



Affix Patient Label

Name _____ Date of Birth _____

Informed Consent:

INSERTION OF MEDTRONIC DIABETES iPRO CGM™ (Continuous Glucose Monitoring)

This information is given to you so that you can make an informed decision about having insertion of **the Medtronic Diabetes iPro CGM™ (Continuous Glucose Monitoring.)**

Reason and Purpose of the Procedure:

The iPro™ continuous glucose monitoring system is attached to a tiny glucose sensor that is inserted just under the skin.

It then collects data on your blood glucose levels over a period of 3 days. You will not be able to see this information. You will then return the unit to your healthcare provider. They will download the information. The report will help your provider to understand the affects of your diet, daily activity, sleep, medication and behavior that may affect your glucose levels. This will help your provider to make treatment decisions, and to educate you on lifestyle choices to manage your blood glucose. The recorder is small, lightweight and waterproof. It should not interfere with your normal daily activities.

Benefits of this procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- **Assist your provider in making treatment decisions to control your blood glucose levels more appropriately.**
- **Assist your provider in teaching you ways to help control your blood glucose levels.**

Risks of Procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

Risks of this procedure:

- **Bleeding at insertion site:** If this occurs, contact the office.
- **Skin irritation at insertion site or rash from the tape or bandage to secure the iPro CGM to the skin.** If this occurs, you may need a different tape to secure. Notify the office.
- **Infection at insertion site or within the tissue:** If this occurs, you may need antibiotics.

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Risks associated with smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks associated with obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks specific to you:

Alternative Treatments:

Other choices:

- Do nothing. You can decide not to have the procedure

If you choose not to have this treatment:

- Your blood glucose levels may be more difficult for your provider to assist you in controlling.

General Information

I understand that I may be financially responsible for losing or damaging the iPro Recorder.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

I agree to release my social security number, my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to locate me.

My insurance company may not pay for this device or procedure. I know I am responsible for charges not covered by my insurance.

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By signing this form I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Insertion of Medtronic Diabetes iPro Continuous Glucose Monitoring™ device.**
- _____
- I understand that my doctor may ask another provider to do the procedure.

Patient Signature _____ **Date** _____ **Time** _____
Relationship Patient Closest relative (relationship) Guardian

Interpreter's Statement: I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

 Interpreter (if applicable) Date Time

For provider use only:
 I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options and possibility of complications and side effects of the intended intervention. I have answered questions and patient has agreed to procedure.

Provider Signature _____ Date _____ Time _____

Teach Back

Patient shows understanding by stating in his or her own words:
 Reason(s) for the treatment/procedure: _____
 Area(s) of the body that will be affected: _____
 Benefit(s) of the procedure : _____
 Risk(s) of the procedure: _____
 Alternative(s) to the procedure: _____

or

_____ Patient elects not to proceed _____ (patient signature)

Validated/Witness: _____ Date: _____ Time: _____