



## GT400 Disposable Automatic

### Biopsy Instrument

#### with Safety

#### Manufacturer:

**German Medical Technology (Beijing) Co., Ltd.**

#### Registered Headquarters

Building 68A,A 1-2 Floor, No.16,Huan Ke Zhong Lu Jinqiao Science  
& Technology Industrial

Base Zhongguancun Science Park Tongzhou Park, Tongzhou

District BEIJING 101102, P.R. CHINA

#### Certified sites

Building 68A,A 1-2 Floor, No.16,Huan Ke Zhong Lu Jinqiao Science  
& Technology Industrial

Base Zhongguancun Science Park Tongzhou Park, Tongzhou

District BEIJING 101102, P.R. CHINA

Zone 1, Room 401, Floor 4, Building 24, No. 16, Huan Ke Zhong Lu,  
Tongzhou District, BEIJING 101102, P.R. CHINA

Room 301, Floor 3, Building 24, No. 16, Huan Ke Zhong Lu,

Tongzhou District, BEIJING 101102, P.R. CHINA

Tel: +86(10) 56940198 Fax: +86(10) 56940199

SRN: CN-MF-000011489



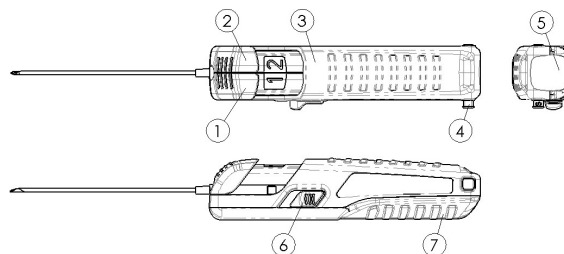
#### EC Authorized Representative:

#### Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd,  
2595AA, The Hague, Netherlands.

info@lotusnl.com

REV. 01/U



- |                          |                        |
|--------------------------|------------------------|
| 1. Cannula Thumb Knob    | 5. Rear Trigger Button |
| 2. Stylet Thumb Knob     | 6. Side Trigger Button |
| 3. Housing               | 7. Bottom Plate        |
| 4. Safety Release Button |                        |

### Instructions for Use: GT400 Disposable Automatic Biopsy Instrument with Safety

**Description:** The GT400 Disposable Automatic Biopsy Instrument with Safety is a spring-loaded, automatic, disposable instrument for histological core biopsies. It has 22mm penetration depth. It is available in various needle sizes. The side and rear trigger button are color coded according to the different needle gauges, e.g. Green for 14G, White for 16G, Pink for 18G, Yellow for 20G.

**Indication for Use:** The GT400 Disposable Automatic Biopsy Instrument with Safety is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

#### Precautions:

- This instrument should be used by or under the supervision of a physician who is completely familiar with the use and limitations of this instrument and biopsy sampling.

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- The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.).
- Never test the instrument by firing into the air. This could result in needle/cannula tip damage and/or patient injury.
- Unusual force applied to the stylet or unusual resistance against the stylet, while extended out of the supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with needle function.

#### Contraindications:











- This instrument should be used by a licensed physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of core needle biopsy.
- Good medical judgment is required in considering biopsy on patients who have a bleeding disorder, or are receiving anti-coagulant therapy.

#### Potential Complications:

Potential complications of core biopsy are site specific and may consist of hematoma, hemorrhage, infection, adjacent tissue injury, and pain.

#### Directions for Use:

1. Inspect the product package for damage. If undamaged, using proper aseptic technique, remove the instrument from its package.
2. Inspect the stylet for damage to the point, the cannula for damage to the cutting edge, or other imperfections that would prevent proper operation of the instrument.
3. Remove protective sheath.
4. Energize (cock) the instrument for firing by pulling back cannula thumb knob (as designated by the number "1" on the instrument) and releasing (thumb knob will return to forward position); by pulling back stylet thumb knob

	Do not re-use		Unique device identifier
	Sterilized using ethylene oxide		Keep away from sunlight
	Unit quantity in packaging		Authorized representative in the European Community
	Caution		Keep dry
	Do not use if package is damaged		CE marking of conformity and Identification number of the notified body

(as designated by the number “2” on the instrument) and releasing (thumb knob will return to forward position). Notice the status window is now without color. Or, hold the instrument with two hands. Put the instrument rear end firmly against the surface of the operating table and point the needle tip up. Use two thumbs to pull back both cannula and stylet knobs (as designated by the number “1” and “2” on the instrument) to energize the instrument.

5. Position the needle at the site of the biopsy, proximal to the area to be sampled, using your choice of guidance (Ultrasound, CT, etc.). The physician should determine if puncturing the skin with a scalpel is necessary to facilitate the insertion of the needle in a percutaneous procedure.
6. Release the safety by pushing the safety release button.
7. Firing the instrument can be achieved by pushing in on either the side trigger button or the rear trigger button. This action will trigger the spring mechanism, propelling the needle forward for a core biopsy sample.
8. After removing the needle from the patient, pull back the cannula thumb knob (as designated by the number “1” on the instrument) to expose the biopsy notch located at the distal end of the needle. This action exposes the specimen for removal. Pull back the stylet thumb knob (as designated by the number “2” on the instrument) will activate the instrument for a second biopsy if more samples are required.

**Storage Conditions**

Store the packaged product in a clean environment at room temperature, in a cool, dry, and well-ventilated area. Avoid direct sunlight exposure.

**Shelf Life:**

5 years









**Warning:**

The product must not be used if the packaging is damaged. The GT400 Disposable Automatic Biopsy Instrument with Safety is for **Single Patient Use Only. Do Not Reuse.**

**Do Not Resterilize.** Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient. After use this product may be a potential biohazard. Handle in a manner which will prevent accidental puncture. Dispose in accordance with applicable laws and regulations.

**WARRANTY:**

1. German Medical Technology (Beijing) Co., Ltd. is responsible only for products manufactured, inspected, and packaged. This is the sole effective guarantee and supersedes any other stated guarantees.
2. German Medical Technology (Beijing) Co., Ltd. is not liable for treatment outcomes, complications, or treatment failures due to misuse or improper operation. Defective products from German Medical Technology (Beijing) Co., Ltd. will be replaced.
3. German Medical Technology (Beijing) Co., Ltd. are not authorized to deviate from these terms and conditions, nor to accept additional or supplementary responsibilities.

	Date of manufacture		Use-by date
	Catalogue number		Medical device
	Manufacturer		Batch code
	Do not re-sterilize		Consult instructions for use