Clinical Guidance for Appropriate Use of PROPEL™ Nasal Stent

The Japanese Rhinologic Society
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Purpose of Use

This product is to be used in adult patients with chronic rhinosinusitis to maintain sinus patency following sinus surgery. It stabilizes the middle turbinate prevents obstruction of the middle meatus and sinuses caused by postoperative tissue adhesion, reduces inflammation and edema, and thereby decreases the need for postoperative interventions.

Target Patients

This is the first drug-eluting, bioabsorbable sinus stent approved in Japan. It is placed after endoscopic sinus surgery (ESS) and maintains mechanical sinus patency for 30–45 days while locally and continuously releasing mometasone furoate, which is expected to reduce the risk of postoperative interventions. Multiple randomized clinical studies and meta-analyses conducted in the United States have demonstrated that at 30–90 days post-surgery, the risks of postoperative intervention, including surgical intervention, and the need for oral steroids are significantly lower in the group managed with this device compared to those managed with standard postoperative care alone[1-6]. Subgroup analyses of these clinical trials have shown that the device effectively reduces the risk of postoperative intervention in both patients with nasal polyps (CRSwNP) and those without nasal polyps (CRSsNP)[3]. Therefore, it is important to select target patients based on an appropriate assessment of postoperative recurrence risk, regardless of phenotype or endotype. In Japan, considering the current clinical practice and the postoperative intervention risk assessment indicated by the JESREC Study[7], the target patients for this device are defined as follows:

Patients who meet <u>either</u> of the following criteria:

1. Cases judged to be at a high risk of restenosis of the opened middle meatus (or similar areas) based on intraoperative findings or postoperative observations at the time of hemostatic material removal.
2. Cases of moderate to severe eosinophilic chronic rhinosinusitis judged to be at a high risk of postoperative relapse.

Exclusion Criteria

- Patients with suspected or confirmed hypersensitivity and/or intolerance to mometasone furoate.
- Patients with known hypersensitivity and/or intolerance to lactide, glycolide, or caprolactone copolymers.

Facilities and Physicians Authorized to Use This Device

Based on over 10 years of overseas usage, no serious adverse events have been reported, and clinical trials and published literature from the United States have not identified any safety

concerns. However, considering the novelty of the device, the following facility and physician criteria are established:

Facility Criteria: Facilities must have at least one full-time specialist certified by Japanese Society of Otorhinolaryngology-Head and Neck Surgery.

Physician Criteria: Physicians must be specialists certified by Japanese Society of Otorhinolaryngology-Head and Neck Surgery.

Precautions for Device Placement

- A maximum of two devices (for the frontal and ethmoid sinuses) may be placed per side.
- The device may be placed in the operating room on the day of sinus surgery or in the outpatient/procedure room 3–7 days postoperatively after confirming hemostasis.
- As the device does not have a hemostatic effect, ensure sufficient hemostasis before placement. If postoperative hemostasis is deemed insufficient, place a packing material and confirm hemostasis.
- To maintain moisture and remove unnecessary crusts from the placed device, perform frequent sinus irrigation as is standard after sinus surgery.

References

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