Note: Depending on the medical device (DM) concerned, this file will concern a DM product with one or more part numbers.

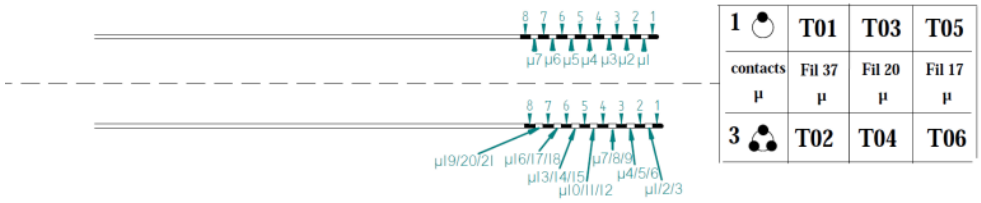
1. Administrative information about the company		Update date: 15 jul 2025
1.1	**Company name:** ALCIS	
1.2	**Address:**2, rue du Professeur Milleret 25000 Besançon - France **Tel :** 03.81.61.54.11 **Fax :** 03.81.53.47.65 **E-mail :** commercial@alcis.net **Website: https:**//www.alcis.net/nos-produits/	Alcis
1.3	**Materialovigilance correspondent :** Marie-Agnès JORDAN **Tel :** 03.81.61.54.14 **Fax :** 03.81.53.47.65 **E-mail :** ajordan@alcis.net	**Business unit:** Quality and regulatory
2. Device information		
2.1	**Common name**: Electrode for neurostimulation in epilepsy	
2.2	**Trade name**: Depth Coagulation Electrode	
2.3	**EMDN Code:** N0101020102 **GMDN Code :** 32556, Depth electrodes	
2.4	**LPP code (List of products and services)** : N/A	
2.5	**DM class:** III **Regulatory provision:** Legacy device 93/42/CEE **According to Annex** II (MDD 93/45/EEC) **Notified body number (certificate):** 1014 **Notified body number (surveillance during transition period):** 2797 **Date first marketed in the EU:** 2002 **DM Manufacturer:** ALCIS	
2.6	**Description of device (dimensions, volume)** : Depth Coagulation Electrodes and Micro-Macro Depth Electrodes are intracerebral electrodes for the pre-surgical diagnosis of epilepsy. They are intended to transmit, to a recording device, the electrical signals emitted by the cerebral areas supposed to be involved in this pathology (stereo-electro encephalographic exploration or SEEG). They can also be used for brief stimulation of these areas. The electrodes are implanted in the brain by means of fitting accessories dedicated for this purpose. They are kept in place for the duration of implantation (up to 2 weeks) by means of a specific fixation system. A cable is used to connect the electrode to a recording / stimulation device. - Diameter: 0,8mm - Distal contact, smooth atraumatic distal part - Repositionable seal and plug to adjust the implantation length, tightness and fixation on the guide screw (2023-VG range).	

Prepared by : Maëlle Lebreton 25 Aug 2025
Reviewed by : Pauline CORDIER 25 Aug 2025
Approved by : Agnès JORDAN 4 Sept 2025

- Three types of contacts:

Type	**Standard Electrode** Type C	**High resolution Electrode** Type E	**Micro-Macro Electrode Type T**
Ring	Annular standards contact 2mm	Annular short contacts 1mm	Annular contact 2mm plus micro contact
Pointe	Distal contact 2mm	Distal contact 2mm	Distal contact 2mm

The micro-macro depth electrodes are electrodes with micro contacts placed between the macro contacts. We have 6 types which define the positioning of the micro contacts on the tube and the diameter of the micro contacts. On the image below, the circle represents the electrode's tube; the micro contacts are flush with the tube:



1	T01	T03	T05
contacts µ	Fil 37 µ	Fil 20 µ	Fil 17 µ
3	T02	T04	T06

2.7 **<u>Catalogue Reference :</u>**

Set: None
Depth coagulation electrodes are sold without accessories.

Reference and description:
Different references depend on the type of contact (ring width), the number of contacts, the pitch between contacts, and whether or not there is a contact group.



Reference	Type	Number of contact macro	Ring length/pitch	Number of micro contact/type	Presence of group
2069-EPC-05C-35	Standard	5	2 mm/ 3.5mm	N/A	No
2069-EPC-08C-35	Standard	8	2 mm/ 3.5mm	N/A	No
2069-EPC-10C-35	Standard	10	2 mm/ 3.5mm	N/A	No
2069-EPC-12C-35	Standard	12	2 mm/ 3.5mm	N/A	No
2069-EPC-15C-35	Standard	15	2 mm/ 3.5mm	N/A	No
2069-EPC-18C-35	Standard	18	2 mm/ 3.5mm	N/A	No
2069-EPC-15C-35-3G-07	Standard	15	2 mm/ 3.5mm	N/A	3 groups distance of 7 mm
2069-EPC-15C-35-3G-11	Standard	15	2 mm/ 3.5mm	N/A	3 groups distance of 11 mm
2069-EPC-18C-35-3G-11	Standard	18	2 mm/ 3.5mm	N/A	3 groups distance of 11 mm
2069-EPC-08C-40	Standard	8	2 mm/4.0 mm	N/A	No
2069-EPC-12C-40	Standard	12	2 mm/4.0 mm	N/A	No
2069-EPC-18C-40	Standard	18	2 mm/4.0 mm	N/A	No
2069-EPC-06E-20	High resolution	6	1mm/2.0mm	N/A	No
2069-EPC-09E-20	High resolution	9	1mm/2.0mm	N/A	No
2069-EPC-12E-20	High resolution	12	1mm/2.0mm	N/A	No
2069-EPC-15E-20	High resolution	15	1mm/2.0mm	N/A	No
2069-EPC-18E-20	High resolution	18	1mm/2.0mm	N/A	No

2069-EPC-5C9-35T02	Micro-macro	5	2 mm/3.5 mm	9/T02	No
2069-EPC-8C6-35T02	Micro-macro	8	2 mm/3.5 mm	6/T02	No
2069-EPC-8C9-35T02	Micro-macro	8	2 mm/3.5 mm	9/T02	No
2069-EPC-5C9-35T06	Micro-macro	5	2 mm/3.5 mm	9/T06	No
2069-EPC-8C6-35T06	Micro-macro	8	2 mm/3.5 mm	6/T06	No
2069-EPC-8C9-35T06	Micro-macro	8	2 mm/3.5 mm	9/T06	No

Packaging :

The Depth Coagulation Electrodes (EPC) on a strip are packaged in Tyvek Peelable pouch and sealed with thermosealer. The Tyvek Peelable pouch is then introduced inside an internall pouch and sealed. A label is apposed on the external pouch. Finally, the external pouch with the electrode is placed inside a box with instruction for use and label.

UCD (Ordering Unit): 1 box
CDT (sterile integrated unit): 1 double pouch per box.
QML (Minimum delivery quantity): 1 box

Labelling: see part 9.

2.8 **Device composition and accessories:**

The compositions of the parts in contact with the patient are indicated below:

Element	Materials
Rings contacts	Alloy 10% Iridium 90% Platinum
Distal plot	Alloy 10% Iridium 90% Platinum
Distal tube	Medical grade Polyurethane Tecothane
Distal tube for micro-macro electrodes only	Medical grade Polyurethane Tecothane and 5-BK-20 Black TPU concentrate[1]
Sliding relocatable seal	Medical grade Silicone
Medical grade glue	• Loctite 3311 de grade medical • Loctite 4011 de grade médical
Cap	Natural acetal / Polyoxymethylene (POM C)
Silicone body tube	Silicone EC
Marked Transition cuff	Silicone + ink
Marked housing connector	Polyamide + ink
Connector housing's label and ink	Polyethylene + ink

[1] The 5-BK-20 Black TPU concentrate is embedded in the Tecothane TT 1065D.

The materials that do not come into contact with the patient are as follows:

Part of the dispositif conscerned	Composition of materials
Reinforcement tube (in the distal tube)	Polyimide
Security wire (in the distal part)	Polyester
Tungsten wire Ø0.3 mm	Tungsten alloy (purity of 99.95%)
Platinum wire	Alloy 10% Iridium 90% Platinum
Body tube	Polyurethane + Baryum sulfate
Male connector 20 points	Special PPS
Conducting glue H20E	EPO-TEK H20E
Lock rods	Brass CuZn39Pb3 Coating: 3 µg of Nickel + 0.15 µg Gold

Substances: The medical device contains no active substances,

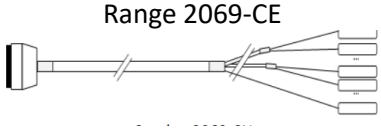
✓ Latex-free
✓ Phthalate-free (DHP)

- ✓ No products of animal or organic origin
- ✓ No endocrine disruptors
- ✓ Absence of carcinogenic, mutagenic and reprotoxic substances
- ✓ MRI compatibility: Not applicable

<u>Associated devices and accessories to be listed</u>.

The following devices are not furnished with the Depth Coagulation Electrode.

Reference Product	Usage	Characteristics
2023-EC 	The coagulation electrode used to coagulate the dura mater and the skin.	Max allowable voltage 2kV 30W in coagulation mode recommended. **Usage of the Alcis 2023-EC recommended.**
2023-VG 	Guidance screws are used to be anchored on the skull - preliminarily drilled - to allow the fixation of Alcis Depth Coagulation Electrodes (range 2069-EPC)	Screws are disponible in two different model: - Standard screw (Disponible in length 15, 20, 25, 30 et 35mm) - Short screw for the MEG (Disponible in length 10, 15, 20, 25 et 30mm) **Usage of the Alcis screw 2023-VG required.**
2023-ST-AB 	The stylet is used to prepare the path for depth coagulation electrode insertion.	Outer diameter: 0,8 mm **Usage of stylets 2023-ST-AB Alcis recommended.**
2023-TG2 	The Graduated ruler is used to measure or setup distance when using Depth Coagulation Electrodes and accessories from ALCIS ranges 2069, 2023 & 2036	Maximum measuring length: 175 mm Compatible with depth coagulation electrodes and micro-macro depth electrodes of the 2069-EPC range and ancillaries of the 2023 or 2036 ranges. **Usage of the Alcis Graduated ruler is recommended**
2069-CE-BC3EPC 	Extension cable BC3 to EPC is used to connect the connecting box 2069-BC3-kit2 with the depth coagulation electrodes or the micro-macro depth electrodes.	Length: 135 cm to 155 cm Electrical resistance < 2 Ohms **Usage of the Alcis Extension cable 2069-CE-BC3EPC recommended**
2069-BC3-kit2 	Connecting box is used to pilot RF thermocoagulation and allow the recording via connection and extension cables	Portable connections Box, self-powered with divers connectors and boutons. Two different modes of operation are available: COAG for the coagulation and EEG.

			Usage of the Alcis Connecting box 2069-BC3-kit2 recommended.
	Range 2069-CE 	Micro-macro extension cable is used to connect the electrode or the connecting box to the recorder 1 stimulator	Use exclusively with 2069-EPC range of Alcis micro-macro depth electrodes Connection: Specific connector 2069 range Ø1.5 mm insulated banana plug For micro-macro EPC **Usage of the Alcis micro-macro Extension cable 2069-CE required.**
	Range 2069-CE 	Extension cable is used to connect the electrode or the connecting box to the recorder 1 stimulator	Use exclusively with ALCIS products of the 2069 range (depth coagulation electrodes and accessories) Connection: Specific connector 2069 range Ø1.5 mm insulated banana plug **Usage of the Alcis Extension cable 2069-CE required.**
	2023-CE-L2 	Removable link is used to maintain the connection between electrode connector and extension cable connector.	Use exclusively with Alcis range of depth coagulation electrodes, micro-macro depth electrodes and extension cables, from ranges 2069-EPC and 2069-EC **Usage of the Alcis Extension cable 2069-CE required.**
2.9	**Domain: filled in by E-P according to nomenclature and linked to the common denomination** N/A		
2.10	**<u>Intended use</u>**: The device is an intracerebral multi-contacts electrode intended for pre-surgical diagnosis of drug-resistant epilepsies. They are designed for: • Stereo-electroencephalography (SEEG) recording, monitoring, and short stimulation, in association with recording, monitoring and stimulation systems, • Coagulation in situ, in association with RF generator, as a therapeutic alternative to conventional epilepsy surgery. **<u>Indication:</u>** The use of ALCIS Depth Coagulation Electrodes and its accessories are indicated for: - The recording and/or the short electrical stimulation, for the pre-surgical diagnosis of drug-resistant epilepsies - The bipolar thermo-coagulation in situ between two contiguous macro contacts, (see instruction for coagulation), for the therapeutic treatment of epilepsy, especially for patients for who conventional surgery is excluded. (For the time being, thermocoagulation with this type of electrodes was made in cases of cortical dysplasia, sclerosis of the hippocampus, periventricular heterotopia, cryptogenic epilepsy, and post meningitis epilepsy). **<u>Population:</u>** The target population is drug-resistant epilepsies patients. The medical conditions to be diagnosed and/or treated are epilepsies.		

User:
The use of the device and its accessories is limited to experienced neurosurgeons and neurologists.

Contraindications:

- The contraindications related to allergies to electrodes materials are applicable
- The contraindications related to neurosurgical interventions techniques in stereotactic conditions are applicable
- The neurosurgeon must verity the adequacy of pathological and anatomical condition of the patient with the recording stimulation, and coagulation procedures via ALCIS Depth Coagulation Electrodes
- The use of other electrotherapy technics than RF thermo-coagulation is formally contraindicated on a patient carrying neurological electrodes.
- The use of other techniques using the electromagnetic waves on a patient carrying neurological electrodes must be submitted to the agreement of the doctor responsible for the implantation and/or of the patient follow-up

Specific contraindications for coagulation:
The contraindications related to RF thermo-coagulation techniques are applicable.

- Do not coagulate on a patient carrying a cardiac pacemaker an implanted defibrillator or a neuro stimulator. Indeed, the reaction of stimulator to the electromagnetic interferences caused by the use of these techniques or by the use of the electrodes for stimulation can result in dysfunctions or the brutal stop of the stimulator.
- The neurosurgeon must verity the relevance to thermocoagulate in the selected brain area
    - Do not thermo-coagulate between contacts which have caused functional signs during stimulation phases.
    - Do not thermo-coagulate when vessels are close to the lesion area, they can alter the shape of the lesion due to cooling effect or be damaged (risk of haemorrhage, hematoma, thrombosis, or stenosis).
    - Do not thermo-coagulate with electrodes if brain functional areas are close to the lesion.

Warnings:
The implantation, the stimulation, and the coagulation with ALCIS electrodes must be carried out by an experienced neurosurgeon and according to a controlled stereotactic procedure. The choice of the model and the number of electrodes to be established, as well as the type of coagulations to create are responsibility for the neurosurgeon. The patient must be placed under a continuous surveillance and in an adapted environment to avoid every risk of incidents.

- Handle Depth Coagulation Electrodes with care
- No modification of the device is allowed
- Check that the equipment to which the depth electrode 2069-EPC are connected are operational and meet the international standards of safety. Notably: SEEG Recorder used must comply with IEC/EN 60601-1 & IEC/EN 60601-2-26 (and associated applicable standards). Their good working order have to be regularly controlled.

Implantation, Recording and Stimulation

- Plan electrodes trajectories in vessel-free corridors
- Ensure that an available product is always ready for replacement in case of dysfunction of the first used.
- Do not twist the cables of themselves
- Check the integrity and the good state of electrodes and ail accessories before use (including fixing accessories).
- Do not use a product in case of wear and/or damage
- Before the first implantation check the compatibility of recording and short stimulation systems with the ALCIS depth electrodes and extension cables. It is the responsibility of the user to ensure himself before use of the mutual compatibility of the products.
- It is responsibility of the user to use equipment complying with the local regulation.
- To avoid any risk of deterioration of electrode performances, always respect the minimal length of implantation indicated on label and on product technical form
- It is recommended to use antistatic gloves.
- It is not recommended to use needle monitoring electrodes.
- Implanted, the depth electrode establishes a direct conductive connection with patient.
    - Avoid any contact with any powered device or any device that could be powered.
    - Keep as far as possible any powered device or devices that could be powered.
- After linking to any electro medical system, the distal part of electrode becomes an applied part type BF

Removal

- Explant gently the electrodes

Cleaning, Disinfection and Sterilization

Given the nature of the act (surgery affecting the central nervous system), do respect the laws in force for the prevention of infectious risks include transmission of prions.

- Single-use and provided sterile by ethylene oxide
- Do not re-use (re-use may expose patients to unacceptable risks of infection)
- Do not re-sterilize (re-sterilization may induce damages and performance decrease)

Storage and maintenance

Cf part 4 Storage conditions

Patient monitoring

To avoid any risk of incidents, the patient must be placed under monitoring during the phases of recording, stimulation, and coagulation.

Specific Warning for coagulation:

- Check that the equipment to which the Depth Coagulation Electrode 2069-EPC are connected are operational and meet the international standards of safety. Notably: RF Generator used must comply with IEC/EN 60601-1 & IEC/EN 60601-2-2 and associated applicable standards). Their good working order have to be regularly controlled.
- All the recommendations and warning related to connected equipment have to be considered

	- The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). - When RF generator and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. - It is recommended to avoid skin- to-skin contact (for example between the arms and body of the patient). - The patient leads should be positioned in such a way that contact with the patient or other leads is avoided. - Interferences produced by the operation of RF generator may adversely influence the operation of other electronic equipment. - Do not use flammable anaesthetics, gases, or liquids while the RF generator is used. - It is recommended to note / record the data emitted by the RF generator. - It is recommended to store in a location that is isolated from the patient the temporarily unused active electrodes. Specific to the application of bipolar RF Coagulation with Alcis Depth Coagulation electrodes - Do not use neutral electrode. - Do not coagulate, if the size of the maximal les ion area to achieve is greater than the size of the area which is intended be treated by conventional surgery. - After thermos-coagulation, a safe distance of at least 10mm between the lesion and a vessel or a functional area. is recommended. - Coagulate only between 2 macro contiguous contacts. • Coagulation between contacts 5-6 and 10 -11 is not possible for 3x5 electrodes • Coagulation between contacts 6-7 and 12-13 is not possible for 3x6 electrodes. - Do not coagulate on micro contacts for micro-macro electrodes. - Prior to coagulate check the electrode integrity (violent epilepsy crisis may induce the loss of some contact), and according the SEEG signal observation the absence of anomaly (absence of signal, shortcut.). In case of doubt do not coagulate with the suspicious contact (risk of thermos lesions in an unintended area). - Stop immediately coagulation, in case of heat sensation by the patient. - It is recommended to explant the electrodes just after thermo-coagulation
3. Sterilization process	
	Sterile DM : yes **Device sterilization method**: Ethylene oxide **Single-use DM**: yes
4. Storage conditions	
	Storage and maintenance - Store in a dry environment at room temperature - Inspect packaging before use to detect any damage - Do not use if package is opened or damaged - For all products provided sterile, do not use after expiry date printed on the packaging Shelf-life validation of Depth Coagulation Electrode is 59 month Expected Lifespan: The Depth Coagulation Electrodes are single use devices. The devices use is done up to 2 weeks

Temperature indicators, if applicable: No

5. Documents attached to the DM file

- ✓ Brochure
- ✓ Instructions for use

6. Images



Figure 1 : Photo of an EPC

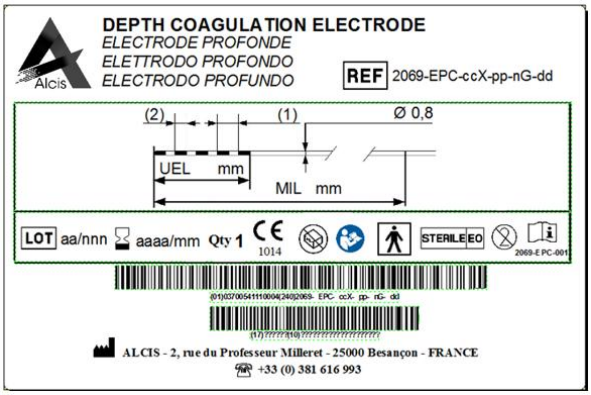


Figure 2: pouch label template EPC standard

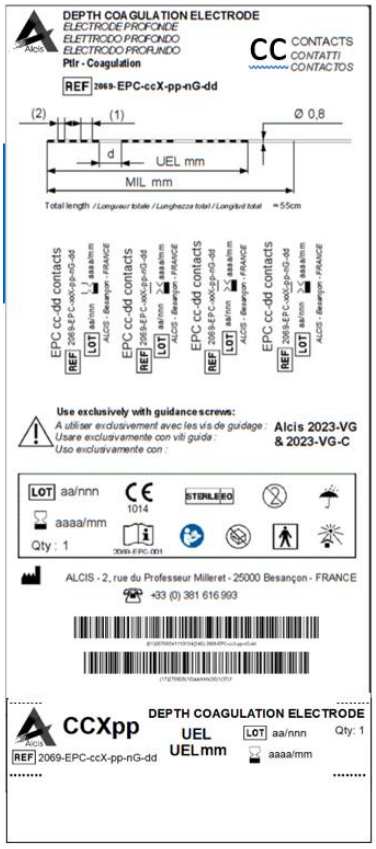


Figure 3: box label template EPC standard

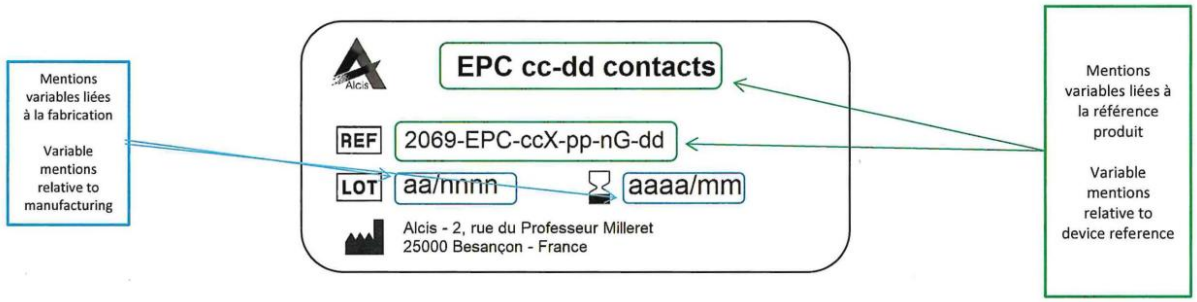
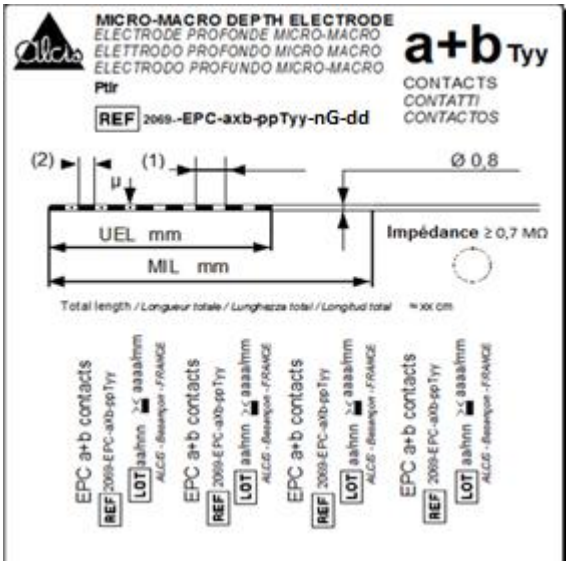


Figure 4 : traceability label



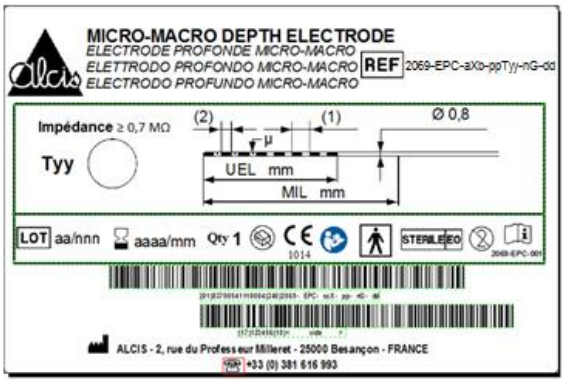


Figure 5: pouch label template EPC micro-macro



Figure 6: box label template EPC micro-macro