

Device Schedule

Intended Purpose as per the Instructions for Use:

VICRYL™ Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological tissues.

Endosuture System made with VICRYL™ Suture is intended for use in general soft tissue approximation and/or ligation involving endoscopic suturing when the use of absorbable suture is appropriate. Standard endoscopic procedures should be followed up to the point where Endosuture System made with VICRYL™ Suture is used.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
VICRYL Suture	VICRYL Suture	MDN 1104	Class III, Implantable	0705031a0113148
Endosuture System Made with VICRYL Suture	Endosuture System Made with VICRYL Suture	MDN 1104	Class III, Implantable	0705031a020314A

Additional Information:

Surgical needle and suture combinations from within the following limits define the device range for VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture:

Suture/Needle Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.2 - 7.0 (metric)
Suture Length	5 cm - 250 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Violet
Coated/Uncoated	Coated (Copolymer of glycolide and L-lactide, calcium stearate)/Uncoated
Multifilament/Monofilament	Multifilament/Monofilament
Accessories to suture type	N/A

Suture/Needle Characteristics	Range
Needled/Non-Needled	Needled (also available with CONTROL RELEASE needles)/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, and ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Curved/Straight
Needle Color	Silver/Black
Needle Length	2 mm - 110 mm
Needle Wire Diameter	0.015 mm - 1.80 mm

Product Name (as indicated on DoC)	Product Code	Product Description
Endosuture System ENDONEEDLE made with VICRYL™ Suture	EB11	VICRYL CT BRD VIO 44IN(110CM) USP0(M3.5) S/A EN-3 + ESS
	EB12	VICRYL CT BRD VIO 44IN(110CM) USP2-0(M3) S/A EN-3 + ESS
	EB13	VICRYL CT BRD VIO 44IN(110CM) USP3-0(M2) S/A DT-6 + ESS
	EB14	VICRYL CT BRD VIO 44IN(110CM) USP4-0(M1.5) S/A DT-6 + ESS
	EB22	VICRYL CT BRD VIO 44IN(110CM) USP2-0(M3) S/A EN-4 + ESS
Endosuture System ENDOLOOP made with VICRYL™ Suture	EJ11	VICRYL CT BRD VIO 20IN(50CM) USP0(M3.5) NON NDL ESS ENDOLOOP