

Product Safety Data Sheet

SMITH & NEPHEW WOUND MANAGEMENT PRODUCT SAFETY DATA SHEET

1. PRODUCT NAME/CODES: VersaJet Hydrosurgery System

50700	VersaJet Console 115 Volt
50750	VersaJet Console 230 Volt
50635	VersaJet EXACT Handpiece 15° 14mm Disposable Handpiece
50636	VersaJet EXACT Handpiece 45° 14mm Disposable Handpiece
50637	VersaJet EXACT Handpiece 45° 8mm Disposable Handpiece
52635	VersaJet Plus Handpiece 15° 14mm Disposable Handpiece
52636	VersaJet Plus Handpiece 45° 14mm Disposable Handpiece
52637	VersaJet Plus Handpiece 45° 8mm Disposable Handpiece

2. INTENDED USES:

The VersaJet Hydrosurgery System is intended to cut, ablate and remove tissue from wounds and to resect and remove material in various surgical procedures including wound debridement.

3. COMPOSITION:

The VersaJet Hydrosurgery System contains three basic components: the Disposable Handpiece Assembly, Console, and Foot Switch.

The Disposable Handpiece Assembly consists of the Handpiece, Pump Cartridge, and Hoses. The Pump Cartridge mounts onto a clamp assembly on the front of the Console; this connection provides the power to the Disposable Handpiece Assembly. The Foot Switch provides remote actuation of the Console.

There are two types of handpieces available: VersaJet EXACT and VersaJet Plus. Each of these handpieces comes in three geometric configurations.

4. PHYSICAL AND CHEMICAL PROPERTIES:

The Console includes a motor, pulley, drive linkage, printed circuit boards, electrical wiring and connectors all housed in a fire rated ABS /PVC enclosure. The Disposable Handpiece Assembly is comprised of stainless steel and other metals, ABS plastic, PVC tubing, Aramid braid (Kevlar), and various small components made of nylon, acetal, polypropylene, and viton. The lubricants, solvents, and adhesives used in manufacturing are Silicon fluid (12500 cps), Loctite #4011 (Ethyl Cyanoacrylate), and Cyclohexane.

5. HAZARD INFORMATION:

According to experience the product is considered to cause no adverse effects on health or the environment during normal handling and use.

This is not considered to be hazardous or toxic material.

When activated, the water jet will cut and is therefore a sharp hazard to the user. See section 10.

6. FIRST AID:

a) Inhalation	Not applicable
b) Skin	Not applicable
c) Eyes	Not applicable
d) Ingestion	Not applicable

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7. FIRE AND EMERGENCY MEASURES: Acrylonitrile Butadiene Styrene

The ABS case is a combustible material, which under certain conditions could be flammable if exposed to a heat source greater than 288°C. A heat source of greater than 102°C may cause dripping and flow of molten material.

If ignited, toxic fumes may be expelled including ammonia, aromatic and aliphatic hydrocarbon fractions, carbon monoxide, carbon dioxide and hydrogen cyanide. Therefore, appropriate self contained breathing apparatus should be worn when fighting a fire. Keep all personnel away from the fire.

Fire may be controlled with carbon dioxide and dry powder fire extinguisher. If fire is in a confined space, self contained breathing apparatus should be worn. As this is an electrical device water should not be used as an extinguishing medium if installed into the mains.

8. ACCIDENTAL RELEASE MEASURES:

Not applicable

9. HANDLING AND STORAGE PRECAUTIONS:

Store in a dry place, at a temperature above 4°C and below 52°C. Keep away from sources of ignition.

10. EXPOSURE CONTROLS/PERSONAL PROTECTION:

The system uses water at high pressure and the use of Cut/tear resistance surgical gloves, surgical mask and goggles are recommended.

11. STABILITY AND REACTIVITY:

See Section 9

12. TOXICOLOGICAL INFORMATION:

Not applicable

13. ECOLOGICAL INFORMATION:

Not applicable.

14. DISPOSAL:

Control disposal in accordance with local / national environmental waste guidelines for electrical medical devices.

15. TRANSPORT PRECAUTIONS:

Transport under the same conditions as handling and storage

16. REGULATORY INFORMATION:

Not applicable.

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17. ADDITIONAL INFORMATION:

Not applicable.

18. NAME, ADDRESS AND TELEPHONE NUMBER OF SUPPLIER:

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19. REFERENCE NUMBER, DATE OF ISSUE:

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