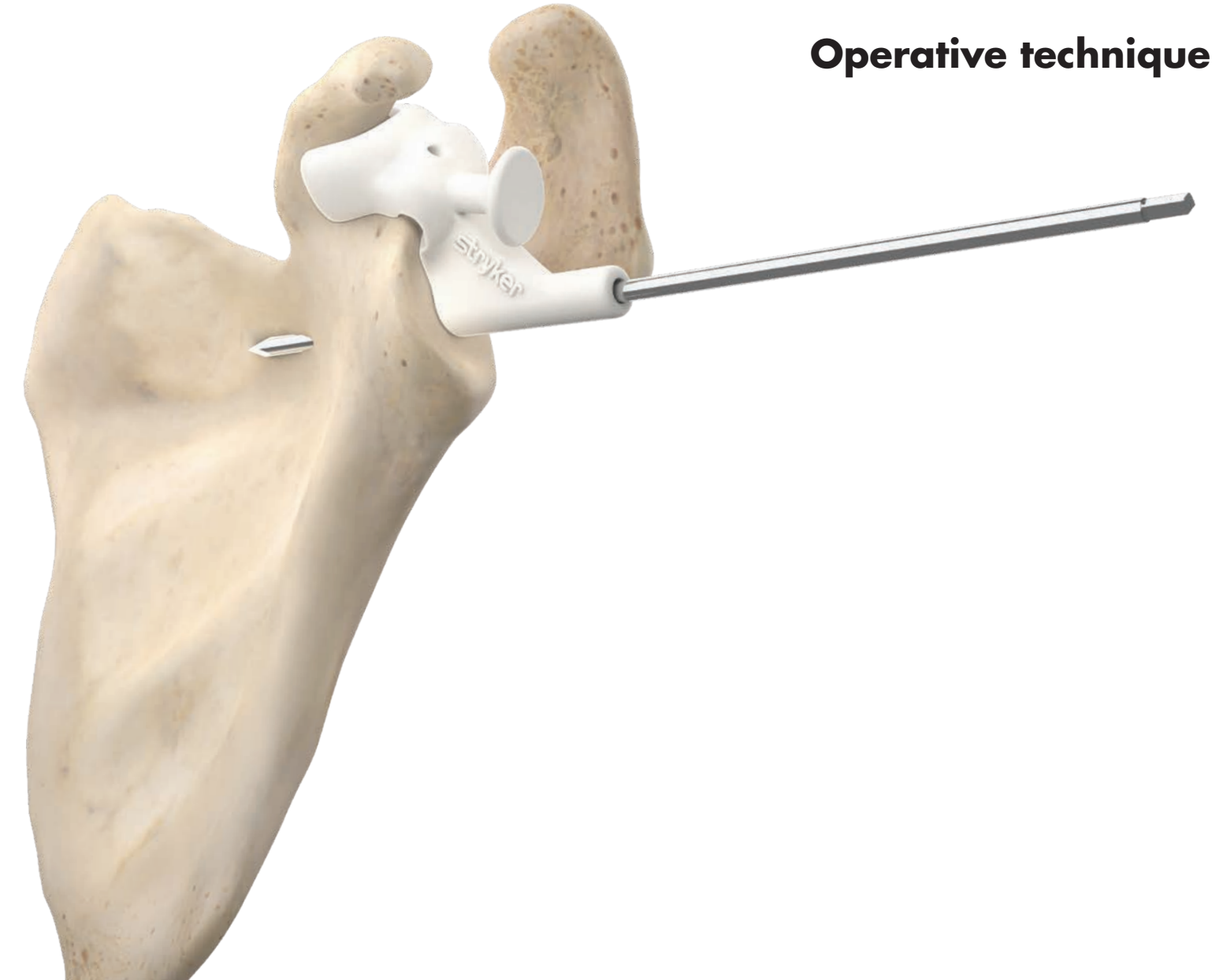
stryker

TrueSight®
Personalized Planning & Targeting System

Operative technique



TrueSight
Personalized Planning & Targeting System

Contents

Introduction

This brochure is presented to demonstrate a surgical technique. The manufacturer of this device does not practice medicine and cannot recommend this or any other surgical technique for use on a specific patient. The choice of the appropriate surgical technique is the responsibility of the surgeon performing the operation.

Caution: Federal law in the USA restricts this device to sale by or on the order of a physician.

See package insert (Instruction for Use) (TRU-IFO-1) 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.

Indications and contraindications

Indications

The TrueSight system is indicated for use as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty by referencing anatomical landmarks of the shoulder that are identifiable on preoperative CT- imaging scans.

The TrueSight system can be used in conjunction with Stryker's following total and reverse shoulder implant systems and their respective compatible components: ReUnion TSA Total Shoulder Arthroplasty System (K183039), ReUnion RSA Reverse Shoulder System (K183039).

The TrueSight Guide is single use only.

Contraindications

The TrueSight system is contraindicated in patients with conditions or diseases that affect bony landmark recognition.

Any active infection of the surgical area where the surgery will be performed is a contraindication for the TrueSight system.

The SurgiCase shoulder planner may restrict use for the TrueSight system when placement of the pilot wire is not optimal for implant placement.

To ensure safety and effectiveness of the TrueSight system guides, the SurgiCase shoulder planner restricts the placement of the pilot wire within the intersection of two cones – a 45° cone from the neutral axis and a 60° cone from the normal of the glenoid face.

Design rationale

TrueSight design rationale
The TrueSight system guide is an ergonomically designed, glenoid positioning guide made of polyamide that is customized to your patient's anatomy based on preoperative computerized tomography (CT) scans.

The software and guide are designed to allow for accurate implant placement and may improve alignment and surgical outcomes.

The TrueSight system is designed to allow you to take your patient's existing preoperative CT scans, identify specific anatomical landmarks, and create a detailed pre-operative plan using Stryker's ReUnion total and reverse shoulder implants.

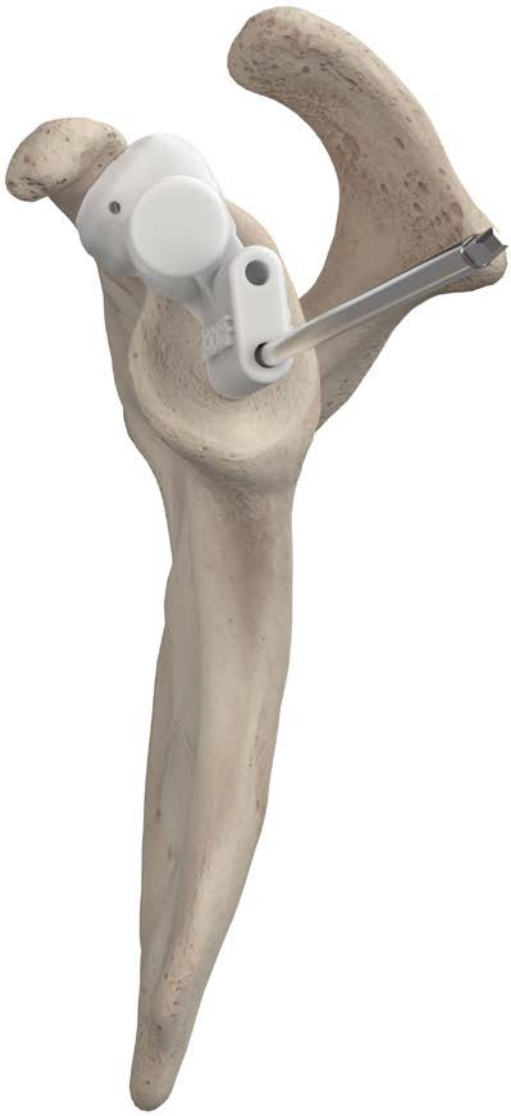


Figure 1

Bone (glenoid) model

The bone model is a 3D reproduction of your patient's glenoid. This 3D model is intended to be used as a reference tool for implant placement in conjunction with the TrueSight guide.

The bone model will be marked with a unique patient identifier, is made of polyamide, and will be provided non-sterile.

TrueSight RSA bone model

Your patient's TrueSight RSA bone model is provided with two separate entry holes. The first hole is for a 1.5mm k-wire that is intended to help stabilize the guide when in use and the second hole represents the entry hole for the 3.2mm pilot wire.

TrueSight TSA bone model

Your patient's TrueSight TSA bone model is provided with three separate entry holes. The first hole is for a 1.5mm k-wire that is intended to help stabilize the guide when in use and the two additional holes represent the entry holes for the 3.2mm pilot wire.

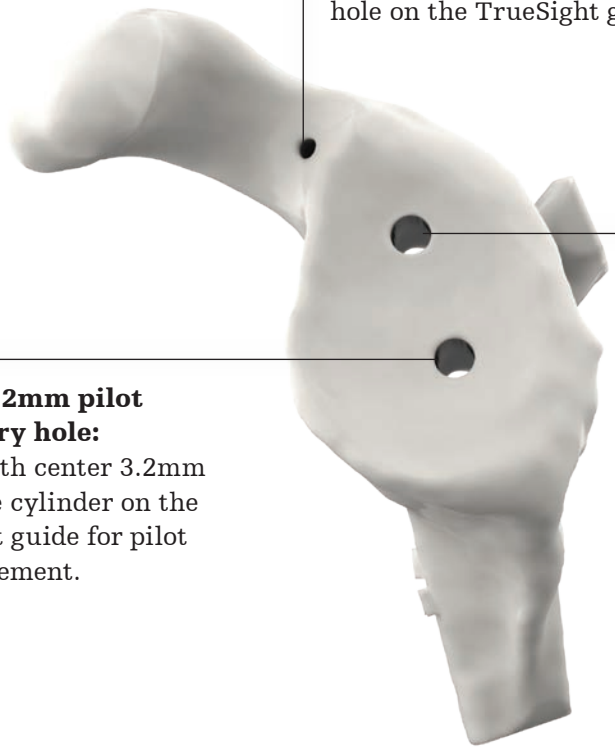


Figure 2

The TrueSight guide

The TrueSight guide is created based off your pre-operative plan and will have several features designed to facilitate the surgical procedure.

The guide will be marked with a unique patient identifier, is made of polyamide, and will be provided non-sterile.

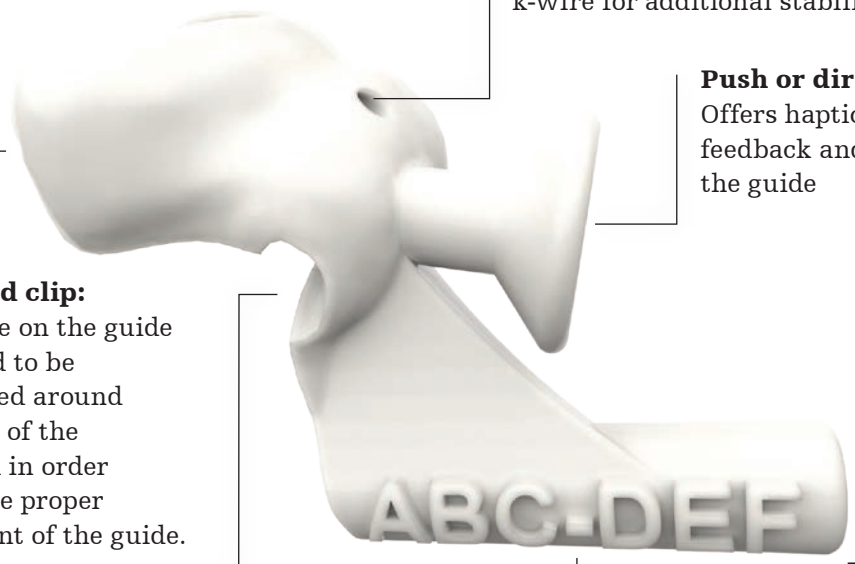
TrueSight RSA guide

The TrueSight RSA guide will be provided with one 1.5mm k-wire entry hole, one 3.2mm pilot wire cylinder, a push/directional handle, a coracoid clip, and a 2mm labrum offset.

TrueSight TSA guide

The TSA TrueSight Guide guide will be provided with one 1.5mm k-wire entry hole, two 3.2mm pilot wire cylinders, a push/directional handle, a coracoid clip, and a 2mm labrum offset.

Figure 3



1.5mm k-wire hole:
A feature to allow the guide to be affixed to the glenoid using a 1.5mm k-wire for additional stability.

Push or directional handle:
Offers haptic or "sensorial touch" feedback and stability when seating the guide

Center 3.2mm pilot wire cylinder:
A feature intended to allow for accurate placement of the 3.2mm pilot wire per your pre-operative plan.

Coracoid clip:
A feature on the guide designed to be positioned around the base of the coracoid in order to ensure proper alignment of the guide.

Patient specific guide identifier:
A unique alphanumeric identifier specific to your patient.

2mm labrum offset:
Bridges between the coracoid clip and the lateral body of the guide designed to prevent soft tissue interference at the antero-superior border of the glenoid surface.

TrueSight TSA guide only

Superior 3.2mm pilot wire cylinder:
A feature intended to allow for accurate marking of the superior peripheral hole to allow execution of planned glenoid rotation. with the 3.2mm pilot wire per your pre-operative plan.

Glenoid preparation

The TrueSight guide was designed to use the base and neck of the coracoid process as an anatomic reference for proper placement of the guide onto your patient's glenoid.

Prepare the anatomy by completely exposing the glenoid face; performing the necessary soft tissue dissection to gain complete visualization of the glenoid and to ensure optimal guide positioning and placement.

Note
Each guide is designed and manufactured to fit securely at the base and neck of the patient's coracoid process.

Upon completion of adequate glenoid exposure, prepare the scapula to receive the TrueSight guide by removing all soft tissue around the neck and lateral face of the coracoid and obtaining hemostasis.

Note
Since the guide fits around the coracoid and anterior glenoid face, adjust retractors to ensure direct contact with coracoid. Place an anterior glenoid retractor at the lower half of the glenoid so as to not interfere with the access to the coracoid.

Compare the fit and position of the guide on the bone model to the planned fit and position on your patient's glenoid.

Caution
Do not remove osteophytes or alter the glenoid bony anatomy before securing the guide.

Caution
Do not damage the bony surface where the guide is in contact with your patient's glenoid anatomy. Do not remove cartilage.

TrueSight guide placement

The following applies to both TSA and RSA TrueSight guides unless otherwise stated.

Secure the guide onto your patient's glenoid by seating the coracoid clip onto the base of coracoid and verify that the pilot wire cylinder is fully contacting or seated on the glenoid face (Figure 4).

Check for gaps between the TrueSight guide and the glenoid anatomy to ensure a proper fit (Figure 5).

Caution
Do not alter the guide before use. Doing so could generate debris which could contaminate the operating region. In addition, altering the guide could compromise its fit to the patient's glenoid anatomy.

Apply and maintain axial pressure on the directional/push handle of the guide to keep contact between the guide and underlying glenoid during pilot wire placement (Figure 6).

Caution
Avoid excessive inferior pushing of the guide. Make sure critical anatomic structures are not damaged during the guide attachment.

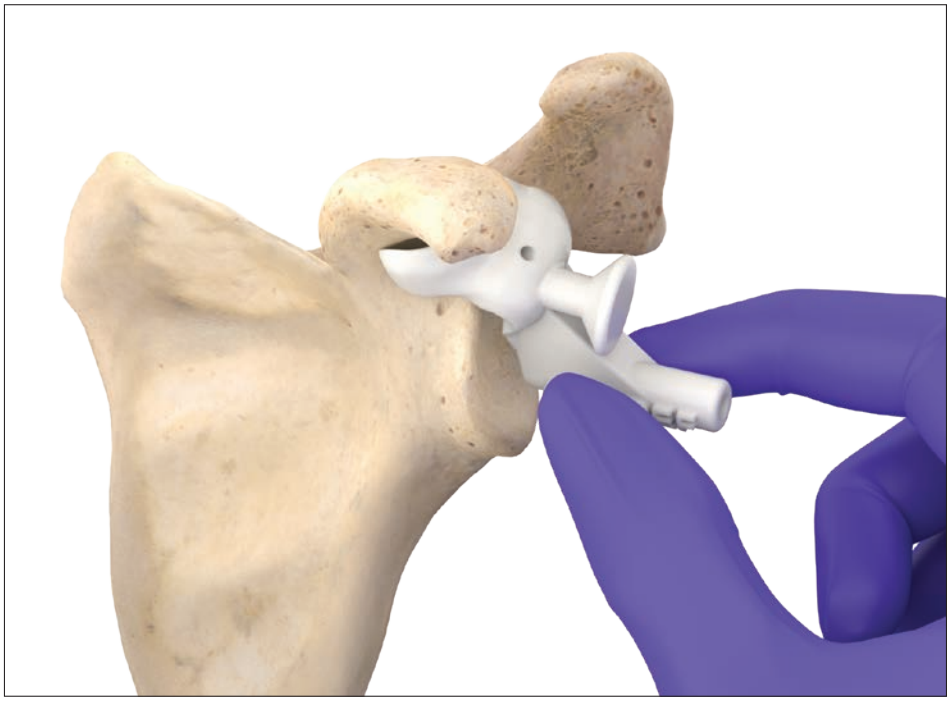


Figure 4

Figure 5

Verify full surface contact is achieved between the guide and the underlying glenoid face with the exception of the 2mm Labrum Offset over the superior glenoid rim (Figure 6).

Note

There is approximately 1 – 2 mm of clearance between the bottom of the 2mm labrum offset on the guide and the superior glenoid rim (Figure 8)

Tech Tip

A 1.5mm k-wire can be used to affix the guide to the glenoid using the 1.5mm k-wire hole (Figure 7).

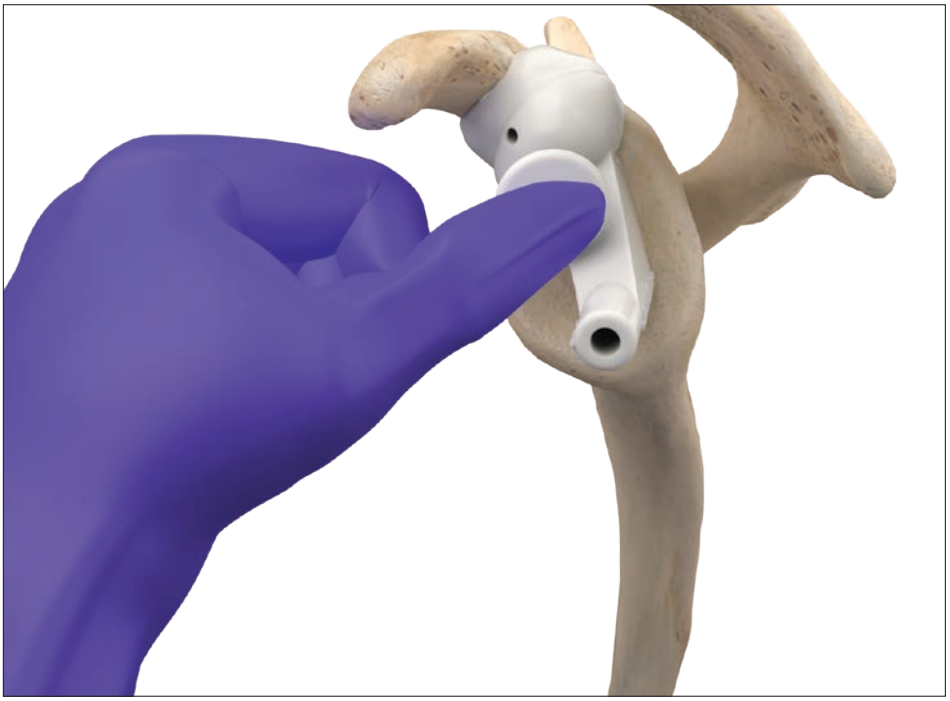


Figure 6

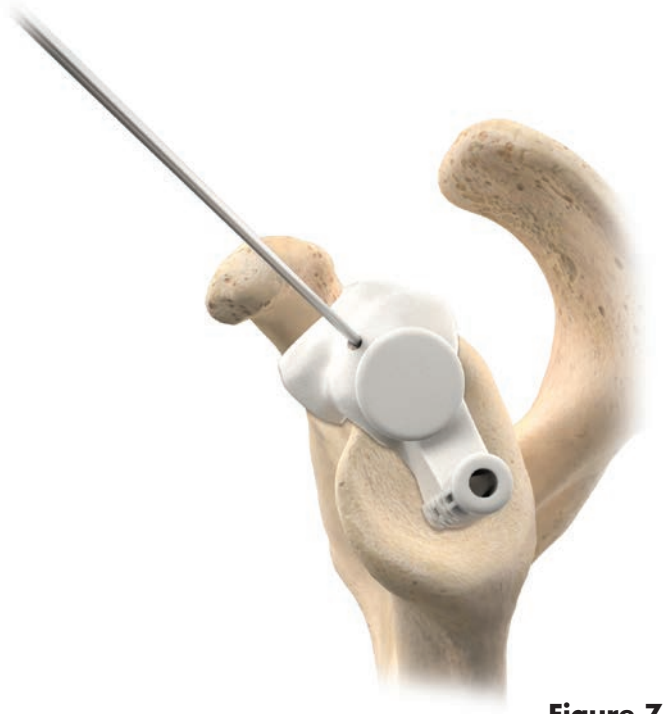


Figure 7

Figure 8

RSA pilot wire placement

Once the guide is seated properly, apply pressure to the directional handle and drive the pilot wire into the glenoid using the pilot wire cylinder (Figure 9).

Note
Confirm the guide fit prior to and after pilot wire placement for added measure.

While driving the pilot wire, irrigate to reduce heat and any debris generated.

Make sure the guide maintains its position on the fitting surface during pilot wire placement.

Verify that the correct pilot wire diameter is being used which corresponds to the guide's diameter.

If the guide was initially positioned using the 1.5mm stabilizing k-wire, remove the k-wire prior to removing the guide while leaving the 3.2mm pilot wire in place.

If the guide cannot be easily removed over the pilot wire, first remove the pilot wire, then remove the guide, and then re-insert the pilot wire carefully into the bone.

Follow the appropriate ReUnion RSA reverse shoulder implant operative technique to complete the steps required to finalize the glenoid preparation for the prosthesis.

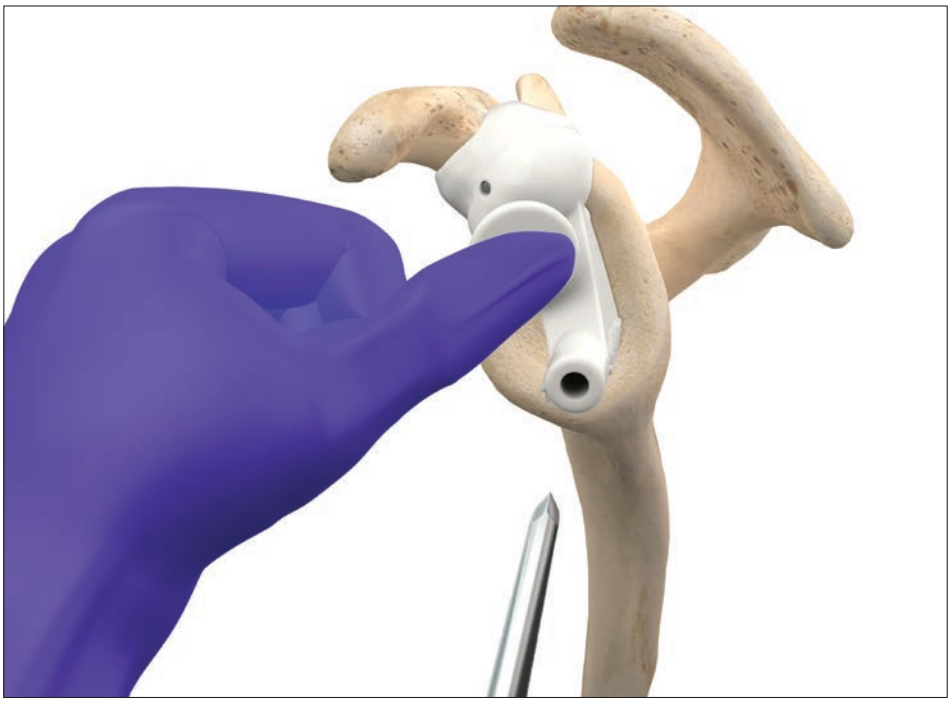


Figure 9

Caution
Do not modify the pilot wire direction by driving through the pilot wire cylinder's surface.

Caution
Do not use the guide if it is not possible to place the pilot wire in a stable position on the patient's glenoid anatomy as the instability can negatively impact the guide's ability to transfer the pre-operative plan. In the event the TrueSight Guide cannot be used, please follow the standard surgical technique.

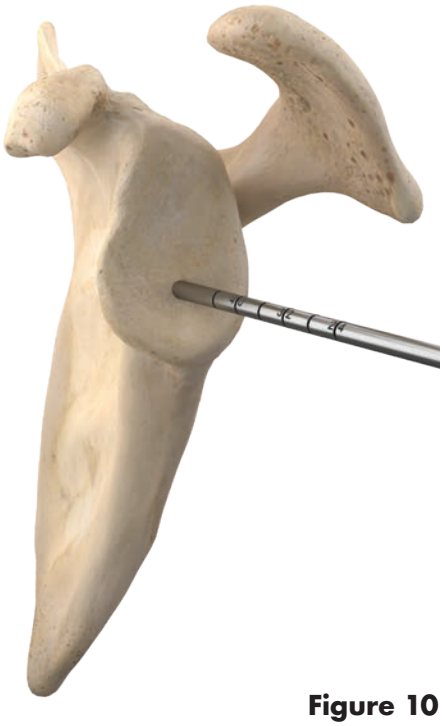


Figure 10

TSA pilot wire placement

Once the guide is seated properly, apply pressure to the directional handle and drive the pilot wire into the glenoid using the superior pilot wire cylinder. Drilling is not bi-cortical, instead the pilot wire should only perforate the subchondral plate and not be advanced past that point. (Figure 11).

Continue to apply pressure to the directional handle and drive the pilot wire into the glenoid using the center pilot wire cylinder without perforating the far cortex of the scapula.

Note
Confirm the guide fit prior to and after pilot wire placement for added measure.

While driving the pilot wire, irrigate to reduce heat and any debris generated.

Make sure the guide maintains its position on the fitting surface during pilot wire placement.

Verify that the correct pilot wire diameter is being used which corresponds to the guide's diameter.

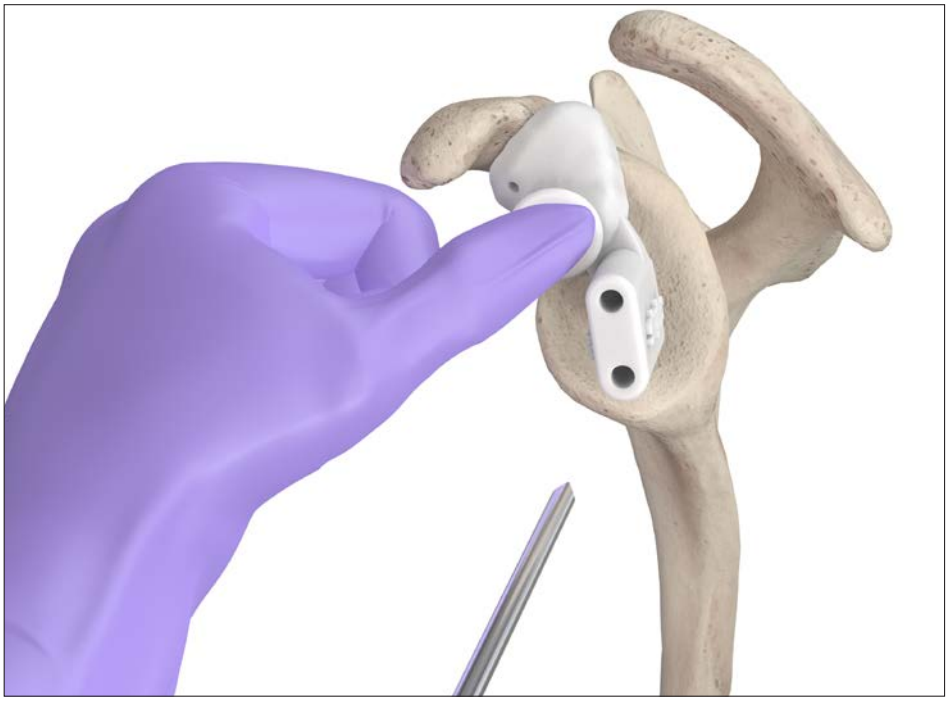


Figure 11

If the guide was initially positioned using the 1.5mm stabilizing k-wire, remove the k-wire prior to removing the guide while leaving the 3.2mm pilot wire in place.

If the guide cannot be easily removed over the pilot wire, first remove the pilot wire, then remove the guide, and then re-insert the pilot wire carefully into the bone.

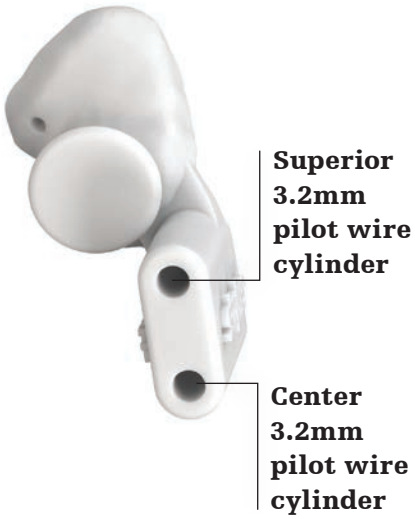


Figure 12

Follow the appropriate ReUnion TSA total shoulder operative technique to complete the steps required to finalize the glenoid preparation for the prosthesis.

When preparing the peripheral peg holes of the pegged or keeled glenoid implants, ensure that the superior peripheral hole is prepared first. Place the Pegged or Keeled Drill Guide onto the glenoid face, taking care to align the previously drilled superior hole with the opening in the drill guide.

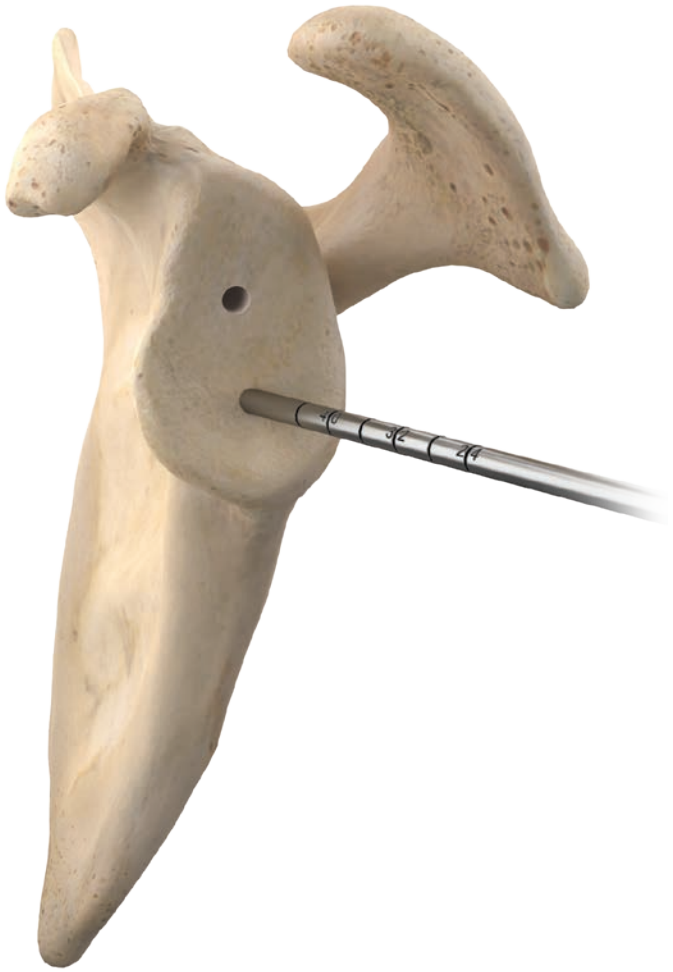


Figure 13

Caution
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Caution
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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.

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