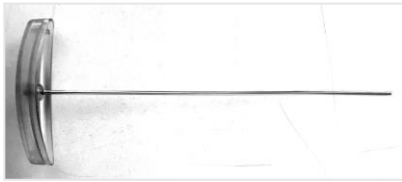
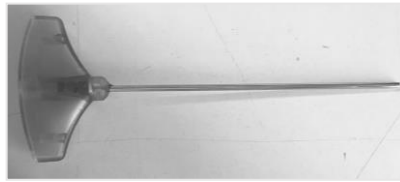


BON-CORE BONE MARROW BIOPSY NEEDLE

A. Bone Marrow Biopsy Needle Application



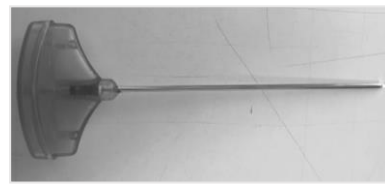
Visual.1 Bon-Core® Stylet



Visual.2 Bon-Core® Cannula



Visual.3 Bon-Core® Pushing Stylet



Visual.4 Bon-Core® Needle

1. It is used for biopsy prepare from bone marrow.
2. Check whether the package is sterile before use. The sterility of an open or damaged packaged product is impaired and cannot be used.
3. The patient is prepared for the procedure and the patient is maintained in the appropriate position during the procedure.
4. The package is opened in hygienic conditions.
5. Package content and product control:
 - 5.1 The needle is checked to make sure it is not damaged in any way. Plastic protective tip is removed. If there is any damage, it shall not be attempted to repair.
6. Check the needle to make sure it is not damaged in any way. The plastic protective tip is removed. If there is any damage, no trying to repair it.
7. The needle is held 90 degrees perpendicular to the bone surface and pressed down while turning it to the left and right.
8. When light resistance is felt, it means that it has entered the bone tissue, after removing the stylet and entering the bone marrow 2-3 mm, a luer lock syringe is inserted and the prepare is taken. Ensure that the luer lock injector is properly seated and secured.
9. Care is taken to ensure that the needle does not move when the syringe is inserted.
10. After the needle is pulled out 2-3 mm, the entrance angle is changed and the bone marrow is inserted again 2-3 mm. The needle is moved to the right and left to take the biopsy prepare.
11. Bone marrow is collected until sufficient prepare is in the syringe.
12. The needle is slowly removed from the patient and care is taken not to lose the biopsy prepare.
13. After the process is completed, the needle and the injector are disposed of in accordance with the medical waste regulations.

B. Bone Marrow Biopsy Needle with Probe



Visual.5 Bon-Core® Probe/ Marrow collection cannula



Visual.6 Bon-Core® Probe Pushing stylet

1. It is used for biopsy prepare from bone marrow.

BON-CORE BONE MARROW BIOPSY NEEDLE

2. Check whether the package is sterile before use. The sterility of an open or damaged packaged product is impaired and cannot be used.
3. The patient is prepared for the procedure and the patient is maintained in the appropriate position during the procedure.
4. The package is opened in hygienic conditions.
5. Package content and product control:
 - 5.1 The needle is checked to make sure it is not damaged in any way. Plastic protective tip is removed. If there is any damage, it shall not be attempted to repair.
6. The needle is held 90 degrees perpendicular to the bone surface and pressed down while turning it to the left and right.
7. When light resistance is felt, it means that entered into the bone tissue. The stylet is removed and the probe (bone marrow collection cannula) is passed through.
8. A biopsy prepareate is taken by rotating the probe clockwise and counterclockwise with the bone marrow biopsy needle.
9. Once the biopsy prepareate has been taken, the probe is gently inverted with the bone marrow biopsy needle and removed from the patient.
10. The probe is carefully removed from the bone marrow biopsy needle and taking care not to lose the biopsy prepareate during the procedure.
11. The Probe Pushing stylet is used to collect the biopsy prepareate through the probe and is placed in the corresponding sterile prepareate cup.
12. After the procedure is completed, the needle, bone marrow collection cannula and styletes are disposed of in accordance with medical waste regulations.

BON-CORE BONE MARROW BIOPSY NEEDLE MODEL LIST:

Reference code	Product Description
BC08	Bone Marrow Biopsy Needle, 8G
BC08100	Bone Marrow Biopsy Needle, 8Gx100mm
BC09	Bone Marrow Biopsy Needle, 9G
BC09100	Bone Marrow Biopsy Needle, 9Gx100mm
BCP09100	Bone Marrow Biopsy Needle With Probe, 9Gx100 mm
BCKIT09100	Bone Marrow Biopsy Kit, 9Gx100 mm
BC09150	Bone Marrow Biopsy Needle, 9Gx150 mm
BCP09150	Bone Marrow Biopsy Needle With Probe, 9Gx150 mm
BCKIT09150	Bone Marrow Biopsy Kit, 9Gx150 mm
BC11	Bone Marrow Biopsy Needle, 11G
BC11100	Bone Marrow Biopsy Needle, 11Gx100mm
BCP11100	Bone Marrow Biopsy Needle With Probe, 11Gx100 mm
BCKIT11100	Bone Marrow Biopsy Kit, 11Gx100 mm
BC11150	Bone Marrow Biopsy Needle, 11Gx150mm
BCP11150	Bone Marrow Biopsy Needle With Probe, 11Gx150 mm
BCKIT11150	Bone Marrow Biopsy Kit, 11Gx150 mm
BC13	Bone Marrow Biopsy Needle, 13G
BC13100	Bone Marrow Biopsy Needle, 13Gx100mm
BCP13100	Bone Marrow Biopsy Needle With Probe, 13Gx100 mm
BCKIT13100	Bone Marrow Biopsy Kit, 13Gx100 mm
BC13150	Bone Marrow Biopsy Needle, 13Gx150mm
BCP13150	Bone Marrow Biopsy Needle With Probe, 13Gx150 mm
BCKIT13150	Bone Marrow Biopsy Kit, 13Gx150 mm

BON-CORE BONE MARROW BIOPSY NEEDLE

INDICATIONS

- Evaluation of hematological disorders
- Investigation of suspicion of bone marrow fibrosis
- Investigation of neuroblastoma, rhabdomyosarcoma and Ewing sarcoma stages, Hodgkin lymphoma, non-Hodgkin lymphoma and small blue round cell tumors in children.
- Aplastic anemia, diagnosis of myelodysplastic syndrome
- Investigation of fever of unknown cause
- Evaluation of bone marrow porosity

CONTRAINDICATIONS

- Bleeding disorders
- Infection on the hip or soft tissue.
- Thrombocytopenia

RISKS:

- Excessive bleeding,
- Infection

SIDE EFFECTS:

- Bruising
- Discomfort at the biopsy point

! WARNINGS:

- In this medical device, interventions during and after the application should be done by doctors who are experts in their field.
- Do not use if the packaging is torn or damaged. It is not sterile.
- Store in a cool, dry and dust-free environment.
- Excessive force during interference can cause the needle cannula to bent or break.
- In case of an emergency, the manufacturer and the competent authorities should be informed.
- Dispose of in accordance with medical waste regulations.
- Do not perform any procedure other than the approved procedure during the application.
- Use this medical device only for the specified purpose.
- Re-use or re-sterilization after opening the original packaging is dangerous. Cross-contamination can cause infection and trauma.

! ADVISORY WARNING

- *Before the biopsy procedure, it is recommended that the patient's history be learned and the use of the product in patients with thrombocytopenia and bleeding disorders should be evaluated within the knowledge of the end-user specialist*
- *The intercompability of the plastic parts in the needle cannula and stylet should be checked and the working mechanism should be understood.*
- *In case needle bents during the operation, the stylet should not be attempted to remove as there will be a risk of jamming in the cannula. In such a case, continuing the operation will increase the risk of deviation from the biopsy area and the occurrence of complications and side effects in the procedure*
- *The pushing stylet (Visual .6) included in the Bon-Core® Bone Marrow Biopsy Kit is adjusted according to the probe (Marrow Collection Cannula / Visual.5). In case of not processing according to the procedure (part B)*

BON-CORE BONE MARROW BIOPSY NEEDLE

(Continuation with the process with Bone Marrow Biopsy Needle without using the probe), it is not appropriate to use the pushing stylet to remove the biopsy preparation from the needle. As the pushing stylet will be thinner than the biopsy needle, it causes crushing and deformations in the biopsy preparation and decreases the quality of the biopsy preparation.

The procedure referred to in this manual and other sources of Egemen International® (TMT Tıbbi Medikal Malz. San. Tic. A.Ş.) is for guidance only. The use of the device should be based on the physician's own clinical training.

SYMBOLS:



Sterilized using ethylene oxide



Keep dry



Do not re-use



Humidity limitation



Do not use if package is damaged



Batch code



Use-by date



Do not re-sterilize



Date of manufacture



Non-pyrogenic



Temperature limit



Keep away from sunlight



Consult (e IFU) instructions for use
www.egemen.com.tr

Manufacturer:

TMT TIBBİ MEDİKAL MALZ. SAN. TİC. AŞ.
Fatih Mah.1188 Sok.No14 PK 35414
Sarıç, Gaziemir – İzmir / Turkey
(Tel: + 90232 278 15 93; Fax: + 90 232 279 32 08)



Emergo Europe: Prinsessegracht 20,
2514 AP, The Hague, **The Netherlands.**

Sterilization Address:

Fatih Mah.1188 Sok. No:14 PK:35414 Sarıç / Gaziemir / İzmir/ TURKEY

Warehouse Address:

Fatih Mah. 1188 Sok. No: 12/A PK:35414 Sarıç / Gaziemir / İzmir/ TURKEY