Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany
Tel.: +49 (0) 661-9 41 95-0
Fax: +49 (0) 661-9 41 95-850
info@moeller-medical.com
www.moeller-medical.com

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Instruction leaflet

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MöllerMedical

Instructions for Use TRAUMACEM™ V+ Injection Cannula

Manufacturer:
Möller Medical GmbH

Distributed by:
DePuy Synthes
COMPANIES OF Johnson & Johnson

Device in scope

03.702.121S	TRAUMACEM™ V+ Injection Cannula, for TFNA System

Description
The TRAUMACEM™ V+ Injection Cannula, for TFNA System is a sterile packed injection cannula designed for the augmentation of suitable DePuy Synthes implants.

Intended use
The TRAUMACEM™ V+ Injection Cannula, for TFNA System is intended for the augmentation of suitable TFN-ADVANCED® Proximal Femoral Nailing System Head Elements (TFNA Helical Blades and TFNA Screws) with PMMA[1]-based bone cement in the proximal femur region. The injection cannula may only be used with the TRAUMACEM™ V+ Injectable Bone Cement and the TRAUMACEM™ V+ Syringe Kit.

[1] PMMA = Polymethyl Methacrylate

Refer to the corresponding instruction for use regarding indications, contraindications, compatibility, use, precautions, warnings and side effects of the bone cement used in conjunction with the TRAUMACEM™ V+ Injection Cannula. For information on compatibility with other devices or systems, consultation with a DePuy Synthes representative is recommended.

Indications
The indications for the augmentation procedure using the TRAUMACEM™ V+ Injection Cannula are defined by the PMMA-based bone cement and can be found in the respective instructions for use.

Contraindications
This device is not to be used in patients with coagulation disorders or infections. Further contraindications are defined by the PMMA-based bone cement and can be found in the respective instructions for use.

Patient Target Group
The patient target group is defined by the PMMA-based bone cement and can be found in the respective instructions for use.

Warnings and precautions
Since the device is used in technically complex surgery, the physician should be familiar with handling and use of the device, the other instrumentation and the procedure. It is also necessary to check whether the patient has allergies to materials (e.g. nickel) contained in the device. Should this be the case, the use of the device is at the

discretion of the attending physician.
The safe use of the device cannot be guaranteed if used in conjunction with MRI, which is associated with certain risks, including heating or migration of the device and artefacts on the MRI image.
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established (only for European Union). Other countries should follow local regulations or procedures.

Side effects
The side effects are defined by the PMMA-based bone cement and can be found in the respective instructions for use.

Materials
The device contains the following materials:
- Stainless steel: Cannula including sleeve and plunger
- Polybutylene terephthalate: Handles and other plastic components

Device content
Each device contains a side-opening cannula (with Luer-lock) including a sleeve and a plunger.

Mode of use
For further information on the use of the TRAUMACEM™ V+ Injection Cannula, for TFNA System please refer to the DePuy Synthes surgical technique for TFN-ADVANCED® Proximal Femoral Nailing System.

Sterility
The device is supplied sterile. Before opening, check that the packaging is intact. Remove items from the packaging while maintaining aseptic conditions. Do not use if the packaging seal is broken or if the sterile barrier has been breached.

Single-use
The device is intended for single-use only and may not under any circumstances be reused. The reuse of a single-use device poses an infection risk to patients and users. Contamination of the device can lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization can adversely affect important material and design properties and product function.

Storage
The device should be stored in a clean, dry environment and protected from direct sunlight. Do not use after the expiration date on the label.

Disposal
Disposal takes place in accordance with the hospital ordinance or the applicable laws. Due to the risk of infection and injury, care must be taken to avoid all contact with the tips or sharp edges of the instruments. This is especially important for contaminated instruments.

Symbols


Consult instructions for use

Batch code

Catalogue number


Keep dry


Keep away from sunlight


Manufacturer


Use by YYYY-MM-DD

Sterilized using ethylene oxide


Do not reuse


Do not resterilize


Do not use if the packaging is damaged

Only for USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

For further information about symbols used please refer to our homepage: **www.moeller-medical.com/glossary-symbols**