Instructions for Use

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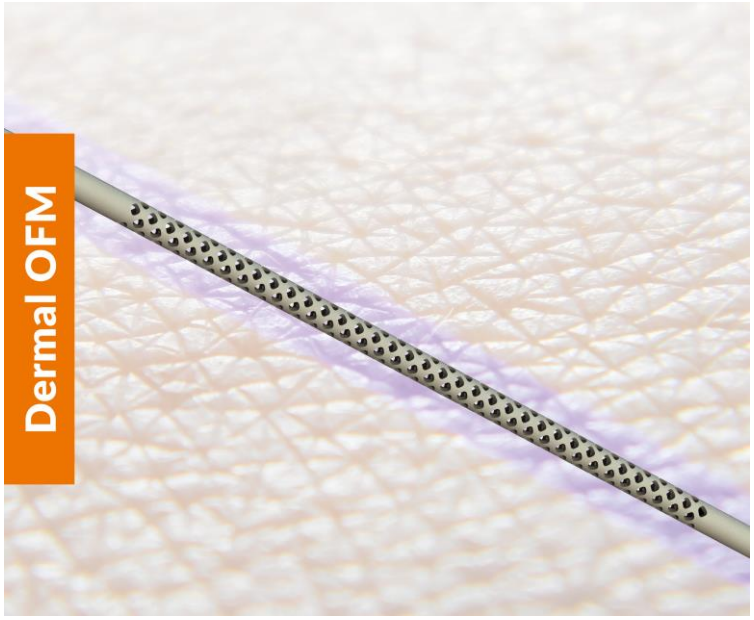
Linear OFM Probe for Skin and Adipose Tissue



Product number: a/d OFM-P-15

Patent number:

EP 2,326,379
EP 2,023,994
US 9,039,665

JOANNEUM RESEARCH Forschungsgesellschaft m.b.H.
Health-Institute for Biomedicine and Health Sciences
Leonhardstrasse 59
8010 Graz
Austria
Phone: +43-316-876-4000
Fax: +43-316-8769-4000
Email: ofm@joanneum.at

Table of Contents

1 Overview

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

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

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

2 Intended Use

The Linear OFM Probe is a minimally invasive linear-type probe for use in skin and subcutaneous adipose tissue in laboratory animals, such as mice, rats, dogs, pigs, and primates.

CAUTION

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

The Linear OFM Probe provides easy access to the target tissue. The Linear OFM Probe allows extracting fluid samples of the target tissue to allow analyzing its biochemical conditions by passing a physiologically compatible liquid (‘perfusate’) through the Linear OFM Probe at a very low flow rate (0.1 – 10µl/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.

3 Safety Information

3.1 Explanation of Symbols

Symbol	Meaning
	Designates the order number, which also represents the type designation for the Linear OFM Probe.
	Lot number
	Date of production
	Name and address of manufacturer
	Always observe the Instructions for Use before using the Linear OFM Probe.
	The Linear OFM Probe is delivered Gamma irradiated and may only be used once, re-sterilization is not permitted.
	Do not use the Linear OFM Probe if individual packaging is damaged.
	Store dry.
40°C  4°C	Storage temperature must be between 4°C – 40°C.
	Here the irradiation point is attached, which indicates if Linear OFM Probe 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 Linear OFM Probes are biohazards and must be disposed accordingly.
	Wear sterile protective gloves while operating Linear OFM Probe.

3.2 General Warnings and Safety Information

WARNING

1. **READ** Instructions for Use prior use.
2. **DO NOT** use on humans! The Linear OFM Probe has **NOT** been approved for use on humans**.**
3. **DO NOT** use on household pets or other animals that are not laboratory animals. Linear OFM Probes are designed **ONLY** for use in laboratory animals or ex-vivo setups!
4. **ALWAYS** wear sterile disposable protective gloves when operating pump and accessories to avoid any contamination or risk of infection.
5. **ONLY** use the Linear OFM Probe **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 Linear OFM Probe has been sterilized through Gamma Irradiation Processing. **DO NOT** use the Linear OFM Probe, if the packaging is damaged.
7. **DO NOT** use the Linear OFM Probe, if the label is missing or illegible.
8. **DO NOT** use the Linear OFM Probe, if kinked or damaged.
9. **ONLY** use sterile aids (guide cannula, acutenaculum, etc.) for insertion.
10. **DO NOT** pierce yourself with guide cannula during insertion. This can lead to the potential risk of serious injury and/or infection, which can result in death.
11. **ONLY** use sterile pens that are approved for medical use to mark entry and exit points for insertion.
12. Insert the Linear OFM Probe next to the marks to avoid introducing the pen color into the skin.
13. **ONLY** use sterile, physiologically compatible fluids for perfusion.
14. When using electrical equipment (e.g. micro perfusion pump) in connection with the Linear OFM Probe, the general electrical safety regulations for the use of electrical equipment must be considered.
15. **ALWAYS** observe the animals throughout the application.
16. **REMOVE** the Linear OFM Probe if there are signs of inflammation in the insertion area.
17. **ONLY** use the Linear OFM Probe for a maximum of 72 hours on animals.
18. **KEEP** the Linear OFM Probe in the packaging until used to prevent mechanical damage and to protect it from light.
19. **STORE** the Linear OFM Probe under dry and dark conditions. **DO NOT** store the Linear OFM Probe in a heavily contaminated environment.
20. **STORE** the Linear OFM Probe between 4°C – 40°C.

4 Directions for Use

4.1 Inserting the Linear OFM Probe Into the Skin or Adipose Tissue (Step-by-Step)

1. Disinfect the skin where the Linear OFM Probe shall be inserted.
2. Mark the entry and exit points with a sterile pen at a distance of ~30mm (Figure 1).

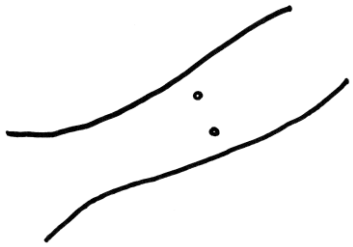


Figure 1: Mark entry and exit points ~30mm

3. Use a sterile guide cannula with a larger inside diameter than the outside diameter of the Linear OFM Probe (e.g., ID: 0.65mm).
4. Place the opened sterile inner packaging so that the opening is directly at the place of insertion. Using a sterile acutenaculum (needle holder), grasp the prepared sterile guide cannula and push it through the tissue until it protrudes 1cm from the skin. Avoid piercing directly through entry and exit points (slightly off). When inserting the guide cannula in the skin (dermis), the skin should be kept taut with the second hand. When inserting the guide cannula in the subcutaneous adipose tissue, it is recommended to form a slight skin fold with the second hand (Figure 2).

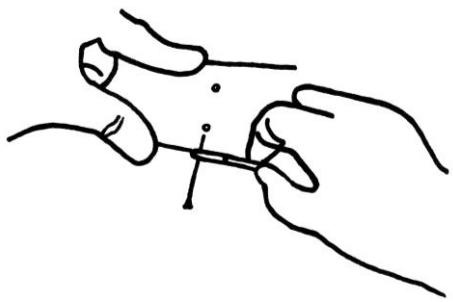


Figure 2: Insert guide cannula

5. Take the Linear OFM Probe and thread it carefully, beginning at the tip, through the guide cannula (Figure 3). Never touch or compress the exchange area of the Linear OFM Probe (area between the markings)!

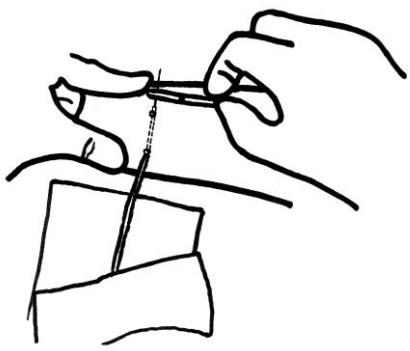


Figure 3: Insert Linear OFM Probe in guide cannula

6. Carefully remove the guide cannula. Position the Linear OFM Probe with its exchange area centered between the entry and exit points in the skin or adipose tissue, respectively. Pull in such a way that the insertion pathway and the Linear OFM Probe always form a straight line. With the second hand, hold tissue or skin tightened (Figure 4).

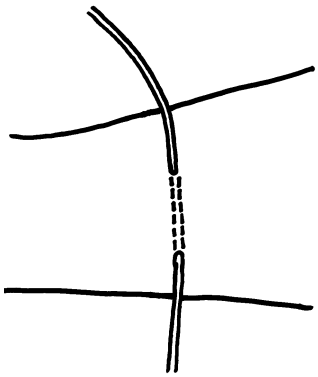


Figure 4: Remove guide cannula and place Linear OFM Probe centered

7. Seal the entry and exit points of the Linear OFM Probe with topical tissue adhesive (e.g. INDERMIL® flexifuze™).

4.2 Connecting the Linear OFM Probe (Step-by-Step)

Linear OFM Probe can be connected as follows:

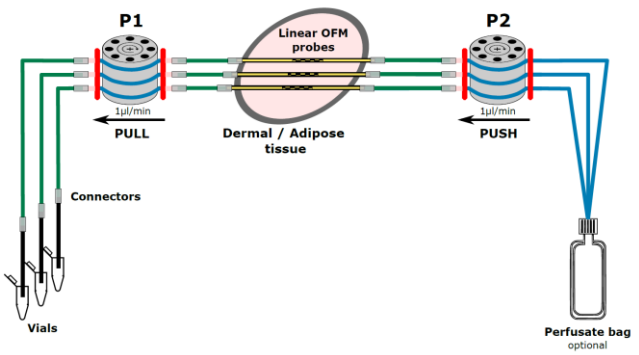
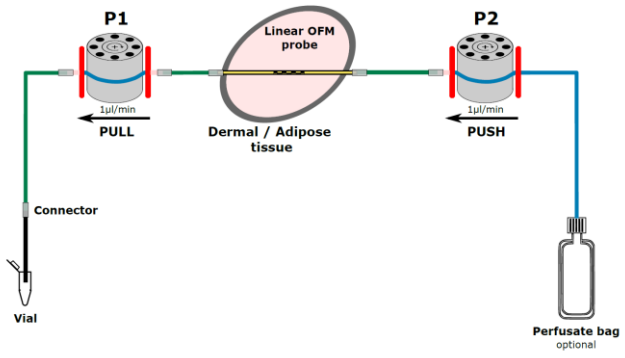


Figure 5a: Linear OFM Probe connected to MPP10x – multi channel use



b: Linear OFM Probe connected to MPP10x – single channel

1. Connect inflow (PUSH) to perfusate bag and flush (e.g. 10µl/min).
2. Connect inflow (PUSH) of the Linear OFM Probe via tubing to the perfusate bag.
3. Flush inflow (e.g. 10µl/min) while removing the guide wire.
4. Immediately connect outflow (PULL) of the Linear OFM Probe via tubing to sample container or sample collector.
5. Flush system (e.g. 10µl/min).
6. The connection of the Linear OFM Probe and the other components is described in detail in the Instructions for Use of the MPP10x pump. Always observe the instructions when using the MPP10x pump!
7. Apply strain relief to the tubing to avoid unintentional slipping or snagging.

4.3 Removing the Linear OFM Probe (Step-by-Step)

1. Remove the topical tissue adhesive.
2. Cut the Linear OFM Probe with sharp sterile scissors as close to an entry point as possible.
3. Before pulling the Linear OFM Probe out, make sure there are no sharp edges. Carefully pull the Linear OFM Probe out lengthwise (Figure 6). In case of resistance tighten the skin slightly.

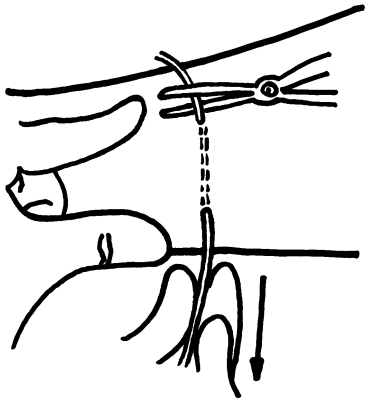


Figure 6: Removing the Linear OFM Probe

BIOHAZARD

Used and removed Linear OFM Probes are biohazards and must be disposed accordingly!

5 Combination with Other Products

The manufacturer recommends using the linear Linear OFM Probe with the following products from the manufacturer JOANNEUM RESEARCH Forschungsgesellschaft m.b.H.:

- Microperfusion Pump MPP10x
- OFM Tubing Sets (single-/multi-channel)
- OFM Perfusate Bag
- Topical Tissue Adhesive – INDERMIL® flexifuze™
- Guide Cannula – BBRAUN Sterican 0.90 x 70mm (20G x 2 ¾); minimal inner diameter: 0.65mm!
- Skin Marker – Edding 8020 special

CAUTION

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