

Instructions for Use

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Perfusate Bag – 10ml



Product number: OFM-BAG 10ml

consisting of:
10ml bag, protection cap,
injection port



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1 Overview



READ Instructions for Use before using the Perfusate Bag. ALWAYS follow the warnings, cautions, and notes throughout this document. If you have questions regarding the safe or correct use of the Perfusate Bag, please contact the American distributor:

BASi (<https://www.basinc.com/ask>)



U.S. PHONE NUMBER +1-800-845-4246

2 Intended Use

The Perfusate Bag is an accessory for the microperfusion pump (Type: MPP10x) to be used for performing microdialysis or microperfusion in laboratory animals, such as mice, rats, dogs, pigs, and primates.

The microperfusion pump is used to operate microdialysis or microperfusion catheters in the skin, subcutaneous adipose tissue or brain during pre-clinical trials.

For this purpose, a physiologically compatible liquid ('perfusate') is pumped out of the Perfusate Bag through a microperfusion catheter at a very low flow rate (0.1-10 $\mu\text{l}/\text{min}$) ('microperfusion'). Due to the open (membrane-free) exchange surface, the perfusate can absorb practically any substances in the surrounding environment. Afterwards, the collected sample fractions of the perfusate can be sent to the laboratory for analysis.

















CAUTION

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1. **ONLY USE** Perfusate Bag on laboratory animals or ex-vivo setups.
 2. **DO NOT** use on humans! This Perfusate Bag has **NOT** been approved for use on humans!
 3. **DO NOT** use Perfusate Bag on household pets and other non-laboratory animals.

3 Safety Information

3.1 Explanation of Symbols

Symbol	Meaning
	Designates the order number, which also represents the type designation for the Perfusate Bag.
	Lot number
	Date of production
	Name and address of manufacturer
	Always observe the Instructions for Use before using the Perfusate Bag.
	The Perfusate Bag is delivered Gamma irradiated and may only be used once, re-sterilization is not permitted.
	Do not use the Perfusate Bag if individual packaging is damaged.
	Store dry.
 4°C 40°C	Storage temperature must be between 4°C – 40°C.
	Here the irradiation point is attached, which indicates if Perfusate Bag was exposed (red = exposed).
	Identifies a warning statement that warns about the possibility of injury, death, or other serious adverse reaction associated with the use or misuse of the device.
	Additional safety instructions must be observed in the Instructions for Use.
	Used Perfusate Bag are biohazards and must be disposed accordingly.
	Wear sterile protective gloves while operating Perfusate Bag.

3.2 General Warnings and Safety Instructions



WARNING

1. **READ** Instructions for Use prior use.
2. **DO NOT** use on humans! The Perfusate Bag has **NOT** been approved for use on humans.
3. **DO NOT** use on household pets or other animals that are not laboratory animals. Perfusate Bags are designed **ONLY** for use in laboratory animals!
4. **ALWAYS** wear sterile disposable protective gloves when operating pump and accessories to avoid any contamination or risk of infection.
5. **ONLY** use the Perfusate Bag **ONCE!** **DO NOT** reuse, reprocess or sterilize. Reuse leads to the potential risk of serious injury and/or infection, which can result in death.
6. The Perfusate Bag is has been treated by Gamma Irradiation Processing. **DO NOT** use the Perfusate Bag, if the packaging is damaged.
7. **DO NOT** use the Perfusate Bag, if the label is missing or illegible.
8. **DO NOT** use the Perfusate Bag, if kinked or damaged.
9. **ONLY** use sterile aids for insertion.
10. **ONLY** use sterile, physiologically compatible fluids for perfusion.
11. When using electrical equipment (e.g. micro perfusion pump) in connection with the Perfusate Bag, the general electrical safety regulations for the use of electrical equipment must be considered.
12. **ALWAYS** observe animals throughout the application.
13. **KEEP** the Perfusate Bag in the packaging until used to prevent mechanical damage and to protect it from light.
14. **STORE** the Perfusate Bag under dry and dark conditions. **DO NOT** store the Perfusate Bag in a heavily contaminated environment.
15. **STORE** the Perfusate Bag between 4°C – 40°C.

4 Directions for Use

4.1 Included Parts of Perfusate Bag

Capacity of Perfusate Bag: 10ml

Dimensions: Height: 91mm (without connections), width: 30mm

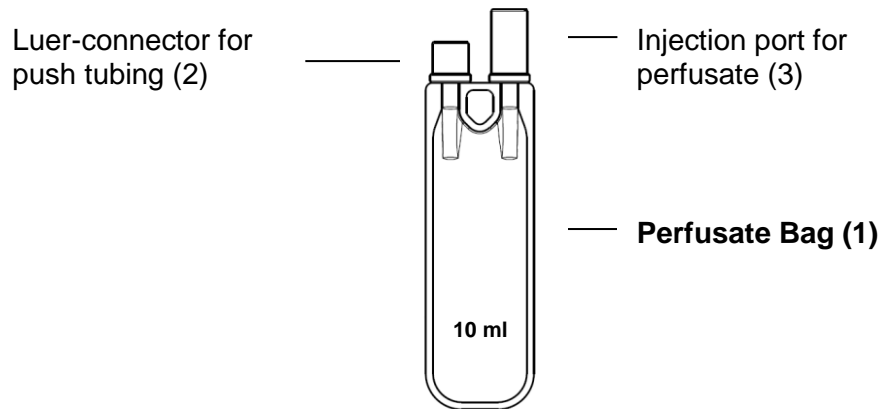


Figure 1: Included parts of Perfusate Bag:

(1) Perfusate Bag, (2) Luer-connector for push tubing, (3) Injection port for perfusate

4.2 Filling the Perfusate Bag (Step-by-Step)

1. Perfusate Bag is ready to be used when delivered.
2. Unpack tubing set and perfusate bag.
3. Remove red protection cap of perfusate bag by turning it counter clock wise. DO NOT remove injection port.



Figure 2: Remove red protection cap from the perfusate bag

4. Connect perfusate bag with the push tubing by turning the luer-connector clock wise.

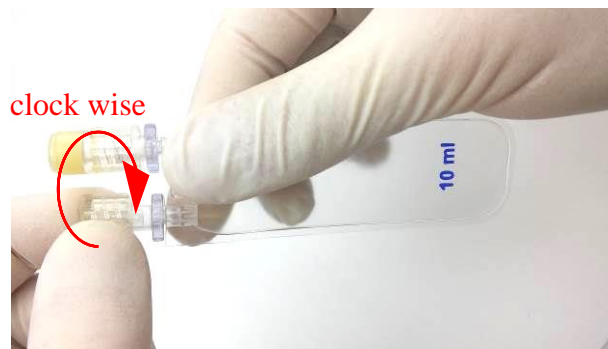


Figure 3: Connecting the perfusate bag via luer-connector with the push tubing

5. Fill the perfusate bag with a (sterile) syringe via the injection port.
6. Removal of air bubbles: Tap the Perfusate Bag with your finger while injection port is facing upwards. The air bubbles should then collect at the top of the bag near the injection port. Withdraw air bubbles with the same syringe that was used for filling.



Figure 4: Filling the perfusate bag via injection port



CAUTION

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- **DO NOT** pierce perfusate bag with the needle. Risk of contamination.
 - **DO NOT** pierce yourself with the needle. Risk of injury or infection.
 - **DO NOT** use aggressive fluids (alcohols, acids, bleaches, etc.) and hot fluids (>45°C) as perfusate.

7. Open the cover of the pump heads.
8. Insert tubing into pump heads as described in the Instructions for Use of the microperfusion pump.
9. Refill of perfusate: If refilling of the perfusate becomes necessary due to the study protocol, this can be done during operation of the pump. Simply refill Perfusate Bag with a (sterile) syringe via the injection port.

4.3 Connecting Perfusate Bag

Perfusate Bags can be connected as follows:

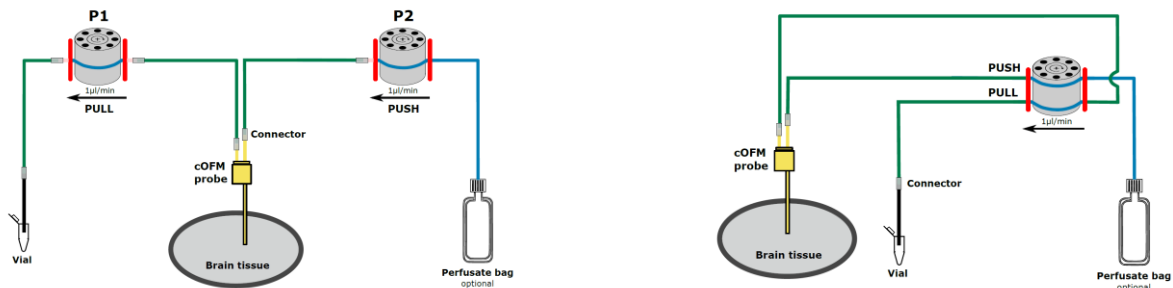


Figure 5a: Perfusate Bag connected to MPP10x – single channel use
b: Perfusate Bag connected to MPP10x – single channel use (Alternative)



BIOHAZARD

Used and removed Perfusate Bags are biohazards and must be disposed accordingly!

5 Combination with Other Products

The manufacturer recommends using the Perfusate Bag with the following products from the manufacturer JOANNEUM RESEARCH Forschungsgesellschaft m.b.H.:

- Microperfusion Pump MPP10x
- OFM Tubing Sets (single-/multi-channel)
- cOFM-P-X-Y
- a/d OFM-P-15
- Flanged Tubing Connector (inner diameter 0.6 to 0.8mm)
- Interconnecting Tubing (outer diameter 0.6 to 0.8mm)



CAUTION

- When using above-listed products with the Perfusate Bag, **ALWAYS** observe the Instructions for Use of the respective product!
- Use the Perfusate Bag with other manufacturers' products **AT OWN RISK!**