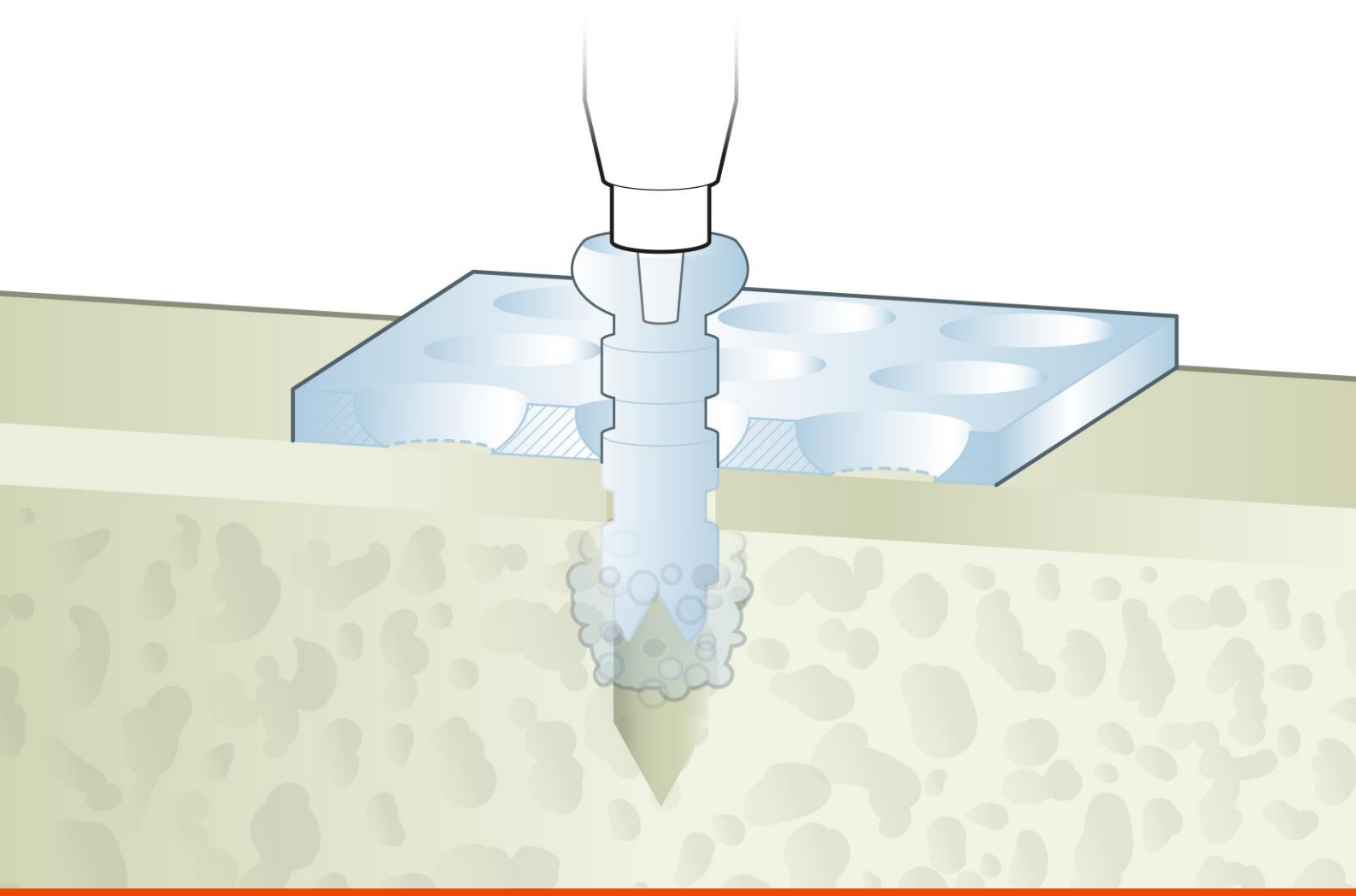
Vet Welding

A Company of WoodWelding SA using BoneWelding® Technology



Surgical Technique
Resorb Pin and Plate System

Revolutionary technique for osteosynthesis

Resorb Pin and Plate System

Table of Contents

Nota Bene

The technique description herein is made available to the veterinary healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient. It is the responsibility of treating veterinary physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. Prior to performing this technique, please consult the Instructions for Use documentation provided for each device for additional health and safety information.

INTRODUCTION

BoneWelding® Fixation

The Resorb Pin and Plate System is a fully bioresorbable implant intended for surgical procedures in which an internal fixation by resorbable implants is required for aligning, reconstructing, and stabilizing bone tissue. The BoneWelding® technology employs ultrasonic energy to liquefy the polymeric components of the resorbable pins at the interface with bone tissue. The liquid polymer flows into the marrow space of the surrounding cancellous bone where it is immediately quenched and provides anchorage of the implant.

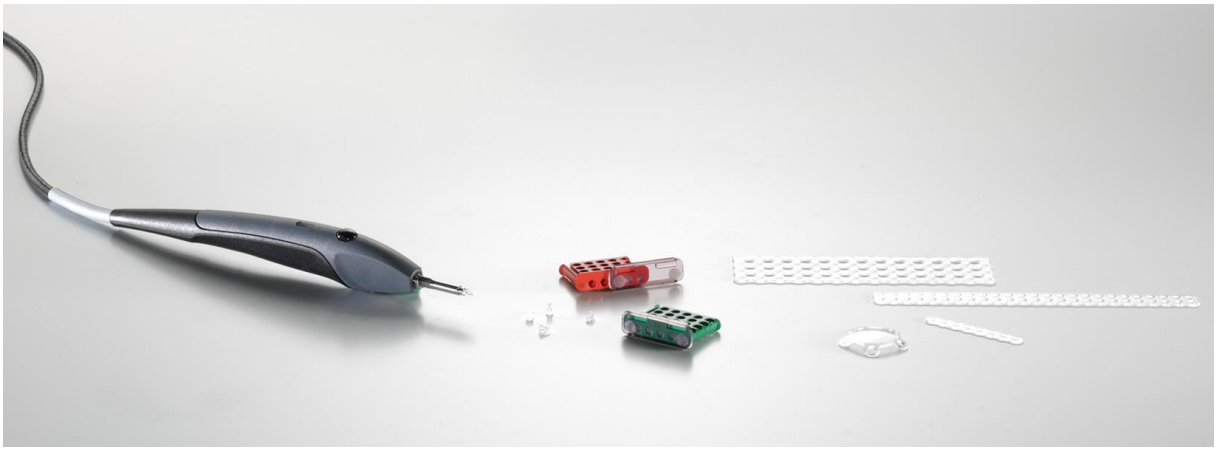
Resorb Pin and Plate System

The Resorb Pin and Plate System is a revolutionary technique for use in osteosynthesis. It combines highly advanced ultrasound technology with resorbable implants to provide extremely stable fixation and completely eliminate the need for a second operation.

The Resorb Pin and Plates are made of biocompatible and fully bioresorbable Polylactide (PDLLA). The “in-vivo” degradation is based on the natural physiological process of hydrolysis, which results in a complete metabolization of the polymer into H2O and CO2.

The procedure is simple: Resorb meshes or plates are warmed up, shaped to fit the application site and then fixed in place with pins inserted into predrilled holes. This is done with a sonotrode that liquefies the pins, thus causing them to bond with the meshes and penetrate into the bone cavities to anchor themselves securely.

The Resorb pins are 2.1 mm in diameter and provided in lengths from 4 mm to 9 mm. The plates and meshes are provided in a huge variety of different geometries, sizes and thicknesses that can be easily contoured or cut with scissors intraoperatively. This ensures the right implant for every indication and easy adaption to patient specific anatomy.



INDICATIONS / CONTRAINDICATIONS

Indications

The Resorb Pin and Plate System is intended for surgical procedures in which an internal fixation by resorbable implants is required for aligning, reconstructing, and stabilizing bone tissue. It is indicated for use in non-load-bearing applications. The Resorb pins are designed only to be inserted with the BoneWelder® Vet system.

Some of the many indications include:

- Osteosyntheses in non-load-bearing areas
- Treatment of maxillofacial fractures
- Laminoplasty
- Reconstruction of bone defects after cranial tumor resection
- Wound closure following equine tooth extraction to prevent food contamination
- Craniofacial corrective osteotomies
- Neurosurgery

WARNING: Do not re-use or re-sterilize the implants! The re-use of the any implant (pin or plate) is not possible. By being inserted with the BoneWelder® Vet equipment the implants liquefy and are firmly bonded with the cancellous bone. Implants, which have been taken from the sterile package and are not used for the procedure and the patient they were intended for, must be discarded as they cannot be re-sterilized. The product shall only be used by persons trained in the insertion technique of the Resorb Pin and Plate system.

Contraindications

The veterinary surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment.

Conditions presenting an increased risk of failure include:

- The osteosynthesis material Resorb must not be used in areas exposed to mechanical overload (e. g. fractures of the mandible). Otherwise, the Resorb pins, plates, and meshes can break due to overstrain and compromise the success of the treatment.
- Resorb plates and meshes cannot steadily replace bone tissue. That is why they may not be used as permanent bone substitute material. (i.e. use in applications containing a large gap that will not bridge)
- Active or latent soft tissue and/or skin infections at the site of the operation.
- Local inflammation of any origin at the repair site.
- Hypersensitivity to foreign bodies.
- Suspected material sensitivity or allergies and/or reactions to the implant materials used.
- Autoimmune diseases.
- Inadequate circulation or other pathological changes of the bone and/or soft tissue at the repair site.
- A bad general state of health and/or vascular disorders and/or metabolic disorders (such as diabetes) that may affect healing.
- Bone tumors in the area of implant anchoring.
- Insufficient quantitative or qualitative hard and soft tissue.
- Concomitant diseases, e.g. degenerative disease processes with negative influence on successful healing.
- Osteoporosis or osteomalacia and other serious damage to the bone structure conflicting with solid anchoring of the implant components.
- Factors which may also impair the success of operations include:
    - Incorrect implantation technique.
    - Inadequate (too little, too short) postoperative load reduction and immobilization for healing.)

The Resorb Pin and Plates (polymer implants) are safe for use in magnetic resonance (MR) environments.

BoneWelding® EQUIPMENT

BoneWelder® Vet Ultrasonic Device and Handpiece

The ultrasonic energy for the implantation of the Resorb Pin and Plates is provided by the BoneWelder® Vet ultrasound generator and applied via the attached handpiece.

Product Name	Description.	REF Nr.
BoneWelder® Vet System Incl. Ultrasonic Device, Handpiece, Wrench and Power Cord	Set	01-00-001
BoneWelder® Vet Ultrasonic Device	Ultrasonic Device	01-01-001
BoneWelder® Vet Handpiece	Instrument	01-02-001

Wrench

BoneWelder® Vet Wrench
REF: 01-03-001

The wrench helps you to mount the sonotrode properly on the handpiece making sure the connection is tight for an appropriate transfer of the ultrasonic energy into the implant.

Sonotrodes

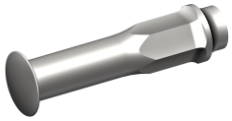
BoneWelder® Vet Standard Sonotrode, Straight

REF: V52-501-21-04

BoneWelder® Vet Standard Sonotrode, Angled

REF: V52-501-22-04

The standard sonotrode (handpiece tip) is mounted on the handpiece. It transmits the ultrasonic energy required to insert pins at either angled or straight positions.



BoneWelder® Vet Smoothing Sonotrode, Straight

REF: V52-501-23-04

BoneWelder® Vet Smoothing Sonotrode, angled

REF: V52-501-24-04

The smoothing sonotrode (handpiece tip) is mounted on the handpiece. It transmits the ultrasonic energy to smooth implants.

Drill Bit

Ø 1.6 mm drill bit

Drill bit for pin lengths up to:	REF Nr.
4.0 mm	V52-616-04-07
5.0 mm	V52-616-05-07
9.0 mm	V52-616-10-07

The **Ø 1.6 mm drill bit** is sized specifically for the 2.1 mm pins and is offered in lengths of 4,5 & 10 mm for use with the corresponding pins. It helps ensure safe and easy handling of the implants and correct implantation.

Water Bath

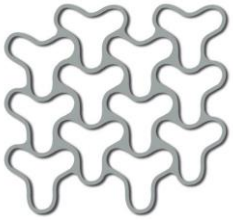
The water bath can be used to warm the Resorb plates just before use. After only a few seconds the implant can be shaped, contoured, and cut. Allowing them to be easily adapted to the surface of the bone segments.

Water Bath
(Incl. Thermal Unit, Cover Hood, Water Container and Power Cord)
REF: V52-400-10-04

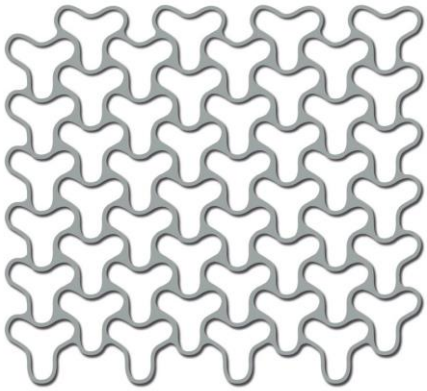
Resorb Templates

The Various templates available can help to adapt the implants to the shape of the bone.

Scale: 1/1
REF: V52-313-25-04
Dimensions: 25 x 25 mm
Titanium Template (Autoclavable)



Scale: 1/1
REF: V52-313-50-04
Dimensions: 50 x 50 mm
Titanium Template (Autoclavable)



Additional Instruments

The following instruments are not included but should be available in the operating room to aid in the implantation of the Resorb Plates and Pin System:

- **Plate holding instrument:** can be used to hold the plate in place during insertion of pins and assist in reducing the fracture.
- **Plate holding forceps:** can be used to position and hold the plate in place until pins are inserted.
- **Scissors:** can be used to cut a plate to the desired shape and size.

All components of the Resorb Pin and Plates System are developed and manufactured in cooperation with specialized partners.

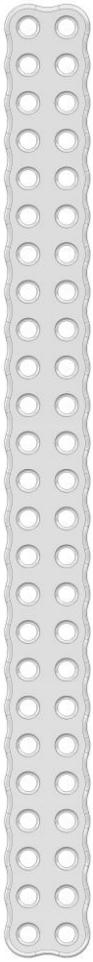
RESORB PRODUCT RANGE

Resorb Plates, Meshes and Sheets

Scale: 1/1
REF: V52-077-04-04
Dimensions: 27 x 7 mm
Thickness: 1 mm

Scale: 1/1
REF: V52-085-05-04
Dimensions: 25 x 14 mm
Thickness: 1 mm

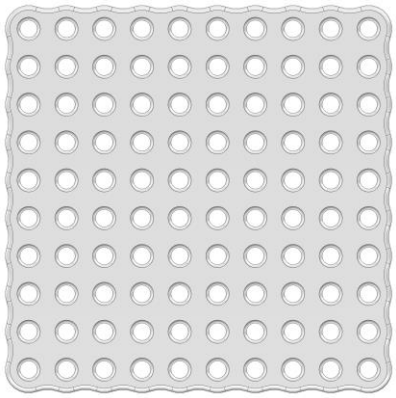
Scale: 1/1
REF: V52-076-22-04
Dimensions: 112 x 7 mm
Thickness: 1 mm



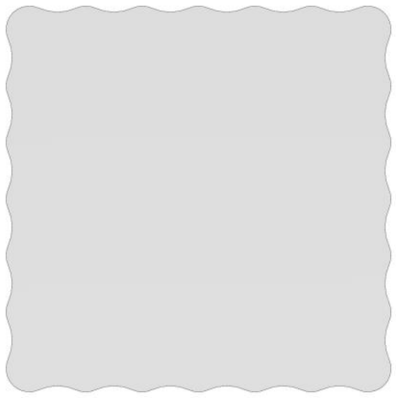
Scale: 1/1
REF: V52-310-11-04
Dimensions: 11 x126 mm
Thickness: 1 mm

Scale: 1/1
REF: V52-310-25-04
Dimensions: 26 x 26 mm
Thickness: 1.0 mm

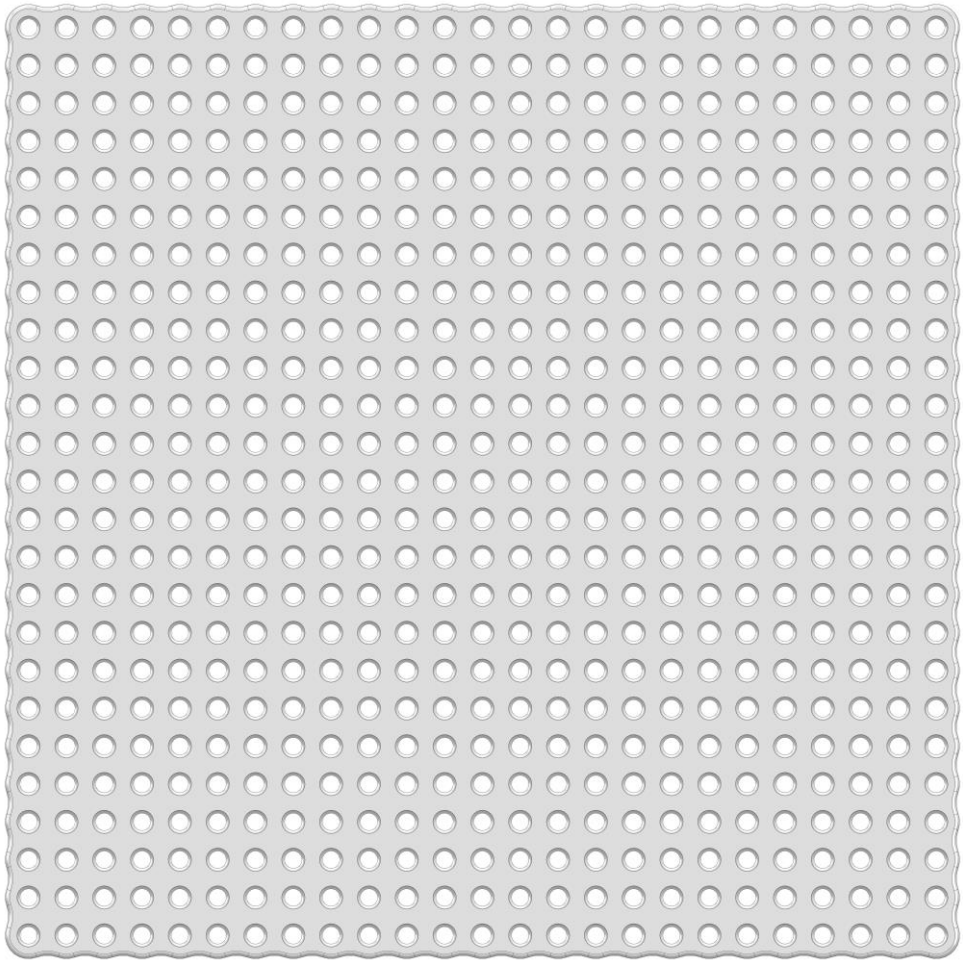
Scale: 1/1
REF: V52-311-15-04
Dimensions: 11 x 249 mm
Thickness: 1.5 mm



Scale: 1/1
REF: V52-310-50-04
Dimensions: 51 x 51 mm
Thickness: 1 mm



Scale: 1/1
REF: V52-306-52-04
Dimensions: 51 X 51 mm
Thickness: 0.6 mm



Scale: 1/1
REF: V52-310-13-04
Dimensions: 126 x126 mm
Thickness: 1 mm

Resorb Pins

2.1 mm Ø Pin

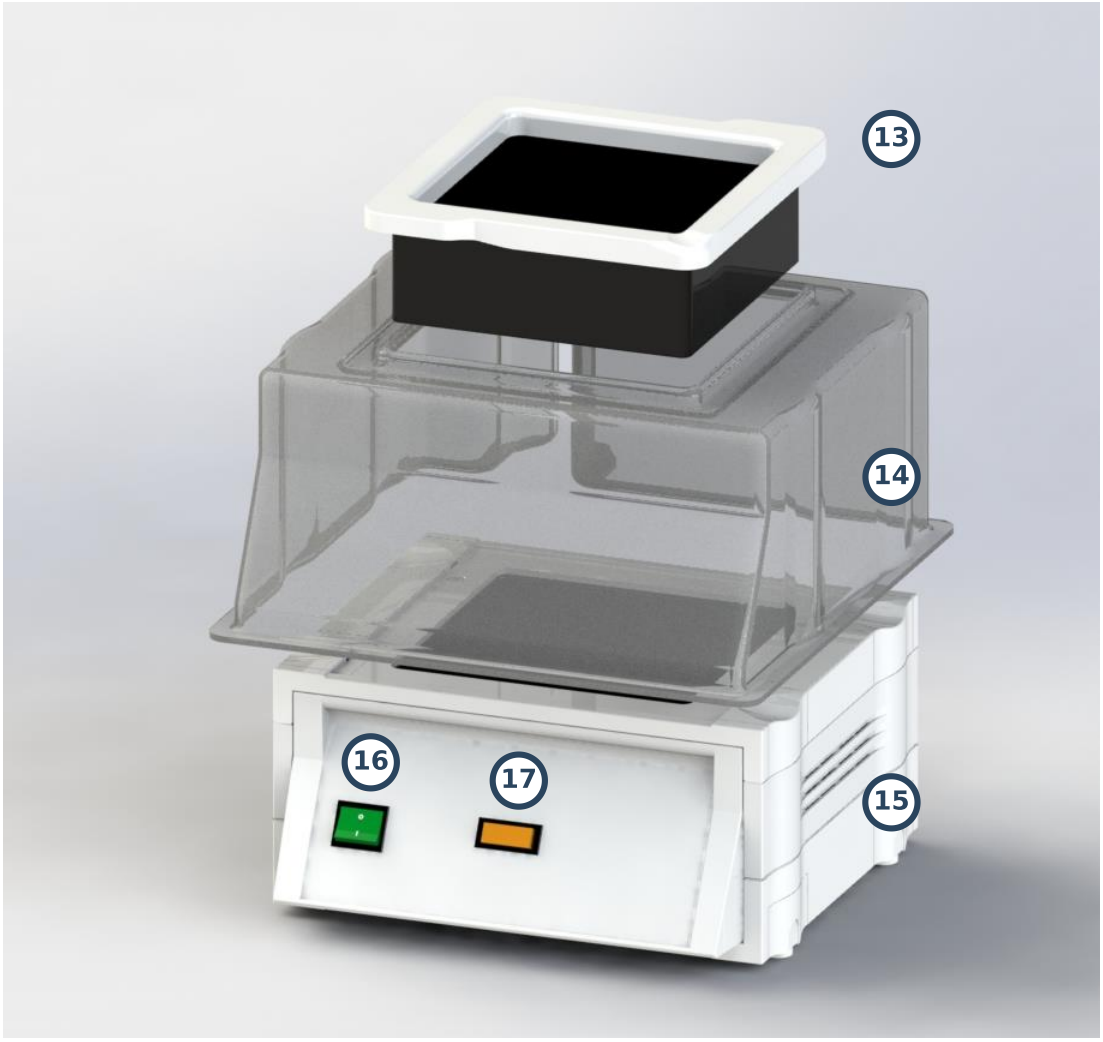
Pin Length	REF Nr.	Quantity
4.0 mm	V52-521-54-04	5
5.0 mm	V52-521-55-04	5
7.0 mm	V52-521-57-04	5
9.0 mm	V52-521-59-04	5

SYSTEM DESCRIPTION

BoneWelder® Vet

1. BoneWelder® Vet Ultrasonic Device
2. Connection sockets (2x) for handpiece
3. Display
4. Switch On/Standby
5. Power cord socket (IEC-C14)
6. Fuse socket
7. Connecting cable (handpiece)
8. Handpiece
9. Activation LED (blue)
10. Pushbutton handactivation
11. Sonotrode
12. Open-end wrench for sonotrodes

Water Bath



13 Water container with frame

14 Cover hood

15 Water bath thermal unit

16 Water bath on-off switch

17 Orange thermo control “OK” light

PREPARATION AND CLEANING

The warranty regarding handpiece cleaning and sterilization is limited to 250 reprocessing and sterilization cycles. Once the maximum number of cycles has been reached, a corresponding message will be displayed.

NOTICE

All components of the BoneWelder® Vet System are delivered non-sterile.

Preparation for Cleaning

- Remove visible contamination directly after use but latest within 2 hours after use.
- Remove sonotrode from the handpiece.
- Fully disconnect the BoneWelder® Vet from the power supply in all poles.
- Turn off and fully disconnect the water bath heating unit from the power supply in all poles.
- Disconnect the handpiece from the ultrasonic device.
- Brush down the handpiece with a soft nylon brush under running water until it appears visually clean.
- Generally, use aldehyde-free, non-fixating cleaning and disinfection agents for manual as well as machine cleaning and disinfection.

Cleaning / Disinfection

Sonotrode, Pre-Cleaning by Hand

- Rinse sonotrode under running water for 1 min (water temperature < 35°C (< 95°F)).
- Flush blind hole three times with 5 ml of water using a syringe and cannula attachment.
- Immerse sonotrode into a cleaning solution (e.g. 0.5% neodisher MediClean) for 10 min. Ensure that the cleaning solution also enters the blind hole, and that the sonotrode does not come into contact with other sonotrodes or instruments.
- Remove visible contamination using a soft plastic brush.
- Intensively clean the blind hole using a conical interdental brush.
- Then rinse the sonotrode again under running water for one minute and flush the blind hole three times with 5 ml of water using a syringe and cannula attachment.

Sonotrode, by Machine

- After manual pre-cleaning, machine-clean and disinfect the sonotrode. Thermal disinfection is carried out at 90°C (194°F) for 5 minutes (e.g. with cleaner neodisher MediClean).
- Store the sonotrode in a small tray basket during machine cleaning/disinfection.

The drying process is carried out at 125°C (257°F). If necessary, subsequent manual drying of the blind hole is carried out using filtered, oil-free compressed air.

Handpiece, by Machine

- The handpiece of the BoneWelder® Vet is suitable for machine processing/thermal disinfection. It can be processed with the same programs that have been released for surgical instruments and implants. As regards to cleaning, be sure to follow the instructions provided by the manufacturer of your washer disinfector(s) (W/D) as well as those provided by the manufacturers of the cleaners and disinfectants used. The process (including loading) must guarantee sufficient removal of residues.
- Only mildly alkaline cleaning agents are authorized for use.
- Coil the connecting cable with handpiece in a circle having a diameter of at least 20 cm.
- Arrange the handpiece so inside the washer disinfector that the sonotrode side of the handpiece points downward. This prevents any accumulation of rinsing liquid in the handpiece.

Handpiece, by Hand

Clean the handpiece with a clean, lint-free cloth moistened with a commercially available disinfectant approved for use with instruments and based on ethanol (50/50) or isopropanol (70/30) (e.g. neodisher® MediClean by Dr. Weigert).

NOTICE

Risk of damage due to improper handling!

- The handpiece must not be immersed in a disinfecting or ultrasonic bath.
- Do not use any acetone-containing disinfectants for cleaning and disinfecting the handpiece.

Ultrasonic Device, by Hand

Clean the BoneWelder® Vet ultrasonic unit with a clean, lint-free cloth moistened with a commercially available disinfectant approved for surface disinfection and based on ethanol or methanol (e.g. neoform MED AF by Dr. Weigert).

WARNING

Danger of death by electric shock!

- Ingress of liquids into the device must be avoided under any circumstances!
- Before cleaning or disinfecting the BoneWelder® Vet, the device must be fully disconnected from the power supply in all poles.
- Should moisture have penetrated into the device, dry it after disconnecting it from the supply.

Water Bath Device, by Hand

- All externally accessible parts of the heating unit can be cleaned with neutral, tenside based cleaning agents (mild liquid detergents for manual use, neutral detergents).
- For wiping disinfection, neutral disinfectants (e.g. surface disinfectants) based on aldehydes, quaternary ammonium compounds, etc., can be used.
- As regards surface cleaning and disinfection, follow the procedure recommended by the hygiene board of your hospital or use another nationally recognized and approved method.
- Make sure that all disinfectant residues have been carefully removed before putting the device into service.

WARNING

Danger of death by electric shock!

If liquid is inadvertently spilled over the heating plate of the heating unit or over the electrical connections, there will be a risk of electric shock.

- Before cleaning or disinfecting the water bath, the device must be fully disconnected from the power supply in all poles.
- Ingress of liquids into the water bath heating unit must be avoided under any circumstances! This also applies when using sprays for cleaning and disinfection.
- Never pour liquid directly onto the heating plate of the heating unit.
- Should liquid happen to penetrate into the device (outside the water container), the water bath must be withdrawn from service at once.

NOTICE

Risk of damage due to improper handling!

- Do not use any acetone-containing disinfectants for cleaning and disinfecting the water bath cover or heating unit.
- Never use abrasives, disinfectants or solvents that could scratch the housing or damage the device in any other way.

Use of disinfectants containing alcohol

Be sure to observe the contact times, concentrations and application guidelines specified by the manufacturer of the product.

To give you a guideline for the use of disinfectants, we have found after testing that the following substances contained in the products in the concentrations shown below are safe.

The values indicated are maximum values and must not be exceeded!

- 96% ethanol = max. 40 g per 100 g disinfectant
- Propanol (propyl alcohol) = max. 35 g per 100 g disinfectant
- 25% glutaraldehyde = max. 75 mg per 100 g disinfectant
- Ethyl hexanol = max. 10 mg per 100 g disinfectant
- Formaldehyde solution = max. 10 mg per 100 g disinfectant
- Glyoxal = max. 165 mg per 100 g disinfectant

The safe use of products with a different composition is not warranted.

Be sure to observe the instructions provided by the manufacturers of both your washer disinfector(s) (W/D) and the treatment agents used.

To prevent spotting, stains and other deposits or surface changes, we recommend using fully demineralized water for the final rinse.

Water Bath Cover & Water Container, by Machine

The cover and the water container receptacle can be processed by machine with the same validated programs used for anodized aluminum. The cover is heat-resistant and can thus be thermally disinfected by machine.

To ensure the long-term service and performance of the water bath, careful maintenance is required.

Drill Bits, by Machine

We recommend a manual pre-cleaning with non-fixating cleaning and disinfecting detergents already at the operating theatre.

Drills are suitable for machine processing/thermal disinfection. They can be processed with the same programs that have been released for surgical instruments and implants. As regards cleaning, be sure to follow the instructions provided by the manufacturer of your washer disinfector(s) (W/D) as well as those provided by the manufacturers of the cleaners and disinfectants used. The process (including loading) must guarantee sufficient removal of residues.

Sterilization

The following parts of the BoneWelder® Vet System are sterilizable:

- Handpiece
- Sonotrodes
- Wrench
- Water bath cover
- Water bath water container with white plastic frame
- Drill Bits

Improper sterilization and non-sterile handling can lead to serious health hazards for patients.

Sterilization must be carried out according to a validated steam sterilization process, for example in a sterilizer complying with EN 285:2009 and ANSI/AAMI ST79, validated in accordance with ISO 17665 1:2006.

The fractionated (pulsing) vacuum method requires sterilization at 134°C (273°F)/2 bar with a minimum holding time of 5 min.

ANSI/AAMI ST79 recommends a minimum cycle time of 4 min at 132°C (270°F) for dynamic air removal steam sterilization cycles. Please follow the instructions of the user manual of your steam sterilizer.

We recommend using a tray basket or, for small parts, a tray basket with cover.

For each use of the BoneWelder® Vet ultrasonic device a wrench, sonotrodes and handpiece in sterile packaging is required.

NOTICE

Risk of damage due to improper handling!

- Do not sterilize the water bath heating unit, BoneWelder® Vet ultrasonic unit

Visual Check

- Check visually that all components used are free of defects.
- Damaged components must not be used and need to be replaced.

NOTICE

The tip of the sonotrode must not show any signs of mechanical damage. It must not be bent or rammed (typical damage after the handpiece has fallen down).

SET-UP

BoneWelder® Vet: Set-up Steps

1. Connect the connecting cable (7) of the handpiece (8) to the connecting socket (2) of the BoneWelder® Vet ultrasonic device (1). The ultrasonic unit features 2 connecting sockets for handpieces (2).
2. Screw the sonotrode (11) manually in place on the handpiece and use the open-end wrench (12) to ensure secure attachment (torque: max. 0.3 Nm).
3. Plug the power cord into the power cord socket (5) of the ultrasonic device and then into a mains socket-outlet with ground contact. As soon as the unit has been connected to the power supply, it is automatically set to standby mode. Therefore, full disconnection is possible only by pulling the plug of the mains cable out of the socket-outlet.
4. Turning on the device with the On/Standby switch (4)

BoneWelder® Vet: Self-Test

CAUTION

Danger of burns!

If the sonotrode is allowed to make skin contact during the functional test, this can cause burns. Avoid contact with skin, eyes, etc.!

5. The handpiece (if connected) is ready for a self-test indicated by:

a. the flashing activation LED (9) on the handpiece (8)

b. and the following symbol flashing on the corresponding side of the display (3):

6. The self-test for this handpiece will be started upon operating the hand activation pushbutton (10). The message “Active” is shown on the display (3) and an acoustic signal appears. Hold down the pushbutton (10) until the display (3) message changes from “Active” to “Cooling”, the checkmark ✓ appears, the activation LED stops flashing and the acoustic signal changes.

NOTE: Be sure to keep the tip of the sonotrode out of contact with objects during this process. If the test is successful, the device is automatically set to working mode.

BoneWelder® Vet: Ready

- Checkmark ✓ displayed (checkmark right or left, depending on which handpiece has been tested): Means “no malfunction detected”.

- Generator-related error messages are displayed in text form, see section TOUBLESHOOTING.

Water Bath: Set-up Steps

1. The water bath must be set up and operated in the sterile area of the operating environment. After plugging the mains cable into the device and then into a mains socket-outlet with ground contact, the water bath can be turned on with the on-off switch (16).
2. Then, cover the thermal unit (15) with the sterile cover hood (14). From this point, only sterile persons are permitted to operate the device.
3. Place the sterile water container with the frame (13) into the sterile cover hood (14).
4. The water container can then be filled up with sterile fluid (e. g. aqua destilata, physiologic saline) until the water level reaches the marking (approx. 500 ml).
5. The water bath is ready for action, when the orange thermo control display „OK“ (17) lights up. Depending on the amount of liquid in the water container, heating time of the device is approx. 20 minutes.

NOTICE

Risk of damaging the implants!

Some of the sterile water bath liquid will evaporate during operation. To keep temperature variations as low as possible, we recommend refilling in small quantities.

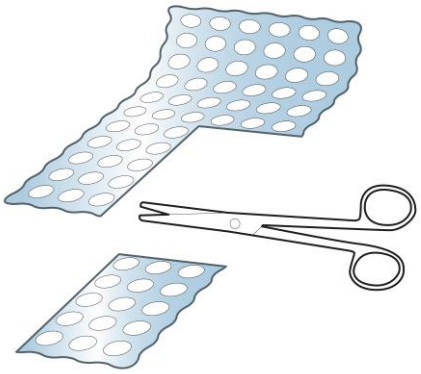
SURGICAL PROCEDURE

Preoperative Planning

X-ray images or a CT scan should be used to identify fractures and plan reduction and implant choice.

Plate Selection

For fixation of the segments, plates and larger meshes can be used, which can be cut to the required size with scissors if necessary. The various implant types must be cut in soft condition after having been warmed.



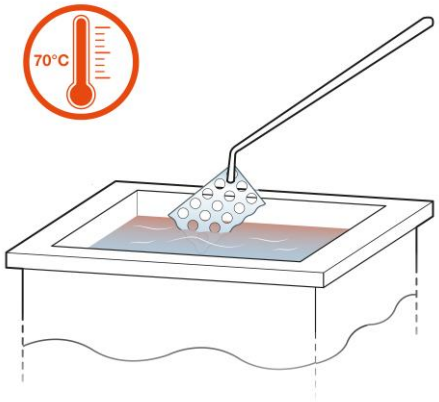
We recommend warming the implants in the prewarmed liquid of the water bath just before they are used. After only a few seconds the implant can be shaped, as a result of which it can easily be adapted to the surface of the bone segment.

Fracture Reduction and Plate Contouring

First, the bone fragments need to be mobilized into their proper position. Then the plate or mesh can be shaped to the bone with one of the following two methods:

Option 1: A template for the chosen implant is placed across the fracture area and bent to fit the bone surface. Then, the template is removed from the patient. The appropriate Resorb plate is preheated in the water bath. To ensure uniform heating of the implant, use a pair of forceps to move the implant to and from in the liquid. After only a few seconds the Resorb plate is formable and can be adapted to the shape of the template.

Option 2: The Resorb plate or mesh is warmed in the preheated water of the water bath. To ensure uniform heating of the implant, use a pair of forceps to move the implant to and from in the liquid. After only a few seconds the Resorb plate is formable and can be shaped to the surface of the bone. This can be performed either manually or directly on the patient's bone if the location permits.

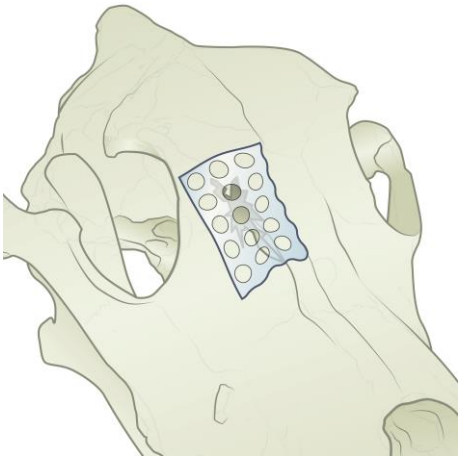


NOTICE

- Resorb implants can be reheated up to 3 times during the modeling process.
- Bending Resorb implants after they have cooled down can lead to fracture.
- Care must be taken that the plate holes to be used for fixation will not deform in the shaping process
- Implants should be heated up and shaped only immediately prior to use. It is not recommended to leave the implant immersed in the water bath for an extended period of time.

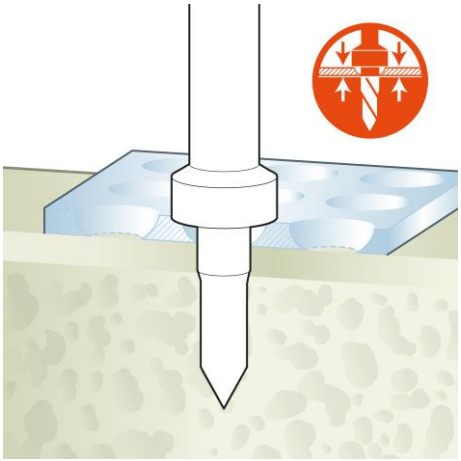
Implant Placement

The material cools down quite fast and the implant keeps its shape. The plate is then placed across the fracture area. It fits to the bone surface perfectly.



Pre-Drilling

After proper placement of the plate according to the indication, use the drill bit to create the pilot hole for the pin. The pin that is closest to the fracture should be inserted first. The correct drill depth is reached when the drill mechanically stops at the plate surface, which is ensured by the integrated drill stop.

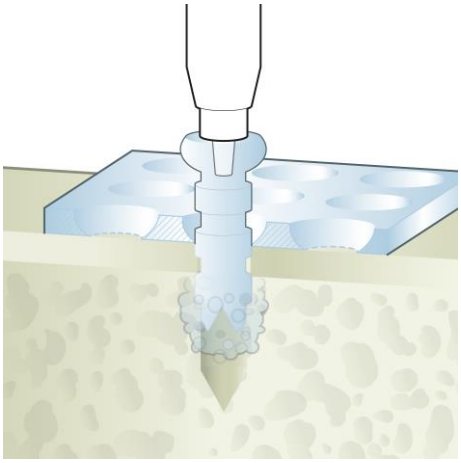


NOTICE

- It is important for the for the BoneWelding process that the hole is drilled until the drill stop is reached.
- Surgeon is free to choose drill depth on a case by case basis. However, drill depth should be at least the length of the pin. If the pin is longer, either a shorter pin or a longer drill may be used. Alternatively, pins can be cut to desired length.

Positioning and Implantation

1) The pin is removed from its packaging under aseptic conditions and mounted onto the handpiece tip. The pin holds onto the handpiece tip in the non-actuated state by means of a taper joint. The implant should be pushed onto the handpiece tip as far as the limit stop.
2) Seat the pin into the top of the pilot hole with slight pressure (approx. 10 N).
3) Actuate the pushbutton on the handpiece and insert the pin into the hole by light, manual axial pressure and concurrent application of the ultrasonic energy.
4) Maintain the axial force during insertion and do not release the pushbutton until the implant is fully advanced into the bone and plate.
5) Stop the ultrasonic process (release the pushbutton) as soon as the implant is successfully inserted (i.e. when it is flush with the plate surface).



NOTICE

- The insertion process shall not take longer than 2-3 sec. between actuating and releasing the pushbutton.
- The direction of the insertion has to exactly follow the pre-drilled hole.

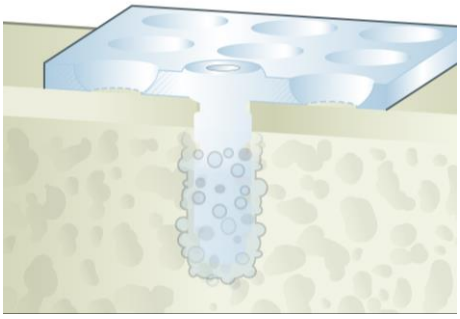
Solidification

Immediately after insertion, the handpiece tip must be held in place for a minimum of 3 seconds to allow the implant interface to cool down and solidify. After solidification of the Resorb pin, the handpiece tip can be removed from the pin with a light twisting movement.

NOTICE

If a pin is not correctly inserted…

- An additional pin can be inserted in an adjacent hole.
- Or it may be replaced by drilling out the pin and inserting a new pin in its place.

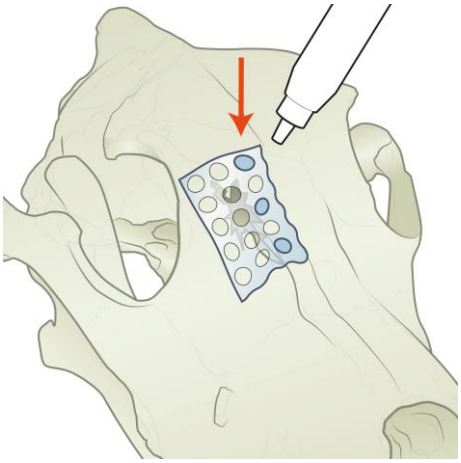


Insertion of Further Pins

Consecutive pins are inserted as before (following steps from Predrilling to Solidification) until all pins have been inserted onto the desired bone fragment. If fracture reduction is necessary, it is recommended to start with the unstable bone fragment when possible.

NOTICE

- It is recommended to insert at least 3 pins per fragment. The more pins that are used the stronger the fixation.

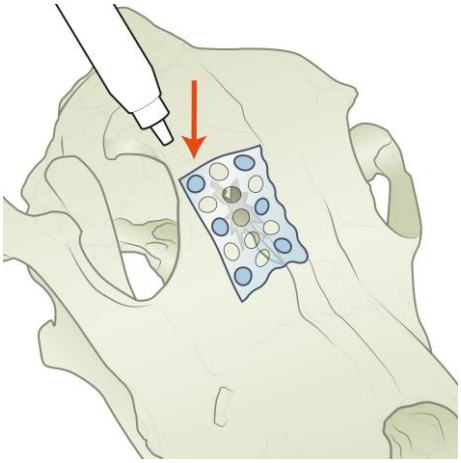


Reduction & Insertion of Pins into Remaining Bone Fragments

If the Resorb Pin and Plate system is being used to reconstruct and stabilize a fracture, once all pins have been inserted into the initial fragment, the fracture is once again reduced. Then pins are inserted as before (following steps from Predrilling to Solidification) into the remaining fragments until all desired pins have been inserted.

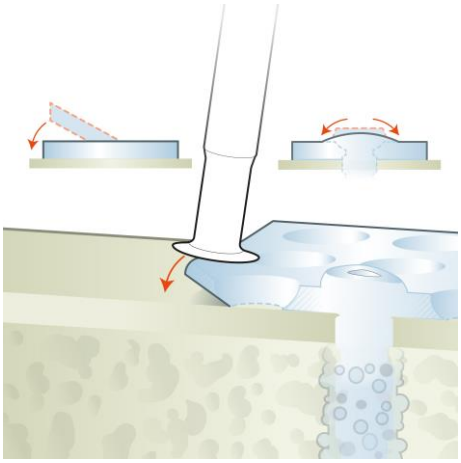
If necessary, the plate contours can be smoothed using the smoothing sonotrode.

Finally, after the plate is inserted successfully, the wound can be closed.



Smoothing (Optional)

For smoothing the contours, the smoothing sonotrode may be used as follows: Bring the sonotrode in contact with the plate, press the activation switch until the material liquefies, release the activation switch, and finally release the sonotrode.



Postoperative Treatment

Postoperative follow up, postoperative care and the duration of treatment depends on the patient's condition and are determined by the surgeon.

NOTICE

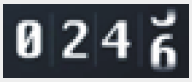
Implants are radiolucent and are not visible in x-ray or CT images.

TROUBLESHOOTING

Display

Message displayed	Cause	Remedy
1. Power supply error 2. Temperature meter defective 3. Generator overtemperature 4. Internal fault	Generator error or fault.	Disconnect the unit from the power supply, and then reconnect it. If the problem persists, return unit to manufacturer.
Ultrasound trouble	Generator problem (during welding process).	Acknowledge by pressing the On/Standby switch. If the problem persists, disconnect the unit from the supply.
1. Relieve pressure on handpiece! 2. Press On/Standby!	System overload (sonotrode tip stuck/jammed, excessive pressure).	Acknowledge by pressing the On/Standby switch, then clear the handpiece problem and operate the activation pushbutton again
Welding time	Maximum welding time of 60 s exceeded.	After a cooling-down time of 5 s, the unit is ready for use again.
1. Tighten sonotrode! 2. Press On/Standby!	Sonotrode seated too loosely.	Tighten sonotrode with wrench and acknowledge error.
Internal fault	Monitoring of all important program modules.	Disconnect the unit from the power supply, and then reconnect it. If the problem persists, return unit to manufacturer.

Handpiece Statuses

Message displayed	Cause	Remedy
X	No handpiece connected.	Connect handpiece.
	Temperature values measured on handpiece not plausible.	Replace handpiece.
	Max. temperature reached on handpiece.	Message disappears automatically as soon as the temperature drops below 70°C (158°F). Alternative: Replace handpiece.
	The handpiece cycle counter pictogram appears during self-test. (240 ≤cycle counter <250)	Message disappears automatically once the self-test has been completed.
	The flashing handpiece cycle counter pictogram appears during self-test. (cycle counter ≥250)	Following completion of the self-test, the message must be acknowledged with the On/Standby switch.
	Handpiece pushbutton defective.	Replace handpiece.

Potential Malfunctions

Trouble	Cause	Identification	Remedy
"Screeching" noises heard during the self-test or during use of the BoneWelder® Vet system.	Residual moisture or condensate on the contact points.	Clearly audible.	This does not compromise the proper functioning of the BoneWelder® Vet system. Noise will subside automatically during normal use of the device. It may be helpful to use longer drying times after sterilization.
Sonotrode tip will not detach from Resorb pins.	Bent or rammed sonotrode tip.	Visual check.	Replace sonotrode tip.
Resorb pins fails to attach to sonotrode tip.			
Sonotrode tip sticks to Resorb pins.	Ultrasound applied too long.	Pin is generally deformed, sonotrode cannot be removed residue-free.	Observe required cooling-down time. Rotate the sonotrode axially (twist) to break the connection, see section.
	Bent sonotrode tip.	Visual check.	Replace sonotrode tip.
Handpiece indicator does not light up during activation.	LED life exceeded.	Visual check.	Replace the handpiece. A defective indicator on the handpiece has no adverse effect on ultrasound application.
Display dark.	No power supply.	Visual check.	Connect the system to the power supply and operate the On/Standby switch.
	Mains fuse defective.	Electrical test.	Replace mains fuse.
	Unit not switched on.	Visual check.	Press On/Standby switch until display lights up.
Pin insertion interrupted	Sonotrode activation stopped before insertion complete	Visual check	Insert pin in adjacent hole Or Drill out pin and insert new pin

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