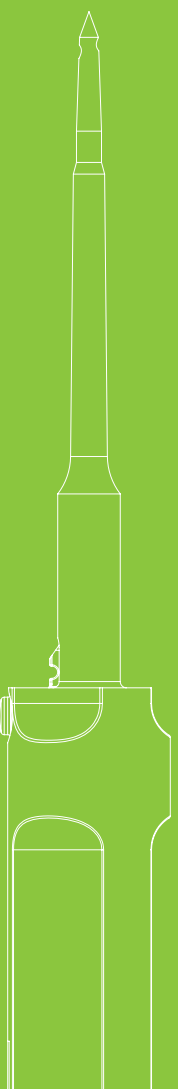
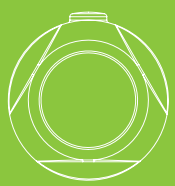
drillbone

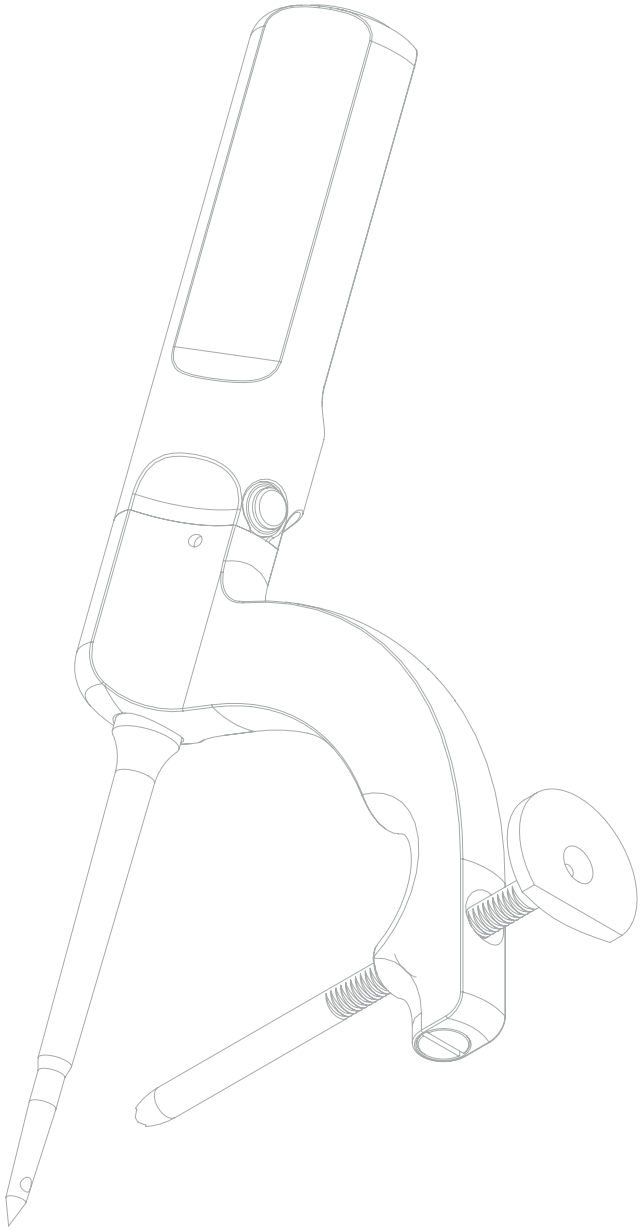
INSTRUCTIONS FOR USE

Drillbone Tunneler

Rotator Cuff Repair Tunneler



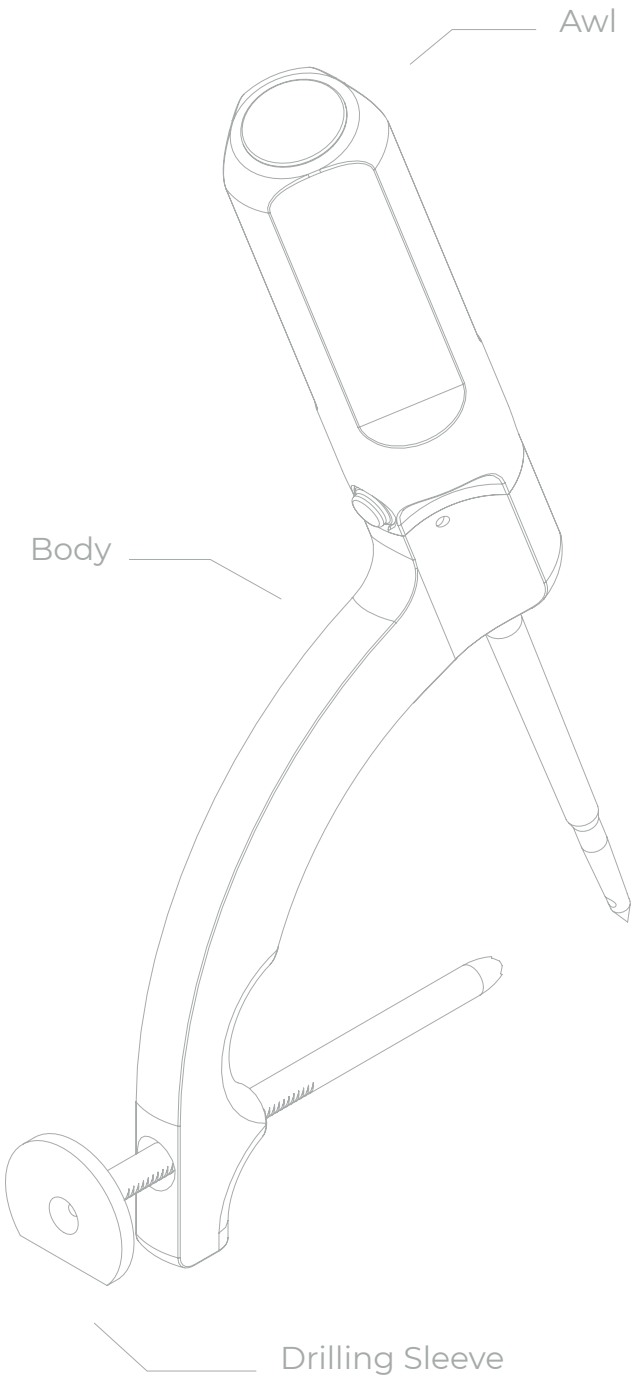




Date: 15.02.2023
Version: ENG01

drillbone

"strong solutions
for better healing"



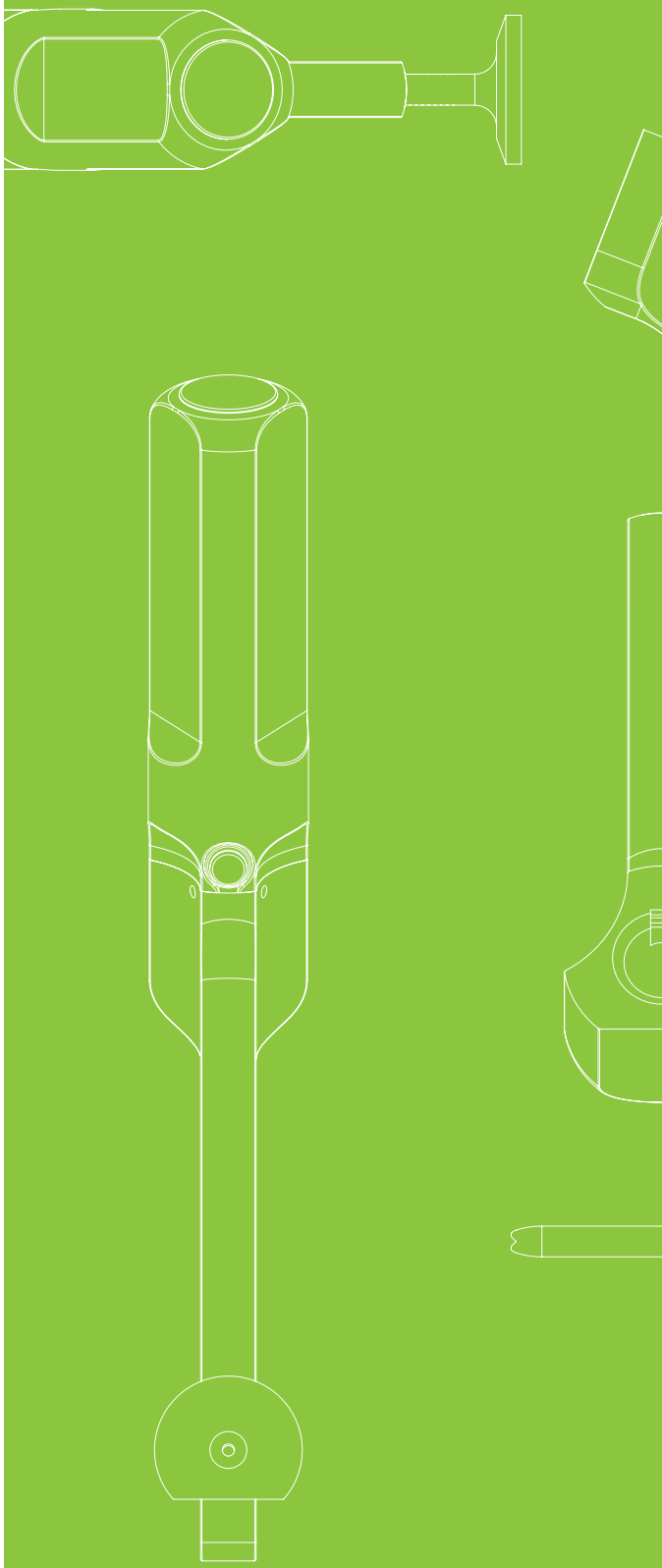


TABLE OF CONTENTS

1. Device description and specification

1.1 Manufacturer

Business name:	Sportbalance s.r.o.
Address:	Bulharská 1173/37, Brno - Královo pole 612 00, Czech Republic
ID:	03960293
VAT No:	CZ03960293

1.2 Product name and commercial name

Product name:	Rotator Cuff Repair Tunneler
Other commercial name:	Drillbone Tunneler

1.3 Medical device classification

Class I, non-sterile, non-measuring.

1.4 Intended use

The Rotator Cuff Repair Tunneler medical device is intended for precision targeting of planned bone tunnels for performing the rotator cuff repair.

1.5 Intended user and target population

The medical device is intended for use by expert medical professionals and is indicated for all adult patients and children aged 12 or more.

1.6 Indication and medical conditions

The Rotator Cuff Repair Tunneler medical device is indicated for use in transosseous rotator cuff repair, for precision targeting of planned bone tunnels for performing the rotator cuff repair.

1.7 Contraindications, warnings, and safety measures

- Osteoporosis
- Higher age
- Patients with active infections
- Medical conditions slowing healing, such as restriction of blood supply or infection
- Conditions that tend to limit the patient's capacity or willingness to observe instructions during the healing period.

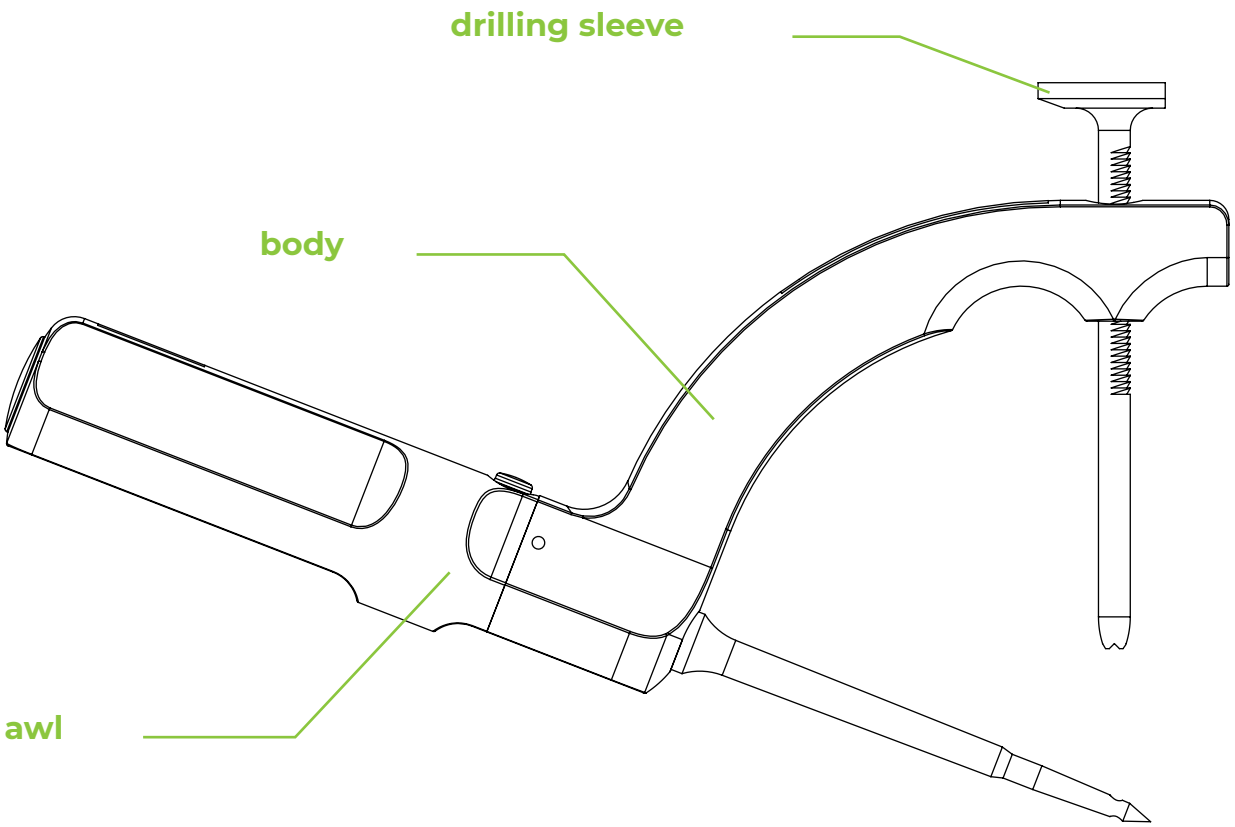
1.8 Principles of operation and mode of action

The principle of operation of the Rotator Cuff Repair Tunneler is described in a separate document (Surgical Technique) that is provided with the delivery of each device package. The Surgical Technique document is also available for download on www.drillbone.com. Providers of medical services provider shall ensure that the medical device is used strictly in compliance with the instructions of the manufacturer.

2. Technical specifications

The Rotator Cuff Repair Tunneler consists of the following components:

- body, as a supporting structure,
- tip, as an awl,
- drilling sleeve as a guide for drill bit



The individual components consist of the following basic structural elements:

- The body of the device has two precision holes for positioning the tip and the drilling sleeve.
- The axis of the awl and axis of the drilling sleeve are inclined towards each other at an angle and intersect at one point.
- A button on the handle of the punch releases the tip from the body. After that the awl can be turned or removed from the body.
- The drilling sleeve is designed as a ratchet, with a moving bolt inside the body.

3. Use

- During the operation, continuously wipe away blood and any other tissue materials from the Rotator Cuff Repair Tunneler medical device to prevent them from drying and sticking to the surface.
- Rinse the apertures in the Rotator Cuff Repair Tunneler medical device with sterile or purified water to prevent drying and sticking of any blood or other tissue materials inside.
- The Rotator Cuff Repair Tunneler medical device should be covered with a moistened tissue (moistened with sterile or purified water) to prevent drying and sticking of any blood or other tissue materials.
- Znečištěný zdravotnický prostředek Cílič pro suturu rotátorové manžety je nutno oddělit od jiných neznečištěných chirurgických nástrojů, aby nedošlo ke kontaminaci nepoužitých chirurgických nástrojů, personálu a okolí.
- Stained Rotator Cuff Repair Tunneler medical device shall be kept separate from other unstained surgical instruments to prevent any contamination of unused surgical instruments, personnel, and environment.
-  Keep stained Rotator Cuff Repair Tunneler medical device away from medical waste.

4. Reuse

The medical device is intended for reuse for which it needs to be thoroughly cleaned, sanitized, and sterilized. It can be used for individual patients during only one operation of rotator cuff tear to establish the transosseous tunnels.

After the operation and prior to sterilization the Rotator Cuff Repair Tunneler medical device must be checked for:

- cleanliness
- any damage (e.g. corrosion, colour change, wear and tear, cracks, excessive and significant scratching, chipping),
- correct function of the Rotator Cuff Repair Tunneler,
- any missing or removed numbers or marks on the medical device.

If showing any of the above signs of damage, discard the Rotator Cuff Repair Tunneler medical device.

Prior to using the Rotator Cuff Repair Tunneler medical device make sure its surface is undamaged and free of any visible defects and that it is fully functional. Do not use the Rotator Cuff Repair Tunneler medical device for rotator cuff repair if visibly and significantly damaged, if the marks are illegible, if showing signs of corrosion or any other damage. Discard the medical device.

4.1 Cleaning

- Wipe all parts of a new Rotator Cuff Repair Tunneler medical device with a clean cloth.
- Prior to manual cleaning, remove all removable parts of the Rotator Cuff Repair Tunneler medical device or place them on a separate tray.
-  Do not use alkaline cleaning agents (maximum pH 9).

4.1.1 Cleaning and sanitation – manual

- Place the Rotator Cuff Repair Tunneler medical device into sanitizing bath and make sure it does not move freely during the cleaning process or that it does not touch other devices; damage may occur.
- After the recommended time of exposure, remove the Rotator Cuff Repair Tunneler medical device from the sanitizing bath and rinse it thoroughly with clean water.
- Wash the Rotator Cuff Repair Tunneler medical device by hand, remove any gross impurities mechanically using a brush and a cleaning and sanitizer solution in an ultrasound bath, and then rinse the device thoroughly under running water.
- The manufacturer does not prescribe any specific cleaning and sanitizing agents for the Rotator Cuff Repair Tunneler medical device. When using such agents, follow the instructions of the respective manufacturer of the agent:
  - respect the prescribed concentration,
  - bath temperature
  - quality of water and time of exposure

- After the recommended time of exposure, rinse the cleaning agent off under running water.

4.1.2 Cleaning and sterilization – automated

- Validated cleaning and sterilization routines using automatic machines are always preferred to manual cleaning. Good cleaning is the precondition of successful sterilization and thanks to automated cleaning/ sterilization higher degree of process safety can be achieved.
- It is recommended to clean the Rotator Cuff Repair tunneler medical device in automatic washers with thermal sanitization cycle prior to sterilization.
- Place the Rotator Cuff Repair Tunneler medical device into a sanitizer bath and make sure it does not move freely during the cleaning process or that it does not touch other devices; damage may occur.

- The manufacturer does not prescribe any specific cleaning and sanitizer agents for the Rotator Cuff Repair Tunneler medical device.
- When using such agents, follow the instructions of the respective manufacturer of the agent. Observe especially the following:

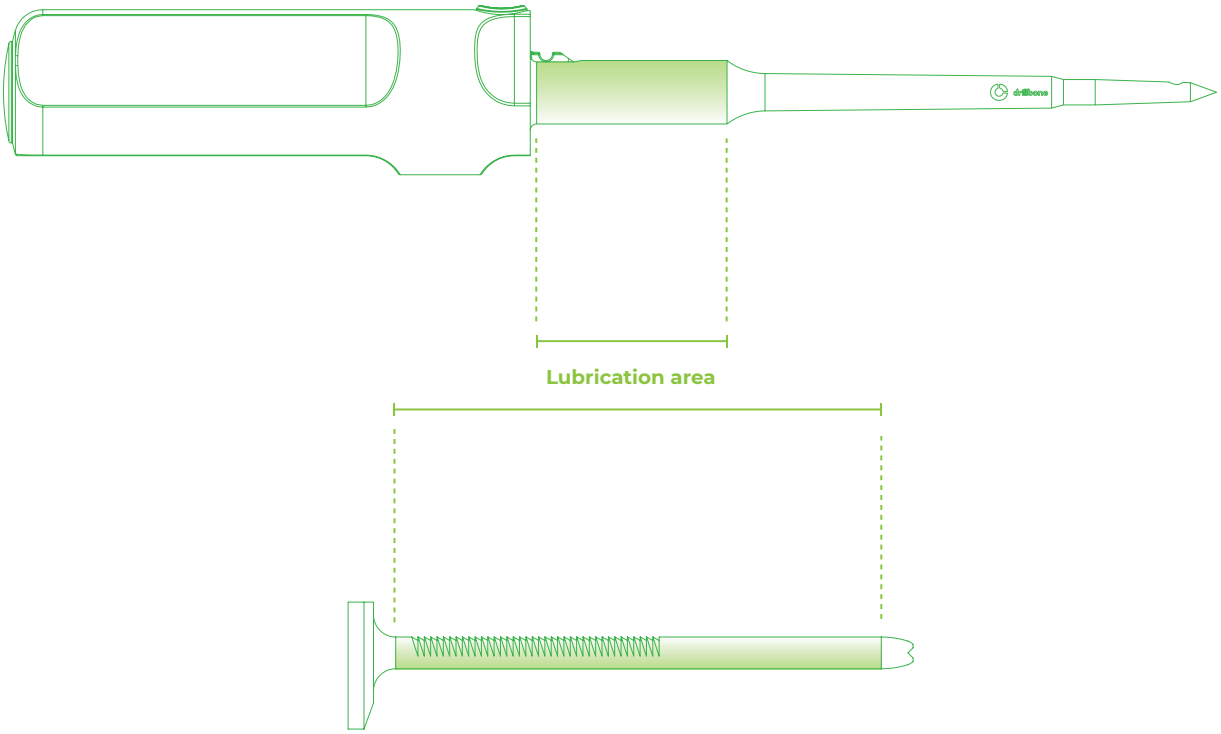
  – prescribed concentration,
  – temperature of the solution,
  – quality of water,
  – time of exposure.

4.2 Sanitization

When cleaning the Rotator Cuff Repair Tunneler in an automatic washer, sanitize it at a minimum temperature of 90 °C for at least 5 minutes.

4.3 Lubrication

For proper long-term function, the Rotator Cuff Repair Tunneler must be properly lubricated. Lubrication points are shown in the figure below. Apply the lubricant to the cylindrical surfaces of the awl and drill sleeve. Subsequently, gradually insert the awl and drill sleeve into the caliper using circular motions. Then rotate the awl and drill sleeve several times simultaneously with axial movements. This creates a sufficient lubricating film for the tool to function properly. As a lubricant, use commonly used preservative sprays or medical lubricants Tools.



4.4 Sterilizace

Sterilize only cleaned and sanitized Rotator Cuff Repair Tunneler medical device. The manufacturer recommends sterilizing the Rotator Cuff Repair tunneler with damp heat in a hot steam sterilizer:

Temperature	134 °C
Sterilization time	7 minutes
Pressure	310 kPa

When using hot-air sterilization in forced air circulation devices, apply one of the following settings:

	Setting 1	Setting 2	Setting 3
Temperature	160 °C	170 °C	180 °C
Sterilization time	60 minutes	30 minutes	20 minutes

4.5 Additional information

- Cleaning process with thermal sanitation has been validated for the Rotator Cuff Repair Tunneler. The manufacturer does not guarantee the result of other cleaning methods. The manufacturer recommends that any other methods should be validated by the supplier of the particular washing machine in question.
- Damp heat sterilization method has been validated for the Rotator Cuff Repair tunneler:

Temperature	134 °C
Sterilization time	7 minutes
Pressure	310 kPa

- Instructions for cleaning and sterilization are provided in compliance with ISO 15883, ISO 17664 and ISO 17665-1 standards.
- It is the responsibility of the processor to achieve the desired result by preparing the product using devices, materials, and staff at a preparatory workplace. The manufacturer warns that validation and routine observance of the established methods is required. Any deviations from these recommendations must be evaluated accordingly.

4.6 Packaging and storage

- Stained Rotator Cuff Repair Tunneler medical device shall be shipped separately from unstained instruments to prevent contamination.
- Store sanitized, cleaned, rinsed, and dry Rotator Cuff Repair Tunneler in a convenient way and place. Use convenient sterilization cover or reusable solid container (packaging and containers for providing a sterile barrier in compliance with ISO 11607 Packaging for terminally sterilized medical devices).
- Avoid any sharp and pointed parts of the Rotator Cuff Repair Tunneler medical device. If in contact with other objects, damage to the surface may occur.
- The Rotator Cuff Repair Tunneler medical device can be packaged also in sterilizing packaging and containers meeting the requirements of the ISO 11607 standard.
- Keep packaged Rotator Cuff Repair Tunneler medical device in clean and dry environment without extreme temperatures and humidity, away from direct sunlight. Keep away from animals, insects, dust, mould, and chemicals.

4.7 Warning

- Do not place the medical device into saline containing salt (NaCl solution). The Rotator Cuff Repair Tunneler medical device is made from stainless steel materials and prolonged contact with salt could lead to corrosion (pitting corrosion, stress corrosion)
- Be careful when using cleaning solutions with higher alkalinity and/or solutions with added hydrogen peroxide. They can cause colour change. This may damage the identification symbols on the Rotator Cuff Repair Tunneler medical device.
- Do not use rough cleaning materials (such as steel wool, etc.) or abrasive detergents. We recommend cleaning the Rotator Cuff Repair tunneler medical device in a cleaning and sanitizing machine intended for surgical instruments compliant with ISO 15883-1.
- Pay special attention to cleaning the apertures, narrow and small parts

of the Rotator Cuff Repair Tunneler medical device.

- Always thoroughly clean the Rotator Cuff Repair Tunneler medical device prior to sterilizing.
- The Rotator Cuff Repair Tunneler medical device is supplied as NON-STERILE. Clean, sanitize, and sterilize it before use.
- Before using the Rotator Cuff Repair Tunneler medical device for the first time, check it for any visible damage. Contact the manufacturer if suspecting any damage.
- Before using the Rotator Cuff Repair Tunneler medical device for the first time, clean, sanitize, and sterilize the device according to the instructions provided in this manual.
- Always clean and sterilize the Rotator Cuff Repair Tunneler medical device immediately after use.
- Keep the Rotator Cuff Repair Tunneler medical device in mobile condition by proper lubration according to ch. 4.3.
- After thorough cleaning and sanitization of the Rotator Cuff Repair Tunneler medical device for maintenance purposes, apply preservatives. Applying a preservative prevents metal friction and potential friction corrosion.
- To maintain the Rotator Cuff Repair Tunneler medical device, use only preservatives meeting the following requirements:

  – based on paraffin/white,
  – meeting the valid European pharmacopoeia,
  – biologically compatible,
  – suitable for steam sterilization and steam-permeable.

- The Rotator Cuff Repair Tunneler medical device may not be treated with silicone preservatives. These preservatives may restrict mobility and limit the effect of steam sterilization.
- A disassembled Rotator Cuff Repair Tunneler should be assembled prior to sterilization.
- Repairs of the medical device may be performed by the manufacturer only.

4.8 Frequency of application

Expected service time of the device is 5 years with 100 operations per year. The life expectancy of the Rotator Cuff Repair Tunneler medical device is determined by the degree of wear and tear caused by use. Repeated cleaning, sanitization and sterilization of the medical device have minimum impact on the Rotator Cuff Repair Tunneler.

5. Patient benefits

The benefit of using the Rotator Cuff Repair Tunneler medical device during a transosseous surgical operation is the establishment of precisely located bone tunnels. Using the medical device allows for establishing tunnels that respect the anatomical conditions, bone architecture and variation in shoulder size between different individuals. Thanks to this the patient experiences faster relief of postoperative pain with a higher biological potential for healing thanks to the tunnels and direct bone-tendon contact (compared to other surgical techniques).

6. Risks

Clinical risks for the users of the Rotator Cuff Repair Tunneler medical device issue mainly from the possibility of: fragment of a part of the tunneler, incorrect positioning of the targeter followed by incorrectly drilled bone tunnel, insufficient sterilization of the medical device, noncompliance with the conditions and purpose of use.

6.1 Reporting adverse events

Report any serious incidents directly or indirectly linked to this medical device to Sportbalance s.r.o., competent authority of your country and the country of patient's origin (if different).
Report via e-mail (hudecek@drillbone.cz) or by regular mail (Sportbalance s.r.o., MUDr. Filip Hudeček, Bulharská 1173/37, Královo Pole, 612 00 Brno, Czech Republic).

7. Disposal

Discarded Rotator Cuff Repair Tunneler medical device is considered hazardous waste. The user is responsible for adopting measures for safe handling and disposal of the product. Damaged Rotator Cuff Repair Tunneler medical device, decontaminated, cleaned and dry, shall be disposed as potentially hazardous waste as per the Waste Catalogue – Chapter 18 – Wastes arising from healthcare.

8. Disclaimer

Sportbalance s.r.o. disclaims any liability for direct or consequential injuries or damage resulting from improper use of the device, and in particular from non-compliance with the instructions in the operating manual or in the instructions for preparation and maintenance.

9. Symbols


Manufacturer


Manufacturing date


Read the instructions

Non-sterile medical device


Conformity mark


Warning / alert

Reference catalog number

Batch code identifying the batch or lot

Serial number identifying the medical device

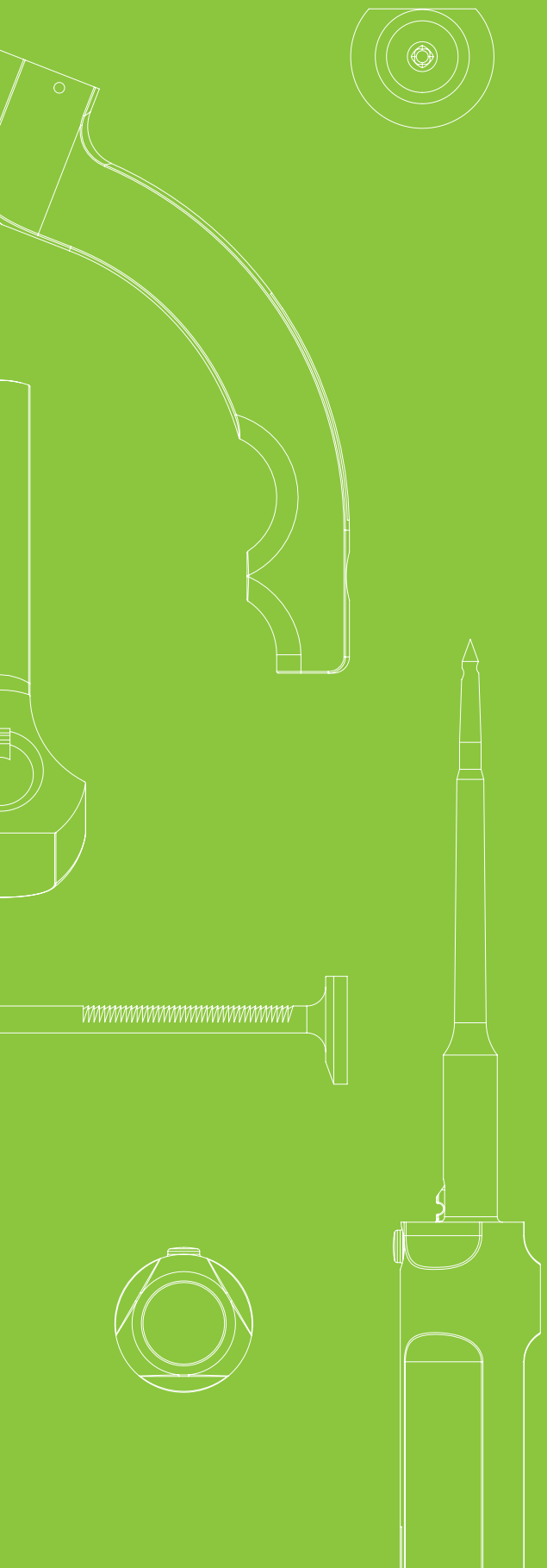
Quantity per package

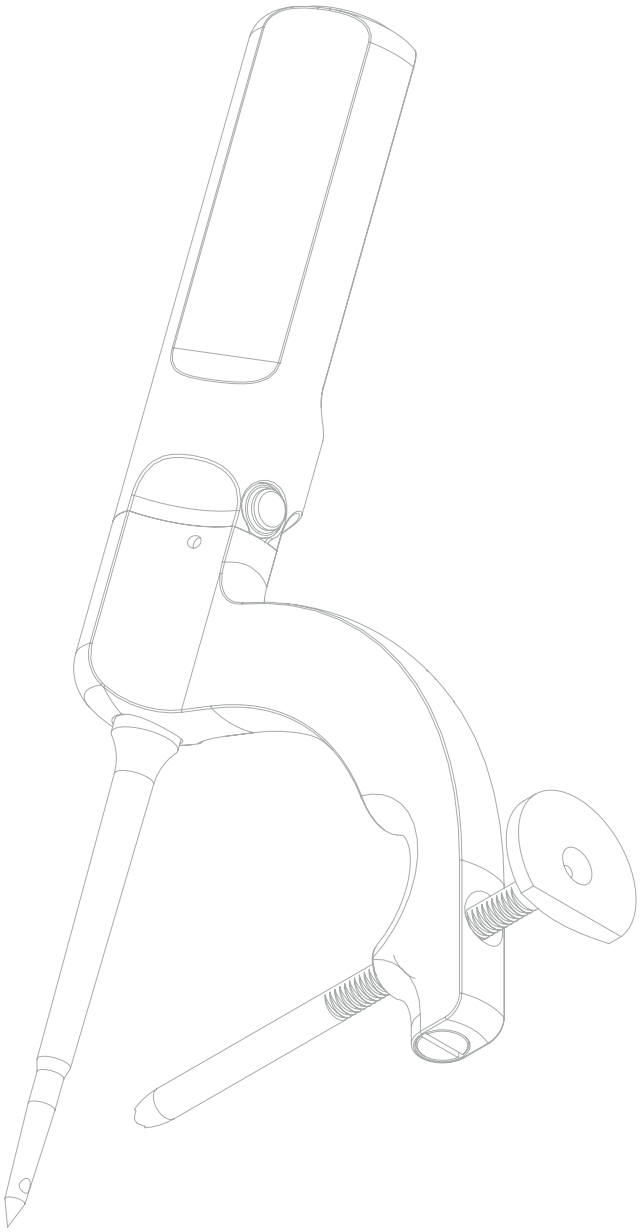
drillbone

INSTRUCTIONS FOR USE

Drillbone Tunneler

Rotator Cuff Repair Tunneler

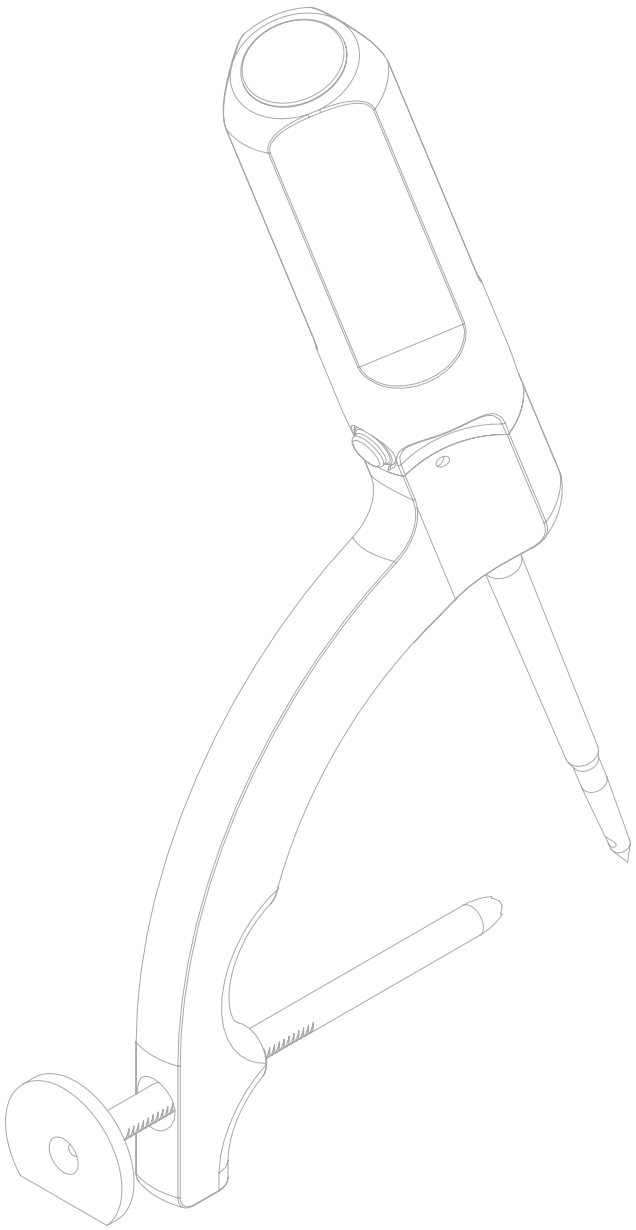


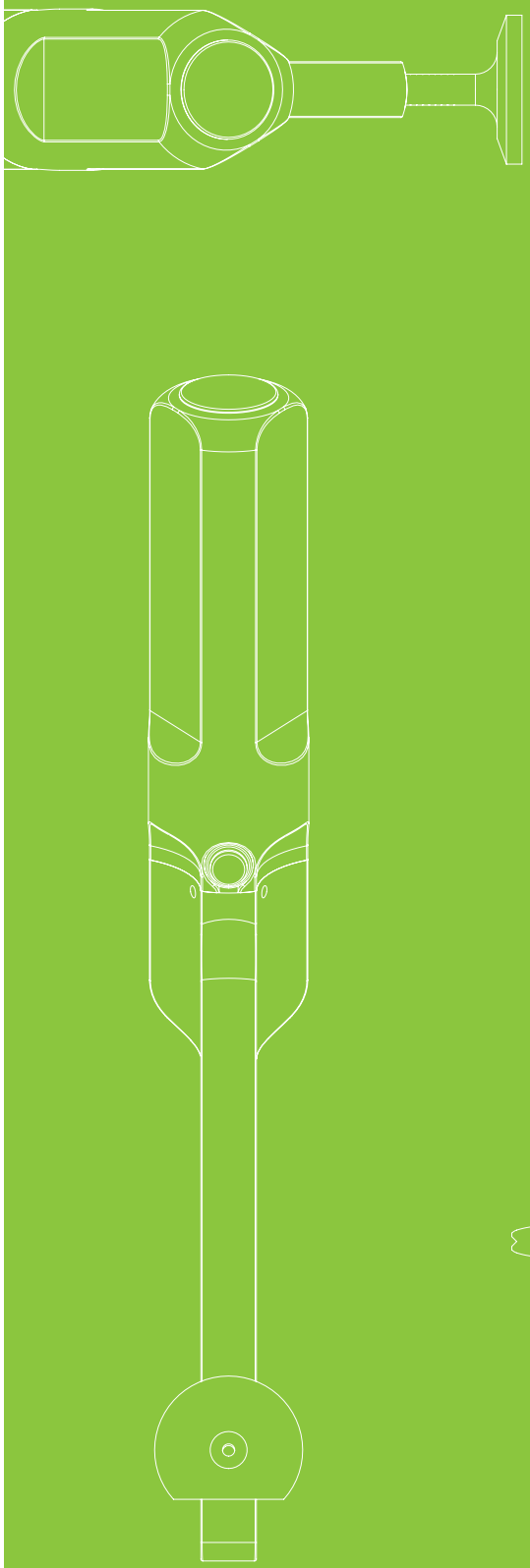


Date: 15.02.2023
Version: ENG01

drillbone

"strong solutions
for better healing"





Sportbalance s.r.o.
Bulharská 1173/37, Brno
www.drillbone.cz
info@drillbone.cz