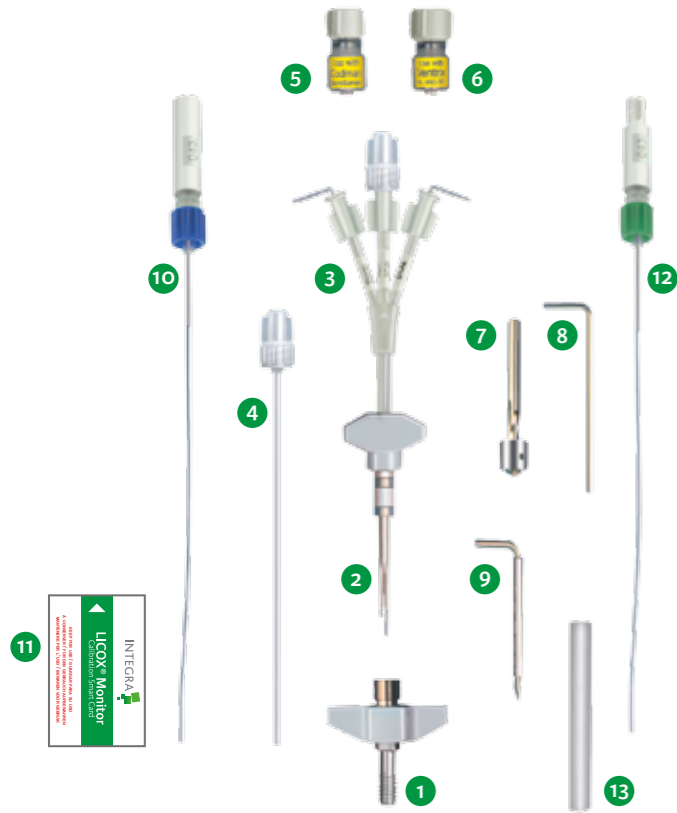


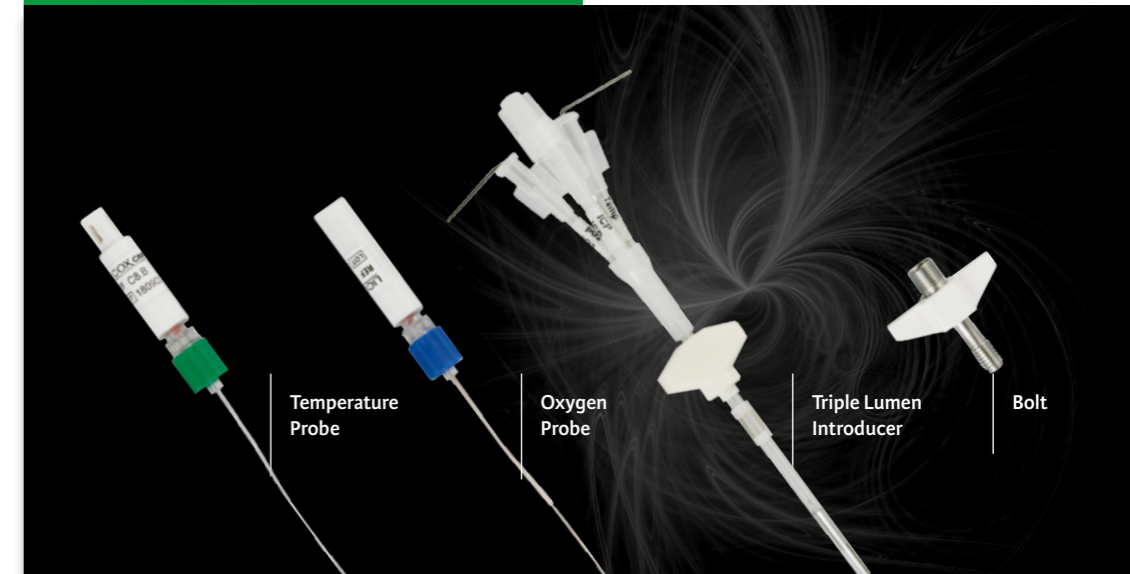
**Kit Components**



- 1 Bolt
- 2 Compression cap
- 3 Triple lumen introducer
- 4 ICP obturator
- 5 Compression fitting for CODMAN® ICP MICROSENSOR® catheter
- 6 Compression fitting for VENTRIX® ICP catheter
- 7 Drill bit (Ø 5.3 mm)
- 8 Hex wrench for adjustment of the drill stop
- 9 Stylet
- 10 Oxygen Probe
- 11 Smart card calibration data for the probe
- 12 Temperature probe
- 13 Test tube to perform the plausibility check

**Specifications**

<b>Drill Bit Diameter</b> (always use the drill bit provided in the kit)	5.3 mm
<b>Run-In Time</b>	After insertion the stabilization time (time until PbtO <sub>2</sub> values are representative for the surrounding tissue ) may last from 20 minutes to 2 hours.
<b>Accuracy</b> (determined during continuous PbtO <sub>2</sub> measurement at 37°C)	<ul style="list-style-type: none"> <li>• PbtO<sub>2</sub> 0-20 mmHg ± 2mmHg</li> <li>• PbtO<sub>2</sub> 21-50 mmHg ± 10%</li> <li>• PbtO<sub>2</sub> 51-150 mmHg ± 13%</li> <li>• Temperature ± 0.2°C</li> <li>• Max. duration of use 5 days</li> </ul>
<b>Magnetic Resonance (MR) Compatibility</b>	Integra has not performed testing to determine the MRI Safety or compatibility of the IM3.ST_EU. Therefore, Integra cannot recommend the use of this product in an MR environment.
<b>CT Scan</b>	Yes



If you want to measure intracranial pressure (ICP), you have to order separately one of the following items:

CAMINO® CATHETER 110-4L



OR

VENTRIX® CATHETER NL950-SD



Integra LifeSciences Services (France) SAS  
Sales & Marketing EMEA  
Immeuble Séquoia 2 • 97 allée Alexandre Borodine  
Parc technologique de la Porte des Alpes  
69800 Saint Priest • FRANCE  
Phone: +33 (0)4 37 47 59 00 • Fax: +33 (0)4 37 47 59 99  
emea.info@integralife.com • [integralife.com](http://integralife.com)

■ GMS • Gesellschaft für Medizinische  
Sondentechnik mbH  
Dorfstrasse 2, 24247 Mielkendorf • Germany  
Tel: +49 (0) 4347 7051 • Fax: +49 (0) 4347 7051 29  
gms-licox@integralife.com

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PRODUCTS FOR SALE IN EUROPE, MIDDLE-EAST AND AFRICA ONLY

**Customer Service**  
International: +33 (0)4 37 47 59 50 • +33 (0)4 37 47 59 25 (Fax) • [csemea@integralife.com](mailto:csemea@integralife.com)  
France: +33 (0)4 37 47 59 10 • +33 (0)4 37 47 59 29 (Fax) • [custsvcfrence@integralife.com](mailto:custsvcfrence@integralife.com)  
United Kingdom: +44 (0)1 264 345 780 • +44 (0)1 264 363 782 (Fax) • [custsvcs.uk@integralife.com](mailto:custsvcs.uk@integralife.com)  
Germany: +49 (0) 2102 5535 6200 • +49 (0)2 102 5536 636 (Fax) • [custsvcgermany@integralife.com](mailto:custsvcgermany@integralife.com)  
Benelux: +32 (0)2 257 4130 • +32 (0)2 253 2466 (Fax) • [custsvcbenelux@integralife.com](mailto:custsvcbenelux@integralife.com)  
Switzerland: +41 (0)2 27 21 23 30 • +41 (0)2 27 21 23 99 (Fax) • [custsvcsuisse@integralife.com](mailto:custsvcsuisse@integralife.com)

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# Integra

LICOX® Brain Tissue Oxygen Monitoring

Ref: IM3.ST\_EU

# Integra

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LICOX® Brain Tissue Oxygen Monitoring

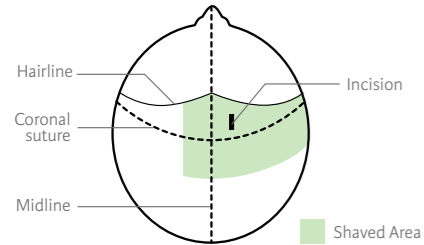
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## Steps of Use

This chart does not replace the Instructions for Use accompanying the LICOX® IM3ST\_EU product. The Instructions for Use must be read carefully before using this product.

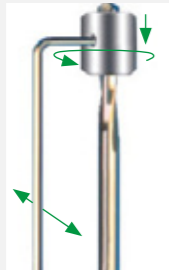
### 1. Placement

If possible place the probe 20–40 mm off the midline, staying clear of the sagittal sinus, anterior to the coronal suture. The position of the drill hole should be at least 10 mm from other probes.



### 2. Preparation for Drilling the Hole

- Estimate the thickness off the skull and adjust the drill stop accordingly. The tip of the drill-bit should not penetrate the inner table by more than 1 mm.
- Attach the drill-bit to a hand drill. Do not use a powered drill.
- Drape the shaved and prepared area. Infiltrating in the area of the incision subcutaneously with a local anaesthetic is a surgical option.
- Make an appropriate linear incision, carrying it to the bone.

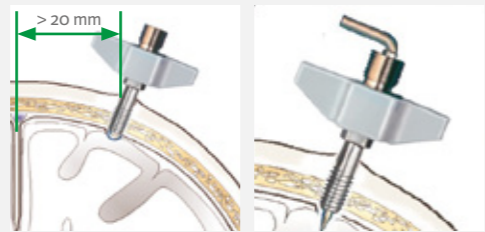


### 3. Drilling the Hole and Open the Dura

- Drill the hole. Do not change the direction of the drill while drilling. Remove the drill and rinse the hole with sterile isotonic solution.
- Incise the dura carefully with a number eleven (#11) blade, securing hemostasis as necessary.

### 4. Fixation of the Bolt

- Thread the bolt into the hole.
- The stylet is advanced through the bolt to create a pathway for the probe and then the stylet is removed.

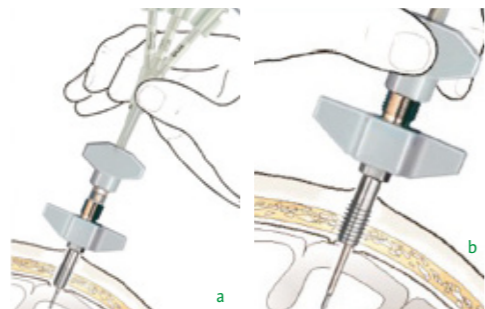


### 5. Insertion of the Introducer

#### Caution

Do not remove the guide wire or ICP obturator before the introducer is inserted into the bolt.

- Hold the introducer by the outer tube above the compression cap (a). Rotate until the seal fits into the bolt channel and then insert it as far as possible into the bolt.
- Continue to hold outer tube and rotate the compression cap clockwise one full turn (360°) (b).



#### Caution for Steps 6, 7 & 8

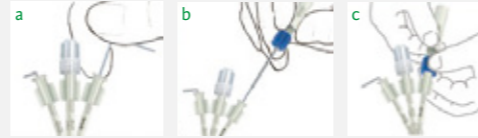
Please respect the insertion order of the different probes.

### 6. Insertion of the PbtO<sub>2</sub> Probe

#### Caution

Please use only the smart card supplied with the oxygen probe (cross check serial number on probe and smart card). Use of the wrong smart card can cause measurement errors.

- Remove the guide wire (a) from the «pO<sub>2</sub>» labelled introducer channel.
- Insert the oxygen probe as far as possible into the «pO<sub>2</sub>» labelled introducer channel (b).
- Connect with the Luer-type connection (c).



### 7. Insertion of the ICP Catheter

- Prior to insertion, each of the compatible ICP sensors must be connected to its monitor and zeroed according to its instructions for use.
- Remove the ICP obturator from the «ICP» labelled introducer channel.



If CAMINO® 110-4L ICP catheter is used: (sold separately)

#### Caution

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.

- Insert the tip of the Camino® 110-4L catheter into the «ICP» labelled introducer lumen until its male Luer-type connector contacts the female Luer-Type connector.



- Engage the male and female Luer-Type connectors and tighten by rotating in a clockwise direction.
- Grasp the white plastic sleeve and retract the Camino® 110-4L catheter until the black ring plastic sleeve is exposed (a).
- Tighten the bolt adapter fitting compressor cap.

If VENTRIX® NL950-SD is used: (sold separately)

- Attach the corresponding compression fitting to the channel.



- Insert the tip of the VENTRIX® NL950-SD ICP catheter into the «ICP» labelled introducer channel until the first ring (counting from the catheter tip) of the 150 mm marker (three black rings), is 12mm above the white cap of the compression fitting.

The ICP catheter should not be advanced deeper than 15 mm below the dura because the local tissue irritation induced by the ICP catheter can cause PbtO<sub>2</sub> measurement artifacts.

- The compression fitting must be closed tightly by rotating its cap clockwise.
- If CODMAN® ICP MICROSENSOR® catheter is used: (sold separately)

- Attach the corresponding compression fitting to the channel.
- Mark the CODMAN® ICP MICROSENSOR® catheter 155 mm from the tip and insert it into the «ICP» labelled introducer channel so that the mark is visible above the cap of the compression fitting.

The ICP catheter should not be advanced deeper than 15 mm below the dura because the local tissue irritation induced by the ICP catheter can cause PbtO<sub>2</sub> measurement artifacts.

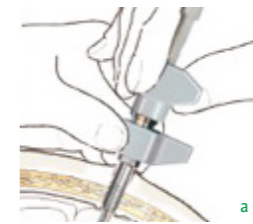
- The compression fitting must be closed tightly by rotating its cap clockwise.

### 8. Insertion of the Temperature Probe

- Remove the guide wire from the remaining channel of the introducer assembly that is labelled with «Temp».
- Remove the temperature probe from its protection tube.
- Insert the probe as far as possible into the «Temp» labelled introducer channel, and fix it in place at the Luer-type connector of the introducer by rotating its green lock ring clockwise.

### 9. Tightening the Compression Cap

- Rotate the compression cap 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 hand (a). The distance between the wings of the bolt and compression cap is small when tight, approximately 2 mm.



#### Caution

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 the possibility of infection.

In the event that an ICP catheter is not used, ensure that the ICP obturator is inserted into the ICP channel of the IM3\_EU introducer and that the compression cap is tightened enough to prevent leakage of CSF. This may require more rotations of the compression cap as if an ICP catheter is used.

### 10. PbtO<sub>2</sub> and Temperature Monitoring

- Insert the smart card into the smart card slot on the front panel of the LICOX® CMP monitor.



- Connect the PbtO<sub>2</sub> probe to the blue PO<sub>2</sub> monitor cable (REF BC10PA).
- Connect the temperature probe to the green temperature monitor cable (REF BC10TA).



If you do not use a brain temperature probe for temperature measurement, the patient's core temperature may be set at the dial on the front panel of the LICOX® CMP Monitor in °C. The patient's core temperature should be checked regularly and adjusted accordingly.

### 11. Removing LICOX® System

- 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.
- Dispose off the single use components according to the hospital policy.