Versius Surgical System

Instrument and Accessories Manual (Version 15.0)

Read before use

CERTIFIED SAFETY US-CA E487417

CE XXXX REF 70050

CMR Surgical Ltd
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Milton Road, Cambridge CB24 9NG, UK

CMR SURGICAL

AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012, IEC 60601-1-6:2010 + A1:2013, ANSI/AAMI/IEC 60601-1-8:2006 + A1:2012, IEC 60601-2-18:2009, ANSI/AAMI/IEC 60601-2-2:2017, CAN/CSA-C22.2 No. 60601-1:2014, CAN/CSA-C22.2 No. 60601-1-6:2011 + A1:2015, CAN/CSA-C22.2 No. 60601-1-8:2008 + A1:2014, CAN/CSA-C22.2 No. 60601-2-18:2011, CAN/CSA C22.2 NO. 60601-2-2:19

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REF 70050 **Versius Instrument and Accessories Manual**

2022-04

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This user manual provides the Instructions for Use for the Versius Instruments, Endoscopes and Accessories.

Rx only

Table of Contents

Chapter 1

General information

1.1 Overview of this manual

Read the Versius Surgical System User Manual and the Versius Instrument and Accessories Manual. All instructions, warnings and precautions in both the Versius Surgical System User Manual (REF 70000) and this Versius Instrument and Accessories Manual must be followed for safe use of the system

Read the separate user manuals for the light cable (GA-A287) and light source (GA-A307)

1.1.1 Purpose of this manual

This manual provides specific information and instructions for use for Versius Instruments, Endoscopes and Accessories. See chapter 12 for a list of the Versius Instruments, Endoscopes and Accessories. This manual must be used with the Versius Surgical System User Manual (REF 70000) and should be kept with the Versius Surgical System.

Reprocessing Instructions for the Versius Instruments, Endoscopes and Accessories are provided separately. See section 1.6.

1.1.2 The version of this user manual

This user manual is version 15.0.

1.1.3 Content of chapters

Chapter 1 contains general information that applies to all instruments, endoscopes and accessories supplied by CMR Surgical.

Chapter 2 contains information and instructions for the Versius Endoscopes.

Chapter 3 contains information and instructions that apply to all Versius Instruments.

Chapters 4 to 9 contain information and instructions specific to each Versius Instrument.

Chapter 10 contains instructions on electrosurgery connections for the Versius Surgical System.

Chapter 11 contains appropriate electrosurgery settings for suitable electrosurgery units.

1.1.4 Warning, precaution and information symbols in this user manual

Warnings, precautions and information points can be found throughout this user manual. For safe use of the Versius Surgical System, users shall follow all instructions highlighted by warning and precaution symbols as well as reading the important reference information, highlighted by the information symbol.

⚠ This symbol indicates a warning. Warnings in this user manual indicate situations that could result in injury to the patient or user

⚠ This symbol indicates a precaution. Precautions in this user manual indicate situations that could result in minor injury to the patient or user, or damage to the Versius Surgical System

ⓘ This symbol indicates an information point. Information points in this user manual indicate important reference information

1.2 Contact information

Contact CMR Surgical customer services for ordering, reporting complaints or adverse events and for general information on CMR Surgical products.

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

Tel: +44 (0) 1223 750 975

If the Versius Surgical System requires technical support or service, please call the CMR Surgical 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

1.3 Compliance and classifications

The Versius Instruments and Accessories are designed and manufactured in conformance with the essential requirements and provisions of the Medical Device Directive 93/42/EEC, the Medical Device Regulations (EU 2017/745) and the following standards:

- BS EN 60601-1 General requirements
- BS EN 60601-1-2 EMC requirements and tests
- BS EN 60601-1-6 Usability
- BS EN 60601-2-2 HF Surgical Equipment
- BS EN 60601-2-18 Endoscopic Equipment

Versius Instruments are Type BF applied parts

1.4 General warnings and precautions

⚠ No modification of Versius Instruments or other Versius accessories is allowed

⚠ **Do not** use a Versius Instrument that has been dropped. Dispose of the instrument safely

⚠ Healthcare professionals must complete the Introduction to Versius Training Course provided by CMR Surgical, or for sterile nurses the Sterile Nurse Training Course provided by CMR Surgical, before using the Versius Surgical System.

The Versius Surgical System must only be operated by surgeons already trained and competent in minimal access surgery and who have developed adequate robotic skills to perform the tasks associated with the surgical procedure. Training provided by CMR Surgical does not replace the medical training and experience necessary to perform minimal access surgery

⚠ Versius Instruments, endoscope, monopolar instrument cables and bipolar instrument cables are supplied non-sterile, and must be reprocessed using a validated process before every use

⚠ Follow all instructions and warnings in the Reprocessing Instructions for the instruments and sterilisable accessories to reduce the risk of cross-infection

⚠ Follow all instructions in chapter 11 of this manual for use of compatible electrosurgery units with Versius. Other modes or settings may cause damage to Versius instruments or may cause harm to the patient

⚠ Store Versius Electrosurgery Instrument Cables in an area that meets local requirements for temperature and humidity. Incorrect storage could lead to damage to the electrosurgery instrument cables

⚠ **Do not** allow the end of the light cable to touch or point towards the patient or user when changing the endoscope as it may result in burns

⚠ **Do not** let the light cable rest on patient skin. Inadvertent contact with the patient may result in burns

⚠ **Do not** use Versius Instruments on a patient with an allergy to the metal materials used

⚠ **Do not** attempt to use Versius Instruments, cables or any other Versius components except when connected to the Versius Surgical System as described in the Versius Surgical System User Manual (REF 70000)

1.5 Operating, storage and transport conditions

Store all Versius Instruments and Accessories in a clean, dry, dark place in the original packaging, in line with local guidelines until first reprocessed (or until use in the case of accessories that do not require reprocessing before use).

The tables in this section provide the specific environmental conditions for the Versius Instruments and Accessories.

1.5.1 Versius Instruments

Environmental conditions for the Versius Instruments

	Temperature (°C)	Humidity non-condensing (%)	Pressure (hPa)
Operating	15 to 27	30% to 75%	700 to 1060
Storage	−5 to 55	10% to 90%	500 to 1060
Transport	−20 to 55	10% to 90%	500 to 1060

Take care to protect instrument tips from damage, and avoid exposing instruments to X-rays, radioactive rays or strong electromagnetic waves.

1.5.2 Versius Electrosurgery Cables

Environmental conditions for the Versius Electrosurgery Cables

	Temperature (°C)	Humidity (%)	Pressure (hPa)
Storage	−20 to 50	0% to 75%	500 to 1600

1.5.3 Versius Endoscopes

Environmental conditions for the Versius Endoscopes

	Temperature (°C)	Humidity (%)	Pressure (hPa)
Operating	10 to 40	20% to 75%	700 to 1060
Storage	−20 to 60	10% to 90%	700 to 1060
Transport	−20 to 60	10% to 90%	700 to 1060

1.5.4 Versius Insulating Sleeve

Environmental conditions for the Versius Insulating Sleeve

	Temperature (°C)	Humidity non-condensing (%)	Pressure (hPa)
Operating	15 to 25	30% to 75%	700 to 1060
Storage	5 to 35	20% to 80%	500 to 1060

1.5.5 Versius Drapes

Environmental conditions for the Versius Drapes

	Temperature (°C)	Humidity (%)	Pressure (hPa)
Storage	5 to 50	20% to 80%	700 to 1060

1.5.6 Exposure to adverse environmental conditions

If a Versius Insulating Sleeve or Versius Drape has been exposed to environmental conditions outside those listed in the relevant table on page 8, do not use the affected accessory. Dispose of the affected accessory in accordance with local guidelines.

If a Versius Instrument, Versius Endoscope or Versius Electrosurgery Cable has been exposed to environmental conditions outside those listed in the relevant table on pages 7–8, carry out the steps below:

1. Reprocess the affected accessory (see section 1.6 for a list of the reprocessing instructions)
2. Carry out inspections and checks on the affected accessory. See section 2.2.1 in this manual for the endoscope and the relevant reprocessing instructions for other accessories (see section 1.6)
3. If the affected accessory does not pass the inspection or checks, contact CMR Surgical customer services (see section 1.2). Do not use the affected accessory. If the accessory passes the inspection and checks, continue to use the accessory as normal

1.6 Reprocessing

Versius Instruments, Endoscopes and Electrosurgery Instrument Cables are supplied non-sterile and require reprocessing using a validated process before first use and after each use.

Refer to the separate validated Reprocessing Instructions:

- Versius Instrument Reprocessing Instructions (REF 70100)
- Versius Endoscope Reprocessing Instructions (REF 70200)
- Versius Electrosurgery Instrument Cables Reprocessing Instructions (REF 70300)

The Versius Insulating Sleeve is supplied sterile and does not require reprocessing as it is single-use only.

For reprocessing instructions for the Versius Electrosurgery Bedside Unit Cables, refer to the Versius Surgical System User Manual (REF 70000).

1.7 Disposal

Dispose of Versius Instruments, Endoscopes, Drapes and Insulating Sleeves following the hospital procedure for processing biologically contaminated materials. All other accessories, with the exception of those listed below, are to be disposed of following all applicable national and local laws and guidelines.

Return the following accessories to CMR Surgical for disposal:

- Camera head
- Bedside unit cables
- Monopolar and bipolar bedside unit cables
- Monopolar and bipolar instrument cables

Versius Instruments are limited use and must be properly disposed of after the maximum number of uses. Refer to the Versius Surgical System User Manual (REF 70000) for instructions on how to access instrument information, including the number of uses of each instrument, via the HUD menu.

1.7.1 Service and repair

The Versius Instruments, Endoscopes and Accessories are not user-serviceable and require no routine adjustments by the user to maintain operation. Unauthorised repairs or dismantling will invalidate the warranty.

Chapter 2

Versius Endoscopes

2.1 Introduction

This chapter provides information relevant to Versius Endoscopes.

For endoscope storage information, see section 1.5. For endoscope reprocessing information, see section 1.6, and for endoscope disposal information, see section 1.7.

For validated endoscope reprocessing instructions, refer to the separate Versius Endoscope Reprocessing Instructions (REF 70200).

For compatible ports to use with the Versius Endoscopes, see section 12.2.

2.1.1 Endoscope intended use

The Versius Endoscopes are intended for use with the Versius Surgical System. The Versius Endoscopes are intended for visualising the inside of the patient via natural or surgically created passages.

2.1.2 Warnings, precautions and information points

⚠ **Do not** apply unnecessary force to the Versius Endoscope shaft. Excessive force will cause damage to the endoscope

⚠ Inspect Versius Endoscopes before and after use for damage, loose parts and completeness. Do not use the endoscope if it is damaged

⚠ If a Versius Endoscope or Versius Instrument is damaged during surgery, check that no parts of the instrument or endoscope have been left inside the patient. A foreign body left inside the patient could lead to patient harm

⚠ **Do not** touch the endoscope tip and avoid direct contact of the tip with patient tissue. The endoscope tip may become very hot during use and if the endoscope is tip is too close to patient tissue this may lead to patient burns

⚠ Remove soiling from the endoscope tip regularly during use. Soiling on the tip during use may cause the endoscope tip to get very hot

⚠ Check the image quality on the console screen before using the endoscope. If the image is blurred, replace the endoscope. If the image becomes blurred during the surgery, replace the endoscope

⚠ Always use the light cable provided with the Versius Endoscope. Set the light output on the light source as low as is necessary to achieve the desired effect to avoid excessive heating of the endoscope tip and the light cable connection point

⚠ Store Versius Endoscopes in a safe place

⚠ Power off the light source if the endoscope is not going to be in use for a period of time to prevent unnecessary heating of the endoscope

⚠ Always allow the light cable to cool down after use before handling

⚠ Do not look into the end of an endoscope or a light cable that is connected to a light source. The intense light may cause damage to the eyes

⚠ Conduct a functional check and inspection of the endoscope before each use. If the endoscope fails the check, clean and sterilise the endoscope and return the endoscope and any loose parts to CMR Surgical

⚠ Only use the Versius Endoscope through ports that have been identified as compatible for use with the Versius Surgical System

Store the endoscope in the original packaging until it is reprocessed

Make sure there is no moisture on the connection between the endoscope and the camera head before attaching the endoscope to the camera head

2.1.3 Endoscope classification

The Versius Endoscopes are type BF applied parts

2.1.4 Endoscope description

The Versius Endoscopes have shafts with a diameter of 10 mm and a working length of 300 mm. There are two types of endoscope:

- Straight 0°
- Angled 30°

The angled endoscope can be attached 30° up or 30° down.

Figure 2.1 *Versius Endoscope tips*

Versius Endoscopes (straight 0° and angled 30°) have these features:

- Tip (Figure 2.1)
- Shaft (Figure 2.2)
- Glass surfaces (Figure 2.3)
- Light cable post (Figure 2.4)
- Light cable adapter (Figure 2.4)

The light cable adapter unscrews from the light cable post (see Figure 2.4). This is required during reprocessing. See the Versius Endoscope Reprocessing Instructions (REF 70200).

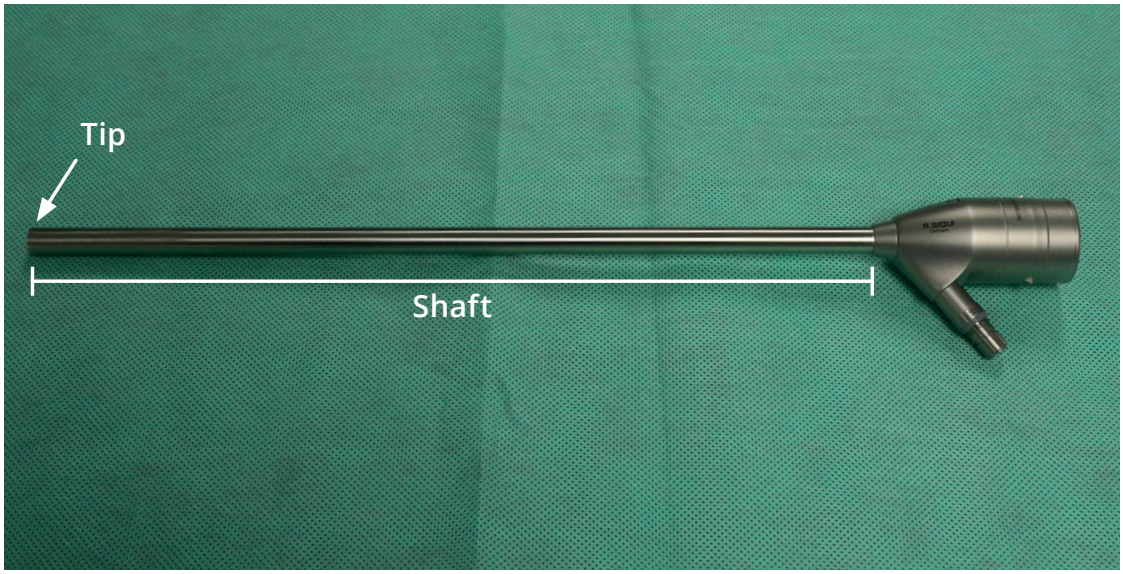


Figure 2.2 *Versius Endoscope*

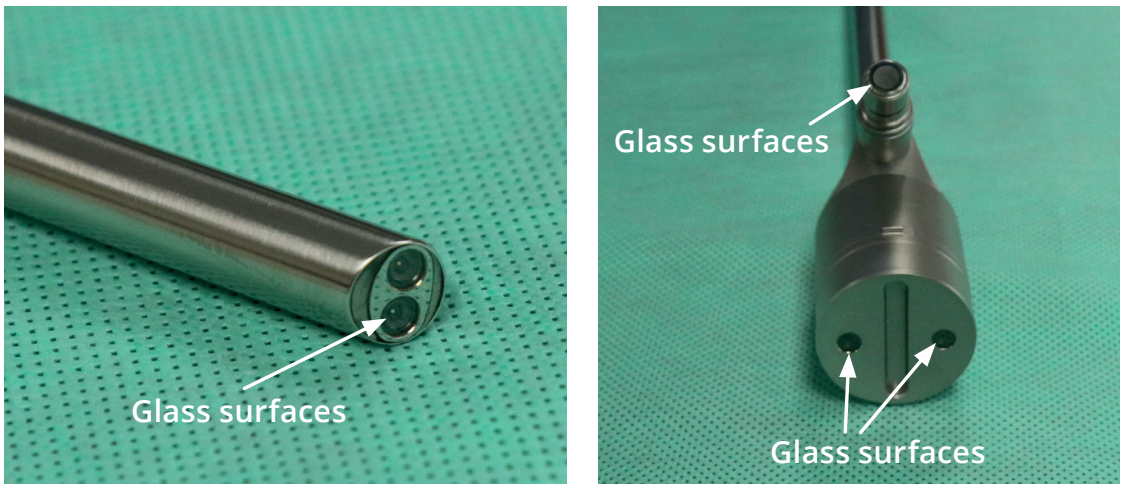


Figure 2.3 *Glass surfaces on the Versius Endoscopes*

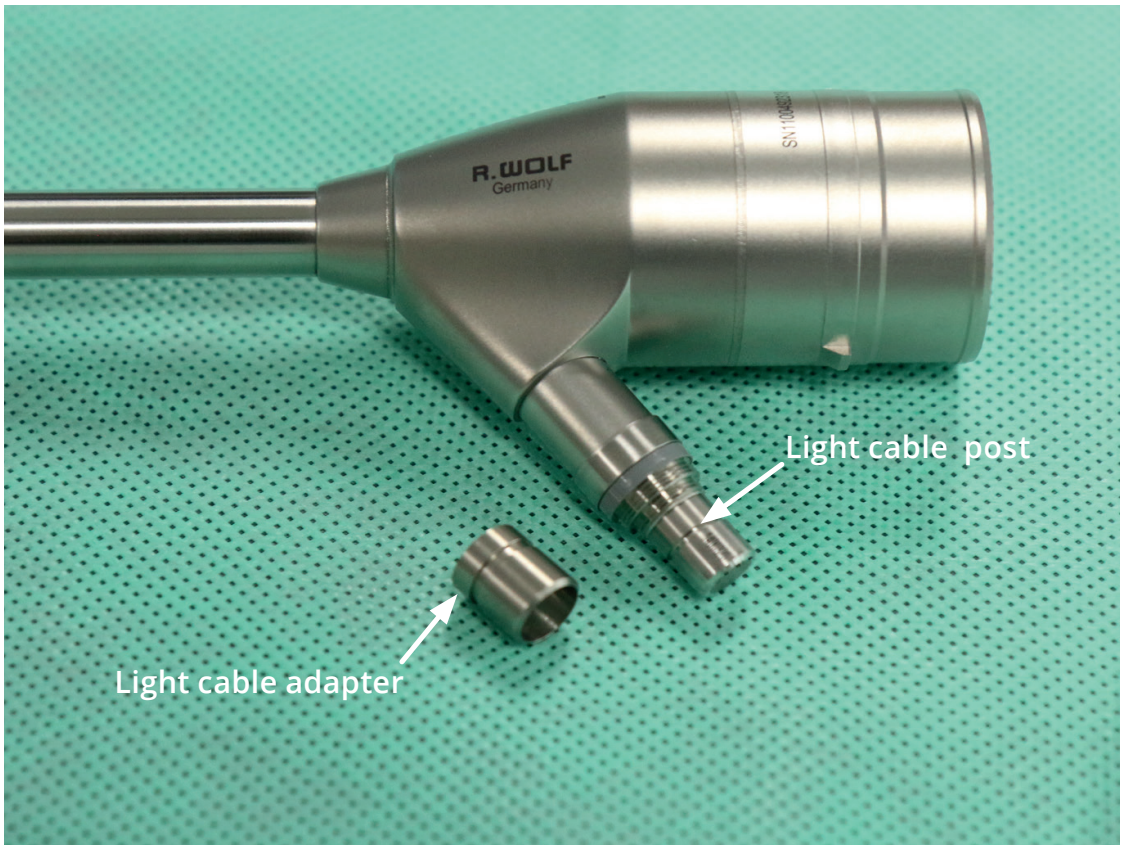


Figure 2.4 *Versius Endsocope (disassembled)*

2.2 Endoscope instructions for use

2.2.1 Before use inspection and checks

Inspection for damage

Before each use, visually check the endoscope for damage:

- Rough surfaces or surface changes (e.g. corrosion)
- Loose or missing parts
- Sharp edges
- Damage to inscriptions or identification necessary for the safe intended use, handling and processing

See section 2.2.2 if the endoscope is damaged.

Light cable adapter connection check

Before each use, check that:

- The light cable adapter is securely screwed to the endoscope
- The light cable adapter and endoscope assemble easily

If the connection is not secure or is difficult to assemble, use a replacement endoscope and light cable adapter and refer to section 2.2.2.

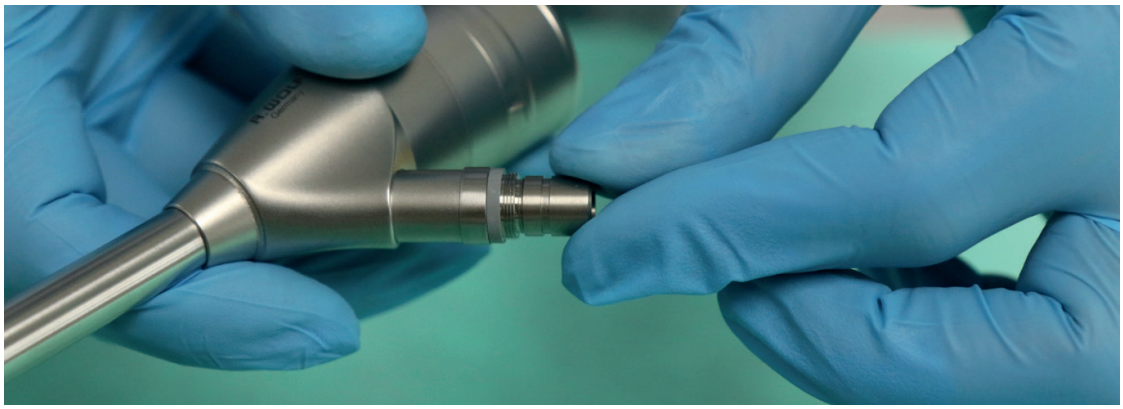


Figure 2.5 *Checking the light cable adapter and endoscope connection*

2.2.2 Damaged or faulty endoscopes

⚠ Inspect Versius Endoscopes before and after use for damage, loose parts and completeness. Do not use the endoscope if it is damaged

If a Versius Endoscope is damaged or faulty:

1. Clean and sterilise the damaged or faulty endoscope. See the Versius Endoscope Reprocessing Instructions (REF 70200)
2. Contact CMR Surgical customer services. See section 1.2 for contact details

If a Versius Endoscope is damaged or faulty, use a replacement functioning Versius Endoscope.

2.2.3 Dropped endoscopes

If a Versius Endoscope has been dropped:

1. Clean and sterilise the dropped endoscope. See the Versius Endoscope Reprocessing Instructions (REF 70200)
2. Carry out the inspection and checks in section 2.2.1
3. Contact CMR Surgical customer services (see section 1.2) if the endoscope does not pass the inspection or checks. Do not use the endoscope. If the endoscope passes the inspection and checks, continue using as the endoscope as normal.

2.2.4 Endoscope intraoperative use

Only use Versius Endoscopes with the Versius Surgical System.

Refer to the Versius Surgical System User Manual (REF 70000) for information and instructions on using the Versius Endoscopes in conjunction with the Versius Surgical System and for a list of compatible light sources.

Always use the light cable provided and a light source that is compatible for use with the system.

Chapter 3

Versius Instruments

3.1 Introduction

This chapter provides information relevant to all Versius Instruments. Chapters 4 to 9 provide specific detailed information on each Versius Instrument and section 12.2 lists the ports that are compatible for use with the Versius Instruments.

3.1.1 Instrument intended use

The Versius Instruments are intended for use only with the Versius Surgical System.

The Versius Instruments, including scissors, needle holders, hooks, graspers and electrosurgery instruments, are intended for endoscopic manipulation of tissue including blunt and sharp dissection of tissue, cutting of tissue, grasping of tissue, suturing and electrosurgery.

3.1.2 Instrument general warnings and precautions

⚠ Versius Instruments are supplied non-sterile and must be reprocessed using a validated process prior to first use and after each use. Refer to the Versius Instrument Reprocessing Instructions (REF 70100)

⚠ Inspect the Versius Instruments for damage before use. **Do not** use a damaged instrument

⚠ Check the outer surfaces of the instruments and endoscope for any unintended rough surfaces, sharp edges or protrusions which may cause harm. **Do not** use instruments or endoscopes found to have any abnormalities

⚠ If an instrument is damaged during surgery, check that no part of the instrument has been left inside the patient cavity. A foreign body left inside the patient cavity could lead to harm to the patient

⚠ **Do not** use a Versius Instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ **Do not** handle Versius Instruments by the instrument tip due to the risk of sharps injury and burns. Hold the instrument at the proximal end (the end that attaches to the drape cap)

⚠ Check instrument life after surgery and discard any instruments that are out of life

⚠ Versius Instruments are only compatible with the Versius Surgical System

⚠ Only use Versius Instruments through ports that have been identified as compatible for use with the Versius Surgical System. Inappropriate port size could lead to an incorrect fulcrum being detected during port-training

3.1.3 Instrument classification

 The Versius Instruments are type BF applied parts

3.1.4 Instrument description

The Versius Instruments are wristed instruments with a shaft diameter of 6.8 mm and a working length of 300 mm. The Versius Instruments are attached to the arms on Versius Instrument Bedside Units by the attachment head (Figure 3.1). The attachment head has latches for attaching the instrument to the arm and three fins, which mechanically drive the instrument during surgery.

Each Versius Instrument has the following features (labelled in Figure 3.1 and Figure 3.3):

- Cable connector pin for electrosurgery cables to connect to (if the instrument is capable of electrosurgery)
- Latches
- Attachment head (the most proximal end of the instrument)
- 6.8 mm shaft diameter that provides a 300 mm working length
- Wrist that allows the tip to rotate
- Tip
- Fins

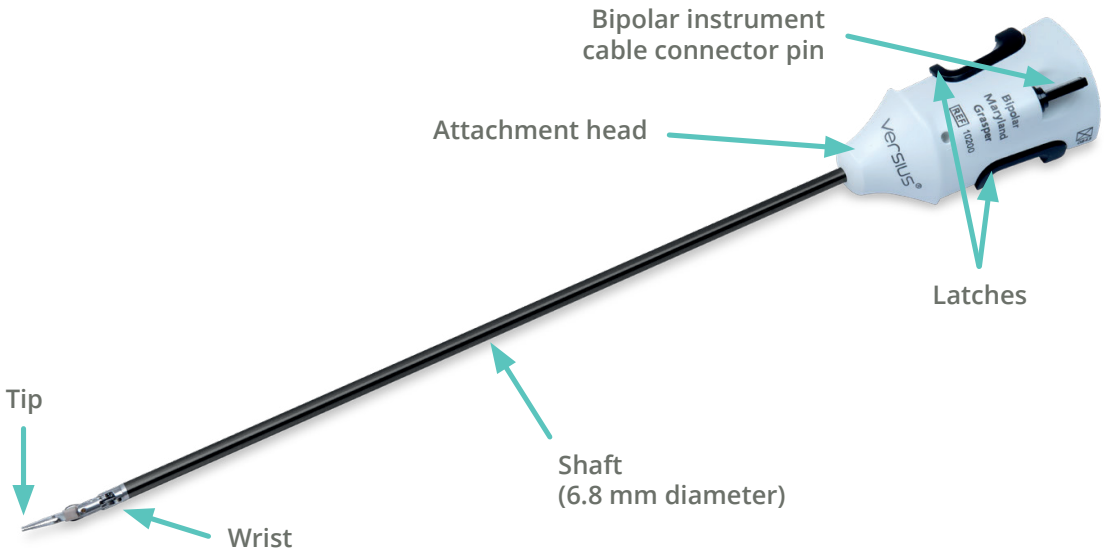


Figure 3.1 *A Versius Instrument with key components labelled*

Figure 3.2 *An example Versius Instrument tip*

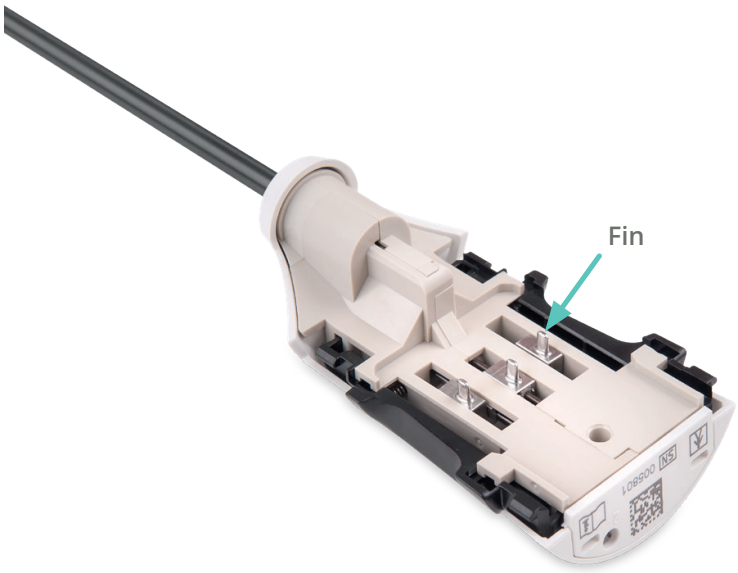


Figure 3.3 *Versius Instrument fins*

3.1.5 Flush ports

Each Versius Instrument has two flush ports: flush port 1 and flush port 2 (Figure 3.4). Refer to the Versius Instrument Reprocessing Instructions (REF 70100) for information on these flush ports.

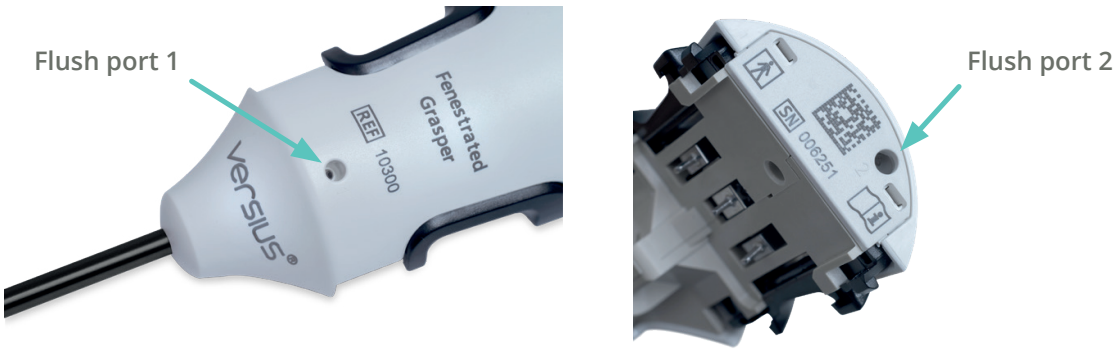


Figure 3.4 *Flush port 1 and flush port 2 on a Versius Instrument*

3.2 Instrument instructions for use

For instrument storage information, see section 1.5. For instrument reprocessing information, see section 1.6 and for instrument disposal information, see section 1.7.

3.2.1 Instrument inspection before use

⚠ **Inspect** the Versius Instruments for damage before use. If the instrument is damaged, do not use that instrument

3.2.2 Instrument intraoperative use

Refer to the Versius Surgical System User Manual (REF 70000) for instructions on using the Versius Instruments in conjunction with the Versius Surgical System.

⚠ Using the hand controllers, move the instruments in free space inside the patient cavity to test that the instruments are assigned to each hand controller, as intended, and are functioning correctly.
Do not use an instrument that is not functioning correctly

If a fault occurs in a Versius Instrument, a replacement functioning Versius Instrument can be used.

Chapter 4

Versius Fenestrated Grasper

4.1 Introduction

This chapter contains the instructions for use for the Versius Fenestrated Grasper.

4.1.1 Instrument description

The Versius Fenestrated Grasper is used in conjunction with the Versius Surgical System. The Versius Surgical System User Manual (REF 70000) provides instructions on controlling the Versius Instruments.

All key components of the Versius Fenestrated Graspers are labelled in Figure 4.1. The instrument tip is shown in Figure 4.2.

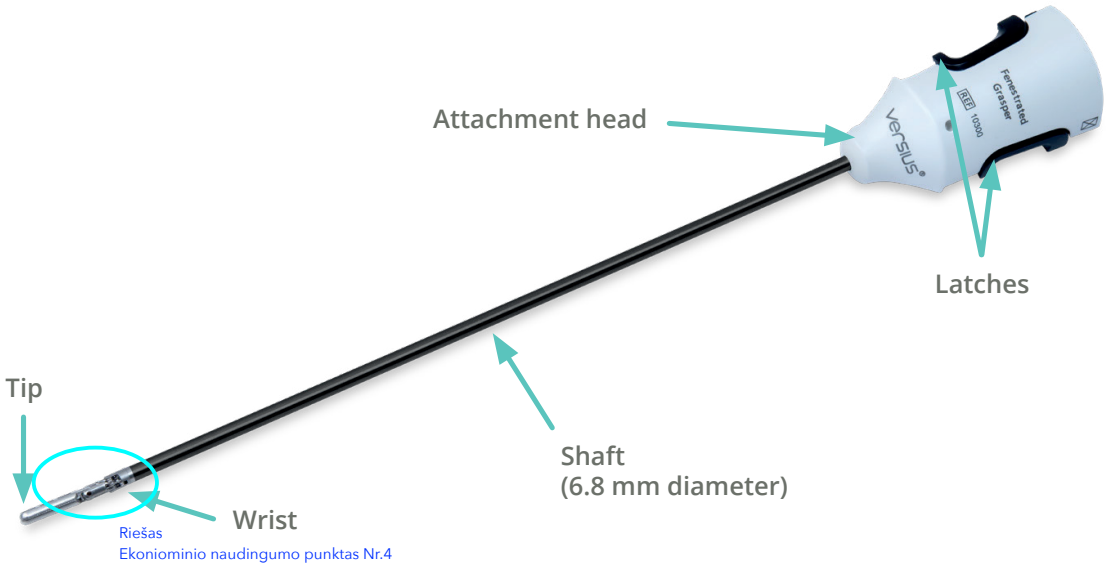


Figure 4.1 *Versius Fenestrated Grasper*

Figure 4.2 *Versius Fenestrated Grasper instrument tip*

4.1.2 General warnings and precautions

⚠ Versius Instruments are supplied non-sterile and must be reprocessed using a validated process prior to first use and after each use. Refer to the Versius Instrument Reprocessing Instructions (REF 70100)

⚠ **Do not** use an instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ **Check** the outer surfaces of the instruments and endoscope for any unintended rough surfaces, sharp edges or protrusions which may cause harm. **Do not** use instruments or endoscopes found to have any abnormalities

⚠ If an instrument is damaged during surgery, check that no part of the instrument has been left inside the patient cavity. A foreign body left inside the patient cavity could lead to harm to the patient

4.2 Instructions for use

For storage information, see section 1.5. For reprocessing information, see section 1.6, and for disposal information, see section 1.7.

4.2.1 Inspection before use

⚠ **Inspect** the Versius Instruments for damage before use. **Do not** use a damaged instrument

4.2.2 Intraoperative use

When the Versius Fenestrated Grasper is attached to the Versius Instrument Arm, this icon appears on the head-up display on the console screen:

Refer to the Versius Surgical System User Manual (REF 70000) for instructions on controlling the Versius Instruments.

If a fault occurs in a Versius Instrument, a replacement functioning Versius Instrument can be used.

Chapter 5

Versius Curved Scissors

5.1 Introduction

This chapter contains the instructions for use for the Versius Curved Scissors.

5.1.1 Instrument description

The Versius Curved Scissors are used in conjunction with the Versius Surgical System. The Versius Surgical System User Manual (REF 70000) provides instructions on controlling the Versius Instruments.

All key components of the Versius Curved Scissors are labelled in Figure 5.1. The instrument tip is shown in Figure 5.2.

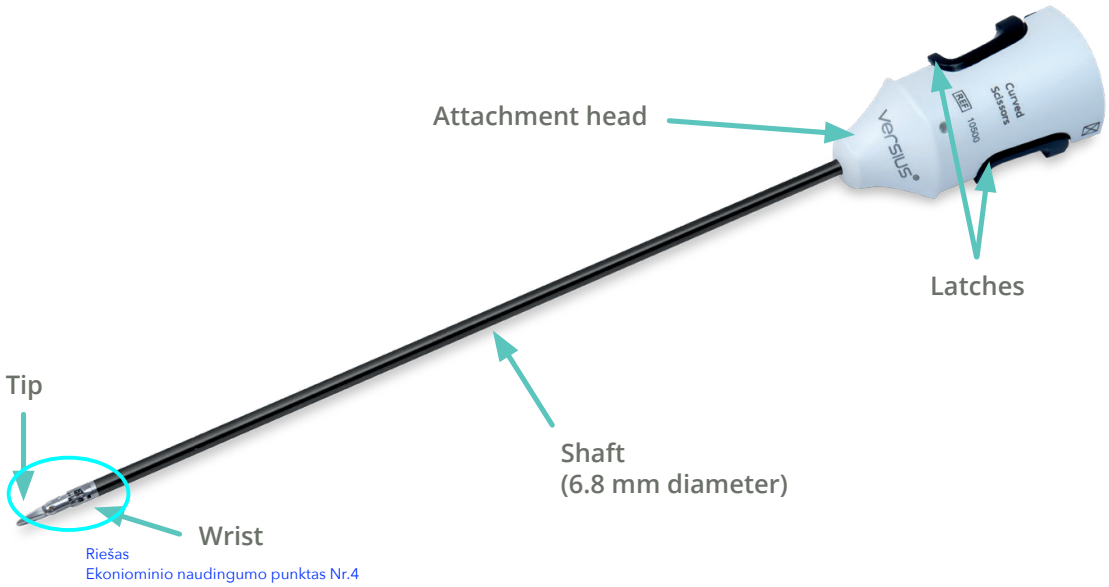


Figure 5.1 *Versius Curved Scissors*

Punktas 7.5 Lenktos žirklės

Figure 5.2 *Versius Curved Scissors instrument tip*

5.1.2 General warnings and precautions

⚠ Versius Instruments are supplied non-sterile and must be reprocessed using a validated process prior to first use and after each use. Refer to the Versius Instrument Reprocessing Instructions (REF 70100)

⚠ **Do not** use an instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ **Check** the outer surfaces of the instruments and endoscope for any unintended rough surfaces, sharp edges or protrusions which may cause harm. **Do not** use instruments or endoscopes found to have any abnormalities

⚠ If an instrument is damaged during surgery, check that no part of the instrument has been left inside the patient cavity. A foreign body left inside the patient cavity could lead to harm to the patient

5.2 Instructions for use

For storage information, see section 1.5. For reprocessing information, see section 1.6, and for disposal information, see section 1.7.

5.2.1 Inspection before use

⚠ **Inspect** the Versius Instruments for damage before use. **Do not** use a damaged instrument

5.2.2 Intraoperative use

When the Versius Curved Scissors are attached to the Versius Instrument Arm, this icon appears on the head-up display on the console screen:

Refer to the Versius Surgical System User Manual (REF 70000) for instructions on controlling the Versius Instruments.

If a fault occurs in a Versius Instrument, a replacement functioning Versius Instrument can be used.

Chapter 6

Versius Needle Holder

6.1 Introduction

This chapter contains the instructions for use for the Versius Needle Holder.

6.1.1 Instrument description

The Versius Needle Holder is an instrument used in conjunction with the Versius Surgical System. The Versius Surgical System User Manual (REF 70000) provides instructions on controlling the Versius Instruments.

All key components of the Versius Needle Holder are labelled in Figure 6.1. The instrument tip is shown in Figure 6.2.

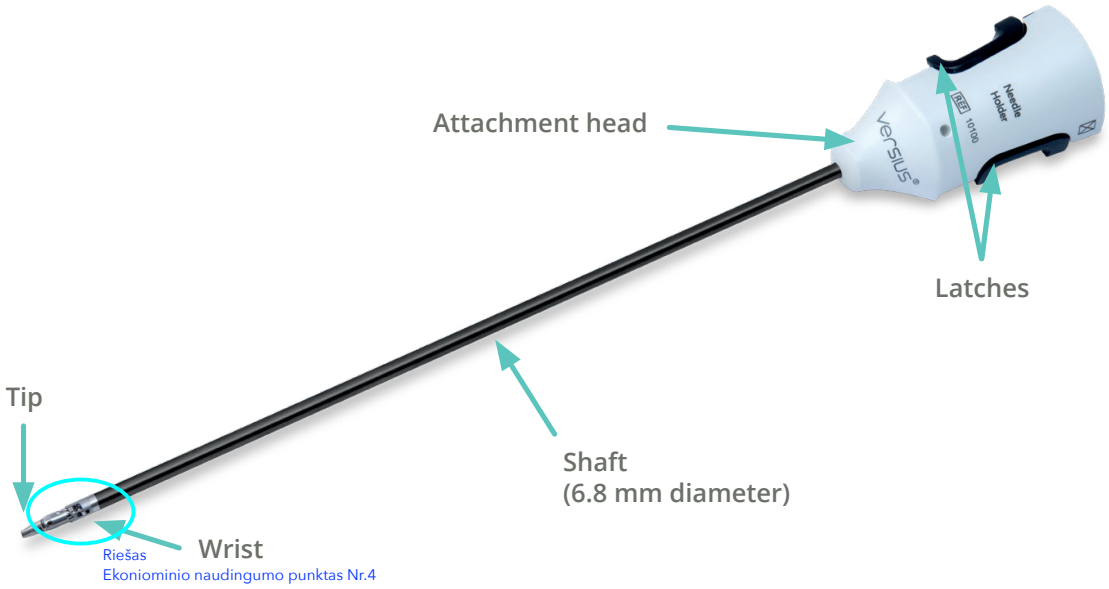


Figure 6.1 *Versius Needle Holder*

Punktas 7.1 Adatkotis

Figure 6.2 *Versius Needle Holder instrument tip*

6.1.2 General warnings and precautions

⚠ Versius Instruments are supplied non-sterile and must be reprocessed using a validated process prior to first use and after each use. Refer to the Versius Instrument Reprocessing Instructions (REF 70100)

⚠ **Do not** use an instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ **Check** the outer surfaces of the instruments and endoscope for any unintended rough surfaces, sharp edges or protrusions which may cause harm. **Do not** use instruments or endoscopes found to have any abnormalities

⚠ If an instrument is damaged during surgery, check that no part of the instrument has been left inside the patient cavity. A foreign body left inside the patient cavity could lead to harm to the patient

⚠ No modification of Versius Instruments or other Versius accessories is allowed

⚠ **Do not** attempt to use Versius Instruments, cables or any other Versius components except when connected to the Versius Surgical System as described in the Versius User Manual (REF 70000)

6.2 Instructions for use

For storage information, see section 1.5. For reprocessing information, see section 1.6, and for disposal information, see section 1.7.

6.2.1 Inspection before use

⚠ **Inspect** the Versius Instruments for damage before use. **Do not** use a damaged instrument

6.2.2 Intraoperative use

When the Versius Needle Holder is attached to the Versius Instrument Arm, this icon appears on the head-up display on the console screen:

Refer to the Versius Surgical System User Manual (REF 70000) for instructions on controlling the Versius Instruments.

If a fault occurs in a Versius Instrument, a replacement functioning Versius Instrument can be used.

Chapter 7

Versius Bipolar Maryland Grasper

7.1 Introduction

This chapter contains the instructions for use for the Versius Bipolar Maryland Grasper. For the appropriate electrosurgery settings for the Versius Bipolar Maryland Grasper, refer to Chapter 11.

7.1.1 Instrument description

The Versius Bipolar Maryland Grasper is an electrosurgery instrument used in conjunction with the Versius Surgical System and an electrosurgery unit (not supplied with the Versius Surgical System). Refer to electrosurgery unit instruction manual before using this instrument. The Versius Surgical System User Manual (REF 70000) provides instructions on controlling the Versius Instruments.

The Versius Bipolar Maryland Grasper has a pin for the bipolar instrument cable to connect to (Figure 7.1).

All key components of the Versius Bipolar Maryland Grasper are labelled in Figure 7.1. The instrument tip is shown in Figure 7.2.

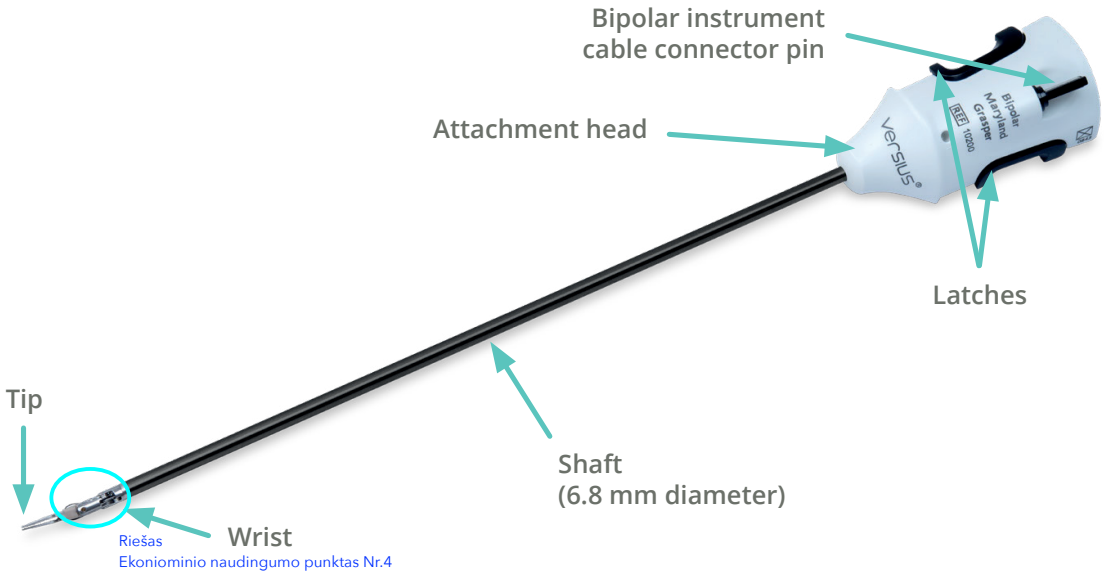


Figure 7.1 *Versius Bipolar Maryland Grasper*

Punktas7.2 Merilendo tipo bipolinės žnyplės

Figure 7.2 *Versius Bipolar Maryland Grasper instrument tip*

7.1.2 General warnings and precautions

⚠ Versius Instruments are supplied non-sterile and must be reprocessed using a validated process prior to first use and after each use. Refer to the Versius Instrument Reprocessing Instructions (REF 70100)

⚠ **Do not** use an instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ Check the outer surfaces of the instruments and endoscope for any unintended rough surfaces, sharp edges or protrusions which may cause harm. **Do not** use instruments or endoscopes found to have any abnormalities

⚠ If an instrument is damaged during surgery, check that no part of the instrument has been left inside the patient cavity. A foreign body left inside the patient cavity could lead to harm to the patient

⚠ **Do not** activate electrosurgery on an electrosurgery instrument while that instrument is not in contact with target tissue

⚠ Be careful when operating electrosurgery instruments close to other instruments or equipment. Energy may unintentionally be applied to another instrument or equipment, which could lead to burns to the tissue that the other instrument or equipment was in contact with

⚠ Always activate electrosurgery in the field of view. Ensure the entire surgical field is inspected, paying particular attention to areas of the instrument that may have been in contact with tissue during electrosurgery activation

⚠ The Versius Bipolar Maryland Grasper is designed for a maximum peak voltage of 500V. Do not use settings on the electrosurgery unit which exceed a peak voltage of 500V

⚠ **Do not** exceed the electrosurgery unit settings given for Versius Bipolar Instruments in chapter 11 for the Versius Bipolar Maryland Grasper

⚠ No modification of Versius Instruments or other Versius accessories is allowed

⚠ **Do not** attempt to use Versius Instruments, cables or any other Versius components except when connected to the Versius Surgical System as described in the Versius User Manual (REF 70000)

7.2 Instructions for use

For storage information, see section 1.5. For reprocessing information, see section 1.6, and for disposal information, see section 1.7.

7.2.1 Inspection before use

⚠ **Inspect** the Versius Instruments for damage before use. **Do not** use a damaged instrument

7.2.2 Intraoperative use

When the Versius Bipolar Maryland Grasper is attached to the Versius Instrument Arm, this icon appears on the head-up display on the console screen:

Refer to the Versius Surgical System User Manual (REF 70000) for instructions on controlling the Versius Instruments and activating electrosurgery.

If a fault occurs in a Versius Instrument, a replacement functioning Versius Instrument can be used.

Chapter 8

Versius Monopolar Hook

8.1 Introduction

This chapter contains the instructions for use for the Versius Monopolar Hook. For the appropriate electrosurgery settings for the Versius Monopolar Hook, refer to Chapter 11.

8.1.1 Instrument description

The Versius Monopolar Hook is an electrosurgery instrument used in conjunction with the Versius Surgical System and an electrosurgery unit (not supplied with the Versius Surgical System). Refer to electrosurgery unit instruction manual before using this instrument. The Versius Surgical System User Manual (REF 70000) provides instructions on controlling the Versius Instruments.

The Versius Monopolar Hook has a pin for the monopolar instrument cable to connect to (Figure 8.1).

All key components of the Versius Monopolar Hook are labelled in Figure 8.1. The instrument tip is shown in Figure 8.2.

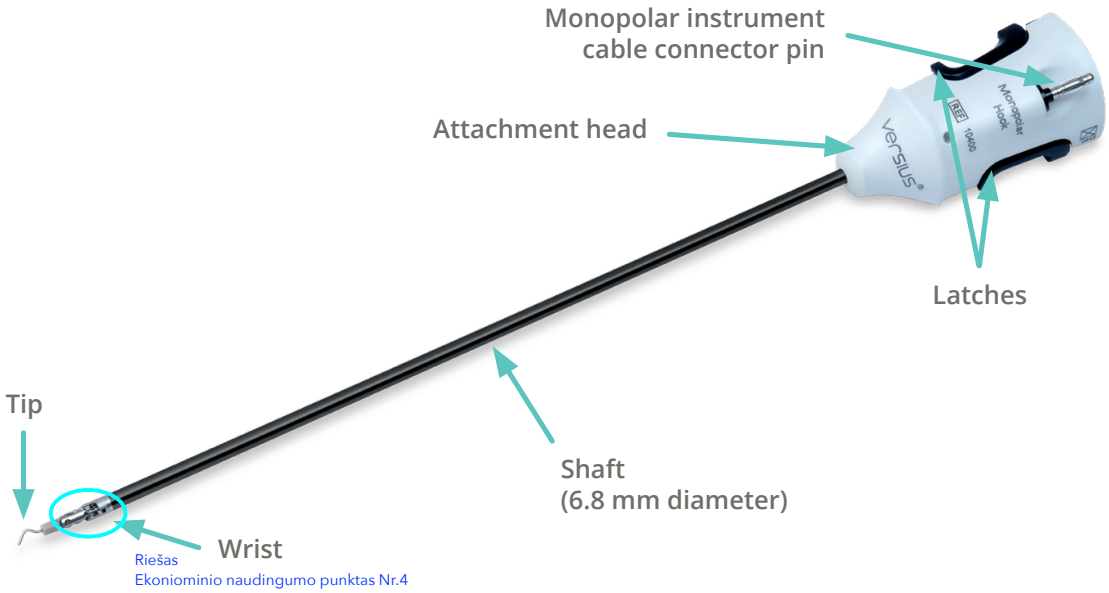


Figure 8.1 *Versius Monopolar Hook*

Punktas 7.4, Monopoliarinis kablys

Figure 8.2 *Versius Monopolar Hook instrument tip*

8.1.2 General warnings and precautions

⚠ Versius Instruments are supplied non-sterile and must be reprocessed using a validated process prior to first use and after each use. Refer to the Versius Instrument Reprocessing Instructions (REF 70100)

⚠ **Do not** use an instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ Check the outer surfaces of the instruments and endoscope for any unintended rough surfaces, sharp edges or protrusions which may cause harm. **Do not** use instruments or endoscopes found to have any abnormalities

⚠ If an instrument is damaged during surgery, check that no part of the instrument has been left inside the patient cavity. A foreign body left inside the patient cavity could lead to harm to the patient

⚠ **Do not** activate electrosurgery on an electrosurgery instrument while that instrument is not in contact with target tissue

⚠ Be careful when operating electrosurgery instruments close to other instruments or equipment. Energy may unintentionally be applied to another instrument or equipment, which could lead to burns to the tissue that the other instrument or equipment was in contact with

⚠ Always activate electrosurgery in the field of view. Ensure the entire surgical field is inspected, paying particular attention to areas of the instrument that may have been in contact with tissue during electrosurgery activation

⚠ The Versius Monopolar Hook is designed for a maximum peak voltage of 1333V. **Do not** use settings on the electrosurgery unit which exceed 1333V peak

⚠ **Do not** exceed the electrosurgery unit settings given for Versius Monopolar Instruments in chapter 11 for the Versius Monopolar Hook

⚠ No modification of Versius Instruments or other Versius accessories is allowed

⚠ Follow all instructions and warnings in the Reprocessing Instructions for the instruments and sterilisable accessories to reduce the risk of cross-infection

⚠ **Do not** attempt to use Versius Instruments, cables or any other Versius components except when connected to the Versius Surgical System as described in the Versius User Manual (REF 70000)

⚠ **Do not** use Versius Instruments on a patient with an allergy to the metal materials used

8.2 Instructions for use

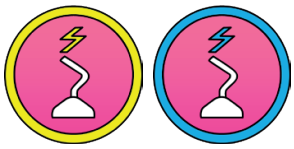
For storage information, see section 1.5. For reprocessing information, see section 1.6, and for disposal information, see section 1.7.

8.2.1 Inspection before use

⚠ **Inspect** the Versius Instruments for damage before use. **Do not** use a damaged instrument

8.2.2 Intraoperative use

When the Versius Monopolar Hook is attached to the Versius Instrument Arm, these icons appear on the head-up display on the console screen:



Refer to the Versius Surgical System User Manual (REF 70000) for instructions on controlling the Versius Instruments and activating electrosurgery.

If a fault occurs in a Versius Instrument, a replacement functioning Versius Instrument can be used.

Chapter 9

Versius Monopolar Curved Scissors

9.1 Introduction

This chapter contains the instructions for use for the Versius Monopolar Curved Scissors. For the appropriate electrosurgery settings for the Versius Monopolar Curved Scissors, refer to Chapter 11.

The Versius Monopolar Curved Scissors have an accompanying accessory called the Versius Insulating Sleeve. The Insulating Sleeve is a sterile, single-use accessory that is applied to the Monopolar Curved Scissors before each use and removed after each use. The Monopolar Curved Scissors must not be used without the Insulating Sleeve. See section 9.3 for specific information about the Insulating Sleeve and instructions for its application to the Monopolar Curved Scissors.

⚠ Always apply the Insulating Sleeve when using the Monopolar Curved Scissors

⚠ Failure to correctly apply the Insulating Sleeve to the Monopolar Curved Scissors before use could lead to: restricted scissor manipulation; the Insulating Sleeve becoming detached from the instrument during use; and electrical arching and/or electrical burns

9.1.1 Instrument description

The Versius Monopolar Curved Scissors are an electrosurgery instrument used in conjunction with the Versius Surgical System and an electrosurgery unit (not supplied with the Versius Surgical System). Refer to electrosurgery unit instruction manual before using this instrument. The Versius Surgical System User Manual (REF 70000) provides instructions on controlling the Versius Instruments.

The Versius Monopolar Curved Scissors have a connector pin for the monopolar instrument cable to connect to (Figure 9.1).

All key components of the Versius Monopolar Curved Scissors are labelled in Figure 9.1. The instrument tip is shown in Figure 9.2.

The Versius Monopolar Curved Scissors have a Position Marker near the tip of the shaft. This is used as a visual guide when checking the Insulating Sleeve is positioned correctly (see section 9.3.3).

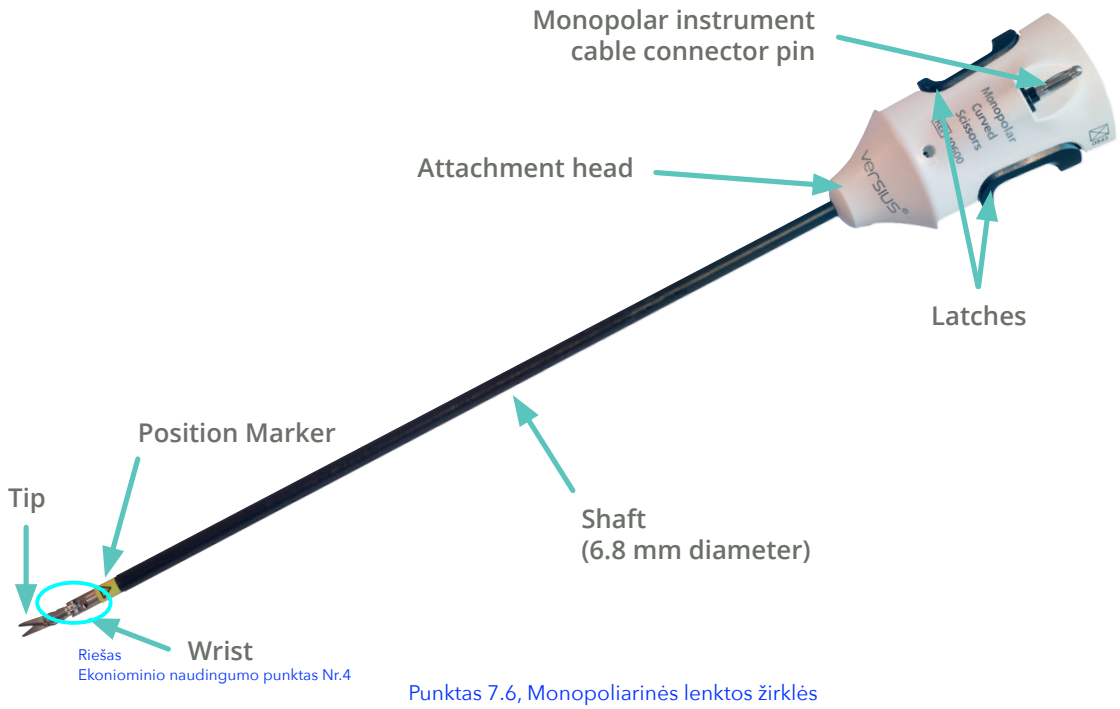


Figure 9.1 *Versius Monopolar Curved Scissors*

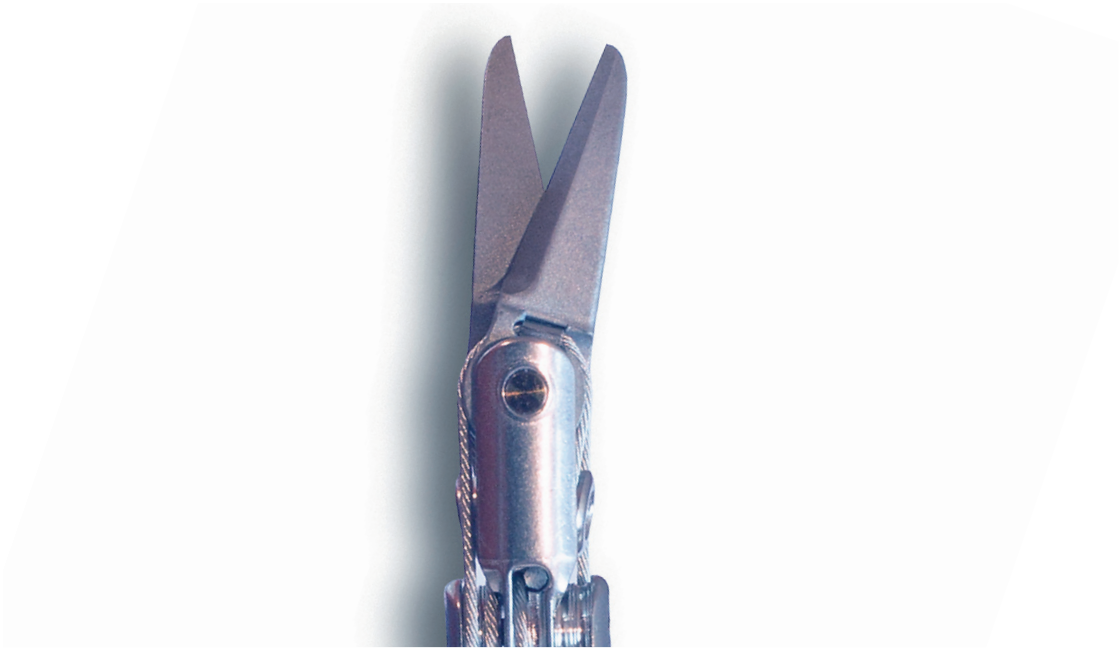


Figure 9.2 *Versius Monopolar Curved Scissors instrument tip*

9.1.2 General warnings and precautions

⚠ Versius Instruments are supplied non-sterile and must be reprocessed using a validated process prior to first use and after each use. Refer to the Versius Instrument Reprocessing Instructions (REF 70100)

⚠ **Do not** use an instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ Check the outer surfaces of the instruments and endoscope for any unintended rough surfaces, sharp edges or protrusions which may cause harm. **Do not** use instruments or endoscopes found to have any abnormalities

⚠ If an instrument is damaged during surgery, check that no part of the instrument has been left inside the patient cavity. A foreign body left inside the patient cavity could lead to harm to the patient

⚠ **Do not** activate electrosurgery on an electrosurgery instrument while that instrument is not in contact with target tissue

⚠ Be careful when operating electrosurgery instruments close to other instruments or equipment. Energy may unintentionally be applied to another instrument or equipment, which could lead to burns to the tissue that the other instrument or equipment was in contact with

⚠ Always activate electrosurgery in the field of view. Ensure the entire surgical field is inspected, paying particular attention to areas of the instrument that may have been in contact with tissue during electrosurgery activation

⚠ **Do not** exceed a maximum peak voltage of 1333V on the electrosurgery unit for the Versius Monopolar Curved Scissors

⚠ **Do not** exceed the electrosurgery unit settings given for Versius Monopolar Instruments in chapter 11 for the Versius Monopolar Curved Scissors

⚠ Always inspect the Versius Monopolar Curved Scissors after use and discard any damaged instrument

⚠ No modification of Versius Instruments or other Versius accessories is allowed

⚠ Always apply the Insulating Sleeve when using the Monopolar Curved Scissors

⚠ Failure to correctly apply the Insulating Sleeve to the Monopolar Curved Scissors before use could lead to: restricted scissor manipulation; the Insulating Sleeve becoming detached from the instrument during use; and electrical arching and/or electrical burns

⚠ **Do not** attempt to use Versius Instruments, cables or any other Versius components except when connected to the Versius Surgical System as described in the Versius User Manual (REF 70000)

9.2 Instructions for use

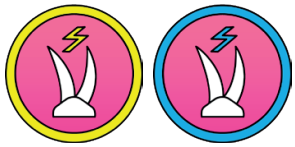
For storage information, see section 1.5. For reprocessing information, see section 1.6, and for disposal information, see section 1.7.

9.2.1 Inspection before use

⚠ **Inspect** the Versius Instruments for damage before use. **Do not** use a damaged instrument

9.2.2 Intraoperative use

When the Versius Monopolar Curved Scissors are attached to the Versius Instrument Arm, these icons appears on the head-up display on the console screen:



Refer to the Versius Surgical System User Manual (REF 70000) for instructions on controlling the Versius Instruments and activating electrosurgery.

If a fault occurs in a Versius Instrument, a replacement functioning Versius Instrument can be used.

9.3 Versius Insulating Sleeve

The Versius Insulating Sleeve (Figure 9.3) provides a flexible insulative layer between live elements of the Versius Monopolar Curved Scissors and the patient. The Insulating Sleeve and its application and removal tool (the Insulating Sleeve Tool) are provided sterile in individual Insulating Sleeve Accessory peel packs (see section 9.3.2).

Figure 9.3 *Versius Insulating Sleeve*

9.3.1 Warnings, precautions and information points

⚠ **Do not** use the Insulating Sleeve or its tool if its packaging is torn, damaged or open, or if it has passed its expiry date, as it may be contaminated. Dispose of the affected Insulating Sleeve and its tool

⚠ **Do not** re-use the Insulating Sleeve. Dispose of the sleeve and its tool at the end of each surgery following the hospital procedure for processing biologically contaminated materials. Attempting to re-sterilise the Insulating Sleeve may result in an ineffective sterile insulation barrier

⚠ Always inspect the tip of the Monopolar Curved Scissors for damage before application and after removal of the Insulating Sleeve

⚠ Always apply the Insulating Sleeve when using the Monopolar Curved Scissors

⚠ Failure to correctly apply the Insulating Sleeve to the Monopolar Curved Scissors before use could lead to: restricted scissor manipulation; the Insulating Sleeve becoming detached from the instrument during use; and electrical arching and/or electrical burns

⚠ **Do not** use lubricants, liquids or gels to aid application of the Insulating Sleeve

⚠ Check that you have only the *Versius* Insulating Sleeve for use with Versius Monopolar Curved Scissors

⚠ Always open and handle the Insulating Sleeve and its tool using aseptic technique. If aseptic technique is not used when handling the Insulating Sleeve and its tool, they could become contaminated and lead to the patient contracting an infection

⚠ Take care when applying and removing the Insulating Sleeve to avoid the risk of sharps injury and contamination

⚠ Always inspect the Insulating Sleeve after application for signs of damage and to confirm its correct positioning

⚠ Follow instructions for effective application of the Insulating Sleeve

⚠ Always detach the Monopolar Curved Scissors from the instrument arm before application, removal or adjustment of the Insulating Sleeve

⚠ Always ensure the tip of the Monopolar Curved Scissors is dry before applying the Insulating Sleeve

⚠ Always check for damage to the Insulating Sleeve if the Monopolar Curved Scissors collide with another instrument or surgical equipment. Check that no part of the Insulating Sleeve has been left inside the patient's cavity. A foreign body left inside the cavity could lead to harm to the patient

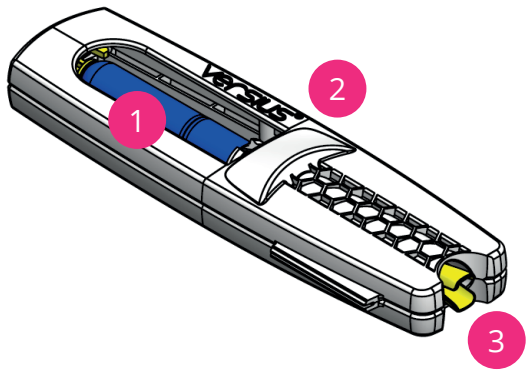
⚠ Take care not to move the instrument fins during application of the Insulating Sleeve

⚠ Do not attempt to reapply the Insulating Sleeve after initial use, and do not use the Insulating Sleeve Tool to reapply a sleeve. Once the sleeve has been removed the silicone material is likely to be damaged and the shape and stretching of the sleeve means it is likely to roll up. If reapplied the sleeve may not provide an effective insulating barrier and the sleeve or a part of the sleeve may fall off the instrument inside the patient.

ⓘ The Insulating Sleeve Accessory is supplied sterile, for single use only. The Insulating Sleeve Accessory is sterilised using ethylene oxide

ⓘ Before beginning system set-up, ensure a sufficient number of Insulating Sleeves are available to complete the full surgical procedure

9.3.2 Insulating Sleeve Accessory pack contents



1. Insulating Sleeve
2. Insulating Sleeve Tool
3. Instrument Tip Guide

9.3.3 Applying the Insulating Sleeve

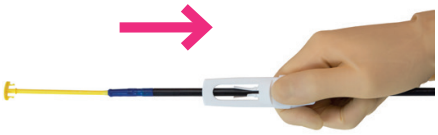
Non-sterile tasks

⚠ Always detach the Monopolar Curved Scissors from the instrument arm before application, removal or adjustment of the Insulating Sleeve

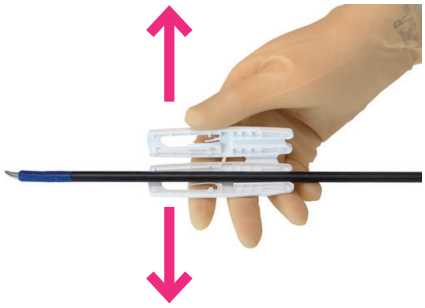
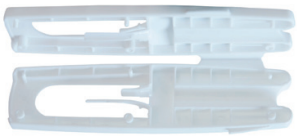
1. Open the Insulating Sleeve Accessory packaging

Sterile tasks

2. Remove the Insulating Sleeve Accessory from its packaging. The Insulating Sleeve is already attached to the Insulating Sleeve Tool

⚠ Always inspect the tip of the Monopolar Curved Scissors for damage before application and after removal of the Insulating Sleeve ⚠ Always ensure the tip of the Monopolar Curved Scissors is dry before applying the Insulating Sleeve ⚠ **Do not** use lubricants, liquids or gels to aid application of the Insulating Sleeve **3.** Slide the Insulating Sleeve Tool over the tip of the Monopolar Curved Scissors to apply the sleeve. Ensure a firm grip is maintained in the area shown	
⚠ Take care not to move the instrument fins during application of the Insulating Sleeve **4.** Continue to slide the tool until the sleeve is released	
5. Remove and discard the yellow Instrument Tip Guide	

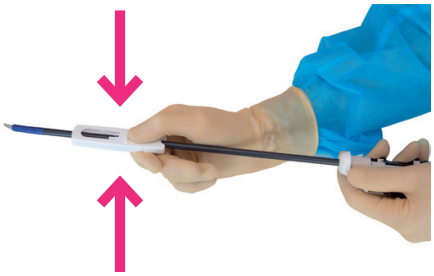
6. Ensure the yellow Position Marker is fully covered but the Insulating Sleeve is not overstretched	
7. If any portion of the yellow Position Marker is exposed, adjust the sleeve so it is level with the black shaft and covering the yellow Position Marker	
8. If any portion of the instrument tip other than the blades is exposed, adjust the sleeve so only the instrument blades are left exposed as shown in step 6 above	
9. If any portion of the Insulating Sleeve is over the black instrument shaft, adjust the sleeve so it is level with the black shaft and covering the yellow Position Marker	

⚠ Always inspect the Insulating Sleeve after application for signs of damage and to confirm its correct positioning **10.** Open out the Insulating Sleeve Tool and remove it	
11. Retain the Insulating Sleeve Tool on a sterile tray or sterile table until the sleeve needs to be removed	

9.3.4 Before inserting the instrument into the port

⚠ Always detach the Monopolar Curved Scissors from the instrument arm before application, removal or adjustment of the Insulating Sleeve ⚠ Always inspect the Insulating Sleeve after application for signs of damage and to confirm its correct positioning **1.** Visually inspect the position of the Insulating Sleeve before inserting the Monopolar Curved Scissors into the port	

9.3.5 Removing the Insulating Sleeve

⚠ Always detach the Monopolar Curved Scissors from the instrument arm before application, removal or adjustment of the Insulating Sleeve **1.** Wrap the Insulating Sleeve Tool around the instrument shaft	
2. Close the Insulating Sleeve Tool around the instrument shaft	
⚠ Always inspect the tip of the Monopolar Curved Scissors for damage before application and after removal of the Insulating Sleeve **3.** Squeeze the Insulating Sleeve Tool tightly and push it towards the sleeve. The tool will remove the sleeve	

⚠ **Do not** re-use the Insulating Sleeve. Dispose of the sleeve and its tool at the end of each surgery following the hospital procedure for processing biologically contaminated materials. Attempting to re-sterilise the Insulating Sleeve may result in an ineffective sterile insulation barrier ⚠ Do not attempt to reapply the Insulating Sleeve after initial use, and do not use the Insulating Sleeve Tool to reapply a sleeve. Once the sleeve has been removed the silicone material is likely to be damaged and the shape and stretching of the sleeve means it is likely to roll up. If reapplied the sleeve may not provide an effective insulating barrier and the sleeve or a part of the sleeve may fall off the instrument inside the patient	

Chapter 10

Versius Electrosurgery Cables

10.1 Introduction

This chapter provides the information and instructions relevant to the Versius Electrosurgery Cables.

For compatible electrosurgery units and settings that have been evaluated and tested for use with the Versius Surgical System, see chapter 11.

For instructions on using and configuring each electrosurgery unit, refer to the instruction manual provided with the electrosurgery unit.

For storage information, see section 1.5. For reprocessing information, see section 1.6, and for disposal information, see section 1.7.

For validated electrosurgery cable reprocessing instructions, refer to the separate Versius Electrosurgery Instrument Cable Reprocessing Instructions (REF 70300).

10.1.1 Warnings and precautions

⚠ Place the monopolar instrument cables and bipolar instrument cables where they do not come into contact with the patient, with other cables or metal parts. Failure to do so could lead to transfer of monopolar energy by capacitive coupling and may cause burns to the patient

⚠ **Never** detach an electrosurgery instrument or clean its tip without first disconnecting the instrument electrosurgery cable as this may compromise patient and user safety

⚠ Always hold the plug when unplugging the electrosurgery cable. **Never** pull on the electrosurgery cable, as this may damage it. Cables with faulty/cracked insulation or with a broken electrical wire (as a result of severe kinking or crushing of the cable) may result in user/patient burns or fire

⚠ **Do not** use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g. cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged

⚠ Inspect instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high-voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or user

⚠ Visual inspection alone may not be sufficient to ensure that the insulation is intact

⚠ Tether the electrosurgery instrument cable to the instrument arm drape to keep it from touching the patient when the cable is carrying current. Tethering the cable is also important as it balances the forces on the arm during surgery and helps to prevent the cable becoming snagged or entangled during use

10.2 Versius Electrosurgery Cable description

There are four different Versius Electrosurgery Cables:

- Monopolar bedside unit cable
- Bipolar bedside unit cable
- Monopolar instrument cable
- Bipolar instrument cable

The monopolar and bipolar bedside unit cables connect Versius Instrument Bedside Units to compatible electrosurgery units.

The monopolar and bipolar instrument cables connect Versius Instruments to Versius Bedside Units.

10.2.1 Monopolar and bipolar bedside unit cables

Monopolar bedside unit cables are blue (Figure 10.1) and connect instrument bedside units to compatible electrosurgery units.

Figure 10.1 *Monopolar bedside unit cable*

Bipolar bedside unit cables are grey (Figure 10.2) and connect instrument bedside units to compatible electrosurgery units.

Figure 10.2 *Bipolar bedside unit cable*

Electrosurgery Bedside Unit Cable Connector Dimensions

The monopolar bedside unit cable has the connector dimensions shown in Figure 10.3. The bipolar bedside unit cable has the connector dimensions shown in Figure 10.4. The compatible electrosurgery units listed in chapter 11 have corresponding socket dimensions.

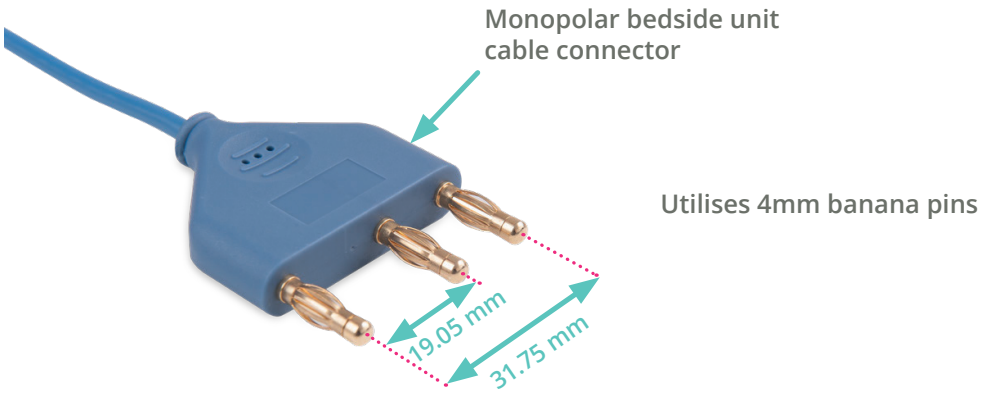


Figure 10.3 *Monopolar bedside unit cable connector dimensions*

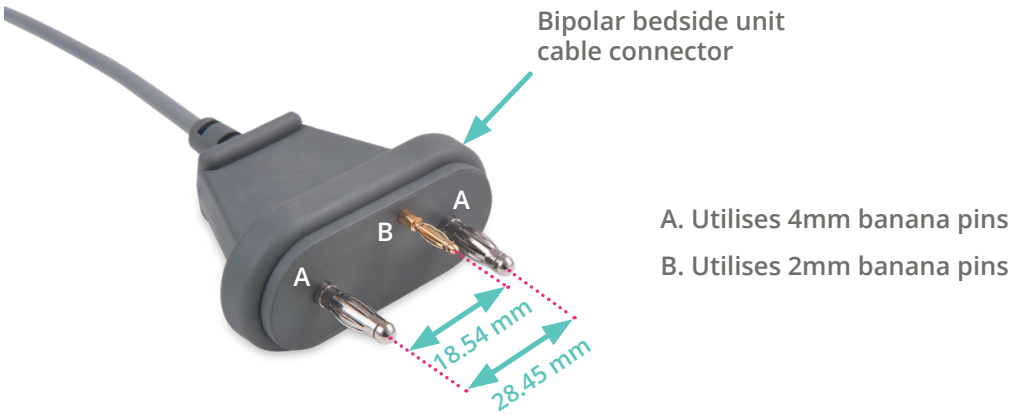


Figure 10.4 *Bipolar bedside unit cable connector dimensions*

10.2.2 Monopolar and bipolar instrument cables

Monopolar instrument cables are blue (Figure 10.5) and connect monopolar instruments, such as the Versius Monopolar Hook, to a bedside unit.

Figure 10.5 *Monopolar instrument cable*

Bipolar instrument cables are grey (Figure 10.6) and connect bipolar instruments, such as the Versius Bipolar Maryland Grasper, to a bedside unit.

Figure 10.6 *Bipolar instrument cable*

10.2.3 Electrosurgery cable maximum peak voltage

Monopolar bedside unit cable and monopolar instrument cable maximum peak voltage: 3000V

Bipolar bedside unit cable and bipolar instrument cable maximum peak voltage: 500V

⚠ Always refer to the specific maximum peak voltage limits for each instrument (given in each instrument chapter). **These limits may be less than those specified above**

10.3 Instructions for use

10.3.1 Inspection before use

Electrosurgery cables are subject to varying degrees of unavoidable wear, depending on the intensity of use. Carry out a thorough visual inspection before each use of the electrosurgery cables. Do not use the cable if it shows signs of wear.

10.3.2 Intraoperative use

Refer to the Versius Surgical System User Manual (REF 70000) for instructions on activating electrosurgery using the Versius Surgical System.

10.4 System connections for electrosurgery

To connect an electrosurgery instrument to a compatible electrosurgery unit, two electrosurgery cables are required (see Figure 10.7):

- A monopolar or bipolar bedside unit cable to connect an instrument bedside unit to an electrosurgery unit
- A monopolar or bipolar instrument cable to connect an instrument bedside unit to an electrosurgery instrument

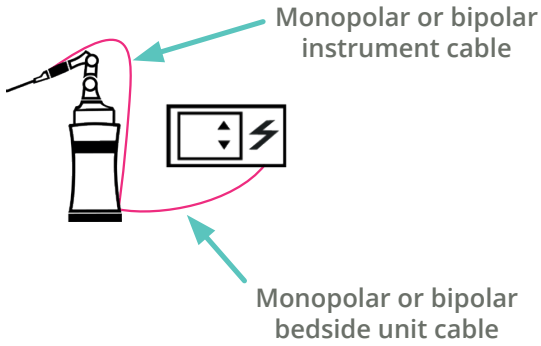


Figure 10.7 *Electrosurgery connections between an instrument bedside unit and an electrosurgery unit*

10.4.1 Instrument bedside unit connection panel

The electrosurgery cable sockets on an instrument bedside unit are found in the instrument bedside unit connection panel (Figure 10.8) located below the brake button. Figure 10.8 shows where to connect each electrosurgery cable on an instrument bedside unit.

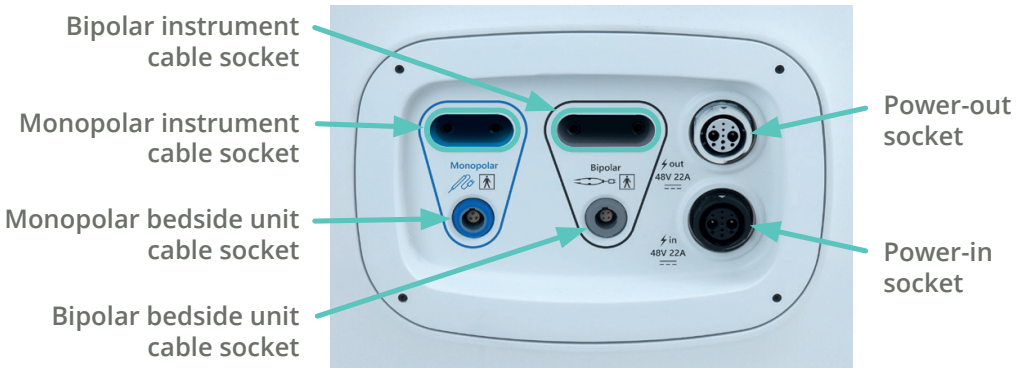


Figure 10.8 *Instrument bedside unit connection panel*

10.4.2 Connecting the monopolar bedside unit cable

Connect the monopolar bedside unit cable to:

1. The instrument bedside unit connection panel (Figure 10.8)
2. The electrosurgery unit

An audible click will confirm that the cable is correctly connected to the instrument bedside unit. The cable should not come loose when pulled.

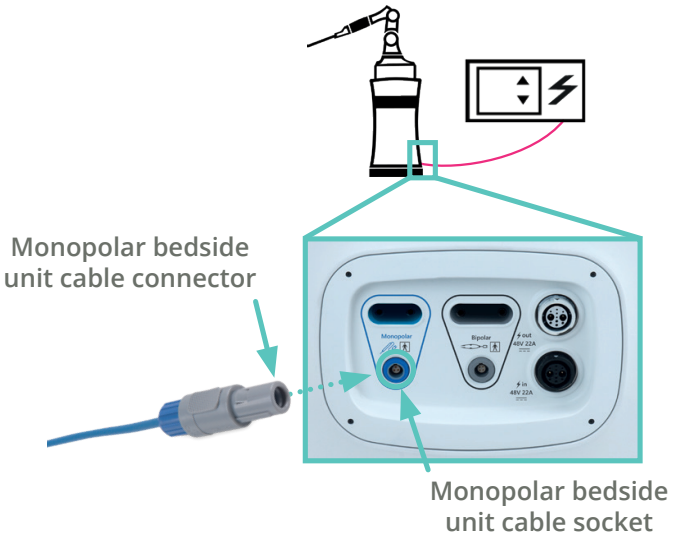


Figure 10.9 *Connecting the monopolar bedside unit cable to the instrument bedside unit*

10.4.3 Connecting the monopolar instrument cable

Once the Versius Bedside Units are draped the electrosurgery instrument cables can be connected.

Connect the monopolar instrument cable to:

1. The connector pin on the monopolar instrument (Figure 10.10)
2. The instrument bedside unit connection panel (Figure 10.11)

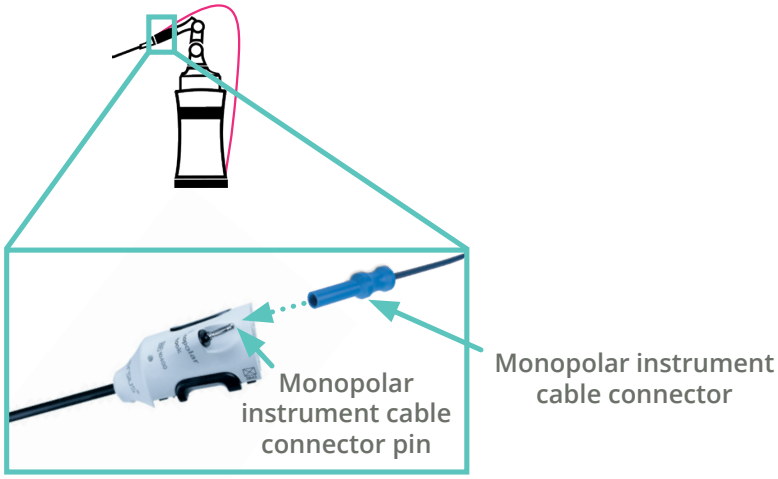


Figure 10.10 *Connecting the monopolar instrument cable to the instrument*

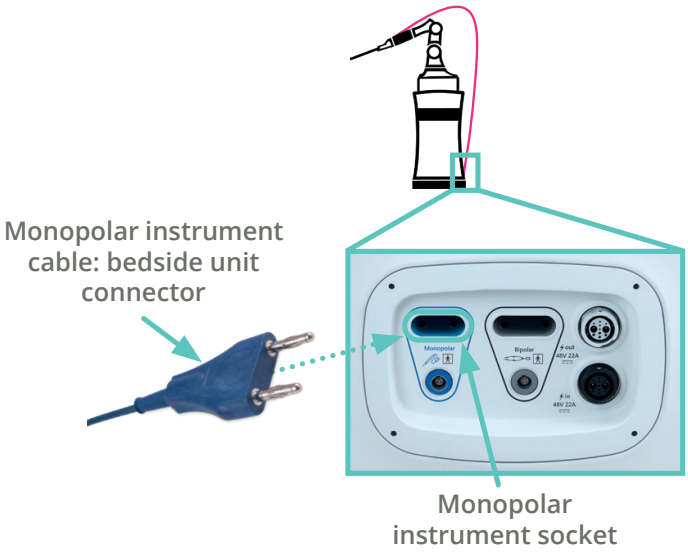


Figure 10.11 *Connecting the monopolar instrument cable to the instrument bedside unit*

10.4.4 Connecting the bipolar bedside unit cable

Connect the bipolar bedside unit cable to:

1. The instrument bedside unit connection panel (Figure 10.8)
2. The electrosurgery unit

An audible click will confirm that the cable is correctly connected to the instrument bedside unit. The cable should not come loose when pulled.

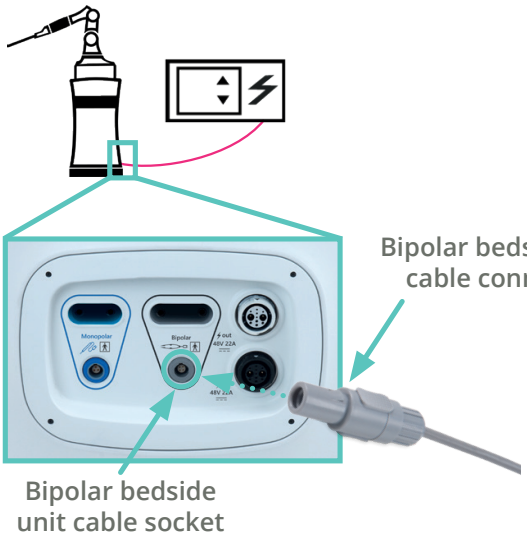


Figure 10.12 *Connecting the bipolar bedside unit cable to the instrument bedside unit*

10.4.5 Connecting the bipolar instrument cable

Once the Versius Bedside Units are draped the electrosurgery instrument cables can be connected.

Connect the bipolar instrument cable to:

1. The connector pin on the bipolar instrument (Figure 10.13)
2. The instrument bedside unit connection panel (Figure 10.14)

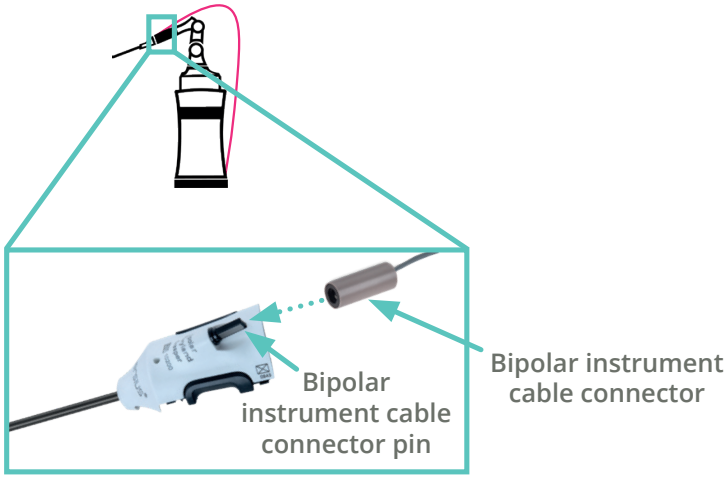


Figure 10.13 *Connecting the bipolar instrument cable to the instrument*

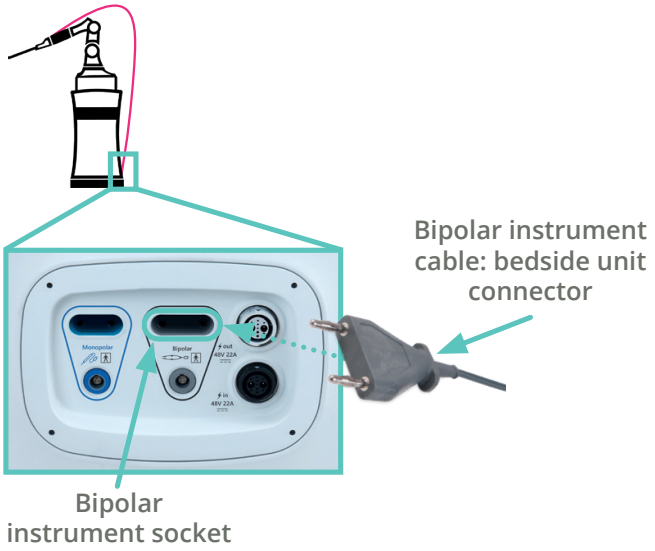


Figure 10.14 *Connecting the bipolar instrument cable to the instrument bedside unit*

Chapter 11

Electrosurgery settings

Warnings and precautions

⚠ Follow all instructions, cautions and warnings provided with the electrosurgery unit, to avoid serious injury to the patient

⚠ Keep all electrosurgery instruments in the field of view when activating electrosurgery and beware that capacitive coupling can produce heating of an inactive electrosurgery instrument

⚠ Place the monopolar instrument cables and bipolar instrument cables where they do not come into contact with the patient, with other cables or metal parts. Failure to do so could lead to transfer of monopolar energy by capacitive coupling and may cause burns to the patient

⚠ **Never** detach an electrosurgery instrument or clean its tip without first disconnecting the instrument electrosurgery cable as this may compromise patient and user safety

⚠ Always hold the plug when unplugging the electrosurgery cable. **Never** pull on the electrosurgery cable, as this may damage it. Cables with faulty/cracked insulation or with a broken electrical wire (as a result of severe kinking or crushing of the cable) may result in user/patient burns or fire

⚠ **Do not** activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment

⚠ **Do not** use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g. cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged

⚠ Electrosurgery may produce interference that adversely affects other electronic equipment in the operating theatre

⚠ **Do not** attempt to use the electrosurgery buttons on the hand controllers with electrosurgery units that are not compatible with the Versius Surgical System. See section 12.3 for a list of compatible electrosurgery models

⚠ Follow all instructions in this chapter for use of compatible electrosurgery units with Versius. Other modes or settings may cause damage to Versius instruments or may cause harm to the patient

⚠ **Do not** place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire

⚠ **Do not** use electrosurgery instruments in the presence of flammable anaesthetics or oxidising gases (such as nitrous oxide or oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur

⚠ When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns

⚠ Inspect instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high-voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or user

⚠ Take care when cleaning the instrument tip as it may still be hot enough to cause burns even after the RF current has been deactivated

⚠ Visual inspection alone may not be sufficient to ensure that the insulation is intact

⚠ Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g. blood or saline) in direct contact with or in close proximity to an instrument may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient

⚠ **Do not** use with hybrid trocar systems, i.e. a combination of metal and plastic, when using monopolar active components. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems

⚠ **Do not** activate electrosurgery on an electrosurgery instrument while that instrument is not in contact with target tissue

⚠ Be careful when operating electrosurgery instruments close to other instruments or equipment. Energy may unintentionally be applied to another instrument or equipment, which could lead to burns to the tissue that the other instrument or equipment was in contact with

⚠ Always activate electrosurgery in the field of view. Ensure the entire surgical field is inspected, paying particular attention to areas of the instrument that may have been in contact with tissue during electrosurgery activation

⚠ The Versius Monopolar Hook is designed for a maximum peak voltage of 1333V. **Do not** use settings on the electrosurgery unit which exceed 1333V peak

⚠ **Do not** exceed a maximum peak voltage of 1333V on the electrosurgery unit for the Versius Monopolar Curved Scissors

⚠ **Do not** exceed the electrosurgery unit settings given for Versius Bipolar Instruments in this chapter for the Versius Bipolar Maryland Grasper

⚠ **Do not** exceed the electrosurgery unit settings given for Versius Monopolar Instruments in this chapter for the Versius Monopolar Hook

⚠ **Do not** exceed the electrosurgery unit settings given for Versius Monopolar Instruments in this chapter for the Versius Monopolar Curved Scissors

⚠ Always use the lowest output setting that achieves the desired surgical effect while staying within the maximum peak voltage. Maximum power levels to stay below this limit are listed in this chapter

⚠ Keep the instrument clean. Build-up of eschar may reduce the instrument's effectiveness. **Do not** activate the instrument while cleaning. Injury to operating theatre personnel may result

⚠ **Do not** attempt to use Versius Instruments, cables or any other Versius components except when connected to the Versius Surgical System as described in the Versius User Manual (REF 70000)

11.1 Introduction

This chapter provides appropriate settings to use for each suitable electrosurgery unit that has been evaluated and tested for use with the Versius Surgical System. The Versius Surgical System was validated using a Valleylab ForceTriad electrosurgery unit. Only electrosurgery units listed in this chapter can be used with Versius and the maximum peak voltage limits given in this manual must be observed. If electrosurgery units not listed in this chapter are used with the Versius Surgical System, performance of electrosurgery instruments is not guaranteed.

For instructions on using and configuring each electrosurgery unit, refer to the instruction manual provided with the electrosurgery unit. For instructions on how to connect suitable electrosurgery units to the Versius Surgical System, refer to chapter 9 in this user manual.

⚠ Follow all instructions, cautions and warnings provided with the electrosurgery unit, to avoid serious injury to the patient

ⓘ The same Versius Cables are used for connecting all suitable electrosurgery units

11.2 Electrosurgery settings for the Valleylab ForceTriad

This section contains the settings to use on the Valleylab ForceTriad when using this electrosurgery unit with the Versius Surgical System. Only the modes of the Valleylab ForceTriad listed in Table 11.2 and Table 11.3 have been evaluated as safe for use with the Versius Surgical System. The electrosurgery unit must be appropriately configured before it is used with Versius.

Features of the Valleylab ForceTriad are labelled in Figure 11.1.

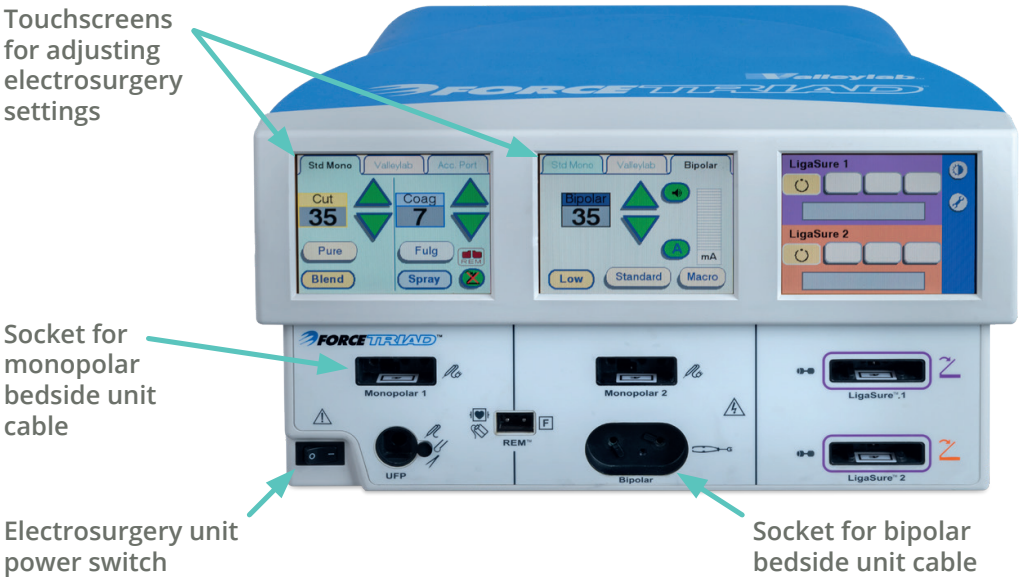


Figure 11.1 *Valleylab ForceTriad electrosurgery unit*

11.2.1 Bipolar settings on the Valleylab ForceTriad

The maximum settings on the Valleylab ForceTriad for Versius Bipolar Instruments are detailed in Table 11.2. Only the modes of the Valleylab ForceTriad listed in Table 11.2 have been evaluated as safe for use with the Versius Surgical System.

Mode	Maximum setting
Bipolar Low (1–95W)	95
Bipolar Standard (1–95W)	95
Bipolar Macro (1–95W)	50

Table 11.2 *Maximum settings for Versius Bipolar Instruments on the Valleylab ForceTriad electrosurgery unit*

11.2.2 Monopolar settings on the Valleylab ForceTriad

The maximum settings on the Valleylab ForceTriad for Versius Monopolar Instruments are detailed in Table 11.3.

Mode	Maximum setting
Monopolar Pure Cut	35
Monopolar Blend	50
Monopolar Fulgurate (Coag)	14
Monopolar Spray (Coag)	9

Table 11.3 *Maximum settings for Versius Monopolar Instruments on the Valleylab ForceTriad electrosurgery unit*

11.3 Electrosurgery settings for the Valleylab FX8

This section contains the settings to use on the Valleylab FX8 when using this electrosurgery unit with the Versius Surgical System. Only the modes of the Valleylab FX8 listed in Table 11.5 and Table 11.6 have been evaluated as safe for use with the Versius Surgical System. The electrosurgery unit must be appropriately configured before it is used with Versius.

Features of the Valleylab FX8 are labelled in Figure 11.4.

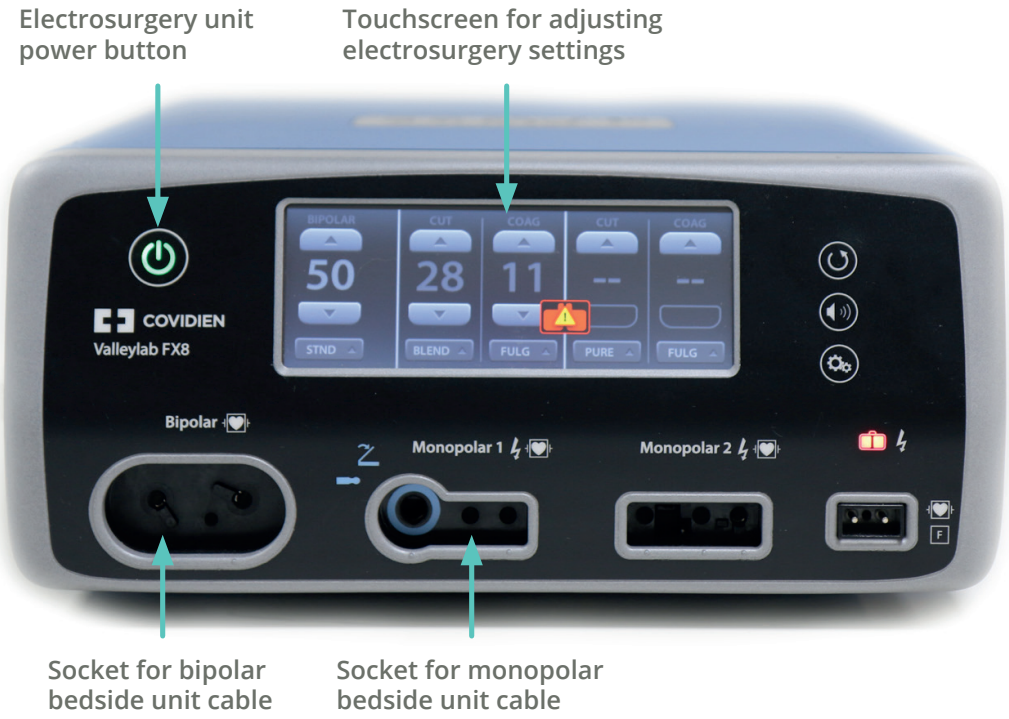


Figure 11.4 *Valleylab FX8 electrosurgery unit*

11.3.1 Bipolar settings on the Valleylab FX8

The maximum settings on the Valleylab FX8 for Versius Bipolar Instruments are detailed in Table 11.5.

Mode	Maximum setting
FX Bipolar Precise (1–70W)	50
FX Bipolar Standard (1–70W)	50

Table 11.5 *Maximum settings for Versius Bipolar Instruments on the Valleylab FX8 electrosurgery unit*

To access the Bipolar Precise and Bipolar Standard modes, the 'FX modes' need to be enabled in the settings on the Valleylab FX8 electrosurgery unit.

11.3.2 Monopolar settings on the Valleylab FX8

The maximum settings on the Valleylab FX8 for Versius Monopolar Instruments are detailed in Table 11.6.

Mode	Maximum setting
Monopolar Pure Cut	35
Monopolar Blend	28
Monopolar Fulgurate (Coag)	11
Monopolar Spray (Coag)	8

Table 11.6 *Maximum settings for Versius Monopolar Instruments on the Valleylab FX8 electrosurgery unit*

11.4 Electrosurgery settings for the Valleylab Force FX-8CAS

This section contains the settings to use on the Valleylab Force FX-8CAS when using this electrosurgery unit with the Versius Surgical System. Only the modes of the Valleylab Force FX-8CAS listed in Table 11.8 and Table 11.9 have been evaluated as safe for use with the Versius Surgical System. The electrosurgery unit must be appropriately configured before it is used with Versius.

Features of the Valleylab Force FX-8CAS are labelled in Figure 11.7.

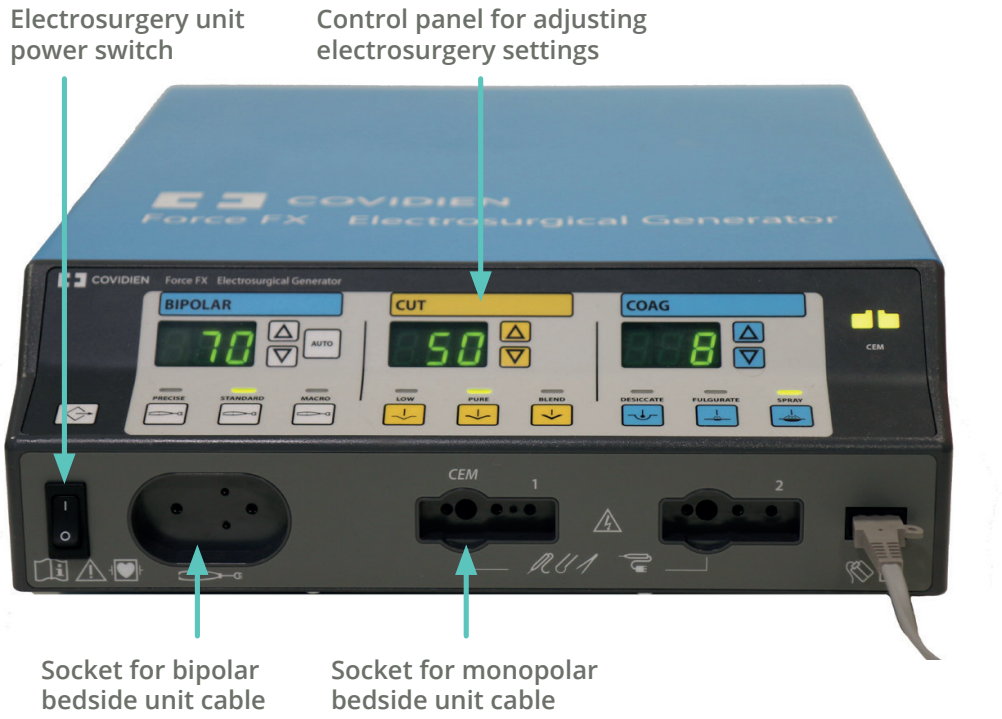


Figure 11.7 *Valleylab Force FX-8CAS electrosurgery unit*

11.4.1 Bipolar settings on the Valleylab Force FX-8CAS

The maximum settings on the Valleylab Force FX-8CAS for Versius Bipolar Instruments are detailed in Table 11.8.

Mode	Maximum setting
Bipolar Precise (1–70W)	70
Bipolar Standard (1–70W)	70
Bipolar Macro (1–70W)	70

Table 11.8 *Maximum settings for Versius Bipolar Instruments on the Valleylab Force FX-8CAS electrosurgery unit*

11.4.2 Monopolar settings on the Valleylab Force FX-8CAS

The maximum settings on the Valleylab Force FX-8CAS for Versius Monopolar Instruments are detailed in Table 11.9.

Mode	Maximum setting
Monopolar Cut/Low (1–300W)	50
Monopolar Cut/Pure (1–300W)	50
Monopolar Cut/Blend (1–200W)	50
Monopolar Coag/Dessicate 1 (1–120W)	30
Monopolar Coag/Fulgurate (1–120W)	9
Monopolar Coag/Fulgurate LCF (1–120W)	16
Monopolar Coag/Spray (1–120W)	8

Table 11.9 *Maximum settings for Versius Monopolar Instruments on the Valleylab Force FX-8CAS electrosurgery unit*

11.5 Electrosurgery settings for the ConMed System 5000

This section contains the settings to use on the ConMed System 5000 when using this electrosurgery unit with the Versius Surgical System. Only the modes of the ConMed System 5000 listed in Table 11.11 and Table 11.12 have been evaluated as safe for use with the Versius Surgical System. The electrosurgery unit must be appropriately configured before it is used with Versius.

Features of the ConMed System 5000 are labelled in Figure 11.10.

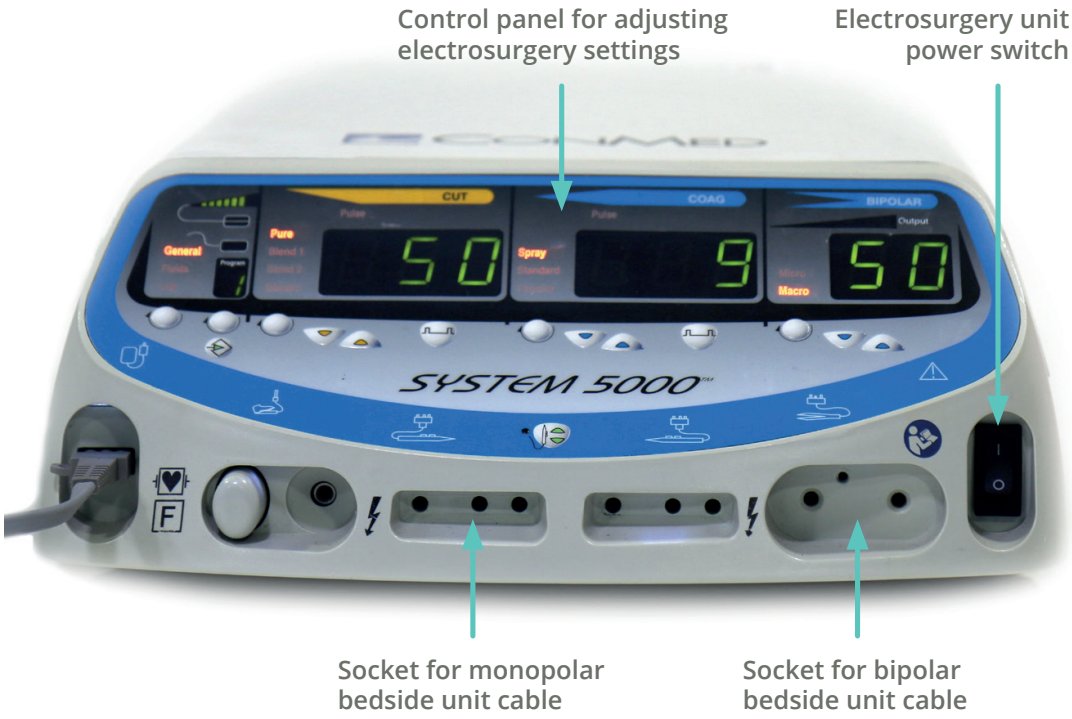


Figure 11.10 *ConMed System 5000 electrosurgery unit*

11.5.1 Bipolar settings on the ConMed System 5000

The maximum settings on the ConMed System 5000 for Versius Bipolar Instruments are detailed in Table 11.11.

Mode	Maximum setting
Bipolar Micro (1–50W)	50
Bipolar Macro (1–90W)	50

Table 11.11 *Maximum settings for Versius Bipolar Instruments on the ConMed System 5000 electrosurgery unit*

11.5.2 Monopolar settings on the ConMed System 5000

The maximum settings on the ConMed System 5000 for Versius Monopolar Instruments are detailed in Table 11.12.

> The ConMed System 5000 provides 'general', 'lap' and 'fluids' monopolar mode variants, which can be selected from the control panel. However, only the 'general' and 'lap' modes have been validated. The ConMed System 5000 also offers a 'pulse' option, which has not been validated and is not recommended for use with the Versius Surgical System

Mode	Maximum setting
General and lap modes	
Monopolar Cut/Pure (1–300W)	50
Monopolar Cut/Blend 1 (1–200W)	50
Monopolar Cut/Blend 2 (1–200W)	50
Monopolar Cut/Blend 3 (1–200W)	50
Monopolar Coag/Pinpoint (1–120W)	32
Monopolar Coag/Standard (1–120W)	11
Monopolar Coag/Spray (1–80W)	9

Table 11.12 *Maximum settings for Versius Monopolar Instruments on the ConMed System 5000 electrosurgery unit*

11.6 Electrosurgery settings for the Valleylab FT10

This section contains the settings to use on the Valleylab FT10 when using this electrosurgery unit with the Versius Surgical System. Only the modes of the Valleylab FT10 listed in Table 11.14 and Table 11.15 have been evaluated as safe for use with the Versius Surgical System. The electrosurgery unit must be appropriately configured before it is used with Versius.

> Only use the Valleylab FT10 with the Versius Surgical System if the FT10 software version is 4.0 or above. Valleylab FT10 electrosurgery units with a software version below 4.0 generate different bipolar modes

Features of the Valleylab FT10 are labelled in Figure 11.13.

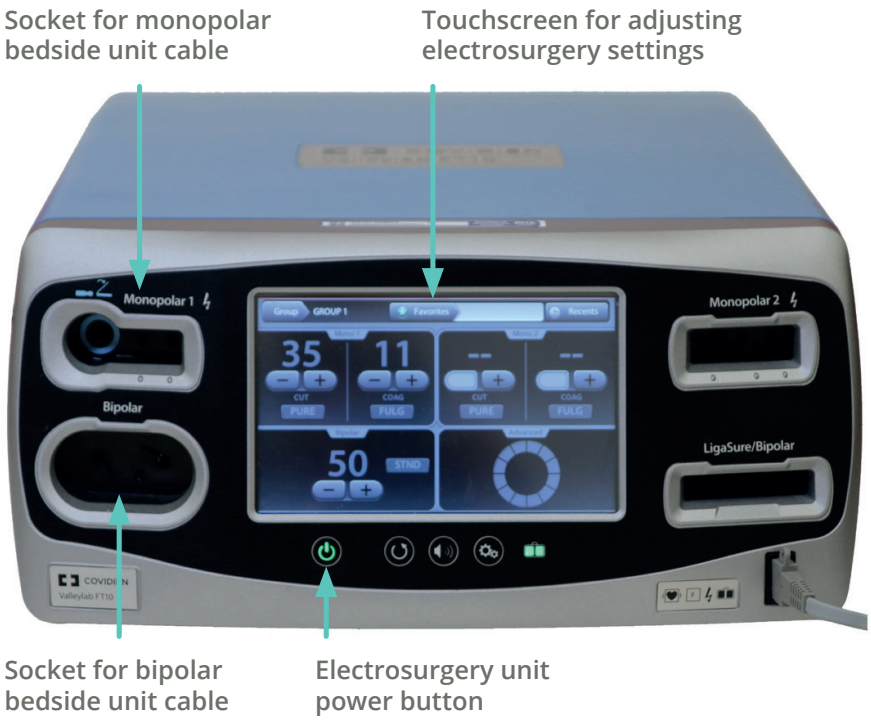


Figure 11.13 *Valleylab FT10 electrosurgery unit*

Šiame skyriuje pateikiami nustatymai, kuriuos reikia naudoti „Valleylab FT10“, kai naudojamas šis elektrochirurgijos įrenginys su „Versius Surgical System“. Tik 11.14 ir 11.15 lentelėse išvardyti Valleylab FT10 režimai buvo įvertinti kaip saugūs naudoti su Versius chirurgine sistema. Elektrochirurgijos blokas turi būti tinkamai sukonfigūruotas prieš naudojant jį su Versius.

11.6.1 Bipolar settings on the Valleylab FT10

The maximum settings on the Valleylab FT10 for Versius Bipolar Instruments are detailed in Table 11.14.

Mode	Maximum setting
Bipolar Precise (1–70W)	70
Bipolar Standard (1–70W)	50

Table 11.14 *Maximum settings for Versius Bipolar Instruments on the Valleylab FT10 electrosurgery unit*

11.6.2 Monopolar settings on the Valleylab FT10

The maximum settings on the Valleylab FT10 for Versius Monopolar Instruments are detailed in Table 11.15.

Mode	Maximum setting
Monopolar Cut/Pure	35
Monopolar Cut/Blend	28
Monopolar Coag/Fulgurate	11
Monopolar Coag/Spray	9

Table 11.15 *Maximum settings for Versius Monopolar Instruments on the Valleylab FT10 electrosurgery unit*

Chapter 12

List of accessories and compatible products

12.1 Versius Surgical System Accessories

Versius Surgical System Accessory	Reference number (REF)
Versius Camera Head	90900
Versius 30° Endoscope	90907
Versius 0° Endoscope	90908
Light Cable (3.5 m)	90903 (Wolf 806550351)
Adapter Projector Side	90906 (Wolf 8096.811)
Light Source (Wolf Endolight LED 2.2)	90904 (Wolf 51640011)
Versius Instrument Bedside Unit Drape (Standard)	20100
Versius Instrument Bedside Unit Drape (Standard) – Pack of 5	20101
Versius Visualisation Bedside Unit Drape (Standard)	20200
Versius Visualisation Bedside Unit Drape (Standard) – Pack of 10	20201
Versius Instrument Bedside Unit Drape (Long)	20300
Versius Instrument Bedside Unit Drape (Long) – Pack of 5	20301
Versius Visualisation Bedside Unit Drape (Long)	20400
Versius Visualisation Bedside Unit Drape (Long) – Pack of 10	20401
Versius Camera Head Drape	20500
Versius Camera Head Drape – Pack of 25	20501

Versius Surgical System Accessory	Reference number (REF)
Drape Cap Insert	20900
Drape Cap Insert – Pack of 100	20901
Needle Holder	10100
Needle Holder – Pack of 6	10101
Bipolar Maryland Grasper	10200
Bipolar Maryland Grasper – Pack of 6	10201
Fenestrated Grasper	10300
Fenestrated Grasper – Pack of 6	10301
Monopolar Hook	10400
Monopolar Hook – Pack of 6	10401
Curved Scissors	10500
Curved Scissors – Pack of 6	10501
Monopolar Curved Scissors	10600
Monopolar Curved Scissors – Pack of 6	10601
Insulating Sleeve Accessory	10001
Insulating Sleeve Accessory – Carton Pack (Qty 12 x 10001)	10002
Insulating Sleeve Accessory – Shipper Pack (Qty 8 x 10002 [Qty 96 x 10001])	10003
Video Feed Cable – Short (5 m)	90100/5
Video Feed Cable – Long (10 m)	90100/10
Auxiliary Screen Cable – Short (5 m)	90200/5
Auxiliary Screen Cable – Long (10 m)	90200/10

Versius Surgical System Accessory	Reference number (REF)
Secondary Auxiliary Screen Cable – Short (5 m)	90201/5
Secondary Auxiliary Screen Cable – Long (10 m)	90201/10
Bipolar Instrument Cable	90300
Bipolar Bedside Unit Cable	90400
Monopolar Instrument Cable	90500
Monopolar Bedside Unit Cable	90600
Bedside Unit Cable – Short (5 m)	90800/5
Bedside Unit Cable – Long (10 m)	90800/10
Network Cable	91000/5

Console Power Cables	Reference number (REF)	For use in the following countries
Console Power Cable – BS1363 Plug	90701	AE, CY, GB, HK, IE, MT, SA
Console Power Cable – NEMA 5-20 P Hospital Grade Plug	90702	US
Console Power Cable – CEE 7/7 Plug	90703	AT, BE, BG, CZ, DE, EE, EG, ES, FI, FR, GR, HR, HU, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, RS, RU, SE, SI, TR
Console Power Cable – Type I Plug	90704	AU
Console Power Cable – Type L Plug	90705	CL

Console Power Cables	Reference number (REF)	For use in the following countries
Console Power Cable – Type M Plug	90706	IN
Console Power Cable – Type N Plug	90707	BR

Light Source Power Cables	Reference number (REF)	For use in the following countries
Light Source Power Cable A	90920 (Wolf 244003A)	AN, AO, AT, AW, BE, BF, BG, BI, BO, BY, CD, CF, CI, CM, CS, CV, CZ, DE, DJ, DZ, EA, EE, EG, ES, ET, FI, FR, GA, GF, GL, GN, GP, GQ, GR, GUS, GW, HR, HU, ID, IR, IS, JO, KH, KR, LB, LT, LV, LU, MA, MC, MG, ML, MN, MQ, MR, MZ, NC, NE, NL, NO, PE, PF, PL, PT, PY, RO, RS, RW, SA, SD, SE, SJ, SK, SN, SO, SR, SY, TD, TG, TJ, TN, TR, VN, XA
Light Source Power Cable C	90921 (Wolf 244003C)	AS, AU, CC, CK, CX, FJ, NF, NZ, PG, TO, UY, WS
Light Source Power Cable D	90922 (Wolf 244003D)	AE, AG, AI, BH, BU, BW, CY, DM, GB, GD, GG, GH, GI, GM, GY, HK, IE, IM, IQ, KE, KN, KW, LC, MS, MT, MU, MW, MY, NG, OM, QA, SC, SG, SL, TT, TZ, VC, YE, ZW, ZM
Light Source Power Cable E	90923 (Wolf 244003E)	DK
Light Source Power Cable G	90924 (Wolf 244003G)	AE, AF, BD, BH, BJ, BT, BW, GD, GH, GY, HK, IN, IQ, KE, KN, KW, LB, LK, LS, LY, MM, MO, MU, MV, NA, NG, NP, OM, PK, PN, PT, QA, SC, SG, SL, SZ, TO, TT, TZ, UG, YE, ZA, ZW

Light Source Power Cables	Reference number (REF)	For use in the following countries
Light Source Power Cable H	90925 (Wolf 244003H)	IL
Light Source Power Cable I	90926 (Wolf 244003I)	CL, IT, LY
Light Source Power Cable J	90927 (Wolf 244003J)	JP
Light Source Power Cable K	90928 (Wolf 244003K)	AG, AN, AS, AW, BB, BM, BS, BZ, CA, CO, CR, DO, EC, GU, GT, HN, HT, JM, JP, KY, LA, LR, MP, MX, NI, PA, PH, PM, PR, SA, SV, TH, TT, TW, US, VE, VG, VN
Light Source Power Cable L	90929 (Wolf 244003L)	CH, LI
Light Source Power Cable O	90930 (Wolf 244003O)	KZ, SI, UA
Light Source Power Cable T	90931 (Wolf 244003T)	AR
Light Source Power Cable W	90932 (Wolf 244003W)	BR
Light Source Power Cable X	90933 (Wolf 244003X)	CN

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

Tel: +44 (0) 1223 750 975

12.2 Compatible surgical ports

The following ports are compatible for use with the Versius Endoscopes:

Compatible ports for the Versius Endoscopes		
Manufacturer	**Brand**	**Dimensions (mm)**
Applied Medical	Kii® Fios® Advanced Fixation	11 x 100
Applied Medical	Kii® Fios® Advanced Fixation	12 x 100
Applied Medical	Kii® Shielded Bladed Access System	11 x 100
Conmed	AirSeal	12 x 100
Ethicon	Endopath Xcel™	11 x 100
Ethicon	Endopath Xcel™	15 x 100
B. Braun	Aesculap® RHP	12 x 100

⚠ Only use the Versius Endoscope through ports that have been identified as compatible for use with the Versius Surgical System

The following ports are compatible for use with the Versius Instruments:

Compatible ports for the Versius Instruments		
Manufacturer	**Brand**	**Dimensions (mm)**
Applied Medical	Kii® Fios® Advanced Fixation	5 x 100
Applied Medical	Kii® Fios® Advanced Fixation	5 x 75
Applied Medical	Kii® Fios® First Entry	8 x 100
Applied Medical	Kii® Shielded Bladed Access System	5 x 100
Applied Medical	Kii® Shielded Bladed Access System	8 x 100
Conmed	AirSeal	5 x 100
Conmed	AirSeal	8 x 100
Ethicon	Endopath Xcel™	8 x 100
Ethicon	Endopath Xcel™	11 x 100
Medtronic	VersaOne™ Bladeless Trocar with Fixation Cannula	8 x 100

⚠ Only use Versius Instruments through ports that have been identified as compatible for use with the Versius Surgical System. Inappropriate port size could lead to an incorrect fulcrum being detected during port-training

12.3 Compatible electrosurgery units

The electrosurgery units listed in the table are compatible for use with the Versius Surgical System. See chapter 11 for the appropriate settings for each electrosurgery unit.

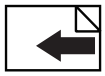
Compatible electrosurgery units	
Manufacturer	**Model**
Valleylab	ForceTriad
Valleylab	FX8
Valleylab	Force FX-8CAS
ConMed	System 5000
Valleylab	FT10

Appendix A

Symbols

The symbols in this table may appear on packaging and labels for Versius instruments or accessories. The meaning of the symbols is included in the table.

Symbol	Meaning	Symbol	Meaning
CMR	CMR Surgical logo	versius®	Versius Surgical System logo
UL CERTIFIED E487417	UL Certification Mark	CE XXXX	CE Mark
	Manufacturer		Date of manufacture
	Use by date		Caution
MD	Medical device	EC REP	Authorised representative in the European Union (EU)
LOT	Batch code	REF	Catalogue number
SN	Serial number	QTY	Quantity

Symbol	Meaning	Symbol	Meaning
	Do not use if package is damaged		Fragile. Handle with care
	This way up		Type BF applied part
	Peel this way		Turn page over
	Keep dry		Keep away from sunlight
	Temperature limits		Humidity limits
	Atmospheric pressure limits	**Rx ONLY**	Prescription only
	Consult the instructions for use		Read the user manual before operating the system
	Do not re-use		Latex-free

Symbol	Meaning	Symbol	Meaning
	Non-pyrogenic		Non-sterile
	Sterilised using ethylene oxide		Sterilised using ethylene oxide (single sterile barrier system)
	Sterilised using ethylene oxide (single sterile barrier system with protective packaging outside)		

Glossary of Terms

A	
Accessories	Items used in conjunction with the Versius Surgical System
Attachment head	Area of the instrument that can be attached to Versius arms. This is key for instrument control by the robotic arms
B	
Bedside unit	A robotic arm mounted on a cart, that holds either an instrument (instrument bedside unit) or endoscopic camera (visualisation bedside unit)
Bipolar bedside unit cable	Cable that connects a bedside unit (that has a bipolar instrument attached to its arm) to the electrosurgery unit
Bipolar instrument cable	Cable that connects a bipolar instrument to an instrument bedside unit
Bipolar instrument cable connector pin	Pin on a bipolar instrument that a bipolar instrument cable connects to
Brake button	Button on the bedside unit that activates and deactivates the bedside unit brake
C	
Capacitive coupling	When electric current is passed from an activated electrosurgery instrument to another material (for example tissue, another surgical instrument, cable or metal part) without the activated electrosurgery instrument directly touching the material
ConMed System 5000	Electrosurgery unit that is compatible with the Versius Surgical System

Console screen	Screen on the surgeon console showing in 3D (or optionally 2D) the endoscope video feed overlaid by the HUD
D	
Disposal	Removal of an instrument or accessory out of circulation. For example when an instrument has been dropped, damaged or reached its maximum number of uses
E	
Electrosurgery cable	One of four types of electrosurgery cables, for connecting an electrosurgery instrument to the bedside unit (monopolar or bipolar instrument cable) and the bedside unit to the electrosurgery unit (monopolar or bipolar bedside unit cable)
Electrosurgery instrument	Surgical instrument compatible with a Versius Arm and equipped with a cable connection for electrosurgery
Electrosurgery socket	One of four sockets on the instrument bedside unit connection panel, for connecting an electrosurgery cable
Electrosurgery unit (ESU)	Generator of radio frequency current for electrosurgery (ESU not supplied with the Versius Surgical System)
Endoscope	Device containing optics for viewing a surgical site. The Versius Endoscope connects to the Versius Camera Head to form an endoscopic camera
Endoscope glass surfaces	Areas on the endoscope that are made of glass. These areas are located at either end of the endoscope

ESU	See electrosurgery unit
ESU settings	Settings on the electrosurgery unit. Versius instruments require specific settings to function safely and effectively
F	
Fins	Used to mechanically drive the Versius instrument tip, these are found on the underside of the attachment head
Flush port	Opening in the attachment head to accommodate a Luer slip fitting, which allows flushing of the inside of the instrument shaft
Flush port 1	Opening labelled with the number 1 in the attachment head, to accommodate a Luer slip fitting, which allows flushing of the inside of the instrument shaft
Flush port 2	Opening labelled with the number 2 in the attachment head, to accommodate a Luer slip fitting, which allows flushing of the inside of the attachment head
H	
Hand controller	Controller on the surgeon console that is held by the surgeon and used to control the instruments and endoscopic camera, and to navigate the HUD
Head-up display (HUD)	Interactive system with icons and menu that overlays the endoscope video feed on the console screen and the auxiliary screen, and provides information about the status of the system

I	
Icon	Graphic that represents information about the bedside units and the system. For example, icons represent the instruments attached to arms
Instrument	Versius instrument that is attached to an instrument arm for use during surgery
Instrument arm	Arm that can hold an instrument
Instrument arm drape	Material placed around the instrument arm to maintain a sterile barrier
Instrument bedside unit	Bedside unit that can hold an instrument, consisting of an instrument arm mounted on a cart
Instrument bedside unit connection panel	Section of the instrument bedside unit, below the brake button, where sockets are located for cables to connect to
Instrument icons	Icon indicating which instrument is attached to an instrument arm, with a background coloured to match the arm colour identifier
Instrument shaft insulation	Black coating around the instrument shaft to protect the patient from shaft burns
Instrument Tip Guide	Yellow plastic piece that helps guide the tip of the instrument into the Insulating Sleeve
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
Insulating Sleeve Accessory	Comprises the Insulating Sleeve, the Insulating Sleeve Tool and the Instrument Tip Guide
Insulating Sleeve Tool	Single-use plastic tool used to apply and remove the Insulating Sleeve

J	
Jaws	Parts of an instrument that can open and close
L	
Latches	Used to attach the instrument to the robotic arm, these are found on the side of the attachment head
Light cable adapter	Small, removable part of the endoscope that connects the light cable to the endoscope
Light cable post	Small arm at the top end of the endoscope, near the camera head connection, that the light cable attaches to
M	
Maximum peak voltage limits	The maximum voltage setting that can be used with Versius Electrosurgery Instruments. Always refer to information on specific instruments for the unique settings
Monopolar bedside unit cable	Cable that connects a bedside unit (that has a monopolar instrument attached to its arm) to an electrosurgery unit
Monopolar instrument cable	Cable that connects a monopolar instrument to a bedside unit
Monopolar instrument cable connector pin	Pin on a monopolar instrument that a monopolar instrument cable connects to
P	
Position Marker	Yellow label around the Monopolar Curved Scissors shaft, at the edge of the instrument shaft insulation, used as a visual reference for the correct positioning of the Insulating Sleeve

R	
Reprocessing	Process of preparing an accessory for use. The process involves cleaning, disinfection and sterilisation (where applicable)
Reprocessing instructions	Separate sets of instructions provided with the Versius Surgical System that instruct users on how to reprocess the sterile accessories before first use and after each use
S	
Shaft	Long cylindrical part of the instrument or endoscope that is inserted in the patient cavity during surgery
System	See Versius Surgical System
T	
Tip	End of the instrument or endoscope furthest from the part that attaches to the bedside unit or camera head
V	
Valleylab Force FX-8CAS	Electrosurgery unit that is compatible with the Versius Surgical System
Valleylab ForceTriad	Electrosurgery unit validated with the Versius Surgical System
Valleylab FT10	Electrosurgery unit that is compatible with the Versius Surgical System
Valleylab FX8	Electrosurgery unit that is compatible with the Versius Surgical System
Versius	See Versius Surgical System

Versius Instrument Arm	Arm on a Versius Instrument Bedside Unit that can hold an instrument
Versius Instruments	Surgical instruments for use with the Versius Surgical System
Versius Surgical System	Connected system of bedside units, surgeon console, endoscopic camera, instruments, drapes and cables
W	
Warning	Indicates situations that could result in injury to the patient or user. For safe use of the Versius Instruments in conjunction with the Versius Surgical System, users should follow instructions highlighted by warning symbols
Wrist	Part of an instrument that allows rotating for better access and control within the patient cavity

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