
Global Medical Device Nomenclature (GMDN): An Update

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GMDN Agency

www.gmdnagency.org



-
- ☐ GMDN introduction
 - ☐ GMDN data
 - ☐ GMDN uses
 - ☐ GMDN website
 - ☐ Key Updates
 - ☐ Questions

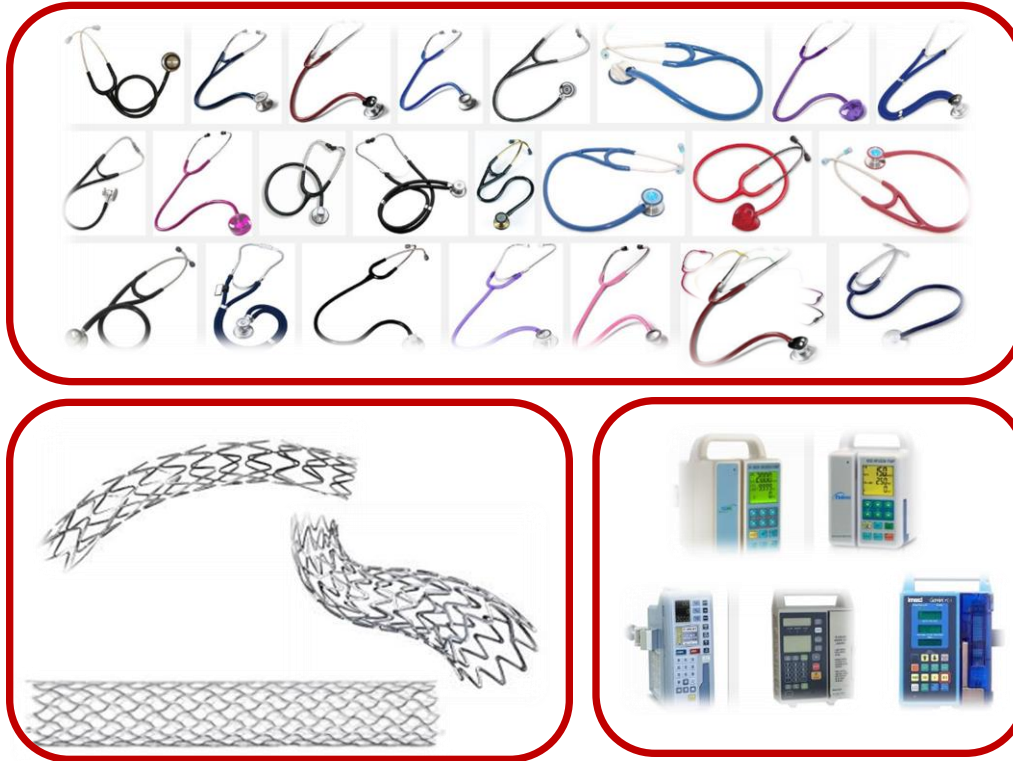
GMDN Uses

- Used by:
 - 70 national Medical Device Regulators
 - 4000+ Manufacturers worldwide
- US FDA implementation of UDI Rule
 - All medical devices sold in the US will need a GMDN code
- European Commission only uses GMDN
 - New MD regulation due 2017 (UDI Europe)
- Regional Trade Associations (EUCOMED/ EDMA/ ADVAMED/ GMTA) recommend GMDN
- Complies with ISO15225





To this ?



Device Group



How do we define the group?



What is it?

GMDN Term



GMDN Code: 35195

GMDN Term Name: Electrocardiographic monitor

GMDN Term Definition:

A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG)...

Give the group a name



GMDN Term Name **Electrocardiographic monitor**

GMDN Term Definition:

A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

Define the group



GMDN Term Definition:

A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.



GMDN Term Definition:

A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

Intended use

Technology

Important attributes

e.g.,

Sterility

Use frequency

Power source

Give the group a code



GMDN Code: 35195

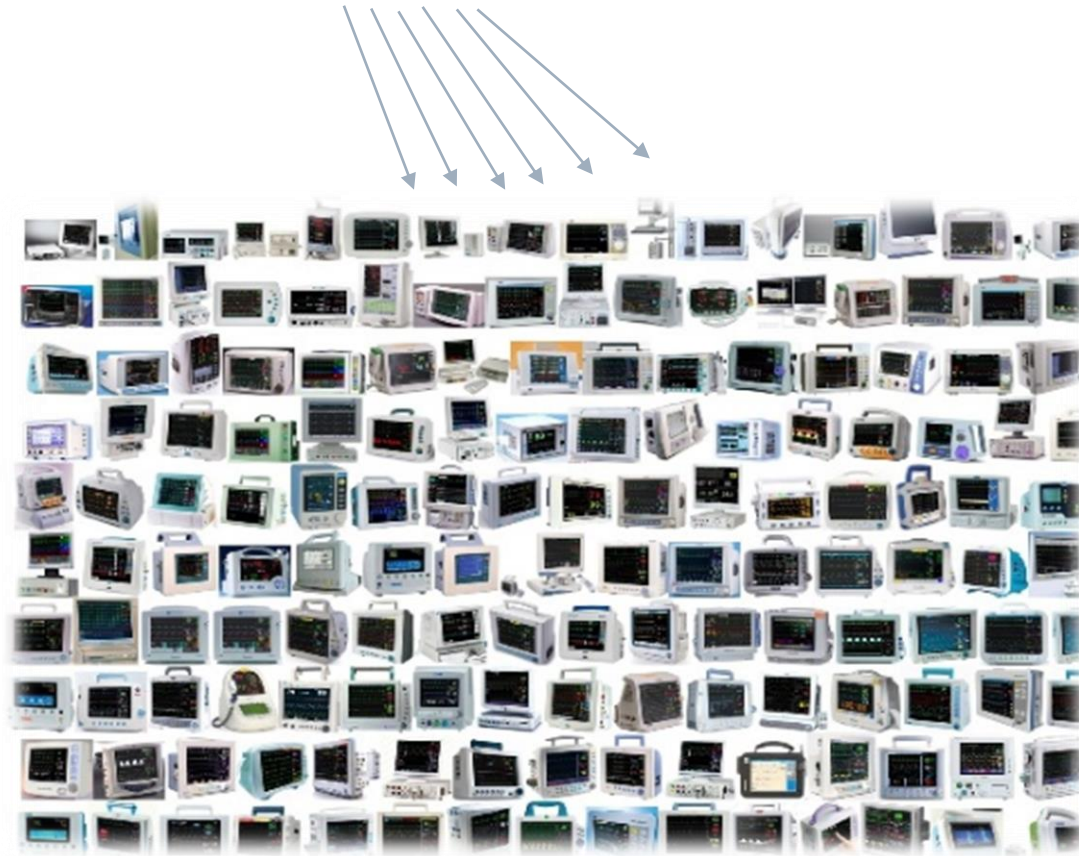
GMDN Term Name: Electrocardiographic monitor

GMDN Term Definition: A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

Device group = GMDN Term



But all Electrocardiographic monitors have a different DI



Collective Terms

- GMDN uses **Collective Terms (CT's)** to group/organize related Preferred terms:
 - By clinical application (e.g., cardiovascular devices)
 - By name (e.g., prosthesis, scissors, catheter)
 - By attribute (e.g., Material, Invasiveness, sterility, Use frequency)

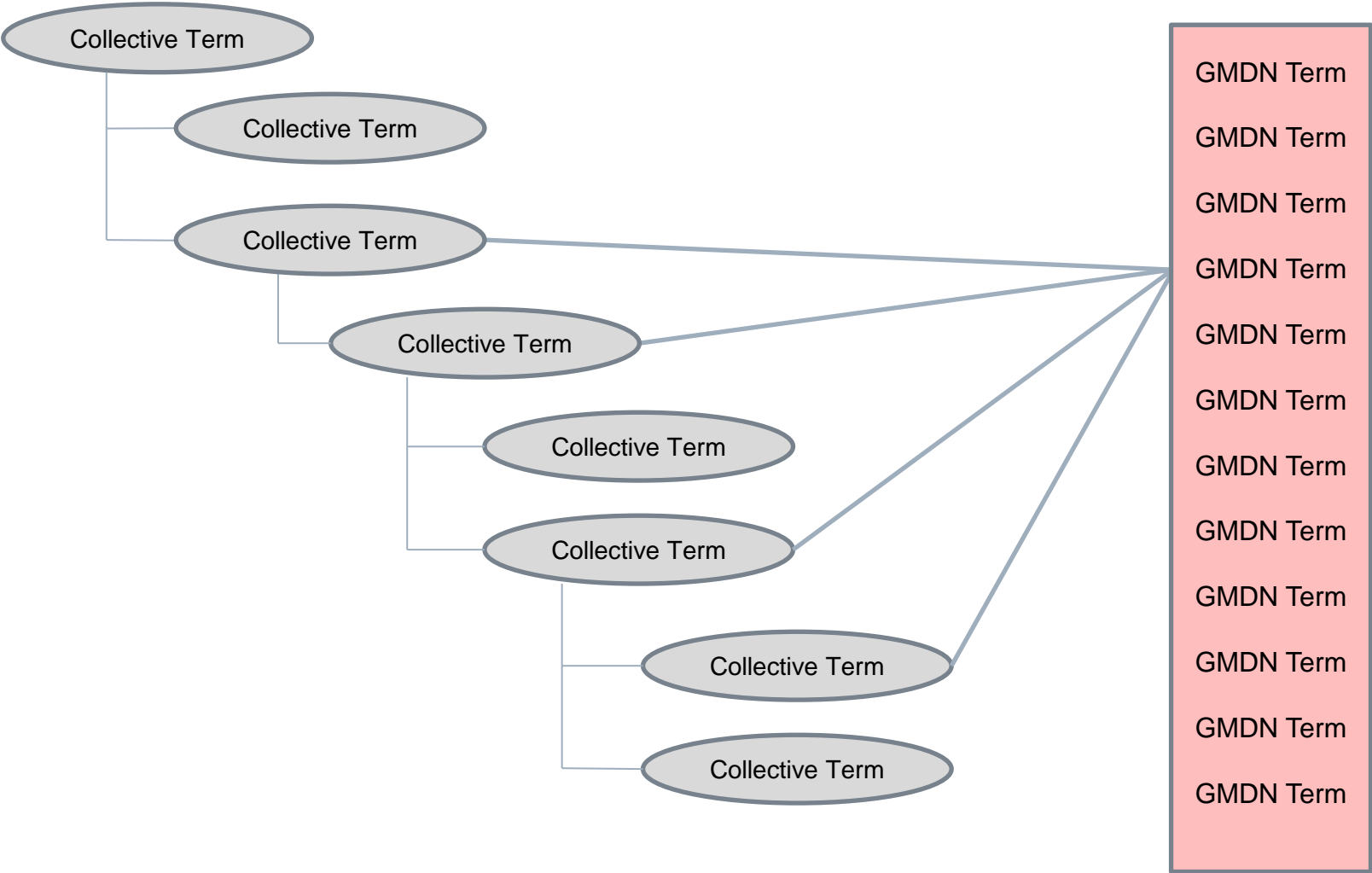
- A hierarchical categorisation ...

Hierarchical classification

Collective Terms

Nomenclature

GMDN terms



Explorer

Find

☐ Hide sub-group terms

- ▲ Device Applications
 - ▶ Anaesthesia and respiratory devices
 - ▶ Body fluid and tissue management devices
 - ▲ Body tissue manipulation and reparation devices
 - ▲ Dressings and associated devices
 - ▲ Dressings
 - ▶ Body support/pressure dressings
 - ▲ Dermal dressings
 - Burn dressings
 - Exudate-absorbent dressings
 - ▶ Film dressings
 - Hydrogel dressings**
 - Skin closure/cover adhesive strips
 - Wound-nonadherent dressings
 - Gauze dressings
 - ▶ Mucosal dressings
 - Nail dressings
 - ▶ Scar dressings
 - ▶ Haemostatic agents
 - Hernia trusses
 - ▶ Hot/Cold therapy packs
 - Wound irrigation solutions

GMDN Records 1 - 5 of 5 RESULTS FOR GROUP: Hydrogel dressings

1

Dermatological hydrogel dressing

Wound hydrogel dressing, non-sterile

Wound hydrogel dressing, non-sterile, antimicrobial

Wound hydrogel dressing, sterile

Wound hydrogel dressing, sterile, antimicrobial

GUDID

- ❑ US FDA UDI
- ❑ Deadline for Class II medical devices was September 2016
- ❑ Database = GUDID
 - Mandatory field on record submission

ACCESS GUDID

IDENTIFY YOUR MEDICAL DEVICE



- basic **coronary angioplasty** balloon catheter
- catheter, percutaneous transluminal **coronary angioplasty** (ptca), cutting/scoring
- cutting/scoring **coronary angioplasty** balloon catheter
- atherectomy **coronary angioplasty** system
- device, angioplasty, laser, coronary
- atherectomy laser system beam guide-catheter, **coronary angioplasty**
- imaging **coronary angioplasty** balloon catheter
- atherectomy **coronary angioplasty** system, line-powered

ABOUT

The Global
Identificatio
have Unique

The FDA is
identify dev
patient use.
download a
web services
for testing by
the end of 2015.
Please see the
[API Documentation](#)
for more information.

[MORE INFO](#)

[ABOUT UDI](#)

[ABOUT GUDID](#)

NEWS

[AccessGUDID News](#)

Posted: August 13, 2015

AccessGUDID Release Files Notification

Updated: 8/16/2015 - GUDID functionality has been restored and is now full



Coming Soon!

Resources for application developers to get the most out of AccessGUDID.

HELP

[Help using AccessGUDID](#)



[Searching AccessGUDID](#)

[Downloading Release Files](#)

[NLM Web Guidelines](#)

[Still Need Help?](#)

FDA TOOLS AND RESOURCES



[FDA UDI Home](#)

[FDA Medical Devices Home](#)

[Download a Device Dashboard \(Beta/Alpha\)](#)

drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated



HOME

ABOUT

NEWS

API

DOWNLOAD

HELP

SEARCH RESULTS FOR: **drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated** (722 results)

[EXPORT RESULTS](#)



FILTERS



SORT BY

10 RESULTS PER PAGE



PAGE

1



Company Name



[XIENCE ALPINE - 08717648200380](#)



Brand Name



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 38 mm / Over-The-Wire

Company Name: ABBOTT VASCULAR INC.

Version or Model: 1145400-38

GMDN Term



[XIENCE ALPINE - 08717648200373](#)



FDA Product Code Name



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 33 mm / Over-The-Wire

Company Name: ABBOTT VASCULAR INC.

Version or Model: 1145400-33

FDA Product Code



Device Packaged as Sterile



[XIENCE ALPINE - 08717648200366](#)



Sterilization Prior To Use



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 28 mm / Over-The-Wire

Company Name: ABBOTT VASCULAR INC.

Version or Model: 1145400-28

Issuing Agency



[XIENCE ALPINE - 08717648200359](#)



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 23 mm / Over-The-Wire

Company Name: ABBOTT VASCULAR INC.

Version or Model: 1145400-23

[XIENCE ALPINE - 08717648200342](#)



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 18 mm / Over-The-Wire

Company Name: ABBOTT VASCULAR INC.

Version or Model: 1145400-18



UDI November 2016

- ❑ DI records: 1,140,006
- ❑ Unique GMDN codes: 7,114
(Active GMDN = 7,035)
- ❑ Therefore ratio = 1:160

- ❑ Active implantable device records:
2813
- ❑ Non-active implantable device records:
524,094
- ❑ IVD device records:
24,817

GMDN Agency working with the FDA

- Device registries are using UDI data to their maximum advantage
- Started with “RAPID project” (Pilot study MDEpiNet)
 - Trial project for peripheral vascular intervention (PVI) registry
 - Focus on peripheral stents
- FDA have now created a “Learning UDI Community” initiative with a focus on GMDN led device categorisation

Helping to improve GMDN definitions and user assignment of terms.



Collective terms:

Device Applications

Anaesthesia and respiratory devices

Body fluid and tissue management devices

Body tissue manipulation and reparation devices

Cardiovascular devices

Angioscopes

Arterioscopes

Cardiac catheters and associated devices

Cardiac pacemakers and associated devices

Cardiac physiology/mapping devices

Cardiac resuscitators

Cardiovascular guidewires

Cardiovascular monitors/monitoring systems and associated devices

Cardiovascular prostheses and associated devices

Heart valve prostheses and associated devices

Heart ventricle spatial modification implants

Vascular stents

Aortic stents

Bioabsorbable vascular stents

Carotid artery stents

Coronary artery stents

Drug-eluting vascular stents

Endovascular stent-grafts

Intracranial vascular stents

Peripheral artery stents

Cardiovascular surgical devices

Circulatory assist devices

Defibrillators and associated devices

GMDN terms: 8 / 22,800

Bare-metal renal artery stent

Drug-eluting femoral artery stent

Drug-eluting infrapopliteal artery stent

Drug-eluting renal artery stent

Iliac artery stent, bare-metal

Iliofemoral artery endovascular stent-graft

Multiple peripheral artery stent, bare-metal

Multiple peripheral artery stent, bioabsorbable

A sterile non-bioabsorbable tubular device intended to be implanted in a renal artery to maintain arterial patency and improve luminal diameter in patients with symptomatic atherosclerotic disease. It is made of metal [e.g., stainless steel, cobalt-chrome (Co-Cr), nickel-titanium alloy (Nitinol)] typically in a tubular mesh structure, sometimes bifurcation (Y-shaped) design, and is typically delivered to the site of implantation with a balloon catheter which will expand the device upon balloon inflation. It is available in a variety of lengths and diameters.

Products: 64 / 551,489

08714729484851	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729484844	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729484837	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729484820	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390527	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390510	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390480	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390473	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390466	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390459	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390442	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390435	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390404	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390398	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390381	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
08714729390374	Express® SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
10827002185286	Formula	William Cook Europe ApS
10827002185279	Formula	William Cook Europe ApS
10827002185262	Formula	William Cook Europe ApS
10827002185255	Formula	William Cook Europe ApS
10827002185248	Formula	William Cook Europe ApS
10827002185231	Formula	William Cook Europe ApS
10827002569758	Formula	William Cook Europe ApS
10827002569741	Formula	William Cook Europe ApS
10827002569734	Formula	William Cook Europe ApS
10827002569727	Formula	William Cook Europe ApS
10827002569710	Formula	William Cook Europe ApS
10827002569703	Formula	William Cook Europe ApS
10827002569697	Formula	William Cook Europe ApS

Company

BOSTON SCIENTIFIC CORPORATION

Brand name

Express® SD Renal/Biliary

Version/Model

H74937912618900

Device description

Premounted Stent System

GMDN Website

- ☐ Membership
- ☐ Search
- ☐ Explorer
- ☐ My Shortlist
- ☐ My Terms
- ☐ Enquiry

GMDN Website – Membership

Membership

Is my organisation already a member?

Membership Type

- Select -

Annual Sales

Additional Info

Currency

Euro (EUR)

Total

Method

- ☐ Credit Card
☒ Invoice
☐ Quote

MasterCard, Visa (EUR, GBP, USD), Amex (USD), JCB, Maestro (GBP).

Purchase Order

Invoice purchase order number (optional).



GMDN Website – User Management

GMDN Agency

About ▾

Terms ▾

Help ▾

English

Test ▾

Users.

Manage your users.

You have 3 remaining user credit(s). [Request User Credits](#)

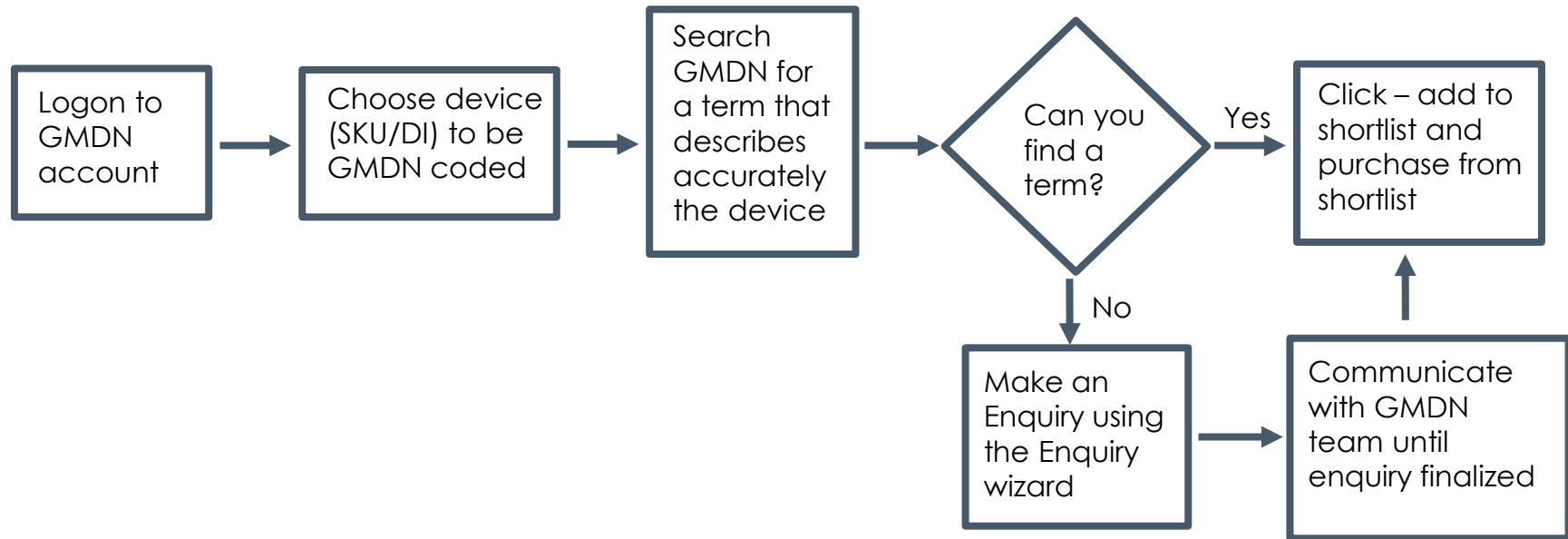
[New User »](#)

Full Name	Email	Group	Job Title	Edit Permission	
Test One	test1@gmdnagency.org	Team 2		Users; Orders; Terms; Enquiry	Edit
Test Two	test2@gmdnagency.org	Team 1		Terms; Enquiry	Edit

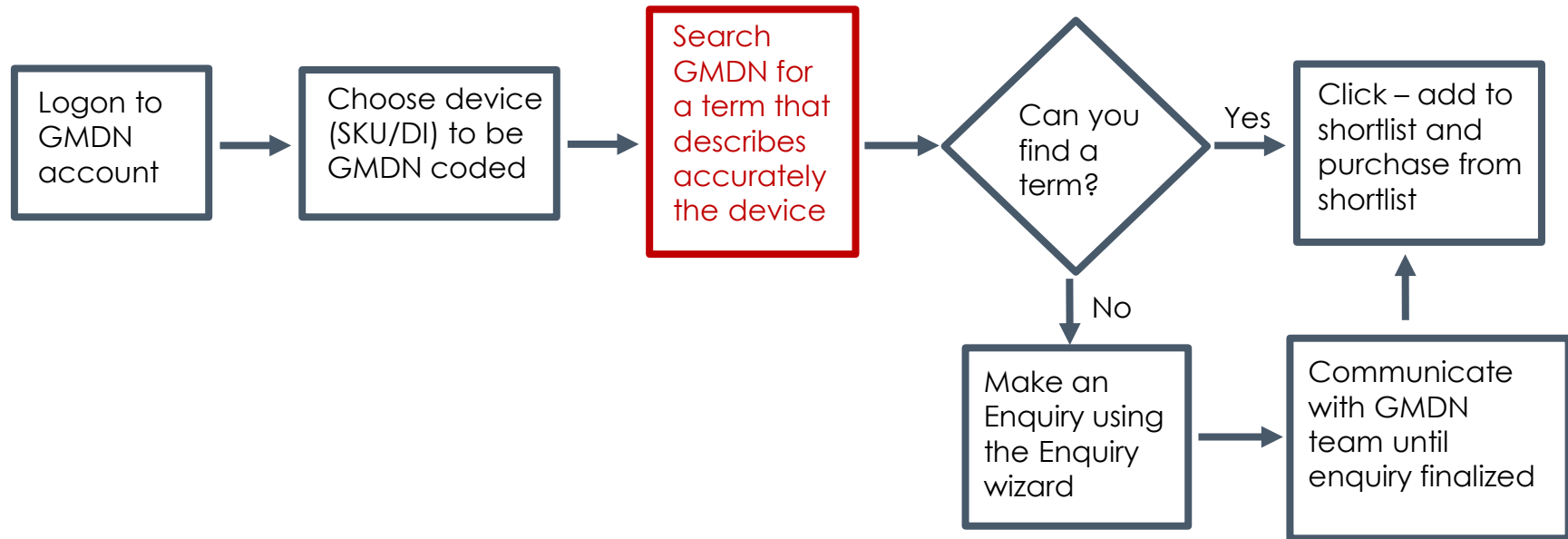
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The Process for Manufacturer members



The Process for Manufacturer members



GMDN Website – Search 1

Search

Find device definitions by keyword(s).

<input type="text" value="cardiac catheter"/>	English ▼	Q Search
---	-----------	--------------------------

[Advanced](#) [Reset](#) [Help](#) [My Shortlist](#)

Examples: stent ; aorta OR stent ; aorta stent ; "aortic stent" ; catheter -catheterization ; 45678 ; " stent "

Note: Translations may not be available for some terms.

1-25 of 26 term(s)

[Cardiac catheterization laboratory computer](#)

[Details](#) [Shortlist](#)

[Cardiac catheterization mobile medical facility](#)

[Details](#) [Shortlist](#)

[Cardiac catheterization monitoring system](#)

[Details](#) [Shortlist](#)

[Chamber-decompression cardiac catheter](#)

[Details](#) [Shortlist](#)

[Diagnostic ultrasound cardiac catheter, non-steerable](#)

[Details](#) [Shortlist](#)



GMDN Website – Search 2

Term Details

Name	Butterfly skin-closure adhesive strip
Definition	A small, narrow piece of flexible material covered on one side with a pressure-sensitive adhesive, and with broad, wing-shaped ends that function to approximate the edges of a superficial wound. The device may be hypoallergenic and/or waterproof. This is a single-use device.
Code	
Status	Active
Created Date	2005-01-14
Modified Date	2011-10-04
<div>Add to Enquiry Add to My Shortlist Move to My Archive Return to My Terms</div> <p>Note: Terms in "My Archive" do not generate Alerts.</p>	

Explorer Groups

[Device Applications](#) / [Body tissue manipulation and reparation devices](#) / [Dressings and associated devices](#) / [Dressings](#) / [Dermal dressings](#) / [Skin closure/cover adhesive strips](#)

[Device Applications](#) / [Disability-assistive products](#) / [Personal care and protection assistive products](#) / [Skin cleaning/protecting devices](#)

[High-Level Device Groups](#) / [Adhesive strips](#) / [Skin closure/cover adhesive strips](#)



GMDN Website – Explorer

Explorer

Browse device definitions by group.

[Advanced](#) [Reset](#) [Help](#) [My Shortlist](#)

ExplorerFind

- By Name
- ▴ By Use
 - CT996:Anaesthesia and respiratory devices
 - CT997:Body fluid and tissue management devices
 - ▴ CT1007:Body tissue manipulation and reparation devices
 - ▴ CT124:Dressings and associated devices
 - ▴ CT554:Dressings
 - CT2150:Body support/pressure dressings
 - ▴ CT2148:Dermal dressings
 - CT1342:Burn dressings
 - CT1345:Exudate-absorbent dressings
 - CT2154:Film dressings
 - CT1348:Hydrogel dressings
 - CT987:Skin closure/cover adhesive strips**
 - CT1352:Wound-nonadherent dressings
 - CT1344:Gauze dressings

1-4 of 4 term(s)

[Butterfly skin-closure adhesive strip](#)

[Skin-closure adhesive strip](#)

[Skin-cover adhesive strip](#)

[Skin-cover adhesive strip, antimicrobial](#)

« 1 »

[Details](#) [Shortlist](#)

[Details](#) [Shortlist](#)

[Details](#) [Shortlist](#)

[Details](#) [Shortlist](#)

GMDN Website – Shortlist

My Shortlist

Compare and review your chosen definitions before purchase.

You have 39 remaining code credits. [Buy Code Credits](#)

Buy All

Remove All

Export

2 term(s)

Butterfly skin-closure adhesive strip

[Details](#)

[Buy](#)

[Remove](#)

A small, narrow piece of flexible material covered on one side with a pressure-sensitive adhesive, and with broad, wing-shaped ends that function to approximate the edges of a superficial wound. The device may be hypoallergenic and/or waterproof. This is a single-use device.

Skin-closure adhesive strip

[Details](#)

[Buy](#)

[Remove](#)

A small, narrow flexible band (of fabric, plastic, paper, or other material) coated on one side with a pressure-sensitive adhesive, used to approximate the edges of superficial wounds. The device may be hypoallergenic and/or waterproof. This is a single-use device.



GMDN Website – My Terms

My Terms

View your purchased GMDN Codes for your devices.

Export

Sort

Purchase Date ▼

5 term(s)

[Arthroscopic gas distention system \(55555\)](#) 2016-05-19

[Details](#)

[Abdominal aorta endovascular stent-graft \(55555\)](#) 2016-05-19

[Details](#)

[Antibody-coated coronary artery stent \(55555\)](#) 2016-05-19

[Details](#)

[Aortic transcatheter heart valve bioprosthesis, stent-like framework \(55555\)](#) 2016-05-19

[Details](#)

[Antibody-coated coronary artery stent, drug-eluting \(55555\)](#) 2016-05-19

[Details](#)



GMDN Website - Enquiry

- Search first – if cant find suitable term use Enquiry.
- Enquiry is the only way to get help from the GMDN Agency for assigning Terms to products. The outcome will be:
 - An appropriate existing Term.
 - Modification of an existing Term to include the new product's characteristics.
 - A new GMDN Term is created.

Enquiry - list

GMDN Agency

About ▾

Terms ▾

Help ▾

English

Test ▾

Enquiry

Can't find a term for your product?

New Enquiry

Make sure you have used the Search and Browse – if you still can't find a suitable term use this 'enquiry wizard' to tell us about your product and we will get back to you with a suitable term. It will usually take us about 3 weeks before we can supply you with a term/code.

Note: We only accept enquiries in English at the present time.

Filter

- All - ▾

Ref	Status	Modified Date	Submitted Date	Generic Device Name	User	
EQ160028	In Progress	29 Feb 2016	29 Feb 2016	bone plus tendon	Mr. Test A One	View
EQ160026	In Progress	28 Jan 2016	28 Jan 2016	bd test 28_1_1	Mr. Test A One	View
EQ160025	Finished	26 Jan 2016	26 Jan 2016	bdtest1	Mr. Test A One	View



Enquiry - step 1

GMDN Agency About ▾ Terms ▾ Help ▾ English Test ▾

Enquiry.

Step 1

Product details.

Your Email

test1@gmdnagency.org

[My Profile](#)

Generic Device Name

Make

Model

Trade Name

Files

Choose Files

No file chosen

We must have product documentation (e.g., IFU, brochure) which includes an image.

Url

<http://www.example.com>

Reason

Enquiry - choice

Step 2

- ☐ Software details
- ☐ In vitro diagnostic (IVD) (not capital goods)
- ☐ Similar to existing Term
- ☐ Device details

Please choose your enquiry type to proceed to the next step.

◀ Back

Cancel

Next ▶

Enquiry - software

GMDN Agency [About](#) [Terms](#) [Help](#)

English [Test](#)

Enquiry.

Step 1

Step 2

Software details.

Used For

Functionality

Technology

Platform

Features

Additional

[← Back](#)

[Cancel](#)

[Next →](#)

Enquiry - IVD

GMDN Agency [About](#) [Terms](#) [Help](#) [English](#) [Test](#)

Enquiry.

Step 1

Step 2

In vitro diagnostic (IVD) details.

Nature of Device	<div>- Select -</div>
Target Analyte	<div></div>
Components	<div>- Multi Select -</div> <div>Select all components requiring GMDN Code</div>
Components (Other)	<div></div>
Assay Type / Methodology	<div></div> <div>Assay analysis technique / methodology</div>
Clinical application	<div></div> <div>Clinical application / Associated clinical condition</div>
Usage	<div>- Select -</div>
Additional	<div></div>

◀ Back

Cancel

Next ▶

Enquiry – similar term

GMDN Agency [About](#) [Terms](#) [Help](#) [English](#) [Test](#)

Enquiry.

Step 1

Step 2

Similar to existing term.

Use this form if you have found a similar or related existing GMDN term and can tell us how/why your product is not covered by that term.

My Terms

Bare-metal biliary stent

Search »

Search and add term from GMDN terms.

Name

Bare-metal biliary stent

Definition

A sterile non-bioabsorbable tubular device intended to be implanted in an obstructed biliary duct (e.g., common bile duct) to maintain luminal patency. It may be a mesh structure or a continuous tube and is made entirely of metal [e.g., high-grade stainless steel, cobalt-chrome (Co-Cr), nickel-titanium alloy (Nitinol)]. It may be expandable in situ (e.g., with a balloon catheter or self-expands) and disposable devices intended to assist implantation may be included.

470 / 700

Modify the definition above and explain below, or specify differences / additions.

Additional

◀ Back

Cancel

Next ▶

Enquiry - details

Enquiry.

Step 1

Step 2

Device details.

Intended Use / Target

Components

Name	Use Frequency	Sterility	Invasiveness	Sold Separately	Power	Materials
------	---------------	-----------	--------------	-----------------	-------	-----------

[Add](#)

Please complete this table to include all components only if supplied separately, i.e. outside of the system or kit.

Key Attributes

- Multi Select - ▾

Additional

◀ Back

Cancel

Next ▶

Enquiry - end

Enquiry

Update your product enquiry.

Ref EQ160023

Status **Finished**

Provisional Term(s) [Descending thoracic aorta endovascular stent-graft](#)

User

GMDN test Academic



Principle contact, receives email notifications from GMDN Experts. [New User](#)

Message

Files

[Browse...](#)

Supports Images, Adobe Acrobat, Microsoft Word.

[Send](#)



Enquiry – purchase new term

Term Details

This term is in your shortlist.

Name Descending thoracic aorta endovascular stent-graft

Definition A sterile non-bioabsorbable tubular device implanted to repair the descending thoracic aorta [includes repair of thoracic aortic aneurysm (TAA), traumatic transections/dissections, fistulae, penetrating ulcers]. It is percutaneously inserted via the femoral artery to the site of implantation, with a disposable delivery device, where it self-expands or is balloon-expandable. It is typically made of a metal alloy [e.g., nickel-titanium alloy (Nitinol)] that forms an outer mesh structure with an inner synthetic polymer tube (endovascular graft). It is typically designed as a single continuous tube for insertion into the thoracic aorta and may be used in singular or modular configurations.

Code

Status **Active**

Created Date 04 Aug 2009

Modified Date 04 Jan 2013

[Add To Enquiry](#)

[Add to My Shortlist](#)

[Move to My Archive](#)

[Return to My Terms](#)



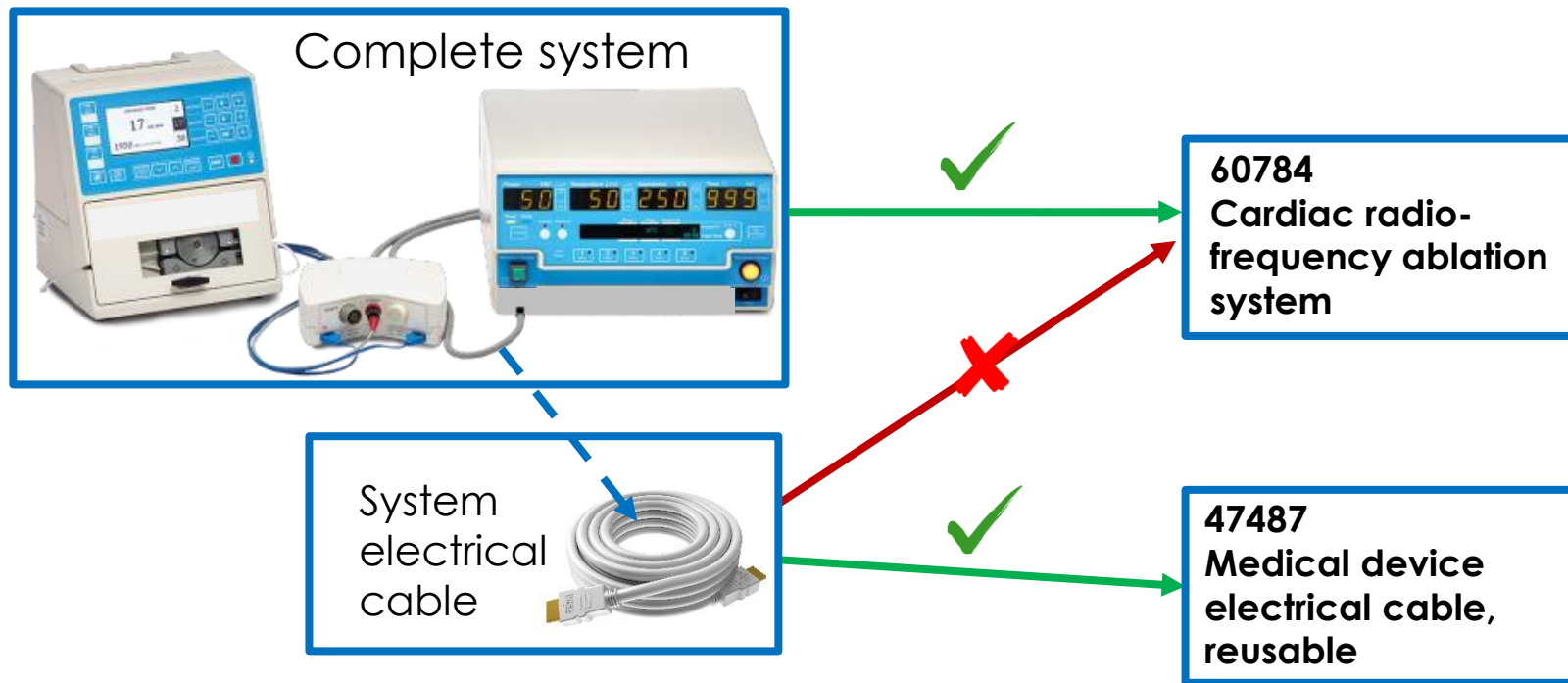
Golden rule

Every device (that is placed on the market separately) should be assigned to a single GMDN term that represents that device explicitly

Common mistake 1

A GMDN term for a system term applied to a component of the system

Example:



Common mistake 2

Multiple terms assigned to a device (often with kits, systems or implant sets)

Example (in GUDID):

8714729844938

Coronary Stent System

Company Name: CORPORATION

Model Number:

Device IDs:

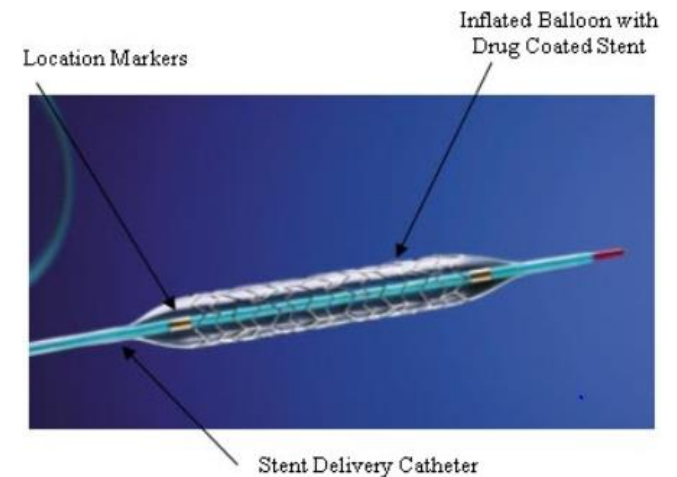
- (Primary)

Device Sizes:

- Device Size Text, specify : 4.00 mm Stent Diameter
- Device Size Text, specify : 28 mm Stent Length

GMDN Terms:

- Basic coronary angioplasty balloon catheter
- Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated



Common mistake 2

Multiple terms assigned to a device (often with kits, systems or implant sets)

8714729844938

Coronary Stent System

Company Name: CORPORATION

Model Number:

Device IDs:

- (Primary)

Device Sizes:

- Device Size Text, specify : 4.00 mm Stent Diameter
- Device Size Text, specify : 28 mm Stent Length

GMDN Terms:

- Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated

56284

Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated

A sterile non-bioabsorbable metal tubular mesh structure covered with a non-bioabsorbable polymer and a drug coating that is designed to be implanted, via a delivery catheter, into a coronary artery (or saphenous vein graft) to maintain its patency typically in a patient with symptomatic atherosclerotic heart disease. The drug coating is slowly released and intended to inhibit restenosis by reducing vessel

smooth muscle cell proliferation. **Disposable devices associated with implantation may be included.**

Common mistake 3

Judging the term by the name without review of the definition

Ophthalmic use

752SS11170071

CUSTOM SURGICAL KIT EYE PACK

Company Name: [REDACTED] Version or Model: 001-117-007

Device IDs:

- [REDACTED] (Primary)

GMDN Terms:

- General surgical procedure kit, non-medicated, single-use

33961

General surgical procedure kit, non-medicated, single-use

A general-purpose collection of various sterile surgical instruments, dressings, and materials **intended to be used to assist a range of surgical procedures across multiple clinical specialities**. It does not contain pharmaceuticals. This is a single-use device.

Is this term more appropriate?

Ophthalmic surgical procedure kit, non-medicated, single-use

Changes to GMDN data

- Develop new terms (average 2-3 days)
- We only modify existing Terms (average 2-3 days)
 - **To increase the scope / improve the definitions**
- We obsolete Terms (average 10/m or 0.5% per year)
 - **To remove ambiguity / term overlap**
- GMDN is dynamic and current to keep up with innovation
- Members are notified about changes

Term details - amendments

Alerts

Notifications about your account and purchased terms.

To subscribe to email notifications, please see [My Profile](#).

System News

The new GMDN Website – Website launch date – 18 December 2016

02 Dec 2016

Dear Customers, After some time in development we are pleased to announce the GMDN website is going to be upgraded in the next few weeks. The expected launch date is Sunday 18th December 2016. Here is a list of some of the improvements we have made, many following your suggestions: • Better site navigation, with a simple Start menu • A free Enquiry service for a quicker response to requests for new terms • New Search tools, including better use of Collective Terms • Easier management of users and their permissions • Ability to Archive terms you no longer use • New Alerts and less reliance on email communication • Self-service for all invoicing and account management • A website fully translated for your convenience • Better navigation for translated terms. We have a transition guide 'What's Changed' and other guides and videos are available on the website if needed. All your existing GMDN data and user information will be transferred to the new website at the same address <https://www.gmdnagency.org> and you will be able to login using your existing username (or alternatively email address) and password. The website will be unavailable for the weekend of 17 & 18 December while we do the data transfer, so sorry of any inconvenience this might cause. After the launch of the site, please let us know if you are experiencing any difficulty or you want any further improvements made and we will try to put any changes in place as quickly as possible. Please can you use the dedicated email address webmaster@gmdnagency.org if possible, but we will be providing an extended duration (7am until 7pm UTC) customer service helpline on our usual number +44 1235 799759 if needed.

My Account

Your account expires in 23 days. [Buy Membership](#)

You have 15 remaining code credits. [Buy Code Credits](#)

You have 4 remaining user credits. [Request User Credits](#)

My Terms

Modified - 24 Jan 2017 - **Intracerebral infusion/drainage catheter, long-term AMEND** (61376)

Purchased - 05 Dec 2016 - **Intracerebral infusion/drainage catheter, long-term AMEND** (61376)



Term details - amendments

Term Details

You purchased this term on 05 Dec 2016

Name Intracerebral infusion/drainage catheter, long-term AMEND

Definition A sterile, flexible tube intended to be surgically inserted through the skull for long-term (> 30 days) subdural access to the brain (e.g., cerebral ventricles, cystic tumours) for cerebrospinal fluid (CSF) drainage and/or infusion of materials (e.g., chemotherapeutic agents); it is typically used for measurement of intracranial pressure (ICP) and as part of a shunt system. It may include an attached port/reservoir at its proximal end that is placed subcutaneously to facilitate material infusion/collection, and/or accessory devices intended to facilitate catheter introduction and/or stabilization (e.g., stylet, catheter holder); it does not include a sensor. This is a single-use device.

Code 61376

Status **Active**

Created Date 16 Dec 2014

Modified Date 24 Jan 2017

[Add To Enquiry](#)

[Add to My Shortlist](#)

[Move to My Archive](#)

[Return to My Terms](#)

Note: Terms in "My Archive" do not generate Alerts.

[Previous Version](#)

Name Intracerebral infusion/drainage catheter, long-term

Definition A sterile, flexible tube intended to be surgically inserted through the skull for long-term (> 30 days) subdural access to the brain (e.g., cerebral ventricles, cystic tumours) for cerebrospinal fluid (CSF) drainage and/or infusion of materials (e.g., chemotherapeutic agents); it is typically used for measurement of intracranial pressure (ICP) and as part of a shunt system. It may include an attached port/reservoir at its proximal end that is placed subcutaneously to facilitate material infusion/collection, and/or accessory devices intended to facilitate catheter introduction and/or stabilization (e.g., stylet, catheter holder); it does not include a sensor. This is a single-use device.



My term has been made obsolete

Term Details

Again from your 'Alerts' page open 'Term Details'

Name Abdominal wall prosthesis

Definition A sterile implantable device intended to substitute for part of the abdominal wall. It is made of synthetic polymer materials such as polytetrafluoroethylene (PTFE) or expanded polytetrafluoroethylene (ePTFE), and is used to close large abdominal wall defects that result from, e.g., trauma, tumour resection, or complications of previous surgery.

Code 35654

Status **Obsolete**

Explorer Groups

[By Name](#) / [Prostheses and associated devices](#) / [Prostheses](#) / [Implantable prostheses](#)

[By Use](#) / [Body tissue manipulation and reparation devices](#) / [Surgical mesh and associated devices](#)

[Clinical Specialties](#) / [General/Plastic surgery](#)

[Device Attribute Assortment](#) / [Implantable](#) / [Non-active implantable](#)

[Device Attribute Assortment](#) / [Single-patient use](#)

[Device Attribute Assortment](#) / [Surgical](#)

[Device Invasiveness](#) / [Surgical invasive](#) / [Long-term surgical invasive](#)

[Device Materials](#) / [Inorganic materials](#) / [Synthetic polymers](#) / [Plastics](#)

[Device Sterility](#) / [Sterile](#)

Use the 'Explorer Groups' (aka Collective Terms) to help you find the term you need



How should you manage GMDN Term changes?

- ❑ Who needs to receive notifications? (update your account)
- ❑ How is this communicated internally?
- ❑ GMDN is a data element in the DI record that can be edited after the Grace Period.
- ❑ Labellers are required (per UDI Rule) to keep their device information current and correct with any data that may have changed.



GMDN 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
- ❑ Replace your existing inventory classification with an externally managed globally recognized nomenclature

Equipment Commissioning

Nottingham University Hospitals NHS Trust

Medusa Web

Medusa Service Delivery

Logged on as: Mark Callaghan (ECU - Manager) Log Out

100571

Equipment

- Search Equipment
- My Team's Equipment
- All Equipment
- New Equipment
- Mass Update

Equipment Systems

Service Requests

- Search Service Requests
- Service Requests Assigned to my Team
- New Service Request

Jobs

Scheduled APM

Other Scheduled Work

External Dispatch

Contract

Medusa Users

Basic Data Registry

Customer Organisations

Equipment

WARRANTY EXPIRY

Equipment info IT System

Equipment No. 100571 Serial No. 11014814 Signature

Device Group General-purpose infusion p Code 13215-0679-00918 CE Team MESU Electronics (QMC)

Make Graseby Model 500 Inventory Clinical Engineering

Owner BSU (Library) - QMC; Clinical Engineering; Diagnostics and Clinical Nickname

Location BSU (Library) - QMC; Clinical Engineering; Diagnostics and Clinical Room/Lab

Supplier Smiths Medical Delivery Date 14/02/2011

Notes

Job

External Dispatch

Performance

Operational Data

Documents

Other Supplier Information

Financial & Warranty Info

Preventive maintenance

Attributes

Contract

Service Requests

Medical Incidents

No rows found

New note Edit list columns

GMDN – Snomed link

- UDI database
- GMDN



- Linkage table



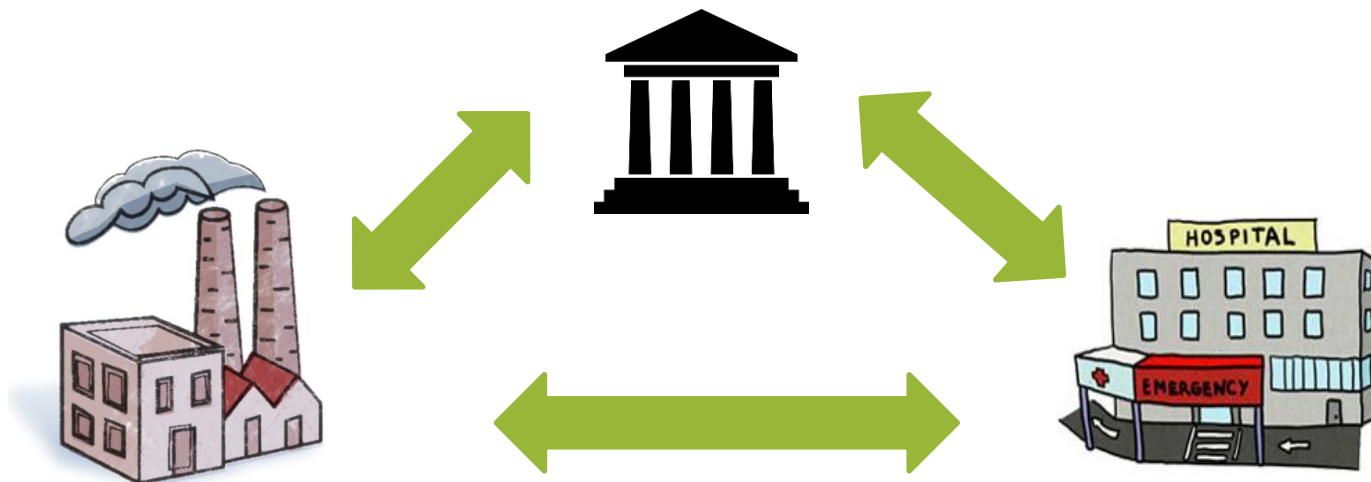
- Electronic medical record
- Snomed

Key Updates

- ❑ **Europe:** Eudamed Adverse Incidents Reporting
- ❑ **China:** Will be using the GMDN in their UDI database
- ❑ **Russia:** GMDN is a regulatory requirement
- ❑ Complete Russian translation of the GMDN data set

GMDN is improving communication

- GMDN is now the global language



Thank you for listening

Any questions now?

Website: www.gmdnagency.org

☐ Enquiry – product/term

☐ Contact us – anything else

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