

Dokumentennummer: IFU- W-Gun II Documentation No:	Erstveröffentlichung: 02.05.2019 Valid from:	Revisionsnummer: 00 Revisionno:	Revisionsdatum: Revision date:
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## W-CORE II REUSABLE BIOPSY INSTRUMENT

### INSTRUCTION FOR USE:

It is a reusable full automatic biopsy instrument used for obtaining histological core samples from soft tissue and organs. W-Core II is full automatic biopsy instrument with adjustable throw between 15mm and 22mm.

**INDICATIONS:** It is used for obtaining histological core samples from soft tissue and organs.

**CONTRAINDICATIONS:** This instrument should be used by a physician trained in interventional techniques and familiar with the possible side effects typical findings, limitations, indications and contraindications of biopsy procedures. Physician judgement is required when considering biopsy on patients with bleeding disorder or receiving anti-coagulant medications

**CAUTIONS:** Not Sterilized. Reusable. It must be used only in hospitals by physicians familiar with the device and procedures. It must be cleaned and sterilized after each patient. Check the working mechanism of the biopsy instrument after sterilization procedures. Do not clean with bleach or any other chemical reagents. The biopsy instrument can be cleaned by enzymatic detergents with warm water. Be sure that it is dried entirely after cleaning. The biopsy instrument can be sterilized with ethylene oxide and autoclave. Before sterilization, the instrument must be cleaned carefully.

**STERILIZATION INSTRUCTIONS:** Sterilize either by autoclave or ethylenoxide. Prior the sterilization instrument should be cleaned and placed in appropriate packaging materials.







Although cycle conditions and time will vary, typical conditions for autoclave are; 121°C for 40 minutes or 132°C for 15 minutes and EO sterilization; temperature 40°C to 60°C; relative humidity 30% to 70%, gas concentration and exposure time dependent on type of vessel.

For correct implantation: Please double check device function and possible damage and do not use if the device is damaged.

### BIOPSY PROCEDURE:

1. Charge the biopsy instrument 2 times as shown. (Fig.1)
2. Open the cover and insert the needle with removing spacer. (Fig.2)
3. Adjust the penetration depth (15mm or 22mm). (Fig.3)
4. Switch the safety button from "S" to "F". (Fig.4)
5. Press the fire button to take sample. (Fig.5)
6. Charge the instrument one time to open sample notch for taking sample out. (Fig.6)

**NOTE: These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the procedure and technique to be used with this device.**

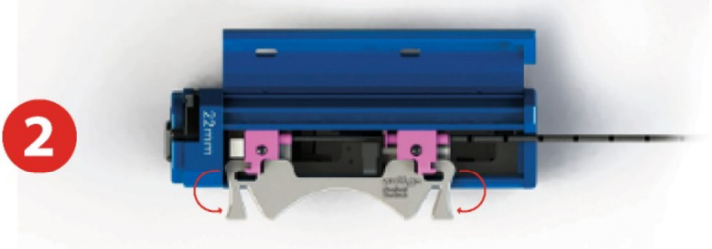
Symbol	Aussage	Description
	Aufbewahrungsbedingungen	Storage limits
	Verwendbar bis:	Expiry Date
	Herstellungsdatum	Manufacturing Date
	Produkt Referenznummer	Reference Number
	Produkt Stapelnummer	Lot (batch) Number
	Trocken lagern	Keep dry
	Von Sonnenlicht fernhalten	Keep away from sun light

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**W-CORE II IFU**



**CHARGE TWO TIMES**



**OPEN THE COVER, INSERT THE NEEDLE, REMOVE THE SPACER**



**ADJUST THE PENETRATION DEPTH**



**SWITCH THE SAFETY      PRESS THE FIRE BUTTON**



**CHARGE ONE TIME TO OPEN SAMPLE NOTCH FOR TAKING SAMPLE OUT**

**CE** 1984: CE-Zeichen und NB-Identifikationsnummer

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