Instructions for Use
Reprocessed NRG Transseptal Needle

Reprocessed Device for Single Use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Reprocessed NRG Transseptal Needle delivers radiofrequency (RF) power in a monopolar mode between its distal electrode and a commercially available Disposable Indifferent (Dispersive) patch (DIP) Electrode. The NRG Transseptal Needle is loaded through a Transseptal Sheath/Dilator set and is connected at its proximal end to the BMC Radiofrequency Puncture Generator via the BMC Connector Cable and, optionally, to an external pressure monitoring system via a luer connection.

The distal end of the needle contains a hole to facilitate injection of contrast solution and the monitoring of cardiac pressures. The active tip is specially shaped to be atraumatic to the cardiac tissue unless RF energy is applied.

Note: Detailed information concerning the BMC Radiofrequency Puncture Generator is contained in a separate manual that accompanies the Generator (entitled “BMC Radiofrequency Puncture Generator Instructions for Use”). Please refer to the applicable user manual for recommended settings for the compatible generators.

INDICATIONS FOR USE

The Reprocessed NRG Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS FOR USE

- The reprocessed NRG Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.
- The reprocessed NRG Transseptal Needle is contraindicated in patients who cannot be anticoagulated or infused with heparinized saline.

WARNINGS

- Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. It is recommended for the physician to determine, assess, and communicate to each individual patient all foreseeable risks.
- Do not alter this device in any way.
- Tactile feedback of reprocessed devices may vary during use.
- Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.
- The NRG Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

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- Note: Please refer to the applicable user manual for recommended settings for the compatible generators.
- The pressure transducer system used with the NRG Transseptal Needle must comply with the electrical safety requirements of IEC 60601. Failure to use compliant pressure transducers may result inpatient or operator injury.

PRECAUTIONS

- Do not attempt to use the NRG Transseptal Needle or ancillary equipment before thoroughly reading the accompanying Instructions for Use.
- Radiofrequency puncture procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered puncture in a fully equipped catheterization laboratory.
- Do not use the NRG Transseptal Needle after the “Use By” date indicated on the label.
- The NRG Transseptal Needle is intended for use with only those devices listed in section “Equipment Required”.
- Read and follow the manufacturer’s instructions for use of the Disposable Indifferent (Dispersive) Patch (DIP) electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements.
- Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance.
- In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application.
- Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Generator.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.
- Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle.
- Do not attempt to puncture until firm position of the active tip has been achieved against the atrial septum.
- It is not recommended to exceed five (5) radiofrequency power applications per needle.
- Do not bend the Reprocessed NRG Transseptal Needle. Excessive bending or kinking of the needle shaft may damage the integrity of the needle and may cause patient injury. Care must be taken when handling the needle.
- The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the needle and DIP electrode, particularly when operating the device.
- During power delivery, the patient should not be allowed to come in contact with ground metal surfaces.
- Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the tip of the needle against the atrial septum. Only increase the power if low power output persists.
- Ensure the distal tip is protruding the dilator/sheath assembly when visualizing electroanatomic mapping systems. Visualization of the distal tip of the Reprocessed NRG Transseptal Needle may be lost when retracted within the dilator/sheath assembly.

ADVERSE REACTIONS

Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: tamponade, vessel perforation, vessel spasm, hemorrhage, hematoma, pain and tenderness, thermal damage to tissue, sepsis/infection, atrial fibrillation, sustained arrhythmias, vascular thrombosis, allergic

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reaction to contrast medium, arteriovenous fistula, thromboembolic episodes, myocardial infarction, atrial flutter, perforation of the myocardium, pericardial effusion and ventricular tachycardia.

EQUIPMENT REQUIRED (Not Supplied by Innovative Health)

Intracardiac puncture procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access. Ancillary materials required to perform cardiac Puncture include:

- BMC Radiofrequency Puncture Generator
- Baylis Connector Cable (RFP-102 or RFP-103 (model dependent for NRG Transseptal Needle) for use with RFP-100 Generator, or RFX-BAY-TS for use with RFP-100A Generator).
- Transseptal Sheath/Dilator kit, such as the Baylis Medical Company TorFlex™ Transseptal Guiding Sheath.
- Disposable Indifferent (dispersive) Patch (DIP) electrode must meet or exceed IEC 60601-2-2 requirements for electrosurgical electrodes.
- DuoMode Cable for use with electroanatomic mapping systems

Please refer to applicable user manual to verify compatibility details for equipment above.

INSPECTION PRIOR TO USE

Prior to use of the Baylis Medical Radiofrequency Puncture System, the individual components including the BMC Radiofrequency Puncture Generator, NRG Transseptal Needle, and the BMC Connector Cable should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use defective equipment.

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- All instructions for equipment required should be carefully read, understood, and followed. Failure to do so may result in complications.
- Inspect the needle and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the needle is damaged (i.e. kinks and/or breaks) or if the package is compromised, do not use the needle. Return the needle to Innovative Health. **Do not attempt to resterilize**.
- Using proper sterile technique, remove the needle from its package and place it in a sterile work area.
- Thoroughly flush the NRG Transseptal Needle with a minimum of 10 units/ml of heparinized saline solution prior to use.
- A Transseptal Sheath and Dilator are usually inserted through the right femoral vein and are then advanced over a guidewire to be positioned into the superior vena cava (SVC) under fluoroscopic guidance. The Baylis Medical TorFlex Transseptal Guiding Sheath is recommended for this purpose.
- Insert the NRG Transseptal Needle through the sheath/dilator set until the tip of the needle is just within the dilator. Ensure the needle is free to twist and/or rotate without resistance, as it is advanced to this position.
- If using a pressure monitoring system, connect the NRG Transseptal Needle to it by joining its luer connector on the handle to a luer lock and rotating the connector to ensure a secure connection.
- Connect the NRG Transseptal Needle to the BMC Connector Cable. Make sure that the Connector Cable is plugged into the appropriate port on the BMC Radiofrequency Puncture Generator. Be sure to carefully follow the Instructions for Use provided with the Generator and Cable.
- Position the tip of the transseptal assembly (NRG Transseptal needle/sheath/dilator) in the right atrium against the fossa ovalis under appropriate imaging guidance including but not limited to

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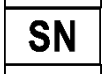
fluoroscopic, echocardiographic and/or electroanatomic mapping guidance using standard technique.

- If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with echocardiographic imaging or another imaging modality.
- Deliver radiofrequency power via the BMC Radiofrequency Puncture Generator and advance the NRG Transseptal Needle through the septum into the left atrium. Please refer to the Generator Instructions for Use before using the Generator.
- **NOTE: It is recommended that the user use the least amount of energy to achieve the desired puncture.** For RFP-100: A power setting of 10 Watts has been experimentally determined to be sufficient for successful puncture. For RFP-100A: An initial RF setting between one (1) second on "PULSE" mode to two (2) seconds on "CONSTANT" mode has been shown to be sufficient for successful puncture. **Please refer to the applicable user manual for recommended settings for the compatible generators.**
- Radiofrequency power delivery can be terminated by pressing the RF ON/OFF button on the Generator if the timer has not expired.
- Entry into the left atrium can be confirmed using appropriate imaging guidance. Further confirmation can be obtained by either observing a left atrial pressure tracing, by injecting a small amount of contrast media through the needle, or by aspiration of blood.
- If septal puncture is not successful after five (5) radiofrequency power applications, it is advised that the user proceed with an alternate method for the procedure.
- Once successful puncture into the left atrium is confirmed, the NRG Transseptal Needle may be carefully advanced without any radiofrequency power.
- The transseptal dilator can be advanced over the needle to enlarge the puncture.
- Remove the NRG Transseptal Needle slowly.

Explanation of Symbols

	Federal Law in the USA restricts this device to sale by or on the order of a physician
	Sterilized by Ethylene Oxide Gas
	Catalog Number
	Serial Number
	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Keep Product Dry
	Keep Away from Sunlight
	Do Not Use if Package is Damaged
	Non-pyrogenic
	Manufacturer

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with Ethylene Oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

NRG and TorFlex are trademarks of Baylis Medical Company, Inc.

Please refer to www.innovative-health.com for product warranty.