COOK MEDICAL

CE 0123

EN XX **Salivary Access Dilator Set**
Instructions for Use

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SALIVARY ACCESS DILATOR SET

Read all instructions carefully. Failure to properly follow the information provided may lead to the device not performing as intended or injury to the patient.

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

DEVICE DESCRIPTION

The Salivary Access Dilator Set (SDDS) is comprised of a set of four dilators. The dilators are manufactured from polyethylene tubing in 4.0, 5.0, 6.0, and 7.0 French sizes and a length of 20 centimeters. The distal end hole of all four dilators is tapered to a 0.018 inch diameter. Hydrophilic coating is applied to the distal three centimeters of each dilator. The dilator hubs are pre-molded onto the dilator shafts.

Performance Characteristics

- The dilators are made from a flexible polyethylene tubing.
- Hydrophilic coating is applied to the tapered distal end to facilitate minimally traumatic insertion into the salivary duct papilla.
- The set includes multiple dilator sizes for sequential duct dilation.

Device Compatibility

The dilators are compatible with a wire guide up to 0.018" in diameter.

Patient Population

The device is used to treat adult patients with obstructive salivary gland disease who require salivary duct dilation to facilitate access for diagnostic or interventional procedures or who require dilation of stenosis or stricture.

Intended Users

The product is intended for use by physicians (or properly licensed and privileged practitioners) trained and experienced in diagnostic and interventional techniques.

Contact with Body Tissue

The device is tissue contacting with the oral mucosa and salivary ducts.

Operating Principle

The dilators are used to expand the working tract to facilitate the introduction of other devices. The distal tip of each dilator has a hydrophilic coating to reduce resistance when inserting the dilator. Multiple dilators may be required to properly dilate the target tract, in which case the indicated dilators should be used in sequential order starting with the smallest.

INTENDED USE

The Salivary Access Dilator Set is intended to expand the papilla and prepare the salivary duct for introduction of diagnostic or interventional procedural instruments or to dilate stenosis or stricture by sequential dilation with a series of flexible dilators over a wire guide.

DEVICE AND CLINICAL BENEFITS

- Salivary duct dilation facilitates minimally invasive diagnostic and interventional procedures.
- Dilation of stenosis or stricture corrects the cause of obstructive sialoadenitis and preserves the salivary gland.

INDICATIONS FOR USE

The device is used to expand duct access for sialendoscopy or related procedures requiring dilation for patients with obstructive salivary gland disease and to dilate stenosis or stricture.

CONTRAINDICATIONS

Acute sialoadenitis

WARNINGS

- This single use device is not designed for re-use. Attempts to reprocess (re-sterilize) and/or to re-use may lead to device failure and/or transmission of disease.
- Do not use the device if the sterile packaging is damaged or unintentionally opened before use.
- This device is not intended for use in the vasculature.
- This device is not intended for use in the sublingual salivary ducts or glands.

PRECAUTIONS

- Standard techniques for placement of salivary access dilators should be employed.

- Ensure compatibility of dilators with an appropriately sized wire guide.
- When inserting, manipulating, or withdrawing the device, do not use excessive force.

POTENTIAL ADVERSE EVENTS

Potential adverse events to instrumentation of salivary ducts include but are not limited to:

- Airway obstruction
- Bleeding
- Cyst formation (ranula, sialocele)
- Damage to facial or lingual nerve
- Dissection, perforation, rupture, avulsion, or other injury to salivary gland, salivary duct, or adjacent tissue
- Infection
- Pain
- Salivary duct occlusion, stenosis, or stricture
- Swelling

HOW SUPPLIED

Supplied Sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Keep dry and away from sunlight. Upon removal from package, inspect the product to ensure no damage has occurred.

INSPECTION OF DEVICE

Visually inspect the device thoroughly including all levels of the packaging (as applicable) to verify that there is no damage prior to use. Visually inspect and confirm that the integrity of the sterile barrier has not been compromised in any way.

INSTRUCTIONS FOR USE

1. Upon removal from package, ensure all stated components are present and intact. Ensure the inner diameter of the dilators are appropriate for the maximum diameter of the wire guide to be used.
2. Prior to use, immerse dilators in sterile water or saline to allow the hydrophilic surface to absorb water and become lubricious.
3. Once the wire guide is in position, pass the dilators over the wire guide and through the papilla into the salivary duct while maintaining the wire guide's position. If resistance is encountered, do not force; damage to the duct may occur.

   Note: Multiple dilators may be required to properly dilate the target tract, in which case the indicated dilators should be used in sequential order starting with the smallest.

DISPOSAL OF DEVICES

Following use, this device may be contaminated with potentially infectious substances of human origin and should be disposed of in accordance with institutional guidelines.

REFERENCES

These instructions for use are based on experience from physicians and/or published literature. Refer to your local Cook sales representative for information on available literature.

PATIENT COUNSELING INFORMATION

Please inform the patient as necessary of the relevant warnings, precautions, contraindications, measures to be taken, and limitations of use.

SERIOUS INCIDENT REPORTING

If any serious incident has occurred in relation to the device, this should be reported to Cook Medical and, if indicated, the competent authority where the device was used.

Single Sterile Barrier System with Protective Packaging Inside

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