



Form meets Function

FUSION™

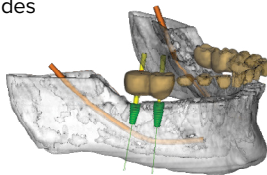
Guided Surgery

The guided surgery workflows for the Fusion implant system offer more control and precision for osteotomy development than traditional protocols. The surgical kit uses a streamlined design, with color coding to simplify the surgical process. The included instruments allow for guided placement of all Fusion implants, regardless of length or diameter.



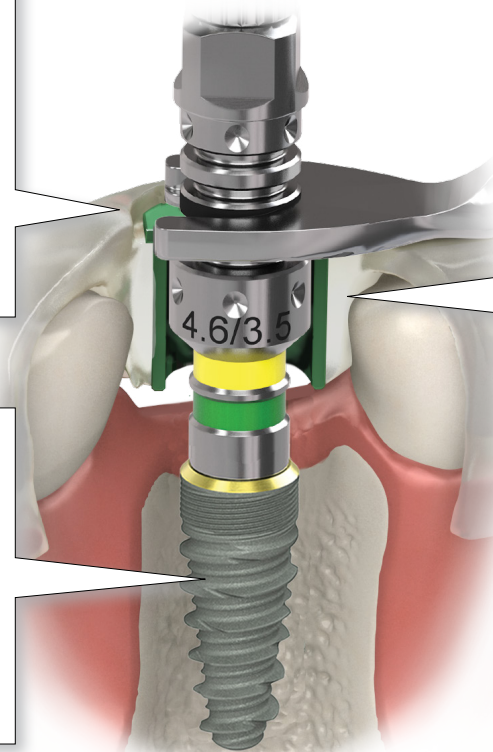
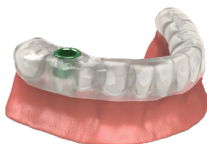
surgical guide flexibility

Open architecture design for fabrication of surgical guides



guided implant control

Implant is placed to planned depth using a surgical guide created from a virtual treatment plan

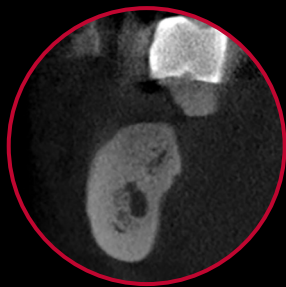


ease of use

Guided cylinders and instruments are color-coded to ensure proper component usage



Surgical plan to Surgical guide



1. Clinical step CT scan appointment

Initial patient records and CT scan. CT scan protocols will vary depending on the guide manufacturer.



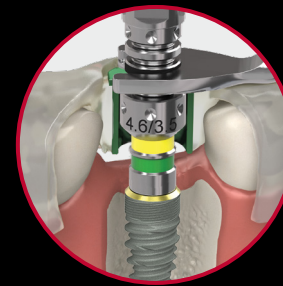
2. Clinical step Treatment plan

Diagnose and treatment plan for guided surgery. Determine if adequate vertical space is available to accommodate the surgical guide and related components. Import CT scan data into the treatment planning software and design the case.



3. Partner step Guide fabrication

Guide manufacturer fabricates the surgical guide using the virtual treatment plan, Fusion guided cylinders and pilot cylinders. A patient-specific surgical protocol is generated for the clinician to follow.



4. Clinical step Guided surgery

Clinician performs the procedure using the surgical guide and the Intra-Lock guided kit while following the surgical protocol.



The surgical guide must be fabricated using authentic Fusion guided cylinders and pilot cylinders. Please contact your guide manufacturer for further information.

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GUIDED INSTRUMENTS

Guided Kit



IL-GK Intra-Lock Guided Kit

For use with a surgical protocol developed by digital planning software. Includes instrumentation required for placement of all Fusion implants.

IL-GT Intra-Lock Guided Tray

Does not include instrumentation.

features:

- color-coded layout for easy identification
- easy to disassemble and assemble during cleaning
- spare slots for additional instrumentation
- single kit for placement of Intra-Lock Fusion implants

Guided Cylinders & Pilot Sleeves

Patient anatomy and the virtual treatment plan determine the guided cylinder and/or pilot sleeve to be used in the surgical guide. Two different guided cylinder diameters and one pilot sleeve are available.



Product Description

Ref. No.

Guided Cylinder, Yellow (pack of 10)

GS-GC-YW

Guided Cylinder, Green (pack of 10)

GS-GC-GN

Guided Cylinder, Pilot (pack of 10)

GS-GC-P

Tissue Punches



Product Description

Ref. No.

Guided Surgery Tissue Punch, Yellow

GS-TP-YW

Guided Surgery Tissue Punch, Green

GS-TP-GN

GUIDED INSTRUMENTS

Guided Surgery Drills

Guided surgery drills with definitive depth stops follow the standard drill sequences and come in four different lengths. The patient-specific surgical protocol that accompanies the surgical guide will indicate which drill length and widths to use.



	2.5mm width	2.8mm width	3.2mm width	3.7mm width	4.1mm width	4.5mm width
17mm stop	GD-2517	-	GD-3217	GD-3717	GD-4117	GD-4517
21mm stop	GD-2521	GD-2821*	GD-3221	GD-3721	GD-4121	GD-4521
24mm stop	GD-2524	GD-2824*	GD-3224	GD-3724	GD-4124	GD-4524
28mm stop	GD-2528	GD-2828*	GD-3228	GD-3728	GD-4128	GD-4528

* 2.8mm instruments are only required to place the 3.3mm diameter implant.

Drill Guides

Drill guides are color-coded to match the guided cylinders. Use the proper size drill guide with the corresponding drill diameter to sequentially widen the osteotomy. The text on the drill guide specifies the corresponding drill width.

	2.5mm	2.8mm	3.2mm	3.7mm	4.1mm	4.5mm
Yellow	DG-YW-25 	DG-YW-28* 	DG-YW-32 	-	-	-
Green	DG-GN-25 	-	DG-GN-32 	DG-GN-37 	DG-GN-41 	DG-GN-45

* 2.8mm instruments are only required to place the 3.3mm diameter implant.

Drill Guide Handle



Product Description

Guided Surgery Drill Guide Handle

Drill guide handles are used in combination with the drill guides. The handles can be assembled pre-operatively with the specified drill guides.

Ref. No.

GS-DGH

GUIDED INSTRUMENTS

Screw-retained Implant Drivers

Screw-retained implant drivers are used to pickup and seat implants when used with a 4mm square ratchet. The driver is secured to the implant using the captured screw and can be easily released after implant placement. Use the depth stops to seat the implants to the planned depth. Orient the implant hex using the dimples as a visual reference. The screw-retained drivers' low profile improves access when vertical space is limited. These drivers can be used with a handpiece when using the 4mm Square Driver Converter.



Product Description	Ref. No.
Guided Surgery Grey Implant Driver	GS-GY-ID
Guided Surgery Yellow Implant Driver	GS-YW-ID

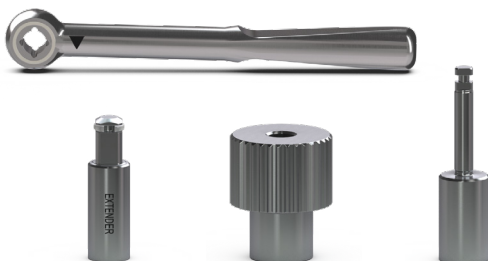
Depth Stops



Product Description	Ref. No.
Guided Surgery Depth Stop Handle	GS-DH
Engages the implant driver to place the implant at the proper depth through the guided cylinder.	
Guided Surgery Disposable Depth Stop	GS-DDS
Snaps onto the specified stop position preoperatively for hands-free implant depth control.	

Ratchet & Attachments

The driver attachments allow for the screw-retained drivers to be extended or used manually.

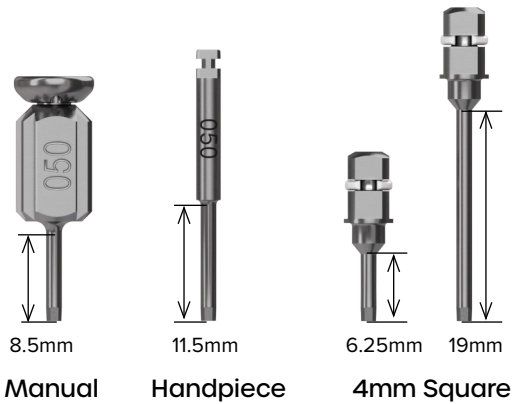


Product Description	Ref. No.
Ratchet	R-4MM
Ratchet & Hand Wrench Extender	RE-4MM
Hand Wrench	HW-4MM
Guided Surgery Driver 4mm Square Drive Converter	GS-4SC
Drive converter allows the screw-retained drivers to be used with a handpiece.	

GUIDED INSTRUMENTS

.050 Hex Drivers

For installation and removal of cover caps, prosthetic and abutment screws.



Product Description	Ref. No.
.050 Hex Driver, Manual	HD-MAN
.050 Hex Driver, Handpiece	HD-ISO
.050 Hex Driver, 4mm Square, Short	HD-4MMS
.050 Hex Driver, 4mm Square, Long	HD-4MML

Torque Wrenches



Product Description	Ref. No.
30 Ncm Torque Wrench	300-430
ITL Precise Adjustable Torque Wrench	ATW


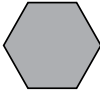





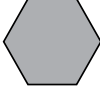




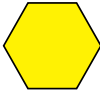




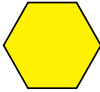



Place both implants and abutments with 9 distinct torque settings (15, 20, 25, 30, 35, 40, 45, 50 and 60 Ncm). A simple twist of the handle locks in precision-engineered torque values and guarantees accuracy and repeatability.

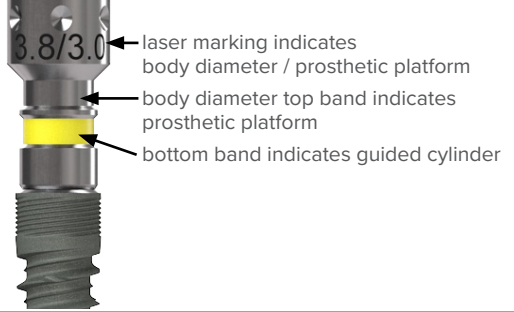

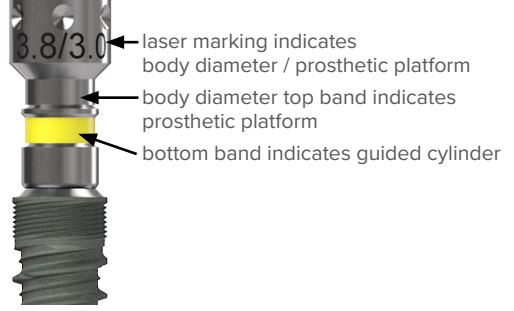


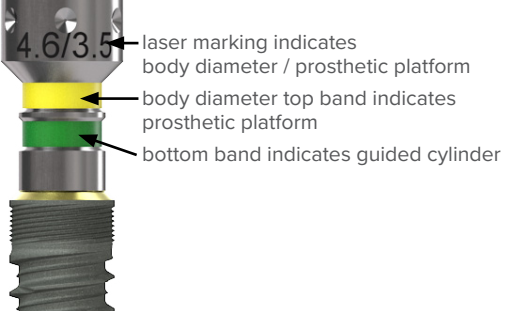




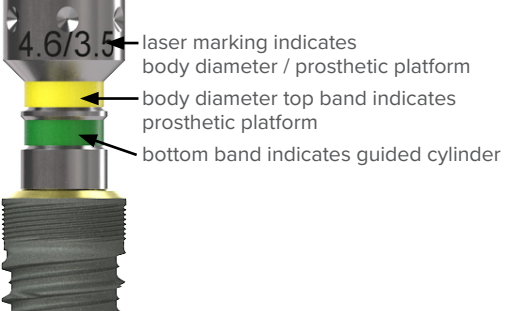
Drive Converter & Fixation Pins



Product Description	Ref. No.
Guided Drill, Grey, 2.0 x 24mm	GD-2024
Used with GS-FPS to develop site for fixation pins. Also used for pilot guided protocols.	
Guided Surgery Fixation Pin	GS-FP
Used to stabilize guide during extraction or multi-unit procedures	
Guided Surgery Fixation Pin Sleeve	GS-FPS
Retains the fixation pin in the guide during use.	

**COLOR CODING &
DRILL SEQUENCE**

Implant Body	Prosthetic Connection	Guided Cylinder	Drill Guides	Guided Surgery Drill, Grey, 2.5mm	Guided Surgery Drill, Purple, 2.8mm
 3.3mm (10.5, 12 & 15mm lengths)	 Gray	 Yellow	 Yellow		
 3.8mm (9, 10.5, 12 & 15mm lengths)	 Gray	 Yellow	 Yellow		
 4.2mm (9, 10.5, 12 & 15mm lengths)	 Yellow	 Green	 Green		
 5.0mm (7.5, 9, 10.5, 12 & 15mm lengths)	 Yellow	 Green	 Green		
<p><i>*Full implant specifications and ordering information can be found in document L01082.</i></p>				<p>Initiate osteotomy. Recommended drill speed: 1,500 - 2,000 RPM.</p>	

<p>Guided Surgery Drill, Yellow, 3.2mm</p>	<p>Guided Surgery Drill, Green, 3.7mm</p>	<p>Guided Surgery Drill, Red, 4.1mm</p>	<p>Guided Surgery Drill, Blue, 4.5mm</p>	<p>Grey Implant Driver 3.3mm, 3.8mm implants Yellow Implant Driver 4.2mm, 5.0mm implants</p>
				
				
				
				
<p>Develop osteotomy. Recommended drill speed: 1,000 RPM.</p>				<p>Place implant matching the length of the prepared osteotomy. Maximum 30 RPM or use manually.</p>

Instructions For Use

This surgical manual serves as a reference for using the Guided Kit. It is intended solely to provide instructions on the use of Intra-Lock products. It is not intended to describe the methods or procedures for diagnosis, treatment planning, or placement of implants, nor does it replace clinical training or a clinician's best judgment regarding the needs of each patient. Intra-Lock strongly recommends appropriate training as a prerequisite for the placement of implants and associated treatment.

The procedures illustrated and described within this manual reflect idealized patient presentations with adequate bone and soft tissue to accommodate implant placement. No attempt has been made to cover the wide range of actual patient conditions that may adversely affect surgical and prosthetic outcomes. Clinician judgment as related to any specific case must always supersede any recommendations made in this or any Intra-Lock literature.



Before beginning any implant surgical procedure using the Intra-Lock Guided Kit:

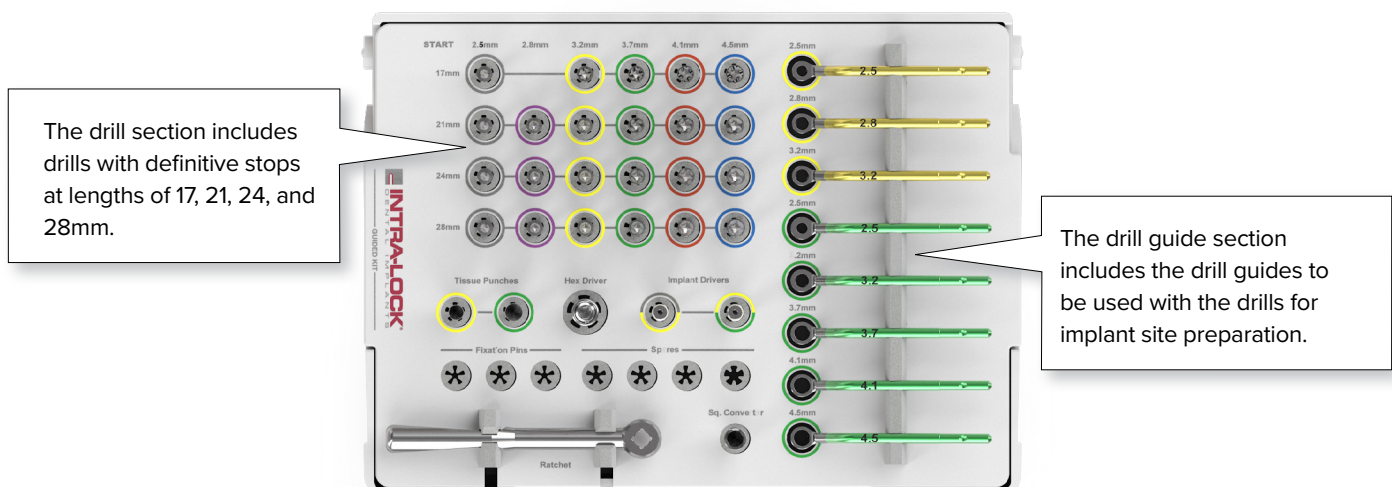
- Read and understand the Instructions for Use that accompany the products.
- Clean and sterilize the surgical tray and instruments per Instructions for Use.
- Become thoroughly familiar with all instruments and their uses.
- Study surgical kit layout and iconography.
- Design a surgical treatment plan to satisfy the prosthetic requirements of the case.

Indications

The Guided Kit is intended to facilitate the creation of an osteotomy for placement of Fusion implants using a surgical guide that incorporates authentic Fusion guided cylinders. The bone cutting instruments are intended for use in the mandible or maxilla for partially and fully edentulous arches.

Surgical Kit Instructions

Prior to use, clean and sterilize the surgical tray and instruments according to the Instructions for Use included with the kit. Study the surgical kit layout, color coding and iconography. Surgical assistants should be thoroughly familiar with all instruments and their uses prior to initiating the surgical procedure.



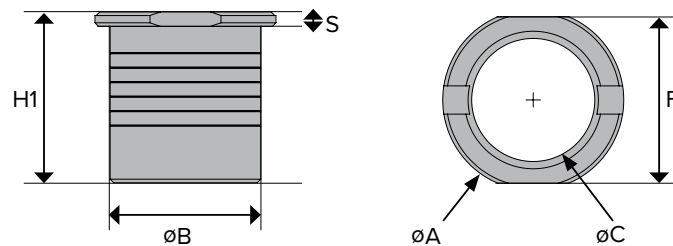
OFFSETS & DIMENSIONS

Guided Offsets For Implants

The implant length, requested in the treatment plan, will determine the cylinder offset, drill length and depth stop position. Some implant lengths have more than one option available. Choose the option that best fits the treatment plan by factoring in occlusal space and crown height.

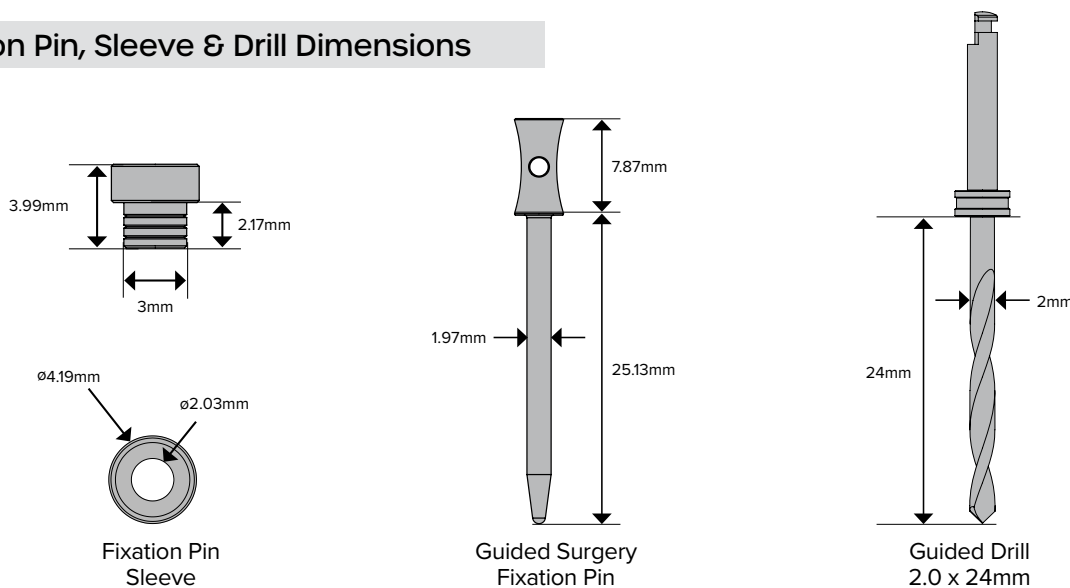
Implant Length	7.5mm		9mm	10.5mm		12mm	15mm
Offset	8.03mm	12.03mm	10.53mm	9.03mm	12.03mm	10.53mm	11.53mm
Drill	17mm	21mm	21mm	21mm	24mm	24mm	28mm
Stop Position	SP1	SP4	SP3	SP2	SP4	SP3	SP4

Guided Cylinders



	Height (H1)	Shoulder Height (S)	Body Outer Diameter (B)	Top Outer Diameter (A)	Inner Diameter (C)	Flat to Flat (F)	Drill Guide Requirement	Implant Body Diameter
GS-GC-YW	5.99mm	0.51mm	5.28mm	6.35mm	4.32mm	5.84mm	yes	3.3mm & 3.8mm
GS-GC-GN			6.07mm	7.32mm	5.11mm	6.58mm	yes	4.2mm & 5.0mm

Fixation Pin, Sleeve & Drill Dimensions



SURGICAL OVERVIEW

Pre-surgery

Inspect the surgical guide for defects and potential weak areas. Visually evaluate the position of the guided and/or pilot cylinder to ensure it is placed according to the treatment plan.

Ensure the thru hole of the drill guides, pilot and guided cylinders are free of debris.

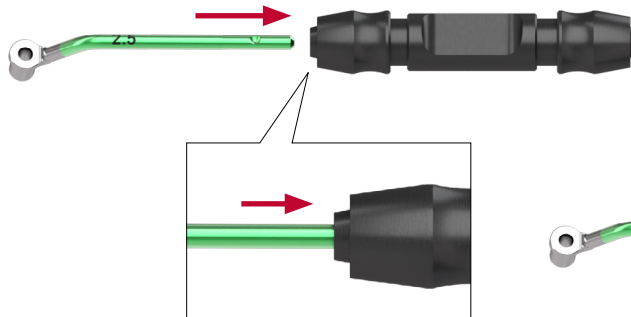
The surgical guide must have a stable fit to the patient's anatomy. If a stable fit cannot be obtained at time of surgery, the surgical guide should not be used. Do not use excessive force to seat the surgical guide.

Review the surgical plan and instruments within the kit prior to surgery. Drill use should be cross-checked against the drill usage chart. Any drills that are worn, marked or dull should be replaced. Be conscious of the specified implant driver stop position (SP1 – SP4) if indicated.

Place the drill in the handpiece and check the fit with all the drill guides and pilot cylinders prior to surgery.



Drill Guide Handle (Optional)



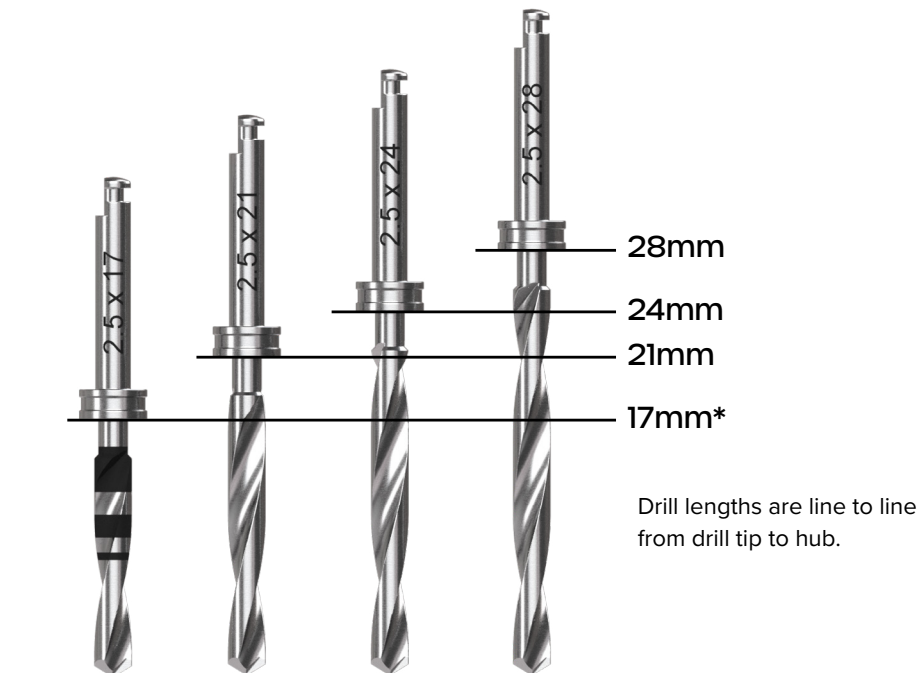
Assemble the drill guide handle. Insert the drill guide into the handle while depressing the end portion.



Firmly hold the drill guide handle or drill guide while progressing through the drill sequence.

Drill Depth Stops

The drills include lengths of 17, 21, 24, and 28mm and the standard diameters for all Fusion implants. All drills included with this system are externally irrigated and require an intermittent drilling technique with steady sterile irrigation.



** only 17mm drills have depth markings, should they need to be used without the guide.*

Important Considerations

- Peri-operative oral rinses with a 0.12% Chlorhexidine Digluconate solution have been shown to significantly lower the incidence of post-implantation infectious complications.¹ A pre-operative 30-second rinse is recommended, followed by twice daily rinses for two weeks following surgery.
- Drilling must be done under a constant stream of sterile irrigation. A pumping motion should be employed to prevent overheating the bone. Surgical drills should be replaced when they are worn, dull, corroded or in any way compromised. Intra-Lock recommends replacing drills after 12 to 20 osteotomies.²
- There is a risk of injury to the mandibular nerve associated with surgical drilling in posterior mandibular regions. To minimize the risk of nerve injury, it is imperative that the clinician understands the virtual treatment plan created and ensures the surgical guide corresponds to the clinician's virtual treatment plan.

Placing a 4.2 x 10.5mm Fusion Implant

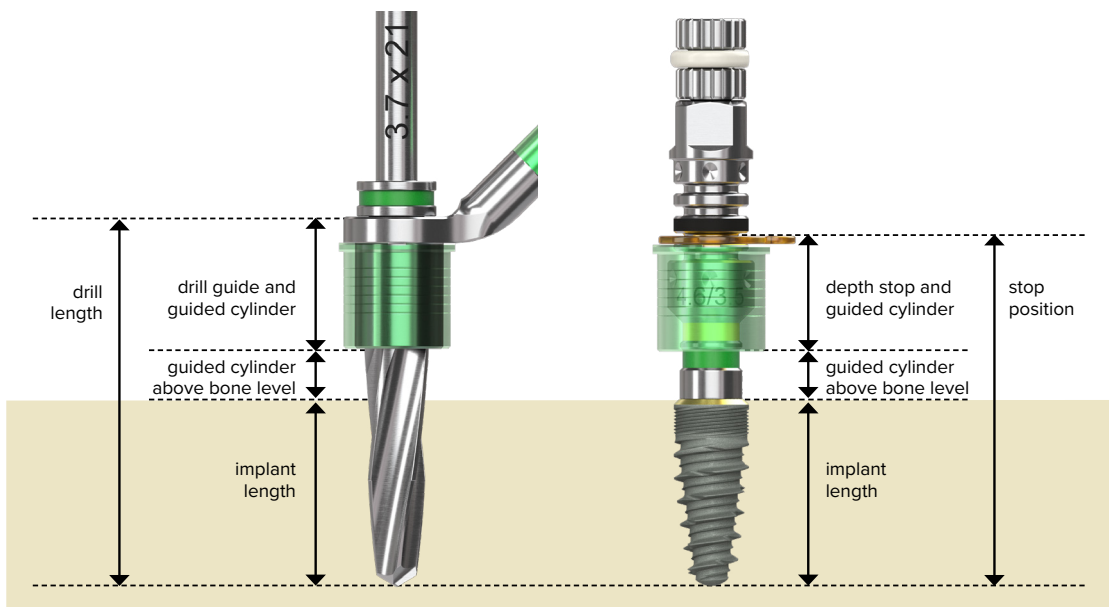
A patient-specific surgical protocol is included with the surgical guide. The surgical protocol includes the recommended components to be used for each implant site. Verify the protocol corresponds to the submitted virtual treatment plan prior to surgery.

Clinician judgment must always supersede any recommendations in the surgical protocol and any Intra-Lock Instructions for Use.

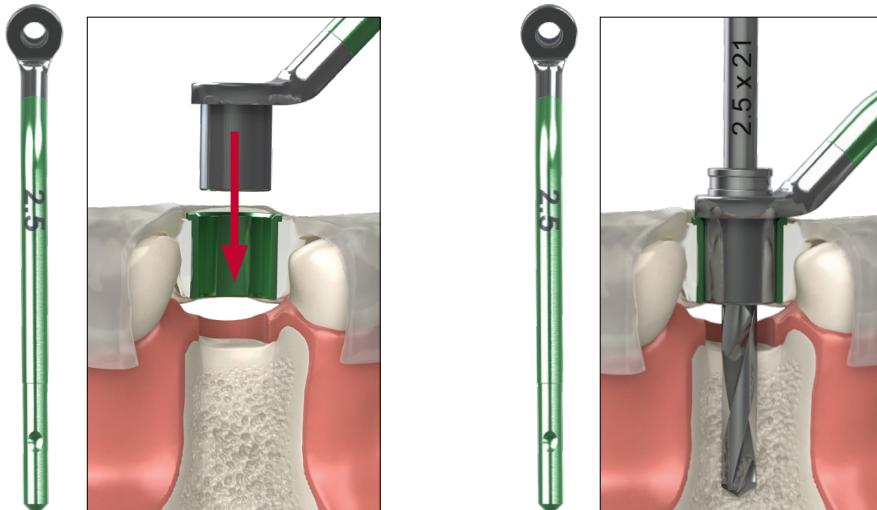
Sample Protocol for Intra-Lock Guided Kit	
implant label	29
implant type	IL-4210
implant length	10.5
guide site	Complete
implant site preparation	
drill length	21
drill guide/drill	2.5
drill guide/drill	3.2
drill guide/drill	3.7
drill guide/drill	
drill guide/drill	
guided implant placement	
depth position	SP2
implant driver	Yellow

Clinician judgement, as related to individual patient presentations, must always supersede recommendations in any Intra-Lock Instructions for Use (IFU). Additional technical information may be viewed and/or downloaded at eifu.intra-lock.com.

Guided Cylinder Position Reference



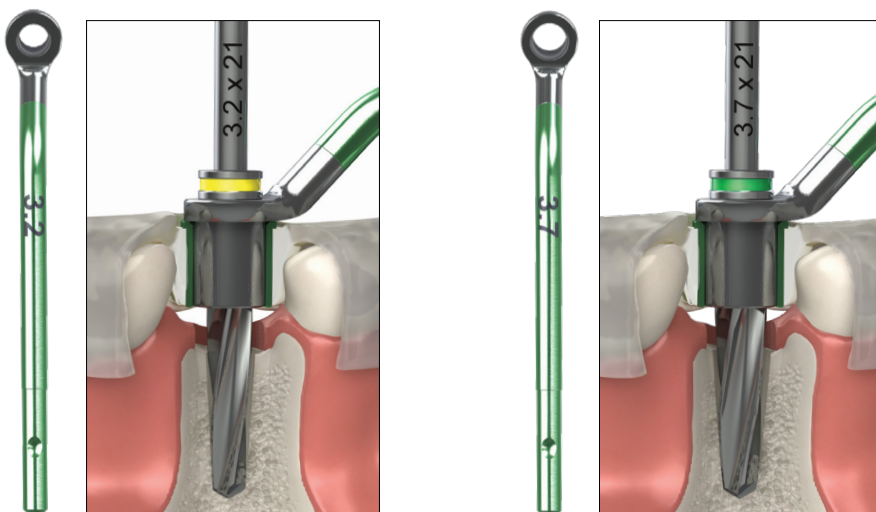
2.5 Pilot Drill and Drill Guide



Initiate osteotomy with pilot drill

- Select the 2.5 x 21mm drill
- Place the Green 2.5mm drill guide in the Green guided cylinder
- Insert the drill in the drill guide and use short, light strokes to progressively advance the drills until the depth stop rests on the drill guide
- Remove the 2.5mm drill guide

Width Increasing Drills and Drill Guides



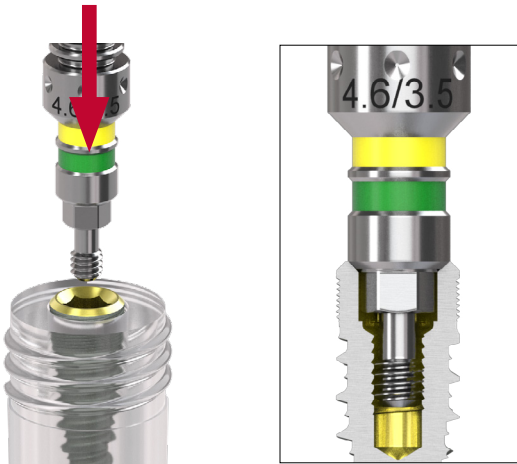
Incrementally widen the osteotomy

- Continue through the drill sequence using the specified drills and drill guides

IMPLANT PLACEMENT

Implant Transfer

Vial caps are a surgical reference and are color-coded to indicate body diameter (3.3mm=purple, 3.8mm=yellow, 4.2mm=green, 5.0mm=blue). Implant drivers are color-coded by prosthetic platform (Grey, Yellow) and guided cylinder (Yellow, Green) for proper mating with the implant connection.



Engage the implant with screw-retained driver by inserting the driver into the implant platform and tightening the screw. The driver can then be picked up with a handpiece by using the converter (GS-4SC) or manually using a ratchet.

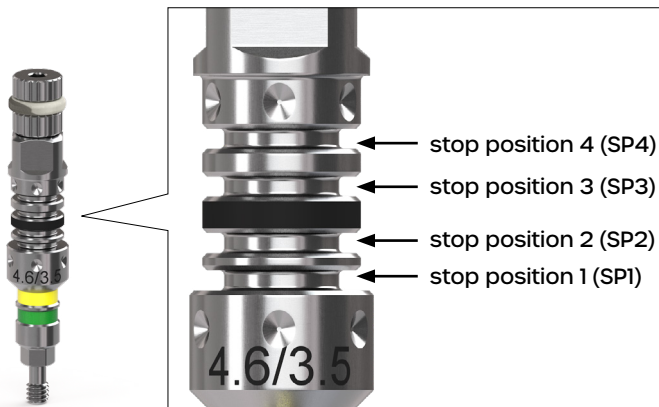


cover screw

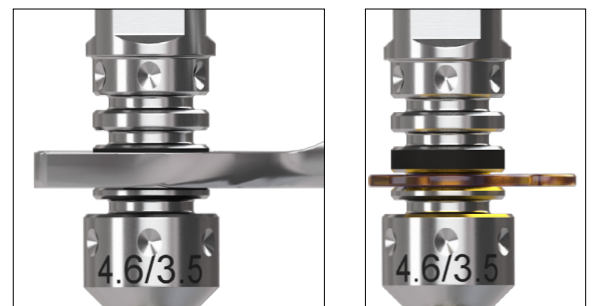
The cover screw for the implant is mounted in the vial cap.

Depth Stop Positions

Implant drivers include four stop positions for the depth stops to engage. Reference the patient-specific surgical protocol for the required stop position. Visual depth control can be used as an alternative to using the depth stops.



The laser-marked band above SP2 is used as a visual indicator to assist in delineating the four stop positions.



The depth stop handle or disposable depth stops can be used for guided implant depth control.



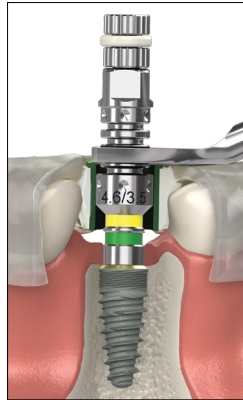
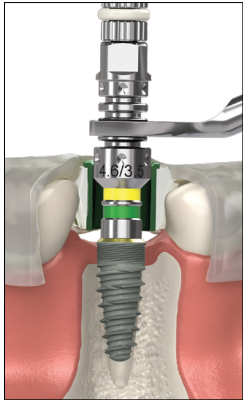
Disposable depth stops are for single-patient use only.

IMPLANT
PLACEMENT

Guided Implant Delivery

A handpiece or ratchet can be used to place the implant through the guided cylinder. If a pilot sleeve is being used, the surgical guide should be removed to deliver the implant using the conventional implant placement protocol.

Implant Placement

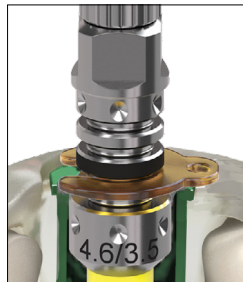


Place the implant through the guided cylinder

- Using the depth stop, engage the implant driver at the SP2 position
- Ensure the shaft of the implant driver is properly aligned with the guided cylinder
- Place the 4.2 x 10.5mm implant through the guided cylinder



depth stop handle

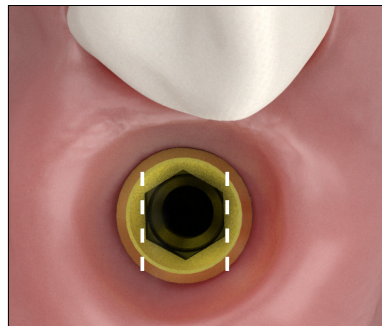
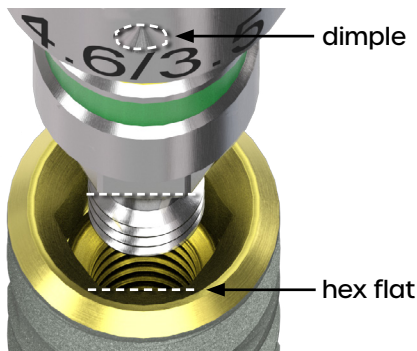


disposable depth stop

Implant depth control

- Depth placement of the implant is controlled by the depth stop engaging the indicated stop position
- The depth stop handle or disposable depth stop should firmly rest on top of the guided cylinder

Screw-retained Driver Hex Orientation



PILOT PROTOCOLS

Pilot Sleeves

Pilot sleeves can be used when interdental space is limited due to patient anatomy or if a collision between the guided cylinders is anticipated.



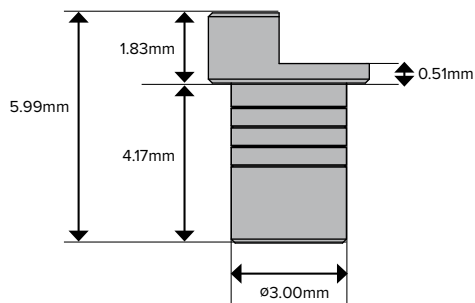
Guided Cylinder Collision

Guided Cylinder Collision Correction

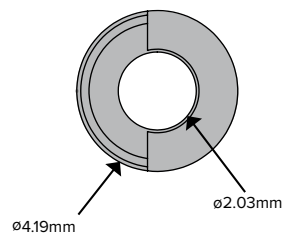
Pilot Offsets For Implants

Implant Length	7.5mm	9mm	10.5mm	12mm	15mm
Offset	16.5mm	15.0mm	13.5mm	12.0mm	9.0mm

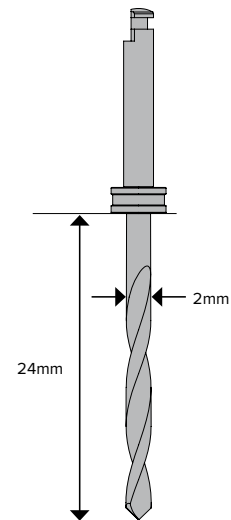
Guided Cylinders - Pilot & Drill Dimensions



Guided Pilot Cylinder



Guided Pilot Cylinder (Top)



Guided Drill
2.0 x 24mm

1. The influence of 0.12 percent chlorhexidine digluconate rinses on the incidence of infectious complications and implant success.
Lambert PM, Morris HF, Ochi S. J Oral Maxillofac Surg 1997;55(12 supplement 5):25-30. R10021c
2. Heat production by 3 implant drill systems after repeated drilling and sterilization.
Chacon GE, Bower DL, Larsen PE, McGlumphy EA, Beck FM. J Oral Maxillofac Surg. 2006 Feb;64(2):265-9. R30003b



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