



Disposable Sindt Ophthalmic Spatula

Instructions for Use

Important

- This product is intended to be used by a physician or technician with appropriate training and experience
- Do not attempt to use the Disposable Sindt Ophthalmic Spatula before completely reading and understanding the information contained in this Instructions for Use

Device Description

The Disposable Sindt Ophthalmic Spatula is a handheld mechanical device designed to perform proper and efficient Meibomian gland expression. It is intended to be used in a clinical setting as an alternative to current Meibomian gland expression instruments such as a cotton swab, finger, Mastrotta Paddle, or Collins Expressor Forceps. Consisting of Acrylonitrile Butadiene Styrene (ABS), the tool can evert a patient's eyelid gaining access to the patient's Meibomian glands and gland openings.

The Disposable Sindt Ophthalmic Spatula is comprised of a single ABS piece and can be used by itself for visualizing glands or used with other instruments such as a heated sonic vibration eye massager for gland expression.

The device has a concave and convex end with curvatures dimensioned to conform to the curvature of the eyelids or the globe of the eye. As shown in Figure 1, the device has a maximum width of 1.32 inches and a length of 4 inches.

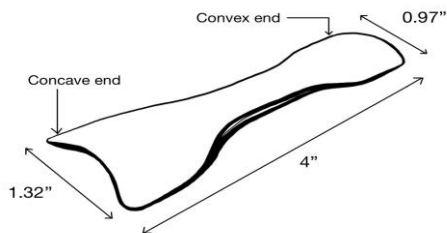


Figure 1

Disposable Sindt Ophthalmic Spatula

Contents of Packaging

- ABS ophthalmic spatula
- Instructions for Use

How Supplied

Individually packaged devices are clean and sterile.

Indications for Use

The Disposable Sindt Ophthalmic Spatula is indicated for use as an ophthalmic spatula for use on patients with Meibomian gland dysfunction and blepharitis who would benefit from treatment by expressing the Meibomian glands.

The Disposable Sindt Ophthalmic Spatula is also indicated as an ophthalmic spatula to evert the eyelid to expose Meibomian glands as needed for Meibomian Gland Evaluation.

The Disposable Sindt Ophthalmic Spatula should not be used

Contraindications

on any patient who is:

- Pediatric
- Allergic to Acrylonitrile Butadiene Styrene (ABS)

Warnings

- If excessive force is needed to evert the eyelid, the Meibomian gland expression procedure should be terminated to reduce the risk of corneal abrasion.
- Never advance the Disposable Sindt Ophthalmic Spatula into or across the cornea.
- If corneal abrasion occurs or is suspected, immediately discontinue the Meibomian gland expression procedure.
- Do not use Disposable Sindt Ophthalmic Spatula if bent or damaged. Inspect device before each use.

Precautions

- Do not use Disposable Sindt Ophthalmic Spatula if package is open or damaged.
- Use of a device for a task other than what it is intended for may result in a damaged or broken device.
- To avoid mechanical shock or overstressing the device, store in a manner that protects the Disposable Sindt Ophthalmic Spatula from excessive force.
- Irregular or unusual eye shape may make use of Disposable Sindt Ophthalmic Spatula difficult.
- Do not expose patient to device with direct skin contact for greater than 60 seconds at a time.
- There is no data on the effectiveness of using the Disposable Sindt Ophthalmic Spatula to treat Dry Eye.

Adverse Events

Patient Population

Sindt Ophthalmic Spatula has been used in patients at multiple centers to express Meibomian gland expression

Observed Adverse Events

Zero corneal abrasions or other adverse events have been observed using the Disposable Sindt Ophthalmic Spatula for either Meibomian gland expression or evaluation.

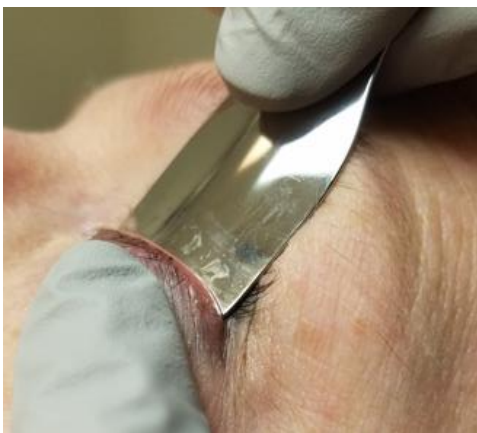
Adverse Event Reporting

For any adverse event involving the Disposable Sindt Ophthalmic Spatula contact Iowa MADE customer services. To reach Iowa MADE customer services, call 319-384-3425 or email iowa-made@uiowa.edu

Directions for Use

Meibomian Gland Expression Procedure

1. Place convex end of spatula behind eye lid.
2. Use expression tools such as eye massager to gently press on the Meibomian glands.
3. Glands will secrete meibum.
4. Wipe away the meibum secretion.
5. Remove Disposable Sindt Ophthalmic Spatula.



Meibomian Gland Expression of the lower eyelid.



Meibomian Gland Expression of the upper eye lid.

Meibomian Gland Imaging Procedure

1. Line up concave end of spatula with eyelid.
2. Gently exert force to evert edge of eyelid.
3. Observe Meibomian glands.
4. Remove Disposable Sindt Ophthalmic Spatula



Example of Step 1



Example of Step 2

Instrument Cleaning and Sterilization

Disposable Sindt Ophthalmic Spatula is intended for single use only and is provided ready for use. Do not clean or sterilize the device.



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For product ordering or reporting of adverse events,
please call (319) 384-3425, email iowa-made@uiowa.edu,
or visit iowamade.org.

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