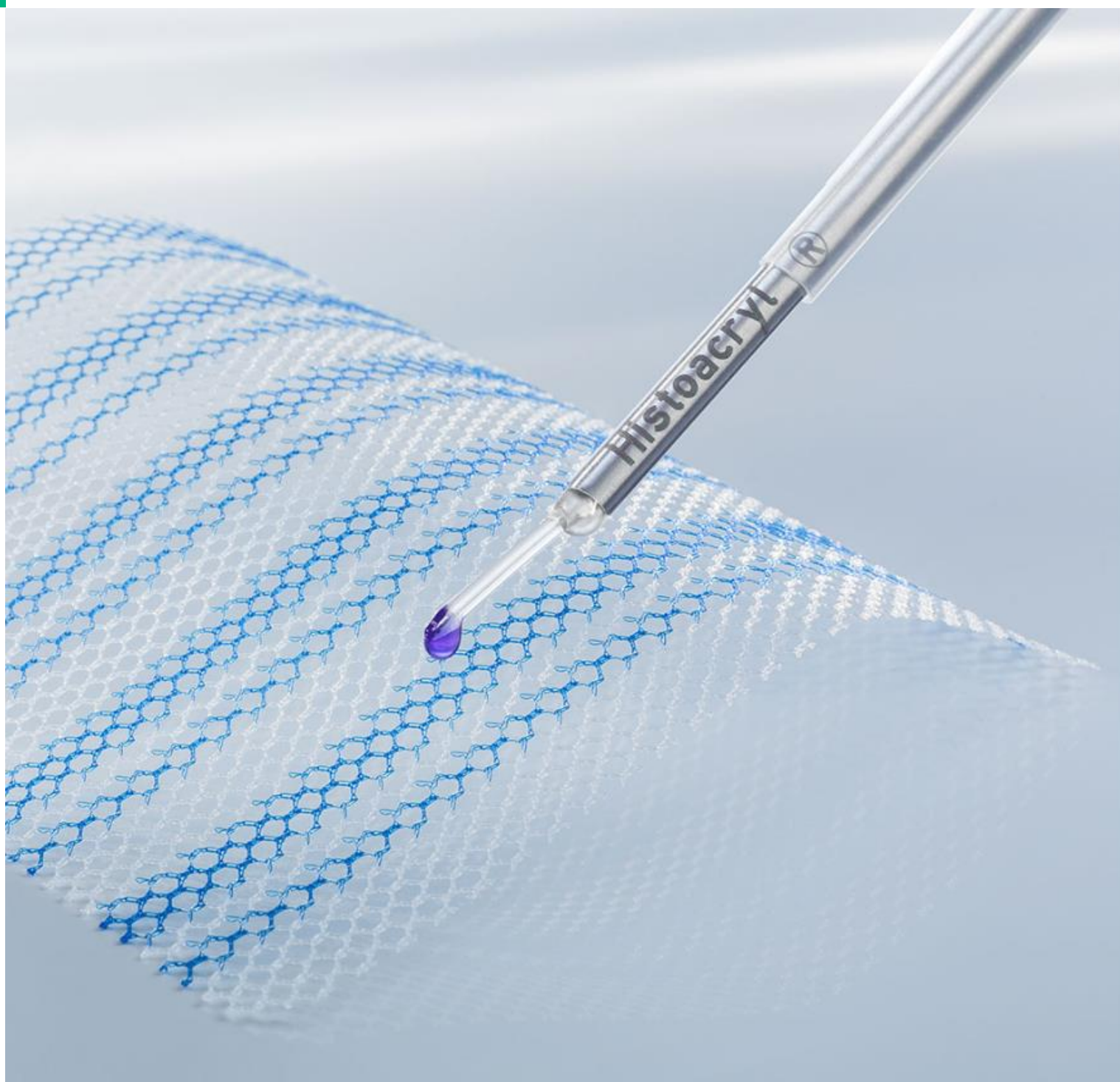


# HISTOACRYL® LAPFIX PACK TECHNICAL FILE



1

DESCRIPTION

Histoacryl® LapFix is a procedure pack designed to provide the needed for the laparoscopic fixation of surgical meshes in hernia surgeries when the meshes are not in contact with internal organs.

Histoacryl® LapFix is compounded of the following one single use sterile products:

- Histoacryl® LapFix Cannula (B. Braun Surgical, S.A.)
- Histoacryl® 0.5 mL (B. Braun Surgical, S.A.)
- Injekt® 2 mL Luer Lock Solo Syringe (B. Braun Melsungen AG)

Histoacryl® LapFix – Cannula is a single-use medical device. The cannula is designed for exclusive use with Histoacryl® and Injekt® 2mL Luer Lock Solo for the laparoscopic fixation of surgical meshes in hernia surgeries when the meshes are not in contact with internal organs. The cannula is supplied sterile packaged with easy peel opening.

Histoacryl® is a tissue adhesive produced from n-butyl-2-cyanoacrylate which can be used for mesh fixation during hernia procedures. The adhesive is presented in flexible plastic ampoules of 0.5 mL. For easy assessment of the thickness of the layer which has been applied Histoacryl® is coloured blue with the dye D&C violet No. 2.

2

INDICATIONS

Histoacryl® LapFix is indicated to deliver Histoacryl® for the laparoscopic fixation of surgical meshes in hernia surgeries when the meshes are not in contact with internal organs.

3

MATERIAL SPECIFICATION

Components Histoacryl® LapFix			
	Histoacryl®	Histoacryl® LapFix Cannula	Injekt® 2 mL Luer Lock Solo Syringe
Material	n-butyl-2-cyanoacrylate	Stainless steel 1.4301, Polyurethane, Polyethylene, Acrylonitrile Butadiene Styrene	Polypropylene / Polyethylene
Colour	Blue	Metallic cannula, transparent tip and cover tube.	Green plunger, transparent barrel
Sterilization	Aseptic technique	ethylene oxide gas	ethylene oxide gas
	The procedure pack is not sterilized.		

**4**

**STORAGE / SHELF LIFE**

Storage: Storable at temperatures below 22°C

Shelf-Life: 2 years

Packaging:

- Foil packaging (Histoacryl®).
- Tyvek Peel Pouch (Histoacryl® LapFix – Cannula)
- Medical grade paper and plastic Film (Injeckt® 2 mL Luer Lock Solo Syringe).

**5**

**CERTIFICATIONS**

All products included in this pack are CE marked products.

Histoacryl® is a class III product (fixation of hernia meshes).

Histoacryl® LapFix – Cannula is a class IIa product.

Injeckt® 2 mL Luer Lock Solo Syringe is a class Ism product

**6**

**LABEL POUCH**

Name of component → **Histoacryl® LapFix – Cannula**

Description → **Histoacryl® Applicator**

CE Mark → **CE 0123**

Sterilization → **STERILE EO**

**Do not resterilize**

**B|BRAUN**

Manufacturer → **B. Braun Surgical, S.A. Rubí. Spain**

Warnings → **Rx Only**

Reference → **REF 1052008C**

Batch → **LOT 122081**

Expiration date → **2027-02-21**

Description

DE Histoacryl® Applikator FR Applicateur d'Histoacryl® ES Aplicador de Histoacryl®  
 IT Applicatore per Histoacryl® NL Histoacryl® applicator PT Aplicador Histoacryl®  
 FI Histoacryl® kudosliima-applikaattori GR Εφαρμογέας Histoacryl® DK Histoacryl®  
 applikator SE Histoacryl®-applikator PL Aplikator preparatu Histoacryl® CZ Aplikátor  
 Histoacryl® HU Histoacryl® felrakó SK Aplikátor Histoacryl® BG Апликатор на  
 Histoacryl® NO Histoacryl®-applikator RO Aplicator Histoacryl® RU Аппликатор  
 Histoacryl® TR Histoacryl® Aplikatör

MFG. use only

Warning

Histoacryl® 塗料器



Histoacryl® Applicator

280

Name of component

Expiration date

Manufacturing date

Batch, reference and  
GTIN code

Drawing of the  
product

Manufacturing site

Sterilization

Warnings

Manufacturer











CE Mark



For label pouch of Histoacryl®, check Histoacryl® Technical File.








## 7 BOX SYMBOLS included from CE MDR


- |  |                                |
|--|--------------------------------|
|   | (1) Catalogue number           |
|   | (2) Unique Device Identifier   |
|   | (3) Batch code                 |
|   | (4) Use-by date                |
|   | (5) Consult                    |
|   | (6) Do not reuse               |
|   | (7) Caution                    |
|  | (8) Upper limit of temperature |

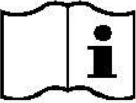



Product Name → **Histoacryl® LapFix X1** <sup>1</sup>  1052008  <sup>2</sup>

Units and codes of pack components	Nr	Qty	Code	Description
	1	1	4606701V	INJEKT 2 ML LUER-LOCK
	2	2	1050044	HISTOACRYL BLUE 0,5ML
	3	1	1052008C	HISTOACRYL LAPFIX -CANNULA

 P240506001 <sup>3</sup>  2026-05-06 <sup>4</sup>

 (01)04046955052066  
(17)260506  
(10)P240506001

   
(01)04046955052066  
  
(17)260506(10)P240506001

<sup>5</sup>  <sup>6</sup>  <sup>7</sup>  <sup>8</sup>  +22 °C

**B|BRAUN**

B. Braun Surgical, S.A.  
Ctra. de Terrassa, 121  
08191 Rubí (Spain)

Manufacturer