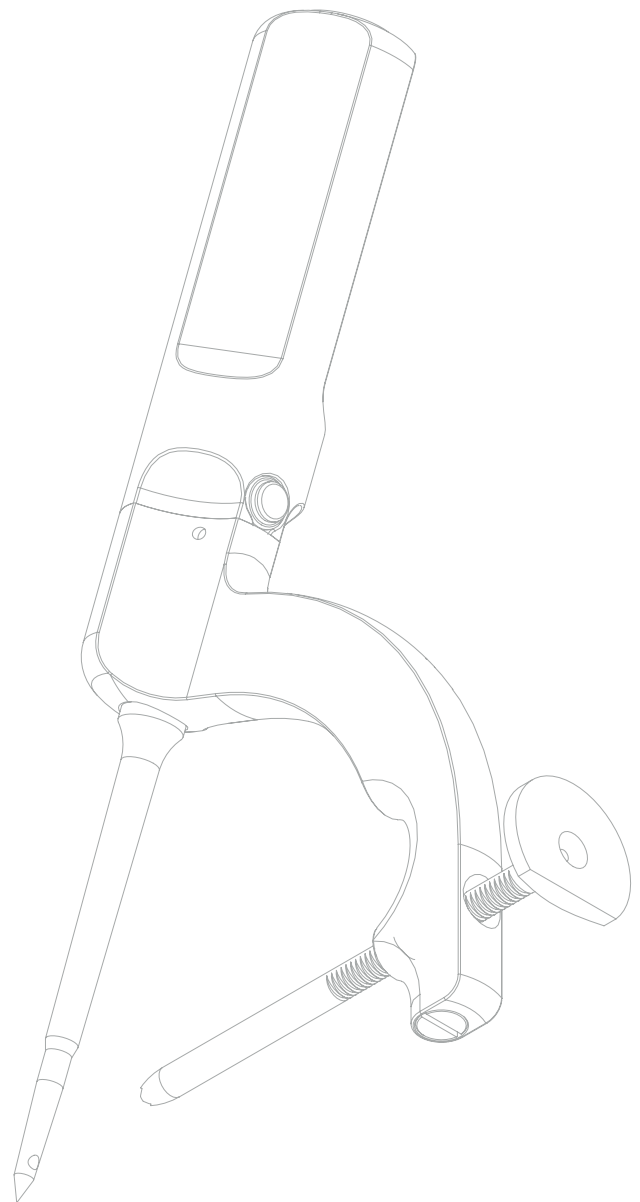
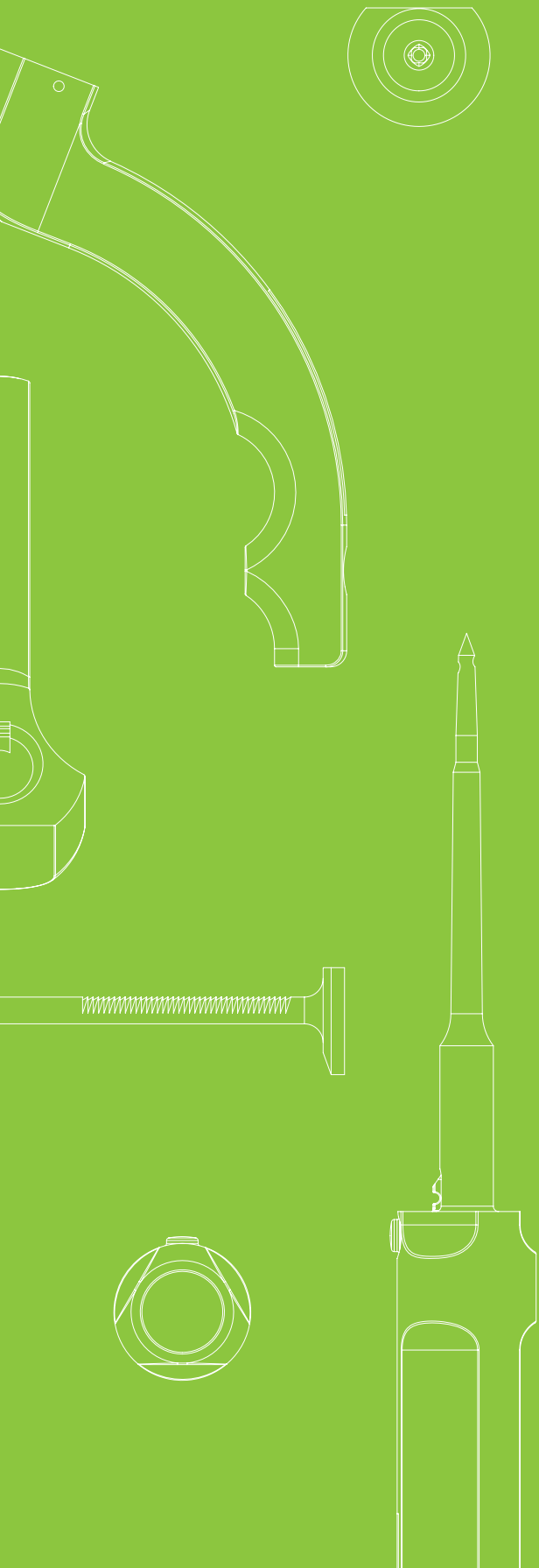


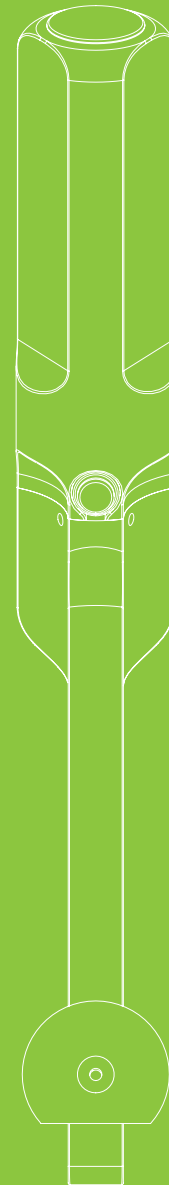
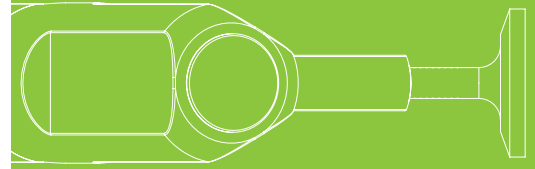
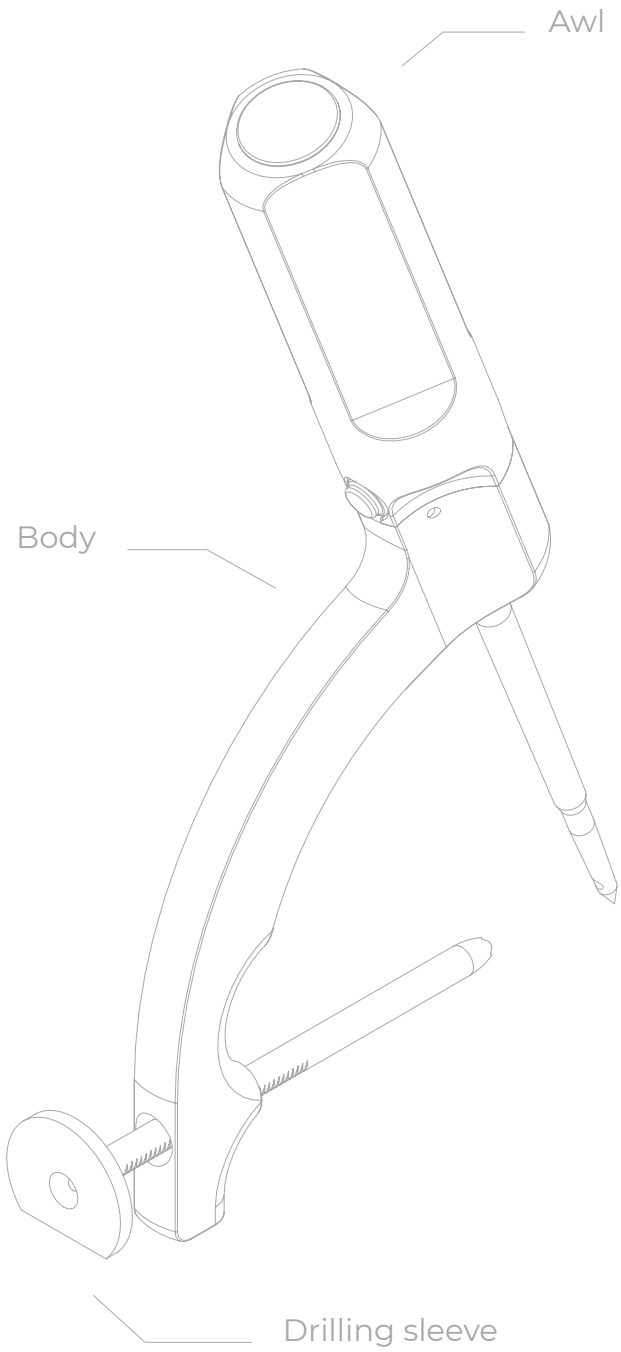


# INSTRUCTIONS FOR USE

Drillbone Tunneler

Rotator Cuff Repair  
Tunneler





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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, Brno - Královo Pole 612 00,  
Czech Republic  
Business ID: 03960293  
Tax ID: CZ03960293

## 1.2 Product name and trade name

Product name: **Drillbone Tunneler**  
Other names  
of the product: Rotator Cuff Repair Tunneler

## 1.3 Risk class of the device

Class Ir, non-sterile, non-measuring.

## 1.4 Intended purpose

The Drillbone Tunneler medical device is intended for precision targeting of planned bone tunnels for performing the rotator cuff repair. 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 Tunneler medical device is indicated for use in the transosseous rotator cuff repair to precise targeting of the planned bone tunnels placement.

## **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.

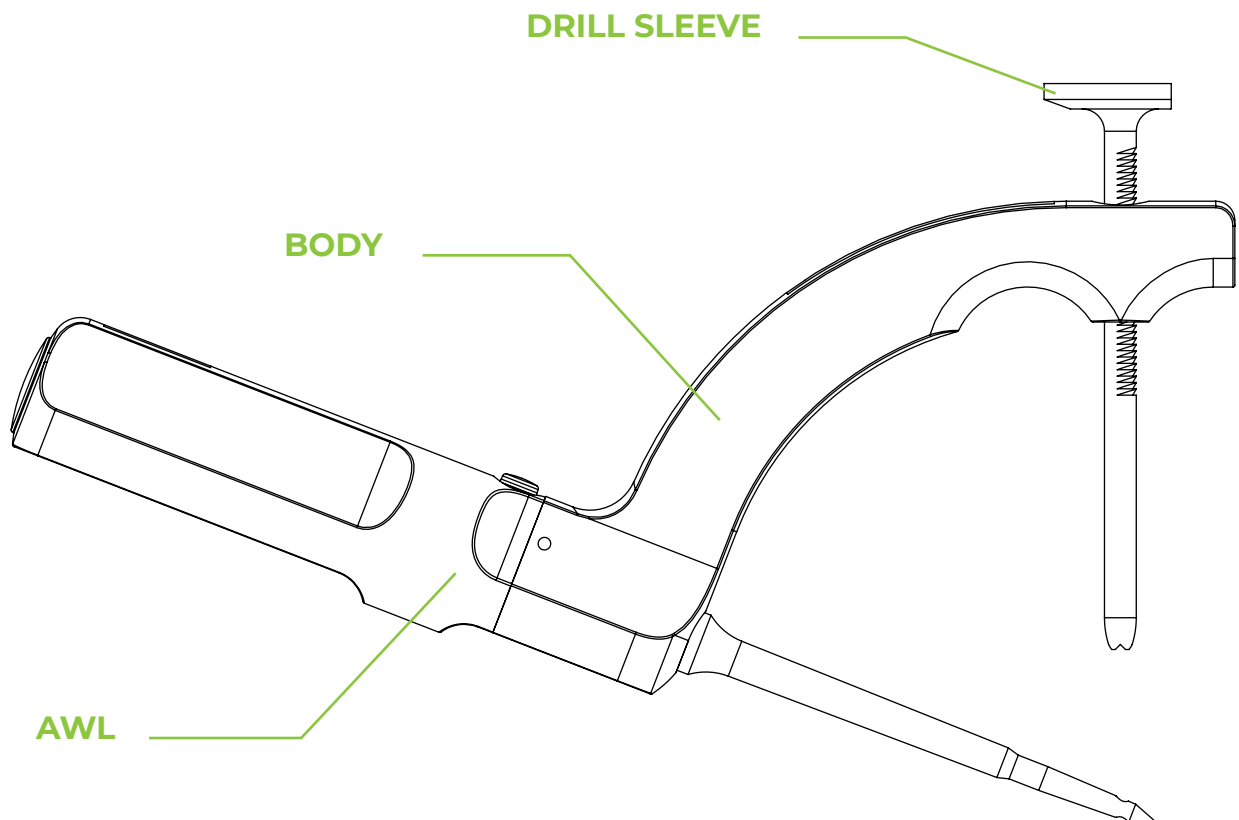
## **1.8 Principles of operation and mode of action**

The principle of action of Drillbone Tunneler 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 Tunneler includes the basic components as follows:**

- The Body, as a supporting structure,
- The Awl, with a point at its end,
- Drill Sleeve, 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 Awl (tip) and Drill Sleeve. The axis of the Awl and the axis of the Drill Sleeve are inclined at a certain angle to each other and intersect at one point.
- The grip part of the Awl contains a button that releases the Awl in the Body. The Awl can then be rotated or removed from the Body.
- The Drill Sleeve is designed as a ratchet wheel. The Body contains a moving latch.

### 3. Use

- Before first use, remove the warning label attached to the Drillbone Tunneler device to provide important safety information.
- Before first use, clean, lubricate, package and sterilize the device according to Chapter 4. Reuse.
- In the initial setting of the Drillbone Tunneler device, the Awl is connected to the Body and the Drill Sleeve is arranged outside the Body on the instrumentation table.
- During the surgical procedure, continuously wipe blood and any tissue debris from the Drillbone Tunneler device to prevent them from drying to the surface. Be careful of lubricated parts of the device. Wipe them very 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 Tunneler device with sterile or purified water to prevent dirt and/or tissue debris from drying inside.
- The contaminated Drillbone Tunneler device must be separated from other uncontaminated surgical instruments to avoid contamination of unused surgical instruments, personnel, and the environment.
- Separate contaminated Drillbone Tunneler from medical waste.
-  Before each use, check whether the guide surfaces of the Awl and 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, and sterilized. Can be used in individual patients only within one rotator cuff tear surgery during transosseous tunnel creation. 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),
- Drillbone Tunneler function,
- missing or removed numbers or markings on the device.

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

Before using the Drillbone Tunneler device, make sure that the device has an undamaged surface, is free of visible defects, and is functional. In particular, check the function of the Awl rotation in the Body and the movement of the Drill Sleeve in the Body. This movement is dependent on sufficient lubrication. Do not use Drillbone Tunneler that is severely damaged, has illegible markings, shows signs of corrosion, or is otherwise damaged. Remove the medical device from service and contact the manufacturer.

### 4.1 Cleaning

- Wipe all parts of the new Drillbone Tunneler with a cloth.
- Remove all removable parts of the Drillbone Tunneler 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 Tunneler 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 Tunneler and rinse with water.
- Wash Drillbone Tunneler manually, remove gross 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 “Drill Sleeve teeth” with a brush. The bristles of the brush must be perpendicular to the surface being cleaned.
- When using detergents and disinfectants, follow the instructions of the manufacturer of the specific product:
  - adhere to the prescribed concentration,
  - solution temperature,
  - water quality and exposure 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 Tunneler before sterilization using automatic washer - disinfectant with thermal disinfection.
- Place Drillbone Tunneler 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.

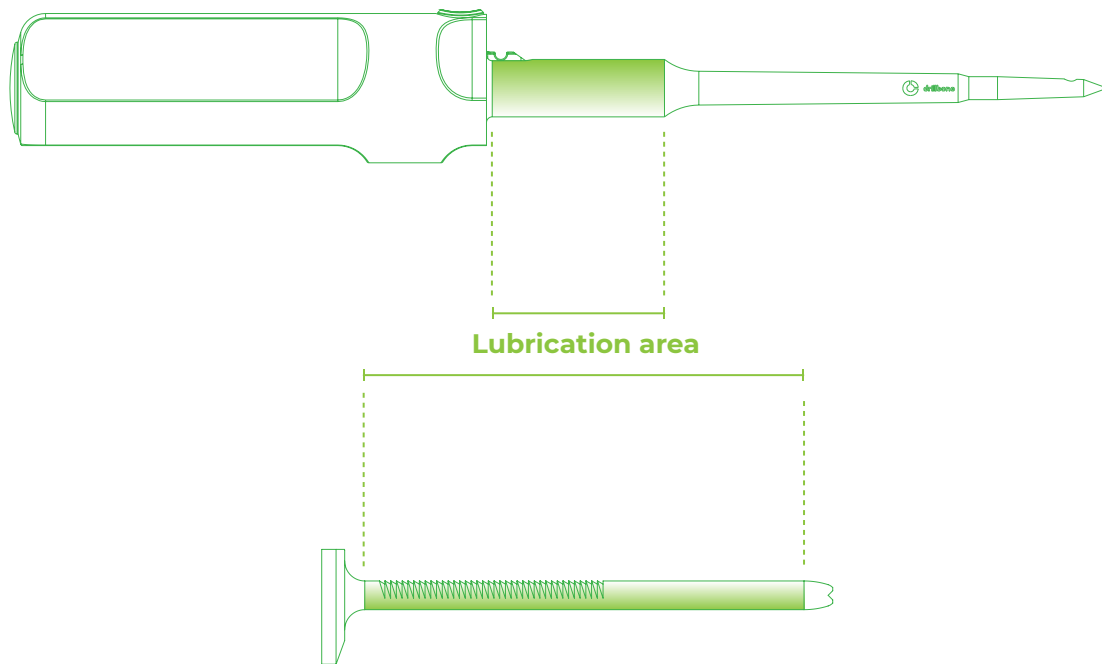
Note: For validation purposes, Drillbone used the following formulation and parameters: Mediclean forte disinfectant.

- 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



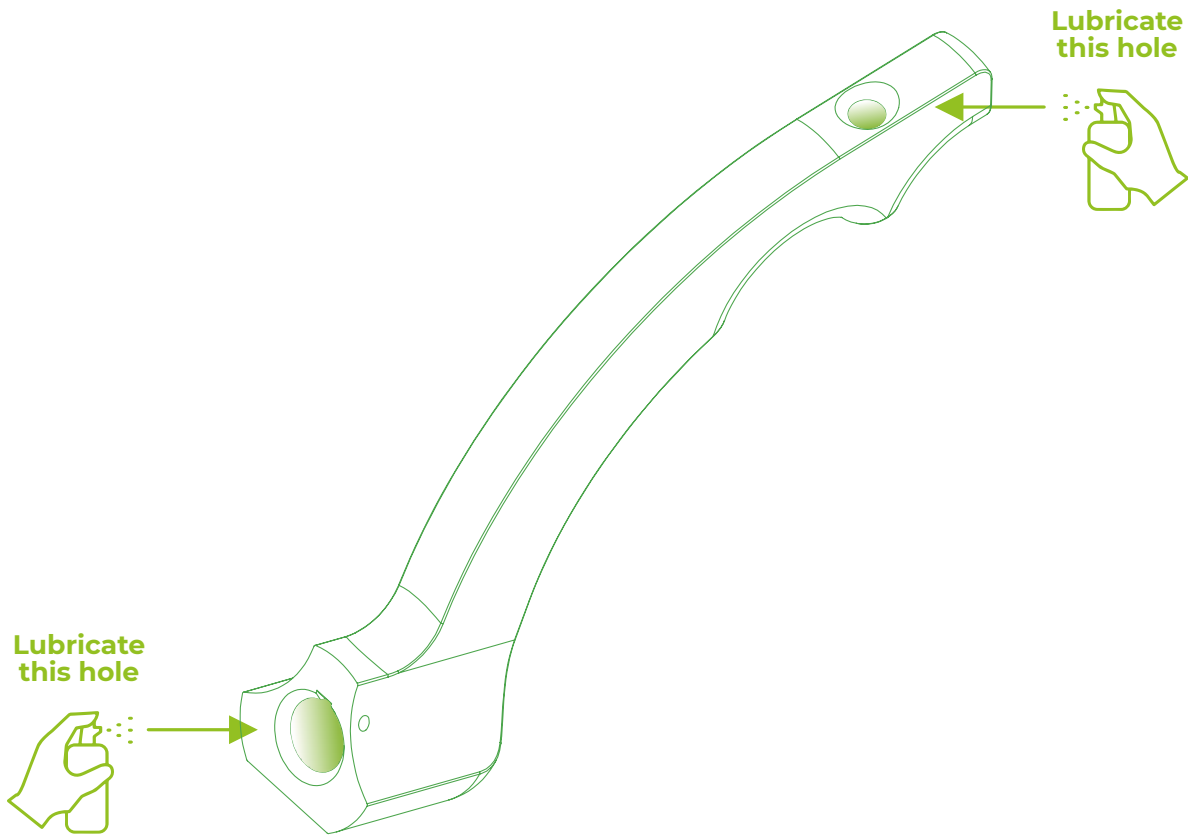
For proper long-term functioning, Drillbone Tunneler must be properly lubricated. The lubrication points are shown in the figure below. Apply lubricant to the cylindrical surfaces of the Awl and Drill Sleeve. Then use circular motions to gradually insert the Awl and Drill Sleeve into the Body. Then rotate the Awl and the Drill Sleeve 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 Tunneler device, it is necessary to check its functionality.



**Figure 2:** *Lubrication detail*

### 4.3 Packaging (before sterilization)

- Store the disinfected, cleaned, rinsed, dried and lubricated Drillbone Tunneler 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 Tunneler device. Contact with other objects could damage their surface.
- The Drillbone Tunneler device can be packaged in sterilization packaging that meets the requirements of the ISO 11607 standard.



**Figure 3:** Lubrication detail

#### 4.4 Sterilization

Sterilize only a cleaned and disinfected Drillbone Tunneler. 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 Tunneler. The manufacturer does not guarantee the results when using other washing methods.
- A moist heat sterilization method is validated for Drillbone Tunneler, 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 Tunneler 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 Tunneler 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 Tunneler 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 Tunneler device.

- Before first use, carefully inspect the Drillbone Tunneler device for visible damage. If you suspect product damage, contact the manufacturer.
- Disinfect, clean, lubricate and sterilize the Drillbone Tunneler as soon as possible after use.
- Keep the Drillbone Tunneler device in a mobile state by proper lubrication according to Chapter 4.2. Lubricate after thorough cleaning and disinfection of the device. To maintain the Drillbone Tunneler, 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 Tunneler 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 Tunneler device can be subjected to 200 sterilization cycles. The lifespan of the Drillbone Tunneler 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 Tunneler.

### **5. Benefits for the patient**

The benefit of using the Drillbone Tunneler for transosseous rotator cuff repair lies in the creation of precisely localized bone tunnels. The device enables tunnel placement that respects anatomical conditions, bone architecture, and the variability in shoulder size among patients.

By avoiding the use of anchors, this technique allows for faster resolution of postoperative pain. Compared to other surgical techniques, this method offers greater biological healing potential due to the tunnels and the direct contact between tendon and bone.

## 6. Risks

Before using the Drillbone Tunneler device, it is essential that the healthcare professional informs the patient about the potential risks and complications associated with using the Drillbone Tunneler 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).

Make the report by email (contact: Tomáš Valenta, [valenta@drillbone.com](mailto: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

The discarded Drillbone Tunneler device is considered hazardous waste. The user is responsible for taking precautions for the safe handling and disposal of the product. The damaged Drillbone Tunneler 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.** declines any liability for direct or consequential injuries or damages resulting from improper use of the medical device, 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



USB Flash Disk

Consult electronic Instructions for Use at USB Flash Disk



Non-sterile medical device



Conformity mark



Caution/Warning



Reference catalogue number



Batch code to identify  
the batch or LOT



Serial number for medical  
device identification



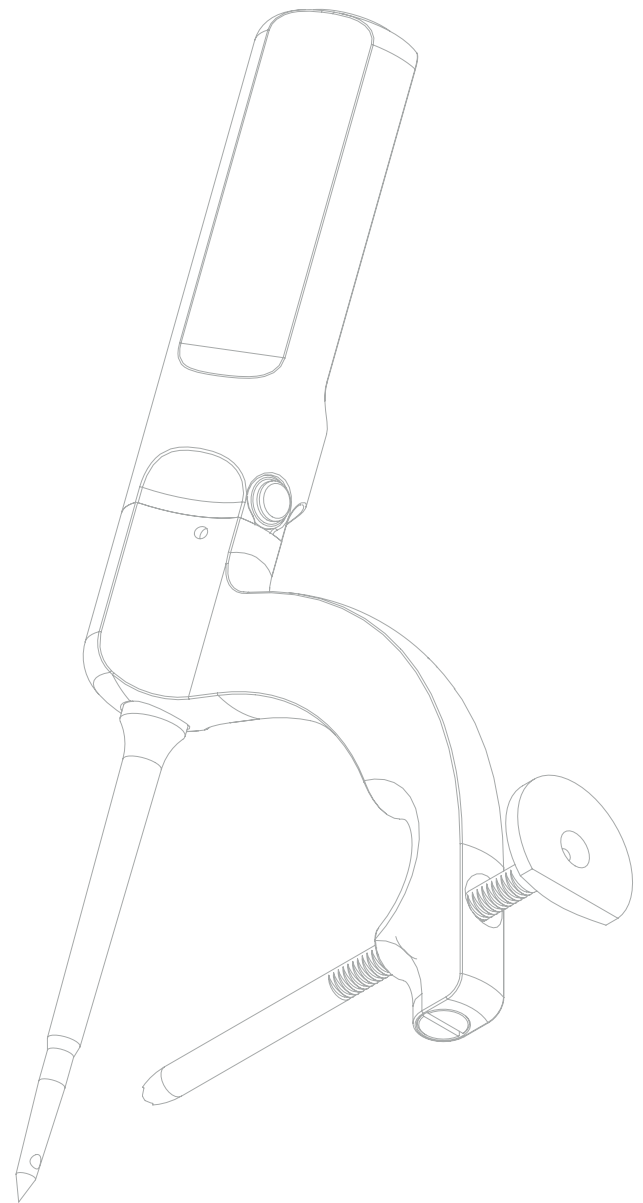
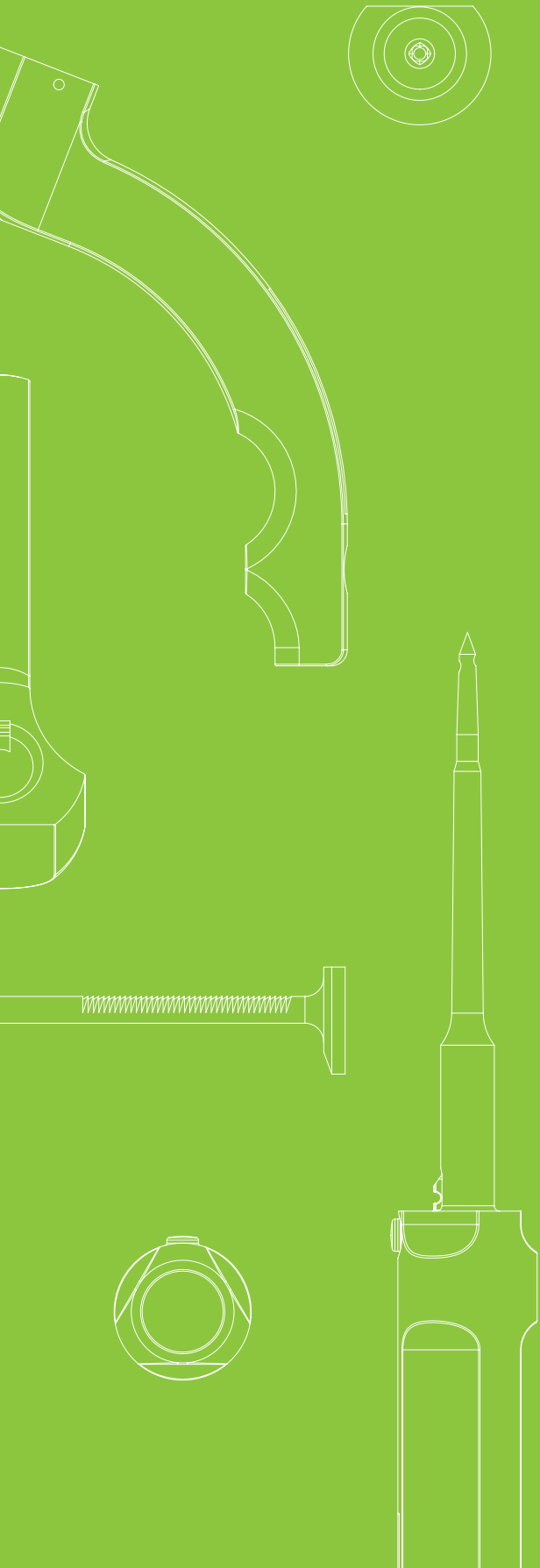
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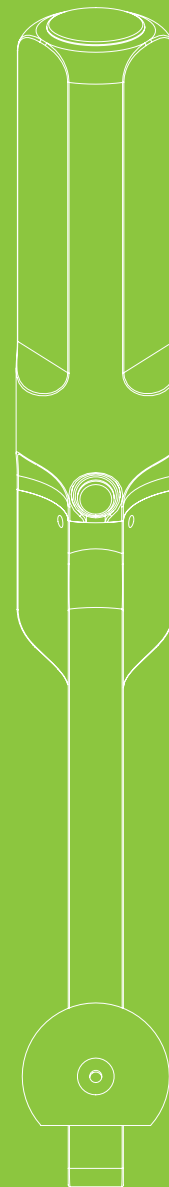
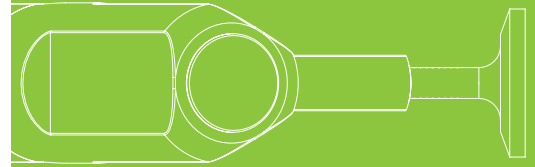
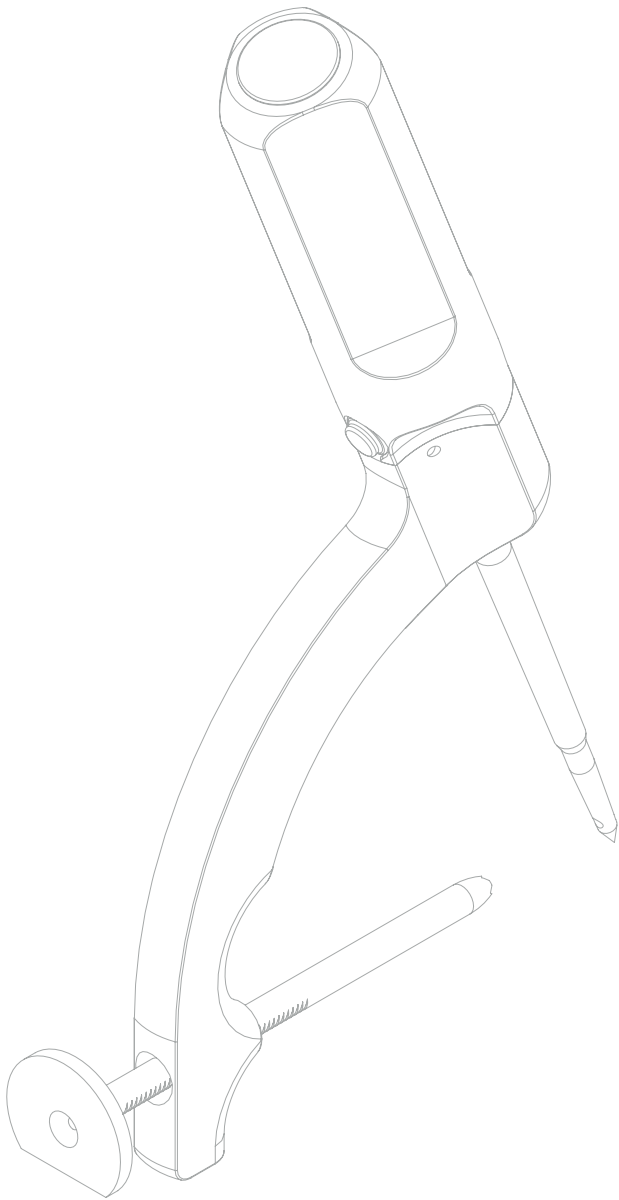


# INSTRUCTIONS FOR USE

Drillbone Tunneler

Rotator Cuff Repair  
Tunneler





Product  
Website



Surgical  
Technique  
3D Animation

**CE**  
**1383**

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