Drill-bit Product Range

Signature Orthopaedics' Range of Drill Bits

Instructions for Use 192-111-001 Rev. J Issue Date: JUL-2023

CE 0123

Caution:

Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.

U.S. Federal law restricts this device to sale by or on the order of a physician.

1 General Instructions

The Signature Orthopaedics' range of drill bits are intended to drill holes in bone. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the parts, but must also be aware of their mechanical limitations. The device is intended to drill holes of certain diameter, and not withstand excessive loads.

Signature Orthopaedics instruments should only be used with approved devices and accessories.

2 Design

Signature Orthopaedics' drill bits are typically designed with a drive feature to connect to the driving device, and a fluted body to cut bone. These features are designed to meet the specific needs of the drill bit. Drill bits are typically manufactured from Stainless Steel.

3 Indications for Use

Signature Orthopaedics' drill bit product range is indicated for use at various anatomical locations and bone densities.

4 Contraindications for Use

Signature Orthopaedics' drill bit range is contraindicated at anatomical locations where risk to damaging adjacent vasculature is excessive.

5 Precautions

1) U.S Federal law restricts this device to sale by or on the order of a physician.
2) If the instrument is subjected to excessive load, speed or bone mineral density, breakage or damage is possible; therefore the surgeon should be aware of the details and limitations of the procedure.
3) It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device. These instructions must be read in their entirety before use of the device.
4) Where package labelling indicates, devices are supplied sterile and intended for single use only. Resterilization and re-use of these devices is strictly prohibited. Resterilization of the device may alter device material properties including reducing mechanical properties and/or biocompatibility. Re-use of devices may result in cross-contamination between patients and decreased mechanical performance. Do not use the device if its packaging is damaged. Explanted devices are to be treated as biological hazards and disposed of immediately.
5) Where reuse of the device is not indicated by the device's labelling, the device may be reused following cleaning and sterilization in accordance with sections 7 and 8 of this IFU.
6) The patient must be cautioned about the associated risks and may need to sign documentations declaring his/her will to under go the surgery.
7) Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.
8) Correct handling of devices is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
9) Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
10) Careful attention should be paid to asepsis and avoidance of anatomical hazards.
11) Care must be taken whilst handling the drill bits as the cutting edges are sharp and may cause accidental damage to the patient or operator.

6 Packaging and Labelling

Components should only be used if the factory packaging and labelling are intact. If the sterile barrier has been broken, return the component to Signature Orthopaedics.

7 Sterilization

Drill bits may be supplied sterile, as indicated on the device's labelling. Dispose of these drill bits if the packaging is damaged. Resterilization of the drill bits is strictly prohibited, as it may alter the mechanical integrity of the device.

Unless specifically labelled sterile, the drill bits are supplied non-sterile and must be sterilized prior to use as per the guidelines for reprocessing reusable instruments provided.

8 Cleaning

If indicated on the labelling, the drill bits are supplied sterile and intended for single use only. Dispose of the drill bits if the packaging is damaged. Cleaning of the drill bits is not recommended.

Otherwise, drill bits are delivered non-sterile and must be sterilised prior to use as per the guidelines for reprocessing reusable instruments provided.

Manual Cleaning

Drill bits are to be cleaned immediately after use with warm water and a mild detergent. Drill bits consisting of multiple components must be disassembled (if possible) prior to cleaning. After cleaning, the drill bits should be rinsed thoroughly with de-ionized water and dried.

Cleaning before Sterilization

Instruments may be cleaned using a broad spectrum bactericide and fungicide agent in accordance with the instructions of the manufacturer of the agent.

Caution:

Do not clean instruments with products containing Sodium Hypochlorite (NaOCl) and Sodium Hydroxide (NaOH).

Corrosive products or abrasive instruments should not be used.

Instruments should be thoroughly inspected to ensure that they are in good condition and operating order.

9 Storage and Handling

Drill bits are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilization tray respectively.

10 Limited Warranty / Liability

Signature Orthopaedics Europe Ltd. products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Signature Orthopaedics Europe Ltd. shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Signature Orthopaedics Europe Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Signature Orthopaedics Europe Ltd. intends that these instruments should be used only by physicians having received appropriate training in orthopaedic surgical techniques.

11 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Signature Orthopaedics location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below:

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12 Glossary of Symbols

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD REFERENCE
REF	**Catalogue Number**	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 Ref # 5.1.6 FDA Recognition #5-117
LOT	**Batch Code**	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Ref # 5.1.5 FDA Recognition #5-117
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Ref # 5.4.3 FDA Recognition #5-117
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 Ref # 5.2.6 FDA Recognition #5-117

	**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.	ISO 15223-1 Ref # 5.4.2 FDA Recognition #5-117
	**Do not use if package damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 Ref # 5.2.8 FDA Recognition #5-117
	**Symbol for Prescription Device**	Caution: Federal law restricts this device to sale by or on the order of a physician.	Guidance for Industry and FDA on Alternative to certain Prescription Device Labelling Requirements
	**Sterilized by Ethylene Oxide**	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 Ref # 5.2.3 FDA Recognition #5-117
	**Sterilized by irradiation**	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1 Ref # 5.2.4 FDA Recognition #5-117
	**Date of Manufacture**	Indicates the date when the medical device was manufactured.	ISO 15223-1 Ref# 5.1.3 FDA Recognition #5-117
	**Manufacturer**	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 89/79/EC	ISO 15223-1 Ref # 5.1.1 FDA Recognition #5-117
	**Use-by-date**	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Ref # 5.1.4 FDA Recognition #5-117
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Ref # 5.4.4 FDA Recognition #5-117

	**CE marking and notified body number**	Indicates a product have been assessed by a notified body (xxxx) to meet safety, health, and environmental protection requirements for the European Economic Area (EEA).	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2023] OJ L117/1, art 20

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