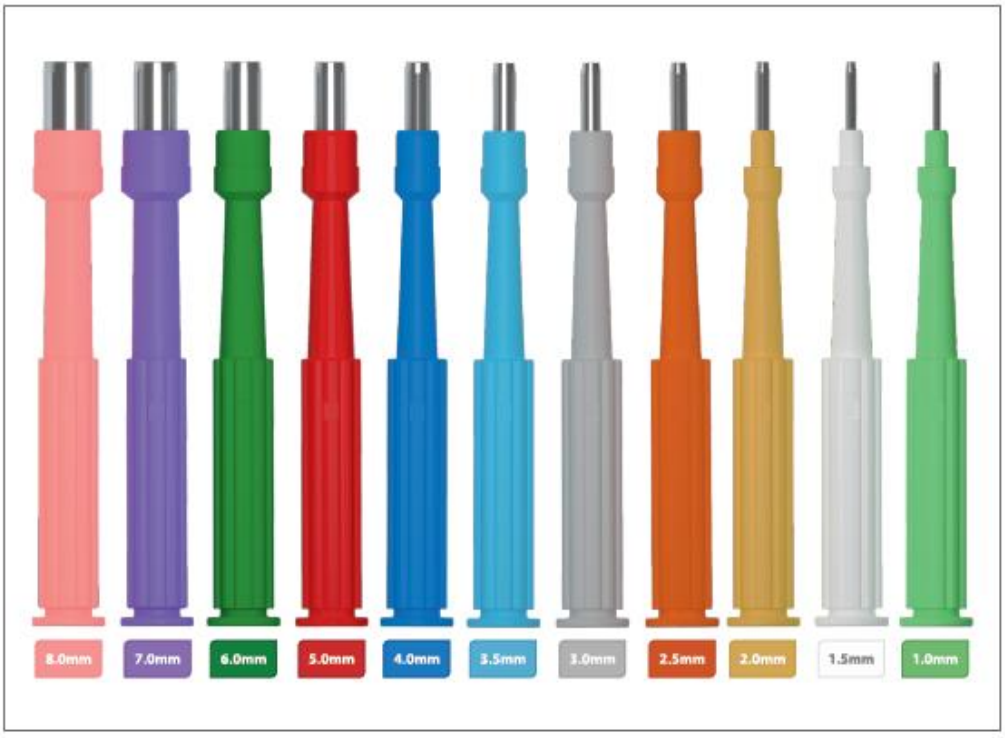


DISPOSAFE BRAND NAME	BRAND NAME
Disposafe Biopsy Punch	**Disposafe**

1. PRODUCT DESCRIPTION

Biopsy Punch is made of plastic handle fixed with a cylindrical hollow sharp blade. It is a single use device. Duration of Use: Transient Use.

2. DEVICE CLASSIFICATION AND RULE

Biopsy Punch falls under Class-IIa (Rule 6) device as per EU MDR 2017/745 Annexure VIII.

3. PRODUCT CHARACTERISTICS & INTENDED USE

INTENDED USE:

Biopsy punches uses to take mimimally invasive, small samples of tissue and removing the small dermal glands.

- Punches made of High Quality Steel which are super grounded for super sharp edges for sharp cut.
- Smooth large ribbed handle allow secure grip and large round head allows thumb control while performing procedure.

- Ready to use Sterile Blister pack.
- Disposafe sharp punches perform very effectively while using on skin without any skin trauma.
- Sizes from 1mm to large 8mm gives huge comfort of size selection to use.
- Super sharp grinding allow smooth surface penetration with very small force.
- Also long punch length allow deep penetration.

4. PRODUCT VARIANTS

Following variants are available for the products

Sr. No.	Product	GMDN	Gauge/Size
1.	Biopsy Punch	35286	1.00MM, 1.5MM, 2.0MM, 2.5MM, 3.0MM, 3.5MM, 4.0MM, 5.0MM, 6.0MM, 7.0MM, 8.0MM

5. MATERIAL OF CONSTRUCTION

S.No.	Component description	Material Used
1.	Handle	ABS
2.	Punch	AISI 304
3.	Protective Cover	LLDPE/PP

6. TECHNICALSPECIFICATION

Parameter		Specified Value							
Size (Mm)	Tolerance (mm)	1.0	1.5	2.0	2.5	3.0	3.5	4.0	5.0
Outer Dia	±0.01	1.4	1.9	2.4	2.9	3.4	3.9	4.4	5.4
Inner Dia	± 0.05	1.0	1.5	2.0	2.5	3.0	3.5	4.0	5.0
Thickness	± 0.05	0.225±0.05mm							
Hardness	-	320 HV to 360 HV at 5 kg load							
Material	-	Stainless steel (SS 304)							

7. REFERENCE COMPLIANCE STANDARD

S.No	Harmonized standards	Standard Number
1.	Sampling Procedure For Inspection By attributes	ISO 2859-1 : 1999/ And 1:2011 ISO 2500-1:2000
2.	Instruments for surgery - Scalpels with detachable blades - Fitting dimensions	ISO 7740 : 1985
3.	Specification for materials and packaging of surgical scalpels with detachable blades	BS 2982 : 1992
4.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
5.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015
6.	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	EN ISO 15223-1:2021
7.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.	EN ISO 11607-2:2019
10.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
11.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
12.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
13.	Biological evaluation of medical devices — Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009
14.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
15.	Biological evaluation of medical devices - Part 11 : Tests for	EN ISO 10993-11:2018

	systemic toxicity	
16.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10993-12:2021
17.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
18.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
19.	The European Union Medical Device Regulations	MDR 2017/745
20.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
21.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
22.	Medical devices - Part - 1: Applications of Usability engineering to the medical devices.	IEC 62366-1:2015
23.	Clinical Investigations of medical devices for human subjects - Good Clinical Practices	ISO 14155:2020
24.	Medical Devices- Post Market Surveillance for manufacturers	ISO 20416:2020
25.	Clinical Evaluation Assessment Report Template	MDCG 2020-13
26.	Medical Devices Regulations Clinical Evidence Requirements	MEDDEV 2.7.1 Rev 4,
27.	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11135:2014
28.	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	TYPE OF MATERIAL	PACKAGING
Primary Packaging	Hard Blister	01
Secondary Packaging (Inner Carton)	SGS Board	10
Tertiary Packaging (Master Carton)	3 Ply	500

9. OTHER DETAILS

a. **Intended Use:** refer the instruction for use before the application.
b. **Storage:** store in a cool and dry place and keep away from direct sunlight and extreme heat.
c. **Method of Sterilization:** sterilized using ethylene oxide.
d. **Shelf life:** 05 years from the month / date of sterilization.

e. **Testing and Analysis:** Testing for sterility, pyrogen content and physical characteristics (Visual Checking, Moulding defect, Packaging Condition, Length of biopsy punch, Colour Coding, Corrosion, Sharpness, sealing etc) is performed on each batch before release.

f. **Biocompatibility:** the product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

g. **Disposal:** Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

10. COMPLIANCE INFORMATION

Manufacturing Site Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2,Sec- 59, Phase-II, Ballabhgarh, Faridabad-121004, Haryana (INDIA)
Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016
CE Marking: TUV-SUD Product Services GmbH 0123
GMDN: 35286