Integra®
Licox® Brain Tissue
Oxygen Monitoring

REF IP2.P

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MANUFACTURER:
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Dorfrasse 2, 24247 Mielkendorf
Germany
MADE IN GERMANY
Integra®
Licox® Brain Tissue
Oxygen Monitoring

Directions for Use
REF IP2.P*
Complete Brain Probe Kit

Consisting Of

REF IP2
Dual Lumen Introducer Kit

REF CC1.P1
Combined Oxygen and Temperature Probe

Camino® 110-4L
or
Ventrix® NL-950-SD
ICP Catheters
Are Sold Separately

* These Directions for Use may also be used with REF IP2, packaged separately, and/or the combined oxygen and temperature probe REF CC1.P1, packaged separately.
COMPONENTS OF THE PRODUCT ASSEMBLY REF IP2.P

REF CC1.P1
COMBINED OXYGEN AND TEMPERATURE PROBE
For oxygen and temperature monitoring in cerebral tissue

REF IP2
DUAL LUMEN INTRODUCER KIT
Two Channel Brain Access System with Introducer and Bolt

NOT INCLUDED IN THE PACKAGE: INTRACRANIAL PRESSURE (ICP) CATHETERS COMPATIBLE WITH IP2

COMPLETE SYSTEM WITH COMBINED OXYGEN AND TEMPERATURE PROBE AND ICP CATHETER, SHOWN WITH Ventrix NL950-SD ICP CATHETER - assembly completed -

NOT INCLUDED IN THE PACKAGE:

EXPLANATION OF SYMBOLS

Rx ONLY
Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician

Consult the directions for use

Temperature limitation: CC1.P1 must be stored cool, between 2°C and 10°C

Reference number

Lot Number

Serial Number

Use by date

Manufacturer

Do not use if package is damaged

Single use only. Do not reuse

Do not resterilize

These products are sterile and sterilized by gamma irradiation

This product is not manufactured with Dry Natural Rubber or Natural Rubber Latex

Non-pyrogenic

Keep away from sunlight

ATTENTION!

Device is manufactured in compliance with the requirements of the European Medical Device Directive 93/42/EEC.
REF IP2
DUAL LUMEN INTRODUCER KIT
Packaged in a sterile double tray. When REF IP2 is supplied as kit with REF CC1.P1 this kit is protected by an outer plastic bag.

This outer plastic bag is non-sterile. It serves to protect the inner packages from moisture during shipping and storage.

Please remove and discard the plastic bag prior to use.

a  Dual lumen introducer (Ø 2.0 mm) with:
   a1 Connector for ICP catheter (Ø <1.9 mm)
   a2 Connector for combined oxygen and temperature probe (Ø <1.4 mm)
   a3 Compression seal
   a4 End of lumen of ICP catheter
   a5 End of lumen for combined oxygen and temperature probe
b  Guide wire
c  Compression cap
d  Bolt
e  Drill bit (Ø 6.3 mm)
f  Adjustable drill stop with set screw
g  Hex wrench for adjustment of the drill stop
h  Stylet
i  Compression fitting for Ventrix ICP catheter
j  ICP obturator

REF CC1.P1
COMBINED OXYGEN AND TEMPERATURE PROBE
For Oxygen Pressure ($p_{O_2}$) Monitoring in Cerebral Tissue.

Packed in a sterile double tray protected by an outer plastic bag.

This outer plastic bag is non-sterile. It serves to protect the inner packages from moisture during shipping and storage.

Please remove and discard the plastic bag prior to use.

The probe (length 462 mm) [c, d, e] is delivered (as shown on the right [a, b]) in a closed protection tube [b], which provides mechanical protection and protects the probe from drying out. The calibration data for the probe are electronically stored on a smart card [g]. Probe and smart card have the same number. The extension tube [d] serves to connect the probe to the bolt system. The probe is connected at the rear end [c] of its plug to the probe cable REF PMOCAB.

At [e] the probe has its $p_{O_2}$ sensitive area of approximately 18 mm$^2$ (Ø 0.65 mm). At [f] the probe has its temperature sensitive area of approximately 23 mm$^2$ (Ø 1.3 mm). The entire protection tube must be removed at [a] before use.
PRECAUTIONS

These directions are to be used in conjunction with the Licox PMOBOX, the Licox CMP Operations Manual or the Licox P\textsubscript{O}\textsubscript{2} monitor’s User’s manual.

Integra intends that this device should be used only by physicians with educational and training background enabling the proper use of the device.

The Licox introducing system is intended for use only with the probes specified herein.

The Licox probes are intended for use only with the introducing system specified herein.

Licox products specified herein are intended only for use with the Licox CMP, the Licox PMOBOX or the Licox P\textsubscript{O}\textsubscript{2} monitor and all corresponding Licox cables.

After implantation of a probe it takes 1 - 2 minutes before the local brain oxygen tension is correctly displayed. However, due to the micro trauma of implantation, the initial values displayed may not represent the oxygen tension of the surrounding tissue. After implantation, the tissue stabilization time (time until the oxygen tension values are representative of the surrounding region of the brain) may be as long as two hours.

Do not attempt to disassemble the introducer.

Only use probes and introducing systems if their sterile packaging is not open, damaged or broken.

Only use probes and introducing systems before their expiration date labelled on the package.

These devices are intended for single use only. All components are extremely difficult to clean after being exposed to biological materials and adverse patient reactions may result from reuse.

Caution – Do not resterilize. Integra/GMS will not be liable for any or all damages including, but not limited to, direct, indirect, incidental, consequential or punitive damages resulting from or related to resterilization.

Only use the combined oxygen and temperature probe which has been stored cool at a temperature between 2\degree C and 10\degree C.

Do not discard the combined oxygen and temperature probe packaging before the smart card has been removed. Probe calibration data is stored on the smart card.

Use only the smart card supplied with the combined probe. Cross check serial number on probe and smart card. Use of the wrong smart card can cause measurement errors.

The smart card is not required if using the Licox PMOBOX.

Do not cut or tear the catheter body. A catheter with a cut or torn body will no longer function.

Only use the drill bit provided with the introducing system. If a drill bit other than that delivered with the kit is used, the hole may be too large or too small.

Do not use a power drill.

Adequate blood coagulation must be ensured before inserting an invasive cerebral monitoring probe.

In order to avoid intracranial hemorrhage, blood coagulation must be checked before probe insertion and must be carefully monitored when measuring in patients in hepatic coma or with other diseases which could impair blood coagulation properties. This also applies to conditions in which therapeutic maneuvers may interfere with blood coagulation (e.g. hypothermia, pharmacologic agents).

If the dura mater is not opened before the stylet is advanced, the dura mater could be torn away from the skull, possibly resulting in hemorrhage/hematoma.

Inadequate opening of the dura mater may also result in improper placement of the probe.

The device must not be placed too near the sagittal line in order to avoid the sagittal sinus and major cerebral veins near the sagittal line.

The introducer must be sealed to avoid infection. If the seal is not made, cerebrospinal fluid may appear within the outer tube of the introducer. The compression cap must be tightened further to avoid leakage (see directions for use).

The actual position of the sensor must be considered for interpretation of data. It is possible that the sensor may get displaced from its original position.

When monitoring is complete, remove probes and introducer prior to bolt removal.

The tip of the oxygen sensing catheter may not lie in the cerebral white matter after implantation if it is inserted in a sulcus of the brain or in an atrophic brain. In this case the probe may not respond to an oxygen challenge performed after the initial stabilization time of at least 20 min. The location of the probe may be verified via CT scan. Remove probe if it does not respond to the oxygen challenge or if its tip is not within parenchyma or lies on the surface of brain. Please note that if the probe tip lies within the cortex, the measured oxygen values may be higher and less stable than measurements made with the probe tip within the white matter.

If the oxygen probe is placed in cerebrospinal fluid (CSF) the readings will be false high. This may occur if the sensor is placed in the subcortical CSF space or if it is placed in ventricular CSF spaces, e.g. in hydrocephalic patients.

Only insert the combined oxygen and the ICP probes into their dedicated channels, respectively labelled “pO\textsubscript{2}” and “ICP”.

WARNINGS

- Use the compression fitting for Ventrix ICP catheter if using a Ventrix ICP catheter.
- The Licox probes and introducers specified herein have not been tested for compatibility with Magnetic Resonance (MR) systems. Therefore the use of these devices in MR environments is not recommended. Integra should be contacted if more information is needed.

- Do not bend the probe around a radius of curvature of less than 2 mm.
- Neurosurgery treatment facilities must be available for monitoring related adverse events, e.g. hemorrhage or infection.
- In rare cases, e.g. if a vessel is punctured during implantation or when coagulation is insufficient, hemorrhage can occur. This may lead to a transient rise in tissue oxygen values. Once bleeding stops, tissue oxygen values are usually decreased in surrounding non-affected tissue if the blood infiltration surrounding the puncture is thicker than approximately 100 μm.
- If the patient has enlarged or shifted ventricles, the probe or its introducer may puncture the lateral ventricle when inserted (the oxygen probe tip reaches approximately 35 mm below the dura level). If this occurs, the probe will create a channel that directly connects the ventricular system with the subarachnoid space, bypassing the natural CSF pathways. Because of the pressure difference between the lateral ventricle and the subarachnoid space, it is possible that cerebrospinal fluid from the ventricle could flow along the probe. The measured value will correspond to the partial oxygen pressure of the cerebrospinal fluid and will not be representative of the tissue.

- Do not touch Licox probes with cautery forceps or HF scalpels; this may damage the preamplifier of the Licox CMP, the Licox PMOBOX or the Licox P02 monitor.
- Strong electrical interference (e.g., during cauteration) can cause a disturbance of the measurement that outlasts the interference by a few seconds.
- Do not use Licox probes or introducing systems for more than 5 days.
- Only original Licox parts may be used with the system. This applies in particular to probes, cables and the power supply.
- The user must be aware that cerebral oxygen pressure values differ between and within patients depending on the nature of the damage and the individual treatment course. It is highly recommended that users are aware of the current knowledge relating to brain tissue oxygen pressure (pO2) measurements which has been published in the scientific literature.
- Special consideration must be given to the maturity of the skull when using a bolt fixation in paediatric patients.

COMPLICATIONS, ADVERSE EVENTS

- Complications associated with intracranial sensors may occur during the use of this device. Complications include, but are not limited to, infection, thrombosis and hemorrhage.

CONTRAINDICATIONS

- Licox products are not intended for any use other than that indicated.
- Contraindications for device insertion into the body apply, e.g. coagulopathy and/or susceptibility to infections or infected tissue. A platelet count of less than 50 000 per μl is considered a contraindication. This value may differ according to different hospital protocols.
SYSTEM DESCRIPTION

The complete brain probe kit REF IP2.P consists of a dual lumen introducer kit REF IP2 and a combined oxygen and temperature probe REF CC1.P1. The system may be used for simultaneous monitoring of oxygen partial pressure \( (p_O_2) \), temperature as well as intracranial pressure (ICP) in the cerebral white matter. For oxygen partial pressure and temperature monitoring Licox probe is used. For intracranial pressure (ICP) monitoring, a Camino or Ventrix ICP catheter may be used. The REF IP2.P is used in conjunction with the Licox PMOBOX, Licox CMP monitor or the Licox P₂O₂ monitor.

The combined probe is inserted into brain tissue through the “pO₂” labelled channel of the dual lumen introducer REF IP2 to a depth of approximately 35mm below the dura (Fig. 16). The probe’s oxygen sensing part starts 4 to 6 mm from the tip of the probe. The probe’s temperature sensing part starts 13 to 15 mm from the end of the probe’s oxygen sensing part. The ICP catheter is inserted into brain tissue through the “ICP” labelled channel to an adjustable depth of 0 to 12mm. The system is designed for no more than five days of continuous monitoring.

INDICATIONS FOR USE

The Licox Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. Licox System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

DIRECTIONS FOR USE

The probes are inserted into the brain tissue via an introducer (Fig. 4, a, b, c) and bolt (Fig. 4, d). The introducer seals the system hermetically at the connection to the bolt and provides mechanical protection and strain-relief to the probes.

Preparation

- Select an insertion site. Positioning of the probe must be given careful consideration due to the heterogeneity of the oxygen partial pressure in brain tissue. The probe should be placed in viable tissue, when monitoring oxygen availability. Viable tissue may be found in a peri-focal lesion, e.g. the penumbra, or in undamaged tissue, e.g. the contra lateral side of a focal lesion. The probe should not be placed into a hematoma or non-vital tissue. The user should be aware of the current issues in the pertaining scientific literature when making the choice of catheter placement and for interpretation of the oxygen measurements obtained.

- If possible, place the probe 20 – 40 mm off the midline, just anterior to the coronal suture. Other locations may be chosen according to the location of a lesion.

- The position of the drill hole should be at least 10 mm away from other probes.

- To reduce the risk of infection, the use of depilatory agents or no hair removal is recommended.

- If shaving or clipping is performed it should be done immediately before the operation, preferably with electric clippers. The scalp should be free of gross contamination.

- To minimize the risk of surgical site infections, it is recommended to prepare the surgical area in accordance with evidence-based guidelines, such as Mangram et al. Guideline for Prevention of Surgical Site Infection, 1999. Infection Control and Hospital Epidemiology, 20(4), pp. 257-258, and Nichols RL. Preventing Surgical Site Infections: A Surgeon’s Perspective. Emerging Infectious Diseases. 7(2), Mar-Apr 2001.

- Use an appropriate antiseptic agent available for preoperative preparation of the skin at the incision site. Members of the surgical team who have direct contact with the sterile operating field or sterile instruments or supplies used in the field, should wash their hands and forearms by surgical scrubbing immediately before the procedure for at least 2-5 minutes. After scrub, keep hands up and away from body. Dry hands with a sterile towel then don a sterile gown and gloves.

- Apply an antiseptic in concentric circles, beginning in the area of the proposed incision. The prepared area should be large enough to extend the incision or create new incisions, if necessary. The skin preparation procedure may need to be modified depending on the condition of the skin or location of the incision site.

- Estimate the thickness of the skull and adjust the drill stop accordingly. Loosen the drill stop (Fig. 4, f) with the hex wrench (Fig. 4, g) about half to one turn, so that the set screw is still in the groove of the drill-bit (Fig. 4, e). Rotate the drill stop around the drill-bit (Fig. 6) until the exposed tip of the drill-bit is just long enough to completely drill through the skull with its inner table. The tip of the drill-bit should not penetrate the inner table by more than 1 mm. Tighten the drill stop.
• Attach the drill-bit to a hand drill. Do not use a powered drill, such as those driven by compressed air or electricity.

**Drilling**

• Drape the shaved and prepared area. Infiltrating in the area of the incision subcutaneously with a local anaesthetic is a surgical option.

• Make a small linear incision carrying it to the bone. A self-retaining retractor is then inserted to provide good bone exposure.

• Drill the hole. Do not change the direction of the drill while drilling, this could cause the hole to become too wide or conical. Ensure that the twist drill hole extends through the inner table of the skull exposing the dura. Care must be taken when penetrating the inner table of the skull, to prevent damage to the dura or brain. Remove the drill and rinse the hole with sterile isotonic solution.

**Dura mater opening**

• Open the dura mater carefully by using an appropriate blade to make a cruciate incision, securing haemostasis is necessary.

• Irrigate the skull hole with sterile isotonic solution and make sure that the entry site in the dura is of adequate size to allow the probe to pass through without bending, and that it is cleared of any debris.

**Fixation of the bolt**

• Thread the bolt into the hole. Fig. 7 and Fig. 8 illustrate proper placement. Should undue resistance be encountered, do not use excessive force. If necessary, drill the inner table again. If the bolt is too loose a new hole must be drilled.

• The skin may be sutured around the shaft of the bolt, at location [a] in Fig. 7.

• The stylet (Fig. 4, h) is advanced through the bolt to ensure a good pathway for the introducer and for the probes (Fig. 8); the stylet is then removed.

**Insertion of the introducer**

DO NOT REMOVE THE GUIDE WIRE OR ICP OBTURATOR, (Fig. 4, b, j) BEFORE THE INTRODUCER IS INSERTED INTO THE BOLT.

**Fig. 6: Adjustment of the drill stop**

**Fig. 7: Distance to the sagittal line >20 mm; scalp may be sutured to bolt**

**Fig. 8: Insertion of stylet through the bolt ensures a good Pathway for the probe**

**Fig. 9: Insertion of the introducer**

**Fig. 9: Insertion of the introducer**
Hold the introducer by the outer tube above the compression cap (see Fig. 9). Rotate until the seal fits into the bolt channel and then insert it as far as possible into the bolt. Then the introducer tip reaches approximately 20 mm (Fig. 16) out of the bolt.

Continue to hold outer tube and rotate the compression cap (Fig. 10) clockwise one full turn (360°). The introducer should now be loosely attached to the bolt. The compression cap must not be tightened yet, as this will prevent removal of the guide wire and insertion of the probes.

### Insertion of the combined $p\text{O}_2$ and temperature probe

- Remove the guide wire (Fig. 4, b) from the "pO$_2$" labelled introducer channel. (Fig. 11).
- Remove the protection tube (Fig. 5, b) from the probe at location [a] in Fig. 5.
- Do not disconnect the extension tube ([d] in Fig. 5) because it serves to connect the probe and the introducer.
- Insert the probe as far as possible into the "pO$_2$" labelled introducer channel (Fig. 12). Rotate the blue, free rotating lock ring clockwise onto the female Luer-type connector of the introducer. To prevent rotation of the probe body hold the protection tube while securing the Luer-type connection (Fig. 13).
- In this position, the tip of the combined $p\text{O}_2$ and temperature probe is advanced through the pO$_2$ channel (labelled "pO$_2$") of the brain access system REF IP2 to a depth of approximately 35 mm below the dura (Fig. 16).

### Insertion of the ICP catheter

Prior to insertion, each of the compatible ICP sensors must be connected to its monitor and zeroed in accordance with its instructions for use.
Ventrix NL950-SD ICP catheter (sold separately)

Remove the ICP obturator (Fig. 14, Fig. 4, j) from the “ICP” labelled introducer channel (Fig. 4, a1) and attach the corresponding compression fitting (Fig. 4, i) to the channel.

Remove the protection tube from the tip of the ICP catheter and carefully insert it into the “ICP” labelled introducer channel until the first ring (counting from the catheter tip) of the 150 mm marker (three black rings), is 12 mm above the blue cap of the compression fitting (see Fig. 15). In this position the tip of the ICP catheter lies at the level of the dura. Advancing it further will bring the catheter tip into the cranial cavity. Normally, the tip of the Ventrix NL950-SD ICP catheter is advanced 12 mm below the level of the dura (Fig. 16). The ICP catheter should not be advanced deeper than 15 mm below the dura because the local tissue irritation induced by the ICP catheter could cause artifacts in the $p_O_2$ measurement.

Tightening the compression fitting

The compression fitting for Ventrix ICP catheter (Fig. 4, i) must be closed tightly by rotating its blue cap clockwise.

The compression fitting provides mechanical strain-relief when it compresses the catheter.

Camino 110-4L ICP catheter (sold separately)

Remove the ICP obturator (Fig. 14, Fig. 17, Fig. 4, j) from the “ICP” labelled introducer channel (Fig. 4, a1). The compression fitting (Fig. 4, i) is not used.

USE CARE WHEN REMOVING THE Camino 110-4L ICP CATHETER FROM THE PACKAGING TO PREVENT THE Licox BOLT ADAPTER FITTING COMPONENTS FROM SLIDING OFF THE CATHETER.
Refer to the Camino 110-4L catheter’s directions for use. Insert the tip of the Camino 110-4L catheter into the “ICP” labelled introducer lumen until its male Luer-type connector (Fig. 18, a) contacts the female Luer-type connector (Fig. 4, a1) on the introducer channel. Engage the male and female Luer-type connectors and tighten by rotating in a clockwise direction. Verify that the shoulder of the white plastic sleeve on the the Camino 110-4L catheter makes contact with the Bolt Adapter Fitting compressor cap (Fig. 18). The tip of the the Camino 110-4L catheter will extend beyond the bolt 15 mm.

Grasp the white plastic sleeve and retract the Camino 110-4L catheter until the black ring on the white plastic sleeve (a in Fig. 19) is exposed. Tighten the Bolt Adapter Fitting compressor cap (b in Fig. 19). Finally, the tip of the the Camino 110-4L catheter will extend beyond the bolt approximately 12 mm.

**Tightening of the compression cap**

- Rotate he compression cap (Fig. 4, c) of the introducer clockwise tightly onto the bolt. Hold the wings of the bolt with one hand while tightening the compression cap with the other (Fig. 21). The distance between the wings of the bolt and compression cap is small when tight, approximately 5 mm (see location [a] in Fig. 16 and in Fig. 20).

**AFTER TIGHTENING THE COMPRESSION CAP, CHECK THE ASSEMBLY FOR CSF LEAKAGE. IF A LEAK IS NOTED, HOLD THE WINGS OF THE BOLT FIRMLY IN ONE HAND AND TIGHTEN THE COMPRESSION CAP FURTHER. IF THE CSF LEAKAGE PERSISTS, REMOVE THE ASSEMBLY IN ORDER TO PREVENT INFECTION.**

**IN THE EVENT THAT AN ICP CATHETER IS NOT USED, ENSURE THAT THE ICP OBTURATOR (Fig. 4, j) IS INSERTED INTO THE ICP CHANNEL OF THE IP2 INTRODUCER AND THAT THE COMPRESSION CAP IS TIGHTENED ENOUGH TO PREVENT LEAKAGE OF CSF. THIS MAY REQUIRE MORE ROTATIONS OF THE COMPRESSION CAP THAN IF AN ICP CATHETER IS USED.**

![Fig. 18: Maximum insertion of the Camino 110-4L ICP catheter](image)

![Fig. 19: Ready for measurement with the Camino 110-4L ICP catheter](image)
Prior to measurement the patient bedside monitor must be zeroed according to the Licox PMOBOX operations manual. Please note that temperature will not be displayed on the bedside monitor.

- Connect the combined oxygen and temperature probe to the blue monitor cable REF PMOCAB.
- The smart card is not required. Connect the Licox PMOBOX and the patient bedside monitor using NL950-MC-xx cable.

**P_{bt}O_2 and Temperature Monitoring using the Licox PMOBOX**

- Insert the smart card into the smart card slot on the front panel of the Licox CMP monitor or the Licox P_{bt}O_2 monitor or, if using the Licox p_{bt}O_2 Monitor, into the smart card slot on the right panel of the p_{bt}O_2 monitor.

Normally, reliable p_{bt}O_2 readings are available after a tissue stabilization time of 20 minutes (when the tissue has stabilized after the microtrauma of implantation). However, it may occasionally take up to two hours until the readings stabilize.

For related information regarding set up and use please refer to the Licox CMP monitor operations manual or the Licox P_{bt}O_2 Monitor User’s manual and/or PMOBOX operations manual.

**Safe Removal and Disposal**

- Removal of the system should occur in reverse order of the insertion, i.e. loosen the compression cap and fittings, remove each catheter individually, then remove the introducer and finally the bolt.

**DO NOT REMOVE THE BOLT FROM THE PATIENT WITH THE INTRODUCER STILL IN PLACE.**

- The skin may be closed with a suture or staples.

**The single use components must be handled as biohazardous material. Dispose off the single use components according to the hospital policy.**
ACCURACY

Accuracy determined during continuous $p_{bt}O_2$ measurement at 37°C.

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HOW SUPPLIED

Licox Brain Tissue Oxygen Monitoring Probes and Introducer Kits are supplied sterile and non-pyrogenic in a double-wrap packaging.

RETURN POLICY

Authorization from customer service must be obtained prior to returning product.

No product return is accepted except if previously agreed by Integra in the framework of a complaint.

Determination of a product defect will be made by Integra.

All products can be ordered through your Integra SalesSpecialist.

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