3.85 Product Instance

`[participantRole: identifier urn:oid:2.16.840.1.113883.10.20.22.4.37 (open)]`

Table 440: Product Instance Contexts

Contained By:	Contains:
Procedure Activity Procedure (V2) (optional) Non-Medicinal Supply Activity (V2) (optional) Planned Supply (V2) (optional)	

This clinical statement represents a particular device that was placed in a patient or used as part of a procedure or other act. This provides a record of the identifier and other details about the given product that was used. For example, it is important to have a record that indicates not just that a hip prostheses was placed in a patient but that it was a particular hip prostheses number with a unique identifier.

The FDA Amendments Act specifies the creation of a Unique Device Identification (UDI) System that requires the label of devices to bear a unique identifier that will standardize device identification and identify the device through distribution and use.

The FDA permits an issuing agency to designate that their Device Identifier (DI) + Production Identifier (PI) format qualifies as a UDI through a process of accreditation. Currently, there are three FDA-accredited issuing agencies that are allowed to call their format a UDI. These organizations are GS1, HIBCC, and ICCBBA. For additional information on technical formats that qualify as UDI from each of the issuing agencies see the UDI Appendix.

When communicating only the issuing agency device identifier (i.e., subcomponent of the UDI), the use of the issuing agency OID is appropriate. However, when communicating the unique device identifier (DI + PI), the FDA OID (2.16.840.1.113883.3.3719) must be used.

When sending a UDI, populate the participantRole/id/@root with the FDA OID (2.16.840.1.113883.3.3719) and participantRole/id/@extension with the UDI.

When sending a DI, populate the participantRole/id/@root with the appropriate assigning agency OID and participantRole/id/@extension with the DI.

The scopingEntity/id should correspond to FDA or the appropriate issuing agency.

Table 441: Product Instance Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
participantRole (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.37)					
@classCode	1..1	SHALL		81-7900	urn:oid:2.16.840.1.113883.5.110 (HL7RoleClass) = MANU
templateId	1..1	SHALL		81-7901	
@root	1..1	SHALL		81-10522	2.16.840.1.113883.10.20.22.4.37
id	1..*	SHALL		81-7902	
playingDevice	1..1	SHALL		81-7903	
code	0..1	SHOULD		81-16837	
scopingEntity	1..1	SHALL		81-7905	
id	1..*	SHALL		81-7908	

1. **SHALL** contain exactly one [1..1] **@classCode**="MANU" Manufactured Product (CodeSystem: HL7RoleClass urn:oid:2.16.840.1.113883.5.110 **STATIC**) (CONF:81-7900).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-7901) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.37" (CONF:81-10522).
3. **SHALL** contain at least one [1..*] **id** (CONF:81-7902).
4. **SHALL** contain exactly one [1..1] **playingDevice** (CONF:81-7903).
    a. This playingDevice **SHOULD** contain zero or one [0..1] **code** (CONF:81-16837).
5. **SHALL** contain exactly one [1..1] **scopingEntity** (CONF:81-7905).
    a. This scopingEntity **SHALL** contain at least one [1..*] **id** (CONF:81-7908).

Figure 204: Product Instance Example

```
<participantRole classCode="MANU">
  <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
  <id root="2.16.840.1.113883.3.3719"
      extension="(01)51022222233336(11)141231(17)150707(10)A213B1(21)1234"
      assigningAuthorityName="FDA"/>
  <playingDevice>
    <code code="90412006" codeSystem="2.16.840.1.113883.6.96"
          displayName="Colonoscope"/>
  </playingDevice>
  <scopingEntity>
    <id root="2.16.840.1.113883.3.3719"/>
  </scopingEntity>
</participantRole>
```

3.86 Prognosis Observation

`[observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.113 (open)]`

Table 442: Prognosis Observation Contexts

Contained By:	Contains:
Problem Observation (V3) (optional)	

This template represents the patient's prognosis, which must be associated with a problem observation. It may serve as an alert to scope intervention plans.
The effectiveTime represents the clinically relevant time of the observation. The observation/value is not constrained and can represent the expected life duration in PQ, an anticipated course of the disease in text, or coded term.

Table 443: Prognosis Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.113)					
@classCode	1..1	SHALL		1098-29035	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		1098-29036	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		1098-29037	
@root	1..1	SHALL		1098-29038	2.16.840.1.113883.10.20.22.4.113
code	1..1	SHALL		1098-29039	
@code	1..1	SHALL		1098-29468	75328-5
@codeSystem	1..1	SHALL		1098-31349	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
statusCode	1..1	SHALL		1098-31350	
@code	1..1	SHALL		1098-31351	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
effectiveTime	1..1	SHALL		1098-31123	
value	1..1	SHALL		1098-29469	

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:1098-29035).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:1098-29036).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-29037) such that it