Instructions For Use

Sinusleeve® DOS Balloon Sinus Dilation Sleeve

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal (USA) law restricts the sale of this device to, by or on the order of a physician.

DESCRIPTION

The Dalent® Sinusleeve® DOS Balloon (Figure 1) is a single-use surgical instrument used to dilate sinus ostia. The Sinusleeve® DOS balloon is compatible with 6F ENT instruments. Sinusleeve® Model SLV618 is available with a 6 mm diameter an 18 mm working length balloon.

INDICATIONS FOR USE

This device is intended to be used with commonly used 6F ENT instruments to dilate the sinus ostia and spaces within the maxillary, frontal and sphenoid paranasal sinus cavities.

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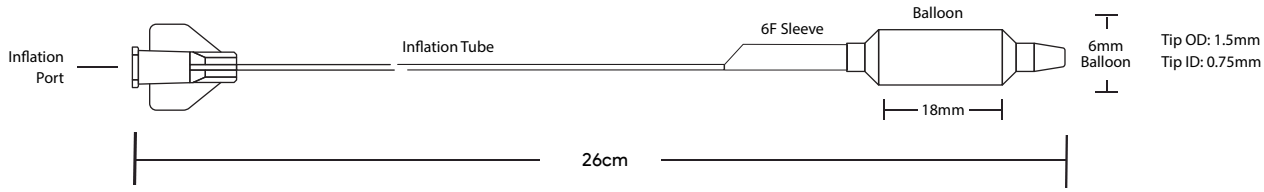

Figure 1. Dalent® Sinusleeve® DOS SLV618

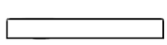

Figure 1a. Balloon Guard

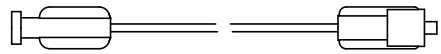

Figure 1b. 20" Inflation Tube Extension Line

CONTRAINDICATIONS

Device is not intended or indicated to break or rearrange bone.

WARNINGS

Prior to use examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a sterile package. Do Not Use if package is damaged, opened or the expiration date has passed.

Intended for Single Patient Use only, DO NOT REUSE. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Never advance or retract the device against resistance, as this could cause tissue trauma or device damage.

Do not try to move the sinus balloon sleeve while the sinus balloon is inflated.

Deflate the sinus balloon fully before withdrawing from the dilated space.

Use only liquid media for inflation. Do not inflate with air.

It is the responsibility of the user to dispose of the device in accordance with local regulations and hospital procedures.

⚠ Always discontinue use of suction while balloon is inflated to reduce risk of barotrauma.

⚠ Do not exceed 12 ATM inflation pressure.

⚠ Do not inflate balloon more than 12 times.

⚠ Do not kink inflation tube.

PRECAUTIONS

Prior to use, ensure the connector tubing of the inflation device is free of air.

Use direct endoscope visualization with or without the Sinusleeve® Light Fiber to ensure accurate placement of the balloon prior to dilation. If balloon location cannot be verified, image guidance or fluoroscopy can be used. If balloon location still cannot be verified, the balloon should not be inflated.

HOW SUPPLIED

Sterile in unopened, undamaged package.

STORAGE

Store sterile, packaged device in a cool, dry place until ready for use.

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Sinusleeve® DOS Balloon Sinus Dilation Sleeve

DIRECTIONS FOR USE

EMPLOY AESEPTIC TECHNIQUE WHEN OPENING THE PACKAGE TO AVOID CONTAMINATION.

1. Prior to use, visually inspect the product to verify that there is no damage. If damaged, DO NOT USE.
2. Prepare and test the inflation device chosen by the surgeon, according to the manufacturer's directions for use.
3. Open Sinusleeve® balloon packaging and remove from the mounting card. Remove the Balloon Guard (Figure 1a) from the balloon by sliding it off the tip.
4. Create a fluid-fluid connection between the Sinusleeve® DOS and inflation device by connecting the male luer adapter with the female luer inflation port on the Sinusleeve® DOS balloon. If desired, the 20" Inflation Tube Extension Line (Figure 1b) can be connected to the Sinusleeve® DOS prior to connecting the inflation device to provide a longer connection.
5. Gently slide the balloon sleeve over the sinus instrument chosen by the surgeon until the end of the instrument reaches the tip of the balloon sleeve.
6. With the balloon sleeve confirmed in place, insert the sinus instrument to the desired anatomical location. Do not use excessive force.
7. Inflate the balloon to desired pressure using the chosen inflation device. Do not exceed 12 ATM inflation pressure.
8. Repeat steps 5 - 7 as needed up to six times.

EXPLANATION OF SYMBOLS

Consult Instructions For Use	Do Not Use if Package is Damaged	Do Not Reuse
STERILE EO Sterilized Using Ethylene Oxide	Do Not Resterilize	Quantity Packaged
Use By	LOT Lot Number	RX ONLY Prescription Only
REF Reference Number	Caution	Manufacturer
PHT DEHP Not Made with DEHP	LATEX Not Made with Natural Rubber Latex	

DISCLAIMER OF WARRANTY

Although the Dalent® Sinusleeve® DOS device, hereafter referred to as "Product" has been manufactured under carefully controlled conditions, Dalent, LLC has no control over the conditions under which this product is used. Dalent, LLC therefore disclaims all warranties, both expressed and implied, with respect to the Product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Dalent, LLC shall not be liable to any person or entity for any medical expenses or any direct, incidental, or consequential damages caused by any use, defect, failure or malfunction of the Product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Dalent, LLC to any representation or warranty with respect to the Product.

The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law, by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Purchaser must determine the suitability of this product for their particular use.

Support for physicians and medical professionals: Go to Product Support page at www.dalentmedical.com

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