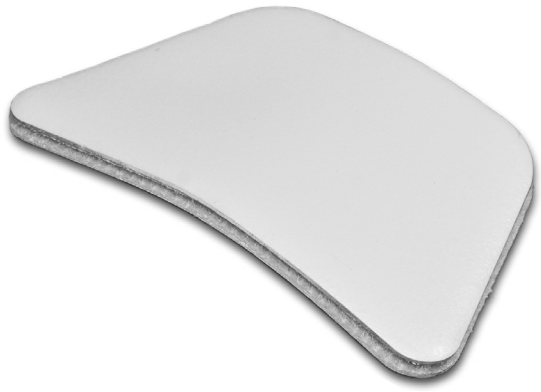
SYMBOL REFERENCE TABLE	
	Consult instructions for use
QTY	Quantity
REF	Catalogue number
	Date of manufacture
LOT	Batch code
	Do not resterilize
STERILE R	Sterilized using irradiation
STERILE EO	Sterilized by Ethylene Oxide
NON STERILE	Non-sterile
	Do not use if package is damaged
	Caution
	Do not reuse
	Use by date
	Manufacturer
	Keep dry
	Keep away from sunlight
	Upper limit of temperature
	Flammable
	Health hazard/hazardous to the ozone layer
US	Country of Manufacture (Made in the US)
Rx Only	Caution: US Federal law restricts this device to sale by or on the order of a physician
MD	Medical Device
UDI	Unique Device Identifier
LATEX	*Not made with natural rubber latex*

innovia® medical

The Denver Splint®

Series: 1800

Kits and Non-Kits



Contents		Sterilization
Kits		
Protecto™ Tape	Aspen Surgical Products, Inc	STERILE EO
Adapt™	Hollister Incorporated	NON STERILE
Webcol™	Covidien LLC	STERILE R
Denver Splint® Dorsal Pad	Summit Medical LLC	NON STERILE
Non-Kits		
Denver Splint® Dorsal Pad	Summit Medical LLC	NON STERILE

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*SIZES AVAILABLE: Large, Small/Medium, Petite & Mini
Patent #'s 4,153,051 4,213,452

INTENDED USE/INDICATIONS FOR USE
The Denver Splint® is intended to provide external support after rhinoplasty or nasal fractures.
The Denver Splint is indicated to be used postoperatively on rhinoplasty and nasal fracture patients to provide cushioned pressure to reduce edema and to provide external stabilization of bony fragments.

INTENDED USER
The Denver Splint is intended to be used by healthcare professionals, such as, plastic and cosmetic surgeons, facial trauma surgeons, and otolaryngologists.

CONTRAINDICATIONS
Adapt™ for use on intact skin only.

WARNINGS AND PRECAUTIONS
1. Do not apply splint directly to skin- may cause mild sensitization in certain sensitive individuals.
   Apply paper tape first.
2. For Single Use Only. Do not reuse. Reuse of device could result in infection, contamination or device failure which could lead to patient harm.
3. Do not resterilize.
4. Do not use if package is damaged or unintentionally opened prior to use, or if dorsal pad is compressed.
5. Do not use in known cases of severe soft tissue injuries that compromise blood supply to the skin.
6. Remove splint prior to X-ray, CT or MRI imaging. Splints may interfere with image quality.
7. Adapt™ – Warning: causes serious eye irritation. Avoid contact with eyes. In the case of accidental contact, flush eyes well with water. Should redness or other signs of irritation appear, discontinue use. Warning: may cause drowsiness and dizziness. Danger: Highly flammable liquid and vapor.
   Storage: Keep dry and away from sunlight, upper temperature limit of 25°C/77°F.
8. Protecto Tape - Skin should be clean, dry, and free of oils to assure good adhesion.

APPLICATION INSTRUCTIONS

PREPARATION
1. Cleanse and dry skin of nose.
2. Use alcohol sponge to wipe nose. Dry skin of nose after wiping.
3. Express edema manually from skin.
4. Apply a uniform coating of Adapt™ to nasal skin and allow to dry (approximately 30 seconds).
   If an area intended to be covered is missed, wait until Adapt™ has dried then reapply.
5. Express edema again.
6. Apply overlapping paper tape to nose.

APPLICATION

Series 1800 Kit & Non-Kit

7. Trim dorsal pad length to fit splint size. Apply center dorsal pad vertically to tape on the dorsum of the nose.
   DO NOT TOUCH SKIN WITH DORSAL PAD.
8. Remove paper backing from Velfoam® adhesive segment of splint and apply to paper tape on nose.
   DO NOT TOUCH SKIN WITH SPLINT. Narrow end of splint should point toward nasofrontal angle.
9. Shape metal segment of splint and attach hook Velcro® to Velfoam splint segment.
10. Mold by bending wings of splint toward face to make Velcro contact.
    DO NOT PINCH. DO NOT TOUCH SKIN WITH SPLINT.

REMOVAL
Remove splint in seven to ten days. Recommend removing by spreading bayonet forceps (dull) between skin and tape. Do not tent up skin with removal. Dispose of device as clinical waste in line with local protocol.

SERIOUS INCIDENT REPORTING
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the FDA/competent authority of the Member State in which the user and/or patient is established.