

stryker



VariAx[®] 2

SpeedGuide

Operative Technique



Stryker Plating

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Product Overview

Introduction

The VariAx 2 SpeedGuide is a 3-in-1 instrument that combines the separate components of a drill, drill guide, and depth gauge into a single device.

Single-Handed Drilling

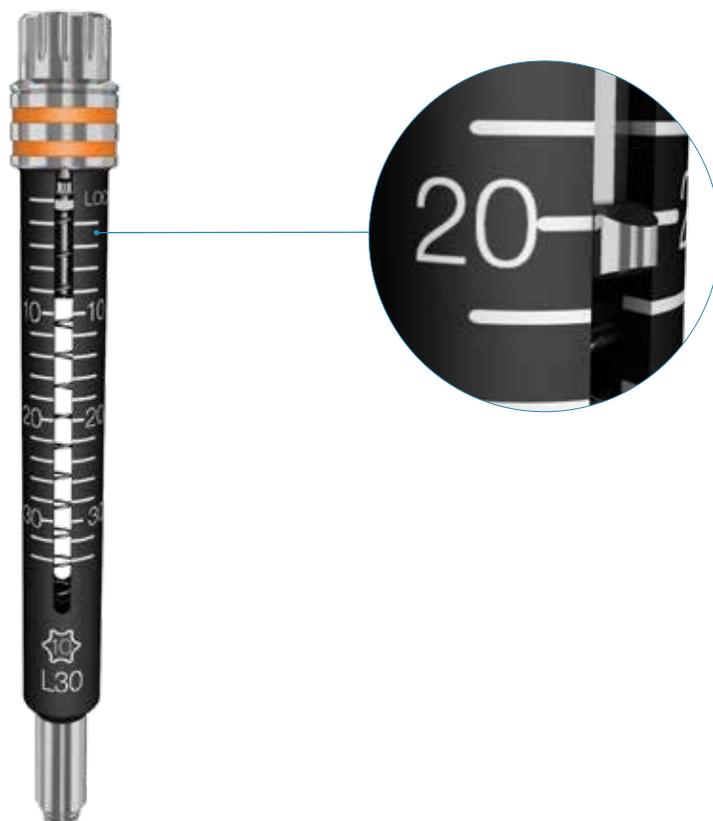
The VariAx 2 SpeedGuide enables single-handed drilling since the drill guide is integrated with the drill, as shown in Figure 1. The surgeon's non-drilling hand is free to help aid in the fracture reduction.

Drilling with Integrated Depth Measuring

A spring-loaded depth marker is attached to the drill and moves relative to the sleeve as drilling is performed. This allows the user the ability to drill and measure in an integrated step.



Fig. 1



Intended Use Statement

Intended Use

The Stryker VariAx 2 Instruments are exclusively intended for use in combination with the VariAx and VariAx 2 Plating Systems and VariAx 2 Screws. The Stryker VariAx 2 Instruments are only to be used by a physician with special skill in traumatology and reconstructive surgery in a sterile operating room environment in hospitals or specially equipped offices. Stryker medical devices must be used sterile.

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 performing your first surgery.

WARNING

Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1). All non-sterile devices must be cleaned and sterilized before use.

WARNING

Multicomponent 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.

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects, contraindications, warnings and precautions.

WARNING

- The surgeon must warn patients of surgical risks, and make them aware of possible adverse effects.
- The patient should be warned that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma, malunion or nonunion.
- The surgeon must warn the patient that the device has a finite expected service life and may need to be removed at some time in the future.

WARNING

The licensed healthcare professional and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants to be applied. Complete information on these subjects must be readily available at the workplace. All instructions for use and labelling must be read carefully prior to clinical use.

WARNING

In the event of contamination, or expiration of shelf life or in the case of products supplied non-sterile, the product must be subjected to an appropriate cleaning process and sterilized by means of a validated sterilization procedure before use, unless specified otherwise in the product labeling or respective product technical guides.

Preparation for Use & Instructions After Use

Assembly / Disassembly

WARNING

The VariAx 2 SpeedGuide should be disassembled before cleaning.

Start disassembly by removing the cap from the drill sleeve. The inner sleeve and spring (connected) may then be removed. Place all items in a cleaning box. Ensure that bone material is removed from the cannula of the drill sleeve before cleaning.

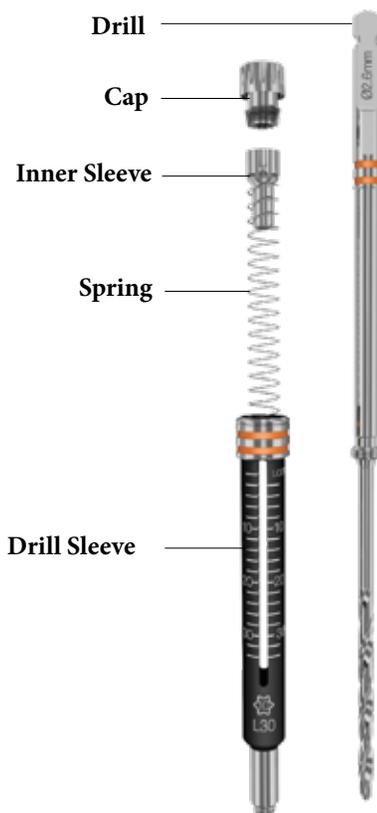
After cleaning, the SpeedGuide can be reassembled. Slide the spring and the inner sleeve into the drill sleeve. Ensure that the notches on the inner sleeve are engaged in the drill sleeve. For final positioning the Inner Sleeve has to be advanced and locked with the Cap.

NOTICE

Ensure that the cap is fully tightened to ensure that it does not loosen during drilling.

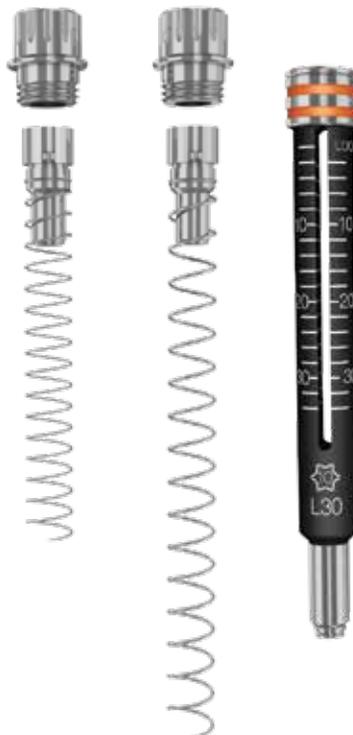
NOTICE

Ensure that the correct spring size is chosen. In the event a wrong spring was assembled, the spring will be either too long or too short when fully inserted.



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Operative Technique

SpeedGuide Selection

Select the appropriate SpeedGuide using the compatibility table below:

Interface/Drill Length	Screw Size	Drill Hole Diameter	SpeedGuide
T8 	2.7mm, 2.4mm, 2.0mm peg 	2.0mm 	
T10 	2.7mm 	2.0mm 	
T10 	3.5mm 	2.6mm 	
T10 	2.7mm 	2.0mm 	
T10 	3.5mm 	2.6mm 	

NOTICE

Despite similarity in appearance, there are 2 separate SpeedGuides for T8 and T10 screw platforms.

Operative Technique

SpeedGuide Locking

Ensure that the drill is in the locked position on the SpeedGuide outer sleeve before engaging the SpeedGuide to the plate hole.

The locked position prevents the drill from moving axially inside the sleeve and facilitates correct engagement of the SpeedGuide in the plate hole.

The locked position can be attained by spinning the outer drill sleeve clockwise with respect to the drill. The locked position can also be attained by holding the outer drill sleeve and reversing the drill using the power tool for a single revolution. The marker will align with the word "LOCK" on the outer drill sleeve when the drill is in the locked position as shown in Figure 3.

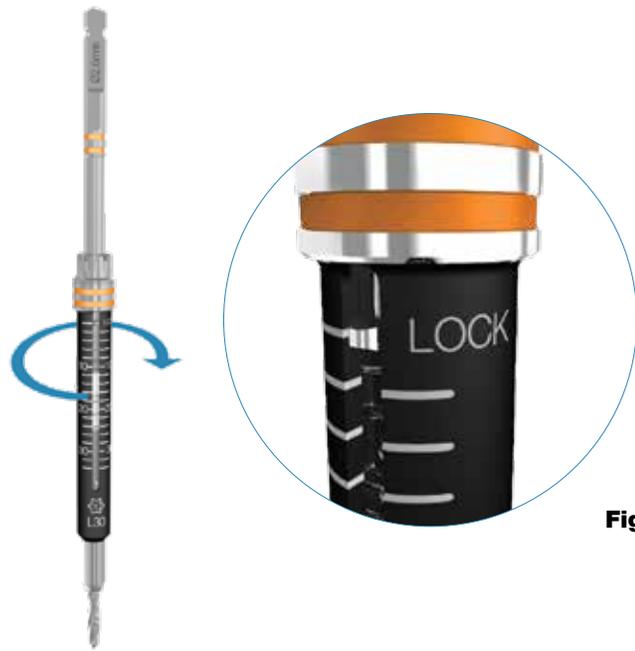


Fig. 3

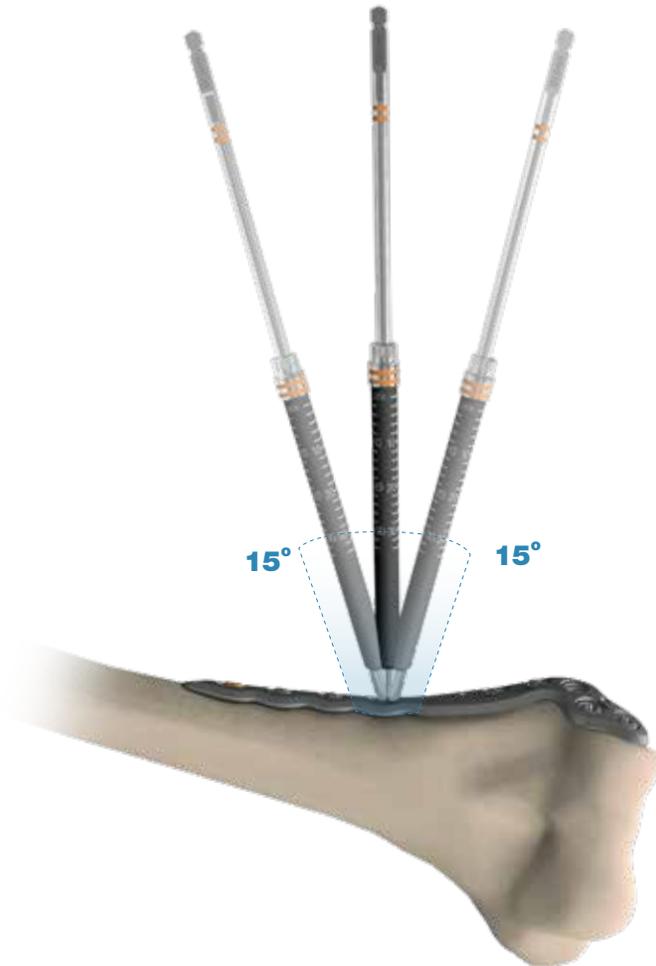
Locked

SpeedGuide Position

While in the locked mode, bring the SpeedGuide into the drill position by placing the tip of the instrument into the conical hole of the plate. Ensure that the SpeedGuide remains within a 15° cone relative to the perpendicular axis of the plate. When correctly placed, the SpeedGuide will engage the plate.

CAUTION

The SpeedGuide must remain engaged in the plate throughout the drilling and measuring process.



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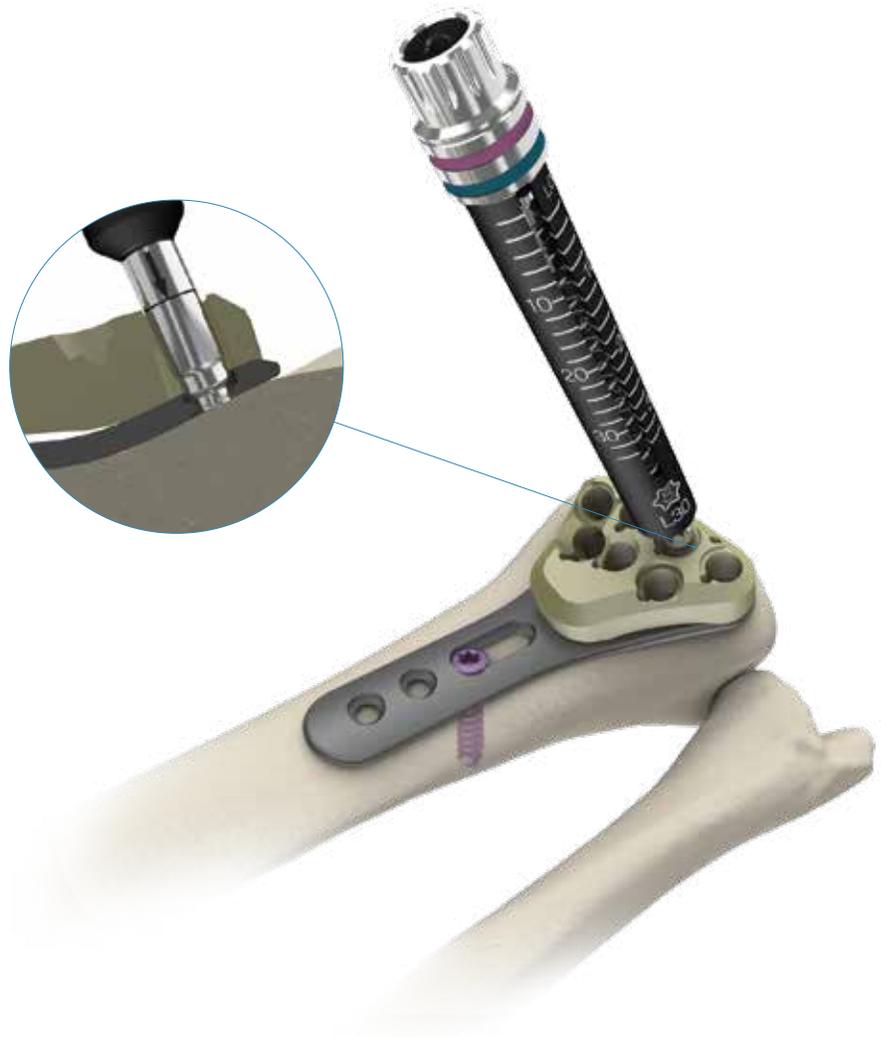
SpeedGuide Position in Conjunction with an Aiming Block

The T8 SpeedGuide may be used in conjunction with the VariAx Distal Radius Aiming Block for drilling a 2.0mm diameter pilot hole. The T8 SpeedGuide is marked with an arrow to indicate that it is fully seated in the Aiming Block.

Likewise, T10 SpeedGuides can be used in conjunction with the VariAx Clavicle Aiming Block to drill a 2.0 or 2.6mm pilot hole. Bring the SpeedGuide into the drill position by placing the tip of the instrument into the selected aiming block hole. When correctly placed, SpeedGuide will engage the plate.

CAUTION

- The SpeedGuide must remain engaged in the plate throughout the drilling and measuring process.
- Ensure that the SpeedGuide is in the locked position when engaging the plate hole.



Operative Technique

Drilling & Depth Measuring

Drill according to the desired screw trajectory. The drill depth can be measured as drilling is performed. The drill sleeve may start to spin with the drill, especially when it becomes congested with debris. The drill should be cleaned to prevent this. Sleeve spinning may be avoided by applying light pressure to the side of the sleeve. If spinning occurs, ensure proper soft tissue protection by utilizing standard retraction instrumentation.

NOTICE

Ensure soft tissue protection when using the speed guide.

NOTICE

When the drill is in the locked position within the sleeve, the drill tip does not rest on bone. Therefore, at the start of drilling, be aware that there may be an initial gap between the drill tip and the bone. As the drill moves from the locked to the unlocked position, an initial forward movement of the drill can be felt.

A suggested method of obtaining a depth reading and screw selection is as follows:

1. Drill until the far cortex is touched
2. Take a depth reading from the SpeedGuide
3. Add the appropriate length of the far cortex to obtain the desired length and proper fixation of the screw



Notes

Notes

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area. The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com. If saving the Instructions for Use, Operative Techniques, Cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

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The products listed above are CE marked.

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