ISO 9001/ ISO 13485

CE 0197

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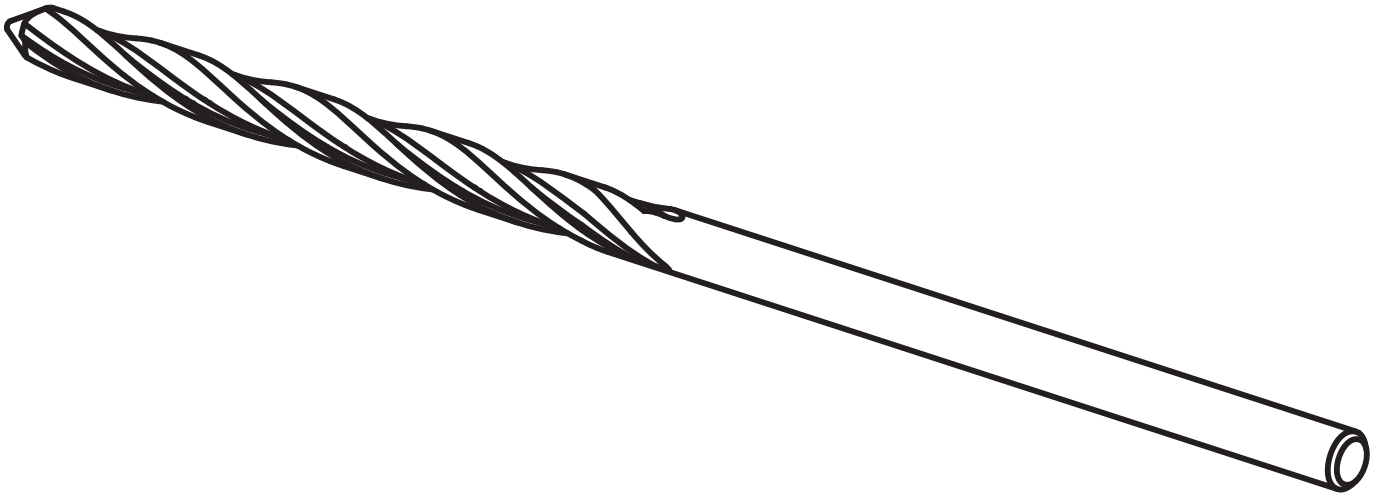
**IFU-IIa-003/01.18**



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# INSTRUCTIONS FOR USE

*Important product information for*

# SINGLE-USE SURGICAL DRILL BITS

## 1 INDICATIONS

1. Single-use surgical drills are used for drilling and reaming a socket of a metallic ChLP screw when the treatment is completed. These drills are used during the removal of screws whose connecting sockets were damaged and their removal with the use of a screwdriver is impossible.
2. Drills are included to the group of rotary surgical instruments used in conjunction with a driller or another active drive.
3. Surgical and orthopaedic instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.
4. CAUTION: DO NOT USE THE HSS *(TiN)* DRILL BIT FOR BONE DRILLING!

## 2 DESCRIPTION

1. Surgical drills are single-use devices, provided in a sterile version only.
2. Packaging of a drill should be intact at the time of receipt.
3. The unit package of a sterile device contains: one piece of a device in a sterile condition.
4. A sterility indicator is placed on the sterile package.
5. The package in equipped with the product label. This label *(as a primary label)* contains:
   1) Logo **ChM** and the address of the manufacturer.
   2) Material: HSS *(TiN)*.
   3) The name and size of the device.
   4) Production batch number *(LOT)*, e.g. XXXXXXX.
   5) STERILE sign - indicates a sterilized product.
   6) Sterilization batch number, e.g.: S-XXXXXXX.
   7) Expiration date and sterilization method.
   8) Catalogue number *(REF)*, e.g.: 40.XXXX.XXX.
   9) CE conformity mark and the Notified Body number *(0197)*.
6. In addition to the device primary label, an auxiliary label with specific market requirements of a given area may be placed on the unit package *(e.g. legal requirements of the country in which the device will be distributed)*.
7. The package contains: Instructions For Use of a surgical drill.
8. Depending on the size or type of the drill bit, the following information may be marked on its surface:
   1) Logo **ChM**.
   2) Production batch number *(LOT)*, e.g. XXXXXXX.
   3) Catalogue number *(REF)*, e.g.: 40.XXXX.XXX.
   4) Size - e.g. 1.2 *(diameter)*.
   5) CE conformity mark and the Notified Body number *(0197)*.
9. Right-handed drill bit.

## 3 MATERIALS

1. Surgical instruments are made of high-speed steel.
2. Each instrument is exposed to occurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

## 4 WARNINGS AND PRECAUTIONS

1. The operator should consciously decide about the use of a drill made of high-speed steel during the procedure of ChLP bone screws removal.
2. Instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.
3. The surgeon should be familiar with all components of the device before use and should personally verify if all components and instruments are present before the surgery begins.
4. Before the procedure begins, all instruments should be carefully inspected for their condition and proper functioning. They should be undamaged and without any signs of corrosion. Blades and cutting edges should be sharp and undamaged. Damaged or corroded instruments should be immediately replaced. The use of bent, damaged or corroded instruments is not allowed.
5. The surgeon should verify if the rotary instrument has been properly inserted and tightened into the drive before activation to avoid migration and possible injury.
6. Operating room personnel should wear proper eye protection during the surgical procedure requiring the use of rotary instruments and medical drive.
7. The drills for metal are hard and brittle. In order to avoid cracking, begin the drilling with an already rotating drill and maintain the chosen axis during the whole drilling process.
8. Manual cooling with the use of physiological saline should be applied.

9. A proper removal of the screws procedure should be carried out with a maximum protection of a surgical field, e.g.: with swabs soaked in physiological saline, and the use of a rinsing-sucking system, which should be available in the operating theatre.
10. It is necessary to suck-in the metallic swarfs during the drilling procedure. The surgical field should be well secured so no swarfs enter the patient's tissues. The left swarfs may cause the occurrence of *"metallosis"* which is a direct cause of pain, limb dysesthesia, and even polyneuropathy *(a syndrome of peripheral nerves damage)*. Delayed oversensitivity, increased susceptibility to infection and osteolysis are also on the list of possible complications.
11. Do not apply excessive force when using the instrument – it may lead to its permanent damage and, in consequences, to mal-function of the device.
12. While rare, intraoperative fracture or breakage of the instrument can occur. It is necessary to remove the instrument fragments from the operative field immediately and dispose of them following the appropriate protocol of the hospital.
13. Avoid excessive speed as it can cause temporary rise in temperature of adjacent bone and surrounding tissues above normal physiological level. It may result in tissue necrosis.
14. In the case of suspected or documented allergy or intolerance to metallic materials, surgeon shall find out if the patient develops allergic reaction to the instrument material by ordering appropriate tests.
15. Instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and, in consequences, damage to the instrument.
16. Single-use surgical drill which was in contact with patient's tissues and body fluids must not be re-used due to a potential risk of cross-infection *(with viruses, bacteria and prions)*.
17. A reuse or clinical processing of a single-use product may lead to its contamination, e.g.: due to transfer of an infectious material from one patient to another. It can result in injuries or death of a patient or a user.
18. After the drilling procedure, single-use surgical drill should be disposed of in accordance with appropriate hospital procedures.
19. Firm control of the drive with the instrument attached must be maintained to avoid injury to the patient or operating room personnel.

## 5 STORAGE

1. The products should be stored in their protective packagings in a clean and dry room, at the room temperature and off the direct sunlight.

## 6 CONTRAINDICATIONS

1. Infection or inflammation in the operative site.
2. Suspected or documented allergy or intolerance to implant materials. Prior to device use, if oversensitivity is suspected, the surgeon should establish whether the patient may develop any allergic reaction to the device material by ordering the execution of appropriate tests.
3. Blood supply limitation in the operative site.
4. Any situation in which the implant removal procedure would interfere with the anatomical structures or physiological performance.
5. Any situation in which the implant removal should be considered *(e.g.: pregnancy)*.
6. Any other medical conditions which exclude the potential benefits of the procedure.
7. Any situation in which, according to the physician, there is any contraindication against the removal of a metallic implant fixation.
8. The above-mentioned list of contraindications is not exhaustive.

## 7 PRE-OPERATIVE RECOMMENDATIONS

1. The drill must be stored in a protective packaging for a sterile product. The packaging shall not be opened before the beginning of a surgical procedure.

2. Do not use the drill if the original, sterile packaging is damaged. Sterility cannot be guaranteed if the packaging is not intact. The package shall be carefully checked prior to use.
3. The product should be removed from the packaging with the proper use of aseptic techniques.
4. The removal procedure shall be carried out by a surgeon familiar and experienced with adequate operating rules and techniques and skilled in the practical use of instrument sets for **ChM** implants. The selection of surgical technique adequate for specific patient remains surgeon's responsibility.
5. The operator should consciously decide about the use of a drill made of high-speed steel during the procedure of ChLP bone screws removal.
7. The surgical procedure shall be carefully planned. In order to assure that the surgeon has all necessary instruments for implants removal, the following information is indispensable: implant type, the time/date of implantation, implant material *(implantable steel or titanium)*, size and shape of the socket *(hexagonal, star, cruciform)*, screw diameter, visible implant damage.
8. An appropriate number of drills of proper sizes should be available at the time of surgery. It is recommended to use only one drill for reaming of a maximum two bone screw sockets.

## 8 RECOMMENDATIONS FOR SURGICAL DRILLS PROVIDED STERILE

1. Surgical drill is delivered as a sterile product in a sterile packaging with the inscription *"STERILE"*. This means that the product is sterile, and the manufacturer is responsible for the process of sterilization.
2. Sterilization was conducted with the use of gamma radiation with a minimum dose of **25kGy**.
3. Prior to use of a sterile device the following rules apply:
   1) Check out the expiration date of sterilization.
   a) Do not use the device with an overstepped sterility date!
   2) Check out if the sterile package is not damaged.
   a) Do not use the device if the sterile package is damaged.
   3) Check out whether the colour of the sterility indicator on the sterile packaging is red, as it indicates that irradiation sterilization of the device was performed.
   a) Do not use the device if the sterility indicator colour is different than red!
   4) CAUTION:
   a) The products should be used in the order of their receipt *(the FIFO rule "*first in, first out"), paying particular attention to all expiration dates on the label.

## 9 RE-STERILIZATION

1. It is forbidden to re-sterilize single-use surgical drills.

## 10 RE-PROCESSING

1. It is forbidden to re-process single-use surgical drills.

*If this instruction appears unclear, please contact the manufacturer, who shall provide all required explanations.*

*Updated INSTRUCTIONS FOR USE are available at the following website:* **www.chm.eu**

*IFU-IIa-003/01.18; Date of verification: January 2018*

**SYMBOL TRANSLATION • OBJAŚNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ • EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY • TRADUZIONE SIMBOLI**

| | |
|---|---|
|  | Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare |
|   | Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterlilizzare |
|  | Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при повреждённой упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione é danneggiata |
|  | Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le instruzioni per l'uso |
|   | Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile |
|  | Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza |
| **STERILE R** | Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione |
| **STERILE VH202** | Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno |
| **REF** | Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo |
| **LOT** | Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto |
| **Mat:** | Material • Materiał • Материал • Material • Material • Materiál • Materiale |
| **Qty:** | Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita' |
|  | Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il |

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