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# Use and Care Instructions

## PHD II – Step Scalpel

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## About:

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The PHD II™ step diamond scalpel offers the ultimate combination of simplicity and versatility for controlled depth incisions. The full extension setting enables paracenteses, wound enlargement and free hand dissection.

## Product Application:

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Creates groove incisions for:

- Astigmatic Keratotomy - AK
- Corneal Relaxing Incisions - CRI
- Limbal Relaxing Incisions – LRI
- Peripheral Corneal Relaxing Incisions - PCRI

Four thimble versions are available with depth settings as follows:

1. Refractive Cataract I  
0, 300, 550, Ext, Ret, 600, 650, 700, 750  $\mu\text{m}$
2. Cataract/Glaucoma  
0, 300, 500, 550, Ext, Ret, 600, 650, 700  $\mu\text{m}$
3. Miller LRI  
0, 300, 400, 500, 550, Ext, Ret, 600, 700  $\mu\text{m}$
4. Glaucoma  
0, 250, 400, 550, Ext, Ret, 600, 650, 700  $\mu\text{m}$

## Additional Information:

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Your PHD II™ has one of four different footplates shown on right. Regardless of the footplate choice, use and care procedures are the same.

Corneal View (316.)



Inset Profile (315.)



Glaucoma (317.)



Miller (318.)



## Setting the Blade Depth:

1. Hold the body of the scalpel with one hand and the thimble portion in the other.
2. Depress the thimble and rotate the body of the scalpel.
3. Once the pin is aligned with the desired depth setting's slot gradually release thimble allowing the pin to slide completely into the groove.



Note: Rotating the scalpel body rather than the thimble reduces the risk of pinching surgical gloves during rotation.



### Example set at 600 $\mu\text{m}$ :

Following steps 1-3 (above) set blade at “.600” blade will extend 600  $\mu\text{m}$  past the footplate.

### Calibrate :

This setting is used to ensure calibration at beginning of a case. Following steps 1-3 (above) set blade at “0” if the blade edge is flush with the footplate, you are “calibrated.”

### EXTEND :

This setting places the blade in a fully extended position for paracentesis and/or cleaning.

### RETRACT :

This setting stores the blade safely inside the scalpel body for sterilization and handling. Always return scalpel to this setting after use or cleaning.

Once retracted return scalpel to its dedicated tray for transport, sterilization and storage.



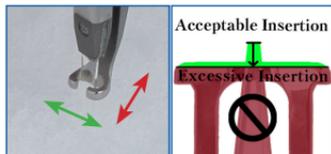
## Surgical Use:

1. Remove the scalpel from its case. It should be in the fully retracted position.
2. Calibrate. Ensure the '0' position aligns the diamond tip flush with the footplate (Page 3).
3. Follow the “Setting the Blade Depth” instructions on page 3 to set the desired depth.
4. Place the scalpel footplate on the patient cornea with the diamond extended to the proper depth.
5. Push or pull the scalpel along the surface of the cornea in the direction of the diamonds sharp edges using minimal downward pressure.
6. When desired arc length is achieved, reverse direction slightly to protect the wound margin from inadvertent extension. Remove the scalpel perpendicularly from the cornea.
7. Important: Upon completion of the procedure clean the blade [We recommend using the Mastel Diamond Blade Cleaning System (DBCS) to clean blades immediately after use. (See page 5)], retract blade and return scalpel to its dedicated tray for sterilization.



## How to clean your PHD II™ Scalpel with DBCS:

1. Open holding tray lid and remove foil if necessary.
2. Fully extend the blade. (See page 3)
3. Carefully push blade into the detergent until the footplate touches the foam pad.
4. Gently move the blade in the cutting direction 5-10 swipes.
  - » Avoid lateral motion
  - » Visually inspect the blade.
5. Once visually clean move to each of the rinses repeating step 4.
  - » A quick inspection under magnification can reveal any material missed.
  - » Repeat cleaning if necessary.
6. Once you are confident the blade is clean, retract the blade fully. Reference RETRACT on page 3.
7. Return the scalpel to its dedicated sterilization tray and proceed to the sterilization process.
  - » Always store scalpel in the case with blade in its retracted position. Make sure blade end points towards designated end of case.



**Diamond blades are very fragile!**



Ensure the blade edge(s) do NOT contact other instruments or the bottom of the cleaning tray during this process.

## Sterilization:

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The times and temperatures specified are minimum requirements. If, for procedural reasons, the values have to be lowered, the user must validate these. It is possible to exceed the time and temperature specifications. However, longer sterilization times and higher temperatures stress the materials, causing them to age prematurely.

Only products that have been cleaned and disinfected can be sterilized.

General sterilization criteria are listed below. Download complete *“Packaging and Sterilizing Instructions”* from the link on the following page.

Prevacuum high temperature steam sterilizer

- Four minutes at 132°C/134°C (270°F/273°F), or
- Twenty minutes at 121°C (250°F) wrapped

Gravity displacement autoclave

- Five minutes at 132°C / 134°C (270°F / 273°F), or
- Twenty minutes at 121°C (250°F) unwrapped
- Thirty minutes at 121°C (250°F) wrapped

Statim® steam sterilizer with radiant heat drying

- Three and one half minutes at 135°C (275°F) for unwrapped, or
- Ten minutes at 135°C (275°F) wrapped

\* Note: If using a steam autoclave, Mastel recommends running all scalpels through a dry cycle at the end of each surgical day.

## Sterilization Continued:

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-  The use of gravity displacement process must be approved by means of additional validation (longer sterilization times may be necessary).
-  A steam sterilizer in accordance with DIN EN 13060 and DIN EN 285 and validated in accordance with ISO 17665 (valid selection and product-specific performance qualification)
-  Maximum sterilization temperature 137°C (279°F) (plus tolerance range in accordance with ISO 17665)
-  Drying times as recommended by the sterilizer manufacturer

The manufacturer will accept no liability for other sterilization processes (e.g., hot-air, ethylene oxide, formaldehyde, radiation or low temperature plasma sterilization).

Should these be selected, validate them in accordance with the applicable standards DIN EN ISO 14937/ANSI AAMI ISO 14937 and/or process-specific standards, taking into account the specific geometry of the product, and be able to provide proof of the suitability and effectiveness of the process (including analysis of the sterilizing agent residue if applicable).

**Please Visit: [www.mastel.com/faq/uci/](http://www.mastel.com/faq/uci/)**

To download relevant PDF's including

### **Validation Documents**

These files contain complete information on **packaging**, **sterilizing**, and **preserving** the life of your instrument.

## Product Numbers:

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11.315.1011	11.316.1011	11.317.1011	11.318.5016
11.315.1016	11.316.1016	11.317.1016	
11.315.1089	11.316.1089	11.317.1089	
11.315.2011	11.316.2011	11.317.2011	
11.315.2016	11.316.2016	11.317.2016	
11.315.2089	11.316.2089	11.317.2089	
11.315.3011	11.316.3011	11.317.3011	
11.315.3016	11.316.3016	11.317.3016	
11.315.3089	11.316.3089	11.317.3089	

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and its team of craftsmen, engineers and service representatives strive to provide you with the very best in ophthalmic surgical instruments. Our products are delivered to you with pride.

If, for any reason, you need further assistance, please call one of our service representatives. They will provide the help you seek.

Thank You!

## Certifications & Licenses:

Mastel is FDA registered.

### Certifications:

- ISO 13485:2016 (MDSAP)

### Licenses:

- Health Canada

Product numbers were updated  
3/1/2022. For more information:  
please visit [mastel.com/sku-update/](http://mastel.com/sku-update/)



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