Instructions for Use
Access Kit, 10 G
Biopsy Kit, 10 G
Access Drill, 10 G

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

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DePuy Synthes
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Instructions for Use

Access Kit, 10 G
Biopsy Kit, 10 G
Access Drill, 10 G

The Access Kits, Access Drill and Biopsy Kits are single use instruments. The Access Kit instruments are used to establish percutaneous access and to prepare the vertebral body for the injection of bone fillers. The Biopsy Kit instruments are designed to obtain vertebral body bone biopsies.

This instructions for use contains information about the following products:
03.804.514S Access Kit, 10 G, Diamond Tip, Double Pack
03.804.515S Access Kit, 10 G, Beveled Tip, Double Pack
03.804.519S Access Kit, 10 G, Diamond Tip, Single Pack
03.804.520S Access Kit, 10 G, Beveled Tip, Single Pack
03.804.521S Access Drill, 10 G
03.804.522S Biopsy Kit, 10 G

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials
Stainless Steel
Reinforced Plastic

Intended Use
The Access Kit and Access Drill are intended to prepare the access to the vertebral body for subsequent use of:
– vertebral augmentation procedures
– bone filler applications
– other applications where minimal invasive access to the vertebral body is needed

The Biopsy Kit is intended for obtaining vertebral body bone biopsies in conjunction with Access Kit instruments.

Note: For use of Access Instruments and Biopsy Kit in conjunction with other systems and bone fillers, please refer to the corresponding system's directions for specific information on its compatibility, use, precautions, warnings, potential adverse events, undesirable side effects and residual risks.

Indications/Contraindications
For use in conjunction with other systems and bone fillers, please refer to the corresponding indications and contraindications.

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
This IFU alone does not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the instructions for use and, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there are risks of side effects and adverse events. Possible adverse effects may include: embolization of thrombus or other materials which can in turn lead to a symptomatic pulmonary embolism or other clinical consequences, neurological injury, injury to vessels, organs, bone or soft tissue; early and late infections, haematoma and impaired wound healing, pain and death.

Sterile Device

Sterilized using ethylene oxide

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.


Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.


Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single Use Device


Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, re-use or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Warnings and Precautions
– The product may only be used by surgeons who are experienced in spinal surgery and who are aware of general risks of spinal surgery and the product-specific surgical procedures. The surgeon is responsible for ensuring that the operation is carried out properly.
– The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect bone filler, incorrectly combined components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
– Before using the system, ensure that the length and gauge size is suitable for the specific procedure.
– The system may only be used under fluoroscopic control with high quality imaging.
– Care should be taken in the handling of sharp devices. Incorrect handling might cause injury to patient and/or user.
– Breakage of the device may require intervention or retrieval.
– The timing for release of the bone filler is dependent on the bone filler selection.

General risks of surgery are not described in this instructions for use. For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
For use of Access Instruments and Biopsy Kit in conjunction with other systems and bone fillers, please refer to the corresponding system's directions for specific information on its compatibility, use, precautions, warnings, potential adverse events, undesirable side effects and residual risks.

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Treatment before Device is Used
Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged.

Disposal
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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