

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:

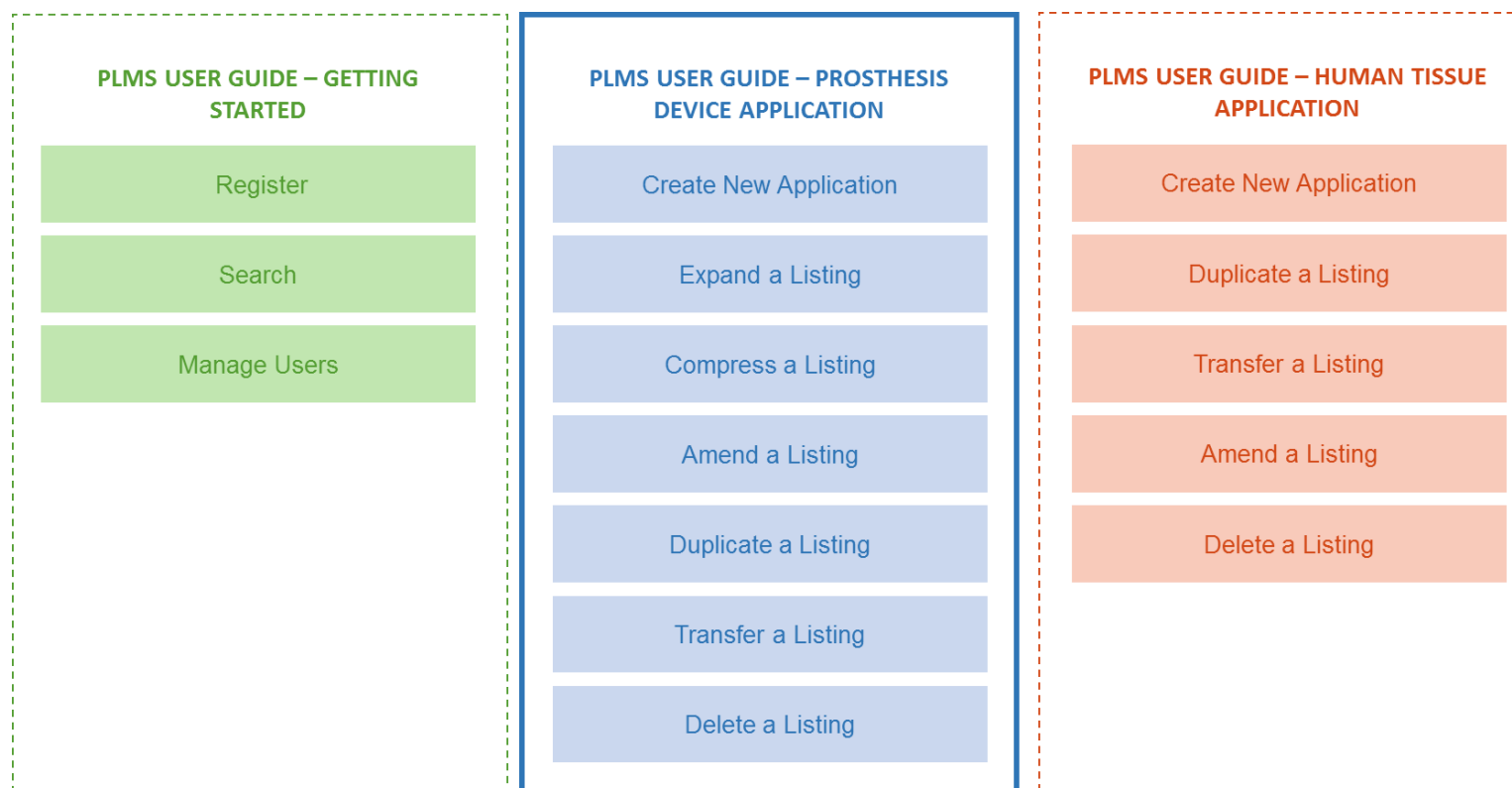
1. Creating a New Application
2. Expanding a Listing
3. Compressing a Listing
4. Amending a Listing
5. Duplicating a Listing
6. Transferring a Listing
7. Deleting a Listing

If you have any questions about using the Prostheses List Management System, contact the Department of Health at prostheses@health.gov.au

PLMS User Guides

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)



PROSTHESES LIST MANAGEMENT SYSTEM – USER GUIDE

PLMS Home

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

Protheses List Management System

Home

Create Application Click here to create, delete, transfer, amend, expand, compress or duplicate a listing.

Manage Users Click here to manage user access roles.

Search Click here to search for applications.

RECENT APPLICATIONS				
Reference Number	Type	Status	Last Modified	Actions
N000010	NEW	Draft	12/07/2017 17:22. HEALTH	
R000005	DUPLICATE	Submitted	14/06/2017 16:14	
D000004	DELETE	View Status Details	14/06/2017 16:12	
03HV-ORF5	AMEND	Application Recommended, Pending ARTG and/or MBS	24/05/2017 09:11. HEALTH	
0075-XMLG	AMEND	Application Recommended	23/05/2017 14:47. HEALTH	
N000004	NEW	Submitted	19/05/2017 15:33	
J4GU-GQLY	DUPLICATE	Draft	16/03/2017 10:52. HEALTH	
D5UR-4K1G	NEW	Cancelled	16/03/2017 10:39. HEALTH	
GSF8-NKRW	NEW	Draft	16/03/2017 09:51. HEALTH	
AX0Q-9K6N	DELETE	View Status Details	01/03/2017 11:11. HEALTH	

[Show All](#) →

NOTIFICATIONS	
Date	Description
31/07/2017 07:49	Your Access Roles have changed
31/07/2017 07:43	has registered for the Protheses List Management System
12/07/2017 17:22	Application (N000010) has been created
16/06/2017 10:46	Data Portal - Interactive_Report_Viewers1 DP has registered for the System
16/06/2017 10:40	Data Portal - Interactive_Report_Developers1 DP has registered for the System
14/06/2017 16:14	Application Status of PEEK Interbody system - Cervical (R000005) has been updated to SUBMITTED
14/06/2017 16:12	Application (R000005) has been created
14/06/2017 16:12	Application Status of (D000004) has been updated to CANCELLED
14/06/2017 16:11	Application (D000004) has been created

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

WHAT	HELPFUL HINT
Mandatory fields	Mandatory fields are marked with an asterisk (*). These fields need to be completed in order to progress to the next screen
Error messages	Error messages will appear in red text if information in a field is missing or incorrect. These error messages will appear at the top of the screen, and you will need to scroll to the top of the page to see them
Save	Click the Save button to save information on a page
Next	Click the Next button to save information and go to the next page
Previous	Click the Previous button to go to the previous page. Ensure you save information on the current page by clicking the Save button
Cancel Application	Click the Cancel Application button to discard your application
Application Summary	Click the Application Summary button to view a summary of your application
Exit Application	Click the Exit Application button to leave your application. Ensure you save information on the current page by clicking the Save button
?	Click on the  icon to view help text for a page.

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:

Create New Application

- | | |
|------|--|
| 1.1 | PLMS Home |
| 1.2 | Start Application |
| 1.3 | Product Summary |
| 1.4 | New Prosthesis Device |
| 1.5 | Comparator(s) |
| 1.6 | Evidence, Benefit and Economic Information for New Grouping* |
| 1.7 | MBS Item(s) |
| 1.8 | Product Setting and Product Purpose |
| 1.9 | Comparative Clinical Effectiveness |
| 1.10 | Attachments |
| 1.11 | Review and Submit |
| 1.12 | Application Summary |

* 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.

RECENT APPLICATIONS

Reference Number	Type	Status	Last Modified	Actions
N00010	NEW	Draft	12/07/2017 17:22, HEALTH	View Status Details
R000005	DUPLICATE	Submitted	14/06/2017 16:14	View Status Details
D000004	DELETE	View Status Details	14/06/2017 16:12	View Status Details
03HV-ORF5	AMEND	Application Recommended, Pending ARTG and/or MBS	24/05/2017 09:11, HEALTH	View Status Details
0075-XMLG	AMEND	Application Recommended	23/05/2017 14:47, HEALTH	View Status Details
N000004	NEW	Submitted	19/05/2017 15:33	View Status Details
J4GU-GQLY	DUPLICATE	Draft	16/03/2017 10:52, HEALTH	View Status Details
D0UR-4K1G	NEW	Cancelled	16/03/2017 10:39, HEALTH	View Status Details
G0F8-NKRW	NEW	Draft	16/03/2017 09:51, HEALTH	View Status Details
AX0Q-9KGN	DELETE	View Status Details	01/03/2017 11:11, HEALTH	View Status Details

[Show All](#)

NOTIFICATIONS

Date	Description
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16/06/2017 10:40	Data Portal - Interactive_Report_Developer1 DP has registered for the System
14/06/2017 16:14	Application Status of PEEK Interbody system - Cervical (R000005) has been updated to SUBMITTED
14/06/2017 16:12	Application (R000005) has been created
14/06/2017 16:12	Application Status of (D000004) has been updated to CANCELLED
14/06/2017 16:11	Application (D000004) has been created

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.

*Mandatory field

Start Application ?

Application Type

Select Application Type * — Choose type —

Application Contacts

Select a Primary Contact * Samantha Smith

☐ Create New Contact

Phone Number #1 Office (02) 0000 0000

Phone Number #2 Mobile (0400) 000 000

Email Samantha@health.gov.au

Select a Secondary Contact — Choose contact —

☐ Create New Contact

Phone Number #1 — Choose type —

Phone Number #2 — Choose type —

Email e.g. example@domain.com.au

Application Contacts

Select a Primary Contact * — Choose contact —

☒ Create New Contact

First Name

Last Name

Phone Number #1 — Choose type —

Phone Number #2 — Choose type —

Email e.g. example@domain.com.au

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

*Mandatory field

Product Summary ?

Product Type

What type of product are you applying to list?

☐ Prosthesis Device

☐ Human Tissue

Prev Save Next

What type of product are you applying to list?

☒ Prosthesis Device

☐ Human Tissue

Are you applying to list a Product System (multiple related products)?

☐ Yes

☐ No

Are you applying to list a Product System (multiple related products)?

☒ Yes

☐ No

Product System Name *

Knee system

Products System Components

Product #	Product Name
-----------	--------------

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*

What type of product are you applying to list?

☒ Prosthesis Device

☐ Human Tissue

Are you applying to list a Product System (multiple related products)?

☒ Yes

☐ No

Product System Name *

Knee system

Products System Components:

Product #	Product Name
1	xxx

Add Product

Prev Save Next

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

* Mandatory field

New Prosthesis Device ?

Product Details

Product Name: *

Description: *

Size(s): *

Catalogue Number(s) *

ARTG ID Number

Please identify the ARTG ID Number(s) below for your product: *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class
Enter Number			

(please separate numbers using a comma (,) delimiter or enter each number on a new line)

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

Please identify the ARTG ID Number(s) below for your product: *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class	
<input type="text" value="Enter Number"/>				

☒ Alternatively, tick here if you have applied to include your device on the ARTG
(ARTG ID Number is pending)

Grouping

Select Category *

Select Subcategory *

Select Group *

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 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 (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.

*Mandatory field

Comparator(s) ?

Comparator Details

Please list the comparator(s) (maximum of 5) for your product: *

☐ Comparator is an existing item on the prostheses list
☐ Comparator is not on the prostheses list (other treatment or therapy)
☐ No Comparator assessment required

Add Comparator

Prev Save Next

Comparator Details

Please list the comparator(s) (maximum of 5) for your product: *

☒ Comparator is an existing item on the prostheses list
☐ Comparator is not on the prostheses list (other treatment or therapy)
☐ No Comparator assessment required

Add Comparator

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*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code

Product Name

Product Description

Sponsor Name

Product Grouping

Select Category

Select Subcategory

Select Group

Select Subgroup

Select Suffix(es)

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh		02 - General Miscellaneous 03.06 - CLOSURE DEVICES 03.06.05 - Polypropylene/Polyester Mesh 03.06.05.04 - >800-<2500cm ²	Covidien Pty Ltd
BB123	Vasougraft	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

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*

Confirm Selected Listing

Billing Code	AS123
Sponsor	Covidien Pty Ltd
Product Name	Parietene-Monofilament Polypropylene mesh
Description	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh
Size(s)	30 X 30 cm, 30 x 32 cm
Benefit	\$275
Category	03 - General Miscellaneous
Subcategory	03.08 - CLOSURE DEVICES
Group	03.08.05 - Polypropylene/Polyester Mesh
Subgroup	03.08.05.04 - >600<=2500cm²
Suffixes	

Confirm **Cancel**

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.

Comparator(s)

Comparator Details

Please list the comparator(s) (maximum of 5) for your product. *

☒ Comparator is an existing item on the prostheses list
☐ Comparator is not on the prostheses list
☐ No Comparator assessment required

Delete

Billing Code:	AS123
Comparator Product Name:	Parietene-Monofilament Polypropylene mesh
Comparator Grouping:	03 - General Miscellaneous 03.08 - CLOSURE DEVICES 03.08.05 - Polypropylene/Polyester Mesh 03.08.05.04 - >600<=2500cm²

Comparator Selection Explanation

500 characters remaining

☒ Main Comparator for Product

1.5 Comparator(s) *continued*

* Mandatory field

Comparator(s) ?

Comparator Details

Please list the comparator(s) (maximum of 5) for your product: *

☐ Comparator is an existing item on the prostheses list.
☒ Comparator is not on the prostheses list.
☐ No Comparator assessment required.

Delete

Treatment/Therapy Name*

Description

Benefit/Cost*

Comparator Selection Explanation

800 characters remaining

☒ Main Comparator for Product

☐ Comparator is an existing item on the prostheses list.
☒ Comparator is not on the prostheses list (other treatment or therapy).
☐ No Comparator assessment required.

Add Comparator

Prev Save Next

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).

*Mandatory field

Evidence, Benefit and Economic Information for New Grouping

Product Name: Medishield Anti-Adhesion Gel
 Category: 03 - General Miscellaneous
 SubCategory: 03.08 - CLOSURE DEVICES
 Group: xx
 SubGroup:
 Suffix(es):
 Proposed Benefit: \$1300

Proposed Benefit

Proposed Benefit (amount is exclusive of GST): *

Please explain how you calculated this benefit: *

500 characters remaining
 (supporting document may be uploaded in the Attachments section)

Clinical Outcomes

Please identify the quantifiable or measurable clinical outcomes delivered by your product, compared with the comparator(s). Refer to the measurable and/or quantifiable factors relating to patient outcomes, such as recovery time, failure rates, complications, life expectancy: *

1000 characters remaining.

Cost Comparison

Please provide details of measurable evidence of any cost savings achieved through the use of the product: *

1.6 Evidence, Benefit and Economic Information for New Grouping *continued*

1000 characters remaining

Cost Comparison

Please provide details of measurable evidence of any cost savings achieved through the use of the product: *

4000 characters remaining

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

If your product is sold in Australia and/or any other country, please provide utilisation and price details below:

Country	Utilisation per year	Cost (in local currency)	
<input type="text" value="Enter text"/>	<input type="text" value="Enter text"/>	<input type="text" value="Enter text"/>	

What is the projected utilisation of the product over the first two years of listing on the Prostheses List? *

200 characters remaining

What is the basis for the projection? *

1500 characters remaining

Will the use of this product replace the use of another product? *

☐ Yes ☐ No

Other Information

Is there any other information you can provide to support your proposed benefits for your product?

4000 characters remaining

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.

*Mandatory field

MBS Item(s) 

Medical Benefits Schedule (MBS) Item(s) and Descriptor(s)

Please list up to ten (10) MBS item numbers for professional services in which the product is intended to be implanted or applied. *

(Note: An application will be processed without an MBS Number however it will not be listed until a valid MBS Number is provided by the sponsor).

MBS Item Number	MBS Item Description
No records found.	

[Add MBS Item](#)

☐ Alternatively, tick here if you have applied for an MBS item number (MBS item(s) number is Pending).

Please provide a reason for selecting the above MBS item(s): *

Enter text...

1000 characters remaining

[Prev](#) [Save](#) [Next](#)

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.

Keyword Search

Conduct a keyword search using an MBS Item number or MBS Item Description.

[Search](#) [Cancel](#)

Search Results

To select an item, please click the MBS Item Number hyperlink

MBS Item Number	MBS Item Description
112	Professional attendance on a patient by a consultant physician or specialist practising in his or her specialty of geriatric medicine if: (a) the attendance is by video conference; and (b) item 141 or 143 applies to the attendance; and (c) the patient is not an admitted patient; and
122	Professional attendance at a place other than consulting rooms or hospital, by a consultant physician in the practice of his or her specialty (other than psychiatry) following referral of the patient to him or her by a referring practitioner-initial attendance in a single course of treatment
128	Professional attendance at a place other than consulting rooms or hospital, by a consultant physician in the practice of his or her specialty (other than psychiatry) following referral of the patient to him or her by a referring practitioner-each attendance (other than a service to which item
288	Professional attendance on a patient by a consultant physician practising in his or her specialty of psychiatry if: (a) the attendance is by video conference; and (b) item 291, 293, 298, 300, 302, 304, 306, 308, 310, 312, 314, 316, 318, 319, 348, 350 or 352 applies to the attendance;
291	Professional attendance of more than 45 minutes in duration at consulting rooms by a consultant physician in the practice of his or her specialty of psychiatry, if: (a) the attendance follows referral of the patient to the consultant for an assessment or management by a medical practitioner
293	Professional attendance of more than 30 minutes but not more than 45 minutes in duration at consulting rooms by a consultant physician in the practice of his or her specialty of psychiatry, if: (a) the patient is being managed by a medical practitioner or a participating nurse practitioner
312	Professional attendance by a consultant physician in the practice of his or her specialty of psychiatry following referral of the patient to him or her by a referring practitioner-an attendance of more than 15 minutes, but not more than 30 minutes, in duration at consulting rooms, if that attendance
319	- An attendance of more than 45 minutes duration at consulting rooms, where that attendance and any other attendance to which items 300 to 308 or 319 apply exceed 50 but not more than 160 attendances in a 12 month period and where the patient has: (i) a history of severe sexual or physical
353	Professional attendance by a consultant physician in the practice of his or her specialty of psychiatry following referral of the patient to him or her by a referring practitioner-a telepsychiatry consultation of not more than 15 minutes in duration, if: (a) that attendance and another at
355	Professional attendance by a consultant physician in the practice of his or her specialty of psychiatry following referral of the patient to him or her by a referring practitioner-a telepsychiatry consultation of more than 15 minutes, but not more than 30 minutes, in duration, if: (a) that

Showing 1 to 10 of 562 entries

[New Search](#) [Cancel](#)

1000 characters remaining

1.7 MBS Item(s) *continued*

Confirm Selected Item

MBS Item Number: 112

MBS Item Description: Professional attendance on a patient by a consultant physician or specialist practising in his or her specialty of geriatric medicine if:
(a) the attendance is by video conference; and
(b) item 141 or 143 applies to the attendance; and
(c) the patient is not an admitted patient; and

Confirm **Cancel**

MBS Item Number | MBS Item Description

No records found.

Add MBS Item

☒ Alternatively, tick here if you have applied for an MBS Item number (MBS Item(s) number is Pending).

Please provide a reason for selecting the above MBS item(s): *

Enter text...

1000 characters remaining

Prev **Save** **Next**

MBS Item Number | MBS Item Description

No records found.

Add MBS Item

☒ Alternatively, tick here if you have applied for an MBS Item number (MBS Item(s) number is Pending).

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

*Mandatory field

Product Setting and Product Purpose

Product Setting

Please select the setting in which the product/product system is provided *

☐ (a) Patient is receiving treatment in hospital

☐ (b) Patient is receiving hospital substitute treatment

☐ (c) Patient is receiving treatment outside of hospital

Product Setting

Please select the setting in which the product/product system is provided *

☐ (a) Patient is receiving treatment in hospital

☐ (b) Patient is receiving hospital substitute treatment

☒ (c) Patient is receiving treatment outside of hospital

Please describe *

Enter text...

1200 characters remaining

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

Please select the purpose of the product/product system *

☒ (a) The product is surgically implanted in the patient and purposely designed in order to:
 (i) replace an anatomical body part; or
 (ii) combat a pathological process; or
 (iii) modulate a physiological process?

☐ (b) The product is essential to and specifically designed as an integral single-use aid for implanting a product described in (a) (i), (ii) or (iii) which is only suitable for use in the patient in whom the product is implanted

☐ (c) The product is critical to the continuing function of the surgically implanted product to achieve the outcomes described in (a) (i), (ii) or (iii), and only suitable for use by the patient in whom that product has been implanted

Briefly explain the function of the product *

Enter text...

2000 characters remaining

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.

☐ (a) The product is surgically implanted in the patient and purposely designed in order to:
 (i) replace an anatomical body part; or
 (ii) combat a pathological process; or
 (iii) modulate a physiological process?

☒ (b) The product is essential to and specifically designed as an integral single-use aid for implanting a product described in (a) (i), (ii) or (iii) which is only suitable for use in the patient in whom the product is implanted

☐ (c) The product is critical to the continuing function of the surgically implanted product to achieve the outcomes described in (a) (i), (ii) or (iii), and only suitable for use by the patient in whom that product has been implanted

Please advise what the surgically implanted product is that this product is integral to implanting *

Enter text...

200 characters remaining

Briefly explain the function of the product *

Enter text...

2000 characters remaining

1.8 Product Setting and Product Purpose *continued*

Product Purpose

Please select the purpose of the product/product system *

☐ (a) The product is surgically implanted in the patient and purposely designed in order to:
 (i) replace an anatomical body part; or
 (ii) combat a pathological process; or
 (iii) modulate a physiological process?

☐ (b) The product is essential to and specifically designed as an integral single-use aid for implanting a product described in (a) (i), (ii) or (iii) which is only suitable for use in the patient in whom the product is implanted

☒ (c) The product is critical to the continuing function of the surgically implanted product to achieve the outcomes described in (a) (i), (ii) or (iii), and only suitable for use by the patient in whom that product has been implanted

Please advise what the surgically implanted product is that this product is critical to the continuing function of *

Enter text...

200 characters remaining

Briefly explain the function of the product *

Enter text...

2000 characters remaining

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

*Mandatory field

Comparative Clinical Effectiveness ?

Overseas Status

Has authority been given to sell this product / product system in any other country? *

☒ Yes
☐ No
☐ Unknown / Not available

Please provide information about the approvals *

Enter text...

1000 characters remaining

Has the product/product system been sold or being sold, under any other name in any country? *

☒ Yes
☐ No

Please provide the name(s) *

Enter text...

300 characters remaining

OVERSEAS STATUS

STEP 1 – Select the appropriate option for the product.

- If you choose **Yes**, got 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**, got 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*

The screenshot shows a web form titled 'Comparative Clinical Effectiveness'. At the top left, there is a radio button labeled 'No'. Below the title, a text box contains the instruction: '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 *'. Below this instruction is a large text input area with the placeholder text 'Enter text...'. At the bottom left of the text area, it says '1000 characters remaining'. At the bottom of the form, there are three buttons: 'Prev' (disabled), 'Save' (active), and 'Next' (active).

COMPARATIVE CLINICAL EFFECTIVENESS

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

1.10 Attachments

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

Attachments

Listed below are attachments related to your application. Please upload all relevant files prior to submitting your application.

Required Attachments:

- An image of the product (Attachment Type = Product Image)
- Supporting literature - full studies/report (Attachment Type = Supporting Literature)
- Documentation to support the proposed benefit (Attachment Type = Supporting Document)

Optional Attachments:

- Economic and cost analysis studies/reports (Attachment Type = Econ & Cost Analysis)
- Overseas approval certificates - e.g. CE mark, FDA approval (Attachment Type = Overseas Approval Cert)
- ARTG certificate (if available) (Attachment Type = ARTG Certificate)
- Documentation describing: product features, indications, contraindications, technical specifications, instructions for use, surgical technique etc. (Attachment Type = Other)

File Name	Type *	Description / Study Name & Journal Reference *
No records found.		

[Add](#)

[Prev](#) [Save](#) [Next](#)

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*

*Mandatory field

Select File(s): *

+ Choose File(s)

Drag and drop file(s) into the panel above

Cancel

File Name	Type *	Description / Study Name & Journal Reference *
PLMS.docx.pdf	Financial Statement ▼ Financial Statement	
PLMS.docx.pdf	Supporting Document ▼	

Add

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.

* Mandatory field

Review ?

Application Fee: \$600

The application fee's can be paid:

- **By cheque:**
Payable to: Attention: Accounts, Department of Health, GPO Box 9848, CANBERRA ACT 2601
- **By credit card:**
Please call (02) 6289 1095 (Max: \$15,000)
Please quote:
 - Cost Centre: 308025
 - GL: 4100004000
 - Internal Order code: DPROSAPPLIC
- **By EFT:**
BSB No: 092 009
Account No: 115031
Please quote "GL4100004000" and as much of your sponsor name as possible, in the "To account" information field.

Application Type: Create New Listing - Prosthesis Device

Application Contacts Edit

Primary Contact:

Phone Number #1:

Submit

Submit Application:

(This section must be completed by a user with the "Approver" role)

☐ I declare that all information provided in this application is true and correct. I agree to pay the application fee listed above. *

Prev Save Submit

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

Cancel Application View/Edit Application Exit Application

Application Type: NEW
Reference Number: ND000013
Product / System: xxx

Status: Submitted
Last Update Date: 31/07/2017 10:31

Print as RTF Print as PDF

ATTACHMENTS				
Name	Date Uploaded	Type	Size	Available Actions
PLMS doc.pdf	31/07/2017 10:25	PDF	40 KB	
PLMS doc.pdf	31/07/2017 10:25	PDF	40 KB	

STATUS/NOTIFICATION HISTORY	
Status	Date/Description
Submitted	31/07/2017 10:31
Draft	31/07/2017 10:07

MANAGE APPLICATION ACCESS

To change access to this application select the applicable option and remember to save changes.

ACCESS LEVELS

Alert! This is the default access for an Application unless it is modified by an appropriately delegated user belonging to that particular organisation

☒ Open to All

☐ Allow Access to

☐ Deny Access to

Application Contacts have access to the application by default (access cannot be omitted)

Primary Contact: Samantha Smith

Secondary Contact: <Not Listed>

Save Cancel

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** 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:

Expand a Listing

- 2.1 PLMS Home
- 2.2 Start Application
- 2.3 Expand a Prostheses Listing
- 2.4 New Prosthesis Device
- 2.5 Comparator(s)
- 2.6 Evidence, Benefit and Economic Information for New Grouping*
- 2.7 Comparative Clinical Effectiveness
- 2.8 Attachments
- 2.9 Review and Submit

* You only need to complete this application step if applicable

2.1 PLMS Home

RECENT APPLICATIONS

Reference Number	Type	Status	Last Modified	Actions
N000010	NEW	Draft	12/07/2017 17:22, HEALTH	View Edit
R000005	DUPLICATE	Submitted	14/06/2017 16:14	View Edit
D000004	DELETE	View Status Details	14/06/2017 16:12	View Edit
03HV-0RF5	AMEND	Application Recommended, Pending ARTG and/or MBS	24/05/2017 09:11, HEALTH	View Edit
0075-XMLG	AMEND	Application Recommended	23/05/2017 14:47, HEALTH	View Edit
N000004	NEW	Submitted	19/05/2017 15:33	View Edit
J4GU-GQLY	DUPLICATE	Draft	16/03/2017 10:52, HEALTH	View Edit
DSUR-4K1G	NEW	Cancelled	16/03/2017 10:39, HEALTH	View Edit
GSF8-NKRW	NEW	Draft	16/03/2017 09:51, HEALTH	View Edit
AX0Q-9K6N	DELETE	View Status Details	01/03/2017 11:11, HEALTH	View Edit

[Show All](#) →

NOTIFICATIONS

Date	Description
31/07/2017 07:49	Your Access Roles have changed
31/07/2017 07:43	has registered for the Protheses List Management System
12/07/2017 17:22	Application (N000010) has been created
16/06/2017 10:46	Data Portal - Interactive_Report_Viewer1 DP has registered for the System
16/06/2017 10:40	Data Portal - Interactive_Report_Developer1 DP has registered for the System
14/06/2017 16:14	Application Status of PEEK Interbody system - Cervical (R000005) has been updated to SUBMITTED
14/06/2017 16:12	Application (R000005) has been created
14/06/2017 16:12	Application Status of (D000004) has been updated to CANCELLED
14/06/2017 16:11	Application (D000004) has been created

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.

The screenshot shows the 'Expand a Prostheses Listing' form. At the top, there is a title bar with the text 'Expand a Prostheses Listing' and a help icon. Below the title bar, there is a message: 'Please select a listing to expand.' followed by a 'Selected Listing' section. A blue button labeled 'Select a Listing' is positioned below the 'Selected Listing' section. The form contains several input fields for details about the prosthesis: 'Current Sponsor', 'Billing Code', 'Product Name', 'Description', 'Sketch', 'Benefit', 'Catalogue Numbers', 'Category', 'Subcategory', 'Group', 'Subgroup', 'Suffix(es)', and 'Group Benefit'. At the bottom, there is a 'Reason for Expansion' section with a message: 'Please select the main reason for the expansion.'

SELECT A LISTING

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

2.3 Expand a Prostheses Listing *continued*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code	<input type="text"/>
Product Name	<input type="text"/>
Product Description	<input type="text"/>
Sponsor Name	<input type="text"/>

Product Grouping

Select Category	-- Choose category -- ▾
Select Subcategory	-- Choose subcategory -- ▾
Select Group	-- Choose group -- ▾
Select Subgroup	-- Choose subgroup -- ▾
Select Suffix(es)	-- Choose suffix -- ▾

[Search](#) [Cancel](#)

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.

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
A5123	Parietene-Monofilament Polypropylene standard mesh / light mesh / X-shaped mesh	Parietene-Monofilament Polypropylene standard mesh / light mesh / X-shaped mesh	03 - General Miscellaneous 03.06 - CLOSURE DEVICES 03.06.05 - Polypropylene/Polyester Mesh 03.06.05.04 - >600-<2500cm ²	Covidien Pty Ltd
BB123	Vascugraft	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

2.3 Expand a Prostheses Listing *continued*

Confirm Selected Listing

Billing Code	AS123
Sponsor	Covidien Pty Ltd
Product Name	Parietene-Monofilament Polypropylene mesh
Description	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh
Size(s)	30 X 30 cm, 30 x 32 cm
Benefit	\$275
Category	03 - General Miscellaneous
Subcategory	03.08 - CLOSURE DEVICES
Group	03.08.05 - Polypropylene/Polyester Mesh
Subgroup	03.08.05.04 - >=900-<2500cm²
Suffixes	

[Confirm](#) [Cancel](#)

STEP 4 – Click [Confirm](#). Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis.

* Mandatory field

Expand a Prostheses Listing

* Please select a listing to expand *

Selected Listing

[Select a Listing](#)

Current Sponsor	Sponsor 123
Billing Code	1000058
Product Name	Prosthesis Device
Description	Knee System
Size(s)	

2.3 Expand a Prostheses Listing *continued*

Reason for Expansion

Please select the main reason for the expansion: *

Billing code includes prostheses that need a separate billing code ▼

Additional Information:

Enter text...

1000 characters remaining

Resultant (new) Prostheses Listings

Product #	Product Name
No records found.	

Add

Prev

SaveNext

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*

Reason for Expansion

Please select the main reason for the expansion: *

Billing code includes prostheses that need a separate billing code ▼

Additional Information:

Enter text...

1000 characters remaining

Resultant (new) Prostheses Listings

Product #	Product Name
No records found.	

Add

Resultant (new) Prostheses Listings

Product #	Product Name
1	ⓧ
2	ⓧ

Add

Prev Save Next

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

Product Name *

Description *

Size(s) *

Catalogue Number(s) *

ARTG ID Number

Please identify the ARTG ID Number(s) below for your product *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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

Please identify the ARTG ID Number(s) below for your product: *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class
<input type="text" value="Enter Number"/>			

☒ Alternatively, tick here if you have applied to include your device on the ARTG
(ARTG ID Number is pending)

Grouping

Select Category *

Select Subcategory *

Select Group *

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.

Enter Number

☒ Alternatively, tick here if you have applied to include your device on the ARTG
(ARTG ID Number is pending)

Grouping

Select Category * -- Choose category --

Select Subcategory * -- Choose subcategory --

Select Group * -- Choose group --

Add Click Add to create a new Group

Select Subgroup -- Choose subgroup --

Add Click Add to create a new Subgroup

Select Suffix(es) -- Choose suffixes --

Add Click Add to create a new Suffix

Group Benefit: Not available for this grouping

Grouping

Select Category * 12 - Knee

Select Subcategory * 12.01 - FEMORAL COMPONENT: TOTAL KNEE ARTHI

Select Group * -- Choose group --

Add Click Add to create a new Group

Save Cancel

Select Subgroup -- Choose subgroup --

Add Click Add to create a new Subgroup

Select Suffix(es) -- Choose suffixes --

Add Click Add to create a new Suffix

Group Benefit: Not available for this grouping

Prev Save Next

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.

The screenshot shows a web form titled "Comparator(s)" with a help icon. Below the title is the section "Comparator Details" with the instruction "Please list the comparator(s) (maximum of 5) for your product: *". There are three radio button options: "Comparator is an existing item on the prostheses list", "Comparator is not on the prostheses list (other treatment or therapy)", and "No Comparator assessment required". An "Add Comparator" button is below these options. At the bottom of the form are "Prev", "Save", and "Next" buttons. The second part of the screenshot shows the same form after the first option is selected, with the "Add Comparator" button now highlighted in blue.

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*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code	<input type="text"/>
Product Name	<input type="text"/>
Product Description	<input type="text"/>
Sponsor Name	<input type="text"/>

Product Grouping

Select Category	-- Choose category -- ▼
Select Subcategory	-- Choose subcategory -- ▼
Select Group	-- Choose group -- ▼
Select Subgroup	-- Choose subgroup -- ▼
Select Suffix(es)	-- Choose suffix -- ▼

[Search](#) [Cancel](#)

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**.

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh		03 - General Miscellaneous 03.06 - CLOSURE DEVICES 03.06.05 - Polypropylene/Polyester Mesh 03.06.05.04 - >600-<2500cm ²	Covidien Pty Ltd
BB123	Vasougraft	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

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*

* Mandatory field

Comparator(s) ?

Comparator Details

Please list the comparator(s) (maximum of 5) for your product: *

☐ Comparator is an existing item on the prostheses list

☒ Comparator is not on the prostheses list

☐ No Comparator assessment required

Delete

Treatment/Therapy Name*

Description

Benefit/Cost*

Comparator Selection Explanation

500 characters remaining

☒ Main Comparator for Product

☐ Comparator is an existing item on the prostheses list

☐ Comparator is not on the prostheses list (other treatment or therapy)

☐ No Comparator assessment required

Add Comparator

Prev **Save** **Next**

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).

*Mandatory field

Evidence, Benefit and Economic Information for New Grouping

Product Name: Medishield Anti-Adhesion Gel
 Category: 03 - General Miscellaneous
 SubCategory: 03.08 - CLOSURE DEVICES
 Group: xx
 SubGroup:
 Suffix(es):
 Proposed Benefit: \$1300

Proposed Benefit

Proposed Benefit (amount is exclusive of GST): *

Please explain how you calculated this benefit: *

500 characters remaining
 (supporting document may be uploaded in the Attachments section)

Clinical Outcomes

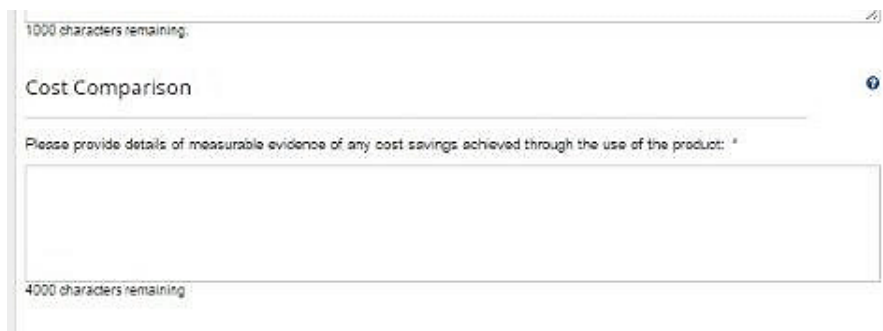
Please identify the quantifiable or measurable clinical outcomes delivered by your product, compared with the comparator(s). Refer to the measurable and/or quantifiable factors relating to patient outcomes, such as recovery time, failure rates, complications, life expectancy: *

1000 characters remaining.

Cost Comparison

Please provide details of measurable evidence of any cost savings achieved through the use of the product: *

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 *continued*

Product Utilisation

If your product is sold in Australia and/or any other country, please provide utilisation and price details below.

Country	Utilisation per year	Cost (in local currency)	
<input type="text" value="Enter text"/>	<input type="text" value="Enter text"/>	<input type="text" value="Enter text"/>	

What is the projected utilisation of the product over the first two years of listing on the Prostheses List? *

200 characters remaining

What is the basis for the projection? *

1500 characters remaining

Will the use of this product replace the use of another product? *

☐ Yes
☐ No

Other Information

Is there any other information you can provide to support your proposed benefits for your product?

4000 characters remaining

Prev

Save

Next

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.

*Mandatory field

Comparative Clinical Effectiveness 

Comparative Clinical Effectiveness

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

Prev Save Next

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

Listed below are attachments related to your application. Please upload all relevant files prior to submitting your application.

Required Attachments:

- An image of the product (Attachment Type = Product#1 xx - Product#1 xx - Product Image)
- An image of the product (Attachment Type = Product#2 x - Product#2 x - Product Image)

Optional Attachments:

- Supporting literature - full studies/report (Attachment Type = Product#1 xx - Product#1 xx - Supporting Literature)
- Supporting literature - full studies/report (Attachment Type = Product#2 x - Product#2 x - Supporting Literature)
- Documentation describing: product features, indications, contraindications, technical specifications, instructions for use, surgical technique etc. (Attachment Type = Product#1 xx - Product#1 xx - Other)
- Documentation describing: product features, indications, contraindications, technical specifications, instructions for use, surgical technique etc. (Attachment Type = Product#2 x - Product#2 x - Other)

File Name	Type *	Description / Study Name & Journal Reference *
No records found.		

Add

Prev Save Next

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*

File Name	Type *	Description / Study Name & Journal Reference *
PLMS.doc.pdf	Product#1 xxx - Product	
PLMS.doc.pdf	Product#2 x - Product	

[Add](#)

[Prev](#) [Save](#) [Next](#)

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.

The screenshot shows a web form titled "Review" with a "Review" button at the top. Below the title, there are sections for "Application Type: Expand a Prostheses Listing" and "Application Contacts". The "Application Contacts" section includes a "Primary Contact" field with the name "Samantha Smith" and a "Phone Number #1" field with a dropdown menu set to "PERSONAL" and a text input field containing "(02) 0000 0000". There is an "Edit" link next to the "Application Contacts" section. Below these sections, there is a "Submit" button. At the bottom, there is a "Submit Application:" section with a note: "(This section must be completed by a user with the 'Approver' role)". Below this note is a checkbox and a declaration: "I declare that all information provided in this application is true and correct. I agree to pay the application fee listed above. *". At the very bottom, there are three buttons: "Prev", "Save", and "Submit".

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.

RECENT APPLICATIONS

Reference Number	Type	Status	Last Modified	Actions
N00010	NEW	Draft	12/07/2017 17:22, HEALTH	View Status Details
R000005	DUPLICATE	Submitted	14/06/2017 16:14	View Status Details
D000004	DELETE	View Status Details	14/06/2017 16:12	View Status Details
03HV-ORF5	AMEND	Application Recommended, Pending ARTG and/or MBS	24/05/2017 09:11, HEALTH	View Status Details
0075-XMLG	AMEND	Application Recommended	23/05/2017 14:47, HEALTH	View Status Details
N000004	NEW	Submitted	19/05/2017 16:33	View Status Details
J4GU-GQLY	DUPLICATE	Draft	16/03/2017 10:52, HEALTH	View Status Details
DSUR-4K1G	NEW	Cancelled	16/03/2017 10:39, HEALTH	View Status Details
GSF8-NKRW	NEW	Draft	16/03/2017 09:51, HEALTH	View Status Details
AX0Q-9K6N	DELETE	View Status Details	01/03/2017 11:11, HEALTH	View Status Details

[Show All](#)

NOTIFICATIONS

Date	Description
31/07/2017 07:49	Your Access Roles have changed
31/07/2017 07:43	has registered for the Protheses List Management System
12/07/2017 17:22	Application (N000010) has been created
16/06/2017 10:46	Data Portal - Interactive_Report_View1 DP has registered for the System
16/06/2017 10:40	Data Portal - Interactive_Report_Developer1 DP has registered for the System
14/06/2017 16:14	Application Status of PEEK Interbody system - Cervical (R000005) has been updated to SUBMITTED
14/06/2017 16:12	Application (R000005) has been created
14/06/2017 16:12	Application Status of (D000004) has been updated to CANCELLED
14/06/2017 16:11	Application (D000004) has been created

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.

Start Application

*Mandatory field

Application Type

Select Application Type * -- Choose type --

Application Contacts

Select a Primary Contact * Samantha Smith

☐ Create New Contact

Phone Number #1 Office (02) 0000 0000

Phone Number #2 Mobile (0400) 000 000

Email Samantha@health.gov.au

Select a Secondary Contact -- Choose contact --

☐ Create New Contact

Phone Number #1 -- Choose type --

Phone Number #2 -- Choose type --

Email e.g. example@domain.com.au

Application Contacts

Select a Primary Contact * -- Choose contact --

☒ Create New Contact

First Name

Last Name

Phone Number #1 -- Choose type --

Phone Number #2 -- Choose type --

Email e.g. example@domain.com.au

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.

*Mandatory field

Compressed Listings Summary

Select Prostheses Listings to Compress

Please select the listings you wish to compress and add them to the table below:

Billing Code	Product Name	Description	Benefit	
No records found.				

[Select a Listing](#)

Reason for Compression

Please select the main reason for the compression: *

-- Choose a reason --

Additional Information:

Enter text...

1000 characters remaining

Prev Save Next

3.3 Compressed Listings Summary *continued*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code	<input type="text"/>
Product Name	<input type="text"/>
Product Description	<input type="text"/>
Sponsor Name	<input type="text"/>

Product Grouping

Select Category	-- Choose category --
Select Subcategory	-- Choose subcategory --
Select Group	-- Choose group --
Select Subgroup	-- Choose subgroup --
Select Suffix(es)	-- Choose suffix --

[Search](#) [Cancel](#)

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.

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietene-Monofilament Polypropylene mesh	Parietene-Monofilament Polypropylene standard mesh / light mesh / X-shaped mesh	03 - General Miscellaneous 03.06 - CLOSURE DEVICES 03.06.05 - Polypropylene/Polyester Mesh 03.06.05.04 - >600-<2500cm ²	Covidien Pty Ltd
BB123	Vascougraf	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

3.3 Compressed Listings Summary *continued*

Confirm Selected Listing

Billing Code	AS123
Sponsor	Covidien Pty Ltd
Product Name	Parietene-Monofilament Polypropylene mesh
Description	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh
Size(s)	30 X 30 cm, 30 x 32 cm
Benefit	\$275
Category	03 - General Miscellaneous
Subcategory	03.08 - CLOSURE DEVICES
Group	03.08.05 - Polypropylene/Polyester Mesh
Subgroup	03.08.05.04 - >600-<2500cm²
Suffixes	

[Confirm](#) [Cancel](#)

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.

*Mandatory field

Compressed Listings Summary

Select Prostheses Listings to Compress

Please select the listings you wish to compress and add them to the table below.*

Billing Code	Product Name	Description	Benefit
No records found.			

[Select a Listing](#)

3.3 Compressed Listings Summary *continued*

Billing Code	Product Name	Description	Benefit	
No records found.				
Select a Listing				
Reason for Compression				
Please select the main reason for the compression: *				
<div>-- Choose a reason --</div>				
Additional Information:				
<div>Enter text...</div>				
1000 characters remaining				
Prev		Save Next		

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.

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

Product Name *

Description *

400 characters remaining

Size(s) *

2500 characters remaining

Catalogue Number(s) *

(please separate numbers using a comma (,) delimiter or enter each number on a new line)

ARTG ID Number

Please identify the ARTG ID Number(s) below for your product *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class
Enter Number			

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

Please identify the ARTG ID Number(s) below for your product: *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class
<input type="text" value="Enter Number"/>			

☒ Alternatively, tick here if you have applied to include your device on the ARTG
(ARTG ID Number is pending)

Grouping

Select Category *

Select Subcategory *

Select Group *

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.

The screenshot displays the 'Comparator(s)' section of the Prosthesis List Management System. It features a title 'Comparator(s)' with a help icon. Below is the 'Comparator Details' section with the instruction: 'Please list the comparator(s) (maximum of 5) for your product: *'. Three radio button options are presented: 'Comparator is an existing item on the prostheses list', 'Comparator is not on the prostheses list (other treatment or therapy)', and 'No Comparator assessment required'. An 'Add Comparator' button is located below these options. At the bottom of the form are 'Prev', 'Save', and 'Next' buttons. The bottom portion of the image shows the same form after a selection, where the first radio button is selected and the 'Add Comparator' button is highlighted in blue.

3.5 Comparator(s) *continued*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code	<input type="text"/>
Product Name	<input type="text"/>
Product Description	<input type="text"/>
Sponsor Name	<input type="text"/>

Product Grouping

Select Category	-- Choose category -- ▼
Select Subcategory	-- Choose subcategory -- ▼
Select Group	-- Choose group -- ▼
Select Subgroup	-- Choose subgroup -- ▼
Select Suffix(es)	-- Choose suffix -- ▼

[Search](#) [Cancel](#)

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**.

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietena-Monofilament Polypropylene mesh	Parietena-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh	03 - General Miscellaneous 03.05 - CLOSURE DEVICES 03.05.05 - Polypropylene/Polyester Mesh 03.05.05.04 - >800-<2500cm ²	Covidien Pty Ltd
BB123	Vascugraft	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

3.5 Comparator(s) *continued*

Confirm Selected Listing

Billing Code	AS123
Sponsor	Covidien Pty Ltd
Product Name	Parietene-Monofilament Polypropylene mesh
Description	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh
Size(s)	30 X 30 cm, 30 x 32 cm
Benefit	\$275
Category	03 - General Miscellaneous
Subcategory	03.08 - CLOSURE DEVICES
Group	03.08.05 - Polypropylene/Polyester Mesh
Subgroup	03.08.05.04 - >600-<2500cm²
Suffixes	

[Confirm](#) [Cancel](#)

Comparator(s) ?

Comparator Details

Please list the comparator(s) (maximum of 5) for your product.*

☒ Comparator is an existing item on the prostheses list
☐ Comparator is not on the prostheses list
☐ No Comparator assessment required

[Delete](#)

Billing Code:	AS123
Comparator Product Name:	Parietene-Monofilament Polypropylene mesh
Comparator Grouping:	03 - General Miscellaneous 03.08 - CLOSURE DEVICES 03.08.05 - Polypropylene/Polyester Mesh 03.08.05.04 - >600-<2500cm²

Comparator Selection Explanation

☒ Main Comparator for Product

500 characters remaining

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.

3.5 Comparator(s) *continued*

* Mandatory field

Comparator(s) ?

Comparator Details

Please list the comparator(s) (maximum of 5) for your product: *

☐ Comparator is an existing item on the prostheses list
☒ Comparator is not on the prostheses list
☐ No Comparator assessment required

Details

Treatment/Therapy Name*

Description

Benefit/Cost*

Comparator Selection Explanation

800 characters remaining

☒ Main Comparator for Product

☐ Comparator is an existing item on the prostheses list
☐ Comparator is not on the prostheses list (other treatment or therapy)
☐ No Comparator assessment required

Add Comparator

Prev Save Next

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.

*Mandatory field

Evidence, Benefit and Economic Information for New Grouping

Product Name: Medishield Anti-Adhesion Gel
 Category: 03 - General Miscellaneous
 SubCategory: 03.08 - CLOSURE DEVICES
 Group: xx
 SubGroup:
 Suffix(es):
 Proposed Benefit: \$1300

Proposed Benefit

Proposed Benefit (amount is exclusive of GST): *

Please explain how you calculated this benefit: *

500 characters remaining
(supporting document may be uploaded in the Attachments section)

Clinical Outcomes

Please identify the quantifiable or measurable clinical outcomes delivered by your product, compared with the comparator(s). Refer to the measurable and/or quantifiable factors relating to patient outcomes, such as recovery time, failure rates, complications, life expectancy: *

1000 characters remaining.

Cost Comparison

Please provide details of measurable evidence of any cost savings achieved through the use of the product: *

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.

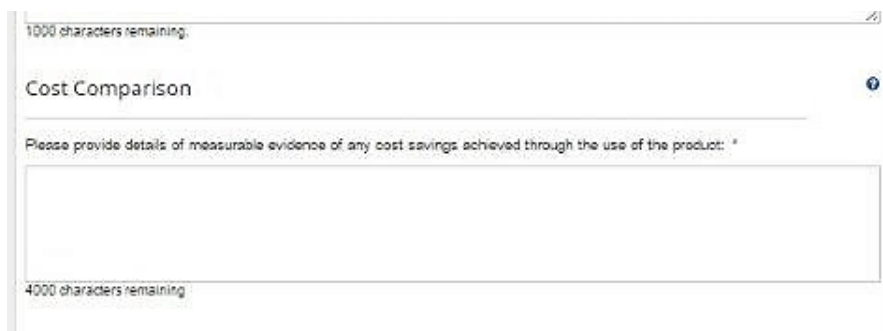
Hint: Factors you may like to consider include:

- 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

If your product is sold in Australia and/or any other country, please provide utilisation and price details below:

Country	Utilisation per year	Cost (in local currency)	
<input type="text" value="Enter text"/>	<input type="text" value="Enter text"/>	<input type="text" value="Enter text"/>	

What is the projected utilisation of the product over the first two years of listing on the Prostheses List? *

200 characters remaining

What is the basis for the projection? *

1500 characters remaining

Will the use of this product replace the use of another product? *

☐ Yes ☐ No

Other Information

Is there any other information you can provide to support your proposed benefits for your product?

4000 characters remaining

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

*Mandatory field

Comparative Clinical Effectiveness 

Comparative Clinical Effectiveness

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

Prev Save Next

COMPARATIVE CLINICAL EFFECTIVENESS

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

3.8 Attachments

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

Attachments

Listed below are attachments related to your application. Please upload all relevant files prior to submitting your application.

Required Attachments:

- An image of the product (Attachment Type = Product Image)
- Brochure describing the product (Attachment Type = Product Brochure)

Optional Attachments:

- Supporting literature - full studies/report (Attachment Type = Supporting Literature)
- Documentation describing: product features, indications, contraindications, technical specifications, instructions for use, surgical technique etc. (Attachment Type = Other)

File Name	Type *	Description / Study Name & Journal Reference *
No records found.		

Add

Prev Save Next

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*

• Supporting literature : full studies/report (Attachment Type = Supporting Literature)
 • Documentation describing; product features, indications, contraindications, technical specifications, instructions for use, surgical technique etc. (Attachment Type = Other)

File Name	Type *	Description / Study Name & Journal Reference *
PLMS.docx.pdf	Product Image ▼	x
PLMS.docx.pdf	Product Brochure ▼	x

Add

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.

*Mandatory field

Review

Application Type: Compress Protheses Listings

Application Contacts

Primary Contact: Samantha Smith

Phone Number #1: PERSONAL (02) 0000 0000

Submit

Submit Application:

(This section must be completed by a user with the "Approver" role)

☐ I declare that all information provided in this application is true and correct. I agree to pay the application fee listed above. *

Prev Save Submit

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:

Amend a Listing

- | | |
|-----|--|
| 4.1 | PLMS Home |
| 4.2 | Start Application |
| 4.3 | Select a Listing |
| 4.4 | Amend Listing – Prosthesis Device |
| 4.5 | Comparator(s) |
| 4.6 | Evidence, Benefit and Economic Information for New Grouping* |
| 4.7 | Comparative Clinical Effectiveness |
| 4.8 | Attachments |
| 4.9 | Review and Submit |

* 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.

RECENT APPLICATIONS

Reference Number	Type	Status	Last Modified	Actions
N00010	NEW	Draft	12/07/2017 17:22, HEALTH	View Status Details
R000005	DUPLICATE	Submitted	14/06/2017 16:14	View Status Details
D000004	DELETE	View Status Details	14/06/2017 16:12	View Status Details
03HV-ORF5	AMEND	Application Recommended, Pending ARTG and/or MBS	24/05/2017 09:11, HEALTH	View Status Details
0075-XMLG	AMEND	Application Recommended	23/05/2017 14:47, HEALTH	View Status Details
N000004	NEW	Submitted	19/05/2017 16:33	View Status Details
J4GU-GQLY	DUPLICATE	Draft	16/03/2017 10:52, HEALTH	View Status Details
DSUR-4K1G	NEW	Cancelled	16/03/2017 10:39, HEALTH	View Status Details
GSF8-NKRW	NEW	Draft	16/03/2017 09:51, HEALTH	View Status Details
AX0Q-9K6N	DELETE	View Status Details	01/03/2017 11:11, HEALTH	View Status Details

[Show All](#)

NOTIFICATIONS

Date	Description
31/07/2017 07:49	Your Access Roles have changed
31/07/2017 07:43	has registered for the Protheses List Management System
12/07/2017 17:22	Application (N000010) has been created
16/06/2017 10:46	Data Portal - Interactive_Report_View1 DP has registered for the System
16/06/2017 10:40	Data Portal - Interactive_Report_Developer1 DP has registered for the System
14/06/2017 16:14	Application Status of PEEK Interbody system - Cervical (R000005) has been updated to SUBMITTED
14/06/2017 16:12	Application (R000005) has been created
14/06/2017 16:12	Application Status of (D000004) has been updated to CANCELLED
14/06/2017 16:11	Application (D000004) has been created

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

*Mandatory field

Select a Listing ?

Please select a listing to amend: *

☒ Prosthesis Device

☐ Human Tissue

Selected Listing

Select a Listing

Product Name:

Description:

Catalogue Numbers:

Reason for Amendment

Please select the main reason for the amendment: *

... Choose a reason ... ▼

Additional Information:

Enter text...

1000 characters remaining

Prev Save Next

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 *continued*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code	<input type="text"/>
Product Name	<input type="text"/>
Product Description	<input type="text"/>
Sponsor Name	<input type="text"/>

Product Grouping

Select Category	-- Choose category --
Select Subcategory	-- Choose subcategory --
Select Group	-- Choose group --
Select Subgroup	-- Choose subgroup --
Select Suffix(es)	-- Choose suffix --

[Search](#) [Cancel](#)

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietene-Monofilament Polypropylene mesh	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh	03 - General Miscellaneous 03.05 - CLOSURE DEVICES 03.05.05 - Polypropylene/Polyester Mesh 03.05.05.04 - >600-<2500cm ²	Covidien Pty Ltd
BB123	Vascugraft	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

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.

4.3 Select a Listing *continued*

Confirm Selected Listing

Billing Code	AS123
Sponsor	Covidien Pty Ltd
Product Name	Parietene-Monofilament Polypropylene mesh
Description	Parietene-Monofilament Polypropylene standard mesh / light mesh / X-shaped mesh
Size(s)	30 X 30 cm, 30 x 32 cm
Benefit	\$275
Category	03 - General Miscellaneous
Subcategory	03.08 - CLOSURE DEVICES
Group	03.08.05 - Polypropylene/Polyester Mesh
Subgroup	03.08.05.04 - >600-<2500cm²
Suffixes	

[Confirm](#) [Cancel](#)

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

Selected Listing

[Select a Listing](#)

Product Name:	Prosthesis Device
Description:	Prosthesis System
Catalogue Numbers:	0000000
Reason for Amendment	

4.3 Select a Listing *continued*

The screenshot shows a web form for amending a listing. At the top, there is a label 'Catalogue Numbers:' followed by a text input field containing '0000000'. Below this is a section titled 'Reason for Amendment'. Inside this section, there is a prompt 'Please select the main reason for the amendment: *' followed by a dropdown menu with the text '-- Choose a reason --'. Below the dropdown is a label 'Additional Information:' followed by a large text area with the placeholder text 'Enter text...'. At the bottom left of the text area, it says '1000 characters remaining'. At the bottom of the form, there are three buttons: 'Prev' (disabled), 'Save' (active), and 'Next' (active).

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.*

* Mandatory field

Amend Listing - Prosthesis Device

Note: The system will highlight prepopulated fields that have been edited from the original listing.

Product Details

Product Name:

Description:

Size:

Catalogue Number(s):

(Please separate numbers using a comma (,) delimiter or enter each number on a new line)

ARTG ID Number(s)

Please identify the ARTG ID Number(s) below for your product:

--	--	--	--	--

4.4 Amend Listing – Prosthesis Device *continued*

ARTG ID Number

Please identify the ARTG ID Number(s) below for your product: *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class	
<input type="text" value="Enter Number"/>				

☒ Alternatively, tick here if you have applied to include your device on the ARTG
(ARTG ID Number is pending)

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.

4.4 Amend Listing – Prosthesis Device *continued*

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

Grouping

Select Category * 03 - General Miscellaneous ▼

Select Subcategory * 03.05 - CLOSURE DEVICES ▼

Select Group * 03.05.01 - Adhesion Barriers ▼

Add Click Add to create a new Group

Select Subgroup 03.05.01.04 - Gel/Liquid ▼

Add Click Add to create a new Subgroup

Select Suffix(es) Complex ▼

Add Click Add to create a new Suffix

Group Benefit: \$100

Grouping

Select Category * 12 - Knee ▼

Select Subcategory * 12.01 - FEMORAL COMPONENT: TOTAL KNEE ARTHI ▼

Select Group * -- Choose group -- ▼

Add Click Add to create a new Group

Save **Cancel**

Select Subgroup -- Choose subgroup -- ▼

Add Click Add to create a new Subgroup

Select Suffix(es) -- Choose suffixes -- ▼

Add Click Add to create a new Suffix

Group Benefit: Not available for this grouping

Prev **Save** **Next**

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.

*Mandatory field

Comparator(s) ?

Comparator Details

Please list the comparator(s) (maximum of 5) for your product: *

☐ Comparator is an existing item on the prostheses list

☐ Comparator is not on the prostheses list (other treatment or therapy)

☐ No Comparator assessment required

Add Comparator

Prev Save Next

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.

Comparator Details

Please list the comparator(s) (maximum of 5) for your product: *

☒ Comparator is an existing item on the prostheses list

☐ Comparator is not on the prostheses list (other treatment or therapy)

☐ No Comparator assessment required

Add Comparator

4.5 Comparator(s) *continued*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code	<input type="text"/>
Product Name	<input type="text"/>
Product Description	<input type="text"/>
Sponsor Name	<input type="text"/>

Product Grouping

Select Category	-- Choose category -- ▼
Select Subcategory	-- Choose subcategory -- ▼
Select Group	-- Choose group -- ▼
Select Subgroup	-- Choose subgroup -- ▼
Select Suffix(es)	-- Choose suffix -- ▼

[Search](#) [Cancel](#)

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietene-Monofilament Polypropylene mesh	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh	03 - General Miscellaneous 03.05 - CLOSURE DEVICES 03.05.05 - Polypropylene/Polyester Mesh 03.05.05.04 - >600-<2500cm ²	Covidien Pty Ltd
BB123	Vascugraft	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

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**.

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*

* Mandatory field

Comparator(s) ?

Comparator Details

Please list the comparator(s) (maximum of 5) for your product: *

☐ Comparator is an existing item on the prostheses list

☒ Comparator is not on the prostheses list

☐ No Comparator assessment required

Details

Treatment/Therapy Name*

Description

Benefit/Cost*

Comparator Selection Explanation

800 characters remaining

☒ Main Comparator for Product

☐ Comparator is an existing item on the prostheses list

☐ Comparator is not on the prostheses list (other treatment or therapy)

☐ No Comparator assessment required

Prev Save Next

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

*Mandatory field

Comparative Clinical Effectiveness 

Comparative Clinical Effectiveness

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

Prev Save Next

COMPARATIVE CLINICAL EFFECTIVENESS

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

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.

*Mandatory field

Evidence, Benefit and Economic Information for New Grouping

Product Name: Medishield Anti-Adhesion Gel
 Category: 03 - General Miscellaneous
 SubCategory: 03.08 - CLOSURE DEVICES
 Group: xx
 SubGroup:
 Suffix(es):
 Proposed Benefit: \$1300

Proposed Benefit

Proposed Benefit (amount is exclusive of GST): *

Please explain how you calculated this benefit: *

500 characters remaining
(supporting document may be uploaded in the Attachments section)

Clinical Outcomes

Please identify the quantifiable or measurable clinical outcomes delivered by your product, compared with the comparator(s). Refer to the measurable and/or quantifiable factors relating to patient outcomes, such as recovery time, failure rates, complications, life expectancy: *

1000 characters remaining.

Cost Comparison

Please provide details of measurable evidence of any cost savings achieved through the use of the product: *

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.

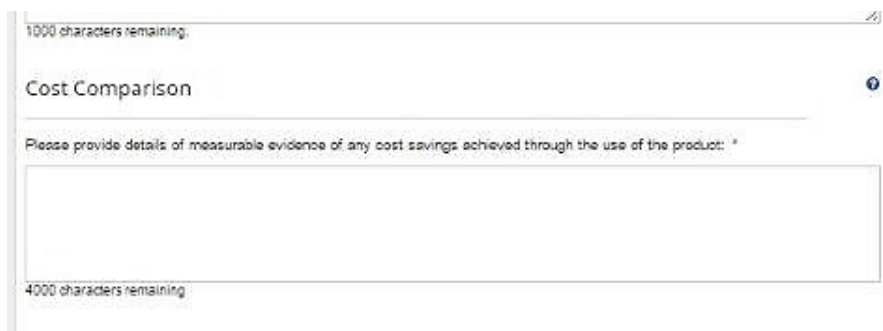
Hint: Factors you may like to consider include:

- *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*



1000 characters remaining

Cost Comparison

Please provide details of measurable evidence of any cost savings achieved through the use of the product: *

4000 characters remaining

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

If your product is sold in Australia and/or any other country, please provide utilisation and price details below:

Country	Utilisation per year	Cost (in local currency)	
<input type="text" value="Enter text"/>	<input type="text" value="Enter text"/>	<input type="text" value="Enter text"/>	

What is the projected utilisation of the product over the first two years of listing on the Prostheses List? *

200 characters remaining

What is the basis for the projection? *

1500 characters remaining

Will the use of this product replace the use of another product? *

☐ Yes ☐ No

Other Information

Is there any other information you can provide to support your proposed benefits for your product?

4000 characters remaining

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

Listed below are attachments related to your application. Please upload all relevant files prior to submitting your application.

Required Attachments:

- Brochure describing the product (Attachment Type = Product Brochure)

Optional Attachments:

No optional attachments

File Name	Type *	Description / Study Name & Journal Reference *
No records found.		

Add

Prev Save Next

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 *continued*

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.

File Name	Type *	Description / Study Name & Journal Reference *
PLMS doc.pdf	Product Brochure	

Add

Prev Save Next

4.9 Review and Submit

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

The screenshot shows a web form titled 'Review' with a blue question mark icon in the top right corner. A note at the top left states '* Mandatory field'. The form contains several sections: 'Application Type: Amend a Listing', 'Application Contacts' with an 'Edit' link, and a 'Submit' button. Below these is a 'Submit Application:' section with a note '(This section must be completed by a user with the "Approver" role)'. It includes a checkbox and a declaration: 'I declare that all information provided in this application is true and correct. I agree to pay the application fee listed above. *'. At the bottom, there are three buttons: 'Prev', 'Save', and 'Submit'.

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.

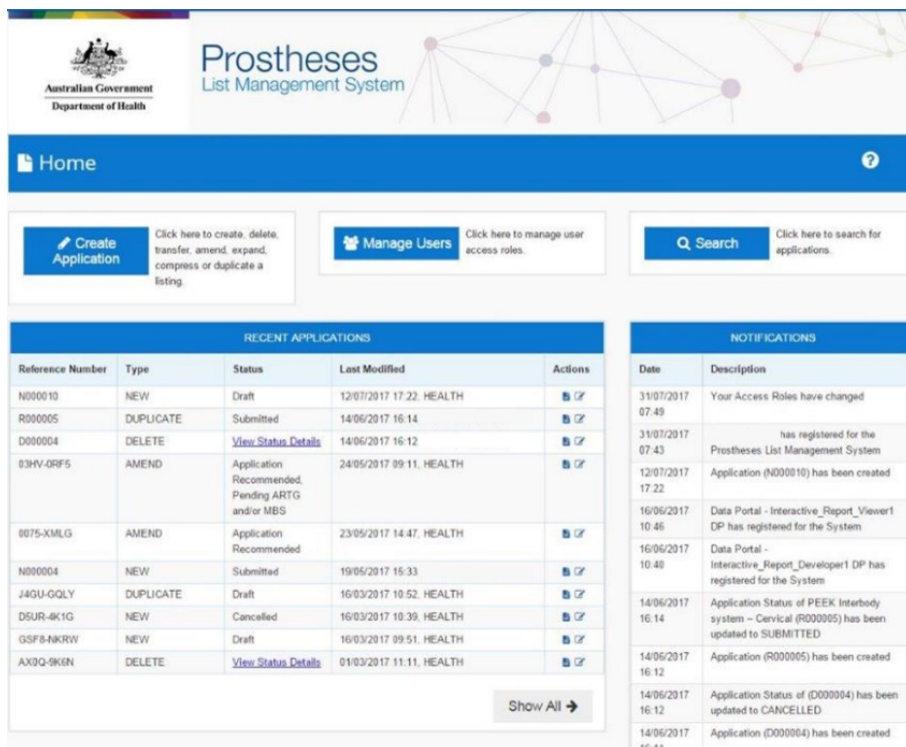
The steps to Duplicate a Listing are:

Duplicate a Listing

- 5.1 PLMS Home
- 5.2 Start Application
- 5.3 Select a Duplicate Listing
- 5.4 Duplicate a Prostheses Listing
- 5.5 Attachments
- 5.6 Review and Submit

5.1 PLMS Home

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



RECENT APPLICATIONS

Reference Number	Type	Status	Last Modified	Actions
N00010	NEW	Draft	12/07/2017 17:22, HEALTH	View Status Details
R000005	DUPLICATE	Submitted	14/06/2017 16:14	View Status Details
D000004	DELETE	View Status Details	14/06/2017 16:12	View Status Details
03HV-ORF5	AMEND	Application Recommended, Pending ARTG and/or MBS	24/05/2017 09:11, HEALTH	View Status Details
0075-XMLG	AMEND	Application Recommended	23/05/2017 14:47, HEALTH	View Status Details
N000004	NEW	Submitted	19/05/2017 16:33	View Status Details
J4GU-GQLY	DUPLICATE	Draft	16/03/2017 10:52, HEALTH	View Status Details
DSUR-4K1G	NEW	Cancelled	16/03/2017 10:39, HEALTH	View Status Details
GSF8-NKRW	NEW	Draft	16/03/2017 09:51, HEALTH	View Status Details
AX0Q-9K6N	DELETE	View Status Details	01/03/2017 11:11, HEALTH	View Status Details

[Show All](#)

NOTIFICATIONS

Date	Description
31/07/2017 07:49	Your Access Roles have changed
31/07/2017 07:43	has registered for the Protheses List Management System
12/07/2017 17:22	Application (N000010) has been created
16/06/2017 10:46	Data Portal - Interactive_Report_View1 DP has registered for the System
16/06/2017 10:40	Data Portal - Interactive_Report_Developer1 DP has registered for the System
14/06/2017 16:14	Application Status of PEEK Interbody system - Cervical (R000005) has been updated to SUBMITTED
14/06/2017 16:12	Application (R000005) has been created
14/06/2017 16:12	Application Status of (D000004) has been updated to CANCELLED
14/06/2017 16:11	Application (D000004) has been created

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.

*Mandatory field

Start Application ?

Application Type

Select Application Type * -- Choose type --

Application Contacts

Select a Primary Contact * Samantha Smith

☐ Create New Contact

Phone Number #1 Office (02) 0000 0000

Phone Number #2 Mobile (0400) 000 000

Email Samantha@health.gov.au

Select a Secondary Contact -- Choose contact --

☐ Create New Contact

Phone Number #1 -- Choose type --

Phone Number #2 -- Choose type --

Email e.g. example@domain.com.au

Application Contacts

Select a Primary Contact * -- Choose contact --

☒ Create New Contact

First Name

Last Name

Phone Number #1 -- Choose type --

Phone Number #2 -- Choose type --

Email e.g. example@domain.com.au

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.

*Mandatory field

Select a Duplicate Listing 

Please select a listing to duplicate: *

Selected Listing

[Select a Listing](#)

Current Sponsor:

Billing Code:

Product Name:

Description:

Size(s):

Benefit:

[Prev](#) [Save](#) [Next](#)

5.3 Select a Duplicate Listing *continued*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code	<input type="text"/>
Product Name	<input type="text"/>
Product Description	<input type="text"/>
Sponsor Name	<input type="text"/>

Product Grouping

Select Category	-- Choose category --
Select Subcategory	-- Choose subcategory --
Select Group	-- Choose group --
Select Subgroup	-- Choose subgroup --
Select Suffix(es)	-- Choose suffix --

[Search](#) [Cancel](#)

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietene-Monofilament Polypropylene mesh	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh	03 - General Miscellaneous 03.06 - CLOSURE DEVICES 03.06.05 - Polypropylene/Polyester Mesh 03.06.05.04 - >800-<2500cm ²	Covidien Pty Ltd
BB123	Vasculgraf	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

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.

5.3 Select a Duplicate Listing *continued*

Confirm Selected Listing

Billing Code	AS123
Sponsor	Covidien Pty Ltd
Product Name	Parietene-Monofilament Polypropylene mesh
Description	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh
Size(s)	30 X 30 cm, 30 x 32 cm
Benefit	\$275
Category	03 - General Miscellaneous
Subcategory	03.08 - CLOSURE DEVICES
Group	03.08.05 - Polypropylene/Polyester Mesh
Subgroup	03.08.05.04 - >600-<2500cm²
Suffixes	

[Confirm](#) [Cancel](#)

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

Select a Listing

Current Sponsor	Sponsor 123
Billing Code	1000058
Product Name	Prosthesis Device
Description	Knee System
Size(s)	

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.

Standardby
Web

Duplicate a Prostheses Listing

Note: The system will highlight prepopulated fields that have been edited from the original listing.

Product Details

Product Name: * TyPEEK Interbody system – Lumbar PLURTUP (single)

Description: * Sterile
PLUP Implants
TUP Implants
Commercially Pure Titanium and Polyetheretherketone (PEEK-Optima®)

Sizes: * 1234 characters remaining
Width 8-12mm
Length 32-34mm
Height 7-17mm
Coronary Angle 0-6 degrees

Catalogue Number(s) * 2222 characters remaining

(Please separate numbers using a comma (,) delimiter or enter each number on a new line)

Category: 13 - Spinal

Subcategory: 13.10 - Fusion Cage

Group: 13.10.02 - Interbody, No Integral Fixation

Subgroup: 13.10.02.02 - ThoracoLumbar / Lumbar

Suffixes:

Group Benefit: 03600

ARTG ID Number(s)

Please identify the ARTG ID Number(s) below for your product: *

ARTG ID Number	Supplier Name	ARTG Entry Name	Class

5.4 Duplicate a Prostheses Listing *continued*

Subcategory: 13.10 - Fusion Cage

Group: 13.10.02 - Interbody, No Integral Fixation

Subgroup: 13.10.02.02 - Thoracolumbar / Lumbar

Suffix(es):

Group Benefit: 03600

ARTG ID Number(s)

Please identify the ARTG ID Number(s) below for your product: *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class
<input type="text" value="Enter Number"/>			

☐ Alternatively, tick here if you have applied to include your device on the ARTG (ARTG ID Number is pending)

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

Listed below are attachments related to your application. Please upload all relevant files prior to submitting your application.

Required Attachments:

- Letter from manufacturer authorising your organisation to be a sponsor for the product (Attachment Type = Manufacturer Authorisation)

Optional Attachments:

- Additional documentation to support the duplication of the listing (Attachment Type = Other)

File Name	Type *	Description / Study Name & Journal Reference *
No records found.		

Add

Prev Save Next

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*

*Mandatory field

Select File(s): *

+ Choose File(s)

Drag and drop file(s) into the panel above

Cancel

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.

File Name	Type *	Description / Study Name & Journal Reference *
PLMS doc.pdf	Manufacturer Author ▼	

Add

Prev Save Next

5.6 Review and Submit

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

The screenshot shows a web form titled 'Review' with a blue question mark icon in the top right corner. At the top left, there is a note: '*Mandatory field'. The form contains several sections: 'Application Type: Duplicate a Listing', 'Application Contacts' (with an 'Edit' link to its right), and a 'Submit Application:' section. Below the 'Submit Application:' heading, there is a note: '(This section must be completed by a user with the "Approver" role)'. This is followed by a checkbox and the text: 'I declare that all information provided in this application is true and correct. I agree to pay the application fee listed above. *'. At the bottom of the form, there are three buttons: 'Prev' (disabled), 'Save' (active), and 'Submit' (active).

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:

Transfer a Listing

- 6.1 PLMS Home
- 6.2 Start Application
- 6.3 Transfer a Prostheses Listing
- 6.4 Attachments
- 6.5 Review and Submit

6.1 PLMS Home

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

RECENT APPLICATIONS

Reference Number	Type	Status	Last Modified	Actions
N00010	NEW	Draft	12/07/2017 17:22, HEALTH	View Status Details
R000005	DUPLICATE	Submitted	14/06/2017 16:14	View Status Details
D000004	DELETE	View Status Details	14/06/2017 16:12	View Status Details
03HV-ORF5	AMEND	Application Recommended, Pending ARTG and/or MBS	24/05/2017 09:11, HEALTH	View Status Details
0075-XMLG	AMEND	Application Recommended	23/05/2017 14:47, HEALTH	View Status Details
N000004	NEW	Submitted	19/05/2017 16:33	View Status Details
J4GU-GQLY	DUPLICATE	Draft	16/03/2017 10:52, HEALTH	View Status Details
DSUR-4K1G	NEW	Cancelled	16/03/2017 10:39, HEALTH	View Status Details
GSF8-NKRW	NEW	Draft	16/03/2017 09:51, HEALTH	View Status Details
AX0Q-9K6N	DELETE	View Status Details	01/03/2017 11:11, HEALTH	View Status Details

[Show All](#)

NOTIFICATIONS

Date	Description
31/07/2017 07:49	Your Access Roles have changed
31/07/2017 07:43	has registered for the Protheses List Management System
12/07/2017 17:22	Application (N000010) has been created
16/06/2017 10:46	Data Portal - Interactive_Report_View1 DP has registered for the System
16/06/2017 10:40	Data Portal - Interactive_Report_Developer1 DP has registered for the System
14/06/2017 16:14	Application Status of PEEK Interbody system - Cervical (R000005) has been updated to SUBMITTED
14/06/2017 16:12	Application (R000005) has been created
14/06/2017 16:12	Application Status of (D000004) has been updated to CANCELLED
14/06/2017 16:11	Application (D000004) has been created

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.

*Mandatory field

Start Application ?

Application Type

Select Application Type * -- Choose type --

Application Contacts

Select a Primary Contact * Samantha Smith

☐ Create New Contact

Phone Number #1 Office (02) 0000 0000

Phone Number #2 Mobile (0400) 000 000

Email Samantha@health.gov.au

Select a Secondary Contact -- Choose contact --

☐ Create New Contact

Phone Number #1 -- Choose type --

Phone Number #2 -- Choose type --

Email e.g. example@domain.com.au

Application Contacts

Select a Primary Contact * -- Choose contact --

☒ Create New Contact

First Name

Last Name

Phone Number #1 -- Choose type --

Phone Number #2 -- Choose type --

Email e.g. example@domain.com.au

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.

* Mandatory field

Transfer a Prostheses Listing

Please select a listing to transfer to your organisation: *

Selected Listing

[Select a Listing](#)

Current Sponsor:

Billing Code:

Product Name:

Description:

Size(s):

Benefit:

Category:

Subcategory:

Group:

Subgroup:

Suffix(es):

Group Benefit:

6.3 Transfer a Prostheses Listing *continued*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code	<input type="text"/>
Product Name	<input type="text"/>
Product Description	<input type="text"/>
Sponsor Name	<input type="text"/>

Product Grouping

Select Category	-- Choose category --
Select Subcategory	-- Choose subcategory --
Select Group	-- Choose group --
Select Subgroup	-- Choose subgroup --
Select Suffix(es)	-- Choose suffix --

[Search](#) [Cancel](#)

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.

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh		03 - General Miscellaneous 03.06 - CLOSURE DEVICES 03.06.05 - Polypropylene/Polyester Mesh 03.06.05.04 - >800-<2500cm ²	Covidien Pty Ltd
BB123	Vascougraf	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

6.3 Transfer a Prostheses Listing *continued*

Confirm Selected Listing

Billing Code	AS123
Sponsor	Covidien Pty Ltd
Product Name	Parietene-Monofilament Polypropylene mesh
Description	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh
Size(s)	30 X 30 cm, 30 x 32 cm
Benefit	\$275
Category	03 - General Miscellaneous
Subcategory	03.08 - CLOSURE DEVICES
Group	03.08.05 - Polypropylene/Polyester Mesh
Subgroup	03.08.05.04 - >600-<2500cm²
Suffixes	

[Confirm](#) [Cancel](#)

STEP 4 – Click [Confirm](#). Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis.

Selected Listing

[Select a Listing](#)

Current Sponsor	Sponsor 123
Billing Code	1000058
Product Name	Prosthesis Device
Description	Knee System
Size(s)	

6.3 Transfer a Prostheses Listing *continued*

Group Benefit:

Catalogue Number(s)

Please enter the catalogue number(s) under which your organisation (the new sponsor) will be selling the product: *

Enter comma-separated list values

(please separate numbers using a comma (,) delimiter or enter each number on a new line)

ARTG ID Number(s)

Please identify the ARTG ID Number(s) below for your product: *

ARTG ID Number	Sponsor Name	ARTG Entry Name	Class	
Enter Number				

☐ Alternatively, tick here if you have applied to include your device on the ARTG (ARTG ID Number is pending)

Print Save Next

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

Listed below are attachments related to your application. Please upload all relevant files prior to submitting your application.

Required Attachments:

- Letter from current sponsor authorising transfer to your organisation (Attachment Type = Transfer Authority)

Optional Attachments:

- Additional documentation to support the transfer (Attachment Type = Other)

File Name	Type *	Description / Study Name & Journal Reference *
No records found.		

Add

Prev Save Next

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:

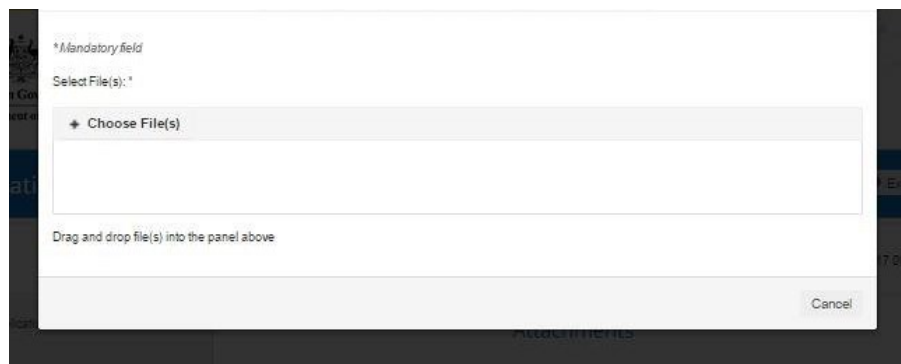
- In PDF format*
- In English*
- Specific to the prosthesis*

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.

Application Type:	TRANSFER	Status:	Draft
Reference Number:	T000004	Last Update Date:	31/07/2017 10:43
Product / System:	Carpal Fusion Compression Plate		

* Mandatory field

Review

Application Type: Transfer a Listing to DEPARTMENT OF HEALTH AND AGEING

Submit

Submit Application:

(This section must be completed by a user with the 'Approver' role)

☐ I declare that all information provided in this application is true and correct. I agree to pay the application fee listed above. *

Prev

Save Submit

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:

Delete a Listing

- 7.1 PLMS Home
- 7.2 Start Application
- 7.3 Delete a Listing
- 7.4 Review and Submit

7.1 PLMS Home

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

RECENT APPLICATIONS

Reference Number	Type	Status	Last Modified	Actions
N000010	NEW	Draft	12/07/2017 17:22. HEALTH	View Status Details
R000005	DUPLICATE	Submitted	14/06/2017 16:14	View Status Details
D000004	DELETE	View Status Details	14/06/2017 16:12	View Status Details
03HV-GRF5	AMEND	Application Recommended, Pending ARTG and/or MBS	24/05/2017 09:11. HEALTH	View Status Details
0075-XMLG	AMEND	Application Recommended	23/05/2017 14:47. HEALTH	View Status Details
N000004	NEW	Submitted	19/05/2017 15:33	View Status Details
J40U-GQLY	DUPLICATE	Draft	16/03/2017 10:52. HEALTH	View Status Details
D5UR-4K1G	NEW	Cancelled	16/03/2017 10:39. HEALTH	View Status Details
G5F8-NKRW	NEW	Draft	16/03/2017 09:51. HEALTH	View Status Details
AX0Q-9K6N	DELETE	View Status Details	01/03/2017 11:11. HEALTH	View Status Details

[Show All](#)

NOTIFICATIONS

Date	Description
31/07/2017 07:49	Your Access Roles have changed
31/07/2017 07:43	has registered for the Protheses List Management System
12/07/2017 17:22	Application (N000010) has been created
16/06/2017 10:46	Data Portal - Interactive_Report_Viewer1 DP has registered for the System
16/06/2017 10:48	Data Portal - Interactive_Report_Developer1 DP has registered for the System
14/06/2017 16:14	Application Status of PEEK Interbody system - Cervical (R000005) has been updated to SUBMITTED
14/06/2017 16:12	Application (R000005) has been created
14/06/2017 16:12	Application Status of (D000004) has been updated to CANCELLED
14/06/2017 16:11	Application (D000004) has been created

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.

Start Application

*Mandatory field

Application Type

Select Application Type * -- Choose type --

Application Contacts

Select a Primary Contact * Samantha Smith

☐ Create New Contact

Phone Number #1 Office (02) 0000 0000

Phone Number #2 Mobile (0400) 000 000

Email Samantha@health.gov.au

Select a Secondary Contact -- Choose contact --

☐ Create New Contact

Phone Number #1 -- Choose type --

Phone Number #2 -- Choose type --

Email e.g. example@domain.com.au

Application Contacts

Select a Primary Contact * -- Choose contact --

☒ Create New Contact

First Name

Last Name

Phone Number #1 -- Choose type --

Phone Number #2 -- Choose type --

Email e.g. example@domain.com.au

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.

*Mandatory field

Delete a Listing

Please select a listing to delete: *

☐ Prosthesis Device

☐ Human Tissue

Selected Listing

Product #	Billing Code	Product Name	Actions
No records found.			

Select a Listing

Reason for Deletion

Please select a reason for the deletion of this listing: *

-- Choose a reason --

Prev Save Next

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*

Keyword Search

(Conduct a keyword search against a combination of Billing Code, Product Name, Product Description or Sponsor Name. Please note that whilst creating certain types of applications, a user will be unable to conduct a keyword search on the sponsor name due to constraints that are imposed by the requirements for that application type)

Billing Code

Product Name

Product Description

Sponsor Name

Product Grouping

Select Category

Select Subcategory

Select Group

Select Subgroup

Select Suffix(es)

[Search](#) [Cancel](#)

Search Results

To select a listing, please click the Billing Code hyperlink

PRODUCTS				
Billing Code	Product Name	Product Description	Product Grouping	Sponsor
AS123	Parietene-Monofilament Polypropylene standard mesh / light mesh/X-shaped mesh	Parietene-Monofilament Polypropylene standard mesh / light mesh/X-shaped mesh	03 - General Miscellaneous 03.05 - CLOSURE DEVICES 03.05.05 - Polypropylene/Polyester Mesh 03.05.05.04 - >600-<2500cm ²	Covidien Pty Ltd
BB123	Vasograft	PTFE - Straight Standard Wall	10 - Vascular 10.03 - Grafts	B Braun Australia

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.

7.3 Delete a Listing *continued*

Confirm Selected Listing

Billing Code	AS123
Sponsor	Covidien Pty Ltd
Product Name	Parietene-Monofilament Polypropylene mesh
Description	Parietene-Monofilament Polypropylene standard mesh / light mesh/ X-shaped mesh
Size(s)	30 X 30 cm, 30 x 32 cm
Benefit	\$275
Category	03 - General Miscellaneous
Subcategory	03.08 - CLOSURE DEVICES
Group	03.08.05 - Polypropylene/Polyester Mesh
Subgroup	03.08.05.04 - >600-<2500cm²
Suffixes	

[Confirm](#) [Cancel](#)

Selected Listing

Product #	Billing Code	Product Name	Actions
No records found.			

[Select a Listing](#)

Reason for Deletion

Please select a reason for the deletion of this listing: *

-- Choose a reason -- ▼

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.

The screenshot displays the 'Review and Submit' interface. At the top, application details are shown: Application Type: DELETE, Reference Number: D000011, Product / System: Septal Button, Status: View Status Details, and Last Update Date: 31/07/2017 11:24. Below this is a 'Review' button and a help icon. The 'Application Type: Delete a Listing' is displayed. A 'Submit' button is visible. The 'Submit Application:' section includes a note: '(This section must be completed by a user with the "Approver" role)'. A checkbox is present with the text: 'I declare that all information provided in this application is true and correct. I agree to pay the application fee listed above. *'. At the bottom, there are 'Prev', 'Save', and 'Submit' buttons.

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.

