Doc: MHD-04(21279) WC
September 2023

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

फाइब्रिन गोंद

Draft Indian Standard

Fibrin Glue

[ICS 11.040.30]

Ear, Nose and Throat Surgery Instruments Sectional Committee, MHD 04

Last date for comments: 21 November, 2023

FOREWORD

(Formal clauses will be added later)

The standard provides requirements for Fibrin Glue or Sealant used in ENT Surgery/HNS.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

1 SCOPE

This standard specifies requirements for Fibrin Sealant made of Human Fibrin.

2 REFERENCES

No standards are referred in this text.

3 MATERIAL & COMPOSITION

3.1 Material

The glue shall be made from Human Fibrin.

3.2 Composition

The composition of the glue shall be as:

Fibrinogen	55-106 mg/mL
Thrombin	400-1200 units/mL

3.3 The Fibrin sealant shall be sterile and non-pyrogenic.

3.4 Extraction of Fibrin Glue

The Donor of the fibrin glue must be selected according to standards of Blood Center Donor who is free of infectious diseases, Hb should be assessed etc.

4 REQUIREMENTS

4.1 Storage

The glue shall be stored in the OT refrigerator at temperature of 2-8 °C.

4.2 Preparation time

The glue should be useable within 5 minutes. The reconstitution should not take more than 2 minutes.

4.3 Application

4.3.1 Should come with sterile syringes/ devices for applying it effectively and ergonomically.

4.3.2 Should come with spare application multiple nozzles (preferably malleable) and connector of lengths suitable for endoscopic endonasal usage

4.3.3 After applying fibrin glue, approximate time available for manipulation/positioning should be around 60 seconds.

5 PACKAGING & LABELLING

The product shall have the following details.

5.1 Quantity

The product should be available in a package of fixed quantity: 1 ml or 2 ml.

5.2 Shelf-life

The shelf life should be mentioned on package along with desired temperature of storage.

5.3 Details for application

The minimum recommended distance from the applicator tip to the target site for spray should be mentioned on the package.

5.4 Post-marketing experience

Any incidence of adverse reactions should be available.

6 MARKING

6.1 The product shall be marked with the manufacturer's name, initials or registered trade-mark.

6.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.