

Microdialysis for Clinical Use

Portable Microdialysis Pumps



Microdialysis Analyzers



Sterile Microdialysis Catheters



μ dialysis

u

Introduction

The ability to diagnose a disease prior to the onset of clinical signs would markedly change the way medicine is practiced today and ultimately drive the improvement of patient care. Monitoring local tissue chemistry changes offer windows of opportunities that may lead to improved patient treatment and patient quality of life.

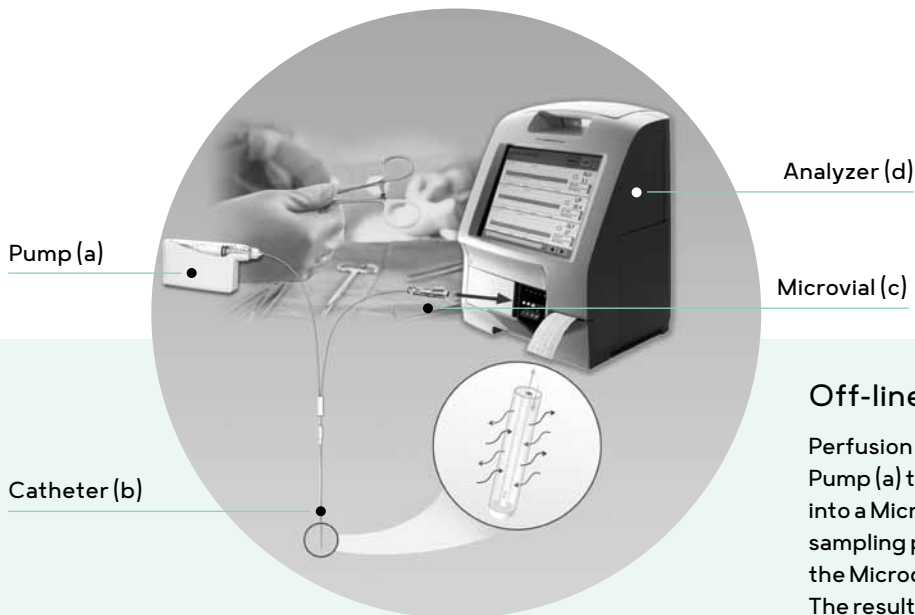
Today Microdialysis is being used throughout the world for clinical research as well as for routine monitoring of the human brain in neurointensive care and free flaps following reconstructive surgery. In Europe, microdialysis products are CE labeled according to the Medical Device Directive (MDD).

Some of the Microdialysis catheters have been cleared by the USFDA for the Neuromonitoring application. Other catheters in this catalogue are in the US considered investigational devices. Therefore they are limited by US law to investigational use, either only in Institutional Review Board (IRB) approved studies or, if applicable, FDA approved studies.

The idea of Microdialysis is simple: a thin dialysis tube is introduced into the tissue and perfused with a physiological salt solution. Molecules diffuse over the membrane and the perfusate gradually equilibrates with the composition of the interstitial fluid - analogous to a capillary perfused with blood. The technique of microdialysis has advanced well beyond its first application in the brain tissue of small rodents, and is continually finding new applications in larger animals and patients.

Traditional off-line Clinical Microdialysis consists of a microinfusion pump and a microdialysis catheter. Perfusion fluid is pumped through the catheter into a microvial where the sample is collected and then transferred to the analyzer. The analysis results are displayed as trend curves on the screen (see figure below).

The continuous MD System Loke provides Clinical Microdialysis data in real-time. A built in pump system perfuses the Microdialysis catheter, a biosensor is connected to the catheter outlet and enables continuous monitoring of Glucose and Lactate (Pyruvate monitoring is under development). For more information see page 34.



Off-line Microdialysis System

Perfusion Fluid flows from the Microdialysis Pump (a) through the Microdialysis Catheter (b) into a Microvial (c) for collection. After the sampling period, the microvial is transferred to the Microdialysis Analyzer (d) for the analysis. The results are then displayed on the screen.

61 Microdialysis Catheter

for metabolic research in liver tissue or intraperitoneal cavity

Ordering information

61 Microdialysis Catheter 4/pkg

61 Microdialysis Catheter
includes Splitable
Introducer SI-2 (4/pkg)

Ref. No.
8010226

Accessories

For product information on Microvials, Microvial racks, Syringes, Perfusion Fluid and Tunneling needle, see page 24-27.

Technical information

Membrane cut-off: 20 000 Dalton

	Material	Length	Ø
Inner Shaft	PUR**	310 mm	0.9 mm
Outer Shaft	PUR**	280 mm	1.5 mm
Membrane	PAES*	30 mm	0.6 mm
Inlet tubing	PUR**	400 mm	1.0 mm
Outlet tubing	PUR**	70 mm	1.0 mm

*polyarylethersulfone **polyurethane

CE 0413	CE marked according Medical Device Directive, 93/42/EEC
STERILE	Sterilized by β -radiation
2	Storage temperature: 4-25 °C
1	Single use only
MD	Shelf life: 2 years from manufacturing
	Medical Device

CAUTION: Investigational Device. Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

The 61 Microdialysis Catheter is intended to enable microdialysis in hepatic tissue or in the intraperitoneal cavity.

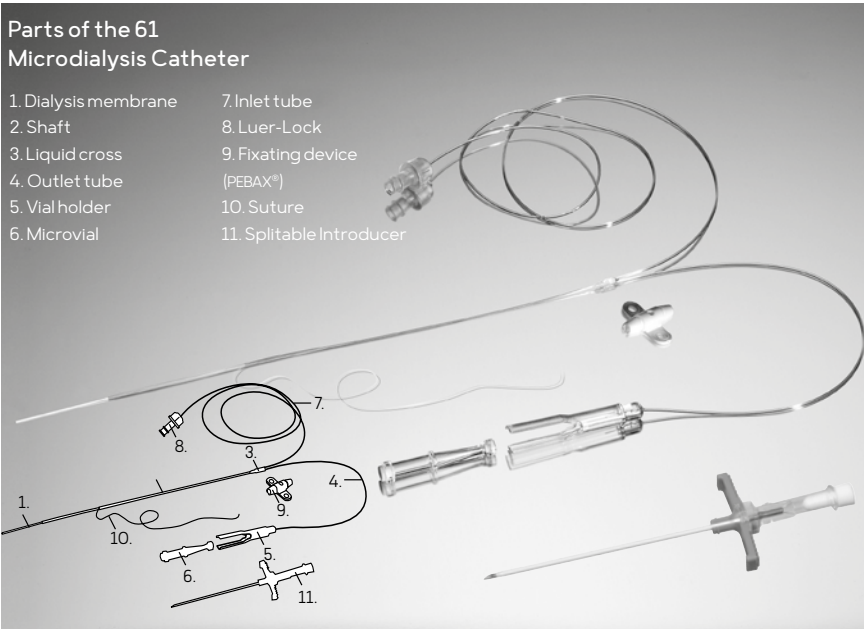
The 61 Microdialysis Catheter has a shaft length of 310 mm with a 30 mm dialysis membrane. It is introduced into the abdominal cavity via a tunneling needle during open surgery. When introduced in the Intraperitoneal cavity the membrane is sited near the anastomosis of the intestine. When inserted into the liver tissue it is achieved with the help of the enclosed splitable introducer.

The inlet tubing of the catheter is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. After collection the samples can be analyzed in the ISCUS^{flex} Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol, Glutamate and Urea or sent to the laboratory for further analysis.

- For monitoring in Hepatic tissue or Intraperitoneal cavity
- Easy to insert into the liver tissue with the splitable introducer
- 20.000 Dalton cut-off membrane

Parts of the 61 Microdialysis Catheter

- | | |
|----------------------|-----------------------------|
| 1. Dialysis membrane | 7. Inlet tube |
| 2. Shaft | 8. Luer-Lock |
| 3. Liquid cross | 9. Fixating device (PEBAX®) |
| 4. Outlet tube | 10. Suture |
| 5. Vial holder | 11. Splitable Introducer |
| 6. Microvial | |



61 High Cut-Off Microdialysis Catheter

for metabolic research in liver tissue or intraperitoneal cavity

The 61 High Cut-Off Microdialysis Catheter is intended to enable microdialysis in hepatic tissue or in the intraperitoneal cavity.

The 61 High Cut-Off Microdialysis Catheter has a shaft length of 310 mm with a 30 mm high cut-off dialysis membrane. It is introduced into the abdominal cavity via a tunneling needle during open surgery. When introduced in the Intraperitoneal cavity the membrane is sited near the anastomosis of the intestine. When inserted into the liver tissue it is achieved with the help of the enclosed splitable introducer.

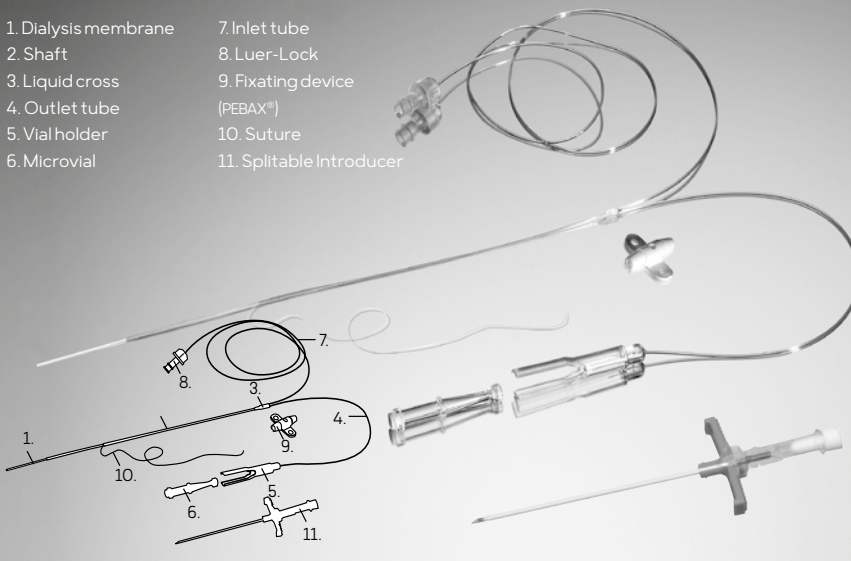
The inlet tubing of the catheter is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. After collection the samples can be analyzed in the ISCUS^{flex} Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol, Glutamate and Urea or sent to the laboratory for further analysis.

If ultrafiltration occurs when using this high cut-off membrane catheter, it is recommended to perfuse the catheter Perfusion fluid containing high molecular weight substances to balance colloidal osmosis (e.g. 30g Dextran 60/1000mL).

- For monitoring in Hepatic tissue or Intraperitoneal cavity
- Easy to insert into the liver tissue with the splitable introducer
- 100.000 Dalton Cut-off membrane allows monitoring of e.g cytokines.

Parts of the 61 High Cut-Off Microdialysis Catheter

- | | |
|----------------------|--------------------------|
| 1. Dialysis membrane | 7. Inlet tube |
| 2. Shaft | 8. Luer-Lock |
| 3. Liquid cross | 9. Fixating device |
| 4. Outlet tube | (PEBAX®) |
| 5. Vial holder | 10. Suture |
| 6. Microvial | 11. Splitable Introducer |



Ordering information

61 High Cut-Off Microdialysis Catheter 4/pkg

61 High Cut-Off Microdialysis Catheter, includes Splitable Introducer SI-2 (4/pkg)

Ref. No.
8050191

Accessories

For product information on Microvials, Microvial racks, Syringes, Perfusion Fluid and Tunneling needle, see page 24-27.

Technical information

Membrane cut-off: 100 000 Dalton

	Material	Length	Ø
Inner Shaft	PUR**	310 mm	0.9 mm
Outer Shaft	PUR**	280 mm	1.5 mm
Membrane	PAES*	30 mm	0.6 mm
Inlet tubing	PUR**	400 mm	1.0 mm
Outlet tubing	PUR**	70 mm	1.0 mm

*polyarylethersulfone **polyurethane



CE marked according Medical Device Directive: 93/42/EEC

STERILE

Sterilized by β -radiation



Storage temperature: 4-25 °C



Single use only



Shelf life: 2 years from manufacturing



Medical Device

CAUTION: Investigational Device. Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

63 Microdialysis Catheter

for use in liver, resting skeletal muscle and adipose tissue

Ordering information

63 Microdialysis Catheter	
4/pkg	
63 Microdialysis Catheter, 60/10	Ref. No. 8010509
includes Splitable Introducer	
63 Microdialysis Catheter, 40/30	8010514
includes Splitable Introducers	

Accessories

For product information on Microvials, Microvial racks, Syringes, Perfusion Fluid and Splitable Introducer, see page 24-27.

Technical information

Membrane cut-off: 20 000 Dalton

	Material	Length (mm)		Ø
		8010509 60	8010514 40	
Shaft	PUR**	60	40	0.9 mm
Membrane	PAES*	10	30	0.6 mm
Inlet tubing	PUR**	600	600	1.0 mm
Outlet tubing	PUR**	220	220	1.0 mm

*polyarylethersulfone **polyurethane

CE 0413	CE marked according Medical Device Directive, 93/42/EEC
STERILE	Sterilized by β -radiation
Storage temperature: 4-25 °C	
Single use only	
Shelf life: 2 years from manufacturing	
MD	Medical Device

CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

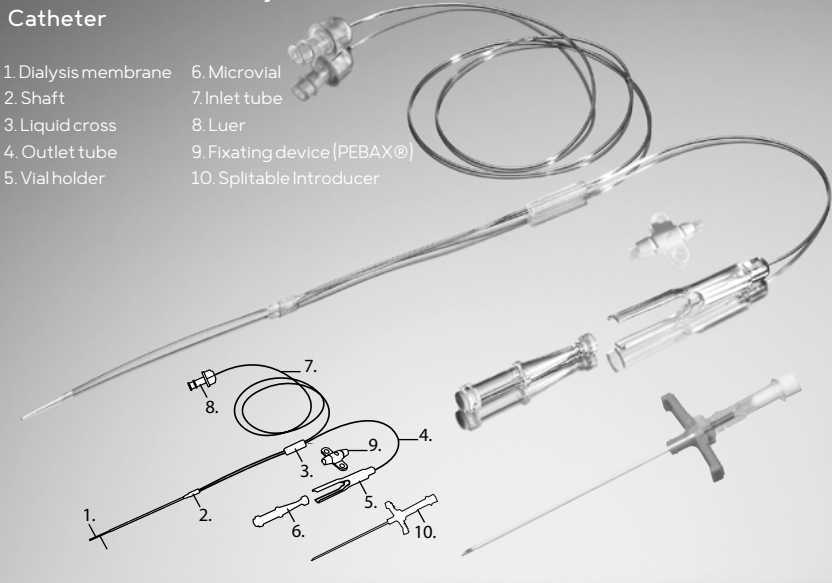
63 Microdialysis Catheter is intended to enable microdialysis in subcutaneous adipose tissue, resting skeletal muscle or in hepatic tissue during open surgery.

It is available in two different membrane and shaft lengths for the different applications. The catheter is easily introduced into the tissue with a splitable introducer (included) and can be implanted for several days.

The catheter's inlet tubing is connected to a Microdialysis pump and the outlet tubing ends with a microvial holder where the sample is collected into microvials. The samples can be analyzed in the ISCUS^{flex} Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol, Glutamate and Urea or sent to the laboratory for further analysis.

- Metabolic monitoring in deep buried flaps, subcutaneous adipose tissue, resting skeletal muscle or hepatic tissue
- Gold tip for location by CT scan
- Easy insertion with enclosed Splitable Introducer

Parts of the 63 Microdialysis Catheter



66 Linear Microdialysis Catheter

for use in skin, adipose, and resting skeletal muscle tissue

66 Linear Microdialysis Catheter is intended to enable microdialysis in skin, adipose and resting skeletal muscle tissues.

It is minimally invasive and available with either 20,000 or 100,000 Daltons cut off membrane. The 66 is suitable for many research applications: metabolic research, pharmacokinetic and pharmacodynamic studies or monitoring inflammatory processes in vivo.

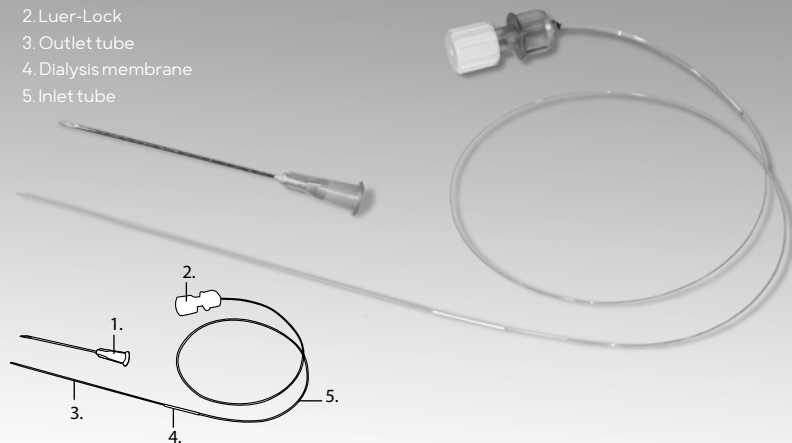
Insertion into the tissue is easily done with the help of a small needle introducer. The unique patented linear design makes the catheter robust and safe to use for several days. If ultrafiltration occurs when using the high cut off membrane catheter, we recommend perfusing the catheter with a fluid containing high molecular weight substances to balance colloidal osmosis (e.g. 30g Dextran 60/1000mL).

The samples can be analyzed in the ISCUS^{flex} Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glutamate, Glycerol and Urea or sent to the clinical laboratory for various analyses by methods such as ELISA or HPLC.

- Available with 20 000 or 100 000 Dalton cut-off
- Unique Linear Microdialysis Catheter for clinical use

Parts of the 66 Linear Microdialysis Catheter

1. Introducer needle 21 G, 50 mm
2. Luer-Lock
3. Outlet tube
4. Dialysis membrane
5. Inlet tube



Ordering information

66 Linear Microdialysis Catheter 4/pkg

	Ref. No.
66 Linear Catheter, 30 mm, 20kD, incl.introducer	8010650
66 High Cut-Off Linear Catheter, 30 mm, 100kD, incl.introducer	8010651
66 Linear Catheter, 10 mm, 20kD, incl.introducer	8010670
66 High Cut-Off Linear Catheter, 10 mm, 100kD, incl.introducer	8010671

Accessories

For product information on Perfusion Fluid and Syringes, see page 25-26

Technical information

Membrane cut-off: 20 000 Dalton
High Cut Off membrane: 100 000 Dalton

	Material	Length (mm)		Ø
Membrane	PAES*	8010650/51 30	8010670/71 10	0.5 mm
Inlet tubing	PAES*	400	400	0.38 mm
Outlet tubing	PUR**	100	100	0.38 mm

*polyarylethersulfone **polyurethane

CE 0413 CE marked according Medical Device Directive, 93/42/EEC

STERILE Sterilized by β -radiation



Storage temperature: 4-25 °C



Single use only



Shelf life: 2 years from manufacturing



Medical Device

CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

67 Intravenous Microdialysis Catheter

for blood or CSF monitoring

Ordering information

67 IV Microdialysis Catheter 4/pkg	
67 IV Microdialysis Catheter 46/10, includes Introducer	Ref. No. 8050090
67 IV Microdialysis Catheter 46/20, includes Introducer	8050091
67 IV Microdialysis Catheter 46/30, includes Introducer	8050092
67 IV Microdialysis Catheter 130/10, includes Introducer	8050093

Accessories

For product information on Microvials, Microvial racks and Syringes see page 24-25.

Technical information

Membrane cut-off: 20 000 Dalton

	Material	Length (mm)				Ø
		8050090	8050091	8050092	8050093	
Shaft	PUR**	46	46	46	130	0.9 mm
Membrane	PAES*	10	20	30	10	0.6 mm
Inlet tubing	PUR**	200	200	200	200	1.0 mm
Outlet tubing	PUR**	45	45	45	45	1.0 mm

*polyarylethersulfone **polyurethane



CE marked according Medical Device Directive, 93/42/EEC



Sterilized by β -radiation



Storage temperature: 4-25 °C



Single use only



Shelf life: 2 years from manufacturing



Medical Device

CAUTION: Investigational Device Limited by United States Law to Investigational Use.
To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

67 IV Microdialysis Catheter is intended to enable microdialysis in the peripheral venous system or of the Cerebrospinal Fluid (CSF) via an External Ventricular Drain (EVD) for up to three days .

The clean samples and possibility for frequent sampling make it ideal for research. Small substances diffuse into the catheter reflecting accurate concentrations in blood or Cerebral Spinal Fluid (CSF).

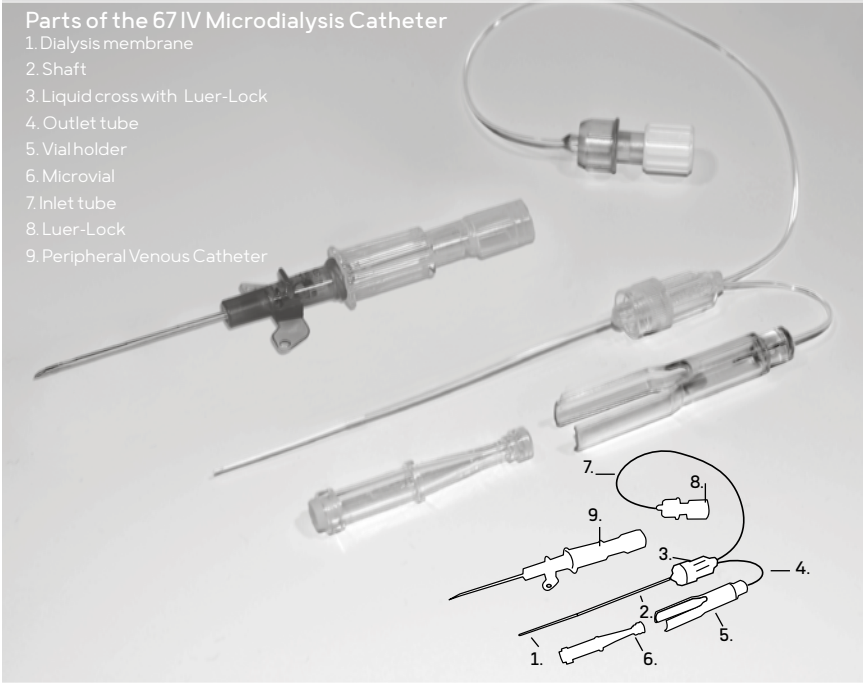
When used in vein, the catheter should be perfused with a physiologic solution containing the anticoagulant dalteparin sodium to avoid clotting. When monitoring in CSF drain the 67 IV Microdialysis catheter is inserted into a Stop cock connector that is attached to the outflow of a CSF drain pump e.g. LiquoGuard®

The catheter forms a complete system together with the 106 or 107 Microdialysis Pump and the ISCUS^{flex} Microdialysis Analyzer. The catheter is also excellent for monitoring the free concentrations of drugs in blood during pharmacokinetic and pharmacodynamic studies.

- For blood or CSF monitoring for up to 72 hours
- Easy insertion in vein, using a standard peripheral venous catheter

Parts of the 67 IV Microdialysis Catheter

1. Dialysis membrane
2. Shaft
3. Liquid cross with Luer-Lock
4. Outlet tube
5. Vial holder
6. Microvial
7. Inlet tube
8. Luer-Lock
9. Peripheral Venous Catheter



70 Brain Microdialysis Catheter

for use in brain tissue

70 Brain Microdialysis Catheter is intended to enable microdialysis of the extracellular (interstitial) fluid of the brain tissue.

A selection of this model of catheters is available with different membrane and shaft lengths suitable for stereotaxic as well as manual implantation.

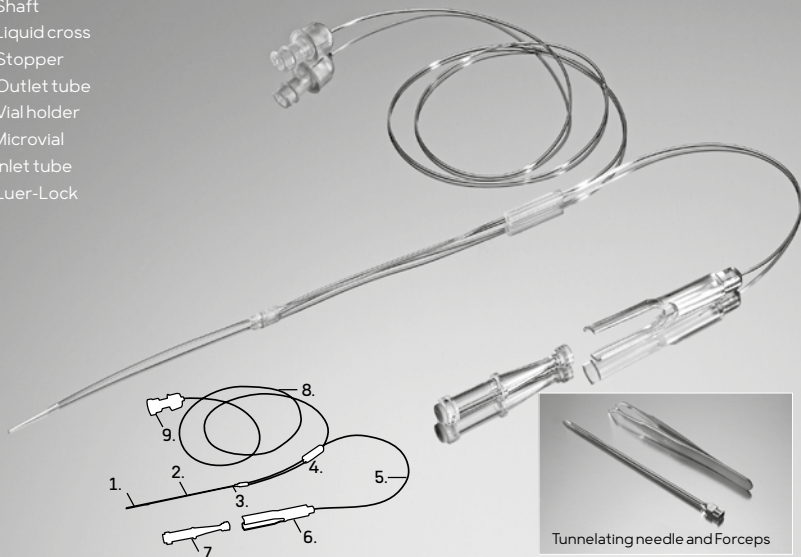
When manually implanted in the brain, the 70 Brain Microdialysis Catheter can be tunneled under the scalp and then inserted into the brain tissue through a hole drilled in the skull bone with the help of non-crushing forceps. The tip of the catheter has a gold thread, which makes it visible on a CT-scan to easily determine its position in vivo.

The catheter inlet tubing is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. The samples can be analyzed in the ISCUS^{flex} Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol and Glutamate or sent to the laboratory for further analysis.

- Implanted via tunnelation technique
- With gold tip, visible on CT

Parts of the 70 Brain Microdialysis Catheter

1. Dialysis membrane
2. Shaft
3. Liquid cross
4. Stopper
5. Outlet tube
6. Vial holder
7. Microvial
8. Inlet tube
9. Luer-Lock



10mm membrane sizes are cleared for use in the USA as part of the neuromonitoring system.

CAUTION: All other uses for that catheter and the others noted below (20 and 30 mm membranes) are not FDA cleared and therefore in the USA may only be used with IRB approval or with an IDE from the FDA.

Ordering information

70 Brain Microdialysis Catheter 4/pkg

	Ref. No.
70 Brain MD Catheter, 60/10	P000049
70 Brain MD Catheter, 60/20	P000080
70 Brain MD Catheter, 60/30	P000081
70 Brain MD Catheter, 100/10	P000050
70 Brain MD Catheter, 90/20	P000051
70 Brain MD Catheter, 80/30	P000052

Accessories

Ref. No. P000055 Tunneling needle

Ref. No. P00005 Forceps

For product information on Microvials, Microvial racks, Syringes, Perfusion Fluid, Tunneling needle and Forceps, see page 24-27.

Technical information

Membrane cut-off: 20 000 Dalton

	Material	Length (mm)			Ø
		P000049	P000080	P000081	
Shaft	PUR**	60	60	60	0.9mm
Membrane	PA*	10	20	30	0.6mm
Inlet tubing	PUR**	600	600	600	1.0mm
Outlet tubing	PUR**	220	220	220	1.0mm
		P000050	P000051	P000052	
Shaft	PUR**	100	90	80	0.9mm
Membrane	PA*	10	20	30	0.6mm
Inlet tubing	PUR**	600	600	600	1.0mm
Outlet tubing	PUR**	220	220	220	1.0mm

*polyamide **polyurethane

CE 0413	CE marked according Medical Device Directive, 93/42/EEC
STERILE R	Sterilized by B-radiation
	Storage temperature: 4-25 °C
	Single use only
	Shelf life: 2 years from manufacturing
MD	Medical Device

70 Microdialysis Bolt Catheter

for use in brain tissue

Ordering information

70 Microdialysis Bolt Catheter

4/pkg

70 Microdialysis Bolt Catheter
130/10

Ref. No.

P000131

Accessories

For product information on Microvials, Microvial racks, Syringes and Perfusion Fluid, see page 24-26.

Technical information

Membrane cut-off: 20 000 Dalton

	Material	Length	Ø
Shaft	PUR**	130 mm	0.9 mm
Membrane	PA*	10 mm	0.6 mm
Inlet tubing	PUR**	600 mm	1.0 mm
Outlet tubing	PUR**	220 mm	1.0 mm

* polyamide ** polyurethane



CE marked according Medical Device Directive, 93/42/EEC

STERILE

Sterilized by β -radiation



Storage temperature: 4-25 °C



Single use only



Shelf life: 2 years from manufacturing



Medical Device

70 Microdialysis Bolt Catheter is intended to enable microdialysis of the extracellular (interstitial) fluid of the brain tissue.

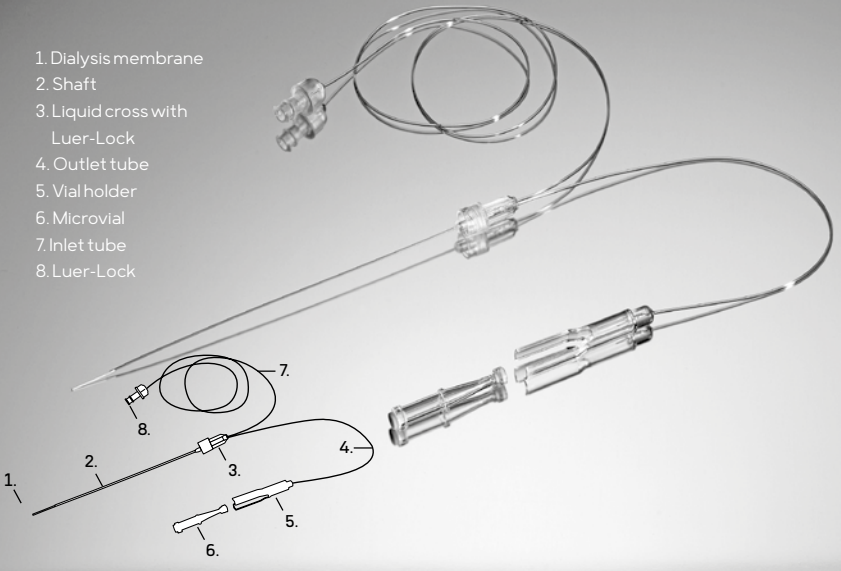
The Luer-Lock fitting on the shaft of the catheter connects to a port in an Intracranial access bolt from Integra (IM3) or Raumedic (Neurvent 2 L). The catheter's steel reinforcement prevents flow obstruction when the compression screw of the bolt is tightened. The shaft length of the microdialysis catheter is 130 mm and the dialyzing membrane length is 10 mm.

The catheter inlet is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. The samples can be analyzed in the ISCUS^{flex} Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol and Glutamate or sent to the laboratory for further analysis.

The catheter is FDA-cleared for use in humans as a part of the Neuromonitoring System

- Implanted through a lumen in an intracranial access bolt from Integra or Raumedic
- With gold tip, visible on CT

Parts of the 70 Microdialysis Bolt Catheter



71 High Cut-Off Brain Microdialysis Catheter

for use in brain tissue

71 High Cut-Off Brain Microdialysis Catheter is intended to enable microdialysis of the extracellular (interstitial) fluid of the brain tissue.

The large pore size membrane of this catheter allows diffusion of molecules such as cytokines and other inflammatory markers. To avoid ultrafiltration we recommend perfusing the catheter with Perfusion Fluid CNS Dextran.

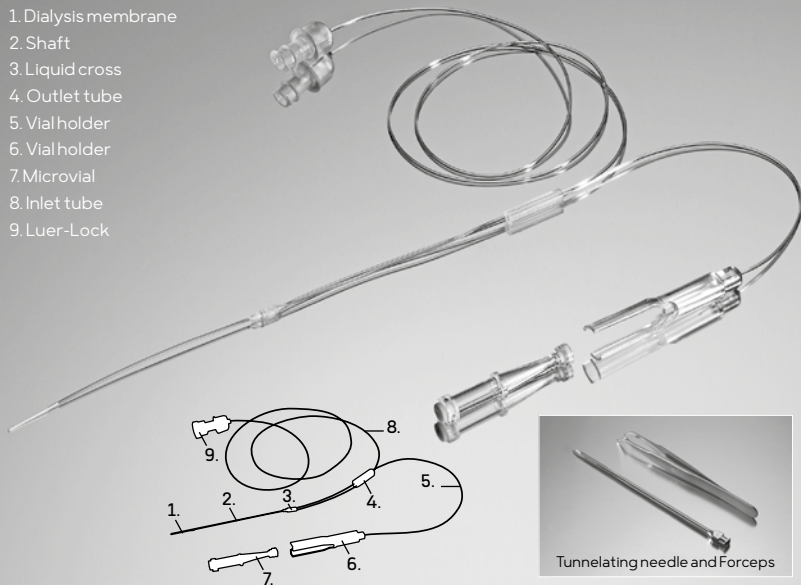
The High Cut-Off Brain Microdialysis Catheter can be tunneled under the scalp and then inserted into the brain tissue through a hole drilled in the skull bone with the help of non-crushing forceps. The tip of the catheter has a gold thread, which makes it visible on a CT-scan to easily determine its position in vivo.

The catheter inlet tubing is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. The samples can be analyzed in the ISCUS^{flex} Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol and Glutamate or sent to the laboratory for further analysis.

- Implanted via tunneling technique
- 100.000 Dalton Cut-off dialysis membrane
- With gold tip, visible on CT

Parts of the 71 High cut-off Brain Microdialysis Catheter

1. Dialysis membrane
2. Shaft
3. Liquid cross
4. Outlet tube
5. Vial holder
6. Vial holder
7. Microvial
8. Inlet tube
9. Luer-Lock



Tunneling needle and Forceps

Ordering information

71 High Cut-Off Brain Microdialysis Catheter 4/pkg
Ref. No. **8010320**

71 High Cut-Off Brain MD Catheter, 8010331
60/10

71 High Cut-Off Brain MD Catheter, 8010331
60/20

71 High Cut-Off Brain MD Catheter, 8010337
60/30

Accessories

Ref. No. P000055 Tunneling needle

Ref. No. P00005 Forceps

For product information on Microvials, Microvial racks, Syringes, Perfusion Fluid, Tunneling needle and Forceps, see page 24-27.

Technical information

Membrane cut-off: 100 000 Dalton

	Material	Length (mm)			Ø
		8010320	8010331	8010337	
Shaft	PUR**	60	60	60	0.9 mm
Membrane	PA*	10	20	30	0.6 mm
Inlet tubing	PUR**	600	600	600	1.0 mm
Outlet tubing	PUR**	220	220	220	1.0 mm

*polyarylethersulfone **polyurethane

CE 0413	CE marked according Medical Device Directive, 93/42/EEC
STERILE	Sterilized by β -radiation
	Storage temperature: 4-25 °C
	Single use only
	Shelf life: 2 years from manufacturing
MD	Medical Device

CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

71 High Cut-Off Microdialysis Bolt Catheter

for use in brain tissue

Ordering information

71 High Cut-Off Microdialysis Bolt Catheter 4/pkg

71 High Cut-Off Microdialysis Bolt Catheter 130/10
Ref. No. **8010954**

Accessories

For product information on Microvials, Microvial racks, Syringes and Perfusion Fluid, see page 24-25.

Technical information

Membrane cut-off: 100 000 Dalton

	Material	Length	Ø
Shaft	PUR**	130 mm	0.9 mm
Membrane	PAES*	10 mm	0.6 mm
Inlet tubing	PUR**	600 mm	1.0 mm
Outlet tubing	PUR**	220 mm	1.0 mm

*polyarylethersulfone**polyurethane

CE 0413

CE marked according Medical Device Directive, 93/42/EEC

STERILE

Sterilized by β -radiation



Storage temperature: 4-25 °C



Single use only



Shelf life: 2 years from manufacturing



Medical Device

CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

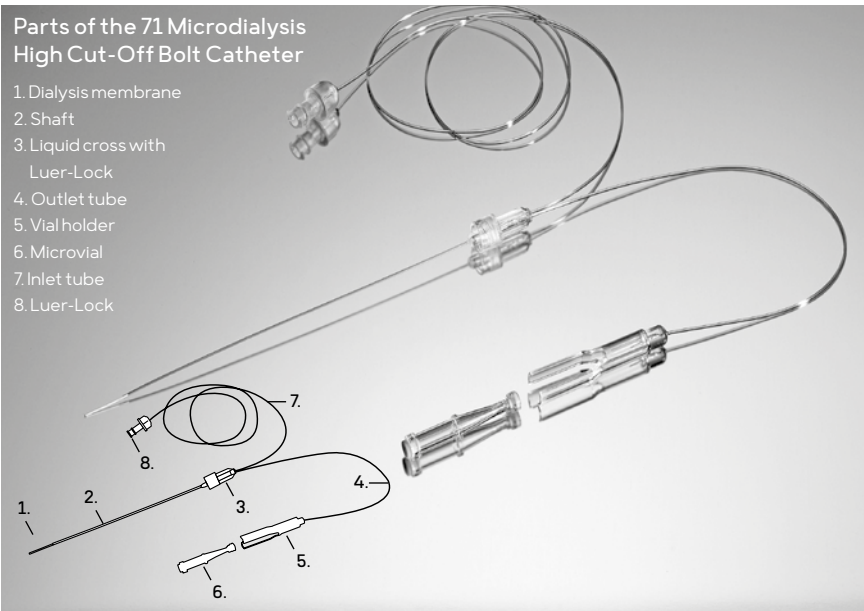
The 71 High Cut-Off Microdialysis Bolt Catheter is intended to enable microdialysis of the extracellular (interstitial) fluid of the brain tissue.

The Luer-Lock fitting on the shaft of the catheter connects to a port in an Intracranial access bolt from Integra (IM3) or Raumedic (Neurvent 2 L). The catheter's steel reinforcement prevents flow obstruction when the compression screw of the bolt is tightened. The shaft length of the microdialysis catheter is 130 mm and the dialyzing membrane length is 10 mm.

The large pore size membrane of this catheter allows diffusion of molecules such as cytokines and other inflammatory markers. We recommend perfusing the catheter with Perfusion Fluid CNS Dextran to avoid ultra-filtration.

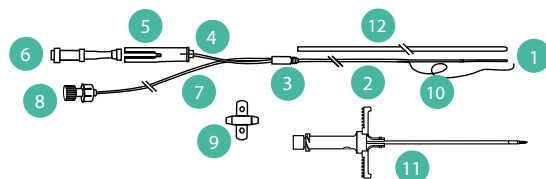
The catheter inlet is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. The samples can be analyzed in the ISCUS^{flex} Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol and Glutamate or sent to the laboratory for further analysis.

- Implanted through a lumen in an intracranial access bolt from Integra or Raumedic
- With gold tip, visible on CT
- 100.000 Dalton Cut-off dialysis membrane



u

61/61 High Cut-Off Microdialysis Catheter for implantation in liver tissue

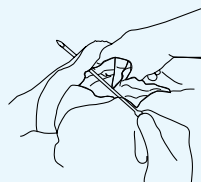


- | | |
|----------------------|-----------------------------|
| 1. Dialysis membrane | 7. Inlet tube |
| 2. Shaft | 8. Luer-Lock connection |
| 3. Liquid cross | 9. Fixating device (PEBAX®) |
| 4. Outlet tube | 10. Suture |
| 5. Vial holder | 11. Splitable Introducer |
| 6. Microvial | 12. Protection tube |

STEP BY STEP

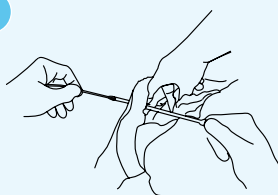
The following procedure shall be performed by a by a surgeon under aseptic conditions.

1



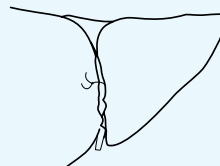
Introduce the tunneling needle lateral to the rectus muscle, preferably in the linea semilunaris, from the inside of the abdominal wall going out through the skin.

2



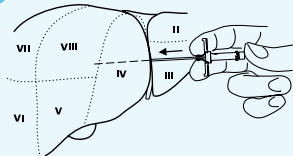
Insert the catheter, with the protective tubing on, through the tip of the tunneling needle.

3



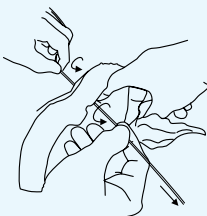
Place a 6-0 resorbable suture in the falciform ligament

4



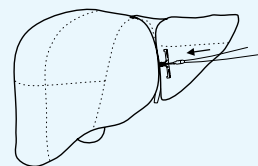
Insert the introducer in the middle of the falciform ligament, in direction to segment IV and VIII as close to the suture in the ligament as possible.

5



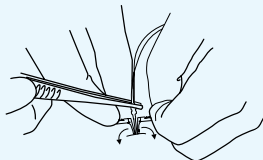
Unscrew the protective tubing on the catheter by turning it counterclockwise.

6



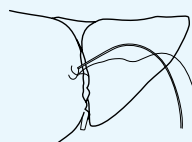
Remove the needle from the splitable introducer. Carefully insert the catheter.

7



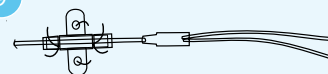
Grasp the tabs of the splitable tube (three hands needed) and pull the tabs apart, away from the indwelling catheter, until the tube splits down its entire length and is removed in two pieces.

8



Keep holding the catheter in place with the forceps. Tie the suture already placed in the falciform ligament to the suture of the catheter. Tie the catheter as tightly as possible to the ligament. Cut off the excess suture material.

9



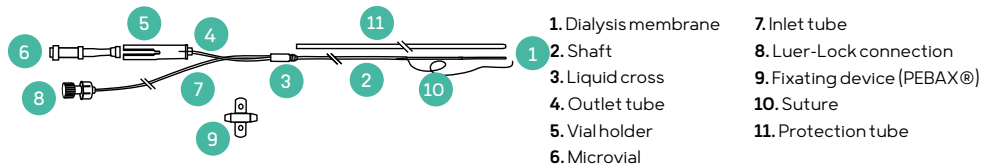
Place the fixation device (white plastic wing) close to the insertion site and secure it to the catheter by suturing over the grooves/indentations.

Suture the fixation device to the skin through the two holes.

Put a protective bandage over the insertion site, e.g. Tegaderm®, OpSite® or similar.

61/61 High Cut-Off Microdialysis

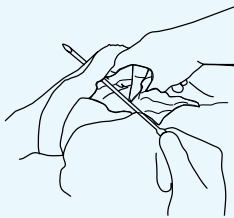
for research in intraperitoneal cavity



STEP BY STEP

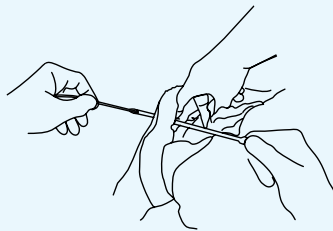
The following procedure shall be performed by a by a surgeon under aseptic conditions.

1



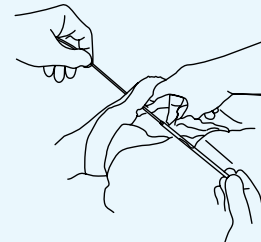
Introduce the tunneling needle lateral to the rectus muscle, preferably in the linea semilunaris, from the inside of the abdominal wall going out through the skin.

2



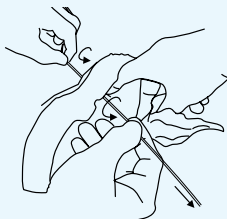
Insert the catheter, with the protective tubing on, through the tip of the tunneling needle.

3



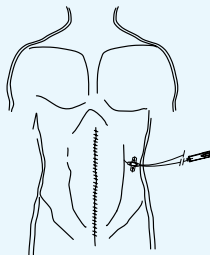
Withdraw the Tunneling needle.

4



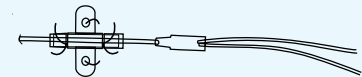
Unscrew the protective tubing on the catheter.
Place the membrane of the catheter close to the anastomosis or in the region of interest.

5



Place the fixation device (white plastic wing) close to the insertion site and secure it to the catheter by suturing over the grooves/indentations.

6

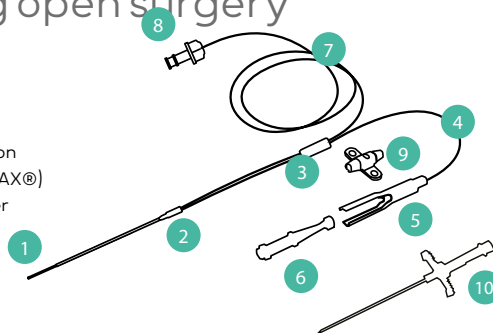


Suture the fixation device to the skin through the two holes.

63 Microdialysis Catheter

for resting skeletal muscle, subcutaneous adipose tissue and research in liver during open surgery

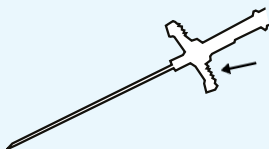
1. Dialysis membrane
2. Shaft
3. Liquid cross
4. Outlet tube
5. Vial holder
6. Microvial
7. Inlet tube
8. Luer-Lock connection
9. Fixating device (PEBAX®)
10. Splitable Introducer



STEP BY STEP

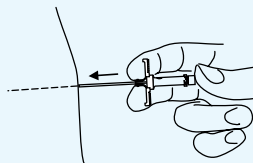
The following procedure shall be performed by a physician or a nurse under aseptic conditions.

1



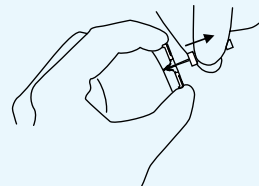
Break the handles of the Splitable Introducer before insertion to avoid damaging the tissue.

2



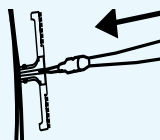
Insert the Introducer completely to the handle of the splitable tube into the tissue.

3



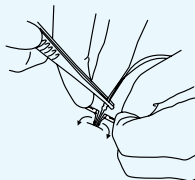
Remove the Introducer needle carefully while keeping the splitable tube in position. Do not reinsert the introducer needle after withdrawal.

4



Carefully insert the Microdialysis Catheter into the splitable tube. **Do not touch the white membrane of the catheter.**

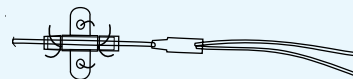
5



Grasp the tabs of the splitable tube (three hands needed) and pull the tabs apart, away from the indwelling catheter, until the tube splits down its entire length.

If needed, carefully anchor the catheter. Please use the fixation devices included in the package.

6

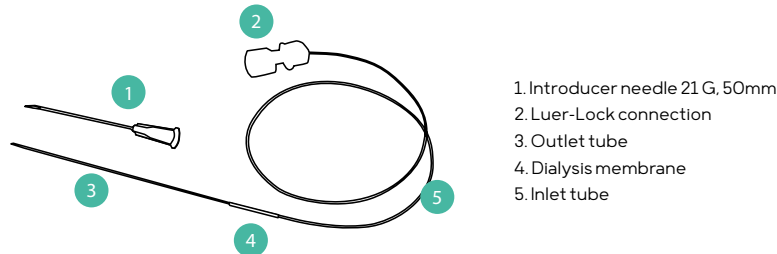


If needed the Microdialysis Catheter can also be fixated to the skin by sutures around the stopper on the catheter.

Cover the insertion site with a protective bandage.

66 Linear Microdialysis Catheter

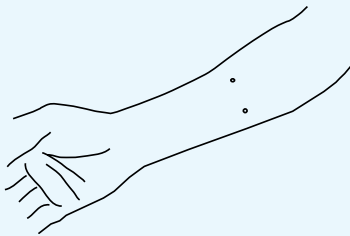
for use in skin, adipose, and resting skeletal muscle tissue



STEP BY STEP

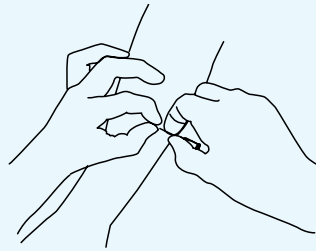
The following procedure shall be performed by a physician or a nurse under aseptic conditions.

1



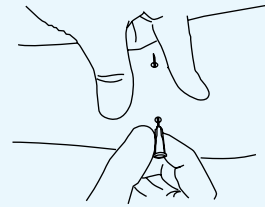
Make marks for catheter entrance and exit holes with circles.

2



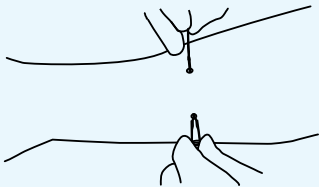
Take the introducer cannula and insert it through the center of the circle marking the catheter exit.

3



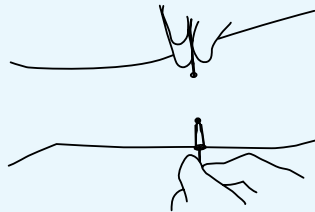
Continue through the skin to the center of the marked catheter entrance hole. Avoid penetration of actual markings.

4



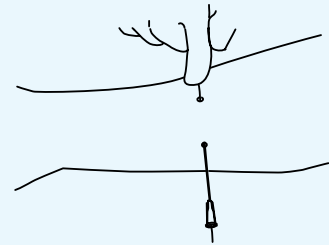
Remove the catheter from the protective tube and guide the catheter gently into the sharp end of the introducer cannula.

5



Push it carefully through the introducer cannula until it appears at the opposite side of the cannula and continue until the membrane is in position. Important: **Be very gentle when inserting the membrane into the introducer cannula.**

6

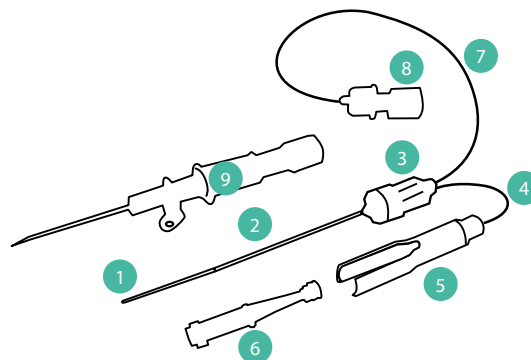


When the catheter and membrane is in position, the introducer cannula is removed, after which the catheter is fixed to the skin.

67 IV Microdialysis Catheter

for monitoring peripheral blood
or CSF drain

1. Dialysis membrane
2. Shaft
3. Liquid cross with Luer-Lock connector
4. Outlet tube
5. Vial holder
6. Microvial
7. Inlet tube
8. Luer-Lock connection
9. Peripheral Venous Catheter (PVC)



STEP BY STEP

The following procedure shall be performed by a physician or a nurse under aseptic conditions.

1 Insertion in peripheral vein

Connect the inlet tubing of the 67 IV MD catheter to the syringe and place it in a 106/107 Pump. Close the lid to start the pump.

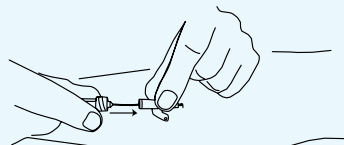
Fig1



Insert the peripheral venous catheter (PVC) delivered with 67 IV Microdialysis catheter in a peripheral vein according to normal hospital routines (Fig1). Observe that the PVC delivered with the 67 IV Microdialysis catheter must be used. Flush the PVC with a saline solution.

2

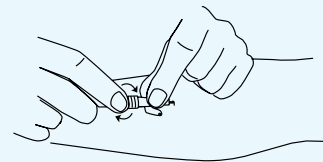
Fig 2



Unscrew the protective tubing and remove it from the 67 IV MD catheter. Insert 67 IV MD Catheter through the Peripheral venous catheter (Fig 2). **Be careful when inserting the Microdialysis catheter so the white dialysis membrane does not get damaged.**

3

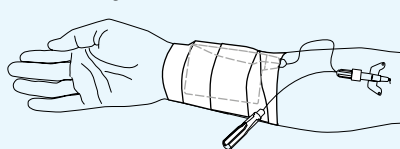
Fig 3



Fixate the 67 IV MD Catheter by attaching the Luer-lock of the Microdialysis catheter to the Luer-lock of the Peripheral venous catheter. (Fig 3).

4

Fig 4



Attach the pump to the patient by a bandage or similar (fig 4).

Insertion in CSF Drain

Connect the inlet tubing of the 67 IV MD catheter to the syringe and place it in a 106/107 Pump. Close the lid to start the pump. Insert and connect the 67 IV Microdialysis Catheter Luer-lock to a Stop cock connector, **be careful when inserting the Microdialysis catheter so the white dialysis membrane does not get damaged.**

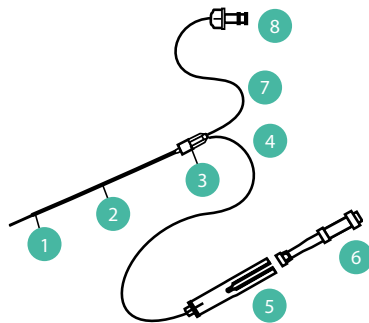
Connect the Stop cock connector to a CSF Drain out-flow from a CSF drain pump e.g. LingoGuard®.

It is recommended to use the shorter version of the 67 Microdialysis Catheter (Ref 8050090) to ensure that the catheter fits to the Stop cock connector.

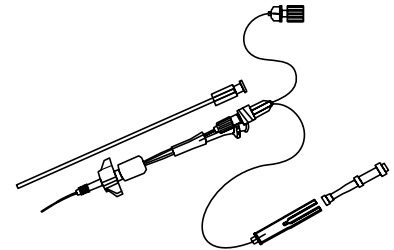
Find more information in the Reference Publication:
Microdialysis monitoring of CSF parameters in severe traumatic brain injury patients: a novel approach.
Frontiers in Neurology, September 2014.

70 /71 Microdialysis Bolt Catheter

for microdialysis in brain tissue,
percutaneous implantation



1. Dialysis membrane
2. Shaft
3. Liquid cross with Luer-Lock™ Connection
4. Outlet tube
5. Vial holder
6. Microvial
7. Inlet tube
8. Luer-Lock connection

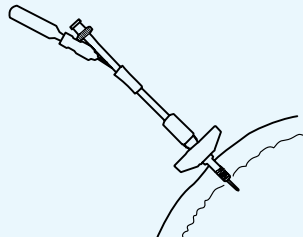


The 70 /71 Microdialysis Bolt Catheter connected to the Intracranial Access Bolt Kit (|| NeuroVent 2L from Raumedic or IM3 from Integra).

STEP BY STEP

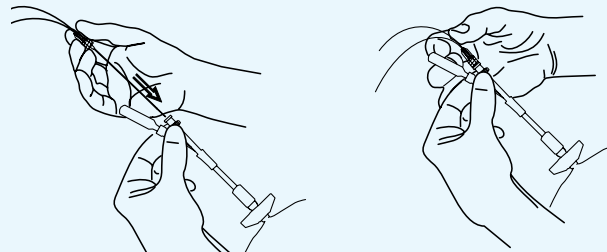
The following procedure shall be performed by a physician or a nurse under aseptic conditions.

1



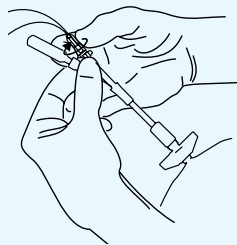
The Intracranial Access Bolt Kit (NeuroVent 2L from Raumedic or IM3 from Integra) fixed to the skull.

2



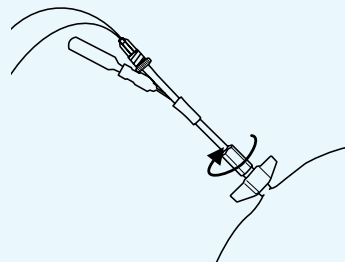
Remove the protection tube from the Microdialysis catheter. Insert the catheter in the microdialysis port of the bolt. Be careful not to damage the white dialysis membrane

3



Fix the catheter at the Luer Lock.

4

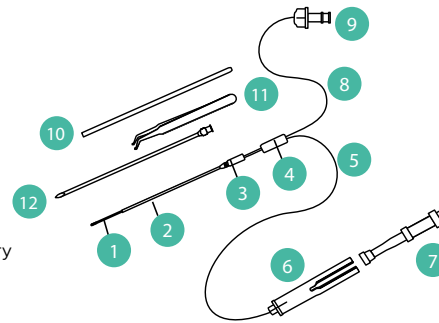


Tighten the compression screw.

70/71 Brain Microdialysis Catheter

for microdialysis in brain tissue. Implantation during surgery.

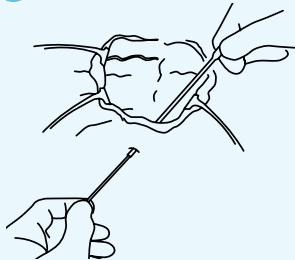
- | | |
|----------------------|----------------------------------|
| 1. Dialysis membrane | 7. Microvial |
| 2. Shaft | 8. Inlet tube |
| 3. Liquid cross | 9. Luer-Lock connection |
| 4. Stopper | 10. Protection tube |
| 5. Outlet tube | 11. Forceps - accessory |
| 6. Vial holder | 12. Tunneling needle - accessory |



STEP BY STEP

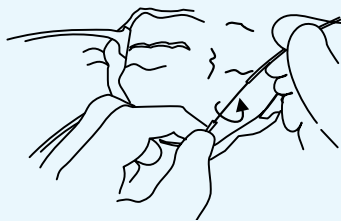
The following procedure shall be performed by a neurosurgeon under aseptic conditions.

1



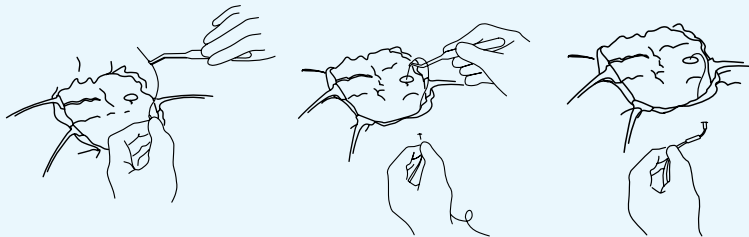
Tunnelate from the wound out through the scalp. Pass the catheter through the tunneling tube. Withdraw the tunneling needle

2



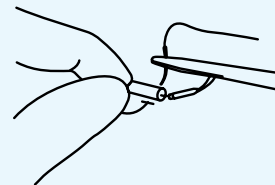
Remove the protection tube by unscrewing it from the liquid cross.

3



Grip the catheter just proximal to the membrane with the forceps. **Do not touch the white membrane of the catheter.** Pass it into the brain tissue through a hole made in the meninges. **Make sure not to get in contact with the meninges or brain tissue with the forceps.**

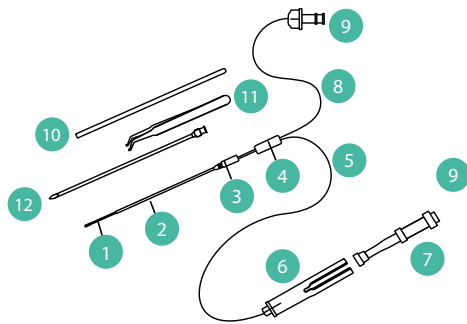
4



Stretch the catheter inlet and outlet tubing to externalize the excess and fix it firmly to the scalp by suturing around the stopper.

70/71 Brain Microdialysis Catheter

for microdialysis in brain tissue,
percutaneous implantation

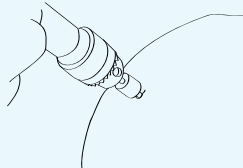


1. Dialysis membrane
2. Shaft
3. Liquid cross
4. Stopper
5. Outlet tube
6. Vial holder
7. Microvial
8. Inlet tube
9. Luer-Lock connection
10. Protection tube
11. Forceps - accessory
12. Tunneling needle - accessory

STEP BY STEP

The following procedure shall be performed by a neurosurgeon under aseptic conditions.

1



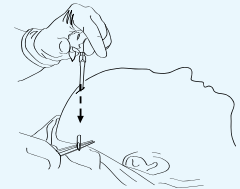
Drill a small hole.

2



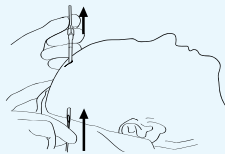
Perforate the meninges (including the Pia Mater).

3



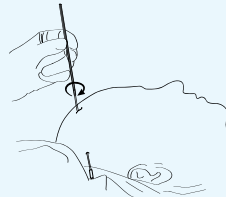
Create a tunnel under the skin using the tunneling needle direction from the drilled hole.

4



Insert the 70/71 Brain Microdialysis catheter into the beveled end of the tunneling needle, then remove the tunneling needle.

5

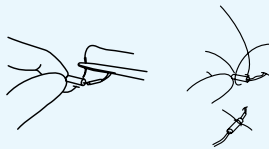


Unscrew the protection tube from the catheter.

6



Insert the catheter with the forceps through the hole made in the meninges. Do not touch the white membrane of the catheter with the forceps. Make sure not to get in contact with the meninges or brain tissue with the forceps.



Stretch the catheter inlet and outlet tubing to externalize the excess and fix it firmly to the scalp by suturing around the stopper.

106 Microdialysis Pump

a portable, fixed-flow, battery-operated pump

Ordering information

106 Microdialysis Pump	
106 Microdialysis Pump	Ref. No. P000003
Accessories	
MD Pump Kit, Peripheral Tissue	8003790
MD Pump Kit, Brain Tissue	8003791
106 Syringe, 20/pkg	8010191
Battery, 2x3 V	8001788
Perfusion Fluid, T1, 5 mL, 10/pkg	P000034
Perfusion Fluid, CNS, 5 mL, 10/pkg	P000151
Perfusion Fluid, CNS Dextran, 7.5 mL, 2/pkg	P000151

Technical information

Normal Flow rate:	Fixed, 0.3 µL/min
Flush flow:	15 µL/min
Dimension:	90 x 50 x 20 mm
Weight:	70g (incl. Battery)
Battery:	6V Silver oxide
Casing:	ABS plastic, splash proof
Operating temp:	+5 to +40°C
Alarms:	Error, Low battery

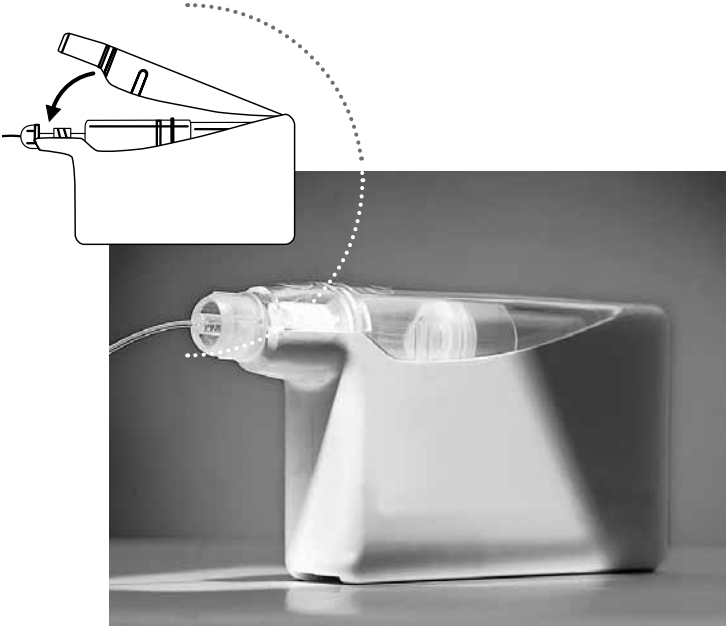
CE 0413	CE marked according Medical Device Directive, 93/42/EEC
Heart icon	Defibrillation-proof type CF applied part
IPX4	Protection class, protected against dripping water
ETL icon	ETL-listed product. Conforms to ES-60601-1:2005+A1 and CSA C22.2 #6061-1:2014 Ed.3
MD icon	Medical Device

The 106 Microdialysis Pump has been developed to function together with Microdialysis Catheters from M Dialysis.

It is a portable, battery-driven, microprocessor-controlled syringe pump which is very easy to use.

The 106 Syringe, filled with 2.5 mL of a sterile perfusion fluid and connected to a Microdialysis catheter, is placed in the carriage of the pump. When the lid is closed, the pump automatically starts a flush sequence (15 µL/min) for the first 5 minutes to fill the lines. Thereafter the flow rate decreases automatically to 0.3 µL/min. Colored LEDs indicate function, enabling the user to easily oversee the operation.

- Portable, small and lightweight
- Easy to handle
- Self-controlled with LED function signals
- Splash proof



107 Microdialysis Pump

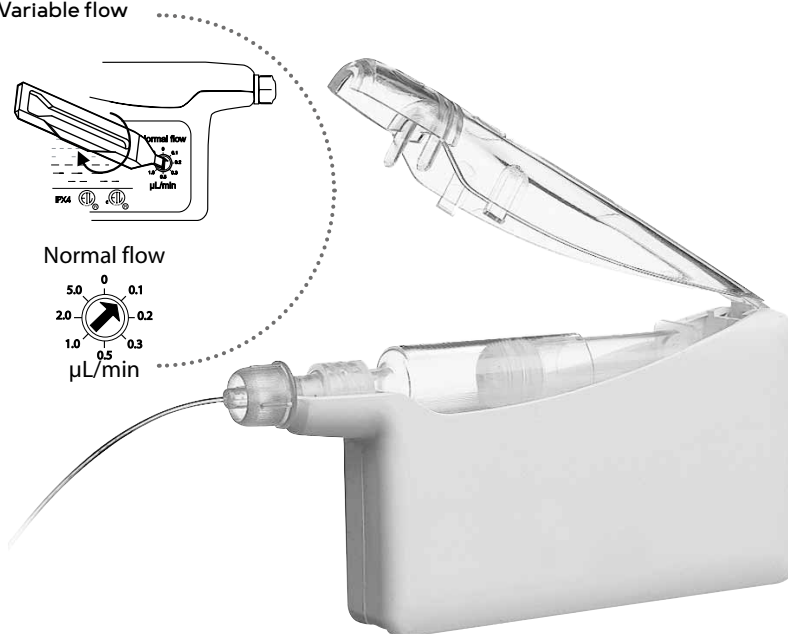
a portable, adjustable flow, battery-operated pump

The 107 Microdialysis Pump is a unique syringe pump with flexibility in flow rate that enables the user to change the flow for different purposes: low flow rate for high recovery of low molecular weight substances in a tissue, or high flow rate for more frequent sampling intervals. The operating flow is adjustable to eight different settings: 0, 0.1, 0.2, 0.3, 0.5, 1.0, 2.0 and 5.0 $\mu\text{L}/\text{min}$.

The pump has been developed to function together with Microdialysis Catheters from MDialysis.

The 106 Syringe is filled with 2.5 mL of sterile perfusion fluid, connected to the microdialysis catheter and then placed in the pump. When the pump lid is closed, a 5-minute flush cycle begins and is followed by an automatic decrease to the pre-set operating rate. Colored LEDs indicate function, enabling the user to easily oversee the operation.

- Portable, small and lightweight
- Easy to handle
- Self-controlled with LED function signals
- Splash proof
- Variable flow



Ordering information

107 Microdialysis Pump

107 Microdialysis Pump	Ref. No. P000127
------------------------	----------------------------

Accessories

MD Pump Kit, Peripheral Tissue	8003790
MD Pump Kit, Brain Tissue	8003791
106 Syringe, 20/pkg	8010191
Battery, 2x3 V	8001788
Perfusion Fluid, T1, 5 mL, 10/pkg	P000034
Perfusion Fluid, CNS, 5 mL, 10/pkg	P000151
Perfusion Fluid, CNS Dextran, 7.5 mL, 2/pkg	P000151

Technical information

Normal Flow rate:	Variable, 0.1-5 $\mu\text{L}/\text{min}$, 8 settings
Flush flow:	15 $\mu\text{L}/\text{min}$
Dimension:	90 x 50 x 20 mm
Weight:	70g (incl. Battery)
Battery:	6V Silver oxide
Casing:	ABS plastic, splash proof
Operating temp:	+5 to +40°C
Alarms:	Error, Low battery

CE 0413

CE marked according Medical Device Directive, 93/42/EEC



Defibrillation-proof type CF applied part

IPX4

Protection class, protected against dripping water



ETL-listed product. Conforms to ES-60601-1:2005+A1 and CSA C22.2 #6061-1:2014 Ed.3

MD

Medical Device

CAUTION: Investigational Device Limited by United States Law to Investigational Use.

To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

Microvials and Microvial Racks

accessories/ consumables for microdialysis catheters and analyzer

Ordering information

Microvials	Ref. No.
Microvials, 250/pkg	P000001
Microvial Racks	
Microvial Rack, 12/pkg	P000028
Microvial Racks, Sterile	
Microvials in a rack, 12 x 4	P000154

CE 0413

CE marked according Medical Device Directive, 93/42/EEC

STERILE R

Sterilized by β -radiation



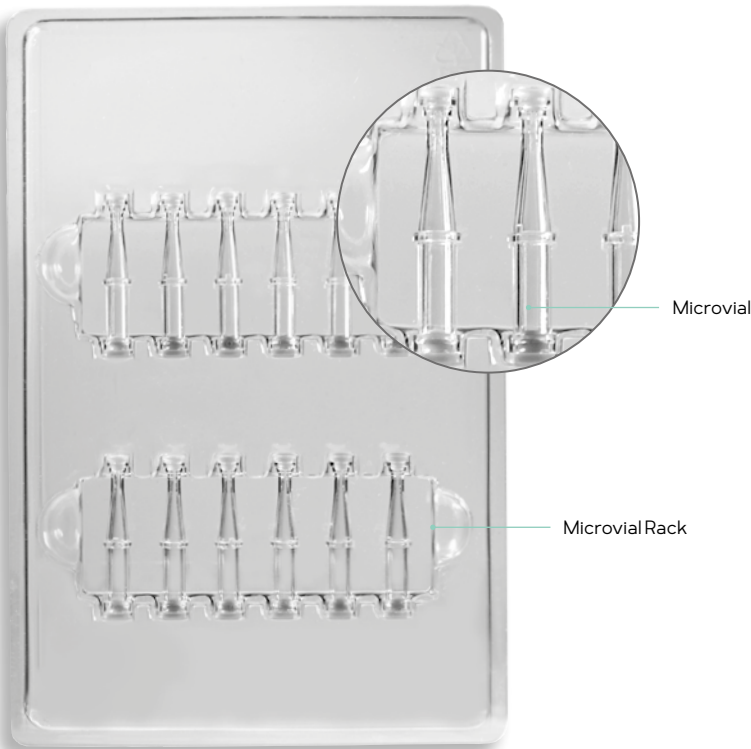
Single use only

MD

Medical Device

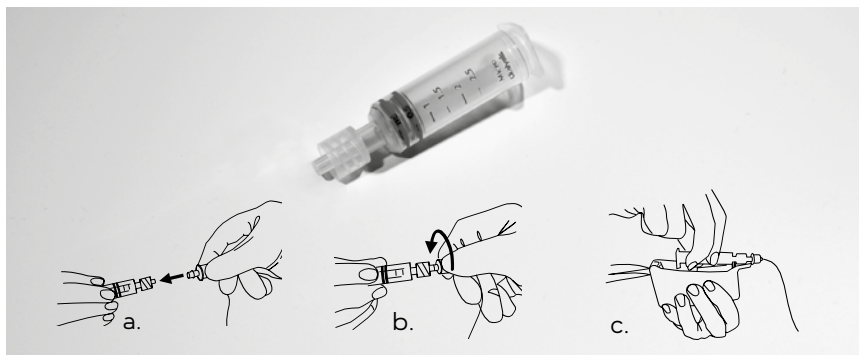
Microvials for analysis in ISCUSflex are designed to collect micro-volume samples and minimize evaporation. Each vial holds 200 μ L. If needed sterile microvials are packed and sold in racks for use under sterile conditions.

Microvial racks. To minimize evaporation, samples in microvials can be placed in a Microvial Rack prior to storage in the refrigerator or freezer. The rack can store and close 12 microvials and facilitate the logistics of sample handling.



Syringe and Perfusion Fluid

accessories for microdialysis catheters and pumps



The 106 Syringe is a sterile, single use syringe intended to contain and supply the perfusion fluid to MDialysis catheters.

It is specially designed to be used with 106 Microdialysis Pump, 107 Microdialysis Pump and MD System. The syringe holds 2.5 mL of Perfusion Fluid.

All MDialysis Perfusion Fluids are intended to act as a carrier inside the MDialysis Microdialysis Catheters. The Perfusion Fluids are available for use in both the brain (CNS) and peripheral tissues (T1).

The new Perfusion Fluid CNS Dextran is especially developed to use with 71 High Cut-Off Brain and Bolt Microdialysis Catheter. The large Dextran 500 molecule in the solution prevents the high cut-off membrane to ultrafiltrate.

The three different Perfusion fluids are conveniently packaged in glass bottles sterile and ready to use.



Ordering information

106 Syringe

Ref. No.

106 Syringe, 20/pkg

8010191

Perfusion Fluids

Ref. No.

Perfusion Fluid T1

P000034

10x5 mL / pkg

Contents:

NaCl 147 mmol/L

KCl 4 mmol/L

CaCl₂ 2.3 mmol/L

Total chloride content: 155.6 mmol/L

Perfusion Fluid CNS

P000151

10x5 mL / pkg

Contents:

NaCl 147 mmol/L

KCl 2.7 mmol/L

CaCl₂ 1.2 mmol/L

MgCl₂ 0.85 mmol/L

Total chloride content: 153.8 mmol/L

Perfusion Fluid CNS Dextran

P000151

2x7.5 mL / pkg

Contents:

NaCl 147 mmol/L

KCl 2.7 mmol/L

CaCl₂ 1.2 mmol/L

MgCl₂ 0.85 mmol/L

Total chloride content: 153.8 mmol/L

+Dextran MW 500 kDa 3%

CE 0413

CE marked according Medical Device Directive, 93/42/EEC

STERILE

Sterilized by steam

STERILE A

Sterilized by aseptic process technique

2

Single use only

MD

Medical Device

Microdialysis Pump Kit

accessories for microdialysis catheters and pumps

Ordering information

MD Pump Kit, Peripheral Tissue	Ref. No. 8003790
MD Pump Kit, Peripheral Tissue 1106/107 Syringe, 1 battery, 1 Perfusion Fluid T1	
MD Pump Kit, Brain Tissue	
MD Pump Kit, Brain Tissue 1106/107 Syringe, 1 battery, 1 Perfusion Fluid CNS	8003790

CE 0413	CE marked according Medical Device Directive, 93/42/EEC
STERILE	Sterilized by steam
Single use only	Single use only
MD	Medical Device

Microdialysis Pump Kit, Peripheral Tissue

This Pump Kit includes the accessories needed for single patient microdialysis monitoring in peripheral tissue. The kit contains a syringe, a battery and a T1 perfusion fluid ampoule.

Microdialysis Pump Kit, Brain Tissue

This Pump Kit includes the accessories needed for single patient microdialysis monitoring in brain tissue. The kit contains a syringe, a battery and a CNS perfusion fluid ampoule.



Splitable Introducer, Tunneling Needle and Forceps

accessories for microdialysis catheters



The **splitable introducer** is intended for easy insertion of the 61 Microdialysis Catheter and the 63 Microdialysis Catheter.



Tunneling needle and forceps. A tunneling needle and a special forceps simplify the insertion when using the Brain Microdialysis Catheters. The tunneling needle is also used to introduce the catheter through the abdominal wall during Gastro Intestinal Surgery and Transplant Surgery.

Ordering information

Splitable Introducer SI-2
4/pkg

Ref. No.

Splitable Introducer SI-2 **8010343**

Tunneling Needle & Forceps

Ref. No.

Tunneling Needle, 1/pkg **P000055**
Forceps, 1/pkg **P000056**

Technical information

Splitable Introducer SI-2

	Material	Length (mm)	ID (OD) (mm)
Splitable tube	HDPE*	74	1.0 (1.5)
Cannula	Stainless Steel	77	(1.0)



CE marked according Medical Device Directive, 93/42/EEC



Sterilized by β -radiation



Single use only



Medical Device

Tunneling Needle & Forceps

	Material	Length (mm)	ID (OD) (mm)
Tunneling Needle	Stainless Steel	139	3.0 (3.5)
Forceps	Stainless Steel	118	



CE marked according Medical Device Directive, 93/42/EEC



Medical Device

ISCUS^{flex} Microdialysis Analyzer

for point-of-care and advanced research

Ordering information

ISCUS^{flex} Microdialysis Analyzer

Ref. No. 8003295
ISCUS^{flex} Microdialysis Analyzer

Ref. No. 8003296
ISCUS^{flex} Microdialysis Analyzer, Research
For research use only

Technical information

Weight	29lbs/13 kg
Voltage	100-240 V~, 50/60 Hz
Power consumption	100 VA
Dimensions	430 (H) x 350 (W) x 270 (D) mm
Type of protection	Class 1, Type B
Measurement principle	Kinetic enzymatic analyzer
Vials	Microvials, 300uL glass vials
Samples	Microdialysates
Sample volume used	0.2 - 2 µL/analysis (depending on analyte)
Min. sample volume	Sum of sample volumes per analyte + 2 µL
Reagent consumption	<15 µL/analysis (depending on analyte)
Pipetting imprecision	< 2% (0.5 µL) rel. standard deviation
Calibration	Automatic (every 6 hrs)
Warm-up time	10 minutes
Measuring time	30 seconds
Time per test	60 - 90 seconds
Throughput	30 measurements per hour
Detector type	Single beam filter photometer
Light source	Class 1 MLED
Wavelengths	375 and 530 nm
Detector cell temp.	99°F/37°C
Detector cell	Capillary flow cell 10mm, 2 µL
Assay imprecision	<4 % rel. standard deviation for Control Sample Normal
Assay inaccuracy	<10% for Control Sample Normal

ISCUS^{flex} is a Microdialysis Analyzer for point-of-care and advanced research. This analyzer uses enzymatic reagents and colorimetric measurements to monitor tissue chemistry from within microdialysis samples taken from virtually any tissue or organ in the body.

The analyzer is easy to operate by medical professionals and researchers alike. Up to six different reagents (glucose, lactate, pyruvate, glycerol, glutamate, and urea) provide unique opportunities for early detection of metabolic crisis and ischemia and to guide therapeutic interventions. The analysis results are displayed as trend curves for easy and fast interpretation. For comparison with other monitoring data, the unique ICUpilot™ software is included for installation on a separate computer.

ISCUS^{flex} combines reliability and flexibility. It offers the opportunity to monitor several subjects at a time and with a capacity of 16 vials, the ISCUS^{flex} offers batch analysis for advanced research. The throughput of the analyzer is 30 measurements per hour.

- Easy to operate graphical user interface
- Quick one-button 2 minute analysis
- Batch capacity of 16 samples
- Less than 2 µL of sample required per analysis
- Automatic calibration and controls



NOTE: This product may not be approved by your national regulatory authorities. Please contact your local representative for further information

ISCUS^{flex} Microdialysis Analyzer

for point-of-care and advanced research



Ordering information

Accessories

	Ref. No.		Ref. No.
Reagent Set A, Incl. Reagent Glucose 1 x 6 mL Reagent Lactate 1 x 6 mL Reagent Pyruvate 1 x 6 mL Reagent Glycerol 1 x 6 mL Calibrator A 1 x 6 mL	8002163	Control Samples 5 mL, 2 levels 2 x 5/pkg	8010201
Reagent Set B, Incl. Reagent Glucose 1 x 6 mL Reagent Lactate 1 x 6 mL Reagent Pyruvate 1 x 6 mL Reagent Glycerol 1 x 6 mL Reagent Glutamate 1 x 4 mL Calibrator A 1 x 6 mL	8002164	Control Samples for US 5 mL, 2 levels 2 x 5/pkg	8010306
Reagent Set C, Incl. Reagent Glucose 1 x 6 mL Reagent Lactate 1 x 6 mL Reagent Pyruvate 1 x 6 mL Reagent Glycerol 1 x 6 mL Calibrator A 1 x 6 mL	8002165	Rinsing Fluid for Analyzer , 8 x 0.5 L	8002171
Reagent kit, Incl. Reagent Glucose 1 x 6 mL Reagent Lactate 1 x 6 mL Reagent Pyruvate 1 x 6 mL Reagent Glycerol 1 x 6 mL Calibrator A 1 x 6 mL	P000011	Waste Bottles , 0.5L 8/pkg	8002161
LPG kit, Incl. Reagent Glucose 1 x 6 mL Reagent Lactate 1 x 6 mL Reagent Pyruvate 1 x 6 mL Calibrator A 1 x 6 mL	8010361	Thermal Print Paper roll, 4/pkg	8002162
Glucose Reagent , 6 mL, 5/pkg	P000023	Sample Cannula	8001721
Lactate Reagent , 6 mL, 5/pkg	P000024	Secure Digital Memory Card	8002360
Pyruvate Reagent , 6 mL, 5/pkg	P000063	Microvials , 250/pkg	P000011
Glycerol Reagent , 6 mL, 5/pkg	P000025	Vial Glass 300µL*	7431007
Glutamate Reagent , 4 mL, 5/pkg	P000064	Vial Adapter	P000114
Urea Reagent , 6 mL, 5/pkg	P000026	ISCUS Vial Cassette	8003409
Calibrator A 6 mL, 10/pkg	P000057	ISCUS Maintenance kit	8002792



Intended for Medical Purpose according to EU In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746



In Vitro Diagnostic Medical Device

* Needs to be bought by CMA Microdialysis AB
For product information on Reagents, see page 30-31
For product information on LABpilot™ and ICUpilot™, see page 32

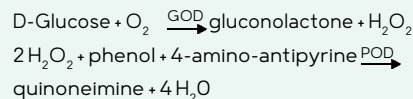
Reagents for ISCUS^{flex} MD Analyzer

Glucose

Glucose oxidase method for analysis of microdialysates

Measuring principle

Glucose is enzymatically oxidized by glucose oxidase (GOD). The hydrogen peroxide formed reacts with phenol and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinoneimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Glucose concentration.

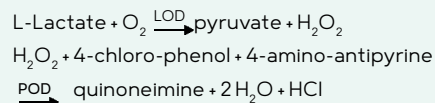


Lactate

Lactate oxidase method for analysis of microdialysates

Measuring principle

Lactate is enzymatically oxidized by lactate oxidase. The hydrogen peroxide formed reacts with 4-chlorophenol and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinoneimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Lactate concentration.

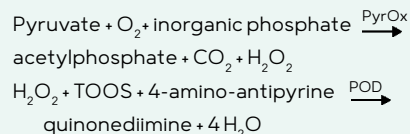


Pyruvate

Pyruvate oxidase method for analysis of microdialysates

Measuring principle

Pyruvate is enzymatically oxidized by pyruvate oxidase (PyrOx). The hydrogen peroxide formed reacts with N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine (TOOS) and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinonediimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Pyruvate concentration.

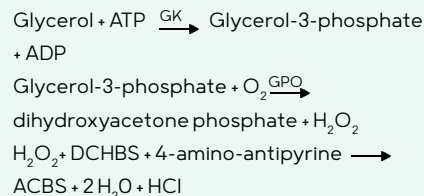


Glycerol

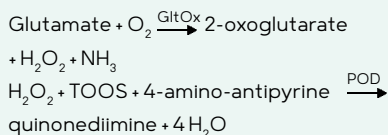
Glycerol colorimetric method for analysis of microdialysates

Measuring principle

Glycerol is phosphorylated by adenosine triphosphate (ATP) and glycerol kinase (GK) to glycerol-3-phosphate, which is subsequently oxidized in the presence of glycerol-3-phosphate oxidase (GPO). The hydrogen peroxide formed reacts with 3,5-dichloro-2-hydroxy-benzene sulphonic acid (DCHBS) and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinoneimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Glycerol concentration.



Reagents for ISCUS^{flex} MD Analyzer

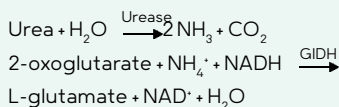


Glutamate

Glutamate oxidase method for analysis of microdialysates

Measuring principle

Glutamate is enzymatically oxidized by glutamate oxidase (GltOx). The hydrogen peroxide formed reacts with N-ethyl-N-(2-hydroxy-3-sulfoethyl)-m-toluidine (TOOS) and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinonediimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Glutamate concentration.



Urea

Urea UV-method for analysis of microdialysates

Measuring principle

Urea is hydrolyzed in the presence of urease to ammonium ions and carbon dioxide. The ammonium ions react with 2-oxoglutarate in the presence of glutamate dehydrogenase (GIDH) and NADH to form glutamate and NAD⁺. The rate of utilization of NADH is measured photometrically at 370 nm and is proportional to the Urea concentration.

Analyte Concentration

Glucose	5.55 mmol/L
Lactate	2.5 mmol/L
Pyruvate	250 µmol/L
Glycerol	475 µmol/L
Glutamate	25 µmol/L
Urea	13.3 mmol/L

Calibrator A

For calibration of Glucose Reagent, Lactate Reagent, Pyruvate Reagent, Glycerol Reagent, Glutamate Reagent and Urea Reagent. The Microdialysis Analyzers use enzymatic reagents that are commonly used in clinical chemistry.

At present reagents for glucose, lactate, pyruvate, glycerol, glutamate and urea are available. The assays are based on kinetic measurements in order to get the analytical results as quickly as possible instead of waiting for the enzymatic reaction to reach completion, which might take several minutes. The absorbance change during the first 30 s of the reaction is monitored and the maximal reaction rate during this time is used for quantification.

A single multicomponent calibrator, containing known concentrations of the different analytes is used for calibrating the assays. Since the reaction rate is proportional to the analyte concentration, quantification is done by comparing the calculated slope of the obtained absorbance versus time curve with that obtained from measuring the calibrator solution with its known analyte concentrations.

For ordering information, see page 29.

LABpilot™ and ICUpilot™ Software

data navigation in the laboratory

Ordering information

LABpilot™ Software and ICUpilot™ Software

Ref. No. P000157
LABpilot™ Software

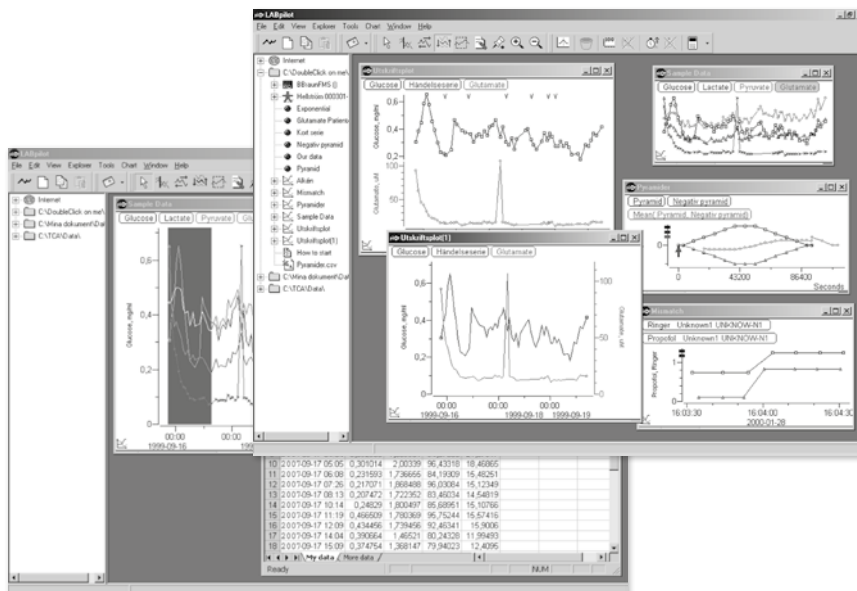
Ref. No. 8001027
ICUpilot™ Software

These two computer programs are designed to handle microdialysis and other data collected over time. The programs' graphic interfaces allow integration and synchronization of microdialysis data from several subjects for faster data interpretation.

Simply copy MS Excel files and paste or drag directly onto the LABpilot™ or ICUpilot™ window to instantaneously generate graphs. Just one click can transform data from real time to elapsed time, from absolute values to percent values, view data as regression plots, display means, medians, SEM or SD.

The ICUpilot™ software enables connection with other patient monitors and automatic collection of multimodal monitoring data.

- Easy to handle graphic interface
- Display, compare, comment and interpret graphs
- Allows for faster data interpretation
- Allows for easy collaboration and communication



Designed to work using a graphical interface. The software facilitates processing a large number of data using graphs - not numbers. Display, compare, comment and interpret the data.

Vial Adapter for ISCUS^{flex} MD Analyzer

The ISCUS^{flex} Microdialysis Analyzer was originally developed to handle samples collected in Microvials (P000001). However, with the Vial Adapter for MD Analyzers, it is possible to use the ISCUS^{flex} for analysis of samples collected in 300 µL glass vials.



ISCUS^{flex} Normal Linear Range

Reagent	Linear Interval	Sample Volume µL	Reagent Volume µL
Glucose	0.1 - 25 mmol/L	0.5	14.5
Lactate	0.1 - 12 mmol/L	0.4	14.6
Pyruvate*	10 - 1500 µmol/L	0.5	14.5
Glycerol	10 - 1500 µmol/L	0.4	14.6
Glutamate	1 - 150 µmol/L	1.3	7.7
Urea	0.5 - 25 mmol/L	0.5	14.5

* Pyruvate default linear range is low linear range

Methods for lower sample concentration

In basic research, samples are generally acquired at higher flow rates (1 - 5 µL/min) which results in lower analyte recoveries. In order to facilitate the analysis of these samples, the ISCUS^{flex} Microdialysis Analyzer can be configured to use more sensitive methods for the following analytes:

ISCUS^{flex} Low Linear Range

Reagent	Linear Interval	Sample Volume µL	Reagent Volume µL
Glucose	0.02 - 6.0 mmol/L	2.0	13.0
Lactate	0.02 - 2.5 mmol/L	0.8	14.2
Pyruvate*	10 - 300 µmol/L	2.0	13.0
Glycerol	2 - 500 µmol/L	2.0	13.0

* Pyruvate default linear range is low linear range

Ordering information

Vial Adapter for MD Analyzers

Ref. No. P000114
35 Vial Adapters
Used with glass vials from CMA Microdialysis AB.



MD System, Loke

for continuous microdialysis monitoring

Ordering information

MD System, Loke

	Ref. No.
MD System Loke	8070228
Accessories	
MD Sensor & Calibrators kit	8050204
Incl.MD Sensor & MD Calibrator	
MD System Syringe kit , brain	8050206
incl. 106 Syringe + Orange Syringe, Perfusion Fluid CNS + Catheter Extension	
MD System Syringe kit , periph.	8050207
incl. 106 Syringe + Orange Syringe, Perfusion Fluid T1 + Catheter Extension	
MD Syringe Orange, 20/pkg	8070081
MD Calibrators, 2x7.5mL	8072009
Catheter Extension, sterile, 2/pkg	8072008

Technical information

Weight	11lbs/5 kg
Voltage	100-240V~, 50/60Hz
Power consumption	Max. 40 VA
Compliance:	Power adapter complies with 60601-1
Insulation	MD Unit power adaptor is double isolated
Measurement principle	Electrochemical biosensor
Calibration	Automatic



CE marked according to the Medical Device Directive (MDD 93/42/EEC), EU Directive (2014/30/EU) (EMC), EU Directive 2012/19/EC (WEEE II) & EU Directive 2011/65/EC (RoHS II)



Defibrillation-proof type CF applied part

IPX4

Protection class, protected against dripping water



ETL-listed product. Conforms to ES-60601-1:2005+A1 and CSA C22.2#6061.-1:2014 Ed.3



Medical Device

MD System is a microdialysis analyzing system, which is used in conjunction only with M Dialysis catheters, performing continuous monitoring of microdialysates.

A built in pump system perfuses the Microdialysis catheter and a biosensor connected to the catheter outlet enables continuous monitoring of Glucose and Lactate. A solution for Pyruvate monitoring with the MD System is presently under development.

The microdialysis values are continuous displayed both numerically and graphically on the MD Monitor screen as trend curves for fast and easy interpretation.

MD System with continuous real-time Microdialysis monitoring is the fourth generation of Clinical Microdialysis Analyzer designed to support maximum patient benefit and decrease health care costs.

Note! The MD System should only be used with Microdialysis catheters with 20 k Dalton cut-off membrane pore size .

- Easy to operate
- For routine Microdialysis monitoring in Critical care patients
- Microdialysis - Reinvented
- Microdialysis data in real-time, continuously,



General Information

Customer Support



Internet Support



Technical Support



Customer Support

Contact Us

Head Office



Phone: +46-8-4701020

Email: info@mdialysis.se
order@mdialysis.se
service@mdialysis.se

US Office

Phone: +1 978 710 3296

Toll free: +1 866 868 9236

Fax: (978) 251 1960

Email: usa@mdialysis.com
service.usa@mdialysis.com

Support and Technical Service

For general information about the technique and for more information regarding our products you are welcome to contact us or the local distributor in your area.

We have a skilled staff available to solve your technical problems if an equipment oriented problem should arise.

Obtain a return authorization number from either your local Representative or

Service before you return any products for repair.

A detailed description will help minimize cost and turnaround time.

Visit **www.mdialysis.com** for the latest technical support and service information.

u

Contact Us

The head office of MDialysis is located in Stockholm, Sweden not far from the Karolinska Institute.

The branch office outside Boston is responsible for the US, Canada and South America.

Distributors in other countries can be found at **www.mdialysis.com**



Head Office (Sweden)

MDialysis AB

Phone: +46 8 470 10 20

E-mail: info@mdialysis.se

Visiting address:

Hammarby Fabriksväg 43
SE-120 30 Stockholm
Sweden

Delivery address:

Virkesvägen 26
SE-120 30 Stockholm
Sweden

US Office

MDialysis Inc.

Phone: +1 978 710 3296

Toll Free: +1 866 868 9236

Fax: +1 978 251 1960

E-mail: usa@mdialysis.com

Address:

73 Princeton Street, Suite 302
North Chelmsford, USA
MA 01863, USA

Notes

M Dialysis AB

Hammarby Fabriksväg 43
SE-120 30 Stockholm, Sweden
Phone: +46 8 470 10 20
E-mail: info@mdialysis.se

US Office: MDialysis Inc.
73 Princeton Street
North Chelmsford
MA 01863, USA
Phone: +1 (866) 868 9236
Fax: +1 (978) 251 1960

www.mdialysis.com

Distributor