Global Medical Device Nomenclature (GMDN)

GMDN – A Requirement for UDI

Edward Glenn, Term Developer - GMDN Agency
What we will be discussing

☐ Why is the GMDN needed
☐ GMDN data structure
☐ How to find GMDN terms
☐ Unique Device Identification
☐ UDI & GMDN Relationship
☐ Examples of GMDN in use
☐ Questions?
Why the need for Device names?

Large variety of devices!
Why is consistent naming important?

- Medical Devices are traded internationally
- **Regulators** need to approve devices efficiently by identifying the product group and the related hazards / risks
- **Regulators** need to identify ‘systematic’ failures of medical devices
- **Hospitals** can identify the products they need and manage their inventory
Why was the GMDN needed?

Existing nomenclatures:

- ‘National’ systems (not suitable for international harmonisation) & Single language
- Unstructured / un-standardised
- Too vague / poor definitions
- Too rigid – difficult to include new technology
- Can’t keep up with volume of innovation
- Too many duplicates / overlap
- Uncontrolled – no update method for users

Not meeting Regulator needs
What is the GMDN?

Global Medical Device Nomenclature (GMDN)

- The international standard (ISO 15225) for naming Medical Devices
- Used by 70 national Medical Device Regulators - Backed by IMDRF
- Over 4000 Manufacturers worldwide
- Translated into 25 languages
- 22,000 Preferred Terms with Definitions
- Controlled distribution and updating
- International acceptance
Global acceptance

- IMDRF only recommend GMDN
- European Commission only use GMDN
- Trade Associations (EUCOMED / EDMA / ADVAMED / GMTA ) propose GMDN
- EC has translated the GMDN into 20 languages
- World Heath Organisation published guidance
- PAHWP propose for Africa
- Eurasia Economic Commission propose for CIS
- Adopted by IHTSDO (Snomed CT) for patient records
- US FDA implementation of UDI Rule.
Used by National Regulators

- European Union
- Australia
- Canada
- Japan
- United States
- Colombia
- Egypt
- Mexico
- Nigeria
- Russia
- Saudi Arabia
- Singapore
- South Africa
- South Korea
- Turkey
- ...

G•M•D•N
Manufacturer Membership by country

- USA: 21%
- Germany: 13%
- Others: 24%
- Sweden: 3%
- Switzerland: 3%
- Czech Republic: 3%
- Italy: 4%
- China: 4%
- Japan: 5%
- France: 7%
- United Kingdom: 13%
- France: 7%
GMDN Term Structure

Each GMDN Term consists of 3 parts:

- **Code:** 33719

- **Term Name:** Ceramic-on-metal total hip prosthesis

- **Definition:** A sterile implantable artificial substitute for a diseased (e.g., arthritic) or injured hip joint consisting of matching femoral (head/shaft) and acetabular components articulated at a ceramic-on-metal interface. Fixation devices for implantation (e.g., screws and bolts) may be included and implantation may be performed with or without bone cement.
How can you find GMDN Codes?

www.gmdnagency.org
Searching for GMDN Terms

There are 2 approaches to searching for a term.
- Word searching
- Using the collective terms (CT’s)

E.g., consider the Ceramic-on-metal total hip prosthesis
Word searching for GMDN Terms
Word searching for GMDN Terms

Search text: hip implant
For:
- All the words
- Any of the words
- The exact phrase
- None of these words
In: All Fields

Search text: Ceramic-on-metal total hip prosthesis
Categories: 07 Non-active implantable devices

Ceramic-on-metal total hip prosthesis
A sterile implantable artificial substitute for a diseased (e.g., arthritic) or injured hip joint consisting of matching femoral (head SHAFT) and acetabular components articulated at a ceramic-on-metal interface. Fixation devices for implantation (e.g., screws and bolts) may be included and implantation may be performed with or without bone cement.
Word searching for GMDN Terms

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Ceramic-on-metal total hip prosthesis
Categories: 07 Non-active implantable devices

Add To Basket
A sterile implantable artificial substitute for a diseased (e.g., arthritic) or injured hip joint consisting of matching femoral (head/ shaft) and acetabular components articulated at a ceramic-on-metal interface. Fixation devices for implantation (e.g., screws and bolts) may be included and implantation may be performed with or without bone cement.
Purchase of GMDN Terms

3. Ceramic-on-metal total hip prosthesis
Categories: 07 Non-active implantable devices

A sterile implantable artificial substitute for a diseased (e.g., arthritic) or injured hip joint consisting of matching femoral (head/shaft) and acetabular components articulated at a ceramic-on-metal interface. Fixation devices for implantation (e.g., screws and bolts) may be included and implantation may be performed with or without bone cement.

Get Codes

3. Ceramic-on-metal total hip prosthesis
Categories: 07 Non-active implantable devices

A sterile implantable artificial substitute for a diseased (e.g., arthritic) or injured hip joint consisting of matching femoral (head/shaft) and acetabular components articulated at a ceramic-on-metal interface. Fixation devices for implantation (e.g., screws and bolts) may be included and implantation may be performed with or without bone cement.
Collective Terms

GMDN uses **Collective Terms** to provide:

- Better navigation with variable hierarchies
- Compare common features:
  - Materials (Inert, Latex, Animal)
  - Invasivenessness (Internal / External)
  - Sterility (Supplied Sterile / non-sterile)
  - Use Frequency (Single Use / Reusable)
  - Powered by (mains, battery, air, etc.)
- Flexible to meet future needs
Collective Terms

33719 Ceramic-on-metal total hip prosthesis

Collective terms by name
- Device Applications
  - CT1006 Orthopaedic devices
    - CT125 Implantable joint prostheses and associated
      - CT1372 Implantable joint prostheses
      - CT837 Implantable hip prostheses
      - CT1112 Total hip prostheses
  - High-Level Device Groups
    - CT244 Prostheses and associated devices
      - CT1370 Prostheses
        - CT446 Implantable prostheses
          - CT1372 Implantable joint prostheses
      - CT837 Implantable hip prostheses
        - CT1112 Total hip prostheses

Collective terms by attribute
- Device Attribute Assortment
  - CT2406 Implantable
    - CT2408 Non-active implantable
  - CT334 Single-patient use
  - Clinical Specialties
    - CT156 Orthopaedics
  - Device Invasiveness
    - CT983 Surgical invasive
      - CT321 Long-term surgical invasive
  - Device Materials
    - CT979 Inorganic materials
      - CT203 Ceramics
      - CT177 Metals
  - Device Sterility
    - CT336 Sterile
Using Collective Terms to search

![CT Quick Finder interface](image)

Records 1-8 from 8

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<th>Code</th>
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<tr>
<td>CT1240</td>
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<tr>
<td>CT2400</td>
<td>Acetabulum prostheses</td>
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<td>CT837</td>
<td>Implantable hip prostheses</td>
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<tr>
<td>CT1112</td>
<td>Total hip prostheses</td>
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</table>

Device assemblies designed as implantable artificial substitutes to replace an injured or diseased hip joint in total (femoral and acetabular components).
Using Collective Terms to search

Records 1-5 from 5

Term
1. Ceramic-on-ceramic total hip prosthesis
2. Ceramic-on-metal total hip prosthesis
3. Ceramic-on-polyethylene total hip prosthesis
4. Metal-on-metal total hip prosthesis
5. Metal-on-polyethylene total hip prosthesis

Records 1-5 from 5

Term
1. Ceramic-on-ceramic total hip prosthesis
2. Ceramic-on-metal total hip prosthesis
3. Ceramic-on-polyethylene total hip prosthesis
4. Metal-on-metal total hip prosthesis
5. Metal-on-polyethylene total hip prosthesis
What’s the process?

- Identify the GMDN Code for all of your products, from the GMDN database
- Provide the GMDN Code to your Customers / Distributors / Data Pools
- Use the GMDN Code to register your products with your MD Regulator
- Meeting the requirements for Unique Device Identification (UDI)
Unique Device Identification

- Pack / product marking of ‘unique’ identifier
- Marking also includes production identifiers (e.g. Batch No., Expiry Date, Serial No…)
- **Machine** readable (e.g. bar code) and human readable
- Linked to other product data in a database (e.g. make, model, etc.)
UDI Database

- The GMDN code is one of the 25 mandatory core data elements identified in the IMDRF ‘UDI System for Medical Devices’ Guidance Document.
- Data for each device is provided by the manufacturer to the **UDI Database** (UDID).
UDI requires a Carrier & Scanner

- Product Label (Carrier)
  - Linear Bar Code
  - 2D Bar Code (more data)
  - RFID - Radio Frequency Identification (non-contact)

- Scanner to read labels
  - Bar code Reader
  - Image Scanner
  - RFID Scanner
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier
(e.g. 12345678909874)

47017
General-purpose syringe
A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used to inject fluids (e.g., medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical applications. At the distal end of the barrel is a male connector (typically a Luer-lock type) for the attachment of the female connector (hub) of a hypodermic needle or an administration set. It is typically made of plastic and silicone materials and may have plunger anti-sticking properties (internally precoated with compatible substances) allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier
(e.g. 12345678909874)

Other device under generic Device Group (47071)

Hudson
12345678909874

Brooks
19876543218976

Woods
32345678908765
When you can’t find a Term?

If you can’t find a GMDN Term for your product:

1. Ask us for assistance
2. Apply for a new Term:
   - On-line Request Application
   - Attach your product datasheet / pictures
   - We discuss the draft Term with you
   - Two week public comment period
   - Database updated daily
Modifying or Obsoleting Terms?

- We modify existing Terms
  - To increase the scope
  - Improve the definitions
- Make Terms Obsolete
  - To remove inadequate Terms
  - Reducing over time
- Notifications by email to Members
Example of GMDN & UDI for Regulation

- Post Market surveillance
  - Identify systematic (generic) product failure
  - Support rapid product recall

- Better Regulation
  - Speed up Pre-market approval
  - Identify products quickly
  - Detailed information on imports and exports
  - Quickly identify trends about new equipment use and problems
GMDN speeding up pre-market approval

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<tr>
<td>Hudson</td>
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<table>
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<tr>
<th>Regulator Device Register</th>
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<table>
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<tr>
<th>GMDN</th>
<th>Make</th>
<th>Test Method</th>
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GMDN speeding up pre-market approval

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### New Applicant
- Hudson
- Jones

### Previously Approved Device
GMDN speeding up product recall

**Product Failure**

**Regulator Device Register**

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GMDN speeding up product recall

Product Failure

Hudson

Jones

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Investigate this product too?
Example of GMDN & UDI in Hospitals

- Asset Management
  - Support equipment commissioning
  - Help identify equipment location
  - Support maintenance programmes

- Inventory Control
  - Reduce wastage
  - Translate product labels with poor descriptions
  - Improve stock control
Use the GMDN to find missing stock

e.g. Need 20 equivalent crutches in Ward C
Use the GMDN to find missing stock

**P31115 Axillary crutch**
A staff-like mobility aid used to assist a person with a disability to support their weight while walking. The device has one leg, a padded hand support at the level of the user’s wrist, and an under-arm (the armpit or axilla) padded platform. The pads are typically made of non-slip material (e.g., rubber, glycerin gel, sheepskin). The device may be adjustable in length and is typically made of wood or metal [e.g., aluminium (Al), titanium (Ti)].

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Need more Axillary crutches
Use the GMDN to find missing stock

**P31115 Axillary crutch**
A staff-like mobility aid used to assist a person with a disability to support their weight while walking. The device has one leg, a padded hand support at the level of the user's wrist, and an under-arm (the armpit or axilla) padded platform. The pads are typically made of non-slip material (e.g., rubber, glycerin gel, sheepskin). The device may be adjustable in length and is typically made of wood or metal [e.g., aluminium (Al), titanium (Ti)].

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Found more Axillary crutches
Nottingham University Hospital

- Clinical Engineering application
Thank you for listening

Any questions?

enquiries@gmdnagency.org