English

TEMNO ELITE™

Biopsy Needles

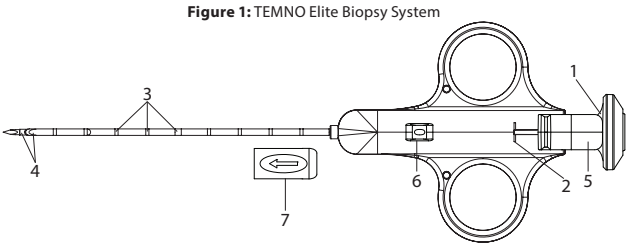
INSTRUCTIONS FOR USE

℞ ONLY **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



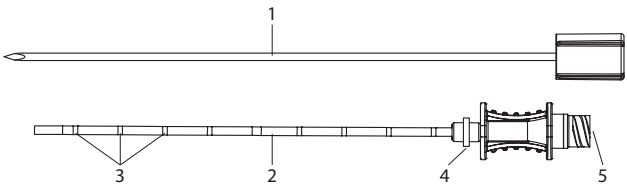
As packaged, protective needle sheath not shown

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

a. The Valved Coaxial Introducer Needle consists of an outer cannula with an attached female luer-style 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.
c. 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 biopsy system (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).

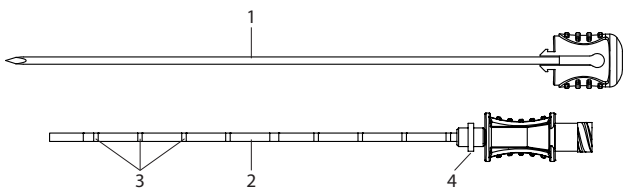
Figure 2: Valved Coaxial Introducer Needle



As packaged, protective needle sheath not shown

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

Figure 3: Standard Coaxial Introducer Needle



As packaged, protective needle sheath not shown

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

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
1. 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.
2. 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.
3. 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.

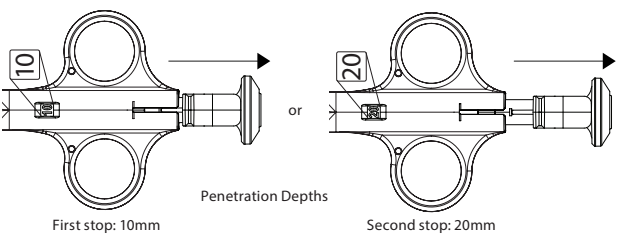
PRECAUTIONS
1. The TEMNO Elite biopsy system, Valved Coaxial Introducer Needle, and Standard Coaxial Introducer Needle should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings, and possible side effects of core needle biopsy.
2. The 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.
3. 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.
4. 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; hemoptysis; hemothorax; foreign body non-vascular; inflammatory reaction; non-target 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
4. 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
3. 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.**

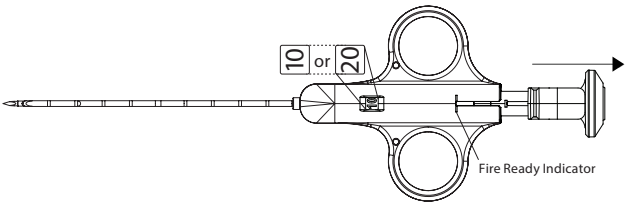
Figure 4: Plunger retracted to energize (cock) Instrument



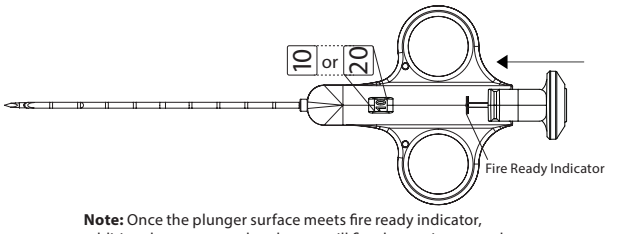
BIOPSY PROCEDURE FOR THE TEMNO ELITE BIOPSY SYSTEM
The biopsy procedure must be performed using appropriate aseptic techniques.
1. Prepare site as required. Adequate anesthesia should be administered prior to procedure.
2. For ease of insertion, puncture the skin with a scalpel at the entry site (OPTIONAL)
3. 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.
6. Fire the cutting cannula by depressing the plunger past the fire ready indicator to capture the biopsy specimen in the sample notch.
7. 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.

Figure 5: Plunger retracted to energize or arm the device



Plunger advanced to fire the device



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

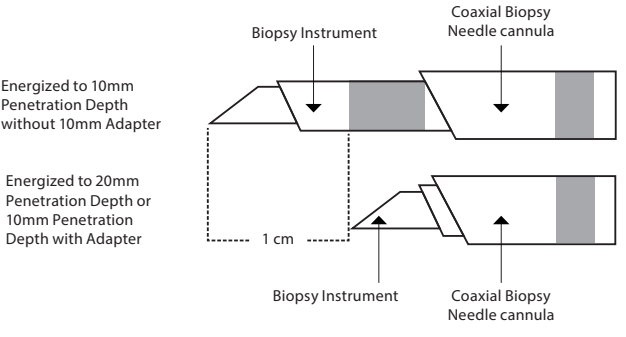
BIOPSY PROCEDURE FOR THE TEMNO ELITE BIOPSY SYSTEM WITH VALVED COAXIAL INTRODUCER NEEDLE OR STANDARD COAXIAL INTRODUCER NEEDLE

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Using aseptic technique, remove the instrument and the coaxial introducer from its package.
2. Remove the protective needle sheath from the instrument and the coaxial introducer.
3. 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.
8. 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.**

Figure 6



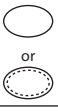
10. Verify the instrument is energized (armed) by looking at the penetration depth indicator and confirming either a "10" or "20" is visible . **See Figure 5.**
11. With the inner stylet fully retracted so that the sample notch is covered by the cannula, insert the tip of needle to the point to be biopsied. 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.
13. 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.
15. 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.
16. (Optional) Push the Sample Assist™ for assistance with removing the sample from the notch.
17. 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
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single Use
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Do Not Re-sterilize
	Caution
	Date of Manufacture: YYYY-MM-DD
MD	Medical Device
	Single sterile barrier system or Single sterile barrier system with protective packaging inside
EC REP	Authorized Representative in European Community
	Manufacturer
	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

CE 2797

www.merit.com

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:**
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Galway, Ireland
EU Customer Service +31 43 358 82 22

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