Zorginformatiebouwsteen:

nl.zorg.MedicalDevice-v3.1

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Beheerd door:

Betere gezondheid
door betere informatie

Nictiz

Inhoudsopgave

1. nl.zorg.MedicalDevice-v3.1

DCM::CoderList	Kerngroep Registratie aan de Bron
DCM::ContactInformation.Address	*
DCM::ContactInformation.Name	*
DCM::ContactInformation.Telecom	*
DCM::ContentAuthorList	Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron
DCM::CreationDate	2-1-2013
DCM::DeprecatedDate	
DCM::DescriptionLanguage	nl
DCM::EndorsingAuthority.Address	
DCM::EndorsingAuthority.Name	PM
DCM::EndorsingAuthority.Telecom	
DCM::Id	2.16.840.1.113883.2.4.3.11.60.40.3.10.1
DCM::KeywordList	medisch hulpmiddel, implantaat
DCM::LifecycleStatus	Final
DCM::ModelerList	Kerngroep Registratie aan de Bron
DCM::Name	nl.zorg.MedischHulpmiddel
DCM::PublicationDate	04-09-2017
DCM::PublicationStatus	Prepublished
DCM::ReviewerList	Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron
DCM::RevisionDate	04-09-2017
DCM::Superseeds	nl.zorg.MedischHulpmiddel-v3.0
DCM::Version	3.1
HCIM::PublicationLanguage	EN

1.1 Revision History

Publicatieversie 1.0 (15-02-2013)
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Publicatieversie 1.1 (01-07-2013)
Bevat: ZIB-11.

Publicatieversie 1.2 (01-04-2015)
Bevat: ZIB-83, ZIB-88, ZIB-110, ZIB-249, ZIB-250, ZIB-251, ZIB-252, ZIB-308, ZIB-327, ZIB-353.

Incl. algemene wijzigingsverzoeken:
ZIB-94, ZIB-154, ZIB-200, ZIB-201, ZIB-309, ZIB-324, ZIB-326.

Publicatieversie 3.0 (01-05-2016)
Bevat: ZIB-453

Publicatieversie 3.1 (04-09-2017)
Bevat: ZIB-457, ZIB-461, ZIB-517, ZIB-522, ZIB-547, ZIB-549, ZIB-564,. ZIB-568, ZIB-573, ZIB-574, ZIB-578, ZIB-585.

1.2 Concept

Medical devices are any internally implanted and external devices and/or aids used by the patient (in the past) to reduce the effects of functional limitations in organ systems or to facilitate the treatment of a disease.

1.3 Purpose

Data on medical devices is recorded for several reasons. Knowledge of the presence of these implants enables tracing and taking the aid or device into account in diagnostic or therapeutic procedures, care and transport.

Examples include:

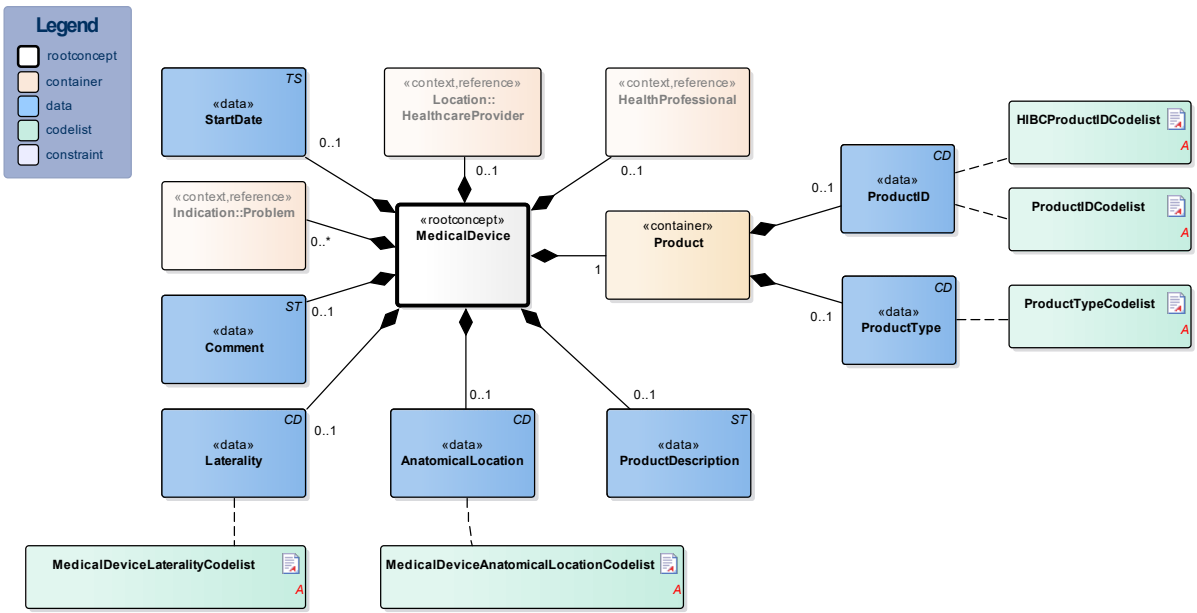
- Consequences for transportation, toilet use, etc., in the case of a wheelchair;
- A pacemaker can be of medical importance, but also has consequences for planning radiological exams.

1.4 Patient Population

1.5 Evidence Base

Recording data on medically complex devices such as pacemakers is not yet common in EPD systems in the Netherlands, but is sometimes lacking: a letter from a specialist for example often does not include information on which type of pacemaker the patient has (and from which manufacturer). The Dutch Ministry of Health, Welfare and Sport (VWS) will pass legislation for a national basic register of implants. Every healthcare center will have to supply a UDI (Unique Device Identification, with a link to GTIN) and a UPI (Unique Patient Identification) to the basic register. This will prevent situations in which a large group of patients have an aid or implant in which problems have been detected that cannot be traced.

1.6 Information Model



«rootconcept»	MedicalDevice	
Definitie	Root concept of the MedicalDevice information model. This root concept contains all data elements of the MedicalDevice information model.	
Datatype		
DCM::ConceptId	NL-CM:10.1.1	
DCM::DefinitionCode	SNOMED CT: 49062001 Device (physical object)	
Opties		

«container»	Product	
Definitie	The medical aid used (internally or externally).	
Datatype		
DCM::ConceptId	NL-CM:10.1.2	
DCM::DefinitionCode	SNOMED CT: 405815000 Procedure device	
Opties		

«data»	ProductID
Definitie	Unique identification of the product, such as the serial number. Frequently used coding systems are HIBC and GTIN. If the law requires this to be registered on the basis of a UDI (Unique Device Identifier), the unique identification must consist of a UDI-DI (Device Identifier) and a UDI-PI (Production Identifier(s)). See http://www.gs1.org/healthcare/udi for more information. The UDI-DI must be recorded in reference to GS1 GTIN (01) encryptions, with which for example a firm is linked to the product type. The UDI-PI must consist of the following: application identifier (AI); expiration date (17) and serial number (21) and/or batch or lot number (10).

Datatype	CD	
DCM::ConceptId	NL-CM:10.1.4	
DCM::ExampleValue	(01)08712345000004(17)160131(10)200652	
DCM::ValueSet	ProductIDCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3
DCM::ValueSet	HIBCProductIDCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5
Opties		

«data»	ProductType	
Definitie	The code of the type of product.	
Datatype	CD	
DCM::ConceptId	NL-CM:10.1.3	
DCM::ExampleValue	58938008 Wheelchair	
DCM::ValueSet	ProductTypeCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1
Opties		

«data»	ProductDescription	
Definitie	Textual description of the product.	
Datatype	ST	
DCM::ConceptId	NL-CM:10.1.13	
Opties		

«data»	StartDate	
Definitie	The start date of the first use or implant of the medical aid. A ‘vague’ date, such as only the year, is permitted.	
Datatype	TS	
DCM::ConceptId	NL-CM:10.1.11	
DCM::ExampleValue	24-02-2003	
Opties		

«context»	Indication::Problem	
Definitie	The medical reason for use of the medical device.	
Datatype		
DCM::ConceptId	NL-CM:10.1.7	
DCM::ExampleValue	presbyacusis (ICD10::H91.1)	
DCM::ReferencedConceptId	NL-CM:5.1.1	This is a reference to the rootconcept of information model Problem.
Opties		

«data»	Comment
Definitie	Comment about use or information on the medical aid used.

Datatype	ST	
DCM::ConceptId	NL-CM:10.1.10	
DCM::DefinitionCode	LOINC: 48767-8 Annotation comment	
Opties		

«data»	AnatomicalLocation	
Definitie	Patient's anatomical location of the medical device used.	
Datatype	CD	
DCM::ConceptId	NL-CM:10.1.6	
DCM::DefinitionCode	SNOMED CT: 363698007 Finding site	
DCM::ExampleValue	Oor	
DCM::ValueSet	MedicalDeviceAnatomicalLocationCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2
Opties		

«data»	Laterality	
Definitie	Laterality adds information about body side to the anatomic location, *e.g.* left	
Datatype	CD	
DCM::ConceptId	NL-CM:10.1.12	
DCM::DefinitionCode	SNOMED CT: 272741003 Laterality	
DCM::ExampleValue	Links	
DCM::ValueSet	MedicalDeviceLateralityCodelist	OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.4
Opties		

«context»	Location::HealthcareProvider	
Definitie	The healthcare provider at which use of the medical aid was initiated or where the aid was implanted.	
Datatype		
DCM::ConceptId	NL-CM:10.1.8	
DCM::ReferencedConceptId	NL-CM:17.2.1	This is a reference to the rootconcept of information model HealthcareProvider
Opties		

«context»	HealthProfessional	
Definitie	The healthcare provider involved in the indication for use of the medical aid implant.	
Datatype		
DCM::ConceptId	NL-CM:10.1.9	
DCM::ReferencedConceptId	NL-CM:17.1.1	This is a reference to rootconcept of information model HealthProfessional
Opties		

«document»	HIBCProductIDCodelist	
Definitie		
Datatype		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5	
Opties		

HIBCProductIDCodelijst		OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.5
Codes	Coding Syst. Name	Coding System OID
Alle waarden	Health Industry Bar Code (HIBC)	2.16.840.1.113883.6.40

«document»	MedicalDeviceAnatomicalLocationCodelist	
Definitie		
Datatype		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2	
Opties		

HulpmiddelAnatomischeLocatieCodelijst		OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.2
Codes	Coding Syst. Name	Coding System OID
SNOMED CT: < 442083009 |Anatomical or acquired body structure|	SNOMED CT	2.16.840.1.113883.6.96

«document»	MedicalDeviceLateralityCodelist	
Definitie		
Datatype		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.4	
Opties		

MedischHulpmiddelLateraliteitCodelijst		OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.4		
Concept Name	**Concept Code**	**CodeSys. Name**	**CodeSystem OID**	**Description**
Left	7771000	SNOMED CT	2.16.840.1.113883.6.96	Links
Right	24028007	SNOMED CT	2.16.840.1.113883.6.96	Rechts
Right and left	51440002	SNOMED CT	2.16.840.1.113883.6.96	Rechts en links

«document»	ProductIDCodelist	
Definitie		
Datatype		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3	
Opties		

GTINProductIDCodelijst		OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.3
Codes	Coding Syst. Name	Coding System OID
Alle waarden	Global Trade Item Number (GTIN)	1.3.160

«document»	ProductTypeCodelist	
Definitie		
Datatype		
DCM::ValueSetId	2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1	
Opties		

ProductTypeCodelijst		OID: 2.16.840.1.113883.2.4.3.11.60.40.2.10.1.1
Codes	Coding Syst. Name	Coding System OID
Alle waarden	SNOMED CT	2.16.840.1.113883.6.96

1.7 Example Instances

Begin Datum	Product		Anatomische Locatie	Lateraliteit	Indicatie	Locatie		Toelichting
	ProductID	ProductType			ProbleemNaam	Organisatie Naam	Afdeling Specialisme	
08-03-2012	GTIN/HIBC code	Rolstoel			Multiple sclerose			Kan korte afstanden lopen

Begin Datum	Product		Anatomische Locatie	Lateraliteit	Lateraliteit	Locatie		Toelichting
	ProductID	ProductType			ProbleemNaam	Organisatie Naam	Afdeling Specialisme	
2007	GTIN/HIBC code	Gehoorapparaat	Oor	Rechts	Presbyacusis	St. Franciscus Gasthuis	Audiologie	Apparaat niet zichtbaar (diep in de gehooringang)

Begin Datum	Product		Anatomische Locatie	Lateraliteit	Indicatie	Locatie		Toelichting
	ProductID	ProductType			ProbleemNaam	Organisatie Naam	Afdeling Specialisme	
10-02-2004	GTIN/HIBC code	Pacemaker	Subclavian pouch	Links	Paroxymaal boezemfibrilleren	Academisch Medisch Centrum	Cardiologie	Laatst doorgemeten in 2011

1.8 Instructions

1.9 Interpretation

1.10 Care Process

1.11 Example of the Instrument

1.12 Constraints

1.13 Issues

The UNSPSC code system has a great many products (including non-medical products). That is why a Dutch set and/or subcollection of this code system is required to indicate the type of product. We have currently opted to consider all values in the UNPSPSC for documenting the type of medical aid product in the absence of such a set.

1.14 References

1. Kamerbrief over het voorstel voor een register van implantaten. [Online] Beschikbaar op: http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2012/11/20/kamerbrief-over-het-voorstel-voor-een-register-van-implantaten.html [Geraadpleegd: 15 september 2014].

1.15 Functional Model

1.16 Traceability to other Standards

1.17 Disclaimer

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