Т

Biopsy Needles

INSTRUCTIONS FOR USE

RONLY CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The TEMNO Elite™ biopsy system is a single use Total Core™ biopsy device. It is available in several needle gauge sizes and lengths. The plunger is color coded according to the various gauge sizes (e.g., yellow=20G, pink=18G, purple=16G, green=14G, and blue=12G).

Figure 1: TEMNO Elite Biopsy System



- As packaged, protective needle sheath not shown
- Plunger: Used to energize (arm), advance the sample notch, and fire the cutting cannula.
- Fire ready indicator: When line is solid, indicates sample notch has been fully advanced and biopsy 2 device is ready to be fired. Centimeter Markings
- 3 4
- 5
- Sample Assist™ optional feature for sample core retrieval Penetration depth indicator 6
- a. Not energized: 0
 - b. Energized (armed) to 10mm penetration depth: 10
 - Energized (armed) to 20mm penetration depth: 20 с.
- 7. 10mm adapter (optional)

The TEMNO Elite biopsy system includes a biopsy device and has the option of including a compatible Valved Coaxial Introducer Needle, or a Standard Coaxial Introducer Needle.

- The Valved Coaxial Introducer Needle consists of an outer cannula with an attached female luer-style a. lock hub with valve, an inner trocar stylet with an attached male luer-style lock hub, and a slip ring style depth stop.
- i. The Valved Coaxial Introducer Needle is designed for use with the TEMNO Elite Biopsy System. b The Standard Coaxial Introducer Needle consists of an outer cannula with an attached female luer-style lock hub, an inner trocar stylet with an attached male luer-style lock hub, and a slip ring style depth stop.
- i. The Standard Coaxial Introducer Needle is designed for use with the TEMNO Elite Biopsy System. The depth stop on both the Valved Coaxial Introducer Needle and the Standard Coaxial Introducer
- Needle is color coded to match the gauge size of the TEMNO Elite biops ysystem (e.g., yellow=20G, pink=18G, purple=16G, green=14G, and blue=12G). The outer cannula is only one-gauge size larger than the appropriate TEMNO Elite Biopsy System (e.g., 19G Valved Coaxial Introducer Needle for a 20G TEMNO Elite Biopsy System).



- 3 Centimeter Marks
- 4 Depth Stop
- 5 Valve

1

2.





As packaged, protective needle sheath not shown

- Trocar Stylet 1. Coaxial Cannula 2
- Centimeter Marks 3.
- Depth Stop 4

HOW SUPPLIED

The product is supplied sterile unless the package has been opened or damaged. **Sterilized using** Ethylene Oxide. For single patient use only. Do not reuse. Do not resterilize.

INDICATIONS FOR USE/CLINICAL BENEFIT

The TEMNO Elite biopsy system is intended for use in obtaining biopsies from soft tissues such as liver, kidney, breast, prostate, spleen, lung, lymph nodes, thyroid, and various soft tissue masses. It is NOT intended for use in bone.

The Valved Coaxial Introducer Needle and Standard Coaxial Introducer Needle are intended for use as a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, breast, prostate, spleen, lung, lymph nodes, thyroid, and various soft tissue masses. It is NOT intended for use in bone.

CONTRAINDICATIONS

The TEMNO Elite biopsy system: Good medical judgement should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding disorder.

WARNINGS

- Post-biopsy patient care may vary with the biopsy technique utilized and the individual patient's
 physiological condition. Observation of vital signs and other precautions should be taken to avoid
 and/or treat potential complications that may be associated with biopsy procedures.
- The collection of multiple core biopsy samples may help to ensure the detection of any cancer tissue. A "negative" biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma.

NOTE: Inspect the TEMNO Elite biopsy system, Valved Coaxial Introducer Needle, or Standard Coaxial Introducer Needle for damaged point, bent shaft, or other imperfections prior to use and after each sample is collected.

DO NOT USE the device if any imperfection is noted.

NOTE: After use, the TEMNO Elite biopsy system, Valved Coaxial Introducer Needle, or Standard Coaxial Introducer Needle may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations.

In EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable member state.

PRECAUTIONS

- The TEMNO Elite biopsy system, Valved Coaxial Introducer Needle, and Standard Coaxial Introducer Needle should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings, and possible side effects of core needle biopsy.
- The introduction of the needle into the body should be carried out under imaging guidance, ultrasound, x-ray, CT, etc.
- **NOTE:** This product has not been tested for MRI imaging compatibility.
- Never test the TEMNO Elite biopsy system by firing into the air. Damage may occur to the needle/ cannula tip and could result in patient and/or user injury.
- Unusual force applied to the TEMNO Elite Biopsy System 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.
- 5. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

POTENTIAL COMPLICATIONS

Potential complications associated with core biopsy procedures and coaxial guided biopsy procedures are site specific and may include but are not limited to: hematoma; hemorrhage; infection; adjacent tissue injury; pain; bleeding; hemotpvis; hemothorax; foreign body non-vascular; inflammatory reaction; nontarget tissue, organ or vessel perforation; pneumothorax; track seeding; and air embolism. Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

EQUIPMENT REQUIRED

- 1. Appropriate imaging modality
- 2. Surgical gloves and drapes
- 3. Local anesthetic
- TEMNO Elite Biopsy System
- 5. Valved or Standard Coaxial Introducer Needle (optional)
- 6. Sample collection container
- 7. Other equipment as necessary

DIRECTIONS FOR USE FOR TEMNO ELITE BIOPSY SYSTEM

- 1. Using aseptic technique, remove the instrument from its package.
- 2. Remove the protective needle sheath
- Before using the TEMNO Elite biopsy system, inspect the needle for damaged point, bent shaft, or other imperfections that would prevent proper function. If the needle is damaged or bent; DO NOT USE.
- 4. Energize or arm the instrument by pulling back on the plunger to withdraw the cannula and inner stylet and lock the cannula in place. The instrument can be energized to one of two penetration depths. Pulling the plunger to the first stop, indicated by a firm click, sets the device penetration depth to 10mm. Pulling the plunger farther back to the second stop, indicated by a firm click, sets the penetration depth to 20mm See Figure 4.

Figure 4: Plunger retracted to energize (cock) Instrument



BIOPSY PROCEDURE FOR THE TEMNO ELITE BIOPSY SYSTEM

The biopsy procedure must be performed using appropriate aseptic techniques.

- 1. Prepare site as required. Adequate anesthesia should be administered prior to procedure.
- 2. For ease of insertion, puncture the skin with a scalpel at the entry site (OPTIONAL)
- Verify the instrument is energized (armed) by looking at the penetration depth indicator and confirming either a "10" or "20" is visible. See Figure 5.

- 4. With the inner stylet fully retracted so that the sample notch is covered by the cannula, insert the tip of needle to the point to be biopsied. DO NOT advance the inner stylet by pressing on the plunger until the instrument is in position.
- 5. Press the plunger to advance the inner stylet (i.e. sample notch) into tissue. At the end of the advancement the plunger will encounter a stop and the fire ready indicator will form a solid line. See Figure 5. With imaging verify the sample notch is in the target area to be biopsied.
- Fire the cutting cannula by depressing the plunger past the fire ready indicator to capture the biopsy specimen in the sample notch.
- Remove the needle from the patient and pull the plunger back to acquire the biopsy specimen. Gently advance the plunger forward to expose the biopsy specimen. DO NOT press the plunger past the fire ready indicator during this step.
- 8. (Optional) Push the Sample Assist[™] forward for assistance with removing the sample from the notch.
- 9. If additional biopsies are required, pull back on the plunger to withdraw the inner stylet and repeat steps 3 through 8.



Note: Once the plunger surface meets fire ready indicator, additional pressure on the plunger will fire the cutting cannula.

, Fire Ready Indicator

BIOPSY PROCEDURE FOR THE TEMNO ELITE BIOPSY SYSTEM WITH VALVED COAXIAL INTRODUCER NEEDLE OR STANDARD COAXIAL INTRODUCER NEEDLE

- The biopsy procedure must be performed using appropriate aseptic techniques.
- 1. Using aseptic technique, remove the instrument and the coaxial introducer from its package.
- Remove the protective needle sheath from the instrument and the coaxial introducer.
 Before using the TEMNO Elite biopsy system and/or Valved or Standard Coaxial Introducer I
- Before using the TEMNO Elite biopsy system and/or Valved or Standard Coaxial Introducer Needle, inspect the needle for damaged point, bent shaft, or other imperfections that would prevent proper function. If the needle is damaged or bent; DO NOT USE.
- 4. Prepare site as required. Adequate anesthesia should be administered prior to procedure.
- 5. For ease of insertion, puncture the skin with a scalpel at the entry site (OPTIONAL).
- 6. If preferred, set the depth stop at the predetermined placement on the coaxial introducer cannula.7. Using imaging guidance, insert the tip of the coaxial introducer proximal to the lesion to be
- biopsied. The depth stop may be used as an aid for proper placement and adjust as necessary. NOTE: The depth stop should be adjusted so that the needle is in proper position when the depth stop is in contact with the skin. This will help stabilize the coaxial needle.
- Hold the coaxial cannula hub and disconnect (squeeze or twist) the stylet hub to remove the stylet from the outer cannula. Leave the cannula in place as a guide for the placement of the biopsy instrument.
- 9. Energize or arm the instrument by pulling back on the plunger to withdraw the cannula and inner stylet and lock the cannula in place. The instrument can be set to one of two penetration depths. Pulling back the plunger to the first stop, indicated by a firm click, sets the device penetration depth to 10mm. Pulling the plunger farther back to the second stop, indicated by a firm click, sets the device penetration depth to 20mm. See Figure 4.

NOTE: When the instrument is energized to the 10mm penetration depth, the enclosed 10mm adapter should be used. Ensure the arrow on the 10mm spacer points to the distal needle tip. If the 10mm adapter is not used, the tip of the instrument will extend one centimeter farther relative to the 10mm energized position. **See Figure 6.**



- Verify the instrument is energized (armed) by looking at the penetration depth indicator and confirming either a "10" or "20" is visible . See Figure 5.
- 11. With the inner stylet fully retracted so that the sample notch is covered by the cannula, insert the tip of needle to the point to be biopsied. DO NOT advance the inner stylet by pressing on the plunger until the instrument is in position.
- 12. Press the plunger to advance the inner stylet (i.e. sample notch) into tissue. At the end of the advancement the plunger will encounter a stop and the fire ready indicator will form a solid line. See Figure 5. With imaging verify the sample notch is in the target area to be biopsied.
- Fire the cutting cannula by depressing the plunger past the fire ready indicator to capture the biopsy specimen in the sample notch.

14. Remove the needle from the coaxial introducer, leaving the coaxial introducer cannula in place.

 Pull the plunger back to acquire the biopsy specimen. Gently advance the plunger forward to expose the biopsy specimen. DO NOT press the plunger past the fire ready indicator during this step.
 (Optional) Push the Sample Assist™ for assistance with removing the sample from the notch.

 (pptional) rush the Sample Assist⁻⁻ for assistance with removing the sample from the notch.
 If additional biopsies are required, pull back on the plunger to withdraw the inner stylet and repeat steps 9 through 16.

18. Remove the coaxial introducer cannula from the patient.

| Temno Elite Biopsy System | | | | | | | |
|---------------------------|----------------------------------|-----------------------|--------------------------------|----------------------------|----------------------|--|--|
| Catalogue Number | Coax Bundle | | | | | | |
| | Biopsy Needle | | Coaxial Introducer | | | | |
| | Gauge Size & Needle Length | Penetration Depths | Gauge Size & Needle Length* | Overall Needle Length** | Coax. Reorder No. | | |
| TEC1210 | 12G x 10cm | 10mm and 20mm | 11G x 5.2cm | 7.6cm | CX1210 | | |
| TEC1215 | 12G x 15cm | 10mm and 20mm | 11G x 10.2cm | 12.6cm | CX1215 | | |
| TEC1410 | 14G x 10cm | 10mm and 20mm | 13G x 5.3cm | 7.7cm | CX1410 | | |
| TEC1415 | 14G x 15cm | 10mm and 20mm | 13G x 10.3cm | 12.7cm | CX1415 | | |
| TEC1610 | 16G x 10cm | 10mm and 20mm | 15G x 5.3cm | 7.7cm | CX1610 | | |
| TEC1615 | 16G x 15cm | 10mm and 20mm | 15G x 10.3cm | 12.7cm | CX1615 | | |
| TEC1810 | 18G x 10cm | 10mm and 20mm | 17G x 5.3cm | 7.7cm | CX1810 | | |
| TEC1815 | 18G x 15cm | 10mm and 20mm | 17G x 10.3cm | 12.7cm | CX1815 | | |
| TEC1820 | 18G x 20cm | 10mm and 20mm | 17G x 15.3cm | 17.7cm | CX1820 | | |
| TEC2010 | 20G x 10cm | 10mm and 20mm | 19G x 5.4cm | 7.8cm | CX2010 | | |
| TEC2015 | 20G x 15cm | 10mm and 20mm | 19G x 10.4cm | 12.8cm | CX2015 | | |
| TEC2020 | 20G x 20cm | 10mm and 20mm | 19G x 15.4cm | 17.8cm | CX2020 | | |

| Valved Coax Bundle | | | | | |
|---------------------|----------------------------------|-----------------------|--------------------------------|----------------------------|----------------------|
| Catalogue Number | Biopsy Needle | | Valved Coaxial Introducer | | |
| | Gauge Size & Needle Length | Penetration Depths | Gauge Size & Needle Length* | Overall Needle Length** | Coax. Reorder No. |
| TEVC1210 | 12G x 10cm | 10mm and 20mm | 11G x 5.2cm | 7.6cm | VC1210 |
| TEVC1215 | 12G x 15cm | 10mm and 20mm | 11G x 10.2cm | 12.6cm | VC1215 |
| TEVC1410 | 14G x 10cm | 10mm and 20mm | 13G x 5.3cm | 7.7cm | VC1410 |
| TEVC1415 | 14G x 15cm | 10mm and 20mm | 13G x 10.3cm | 12.7cm | VC1415 |
| TEVC1610 | 16G x 10cm | 10mm and 20mm | 15G x 5.3cm | 7.7cm | VC1610 |
| TEVC1615 | 16G x 15cm | 10mm and 20mm | 15G x 10.3cm | 12.7cm | VC1615 |
| TEVC1810 | 18G x 10cm | 10mm and 20mm | 17G x 5.3cm | 7.7cm | VC1810 |
| TEVC1815 | 18G x 15cm | 10mm and 20mm | 17G x 10.3cm | 12.7cm | VC1815 |
| TEVC1820 | 18G x 20cm | 10mm and 20mm | 17G x 15.3cm | 17.7cm | VC1820 |
| TEVC2010 | 20G x 10cm | 10mm and 20mm | 19G x 5.4cm | 7.8cm | VC2010 |
| TEVC2015 | 20G x 15cm | 10mm and 20mm | 19G x 10.4cm | 12.8cm | VC2015 |
| TEVC2020 | 20G x 20cm | 10mm and 20mm | 19G x 15.4cm | 17.8cm | VC2020 |

*Measured from the distal end of the hub to the distal end of the coaxial cannula **Measured from the proximal end of the hub to the distal end of the coaxial cannula

| Temno Elite Biopsy System | | | | |
|---------------------------|----------------------------|--------------------|--|--|
| Catalogue Number | Stand Alone Biopsy Needle | | | |
| | Gauge Size & Needle Length | Penetration Depths | | |
| TE1210 | 12G x 10cm | 10mm and 20mm | | |
| TE1215 | 12G x 15cm | 10mm and 20mm | | |
| TE1406 | 14G x 6cm | 10mm and 20mm | | |
| TE1410 | 14G x 10cm | 10mm and 20mm | | |
| TE1415 | 14G x 15cm | 10mm and 20mm | | |
| TE1606 | 16G x 6cm | 10mm and 20mm | | |
| TE1610 | 16G x 10cm | 10mm and 20mm | | |
| TE1615 | 16G x 15cm | 10mm and 20mm | | |
| TE1806 | 18G x 6cm | 10mm and 20mm | | |
| TE1810 | 18G x 10cm | 10mm and 20mm | | |
| TE1815 | 18G x 15cm | 10mm and 20mm | | |
| TE1820 | 18G x 20cm | 10mm and 20mm | | |
| TE2006 | 20G x 6cm | 10mm and 20mm | | |
| TE2010 | 20G x 10cm | 10mm and 20mm | | |
| TE2015 | 20G x 15cm | 10mm and 20mm | | |
| TE2020 | 20G x 20cm | 10mm and 20mm | | |

| SYMBOL | DESIGNATION | | |
|---------------|--|--|--|
| | Use By: YYYY-MM-DD | | |
| LOT | Lot Number | | |
| REF | Catalog Number | | |
| STERILEEO | Sterilized Using Ethylene Oxide | | |
| | Do Not Use If Package is Damaged and Consult Instruction for Use | | |
| 2 | Single Use | | |
| R ONLY | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician | | |
| STERNAR | Do Not Re-sterilize | | |
| | Caution | | |
| | Date of Manufacture: YYYY-MM-DD | | |
| MD | Medical Device | | |
| \bigcirc | Single sterile barrier system | | |
| or | or Single sterile barrier system with protective packaging inside | | |
| EC REP | Authorized Representative in European Community | | |
| | Manufacturer | | |
| Ĩ | Consult Instructions for use. For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service. | | |
| UDI | Unique Device Identifier | | |





Manufacturer: Merit Medical Systems, Inc. 1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A. 1-801-253-1600 U.S.A Customer Service 1-800-356-3748

EC REP Authorized Representative: Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland EU Customer Service +31 43 358 82 22

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