**Stoma Product Assessment Panel**

**Public Summary Documents**

Multigate Medical Devices– 2 May 2023

Contents

[Nelaton Catheter – Male Coude Tip – MG#01MAY2023 2](#_Toc132113193)

[Nelaton Catheter – Hydrophilic Coated – MG#02MAY2023 4](#_Toc132113194)

[Nelaton Catheter – Hydrophilic with water sachet – MG#03MAY2023 6](#_Toc132113195)

[Nelaton Catheter – Standard – MG#04MAY2023 8](#_Toc132113196)

[Enclosed Sterile Intermittent Catheter with Gel and 1500ml Bag – MG#05MAY2023 10](#_Toc132113197)

# Nelaton Catheter – Male Coude Tip – MG#01MAY2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Multigate Medical Devices, sought listing of Nelaton Catheter – Male Coude Tip with water sachet in subgroup 8(c) of the Stoma Appliance Scheme (SAS) Schedule. The product (6 variants) was proposed for listing at a unit price of $1.900, with a maximum monthly quantity of 100 units.

### Comparator

The applicant nominated Apogee Essentials intermittent catheter tieman coude (SAS Code 80157T) as the comparator. The comparator product (4 variants) is currently listed in subgroup 8(c) of the SAS Schedule at the unit price of $1.657, with a maximum monthly quantity of 90 units and a R1 restriction.

### Background

This was the Stoma Product Assessment Panel’s (the Panel) first consideration of this product.

### Clinical Place for the Product

The proposed product would provide an alternative for users requiring a catheter.

### Clinical Analysis

The Panel questioned if the appropriate comparator was selected and noted that this product is a self-lubricating urethral catheter providing smooth, painless insertion into the urethra, which is not necessary when catheterising a stoma.

### Economic Analysis

The Panel noted that if the listing of this new product was recommended, it would be recommended for listing at the same price and the same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost to the SAS Schedule.

### Financial Analysis

Should listing of this product be recommended in the future, the likely budgetary impact for the SAS would be dependent on the agreed price per unit and maximum quantity in comparison to other products listed in the same group and subgroup.

### Panel Recommendation

The Panel rejected the application for Nelaton Catheter – Male Coude Tip with water sachet in subgroup 8(c) of the SAS Schedule with 6 variants, at the unit price of $1.900, with a maximum monthly quantity of 100 units.

The Panel noted these products have limited utility for patients accessing the SAS and are available for use through other government schemes such as the National Disability Insurance Scheme, the Continence Aids Payments Scheme and state‑based equipment schemes. The Panel noted that they would welcome a resubmission that clearly outlines how these products would benefit ostomates.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. Applications are considered in this context. Panel advice not to recommend listing or changes to a listing does not represent a final Panel view about the merits of a particular stoma product. A company can resubmit to the Panel following advice not to recommend listing or changes to a listing. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant’s Comment

The applicant noted the Panel recommendation.

# Nelaton Catheter – Hydrophilic Coated – MG#02MAY2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Multigate Medical Devices, sought listing of Nelaton Catheter – Hydrophilic Coated, in subgroup 8(c) of the Stoma Appliance Scheme (SAS) Schedule. The product (14 variants) was proposed for listing at a unit price of $1.400, with a maximum monthly quantity of 100 units.

### Comparator

The applicant nominated Mediplast Australia, LoFric Hydrophilic, Intermittent Catheter (SAS Code 80184F) as the comparator. The comparator product (19 variants) is currently listed in subgroup 8(c) of the SAS Schedule at the unit price of $1.034, with a maximum monthly quantity of 120 units.

### Background

This was the Stoma Product Assessment Panel’s (the Panel) first consideration of this product.

### Clinical Place for the Product

The proposed product would provide an alternative for users requiring a catheter.

### Clinical Analysis

The Panel questioned if the appropriate comparator was selected and noted this product has a smooth water-soluble polymer coating which supports lubricant free insertion, which is not necessary when catheterising a stoma.

### Economic Analysis

The Panel noted that if the listing of this new product was recommended, it would be recommended for listing at the same price and the same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost on the SAS Schedule.

### Financial Analysis

Should listing of this product be recommended in the future, the likely budgetary impact for the SAS would be dependent on the agreed price per unit and maximum quantity in comparison to other products listed in the same group and subgroup.

### Panel Recommendation

The Panel rejected the application for Nelaton Catheter – Hydrophilic Coated, in subgroup 8(c) of the SAS Schedule with 14 variants, at the unit price of $1.400, with a maximum monthly quantity of 100 units.

The Panel noted these products have limited utility for patients accessing the SAS and are available for use through other government schemes such as the National Disability Insurance Scheme, the Continence Aids Payments Scheme and state‑based equipment schemes. The Panel noted that they would welcome a resubmission that clearly outlines how these products would benefit ostomates.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. Applications are considered in this context. Panel advice not to recommend listing or changes to a listing does not represent a final Panel view about the merits of a particular stoma product. A company can resubmit to the Panel following advice not to recommend listing or changes to a listing. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant’s Comment

The applicant noted the Panel recommendation.

# Nelaton Catheter – Hydrophilic with water sachet – MG#03MAY2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Multigate Medical Devices, sought listing of Nelaton Catheter – Hydrophilic with water sachet in subgroup 8(c) of the Stoma Appliance Scheme (SAS) Schedule. The product (16 variants) was proposed for listing at a unit price of $1.850, with a maximum monthly quantity of 100 units.

### Comparator

The applicant did not nominate a comparator.

### Background

This was the Stoma Product Assessment Panel’s (the Panel) first consideration of this product.

### Clinical Place for the Product

The proposed product would provide an alternative for users requiring a catheter.

### Clinical Analysis

The Panel noted this product has a smooth water-soluble polymer coating which supports lubricant free insertion, which is not necessary when catheterising a stoma.

### Economic Analysis

The Panel noted that if the listing of this new product was recommended, it would be recommended for listing at the same price and the same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost to the SAS Schedule.

### Financial Analysis

Should listing of this product be recommended in the future, the likely budgetary impact for the SAS would be dependent on the agreed price per unit and maximum quantity in comparison to other products listed in the same group and subgroup.

### Panel Recommendation

The Panel rejected the application for Nelaton Catheter – Hydrophilic with water sachet in subgroup 8(c) of the SAS Schedule with 6 variants, at the unit price of $1.850, with a maximum monthly quantity of 100 units.

The Panel noted these products have limited utility for patients accessing the SAS and are available for use through other government schemes such as the National Disability Insurance Scheme, the Continence Aids Payments Scheme and state‑based equipment schemes. The Panel noted that they would welcome a resubmission that clearly outlines how these products would benefit ostomates.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. Applications are considered in this context. Panel advice not to recommend listing or changes to a listing does not represent a final Panel view about the merits of a particular stoma product. A company can resubmit to the Panel following advice not to recommend listing or changes to a listing. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant’s Comment

The applicant noted the Panel recommendation.

# Nelaton Catheter – Standard – MG#04MAY2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Multigate Medical Devices, sought listing of Nelaton Catheter – Standard in subgroup 8(c) of the Stoma Appliance Scheme (SAS) Schedule. The product (15 variants) was proposed for listing at a unit price of $0.530, with a maximum monthly quantity of 100 units.

### Comparator

The applicant nominated Unomedical nelaton catheter (SAS Code 3671F) as the comparator. The comparator product (28 variants) is currently listed in subgroup 8(c) of the SAS Schedule at the unit price of $1.034, with a maximum monthly quantity of 100 units.

### Background

This was the Stoma Product Assessment Panel’s (the Panel) first consideration of this product.

### Clinical Place for the Product

The proposed product would provide an alternative for users requiring a catheter.

### Clinical Analysis

The Panel noted limited clinical evidence was provided to support the product’s use for patients covered by the SAS and questioned if the appropriate comparator was selected.

### Economic Analysis

The Panel noted that if the listing of this new product was recommended, it would be at a lower price and the same maximum monthly quantity as currently listed products in the same subgroup, and likely result in a reduced monthly cost on the SAS Schedule.

### Financial Analysis

Should listing of this product be recommended in the future, the likely budgetary impact for the SAS would be dependent on the agreed price per unit and maximum quantity in comparison to other products listed in the same group and subgroup.

### Panel Recommendation

The Panel rejected the application for Nelaton Catheter – Standard in subgroup 8(c) of the SAS Schedule with 15 variants, at the unit price of $0.530, with a maximum monthly quantity of 100 units.

The Panel noted these products have limited utility for patients accessing the SAS and are available for use through other government schemes such as the National Disability Insurance Scheme, the Continence Aids Payments Scheme and state‑based equipment schemes. The Panel noted that they would welcome a resubmission that clearly outlines how these products would benefit ostomates.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. Applications are considered in this context. Panel advice not to recommend listing or changes to a listing does not represent a final Panel view about the merits of a particular stoma product. A company can resubmit to the Panel following advice not to recommend listing or changes to a listing. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant’s Comment

The applicant noted the Panel recommendation.

# Enclosed Sterile Intermittent Catheter with Gel and 1500ml Bag – MG#05MAY2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Multigate Medical Devices, sought listing of Enclosed Sterile Intermittent Catheter with Gel and 1500ml Bag in subgroup 8(c) of the Stoma Appliance Scheme (SAS) Schedule. The product (5 variants) was proposed for listing at a unit price of $3.500, with a maximum monthly quantity of 25 units.

### Comparator

The applicant did not nominate a comparator.

### Background

This was the Stoma Product Assessment Panel’s (the Panel) first consideration of this product.

### Clinical Place for the Product

The proposed product would provide an alternative for users requiring a catheter.

### Clinical Analysis

The Panel noted this product is pre lubricated with hydrophilic gel for simple insertion to the urethra and has a closed sterile system to reduce the risk of urinary tract infections, which is not necessary when catheterising a stoma.

### Economic Analysis

The Panel noted that if the listing of this new product was recommended, it would be recommended for listing at the same price and the same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost on the SAS Schedule.

### Financial Analysis

Should listing of this product be recommended in the future, the likely budgetary impact for the SAS would be dependent on the agreed price per unit and maximum quantity in comparison to other products listed in the same group and subgroup.

### Panel Recommendation

The Panel rejected the application for the Enclosed Sterile Intermittent Catheter with Gel and 1500ml Bag in subgroup 8(c) of the SAS Schedule with 5 variants, at the unit price of $3.500, with a maximum monthly quantity of 25 units.

The Panel noted these products have limited utility for patients accessing the SAS and are available for use through other government schemes such as the National Disability Insurance Scheme, the Continence Aids Payments Scheme and state‑based equipment schemes. The Panel noted that they would welcome a resubmission that clearly outlines how these products would benefit ostomates.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. Applications are considered in this context. Panel advice not to recommend listing or changes to a listing does not represent a final Panel view about the merits of a particular stoma product. A company can resubmit to the Panel following advice not to recommend listing or changes to a listing. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant’s Comment

The applicant noted the Panel recommendation.