Technical Specification

NanoKnife Disposables
(Single Electrode Probe and Probe Spacer)

Administrative:

Legal Manufacturer:
AngioDynamics, Inc.
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Authorized Representative:
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Device Description and Product Specification:

Product Name:

NanoKnife Single Electrode Probe
NanoKnife Single Electrode Probe Spacer

Device Description:

The NanoKnife Single Electrode Probes consists of a primary trocar with an adjustable electrode. The probe is available in 15 cm and 25 cm trocar lengths and includes a main cable with a connector incorporating RFID technology. The 15cm and 25cm Single Electrode probes are available in Activator or Standard configurations. One Activator probe is required per procedure plus up to 5 Standard probes depending on the desired clinical outcome.

The NanoKnife Single Electrode Probe Spacer is intended for use with AngioDynamics NanoKnife Single Electrode Probes only. The NanoKnife Single Electrode Probe Spacer is a single use component which is intended to aid in positioning and spacing of the NanoKnife Single Electrode Probes during probe placement. It is critical that the Single Electrode Probes are placed at the appropriate spacing and parallel to each other. The Spacer has one primary probe location and 4 secondary probe locations allowing the user to position probes from 10 mm to 25 mm apart in 5 mm increments (10, 15, 20 and 25 mm probe spacing) while maintaining a parallel orientation prior to needle insertion into tissue. The Single Electrode Probes can either be slid or snapped into the spacer.

Classification according to European Directive 93/42/EEC:

EU Classification for the NanoKnife Single Electrode Probes: Class IIb, Rule 6 Annex II

EU Classification for the NanoKnife Single Electrode Probe Spacer: Class 1, Rule 1 Annex VII

Biological Safety:
The AngioDynamics, Inc. NanoKnife Single Electrode Probes and NanoKnife Single Electrode Probes Spacer do not contain biological tissues or materials derived there from, and have no biologically active elements, materials, or coatings.

Configurations:

Model Number	Description
20400103	NanoKnife Single Electrode Activator Probe (15 cm)
20400104	NanoKnife Single Electrode Standard Probe (15 cm)
20400105	NanoKnife Single Electrode Activator Probe (25 cm)
20400106	NanoKnife Single Electrode Standard Probe (25 cm)
20400301	NanoKnife Single Electrode Probe Spacer

Patient Contact Materials:

NanoKnife Single Electrode Probe:

Handle	Acetal resin
Stylet Hub	304 Stainless Steel
Trocar Stylet	304 Stainless Steel
End Cap	Acetal resin
Nose Cap	Acetal resin
Insulator Tube	Polyimide
Ink	Tampapur TPU Black ink
Trigger	ABS Plastic
Graduation Label	Mylar
Adhesive	Loctite 4011 – Ethyl Cyanoacrylate

NanoKnife Single Electrode Probe Spacer:

Spacer	ISOPLAST 2510 PU resin + Clariant (RV53631428); 293C Blue

The NanoKnife Single Electrode Probe and NanoKnife Single Electrode Probe Spacer are not manufactured from materials containing Latex, DEHP or BPA.

Packaging Materials:

Single Electrode Probe:

Pouch	Tyvek/Mylar
Packaging Tube	Polyurethane
Box	Chipboard

NanoKnife Spacer:

Pouch	Tyvek / Polyester/2.0 mil Polyethylene
Box	SBS

Sterilization:

The NanoKnife Single Electrode Probe and NanoKnife Single Electrode Probe Spacer are provided sterile and are intended for single use only. The NanoKnife Single Electrode Probe and NanoKnife Single Electrode Probe Spacer sterilization cycle has been validated in accordance with the following standards and references:

- ISO 11135-1:2007, Medical Devices: Validation and Routine Control of Ethylene Oxide Sterilization
- EN ISO 11138-2:2009, Biological Indicators for Ethylene Oxide Sterilization
- ISO 10993-7:2008 Biological Evaluation of Medical Devices – Part 7 Ethylene oxide sterilization residuals
- AAMI TIR 16, 2009, Process Development and Performance Qualification for Ethylene Oxide Sterilization – Microbiological Aspects

Biocompatibility:

Appropriate biocompatibility testing has been completed per the requirements of ISO 10993-1 and its relevant sub-guidance.