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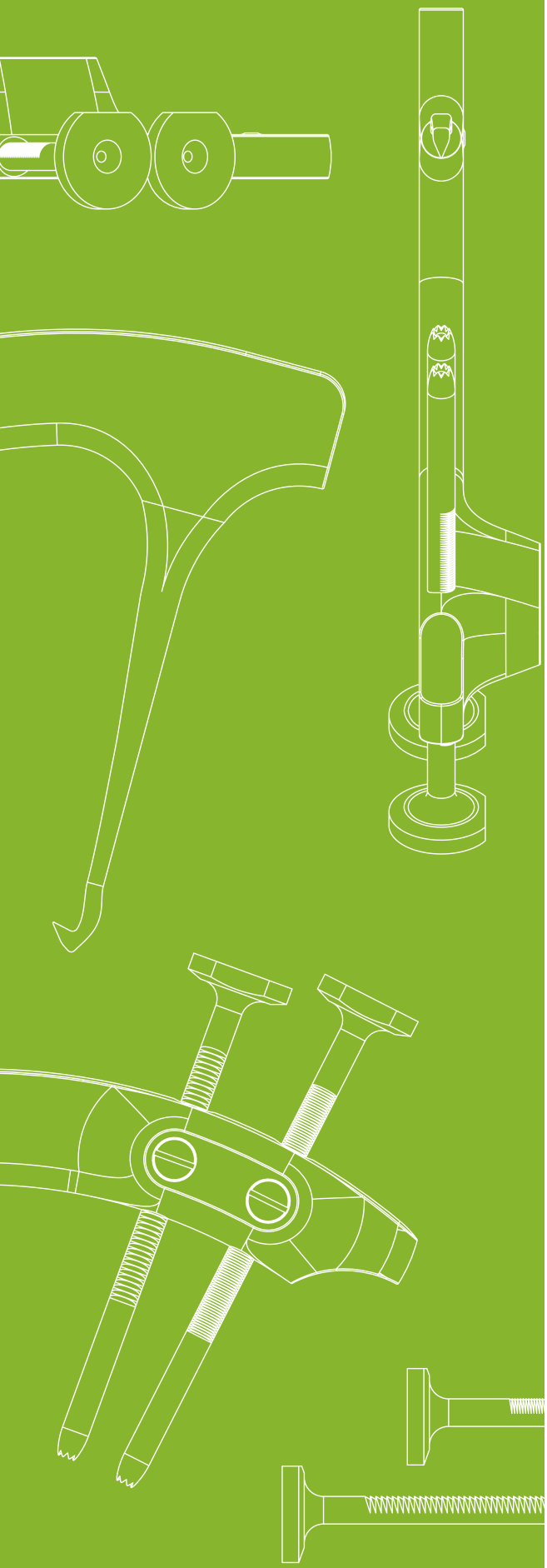
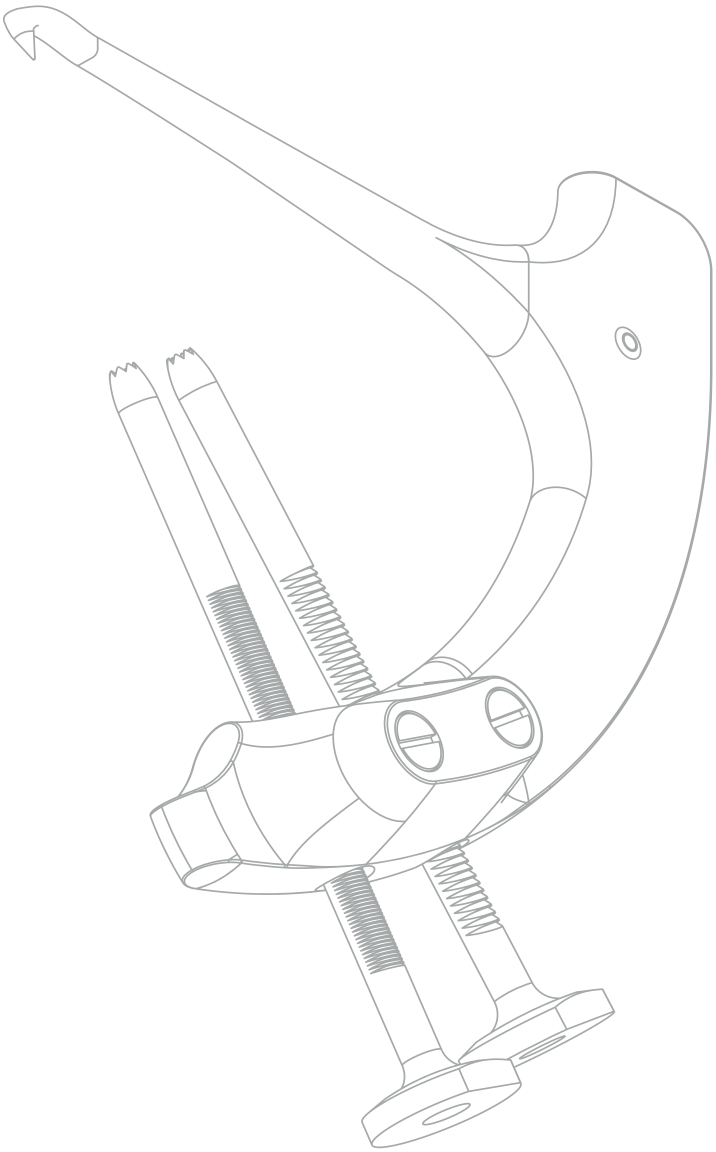


INSTRUCTIONS FOR USE

Drillbone Root Repair

Guide for Meniscal Root Repair



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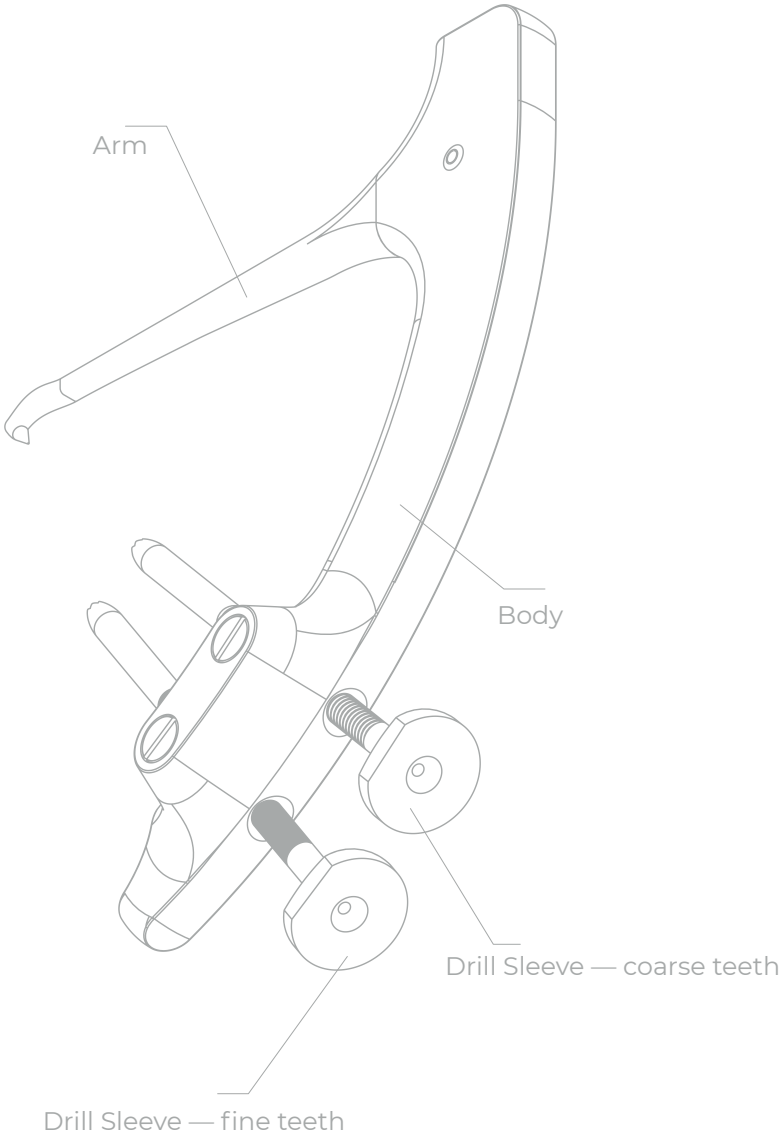

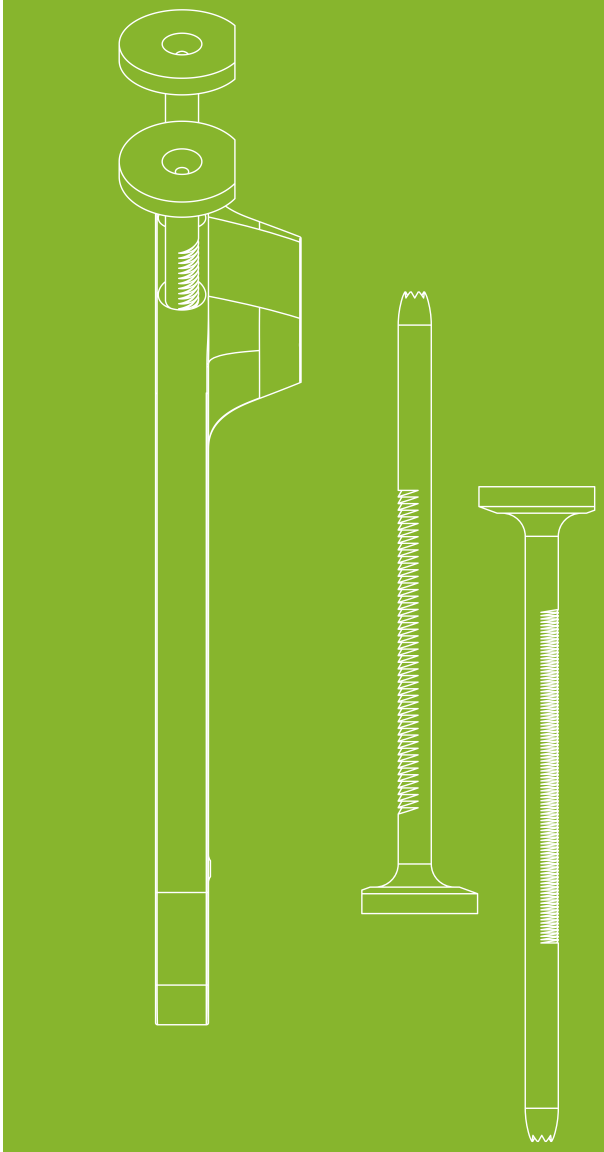

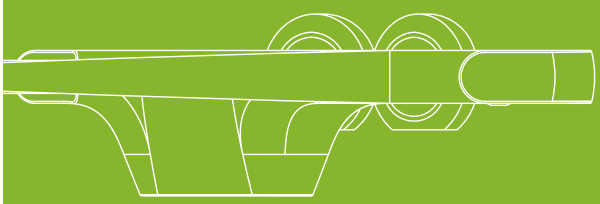

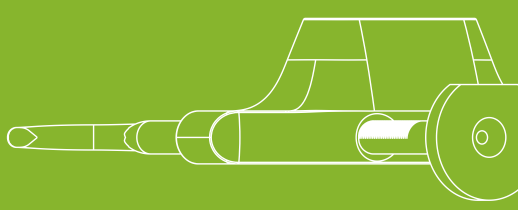

Product Website

Surgical Technique 3D Animation

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1. Description and specifications of the device

1.1 Manufacturer

Trade name:	Drillbone s.r.o.
Registered office:	Bulharská 1173/37, Královo Pole, 612 00 Brno, Czech Republic
Business ID:	03960293
Tax ID:	CZ03960293

1.2 Product name and trade name

Product name:	**Drillbone Root Repair**
Other names of the product:	Guide for Meniscal Root Repair

1.3 Risk class of the device

Class Ir, reusable, non-sterile, without measuring function.

1.4 Intended purpose

The Drillbone Root Repair medical device allows drilling precisely localized canals to perform a two-canal technique for refixation of a detached root of the posterior corner of the medial or lateral meniscus. The medical device is intended for use by expert medical professionals.

1.5 Target population

The medical device is indicated for all adult patients and children aged 12 and over.

1.6 Indications and medical conditions

The Drillbone Root Repair device is indicated for use in meniscal root repair to precise targeting of planned bone tunnels for performing a two-channel technique for refixation of a torn root of the posterior horn of the medial or lateral meniscus.

1.7 Contraindications, warnings and precautions

- Osteoporosis,
- older age of the patient,
- patients with active infection,
- medical conditions that would slow healing, such as restricted blood supply or infection,
- conditions that tend to limit the patient's ability or willingness to follow the instructions during the healing period.

1.8 Principles of operation and mode of action

Drillbone Root Repair allows precise drilling of localized tunnels to perform a two-tunnel technique for refixation of the torn root of the posterior horn of the medial or lateral meniscus. The use of an implant when tying sutures is optional. The procedure can be performed with or without implants. Sutures can be tied over a bone bridge, which is sufficiently strong for divergently drilled tunnels. Sutures tightened over this bone bridge will ensure sufficient primary fixation of the meniscus root to the insertion site.

The principle of action of Drillbone Root Repair is described in Annex 1, Operating procedure, which is included in the product package or can be downloaded from the website https://drillbone.com/en/downloads/. The healthcare provider is responsible for ensuring that the device is used in accordance with the manufacturer's instructions.

2. Technical description

Drillbone Root Repair includes the basic components as follows:

- The Body, as a supporting structure,
- The Arm, firmly connected to the Body,
- Drill Sleeve — coarse teeth, as a guide for K-wire,
- Drill Sleeve — fine teeth, as a guide for K-wire.

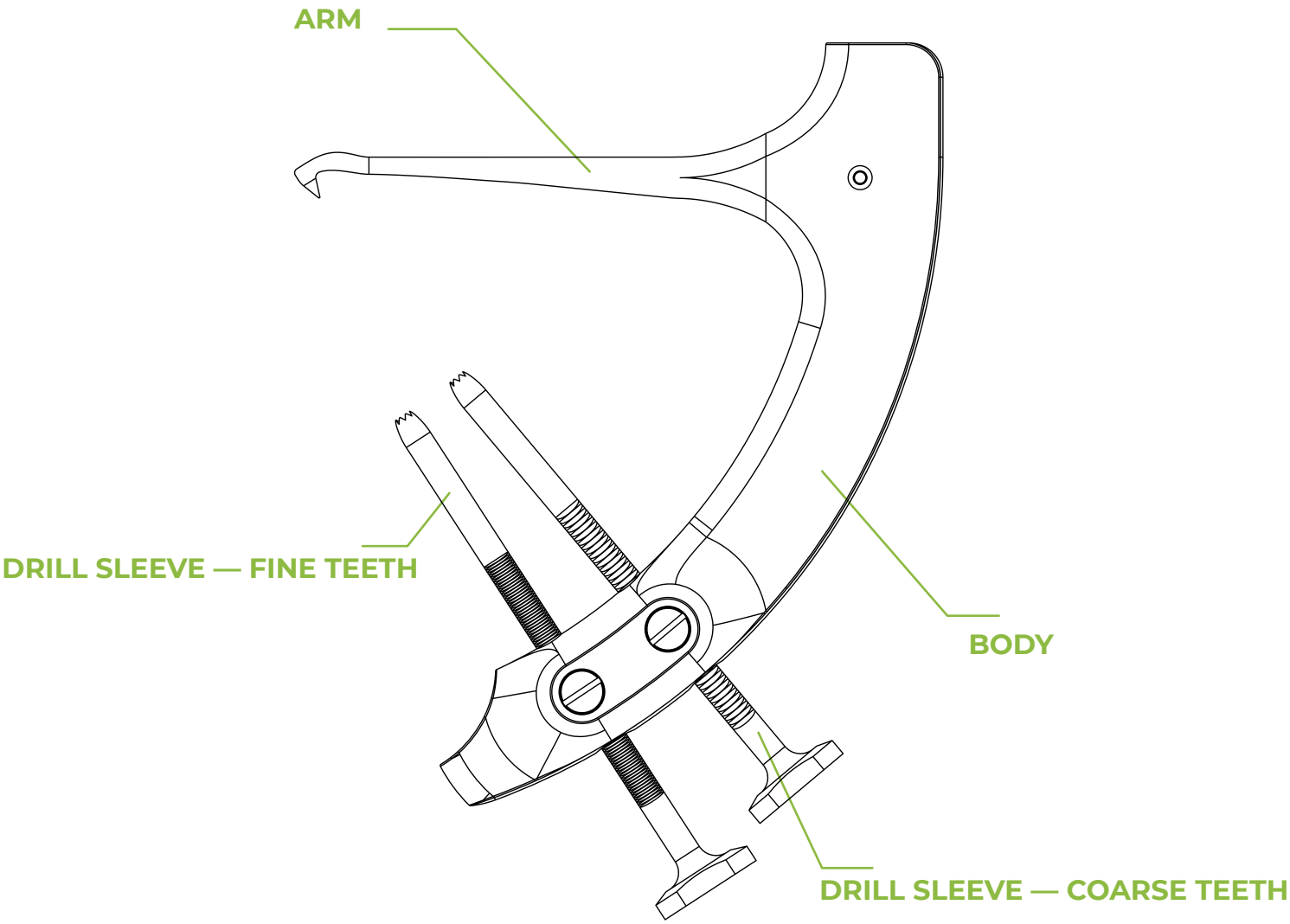


Figure 1: *Device description*

The individual components contain the following basic structure elements:

- The Body contains two precise holes for accommodating the Drill Sleeves. The axes of the Drill Sleeve are inclined at a certain angle to each other. The Body contains a latch mechanism at the site of the holes for the Drill Sleeve.
- The Arm is firmly connected to the Body. It has a hook at its end that serves to anchor it in the knee at the site of the meniscal root bed.
- There are two Drilling Sleeves: a fine tooth sleeve and a rough tooth sleeve. Drill Sleeves are designed as a ratchet wheel. The Body contains moving latches.

3. Use

- Before first use, remove the warning label attached to the Drillbone Root Repair device to provide important safety information.
- Before first use, clean, lubricate, package and sterilize the device according to Chapter 4. Reuse.
- During the surgical procedure, continuously wipe blood and tissue debris from the Drillbone Root Repair device to prevent them from drying to the surface. Be careful of lubricated parts of the device. Wipe lightly so that they remain lubricated.
- Recommended accessories: Drillbone Loop, Kirschner wire (2 mm, length 160 mm), #2 suture thread (different colours).
- Rinse the holes of the Drillbone Root Repair device with sterile or purified water to prevent dirt and/or tissue debris from drying inside.
- The Drillbone Root Repair device should be covered with a moistened drape (sterile or purified water) to prevent blood or tissue debris from drying.
- The contaminated Drillbone Root Repair device must be separated from other uncontaminated surgical instruments to avoid contamination of unused surgical instruments, personnel, and the environment.
- Separate contaminated Drillbone Root Repair from medical waste.
-  Before each use, check whether the guide surfaces of the Drill Sleeve are sufficiently lubricated (see Chapter 4.2).

4. Reuse

The medical device is intended for repeated use, for which it must be cleaned, disinfected, lubricated and sterilized. It can be used in individual patients only within a single operation using a two-tunnel technique for refixation of the torn root of the posterior horn of the medial or lateral meniscus. The package includes Annex 2, Procedure for repeated use, a photo series that describes in detail the individual steps of cleaning, disinfection, lubrication and sterilization; and Annex 3, Infographics, which clearly shows the individual steps of the cleaning, lubrication and sterilization procedure.

After cleaning and before sterilization, check the device for the following:

- cleanliness,
- damage (e.g. corrosion, discolouration, wear, cracks, excessive and significant scratches, peeling),
- proper function of the medical device, especially the clicking of the ratchet when inserting the Drill Sleeves,
- missing or removed numbers or markings on the device.

The Drillbone Root Repair device with the above defects should be removed from use.

Before using the Drillbone Root Repair device, make sure that the device has an undamaged surface, is free of visible defects, and is functional. In particular, check the function and movement of the Drill Sleeves. Do not use Drillbone Root Repair that is severely damaged, has illegible markings, shows signs of corrosion, or is otherwise damaged. In these cases, remove the medical device from service and contact the manufacturer.

4.1 Cleaning

- Wipe all parts of the new Drillbone Root Repair with a cloth.
- Remove all removable parts of the Drillbone Root Repair device or place them on a separate tray before manual cleaning.
-  Do not use alkaline cleaning agents (maximum pH 9).

4.1.1 Cleaning and disinfection, manual

- Place Drillbone Root Repair in the disinfectant for washing so that it cannot move freely during the washing process or overlap with other products, which could damage the surface of the medical device.
- After the recommended exposure time to the disinfectant, remove the Drillbone Root Repair and rinse with water.
- Wash Drillbone Root Repair manually, remove coarse dirt mechanically with a brush in a cleaning and disinfecting solution, and then rinse the product under running water.
- Pay special attention to cleaning the "teeth of the Drill Sleeve" with a brush. The bristles of the brush must be perpendicular to the surface being cleaned.
- When using them, follow the instructions from the manufacturer of the product:

  – adhere to the prescribed concentration
  – solution temperature
  – water quality and application time

- After the recommended exposure time, rinse the cleaning agent off with running water.
- Note: Drillbone company used the following formulation and parameters for validation: 1% Stabimed Fresh (BRAUN) in demineralized water, for 5 minutes.

4.1.2 Cleaning and disinfection, automated

- A validated cleaning and disinfection procedure using an instrument is always preferred over manual cleaning. Good cleaning is a prerequisite for successful sterilization, and automated cleaning/disinfection achieves higher process safety.
- It is recommended to wash Drillbone Root Repair before sterilization using automatic washer - disinfector with thermal disinfection.
- Place Drillbone Root Repair in the washing detergent so that it cannot move freely during the washing process or overlap with other products, which could damage the surface of the medical device.

- When using detergents and disinfectants, follow the manufacturer's instructions. In particular, adhere to the:

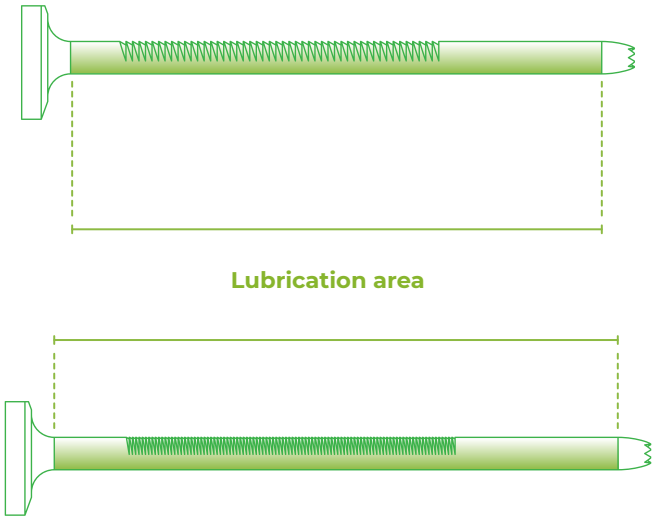
  - prescribed concentration,
  - solution temperature,
  - water quality,
  - cleaning time.

Note: For validation purposes, Drillbone company used the following formulation and parameters: Mediclean forte disinfectant.

- Pre-wash phase: demineralized water, 30 minutes, 50°C
- Rinsing phase: demineralized water, 6 minutes, 50°C
- Thermal disinfection phase: demineralized water, 6 minutes, 93°C
- Drying phase: 7 minutes, 110°C
- Device drain phase
- The validation was performed on the "Miele PG 8528D washer-disinfector" device, which is validated according to ČSN EN ISO 15883-1

4.2 Lubrication

For proper long-term functioning, Drillbone Root Repair must be properly lubricated. The lubrication points are shown in the figure below/further. Apply lubricant to the cylindrical surfaces of both Drill Sleeves and into the holes in the Body (the holes are marked with an arrow in the picture). Then use circular motions to gradually insert the Drill Sleeve into the Body. Then rotate the Drill Sleeves several times simultaneously with the axial movements. This will create a sufficient lubricating film for the tool to function properly. Apply commonly used preservative sprays or lubricants for medical instruments as lubricant. After applying the lubricant to the Drillbone Root Repair device, it is necessary to check its functionality.



4.3 Packaging (before sterilization)

- A contaminated Drillbone Root Repair device must be transported separately from uncontaminated instruments to avoid contamination.
- Store the disinfected, cleaned, rinsed, dried and lubricated Drillbone Root Repair in a suitable manner. Use a suitable sterilization wrap or reusable rigid container (wraps and containers to ensure a sterile barrier according to ISO 11607 Packaging for terminally sterilized medical devices).
- Be careful of the pointed and sharp parts of the Drillbone Root Repair device. Contact with other objects could damage their surface.
- The Drillbone Root Repair device can be packaged in sterilization packaging that meets the requirements of the ISO 11607 standard.

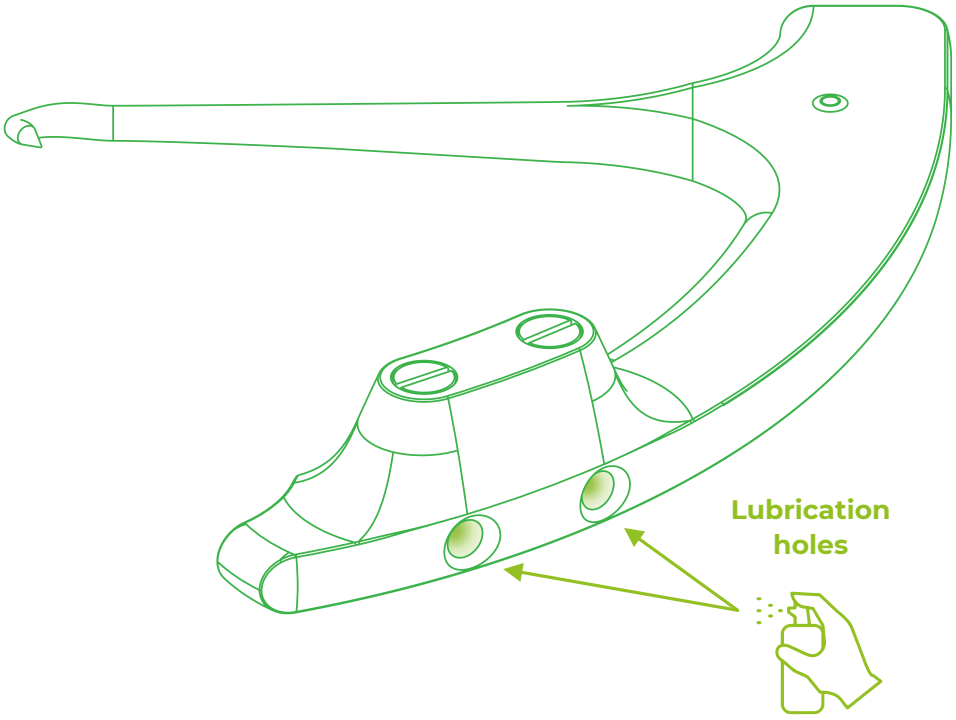


Figure 2: *Lubrication detail*

4.4 Sterilization

Sterilize only cleaned, disinfected and lubricated Drillbone Root Repair. The manufacturer recommends sterilizing with moist heat (steam sterilization), which is controlled according to **ČSN EN ISO 17665**.

Temperature	134 °C
Sterilization time	7 minutes
Pressure	312 kPa

Table 1. *Sterilization parameters*

4.5 Additional information

- A thermal disinfection washing process has been validated for Drillbone Root Repair. The manufacturer does not guarantee the results when using other washing methods.
- A moist heat sterilization method is validated for Drillbone Root Repair, see Table 1.
- It is the processor's responsibility to achieve desired result by preparing the product using equipment, materials and workers at the preparation workplace. The manufacturer notes that validation and routine monitoring of established procedures are needed. Any deviation from the above recommendations must be appropriately evaluated.

4.6 Storage

- After sterilization, the Drillbone Root Repair device must be stored in a dry place at a temperature of 10–25°C.
- The maximum shelf life of sterilized reusable medical devices must be defined by each healthcare facility according to the recommendations of the sterilization packaging manufacturer, which comply with the requirements of the ISO 11607 standard.

4.7 Precautions

- Do not place the device in normal saline (NaCl) solution. The Drillbone Root Repair device is made of stainless steel and prolonged contact could lead to corrosion (pitting, stress corrosion).
- Avoid using cleaning solutions with higher alkalinity and/or solutions where hydrogen peroxide is added. Their use may lead to discolouration. This may damage the identification symbols on the Drillbone Root Repair device.
- Do not use abrasive cleaning materials (e.g. steel wool) or abrasive detergents for cleaning.
- Pay special attention to cleaning the holes, narrow and small parts of the Drillbone Root Repair device.
- Always thoroughly clean the Drillbone Root Repair device before sterilization and properly lubricate the moving parts (see Chapter 4.2).

- Before first use, carefully inspect the Drillbone Root Repair device for visible damage. If you suspect product damage, contact the manufacturer.
- Before first use, clean, disinfect, lubricate and sterilize the device according to the instructions in this manual.
- Disinfect, clean, lubricate and sterilize the Drillbone Root Repair device as soon as possible after use.
- Keep the Drillbone Root Repair device in a mobile state by proper lubrication according to Chapter 4.2. Lubricate after thorough cleaning and disinfection of the device and before each sterilization. To maintain the Drillbone Root Repair device, use preservatives and lubricants that meet the following requirements:

  – paraffin/white oil based lubricants,
  – compliant with the valid European Pharmacopoeia,
  – biologically compatible,
  – suitable for steam sterilization and permeable to steam.

- Drillbone Root Repair must not be treated with silicone preservatives. These preservatives can make movement difficult and limit the effect of steam sterilization.
- Only the manufacturer is authorized to repair the medical device.
- DataMatrix explanations on Drillbone Root Repair:
  (01) UDI-DI (GTIN)
  (10) LOT
  (11) date of manufacture
  (21) serial number

4.8 Frequency of application

The Drillbone Root Repair device can be subjected to 200 sterilization cycles. The lifespan of the Drillbone Root Repair device is determined by wear and tear due to their use. Repeated cleaning, disinfection, proper lubrication and sterilization of the medical device have minimal impact on wear of the Drillbone Root Repair.

5. Benefits for the patient

The benefit of using the Drillbone Root Repair device in meniscus root repair is the creation of precisely localized bone tunnels. Precise localization of the tunnels ensures repair in an anatomical position, which is necessary for minimizing the risk of failure. The ease of use reduces surgical time and the small diameter of the drilled tunnels reduces the invasiveness of the procedure, which reduces the risk of mechanical or infectious complications.

6. Risks

Before using the Drillbone Root Repair device, it is essential that the healthcare professional informs the patient about the potential risks and complications associated with using the Drillbone Root Repair device during surgery.

6.1 Reporting adverse events

If any serious incident occurs that is directly or indirectly related to this medical device, immediately report it to Drillbone s.r.o., the competent authority of your country and the country of origin of the patient (if different).

Reports can be submitted by email (contact: Tomáš Valenta, valenta@drillbone.com) or postal service (Drillbone s.r.o., MUDr. Filip Hudeček, Bulharská 1173/37, Královo Pole, 612 00 Brno, Czech Republic).

7. Disposal

Discarded Drillbone Root Repair device must be treated as hazardous waste. The user is responsible for taking precautions for the safe handling and disposal of the product. The damaged Drillbone Root Repair device is disposed of as potentially hazardous waste according to the Waste Catalogue, Group 18, Healthcare waste (European Union) after decontamination, washing and drying.

8. Warranty

Drillbone s.r.o. is not liable for direct or consequential injury or damage resulting from improper use, and in particular from failure to follow the instructions in the instructions for use or the preparation and maintenance instructions.

9. Symbols

Manufacturer identification

Date of manufacture

Consult electronic Instructions for Use at USB Flash Disk

Non-sterile medical device

Conformity marking

Caution/Warning

Reference catalogue number

Batch code to identify
the batch or LOT

Serial number for medical
device identification

Number of pieces per package

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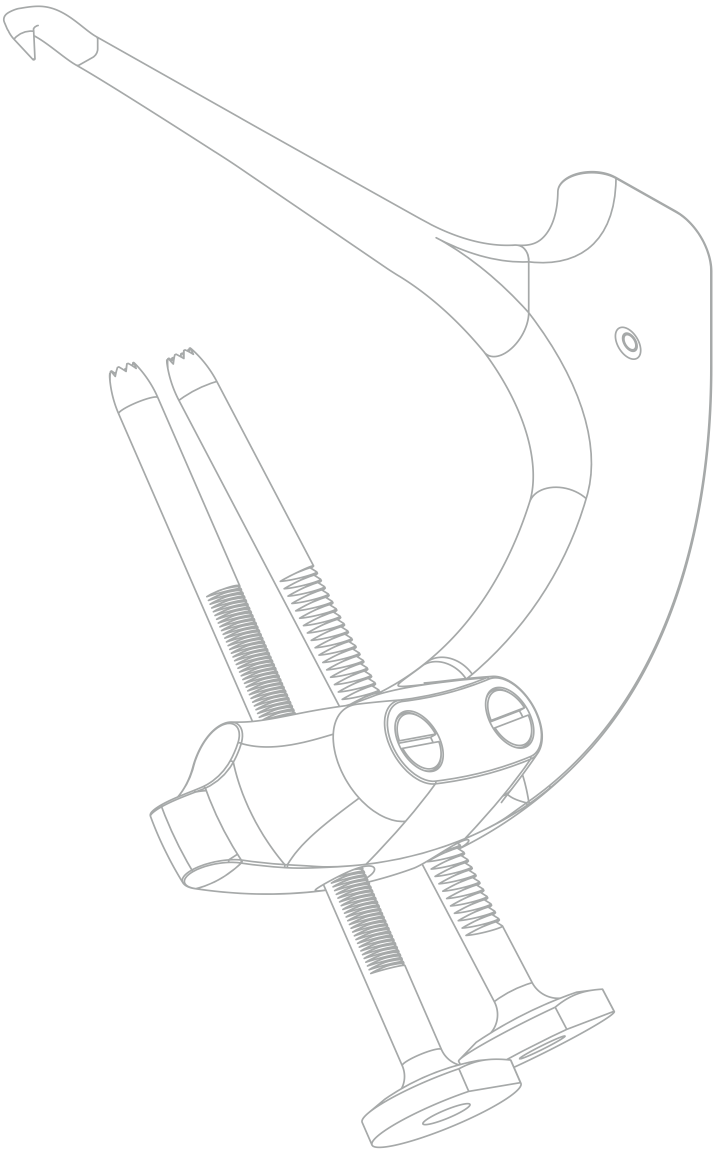
INSTRUCTIONS FOR USE

Drillbone Root Repair

Guide for Meniscal Root Repair



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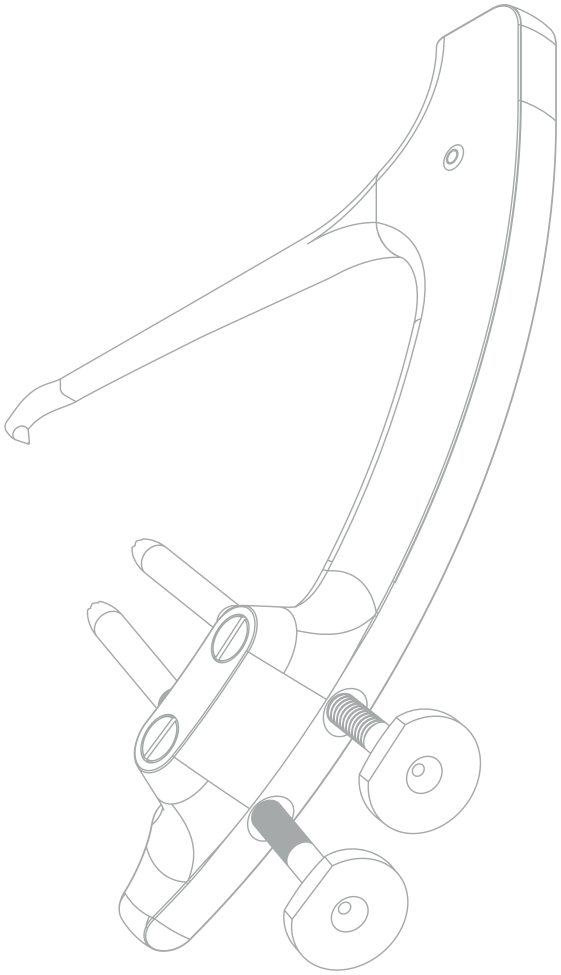

Product Website

Surgical Technique 3D Animation

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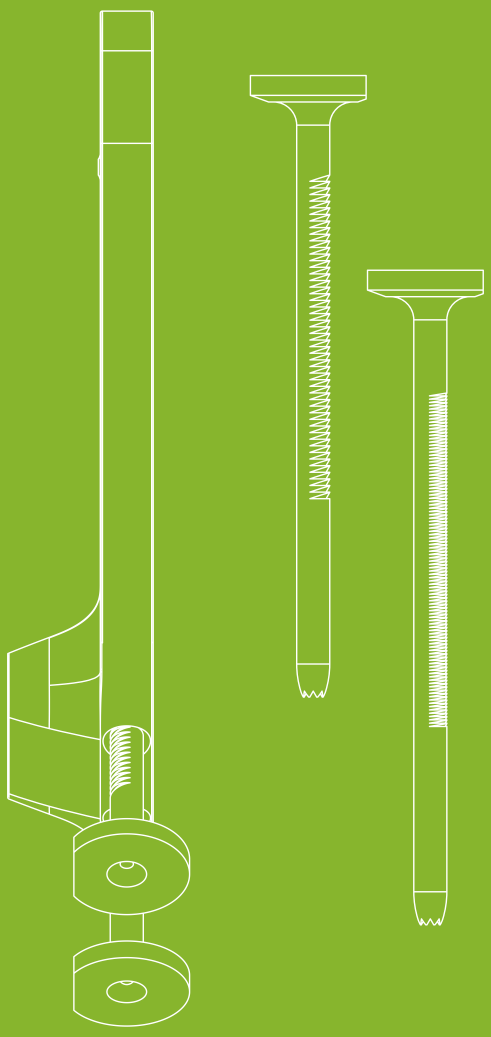

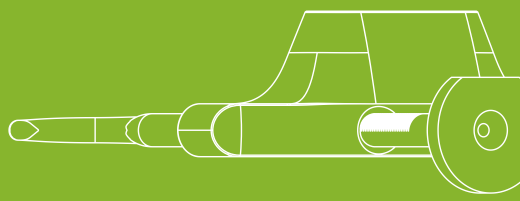

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