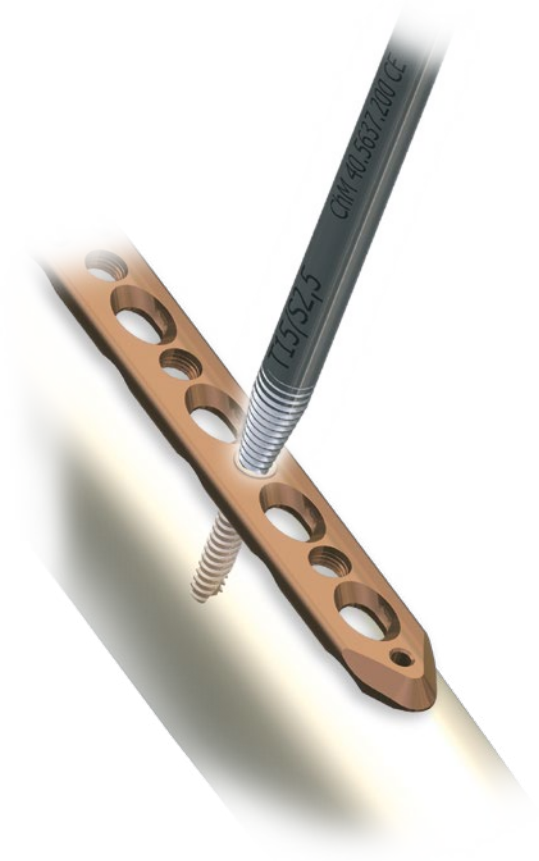
ChM®

ChLP SCREWS REMOVING

- *INSTRUMENT SET 40.5655.000*
- *SURGICAL TECHNIQUE*



www.chm.eu

SYMBOLS DESCRIPTIONS	
	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the proceeding.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.

www.chm.eu

Document No ST/36C
Date of issue 13.06.2014
Review date P-002-14.09.2016

I. INTRODUCTION

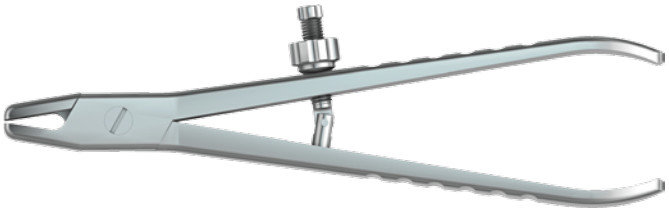
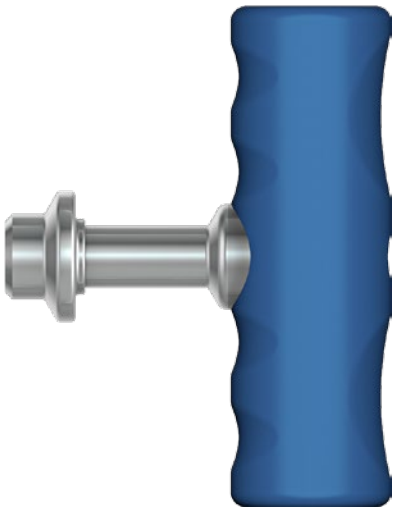
Instrument set is intended for implants removing of ***ChLP*** plating system. For selection of adequate instruments, depending on type of removed implant, use the table presented below.

TABLE 1. Selection of adequate instruments for removing of ChLP screws

				Instruments						
				1		2	3	4	5	6
System	Ø screw	Screw socket		Screwdriver tip		Extractor *(used for socket)*	Drill bit	Trephine	Extractor *(used for cortical part)*	Holder
		S	T	S	T					
4.0ChLP	2.4	-	8	-	**40.5715.000**	**40.5637.400**	**40.5657.026**	**40.5639.100**	**40.5999.100**	**40.1973.000**
	2.7									
5.0ChLP	2.4	2.5	15	**40.5717.000**	**40.5716.000**	**40.5637.200**	**40.5657.034**	**40.5639.100**	**40.5999.100**	**40.1973.000**
	2.7									
	3.5							**40.5639.200**	**40.5999.200**	**40.1761.000**
	3.9									
7.0ChLP	5	3.5	25	**40.5719.000**	**40.5718.000**	**40.5637.300**	**40.5657.047**	**40.5639.300**	**40.5999.300**	**40.1761.000**
	5.4									
	6.5	5	30	**40.5721.000**	**40.5720.000**	**40.5637.500**	**40.5657.062**	**40.5639.400**	**40.5999.400**	**40.1761.000**
	7.3									

II. INSTRUMENTS

40.5655.000

		Name	Catalogue No.	Pcs
1		Holder for 1.5-2.7mm screws	**40.1973.000**	1
2		Holder for 3.5-6.5mm screws	**40.1761.000**	1
3		Extractor for ***ChLP*** screws - T8	**40.5637.400**	1
4		Extractor for ***ChLP*** screws - T15/S2.5	**40.5637.200**	1
5		Extractor for ***ChLP*** screws - T25/S3.5	**40.5637.300**	1
6		Extractor for ***ChLP*** screws - T30/S5	**40.5637.500**	1
7		Screwdriver tip T8/100 - 1/4	**40.5715.000**	1
8		Screwdriver tip T15/100 - 1/4	**40.5716.000**	1
9		Screwdriver tip T25/100 - 1/4	**40.5718.000**	1
10		Screwdriver tip T30/100 - 1/4	**40.5720.000**	1
11		Screwdriver tip S2.5/100 - 1/4	**40.5717.000**	1
12		Screwdriver tip S3.5/100 - 1/4	**40.5719.000**	1
13		Screwdriver tip S5/100 - 1/4	**40.5721.000**	1
14		Trephine 2.4/2.7	**40.5639.100**	1
15		Trephine 3.5	**40.5639.200**	1
16		Trephine 5.0	**40.5639.300**	1
17		Trephine 7.3	**40.5639.400**	1
18		Extractor for ***ChLP*** screws 2.4/2.7	**40.5999.100**	1
19		Extractor for ***ChLP*** screws - 3.5	**40.5999.200**	1
20		Extractor for ***ChLP*** screws - 5.0	**40.5999.300**	1
21		Extractor for ***ChLP*** screws - 7.3	**40.5999.400**	1
22		Quick coupling handle T-type	**40.5638.000**	1

		Name	Catalogue No.	Pcs
18		Stand insert for instrument set for removing ***ChLP*** screws	**40.5656.100**	1
		Perforated aluminum lid 1/2 306x272x15mm Gray	**12.0751.200**	1
		Container with solid bottom 1/2 306x272x85mm	**12.0751.100**	1

ATTENTION
Drills are not included in the set. Drills are single-use only, delivered as sterile products. Do not regenerate and resterilize after usage.

ATTENTION
Do not use HSS drill *(TiN)* for drilling in the bone!

		Name	Catalogue No.	Pcs
1		Drill 2.6	**40.5657.026**	1
2		Drill 3.4	**40.5657.034**	1
3		Drill 4.7	**40.5657.047**	1
4		Drill 6.2	**40.5657.062**	1

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

III. UNLOCKING OF *ChLP* SCREWS

NOTE:
Make sure that the screwdriver tip is inserted as deep in the screw head as possible.
Clean the screw head thoroughly prior to the introduction of the screwdriver tip.

Select a proper screwdriver tip *(column 1 of table 1)* for adequate screw socket. *(Fig.1)*

FIG. 1.

Assembly the screwdriver tip with quick coupling T handle **[40.5638.000]** or drive. *(Fig.2)*

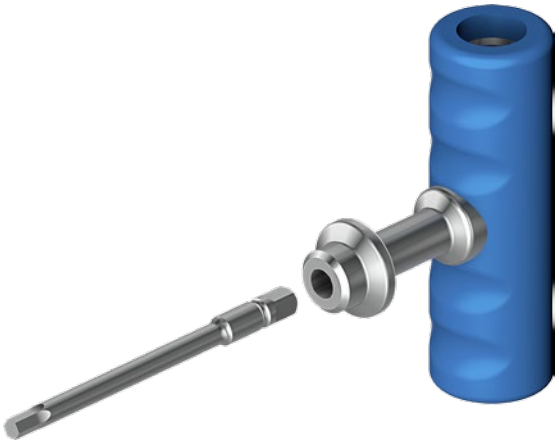


FIG. 2.

Unlock all the ***ChLP*** locking screws in the plate. It will eliminate the risk of the plate rotation while the last locking screw unlocking. *(Fig.3)*

Unscrew loosened ***ChLP*** screws and remove the plate from the bone.

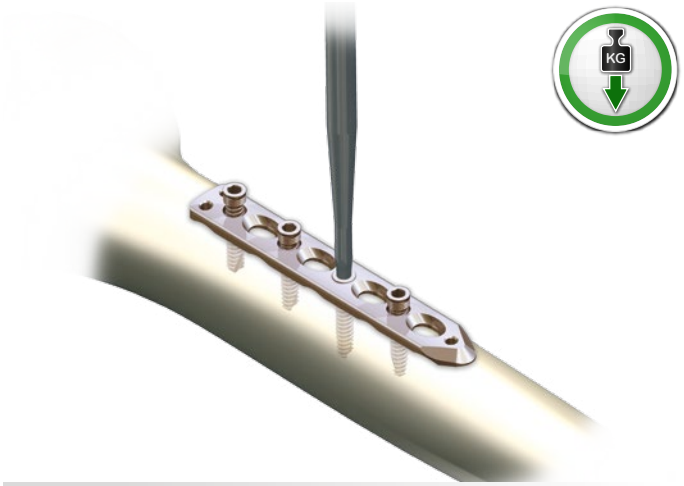


FIG. 3.

In the case of socket damaging, go to point IV.

In the case of success, go to point VIII.

IV. EXTRACTOR USAGE

Select a proper extractor of ***ChLP*** screws *(column 2 of the table 1)* for adequate socket [Fig.4]. Assembly the extractor with quick coupling T handle **[40.5638.000]** or drive *(Fig.5)*.

FIG. 4.

ATTENTION!
It is recommended to cover the surrounding soft tissues.

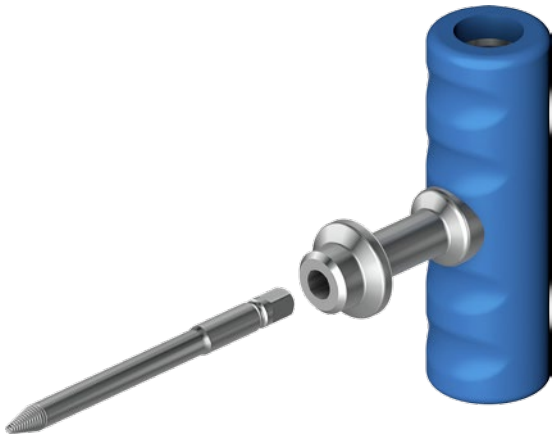


FIG. 5.

Place the tip of the extractor in screw socket. Turning counter-clockwise ***(left-handed turns)***, with axial load, unscrew the screw. Remove all implants. *(Fig.6)*.

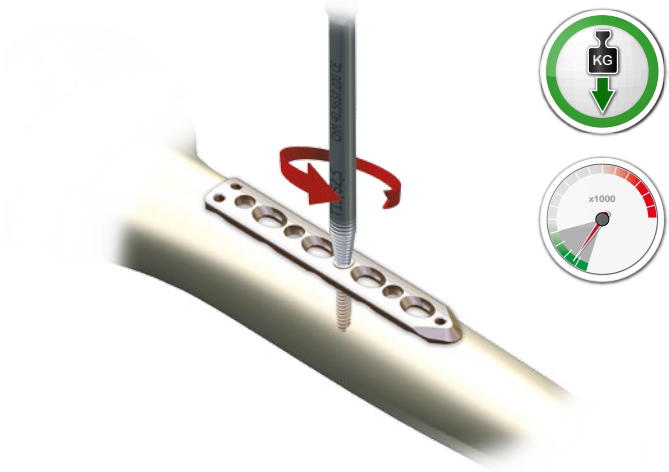


FIG. 6.

Screw removal from the extractor
Using a chosen holder *(column 6 of table 1)*, hold the removed screw and by turning the extractor clockwise, unscrew the screw from the extractor thread *(Fig.7.)*

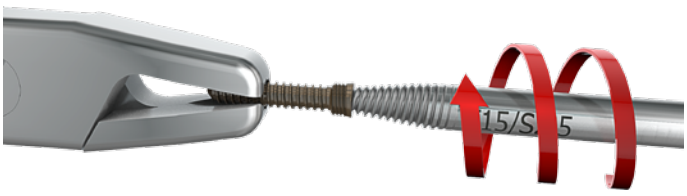


FIG. 7.

In the case of failure, go to point V.

In the case of success, go to point VIII.

V. DRILLING

Select a proper drill diameter *(column 3 of the table 1)*. *(Fig.8)*

FIG. 8.

Mount the drill bit in drive and start the drilling process *(Fig.9)*.

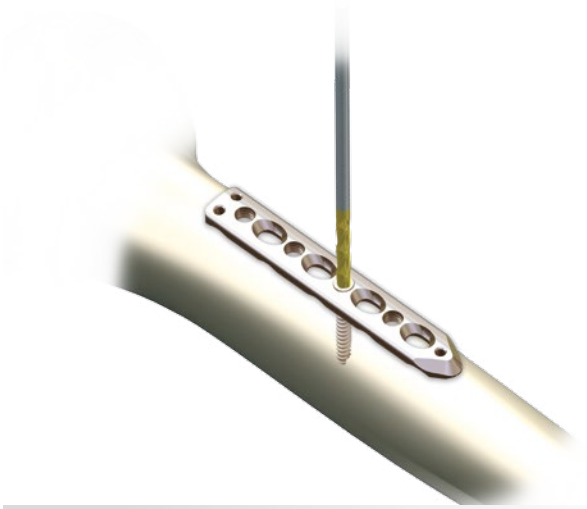


FIG. 9.

Continue the drilling proces until the screw head has been reamed *(Fig.10)*.

During the drilling process it is necessary:
- to begin the drilling with an already rotating drill bit with very low axial pressure;
- to maintain the selected drill axis;
- to avoid using any excessive force;
- to avoid using any excessive rotational speed;
- to use manual cooling with the sterile physiological saline;
- to systematically suck off and remove the drilling residue.

ATTENTION!
It is possible to partially pre-drill the damaged screw socket and reuse the extractor *(see point III)*.

ATTENTION!
Stop the drilling process immediately as the screw head has been reamed.
A properly conducted drilling process makes it impossible for the drill bit to have contact with the tissues.

Important:
1. **Cover the drilling area with the gauze soaked with physiological saline to secure surrounding tissues from material remains of drilling.**
2. **Use the irrigation and suction system while drilling to remove the material remains.**
3. **One drill bit can be used for reaming of maximum two screw sockets.**

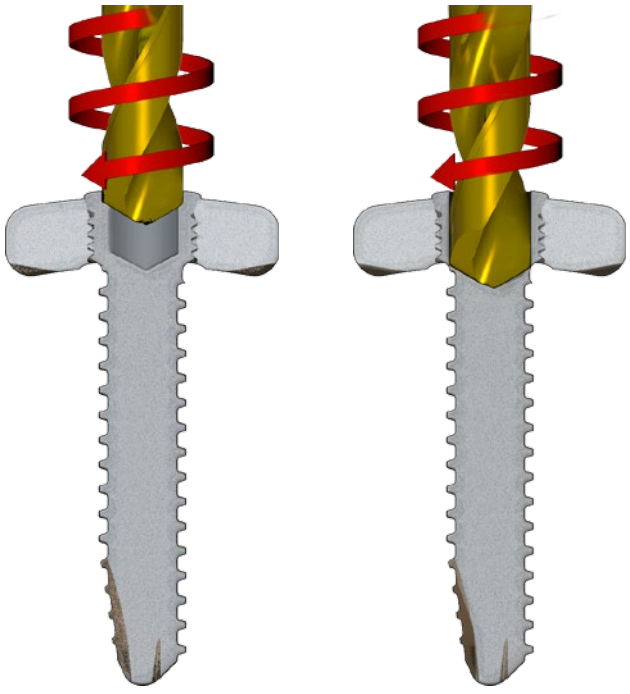


FIG. 10.

VI. TREPHINE USAGE

If the screw protrudes from the bone *(Fig.11)*, **do not use trephines, go to the point VII.**

If the screw does not protrude from the bone *(Fig.12)*, use the trephine to ream the cortical bone.

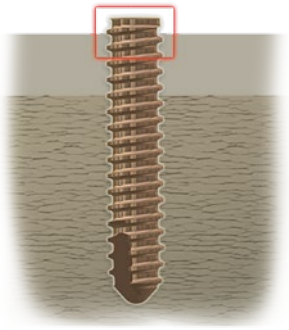


FIG. 11.

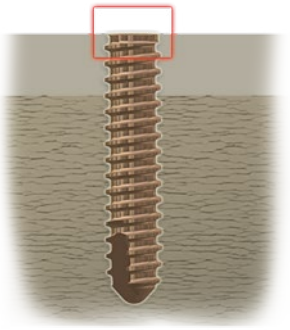


FIG. 12.

FIG. 13.

Select a proper trephine *(Fig.13)* adequate to screw diameter *(column 4 of the table 1)*. Assembly the trephine with T handle **[40.5638.000]** or drive *(Fig.14)*.

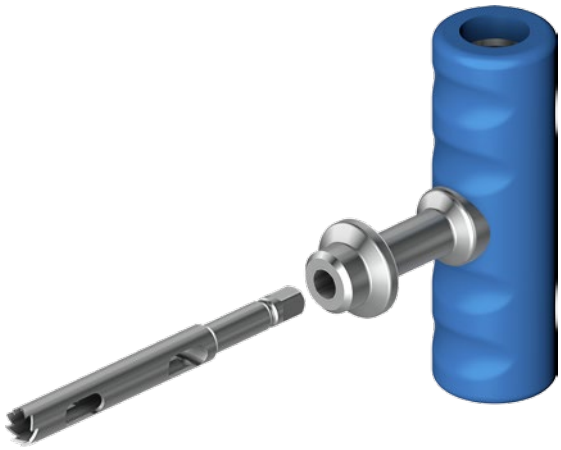


FIG. 14.

While turning counter-clockwise ***(left-handed turns)*** ream the cortical bone to the desirable depth *(about 5mm) (Fig.15)*.

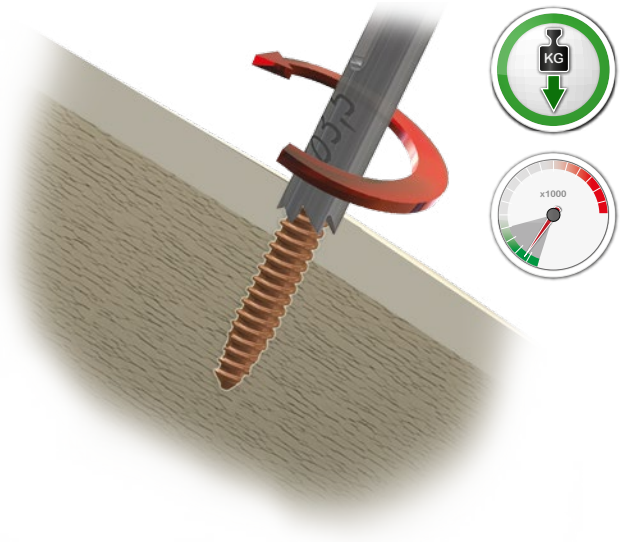


FIG. 15.

VII. CORTICAL SCREW PART REMOVAL

Use extractor *(section VII.1)* or holder *(section VII.2)* to remove the cortical part of locking screw.

VII.1. Use of extractor of screw cortical part

Select a proper extractor *(column 5 of the table 1)* to the diameter of the cortical part of the screw *(Fig.16)*

FIG. 16.

Mount the extractor with quick coupling T handle **[40.5638.000]** or drive. *(Fig.17)*

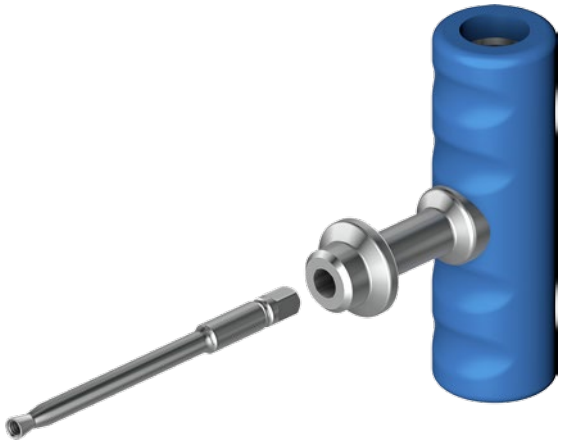


FIG. 17.

ATTENTION:
It is recommended to cover the surrounding soft tissues.

Place the tip of the extractor in the axis of cortical part of the screw. Turning counter-clockwise *(left-handed turns)*, with axial load, remove the remaining in the bone screw part. *(Fig.18.)*

While removing the screw, it is necessary:
- to maintain the selected axis and direction throughout the entire screw removing process;
- to maintain slow rotational speed;
- to use manual cooling with the sterile physiological saline;

IMPORTANT:
1. **Cover the surgical site with the gauze soaked in physiological saline to secure surrounding tissues from material remains of screw removal.**
2. **Use the irrigation and suction system to remove the material remains of screw removal.**

FIG. 18.

Screw removal from the extractor
Using a chosen holder *(column 6 of table 1)*, hold the removed cortical part of the screw and by turning the extractor clockwise, unscrew the screw from the extractor *(Fig. 19.)*

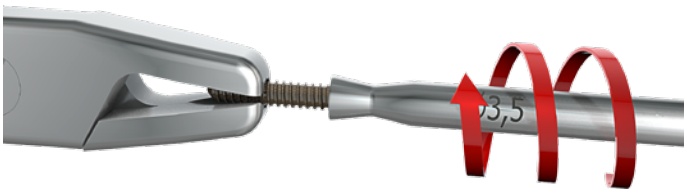


FIG. 19.

VII.2. Holder usage

Choose the proper holder to match the cortical diameter of the screw *(column 6 of the table 1) (Fig.20)*.

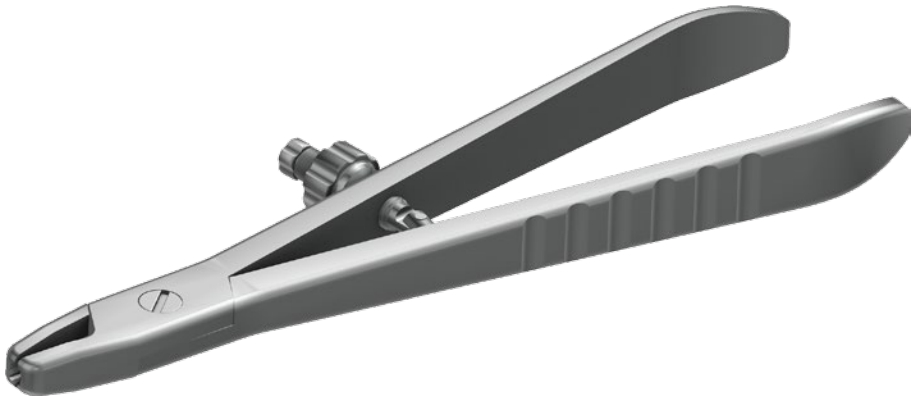


FIG. 20.

Remove the remaining cortical part of the screw from the bone *(Fig.21)*.

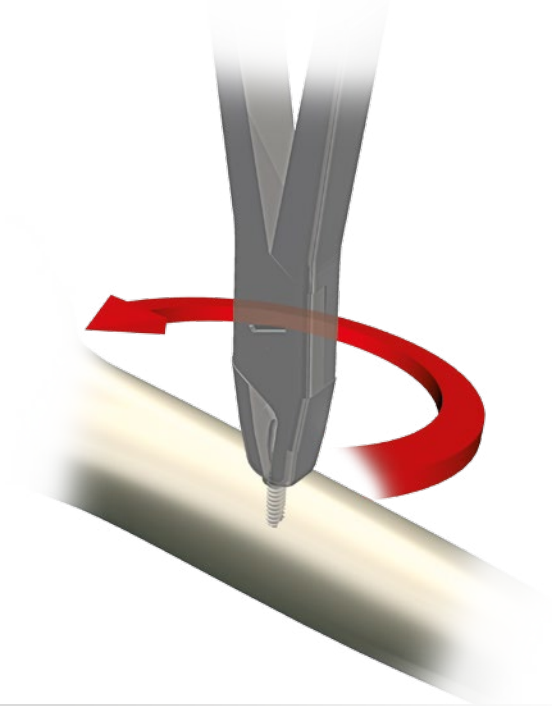


FIG. 21.

VIII. WOUND CLOSURE

Before closing, clean the wound. Perform a final X-ray examination to confirm the removal of all implants, their parts or other undesirable materials from the body.

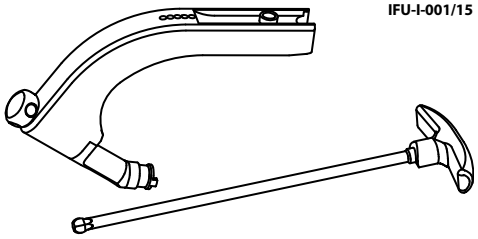
GB

ISO 9001/ ISO 13485

CE

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

IFU-I-001/15



GB

INSTRUCTIONS FOR USE
REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

DESCRIPTION AND INDICATIONS

Instruments manufactured by **ChM** sp. z o.o. are mainly made of steel, aluminium alloys and plastics used in medicine and in accordance with the applicable procedures.

Each medical instrument is exposed tooccurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

The use of instruments in accordance with their intended purpose prolongs their usability.

Instrument's durability is limited and highly related to the manner and frequency of its usage.

The unit package contains one piece of the product in non-sterile condition. The welded clear foil sleeve is typical packaging material. The products may also be supplied as complete sets *(arranged on trays and placed into specially designed sterilization containers)*.

This Instructions For Use is attached both to the unit package and to the instrument set as well.

The packaging is equipped with the product label. The label contains:
- **ChM** logo and the manufacturer's address,
- name, size and catalogue number of the device *(REF)*, e.g.: 40.XXXX.XXX,
- production batch number *(LOT)*, e.g.: XXXXXXX,
- NON-STERILE sign: indicates non-sterile product,
- information symbols *(described in the footer of this Instructions For Use)*.

Depending on the size or type of the product, the following information may be marked on its surface: **ChM** logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stays in natural colour *(silvery-grey)*, is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance.

The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE - Polytetrafluoroethylene)*.

The above mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 10.8.

If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

WARNINGS AND PRECAUTIONS

1. Reusable orthopaedic and surgical instruments are intended for use in operating room conditions only by skilled and trained medical professionals, specialists in surgery, who are familiar with their use and application.
2. The surgeon should be familiar with all components of the device before use and should personally verify if all components and devices are present before the surgery begins.
3. Prior to the device usage and before procedure begins, all components of instruments should be carefully inspected for proper functioning and condition.Blades of all cutting edges should be sharp and undamaged. Replace any damaged accessory immediately. Employing bent or damaged surgical instruments in surgery is not allowed.
4. Tissue structures close tooperative site must be protected.
5. Contact of the instrument with metal operating equipment, retractors or other devices may cause damage that necessitates intraoperative replacement of that instrument.
6. Do not apply excessive force when using the instrument – it may lead to its faulty operation and, in consequences, to permanent damage.
7. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to extensive use or extensive force are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed.
8. In the case of breakage and presence of instrument fragments in the patients' body, remove and dispose of them following the appropriate protocol of the unit.
9. 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.
10. Improper or careless handling of the instruments and related chemical, electrochemical and physical damage may adversely affect the corrosion resistance and shorten the life of the instruments.
11. Reusable orthopaedic and surgical 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 of the instrument.
12. It is extremely important to follow the calibration deadline which is permanently marked on the torque instruments *(see CALIBRATION)*. Use of a torque instrument with an overstepped calibration date may lead to potential injury, implant or device damage, or loss of correction.
    If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.

CLEANING, DISINFECTION AND STERILIZATION

Prior to use of a non-sterile device the following rules apply:
- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure *(washer-disinfector)* for cleaning and disinfecting.
- Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

Preparation for cleaning

After removing the product from its original packaging and before each cleaning, remove possible surface contamination using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.

It is not permitted to use brushes made of metal, bristles or materials which can cause damage to the device.

Cleaning and disinfection process

Chosen detergents and disinfectants must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of these detergents.

CAUTION:

To avoid product damage (pitting, rust), **DO NOT** *use highly aggressive agents (NaOH, NaOCl), salt solutions and other unsuitable cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.*

Manual cleaning
- Apply cleaning agent solution to the product surfaces with careful brushing. A suitable brush must be used for cleaning holes.
- If applicable, ultrasonic cleaning may be used. The ultrasonic bath must be prepared according to the manufacturer's instructions.
- Next rinse thoroughly under running water. It is recommended to use demineralized water.
- Visually inspect the entire surface of the device for damage and contaminants. Damaged products must be removed. For contaminated products, the cleaning process should be repeated.

CAUTION:
- *Never use metal brushes, files or sponges for contaminants removal.*
- *Rinse thoroughly and carefully. Sterile demineralized water facilitates water spots removal from the instrument's surface.*
- *Instruments with cannula should be blown through using compressed air gun, or air supplied from a syringe.*
- *If the accumulated in the cannula material cannot be removed in accordance with the instructions, the device should be considered at the end of its useful life and should be disposed of in accordance with the facility procedures and guidelines.*

Cleaning with washer-disinfector

The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*.

CAUTION: The cleaning/disinfecting appliances should be compliant with requirements specified in ISO 15883.

Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.

Disinfection should be carried out at 90° *(soak for at least 10 minutes in demineralized water)* without the use of detergents.

Drying

Drying of the device must be performed as a part of the cleaning/ disinfection process.

Inspection

Before preparing for sterilization, all medical devices should be inspected.

Generally, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:
- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
- holes, cannulations,
- places where soil may be pressed during use,
- cutting edges should be checked for sharpness and damage,
- special care should be taken to inspect the instruments for complete dryness prior to their storage.

Functional checks should be performed where possible:
- mating devices should be checked for proper assembly,
- all reusable orthopaedic and surgical instruments should be checked for straightness.

CAUTION:

The **ChM** *sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The life of these devices depends on many factors including the method, way and duration of each use, and the handling between uses.*

Inspection and functional testing of the device must be carried out before each use. In the case of identified damage, the instrument must not be used again.

ATTENTION! The manufacturer does not recommend using any preservatives on surgical and orthopedic devices.

Packaging

The product supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1 and is marked with CE sign. The packaging procedure must be performed in controlled purity conditions. The product must be packed in such a way that during removal from the package to be used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.

Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes and without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

Disinfected, washed, and dried device shall undergo the sterilization process in accordance with the client procedures. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
- temperature: 134°C,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

CAUTION:
- *Sterilization must be effective and in accordance with requirements of the EN 556 standard which means that theoretical probability of presence of a living microorganism is less than 1/10⁶ (SAL=10⁻⁶, where SAL stands for Sterility Assurance Level).*
- *Device must not be sterilized in the package in which it was delivered, except specially designed sterilization containers.*
- *Validated sterilization methods are allowed.*
- *Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards.*
- *Devices manufactured out of plastics (PPSU, PEEK, PTFE) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

STORAGE

The devices should be properly stored. When storing surgical instruments it is recommended that they never be stacked together. It may lead to damage of cutting edges *(nick or dull)* and/or initiation of corrosion centers. Instruments should be stored in dark, dry room, if possible – in suitable storage racks and placed into specially designed sterilization containers.

CALIBRATION

1. Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device *(e.g. 4 Nm)*.
   To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.
2. The calibration is conducted by the manufacturer – **ChM** sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

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

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

IFU-I-001/15; Date of verification: December 2015

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 risterilizzare
	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 è 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	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Attenzione leggere il foglietto illustrativo
STERILE R	Sterilized using irradiation • Sterylizowany przez napromienionowanie • 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

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

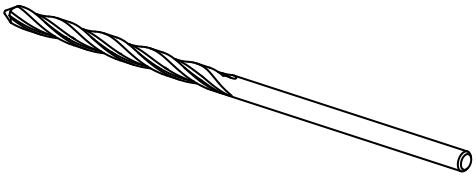
GB

ISO 9001/ ISO 13485

CE 0197

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

IFU-IIa-003/15



GB

INSTRUCTIONS FOR USE

Important product information for

SINGLE-USE SURGICAL DRILL BITS

DESCRIPTION AND PURPOSE

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 socket was damaged and its removal with the use of screwdriver is impossible. They are used in the operating theatre by qualified doctors and specialists in the field of orthopedic surgery. Drills are included into the group of rotary surgical instruments used in conjunction with a driller or another active drive.

CAUTION: DO NOT USE THE HSS** (TiN) **DRILL BIT FOR BONE DRILLING!

PRODUCT DESCRIPTION

1. Surgical drills are single-use devices, provided in sterile version only.
2. Package 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 packaging in equipped with the product label. This label *(as a primary label)* contains:
   - **ChM** logo and the address of manufacturer,
   - material: HSS *(TiN)*,
   - the name and size of the product,
   - batch code *(LOT)*, e.g.: *"1300000"*,
   - STERILE sign: indicates a sterilized product,
   - sterilization batch number, e.g.: S-1234567,
   - expiration date and sterilization method,
   - catalogue number *(REF)*, e.g.: *"40.xxxx.xxx"*,
   - CE conformity marking and the Notified Body number *(0197)*.
6. In addition to the product 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 a country in which the product will be distributed)*.
7. Inside the package, there are: instructions for use of a surgical drill.
8. Depending on the size and type of drill, the following information may be marked on its surface:
   - manufacturer's logo: **ChM**,
   - production batch code *(LOT)*, e.g.: *"1300000"*,
   - catalogue number *(REF)*, e.g.: *"40.xxxx.xxx"*,
   - size – e.g.: 1.2 *(diameter)*,
   - CE conformity marking and the Notified Body number *(0197)*.
9. Right hand drill bit.

MATERIAL

Surgical instruments are made of high-speed steel. Each instrument is exposed to corrosion, discoloration and damage if it is not treated with proper care and according to the following recommendations.

WARNINGS AND PRECAUTIONS

1. **The operator should consciously decide about the use of a drill made of a high-speed steel during the procedure of ChLP bone screws removal.**
2. Surgical drills are intended to be used only by trained medical professionals who are familiar with their use and application.
3. Prior to surgery, all instruments should be carefully inspected paying special attention to their condition and functioning. The drill point and cutting edges should be sharp and undamaged.
4. Damaged instruments should be immediately replaced. It is unacceptable to use chipped or damaged instruments.
5. The surgeon should be familiar with all components of the product prior to its use and should personally verify the completeness of all elements and instruments prior to the beginning of the surgery.
6. The surgeon should verify whether the drill has been properly inserted and attached to the drive prior to its activation, in order to avoid migration and any potential injury.
7. In order to avoid any injury to the patient or the operating theatre personnel, the drive with an instrument attached should be firmly controlled.
8. During the surgical procedure requiring the use of rotary instruments, all operating theatre personnel should wear appropriate eye protection.
9. 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.
10. It is advised to avoid excessive rotational speed during the drilling, as it may cause a temporary temperature increase of the bone above the physiological level, which may be the cause of necrosis.
11. Manual cooling with the use of physiological saline should be applied.
12. A proper screws removal 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.
13. 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 hypersensitivity, increased susceptibility to infection and osteolysis are also on the list of possible complications.
14. Do not apply excessive force when using the instrument, as it may lead to its damage.
15. While rare, intraoperative fracture or breakage of the instrument can occur. The instrument fragments should be immediately removed following the appropriate hospital procedures. It is advisable to use an intraoperative X-Ray scan to confirm proper screws removal and lack of any metallic residue.
16. In the case of suspected or documented allergy or intolerance to metallic materials, the surgeon should establish whether the patient develops any allergic reaction to the instruments material by ordering the execution of appropriate tests.
17. Single-use surgical drills are intended only for specific procedures and must be used strictly with their intended purpose. Any use inconsistent with their intended purpose may lead to malfunction, accelerated wear and, in consequence, to damage of the instrument.
18. Single-use surgical drill which was in contact with patient's tissues and body fluids should not be used again due to a potential risk of cross-infection *(with viruses, bacteria and prions)*.
19. 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.
20. After the drilling procedure, single-use surgical drill should be utilized in accordance with appropriate hospital procedures.

CONTRAINDICATIONS

1. Infection or inflammation in the operative site.
2. Suspected or documented allergy or intolerance to instrument materials. If material sensitivity is suspected, testing is to be completed prior to instrument use.
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 in to exhaustive.

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 packaging 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 instruments set for **ChM** implants.
5. The operator should consciously decide about the use of a drill made of a high-speed steel during the procedure of ChLP bone screws removal.
6. 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.
7. 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 of two bone screw sockets.**
8. All elements, including the instruments, should be carefully checked prior to the beginning of the surgery. The surgeon should be familiar with each element before using the device, and should also personally verify the completeness of all necessary elements and instruments before the surgery.

RECOMMENDATIONS FOR SURGICAL DRILLS PROVIDED STERILE

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.

Sterilization was conducted with the use of gamma radiation with a minimum dose of **25kGy**.

Before using the sterile product, the following rules must be applied:

a) Check out the expiration date of sterilization.
Do not use the product with overstepped sterility date!

b) Check out if the sterile packaging is not damaged.
Do not use the product if the sterile packaging is damaged!

c) Check out if the sterility indicator on the sterile packaging is red, as it indicates that the radiation sterilization of the product was performed.
Do not use the product if the sterility indicator is other than red!

CAUTION:

Sterilization must be effective and in accordance with the requirement of EN 556 standard, which states that the theoretical probability of a living microorganism presence is less than 1/10^6 (SAL=10^{-6}, where SAL stands for Sterility Assurance Level).

CAUTION:

The products should be used in the order of their receipt (the FIFO rule "first in, first out"), paying particular attention to expiration dates visible on the labels.

RE-STERILIZATION

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

RE-PROCESSING

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

STORING

Packed single-use surgical drills should be stored in a clean, dry place, with the conditions allowing for proper protection against direct sunlight, pests, disinfection agents, extreme temperatures and humidity.

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-003/15; Date of verification: December 2015

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 risterilizzare
	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 è 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	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Attenzione leggere il foglietto illustrativo
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 • Materiál • 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

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny
Poland
tel. +48 85 713 13 20
fax +48 85 713 13 19
chm@chm.eu
www.chm.eu

CE 0197
ISO 9001
ISO 13485