Improved closure of surgical incisions



Closure Technologies



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New Histoacryl[®] Flexible

The new generation of Histoacryl[®] glue has been designed to close and protect surgical wounds.

Due to its new formulation, Histoacryl[®] Flexible is specially suitable for long incisions:

Flexibility

NEV

Allows closure of incisions up to 25 cm¹

Microbial barrier

Polymerized Histoacryl[®] Flexible adhesive films are an effective microbial barrier²

Ease of use

Ready to use product storable at temperatures below $25^{\circ}C$

Accuracy

Special tip permits a better control and improved application

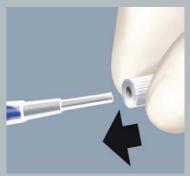
Excellent cosmetic results

Cyanoacrylate based topical skin adhesives yield excellent cosmetic results^{3,4,5,6}

- Just a small amount is necessary to provide an effective wound closure⁷
- The polymerization of Histoacryl[®]
 Flexible starts immediately
- Edges must be held together for just 30 seconds⁷









Open the blister and take out the application tip

Open the ampoule by twisting off the ribbed tip

Attach the tip to opened ampoule

Apply the glue in a thin layer to the approximated wound edges and hold in apposition for 30 seconds

Histoacryl[®] Flexible

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Improved formula. Improved outcomes

Compared to classical Histoacryl®

The new formula of Histoacryl® Flexible provides:

Closure of longer incisions

Histoacryl $^{\circ}$ Flexible can be used to close surgical incisions of up to 25 cm 1

Enhanced flexibility

Histoacryl[®] Flexible adhesive films adapt easier three-dimensionally⁸

More comfort

Histoacryl[®] Flexible generates less heat during polymerization⁹

More adaptable

 $Histoacryl^{\circ} \ Flexible \ provides \ a \ more \ flexible \\ coverage^{8}$

Easier to apply

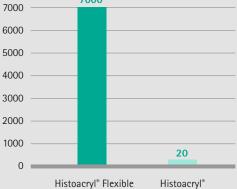
Histoacryl[®] Flexible contains an applicator tip that permits the easy creation of longer layers onto the surgical incision

Figure 1:

Comparison of flexibility (bending cycles) of Histoacryl[®] Flexible vs. classical Histoacryl[®]

N° bending cycles without cracks





Compared to leading competitors in the market

The new Histoacryl® Flexible:

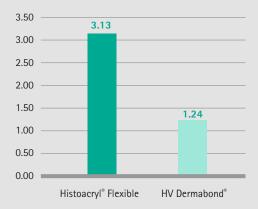
Is stronger

Peel strength significantly higher (p<0.001) for Histoacryl[®] Flexible than for Dermabond[®] High Viscosity⁹

Figure 2:

Peel strength comparison of $\mathsf{Histoacryl}^{*}\,\mathsf{Flexible}$ vs. $\mathsf{Dermabond}^{*}\,\mathsf{High}\,\mathsf{Viscosity}$

Average T-Peel Strength (N/cm)

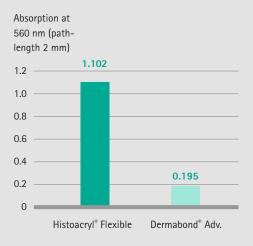


Enhanced visibility

Histoacryl[®] Flexible is more intensely coloured than Dermabond[®] Advanced, thus allowing a better visualization during application of the product even if just one single layer is applied¹⁰

Figure 3:

Comparison of colour intensity of Histoacryl[®] Flexible vs. Dermabond[®] Advanced



In addition to all these advantages, in vitro tests showed that Histoacryl® Flexible provided an **100** % **effective antimicrobial barrier***¹¹ against microbial penetration for **7 days** and for the following bacteria²: *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Enterococcus faecium, Brevundimonas diminuta and Candida albicans*

*In vitro results may not be representative of antimicrobial barrier properties in vivo.

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Skin Closure

Histoacryl[®] Flexible is suitable to close and protect the skin of small and long incisions^{*} in a broad variety of surgical disciplines such as plastic surgery (mammaplasties, abdominoplasties, hand surgery), general surgery (inguinal hernia repair, colectomies), cardiovascular surgery (valve repair, CABG), etc.

*Subcutaneous suturing might be necessary according to the surgeon's criteria.

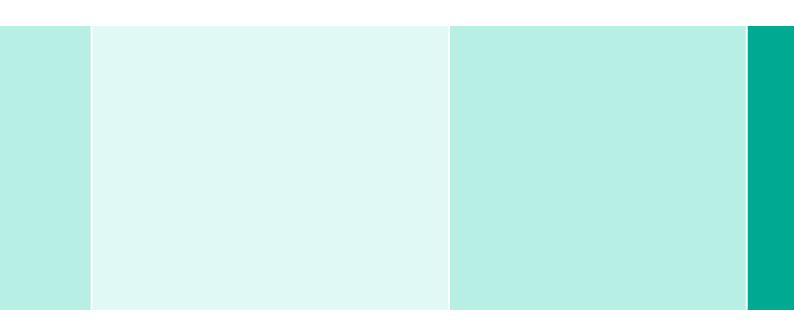
Ordering information

Code	Description
1051250P	5 ampoules of Histoacryl® Flexible (0.5 mL) and 5 tips per box
1051260P	10 ampoules of Histoacryl® Flexible (0.5 mL) and 10 tips per box



References

- ¹ Data on file, in vitro test with pork skin.
- ² Data on file, in vitro test according to: Bhende S, Rothenburger S, Spangler DJ, Dito M. In vitro assessment of microbial barrier properties of Dermabond topical skin adhesive. Surg Infect (Larchmt). 2002 Fall;3(3):251-7.
- ³ Amiel GE, Sukhotnik I, Kawar B, Siplovich L. Use of N-butyl-2-cyanoacrylate in elective surgical incisions longterm outcomes. J Am Coll Surg. 1999 Jul;189(1):21–5.
- ⁴ Barnett P, Jarman FC, Goodge J, Silk G, Aickin R. Randomised trial of Histoacryl blue tissue adhesive glue versus suturing in the repair of paediatric lacerations. J Paediatr Child Health. 1998 Dec;34(6):548-50.
- ⁵ Simon HK, McLario DJ, Bruns TB, Zempsky WT, Wood RJ, Sullivan KM. Long-Term appearance of lacerations repaired using a tissue adhesive. Pediatrics. 1997 Feb;99(2):193-5.
- ⁶ Ellis DA, Shaik A. The ideal tissue adhesive in facial plastic and reconstructive surgery. J Otolaryngol. 1990 Feb;19(1):68-72.
- ⁷ Histoacryl[®] Flexible Instructions for Use.
- ⁸ Data on file, in vitro test in the style of the mandrel bend test ASTM D522 93 a (2008).
- ⁹ Data on file, in vitro test, internal SOP: AAVS 108 version 3.
- ¹⁰ Data on file, in vitro test according to ASTM F2256 05(2010).
- ¹¹ Data on file, determined by UV-spectrometry.



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