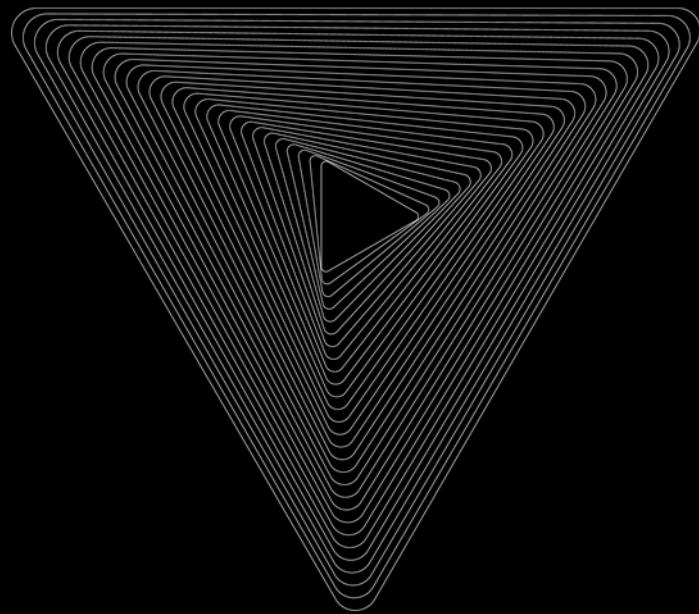


VERSO
BIOSENSE



IRIS Hydration Instructions

1. Introduction

- This instruction for use describes the process for hydrating an IRIS prior to insertion.
- Hydration of IRIS is essential in ensuring that the IRIS can meet its performance specification.
- Hydration must only be carried out by individuals trained by Verso Biosense.
- Verso Biosense will provide all equipment required to perform this process.
- All packaging and instructions for use must be retained from the clinician kit.

2. Hydration Procedure

Important Note:

- Please check that the sterile packaging is not damaged (if it's wet or there is evidence of saline leakage). If the packaging is damaged, please do not use and contact customer support (see section 3).
- Please check that the product is in date.
- Please ensure that the area where the hydration is being undertaken is clean.

2.1. Positioning the hydration saline vial

- Locate the hydration saline vial within the sterile package.
- Gently push on the vial through the transparent face of the sterile bag to manoeuvre the hydration saline vial. Ensure that the neck of the vial is fully inserted into the hydration pocket to a distance of 2cm.

Important Note:

- Care is required to ensure that the sterile barrier of the bag is not pierced.

Critical:

- **If the sterile barrier of the bag is pierced, please DO NOT USE the IRIS.**

2.2. Breaking the hydration saline vial seal

- Grasp the vial body through the transparent face material of the sterile bag between the thumb and forefinger of one hand.
- Grasp the twist tab of the hydration saline vial through the transparent face material of the sterile bag between the thumb and forefinger of the other hand.
- Twist the hydration saline vial tab relative to the body of the vial through 180 degrees and bend to one side to break the seal.

Important Note:

- Care is required to ensure that the sterile barrier of the bag is not pierced.
- Care is required to ensure that no hydration saline leaks outside the hydration pocket.

Critical:

- **If the sterile barrier of the bag is pierced, please DO NOT USE the IRIS.**
- **If hydration saline leaks outside of the hydration pocket, please DO NOT USE the IRIS.**

2.3. Emptying the hydration saline vial contents into the hydration pocket

- Ensure that the neck of the hydration saline vial is in the hydration pocket.
- Gently squeeze the body of the hydration saline vial so that the hydration saline empties into the hydration pocket.
- Empty the entire contents of the hydration saline vial into the hydration pocket.

Important Note:

- Empty the contents of the vial slowly to avoid splashing of the vial contents outside of the hydration pocket.

Critical:

- **If hydration saline leaks outside of the hydration pocket, please DO NOT USE the IRIS.**

2.4. Storing the Hydrating IRIS

- Place the sterile bag inside the sterile bag holder, to keep the saline held upright, as per the images below.
- Leave to hydrate for at least 2 hours and no more than 48 hours.
- Insertion of the IRIS must take place within 24 hours of the end of hydration.
- Prior to insertion, pre-checks must be carried out, following the instructions for use contained within the “IRIS Performance Check Instructions (0300-IFU-03)



Important Note:

- Keep the sterile bag upright to avoid hydration saline leaking out of the hydration pocket.

Critical:

- **If hydration saline leaks outside of the hydration pocket, please DO NOT USE the IRIS.**

3. Technical Support

Technical Support at Verso Biosense Limited can be reached on:

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E: customercare@versobiosense.com

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This IFU can also be found at: <https://versobiosense.com/product-docs/>

