English

Monitoring Life™

Floswitch™

INSTRUCTIONS FOR USE

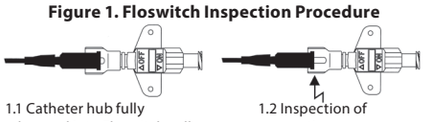
INTENDED USE
The Merit Floswitch™ is an accessory intended for use as an on/off device for control of fluid flow when connected to devices including infusion sets and catheters.

INDICATIONS FOR USE
The Merit Floswitch is indicated for use in patients undergoing fluid administration as part of therapeutic or diagnostic procedures.

USER / PATIENT / CLINICAL
User: Qualified nurses, clinicians and physicians
Patient: Pediatric and adult applications
Clinical: Hospitals or appropriate clinical environments

INSTRUCTIONS
This device may be attached to a luer hub of a central venous catheter.
1. As standard practice the catheter should be secured to the skin.
2. To attach the Floswitch, insert the Floswitch luer into the catheter hub. Tighten the rotating collar ensuring that 'hand tight' connection has been made and that the catheter hub is fully advanced into the Floswitch collar (see figure 1.1).
3. The Floswitch should be fixed in position by either suturing or taping the wings. The recommended procedure for taping is shown in figure 2.
4. The black markings indicate flow status. When visible the catheter is open and there is free flow. When covered, the catheter is closed.
5. Use aseptic technique and proper setup when handling the device.

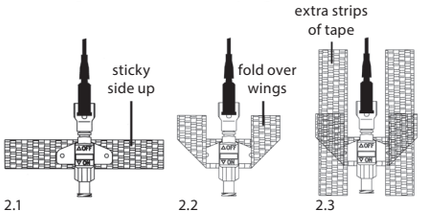
Figure 1. Floswitch Inspection Procedure



1.1 Catheter hub fully advanced into Floswitch collar

1.2 Inspection of connection necessary

Figure 2. Floswitch Taping Procedure



2.1 2.2 2.3

WARNINGS - FLOSWITCH PRODUCTS
1. The Floswitch should not be switched off (black marks covered) before the needle has been fully withdrawn. This applies to Floswitch introducers only.
2. The Floswitch must not be switched 'OFF' (black marks covered) until the guidewire has been fully withdrawn.
3. When the catheter is not in use for infusion or aspiration, the Floswitch must be switched off and a suitable luer cap locked into the hub.
4. When using an intermittent injection bung attached to a Floswitch, only use short needles. Ensure Floswitch is in 'ON' position prior to injecting or aspirating. Do not insert the needle more than 8 mm into the Floswitch.
5. As standard practice, the security of the luer connection must be checked routinely. This is essential when lubricious substances such as Intralipids are being used. This applies to Floswitch luer lock attachment only.

COMPLICATIONS
Risks associated with the use of this product include: Sepsis/infection, air emboli, soft tissue injury, inflammation, other illness and injury. For further information regarding complications, contact your Merit representative.

CLINICAL BENEFITS
- To control the flow of liquids (flow or no flow)

STORAGE CONDITIONS
Store in cool dry place away from direct sunlight.

STERILE and non-pyrogenic in unopened, undamaged package. For single use only. Check integrity of the individual package before use. After use, dispose of device in a manner consistent with standard protocols for waste disposal. Do not resterilize.

Device lifetime is 72 - 96 hours base on CDC & Joint Commission Intl (JCI) recommendation.

Re-use may lead to infection or other illness/ injury.

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.

For reordering information or assistance please contact local representative.

	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single use
	Do not resterilize
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution
	Keep Dry
	Keep away from sunlight
	Non-pyrogenic
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
STERILE EO	Sterilized using ethylene oxide
MD	Medical Device
	Single Sterile Barrier System
UDI	Unique Device Identifier
PHT DEHP DIBP DBP BBP	Does not Contain DEHP, DIBP, DBP, BBP
MR	MR Conditional Non-clinical testing demonstrated that the device is MR Conditional. Per ASTM F2503-13, an MR Conditional item is one with demonstrated safety in the MR environment within defined conditions. A patient with this device can be scanned safely in an MR system under the following conditions: • Static magnetic field of 1.5-Tesla and 3-Tesla, only • Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m) • Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode The information provided here should be used in conjunction with your institution's policies to evaluate the risks to patients and operators when using Floswitches™ in an MR environment.
	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 7 calendar days, call U.S.A. or EU Customer Service.
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog number
LOT	Batch code

CE 2797

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