CORE DECOMPRESSION PROCEDURE KIT: INSTRUMENTS

135497-6

The following languages are included in this packet:

English (en)	Deutsch (de)	Nederlands (nl)	Français (fr)
Español (es)	Italiano (it)	Português (pt)	中文- Chinese (sch)
Türkçe (tk)			

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.

CE 0086*

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

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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
LOT	Batch code
REF	Catalog number
②	Do not re-use
⚠	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Storage temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
℞ ONLY	For prescription use only
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel

UHMWPE	Ultra High Molecular Weight Polyethylene
CaSO4	Calcium Sulfate
HA	Hydroxyapatite

Description

The Core Decompression Procedure Kit consists of single-use, disposable instruments and PRO-DENSE™ Injectable graft (where applicable) designed to efficiently facilitate a standard core decompression surgical procedure. This product is provided sterile for single patient use. PRO-DENSE™ Injectable graft medical information can be found in the graft's package literature.

Warnings and Precautions

Proper surgical techniques are necessarily the responsibility of the medical professional. The Core Decompression Procedure Kit instruments are furnished as tools to facilitate standard core decompression or other standard surgical procedure. 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. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

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

Caution: Do not puncture/disrupt the articulating surface or joint space.

<u>Intra-Operative Precautions</u>

Use medical devices in accordance with their labeled indications and Wright Medical Technology's 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 Wright Medical Technology'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.

Handling and Use

The Core Decompression 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 Core Decompression Procedure Kit is for single patient use and should never be reused.

Devices labeled for single-use only should never be reused. 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. Unused or expired product should be properly discarded. This kit, or provided graft implant, is designed for single site use. Use the Core Decompression Procedure Kit aseptically.

Surgical Instruments Included:

3.2mm Guide Wire:	Guides 9mm Cannulated Drill Bit to desired location.
Tissue Protector:	Minimizes soft tissue interference during drill bit use.
9.0mm Cannulated Drill Bit:	Slides over the 3.2mm Guide Wire to create tunnel.
Working Cannula Obturator:	Fits inside working cannula and over guide wire to help direct working cannula into created tunnel.
Working Cannula:	Provides continuous access to surgical site when placed into created tunnel.
Curette:	Aids in the debridement of necrotic bone.
Tamp:	Used to clear obstructions in working cannula & tunnel.
Needle/Suction:	May be used to flush and aspirate created tunnel.

Note: Care should be taken not to use instruments for leverage as fractures may result.