**WMT EXTREMITY PROCEDURE KIT**

**143802-1**

The following languages are included in this packet:

English (en)

For additional languages, visit our website www.wmt.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.

M
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℞ ONLY

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***Attention Operating Surgeon***
**IMPORTANT MEDICAL INFORMATION**
**WMT Extremity Procedure Kit**
**(143802-1)**

OUTLINE:



**DEFINITIONS**

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

| Symbol | Definition |
|---|---|
| g | Batch code |
| h | Catalog number |
| D | Do not re-use |
| Y | Caution, consult accompanying documents |
| i | Consult operating instructions |
| H | Use by |
| p | Keep dry |
| | Keep away from sunlight |
| N | Date of manufacture |
| M | Manufacturer |
| K | Sterilized using radiation |
| ℞ ONLY | For prescription use only |
| | Do not use if package is damaged |

**GENERAL PRODUCT INFORMATION**

**A. Description**
The WMT Extremity Procedure Kit consists of single-use, disposable instruments designed to efficiently facilitate retrograde drilling, debriding and removing tissue from osseous defects. This product is provided sterile for single patient use.

**B. Warnings and Precautions**
Proper surgical techniques are the responsibility of the medical professional. The WMT Extremity Procedure Kit instruments are furnished as tools to facilitate drilling and debriding of osseous defects. Each surgeon must evaluate the appropriateness of the instruments and techniques for each patient based on his or her own medical training and expertise. As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, or immunosuppressive therapy or high dosage radiation therapy. Every patient is different and patient results may vary.

**Intra-Operative Precautions**
Use medical devices in accordance with their labeled indications and WMT instructions for use, especially during insertion and removal.

- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with WMT's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
  a. The material composition of the fragment (if known);
  b. The size of the fragment (if known);
  c. The location of the fragment;
  d. The potential mechanisms for injury, e.g., migration, infection;
  e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Use this device as supplied and according to the **Handling and Use** information provided below.

**CAUTION: DO NOT PUNCTURE/DISRUPT AN ARTICULATING SURFACE OR JOINT SPACE, WHERE APPLICABLE.**

**NOTE: CARE SHOULD BE TAKEN NOT TO USE INSTRUMENTS FOR LEVERAGE AS FRACTURES MAY RESULT.**

**C. Handling**
The WMT Extremity Procedure Kit is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product should not be resterilized. The WMT Extremity Procedure Kit is for single patient use and should never be reused. Unused or expired product should be properly discarded. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination. Use the WMT Extremity Procedure Kit aseptically.


**Surgical Instruments Included:**

**1. Working Cannula**
Provides continuous access to surgical site when placed into core tunnel.
**2. Needle with Stylet**
Facilitate in the delivery of injectable graft material* to fill bone void.
**3. Guide Wire**
Guides drill bit to desired location.
**4. Curette**
Aids in debridement of bone.
**5. 5.3mm Drill Bit**
Defect access.
**6. Tissue Protector**
Minimizes soft tissue interference during drill bit use.

**7. Suction Tip and Handle**
Minimizes soft tissue interference during drill bit use.
**8. Tamp**
Used to clear obstructions in working cannula and core tunnel.
**9. Drill Guide (Optional)**
Aids in guide wire placement.

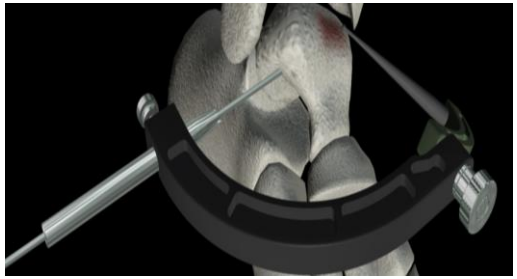
* = These open voids can be injected with currently available WMT bone void filler products such as: PRO-DENSE®, PRO-STIM™, MIIG®, IGNITE®

**D. Directions For Use**

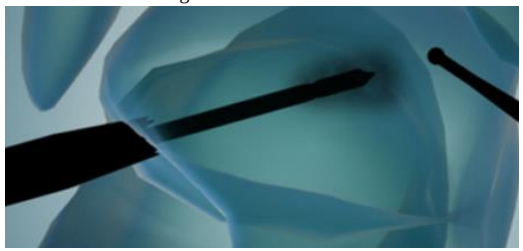
Each instrument is single use disposable

1. Begin by orienting the Drill Guide such that the wire guide and the ball tipped probe intercept the desired bone defect. Turn the large knob to lock the guide into an acceptable position. Push the sharp teeth of the wire guide onto the bone to ensure guide wire drills to the ball tip. Turn the small knob to lock the wire guide.

2. Introduce the Guide Wwire into the Drill Guide.

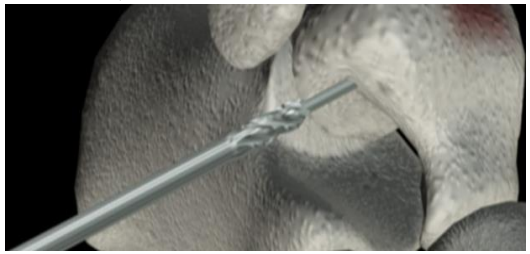


3. Check the placement with fluoroscopic guidance. Reposition if needed and insert the guide wire into the defect.

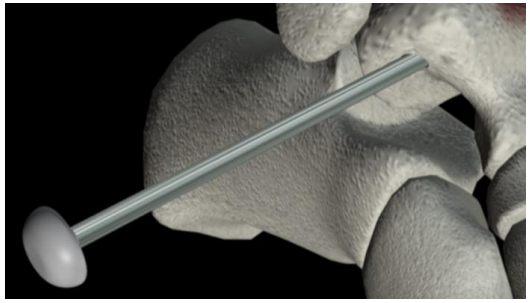


4. Re-check final guide wire placement under fluoroscopic guidance both AP and lateral. If the position is correct, remove the targeting guide.

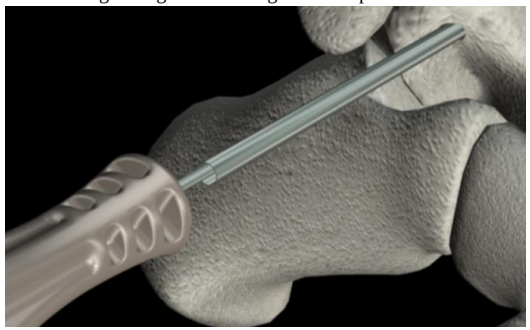
5. Using the cannulated 5.3mm drill, insert over the guide wire and drill to the desired bone defect under fluoroscopic guidance (both AP and lateral).



6. Insert the working cannula with obturator; once in place, remove the obturator. Note: The working cannula may help reduce backpressure while injecting the optional graft*.

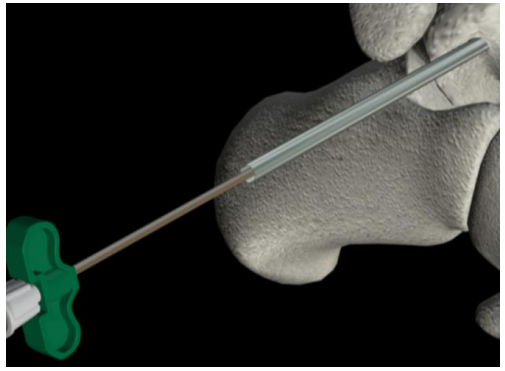


7. Begin debridement of the bone defect using the closed curette and inserting through the working cannula up to the bone defect.



8. Using a combination of suction and lavage, remove debrided tissue from the defect.

9. Inject optional WMT graft*, starting at the back of defect, begin injection until resistance is felt, and then begin withdrawing needle and working cannula as injection proceeds. This will help eliminate backpressure that can make injection difficult.



10. If needed, the supplied tamp may be used to pack the graft to ensure complete filling.

11. Once complete, confirm graft placement and close in standard fashion. Note: If graft material extravasates from the drill hole, simply use a gentle wash and suction to remove