



Indication for use:

Kerify™ is indicated for use by eye bank technicians to determine donor corneal graft viability in percentage area of cell damage, or ACD, from brightfield images of corneas stained with 0.06% trypan blue. ACD is provided as an aid to determining corneal tissue quality. Kerify™ generated report is indicated to be sent to the cornea graft surgeon ahead of the surgery as additional information about tissue quality. Kerify is indicated for use with Dino-Lite USB 3.0 cameras.

Contraindications:

- Do not use with processing methods that deliberately expose anterior DM to trypan blue for prolonged periods of time
- Do not use with trypan blue that is not FDA-registered for donor or human ocular use.
- Do not use with a camera system that has not been confirmed to be ≥ 57 line pair/mm resolution
- Not intended to determine graft-wide ACD for grafts larger than 8.5mm diameter. For such grafts, the ACD of an 8.5mm diameter region of interest can be reported at the discretion of the eye bank.

Warnings:

- Kerify™ may be used to assist in the determination of suitability for transplant use. However, the final decision on suitability for transplant use rests with the transplanting surgeon.
- Kerify™ is only intended to be used with Dino-Lite camera
- Kerify™ ACD is considered accurate when the ACD result comes with a green confidence score. Another validated method of post-processing suitability evaluation should be used when confidence is not green.
- Images are taken in an aseptic processing environment. Follow EBAA guidelines and FDA GTP rules for maintaining asepsis during imaging.
- Image quality is important for a reliable result. Visual artifacts can obscure or resemble trypan blue stain. Kerify™ performs a quality check but it cannot eliminate all artifacts. The operator is responsible for generating a high quality brightfield image and reducing artifacts as much as possible.

Cybersecurity controls:

- Kerify™ portal is encrypted with an SSL certificate



- Credentials Management to mitigate attacks caused by human factors:
 - It is necessary to create strong passwords to prevent brute force or dictionary attacks.
 - It is essential for the user to not share their login credentials so as to prevent data leakage to third parties or a person with malicious intent.
 - Do not save credentials in an unencrypted location.
- Do not leave the computer without logging out of your account

Cloud service provider:

- Kerify™ utilizes a Cloud Service Provider (CSP). Amongst the well-established and reliable CSPs such as used Kerify Vision, the choice of a particular CSP does not affect the Intended Use of the device, nor does it affect the Device User Interface, Usability, Safety, or Efficacy of the solution. The solution's use of a CSP has no environment associated dependencies. To ensure patients always have access to the best state-of-the-art service and cybersecurity controls, the particular CSP along with its internal configurations are subject to change (with appropriate documentation, change controls, and notification) to other CSP or multi-CSP configurations that satisfy requisite state-of-the-art cybersecurity specifications and controls.

Ports:

- Kerify™ web application has the standard ports 80 (http) and 443 (https) open for inbound and outbound traffic. However, traffic is redirected to 443

Supporting infrastructure requirements:

- The supporting infrastructure requirements for the Kerify™ solution are as follows:
 - Kerify™ shall be compatible with DinoLite USB 3.0 camera (model AM73515MZTL) , operated by a computer with USB 3.0 or higher port.
 - A computer with a device-compatible browser. Compatible browsers are: Chrome, Safari, Edge, and Firefox.
 - Kerify™ is supported on screens and browser windows that have a width of 1024px or more. Mobile devices and screen sizes that are less than 1024px width are not supported.
 - Kerify™ requires a working internet connection.