Granta EduPack White Paper

Medical Devices: biomedical applications of materials

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Abstract

The Medical Devices and FDA Approved Example datatables 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 datatables provide information about medical devices, provides background on the materials they contain and links them to current standards and legislation that impinge on them. They are accessed using the Level 2 Bioengineering or Level 3 Bioengineering databases in Ansys 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.

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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 Ansys 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 white paper provides an overview of the type of support available in Granta EduPack to support the teaching of medical devices and biomedical applications of materials.

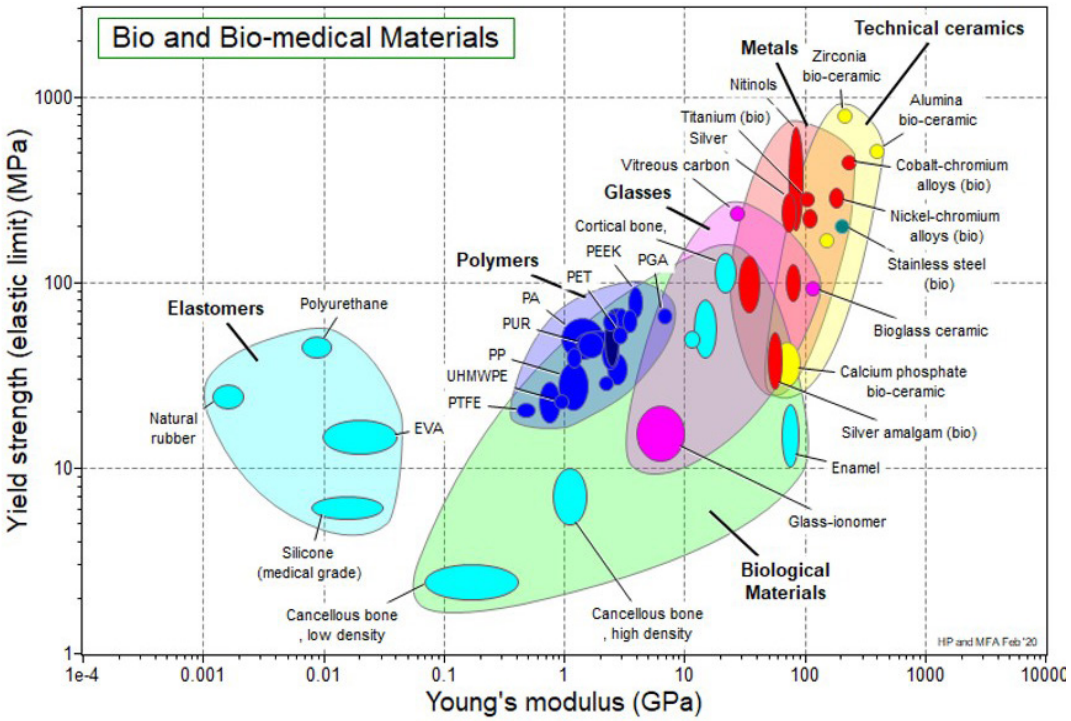


Figure 1: An example of a material property chart plotted using MaterialsUniverse data in the Level 2 Bioengineering database.

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 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 Vanderbilt University in collaboration with Northwestern University, the University of Texas at Austin, and the Harvard/MIT Health Sciences and Technology Program. Together they formed an Engineering Research Center 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 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

2.3. 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.

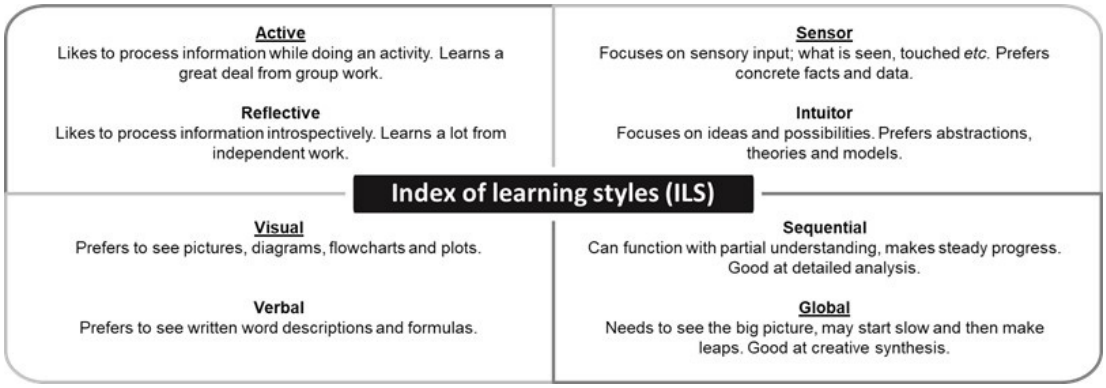


Figure 2: Index of Learning Styles (ILS).

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. Medical Device Resources in Ansys Granta EduPack

3.1. Useful software terminology

Before discussing what Medical Device resources are available in Granta EduPack, it is perhaps useful to define basic software terminology: databases *vs* datatables. For those entirely new to Granta EduPack, a product overview can be found elsewhere.

Granta EduPack is an education software which contains several **databases** that support specific disciplines within the field of materials science, engineering, and design. Each database is built from several **datatables** which may or may not be unique to that database. Figure 3 provides an overly simplistic schematic of this model.

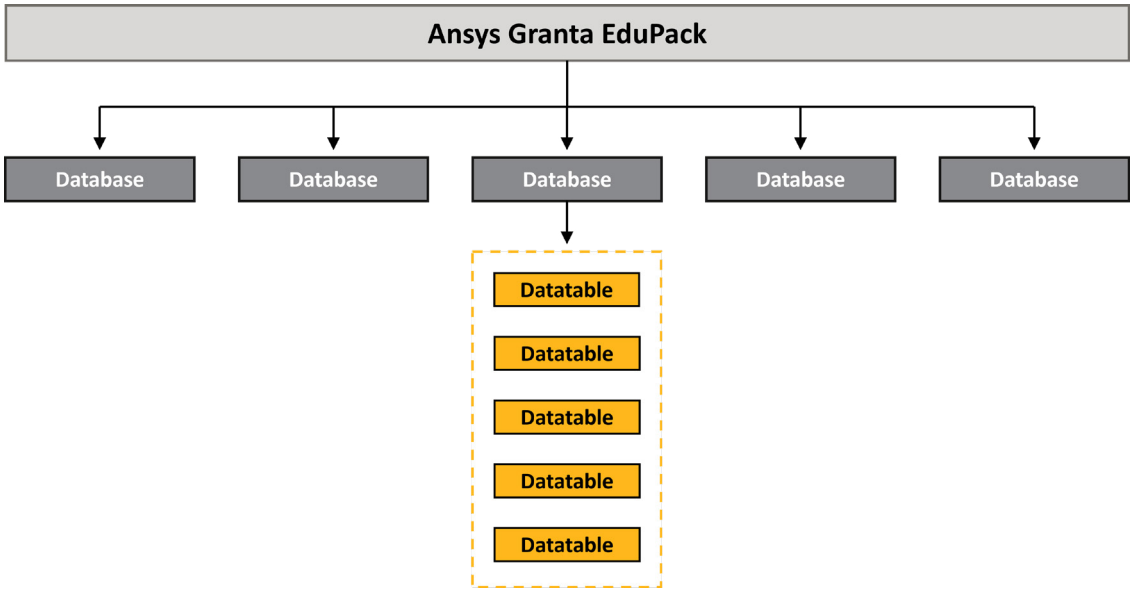


Figure 3: Simplistic model of the database and datatable relationship in Granta EduPack.

3.2. Relevant databases in Granta EduPack for BME

There are two databases relevant for Biomedical Engineering teaching: Level 2 Bioengineering which is an introductory database and Level 3 Bioengineering which is an advanced database, thumbnails can be seen in Figure 4.

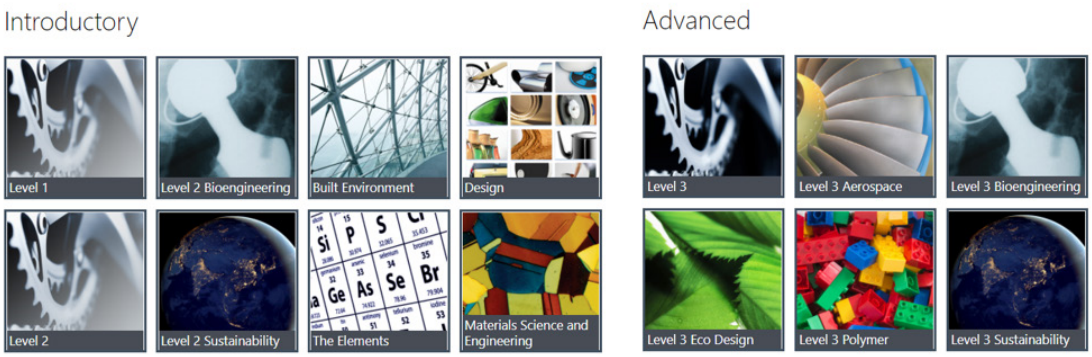
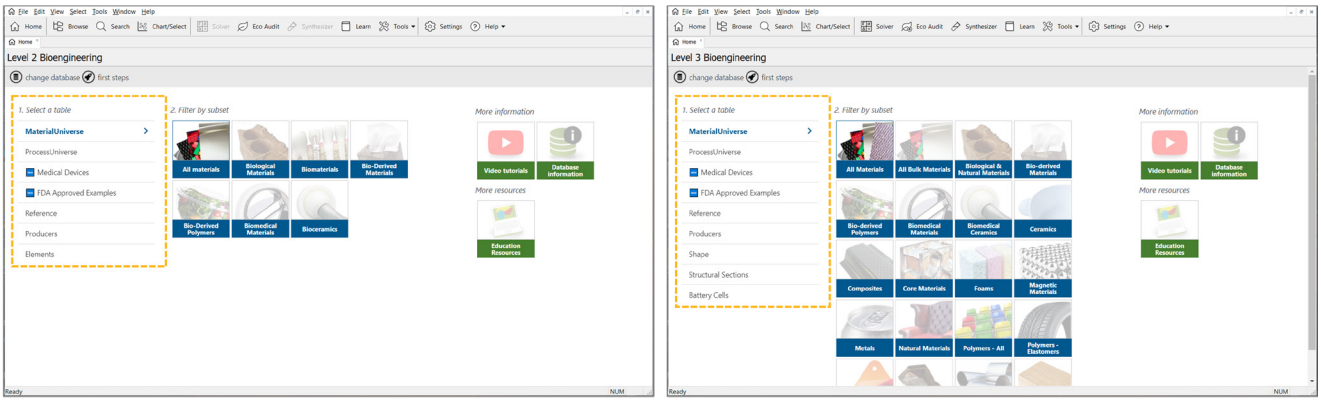


Figure 4: Databases available in Granta EduPack. Level 2 Bioengineering can be found in the Introductory offerings while Level 3 Bioengineering is found with the Advanced databases.

Depending on the students' understanding, educators may find the introductory Level 2 Bioengineering database suitable for teaching, while others may wish to stretch students using the advanced Level 3 Bioengineering database, say on a capstone design course. The database homepages can be seen in Figure 5 and give a good overview of their contents. There are two noteworthy differences. The first is number, and type, of datatables available as highlighted by the dashed gold box. Level 2 Bioengineering (Figure 5a) contains seven datatables whereas, Level 3 Bioengineering (Figure 5b) contains nine. The second difference is the greater level of data available in an advanced databases, as shown by the increased number of MaterialUniverse subsets shown in Figure 5b.

More information about the contents of each database can be found under the 'Database information' thumbnail. Here, for example, you will discover that there are 250+ material records available at Level 2 Bioengineering, compared to 4000+ materials at Level 3 Bioengineering.



(a) (b)

Figure 5: Granta EduPack homepages for (a) Level 2 Bioengineering and (b) Level 3 Bioengineering.

3.3. Relevant datatables for medical device-related teaching

There are four key datatables present within Level 2 Bioengineering and Level 3 Bioengineering for BME teaching: Medical Devices; FDA Approved Examples; MaterialUniverse; and ProcessUniverse. Not only do they act as an excellent library of data, but crucially, they are also linked (see Figure 6). This means that when students open a medical device record, for example, they will find relevant links to the MaterialUniverse as well as real-life FDA Approved Examples.

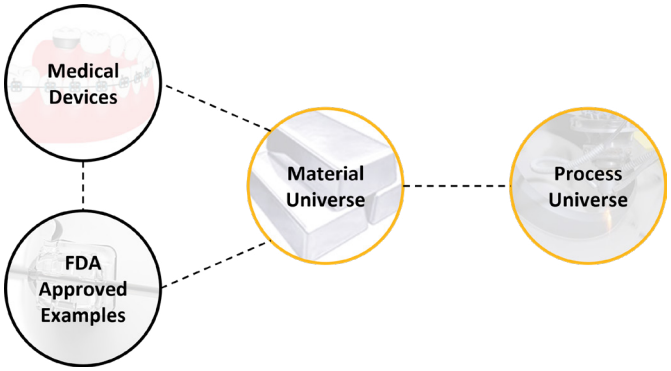


Figure 6: Key datatables available both at Level 2 Bioengineering and Level 3 Bioengineering. Black circles indicate no data changes while gold circles indicate data change across the two database.

Additionally, the use of color in Figure 6 is also significant. The 'Medical Devices' and 'FDA Approved Examples' datatables are bordered with a black line. This means they contain the exact same information across Level 2 Bioengineering and Level 3 Bioengineering. The 'MaterialUniverse' and 'ProcessUniverse', on the other hand, have a gold border. This means that the level of information differs across the two databases. So, although the Medical Devices data will be the same regardless of the chosen database, the number of linked materials will change. For example, in Level 2 Bioengineering the 'Forceps' medical device record is linked simply to the 'stainless steel' material record. In Level 3 Bioengineering, it is linked to numerous stainless steel grades e.g. Austenitic AISI 316L, annealed. This is useful to consider when tailoring the level of learning to the student class.

3.3. Data sources

The main source of information used to construct the 'Medical Devices' and 'FDA Approved Examples' datatables 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 7.

More information about this data source can be found via the link in the references of this paper.

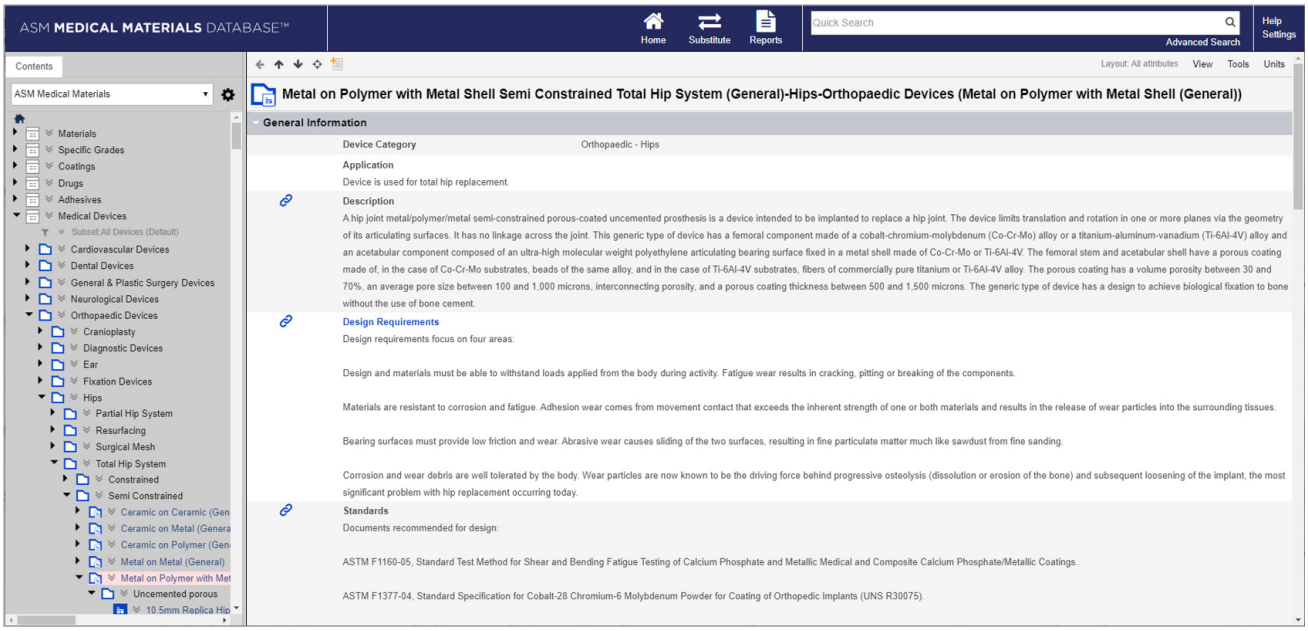


Figure 7: Part of a Metal-on-polymer total hip replacement record from the ASM Medical Materials database.

4. Database contents

This section explores examples from the *Medical Device and FDA approved examples* datatables, which are unique to Level 2 Bioengineering and Level 3 Bioengineering.

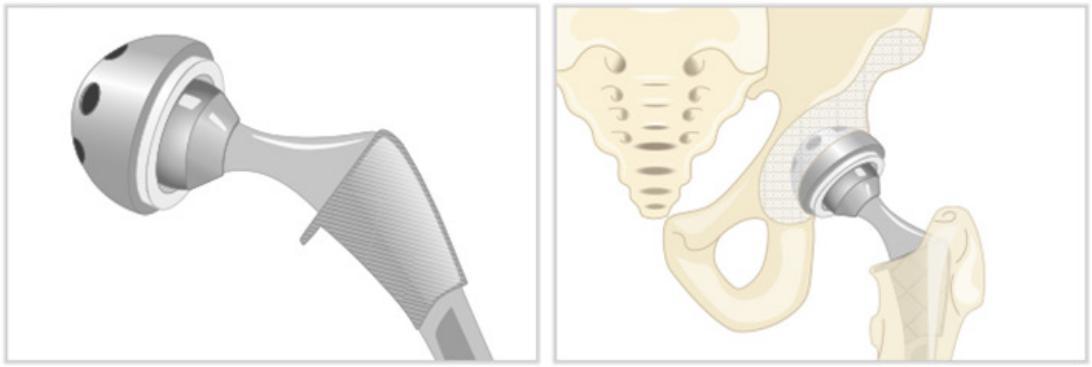
4.1. Medical Device data-table

The Medical Device datatable contains records for 60+ generic medical devices from the cardiovascular, orthopedic, and dental systems, as well as general surgery. Each record acts like a mini case study, providing a general overview of the product and an introduction to regulations it must meet. Figure 8 shows an example.

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

As part of the visual approach that has been adopted during development, 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.

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 9.

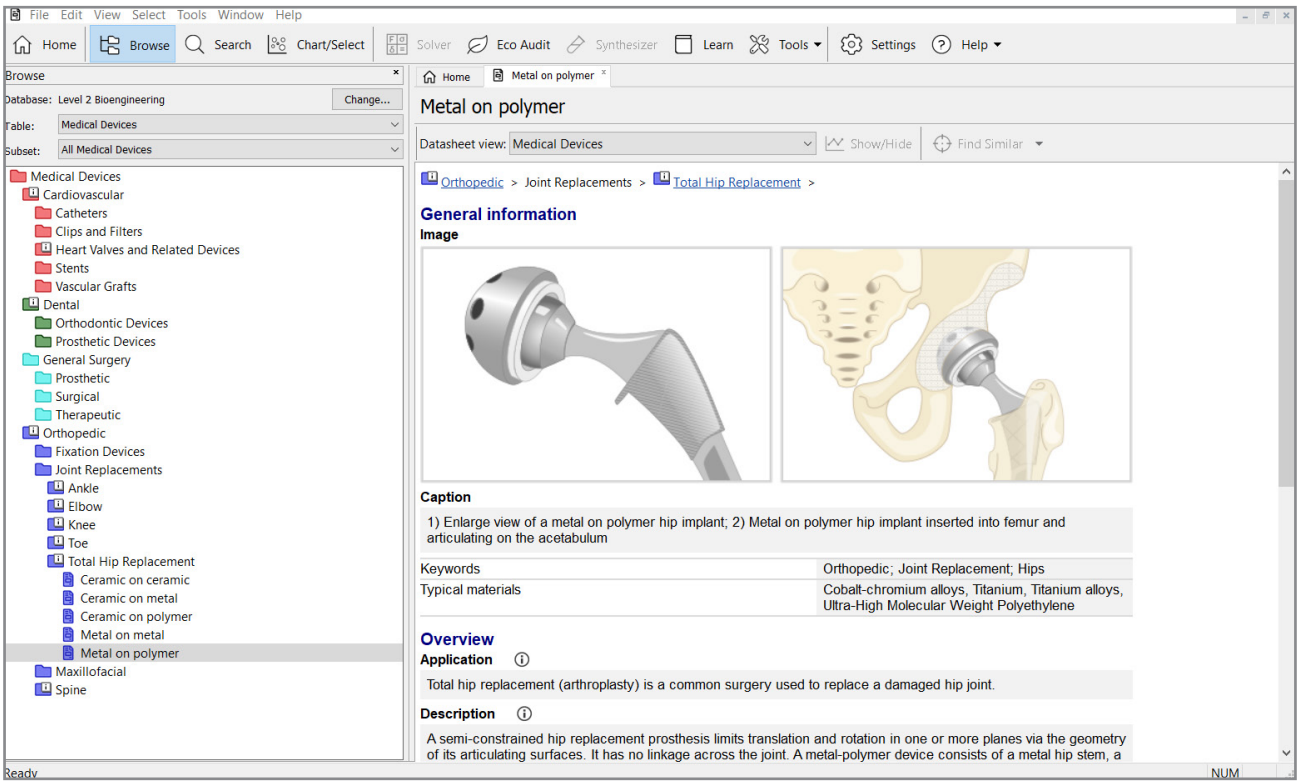


Figure 9: Medical Device data-table, showing folder structure and a typical record.

As with other Granta EduPack datatables, 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 Devices datatable so that students, regardless of their background, can understand basic medical terminology and human anatomy. An example is given in Figure 10.

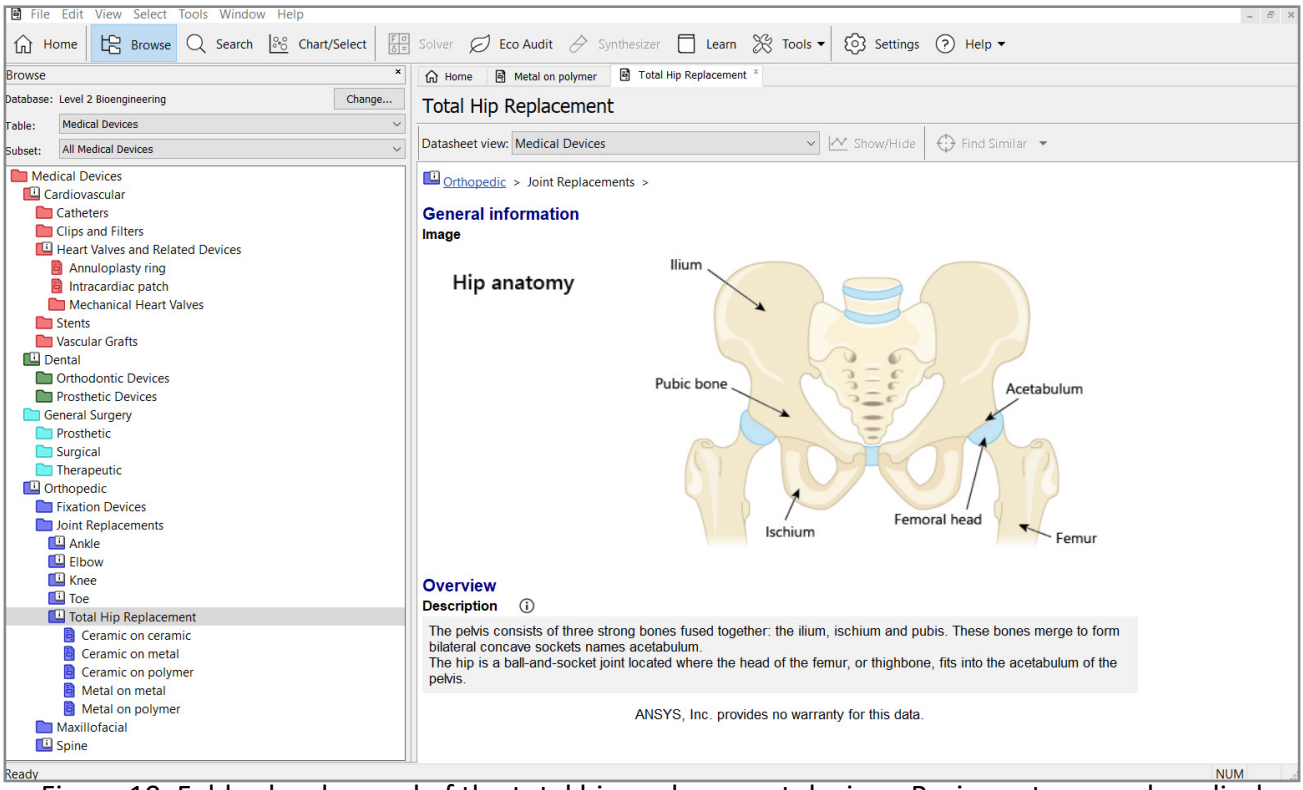


Figure 10: Folder-level record of the total hip replacement devices. Basic anatomy and medical terminology are provided.

To provide further self-learning support, 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 8). The Science note for the attribute "FDA" Classification is shown in Figure 11, as an example.

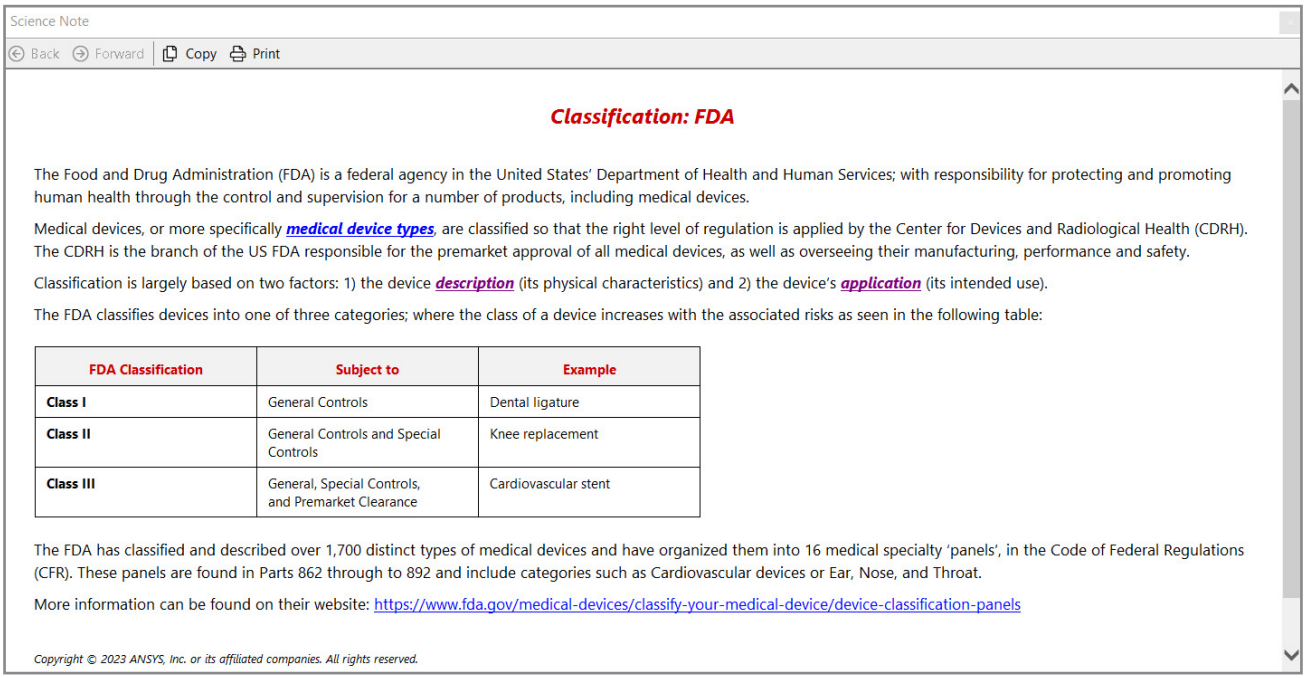


Figure 11: Example *Science note*. The FDA classification is shown here.

4.2. FDA Approved Example data-table

The *FDA Approved Example* datatable contains records for over 100 real-life medical devices which have been on the market, each linked to their generic equivalent in the *Medical Device* datatable. An example record is shown in Figure 12. 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* datatable, attributes are defined and explained in accompanying Science Notes.

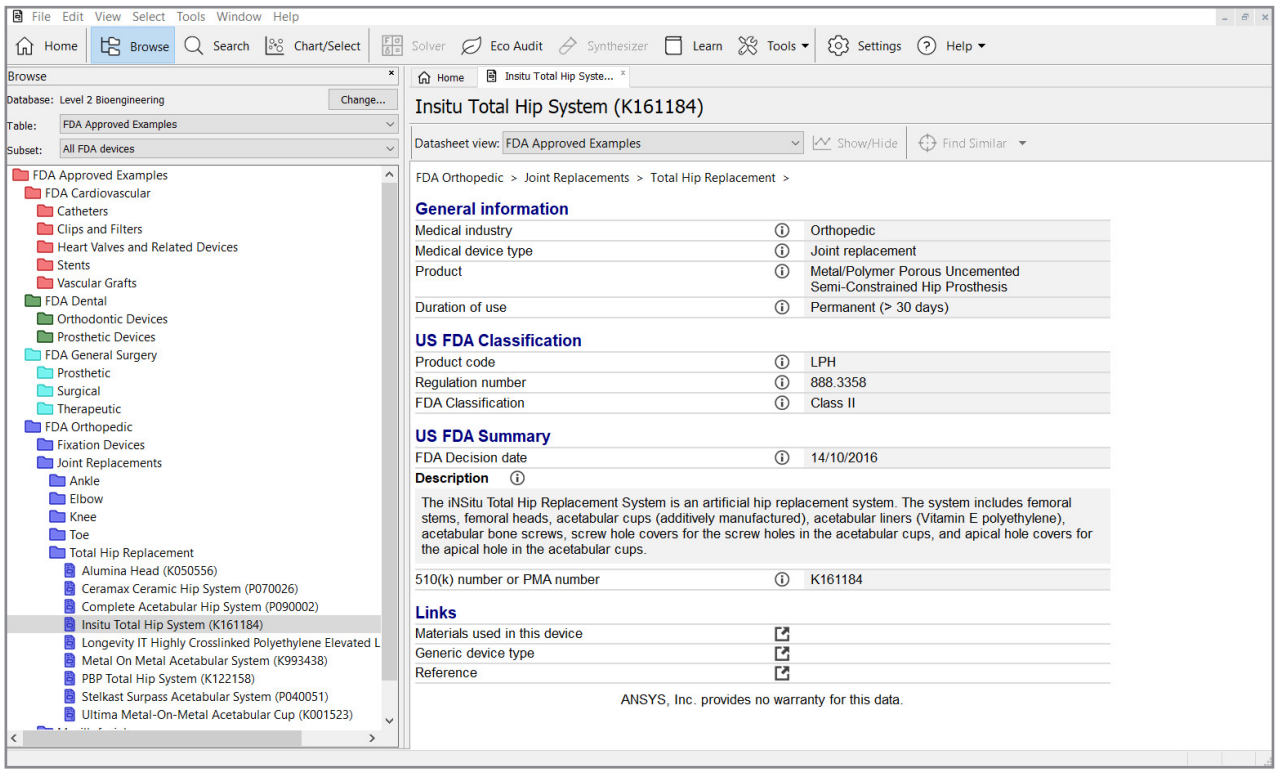


Figure 12: FDA Approved Example record.

When specific materials are mentioned within the record, that FDA Approved Example is linked to relevant records within the *MaterialUniverse* datatable (see Figure 6). For example, the record shown in Figure 12 is linked to the record for Ultra-high Molecular Weight Polyethylene (UHMWPE) in the Level 2 Bioengineering *MaterialUniverse* datatable.

5. Using the Medical Devices datatable

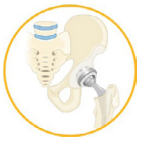
The Medical Devices datatable can be used in many ways: to engage interest, to provide images, descriptions and data for medical devices, to explore the materials that appear in them, and as a basis for case studies. To illustrate, this section presents an orthopedic micro-project (Figure 13) that can 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, so far, 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.ansys.com/academic/educators/education-resources.

EXAMPLE: Medical Devices MicroProject 1
Hip replacements for hypochondriacs



Horace, life-long hypochondriac, has a pain in his hip. To Horace, this means hip replacement, but there is much to cause anxiety along that path. Are all hip replacements metallic? That will trigger security alarms. Is nickel involved? Allergy risk there. Is the metal ferromagnetic? Say goodbye to MRI scans. Just how bio-compatible are hip-replacement materials? Horace has heard that some elements in hip replacements are classified as "critical". To a hypochondriac, "critical" is one step from "terminal". Should he be concerned?

- What material combinations are involved in hip replacements? Are there any that are completely non-metallic? (Use the Medical Devices data-table to explore the Orthopedic folder and the Total Hip Replacements sub-folder.)

- If metals are involved, which elements do they contain? Is nickel among them? (The records list Typical Materials)

- Are the alloys used in hip replacements MRI compatible? (Search through the relevant material records and look for the attribute 'Guidance for MRI Safety')

- What assurance have we got that the metals used in hip replacements are really biocompatible? (The Device Design field in each hip-replacement record gives links to FDA Guidance on biocompatibility testing.)

- Are any of the elements classified as critical? What does "critical" mean? Does it raise concerns? (At the bottom of each Medical Device record there are links to records for the materials the device contains. Try these for critical status and click on the (i) for a definition of criticality.)

Discussion point.

Bone is a complex composite involving collagen and hydroxyapatite. Its properties differ greatly from those of the materials (metals, ceramics) used in hip replacements. Might it be better to synthesize a material that simulates bone more closely? Use the internet to explore "Hydroxyapatite – Polyethylene composites".

Figure 10: Orthopedic microproject.

6. Conclusions

The datatables documented in this White Paper provide a resource to supports the teaching of Biomedical Engineering (BME) at the introductory and more advanced levels. They contain 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.

At present it is limited to cardiovascular, orthopedic and dental devices, as well as general surgery examples. We actively work with collaborators to expand the datatables further and would welcome suggestions for its expansion and the directions in which it might be developed. Please contact education@ansys.com for access to the database.

7. References

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