



SHAVER - SYSTEM 54-301.01

Operator`s Manual

ORTHOMEDICAL GmbH IMPLANTS
Hauptstrasse 5
D-78589 Dürbheim

Tel. +49 (7424) 9403-40
Fax +49 (7424) 9403-43
www.orthomedical.de

CONTENTS

1. Introduction	4
2. Specifications	5
3. Safety notes	6
4. Inspection and maintenance	7
5. Unit description	8
6. Startup	9
7. Operation	10
8. Replacing the shaver blades	11
9. Cleaning and disinfection	12
10. Malfunctions	14
11. Shipping and storage	15
12. Disposal	16
Panel description	
Explanation of symbols	
Drawings	

This manual contains proprietary information subject to the copyright law. All rights are protected. Without the express written approval of producer the reproduction by photocopy, microfilm or other methods or the circulation of this manual, whether fully or in part, is not permitted.

Intended use

The Shaver-System 54-301.01 has been designed especially for use in arthroscopy and shall be operated by trained personnel only.

Dear customer

Please read this manual carefully before putting the equipment to use for the first time. This will prevent damages that may otherwise occur due to faulty connections or incorrect operation.

Use this arthroscopy pump only for the purpose described in this Operating Manual. We assume no liability for damages resulting from any misuse of the instrument.

This Operating Manual provides no detailed description of endoscopic or any other special treatment procedures!

1.Introduction

The **Shaver-System 54-301.01** is designed for arthroscopic surgical procedures. It is intended for the resection of fibrous and cartilage tissue in joints.

The Shaver-System consists of the electronic controlled control unit, the handpiece and the footswitch.

Equipment parts:

- Control unit
- Handpiece with integral cable
- Footswitch
- Power cord

The components of the System are designed and intended to be operated exclusively as a unit.

Direction and speed of rotation of the cutting tool can be selected by the surgeon either by means of the footswitch or directly at the control unit. The cutting tool has five RPM steps in clockwise, counterclockwise or oscillation mode.

CAUTION

This device is to be used only under the supervision of a trained and licensed physician.

This device should not be used by untrained personnel or used for indications other than those described in this Operating Manual.

2. Technical Specifications

Control unit

- Width: 360 mm
- Height: 90 mm
- Depth: 268 mm
- Weight: 6 kg
- Power input: 230 V AC / 50 Hz
- Capacity: 50 VA
- Fuses: 2 x 3 A automatic
- Protection Class: I
- Type: B
- Operating mode: continuous
- Mode of Operation: Intermittent operation with short time loading of 3 minutes
- Water Protection: IP X0
- EN-Class: 2a
- Connections: Handpiece, Footswitch
- Cleaning: Surface cleaning with mild cleaning solution

Handpiece

- Length: 165 mm
- Weight: 475 g
- Speed Range: 1000-8000 rpm +10%
- Oscillating Cycle: 1,2 s
- Operating mode: intermittent mode – 3 minutes ON / 3 minutes OFF (at max speed)
- Length of cable: 3 m
- Sterilisation: autoclave

Footswitch

- Width: 266 mm
- Height: 20 mm
- Depth: 209 mm
- Weight: 1400 g
- Mode of operation: Clockwise, Counterclockwise, Oscillation, Speed Level Adjustment
- Length of cable: 3 m
- Cleaning: Surface cleaning with mild cleaning solution

Power cord: 230 V, 10 A, 3-pole

3.Safety information

Please read through these operating instructions carefully before working with Shaver-System.

These instructions cover the handling and operation of the Shaver-System .

The Shaver-System complies with the relevant Health and Safety requirements, is designed according to the latest state of the art technology, and is safe to operate.

This equipment can be dangerous if operated by untrained personnel and / or if used incorrectly.

No interference is known to occur between the Shaver-System and any other equipment used in the OP.

There is no contraindication noticed as long as the Shaver-System is used correctly.

If any component of the Shaver-System fails or appears to malfunction please contact the manufacturer.

The following designations are used in these operating instructions to indicate safety information:

ATTENTION

Damage to equipment may occur in the absence of full compliance with the operating instructions indicated with this designation.

NOTE

More effective and easier work is possible when the instructions marked with this designation are followed.

4. Inspection and maintenance

To ensure the fully functional condition of the Shaver-System it is essential to perform an inspection after receiving the unit.

Carefully unpack the unit and inspect the housing for scratches, indentations and other signs of physical damage.

If the Shaver-System is in perfect physical condition, perform a first functional test by following the sections *Startup* and *Operation*.

In case of an instrument failure please contact the manufacturer.

Prior to each use of the instrument check that the power cable is in good operating condition, i.e. that the cable is free of fissures, cracks or interrupted conductors.

The instrument should be inspected for safe and proper operation by a qualified technician at least every six month.

Once a year the instrument should be subjected to a complete check-up by the manufacturer.

5. System Description

The **ON/OFF (1)** power switch is located left on the front panel of the control unit.

On the front panel left is set also the illuminated display **RPM (2)** and the pushbutton **SPEED (3)** for selecting the required speed of rotation. The required speed can also be set with the footswitch **SPEED (19)**.

Further right of the control panel is the illuminated display **DIRECTION (4)** and the pushbuttons **REV (5)** and **FWD(6)** for selecting the direction of rotation of the cutting tool.

The direction of rotation can also be set with the footswitch **REV (16)** and footswitch **FWD (17)** on the foot control.

The oscillation interval required can be set either directly on the control panel of the control unit by simultaneously pressing the buttons **REV (5)** and **FWD (6)** or by pressing the footswitch **OSC (18)** on the foot control, or else by simultaneously pressing the foot switches **REV (16)** and **FWD (17)**.

Under the display **DIRECTION** on the front panel of the control unit are located the connection socket **(7)** for the connecting cable **(12)** to the Shaver handpiece, and the connection socket **(8)** for the connecting cable **(20)** to the foot control.

The Shaver handpiece is provided with a cutting tool interlock **(9)**, a connection **(15)** for the aspiration device and the suction control **(10)**.

The following are located on the rear side of the control unit: the fuses **(22)**, the power supply socket **(23)** for the power cord, the equipotential bonding pin **(24)** with the equipotential bonding plate **(25)**, and the nameplate **(26)**.

7.Directions for Use

- Switch on Shaver-System using the power switch **ON/OFF (1)**.

After it is switched on, the control unit carries out a self test.

The illuminated display **RPM (2)** signals "0000" and the display **DIRECTION (4)** a dashed line "---". After about 4 sec. the control unit display "0000" on the display **RPM (2)** and "NO-PIECE" on the display **DIRECTION (4)**.

After the inserting the connector **(13)** of the handpiece connecting cable **(12)** into socket **(7)** signals the display **DIRECTION (4)** "SHAV 5.0" and the shaver is ready to operate.

Setting the operating mode with the footswitch

- Press the footswitch **SPEED (19)** and set the required speed.
- Pressing the footswitch **FWD (17)** causes the cutting tool to be turned clockwise.
- Pressing the footswitch **REV (16)** causes the cutting tool to be turned counterclockwise.
- To set the oscillation mode, simultaneously press either foot switches **REV (16)** and **FWD (17)**, or foot switch **OSC (18)**.
- Set the required flow volume with the aspiration control **(10)**.
For maximum flow rate, slide the aspiration control **(10)** backwards;
to reduce the flow volume, slide the aspiration control **(10)** forwards.

ATTENTION ***Under no circumstances immerse the handpiece in a liquid for cooling!***

ATTENTION ***Use cutting tools only in fluid medium, otherwise there is danger of blockage and overheating!***

ATTENTION ***The handpiece should not be used continuously at full load to prevent overheating. The working cycle should last max. 3 minutes followed by a cool down phase to allow the handpiece to return to room temperature. If fluid is flowing through the handpiece, the cool down phase will be greatly reduced.***

Setting the operating mode on the control unit:

- Press the button **SPEED (3)** and set the required rotary speed.
- Pressing the button **FWD (6)** causes the cutting tool to be driven clockwise.
- Pressing the button **REV (5)** causes the cutting tool to be driven counterclockwise.
- To set the oscillation mode, simultaneously press the buttons **REV (5)** and **FWD (6)**.

8.Cutting Tools Changing

ATTENTION

Whenever fitting or changing the cutting tool, ensure that the control unit is disconnected!

- Insert sterile cutting tool into the handpiece
- Lock it by turning the cutting tool lock

ATTENTION

Whenever fitting or changing the cutting tool, ensure that the cutting tool lock is fully closed and engaged!

9.Cleaning and Sterilization

Cleaning

Control Unit

- Clean and disinfect the console with a commercially available surface disinfectant. Always comply with the instructions issued by the manufacturer of the disinfectant.

ATTENTION

Never clean the console jacks with liquid cleaners. Remove dust, if necessary, with dry compressed air.

Handpiece

- Remove any shaver blades
- Prior to sterilization, seal off the handpiece connector with protective cover
- Open the suction control fully
- Clean the shaver handpiece with an enzymatic cleaner without subsequent acid neutralization
- Clean the suction control connection with a cleaning brush
- Rinse the handpiece thoroughly after cleaning under lukewarm water
- Disinfect the handpiece with a commercially available disinfectant.
Always comply with the instructions issued by the manufacturer of the disinfectant

ATTENTION

Never allow the handpiece connector to have any contact with liquids. Remove dust or moisture, if necessary, with dry compressed air. Only dry connectors may be plugged into the console.

ATTENTION

Never place the shaver handpiece in Cidex or other aldehyde disinfectant solution.

Footswitch

- Clean the footswitch with an enzyme cleaner without subsequent acid neutralization.
- Rinse the footswitch thoroughly after cleaning under lukewarm water
- Disinfect the footswitch with a commercially available disinfectant.
Always comply with the instructions issued by the manufacturer of the disinfectant

ATTENTION

Never allow the footswitch connector to have any contact with liquids. Remove dust or moisture, if necessary, with dry compressed air. Only dry connectors may be plugged into the console.

Sterilization

Sterilization does not eliminate the need for proper cleaning and disinfection of handpiece and cables prior to sterilization.

Sterilization capabilities, cleaning, disinfecting, handling and storage of handpiece are the responsibility of qualified facility/user personnel.

Handpiece that is provided non-sterile, may be sterilized by one of the following methods:

Gravity displacement cycles :

- 134°C: exposure time 18 minutes (min)
- 121°C. exposure time 60 minutes

Prevacuum cycle:

- 134°C: 5 minutes

Sterilizers vary in design and performance characteristics, so cycle parameters should be verified against the sterilizer manufacturer's instructions for the specific sterilizer and load configuration being used.

It is the duty of the user to perform appropriate validation tests.

Cooling – the device must be adequately cooled, after being removed from the sterilizer. It should not be touch during the cooling process. Do not place the device on a cold surface or immerse in a cold fluid.

ATTENTION

After autoclaving the handpiece is very hot. Careless handling can result in burns.

After sterilization in the autoclave let the handpiece cool down slowly, never use cold water to cool the handpiece; this can damage the electronic components and seals.

Liquid on the cable connector of the handpiece can cause damage to the device. Before connecting the handpiece ensure that the jacks are clean und dry.

Shaver blades

The multi-use shaver blades sterilize always comply with the instructions issued by the manufacturer.

Do not resterilize the one way products.

10. Malfunctions

In case of any functional problem with the unit immediately contact the responsible technical department or the supplier.

The producer assumes a warranty to the first purchaser for a twelve month Period with regard to defects or failure of its medical devices. All defective products covered by the warranty are repaired or replaced free of charge.

Warranty claims will not be accepted if:

- the unit is damaged as a result of force majeure or negative environmental influences (like moisture, electrical interferences, etc.);
- the unit has been opened or repaired by non-authorized service stations or other personnel;
- sterilization regulations have not been complied with.
- when the unit is changed in any way or repairs are performed by any party other than producer.

Malfunction

Corrective action

1.No system messages when the control unit is switched on

- Check the power supply.
- Check the power cord.
- Check power switch **(1)**.
- Check automatic fuses **(22)**, if necessary push to reset.

2.Cutting tool does not operate

- Check the cutting tool, exchange if necessary.

3.Cutting tool does not operate, no sound of function

- Check connecting cable **(12)**, send for repair if necessary.
- Check handpiece **(11)**, send for repair if necessary.
- Check connection between Handpiece connector **(13)** and handpiece connection socket **(7)**; if socket **(7)** defective send equipment for repair.
- Check connecting cable **(20)**, if defective send foot control with cable for repair.

11. Transport und storage

Save all containers and packing material, they will be required if it becomes necessary to return the equipment to manufacturer.

In other case please contact the manufacturer to receive the packing material for your Shaver-System.

Claims under warranty are invalid when the equipment has been incorrectly packed.

Operation condition:

Temperature: +10°C to +50°C

Relative Humidity: 30% to 75%

Storage:

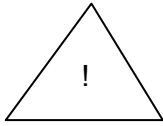
Temperature: -10°C to +50°C

12. Disposal

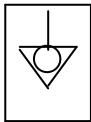
The final disposal of the shaver-system creates no problem since the unit does not contain any material harmful to the environment.

At the end of its service life the pump can be disposed of as electronic waste in public scrap yards.

Symbol Explanation



Attention Symbol: Read this accompanying documentation before operating this equipment



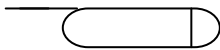
Electrical Ground Symbol



Alternating Current



Proof Type B



Handpiece



Footswitch



FWD



REV



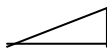
Oscillation OSC



Direction



RPM



Speed

CE 0483

European Certification Symbol

Drawing legend

Control unit - front panel:

- (1) ***ON/OFF*** power switch
- (2) Speed display ***RPM***
- (3) Rotary ***SPEED*** button
- (4) Rotary direction display ***DIRECTION***
- (5) Counterclockwise rotary direction button ***REV***
- (6) Clockwise rotary direction button ***FWD***
- (7) ***HANDPIECE*** connection socket
- (8) ***FOOTSWITCH*** connection socket

Handpiece:

- (9) Cutting attachment lock
- (10) Aspiration control
- (11) Handpiece
- (12) Connecting cable
- (13) Handpiece connector
- (14) Protective cap
- (15) Aspiration connection

Footswitch:

- (16) Footswitch - counterclockwise ***REV***
- (17) Footswitch - clockwise ***FWD***
- (18) Footswitch - Oscillation ***OSC***
- (19) Footswitch - ***SPEED***
- (20) Connecting cable
- (21) Connector

Control unit - rear panel:

- (22) Fuses
- (23) Power supply socket
- (24) Equipotential bonding pin
- (25) Equipotential bonding plate
- (26) Nameplate

