

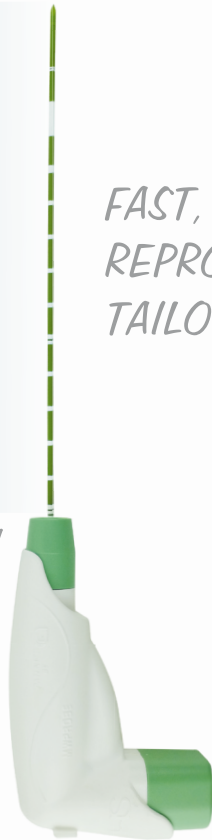
# AMICA-PROBE

MICROWAVE APPLICATORS  
FOR THERMOABLATION



*...and much more!*

*FAST, SAFE,  
REPRODUCIBLE,  
TAILORED ABLATION*



## DESCRIZIONE DEL PRODOTTO

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**AMICA-PROBE** è un applicatore monouso per termoablazione a microonde.

- corpo in acciaio medico con rivestimento anti-aderente, centimetratura e indicatore di profondità scorrevole
- possibilità di introduzione diretta nei tessuti (accesso percutaneo) grazie alla punta metallica ad affilatura piramidale
- mini-choke (sistema brevettato dal Consiglio Nazionale delle Ricerche e in licenza esclusiva a H.S. HOSPITAL SERVICE S.p.A.) per il controllo delle microonde riflesse e della forma e delle dimensioni della figura di necrosi coagulativa indotta nei tessuti
- impugnatura ergonomica a "L" o dritta
- circuito idraulico e cablaggi integrati e pre-assemblati, completamente monouso
- termocoppia interna per la verifica del corretto funzionamento del circuito idraulico di raffreddamento
- memoria digitale per l'identificazione, la verifica d'integrità e l'auto-impostazione di opportuni parametri di lavoro e limiti di sicurezza
- disponibili modelli standard con cavi di lunghezza 2.5m, o 1.5m, oppure con cavi staccabili (per la disconnessione temporanea del cavo di alimentazione dell'antenna e del circuito idraulico allo scopo di facilitarne le operazioni di posizionamento dell'applicatore, ad esempio nell'utilizzo sotto guida TAC)
- disponibili modelli con antenne multiple (2 o 3), da usare in combinazione con AMICA-SWITCHBOX
- ottima visibilità della parte attiva sotto guida TAC o ultrasonografica
- possibilità di variare la performance coagulativa semplicemente variando la modalità di erogazione (manuale o pulsata), la potenza erogata e la durata del trattamento
- ablazioni fino a circa 5cm di diametro in 10 minuti con un singolo ago
- sfericità dell'ablazione (definita come rapporto tra gli assi corto e lungo dell'ablazione) pari in media a 0.7 in modalità continua e circa pari a 0.8 in modalità pulsata con un singolo ago
- ablazione quasi perfettamente sferiche di diametro > 5 cm e fino a 6,5 cm ottenibili con 3 antenne azionate in simultanea
- AMICA-PROBE è fornito in un kit sterile contenente: bisturi per la precisione cutanea, spugna per disinfettante, supporti di fissaggio e telo per campo sterile con foro centrale
- possibilità di misurare la temperatura in un bersaglio profondo durante un trattamento con sensore interstiziale (ITC) e lettore di temperatura.

## PRODUCT DESCRIPTION

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**AMICA-PROBE** is a disposable applicator for microwave thermoablation.

- medical grade stainless steel cannula, with anti-stilling coating, spacing markers, marks and a sliding depth stop
- pyramidal metallic tip to facilitate percutaneous access
- mini-choke (patented by the Italian National Research Council (CNR), exclusively licensed to H.S. HOSPITAL SERVICE S.p.A.) for reflected microwaves entrapment and elimination of back heating effects. Enhanced control over the coagulation pattern and size, enhanced treatment safety and repeatability
- ergonomic "L" shaped or straight handle
- totally disposable and pre-assembled hydraulic circuit and cables
- built-in thermocouple for cooling control
- embedded memory chip for probe identification, verification and self-setting of appropriate working parameters and safety limits
- different cabling solutions available: integrated 2.5m or 1.5m cables or detachable cables (for easier probe positioning during ct-guided procedures)
- Multi-probe models available (2 or 3 antennas, to be used in conjunction with AMICA-SWITCHBOX)
- excellent tip visibility under CT and US scanning
- adaptable coagulative performance through appropriate setting of the energy delivery mode (either manual or pulsed), treatment power and treatment duration
- up to 5cm ablation diameter in 10 minutes with a single probe
- average ablation sphericity (i.e. short to long ablation axis ratio) approximately equal to 0.7 in manual mode and about 0.8 in pulsed mode with a single probe
- nearly spherical ablations with diameter >5 cm and up to 6,5 cm when 3 antennas are operated simultaneously
- AMICA-PROBE is provided in a sterile kit with: scalpel for pre-incision of the patient's skin, sponge applicator for disinfectant, cable holders, surgical drape with central hole
- optional temperature monitoring ready the ablation site trough interstitial thermocouple probes (ITC) interconnected with a temperature meter.

# AMICA-PROBE

Code*	Description	Code*	Description
APK11150T19V5	11G x 150mm - cable length 2.5m	APK14320T19V5-DC	14G x 320mm - cable length 2.5m detachable cable
APK11150T19V5-DC	11G x 150mm - cable length 2.5m detachable cable	APK14320T19V5-S1.5	14G x 320mm - cable length 1.5m
APK11150T19V5-S1.5	11G x 150mm - cable length 1.5m	APK16100T19V5	16G x 100mm - cable length 2.5m
APK11270T19V5	11G x 270mm - cable length 2.5m	APK16100T19V5-DC	16G x 100mm - cable length 2.5m detachable cable
APK11270T19V5-DC	11G x 270mm - cable length 2.5m detachable cable	APK16150T19V5	16G x 150mm - cable length 2.5m
APK11270T19V5-S1.5	11G x 270mm - cable length 1.5m	APK16150T19V5-DC	16G x 150mm - cable length 2.5m detachable cable
APK11320T19V5	11G x 320mm - cable length 2.5m	APK16150T19V5-2X	16G x 150mm - 2 probes cable length 1m + 1.2m
APK11320T19V5-DC	11G x 320mm - cable length 2.5m detachable cable	APK16150T19V5-3X	16G x 150mm - 3 probes cable length 1m + 1.2m
APK11320T19V5-S1.5	11G x 320mm - cable length 1.5m	APK16200T19V5	16G x 200mm - cable length 2.5m
APK14150T19V5	14G x 150mm - cable length 2.5m	APK16200T19V5-DC	16G x 200mm - cable length 2.5m detachable cable
APK14150T19V5-DC	14G x 150mm - cable length 2.5m detachable cable	APK16200T19V5-2X	16G x 200mm - 2 probes cable length 1m + 1.2m
APK14150T19V5-S1.5	14G x 150mm - cable length 1.5m	APK16200T19V5-3X	16G x 200mm - 3 probes cable length 1m + 1.2m
APK14150T19V5-2X	14G x 150mm - 2 probes cable length 1m + 1.2m	APK16270T19V5	16G x 270mm - cable length 2.5m
APK14150T19V5-3X	14G x 150mm - 3 probes cable length 1m + 1.2m	APK16270T19V5-DC	16G x 270mm - cable length 2.5m detachable cable
APK14200T19V5	14G x 200mm - cable length 2.5m	APK16270T19V5-2X	16G x 270mm - 2 probes cable length 1m + 1.2m
APK14200T19V5-DC	14G x 200mm - cable length 2.5m detachable cable	APK16270T19V5-3X	16G x 270mm - 3 probes cable length 1m + 1.2m
APK14200T19V5-S1.5	14G x 200mm - cable length 1.5m	APK16320T19V5	16G x 320mm - cable length 2.5m
APK14200T19V5-2X	14G x 200mm - 2 probes cable length 1m + 1.2m	APK16320T19V5-DC	16G x 320mm - cable length 2.5m detachable cable
APK14200T19V5-3X	14G x 200mm - 3 probes cable length 1m + 1.2m	APK17070T19V5	17G x 70mm - cable length 2.5m
APK14270T19V5	14G x 270mm - cable length 2.5m	APK17100T19V5	17G x 100mm - cable length 2.5m
APK14270T19V5-DC	14G x 270mm - cable length 2.5m detachable cable	APK17150T19V5	17G x 150mm - cable length 2.5m
APK14270T19V5-S1.5	14G x 270mm - cable length 1.5m	APK18070T19V5	18G x 70mm - cable length 2.5m
APK14270T19V5-2X	14G x 270mm - 2 probes cable length 1m + 1.2m	APK18100T19V5	18G x 100mm - cable length 2.5m
APK14270T19V5-3X	14G x 270mm - 3 probes cable length 1m + 1.2m	APK18150T19V5	18G x 150mm - cable length 2.5m
APK14320T19V5	14G x 320mm - cable length 2.5m		

\*Tutti i modelli sono disponibili anche con impugnatura dritta (sostituire V5 con V6 all'interno del codice prodotto)

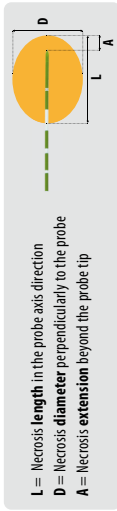
\*All models are also available with straight handle (replace V5 with V6 into the product codes)

Ablation size (LxDxA)		TIME			
		3 min	5 min	10 min	15 min
Power <sup>2</sup>	20 W	24x16x3 mm	27x20x5 mm	31x27x6 mm	38x33x8 mm
	40 W	29x20x4 mm	36x27x7 mm	48x36x9 mm	50x42x9 mm
	60 W	37x26x4 mm	46x33x7 mm	53x40x9 mm	61x48x12 mm
	80 W	47x32x8 mm	48x35x8 mm	63x44x9 mm	73x58x12 mm

Size of necrosis obtained on ex-vivo adult bovine liver, initially at room temperature (~20 °C): all sizes were obtained using a single applicator in a single insertion. The actual coagulation performance in the clinical scenario may vary with respect to this ex-vivo chart due to a number of factors (e.g. blood perfusion, biological or physical peculiarities of the target tissues, prior or concurring local treatments, boundary conditions, etc.). Do not rely on the ex-vivo model alone for planning a microwave ablation treatment with HS AMICA. Real-time intra-operative monitoring of treatment progression through appropriate imaging techniques is mandatory.

<sup>1</sup>Manual.

<sup>2</sup>Net power at probe end.



20 Watt / 3 min



L	D	A
24mm	16mm	3mm

20 Watt / 5 min



L	D	A
27mm	20mm	5mm

20 Watt / 10 min



L	D	A
31mm	27mm	6mm

20 Watt / 15 min



L	D	A
38mm	33mm	8mm

40 Watt / 3 min



L	D	A
29mm	20mm	4mm

40 Watt / 5 min



L	D	A
36mm	27mm	7mm

40 Watt / 10 min



L	D	A
48mm	36mm	9mm

40 Watt / 15 min



L	D	A
50mm	42mm	9mm

60 Watt / 3 min



L	D	A
37mm	26mm	4mm

60 Watt / 5 min



L	D	A
46mm	33mm	7mm

60 Watt / 10 min



L	D	A
53mm	40mm	9mm

60 Watt / 15 min



L	D	A
61mm	48mm	12mm

80 Watt / 3 min



L	D	A
47mm	32mm	8mm

80 Watt / 5 min



L	D	A
48mm	35mm	8mm

80 Watt / 10 min



L	D	A
63mm	44mm	9mm

80 Watt / 15 min



L	D	A
73mm	58mm	12mm

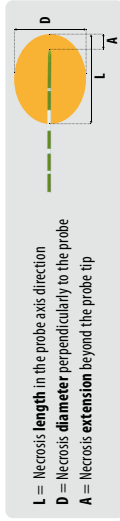
Ablation size (LxDxA)	TIME		
	3 min	5 min	10 min
60 W	28x21x4 mm	29x24x5 mm	35x29x6 mm
100 W	35x27x4 mm	39x31x5 mm	44x38x6 mm
140 W <sup>2</sup>	39x29x6 mm	45x34x6 mm	53x43x6 mm
180 W <sup>3</sup>	46x30x6 mm	53x40x9 mm	66x47x11 mm

Performance chart applicable to 14G AMICA-PROBE models only, cooled using pre-refrigerated saline solution ( $\leq 5^{\circ}\text{C}$ ) flowing at approximately 100ml/min. Size of necrosis obtained on ex-vivo adult bovine liver, initially at room temperature ( $\sim 20^{\circ}\text{C}$ ); all sizes were obtained using a single applicator in a single insertion. The actual coagulation performance in the clinical scenario may vary with respect to this ex-vivo chart due to a number of factors (e.g. blood perfusion, biological or physical peculiarities of the target tissues, prior or concurring local treatments, boundary conditions, etc.). Do not rely on the ex-vivo model alone for planning a microwave ablation treatment with HS AMICA. Real-time intra-operative monitoring of treatment progression through appropriate imaging techniques is mandatory.

<sup>1</sup>Net power at the probe end.

<sup>2</sup>Only using AMICA-GEN models AGN-H-1.2 and AGN-3.2.

<sup>3</sup>Only using AMICA-GEN models AGN-H-1.3 and AGN-3.3



**L** = Necrosis length in the probe axis direction

**D** = Necrosis diameter perpendicularly to the probe

**A** = Necrosis extension beyond the probe tip

**60 Watt / 3 min**



L	D	A
28mm	21mm	4mm

**100 Watt / 3 min**



L	D	A
35mm	27mm	4mm

**140 Watt / 3 min**



L	D	A
39mm	29mm	6mm

**180 Watt / 3 min**



L	D	A
46mm	30mm	6mm

**60 Watt / 5 min**



L	D	A
29mm	24mm	5mm

**100 Watt / 5 min**



L	D	A
39mm	31mm	5mm

**140 Watt / 5 min**



L	D	A
45mm	34mm	6mm

**180 Watt / 5 min**



L	D	A
53mm	40mm	9mm

**60 Watt / 10 min**



L	D	A
35mm	29mm	6mm

**100 Watt / 10 min**



L	D	A
44mm	38mm	6mm

**140 Watt / 10 min**



L	D	A
53mm	43mm	6mm

**180 Watt / 10 min**



L	D	A
66mm	47mm	11mm



# CLINICAL PERFORMANCE OF AMICA-PROBE

The following tables summarize clinical data published on peer-reviewed scientific journals related to the use of AMICA-PROBE in the percutaneous MWA treatment of liver, lung and kidney tumors.

In all tables:

- data refer to the use of a single probe operated IN CONTINUOUS MODE at pre-defined power (P) and time (t) settings; overlapping ablations, multi-probe ablations or combined treatments (e.g. MWA following TAE or TACE in the same region) were not considered
- the ablations observed on immediate (<72 hours) or early (1-month) post-MWA CT scans are represented in terms of their longitudinal (L, along the MW probe axis) and transversal (D, perpendicular to the MW probe) dimensions
- each table entry stems from averages on several treatments performed under equal P x t settings.

See the original publications for all the details and limitations of these data.

N.B. Do not use the following tables as the only or priority reference when planning a treatment with AMICA-PROBE: the actual treatment outcome depends on a number of factors which vary significantly from case to case (such as, though not limited to, tumor biology, location, size and vascularization, prior treatments, etc.).



# LIVER ABLATION

## COAGULATION CHART FOR MW ABLATION TREATMENTS WITH AMICA-PROBE ON HEPATOCELLULAR CARCINOMAS

MWA SETTINGS (P x t)	ABLATION SIZE (L x D)
40W x 3min*	32.1 mm x 22.2 mm
40W x 5min*	35.6 mm x 22.9 mm
60W x 5min*	43.6 mm x 28.2 mm
60W x 10min**	52 mm x 37 mm

## COAGULATION CHART FOR MW ABLATION TREATMENTS WITH AMICA-PROBE ON LIVER METASTASES

MWA SETTINGS (P x t)	ABLATION SIZE (L x D)
60W x 5min**	55 mm x 40 mm
60W x 10min**	65 mm x 41 mm

Data excerpted from:

\* Crocetti L, Amabile C, Scalise P, Tosoratti N, Bozzi E, Rossi P, Cervelli R, Cassarino S, Cioni R. Predicting the coagulation volume induced by microwave ablation of hepatocellular carcinoma: the role of deposited energy, ex-vivo bovine liver charts and central hyperdense area on post-treatment CT. *Int J Hyperthermia*. 2021;38(1):1486-1494. doi: 10.1080/02656736.2021.1986642. PMID: 34927518. Ablation measures were taken 1-month post-MWA.

\*\* Amabile C, Ahmed M, Solbiati L, Meloni MF, Solbiati M, Cassarino S, Tosoratti N, Nissenbaum Y, Ierace T, Goldberg SN. Microwave ablation of primary and secondary liver tumours: ex vivo, in vivo, and clinical characterisation. *Int J Hyperthermia*. 2017 Feb;33(1):34-42. doi: 10.1080/02656736.2016.1196830. Epub 2016 Jul 25. PMID: 27443519. Ablation measures were taken 24 hours post-MWA.



# LUNG ABLATION

## COAGULATION CHART FOR MW ABLATION TREATMENTS WITH AMICA-PROBE ON LUNG METASTASES

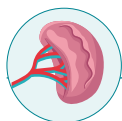
MWA SETTINGS (P x t)	ABLATION SIZE (L x D)
30W x 10min	32.4 mm x 20.2 mm
50W x 10min	38.8 mm x 27.5 mm
70W x 10min	40.1 mm x 32.0 mm

## COAGULATION CHART FOR MW ABLATION TREATMENTS WITH AMICA-PROBE ON PRIMARY LUNG TUMORS

MWA SETTINGS (P x t)	ABLATION SIZE (L x D)
40W x 10min	32.7 mm x 26.8 mm
60W x 10min	48.6 mm x 35.1 mm
80W x 10min	49.1 mm x 36.1 mm

Data excerpted from:

Iezzi R, Cioni R, Basile D, Tosoratti N, Posa A, Busso M, Cappelli C, Margaritora S, Ambrogi MC, Cassano A, Scandiffio R, Calandri M, Crocetti L, Valentini V, Manfredi R, Veltri A. Standardizing percutaneous Microwave Ablation in the treatment of Lung Tumors: a prospective multicenter trial (MALT study). *Eur Radiol.* 2021 Apr;31(4):2173-2182. doi: 10.1007/s00330-020-07299-2. Epub 2020 Sep 30. PMID: 32997180. Ablation measures were taken within 48 hours post-MWA.



# KIDNEY ABLATION

## COAGULATION CHART FOR MW ABLATION TREATMENTS WITH AMICA-PROBE ON RENAL TUMORS

MWA SETTINGS (P x t)	ABLATION SIZE (L x D)
40W x 5min	50 mm x 33 mm
40W x 10min	61 mm x 37 mm
40W x 15min	73 mm x 43 mm
60W x 5min	61 mm x 38 mm
60W x 10min	64 mm x 42 mm
60W x 15min	78 mm x 55 mm

Data excerpted from:

Noventa A, Herpe G, Vesselle G, Guibal A, Velasco S, Chan P, Ingrand P, Boucebci S, Tasu JP. Chart for renal tumor microwave ablation from human study. *Diagn Interv Imaging*. 2018 Oct;99(10):609-614. doi: 10.1016/j.diii.2018.05.005. Epub 2018 Jun 15. Erratum in: *Diagn Interv Imaging*. 2020 May;101(5):327. PMID: 29914815. Ablation measures were taken 1-month post-MWA.