Smith+Nephew

BRAND	VERSAJET® III		
SKU	N/A		
COMPONENT	User Manual		
PRODUCT	Hydrosurgery System		
THIS BSC/REF	30958		
PREV BSC/REF	N/A		
DIMENSIONS	A5 (24pp)		
COLOURS *Match to coated stock PMS*	Black Pantone 1375 C (Cover only) CMY (Pages 6, 14 & 16 only)		
DATE	12.04.2022	**REVISION**	17

Strawberry

JOB NUMBER	S38163 - 6389		
ARTWORK	MP	**CHECKED**	ARN

Smith+Nephew

VERSAJET® III

Hydrosurgery System
User Manual

Table of Contents

1. Description 4
2. Indications for Use 4
3. Safety 4
4. Contraindications 4
5. Warnings and Precautions 4
6. System components 5
   - 6.1 Console 5
     - 6.1.1 Front panel layout 5
     - 6.1.2 Side panel 5
     - 6.1.3 Rear panel layout 6
   - 6.2 Foot pedal 6
   - 6.3 Single-Use Hand Piece 7
     - 6.3.1 Hand Piece Options 8
7. Instructions for Use 9
   - 7.1 System set-up 9
   - 7.2 Placement of the console 9
   - 7.3 Power cord socket 9
   - 7.4 Turning the console ON 9
   - 7.5 Setting up the Device 9
     - 7.5.1 Connect the foot pedal 9
     - 7.5.2 Connect the Hand Piece 9
     - 7.5.3 Connect the Saline Bag(s) 10
     - 7.5.4 Connect the Waste Canister 10
   - 7.6 Prime the Hand Piece 10
   - 7.7 Debriding 10
   - 7.8 Removal of an obstruction in the evacuation orifice 11
   - 7.9 Changing the Saline Bag(s) 11
   - 7.10 Replace Hand Piece 11
   - 7.11 End of procedure 11
   - 7.12 Hand piece quick set-up pictorial guide 12
8. Console cleaning and maintenance 13
   - 8.1 Cleaning 13
   - 8.2 Maintenance 13
9. Disposal of the console and accessories 13
10. Troubleshooting Guide 14
11. Glossary of symbols 16
12. Technical information 16
13. System specifications 17
14. Environmental Conditions 17
15. Electromagnetic compatibility VERSAJET III Hydrosurgery System (REF 66802146) 18
16. Guidance and manufacturer's declaration – electromagnetic emissions
    VERSAJET III Hydrosurgery System (REF 66802146) 20
17. Warranty 21
18. Appendix A
    Company position regarding the reprocessing and reuse of single-use only medical devices 22
19. Appendix B
    Ordering Information 22

1. Description

The VERSAJET◊ III Hydrosurgery System consists of a console, foot pedal and a hand piece. There are different hand piece types for the VERSAJET◊ III System for use in the operating room and outpatient setting, for further detail refer to section 6.3.1.

This device can cut soft tissue. Apply only to tissues and debris intended to be excised from the wound.

2. Indications for Use

The VERSAJET III◊ Hydrosurgery System is intended for applications that in the healthcare professionals' judgment, require sharp debridement:

- wound debridement (acute and chronic wounds, burns),
- soft tissue debridement and cleansing of surgical sites.

3. Safety

This user manual contains important information regarding the safe and effective operation of the VERSAJET◊ III System. The system is designed for use by qualified and trained healthcare professionals. Improper system use or set up, or failure to follow this user guide may cause injury or damage not covered under the warranty.

4. Contraindications

There are no known contraindications with the use of this device.

5. Warnings and Precautions

- This device is not suitable for use in an oxygen rich environment (e.g. oxygen tent, hyperbaric chamber).
- DO NOT directly expose the console to a flammable anesthetic mixture.
- In order to avoid unwanted procedural delays, ensure the system is fully operational prior to administration of anesthesia.
- This device should be used with particular care in patients with hemophilia or other blood clotting disorders and in patients receiving anti-coagulant medication.
- This device can cut soft tissue. Apply only to tissues and debris intended to be excised from the wound.
- Increasing console power settings will lead to more aggressive tissue removal.
- Use caution near delicate vessels and structures, such as neurovascular bundles.
- When used on wounds where bone, tendon or other hard tissue (e.g. leathery eschar) may be encountered during the debridement procedure, excessive spraying and/or misting may occur due to the interruption of the stream of sterile saline by hard tissues.
- DO NOT touch the high-pressure jet in the operating window of the hand piece.
- As with all surgical procedures, the VERSAJET◊ III System operator and other clinical personnel should follow the universal precautions for infection control.
- Examine all components before use. DO NOT use, if you believe a component to be faulty or damaged. Contact your local Smith+Nephew VERSAJET◊ III System representative.
- DO NOT use if the hand piece packaging seal is broken or the pouch is damaged.
- Place the console and waste canister onto flat and stable surfaces to prevent the console and waste canister from tilting or falling.
- DO NOT cover the air vents on the side of the console. A minimum of 12 cm clearance is advised to prevent the system from overheating.
- DO NOT pull hand piece tubing in an attempt to bring the console closer for use.
- Select an appropriate waste canister for the procedure.
- DO NOT connect the waste evacuation tubing hose or any container connected to it, to a vacuum source.
- DO NOT preheat saline before use the device.
- Use only sterile saline solution with this device.
- The VERSAJET◊ III Hydrosurgery System Hand Piece and VERSAJET◊ III Hydrosurgery System Console are not compatible with previous generations of the VERSAJET◊ console and hand pieces respectively.
- Each VERSAJET◊ III Hand Piece is intended for SINGLE-USE ONLY. DO NOT RE-STERILIZE. Device performance will be compromised and sterility cannot be assured. Discard appropriately after use.
- Refer to our company position regarding the reprocessing and reuse of single-use only medical devices in Appendix A of this manual.
- DO NOT use where there is any significant risk of reciprocal interference between the VERSAJET◊ III Console and another medical device or treatment.
- To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.
- No modification to this equipment is allowed. Modifications could lead to electric shock.
- Use of non-consigned parts (e.g. non-compatible hand piece, power cord and foot switch) will result in malfunction of device.

6. System components

The VERSAJET◊ III System consists of four primary components:

Reusable Equipment:

- Console
- Foot pedal
- Power cord

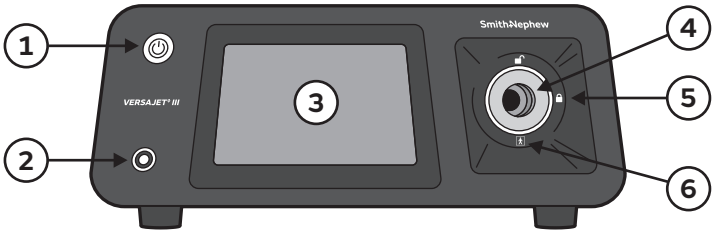
Single-Use Equipment:

- Single-use hand piece and associated tubing

6.1. Console

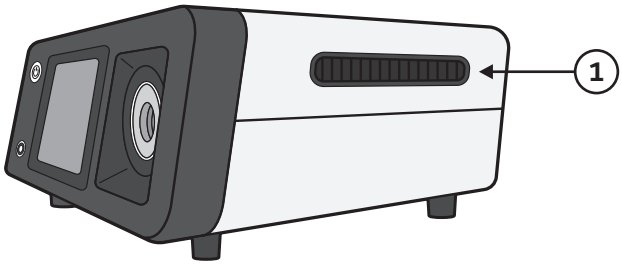
- The VERSAJET◊ III Console is an electrically powered device that controls the pumping of high-pressure saline through the hand piece, providing hydrosurgical debridement.
- A foot pedal and power cord are provided with the console.

6.1.1. Front panel layout



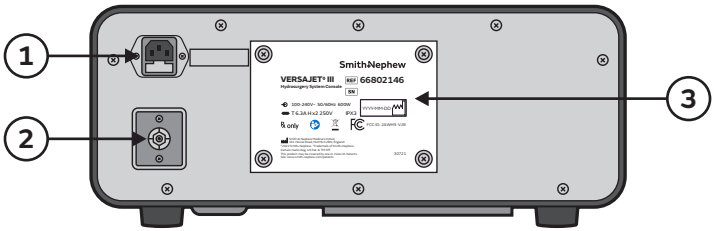
1. *Illuminated power switch – turns the power ON and OFF*
2. *Foot pedal socket – interfaces with the foot pedal*
3. *7-inch LED Touchscreen Display – displays the set-up guidance, power setting, and service information. Power settings can sequentially be selected from 1 (lowest) through 10 (highest).*
4. *Hand Piece insertion port – secures the hand piece to the console*
5. *Key lock symbols – provide the user information on the hand piece pump positions (Unlocked and Locked)*
6. *Type BF Applied Part – the hand piece has a type BF rating*

6.1.2. Side panel



1. *Side air vents – allow for air to enter the console to cool the motor*

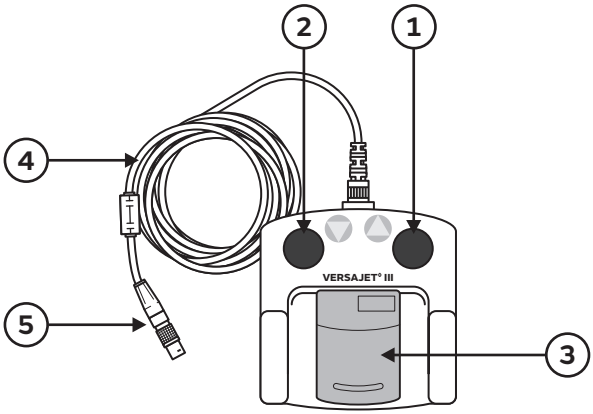
6.1.3. Rear panel layout



1. *Power cord socket – interfaces with the detachable power cord through a three-prong socket*
   - *The power cord provides electrical power to the console from an electrical outlet. For details of available power cords, please refer to the Ordering Information section.*
2. *Protective earth ground terminal– allows connection to the main system ground for testing the equipment*
3. *Device label – contains information and symbols specific to the device*

6.2. Foot pedal

NOTE: Only a VERSAJET◊ III Foot Pedal should be used with the VERSAJET◊ III Console.



1. *UP button – pressing the button next to the UP arrow increases the power setting*
2. *DOWN button – pressing the button next to the DOWN arrow decreases the power setting*
3. *Foot pedal – pressing the foot pedal activates the motor*
4. *Foot pedal cable – connects the foot pedal connector to the foot pedal*
5. *Foot pedal connector – connects the foot pedal to the socket on the console*

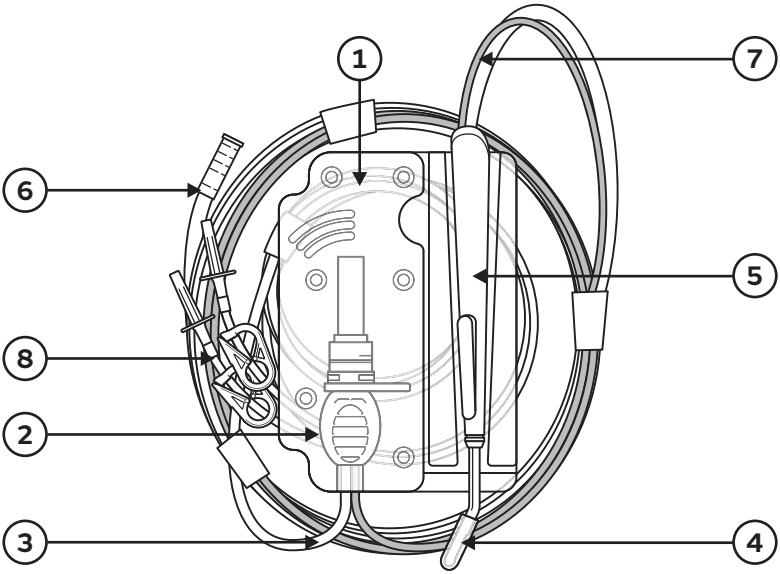
6.3. Single-Use Hand Piece

The sterile VERSAJET◊ III Hand Piece and associated tubing should be disposed of after use as clinical waste.

The hand piece has an operating window located at the instrument's distal tip. When the system is in operation, a stream of pressurized saline travels across the opening and creates a localized vacuum effect, following the principles of the Venturi effect. By applying/passing the operating window over the area to be debrided the user can excise nonviable tissue and contaminants. The system can be used to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications.

CAUTION: The VERSAJET◊ III Hand Piece and VERSAJET◊ III Console are not compatible with previous generations of the VERSAJET◊ console and hand pieces respectively.

NOTE: The VERSAJET◊ III Hand Piece is only designed for connection to the VERSAJET◊ III Console (66802146). DO NOT attempt to connect to any other equipment.

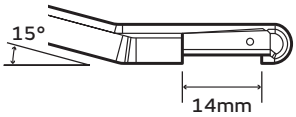
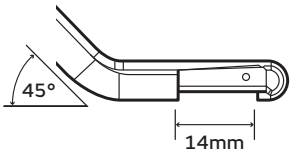
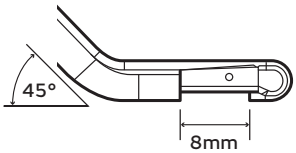


1. *Clam shell – a clear plastic enclosure that holds the hand piece and pump cartridge*
2. *Pump cartridge (orange connector) – connects the hand piece to the console*
3. *Saline Inflow tube – two clear tubes with white spike and pinch clamp that connects to saline bags*
4. *Instrument tip – the metal tip (PRECISION Hand Piece) or plastic tip (PROCLINICAL Hand Piece) with a small, precise opening where a high velocity stream of sterile saline selects and excises non-viable tissue and contaminants contained in the operating site. The instrument tip contains the evacuation orifice*
5. *Hand piece – an ergonomic handle supporting the instrument tip; receives the high-pressure line and waste evacuation line at the proximal end (white)*
6. *Waste evacuation tube – a clear tube with a blue connector end that carries evacuated fluid, non-viable tissue and contaminants to an appropriate waste container*
7. *High pressure tube – a tube that carries pressurized saline to the distal tip of the hand piece*
8. *Saline inflow tube*

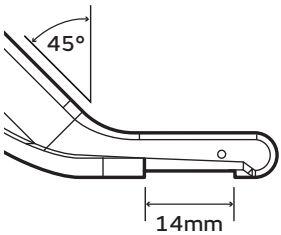
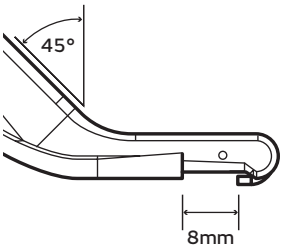
6.3.1. Hand Piece Options

There are two single-use VERSAJET◊ III hand piece types – PRECISION and PROCLINICAL.

VERSAJET◊ III PRECISION Hydrosurgery System Hand Piece

	Order no.	Description
	66802147	VERSAJET◊ III PRECISION Hand Piece (15°/14mm) **For operating room only**
	66802148	VERSAJET◊ III PRECISION Hand Piece (45°/14mm) **For operating room and outpatient setting**
	66802149	VERSAJET◊ III PRECISION Hand Piece (45°/8mm) **For operating room and outpatient setting**

VERSAJET◊ III PROCLINICAL Hydrosurgery System Hand Piece

This Hand Piece has a **20 minute continuous debridement time limit**.		
	Order no.	Description
	66802150	VERSAJET◊ III PROCLINICAL Hand Piece (45°/14mm) **For outpatient setting only**
	66802151	VERSAJET◊ III PROCLINICAL Hand Piece (45°/8mm) **For outpatient setting only**

7. Instructions for Use

It is recommended that prior to clinical use of VERSAJET◊ III System, all operators of the device should be trained in the proper use of VERSAJET◊ III System. Smith+Nephew Representatives will be available to provide a tailored introduction to the use of the system, on the request of the clinician. Contact your local representative for details.

In order to avoid unwanted procedural delays, ensure the system is fully operational prior to the administration of anesthesia.

7.1. System set-up

This section provides the procedures for set up and operation of the VERSAJET◊ III System.

NOTE: To ensure adequate saline supply is selected, consider the power setting to be used for the procedure and procedure length. To calculate the saline volume required, refer to the Flow Rates and Pressures table below.

Flow Rates and Pressures

Values provided in the table are typical values and are provided as guidance only. Actual values may vary.

Power Setting	VERSAJET◊ III Hand Piece	
	Flow Rate (mL/min)	Pressure (psi / bar)
1	82	1448/100
2	96	1962/135
3	110	2518/174
4	123	3139/216
5	137	3856/266
6	150	4635/320
7	167	5713/394
8	179	6549/452
9	189	7308/504
10	197	7950/548

7.2. Placement of the console

Place the console on a stable, flat surface, close for operating purposes. Ensure the side air vents are not covered.

CAUTION: DO NOT block the air vents, on the bottom or sides of the console, during use. Failure to do so could lead to overheating issues.

CAUTION: DO NOT pull hand piece tubing in an attempt to bring the console closer for use.

7.3. Power cord socket

CAUTION: Before connecting the device to an electrical outlet, ensure that you have selected the appropriate power cord for the local power requirements and that the device is connected to a socket that meets the system requirements. Failure to do so may cause damage to the equipment and void the warranty.

CAUTION: DO NOT position the VERSAJET◊ III Console so it is difficult to disconnect the power supply from the mains supply.

1. Insert the power cord into the back of the console.
2. Plug the power cord into an appropriate electrical outlet.

7.4. Turning the console ON

Press the power button. The button will illuminate, following which the display will start up.

7.5. Setting up the Device

Select 'Start Set-up' to initiate the set-up guidance.

CAUTION: DO NOT use a sharp tool or apply excessive force on the power button and the touch-screen display.

7.5.1. Connect the foot pedal

1. Connect the foot pedal connector into the foot pedal socket on the front of the console, ensuring the red dots on the connector and socket are aligned. Once the connection is achieved, a green 'tick' will appear on the screen.
2. Position the foot pedal for convenient access.

7.5.2. Connect the Hand Piece

1. Remove the pouch from carton. Inspect pouch to ensure seals are intact and pouch is undamaged. Open the pouch, ensuring that the sterility of the inner pouch is not compromised.
2. Aseptically transfer inner pouch and contents to the sterile field (in the operating room) or onto a sterile surface (in an outpatient environment).
3. Aseptically inspect inner pouch to ensure seals are intact and pouch is not damaged. Open inner pouch, remove the sterile contents and place securely in the sterile field or onto a sterile surface. Avoid tangling of the tubing.

4. Remove the hand piece from the clam shell and place in the sterile field or onto a sterile surface. DO NOT remove the orange connector (pump cartridge) from the clam shell tray.
5. Uncoil the tubing lines. DO NOT remove orange bands surrounding the tubing. Maintain aseptic technique for the hand piece and sufficient tubing to allow access to the surgical site.
6. Remove the orange connector from the clam shell and insert the metal end into the connection port on the front of the console. Rotate the connector clockwise to the lock position. Once the connection is achieved, a green 'tick' will appear on the screen.

7.5.3. Connect the Saline Bag(s)

It is recommended that full saline bags are connected prior to commencing with the procedure.

CAUTION: Only spike the saline bag(s) once the hand piece has been connected to the console. Failure to do so may result in fluid leakage from the pump cartridge.

CAUTION: Do not preheat saline before use of the device.

CAUTION: The system can be operated with either one or two saline bags. If only one bag is required, **leave the unused inflow line clamp closed** and the bag spike cap on.

1. Ensure the inflow line clamp is closed.
2. Remove the sterile cover from the bag spike and insert into the saline supply bag. Repeat for the second bag if necessary.
3. Press the right arrow on the screen to proceed to the next step.

   NOTE: The saline bag MUST be placed a minimum of 24in/60cm above the console.

7.5.4. Connect the Waste Canister

CAUTION: Place the waste canister onto a flat and stable surface to prevent the waste canister from tilting or falling.

1. Attach the waste evacuation tube (blue tip) to the waste canister.

   CAUTION: DO NOT connect to a port containing a filter or to the VACUUM port. Ensure there is an additional open port on the waste canister lid, to prevent a pressure build-up inside the canister.
2. Ensure there are no kinks or other external obstructions in the tubes.

   NOTE: The waste canister should be below the level of the hand piece during priming and debriding.

   CAUTION: To avoid the canister overflowing, ensure the waste canister volume will contain the volume of saline used during the procedure.
3. Press the right arrow on the screen to complete the set-up.

   CAUTION: Monitor the waste canister and ensure it is emptied to prevent overflowing.

7.6. Prime the Hand Piece

1. Remove the protective cover from the tip of the hand piece.
2. Initiate the priming sequence on the screen.
3. Power levels will automatically increase from 1 to 10.
4. Open the saline clamps.
5. While holding the hand piece at a safe distance, depress the foot pedal and observe a steady flow of saline at the distal tip of the hand piece.

   NOTE: A visible saline stream flowing down the waste tube, indicates priming is complete.
6. Release the foot pedal. Indicate that the priming is complete on the screen.

CAUTION: Once the system has been primed with saline, do not allow the saline bag to empty. An empty bag can cause air to enter the system and require re-priming of the system.

NOTE: Do not place the hand piece tip too close to eyes to avoid saline splash to eyes.

7.7. Debriding

Once priming is complete the system is ready for debridement. To prevent saline splashing back into the eyes, avoid bringing the hand piece tip close to the eyes during use.

CAUTION: This device can cut soft tissue. Apply only to tissues and debris intended to be excised from the wound.

NOTE: For optimal results when debriding hard or leathery eschar resulting from

burn injuries, it is recommended to first debride the eschar using sharp debridement techniques followed by the use of VERSAJET◊ III System to complete debridement or excision of the wound.

1. To begin debriding, begin at the lowest power setting and increase as necessary.

   The power setting can be adjusted using the UP and DOWN buttons on the foot pedal, or the + and – buttons on the screen. When the foot pedal is active the + and – buttons on the screen will be inactive.

   WARNING: Increasing the console power setting will lead to more aggressive tissue removal. Use caution near delicate vessels, structures and surrounding tissues.

   CAUTION: Monitor the waste canister and ensure it is emptied to prevent overflowing.

   NOTE: Spraying or misting is more frequent at lower power settings due to reduced pressure. Spraying or misting may be reduced by keeping the waste evacuation tube straight.
2. While securely holding the hand piece, depress the foot pedal to activate the motor. A constant stream of saline will appear at the distal tip of the hand piece.
3. Position the distal tip over the area requiring debriding.
4. Release foot pedal before removing the hand piece from the wound.

NOTE: The VERSAJET◊ III PROCLINICAL Hand Piece has a 20 minute continuous debridement time limit. The time counter is only active when the foot pedal is depressed and debridement is conducted. Once the 20 minutes are completed, if further debridement is required, a second hand piece will need to be connected to the console.

NOTE: If leaking is observed at the connection interface to the console, please remove and replace the hand piece with a new one.

7.8. Removal of an obstruction in the evacuation orifice

If the evacuation orifice becomes blocked with foreign matter, a reduction in device efficiency or the presence of spray from the instrument tip may result.

To remove the obstruction:

1. Remove the hand piece from the wound site.
2. Release the foot pedal and remove the obstruction with forceps.

   NOTE: Avoid touching the opening in the high-pressure jet with forceps.
3. Once the obstruction is removed, depress the foot pedal and check for steady stream of sterile saline flow.
4. If the obstruction is not completely removed, repeat the hand piece set-up and system priming procedure or check that the waste evacuation tube is not pinched by forceps, stepped on or that the collection container is full.

7.9. Changing the Saline Bag(s)

When using one saline bag: If additional saline is required, attach an additional bag to the second line prior to the first bag emptying. Open the second saline line clamp prior to the first bag emptying.

When using two bags: Open the second inflow line prior to the first bag emptying. Should additional saline be required for the debridement, ensure the clamp is closed prior to changing the bag.

NOTE: Monitor the saline levels during use to ensure the bags are replaced prior to emptying.

7.10. Replace Hand Piece

If a notification appears on the screen with instructions to replace the hand piece, please disconnect the saline bag(s), waste canister, and hand piece from the console.

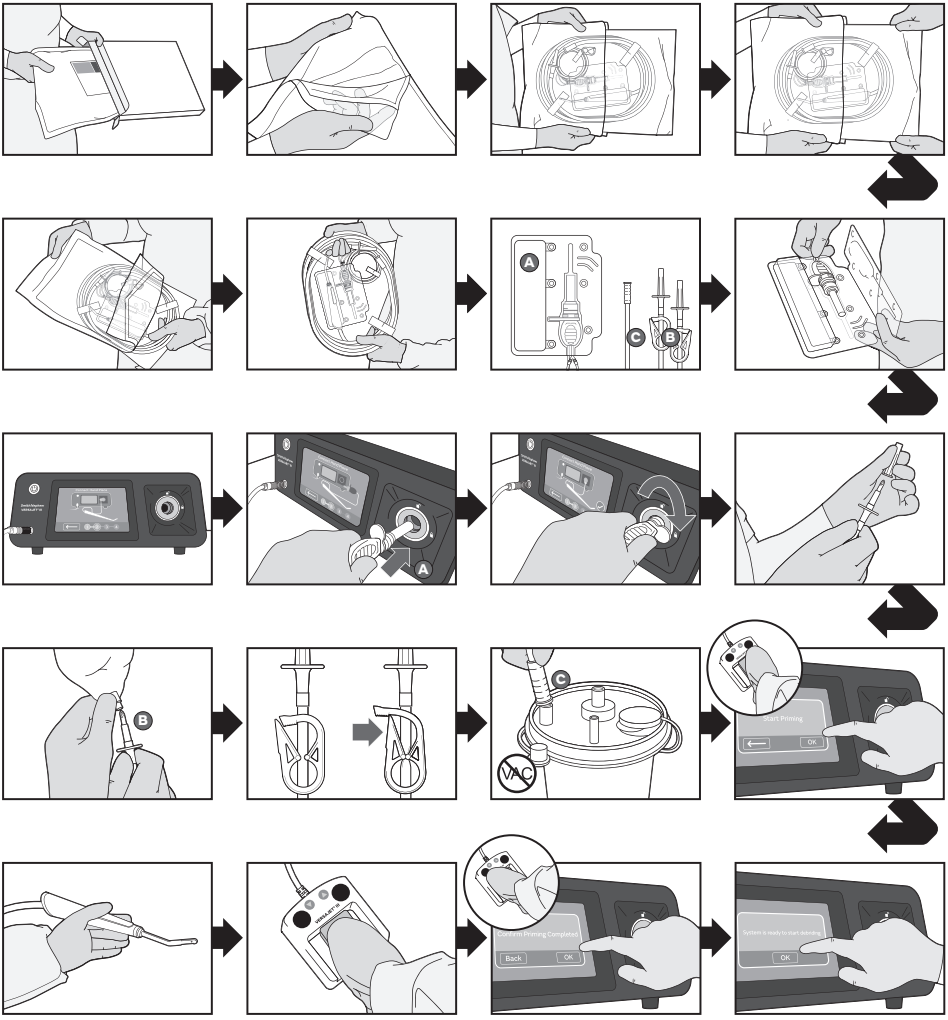
Press ‘OK’ on the notification and proceed to set up a new hand piece.

7.11. End of procedure

1. After completing the procedure, disconnect the saline bags, waste canister, hand piece and foot pedal.
2. Discard the hand piece in accordance with your local healthcare facility’s standard guidelines for biohazardous waste disposal.
3. Switch the device off by pressing the power button.
4. Disconnect the power supply cable.

NOTE: After each use, thoroughly clean the console, foot pedal and power cord. Please refer to the Cleaning and Maintenance section.

7.12. Hand piece quick set-up pictorial guide



8. Console cleaning and maintenance

8.1. Cleaning

Follow your healthcare facility's standard procedures for decontaminating surgical equipment to decontaminate the console, foot pedal and power cord.

The following are the recommendations for console decontamination:

1. Wear protective gloves, gown and eye wear.
2. Wipe all surfaces of the console and foot pedal with a disposable towel or cloth soaked in the disinfectant solution.
3. Dilute the disinfectant solution according to the manufacturer's instructions. After disconnecting the foot pedal and power cord from the console, wipe down all exposed surfaces of both components in accordance with the guidance for the console.
4. Dispose of towels, gloves and gown in accordance with your healthcare facility's standard guidelines for biohazardous waste disposal or as prescribed by the environment in which the console was used.

This procedure should be performed after each console use.

The fan slot and vents on the sides of the console should be kept free from obstructions and periodically inspected for excessive build-up of dust and/or foreign material. The pump interface should be inspected periodically for build-up of deposits and/or debris. A damp cloth with mild detergent can be used to remove material.

NOTE: Using a wet cloth or excessive fluid to clean the console can cause damage.

If the power cord or foot pedal are damaged, these should be replaced. Please refer to Appendix B, Ordering Information.

8.2. Maintenance

Smith+Nephew recommends that dielectric strength, earth leakage current and protective earth testing be performed annually to assure continued compliance with applicable safety requirements.

These tests should be conducted in accordance with specifications UL 60601-1/ IEC 60601-1.

CAUTION: Electrical safety testing should be performed by a biomedical engineer or other qualified person.

CAUTION: Device should be repaired by authorized person only.

Brightness and Language can be changed under the Menu. However, the Maintenance Menu is password protected and can only be accessed by an authorized person.

A physical appearance check and system diagnostics check should be performed annually, or following 240 hours of debridement, as part of the maintenance routine for VERSAJET◊ III System. The device will notify you at 230 hours that there are 10 debridement hours remaining, and to prompt you to arrange for your device to be sent for maintenance.

9. Disposal of the console and accessories

At the end of the console's expected service life (5 years), it should be disposed of in accordance with local laws and regulations.

Please contact Customer Care at 1-800-876-1261 (USA only) or local Smith+Nephew representative to return a console for repair or replacement.

10. Troubleshooting Guide

Follow the below troubleshooting steps. If the fault is not resolved, contact Customer Care at 1-800-876-1261 (USA Only) or your local Smith+Nephew Representative.

Fault	Potential Cause	Solution
No / intermittent electrical power	Console power switch not illuminated	▪ Press power switch; power switch should become illuminated
	Power not present at electrical outlet	▪ Ensure that the electrical outlet has power ▪ Connect to a different electrical outlet
	Power cord not connected or connected loosely at console or electrical outlet Note: The console will default to power level 1 if power is interrupted	Ensure that power cord is: ▪ Fully seated into the back of the console and electrical outlet ▪ Not damaged and free of defects If the fault persists, order a replacement power cord.
Foot pedal notification window appears on screen	Foot pedal not connected properly	▪ Observe red alignment dots on foot pedal connector and foot pedal socket are properly aligned ▪ Ensure the foot pedal connector is fully inserted
	Foot pedal obstructed	Ensure that there are no objects obstructing the Foot Pedal from being depressed or releasing
	Foot pedal inoperative	Order replacement foot pedal (66802155) from Customer Care
Hand piece notification window "Hand piece disconnected" appears on screen	Hand piece is removed	Connect new hand piece
Hand piece notification window "Hand piece not recognized" appears on screen	Console fails to recognize hand piece	Connect new hand piece
Hand piece notification window "Hand piece unlocked" appears on screen	Hand piece is loosing	Rotated and locked hand piece
Hand piece notification window "time ended" appears on screen	PROCLINICAL hand piece accumulated debridement time reaches limit	Connect new hand piece
System fault notification window appears on screen 	Power fault caused by over-current or System Over Pressure condition out of tolerance	1. Turn console OFF by pressing power switch 2. Ensure power cord is connected to an appropriate power source. If necessary, try a different electrical outlet 3. Ensure the yellow high-pressure tube on Hand piece is not kinked, obstructed or tangled 4. Wait at least 5 seconds after turning OFF 5. Turn console ON by pressing power switch 6. Should the problem persist contact Customer Care, 1-800-876-1261 (USA only) or local Smith+Nephew representative to arrange a return
System overheating notification window appears on screen 	Side vent and/or fan fence are blocked	1. Turn console OFF by pressing power switch 2. Check the side vent hole and fan fence, clean and remove obstructers if any; 3. Wait 10 minutes to let console cooling; 4. Restart the console.
	Console damage (e.g. fan stops)	Stop using device.

Contact Customer Care at 1-800-876-1261 (USA Only) or your local Smith+Nephew Representative

Follow the below troubleshooting steps. If the fault is not resolved, contact Customer Care at 1-800-876-1261 (USA Only) or your local Smith+Nephew Representative.

Fault	Potential Cause	Solution
Hand piece does not Prime Note: Priming takes approximately 1 min at power level 10	No / obstructed fluid supply	1. Ensure saline bag is full and fluid flows freely 2. Check that pinch clamp is fully open 3. Check high pressure tube for kinks, obstructions or leaks 4. Ensure saline bag is set at least 24in / 60cm higher than the console 5. Reconnect or replace as necessary.
	Air in saline inflow line	1. Open the pinch clamps of both saline bags to release the air trapped in tube. 2. While keeping hand piece at a safe distance set console power level to 10 and depress foot pedal to remove air from the pump and resume priming 3. If only one saline bag is connected, connect a saline bag to the unused line and open the clamp to release the trapped air. **CAUTION:** Ensure continuous flow of saline. DO NOT allow saline bag to empty completely before changing
Excessive spray / spattering Note: Hand piece should not come into contact with bone tissue as it obstructs fluid flow and causes spraying	Obstruction of evacuation orifice (debris, tissue or other foreign material) (Section 8.8 page 11)	1. Release foot pedal 2. Remove hand piece from wound 3. Remove obstruction with forceps 4. Re-prime hand piece 5. If the obstruction is not completely removed, repeat the hand piece set-up and system priming procedure. 6. Check that the waste evacuation tube is not pinched by forceps, stepped on or that the collection container is full.
	Obstructed waste evacuation tube	Ensure that: ▪ The distal end of the evacuation tube is connected to a non-filtered port of a waste collection container ▪ Waste container is vented ▪ Evacuation tube is not obstructed, kinked or pinched ▪ Waste container is at lowest possible point below console level ▪ Waste container is not full ▪ Saline supply is above console (provides gravity feed/pressure)
	Fluid jet striking edge of metal evacuation orifice	Replace hand piece. Return initial hand piece by contacting Customer Care at 1-800-876-1261 (USA only) or local Smith+Nephew representative
Screen blanks out and power button LED flashing	Screen is damaged	1. Stop using device. 2. Contact Customer Care, 1-800-876-1261 (USA only) or local Smith+Nephew representative to arrange a return

Contact Customer Care at 1-800-876-1261 (USA Only) or your local Smith+Nephew Representative

11. Glossary of symbols

	Follow instructions for use		Do not re-use		Lot number
	Consult instructions for use		Date of manufacture		Serial number
	Sterilized using ethylene oxide		Manufacturer		Product catalog number
	Do not use if package is damaged		Keep Away From Sunlight		Keep dry
	Temperature limitation		Humidity limitation		Atmospheric pressure
	This way up		Equipment classification Isolation type BF applied part		Fuse Rating
	Non-ionizing electromagnetic radiation		Caution		Brightness
	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.		Federal Communications Commission Certification Identification Number		

12. Technical information

CAUTION: Only VERSAJET◊ III System equipment should be connected to the console.

There are no user serviceable parts within the console. All required service must be performed by the manufacturer.

Contact Customer Care at 1-800-876-1261 (USA only) or local Smith+Nephew representative to return console for repair or replacement.

13. System specifications

Front panel

	Power switch, ON/OFF (I/O)
	Foot pedal connection
	Hand piece unlocked
	Hand piece locked
	Adjusting Power Setting

Rear panel

Prior to connecting the device to an electrical outlet, determine local voltage and electrical supply requirements. Ensure the cable is compatible.

Power inlet	IEC60320-1 C14 style power inlet with dual fuse holder
Power cord	Detachable hospital grade power cord with C13 plug
Power input rating	100-240V~ 50/60Hz 600W T 6.3A H x2 ⎓ 250V
Fuse ratings	Dual T 6.3A H 250V 5x20mm
Mode of operation	Continuous
Applied part classification	Type BF
Equipment classification	Class I
Compliance	IEC60601-1 IEC60601-1-6
Listing	To be defined

Product dimensions and weights

Console	
Size	40cm W x 35cm D x 18cm H 15.8in W x 13.8in D x 7.1in H
Weight	13.6kg / 30lbs
IP classification	IPX3
Footswitch	
Size	19cm W x 18.4cm D x 5cm H 7.5in W x 7.25in D x 2in H
Weight	1.7kg / 3.7lbs
Cord length	4.6m / 15ft
IP classification	IPX8
Power cord	
Length	4.6m / 15ft (US)

14. Environmental Conditions

Single-use hand piece environmental conditions

Unless otherwise stated, the following conditions apply for product use as well as shipping and handling.

Temperature range	
Storage	41°F (5°C) to 77°F (25°C)
Product use	50°F (10°C) to 90°F (32°C)
Humidity range	10% to 90% RH, non-condensing
Atmospheric pressure	700 to 1060 hPa

Console environmental conditions

Unless otherwise stated, the following conditions apply for product use as well as shipping and handling.

Temperature range	
Storage	-4°F (-20°C) to 131°F (55°C)
Product use	50°F (10°C) to 90°F (32°C)
Humidity range	10% to 90% RH, non-condensing
Atmospheric pressure	700 to 1060 hPa

15. Electromagnetic compatibility VERSAJET◊ III System (REF 66802146)

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2-2014 4th edition as a Class B digital device, pursuant to part 15 of the FCC Rules. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the device is used in a typical medical installation. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- In case of the power supplier of the Relay Antenna connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The field strength of radiated emission is below 150 microvolts/meter from 88 MHz to 13 GHz.

This device does not have essential performance.

The Wireless Quality of Service (QoS) in VERSAJET◊ III System is implemented in the only wireless RFID/NFC communication between the VERSAJET◊ III console and VERSAJET◊ III Hand piece. This device use RFID to recognize the hand piece. The field strength of radiated emission is below 62.5 db microvolts/meter at operating frequency 13.56 MHz. The communication range between hand piece and console is less than 50mm. There is no harm when RFID is interfered but suggest to keep separate distance more than 50mm with other RFID devices/tags.

IC (Industry Canada) Statement

Antenna Statement

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope ayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Canadian Department of Communications Compliance Statement CAN ICES-3(B)/NMB-3(B)

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VERSAJET◊ III System (REF 66802146), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV For power supply lines 100 kHz repetition frequency	±2 kV For power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground	±0.5 kV, ±1 kV, Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short Interruptions and voltage variations on power supply input lines IEC 61000-4-11	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases 0% UT (100% dip in UT) for 0.5 cycle At 0° single phase 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 250 cycles 0% UT (100% dip in UT) for 300 cycles	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases 0% UT (100% dip in UT) for 0.5 cycle At 0°, 180° phase 5% UT (100% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 5% UT (100% dip in UT) for 5 seconds At 0° single phase 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
NOTE *UT is the a.c. mains voltage prior to application of the test level*			
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
			Portable and mobile communications equipment should be separated from the device by no less than distances calculated/listed below: **Recommended separation distance:**
Conducted RF	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	
IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz In ISM radio bands	6 Vrms 150 kHz to 80 MHz In ISM radio bands	d= 0,58 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:2014 Table 9	3 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:2014 Table 9	d= 0,175 √P (80 MHz to 800 MHz) d= 0,35 √P (800 MHz to 2.7 GHz)

NOTE 1: At 80 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuacy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds 3 V/m, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a]should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:

16. Guidance and manufacturer's declaration – electromagnetic emissions VERSAJET◊ III System (REF 66802146)

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11 Harmonic emissions IEC 61000-3-2 Voltage fluctuations/ flicker emissions IEC 61000-3-2	Class B Class A Comply	The device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

WARNING: The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Do not use cables and accessories other than those specified or sold by Smith+Nephew as it may result in increased electromagnetic emissions or decreased electromagnetic immunity of the VERSAJET◊ III System (REF 66802146).

Portable and mobile RF communication devices (mobile telephones) can affect VERSAJET◊ III System (REF 66802146).

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m):		
	150 kHz to 80 MHz $d = 0.58\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.06	0.12	0.23
0.1	0.2	0.37	0.74
1	0.6	1.2	2.3
10	1.8	3.7	7.4
100	5.8	11.7	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

17. Warranty

Limited one-year warranty

S&N products are warranted to conform in all material respects to S&N's standard specification for a particular product in effect at the time of product delivery to the buyer (including any tolerance parameters) for the warranty period specified for the products at www.SNWarranties.com.

18. Appendix A

Company position regarding the reprocessing and reuse of single-use only medical devices

As a manufacturer of single-use medical devices, including multi-use systems with single-use patient contact components, it is our position that these devices are not designed or manufactured to withstand the rigors of reprocessing and therefore should not be reprocessed.

Single-use medical devices are intended to be used on an individual patient during a single procedure and then discarded. They are not intended to be reprocessed and used again. Labelling identifies such devices as single-use.

The use of reprocessed devices may present unacceptable risks to the health and safety of patients and healthcare professionals. Tissue and organ damage as well as cross-infection can result from the reuse of a single-use device, because of practical issues of cleaning single-use devices. Moreover, the rigors of reprocessing can impair the performance and adversely affect the safety of a single-use device, as a result of changes in the physical state of the device.

19. Appendix B

Ordering Information

Ordering information		
66802146	VERSAJET® III HYDROSURGERY SYSTEM CONSOLE	
66802147	VERSAJET® III PRECISION 15° x 14mm	15°/14mm
66802148	VERSAJET® III PRECISION 45° x 14mm	45°/14mm
66802149	VERSAJET® III PRECISION 45° x 8mm	45°/8mm
66802150	VERSAJET® III PROCLINICAL 45° x 14mm	45°/14mm
66802151	VERSAJET® III PROCLINICAL 45° x 8mm	45°/8mm
66802152	VERSAJET® III CONSOLE USER MANUAL	
66802153	VERSAJET® III HAND PIECE USER MANUAL	
66802154	VERSAJET® III CART[1]	
66802155	VERSAJET® III MULTI-FUNCTIONAL FOOT PEDAL	
66800193	POWER CORD, NORTH AMERICA	
66800213	POWER CORD, UNITED KINGDOM	
66800291	POWER CORD, CENTRAL EUROPE	
66800302	POWER CORD, SOUTH AFRICA	
66800303	POWER CORD, AUSTRALIA / NEW ZEALAND	
66801308	POWER CORD, PHILIPPINES	
66801056	CHINA POWER CORD PACK OF 1	
66801063	VERSAJET® III Speed Stick (RPM verification) tool	
To order, contact Customer Care at 1-800-876-1261 (USA only) or local Smith+Nephew representative		

[1] Refer to the user manual of optional compatible cart for using instruction.

Smith & Nephew Medical Limited,
101 Hessle Road, Hull HU3 2BN England

Customer Care Center
1 800-876-1261
www.smith-nephew.com
www.educationunlimited.smith-nephew.com

℞ only

04/2022 30958

Smith+Nephew

BRAND	VERSAJET® III		
SKU	N/A		
COMPONENT	User Manual Review		
PRODUCT	Hydrosurgery System		
THIS BSC/REF	31230		
BASED ON	27441		
DIMENSIONS	215.9 x 279.4 (2pp)		
COLOURS *Match to coated stock PMS*	Black Pantone 1375 C (One side only)		
DATE	03.03.2022	**REVISION**	04

Strawberry

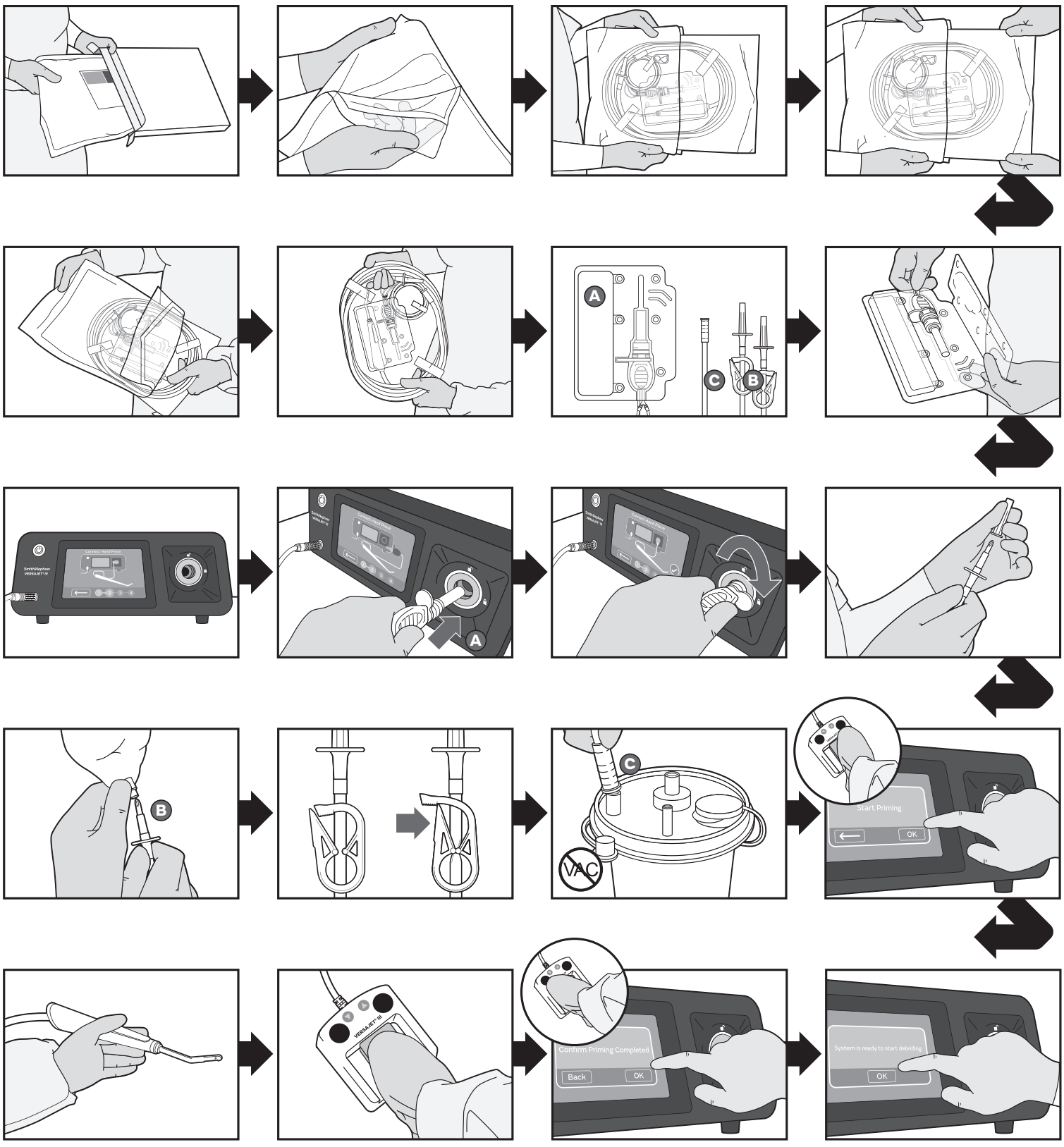
JOB NUMBER	S38181 - 6433		
ARTWORK	MP	**CHECKED**	ARN

Smith+Nephew

System Installation

VERSAJET◊ III PRECISION/ VERSAJET◊ III PROCLINICAL

Hydrosurgery System Hand Piece



VERSAJET◊ III PRECISION/ VERSAJET◊ III PROCLINICAL

Hydrosurgery System Hand Piece

Do not use contents if package is opened or damaged.
Single use Hand Piece Assembly — Do not re-sterilize.

Indications for Use

The VERSAJET° III Hydrosurgery System is intended for applications that in the healthcare professionals' judgment, require sharp debridement:

- Wound debridement (acute and chronic wounds, burns),
- Soft tissue debridement and cleansing of surgical sites

Device Description

The VERSAJET° III System consists of a console, foot pedal and a hand piece. There are two hand piece types: VERSAJET° III PRECISION Hydrosurgery System Hand Piece for use in the operating room and VERSAJET° III PROCLINICAL Hydrosurgery System Hand Piece for the use in the outpatient setting. This device can cut soft tissue. Apply only to tissues and debris intended to be excised from the wound.

Warnings and Precautions

- In order to avoid unwanted procedural delays, ensure the system is fully operational prior to administration of anesthesia.
- This device should be used with particular care in patients with hemophilia or other blood clotting disorders and in patients receiving anti-coagulant medication.
- This device can cut soft tissue. Apply only to tissues and debris intended to be excised from the wound.
- Increasing console power settings will lead to more aggressive tissue removal.
- Use caution near delicate vessels and structures, such as neurovascular bundles.
- When used on wounds where bone, tendon or other hard tissue (e.g. leathery eschar) may be encountered during the debridement procedure, excessive spraying and/or misting may occur due to the interruption of the stream of sterile saline by hard tissues.
- DO NOT touch the high-pressure jet in the operating window of the hand piece.
- As with all surgical procedures, the VERSAJET° III System operator and other clinical personnel should follow the universal precautions for infection control.
- Examine all components before use. DO NOT use, if you believe a component to be faulty or damaged. Contact your local Smith+Nephew VERSAJET° III System representative.
- DO NOT use if the hand piece packaging seal is broken or the pouch is damaged.
- Place the console and waste canister onto flat and stable surfaces to prevent the console and waste canister from tilting or falling.
- DO NOT pull hand piece tubing in an attempt to bring the console closer for use.
- Select an appropriate waste canister for the procedure.
- DO NOT connect the waste evacuation tubing hose or any container connected to it, to a vacuum source.
- DO NOT preheat saline before use the device.
- Use only sterile saline solution with this device.
- The VERSAJET° III Hydrosurgery System Hand Piece and VERSAJET° III Hydrosurgery System Console are not compatible with previous generations of the VERSAJET◊ III console and hand pieces respectively.
- Each VERSAJET° III disposable hand piece is intended for SINGLE-USE ONLY. DO NOT RE-STERILIZE. Device performance will be compromised and sterility cannot be assured. Discard appropriately after use.
- Refer to our company position regarding the reprocessing and reuse of single-use only medical devices in Appendix A of VERSAJET° III Hydrosurgery System User Manual.

Special Storage and Handling Instructions

Store in a dry place (5 °C/41 °F-25 °C / 77 °F). For further information, consult the VERSAJET° III Hydrosurgery System User Manual.

Instructions for Use

It is recommended that prior to clinical use of VERSAJET° III System, all operators of the device should be trained in the proper use of VERSAJET° III System. Smith+Nephew Representatives will be available to provide a tailored introduction to the use of the system, on the request of the clinician. Contact your local representative for details.

1. Unpack the Hand Piece

1. Remove the pouch from carton. Inspect pouch to ensure seals are intact and pouch is undamaged. Open the pouch, ensuring that the sterility of the inner pouch is not compromised.
2. Aseptically transfer inner pouch and contents to the sterile field (in the operating room) or onto a sterile surface (in an outpatient environment).
3. Aseptically inspect inner pouch to ensure seals are intact and pouch is not damaged. Open inner pouch, remove the sterile contents and place securely in the sterile field or onto a sterile surface. Avoid tangling of the tubing.
4. Remove the hand piece from the clam shell and place in the sterile field or onto a sterile surface. DO NOT remove the orange connector (pump cartridge) from the clam shell tray.
5. Uncoil the tubing lines. DO NOT remove orange bands surrounding the tubing. Maintain aseptic technique for the hand piece and sufficient tubing to allow access to the surgical site.
6. Remove the orange connector from the clam shell and insert the metal end into the connection port on the front of the console. Rotate the connector clockwise to the lock position. Once the connection is achieved, a green 'tick' will appear on the screen.

2. Connect Saline Bag(s)

It is recommended that full saline bag(s) are connected prior to commencing with the procedure.

CAUTION: Only spike the saline bag(s) once the hand piece has been connected to the console. Failure to do so may result in fluid leakage from the pump cartridge.

CAUTION: The system can be operated with either one or two saline bags. If only one bag is required, **leave the unused inflow line clamp closed** and the bag spike cap on.

CAUTION: DO NOT preheat the saline before use.

1. Ensure the inflow line clamp is closed.
2. Remove the sterile cover from the bag spike and insert into the saline supply bag. Repeat for the second bag if necessary.
3. Press the right arrow on the screen to proceed to the next step.

NOTE: The saline bag MUST be placed a minimum of 24in / 60 cm above the console.

NOTE: To ensure adequate saline supply is selected, consider the power setting to be used for the procedure and procedure length. To calculate the saline volume required, refer to the Flow Rates and Pressures table.

3. Connect waste canister

CAUTION: Place the waste canister onto a flat and stable surface to prevent the waste canister from tilting or falling.

1. Attach the waste evacuation tube (blue tip) to the waste canister.

CAUTION: DO NOT connect to a port containing a filter or to the VACUUM port. Ensure there is an additional open port on the waste canister lid, to prevent a pressure build-up inside the canister.

2. Ensure there are no kinks or other external obstructions in the tubes.

NOTE: The waste canister should be below the level of the hand piece during priming and debriding.

CAUTION: To avoid the canister overflowing, ensure the waste canister volume will contain the volume of saline used during the procedure.

3. Press the right arrow on the screen to complete the set-up.

CAUTION: Monitor the waste canister and ensure it is emptied to prevent overflowing.

4. Prime the Hand Piece

1. Remove the protective cover from the tip of the hand piece.
2. Initiate the priming sequence on the screen.
3. Power levels will automatically increase from 1 to 10.
4. Open the saline clamps.
5. While holding the hand piece at a safe distance, depress the foot pedal and observe a steady flow of saline at the distal tip of the hand piece.

NOTE: A visible saline flow down in the waste tube indicates priming is complete.

6. Release the foot pedal. Indicate that the priming is complete on the screen.

NOTE: Once the system has been primed with saline, do not allow the saline bag to empty. An empty bag can cause air to enter the system and require re-priming of the system.

5. Debriding

Once priming is complete the system is ready for debridement. To prevent saline splashing back into the eyes, avoid bringing the hand piece tip close to the eyes.

CAUTION: This device can cut soft tissue. Apply only to tissues and debris intended to be excised from the wound.

NOTE: For optimal results when debriding hard or leathery eschar resulting from burn injuries, it is recommended to first debride the eschar using sharp debridement techniques followed by the use of VERSAJET° III System to complete debridement or excision of the wound.

1. To begin debriding, begin at the lowest power setting and increase as necessary. The power setting can be adjusted using the UP and DOWN buttons on the foot pedal, or the + and – buttons on the screen. When the foot pedal is active the + and – buttons on the screen will be inactive.

WARNING: Increasing console power settings will lead to more aggressive tissue removal. Use caution near delicate vessels, structures and surrounding tissues.

WARNING: Empty waste canister before it is full.

2. While securely holding the hand piece, depress the foot pedal to activate the motor. A constant stream of saline will appear at the distal tip of the hand piece.
3. Position the distal tip over the area requiring debriding.
4. Release foot pedal before removing the hand piece from the wound.

NOTE: The VERSAJET° III PROCLINICAL Hand Piece has a 20 minutes continuous debridement time limit. The time counter is only active when the foot pedal is depressed and debridement is conducted. Once the 20 minutes are completed, if further debridement is required, a secondhand piece will need to be connected to the console.

NOTE: If leaking is observed at the connection interface to the console, replace with a new hand piece.

6. Removal of an obstruction in the evacuation orifice

If the evacuation orifice becomes blocked with foreign matter, a reduction in device efficiency or the presence of spray from the instrument tip may result.

To remove the obstruction:

1. Remove the hand piece from the wound site
2. Release the foot pedal and remove the obstruction with forceps.

NOTE: Avoid touching the opening in the high-pressure jet with forceps.

3. Once the obstruction is removed, depress the foot pedal and check for steady stream of sterile saline flow.
4. If the obstruction is not completely removed, repeat the hand piece set-up and system priming procedure or check that the waste evacuation tube is not pinched by forceps, stepped on or that the collection container is full.

7. Changing the Saline Bag(s)

1. *When using one saline bag:* If additional saline is required, attach an additional bag to the second line prior to the first bag emptying. Open the second saline line clamp prior to the first bag emptying.
   When using two bags: Open the second inflow line prior to the first bag emptying. Should additional saline be required for the debridement, ensure the clamp is closed prior to changing the bag.

NOTE: Monitor the saline levels during use to ensure the bags are replaced prior to emptying.

8. Replace Hand Piece

1. If a notification appears on the screen with instructions to replace the hand piece, please disconnect the saline bag(s), waste canister, and hand piece from the console.
2. Press 'OK' on the notification and proceed to set up a new hand piece.

9. End of procedure

1. After completing the procedure, disconnect the saline bags, waste canister, hand piece and foot pedal.
2. Discard the hand piece in accordance with your local healthcare facility's standard guidelines for biohazardous waste disposal.
3. Switch the device off by pressing the power button.
4. Disconnect the power supply cable.

Flow Rate and Pressures

Values provided in the table are typical values and are provided as guidance only. Actual values may vary.

Power Setting	VERSAJET° III Hand Piece	
	Flow Rate (mL / min)	Pressure (psi / bar)
1	82	1448/100
2	96	1962/135
3	110	2518/174
4	123	3139/216
5	137	3856/266
6	150	4635/320
7	167	5713/394
8	179	6549/452
9	189	7308/504
10	197	7950/548

Glossary of symbols

℞ only	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician		Do not re-use
			Caution
	Consult instructions for use	STERILE EO	Sterilized using ethylene oxide
	Do not use if package is damaged		Keep Away From Sunlight
	Keep dry		Temperature limitation

Product Availability

Part Number	Description
66802147	VERSAJET° III PRECISION Hand Piece (15°/14mm)
66802148	VERSAJET° III PRECISION Hand Piece (45°/14mm)
66802149	VERSAJET° III PRECISION Hand Piece (45°/8mm)
66802150	VERSAJET° III PROCLINICAL Hand Piece (45°/14mm)
66802151	VERSAJET° III PROCLINICAL Hand Piece (45°/8mm)

Technical support

For further information and troubleshooting guide, consult the VERSAJET° III Hydrosurgery System User Manual.

Contact Customer Care at 1-800-876-1261 (USA only) or local Smith+Nephew representative.

Smith & Nephew Medical Limited,
101 Hessle Road, Hull HU3 2BN England