

Disposable Handle Assembly Instructions For Use/Care

Revised 09/2009

Device Description

The **DH0100** and **DH0500** series **Disposable** Handle Assemblies are fully disposable surgical instruments which are packaged for use without additional setup. Most inserts fit standard 5.5mm trocar cannulas. (Inserts with a larger or smaller cross-section are identified in the catalog description.)

The Disposable Handle Assemblies are available in various operative lengths and styles. Refer to your Encision catalog for specific catalog numbers.

NOTES:

- **This device does not transmit electrosurgical energy.**
- The DH0100 and DH0500 series Disposable Handle Assembly is supplied sterile and is not intended for more than one use. No attempt should be made to reprocess this device.
- Minimally invasive procedures should be performed only by surgeons having adequate training and familiarity with minimally invasive techniques and who are also knowledgeable about anatomy and pathology as well as the complications, hazards, risks and benefits of the procedure.

Indications/Intended Use

Indications for Use:

The Encision Disposable Handle Assemblies are used for minimally invasive surgical, laparoscopic and endoscopic procedures performed in general surgery, obstetrics/gynecology and gastroenterology/urology.

Contraindications:

- These instruments have not been shown to be effective for tubal sterilization procedures, and should not be used for these procedures.
- These instruments are not intended for use when minimally invasive techniques are contraindicated.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Instructions for Use

Prior to Use

- The DH0100 and DH0500 series Disposable Handle Assembly is supplied sterile.
- Inspect the package and instrument for damage prior to use. Do not use if package or product appears to be damaged.

Precautions

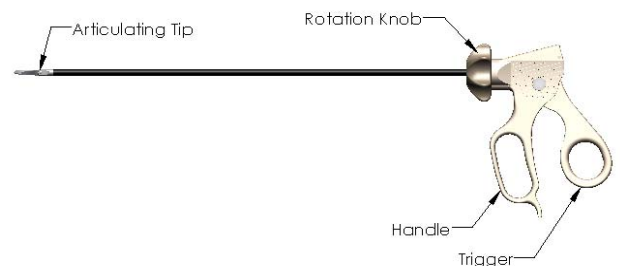
- **Warning:** Laparoscopic surgery may result in gas embolism due to insufflation of gas into the abdomen.
- Use these instruments only under conditions that assure adequate visualization.
- Do not conduct energy by touching an active instrument to the DH0100 and DH0500 series Disposable Handle Assembly. The handle assembly is not protected from capacitive coupling or insulation failure.
- Damaged external shaft insulation AND electrical contact with an active instrument may result in a risk of unintended patient burn, shock or fire hazard. Do not use product having damaged external insulation.

Principles of Operation

The handle and trigger open and close the working tip of the instrument.

The rotation knob turns to allow 360° orientation of the tip as the surgeon prefers.

The working tip of the instrument should always be closed when introducing or removing the instrument from the cannula.



End of Life Indicators

Discontinue use if any of the following are evident:

- Dulling of scissors
- Binding or impaired mechanical function
- After one (1) use.

Reprocessing

NOTES:

This product is intended for single use and shall not be reprocessed or resterilized. Resterilization may compromise the integrity of the device which may result in malfunction.

Used instruments are considered medical waste. Dispose of in accordance with local regulations.

Disposable Handle Assembly Instructions For Use/Care

Express Warranty

ENCISION hereby warrants to Buyer that products purchased hereunder shall be free from defects in materials and workmanship under normal use and service, as specified in these Instructions for Use/Care, until the labeled **USE BY** date, or one use, whichever occurs first.

Disclaimer: THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT ARE IN LIEU OF, AND BUYER HEREBY EXPRESSLY WAIVES, ALL OTHER GUARANTEES AND WARRANTIES OF ANY KIND, WHETHER EXPRESS, IMPLIED OR STATUTORY INCLUDING, WITHOUT LIMITATION, MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, NON-INFRINGEMENT OR BY SAMPLE, AND ALL SUCH OTHER WARRANTIES ARE HEREBY DISCLAIMED AND EXCLUDED BY ENCISION. THE SOLE AND EXCLUSIVE REMEDY FOR BREACH OF ENCISION'S WARRANTY OF THE PRODUCTS SHALL BE AS STATED HEREIN.

Exclusions: The express warranty set forth above specifically excludes and does not apply to defects (i) caused through no fault of ENCISION during shipment to or from Buyer, (ii) caused by modifications or alterations made to the products by Buyer or any third party (iii) caused by unauthorized repair or maintenance performed on the products by Buyer or any third party, (iv) caused by the failure of Buyer to comply with any of the return procedures specified below, or (v) damaged by excessive current, temperature, physical stress or other deviation from the applicable environmental specifications.

Limitation of Remedies: ENCISION's sole obligation and Buyer's exclusive remedy for any breach of warranty is limited to the repair or replacement, at Encision's option, of any warranted product that is returned to ENCISION in its standard shipping container or properly packed in accordance with ENCISION's packing procedures, freight prepaid, where ENCISION's examination shows the product to have failed under normal use. If ENCISION's examination discloses that the returned product is not defective within the terms of this warranty, Buyer shall be subject to a \$200.00 charge per individual product for testing expenses incurred by ENCISION and the product will be returned to Buyer, freight collect. Such repair or replacement and reshipment at ENCISION's expense will be Buyer's sole and exclusive remedy for such defect. ENCISION will pay shipping charges for the repaired or replaced products from ENCISION's factory to Buyer's location. If, notwithstanding the foregoing, Buyer ships any product to ENCISION's factory freight collect, then ENCISION shall ship the repaired or replaced products from ENCISION's factory to Buyer's location. If, notwithstanding the foregoing, Buyers ships any product to ENCISION's factory freight collect, then ENCISION shall ship the repaired or replaced product freight collect.

Warranty Procedures: Buyer shall request authorization from ENCISION prior to the return of each defective product for repair or replacement by ENCISION. Upon such request, ENCISION shall provide the address of the facility to which such product must be returned, together with a Return Material Authorization (RMA) tracer number. ENCISION may, at its sole option, employ new or used parts for products to make such repair or replacement.

Stored Data: ENCISION shall not be liable for any loss or damage to any data stored in any product, including, without limitation, any data loss or damage resulting from any malfunction or defect or any loss or damage resulting from any inspection, repair, refurbishment, reconditioning or testing of the product or incurred in connection with transportation of the product to ENCISION or ENCISION's authorized repair center.

Technical Assistance: ENCISION's warranty shall not be enlarged, and no obligation or liability shall arise out of ENCISION's rendering of technical advice or assistance in connection with the products sold hereunder.

LIMITATION OF LIABILITY. TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, IN NO EVENT SHALL ENCISION BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH OR ARISING OUT OF THE SALE, INSTALLATION, USE, OPERATION, SERVICE OR REPAIR OF ANY PRODUCT, WHETHER BASED ON BREACH OF WARRANTY OR CONTRACT, STRICT LIABILITY, NEGLIGENCE OR OTHERWISE, WHETHER OR NOT ENCISION SHALL HAVE BEEN ADVISED AS TO THE POSSIBILITY OR REASON FOR ANY SUCH POTENTIAL LOSS OR DAMAGE. DIRECT DAMAGES SHALL BE STRICTLY LIMITED TO THE COST TO BUYER OF THE PRODUCTS SOLD OR PROVIDED TO BUYER, NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

Return of Used Product

If for any reason this product must be returned to ENCISION, a returned goods authorization is required prior to shipping. Appropriate return instructions may be obtained from ENCISION at 303-444-2600.

Manufactured For

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Product

We reserve the right to amend, modify or to change any product, to introduce new products, to withdraw products and otherwise vary product specifications at any time without notice.

Symbols

 IRRADIATION STERILIZATION

 Federal (USA) law restricts this device to sale by or on the order of a physician.

 CATALOG NUMBER

 CAUTION, CONSULT ACCOMPANYING DOCUMENTS


 CONSULT INSTRUCTIONS FOR USE

 BATCH CODE

 USE BY

 DO NOT REUSE

 LATEX FREE

 Storage and Transport Conditions

 MANUFACTURER

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