*भारतीय मानक*

# पीटीएफई पिस्टन कटिंग जिग – विशिष्टि

# *(पहला पुनरीक्षण)*

***Indian Standard***

# PTFE Piston Cutting Jig – Specification

(*First Revision)*

## ICS 11.040.30

Ear, Nose, Throat, Head & Neck Surgery Instruments Sectional Committee, MHD 04

FOREWORD

This standard was originally published in 1981. The first revision of this standard has been brought out to align the standard with the latest style and format of Indian Standards. In this revision, the grade designation of stainless steel 316 has been included in the material clause and a test for hardness has been included.

The composition of the Committee responsible for formulation of this standard is given in Annex A.

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.

## SCOPE

This standard covers the requirement for PTFE (Teflon) piston cutting Jig used by ENT surgeons while cutting PTFE pistons of suitable size.

## REFERENCES

The standards given below contain provisions, which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

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| --- | --- |
| **IS No.** | **Title** |
| IS 1501 (Part 1): 2020/ISO 6507-1: 2018 | Metallic Materials – Vickers hardness test Part 1 Test method |
| IS 6603: 2024 | Stainless Steel Semi-Finished Products, Bars, Wire Rods and Bright Bars Specification (Second Revision) |
| IS 12937: 1990 | Engineering metrology – Methods of testing straightness, flatness and perpendicularity |

## MATERIAL

The material shall be stainless steel of grade X 04Cr17Ni12Mo2 (Alloy 316) of IS 6603.

## SHAPE AND DIMENSIONS

* 1. The shape and dimensions shall be as per Fig. 1.
	2. The tolerances on various dimensions shall be permitted as given below:
		1. ± 0.05 mm on dimensions up to 5 mm, and
		2. ± 0.1 mm on dimensions above 5 mm and below 10 mm.

## WORKMANSHIP AND FINISH

* 1. The flatness of measuring surface shall be checked with a knife straight edge. There shall be no visible clearance between the surface and the edge. Alternatively, flatness can be tested in accordance with IS 12937.
	2. The marking depicting depth of the holes shall be clearly and uniformly etched as shown in

**Fig. 1.** Etching may be done by laser.

* 1. The central line of holes shall be parallel to the longitudinal axis of the jig.
	2. All the surfaces shall be free from scales, burrs, cracks, tool-marks and other defects and shall be finished smooth.



## HEAT TREATMENT

The jig shall be uniformly hardened and tempered to a hardness of 450 to 550 *HV.* It shall be tested for hardness in accordance with IS 1501 (Part 1).

## MARKING

* 1. The jigs shall be marked clearly and indelibly with the manufacturer’s name, initials or registered trademark, Serial number, batch number and lot number.

## 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 there under, and the product(s) may be marked with the Standard Mark.

## PACKING

The surfaces shall be coated with a suitable anticorrosive coating and shall be wrapped in a moisture proof paper or any other suitable packing material. Jigs may also be packed as agreed to between the supplier and the purchaser.

**ANNEX A**

(*Foreword*)

 **COMMITTEE COMPOSITION**

Ear, Nose, Throat and Head & Neck Surgery Instruments Sectional Committee, MHD 04

| ***Organization*** | ***Representative(s)*** |
| --- | --- |
| All India Institute of Medical Sciences, New Delhi | Dr. RAKESH KUMAR *(Chairperson)* |
| ALPS International, New Delhi | MR. ALOK NARANG,  |
|  MR. KARAN NARANG (*Alternate*) |
| All India Institute of Medical Sciences, New Delhi | Dr. PREM SAGAR  |
|  Dr. ARVIND KUMAR *(Alternate I)* |
| All India Institute of Medical Sciences, Bhopal | Dr. VIKAS GUPTA  |
|  Dr. GANAKALYAN BEHERA *(Alternate I)* |
| Association of Indian Medical Device Industry, New Delhi | Mr. TARLOCHAN DEV  |
|  Mr. ANKUR BHARGAVA *(Alternate I)* |
|  Dr. C.S.PRASAD *(Alternate II)* |
| Government Medical College & Hospital, Chandigarh | Dr. SURINDER K SINGHAL  |
|  Mr. NITIN GUPTA *(Alternate)* |
| Happy Reliable Surgeries Private Limited, Bangalore | Mr. HEMANT SAVALE  |
|  Mr. SANJEEV GAUTAM *(Alternate)* |
| India Medtronic Private Limited, Gurugram | Ms. LATIKA VATS  |
|  Mr. SAURABH SABLE *(Alternate I)* |
|  Mr. SANDEEP VERMA *(Alternate II )* |
| Indian Institute of Technology Kanpur, Kanpur | Dr. A. R. HARISH  |
| Kalam Institute of Health Technology, Vishakhapatnam | Dr. ARJUN THIMMAIAH  |
|  Mr. AMIT SHARMA *(Alternate)* |
| Serwell MediEquip, Chennai | Mr. T. JEBIN SAMUEL  |
|  Mr. R. RADHAKRISHNAN *(Alternate I)* |
|  Mr. G. SATHISH *(Alternate II)* |
| Tata Memorial Center (Hospital), Mumbai | Dr. RICHA VAISH  |
|  Mr. VIJAY YASHWANT MESTRI *(Alternate I)* |
|  Dr. ARJUN SINGH *(Alternate II)* |
| BIS Directorate General | SHRI A. R. UNNIKRISHNAN, SCIENTIST ‘G’/ HEAD (MEDICAL EQUIPMENT AND HOSPITAL PLANNING) [REPRESENTING DIRECTOR GENERAL (Ex-officio)] |

*Member Secretary*

Ms. HARSHADA GANESH KADAM

SCIENTIST ‘B’/ASSISTANT DIRECTOR

(MEDICAL EQUIPMENT AND HOSPITAL PLANNING). BIS