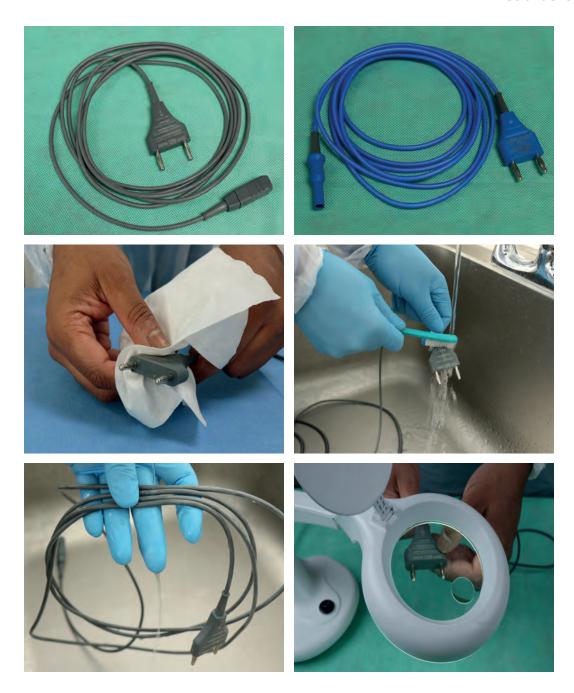


Versius Surgical System

Electrosurgery Instrument Cables Reprocessing Instructions (Version 2.0)

Read before use











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REF 70300 Versius Electrosurgery Instrument Cables Reprocessing Instructions

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This document provides instructions for the reprocessing of the Versius Electrosurgery Instrument Cables.

Rx only

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Introduction

This manual provides reprocessing instructions for Versius Electrosurgery Instrument Cables including cleaning, disinfection and sterilisation, and equipment recommended by CMR Surgical Ltd.

These instructions must be read and fully understood before reprocessing Versius Electrosurgery Instrument Cables.

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 Electrosurgery Instrument Cables are supplied non-sterile, and must be reprocessed before first use.

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 Electrosurgery Instrument Cables.

If there are any questions regarding these instructions or if any Versius Electrosurgery Instrument Cables show signs of defects or damage, please contact CMR Surgical customer services. To arrange the return of any affected Versius Electrosurgery Instrument Cables, please contact CMR Surgical technical support.

CMR Surgical Limited, 1 Evolution Business Park, Milton Road, Cambridge CB24 9NG, UK

Tel: +44 (0) 1223 750 975

For technical support:

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

+44 (0) 1223 750 975

Email: customer.service@cmrsurgical.com



CMR Surgical Limited, 1 Evolution Business Park, Milton Road, Cambridge CB24 9NG, UK www.cmrsurgical.com

Warning, precaution and information symbols in this manual



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 Electrosurgery Instrument Cables are supplied non-sterile and must be reprocessed before first use.



Transport and store cables in line with local guidelines. Incorrect storage could lead to damage to the cables.



Do not attempt to repair or modify Versius Electrosurgery Instrument Cables.



Only use validated cleaning solutions. Cleaning solutions that have not been validated (e.g. bleach or hydrogen peroxide) may result in damage to, or ineffective cleaning of, cables.



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.



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 cause proteins to stick to the surfaces of the Versius **Electrosurgery Instrument Cables and** may result in ineffective cleaning.



Do not use strong acidic (pH < 7) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.



Do not use strong alkaline (pH > 11) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.

Full list of warnings (continued)

Always seal the container with the cables inside before sending it to sterile services. Sealing the container prevents splashes of contaminated fluid.

During full manual cleaning, always rinse the cables under running critical water for at least 1 minute 30 seconds after exposing the cables to pH 7-11 enzymatic detergent, as some detergent or contaminants could remain on the cables.

During full manual cleaning, always brush the cables under cold running water using a soft-bristled brush until there is no visible soil.

During full manual cleaning, ensure that the cable is fully covered in pH 7–11 enzymatic detergent when soaking the cable.

Always use ISO 15883 compliant washer/disinfectors.

♠ Check that items placed into the washer/disinfector tray are not touching or shadowing each other. This could result in ineffective cleaning/disinfection of the items.

Only use validated parameter settings. Parameter settings that have not been validated could result in damage to, or ineffective cleaning of, Versius Electrosurgery Instrument Cables.

♠ Always dry the electrosurgery instrument cables using a lint-free cloth or with pressurised/medical air before sterilisation. This is required if using manual cleaning to clean the cables and should be done if the cables are still wet after automated cleaning and thermal disinfection. Failure to dry the cables could lead to the cables not being fully sterilised.

If using a cloth to dry electrosurgery instrument cables, ensure that the cloth is lint-free as lint could cause contamination and/or ineffective sterilisation.



♠ Ensure that electrosurgery instrument cables have been thoroughly dried before sterilisation as any moisture remaining could result in ineffective sterilisation.

Full list of warnings (continued)

Always inspect cables using a magnifying glass to detect possible damage or soiling before sterilisation.

Always repeat the entire cleaning process, including initial manual cleaning, if any soil is present on the electrosurgery instrument cables during the inspection stage.

Do not pack electrosurgery instrument cables that are cracked or have faulty insulation as this may result in burns or other injuries to the patient or user.

Always pack the cables into appropriately sized, steampermeable sterilisation peel pouches with one cable only in each peel pouch for sterilisation. Failure to do so could result in damage or ineffective sterilisation.

Check that items placed in the sterilisation tray are not touching or shadowing each other as this could result in ineffective sterilisation.

Always place packaged cables into a sterilisation tray before placing the tray into the steam steriliser to avoid damage.

The sterilisation process should conform with ISO 17665-1.

Allow electrosurgery instrument cables to cool down gradually to room temperature before handling. Sudden changes in temperature could damage electrosurgery instrument cables.

Full list of precautions

Take care when handling and transporting Versius Electrosurgery Instrument Cables to avoid damage.

⚠ Do not use an ultrasonic bath when reprocessing the electrosurgery instrument cables. Using an ultrasonic bath will cause damage to the cables.

Appendix A lists the maximum number of reprocessing cycles for Versius Electrosurgery Instrument Cables. **Do not** reprocess Versius Electrosurgery Instrument Cables beyond their maximum number of reprocessing cycles as this may result in damage to the cables.

Full list of precautions (continued)

- ♠ Always place the cables into a washer/disinfector tray before loading the tray into the washer/ disinfector to avoid damage.
- ♠ Do not use pressurised or medical air at greater than 3 bar (43.5 psi) to avoid damage to the electrosurgery instrument cables.



Do not coil the cables too tightly when packing into a peel pouch as this could result in damage to the cable. The coil diameter should be at least 16 mm.

Full list of information points

- Follow all applicable national and local laws and guidelines or hospital protocols for cleaning/disinfection and sterilisation.
- Always follow the manufacturer's recommended concentrations and application times for the detergent and disinfectant.
- Begin point-of-use preparation within 30 minutes of the surgical procedure ending.

- Do not use abrasive metal brushes as these may damage the Versius Electrosurgery Instrument Cables.
- Transport and store cables in line with local guidelines.
- Start initial manual cleaning within 4 hours of finishing point-of-use preparation.

Versius Electrosurgery Instrument Cables description

Versius Electrosurgery Instrument Cables connect Versius Instruments to Versius Bedside Units. Refer to the Versius Instrument and Accessories Manual (REF 70050) for instructions on using the cables with the Versius Surgical System.

There are two types of Versius Electrosurgery Instrument Cables: monopolar instrument cables and bipolar instrument cables.

Monopolar instrument cables are blue (see Figure 1) and connect monopolar instruments, such as the Versius Monopolar Hook, to a bedside unit.

Bipolar instrument cables are grey (see Figure 1) and connect bipolar instruments, such as the Versius Bipolar Maryland Grasper, to a bedside unit.



Figure 1 Monopolar and bipolar instrument cables

Electrosurgery instrument cables have connectors at either end: one connector to connect the cable to the bedside unit and one connector to connect it to the instrument (see Figure 2).



Figure 2 Monopolar and bipolar instrument cable connectors

Receiving new electrosurgery instrument cables



M Versius Electrosurgery Instrument Cables are supplied non-sterile and must be reprocessed before first use.

Transport and storage



⚠ Transport and store cables in line with local guidelines. Incorrect storage could lead to damage to the cables.

Protect cables in storage from direct sunlight. Keep cables in their original packaging until first reprocessing the cables.

Repair



Do not attempt to repair or modify Versius Electrosurgery Instrument Cables.

If any Versius Electrosurgery Instrument Cables show signs of defects or damage, please contact CMR Surgical Customer Services. See page 7 for contact details.

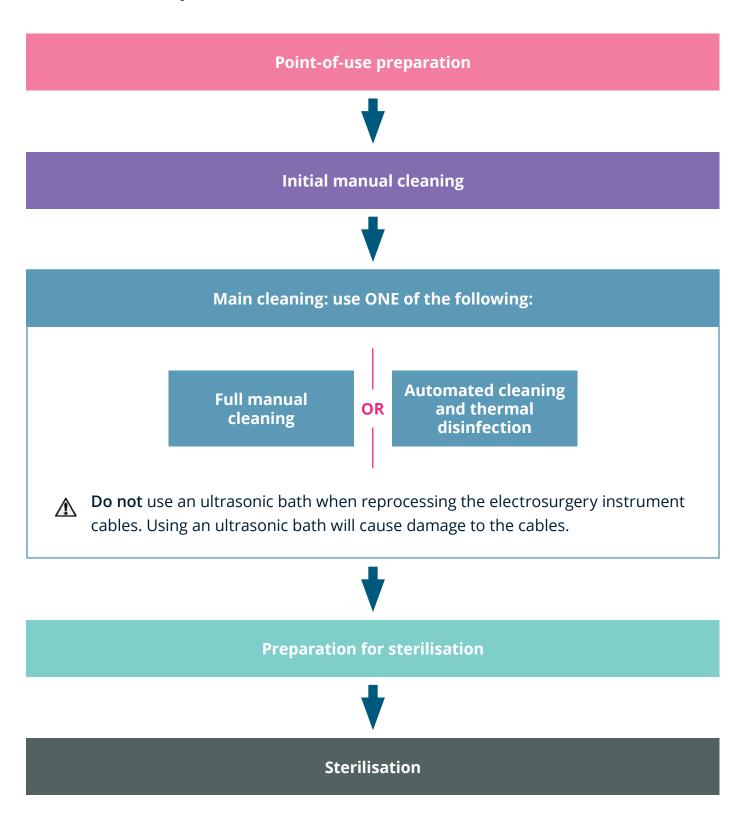
Disposal

Return the Versius Electrosurgery Instrument Cables to CMR Surgical for disposal.

Reprocessing Versius Electrosurgery Instrument Cables

Procedures Overview

Outline of all procedures



Point-of-use preparation

Step 1

Moisten cable (page 24)

Step 2

Transport cable (page 26)

Initial manual cleaning

Step 1

Remove cable from container

(page 32)

Step 2

Brush cable

(page 32)

Step 3

Soak cable

(page 33)

Step 4

Rinse cable under cold running water

(page 34)

Proceed to main cleaning with ONE of the following methods:

Full manual cleaning

continue to page 37

or

Automated cleaning and thermal disinfection

continue to page 45

Main cl	eaning:	Full	manual	cleaning
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Step 1 Immerse cable in detergent (first time) (page 40)

Step 2 Brush cable under cold running water (first time) (page 41)

Step 3 Immerse cable in detergent (second time) (page 41)

Step 4 Brush cable under cold running water (second time) (page 42)

Step 5 Rinse cable under running critical water (page 42)

Main cleaning: Automated cleaning and thermal disinfection

Step 1 Place cable into washer/disinfector tray (page 48)

Step 2 Load tray into washer/disinfector (page 48)

Step 3 Run washer/disinfector (page 49)

Step 4 Remove cable from washer/disinfector (page 50)

Preparation for sterilisation

Step 1 Dry cable (page 56)

Step 2 Inspect cable (page 57)

Step 3 Pack cable (page 59)

Step 4 Place packed cable into sterilisation tray (page 60)

Sterilisation

Step 1 Load sterilisation tray into steam steriliser (page 66)

Step 2 Run steriliser (page 66)

Step 3 Leave cables to cool down (page 67)

Step 4 Transport and store cables (page 67)

Point-of-use preparation

Warnings

- Only use validated cleaning solutions. Cleaning solutions that have not been validated (e.g. bleach or hydrogen peroxide) may result in damage to, or ineffective cleaning of, cables.
- 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.
- 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 cause proteins to stick to the surfaces of the Versius Electrosurgery Instrument Cables and may result in ineffective cleaning.

- **Do not** use strong acidic (pH < 7) solutions, cleaners or rinse aids as these may damage Versius
- **Do not** use strong alkaline (pH > 11) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.

Electrosurgery Instrument Cables.

- ⚠ Always seal the container with the cables inside before sending it to sterile services. Sealing the container prevents splashes of contaminated fluid.

Precautions

Take care when handling and transporting Versius Electrosurgery Instrument Cables to avoid damage.

Information points

- Follow all applicable national and local laws and guidelines or hospital protocols for cleaning/disinfection and sterilisation.
- Always follow the manufacturer's recommended concentrations and application times for the detergent and disinfectant.
- Begin point-of-use preparation within 30 minutes of the surgical procedure ending.
- Start initial manual cleaning within 4 hours of finishing point-of-use preparation.

Equipment required



Sealable container large enough for the cables

Choose one of the following methods for keeping the cables moist:



pH 7–11 enzymatic detergent (preferred) premixed according to the manufacturer's instructions

OR



pH 7–11 enzymatic foam spray

OR



Cold water

Moisten cable do ONE of the following options

Choose either Option A or Option B to keep the cable moist. Alternative methods may be used, according to local guidelines.

Begin point-of-use preparation within 30 minutes of the surgical procedure ending.

Option A: using liquid solution

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

> premixed pH 7-11 enzymatic detergent (preferred solution)

OR

cold water



Continue to Step 2 on page 26

Moisten cable (continued)

Option B: using foam spray

- 1. Place the cable into the container.
- 2. Spray the cable, including its connectors and grooves, with pH 7–11 enzymatic foam spray.



Continue to Step 2 on page 26

Step 2 Transport cable

- 1. Seal the container with the cable inside.
- 2. Transport the cable with care, in line with local guidelines or hospital protocol.
- Start initial manual cleaning within 4 hours of finishing point-of-use preparation.



Continue to Initial manual cleaning on page 29

Initial manual cleaning

Warnings

Only use validated cleaning solutions. Cleaning solutions that have not been validated (e.g. bleach or hydrogen peroxide) may result in damage to, or ineffective cleaning of, cables.



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.



Do not use strong acidic (pH < 7) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.



Do not use strong alkaline (pH > 11) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.



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 cause proteins to stick to the surfaces of the Versius Electrosurgery Instrument Cables and may result in ineffective cleaning.

Precautions



Do not use an ultrasonic bath when reprocessing the electrosurgery instrument cables. Using an ultrasonic bath will cause damage to the cables.



Appendix A lists the maximum number of reprocessing cycles for Versius Electrosurgery Instrument Cables. **Do not** reprocess Versius Electrosurgery Instrument Cables beyond their maximum number of reprocessing cycles as this may result in damage to the cables.

Information points

- Follow all applicable national and local laws and guidelines or hospital protocols for cleaning/disinfection and sterilisation.
- Always follow the manufacturer's recommended concentrations and application times for the detergent and disinfectant.
- Start initial manual cleaning within 4 hours of finishing point-of-use preparation.
- **Do not** use abrasive metal brushes as these may damage the Versius Electrosurgery Instrument Cables.

Equipment required



pH 7–11 enzymatic detergent premixed according to the manufacturer's instructions and

enough to completely cover the cables



Soft-bristled brush



Sink or container large enough for the cables



Cold running water

Remove cable from container

- - Start initial manual cleaning within 4 hours of finishing point-of-use preparation.
- 1. Remove the cable from the container.
- 2. Drain the container of the enzymatic detergent or water.

Step 2

Brush cable

Using a soft-bristled brush, brush the entire length of the cable under cold running water to remove excess soil.

Pay particular attention to connectors, crevices, and difficult-toclean areas.





Continue to Step 3 on page 33



Soak cable

- 1. Fill a sink or container with enough fresh pH 7–11 enzymatic detergent to completely immerse the cable.
- 2. Place the cable in the sink or container.



Leave the cable to soak for a minimum of 10 minutes (unless the detergent В manufacturer's instructions recommend a longer soaking period).

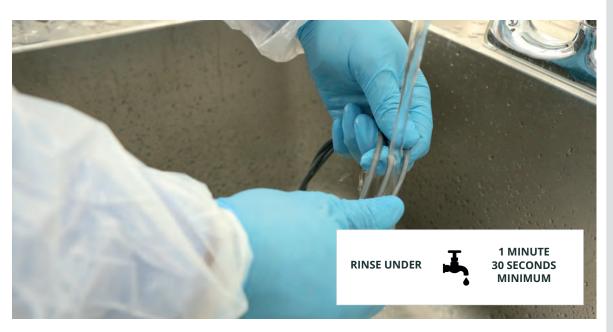
> **SOAK 10 MINUTES** MINIMUM

- When the soaking period is complete, remove the cable from the sink or container.
- Drain the sink or container of the detergent. D

Continue to Step 4 on page 34

Rinse cable under cold running water

Rinse the cable under cold running water for a minimum rinsing time of 1 minute 30 seconds.



Continue to page 35



Next step: main cleaning

Proceed to main cleaning with ONE of the following methods:

Full manual cleaning

continue to page 37

or

Automated cleaning and thermal disinfection

continue to page 45

Main cleaning: Full manual cleaning

Warnings

- Only use validated cleaning solutions.

 Cleaning solutions that have not been validated (e.g. bleach or hydrogen peroxide) may result in damage to, or ineffective cleaning of, cables.
- 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.
- ♠ Do not use strong acidic (pH < 7) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.</p>
- **Do not** use strong alkaline (pH > 11) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.

- During full manual cleaning, always rinse the cables under running critical water for at least 1 minute 30 seconds after exposing the cables to pH 7-11 enzymatic detergent, as some detergent or contaminants could remain on the cables.
- During full manual cleaning, always brush the cables under cold running water using a soft-bristled brush until there is no visible soil.
- ⚠ During full manual cleaning, ensure that the cable is fully covered in pH 7–11 enzymatic detergent when soaking the cable.

Precautions

Do not use an ultrasonic bath when reprocessing the electrosurgery instrument cables. Using an ultrasonic bath will cause damage to the cables.

↑ Appendix A lists the maximum number of reprocessing cycles for Versius Electrosurgery Instrument Cables. Do not reprocess Versius **Electrosurgery Instrument Cables** beyond their maximum number of reprocessing cycles as this may result in damage to the cables.

Information points

- Follow all applicable national and local laws and guidelines or hospital protocols for cleaning/disinfection and sterilisation.
- Always follow the manufacturer's recommended concentrations and application times for the detergent and disinfectant.
- Do not use abrasive metal brushes as these may damage the Versius Electrosurgery Instrument Cables.

Equipment required



pH 7-11 enzymatic detergent premixed according to the manufacturer's instructions



Soft-bristled brush



Sink or container large enough for the cables



Cold running water



Running critical water

Immerse cable in detergent (first time)

- Fill a sink or container with enough fresh pH 7-11 enzymatic detergent to Α completely immerse the cable.
- Place the cable in the sink or В container so that all parts and surfaces of the cable are immersed in the detergent.





Remove the cable from the sink or container and drain the sink or container C of the detergent.

Continue to Step 2 on page 41



Brush cable under cold running water (first time)

Using a soft-bristled brush, brush the entire length of the cable under cold running water.

Pay particular attention to connectors, crevices, and difficult-toclean areas.





Step 3

C

Immerse cable in detergent (second time)

- Fill a sink or container with enough fresh pH 7-11 enzymatic detergent to Α completely immerse the cable.
- В Place the cable in the sink or container so that all parts and surfaces of the cable are immersed in the detergent.





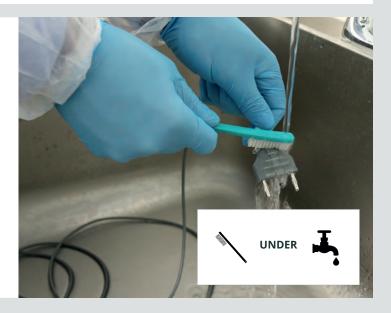
Remove cable from the sink or container and drain the sink or container of pH 7–11 enzymatic detergent.

Continue to Step 4 on page 42

Brush cable under cold running water (second time)

Using a soft-bristled brush, brush the entire length of cable under cold running water.

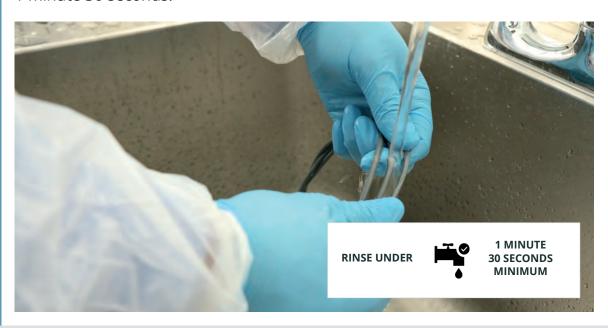
Pay particular attention to connectors, crevices, and difficult-to-clean areas.



Step 5

Rinse cable under running critical water

Rinse the cable under running critical water for a minimum rinsing time of 1 minute 30 seconds.



Continue to Preparation for sterilisation on page 53



Main cleaning: Automated cleaning and thermal disinfection

Warnings

- Only use validated cleaning solutions.

 Cleaning solutions that have not been validated (e.g. bleach or hydrogen peroxide) may result in damage to, or ineffective cleaning of, cables.
- 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.
- ♠ Do not use strong acidic (pH < 7) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.</p>
- **Do not** use strong alkaline (pH > 11) solutions, cleaners or rinse aids as these may damage Versius Electrosurgery Instrument Cables.

- Always use ISO 15883 compliant washer/disinfectors.
- ↑ Check that items placed into the washer/disinfector tray are not touching or shadowing each other. This could result in ineffective cleaning/disinfection of the items.
- Only use validated parameter settings. Parameter settings that have not been validated could result in damage to, or ineffective cleaning of, Versius Electrosurgery Instrument Cables.

Precautions

Do not use an ultrasonic bath when reprocessing the electrosurgery instrument cables. Using an ultrasonic bath will cause damage to the cables.

Always place the cables into a washer/disinfector tray before loading the tray into the washer/ disinfector to avoid damage.

↑ Appendix A lists the maximum number of reprocessing cycles for Versius Electrosurgery Instrument Cables. Do not reprocess Versius **Electrosurgery Instrument Cables** beyond their maximum number of reprocessing cycles as this may result in damage to the cables.

Information points

- Follow all applicable national and local laws and guidelines or hospital protocols for cleaning/disinfection and sterilisation.
- Always follow the manufacturer's recommended concentrations and application times for the detergent and disinfectant.

Equipment required



Washer/disinfector tray

appropriately sized to ensure that the cables are not touching or shadowing



pH 7-11 enzymatic detergent

premixed according to the manufacturer's instructions



Washer/disinfector, cycle in compliance with ISO 15883 and with the following parameters:



Always use ISO 15883 compliant washer/disinfectors.

Washer/disinfector parameters

Stage of cycle	Parameter setting	Minimum time
Pre-cleaning	Cold water	2 minutes
Cleaning	Hot water (43 °C/110 °F)	2 minutes
Rinsing	Critical water	2 minutes
Thermal disinfection	Follow the national requirements for the A ₀ value (see ISO 15883)	
Drying	Hot air (115 °C/239 °F)	5 minutes

Carry out thermal machine disinfection in compliance with ISO 15883 and follow the national requirements with regard to the A_o value (see ISO 15883).

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

Place cable into washer/disinfector tray

Carefully place the cable into the washer/disinfector tray.



↑ Check that items placed into the washer/disinfector tray are not touching or shadowing each other. This could result in ineffective cleaning/disinfection of the items.



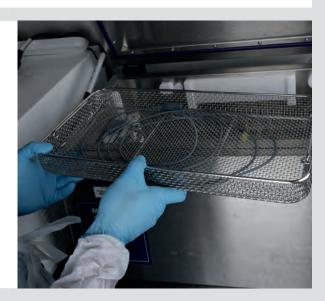
PLACE

Step 2 Load tray into washer/disinfector

Carefully load the washer/disinfector tray containing the cable into the washer/disinfector.

Check that items have not moved during loading.

> LOAD INTO



Continue to Step 3 on page 49

Run washer/disinfector

Set parameters and run the washer/disinfector cycle in compliance with ISO 15883. The cycle should include the parameters shown in the table below:

Washer/disinfector parameters

Stage of cycle	Parameter setting	Minimum time
Pre-cleaning	Cold water	2 minutes
Cleaning	Hot water (43 °C/110 °F)	2 minutes
Rinsing	Critical water	2 minutes
Thermal disinfection	Use national requirements for A ₀ v	value (see ISO 15883)
Drying	Hot air (115 °C/239 °F)	5 minutes

Carry out thermal disinfection in compliance with ISO 15883 and follow the national requirements with regard to the A_0 value (see ISO 15883).

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



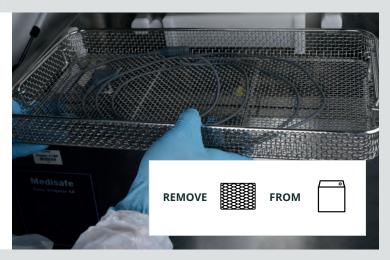
Always use ISO 15883 compliant washer/disinfectors.



Continue to Step 4 on page 50

Remove cable from washer/disinfector

Remove the washer/ disinfector tray containing the cable from the washer/ disinfector after the cycle finishes.



Continue to Preparation for sterilisation on page 53



Preparation for sterilisation

Warnings

- Always dry the electrosurgery instrument cables using a lint-free cloth or with pressurised/medical air before sterilisation. This is required if using manual cleaning to clean the cables and should be done if the cables are still wet after automated cleaning and thermal disinfection. Failure to dry the cables could lead to the cables not being fully sterilised.
- If using a cloth to dry electrosurgery instrument cables, ensure that the cloth is lint-free as lint could cause contamination and/or ineffective sterilisation.
- instrument cables have been thoroughly dried before sterilisation as any moisture remaining could result in ineffective sterilisation.
- Always inspect cables using a magnifying glass to detect possible damage or soiling before sterilisation.

- Do not pack electrosurgery instrument cables that are cracked or have faulty insulation as this may result in burns or other injuries to the patient or user.
- Always pack the cables into appropriately sized, steampermeable sterilisation peel pouches with one cable only in each peel pouch for sterilisation. Failure to do so could result in damage or ineffective sterilisation.
- Check that items placed in the sterilisation tray are not touching or shadowing each other as this could result in ineffective sterilisation.
- Always place packaged cables into a sterilisation tray before placing the tray into the steam steriliser to avoid damage.



Always repeat the entire cleaning process, including initial manual cleaning, if any soil is present on the electrosurgery instrument cables during the inspection stage.

Precautions



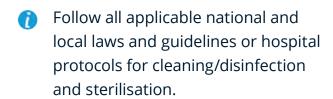
↑ Appendix A lists the maximum number of reprocessing cycles for Versius Electrosurgery Instrument Cables. **Do not** reprocess Versius **Electrosurgery Instrument Cables** beyond their maximum number of reprocessing cycles as this may result in damage to the cables.



♠ Do not use pressurised or medical air at greater than 3 bar (43.5 psi) to avoid damage to the electrosurgery instrument cables.

Do not coil the cable too tightly when packing into a peel pouch as this could result in damage to the cable. The coil diameter should be at least 16 mm.

Information points



Equipment required



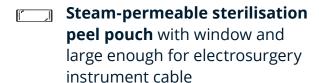
Lint-free cloth



Clean, dry, pressurised or medical air (maximum air pressure 3 bar [43.5 psi])



Magnifying glass





Sterilisation tray

Dry cable

Dry the cable with a lint-free cloth and/or pressurised or medical air (maximum air pressure 3 bar [43.5 psi]).

Ensure that the cable, including its connectors and grooves, is dry before moving to the next step.



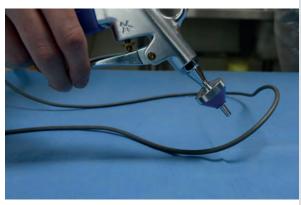
Ensure that electrosurgery instrument cables have been thoroughly dried before sterilisation as any moisture remaining could result in ineffective sterilisation.



⚠ If using a cloth to dry electrosurgery instrument cables, ensure that the cloth is lint-free as lint could cause contamination and/or ineffective sterilisation.









AND/OR



MAX AIR PRESSURE 3 BAR (43.5 PSI)

Continue to Step 2 on page 57



Inspect cable

Use a magnifying glass to inspect the cable for any remaining soil. Pay particular attention to crevices, grooves and difficult-to-clean areas.



Always repeat the entire cleaning process, including initial manual cleaning, if any soil is present during the inspection stage.







Continue to part B of Step 2 on page 58

Inspect cable (continued)

В

- 1. Check the connector is securely attached to the cable.
- 2. Use a magnifying glass to inspect the cable for damage. Check for:
 - Faulty or cracked insulation
 - Broken electrical wires
 - Crushed or kinked cable
 - Damaged connector

FOR DAMAGE

If a Versius Electrosurgery Instrument Cable shows signs of defects or damage, contact CMR Surgical Customer Services (see page 7).



Continue to Step 3 on page 59

Pack cable

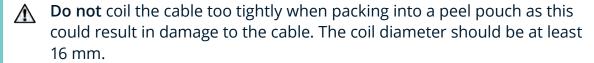
- 1. Select an appropriately sized steam-permeable sterilisation peel pouch for the cable.
- 2. Pack the cable into the peel pouch.
- 3. Seal the peel pouch according to the manufacturer's instructions. The cables can be double packed in another steam-permeable sterilisation peel pouch if desired.







Always pack the cables into appropriately sized, steam-permeable sterilisation pouches with one cable only in each pouch for sterilisation. Failure to do so could result in damage or ineffective sterilisation.



The images below show:

- Cable coiled too tightly for sterilisation
- Cable with a suitable coil size for sterilisation





Continue to Step 4 on page 60

Place packed cable into sterilisation tray

Place the packed cable into a sterilisation tray, making sure items are not touching or shadowing each other.



⚠ Check that items placed into the sterilisation tray are not touching or shadowing each other. This could result in ineffective sterilisation.



PLACE INTO

Continue to Sterilisation on page 63

Sterilisation

Warnings

- Check that items placed in the sterilisation tray are not touching or shadowing each other as this could result in ineffective sterilisation.
- Ensure that electrosurgery instrument cables have been thoroughly dried before sterilisation as any moisture remaining could result in ineffective sterilisation.
- Always place packaged cables into a sterilisation tray before placing the tray into the steam steriliser to avoid damage.
- Only use validated parameter settings. Parameter settings that have not been validated could result in damage to, or ineffective sterilisation of, Versius Electrosurgery Instrument Cables.
- The sterilisation process should conform with ISO 17665-1.
- Allow electrosurgery instrument cables to cool down gradually to room temperature before handling. Sudden changes in temperature could damage electrosurgery instrument cables.

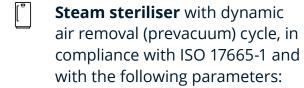
Precautions

- Appendix A lists the maximum number of reprocessing cycles for Versius Electrosurgery Instrument Cables. **Do not** reprocess Versius Electrosurgery Instrument Cables beyond their maximum number of reprocessing cycles as this may result in damage to the cables.
- Take care when handling and transporting Versius Electrosurgery Instrument Cables to avoid damage.

Information points

- Follow all applicable national and local laws and guidelines or hospital protocols for cleaning/disinfection and sterilisation.
- Transport and store cables in line with local guidelines.

Equipment required





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

Load sterilisation tray into steam steriliser

Load the sterilisation tray into the steam steriliser according to the steam steriliser manufacturer's instructions.





Step 2

Run steriliser

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



⚠ The sterilisation process should conform with ISO 17665-1.



Leave cables to cool down

- 1. Remove the sterilisation tray from the steriliser after the cycle finishes.
- 2. Leave the cable to cool down before continuing to Step 4.



Allow electrosurgery instrument cables to cool down gradually to room temperature before handling. Sudden changes in temperature could damage electrosurgery instrument cables.

Step 4

Transport and store cables

Transport and store the required cables in individual steam-permeable sterilisation peel pouches to point of use in line with local guidelines or hospital protocol.



Transport and store cables in line with local guidelines.



Take care when handling and transporting Versius Electrosurgery Instrument Cables to avoid damage.

Reprocessing is complete

Appendix A Versius Electrosurgery Instrument Cables

Versius Electrosurgery Instrument Cables

Reference number (REF)	Description	Maximum number of reprocessing cycles
90300	Bipolar instrument cable	50
90500	Monopolar instrument cable	50

 Λ

Do not reprocess electrosurgery instrument cables beyond their maximum number of reprocessing cycles as this may result in damage to the cables.

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

Tel: +44 (0) 1223 750 975

Appendix B Validated equipment and parameters

Washer/disinfector parameters required for automated cleaning and thermal disinfection

Stage of cycle	Parameter setting	Minimum time
Pre-cleaning	Cold water	2 minutes
Cleaning	Hot water (43 °C/110 °F)	2 minutes
Rinsing	Critical water	2 minutes
Thermal disinfection	Follow the national requirements for the $\rm A_{\rm 0}$ value (see ISO 15883)	
Drying	Hot air (115 °C/239 °F)	5 minutes



Always use ISO 15883 compliant washer/disinfectors.

Carry out thermal disinfection in compliance with ISO 15883 and follow the national requirements with regard to the A₀ value (see ISO 15883).

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



Do not use an ultrasonic bath when reprocessing the electrosurgery instrument cables. Using an ultrasonic bath will cause damage to the cables.

Prevacuum steam sterilisation parameters

Parameter	Value
Temperature	132 °C (270 °F)
Exposure time	4 minutes (minimum holding time)
Dry time	20 minutes (minimum)
Parameter	Value
Parameter Temperature	Value 134–137 °C (273–279 °F)



The sterilisation process should conform with ISO 17665-1.

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 a dry time of 20 minutes.



Do not use an ultrasonic bath when reprocessing the electrosurgery instrument cables. Using an ultrasonic bath will cause damage to the cables.

Glossary

A _o value	The time taken to reduce the number of microorganisms to an acceptable level, based on the temperature of the thermal disinfection cycle.
Bipolar instrument cable	One of two types of electrosurgery instrument cable used for bipolar electrosurgery. The cable connects a Versius Bipolar Instrument to a Versius Instrument Bedside Unit. Bipolar instrument cables are grey.
Cable	In these instructions, cable means electrosurgery instrument cable.
Cold water	Water that is between 10–25 °C (50–77 °F).
Connector	Part on the end of an electrosurgery instrument cable, that connects to a Versius Electrosurgery Instrument or to a Versius Instrument Bedside Unit.
Crevice	Small, narrow space. Crevices on the connector of an electrosurgery instrument cable may contain soil.
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.
Disinfection	Treatment of items to reduce the number of microorganisms to an acceptable level.
Dynamic air removal	Method for removing air from the sterilisation chamber.

Electrosurgery instrument cable	Cable that connects a Versius Electrosurgery Instrument to the Versius Instrument Bedside Unit to allow electrosurgery. There are two types: bipolar instrument cable and monopolar instrument cable.
Enzymatic detergent	Cleaning substance that uses enzyme proteins to remove soil.
Enzymatic foam spray	Cleaning spray that uses enzyme proteins to remove soil.
Groove	Narrow line cut into the surface of the electrosurgery instrument cable connector (which contains information about the connector). Grooves on the electrosurgery instrument cable connector may contain soil.
High-voltage insulation testing device	A device that measures the insulation of high- voltage equipment to assess if there is any leakage current.
Hot water	Water that is 45 °C (113 °F) or hotter.
Insulation	Plastic outer layer of the electrosurgery instrument cable that gives protection against electric shock when the cable is used.
ISO 15883	International Organization for Standardization (ISO) standard for Washer-disinfectors.
ISO 17665-1	International Organization for Standardization (ISO) standard for Sterilization of health care products with moist heat.

Monopolar instrument cable	One of two types of electrosurgery instrument cable used for monopolar electrosurgery. The cable connects a Versius Monopolar Instrument to a Versius Instrument Bedside Unit. Monopolar instrument cables are blue.
Peel pouch	Flat bag (usually with a window) that an item is put into before sterilisation. The bag has a strip on one end that is peeled off, exposing an adhesive seal which is used to close and seal the bag.
Pressurised air	Clean, dry air that is stored under pressure and is free from contamination. In a healthcare setting pressurised air is also referred to as medical air.
Prevacuum	A method that uses a vacuum pump to remove air from the sterilisation chamber before sterilisation takes place.
Reprocessing	Cleaning, disinfecting and sterilising medical devices to prepare them for use.
Reprocessing cycle	Term given to the whole process that is followed to clean, disinfect and sterilise contaminated and/or reusable items. The maximum number of reprocessing cycles is the maximum number of times the complete process for cleaning, disinfecting and sterilisation should be followed before the item is no longer used.
Running water	Water continuously flowing over the item being cleaned.
Shadowing	The position of one item preventing water, steam or air getting to another item inside the washer/disinfector or steam steriliser.

Soft-bristled brush	Brush with soft parts made of plastic that will not damage the electrosurgery instrument cables.
Soil	Material including blood and protein that may be on a cable and must be cleaned off before sterilisation.
Steam-permeable	Allows steam through to sterilise the item inside.
Sterilisation	Treatment of items to destroy all microorganisms.
Thermal disinfection	Heat treatment of items to reduce the number of microorganisms to an acceptable level.
Validated	Tested to show that a process, equipment or setting gives the necessary result.
Versius	A Versius product supplied by CMR Surgical for use with the Versius Surgical System: a connected system of bedside units, surgeon console, endoscopic camera, instruments, drapes and cables.

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Procedures Overview

Outline of all procedures

