

Icon Cleaning & Disinfecting Manual

HANDPIECE PREPARATION

Cynosure® recommends cleaning between treatments of different individuals as described in the Chapters in the Operator's Manual about the Base Module and different handpieces. Please refer to the handpiece Chapters for more details.

- Each pulsed-light handpiece and each non-ablative handpiece require cleaning and disinfection before and after treatments. In addition, the light-emitting window should be periodically wiped clean of hair and other debris between treatments.
- Each ablative handpiece requires cleaning and disinfection before and after treatments; consult the specific handpiece's Chapter for complete handpiece cleaning and setup information.
- For ablative treatments, in the event that a handpiece comes in contact with mucous membranes, broken, infected, bleeding or otherwise potentially infectious areas of the skin, Cynosure® recommends cleaning the handpiece with an EPA-registered disinfectant/detergent, e.g., Sani-Cloth® Plus, LpHse®, and Birex®. Please follow the cleanser manufacturer's directions.

BASE MODULE AND HANDPIECE CLEANING



- See relevant handpiece Chapters for any specific cleaning details, such as with the 2940 handpiece cleaning and disinfecting.
- During cleaning and disinfection, the Icon™ Aesthetic System should be switched off and disconnected from the main power supply.
- Pure, undiluted alcohol or detergents should not be used.
- Cleaning between treatments of different individuals: Clean the Base Module and umbilical using gauze or cloth moistened with a mixture of 70% alcohol and 30% water. Cynosure® recommends cleaning the handpiece window with an EPA-registered disinfectant/detergent, e.g., Sani-Cloth® Plus, LpHse®, or Birex®. Please follow the cleanser manufacturer's directions. (For Sani-Cloth® users, ensure the product is the stronger Plus version and not HB.)
- During treatment on same person: Cynosure® recommends gauze or cloth moistened with a mixture of 70% alcohol and 30% water.
- Do not submerge a handpiece in any solution as it may cause a hazardous condition for the operator and possibly those being treated. Submerging may also cause the Icon™ Aesthetic System to malfunction.

BASE MODULE AND HANDPIECE CLEANING

Cynosure® recommends cleaning and disinfecting between persons being treated as described in the section below.

In the event that a Handpiece comes in contact with mucous membranes, broken, infected, bleeding or otherwise potentially infectious areas of the skin, Cynosure® recommends cleaning and disinfecting the light-emitting end of the Handpiece. (For SaniCloth® users, ensure the product is the stronger Plus version, and not HB.) See below for cleaning instructions for the Handpiece and Base Module.



- During cleaning and disinfection, the Icon™ System should be switched off and disconnected from the main power supply.
- Pure, undiluted alcohol or detergents should not be used.



- **Cleaning and disinfecting between persons being treated:** Clean the Base Module and umbilical using gauze or cloth moistened with a mixture of 70% alcohol and 30% water. Cynosure recommends cleaning and disinfecting the Handpiece window with an EPA-registered disinfectant / detergent e.g. SaniCloth® Plus, LpHse®, or Birex®. Please follow the cleanser manufacturer's directions.
- The use of SaniCloth® Plus meets the requirements for OSHA level disinfection of surfaces.
- **During treatment on same person:** Cynosure recommends gauze or cloth moistened with a mixture of 70% alcohol and 30% water. Make sure the Handpiece is totally dry before pulsing.
- Do not submerge the Handpiece in any solution as it may cause a hazardous condition for the operator and possibly those being treated and also cause the System to malfunction.

PROCEDURE TO CLEAN/CHANGE TREATMENT OPTICS AND DISPOSABLE SINGLE-USE FOCAL GUIDES

NOTE: Do not attempt to change treatment Optics until your Icon™ Aesthetic System screen prompts to do so. Refer to the following instructions when prompted to install Optics or disposable single-use Focal Guides.

It is required that the Optics be cleaned prior to administering treatments. Protective gloves, laser plume protective masks, and protective eyewear must be worn during cleaning procedure.

To clean and sanitize the Optic, wipe all surfaces (including the front and rear window) with a Sani-Cloth® Plus. Next, wrap the Optic in a Sani-Cloth® Plus and place in a sealed plastic bag for **no longer than 5-10 minutes—any longer may damage the Optic.** Lastly, wipe the Optic window with an isopropyl alcohol wipe.



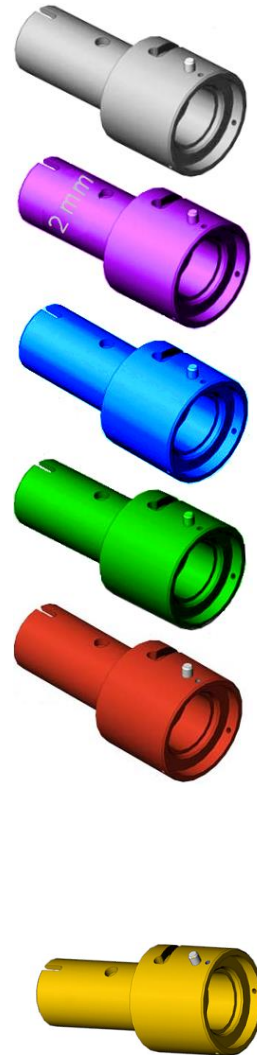
CAUTION: Do not submerge an Optic in fluid, and do not wrap an Optic in a Sani-Cloth® Plus for longer than 10 minutes, as damage to the Optic may result.

Never autoclave an Optic.

CHANGING THE OPTIC

- To remove a treatment Optic, rotate the locking collar towards the “unlock” position until the Optic disengages.
- Visually inspect the Optic window for any contamination. Clean with a Sani-Cloth® Plus as required for **no longer than ten minutes**, or damage to the Optic may result.
- Place the protective cap on the Optic and place into the storage box.
- Install a treatment Optic by gently inserting the Optic into the distal end of the Handpiece. Tighten the Optic by rotating the locking collar towards the “lock” position until secure.

NOTE: The gold Calibration Optic, shown at right, is matched to your specific Handpiece and is not interchangeable with other 2940 Handpieces.



CAUTION: Disposable single-use Focal Guides are designed to be autoclave steam sterilized before use. Multiple use, or use without autoclave steam sterilization, may cause cross-contamination to patient and damage to the device.

During the treatment, the Focal Guide may collect debris. The debris may be wiped away with a 4x4 wipe dampened with sterile water.

STERILIZING THE DISPOSABLE SINGLE-USE FOCAL GUIDE

The Focal Guide must be sterilized before use. To sterilize, seal the Focal Guide in an autoclavable sterilization pouch. The pouch should be large enough to hold the Focal Guide without stressing the pouch’s seals. Place the pouch in a steam autoclave and select the settings below:



(Applied part)

Temperature	Time	Cycle Type	Minimum Dry Time
250°F (121°C)	30 minutes	Gravity	15 minutes

The Focal Guide is designed for single, one time use.

2940 Handpiece

HANDPIECE CLEANING

- Pure, undiluted alcohol or detergents should not be used.



During cleaning and disinfection, the system should be switched off and disconnected from the main power supply.

- For instructions on cleaning and disinfecting the Optic, see section titled SINGLE USE PROCEDURE TO CLEAN/CHANGE TREATMENT OPTICS AND DISPOSABLE FOCAL GUIDES. Do not submerge the Handpiece, Optics, or disposable single use Focal Guides in any type of solution. Submerging the Handpiece and its accessories may cause hazardous condition for the user and possibly the person being treated. Submersing may also cause the system to malfunction or permanent damage. Do not autoclave the Optics.
- Follow the instructions on the Sani-Cloth® Plus container.



Since the Handpiece may become contaminated with blood, fluids or human tissue, it must be cleaned and disinfected after every treatment with Sani-Cloth® Plus disposable wipes or equivalent.

Use of Sani-cloth meets the requirements for OSHA level disinfection of surfaces. After every treatment, you must wipe down the entire 2940 Handpiece, Optic and its umbilical. Per Cleaning Procedure, the Optic also needs to be wrapped in a Sani-Cloth® Plus disposable wipe for no more than 5-10 minutes. Longer than ten minutes may damage the Optic. Complete cleaning and disinfecting of the Optics by wiping the distal end of the Optic (the Optic window) closest to the disposable Focal Guide with an isopropyl alcohol wipe. Do not immerse the Optics in any type of liquid as it may permanently damage the Optics.

The disposable single use Focal Guide must be sterilized before use. Refer to PROCEDURE TO CLEAN/CHANGE TREATMENT OPTICS AND DISPOSABLE SINGLE USE FOCAL GUIDES. Do not reuse the disposable Focal Guides due to potential cross contamination.

Contact your local Department of Public Health for specific waste handling and disposal regulations that apply to the used disposable Focal Guides, other contaminated disposables, and medical waste material.



CAUTION: Disposable single-use Focal Guides are designed to be autoclave steam sterilized before use. Multiple use, or use without autoclave steam sterilization, may cause cross-contamination to patient and damage to the device.

1540 Handpiece

BASE MODULE AND HANDPIECE CLEANING

Cynosure® recommends cleaning and disinfecting between persons being treated as described in the section below.

In the event that a Handpiece comes in contact with mucous membranes, broken, infected, bleeding or otherwise potentially infectious areas of the skin, Cynosure® recommends cleaning and disinfecting the light-emitting end of the Handpiece with an EPA-registered disinfectant/detergent, e.g., SaniCloth® Plus, LpHse®, or Birex®. Follow the cleanser manufacturer's directions.

The use of SaniCloth® Plus meets the requirements for OSHA level disinfection of surfaces.

Follow instructions on the detergent packaging.



- During cleaning and disinfection, the System should be switched off and disconnected from the main power supply.
- Pure, undiluted alcohol or detergents should not be used.



- **Cleaning between persons being treated:** Clean and disinfect the Base Module and umbilical using gauze or cloth moistened with a mixture of 70% alcohol and 30% water. Cynosure® recommends cleaning and disinfecting the Handpiece window with an EPA-registered disinfectant / detergent e.g. SaniCloth® Plus, LpHse®, or Birex®. Please follow the cleanser manufacturer's directions. (For SaniCloth® users, ensure the product is the stronger Plus version, and not HB.)
- **During treatment on same person:** Cynosure® recommends gauze or cloth moistened with a mixture of 70% alcohol and 30% water.
- Do not submerge the Handpiece in any solution as it may cause a hazardous condition for the operator and possibly those being treated. Submerging may also cause the System to malfunction.

XD MICROLENS™ OPTIC CLEANING

Immediately after XD Microlens™ optic treatment, Cynosure® recommends cleaning the XD Microlens™ per the following steps.



NOTE: Wear protective glasses, gloves, gowns and facemasks per the device user's office protocols for scrubbing and cleaning patient-contact surfaces.

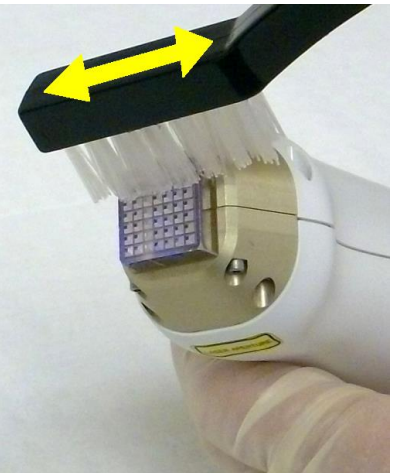
STEP 1. Ensure protective rear cover is attached, as shown at right.



STEP 2. Saturate a SELECT SAT™ dry wipe (or equivalent, 7x7" size or larger) with a 70% isopropyl alcohol (IPA) solution and wipe down the XD Microlens sapphire surface to clean any loose debris that may be present.



STEP 3: Using a clean, soft nylon brush (e.g., toothbrush or similar detail brush), gently clean the XD Microlens sapphire face in two directions as shown in the photos below using gentle strokes to avoid damaging the sapphire surface.



XD MICROLENS™ OPTIC CLEANING, CONTINUED

STEP 4: Using a fresh 70% IPA saturated wipe, re-wipe the XD Microlens sapphire head as shown at right.



STEP 5: Wrap the XD Microlens with a fresh 70% IPA saturated wipe, ensuring continual contact with the wipe and the sapphire surface. An elastic band can be used to hold the wipe in place.

After ten (10) minutes have elapsed, unwrap the XD Microlens and wipe it with a clean, soft damp cloth to remove any residue. Let the XD Microlens air dry, and store in a safe place.

