Figure 203: Procedure Activity Procedure (V2) Example

```
<procedure classCode="PROC" moodCode="EVN">
    <!-- Procedure Activity Procedure V2-->
    <templateId root="2.16.840.1.113883.10.20.22.4.14" extension="2014-06-09" />
    <id root="d5b614bd-01ce-410d-8726-e1fd01dcc72a" />
    <code code="103716009" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Stent Placement">
        <originalText>
            <reference value="#Proc1" />
        </originalText>
    </code>
    <statusCode code="completed" />
    <effectiveTime value="20130512" />
    <targetSiteCode code="28273000" displayName="bile duct"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" />
    <specimen typeCode="SPC">
        <specimenRole classCode="SPEC">
            <id root="a6d7b927-2b70-43c7-bdf3-0e7c4133062c" />
            <specimenPlayingEntity>
                <code code="57259009" codeSystem="2.16.840.1.113883.6.96"
displayName="gallbladder bile" />
            </specimenPlayingEntity>
        </specimenRole>
    </specimen>
    <performer>
        ...
    </performer>
</procedure>
```

3.84 Procedure Context

[act: identifier urn:oid:2.16.840.1.113883.10.20.6.2.5 (open)]

Table 438: Procedure Context Contexts

Contained By:	Contains:
Diagnostic Imaging Report (V3) (optional)	

The ServiceEvent Procedure Context of the document header may be overridden in the CDA structured body if there is a need to refer to multiple imaging procedures or acts. The selection of the Procedure or Act entry from the clinical statement choice box depends on the nature of the imaging service that has been performed. The Procedure entry shall be used for image-guided interventions and minimally invasive imaging services, whereas the Act entry shall be used for diagnostic imaging services.

Table 439: Procedure Context Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
act (identifier: urn:oid:2.16.840.1.113883.10.20.6.2.5)					
@classCode	1..1	SHALL		81-26452	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = ACT
@moodCode	1..1	SHALL		81-26453	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		81-9200	
@root	1..1	SHALL		81-10530	2.16.840.1.113883.10.20.6.2.5
code	1..1	SHALL		81-9201	
effectiveTime	0..1	SHOULD	TS	81-9203	
@value	1..1	SHALL		81-17173	

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:81-26452).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:81-26453).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-9200) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.6.2.5" (CONF:81-10530).
4. **SHALL** contain exactly one [1..1] **code** (CONF:81-9201).
5. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:81-9203).
    a. The effectiveTime, if present, **SHALL** contain exactly one [1..1] **@value** (CONF:81-17173).
6. Procedure Context **SHALL** be represented with the procedure or act elements depending on the nature of the procedure (CONF:81-9199).

Figure 204: Procedure Context Example

```
<act moodCode="EVN" classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.6.2.5"/>
    <code code="70548"
          displayName="Magnetic resonance angiography, head; with contrast material(s)"
          codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT"/>
    <!-- Note: This code is slightly different from the code used in the header
         documentationOf and overrides it, which is what this entry is for. -->
    <effectiveTime value="20060823123529+0400"/>
</act>
```

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.