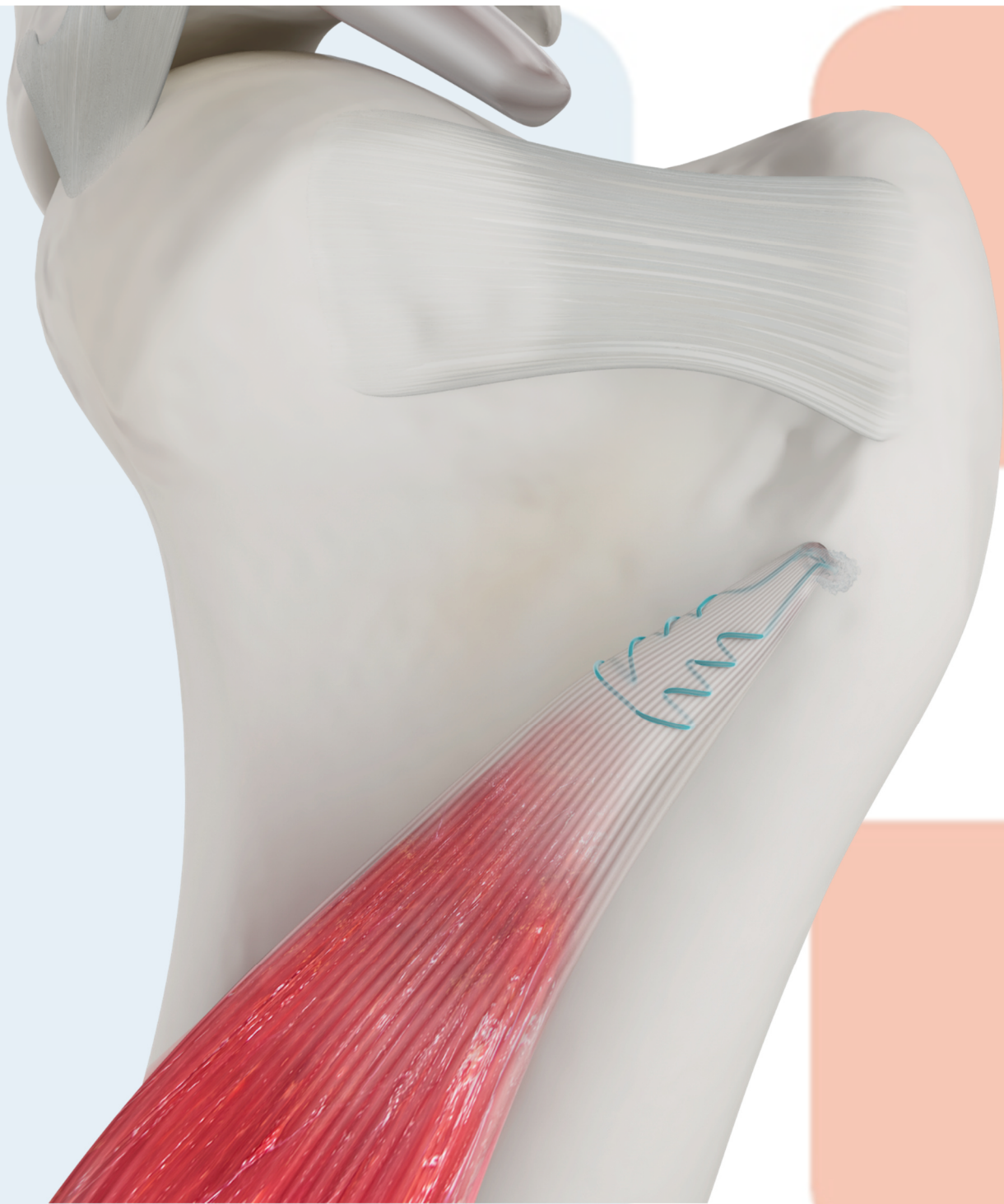


Biceps Tendon Reattachment using the Weldix® Suture Anchor

Surgical Technique







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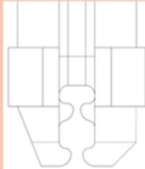
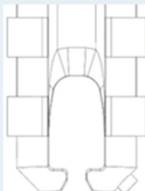
Overview

Weight Chart

| |  |  |  |  |
|---|---|---|--|---|
| Biceps Tendon Reattachment | 3-7 kg | 8-12 kg | 13-17 kg | 18-25 kg |
| Weldix® 2.3mm Anchor: multifilament sutures | 3-10 kg | | | |
| Weldix® 2.3mm Anchor: monofilament sutures | 3-10 kg | | | |
| Weldix® 3.0mm Anchor: multifilament sutures | 3-25 kg | | | |
| Weldix® 3.0mm Anchor: monofilament sutures | 3-25 kg | | | |

As with all orthopedic procedures, post operative care is of utmost importance and owner compliance an absolute necessity. Patient must be discouraged from running and jumping for at least six weeks. Walks on a static (not retractable) leash should be limited to 5 minutes for the first 2 weeks, gradually increasing in time. If the patient is excitable or unpredictable when out of the owner's direct supervision, crate rest is recommended.

Suture Compatibility

| Weldix [®] Anchor | Suture Type | Suture Size |
|--|---|----------------|
| <div>Weldix[®] 2.3mm</div> <div></div> | Monofilament, resorbable, single loaded | |
| | Polyglyconate (copolymer of glycolic acid & trimethylene carbonate) | USP #2/0 to #2 |
| | Monofilament, non-resorbable, single loaded | |
| | Polypropylene | USP #2/0 to #1 |
| | Polyamide 6 and 6.6 | |
| | Multifilament, non-resorbable, single loaded | |
| | Polyester (polyethylene terephthalate) | USP #3/0 to #2 |
| | UHMWPE/polyester | USP #4/0 to #1 |
| <div>Weldix[®] 3.0mm</div> <div></div> | Monofilament, non-resorbable, single loaded | |
| | Polypropylene | USP #2 to #5 |
| | Multifilament, non-resorbable, single loaded | |
| | Polyester (UHMWPE & polyethylene terephthalate) | USP #2 to #5 |
| | Polyester Tape | Up to 2 mm |

BoneWelder® Vet Equipment

BoneWelder® Vet



The BoneWelder® Vet is the heart of the BoneWelding® system. This small, user-friendly machine provides the energy to power the ultrasonic handpiece. Two handpiece plug-in option allows for dual user capabilities.

Handpiece



The handpiece to the BoneWelder® Vet is lightweight and ergonomically designed for comfort in handling. One-button technology allows for ease in use for transferring the ultrasonic power to the implant.

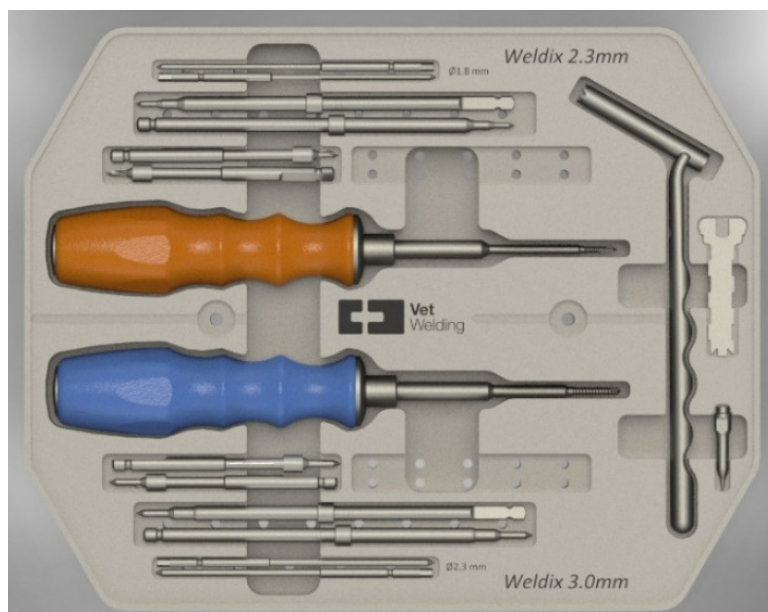
Wrench



The wrench allows 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. Fits to every sonotrode.

Weldix® Instrument Set

The Instrument Set provides all the instruments to implant the Weldix Anchors

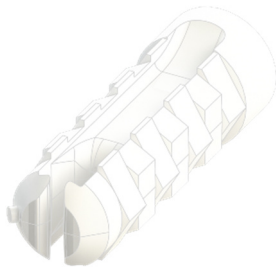


Weldix® Anchor



Weldix® 2.3 Anchor

| | |
|-----------------|----------------|
| Diameter | 2.3mm |
| Length | 7.2mm |
| Material | PLDLLA |
| Suture Sizes | USP #4-0 to #2 |
| Drill Footprint | 1.8mm x 8.5mm |



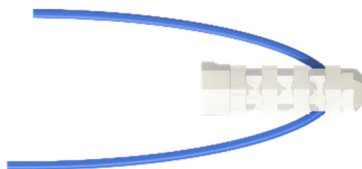
Weldix® 3.0 Anchor

| | |
|-----------------|---|
| Diameter | 3.0mm |
| Length | 8.7mm |
| Material | PLDLLA & β TCP (composite material) |
| Suture Sizes | USP #2 to #5 and up to 2mm Tapes |
| Drill Footprint | 2.3mm x 12mm |

The Weldix® polymer material is resorbed and substituted by natural bone within 12 – 24 months.

The Weldix® Anchors come without sutures, allowing the surgeon to use the suture of his preference (see suture compatibility table on page 3).

Suture



The Weldix® 2.3mm Anchor fits with a suture USP #4-0 up to #2. Both multi- and monofilament sutures are compatible with the Weldix® 2.3mm Anchor.

The Weldix® 3.0mm Anchor fits with a suture USP #2 up to #5 and up to 2mm Tapes. Both multi- and monofilament sutures are compatible with the Weldix® 3.0mm Anchor.

Sonotrode



The sonotrode is mounted on the handpiece. It transmits ultrasonic energy to the Weldix® Anchor. The sonotrode has a press-fit with the Weldix® Anchor preventing it from falling off.

The same sonotrode is used for both anchors.

Drill Bits



The drill bits are sized specifically for the Weldix® 2.3 and 3.0mm Anchors.
















There are two types:

A) Drill bits with a drill stop.

B) Drill bits to be used with a drill guide.

The Drill bits are available with an AO or a BOS quick coupling.

Drill Usage Guide

| | Weldix® 2.3mm Anchor | Weldix® 3.0mm Anchor |
|--|---|--|
| Drill Bit with Drill Stop | Drill Bit Weldix® 2.3mm Anchor with Drill Stop, AO quick coupling  | Drill Bit Weldix® 3.0mm Anchor with Drill Stop, AO quick coupling  |
| | Drill Bit Weldix® 2.3mm Anchor with Drill Stop, BOS quick coupling  | Drill Bit Weldix® 3.0mm Anchor with Drill Stop, BOS quick coupling  |
| Optionally available: Drill Guide with Stop  | Drill Bit Weldix® 2.3mm Anchor Drill Stop with Guide, AO quick coupling  | Drill Bit Weldix® 3.0mm Anchor Drill Stop with Guide, AO quick coupling  |
| | Drill Bit Weldix® 2.3mm Anchor Drill Stop with Guide, BOS quick coupling  | Drill Bit Weldix® 3.0mm Anchor Drill Stop with Guide, BOS quick coupling  |
| Tunnel Drill* | Drill Bit for Bone Tunnel 1.8mm, AO quick coupling  | Drill Bit for Bone Tunnel 2.3mm, AO quick coupling  |
| | Drill Bit for Bone Tunnel 1.8mm, BOS quick coupling  | Drill Bit for Bone Tunnel 2.3mm, BOS quick coupling  |
| Bone Tap** | 1.7mm Tap for Weldix® 2.3mm Anchor  | 2.9mm Tap for Weldix® 3.0mm Anchor  |

* Not for this indication

** The Bone Taps are used when there is no cancellous bone available in which the anchor can safely be attached (e.g. calcaneus of a cat).

Surgical Technique

1. Position Patient and Prepare Footprint

Place the patient in lateral recumbency with the affected limb exposed.

2. Identify Landmarks

Release the biceps tendon as proximal as possible and shorten it to a point where it approximates its original length with regards to a more distal insertion point mediodistal to the tuberculum majus.

3. Drilling the Hole

After identifying the landmarks, the pilot hole must be drilled. Use the corresponding drill bit for the Weldix® 2.3mm or 3.0mm Anchor to create the pilot hole. The correct drill depth is reached when the drill stop touches the bone surface.

Attention!

Drilling too deep or not deep enough can cause insufficient anchor stability or increased risk of suture damage. Particular attention has also to be paid not to enlarge the hole diameter during drilling, as this would compromise polymer intercalation into the bone.

4. Optional: Tapping the Hole

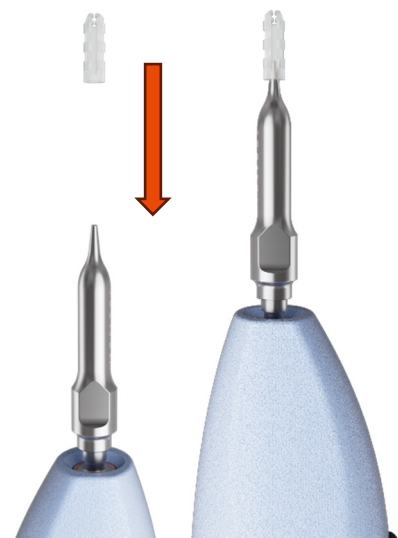
In case the hole is drilled in a place with no or minimal cancellous bone stock, it is recommended to tap the pilot hole with the corresponding Weldix® Tap. **Make sure to tap in the same direction as the drill hole to avoid enlarging the cavity.** Once resistance indicates the bottom of the pilot hole the tap can be screw out.

5. Weldix® Anchor Preparation

Remove the Weldix® Anchor from its packaging under aseptic conditions. Secure the Weldix® Anchor on the tip of the sonotrode and clinch an adequate suture into the dedicated suture grooves situated on the tip of the anchor.

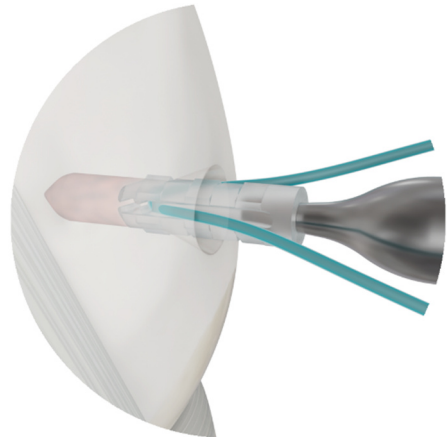
Attention!

- Verify that the Weldix® Anchor is firmly sitting on the sonotrode to ensure optimal ultrasound transmission to the Weldix® Anchor.
- Be careful not to actuate the sonotrode while mounting the anchor and clenching the suture.



6. Insertion of the Weldix® Anchor

- a) Position the Weldix® Anchor in the countersink of the pre-drilled pilot hole and make sure that it is aligned with the drill hole.
- b) Apply an axial compression force before starting the ultrasound process. The weight applied should be approximately **1 kg for the Weldix® 2.3mm Anchor** and **3kg for the Weldix® 3.0mm Anchor**.
- c) Press the pushbutton on the handpiece and insert the Weldix® Anchor by applying constant force until complete implantation (2-3 sec).
- d) Stop the implantation process by releasing the pushbutton as soon as the implant is flush with the bone surface.
- e) **The handpiece tip must be held in place for at least 5 seconds** to allow solidification of the polymer.
- f) Remove the handpiece tip from the Weldix® Anchor with a light twisting movement.
- g) Verify the mechanical fixation of the Weldix® Anchor in the bone intraoperatively by pulling concurrently on both suture strands.
- h) If you require a gliding suture in the anchor, pull the suture through the anchor with force to release it from the anchor.



Attention!

- During the insertion procedure, the suture must NOT be kept under tension.
- The direction of the insertion must exactly follow the pre-drilled hole.
- If the Weldix® Anchor is not fully inserted the implant performance cannot be ensured.

■ Tip

Holding the handpiece like a pen makes it easier to simultaneously press the button and apply a constant force to the handpiece.

6.1 Troubleshooting

| COMPLICATIONS | CAUSE | REMEDY |
|--|---|---|
| Weldix® Anchor pull-out with partial melting and backflow of polymer to the surface during insertion. | Very dense bone, which prevents the liquefied polymer from infiltrating into the surrounding cancellous bone. | Remove the anchor either by pulling it out or drilling it out using the same drill bit. Then carefully tap the pilot hole with the appositely designed Weldix® Tap. A new Weldix® Anchor can be placed in the tapped hole. |
| Weldix® Anchor pull-out with no or with only very limited melting of the surface. Anchor “falling into the hole” during insertion. | The pre-drilled and/or tapped cavity is enlarged. Insufficient bone-anchor contact during insertion. | The cavity cannot be re-used! Drill a new cavity and insert a new Weldix® Anchor. |
| The Weldix® Anchor is not fully inserted. | Either the button was released too early or not enough axial force was applied to the Weldix® Anchor. | Remove the Weldix® Anchor either by pulling it out or by drilling it out using the same drill bit. Care must be taken to drill in the same direction as the original hole. A new anchor of the same size can be placed in the same hole. |
| The Weldix® Anchor won't insert, the head of the Weldix® Anchor melts. | The Weldix® Anchor is not aligned properly to the countersink. The direction of insertion does not exactly follow the pre-drilled hole. Insufficient pre-load on the implant during the activation of the ultrasound. | A new Weldix® Anchor can be placed in the same location. Ensure that the Weldix® Anchor is properly placed in the countersink and aligned with the hole. Apply sufficient axial force (1kg for 2.3-Anchor / 3kg for 3.0-Anchor) before activating the ultrasound. |

Attention!

- Do not re-use or re-sterilize the Weldix® Anchor!

7. Suture Pattern

We recommend using the Bunnell Mayer suture pattern to reattach the tendon. This is a suggestion based on the recommendation of trusted surgeons with whom we work. It is the choice of the veterinarian to use their technique of preference.



8. Postoperative Care

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

We recommend physiotherapy and leash walks for 6 weeks.

Ordering information

1. Implants

| PRODUCT NAME | DESCRIPTION | REF NO. |
|---|--------------|-----------|
| Weldix Anchor 2.3mm (1pcs) in a 10box (10total) | Implant | 02-01-007 |
| Weldix Anchor 2.3mm (2pcs) in a 10box (20total) | Implant | 02-01-008 |
| DEMO Weldix® 2.3mm Anchor, 10pcs (not for clinical use) | DEMO Implant | 02-01-901 |
| Weldix Anchor 3.0mm (1pcs) in a 10box (10total) | Implant | 02-01-011 |
| Weldix Anchor 3.0mm (2pcs) in a 10box (20total) | Implant | 02-01-012 |
| DEMO Weldix® 3.0mm Anchor, 10pcs (not for clinical use) | DEMO Implant | 02-01-903 |

2. Instruments

| PRODUCT NAME | DESCRIPTION | REF NO. |
|---|-------------------|-----------|
| BoneWelder® Vet System Incl. Ultrasonic Device, Handpiece, Wrench and Power Cord | Set | 01-00-001 |
| BoneWelder® Vet Ultrasonic Device - Incl. Power Cord | Ultrasonic Device | 01-01-001 |
| BoneWelder® Vet Handpiece | Instrument | 01-02-001 |
| BoneWelder® Vet Wrench | Instrument | 01-03-001 |
| BoneWelder® Vet Long Conical 1.4mm Sonotrode (for Weldix 2.3 & 3.0) | Instrument | 01-04-004 |
| Drill Bit Weldix® 2.3mm Anchor with Drill Stop, AO Quick coupling (NEW drillstop) | Instrument | 01-05-009 |
| Drill Bit Weldix 2.3mm Anchor with Drill Stop, BOS Quick coupling (NEW drillstop) | Instrument | 01-05-010 |
| Drill Bit for Tunnel 1.8mm AO Quick coupling | Instrument | 01-05-011 |
| Drill Bit for Tunnel 1.8mm BOS Quick coupling | Instrument | 01-05-012 |
| Drill Bit Weldix® 2.3mm Anchor Drill Stop with guide, AO | Instrument | 01-05-017 |
| Drill Bit Weldix® 2.3mm Anchor Drill Stop with guide, BOS | Instrument | 01-05-018 |
| Drill Bit Weldix® 3.0mm Anchor with Drill Stop, AO Quick coupling (NEW drillstop) | Instrument | 01-05-006 |
| Drill Bit Weldix® 3.0mm Anchor with Drill Stop, BOS Quick coupling (NEW drillstop) | Instrument | 01-05-015 |
| Drill Bit Weldix® 3.0mm Anchor Drill Stop with guide, AO | Instrument | 01-05-008 |
| Drill Bit Weldix® 3.0mm Anchor Drill Stop with guide, BOS | Instrument | 01-05-016 |
| Weldix® Drill Guide - Short | Instrument | 01-06-001 |
| 2.3mm Tap for Weldix® 2.3mm Anchor | Instrument | 01-07-001 |
| 2.9mm Tap for Weldix® 3.0mm Anchor | Instrument | 01-07-002 |
| Tray for Weldix Instruments | Casing | 01-09-001 |

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