Guide Right<sup>™</sup> 4.4 mm Depth Stop 2° Tapered Drill Set 6 mm to 15 mm L

Instructions for Use

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# Sections

1.	Unique Characteristics	3
2.	Clinical Advantages	4
3.	Indications for Use	5
4.	Contraindications	6
5.	Versatile Utilization	6
6.	Universal 2° Tapered 4.4 mm Depth Stop Drill Set	7
	a. Storage Container	8
	b. Drilling Protocol	12
	c. Specifications	14
	d. Drilling Sequence	15
	e. Depth Stop Drill Sequence	16
7.	Accessories (Sold Separately)	
	a. 2° Tapered Depth Gauges	17
	b. Punch, Flattening, + Pilot Drills	18
	c. Handheld Drill Handle	19
8.	Maintenance, Cleaning + Storage	
	a. Prior to First Time Use	20
	b. Cleaning + Storage of Drills After Use	21
	c. First-Time Surgical Use + Accessory Maintenance	22
9.	Guide Right™ Terms + Conditions of Sale	23
10.	Drill Set Return Policy	24

#### 1. Unique Characteristics

- Nesting drill series: each sequential drill diameter tip fits in the hole made by the previous drill. The cutting shaft of the drills have a 2° taper allowing this to occur.
- Only one 4.5 mm Guide Sleeve is necessary when using the 4.4 mm drills.
- Irrigation is not needed when used sequentially, (see: pages 12 & 15).
- If the surgery is guided and flapless, the patient discomfort level is minimal compared with open flap surgery.
- The tapered depth stop drill sequential protocol with a 3D evaluated and corrected surgical guide or printed surgical guide, allows confident flapless surgery.
- The depth stop safely limits the depth of drilling.
- Single drill replacements are available if lost or worn out.

# 2. Clinical Advantages

- The depth stop drill sequence prevents drilling beyond a certain depth.
- The diameter and the length of the fluted body of the drill are inscribed on the shank of the drill and on the index tray.
- The diameter of the Guide Sleeve is 0.05 mm to 0.1 mm larger than the outside diameter of the drill for greatest accuracy.
- This system does not require the use of multiple drill inserts. Only one Guide Sleeve is necessary for all the drills in each set.
- Drills can be used in reverse to widen the osteotomy diameter if the bone is soft (maxillary bone).
- Sequential protocol does not require irrigation.
- Less postoperative discomfort when sequential drill protocol is followed with flapless surgery.
- Patients with inadequate opening may require use of Short or Angle-Cut Guide Sleeves.

## 3. Indications for Use

- Where accuracy is important:
  - Narrow spaces or narrow ridge for placing implants
  - Close proximity to natural teeth 1 ≥ 1.5 mm
  - Adjacent implant proximity ≥ 3 mm
  - Should be used with 3D imaging for accurate placement
  - Minimally invasive flapless surgery
  - To maintain longevity of the implant, avoiding perforation of the buccal or lingual plates
  - Reducing the risk of peri-implantitis, if the implant is fully incased in bone rather than partially connective tissue, etc.
  - When implant depth is critical adjacent to nerve canal
  - With sequential drilling (see: pages 12 & 15), less heat generated is desirable; removing the need for irrigation

# 4. Contraindications

- Symptoms or conditions where Depth Stop Drills may not be advisable:
  - In soft bone or immediate placement in extraction sites, the depth stop will not be effective or accurate.
  - Osteotomy sites where there is inadequate space for the outside diameter of the Guide Sleeve, smaller Guide Sleeves and drill sets must be used. Example: 3 mm Guide Sleeves
  - When 3D imaging is not available to determine drilling length in 2 planes.

#### 5. Versatile Utilization

- All drills can be used sequentially without Guide Sleeves in open flap surgery.
- Can be used with any implant system.

# **4.4 mm** Tapered Depth Stop Drill Set



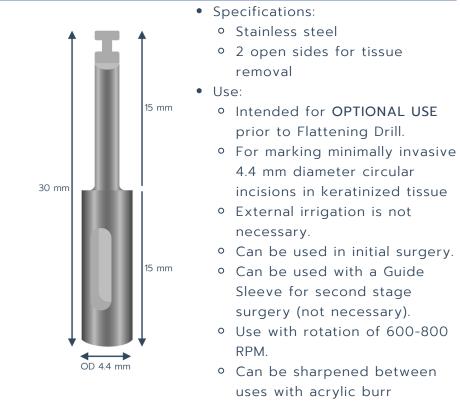
## **Storage Container**





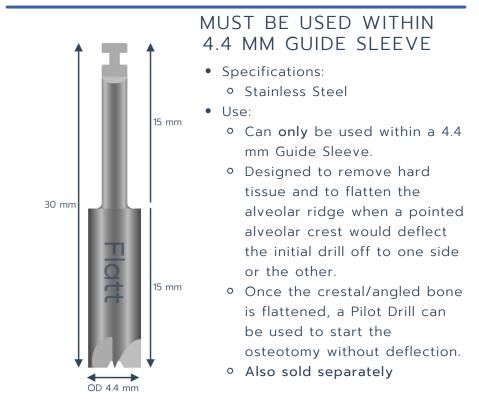
- 3<sup>5</sup>/<sub>8</sub>" x 4<sup>1</sup>/<sub>4</sub>" x 2<sup>3</sup>/<sub>4</sub>"
- PVD Coated Stainless steel box
- Used to store and clean drills
- Silicone receptacle inserts to stabilize drills in storage container
- Autoclavable (recommended: milk bath prior to autoclaving to maintain sharpness)
- Contains drills with mm size indication inscribed for easy recognition

## 4.4 mm Punch Drill



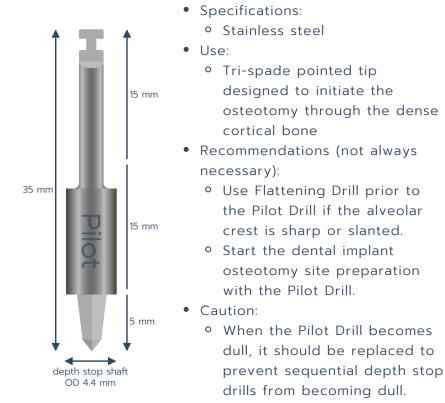
Also sold separately

# 4.4 mm Flattening Drill



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# 4.4 mm Pilot Drill



• Also sold separately

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# 4.4 mm Drilling Protocol

To gain a clearer illustration for sequential visual for use, it is suggested to view the drill sequence chart when using the drill set.

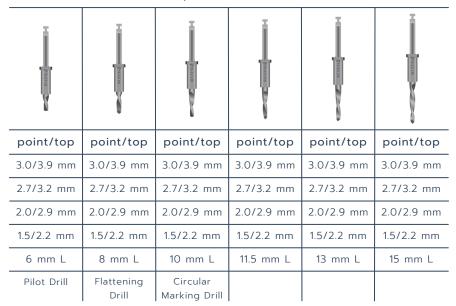
- The 4.4 mm Depth Stop Drills are designed to be used with 4.5 mm Guide Sleeves.
- The drills are intended for placing implants up to OD 4.4 mm (inserted through the Guide Sleeve) or larger than OD 4.4 mm (placed without the Guide Sleeve).
- A drill shaft of 8 mm or longer, used to initiate the osteotomy, may not be aligned within the Guide Sleeve.
- Always start with the smallest drill length and diameter, (1.5 mm 2.2 mm x 6 mm L) followed by increasing drill lengths to the final drill length for the osteotomy site.
- To widen the osteotomy, start with the 8 mm or 10 mm drill length of the next larger diameter series until the desired depth is reached.
- Drills can be used without irrigation **sequentially** for short periods of time, as heat production is minimal.

## 4.4 mm Drilling Protocol

- The drills are used for a short period of time in succession:
  6, 8, 10, 11.5, 13, and 15 mm. Normally the bone does not heat up because of the short drilling interval, however, extremely dense bone may require irrigation. The flat side of the drill shaft allows irrigation to flow between the depth stop shaft and the Guide Sleeve to cool it.
- When widening the osteotomy with the next larger diameter drill, the operator should start with depth stop length that fits within the Guide Sleeve.
- If starting with a 15 mm drill, the osteotomy will not be guided because the depth stop cylinder will be positioned superior to the Guide Sleeve.
- Only one Guide Sleeve is necessary for all the drills in each system, eliminating need for multiple size drill inserts/keys.

#### 4.4 mm Depth Stop Specifications

#### 4.4 mm 2° Tapered Drill Shaft OD ±0.1 mm





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#### 4.4 mm Drilling Sequence

- It is recommended to start with a Pilot Drill in dense bone.
- The diameter of the osteotomy depends on the diameter of the implant being placed. The depth of the osteotomy depends on the length of the implant. If flapless surgery is planned, the thickness of the soft tissue is added to the length of the implant placed to determine the depth of the osteotomy (1.5 mm 2 mm).
- Always select the shortest, narrowest drill to start drilling.
- Example for 4.5 mm diameter implants x 10 mm L:
  - start: 1.5 mm 2.2 mm x 6 mm drill→ 1.5 mm 2.2 mm x 8 mm drill→ 1.5 mm - 2.2 mm x 10 mm drill→ 1.5 mm - 2.2 mm x 11.5 mm drill
  - increase drill diameter to 2 mm 2.9 mm and continue with 8 mm L  $\rightarrow$  10 mm L  $\rightarrow$  11.5 mm L
  - increase drill diameter to 2.7 mm 3.2 mm and continue with 8 mm L→ 10 mm L→ 11.5 mm L
  - increase drill diameter to 3 mm 3.9 mm and continue with 8 mm L  $\rightarrow$  10 mm L  $\rightarrow$  11.5 mm L
- If the manufacturer's largest drill is smaller than the 2.7 mm 3.2 mm drill, stop after the 1.5 mm 2 mm drill.
- All of the drills should be used in the same 4.5 mm Guide Sleeve.

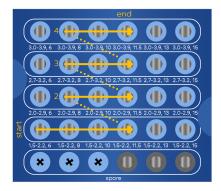
Users of DePlaque drills have the responsibility to determine whether the diameter and length of these products are suitable for the particular surgical procedure.

#### 4.4 mm Depth Stop Drill Sequence



Always start with the smallest drill length and diameter followed by increasing drill length to the final drill length for the osteotomy site. Then widen the osteotomy using drills of the same length with larger diameter.

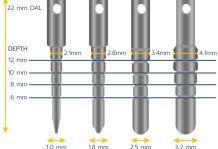
Flapless drilling protocol without irrigation:



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## 7a. 2° Tapered Depth Gauges

- Purpose:
  - Used to assess the osteotomy depth prior to placing the implant rather than using depth stop drills.
- Specifications:
  - Stainless Steel
  - Overall Length 22 mm
  - Available OD sizes:
    - 1.0 mm 2.1 mm
    - 1.8 mm 2.8 mm
    - 2.5 mm 3.4 mm
    - 3.2 mm 4.1 mm



- Depth Markings on each at 6 mm, 8 mm, 10 mm, + 12 mm
- Opening located at top of depth gauge to attach floss for safe retrieval
- Instructions for use:
  - Attach floss to hole at top of depth gauge.
  - Place depth gauge in the osteotomy.
  - Take a radiograph.
  - View image to determine if the drilled depth is adequate for the planned implant to be placed.

# 7b. Punch, Flattening, + Pilot Drills

Appropriate size included in all Universal 2° Tapered Depth Stop Drill Sets, or available for purchase individually.



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# 7c. Handheld Drill Handle

- Purpose:
  - Used for securing and manually holding a 3/32" drill shaft or any drill that fits in a lab hand piece.
- Specifications:
  - Stainless steel
  - Knurled handle
  - Set screw- requires a 5/64" driver (same driver used for the Guide Right Bending Tool Stylus)



- 3/32" channel opening to accommodate any drill that fits in a lab hand piece
- Instructions for use:
  - If the hole is drilled in a cast unintentionally less than 10 mm, it can be carefully deepened with a handheld 3/32" drill without using it in a hand piece.
  - Insert the 3/32" drill into the channel opening and turn clockwise to deepen the 3/32" hole in the cast.

#### 8a. Maintenance Prior to First Time Use

- STAGE 1: Light Cleaning and Rinsing Drill should be brushed and visually inspected for cleanliness, then dipped in detergent, rinsed and dried.
- STAGE 2: Preparation Dip drills in Surgical Milk solution or 70% Isopropyl Alcohol for approximately 30 seconds, remove, let drain to dry. Do not rinse or wipe drills again.
- STAGE 3: Sterilization Drills should be placed in storage container and sterilized in an autoclave at 132°C (269.6°F) for a 4 minute duration in a standard approved sterilization wrap. Dry time: 30 minutes.
- STAGE 4: During Use Drills should be soaked in a sterile water solution until the cleaning stage.

To minimize staining residue, it is strongly recommended to use sterile water surgical irrigation instead of sodium chloride for irrigation.

#### 8b. Cleaning + Storage of Drills After Use

- STAGE 1: Cleaning Drills should be brushed and rinsed with detergent to remove any remaining blood or tissue. Complete visual inspection for cleanliness.
- STAGE 2: Ultrasonic Cleaning Drills should be cleaned in an ultrasonic bath using appropriate enzymatic detergent (10% solution) following detergent manufacturer's instructions.
- STAGE 3: Rinsing Drills should be rinsed with running water to completely remove detergent. Dip drills in Surgical Milk solution or 70% Isopropyl Alcohol for approximately 30 seconds, remove, let drain to dry. Do not rinse or wipe drills again.
- STAGE 4: Sterilization Drills should be replaced in storage container and sterilized in an autoclave at 132°C (269.6°F) for 4 minutes in a standard approved sterilization wrap. Dry time: 30 minutes.

To minimize staining residue, it is strongly recommended to use sterile water surgical irrigation instead of sodium chloride for irrigation.

#### 8c. First-Time Surgical Use + Accessory Maintenance

- STAGE 1: Light Cleaning and Rinsing Accessories should be rinsed under cold tap water. During the rinse, use an appropriately sized lumen brush to brush the lumen of the article and a soft-bristled brush to brush the exterior surface of the article.
- STAGE 2: Preparation Prepare a detergent solution using Palmolive Dish detergent or comparative brand, using 1 tbsp per gallon of tap water. Brush the lumen of the article using appropriately sized lumen brush that has been wetted with the prepared detergent solution. Brush the exterior surface of the article using a soft-bristled brush that has also been wetted with the detergent solution.
- STAGE 3: Ultrasonic Cleaning Prepare a detergent solution using Enzol or comparative brand in an ultrasonic unit, following the manufacturer's recommendation of 1 oz. per gallon using warm tap water. Immerse the articles in the detergent solution and allow them to sonicate for 5 minutes. While sonicating, ensure that there is no contact between articles. Rinse the articles under cold tap water. Allow the articles to air dry completely.
- STAGE 4: Sterilization Accessories should be sterilized in an autoclave at 132°C (269.6°F) for a 4 minute duration in a standard approved sterilization wrap. Dry time: 30 minutes.

#### 9. Terms + Conditions of Sale

- CAUTION: Federal law restricts the sale of this device to or on the order of a licensed dentist.
- Treatment planning and clinical use of the Guide Right™ Drills and accessories are the responsibility of each individual clinician.
- Surgeon preference and clinical judgment overrules the suggestive Guide Right Surgical protocol. Guide Right™ strongly recommends completion of ADHERENCE to this manual.
- Guide Right<sup>™</sup> is not responsible for incidental or consequential damages or liability relating to the use of the Guide Right<sup>™</sup> Drills and accessories alone or in conjunction with other products other than replacement under warranty.
- Guide Right<sup>™</sup> Drills and accessories are warranted for a period of thirty (30) days from the date of initial invoice.

# 10. Return Policy

- If you are not completely satisfied with your purchase for any reason, you may return it within 30 days for a full refund.
- TO INITIATE RETURN:
  - Contact DePlaque Customer Service at: (585) 924-3190
    or <u>customerservice@deplaque.com</u>
  - Return in original container with all drills in original set up location.
  - Customer is responsible for secure packaging and return postage.
  - When returned within 30 days, original payment method will be credited.

