



Tricera Handpiece, Autoclavable (R-10011)

Instructions for Use

PREFACE

This manual provides the information to operate and maintain the Tricera Handpiece. It is essential to read and understand all the information in this manual before using or maintaining this device. Refer to www.religncorp.com for the latest revision of this document.

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1. SYMBOLS USED ON LABELING

	Catalog Number		Consult Instructions for Use
	Serial Number		Non-Sterile
	Store in a cool dry place		MRI unsafe
	Date of Manufacture		Manufacturer
	Type BF Applied Part		Waste Electrical and Electronic Equipment. Must follow local law for equipment disposal.

2. DEVICE DESCRIPTION

The Tricera Handpiece is a reusable, electrically powered, hand-held surgical instrument that uses interchangeable shaver blades/RF probes to abrade and remove bone and accomplish the debridement of soft tissue. The handpiece features a quick-locking mechanism for easy blade insertion and removal, and a suction irrigation port for removing irrigant from the operating site.

The Tricera Handpiece is for use with the Relign Tricera System.
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3. INDICATIONS FOR USE

The Relign Arthroscopic System is indicated for use in orthopedic and arthroscopic procedures. The Fluid Management System of the Relign Arthroscopic System provides fluid distension and irrigation of the knee, shoulder, ankle, elbow, wrist and hip, and fluid suction during diagnostic and operative arthroscopic procedures. The Shaver Blade/RF Probe of the Relign Arthroscopic System provides abrasion, resection, debridement, and removal of bone through its shaver blade; removal, ablation, and coagulation of soft tissue; as well as hemostasis of blood vessels through its shaver blade and probe. Examples of uses of the product include resection of torn knee cartilage, subacromial decompression, and resection of synovial tissue in other joints.

Contraindications: The electrosurgical probe should not be used in procedures where a nonconductive irrigant is used or with patients having cardiac pacemakers or other electronic implants.

4. CONTRAINDICATIONS

The Relign Arthroscopic System contains a large amount of metal components. Therefore, it is MRI unsafe. DO NOT use the Relign Arthroscopic System in conjunction with MRI, CT or RFID.

5. WARNINGS AND CAUTIONS

Please read this manual and follow its instructions carefully. The words **warning**, **caution**, and **note** carry special meanings and should be carefully reviewed:

Warning The personal safety of the patient or physician may be involved. Disregarding the information could result in injury to the patient or physician.

Caution Special service procedures or precautions must be followed to avoid damaging the instrument.

Note Special information to make maintenance easier or important information more clear.



An exclamation mark within a triangle is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying the product.

Warning



To avoid potential serious injury to the user and the patient and/or damage to this device, please note the following warnings:

- 1) Federal law (United States of America) restricts this device to use by, or on order of, a physician.
- 2) To avoid potential serious injury to the user and patient and/or damage to this device, read this operating manual thoroughly and be familiar with its contents prior to using this equipment.
- 3) The Tricera Handpiece is designed to be used by a qualified physician familiar with arthroscopic procedures. It is the responsibility of the user to be familiar with indications, contraindications, potential complications and risks associated with the arthroscopic procedures being performed. Misusing the Tricera Handpiece may cause damage to both the patient and system components.
- 4) Carefully unpack the unit and check if any damage occurred during shipment. DO NOT use the instrument if damage is detected. Please refer to the Customer Service/ Technical Support section in this manual.

- 5) The Tricera Handpiece is supplied non-sterile. It must be cleaned and sterilized before the first use. Prior to each subsequent use, it must be cleaned and sterilized.

Caution



To avoid potential damage to this device, please note the following cautions:

- 1) Test this instrument for functionality prior to a surgical procedure. This unit was fully tested at the factory before shipment.
- 2) Attempt no internal repairs or adjustments not specifically detailed in this manual. Doing so may cause damage to the device.
- 3) Pay close attention to the care and cleaning instructions in this manual. Any deviations may cause damage.
- 4) Avoid exposing the handpiece to sudden temperature changes. Do not immerse hot handpiece into cold water or liquid. Allow the handpiece to properly cool after sterilization cycles.
- 5) Between uses, the device must be stored in accordance with these instructions. Storing in another manner may result in damage or loss of function.
- 6) Read the entire instruction manual before using or connecting the unit.

The warranty is void if any of these warnings or cautions is disregarded.

Relign Corporation accepts full responsibility for the effects on safety, reliability, and performance of the instrument only if:

- Readjustments, modifications, and/or repairs are carried out exclusively by Relign Corporation.
- The electrical installation of the relevant operating room complies with the applicable IEC, CEC, and NEC requirements.

Relign Corporation is not responsible for damage caused by misuse of the Tricera Handpiece. Misuse of the Tricera Handpiece shall void the warranty.

Relign Corporation reserves the right to make improvements in the product(s) described herein. Product(s), therefore, may not agree in detail to the published design or specifications. All specifications are subject to change without notice. Please contact the local Relign Corporation sales representative or agent for information on changes and new products.

6. COMPATIBILITY

Tricera Handpiece is for use in conjunction with the Relign Tricera System. Refer to Relign Tricera System instructions for directions on use of the Tricera Handpiece as part of the Relign Tricera System.

Before using the Tricera Handpiece with any other accessory or device, be sure to follow the instructions provided with the accessory or device.

7. HOW SUPPLIED

Warning



The Tricera Handpiece is supplied non-sterile. It must be cleaned and sterilized before the first use. Prior to each subsequent use, it must be cleaned and sterilized.

The shipping box contains:

- 1 ea Relign Tricera Handpiece, Autoclavable
- 1 ea Shaver Blade/RF Probe Cavity Brush (Gordon Brush PN 721012 or equivalent)

- 1 ea Motor Shaft Brush (Key Surgical PN AT-12-197 or equivalent)
- 1 ea Fluid Channel Brush (Gordon Brush PN 499NAD-ST or equivalent)

8. REQUIRED MATERIALS

8.1. MATERIALS USED EACH TIME THE TRICERA HANDPIECE IS BEING REPROCESSED

Cleaning

- Enzymatic neutral pH cleaner (ENZOL® or equivalent)
- 25mL volume disposable syringe (2 each)
- Shaver Blade/RF Probe Cavity brush (**Appendix A**)
- Motor Shaft brush (**Appendix A**)
- Fluid Channel brush (**Appendix A**)
- Gauze pads
- Lukewarm running tap water 72° - 109°F (22° - 43°C)
- Optional Sterilization Tray (ASP PN 13836), which can be purchased directly from the manufacturer (**Appendix A**)

Sterilization

- STERRAD 100S
- STERRAD 100NX
- STERRAD NX
- STERIS V-PRO
- AUTOCLAVE

8.2. MATERIALS MAY BE USED FOR CLEANING VERIFICATION

- 3% hydrogen peroxide

9. INSPECTION, MAINTENANCE AND TESTING

Warning



The handpiece is supplied non-sterile. It must be cleaned and sterilized before the first use. Prior to each subsequent use, it must be cleaned and sterilized.

9.1. INSPECTION PRIOR TO USE

Prior to each use, inspect the outer surface of the handpiece and the inner surface of the shaver blade/RF probe cavity and fluid channel to ensure there are no unintended rough surfaces, sharp edges, or protrusions.

9.2. MAINTENANCE AND TESTING

Relign recommends careful inspection of the handpiece and any accessories before and after each procedure for possible signs of damage. This will allow early detection of minor damage, which if repaired immediately will increase the life of the handpiece.

Caution



To avoid potential use of damaged device that could lead to injury to the user and/or the patient, please note the following cautions:

- 1) If deposits are not removable by cleaning, the handpiece should be sent to the manufacturer or an authorized service specialist to be checked.
- 2) A handpiece with a damaged cable should be sent to the manufacturer or an authorized service specialist to be checked.

10. REPROCESSING INSTRUCTIONS

Warning To minimize the risk of infection, clean and sterilize the handpiece prior to the first use and every use thereafter. Please note the following warnings:



- 1) Concentration levels specified by the manufacturer of the detergent must be strictly adhered to. Contact times specified in these instructions for use must be strictly adhered to. Use only freshly prepared solutions.
- 2) Do not soak the handpiece in Isopropyl Alcohol or other corrosive liquids that may not be compatible with the instrument.
- 3) Always use fresh volumes of water for rinsing. Do not reuse rinsing water for rinsing or any other purpose.

10.1. CLEANING INSTRUCTIONS

Proper cleaning must be performed prior to sterilization. An effective cleaning process is essential to ensure effective sterilization.

Clean the handpiece as soon as possible after use.

If it is not possible to clean/rinse the handpiece immediately following a procedure, the instrument should be placed in a basin with clean lukewarm tap water until proper cleaning can be commenced per the instructions below.

Cleaning Agent:

Use ENZOL® or an equivalent neutral pH enzymatic detergent. Enzymatic detergents aid in the removal of organic soil such as blood.

Cleaning the Handpiece:

- 1) Disassemble the handpiece from the other system components.
 - a. Remove the shaver blade/RF probe from the handpiece.



- b. Dispose of all used shaver blades/RF probes according to hospital regulations.



- c. Disconnect the handpiece from the Relign Controller.



- 2) Attach the soaking cap to the cable connector.

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Caution Always install the soaking cap prior to cleaning or sterilization. If moisture reaches the connection pins of the cable connector, it could damage the connector.



- 3) Gently and thoroughly rinse the handpiece under running lukewarm tap water 72° - 109°F (22° - 43°C) for a minimum of 2 minutes, flushing water through all passages.



- 4) Lay the handpiece horizontally in a clean pan.



- 5) Prepare the cleaning solution, enzymatic neutral pH cleaner (ENZOL® or equivalent), in accordance with the concentration defined by the manufacturer of the detergent.
- 6) Add a sufficient amount of the prepared cleaning solution to the pan to completely cover the handpiece.

Caution Do not immerse the handpiece when it is hot. This may damage the handpiece.



- 7) Soak the handpiece for a minimum of 10 minutes. Move the handpiece back and forth 5 times to ensure that all surfaces are exposed to cleaning solution. This will reduce blood, protein, and mucus from the instrument.
- 8) Flush the cavity and lumens of the instrument 5 times with minimum 25mL volume of cleaning solution using a disposable syringe.



- 9) Scrub the Shaver Blade/RF Probe Cavity using the Shaver Blade Cavity cleaning brush for a minimum of 1 minute.



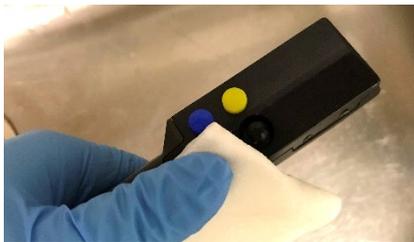
- 10) Scrub the Motor Shaft using the Motor Shaft cleaning brush for a minimum of 1 minute.



- 11) Scrub the Fluid Channel using the Fluid Channel cleaning brush for a minimum of 1 minute.



- 12) Ensure that all interior surfaces, crevices, lumens, cavities, and holes of the handpiece are scrubbed thoroughly to remove any visible debris.
- 13) Scrub the exterior surface of the handpiece with a gauze pad soaked in the cleaning solution for a minimum of 1 minute.



- 14) Remove the handpiece from the cleaning bath and rinse it thoroughly, flushing the interior lumens and cavities, for a minimum of 2 minutes under running lukewarm tap water 72° - 109°F (22° - 43°C).



Cleaning Verification

- 15) After cleaning, inspect the handpiece under normal lighting to ensure that all visible debris has been removed.
- 16) If not visibly clean, repeat cleaning and re-inspect.
- 17) For difficult-to-view areas, 3% hydrogen peroxide may be applied (bubbling is evidence of the presence of blood).

Note: Rinse the handpiece thoroughly under running lukewarm tap water 72° - 109°F (22° - 43°C) following any hydrogen peroxide testing.

- 18) Shake the handpiece with the shaver blade cavity end pointing downward to remove any water.
- 19) Dry the handpiece with a lint-free towel.

Note: Compressed air or nitrogen may be used to remove any additional moisture from the handpiece.

10.2. STERILIZATION INSTRUCTIONS

Clean and sterilize the handpiece prior to the first use and every use thereafter.

Caution Never sterilize the handpiece that has not been cleaned. The success of the sterilization process depends on the previous state of cleaning.



Caution Always install the soaking cap prior to cleaning or sterilization. If moisture reaches the connection pins of the cable connector, it could damage the connector.



Caution The handpiece can be sterilized by using the following methods only.



Sterilizing the Handpiece:

- Clean the handpiece according to the "Cleaning Instructions" section of this manual.
- Attach the soaking cap to the cable connector if it is not already attached.

Caution Do not cross-sterilize the handpiece. Alternating between different methods of sterilization may cause undue wear on the handpiece. Product longevity is extended by the consistent use of a single sterilization method.



Caution Remove the handpiece from the sterilizer immediately after sterilization, or product damage may result.



Caution Never immerse the handpiece in a liquid to help it cool after sterilization, or product damage may result. If necessary, cool the handpiece by wrapping it in a sterilized damp sponge or cloth.



- Prepare the handpiece for sterilization by either:
 - Wrapping the handpiece in Kimberly-Clark Kimguard KC400 Sterilization Wrap or equivalent
 - Following the steps below if the optional Sterilization Tray is to be used.
- Place the handpiece into the optional Sterilization Tray as shown in the figure below. Ensure that the handpiece is snapped into the rubber holders.



- 5) Coil the cable up adjacent to the handpiece. Ensure that the soaking cap is placed on the cable connector
- 6) Place the lid onto the sterilization tray.



- 7) Wrap the sterilization tray in Kimberly-Clark Kimguard KC400 Sterilization Wrap or equivalent.
- 8) Sterilize the handpiece according to the parameters listed for one of the following methods:

STERRAD 100S Method:

- 1) Clean the handpiece according to the "Cleaning Instructions" section of this manual.
- 2) Ensure the soaking cap is installed.
- 3) Run STERRAD 100S Short Cycle Sterilization System per the manufacturer's instructions.

STERRAD 100NX Method:

- 1) Clean the handpiece according to the "Cleaning Instructions" section of this manual.
- 2) Ensure the soaking cap is installed.
- 3) Run STERRAD 100NX STANDARD Cycle Sterilization System per the manufacturer's instructions.

STERRAD NX Method:

- 1) Clean the handpiece according to the "Cleaning Instructions" section of this manual.
- 2) Ensure the soaking cap is installed.
- 3) Run STERRAD NX Standard Cycle Sterilization System per the manufacturer's instructions.

STERIS V-PRO Method:

- 1) Clean the handpiece according to the "Cleaning Instructions" section of this manual.
- 2) Ensure the soaking cap is installed.
- 3) Run the Lumen Cycle on any of the following STERIS V-PRO Sterilization Systems per the manufacturer's instructions: V-PRO 1, V-PRO PLUS, V-PRO MAX, V-PRO MAX 2.

AUTOCLAVE Method:

- 1) Clean the handpiece according to the "Cleaning Instructions" section of this manual.
- 2) Ensure the soaking cap is installed.
- 3) Run the Steam Pre-vacuum Cycle on the Autoclave per manufacturer's instructions.

Refer to the sterilization parameters below:

- | | |
|------------------------------|-------------------------|
| a. Temperature: | 132-134 °C (270-273 °F) |
| b. Min. Steam Exposure Time: | 4 minutes |
| c. Min. Dry Time: | 20 minutes |

11. STORAGE

The handpiece and accessories should be stored either in their shipping box or in a sterilization tray. In either case, ensure that the Tricera Handpiece is immobile to prevent any damage.

12. PERIODIC MAINTENANCE SCHEDULE

To ensure the safety and longevity of your handpiece, observe the following maintenance procedures.

Before every surgical procedure:

- 1) Assemble the entire system, including the controller, footswitch, handpiece, and shaver blade/RF probe.



Caution To ensure proper heat dissipation and keep the joints clear, do not run the handpiece without proper suction or irrigation. Immerse the blade in a sterile irrigant and activate suction while testing the handpiece.

- 2) Run the handpiece through its various functions, modes, and settings to ensure it responds properly to commands. Ensure that all parts move freely and that there are no loose or missing components. Note any unusual sounds or vibrations, and note operating speeds.
- 3) Refer any calibration or operating difficulties to your Relign sales representative or Relign Customer Service.

Every 12 Months:

Check the leakage current using a true RMS digital multimeter and safety analyzer. Consult the analyzer's instructions for details.

13. LIMITED WARRANTY

Relign warrants to the original purchaser of Tricera Handpiece that the Tricera Handpiece will be free of defects in material and workmanship for a period of one year after the date of purchase when used as intended under normal operating conditions and in conformance with its instructions for use and maintenance instructions. Any warranty concerning software and/or hardware upgrades shall expire in the original one-year warranty. The sole obligation of Relign and its affiliates under this warranty shall be limited to the replacement of the Tricera Handpiece or equivalent models, at no charge to the original purchaser and at the option of Relign, during the warranty period but only if examination reveals to the satisfaction of Relign that the Tricera

Handpiece contains a defect in material or workmanship. Relign and its affiliates will not be liable for any incidental, special or consequential loss, damage, or expense resulting, directly or indirectly, from the use of its product regardless of whether Relign or its affiliates have been advised of the possibility of such loss, damage or expense.

This warranty is made in lieu of all other warranties, expressed, implied or statutory, including, but not limited to the implied warranties of merchantability and fitness for a particular purpose and all other obligations and liabilities on the part of Relign. Relign neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale of the Tricera Handpiece. This warranty shall not apply to the Tricera Handpiece or any other part thereof that has been subject to accident, negligence, alteration, abuse or misuse. Relign makes no warranty whatsoever with regard to accessories or parts used in conjunction with the Tricera Handpiece and not supplied and manufactured by Relign.

No agent, employee, or representative of Relign or its affiliates has any authority to change any of the foregoing or assume or bind Relign or any of its affiliates to any additional liability or responsibility in connection with this device. The essential purpose of this provision is to limit the potential liability of Relign and its affiliates arising out of this agreement and/or any purchase and sale hereunder. Original purchaser shall be responsible for ongoing equipment support and maintenance not covered by this warranty and after the warranty period has expired.

The term "original purchaser," as used in this warranty means that person or organization and its employees, if applicable, to whom the Tricera Handpiece was sold by Relign. This warranty may not be assigned or transferred in any manner.

In order to make a warranty claim, the original customer must obtain a Return Materials Authorization Number ("RMA Number") and return instructions from Relign's Customer Service Department or authorized representative. The allegedly defective Tricera Handpiece must be returned, cleaned, repackaged, clearly marked with the RMA number on all packaging, and adequately insured, to the following address: Relign Corporation, 655 Campbell Technology Parkway, Suite 275, Campbell, CA 95008.

14. CUSTOMER SERVICE/TECHNICAL SUPPORT

Contact Relign's Customer Service for any customer or technical support. Call 866-608-0131 or e-mail us at customer.service@Religncorp.com.

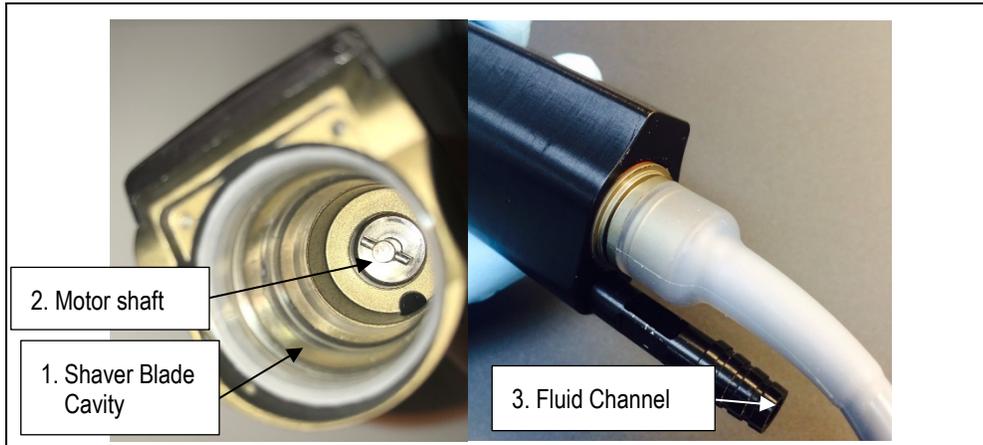
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APPENDIX A: TRICERA HANDPIECE, AUTOCLAVABLE COMPONENTS

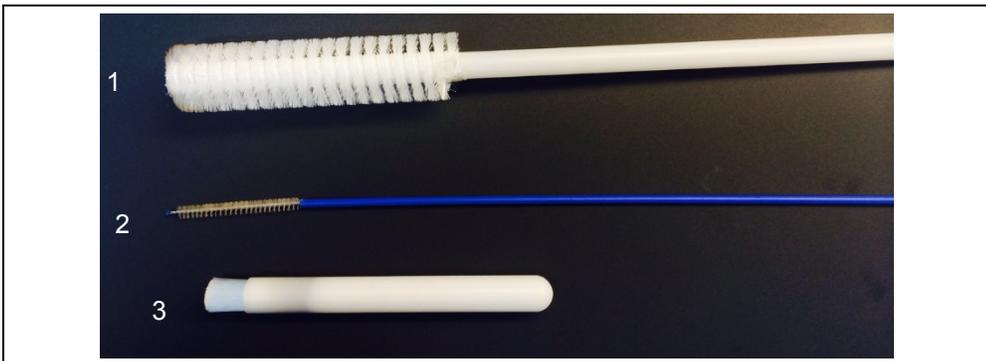


Figure A1: Relign Tricera Handpiece, Autoclavable



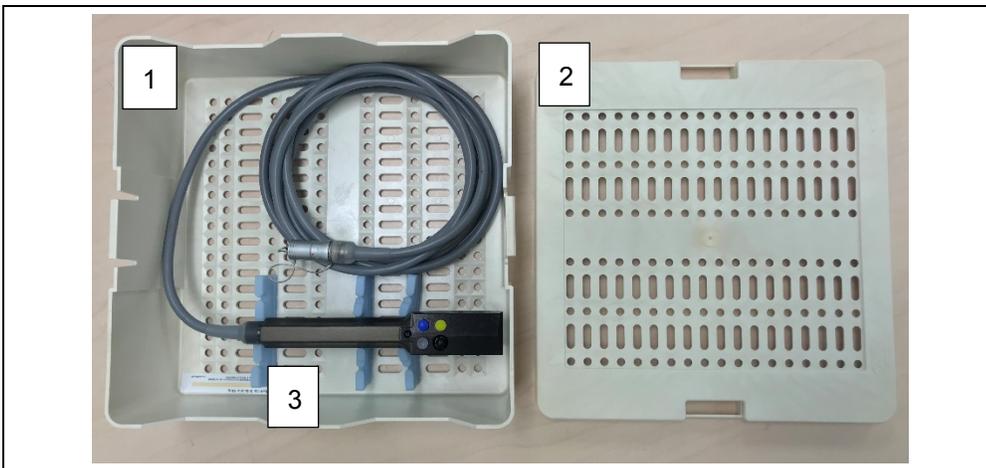
- 1. Shaver Blade/RF Probe Cavity
- 2. Motor Shaft
- 3. Fluid Channel

Figure A2: Tricera Handpiece



- 1. Shaver Blade/RF Probe Cavity Brush (Gordon Brush PN 721012 or equivalent)
- 2. Fluid Channel Brush (Key Surgical PN AT-12-197 or equivalent)
- 3. Motor Shaft Brush (Gordon Brush PN 499NAD-ST or equivalent)

Figure A3: Cleaning Brushes



- 1. Sterilization Tray
- 2. Sterilization Tray Lid
- 3. Rubber Holders

Figure A4: Optional Sterilization Tray (if available)

APPENDIX B: TROUBLESHOOTING

Problem	Possible Cause	Recommended Action
Staining, discoloration	- Inadequate cleaning (for example, remaining protein residues)	- Clean in accordance with section 10.1
	- Cleaning solutions are contaminated or being reused	- Always use freshly prepared solutions - Repeat cleaning in accordance with section 10.1
The shaver blade does not turn.	The shaver blade is not inserted properly.	Remove the blade and reinsert it according to the Relign Tricera System instructions for directions on use of the Tricera Handpiece as part of the Relign Tricera System.
The handpiece will not run.	The handpiece is not properly connected to the controller.	Remove and reconnect the handpiece cable to the controller according to the Relign Tricera System instructions for directions on use of the Tricera Handpiece as part of the Relign Tricera System.
	The cord is malfunctioning.	Send the handpiece in to Relign for repair.
The Activate function is not operating smoothly.	- The cable is malfunctioning. - The Controller is malfunctioning.	- Remove and reconnect the handpiece to a different Controller. If the problem persists, send the Tricera Handpiece to Relign for repair.
The shaver blade/RF probe is not correctly detected by the handpiece.	The shaver blade/RF probe is not inserted properly.	Remove the shaver blade/RF probe and reinsert it according to the Relign Tricera System instructions for directions on use of the Tricera Handpiece as part of the Relign Tricera System.
	The handpiece is malfunctioning.	Remove and reconnect the shaver blade/RF probe to another Tricera Handpiece to confirm the possible cause. Send the malfunctioning Tricera Handpiece to Relign for repair.