

# Introducing the NxStage®

# System One™

An overview of a simple, flexible therapy option for home hemodialysis





# Living with Kidney Disease: Considering your Options

Living with chronic kidney disease is a journey. While your goal is to find a treatment option that offers optimal health and lifestyle benefits, in reality your journey may take you through a number of different therapies before you find what works best for you.

Your doctor or dialysis center may have already talked to you about conventional treatment options such as in-center (three-times-weekly) hemodialysis and peritoneal dialysis. These therapies are available to most kidney patients (depending on health status and location). Transplant is also an option, and for many the ultimate treatment solution. If you are predialysis or new to dialysis, you may be able to consider all options equally. If you've been on dialysis for a while you know that, as circumstances of your disease and life change, you may need to reevaluate your options. Regardless of where you are in your journey, you owe it to yourself to learn all you can about all available therapy choices.

NxStage offers an alternative option: home hemodialysis with the NxStage System One. As a home-based therapy, more frequent hemodialysis may offer several important health and quality of life advantages over other options. We encourage you to get all the facts and learn why thousands of people at all points in their journeys are choosing NxStage.





# Why Should You Consider Home Hemodialysis?

#### With dialysis therapy, more is better.

Patients report, and studies confirm, that compared to three-times-weekly hemodialysis, more frequent hemodialysis can offer significant health and quality of life benefits\* including<sup>1-4</sup>:

- More energy and quicker recovery time after treatment.
- Less stress on the heart.
- Better blood pressure control with fewer medications.
- Improved appetite and the ability to drink more.
- Lower risk of death.

# Home dialysis with NxStage makes more frequent dialysis practical.

NxStage patients usually dialyze 5 to 6 times a week, 2½ to 3 hours per treatment. But unlike in-center dialysis, home patients can choose when and where they wish to do their treatments. Activities that may not have seemed possible before – such as maintaining a normal work schedule or traveling – may become possible again with NxStage.

\*All of these experiences will not necessarily by experienced by all patients. All patients are different and their experiences will vary.

The NxStage System One is a prescription device. All forms of hemodialysis, including treatments performed in-center and at home, involve some risks. In addition, there are certain risks unique to treatment in the home environment. Patients differ and not everyone will experience the reported benefits of more frequent home hemodialysis. Talk to your doctor to see if more frequent home hemodialysis with NxStage is right for you.





## Beyond its use in the home, the NxStage System One is designed to be portable.

With the approval of their doctor and the help of NxStage Customer Support, System One users can take their dialysis on the road. Many NxStage patients enjoy the health benefits of more frequent hemodialysis while on vacations, motor home excursions, and ocean cruises. For thousands of people living with kidney failure, the benefit of NxStage portability has enabled them to realize the promise of a more normal, flexible, and meaningful life.

While more frequent home hemodialysis with NxStage may offer many important health and lifestyle benefits, it is not for everyone. Hemodialysis, like all medical procedures, involves some risk, and there are certain risks unique to treatment in the home environment. Treatments at home are done without the presence of medical personnel and on-site technical support. Patients and their care partners must be trained on what to do and how to get medical or technical help if needed. Doing daily home therapy requires a serious commitment from you and your partner.

This booklet describes the potential benefits, burdens, and risks of more frequent home hemodialysis therapy as well as the impact it will have on your life and your home. We encourage you to learn as much as you can about NxStage and other treatment options so you can make the best, most informed decision possible, with input from your doctor, care team, and family, about your kidney health and the therapy that is right for you.



# Overview of the **System One**

#### What makes NxStage different?

A combination of factors makes NxStage unique among dialysis therapies:

- The System One is small and portable; it weighs about 70 pounds and is roughly the size of a desktop laser printer.
- It was designed for home use by patients and care partners.
- It plugs into any standard grounded outlet and requires no special electrical connections.
- It requires no special plumbing modifications; the dialysate preparation system utilizes a simple faucet, under-sink, or washer connection and drains into any sink, toilet, or drain.
- Sterile premixed dialysate bags are available so you can take your treatment on the road.

#### **How does the NxStage system work?**

The NxStage System One delivers hemodialysis therapy in a home setting. The System One consists of the following elements:

- A small control unit containing a fluid pump and user interface (cycler).
- A disposable dialyzer and tubing set (cartridge).
- High-purity fluid (dialysate), prepared by the PureFlow<sup>TM</sup> SL dialysate preparation system or in premixed bags for travel.

For each treatment a cartridge is inserted into the cycler where it is automatically prepared for use, or "primed", prior to treatment. The dialysate is generally prepared in advance, in batches, by the PureFlow SL, and is then connected to the cartridge.

During treatment, the cartridge tubing is attached to your blood access. Blood and dialysate pass through the dialyzer to clean the blood. Used dialysate, wastes, and excess fluids removed from the blood pass through the cartridge, and then through a waste line into a standard drain.

Therapy is complete when the prescribed dialysate volume has been delivered. Treatment supplies are thrown away, and the cycler is simply wiped down after use.



### System Components



This is the "heart" of the system, containing the fluid pumps and system controls.



The dialyzer (filter) and tubing are pre-attached for easy setup.



The PureFlow system prepares high-purity dialysate from regular tap water.



When stacked together, the cycler and PureFlow SL stand only 40 inches high.

#### **How is NxStage therapy prescribed?**

Your doctor prescribes the dialysis therapy that is best for you. Based on your needs, he or she will decide how frequently you will perform your therapy, how much and what kind of dialysate you will use, how long the treatment will last, and what your weight at the end of each treatment should be.

Treatment times will vary based upon your body size and physician's prescription. A typical short daily treatment uses 20 to 30 liters of dialysate and takes 2½ to 3 hours to complete.

#### Why flexible therapy options?

The naturally functioning kidney works continuously: 24 hours a day, 7 days a week. It plays an essential role in balancing the fluids, toxins, and electrolytes in your body.

The most common form of hemodialysis is performed three times a week, approximately four hours per session. This therapy is known as traditional in-center or intermittent dialysis. This schedule was arrived at decades ago as a "practical compromise" between clinical benefits, dialysis provider resources, and the conventional work week. Because of the number of days (2 to 3) between treatments, intermittent dialysis can lead to large fluctuations in body weight due to water retention, accumulation of wastes, and electrolyte imbalances.

Times have changed. The flexible dosing options of the System One allows you to be in control of your treatments. Now you and your doctor can choose: where, how long, and how often you dialyze, providing tailored treatments that fit around your lifestyle.





#### How much time will therapy take?

It may surprise you, but because of the flexibility in dosing options of more frequent home hemodialysis with NxStage, it may take no more of your time than either three-times-weekly in-center dialysis or continuous ambulatory peritoneal dialysis (CAPD).

If you think about it, treatment time is only one element to consider. When determining how much time you will devote to any type of therapy, you should also consider your travel, preparation, and wrap-up time, as well as time spent recovering.

	In-Center HD	NxStage Home HD	CAPD (4 exchanges)	CAPD (5 exchanges)
Treatments/week	3	5	7	7
Travel to	1/2-1 hour	-	-	-
Preparation	1/4 hour	1/2 hour	1/4 hour	1/4 hour
Treatment	3-4 hours	2½ -3 hours	1/2 hours	1/2 hours
Wrap-up	1/4 hour	1/4 hour	1/4 hour	1/4 hour
Travel from	1/2-1 hour	-	-	-
Recovery <sup>6*</sup>	8.9 hour	1.2 hour	-	-
Total weekly time	40-46 hours	27-30 hours	28 hours	35 hours

<sup>\*</sup>In-center HD and NxStage home HD recovery times based on results from the FREEDOM study.



#### How will I be trained?

One of the requirements for doing home dialysis with NxStage is that you need to have a care partner who is willing to share in the training and responsibility for your home care. Your dialysis center will train you and your partner on home dialysis therapy. During the training, you and your care partner will learn how to access your blood, operate the NxStage system, monitor your vital signs, administer your drugs, and handle emergency situations.

The training nurse will adapt the program to meet your needs. You may be encouraged to do as much of the therapy as you can, and your center may not require your partner to attend every day of your training program.

You will generally complete training in 3 to 4 weeks. However, you will not start treatments at home until you, your care partner, and the center staff feel comfortable that you can safely and confidently perform your treatments.

#### Which blood access will I use? Can I access my blood myself?

Any of the three types of access – fistula, graft, or catheter – may be used with the NxStage therapy. You will learn how to access your blood during training if you do not already know how.

Don't worry – you can do it! Consider this: you are the best person to feel the location of the needle. If you are uncomfortable with sticking yourself, or self-cannulating, your trained care partner may also be an option. Home dialysis programs have found that virtually everyone can learn, and you may actually prefer self-access after being trained.

Patients report that they are less anxious and have less discomfort when doing the access procedure themselves because they are in control. One patient said, "It's like the difference between being a passenger and the driver of a car on a twisting mountain road. The passenger may feel uncomfortable or sick. As the driver, though, you are in control and you feel fine."

#### What help is available?

Your dialysis center is always there to support you. Additionally, NxStage staff is available 24/7 to support you and your dialysis center with any technical or equipment questions that might arise.

When doing home therapy, you will most likely visit your dialysis center at least once a month. They will also give you a number to call if you have questions about your therapy or your system.

If a problem with your system cannot be resolved by phone, NxStage has a "service-swap" program. This means that a replacement machine will be sent to you within one business day, and the machine with problems will be exchanged. This service is provided at no cost to you.

#### How will I get my supplies?

Supplies for the System One and PureFlow SL are delivered once a month. NxStage Customer Service will work with you and your dialysis center so that the delivery schedule fits your needs.

On average, you will use one box of cartridges per week and, depending on your prescription, one to two boxes of PureFlow SL dialysate sacks per week.

NxStage has extensive experience shipping supplies to remote residential locations and vacation spots. In the event of a natural disaster or other emergency situation, NxStage will ship supplies to your evacuation location.

"Home dialysis was right for me! Everyone is different. I have young kids so I'm home more and I love to travel. There is risk in everything but life is short, so enjoy your time away from the in-center unit. Live strong and ride hard!"

-NxStage Patient since 2009

#### Can I travel?

NxStage supports your travel plans, when approved by your physician and center. The NxStage System One is designed to be **portable** and taken with you when you travel. The PureFlow SL is not designed for travel, you will need to use **premixed bagged dialysate** when you travel.

Patients are responsible for transporting their System One cycler. Soft cases are available for personal travel, and hard cases are available for commercial travel.

For shorter trips patients typically take supplies from home. For longer trips NxStage can ship supplies to your destination (within the United States) if prescribed by your doctor. Your center can provide specific instructions on how to coordinate all travel plans. NxStage technical support is available 24 hours a day 7 days a week when you travel.

#### Is More Frequent Home Hemodialysis Right For Me?

Despite the health and quality of life benefits that more frequent home hemodialysis may provide to those with chronic kidney disease this form of therapy is not for everyone. Please review this information carefully and discuss it with your doctor as you evaluate your therapy options.





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#### **Personal and Partner Responsibility**

Home hemodialysis with NxStage requires a patient and partner who are committed to being trained on and following the guidelines for proper system operation. If you choose to do more frequent home hemodialysis, you will be responsible for complying with your dialysis prescription, which may require treatments up to six days per week. Each treatment can take about  $2\frac{1}{2}$  to 3 hours or more including set-up and tear-down.

If you choose to do home hemodialysis, you and your partner will need to take on the responsibility for tasks that would normally be taken care of by center staff when receiving treatment in-center. You will need to perform all aspects of the dialysis treatment from start to finish, including setting up the dialysis equipment, needle sticks, responding to and resolving all system alarms, and system tear-down at the end of treatment.

In addition, you must monitor your blood pressure, ensure that proper aseptic technique is followed, and follow all of the training material and instructions given to you by your training nurses. You and your partner will also be trained on and need to know how to respond to any health emergencies that might happen during treatment at home, including dizziness, nausea, hypotension (low blood pressure), and fluid or blood leaks.





#### **Treatment Environment**

To do home hemodialysis successfully, you must take care to ensure that you have a clean and safe environment for your treatments. You will also need to set aside space in your home for the needed supplies.

#### **Risks Associated with All Forms of Hemodialysis**

All forms of hemodialysis, including treatments performed in-center and at home, involve some risks. These may include high blood pressure, fluid overload, low blood pressure, heart-related issues, vascular access complications, cramps, backache, headache, dizziness, nausea, an "off" taste in the mouth, fatigue, fever, chills, joint pain, itching, seizures or sinusitis.

All hemodialysis therapies also involve the use of medical devices that introduce the potential for additional risks, including air entering the bloodstream, damage of red blood cells, inflammatory reactions, blood chemistry imbalances, blood loss due to clotting of the blood tubing set or accidental blood line disconnection or other leak, allergic reactions, and excess warming or cooling of the dialysate. In addition, dialysis patients may have other underlying diseases that may, in some cases, make it more difficult for them to manage their hemodialysis treatments.



## Risks associated with Daily/More Frequent Home Hemodialysis

Studies suggest that patients performing more frequent home hemodialysis may experience slightly fewer complications associated with their treatments, and actually may enjoy improved clinical outcomes. However, there are certain risks unique to treatment in the home environment. Treatments at home are done without the presence of medical personnel and on-site technical support. Patients and their partners must be trained on what to do and how to get medical or technical help if needed. When vascular access is exposed to more frequent use, infection of the site, and other access related complications may also be potential risks.

With more frequent home hemodialysis, you and your partner would be taking on a great deal of responsibility, but many NxStage patients feel that the benefits of this therapy are worth taking on these responsibilities. Thousands of patients are performing more frequent home hemodialysis with the NxStage System One and are enjoying the health benefits, improved quality of life, and additional freedom it can provide.

When performed correctly under the direction and with the support of your medical care team, more frequent home hemodialysis with NxStage may offer tremendous health and quality of life benefits. You should talk to your doctor to better understand the risks involved and how they might apply to you – and to determine if more frequent home hemodialysis is right for you.





As a patient, you now have more options than ever before.

We hope this guide has been helpful in explaining
therapy with the NxStage System One.

For more information, please visit www.nxstage.com.

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