

WARNING

This device has been validated and is warranted for single-use only. Any re-use or reprocessing could destabilize the design structure of the device, which could result in device failure, which in turn could result in patient and/or user injury, illness or death. Also, any re-use or reprocessing could create the risk of cross-contamination of the device, which could result in patient infection or cross-infection.

WARNING

Potential adverse effects of argon coagulation therapy include, but are not limited to: risk of perforation, hemorrhage, thermal burns and explosion.

The Genii ArConnect™ can only be used with the Genii GI4000 generator. In conjunction with the Genii GI4000, the ArConnect™ can be used with standard disposable argon coagulation probes such as the Erbe 20132-156.

NOTE: Based on test results, the ArConnect meets all applicable requirements of IEC 60601-2-2 to support a high-frequency rating of 4kVp.

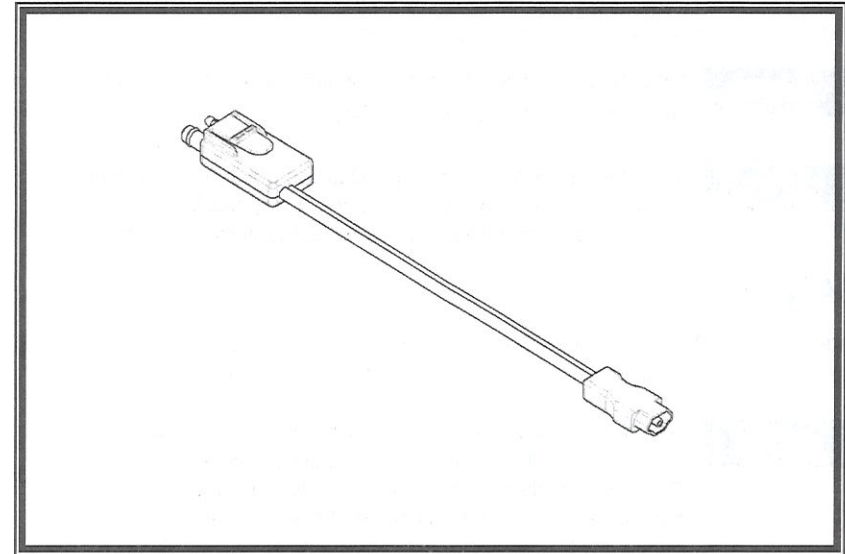
genii®
generating ingenuity

ArConnect™

Single Use

**Conducting Adapter for
Argon Coagulation Probe Attachment**

Part number: G11-200-20

INSTRUCTIONS FOR USE

Genii, Inc.
2145 Woodlane Drive, Suite 101-W
St. Paul, MN 55125
1-855-501-4810
www.genii-gi.com










Rx Only

REV 3 11
NR87011 Rev A

READ CAREFULLY BEFORE USING

SYMBOLS

The meaning(s) of the symbol(s) shown on the package and/or this device are as follows:

	Consult Instructions		Prescription Statement
	Non Sterile		Do Not Use If Package Is Opened Or Damaged
	Date of Manufacture		Batch Number
	Catalog Number		Manufacturer
	Do Not Reuse		

SIGNAL WORDS

The following signal words are used throughout this insert:

WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

SAFETY

Indications for Use: The Genii ArConnect™ conducting adapter is intended for use with the Genii™ GI4000 electrosurgery generator during argon assisted coagulation.

CAUTION Only the user can evaluate the clinical factors involved with each patient to determine if the use of this device is indicated. The user must then decide on the specific technique and procedure that will best accomplish the desired clinical effect. Do not use this device for any purpose other than the stated indication for use.

WARNING The user must thoroughly understand the technical principles, clinical techniques and risks associated with the use of high frequency electrosurgical energy and argon coagulation in general and the characteristics of the GI4000 and the chosen argon coagulation probe before using this product.

No latex is used in the manufacturing process.

CONSTRUCTION

Design: The single use ArConnect™ has been designed to allow the delivery of monopolar high frequency electrosurgical energy and argon gas to a single use argon coagulation probe sold separately. Designed for use only with the Genii GI4000 generator with positive pressure gas control to prevent fluid contamination of the generator.

CONTRAINDICATIONS

Argon coagulation therapy, and therefore this device, must never be used in the treatment of patients with the following:

- Massive active hemorrhage requiring open surgical intervention
- Esophageal or gastric varices
- Any indication of free peritoneal air
- Inadequately visualized bleeding sites
- Inadequate colon preparation

INSTRUCTIONS FOR USE

1. Remove the device from the package and handle with clean technique. **Save the product lot number for future reference.**
2. Inspect for any functional abnormality and ensure that insulation is intact. If any irregularities are noted, call Genii, Inc. for a return authorization number.
3. Apply grounding pad to patient according to your facility's protocol and manufacturer's recommendation and attach ArConnect to the GI4000 electrosurgical generator at the picture matched compatible connector port.
4. Attach a compatible single use argon coagulation probe of choice.
5. Proceed with the argon coagulation procedure per facility protocol.
6. When treatment is complete, carefully withdraw the argon coagulation probe from the endoscope and disconnect the ArConnect from the GI4000 by depressing the thumb tab and pulling the device toward you.
7. Dispose of both of the used devices according to your healthcare facility's disposable instrument protocol.