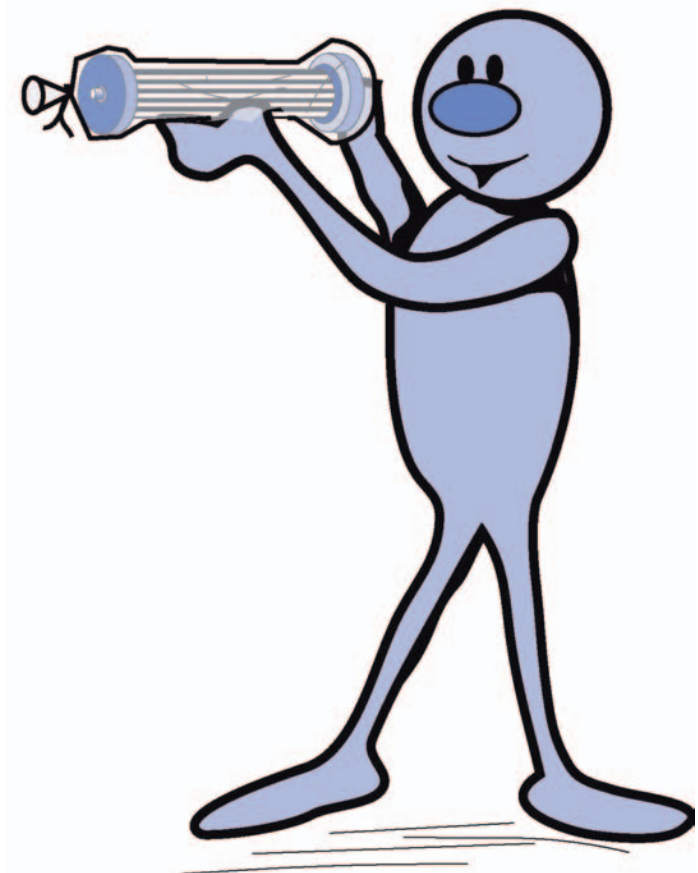


A Patient's Guide to Dialyzer Reprocessing

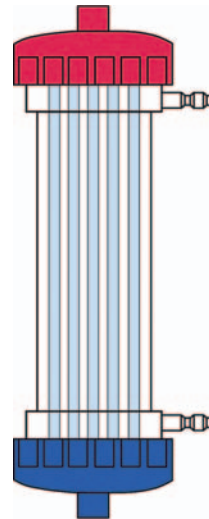


What is dialyzer reuse?

Dialyzer **reuse** is the practice of you, the patient, using the same dialyzer for multiple treatments. Dialyzers are not just reused, they are **reprocessed**. The reprocessing procedure involves cleaning, testing, filling your dialyzer with a **sterilant (Renalin® Cold Sterilant)**, inspecting, labeling, storing and rinsing your dialyzer before it is reused for your next treatment. Your dialyzer will be reprocessed carefully after each use by trained personnel. Detailed records of the dialyzer history will be kept. This will ensure that the dialyzer is safe for you to use again.

Reuse - To use your own dialyzer, after being reprocessed, for multiple treatments.

Sterilant - A substance that kills all infectious microorganisms.



Reprocessed - A dialyzer that has been cleaned, tested and filled with a sterilant (Renalin).

Renalin - A peracetic acid-based liquid sterilant used for reprocessing dialyzers.

How long has dialyzer reuse been practiced?

Dialyzer reuse is as old as chronic dialysis itself! Dialyzer reuse has been done safely in the United States since the 1960's, and it continues to be a common practice in a significant number of dialysis facilities, including the clinic where you receive your dialysis treatment.

Why do dialysis facilities reuse dialyzers?

The primary reason is economics. The cost of treatment keeps going up, but the amount of money that the government pays the dialysis facility for each treatment is fixed. This fixed rate is supposed to pay for all dialysis supplies, staffing and other services that are part of your treatment. The fixed rate is less today than it was 20 years ago. Savings from dialyzer reprocessing can be used to provide additional patient services.

Also, dialyzer reuse can lower or get rid of the chance of you having a “first-use” reaction. A “first-use” reaction can happen when your blood touches certain new dialyzer fibers which your immune system knows are strange to your body. When your dialyzer is reused, your immune system knows that your blood has touched the fibers before so they are no longer strange to your body.

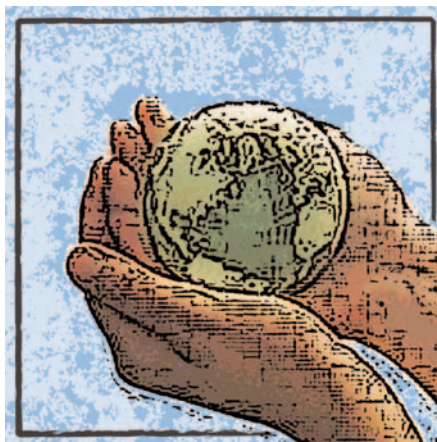
Companies that make dialyzers sometimes use **ethylene oxide** (ETO) to sterilize them.

Ethylene oxide - A colorless, flammable, toxic gas that is often used to sterilize medical supplies.

You can also have a “first-use” reaction if the ETO in a new dialyzer is not rinsed out before your treatment is started. Unfortunately, there is not a test to make sure that all of the ETO has been rinsed out. Facilities that reuse dialyzers usually **preprocess** all new dialyzers before they are used for the first time. Preprocessing flushes out the ETO and other manufacturing residues, tests and re-sterilizes your dialyzer before you use it for the first time.

Preprocess -To flush out manufacturing residues, test and fill a dialyzer with a sterilant (Renalin) before it is used for the first time.

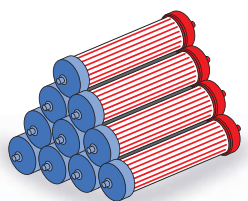
Finally, by choosing to be treated with a reprocessed dialyzer, you are helping the environment. Reprocessing reduces the amount of raw materials necessary to manufacture all the dialyzers needed for your treatments and dramatically decreases the number of discarded dialyzers that end up in community landfills.



100% of the components of a synthetic-fiber dialyzer come from oil, a non-renewable resource. The production, distribution and final disposal of oil-based products have a significant effect on the environment. The manufacturing and distribution of products that are oil based increases the amount of carbon (a greenhouse gas) released into the atmosphere. "Carbon dioxide is released to the atmosphere when solid waste, fossil fuels (oil, natural gas, and coal), and wood and wood products are burned."¹ This increases the amount of greenhouse gases in the atmosphere, and an increase in greenhouse gases leads to an increase in the Earth's temperature. "World carbon dioxide emissions are expected to increase by 1.9 percent annually between 2001 and 2025."² Also, dialyzers discarded in landfills will remain intact virtually forever; they do not biodegrade. Discarded dialyzers may disappear from sight, but they never really go away. On the other hand, the components of Renalin breakdown easily and do not harm the environment. Renalin byproducts are all natural and break down into oxygen, water and acetic acid (an organic compound that gives vinegar its unique smell).

If you are treated with a disposable dialyzer three times a week, you will need 156 dialyzers per year. However, if you are treated with reprocessed dialyzers and each dialyzer is used 16 times, you will only need 10 dialyzers per year. This saves 146 dialyzers per person from entering the waste stream each year. And keep in mind that there are over 325,000 people on hemodialysis in the U.S. alone. If no one reused dialyzers, almost 50 million dialyzers would be added to community landfills year after year. That mountain of medical waste will stay around forever.

How many of your dialyzers will end up in the landfill?

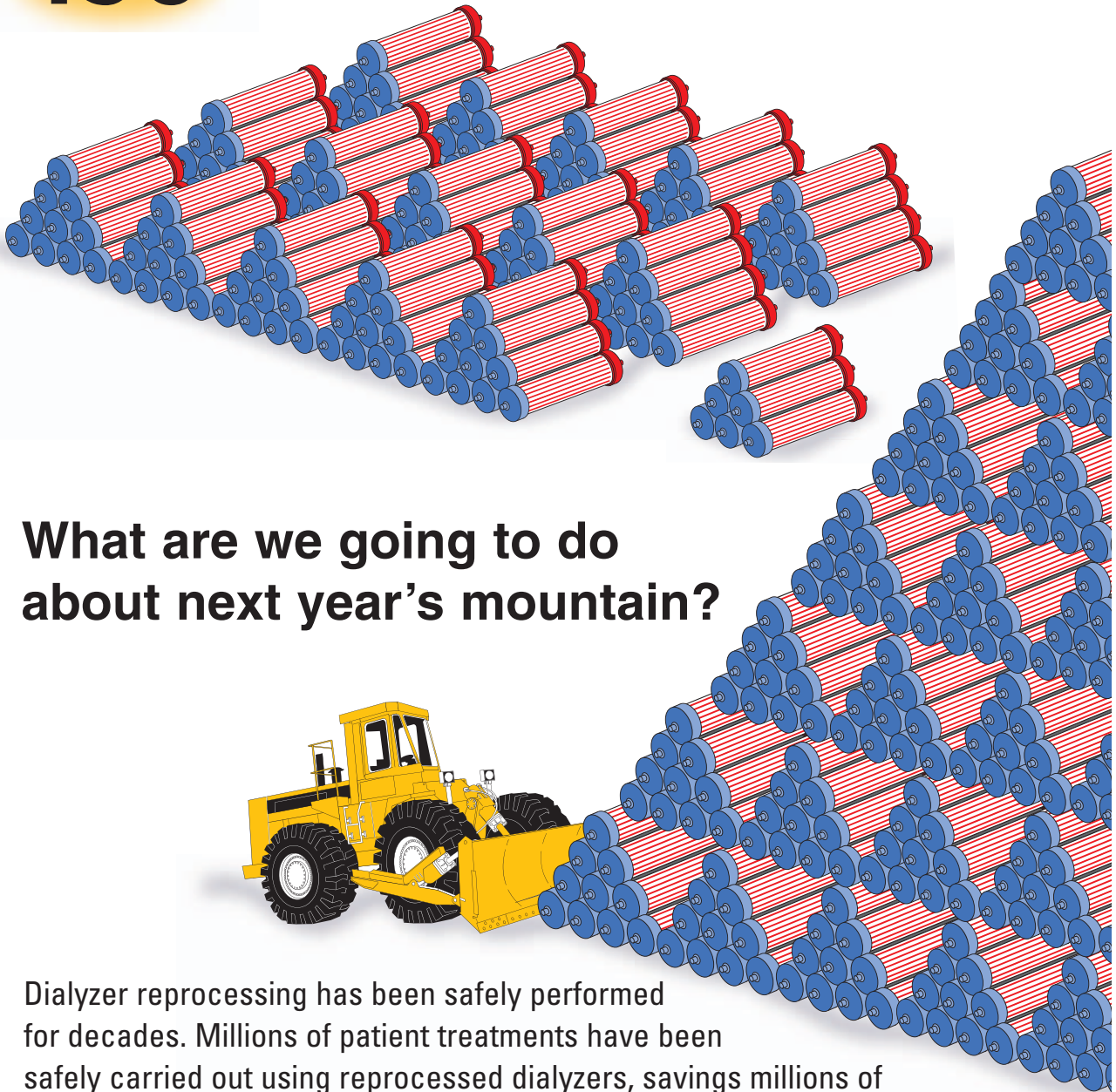


If you are on reuse =
10 dialyzers/year/person

¹ Global Warming – Emissions, What are Greenhouse gases? Retrieved August 24, 2007, from <http://yosemite.epa.gov/oar/globalwarming.nsf/content/emissions.html>

² Greenhouse Gases, Climate Change, and Energy, Why are Atmospheric Levels Increasing? Retrieved August 24, 2007, from, <http://www.eia.doe.gov/oiaf/1605/ggccebro/chapter1.html>

If you dispose of your dialyzer after every treatment =
156 dialyzers/year/person



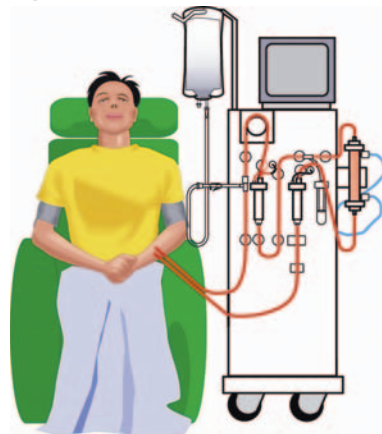
What are we going to do about next year's mountain?

Dialyzer reprocessing has been safely performed for decades. Millions of patient treatments have been safely carried out using reprocessed dialyzers, saving millions of dialyzers from being prematurely discarded. Extensive studies show reuse to be as safe and effective as single use. Dialyzer reprocessing dramatically reduces the number of dialyzers needed to treat all the patients in the U.S., thus reducing the amount of oil needed to manufacture all those dialyzers. Dialyzer reprocessing significantly minimizes the amount of medical waste generated by dialysis facilities. The bottom line is that the single use of dialyzers is wasteful and harmful to the environment; dialyzer reuse is much more environmentally friendly.

Is dialyzer reuse safe?

Yes. Dialyzer reuse is safe when the process is done correctly. Facilities must follow strict rules that were created by patients, health and business experts, scientists and government officials. These rules cover:

- Training.
- Water quality.
- Reprocessing the dialyzer.
- Dialyzer inspection.
- Dialyzer labeling.
- Storage.
- Testing the reprocessed dialyzer for the presence of sterilant (Renalin).
- Testing the reprocessed dialyzer for residual sterilant (Renalin).
- Monitoring you during your treatment.
- Quality assurance activities.



Also, your dialysis nurse or technician will draw monthly blood samples. These monthly blood tests are standard practice for all patients on dialysis, whether they are treated with a reusable dialyzer or they throw away their dialyzer after every treatment. These monthly tests will confirm that your dialyzer is working properly and that you are receiving adequate treatment.

Are the reuse technicians trained?

Yes. All reuse technicians participate in an in-depth training program. The training program covers at least the following:

- Principles of hemodialysis.
- Facility reprocessing policies and procedures.
- Reprocessing records and documentation.
- Operation and maintenance of the reprocessing equipment.

- Infection control practices.
- Emergency procedures.

Successful completion of the training will be documented in the employee's file. The reprocessing technician is tested annually to verify competency and is retrained if new procedures are instituted.



What happens to a reprocessed dialyzer?

- 1. Reprocessing** – After your treatment is finished, your dialyzer is cleaned, tested and then filled with a sterilant (Renalin).
 - a. During the **cleaning phase**, any blood that remains in your dialyzer at the end of treatment is flushed out of the fibers.
 - b. A **volume test** is performed on the dialyzer to ensure that the fibers that carry the blood are open and not clotted off. If your dialyzer fails the volume test, it will be thrown away, and a new dialyzer will be preprocessed for your next treatment.

- c. A **pressure test** is performed on the dialyzer to ensure that the fibers that carry the blood are not broken. If your dialyzer fails the pressure test, it will be thrown away, and a new dialyzer will be preprocessed for your next treatment.
- d. Your dialyzer is **filled with a sterilant (Renalin)**.

These steps are done with automatic equipment. Automatic equipment allows the process to be repeated over and over again without mistakes.



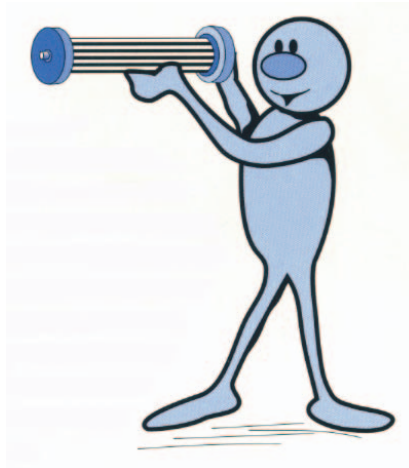
Renatron® II 100 Series Dialyzer Reprocessing Station

Detailed records are kept for every reprocessed dialyzer. These records show every step that your dialyzer went through, the dates, the test results and the name or initials of the technician who reprocessed your dialyzer. These records are maintained electronically or also can be recorded by hand. These records can be made available to you by your nurse or technician.



2. Inspection – After your dialyzer is reprocessed, the reuse technician will visually inspect your dialyzer and check for the following:

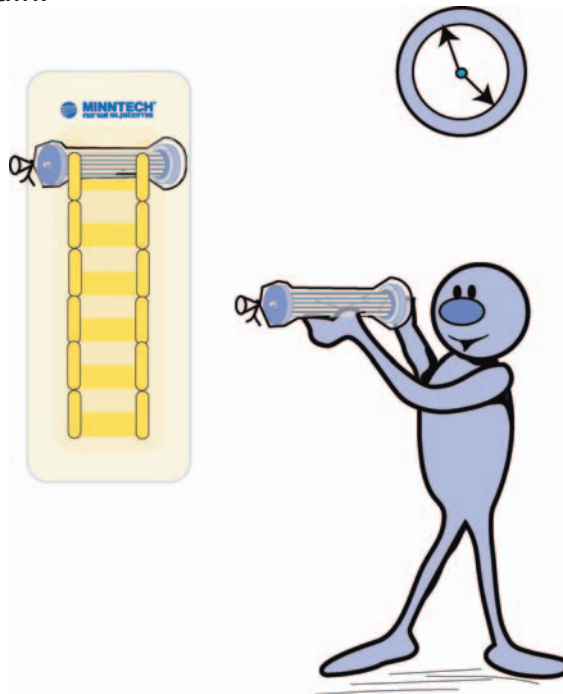
- a. Confirm that the level (volume) of sterilant (Renalin) in the dialyzer is sufficient
- b. Confirm that the blood and dialysate ports on your dialyzer are capped and not leaking.
- c. Check that the dialyzer is not damaged or leaking.
- d. Confirm that both the inside and outside of your dialyzer look clean.



3. Labeling – After passing the inspection, the technician will place a new information label on your dialyzer. The label will show:

- a. Your name.
- b. Number of times you have used your dialyzer.
- c. Date and time your dialyzer was last reprocessed.
- d. Initials of the person who reprocessed your dialyzer.

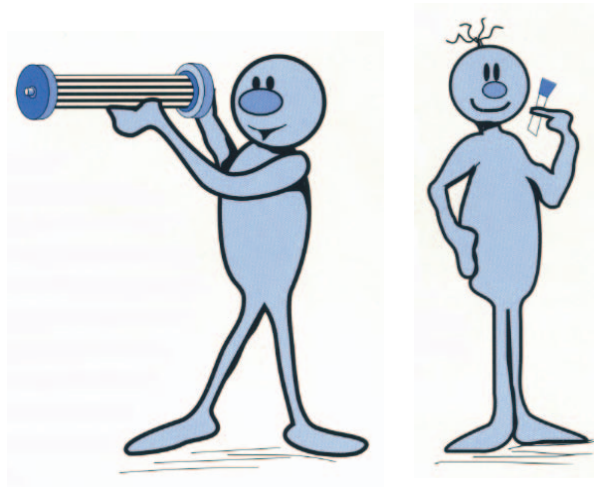
4. **Storage** – After your dialyzer is reprocessed, inspected and labeled, the technician will store your dialyzer in a clean and safe area until it is time for you to use it again.



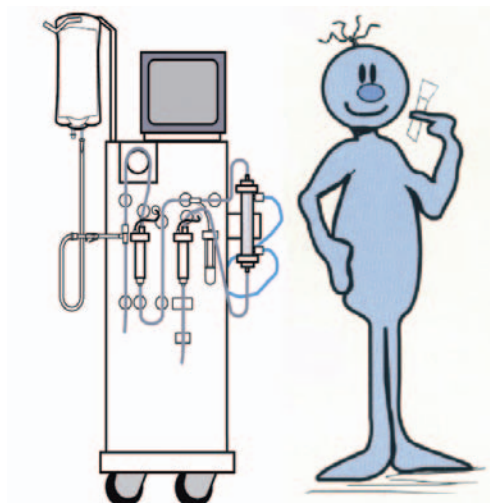
5. **Inspection and presence testing** – Before your dialyzer is prepared for use, the dialysis staff must inspect your dialyzer **AGAIN** and test your dialyzer for the following:

- Verify that the sterilant (Renalin) was in your dialyzer for the correct amount of time.
- Confirm that the level (volume) of sterilant (Renalin) in the dialyzer is sufficient.
- Confirm that the dialyzer is properly labeled and that it passed all the tests when it was reprocessed. Your name must also be printed clearly and correctly on your dialyzer.
- Make sure that the blood and dialysate ports are capped and that no fluid is leaking from the dialyzer.

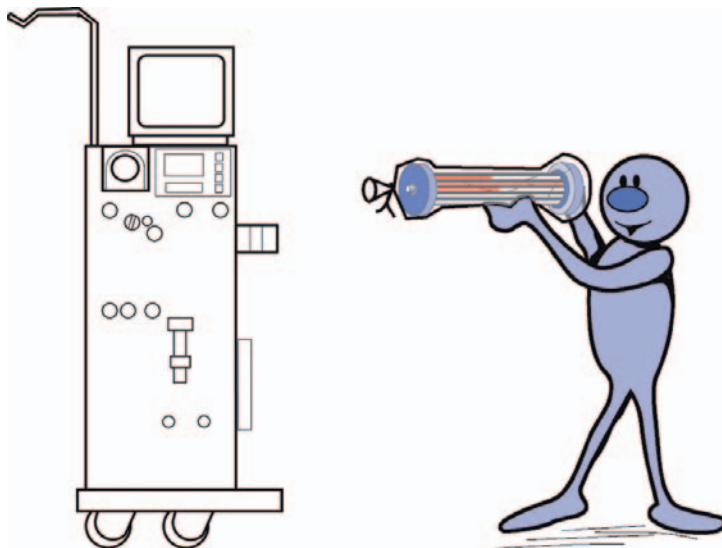
- e. Visually inspect both the interior and exterior of the dialyzer for cleanliness and aesthetic appearance.
- f. Perform a presence test to verify that the concentration of sterilant (Renalin) in your dialyzer is effective.



6. Rinsing and residual testing – Before your treatment begins, the staff must rinse the sterilant (Renalin) from your dialyzer and then perform a residual test to confirm that the sterilant (Renalin) has been rinsed out.



7. Post treatment – When your treatment is completed, your dialyzer will be capped and sent to the dialyzer reprocessing room. Your dialyzer will be reprocessed, and the cycle will be repeated.



How many times can I reuse my dialyzer?

Your Medical Director will establish the maximum number of times your dialyzer can be used. Additionally, your dialyzer must pass all the required tests in order to be reused.



What part do I play in the reuse process?

If you are able, inspect your dialyzer to make sure that it is clearly labeled with your name, that it is clean and that it is not damaged or leaking before your treatment starts. Also, ask your nurse or technician to show you the result of the Renalin residual test.

You may choose not to participate in the dialyzer reprocessing program, but by participating you are receiving the highest quality of care and, at the same time, taking positive steps to help your environment.

