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|  | <b>SPECIFICATION</b>   | PN 300374 Rev A |
|   | 310 Interface Specification for Implant Module for TSolution One |                 |

## A Introduction

The document specifies the format and content of the implant files contained in an implant module developed to be compatible with TSolution One™.

## B Definitions

Implant Module: Collection of data for systems to support a specific implant line

Implant Installation Media: Installation media containing the implant module data

TKA: Total Knee Arthroplasty

Pdf: Pdf file format shall be defined by Adobe™ as a document file format.

Note: Refer to SOP-037 for more definitions

## C Scope

Functional requirements of the implant files are found in the individual Implant Module Specifications are not the scope of this document.

## D References

P/N 300071, Specification, Cut Binary Format (CBF)

P/N 301096 NFO file for TSolution One™ TKA application.

P/N 300315, Interface Specification for Cutter Definition for TSolution One.

P/N 300316, Specification, TL interface for TSolution One.

P/N 300317 Interface Specification for cut message file for TSolution One.

P/N 300318 Interface Specification for check volume for TSolution One.

P/N 301042 Implant Relationship Interface Spec

P/N 700171 Implant Module User Needs

P/N301086 Implant Feature File Spec.

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## E Installation media requirements for implant module

E 1 310-Imp-7 The Implant Installation Media shall have a single compressed (gzip format) tar file in the root folder. This archive shall have extension “tar”.

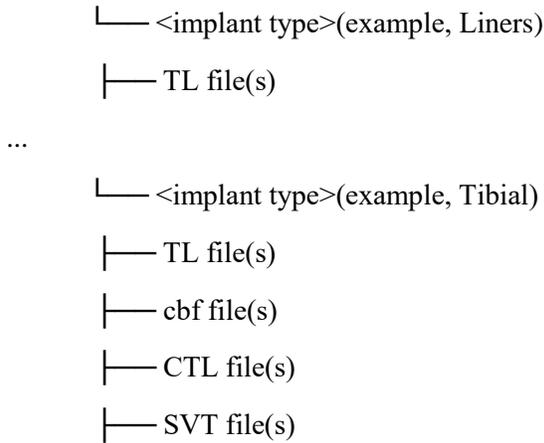
E 2 310-Imp-9 Tar file contents:

E 2.1 310-Imp-10 Contents of the tar archive for TSolution One™ system shall follow this layout:

```

├── desc
|
| ├── relationship file
| ├── cutter definition file
| ├── cutter verification screen file(s)
| ├── (TKA only) feature file
|
├── doc
|
| ├── release notes
| ├── cutter message file
| ├── information file
|
├── lib
|
| ├── <mfgr>
|   ├── <model>
|   ├── <rev>
|   ├── <implant type> (example, Femoral)
|   ├── TL file(s)
|   ├── cbf file(s)
|   ├── CTL file(s)
|   ├── SVT file(s)
|
| ...

```



**Figure 1:** TAR archive layout

## F File purpose, format and definitions

F 3Table: Information about the files in the TAR archive

| File(s) / Example                                | Format               | Purpose   | Defined in                                  | File Naming Conventions  | Multiplicities  | Affected System          |
|--|----------------------|---|---|--|---|--------------------------|
| relationship file<br>rel_PersonaFemur-Liners.txt | ASCII, tab-delimited | Specifies the relationships between supported implants. | 301042 Implant Relationship Interface Spec. | <p>The base name used shall be constructed as follows,</p> <ul style="list-style-type: none"> <li>rel_&lt;source&gt;-&lt;dest&gt;.txt</li> </ul> <p>The only valid &lt;source&gt;-&lt;dest&gt; combinations are the following (case-sensitive),</p> <ul style="list-style-type: none"> <li>Femur-Liners</li> <li>Tibia-Liners</li> </ul> | For TKA, the module must have the Femur-Liners and Tibia-Liners relationship files. | Parsed and used in TPLAN |
| cutter definition                                | ASCII,               | Specifies the   | PN 300315                                   | The base name used for   | Exactly One   | Parsed                   |

| File(s) / Example                                | Format        | Purpose  | Defined in  | File Naming Conventions   | Multiplicities  | Affected System  |
|--|---------------|--|---|---|---|--|
| file<br>107716_cutters.<br>def                   | tab-delimited | cutters compatible with this implant module, including their parameters                | Interface Specification for Cutter Definition for TSolution One   | <p>a cutter verification screen file shall be constructed as follows,</p> <ul style="list-style-type: none"> <li>• &lt;partnumber of cutter defined within the cutter definition file&gt;.png</li> <li>• The path of this file must match the path defined in the cutter definition file.</li> </ul>                        |   | and used in TPLAN  |
| cutter verification screen file(s)<br>106428.png | png           | Specifies which images shall be used for cutter verification in png image file format. | Png file format shall be defined Portable Network Graphics and shall be a raster graphics file format that supports lossless data compression. The Image content shall be defined by marketing and clinical applications as part of the cutter definition workflow. | <p>The base name used for a cutter verification screen file shall be constructed as follows,</p> <ul style="list-style-type: none"> <li>• &lt;partnumber of cutter defined within the cutter definition file&gt;.png</li> <li>• The path of this file must match the path defined in the cutter definition file.</li> </ul> | One for every cutter defined in the cutter definition file. | <p>TPLAN pass through to TCAT</p> <p>Parsed and used by TCAT</p> |

| File(s) / Example                                    | Format               | Purpose  | Defined in  | File Naming Conventions   | Multiplicities | Affected System   |
|--|----------------------|--|---|---|----------------|---|
| cutter message file<br>107716.msg                    | XML                  | Specifies which messages shall be displayed during cutting procedure as specified within the cutfile if applicable.                    | PN 300317 Interface Specification for Cutter Message File for TSolution One | The base name used for the cut message file shall be constructed as follows: <ul style="list-style-type: none"> <li>&lt;implant module p/n &gt;.msg</li> </ul>  | Exactly One    | TPLAN pass through to TCAT<br><br>Parsed and used in TCAT |
| Implant Feature File (TKA only)<br>107716_feature.ff | ASCII, tab-delimited | Specifies the transformation matrix, Contours, and other parameters used for specifying the cut planes per phase per supported implant | PN 301086 Implant Feature File Specification                                | The base name used for the implant feature file shall be specified as follows: <ul style="list-style-type: none"> <li>&lt;implant module p/n &gt;.ff</li> </ul> | Exactly One    | Parsed and used in TPLAN                                  |
| Information file<br>107716RA.nfo                     | ASCII, tab-delimited | Human-readable descriptors for each implant size   | PN 301096 Implant information file specification                            | The base name used for the nfo file shall be constructed as follows: <ul style="list-style-type: none"> <li>&lt;implant module p/n &gt;.nfo</li> </ul>          | Exactly One    | Parsed and used in TPLAN                                  |
| Release notes file<br>Zimmer Persona Release         | PDF                  | Technical documentation for implant module   | PDF file format per Adobe™ of the Release notes (previously released to     | The name should be a valid linux filename (maybe reference to an ISO that defines filename restrictions for   | Exactly One    | Used in TPLAN   |

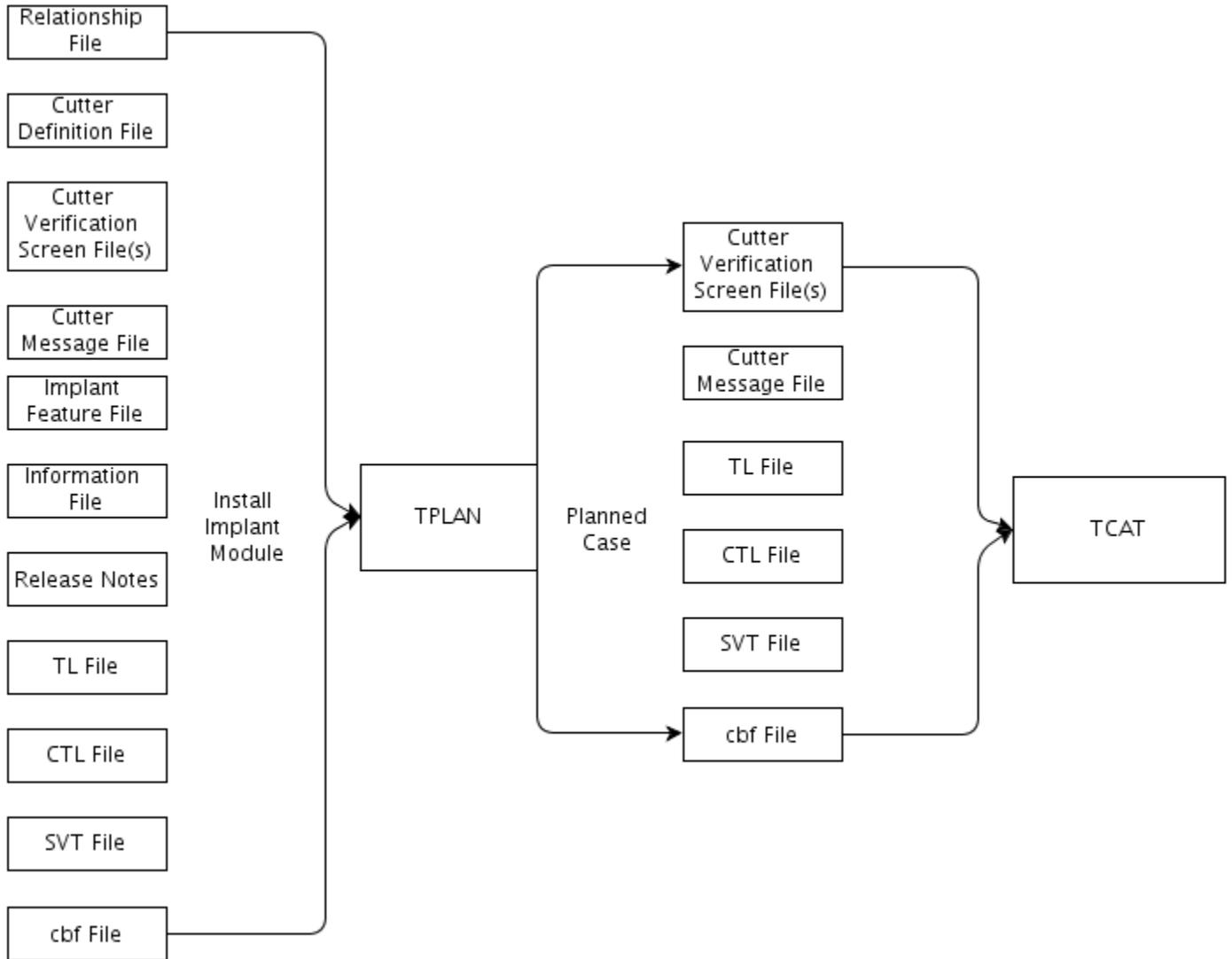
| File(s) / Example        | Format | Purpose                                 | Defined in  | File Naming Conventions  | Multiplicities  | Affected System   |
|--------------------------|--------|---|---|--|---|---|
| Notes.pdf                |        |   | document control for a given implant module.  | Linux systems) <ul style="list-style-type: none"> <li>&lt;filename&gt;.pdf</li> </ul>  |   |   |
| TL file<br>fCRSt3L.TL    | ASCII  | Implant geometry, topology and metadata | PN 300316 Specification TL interface for TSolution One  | The TL file name shall be a unique identifier for each supported implant, <ul style="list-style-type: none"> <li>&lt;filename&gt;.TL</li> <li>Right Side implants shall have a file name that ends with an 'R' (case-sensitive)</li> <li>Left Side implants shall have a file name that ends with an 'L' (case-sensitive)</li> <li>The file name must match the filename in the NFO file (case-sensitive)</li> </ul> | One for every implant in the NFO File                 | Used in TPLAN<br><br>Parsed and used by TCAT              |
| CTL file<br>fCRSt3LL.CTL | ASCII  | Cavity shape milled out during cutting  | CTL follows the same format as the geometry with the TL file with no Header information. The format for CTL follows PN 300316 Section 4.4 | Each CTL file shall correspond to a specific TL file by common basename, and shall have an additional characters added to the basename to specify each CTL file set unique. <ul style="list-style-type: none"> <li>The file name</li> </ul>  | One for each implant component (row) in the NFO File. | TPLAN pass through to TCAT<br><br>Parsed and used by TCAT |

| File(s) / Example        | Format | Purpose  | Defined in   | File Naming Conventions  | Multiplicities  | Affected System   |
|--------------------------|--------|--|--|--|---|---|
|                          |        |  | Specification TL interface for TSolution One                                       | must match the filename in the NFO file (case-sensitive)   |   |   |
| SVT file<br>fCRSt3LL.SVT | ASCII  | Safety margin for the robotic cutting          | PN 300318 Specification Interface, Implant check (safety) volume for TSolution One | Each SVT file shall correspond to a specific TL file by common basename, and shall have an additional characters added to the basename to specify each SVT file set unique. <ul style="list-style-type: none"> <li>The file name must match the filename in the NFO file (case-sensitive)</li> </ul> | One for each implant component (row) in the NFO File. | TPLAN pass through to TCAT<br><br>Parsed and used by TCAT |
| cbf file<br>fCRSt3LL.cbf | binary | Robot cutting commands for a specific implant. | PN 300071 Specification, Cut File Binary Format(CBF)                               | Each cbf file shall correspond to a specific TL file by common basename, and shall have an additional characters added to the basename to specify each cbf file set unique. <ul style="list-style-type: none"> <li>The file name must match the filename in the NFO file (case-sensitive)</li> </ul> | One for each implant component (row) in the NFO File. | TPLAN pass through to TCAT<br><br>Parsed and used by TCAT |

\*All file extensions are case sensitive. They should match the case as defined in the file specifications.

F 4File Topology for TSolution One™ interface:

F 4.1 310-Imp-63 Figure



**Figure 5:** Implant Module File Topology

The **Figure 5** above depicts the implant module data outline for TSolution One.

F 5Relationship file(s) (.txt)

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|---|--|-----------------|
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F 5.1 310-Imp-17 The relationship files within an implant module shall specify the parent to child relationships for all parent and child entities within the implant module.

#### F 6 Cutter Definition File (.def)

F 6.1 310-Imp-22 The cutter definition file shall be defined in specification P/N 300315.

#### F 7 310-Imp-24 Cutter verification screen file(s) (.png)

The cutter verification screen files shall depict verification screen images that shall be used to display the type and verification method graphically. Each image is considered product labeling and is subject to the requirements of SOP-031 (ex. label review). There shall be one cutter verification screen for each part number within the cutter definition file.

#### F 8 310-Imp-25 Cut Message File (.msg)

The cutter message file specifies the messages that shall be displayed by TCAT as part of the cutfile guide command. The cutter message file shall support the guide command as specified in P/N 300317 Interface Specification for Cutter Message File for TSolution One. The cut message file is considered product labeling and is subject to the requirements of SOP-031 (ex. label review) as a part of the design control process.

#### F 9 310-Imp-26 Implant Feature File (.ff)

The implant Feature File shall be defined as a tab delimited file that specifies the planar features of the knee cut paths for each phase.

#### F 10 310-Imp-27 nfo file (.nfo)

The nfo file shall be specified to display the implant information that are displayed by TCAT as part of the implant verification procedure during surgery. nfo file shall be specified in PN 301096 Implant information file specification for TSolution One™ TKA application. The nfo file is considered product labeling and is subject to the requirements of SOP-031 (ex. label review) as a part of the design control process.

#### F 11 310-Imp-28 Release Notes (.pdf)

The Release Notes are a required document for information transfer and training specific to each implant module. The release notes are written to inform the user about the implant module, and are released to manufacturing via document control in conjunction with the supported implant module. The Release

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Notes are considered product labeling and are subject to the requirements of SOP-031 (ex. label review) as a part of the design control process. An electronic version of the release notes in pdf format (Adobe™) shall be added to the implant module tar file prior to its commercial release.

F 12 310-Imp-29 TL file (.TL)

The TL file shall contain the 3D shape of the implant, in the same format as described in P/N 300316.

F 13 310-Imp-30 Cut files (.cbf)

The cbf file shall contain the 3D toolpath of the implant, in binary format as described in P/N 300071.

F 14 310-Imp-31 Check volume files (.SVT)

The .SVT file shall contain a volume in 3D space that TCAT uses to make sure the cutter tip does not deviate from its path by more than the clinically accepted value., in ASCII format as described in P/N 300318.

F 15 310-Imp-32 CTL files (.CTL)

CTL follows the same format as TL file, except it uses only the 3D shape information. Header (contents appearing before the line starting with '\*') shall be ignored.

G 310-Imp-33 Labeling Support (User Needs P/N 700171 Section 7.3.12)

All textual description shall use UTF-8 encoding.

All Implant Modules shall list matching and consistent labeling via the .nfo file and guide command keys defined within the message file tags within each module.

H 310-Imp-34 Local Language Support (User Needs P/N 700171 Section 7.3.5,7.3.26, 7.5.6,7.2.14)

All textual description shall use UTF-8 encoding.

All Implant Modules shall support applicable territorial and local language labeling requirements of the legally marketed implants as required.

Local language labeling shall be implemented via nfo and or message file tags as required.

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The specific languages supported for a given implant module shall be listed within the Implant Specification for that Implant Module.

## I Implant File Naming Convention

I 16 The implant files(TL, CTL, cbf and SVT) shall have the following naming convention:

I 16.1 310-Imp-38 Unique TL File

Each supported implant defined by a unique TL file shall support multiple CTL, cbf, and SVT files or "set of cut files".

I 17 310-Imp-40 File name shall be constructed from the following composition:

At least one letter representing the Implant Manufacturer.

At least one letter representing the Implant Family.

If a different sub group of the implant line exists (e.g. standard and extended or Femoral and Tibial) then at least one letter shall be used to represent the subgroup.

The size of the implant shall be listed in the file name.

## J Implant File Origin and coordinate system Convention

J 18 The implant files shall have a specific origin defined consistent with the implant application.

J 18.1 For TKA, the origin of the implant shall be defined as follows:

J 18.1.1 For Femoral Components,

J 18.1.1.1 310-Imp-45 Origin

The origin shall be consistent for each implant model and toolpath within an implant module. However it's location shall be dependent upon the origin of the manufacturer's data and translations specified to accommodate design and development. For example in the implant shown below the origin shall be define equa-distance in the medial and lateral and aligned with the distal cut plane of the implant.

J 18.1.1.2 310-Imp-46 X

Positive X direction of the coordinate system shall be toward the medial from the origin.

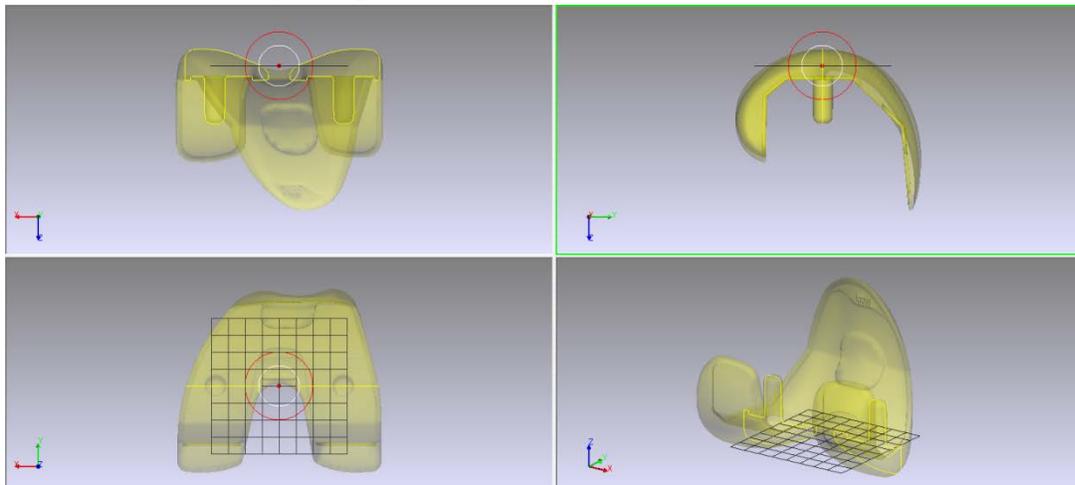
J 18.1.1.3 310-Imp-47 Z

Positive Z direction of the coordinate system shall be from the origin toward the proximal most part of the implant.

J 18.1.1.4 310-Imp-48 Y

Positive Y direction shall be a function of the cross product of the X axis with the Z axis per right hand rule forming a fully defined coordinate system. This shall result in the y axis flipping direction for right vs left for a given size implant.

J 18.1.1.5 310-Imp-49 Figure



**Figure 2:** Femoral component

J 18.1.2 For Tibial Components,

J 18.1.2.1 310-Imp-51 Origin

The origin shall be consistent for each implant model and toolpath within an implant module. However it's location shall be dependent upon the origin of the manufacturer's data and translations specified to accommodate design and development. For example in the implant shown below the origin shall be defined at a 5 degree angle relative to the tibial plateau.

J 18.1.2.2 310-Imp-52 X

Positive X direction of the coordinate system shall be toward the medial from the origin.

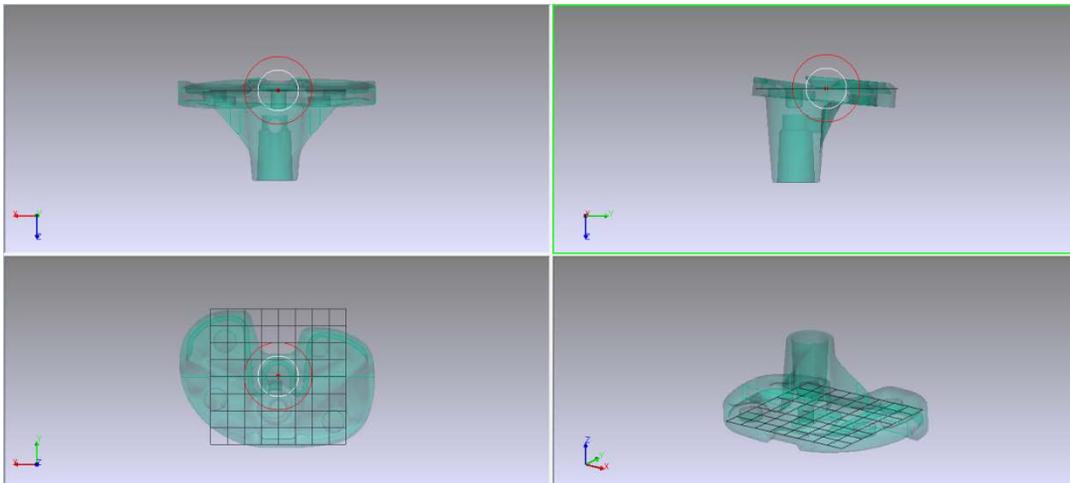
J 18.1.2.3 310-Imp-53 Z

Positive Z direction of the coordinate system shall be from the origin toward the distal tip of the implant.

J 18.1.2.4 310-Imp-54 Y

Positive Y direction shall be a function of the cross product of the X axis with the Z axis per right hand rule forming a fully defined coordinate system. This will result in the y axis flipping direction for right vs left for a given size implant.

J 18.1.2.5 310-Imp-55 Figure



**Figure 3:** Tibial Component

J 18.1.3 For Tibial Liners,

J 18.1.3.1 310-Imp-57 Origin

The origin shall be consistent for each implant model and toolpath within an implant module. However its location shall be dependent upon the origin of the manufacturer's data and translations specified to accommodate design and development. For example in the implant shown below the origin shall be defined relative to the origin and coordinate system of the tibial component.

J 18.1.3.2 310-Imp-58 X

Positive X direction of the coordinate system shall be toward the medial from the origin.

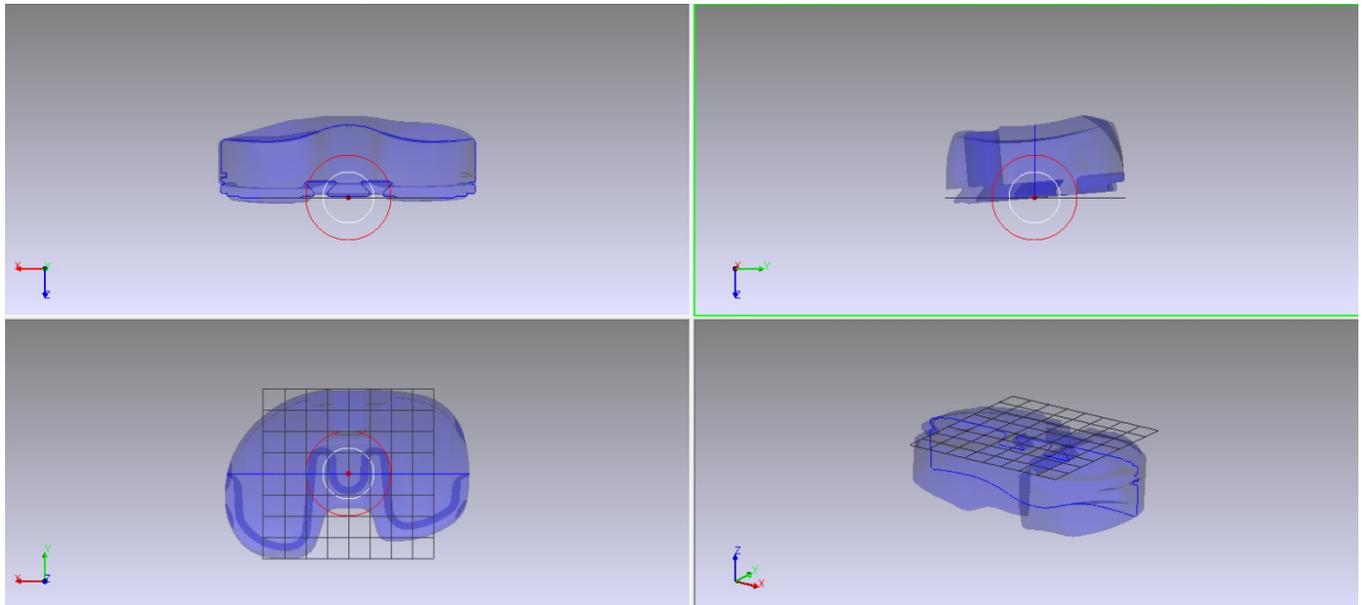
J 18.1.3.3 310-Imp-59 Z

Positive Z direction of the coordinate system shall be from the origin toward the distal of the implant as the origin shall be distal in this case the z direction points away from the liner body at a 5 degree angle relative to the attachment plane of the liner.

J 18.1.3.4 310-Imp-60 Y

Positive Y direction shall be a function of the cross product of the X axis with the Z axis per right hand rule forming a fully defined coordinate system. This will result in the y axis flipping direction for right vs left for a given size implant.

J 18.1.3.5 310-Imp-61 Figure



**Figure 4:** Tibial Liners

## K Revision History

| <b>Rev</b> | <b>DCO</b> | <b>Change Description</b> | <b>Date</b> |
|------------|------------|---------------------------|-------------|
| A          | 6626       | Initial Release           | 01/09/18    |