

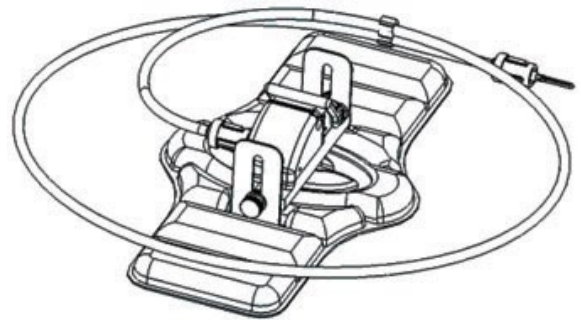
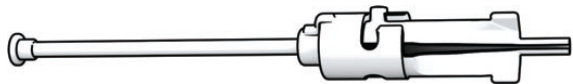


*QuikCAS*TM

Cardiodrive[®] Sterile Components

REF 001-001751-1

INSTRUCTIONS FOR USE



TRADEMARKS

- *Cardiodrive* and *Navigant* are trademarks of Stereotaxis, Inc., registered in the United States, the European Community, and Japan.
- *QuikCAS* is a trademark of Stereotaxis, Inc.

All other brand names, product names, or trademarks are the property of their respective owners.










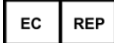

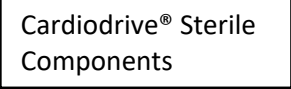


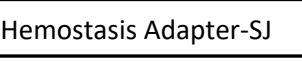




Manufactured under one or more of the following patents:

United States: 7,276,044; 7,635,342; 7,766,856

European Patents: EP 1 389 958 (B1); EP 1 781 364 (A2)

R_x Only

SYMBOL LEGEND

	Catalog Number
	Lot Number
	Use By
	Consult Operating Instructions
	Single Use Only
	Do Not Use if Package is Damaged or Opened
	Keep Dry
	Keep Away from Sunlight
	Sterilized using Ethylene Oxide
	Authorized Representative in the European Community
	Activation Code
	<i>Cardiodrive</i> Sterile Components
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physicians
	Hemostasis Adapter
	Hemostasis Adapter-SJ
	Protect from Heat and Radioactive Sources
	Product Manufacturer
	Marking for devices entering the European market
 标准编号: YZB/USA 1221-2010 国械注进20142665593	Chinese label verification symbol with Chinese Regulatory Registration Numbers

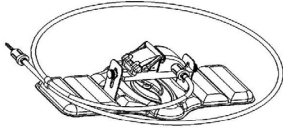
ENGLISH

DEVICE DESCRIPTION

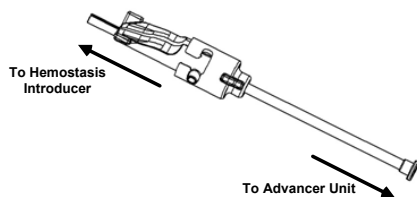
The *QuikCAS* device advances or retracts a compatible magnetic electrophysiology (EP) catheter, through a hemostasis introducer, remotely via a user interface (UI) located either at the patient table or in the control room.

Sterile Disposable Components include:

Pre-Assembled Advancer Unit



Hemostasis Adapter with Insertion Tool



HARDWARE COMPONENTS (PACKAGED SEPARATELY)

For more information on the individually packaged hardware components, refer to the *Cardiodrive* Installation, Operation, and Service Manual.

ADDITIONAL REQUIRED COMPONENTS

The *QuikCAS* unit is designed for use in conjunction with the Stereotaxis magnetic navigation system.

The following three disposable items are specified for *QuikCAS* operation and are sold separately.

- Compatible magnetic EP catheter.
Biosense Webster Inc.'s:
 - NaviStar® RMT Diagnostic
 - NaviStar® RMT Ablation
 - NaviStar® RMT DS
 - NaviStar® RMT ThermoCool
 - Celsius® RMT
- Designated introducer sheath or guiding sheath:
 - St. Jude Medical™ Fast-Cath™ 8.5F Hemostasis Introducer 12cm (P/N: 406207)
 - St. Jude Medical™ Fast-Cath™ 8.5F Transseptal Guiding Introducer 61cm (P/N: 406804)
 - St. Jude Medical™ Swartz™ SL0 8.5F Braided Transseptal Guiding Introducer (P/N: 407451)
 - St. Jude Medical™ Agilis NxT™ 8.5F Steerable Introducer Small Curl (P/N: G408318)
 - Biosense Webster Preface® 8F Guiding Sheath (P/N: 301803A)
 - Biosense Webster MOBICATH™ 8.5F Bi-Directional Guiding Sheath-Small Curve (P/N: D140010)
- OPTIONAL COMPONENTS:
 - Cardiodrive* Hemostasis Adapter

INDICATIONS

In the United States and Canada, the following Indications are applicable for the *Cardiodrive* system.

DSP-0224
Rev: AA
Effective Date: 12/17/2019

- The Stereotaxis *Cardiodrive* automated catheter advancement system (CAS) is intended for automatically advancing and retracting only compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis Magnetic Navigation System.
- The *Cardiodrive* system is not intended to advance the EP mapping and ablation catheters through the coronary vasculature or the coronary sinus.

In all other geographies, the following Indications are applicable for the *Cardiodrive* system.

The Stereotaxis *Cardiodrive* automated catheter advancement system (CAS) is intended for automatically advancing and retracting only compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart and pericardial space when used in conjunction with a Stereotaxis Magnetic Navigation System.

Warnings

- The *QuikCAS* sterile components are intended for **SINGLE USE** only. Do not resterilize. Reuse can compromise the *QuikCAS* performance characteristics and may result in infection.
- The *QuikCAS* system should only be operated for advancement or retraction while the catheter is under direct fluoroscopic visualization.
- Ensure all blood is flushed out of the Hemostasis Adapter during the patient setup.
- Inadvertent advancement or retraction of the *QuikCAS* may cause contact with sensitive heart tissue leading to a possible arrhythmia.
- The components of the *QuikCAS* are sterile and should be handled under sterile conditions. Verify that the package integrity has been maintained so that the sterility of the device has not been compromised.

Precautions

- The *QuikCAS* system should be used only by properly trained physicians.
- Always reduce the magnetic fields before attempting to connect/disconnect the *QuikCAS* components or to insert/remove the catheter.
- The Magnetic Navigation System, used in conjunction with the *QuikCAS* system, produces a strong magnetic field during operation. This magnetic field may cause metal objects to become airborne projectiles if such objects are not kept sufficiently isolated from the magnetic field.
- Refer to the Magnetic Navigation System User Guide for user precautions.
- Restrain the patient's leg to avoid excess bending, which may interfere with *QuikCAS* performance and place excessive pressure on the vascular access site.
- Carefully examine the device for defects and verify proper device function and integrity before catheter insertion into the patient.
- Do not use any *QuikCAS* components that have been damaged.
- Use the sterile components of the *QuikCAS* device before the expiration date printed on the product package.

PREPARATION FOR USE

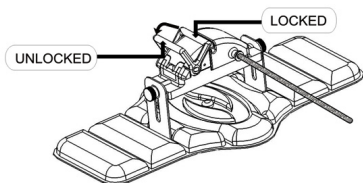
- Follow instructions in the *Cardiodrive* Installation, Operation, and Service Manual for setup of the User Interface and Motor components of the system.
- Remove the *QuikCAS* Sterile Components tray from the box.
- Navigant* software version 3.0.6.X and later will require an activation bar code to be scanned in by the user before use. This bar code can be found on both the tray label and on the box top located by the "Activation Code" symbol that appears below. When prompted by the system, use the bar code scanner to read the bar code at either location. It only needs to be read once.



Activation Code Symbol

- Using sterile technique, peel back the lid from the Sterile Components outer tray.
- Using sterile technique, remove the inner tray from the outer tray and peel back the lid from the inner tray.

6. Inspect the parts to confirm that they are undamaged. If damage is detected, do not attempt to repair. Use the new *QuikCAS* Sterile Components for the procedure.
7. Remove the pre-assembled Advancer Unit from the tray. Orient the Advancer Unit so the drive cable (on the Advancer Unit) is pointing away from the intended introducer access site.
8. Position the Advancer Unit on the patient's leg to optimize horizontal placement.
9. Pull back the lever arm on the Advancer Unit to put it in the UNLOCKED position.



10. Attach the Flexible Drive Cable to the Motor Assembly.

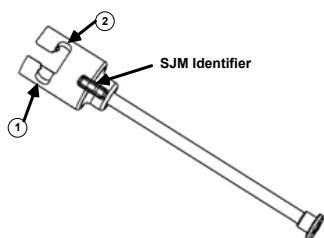
Caution: Sterile to non-sterile area connection required.

- a. Hand the end of the sterile Flexible Drive Cable to another person to connect the cable to the Motor Assembly (out of the sterile field).
 - b. Grasp the metal Flexible Drive Cable and insert it through the Luer-Lok fitting that is located on the Motor Assembly. Ensure the drive cable square profile aligns with the square profile of the coupler on the Motor Assembly shaft.
 - c. Tighten the Luer-Lok fitting to secure the connection.
11. Position the Motor Assembly near the foot of the bed such that the Flexible Drive Cable is in an "S" shape on the patient drape. Reduce the slack in the Flexible Drive Cable as much as possible without pulling against the Advancer Unit.
 12. Proceed to the Patient Setup procedure.

PATIENT SETUP

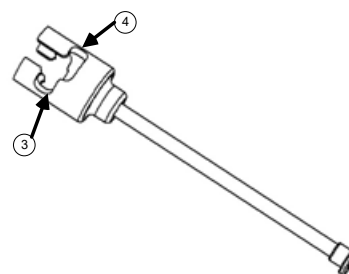
Note: Immobilize or restrain the patient's leg to avoid excess bending, which may interfere with *QuikCAS* performance and place excessive pressure on the vascular access site.

1. Prepare and advance the introducer in accordance with the manufacturer's Instructions for Use. Remove the compatible magnetic EP catheter from its sterile packaging.
2. Remove the Hemostasis Adapter with Insertion Tool from the sterile tray. The Hemostasis Adapter is designed for use with six different commercially available introducer sheaths. Use slot 1 for the St. Jude Medical™ Fast-Cath™ 8.5F Hemostasis Introducer 12cm or the St. Jude Medical™ Fast-Cath™ 8.5F Transseptal Guiding Introducer 61cm, and slot 2 for the St. Jude Medical™ Swartz™ SL0 8.5F Braided Transseptal Guiding Introducer or the St. Jude Medical™ Agilis™ NxT 8.5F Steerable Introducer Small Curl.



1. St. Jude Medical™ Fast Cath™ 8.5F Guiding Introducer
St. Jude Medical™ Fast Cath™ 8.5F Hemostasis Introducer
2. St. Jude Medical™ Swartz™ 8.5F Guiding Introducer
St. Jude Medical™ Agilis™ NxT 8.5F Guiding Introducer

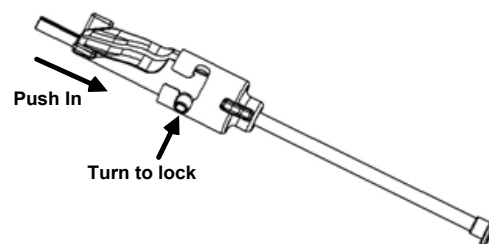
Use slot 3 for the Biosense Webster MOBICATH™ Bi-Directional Guiding Sheath Small-Curve and slot 4 for the Biosense Webster Preface® 8F Guiding Sheath.



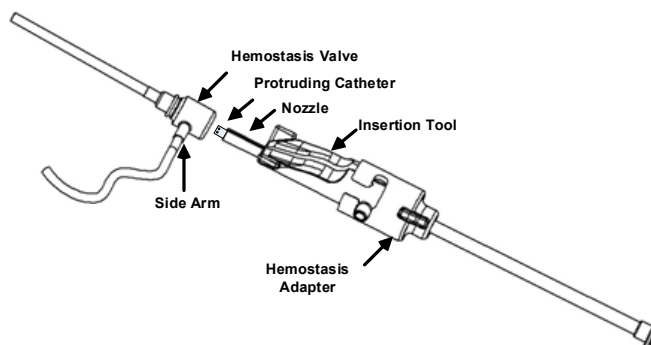
3. Biosense Webster MOBICATH™ Guiding Sheath

4. Biosense Webster Preface® 8F Guiding Sheath

3. Ensure the Insertion Tool is locked into slot 1 on the Hemostasis Adapter. If it is not locked into slot 1, push the Insertion Tool into the Hemostasis adapter and then turn to lock.



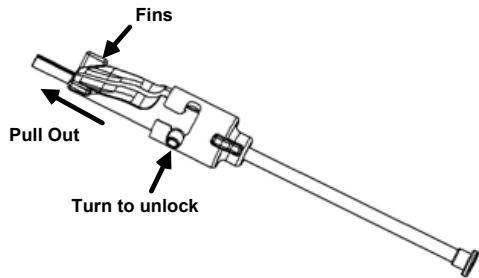
4. Prepare the compatible magnetic EP catheter in accordance with the manufacturer's Instructions for Use.
5. Attach a syringe to the sidearm of the hemostasis introducer.
6. Insert and slowly advance the tip of the compatible magnetic EP catheter through the Hemostasis Adapter and Insertion Tool until the tip is slightly protruding beyond the end of the Insertion Tool's nozzle.
7. Advance both the tip of the Insertion Tool nozzle and the EP catheter tip **simultaneously** into the hemostasis introducer. Open up the hemostasis valve to allow the catheter to be advanced without resistance.
8. Once the hemostasis valve is open, continue advancing the flexible distal section of the catheter into the introducer and past the hemostasis valve.



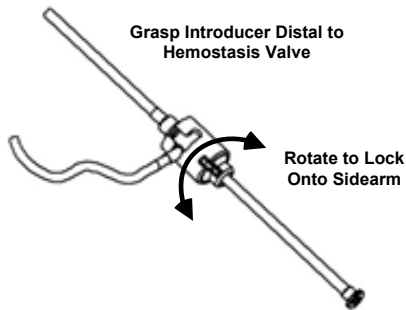
Note: Unlike conventional EP Catheters, compatible magnetic EP catheters feature a very flexible distal section. To prevent possible catheter damage, always use the Hemostasis Adapter to open the hemostasis valve when passing the flexible distal section of the catheter through the hemostasis valve.

9. Withdraw the Insertion Tool nozzle from the introducer.
10. Open up the sidearm valve and **SLOWLY** drawback blood into the syringe until all the air is out of the system.

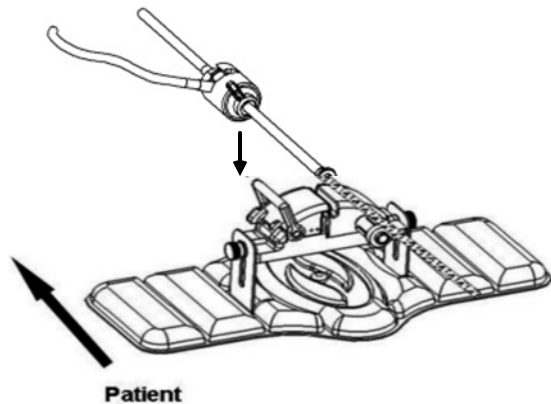
11. Close the sidearm valve and disconnect the syringe from the sidearm. Evacuate the syringe and fill the syringe with sterile saline. Remove all air from the saline-filled syringe and reattach the syringe to the sidearm. Open the sidearm, and flush the introducer.
12. Unlock the Insertion Tool and remove it from the Hemostasis Adapter. Gently push down on the fins of the Insertion Tool to open it up and remove it from around the catheter.



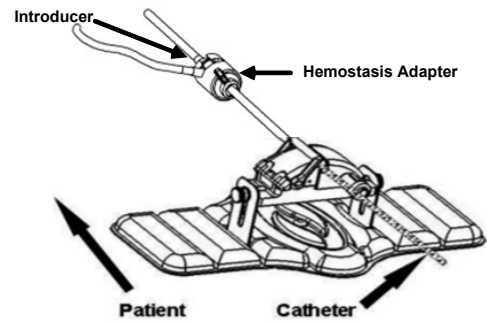
13. Grasp the introducer just distal to the hemostasis valve. Slide the Hemostasis Adapter over the hemostasis valve, and rotate into the correct slot to lock onto the sidearm. If there is resistance rotating and locking the sidearm in place, the components are not correctly aligned.



14. Lower the catheter and the Hemostasis Adapter into the Advancer Unit:
 - a. Seat the proximal end of the Hemostasis Adapter into the slot of the Advancer Unit. The slot is at the end of the catheter channel, on the opposite side of the drive cable.
 - b. Position the catheter into the bottom of the catheter channel. *If the catheter is not fully Seated in the channel, it may be pinched when the Advancer Unit is closed.*

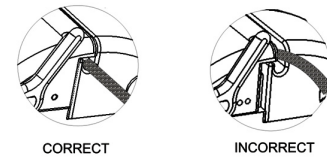


15. Close the Advancer Unit. *Verify the catheter is fully seated in the catheter channel and the lever is in the LOCKED position.*



16. Loosen the thumbscrews on the Advancer Unit to allow vertical adjustment while positioning onto the patient.
17. Adjust Advancer Unit position to allow the Hemostasis Adapter tubing to be as straight as possible. Retighten the thumbscrews.
18. Ensure the Flexible Drive Cable is in an "S" shape on the patient drape. Secure the Flexible Drive Cable to the drape with tape.
19. Move the lever arm to the UNLOCKED position on the Advancer Unit and manually advance the catheter until the tip has entered the heart.

Note: Do not use the QuikCAS device to advance the catheter tip through the introducer. Depending on the introducer type and distal curve, the force needed to advance the catheter tip through the introducer may be more than the QuikCAS unit is designed to deliver.
20. Move the lever arm to the "LOCKED" position on the Advancer Unit. Verify that the catheter is fully seated in the catheter channel and the lever is in the LOCKED position. This connects the catheter to the Advancer Unit and enables The use of the QuikCAS. If the catheter is pinched in the Advancer Unit, move the lever to the UNLOCKED position. Position the catheter in the bottom of the catheter channel, and move the lever to the LOCKED position.



21. Proceed to the QuikCAS Operation procedure.

QUIKCAS OPERATION

Note: If the QuikCAS unit fails to operate correctly, refer to the Troubleshooting section.

1. The catheter may be advanced or retracted at the physician's direction through the User Interface. Refer to the *Cardiodrive* Installation, Operation, and Service Manual for complete instructions.
2. Aspirate and back flush the introducer during the EP procedure in accordance with the manufacturer's Instructions for Use.
3. Follow standard practice of using a continuous drip of anticoagulant fluid under pressure through the sidearm, in accordance with the introducer manufacturer's Instructions for Use.

DISPOSAL

- Contaminated product should be handled and disposed of as a Biohazardous Waste.

TROUBLESHOOTING

Note: If the QuikCAS device fails to operate correctly after following these procedures, refer to the *Cardiodrive* Installation, Operation, and Service Manual.

1. If the catheter ceases to advance or retract smoothly, check the following items.
 - a. Verify the catheter tip has not been retracted into the introducer distal curved section. If so, open the Advancer Unit and manually advance the catheter until the tip has entered the heart.

- b. Verify the Hemostasis Adapter and the catheter channel of the Advancer Unit are still aligned with the introducer. Loosen the thumbscrew and adjust as necessary.
 - c. Aspirate the introducer to remove fibrin buildup, in accordance with the introducer manufacturer's Instructions for Use.
 - d. Observe the inner drive shaft of the Flexible Drive Cable when an advance or retract is commanded. If the inner drive shaft is moving, go to the next step. If the inner drive shaft is not moving, refer to the *Cardiodrive* Installation, Operation, and Service Manual.
 - e. Move the lever to the "UNLOCKED" position on the Advancer Unit. Slowly rotate the shaft of the compatible magnetic EP catheter approximately 90 degrees. Close the Advancer Unit. If the catheter has slipped in the Advancer Unit, a "smooth" spot may be created on the catheter shaft. Rotating the catheter shaft will be necessary to avoid this "smooth" spot during the balance of the EP procedure.
2. If reading the activation barcode does not activate the system, check the following items.
 - a. Verify that the expiration date has not been exceeded. If the device has expired, replace the device with one that has not expired.
 - b. Verify that the device has not already been used. The device is intended for single use only.
 - c. Verify that the activation bar code has not been damaged. If it has been damaged, type in the numerical code where prompted by the system.
 - d. If the previous items have been verified, then call Stereotaxis for further assistance.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

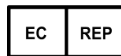
STEREOTAXIS MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH REGARD TO THE DEVICE DESCRIBED IN THIS DOCUMENT. STEREOTAXIS DISCLAIMS ALL REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE, TITLE OR NON-INFRINGEMENT,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

STEREOTAXIS, INC. SHALL NOT BE LIABLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OTHER THAN AS EXPRESSLY PROVIDED BY SPECIFIC LAW.

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



Manufactured for:
Stereotaxis, Inc.
4320 Forest Park Ave. Suite 100
St. Louis, MO 63108
www.stereotaxis.com
1-314-678-6100



MDSS (Medical Device Safety Service GmbH)
Schiffgraben 41
30175 Hannover, Germany

CE 2797

©Stereotaxis, Inc. 2019