

**WARNING**

This device has been validated and is warranted for single-use only. Any re-use, reprocessing or re-sterilization 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, reprocessing or re-sterilization could create the risk of cross-contamination of the device, which could result in patient infection or cross-infection.

**WARNING**

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

**GUIDELINES FOR POWER SETTINGS**

Published literature, testing and experience gained from the use of endoscopic devices similar to the TouchSoft Coagulator® indicate the following recommendations:

1. The TouchSoft Coagulator is a monopolar device and must always be used with monopolar outputs and with a return electrode (grounding pad). A “Split-pad” with contact quality return monitoring is recommended.
2. Always choose the lowest power setting and shortest time duration (3 seconds or less) that will achieve the desired clinical result. If available, choose a generator mode with a low voltage narrow power curve output.  
Always consult the generator manual for recommended mode setting and recommended starting ranges.

**WARNING**

Power settings higher than ranges noted below, or uninterrupted application times longer than 3 seconds can promote sticking of the device to tissue. Maximum wattage must not exceed 60W for TouchSoft™ coagulation or 25W for “Standard Coag”. Not suitable are high crest factor (6.5 and above), spray coagulation or fulguration outputs.

The TouchSoft Coagulator can be used with, but is not limited to, the following generators and flexible endoscopes:

GENERATOR MODEL NUMBER	MODE SETTING	RANGE IN WATTS	RECOMMENDED STARTING WATTS	ENDOSCOPE CHANNEL DIAMETER	ENDOSCOPE WORKING LENGTH
Erbe ICC 200, Erbe VIO 300D, VIO 200S, VIO 100C Olympus ESG 100	Soft Coag®	45-60	50	2.8mm or Larger	260cm Maximum
Genii Gi4000	TouchSoft™	40-60	50-60	2.8mm or Larger	260cm Maximum

**NOTE:** Monopolar Active Cords that are compatible with the TouchSoft Coagulator are commonly available for the generators mentioned above.

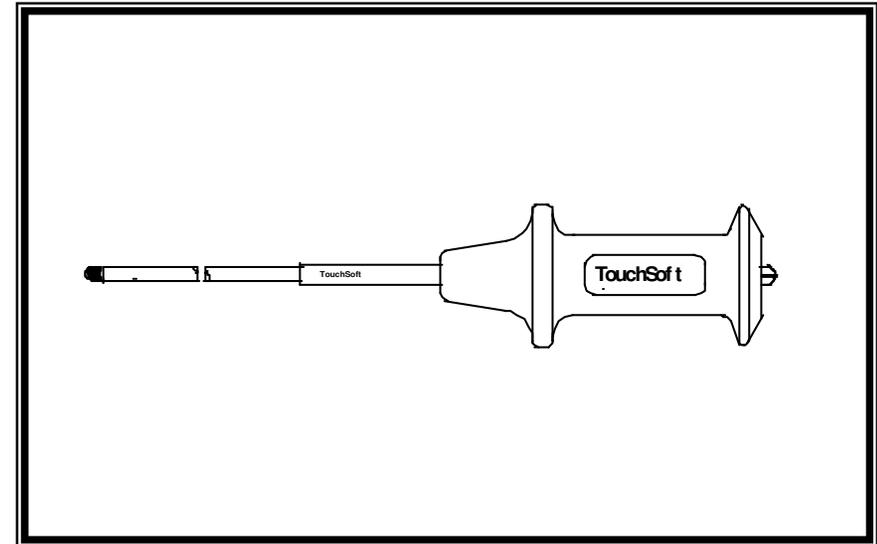
**NOTE:** Based on test results, the TouchSoft Coagulator meets all applicable requirements of IEC 60601-2-2 to support a high-frequency rating of 6kV, peak to peak.

**NOTE:** TouchSoft Coagulator® and Soft Coag® are registered US trademarks of Genii Inc. and Erbe Elektromedizin respectively. TouchSoft™ is a trademark of Genii Inc.



# TouchSoft Coagulator®

## Monopolar Single Use

**INSTRUCTIONS FOR USE**

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**Rx Only**

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# 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
	Use By		Package Damaged
	EO Sterilized		Batch Number
	Date of Manufacture		Manufacturer
	Catalog Number		No Latex
	Do Not Reuse		

## SIGNAL WORDS

The following signal words are used throughout this manual:

**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 TouchSoft Coagulator® is used to provide monopolar therapeutic hemostasis and tissue ablation in the gastrointestinal tract through a flexible endoscope by a trained physician or clinician.

**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 in general and the characteristics of their chosen electrosurgical generator in particular before using this product.

## CONSTRUCTION

**Design:** The single use TouchSoft Coagulator® has been designed to allow the delivery of monopolar high frequency electrosurgical energy to tissue for the treatment of visible active and inactive bleeding sites. This device has been sterilized using Ethylene Oxide.

## CONTRAINDICATIONS

**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 maintain device sterility.  
**Save the product lot number for future reference.**  
**IMPORTANT: Read Section “Guidelines for Power Settings” on next page.**
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 to compatible electrosurgical generator.
4. Attach the TouchSoft Coagulator to the appropriate power connectors (active cord) of the compatible generator.
5. Select the generator output to be used with the TouchSoft Coagulator. Low voltage narrow power curve outputs are preferred. **NOTE:** See Section “Guidelines for Power Settings” on next page.
6. After endoscopically visualizing the treatment site, carefully insert the distal end of the TouchSoft Coagulator into a flexible endoscope with a 2.8mm or larger biopsy channel. Advance the device using short 2cm strokes until the distal tip of the coagulator is fully visualized.

**WARNING** Do not activate the device while in contact with the Endoscope, or any other devices, as unintended tissue injury and/or damage to the scope may occur as a result of capacitive coupling.

7. Apply the tip of the TouchSoft Coagulator to the desired treatment site.  
**NOTE:** Activate the generator only when the distal end is near or touching the target tissue.

**CAUTION** Do not apply excessive heat, force or prolonged application time, as this may cause damage to the device, sticking of the device to the tissue or other undesirable effects, including possible perforation.

8. Begin delivery of electrosurgical power to the treatment site as desired.
9. Maintain visualization of the distal tip and repeat steps 7 & 8 as necessary.
10. When treatment is completed, carefully withdraw the Touchsoft Coagulator from the endoscope.
11. Dispose of the contaminated device according to your healthcare facility’s disposable instrument protocol.