PDS™ Flexible Plate
– STERILE –

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 $(C_4H_6O_3)$. 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.

SYMBOLS USED ON LABELLING

 = Do not reuse

 = Use by – year and month

STERILE EO = Sterile unless package is damaged or opened
Method of sterilization: Ethylene Oxide

LOT = Batch number

 = See instructions for use

℞ Only = Caution: Federal law restricts this device to sale by or on the order of a physician.

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