

Direct Device, Using Device (April 2024 SEAG)

THE ISSUE: For the April 24th SEAG Notes – Pre-meeting

During QI review of procedures, inconsistencies were revealed in the use of USING DEVICE and DIRECT DEVICE in procedures. The current definitions for these attributes from the editorial guide:

Direct device - Direct device (attribute) represents the device on which the method directly acts.

Using device - Using device (attribute) refers to the instrument or equipment utilized to execute an action. It is used when the device is actually used to carry out the action, that is the focus of the procedure. If the device is simply the means to access the site of the procedure, then Using access device is the appropriate attribute.

Examples of inconsistencies:

175254001 |Repair of pulmonary artery using prosthesis (procedure)| = Using device -> Prosthesis device.

771713005 |Open repair of inguinal hernia using sutures (procedure)| = Using device -> Surgical suture, device.

719263004 |Repair of parastomal hernia using mesh patch (procedure)| = Direct device -> Hernia surgical mesh.

719290008 |Repair of umbilical hernia using surgical mesh (procedure)| = Direct device -> Hernia surgical mesh.

238190005 |Repair of incisional hernia using synthetic patch (procedure)| = Using device -> Prosthetic patch.

We would like to come up with more specific editorial guidelines related to what is meant by "the device on which the method directly acts". In general, parameters could include things such as "materially changed by the procedure", "remains in the body following the procedure", etc. The use of the word "using" in FSNs can bias a content author to use the attribute USING DEVICE when the more appropriate DIRECT DEVICE should be used. A broader application of DIRECT DEVICE in procedure modeling could have large impacts on the number of concept affected, but would resolve the current inconsistencies.

An example of where this is an issue is described in the attached document related to the modeling of hernia repair.

USING DEVICE and USING ACCESS DEVICE are also inconsistently used and sometimes incorrectly. In a review of procedure subhierarchies (e.g. arthroplasty), USING ACCESS DEVICE was modeled in the surgical action RG, when in many cases the device does not act as an access to the surgical area, but plays another role, (e.g. illumination). An evaluation of the current benefits of USING ACCESS DEVICE over USING DEVICE is underway.

While it is not part of this topic, we expect the same issues to be present related to USING SUBSTANCE and DIRECT SUBSTANCE

Comments on |Using device| and |Direct Device|

- 719290008 |Repair of umbilical hernia using surgical mesh (procedure)| = Direct device -> Hernia surgical mesh
- 719263004 |Repair of parastomal hernia using mesh patch (procedure)| = Direct device -> Hernia surgical mesh

In my opinion, the 2 examples above (cited in the SEAG note above) are modeled incorrectly. Per the Editorial Guide, "Direct device (attribute) represents the device on which the method directly acts." The mesh is not the Direct Device. The mesh is not being repaired. The mesh is being used to repair the hernial opening. These concepts should be modeled with |Using device|: |Hernia surgical mesh|.

719290008 |Repair of umbilical hernia using surgical mesh (procedure)|

Repair of parastomal hernia using mesh patch (procedure) ☆

SCTID: 719263004

719263004 | Repair of parastomal hernia using mesh patch (procedure) |

en Repair of parastomal hernia using mesh patch (procedure)

en Parastomal hernioplasty

en Repair of parastomal hernia using mesh patch

| Axiom | |
|-------------------------|-------------------------------------|
| Method | → Repair - action |
| Procedure site - Direct | → Anterior abdominal wall structure |
| Direct morphology | → Hernial opening |
| Direct device | → Hernia surgical mesh |

This should be Using device

Additional Examples:

14030001000004108 | Insertion of dialysis catheter into femoral vein (procedure)|

This is an example of where the device would be the Direct Device. The thing being inserted is the Dialysis catheter.

Insertion of dialysis catheter into femoral vein (procedure) ☆

SCTID: 14030001000004108

14030001000004108 | Insertion of dialysis catheter into femoral vein (procedure) |

- en Insertion of dialysis catheter into femoral vein (procedure)
- en Insertion of dialysis catheter into femoral vein
- en Dialysis catheter inserted in groin

Axiom

- Method → Insertion - action
- Procedure site - Indirect → Femoral vein structure
- Direct device → Dialysis catheter

62881002 | Removal of cardiac pacemaker (procedure)|

This is an example of where the device would be the Direct Device. The thing being removed is the Cardiac pacemaker.

Removal of cardiac pacemaker (procedure) ☆

SCTID: 62881002

62881002 | Removal of cardiac pacemaker (procedure) |

- en Removal of cardiac pacemaker (procedure)
- en Removal of cardiac pacemaker
- en Removal of pacemaker device
- en Removal of permanent pacemaker

Axiom

- Method → Removal - action
- Direct device → Cardiac pacemaker, device

Additional analysis of inconsistencies between |Using device| and |Direct Device|

There are inconsistencies in the use of these attributes. Sometimes, the inconsistencies have to do with inconsistent ways of saying similar things (e.g., reconstruction with implantation of prosthesis, reconstruction with prosthesis, implantation with prosthesis, repair using prosthesis). At other times, the inconsistencies have to do with variations in the approach to modeling (sometimes based on differences in the way the FSN is expressed). These issues are complex and not easily resolved.

An additional source of inconsistencies with |Direct Device| is the guidance (in orange below, which was added in recent years) that ***“Subtypes of Surgical repair (procedure) that include a prosthetic device should be modeled using the DIRECT DEVICE attribute when the value is <<53350007 |Prosthesis, device (physical object)|.”*** This guidance is not always true.

Direct device

Direct device (attribute) represents the **device on which the method directly acts**.

For example,

- 431698006 |Adjustment of gastric banding using fluoroscopic guidance (procedure)| has Direct device of Surgical band (physical object)

☑ **Subtypes of Surgical repair (procedure) that include a prosthetic device should be modeled using the DIRECT DEVICE attribute when the value is <<53350007 |Prosthesis, device (physical object)|**

EXAMPLES:

The ECL: “<< 4365001 |Surgical repair (procedure)| : 363699004 |Direct device (attribute)| = << 53350007 |Prosthesis, device (physical object)|” yields 355 concepts. They illustrate the variations in naming as well as cases where the editorial guidance (in orange) is incorrect.

The first 4 examples below are named differently using, “prosthetic arthroplasty”, “replacement with prosthesis”, “implantation of prosthesis”, and “reconstruction with implant”.

They are modelled similarly with respect to using |Method|: |Surgical implantation| and |Direct device|: << 53350007 |Prosthesis, device (physical object)|. This seems like correct use of |Direct device| in these RGs.

However, for the extra RG on each, the first 3 use |Method|: |Repair| while the 4th uses |Method|: |Reconstruction|.

☰ Prosthetic **arthroplasty** of right elbow (procedure) ☆ 📄
 SCTID: 1303523000
 1303523000 | Prosthetic arthroplasty of right elbow (procedure) |
 en Prosthetic arthroplasty of right elbow (procedure)
 en Prosthetic arthroplasty of right elbow

Method → Surgical implantation - action
 Procedure site - Indirect → Structure of joint of right elbow
 Direct device → Implantable elbow prosthesis

Method → Repair - action
 Procedure site - Direct → Structure of joint of right elbow

☰ **Replacement** of sternoclavicular joint with **prosthesis** (procedure) ☆ 📄
 SCTID: 1304147008
 1304147008 | Replacement of sternoclavicular joint with prosthesis (procedure) |
 en Replacement of sternoclavicular joint with prosthesis (procedure)
 en Prosthetic arthroplasty of sternoclavicular joint
 en Replacement of SCJ (sternoclavicular joint) with prosthesis
 en Replacement of sternoclavicular joint with prosthesis

Method → Surgical implantation - action
 Procedure site - Indirect → Sternoclavicular joint structure
 Direct device → Shoulder joint prosthesis

Method → Repair - action
 Procedure site - Direct → Sternoclavicular joint structure

☰ **Implantation of prosthesis** into joint of right wrist (procedure) ☆ 📄
 SCTID: 1264535000
 1264535000 | Implantation of prosthesis into joint of right wrist (procedure) |
 en Implantation of prosthesis into joint of right wrist (procedure)
 en Prosthetic arthroplasty of right wrist
 en Implantation of prosthesis into joint of right wrist

Method → Surgical implantation - action
 Procedure site - Indirect → Structure of joint of right wrist region
 Direct device → Joint prosthesis, device

Method → Repair - action
 Procedure site - Direct → Structure of joint of right wrist region

☰ **Reconstruction** of breast with **submuscular implant** (procedure) ☆ 📄
 SCTID: 85436100000100
 85436100000100 | Reconstruction of breast with submuscular implant (procedure) |
 en Reconstruction of breast with submuscular implant (procedure)
 en Breast reconstruction with submuscular implant
 en Reconstruction of breast with submuscular implant

Method → Reconstruction - action
 Procedure site - Direct → Breast structure

Method → Surgical implantation - action
 Procedure site - Indirect → Breast structure
 Direct device → Prosthetic breast implant

It might be possible to try to make rules like, “For |Method|: << |Surgical implantation|, use |Direct device|: << 53350007 |Prosthesis, device (physical object)|”. However, those rules will not necessarily result in consistency because decisions as to 1) how much needs to be modeled in the concept definition and 2) what value to use for |Method| are often difficult to make with confidence. For example, for the extra RG (non-highlighted) on the concepts above, the first 3 use |Method|: |Repair| while the 4th uses |Method|: |Reconstruction|.

The concept below also uses “reconstruction” in its FSN (like the 4th concept above).

☰ **Excision of lesion of chest wall and reconstruction with prosthesis** (procedure) ☆ 📄
 SCTID: 1144496008
 1144496008 | Excision of lesion of chest wall and reconstruction with prosthesis (procedure) |
 en Excision of lesion of chest wall and reconstruction with prosthesis (procedure)
 en Excision of lesion of chest wall and reconstruction with prosthesis
 en Resection of lesion of chest wall and reconstruction with prosthesis

Method → Excision - action
 Procedure site - Direct → Chest wall structure
 Direct morphology → Lesion

Method → Reconstruction - action
 Procedure site - Direct → Chest wall structure
 Direct device → Prosthetic implant

However, in this case, the RG that includes the prosthetic device is the RG with |Method|: |Reconstruction|. Therefore, |Direct device|: |Prosthetic implant| is not correct. The chest wall is being reconstructed. The |Prosthetic implant| is not being reconstructed. In the RG with |Method|: |Reconstruction| and |Procedure site - Direct|: |Chest wall|, the prosthesis should be represented with |Using device|: |Prosthetic implant|.

Thus, for 1144496008 |Excision of lesion of chest wall and reconstruction with prosthesis (procedure)| (above) the “reconstruction with prosthesis” aspect could possibly be modeled with:

- |Method|: |Surgical implantation|
- |Procedure site - Indirect|: |Chest wall|
- |Direct device|: |Prosthetic implant|

OR

- |Method|: |Reconstruction|
- |Procedure site - Direct|: |Chest wall|
- |Using device|: |Prosthetic implant|

OR

- |Method|: |Surgical implantation|
- |Procedure site - Indirect|: |Chest wall|
- |Direct device|: |Prosthetic implant|

AND

- |Method|: |Reconstruction|
- |Procedure site - Direct|: |Chest wall|

Below is an example of yet another FSN variant that uses “repair with prosthesis” and a different value for |Method| (i.e. |Repair| instead of |Surgical implantation| or |Reconstruction|. Again, |Direct device| is incorrect. The prosthesis is not being repaired. If this pattern is used for modeling, then |Using device| should be used.

The screenshot shows a medical procedure entry in a system. The main entry is "Repair of defect of atrioventricular septum with prosthesis (procedure)" with SCTID: 1279572008. Below the title, there are several English (en) descriptions: "Repair of defect of atrioventricular septum with prosthesis (procedure)", "Repair of defect of atrioventricular septum with prosthesis", "Repair of atrioventricular canal defect with prosthesis", and "Repair of endocardial cushion defect with prosthesis". To the right, a pop-up window displays a mapping of terms: "Method -> Repair - action", "Procedure site - Direct -> Structure of atrioventricular septum", "Direct morphology -> Abnormal communication", and "Direct device -> Prosthesis, device".

As pointed out in the SEAG note, similar issues probably exist with |Using substance| and |Direct substance|

Example: 32413006 |Transplantation of heart (procedure)|

There have been several revisions to the model for this concept. Both versions below are problematic with respect to |Procedure site| and/or |Direct substance|. A “Transplant” is actually a “Surgical removal of a Procedure site - direct:<x>” followed by a “Surgical implantation of a Direct Substance” (or whatever the transplanted material falls under). However, these options have been considered and each has some complexity and fallout. Additionally, as we know, deciding the meaning and model for “Surgical Transplantation” was discussed at the October 2023 SEAG and that is its own project (See: Follow-up BN Surgical Transplantation_202310). Sometimes, things are so complex and intertwined with other dependencies, we may not be able to get it “right”.

Historic Version: 2010-01-31

Transplantation of heart (procedure) ☆

SCTID: 32413006

32413006 | Transplantation of heart (procedure) |

- en Transplantation of heart (procedure)
- en Transplantation of heart
- en CTx - Cardiac transplant
- en HTx - Heart transplant
- en Heart transplant
- en Heart transplantation
- en HTTx - Heart transplant

Method → Surgical transplantation - action
Procedure site - Indirect → Heart structure
Direct substance → Heart graft - material

Method → Surgical transplantation - action
Procedure site - Direct → Thoracic structure

Historic Version: 2024-02-01

Transplantation of heart (procedure) ☆

SCTID: 32413006

32413006 | Transplantation of heart (procedure) |

- en Transplantation of heart (procedure)
- en Transplantation of heart
- en CTx - Cardiac transplant
- en HTx - Heart transplant
- en Heart transplant
- en Heart transplantation
- en HTTx - Heart transplant

Method → Surgical transplantation - action
Procedure site - Direct → Heart structure
Direct substance → Transplant heart

Summary

There are issues with the |Device| attributes and similar issues may exist with |Using substance| and |Direct substance|. However, revisions to the model to address complex problems for complex concepts often fail to satisfactorily resolve the issue and may create new issues. It is possible that GCIs/axioms will help address some of the modeling issues, but I am not yet convinced of that.

Resolving these types of issues remains challenging because:

- Often there is not a one-size-fits-all solution and creating detailed guidance for small subsets of concepts is resource intensive.
- It can be difficult to fully understand the impact of a proposed concept model change based on a short briefing document.
- Once a new model is implemented, even with testing, it can be very difficult to determine the full extent of exactly what changed (e.g., changes to ancestors and descendants) and whether it was beneficial.
- It is hard to establish criteria to demonstrate whether there are benefits from a remodel and whether they are worth the SNOMED resources and the “churn” for implementors.

If rules are established for |Device|, they will likely need to be made in conjunction with advice on role grouping (one or more than one RG) and be implemented at a more granular level like:

- For prostheses that are used to replace a body part (e.g. Joint), use Method: Surgical implantation + Direct device: Prosthesis.
- For prostheses that are used to patch or repair a body part but not really replace it (e.g., mesh to close a hernia opening), use Method: Repair (or Closure etc.) + Direct device: Prosthesis.

In the meantime, the best option may be to review the use of |Direct device (attribute)| and |Using device (attribute)| and fix incorrect uses as currently modeled (e.g., even if the place where they are role grouped varies.)

For example, change this to |Using device|:

Repair of defect of atrioventricular septum with prosthesis (procedure)
SCTID: 1279572008

1279572008 | Repair of defect of atrioventricular septum with prosthesis (procedure) |

- en Repair of defect of atrioventricular septum with prosthesis (procedure)
- en Repair of defect of atrioventricular septum with prosthesis
- en Repair of atrioventricular canal defect with prosthesis
- en Repair of endocardial cushion defect with prosthesis

Method → Repair - action
Procedure site - Direct → Structure of atrioventricular septum
Direct morphology → Abnormal communication
Direct device → Prosthesis, device

If this is done, I would consider reviewing the first 3 query results below and then perhaps expand to the 4th:

- << 4365001 |Surgical repair (procedure)| : 363699004 |Direct device (attribute)| = << 53350007 |Prosthesis, device (physical object)|” (355 concepts)
- << 4365001 |Surgical repair (procedure)| : 424226004 |Using device (attribute)| = << 53350007 |Prosthesis, device (physical object)| (54 concepts)
- << 71388002 |Procedure (procedure)| : 424226004 |Using device (attribute)| = << 53350007 |Prosthesis, device (physical object)| (160 concepts)
- << 71388002 |Procedure (procedure)| : 363699004 |Direct device (attribute)| = << 53350007 |Prosthesis, device (physical object)| (1182 concepts)