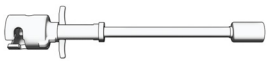
Hemostasis Adapter IV Spares Instructions for Use

REF 001-001114-1



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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.

℞ ONLY **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physian.

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DEVICE DESCRIPTION

Hemostasis Adapter IV works in conjunction with a pre-assembled advancer unit to create *QuikCAS*. *QuikCAS* is a part of the *Cardiodrive* automated Catheter Advancement System (CAS). *Cardiodrive* advances or retracts a compatible magnetic electrophysiology (EP) catheter while used in conjunction with a Stereotaxis Robotic Magnetic Navigation System (RMNS).

STERILE DISPOSABLE COMPONENTS

Hemostasis Adapter
Pre-Assembled Advancer Unit (*not supplied in the Hemostasis Adapter Spares Pack*)

ADDITIONAL EQUIPMENT

The *Cardiodrive* hardware components and Stereotaxis RMNS should be used with *QuikCAS*. For more information, refer to the *Cardiodrive* and RMNS user guides.

HOW SUPPLIED

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 labeling is illegible.

HANDLING AND STORAGE

Store in a dry and dark location.

COMPATIBLE DEVICES

The following compatible devices are specified for *QuikCAS* operation, and sold separately. Compatible **magnetic EP catheters** include **Navistar RMT** (7F), **Navistar RMT Thermocool** (8F), **Celsius RMT** (7F), **Celsius RMT Thermocool** (8F), and **MedFast MagnoFlush** (8F). Compatible **introducer sheaths** or **guiding sheaths** include **Abbott Fast-Cath™ 8.5F Hemostasis** Introducer, **Abbott Fast-Cath™ 8.5F Transseptal** Guiding Introducer, **Abbott Swartz™ 8.5F Braided Transseptal** Guiding Introducer, **Abbott Agilis™ NxT 8.5F** Steerable Introducer, **Biosense Webster Preface** Guiding Sheath, **Biosense Webster MOBICATH® 8.5F** Guiding Sheath Small Curve.

INDICATIONS

Indicationa can be found in the *Cardiodrive* user guide.

WARNINGS

• The QuikCAS sterile components are intended for **SINGLE USE ONLY**. Do not reuse, reprocess, or resterilize. Reuse can compromise device characteristics and may result in patient infection. • The components of QuikCAS are sterile and should be handled under sterile conditions. Verify that the package integrity has been maintained so that sterility has not been compromised. • QuikCAS 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. • After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

Slot 1 Compatibility: Abbott Swartz™ 8.5F Braided Transseptal Guiding Introducer; Abbott Agilis™ NxT 8.5F Steerable Introducer
Slot 2 Compatibility: Abbott Fast-Cath™ 8.5F Hemostasis Introducer, Abbott Fast-Cath™ 8.5F Transseptal Guiding Introducer
Slot 3 Compatibility: Biosense Webster Preface Guiding Sheath
Slot 4 Compatibility: Biosense Webster MOBICATH® 8.5F Guiding Sheath Small Curve

PATIENT SETUP

1. The Hemostasis Adapter is designed for use with different commercially available introducer sheaths. Prepare and advance the introducer in accordance with the manufacturer's Instructions For Use. (The following images detail the introducer sheaths and guiding sheaths and the appropriate slots.) 2. Remove the Hemostasis Adapter from the sterile tray. 3. Prepare the compatible magnetic EP catheter in accordance with the manufacturer's Instructions For Use. 4. Insert the magnetic EP catheter past the tip of the Hemostasis Adapter. 5. Insert the non flexible tip of the magnetic EP catheter into the hemostasis valve. 6. Position the Hemostasis Adapter so the compatible slot is available for easy introducer insertion. 7. Twist the introducer into the correct slot to lock the sidearm into the slot. If there is resistance, the components are not correctly aligned.

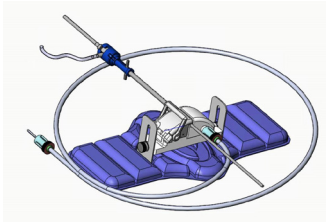
PRECAUTIONS

• QuikCAS 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. • 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 damaged equipment. • Do not use expired equipment.

PREPARATION FOR USE

1. Follow instructions in the Cardiodrive manual for setup of hardware components. 2. Remove the QuikCAS tray from the box. 3. When prompted by Navigant, use the bar code scanner to read the **Activation Code**. This is found near the ***bar code scanner symbol*** on the box label. 4. Using sterile technique, peel back the lid from the sterile tray, remove the inner tray from the outer tray, and peel back the lid from the inner tray. 5. Inspect the parts to confirm they are undamaged. If damaged, use a new QuikCAS for the procedure. 6. Remove the advancer unit from the tray. Orient the advancer unit so the Flexible Drive Cable is pointing away from the intended introducer access site. 7. Position the advancer unit on the patient's leg. 8. Pull back the lever arm on the advancer unit to put it in the UNLOCKED position. 9. Attach the Flexible Drive Cable to the motor assembly. a.) Hand the end of the sterile cable to personnel outside the sterile field. b.) Personnel must then insert the cable through the Luer-Lok fitting located on the Motor Assembly. Ensure the cable aligns with the square profile of the coupler on the Motor Assembly shaft. c.) Tighten the Luer-Lok fitting to secure the connection. 10. Position the Motor Assembly near the foot of the bed such that the cable is in an "S" shape on the patient drape. Reduce the slack in the cable as much as possible without pulling against the Advancer Unit. 11. Proceed to Patient Setup.

8. Move the Hemostasis Adapter handles all the way forwary. The front tube should be extended into the compatible introducer's hemostasis valve. The hemostasis valve is now open. 9. Slowly advance the compatible magnetic EP catheter through the Hemostasis Adapter until the flexible section is completely inside the introducer. If there is resistance, ensure the handles are pushed all the way forward. 10. Grab the handles of the Hemostasis Adapter and move them backward / down until the cap on the end of the Hemostasis Adapter protrudes out of the adapter. 11. Attach a syringe to the sidearm of the introducer. 12. Open up the sidearm valve and SLOWLY drawback blood into the syringe until all the air is out of the system. 13. Close the sidearam 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. 14. Using the distal end of the catheter, continue to feed it through the introducer until the catheter tip is slightly protruding beyond the end of the introducer. 15. The cap should be protruding out of the hemostasis adapter and ready to be seated into the Advancer unit. If the cap is not protruding, pull the Hemostasis Adapter handles all the way back. 16. 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 17. Close the Advancer Unit. Verify the catheter is fully seated in the catheter channel and the level is in the LOCKED position. 18. Loosen the thumbscrews on the Advancer Unit to allow vertical adjustment while positioning onto the patient. 19. Adjust Advancer Unit position to allow the Hemostasis Adapter tubing to be as straight as possible. Retighten the thumbscrews. 20. Ensure the Flexible Drive Cable is in an "S" shape on the patient drape. Secure the cable to the drape with tape. 21. If the catheter needs to be advanced further to reach the heart, move the lever arm to the UNLOCKED position on the Advancer Unit and manually advance the catheter until the tip has entered the heart. 22. Move the lever arm to the LOCKED position on the Advancer Unit. Verify the catheter 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. Ensure the catheter is not pinched in the Advancer Unit. 23. Proceed to the QuikCAS Operation.



QUIKCAS OPERATION

1. With direction from the physician, the catheter may be advanced or retracted. Refer to the Cardiodrive User Guide for instruction of the entire system. 2. Aspirat 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 introducer's sidearm, in accordance with the manufacturer's Instructions for Use.

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.