

Dokumentennummer: IFU- W-core <i>Documentation No:</i>	Erstveröffentlichung: 02.05.2019 <i>Valid from:</i>	Revisionsnummer: 00 <i>Revisionno:</i>	Revisionsdatum: <i>Revision date:</i>
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W-CORE REUSABLE BIOPSY INSTRUMENT

INSTRUCTION FOR USE

weLLgo's W-Core Biopsy Instrument is a reusable full automatic biopsy instrument used to obtain histological core samples from soft tissue and organs.

INDICATIONS: It is used to obtain 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 gun 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 packing materials.







Although cycle conditions and time will vary, typical conditions for autoclave are; 121°C for 40 minutes or 135°C for 10 minutes and EO sterilization; temperature 40°C to 60°C; relative humidity 30% to 70%, gas concentration and exposure time is depending on type of vessel.

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

BIOPSY PROCEDURE:

1. Release the safety, Charge the gun 2 times. **(Fig.1)**
2. Insert the needle with removing the spacer and unlock the safety. **(Fig.2)**
3. Fire the instrument with using any of the trigger at front or rear end, Release Safety. **(Fig.3)**
4. Charge the instrument one time to open the sample notch for taking sample out. **(Fig.4)**

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.

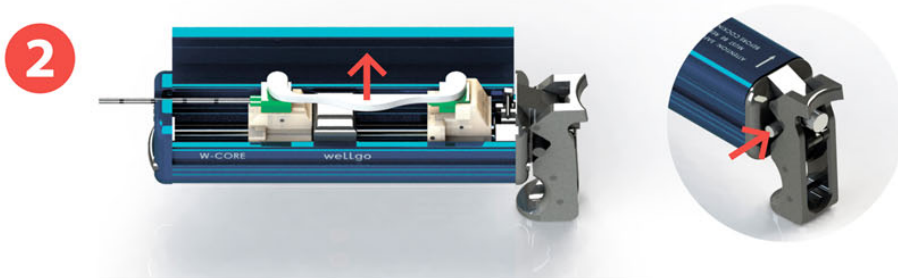
Symbol	Aussage	Description
	Aufbewahrungsbedingungen	Storage limits
	Verwendbar bis:	Expiry Date
	Herstellungsdatum	Manufacturing Date
	Produkt Referenznummer	Reference Number
	Produkt Stapelnummer	Lot (batch) Number
	Trocken lagern	Keep dry
	Von Sonnenlicht fernhalten	Keep away from sun light

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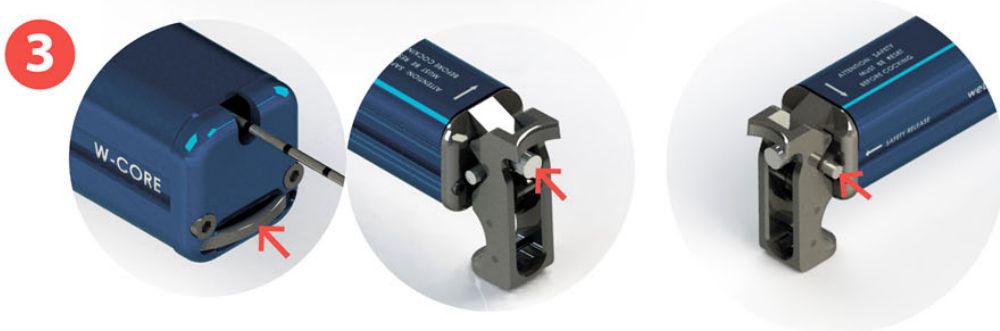
W-CORE IFU



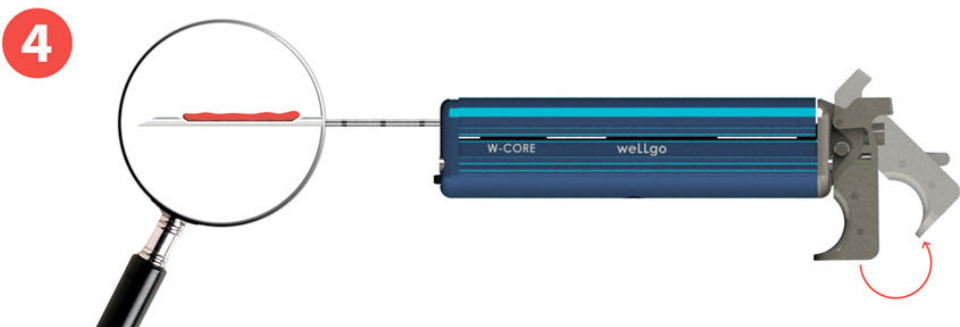
RELEASE SAFETY - CHARGE TWO TIMES



INSERT THE NEEDLE, REMOVE SPACER - UNLOCK SAFETY



FIRE ANY OF THE BUTTON - RELEASE SAFETY



CHARGE ONE TIME TO OPEN SAMPLE NOTCH FOR TAKING SAMPLE OUT



1984: CE-Zeichen und NB-Identifikationsnummer

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