning the design requirements, deployment method and FDA guidance documents. Information presented here indicates why certain materials are used for different applications. For example, a bare metal stent is deployed through a catheter and should *"generate sufficient radial expansive force to maintain patency, and it should be sufficiently pliable to conform to the wall of the artery"*. Shape-memory alloys such as a nickel-titanium (nitinol) can provide this function. Using the '**Links**' at the bottom of a bare metal stent record, students can access a record for the properties of nickel-titanium alloys and the shape-memory effect.

Medical devices are widely used to engage interest in Biomedical Engineering programs, but the choice differs from one program to another. The database provides a range of topics that can be drawn on for introductory classes through to advanced. The information presented so far is perhaps most useful at an introductory level. However, there are opportunities within the records to stretch the student's learning.

The first of these, already mentioned, are the links to FDA Guidance documents located under the '**Design**' section. Clicking on the 'FDA Guidance document' hyperlink, opens the relevant pages of the FDA's website setting out regulations that govern a specific device. An FDA Guidance document is not binding but it indicates the FDA's current thinking surrounding the design, production, labeling, promotion, manufacturing and testing of regulated products.

These links give an industrial perspective of the regulation process, as well as the requirements for that specific device. Returning to the example of the bare metal stent, the 'FDA Guidance document' link brings up a discussion of '*Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems*'. The document contains recommendations for expected material characterization tests; stent dimensions and functional attributes; delivery systems and biocompatibility tests.

After exploring these guidance documents, students can then return to the *Medical* Devices database and follow a second link to '*FDA Approved Examples'* found under the '**Links**' subheading. This will take them to a separate data-table, discussed in Section 4.2, containing real-life examples of medical devices.



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The *Medical Device* data-table is organized first by industry and then by device type. This tree structure, found under the 'Browse' tool, is shown in Figure 6.

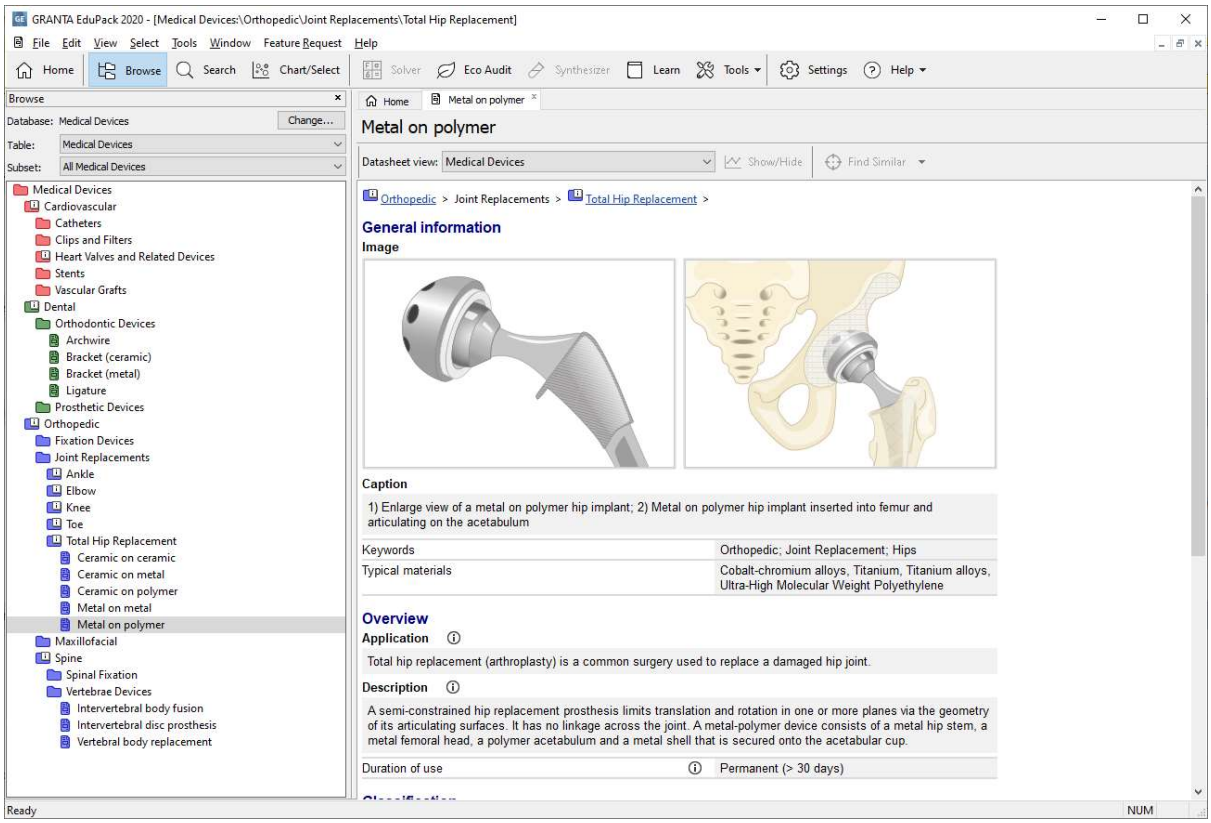


**Figure 6: Medical Device data-table, showing folder structure and a typical record.**

As with other Granta EduPack databases, three standard icons appear in the tree structure. Each indicates a different level, with varying contents:

| | | |
|---|---|---|
| **Record** |  | Records contains information about a particular medical device. An example was shown in Figure 5. |
| **Folder** |  | Related records are contained within a folder. |
| **Folder-level record** |  | The folder itself contains generic information about the related records it contains. |

Folder-level records have been created for the *Medical Device* data-table so that students, regardless of their background, can understand basic medical terminology and human anatomy. An example is given in Figure 7.



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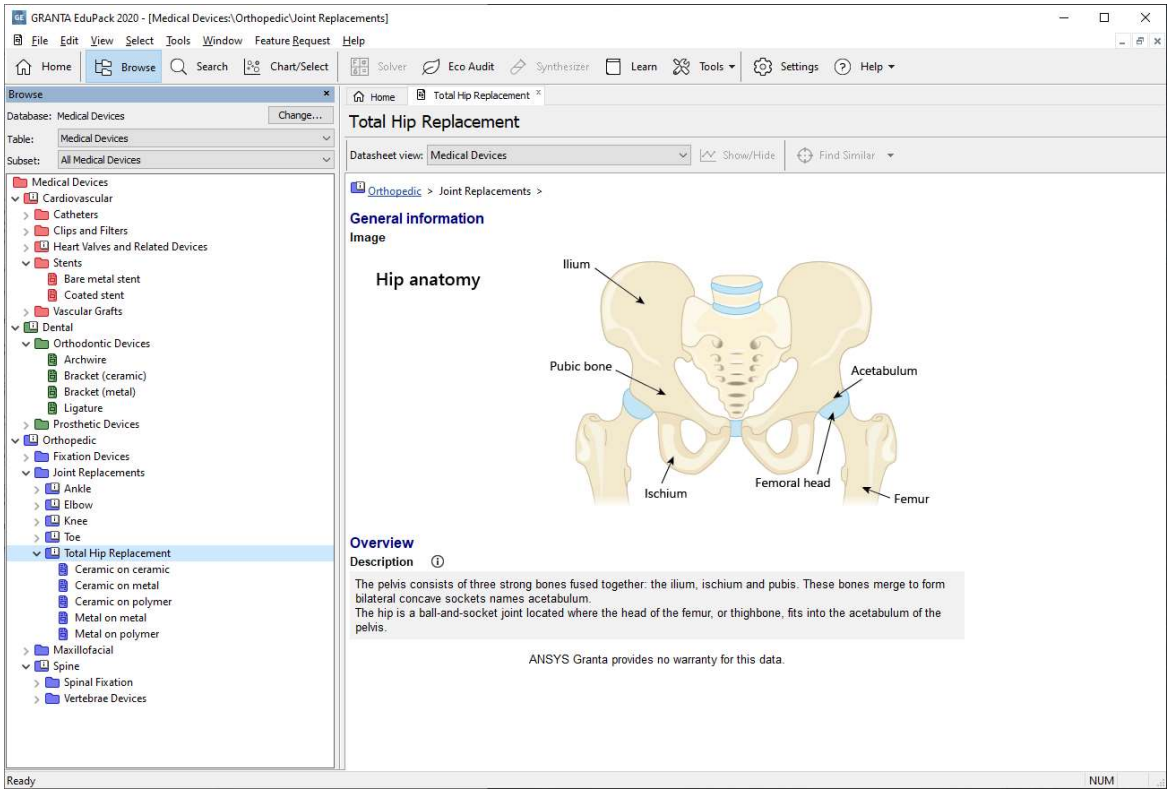


**Figure 7: Folder-level record of the total hip replacement devices. Basic anatomy and medical terminology are provided.**

To provide further back-up, each attribute within a record is linked to a *Science Note* that provides a definition and further information. Science notes are accessed directly from a medical device record by clicking on the ⓘ icon next to the attribute name (see Figure 5). The Science note for the attribute "FDA" Classification is shown in Figure 8, as an example.

## 4.2. FDA Approved Example data-table

The *FDA Approved Example* data-table contains records for approximately 100 real life medical devices which have been on the market, each linked to their generic equivalent in the *Medical Device* data-table. An example record is shown in Figure 9. Information is unique to the FDA approved device including its Product code, Regulation number, date it was accepted by the FDA and its 510(k)/PMA number. As with the *Medical Device* data-table, attributes are defined and explained in accompanying Science Notes.

When specific materials are mentioned within the record, that FDA approved example is linked to relevant records within the *MaterialUniverse* data-table (see Figure 4). For example, the record shown in Figure 9 is linked to the record for Ultra-high Molecular Weight Polyethylene (UHMWPE) in the *MaterialUniverse*.



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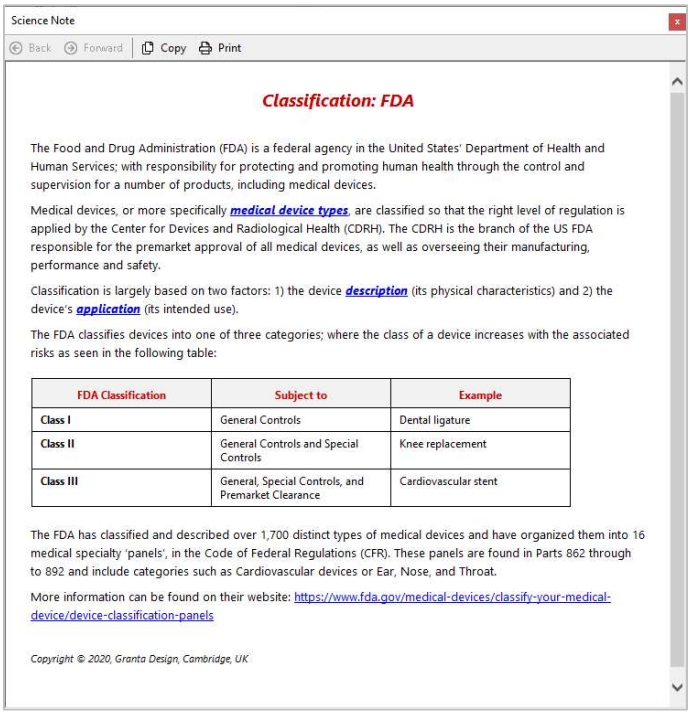

Science Note

Back Forward Copy Print

**Classification: FDA**

The Food and Drug Administration (FDA) is a federal agency in the United States' Department of Health and Human Services; with responsibility for protecting and promoting human health through the control and supervision for a number of products, including medical devices.

Medical devices, or more specifically ***medical device types***, are classified so that the right level of regulation is applied by the Center for Devices and Radiological Health (CDRH). The CDRH is the branch of the US FDA responsible for the premarket approval of all medical devices, as well as overseeing their manufacturing, performance and safety.

Classification is largely based on two factors: 1) the device ***description*** (its physical characteristics) and 2) the device's ***application*** (its intended use).

The FDA classifies devices into one of three categories; where the class of a device increases with the associated risks as seen in the following table:

| FDA Classification | Subject to | Example |
|---|---|---|
| **Class I** | General Controls | Dental ligature |
| **Class II** | General Controls and Special Controls | Knee replacement |
| **Class III** | General, Special Controls, and Premarket Clearance | Cardiovascular stent |

The FDA has classified and described over 1,700 distinct types of medical devices and have organized them into 16 medical specialty 'panels', in the Code of Federal Regulations (CFR). These panels are found in Parts 862 through to 892 and include categories such as Cardiovascular devices or Ear, Nose, and Throat.

More information can be found on their website: https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels

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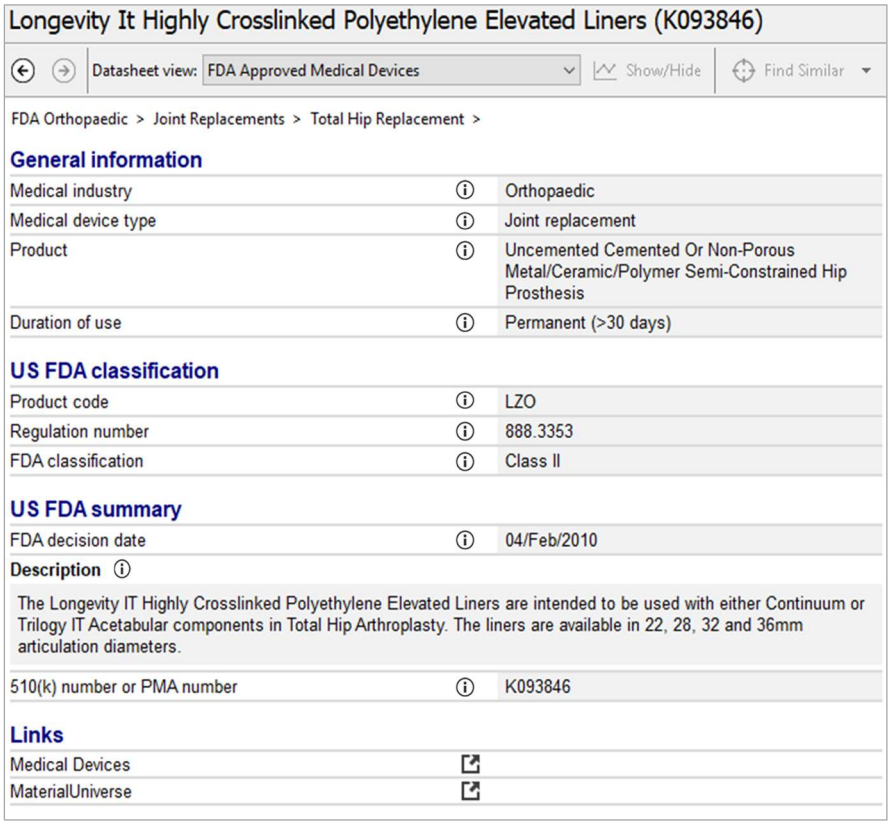
**Figure 8: Example *Science note*. The FDA classification is shown here.**



Longevity It Highly Crosslinked Polyethylene Elevated Liners (K093846)

Datasheet view: FDA Approved Medical Devices | Show/Hide | Find Similar

FDA Orthopaedic > Joint Replacements > Total Hip Replacement >

**General information**

| | |
|---|---|
| Medical industry | Orthopaedic |
| Medical device type | Joint replacement |
| Product | Uncemented Cemented Or Non-Porous Metal/Ceramic/Polymer Semi-Constrained Hip Prosthesis |
| Duration of use | Permanent (>30 days) |

**US FDA classification**

| | |
|---|---|
| Product code | LZO |
| Regulation number | 888.3353 |
| FDA classification | Class II |

**US FDA summary**

| | |
|---|---|
| FDA decision date | 04/Feb/2010 |

**Description**

The Longevity IT Highly Crosslinked Polyethylene Elevated Liners are intended to be used with either Continuum or Trilogy IT Acetabular components in Total Hip Arthroplasty. The liners are available in 22, 28, 32 and 36mm articulation diameters.

| | |
|---|---|
| 510(k) number or PMA number | K093846 |

**Links**

Medical Devices

MaterialUniverse

**Figure 9: FDA Approved Example record.**



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## 5. Using the database

The Medical Devices database can be used in many ways: to engage interest, to provide images, descriptions and data for medical devices, to explore the materials that appear in them, and as a basis for case studies. To illustrate, this section presents an orthodontic micro-project (Figure 10) that can be explored using the software.

A Microproject is a short, progressive investigation of an aspect of Biomedical Engineering that can be completed, by a student or group of students, in less than an hour. The aim is to capture the interest by posing a striking or contemporary question, provide a stepwise path to a sometimes-unexpected answer, and give the satisfaction of discovery - learning something about materials at the same time. It is structured to give positive reinforcement and encourage problem-solving skills by providing help with difficult steps. Biomedical Engineering micro-projects are aimed at students at the University undergraduate level. The premise is that learning by discovery is more effective than learning by listening, and that an engaging project can provoke the sense of "want to know" that is the catalyst of learning. Offering a range of micro-projects allows student choice and provides an element of personalized learning.

Suggested solutions are provided in a separate teaching recourse and can be given to students at the instructor's discretion. Other microprojects can be found in the Education Hub here: www.grantadesign.com/education/teachingresources/.



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*Medical Materials Micro-project 3*

## Brackets, bands and braces

Daisy is turning 18 and is about to start university. She has good teeth, but they are misaligned; her dentist recommends a brace. Daisy feels self-conscious about this and wants to know whether you can get braces which appear 'invisible' or colored. She drinks lemon juice and hot tea and likes spaghetti Bolognese. Will she have to change her diet?

- What are the main components in a conventional fixed brace and where can color be added? (Explore the Dental folder of the Medical Devices data-table and the Orthodontic Devices subfolder.)

- Will Daisy's diet have to change? Focus on the elastomeric ligatures. (Follow the Materials link at the bottom of the record and explore the durability properties of elastomeric polyurethane.)

- Orthodontic brackets make up a large proportion of a fixed brace. Do they have to be made of metal or can they be made to look more like natural teeth? (Compare the two records for Brackets.)

- Which part of the brace provides the force to move teeth? How does it do this? (For each of the components identified, read the short text about their application. For the correct device, follow the Materials link at the bottom of the record and investigate Nickel-Titanium alloys.)

***Discussion point***

What is the FDA classification of Medical Devices? Use the *Science notes* to find out.

What is the FDA classification for the four orthodontic device components listed in the Medical Device data-table?

Why might ceramic brackets have a higher FDA classification than metallic brackets? Explore the Fracture Toughness and Tensile Strength of the materials listed for the four components. First create a subset limited to bracket materials, then make a chart with Fracture toughness on the y-axis and Tensile strength on the x-axis. What can you deduce from it?

**Figure 10: Orthodontic microproject.**



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## 6. Conclusions

The database documented in the White Paper provides a resource to supports the teaching of Biomedical Engineering (BME) at the introductory and more advanced levels. The database contains information about medical devices, provides background on the materials they contain and links them to current standards and legislation that impinge on them. It is accessed using Granta EduPack software platform, already familiar to many engineering students, making the chart-making, selection and analysis functionalities of the system available for BME projects and studies. The package provides a visual, flexible learning platform accessible to interdisciplinary students at an introductory level but with functionality to engage with advanced classes as needed. Its use has been illustrated with a micro-project.

The database forms part of the Granta EduPack, where it is integrated with data-tables for the Elements of the Periodic Table, for Engineering materials and Natural materials and for real-life medical devices. At present it is limited to cardiovascular, orthopedic and dental devices. We are actively working with collaborators to expand the database further and would welcome suggestions for its expansion and the directions in which it might be developed. Please contact granta-education-team@ansys.com for access to the database.

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- Case studies
- Exercises with worked solutions
- Microprojects
- Recorded webinars
- White papers
- Solution manuals
- Interactive exercises

Some of the resources are open access and students can access them. Others are only available to educators using GRANTA EduPack.

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