

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 Sindt Ophthalmic Spatula before completely reading and understanding the information contained in this Instructions for Use

Device Description

The 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, Mastrota Paddle, or Collins Expressor Forceps. Consisting of grade 316L stainless steel, the tool can evert a patient's eyelid, gaining access to the patient's Meibomian glands and gland openings.

The Sindt Ophthalmic Spatula is comprised of a single metal 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.

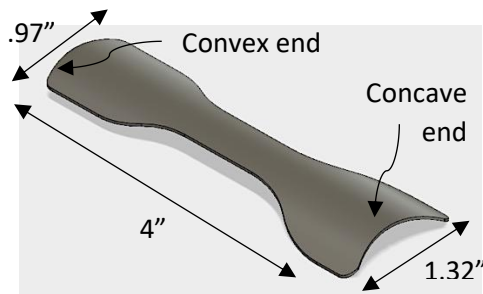


Figure 1

Sindt Ophthalmic Spatula

Contents of Packaging

- One metal ophthalmic spatula
- One instructions for use

How Supplied

Packaged devices are clean and non-sterile. Cleaning and sterilization of devices must occur prior to use.

Indications for Use

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

Contraindications

The Sindt Ophthalmic Spatula should not be used on any patient who is:

- Pediatric
- Allergic to 316L stainless steel or nickel

Warnings

- Improper care and or use of the device may render the device non-sterile prior to patient use and may cause injury to the health care provider or the patient.
- If excessive force is needed to evert the eyelid, the Meibomian gland expression procedure should be terminated to reduce risk of corneal abrasion
- Never advance the 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 Sindt Ophthalmic Spatula if bent or damaged. Inspect device before each use.
- Do not use Sindt Ophthalmic Spatula if it has not been cleaned and sterilized.

Precautions

- If there are any variations between these Instructions for Use and either your facility's policies and/or your cleaning/sterilizing equipment manufacturer's instructions, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your devices.
- Always clean and sterilize the Sindt Ophthalmic Spatula before each use.
- Do not use Sindt Ophthalmic Spatula if package is open or damaged.
- Only the cleaning and sterilization processes which are defined within these Instructions for Use have been validated.
- 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 Sindt Ophthalmic Spatula from excessive force.
- Irregular or unusual eye shape may make use of 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 Sindt Ophthalmic Spatula to treat Dry Eye.

Adverse Events

Patient Population

Over 100 patients at multiple centers have received the Meibomian gland expression or evaluation using the Sindt Ophthalmic Spatula.

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

Adverse Event Reporting

Any adverse event involving the Sindt Ophthalmic Spatula should be reported to Iowa MADE immediately. To report an incident, 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 tool such as eye massager to gently press on the Meibomian glands.
3. Glands will secrete meibum.
4. Wipe away meibum secretion.
5. Remove Sindt Ophthalmic Spatula.



Meibomian Gland Expression of the lower eyelid.



Meibomian Gland Expression of the upper eyelid.

Observed Adverse Events

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 Sindt Ophthalmic Spatula



Example of Step 1



Example of Step 2.

Instrument Cleaning and Sterilization

Processing Prior to Initial Use

Sindt Ophthalmic Spatula must be cleaned and sterilized prior to initial use, using appropriate sterilization accessories and procedures. Recommended procedures are listed below.

Reprocessing Instructions

Special Accessories

No special accessories are required for safe reprocessing.

Point-of-Use Processing

After using the Sindt Ophthalmic Spatula, promptly remove gross soil by rinsing or wiping the spatula to prevent drying of soil on spatula surface.

Disassembly and Reassembly

The Sindt Ophthalmic Spatula does not contain multiple parts and requires neither disassembly nor reassembly.

Method of Cleaning

Manual Cleaning Process - Enzymatic/neutral pH Detergent

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare neutral pH detergent solution, utilizing tap water with a temperature range of 27°C to 44°C (81°F to 111°F), per manufacturer's instructions.
3. Completely immerse the device in the detergent solution and allow it to soak for a minimum of 5 minutes.
4. Using a soft bristled brush, remove all visible soil from the device. Note: It is recommended that the detergent solution be changed when it becomes grossly contaminated (bloody and/or turbid).
5. Rinse the device by completely immersing it in treated, running water with a temperature range of 27°C to 44°C (81°F to 111°F), for a minimum of 30 seconds to remove any residual detergent or debris.
6. Dry the device with a clean, lint-free towel.
7. Visually examine each device for cleanliness.
8. If visible soil remains, repeat cleaning procedure until the device is thoroughly clean.

Cleaning Agents

A neutral pH detergent solution should be used to clean the Sindt Ophthalmic Spatula. Detergent solution should be prepared according to detergent manufacturer's instructions.

Rinsing

The Sindt Ophthalmic Spatula should be rinsed in treated, running water. Care should be taken to rinse all surfaces of the spatula.

Lubricating Agents

Lubrication is not recommended for the Sindt Ophthalmic Spatula.

Visual Inspection and Maintenance

Proper care and handling is essential for satisfactory performance of any device. The previous cautions should be taken to ensure long and trouble-free service from all your devices. Inspect devices before each use for broken, cracked, tarnished surfaces, and chipped or worn parts. If any of these conditions appear, do not use the device.

Method of Sterilization

Packaging for Sterilization

Spatulas can be loaded into FDA cleared sterilization packaging in accordance with packaging manufacturer's sterilization instructions.

Device Configuration for Sterilization

Spatulas should be configured so that water pooling does not occur on concave surfaces.

METHODS of STERILIZATION

STANDARD PREVACUUM STEAM STERILIZATION CYCLES

Prevacuum Steam Sterilization Cycle (U.S. "FDA Compliant – WRAPPED")

- Conditioning Pulses: 4
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes
- Sterilization Configuration: FDA Cleared Sterilization

Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin)

Prevacuum Steam Sterilization Cycle – Immediate Use Steam Sterilization (U.S. "FDA Compliant – WRAPPED")

- Conditioning Pulses: 4
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Sterilization Configuration: FDA Cleared Sterilization

Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin)

NOTE: Devices must be used immediately and cannot be stored for later use.

Immediate Use Steam Sterilization is not recommended as a routine practice. Refer to ANSI/AAMI ST79* for requirements on when to perform and how to control immediate use steam sterilization.

*Reference: ANSI/AAMI ST79: (current revision) Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

After sterilization, devices should remain in sterilization packaging and be stored in a clean, dry environment. Care should be taken to not deform the devices with excessive force during storage.

Reuse Life

Repeated processing has minimal effect on these devices. End of life should be determined by wear and damage due to use. End of life may be determined by of wear and damage via visual inspection to include:

- Misshapen spatula,
- Broken spatula,
- Discoloration,
- Corrosion or pitting.

Other Resources

To learn more about sterilization practices and what is required of manufacturers and end users, visit www.aami.org, www.aorn.org or www.iso.org.

Drying

Active drying of the device should occur after the cleaning process using a lint-free towel and again after sterilization using heat to remove remaining moisture from the spatulas.

Storage

MADIE

 THE UNIVERSITY OF IOWA



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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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