



Versius Surgical System

Instrument Reprocessing Instructions (Version 19.0)

Read before use



CE 1434 REF 70100



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REF 70100 Versius Instrument Reprocessing Instructions

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This document provides instructions for the reprocessing of the Versius Surgical Instruments.

Rx only

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Introduction

This document provides instructions for the reprocessing of the Versius Surgical Instruments, including cleaning, disinfection and sterilisation, and equipment recommended by CMR Surgical Ltd.

These instructions must be read and fully understood before reprocessing Versius instruments.

These instructions have been validated by CMR Surgical. This does not preclude the statutory requirements of the sterile services department to undertake process monitoring, testing and quality control to ensure the effectiveness of the cleaning, disinfection and sterilisation procedures.

Versius instruments are supplied non-sterile, and must be reprocessed before first use.

Stainless steel baskets with electropolished steel of grade 304 or 316 with min of 20 mm gap mesh and minimum contact supports can be used when reprocessing Versius instruments and endoscopes. If using a basket, visually inspect the basket for any wear and tear or sharps which may compromise the performance and for rust. Baskets must follow and complete the full reprocessing and sterilisation cycle before each use and follow the instructions from the basket manufacturer, if applicable. Baskets may be wrapped in interleave wrap that is compliant with ISO-11607-1 and EN868-2 in accordance with international standards or pouched.

Discolouration of metal surfaces is possible when alkaline enzymatic

detergents are used (pH 8-11). However, this does not impair the functional capability of the Versius instruments.

If there are any questions regarding these instructions or if any Versius instruments show signs of defects or damage, please contact CMR Surgical customer services.

To arrange return of any affected instrument, please contact CMR Surgical technical support.

CMR Surgical Limited,
1 Evolution Business Park,
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Tel: +44 (0) 1223 750 975

For technical support:

If your system requires technical support or service, please call our technical support line:

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Email: customer.service@cmrsurgical.com





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Refer to the instructions provided with the endoscope and electrosurgery cables for instructions on reprocessing these items.









Warning, precaution and information symbols in this document













-  This symbol indicates a warning. Warnings in these reprocessing instructions indicate situations that could result in serious injury to the patient or user.











-  This symbol indicates a precaution. Precautions in these reprocessing instructions indicate situations that could result in minor or moderate injury to the patient or user, or damage to Versius instruments.




-  This symbol indicates an information point. Information points indicate important reference information.

Full list of warnings





-  Versius instruments are supplied non-sterile, and must be reprocessed before first use.
-  Follow Versius Instrument Reprocessing Instructions for effective reprocessing of Versius instruments.
-  Always monitor the number of reprocessing cycles completed for each instrument, so as not to exceed the maximum number of cycles.
-  Only trained healthcare professionals and sterile services technicians should handle and reprocess Versius instruments. Inadequate handling may result in damage to, or ineffective reprocessing of, Versius instruments.
-  Do not continue with reprocessing if a Versius instrument has been dropped as it may be damaged. Always dispose of dropped instruments.
-  Take care when handling the Versius instrument tip due to the risk of sharps injury.
-  Only use validated reprocessing products and equipment, including ultrasonic baths, washer/disinfectors and sterilisers. Only use validated parameter settings. Parameter settings that have not been validated could result in damage to, or ineffective cleaning and sterilisation of, Versius instruments.
-  Do not modify Versius instruments.

-  Handle contaminated Versius instruments according to local guidelines.
-  Take care when handling contaminated fluids or chemicals, as skin contact, inhalation or ingestion may cause harm. Personal Protective Equipment (PPE) should be worn, according to local guidelines.
-  Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.
-  Always carefully inspect Versius instruments during every reprocessing cycle. Inspect for any signs of defects, damage or residual soil. Failure to do so may result in patient harm.
-  Do not use salt solution when reprocessing Versius instruments. This could result in damage to the Versius instruments.
-  Do not use abrasive metal brushes as these may damage the Versius instruments.
-  Ensure water pressure does not exceed 2.5 bar (36 psi).
-  When undertaking point-of-use preparation and initial manual cleaning, do not use water or any other fluid, such as enzymatic detergent, at a temperature higher than 45 °C (113 °F). This could coagulate proteins to the surfaces of the Versius instruments and may result in ineffective cleaning.
-  Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of, Versius instruments.
-  Do not use solutions or rinse aids that are acidic (pH<7) or strongly alkaline (pH>11), or hydrogen peroxide based or bleach-based cleaning products, as they may damage Versius instruments.
-  Do not use chemical disinfection of Versius instruments. This could result in damage to, or ineffective disinfection of, Versius instruments.
-  Ensure that Versius instruments have jaws open and are not touching or shadowing each other when placing into the ultrasonic bath and the washer/disinfector. Failure to do so may result in damage to, or ineffective cleaning of, Versius instruments.

-  Always use ISO 15883 compliant washer/disinfectors.
-  During automated cleaning and thermal disinfection, only use washer/disinfectors with irrigation devices that have tapered 6° 4mm Luer slip connector fittings. Use of washer/disinfectors without irrigation devices could result in ineffective cleaning and/or disinfection of Versius instruments.
-  Take care when handling equipment that is hot as it could cause burns. Personal Protective Equipment (PPE) should be worn, according to local guidelines.
-  Always allow Versius instruments to cool down gradually to room temperature after sterilisation. Sudden changes in temperature may cause moisture to condense in the instrument pouch and compromise instrument sterility.
-  Only use validated steam-permeable, pH neutral lubricant and ensure that Versius instruments have been thoroughly dried and are free of excess lubrication before sterilisation as any moisture remaining could result in ineffective sterilisation. Using lubricants that have not been validated may result in damage to, or ineffective sterilisation of, Versius instruments.
-  Ensure air pressure does not exceed 5 bar (73 psi).
-  Do not get lubricant onto the yellow Position Marker when lubricating the Monopolar Curved Scissors, as this may cause the Insulating Sleeve of the Monopolar Curved Scissors to move out of its correct position or to slide off during surgery. Return to the initial manual cleaning step if lubricant gets onto the yellow Position Marker.
-  Always use a steam-permeable instrument point protector or equivalent, as sharp instruments could pierce the steam-permeable sterilisation peel pouch, resulting in ineffective sterilisation. Only use validated peel pouches. Using peel pouches that have not been validated may result in damage to, or ineffective sterilisation of, Versius instruments.
-  The sterilisation process should conform with ISO 17665-1.
-  Do not overload the Versius instruments into the steam steriliser chamber. This could prevent efficient steam penetration and effective sterilisation.

-  Always store and transport Versius instruments in line with local guidelines. Incorrect storage and transportation could lead to damage to the instrument or instrument pouch.
-  During initial manual cleaning and all main cleaning procedures, prepare pH 7-11 enzymatic detergent solution according to the manufacturer's instructions including appropriate dilution, temperature and soaking times.
-  Always flush the instrument through flush port 1 before flushing through flush port 2. Flushing through flush port 1 after flush port 2 may re-contaminate the instrument.

Full list of precautions

-  Do not reprocess instruments beyond their reprocessing life. This could result in damage to the instruments. See Appendix A for maximum number of reprocessing cycles and instrument uses.
-  Instrument cleaning should start within 4 hours of transport from point of use.
-  At point-of-use preparation only use pH-neutral cleaning fluid as splashes of non-pH-neutral fluids may cause skin irritation or burns.
-  Use low-foaming, non-abrasive detergent solutions, and prepare these according to the manufacturer's instructions.

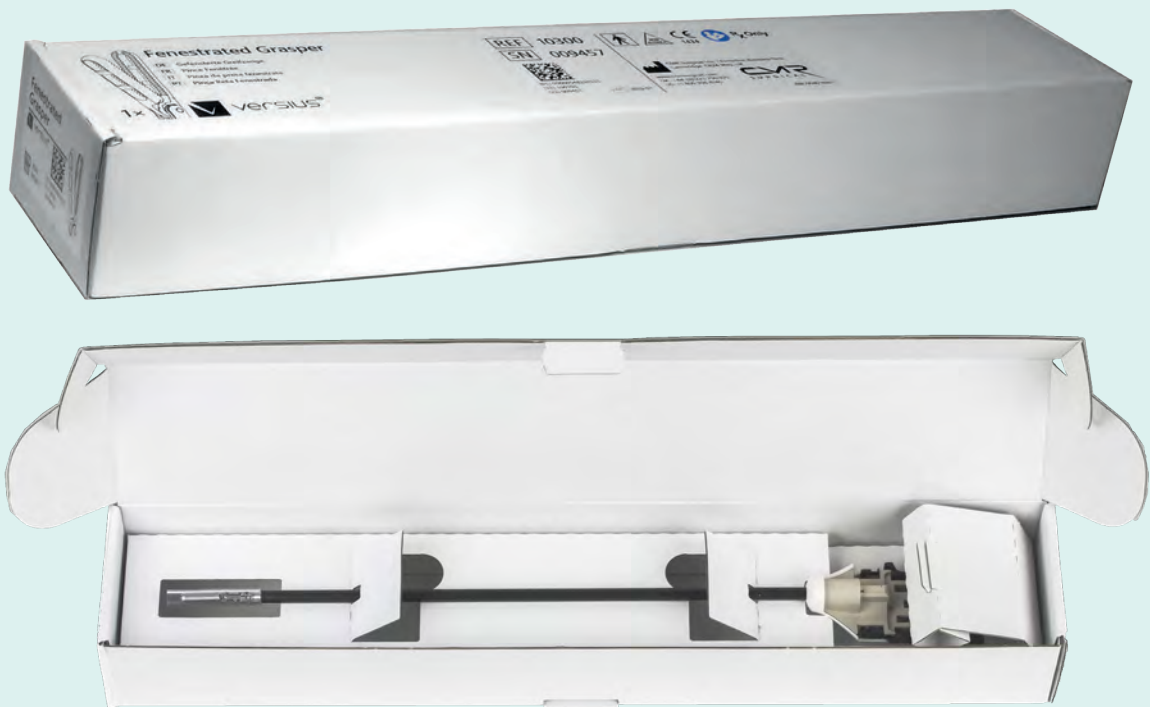
Full list of information points

-  Only use equipment and products cleared for use by competent local authorities.
-  Follow manufacturer's instructions when using reprocessing equipment and products.

- i** Dispose of Versius instruments following all applicable national and local laws and guidelines.
- i** Begin instrument point-of-use preparation within 30 minutes of the surgical procedure ending.
- i** Keep instruments moist at point-of-use preparation to prevent soil drying onto Versius instruments. Neglecting to do so could result in ineffective cleaning.
- i** At point-of-use preparation, manufacturer's instructions should have been followed to premix the pH neutral enzymatic detergent solution, including appropriate dilution and temperature.
- i** It is recommended that, wherever possible, the use of mechanical cleaning with automatic washer/ disinfectors should be used. Where this is not possible, ultrasonic cleaning is recommended.
- i** Follow the manufacturer's instructions when operating the ultrasonic bath, the washer/ disinfectant and the steam steriliser.
- i** The ultrasonic bath should be large enough to accommodate an instrument fully covered in pH 7-11 enzymatic detergent.
- i** During ultrasonic cleaning, irrigation (tapered 6° 4mm Luer slip) connections are recommended. If available, connect irrigation devices to instrument flush ports 1 and 2.
- i** Lubricate each Versius instrument in every reprocessing cycle to maintain their function and protect them from corrosion and aging.
- i** Take care when inserting a Versius instrument into the steam-permeable sterilisation peel pouch to avoid damage to the instrument tip.
- i** It is recommended that the instrument jaws should be open before sealing the steam-permeable sterilisation peel pouch.

Receiving new instruments

Instruments are shipped non-sterile in shipper boxes containing individual boxes. Reprocessing is required before first use.

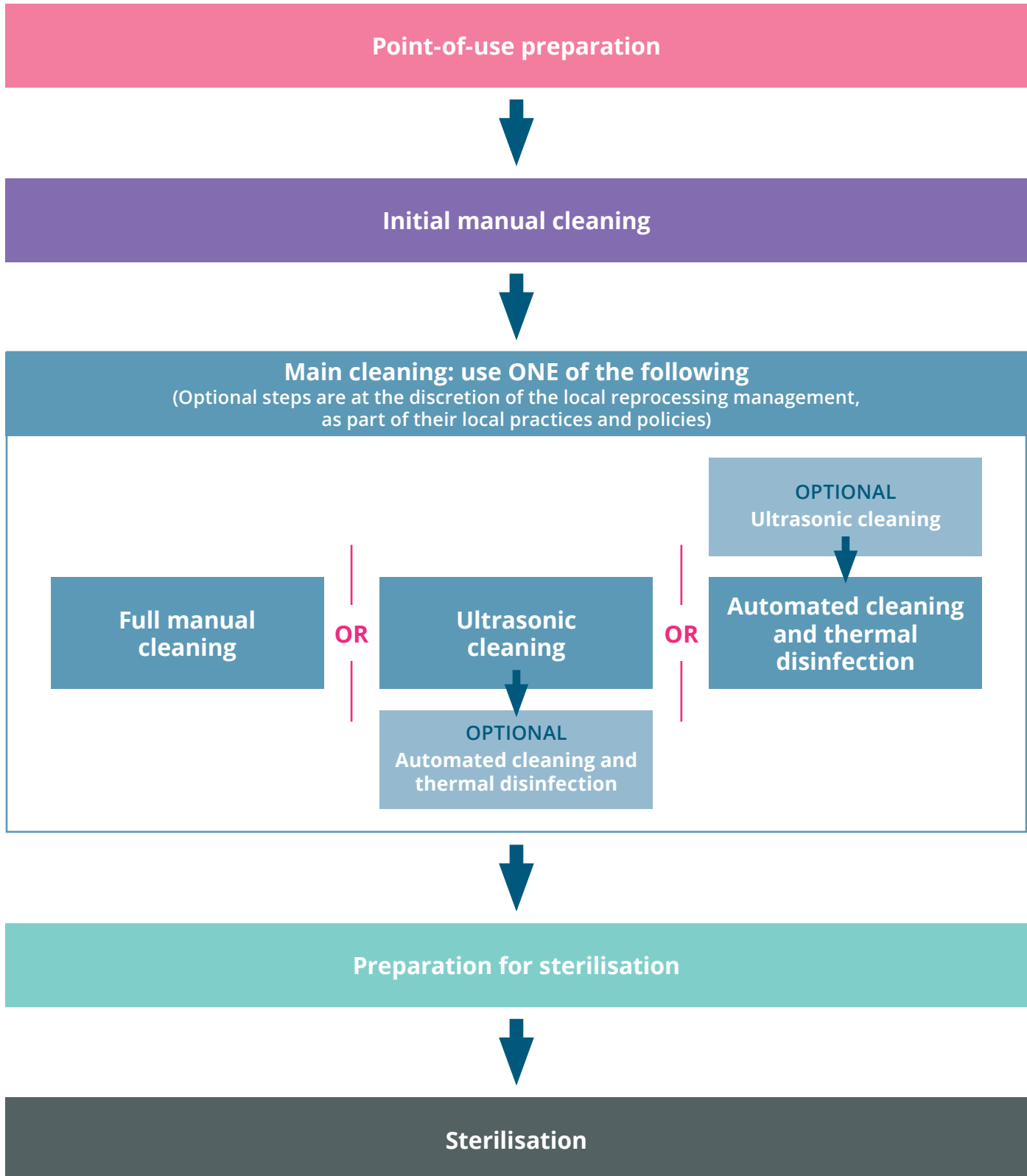


Instrument packaging

Quick Reference

Procedures Overview

Outline of all procedures



Point-of-use preparation

- Step 1** **Wipe off excess soil**
(page 32)
- Step 2** **Flush instrument flush port 1**
(page 33)
- Step 3** **Moisten instrument**
(page 35)
- Step 4** **Seal container and transport**
(page 37)

Initial manual cleaning

- Step 1** Flush instrument flush port 1
(page 42)
- Step 2** Soak instrument
(page 44)
- Step 3** Flush instrument flush ports 1 and 2
(page 45)
- Step 4** Spray instrument tip
(page 47)
- Step 5** Brush instrument
(page 48)
- Step 6** Rinse instrument
(page 49)

Proceed to main cleaning with **ONE** of the following methods:

Full manual cleaning continue to page 53

OR

Ultrasonic cleaning continue to page 67

OR

**Automated cleaning
and thermal disinfection** continue to page 79

Main cleaning: Full manual cleaning

- Step 1** Flush instrument flush port 1
(page 56)
- Step 2** Soak instrument
(page 57)
- Step 3** Flush instrument flush ports 1 and 2
(page 58)
- Step 4** Spray instrument tip
(page 60)
- Step 5** Brush instrument
(page 61)
- Step 6** Flush instrument flush ports 1 and 2
(page 62)
- Step 7** Spray instrument tip
(page 64)
- Step 8** Rinse instrument with critical water
(page 65)

Main cleaning: Ultrasonic cleaning

Step 1

Flush instrument flush port 1
(page 70)

Step 2

Run ultrasonic cycle
(page 71)

Step 3

Flush instrument flush ports 1 and 2
(page 73)

Step 4

Spray instrument tip
(page 75)

Step 5

Rinse instrument with critical water
(page 76)

Main cleaning: Automated cleaning and thermal disinfection

Step 1

Load instruments into washer/disinfector
(page 82)

Step 2

Run washer/disinfector cycle
(page 83)

Preparation for sterilisation

- Step 1** **Dry instrument**
(page 88)
- Step 2** **Inspect instrument**
(page 90)
- Step 3** **Lubricate instrument**
(page 93)
- Step 4** **Pack instrument**
(page 97)

Sterilisation

- Step 1** **Load steam steriliser tray**
(page 102)
- Step 2** **Sterilise instruments**
(page 103)
- Step 3** **Store and transport instruments**
(page 104)

Instrument Overview

Needle Holder



The Needle Holder is used by the surgeon to hold a suturing needle for joining tissues during a surgical procedure. The jaws of the instrument are short and textured in order to maintain a firm grip on the needle.

Reprocessing cycles: 20

Bipolar Maryland Grasper



The Bipolar Maryland Grasper is used by the surgeon to securely grasp or dissect tissue, as well as provide bipolar coagulation via an electrical current, during surgical procedures. The jaws of the instrument feature fenestrations (windows).


Reprocessing cycles: 15

Fenestrated Grasper



The Fenestrated Grasper features long jaws, designed to minimise tissue damage during delicate handling, and fenestrations (windows) along the length of the jaws to enhance the grip on tissue.

Reprocessing cycles: 20

 Versius instruments are supplied non-sterile, and must be reprocessed before first use.

Monopolar Hook



The Monopolar Hook is used by the surgeon during electrosurgery for dissection and can also be a convenient tool for separating tissue when used as a non-powered device. The Monopolar Hook is the only Versius instrument which has only two fins (see page 24; the other instruments all have three fins).

Reprocessing cycles: 7

Curved Scissors



The Curved Scissors are used by the surgeon to dissect tissue. The curved shape of the blades allows for better visualisation of the instrument tip and therefore more precise work by the surgeon at the surgical site.

Reprocessing cycles: 20

Monopolar Curved Scissors



The Monopolar Curved Scissors are used by the surgeon to cut or coagulate tissue during electrosurgery using diathermic heating via an electrical current. The instrument can also be used for mechanical cutting. The Versius Monopolar Curved Scissors Insulating Sleeve (see the Instrument and Accessories Manual [REF 70050]) provides a flexible insulative layer between live elements of the instrument and the patient.

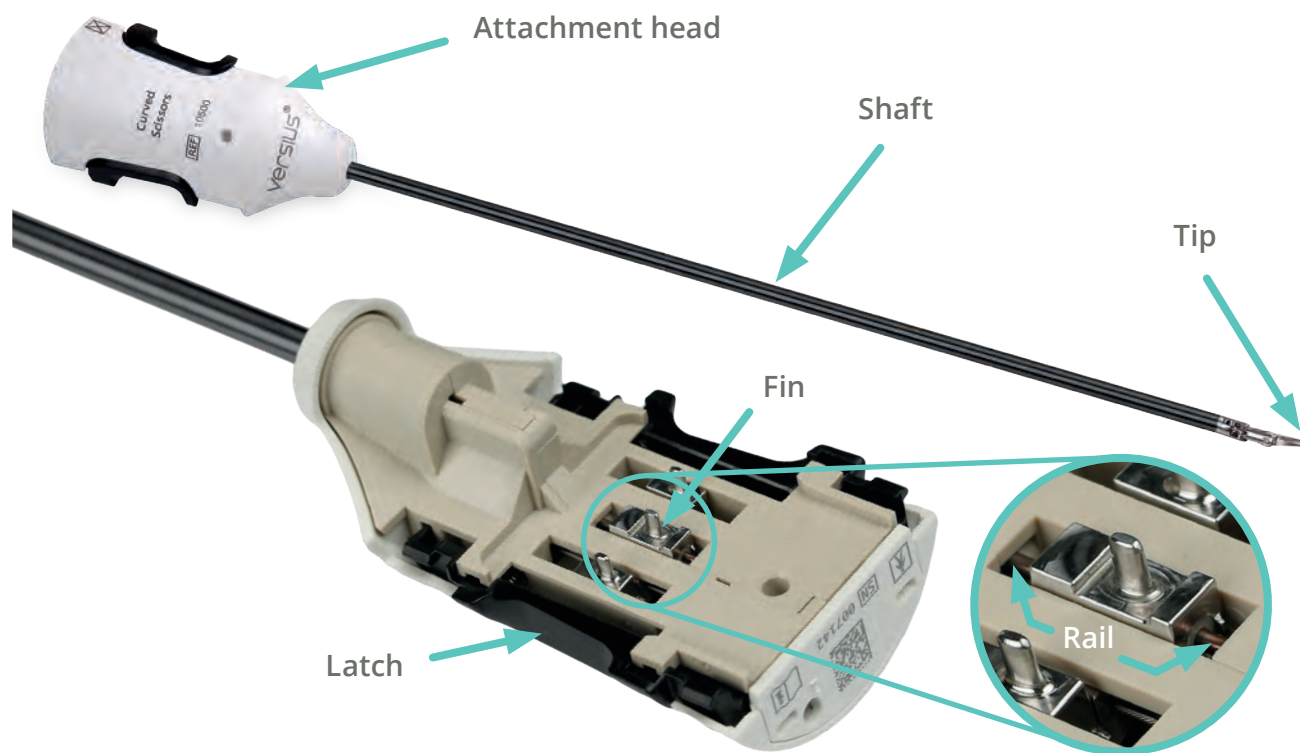
Reprocessing cycles: 10

Insulating Sleeve



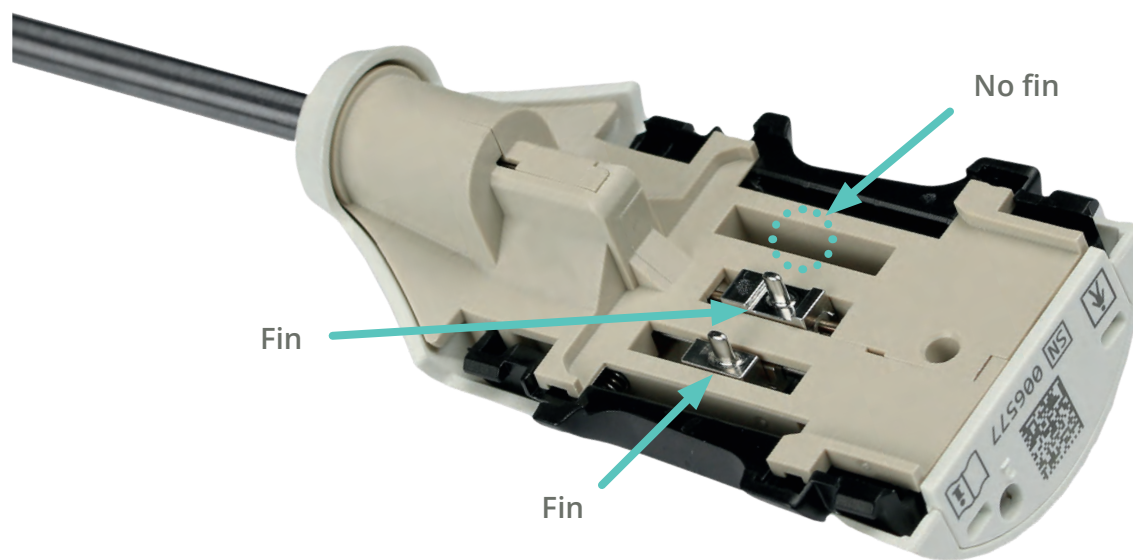
Do not re-use the Insulating Sleeve

⚠ Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.



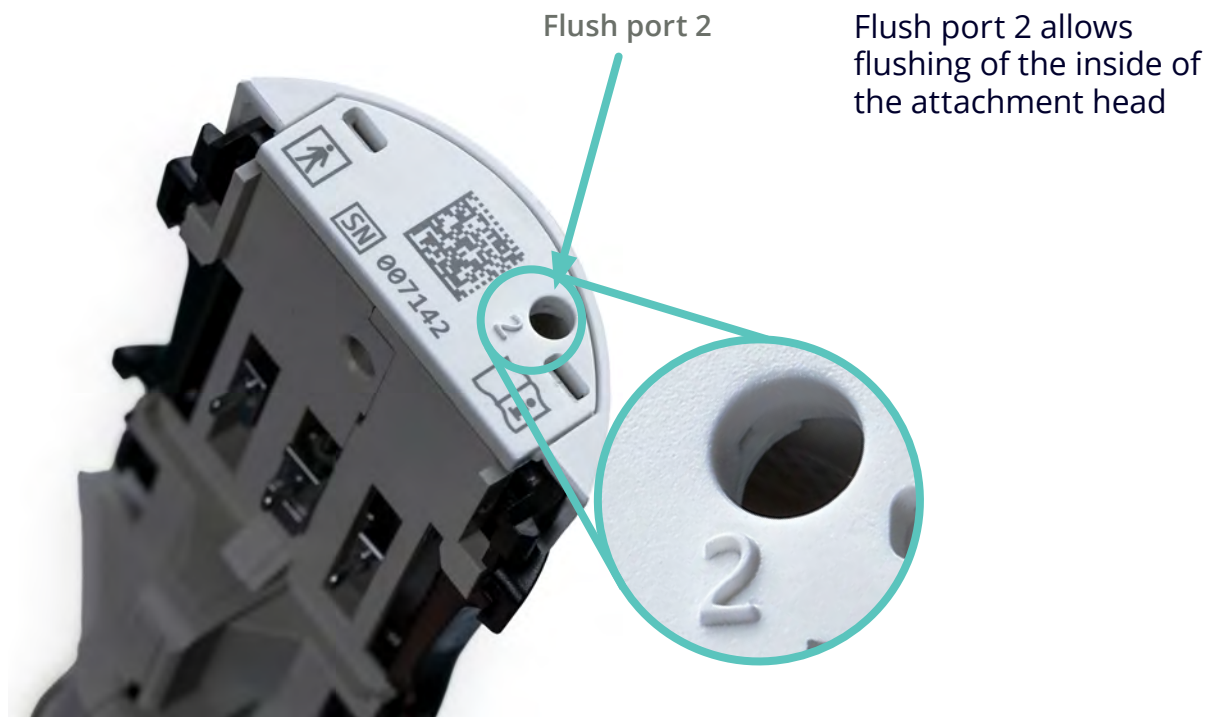
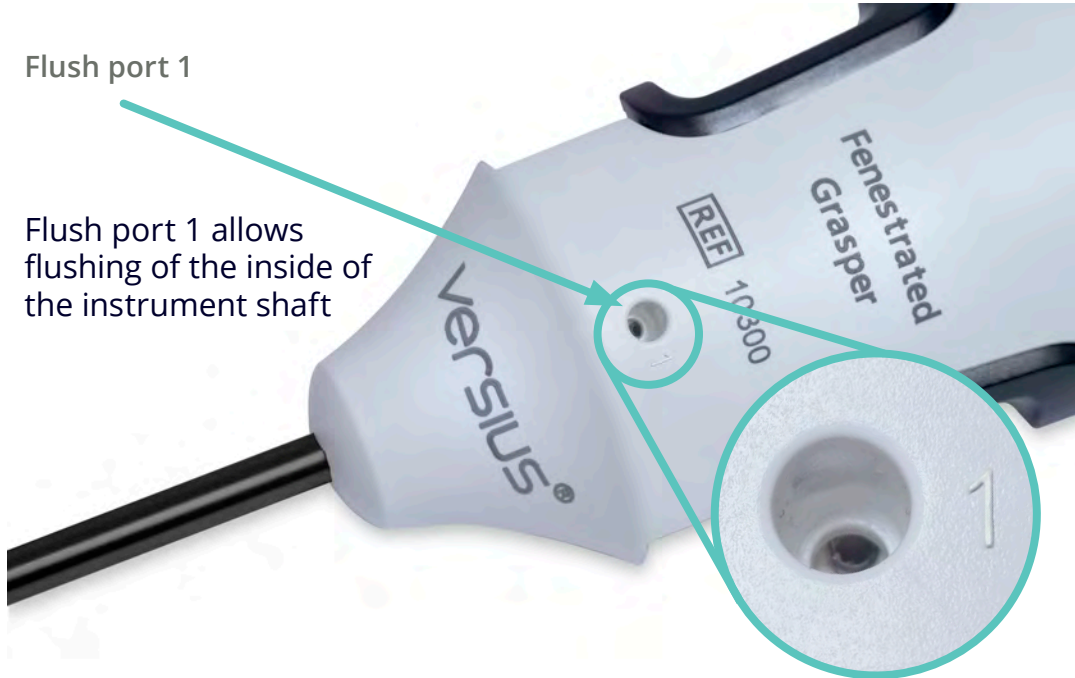
A Versius instrument with key components labelled

All Versius instruments have three fins, except for the Monopolar Hook, which only has two.



Monopolar Hook has only two fins

- ⚠ Always flush the instrument through flush port 1 before flushing through flush port 2. Flushing through flush port 1 after flush port 2 may re-contaminate the instrument.








Flush ports 1 and 2 on a Versius instrument
(connect to irrigation devices that have tapered 6° 4mm Luer slip connector fittings)


Procedures

Point-of-use preparation

Warnings

-  Do not continue with reprocessing if a Versius instrument has been dropped as it may be damaged. Always dispose of dropped instruments.
-  Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.
-  Do not use salt solution when reprocessing Versius instruments. This could result in damage to the Versius instruments.
-  When undertaking point-of-use preparation and initial manual cleaning, do not use water or any other fluid, such as enzymatic detergent, at a temperature higher than 45 °C (113 °F). This could coagulate proteins to the surfaces of the Versius instruments and may result in ineffective cleaning.
-  Do not use solutions or rinse aids that are acidic (pH<7) or strongly alkaline (pH>11), or hydrogen peroxide based or bleach-based cleaning products, as they may damage Versius instruments.

Precautions

-  At point-of-use preparation only use pH-neutral cleaning fluid as splashes of non-pH-neutral fluids may cause skin irritation or burns.

Information points

- i** Begin instrument point-of-use preparation within 30 minutes of the surgical procedure ending.
- i** Keep instruments moist at point-of-use preparation to prevent soil drying onto Versius instruments. Neglecting to do so could result in ineffective cleaning.
- i** At point-of-use preparation, manufacturer's instructions should have been followed to premix the pH neutral enzymatic detergent solution, including appropriate dilution and temperature.

Equipment required



Lint-free cloth



**Syringe with tapered
6° 4mm Luer slip
connector fitting**



Sealable container
large enough for the
instrument



Transport cart

Fluid to flush instrument flush port 1.
Choose one of the following:



**pH neutral enzymatic
detergent (preferred)**
premixed according
to the manufacturer's
instructions

OR



Cold water

Method to keep instrument moist.
Choose one of the following:



**pH neutral enzymatic
detergent (preferred)**
premixed according
to the manufacturer's
instructions

OR



Cold water

OR




**pH neutral enzymatic
foam spray**

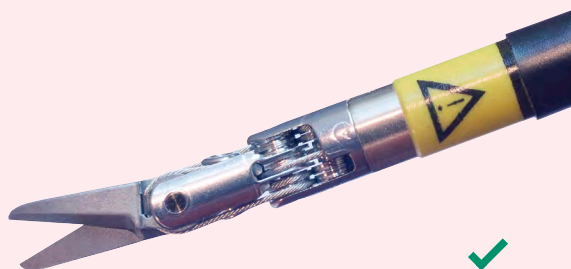
See page 7 for details of reprocessing
baskets


Step 1 Wipe off excess soil

Before starting...

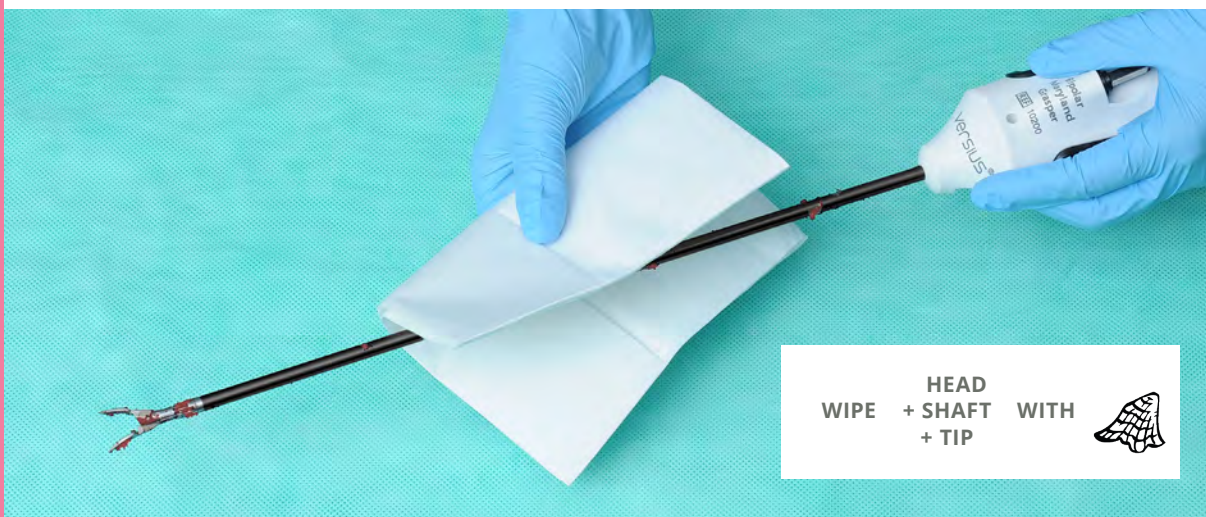
 Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument.

Refer to the Instrument and Accessories Manual [REF 70050] for instructions on removing the Insulating Sleeve.



 Do not re-use the Insulating Sleeve

Wipe the instrument, including its attachment head, shaft and tip, with a lint-free cloth to remove excess soil.



Continue to Step 2 on page 33 

Step 2 Flush instrument flush port 1

A Fill a syringe with either:

premixed pH neutral
enzymatic detergent
(preferred solution)

OR

cold water

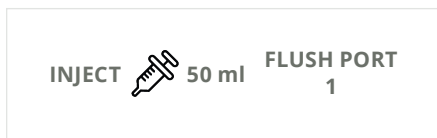
Ensure there is enough liquid to flush instrument flush port 1 and to soak the instrument.




Continue to part B of Step 2 on page 34 

Step 2 Flush instrument flush port 1 (continued)

B Insert the syringe's tapered Luer slip connector fitting into instrument flush port 1 and inject 50 ml.



Continue to Step 3 on page 35 

Step 3 **Moisten instrument** do **ONE** of the following options

Choose either **Option A** or **Option B** in Step 3 to keep the instrument moist. Alternative methods may be used, according to local guidelines.

Option A: using liquid solution

Place the instrument into the container, ensuring that it is lying flat and fully covered by liquid. Choose from either:

premixed pH neutral
enzymatic detergent
(preferred solution)

OR

cold water




Continue to Step 4 on page 37 

Step 3 **Moisten instrument (continued)**

Option B: using foam spray

1. Place the instrument into the container.
2. Spray the instrument, including its attachment head, shaft and tip, with pH neutral enzymatic foam spray.



Continue to Step 4 on page 37 

Step 4 Seal container and transport

1. Seal the container with instruments inside.

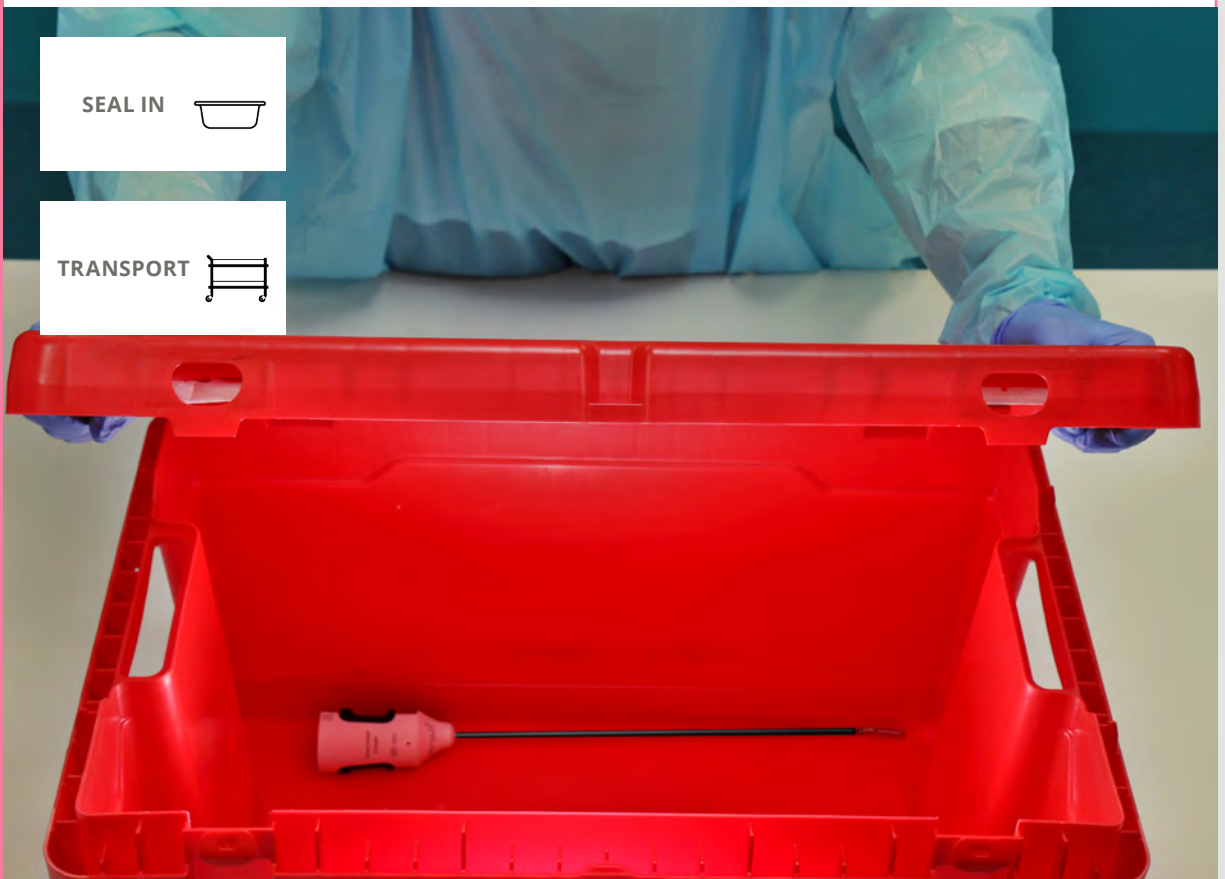
2. Transport the instruments with care, in line with local guidelines or hospital protocol.


Send instruments for reprocessing as soon as possible.

SEAL IN












TRANSPORT




Continue to Initial manual cleaning on page 39 

Initial manual cleaning

Warnings

-  Do not continue with reprocessing if a Versius instrument has been dropped as it may be damaged. Always dispose of dropped instruments.
-  Only use validated reprocessing products, equipment and parameter settings. Parameter settings that have not been validated may result in damage to, or ineffective reprocessing of, Versius instruments.
-  Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.
-  Do not use abrasive metal brushes as these may damage the Versius instruments.
-  Ensure water pressure does not exceed 2.5 bar (36 psi).
-  When undertaking point-of-use preparation and initial manual cleaning, do not use water or any other fluid, such as enzymatic detergent, at a temperature higher than 45 °C (113 °F). This could coagulate proteins to the surfaces of the Versius instruments and may result in ineffective cleaning.
-  Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of, Versius instruments.
-  Do not use solutions or rinse aids that are acidic (pH<7) or strongly alkaline (pH>11), or hydrogen peroxide based or bleach-based cleaning products, as they may damage Versius instruments.
-  During initial manual cleaning and all main cleaning procedures, prepare pH 7-11 enzymatic detergent solution according to the manufacturer's instructions including appropriate dilution, temperature and soaking times.

-  Always flush the instrument through flush port 1 before flushing through flush port 2. Flushing through flush port 1 after flush port 2 may re-contaminate the instrument.

Precautions

-  Instrument cleaning should start within 4 hours of transport from point of use.
-  Use low-foaming, non-abrasive detergent solutions, and prepare these according to the manufacturer's instructions.

Equipment required



pH 7-11 enzymatic detergent



Syringe with tapered 6° 4mm Luer slip connector fitting



Sink or container
large enough for the instrument



Cold water



Running cold water




Soft-bristled nylon brush



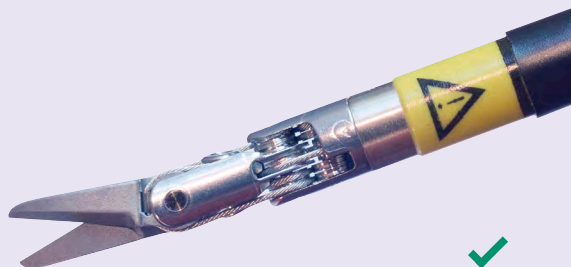
Pressurised spray nozzle with tapered 6° 4mm Luer slip connector fitting (maximum 2.5 bar [36 psi])


See page 7 for details of reprocessing baskets

Step 1 Flush instrument flush port 1**Before starting...**

-  Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.

Refer to the Instrument and Accessories Manual [REF 70050] for instructions on removing the Insulating Sleeve.



 Do not re-use the Insulating Sleeve

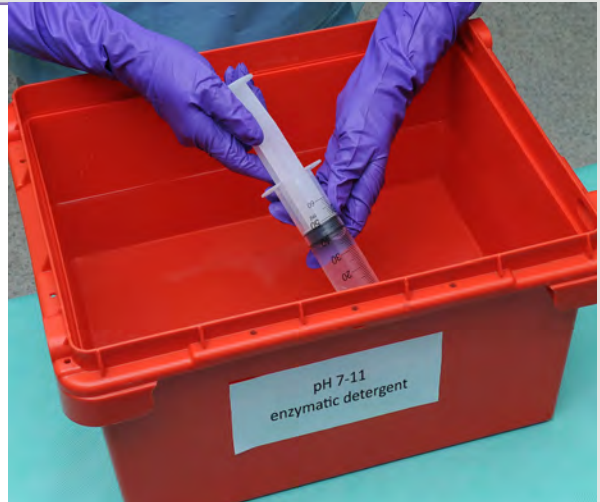
Before starting...

Prepare fresh pH 7-11 enzymatic detergent in a sink or container, according to the manufacturer's instructions. Ensure there is enough liquid to flush instrument flush port 1 and to soak the instrument.

Step 1 Flush instrument flush port 1 (continued)

A Fill a syringe with pH 7-11 enzymatic detergent.


FILL  WITH 



B Insert the syringe's tapered Luer slip connector fitting into instrument flush port 1 and inject 50 ml.

INJECT  50 ml FLUSH PORT
1




Continue to Step 2 on page 44 

Step 2 Soak instrument

1. Place the instrument flat at the bottom of a container or sink filled with enough pH 7-11 enzymatic detergent to completely cover the instrument.
2. Leave the instrument to soak for 10 minutes (unless the manufacturer's instructions recommend a longer soaking period).



Continue to Step 3 on page 45 

Step 3 Flush instrument flush ports 1 and 2

▶ Before starting...

To avoid splashes and aerosolisation, fill a sink or container with enough cold water to cover the instrument when flushing. The sink or container should be deep enough to allow complete immersion of the instrument so that aerosols are not generated during cleaning.

- A** Insert the tapered Luer slip connector fitting of the pressuriser securely into instrument flush port 1.



- B**
1. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
 2. Flush for 1 minute, with jaws open and whilst moving the instrument tip.

Additional flushing may be required until the water runs clear.



Continue to part C of Step 3 on page 46 

Step 3 Flush instrument flush ports 1 and 2 (continued)

C

1. Insert the tapered Luer slip connector fitting of the pressuriser securely into instrument flush port 2 with the **fins facing down**.
2. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
3. Flush in this position for 30 seconds.



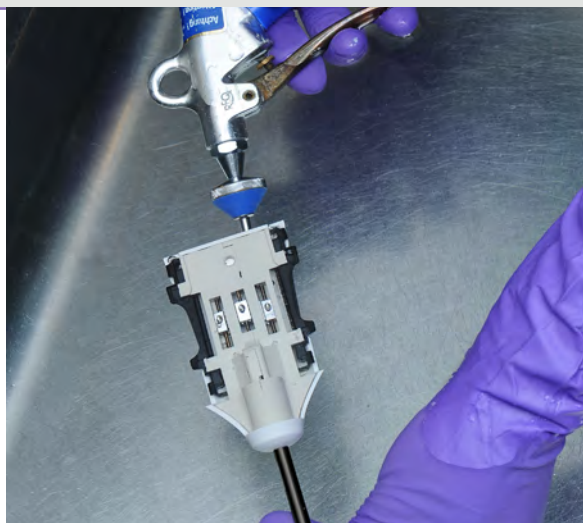
FIT  TO FLUSH PORT 2

FINS DOWN  FLUSH WITH  30 SECONDS


D

1. Rotate the instrument so that the **fins are facing up**.
2. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
3. Flush in this position for 30 seconds.

Additional flushing may be required until the water runs clear.



FINS UP  FLUSH WITH  30 SECONDS

Continue to Step 4 on page 47 

Step 4 Spray instrument tip

▶ Before starting...

To avoid splashes and aerosolisation, cover the instrument tip with cold water while spraying.

Use the pressuriser to spray the instrument tip for 1 minute with cold water, with jaws open and whilst moving the instrument tip. Ensure water pressure does not exceed 2.5 bar (36 psi).



Continue to Step 5 on page 48 

Step 5 Brush instrument



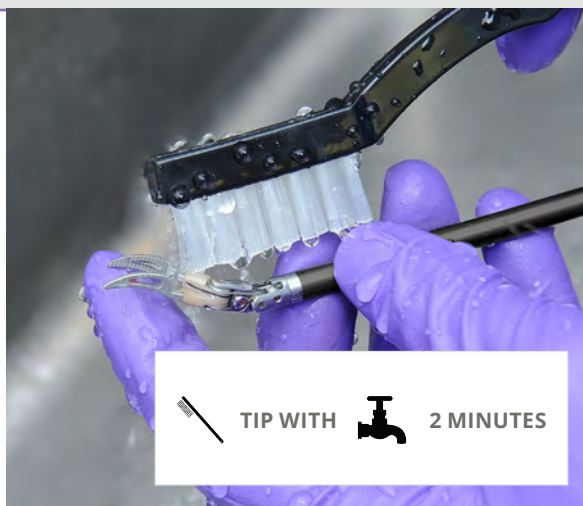
Before starting...

To avoid splashes and aerosolisation, cover the instrument tip with cold water while brushing.

A

Use a soft-bristled nylon brush to brush the instrument tip using cold water for 2 minutes, with jaws open and whilst moving the instrument tip.

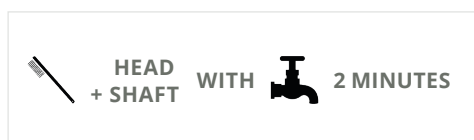
Pay particular attention to crevices, serrated profiles, interior of jaws and recessed surfaces.




B

Brush the instrument shaft and attachment head using cold water for 2 minutes.

Pay particular attention to seams, crevices, latches and recessed surfaces. Make sure to brush along and across seams.

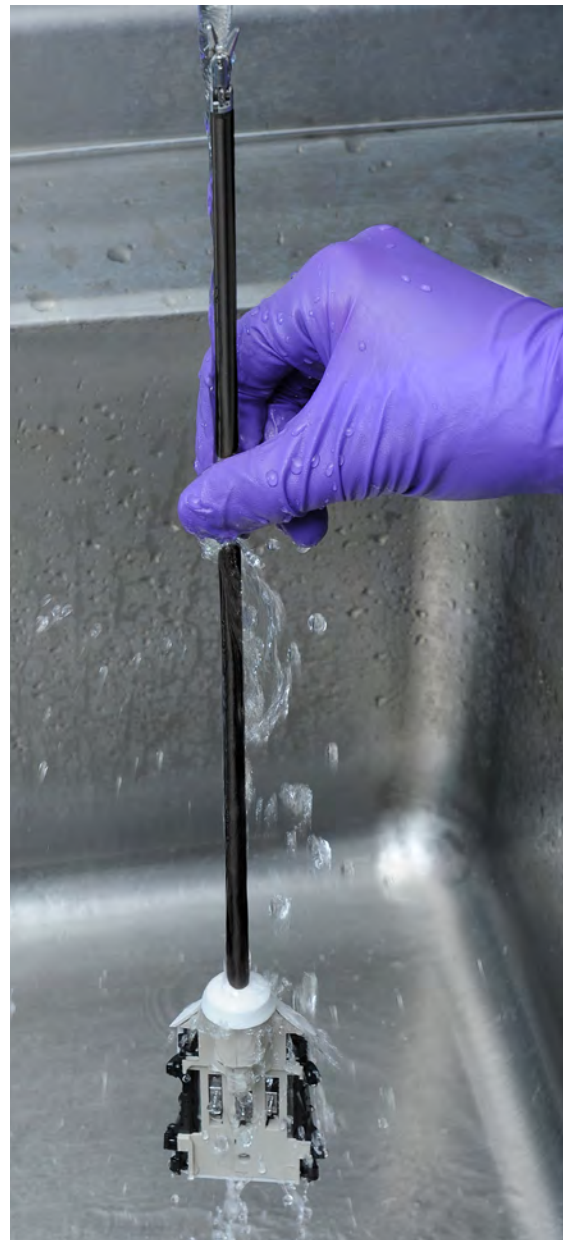



Continue to Step 6 on page 49 

Step 6 Rinse instrument

Rinse the entire instrument under running cold water for a total rinsing time of 1 minute 30 seconds to remove soil and cleaning solutions. Turn the instrument upside down halfway through for effective rinsing.

RINSE WITH  1 MINUTE
30 SECONDS



Continue to page 50 

Next step: Main cleaning

Proceed to main cleaning with **ONE** of the following methods:

Full manual cleaning continue to page 53

OR

Ultrasonic cleaning continue to page 67

OR


**Automated cleaning
and thermal disinfection** continue to page 79

Main cleaning: Full manual cleaning


Warnings

- ⚠ Do not continue with reprocessing if a Versius instrument has been dropped as it may be damaged. Always dispose of dropped instruments.
- ⚠ Only use validated reprocessing products, equipment and parameter settings. Parameter settings that have not been validated may result in damage to, or ineffective reprocessing of, Versius instruments.
- ⚠ Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.
- ⚠ Do not use abrasive metal brushes as these may damage the Versius instruments.
- ⚠ Ensure water pressure does not exceed 2.5 bar (36 psi).
- ⚠ Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of, Versius instruments.
- ⚠ Do not use solutions or rinse aids that are acidic (pH<7) or strongly alkaline (pH>11), or hydrogen peroxide based or bleach-based cleaning products, as they may damage Versius instruments.
- ⚠ During initial manual cleaning and all main cleaning procedures, prepare pH 7-11 enzymatic detergent solution according to the manufacturer's instructions including appropriate dilution, temperature and soaking times.
- ⚠ Always flush the instrument through flush port 1 before flushing through flush port 2. Flushing through flush port 1 after flush port 2 may re-contaminate the instrument.

Precautions

-  Use low-foaming, non-abrasive detergent solutions, and prepare these according to the manufacturer's instructions.

Information points

-  It is recommended that, wherever possible, the use of mechanical cleaning with automatic washer/disinfectors should be used. Where this is not possible, ultrasonic cleaning is recommended.

Equipment required



pH 7-11 enzymatic detergent



Syringe with tapered 6° 4mm Luer slip connector fitting



Sink or container
large enough for the instrument



Cold water



Soft-bristled nylon brush



Running critical water



Pressurised spray nozzle with tapered 6° 4mm Luer slip connector fitting (maximum 2.5 bar [36 psi])

See page 7 for details of reprocessing baskets

Step 1 Flush instrument flush port 1

▶ Before starting...

Prepare fresh pH 7-11 enzymatic detergent in a sink or container, according to the manufacturer's instructions. Ensure there is enough liquid to flush instrument flush port 1 and to soak the instrument.

A Fill a syringe with pH 7-11 enzymatic detergent.



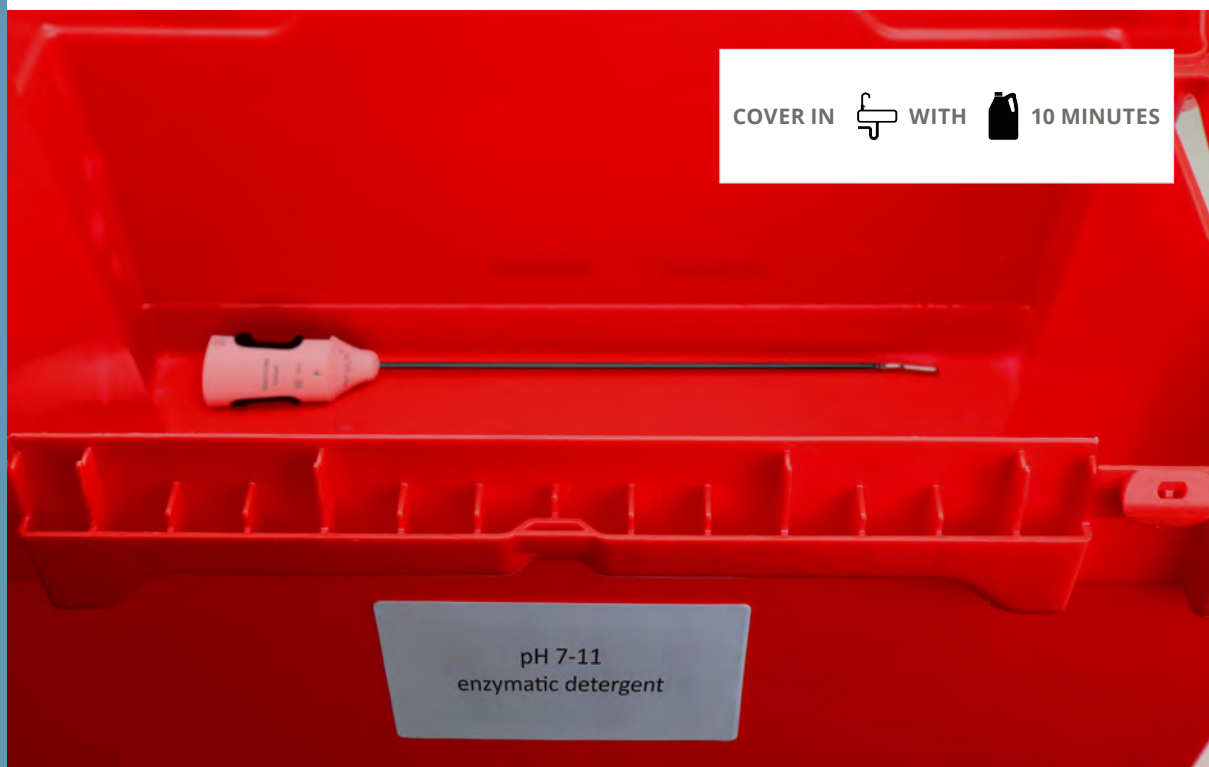
B Insert the syringe's tapered Luer slip connector fitting into instrument flush port 1 and inject 50 ml.



Continue to Step 2 on page 57 

Step 2 Soak instrument

1. Place the instrument flat at the bottom of a container or sink filled with enough pH 7-11 enzymatic detergent to completely cover the instrument.
2. Leave the instrument to soak for 10 minutes (unless the manufacturer's instructions recommend a longer soaking period).



Continue to Step 3 on page 58 

Step 3 Flush instrument flush ports 1 and 2

▶ Before starting...

To avoid splashes and aerosolisation, fill a sink or container with enough fresh cold water to cover the instrument when flushing. The sink or container should be deep enough to allow complete immersion of the instrument so that aerosols are not generated during cleaning.

- A** Insert the tapered Luer slip connector fitting of the pressuriser securely into instrument flush port 1.

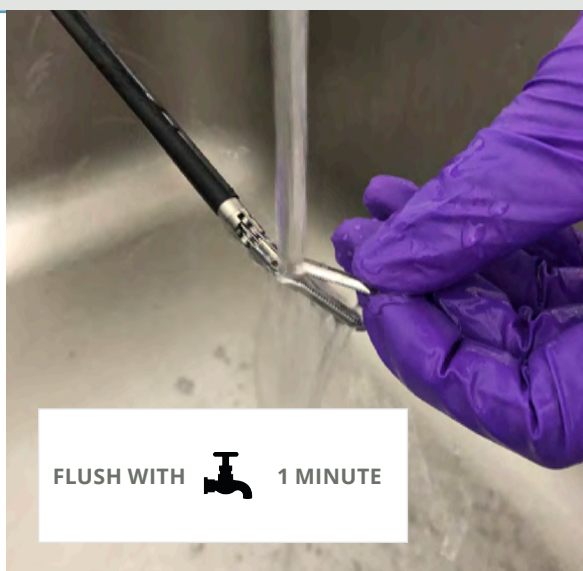
FIT  TO FLUSH PORT 1



- B**
1. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
 2. Flush for 1 minute, with jaws open and whilst moving the instrument tip.

Additional flushing may be required until the water runs clear.

FLUSH WITH  1 MINUTE



Continue to part C of Step 3 on page 59 

Step 3 Flush instrument flush ports 1 and 2 (continued)

C

1. Insert the tapered Luer slip connector fitting of the pressuriser securely into instrument flush port 2 with the **fins facing down**.
2. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
3. Flush in this position for 30 seconds.



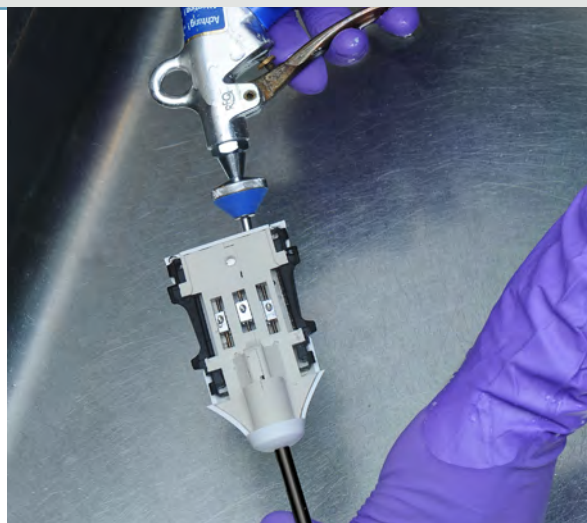
FIT  TO FLUSH PORT 2

FINS DOWN  FLUSH WITH  30 SECONDS


D

1. Rotate the instrument so that the **fins are facing up**.
2. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
3. Flush in this position for 30 seconds.

Additional flushing may be required until the water runs clear.



FINS UP  FLUSH WITH  30 SECONDS

Continue to Step 4 on page 60 


Step 4 Spray instrument tip

▶ Before starting...

To avoid splashes and aerosolisation, cover the instrument tip with cold water while spraying.

Use the pressuriser to spray the instrument tip for 1 minute with cold water, with jaws open and whilst moving the instrument tip. Ensure water pressure does not exceed 2.5 bar (36 psi).



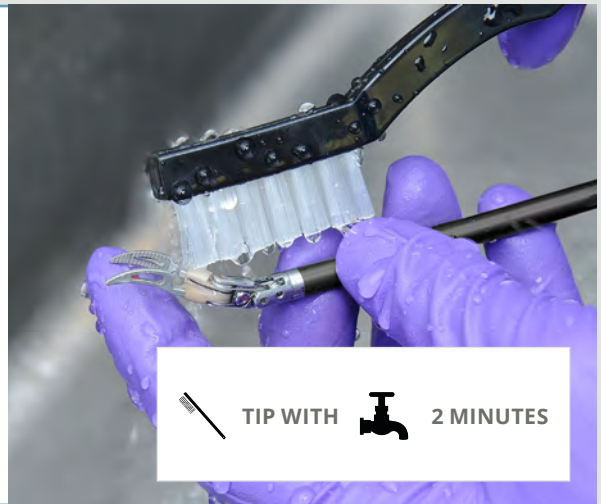
Continue to Step 5 on page 61 

Step 5 Brush instrument

▶ Before starting...


To avoid splashes and aerosolisation, cover the instrument tip with cold water while brushing.

- A** Use a soft-bristled nylon brush to brush the instrument tip using cold water for 2 minutes, with jaws open and whilst moving the instrument tip.
- Pay particular attention to crevices, serrated profiles, interior of jaws and recessed surfaces.



- B** Brush the instrument shaft and attachment head using cold water for 2 minutes.
- Pay particular attention to seams, crevices, latches and recessed surfaces. Make sure to brush along and across seams.



Continue to Step 6 on page 62 

Step 6 Flush instrument flush ports 1 and 2

▶ Before starting...

To avoid splashes and aerosolisation, refill a sink or container with enough cold water to cover the instrument when flushing. The sink or container should be deep enough to allow complete immersion of the instrument so that aerosols are not generated during cleaning.

- A** Insert the tapered Luer slip connector fitting of the pressuriser securely into instrument flush port 1.

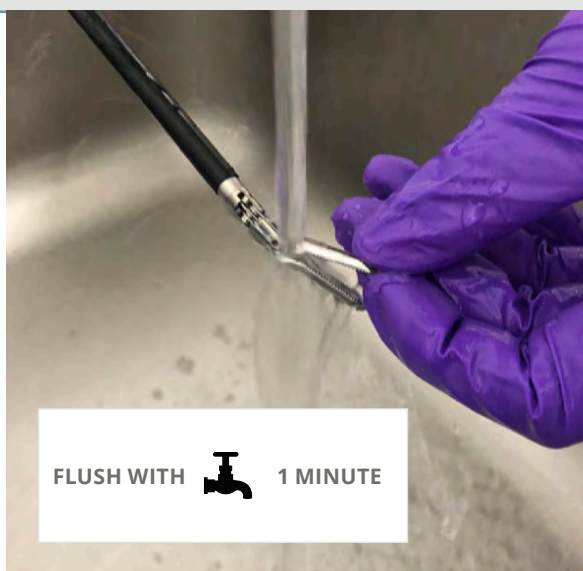
FIT  TO FLUSH PORT 1



- B**
1. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
 2. Flush for 1 minute, with jaws open and whilst moving the instrument tip.

Additional flushing may be required until the water runs clear.

FLUSH WITH  1 MINUTE



Continue to part C of Step 6 on page 63 

Step 6 Flush instrument flush ports 1 and 2 (continued)

C

1. Insert the tapered Luer slip connector fitting of the pressuriser securely into instrument flush port 2 with the **fins facing down**.
2. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
3. Flush in this position for 30 seconds.



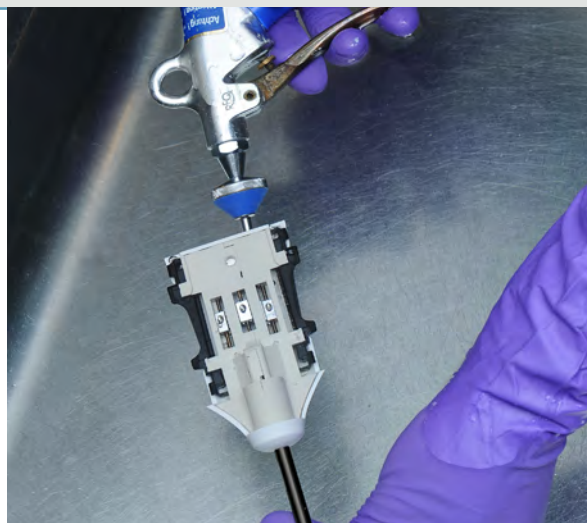
FIT  TO FLUSH PORT 2

FINS DOWN  FLUSH WITH  30 SECONDS


D

1. Rotate the instrument so that the **fins are facing up**.
2. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
3. Flush in this position for 30 seconds.

Additional flushing may be required until the water runs clear.



FINS UP  FLUSH WITH  30 SECONDS

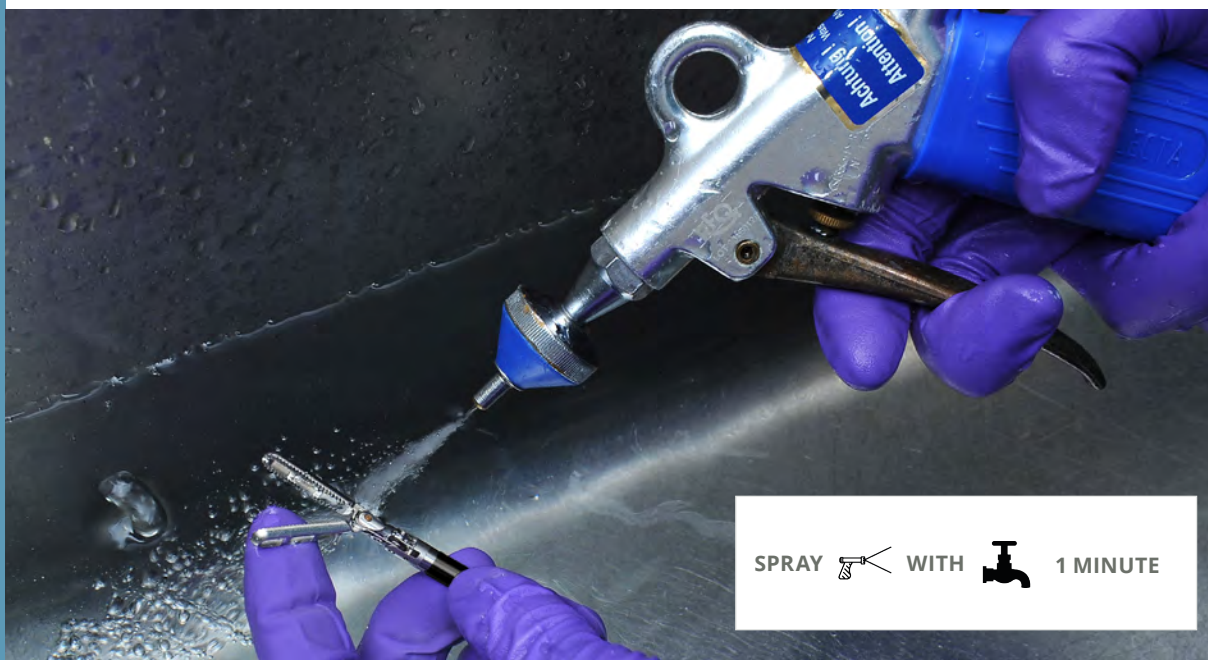
Continue to Step 7 on page 64 

Step 7 Spray instrument tip

▶ Before starting...

To avoid splashes and aerosolisation, cover the instrument tip with cold water while spraying.

Use the pressuriser to spray the instrument tip for 1 minute with cold water, with jaws open and whilst moving the instrument tip. Ensure water pressure does not exceed 2.5 bar (36 psi).




Continue to Step 8 on page 65 

Step 8 Rinse instrument

Rinse the entire instrument under running **critical water** for a total rinsing time of 1 minute 30 seconds to remove soil and cleaning solutions. Turn the instrument upside down halfway through for effective rinsing.









RINSE WITH  1 MINUTE
30 SECONDS




Continue to Preparation for sterilisation on page 85 


Main cleaning: Ultrasonic cleaning

Warnings





-  Do not continue with reprocessing if a Versius instrument has been dropped as it may be damaged. Always dispose of dropped instruments.
-  Only use validated reprocessing products and equipment, including ultrasonic baths. Only use validated parameter settings. Parameter settings that have not been validated could result in damage to, or ineffective cleaning of, Versius instruments.
-  Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.
-  Ensure water pressure does not exceed 2.5 bar (36 psi).
-  Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of, Versius instruments.
-  Do not use solutions or rinse aids that are acidic (pH<7) or strongly alkaline (pH>11), or hydrogen peroxide based or bleach-based cleaning products, as they may damage Versius instruments.
-  Ensure that Versius instruments have jaws open and are not touching or shadowing each other when placing into the ultrasonic bath. Failure to do so may result in damage to, or ineffective cleaning of, Versius instruments.
-  During initial manual cleaning and all main cleaning procedures, prepare pH 7-11 enzymatic detergent solution according to the manufacturer's instructions including appropriate dilution, temperature and soaking times.

-  Always flush the instrument through flush port 1 before flushing through flush port 2. Flushing through flush port 1 after flush port 2 may re-contaminate the instrument.

Precautions

-  Use low-foaming, non-abrasive detergent solutions, and prepare these according to the manufacturer's instructions.

Information points

-  It is recommended that, wherever possible, the use of mechanical cleaning with automatic washer/disinfectors should be used. Where this is not possible, ultrasonic cleaning is recommended.
-  Follow the manufacturer's instructions when operating the ultrasonic bath.
-  The ultrasonic bath should be large enough to accommodate an instrument fully covered in pH 7-11 enzymatic detergent.
-  During ultrasonic cleaning, irrigation (tapered 6° 4mm Luer slip) connections are recommended. If available, connect irrigation devices to instrument flush ports 1 and 2.

Equipment required



pH 7-11 enzymatic detergent



Syringe with tapered 6° 4mm Luer slip connector fitting



Sink or container
large enough for the instrument



Cold water



Running critical water



Pressurised spray nozzle with tapered 6° 4mm Luer slip connector fitting (maximum 2.5 bar [36 psi])



Ultrasonic bath

Large enough to accommodate an instrument fully covered with pH 7-11 enzymatic detergent.

- Recommended:

Irrigation (tapered 6° 4mm Luer slip) connections

- Program cycle:

Frequency: 40 kHz
± 2.4 kHz

Performance: 15 W/L
(57 W/gal) or greater

Time: 10 minutes
(minimum)

See page 7 for details of reprocessing baskets

Step 1 Flush instrument flush port 1

▶ Before starting...

Prepare fresh pH 7-11 enzymatic detergent in a sink or container, according to the manufacturer's instructions. Ensure there is enough liquid to flush instrument flush port 1, and if required, to fill the ultrasonic bath to fully cover the instruments.

- A** Fill a syringe with pH 7-11 enzymatic detergent.


FILL  WITH 



- B** Insert the syringe's tapered Luer slip connector fitting into instrument flush port 1 and inject 50 ml.

INJECT  50 ml FLUSH PORT 1



Continue to Step 2 on page 71 

Step 2 Run ultrasonic cycle

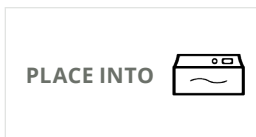
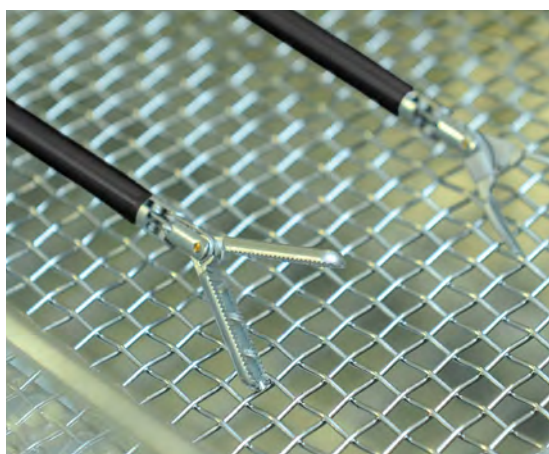
- A If applicable, fill the ultrasonic bath with enough pH 7-11 enzymatic detergent to fully cover the instruments. Insert irrigation devices into instrument flush ports 1 and 2.



Continue to part B of Step 2 on page 72 

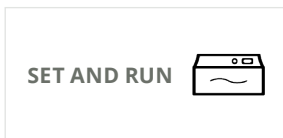
Step 2 Run ultrasonic cycle (continued)

B Carefully place the instruments into the ultrasonic bath with instrument jaws open. Make sure that the instruments are not touching each other.



C Set and run ultrasonic bath cycle.

Parameter	Value
Frequency	40 kHz ± 2.4 kHz
Performance	15 W/L (57 W/gal) or greater
Time	10 minutes (minimum)



Continue to Step 3 on page 73 

Step 3 Flush instrument flush ports 1 and 2

▶ Before starting...

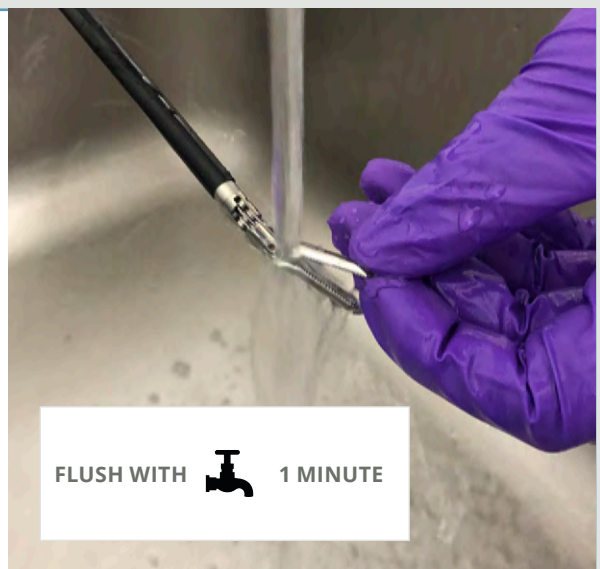
To avoid splashes and aerosolisation, fill a sink or container with enough fresh cold water to cover the instrument when flushing. The sink or container should be deep enough to allow complete immersion of the instrument so that aerosols are not generated during cleaning.

- A** Insert the tapered Luer slip connector fitting of the pressuriser securely into instrument flush port 1.



- B**
1. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
 2. Flush for 1 minute, with jaws open and whilst moving the instrument tip.

Additional flushing may be required until the water runs clear.



Continue to part C of Step 3 on page 74 

Step 3 Flush instrument flush ports 1 and 2 (continued)

- C**
1. Insert the tapered Luer slip connector fitting of the pressuriser securely into instrument flush port 2 with the **fins facing down**.
 2. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
 3. Flush in this position for 30 seconds.

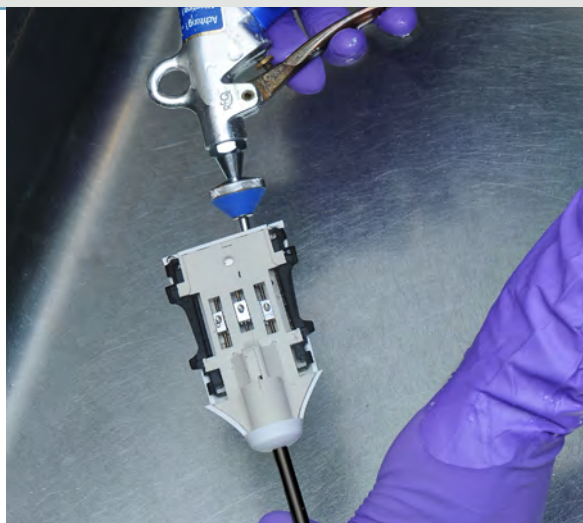


FIT  TO FLUSH PORT 2


FINS DOWN  FLUSH WITH  30 SECONDS

- D**
1. Rotate the instrument so that the **fins are facing up**.
 2. Begin the flow of pressurised cold water. Ensure water pressure does not exceed 2.5 bar (36 psi).
 3. Flush in this position for 30 seconds.

Additional flushing may be required until the water runs clear.



FINS UP  FLUSH WITH  30 SECONDS

Continue to Step 4 on page 75 


Step 4 Spray instrument tip

▶ Before starting...

To avoid splashes and aerosolisation, cover the instrument tip with cold water while spraying.

Use the pressuriser to spray the instrument tip for 1 minute with cold water, with jaws open and whilst moving the instrument tip. Ensure water pressure does not exceed 2.5 bar (36 psi).




Continue to Step 5 on page 76 

Step 5 Rinse instrument

Rinse the entire instrument under running **critical water** for a total rinsing time of 1 minute 30 seconds to remove soil and cleaning solutions. Turn the instrument upside down halfway through for effective rinsing.

RINSE WITH  1 MINUTE
30 SECONDS



Continue to page 77 

Proceed to:

OPTIONAL

**Automated cleaning
and thermal disinfection**

continue to page 79








OR



**Preparation for
sterilisation**


continue to page 85

Main cleaning: Automated cleaning and thermal disinfection


Warnings

-  Do not continue with reprocessing if a Versius instrument has been dropped as it may be damaged. Always dispose of dropped instruments.
-  Only use validated reprocessing products and equipment, including washer/disinfectors. Only use validated parameter settings. Parameter settings that have not been validated could result in damage to, or ineffective cleaning of, Versius instruments.
-  Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.
-  Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of, Versius instruments.
-  Do not use solutions or rinse aids that are acidic (pH<7) or strongly alkaline (pH>11), or hydrogen peroxide based or bleach-based cleaning products, as they may damage Versius instruments.
-  Do not use chemical disinfection of Versius instruments. This could result in damage to, or ineffective disinfection of, Versius instruments.
-  Ensure that Versius instruments have jaws open and are not touching or shadowing each other when placing into the washer/disinfector. Failure to do so may result in damage to, or ineffective cleaning of, Versius instruments.



-  Always use ISO 15883 compliant washer/disinfectors.
-  During automated cleaning and thermal disinfection, only use washer/disinfectors with irrigation devices that have tapered 6° 4mm Luer slip connector fittings. Use of washer/disinfectors without irrigation devices could result in ineffective cleaning and/or disinfection of Versius instruments.

-  During initial manual cleaning and all main cleaning procedures, prepare pH 7-11 enzymatic detergent solution according to the manufacturer's instructions including appropriate dilution, temperature and soaking times.

Precautions

-  Use low-foaming, non-abrasive detergent solutions, and prepare these according to the manufacturer's instructions.

Information points

-  It is recommended that, wherever possible, the use of mechanical cleaning with automatic washer/disinfectors should be used. Where this is not possible, ultrasonic cleaning is recommended.
-  Follow the manufacturer's instructions when operating the washer/disinfectors.

Equipment required



Washer/disinfector with:

- Irrigation (tapered 6° 4mm Luer slip) connections
- Cycle should include:
 - Pre-cleaning, cold water, for 2 minutes (minimum)
 - Cleaning, hot water, for 2 minutes (minimum)
 - Rinsing with critical hot water, for 2 minutes (minimum)
 - Thermal disinfection with national requirements for A_0 value
 - Drying, hot air, at 115 °C (239 °F) for 5 minutes (minimum)



pH 7-11 enzymatic detergent

See page 7 for details of reprocessing baskets

Step 1 Load instruments into washer/disinfector

A Load each instrument securely into the washer/disinfector tray.


Ensure the instrument jaws are open, that the instruments are not touching each other, and that instruments are positioned for adequate drainage.



PLACE INTO  TRAY

B Insert washer/disinfector irrigation devices into instrument flush ports 1 and 2.



Continue to Step 2 on page 83 

Step 2 Run washer/disinfector cycle

Set parameters and run the washer/disinfector cycle.

The cycle should include:


- Pre-cleaning, cold water, for 2 minutes (minimum)
- Cleaning, hot water, for 2 minutes (minimum)
- Rinsing with critical hot water, for 2 minutes (minimum)
- Thermal disinfection following the national requirements with regard to the A_0 value (please refer to ISO 15883)
- Drying, hot air, at 115 °C (239 °F) for 5 minutes (minimum)

Thermal disinfection was validated with $A_0 = 3000$ and $A_0 = 600$.










SET AND RUN





Continue to Preparation for sterilisation on page 85 




Preparation for sterilisation

Warnings

-  Do not continue with reprocessing if a Versius instrument has been dropped as it may be damaged. Always dispose of dropped instruments.
-  Take care when handling the Versius instrument tip due to the risk of sharps injury.
-  Only use validated reprocessing products, equipment and parameter settings. Parameter settings that have not been validated may result in damage to, or ineffective reprocessing of, Versius instruments.
-  Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.
-  Always carefully inspect Versius instruments during every reprocessing cycle. Inspect for any signs of defects, damage or residual soil. Failure to do so may result in patient harm.
-  Only use validated steam-permeable, pH neutral lubricant and ensure that Versius instruments have been thoroughly dried and are free of excess lubrication before sterilisation as any moisture remaining could result in ineffective sterilisation. Using lubricants that have not been validated may result in damage to, or ineffective sterilisation of, Versius instruments.
-  Ensure air pressure does not exceed 5 bar (73 psi).

-  Do not get lubricant onto the yellow Position Marker when lubricating the Monopolar Curved Scissors, as this may cause the Insulating Sleeve of the Monopolar Curved Scissors to move out of its correct position or to slide off during surgery. Return to the initial manual cleaning step if lubricant gets onto the yellow Position Marker.
-  Always use a steam-permeable instrument point protector or equivalent, as sharp instruments could pierce the steam-permeable sterilisation peel pouch, resulting in ineffective sterilisation. Only use validated peel pouches. Using peel pouches that have not been validated may result in damage to, or ineffective sterilisation of, Versius instruments.

Information points

-  Lubricate each Versius instrument in every reprocessing cycle to maintain their function and protect them from corrosion and aging.
-  Take care when inserting a Versius instrument into the steam-permeable sterilisation peel pouch to avoid damage to the instrument tip.
-  It is recommended that the instrument jaws should be open before sealing the steam-permeable sterilisation peel pouch.

Equipment required



Lint-free cloth



Pressurised clean, dry air applied through a tapered 6° 4mm Luer slip connector fitting (maximum 5 bar [73 psi])



Magnifying glass



Steam-permeable, pH neutral lubricant



Steam-permeable sterilisation peel pouch with window and large enough for instrument

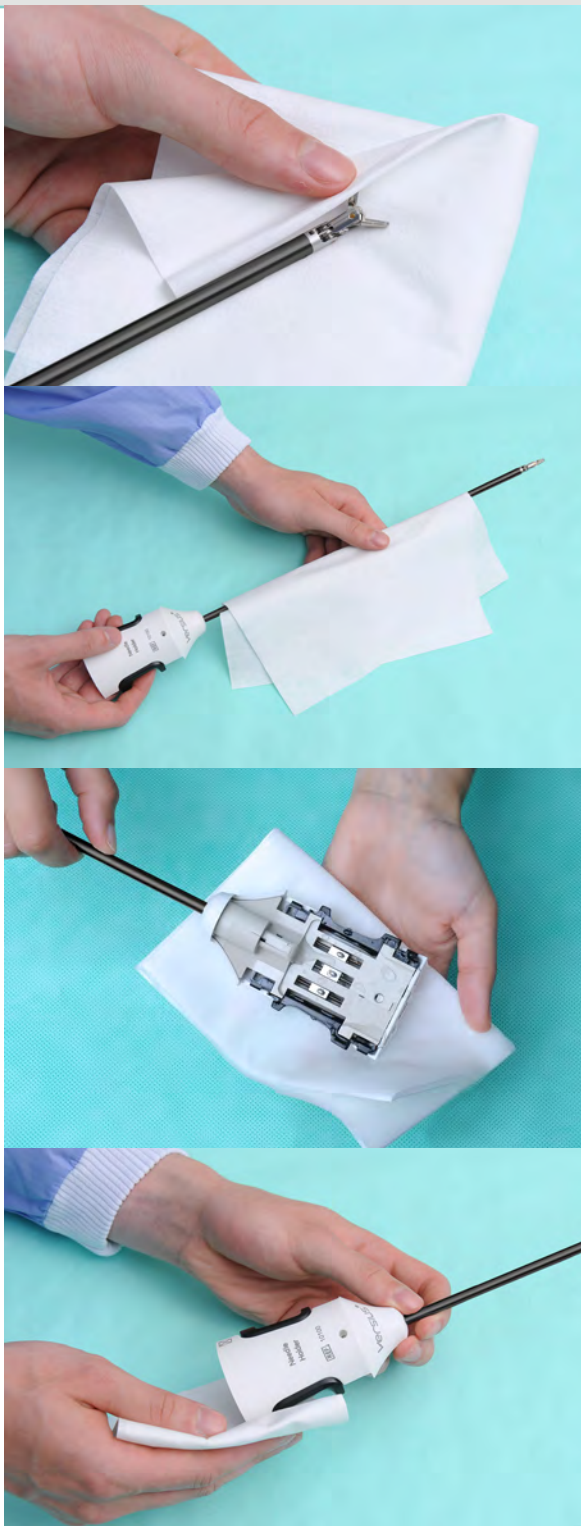



Steam-permeable instrument point protector or equivalent

See page 7 for details of reprocessing baskets and interleaved sterilisation wrap

Step 1 Dry instrument

A Dry the instrument, including its attachment head, shaft and tip, with a lint-free cloth.



DRY HEAD + SHAFT + TIP WITH 

Continue to part B of Step 1 on page 89 

Step 1 Dry instrument (continued)


B


1. Blow pressurised clean, dry air into instrument flush ports 1 and 2 for a minimum of 5 seconds each and continue blowing until dry.
2. Blow pressurised clean, dry air over the instrument attachment head for a minimum of 30 seconds and continue blowing until dry.

Ensure that all moisture has drained from the instrument.

Ensure that instruments are dry before moving to the next step.

If reprocessing is delayed at this point, repeat entire drying step to ensure effective sterilisation.


 Ensure that Versius instruments have been thoroughly dried and are free of excess lubrication before sterilisation as any moisture remaining could result in ineffective sterilisation.

 Ensure air pressure does not exceed 5 bar (73 psi).



BLOW  INTO FLUSH PORT 1 5 SECONDS (MINIMUM) + FLUSH PORT 2 5 SECONDS (MINIMUM)

BLOW  OVER HEAD 30 SECONDS (MINIMUM)

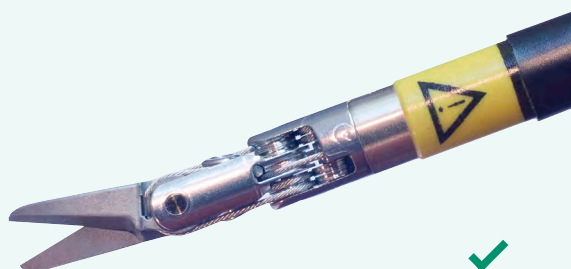
Continue to Step 2 on page 90 

Step 2 Inspect instrument

▶ Before starting...

- ⚠ Always ensure the Insulating Sleeve has been removed from the Monopolar Curved Scissors before beginning reprocessing of the instrument. Return to the initial manual cleaning step if the Insulating Sleeve is discovered at any stage of reprocessing.

Refer to the Instrument and Accessories Manual [REF 70050] for instructions on removing the Insulating Sleeve.



⊗ Do not re-use the Insulating Sleeve

- A Use a magnifying glass to inspect the instrument for any remaining soil.

If any soil is present, repeat the entire cleaning process, including the initial manual cleaning process.

Pay particular attention to crevices, holes and difficult-to-clean areas.



Continue to part B of Step 2 on page 91 

Step 2 Inspect instrument (continued)

B

Use a magnifying glass to inspect the instrument for any damage. In particular, check for:

- Bent or damaged instrument shafts
- Bent or broken instrument tips
- Cracked or broken instrument attachment heads or latches
- Broken or frayed cables
- Broken electrosurgery wire(s) running down the instrument tip
- Breaks, cracks, burns or any damage to the insulation
- Any rotation, movement or looseness of the white shroud at the base of the monopolar hook tip

If any Versius instruments show signs of defects or damage, please contact CMR Surgical customer services.

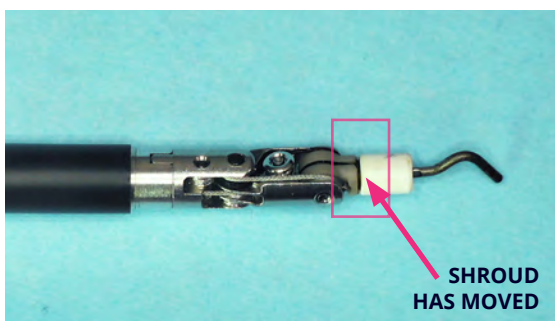
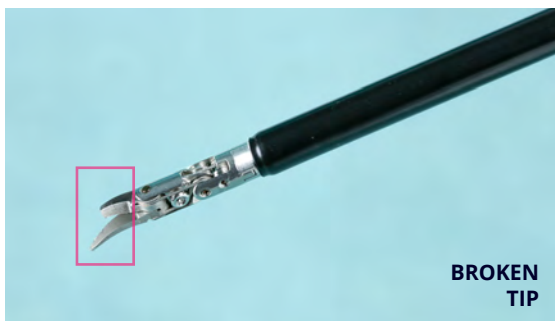
INSPECT  FOR DAMAGE




Continue to part C of Step 2 on page 92 

Step 2 Inspect instrument (continued)

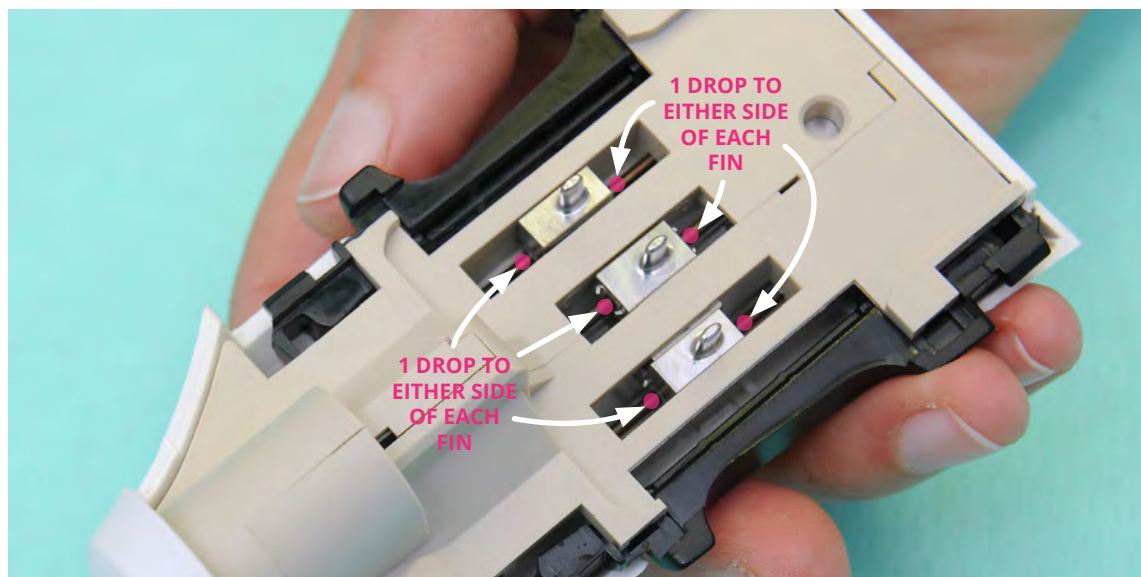
C The photographs on this page show some examples of damage.



Continue to Step 3 on page 93 

Step 3 Lubricate instrument

- A** Apply 1 drop of steam-permeable, pH neutral lubricant to the rail on either side of each instrument fin where shown by the pink dots below.
- The Monopolar Hook is the only Versius instrument which has only two fins (see page 26; the other instruments all have three fins).



Continue to part B of Step 3 on page 94 

Step 3 Lubricate instrument (continued)

B Apply 1 drop of steam-permeable, pH neutral lubricant to the pulleys and cables on **both sides** of the instrument where shown by the **pink** dots below in **image column (1)**.

Apply 1 drop to the base of the instrument tip on **one side only** where shown by the **pink** dots below in **image column (2)**.

Total: 5 drops per instrument

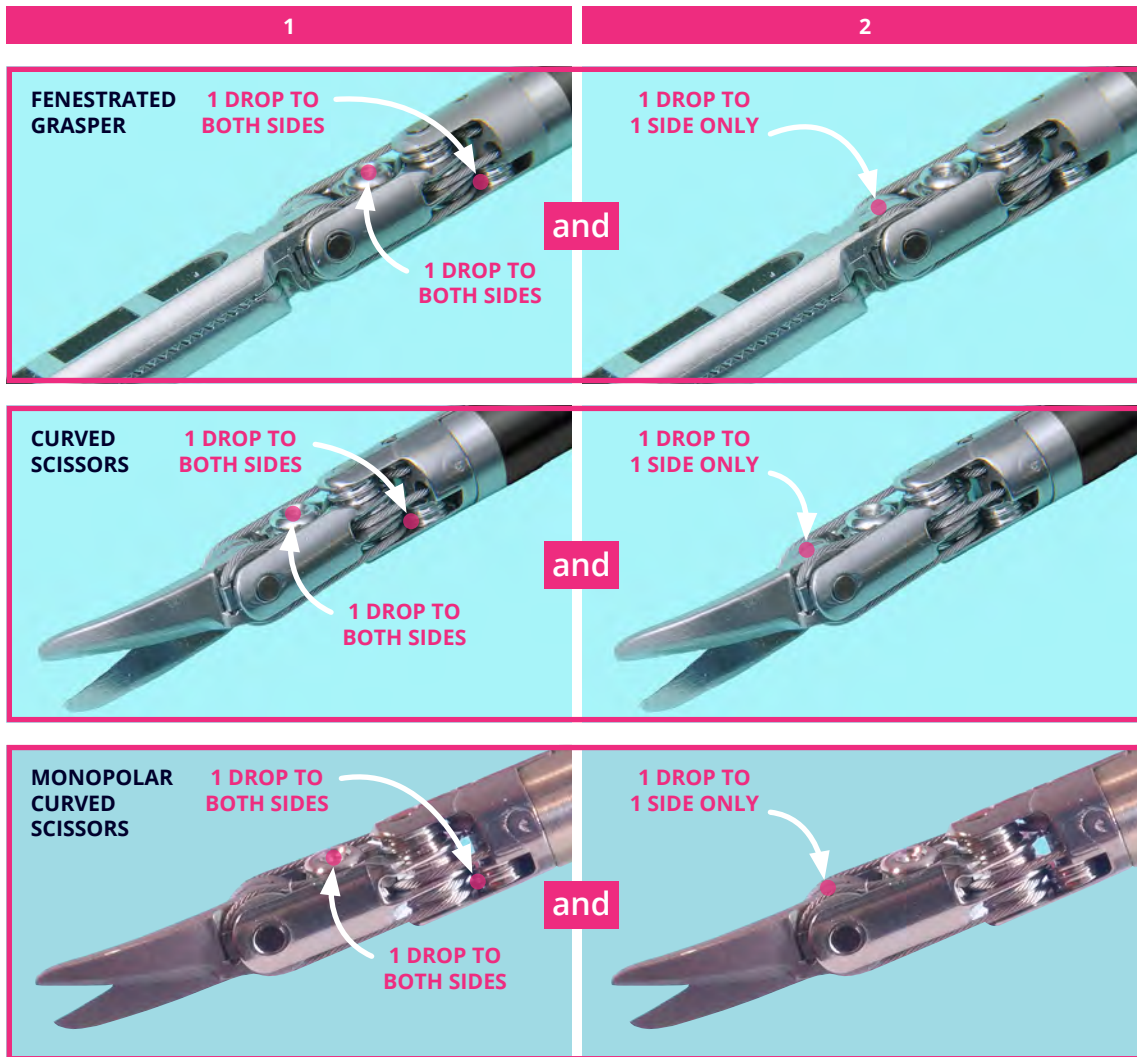


1		2	
<p>NEEDLE HOLDER</p> <p>1 DROP TO BOTH SIDES</p> <p>1 DROP TO BOTH SIDES</p>	and	<p>1 DROP TO 1 SIDE ONLY</p>	
<p>BIPOLAR MARYLAND GRASPER</p> <p>1 DROP TO BOTH SIDES</p> <p>1 DROP TO BOTH SIDES</p>	and	<p>1 DROP TO 1 SIDE ONLY</p>	
<p>MONOPOLAR HOOK</p> <p>1 DROP TO BOTH SIDES</p> <p>1 DROP TO BOTH SIDES</p>	and	<p>1 DROP TO 1 SIDE ONLY</p>	

Continue to page 95

Step 3 Lubricate instrument (continued)

B
(cont'd)



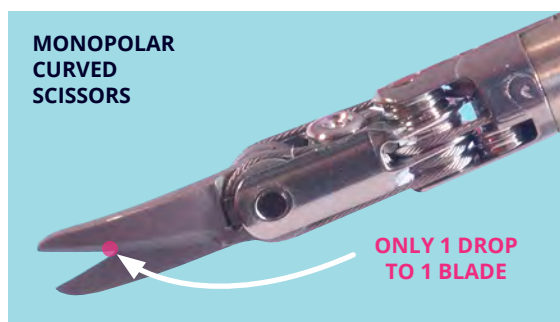
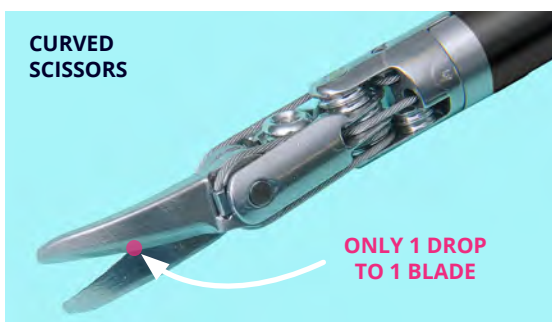
Do not get lubricant onto the yellow Position Marker when lubricating the Monopolar Curved Scissors, as this may cause the Insulating Sleeve of the Monopolar Curved Scissors to move out of its correct position or to slide off during surgery. Return to the initial manual cleaning step if lubricant gets onto the yellow Position Marker.

Continue to part C of Step 3 on page 96 

Step 3 Lubricate instrument (continued)

- C** The Curved Scissors and Monopolar Curved Scissors require an additional drop of lubricant to the centre of the scissor blade. Apply 1 drop only to the blade where shown by the pink dot in each of the images below.

Move the scissor blades after applying lubricant to ensure they are fully coated.




- ⚠** Ensure that Versius instruments have been thoroughly dried and are free of excess lubrication before sterilisation as any moisture remaining could result in ineffective sterilisation.

- D** Rotate and move the instrument tip to ensure the applied lubricant coats the rails, pulleys and cables.

- ⚠** Take care when handling the Versius instrument tip due to the risk of sharps injury.



Continue to Step 4 on page 97 

Step 4 Pack instrument

- A** Carefully apply a steam-permeable instrument point protector or equivalent to the instrument tip.

APPLY



- B**
1. Pack the instrument into a steam-permeable sterilisation peel pouch, with the instrument labelling visible and the **jaws open**.
 2. Seal the peel pouch according to the manufacturer's instructions.

Be careful not to pierce the peel pouch.

Versius instruments can be double packed in peel pouches.








PACK INTO




Continue to Sterilisation on page 99 

Sterilisation

Warnings

-  Do not continue with reprocessing if a Versius instrument has been dropped as it may be damaged. Always dispose of dropped instruments.
-  Only use validated reprocessing products and equipment, including sterilisers. Only use validated parameter settings. Parameter settings that have not been validated could result in damage to, or ineffective sterilisation of, Versius instruments.
-  Take care when handling equipment that is hot as it could cause burns. Personal Protective Equipment (PPE) should be worn, according to local guidelines.
-  Always allow Versius instruments to cool down gradually to room temperature after sterilisation. Sudden changes in temperature may cause moisture to condense in the instrument pouch and compromise instrument sterility.
-  The sterilisation process should conform with ISO 17665-1.
-  Do not overload the Versius instruments into the steam steriliser chamber. This could prevent efficient steam penetration and effective sterilisation.
-  Always store and transport Versius instruments in line with local guidelines. Incorrect storage and transportation could lead to damage to the instrument or instrument pouch.

Information points

-  Follow the manufacturer's instructions when operating the steam steriliser.

Equipment required



Steam steriliser
with dynamic air removal
(prevacuum) cycle,
in compliance with
ISO 17665-1 and with the
following parameters:

See page 7 for details of reprocessing
baskets and interleaved sterilisation wrap

Prevacuum steam sterilisation parameters

Parameter	Value
Temperature	134–137 °C (273–279 °F)
Exposure time	3–18 minutes (minimum holding time)
Dry time	20 minutes (minimum)

OR

Parameter	Value
Temperature	121 °C (250 °F)
Exposure time	15 minutes (minimum holding time)
Dry time	20 minutes (minimum)

OR

Parameter	Value
Temperature	132 °C (270 °F)
Exposure time	4 minutes (minimum holding time)
Dry time	20 minutes (minimum)


Step 1 Load steam steriliser tray

Place packed Versius instruments into a sterilisation tray.

Load the tray according to the manufacturer's instructions.

PLACE INTO  TRAY



Continue to Step 2 on page 103 

Step 2 Sterilise instruments

Set parameters and run sterilisation cycle (according to ISO 17665-1):

Prevacuum steam sterilisation parameters

Parameter	Value
Temperature	134–137 °C (273–279 °F)
Exposure time	3–18 minutes (minimum holding time)
Dry time	20 minutes (minimum)

OR

Parameter	Value
Temperature	121 °C (250 °F)
Exposure time	15 minutes (minimum holding time)
Dry time	20 minutes (minimum)

Allow Versius instruments to cool down before transportation or use.



OR

Parameter	Value
Temperature	132 °C (270 °F)
Exposure time	4 minutes (minimum holding time)
Dry time	20 minutes (minimum)

SET AND RUN



Continue to Step 3 on page 104

Step 3 Store and transport instruments

1. Store Versius instruments with care in a dedicated dry area.
2. Transport the required instruments in individual steam-permeable sterilisation peel pouches to point of use in line with local guidelines or hospital protocol.


Reprocessing is complete

Appendix A

Versius instruments

Versius instruments

Reference number (REF)	Description	Number of reprocessing cycles
10100	Needle Holder	20
10200	Bipolar Maryland Grasper	15
10300	Fenestrated Grasper	20
10400	Monopolar Hook	7
10500	Curved Scissors	20
10600	Monopolar Curved Scissors	10

 Do not reprocess instruments beyond their reprocessing life. This could result in damage to the instruments.

The REF numbers can also be found in labelling on the instrument or its packaging. Use these reference numbers (REF) to order Versius instruments from CMR Surgical using the customer support telephone number:


Tel: +44 (0)1223 750 975

Appendix B

Validated equipment and parameters

Validated cleaning, disinfection and sterilisation methods

Reference number (REF)	Description	Cleaning	Disinfection	Sterilisation
10100	Needle Holder	Initial manual cleaning followed by ONE of: <ul style="list-style-type: none"> • Full manual cleaning • Ultrasonic cleaning • Automated cleaning with pH 7-11 enzymatic detergent	Thermal disinfection	Prevacuum steam steriliser
10200	Bipolar Maryland Grasper			
10300	Fenestrated Grasper			
10400	Monopolar Hook			
10500	Curved Scissors			
10600	Monopolar Curved Scissors			

 When undertaking point-of-use preparation and initial manual cleaning, do not use water or any other fluid, such as enzymatic detergent, at a temperature higher than 45 °C (113 °F). This could coagulate proteins to the surfaces of the Versius instruments and may result in ineffective cleaning.

Ultrasonic bath cleaning parameters

The following parameters were validated:

Parameter	Value
Frequency	40 kHz \pm 2.4 kHz
Performance	15 W/L (57 W/gal) or greater
Time	10 minutes (minimum)

Washer/disinfector parameters required for automated cleaning and thermal disinfection

The cycle should include:

- Pre-cleaning, cold water, for 2 minutes (minimum)
- Cleaning, hot water, for 2 minutes (minimum)
- Rinsing with critical hot water, for 2 minutes (minimum)
- Thermal disinfection following the national requirements with regard to the A_0 value (please refer to ISO 15883)
- Drying, hot air, at 115 °C (239 °F) for 5 minutes (minimum)

Thermal disinfection was validated with $A_0 = 3000$ and $A_0 = 600$.

 Always use ISO 15883 compliant washer/disinfectors.

Prevacuum steam sterilisation parameters

Parameter	Value
Temperature	134–137 °C (273–279 °F)
Exposure time	3–18 minutes (minimum holding time)
Dry time	20 minutes (minimum)

Parameter	Value
Temperature	121 °C (250 °F)
Exposure time	15 minutes (minimum holding time)
Dry time	20 minutes (minimum)

Parameter	Value
Temperature	132 °C (270 °F)
Exposure time	4 minutes (minimum holding time)
Dry time	20 minutes (minimum)

The validated drying times for the parameters outlined were 20 minutes. Drying times are likely to vary depending on the steriliser and loading conditions.

The maximum sterilisation parameters validated were 134 °C (273 °F) for 20 minutes.

Glossary

Aerosolisation	The process or act of converting some physical substance into the form of particles small and light enough to be carried in the air, i.e. into an aerosol. The sink or container used during cleaning should be deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated.
Attachment head	Area of the instrument that can be attached to Versius arms. This is essential for instrument control by the robotic arms.
Critical water	Water treated extensively to ensure that it is free from microorganisms, inorganic and organic material. Examples are: deionised water, reverse osmosis and distilled water.
Fin	Mechanism used to drive the Versius instrument tip. Fins are found on the underside of the attachment head.
Instrument flush port 1	Opening labelled with the number 1 in the attachment head, to accommodate a tapered 6° 4mm Luer slip connector fitting. This allows flushing of the inside of the instrument shaft.
Instrument flush port 2	Opening labelled with the number 2 in the attachment head, to accommodate a tapered 6° 4mm Luer slip connector fitting. This allows flushing of the inside of the attachment head.
Insulating Sleeve	Single-use flexible tube applied to the tip of the Monopolar Curved Scissors, leaving only the blades uncovered, to protect the patient from instrument burns.

Latch	Mechanism used to attach the instrument to the robotic arm. Latches are found on the side of the attachment head.
Rail	Part of the mechanism, on which the fins slide, used to drive the Versius instrument tip. Rails are found inside the attachment head.
Shadowing	Shadowing occurs when an instrument or a part of its surface area is covered by another object (usually another instrument or accessory) that limits exposure to the cleaning medium, preventing the instrument from being effectively cleaned.
Shaft	Rod of the instrument that is inserted in the patient cavity during surgery.
Soil	Body fluids or tissue (e.g. blood, protein substances, and other debris) that may remain on a Versius instrument after its use.
Tip	End of the instrument or endoscope furthest from the part that attaches to the bedside unit or camera head

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Procedures Overview

Outline of all procedures

