

CATALOGUE 2018

ALCIS Neuro

SEEG DEPTH ELECTRODES BIOPSY NEEDLE STEREOTAXY & DBS ACCESSORIES



Manufacturing / Order / Delivery **ALCIS Neuro**

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Compilation of <u>technical forms</u> as following

Depth electrodes	3 pages
Coagulation system	1 page
Extension cables	1 page
Guidance screw	1 page
Short guidance screws	1 page
SEEG setup ancillaries (screwdriver, drills, wrench, stylets, stoppers,)	3 pages
Coagulation electrodes	1 page
Rulers	1 page
Brain biopsy needles	1 page
Bone fiducial and anchoring bolts	1 page
Stereotaxy accessories (screw caps, guides, drills, stoppers)	8 pages
DBS & Parkinson accessories	2 pages

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DEPTH ELECTRODE EPILEPSY / SEEG / COAGULATION

EPILEPSY

Technical Form

EDITION 2069-EPC-FT1c Page 1/2

Range 2069-EPC

ALCIS intracerebral **Depth Electrodes** are multi-contacts electrodes, intended to pre-surgical epilepsy diagnosis, Stereo-ElectroEncephaloGraphy recording (SEEG), short stimulation and thermocoagulation as a therapeutic alternative to conventional epilepsy surgery.



Patient / user comfort ► tip contact, distal part perfectly smooth.

Minimum Implantation Length (MIL) reduced ► 10 mm behind last contact, reduce exceed of the skin when associated to short guidance screw.

Validated for coagulation ▶ easier and safer through connection box.

Contacts configurations ► from 5 to 18.



Platinum iridium contacts & wires ► Better signal & recording / MRI adapted. **Sterile** unit packaging with traceability label ► Eases patient file follow-up. Distal OD ≤ 0.8 mm / Proximal OD ≈ 1.5 mm ► Less invasive / good mechanical strength. Sliding seal ► Adjustment of depth insertion eased with Alcis ruler.

High resistance to bending, doesn't break.

2 contacts types:

Туре	Standard electrodes Type C	High resolution electrodes Type E
	71	7.
Ring	Standard ring contacts	Short ring contacts
Contacts	2 mm	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.

£1014 marked.

2 +33 (0)3 81 61 69 93

EDITION 2069-EPC-FT1c EN JUN2016

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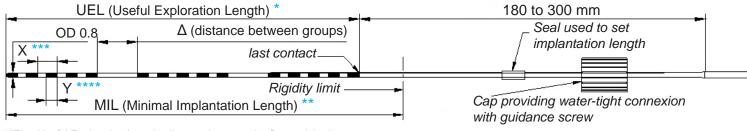
DEPTH ELECTRODE EPILEPSY / SEEG / COAGULATION

Technical Form

EPILEPSY

EDITION 2069-EPC-FT1c Page 2/2

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

References	Nb of contacts	Δ (mm)	UEL * <i>(mm)</i>	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
2069-EPC-ccC-pp-gG-∆		Custom ma	de - please co	ontact us	



Range 2069-EPC Type E - high resolution electrodes

*** Y = 1 mm

** Contact step 2.0 mm

References	Nb of contacts	UEL * (mm)	MIL ** (mm)	Avail.
2069-EPC-06E-20	6	12	22	R
2069-EPC-09E-20	9	18	28	R
2069-EPC-12E-20	12	24	34	R
2069-EPC-15E-20	15	30	40	R
2069-EPC-18E-20	18	36	46	R
2069-EPC-ccE-pp-gG-Δ	Custon	n made - ple	ase contact	us

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

Medical Devices. Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. Always refer to the information on packaging's labels and instructions for use (if applicable). 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." Manufacturer: ALCIS – Besançon, France.

EDITION 2069-EPC-FT1c EN JUN2016



DEPTH ELECTRODE EPILEPSY / SEEG / COAGULATION

Technical Form

EPILEPSY

EDITION 2069-EPC-M-FT1b Page 1/1

2069-EPC type Micro-Macro - (€

ALCIS micro-macro intracerebral Depth Electrodes are multi-contacts electrodes, intended to presurgical epilepsy diagnosis, designed for Stereo-ElectroEncephaloGraphy recording (SEEG), short stimulation and thermocoagulation as a therapeutic alternative to conventional epilepsy surgery.

2069-EPC Micro Macro

Two scales recording ▶ micro and macro.

Coagulation mastered on macro contacts with display ▶ impedance driving, eased and secured via connection box.

Patient / user comfort ► distal part perfectly smooth,

Minimal Implantation Length (MIL) reduced (10 mm after the last macro contact).

Other features:

Platinum iridium contacts & wires ▶ Better signal collection / MRI compatible. 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 / C 1014 marked.

Packaged in sterile individual pouch.

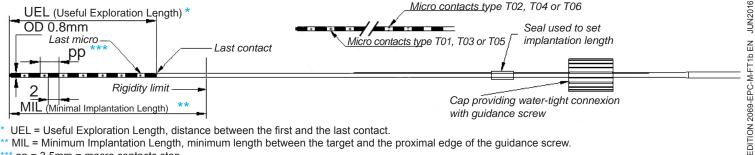
Consult us to identify the compatible recording solutions.

Micro-Macro range:

References	Macro contacts	Micro contacts	Micro size	Micro contacts positioning	UEL * (mm)	MIL ** (mm)	Avail.
2069-EPC-5C9-35T02	5	9	37 µm		16	26	R
2069-EPC-5C9-35T06	5	9	17 um	3 at 120°	16	26	R
2069-EPC-8C9-35T06	8	9 17 μm		26.5	36.5	R	
		Other m	nicro contacts	configurations po	ossible - cons	sult us	
2069-EPC-aXb-ppTxx	1 to 9	1 to 9	37, 20 or 17 μm	1	-	-	R

a = number of macro contacts

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.

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Order / Delivery

b = number micro contacts

Txx = micro contacts type



GLOBAL COAGULATION SOLUTION

Generator - Kit Connecting box - Electrode

EPILEPSY

EDITION ALN-2069-CS-FT1 Page 1/1

Technical Form

Range 2069-CS

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

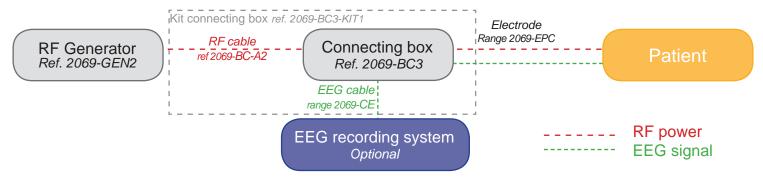
Alcis proposes a Global Solution for Coagulation that includes the following devices:

- RF Generator (ref. 2069-GEN2)
- Kit Connecting box (ref. 2069-BC3-KIT1)

System ref. ALN-2069-CS

• Depth coagulation electrode (range 2069-EPC), for technical information, refer to 2069-EPC-FT technical form.

Please note that Alcis do not provides the EEG recording system. Ask for compatibility information.



Kit Connecting Box (ref. 2069-BC3-KIT1)

The kit Connecting box **(€** marked includes:

- a connecting box (ref. 2069-BC3),
- a RF cable (ref. 2069-BC-A2),
- a EEG cable (ref. 2069CE-18c-150-B-FB5),
- a testing device,

- a battery charger with 2 batteries,
- the IFU of the kit.

The kit is provided in a plastic briefcase.

The Alcis connecting box allows, in user friendly and a safe way 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)

← marked, non sterile, non sterilizable, reusable device.

Compliant to IEC 60601-1 (2007 / AC2010), IEC 60601-2-26 (2004), IEC 60601-2-2 (2009), electrical standards.



RF Generator (ref. 2069-GEN)



A special setup for the thermo-coagulation with Alcis depth coagulation electrodes (ref. 2069-EPC-Ax) is required.

Alcis includes in its global coagulation system the RF generator RFG-1B from Cosman with this special setup.

(€0050 marked, non sterile, non sterilizable, reusable device.

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EDITION ALN-2069-CS-FT1 EN S

EXTENSION CABLES

EPILEPSY

Technical Form

Range 2069-CE

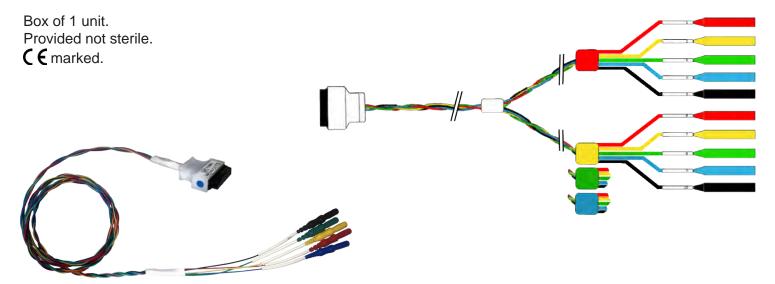
EDITION 2069-CE-FT3 Page 1/1

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

References	Number of contacts	Length	Plug (recorder side)	Cable specifications	Packaging	
2069-CE-05c-150-B-FB5	5		Insulated plugs			
2069-CE-08c-150-B-FB5	8	 Ø 1,5 mm 150 cm FB5 = minimal center-to-center connection 		B = braided		
2069-CE-10c-150-B-FB5	10				Unitary Non Sterile	
2069-CE-12c-150-B-FB5	12					
2069-CE-15c-150-B-FB5	15					
2069-CE-18c-150-B-FB5	18		distance : 5 mm			
2069-CE-XXc-III(-B-FB5)*	Custom made	Custom made - please contact us				

*to define reference, replace:

- III by the length in cm,
- XX by the number of contacts.
- A coding, integrated to the connection casing helps to reduce the risk of connection errors.
- A marker (blue dot) enables a quick retrieval of connection direction.
- · A color coding helps to quickly identify the wire order.
- Compatible with removable link 2023-CE-L2 to secure the electrode connection with the cable.



Removable link 2023-CE-L2

Removable link is intended to strengthen the connection between an extension cable and an electrode.

Ref. 2023-CE-L2 Pouch of 5 reusable units. Provided not sterile.

C € marked.



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Order / Delivery

EDITION 2069-EPC-FT3 EN FEB2016

GUIDANCE SCREW

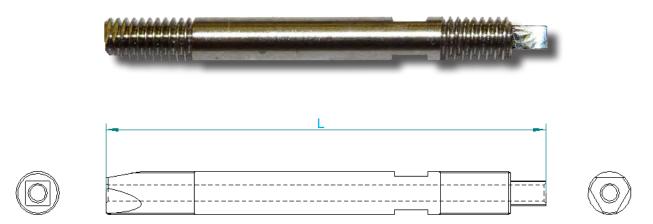
Technical Form

EPILEPSY

EDITION 2023-VG-FT5
Page 1/1

RANGE: 2023-VG

► This range of product allows to implant depth electrodes with a maximum of guidance effect.



Reference	Length (mm) (L)	Material	Packaging	
2023-VG-15	15			
2023-VG-20	20	Titaniana allan	Day of 40 atomila smits	
2023-VG-25	25	Titanium alloy TiAl6V4 ISO 5832-3	Box of 10 sterile units (individual pouch)	
2023-VG-30	30	11A10 V 4 13O 3032-3	11A10V4 10O 3032-3 (IIIdiVidde	(ilidividual podeli)
2023-VG-35	35			

- Calibrated for ID 2.5mm guide.
- Self-threading extremity for direct fixation in a diameter 2.1 mm osseous hole.
- Adapted for MRI location.
- Two external flats for extraction with Alcis wrench 2023-CL.
- use exclusively with alcis depth electrode range 2069-EPC.
- set exclusevily with alcis screwdriver range 2023-TO.
- realise with join and cap a water-tight connexion with electrode.
- Ethylene oxide sterilized.
- · Single use.
- C € 1014.





SHORT GUIDANCE SCREW

MEG compatible

RANGE: 2023-VG-C-II

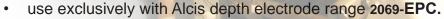
Technical Form

EPILEPSY

EDITION 2023-VG-C-FT3 Page 1/1

► Short guidance screw realises with cap and join integrated to the screw a tight fixing of the electrode. It allows a minimum obstruction on external patient cranium.

- Each short guidance screw is provided with:
 - A guide helping to ensure the realization of a pre-hole with a stylet range 2023-ST through trajectory given by the guidance screw,
 - A thin cap limiting space above guidance screw,
 - A retainer ring maintaining electrode closest to cap.



- set exclusevily with Alcis screwdriver 2023-TO-C-III and ALCIS griper 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.
- Self-threading extremity for direct fixation in a 2.1 mm diameter osseous hole.
- MRI and MEG compatible.
- Ethylene oxide sterilized.
- Single Use.
- **(E**1014.

2023-VG-C-10 10 2023-VG-C-15 15 2023-VG-C-20 20 TiAl6V4 ISO 5832-3 Box of 10 sterile units (individual pouch
2023-VG-C-15 15 alloy Sterile units 2023-VG-C-20 20 TiAl6V4 (individual pouch
2023-VG-C-20 20 (Individual pouch
2023-VG-C-25 25 • Silicone including: screw, quide, can and
• Polymer retainer)

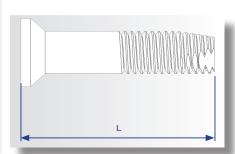












EDITION 2023-VG-C-FT3b EN APR2012

CONNECTION AND SET UP ACCESSORIES

EPILEPSY

Technical Form

EDITION 2023-APR-FT11c Page 1/3

Range: 2023



For standard guidance screw:

Reference	Length L (mm)	Materials	Packaging
2023- TO-020	20	Stainless steel (body)	Unitory non storile
2023- TO-160	160	Delrin (handle)	Unitary non sterile

For short guidance screw:

Reference	Length L (mm)	Materials	Packaging
2023-TO-C-020	20	Stainless steel (body)	Unitary non starila
2023-TO-C-160	160	Delrin (handle)	Unitary non sterile

- EXCLUSIVELY DEDICATED TO SET ALCIS GUIDANCE SCREW RANGE 2023-VG,
- · Calibrated for ID 2.5 mm stereotactic guide (except length 20),
- Utilizable with Alcis depth-stop 2023-BU-25-UU or 2036-BU-25-RU to facilitate control of screwing depth,
- · Supplied non sterile,
- · Re-usable device designed for steam sterilization till 134°C,
- **(E** marked.

Wrench 2023-CL

Reference	Useful opening (mm)	Materials	Packaging
2023-CL	1.9	Stainless steel	Unitary non sterile
2023-CL-C	3.5	Stalliless steel	Officery flori sterile

- Designed to remove alcis guidance screw range 2023-VG and short guidance screw range 2023-VG-C.
- · Elbowed for better use.
- · Supplied non sterile,
- Re-usable device designed for steam sterilization till 134°C,
- C E marked.



CONNECTION AND SET UP ACCESSORIES

Technical Form

EPILEPSY

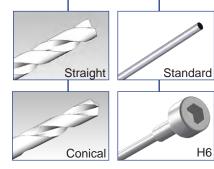
EDITION 2023-APR-FT11c Page 2/3

Range: 2023

Drill 2023-FO



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



to determine the reference, remplace III by the wanted length (in mm), add -C1 for conical shape, add -H6 for H6 proximal end.

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

- DESIGNED TO REALISE Ø2.1mm OSSEOUS HOLE,
- · Compatible with ID 2.5 mm stereotactic guide,
- · Compatible with Alcis depth stop 2023-BU-25-UU or 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 till 134°C,
- **(€**1014 marked.



CONNECTION AND SET UP ACCESSORIES

Technical Form

EPILEPSY

EDITION 2023-APR-FT11c Page 3/3

Range: 2023

Single use Stylet 2023-ST



Reference	Minimum useful length (mm)	OD (mm)	Stopper	Materials	Packaging		
2023-ST-AB	120	0.8	Yes	Stainless steel (stylet)	Box of 10 sterile units,		
2023-ST-SB	120	0.8	No	Polymer (stopper)	(individual pouch)		
2023-ST-xB(-III)	Custom made (length up to 250 mm) - please contact us						

- DESIGNED TO REALISE A 0.8mm OD FIRST HOLE TO EASE THE DEPTH ELECTRODE INTRODUCTION.
- · Soften distal end.
- Supplied with adjustable depth-stop 2023-BU-08-UU to ease the control of insertion depth.
- · Ethylene oxide sterilized.
- Single use.
- **(E**1014 marked.

Single use Stopper 2023-BU-xx-UU



Reference	Instrument OD (mm)	Compatible instruments	Packaging
2023-BU-08-UU	0.8	stylet	Box of 10 sterile units
2023-BU-25-UU	2.3 to 2.5	drill, screwdriver, coagulation electrode	(individual pouch)

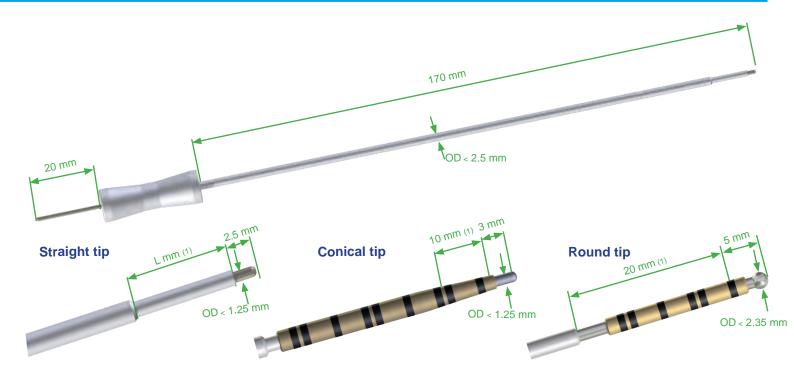
- Fits on all intruments with compatible OD: 0.8mm or 2.3 to 2.5 mm (refer to reference),
- · Allows to control an secure insertion depth of the instruments,
- · Etylene oxide sterilized,
- · Single use,
- **(€1014** marked.

COAGULATION ELECTRODES

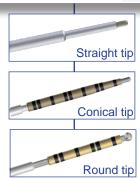
EPILEPSY

EDITION 2023-EC-FT6d Page 1/1

Range 2023-EC



Reference	Shape	Insulated Distal Length (mm) (1)	Active Length (mm)	Active OD	Materials	Packaging
2023-EC-10-STD		10				
2023-EC-20-STD	Straight	20 2.5	4.20	Stainless steel 1.20mm (body) Polymere (handle	Unitary Non sterile	
2023-EC-30-STD		30	1.20mm			
2023-EC-10-CNQ	Conical	10	3.0		and insulating part)	Non Sterne
2023-EC-20-B24	Round	20	5.0	2.35mm	,	



- MONOPOLAR ELECTRODE intended to open the dura mater or skin (round tip) by thermocoagulation.
- MONOPOLAR ELECTRODE intended to open the dura mater or skin (round tip) by thermocoagulation.

 Compatible with ID 2.5 mm stereotactic guides.

 Compatible with single use Alcis depth stop 2023-BU-25-UU or 2036-BU-25-RU in order to ease the control of depth insertion length.

 Provided non sterile.

 Reusable material designed for steam sterilization up to 134°C.

 € 1014 marked.

- **C** €1014 marked.

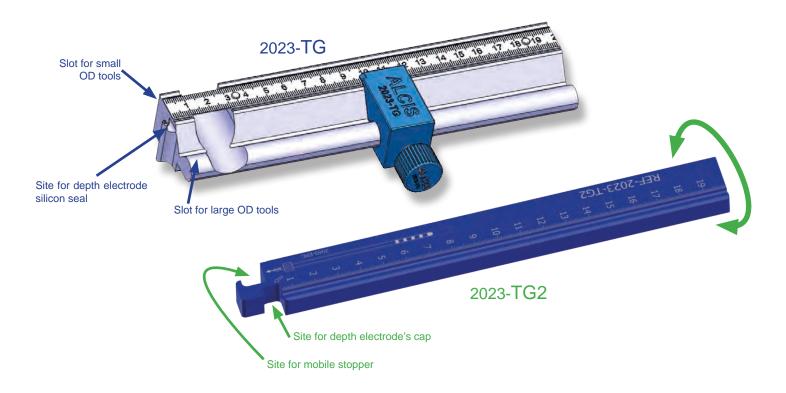


GRADUATED RULERS

EPILEPSY

EDITION 2023-TG-FT5b Page 1/1

Range 2023-TG



Reference	Materials	Packaging	
2023- TG	Fortal, Stainless steel, Polymers	Unitary non starile	
2023- TG2	Polymer	Unitary, non sterile	

2023-TG

Graduated ruler

Allows to control the insertion depth of tools (drill, coagulation electrode, screwdriver).

Allows to set the implantation length of depth electrodes.

The device has a notch to position the silicon seal of the electrode.

Just maintain the seal in position and pull on the electrode to adjust its implantation length.

Ruler length: 200 mm.

Maximal measure length: 175 mm.

Accuracy: 0.75 mm.

Measurement constant: 0.25 mm.

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 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 devices, compatible with steam sterilization up to 134°C.
- **(€**1014 marked.



BRAIN BIOPSY NEEDLE

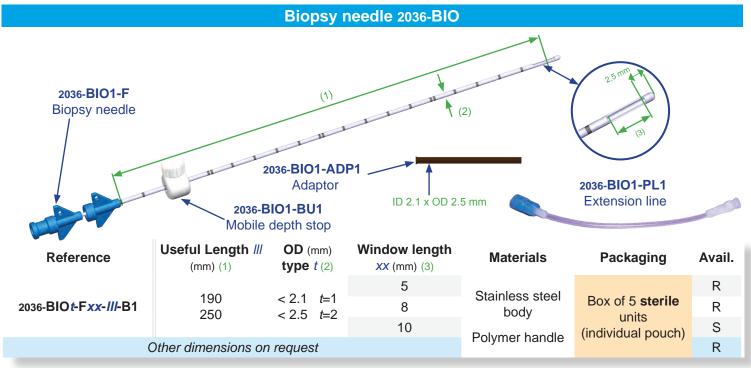
SEDAN TROCART

STEREOTAXY

Technical Form

EDITION 2036-BIO-FT8b Page 1/1

Range: 2036-BIO



Reference example: 2036-BIO2-F10-250-B1 (biopsy needle with diameter 2.5mm, 250mm long and a 10mm window). 2036-BIO1-F08-190-B1 (biopsy needle with diameter 2.1mm, 190mm long and a 8mm window).

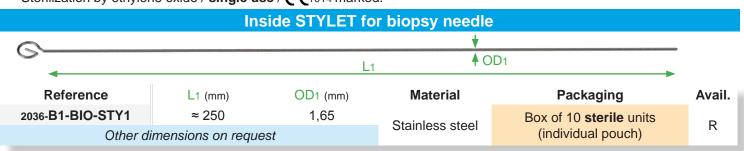
Avail.: Product availability, S: Stock, R: on Request

Brain biopsy kit Ref. 2036-BIO-kitt-Fxx-III-B1

Designation	Reference	Qty	Packaging
iopsy needle	2036-BIO <i>t</i> -F <i>dd-III</i>	1	
iameter adaptor*	2036-BIO-ADP1	1	Box of 5 sterile kits
extension line	2036-BIO-PL1	1	(individual pouch)
Nobile depth stop	2036-BIO-BU1	1	

Reference example: 2036-BIO-kit2-F10-250-B1 (box of 5 kits of biopsy needles - Useful OD 2.5mm, 250mm long with a 10mm window).

- Requires a previous skull bone hole (Alcis drill available, cf. range 2036-FO or 2023-FO).
- The adapter 2036-BIO-ADP1 allows the compatibility with stereotactic guides of OD 2.5mm.
- The mobile stop ALCIS 2036-BIO-BU1 allows (if necessary) the control of the biopsy depth.
- Proximal port (female luer lock) for the connection of a suction device, with marks of the window position (open/close).
- Extension line 2036-BIO-PL1 to facilitate the suction.
- Markings to indicate the length to the biopsy needle.
- Sterilization by ethylene oxide / single use / (£1014 marked.



- Use only with the biopsy needles ref. 2036-BIO1-FII-190.
- Sterilization by ethylene oxide / Single use / (£1014 marked.

STEREOTAXY

EDITION 2023-VG-CM-FT1c Page 1/1

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.



Reference	Length	Materials	Packaging
2023-VG-CM-10	10 mm	Titanium alloy	
2023-VG-CM-15	15 mm	TiAl6V4	Box of 10
2023-VG-CM-20	20 mm	ISO 5832-3	unitary pouch
2023-VG-CM-25	25 mm		Sterile EO
2023-VG-CM-30	30 mm	Silicon	0.01110 20

Single use / €1014 marked.

Accessories

Obturator cap

2023-BO-VG-C Cap to close the inner channel 2036-BM-VG-C Marking cap; MRI, XRay or hybrid

of the screw, apart from surgical steps.

Sterile EO, single use, box of 10 pouches of 10 units.

Nylon

Marking cap

MRI/XRay.

Non sterile, reusable, pouch of 5, non-sterilizable

POM

Implantation/Explantation ancillaries



Drill ref. 2023-FO-100-C1 For osseous drilling.

Suppressive guiding stopper ref. 2036-BU-25-RU-GSxx For the control of drilling depth.

Screwdriver ref. 2023-TO-C-020 For the implantation of screws.

Wrench ref. 2023-CL-C For the explantation of screws.

- Unitary packaging non sterile.
- Reusable devices, designed for steam sterilization up to 134°C.
- **C** € or **C** €1014 marked.

Alcis short guidance screw from range 2023-VG-C are recorded by Medtech SAS company as «Compatible Device».

Medical Devices. Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. Always refer to the information on packaging's labels and instructions for use (if applicable). 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." Manufacturer: ALCIS – Besançon, France.

EDITION 2069-EPC-FT1c EN OCT2016



STEREOTAXY

EDITION 2036-AS-FT11c Page 1/4

Range: 2036

The PERCUTANEOUS SCREW and their ACCESSORIES contribute to:

- a reproducible fixation of stereotactic frame such as Leksell (using adaptation range 2051), Talairach one or similar (set with screw 2036-VP + spacer 2036-ENT or 2051-ENT),
- the realization of MRI imaging (frameless imaging) by using:
 - (1) screw 2036-VPx2 + marking cap 2036-BM
 - (2) only screw 2036-VPx2-M (IRM marker + RX integrated)
- the scanner imaging without any artefact and with the location of screw position (imaging with or without frame):
 - (1) screw 2036-VPx + spacer with marker 2036-ENT2 ou 2051-EV3
 - (2) only screw 2036-VPx-M seule (MRI + RX marker integrated)
- (1): imaging fusion easier due to similar positions of MRI (2036-BM) and RX (2036-ENT2 /2051-EV3) markers.
- (2): marker constituted of a soultion visible with MRI and SCANNER.

Dorch	taneous	CCTOW	anae VD
FEIGU	taneous	SCICW	ZU30-V F

Reference	Designation	Integrated marker	L1 (mm)	L2 (mm)	L3 (mm)	Material	Packaging
2036-VPA2	VP Adult	No	19.0	14.5	9.0	Polymer	
2036-VPE2	VP Child	INO	16.5	12.5	6.5	with superior	20 sterile units
2036-VPA2-M	VP Adult	Yes*	19.0	13.0	9.0	physic	box packaged by pouch of 4 units
2036-VPE2-M	VP Child	res	16.5	10.5	6.5	capacity	

Percutaneous screw with

Ø 6,5 mm

12

Percutaneous screw 2036-VPx



*visible by MRI and SCANNER imaging.

- SET EXCLUSIVELY WITH A SCREWDRIVER ALCIS 2036-TO-III in a osseous hole Ø 6 mm realizable with a drill such as ALCIS 2036-FO-III type
- 2036-VPx: do not generate any MRI neither SCANNER artefact
- Ethylene oxide sterilized
- Single use
- C €1014 marqued

Cap 2036-B (for percutaneous screw 2036-VPx)





Reference	Designation	Material	Packaging
2036-BO	Obturator cap	Dolumor	Pouch of 20 non sterile units
2036-BM	Marking cap	Polymer	Pouch of 4 non sterile units



- SET EXCLUSIVELY WITH A ALCIS PERCUTANEOUS SCREW 2036-VP.
- Obturator caps 2036-BO:
 - allows the protection of the screw impression between the periods of frame fitting,
 - are supplied non sterile and single use.
 - Marking cap 2036-BM:
 - allows MRI localization, are filled (Ø5 x 5 mm) with a contrast solution,
 - are supplied non sterile No stérilisation required for use with MRI (no process validated).
- Marqué ().



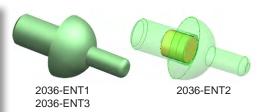
STEREOTAXY

EDITION 2036-AS-FT11c Page 2/4

Range: 2036

Spacers 2036-ENT (for percutaneous screw2036-VPx)

Reference	L (mm)	Ø D (mm)	Material	Packaging	
2036-ENT1			Polymer		
2036-ENT2	10	6	Polymer with Titanium marker (Ø5 x 5 mm)	Pouch of 4 non	
2036-ENT3			Stainless steel	sterile units	
Other dimensions realizable on request					



ØD

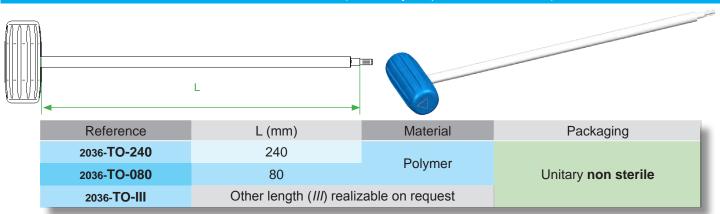
TO BE USE EXCLUSIVELY WITH PERCUTANEOUS SCREW ALCIS 2036-VP,

 Proximal side designed to be use with stereotactic frame equipped with guide or screw pillar compatible with centring Ø D and length L,



C € marked.

Screwdriver 2036-TO (accessory for percutaneous screw)



- TO BE USE EXCLUSIVELY WITH THE ALCIS PERCUTANEOUS SCREW 2036-VPx.
- Proximal side designed for use with stereotactic frames provided with compatible guides (Ø D and centering length L),
- Supplied non sterile Reusable material designed for autoclave sterilisation till 134°C,
- Marqué (E.

Screwdriver 2036-TO-EXT-60 (accessory for percutaneous screw and NATAF



Screwdriver provided with a system allowing to extract the screwdriver from the head of the screw without exerting stress on the patient 's skull.

Reference	Dimensions (mm)	Material	packaging
2036-TO-EXT-60	Useful length (L): 240 Excraction stroke (C): from -7 to +38	Stainless steel (body) Polymer (handle)	Unitary non sterile

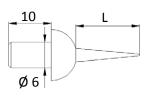
- TO BE USE EXCLUSIVELY WITH ALCIS percutaneous screw 2036-VP and Nataf adaptation kit (range 2051),
- Supplied non sterile Reusable material designed for autoclave sterilisation till 134°C,
- (f marked.

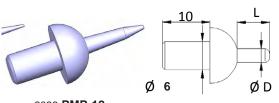


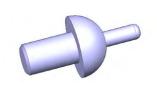
STEREOTAXY

EDITION 2036-AS-FT11c Page 3/4

Range: 2036







:036- PMP-15	2036- PN	IP-12	203	36- PN
L (mm)	ØD (mm)	Material	Packaging	
15				
12				
07	2.9		Pouch of 4 non sterile units	;
11		31001		
14				
	L (mm) 15 12 07 11	L (mm) Ø D (mm) 15 12 07 2.9 11	L (mm) Ø D (mm) Material 15 12 07 2.9 Stainless steel	L (mm) Ø D (mm) Material Packaging 15 12 07 2.9 Stainless steel Pouch of 4 non sterile units

Designed to be place at the distal extremity of micrometric stereotactic frame screw, they contribute to the frame fixing with patient head. Type PMP: Percutaneous Monobloc Point Type PMC: Surgical Monobloc Point*

* the PMC needs a Ø 2.9 mm osseous hole realizable with ALCIS drill 2036-FO-250-29.

- Proximal side designed to be use with stereotactic frame equipped with guide or screw pillar compatible with centring of Ø 6 mm and length 10 mm
- Supplied non sterile
- Re-usable material designed for autoclave sterilization till 134°C
- **€**1014 marked.

Drilling Gun 2036-CPX

Reference	L (mm)	ØD (mm)	Material	Packaging		
2036-CP1-025	10 / 90	2.5	PFFK	I luitan en an		
2036-CP1-060	10 / 90	6.0	PEEK	Unitary non sterile		
Other dimensions realizable on request						

. C marked - Supplied non sterile Adaptable on OD 2.5 or 6 mm instruments (drill 2023-FO or 2036-FO)

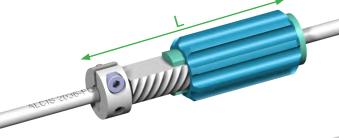
. Re-usable material designed for autoclave sterilization till 134°C

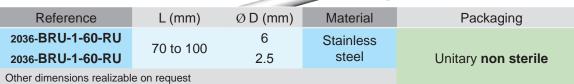
Qty 1+1

Ø>dd mn

Allows the control the trajectory of insertion of these instruments







- Stopper supplied without drill
- Adaptable on OD 6 mm instruments (drill 2036-FO)
- Allows the control of insertion depth of these instruments
- Supplied non sterile Re-usable material designed for autoclave sterilization till 134°C
- **€**1014 marked.

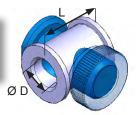


STEREOTAXY

EDITION 2036-AS-FT11c Page 4/4

Range: 2036

Reference	L (mm)	ØD (mm)	Material	Packaging
2036-BU-60-RU	13	> 6,00	Acier	Unitary non storile
2036-BU-25-RU	10	> 2,5	Inoxydable	Unitary non sterile



- Adaptable on OD 2.5 or 6 mm instruments (drill 2036-FO, ...)
- ALLOWS THE CONTROL OF INSERTION DEPTH OF THESE INSTRUMENTS
- Supplied non sterile Re-usable material designed for autoclave sterilization till 134°C
- C Emarked.

Drills 2036-FO

Supplied non sterile - Re-usable material designed for autoclave sterilization till 134°C



Reference	Length (mm)	body Ø (mm)	Cutting length(mm)	cutting Ø (mm)	Material	Packaging
2036-FO-250-29	250	6	20	2.9	Stainless steel	Unitory non storilo
2036-FO-250-40	250	0	20	4.0	and polymer	Unitary non sterile

- Compatible with an ID \geq 6 mm stereotactic guide.
- Usable with mobile depth stop Alcis 2036-BU-60-RU to facilitate control of drilling depth
- Supplied with a fixed stop for using with micrometric frame screw
- Supply with polymer guide to decrease the friction





Features and references of these custom made drills are defined case by case.

- to determine the reference replace:
 - III by the number of millimeters required (max 250);
 - z by the number which corespond to cutting diameter and length required.

				•		•	•	• ,	
Reference	L (mm)	Ø D1 shank (mm)	Ø D2 body (mm)	Ø D3 cutting (mm)	Cutting Lg	Cutting	Material	Packaging	ı
2036-FO-III-T1/z		Т	Type 1 : cutting	g Ø = body Ø =	= shank Ø				=eb 2016
2036-FO-III-T1/1			2,45		14	Straight			Feb
2036-FO-III-T1/2	111		2,5		14	Straight	Stainless	I losten com an	1c EN
2036-FO-III-T2/z	111		Type : cutting	Ø # body Ø =	shank Ø		steel	Unitary non sterile	EDITION 2036-AS-FT11c EN
2036-FO-III-T2/3		α	6	Ø 5	20	120°		5.55	036-A
2036-FO-III-T2/4		Ø	O	Ø 5,2	20	120			ION 2
Autres dimensions réalisab	les sur d	lemande							E

Adaptable length within 250 mm / Drilling Ø marked on product.



(Leksell Frame adapted to become REPOSITIONNABLE)

Technical Form
STEREOTAXY

EDITION 2051-FT2 Page 1/4

RANGE: 2051

This range of product (associated with existing material) allows:

to set up,

to carry out imaging sequences with markers of fusion, to remove then to reset in a precise and rapid way a Leksell frame on a patient.

- ability of carrying out stereotaxic surgery interventions in a split way
- possibility of carrying out the procedure on several places
- Usable with standard Leksell frame basis (no modification necessary),
- Compatible with different scanner localizer box (Leksell, Brainlab...),
- Compatible with realization of examinations such as arteriography, scanner and MRI (minimized artifacts),
- Adapted for radiotherapy,
- Frameless or frame based MRI realizable with a possibility of later fusion (trough markers screw),
- Optimization of fusions of images MRI and Scanner trough the markers associated with screws.

Frame setup and imaging

- Frame setup on patient using KIT Adaptation fixing part (2051-KAFIX) & basis of LEKSELL frame.
- Percutaneous screw placement (Alcis range 2036-VP) using percutaneous screw KIT (2051-KVIS-2036) & Screwable spacer Kit (Alcis range 2051-KEV ≠ standard according to needs).
- Diagnosis intervention and imaging realization ventriculography scanner MRI....

Possible with markers localized to the screws for further 2 types of imaging fusion optimization.

Frame removing after lengths measurement.

The screws can remain in place on patient several weeks (- 30 days).

Planning / location Later intervention(s)

Frame resetting(s) on patient for surgical intervention purpose.

By example treatments such as intracranial splited radiotherapy in stereotaxic conditions.

- Frame removing (as many time than necessary)
- · Removing of screws.

EDITION 2051-FT2b EN JUL2016



(Leksell Frame adapted to become REPOSITIONNABLE)

Technical Form

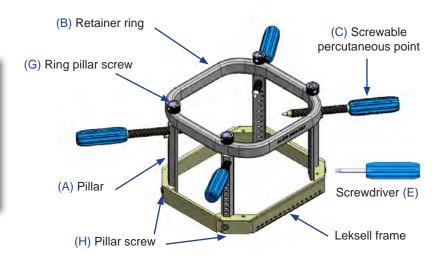
STEREOTAXY

EDITION 2051-FT2 Page 2/4

RANGE: 2051

Kit Adaptation fixing part Ref. 2051-KAFIX-(P60-PL1) containing:

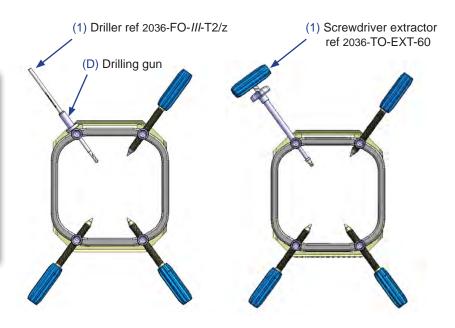
Reference	Material	Qty
2051-AM1	Retainer ring (B)	1
2051-AM1-PI1	Pillar (A)	4
2051- PPV	Screwable (C) percutaneous point	4
2051-TO	Screwdriver (E)	1
2051-AM1-PL1-003	Pillar screw (H)	4
2034-KG-002	Ring Pillar screw (G)	4



Percutaneous screw Kit 2036 / 2051 Ring Ref. 2051-KVIS-2036 containing:

Reference	Material	Qty
2051-AM1-CP60	Drilling gun (D)	1
2036-FO- <i>III</i> -T2/4	Drill length 250/Ø6 / Ø5.2 cut (1)	1
2036-FO- <i>III</i> -T2/3	Drill length 250/Ø6 / Ø5.2 cut (1)	(up to user)
2036-BUR1-06-RU	Zdjustable and (1) mobile stopper Ø6	1
2036-TO-EX	Percutaneous screw screwdriver extractor (1)	1

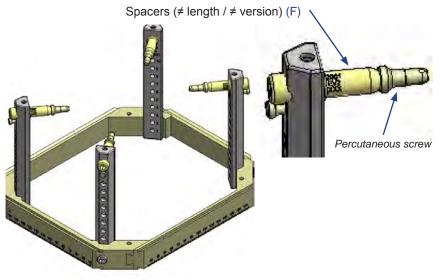
(1) For range 2036 parts please refer to technical form 2036-AS-FT



Various Kits spacers (F) are proposed:

Screwable spacers type 1 Kit (hollow) Ref 2051-KEV1-(C1)
Screwable spacers type 2 Kit (monobloc) Ref 2051-KEV2-(C1)
Screwable spacers type 1 Kit (monobloc interating marked)
Ref 2051-KEV3-(C1)

Cf. page 4 for detail and composition.





(Leksell Frame adapted to become REPOSITIONNABLE)

STEREOTAXY

Technical Form

EDITION 2051-FT2 Page 3/4

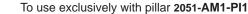
RANGE: 2051

Reference	Designation	Material	Packaging
2051-AM1	Retainer ring (1)	Anodized aluminium alloy	Unitary non sterile
2051- KG-002	Ring-pillar screw	stainless steel	
2051- AM-PI	Pillar (2)	Anodized aluminium alloy & polymer	Pouch of 4 non sterile units
2051-AM1-PI1-003	Pillar screw	Stainless steel	

- (1) Use exclusively with pillar 2051-AM1-PI1 and rings-pillar-screws 2034-KG-002
- (2) Use exclusively with framework de Leksell, pillar-screws 2051-AM1-PI1-003 and screwdriver 2051-TO
- Re-usable material designed for autoclave sterilization till 134°C.
- (E marked.

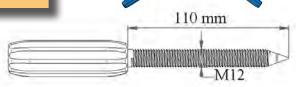
Screwable percutaneous point 2051-PPV (C)

Reference	Material	Packaging
2051- PPV	Polymer (handle) Stainless steel (percutaneous point)	Pouch of 4 non sterile units



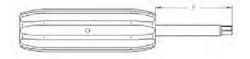
• Re-usable material designed for autoclave sterilization till 134°C.

C E marked.



Screwdriver 2051-TO (E)

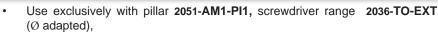
Reference	II (mm)	Material	Packaging
2051- TO	45	Stainless steel (shank) Polymer (handle)	non sterile unit



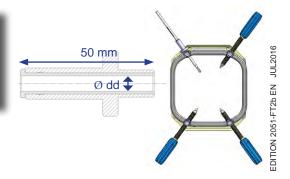
- Use exclusively with pillar 2051-AM1-PI1-003 and screwable spacer range 2051-EV to allow their clamping / screwing, release / unscrewing
- Re-usable material designed for autoclave sterilization till 134°C.
- **(€** marked.

Drilling gun 2051-PPV (D)

Reference	Material	Packaging
2051-AM-CP-60	Polymer (handle) Stainless steel (percutaneous point)	Pouch of 4 non sterile units
2051-AM-CP-dd	other Ø dd available on reques	t please contact us



- Re-usable material designed for autoclave sterilization till 134°C.
- C marked.





(Leksell Frame adapted to become REPOSITIONNABLE)

Technical Form

STEREOTAXY

EDITION 2051-FT2 Page 4/4

RANGE: 2051

Kit Braces Within range type 1 (hollow) Ref. 2051-KEV1-(C1)					
COI	ntaining				
Reference	Length (mm)	Qty			
2051-EV1-035	35	4			
2051-EV1-050	50	4			
2051-EV1-065	65	4			
2051-EV1-080	80	4			
2051-EV1-095 95 2					
2051-EV1-110	110	2			

Kit Braces Within range type 2 (monobloc) Ref. 2051-KEV2-(C1)						
containing						
Reference	Length (mm)	Qty				
2051-EV2-035	35	4				
2051-EV2-050	50	4				
2051-EV2-065	65	4				
2051-EV2-080 80 4						
2051-EV2-095 95 2						
2051-EV2-110	110	2				

(monobloc integrating marker) Ref. 2051-KEV3-(C1)					
COI	ntaining				
Reference	Length (mm)	Qty			
2051-EV3-035	35	4			
2051-EV3-050	50	4			
2051-EV3-065	65	4			
2051-EV3-080	80	4			
2051-EV3-095	95	2			
2051-EV3-110	110	2			

Kit Braces Within range type 3

Spacer within range 2051-EV

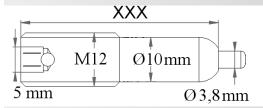
Allow (during imaging sequences realization) by "interfacing" between percutaneous screw and Leksell frame pillar; to **solidarize the frame** with of patient cranium and to locate a scanner marker.

XXX M12 Ø10mm 5 mm Ø6mm

2051-EV1 Screwable spacer

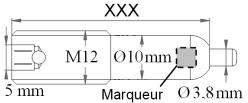
- · Are assembled with the spacers of the range 2036.
- To use exclusively with pillar 2051-AM1-PI1 and the screwdriver 2051-TO.
- · No imaging artefact

2051-EV2 Screwable monobloc spacer

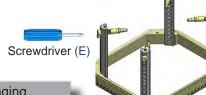


- To use exclusively with pillar 2051-AM1-PI1 and the screwdriver 2051-TO.
- No imaging artefact

2051-EV3 Screwable monobloc spacer containing marker



- use exclusively with pillar 2051-AM1-PI1 and screwdriver 2051-TO.
- RX detectable



Reference	Useful length xxx (mm)	Material	Packaging
2051-EV1-xxx	035	Dolumor	
2051-EV1-xxx	050 065	Polymer	Pouch of 2 or 4
2051-EV1- <i>xxx</i>	080 095 110	Polymer with titanium marker (Ø 5 x 5 mm)	non sterile units

- Re-usable material designed for autoclave sterilization till 134°C.
- C marked.

EDITION 2051-FT2b EN JUL2016



CONNECTION CABLE FOR MICROELECTRODE

Range: 2029-10-000

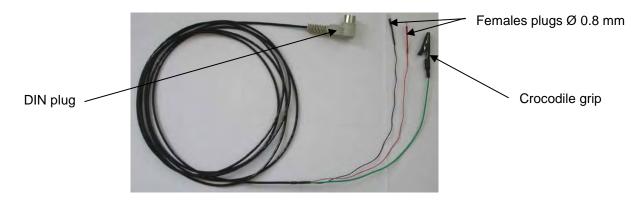
Technical Form

PARKINSON

EDITION 2029-10-FT6

Page 1 / 1

• CONNECTING CABLE FOR MICROELECTRODE: 2029-10



Recording machine connector	Cable section	Microelectrode connector	Packaging
1 DIN male plug 5 ways 60°	3 meters length	2 females plugs Ø 0,8 mm 1 crocodile grip (cable earth)	
3 5			Unitary packaged in sterile pouch and then grouped in 5 units box.
DIN 1 - DIN 2 -		 Black conductor (female plug Ø 0.8 Red conductor (female plug Ø 0.8 n 	
		Black shield	
		➤ Red snield ➤ Cable shield (Crocodile grip)	

- Ethylene oxyde sterilized
- · Single use
- C€1014 Marked







ACCESSORIES FOR MICROELECTRODE

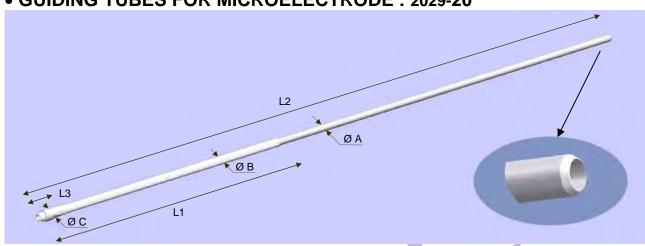
Technical Form

PARKINSON

EDITION 2029-AM-FT8c Page 1 / 1

Range: 2029-20 et 2029-30

GUIDING TUBES FOR MICROELECTRODE: 2029-20



Reference	ØA (mm)	ØB (mm)	ØC (mm)	L3 (mm)	L2 (mm)	L1 (mm)	ID (mm)	Packaging
2029-20- A -120-(50)				5	120	50		
2029-20- A1 -160-(140)					160			
2029-20- A1 -170-(140)		1,5	2	10	170	140		
2029-20- A1 -210-(140)	1,2			10	210		0,8 < Ø < 0,9	10 sterile units box
2029-20- A1 -210-(50)	1,2				210	50	0,0 < 0 < 0,9	(individual packaging)
2029-20- B -120-(50)				5	120	50		(marriadar packaging)
2029-20- B1 -210-(140)		2	2,5	10	210	140		
2029-20- B1 -210-(50)				10	210	50		
Other dimensions realizable on request								

- Proximal part calibrated for insertion in a Ø B hole
- Distal part tipped
- Ethylene oxide sterilized / Single use /C € 0459 marked

STYLET FOR GUIDING TUBES: 2029-30

ØA		L1	
_	L	2	





Reference	L2 (mm)	L1 (mm)	OD A (mm)	Packaging		
2029-30- A -237-(210)		211,5		10 sterile units box		
2029-30- B -237-(210)		213		(individual packaging)		
2029-30- A -237-(160)	~237	171.5				
2029-30- B -237-(160)		173	0.0			
2029-30- A -23 7- (170)		161.5	0,8			
2029-30- B -237-(170)		163				
2029-30- A -147-(120)	4.47	121,5				
2029-30- B -147-(120)	~147	123				
Othe	Other dimensions realizable on request					

- Type A: the hemispheric shape facilitates the penetration of guiding tube through the brain
- Type B: the pointed shape facilitates the crossing through dura mater
- Ethylene oxide sterilized / Single use / C € 1014 marked

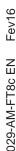
Order / Delivery

ALCIS Neuro

2 rue Paul Milleret - 25000 Besançon - France Tél. +33 (0)3 81 61 69 93 - Fax +33 (0)3 81 53 47 65 @ contact@alcis.net - W www.alcis.net

Medical Devices. Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. Always refer to the information on packaging's labels and instructions for use (if applicable). 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." Manufacturer: ALCIS - Besançon, France.

EDITION







ACCESSORIES FOR MICROELECTRODE

Technical Form

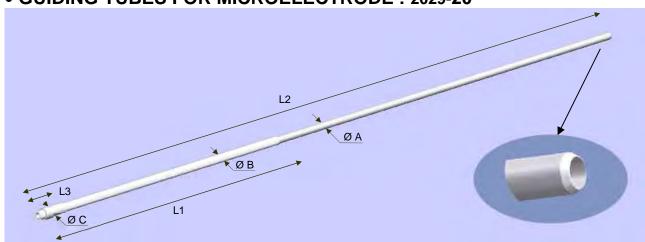
PARKINSON

EDITION 2029-AM-FT8c

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Range: 2029-20 et 2029-30

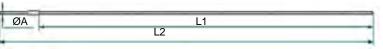
GUIDING TUBES FOR MICROELECTRODE: 2029-20



Reference	ØA (mm)	ØB (mm)	ØC (mm)	L3 (mm)	L2 (mm)	L1 (mm)	ID (mm)	Packaging							
2029-20- A -120-(50)		1,5		5	120	50									
2029-20- A1 -160-(140)			1,5			160									
2029-20- A1 -170-(140)				1,5	2	10	170	140							
2029-20- A1 -210-(140)	1,2								10	10	10	210		0,8 < Ø < 0,9	10 sterile units box
2029-20- A1 -210-(50)	1,2									210	50	0,0 \ 2 \ 0,0	(individual packaging)		
2029-20- B -120-(50)				5	120	50		(marviadar packaging)							
2029-20- B1 -210-(140)		2	2 2,5	10	210	140									
2029-20- B1 -210-(50)					10	210	50								
Other dimensions realizable on request															

- Proximal part calibrated for insertion in a Ø B hole
- Distal part tipped
- Ethylene oxide sterilized / Single use /€ 0459 marked

STYLET FOR GUIDING TUBES: 2029-30







Reference	L2 (mm)	L1 (mm)	OD A (mm)	Packaging
2029-30- A -237-(210)		211,5		10 sterile units box
2029-30- B -237-(210)]	213		(individual packaging)
2029-30- A -237-(160)	~237	171.5		
2029-30- B -237-(160)	~231	173	0.0	
2029-30- A -237-(170)		161.5	0,8	
2029-30- B -237-(170)		163		
2029-30- A -147-(120)	4.47	121,5		
2029-30- B -147-(120)	~147	123		
Othe	r dimensions real	t		

- Type A: the hemispheric shape facilitates the penetration of guiding tube through the brain
- Type B: the pointed shape facilitates the crossing through dura mater
- Ethylene oxide sterilized / Single use / C € 1014 marked

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Notes

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