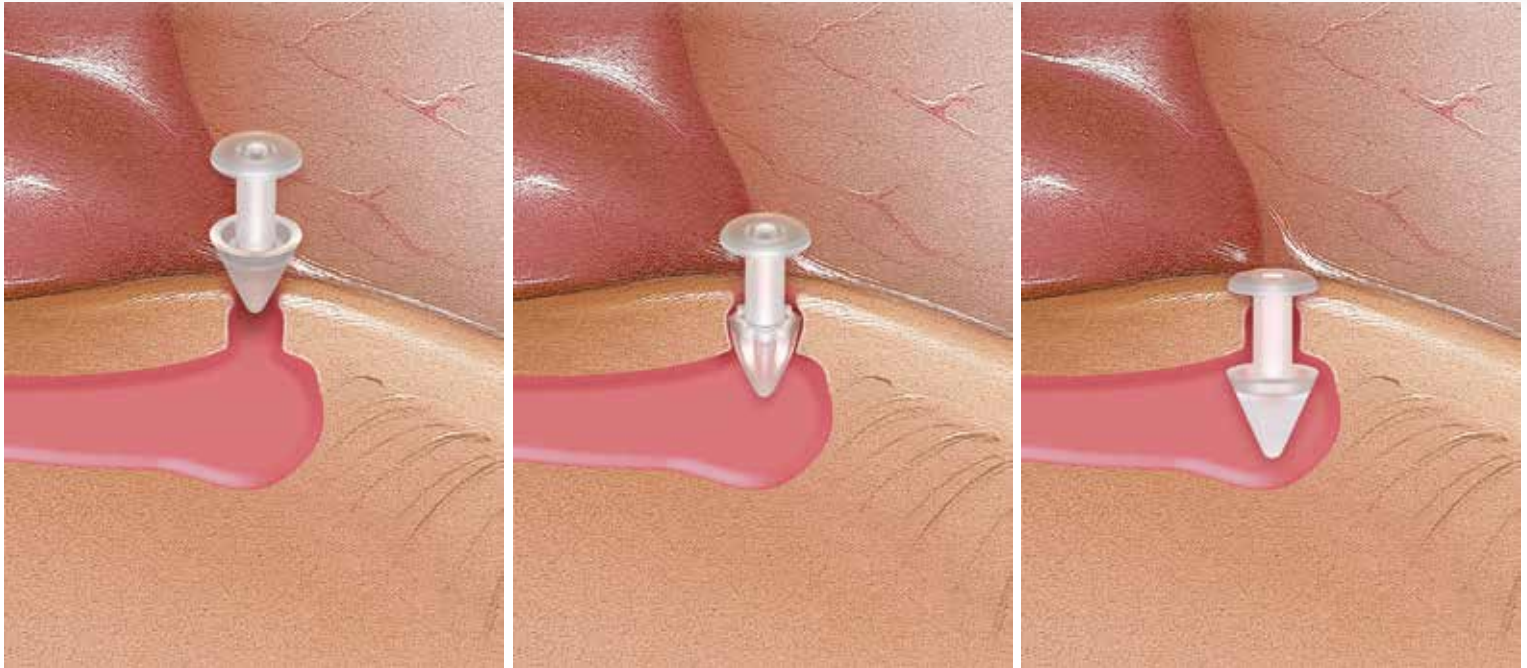


## Lacrimedics Occlusion Therapy Product Specification



### The Design Checklist

- **Options of both dissolvable and non-dissolvable Lacrimal Plugs**
- **Dissolvable VisiPlug<sup>®</sup> Lacrimal Plug:**
  - Medium-term Occlusion Therapy, lasting for approximately 180 days
- **Collagen Plugs:**
  - Short-term Occlusion Therapy and diagnosis of Dry Eye Disease, lasting for approximately 4 - 7 days
- **AccuFlo<sup>™</sup> Punctal Occluder:**
  - Long-term Occlusion Therapy for upper or lower Puncta
  - Specially designed to regulate Tear Drainage through the Puncta
  - Engineered with a shaft molded into the Plug that extends from the cap to the tip, the device allows Tears to flow through the Punctal opening
- **ComfortTip<sup>™</sup> Punctal Occluder:**
  - Long-term Occlusion Therapy for upper or lower Puncta
  - Equipped with a collapsible tip to ensure ease of insertion, improved patient comfort, and superior retention
- **OPAQUE Herrick Lacrimal Plugs<sup>®</sup>:**
  - Long-term Occlusion Therapy for upper or lower Puncta
  - Visible post-insertion using a simple light source
  - Patented VisiPlug<sup>®</sup> Technology
- USA manufactured
- Sterile

#### International Distributor

Network Medical Products Ltd.  
Coronet House, Kearsley Road, Ripon, North Yorkshire, HG4 2SG, UK  
Tel: +44 (0) 1765 609555 Fax: +44 (0)1765 608476  
info@networkmedical.co.uk | www.networkmedical.co.uk

#### USA Distributor

Summit Medical LLC  
815 Vikings Parkway, Suite 100, St. Paul, MN 55121, USA  
Phone: 1.888.229.2875 | 651.789.3939 Fax: 1.888.229.1941 | 651.789.3979  
customerservice@innoviamedical.com | www.summitmedicalusa.com

# Lacrimedics Occlusion Therapy Product Specification

## Intended Use

Lacrimedics' range of Occlusion Therapy products provide effective diagnosis and treatment of Dry Eye Syndrome and the Dry Eye components of varying Ocular Surface Diseases. They are used to temporarily enhance the efficacy of topical medications or Ocular Lubricants, and after Ocular Surgery to prevent complications due to Dry Eyes.

Lacrimedics' Occlusion Therapy devices are packaged sterile and are intended for Single-use only.

## Product Specification

Description	Pack Configuration	Box Size	Code
Dissolvable VisiPlug <sup>®</sup> Lacrimal Plugs, 0.4mm	<b>2</b> Plugs per Pouch with <b>1</b> Pouch per Box	<b>2</b> Units	1638
Dissolvable VisiPlug <sup>®</sup> Lacrimal Plugs, 0.5mm	<b>2</b> Plugs per Pouch with <b>1</b> Pouch per Box	<b>2</b> Units	1639
ComfortTip <sup>™</sup> Punctal Occluder, X-Small	<b>1</b> Plug per Tray with <b>2</b> Trays per Box	<b>2</b> Units	2003
ComfortTip <sup>™</sup> Punctal Occluder, Small	<b>1</b> Plug per Tray with <b>2</b> Trays per Box	<b>2</b> Units	2005
ComfortTip <sup>™</sup> Punctal Occluder, Medium	<b>1</b> Plug per Tray with <b>2</b> Trays per Box	<b>2</b> Units	2008
ComfortTip <sup>™</sup> Punctal Occluder, Large	<b>1</b> Plug per Tray with <b>2</b> Trays per Box	<b>2</b> Units	2010
AccuFlo <sup>™</sup> Punctal Occluder, Small	<b>1</b> Plug per Tray with <b>2</b> Trays per Box	<b>2</b> Units	3000
AccuFlo <sup>™</sup> Punctal Occluder, Medium	<b>1</b> Plug per Tray with <b>2</b> Trays per Box	<b>2</b> Units	3001
AccuFlo <sup>™</sup> Punctal Occluder, Large	<b>1</b> Plug per Tray with <b>2</b> Trays per Box	<b>2</b> Units	3002
AccuFlo <sup>™</sup> Punctal Occluder, X-Large	<b>1</b> Plug per Tray with <b>2</b> Trays per Box	<b>2</b> Units	3003
Collagen Plug, 0.3mm	<b>6</b> Plugs per Pouch with <b>10</b> Pouches per Box	<b>60</b> Units	CP3
Collagen Plug, 0.4mm	<b>6</b> Plugs per Pouch with <b>10</b> Pouches per Box	<b>60</b> Units	CP4
Collagen Plug, 0.5mm	<b>6</b> Plugs per Pouch with <b>10</b> Pouches per Box	<b>60</b> Units	CP5
OPAQUE Herrick Lacrimal Plugs <sup>®</sup> , 0.3mm	<b>1</b> Plug per Pouch with <b>2</b> Pouches per Box	<b>2</b> Units	HP3
OPAQUE Herrick Lacrimal Plugs <sup>®</sup> , 0.5mm	<b>1</b> Plug per Pouch with <b>2</b> Pouches per Box	<b>2</b> Units	HP5
OPAQUE Herrick Lacrimal Plugs <sup>®</sup> , 0.7mm	<b>1</b> Plug per Pouch with <b>2</b> Pouches per Box	<b>2</b> Units	HP7

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# Lacrimedics Occlusion Therapy Product Specification

## Instructions For Use (IFU)

Instructions For Use available on request.

## Conformity to European Regulations

Lacrimedics' Dissolvable VisiPlug<sup>®</sup> Lacrimal Plug and Opaque Herrick Lacrimal Plug<sup>®</sup> are U.S. FDA registered and CE Marked. These devices are classified as IIb implantable medical devices. These devices comply with the requirements of EN ISO 13485:2016 and Medical Device Directive 93/42/EEC.

Lacrimedics' ComfortTip<sup>™</sup> Punctal Occluder and AccuFlo<sup>™</sup> Punctal Occluder are U.S. FDA registered. The CE Mark for these two products is pending, with an anticipated issuance date of March/April 2021.

Lacrimedics' Collagen Plugs are U.S. FDA registered.



## Material Breakdown

Product Component	Details
Dissolvable VisiPlug <sup>®</sup> Lacrimal Plugs	Polydioxanone
ComfortTip <sup>™</sup> Punctal Occluder	Silicone (Medical Grade)
AccuFlo <sup>™</sup> Punctal Occluder	Silicone (Medical Grade)
Collagen Plug	Collagen
OPAQUE Herrick Lacrimal Plugs <sup>®</sup>	Silicone (Medical Grade)

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