



STREAMLINE
CARTILAGE
MANAGEMENT

FLEXIBLE PLATE

STREAMLINE

your next nasal surgery
procedure.

PDS™ Flexible Plate: An absorbable PDS™-based structural support indicated for **nasal soft-tissue** and **cartilage reconstruction**

PLEASE SEE A DESCRIPTION OF RELEVANT INDICATIONS FOR USE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS FOR PDS™ FLEXIBLE PLATE ON LAST PAGE.

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The challenges of nasal surgery

Rhinoplasty and septoplasty are challenging procedures to perform.

- Technically demanding
- Often without enough remaining nasal cartilage
- Time-consuming

“Rhinoplasty is...among the most frequently performed operations in the United States today (305,475 in 2004, according to the American Society of Plastic Surgeons). However, this procedure may also be perceived as one of the most technically demanding of all cosmetic procedures.”²

“...graft requirements may exceed what remaining cartilage is found in septal and auricular sites, especially in secondary rhinoplasty.”³

In Septoplasty “...the pieces of cartilage must be reconnected meticulously to form a straight and solid plate. This difficult and time-consuming technique can be facilitated by the use of a connecting material.”⁴

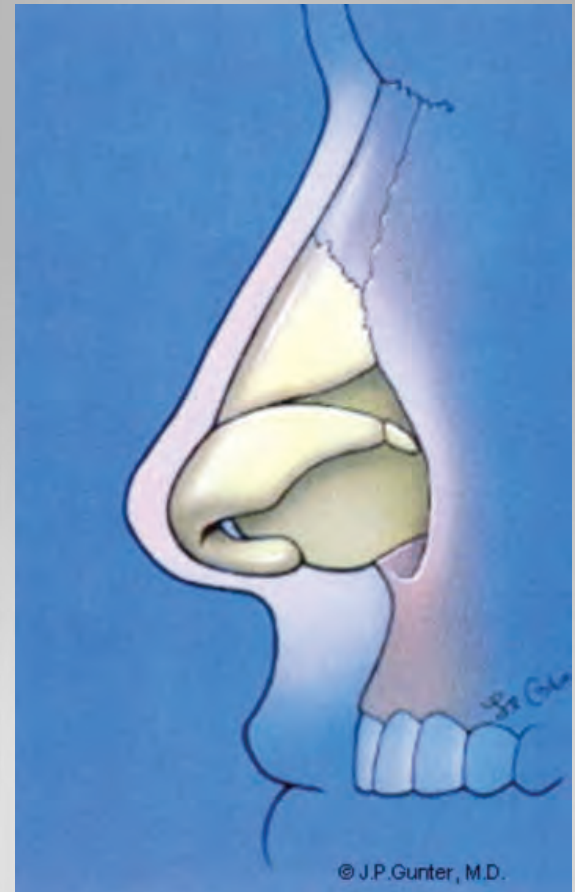
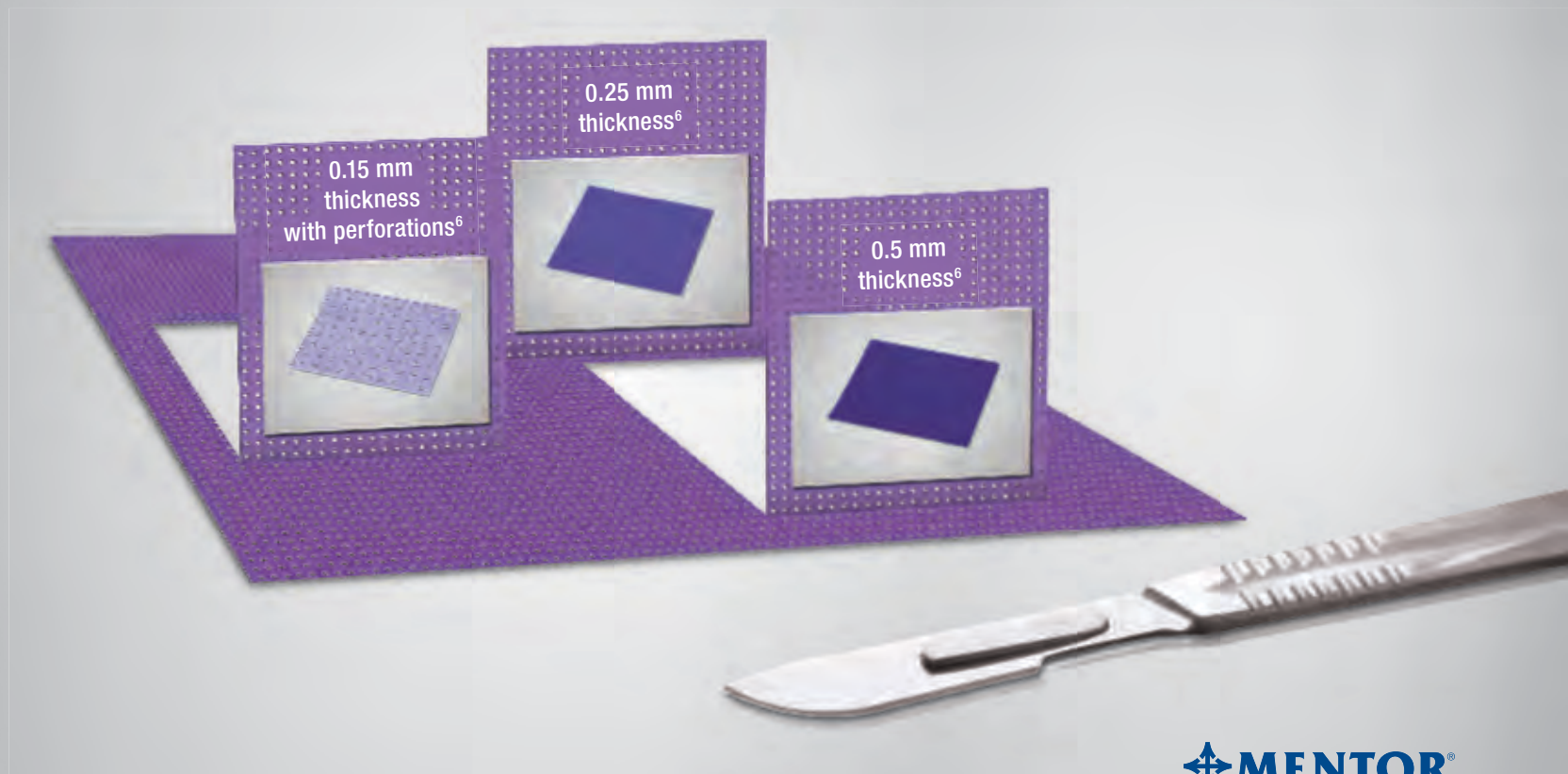


Illustration appears courtesy of Dr. Jack Gunter

PDS™ Flexible Plate is made by Ethicon, Inc. and distributed by Mentor

- PDS™ polymer was invented by Ethicon, Inc. and has been trusted by surgeons for over 20 years
- PDS™ Flexible Plate is manufactured by Ethicon, Inc.
- PDS™ Flexible Plate is distributed by Mentor—a leading global supplier of aesthetic medical products

PDS™ FLEXIBLE PLATE COMES IN THREE SIZES

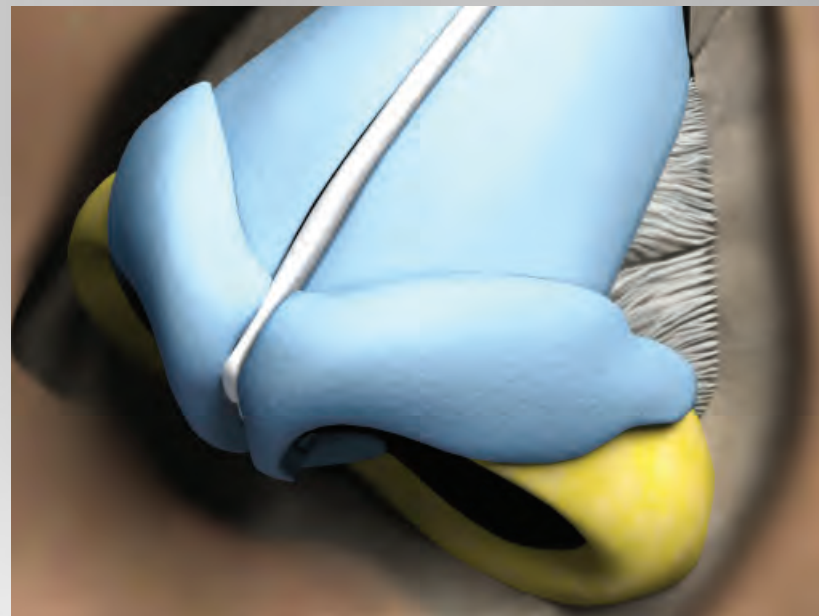


PDS™ Flexible Plate: A streamlined approach to nasal reconstructive surgery

Introducing a new device for use in nasal reconstructive surgery. PDS™ Flexible Plate supports the nasal structures until regrowth of cartilage and scar tissue stabilizes the cartilage fragments fixed to the PDS™ Flexible Plate.^{1,5,6}

PDS™ Flexible Plate can be used in rhinoplasty and septoplasty procedures¹:

- Indicated for nasal soft-tissue and cartilage reconstruction¹
- Provides stability and support during the healing process, then is fully absorbed^{1,3}
- Use of 0.15 mm perforated plate is recommended for septoplasty¹

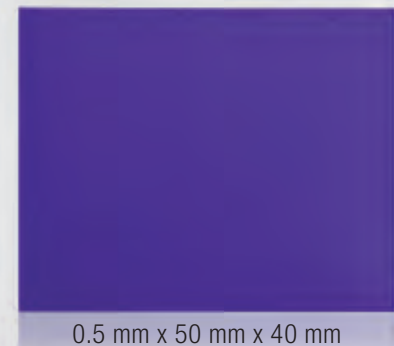
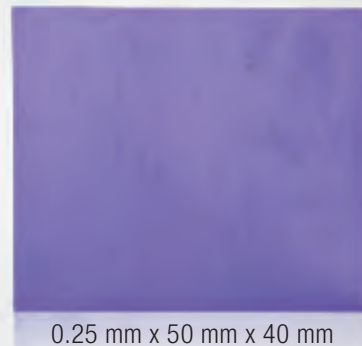
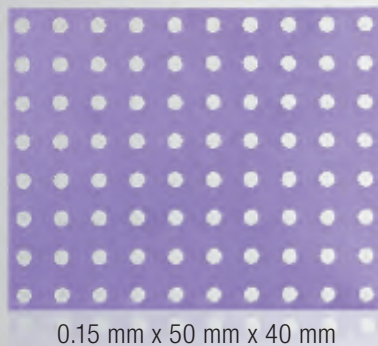


Streamline primary and secondary rhinoplasties

With PDS™ Flexible Plate, you may reduce the need for other donor sites^{1,3}

In a recent study, PDS™ Flexible Plate combined with autologous cartilage was found to be a simple and effective technique³

- May reduce the need for secondary cartilage donor site surgery³
- Allows for the maximum use of cartilage fragments that otherwise would have been discarded³
- May reduce the incidence of the “graft-depleted” patient³



Streamline surgical correction in extracorporeal septoplasty⁴

With PDS™ Flexible Plate, you have the ability to correct septal deformities, potentially avoid the risk of some patient complications, and optimize the outcome of your next septoplasty procedure.⁴

In a clinical study, PDS™ Flexible Plate combined with septal cartilage provided support for the nasal dorsum in external septoplasty and/or septal reconstruction⁴ (n=71)

- No late complications or cosmetic defects such as saddle deformity, retraction of the columella or loss of tip projection (FU Avg. 24 months)⁴
- A postoperative straight septum was achieved in 99% of cases⁴
- No immediate complications such as hematoma, inflammatory response, or necrosis⁴

In the same study, all patients (n=71) undergoing external septoplasty with PDS™ Flexible Plate experienced⁴:

- Improvement of the nasal airway⁴
- No immediate or long-term complications^{4*}
- No rejection of the plate⁴

^{*}In septoplasty and rhinoplasty surgical procedures.¹

PDS™ Flexible Plate provides nonwarping support during healing⁴

- Introduces sufficient structural stability for cartilage reinforcement and increased strength
- Combined with cartilage, the device supports the graft as a guide and can significantly reduce bending and secondary deviations that bending can cause
- In a study of patients undergoing external septoplasty and/or rhinoplasty, PDS™ Flexible Plate provided a stable graft and normal mucosal healing without immediate or delayed postoperative complications⁵
- Designed to stabilize free grafts¹
- Has been shown to prevent overlapping⁵

The PDS™ Flexible Plate used as a temporary scaffold can be used to construct¹:

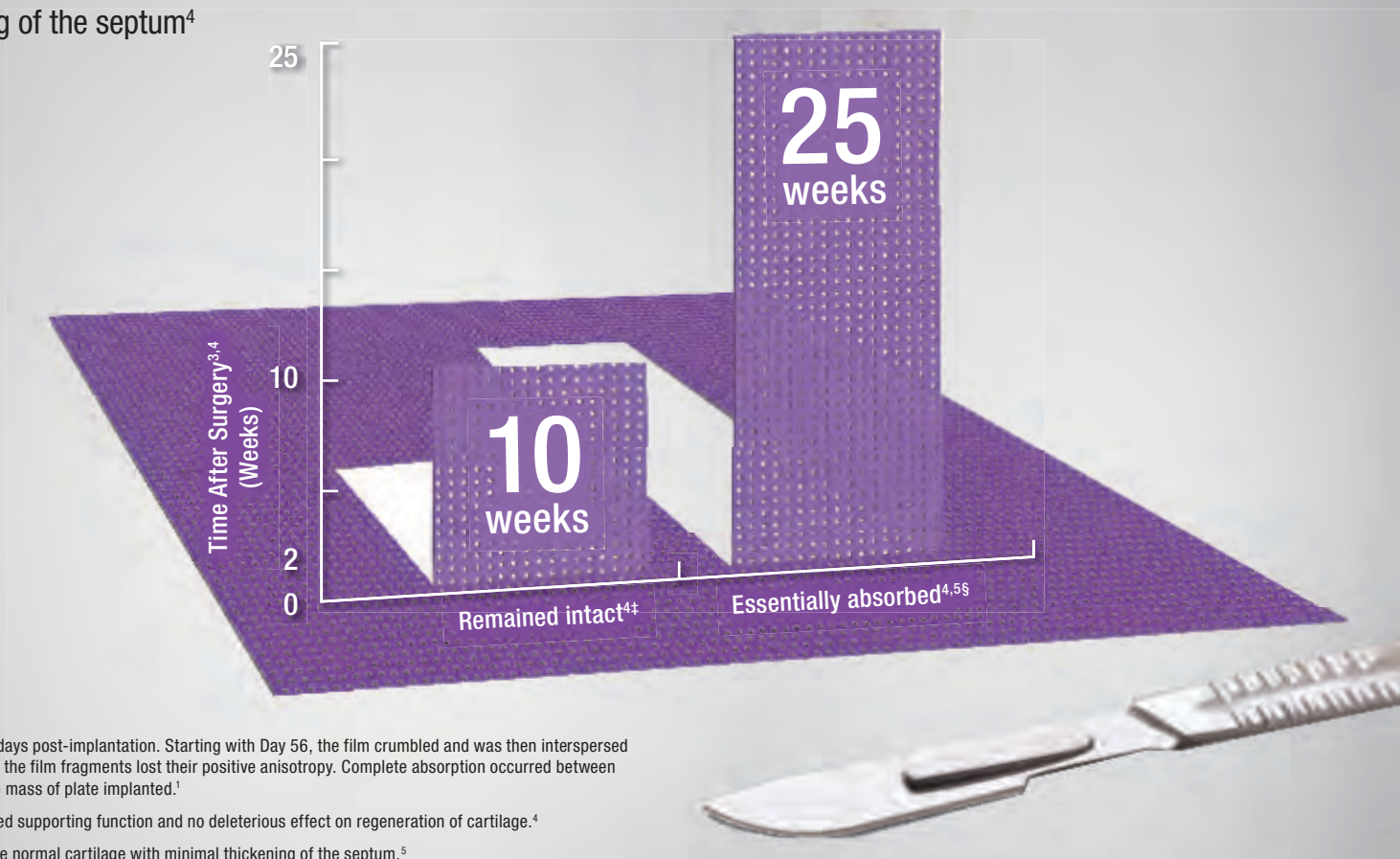
- Columellar struts^{1,3}
- Septal extension grafts^{1,3}
- Alar battens^{1,3}
- Upper lateral replacement grafts^{1,3}



Provides stability and support during the healing process, then is absorbed†

In a pre-clinical study, PDS™ Flexible Plate was shown to remain intact for up to 10 weeks and completely absorbed after Week 25⁴

- Avoids long-term complications associated with nonabsorbable artificial implants⁴
- Only very thin remnants of scar tissue remained with minimal thickening of the septum⁴



[†]No loss of tensile strength occurred up to 42 days post-implantation. Starting with Day 56, the film crumbled and was then interspersed with macrophages and resorbed. By Day 168, the film fragments lost their positive anisotropy. Complete absorption occurred between Days 168 and 224. Absorption varied with the mass of plate implanted.¹

[†]With continued stability of the form and desired supporting function and no deleterious effect on regeneration of cartilage.⁴

[§]Scar tissue remnants were observed under the normal cartilage with minimal thickening of the septum.⁵

Study Descriptions: Boenisch et al.⁴ Animal study in 5 rabbits; PDS™ Flexible Plate was implanted into the outer ear over an intentionally made cartilage defect. Observations were made at 2, 5, 10, 15, and 25 weeks. Resorption of the implant was investigated by histological examination. Time to complete absorption was recorded. Boenisch et al.⁵ Animal study of septal surgery in 45 young rabbits. Septoplastic procedures included elevation of the mucoperichondrium, cartilage excision, and reimplantation of crushed and noncrushed cartilage; PDS™ Flexible Plate was used in half of the animals. Observations of the healing process ranged from 2 weeks to 5 months, until complete outgrowth of the septum and complete resorption of the foil were achieved.



Study Summary

Secondary rhinoplasty using PDS™ Flexible Plate in combination with cartilage at multiple sites³

In a retrospective study of patients (n=21) undergoing secondary rhinoplasties treated by a single surgeon using an open approach in a hospital setting during a 3-year period:

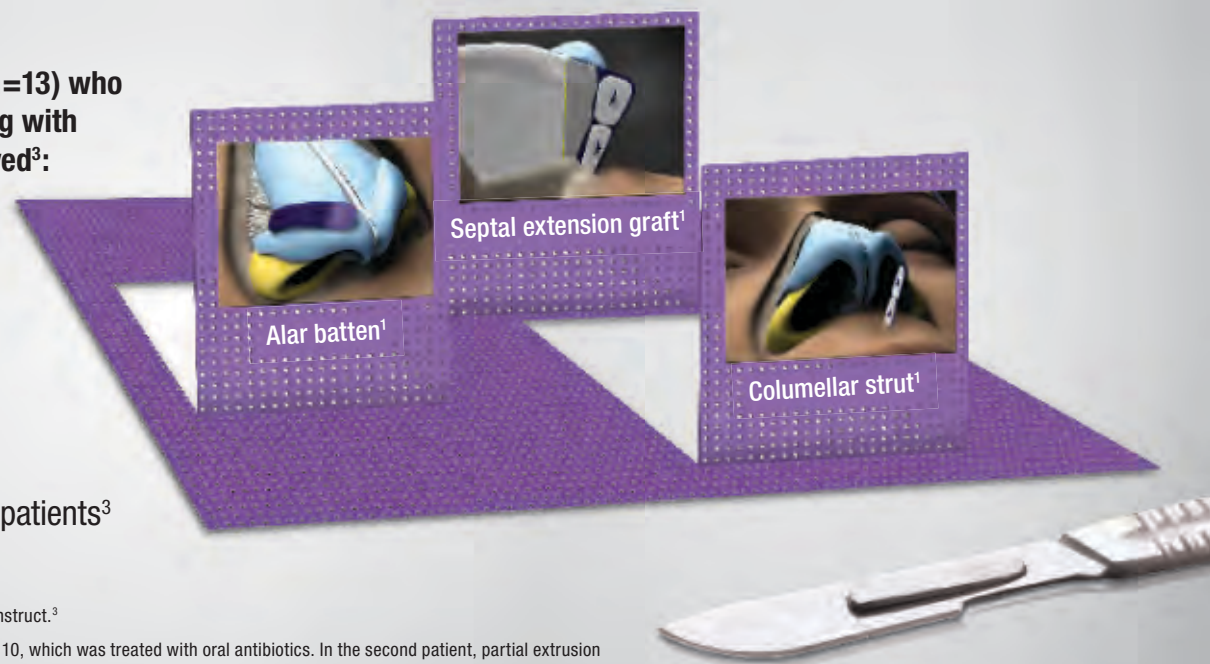
- PDS™ Flexible Plate was combined with costal cartilage to construct alar battens (with lateral crural repositioning), columellar strut, spreader, and tip grafts³
- Thicker cartilage fragments were preferred in constructing columellar struts over thinner cartilage for upper lateral onlay grafts³
- No significant loss of tip projection or valvular weakness occurred^{3†}
- 1 representative case was a female patient with collapse of the middle third, lateral crural malposition, and failure of both internal and external nasal valves³

In the same study, the subgroup of patients (n=13) who received a columellar strut and further grafting with PDS™ Flexible Plate at a variety of sites achieved³:

- Aesthetic and mechanical stability³
- Unimpaired nasal respiratory function in cases of valvular reconstruction³

No operative revisions were required³:

- 2 minor complications occurred^{3§}
- PDS™ Flexible Plate was well tolerated in all patients³



[†]In cases where a columellar strut was used with weaker alar cartilage in the construct.³

[§]Postoperatively, a *Staphylococcus aureus* infection occurred in 1 patient on Day 10, which was treated with oral antibiotics. In the second patient, partial extrusion of the PDS™ Flexible Plate used to construct an alar batten was trimmed in the office and oral antibiotics were given.³

Study Description: James et al.³ Retrospective review in 58 of 211 (27%) patients undergoing primary (n=37) or secondary (n=21) rhinoplasty between June 2003 and May 2006, in which PDS™ Flexible Plate was used as a biomechanical scaffold. All patients were operated on using an open approach; of these, patients in the primary group had an average age of 33.8 years; and in the secondary group an average age of 38.6 years. Comparative clinical and photographic evaluations were made at 4 days, 11 days, 6 weeks, and a mean of 18 months postoperatively (range, 6 to 40 months). Two minor complications occurred. No operative revisions were required; extremely well tolerated in all patients.



Study Summary

External septal reconstruction using PDS™ Flexible Plate to create a stable and solid graft⁷

Retrospective study of patients (n=12) undergoing external septoplasty treated by a surgical team in a hospital setting during a 2-year period;

- The PDS™ Flexible Plate was used in external septoplasty, which included reduction of the bony dorsum (2 mm), cephalic resection of the lower lateral cartilage (2.5 mm), and placement of the columellar strut and tip only grafts⁷
- Satisfactory aesthetic and functional results were achieved⁷
- Stable graft and normal mucosa healing resulted⁷
- No immediate or late postoperative complications occurred^{7,†}
- 1 representative case includes a 28-year-old woman with severe nasal obstruction due to septal deviation combined with exterior nasal deformity most commonly caused by previous nasal trauma⁷

In the same study, the majority of patients (n=11) undergoing external septoplasty with PDS™ Flexible Plate achieved⁷:

- A totally straight septum⁷
- Improved nasal airways⁷
- Satisfactory cosmetic results⁷



[†]No hematoma, inflammatory response, necrosis, rejection of PDS™ Flexible Plate, or secondary deviation of the cartilage grafts occurred.⁷

Study Description: Petropoulos et al.⁷ Surgical team performed external septoplasty in patients (n=12) under the supervision of the authors over a period of 2 years in a hospital setting. Patients admitted into the study presented with severe septal deviation and breathing problems. In all patients, the septum was resected and sutured onto an appropriately sized PDS™ Flexible Plate, then reimplanted together between the mucoperichondrium flaps. Some patients experienced slight thickening of the septum by Week 3, which resolved over the following 2 weeks. In one patient, slight subluxation of the caudal border occurred. There was no rejection of PDS™ Flexible Plate, or secondary deviation of the cartilage grafts. No septal perforation was encountered. No immediate complications such as hematoma, inflammatory response, or necrosis occurred. At 1 year, the PDS™ Flexible Plate was resorbed; a totally straight septum was achieved in the majority of patients (n=11).

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PDS™ Flexible Plate: An absorbable structural support for use in rhinoplasty and septoplasty¹



- May reduce cartilage donor sites for some procedures³
- Low incidence of suboptimal cosmetic and/or functional outcomes⁴
- Low incidence of reoperations to correct suboptimal results^{3,5,7,8}
- Essentially absorbed in approximately 180 days¹
- Can be trimmed to adapt to anatomy¹
- No significant loss of tensile strength at 4 to 5 weeks^{1†}



Visit www.pdsflexibleplate.com to get the *latest* information.

^{*}In septoplasty and rhinoplasty surgical procedures.¹

[†]Retains tensile strength throughout critical healing period. Starting with Day 56, the film crumbled and was then interspersed with macrophages and resorbed. By Day 168, the film fragments lost their positive anisotropy. Complete absorption occurred between Days 168 and 224. Absorption varied with the mass of plate implanted.¹





STREAMLINE CARTILAGE MANAGEMENT

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PDS™ FLEXIBLE PLATE INSTRUCTION FOR USE

DESCRIPTION: PDS™ Flexible Plate is made of poly-p-dioxanone, an aliphatic polyester which is manufactured by polymerization of the monomer p-dioxanone. The chemical formula is (C₄H₆O₃). PDS™ Flexible Plate is dyed with D+C violet # 2 (Color index Number 60725). PDS™ Flexible Plate is available in various film thicknesses, one of which is also perforated. PDS™ Flexible Plate can be trimmed to suit the anatomical conditions. **INDICATION:** Indicated for: Nasal soft-tissue and cartilage reconstruction **APPLICATION:** Standard surgical approach should be used to prepare the site for implantation. The device can then be trimmed to the desired size. Care should be taken to avoid creating sharp contours when trimming. Secure the device to a stable structure. Use of the 0.15 mm perforated PDS™ Flexible Plate is recommended for septoplasty. **PERFORMANCE:** The PDS™ Flexible Plate absorbs over approximately 180 days. **CONTRAINDICATIONS:** Do not implant PDS™ Flexible Plate into patients with active infections at the surgical site. **PRECAUTIONS:** Use of the 0.15 mm perforated PDS™ Flexible Plate is recommended for septoplasty. Thicker and non-perforated flexible plates have not been adequately studied in this application. **WARNINGS/INTERACTIONS:** For the safe and effective use of this device the surgeon should be familiar with appropriate surgical procedures for its application. Improper patient selection, device selection, placement, positioning or fixation may result in undesired effects. Absorbable devices provide temporary reinforcement and bridging and are not intended to replace normal healthy bone or cartilage. Do not use in applications requiring permanent reinforcement. Do not use more than one device per procedure. Use in contaminated or infected areas might lead to potentiation of infection. Subsequent infection may require removal of the device. Do not expose the device to high temperatures such as those generated by electro-surgical instruments. **ADVERSE REACTIONS:** Potential adverse reactions are those typically associated with surgically implanted materials, including chronic inflammatory foreign body reaction, seroma formation, infection potentiation, fistula formation and extrusion. **STERILITY:** The product is sterilized with ethylene oxide. Do not resterilize. Do not use if the device or package is damaged or the package is opened. Do not use if a loss of sterility is suspected. Discard open unused product. **STORAGE:** Recommended storage conditions: below 25° C, away from moisture and direct heat. Do not reuse.

Not all contraindications, warnings, or adverse reactions are included in this brief description. More detailed risk information is available at 1-877-ETHICON.

REFERENCES: 1. Data on file. Ethicon, Inc. 2. Meningaud JP, Lantiré L, Bertrand JC. Rhinoplasty: an outcome research. *Plast Reconstr Surg.* 2007; 121: 251-257 3. James SE, Kelly MH. Cartilage recycling in rhinoplasty: polydioxanone foil as an absorbable biomechanical scaffold. *Plast Reconstr Surg.* 2008;122:254-260. 4. Boenisch M, Mink A. Clinical and histological results of septoplasty with a resorbable implant. *Arch Otolaryngol Head Neck Surg.* 2000;126:1373-1377. 5. Boenisch M, Tamas H, Nolst Trenite GJ. Influence of polydioxanone foil on growing septal cartilage after surgery in an animal model. *Arch Facial Plast Surg.* 2003;5:316-319. 6. Boenisch M, Tamas H, Nolst Trenite GJ. Reconstruction of the nasal septum using polydioxanone plate. *Arch Facial Plast Surg* 2010; 12: 5-9 7. Petropoulos I, Nolst Trenite G, Boenisch M, Nousios G, Kontzoglou G. External septal reconstruction with the use of polydioxanone foil: our experience. *Eur Arch Otorhinolaryngol.* 2006;263:1105-1108. 8. Gubisch W. Extracorporeal septoplasty for the markedly deviated septum. *Arch Facial Plast Surg.* 2005; 7:218-226.

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