STEREOTAXIS

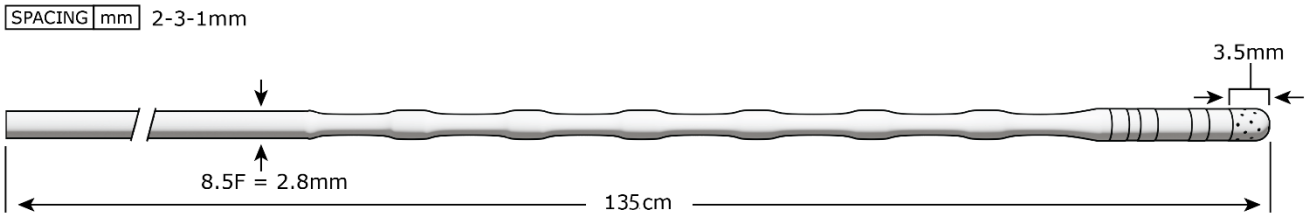
MAGiC

Magnetic Interventional Ablation Catheter

INSTRUCTIONS FOR USE

- English -

SYMBOL LEGEND					
REF	en Order number		en Contents		en Caution
LOT	en Batch name		en For one-time usage only	MD	en Medical Device
	en Manufacturer		en Do not re-sterilize	STERILE EO	en Sterilisation with ethylene oxide
	en Date of manufacture		en Single sterile barrier system with protective packaging inside		en Temperature limitation
	en Consult Instructions for Use		en Do not use if package damaged		en Keep away from Sunlight
	en To be used before		en Keep dry		en Protect from Heat and Radioactive Sources
	en Humidity limitation		en Atmospheric pressure limitation	UDI	en Unique Device Identifier
CE	en European Conformity	UK CA	en United Kingdom Conformity Assessment	Rx	en- By Prescription Only



CE 2797

UK CA 0086 United Kingdom Conformity Assessed

UKRP United Kingdom Responsible Person:
Dot Medical Ltd. trading at Silk Point,
Queens Avenue, Macclesfield, SK10 2BB, United Kingdom

ENGLISH

Caution: Please read these instructions carefully before using the product.

UDI: Basic UDI-DI: 4044508MAGICPM
SSCP: The Summary of Safety and Performance is publicly available at https://ec.europa.eu/tools/eudamed. *If not accessible in EUDAMED, the information shall be made available to the public upon request*
eIFU: http://www.stereotaxis.com/referencelibrary

COMPONENTS

Magnetic Interventional Ablation Catheter (MAGiC™)

DEVICE DESCRIPTION

MAGiC is a sterile, magnetically guided mapping and ablation catheter. *MAGiC* is intended to provide sensing and mapping of the electrical signals in the heart for diagnostic purposes. It has four electrodes for pacing and sensing with an open irrigation tip electrode for delivering ablative energy to the cardiac tissue. *MAGiC* is intended to be used with a compatible Stereotaxis Robotic Magnetic Navigation System (RMNS) and the Cardiodrive® catheter advancement system (CAS).

ESSENTIAL USE INFORMATION

Characteristic	Specification	Accuracy
Catheter shaft diameter	8.5 F	2.67-2.87 mm
Catheter usable length	135 cm	133 cm ± 2 cm
Tip electrode length	3.5 mm	3.5 mm ± 0.1 mm
Tip electrode material	Gold	
Electrode material (except tip)	Platinum/Iridium	
Ring electrode length	1.5 mm	1.5 mm ± 0.1 mm
Electrode Spacing	2-3-1 mm	Tolerance: +0.3/-0.2 mm

COMBINATION WITH OTHER DEVICES

The following devices are compatible with *MAGiC*:

Legal Manufacturer	Device
Stereotaxis	Robotic Magnetic Navigation System (RMNS)
Stereotaxis	Cardiodrive® and QuikCAS™
OSYPKA AG	iCONNECT™ and *iCONNECT* Cables
Abbott	Ampere™ RF Generator, compatible irrigation pump, tubing
In the EU and UK:	
Livetec Ingenieurbuero GmbH	HAT 500® RF Generator, *HAT 500* Irrigation Pump, Remote Control, tubing
Boston Scientific	Maestro Cardiac Ablation System, compatible irrigation pump, tubing
Biosense Webster	SMARTABLATE™ System (RF Generator, pump, and remote control), tubing

INDICATIONS FOR USE

In the European Union and United Kingdom
MAGiC is intended for use in cardiac electrophysiology for mapping, delivering diagnostic pacing stimuli, and for patients indicated for RF catheter ablation of cardiac arrhythmias. The indication for treatment of these arrhythmias is described in the guidelines and consensus statements from major cardiology societies, including the European Society of Cardiology.

In the United States
The MAGiC Magnetic Interventional Ablation Catheter is indicated for cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, and for the creation of endocardial lesions to treat supraventricular tachycardia (e.g., macroreentrant atrial tachycardia, focal atrial tachycardia, atrioventricular nodal reentrant tachycardia, and atrioventricular reentrant tachycardia) in patients with congenital heart disease in whom vascular or target chamber access by conventional manual catheter navigation is limited due to underlying anatomic abnormalities and/or previous surgical interventions.

CONTRAINDICATIONS

The catheter should not be used:

- in patients with intracardiac mural thrombus;
- in patients where the catheter would need to cross a prosthetic valve;
- in the coronary arteries;
- with patients having a systemic infection;
- in patients with history of sensitivity to foreign objects or extreme allergies;
- in patients with histological or anatomical abnormalities that may lead to post-operative complications such as bleeding diathesis, diminished resistance to infection;
- in patients with hemodynamic instability;
- with patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation.

INTENDED PURPOSE

MAGiC together with Stereotaxis RMNS is intended to be used during radio-frequency ablation to produce local lesions in cardiac tissue for the treatment of cardiac arrhythmias, for electrophysiological mapping, and for delivering stimulation pulses.

EXPECTED CLINICAL BENEFIT

Ablation of the tissues that cause or support an arrythmia has been shown in many patients to eliminate the arrythmia and return the heart to a normal sinus rhythm.

PATIENT POPULATION

MAGiC is intended to be used with patients that have cardiac arrythmia whose health status is suitable for a cardiac ablation procedure and do not have any of the listed contraindications.

HOW SUPPLIED

The products are sterilized with ethylene oxide. Packaging is designed to maintain sterility according to the expiration date on the label. Do not use if the expiration date has passed, the package is opened or damaged, or if the labelling is incomplete or illegible.

HANDLING AND STORAGE

Store at ambient temperatures in a dry and dark location (10-25°C, 30-60%RH, 60-120kPa). Keep dry and protect from direct sunlight. Do not expose to generated sources of gamma, neutron, α-particle and β-particle radiation.

REUSE PRECAUTION STATEMENT

Not autoclavable. Single use only. Do not re-sterilize product. Re-use bears the risk of infection and the possibility of malfunction.

WARNINGS

- **For single use only.** Do not reuse, reprocess, or resterilize. Reuse can compromise the catheter performance characteristics and may result in patient injury or infection.
- This catheter should be used only by physicians trained in electrophysiology techniques.
- This catheter should be used only in procedures that use the Stereotaxis RMNS.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- Use of devices or accessories other than those specified could result in improper operation.
- Proper sterile technique must be used when removing the catheter from the packaging and during operation of the catheter to prevent exposing the patient to the possibility of infection.

- Do not modify the product in any way.
- Do not advance through a prosthetic valve.
- Do not use after the expiry date on the package label.

PRECAUTIONS

- The catheter is supplied STERILE in an unopened package. Verify package integrity has been maintained and the sterility of the device has not been compromised.
- Under sterile conditions, examine the device for defects and verify proper device function and integrity.
- If damage to the sterile barrier or device are found, do not use the device. Contact your Stereotaxis representative and exchange the device for a new one.
- If higher power and times are used than indicated in the RF parameters table, there is a possibility of steam pop occurring.
- Always use an irrigation pump with the catheter.
- Always use the RMNS, *Cardiodrive* CAS, and *Cardiodrive* Sterile Components with the catheter.
- Monitor the amount of irrigation fluid used to prevent fluid overload in the patient
- Do not expose the catheter to organic solvents.
- Do not autoclave the catheter.
- Do not immerse the electrical connections in water.
- Do not clean the handle with liquids.
- Ensure that all air is removed from pump tubing and the catheter through proper flushing.
- Use intravenous heparin to avoid thromboemboli, particularly during left-sided heart access.
- Always maintain a base irrigation flow of 2ml/min.
- Do not use in or near MRI equipment.
- Inspect irrigation saline for bubbles. Air bubbles may cause emboli.
- Reduce the magnetic field when inserting or removing the catheter to prevent damage to the catheter.
- Ablating near the SA node or AV node may cause damage requiring temporary or permanent pacing.
- Use fluoroscopic imaging and electrogram signals to monitor catheter movements in order to reduce the risk of tissue injury.
- Before use, check that the irrigation ports are open and irrigation fluid is flowing out of the holes by flushing with saline.
- Do not exceed 24 hour use of the catheter.
- Observe error messages on the ablation generator and consult the IFU for guidance.
- Follow the respective operating instructions when connecting and using external devices.

INTENDED USERS

The product may only be used in a medical treatment facility that has been specifically set up for the appropriate application and by trained staff (electrophysiology cath lab specialists). Physicians and staff using the MAGiC catheter must be trained in the use of the Stereotaxis Magnetic Navigation System. It is the responsibility of the physician to select the medically appropriate procedure for the patient. These operating instructions are intended to provide general information on handling the product. The product must not be modified in any way. Warnings, general information, and precautionary measures must be observed. Failure to observe these instructions can result in procedural complications or malfunctioning of or damage to the device.

PREPARATION FOR USE

1. Carefully remove the catheter from the package using sterile techniques and place in a sterile work area.
2. Inspect the catheter prior to use to confirm it is undamaged. If damage is detected (e.g., bends, kinks, etc.), do not attempt to repair the catheter. Use a new catheter for the procedure and return the damaged catheter to Stereotaxis, Inc.
3. Remove a compatible introducer using sterile techniques and place in a sterile work area.

INSTRUCTIONS FOR USE

1. Using aseptic techniques create vascular access in a large central vessel.
2. Prepare and flush the Irrigation Tubing Set according to the device IFU.
3. Connect the Irrigation Tubing Set to the catheter using standard luer fittings.
4. Flush the catheter and tubing to ensure the removal of any trapped air bubbles and to verify that the irrigation holes are open and irrigation fluid is flowing out of the holes at a flow rate of 2 ml/min.
5. Confirm the magnetic fields are removed.
6. Insert the catheter through the *QuikCAS* hemostasis adapter, following the *QuikCAS* Instructions for Use.
7. Insert the tip of the catheter into the hemostasis valve of the Introducer.
8. Lock the hub of the *QuikCAS* hemostasis adapter to the hub of the introducer.
9. Slide the insertion tube of the *QuikCAS* hemostasis adapter into the hemostasis valve of the introducer to open the hemostasis valve.
10. Advance the catheter until the soft distal section with the magnets has been inserted into the introducer (about 10cm).
11. Aspirate the introducer to remove any air that may have entered the introducer with the catheter's insertion.
12. Retract the handles of the *QuikCAS* hemostasis adapter to withdraw the insertion tube from the hemostasis valve.
13. Advance the catheter into the heart using fluoroscopic guidance.
14. Connect the rear disk of the *QuikCAS* hemostasis adapter to the *QuikCAS*.
15. Place the catheter into the *QuikCAS* and lock the catheter into the drive.

16. Using robotic magnetic navigation, perform the necessary mapping, sensing, and pacing required to diagnose the arrhythmia and identify the location for therapy delivery.
17. Deliver RF energy as necessary to treat the arrhythmia.
18. Reduce the magnetic field using the Apply magnetic field/Reduce magnetic field icon on the Main toolbar of the Navigant™ Workstation Software or retract the RMNS prior to removing the catheter.
19. When removing the catheter (during or after the procedure), remove the hemostasis adapter from the *QuikCAS*. Gently withdraw the catheter following best practices.

RF ABLATION

Connect the catheter to the appropriate input on the *iCONNECT* interface box or the RF generator and use a compatible cable. An indifferent electrode patch must be placed on the patient and connected to the RF generator. Upon inserting the catheter, ensure that the displayed impedance is in an acceptable range and that the displayed temperature is near body temperature (~37°C). If impedance is not acceptable, the generator will not operate. Consult the applicable IFU for questions about the RF generator.

RF PARAMETERS

Characteristic	Specification
Power Range	15-50W
Temperature Monitoring	<50°C
Application time	5-60 seconds for power of 30W or less 5-20 seconds for power greater than 30W
Irrigation Rate	10 ml/min

POTENTIAL ADVERSE EVENTS

Adverse events may result from proper and improper use of the device and may also be due to the procedure itself. Follow instructions for use carefully. Potential adverse events related to the device and/or procedure vary in frequency and severity up to and including Death and include, but are not limited to:

atrioesophageal fistula
bleeding
cardiac arrhythmia
cardiac tamponade
conduction block
diaphragm palsy
embolism
femoral arteriovenous fistula
femoral bleeding
heart failure
hemothorax
inflammation
infection
inguinal hematoma
myocardial infarction
perforation
pericardial effusion
phrenic nerve injury
pulmonary vein stenosis
stroke
thrombosis
transient phrenic palsy

DISPOSAL

The product may be contaminated after use and should be considered a potential biohazard. Handle and dispose-of in accordance with medical practice and applicable local, state, and federal laws and regulations.

TRADEMARKS

STEREOTAXIS TECHNICAL SUPPORT

For technical support, please contact Stereotaxis TeleRobotic Support Team (TST) at 1-866-269-5268 or 1-314-678-6200 or email tst@stereotaxis.com.

NOTICE TO THE USER AND/OR PATIENT

Any adverse event or malfunction that occurred in relation to the device should be reported to the manufacturer. Serious adverse events should be reported to the competent authority of the Member State in which the user and/or patient is established.

DISCLAIMER OF WARRANTY AND LIMITATION OF LIABLILTY

STEREOTAXIS MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH REGARD TO THE DEVICE DESCRIBED IN THIS DOCUMENT. STEREOTAXIS DISCLAIMS ALL REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE, TITLE OR NON-INFRINGEMENT, ARISING BY STATUTE OR IN LAW, OR ARISING FROM A COURSE OF CONDUCT, COURSE OF DEALING OR USAGE OF TRADE.

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STEREOTAXIS IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM REUSE OF THIS DEVICE.

Manufactured for: Stereotaxis, Inc.
710 N. Tucker Blvd, Ste 110
St. Louis, MO 63101 USA
www.stereotaxis.com
1-314-678-6100

OSYPKA AG
Earl-H.-Wood-Str.
1
79618 Rheinfelden
Deutschland / Germany