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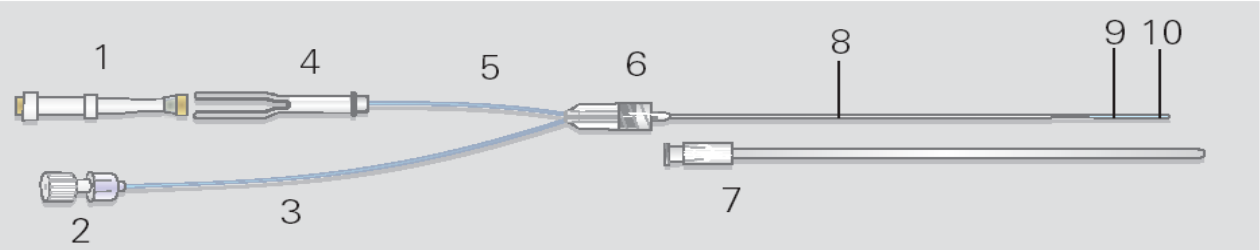
Instructions for use
70 MICRODIALYSIS BOLT CATHETER

US

INTENDED USE

The 70 Microdialysis Bolt Catheter is intended for implantation into human brain tissue in order to enable microdialysis of the extracellular fluid of the brain.

PRODUCT DESCRIPTION & TECHNICAL INFORMATION



	REF P000131
1. Microvial (Polystyrene + Santoprene)	-
2. Luer lock connection (Polycarbonate)	-
3. Inlet tube (Polyurethane, OD 1 mm)	600 mm
4. Vial holder (Polycarbonate)	-
5. Outlet tube (Polyurethane, OD 1 mm)	220 mm
6. Liquid cross (ABS)	-
7. Protection tube (Polyethylene)	145 mm
8. Shaft (Polyurethane, OD 0.9 mm, Stainless steel)	130 mm
9. Dialysis membrane (Polyamide, OD 0.6 mm) Cut off: 20 000 Dalton	10 mm
10. Gold thread within the catheter membrane tip. OD 0.13 mm	3 mm
Dead Volume Time - From membrane to microvial (at 0.3 µl/min)	23 min

The distal part of the catheter has a gold thread within the catheter tip, which makes it possible to detect the location of the catheter in the tissue through CT-scanning.

ACCESSORIES

The 70 Microdialysis Bolt Catheter shall only be used with these accessories.

REF	Name
P000151	Perfusion fluid CNS 10x5 mL
8010191	106 Syringe 20/pkg
P000001	Microvials 250/pkg
P000003	106 Microdialysis Pump
BOLT KIT - PTO 2L, **RAUMEDIC** Art. 096076-001	Bolt Kit for 2 brain probes
INTEGRA REF IM3	Bolt Kit for 3 brain probes

CONTRAINDICATIONS & RISKS

- Patients with coagulopathy, increased susceptibility to infections or bleeding disorders.
- Patients on anticoagulant drug therapy.

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PRECAUTIONS

- This device is sterile unless the package has been opened or damaged.
- The 70 Microdialysis Bolt Catheter shall only be used together with the accessories described in the previous table.
- Be sure to handle the catheter carefully to avoid kinking or other damage, particularly after removal of the protection tube. Avoid contact with the dialysis membrane.
- If any visible damage is observed the catheter shall not be used.
- If there is a suspicion that the catheter has become unsterile prior to insertion the catheter shall not be used.
- Check that liquid is being pumped through the catheter by inspecting the volume in the microvial **each time** the microvials are changed.
- The pump syringe connected to the catheter should not manually be flushed since that could damage the dialysis membrane.
- If there is no fluid in the collected vial, start a flush on the pump: Open the lid, wait 3 seconds and close it again. Wait for the flush (5 minutes). Check that the tubing's are not kinked and that the microvial holder needle is correctly piercing the microvial membrane. If there is still no fluid in the collected vial, the dialysis membrane might be damaged and the catheter has to be removed.
- The catheter shall be removed if there is a permanent stop in the liquid flow.
- When monitoring patients with brain tumors there could be a possibility of dissemination of tumor cells.
- Inserting the catheter into the brain may cause bleeding from damaged vessels.
- Leakage of cerebrospinal fluid may occur at the site of skin penetration.
- The 70 Microdialysis Bolt Catheter is for single use only. If the device is re-used there is a risk for cross-contamination.
- The 70 Microdialysis Bolt Catheter is not tested in MRI.
- 70 Microdialysis Bolt Catheter is biocompatible up to 30 days. It may though stop working earlier because of clogging, duration of use is up to 12 days referring to literature.

INDICATIONS FOR USE

Patients with clinical signs of brain injury or brain disease where craniotomy is required for diagnosis or therapy e.g. monitoring of ischemia in patients suffering traumatic brain injury (TBI) and Subarachnoid Hemorrhage (SAH). Microdialysis shall not be used as the sole basis for diagnosis or therapy.

USAGE

The following procedure should be performed by a Neurosurgeon or Intensivist under aseptic conditions.

1. Follow the instruction for inserting the bolt (see bolt manual).
2. After insertion of the bolt, verify that the compression screw is fully open.
3. Remove the protection tube by holding the liquid cross with the male luerlock connection, and TURNING the protection tube counter clockwise.
4. Insert the catheter through the access for Microdialysis (INTEGRA/Temp channel) in the bolt (see bolt manual).
5. Fix the catheter according to the bolt instructions (see bolt manual).
6. Tighten the compression screw to stop CSF leakage.
7. Insert a sterile microvial into the microvial holder.
8. Connect the female luerlock connection to the syringe filled with CNS perfusion fluid (see instructions for the pump in use).
9. Place the syringe in the pump and close the lid to initiate the flush (see instructions as above)
10. Inspect the microvial after approximately 6 minutes to see that the perfusion fluid flows through the catheter.

REMOVAL OF CATHETER

The catheter is removed by gently pulling it out through the insertion site.
NOTE: Discontinued/removed catheters shall be handled according to the hospital routines for biohazard material.

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SYMBOL EXPLANATION & PRODUCT LIMITATIONS

	Last date of use (YYYY-MM-DD)
LOT	LOT number
REF	Catalogue number
	Single use only
	See instructions for use
STERILE R	Sterilised by ß-radiation
	Storage temperature (4-25 °C, 39-77 °F)
	Manufacturer
	Do not use if package is damaged
Membrane	Membrane material (Polyamid, PA)
Memb.length	Membrane length (mm)
Cut off	Membrane cut off (20 000 Dalton)
Shaft length	Shaft length (mm)
Outlet	Outlet length (mm)
Inlet	Inlet length (mm)