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| <b>Dokumentennummer:</b> IFU-03<br><i>Documentation No:</i> | <b>Erstveröffentlichung:</b> 02.05.2019<br><i>Valid from:</i> | <b>Revisionsnummer:</b> 00<br><i>Revision no:</i> | <b>Revisionsdatum:</b><br><i>Revision date:</i> |
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## WAVE AUTOMATIC BIOPSY NEEDLE

### INSTRUCTIONS FOR USE:

**Indications For Use:** It is a disposable full automatic biopsy device used for histological core samples from soft tissue and organs.

**Contraindications:** This needle 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 judgment is required when considering biopsy on patients with bleeding disorder, or receiving anti-coagulant medications.

**Possible Side Effects:** Pain, fever, bleeding, hematuria and infection.

**Caution:** Ethylen oxide sterilized. Non-pyrogenic. Check the package. if package damaged or opened do not use the products. Check the expiry date and the gauge. Store in dry place, between 5–30°C temperature, protect from sun light. Possible allergic reactions should be considered. It must be used only in hospitals by physicians who familiar with the device and procedures. **For single Patient Use Only.** Do not attempt to clean or resterilize this product. Do not use the device under MRI. 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.  
Please double check for device function and possible damage for correct implantation and do not use if package is opened or damaged.

### BIOPSY PROCEDURE:

1. Identify the biopsy site preferably under US or CT.
2. Using the sterile technique, prepare the skin with antiseptic and drape.
3. If necessary, infiltrate the selected area with local anaesthetic.
4. Open the needle pouch and remove protective sheath from the needle.
5. Charge Biopsy needle as shown at below figures:



**5a:** Pull the button 1 backward firmly



**5b:** Pull the button 2 backward firmly

- 6: Introduce the needle to the patient and advance to the biopsy site.



- 7: Push any of firing buttons to obtain the sample

- 8.: Draw needle out. Pull the button 1 back to expose the specimen notch and remove the biopsy specimen.










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

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## Referenznummern:

*Reference Numbers:*

|                            |                 |   |
|----------------------------|-----------------|---|
| Automatic<br>Biopsy Needle | Without Coaxial | 031409, 031410, 031412, 031415, 031416, 031420, 031609, 031610, 031615, 031616, 031620, 031625, 031809, 031810, 031812, 031815, 031816, 031825, 032009, 032010, 032015, 032016, 032020. |
|                            | With Coaxial    | 03C1410, 03C1412, 03C1415, 03C1416, 03C1420, 03C1610, 03C1612, 03C1615, 03C1616, 03C1620, 03C1625, 03C1810, 03C1812, 03C1815, 03C1816, 03C1820, 03C1825, 03C2010, 03C2015, 03C2020.     |

| Symbol  | Aussage                    | Description              |
|---|----------------------------|--------------------------|
|    | Für einmalige Verwendung   | Single Use               |
|    | Aufbewahrungsbedingungen   | Storage limits           |
|    | Verwendbar bis:            | Expiry Date              |
|    | Herstellungsdatum          | Manufacturing Date       |
|   | Ethylenoxid sterilisiert   | Ethylen oxide sterilized |
|  | Produkt Referenznummer     | Reference Number         |
|  | Produkt Stapelnummer       | Lot (batch) Number       |
|  | Trocken lagern             | Keep dry                 |
|  | Von Sonnenlicht fernhalten | Keep away from sun light |



1984: CE-Zeichen und NB-Identifikationsnummer

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