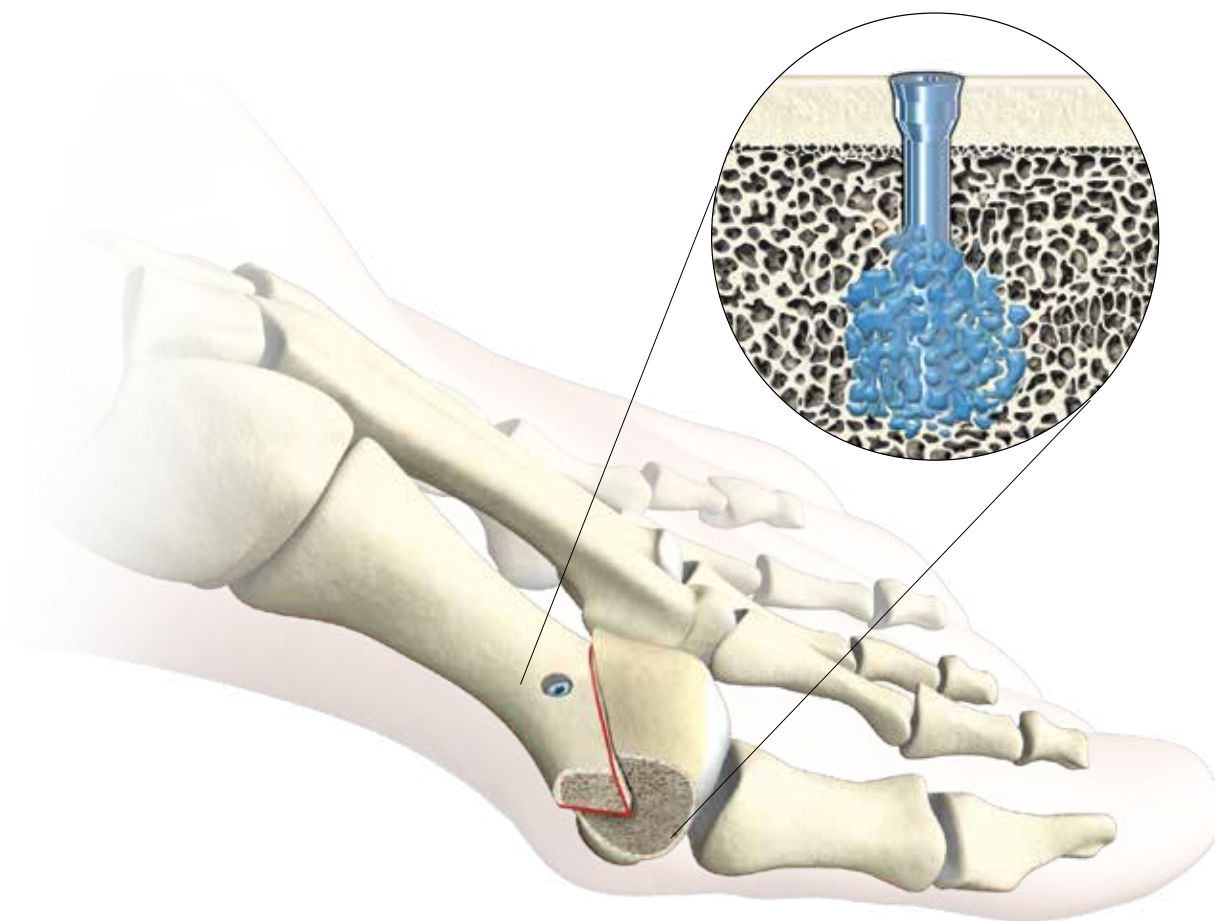


SonicPin[®]

System

Operative technique

Austin/Chevron osteotomy



SonicPin System

This publication sets forth detailed recommended procedures for using Stryker 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 (OT-RG-1). 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 has not been tested unless specified otherwise in the product labeling.

See package inserts (Instructions for Use: L22000032, 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.

Caution:

For appropriate identification of system components, refer to the label, the laser marking on the product as well as the tray layout card.

Warning:

Pay close attention when handling sharp edges of the product and packaging.

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Introduction

Traditional implant fixation

With traditional implant fixation, a pre-existing physical thread on an implant engages with surrounding bone during implant insertion and tightening. Implant fixation is entirely dependent on the screw-thread/bone interface, and implant loosening may occur, especially in patients with poor bone quality.

SonicFusion fixation

The Stryker SonicPin System is intended to maintain alignment and fixation of bone fractures, osteotomies or bone grafts in hallux valgus applications in the presence of appropriate immobilization (e.g. rigid fixation implants, cast and brace).

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

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

The liquefied polymer flows into the surrounding porous cancellous structure, where it solidifies, and allows for a stable interface between the implant and bone (Fig. 1-4, schematic illustration).

Bioresorbable

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



Fig. 1

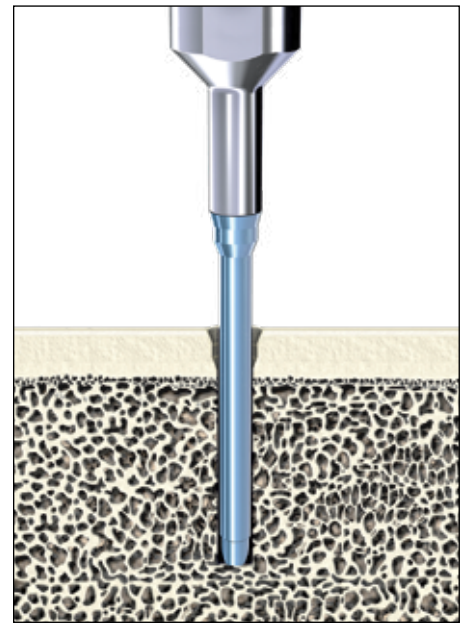


Fig. 2

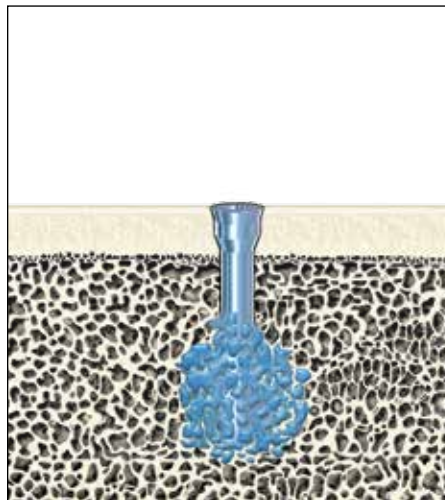


Fig. 3

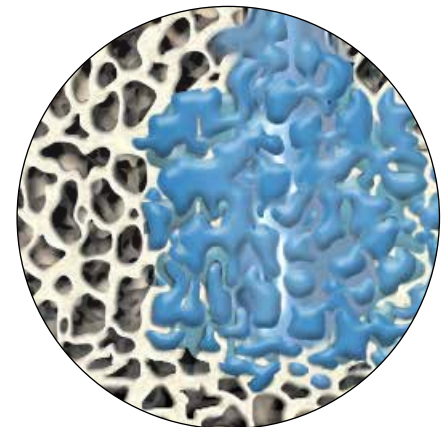


Fig. 4

Implant geometry

The Bioresorbable Pin has a 2.2mm shaft diameter, and comes in 22mm and 26mm lengths (Fig. 5).

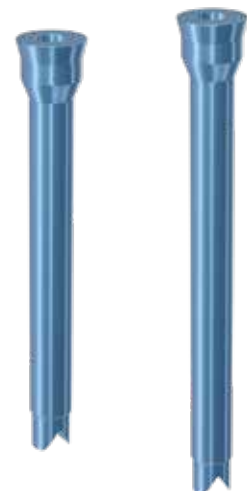


Fig. 5

Indications and contraindications

Indications

The Stryker SonicPin System is intended to maintain alignment and fixation of bone fractures, osteotomies or bone grafts in hallux valgus applications in the presence of appropriate immobilization (e.g. rigid fixation implants, cast and brace). The Stryker SonicPin is designed only to be inserted with the SonicFusion equipment.

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 absence of cancellous bone fixation is not given.
- Implant utilization in load bearing procedures or where fragments are subjected to tension or shear stress.
- 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 fracture or the operative site.
- Bone stock 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.
- 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.
- 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 Bioresorbable Pin is not possible. By being inserted with the SonicFusion equipment the Bioresorbable Pin liquefies and is firmly bonded with the cancellous bone.

The Bioresorbable Pin is a resorbable implant which cannot be extracted. 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 Bioresorbable Pin!

Re-use may result in transmission of contaminated tissues between patients and may compromise the integrity of the design and/or materials leading to diminished safety, performance and/or compliance with relevant specifications.

Caution:

Implant selection and sizing:

The correct selection of the implant(s) is important. Using an inappropriate implant for the clinical condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.



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

System description & start-up

SonicFusion equipment

Before beginning surgery to implant a Bioresorbable Pin, 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. 6).

Warning:

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



Fig. 6

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. 7, handpiece port, footswitch port)

Note:

Leave 10cm (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).

Caution:

Make sure that the non-sterile part of the cable does not enter the sterile field.

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 an applied part.

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. 7).

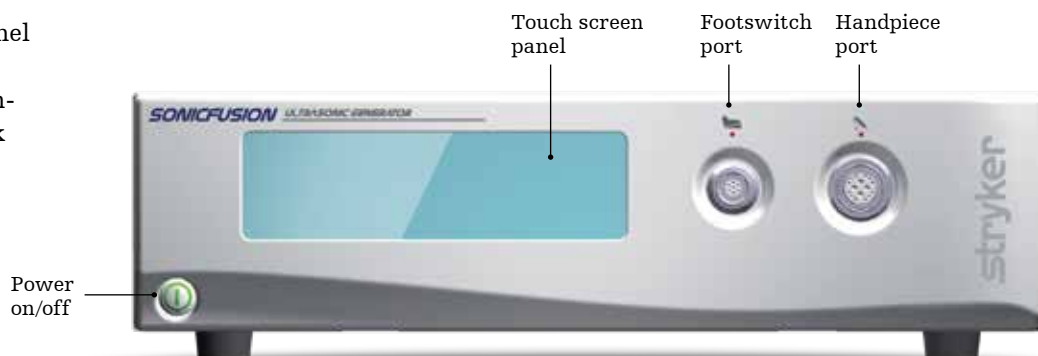


Fig. 7

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. 8.1).



Fig. 8.1

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. 8.2).



Fig. 8.2

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. 8.3).



Fig. 8.3

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 SonicPin

Choose the SonicPin application by pressing it on the touchscreen (Fig. 8.4).



Fig. 8.4

Caution:

Select the SonicPin application to ensure that the device is run with the correct program.

Assembly of handpiece tip

Take one handpiece tip from the tray (Fig. 9).

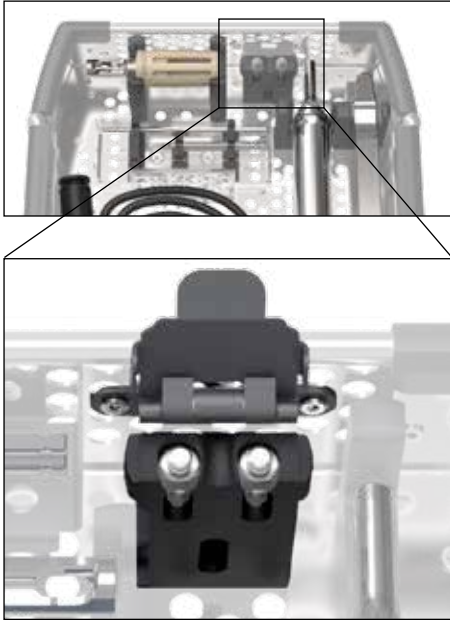


Fig. 9

Assemble the handpiece tip to the tiptool (Fig. 10). Be sure that the handpiece tip is inserted correctly. The tiptool is magnetic and allows self-holding of the handpiece tip.

Screw the handpiece tip onto the handpiece by rotating clockwise and tighten firmly (Fig. 11, Fig. 12).

Caution:

- Use of handpiece tip and tiptool only as illustrated to maintain the functionality and integrity of the instruments.
- Sufficient torque is required to mount the handpiece tip correctly to the handpiece (Fig. 12). Insufficient torque could cause a failed start-up test of the handpiece (Fig. 16).
- Use the handpiece tip of the SonicPin System (M2 thread interface) for the implantation of the Bioresorbable Pin. Different handpiece tip interfaces could result in compromised implantation results.



Fig. 10

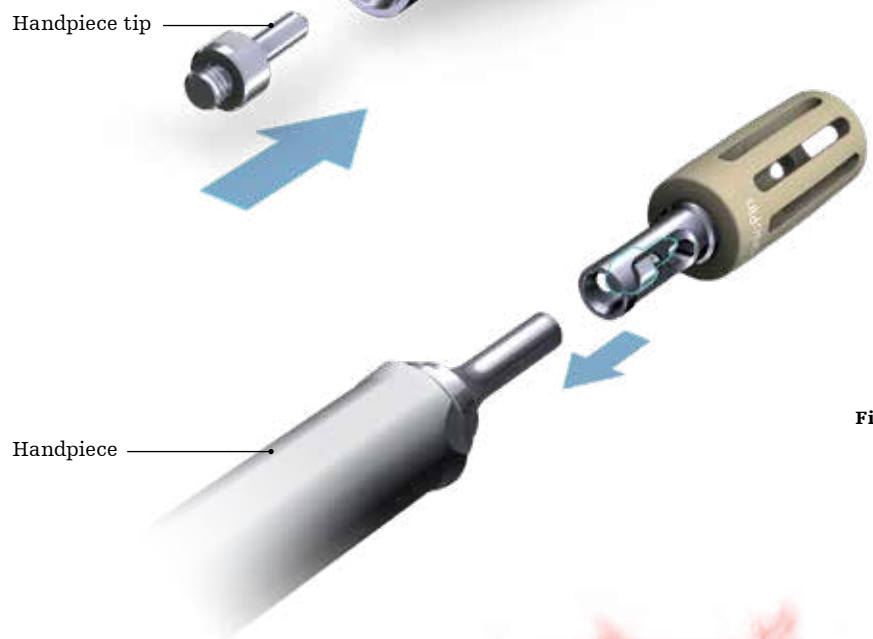


Fig. 11



Fig. 12

Start-up test

The ultrasonic generator start-up test must be performed prior to proceeding with surgery to ensure system calibration. Press the footswitch (Fig. 13) 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. 14).

Caution:

- During the start-up test, hold the handpiece only as illustrated in Fig. 15 or place it on a flat surface. Make sure that the handpiece tip does not come in contact with any objects (Fig. 15) as this might compromise the start-up test or system function (Fig. 16). 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.
- Activate and use the handpiece only as intended because tissue contact during energy delivery could lead to tissue damage.
- Operate the SonicFusion equipment only for the calibration during the start-up test as well as for the implantation. Excessive operation may lead to overheating of the handpiece tip.
- Operate the SonicFusion equipment only after the ultrasonic generator displays the following information which indicates the test run was successfully completed:
 - 100 %
 - a check mark
 SonicFusion equipment is now ready for use.

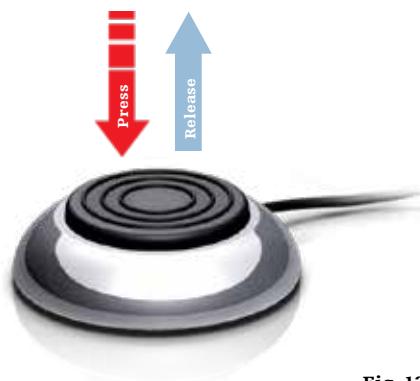


Fig. 13



Fig. 14

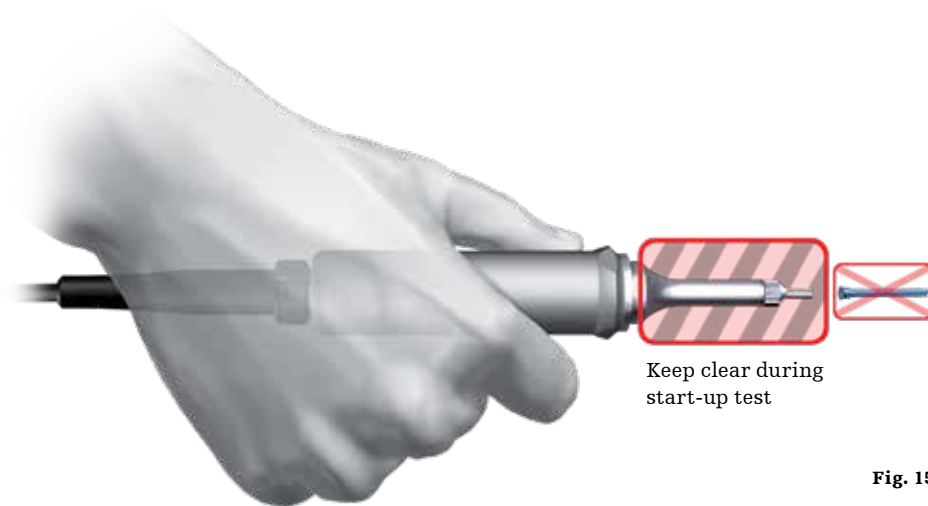


Fig. 15



Fig. 16

Caution:

If the start-up test fails (Fig. 16), the handpiece tip assembly may not be tight enough. Retighten and repeat the handpiece tip assembly with the tiptool (Fig. 17).



Fig. 17

Operative technique

Hallux valgus correction via Austin/Chevron osteotomy

Incision and bone preparation

Make a dorsal medial skin incision crossing the first metatarsophalangeal joint (Fig. 18). Retract the soft tissues carefully, being certain to protect the neurovascular bundle in the skin flap.

Perform a lateral release if necessary through the same incision. This would include the release of the adductor tendon and the fibular sesamoid ligament.

Caution:

Be aware of the superficial branch of the deep peroneal nerve.

Perform a T-shaped incision of the capsule thus exposing the joint (Fig. 19).

Resect the medial eminence, with protection of the sagittal groove (Fig. 20).



Fig. 18



Fig. 19

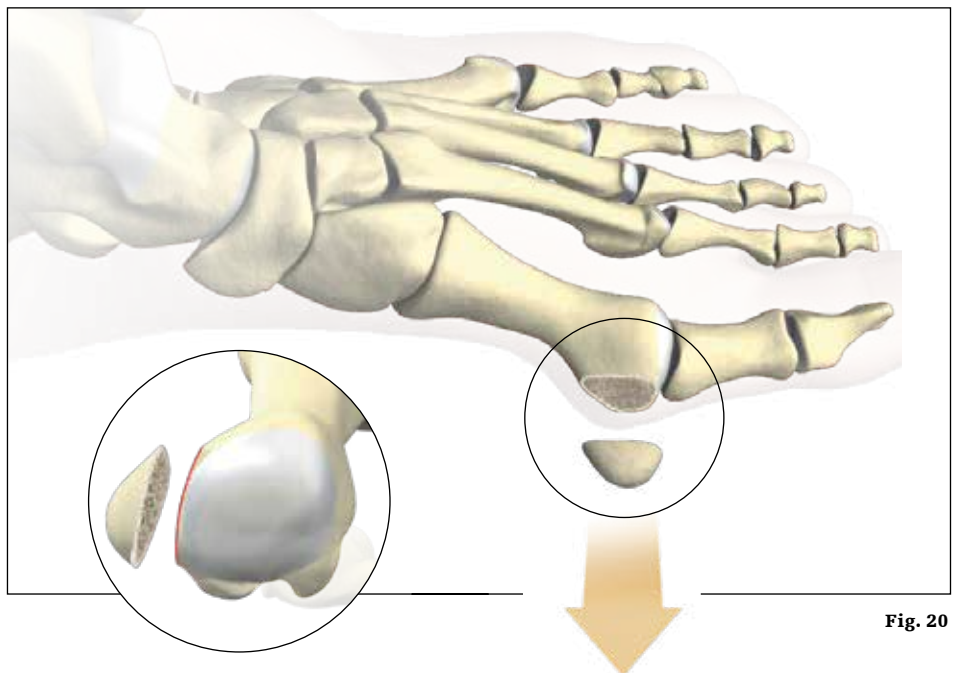


Fig. 20

Osteotomy

Insert a K-wire in the center of the metatarsal head depending on the required osteotomy (Fig. 21).

Warning:

K-wires are single use devices. Do not re-sterilize or re-use K-wires.

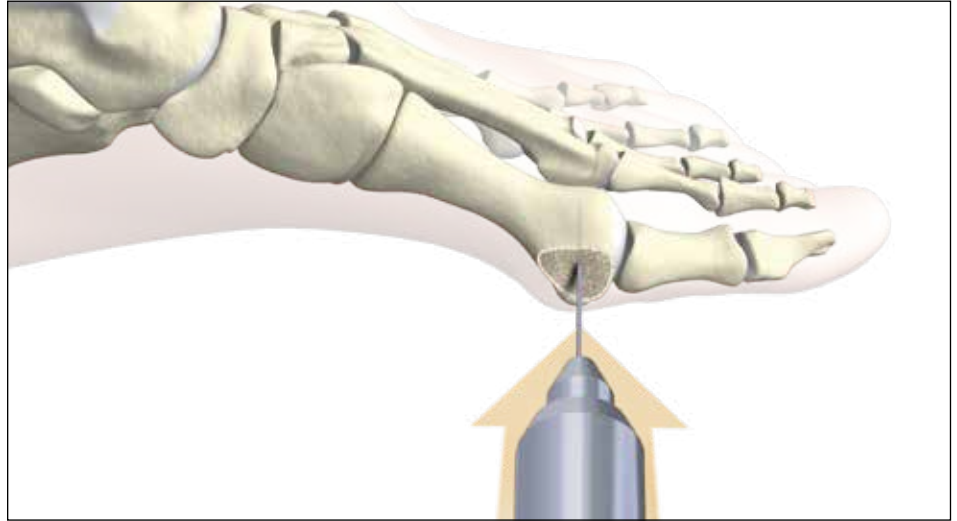


Fig. 21

Perform a V-shaped osteotomy at the head-neck level at an angle of 60° and ideally symmetrical to the bone axis, with the apex at the K-wire.

Alternatively, a modified 90° angle Chevron osteotomy can be performed (Fig. 22).

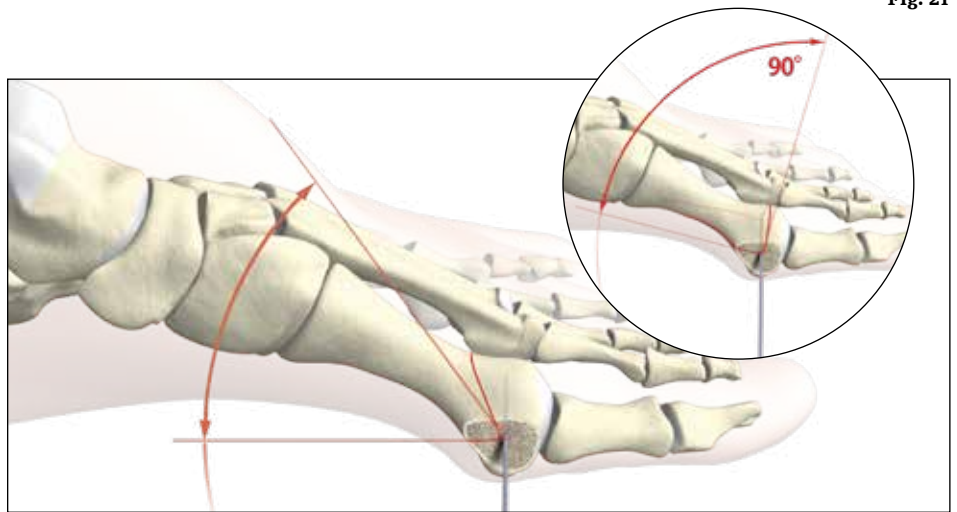


Fig. 22

Note:

The head will follow the direction which is pre-determined by the K-wire placement.

Translate the capital fragment laterally (Fig. 23).

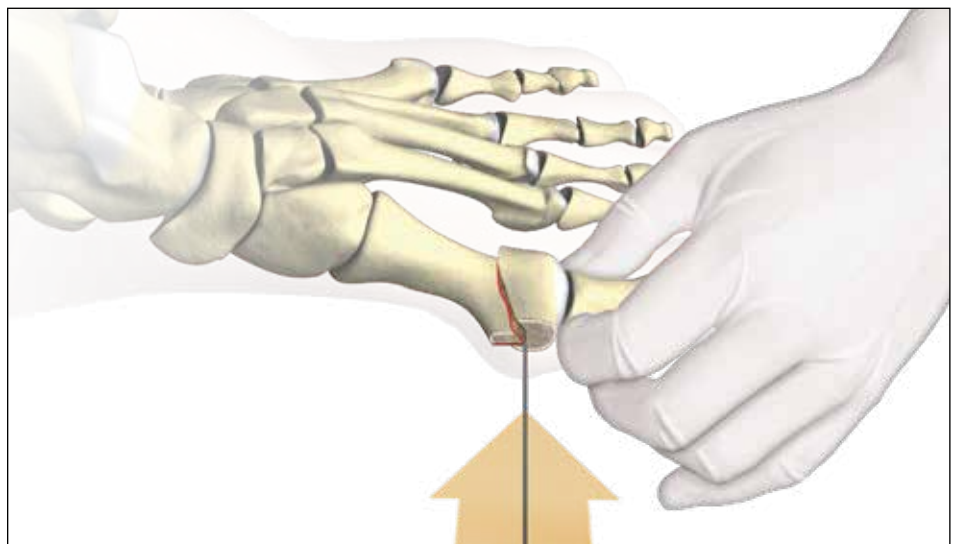


Fig. 23

Bioresorbable Pin length selection and pre-drilling

The Bioresorbable Pin comes in 2 lengths: 22 and 26mm. When implanted, the Bioresorbable Pin should be inserted from the dorsal surface of the first metatarsal. The implant must cross the osteotomy line and project into the distal fragment (see green marked area in Fig. 24).

Prior to inserting the Bioresorbable Pin, a pilot hole must be drilled into the bone. There are dedicated drills for each length of implant, available as cannulated or solid drills.

Note:

Both cannulated and solid drills are designed to drill the pilot hole for the corresponding implant length, at a depth that is 8mm less than the implant length. This is because the implant length will be 8mm shorter after applying the ultrasound energy to liquefy the tip.

Warning:

Drills are single-use devices. Do not re-sterilize or re-use drills.

Caution:

- Make sure that bone fragments are correctly held in position during SonicPin application.
- Make sure no nerves are pinched in the fixated bone fragments to avoid nerve damage.
- Make sure the drill holes do not interfere. This could compromise the implantation and mechanical performance of the device.
- Drill carefully to protect the surrounding tissue.
- Use the drill only as intended to avoid tissue damage (heat-related necrosis).
- Make sure that the drill hole is free of tissue residuals. Tissue residuals in the drill hole could result in compromised implant placement and implantation results.

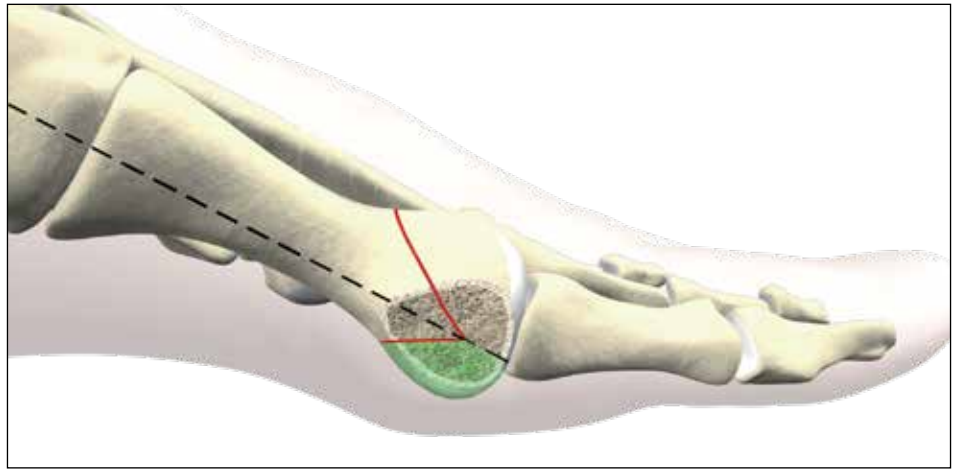


Fig. 24

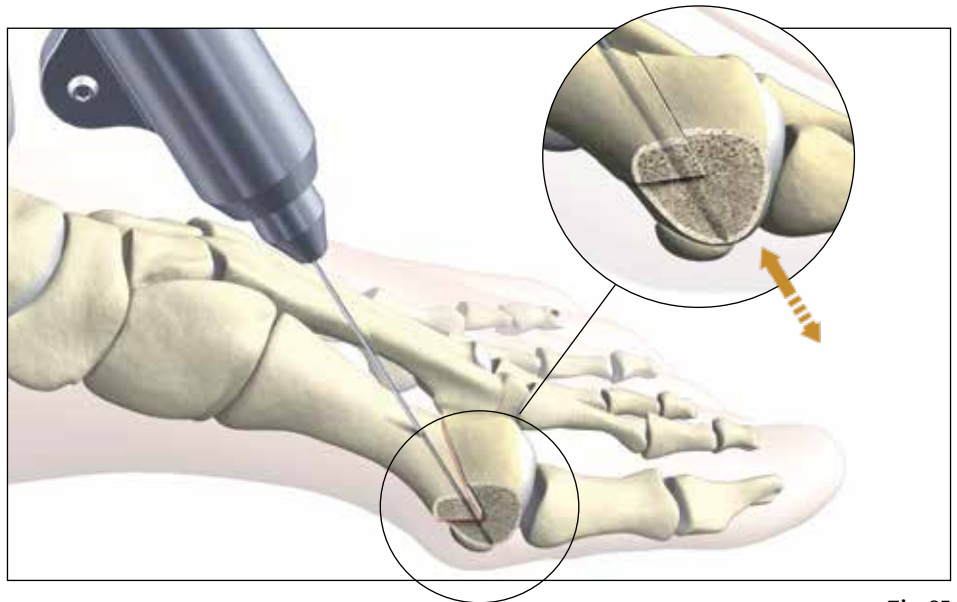


Fig. 25

Alternative 1:

Bioresorbable Pin length selection and pre-drilling with cannulated drill

Place the K-wire (REF 40-20015S, K-wire $\varnothing 0.8 \times 100\text{mm}$) in the appropriate position aiming at the center of the metatarsal head. Insert the K-wire through the metatarsal head until the tip is visible and then retract it slightly so that the tip is below the level of articular cartilage (Fig. 25).

The length of the Bioresorbable Pin to be used should be determined prior

to drilling with the cannulated drill over the K-wire. In order to select the correct implant length, use an image intensifier, or visually check K-wire placement to verify that the K-wire tip is placed in the far cortex, prior to using the direct depth gauge.

Caution:

After using any cannulated instrument over a K-wire, make sure that the K-wire did not shift or dislocate. Slide the direct depth gauge over the K-wire and position it in direct contact with the bone.

The end of the K-wire, when placed against the direct depth gauge, allows for a direct reading of the Bioresorbable Pin length and corresponding drill to be used (Fig. 26).

The scale of the direct depth gauge shows 3 areas:

- The "26" area covers the field in arrow direction excluding the border line to the "22" area. Please use the cannulated drill ($\varnothing 2.4 \times 18\text{mm}$) for the 26mm Bioresorbable Pin, if the K-wire end position falls into this area ("26").
- The "22" area covers the field marked with the double arrow symbol (" \longleftrightarrow ") including both border lines. Please use the cannulated drill ($\varnothing 2.4 \times 14\text{mm}$) for the 22mm Bioresorbable Pin, when the K-wire end position is in this area ("22").
- The "reposition K-wire" area covers the field in arrow direction excluding the border line to the "22" area. If the K-wire end position falls into this area, there is a risk of far cortex penetration by the drill for the 22mm Bioresorbable Pin. Therefore, please remove the K-wire and re-insert it at a different place and/or under a different angle until the K-wire end position falls into the "22" or "26" area.

Caution:

- **The direct depth gauge supports the determination of implant length and respective cannulated drill only based on the distance to the far cortex. Therefore, in addition to the gauge based drill determination, it must be further ensured that the chosen drill crosses the osteotomy line.**
- **If the measuring gauge is not placed perpendicular to the bone surface, the measurement can be influenced by up to 1–2 mm.**

Insert the selected cannulated drill bit into a power tool. Slide it over the K-wire and overdrill carefully the K-wire to the drill stop.

Caution:

- **In order to avoid damaging the K-wire use low speed drilling. Verify after K-wire removal if the K-wire is completely removed and no parts are left in the metatarsal head.**
- **The final position of the cannulated drill tip must be between the osteotomy line**

and the opposite cortex. The opposite cortex must not be penetrated. If the opposite cortex is penetrated, do not insert the Bioresorbable Pin into the pilot hole – a new pilot hole must be drilled.

- **In order to avoid protrusion of the implant head, complete pre-drilling is essential. Insert the SonicPin drill until the drill stop is reached thereby creating the required counter-sink for the implant head.**

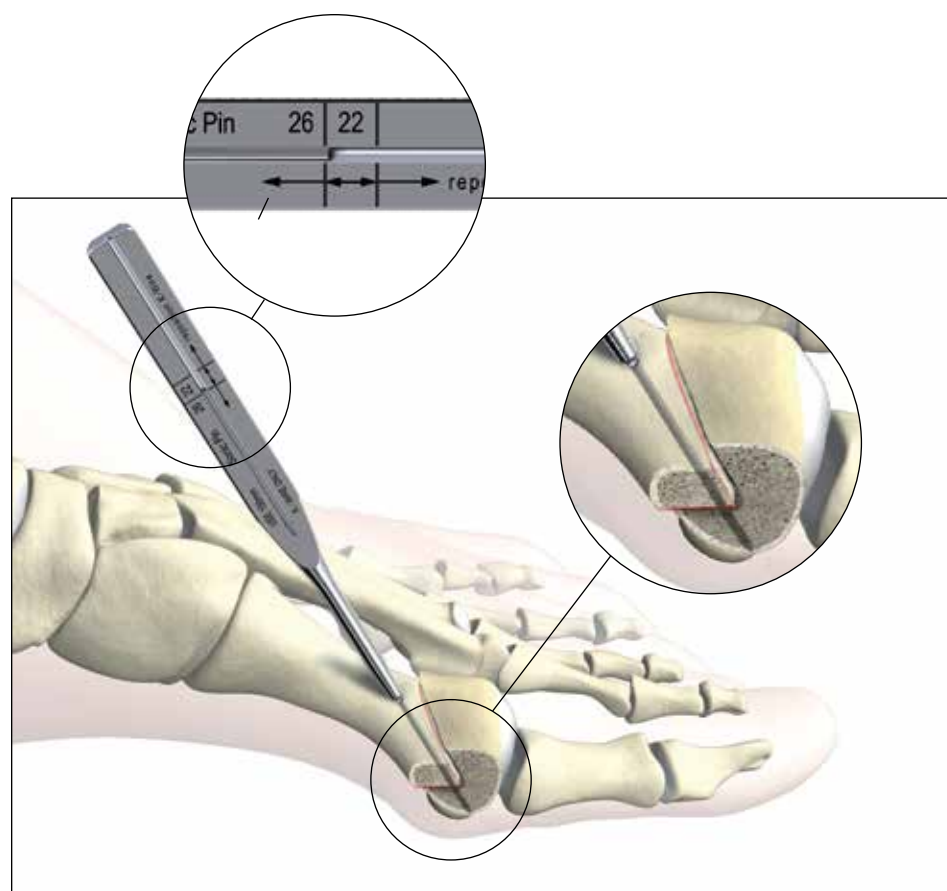


Fig. 26

Alternative 2:

Bioresorbable Pin length selection and pre-drilling with solid drill

The length of the Bioresorbable Pin to be used should be determined prior to drilling with the solid drill. This length must be verified by taking the corresponding drill for the Bioresorbable Pin (either 22 or 26mm), and superimposing it on the medial aspect of the metatarsal, as shown (Fig. 27).

Each drill has a mechanical “stop”, which is designed to make contact with the dorsal surface of the metatarsal. Each drill also has a built-in countersink to accommodate the implant head. The distal tip of the drill must not penetrate the far cortex as that will remove bone substrate required to initiate the SonicFusion process.

Once the length has been verified, the drill is used to create a pilot hole for the Bioresorbable Pin. When drilling, the final position of the drill tip must be placed between the osteotomy line and the opposite (far) cortex, with at least 3mm separating the drill tip and the opposite cortex (Fig. 28).

Caution:

The opposite cortex must not be penetrated. If the opposite cortex is penetrated, do not insert the Bioresorbable Pin into the pilot hole - a new pilot hole must be drilled. Drill placement should be verified visually, and/or by fluoroscopy. Temporary fixation (e.g. K-wires, or an additional SonicPin drill) can be used to achieve provisional fixation of the osteotomy prior to definitive fixation with the Bioresorbable Pin.

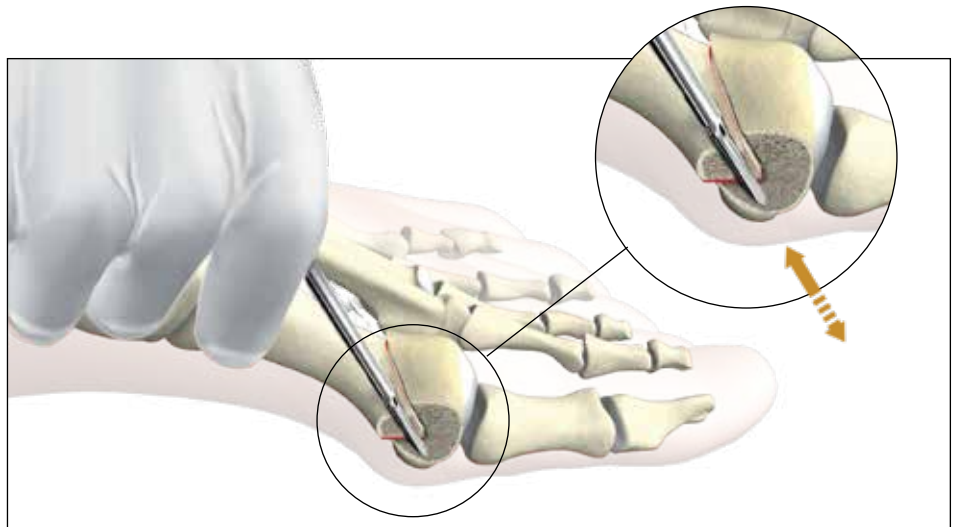


Fig. 27

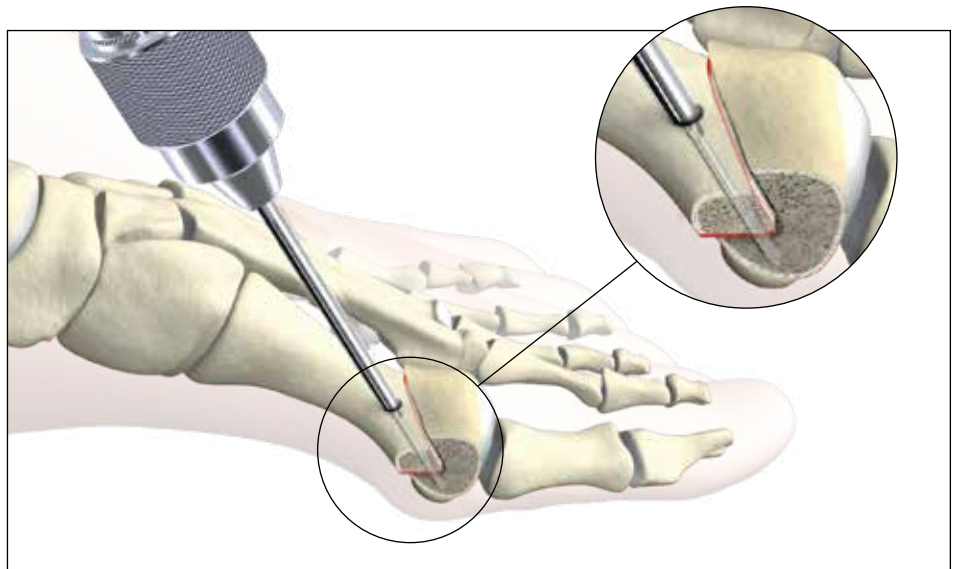


Fig. 28

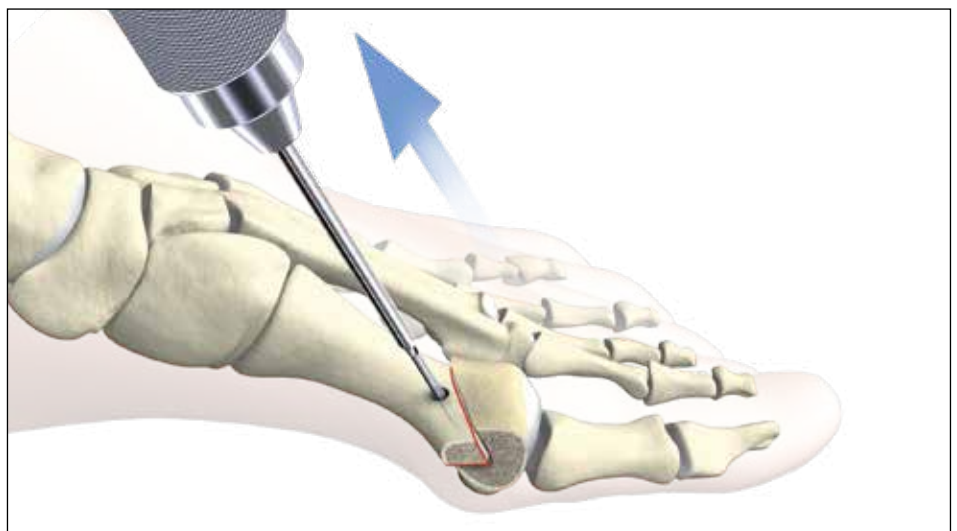


Fig. 29

Assembly

Preparing for insertion of the Bioresorbable Pin

Once the pilot hole has been created, the appropriate Bioresorbable Pin can be mounted onto the handpiece by being screwed on tightly by hand, in a clockwise direction (Fig. 30).

Caution:

Prior to mounting the Bioresorbable Pin, verify that the thread at the tip of the handpiece is not damaged. Do not use any handpiece that was dropped or damaged during cleaning and sterilization as this may compromise the procedure.

Mount the Bioresorbable Pin firmly onto the handpiece tip (Fig. 30a). The axial alignment and fit of the implant is paramount for the fusion process. Ensure there is no gap between the implant and the handpiece tip compromising the ultrasound transmission to the implant.

Caution:

Storage beyond the labeled temperature range can cause deformity of the implant which can prevent a correct sitting of the implant on the handpiece tip. Incorrect sitting of the implant could result in compromised implantation results.

Positioning

While mounted onto the handpiece, the Bioresorbable Pin is placed within the pre-drilled pilot hole. Care must be taken to ensure that the Bioresorbable Pin safely crosses the osteotomy line (Fig. 31).

Note:

Before applying the ultrasound energy to melt the Bioresorbable Pin tip, the implant head will stick out of the pilot hole approximately 8mm (Fig. 31a). Check the distal segment movement to ensure that the Bioresorbable Pin crosses the osteotomy.



Fig. 30

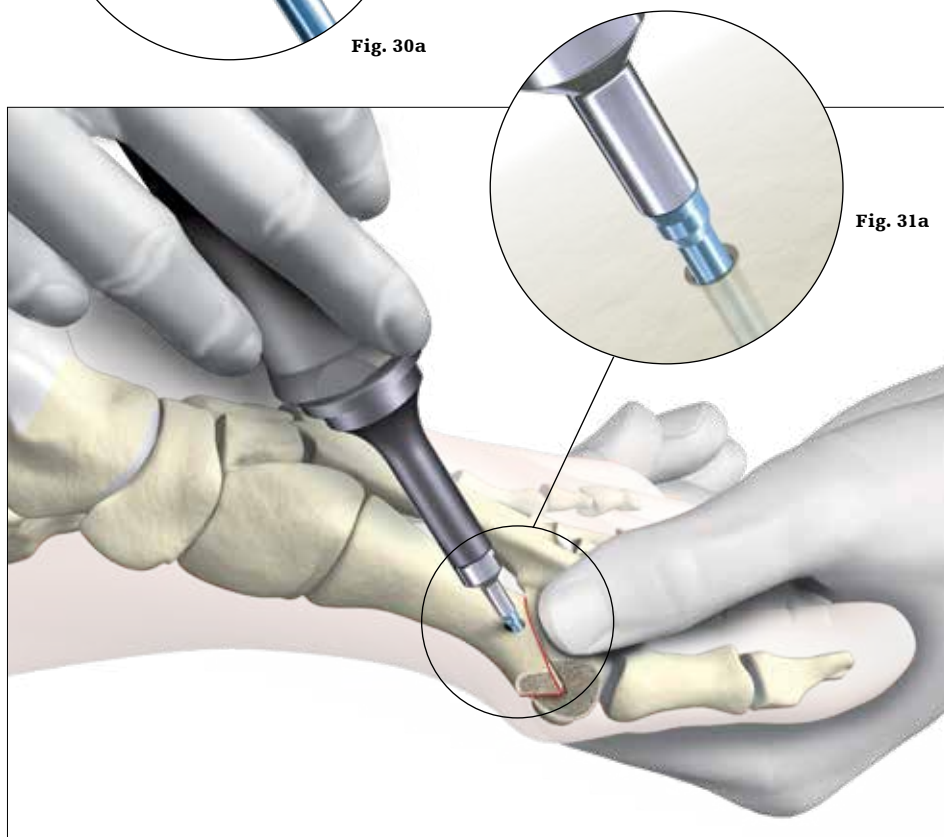


Fig. 31a

Fig. 31

Caution:

If the Bioresorbable Pin is not correctly placed to cross the osteotomy line, the liquification

process will be compromised.

Consequently, the fixation will be compromised.

Fixation

Ultrasound

Apply axial force (Fig. 32) and activate the ultrasound by keeping the footswitch pressed (Fig. 33). Maintain the force (Fig. 34) to fully advance the Bioresorbable Pin into the bone until the implant head mechanically stops below the bone surface (Fig. 35).

Release the footswitch to stop the ultrasound when the full depth is reached and the Bioresorbable Pin is fully disappeared in the bone (Fig. 35). The SonicFusion process automatically stops after 6 seconds.

Caution:

- **An activation of the ultrasound (with assembled implant on the handpiece) prior to the implant positioning requires an exchange of the implant.**
- **Axial force before starting the ultrasound process is necessary to ensure a successful liquification process (Fig. 32)!**
- **Maintain the axial force and do not release the footswitch until the implant is fully advanced into the bone! The implant is successfully inserted when it is below the bone surface (implant head mechanically stops).**
- **Stop the SonicFusion process (release the footswitch) when the implant is fully inserted into the bone to avoid excessive heat development.**
- **The SonicFusion process automatically stops after 6 seconds. If the implant is not fully inserted, the implant performance can not be ensured.**

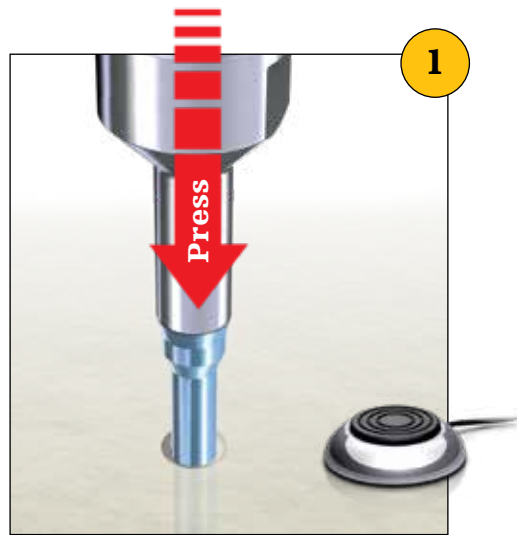


Fig. 32

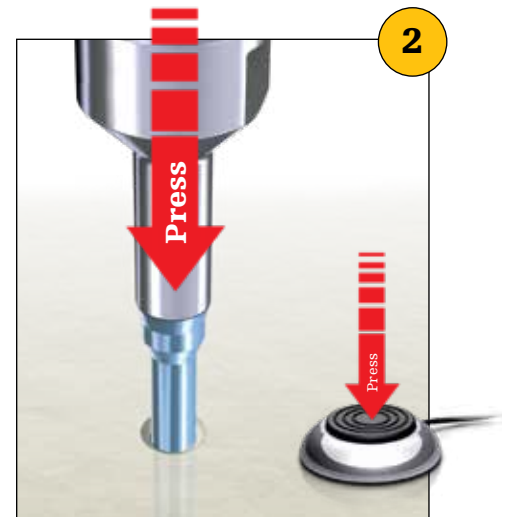


Fig. 33

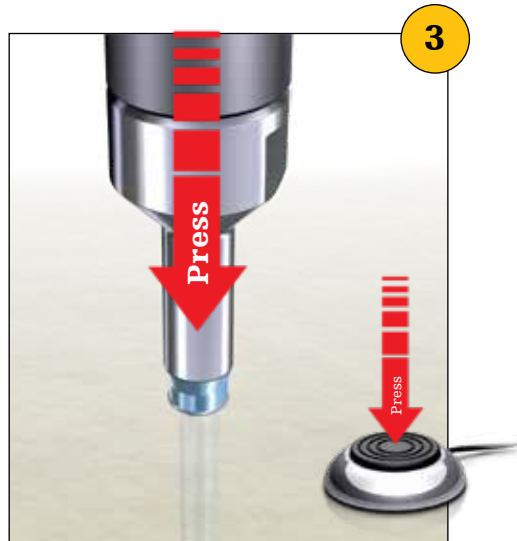


Fig. 34

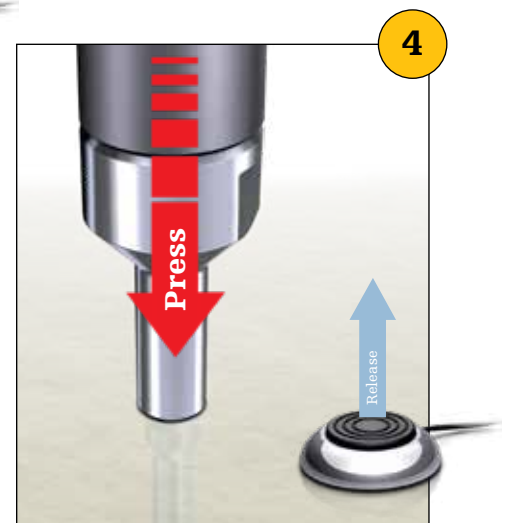


Fig. 35

Wait 5 seconds to allow the Bioresorbable Pin to solidify in the porous structure of the bone before removing the handpiece (Fig. 36, Fig. 36a).

There will be an audible signal from the ultrasonic generator after the cooling process is finished (approx. 5 seconds) and a corresponding image on the ultrasonic generator display, indicating that it is safe to disconnect the Bioresorbable Pin from the handpiece (Fig. 37).

Caution:
Before disconnecting the handpiece from the implant head by unscrewing it, verify that the implant tip is firmly anchored in the bone by carefully lifting up the handpiece.



Fig. 36

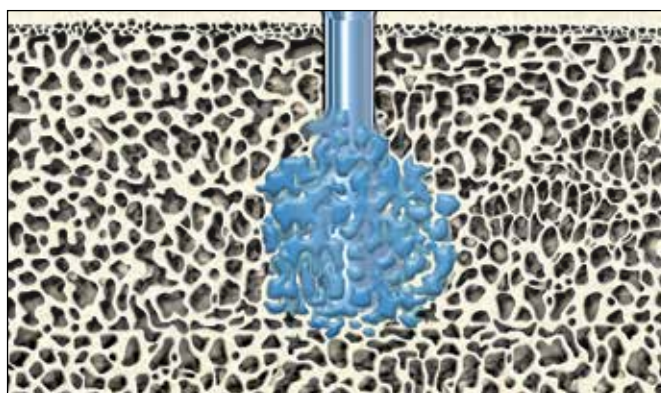


Fig. 36a



Fig. 37

The handpiece is disconnected from the Bioresorbable Pin by turning the entire handpiece in a counter-clockwise direction (Fig. 38).

Note:

In case of slight implant head protrusion, remove implant head prominence if necessary. Before completing the procedure, check stability of fragment fixation.

If the surgeon preference is to use multiple Bioresorbable Pin fixation, the procedure can be repeated for any additional implants, as desired.

Caution:

- **Do not operate the equipment unnecessarily between the insertion of multiple Bioresorbable Pins, 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.**
- **Do not use the drill hole again after you have liquefied the polymer and removed the Bioresorbable Pin.**

The handpiece is ready for the next application when the display indicates "Start" (Fig. 39).

Close the incision following the standard procedure.

Disconnect the handpiece and footswitch and follow the instructions for cleaning from the instructions for use.

Caution:

- **Use instruments only as intended to avoid damage to the instruments and soft tissue.**
- **Use caution to avoid contamination in the OR.**

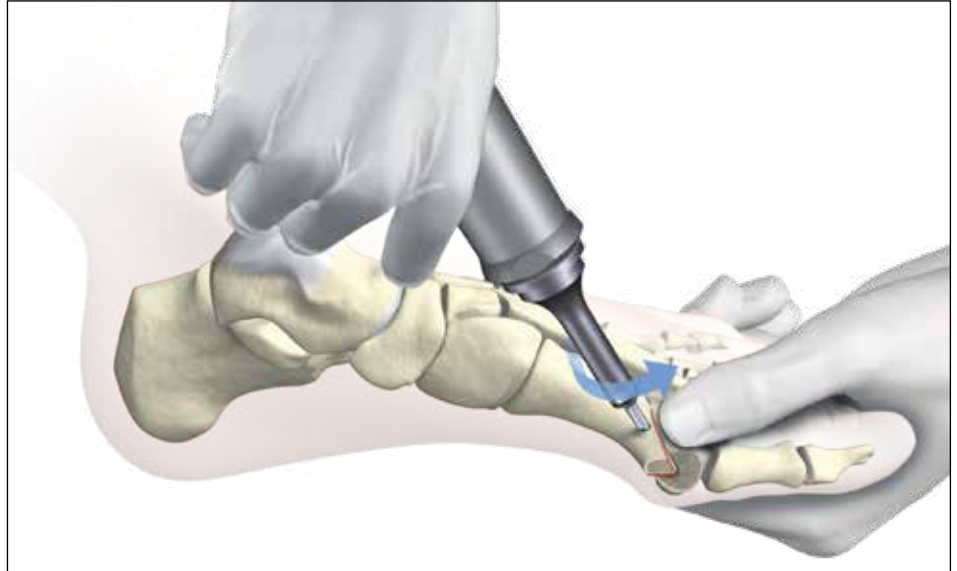


Fig. 38



Fig. 39

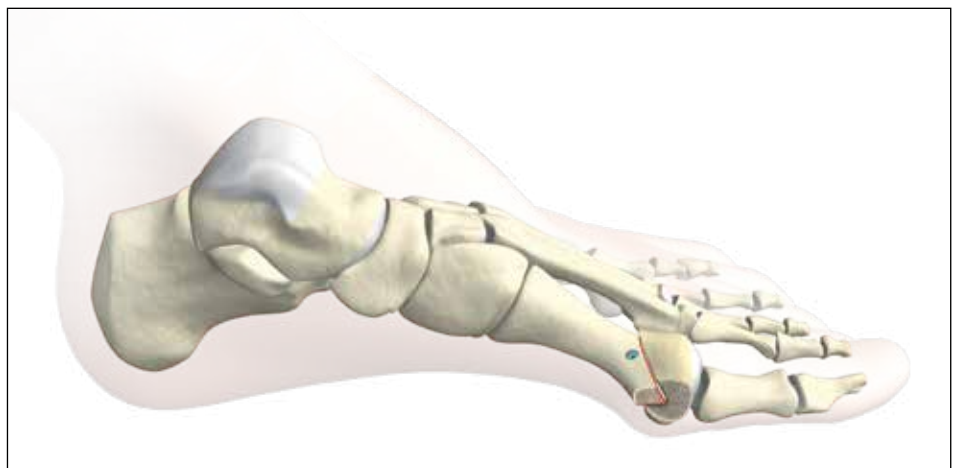


Fig. 40

Additional system information

Sterilization requirements

The ultrasonic generator and foot-switch are not sterile devices and must not enter the sterile field.

Handpiece, handpiece tip and tiptool 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 and tiptool, 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 handpiece plug must be closed prior to the sterilization process.**

Caution:

Consult the Cleaning and Sterilization Guide (OT-RG-1) for information on cleaning and sterilization. The guide is applicable for the following articles:

- handpiece tip
- tiptool
- direct depth gauge
- instrument tray
- handpiece (follow the guidance in the Cleaning and Sterilization Guide only with the restrictions described)

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 symbol for settings
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
& error codes

Troubleshooting

Problem	Possible solution
The AC voltage is incorrect	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Ensure that there is proper airflow around the unit.
The handpiece is heating up	<ul style="list-style-type: none">• Allow the unit to cool before restarting.
A recoverable or non-recoverable error has occurred	<ul style="list-style-type: none">• Consult the error codes on page 21.
The pre-test is not passed	<ul style="list-style-type: none">• Ensure that sufficient torque for the handpiece tip assembly is employed.

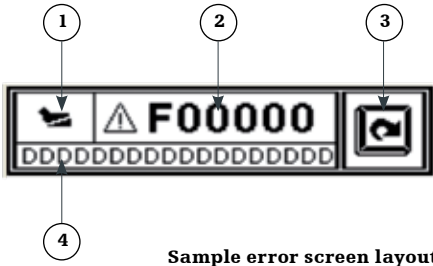
- 1

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

Error code
- 3

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

Text description



Sample error screen layout

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	<ul style="list-style-type: none"> Check handpiece for damage. Rescan handpiece.
F00002	Output voltage too high	
F00004	Ultrasonic generator temperature too high	<ul style="list-style-type: none"> Ensure proper airflow on sides and rear of ultrasonic generator.
F04000	USB communication error	<ul style="list-style-type: none"> Remove the USB. Clear the error and then re-insert the USB.
F00010	Footswitch disconnected during activation	<ul style="list-style-type: none"> Verify footswitch connection.
F00020	Handpiece disconnected during activation	<ul style="list-style-type: none"> Verify handpiece connection.
F00040	Handpiece communication fault	<ul style="list-style-type: none"> Remove and re-insert the handpiece.
F00200	Handpiece data communication fault	<ul style="list-style-type: none"> Remove and re-insert the handpiece. Replace handpiece.
F00080		
F00100		
F00400	Handpiece incompatible with ultrasonic generator	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Unknown or multiple faults have occurred. Clear the error and continue. If errors persist, please contact your authorized Stryker representative.

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	<ul style="list-style-type: none"> Cycle power to the unit (turn the unit off and then on).

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

Foot & Ankle

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