Vascular Access Needle Guide

Instructions For Use

Contents:
1 Single Use Sterile Ark Device (models indicated below)

- ARK-N5MM
- ARK-N6MM
- ARK-N7MM
- ARK-N8MM

This Page Intentionally Left Blank

INTRODUCTION

The Ark is a device implanted in the extravascular soft tissues around an access vein to improve vascular access. Although this device is still in its investigational phase, it has been designed to provide repeatable and reliable vascular access by giving the cannulator a target for needle insertion. The device is an accessory to allow the needle to accurately enter the targeted vessel and is intended for chronic single patient use and may be used multiple times per week, as needed. The Ark has a porous top and bottom component made from titanium metal.
The Ark is available in 4 different models, designed to provide the surgeon with a range of inner channel diameters (5, 6, 7, and 8mm) to choose from based on the patient's anatomy and physiology. This range of sizes accommodates vessel depths of less than or equal to 15mm and vessel diameters of greater than or equal to 4mm.

These instructions contain important information for safe use of the product. Read the entire manual, including Contraindications, Warnings, and Possible Complications before using this product. Failure to properly follow Warnings, Cautions, and Instructions could result in serious injury to the patient and/or the user. This manual is supplemental to training.

INTENTED USE AND INDICATIONS FOR USE

The Ark is intended for use as a vascular access device for hemodialysis.
The Ark is indicated for use as an access device accessory on arteriovenous fistulas (AVFs) to facilitate cannulation for hemodialysis procedures.

PRESCRIPTION USE ONLY

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practioner.

CONTRAINDICATIONS

1. There is known or suspected allergy to titanium, aluminum, or vanadium. Where material sensitivity is suspected, standard appropriate tests should be made prior to implantation. In particular, the surgeon should be aware that implants are made from a material containing titanium, aluminum, and vanadium and should use sound medical judgment if a titanium, aluminum, or vanadium allergy or hypersensitivity is suspected.
2. The patient has a topical or subcutaneous infection associated with the implantation site.
3. The patient has known or suspected systemic infection, bacteremia or septicemia.
4. Local tissue factors which will prevent proper device stabilization and/or access.
5. Patient has risk of skin erosion at the implantation site.

POTENTIAL ADVERSE EVENTS

Any serious incident related to the Ark should be reported to the manufacturer, Biotex, Inc., and the FDA.

DEFINITIONS

WARNINGS: Conditions that may cause injury to a patient, user or operator if instructions are not followed.
CAUTIONS: Conditions that may cause damage to the device or cause inaccurate function.

WARNINGS

1. Only authorized and trained medical professionals who have read these instructions for use and been trained can implant and use the Voyager device.
2. The Ark should be used only by authorized medical professionals who have read and understand the instructions for use. Surgeons and dialysis technicians shall undergo training prior to implantation and use of the device.
3. The Ark is supplied for single patient use only. DO NOT reuse or resterilize. Re-use of the Ark device may

result in infection or contamination of the patient or surgical site.
4. If the device is explanted, it is a potential biohazard. Handle in accordance with accepted medical practice and applicable local and federal laws and regulations.
5. The Ark is supplied sterile and should NOT be used if the packaging is opened or damaged.
6. The Ark should not be modified in any way by the user.

Post implantation care and cannulation

1. Surgical wound should be treated by following accepted clinical practices to minimize risk of infection.
2. Cannulation of the access site should be a minimum of 6 weeks after device implantation.
3. The "Double Skin Preparation," technique as outlined in the Cannulation section herein, is required for the Ark Guided Cannulation technique.
4. Care should be taken to ensure the Ark is not subjected to excessive load or manipulation. Patients should notify their healthcare provider if an excessive load or manipulation is applied to the device.
5. Instruct patients to not tamper or play with the implanted device, surgical wound or cannulation scab.
6. If signs of infection exist, discontinue needle insertions until resolved. Begin appropriate medical intervention immediately.
7. If scarring or hardening of tissue around the Ark should occur and leads to an inability to cannulate with blunt or sharp needles, refer the patient to his/her physician for further evaluation.
8. Choose a needle length based on vessel depth, diameter and cannulation angle such that the needle hub does not enter the insertion site and the needle does not puncture the back wall of the vessel.
9. Select an appropriate cannulation angle based upon the depth of the fistula.
10. Confirm correct positioning of the needle through the Ark by aspiration of blood before initiation of therapy. If there is doubt regarding proper needle placement or access through the device, reposition or remove the needle. Consider performing an ultrasound imaging procedure to aid in placement.
11. Hemostasis clamps are not recommended to be used with the Ark due to the risk of skin injury.
12. If access site performance changes, the patient's healthcare provider should be contacted immediately.

POSSIBLE COMPLICATIONS

Risks that are possible to any operation include infection, bleeding, the risks associated with having an anesthetic (such as an allergic reaction) and death. The use of the Ark provides an important means of vascular access for patients. However, the potential exists for serious complications, including the following:

- Seroma
- Foreign body reaction or rejection
- Vessel trauma
- Device migration, potentially requiring device intervention, explant or replacement
- Wound dehiscence
- Edema
- Infiltration
- Sepsis
- Vessel erosion
- Skin erosion at the access site
- Infection (local and systemic)
- Partial or full occlusion of vessel
- Site pain
- Implant technical failure, potentially requiring device intervention, explant or replacement.
- Aneurysm
- Abnormal healing/skin erosion
- Bleeding
- Hematoma
- Thromboembolism
- Inability to cannulate
- Inflammation, necrosis, or scarring of skin over implant area
- Risks normally associated with local and general anesthesia, surgery and post-operative recovery

CLINICAL EXPERIENCE OF THE ARK FROM THE ACT TRIAL

1. The Voyager Ark was evaluated in a first in human, early feasibility, interventional, prospective, single arm, single site investigation to demonstrate safety and efficacy of the Ark in achieving targeted arteriovenous

fistula (AVF) access for hemodialysis. The investigation had two cohorts: Cohort 1 included patients with previous AVFs and Cohort 2 included patients who underwent Ark implantation at the time of AVF creation. A total of 13 subjects were treated with a total of 25 Ark devices implanted. Subjects returned for follow-up visits at 4 to 6 weeks post-operation to assess healing at the implant site and evaluate readiness for cannulation. Additional visits at 3 and 6 months were conducted to monitor routine hemodialysis.

2. The Intention-to-Treat (ITT) analysis, encompassed all 13 subjects who were treated with the Ark. In this analysis, 11 out of 13 (85%) patients experienced successful primary and secondary effectiveness outcomes in terms of initial cannulation at 6 weeks and ongoing cannulation for 6 months through the Ark. The 2 subjects not included in these outcomes were prematurely withdrawn from the investigation after device implantation due to reasons unrelated to the Ark.
3. The Per-Protocol (PP) analysis included 11 treated subjects who had undergone at least 1 cannulation attempt through the Ark and completed the investigation per the protocol requirements. All 11 subjects (100%) demonstrated successful outcomes for both the primary and secondary efficacy measures concerning the initial and ongoing cannulation through the Ark.
4. The safety assessment yielded promising results, among the 10 adverse events recorded, all were deemed unrelated to the Ark. Out of the total, 3 were attributed to subjects' pre-existing baseline conditions/prior diagnoses, and 7 were unrelated serious adverse events. Furthermore, there were 0 device deficiencies/ malfunctions, 0 unanticipated problems, 0 unanticipated adverse device effects, and 0 deaths reported during the clinical investigation.

INSTRUCTIONS FOR USE - ARK IMPLANTATION

Choosing the Ark Sizing

1. To assist in determining if the vessel is an appropriate size for the Ark, use ultrasound to measure the vessel diameter and depth at the selected implant site.
2. The Ark is available in 4 different models, designed to provide the surgeon with a range of inner channel diameters for them to choose from based on the patient's anatomy and physiology. Ideally, the Ark inner channel diameter is slightly larger than the patient's vessel so the vessel wall has a comfortable amount of contact for tissue integration to develop. If the Ark inner channel is smaller than the patient's vessel at the implant site, it may constrict the vessel. However, too much room between the vessel and the Ark inner channel may lead to an increased risk of a seroma developing in the empty space if the patient's vessel does not dilate quickly enough to fill the Ark. The rate of tissue integration and vessel dilation for each patient cannot be predicted based on initial vessel diameter alone, so the prescribing surgeon should consider the patient's medical history as well as their present state of anatomy/physiology when deciding the appropriate Ark model for implantation.
3. The implant size should be re-evaluated during the implantation procedure before suturing to ensure the best fit.

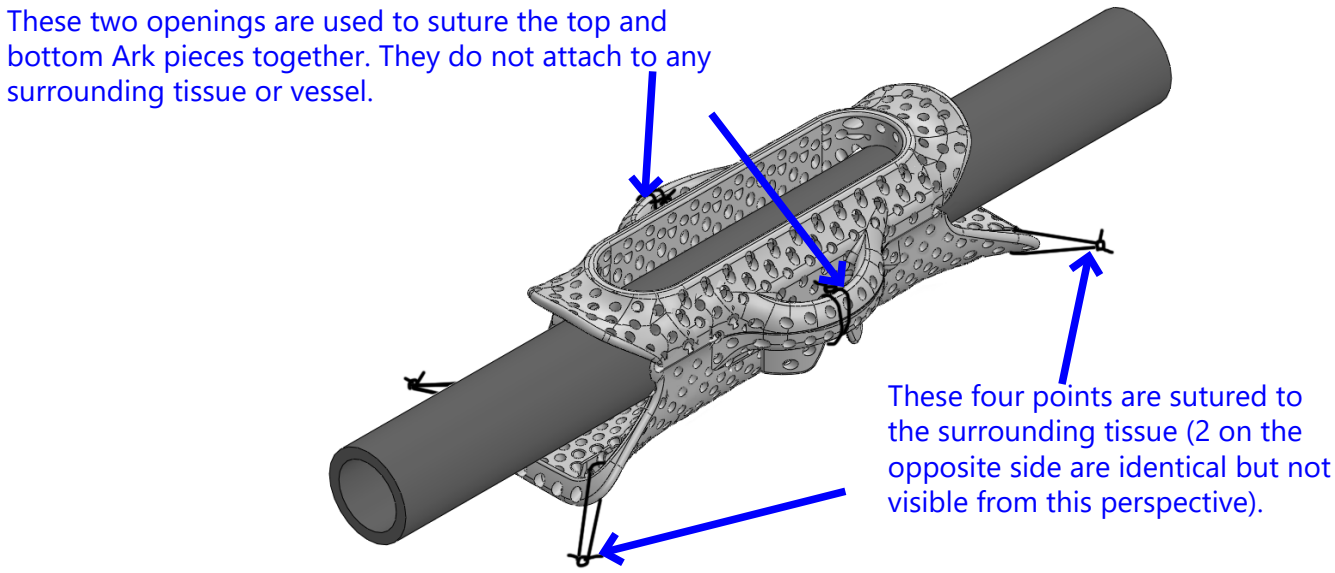
Ark Implantation

WARNING: Follow Universal Precautions and Aseptic Technique

1. Using ultrasound, select the site with a vessel diameter ≥ 4mm and the depth is ≤ 15mm. The vessel length for Ark placement should be approximately 40 to 60mm. If two Arks are placed, at least 20mm of separation between each Ark is recommended. If AVF is present, the arterial Ark should be at least 20 to 30mm distal to the AVF anastomosis. Mark incision site 20mm lateral or medial to the vessel so the incision site will not be over the Access Window of the Ark (cannulation zone).
   CAUTION: Ark separation between multiple implanted Arks is recommended to prevent pinch points between the Arks and subsequent vessel impingement.
2. Perform adequate anesthesia.
3. Use standard surgical techniques to make an incision 20mm lateral or medial to the mapped vessel.
   CAUTION: Avoid incision line directly over the Access Window of the Ark.
4. Dissect tissue to expose 40-60mm of the vein around the Ark implant site (landing zone).
5. Measure the outer diameter of the vessel at the landing zone and re-evaluate the selected Ark for

implantation.
NOTE: Ensure the vessel has not constricted due to vasospasm before measuring.

6. Examine package carefully before opening to confirm its integrity and the expiration date.
   WARNING: Do not use if package is damaged or opened or if the "Use by date" has passed.
7. Open the device package and remove top and bottom components in a manner maintaining sterility of contents.
8. Implant Ark bottom component underneath targeted vessel. Confirm there is adequate spacing for the Ark landing zone and suture zones.
   WARNING: If the Ark is implanted around a vein which is too close to the skin surface, the patient may be at an increased risk of skin erosion over the Ark.
   CAUTION: Avoid twisting of the vein inside the Ark. If manipulating the vessel inside the Ark, the vessel must first be decompressed.
   WARNING: Placing the Ark too close to an AVF can lead to AVF anastomosis puncture during cannulation.
9. Place the Ark top component over the Ark bottom. Ensure the Access Window of the Ark (cannulation zone) is parallel to the skin surface.
   CAUTION: Decompress the vessel while the top is applied to prevent pinching the vessel side walls as the top is secured to the bottom piece.
10. Use the four suture points at the corners of the Ark bottom component to anchor the Ark to the adjacent soft tissue and fascia with absorbable sutures. Consider the position of the adjacent nerves and vessels and make adjustments as needed.
    WARNING: Be sure to not overtighten the sutures to avoid tissue necrosis.
    NOTE: The Ark must be secured using four point restraint to ensure the device remains immobilized to allow successful tissue integration.
    NOTE: Ark top can be removed while securing the bottom for easier access to the Ark bottom's four suture points.
11. Suture the top and bottom components together using absorbable sutures. Ensure the sutures are threaded through the openings in the wings (the opening on the left and right should each be threaded with its own suture). Choose sutures that lose the majority of their tensile strength within 4-6 weeks; otherwise, the Ark top and bottom may not be able to separate as the vessel inside dilates
    NOTE: Sutures are intended to degrade over time as the body's own tissue integrates within the Ark.



12. Test the Ark for palpability to ensure the proper sized device has been chosen and the Access Window is parallel to the skin surface. Known techniques may be used to improve palpability.

13. Ensure hemostasis prior to wound closure.
14. Pull the skin flap over the Ark and suture the area closed so that the suture line is away from the proposed skin cannulation site.
    CAUTION: Ensure device does not rotate and is parallel to the skin. Avoid twisting the vessel during Ark adjustment.
    CAUTION: Ensure there is not significant tension on the skin over the Ark.
15. Dress the incision per clinical facility protocol.
16. Notify the dialysis clinics of the Ark implantation and complete patient implant card, including product reference number and lot number.

Post Operative 2 Week and 6 Week Clinical Follow Up

17. Examine the implant site assessing for healing and any sign of infection.
18. Assess palpability of the Ark and thrill/bruit above and below the Ark to confirm blood flow in and out of the Ark.
19. Assess if a follow up ultrasound is required and determine if an angiogram or further intervention (i.e. angioplasty) is required.
    CAUTION: Allow 6 weeks of Ark healing prior to attempting angioplasty.
    CAUTION: Do not over dilate the Ark channel during angioplasty. Size angioplasty balloon appropriately.

INSTRUCTIONS FOR USE - ARK GUIDED CANNULATION

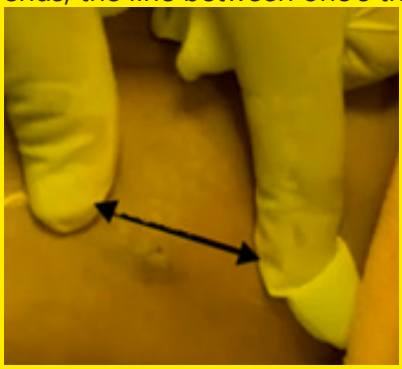
Pre-Dialysis Chart Review

1. Confirm the Ark has been implanted for at least 6 weeks and the medical director has approved cannulation.
   WARNING: Cannulation before tissue integration may lead to increased risk of bleeding.
2. Confirm patient identity, surgical record, and dialysis order from physician.
3. Review Ark implant card if available.

Ark Guided Cannulation

1. Ensure the patient has thoroughly washed his or her arm using facility protocol prior to initiating the cannulation procedure.
2. Perform a complete physical assessment of the vessel and cannulation site and document the findings.
   NOTE: Check Patient Implant Card for pictures of device.
3. Identify the Ark location, Access Window (cannulation site), and orientation by palpation and confirm cannulation direction.
   NOTE: An ultrasound imaging procedure can be performed to confirm or clarify Ark location, orientation or cannulation direction. The Ark is designed to separate as the access vessel matures and may feel different if the Ark top separates from the Ark bottom.

NOTE: A variety of techniques can be used to feel and identify the Ark such as pinching the ends, pinching the sides, or feeling for the access window with one's fingertips. When the Ark is pinched longways at the ends, the line between one's thumb and finger will follow the orientation of the access window.



4. Determine skin puncture site by palpating the Ark Access Window and evaluating cannulation direction and Ark orientation. Review medical director's orders and follow facility protocol to select cannulation technique, needle size and type. **NOTE:** It is recommended to use the Ark Cannulation technique when accessing the vessel. Ark Cannulation is a technique that involves rotation of the access site throughout the week using 1-2 cm separation distance between cannulation sites. To assist in identifying the segments for needle rotation, the Ark is provided with an optional Needle Rotation Accessory that creates a visual map of the Ark access window divided into three equal segments on the skin. See the Needle Rotation Accessory section for more details on how to use the device. The Ark also supports buttonhole cannulation per KDOQI guidelines. **NOTE:** The Ark does not preclude the access in other areas of the fistula that may be amenable to cannulation.
   NOTE: The target for vessel wall puncture is at the Ark Access Window.
5. Disinfect the cannulation site per facility protocol.
6. Apply tourniquet per facility protocol, if needed.
   NOTE: The tourniquet should be applied tight enough to permit engorgement of the vessel, but not too tight to result in pain or reduce blood flow to the limb.
   CAUTION: Avoid placing tourniquet over or around the Ark.
7. Pull skin taut and cannulate the Access Window using the appropriate angle of insertion.
8. A flashback of blood indicates the needle is in the access site. Lower the angle of insertion. Continue to advance the needle into the vessel until it is appropriately positioned within the vessel.
   CAUTION: The Ark bottom protects the back wall of the vessel from infiltration when cannulating; however, a needle advanced outside of the Ark may still result in back wall penetration. **NOTE:** If the backwall is hit or if one feels resistance during cannulation, slightly pull the needle back, lower the angle and advance the needle in line with the vein.
9. Check for adequate needle position and flush lines per facility guidelines.
   NOTE: If there is doubt regarding proper needle placement or access through the device, reposition or remove the needle. Consider performing an ultrasound imaging procedure to aid in placement.
   CAUTION: If you suspect the device is malpositioned and may impact access, contact the nephrologist or the patient's vascular surgeon to determine the appropriate therapy.
10. Secure the needle in place and proceed with the therapy per facility protocol. **NOTE:** For additional guidance on cannulating through the Ark, refer to the cannulation training video using the following QR code.

Post-Dialysis Needle Removal Procedure

1. At the completion of the therapy, withdraw the needle at the same angle as it was secured and immediately apply pressure with two fingers until the bleeding stops per facility protocol.
   NOTE: Hemostasis is best achieved by holding pressure with two fingers at the cannulation site.
   WARNING: 1) Do not apply pressure to the site until the needle is removed from the skin as vessel damage may occur. 2) Hemostasis clamps are not recommended to be used with the Ark. 3) Do not apply excessive prolonged pressure to the tissues directly over the Ark to prevent tissue damage.
   NOTE: Pressure at needle skin entry site should be applied towards the opening of the Ark.
2. Apply the minimum amount of pressure necessary to stop blood flow.
   CAUTION: Avoid using excessive force or pressure.
   NOTE: If prolonged pressure is required for hemostasis, perform adequate breaks for capillary refill to avoid tissue damage.
3. Check for thrill/bruit and verify hemostasis.
4. Dress the cannulation site according to clinical facility protocol.
5. Place needles in a sharps container.

6. Dressing may be removed in 2-4 hours, or per clinical facility protocol.
7. Educate patient on access site care and maintenance.

Explant

1. Perform adequate anesthesia.
2. Create sterile field.
3. Surgically prep and drape implantation site per aseptic institution procedures.
4. Incise skin over the Ark.
5. Use blunt dissection to expose the Ark.
6. Cut and remove any suture remnants that did not already degrade.
7. Excise tissue adhered to the Ark.
8. Excise the Ark from vessel wall or resect the vessel section with the Ark. If the vessel section is resected, assess methods to maintain fistula patency, such as interposition graft or anastomosing the free ends of the vessel.
9. Close subcutaneous and skin tissues.
10. Dress wound per clinical facility protocol.
11. **WARNING:** Do not reuse.

Balloon Angioplasty Assisted Maturation

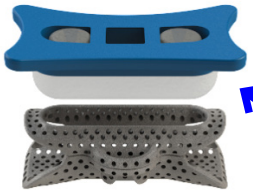
Note: The Ark device is an extravascular device and does not require additional anticoagulation outside of the physician's clinical management plan to maintain patency of the fistula. Physicians can proceed with standard of care procedures as related to thrombectomy for fistula management.

1. Place a balloon catheter (a small tube) into the narrowed vessel within Ark. Use fluoroscopy and contrast (X-ray dye) to help guide the catheter into the correct area for the angioplasty.
2. When the balloon is in the area of the blockage, inflate the balloon. Inflating the balloon stretches out the vessel improving blood flow through the area.
   CAUTION: Ensure balloon is not oversized in comparison to Ark diameter to avoid tearing the vessel between the top and bottom Ark components
3. Inject contrast after angioplasty and assess for extravasation of contrast in the tissues. If identified, prolonged angioplasty is recommended.
   CAUTION: The Ark device should not be used to achieve vascular access during interventional procedures, such as angioplasty or thrombectomy. Vascular access through the Ark for interventional procedures may negatively impact the cannulation zone/access window of the Ark.

ACCESSORY DEVICES

The needle rotation accessory and compression aid are optional accessory tools designed to assist with Ark Cannulation through the Ark and achieving post dialysis hemostasis.

Impression component. Ridged portion presses into the skin to leave indentions that mark cannulation areas.

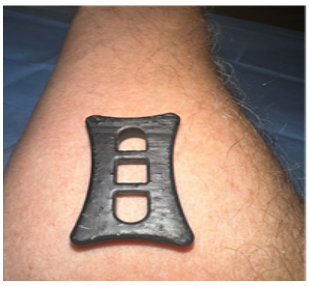
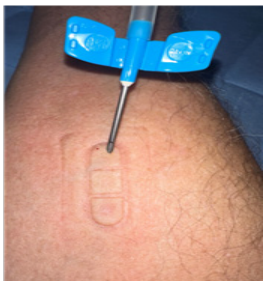


Compression component. Silicone piece attaches to the impression component and fits into the Ark access window.

Needle Rotation Accessory

1. Identify the Ark location, Access Window (cannulation site), and orientation by palpation and confirmation of cannulation direction.
2. Align the ridged oval portion of the impression component with the access window of the Ark.
3. Firmly press the device into the skin and hold for 10-15 seconds. Upon removing the device, there will be three sections impressed into the skin that align with the access window of the Ark.
4. Prepare the access site for cannulation per the Ark Guided Cannulation Section. Use the sectioned off

impressions of the skin to help identify the segment of the vessel within the Ark to be cannulated. To help prevent area puncture, rotate the access segment that is cannulated throughout the week. **WARNING:** The needle rotation accessory is NOT supplied sterile. Disinfect the cannulation site per facility guidelines prior to cannulation through the Ark.

Compression Aid

1. The compression aid is designed to assist with holding pressure over the cannulation site after completion of dialysis through the Ark. Prior to use, place the silicone cap over the ridged end of the needle rotation accessory.
2. After the needle is withdrawn upon completion of a dialysis session, apply gauze to the cannulation site per facility guidelines.
3. Align the silicone cap over the Ark cannulation window. Hold pressure over the access until the bleeding stops per facility guidelines. **WARNING:** The compression aid is not supplied sterile. Do not place the device directly over an open wound.

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing, MRI simulations, and *in vivo* modeling demonstrated that every version of the **Ark Family** of implants is MR Conditional. A patient with **Ark** implants may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	***Condition***
Nominal Values of Static Magnetic Field (T)	1.5-T or 3.0-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (ie., Quadrature-Transmission, Quadrature Driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions.
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Carefully select pulse sequence parameters if the implant is located in the area of interest.

DISPOSAL

International and US regulations require controlled disposal of used and unused medical devices. Products

that are contaminated after use or that contain chemicals or elements which may present hazards to people or the environment must be disposed of in accordance with applicable government regulations per the hospital's Medical Waste Management Plan (MWMP).

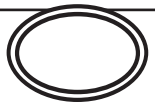
TECHNICAL SPECIFICATIONS

ENVIRONMENT SPECIFICATIONS	
Storage Environment	Temperature: -30°C to 60°C (-22°F to 140°F) Humidity: 0-85% RH, non-condensing

CUSTOMER SERVICE

All questions or concerns should be directed to a Biotex, Inc. representative.

SYMBOLS

	Catalogue number		Batch code
	Date of Manufacture		Manufacturer
	Sterilized using radiation		Use by Date
	Do not re-use		Distributor
	Packaging Unit		Keep dry
	Do not use if package is damaged		Non-pyrogenic
	Consult instructions for use		Federal Law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Single sterile barrier system		MR Conditional
	Patient Identification		Double sterile barrier system
	Date		Humidity Limit
	Temperature Limit		

Voyager Biomedical, Inc.
114 Holmes Rd.
Houston, TX 77045
voyagerbiomedical.com

Biotex, Inc.
114 Holmes Rd.
Houston, TX 77045
Ph: 713-741-0111