The Revolution® ultrasound imaging catheter is intended for the intra-coronary ultrasound assessment of coronary lesions in patients, who are candidates for percutaneous transluminal coronary interventions (PTCIs) or surgical interventions.

APPLICATIONS:
- The Revolution ultrasound imaging system is designed for use in percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass procedures.
- It provides detailed images of the coronary artery walls, including visualization of plaque composition, calcification, and intimal hyperplasia.
- The catheter is ideal for guiding stent placement, assessing stent apposition and expansion, and monitoring drug-eluting stent (DES) deployment.
- It is also useful in the assessment of coronary artery disease in patients with complex lesions, including those with chronic total occlusions (CTOs).
- The Revolution catheter can be used during both diagnostic and interventional procedures to provide real-time imaging of the coronary artery.

TELESCOPING SECTION:
- The telescoping section allows the imaging core to be advanced and retracted from the catheter body, enabling optimal visualization of the coronary artery.
- It facilitates the precise positioning of the imaging core at the desired location for optimal lesion assessment.

INTEGRATION WITH THE INSTRUMENTATION:
- The Revolution catheter is compatible with most interventional cardiology imaging systems, including Doppler and intravascular ultrasound (IVUS) systems.
- It can be integrated seamlessly into the interventional workflow, allowing real-time imaging guidance during PTCA and stenting procedures.

UNIQUE FEATURES:
- The Revolution catheter is designed with a unique tip design that reduces the risk of embolization and microembolization during the imaging procedure.
- It incorporates a one-way valve that helps retain saline in the catheter during use, providing acoustic coupling for optimal imaging.
- The catheter design allows for easy manipulation and precise positioning within the coronary artery, facilitating accurate lesion assessment.

SAFETY PRECAUTIONS:
- Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier is breached, do not use the catheter.
- Use caution when removing the catheter over the guide wire from a stented vessel to minimize patient risk.
- Never advance or withdraw the imaging catheter without the imaging core assembly in the most distal position.
- Make sure the wire remains in the guide catheter of the Y-adapter assembly.

INSTRUCTIONS FOR USE:
- Connect the imaging catheter to the PIM, ensuring the proper end of the sheath is connected to the imaging system. Insert the cord
to the PIM cover, gently twisting the connector until it locks into place. To ensure the sheath has fully seated in the PIM, gently tug on
catheter before proceeding.

IN VITRO TEST RESULTS:
- The system was tested in vitro using a standard protocol at Volcano Corporation. The test results indicated that the system was
capable of providing accurate and reliable imaging data, meeting the requirements for clinical use.

Note: The information provided is intended for the intended audience and is subject to change without notice. Please refer to the latest product literature and instructions for use for the most current information.