ONYXA
MEDICAL

JUNERA – Patient Informed Consent

This is a sample consent template intended to be modified by each practice to align with their own policies, state regulations, and legal requirements.

Patient Information

Patient Name: _____ DOB: _____

Procedure Area(s): _____ Date: _____

Treating Provider: _____ Title: _____

Device Description & Intended Use

The Junera system is a medical diode laser cleared by the U.S. Food and Drug Administration (FDA) for the delivery of laser energy to soft tissue during surgical procedures. FDA-cleared uses include incision, excision, vaporization, ablation, hemostasis, coagulation, and laser-assisted lipolysis. Laser-assisted lipolysis involves the application of laser energy to fatty tissue beneath the skin as part of a surgical procedure, at the discretion of the treating clinician.

General Procedure Acknowledgment

I understand that this is a minimally invasive procedure that may involve small access points and the use of local anesthesia, with or without additional sedation, as determined by my provider. I further understand that a thin optical fiber may be placed beneath the skin to deliver laser energy to subdermal connective tissue and/or fatty tissue. The specific laser parameters, wavelengths, and energy delivery settings are selected by my treating clinician based on their clinical judgment, with the intent of producing a targeted tissue response.

Provider Responsibility & Delegation of Care

I understand that certain aspects of my care before, during, or after the procedure may be performed by qualified, trained healthcare personnel acting under the direction and supervision of the treating clinician, in accordance with applicable state and federal laws and regulations. Decisions regarding delegation of any portion of my care are made solely at the discretion of my treating clinician and are not directed or mandated by the device manufacturer or distributor.

Off-Label Use (If Applicable)

The device is cleared by the U.S. Food and Drug Administration (FDA) for the indications listed above. My treating clinician may independently determine, based on their medical judgment, whether to use the device in a manner not specifically cleared by the FDA. Such uses have not been reviewed or approved by the FDA. No guarantees or assurances have been made regarding outcomes.

Contraindications

This procedure should not be performed in patients who have been determined by their clinician to be unsuitable for laser therapy, including but not limited to:

● Certain cardiac conditions

● Psychosis or significant psychiatric disorders

● Uncontrolled high blood pressure

Final determination of patient suitability is made by the treating clinician.

Precautions & Warnings

Use of this device requires appropriate training and adherence to all safety guidelines provided by the manufacturer, including laser safety precautions. Protective eyewear must be worn during use, and care must be taken to avoid unintended laser exposure to eyes, skin, or non-target tissues.

In addition, certain medical conditions or circumstances may increase the risk of complications and should be carefully considered by the treating clinician, including but not limited to:

● Active infection, cellulitis, or open wounds in the treatment area

● Bleeding disorders or medications increasing bleeding risk (unless appropriately managed)

● Pregnancy or breastfeeding

● Inability to comply with aftercare/follow-up

● Any condition making the procedure unsafe per clinician

The treating clinician is responsible for evaluating these factors and determining whether treatment is appropriate.

Risks & Potential Complications (Not Complete)

As with any surgical or minimally invasive procedure, risks and complications may occur. Possible risks include, but are not limited to:

● Burns/thermal injury; skin discoloration/scarring (including hypertrophic/keloid)

● Seroma/hematoma; infection; delayed healing; prolonged swelling/discomfort

● Contour irregularity/asymmetry; firmness/nodules; unsatisfactory result

● Nerve irritation/numbness/altered sensation (temporary or prolonged)

● Anesthesia-related events

● Need for additional procedures/revisions

I understand that while complications are uncommon, they are possible, and no specific outcome can be guaranteed.

Combination Procedures & Additional Treatments

I understand that my provider may recommend or perform additional procedures, treatments, or the use of other products or technologies in conjunction with this procedure. I acknowledge that the use of combination procedures may be associated with additional or different risks, potential complications, recovery considerations, and outcomes beyond those associated with this procedure alone.

Results & Expectations

I understand that individual results may vary and that no guarantees or assurances have been made regarding the outcome of this procedure. Laser-assisted lipolysis may alter underlying fatty tissue, which may result in changes to body contours; however, the degree of change varies by patient and depends on multiple factors, including my adherence to pre- and post-procedure instructions provided by my treating clinician and their clinical staff.

Alternatives

Alternatives may include no treatment, surgical procedures, or other energy-based or medical options, which have been discussed with me by my provider.

Photography & Video Consent

I consent to clinical photographs and/or video recordings being taken before, during, and after my procedure. I understand these may be used for medical education, marketing materials, and social media platforms.

Medical record (required): _____

Medical education: _____

Marketing materials: _____

Social media platforms: _____

Patient Signature: _____ Date: _____

Provider Signature: _____ Date: _____

SAMPLE – MODIFY AS NEEDED PER PRACTICE POLICY