Prostheses List Management System (PLMS) User Guide – Prosthesis Device Application
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Introduction

ABOUT
The Department of Health developed the Prostheses List Management System (PLMS) to streamline the application process for listing a prosthesis device on the Prostheses List. The system allows sponsors and suppliers to create, edit and monitor applications for prostheses listings.

ABOUT THIS GUIDE
The purpose of this user guide is to assist sponsors and suppliers in using the Prostheses List Management System (PLMS). Pictures of the screens from the online system are used throughout this guide in order to help navigate between the portal and the guide. These screenshots are to provide a visual representation of the look and feel and are not intended to be read in full.

The **PLMS User Guide – Prosthesis Device Application** will provide guidance on:
1. Creating a New Application
2. Expanding a Listing
3. Compressing a Listing
4. Amending a Listing
5. Duplicating a Listing
6. Transferring a Listing
7. Deleting a Listing

If you have any questions about using the Prostheses List Management System, contact the Department of Health at prostheses@health.gov.au
There are three user guides available for the PLMS:

- PLMS User Guide – Getting Started
- PLMS User Guide – Prosthesis Device Application
- PLMS User Guide – Human Tissue Application (in development)
PLMS Home

You can complete a number of actions from the PLMS Home.

Click **Create Application** to create, expand, compress, duplicate, transfer, amend or delete a listing from the Prostheses List.

Click **Search** to search applications.

Click **Manage Users** to manage User Roles (User Administrators only).

Click the **icon** to view the Application Summary of an application.

Click the **icon** to view and edit an application.

Click **Show All** to view a list of all of your applications.
Hints for completing an application

This guide provides help on the functions available to you when completing an application for a prosthesis device.

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1. Create New Application

When you Create a New Application, you are applying to list a new prosthesis device on the Prostheses List.

Before you start an application:

1. Download and read the Prostheses List – guide to listing and benefits for prostheses:
   - Prostheses List Guide (Word 977 KB)
   - Prostheses List Guide (PDF 502 KB)

2. View the grouping schemes for each category of product, including suffix definitions and benefits.

The steps to Create a New Application are:

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* You only need to complete this application step if applicable
1.1 PLMS Home

STEP 1 – Click **Create Application** on the left of the screen.
1.2 Start Application

On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List.

APPLICATION TYPE
STEP 1 – Select Create a New Listing using the drop down menu.

APPLICATION CONTACTS
STEP 2 – Select a Primary Contact for your application using the drop down menu. This action should prefill contact information. You can add a Secondary Contact to your application, if needed.

STEP 3 – To create a New Contact for the application:
- Tick the Create New Contact box
- Enter First Name, Last Name, Phone Number(s) and Email address for the contact

The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department.
1.3 Product Summary

**PRODUCT TYPE**

STEP 1 – Click the option for **Prosthesis Device**.

STEP 2 – Choose **Yes** or **No** to indicate if you are listing a product system.
- If **No**, click **Next** to go to the next page
- If **Yes**, go to STEP 3

*A product system is a prosthesis device made up of two or more components that work together. A product system is clinically assessed as a whole, regardless of the number of parts in the system.*

STEP 3 – If you are applying to list a product system, enter the **Product System Name** in the space provided.

*The product system name is the name the prosthesis is sold under in Australia.*
1.3 Product Summary continued

PRODUCTS SYSTEM COMPONENTS

STEP 4 – Click **Add Product**.

When listing a product system, you will need to complete the following sections for each system component:

- **New Prosthesis Device** (1.4 of this guide)
- **Comparator(s)** (1.5 of this guide)
- **Benefit and Economic Information for New Grouping** (if applicable) (1.6 of this guide)

When you finish adding a system component, it will be listed under the **Products System Components** list.

When naming a product system component, include both the name of the system, and the part (e.g. ACME HIP system – Femoral Head).

Each system component included in your application will:

- Receive a unique billing code
- Require an initial listing payment fee of $200

STEP 5– After adding all the system components, click **Next**.

You must complete all other sections in the application for the product system as a whole.
1.4 New Prosthesis Device

PRODUCT DETAILS

STEP 1 – Enter the Product Name.

The product name is the name the prosthesis is sold under in Australia.

The information you provide for Product Name will be available on the Prostheses List should your application be successful.

STEP 2 – Enter a Description of the product.

Describe the prosthesis in one sentence.

The information you provide for Description will be available on the Prostheses List should your application be successful.

STEP 3 – Enter the Size of the product.

Accurately describe the dimensions of the prosthesis or system in one sentence.

The information you provide for Size will be available on the Prostheses List should your application be successful.

STEP 4 – Enter the Catalogue Number(s).

List the catalogue number(s) under which the product is sold in Australia.
1.4 New Prosthesis Device continued

ARTG ID NUMBER

STEP 5 – If you have a current ARTG entry (ARTG ID Number) for the product, enter the number into the grey box, and select the correct option from the drop down list.

Once selected, the rest of the table should populate with information.

An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).

You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.

STEP 6 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.

Only products entered on the ARTG can be listed on the Prostheses List.

The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.
1.4 New Prostheses Device *continued*

View the [grouping schemes](#) for each category of product, including Suffix definitions and benefits.

**GROUPING**

**STEP 7** – Select a **Category** from the drop down menu.

*If the product fits into more than one category, list the category that will represent the greatest use of the product.*

**STEP 8** – Select a **Subcategory** from the drop down menu.

**STEP 9** – Select a **Group** from the drop down menu.

To add a new Group, click **Add**, enter the new Group name in the space provided, and click **Save**.

**STEP 10** – Select a **Subgroup** from the drop down menu, if needed.

To add a new Subgroup, click **Add**, enter the new Subgroup name in the space provided, and click **Save**.

**STEP 11** – Select a **Suffix** from the drop down menu, if needed.

To add a new Suffix, click **Add**, enter the new Suffix name in the space provided, and click **Save**.

*If you add a new Group, Subgroup or Suffix, you will have to fill out the Evidence, Benefit and Economic Information for New Grouping section (1.6 of this guide) on your application. If you suggest a new Group, Subgroup or Suffix, the Department will review your evidence and either accept or decline your suggestion.*
1.5 Comparator(s)

A comparator is a current product, treatment or therapy that your prosthesis could replace. A comparative product may be similar in form or function to your product.

**COMPARATOR DETAILS**

STEP 1 – Choose the comparator option that applies to your device.
- Comparator is an existing item on the Prostheses List, go to STEP 2.
- Comparator is not on the Prostheses List, go to STEP 8.

STEP 2 – Click Add Comparator.

You must list at least one comparator in your application. Choosing the right comparator(s) is important as it allows clinicians to better understand and assess your product by comparing it to similar products, treatments and therapies.
1.5 Comparator(s) **continued**

**STEP 3** – Search the Prostheses List by:

- **Keyword Search**

  OR

- **Product Grouping** information using the drop down menus

  Click **Search**.

  *If you are aware of an appropriate comparator, search by typing in the billing code for that comparator. If you are not aware of a comparator, you may find an appropriate comparator in the same grouping as your prosthesis.*

**STEP 4** – Click on the **Billing Code** hyperlink for your chosen comparator in the **Search Results**.
1.5 Comparator(s) continued

STEP 5 – Click Confirm. Your comparator should now be listed on the page.

STEP 6 – Provide a clear explanation on why you have chosen this comparator in the space provided.

Things you might consider in your explanation include:

- The clinical outcome for the product
- How the product is used
- How the product is made

STEP 7 – Add any additional comparators, if needed.

If you have listed more than one comparator for your product, please indicate which is the main comparator by ticking the box.

The main comparator is the product that your prosthesis would most often replace.
1.5 Comparator(s) continued

STEP 8 – Enter the **Treatment/Therapy Name**.

STEP 9 – Enter a **Description** of the treatment or therapy.

STEP 10 – Enter **Benefit/Cost** details.

STEP 11 – Provide a clear explanation on why you have chosen this comparator in the space provided.
1.6 Evidence, Benefit and Economic Information for New Grouping

You only need to fill out this page if you have proposed a new Group, Subgroup or Suffix in the New Prosthesis Device section (1.4 of this guide). The Evidence, Benefit and Economic Information for New Grouping page will only appear on your application if applicable.

**PROPOSED BENEFIT**

**STEP 1** – Enter the Proposed Benefit amount for the product.

**STEP 2** – Enter an explanation on how you calculated the benefit amount.

Your explanation should take into consideration:

- Clinical outcomes delivered by the product
- Cost comparisons or savings achieved by using the product

**CLINICAL OUTCOMES**

**STEP 3** – Enter the Clinical Outcomes delivered by your product.

Include information on the differences in clinical outcomes for patients between your prosthesis and any comparators.

Factors you may like to consider include:

- Recovery times
- Failure rates
- Complications
- Life expectancy

The information you provide must be measurable or quantifiable, as well as supported by clinical evidence or data.

Please provide evidence to support your claim in the Attachments section (1.10 of this guide).
1.6 Evidence, Benefit and Economic Information for New Grouping continued

COST COMPARISON

STEP 4 – Enter details of any cost savings achieved by using the product.

*Include information on any cost savings that can be made by using the product instead of the comparator.*

You may like to consider reductions in:

- Theatre time
- Hospital stay time
- Post-surgical care costs
- Reduced revision surgery

Any reductions listed must be real (not potential or theoretical), and be supported by clinical evidence or data. For any cost savings listed, please include actual amounts.

*Please provide evidence to support your claim in the Attachments section (1.10 of this guide).*
1.6 Evidence, Benefit and Economic Information for New Grouping *continued*

### PRODUCT UTILISATION

**STEP 5** – Enter into the grey box, the name of any country where your product is sold, and select the correct option from the drop down list.

Enter **Utilisation per year** in the grey box.

Enter **Cost (in local currency)** in the grey box.

Repeat steps for additional countries.

*Please provide actual utilisation and price information for the product in both public and private markets.*

*If the product has been used in the public system in Australia, please include details.*

**STEP 6** – Briefly describe the projected utilisation of the product over the first two years of listing on the Prostheses List.

Briefly describe the basis for your projection by providing evidence to support your projected utilisation.

**STEP 7** – Click **Yes** or **No** to indicate whether the use of your product would replace another product.

**OTHER INFORMATION**

**STEP 8** – Provide any additional information to support the proposed grouping.
1.7 MBS Item(s)

The Medical Benefits Schedule (MBS) contains a listing of all the Medicare professional services subsidised by the Australian Government. To be eligible for the Prostheses List, your product must have an MBS listed service for either the implantation or application of the product.

MEDICAL BENEFITS SCHEDULE (MBS) ITEMS(S) AND DESCRIPTORS

STEP 1 – If you have a current MBS Item number(s) for your product, go to STEP 2.

If you do not have a current MBS Item number(s) for your product, go to STEP 7.

STEP 2 – To add an MBS Item number, click Add MBS Item. A Keyword Search box will appear.
1.7 MBS Item(s) continued

**MEDICAL BENEFITS SCHEDULE (MBS) ITEMS(S) AND DESCRIPTORS**

**STEP 3** – Search for an MBS Item by entering either the MBS Item number or MBS Item description.

Click **Search**.

**STEP 4** – Click on the **MBS Item Number** hyperlink for your chosen option.
1.7 MBS Item(s) continued

**MEDICAL BENEFITS SCHEDULE (MBS) ITEMS(S) AND DESCRIPTORS**

**STEP 5** – Click **Confirm**. Your MBS Item should now be listed on the page.

Repeat steps to add another MBS Item.

*You can list up to ten MBS Items for your product.*

**STEP 6** – Briefly explain why the service(s) apply to your prosthesis device.

**STEP 7** – If you have applied for an MBS Item number for your product, but the decision is pending, tick the box.

*The Department will progress your application without an MBS Item number, however the product will not be listed on the Prostheses List until the sponsor provides a valid MBS Item number to the Department.*
1.8 Product Setting and Product Purpose

**PRODUCT SETTING**

STEP 1 – Select the option that applies to your product.

- If you choose (a) or (b), go to STEP 3
- If you choose (c), go to STEP 2

To be eligible for the Prostheses List, your product must be provided as part of treatment in a hospital or hospital substitute treatment.

STEP 2 – For option (c), provide details on where the product is provided if outside of a hospital setting.

If the product is used for treatment outside of a hospital setting, it may not be eligible for listing on the Prostheses List.
1.8 Product Setting and Product Purpose continued

PRODUCT PURPOSE

STEP 3 – Select the option that that best describes the purpose of the product.

- If you choose (a), go to STEP 4
- If you choose (b), go to STEP 5
- If you choose (c), go to STEP 6

STEP 4 – For option (a), briefly describe what the product does, to support the assessment of the product.

STEP 5 – For option (b), enter the name of the single use aid that works with your product.

Briefly describe what the product does, to support the assessment of the product.
1.8 Product Setting and Product Purpose continued

PRODUCT PURPOSE

STEP 6 – For option (c), enter the name of the surgically implanted product that works with your product.

Briefly describe what the product does, to support the assessment of the product.
1.9 Comparative Clinical Effectiveness

OVERSEAS STATUS

STEP 1 – Select the appropriate option for the product.

- If you choose Yes, go to STEP 2
- If you chose No, or Unknown/ Not available, go to STEP 3

This information allows clinicians to determine if the product has undergone any clinical assessments in other countries.

STEP 2 – For option Yes, provide information about the approvals.

You may like to provide:

- Information on which countries have given approval for the product
- Approval certificates (attach certificates in the Attachments section)
- Any other names the product is sold under

STEP 3 – Select the appropriate option for the product.

If you choose Yes, go to STEP 4
If you chose No, go to STEP 5

This information allows clinicians to determine if the product has undergone any clinical assessments in other countries.

STEP 4 – For option Yes, provide the name(s), the product of system is being sold under in other countries.
1.9 Comparative Clinical Effectiveness continued

COMPARATIVE CLINICAL EFFECTIVENESS

STEP 5 – Provide details of **Comparative Clinical Effectiveness** for your product.

Please explain how the clinical effectiveness and cost effectiveness of your product / product system compares with the comparator(s). Please refer to the clinical evidence you have provided above to support your application.

Enter text...

1000 characters remaining
1.10 Attachments

The documentation you provide in the Attachments section is used by clinicians to assess your application.

ATTACHMENTS

STEP 1 – To add an attachment to your application, click **Add**.

**Only upload documentation:**
- **In PDF format**
- **In English**
- **Specific to the prosthesis**

**Do NOT upload:**
- Marketing material for the product

One specific study focussing on the prosthesis is better than many studies that do not directly relate to the prosthesis.

Please number the attachments in the order you would like them to be viewed.
1.10 Attachments *continued*

**ATTACHMENTS**

STEP 2 – To add an attachment to your application:
- Click + Choose File(s) to browse your device and insert a file
- OR
- Drag and drop your file into the white panel.

The file will now be listed on the Attachments screen.

STEP 3 – Add additional attachments as needed.

STEP 4 – Use the drop down menu under Type to select the type of document you have uploaded.

STEP 5 – Enter a brief description for each document you have uploaded.
1.11 Review and Submit

Review all sections of your application to ensure the information you provided is correct.

**REVIEW**

STEP 1 – Review all sections of your application to ensure the information you provided is correct.

If you find an error in your application, click Edit, at the top right of the section. This will take you back to the relevant page where you can make any edits required.

Your prosthesis device may have to be clinically reassessed if you do not provide the correct information. This may also cause significant delays in listing the item on the Prostheses List.

**SUBMIT**

STEP 2 – Tick the box if you agree to the declaration.

STEP 3 – Click Save to save the information provided in your application or click Submit to submit your application.
1.12 Application Summary

After you submit your application, you will be directed to the Application Summary for your application.

APPLICATION SUMMARY

Click **Print as RTF**, to download your Application Summary in a Word document.

Click **Print as PDF**, to download your Application Summary in a PDF document.

ATTACHMENTS

Click the 📖 icon to download an attachment from your application.
1.12 Application Summary continued

MANAGE APPLICATION ACCESS

You can manage access to an application so only the users you authorise will be able to see the application listed on the PLMS.

- **Open to All** means any users in your organisation can view your application. Open to All is the default setting.
- **Allow Access to** allows you to choose which users in your organisation can view your application.
- **Deny Access to** allows you to choose which users in your organisation cannot view your application.

To manage user access to your application:

1. Click either **Allow Access to** or **Deny Access to**
2. To manage users:
   - Move all users between the **All** box and the **Selected** box by clicking **>>** or **<<**
   - OR
   - Move a single user between the **All** box and the **Selected** box by clicking on the user name(s) and clicking **>** or **<**
3. Click **Save** after moving your chosen user(s) to the **Selected** box.
2. Expand a Listing

When you Expand a Listing, you are breaking up a single prostheses listing (covering various prostheses) into multiple new billing codes. The Department will remove the current billing code for the prosthesis, and replace it with new billing codes for the expanded listings.

You may choose to Expand a Listing if:

- Products within the current listing need to be listed in different groupings
- You wish to charge separately for different parts of the current listing

There is no cost to Expand a Listing.

The steps to Expand a Listing are:

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* You only need to complete this application step if applicable
2.1 PLMS Home

STEP 1 – Click **Create Application** on the left of the screen.
2.2 Start Application

On the Start Application page you have the option to create, expand, compress, amend, duplicate, transfer or delete a listing from the Prostheses List.

**APPLICATION TYPE**

STEP 1 – Select **Expand Listing** using the drop down menu.

**APPLICATION CONTACTS**

STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.

You can add a **Secondary Contact** to your application, if needed.

STEP 3 – To create a **New Contact** for the application:

- Tick the **Create New Contact** box
- Enter **First Name**, **Last Name**, **Phone Number(s)** and **Email** address for the contact

The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department.
2.3 Expand a Prostheses Listing

On the Expand a Prostheses Listing page, you must select the prosthesis from the Prostheses List you want to expand into multiple billing codes.

**SELECT A LISTING**

**STEP 1** – Click [Select a Listing](#) to select a prosthesis from the Prostheses List.
2.3 Expand a Prostheses Listing *continued*

STEP 2 – Search the Prostheses List by:

- **Keyword Search**
  - OR
- **Product Grouping** information using the drop down menus

Click **Search**.

STEP 3 – Click on the **Billing Code** hyperlink for your chosen product.
2.3 Expand a Prostheses Listing *continued*

STEP 4 – Click **Confirm**. Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis.
2.3 Expand a Prostheses Listing *continued*

**REASON FOR EXPANSION**

STEP 5 – Use the drop down menu to choose the reason for expanding the prostheses listing.

If the reason is different to what is listed, please explain in the space available.
2.3 Expand a Prostheses Listing continued

RESULTANT (NEW) PROSTHESES LISTINGS

STEP 6 – Click **Add**.

When you Expand a Listing, you will need to complete the following sections for each new/expanded component one product at a time:

- **New Prosthesis Device** (2.4 of this guide)
- **Comparator(s)** (2.5 of this guide)
- **Benefit and Economic Information for New Grouping** (if applicable) (2.6 of this guide)
- **Comparative Clinical Effectiveness** (2.7 of this guide)

When you finish adding a component, it will be listed under the **Resultant (new) Prostheses Listings** list.

*Each expanded system component included in your application will receive a unique billing code.*

STEP 8– Add any additional components.

STEP 8– After adding all the expanded components, click **Next**.
2.4 New Prosthesis Device

You will need to fill out the New Prosthesis Device section for each new prosthesis device resulting from the expanded listing.

**PRODUCT DETAILS**

**STEP 1 – Enter the Product Name.**

*The product name is the name the prosthesis is sold under in Australia.*

*The information you provide for Product Name will be available on the Prostheses List should your application be successful.*

**STEP 2 – Enter a Description of the product.**

*Describe the prosthesis in one sentence.*

*The information you provide for Description will be available on the Prostheses List should your application be successful.*

**STEP 3 – Enter the Size of the product.**

*Accurately describe the dimensions of the prosthesis or system in one sentence.*

*The information you provide for Size will be available on the Prostheses List should your application be successful.*

**STEP 4 – Enter the Catalogue Number(s).**

*List the catalogue number(s) under which the product is sold in Australia.*
2.4 New Prosthesis Device continued

**ARTG ID NUMBER**

**STEP 5** – If you have a current ARTG entry (ARTG ID Number) for the product, enter the number into the grey box, and select the correct option from the drop down list.

Once selected, the rest of the table should populate with information.

You will need to provide a new ARTG entry for each new prosthesis device resulting from the expanded listing.

An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).

You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.

**STEP 6** – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.

Only products entered on the ARTG can be listed on the Prostheses List.

The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.
2.4 New Prosthesis Device *continued*

View the grouping schemes for each category of product, including Suffix definitions and benefits.

**GROUPING**

STEP 7 – Select a **Category** from the drop down menu.

*If the product fits into more than one category, list the category that will represent the greatest use of the product.*

STEP 8 – Select a **Subcategory** from the drop down menu.

STEP 9 – Select a **Group** from the drop down menu.

To add a new Group, click **Add**, enter the new Group name in the space provided, and click **Save**.

STEP 10 – Select a **Subgroup** from the drop down menu, if needed.

To add a new Subgroup, click **Add**, enter the new Subgroup name in the space provided, and click **Save**.

STEP 11 – Select a **Suffix** from the drop down menu, if needed.

To add a new Suffix, click **Add**, enter the new Suffix name in the space provided, and click **Save**.

*If you add a new Group, Subgroup or Suffix, you will have to fill out the Evidence, Benefit and Economic Information for New Grouping section (2.6 of this guide). If you suggest a new Group, Subgroup or Suffix, the Department will review your evidence and either accept or decline your suggestion.*
2.5 Comparator(s)

A comparator is a current product, treatment or therapy that your prosthesis could replace. A comparative product may be similar in form or function to your product. You will need to fill out the Comparator(s) section for each new prosthesis device resulting from the expanded listing.

**COMPARATOR DETAILS**

**STEP 1** – Choose the comparator option that applies to your device.

- Comparator is an existing item on the Prostheses List, go to STEP 2.
- Comparator is not on the Prostheses List, go to STEP 8.

**STEP 2** – Click **Add Comparator**.

You must list at least one comparator in your application. Choosing the right comparator(s) is important as it allows clinicians to better understand and assess your product by comparing it to similar products, treatments and therapies.
2.5 Comparator(s) continued

STEP 3 – Search the Prostheses List by:

- **Keyword Search**

- OR

- **Product Grouping** information using the drop down menus

Click Search.

*If you are aware of an appropriate comparator, search by typing in the billing code for that comparator. If you are not aware of a comparator, you may find an appropriate comparator in the same grouping as your prosthesis.*

STEP 4 – Click on the **Billing Code** hyperlink for your chosen comparator in the **Search Results**.
2.5 Comparator(s) *continued*

STEP 5 – Click **Confirm**. Your comparator should now be listed on the page.

STEP 6 – Provide a clear explanation on why you have chosen this comparator in the space provided.

*Things you might consider in your explanation include:*
- The clinical outcome for the product
- How the product is used
- How the product is made

STEP 7 – Add any additional comparators, if needed.

If you have listed more than one comparator for your product, please indicate which is the main comparator by ticking the box.

*The main comparator is the product that your prosthesis would most often replace.*
2.5 Comparator(s) continued

STEP 8 – Enter the Treatment/Therapy Name.

STEP 9 – Enter a Description of the Treatment/Therapy.

STEP 10 – Enter Benefit/Cost details.

STEP 11 – Provide a clear explanation on why you have chosen this comparator in the space provided.
2.6 Evidence, Benefit and Economic Information for New Grouping

You only need to fill out this section if you have proposed a new Group, Subgroup or Suffix in the New Prosthesis Device section (2.4 of this guide). The Evidence, Benefit and Economic Information for New Grouping page will only appear on your application if applicable.

PROPOSED BENEFIT

STEP 1 – Enter the **Proposed Benefit** amount for the product.

STEP 2 – Enter an explanation on how you calculated the benefit amount.

*Your explanation should take into consideration:*

- Clinical outcomes delivered by the product
- Cost comparisons or savings achieved by using the product

CLINICAL OUTCOMES

STEP 3 – Enter the **Clinical Outcomes** delivered by your product.

*Include information on the differences in clinical outcomes for patients between your prosthesis and any comparators.*

*Hint: Factors you may like to consider include:*

- Recovery times
- Failure rates
- Complications
- Life expectancy

*The information you provide must be measurable or quantifiable, as well as supported by clinical evidence or data.*

*Please provide evidence to support your claim in the Attachments section (2.8 of this guide).*
2.6 Evidence, Benefit and Economic Information for New Grouping *continued*

**COST COMPARISON**

STEP 4 – Enter details of any cost savings achieved by using the product.

*Include information on any cost savings that can be made by using the product instead of the comparator.*

You may like to consider reductions in:

- Theatre time
- Hospital stay time
- Post-surgical care costs
- Reduced revision surgery

Any reductions listed must be real (not potential or theoretical), and be supported by clinical evidence or data. For any cost savings listed, please include actual amounts.

*Please provide evidence to support your claim in the Attachments section (2.8 of this guide).*
2.6 Evidence, Benefit and Economic Information for New Grouping  

**PRODUCT UTILISATION**

STEP 5 – Enter into the grey box, the name of any country where your product is sold, and select the correct option from the drop down list.

Enter **Utilisation per year** in the grey box.

Enter **Cost (in local currency)** in the grey box.

Repeat for additional countries.

*Please provide actual utilisation and price information for the product in both public and private markets.*

*If the product has been used in the public system in Australia, please include details.*

STEP 6 – Briefly describe the projected utilisation of the product over the first two years of listing on the Prostheses List.

Briefly describe the basis for your projection by providing evidence to support your projected utilisation.

STEP 7 – Click **Yes** or **No** to indicate whether the use of your product would replace another product.

**OTHER INFORMATION**

STEP 8 – Provide any additional information to support the proposed grouping.
2.7 Comparative Clinical Effectiveness

You will need to fill out the Comparative Clinical Effectiveness section for each new prosthesis device resulting from the expanded listing.

**COMPARATIVE CLINICAL EFFECTIVENESS**

STEP 1 – Provide details of *Comparative Clinical Effectiveness* for your product.
2.8 Attachments

The documentation you provide in this section is used by clinicians to assess your application. You will need to provide separate documentation for each new prosthesis device resulting from the expanded listing.

ATTACHMENTS

STEP 1 – To add an attachment to your application, click **Add**.

Only upload documentation:
- **In PDF format**
- **In English**
- **Specific to the prosthesis**

Please label each individual component on the product image that is being expanded into new billing codes.

Do NOT upload:
- **Marketing material for the product**

Please number the attachments in the order you would like them to be viewed.
2.8 Attachments continued

ATTACHMENTS

STEP 2 – To add an attachment to your application:
- Click + Choose File(s) to browse your device and insert a file
  OR
- Drag and drop your file into the white panel.
The file will now be listed on the Attachments screen.

STEP 3 – Add additional attachments as needed.

STEP 4 – Use the drop down menu under Type to select the type of document you have uploaded.

STEP 5 – Enter a brief description for each document you have uploaded.
2.9 Review and Submit

Review all sections of your application to ensure the information you provided is correct.

**REVIEW**

STEP 1 – Review all sections of your application to ensure the information you provided is correct.

If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.

**SUBMIT**

STEP 2 – Tick the box if you agree to the declaration.

STEP 3 – Click **Save** to save the information provided in your application or click **Submit** to submit your application.
3. Compress a Listing

When you Compress a Listing, you are bringing together multiple prostheses on the Prostheses List to sit under a single billing code. The Department will remove the current billing codes for the prostheses, and replace it with a single new billing code for the compressed listing. You may choose to Compress a Listing if:

- Related products listed separately on the Prostheses List can now be grouped together e.g. the products are only available in a product system. This may be beneficial as it can reduce your future listing fees.

There is no cost to Compress a Listing.

The steps to Compress a Listing are:

Compress a Listing

3.1  PLMS Home
3.2  Start Application
3.3  Compressed Listings Summary
3.4  New Prosthesis Device
3.5  Comparator(s)
3.6  Evidence, Benefit and Economic Information for New Grouping*
3.7  Comparative Clinical Effectiveness
3.8  Attachments
3.9  Review and Submit

* You only need to complete this application step if applicable
3.1 PLMS Home

STEP 1 – Click **Create Application** on the left of the screen.
3.2 Start Application

On the Start Application page you have the option to create, expand, compress, amend, duplicate, transfer or delete a listing from the Prostheses List.

**APPLICATION TYPE**

STEP 1 – Select **Compress a Listing** using the drop down menu.

**APPLICATION CONTACTS**

STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.

You can add a **Secondary Contact** to your application, if needed.

STEP 3 – To create a **New Contact** for the application:

- Tick the **Create New Contact** box
- Enter **First Name**, **Last Name**, **Phone Number(s)** and **Email** address for the contact

*The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department.*
3.3 Compressed Listings Summary

On the Compressed Listings Summary page, you need to include all the prostheses, currently listed on the Prostheses List, that you want to compress into one billing code.

**SELECT PROSTHESES LISTINGS TO COMPRESS**

**STEP 1** – Click **Select a Listing** to add a prosthesis from the Prostheses List.
3.3 Compressed Listings Summary continued

STEP 2 – Search the Prostheses List by:

- **Keyword Search**
- OR
- **Product Grouping** information using the drop down menus

Click **Search**.

STEP 3 – Click on the **Billing Code** hyperlink for your chosen product.
3.3 Compressed Listings Summary continued

STEP 4 – Click **Confirm**. Your product should now be listed on the page under **Select Prostheses Listings to Compress**.

Add additional products to the list, as needed.
### REASON FOR COMPRESSION

**STEP 5** – Use the drop down menu to choose the reason for compressing the prostheses listings.

If the reason is different to what is listed, please explain in the space available.

#### Reason for Compression

Please select the main reason for the compression: *

- [ ] Choose a reason —

Additional Information:

Enter text...

1000 characters remaining

### 3.3 Compressed Listings Summary *continued*

<table>
<thead>
<tr>
<th>Billing Code</th>
<th>Product Name</th>
<th>Description</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No records found.

---

Select a Listing

Prev | Next | Save
3.4 New Prosthesis Device

On the New Prosthesis Device page, provide details for the new prosthesis device resulting from the compressed listings.

**PRODUCT DETAILS**

STEP 1 – Enter the **Product Name**.

_The product name is the name the prosthesis is sold under in Australia._

_The information you provide for Product Name will be available on the Prostheses List should your application be successful._

STEP 2 – Enter a **Description** of the product.

_Describe the prosthesis in one sentence._

_The information you provide for Description will be available on the Prostheses List should your application be successful._

STEP 3 – Enter the **Size** of the product.

_Accurately describe the dimensions of the prosthesis or system in one sentence._

_The information you provide for Size will be available on the Prostheses List should your application be successful._

STEP 4 – Enter the **Catalogue Number(s).**

_List the catalogue number(s) under which the product is sold in Australia._
3.4 New Prosthesis Device *continued*

**ARTG ID NUMBER**

**STEP 5** – If you have a current ARTG entry (ARTG ID Number) for the product, enter the number into the grey box, and select the correct option from the drop down list.

Once selected, the rest of the table should populate with information.

You will need to provide a new ARTG entry for the compressed prosthesis device.

An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).

You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.

**STEP 6** – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.

Only products entered on the ARTG can be listed on the Prostheses List.

The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.
3.4 New Prosthesis Device continued

View the grouping schemes for each category of product, including Suffix definitions and benefits.

GROUPING

STEP 7 – Select a Category from the drop down menu.

*If the product fits into more than one category, list the category that will represent the greatest use of the product.*

STEP 8 – Select a Subcategory from the drop down menu.

STEP 9 – Select a Group from the drop down menu.

To add a new Group, click Add, enter the new Group name in the space provided, and click Save.

STEP 10 – Select a Subgroup from the drop down menu, if needed.

To add a new Subgroup, click Add, enter the new Subgroup name in the space provided, and click Save.

STEP 11 – Select a Suffix from the drop down menu, if needed.

To add a new Suffix, click Add, enter the new Suffix name in the space provided, and click Save.

*If you add a new Group, Subgroup or Suffix, you will have to fill out the Evidence, Benefit and Economic Information for New Grouping section (3.6 of this guide). If you suggest a new Group, Subgroup or Suffix, the Department will review your evidence and either accept or decline your suggestion.*
3.5 Comparator(s)

A comparator is a current product, treatment or therapy that your prosthesis could replace. A comparative product may be similar in form or function to your product.

**COMPARATOR DETAILS**

**STEP 1** – Choose the comparator option that applies to your device.

- Comparator is an existing item on the Prostheses List, go to STEP 2.
- Comparator is not on the Prostheses List, go to STEP 8.

**STEP 2** – Click Add Comparator.

You must list at least one comparator in your application. Choosing the right comparator(s) is important as it allows clinicians to better understand and assess your product by comparing it to similar products, treatments and therapies.
3.5 Comparator(s) continued

STEP 3 – Search the Prostheses List by:

- **Keyword Search**
- OR

- **Product Grouping** information using the drop down menus

Click Search.

*If you are aware of an appropriate comparator, search by typing in the billing code for that comparator. If you are not aware of a comparator, you may find an appropriate comparator in the same grouping as your prosthesis.*

STEP 4 – Click on the **Billing Code** hyperlink for your chosen comparator in the **Search Results**.
3.5 Comparator(s) continued

STEP 5 – Click Confirm. Your comparator should now be listed on the page.

STEP 6 – Provide a clear explanation on why you have chosen this comparator in the space provided.

Things you might consider in your explanation include:
- The clinical outcome for the product
- How the product is used
- How the product is made

STEP 7 – Add any additional comparators, if needed.

If you have listed more than one comparator for your product, please indicate which is the main comparator by ticking the box. The main comparator is the product that your prosthesis would most often replace.
3. Compress a Listing

3.5 Comparator(s) continued

STEP 8 – Enter the Treatment/Therapy Name.

STEP 9 – Enter a Description of the Treatment/Therapy.

STEP 10 – Enter Benefit/Cost details.

STEP 11 – Provide a clear explanation on why you have chosen this comparator in the space provided.
3.6 Evidence, Benefit and Economic Information for New Grouping

You only need to fill out this page if you have proposed a new Group, Subgroup or Suffix in the New Prosthesis Device section (3.4 of this guide). The Evidence, Benefit and Economic Information for New Grouping page will only appear on your application if applicable.

**PROPOSED BENEFIT**

STEP 1 – Enter the **Proposed Benefit** amount for the product.

STEP 2 – Enter an explanation on how you calculated the benefit amount.

Your explanation should take into consideration:
- Clinical outcomes delivered by the product
- Cost comparisons or savings achieved by using the product

**CLINICAL OUTCOMES**

STEP 3 – Enter the **Clinical Outcomes** delivered by your product.

*Include information on the differences in clinical outcomes for patients between your prosthesis and any comparators.*

*Hint: Factors you may like to consider include:*
- Recovery times
- Failure rates
- Complications
- Life expectancy

The information you provide must be measurable or quantifiable, as well as supported by clinical evidence or data.

Please provide evidence to support your claim in the Attachments section (3.8 of this guide).
3.6 Evidence, Benefit and Economic Information for New Grouping *continued*

**COST COMPARISON**

STEP 4 – Enter details of any cost savings achieved by using the product.

*Include information on any cost savings that can be made by using the product instead of the comparator.*

You may like to consider reductions in:

- Theatre time
- Hospital stay time
- Post-surgical care costs
- Reduced revision surgery

Any reductions listed must be real (not potential or theoretical), and be supported by clinical evidence or data. For any cost savings listed, please include actual amounts.

*Please provide evidence to support your claim in the Attachments section (3.8 of this guide).*
3.6 Evidence, Benefit and Economic Information for New Grouping continued

**PRODUCT UTILISATION**

STEP 5 – Enter into the grey box, the name of any country where your product is sold, and select the correct option from the drop down list.

Enter **Utilisation per year** in the grey box.

Enter **Cost (in local currency)** in the grey box.

Repeat for additional countries.

*Please provide actual utilisation and price information for the product in both public and private markets.*

*If the product has been used in the public system in Australia, please include details.*

STEP 6 – Briefly describe the projected utilisation of the product over the first two years of listing on the Prostheses List.

Briefly describe the basis for your projection by providing evidence to support your projected utilisation.

STEP 7 – Click **Yes** or **No** to indicate whether the use of your product would replace another product.

**OTHER INFORMATION**

STEP 8 – Provide any additional information to support the proposed grouping.
3.7 Comparative Clinical Effectiveness

COMPARATIVE CLINICAL EFFECTIVENESS

STEP 1 – Provide details of **Comparative Clinical Effectiveness** for your product.

Please explain how the clinical effectiveness and cost effectiveness of your product (product system compares with the comparator). Please refer to the clinical evidence you have provided above to support your application."
3.8 Attachments

The documentation you provide in this section is used by clinicians to assess your application.

**ATTACHMENTS**

**STEP 1** – To add an attachment to your application, click **Add**.

**Only upload documentation:**
- In PDF format
- In English
- Specific to the prosthesis

**Do NOT upload:**
- Marketing material for the product

Please number the attachments in the order you would like them to be viewed.
3.8 Attachments continued

**ATTACHMENTS**

STEP 2 – To add an attachment to your application:

- Click **Choose File(s)** to browse your device and insert a file
- OR
- Drag and drop your file into the white panel.

The file will now be listed on the **Attachments** screen.

STEP 3 – Add additional attachments as needed.

STEP 4 – Use the drop down menu under **Type** to select the type of document you have uploaded.

STEP 5 – Enter a brief description for each document you have uploaded.
3.9 Review and Submit

Review all sections of your application to ensure the information you provided is correct.

**REVIEW**

STEP 1 – Review all sections of your application to ensure the information you provided is correct.

If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.

**SUBMIT**

STEP 2 – Tick the box if you agree to the declaration.

STEP 3 – Click **Save** to save the information provided in your application or click **Submit** to submit your application.
4. Amend a Listing

When you Amend a Listing, you are making a change to the product or benefit details for a prosthesis on the Prostheses List.

The application must undergo clinical reassessment if you make changes to the:

- Product name, size or description
- Grouping or benefit details

There is no cost to Amend a Listing.

The steps to Amend a Listing are:

<table>
<thead>
<tr>
<th>Amend a Listing</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 PLMS Home</td>
</tr>
<tr>
<td>4.2 Start Application</td>
</tr>
<tr>
<td>4.3 Select a Listing</td>
</tr>
<tr>
<td>4.4 Amend Listing – Prosthesis Device</td>
</tr>
<tr>
<td>4.5 Comparator(s)</td>
</tr>
<tr>
<td>4.6 Evidence, Benefit and Economic Information for New Grouping*</td>
</tr>
<tr>
<td>4.7 Comparative Clinical Effectiveness</td>
</tr>
<tr>
<td>4.8 Attachments</td>
</tr>
<tr>
<td>4.9 Review and Submit</td>
</tr>
</tbody>
</table>

* You only need to complete this application step if applicable
4.1 PLMS Home

STEP 1 – Click [Create Application] on the left of the screen.
4.2 Start Application

On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List.

**APPLICATION TYPE**

STEP 1 – Select **Amend a Listing** using the drop down menu.

**APPLICATION CONTACTS**

STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.

You can add a **Secondary Contact** to your application, if needed.

STEP 3 – To create a **New Contact** for the application:

- Tick the **Create New Contact** box
- Enter **First Name, Last Name, Phone Number(s)** and **Email** address for the contact

The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department.
4.3 Select a Listing

**SELECTED LISTING**

STEP 1 – Click the option for **Prosthesis Device**.

STEP 2 – Click **Select a Listing** to search for the product on the Prostheses List.
4.3 Select a Listing \textit{continued}

STEP 3 – Search the Prostheses List by:

\begin{itemize}
  \item \textbf{Keyword Search}
  \item OR
  \item \textbf{Product Grouping} information using the drop down menus
\end{itemize}

Click \textit{Search}.

STEP 4 – Click on the \textbf{Billing Code} hyperlink for your chosen product.
4.3 Select a Listing continued

STEP 5 – Click **Confirm**. Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis.
4.3 Select a Listing continued

STEP 6 – Use the drop down menu to select a reason for the amendment.

If the reason is different to what is listed, please explain in the space available.
4.4 Amend Listing – Prosthesis Device

On the Amend Listing – Prosthesis Device page, Product Details should be prefilled with information on the prosthesis device application you intend to amend.

**PRODUCT DETAILS**

STEP 1 – Make any required changes to the Product Details section.

The information you provide for the **Product Name**, **Description** and **Size** will be available on the Prostheses List should your application be successful.
4.4 Amend Listing – Prosthesis Device continued

**ARTG ID NUMBER**

STEP 2 – If you have a current ARTG entry (ARTG ID Number) for the product, enter the number into the grey box, and select the correct option from the drop down list.

Once selected, the rest of the table should populate with information.

The ARTG entry for the product should be the same as for the original listing.

An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).

You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.

STEP 3 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.

Only products entered on the ARTG can be listed on the Prostheses List.

The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.
4. Amend a Listing – Prosthesis Device continued

View the grouping schemes for each category of product, including Suffix definitions and benefits.

GROUPING

STEP 4 – Use the drop down menus to make any required changes to the Grouping section.

- To add a new Group, click Add, enter the new Group name in the space provided, and click Save.

- To add a new Subgroup, click Add, enter the new Subgroup name in the space provided, and click Save.

- To add a new Suffix, click Add, enter the new Suffix name in the space provided, and click Save.

If you add a new Group, Subgroup or Suffix, you will have to fill out the Evidence, Benefit and Economic Information for New Grouping section (4.7 of this guide). If you suggest a new Group, Subgroup or Suffix, the Department will review your evidence and either accept or decline your suggestion.
4.5 Comparator(s)

A comparator is a current product, treatment or therapy that your prosthesis could replace. A comparative product may be similar in form or function to your product.

COMPARATOR DETAILS

STEP 1 – Choose the comparator option that applies to your device.

- Comparator is an existing item on the Prostheses List, go to STEP 2.
- Comparator is not on the Prostheses List, go to STEP 8.

STEP 2 – Click Add Comparator.

You must list at least one comparator in your application. Choosing the right comparator(s) is important as it allows clinicians to better understand and assess your product by comparing it to similar products, treatments and therapies.
4.5 Comparator(s) continued

STEP 3 – Search the Prostheses List by:
- **Keyword Search**
- **Product Grouping** information using the drop down menus

Click **Search**.

*If you are aware of an appropriate comparator, search by typing in the billing code for that comparator. If you are not aware of a comparator, you may find an appropriate comparator in the same grouping as your prosthesis.*

STEP 4 – Click on the **Billing Code** hyperlink for your chosen comparator in the **Search Results**.
4.5 Comparator(s) continued

STEP 5 – Click Confirm. Your comparator should now be listed on the page.

STEP 6 – Provide a clear explanation on why you have chosen this comparator in the space provided.

Things you might consider in your explanation include:

- The clinical outcome for the product
- How the product is used
- How the product is made

STEP 7 – Add any additional comparators, if needed.

If you have listed more than one comparator for your product, please indicate which is the main comparator by ticking the box. The main comparator is the product that your prosthesis would most often replace.
### 4.5 Comparator(s) continued

STEP 8 – Enter the **Treatment/ Therapy Name**.

STEP 9 – Enter a **Description** of the Treatment/ Therapy.

STEP 10 – Enter **Benefit/Cost** details.

STEP 11 – Provide a clear explanation on why you have chosen this comparator in the space provided.
4.6 Comparative Clinical Effectiveness

**COMPARATIVE CLINICAL EFFECTIVENESS**

STEP 1 – Provide details of *Comparative Clinical Effectiveness* for your product.

Please explain how the clinical effectiveness and cost effectiveness of your product (product system compares with the comparator(s)). Please refer to the clinical evidence you have provided above to support your application.

[Input field for Comparative Clinical Effectiveness]
4.7 Evidence, Benefit and Economic Information for New Grouping

You only need to fill out this page if you have proposed a new Group, Subgroup or Suffix in the New Prosthesis Device section (4.4 of this guide). The Evidence, Benefit and Economic Information for New Grouping page will only appear on your application if applicable.

**PROPOSED BENEFIT**

STEP 1 – Enter the **Proposed Benefit** amount for the product.

STEP 2 – Enter an explanation on how you calculated the benefit amount.

*Your explanation should take into consideration:*
  - Clinical outcomes delivered by the product
  - Cost comparisons or savings achieved by using the product

**CLINICAL OUTCOMES**

STEP 3 – Enter the **Clinical Outcomes** delivered by your product.

*Include information on the differences in clinical outcomes for patients between your prosthesis and any comparators.*

*Hint: Factors you may like to consider include:*
  - Recovery times
  - Failure rates
  - Complications
  - Life expectancy

*The information you provide must be measurable or quantifiable, as well as supported by clinical evidence or data.*

*Please provide evidence to support your claim in the Attachments section (4.8 of this guide).*
4.7 Evidence, Benefit and Economic Information for New Grouping continued

COST COMPARISON

STEP 4 – Enter details of any cost savings achieved by using the product.

Include information on any cost savings that can be made by using the product instead of the comparator.

You may like to consider reductions in:

- Theatre time
- Hospital stay time
- Post-surgical care costs
- Reduced revision surgery

Any reductions listed must be real (not potential or theoretical), and be supported by clinical evidence or data. For any cost savings listed, please include actual amounts.

Please provide evidence to support your claim in the Attachments section (4.8 of this guide).
4.7 Evidence, Benefit and Economic Information for New Grouping _continued_

**PRODUCT UTILISATION**

STEP 5 – Enter into the grey box, the name of any country where your product is sold, and select the correct option from the drop down list.

Enter **Utilisation per year** in the grey box.

Enter **Cost (in local currency)** in the grey box.

Repeat for additional countries.

*Please provide actual utilisation and price information for the product in both public and private markets.*

*If the product has been used in the public system in Australia, please include details.*

STEP 6 – Briefly describe the projected utilisation of the product over the first two years of listing on the Prostheses List.

Briefly describe the basis for your projection by providing evidence to support your projected utilisation.

STEP 7 – Click **Yes** or **No** to indicate whether the use of your product would replace another product.

**OTHER INFORMATION**

STEP 8 – Provide any additional information to support the proposed grouping.
4.8 Attachments

The documentation you provide in this section is used by clinicians to assess your application.

**ATTACHMENTS**

**STEP 1** – To add an attachment to your application, click **Add**.

**In your supporting documentation, please attach:**

- A before and after image of the prosthesis
- An explanation of what is different and why

**Only upload documentation:**

- In PDF format
- In English
- Specific to the prosthesis

**Do NOT upload:**

- Marketing material for the product

*Please number the attachments in the order you would like them to be viewed.*
4.8 Attachments  

The documentation you provide in this section is used by clinicians to assess your application.

ATTACHMENTS

STEP 2 – To add an attachment to your application:

- Click + Choose File(s) to browse your device and insert a file
  OR
- Drag and drop your file into the white panel.

The file will now be listed on the Attachments screen.

STEP 3 – Add additional attachments as needed.

STEP 4 – Use the drop down menu under Type to select the type of document you have uploaded.

STEP 5 – Enter a brief description for each document you have uploaded.
4.9 Review and Submit

Review all sections of your application to ensure the information you provided is correct.

REVIEW

STEP 1 – Review all sections of your application to ensure the information you provided is correct.

If you find an error in your application, click Edit, at the top right of the section. This will take you back to the relevant page where you can make any edits required.

SUBMIT

STEP 2 – Tick the box if you agree to the declaration.

STEP 3 – Click Save to save the information provided in your application or click Submit to submit your application.
5. Duplicate a Listing

When you Duplicate a Listing, you are making a copy of a current prostheses listing held by another sponsor.

When you Duplicate a Listing:

- The original billing code for the prosthesis will remain on the Prostheses List, and you will receive a new billing code for the duplicated product
- The product will not need to be clinically reassessed

There is no cost to Duplicate a Listing.

The steps to Duplicate a Listing are:

<table>
<thead>
<tr>
<th></th>
<th>Duplicate a Listing</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>PLMS Home</td>
</tr>
<tr>
<td>5.2</td>
<td>Start Application</td>
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<tr>
<td>5.3</td>
<td>Select a Duplicate Listing</td>
</tr>
<tr>
<td>5.4</td>
<td>Duplicate a Prostheses Listing</td>
</tr>
<tr>
<td>5.5</td>
<td>Attachments</td>
</tr>
<tr>
<td>5.6</td>
<td>Review and Submit</td>
</tr>
</tbody>
</table>
5.1 PLMS Home

STEP 1 – Click **Create Application** on the left of the screen.
5.2 Start Application

On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List.

**APPLICATION TYPE**

STEP 1 – Select **Duplicate a Listing** using the drop down menu.

**APPLICATION CONTACTS**

STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.

You can add a **Secondary Contact** to your application, if needed.

STEP 3 – To create a **New Contact** for the application:

- Tick the **Create New Contact** box
- Enter **First Name, Last Name, Phone Number(s)** and **Email** address for the contact

*The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department.*
5.3 Select a Duplicate Listing

On the Select a Duplicate Listing page, select the prosthesis device from the Prostheses List you want to duplicate.

**SELECTED LISTING**

**STEP 1** – Click **Select a Listing** to search for the product on the Prostheses List.
5.3 Select a Duplicate Listing continued

STEP 3 – Search the Prostheses List by:
- **Keyword Search**
- **Product Grouping** information using the drop down menus

Click Search.

STEP 4 – Click on the Billing Code hyperlink for your chosen product.
5.3 Select a Duplicate Listing *continued*

STEP 5 – Click **Confirm**. Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis.

![Image of the selection interface](image-url)
5.4 Duplicate a Prostheses Listing

On the Duplicate a Prostheses Listing page, the Product Details will be prefilled with information.

**PRODUCT DETAILS**

STEP 1 – Enter the **Catalogue Number(s)**.

*List the catalogue number(s) under which the product is sold in Australia.*
5.4 Duplicate a Prostheses Listing continued

**ARTG ID NUMBER(S)**

STEP 2 – If you have a current ARTG entry (ARTG ID Number) for the product, enter the number into the grey box, and select the correct option from the drop down list.

Once selected, the rest of the table should populate with information.

*You will need to provide a new ARTG entry for the duplicated prosthesis device.*

An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).

*You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.*

STEP 3 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.

*Only products entered on the ARTG can be listed on the Prostheses List.*

*The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.*
5.5 Attachments

The documentation you provide in this section is used by clinicians to assess your application.

**ATTACHMENTS**

**STEP 1** – To add an attachment to your application, click **Add**.

In your supporting documentation, please attach:

- A letter of authority from the original sponsor giving approval for the duplication

Only upload documentation:

- In PDF format
- In English
- Specific to the prosthesis

Do NOT upload:

- Marketing material for the product

Please number the attachments in the order you would like them to be viewed.
5.5 Attachments continued

**ATTACHMENTS**

STEP 2 – To add an attachment to your application:

- Click + Choose File(s) to browse your device and insert a file
  OR
- Drag and drop your file into the white panel.

The file will now be listed on the Attachments screen.

STEP 3 – Add additional attachments as needed.

STEP 4 – Use the drop down menu under Type to select the type of document you have uploaded.

STEP 5 – Enter a brief description for each document you have uploaded.
5.6 Review and Submit

Review all sections of your application to ensure the information you provided is correct.

**REVIEW**

STEP 1 – Review all sections of your application to ensure the information you provided is correct.

If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.

**SUBMIT**

STEP 2 – Tick the box if you agree to the declaration.

STEP 3 – Click **Save** to save the information provided in your application or click **Submit** to submit your application.
6. Transfer a Listing

When you Transfer a Listing, you are transferring a current prostheses listing to your organisation from another sponsor.

The receiving sponsor is responsible for submitting the application to transfer a listing.

There is no cost to Transfer a Listing.

The steps to Transfer a Listing are:

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>PLMS Home</td>
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<tr>
<td>6.2</td>
<td>Start Application</td>
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<tr>
<td>6.3</td>
<td>Transfer a Prostheses Listing</td>
</tr>
<tr>
<td>6.4</td>
<td>Attachments</td>
</tr>
<tr>
<td>6.5</td>
<td>Review and Submit</td>
</tr>
</tbody>
</table>
6. Transfer a Listing

6.1 PLMS Home

STEP 1 – Click **Create Application** on the left of the screen.
6.2 Start Application

On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List.

**APPLICATION TYPE**

STEP 1 – Select **Transfer a Listing** using the drop down menu.

**APPLICATION CONTACTS**

STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.

You can add a **Secondary Contact** to your application, if needed.

STEP 3 – To create a **New Contact** for the application:

- Tick the **Create New Contact** box
- Enter **First Name**, **Last Name**, **Phone Number(s)** and **Email** address for the contact

*The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department.*
6.3 Transfer a Prostheses Listing

On the Transfer a Prostheses Listing page, select the prostheses listing you want to transfer to your organisation.

**SELECTED LISTING**

STEP 1 – Click **Select a Listing** to search for the product on the Prostheses List.
6.3 Transfer a Prostheses Listing continued

STEP 2 – Search the Prostheses List by:

- **Keyword Search**
- **Product Grouping** information using the drop down menus

Click Search.

STEP 3 – Click on the **Billing Code** hyperlink for your chosen product.
6.3 Transfer a Prostheses Listing *continued*

**STEP 4** – Click **Confirm**. Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis.
6.3 Transfer a Prostheses Listing continued

**CATALOGUE NUMBER(S)**

STEP 5 – Enter the Catalogue Number(s).

List the catalogue number(s) under which the product is sold in Australia.

**ARTG ID NUMBER(S)**

STEP 6 – If you have a current ARTG entry (ARTG ID Number) for the product, enter the number into the grey box, and select the correct option from the drop down list.

Once selected, the rest of the table should populate with information.

You will need to provide a new ARTG entry for the prosthesis device when transferring it to your organisation.

An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).

You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.

STEP 7 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.

Only products entered on the ARTG can be listed on the Prostheses List.

The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.
6.4 Attachments

The documentation you provide in this section is used by clinicians to assess your application.

ATTACHMENTS

STEP 1 – To add an attachment to your application, click Add.

In your supporting documentation, please attach:

- A letter or authority from the original sponsor and new sponsor giving approval for the transfer.

Only upload documentation:

- In PDF format
- In English
- Specific to the prosthesis

Do NOT upload:

- Marketing material for the product

Please number the attachments in the order you would like them to be viewed.
6.4 Attachments continued

ATTACHMENTS

STEP 2 – To add an attachment to your application:
- Click + Choose File(s) to browse your device and insert a file
- OR
- Drag and drop your file into the white panel.

The file will now be listed on the Attachments screen.

STEP 3 – Add additional attachments as needed.

STEP 4 – Use the drop down menu under Type to select the type of document you have uploaded.

STEP 5 – Enter a brief description for each document you have uploaded.
6.5 Review and Submit

Review all sections of your application to ensure the information you provided is correct.

**REVIEW**

STEP 1 – Review all sections of your application to ensure the information you provided is correct.

If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.

**SUBMIT**

STEP 2 – Tick the box if you agree to the declaration.

STEP 3 – Click **Save** to save the information provided in your application or click **Submit** to submit your application.
7. Delete a Listing

When you Delete a Listing, you are removing a product from the Prostheses List.

You may choose to Delete a Listing if:

- Your organisation no longer sells the product, and it is not being transferred to another sponsor
- The product is being replaced by another product
- The product is no longer registered on the ARTG
- The company no longer exists

The listing for the product will be removed on the next version of the Prostheses List.

There is no cost to Delete a Listing deleting a listing.

The steps to Delete a Listing are:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1</td>
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<tr>
<td>7.2</td>
<td>Start Application</td>
</tr>
<tr>
<td>7.3</td>
<td>Delete a Listing</td>
</tr>
<tr>
<td>7.4</td>
<td>Review and Submit</td>
</tr>
</tbody>
</table>
7. Delete a Listing

7.1 PLMS Home

STEP 1 – Click **Create Application** on the left of the screen.
7.2 Start Application

On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List.

**APPLICATION TYPE**

STEP 1 – Select **Delete a Listing** using the drop down menu.

**APPLICATION CONTACTS**

STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information. You can add a **Secondary Contact** to your application, if needed.

STEP 3 – To create a **New Contact** for the application:

- Tick the **Create New Contact** box
- Enter **First Name**, **Last Name**, **Phone Number(s)** and **Email** address for the contact

*The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department.*
7.3 Delete a Listing

On the Delete a Listing page, select the prosthesis device from the Prostheses List you wish to delete.

**DELETE A LISTING**

STEP 1 – Click the option for *Prosthesis Device*.

**SELECTED LISTING**

STEP 2 – Click *Select a Listing* to search for the product on the Prostheses List.
7.3 Delete a Listing continued

STEP 3 – Search the Prostheses List by:

- **Keyword Search**
- OR

**Product Grouping** information using the drop down menus

Click **Search**.

STEP 4 – Click on the **Billing Code** hyperlink for your chosen product.

---

<table>
<thead>
<tr>
<th>Billing Code</th>
<th>Product Name</th>
<th>Product Description</th>
<th>Product Grouping</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>981 982</td>
<td>Penetron-Monofilament Polypropylene standard mesh / light mesh / shaped mesh</td>
<td>03 - General Wound Repair - 03.06 - CLOSURE DEVICES</td>
<td>03.06.00 - Polypropylene/Mesh</td>
<td>Coherent Pty Ltd</td>
</tr>
<tr>
<td>981 983</td>
<td>Vascobraid PENETRON Straight Standard Wall</td>
<td>10 - Vascular - 10.02 - Dilatation</td>
<td>10.02 - Stents</td>
<td>B Braun Australia</td>
</tr>
</tbody>
</table>
7.3 Delete a Listing continued

STEP 5 – Click Confirm. Your product should now be listed on the page.

REASON FOR DELETION

STEP 6 – Use the drop down menu to select a reason for deleting the product from the Prostheses List.
7.4 Review and Submit

Review all sections of your application to ensure the information you provided is correct.

**REVIEW**

STEP 1 – Review all sections of your application to ensure the information you provided is correct.

If you find an error in your application, click Edit, at the top right of the section. This will take you back to the relevant page where you can make any edits required.

**SUBMIT**

STEP 2 – Tick the box if you agree to the declaration.

STEP 3 – Click Save to save the information provided in your application or click Submit to submit your application.