

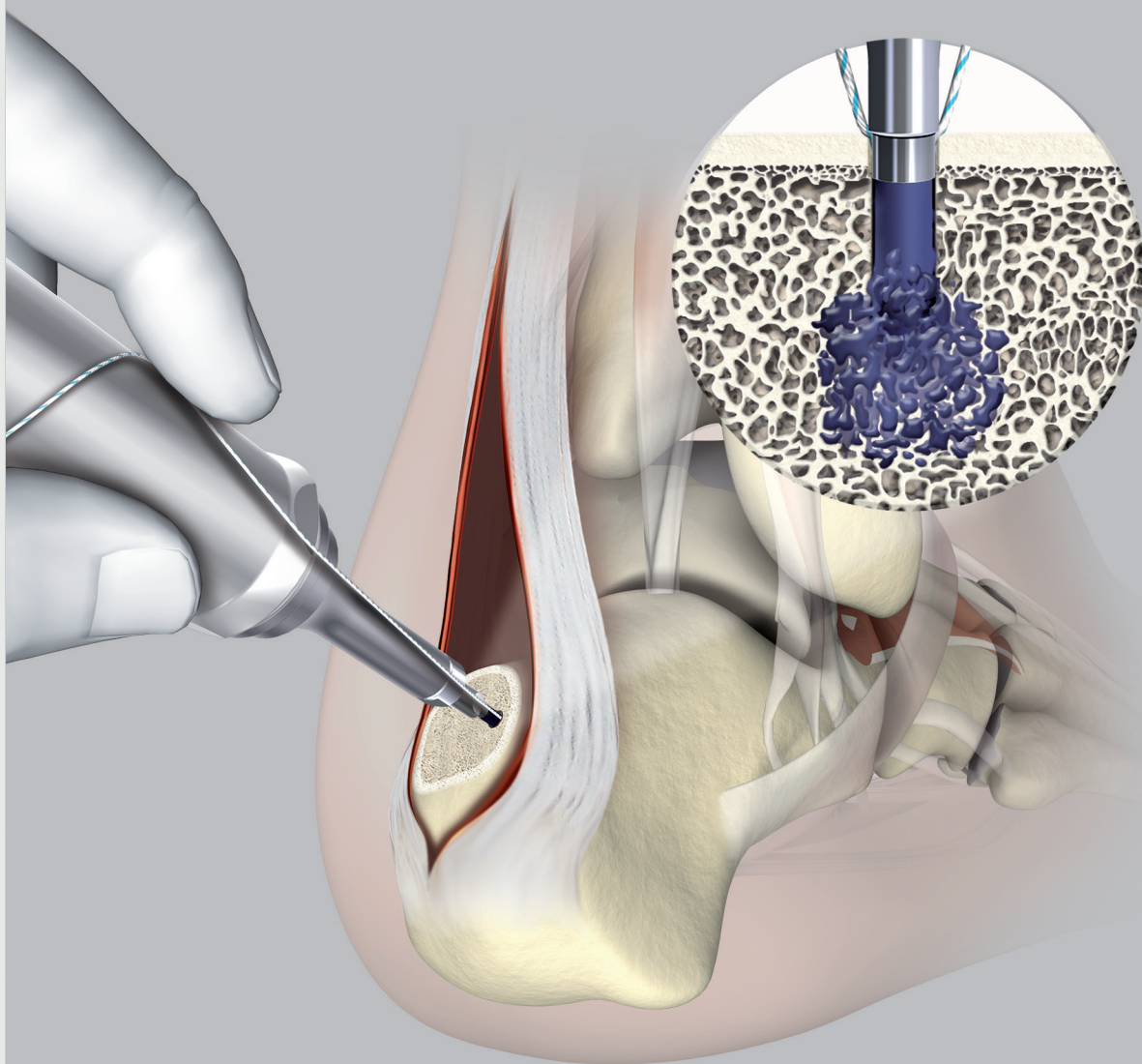


stryker®

SonicAnchor™ System

Operative Technique

Foot & Ankle



This publication sets forth detailed recommended procedures for using Stryker Trauma & Extremities devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to first surgery.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000).

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

See package inserts (Instructions for Use) [L22000028, L22000022, L220105B6] for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

	Page
Introduction	4
Indications and Contraindications	5
Indications	5
Contraindications	5
System Description and Start-up	6
SonicFusion Equipment	6
Front Panel Description	7
Assembly of Handpiece Tip	8
Start-up Test	9
SonicAnchor Insertion	10
Assembly	10
Positioning	10
Fixation	11
Finalization	12
Operative Technique	13
Achilles Tendon Repair	13
Additional System Information	15
Sterilization Requirements	15
Ultrasonic Generator Settings	15
Audible Feedback	15
Troubleshooting and Error Codes	16
Troubleshooting	16
Error Codes	17

Introduction

Traditional Implant Fixation

With traditional anchor fixation, a pre-existing thread on an implant engages with surrounding bone during implant insertion and tightening.

SonicFusion Fixation

The SonicAnchor is a bioresorbable implant, designed to facilitate soft tissue to bone reattachment.

It utilizes SonicFusion technology to allow for the interdigitation of the implant with the surrounding cancellous bone structure.

The principle behind SonicFusion technology is that controlled ultrasonic energy is applied to the SonicAnchor after the implant is placed within a pre-drilled hole in bone. The SonicAnchor is made of a bioresorbable polymer, and the application of ultrasonic energy allows for a brief, controlled liquification of the tip of the SonicAnchor.

The liquified polymer flows into the surrounding porous cancellous structure, where it solidifies, and allows for a stable interface between the implant and bone (Fig. 1.1 and 1.2, schematic illustration).

Bioresorbable

The SonicAnchor is made of PLDLLA (Poly(L-lactide-co-D, L-lactide), a bioresorbable polymer. The breakdown of the SonicAnchor is based on the natural physiologic process of hydrolysis, which produces H_2O and CO_2 bi-products.

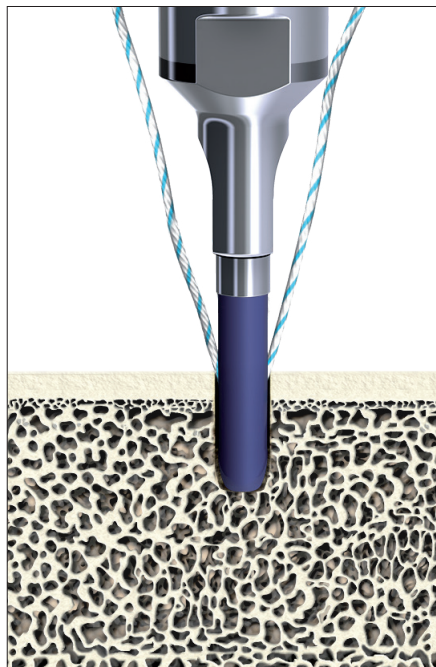


Fig. 1.1

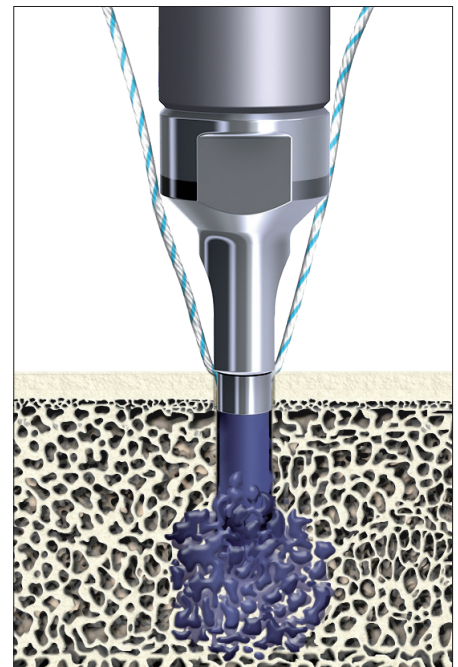


Fig. 1.2

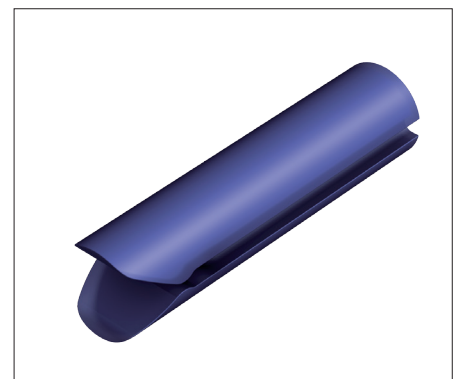


Fig. 2

Implant Geometry

The SonicAnchor is 2.5 mm in diameter (Fig. 2) and comes in a kit with one strand of the following sutures (Force Fiber, non-absorbable) with needles (Fig. 3):

- #2-0 w/ C-2;
- #0 w/ C-2;
- #2 w/ C-7

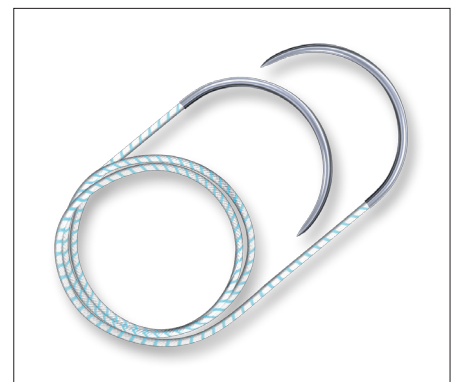


Fig. 3

Indications and Contraindications

Indications

The Stryker SonicAnchor System is intended to be used for suture or tissue fixation in open procedures in the foot, ankle, knee, hand, wrist, elbow and shoulder. The Stryker SonicAnchor is designed only to be inserted with the SonicFusion equipment.

Indications include:

- Foot & Ankle:
 - Achilles Tendon Repair,
 - Lateral Stabilization,
 - Medial Stabilization,
 - Hallux Valgus Reconstruction,
 - Midfoot Reconstruction,
 - Metatarsal Ligament Repair,
 - Digital Tendon Transfer
- Shoulder:
 - Acromio-Clavicular Separation Repair,
 - Proximal Deltoid Repair
- Elbow:
 - Ulnar or Radial Collateral Ligament Reconstruction
- Knee:
 - Patellar Tendon Repair
- Hand & Wrist:
 - Scapholunate Ligament Reconstruction,
 - Carpal Ligament Reconstruction,
 - Repair/Reconstruction of Collateral Ligaments

Contraindications

The physician'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:

- **Bone areas having minimal or no cancellous bone structure. The fusion process requires cancellous bone for implant integration. In the absence of cancellous bone fixation is not given.**
- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the rupture or the operative site.
- Tissue compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.
- Use in arthroscopic procedures.
- Attachment of artificial ligaments or other implants.

The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess the bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.

Warning:

Re-use of single use devices: Single use devices must never be re-used! The re-use of the anchor or suture is not possible. By being inserted with the ultrasonic equipment the SonicAnchor liquifies and is firmly bonded with the cancellous bone. Unused 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. Do not re-use or re-sterilize the anchor or suture!



The SonicAnchor (polymeric implant) is safe for use in magnetic resonance (MR) environments.

System Description and Start-up

SonicFusion Equipment

Before beginning surgery to implant a SonicAnchor, please ensure that all components of the SonicFusion equipment (consisting of SonicFusion ultrasonic generator (including power cord), SonicFusion handpiece and SonicFusion footswitch)* are assembled and properly functioning (Fig 4).

Warning:

Improper connection may cause malfunction of the handpiece or ultrasonic generator, which can result in injury, unintended surgical effect, or product damage.



Fig. 4

Connections

1. Place the ultrasonic generator on a sturdy platform, such as a Stryker cart.
2. Connect the AC power.
3. Connect the handpiece and footswitch to the appropriate ports (Fig. 5, handpiece port, footswitch port)

Note:

Leave 10 cm (4 inches) of space around all sides for convection cooling and make sure that the ultrasonic generator cooling fan at the rear of the ultrasonic generator is not directed towards the face of the patient.

Caution:

Please check the handpiece for obvious damage that might occur during sterilization or handling (the plug connection, cable, thread on the tip of the handpiece).

Warning:

- Be sure that no liquid is present between connections to the ultrasonic generator and the handpiece. Connection of wet accessories may lead to electric shock or electrical short.
- To avoid the risk of electric shock, this equipment must only be connected to a main supply with protective ground.
- Use only hospital-grade power cords.

The ultrasonic generator is compatible only with the Stryker handpieces and footswitches.

Warning:

Do not connect any equipment not specified in this manual, as unexpected results or serious injury will occur.

Should emergency shutdown become necessary, power off the ultrasonic generator. As an added safety measure, the ultrasonic generator can be separated from the AC power mains by disconnecting the AC power cord.

*Components of the SonicFusion equipment are termed in the following text: ultrasonic generator, handpiece and footswitch.

**Handpiece including cable is applied part.

System Description and Start-up

Front Panel Description

The ultrasonic generator front panel features ports for connecting the handpiece and footswitch, a touch-screen to provide system feedback and a power on/off button (Fig. 5).

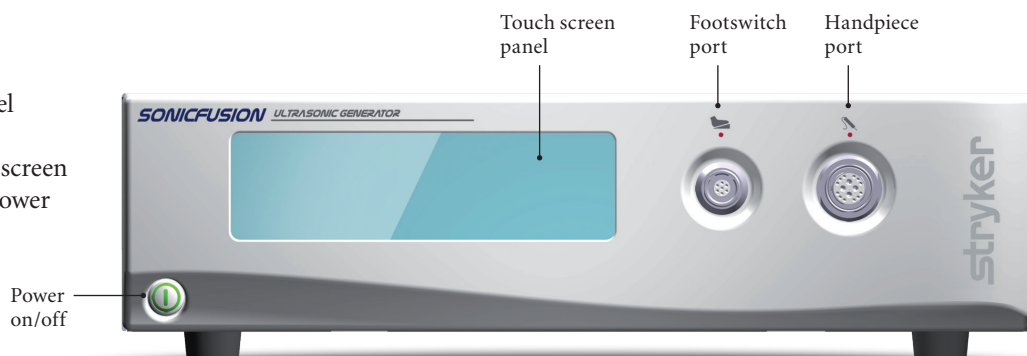


Fig. 5

Press the ultrasonic generator power button. The button will shine green when the ultrasonic generator is on and the Stryker logo will appear on the display (Fig. 6.1).



Fig. 6.1

In a few seconds, the ultrasonic generator starts to boot up, which is indicated on the display together with the revision number of the software (Fig. 6.2).



Fig. 6.2

Connecting the Handpiece and Footswitch

As long as the handpiece and footswitch are not connected, a question mark will flash, alternating with corresponding symbols (Fig. 6.3).

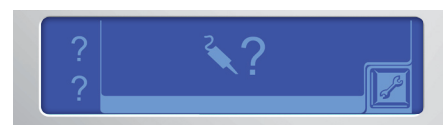


Fig. 6.3

Note:

If the handpiece and footswitch were connected before powering on the ultrasonic generator, the system will recognize them. The ultrasonic generator is equipped with self-recognition software for the respective handpieces.

Choose SonicAnchor

Choose the SonicAnchor application by pressing it on the touchscreen (Fig. 6.4).



Fig. 6.4

System Description and Start-up

Assembly of Handpiece Tip

Take one handpiece tip from the tray (Fig. 7).

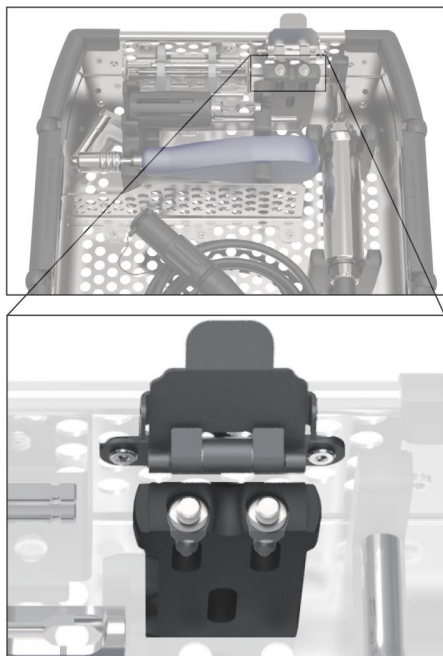


Fig. 7

Assemble the handpiece tip to the tiptool (Fig. 8). Be sure that the handpiece tip is inserted correctly. The tiptool is magnetic and allows self-holding of the handpiece tip.

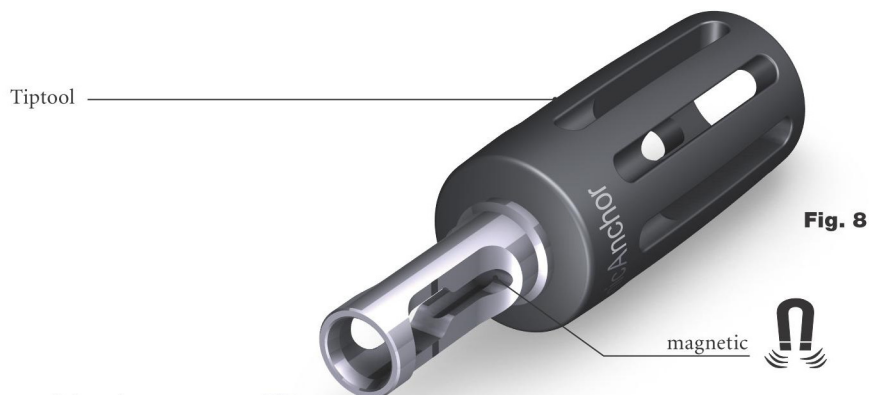


Fig. 8

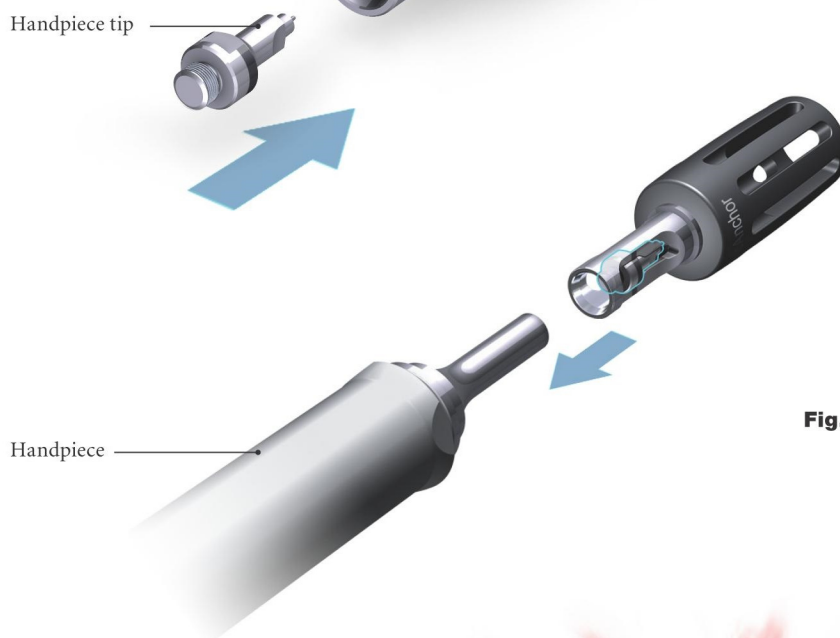


Fig. 9

Screw the handpiece tip onto the handpiece by rotating clockwise and tighten firmly (Fig. 9, Fig. 10).

Caution:

Use of handpiece tip and tiptool only as illustrated to maintain functionality and integrity of the instruments.

Note:

High torque is required to mount the handpiece tip correctly to the handpiece (Fig. 10).

Insufficient torque could cause a failed start-up test of the handpiece (Fig. 14).



Fig. 10

System Description and Start-up

Start-up Test

The ultrasonic generator start-up test (test run) must be performed prior to proceeding with surgery to ensure system calibration. Press the footswitch (Fig. 11) briefly and release to initiate the start-up test. Make sure that the handpiece tip does not come in contact with any objects. The display will show the handpiece being tested (Fig. 12).

Caution:

- During the start-up test, hold the handpiece only as illustrated in Fig. 13 or place it on a flat surface. Make sure that the handpiece tip does not come in contact with any objects (Fig. 13) as this might compromise the start-up test or system function (Fig. 14). Do not touch the tip part as this might damage the surgical gloves. Touching the vibrating tip during the start-up test can trigger an instinctive reaction which leads to dropping the handpiece due to the ultrasonic wave.
- Operate the equipment only as needed for calibration in the start-up test. Excessive operation may lead to overheating of the handpiece tip.

Note:

If the start-up test fails (Fig. 14), the handpiece tip assembly may not be tight enough. Retighten and repeat the handpiece tip assembly with the tiptool (Fig. 15).

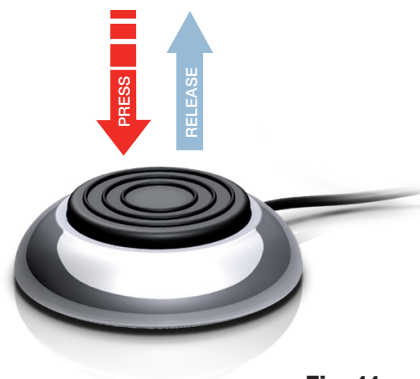


Fig. 11

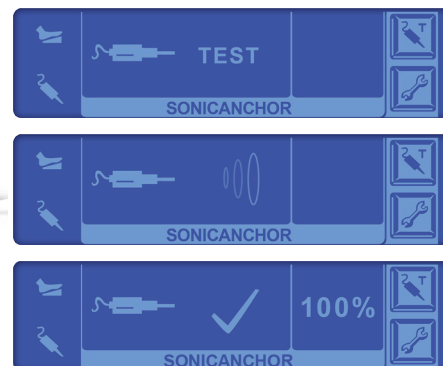


Fig. 12

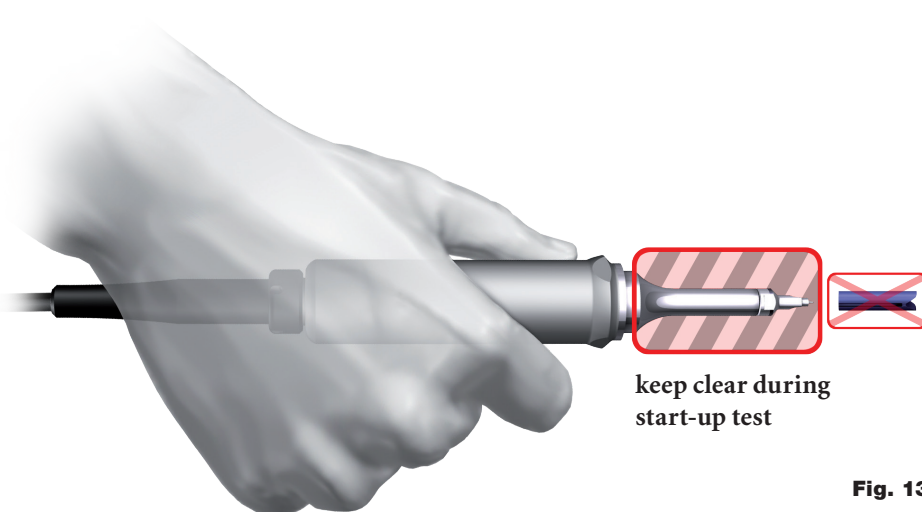


Fig. 13



Fig. 14



Fig. 15

SonicAnchor Insertion

Assembly

Anchor

Mount the SonicAnchor firmly onto the handpiece tip. The axial alignment and fit of the SonicAnchor is paramount for the fusion process. Ensure there is no gap between the SonicAnchor and the handpiece tip compromising the ultrasound transmission to the SonicAnchor (Fig. 15 and 15.1).

Caution:

Storage beyond the labeled temperature range can cause deformity of the implant which can prevent a correct seating of the implant on the handpiece tip.

Suture

Catch the suture provided with the SonicAnchor. The suture clicks into the recess of the SonicAnchor. (Fig. 16.1) The suture must be tensionless during the fusion process (Fig. 16.2).

Choose the correct suture size provided in the appropriate packaging prior to the operation process.

Caution:

- **Do not place more than one suture on the SonicAnchor, its performance cannot be ensured with more than one strand attached.**
- **Do not tension the suture during the fusion process.**

Positioning

Position the SonicAnchor into the prepared hole and apply axial force (Fig. 17).

Slide the suture to the desired position prior to the liquification process since slidability is not guaranteed after fusion process. The SonicAnchor protrudes appr. 4 mm corresponding to the liquifying portion during the fusion process (Fig. 18).

The SonicAnchor must be axially movable. Ensure there is no tissue trapped in the drill hole.

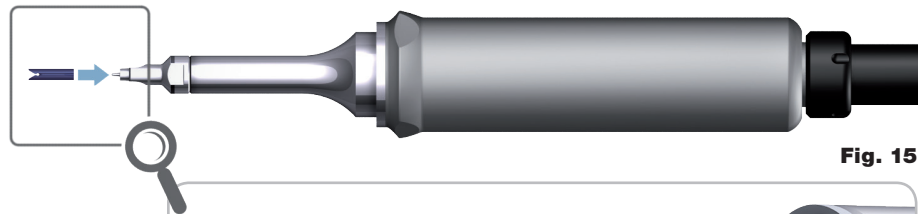


Fig. 15

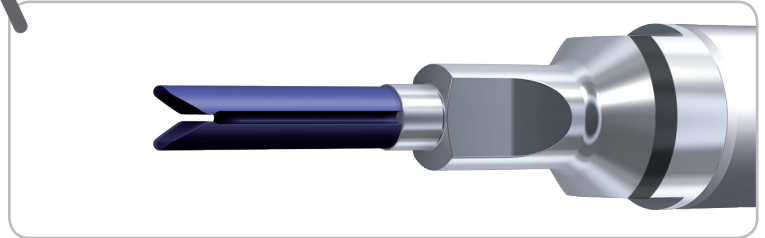


Fig. 15.1

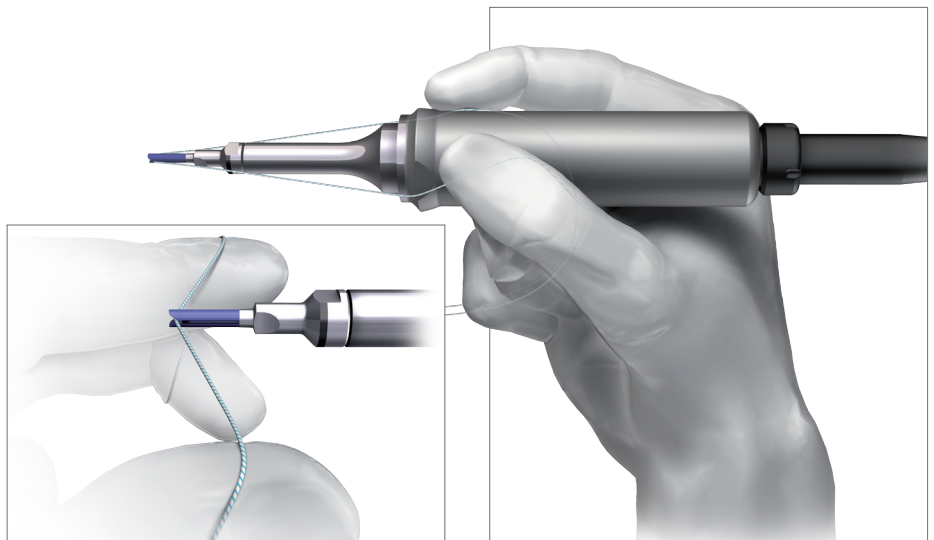


Fig. 16.1

Fig. 16.2

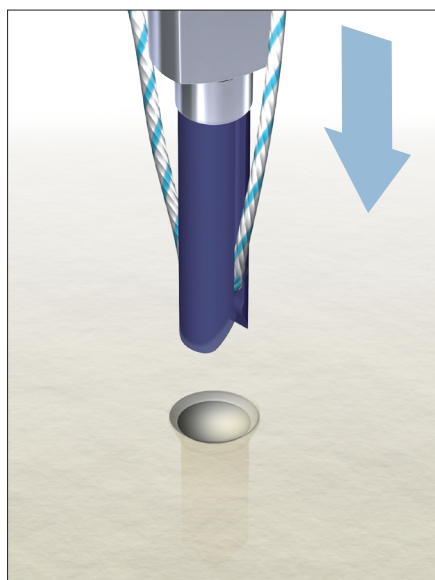


Fig. 17

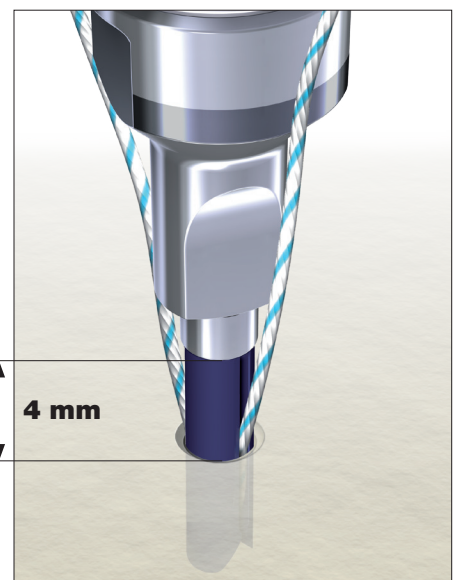


Fig. 18

SonicAnchor Insertion

Fixation

Ultrasound

Apply axial force (Fig. 19) and activate the ultrasound by keeping the foot-switch pressed (Fig. 20). Maintain the force (Fig. 21) to fully advance the SonicAnchor into the bone until the mechanical stop of the handpiece tip reaches the bone surface (Fig. 22).

Release the footswitch to stop the ultrasound when the full depth is reached (mechanical stop) and the SonicAnchor is fully disappeared in the bone (Fig. 22). The SonicFusion process automatically stops after 12 seconds.

Caution:

- An activation of the ultrasound (with assembled SonicAnchor on the handpiece) prior to the anchor positioning requires an exchange of the implant.
- Axial force before starting the ultrasound process is necessary to ensure a successful liquification process (Fig. 19)!
- Maintain the axial force and do not release the footswitch until the SonicAnchor is fully advanced into the bone!
The SonicAnchor is successfully inserted when it is below the bone surface (the mechanical stop of the handpiece tip is on the bone surface).
Do not pull the suture during liquification process, this could result in less anchoring!
- The slidability of the suture may be compromised after fixation.
- Stop the fusion process (release the footswitch) when the SonicAnchor is fully inserted into the bone to avoid excessive heat development.
- The SonicFusion process automatically stops after 12 seconds. If the SonicAnchor is not fully inserted, the implant performance cannot be ensured.



Fig. 19

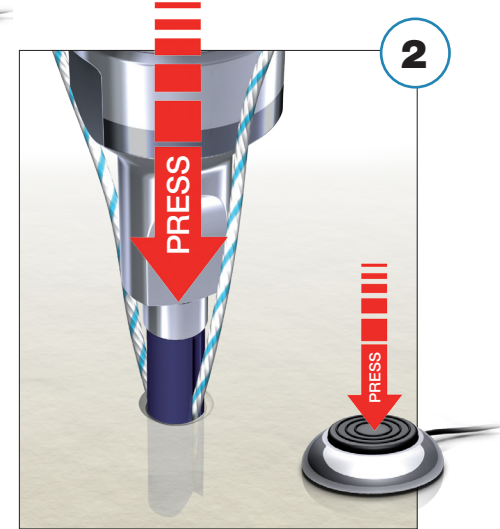


Fig. 20

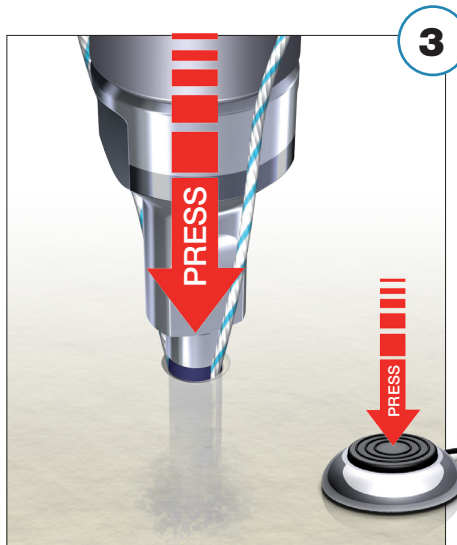


Fig. 21

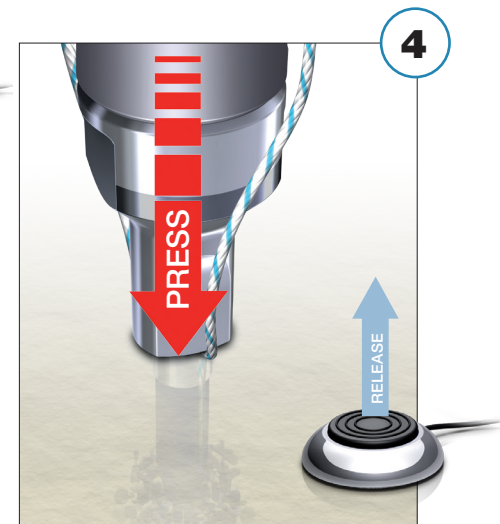


Fig. 22

SonicAnchor Insertion

Finalization

Solidification phase

Wait 5 seconds to allow the SonicAnchor to solidify in the porous structure of the bone before removing the handpiece (Fig. 23 and 25).

The ultrasonic generator creates an audible signal and shows a countdown on the display during the solidification phase (Fig. 24).

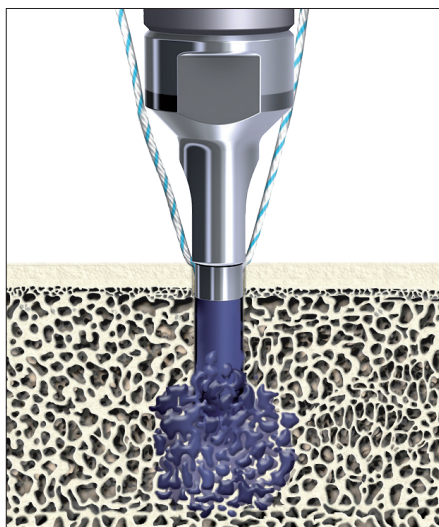


Fig. 23

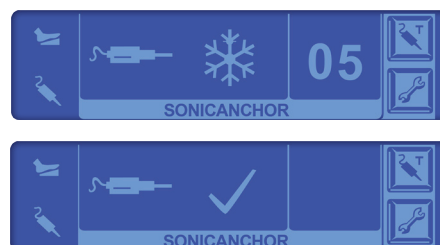


Fig. 24

Inspection

Inspect the mechanical fixation of the SonicAnchor in the bone by pulling the suture strands carefully (Fig. 26).

Continue the procedure with soft tissue fixation or application of additional SonicAnchors as desired.

Caution:

- Do not use the drill hole again after you have liquified the polymer and removed the SonicAnchor.
- Do not operate the equipment unnecessarily between the insertion of multiple SonicAnchors, as excessive uninterrupted operation may cause overheating of the handpiece tip. The handpiece will not overheat when used as prescribed in this operative technique, but it is not designed and intended for nonstop operation.

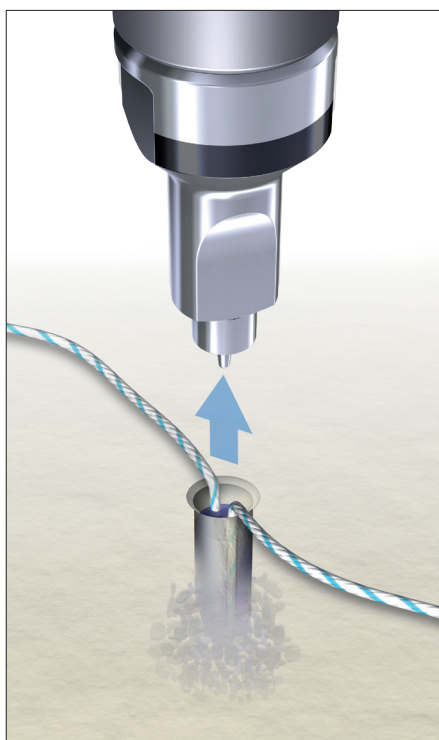


Fig. 25

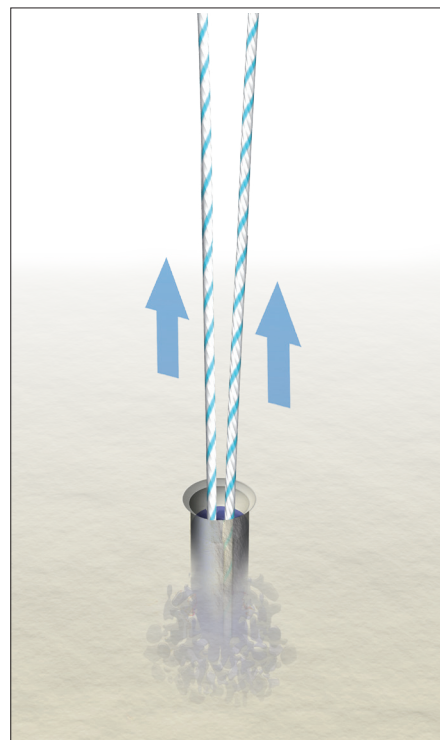


Fig. 26

Additional Anchors

The handpiece is ready for the next application when the display indicates "Start" (Fig. 27).



Fig. 27

Operative Technique

Achilles Tendon Repair

Incisions

The patient is placed in a prone position with a thigh tourniquet (Fig. 28).

A central incision is made directly in the midline (Fig. 29).

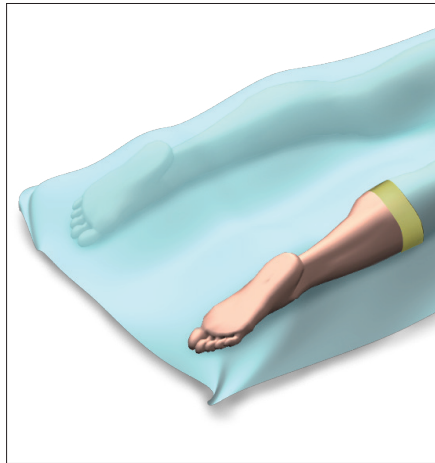


Fig. 28

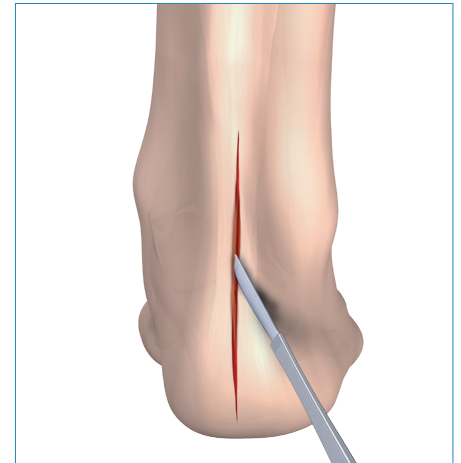


Fig. 29

Tendon Management

The Achilles tendon is split and elevated off the posterior calcaneus (Fig. 30 and 31).

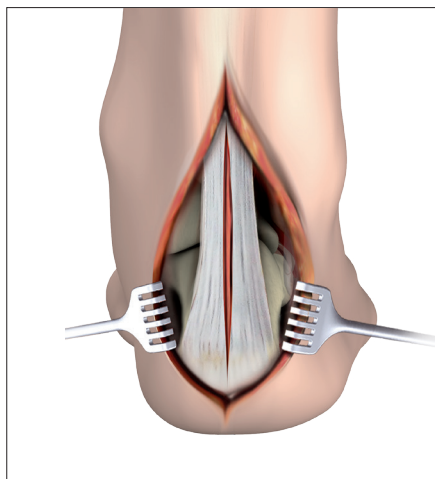


Fig. 30

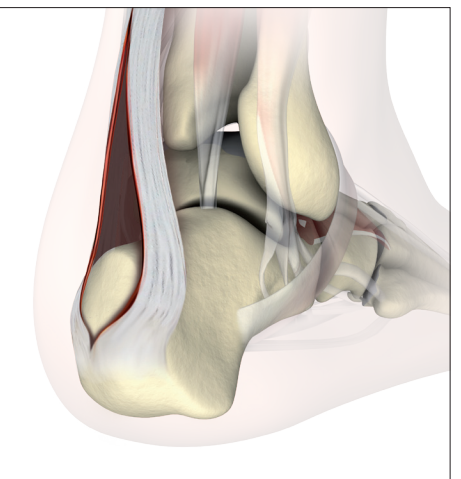


Fig. 31

Resection of Bone

The insertional fibers are detached and debrided and the posterior calcaneal tuberosity is exposed. Care is taken to avoid detachment of the medial and lateral 10-20 percent of the Achilles insertion.

A chisel is inserted to resect the prominent aspects of the calcaneal tuberosity (Fig. 32). Attention is focused on the typical area of the Haglund's deformity in the posterior, superior, and lateral aspect.

The edges of the bone are contoured and smoothed with a power rasp (Fig. 33).

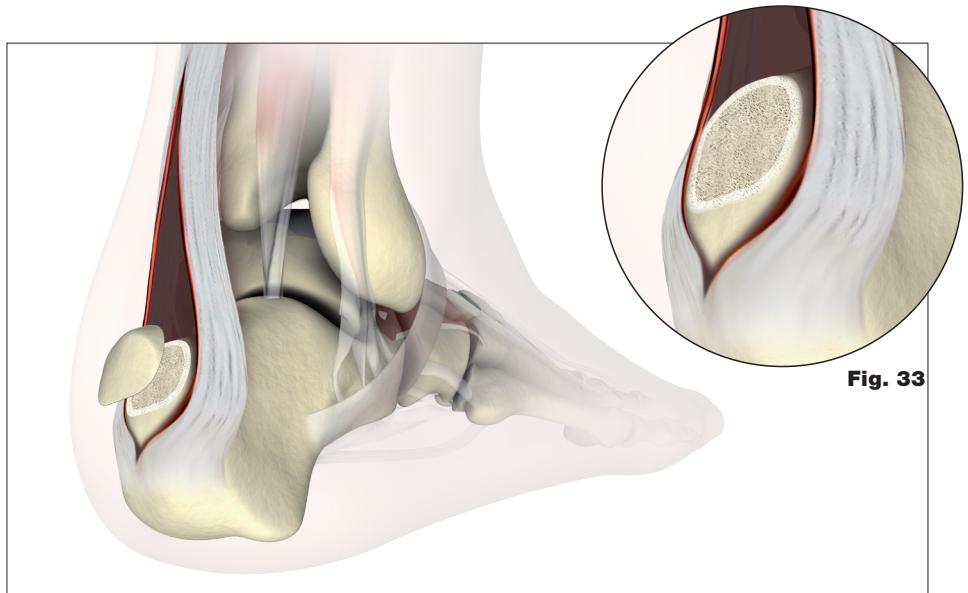


Fig. 33

Fig. 32

Operative Technique

Achilles Tendon Repair

Drilling and Anchor Placement

Use the SonicAnchor drill (in combination with drill sleeve and/or handle) to create the hole for the SonicAnchor. The correct drill depth is reached when the drill mechanically stops at the bone surface, which is ensured by a drill stop (Fig. 34, Fig. 34.1).

Note:

For functionality of the SonicAnchor the bone must be free of soft tissue to:

- prevent soft tissue being trapped into the hole during anchor insertion and
- allow the handpiece being clearly stopped by the bone surface and not by overlying soft tissue.

Caution:

Use the handle provided for manual drilling and/or the drill sleeve to protect the surrounding tissue.

Application of Suture

The central portion of the Achilles is reattached to the raw exposed bone with SonicAnchors.

Two anchors are used to repair the medial and lateral aspect of the distal Achilles. Proper tension of the Achilles tendon is achieved (Fig. 35 - 37).

Closure

Interrupted sutures are used to repair the remaining split portion of the Achilles.

The wound is closed in routine fashion (Fig. 38).

A large bulky Jones dressing is applied with plaster reinforcement and the patient is discharged with crutches and a non-weight bearing stance.

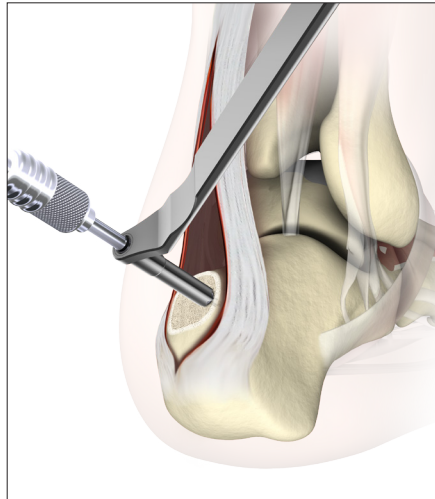


Fig. 34

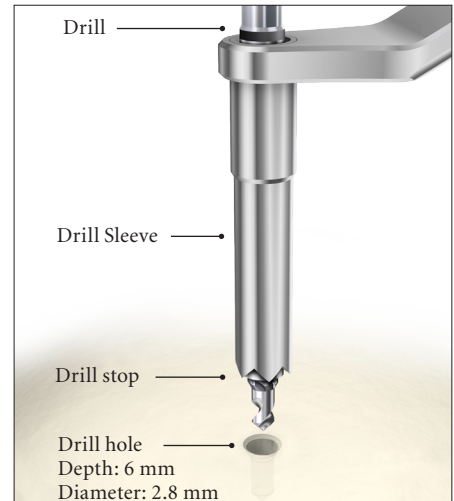


Fig. 34.1

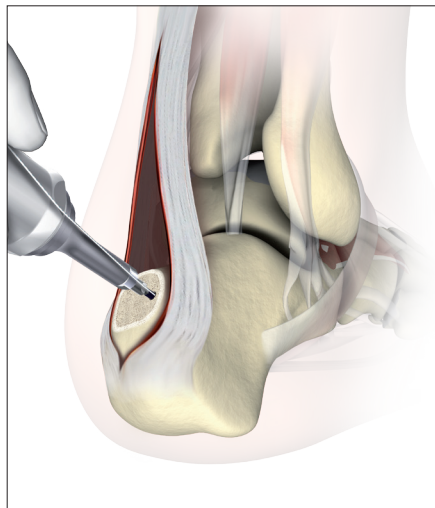


Fig. 35

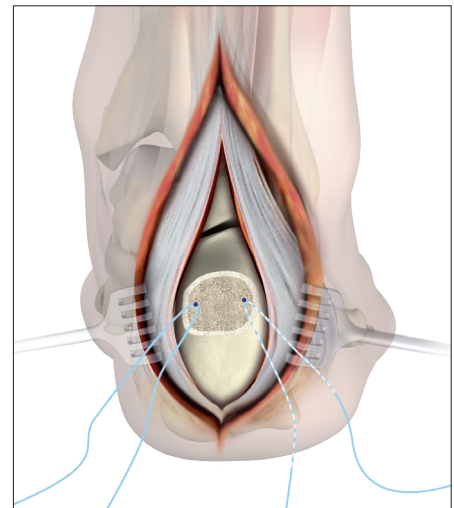


Fig. 36

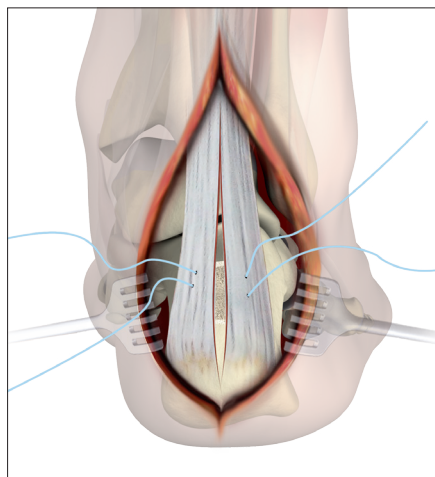


Fig. 37



Fig. 38

Additional System Information

Sterilization Requirements

The ultrasonic generator and footswitch are not sterile devices and must not enter the sterile field.

Handpiece, handpiece tip, tiptool, drill sleeve and handle are provided nonsterile and must be cleaned and sterilized prior to each use. For the handpiece the Reprocessing Guide (L24002000) is applicable with the restriction that the validated

parameters for moist heat sterilization of the handpiece are max. 7 minutes exposure time at 137 °C (277 °F) (according to SonicFusion equipment IFU (L22000022)). For the handpiece tip, tiptool, single-use drill, drill sleeve and handle the Reprocessing Guide (L24002000) is applicable without any restrictions.

Note:
The handpiece tip can also be sterilized when it is placed in the tiptool.

Caution:

- The handpiece and the handpiece tip must be disassembled prior to the sterilization process.
- The screw-cap of the handpiece plug must be closed prior to the sterilization process.

Ultrasonic Generator Settings

Test Run

To repeat the test run, press this icon and the test screen comes up. Follow the instructions from page 9.

Sound Settings

System sound can be adjusted through the ultrasonic generator interface.

1. Press 
2. Press to enter the system's sound settings 
3. Press symbol to adjust the selected function (sound). 
4. Press to exit setting menu 



Note: Press this symbol to see  information about the connected handpiece (current version and serial number).

The "M" symbol only  refers to a technician test button and is not relevant for the end user.

Audible Feedback

Note:
The ultrasonic generator will provide audible feedback for the following events:

Event	Signal
Handpiece or footswitch connection detected	Two beeps, low then high tone
Handpiece or footswitch disconnection detected	Two beeps, high then low tone
Error detected	Five short beeps, high tone
Touchscreen interaction	Single beep
Ultrasonic active	Continuous tone
Cooling period	Single beep each second
Application finished or successful completion of current operation	Three short beeps
Continuous touchscreen interaction more than 15 seconds	Continuous high tone

Troubleshooting and Error Codes

Troubleshooting

Problem	Possible Solution
The AC voltage is incorrect	Turn the power off and on again. If the problem persists, contact a Stryker representative or return the ultrasonic generator for repair.
The system does not power on	- Check the power cord to ensure it is properly connected. - Check to ensure the cord is connected to a grounded outlet.
The electrical interference is sporadic	- Power down all electrical equipment not in use. - Increase distance of other electrical equipment. - Connect the unit and other equipment into different outlets.
The ultrasonic generator is heating up	Ensure that there is proper airflow around the unit.
The handpiece is heating up	Allow the unit to cool before restarting.
A recoverable or non-recoverable error has occurred	Consult the error codes on page 17.
The pre-test is not passed	Ensure that sufficient torque for the handpiece tip assembly is employed.

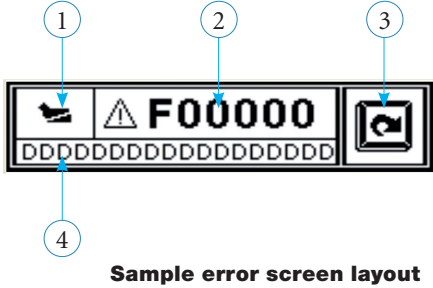
- 1

Possible error source: ultrasonic generator, handpiece or footswitch
- 2

Error code
- 3

Next action: Touchscreen button or footswitch press dismisses the recoverable error. A power cycle is required for non-recoverable errors
- 4

Text description



Troubleshooting and Error Codes

Error Codes

Note:

- Should an error occur, the ultrasonic generator will indicate an error with five short beeps. An error code will also appear on the display. The interpretation of the error code as well as possible causes and solutions appear in Tables 1 and 2.
- If any recoverable errors should occur, an error code with the prefix 'F' will appear. To recover the system, press the back arrow on the touch screen or activate the footswitch and the error display will disappear allowing you to proceed. If the error persists, refer to the possible solutions section contained in Table 1. If an error code appears with the prefix 'F' and does not match the error code shown in the table, multiple errors have occurred. If errors persist, please contact your authorized Stryker representative.

Recoverable errors and corresponding codes		
Error code	Reason for error	Possible solution
F00001	Output current too high	• Check handpiece for damage. • Rescan handpiece.
F00002	Output voltage too high	
F00004	Ultrasonic generator temperature too high	• Ensure proper airflow on sides and rear of ultrasonic generator.
F04000	USB communication error	• Remove the USB. Clear the error and then re-insert the USB.
F00010	Footswitch disconnected during activation	• Verify footswitch connection.
F00020	Handpiece disconnected during activation	• Verify handpiece connection.
F00040	Handpiece communication fault	• Remove and re-insert the handpiece.
F00200	Handpiece data communication fault	• Remove and re-insert the handpiece. • Replace handpiece.
F00080		
F00100		
F00400	Handpiece incompatible with ultrasonic generator	• Replace handpiece with one that is compatible. • A software upgrade may be required. Contact your authorized Stryker representative for more information if you believe that your software is out of date.
FXXXXX	Unknown or multiple faults	• Unknown or multiple faults have occurred. Clear the error and continue.

Table 1: Recoverable error codes with possible causes and solutions

Note:

If any non-recoverable error should occur, an error code with the prefix 'L' will appear. To recover the system, turn the ultrasonic generator off and then on again. If errors persist, please contact your authorized Stryker representative.

Non-recoverable errors and corresponding codes		
Error code	Reason for error	Possible solution
LXXXXX	The ultrasonic generator has detected an internal error	• Cycle power to the unit (turn the unit off and then on).

Table 2: Non-recoverable error codes with possible causes and solutions



Reconstructive

Hips
Knees
Trauma & Extremities
Foot & Ankle
Joint Preservation
Orthobiologics & Biosurgery

MedSurg

Power Tools & Surgical Accessories
Computer Assisted Surgery
Endoscopic Surgical Solutions
Integrated Communications
Beds, Stretchers & EMS
Reprocessing & Remanufacturing

Neurotechnology & Spine

Craniomaxillofacial
Interventional Spine
Neurosurgical, Spine & ENT
Neurovascular
Spinal Implants



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