VersaCross™ RF Transseptal Solution

Full platform of tools to personalize your solution

Personalize your solution

1. Choose your VersaCross™ RF Wire

   **VersaCross™ RF Wire**
   - RF Wire length: 160 cm, 230 cm
   - Wire diameter: 0.055" (J-tip), 0.094" (Pigtail)

2. Choose your VersaCross™ Sheath to complete your solution

   **VersaCross™ Transseptal Sheath**
   - Sheath usable length: 62 cm, 81 cm
   - Dilator usable length: 62 cm, 81 cm

3. Select the VersaCross™ RF Wire and Connector Cable

   **VersaCross™ RF Wire**
   - RF Wire length: 160 cm, 230 cm
   - Wire diameter: 0.055" (J-tip), 0.094" (Pigtail)

   **Connector Cable**
   - Cable length: 5.3 m (17 ft)
   - Connectors: 8-pin, 9-pin


dilator/sheath

Position on fossa

Confirm correct position

Transseptal access

Insert needle

Remove needle to reposition

Insert guidewire & sheath

Remove guidewire

Retract system to reposition

Deliver therapy device

Avoid carelessness

• Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.

Avoid injury

• Patient or operator injury can result from improper handling of the VersaCross™ RF Wire and/or DIP electrode, or if the patient should not be allowed to come in contact with ground metal surfaces. • If using electroanatomical mapping systems, ensure that the patient is not in contact with the ground metal surfaces of the electroanatomical mapping system. • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power delivery. • The VersaCross™ RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.

Avoid microbubble formation

• Microbubble formation can result in electrocution of the patient and/or operator. • Do not use the VersaCross™ RF Wire with electrocautery or other cautery devices.

Avoid reuse

• The VersaCross™ RF Wire and Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Transseptal Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • Do not attempt direct patient use only. Do not attempt to sterilize and reuse the VersaCross™ Transseptal Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • Do not attempt direct

Transport or storage

• The VersaCross™ RF Wire and Connector Cable are rigid and are intended for use in the sterile field. • Do not transport or store the VersaCross™ RF Wire and Connector Cable in an environment with a relative humidity greater than 70%.

Recommended practices

• The VersaCross™ RF Wire and Connector Cable are compatible with all makes and models of electroanatomical mapping systems. • The use of electroanatomical mapping systems is recommended.

Safety studies

• The safety of the VersaCross™ RF Wire and Connector Cable has been evaluated in a series of clinical studies. • The results of these studies have demonstrated that the VersaCross™ RF Wire and Connector Cable are safe and effective for use in the ablation of atrial fibrillation.

Patient selection

• The VersaCross™ RF Wire and Connector Cable are intended for use in patients who are undergoing ablation of atrial fibrillation. • The use of the VersaCross™ RF Wire and Connector Cable in patients with other cardiac arrhythmias is not recommended.

Troubleshooting

• If problems are encountered during the use of the VersaCross™ RF Wire and Connector Cable, contact the manufacturer for assistance.

References


For more information, please contact:

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Baylis Medical Company Inc.
the only EXCHANGELESS® solution for access-to-delivery of left heart therapy devices

ELIMINATE EXCHANGES
Left heart access using a SINGLE SOLUTION from start to finish

Rewire and drop down to optimize transseptal location WITHOUT THE HASSLE of exchanging a needle

ACCES WITH PRECISION
PRECISION RF PUNCTURE TECHNOLOGY to optimize transseptal location for any anatomy

VERSATILITY

VERSATILITY

TRUform™ SHAPABLE TECHNOLOGY
Shapeable dilator with true-to-form curve retention

Snap-fit to maintain hands-free sheath-dilator alignment

PRECISION RF PUNCTURE TECHNOLOGY

VERSATILITY

SECURE EFFORTLESS DELIVERY
Instantly gain and maintain access WITHOUT EXCHANGES

Sturdy 0.035" rail to deliver therapy devices with confidence

Flexible tip cushions against left atrial wall and reduces risk of perforation

Instantly gain and maintain access WITHOUT EXCHANGES

OMNIviz™ Technology
Know where you are at all times with VersaCross™ RF Transseptal Solution

RADIOPAQUE
Visualize your entire solution on fluoroscopy

ECHOGENIC
Reliably locate your devices on ultrasound to reduce reliance on fluoroscopy

POSITIONAL MARKERS
Visibly confirm position of RF tip within dilator

TRACKING
Track and mark RF tip position on your mapping system

VERSATILITY

VersaCross™ RF Wire can be used, without exchanges, as a guidewire, as a transseptal puncture device or as an exchange rail for delivering therapy sheaths.