

HISTOACRYL®

TECHNICAL FILE



1 DESCRIPTION

Histoacryl® is a sterile, liquid tissue adhesive consisting of n-butyl-2-cyanoacrylate. For easy visual assessment of the thickness of the layer which has been applied, Histoacryl® is coloured with D&C violet No. 2 dye. A translucent version (Histoacryl® L), which does not contain dye, is also available.

2 INDICATIONS

1. Closure of skin wounds without tension (including clean surgical incisions and incisions from minimally invasive surgery), and simple, thoroughly cleansed, trauma-induced lacerations.

2. Sclerotherapy of large oesophageal or fundal varices.

3. Fixation of hernia meshes, especially in inguinal hernia surgery.

Histoacryl® is intended to be used in different patient populations. In adults, Histoacryl® is indicated for the 3 indications. In children and neonates, Histoacryl® is only indicated for skin closure. Intended users are healthcare professionals that are qualified and familiar with the technique and with the properties of liquid tissue adhesives, specifically cyanoacrylates.

3 CONTRA INDICATIONS

Histoacryl® is not indicated for holding together wound surfaces on internal organs, the brain surface, central or peripheral nervous system. In addition, it is not to be applied to mucosal surfaces, mucocutaneous junctions or surface of the eye.

Histoacryl® is not indicated on patients with a known hypersensitivity to cyanoacrylate, formaldehyde or the dye D&C Violet No. 2.

No more than 1.5 mL per treatment shall be applied in adult patients and no more than 0.5 mL per treatment shall be applied in paediatric patients weighting less than 10 kg.

No more than a total of 5 mL shall be applied to a single patient during her/his lifetime.

Histoacryl® is not indicated in pregnant, breastfeeding or women planning on pregnancy.

4 MATERIAL SPECIFICATIONS

Material: n-butyl-2-cyanoacrylate (NBCA)

Color: Translucent (no dye) & Blue (coloured with D&C violet No. 2 dye)

Sterilization: ensured by membrane filtration and aseptic filling.

5 STORAGE / HANDLING / SHELF LIFE

Storage: Stored in temperatures at or below +22 °C away from moisture and direct light sources.

Shelf-Life: 24 months (since production date)

Packaging: Supplied in 0.5 mL single use plastic ampoules. Each ampoule is packed in an aluminium pouch to protect the ampoule from external contamination, keeping at the same time the external sterility of the ampoule.

6 CERTIFICATIONS

Histoacryl® is a class III product., CE Certified according to Regulation (EU) 2017/745.

7

LABELS / SYMBOLS

LOT

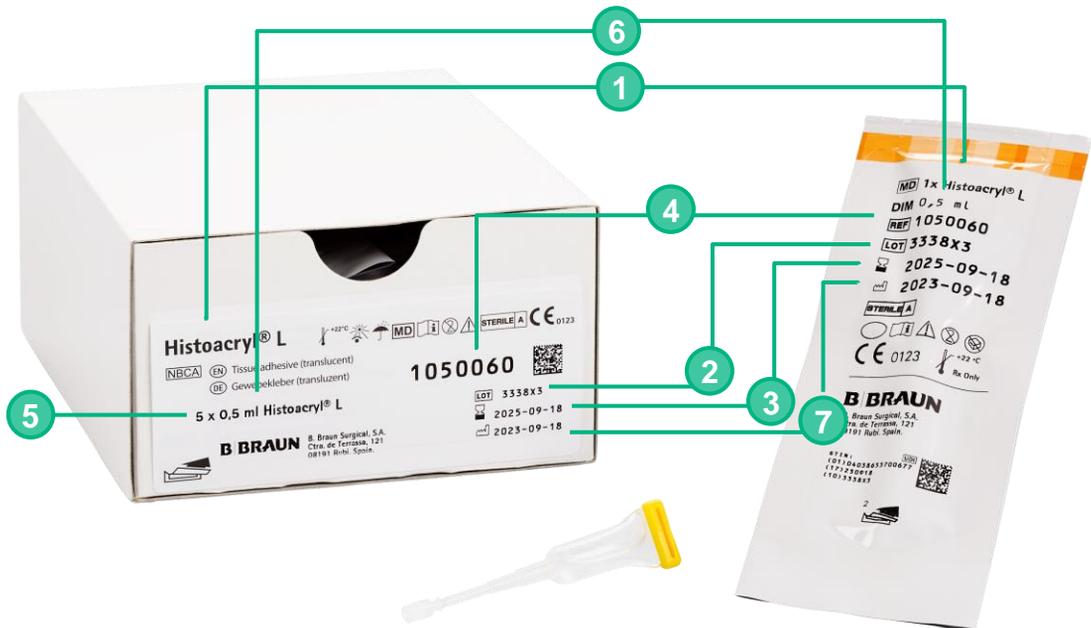


REF

DIM

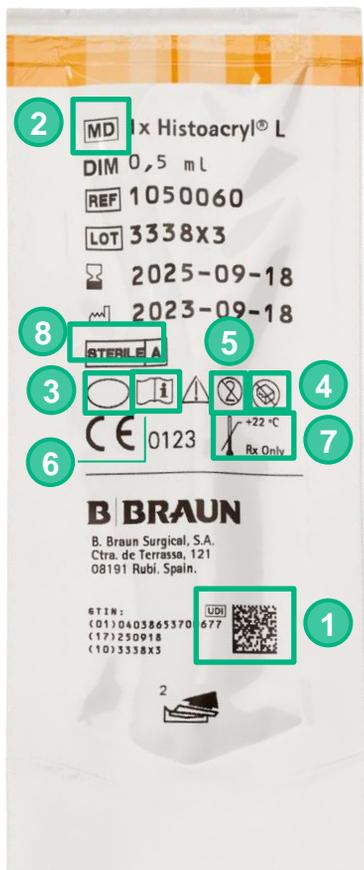


- (1) Product name
- (2) Batch code
- (3) Use-by date
- (4) Catalogue number
- (5) Number of units
- (6) Dimension (ampoule content)
- (7) Date of manufacture



8 POUCH SYMBOLS included from CE MDR

- | | |
|---|---|
|  | (1) This QR code includes Unique Device Identifier (UDI) |
|  | (2) Medical Device |
|  | (3) Single sterile barrier system |
|  | (4) Do not use if package is damaged and consult instructions for use |
|  | (5) Do not reuse |
|  | (6) Consult Instructions For Use |
|  | (7) Upper limit of temperature |
|  | (8) Sterile unless package is opened or damaged. |
- Method of sterilization: Aseptic Filling



9

BOX SYMBOLS included from CE MDR



(1) Medical Device



(2) Consult Instructions For Use



(3) n-butyl-2-cyanoacrylate



(4) Unfold for more languages



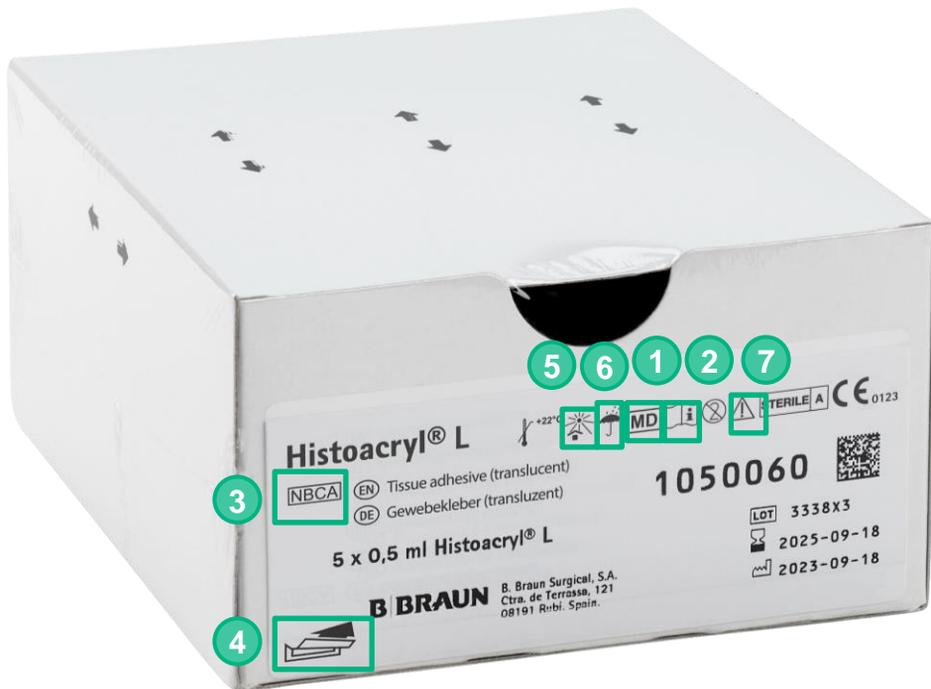
(5) Keep away from sunlight



(6) Keep dry



(7) Caution



9 IMPLANT CARD included from CE MDR



(1) Patient identification



(2) Date of implantation



(3) Health care center or doctor



(4) Patient information website

Histoacryl® L

BG:Тъканно лепило CB:Ткановé lepidlo DE:Gewebekleber DA:Vævslim
 ET:Koeelim ES:Adhesivo tisular FI:Kudosliima FR:Colle tissulaire EL:Συγκολλητικό
 ιστιών EN:Tissue Adhesive HU:Szövetragasztó IT:Adesivo tissutale LT:Audinių
 klajai LV:Audu līme NL:Weefsellijm NO:Vevslim PL:Klej tkankowy PT:Adesivo de
 tecido RO:Adeziv tisular SV:Vävnadslim SL:Tkivno lepilo SK:Tkanivové lepidlo
 TR:Doku Yapıştırıcısı

REF 1050060 **LOT** 124061

MD HISTOACRYL TRANSLUCENT 0,5ML

UDI-DI:(01)04038653700677

UDI



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

B | BRAUN

International implant Card

SHARING EXPERTISE

1



2



3



4



<https://bbraun.info/histoacryl>