



GT20 Disposable Semi Automatic Biopsy Instrument

with Safety and Spacer

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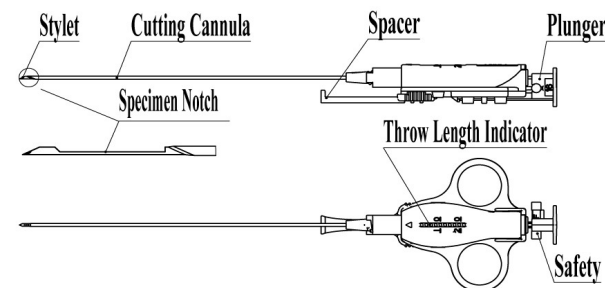


Fig. 1

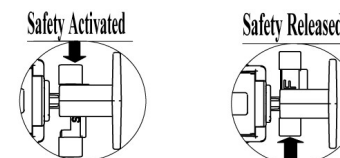


Fig. 2

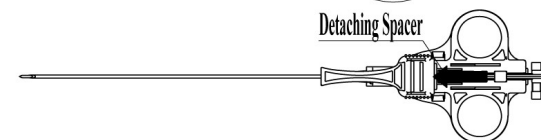


Fig. 3

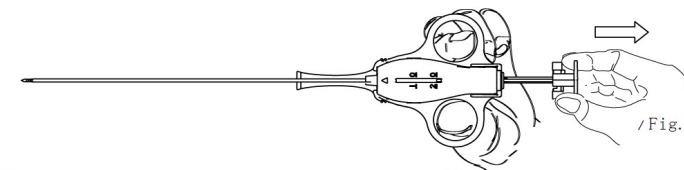


Fig. 4

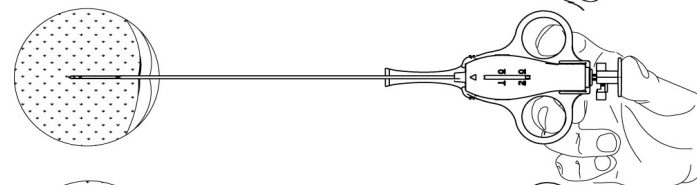


Fig. 5

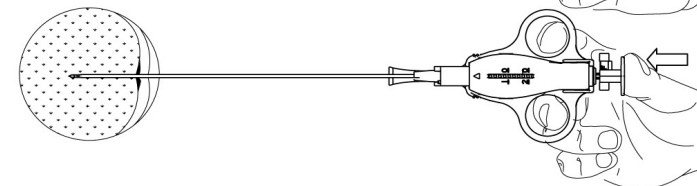


Fig. 6

Instructions for Use:
***GT20 Disposable Semi Automatic Biopsy Instrument
 with Safety and Spacer***

Description: The GT20 Disposable Semi Automatic Biopsy Instrument is a spring-loaded, disposable instrument with a built-in Safety and a detachable Spacer for histological core biopsies. It has 20mm and 10mm two penetration depth. It is available in various needle sizes. The 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 GT20 Disposable Semi Automatic Biopsy Instrument with Safety and Spacer 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.
- 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. Safety can be set before charging the biopsy instrument by pushing safety button towards the direction illustrated in fig. 2.
2. Charge the biopsy instrument by pulling back hard on the plunger until a firm click is felt at either the 10 or 20mm position as in fig. 4. This indicates that the needle spring is locked into ready position.
3. With stylet fully retracted specimen notch is completely covered by cannula. Insert needle proximal to area to be biopsied. **Do not advance stylet until biopsy needle is in position.** Verify proper location of needle.
4. While maintaining needle position, move plunger with thumb to first stop to advance stylet exposing specimen notch (10 or 20mm). Move needle back and forth a few mm to fill specimen notch as in fig. 5. Release the Safety by pushing the safety button towards the opposite direction illustrated in fig. 2.
5. Press plunger past stop with thumb, automatically triggering the cannula to close, trapping the specimen in the sample notch as in fig. 6.
6. Withdraw needle from biopsy area. Set the Safety. Pull back plunger to 10 or 20mm position, recharging the spring. Push plunger to first stop exposing the specimen notch. Remove tissue specimen from notch in stylet.

Note: the Spacer can detached from the biopsy instrument by pushing forward to the direction illustrated in fig. 3.

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 GT20 Disposable Semi Automatic Biopsy Instrument with Safety and Spacer 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.

	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		Batch code
		CE marking of conformity and Identification number of the notified body	

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