

Body Composition, Nutrition, and Health Risk Assessment Informed Consent Form

Release of Liability:

I understand the CornerstoneWellness.md program provides analysis of my personal body composition, using the stay healthy body composition device. This test is safe and accurate, and is based on FDA cleared class II medical device rating. The program will provide recommended caloric intake to achieve weight goals based on lean body mass/fat ratio.

* Currently it is not well known whether body composition devices affect the function of cardiac implantable electromagnetic devices (CIEDs), (*i.e. cardiac defibrillator, pacemakers, etc*). * *I hereby understand that current guidelines warn* of potential electromagnetic interferences when using bioelectrical impedance analysis to measure body composition in patients equipped with implantable cardioverter-defibrillators (ICDs). However, there was a small study published in 2018 which showed no interference and suggests that BIA can be securely performed in these patients. **During BIA, no significant changes in battery voltage, lead impedance or pacing thresholds were detected, nor were there any inappropriate over- or under sensing observed in intracardiac electrograms. Furthermore at 6-12 month follow ups no changes or interference were revealed in CIED's.**

I understand my wellness coach <u>may recommend nutrition supplements</u> in conjunction with a healthy eating plan. This program and its supplements are available only thru physician monitored programs. The use of high quality meal replacements is clinically proven as the most effective method for long term fat loss with studies extending over ten years. I understand these products are based on sound nutrition principles and are an optional component of management. *There have been no known side effects with use of any supplements, if you have any concerns call the office (810) 216-4200. There are no direct medical claims attached to the use of nutritional supplements. The weight results of clients will vary based on their consistent actions of both diet and exercise.*

<u>There is a non-refundable one-time \$60 dollar fee (not covered by insurance</u>). This is for a personalized profile, and covers the use of the BIA device FOR A FULL YEAR.

Procedure of BIA:

The procedure will be done fully clothed and standing. It is recommended that you do not eat 2 hours prior to test. Please note the importance of hydration for most accurate results. Dietary changes prior to test may impact fluid levels on re-test. **This will not impact the results of lean body mass/fat ratio, but simply fluid levels of LBM.**

With my signature, I understand that there may be a risk associated with the bio impedance analysis, and I wish to proceed, and I have been given a copy of the recent study noted above. *

| X | | |
|---|------|--|
| Signature of Patient (Parent or Legal Guardian) | Date | |
| X | | |
| Patient Name | Date | |
| Signature of Witness | Date | |
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