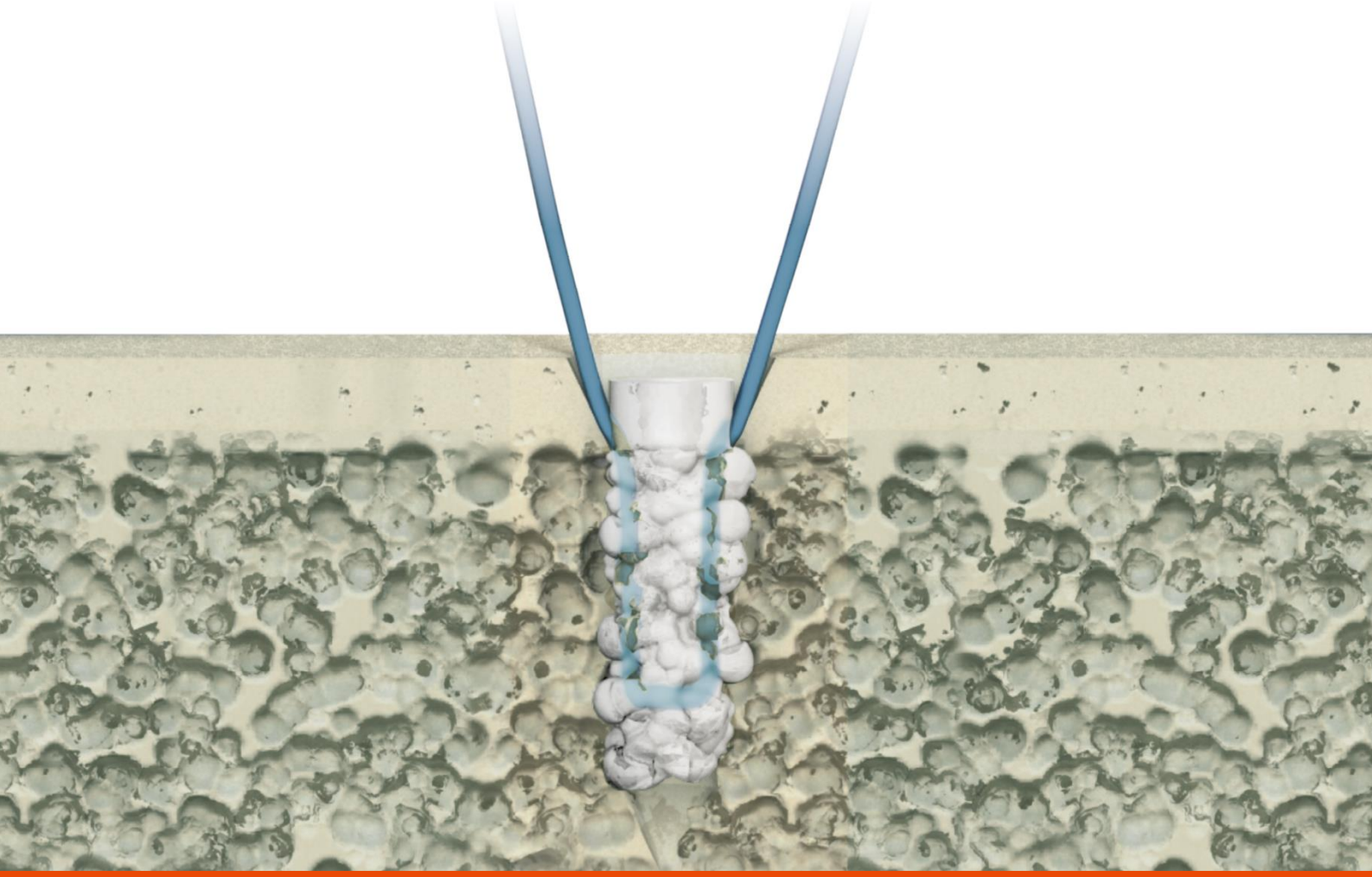
Vet Welding

A Company of WoodWelding SA using BoneWelding® Technology



Surgical Technique

Weldix® 2.3mm Anchor

The revolutionary Ultrasound - Micro - Suture Anchor

Weldix® 2.3mm Anchor

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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.

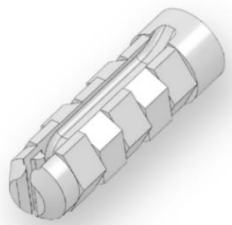
INTRODUCTION

BoneWelding® Fixation

The Weldix® 2.3mm Anchor is a fully bioresorbable implant designed for soft tissue reattachment to bone by means of suture material. The BoneWelding® technology employs ultrasonic energy to liquefy the polymeric components of the Weldix® 2.3mm Anchor 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.

Weldix® 2.3 mm Anchor

The Weldix® 2.3mm Anchor is made of biocompatible and fully bioresorbable Polylactide (PLDLLA 70:30). The "in-vivo" degradation of the Weldix® 2.3mm Anchor is based on the natural physiological process of hydrolysis, which results in a complete metabolization of the polymer into H2O and CO2. The Anchor is 2.3 mm in diameter and 7.2 mm in length and requires a drill hole of 1.8 mm in diameter and 6 mm in depth.

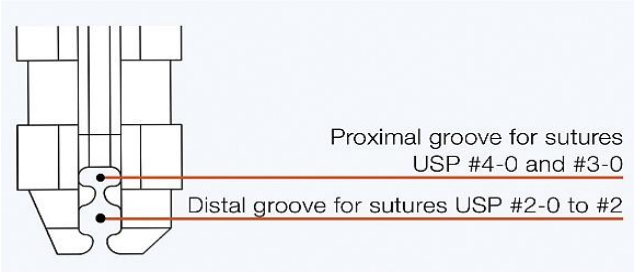


Weldix® 2.3mm Anchors are supplied as packs of one.

Suture Compatibility

The Weldix® 2.3mm Anchor can be combined using the suture types listed in the subsequent table. The sutures are not included in the package and are sold separately.

The Weldix® 2.3mm Anchor features two transverse, apical "click-in" grooves to position the suture before implantation.



Suture Type	Suture Size
Monofilament, resorbable	USP #2/0 to #2
Polyglyconate (copolymer of glycolic acid /trimethylene carbonate copolymer)	
Monofilament, non-resorbable	USP #2/0 to #1
Polypropylene Polyamide 6 and 6.6	
Multifilament, non-resorbable	USP #3/0 to #2
Polyester (polyethylene terephthalate)	
UHMWPE/polyester	USP #4/0 to #2

INDICATIONS / CONTRAINDICATIONS

Indications

The Weldix® Anchor System is intended to be used for suture or tissue fixation in several procedures in cats and dogs. The Weldix® 2.3mm Anchor is designed only to be inserted with the BoneWelder® Vet system.
Indications include:

- Hip luxation (capsule repair, ligamentum teres femoris repair)
- Tarsal collateral ligament reconstruction
- Reattachment of achilles tendon
- CCL extracapsular fixation
- Knee collateral ligament reconstruction
- Elbow / Shoulder luxation repair

WARNING: Do not re-use or re-sterilize the anchor! The re-use of the anchor is not possible. By being inserted with the BoneWelder® Vet equipment the Weldix® 2.3mm Anchor liquefies and is 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 Weldix® 2.3mm Anchor.

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:

- Use in quantitatively and/or qualitatively inadequate bone tissue.
- Implantation in bone areas having minimal or no cancellous bone structure. The BoneWelding® process requires cancellous bone for implant integration. In absence of cancellous bone do not implant the device.
- Active or latent soft tissue and/or skin infections at the site of the operation.
- Local inflammation of any origin at the repair site.
- 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.
- Known allergies and/or reactions to synthetic materials/bioabsorbable materials.
- Factors which may also impair the success of operations include:
    - Incorrect implantation technique.
    - Usage of unsuitable suture material.
    - Inadequate (too little, too short) postoperative load reduction and immobilization for healing.

The Weldix® 2.3mm Anchor (polymer implant) is safe for use in magnetic resonance (MR) environments.

BoneWelding® EQUIPMENT

BoneWelder® Vet Ultrasonic Device and Handpiece

The ultrasonic energy for the implantation of the Weldix® 2.3mm Anchor is provided by the BoneWelder® Vet ultrasound generator and applied via the attached handpiece.

Sonotrode

The sonotrode (handpiece tip) is mounted on the handpiece. It transmits the ultrasonic energy to the Weldix® 2.3mm Anchor.

Wrench

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.

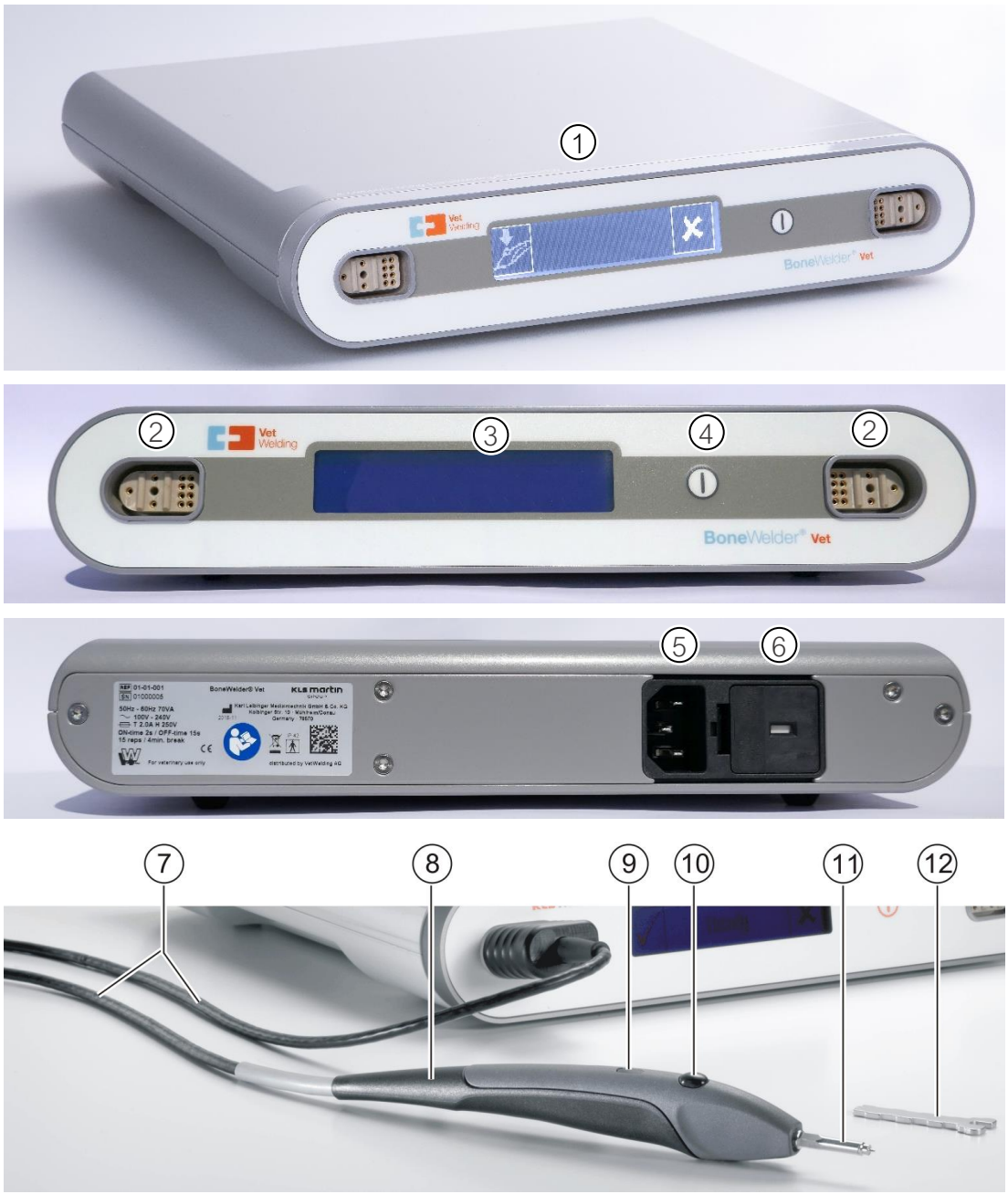
Drill Bit

The drill bit (with or without drill stop) is sized specifically for the Weldix® 2.3mm Anchor. It helps ensure safe and easy handling of the implants and correct implantation.

All components of the Weldix® 2.3mm Anchor are developed and manufactured in cooperation with specialized partners.

PRODUCT NAME	DESCRIPTION	REF NO.
Weldix® 2.3mm Anchor	Implant	02-01-001
DEMO Weldix® 2.3mm Anchor, 10pcs (not for clinical use)	DEMO Implant	02-01-901
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
BoneWelder® Vet Wrench	Instrument	01-03-001
BoneWelder® Vet Conical 2mm Sonotrode	Instrument	01-04-001
Drill Bit Weldix® 2.3mm Anchor with Drill Stop	Instrument	01-05-001
Drill Bit Weldix® 2.3mm Anchor without Drill Stop	Instrument	01-05-002

SYSTEM DESCRIPTION



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

PREPARATION AND SET-UP

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.

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.
- 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.
- Then immerse sonotrode into a cleaning solution (e.g. 0.5% neodisher MediClean) for 10 min. Ensure that the cleaning solution also penetrates 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.
- Thoroughly 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 Hand

Wipe down 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).

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 that the sonotrode side of the handpiece points downward while inside the washer disinfector. This prevents any accumulation of rinsing liquid in the handpiece.

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.

Sterilization (of Handpiece, Sonotrode and Wrench)

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, sonotrode and handpiece in sterile packaging is required.

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 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. Turn on the device with the On/Standby switch (4)

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 is heard. 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.

Ready

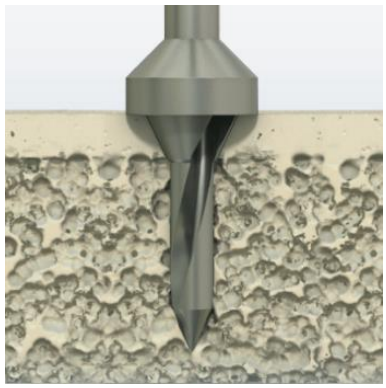
- Checkmark ✓ displayed (checkmark right or left, depending on which handpiece has been tested): Means “no malfunction detected”.

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

SURGICAL PROCEDURE

Pre-Drilling

After identification of the proper location of the Weldix® 2.3mm Anchor according to the indication, use the twist drill to create the pilot hole. Drill geometry is adapted specifically to the Weldix® Anchor design.



The correct drill depth is reached when the drill mechanically stops at the bone surface, which is ensured by the integrated drill stop.

Twist drills are designed and indicated for use at low speed. Operation at higher speeds may result in failure of the twist drill and potential injury to the user, patient, and third parties.

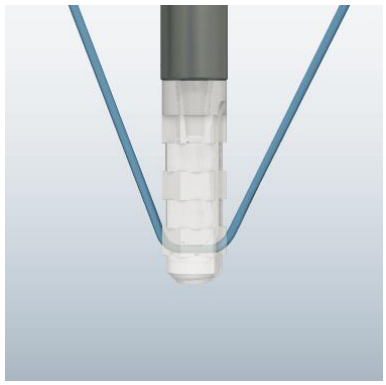
Anchor Preparation

The Weldix® 2.3mm Anchor is removed from its packaging under aseptic conditions and mounted onto the handpiece tip. The Weldix® 2.3mm Anchor grips 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.

NOTICE
The axial alignment and fit of the Weldix® 2.3mm Anchor is crucial for the fusion process. Ensure that there is no gap between the Weldix® 2.3mm Anchor and the handpiece tip as the presence of the gap compromises the ultrasound transmission to the Anchor.

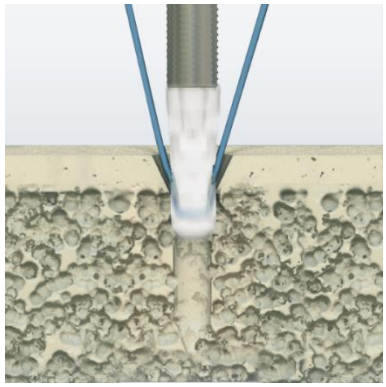
Suture Loading

The Weldix® 2.3mm Anchor features two transverse apical “click-in” grooves to position the suture before implantation. The first, larger, of the apical grooves is used to position sutures of diameters USP #2-0, #0 and #2, the second, smaller groove holds suture diameters USP #4-0 and #3-0.



The product must be used with sutures according to the list in section, “Suture Compatibility”.

Positioning and Implantation



1) Align the Weldix® 2.3mm Anchor at the countersink of the pre-drilled hole with slight pressure.

2) Exert a small axial compression force (approx. 10 N) onto the Weldix® 2.3mm Anchor. Axial force before starting the ultrasound process is necessary to ensure a successful implantation.

3) During the insertion procedure, the sutures must NOT be loaded / kept under tension

4) Press the pushbutton on the handpiece and insert the Weldix® 2.3mm Anchor into the hole by light, manual axial pressure and concurrent application of the ultrasonic energy.

5) Maintain the axial force during insertion and do not release the pushbutton until the implant is fully advanced into the bone.

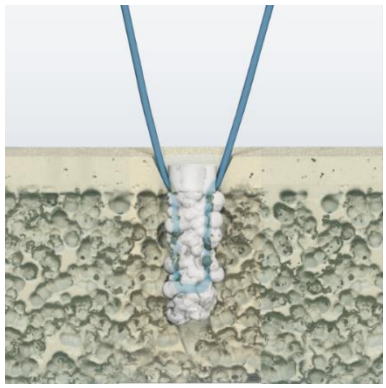
6) Stop the ultrasonic process (release the pushbutton) as soon as the implant is successfully inserted (i.e. when it is flush with the bone surface) to avoid excessive melting at the Anchor-handpiece tip interface.

7) The insertion process shall not take longer than 2-3 sec. between pressing and releasing the pushbutton.

NOTICE

- The direction of the insertion must exactly follow the pre-drilled hole.
- If the Weldix® 2.3mm Anchor is not fully inserted the implant performance cannot be ensured.
- Activation of the ultrasound with assembled Weldix® 2.3mm Anchor on the handpiece before the anchor is positioned requires replacement of the implant.

Solidification



Immediately after the insertion, the handpiece tip must be held in place for a minimum of 5 seconds to allow the implant interface to cool down and solidify. After solidification of the Weldix® 2.3mm Anchor, the handpiece tip can be removed from the Weldix® Anchor with a light twisting movement.

At that time, primary stability of the implant by mechanical interdigitation is achieved. The suture anchor can be subjected to loads immediately. Verify the mechanical fixation of the Weldix® 2.3mm Anchor in the bone intraoperatively by pulling the suture strands carefully.

NOTICE

If the anchor is not fully inserted, the anchor can either be removed by pulling it out manually (if only little anchorage has been achieved) or by drilling it out using the original drill bit. Care must be taken to drill in the same direction as the original hole to prevent enlargement. A new Weldix® 2.3mm Anchor or a different type of suture anchor requiring a drill hole of 1.8mm or larger can be placed in the same location.

Postoperative Treatment

The Weldix® 2.3mm Anchor can be loaded directly after surgery.

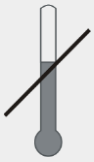
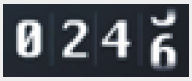
Postoperative follow up, postoperative care and the duration of treatment depends on the patient's condition and are determined by the surgeon.

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 **Weldix® Anchor.**	Bent or rammed sonotrode tip.	Visual check.	Replace sonotrode tip.
Weldix® Anchor fails to attach to sonotrode tip.			
Sonotrode tip sticks to Weldix® Anchor.	Ultrasound applied too long.	Anchor 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.

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