FLOW CONTROL SWITCH

INSTRUCTIONS FOR USE

INTENDED USE
The Merit Flow Control Switch is an angiographic accessory intended for use as an ON/OFF device for angiography and other high-pressure applications.

INTENDED PATIENTS
The Flow Control Switch is intended for use for patients requiring angiography or related procedures. The Flow Control Switch is not directly marketed for use in neonates or children.

INTENDED USER
The Flow Control Switch should be used by healthcare professionals who are trained in angiography or related procedures.

DEVICE DESCRIPTION
The flow control switch is a high pressure accessory device with a male luer lock fitting at one end, a threaded female luer lock fitting at the other end, and a sliding, top-mounted ON/OFF switch.

The device is a one-handed actuation locking shutoff of fluid flow when installed in line. Luer lock fittings on both ends allow for connection to catheters and tubes. The front (male luer) portion of the device is connected to a catheter or other applicable device. The rear (female luer) portion of the device is connected to a compatible luer lock connecting device.

CLINICAL BENEFITS
The indirect clinical benefit to the patient is the control of fluid flow through a device during procedures.

CONTRAINDICATIONS
None known.

PRECAUTIONS
1. Before using this device, there should be a thorough understanding of the technical principles, clinical applications and risks associated with angiography and percutaneous interventional procedures.
2. Prior to use carefully examine the unit to verify the device or sterile package has not been damaged in shipment.
3. Do not exceed 1,200psi/82bar/8274kPa in the ON position and 150psi/10bar/1034kPa in the OFF position.
4. After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
5. In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

POTENTIAL COMPLICATIONS

Arterial/Venous Thrombosis	Allergic Reaction (including anaphylaxis)
Cerebral Vascular Accident	Death
Embolism	Exposure to Biohazards
Hemorrhage	Infection
Myocardial Infarction	

INSTRUCTIONS FOR USE

CONNECT DEVICE AS FOLLOWS
1. Front portion (male luer) to catheter or other applicable device.
2. Rear portion (female luer) to a compatible luer lock connecting device.
3. Ensure all connections are tight.
4. Place device in desired ON/OFF position.

REUSE PRECAUTION STATEMENT
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go to the European database on medical devices (Eudamed), https://ec.europa.eu/tools/eudamed where it is linked to the basic UDI-DI. The basic UDI-DI for the Flow Control Switch device is 0884450BUDI461PX.

SYMBOL	DESIGNATION
	Do not use if package is damaged and consult instrutions for use.
	Non-Pyrogenic
MD	Medical Device
STERILE EO	Sterilized Using Ethylene Oxide
UDI	Unique Device Identifier
	Date of Manufacturer
	Consult Instructions for Use. For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, available within seven calendar days, call U.S.A. or EU Customer Service.
	Caution
REF	Catalog number
LOT	Lot number
	Use by date
	Single use
	Manufacturer
EC REP	Authorized Representative in the European Community
	Single sterile barrier system
	Do not resterilize
#	Contents
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Keep Dry
	Keep away from Sunlight

MERIT MEDICAL®

CE 2797

www.merit.com

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EC REP
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