⚠CAUTION
OrthoMed instruments are developed, designed and manufactured with the highest care. Only an appropriate use of the instruments allows best results and a long shelf life.
Therefore the following instructions for use and safety must be followed. Improper use can lead to a damage to tissue, premature wear or risks for patients and user.

⚠CAUTION
SURGICAL INSTRUMENTS MAY BE USED ONLY BY QUALIFIED AND CERTIFIED MEDICAL STAFF. AS TECHNICAL ISSUES NEVER CAN BE EXCLUDED COMPLETELY, AN ALTERNATIVE SYSTEM WHICH IS READY TO BE USED MUST BE ALWAYS PROVIDED WITHIN THE USE OF THE PRODUCT ON THE PATIENT. ORTHOMED INSTRUMENTS ARE DESIGNATED TO BE USED ON HUMAN BEINGS. THE PRODUCTS ARE NOT DESIGNATED TO BE USED ON THE CENTRAL NERVOUS SYSTEM.
TO GUARANTEE THE SAFE APPLICATION OF THE ORTHOPAEDIC DRILL BITS ONLY ORTHOMED ORIGINAL EQUIPMENT IS ALLOWED TO BE USED WITH THE PRODUCTS.

⚠INTENDED USE
The surgical drill bit is intended to be mounted into an appropriate surgical power tool and rotated to bore into hard/tough tissues (e.g., bone, cartilage) to clear a channel of the same dimension as the diameter of the shaft. This device is used in orthopaedic surgery for clearing of the intramedullary channel prior to the insertion of a prosthetic device. This is a single-use device.
Rotating instruments shall only be used according to this information and the instruction for use of the surgical motor systems. Mount rotating instruments as far as possible into the drive/attachment. Check the safe position of the instrument before use.
Do not use the instruments for the treatment of metals (e.g., implants).

⚠PRIOR TO USE ENSURE THAT THE DEVICES ARE FULLY FUNCTIONAL, STERILE AND IN GOOD CONDITION. DO NOT USE INSTRUMENTS WITH ANY KIND OF DAMAGE!

⚠INDICATION
OrthoMed drill bits are intended for the treatment of bone, skin, tissue and cast. They are used to drill into hard tissue, bone and soft tissue during orthopaedic surgery, general traumatology and procedures in hand, foot and maxillofacial surgery. The orthopaedic burs are used in the bone surgery as well. The instruments are intended to pre-drill the bone for the insertion of screws. The cannulated bur is designed to be able to include a guide wire in order to measure the exact drilling depth. Various materials are available for the materials to be machined. The choice of the right instrument is the responsibility of the surgeon.

- Indicated for drilling and cutting bones
- For the treatment of the intra-articular fracture of the carpal bone, metacarpal bone, tarsal bone and the metatarsal bone
- For the fixation of small bone fragments
- During osteotomy
- For the treatment of arthrodesis of small joints

⚠CONTRAINDICATIONS

- Interference of the bloody supply
- Insufficient bone quality or quantity (severe osteoporosis)
- Allergy to a material component
- Acute and chronic infections; muscle, nerve or vascular diseases.
- Local bone tumors
- Fever or leukocytosis
- Morbid obesity
- Pregnancy

- Grossly distorted anatomy caused by congenital abnormalities.
- Rapid joint disease, bone absorption, osteopenia, ostemalcia and/or osteoporosis. Osteoporosis or osteopenia is relative contraindication since this condition may limit the degree of attainable correction, stabilization, and/or the amount of mechanical fixation.

⚠PROPHYLAXIS OF CORROSION
Corrosion is a destruction or wear which can be caused on account of chemical reaction.

- Careful arrangement of correctly wrapped up and sterilized instruments before the surgical intervention;
- Selection according to type of procedure.
- Pay attention to intact outer packaging and damage to the instrument itself.
- Observe the sterilization indicator.
- Prepare the instruments directly before surgery.

⚠CONTACT PRESSURE
Excessive contact forces must be avoided.

- Excessive contact pressure in connection with cutting devices (steel, nitinol and hard metal instruments) can lead to damage of the working part and to an outbreak of the edge. At the same time an excessive heat evolution can occur which causes the danger of thermal necrosis.
- Simultaneously increased heat development occurs, which creates the risk of thermal necrosis. Excessive contact forces can lead to the breaking out of abrasives.
- Excessive contact pressure can lead to the breakage of the grinding instruments which could lead to a higher heat development.
- In extreme cases, instrument breakage due to excessive pressure forces cannot be excluded. It is essential to avoid leaking or tilting the instrument during the operation. An optimal removal of material takes place at an appropriate pressure force.

COOLING

- When using rotating instruments, ensure adequate cooling. If the cooling is insufficient, the instrument blades balling up with chips. This results in a higher heat development which in the worst case leads to irreversible bone damage (thermal necrosis).
- The drills may be used at a maximum of 2000 rpm.

SELECTION OF DAMAGED INSTRUMENTS
Check the instruments with a loupe before use and pay attention to the following damages:

- Loosened and blunt cutting edges
- Damages to the shaft
- Bent or damaged instruments are not allowed to be used in any case. Failure to observe these instructions could result in instrument breakage and risks to the patient and users!

COMBINATION WITH OTHER PRODUCTS
Are some components of the device exchangeable due to the intended use (e.g., different working lengths) it is forbidden to apply parts from other suppliers! We recommend to also use other accessories (e.g., care products) of the OrthoMed, Inc.

LIABILITY

⚠CAUTION
The user bears the responsibility for proper cleaning, disinfection and sterilization of the instruments. National law and restrictions are to be considered in any case.

OrthoMed excludes all warranty claims and assumes no liability for direct damage or consequential damages which result from:

- Usage for purposes other than that intended.
- Improper use, application or handling.
- Improper cleaning and sterilization.
- Improper maintenance and repairs.
- Failure to observe this instruction for use.

⚠CLEANING AND STERILIZATION
BEFORE USE, THE INSTRUMENTS MUST BE STERILIZED USING A VALIDATED PROCEDURE (AUTOCLAVED). ALL INSTRUMENTS ARE SUPPLIED NON-STERILE AND MUST BE PREPARED (DISINFECTION, CLEANING TO REPACK) AND STERILIZED BEFORE USE. WHEN UNPACKING THE INSTRUMENT, VERIFY THE LABELLING FOR CORRECT ITEM NO./ LOT NO. AND SIZE. ALSO THE ASEPTIC REGULATIONS FOR THE RESPECTIVE COUNTRY SPECIFIC GUIDELINES MUST BE OBSERVED. NO MANUAL REPROCESSING IS ALLOWED!

⚠DECONTAMINATION
Decontamination and cleaning are mandatory before sterilization. The aim of decontamination is to decrease the initial population of bacteria, to facilitate cleaning at a later stage, to protect staff and to avoid any contamination of the environment.
Saline is not allowed to be used because of its corrosive effect on stainless steel.

⚠HYGIENE
- Brand-new instruments must be processed prior to use. The transport protection packaging, protective caps etc. are not suitable for the sterilization.
- Only approved cleaning agents (RKI, DGHM/VHA, FDA, etc.) are allowed to be used.
- Alkaline detergent as well as enzyme-based cleaner are applicable.
- Water quality according to DIN EN 285 appendix B.
- Sterilizer according to DIN EN 285 or DIN EN 13060.
- Cleaning/disinfection devices according DIN EN ISO 15883 part 1 and 2.
- Only sufficient devices and product specific validated procedures are allowed to be used for cleaning/disinfection/sterilization.
- Manufacturer's data and manufacturer's recommendations are to be followed.
- In addition, the legal/hygiene regulations valid in your country are to be followed. Especially for the different requirements with regard to effective prion inactivation.

⚠CLEANING
A manual cleaning procedure cannot be used due to the product characteristics (surface, hollow borings, machined surfaces, drilled holes with narrow lumen). Before the first use the instruments must be cleaned properly by machine.

⚠MACHINE CLEANING
Do not use any fixing agents or hot water (>104° F/40° C) as this can lead to the fixing of residues and influence the cleaning results.

⚠CLEANING
- Completely immerse the instruments in a bath with cold water for 5 minutes followed by a cleaning step with a soft brush under cold water.
- Rinse the inner lumen of the instruments (difficult to access) with a water jet pistol for 10 seconds.
- For machine cleaning use an appropriate qualified cleaning and disinfecting machine (e.g., Miele G7835 CD) with the program "Des-Var-TD".

- Immerse the instruments in an ultrasonic bath with a 0.5% Neodischer Mediclean forte for 15 min. at 104° F/40° C.
- Rinse the instruments with deionized cold water
- Put the instruments on the application of the MIS carriage. In case there is no possibility to put the instruments on the application, lay the instruments in a microstrainer of the MIS carriage.
- Prewash with cold water for 1 min.
- Drain
- Prewash with cold water for 3 min.
- Drain
- Wash at 131° F (55° C) +/-41°F for 5 min. with “Neodischer Mediclean forte”, alkaline, 0.5%
- Drain
- Neutralization step (NeodischerZ) for 3 min. >104° F(40° C)
- Drain
- Wash with deionized water for minimum 2 min. >104° F (40° C)
- Drain

⚠DISINFECTION
Perform the mechanical thermal disinfection according to the national requirements regarding the AO values (see ISO 15883, AO value >3000: 5 min. at 198°F (92° C) +/- 35°F (2° C)).

⚠STERILIZATION
- Sterilize with moist heat in partial cycles. (According ISO 13060/ISO 17665 taking into account the national requirements).
- 3 pre-vacuum steps with at 60 millibar pressure heating to a sterilization temperature of at least 134°F (134°C); max. 278 °F (137°C). Shortest holding time: 5 min. Drying time: at least 10 min.
- It is the responsibility of the user to ensure that the sterilization process including the resources, material and the staff, are suitable to reach the required results. The state of the art and national law require to follow the validated processes.

⚠INSPECTION
- Assemble instruments for function testing!
- Sort out damaged instruments.

PACKAGING
- Packaging according to DIN EN 868 can be used.
- The packaging must be selected in such a way that the instruments fit into the packaging.
- Use a sterilization indicator for packaging and note the sterilization and expiration date on the packaging.

STORAGE
- Store the products in a dry environment protected against dust and without any external force effect and bigger temperature fluctuation.
- Do not store the products nearby any aggressive medium.
- Store the products in trays or closed boards.

TRANSPORTATION
- Storage and transport of the instruments must be carried out in a closed container to the processing site in order to avoid damage to the instrument and contamination of the environment.

SHELF LIFE
The products are for single use only and may not be reused. The shelf life of the product is connected to its sterility.

⚠ORTHOMED, INC. ASSUMES NO LIABILITY IF THE USER OR THIRD PARTIES INFRINGE THIS INSTRUCTION FOR USE. THE USER BEARS THE RESONSIBILTIY FOR THE SURGICAL APPLICATION OF THE PRODUCT. THE PRODUCT HAS NOT BEEN DESIGNED, INTENEDED OR SOLD FOR USES OTHER THAN INDICATED.

REF Item number LOT LOT-No. Manufacturer

REV.	SECTION	DESCRIPTION	DATE	AUTHORIZED BY
	All	Initial Release	6/1/2020	Mardi Trone