Shah Eye Care (P) Ltd
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Redefining Accuracy

BIMANUAL & COAXIAL IFU

Note :
This IFU applies to both bimanual and coaxial IA handpieces, as they share the same intended use and usage process.

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Warning

Using a damaged or non-sterile medical device can lead to an infection or endophthalmitis of the patient. Do not use if package is damaged or sterile barrier is harmed.

Avoid contact with sharp and / or pointed device components in order to facilitate safe use and disposal of the device.

The device must not be used after its expiry date.

Read and observe the respective surgical system operated by the user for instructions for use.

Never reuse the medical device. Reuse or resterilization may compromise the device performance and safety, which could cause infections and serious harm to the patient's health and safety.

The intended users are healthcare professionals.

Product description

IA Handpieces are single use medical devices connected via an irrigation and aspiration tubing system to a phacoemulsification or vitrectomy device during ophthalmic surgery. Tissue and temporarily introduced substances, liquids or particles are aspirated using IA Handpieces. The volume removed by aspiration is compensated for by fluid passed through the IA Handpieces to stabilise the structure of the eye.

The Bimanual variant is made of two handpieces: one for aspiration and one for irrigation. The coaxial variant can perform both aspiration and irrigation via the same handpiece.

Instructions for use

1. Carefully open the primary packaging and place the contents on a sterile surface.
2. Connect the male luer connector of the machine to the irrigation female luer connection of the IA handpiece.
3. Connect the female luer connector of the machine to the aspiration male luer connector of the IA handpiece.
4. Ensure the connectors are firmly fixed with a twist of the connectors of both irrigation and aspiration hands.

Disposal

The medical device may be contaminated with potentially infectious substances of human origin after use. Dispose of the medical device and packaging after use according to the applicable guidelines of biological hazardous waste.

Notifications to manufacturer and authorities

Serious incidents occurring in connection with the device must be reported to the manufacturer and the competent authority in which the user and / or patient is established.

LOT Number
Lot Nummer
Batch
Lotto
Numéro de lot
Lotnummer
Numero di lotto
Numero de lote
Partiebeteckning
Partinumeri
Partinumber
Partinumber
Partinumber