

TIF[®] PROCEDURE WITH Esophyx[®] Z+ DEVICE

Patient Instructions



Before and After Your TIF 2.0[®] or cTIF[®] Procedure

Merit Medical defines the term "cTIF" as a **consecutive** Transoral Incisionless Fundoplication which consists of a Hiatal HerniaRepair (HHR) followed by a Transoral Incisionless Fundoplication (TIF) procedure under a single anesthesia setting.

This brochure is intended to give you a general overview of the TIF 2.0 procedure instructions. ALWAYS follow your doctor's pre-procedure and post-procedure instructions.

Pre-Procedure Instructions

Make sure you inform your doctor about all medications you are currently taking and provide a full history of your medical conditions.

DO NOT take any diet aids or herbal supplements that contain ginkgo, garlic, or St. John's Wort for 10 days prior to surgery.

DO NOT take any aspirin, blood thinners, anti-inflammatory (arthritis) medications, vitamin E or fish oil for 7 days prior to your procedure.

Your doctor will give you additional instructions regarding medications you are currently taking.

DO NOT smoke or drink alcohol for 48 hours prior to your procedure.

DO NOT eat or drink anything for at least 12 hours before your procedure (or longer if instructed by your doctor). The TIF 2.0 procedure cannot be performed if there is food in your stomach. Take the medications your doctor has approved for you to take with a small amount of water.





Post-Procedure Instructions

Your doctor will determine whether it is necessary for you to spend the night in the hospital after your procedure. For the first few days, you will experience some pain and/or discomfort in your chest and shoulder and you may have a sore throat, and/or some discomfort swallowing. These symptoms should resolve within the first week after your procedure and appropriate medication will be provided as needed. If symptoms do not resolve or if discomfort becomes more severe, notify your doctor immediately.

Continue to take your GERD medication after your procedure as recommended by your doctor.

Occasional heartburn is normal in healthy people and may depend on diet and other factors such as stress. If GERD symptoms recur, you should contact your doctor.

Even though the TIF 2.0 Procedure is incisionless, it is still surgery. Like any surgical procedure, success is dependent on how well you adhere to post-procedure instructions including:

- ✓ **Dietary guidelines**
- ✓ **Physical activity, driving**
- ✓ **Medications**
- ✓ **Return to work**
- ✓ **Follow-up**



Dietary Guidelines

The strength of your new antireflux valve is largely determined by how well it heals. What you eat and drink can dramatically impact the durability of your antireflux valve. You will be asked to follow a liquid diet followed by a mashed and soft food diet as your newly reconstructed valve heals.

If you experience heartburn, write down the food that gave you heartburn and avoid eating it. Talk to your doctor at your next visit about your food-associated symptoms. Remember, it's normal for some people (non-GERD patients) to occasionally experience heartburn from specific foods, and this may mean that your valve is functioning correctly. If your symptoms persist, contact your doctor immediately.

During the 6-week post-procedure period, it's important that you adhere to the following guidelines:

Eat 4 to 5 small meals consisting of soft foods throughout the day.

Take small bites and chew your food thoroughly for 30 seconds to avoid swallowing a large bolus of food.

Avoid foods with coarse texture: nuts, raw fruits, and raw vegetables.

Try not to vomit, cough, retch or strain. This can significantly affect the healing and effectiveness of your new antireflux valve.

During the healing process, avoid foods and drinks that triggered your reflux in the past. You may reintroduce them slowly after healing.

To avoid chest pain take small bites, chew for 30 seconds and gradually thicken the texture of your food.

Remain in an upright position for 1 hour after eating.

Do not eat for at least 2 hours before bedtime.

Do not drink carbonated beverages or alcohol.

Avoid spicy foods.

Avoid foods and drinks that are very hot or very cold.

Follow your doctor's instructions to wean yourself off antireflux medications.

Do not smoke.

Avoid gas-forming, acid producing foods, or foods that slow gastric emptying such as tomato-based products, peppermint, black pepper, caffeinated drinks, alcohol, onions, green peppers, fatty foods, beans, spicy foods, citrus fruits, and fiber supplements.

Taking over the counter anti-gas medications may be helpful.

Weeks 1 and 2: Liquid Diet

The first 2 weeks after your procedure are extremely important. That's why we ask you to be particularly cautious with your diet.

You will stay on liquids for the first 1-3 days after your TIF 2.0 procedure. This diet contains only fluids that are clear and very low in sugar. However, it is not nutritionally balanced and will only be used a few days.

Avoid beverages with alcohol, caffeine, carbonation (soft drinks), or acidic drinks (tomato, grapefruit, and orange juice).

Foods that are allowed:

Water, plain or lightly
flavored (non-carbonated)

Milk, decaffeinated tea,
caffeine-free drinks

Diet decaffeinated drinks
(non-carbonated)

Diluted electrolyte drinks
Strained soups

Diluted, light, or diet
apple or white grape juice

Non-acidic fruit or
vegetable juices
(without chunks)

Liquid puddings and
creams

Sherbets or Ice-creams
(without chunks)

Milkshakes

Baby food





Be sure to drink a minimum of 4-8 oz of water between each meal.

Do not take large gulps. Sip liquids and rest between sips. Allow 20 minutes to drink $\frac{1}{2}$ cup. You may sip on fluids all day if you wish but at least 6-8 times per day.

Take your prescribed medications. PPIs should be taken for at least 2 weeks and wean off according to physician recommendation. If pills/capsules are larger than a peanut, discuss with your pharmacist if they can be halved, crushed or if there are liquid options available to minimize hard swallowing.

Take vitamin/mineral supplements every day being mindful of pill/capsule size as noted above. This will help prevent vitamin and mineral deficiencies.

It's helpful to eat a very low fat diet to minimize heartburn symptoms.

Restaurant foods are not recommended during the first few weeks.

The following protein supplements can be used starting on day 4:

Protein-enriched commercially available shakes.

You can also add one scoop of concentrated protein powder to your bowl of soup or glass of juice.

During week 2, a liquid diet is still recommended but you may add very liquid, potato-based and non-stringy vegetable mashes.

This diet consists of high-protein full liquids and blended solids. The portions should remain small and not exceed $\frac{1}{2}$ cup to help prevent vomiting and proper healing of your newly reconstructed valve.

Your meals will be only liquid or blended. They may include milk, vegetable or diluted fruit juice. Sip liquid meals very slowly. Drink 4 oz ($\frac{1}{2}$ cup), over 20-30 minutes.

Eat 4-6 small meals each day. The amount you will be able to eat at one time is very small and should not exceed $\frac{1}{2}$ cup. Eat foods high in protein because they help your body heal from surgery.

Tips on how to blend foods:

Cut foods into small pieces

Place food into blender or food processor

Add liquid such as broth, juice, or milk Blend or puree until smooth

Strain foods that do not blend in a completely smooth consistency

Season foods to taste



Shopping list weeks 1-2

- ☐ Water, plain and lightly flavored (non-carbonated)
- ☐ Milk, decaffeinated tea, caffeine-free drinks
- ☐ Diet decaffeinated drinks (non-carbonated)
- ☐ Electrolyte drinks
- ☐ Apple juice or white grape juice
- ☐ Non-acidic fruit or vegetable juices (without chunks)
- ☐ Strained soups
- ☐ Liquid puddings and creams
- ☐ Sherbets and ice-creams (without chunks)
- ☐ Milk-shakes
- ☐ Baby food

Recipes

Protein Fortified Breakfast Drink

½ packet Carnation Instant Breakfast

½ scoop of whey protein powder

4 oz skim milk

Amount per serving (½ cup): 120 calories, 15 g protein

PB Protein Pudding

1 packet sugar-free pudding

¼ cup dry milk

¼ cup peanut butter

2 cups skim milk

Amount per serving (¼ cup): 100 calories, 6 g protein

Eggnog

½ cup skim milk

½ package Carnation Instant Breakfast

¼ cup liquid egg substitute

Amount per serving (½ cup): 110 calories, 13 g protein

Food Guide

Postoperative Diet	
Clear liquids, low in sugar	Water
	Milk, decaffeinated tea, coffee
	Diet and decaffeinated drinks, diluted
	Broth of any kind, strained soups (noodle)
	Diluted, light or diet apple or orange juice
	Non-acidic fruit or vegetable juice
	Liquid puddings
	Sherbets, ice-creams, milk shakes
Full liquids	Drinkable yogurt
	Protein-enriched commercially prepared soups
	Very liquid, porridge
	Non-stringent soft fruits
	Non-stringent soft vegetables
Soft texture, low fat food	Well-cooked & pureed vegetables (broccoli, cauliflower, green beans, peas, corn)
	Canned fruit
	Banana
	Well-cooked lean ground meat
	Moist, mashed potatoes
	Well-cooked lean ground meat
	Well-cooked lean ground meat
	Well-cooked lean ground meat
Medium texture food	Soft bread
	Soft pasta
	Cereals
	Soft fruits

Food Procedure	Day 0-3	Day 4-14	Weeks 3-4	Weeks 5-6
Water (non-carbonated)	●	●	●	●
Caffeine free drinks	●	●	●	●
Oral electrolyte drinks	●	●	●	●
Apple juice (not tomato based)	●	●	●	●
White grape juice	●	●	●	●
Pineapple (without chunks)	●	●	●	●
Yogurt and creams	●	●	●	●
Smoothies (without chunks)	●	●	●	●
Yogurt (no chunks)	○	●	●	●
Commercially available shakes	○	●	●	●
Potato-based mash	○	●	●	●
Any vegetable mash	○	●	●	●
Baby food	○	●	●	●
Cottage cheese	○	○	●	●
Oatmeal	○	○	●	●
Mashed potatoes	○	○	●	●
Fruit (without skins)	○	○	●	●
Apples, melons, berries	○	○	●	●
Soft eggs, tofu	○	○	●	●
Mashed boneless fish	○	○	●	●
Poultry food (e.g. turkey)	○	○	●	●
Small soft noodles	○	○	○	●
Non-sticky rice	○	○	○	●
Softened cereal (softened in milk)	○	○	○	●
Soft cheeses	○	○	○	●

Shopping list weeks 3-4

- ☐ Milk, fruit and vegetable juices
- ☐ Tea, coffee
- ☐ Potatoes and/or vegetables to mash
- ☐ Oatmeal
- ☐ Puddings, ice-creams, sherbets
- ☐ Butter and margarine
- ☐ Soups (without chunks)
- ☐ Tofu
- ☐ Well-cooked ground food: slowly introduce finely ground fish or turkey

Shopping list weeks 5-6

- ☐ Pasta (small noodles) and non-sticky rice
- ☐ Thicker soups or soups with small pieces of vegetables
- ☐ Sauces
- ☐ Bananas
- ☐ Soft cheeses
- ☐ Vegetables (for cooking, steaming)



Weeks 3 and 4: Soft Diet

This diet consists of blended foods with one new solid food added daily. Portions should be small and not exceeding 1 cup to help prevent vomiting and proper healing of your newly reconstructed valve.

Foods that are allowed:



Water, milk, fruit juices and vegetable juices

Tea and coffee (in small quantities)

Mashed vegetables and/or potatoes

Oatmeal

Puddings, ice-creams, sherbets

Butter and margarine

Soups (without chunks)

Tofu

Slowly introduce well-cooked, finely ground food such as fish or turkey

Food to avoid:

Raw or undercooked food

Alcoholic and carbonated beverages Pasta, bread

Cakes, pancakes, waffles, cookies, etc.

Chips, french fries, popcorn, etc. Pepper and hot sauces

Dry fruits and cereals

High-fat food

Consume vitamin-rich fruit juices each day. Refrain from acidic fruit juices like orange, lemon or lime Plum juice and/or apricot juice will help to avoid constipation.

Weeks 5 and 6: Solid Diet

Depending on your tolerance level you may introduce:

Overcooked pasta (small noodles) and non-sticky rice

Thicker soups or soups with small pieces of vegetables

Sauces

Bananas

Soft cheeses

Cooked vegetables

Meatless casseroles

Food to avoid:

Fibrous meats

Fibrous vegetables

Eat seated, in a quiet place, without stress.

Chew your food thoroughly. Eat slowly.

Avoid consuming large quantities of food.

Avoid carbonated beverages or alcohol.

If you have a burning sensation after consuming a particular food, try to avoid it and mention it to your physician at your next visit.

A burning sensation could mean that your newly reconstructed valve is operating correctly. However, if your symptoms persist, contact your physician as soon as possible.

At the start of the week 7 you can eat normal food. But try to continue eating small meals.

Physical Activity

Walking is permitted and encouraged after your procedure. Begin to walk short distances, at a slow pace, and with someone who can assist you in case you experience any residual weakness due to anesthesia. Gradually increase the distance and duration of your walks until you feel you are back to normal. You may also climb stairs, although do it slowly for the first few weeks to reduce the risk of increasing abdominal pressure.

In order to give your newly reconstructive valve time to heal and fuse, do not lift anything over 5 pounds for the first 2 weeks. During weeks 3-6, you may lift items up to 10 pounds. Beginning in week 7, lift items you normally would.

Sports and other intense exercise should be avoided for the first 6 weeks following your procedure. Then consult with your doctor to determine if you are ready to resume your normal exercise routine.

Driving may be resumed 1-2 days after the procedure. Do not drive if you are taking prescription pain medication, are experiencing fatigue, or are feeling sore.

Sex may be resumed after 7 days.





Medications

Your doctor will determine your need for acid-reducing medications following your procedure.

Before leaving the hospital, your physician may prescribe pain medications. It is important that you take this medication as prescribed. If your pain is not well managed, contact your physician.

Follow Up

After the procedure, your doctor will see you to assess the effectiveness of the TIF 2.0 procedure. Your doctor may also schedule additional follow-up appointments.

Return to Work

Most patients will be able to return to work 3-7 days after the procedure. You and your doctor should determine a timetable for returning to work based on a number of factors including residual fatigue from general anesthesia, any complications during the procedure, your overall medical condition, and your general need for recovery time.

If you work in a job that requires significant physical activity, you should not resume all your normal job functions until after your doctor has cleared you to do so.

If you are experiencing any of the following symptoms after your procedure, call your doctor immediately or go to your doctor's hospital's emergency room.

- ✓ **Fever greater than 101° F**
- ✓ **Increased upper**
- ✓ **abdominal pain**
- ✓ **Difficulty or pain while swallowing**
- ✓ **Sore throat lasting more than seven days**
- ✓ **Chest pain**
- ✓ **Shoulder pain lasting more than 3-7 days**
- ✓ **Any condition not improving or worsening**

Follow your doctor's instructions to wean off antireflux medications.

Monitoring your progress:

It's helpful to chart your progress from before your TIF 2.0 procedure and after. Please answer these questions today and check in again eight weeks after your procedure and to see what's changed.

Rate how you are feeling:

0 = best, 3=neutral, 5 = worst

Before your TIF 2.0 procedure	0	1	2	3	4	5
How much does heartburn bother you on a daily basis?						
How much does regurgitation bother you on a daily basis?						
Do your reflux symptoms prevent you from getting a restful night of sleep?						
Does your reflux condition impact your daily activities?						
How much does coughing bother you on a daily basis?						
Does your reflux condition impact your social life?						
How dependent are you on medications to control reflux symptoms?						
Overall satisfaction with your health condition						



Eight weeks after TIF 2.0 procedure	0	1	2	3	4	5
How much does heartburn bother you on a daily basis?						
How much does regurgitation bother you on a daily basis?						
Do your reflux symptoms prevent you from getting a restful night of sleep?						
Does your reflux condition impact your daily activities?						
How much does coughing bother you on a daily basis?						
Does your reflux condition impact your social life?						
How dependent are you on medications to control reflux symptoms?						
Overall satisfaction with your health condition						



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Important Notice: While clinical studies support the effectiveness of TIF 2.0 (Transoral Incisionless Fundoplication) procedure in treating chronic GERD (gastroesophageal reflux disease), individual results may vary. This information is not intended nor recommended as a substitute for medical advice, diagnosis, or treatment. The TIF 2.0 procedure may not be appropriate for every individual, and it may not be applicable to your condition. Always ask your doctor about all treatment options, as well as their risks and benefits.

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