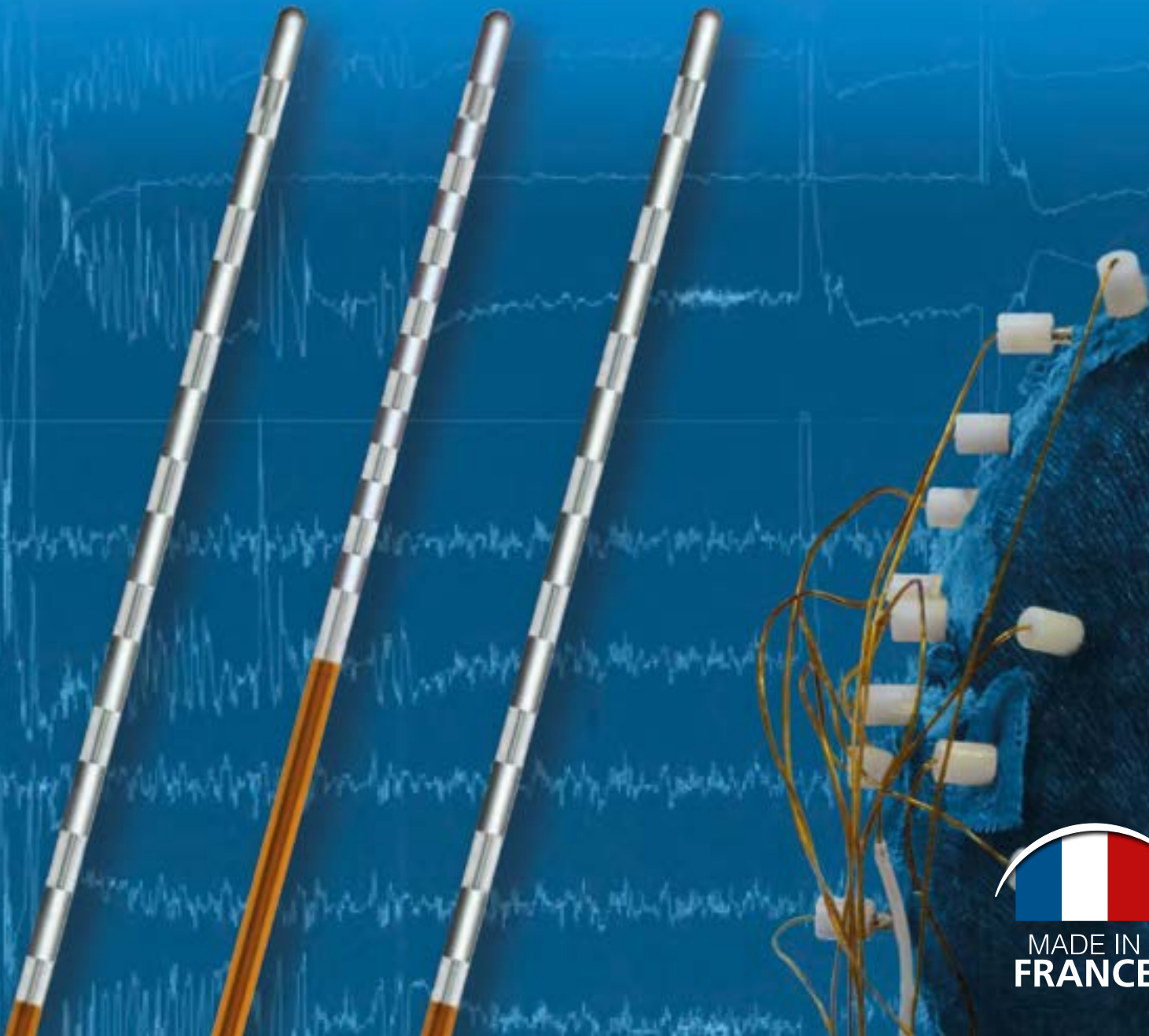




DEPTH COAGULATION ELECTRODES ACCESSORIES SEEG STEREOTAXY





**ONE OF THE
LIGHTEST
CONNECTORS
ON THE MARKET
LESS THAN
4 GRAMS**



**EXCLUSIVELY AT
ALCIS**

**TOUCHLESS
SYSTEM**

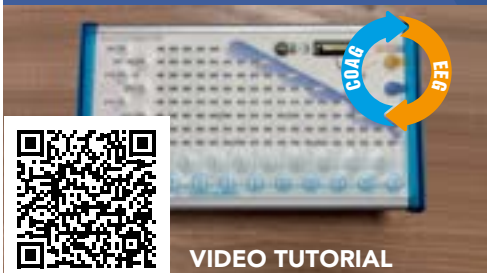
Allows you to use the graduated ruler while keeping the EPC in its protective tube



VIDEO TUTORIAL

**CONNECTING
BOX**

Allows you to
**SWITCH BETWEEN
COAGULATION
AND MONITORING**
at any time



VIDEO TUTORIAL

**EXCLUSIVELY AT
ALCIS**

EPC : 2 specific steps

- 2 mm **HR**
(High Resolution)

- 4 mm





Our aim is to help curing patients by providing the best techniques, technology and services.

Thanks to our constant research for excellence, we offer exclusive electrodes techniques and an exclusive box for thermo lesion with an EEG/Coag switch that enables you to get immediate results after thermocoagulation.

For over 15 years, Alcis has developed and marketed a full range of products dedicated to the neurosurgical field, and particularly the treatment of drug-resistant epilepsy.

This achievement illustrates Alcis's skills as an integrator of technologies and our expertise in manufacturing high-tech medical devices.

Summary

4 ■ **SEEG**
DEPTH COAGULATION ELECTRODES

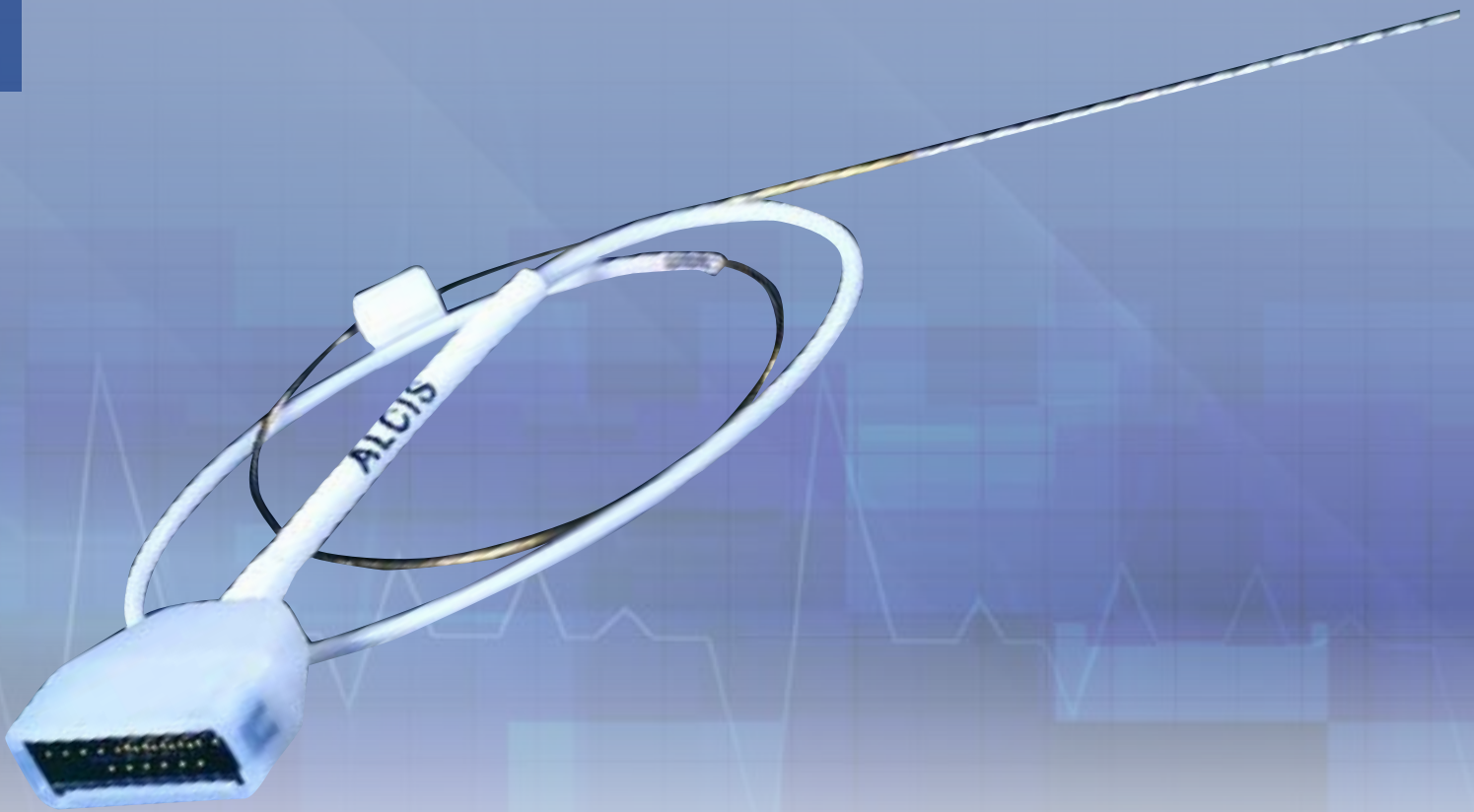
9 ■ **SEEG**
RECORDING AND COAGULATION

13 ■ **ACCESSORIES**

21 ■ **STEREOTAXY**

SEEG DEPTH COAGULATION ELECTRODES

4

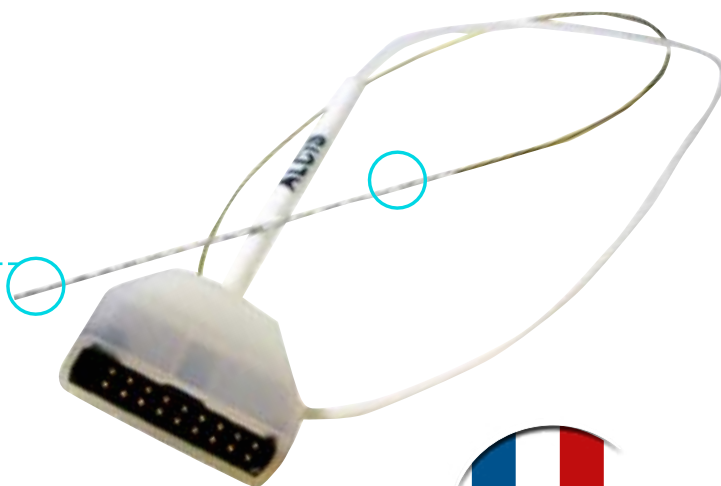


■ EPC Electrodes and Accessories

SEEG / COAGULATION / EPILEPSY

Range 2069-EPC

- > Thermo-Coagulation : Available, thanks to our CE marked Coagulation box BC3,
- > **Exclusive EPC, Step 2mm and 4mm (CE marked),**
- > Distal Tip Contact,
- > From 5 to 18 contacts,
- > Platinum and Iridium contact,
- > Diameter : 0.8 mm,
- > **Atraumatic distal tip,**
- > Light Connector,
- > Protector sheath for **"touchless"** implantation,
- > **High resistance to bending,** (thanks to our exclusive technology)
- > Up to 3-week implantation,
- > **Guidance screws:** standard and **short.** (Alcis neuro exclusivity)



CE 1014 marked

2 CONTACT TYPES

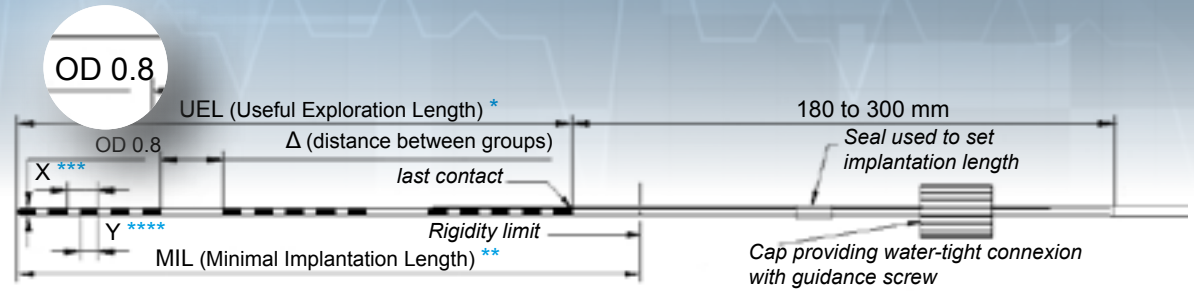
References	Standard electrodes	High resolution electrodes
Type	Type C	Type E
Ring Contacts	Standard ring contacts 2 mm	Standard ring contacts 1 mm
Tip	2 mm distal contact	2 mm distal contact

Designed to be used with Alcis guidance screw from range 2023-VG and 2023-VG-C.
 Compatible with Alcis accessories range 2023 / 2036 / 2069 (cf. IFU).
 Unitary sterile packaging. Single use.

Class III medical device - CE 1014 marked

■ Depth coagulation electrodes

SEEG / COAGULATION / EPILEPSY
Range 2069-EPC




- * UEL = Useful Exploration Length, distance between the first and the last contact.
- ** MIL = Minimum Implantation Length, minimum length between the target and the proximal edge of the guidance screw.
- *** X = Contacts steps.
- *** Y = Ring contacts size.

RANGE 2069-EPC TYPE C







**** Y = 2 mm *** Contact step 3.5 or 4.0 mm S: Stock

References	Nb of contacts	Δ (mm)	UEL * (mm)	MIL ** (mm)	Avail.
2069-EPC-05C-35	5	-	16	26	S
2069-EPC-08C-35	8	-	26.5	36.5	S
2069-EPC-10C-35	10	-	33.5	43.5	S
2069-EPC-12C-35	12	-	40.5	50.5	S
2069-EPC-15C-35	15	-	51	61	S
2069-EPC-18C-35	18	-	61.5	71.5	S
 2069-EPC-18C-40	18	-	70	80	S
2069-EPC-15C-35-3G-07	3 x 5	7	62	72	S
2069-EPC-15C-35-3G-11	3 x 5	11	70	80	S
2069-EPC-18C-35-3G-11	3 x 6	11	80.5	90.5	S

RANGE 2069-EPC TYPE E



**** Y = 1 mm *** Contact step 2.0 mm R: Request

References	Nb of contacts	UEL * (mm)	MIL ** (mm)	Avail.
  2069-EPC-15E-20	15	30	40	R
  2069-EPC-18E-20	18	36	46	R

Depth electrodes

2069-EPC type Micro-Macro

ALCIS micro-macro intracerebral **Depth Electrodes** are multi-contact electrodes used for presurgical epilepsy diagnosis. They are designed for Stereo-ElectroEncephaloGraphy recording (SEEG) which is a short stimulation and thermocoagulation used as a therapeutic alternative to conventional epilepsy surgery.

RANGE 2069-EPC TYPE acb



2069-EPC MICRO MACRO

Two-scale recording > micro and macro.

Coagulation mastered on macro contacts

> Easy and safe impedance driving thanks to our connecting box.

Patient / user comfort > perfectly smooth distal part ; reduced Minimal Implantation Length (MIL) : 10 mm after the last macro contact.

Other features:

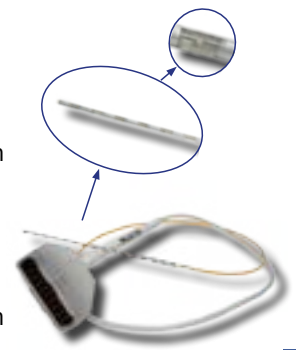
> Platinum iridium contacts & wires > Better signal collection.

> Distal OD ≤ 0.8 mm / proximal OD ≈ 1.5 mm > Less invasive / good mechanical strength.

> Compatible with Alcis standard implantation, connection and coagulation accessories from ranges 2023 and 2069 (refer to IFU).

Single use device / **class III medical device - CE 1014** marked. Packaged in sterile individual pouch.

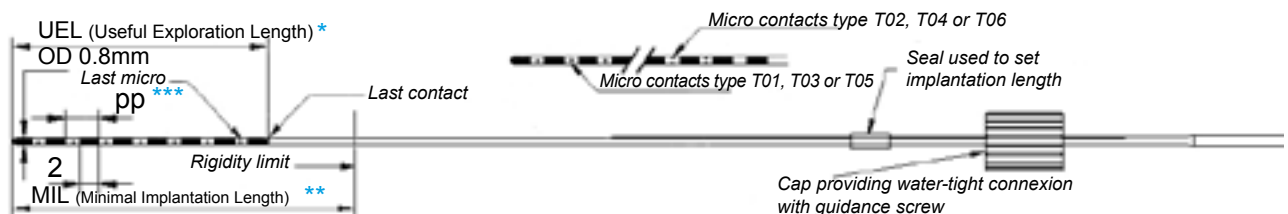
Consult us to identify the compatible recording solutions.



Reference	Macro contact	Micro contact	Micro size	Micro contacts positioning	UEL * (mm)	MIL ** (mm)	Avail
2069-EPC-5C9-35T02	5	9	37 µm	3 at 120°	16	26	R
2069-EPC-8C9-35T02	8	9	37 µm	3 at 120°	26.5	36.5	R
Other micro contacts configurations possible - consult us							

a = number of macro contacts
b = number micro contacts
Txx = micro contacts type

Avail.: Product availability - S = Stock, R = on Request



* UEL = Useful Exploration Length, distance between the first and the last contact.

** MIL = Minimum Implantation Length, minimum length between the target and the proximal edge of the guidance screw.

*** pp = 3.5mm = macro contacts step. NOT CE MARKED. * Manufacturer: ALCIS – Besançon, France.

Reference	Macro contact	Micro contact	Micro size	Micro contacts positioning	UEL * (mm)	MIL ** (mm)	Avail
2069-CE99C070BFB5	9	9	37 µm	3 at 120°	26.5	36.5	R

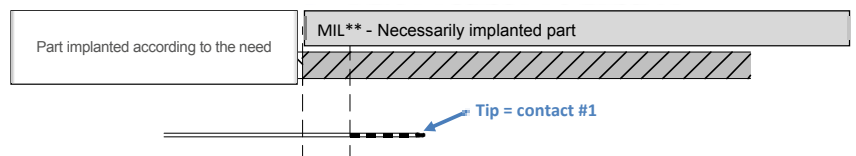
■ ALCIS Neuro SEEG

Electrodes range chart

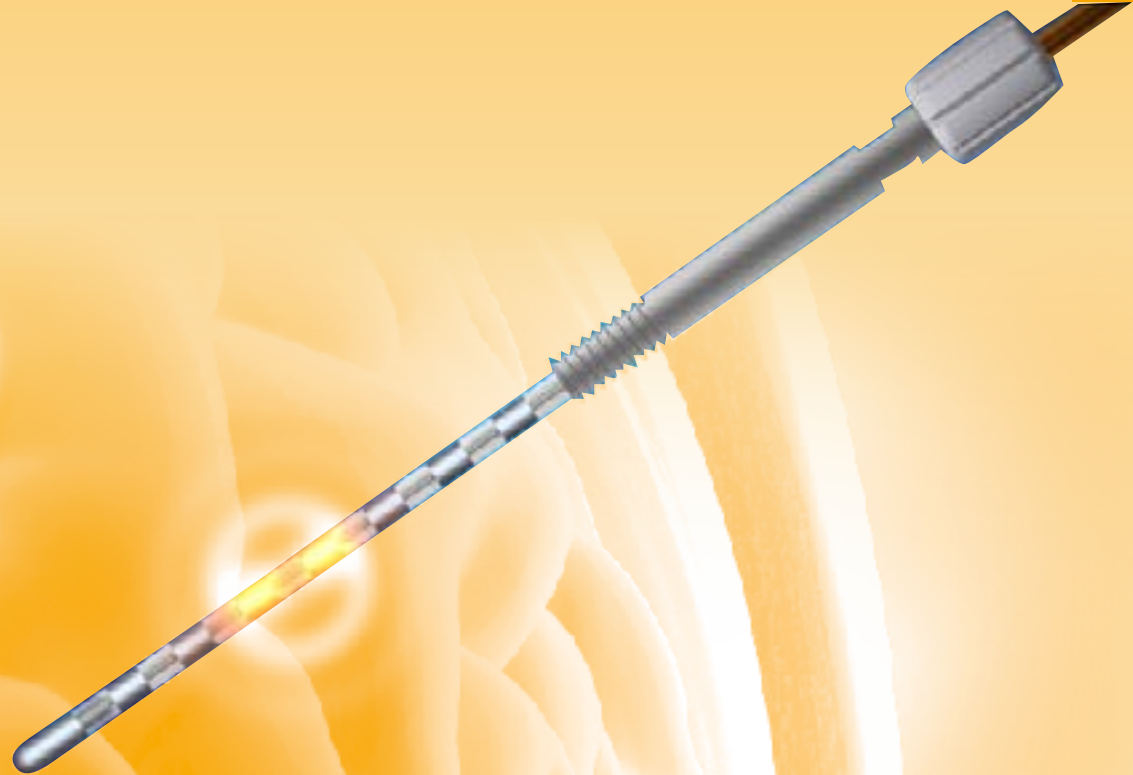
Features	Advantages
Tip contact	Full length Signal retrieving Minimum Invasive SEEG
Smooth tip contact	Atraumatic
Platinum Iridium contact and wire	Better signal and recording
Light Connector	Lighter weight on the patient's head
High resistance to bending	High resistance

References	Nb contacts	UEL * (mm)	MIL ** (mm)	Type	*UEL= Useful Exploration Length **MIL= Minimal Implantation Length
2069-EPC-18C-35-3G-11	3x6	80,5	90,5		
2069-EPC-15C-35-3G-11	3x5	70	80		
2069-EPC-15C-35-3G-07	3x5	62	72		
2069-EPC-18C-40	18	70	80	4.0	
2069-EPC-18C-35	18	61,5	71,5		
2069-EPC-15C-35	15	51	61		
2069-EPC-12C-35	12	40,5	50,5		
2069-EPC-10C-35	10	33,5	43,5		
2069-EPC-08C-35	8	26,5	36,5		
2069-EPC-05C-35	5	16	26		
2069-EPC-15E-20	15	30	40	HR	
2069-EPC-18E-20	18	36	46	HR	

Alcis Neuro exclusive



SEEG RECORDING AND THERMOCOAGULATION



■ COMPLETE COAGULATION SOLUTION

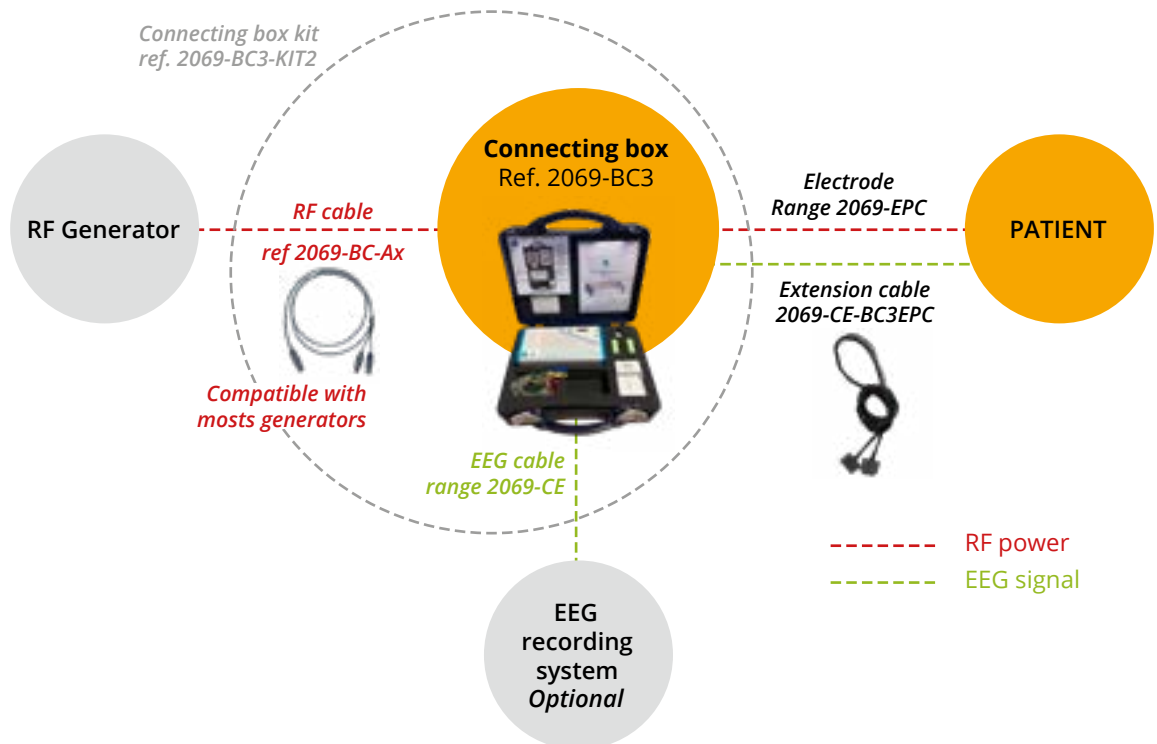
Generator - Connecting box Kit - Electrode Range 2069

The Alcis coagulation depth electrodes are **intended to perform thermocoagulation "in-situ"**, in association with a RF generator, as a therapeutic alternative to conventional epilepsy surgery (especially for patients for whom conventional surgery is excluded).

Alcis offers a complete solution for Coagulation that includes the following devices:

- > Connecting box Kit (ref. 2069-BC3-KIT2)
- > Depth coagulation electrode (range 2069-EPC), for technical information, refer to 2069-EPC-FT technical form.

 <http://www.alcis.net/content/uploads/2021/07/2069-EPC-001o-EU-SEEG-26P.pdf>



Please note that Alcis does not provide the EEG recording system nor the RF generator. Ask for compatibility information.

■ Connecting Box Kit

2069-BC3-KIT2

The Connecting box kit includes:

- > Connecting box (ref. 2069-BC3),
- > EEG cable (ref. 2069CE-18c-150-B-FB5),
- > Testing device,
- > Battery charger with 2 batteries,
- > IFU of the kit.

The kit is provided in a plastic briefcase.



The Alcis Connecting Box is **user-friendly and safe to use**. It makes it possible to:

- > Avoid misconnections,
- > Select the type of depth electrode connected,
- > Select the couple of contacts to coagulate,
- > Control directly after coagulation the EEG signal.
(requires to connect a EEG recording system)

Class IIb medical device - CE 1014



http://www.alcis.net/content/uploads/2021/07/Utilisation_BC3.mp4



■ Extension cable

Range 2069 - CE

Alcis Extension Cables are intended to create a link from intracerebral depth electrodes (range 2069-EPC) to an **EEG recording system**.

References	Nb of contacts	Length	Cable specifications	Packaging
2069-CE-05c-150-B-FB5	5	150 cm	B = braided	Unitary Non Sterile
2069-CE-08c-150-B-FB5	8			
2069-CE-10c-150-B-FB5	10			
2069-CE-12c-150-B-FB5	12			
2069-CE-15c-150-B-FB5	15			
2069-CE-18c-150-B-FB5	18			
2069-CE-XXc-III(-B-FB5)*	Custom made - please contact us			

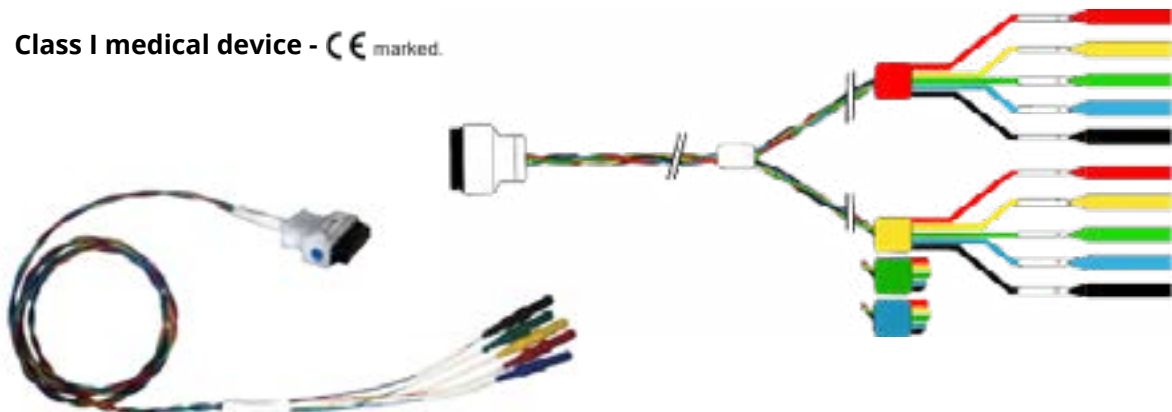
*to define reference, replace:

- III by the length in cm,
- XX by the number of contacts.

- > A colour coding helps you identify each wire and prevents you from making mistakes when you connect the cables to the EEG recording system.
- > A blue spot on both cable and electrode helps you connect these two devices quickly without making any mistakes.
- > Compatible with removable link 2023-CE-L2 to secure the electrode connection with the cable.

Box of 1 unit. Provided non sterile

Class I medical device - CE marked.



■ Removable link

2023-CE-L2

Removable link is intended to ensure a safe connection between the electrode's connector and the extension cable's connector.

Pouch of 5 reusable units. Provided non sterile.

Class I medical device - CE marked.



ACCESSORIES



■ GUIDANCE SCREW

Range 2023-VG

This range of products allows you to implant depth coagulation electrodes and insert a stylet with a maximal guidance effect, but also to position robots.



References	Length (mm) (L)	Material	Packaging
2023-VG-15	15	Titanium alloy	Box of 10 sterile units (individual pouch)
2023-VG-20	20		
2023-VG-25	25		
2023-VG-30	30		
2023-VG-35	35		

- > Calibrated for ID 2.5mm guide,
- > Self-threading extremity for direct fixation in a 2.1 mm diameter mm osseous hole,
- > Two external flats for extraction with Alcis wrench 2023-CL,
- > Use exclusively with Alcis depth coagulation electrodes range 2069-EPC,
- > Set exclusively with Alcis screwdriver range 2023-TO,
- > Offers a watertight connection with the electrode thanks to a seal and a cap,
- > Ethylene oxide sterilized,
- > Single use.

Class III medical device - CE 1014 marked




SHORT GUIDANCE SCREW

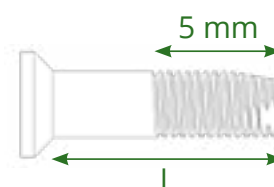
Range 2023-VG-C



- > Short guidance screws allow for a connection even closer to the patient's cranium.
- > Each short guidance screw is provided with:
 - A guide which helps you make a pre-hole with our stylet range 2023-ST following the trajectory given by the guidance screw,
 - A cap to be screwed onto the guidance screw,
 - A retainer ring which keeps the electrode close to the cap.

 Alcis Neuro exclusive

References	Length (mm) (L)	Material	Packaging
2023-VG-C-15	15	<ul style="list-style-type: none"> • Titanium alloy • Silicone • Polymer 	Box of 10 sterile units (individual pouch including: screw, guide, cap and retainer)
2023-VG-C-20	20		
2023-VG-C-25	25		
2023-VG-C-30	30		

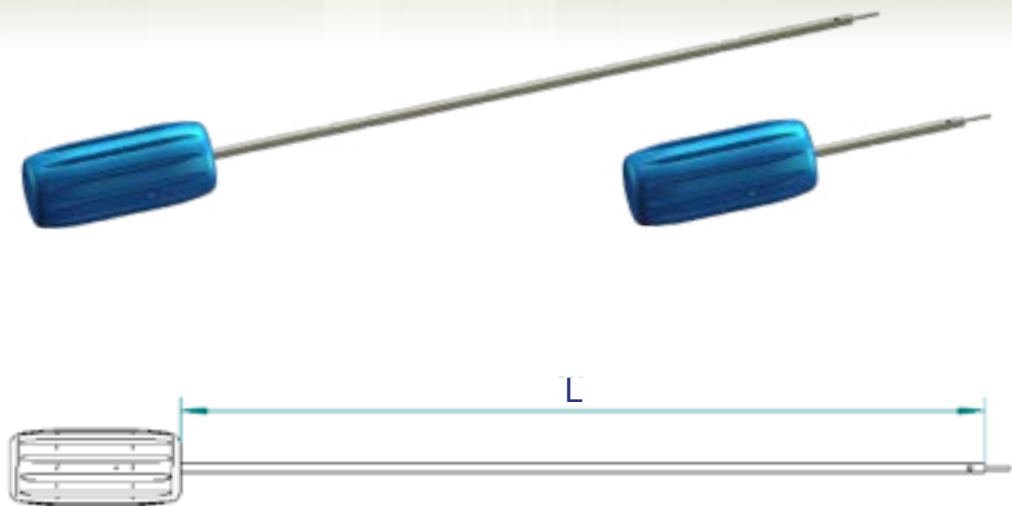


- > Use exclusively with Alcis depth coagulation electrodes range 2069-EPC,
- > Self-threading extremity for direct fixation in a 2.1 mm diameter osseous hole,
- > Set with Alcis screwdriver, 2023-TO-C-III and ALCIS clamp 2023-PIN (see 2023-AVG-C-FT technical form),
- > In the event of difficulty for the screwing / unscrewing of the cap, use exclusively screwdriver Alcis 2023-TO-BC (see page 22),
- > Ethylene oxide sterilized,
- > Single Use.

■ CONNECTION AND SET UP ACCESSORIES

Range 2023

SCREWDRIVER 2023-TO



For standard guidance screw

References	Length L (mm)	Material	Packaging
2023-TO-020	20	Stainless steel (body) POM (handle)	Unitary non sterile
2023-TO-160	160		

For short guidance screw

References	Length L (mm)	Material	Packaging
2023-TO-C-020	20	Stainless steel (body) POM (handle)	Unitary non sterile
2023-TO-C-160	160		
2023-TO-BC	30		

- > For use only with Alcis Guidance screw range 2023-VG,
- > Calibrated for ID 2.5 mm stereotactic guide (except length 20),
- > Supplied non sterile,
- > Re-usable device designed for steam sterilization at 134°C

Class I medical device - CE marked

CONNECTION AND SET UP ACCESSORIES

Range 2023

WRENCH 2023-CL

References	Useful opening (mm)	Material	Packaging
2023-CL	1.9	Stainless steel	Unitary non sterile
2023-CL-C	3.5		

- > Designed to unlock Alcis guidance screw range 2023-VG and short guidance screw range 2023-VG-C,
- > User-friendly curved shape,
- > Supplied non sterile,
- > Re-usable device designed for steam sterilization at 134°C.



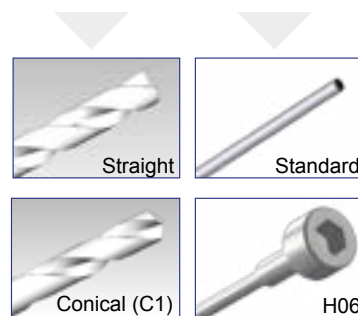
Class I medical device - CE marked

DRILL 2023-FO

References	Total length (mm)	Cutting length (mm)	Material	Distal shape	Proximal end	Packaging
2023-FO-III (-C1-H06)	140	20	Stainless steel	Straight or Conical	Standard or H6	Unitary non sterile
	200					
	250					

To determine the reference, replace III with the wanted length...";
 "Other total length III of max 250mm are feasible on request.

Other total length III in the limit of 250 mm realizable on request.



- > DESIGNED TO PERFORM Ø2.1 mm OSSEOUS HOLE, to place the guidance screw (standard or short)
- > Compatible with ID 2.5 mm stereotactic guide,
- > Compatible with Alcis depth stop 2036-BU-25-RU to ease control of drilling depth,
- > Other designs available see 2036-AS-FT technical form.
- > Provided non sterile,
- > Reusable device designed for steam sterilization at 134°C

Class III medical device - CE 1014 marked

■ GRADUATED RULER

Range 2023-TG



References	Material	Packaging
2023-TG2	Polymer	Unitary non sterile

2023-TG2 SEEG GRADUATED RULER

- > Allows to control on one side the insertion depth of the tools (drill, coagulation electrode, screwdriver),
- > Allows to control on the other side the implantation length of the depth coagulation electrodes,
- > The electrode is directly put with its protective tube on the ruler. Just pull the electrode to adjust the implantation length,
- > Ruler length: 200 mm,
- > Maximal measure length: 200 mm,
- > Accuracy: 0.75 mm,
- > Measurement constant: 0.25 mm,
- > Compatible with ALCIS tools from ranges 2023, 2036 and 2069,
- > Provided non sterile,
- > Reusable device, compatible with steam sterilization at 134°C.

Class Im medical device - CE 1014 marked



http://www.alcis.net/content/uploads/2021/07/Utilisation_reglette.mp4



■ CONNECTION AND SET UP ACCESSORIES

Range 2023



SINGLE USE STYLET 2023-ST

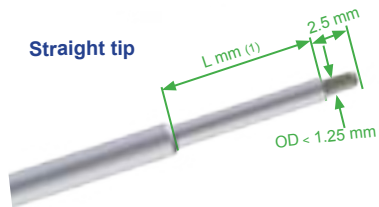
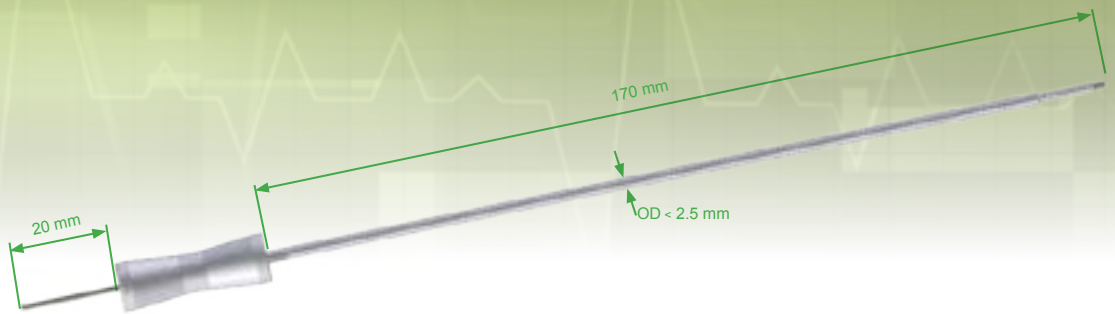
References	Minimum useful length (mm)	OD (mm)	Stopper	Material	Packaging
2023-ST-AB	120	0.8	Yes	Stainless steel (stylet) Polymer (stopper)	Box of 10 sterile units, (individual pouch)

- > Designed to realise a 0.8mm OD first hole to ease the depth coagulation electrodes introduction,
- > Soften distal end,
- > Supplied with adjustable depth stop which makes it easier to control the insertion depth,
- > Ethylene oxide sterilized,
- > Single use.

Class III medical device - CE 1014 marked

■ COAGULATION ELECTRODES

Range 2023-EC

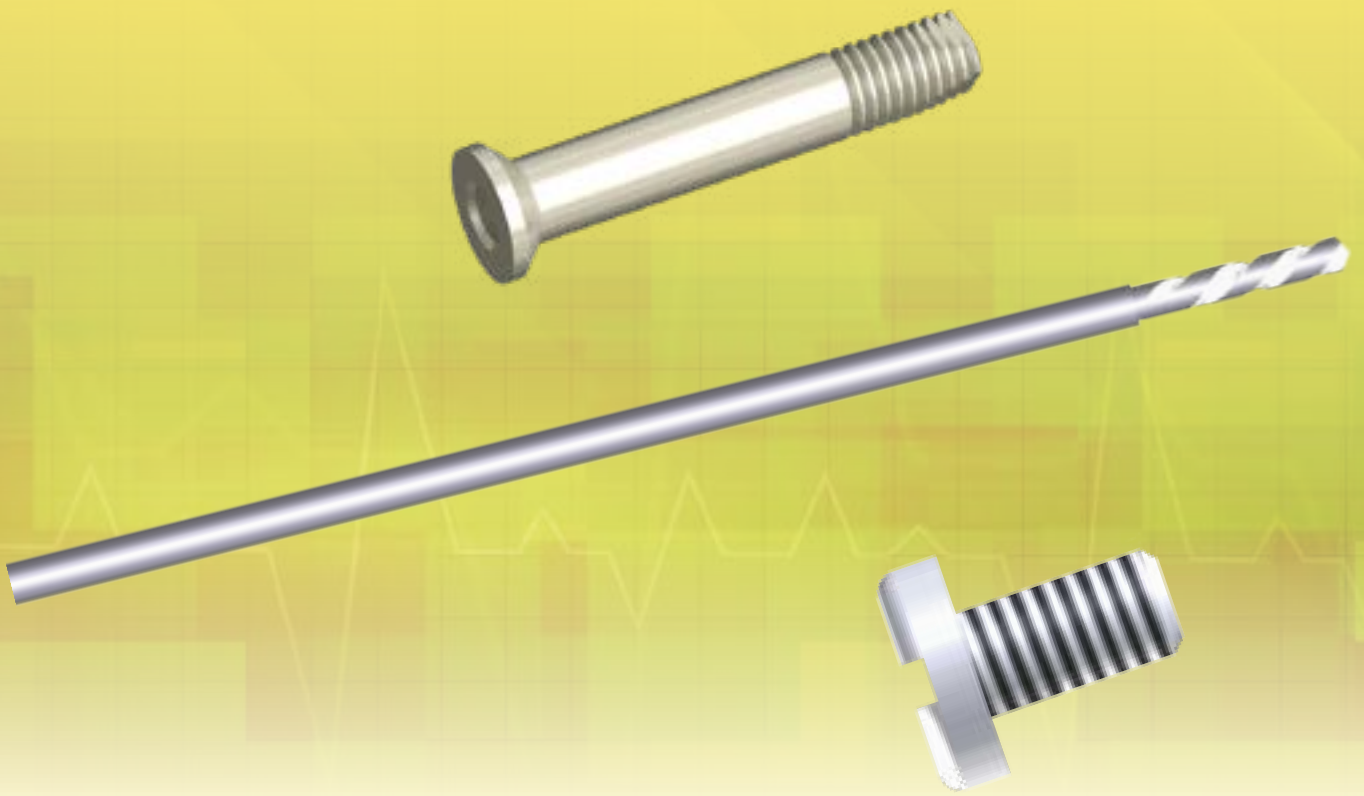


References	Shape	Insulated Distal Length (mm) (1)	Active OD	Active Length (mm)	Materials	Packaging
2023-EC-30-STD	Straight	30	1.20mm	2.5	Stainless steel (body) Polymere (handle and insulating part)	Unitary non sterile

- > Monopolar electrode intended to coagulate the dura mater by thermocoagulation for stilet introduction,
- > Compatible with ID 2.5 mm stereotactic guides,
- > Compatible with single use Alcis depth stop 2036-BU-25-RU, (see page 22)
- > Provided non sterile,
- > Reusable material designed for steam sterilization at 134°C.

Class III medical device – CE 1014

STEREOTAXY



■ BONE FIDUCIAL GUIDANCE SCREW

Range 2023-VG-CM





ALCIS short guidance screws can be used as bone fiducial during surgeries performed with robots. These screws are available in several length in order to adapt to the patient's anatomy.

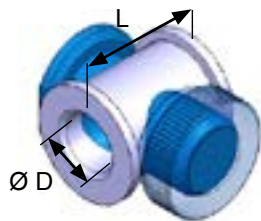
References	Length	Materials	Packaging
2023-VG-CM-15	15 mm	Titanium alloy TiAl6V4 ISO 5832-3	Box of 10 unitary pouch
2023-VG-CM-20	20 mm		
2023-VG-CM-25	25 mm	Silicon	Sterile EO
2023-VG-CM-30	30 mm		



Single use - Class III medical device **CE** 1014 marked

IMPLANTATION/EXPLANTATION ANCILLARIES

-  • Drill ref. 2023-FO-100-C1. For osseous drilling,
-  • Screwdriver ref. 2023-TO-C-020
For the implantation of screws,
-  • Wrench ref. 2023-CL-C.
For the explantation of screws,
-  • Clamp ref. 2023-PIN for short screws.



- > Adaptable on OD 2.5 or 6 mm instruments,
- > allows the control of insertion depth of these instruments

References	L (mm)	Ø D (mm)	Material	Packaging
2036-BU-60-RU	13	> 6,00	Stainless steel	Unitary non sterile
2036-BU-25-RU	10	> 2,5		

- > Provided non sterile
- > Medical devices designed for steam sterilization at 134°C

Class I or III medical devices - CE marked



ALCIS

MANUFACTURING / ORDER / DELIVERY

Temis Sante - Bat. Bioparc
2 rue du Professeur Milleret
25000 BESANCON - FRANCE

Contact

Sales Department
commercial@alcis.net
+33(0)3 81 61 69 93

Jean-Philippe Barbault
jpbarbault@alcis.net
+33(0)6 87 73 97 37

Guillaume Senn
gsenn@alcis.net
+33 (0)7 81 87 71 56

www.alcis.net

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Read carefully the instructions for use for complete clinical instructions. Non contractual document. Alcis reserves the right, without prior notice, to modify the products in order to improve their quality.

WARNING: Applicable laws restrict these products to sale by or on the order of a physician. All the references numbers mentioned on this document are CE or **CE1014** marked according to **European council directive 93/42/EEC** on medical devices and its relatives, unless specifically identified as "NOT CE MARKED." Legal Manufacturer : ALCIS – Besançon, France.