Read this package insert completely before use and comply with the instruction for use

NasoAid® Intranasal Splint

GRAPHICAL SYMBOLS (2) Single use only LOT Lot number Read instructions Store at room temperature before use STERILE R Sterilized by irradiation Keep away from sunlight Do not re-sterilize Do not use if package is damaged Use by expiry date Federal law(USA) restricts this device to sale by or on Manufacturer R_{only} this device to sail \mathbb{Z}_{+} the order of a licensed REF Catalog number healthcare practitioner

Description

NasoAid® Intranasal Splint is a composite of collagen and carboxymethyl cellulose. It is white, porous, and absorbable. It is a biologically safe matrix with a highly interconnected porous structure. This allows for a rapid and high fluid absorbent capacity. The product is supplied in a sterile, non-pyrogenic form and is indicated for single use only.

Indications

The product is indicated for use in patients undergoing nasal/sinus surgery as an intranasal splint to minimize bleeding and edema and to prevent adhesion between the nasal cavity and septum.

Instructions for use

After sinus surgery, using forceps or tweezers, insert NasoAid® Intranasal Splint into the nasal cavity after the use of antibiotics. It gradually breaks down into fragments by absorbing blood and/or nasal fluids while providing wound support. The fragmented pieces can flow out through natural mucus outflow. Following the gradual fragmentation process, the fragments can be removed within 14 days post-surgery. The risk of infection and Toxic Shock Syndrome (TSS) is extremely low.

Precautions

- 1. The product should not be used on infected wound sites.
- 2. Before using the product, carefully clean the contaminated wound to prevent infection.
- Even through NasoAid® Intranasal Splint minimize bleeding, the product is not intended for patients with abnormal blood clotting.
- 4. The clinical safety of NasoAid® Intranasal Splint has not been assessed in pregnant women. If deemed necessary, surgeons may consider using the product in pregnant women based on the individual patient's condition and response.

- 5. Patients with severe allergy history or hypersensitivity to bovine collagen or carboxymethyl cellulose are not recommended to use NasoAid® Intranasal Splint.
- 6. On rare occasions during nasal surgery, the physiological circumstances, with or without the use of intranasal splints, may pose a potential risk for the onset of toxic shock syndrome (TSS). TSS is a potentially fatal illness caused by bacterial toxin. TSS typically manifests in otherwise healthy individuals with high fever, low blood pressure, malaise, and confusion, which can rapidly progress to stupor, coma, and multiple organ failure.
- 7. Check the expiration date of each individual product before use. Do not use expired products.
- 8. Do not use the product when packaging is damaged, as sterility of the contents cannot be assured.
- The product is intended for single use only. Do not re-sterilize or re-use it.

Product Composition and Specifications

Material	Content	Function
Collagen	70±10%	Collagen provides a highly porous sponge structure capable of absorbing a large amount of liquid, thereby facilitating the swelling of the sponge and contributing to maintaining space within the nasal cavity. Forming a physical barrier to prevent adhesion between the nasal cavity and septum.
Carboxymethyl cellulose	30±10%	Carboxymethyl cellulose provides the structure with water-holding and fragmenting abilities, allowing the product to gradually disintegrate within 14 days after being placed in the nasal cavity following surgery or trauma.

Product type	Specification
NSA-202015	20mm × 20mm x 15mm
NSA-402015	40mm × 20mm x 15mm
NSA-602015	60mm × 20mm x 15mm
NSA-802015	80mm × 20mm x 15mm

Storage and Shelf Life

Storage Temperature: $<25^{\circ}$ C. Avoid exposing to extreme environmental conditions.

Shelf Life: 3 years (Stored in room temperature)

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