



# Ark

## VASCULAR ACCESS NEEDLE GUIDE



## PATIENT GUIDE

Everything you need to know about your  
Ark™ Vascular Access Needle Guide

CAUTION - Investigational Device. Limited by Federal  
(or United States) law to investigational use.



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# Ark

## Introduction

Your dialysis treatment is essential to your journey towards a stronger and healthier you. As part of your journey, your doctor has recommended using the Voyager Ark.

This guide has been designed to provide information about the investigational Ark device, how it works, what to expect, potential risks, and other important information.

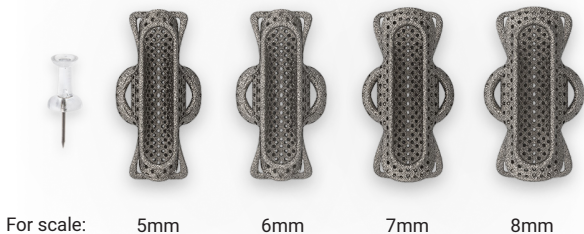
Please ask your healthcare provider if you have questions about the Ark. You can also review the FAQ section in this guide for more information.

# The Ark™

## Your Vascular Access Needle Guide

The investigational Ark device is a small metal device that was implanted by your doctor in the soft tissues around your vein. Although the Ark device is still in its investigation phase, it is being evaluated to see if it helps your healthcare provider in locating and inserting a needle into the target vein for dialysis.

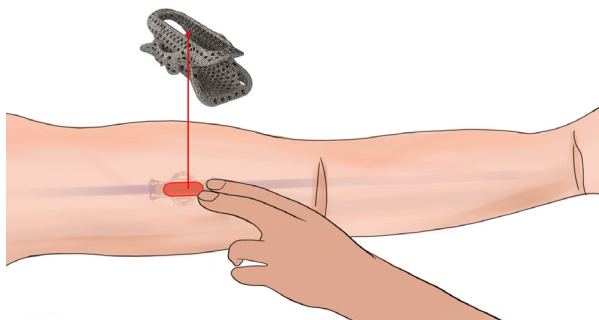
The Ark is also designed to enclose your vein for added protection from unintentional injuries, aiming to prevent damaging needle penetration that can cause blood loss through the back wall of your vein.



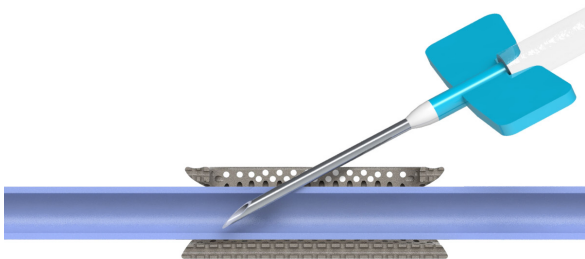
The Ark is made of titanium with a porous top and bottom and comes in four different models. Your doctor will tell you what size has been implanted in you. Your doctor will also determine when your Ark is ready for use, which may be in as little as six weeks.

## How the Ark™ Works

The top and bottom pieces of the Ark are connected through the wings. Its rough and porous structure allows the surrounding tissue to attach itself to the device.



When a needle needs to be inserted into your access vein, your healthcare provider will locate the vein by feeling the ridge of the Ark to identify where to insert the needle safely.



## Why You'll Love Your Ark™

- ▶ Going through hemodialysis is not easy, but with your Ark, you may have a better experience during treatment.
- ▶ Although the Ark is still in its investigation phase, it is being evaluated as a target that your healthcare provider will palpate when locating the right vein to insert the needle.
- ▶ Your treatment may be more comfortable and may be completed in less time.



## What You Should Expect

Your Ark should be ready for needle insertions six weeks after the implant, depending on your doctor's recommendations.

Your healthcare provider will give you a packet (Ark Patient Guide Kit) to ensure you have the essential information, including your implant card and accessories.

Carry your Ark Patient Guide Kit and accessories, as needed, when you go for hemodialysis treatment.

Show your healthcare provider your Implant Card before your hemodialysis treatment to help them correctly identify your Ark implant.

If it's your first time using the Ark, ask your healthcare provider what to expect when the needle is put into and taken out of the device.



## When to Call Your Doctor

Watch for possible complications after your Ark implantation and Ark use during hemodialysis. Risks associated with the device and procedure include injury to the blood vessel, seroma, swelling, infection, difficulties accessing the site, or adverse reaction to anesthesia or medication. Below are some of the events and symptoms to monitor:

- ▶ You see signs of skin erosion or irritation around the implant area.
- ▶ The implant area is swollen, sore, crusty, red, or shows discoloration.
- ▶ You feel pain in the implant area.
- ▶ The implant area is bleeding.
- ▶ You have a fever.
- ▶ You experience chills.
- ▶ You feel nauseous.

Tell your healthcare provider immediately if you experience any of the above conditions.

# Don't Leave Home Without Your Card

What you need to know about your Voyager Ark Implant Card

**voyager** **Ark**  
Vascular Access Needle Guide

1 Patient Name

2 Implant Date

3 Provider Details

4 voyagerbiomedical.com

1. Patient name

4. Voyager Website

2. Implant date

3. Provider information

5 MR Conditional: 1.5 T or 3.0 T  
Max Spatial Gradient Field  
of 4,000 G/cm  
Whole-body averaged SAR, 2-W/kg

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

Voyager Biomedical  
114 Holmes Rd.  
Houston, Texas 77045  
voyagerbiomedical.com

7 403-016-2003v4

**Please complete or affix stickers  
supplied with packaging.**

Upper 8 **REF** \_\_\_\_\_

Lower \_\_\_\_\_

For Push 9 **LOT** \_\_\_\_\_

For Pull \_\_\_\_\_

Upper **REF** \_\_\_\_\_

Lower \_\_\_\_\_

For Push **LOT** \_\_\_\_\_

For Pull \_\_\_\_\_

5. MRI disclaimer

8. Reference # indicates  
your device model and size

6. Manufacturer information

7. Scan to access detailed  
Instructions For Use

9. Lot # specifies your  
device manufacturing batch

## **Your Questions Answered**

### **Q: Who can access the Voyager Ark?**

A: Only authorized and trained personnel can implant and access the Voyager device, including your doctor, nurse, and dialysis technician.

### **Q: How soon can my doctor or nurse access the Ark after my implant?**

A: The Voyager Ark is ready for access in as little as six weeks after the implant, depending on your doctor's recommendations.

### **Q: What should I do if the Ark rotates?**

A: Report it to your healthcare provider to ensure they know how to access your Ark correctly or take the necessary steps to resolve the issue if your Ark becomes inaccessible.

### **Q: Can the Ark be removed?**

A: Although the device is still in its investigation phase, the Ark is intended for use as a permanent implant. However, it can be surgically removed upon your doctor's recommendation.

**WARNING:** Due to tissue ingrowth into the Ark, removal of the Ark will require the vein segment inside the Ark to be removed and either surgically repaired or replaced with a graft. If these procedures are not possible, removal of the Ark could result in loss of the fistula.

### **Q: How do I care for my Ark?**

A: Follow your healthcare provider's advice on how to care for your Ark after the implant.

**CAUTION:** Ensure you do not tamper or play with your implanted device, surgical wound, and scabs from the surgery.

**CAUTION:** Do not play with scabs from needle insertions into the Ark during and after your hemodialysis.

**CAUTION:** Always keep the implant site clean.

**CAUTION:** Avoid putting pressure on or inflicting trauma to the implanted area, such as hitting or aggressively rubbing or scratching your skin.

**CAUTION:** Do not carry heavy items such as big purses or shopping bags with your arm where the Ark has been implanted.

**CAUTION:** The Ark is designed for hemodialysis use only. Do not use it to administer medication, illegal drugs, or blood draws.

**CAUTION:** Do not use your arm with the Ark implant when checking your blood pressure. However, if you don't have a choice, do not put the blood pressure cuff on your Ark implant.

**Q: After my Ark implant, can I still get an MRI?**

A: The Ark device is considered MR Conditional. You may be able to get an MRI if the scan uses the parameters considered safe for the Ark device. Refer Instructions for Use for safe scan conditions. Be sure to consult your doctor for recommendations.

**Q: Will my Ark implant activate security alarms?**

A: The metal in the device may activate security alarms. If this occurs, you can show your Voyager Ark Implant Card to let the establishment know you have an Ark implant.

**Q: Who do I contact for questions or to report a problem with my Ark?**

A: Contact your healthcare provider for assistance if you have questions or need to report an issue with your Ark.



## Don't Forget!

Although the device is still in its investigation phase, it has been designed to help you go through your hemodialysis treatments.

To ensure you have the best experience, here's a helpful checklist you can review before you visit your doctor for your upcoming hemodialysis treatment.

### Remember to:

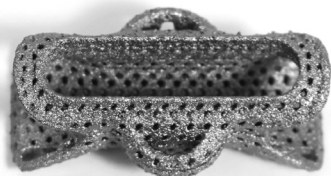
Read your Ark Patient Guide Kit to learn about your Ark and how to care for it.

Carry your Ark Implant Card every time you leave your home.

Show your Ark Implant Card to your healthcare provider before you start your hemodialysis treatment.

Be prepared to show your Ark Implant Card to the establishment's staff, in case your Ark has set off the security alarm, to inform them of your implant.

Contact your healthcare provider for questions about your Ark or to report any problems with your implant.



# Notes



## Implant #1

Implant Date:

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Implant Location:

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Ref:

---

Lot:

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Place Implant  
Card Label Here

## Implant #2

Implant Date:

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Implant Location:

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Ref:

---

Lot:

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Place Implant  
Card Label Here

## My Provider Information:

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## Glossary

**Hemodialysis** - Process of purifying the blood of a person whose kidneys are not working normally.

**Investigational Device** - Device not approved for marketing in the US that is intended to be evaluated by a clinical study.



# Ark

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[voyagerbiomedical.com](http://voyagerbiomedical.com)