3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3420).
   Note: Model Number as a text value

Figure 12: Model Number

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.317" extension="2019-06-21"/>
  <code code="C99285"displayName="Model Number"
      codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <value xsi:type="ED">
    <reference value="#ModelNumber_1"/>
  </value>
</observation>
```

2.12 MRI Safety Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.318: 2019-06-21 (open)]

Table 25: MRI Safety Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the MRI Safety Status of the patient's medical device. The UDI-DI of the medical device may be used to retrieve the **MRI Safety Status** in accessGUDID, which should be considered the source of truth.

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Table 26: MRI Safety Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.318: 2019-06-21)					
templateId	1..1	SHALL		4437-3469	
@root	1..1	SHALL		4437-3471	2.16.840.1.113883.10.20.22.4.318
@extension	1..1	SHALL		4437-3472	2019-06-21
code	1..1	SHALL		4437-3470	
@code	1..1	SHALL		4437-3473	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C106044
@codeSystem	1..1	SHALL		4437-3474	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3475	NCI Thesaurus
@displayName	0..1	MAY		4437-3476	MRI Safety
value	1..1	SHALL	CD	4437-3477	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt))
@code	0..1	SHALL		4437-3478	
@codeSystem	1..1	SHALL		4437-3479	2.16.840.1.113883.3.26.1.1
@sdtc:valueSet	0..1	SHOULD		4437-3537	2.16.840.1.113762.1.4.1021.46

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3469).
   a. This templateId **SHALL** contain exactly one [1..1]
      @root="2.16.840.1.113883.10.20.22.4.318" (CONF:4437-3471).
      Note: template oid

Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21"
      (CONF:4437-3472).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3470).
   Note: Code for "MRI Safety Status"

Code used to specify the **MRI Safety Status**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C106044" MRI Safety
      (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1
      STATIC) (CONF:4437-3473).

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  b. This code **SHALL** contain exactly one [1..1]
    @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3474).

  c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus"
    (CONF:4437-3475).

  d. This code **MAY** contain zero or one [0..1] **@displayName**="MRI Safety" (CONF:4437-3476).

The value of the MRI Safety status.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be
  selected from CodeSystem NCI Thesaurus (NCIt)
  (urn:oid:2.16.840.1.113883.3.26.1.1) (CONF:4437-3477).

Allowed values specified in 2.16.840.1.113762.1.4.1021.46:

C113844 Labeling does not contain MRI Safety Information

C106046 MR Conditional

C106045 MR Safe

C106047 MR Unsafe

  a. This value **SHALL** contain zero or one [0..1] **@code** (CONF:4437-3478).

  b. This value **SHALL** contain exactly one [1..1]
    @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3479).

  c. This value **SHOULD** contain zero or one [0..1]
    @sdtc:valueSet="2.16.840.1.113762.1.4.1021.46" (CONF:4437-3537).

Figure 13: MRI Safety Status

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.318" extension="2019-06-21"/>
  <code code="C106044" displayName="MRI Safety Status"
      codeSystem="2.16.840.1.113883.3.26.1.1"codeSystemName="NCI Thesaurus"/>
  <value xsi:type="CD" code="C113844" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="Labeling does not contain MRI Safety Information"
      codeSystemName="NCI Thesaurus" sdtc:valueSet="2.16.840.1.113762.1.4.1021.46">
   <originalText>
      <reference value="#MRISafety_1"/>
   </originalText>
  </value>
</observation>
```

2.13 Serial Number Observation

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.319: 2019-06-21 (open)]
```

Table 27: Serial Number Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	